U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K133705 - 3839 pages
COMPANY:	GE MEDICAL SYSTEMS, LLC (GEMEDISYSTB)
PRODUCT:	SYSTEM, X-RAY, TOMOGRAPHY, COMPUTED (JAK)
SUMMARY:	Product: REVOLUTION CT
DATE REQUESTED:	Aug 2, 2016
DATE PRINTED:	Aug 2, 2016
Note:	Printed

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date: November 20th, 2013

Submitter:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Primary Contact:
Helen Peng
Regulatory Affairs Leader, RAC
GE Medical Systems, LLC
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e-mail: hong.peng@ge.com

Secondary Contact:
John Jaeckle
Chief Regulatory Affairs Strategist
GE Medical Systems, LLC
Tel: 262-424-9547
e-mail: john.jaeckle@ge.com

PRODUCT IDENTIFICATION

Device Trade Name: Revolution CT

Common/Usual Name: Computed Tomography X-ray System

Classification Name: Computed Tomography X-ray System per 21CFR892.1750

Product Code: 90-JAK

Manufacturer / Design Location:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Manufacturing Location(s):
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Distributor:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices:

The Revolution CT is a new CT device built upon the existing technologies of the predicate device Discovery CT750 HD (K120833). It is of comparable type and substantially equivalent to its predicate device Discovery CT750 HD and GE's other currently marketed Computed Tomography X-ray Systems that comply with the same standards. In addition, the system has the same intended use as that of the predicate device. The proposed device's indications for use have been revised to match the system capabilities as substantiated in the engineering and clinical testing provided. The system is labeled as the Revolution CT.

Predicate Device:

Discovery CT750 HD- K120833

DEVICE DESCRIPTION

The Revolution CT is a multi-slice (256 detector row) CT scanner consisting of a gantry, patient table, scanner desktop (operator console), system cabinet, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.

The system generates images through the computer reconstruction of data acquired at different angles and planes of the rotating gantry. The gantry rotates at up to 0.28 seconds per rotation, and can acquire up to 512 slices of image data per rotation with a maximum total coverage of 160 mm in the z direction. The gantry however is designed to be able to rotate at 0.20 second per rotation. The system can be operated in Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisition modes.

The Revolution CT system is a powerful Volume High Definition CT scanner that is designed to provide best-in-class technologies for whole organ coverage, high image quality and responsible dose performance with the following characteristics:

- 160 mm detector coverage
- 140ms temporal resolution (0.28s rot. Speed) combined with intelligent motion correction with SnapShot Freeze for excellent cardiac imaging at any heart rate.
- 0.23 mm spatial resolution
- A wide bore (80-cm bore size) to image all patients allowing better patient positioning & access.
- The next-generation of iterative reconstruction technology, ASiR-V, designed to deliver ultra-low noise levels, improved low contrast detectability and may enable a reduction in dose for all clinical applications

Built upon the existing technologies the Revolution system is designed to use less radiation dose than the previous generation product while maintaining the same diagnostic level of image quality. Further, the fast speed of the scan could potentially reduce contrast volumes. The hardware platform is also capable of supporting Gemstone spectral imaging and 0.2s rotation speed.

The Revolution CT is intended to be a head and whole body CT system incorporating the same basic fundamental operating principles and the same intended for use as the predicate device. Materials and construction are equivalent to our existing marketed products, which are compliant with AAMI/ES 60601-1, IEC 60601-1(3rd ed) and associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. It has been developed under the same GE quality system and has successfully completed design controls activities, including risk management, verification, and validation.

Intended Use

The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use:

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy..

Technology:

The Revolution CT is built on the existing technologies of the predicate device Discovery CT750 HD. The vast majority of the software features and functions are common between the two products. The software user interface has been redesigned to provide more simplified workflow and user experience. Hardware components including the imaging chain however have been upgraded to support the new and improved capabilities.

The most notable changes in the imaging chain as compared to the predicate device Discovery CT750 HD is described below.

The Revolution CT system features the new "Gemstone Clarity" detector consisting of 256 rows at 0.625mm row thickness and a full 160mm z-coverage, the redesigned gantry with a 80cm bore and improved iterative reconstruction technology, allowing the system to deliver excellent image quality at full 160mm coverage to enable whole organ imaging.

The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems.

To house the wide Gemstone Clarity detector, the Revolution gantry has been redesigned with high specifications of strength and rigidity that support fast rotation speeds for acquisitions with high temporal resolution, while providing an 80cm bore opening to accommodate patients with positioning flexibility and comfort. With an improved center mount design that balances the mechanical forces generated by the rotating components, the gantry and detector assembly is capable of supporting accelerations that ensures reliable operation at today's 0.28 seconds per rotation, and can be extended to support imaging at 0.20 seconds per rotation in the future.

On the rotating gantry, the new Performix HDw tube tailored for the wide angle geometry generates the X-ray beam for patient imaging.

To address the challenges of the wide cone-beam geometry of the new scanner, a new advanced image reconstruction algorithm called Volumetric High Definition (VHD) has been designed specifically to reduce cone-beam artifacts and maintain CT number uniformity.

The image reconstruction engine further includes ASiR-V, the next generation of GE's ASiR iterative recon technology for noise reduction and dose management. Finally, GE's SnapShot Freeze technology is supported on all cardiac acquisitions to improve the temporal properties of the reconstructed images when visualizing the coronaries.

Despite the changes described above, the control mechanism, operating principle, energy type, and intended use have not changed from the predicate device Discovery CT750 HD.

Adverse Effects on Health:

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (AAMI/ES and IEC60601-1 Ed.3 and associated collateral and particular standards for CT).
- Compliance to applicable CDRH 21CFR subchapter J requirements.
- Compliance to NEMA XR-25

The device is designed and manufactured under the Quality System Regulations of 21CFR 820.

Determination of Substantial Equivalence:

The Revolution CT has completed testing and is in compliance with IEC 60601-1 Ed. 3 and its associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. The device has successfully completed all testing per our quality system as well as comparison testing to the predicate device. It was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

GE believes the Revolution CT system is of comparable type and substantially equivalent to our currently marketed system Discovery CT750 HD.

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering (non-Clinical testing) and clinical performance testing was performed to provide the requisite data to substantiate performance claims, the revised indications, and ultimately substantial equivalence.

Non-Clinical Testing

The performance evaluation testing used a variety of test methods, phantoms, and clinical datasets. Various mathematical, physics and statistical analysis were performed to demonstrate that each performance specification was successfully verified and substantiated. The areas additionally evaluated for the non-clinical testing included cardiac, cardiovascular, and thoracic imaging; temporal resolution, dose performance, and image quality. The image quality evaluation included evaluation for artifacts, scatter, spatial resolution, and low contrast detectability. For the LCD evaluation, a model observer study was used along with the MITA LCD phantom. Acceptance testing per IEC 61223-3-5 was also conducted.

Clinical Testing

Sample clinical data was collected from 49 subjects at one site in the US with the approval of appropriate ethics committee and in accordance with 21 CFR Parts 812, 50 and 56, as well as GE Healthcare's quality system's procedures for such evaluations.

The intent of the protocol was to obtain a sample set of clinical images across different patient populations, clinical scenarios, and scanning protocols/techniques. Patients were selected for potential recruitment to meet these needs. Any patient who met these criteria stated in the Protocol and who voluntarily signed the Informed Consent Form was recruited.

This sample image data was representative of a wide range of anatomical coverage and patient indications and was categorized into the following types of scans:

- Cardiac – Coronary CTA, Stress/Rest Perfusion, Cardiac Function, Calcium Burden, Gated Chest (Triple Rule Out), TAVI
- Body & Extremity - Abd/Pelvis, Chest, Ankle, Shoulder, Knee, Spine
- Neuro – Sinus, General Brain, Contrast Enhanced Brain, Neuroangiography, Neuro Perfusion, Neuro 4D CTA

The images were evaluated by multiple readers who are qualified radiologists at different institutions in the United States of America for clinical acceptance and image quality using a 5 point Likert scale.

The results of this clinical assessment demonstrate the acceptable diagnostic imaging performance of the GE Healthcare Revolution CT scanner.

Substantial Equivalence Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering and clinical testing provided, GE Medical Systems believes that the Revolution CT is as safe and effective, and performs in a substantially equivalent manner to the predicate device Discovery CT750 HD (K120833).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems, LLC
% Ms. Helen Peng
Regulatory Affairs Manager
3000 North Grandview Blvd.
WAUKESHA WI 53188

April 11, 2014

Re: K133705
Trade/Device Name: Revolution CT
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 10, 2014
Received: March 11, 2014

Dear Ms. Peng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133705

Device Name
Revolution CT

Indications for Use *(Describe)*

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

Testing

K133705

GE Healthcare
510(k) Premarket Notification Submission- Revolution CT

3000 N. Grandview Blvd. W-1140
Waukesha, WI 53188

November 20th, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Premarket Notification Traditional 510(k) for Revolution CT

To Whom It May Concern:

According to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, GE Medical Systems, LLC (aka GE Healthcare) proposes to introduce into interstate commerce a new device, the **Revolution CT system** intended for human use. Enclosed is the notification to the Food and Drug Administration as required by law. This premarket notification is being submitted at least thirty (30) days prior to the date upon which GE Healthcare proposes to begin the introduction of the device described here.

GE Medical Systems believes that the enclosed information will be sufficient for the FDA to reach a decision on this notification. However, should additional information be required, it will be promptly furnished upon request.

This premarket notification has been prepared in accordance with 21 CFR §807.87 and the latest FDA Guidance titled Format for Traditional and Abbreviated 510(k)s Issued on August 12, 2005.

Following are the principal factors about the design and use of the device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	☒	☐
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	☐	☒
Does the device contain components derived from a tissue or other biologic source?	☐	☒
Is the device provided sterile?	☐	☒
Is the device intended for single use?	☐	☒
Is the device a reprocessed single use device?	☐	☒

K1

3000 N. Grandview Blvd. W-1140
Waukesha, WI 53188

Question	YES	NO
If yes, does this device type require reprocessed validation data?	☐	☒
Does the device contain a drug?	☐	☒
Does the device contain a biologic?	☐	☒
Does the device use software?	☒	☐
Does the submission include clinical information?	☒	☐
Is the device implanted?	☐	☒

The following information is being submitted in accordance with 21CFR 807.87 and is provided in the same order as specified in that section.

(a) Device Name: **Revolution CT**

Classification Name: **Computed Tomography X-ray System**

(b) Establishment Registration Number: **2126677**

Manufacturing Location: **GE Medical Systems, LLC**
3000 N. Grandview Blvd.
Waukesha, WI 53188

(c) FDA has classified CT X-ray systems as **Class II** in **21 CFR 892.1750** (Radiology).

(d) No applicable performance standards have been issued under Section 514 of the Food, Drug, and Cosmetic Act. The device and its labeling comply with the following applicable requirements.

Code of Federal Regulations Tile 21, Subchapter J – Radiological Health, applicable sections that include:

1020.30(c)	Certification of components
1020.30(e)	Identification of X-ray components
1020.30(g)	Information for assemblers
1020.30(h)	Information for users
1020.30(j)	Warning label
1020.30(k)	Leakage radiation from source assembly
1020.30(m)	Beam quality
1020.33(c)	Information for users

3000 N. Grandview Blvd. W-1140
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1020.33(d)	Quality assurance
1020.33(f)	Control and indication of operation conditions
1020.33(g)	Tomo plane indication and alignment
1020.33(h)	Beam-on and shutter status indicators
1020.33(l)	Scan increment accuracy
1020.33(j)	CT number mean and standard deviation

(b)(4) [redacted]

The required documents and reports have been provided to the appropriate oversight agency or organization (e.g. NRTL, CDRH) to establish compliance with the applicable requirements given in the referenced sections of the standards listed above. Compliance with the standards in **Section 9** has been certified.

(e) Labeling

The Revolution CT Scanner System is intended for head and whole body X-ray computed tomography applications in patients of all ages.

For the Indications for Use statement, see **Section 4.** Detailed information about the Revolution CT can be found in the device description in **Section 10** and **Section 11.** The preliminary product datasheets, the operator manuals, and promotional material can be found in **Section 13.** The claims substantiation from bench testing is in **Section 18.**

(f) In the opinion of GE Medical Systems, the Revolution CT Scanner System is of comparable type and substantially equivalent to the currently marketed Discovery CT750 HD (K120833). Additionally it complies with the same or equivalent standards and has the same intended uses, as the predicate device Discovery CT750 HD CT. A manufacturer's assessment of substantial equivalence is in **Section 12.**

A description of the software development and validation process is provided in the attachments in **Section 16.**

(g) Effect of modification or new use: Not applicable. Product continues to meet the same IEC safety standards as well as 21CFR performance standards. The intended use is the same.

(h) The 510(k) summary is included in **Section 5.**

(i) Financial certification is provided in **Section 8.**

(j) Not applicable. The submission is not claiming substantial equivalence to a class III device.

3000 N. Grandview Blvd. W-1140
Waukesha, WI 53188

(k) A truthful and accurate statement is included as **Section 6.**

This premarket notification is submitted in duplicate (including this cover letter), one paper copy and one e-copy stored on a flash drive. The eCopy is an exact duplicate of the paper copy except that the DICOM sample clinical images files referenced in section 20 are only provided in the eCopy. A placeholder was provided in section 20 of the paper copy referring back to the eCopy for that information.

CONFIDENTIALITY

GE Medical Systems regards the information and data provided in this Premarket Notification to be confidential and proprietary in nature. This particularly applies to information related to and performance of the Revolution CT including, but not limited to, the identification of system or circuit architecture, assembly details, performance test results, and technical specifications. Accordingly, this information must be protected from disclosure under the Freedom of Information (FOI) Act, as well as 21 CFR 20.

GE Medical Systems appreciates the administrative and scientific considerations relevant to this submission, and we look forward to receiving a timely decision by the FDA regarding the information presented. Should you have any questions regarding the contents of this submission, please contact me by telephone at **(262) 424-8222** or email at **hong.peng@med.ge.com** or by fax at **(262) 364-2506.** Alternately you may contact Mr. John Jaeckle by telephone at **(262) 424-9547**, or by email at **john.jaeckle@ge.com**., or by fax at **(262) 364-2506.**

Sincerely,

Helen Peng
Regulatory Affairs Manager
GE Medical Systems, LLC
3000 N. Grandview Blvd., W-1140
Waukesha, WI 53188

Revolution CT

Traditional 510(k)

Screening Checklist

For Traditional/Abbreviated Premarket Notification [510(k)] Submissions

Revolution CT	Present	Inadequate	N/A
MDUFMA Cover Sheet	X		
CDRH Premarket Review Submission Cover Sheet	X		
510(k) Cover Letter	X		
Indications for Use Statement	X		
510(k) Summary or 510(k) Statement	X		
Truthful and Accuracy Statement	X		
Class III Summary and Certification			X
Financial Certification or Disclosure Statement	X		
Declarations of Conformity and Summary Reports	X		
Executive Summary	X		
Device Description	X		
Substantial Equivalence Discussion	X		
Proposed Labeling	X		
Sterilization / Shelf Life			X
Biocompatibility	X		
Software	X		
Electromagnetic Compatibility / Electrical Safety	X		
Performance Testing – Bench	X		
Performance Testing – Animal			X
Performance Testing – Clinical	X		
Kit Certification			X

Table of Contents

The paper copy comes in 6 volumes:

Volume I	Sections 1-13A
Volume II	Section 13B
Volume III	Sections 13C-16.9a
Volume IV	Sections 16.9b-16.9i
Volume V	Section 16.9i
Volume VI	Sections 16.9i-21

Note: The pages of the 510(k) are numbered by Section followed by the page of that Section (ex. 3-2 is page 2 in Section 3).

FDA Refuse To Accept Checklist

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K Date Received by DCC:

Lead Reviewer:

Branch: Division: Center/Office:

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions **Answers in the shaded blocks indicate consultations with Center advisor is needed**	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments? NA		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments? Class II product code JAK		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments? No PMA		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments? Traditional		

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content			X	
7) Submission contains clinical data	X			
a) Submission includes completed Financial Certification (Form 3454) or Disclosure (Form 3455) information for each covered clinical study included in the submission.	X			
b) Submission includes completed Certification of Compliance with the requirements of ClinicalTrials.gov Data Bank (Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.	X			
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.				X
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Comments? No Prior submissions				
B. Device Description				
10)				
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				X
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
Comments? User manual and tech Reference Manual in section 13				
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.	X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding* documenting preamendment status *is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
15) Submission includes a comparison of the following for the predicate(s) and subject device				X
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
Comments? section 12				
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			X
Comments? section 12				
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17, 18, & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
Comments? section 13				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			X
Comments? Section 13, User manual, tech reference manual				
19) General labeling provisions				X
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	X			
Comments? Section 13, tech reference manual				
20)				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	X
Comments? Not an in vitro device				
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.				X
Comments? Not applicable. The device does not have a shelf life				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			X
Comments? Section 15				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			X
Comments? Section 15				
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
X does contain software/firmware.				
does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
X does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			
35) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	X			
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.				
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

Decision: ◯ Accept ◯ Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Section 1: Medical Device User Fee Cover Sheet

(Form FDA 3601)

Revolution CT

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted]
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

GE HEALTHCARE
3000 N GRANDVIEW BLVD W 440
WAUKESHA
WI 53188
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****9340

2. CONTACT NAME
Helen Peng
2.1 E-MAIL ADDRESS
hong.peng@ge.com
2.2 TELEPHONE NUMBER (include Area code)
262-5485091
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) [redacted]
24-Sep-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Section 2: CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)

Revolution CT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
November 20th, 2013	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
GE Medical Systems, LLC	2126677		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(262) 424-8222		
Street Address	FAX Number *(including area code)*		
3000 North Grandview Blvd	(262) 364-2506.		
City	State / Province	ZIP/Postal Code	Country
Waukesha	WI	53188	USA
Contact Name			
Helen Peng			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	hong.peng@ge.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	JAK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K120833	1	Discovery CT750 HD	1	GE Medical Systems, LLC
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Computed Tomography System

	Trade or Proprietary or Model Name for This Device		Model Number
1	Revolution CT	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
JAK	892.1750	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Radiology Devices (#90)

Indications *(from labeling)*

The indication for use exceeds the character limit of this section. See form 3514 addendum on page 2-7 for the indication for use

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: GE Medical Systems, LLC		Establishment Registration Number: 2126677
Division Name *(if applicable)*		Phone Number *(including area code)*: 414 721 3470
Street Address: 3000 North Grandview Blvd		FAX Number *(including area code)*: (262) 364-2506.
City: Waukesha	State / Province: WI	ZIP Code: 53188 / Country: USA
Contact Name: Eileen Fick	Contact Title: QA Director	Contact E-mail Address: eileen.fick@med.ge.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number
Division Name *(if applicable)*		Phone Number *(including area code)*
Street Address		FAX Number *(including area code)*
City	State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment, Part 1: General requirements for safety edition 3	Ed 3	Dec 15, 2005
2	60601-1	AAMI/ANSI ES	Medical electrical equipment, Part 1: General requirements for safety	2005 +C1:2009 +A2:2010	Feb 9, 2006
3	60601-2-44	IEC	Medical electrical equipment – Part 2-44: Particular requirements for the basic Safety and essential performance of X-ray equipment for computed tomography	Ed 3	Feb 25, 2009
4	60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. Edition 3	Ed 3	March 30, 2007
5	60601-1-3	IEC	Medical electrical equipment - Part 1: General requirements for safety - 3 - Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment. Edition 2	Ed 2	Jan 22, 2008
6	DICOM	NEMA	Digital Imaging and Communication in Medicine (DICOM) Set	NEMA PS 3.1 – 3.18	Jan 2009
7	XR-25	NEMA	Computed Tomography Dose Check	-	Oct 2010

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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Form 3514 Addendum

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Indication for use

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
This is a continuation of standards from SECTION I (Page 6 of FORM FDA 3514)					
	Standards No.	Standards Organization	Standards Title	Version	Date
8	21CFR 1020.30 and 1020.33	FDA	Radiological Health	--	4/1/2011

3000 N. Grandview Blvd. W-1140
Waukesha, WI 53188

Section 3: 510(k) Cover Letter

Revolution CT

3000 N. Grandview Blvd. W-1140
Waukesha, WI 53188

November 20th, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Premarket Notification Traditional 510(k) for Revolution CT

To Whom It May Concern:

According to Section 510(k) of the Federal Food, Drug, and Cosmetic Act, GE Medical Systems, LLC (aka GE Healthcare) proposes to introduce into interstate commerce a new device, the **Revolution CT system** intended for human use. Enclosed is the notification to the Food and Drug Administration as required by law. This premarket notification is being submitted at least thirty (30) days prior to the date upon which GE Healthcare proposes to begin the introduction of the device described here.

GE Medical Systems believes that the enclosed information will be sufficient for the FDA to reach a decision on this notification. However, should additional information be required, it will be promptly furnished upon request.

This premarket notification has been prepared in accordance with 21 CFR §807.87 and the latest FDA Guidance titled Format for Traditional and Abbreviated 510(k)s issued on August 12, 2005.

Following are the principal factors about the design and use of the device:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	☒	☐
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	☐	☒
Does the device contain components derived from a tissue or other biologic source?	☐	☒
Is the device provided sterile?	☐	☒
Is the device intended for single use?	☐	☒
Is the device a reprocessed single use device?	☐	☒

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Question	YES	NO
If yes, does this device type require reprocessed validation data?	☐	☒
Does the device contain a drug?	☐	☒
Does the device contain a biologic?	☐	☒
Does the device use software?	☒	☐
Does the submission include clinical information?	☒	☐
Is the device implanted?	☐	☒

The following information is being submitted in accordance with 21CFR 807.87 and is provided in the same order as specified in that section.

(a) Device Name: **Revolution CT**

Classification Name: **Computed Tomography X-ray System**

(b) Establishment Registration Number: **2126677**

Manufacturing Location: **GE Medical Systems, LLC**
3000 N. Grandview Blvd.
Waukesha, WI 53188

(c) FDA has classified CT X-ray systems as **Class II** in **21 CFR 892.1750** (Radiology).

(d) No applicable performance standards have been issued under Section 514 of the Food, Drug, and Cosmetic Act. The device and its labeling comply with the following applicable requirements.

Code of Federal Regulations Tile 21, Subchapter J – Radiological Health, applicable sections that include:

1020.30(c)	Certification of components
1020.30(e)	Identification of X-ray components
1020.30(g)	Information for assemblers
1020.30(h)	Information for users
1020.30(j)	Warning label
1020.30(k)	Leakage radiation from source assembly
1020.30(m)	Beam quality
1020.33(c)	Information for users

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1020.33(d)	Quality assurance
1020.33(f)	Control and indication of operation conditions
1020.33(g)	Tomo plane indication and alignment
1020.33(h)	Beam-on and shutter status indicators
1020.33(I)	Scan increment accuracy
1020.33(j)	CT number mean and standard deviation

(b)(4)

The required documents and reports have been provided to the appropriate oversight agency or organization (e.g. NRTL, CDRH) to establish compliance with the applicable requirements given in the referenced sections of the standards listed above. Compliance with the standards in **Section 9** has been certified.

(e) Labeling

The Revolution CT Scanner System is intended for head and whole body X-ray computed tomography applications in patients of all ages.

For the Indications for Use statement, see **Section 4**. Detailed information about the Revolution CT can be found in the device description in **Section 10** and **Section 11**. The preliminary product datasheets, the operator manuals, and promotional material can be found in **Section 13**. The claims substantiation from bench testing is in **Section 18**.

(f) In the opinion of GE Medical Systems, the Revolution CT Scanner System is of comparable type and substantially equivalent to the currently marketed Discovery CT750 HD (K120833). Additionally it complies with the same or equivalent standards and has the same intended uses, as the predicate device Discovery CT750 HD CT. A manufacturer's assessment of substantial equivalence is in **Section 12**.

A description of the software development and validation process is provided in the attachments in **Section 16**.

(g) Effect of modification or new use: Not applicable. Product continues to meet the same IEC safety standards as well as 21CFR performance standards. The intended use is the same.

(h) The 510(k) summary is included in **Section 5**.

(i) Financial certification is provided in **Section 8**.

(j) Not applicable. The submission is not claiming substantial equivalence to a class III device.

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(k) A truthful and accurate statement is included as **Section 6**.

This premarket notification is submitted in duplicate (including this cover letter), one paper copy and one e-copy stored on a flash drive. The eCopy is an exact duplicate of the paper copy except that the DICOM sample clinical images files referenced in section 20 are only provided in the eCopy. A placeholder was provided in section 20 of the paper copy referring back to the eCopy for that information.

CONFIDENTIALITY

GE Medical Systems regards the information and data provided in this Premarket Notification to be confidential and proprietary in nature. This particularly applies to information related to and performance of the Revolution CT including, but not limited to, the identification of system or circuit architecture, assembly details, performance test results, and technical specifications. Accordingly, this information must be protected from disclosure under the Freedom of Information (FOI) Act, as well as 21 CFR 20.

GE Medical Systems appreciates the administrative and scientific considerations relevant to this submission, and we look forward to receiving a timely decision by the FDA regarding the information presented. Should you have any questions regarding the contents of this submission, please contact me by telephone at **(262) 424-8222** or email at **hong.peng@med.ge.com or** by fax at **(262) 364-2506.** Alternately you may contact Mr. John Jaeckle by telephone at **(262) 424-9547**, or by email at **john.jaeckle@ge.com**., or by fax at **(262) 364-2506.**

Sincerely,

Helen Peng
Regulatory Affairs Manager
GE Medical Systems, LLC
3000 N. Grandview Blvd., W-1140
Waukesha, WI 53188

Section 4: Indications for Use Statement

Revolution CT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Revolution CT

Indications for Use *(Describe)*

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Section 5: 510(k) Summary

Revolution CT

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date: November 20th, 2013

Submitter:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Primary Contact:
Helen Peng
Regulatory Affairs Leader, RAC
GE Medical Systems, LLC
Tel: 262-424-8222
e-mail: hong.peng@ge.com

Secondary Contact:
John Jaeckle
Chief Regulatory Affairs Strategist
GE Medical Systems, LLC
Tel: 262-424-9547
e-mail: john.jaeckle@ge.com

PRODUCT IDENTIFICATION

Device Trade Name: Revolution CT

Common/Usual Name: Computed Tomography X-ray System

Classification Name: Computed Tomography X-ray System per 21CFR892.1750

Product Code: 90-JAK

Manufacturer / Design Location:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Manufacturing Location(s):
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Distributor:
GE Medical Systems, LLC (GE Healthcare)
3000 N. Grandview Blvd.
Waukesha, WI 53188

Marketed Devices:

The Revolution CT is a new CT device built upon the existing technologies of the predicate device Discovery CT750 HD (K120833). It is of comparable type and substantially equivalent to its predicate device Discovery CT750 HD and GE's other currently marketed Computed Tomography X-ray Systems that comply with the same standards. In addition, the system has the same intended use as that of the predicate device. The proposed device's indications for use have been revised to match the system capabilities as substantiated in the engineering and clinical testing provided. The system is labeled as the Revolution CT.

Predicate Device:

Discovery CT750 HD- K120833

DEVICE DESCRIPTION

The Revolution CT is a multi-slice (256 detector row) CT scanner consisting of a gantry, patient table, scanner desktop (operator console), system cabinet, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.

The system generates images through the computer reconstruction of data acquired at different angles and planes of the rotating gantry. The gantry rotates at up to 0.28 seconds per rotation, and can acquire up to 512 slices of image data per rotation with a maximum total coverage of 160 mm in the z direction. The gantry however is designed to be able to rotate at 0.20 second per rotation. The system can be operated in Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisition modes.

The Revolution CT system is a powerful Volume High Definition CT scanner that is designed to provide best-in-class technologies for whole organ coverage, high image quality and responsible dose performance with the following characteristics:

- 160 mm detector coverage
- 140ms temporal resolution (0.28s rot. Speed) combined with intelligent motion correction with SnapShot Freeze for excellent cardiac imaging at any heart rate.
- 0.23 mm spatial resolution
- A wide bore (80-cm bore size) to image all patients allowing better patient positioning & access.
- The next-generation of iterative reconstruction technology, ASiR-V, designed to deliver ultra-low noise levels, improved low contrast detectability and may enable a reduction in dose for all clinical applications

Built upon the existing technologies the Revolution system is designed to use less radiation dose than the previous generation product while maintaining the same diagnostic level of image quality. Further, the fast speed of the scan could potentially reduce contrast volumes. The hardware platform is also capable of supporting Gemstone spectral imaging and 0.2s rotation speed.

The Revolution CT is intended to be a head and whole body CT system incorporating the same basic fundamental operating principles and the same intended for use as the predicate device. Materials and construction are equivalent to our existing marketed products, which are compliant with AAMI/ES 60601-1, IEC 60601-1(3rd ed) and associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. It has been developed under the same GE quality system and has successfully completed design controls activities, including risk management, verification, and validation.

Intended Use

The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

Indications for Use:

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy..

Technology:

The Revolution CT is built on the existing technologies of the predicate device Discovery CT750 HD. The vast majority of the software features and functions are common between the two products. The software user interface has been redesigned to provide more simplified workflow and user experience. Hardware components including the imaging chain however have been upgraded to support the new and improved capabilities.

The most notable changes in the imaging chain as compared to the predicate device Discovery CT750 HD is described below.

The Revolution CT system features the new "Gemstone Clarity" detector consisting of 256 rows at 0.625mm row thickness and a full 160mm z-coverage, the redesigned gantry with a 80cm bore and improved iterative reconstruction technology, allowing the system to deliver excellent image quality at full 160mm coverage to enable whole organ imaging.

The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems.

To house the wide Gemstone Clarity detector, the Revolution gantry has been redesigned with high specifications of strength and rigidity that support fast rotation speeds for acquisitions with high temporal resolution, while providing an 80cm bore opening to accommodate patients with positioning flexibility and comfort. With an improved center mount design that balances the mechanical forces generated by the rotating components, the gantry and detector assembly is capable of supporting accelerations that ensures reliable operation at today's 0.28 seconds per rotation, and can be extended to support imaging at 0.20 seconds per rotation in the future.

On the rotating gantry, the new Performix HDw tube tailored for the wide angle geometry generates the X-ray beam for patient imaging.

To address the challenges of the wide cone-beam geometry of the new scanner, a new advanced image reconstruction algorithm called Volumetric High Definition (VHD) has been designed specifically to reduce cone-beam artifacts and maintain CT number uniformity.

The image reconstruction engine further includes ASiR-V, the next generation of GE's ASiR iterative recon technology for noise reduction and dose management. Finally, GE's SnapShot Freeze technology is supported on all cardiac acquisitions to improve the temporal properties of the reconstructed images when visualizing the coronaries.

Despite the changes described above, the control mechanism, operating principle, energy type, and intended use have not changed from the predicate device Discovery CT750 HD.

Adverse Effects on Health:

Potential electrical, mechanical, and radiation hazards are identified in risk management including hazard analysis and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards. (AAMI/ES and IEC60601-1 Ed.3 and associated collateral and particular standards for CT).
- Compliance to applicable CDRH 21CFR subchapter J requirements.
- Compliance to NEMA XR-25

The device is designed and manufactured under the Quality System Regulations of 21CFR 820.

Determination of Substantial Equivalence:

The Revolution CT has completed testing and is in compliance with IEC 60601-1 Ed. 3 and its associated collateral and particular standards, 21CFR Subchapter J, and NEMA XR-25. The device has successfully completed all testing per our quality system as well as comparison testing to the predicate device. It was designed and is manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Required Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

GE believes the Revolution CT system is of comparable type and substantially equivalent to our currently marketed system Discovery CT750 HD.

The substantial equivalence was also based on software documentation for a "Moderate" level of concern device.

Summary of Additional Testing

In addition to the verification and validation testing successfully completed as required by GE Healthcare's quality system, additional engineering (non-Clinical testing) and clinical performance testing was performed to provide the requisite data to substantiate performance claims, the revised indications, and ultimately substantial equivalence.

Non-Clinical Testing

The performance evaluation testing used a variety of test methods, phantoms, and clinical datasets. Various mathematical, physics and statistical analysis were performed to demonstrate that each performance specification was successfully verified and substantiated. The areas additionally evaluated for the non-clinical testing included cardiac, cardiovascular, and thoracic imaging; temporal resolution, dose performance, and image quality. The image quality evaluation included evaluation for artifacts, scatter, spatial resolution, and low contrast detectability. For the LCD evaluation, a model observer study was used along with the MITA LCD phantom. Acceptance testing per IEC 61223-3-5 was also conducted.

Clinical Testing

Sample clinical data was collected from 49 subjects at one site in the US with the approval of appropriate ethics committee and in accordance with 21 CFR Parts 812, 50 and 56, as well as GE Healthcare's quality system's procedures for such evaluations.

The intent of the protocol was to obtain a sample set of clinical images across different patient populations, clinical scenarios, and scanning protocols/techniques. Patients were selected for potential recruitment to meet these needs. Any patient who met these criteria stated in the Protocol and who voluntarily signed the Informed Consent Form was recruited.

This sample image data was representative of a wide range of anatomical coverage and patient indications and was categorized into the following types of scans:

- Cardiac – Coronary CTA, Stress/Rest Perfusion, Cardiac Function, Calcium Burden, Gated Chest (Triple Rule Out), TAVI
- Body & Extremity - Abd/Pelvis, Chest, Ankle, Shoulder, Knee, Spine
- Neuro – Sinus, General Brain, Contrast Enhanced Brain, Neuroangiography, Neuro Perfusion, Neuro 4D CTA

The images were evaluated by multiple readers who are qualified radiologists at different institutions in the United States of America for clinical acceptance and image quality using a 5 point Likert scale.

The results of this clinical assessment demonstrate the acceptable diagnostic imaging performance of the GE Healthcare Revolution CT scanner.

Substantial Equivalence Conclusion:

Based on the conformance to standards, development under our quality system, and the engineering and clinical testing provided, GE Medical Systems believes that the Revolution CT is as safe and effective, and performs in a substantially equivalent manner to the predicate device Discovery CT750 HD (K120833).

Section 6: Premarket Notification Truthful and Accurate Statement

Revolution CT

Premarket Notification

Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify, in my capacity as Chief Regulatory Strategist of GE Healthcare, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(b) (6)

Section 7: Class III Summary and Certificate

Revolution CT

This section is not applicable to this submission for the **Revolution CT**. The **Revolution CT** and its' predicate device(s) have been classified as Class II devices in accordance with 21 CFR 892.1750.

Section 8: Financial Certification or Disclosure Statement

Revolution CT

Section 8: Financial Certification or Disclosure Statement

GE Medical Systems (d.b.a GE Healthcare) (b)(4) to determine substantial equivalence. Refer to Section 20 for description of studies performed.

In accordance with 21 CRF 807.87(j), GE Medical Systems is including financial certification and disclosure statements for each clinical investigator who participated in the study.

Refer to the attached FDA forms:

Form FDA 3454 (b)(4)
Form FDA 3455

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: December 31, 2015

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable check box.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	
(b) (6) [redacted]	(complete list of names attached)

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
(b) (6) [redacted]	Global Research Manager
FIRM/ORGANIZATION: GE Healthcare	
SIGNATURE: (b) (6) [redacted]	DATE *(mm/dd/yyyy)*: 10/31/2013

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Do NOT send your completed form to the PRA Staff email address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
PRAStaff@fda.hhs.gov

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FORM FDA 3454 (4/13)

PSC Publishing Services (301) 443-6740 EF

Investigators listed for 3454 (1)

(b) (6)

[redacted]

10/31/2013

MM/DD/YYYY

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: December 31, 2015

TO BE COMPLETED BY APPLICANT

The following information concerning _____(b) (6)_____ , who participated
Name of clinical investigator

as a clinical investigator in the submitted study Clinical Evaluation for GE Revolution CT System
Name of

_____ is submitted in accordance with 21 CFR part 54. The
clinical study

named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☒ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria; (see attached)

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☐ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
(b) (6)	Global Research Manager
FIRM/ORGANIZATION GE Healthcare	
SIGNATURE (b) (6)	Date *(mm/dd/yyyy)* 10/31/2013

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
PRAStaff@fda.hhs.gov

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FORM FDA 3455 (4/13)

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(b) (6)

[redacted]

(b)(4)

[redacted]

The outcomes of the clinical study are independent from and not influenced by the above payments. Additionally, no payments vary based on the outcomes of the study.

10/31/2013
MM/DD/YYYY

Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.1 Standards

9.1.1 Recognized and Voluntary Standards

The Revolution CT System conforms to applicable portions of the recognized standards listed below and in the attached Standards Data Forms For 510(K) – FDA Form 3654._

Standards No.	Standards Organization	Standards Title	Version	Date
60601-1	ANSI/AAMI ES	Medical Electrical Equipment, Part 1: General Requirements for basic safety and essential requirement - First Edition 2005 and C1:2009 and A2:2010	2005 +C1:2009+A2:2010	2006
60601-1	IEC	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance	Ed.3	2005
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Ed.3	2007
60601-1-3	IEC	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment	Ed.2	2008
60601-2-44	IEC	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	Ed.3	2009
DICOM	NEMA	Digital Imaging and Communication in Medicine (DICOM) Set	NEMA PS 3.1 – 3.18	2009
XR-25	NEMA	Computed Tomography Dose Check	------	2010

(b)(4) a third-party testing laboratory, has evaluated the conformity of the Revolution CT to each of these standards, with the exception of IEC (b)(4). Test reports and certification reports have been issued by (b)(4) Healthcare has received final reports.

(b)(4) [redacted]

9.1.2 Compliance to Federal Performance Standards

The device and its labeling complies with the following applicable requirements in the Code of Federal Regulations, Title 21, Subchapter J – Radiological Health, applicable sections that include:

- 1020.30(c) Certification of Components
- 1020.30(e) Identification of X-ray Components
- 1020.30(g) Information for assemblers
- 1020.30(h) Information for users
- 1020.30(j) Warning Label
- 1020.30(k) Leakage radiation from source assembly
- 1020.30(m) Beam Quality
- 1020.33(c) Information for Users
- 1020.33(d) Quality assurance
- 1020.33(f) Control and indication of operation conditions
- 1020.33(g) Tomographic plane indication and alignment
- 1020.33(h) Beam-on and shutter status indicators
- 1020.33(i) Scan increment accuracy
- 1020.33(j) CT number mean and standard deviation

The product supplement report has been submitted as required. (b)(4) [redacted]

Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.2 System Certificate from NRTL (ATM)

(b)(4)Product Specs

Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3 Standards Data Form for 510(k) – FDA Form 3654

Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3.1 FDA FORM 3654 For ANSI/AAMI ES 60601-1 (10 pages)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI ES60601-1:2005+C1:2009+A2:2010 -- Medical electrical equipment–Part 1: General requirements for basic safety

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

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[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/AAMI ES60601-1:2005+C1:2009+A2:2010 -- Medical electrical equipment–Part 1: General requirements for basic safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	General requirements for testing ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Classification of ME Equipment and ME Systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/AAMI ES60601-1:2005+C1:2009+A2:2010 -- Medical electrical equipment–Part 1: General requirements for basic safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	ME Eqauipment, identification, marking, and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Protection against electrical HAZARDS from ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Protection against MECHANICAL HAZARDS from ME EQUIPMENT and M	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE

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ANSI/AAMI ES60601-1:2005+C1:2009+A2:2010 -- Medical electrical equipment–Part 1: General requirements for basic safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Protection against unwanted and excessive radiation HAZARDS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Protection against excessive temperatures and other HAZARDS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Accuracy of controls and instruments and protection against hazardous outputs	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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SUMMARY REPORT TABLE

STANDARD TITLE
ANSI/AAMI ES60601-1:2005+C1:2009+A2:2010 -- Medical electrical equipment–Part 1: General requirements for basic safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
13	HAZARDOUS SITUATIONS and fault conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15	Construction of ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

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SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/AAMI ES60601-1:2005+C1:2009+A2:2010 -- Medical electrical equipment–Part 1: General requirements for basic safety

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16	ME SYSTEMS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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DESCRIPTION

JUSTIFICATION

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Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3.2 FDA FORM 3654 for IEC 60601-1 (10 pages)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1:2005+C1:2006+C2:2007 -- Medical electrical equipment–Part 1: General requirements for basic safety and essential pe

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
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Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1:2005+C1:2006+C2:2007 -- Medical electrical equipment–Part 1: General requirements for basic safety and essential pe

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	General requirements for testing ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Classification of ME Equipment and ME Systems	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1:2005+C1:2006+C2:2007 -- Medical electrical equipment–Part 1: General requirements for basic safety and essential pe

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	ME Equipment, identification, marking, and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Protection against electrical HAZARDS from ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Protection against MECHANICAL HAZARDS from ME EQUIPMENT and M	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1:2005+C1:2006+C2:2007 -- Medical electrical equipment–Part 1: General requirements for basic safety and essential pe

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Protection against unwanted and excessive radiation HAZARDS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Protection against excessive temperatures and other HAZARDS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Accuracy of controls and instruments and protection against hazardous outputs	☒ Yes ☐ No ☐ N/A

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DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1:2005+C1:2006+C2:2007 -- Medical electrical equipment–Part 1: General requirements for basic safety and essential pe

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
13	HAZARDOUS SITUATIONS and fault conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
15	Construction of ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1:2005+C1:2006+C2:2007 -- Medical electrical equipment–Part 1: General requirements for basic safety and essential pe

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
16	ME SYSTEMS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3.3 FDA FORM 3654 for IEC 60601-1-2 (2 pages)

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STANDARD TITLE [1]

IEC60601-1-2:2007 -- General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and test

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-54	
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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1-2:2007 -- General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and test

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Identification, marking and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	ELECTROMAGNETIC COMPATIBILITY	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Paperwork Reduction Act Statement

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Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3.4 FDA FORM 3654 for IEC 60601-1-3 (8 pages)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-1-3:2008 -- Collateral Standard: Radiation protection in diagnostic X-ray equipment

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#12-210	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1-3:2008 -- Collateral Standard: Radiation protection in diagnostic X-ray equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	ME EQUIPMENT identification, marking and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	RADIATION managements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1-3:2008 -- Collateral Standard: Radiation protection in diagnostic X-ray equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	RADIATION QUALITY	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Limitation of the extent of the X-RAY BEAM and relationship between X-RA	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	FOCAL SPOT TO SKIN DISTANCE	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1-3:2008 -- Collateral Standard: Radiation protection in diagnostic X-ray equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RA	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
11	Protection against RESIDUAL RADIATION	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Protection against LEAKAGE RADIATION	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

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STANDARD TITLE [1]

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-1-3:2008 -- Collateral Standard: Radiation protection in diagnostic X-ray equipment

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
13	Protection against STRAY RADIATION	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3.5 FDA FORM 3654 for IEC 60601-2-44 (10 pages)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.4	General Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.5	General requirements for testing of ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.6	Classification of ME EQUIPMENT and ME SYSTEMS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#N/A	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.7	ME EQUIPMENT identification, marking and documents	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.8	Protection against electrical HAZARDS from ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.9	Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

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Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#N/A	
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STANDARD TITLE
IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.10	Protection against unwanted and excessive RADIATION HAZARDSs	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.11	Protection against excessive temperatures and other HAZARDS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.12	Accuracy of controls and instruments and protection against hazardous outputs	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.13	Hazardous situations and fault conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.15	Construction of ME EQUIPMENT	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

Please answer the following questions	Yes	No
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FDA Recognition number [3]	#N/A	
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC60601-2-44:2009 -- Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for co

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.16	ME SYSTEMS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.17	ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SY	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
203	General requirements for RADIATION protection in diagnostic X-ray equipme	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3.6 FDA FORM 3654 for NEMA XR-25 (2 pages)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

NEMA XR-25 Computed Tomography Dose Check

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#12-225	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
NEMA XR-25 Computed Tomography Dose Check

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	DOSE NOTIFICATIONS AND DOSE ALERTS	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
None

DESCRIPTION
The Discovery CT870 complies with XR-25 Computed Tomography Dose Check

JUSTIFICATION
The Discovery CT870 has been verified to comply with NEMA XR-25 Computed Tomography Dose Check. Verification evidence is available upon request.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

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Section 9: Declarations of Conformity and Summary Reports

Revolution CT

9.3.7 FDA FORM 3654 for DICOM [NEMA PS3.1 - 3.18(2009)] (2 pages)

Attachment

Revolution CT DICOM Conformance Statement (172 pages)

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

NEMA PS3.1-3.18 (2009), Digital Imaging and Communications in Medicine (DICOM) Set. Radiology

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#12-218	
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
NEMA PS3.1-3.18 (2009), Digital Imaging and Communications in Medicine (DICOM) Set. Radiology

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION
Please refer to the attached document titled "CT Discovery 870 Dicom Conformance Statement"

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Imagination at work

Section 10: Executive Summary

Revolution CT

10.1 Reason for Submission

Pursuant to 21 CFR §807.87 GE Healthcare is submitting this pre-market notification for its next generation premium CT scanner system Revolution CT.

Built upon the existing technologies and designs of the predicate device Discovery CT750 HD (K120833), the Revolution CT system is re-designed as a powerful fully volumetric CT scanner to provide whole organ imaging capability for the full range of clinical applications (b) (4) scanner.

(b) (4) These changes however do not constitute new intended uses for CT beyond those of the predicate. The general indication of head and whole-body computed tomography imaging applies both to this system and its predicate system.

A detailed change and comparison between the proposed device Revolution CT and the predicate device Discovery CT750 HD is in section 12.

10.2 Concise Description of Device

The Revolution CT is a multi-slice (256 detector row) CT scanner consisting of a gantry, patient table, scanner desktop (operator console), system cabinet, power distribution unit (PDU), and interconnecting cables. The system includes image acquisition hardware, image acquisition and reconstruction software, and associated accessories.

The system generates images through the computer reconstruction of data acquired at different angles and planes of the rotating gantry. The gantry rotates at up to 0.28 seconds per rotation, and can acquire up to 512 slices of image data per rotation with a maximum total coverage of 160 mm in the z direction. The gantry however is designed to be able to rotate at 0.20 second per rotation. The system can be operated in Axial, Cine, Helical (Volumetric), Cardiac, and Gated acquisition modes.

The Revolution system is a powerful Volume High Definition CT scanner that is designed to provide best-in-class technologies for whole organ coverage, high image quality and responsible dose performance with the following characteristics:

- 160 mm detector coverage
- 140ms temporal resolution (0.28s rot. Speed) + intelligent motion correction for 24 ms effective temporal resolution
- 0.23 mm spatial resolution
- 80 cm bore size

Built upon the existing technologies the Revolution system is designed to use less radiation dose than the previous generation product while maintaining the same superior level of image quality. Further, the fast speed of the scan could potentially reduce contrast volumes. The hardware platform is also capable of supporting Gemstone spectral imaging and 0.2s rotation speed. Key technology enablers include:

- New image chain hardware and reconstruction for uncompromised image quality, designed to overcome the challenges of typical wide detector systems such as cone beam artifacts, HU uniformity, scatter & beam hardening artifacts, while improving dose performance.
- The next-generation of iterative reconstruction technology, ASiR-V, designed to deliver ultra-low noise levels, improved low contrast detectability and may enable a reduction in dose for all clinical applications .
- Best effective temporal resolution enabled by 0.28 second rotation speed combined with intelligent motion correction with SnapShot Freeze (K120910) for excellent cardiac imaging at any heart rate.
- A wide bore to image all patients, allow better patient positioning & access .

A more detailed product description can be found in Section 11 (Device Description) and the product datasheet in Section 13 (Proposed Labeling) of this submission.

During the development process the Revolution CT system was referenced by multiple engineering names in the design history file (DHF), such as “Revolution” (b) (4) [redacted] ” and “Revolution CT”. Some of the DHF documents provided in this 510(k) submission reflect these names.

10.3 Intended Use

The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.

10.4 Indications For Use

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

10.5 Device Modification Overview

The Revolution CT is built on the existing technologies of the predicate device Discovery CT750 HD. (b) (4)

[redacted]

.

(b) (4)

[redacted]

The Revolution CT system features the new "Gemstone Clarity" detector consisting of 256 rows at 0.625mm row thickness and a full 160mm z-coverage, the redesigned gantry with a 80cm bore and improved iterative reconstruction technology, allowing the system to deliver excellent image quality at full 160mm coverage to enable whole organ imaging.

The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems.

(b) (4)

[redacted]

Gemstone Clarity detector is the state of the art solid-state CT detector using Gemstone scintillator technology, which combines high light output, high stopping power, and low radiation damage, with the fastest primary speed and lowest afterglow in the industry to support extremely fast acquisition modes across the full spectrum of modern CT clinical applications. (b) (4)

[redacted]

To house the wide Gemstone Clarity detector, the Revolution gantry has been redesigned (b) (4)

[redacted]

On the rotating gantry, the new Performix HDw tube tailored for the wide angle geometry generates the X-ray beam for patient imaging. The system also features a (b) (4) [redacted]

In the wide cone-beam geometry of the new scanner, (b) (4) [redacted] modeling of (b) (4) [redacted] handling of CT signal challenges to make (b) (4) [redacted] images.

The image reconstruction engine further includes (b) (4) [redacted] Finally, GE's SnapShot Freeze technology is supported on all cardiac acquisitions to improve the temporal properties of the reconstructed images when visualizing the coronaries.

Despite the changes described above, the control mechanism, operating principle, energy type, and intended use have not changed from the predicate device Discovery CT750 HD. We believe the system is of comparable type and substantially equivalent to the currently marketed predicate Discovery CT750 HD system. In addition the system complies with the same International standards and 21CFR performance requirements. It is developed under the same GE quality system and design control processes.

The more detailed comparison between the Revolution CT and its predicate device Discovery CT750 HD is provided in Section 12.

10.6 Technology

The Revolution CT system employs the same fundamental scientific technology as that of its predicate device and other cleared GE CT systems.

10.7 Test Summary and Conclusion

Verification and validation including hazard mitigation has been executed with result demonstrating the Revolution CT system met design input and user needs.

In addition the system complies with the International standards (IEC 60601-1 Ed. 3 series) and 21CFR performance standards. The Revolution CT system is developed under the same design controls processes, software development life cycle, and GE quality system as the predicate. GE believes the system is of comparable type and substantially equivalent to the currently marketed system listed above.

This 510k submission does contain sample clinical images and a write-up of physician assessments of those images on a (b) (4) Extensive engineering testing was performed that demonstrates the system meets input requirements and performs as intended, within specifications.

Refer to System Verification Summary as well as System Validation Summary: in **Section 18**: Bench Test.

SECTION 11

Device Description

Revolution CT

11.1 Product Description

The Revolution CT System is a general purpose, high premium, multi-slice CT Scanning system consisting of a gantry, a detector, power distribution unit (PDU), a table, a system cabinet, scanner desktop and associated accessories. It is designed as a powerful fully volumetric CT scanner to provide whole organ imaging capability for the full range of clinical applications with the same or better state-of-(b) (4) scanner.

The following paragraphs describes briefly its main components.

Gantry

The system uses a rotating gantry with a cylindrical patient bore that houses the X-ray tube, the high voltage generator and detector. The Revolution CT system features a wide 80cm bore diameter to facilitate scanning larger patients and to ensure flexible access and patient positioning in the gantry (b) (4)

The Tube focus to detector distance is (b) (4) (b) (4) The gantry is capable of completing one rotation in 0.28 seconds. It also has the capability to rotate (b) (4) seconds per rotation .

Linear attenuation of X-rays by the patient or object placed on the CT table in the gantry opening is measured at the detector as the gantry rotates around the object.

The Revolution CT system uses the **Performix™ HDw X-Ray Tube**. (b) (4) are (b) (4) and (b) (4) increments. (b) (4)

Detector

The CT Detector is a wide coverage cone beam detector with multiple detector rows along the longitudinal plane. The Detector channels are arranged as an arc diametrically opposite to the Xray tube on the rotating CT gantry. The detector consists of a scintillator that converts X-rays into light, diodes for light conversion into current and analog to digital converter that converts the current into digital signal.

The Data Acquisition System (DAS) samples each detector cell up to about (b) times per gantry rotation, amplifies and quantifies the current from the cells and transmits the resultant data to reconstruction engine. It consists of (b) (4) available input channels and operates at a sample rate (b) (4)

The detector is a full 160mm detector. It allows 256 rows of data to be collected at a time for both axial, helical, and Cine imaging. This allows 256 axial images to be generated in a single gantry rotation in the axial mode. The 256 rows of this detector are comprised of cell elements with an effective pitch of 0.625 mm at isocenter.. Each row consists of (b) detector elements used for imaging. resulting in (b) (4) total data elements.

In addition, the detector features a unique (b) (4) layout and a (b) (4) . Combined with advanced image reconstruction algorithms, the system delivers image quality at full 160mm coverage (b) (4)

Patient Table

The Table provides support and vertical/longitudinal motion of the patient relative to the CT scanner. The Table also mechanically houses and electrically interfaces to the integrated ECG unit. This subcomponent includes patient positioning and support accessories (pads, straps, poles, head holders) as well as foot pedals.

The patient table has the capacity to (b) (4) distributed load with (b) (4) positional accuracy for a scannable range (b) (4) . The table is capable of 300mm/s travel speed. This enables fast scanning for longer range anatomies.

Scanner Desktop

The Scanner Desktop (Operator Console) provides the software user interface in the control room of the scanning suite for all system operations. It governs system operation and workflow until user confirms a scan prescription (resuming control after scan completes), and includes both the software and console hardware.

The Scanner Desktop uses (b) (4)

System Cabinet

The System Cabinet subcomponent provides pre-processing, image reconstruction, post processing and scout image construction operations on data available from scan data management. It includes both the software and computer hardware for image generation and scan data acquisition.

Transaxial images are generated using commonly referenced Filtered Back-projection mathematical operations. The reconstruction engine is custom-designed for CT image generation. The scanner also can use ASiR-V reconstruction.

Additional details about the Revolution CT Scanner can be found in the product data sheet as well as in the Operator Manuals found in **Section 13** of this submittal. Photographs of the product can be found in section 11.3 of this submittal.

11.2 Options and Accessories

The following peripheral devices, software options and accessories are designed and verified to work with the Revolution CT System.

(b) (4)

The following are the software options of the Revolution CT:

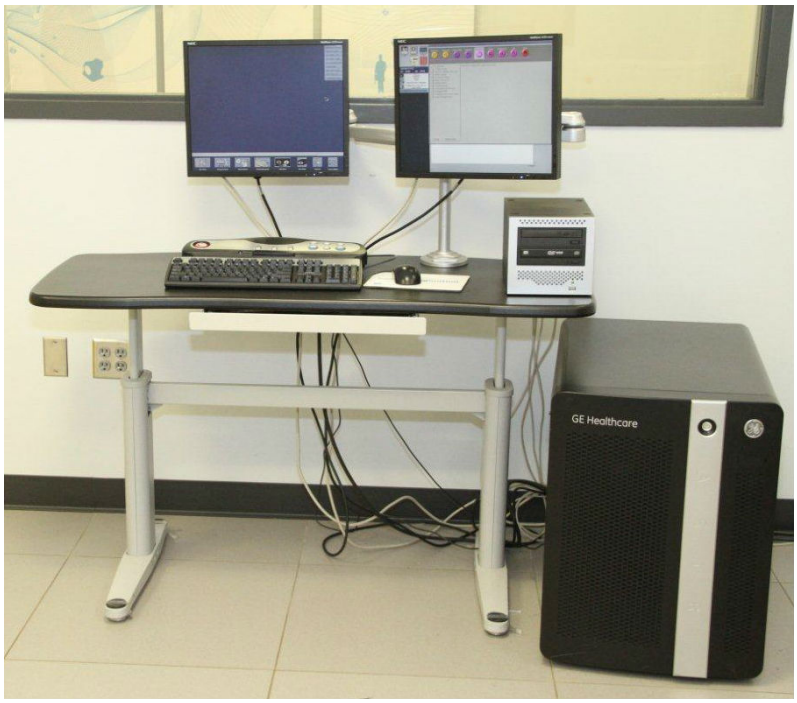
(b) (4)

Additional information concerning options and accessories associated with Revolution CT scanner can be found in the product data sheet included in Section 13 and in the Technical Reference Manual – Chapter 1 included in Section 13.

11.3 Product Photographs

A. Discovery CT870 CT Scanner System viewed from the end of the patient table.

B. Discovery CT870 CT Scanner Desktop (Operator Console)-



C. Discovery CT System Cabinet

D. Discovery CT870 Patient Table

Section 12: Substantial Equivalence Discussion

Revolution CT

12.1 Comparison of Intended Use and Indications for Use

This 510(k) submission for the Revolution CT system includes the same intended use and substantially equivalent indications for use as its predicate device, the GE Discovery CT750 HD(K120833).

The intended use and indications for use statements for both products are provided below:

	Predicate Discovery CT760 HD –K120833	Proposed Device Revolution CT	Discussion
Indented Use	The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.	The system is intended for head, whole body, cardiac and vascular X-ray Computed Tomography applications.	**Same**
Indications for Use	The Computed Tomography X-ray system is intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data taken at different angles and planes, including Axial, Cine, Helical (Volumetric), Cardiac, Spectral, and Gated acquisitions for all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further the images can be post processed to produce additional imaging planes or analysis results.	The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. **The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.** The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories. This device may include data and image processing to produce images in a variety of trans-axial and	**Substantially Equivalent** The capability to image whole organs is added to the indication for use in the proposed device. The Revolution CT system offers a 160 mm detector capable of imaging whole organs in a single rotation for virtually all of the population. (b) (4) The indication for use of the Revolution CT system is substantially equivalent to the predicate device's indication for use.

	The system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications for both single kV acquisitions and with the fast kV switching spectral imaging option (GSI). The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy. If the spectral imaging option is included on the system, the system can acquire CT images using different kV levels of the same anatomical region of a patient in a single rotation from a single source. The differences in the energy dependence of the attenuation coefficient of the different materials provide information about the chemical composition of body materials. This approach enables images to be generated at energies selected from the available spectrum to visualize and analyze information about anatomical and pathological structures.	reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications. The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.	

	GSI provides information of the chemical composition of renal calculi by calculation and graphical display of the spectrum of effective atomic number. GSI Kidney stone characterization provides additional information to aid in the characterization of uric acid versus non-uric acid stones. It is intended to be used as an adjunct to current standard methods for evaluating stone etiology and composition		

12.2 Product Comparison

The GE Revolution CT Scanner system uses the same basic fundamental technology as that of the predicate device Discovery CT750 HD scanner system. (b) (4) [redacted] A detailed description of the Revolution CT Scanner System is provided in Section 11 of this submission.

The table below outlines the major subsystem differences and similarities.

Product Comparison Chart

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
Gantry	➢ Discovery CT750 HD Gantry ➢ 40 mm Detector ➢ 70 cm patient bore	➢ Revolution CT Gantry ➢ 160 mm Detector ➢ 80 cm patient bore	Substantially Equivalent Proposed device uses a (b) (4) [redacted] The Revolution system including the gantry as a major component conforms to the same industry safety standards such as IEC60601-1 series and applicable performance standard in 21 CFR subchapter J The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
X-Ray Tube	Performix HD ➢ Dynamic in-plane focal spot deflection ➢ Independent X and Z focalspot control capability ➢ Same Anode and Frame as Performix Pro	Performix HDw ➢ Dynamic in-plane focal spot deflection ➢ Independent X and Z focalspot control capability	Substantially Equivalent (b) (4) (b) (4) for wide detector coverage, (b) (4) to provide wide detector coverage, (b) (4) accommodate the (b) (4) to increase gantry speed capability to (b) (4) rotation time. The Revolution CT and the tube conform to the same industry safety standards such as IEC60601-1 series and applicable performance standard in 21 CFR subchapter J The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
High Voltage Generator	Jedi-SC ➢ 100 kW Power ➢ Focal Spot deflection and size control ➢ View by view kV Switching capability ➢ 80, 100, 120 ,140 kV	Ultra-fast kV switching generator ➢ 103 kW Power ➢ Focal Spot deflection and size control ➢ View by view kV Switching capability ➢ 70, 80, 100, 120 ,140 kV	Substantially Equivalent  (b) (4) The Revolution CT with the generator being a major component conforms to the same industry safety standards such as IEC60601-1 series and applicable performance standard in 21 CFR subchapter J The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
Source Collimator	➢ 40mm Aperture ➢ Cam control of x-ray beam ➢ 5 beam filters (small, medium, large, Calibration Filter, blocked)	➢ 160 mm Aperture ➢ (b) (4) control of x-ray beam ➢ (beam filters (b) (4)	Substantially Equivalent (b) (4) Proposed device has aperture blades (b) (4) to minimize g force effects on aperture motion (b) (4) The Revolution CT with the collimator being a major component conforms to the same industry safety standards such as IEC60601-1 series and applicable performance standard in 21 CFR subchapter J The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
Detector	➢ 40mm wide ➢ 64 rows, 912 channels/row ➢ Backlit Diode Technology ➢ Gemstone Scintillator Material	➢ 160 mm wide ➢ 256 rows (b) (4) channels/row ➢ Low capacitance backlit photodiode ➢ Gemstone Scintillator Material	Substantially Equivalent (b) (4) The new (b) (4) The proposed device uses a (b) (4) that reduces the scatter to primary ratio. The Revolution CT with the detector being a major component conforms to the same industry safety standards such as IEC60601-1 series The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
Data Acquisition System	➢ 64 rows 912 channels/row ➢ Max sample rate 2496 views per rotation	➢ 256 rows (b) (4) channels/row ➢ Max sample rate (b) (4) views per rotation	Substantially Equivalent The Data Acquisition system in the proposed device is similar to the predicate DAS (b) (4) [redacted] The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
SlipRing	➢ 10.3G bits per second ➢ 208 VAC for rotating side power	➢ (b) (4) bits per second ➢ (b)(4) x-ray power ➢ (b)(4) for rotating (b)(4)	Substantially Equivalent (b)(4) The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
Table	➢ Global Table with scannable range of 1700mm to 2000mm ➢ Load capacity 500 lbs	➢ Table with scannable range of (b)(4) ➢ Load capacity (b)(4)	Substantially Equivalent (b)(4) The Revolution CT with the table being a major component conforms to the same industry safety standards such as IEC60601-1 series and applicable performance standard in 21 CFR subchapter J The changes did not raise new safety and effectiveness concerns.
Scanner desktop & Host Computer	➢ 10G Baud DAS Interface Processor (DIP) ➢ 1 IG Recon Modules / 1 ASIR module	➢ (b)(4) ➢ CPU (b)(4) Core (b)(4) Processors (b)(4)	Substantially Equivalent Proposed device uses improved (b)(4) host computer due to ITE computer obsolescence. The changes did not raise new safety and effectiveness concerns.
Operating system	SLES Linux Enterprise Server 11	(b)(4)	Same
New Features			

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
(b)(4) [redacted]	No	Yes	Substantially Equivalent (b)(4) [redacted] The changes did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
(b)(4) [redacted]	Yes with external cardiac triggering device	Yes with integrated cardiac monitor and external cardiac triggering device	Substantially Equivalent (b)(4) [redacted] The (b)(4) [redacted] The changes did not raise new safety and effectiveness concerns.
Dose Reduction Features			
AutomA /SmartmA	Yes	Yes	Same

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
(b)(4) [redacted]	No	Yes	Substantially Equivalent  The changes did not raise new safety and effectiveness concerns.
ECG Dose Modulation	Yes	Yes	Same
CT4Kids protocols Color Coding for Kids Protocol	Yes	Yes	Same
SmartTrack (Tracking)	Yes	Yes	Same

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
SmartBeam (filters)	Yes	Yes	Same
CTDIvol & DLP display Dose Reporting (DICOM) Dose Check - XR25	Yes	Yes	Same
Reconstruction	Full 3D Volumetric Reconstruction ASiR	(b)(4) [redacted]	Substantially Equivalent (b)(4) [redacted] [redacted] (See Section 18 Revolution Performance Evaluation for more details.) Testing did not raise new safety and effectiveness concerns.

Subsystem	Discovery CT750 HD (Predicate Device K120833)	Revolution CT (Proposed Device)	Discussion of differences
Workflow /Productivity Features	Smartstart Autoscan Prospective & Retrospective Reconstruction Exam Split Queued Reconstruction Retrospective Image Decomposition	Smartstart Autoscan Prospective & Retrospective Reconstruction Exam Split Queued Reconstruction Retrospective Image Decomposition	Same
Scan Modes	Scout Axial Helical Cine Cardiac Gated High Definition **Volume Helical Shuttle** **Volume Shuttle**	(b)(4) [redacted]	Substantially Equivalent (b)(4) [redacted] The changes did not raise new safety and effectiveness concerns.

12.3 Substantial Equivalence Conclusions

GE Revolution CT Scanner is the result of (b)(4) modifications to the GE (b)(4) believe the Revolution CT system is of comparable type and substantially equivalent to the currently marketed system Discovery CT750 HD.

SECTION 13

Proposed Labeling

Revolution CT

13.1 Description of Product Labeling

The GE Revolution CT Scanner labeling includes information that is printed or fixed directly onto the system, documentation that accompanies the system, and informational and advertising information associated with the system.

The Revolution CT performance specifications and the data to substantiate them can be found in **Section 18**.

The accompanying documents include the following items:

Technical Reference Manual: contains important safety/regulatory information and technical details, including the information required by 21CFR 1020.30 and 1020.33. A copy of this document is included as **Attachment 13A**.

User Manual: contains user instructions for the operation of the equipment, along with background materials such as a device description and theory of operation. It is provided in **Attachment 13B**.

Other informational documents associated with the system include:

Preliminary Product Data Sheet: describes the systems specifications and features. A preliminary Product Data Sheet is included as **Attachment 13C**.

Sample Promotional Materials: sample of material that will be used to advertise and promote the product.. A draft promotional brochure for the Revolution CT feature is included as **Attachment 13D**.

(b)(4) Testing

Attachment 13A

Revolution CT Technical Reference Manual

Discovery CT870
Technical Reference Manual

OPERATING DOCUMENTATION

5443887-1EN
Revision 1

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Revision History

Revision	Date	Reason For Change
1	4/23/13	Release for ME program milestone, DOC1312096 Rev 3
1	10/14/2013	Release for 510k/VE program milestone, DOC1312096 Rev 5

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Table of Contents

Chapter 1 User Information

1 Introduction

Anyone who operates this system should have received prior training before they attempt to scan patients. This training should include medical and X-ray education, If necessary, additional training is available from a GE Applications Specialist. Contact your institution's GE Healthcare sales representative for additional information about further safety and operational training. This manual does not provide medical explanations, but it does suggest potential applications for some of the software features. It describes potential safety problems and how to avoid them.

Everyone who uses this equipment must read and understand all instructions, precautions and warnings. Procedures and safety precautions described in the Safety chapter should be read periodically.

This manual is originally written in English.

Do not use the equipment if a known safety problem exists. Call your local service provider and have the system repaired.

2 User Documentation

Description

The user documentation is designed for safe and effective use of the system, and is divided into the following parts:

1. User Manual: This manual contains all the user information required to operate the scanner in a safe and proper manner.
2. Technical Reference Manual: This manual contains safety information and specifications related to dose and image quality performance of the system. The manual is intended to assist with quality assurance testing and planned maintenance to ensure system performance.
3. Application Tips and Workarounds: This manual details workaround information for software and system information.

3 (b)(4)Product Specs

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

- [redacted]
- [redacted]
- [redacted]

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Chapter 2 Regulatory Information

1 Applicable Regulations and Standards

The system is classified as a Class I, IPX0 equipment, not suitable for use in the presence of a flammable anaesthetic mixture with oxygen or nitrous oxide. It is rated for continuous operation with intermittent loading. No sterilization is applied. The patient table cradle and patient support accessories are considered Type B applied parts.

This product complies with the requirements of the following regulations and standards:

Code of Federal Regulations, Title 21, Part 820 — Quality System Regulation

Code of Federal Regulations, Title 21, Subchapter J — Radiological Health

Federal U.S. law restricts this device for sale by or on the order of a physician.

GE Medical Systems is ISO 9001 and ISO 13485 certified.

The Discovery CT870 system complies with IEC 60601-1:2005, ES60601-1, EN60601-1:2006.

- All portions of the Discovery CT870 system are suitable for use in the patient environment.
- The system should be used only with GE approved equipment.

The Discovery CT870 system complies with radiation protection in accordance with IEC 60601-1-3:2008.

The Discovery CT870 system complies with IEC 60601-2-28. X-ray source assembly Performix HDw Tube Unit Assembly IEC 60601-2-28 (1993).

The Discovery CT870 system complies with IEC 60601-2-28. X-ray tube assembly Performix HDw Tube Unit Assembly IEC 60601-2-28:2010.

The Discovery CT870 system complies with IEC 60601-2-44. CT SCANNER Discovery CT870 System IEC 60601-2-44:2009

2 Product Description

2.1 Intended Use of the System

The system is intended for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

2.2 Indications for Use of the System

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

2.3 Contraindications

None known.

3 Product Manufacturer

This section lists the manufacturer of the Discovery™ CT870 product.

Table 1: Discovery™ CT870 Product Manufacturer

Model Name	Manufacturer (*) Manufacturing Site	Manufacturer Address
Discovery™ CT870	GE Medical Systems	3000 N. Grandview Blvd. Waukesha, WI - 53188, USA

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Chapter 3 Safety

1 General Safety Guidelines

This chapter provides information about safety precautions and procedures. It is important for you to read and understand the contents of this chapter so the correct precautions and procedures are followed. This manual should be kept near the scanner desktop for easy access.

United States Federal Regulation 21CFR 801.109

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

- This product was designed and manufactured to ensure maximum safety of operation. It should be operated and maintained in strict compliance with the safety precautions, warnings and operating instructions contained herein, and in any other documentation specific to the product.
- The system has been designed to meet all the safety requirements applicable to medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards.
- The manufacturer or vendor of the equipment makes no representation, however, that the act of reading this manual renders the reader qualified to operate, test or calibrate the system.
- The owner should make certain that only properly trained, fully qualified personnel are authorized to operate the equipment. A list of authorized operators should be maintained.
- This manual should be kept at hand, studied carefully and reviewed periodically by the authorized operators.
- Unauthorized personnel should not be allowed access to the system.
- Do not leave the patient unobserved at any time.
- Become familiar with the functional hardware so that you can recognize serious problems. Do not use the system if it appears damaged or fails. Wait for qualified personnel to correct the problem.
- Abbreviations used in the operator manuals can be found in this manual.
- If the product does not operate properly or if it fails to respond to the controls as described in this manual, the operator should:
    - First ensure the safety of the patient.
    - Next ensure the protection of the equipment.
    - Evacuate the area as quickly as possible in any potentially unsafe situation.
    - Follow the safety precautions and procedures as specified in this manual.

  - Immediately contact the local service office, report the incident and await further instructions.

- The images and calculations provided by this system are intended as tools for the competent user. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.
- Understand the product specifications, system accuracy, and stability limitations. These limitations must be considered before making any decision based on quantitative values. In case of doubt, please consult your sales representative.
- Do not block the ventilation ports of the electronic equipment. Always maintain at least 6 inches (15 cm) clearance around the ventilation ports to prevent overheating and damage to the electronic hardware.
- The supplier will make available on request circuit diagrams, component parts lists, descriptions, calibration instructions which will assist the user's appropriately qualified technical personnel to repair those parts designated to be repairable.

2 Safety Conventions

This manual addresses three safety classifications:

DANGER

THE MOST SEVERE LABEL DESCRIBES CONDITIONS OR ACTIONS WHICH RESULT IN A SPECIFIC HAZARD. YOU WILL CAUSE SEVERE OR FATAL PERSONAL INJURY, OR SUBSTANTIAL PROPERTY DAMAGE IF YOU IGNORE THESE INSTRUCTIONS.

WARNING

THIS LABEL IDENTIFIES CONDITIONS OR ACTIONS WHICH RESULT IN A SPECIFIC HAZARD. YOU WILL CAUSE SEVERE PERSONAL INJURY, OR SUBSTANTIAL PROPERTY DAMAGE IF YOU IGNORE THESE INSTRUCTIONS.

CAUTION

This label applies to conditions or actions that have potential hazard. You may cause minor injury or property damage if you ignore these instructions.

This manual uses pictures, or icons, to reinforce the printed message. It uses the corresponding international symbol or icon next to the danger, warning or caution message. For example, the upright hand with the lightning bolt across it warns of electrical hazards.

3 Symbols and Warning Labels

3.1 Symbols

This chapter uses the international symbol or icon along with the danger, warning or caution message.

Table 1: Symbols Used in Labeling

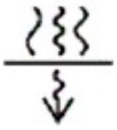
Symbol	Description
	Alternating current
	3 Phase alternating current
	Protective earthing point
	ON / Power ON
	OFF / Power OFF
	Input power
	Output Power
	Type B applied part
	Functional earth ground

Symbol	Description
	Electrical shock hazard
	Caution or warning
	Hand Pinch
	Radiation
	Maximum Weight Capacity
	Emergency Stop

Symbol	Description
	ETL Mark: Proof of product compliance (electrical, gas and other safety standards) to North American safety standards. Authorities Having Jurisdiction (AHJs) in 50 states and Canada and retailers accept the ETL classified/and recognized as proof of product safety..
	The system shall conform to applicable requirements of 21CFR Subchapter J
	WEEE: This symbol indicates that when the end-user wants to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	CE Mark: Manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

Table 2: Symbols Used in Labeling

Symbol	Description
Made for	Indicates the manufacturer (responsible design owner)
Made by or by	Indicates the manufacturing Location
	Refer to instruction manual/booklet Attention, consult accompanying documents
	Pushing prohibited

Symbol	Description
	IEC Manufacture location label
	Date of manufacture
	Serial number
	Catalog number
	X-Ray filtration (Al Equivalent Filtration)
	Minimum filtration
	Laser symbol
	Extra large focal spot
	Large focal spot

Symbol	Description
	Small focal spot

3.2 Equipment Warning Labels

The following Warning Labels are used on the equipment:

3.2.1 Laser Warning Labels

Illustration 1: Warning labels located at the bottom of the gantry cover (Reference 21CFR 1040.10 (g)(4))

CAUTION
LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT

CAUTION
Laser Radiation
Do Not Stare into Beam
635, 670nm Laser Diode

1 Milliwatt Maximum Output

Class II Laser Product

Illustration 2: Labels on the front of the gantry (Reference 21CFR 1040.10 (h))

[redacted]

CAUTION
LASER APERTURE
Do not stare into beam

Illustration 3: Labels on the front of gantry, rear of table, back of PDU, back of Scanner Desktop, and side of System Cabinet.

[redacted]

CAUTION
Avoid Injury. Read and understand information in manuals before operating product.

3.2.2 X-ray Warning Labels

Illustration 4: Label located on Scanner Desktop (Reference 21CFR 1020.30 (j))

[redacted]

WARNING
THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS, OPERATING INSTRUCTIONS AND MAINTENANCE SCHEDULES ARE OBSERVED.
TO BE USED BY AUTHORIZED PERSONNEL ONLY.

3.2.3 Table Warning Labels

Illustration 5: Pinch warning label located on the table

[redacted]

WARNING

FINGER PINCHING CAN CAUSE PHYSICAL INJURY. KEEP FINGERS AWAY FROM THIS AREA BEFORE OPERATING THE SWITCH FOR CRADLE OUT.

Illustration 6: Weight limit warning label located on the table

[redacted]

WARNING

AVOID INJURY. DO NOT EXCEED TABLE MAXIMUM CAPACITY OF 227 KG (500 LB).

3.2.4 Power Distribution Unit (PDU) Warning Labels

Illustration 7: PDU move warning on back of PDU

[redacted]

WARNING

PDU CAN MOVE AND DAMAGE CABLES. DO NOT LEAN ON OR MOVE WHEN CONNECTED TO POWER.

Illustration 8: PDU move caution on back of PDU

[redacted]

CAUTION

PDU can move and damage cables. Do not lean on or move when connected to power.

Illustration 9: WEEE Label

[redacted]

3.2.5 Scanner Desktop Labels

Illustration 10: Label on reading manuals before operating

[redacted]

CAUTION

Avoid Injury. Read and understand information in manuals before operating product.

Illustration 11: WEEE Label

3.2.6 External Accessory Labels

Illustration 12: IV pole warning label on leg of IV pole

WARNING

DO NOT LOAD MORE THAN 4.5 KG OR 10 POUNDS. VERIFY THAT EXTENSION COLLAR IS SECURELY TIGHTENED BEFORE USE.

Illustration 13: Table tray warning label on leg of table tray

WARNING

DO NOT LOAD MORE THAN 9 KG OR 20 POUNDS.

Illustration 14: Axial head holder caution

CAUTION

Accessory may fall and cause injury if not latched to cradle. Make sure that accessory is latched to underside of cradle. Excessive weight can break accessory and cause injury. Do not load more than 34 kg or 75 pounds.

Illustration 15: Axial head holder warning

WARNING

FALL HAZARDS ACCESSORY MAY FALL AND CAUSE INJURY IF NOT LATCHED TO CRADLE. MAKE SURE THAT ACCESSORY IS LATCHED TO UNDERSIDE OF CRADLE. EXCESSIVE WEIGHT CAN BREAK ACCESSORY AND CAUSE INJURY. DO NOT LOAD MORE THAN 34 KG OR 75 POUNDS.

Illustration 16: Coronal head holder caution

CAUTION

Do not hit the accessory against the gantry. Patient injury or equipment damage could result.

Illustration 17: Coronal head holder warning

WARNING

DO NOT HIT THE ACCESSORY AGAINST THE GANTRY. PATIENT INJURY OR EQUIPMENT DAMAGE COULD RESULT. ACCESSORY MAY FALL CAUSE INJURY IF NOT LATCHED TO CRADLE. MAKE SURE THAT ACCESSORY IS LATCHED TO UNDERSIDE OF CRADLE. EXCESSIVE WEIGHT CAN BREAK ACCESSORY AND CAUSE INJURY. DO NOT LOAD MORE THAN 34 KG OR 75 POUNDS.

4 Radiation Safety

(Reference 21CFR 1020.30 (h)(1)(i))

4.1 X-Ray Protection

WARNING

IMPROPERLY USED X-RAY EQUIPMENT MAY CAUSE INJURY. READ AND UNDERSTAND THE INSTRUCTIONS IN THIS BOOK BEFORE YOU ATTEMPT TO OPERATE THIS EQUIPMENT. IF YOU FAIL TO FOLLOW SAFE X-RAY PRACTICES OR IGNORE THE ADVICE PRESENTED IN THE MANUAL, YOU AND YOUR PATIENT RISK EXPOSURE TO HAZARDOUS RADIATION.

Authorized Users

This equipment incorporates a high degree of protection against X-ray radiation outside the useful beam. But this equipment cannot substitute the essential requirement that every user must take adequate precautions to prevent the possibility of any person carelessly, unwisely, or unknowingly exposing themselves or others to radiation.

Everyone having anything to do with X-ray equipment must receive proper training and become fully acquainted with the recommendations of the National Council on Radiation Protection and Measurements and the International Commission on Radiation Protection.

NCRP reports are available from:

NCRP Publications

7910 Woodmont Avenue

Room 1016

Bethesda, Maryland 20814

WARNING

EVERYONE HAVING ANYTHING TO DO WITH X-RAY EQUIPMENT MUST TAKE ADEQUATE STEPS TO ENSURE PROTECTION AGAINST INJURY.

All persons authorized to use the equipment must understand the dangers posed by X-ray exposure so that they can prevent any injury or damage that may result from such exposure. GE Healthcare urges you to use protective materials and devices to prevent any injury or damage from X-ray exposure.

4.2 General Radiation Safety

WARNING

NEVER SCAN A PATIENT WITH UNAUTHORIZED PERSONNEL IN THE SCAN ROOM. WARN VISITORS AND PATIENTS ABOUT POTENTIAL FOR HARM IF THEY FAIL TO FOLLOW INSTRUCTIONS.

WARNING

NEVER CALIBRATE, TEST THE SYSTEM, OR WARM THE TUBE WITH PATIENTS OR PERSONNEL PRESENT IN THE SCAN ROOM WITHOUT ADEQUATE RADIATION SAFETY PRECAUTIONS BEING UTILIZED.

- Stay behind a lead screen or lead glass shield during each X-ray exposure.
- Use technique factors prescribed by the radiologist or diagnostician. Use a dose that produces the best diagnostic results with the least X-ray exposure.
- Amber indicator lights on the gantry display panel, and rear of the gantry, illuminate during X-ray exposure.

WARNING

USE OF CONTROLS OR ADJUSTMENTS, OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN, MAY RESULT IN HAZARDOUS RADIATION EXPOSURE.

4.3 Scans Acquired at the Same Tomographic Plane

IEC standard 60601-2-44:2009, clause 203.107 states that you must be warned when scans are acquired at the same tomographic plane, i.e. same scan location. The need for the warning is to make users aware of the potential dose that can be given to the patient when acquiring scans at the same table location.

When acquiring scans in this mode:

- Utilize the dose information displayed on the *Scan Settings* screen. The dose information displayed is covered in the next section, $CTDI_{vol}$.
- An optional DICOM Structured Report (SR) Dose Report is saved in Series 997.
- Use proper techniques for the application and anatomy you are scanning.

A warning message is posted when [Confirm] is selected for the following scan types:

Axial scans with zero table increment (interval)

WARNING

THIS SERIES CONTAINS ONE OR MORE GROUPS WITH MULTIPLE SCANS AT THE SAME TOMOGRAPHIC PLANE, I.E. SAME LOCATION.
DO YOU WANT TO CONTINUE?

After reading the message, if you wish to continue with the scan, click [Continue], otherwise click [Cancel].

WARNING

PROLONGED EXPOSURE TO X-RAY IN ONE SPOT MAY CAUSE REDDENING OR RADIATION BURNS. USERS MUST BE AWARE OF THE TECHNIQUES USED AND EXPOSURE TIME TO ENSURE SAFE OPERATION.

4.4 Geometric Dose Efficiency

A warning message is posted when the Geometric Dose Efficiency in the Z-direction is less than 70%. Geometric Dose Efficiency is a measure of how much of the X-ray beam in the Z-direction is used by the system.

WARNING

THE FOLLOWING GROUPS IN THIS SERIES CONTAINS GEOMETRIC EFFICIENCY IN THE Z DIRECTION OF LESS THAN 70%: IMAGES 1-12,13-28.

NOTE: Images 1-12, 13-28 is an example of a location where Geometric Efficiency in Z is less than 70%.

4.5 Backup Timer Indicator

The system has backup timers that terminate the X-ray if it remains on longer than the prescribed scan time.

A warning message is posted when a scan is stopped by the backup timer.

Illustration 18: Backup Timer Warning Message

WARNING

BACKUP TIMER STOPPED SCAN. X-RAY STAYED ON LONGER THAN PRESCRIBED.

To continue scanning, press **Resume**.

4.6 Starting Scans from the Scan Room

Start Scan buttons are located on the right and left panels of both the front and rear gantry.

Illustration 19: Start Scan Button

If you want to stand by the gantry and start the scan, you can press **Start Scan** after you have confirmed the prescription and the table has been moved to the start location. Once the tube has reached the exposure speed, the button flashes green for 30 seconds and then times out.

Press the solid green **Start Scan** button again to bring the system back to the ready to scan state.

4.7 $CTDI_{vol}$

As you setup the scan parameters from the ViewEdit screen, the Dose Information area at the upper right of the scan monitor contains updated dose information. This dose information is based on a measurement of the CTDI or CT Dose Index, which is the current standard for CT dosimetry and performance. By using a measurement called $CTDI_{vol}$, a single value is provided to estimate the relative dose for an exam.

The $CTDI_{vol}$ is a weighted average measurement in a reference phantom. This dose is expressed in milliGrays. For additional information on specific $CTDI_{vol}$ doses and their calculations, refer to your Technical Reference manual.

The DLP or Dose Length Product is the product of the $CTDI_{vol}$ and the scan length for a group of scans. This number can be summed over the entire exam to give an estimate of the total dose. The value is expressed in milliGray centimeters.

The Projected Series DLP shows the DLP that would result from scanning the current group or groups.

The Accumulated Exam DLP displays the total exam DLP up to the current point in time. Scout dose is not included in the DLP totals since standards for reporting scout dose are not yet defined. Scout dose is generally a very small part of the exam.

The dose information updates when technique values such as kV, mA, scan time, slice thickness, and scan field of view are changed.

Dose information is saved as a screen save image in Series 999 upon selecting End Exam. Series 997 contains the DICOM Dose Structured Report.

5 Implantable Device Safety

WARNING

CT SCANS MAY CAUSE INTERFERENCE WITH IMPLANTED OR EXTERNALLY WORN ELECTRONIC MEDICAL DEVICES SUCH AS PACEMAKERS, DEFIBRILLATORS, NEUROSTIMULATORS AND DRUG INFUSION PUMPS. THE INTERFERENCE COULD CAUSE OPERATIONAL CHANGES OR MALFUNCTION OF THE ELECTRONIC MEDICAL DEVICE.

5.1 Recommendations prior to scanning

- If practical, try to move external devices out of the scan range.
- Ask patients with neurostimulators to shut off the device temporarily while the scan is performed.
- Minimize the X-ray exposure to the electronic medical device.
- Use the lowest possible X-ray tube current consistent with obtaining the required image quality.
- Do not scan directly over the electronic device for more than a few seconds.

  NOTE: For procedures such as CT Perfusion or CT Interventional scans that require scanning over the electronic medical device for more than a few seconds, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

5.2 Recommendations after scanning

- Have the patient turn the device back on if it had been turned off prior to scanning.
- Have the patient check the device for proper functioning, even if the device was turned off.
- Advise the patient to contact his or her healthcare provider as soon as possible if the patient suspects their device is not functioning properly after a CT scan.

NOTE: Recommendations from FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning date July 14, 2008.

WARNING

THIS SYSTEM IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY. THIS SYSTEM MAY CAUSE RADIO INTERFERENCE OR MAY DISRUPT THE OPERATION OF NEARBY EQUIPMENT. IT MAY BE NECESSARY TO TAKE MITIGATION MEASURES, SUCH AS REORIENTING OR RELOCATING THE SYSTEM OR SHIELDING THE LOCATION.

6 Electrical Safety

DANGER

ELECTRICAL SHOCK HAZARD. AVOID ALL CONTACT WITH ANY ELECTRICAL CONDUCTOR. DO NOT REMOVE OR OPEN SYSTEM COVERS OR PLUGS. INTERNAL CIRCUITS USE HIGH VOLTAGE CAPABLE OF CAUSING SERIOUS INJURY.

AN ELECTRICAL HAZARD MAY EXIST IF ANY LIGHT, MONITOR, OR VISUAL INDICATOR STAYS ON AFTER THE SYSTEM IS SHUT DOWN. TO PREVENT POSSIBLE INJURY, TURN OFF THE MAIN POWER SUPPLY WALL SWITCH, AND CONTACT YOUR SERVICE OFFICE IMMEDIATELY.

DANGER

NO USER SERVICEABLE PARTS. REFER SERVICE TO QUALIFIED SERVICE PERSONNEL. ONLY ALLOW PEOPLE WHO KNOW THE PROPER PROCEDURES, AND USE OF THE PROPER TOOLS, TO INSTALL, ADJUST, REPAIR, OR MODIFY THE EQUIPMENT.

TO GUARANTEE SAFE, RELIABLE EQUIPMENT PERFORMANCE, PREPARE THE SITE ACCORDING TO GE HEALTHCARE REQUIREMENTS. IF YOU HAVE ANY QUESTIONS ABOUT THESE REQUIREMENTS, CONTACT GE HEALTHCARE.

FUSES BLOWN WITHIN 36 HOURS OF BEING REPLACED MAY INDICATE MALFUNCTIONING ELECTRICAL CIRCUITS WITHIN THE SYSTEM. HAVE THE SYSTEM CHECKED BY QUALIFIED SERVICE PERSONNEL, AND DO NOT ATTEMPT TO REPLACE ANY FUSE. THIS INCLUDES MAKING SURE THE EQUIPMENT IS CONNECTED TO A SUPPLY MAINS WITH A PROTECTIVE EARTH.

DANGER

INFORMATION ON INTERNAL GANTRY COMPONENTS IS PROVIDED FOR USER EDUCATION. THE GANTRY CONTAINS DANGEROUS VOLTAGES AND MOVING PARTS.

TO PREVENT ELECTRICAL SHOCK OR CRUSHING INJURIES, DO NOT REMOVE COVERS OR ENTER THE GANTRY. ONLY TRAINED, QUALIFIED SERVICE PERSONNEL MAY REMOVE GANTRY OR OTHER EQUIPMENT COVERS.

DANGER

ELECTRICAL FIRE. CONDUCTIVE FLUIDS THAT SEEP INTO THE ACTIVE CIRCUIT COMPONENTS OF THE SYSTEM MAY CAUSE SHORT CIRCUITS THAT CAN RESULT IN ELECTRICAL FIRES. THEREFORE, DO NOT PLACE ANY LIQUID OR FOOD ON ANY PART OF THE SYSTEM.

To avoid electrical shocks or burns caused by the use of the wrong type of fire extinguisher, make sure that only fire extinguishers approved for use on electrical fires are used.

Surplus lengths of power cords or other cables from mobile accessory units that may be used during patient scanning should be stored in safe and isolated areas. For example: Excess cable may be wound in a figure eight and stored at the base of the stationary equipment. This minimizes signal interference and protects cables from damage due to traffic.

CAUTION

The accessory receptacles located on the Scanner Desktop are not for general use. Verify the accessory power requirements do not exceed the labeled ratings of the receptacles.

CAUTION

The accessory receptacles located on the scanner desktop are not for general use. The combined power consumption of the accessories should not exceed 960 watts.

CAUTION

Included power cord is only to be used when connecting GE approved accessories to the gantry or scanner desktop.

A CT System combined with GE approved accessories complies with the IEC 60601-1 standards related to safety and performance of medical electrical systems. Refer to the standard for more information.

- Do not connect electric devices to the CT System that are not approved by GE. It may create increased electrical leakage current and there is possibility of electric shock.
- The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.
- The Scanner Desktop, LCD monitors and media tower are intended to be powered by the CT System using cables provided. Do not connect these devices to power sources other than the CT system (for example, wall outlets, or other electrical equipment). It may create increased electrical leakage current and there is possibility of electric shock.
- Note that some external powered equipment may only be connected by a signal cable to GE equipment (for example, a network hub). A separation device (for example, an isolated power supply) is required for equipment that is powered by a different power source.

Power Indicator Light Locations

Component	Indicator Light Location
Gantry	Indicator Locations: Gantry control buttons backlight, Gantry indicator/regulatory display and service panel 120VAC LED.
	System ON: gantry control panel backlighting, service panel 120VAC LED will be lit and Indicator display/ regulatory will display table vertical position.
	Shutdown: On the Indicator display the crescent moon will be statically lit (no flashing).
Power Distribution Unit	Indicator Location: PDU light at the front.
	System ON: The light indicator will be ON.
	Shutdown: The light indicator will be ON.
Scanner Desktop	Indicator Locations: Monitors Power ON/OFF buttons lights, Scanner Desktop/NIO Cabinet power on/off light located at the front.
	System ON: The light indicators will be ON.
	Shutdown: The light indicators will be ON.
RSCB	Indicator: Standby Button Light.
	System ON: The button light will be ON.
	Shutdown: The button light will be flashing.
System Cabinet (Image Generation)	Indicators: System Cabinet provides a green light to the service personal to indicate is energized. SDA computer and disks and Image Generation computer front panel Power ON/OFF lights.
	System ON: The light indicators will be ON.
	Shutdown: The light indicators will be ON.
SYS ON light	Indicator: Optional light, customer provided, it indicates that the PDU is energized (A1 breaker is ON).
	System ON: SYS ON light ON.
	Shutdown: SYS ON light ON.

7 Fire Safety

DANGER

THIS DEVICE IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OR IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

8 Mechanical Safety

8.1 General Mechanical Safety

WARNING

DO NOT USE THE TABLE BASE AS A FOOT REST. YOU COULD ENTRAP AND INJURE YOUR FOOT WHILE LOWERING THE TABLE. DO NOT PLACE YOUR HANDS BETWEEN THE TABLE BASE AND THE TABLE SIDE PANELS.

8.2 Patient Positioning

DANGER

DO NOT PLACE A PATIENT ON THE TABLE WEIGHING MORE THAN THE UPPER LIMIT OF 500 POUNDS. THIS COULD CAUSE THE TABLE TO FAIL AND THE PATIENT COULD FALL.

Illustration 20: Warning label located on table

WARNING

AVOID INJURY DO NOT EXCEED THE MAXIMUM CAPACITY OF 227 KG (500 LB).

CAUTION

Temporal sampling may be degraded due to changes in timing for the table to move from location to location if proper positioning methods are not followed. Make sure that the patient is securely positioned on the table and their arms are not allowed to drag on the table or allow clothing, sheets or blankets to get caught causing a table move problem.

CAUTION

When using the external laser alignment light for patient positioning purposes, be aware that the patient's elevation may be slightly lower with the cradle extended than with the cradle fully retracted. This is because the cradle may bend slightly under a patient's weight. This difference should be taken into consideration for applications where patient position information is critical, such as Treatment Planning. To minimize these effects, after using the external laser alignment system to position the patient, advance the patient to the CT scan plane. Turn on the CT alignment lights to determine if they line up with the markers on the patient. If necessary, compensate for the bend in the cradle by elevating the table. When the CT alignment lights line up with the markers, set the landmark for the scan using the Internal laser alignment light.

WARNING

WHEN USING PATIENT POSITIONING ACCESSORIES AND STRAPS, MAKE SURE THERE ARE NO AREAS WHICH MIGHT CAUSE A PINCH POINT OR INTERFERE WITH PATIENT TUBING OR IV.

WARNING

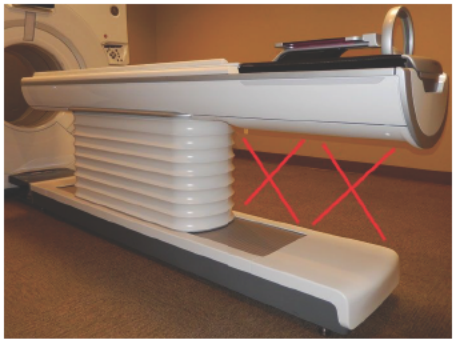
CHECK TO MAKE SURE THE POWER INJECTOR HAS ENOUGH IV TUBING TO ALLOW FREE MOVEMENT OF THE CRADLE. MAKE SURE THE UNIT ITSELF DOES NOT INTERFERE WITH TABLE TRAVEL. ENSURE EXCESS TUBING LENGTH IS SECURED TO THE TABLE TOP. DO NOT LOOP ADDITIONAL IV TUBING IN THE PATIENT'S FINGERS.

Check the length of all patient health lines (IV tubing, oxygen line, etc.) and make sure they accommodate cradle travel. Position these lines so they cannot catch on anything within the patient vicinity or between the table and gantry during cradle travel.

WARNING

THE PATIENT POSITIONING STRAPS PROVIDED WITH THE SYSTEM DO NOT SUPPORT THE FULL WEIGHT OF THE PATIENT. PATIENT POSITIONING STRAPS SHOULD BE USED TO AID IN PATIENT POSITIONING AND ARE NOT MEANT TO FULLY RESTRAIN THE PATIENT.

Illustration 21: Table



CAUTION

If the table is lowered with anything in the designated area below the table, the table could be damaged along with the equipment or object under the table.

WARNING

TO PREVENT PINCHING OR CRUSHING OF THE PATIENT'S EXTREMITIES, KEEP THE PATIENT'S HANDS AND FEET AWAY FROM THE EDGE OF THE MOVING TABLE TOP/CRADLE AND ITS SURROUNDING EQUIPMENT, OR BETWEEN TABLE BASE AND SIDE PANELS OF THE TABLE. TAKE SPECIAL CARE WHEN POSITIONING PHYSICALLY LARGE PATIENTS.

WARNING

TO PREVENT PINCHING OR CRUSHING OF THE PATIENT, WATCH THE PATIENT AND EQUIPMENT CAREFULLY AT ALL TIMES DURING TABLE MOVEMENT. IF UNWANTED MOTION OCCURS OR MOTION DOES NOT STOP, PRESS THE EMERGENCY STOP SWITCHES ON THE SCANNER DESKTOP OR GANTRY.

WARNING

THE HEAD HOLDER MAY CRACK, POSSIBLY INJURING THE PATIENT'S HEAD OR NECK, IF THE PATIENT TRIES TO BRACE HIMSELF OR HERSELF ON THE HEAD HOLDER DURING POSITIONING. THE HEAD HOLDER AND CRADLE EXTENDER ARE ONLY DESIGNED TO SUPPORT 75 POUNDS (34 KG). ASK THE PATIENT TO MOVE UP INTO THE HEAD HOLDER OR MANUALLY HELP THE PATIENT INTO POSITION.

CAUTION

Use of any cradle extension accessories such as the table extension, head holder, coronal head holder, and phantom holder are not accounted for in the table gantry interference matrix. Therefore, additional care needs to be taken to closely monitor any table up/down, in/out or gantry tilt movement to avoid contact of the extended accessory with the gantry.

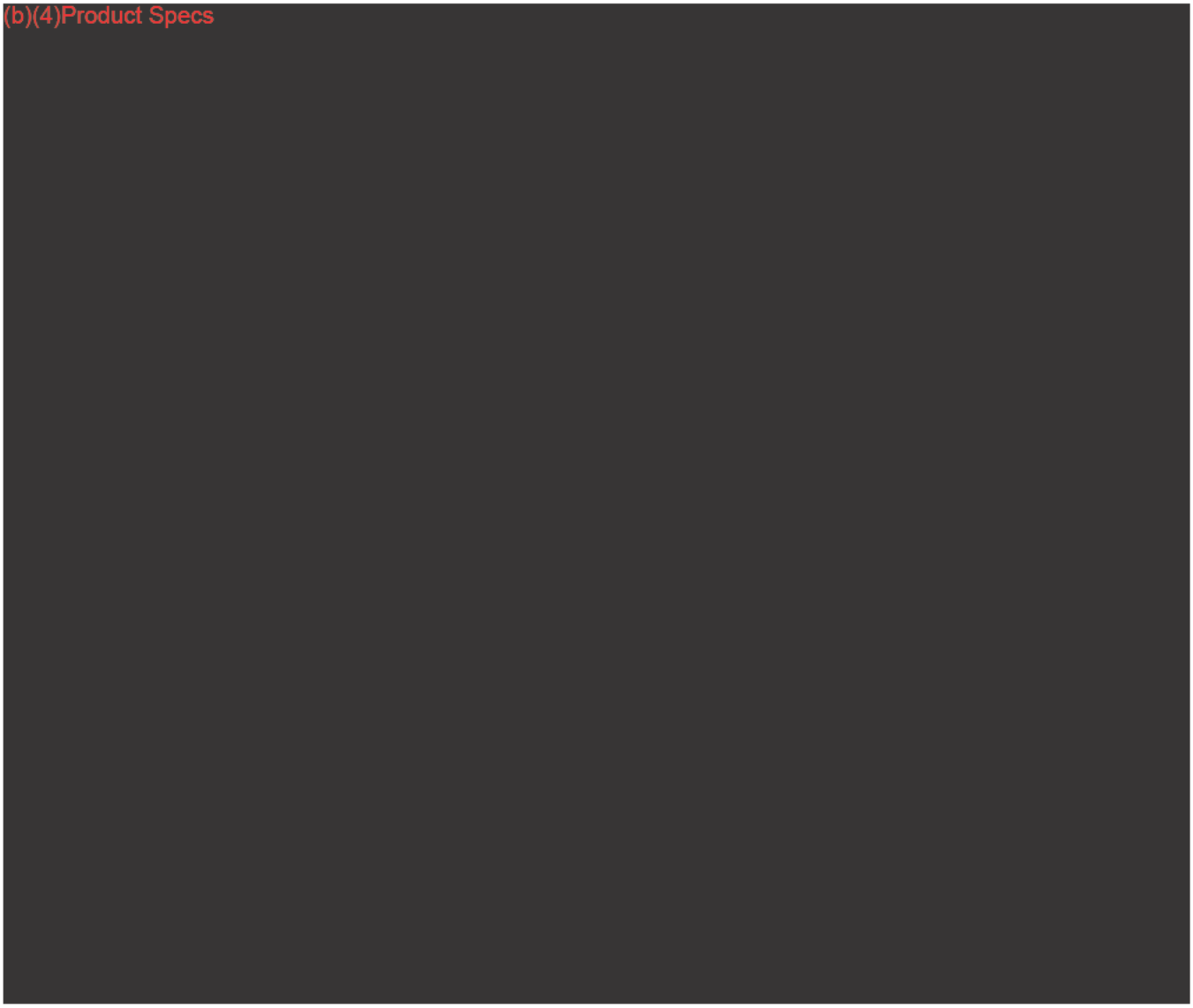
CAUTION

Care should be taken to ensure the patient positioning straps, patient clothing, or other material will not be caught during table motion.

CAUTION

The patient head holder or table extender should be adequately secured to ensure stability. If they are not secured properly, degradation of image quality may result due to introduced motion of the head holder or table extender.

8.3 (b)(4)Product Specs



9 Emergency Devices and Emergency Egress

(Reference 21CFR 1020.33 (f)(2)(ii))

9.1 Emergency Devices

The system has two types of Emergency buttons:

1. **Emergency Stop** — When pressed, all table and gantry motions are halted, generation of X-rays is stopped, laser alignment lights are turned off. The system aborts any data acquisition in progress, and attempts to save all data acquired prior to the abort. Use the Emergency Stop button for patient related emergencies.
2. **System Emergency Off Button** — When pressed, the power to all system components is removed, stopping all table and gantry motion and generation of X-rays. The system aborts any acquisitions in progress, and data obtained prior to the abort can become corrupt or lost. Use the System Emergency OFF button for catastrophic emergencies, such as fire or earthquake.

CAUTION

If you press the Emergency Stop or Emergency OFF buttons during a scan, the system will abort the data acquisition.

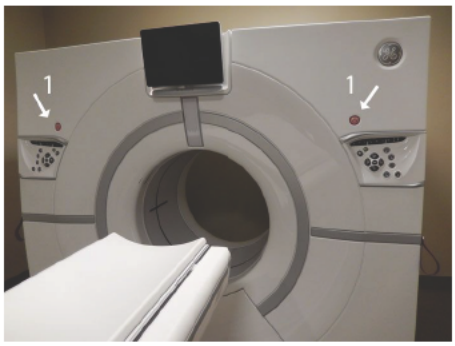
9.1.1 Emergency Stop

NOTE: Every operator should take a few minutes to locate the Emergency Stops on their system before scanning the first patient.

The system has five **Emergency Stop** buttons:

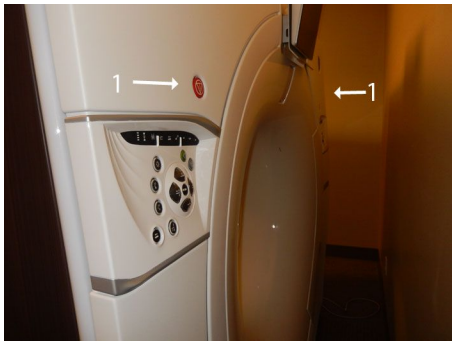
- Two on the front cover of the gantry.

Illustration 23: Front cover of gantry



- Two on the rear cover of the gantry.

Illustration 24: Rear cover of the gantry



- One on the Scan Control Interface.

Illustration 25: Scan Control Interface

Number	Description
1	Emergency Stop Button

Press an **Emergency Stop** button in the event of a patient related emergency or if the cradle, table or gantry starts to move unexpectedly.

- Once an **Emergency Stop** button is pressed, the **Reset** gantry control button, on the gantry control panel, flashes about once every two seconds.
- Press the **Reset** gantry control button to restore power to the gantry and table.

When Emergency Stop is applied, the maximum stopping distance of the moving cradle is 10 mm.

Emergency Stop Button Symbols

Emergency Stop buttons may be accompanied by one of the symbols below.

9.1.2 System Emergency OFF Buttons using Main Disconnect Control

In the event of a fire, flood, earthquake, or any other catastrophic emergency, all power to the system should be turned off. Pressing the **System Emergency OFF** button (red, circular button located on the wall) immediately removes all power to the system by removing power to the Main Disconnect Control (MDC). Because the system has no time to save data, or shutdown in an orderly fashion, pressing the **System Emergency OFF** button can corrupt system files or result in loss of patient data.

The facility designer determines the quantity and locations of the Emergency OFF buttons. GE recommends placing an Emergency OFF button near the doorway of every room in the system scan suite. Ask your supervisor to show you the location of all the Emergency OFF buttons in the system suite. Follow facility guidelines to report an emergency.

Reset the Emergency OFF Button

1. Press the Start button on the Main Disconnect Control.

   Power to the Power Distribution Unit (PDU), scanner desktop and system electronics will be restored.

2. Press the Reset gantry control button on the gantry panel.

   Power to the gantry drives, X-ray system, and table drive will be restored.

CAUTION

The x-ray and Drive power is disabled. Please walk into the scan room and press the Reset button on the Gantry Control Panel.

9.2 Emergency Patient Care During X-ray ON

- Press **STOP SCAN** to abort X-ray and stop gantry/table movement.
- Press **PAUSE SCAN** to pause scanning after the current scan completes.
- During an exam, the system pauses between scans if you Press any button on the control panel other than the alignment lights. It stops X-ray if you Press the same button(s) during a scan.
- Select **Resume** on the screen to continue the exam.

9.3 Emergency Egress

System operation may be stopped due to power failure or a safety event (something coming into contact with the collision sensors), or the system may be halted by the operator in response to emergency conditions.

The cradle unlatch button should only be used in emergency egress situations.

To safely remove the patient:

1. Press the Cradle Release gantry control button or the Emergency Stop button to disengage the clutch.
2. Pull the cradle to its out position, using the Cradle Lip or Cradle Handle.
3. Assist the patient off the table.

10 Laser Safety

(Reference 21CFR 1040.10 (h) 21CFR1020.33 (g)(4))

A laser alignment light system is available in order to accurately define the patient scan region.

From the gantry controls, press the laser alignment light to toggle all laser alignment lights on/off and to move the gantry components from the park or idle position to the alignment lights position. Alignment lights are used to establish landmark locations. Three alignment lights are displayed: axial, sagittal and coronal. Align the laser lights with the desired anatomical reference. A poorly positioned and centered patient can impact the mA values calculated for AutomA/SmartmA.

The laser alignment light switch is provided as an alternative to beam attenuators.

Press the Internal and External Landmark buttons to establish the table's reference point when positioning the patient. This reference point is normally the anatomic reference point used when positioning the patient. For example, if the patient's anatomic reference point is the sternal notch, then the sternal notch would be centered to the laser alignment light.

- For Internal Landmark, the gantry displays a table location of 0 mm. This sets the zero point for which S and I scan locations are centered around.
- For External Landmark , the gantry displays a table location approximately 240 mm from the internal landmark, depending on table characterization.

A landmark must be set before you click Confirm. At Done Scanning, the landmark is cleared. For scan setup details, see the Set up and position the patient procedure.

WARNING

THE LASER BEAM CAN CAUSE EYE INJURY.

- **TELL ALL PATIENTS TO CLOSE THEIR EYES BEFORE YOU SWITCH ON THE ALIGNMENT LIGHTS.**
- **INSTRUCT YOUR PATIENTS TO KEEP THEIR EYES CLOSED UNTIL YOU TURN OFF THE ALIGNMENT LIGHTS.**

NOTE: Closely monitor infants and infirm patients, and prevent them from accidentally staring into the beam.

WARNING

THE DETECTOR AND DAS ROTATE TO POSITION THE ALIGNMENT LIGHTS OVER THE LASER PORTS.

- Keep your hands away from the gantry opening.
- Make sure the gantry covers are in place.
- The indicator on the gantry display panel lights when you turn ON the alignment lights.

- Warning labels regarding laser safety are provided on the gantry, as described in the Warning Labels and Symbols section.

Maintenance

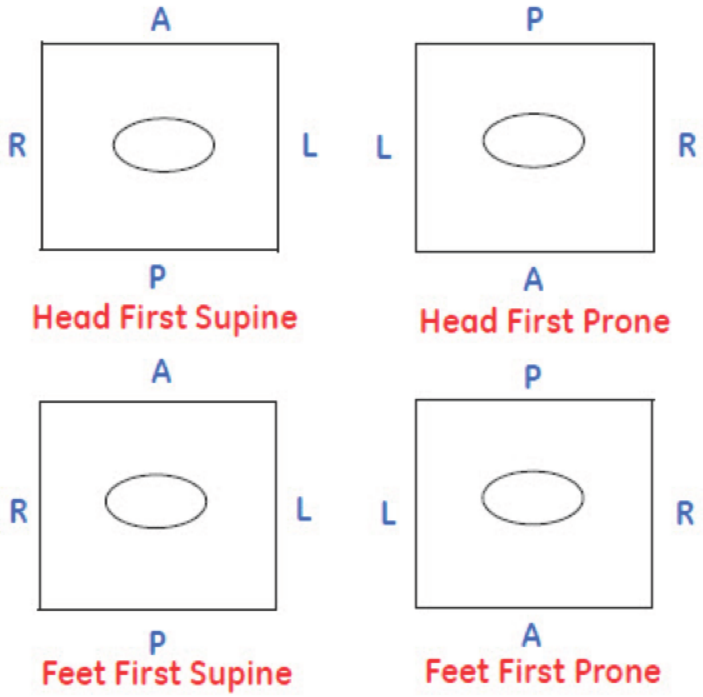
- Laser alignment lights do not require user maintenance.
- Qualified service personnel must inspect the lights periodically to assure proper alignment.

11 Reconstructed Image Orientation

CAUTION

GE CT image reconstruction is in an orientation viewing from the patient's feet. The reconstructed orientation is the orientation the image is installed in the image data base and is the orientation images are networked with to a remote viewing station.

Illustration 26: Patient Orientation



The patient position information stored in the image header correctly reflects the orientation (RAS) information for the patient. Viewing applications will correctly reflect Right (R), Left (L), Anterior (A) and Posterior (P) of the patient.

The reconstructed image orientation may differ from preferred anatomical viewing presentation in which the patient's Right is on the viewers Left and patient's Left is on the viewers Right. For example, when the patient is scanned Head First and Prone the patients's Left is on the viewer's Left and the patient's Right is on the viewer's Right. The image presentation will need to be modified to display preferred anatomical viewing. Some viewing stations may not have the capability to flip the image presentation, but if the capability exists, you must use display tools such as Flip to change the presentation of the image.

Some remote viewing stations may have the capability to set default viewing protocols. This is another tool that can be used to set an anatomical viewing presentation.

Post processing applications automatically orient images in anatomical viewing orientation. These applications create axial images in anatomical viewing presentation. Please see Auto Applications

(Option) for more information. The system also provides the capability to create Gray Scale Presentation State Objects (GSPS) to flip the image orientation.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE IF PATIENT ORIENTATION HAS BEEN CHANGED OR DOES NOT MATCH AFTER START OF EXAM.

12 Data Safety

CAUTION

Incorrect data entries or procedures could result in misinterpretation or misdiagnosis.

WARNING

ATTENTION - DISK SPACE LOW SOFTWARE PROBLEM DETECTED WITH DISK SPACE. PLEASE COMPLETE WHAT YOU ARE CURRENTLY DOING, THEN PERFORM SYSTEM SHUTDOWN. INFORMATION REGARDING WHICH DISK PARTITION(S) ARE FULL CAN BE OBTAINED FROM THE SYSTEM GESYSLOG IN /VAR/ADM.

WARNING

DO NOT LOAD ANY NON-GE APPROVED SOFTWARE ONTO THE COMPUTER.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE IF THERE IS A FAILURE DURING THE ARCHIVE OF PATIENT DATA.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE IF THERE IS A FAILURE DURING THE NETWORK TRANSFER OF PATIENT IMAGE DATA.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE WHEN EXPECTED IMAGE SPACE REQUIRED TO STORE IMAGES FROM PRESCRIBED RECONSTRUCTION IS INSUFFICIENT.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE WHEN EXPECTED DISK SPACE REQUIRED TO STORE SCAN DATA FROM THE PRESCRIBED EXAM IS INSUFFICIENT.

WARNING

MISSING SLICES HAVE BEEN INTERPOLATED TO MAKE REFORMATTED IMAGES.

CAUTION

When entering Patient ID information the system may contain multiple instances of the same Patient ID. Multiple schedule records can be due to multiple procedures being ordered under separate accession numbers or New and Completed records in the Patient schedule for the same Patient ID. When entering the Patient ID verify that the correct Accession number and Exam Description selected is what is desired. Scanning with an incorrect accession number may cause problems reconciling exams on a PACS system. Please see the Scheduling Patients chapter for more information.

NOTE: The Patient Schedule chapter is in the User Manual.

CAUTION

When comparing GE CT images with other images, consult the DICOM Conformance Statement for the details on the DICOM Image Position, Frame of Reference UID and Slice Location values stored.

CAUTION

Some annotation values are stored in private DICOM elements. When viewing images on a remote station these annotations values may not be visible on the image. Consult the DICOM Conformance Statement for information on private DICOM data fields.

CAUTION

Attention! The table landmark has changed. This changes the location of all scans you have prescribed. Double check all scan locations before you start scanning.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE PRIOR TO THE MODIFICATION OF ANY EXISTING PATIENT DATA BY THE USER.

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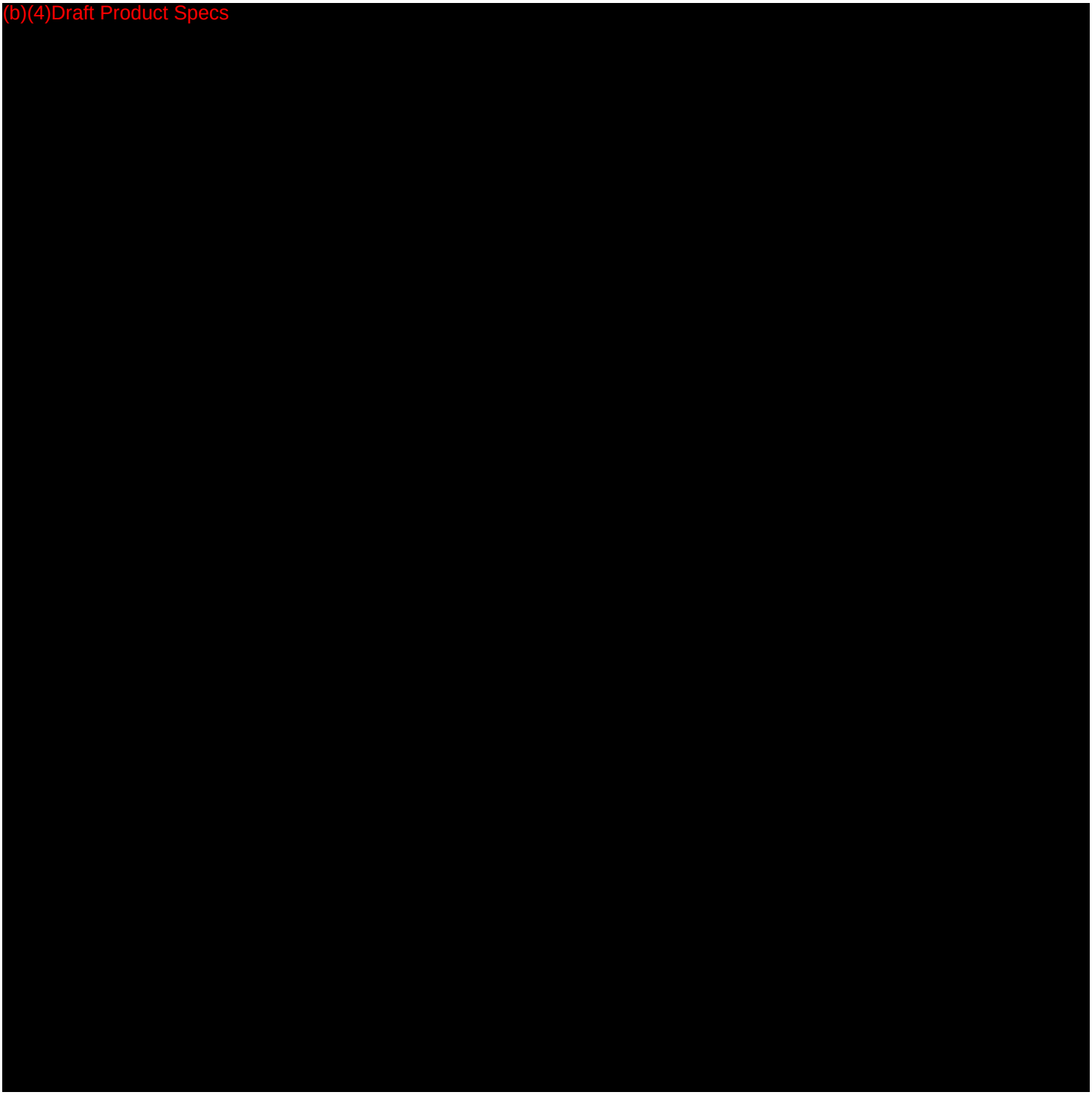

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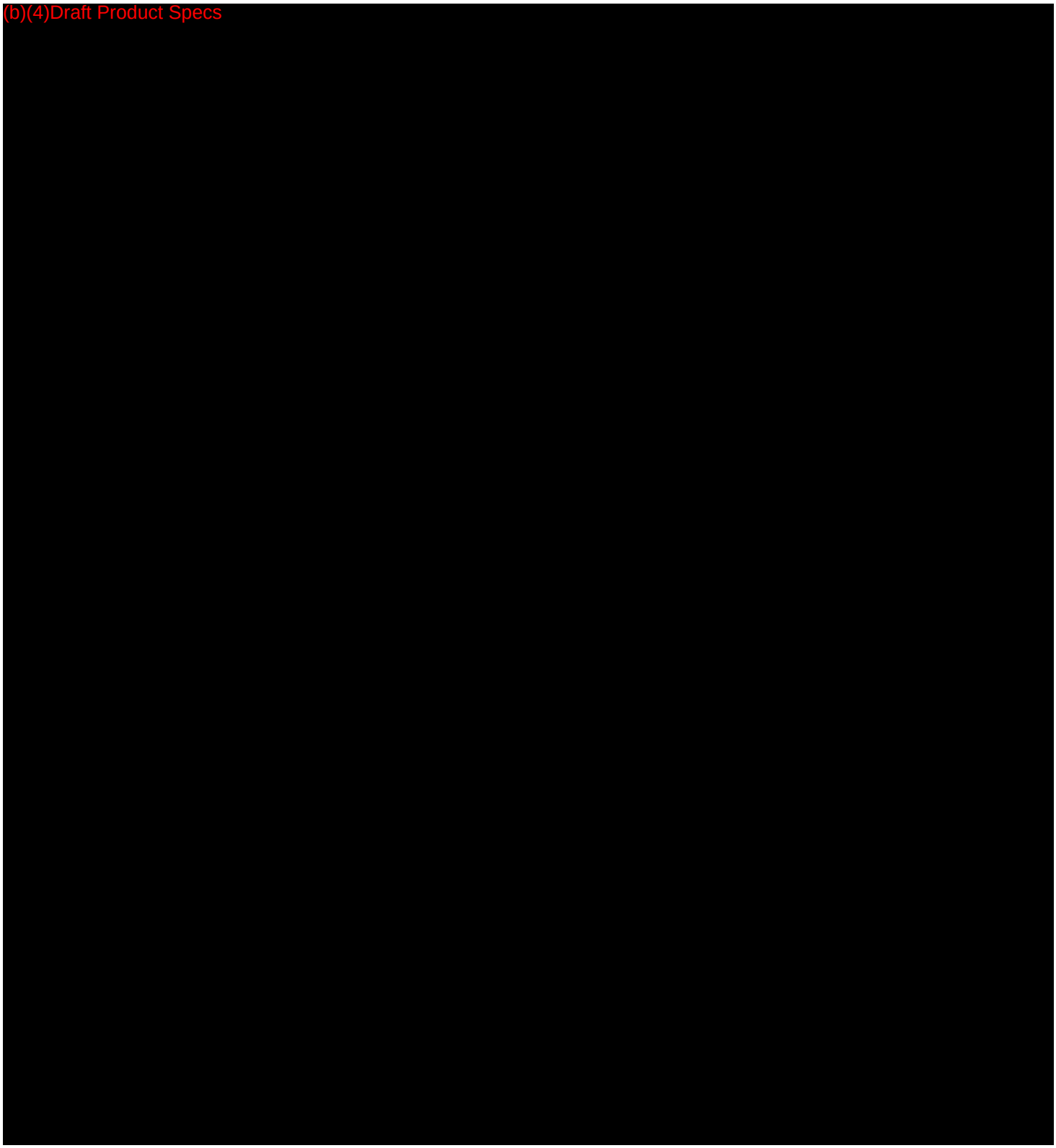

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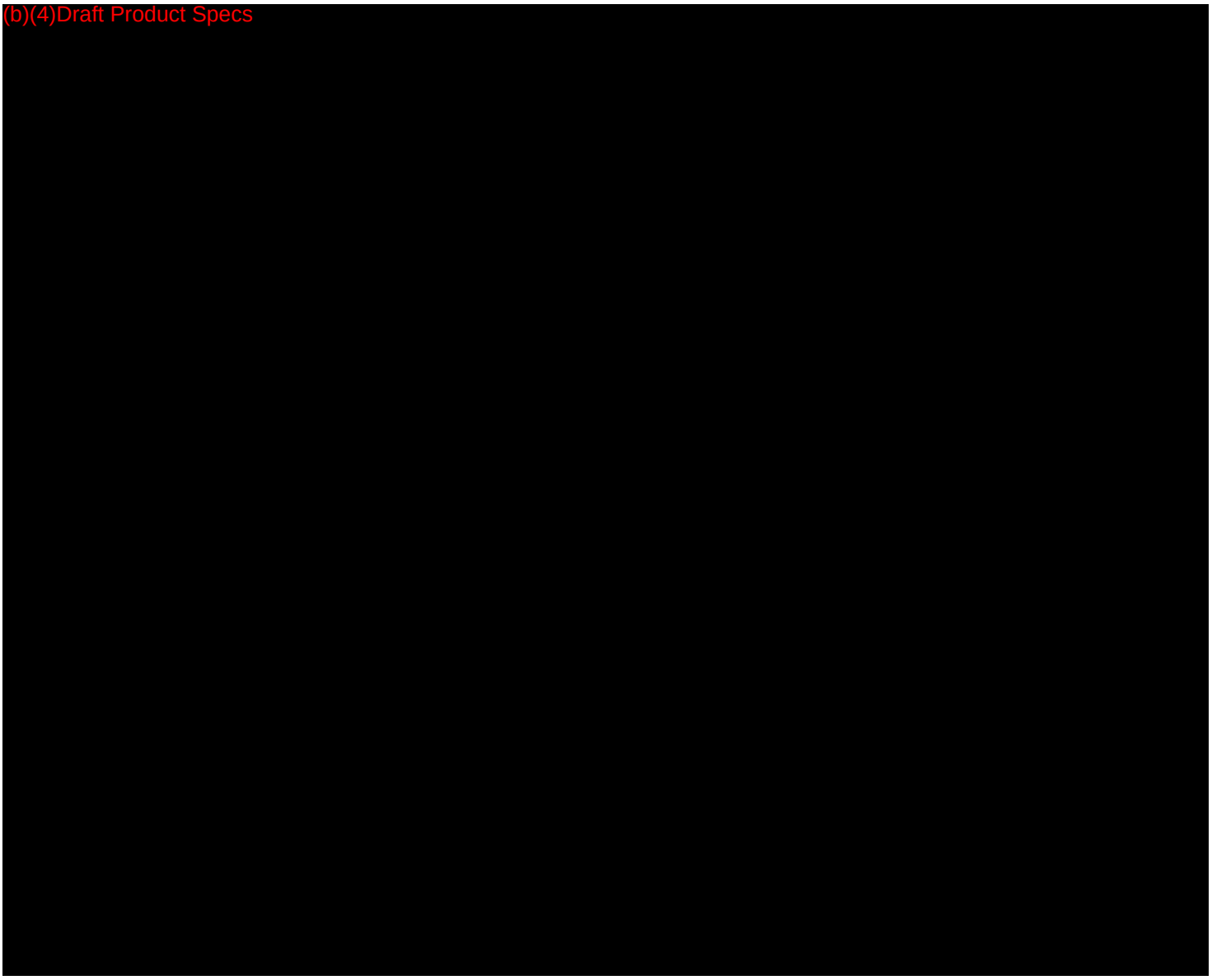

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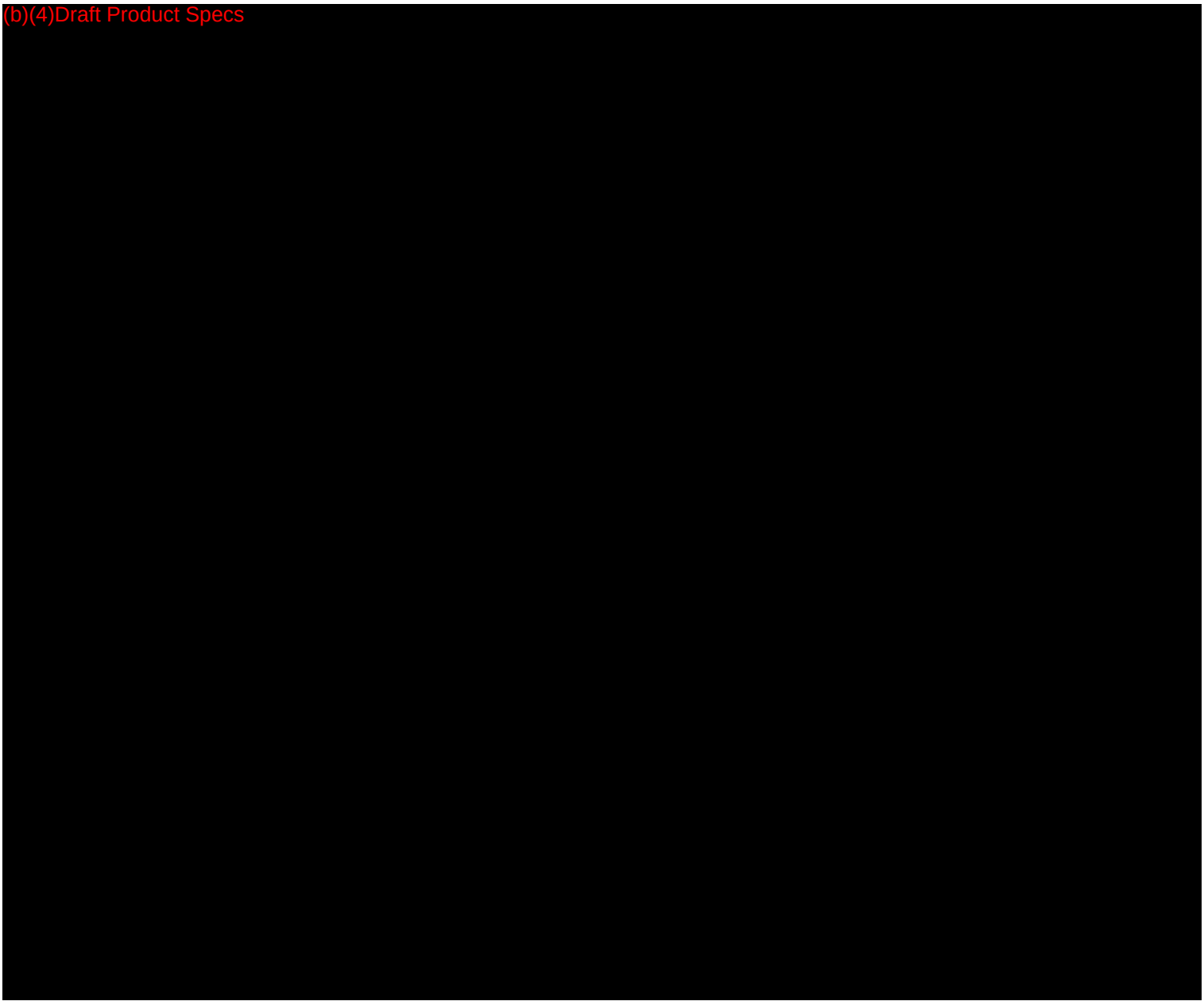

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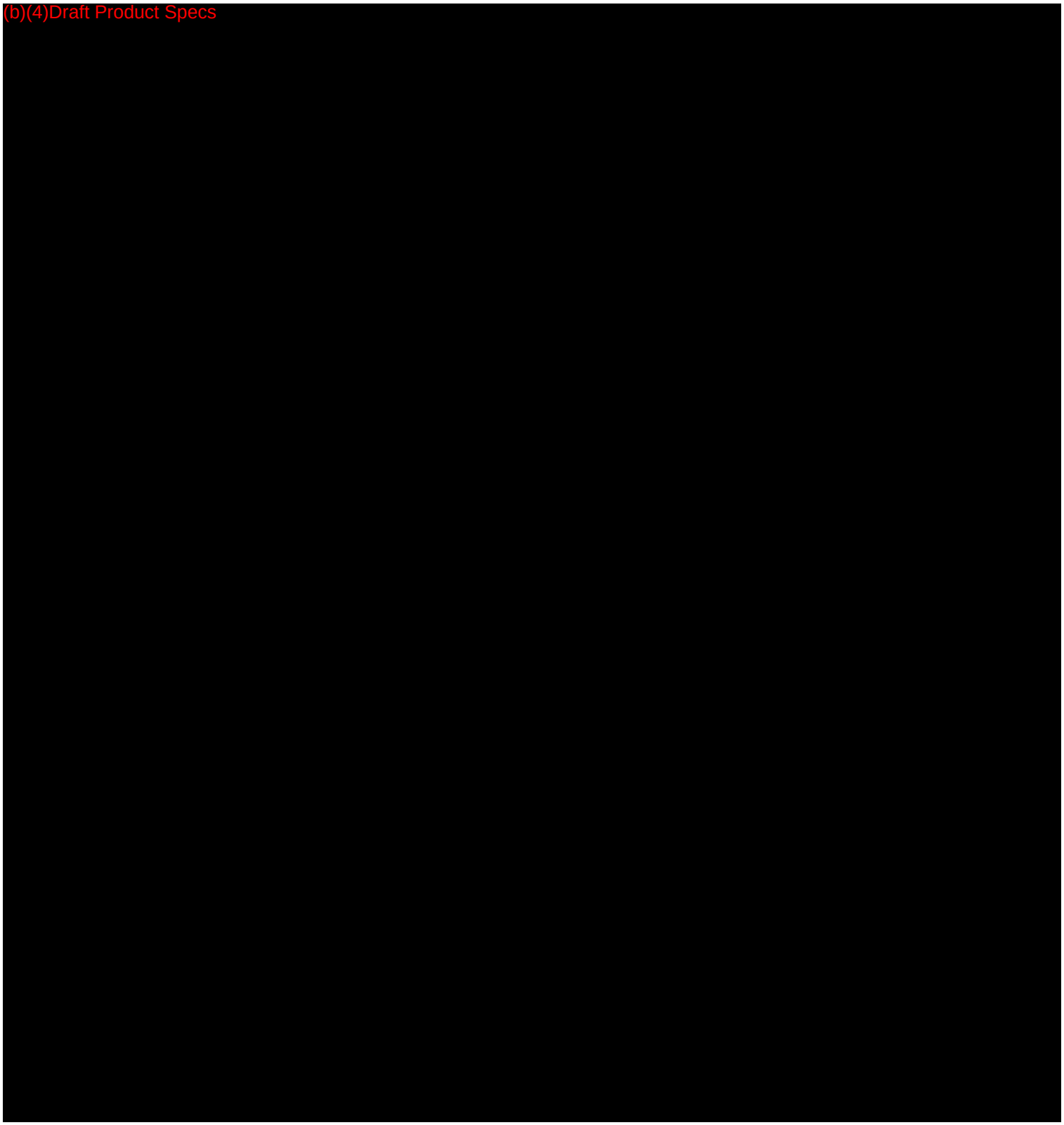

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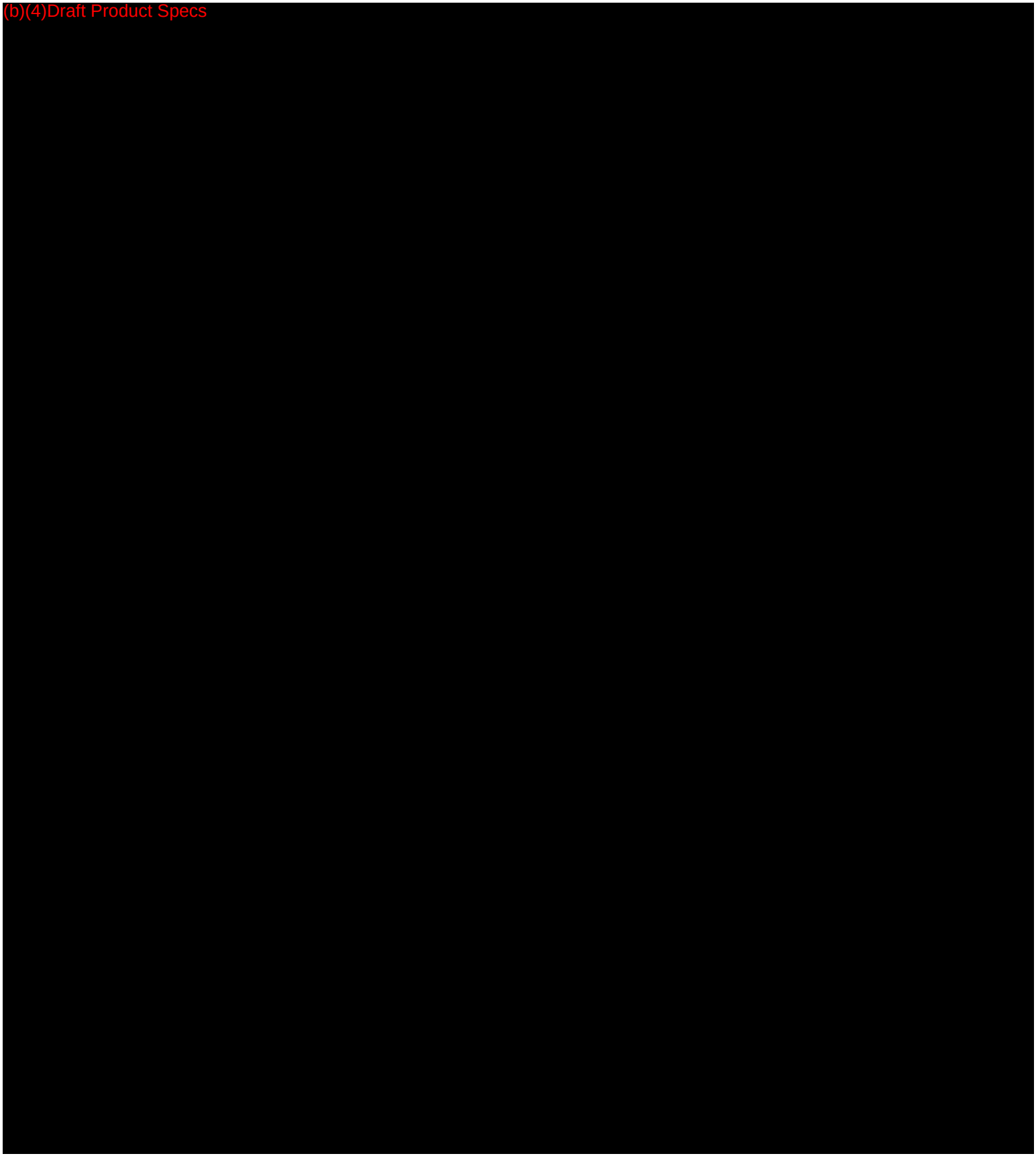

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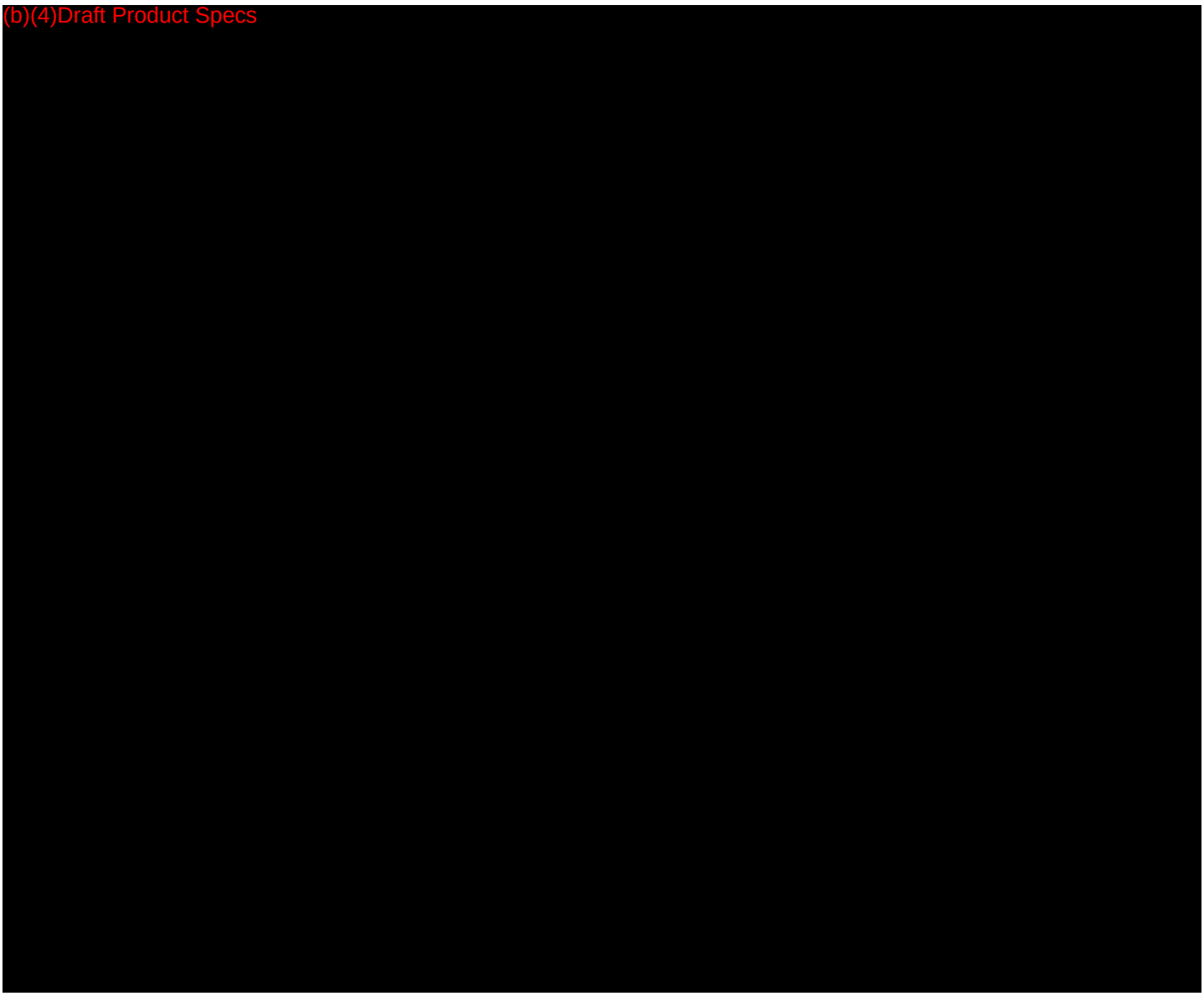

16 Accessory Safety

WARNING

DO NOT CONNECT ACCESSORIES OR OTHER ITEMS THAT ARE NOT APPROVED AS PART OF THE SYSTEM. DO NOT USE ACCESSORIES FROM OTHER MODALITIES.

WARNING

NONE OF THE ACCESSORIES SUPPORT THE FULL WEIGHT OF A PATIENT. IF YOU SIT, STAND, OR OTHERWISE APPLY EXCESSIVE PRESSURE TO THESE DEVICES, THEY COULD BREAK OR COME OFF THE CRADLE AND MAY CAUSE INJURY. IF AN ACCESSORY BREAKS, USE CAUTION WHEN PICKING IT UP AND DO NOT CONTINUE TO USE IT.

CAUTION

Using accessories which are not GE approved accessories might affect dose and image quality.

WARNING

ACCESSORIES LIKE ARM BOARDS AND CATHETER BAG HOLDERS ARE NOT SECURED TO GANTRY AND MAY INTERFERE WITH GANTRY IF NOT POSITIONED PROPERLY.

16.1 Monitor Safety

CAUTION

For a two-monitor configuration it is necessary to check the monitor calibration regularly to ensure images are displayed identically on both monitors.

16.2 IV Pole Safety

Care should be taken in the amount of weight placed on the pole. Ensure that the pole is tightened prior to use.

WARNING

THE IV POLE MAY BEND WHEN EXCESSIVE WEIGHT IS PLACED ON THE POLE. ENSURE NO MORE THAN 4.5 KG OR 10 LB IS PLACED ON THE IV POLE.

WARNING

ENSURE THAT THE IV POLE EXTENSION COLLAR IS TIGHTENED PRIOR TO USE TO PREVENT THE POLE HEIGHT FROM COLLAPSING.

Illustration 28: IV Pole Load Limits

CAUTION

Do not load more than 4,5 kg or 10 pounds. Verify that extension collar is securely tightened before use.

16.3 Table Tray Safety

Care should be taken in the total weight of objects that are placed on the tray.

Illustration 29: Tray Load Limits

WARNING

THE MAXIMUM ALLOWABLE WEIGHT PLACED ON THE TABLE TRAY IS 9KG OR 20 LBS.

WARNING

OBJECTS THAT MAY BE SUSCEPTIBLE TO TIPPING SHOULD BE STRAPPED DOWN WITH THE VELCRO™ STRAP PROVIDED.

16.4 Systems With Metal-Free Cradles and Accessories

CAUTION

Prevent damage to metal-free accessories! Carefully examine the metal-free clasp assembly on the accessory and the catch on the cradle before attempting to attach the accessory for the first time.

Illustration 30: Accessory Load Limit

CAUTION

Accessory may fall and cause injury if not latched to cradle. Make sure that accessory is latched to underside of cradle.

16.5 Power Injector Safety

CAUTION

The injector and the system are operated independently after the Start Scan button is pressed. When you want to stop both the system and the injector, use the Stop Scan button on the Scan Control Interface and the stop injector function on the injector system.

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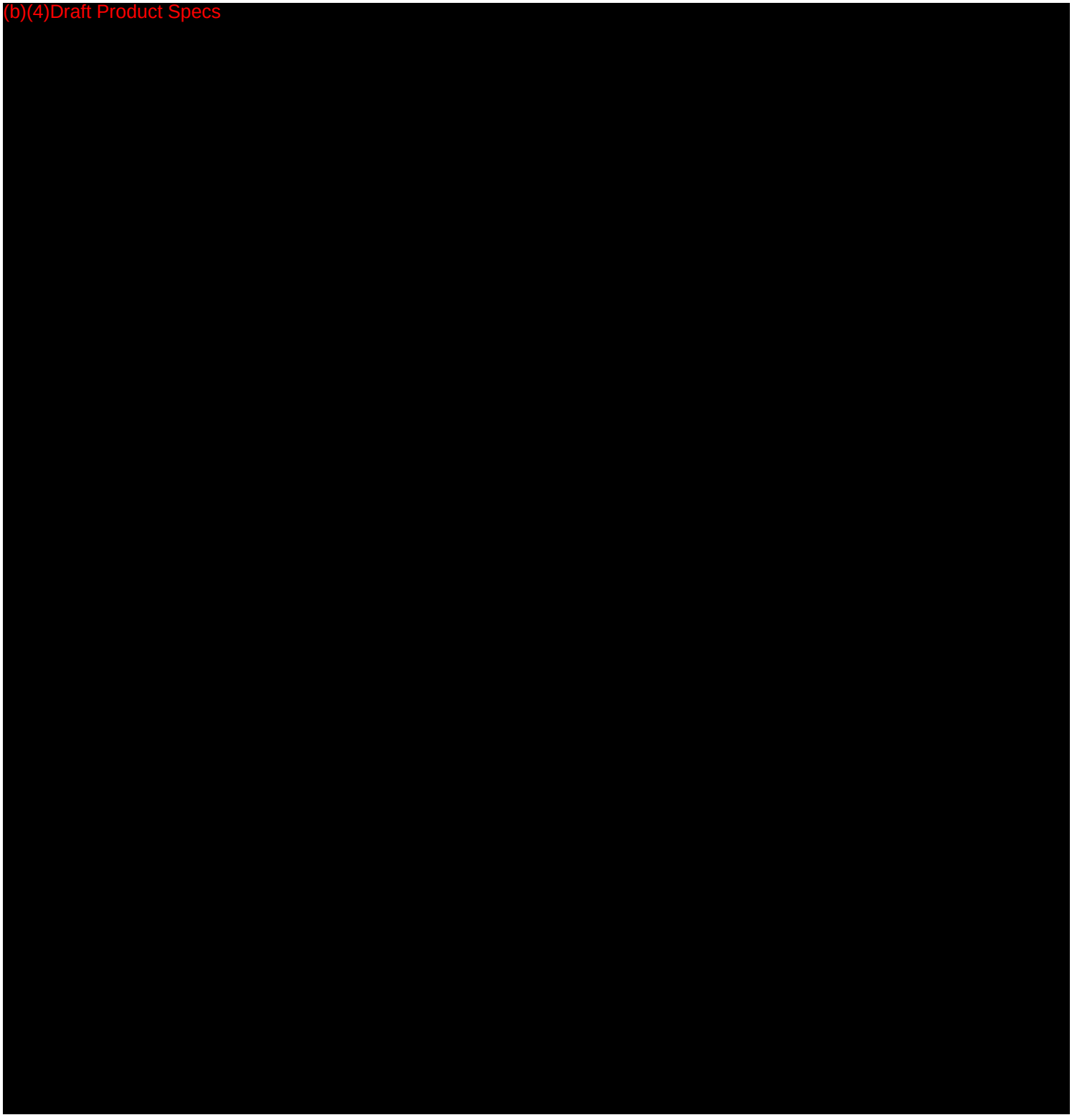

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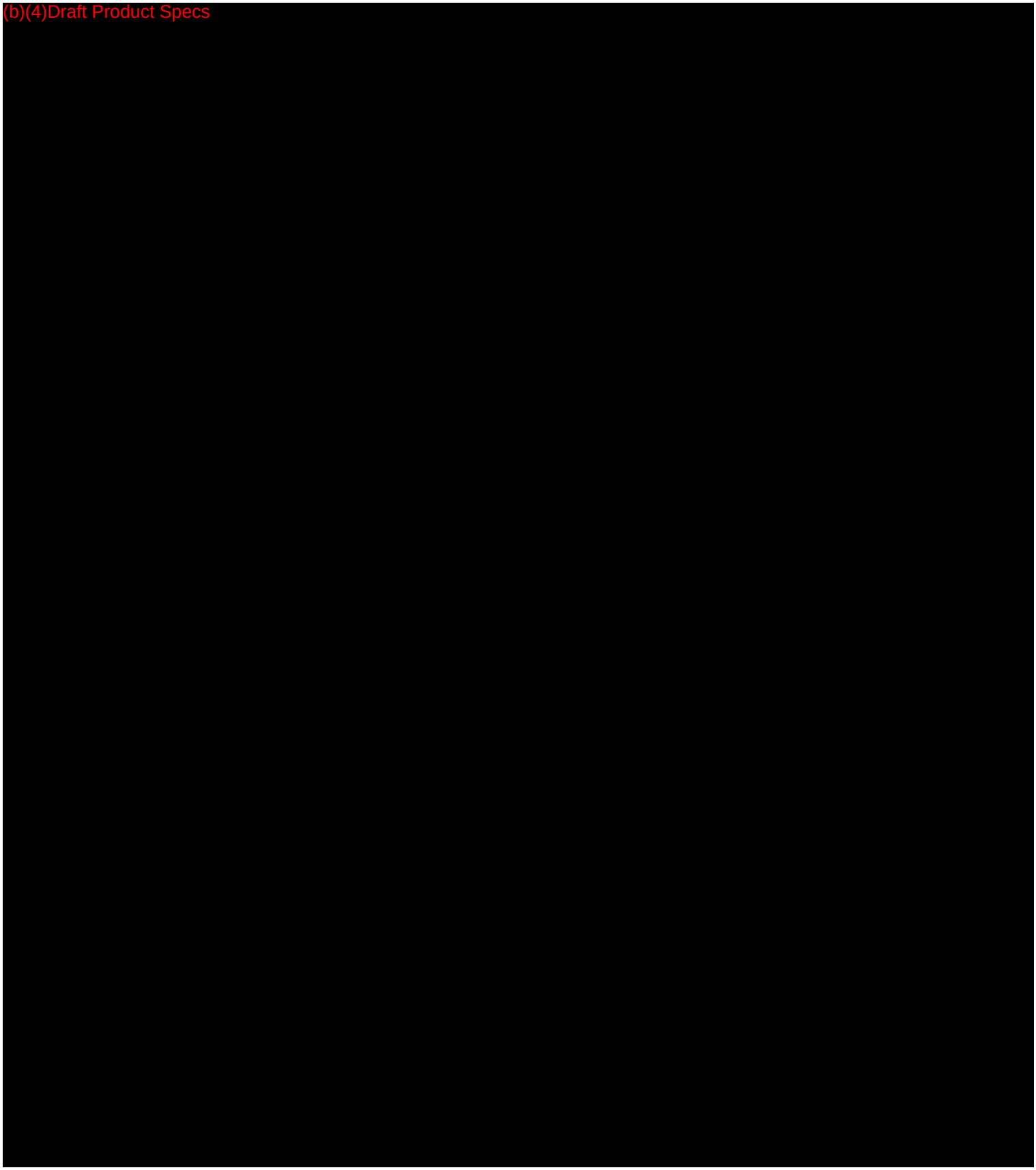

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Chapter 4 Quality Assurance

1 Introduction

(Reference 21 CFR 1020.33(d))

This section outlines the instructions for use of the Discovery CT870 Quality Assurance (QA) Phantom and the 20 cm Water Phantom, including a schedule of testing appropriate for the system, allowable variations for the indicated parameters, and a method to store the QA data as records.

A continuous Quality Assurance (QA) program must be established and implemented to assure consistent image quality.

Perform and track the results of the constancy testing of the CT system in accordance with IEC 61223-2-6 or per your facility's specific QA program.

2 QA Phantom and 20 cm Water Phantom

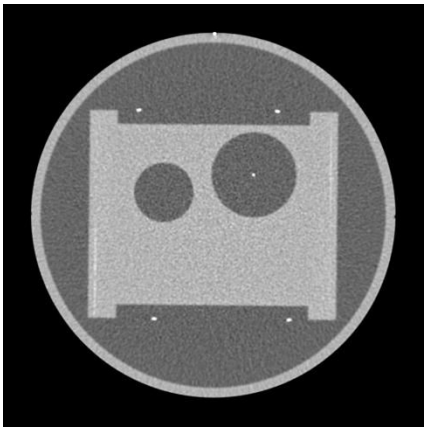
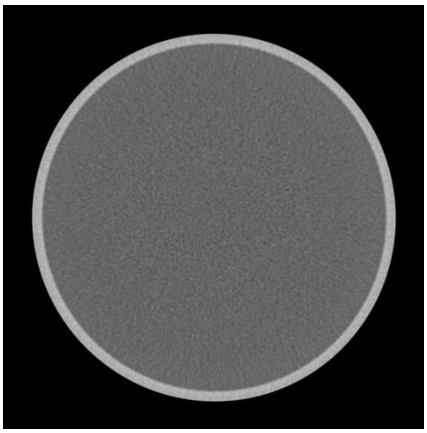
(Reference 21CFR 1020.33(d)(1))

The QA Phantom and the 20 cm Water Phantom are used to assess system performance as part of a QA program.

Image Quality (IQ) metrics evaluated:

- Contrast Scale
- High Contrast Spatial Resolution
- Slice Thickness
- Low Contrast Detectability
- CT Number, Noise and Uniformity

Table 1: QA Phantom and 20 cm Water Phantom

	**Tests for QA Phantom** • Contrast Scale • High Contrast Spatial Resolution • Slice Thickness
	**Tests for 20 cm Water Phantom** • Low Contrast Detectability • CT Number, Noise and Uniformity

3 Proper Handling and Care of Phantoms

1. When installing or removing the phantom from the phantom holder, the table should be backed out of the gantry and lowered far enough so that the user can lift the phantom straight up off the holder.
2. The fit between the bracket and phantom holder is designed to be tight to prevent movement of the phantom during table motion.
3. The phantom should never be carried by its bracket; this is only for mounting the phantom on the phantom holder. Support the weight of the phantom by using both hands on one of the smooth surfaces.

4 (b) (4) [redacted]

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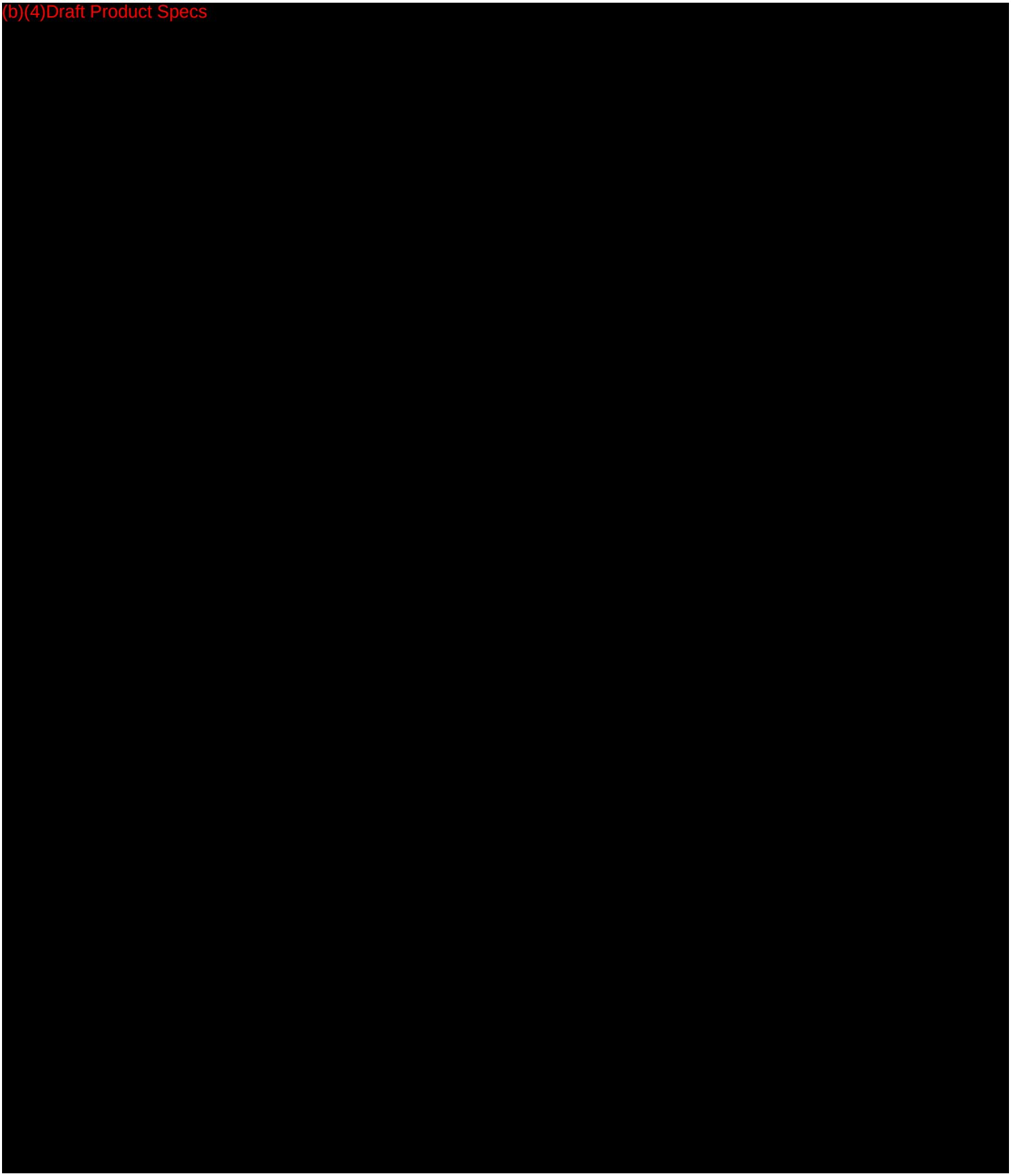

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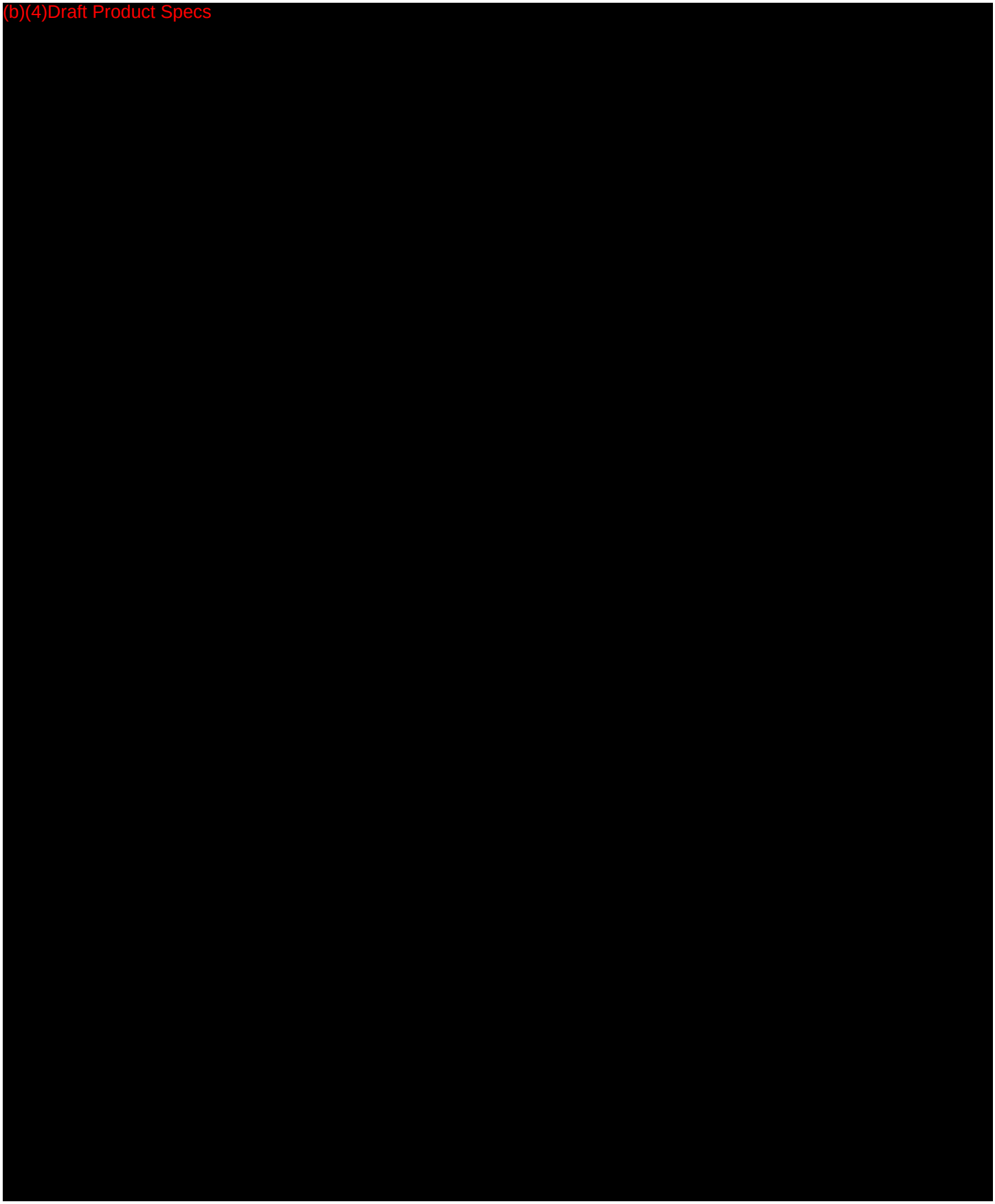

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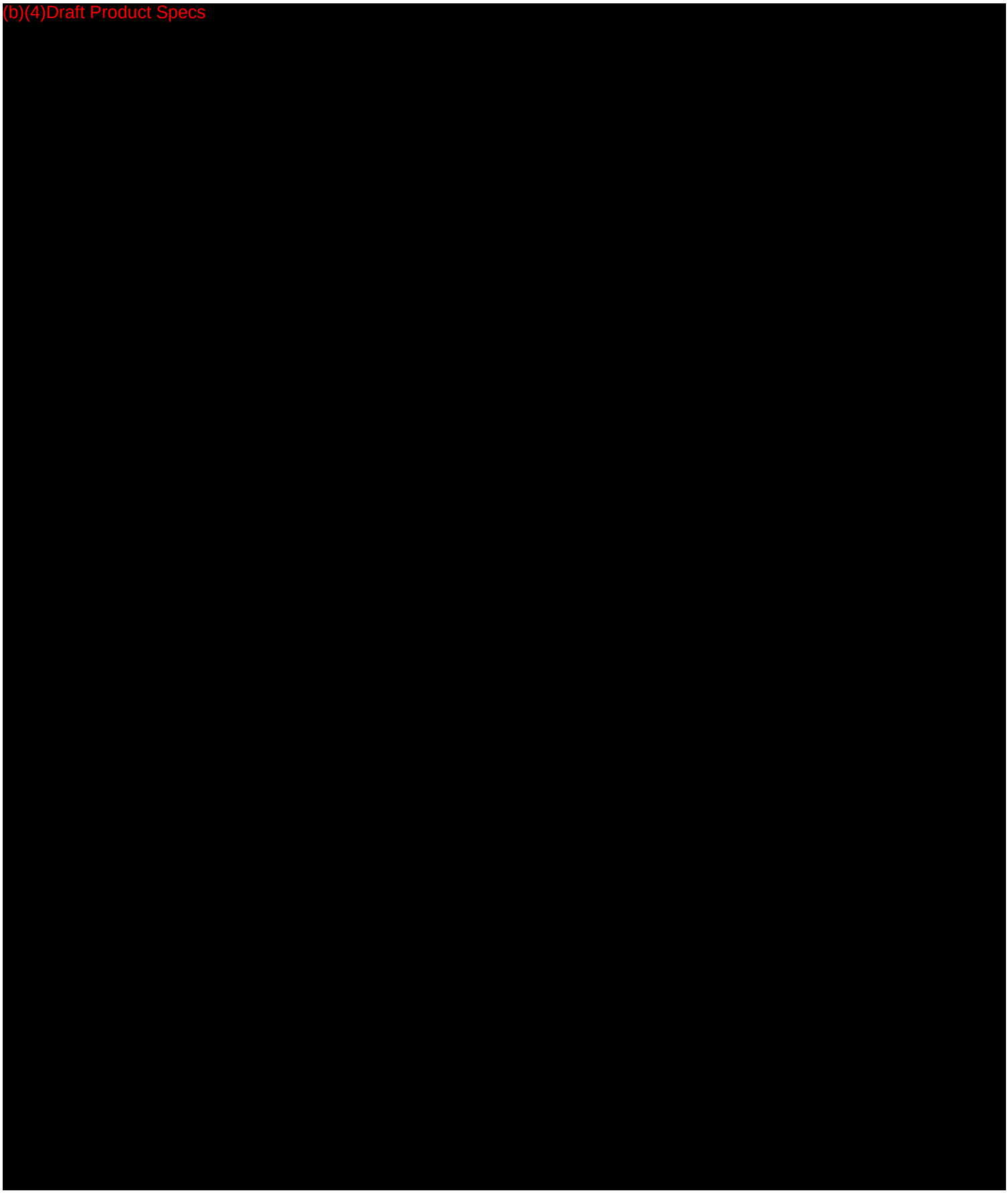

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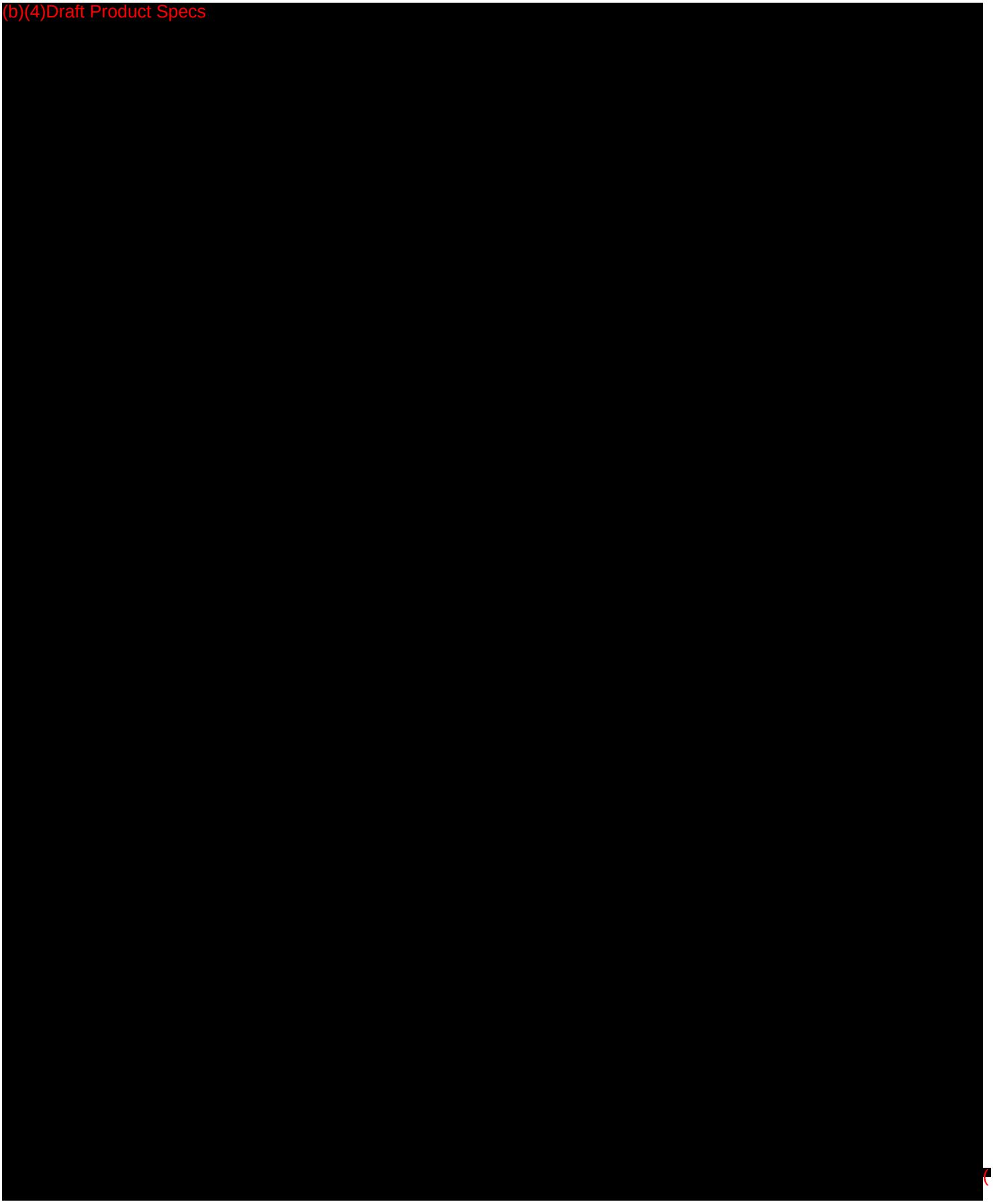

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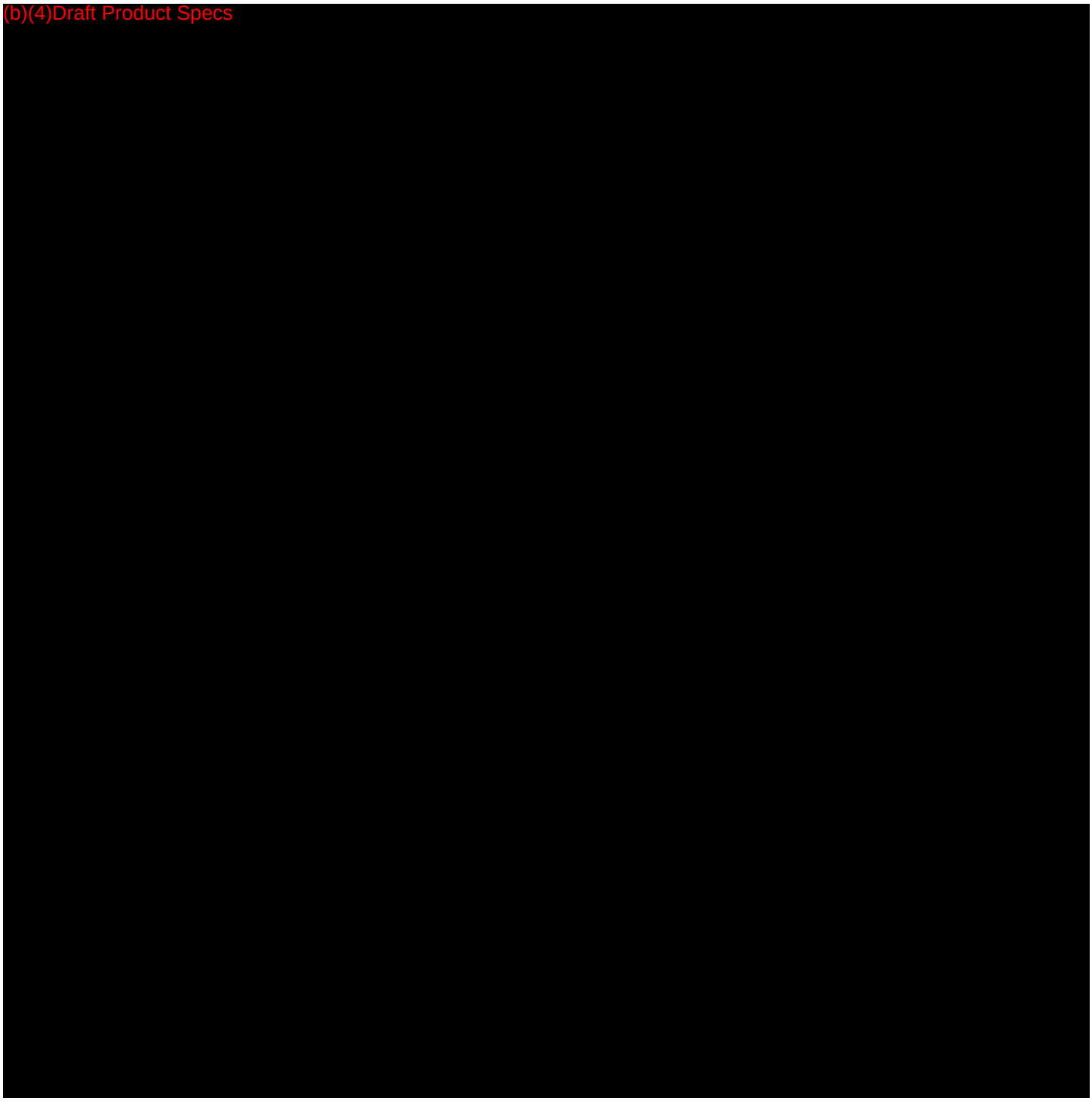

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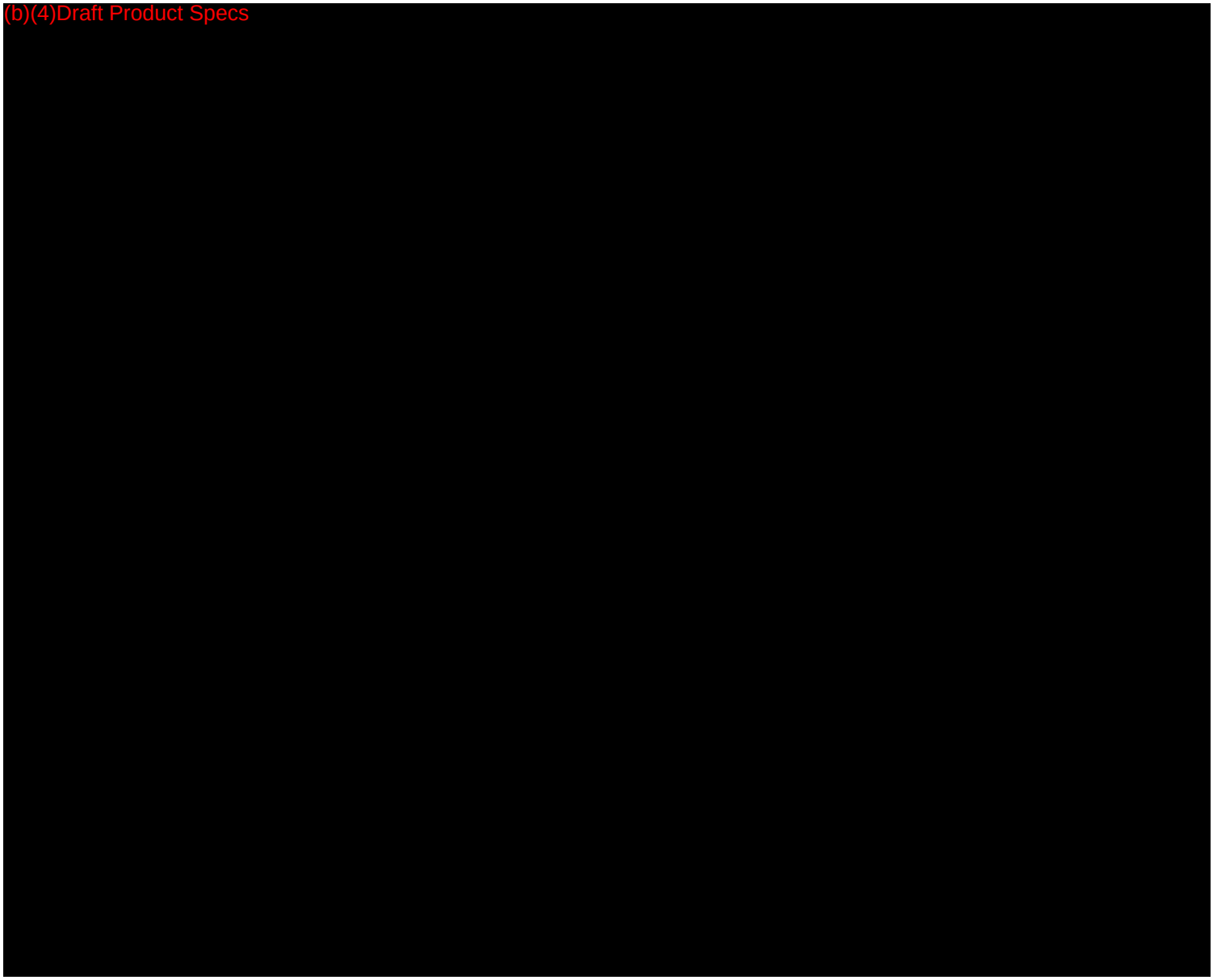

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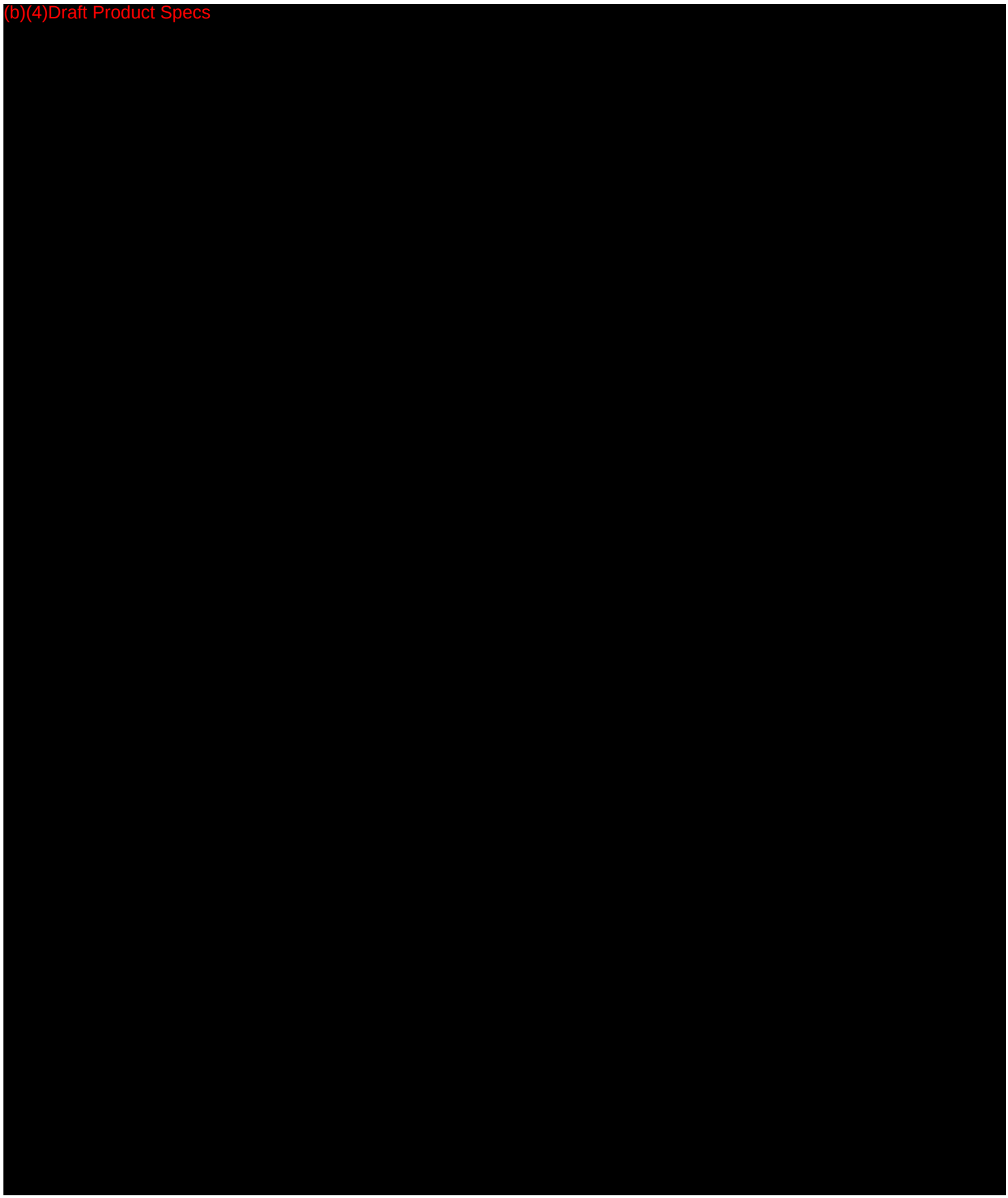

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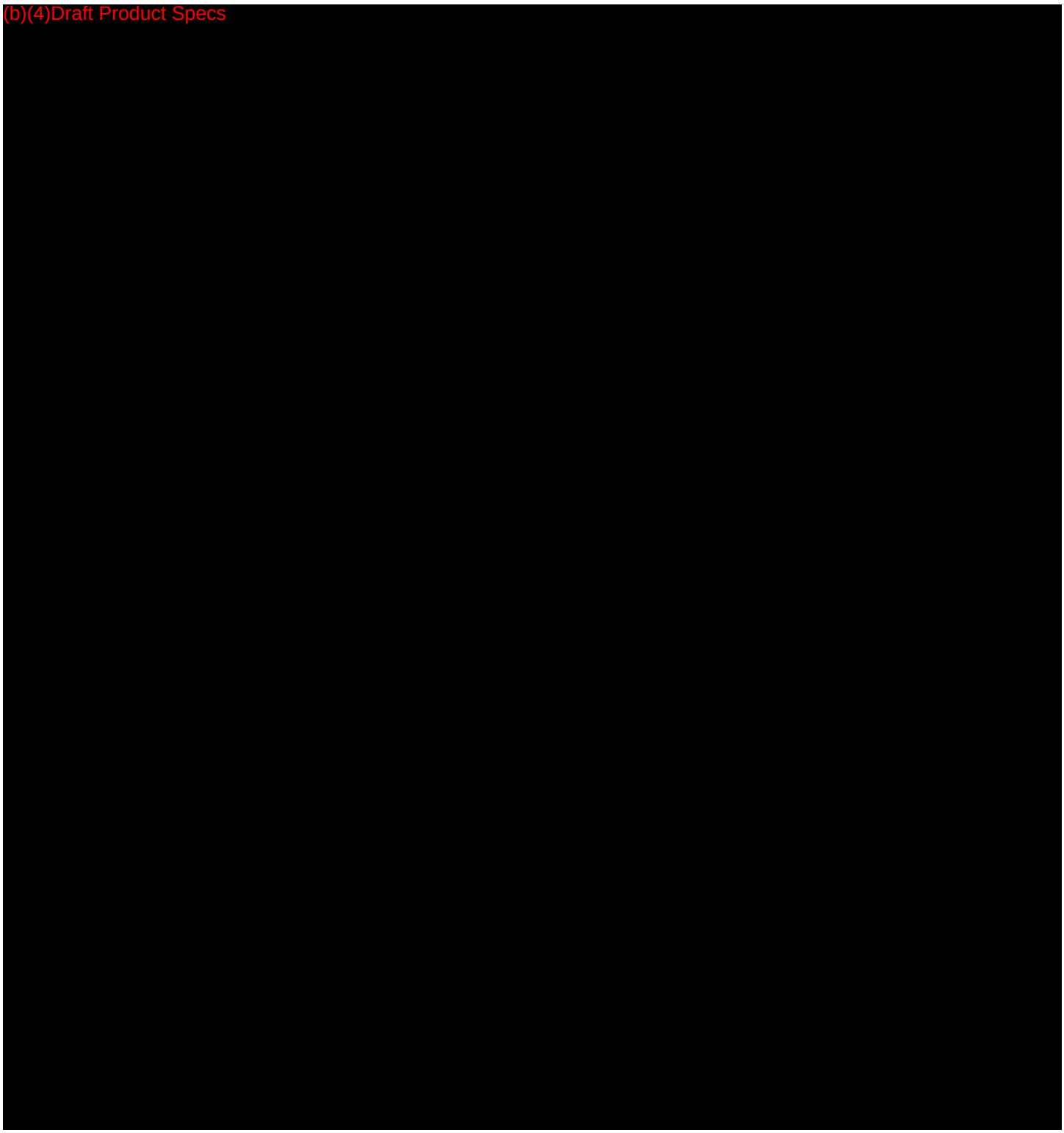

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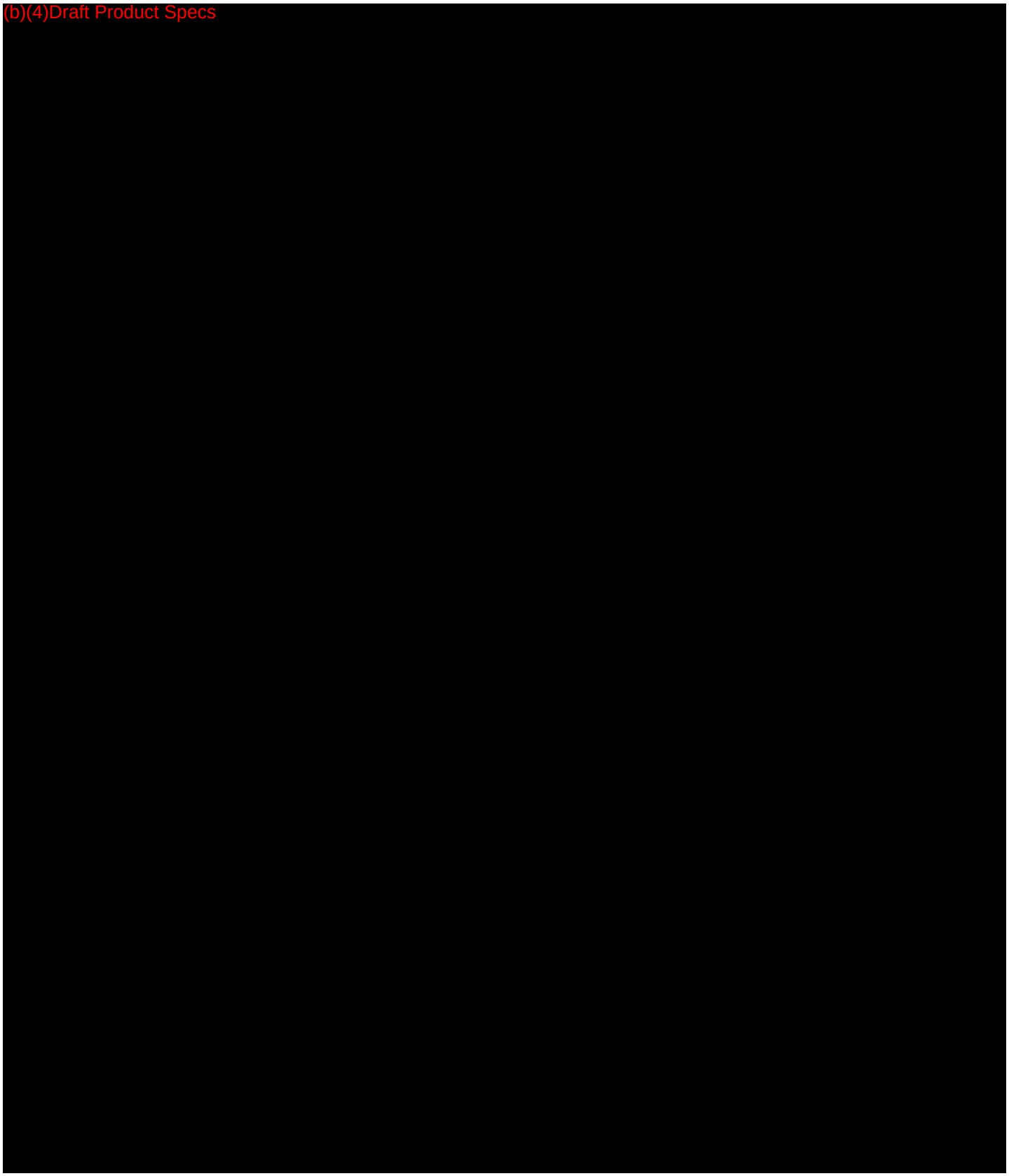

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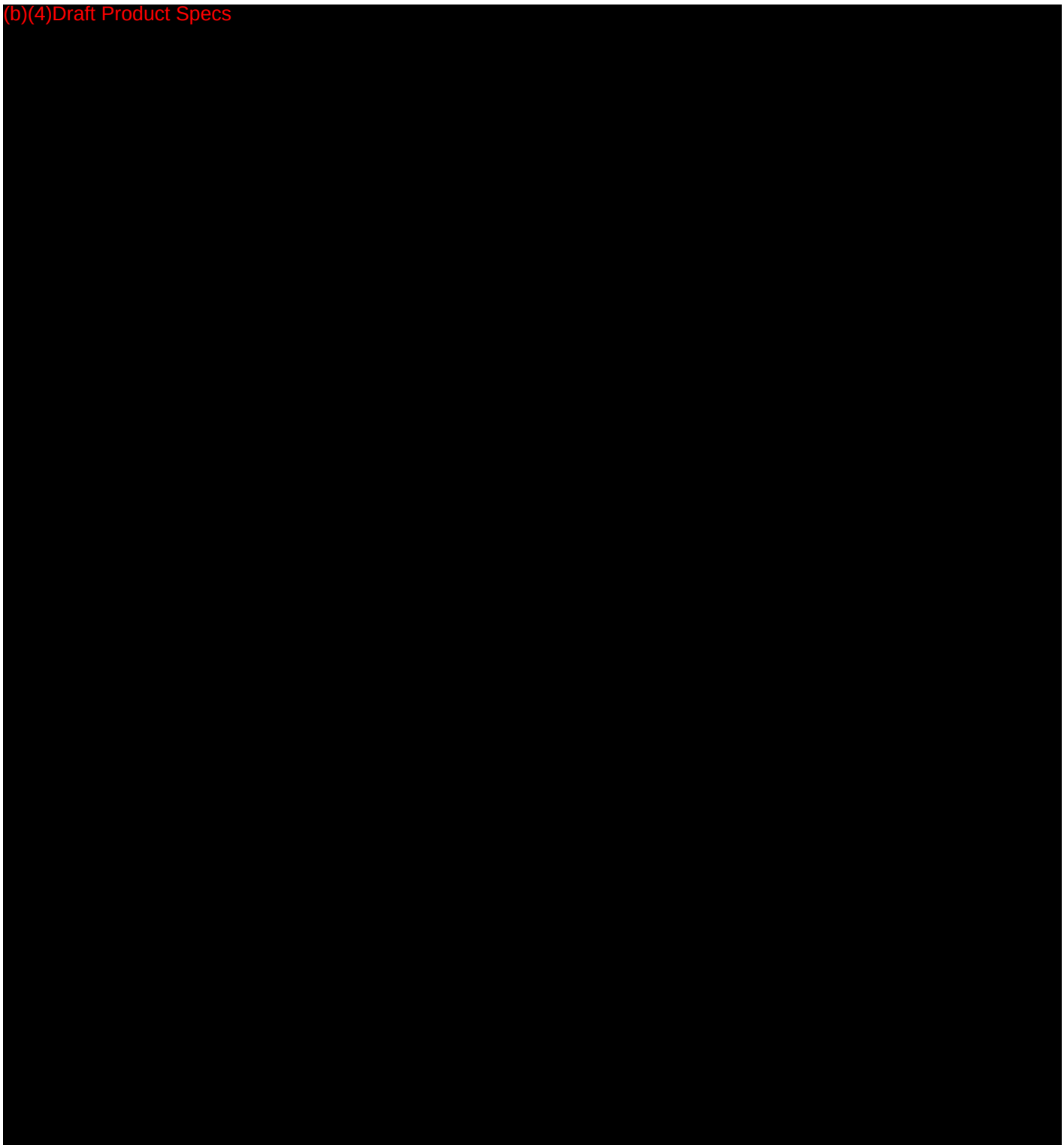

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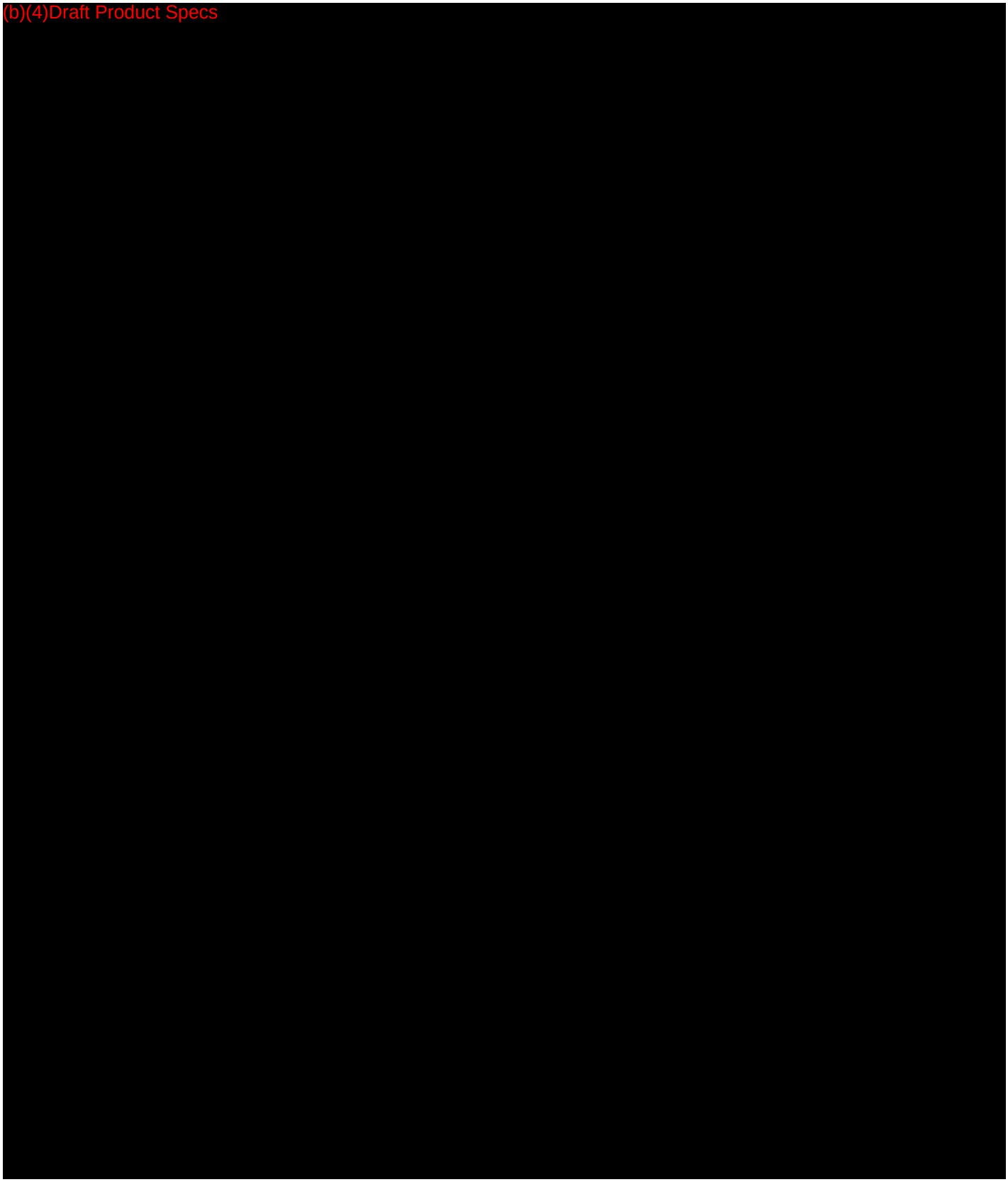

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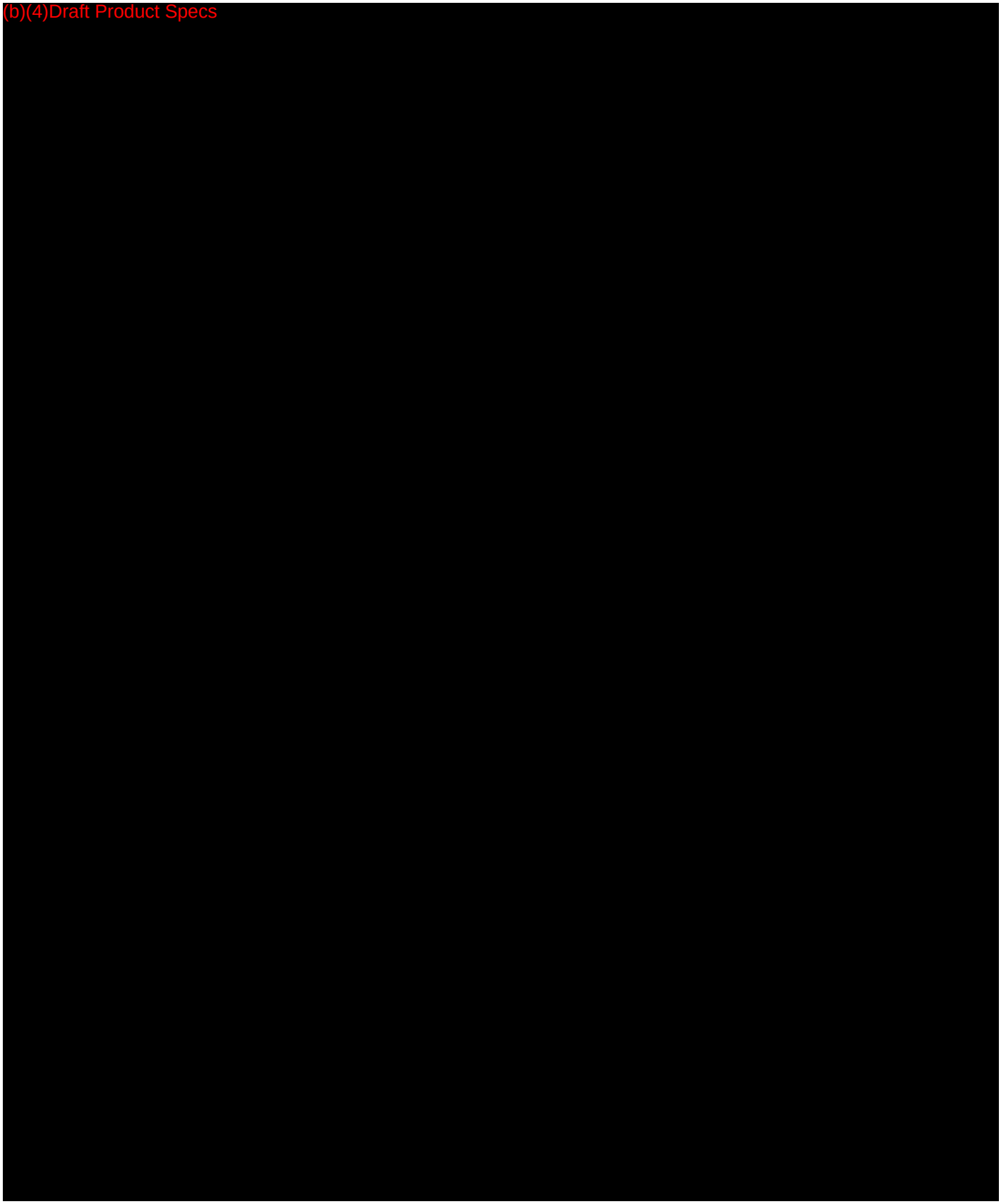

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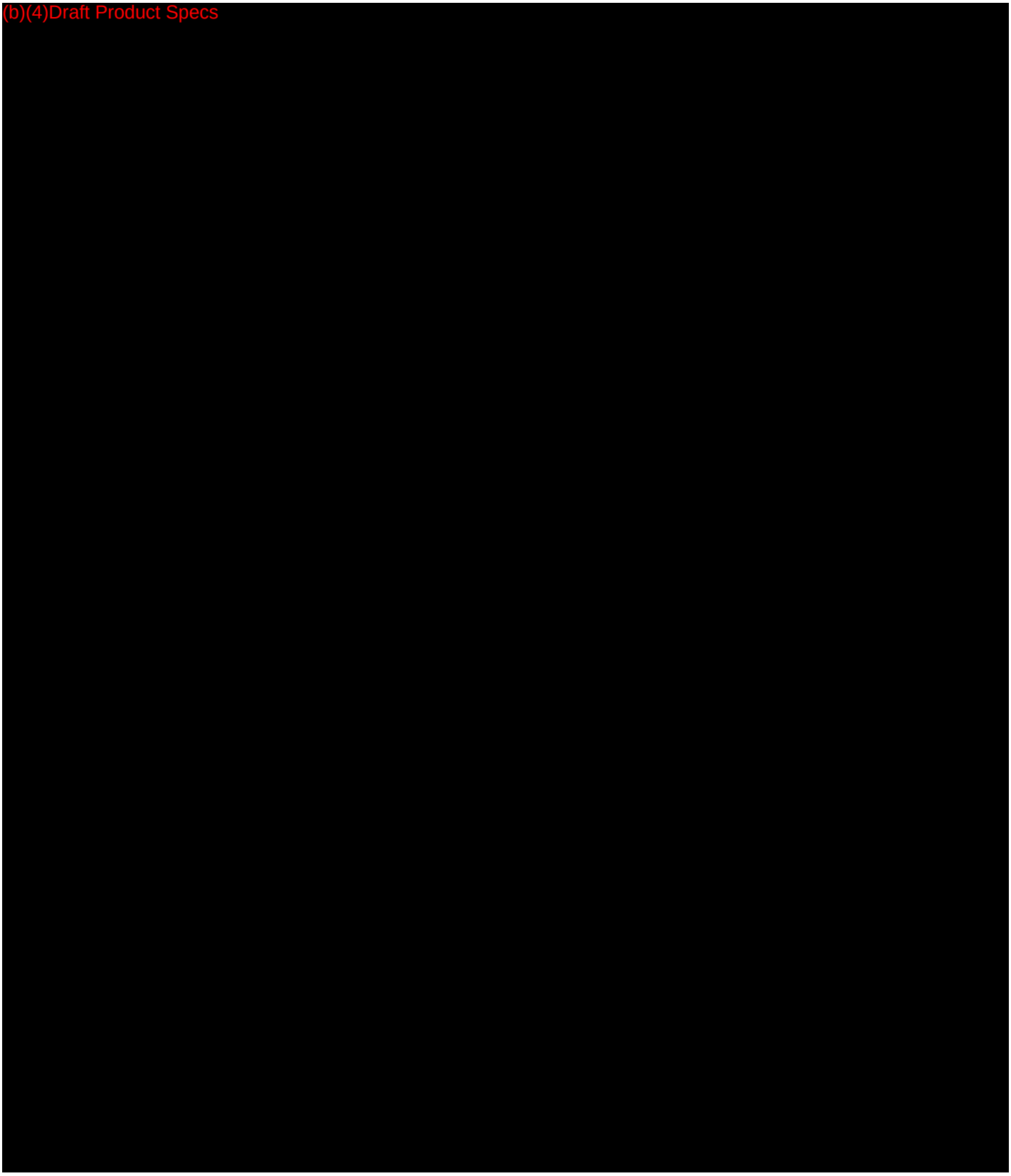

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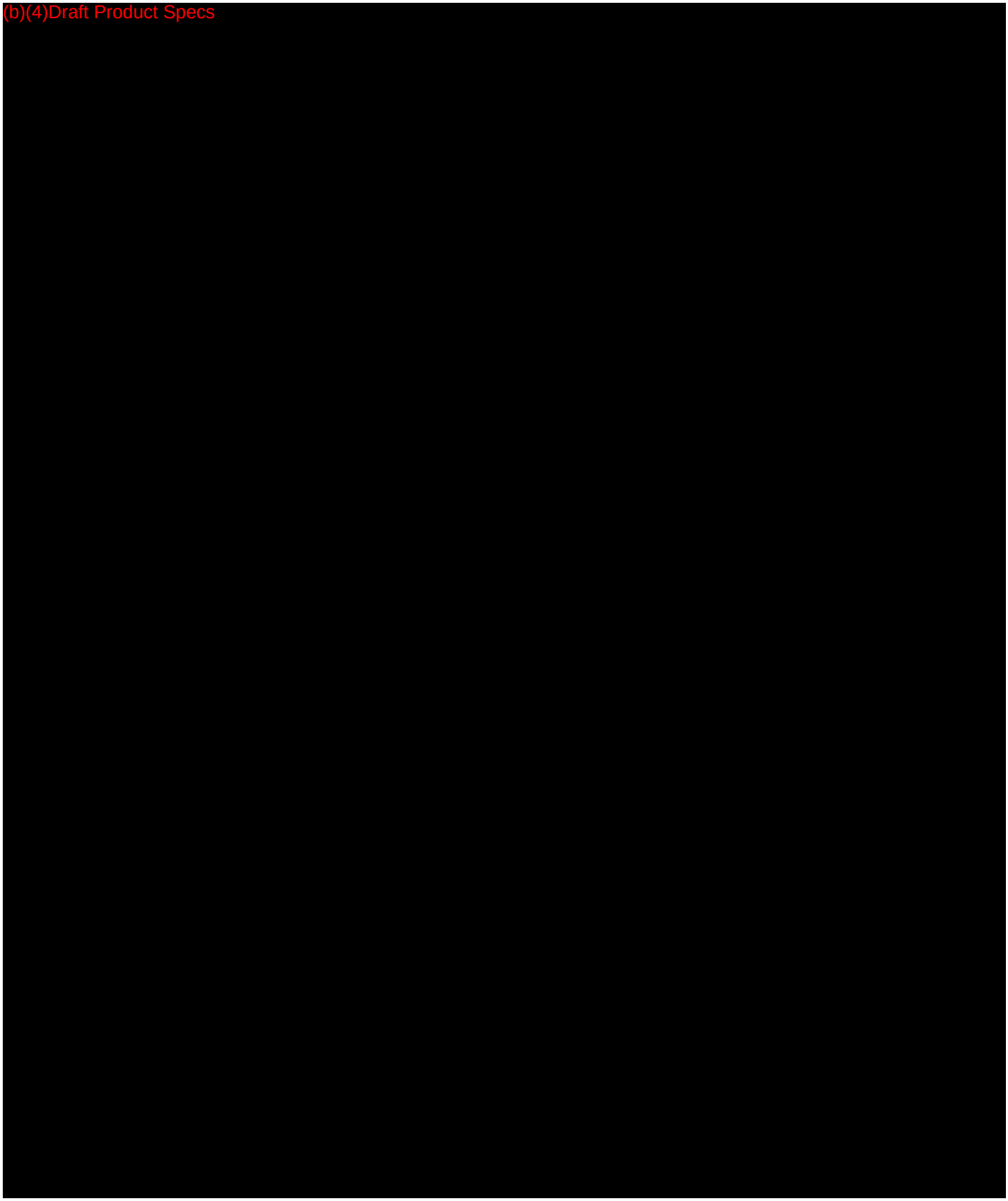

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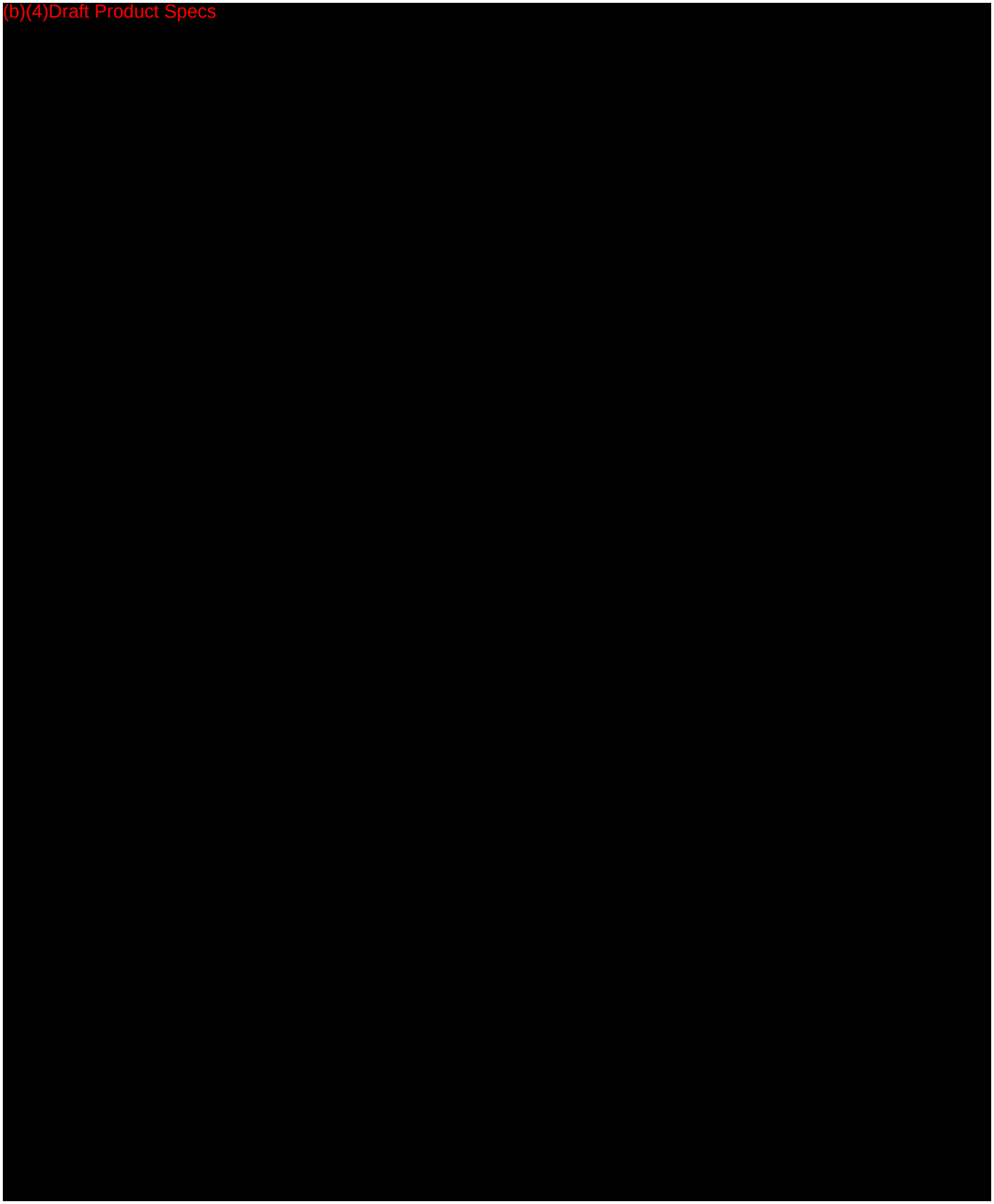

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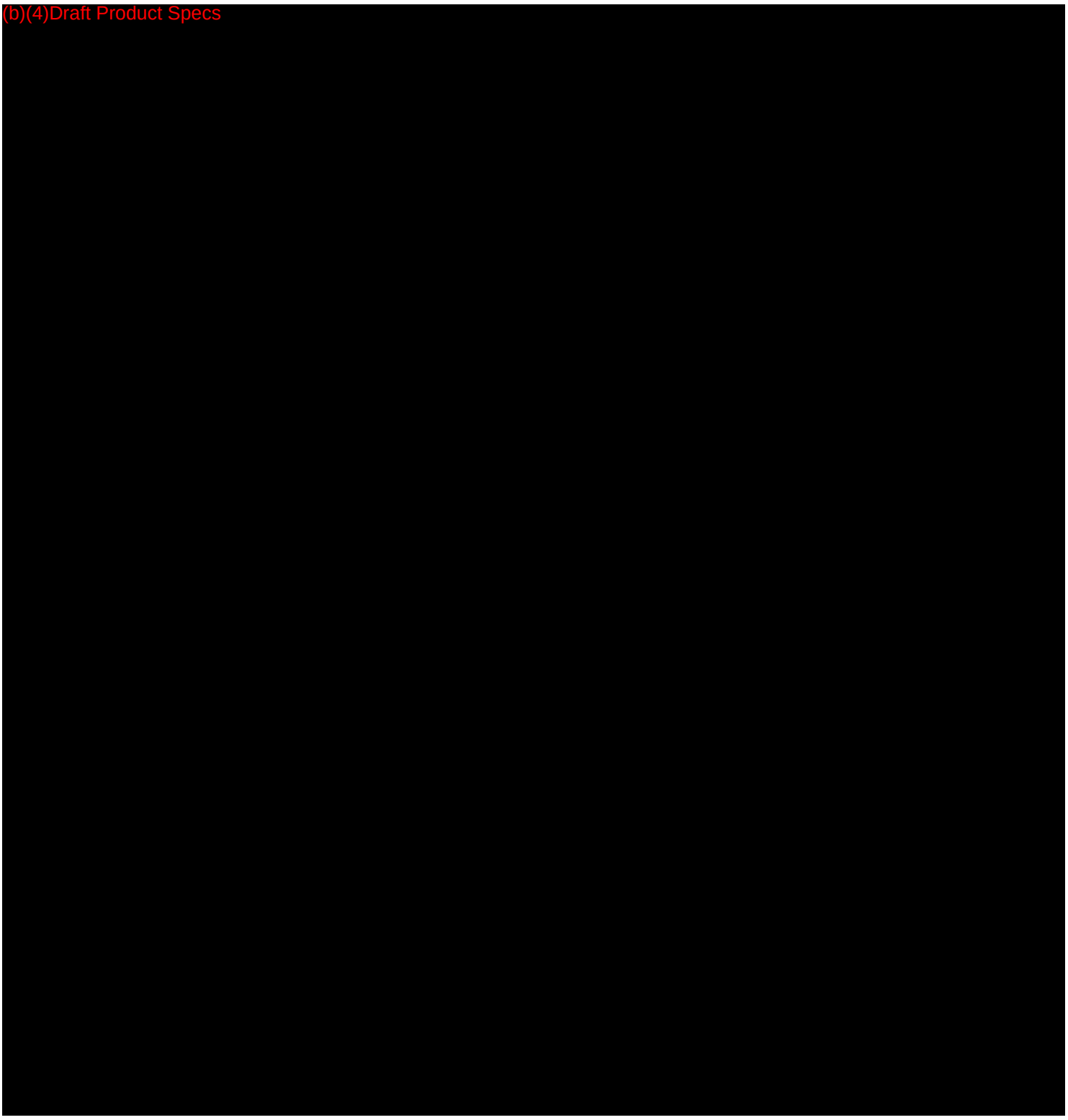

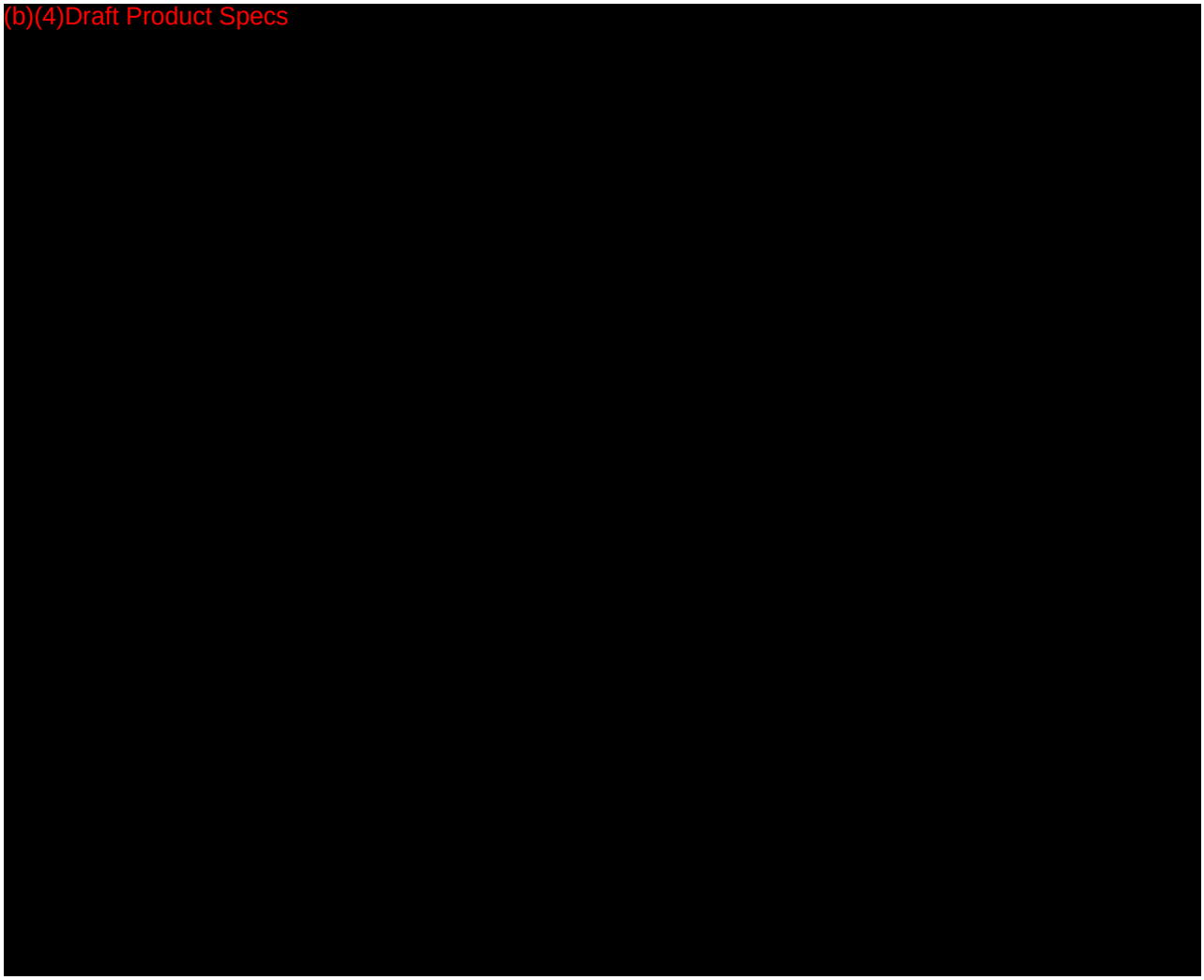
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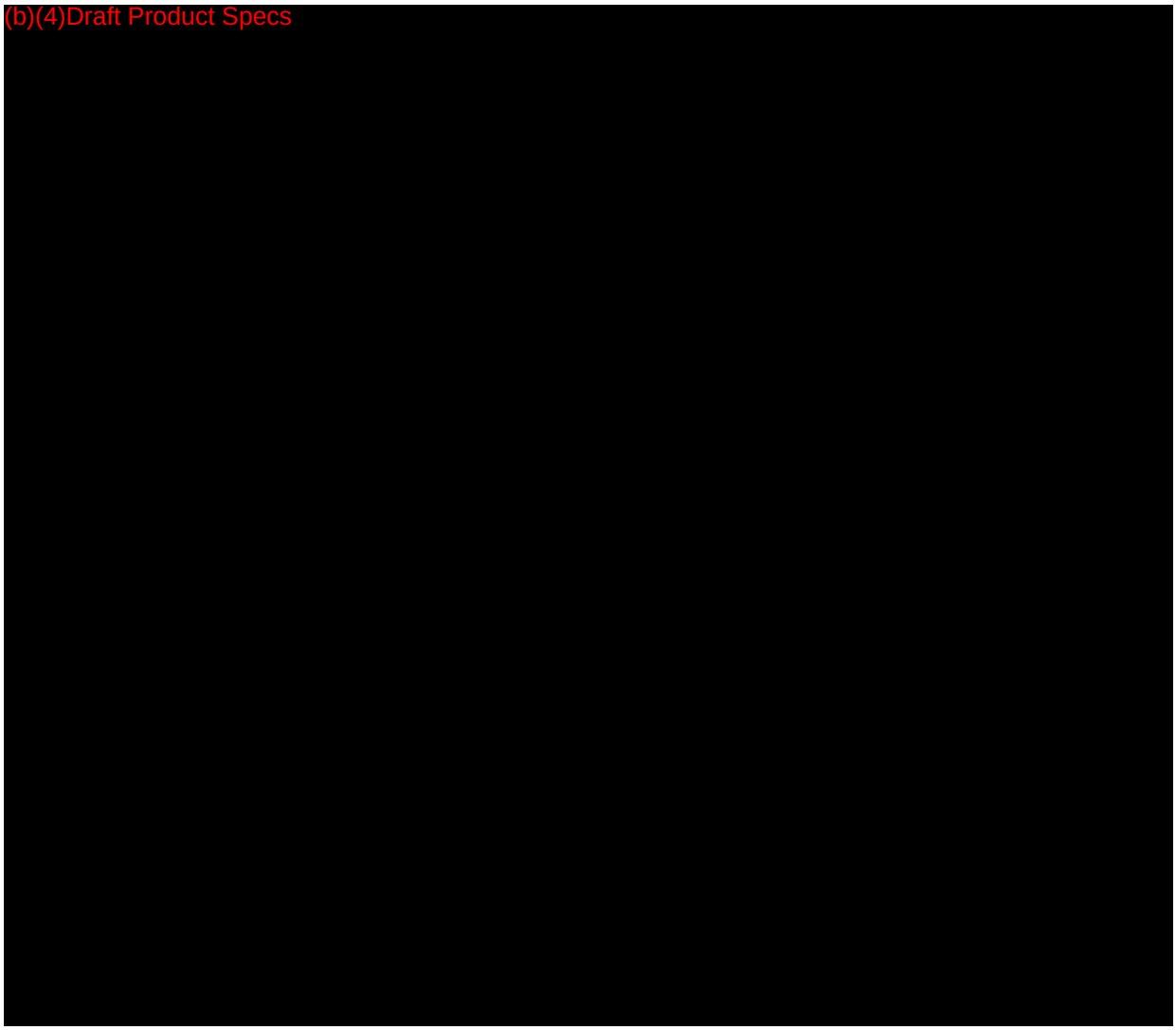

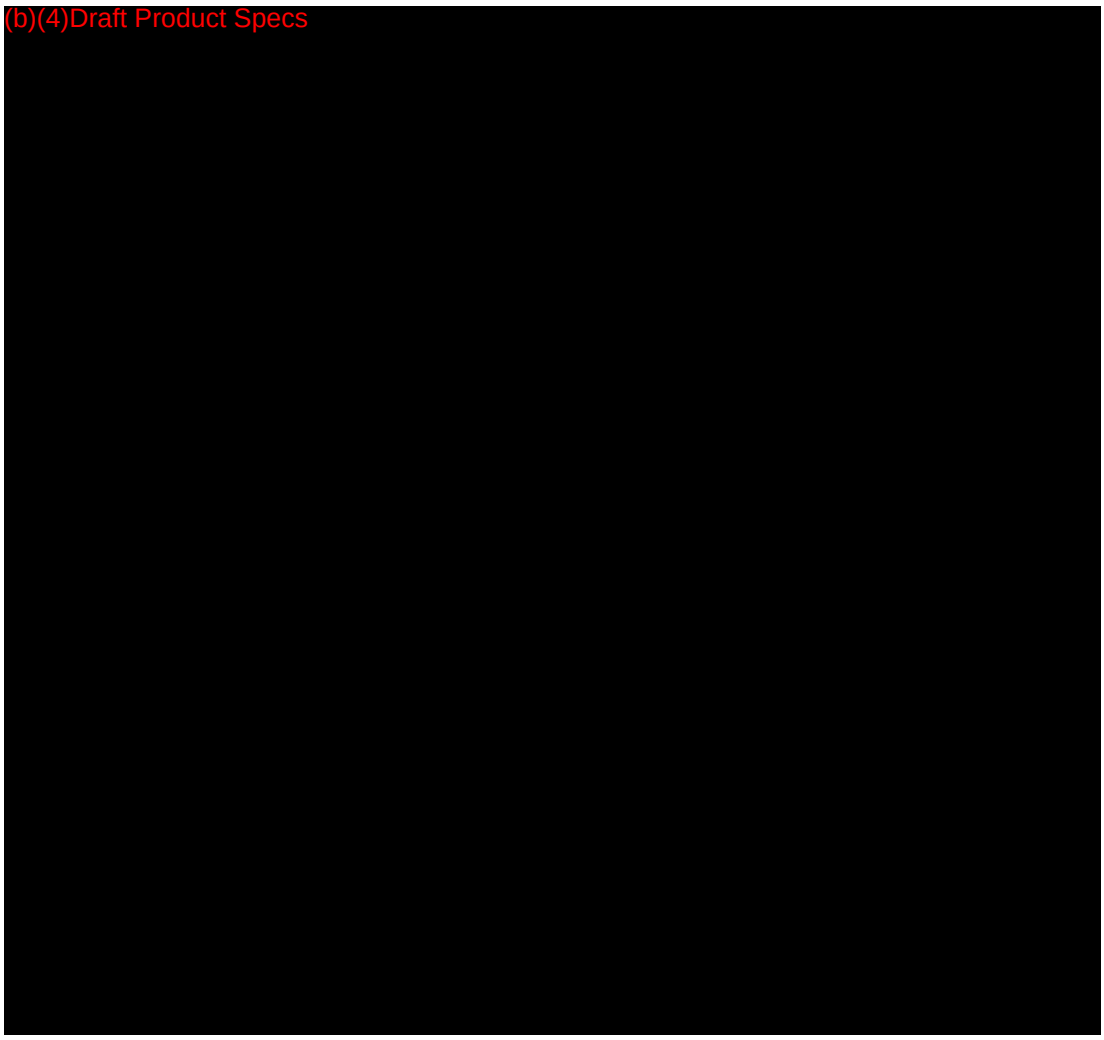
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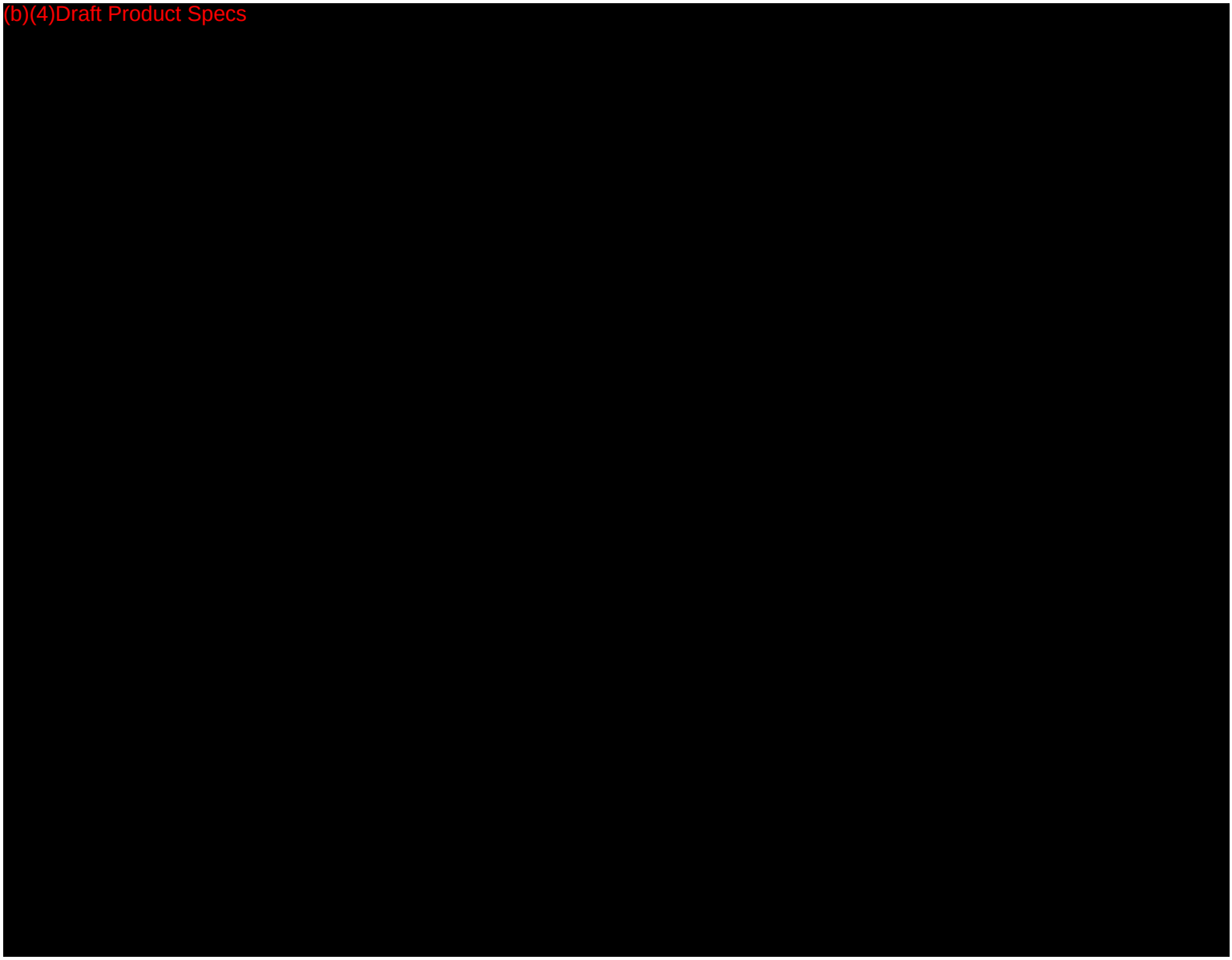

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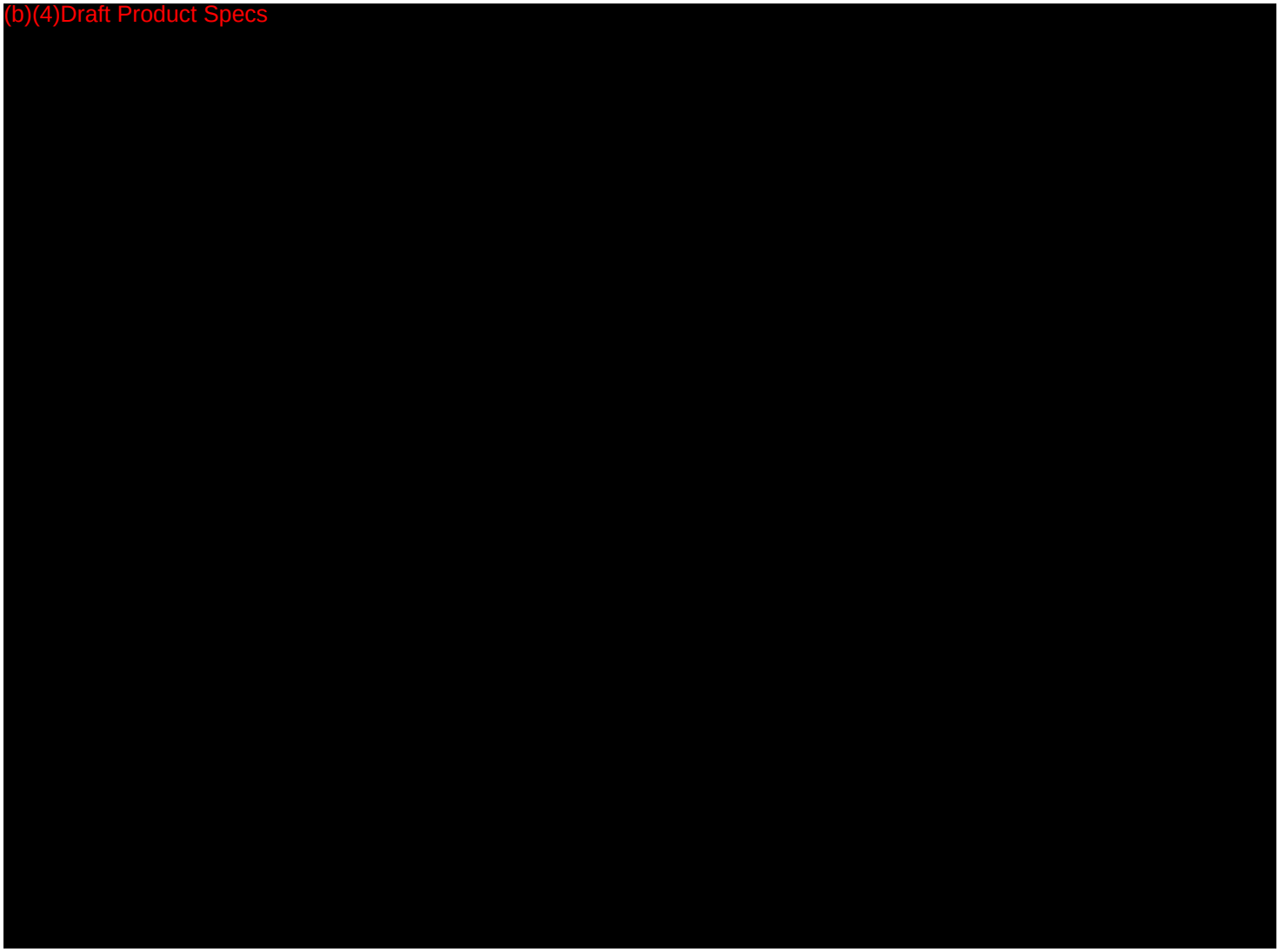

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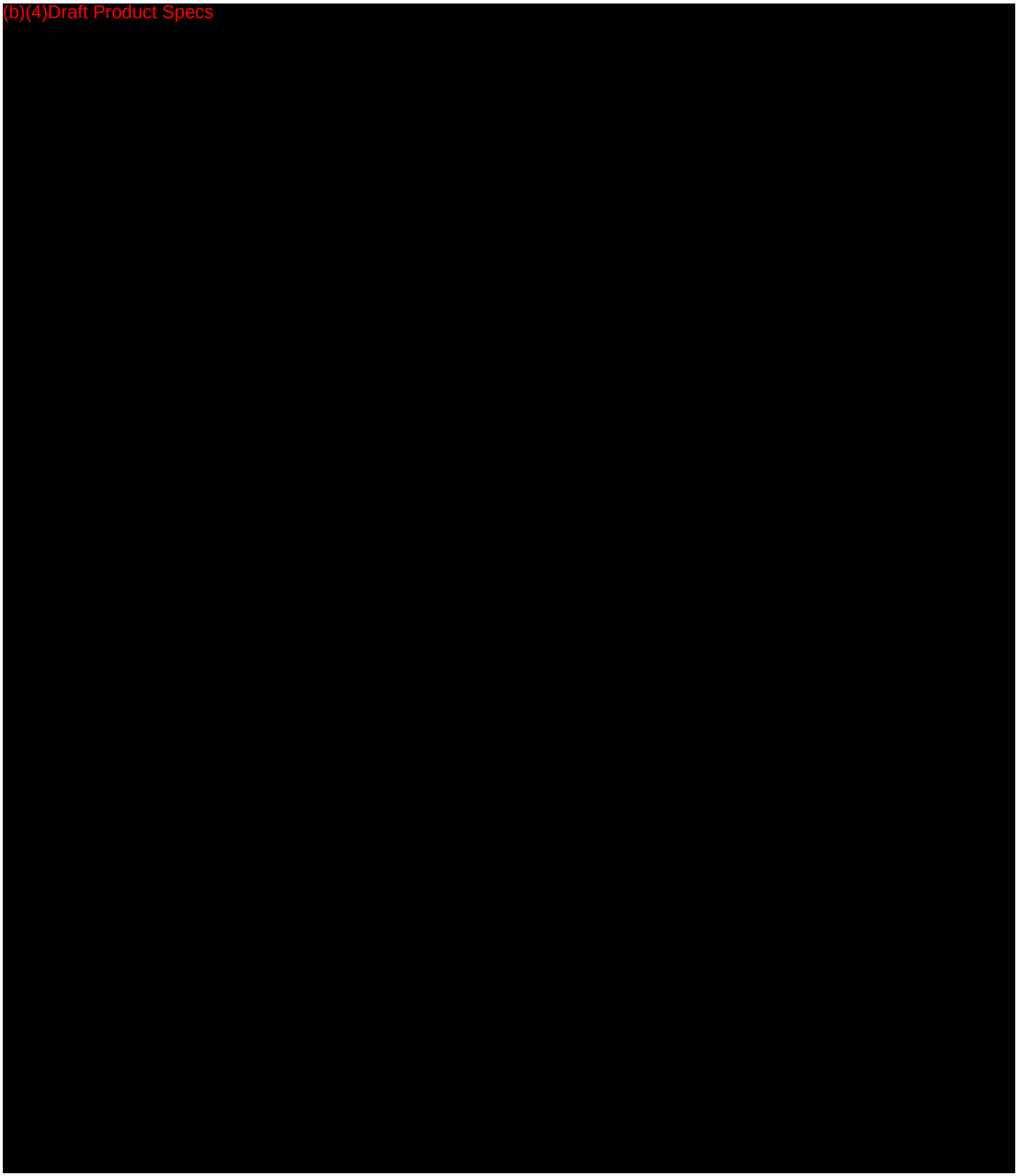

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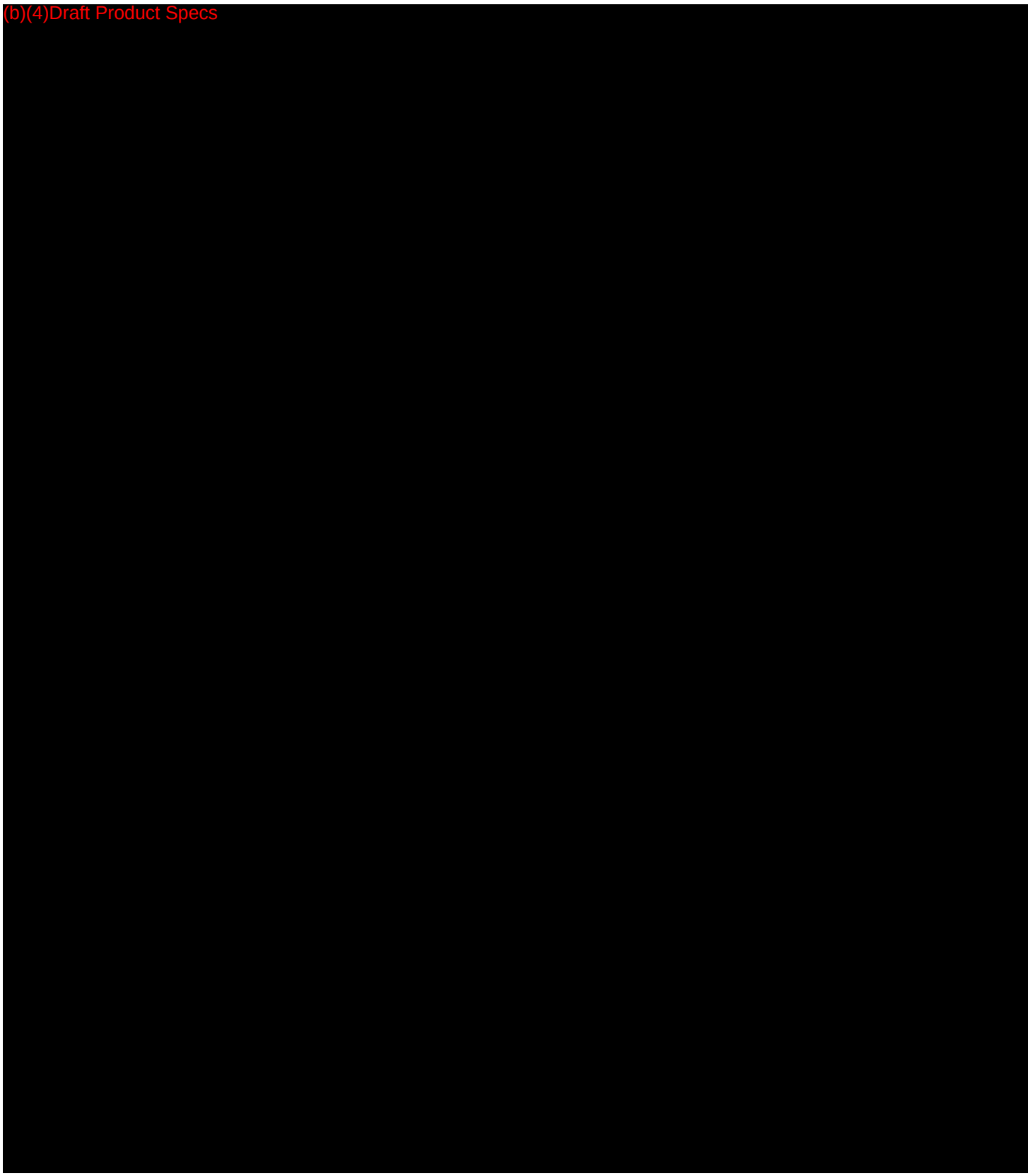

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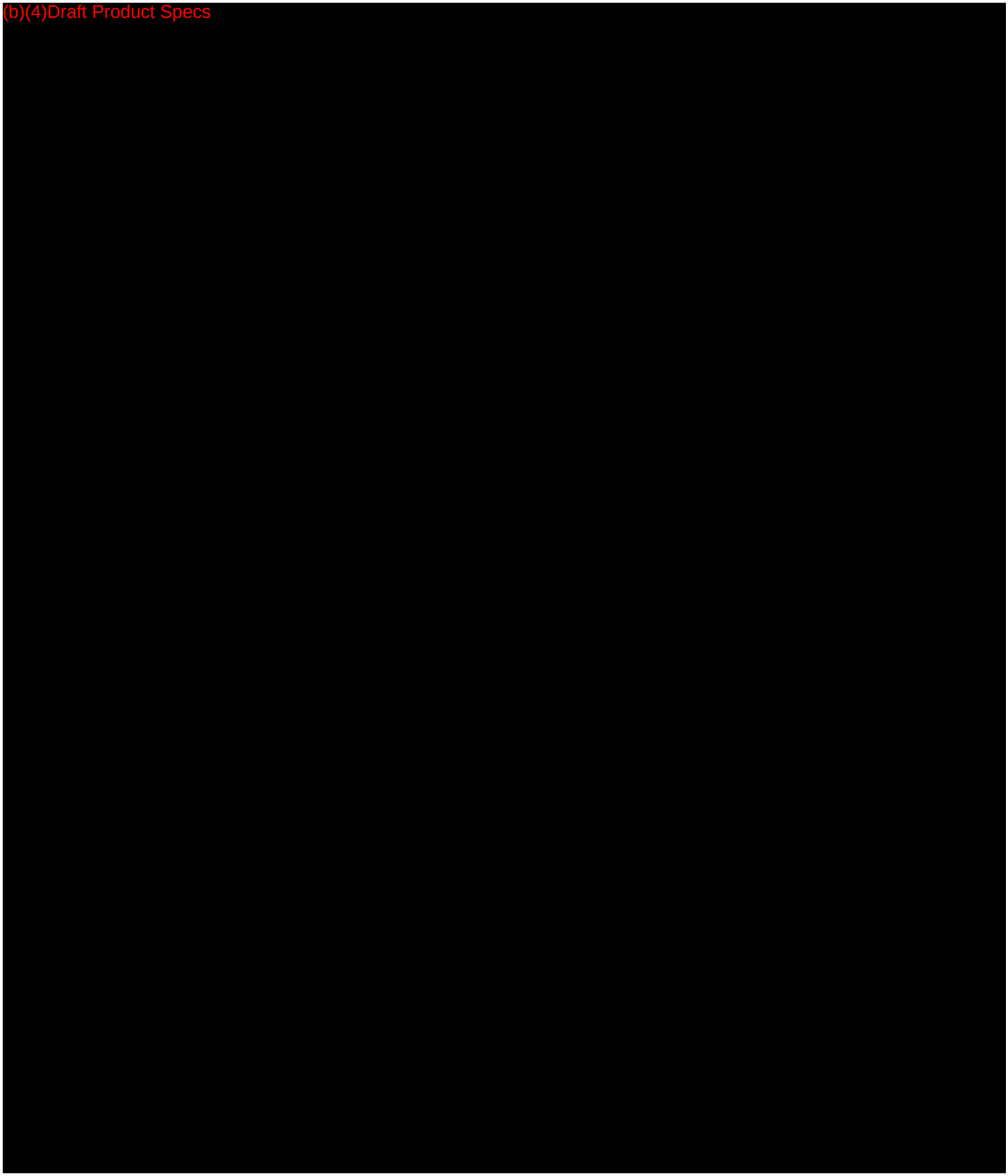

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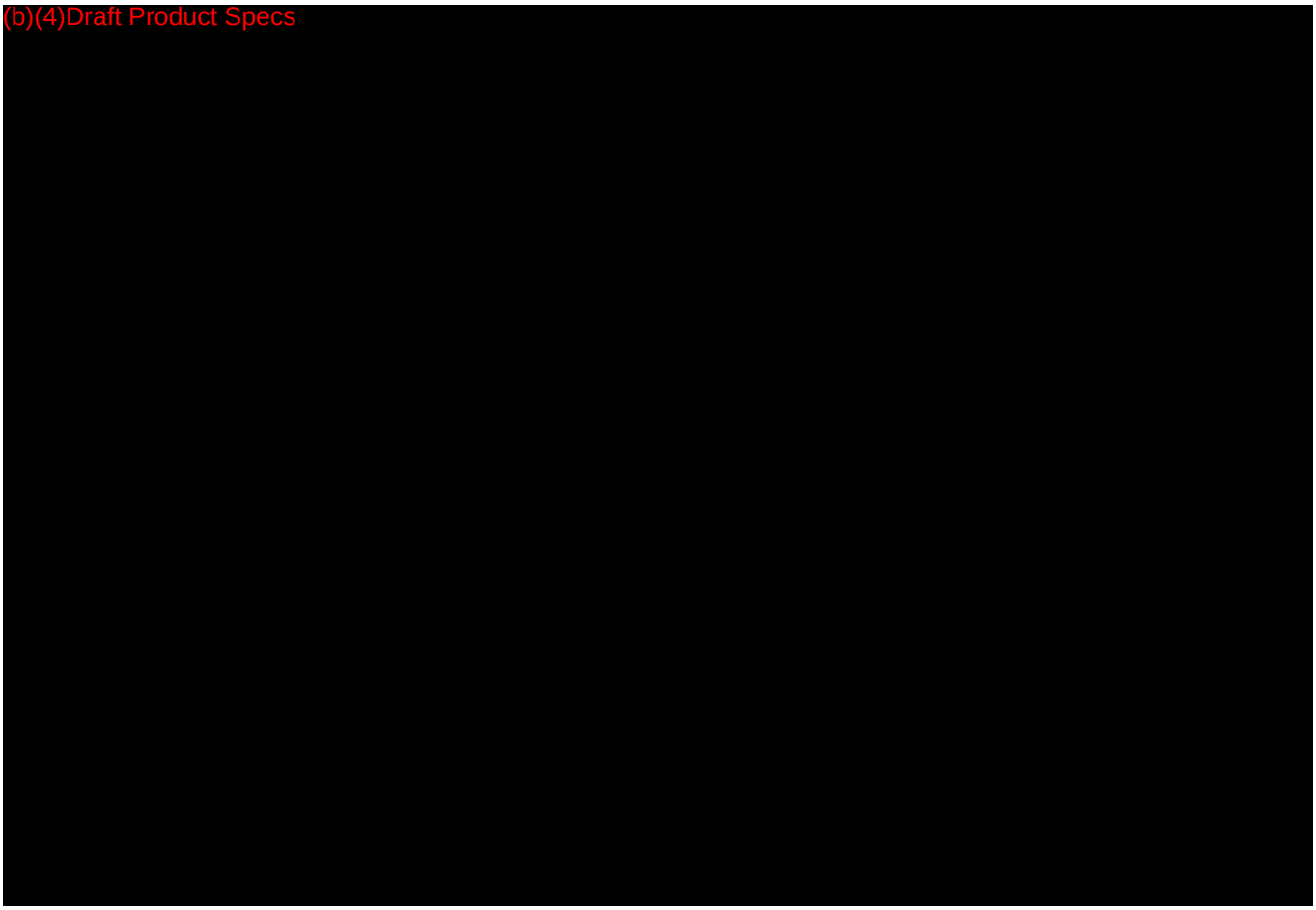

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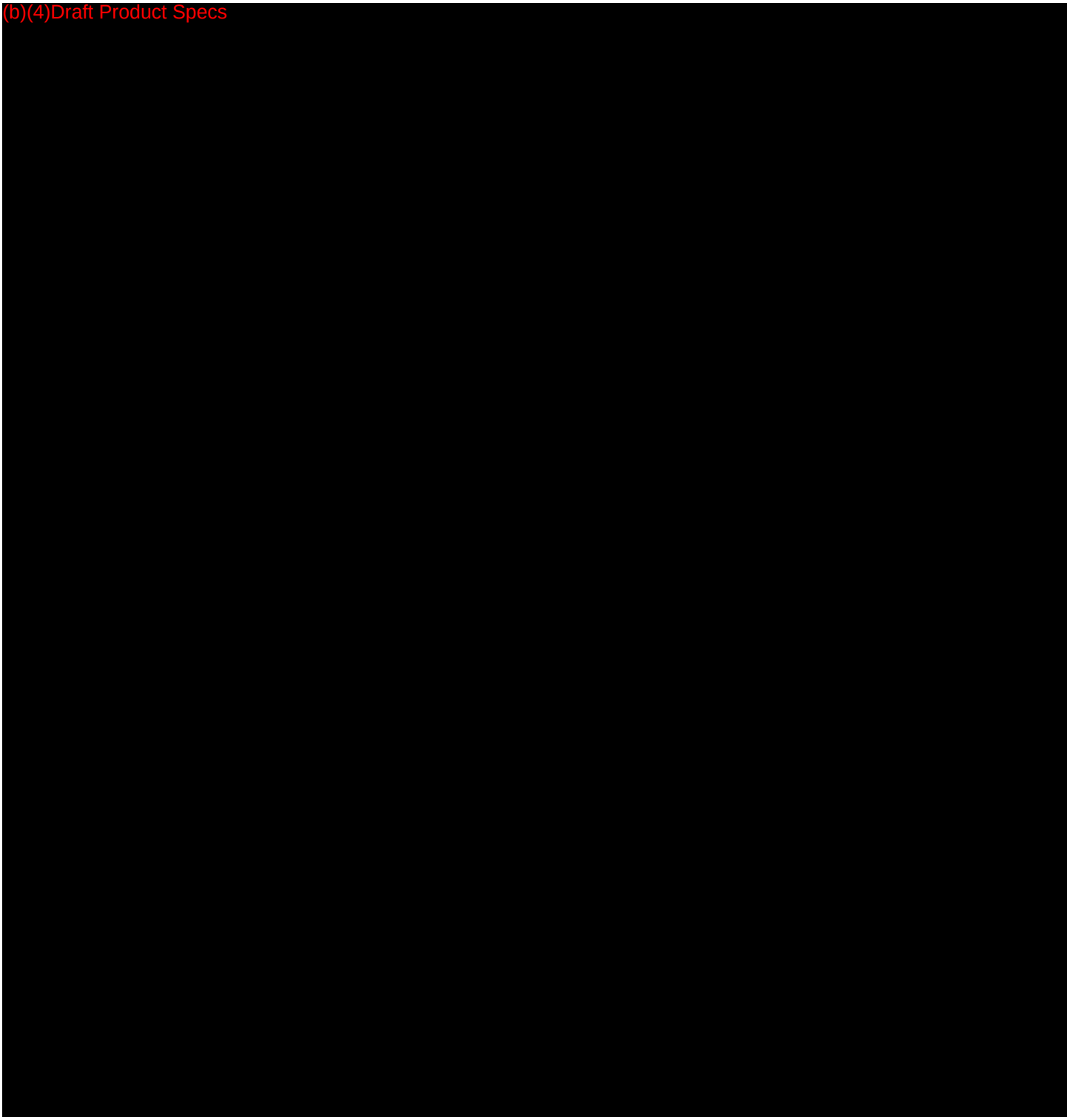

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Chapter 5 Planned Maintenance

1 Planned Maintenance Schedule

(Reference 21CFR 1020.30 (h)(1)(ii))

1.1 Overview

This is the Annual Planned Maintenance (PM) Schedule for the Discovery CT870 System.

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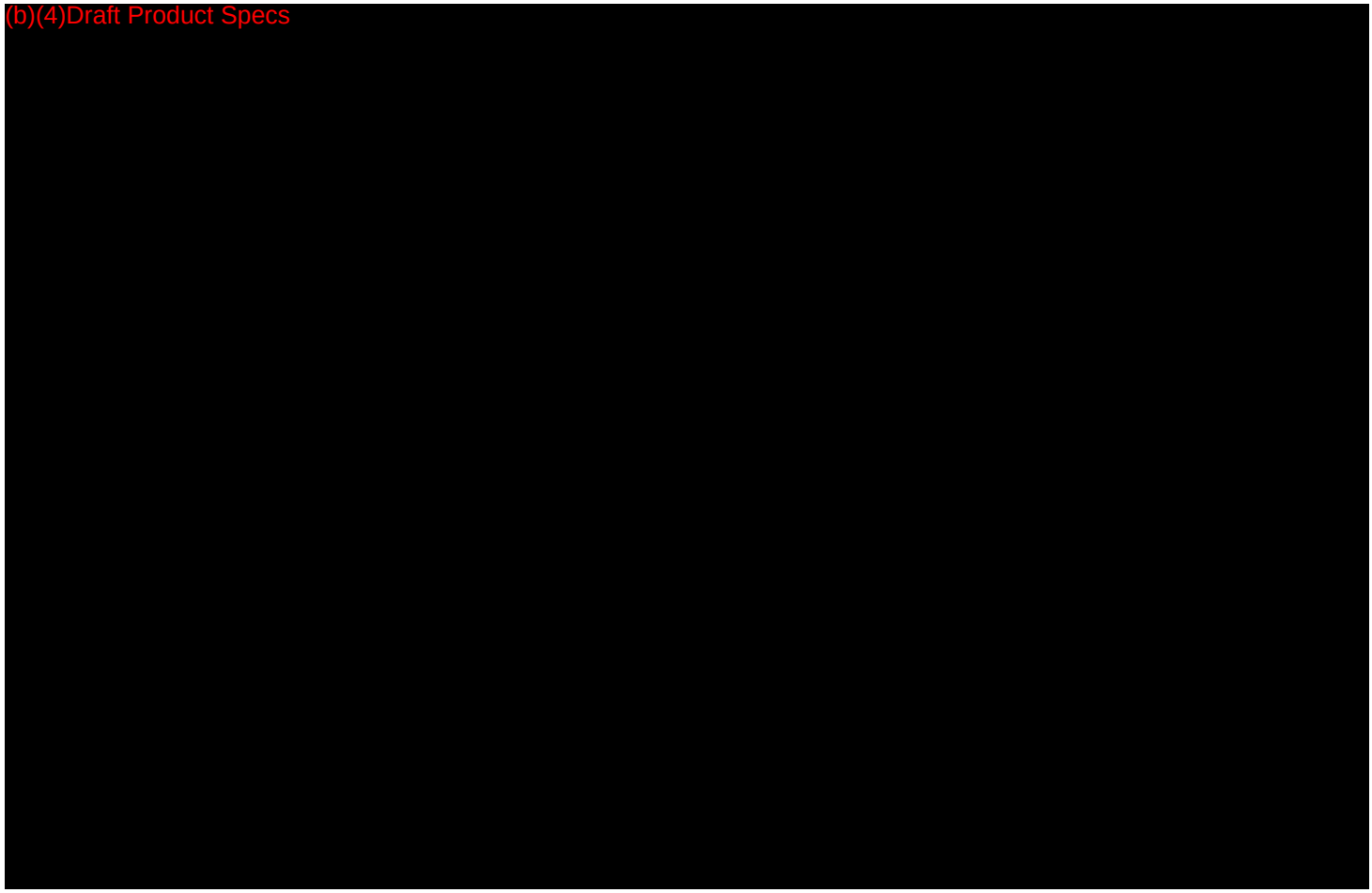

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Chapter 6 Dose and Performance

1 Dose

Dosimetry information is provided in terms of the CTDI and $CTDI_w$ dose indices. Optionally $CTDI_{vol}$ and its associated DLP (dose length product) is automatically computed and displayed on the patient Rx menu to assist in managing patient dose. This section provides a brief description to help you better understand these dose reporting standards.

1.1 General Information

Dose is the amount of energy imparted by the X-ray beam at a given point in an exposed material (patient tissue, phantom, air, etc.) and is measured in units of mGy (milliGray). The old unit was the rad, which equals 10 mGy. Dose is dependent on the energy absorption factors of the material and on the X-ray exposure. The X-ray exposure is measured in C/kg (coulombs per kilogram) and is dependent on the technique factors used for the scan. An absorbed dose of 1 mGy means that 1 Joule per gram of energy has been imparted. The dose is generally proportional to the exposure, which increases with increasing mA, kV and scan time and decreases with increasing patient size. The X-ray exposure to a point occurs from both direct X-ray from the tube and from scattered X-ray due to adjacent material exposure.

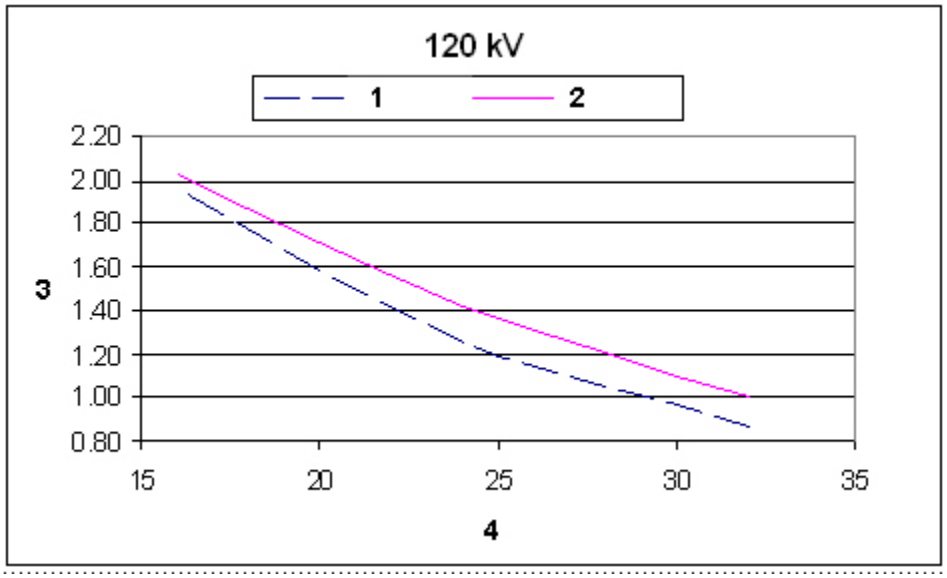
Patient biological risk is related to dose but is also highly dependent on the specific organs exposed and the age and gender of the patient. The effective dose is a way to characterize the stochastic risk to the patient population. The effective dose is the sum of the doses weighted in accordance with the specific radio-sensitivity of the particular organs or tissues exposed. Weighting values are published in ICRP 60 (International Committee on Radiation Protection, Publication 60). The effective dose is a whole body dose equivalent value that has been scaled to represent the dose of the exposed organs. Although we can accurately describe the X-ray exposure potential to a patient for a CT scan, we cannot easily determine the patient dose or risk in terms of effective dose. This is because each patient is anatomically unique and the specific details of his or her anatomy along with the source exposure must be processed using time-consuming monte-carlo computer programs (or other more approximate methods) to predict how radiation will be scattered and accumulated within various patient organs.

Since it is not possible to characterize the specific dose given to individual patients, the CT dose indices are provided to help make relative comparisons. These dose index values can be used to compare CT systems and to help select appropriate operating conditions for scanning. However, it is important to recognize that the dose reported by these indices is inversely proportional to phantoms size (Illustration 1). This means that for the same scan technique (protocol), smaller phantoms will produce a higher absorbed dose than larger phantoms [1]. Table 5 indicates the phantom size used for each SFOV.

[1] Edward L. Nickoloff, Ajoy K. Dutta, and Zheng F. Lu, “Influence of phantom diameter, kVp and scan mode upon computed tomography dose index”, Medical Physics 30, 395 (2003)

It is important to remember that the dose indices reported by the system are determined using the 16cm CTDI phantom for head scans and the 32cm CTDI phantom for body scans.

Illustration 1: Relationship between dose and phantom size for head and body SFOV types at 120 kV. Similar curves are obtained for 70, 80, 100, and 140 kVs.



Number	Description
1	Head
2	Body
3	Relative Dose
4	Phantom Diameter (cm)

1.2 CTDI Dose Calculations

(Reference 21CFR 1020.33 (c)(2))

CT Dose Index (CTDI) was established by the FDA and has been in use for many years. It is the basis for the $CTDI_{100}$ methodology because it defined a way to determine the dose at specific points (center and peripheral) in a head or body size reference phantom (refer to Illustration 1). The CTDI dose is defined as the dose absorbed in the phantom material (PMMA) at a point when a volume of 7 contiguous slices is scanned adjacent to each side of the point.

Mathematical Definition of CTDI

$$CTDI = \frac{1}{nT}\int_{-7T}^{7T} D(z)dz$$

$$n = Number\ detector\ macro\ rows\ per\ scan$$

$$T = Row\ detection\ width$$

$$D(z) = Z\ Axis\ dose\ profile\ (absorbed\ in\ PMMA)$$

The contiguous adjacent slices contribute to much of the total dose for large aperture cases, but it greatly underestimates the dose for narrow slices because the index is defined for 14 slices and typical modern procedures will include scattered dose from more than 7 adjacent slices.

1.2.1 $CTDI_w$ Calculation

(Reference IEC 60601-2-44 and 21 CFR 1020.33 (c))

$CTDI_w$ or weighted $CTDI_{100}$ is a dose index which consists of 2/3 of the $CTDI_{100}$ peripheral dose plus 1/3 of the $CTDI_{100}$ central dose. The $CTDI_{100}$ dose is defined as the integral of the dose profile, Da(z), produced in a single axial scan along a line perpendicular to the imaging plane from -50 mm to +50 mm, divided by the product of the number of slices, n, and the nominal tomographic section thickness (row detection width), T.

$$CTDI_{100} = \left(\frac{1}{nT}\right)\int_{-50mm}^{50mm} Da(z)dz$$

$$CTDI_w = \left(\frac{2}{3}\right) \times CTDI_{100}(Peripheral) + \left(\frac{1}{3}\right) \times CTDI_{100}(Center)$$

$$where:$$

$$n = Number\ of\ detector\ macro\ rows\ per\ scan$$

$$T = Nominal\ Tomographic\ section\ thickness\ (Detector\ Row\ Width)$$

$$Da(z) = Dose\ profile \in the\ Z - Axis\ (Absorbed\ Air)$$

$CTDI_w$ is measured using either a 16 cm (for head scanning) or a 32 cm (for body scanning) PMMA phantom. An overall phantom length of 450 mm is used for all measurements by placing three identical 150 mm length phantom sections together. The dose probe used for the measurement

is placed in the center phantom section. The measurements are taken at the center and peripheral (see Illustration 4). The doses measured at these locations within the PMMA phantom, are quoted as the dose absorbed in air rather than PMMA (absorption in air is about 11% higher than absorption in PMMA).

1.2.2 $CTDI_{vol}$ Calculation

(Reference IEC 60601-2-44)

The volume $CTDI_w$ ($CTDI_{vol}$) describes the average dose over the total volume scanned for the selected CT conditions of operation. The system computes $CTDI_{vol}$ automatically.

NOTE: System computations may vary slightly from manual calculations due to differences in round-off or truncation operations.

The **$CTDI_{vol}$** is defined as follows:

For axial scanning

$$CTDI_{vol} = \frac{N \times T}{\Delta d} CTDI_w$$

Where N is the number of slices produced in a single axial scan, T is the slice thickness (or row detection width), and Δd is the table travel in z-direction between consecutive scans.

For helical scanning

$$CTDI_{vol} = \frac{tracking\ adjustment\ factor}{CT\ pitch\ factor} CTDI_w$$

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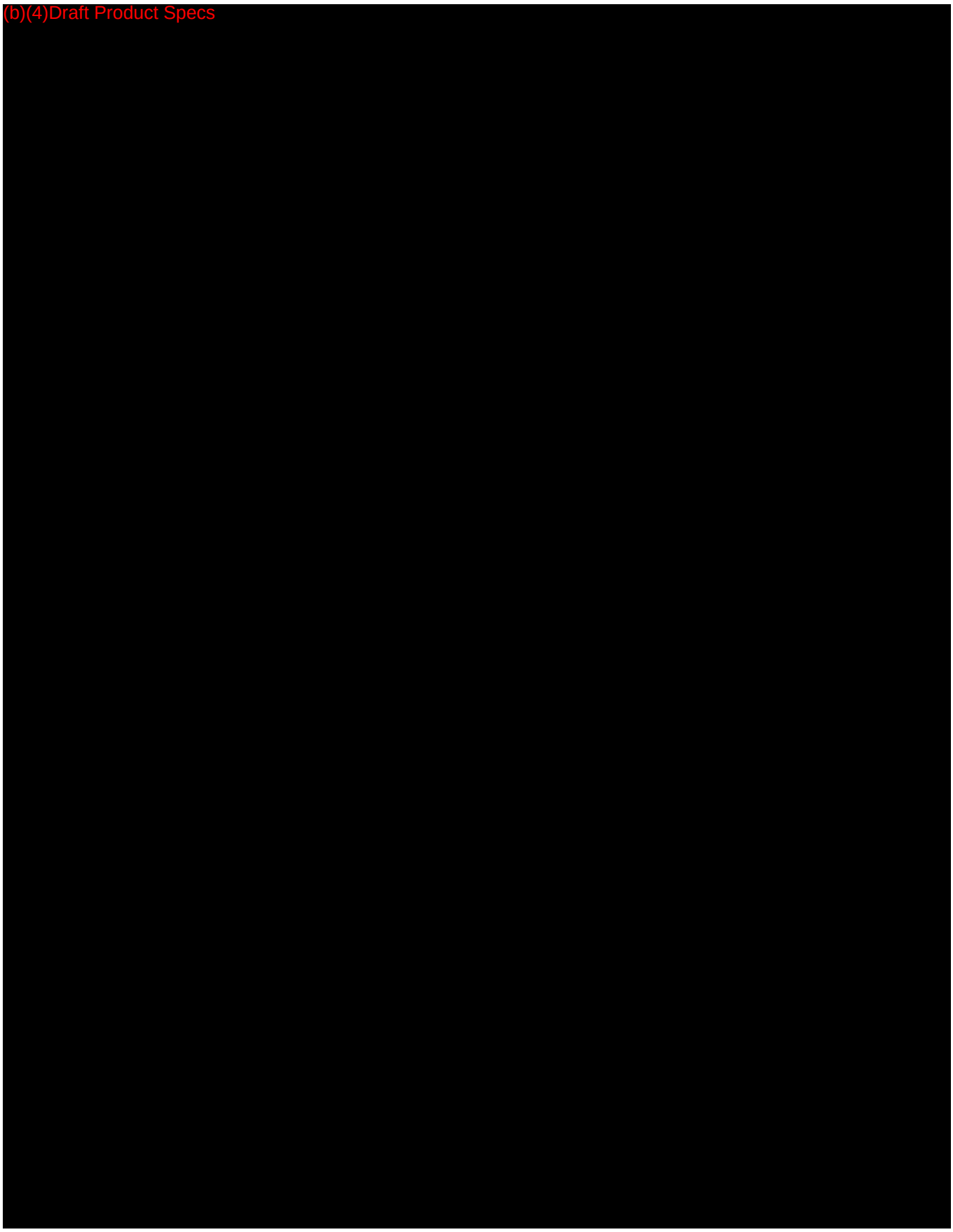

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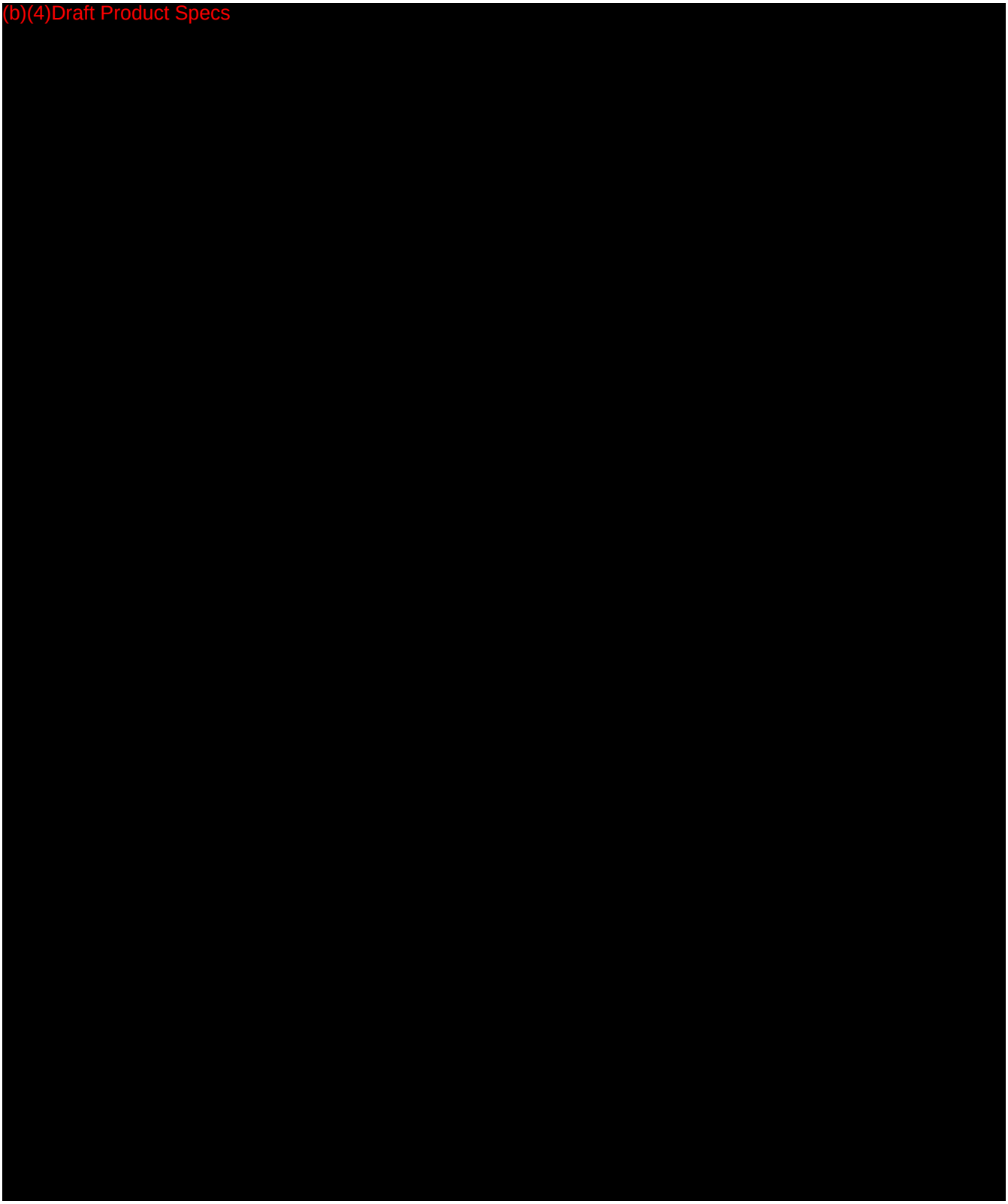

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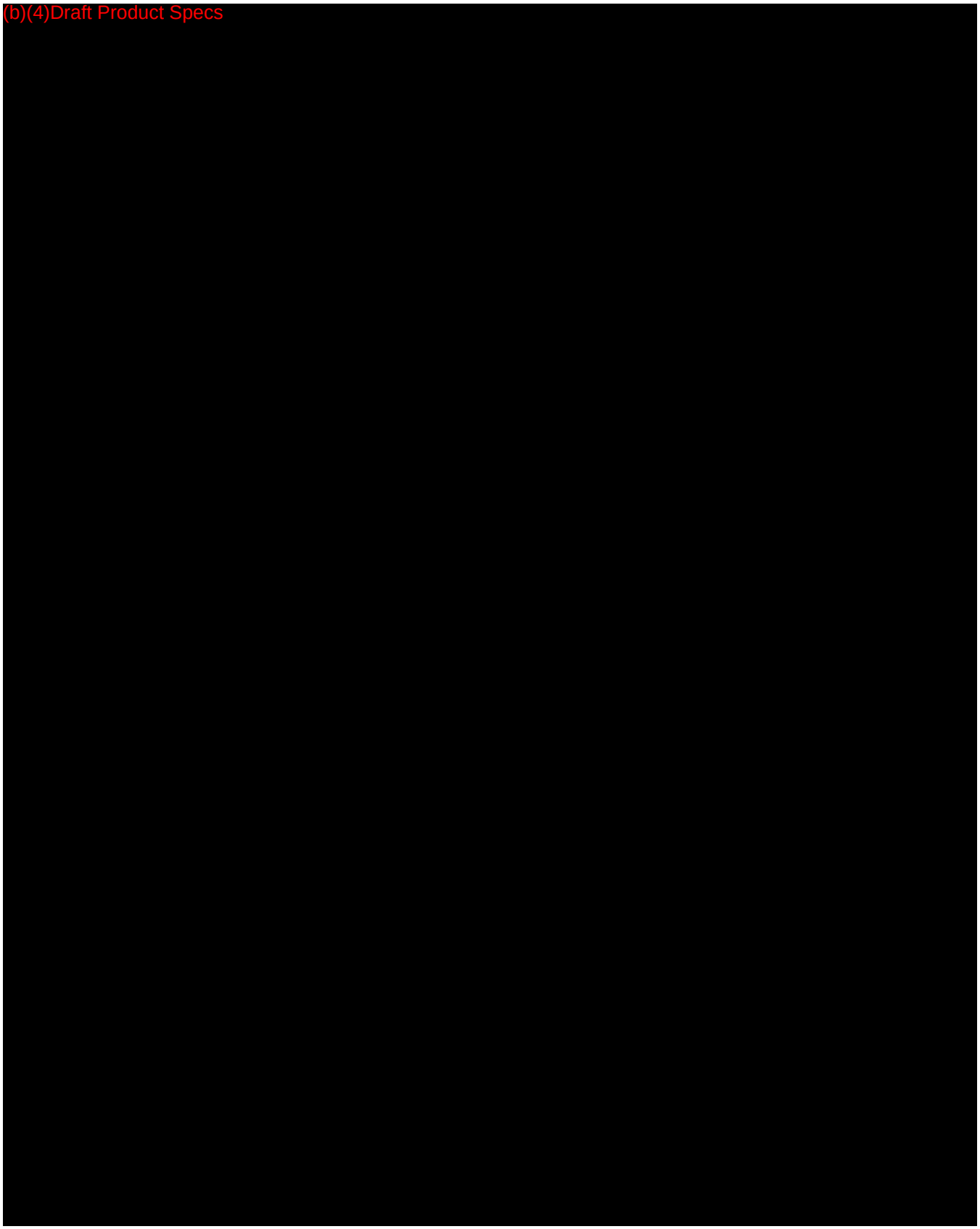

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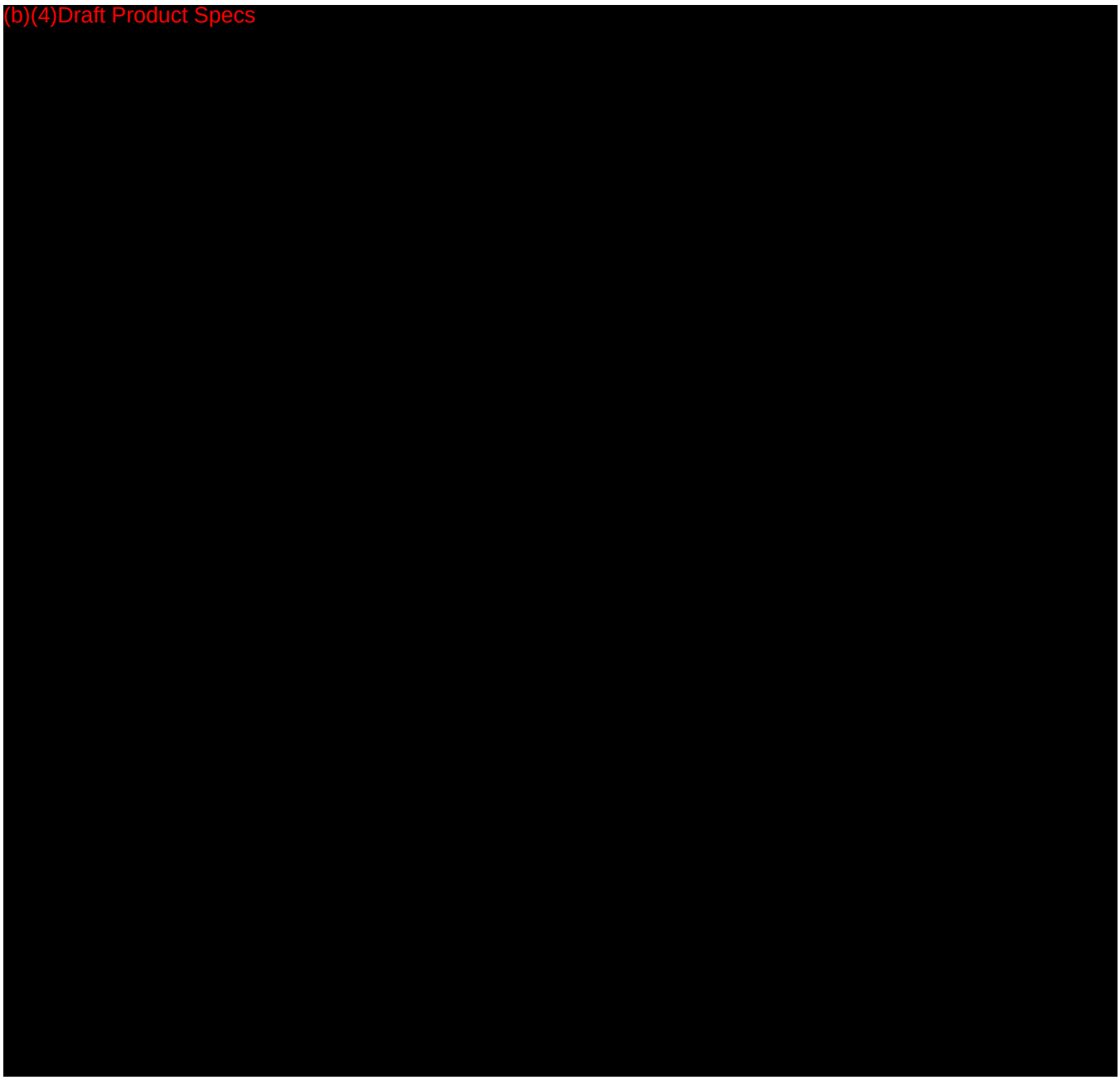

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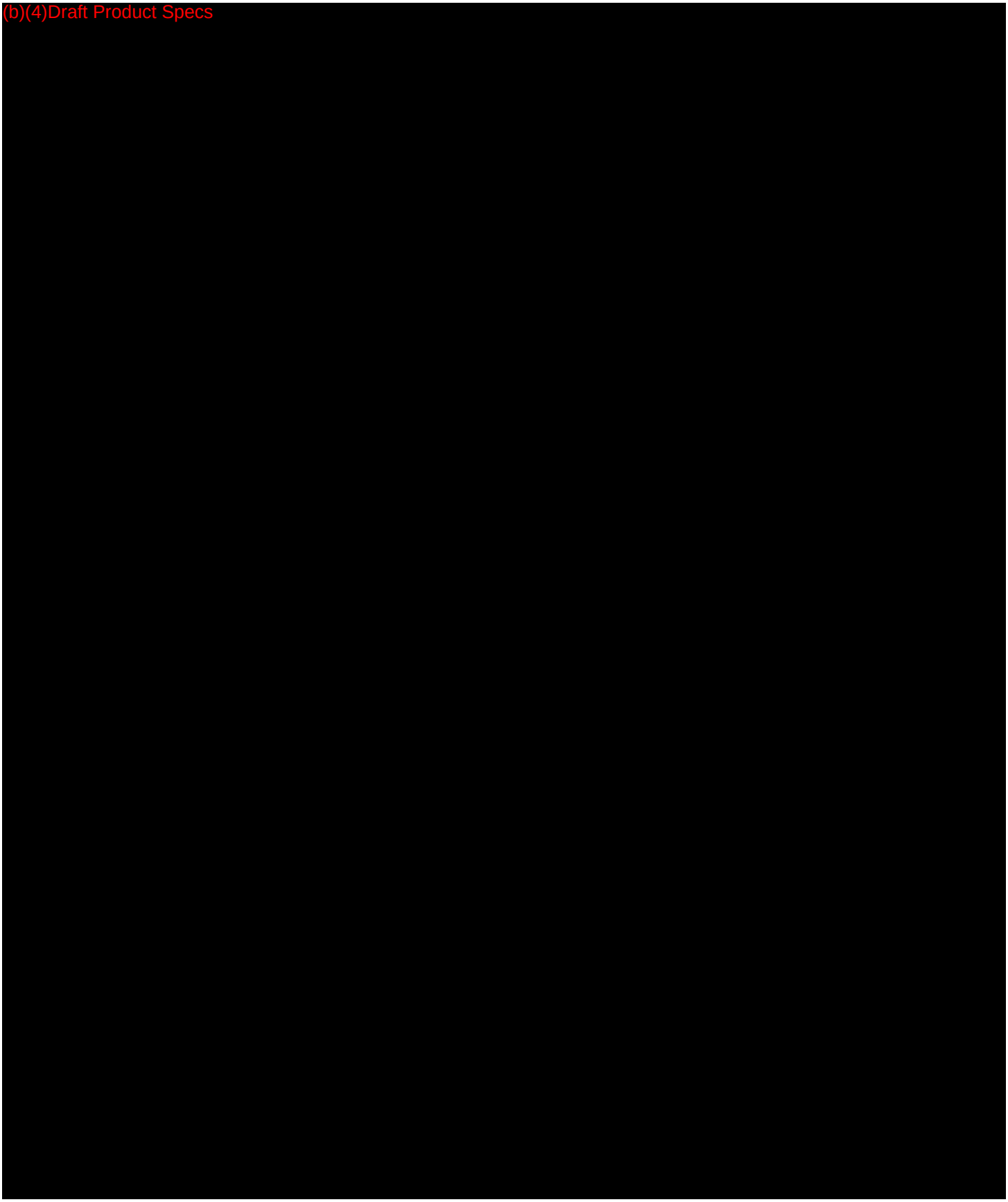

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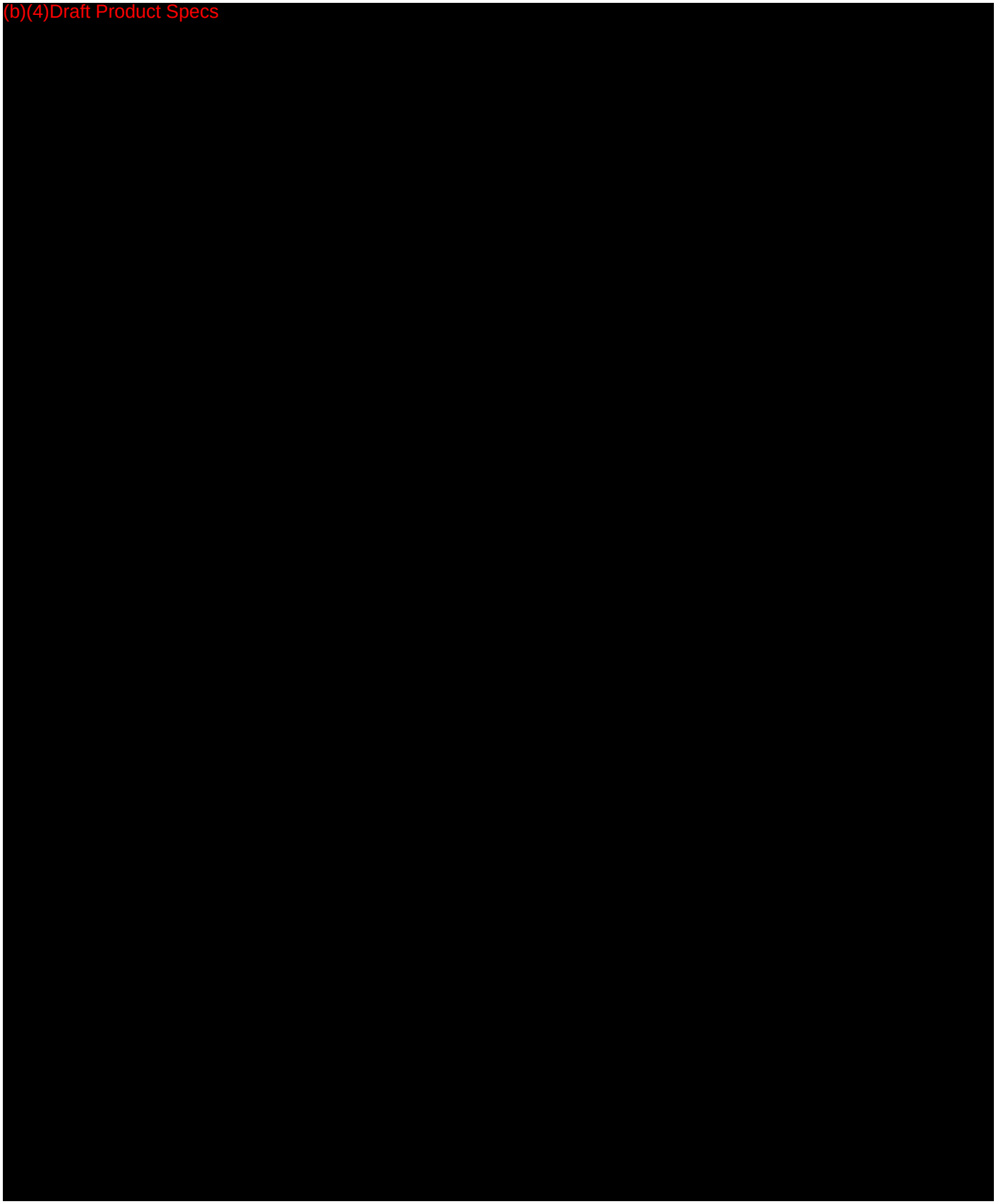

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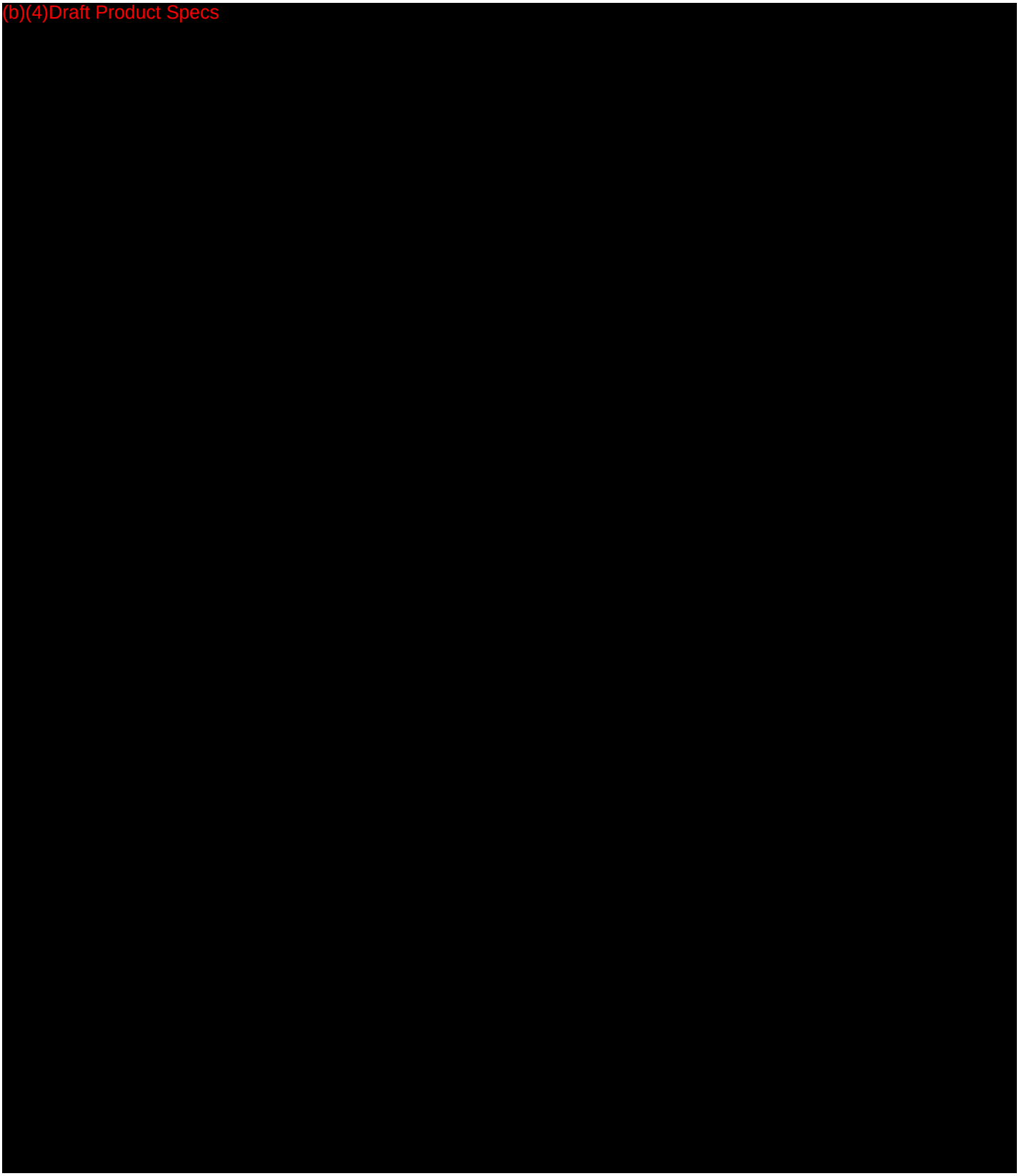

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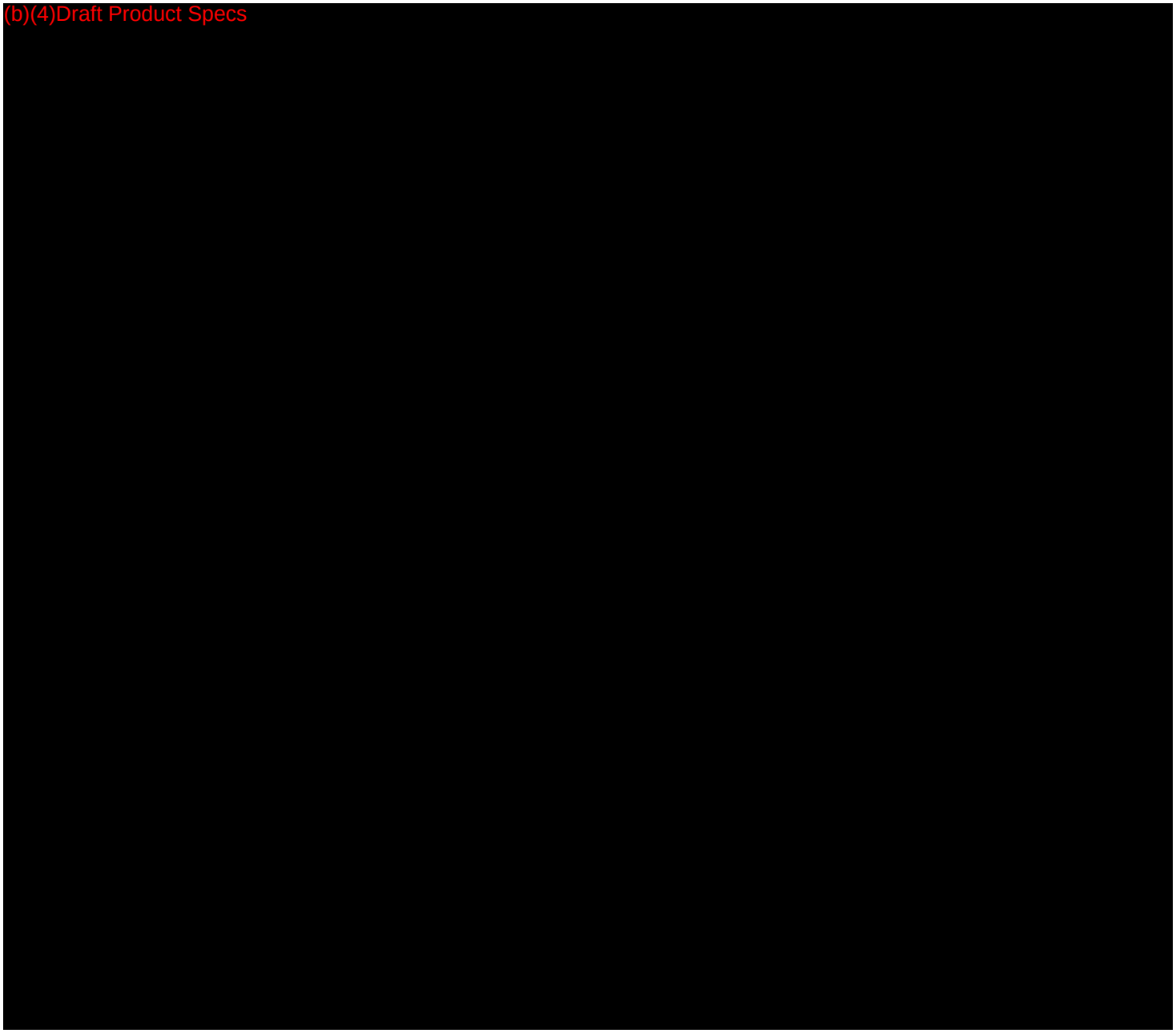

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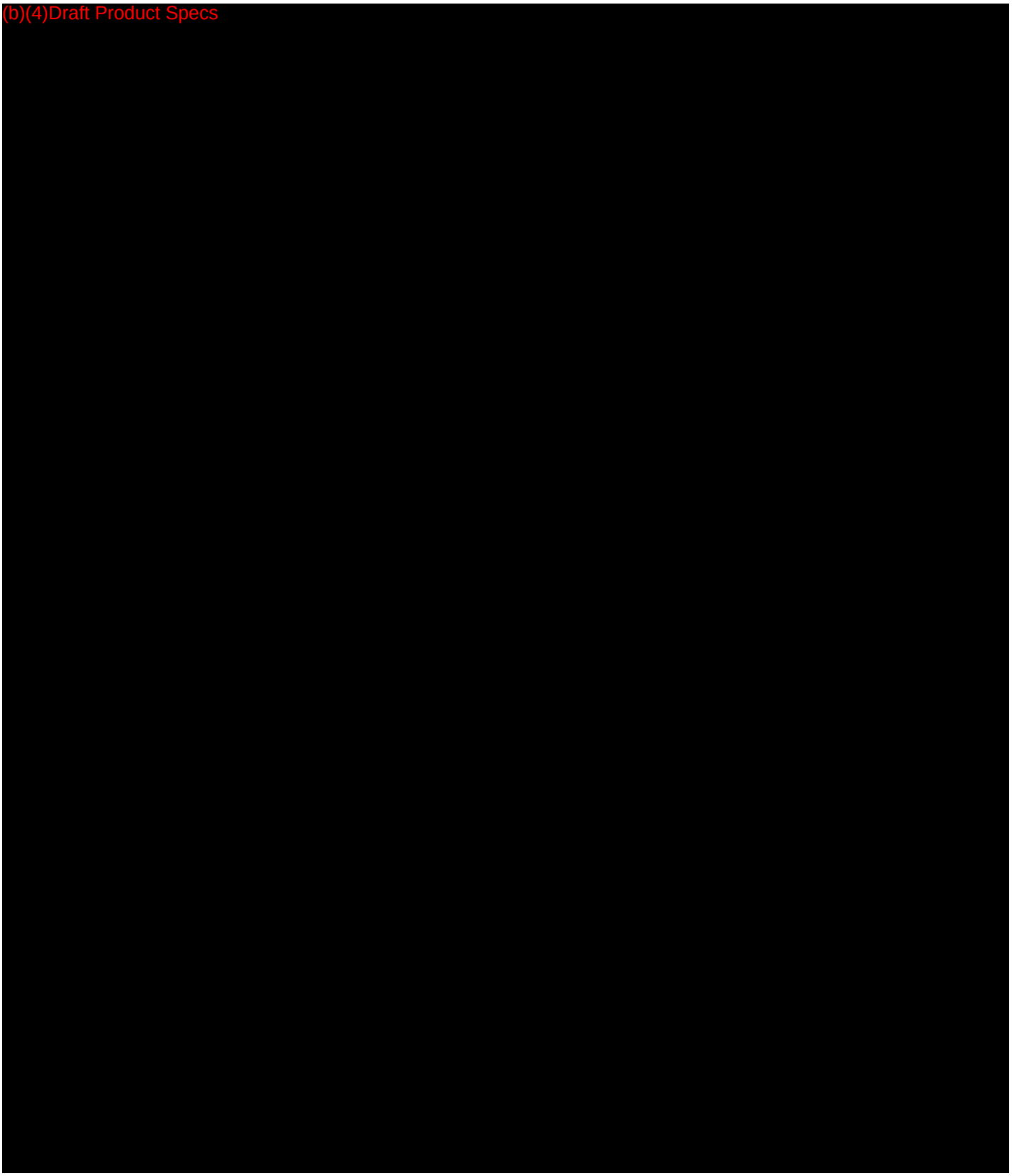

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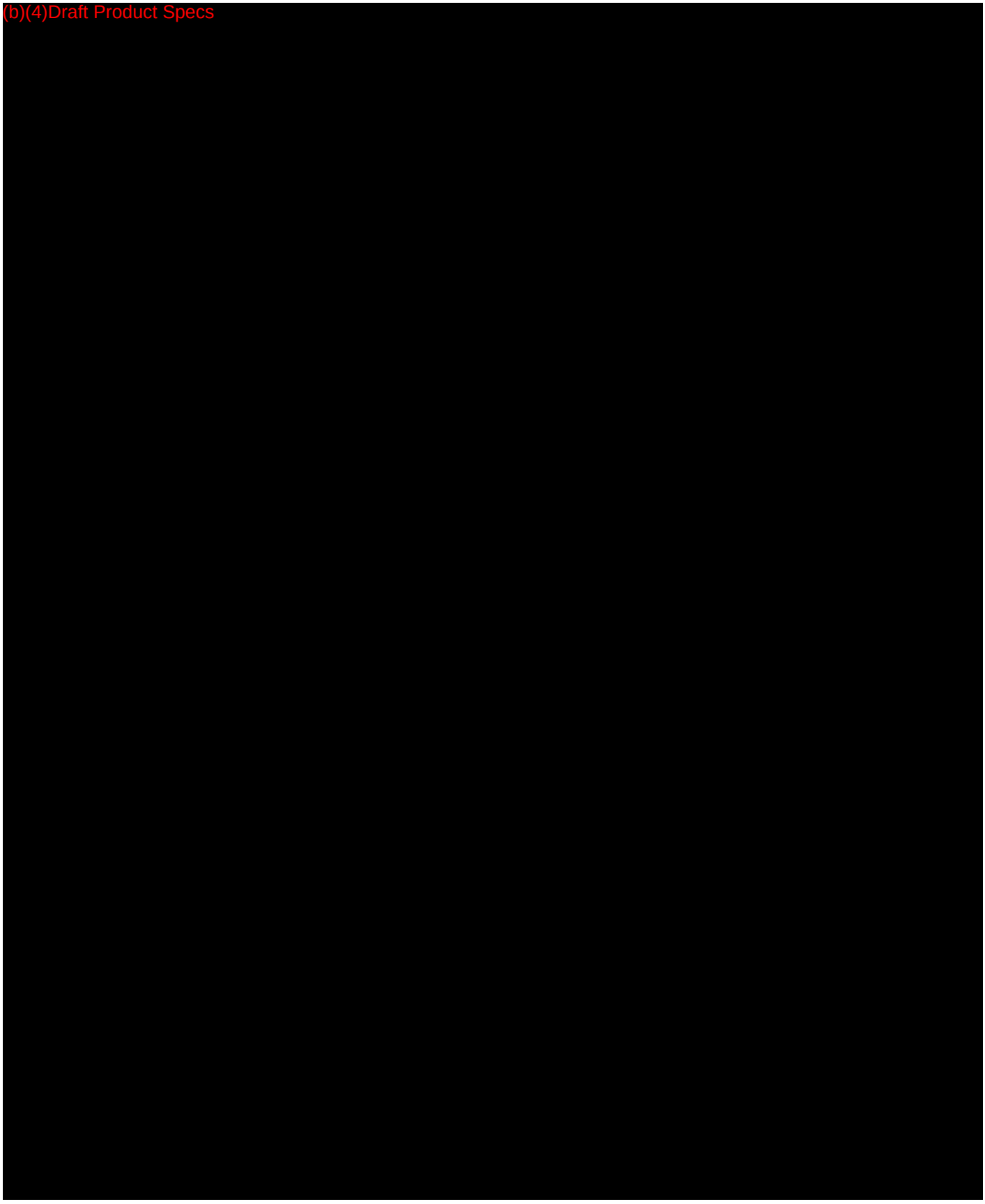

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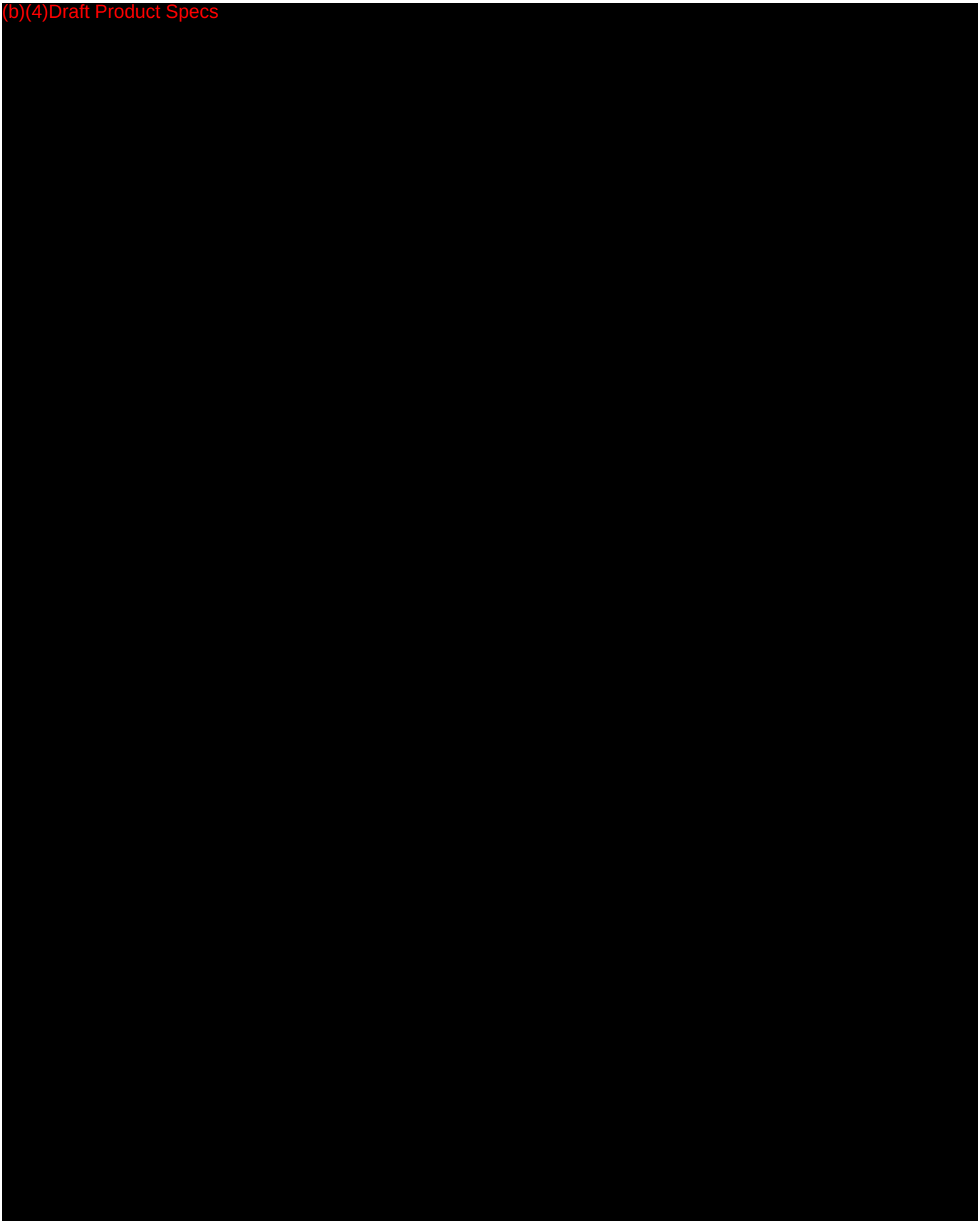

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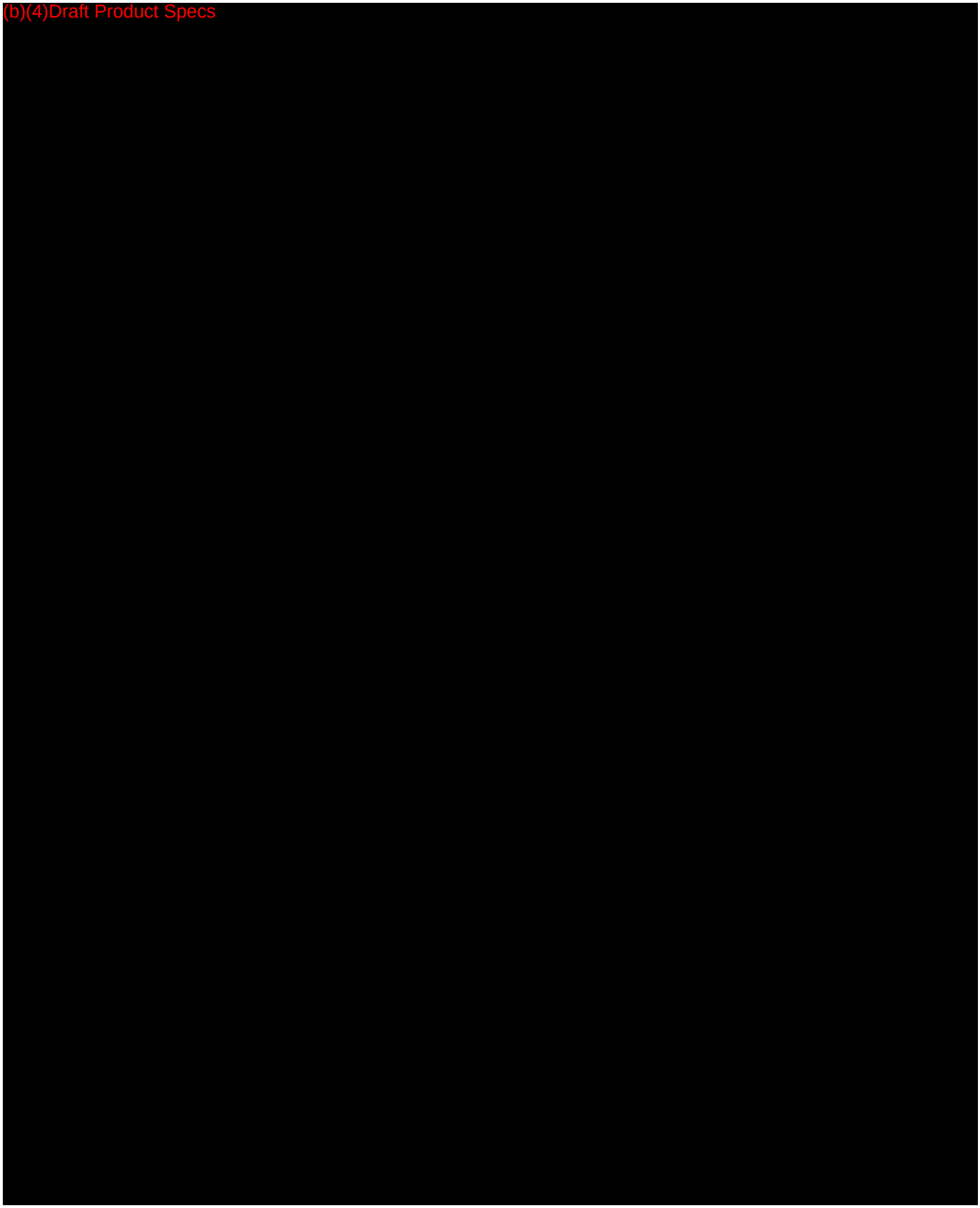

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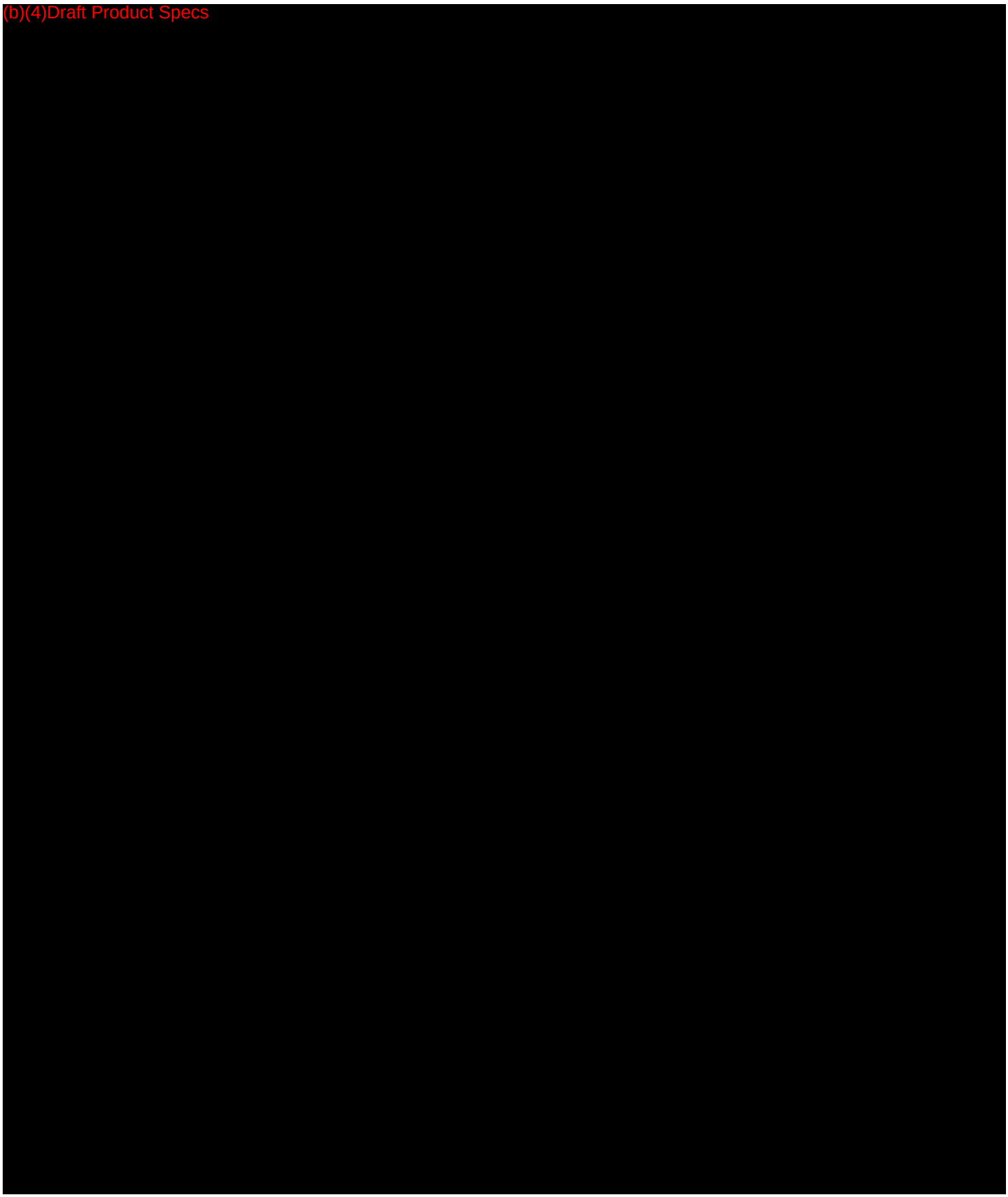

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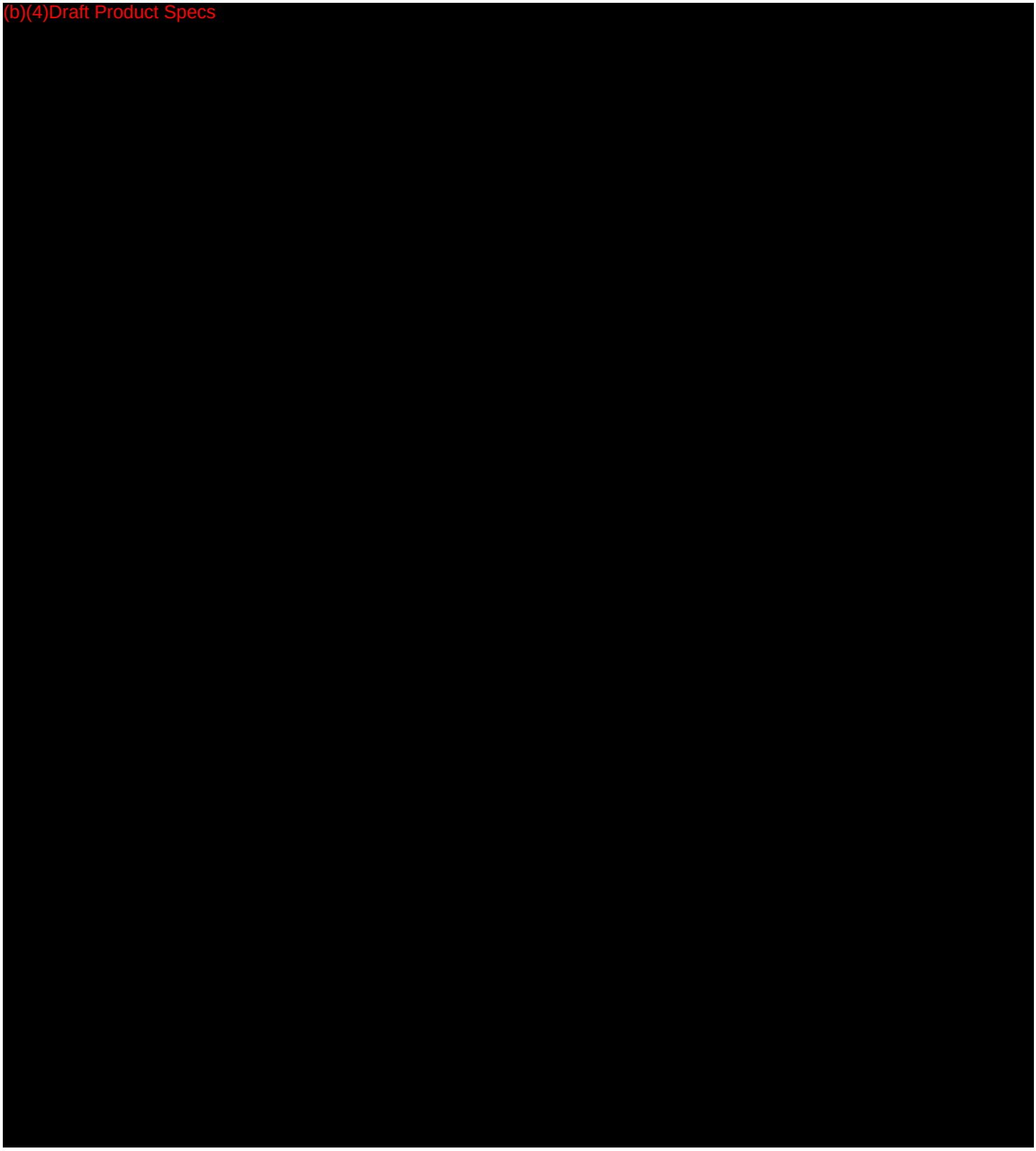

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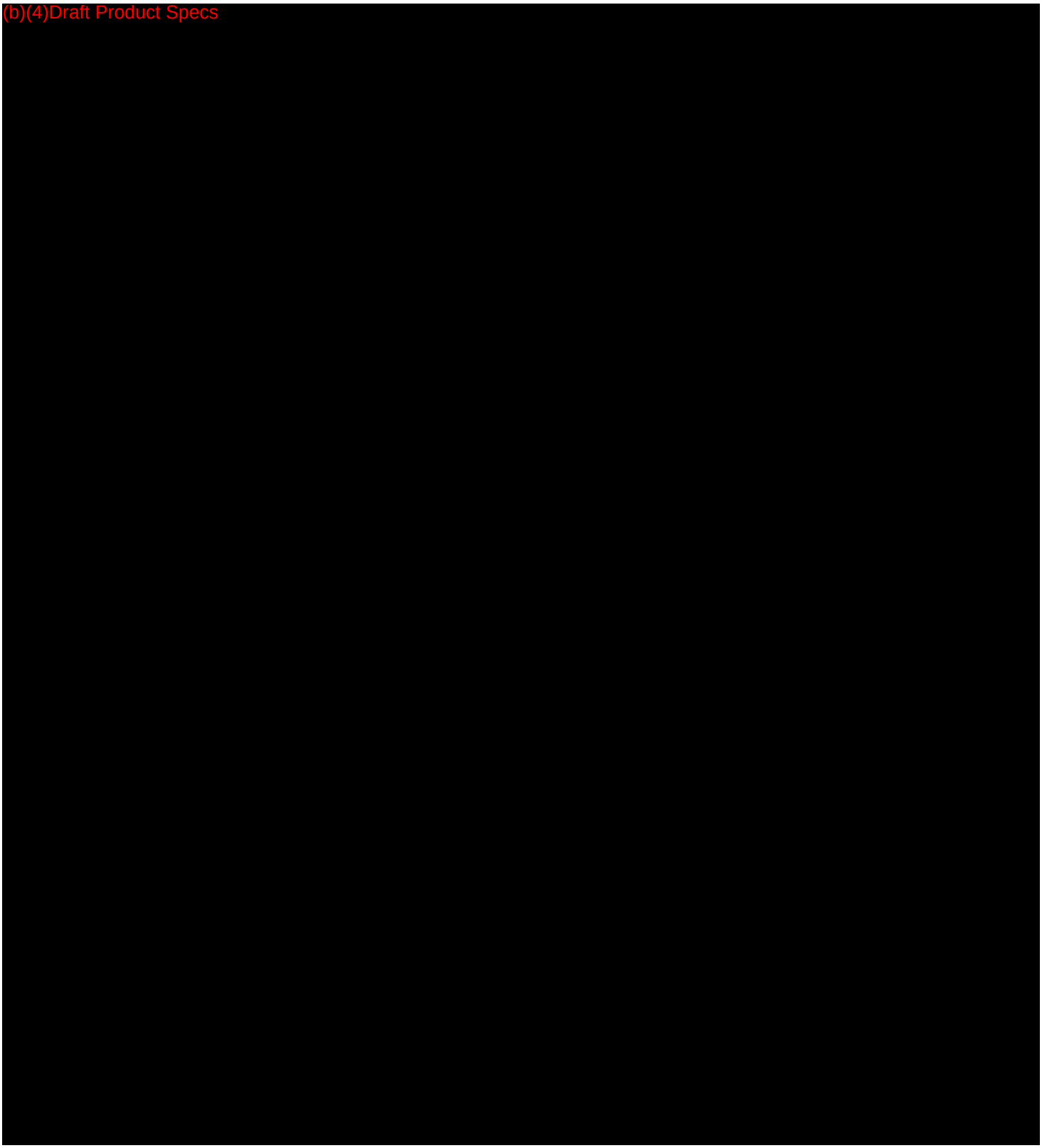

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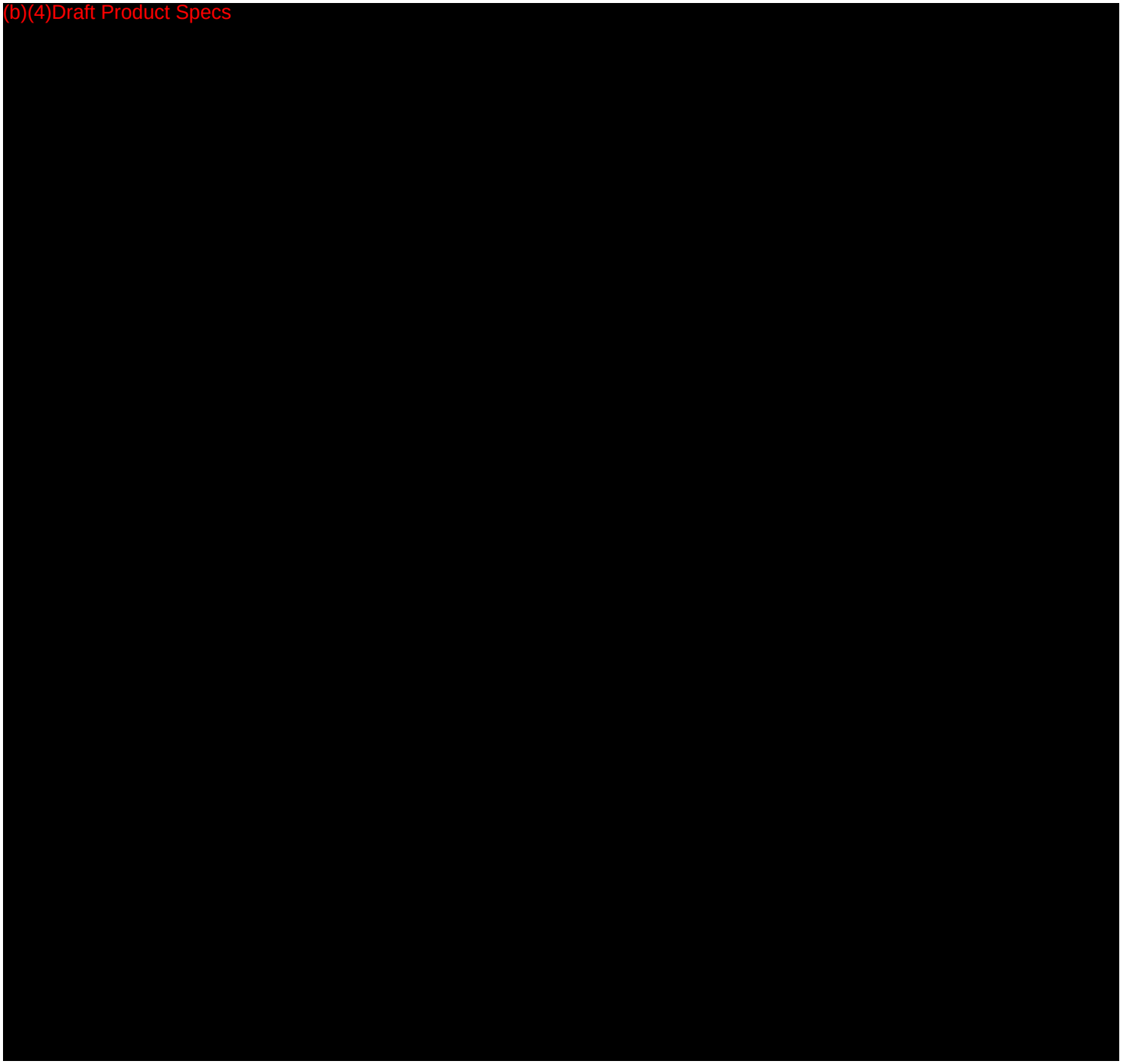

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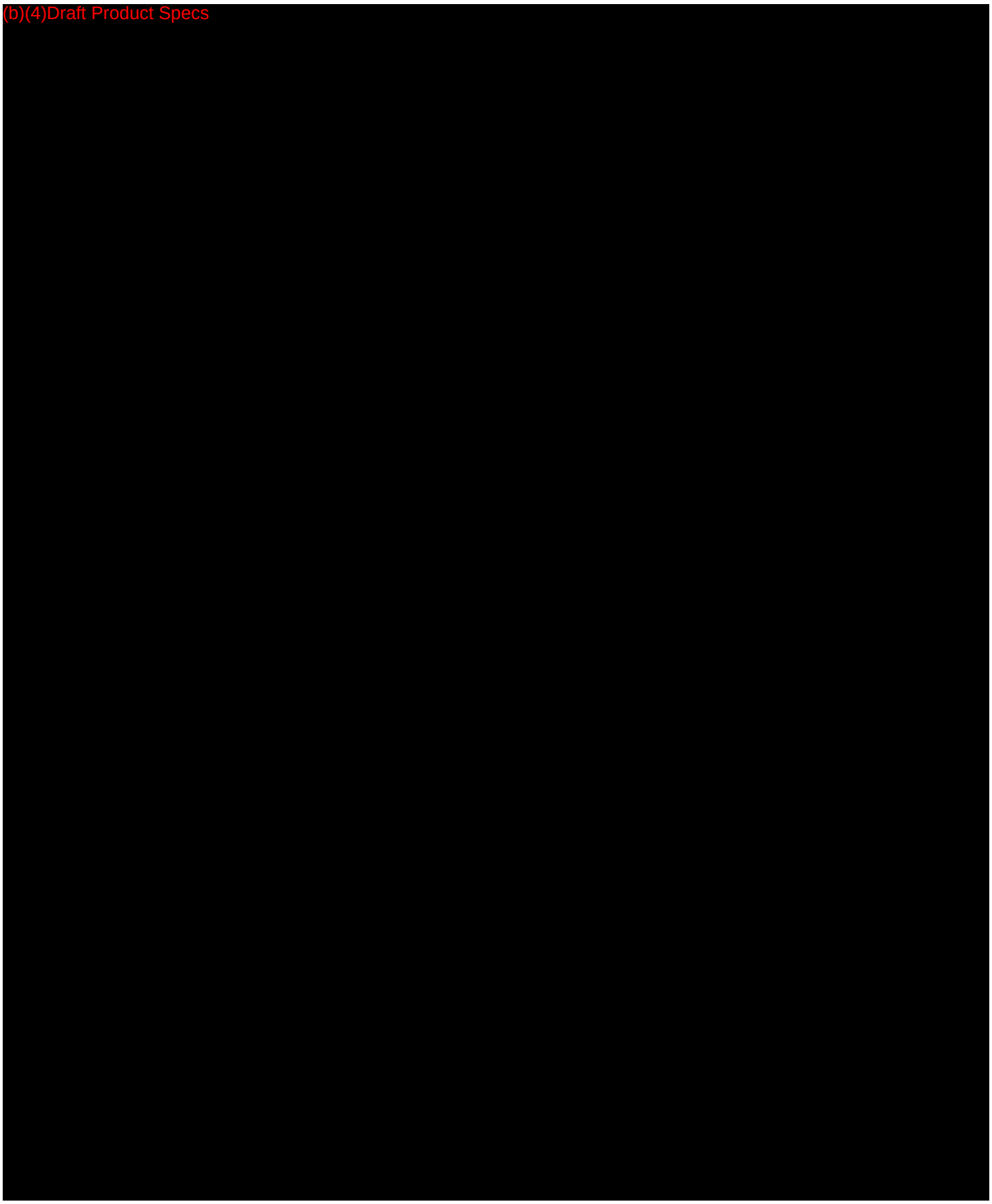

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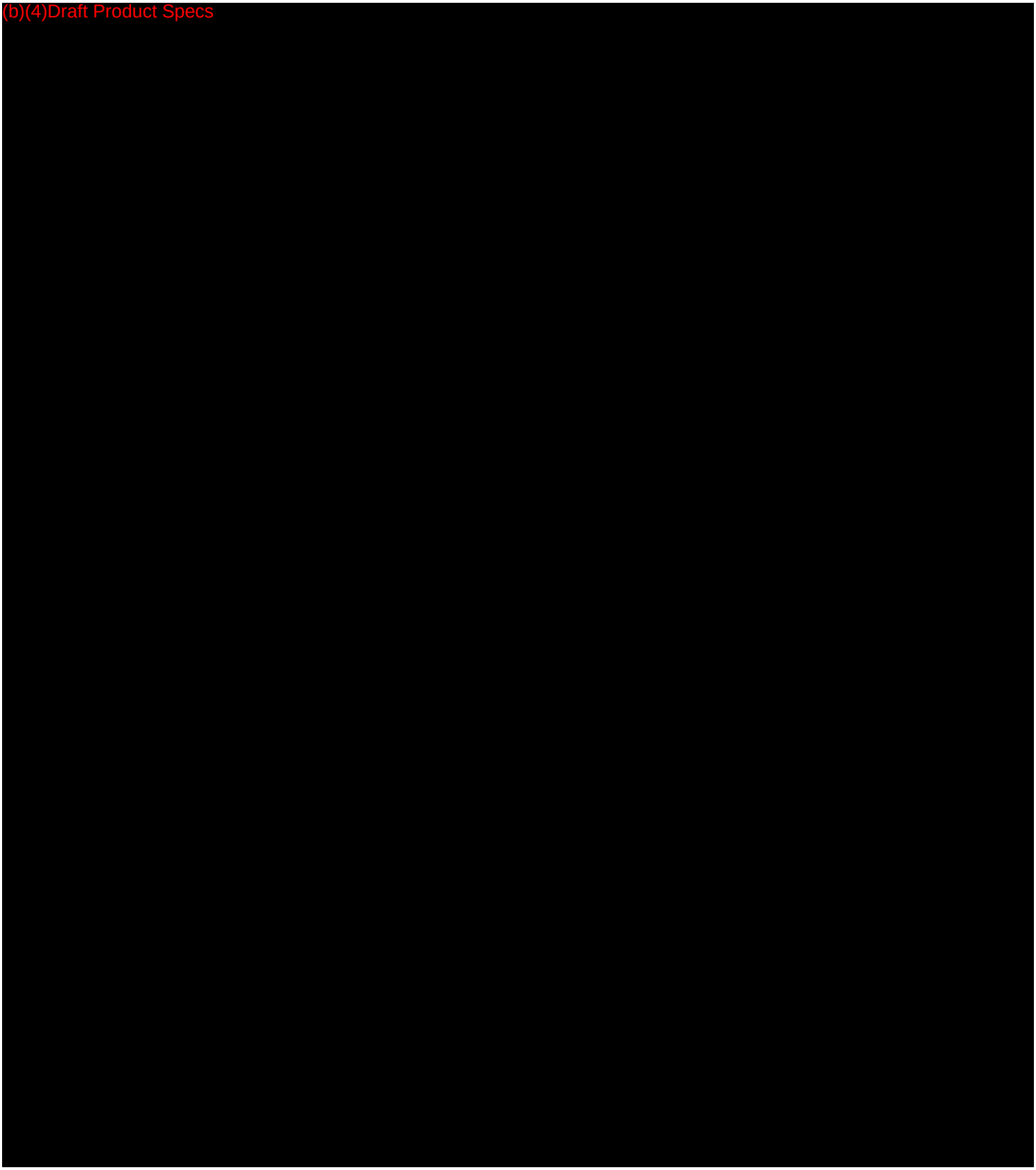

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Chapter 7 System Specifications

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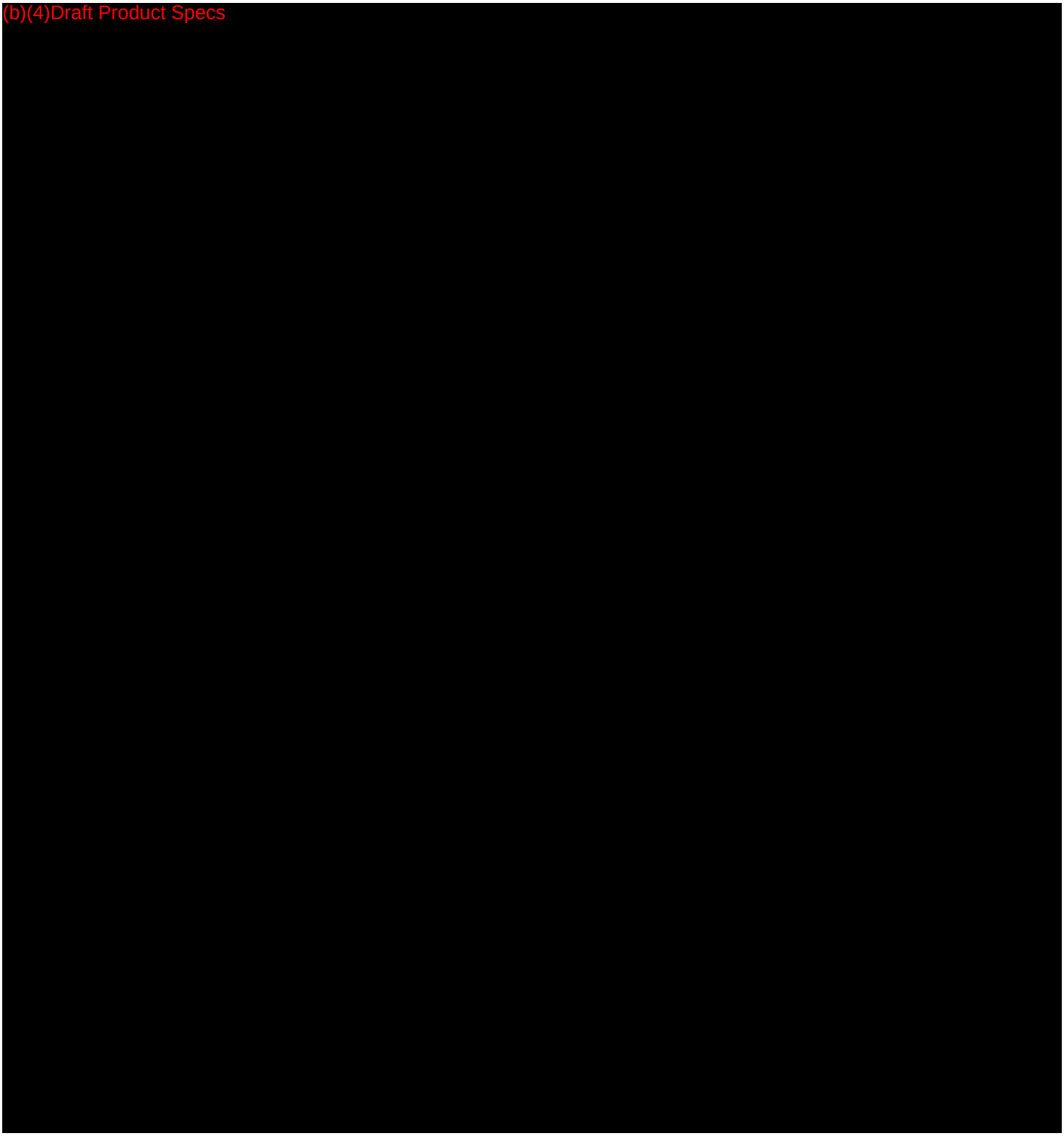

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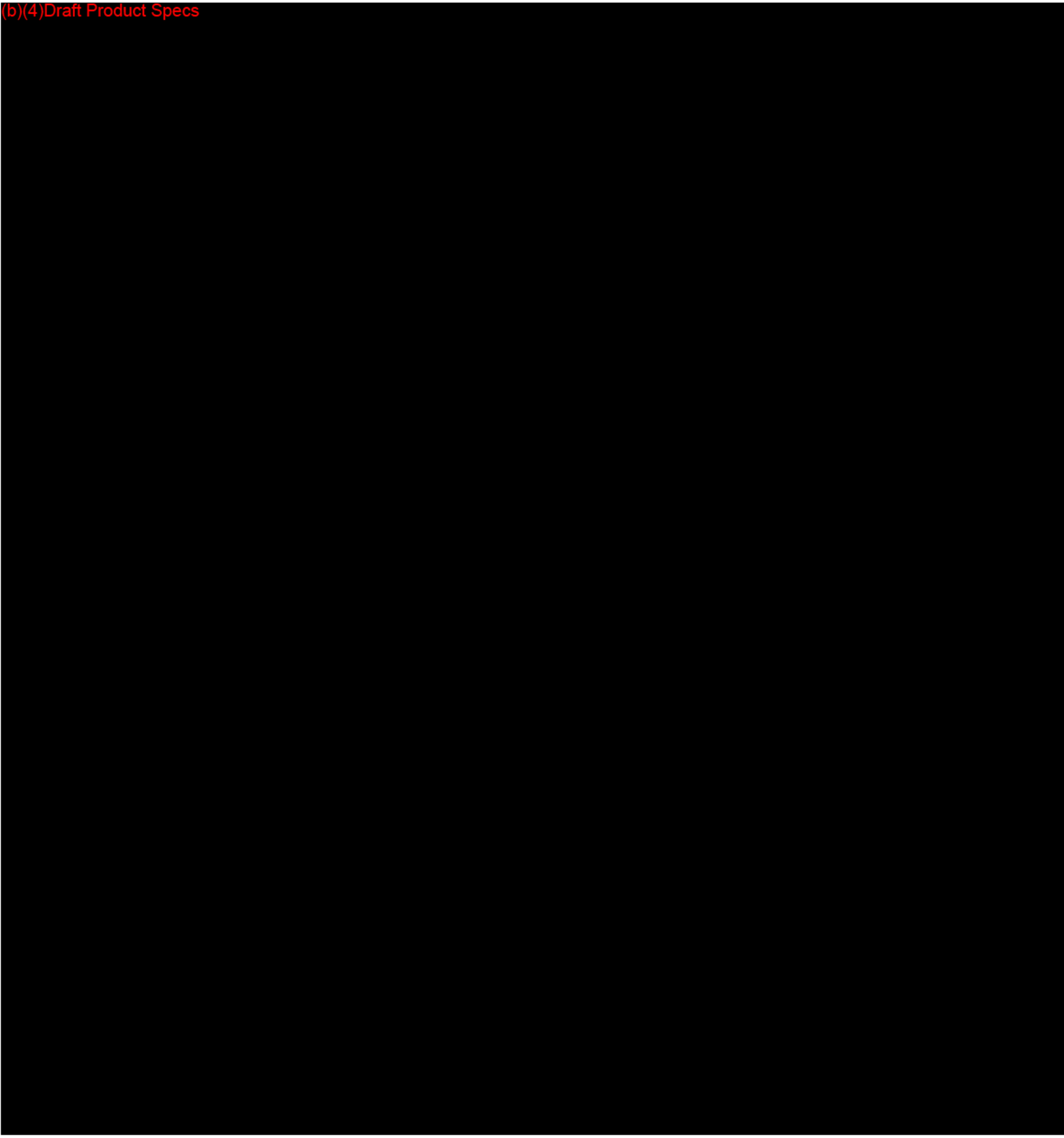

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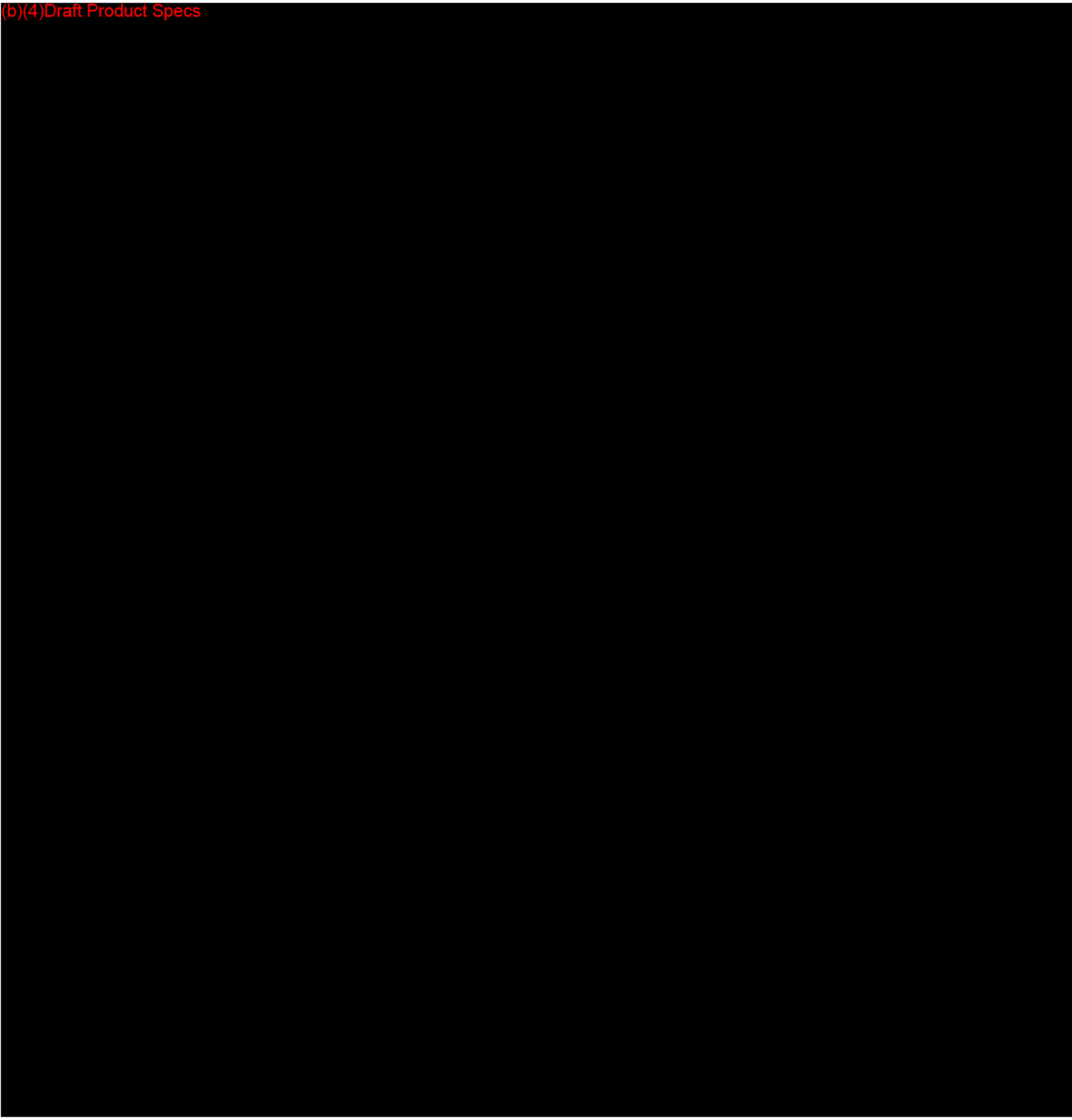

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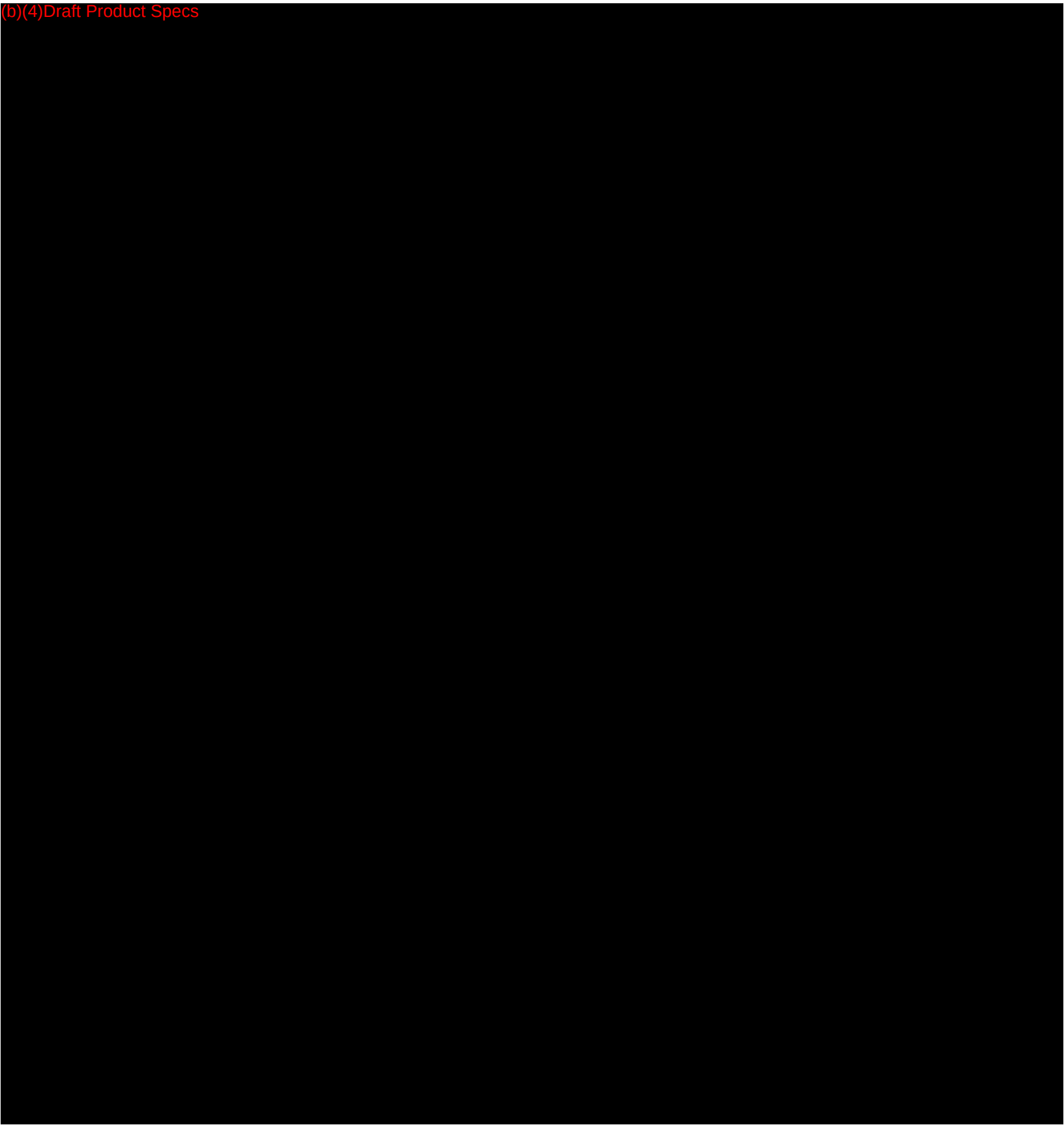

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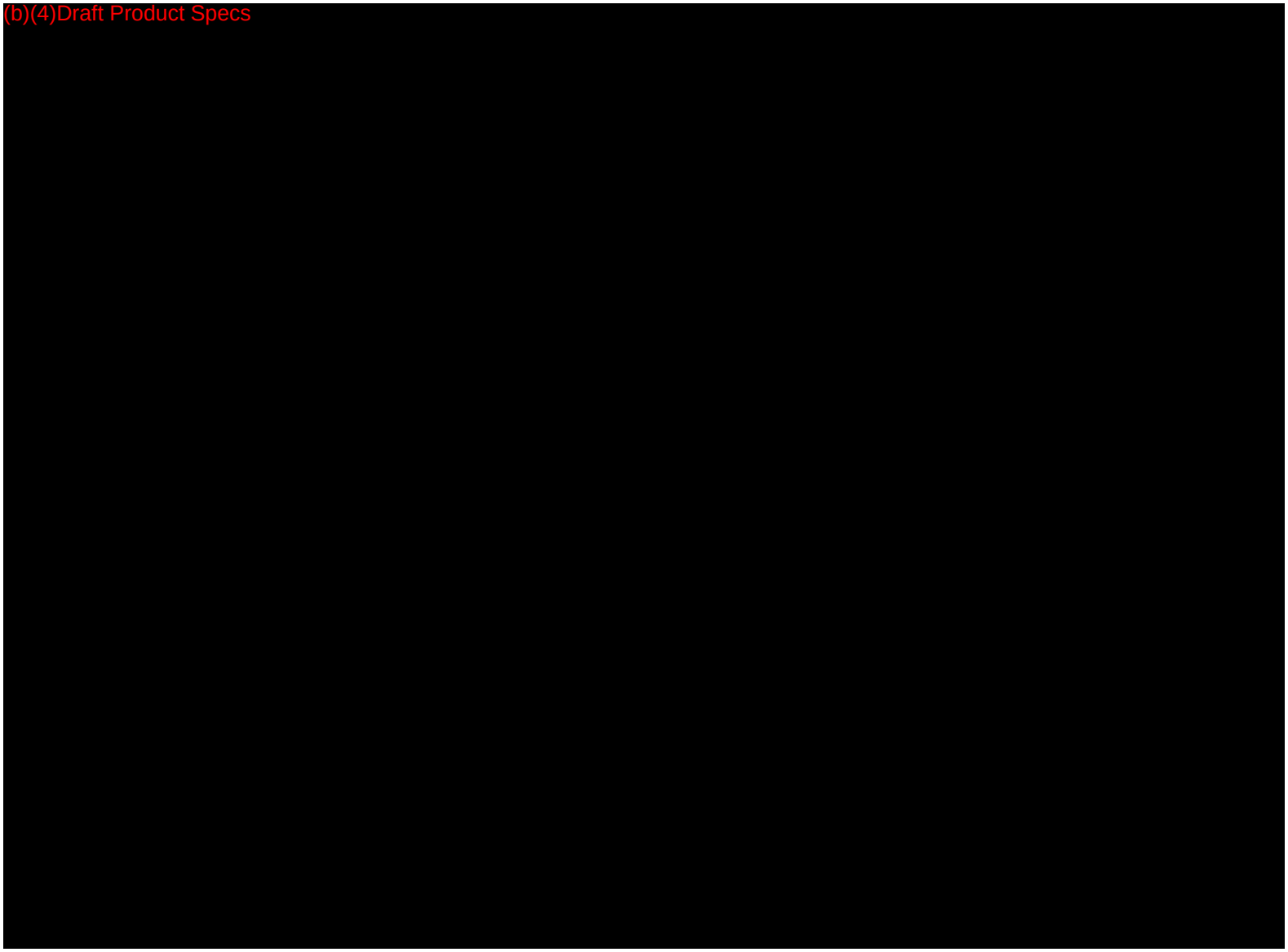

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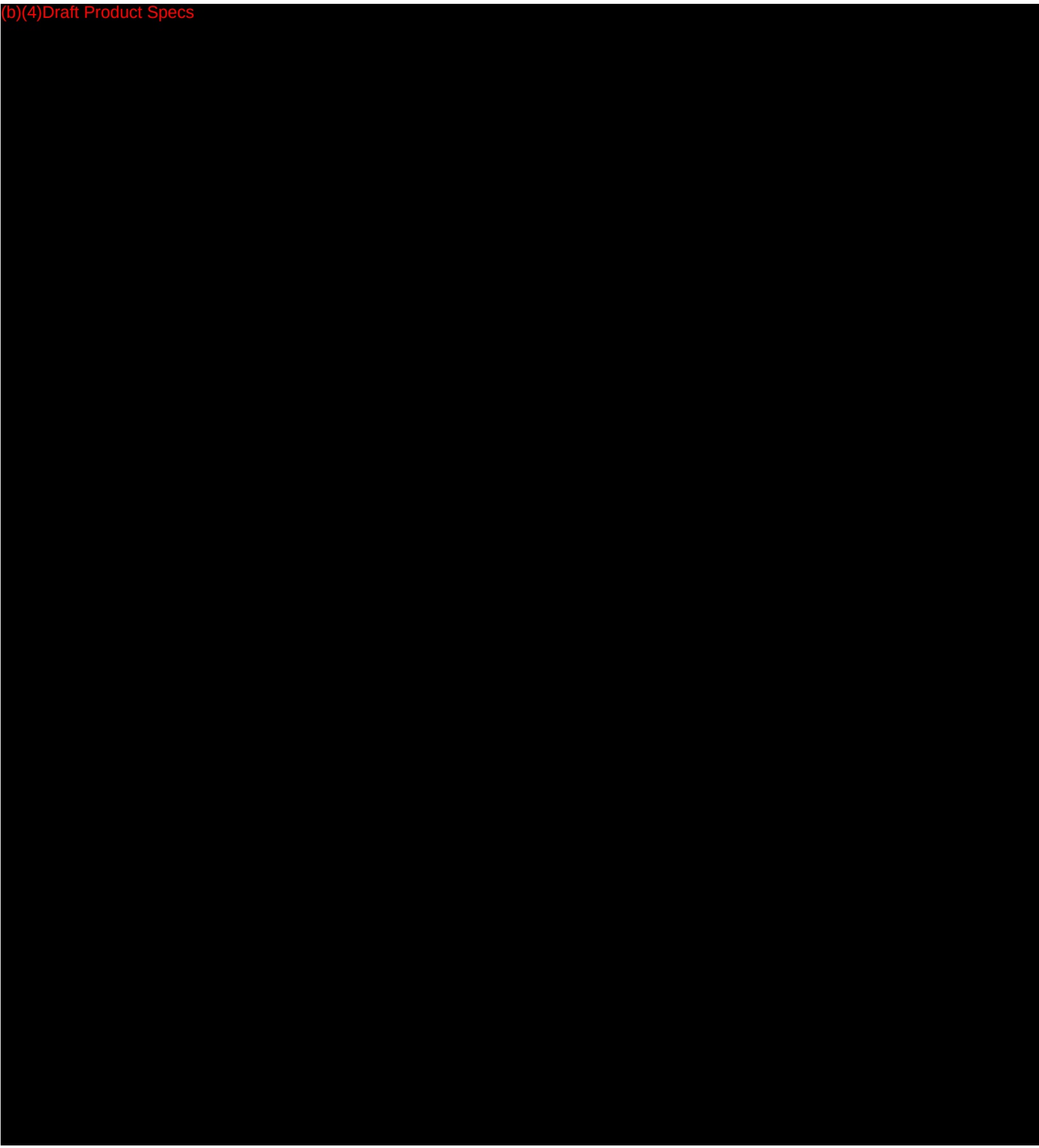

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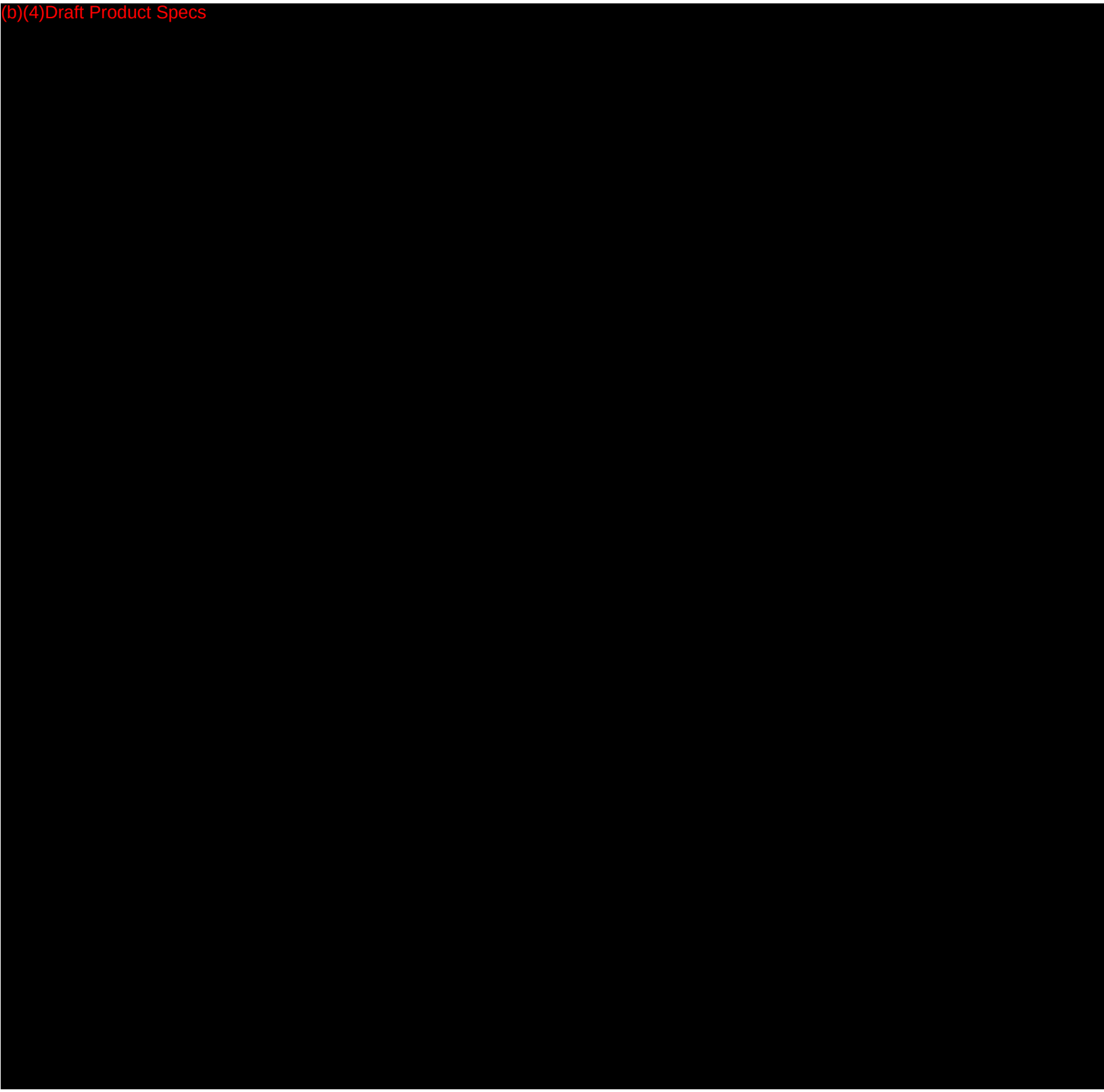

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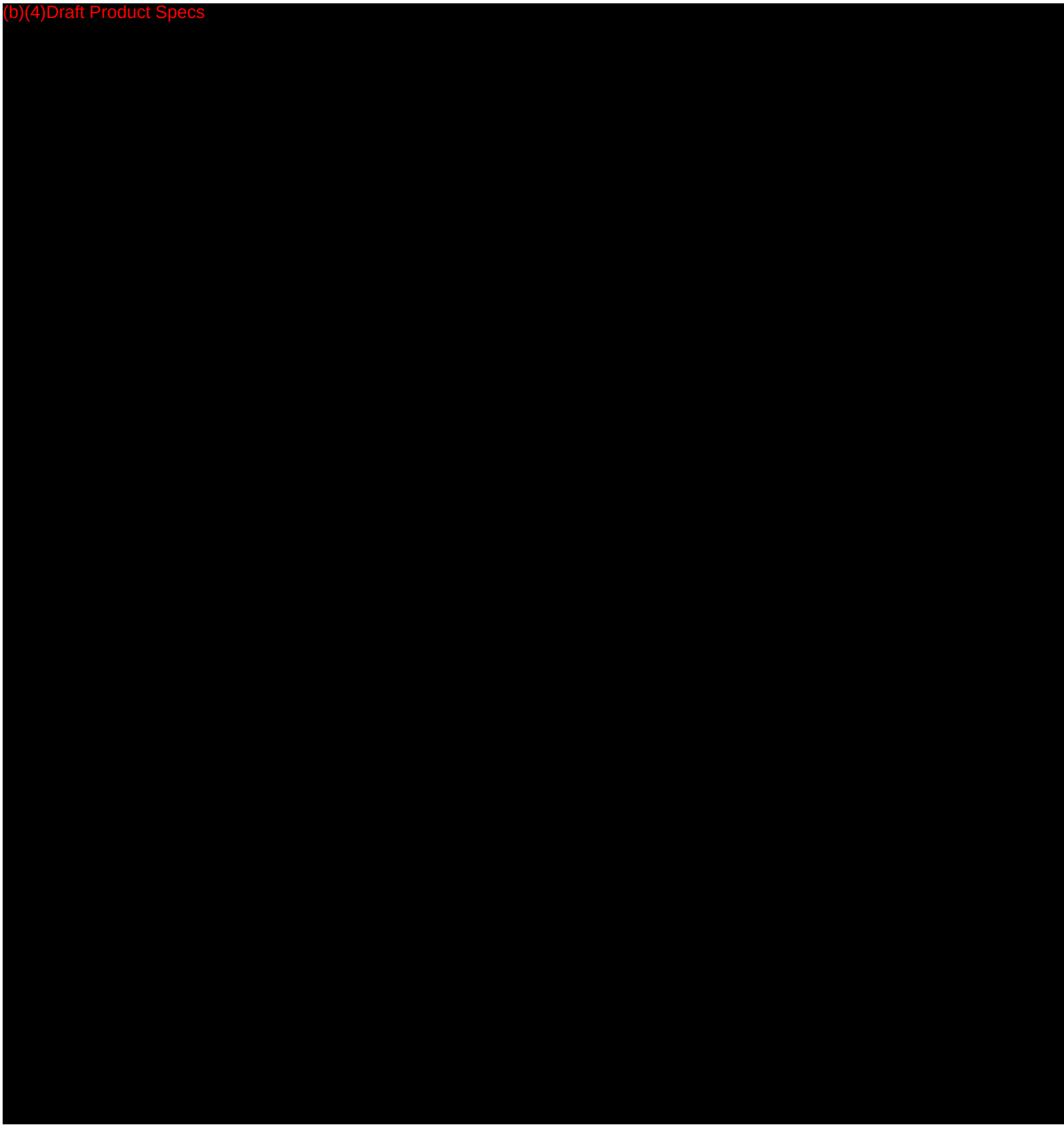

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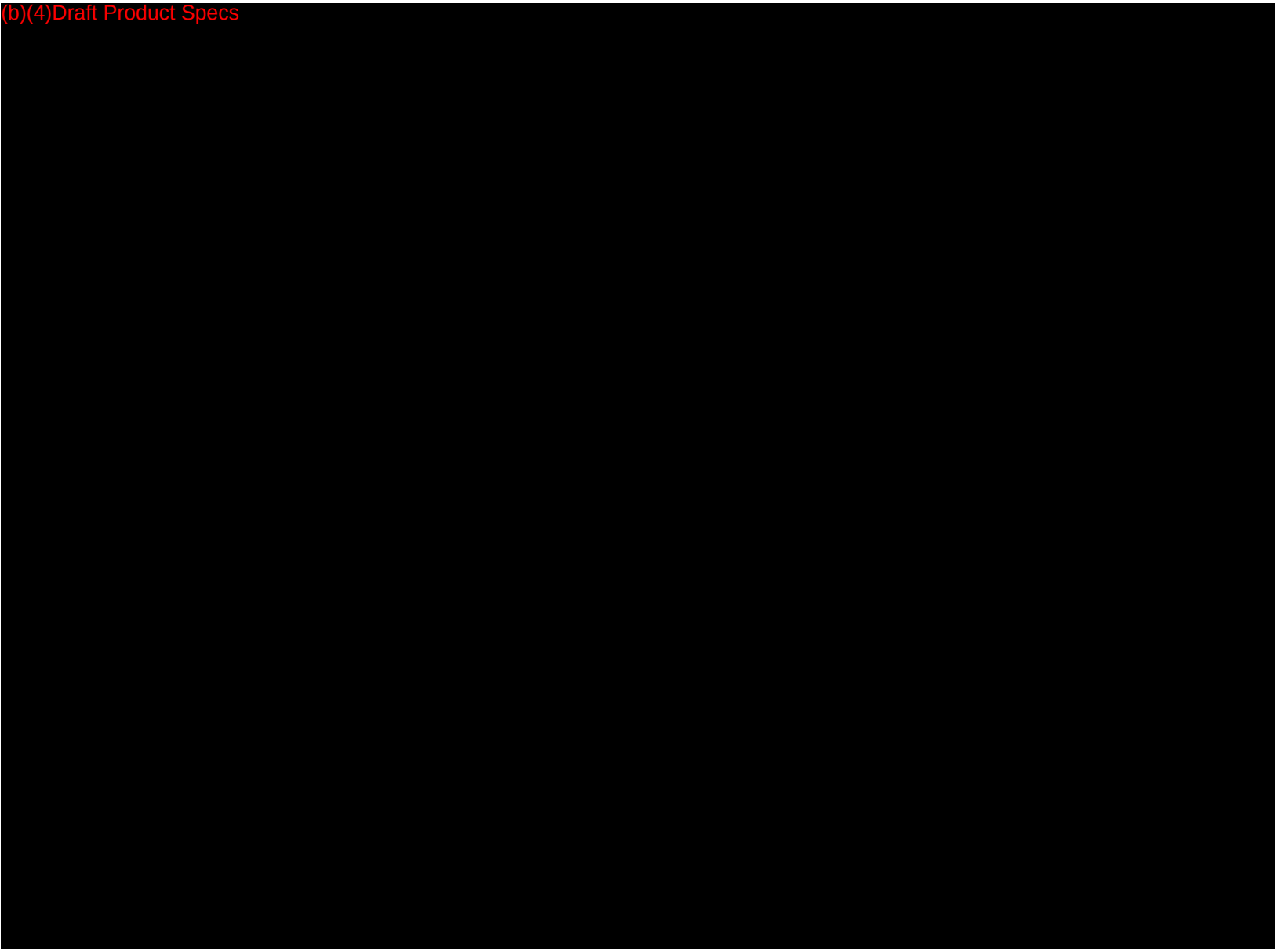

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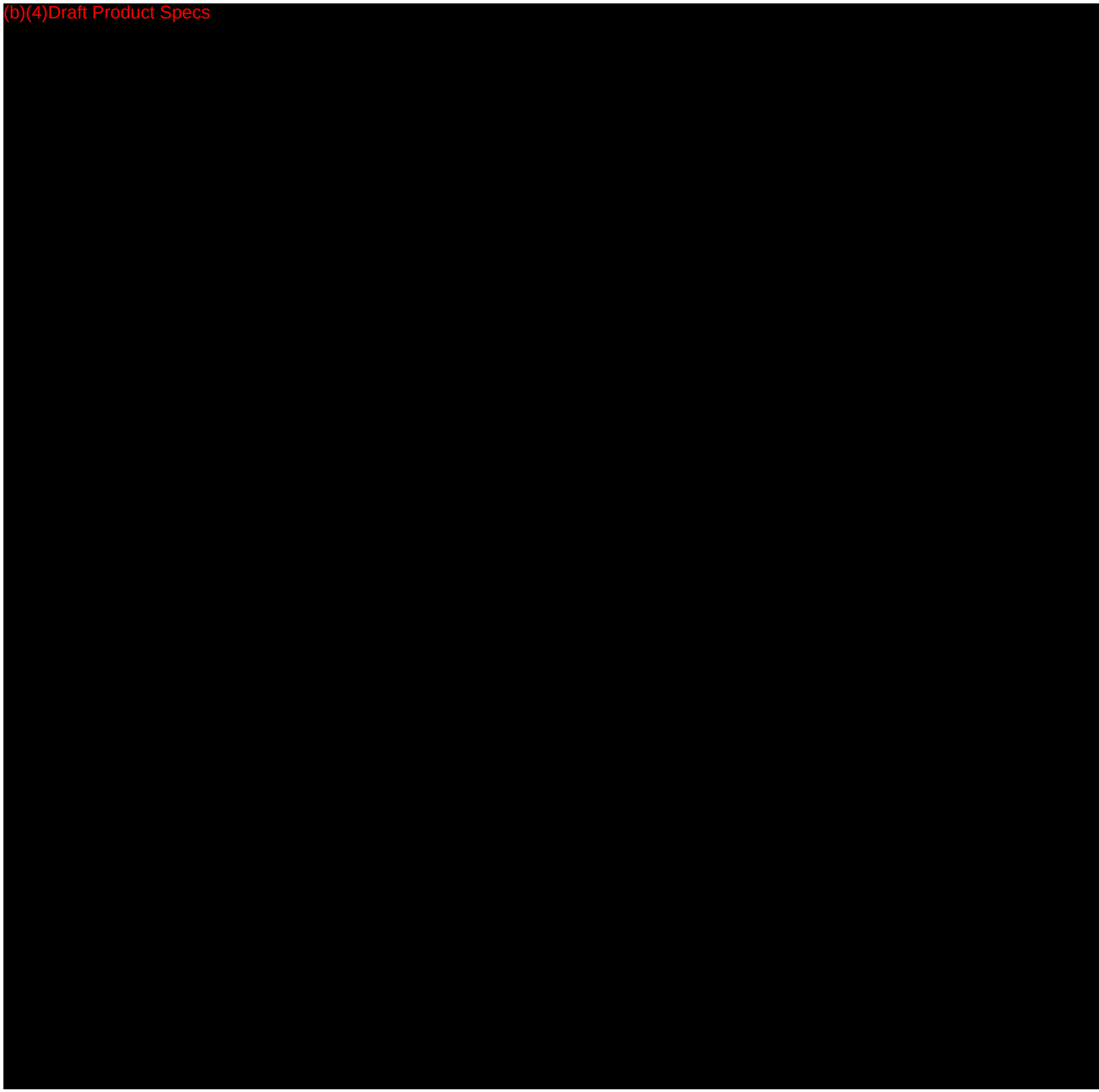

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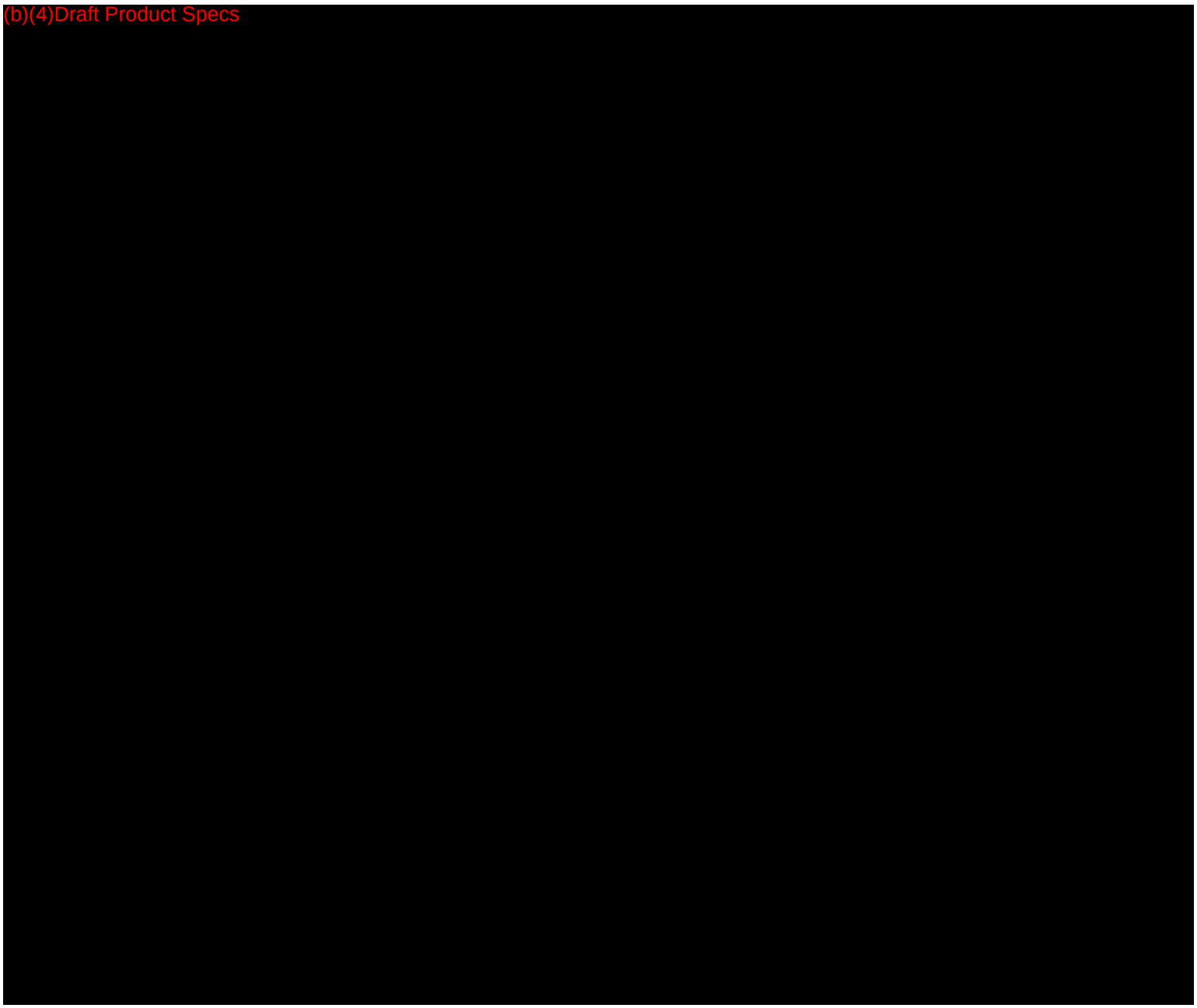

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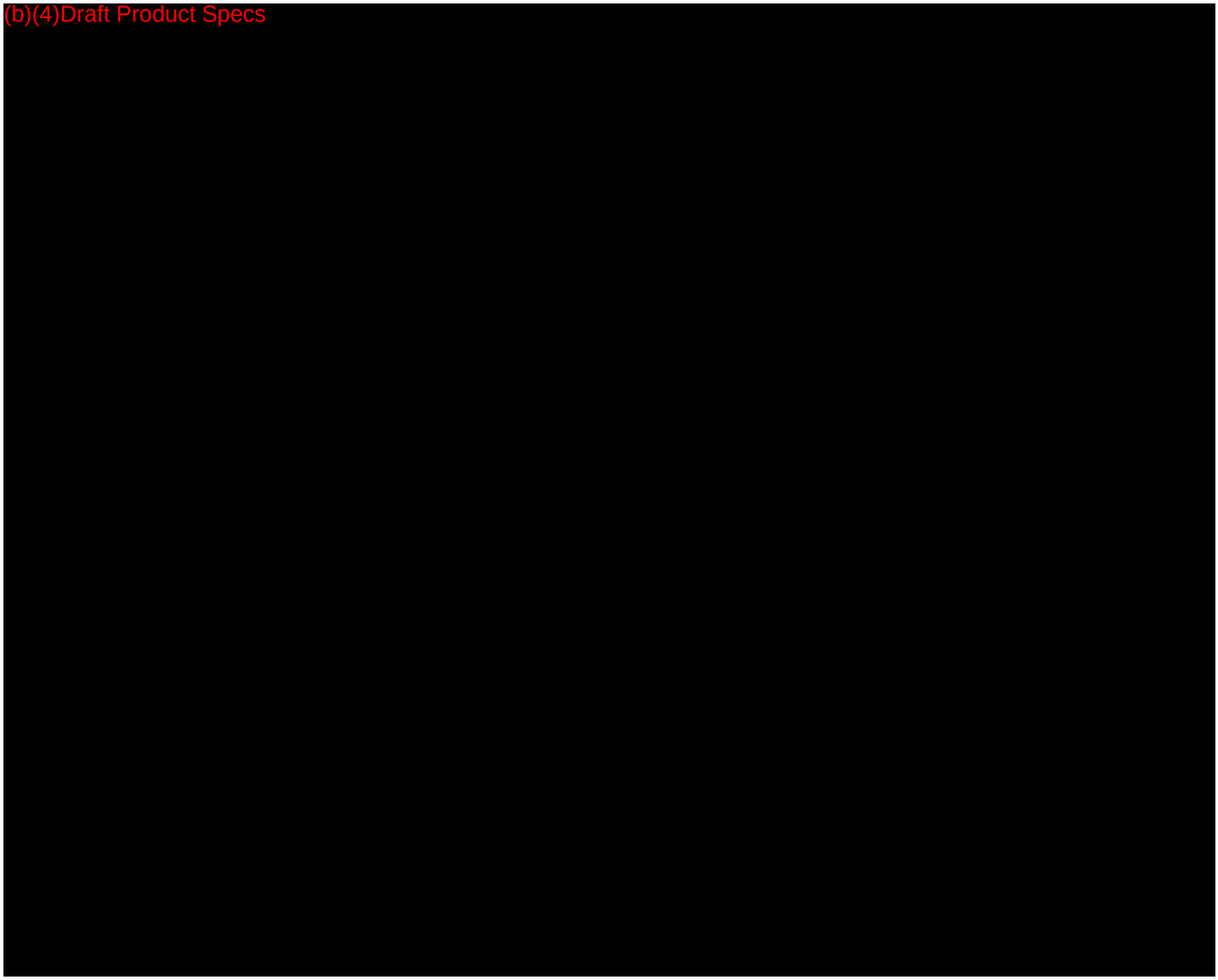

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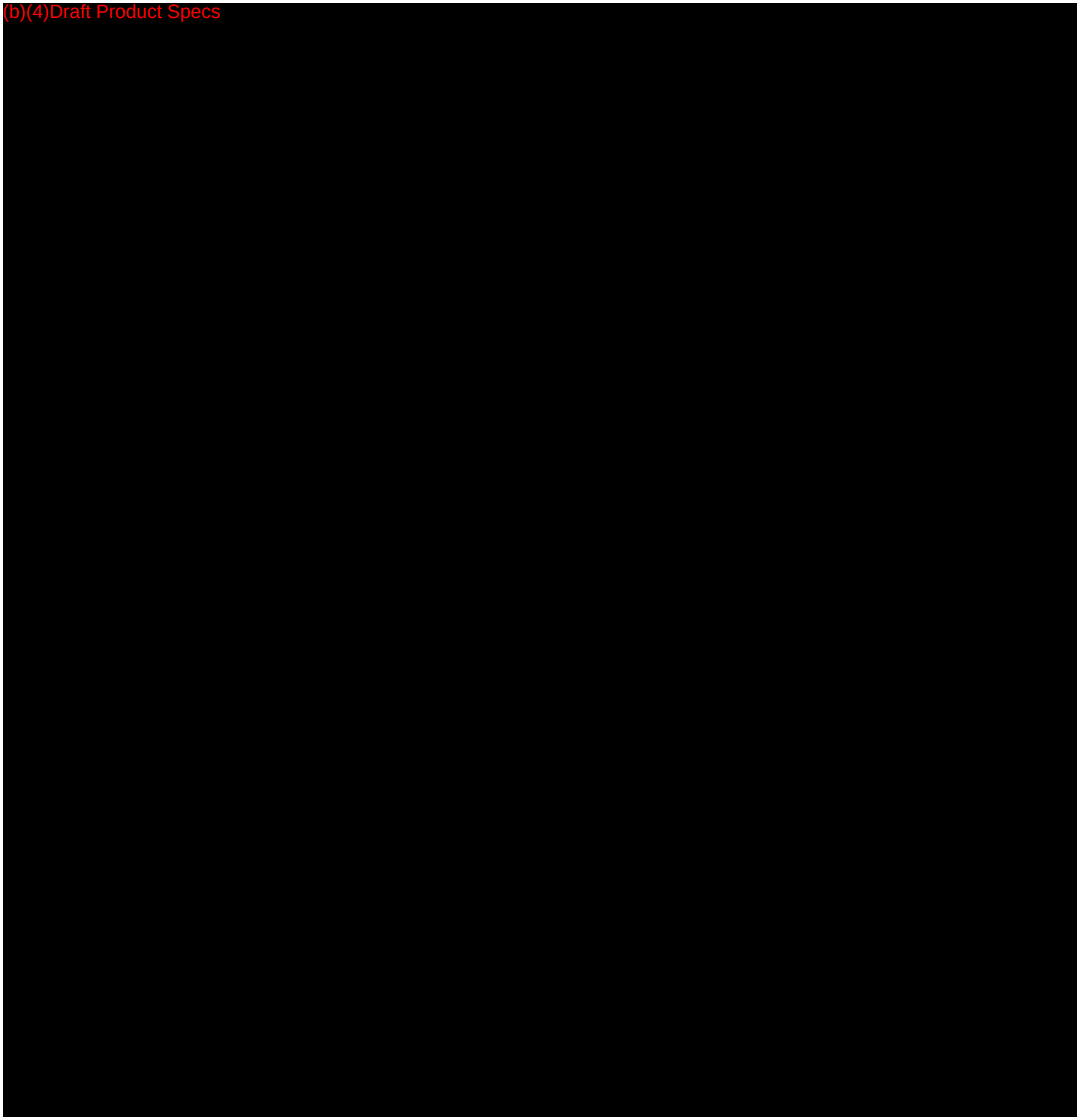

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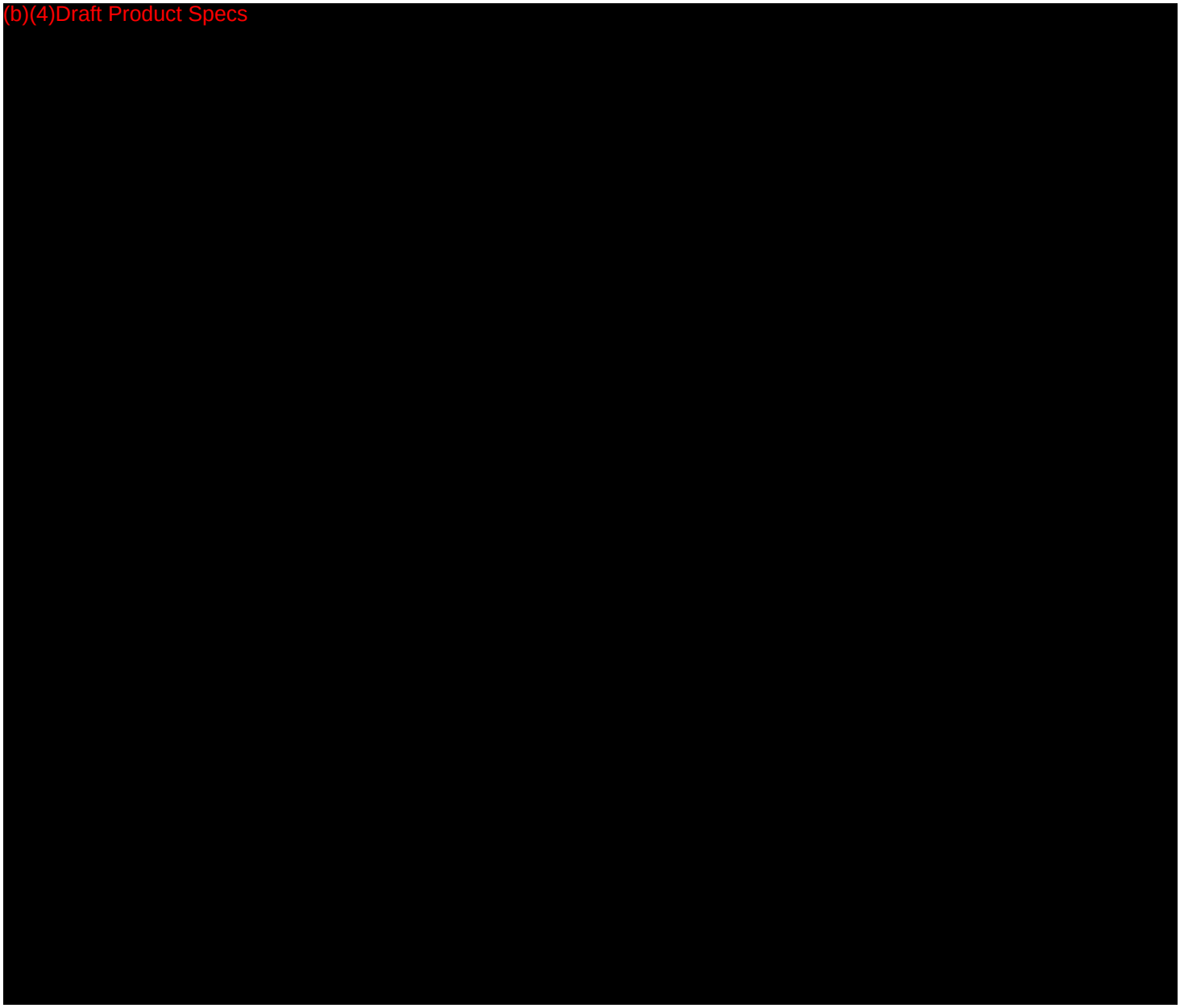

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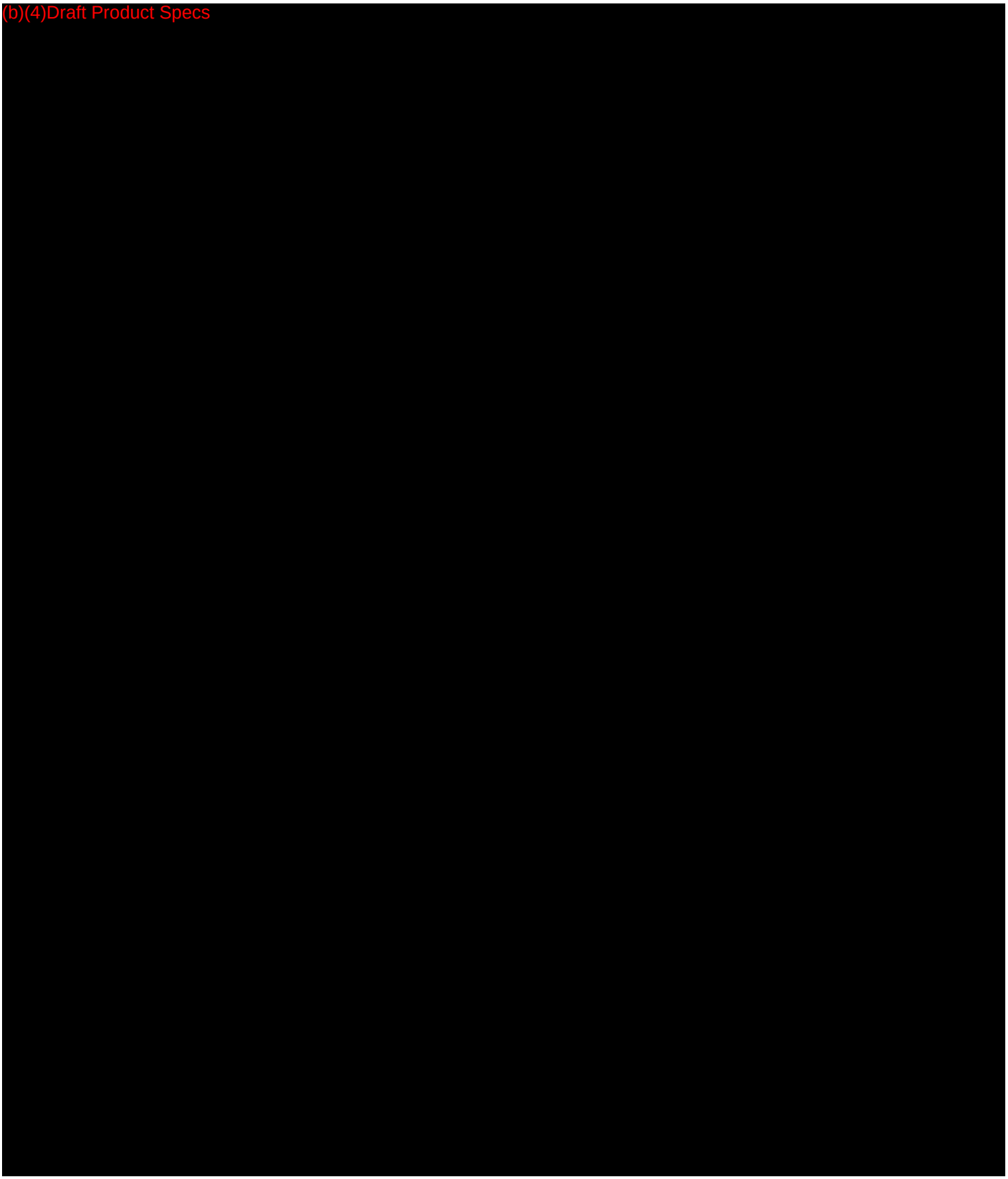

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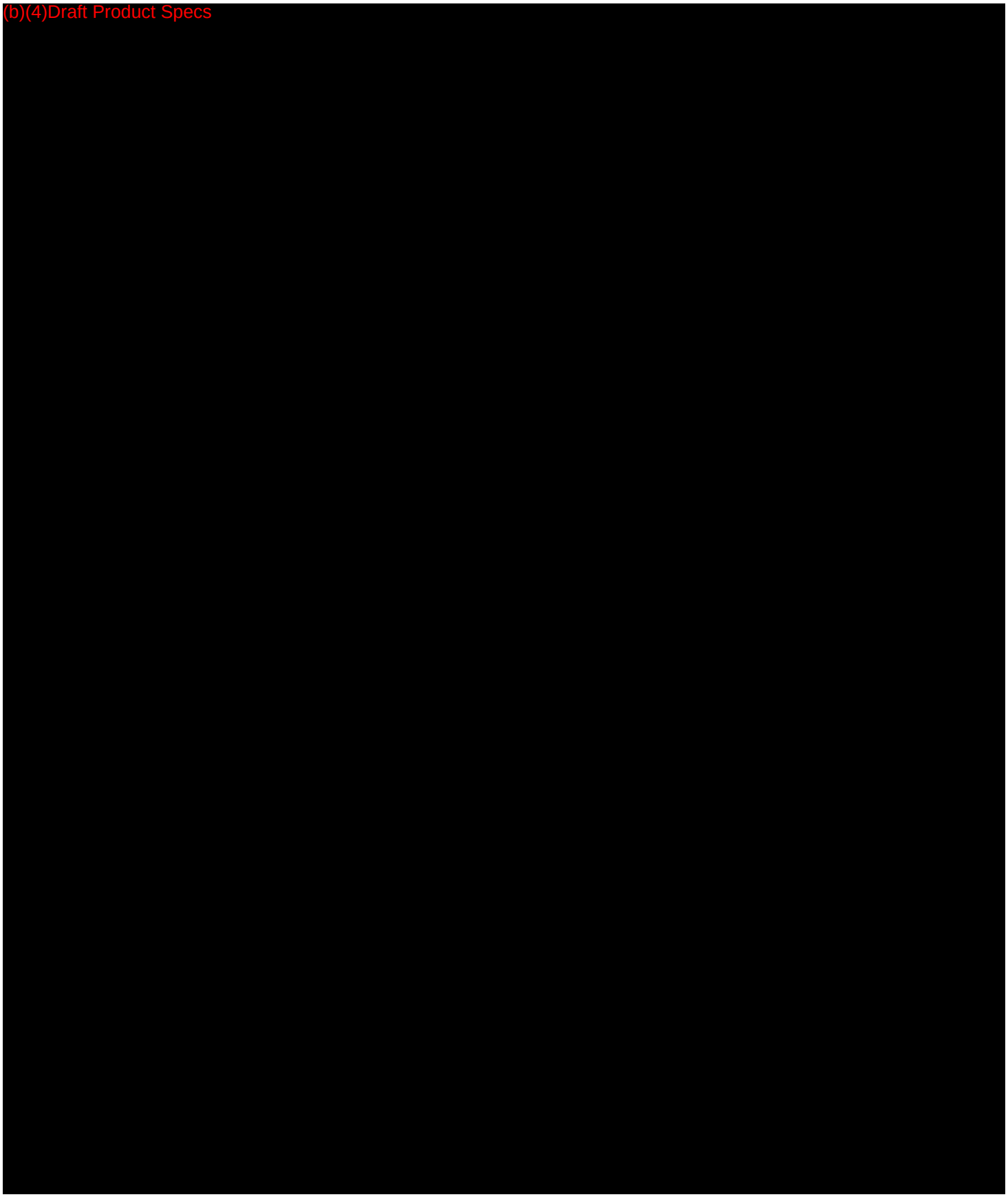

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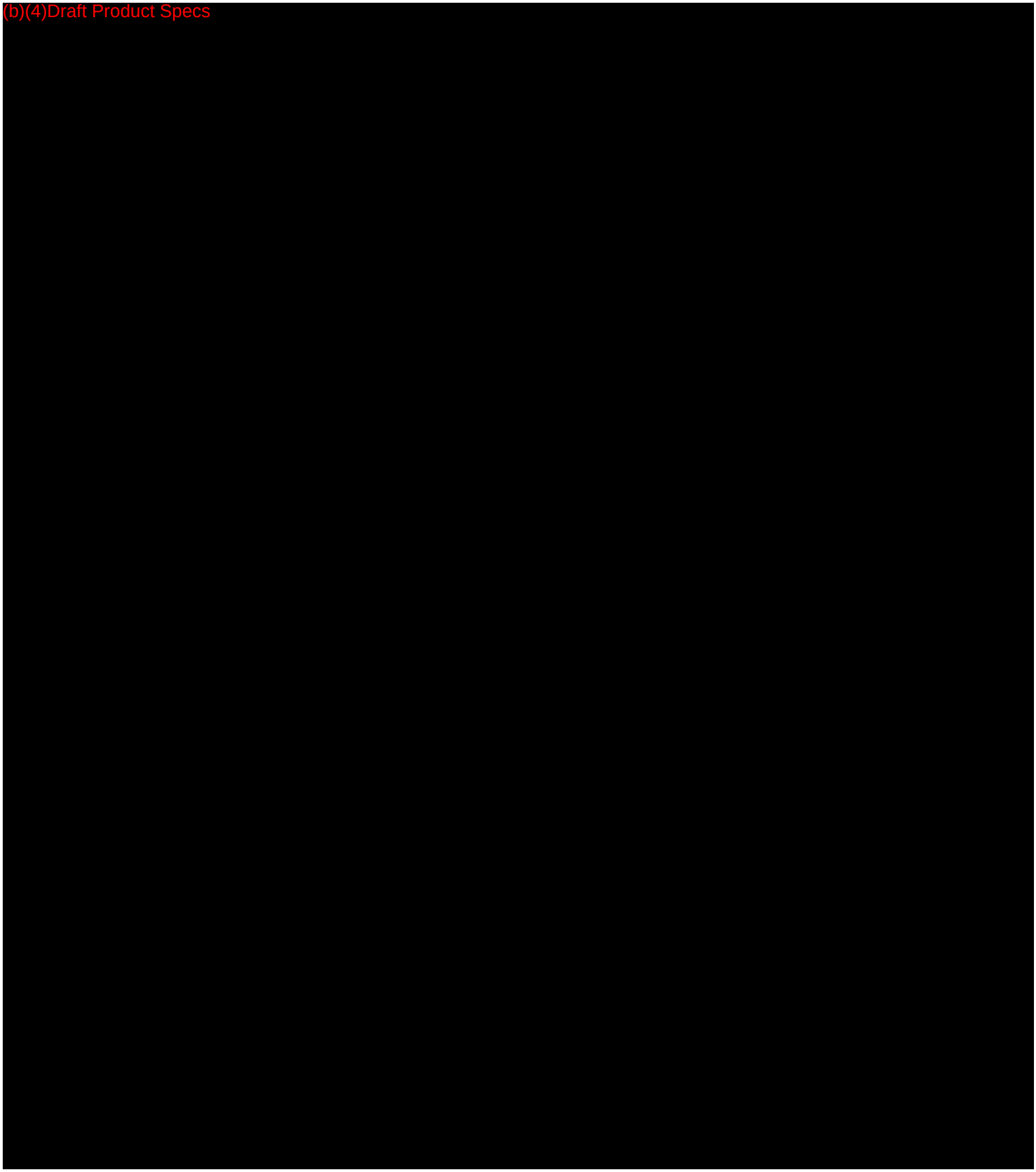

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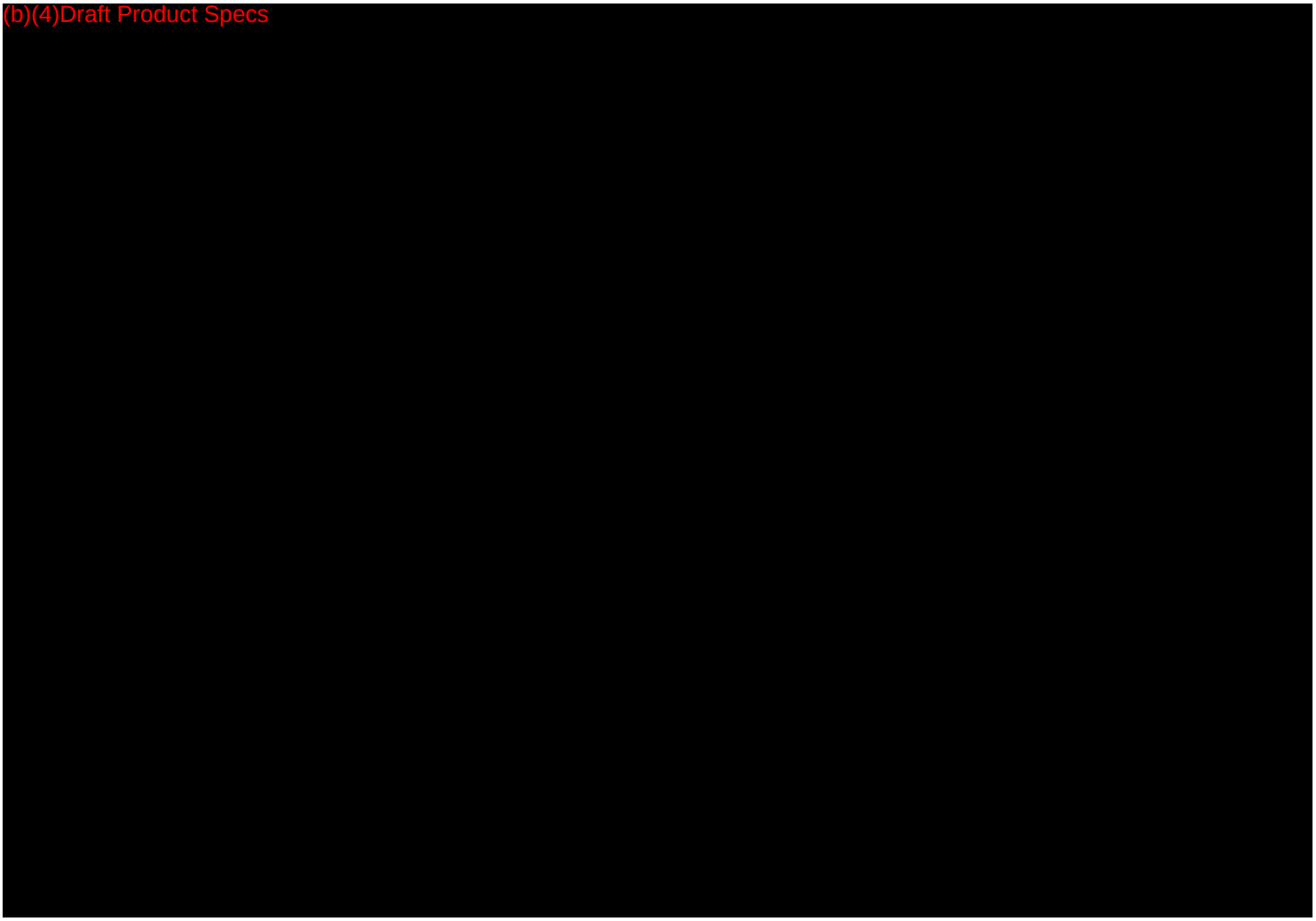

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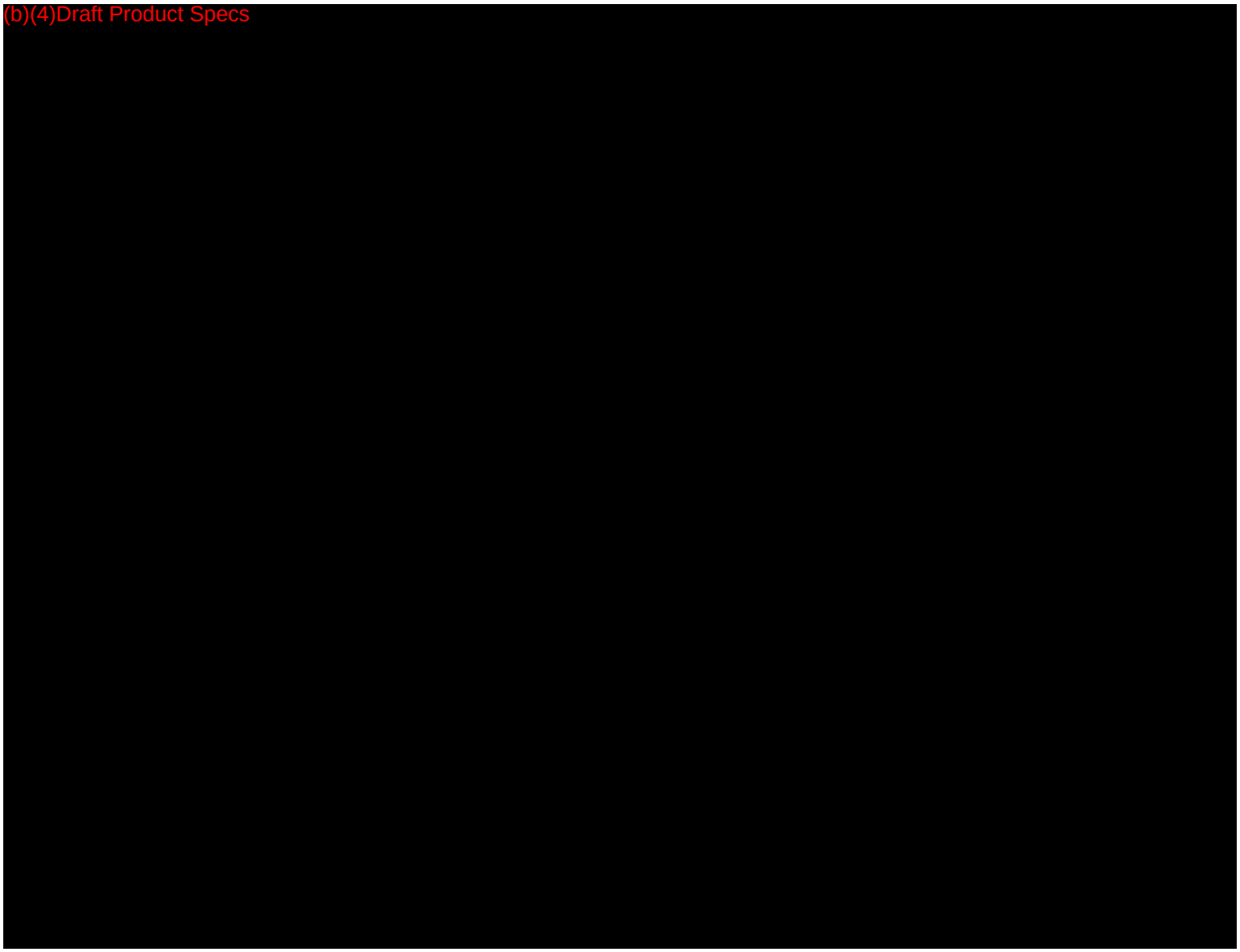

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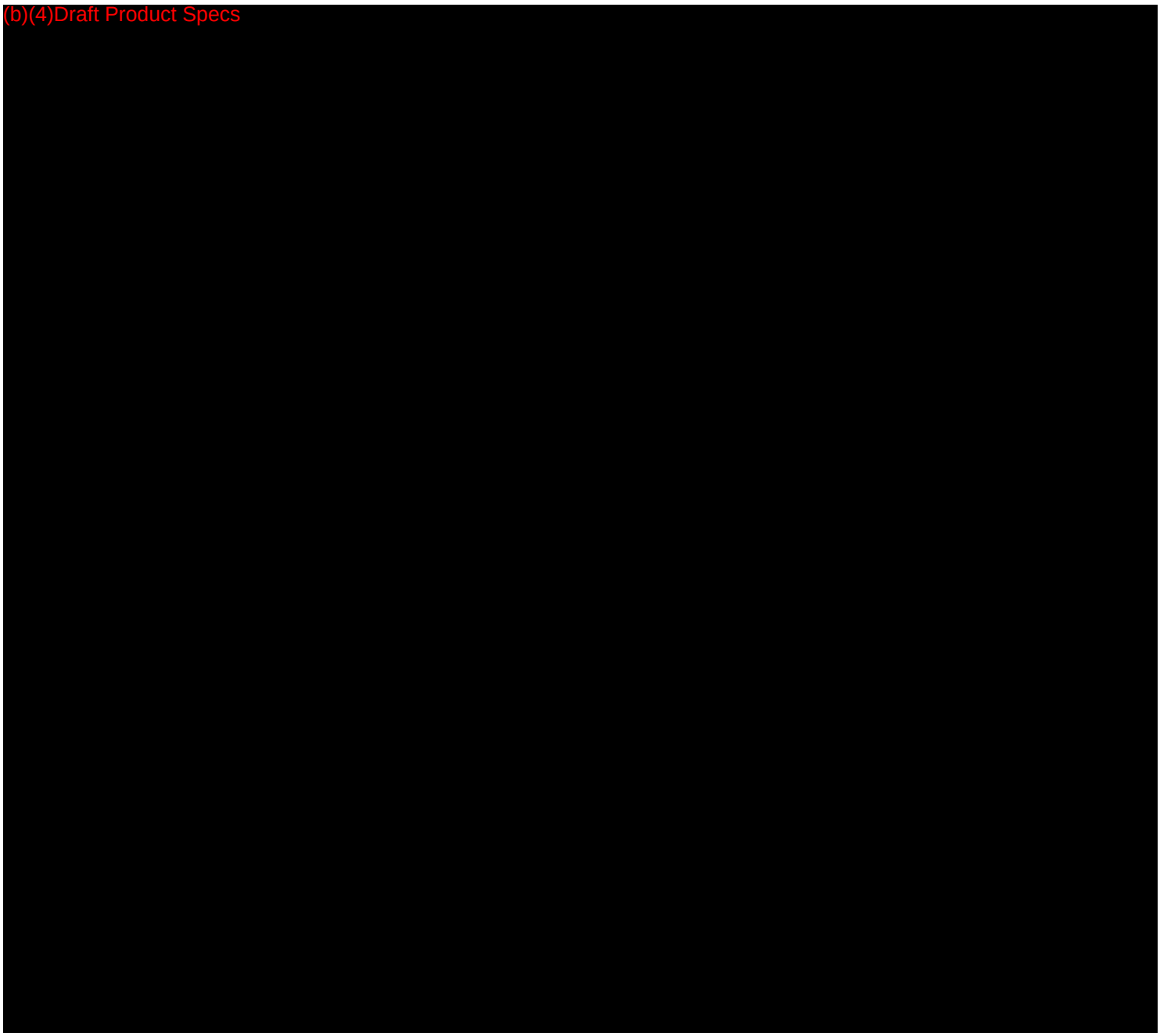

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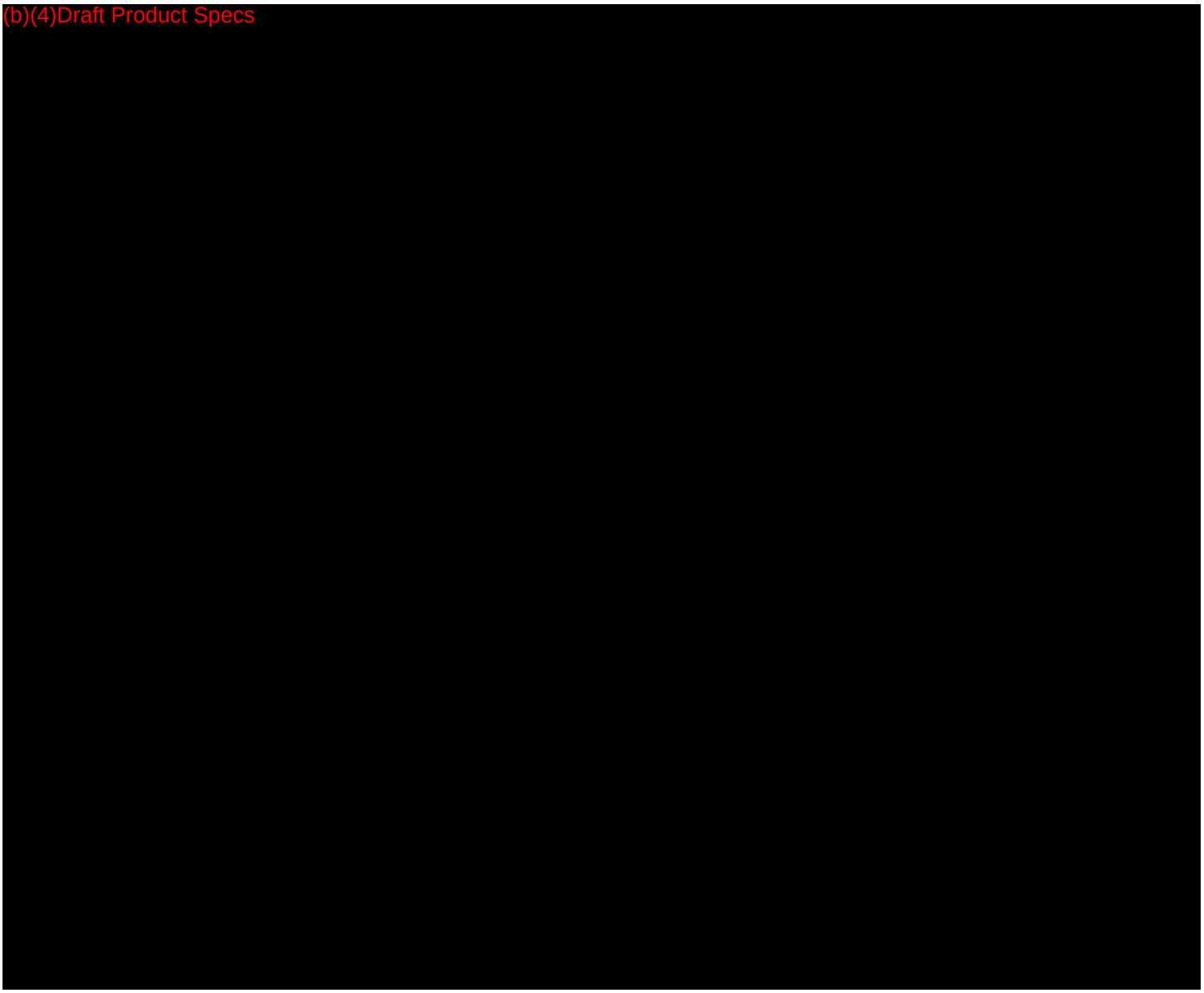

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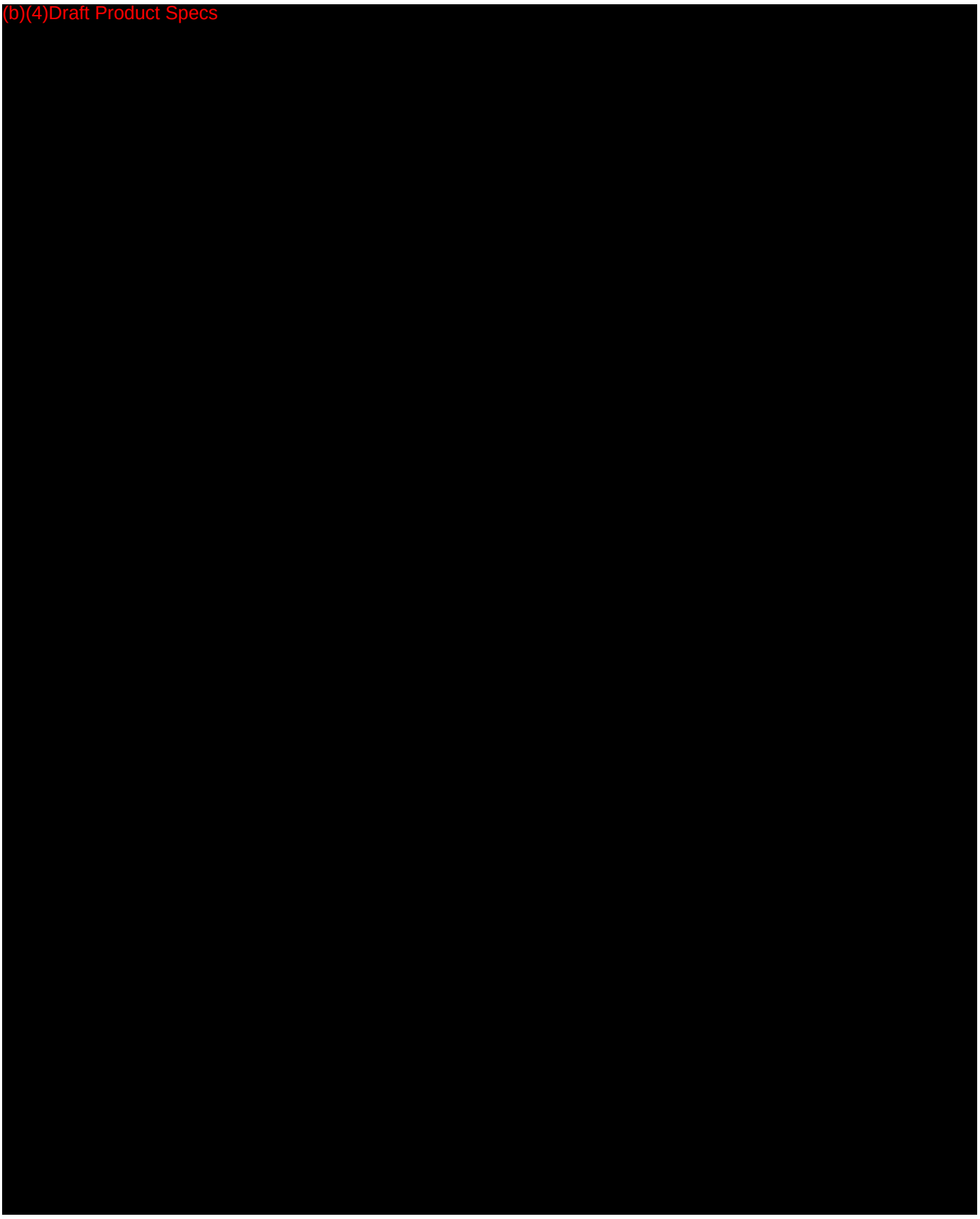

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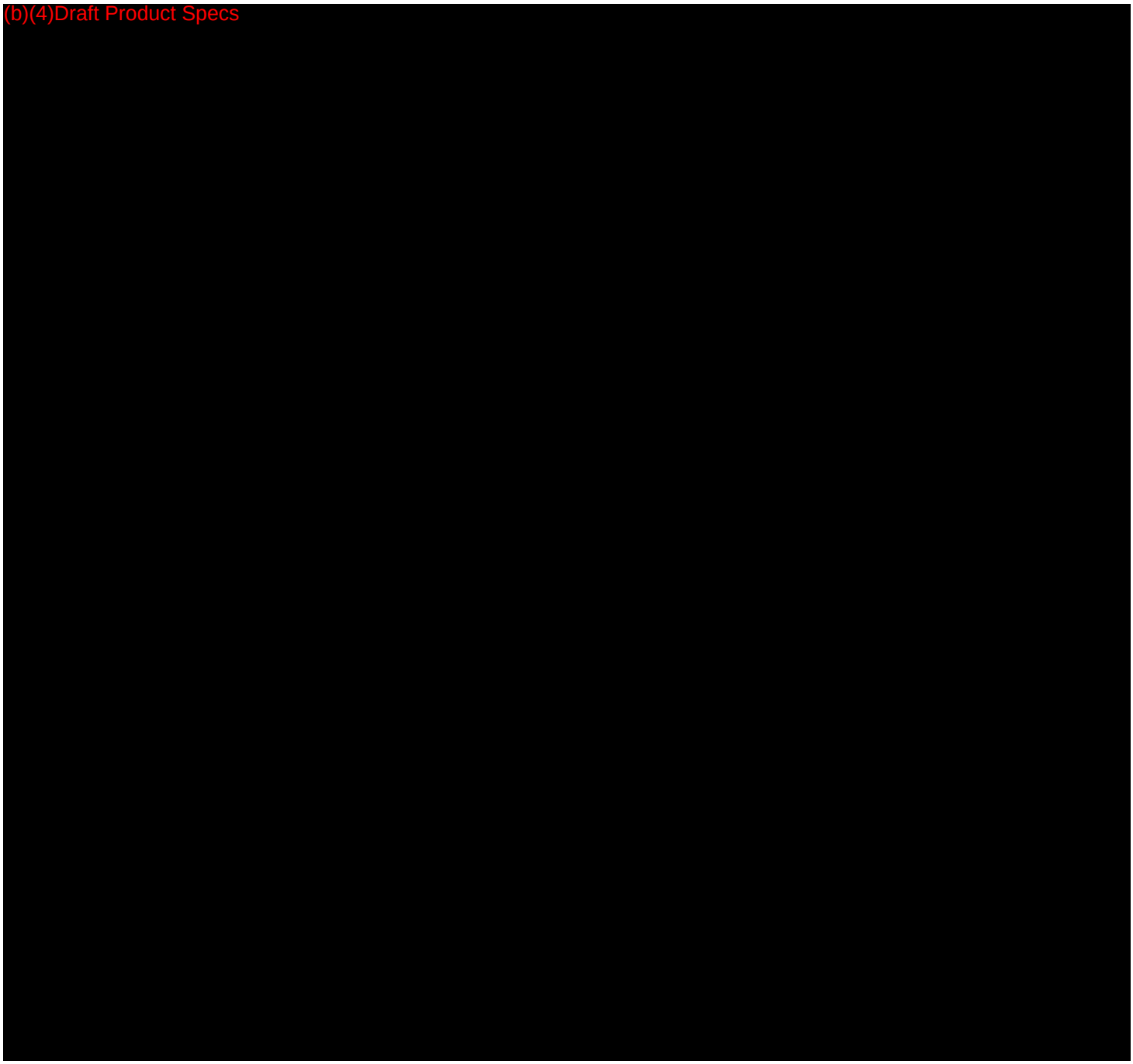

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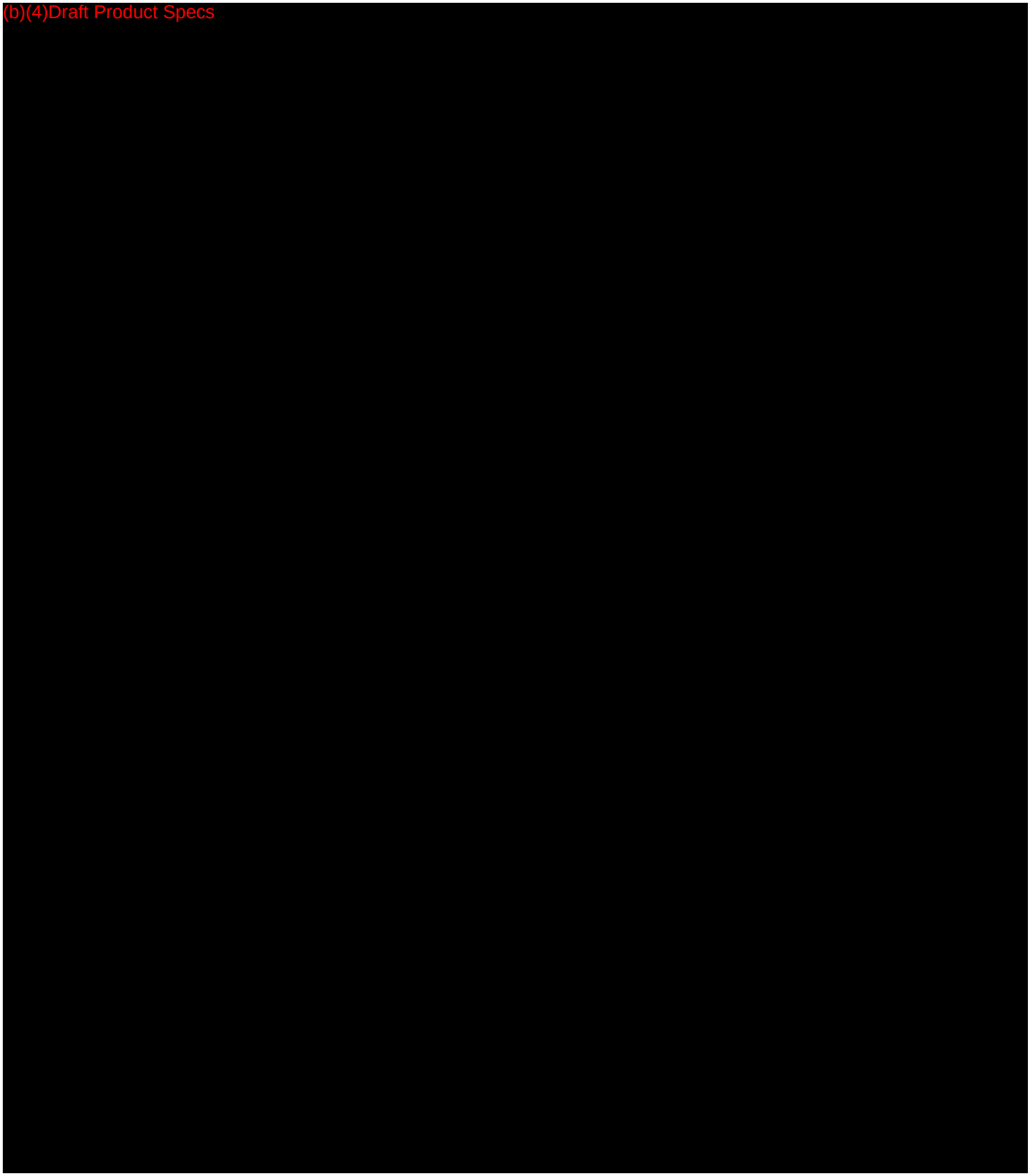

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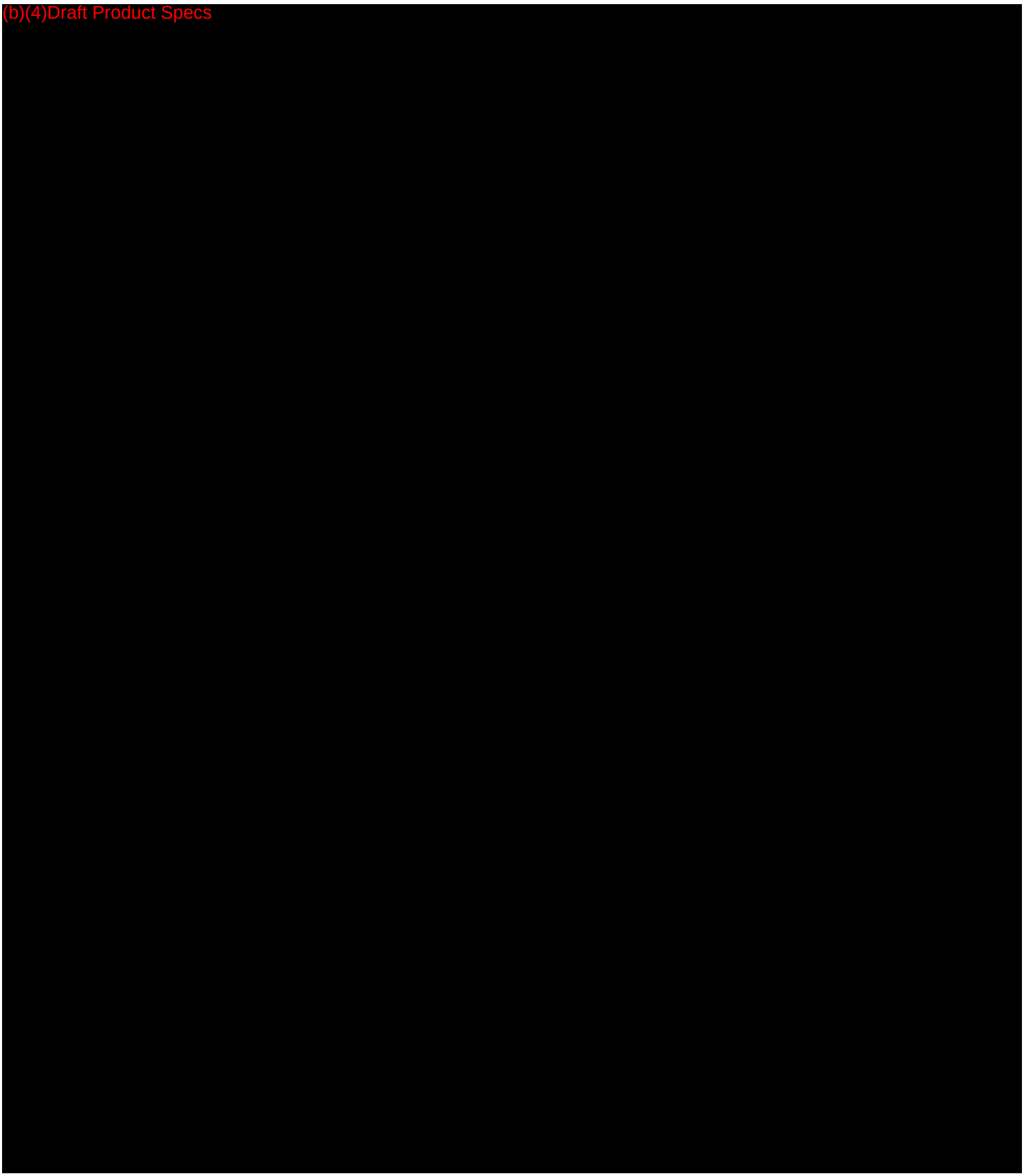

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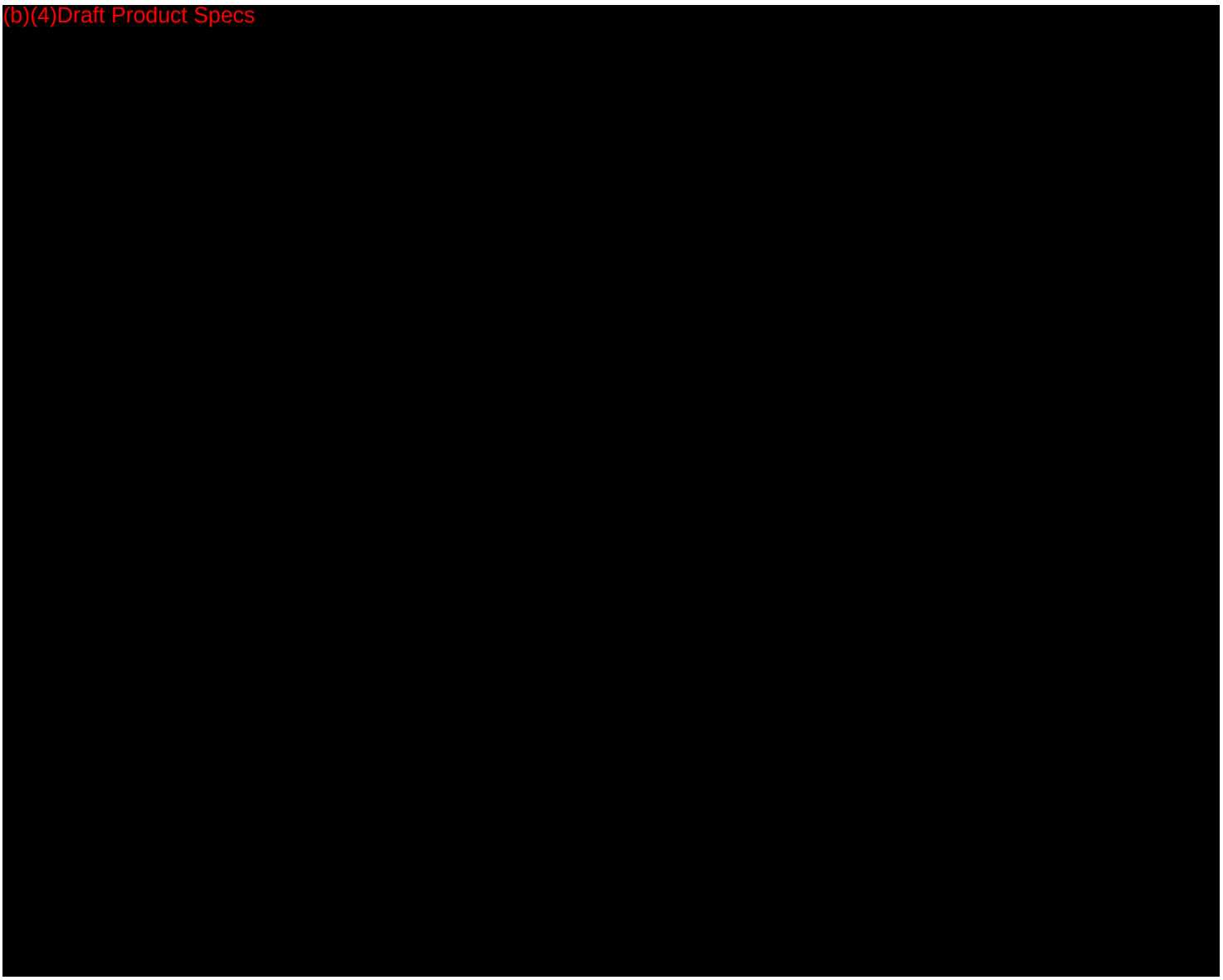

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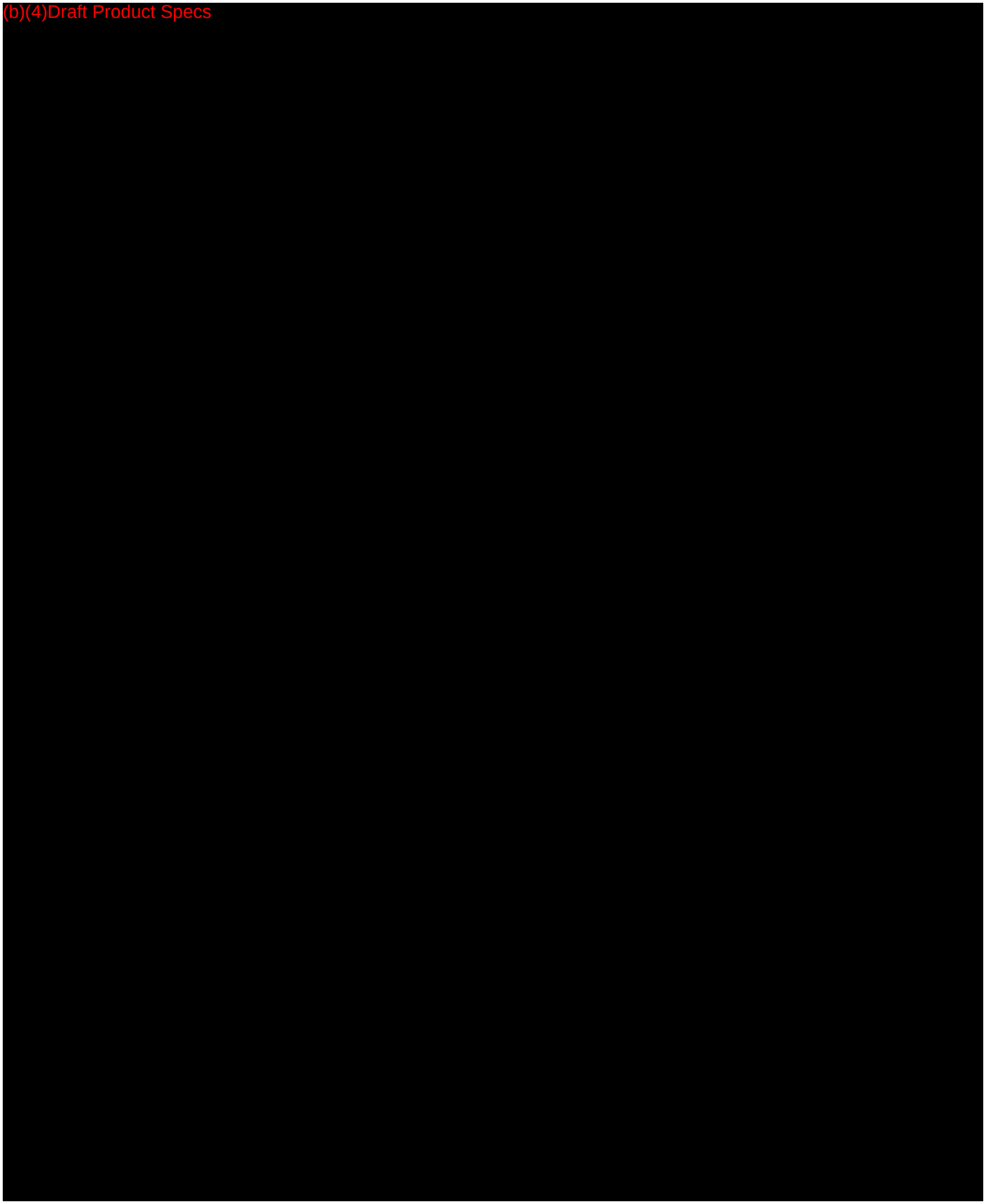

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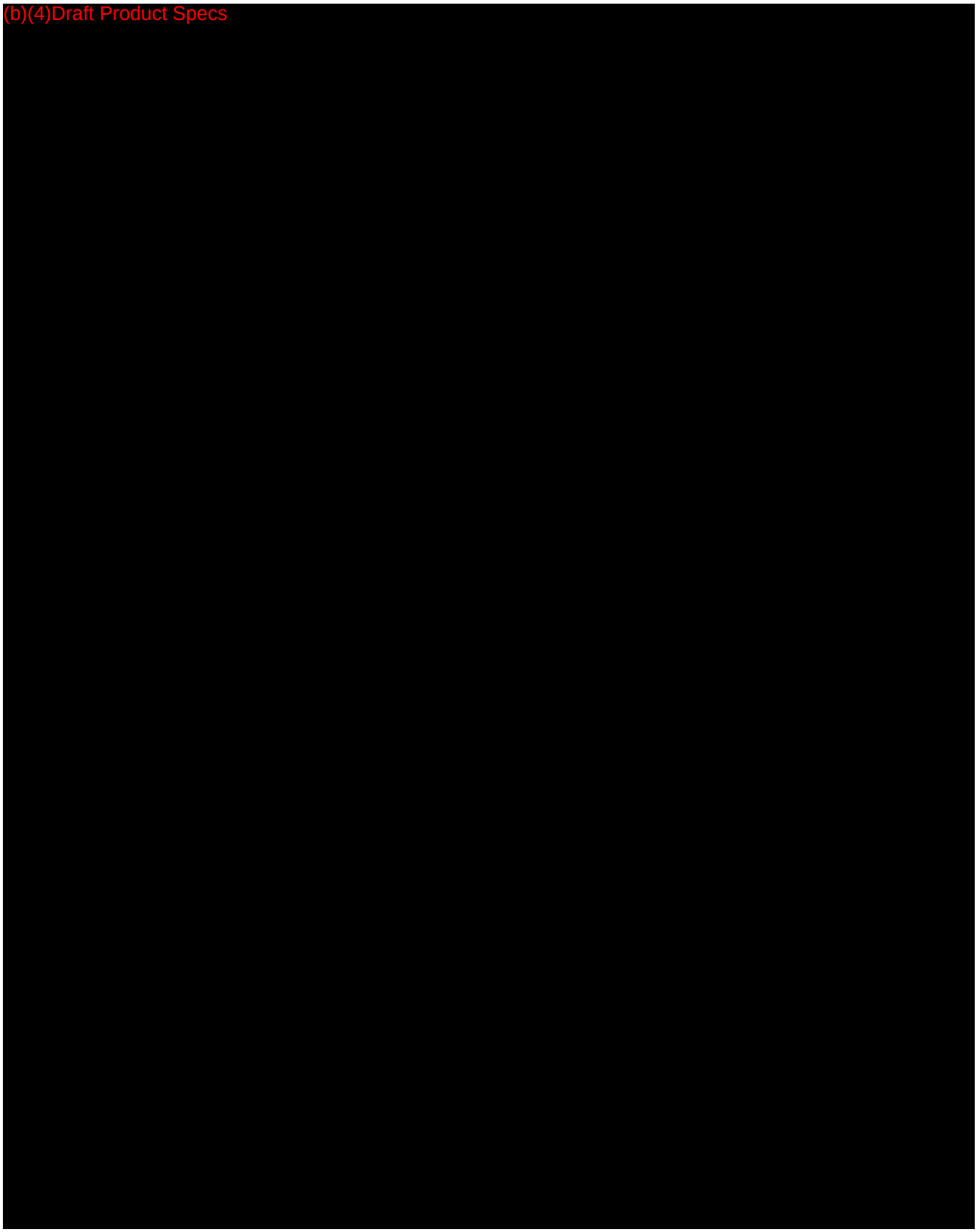

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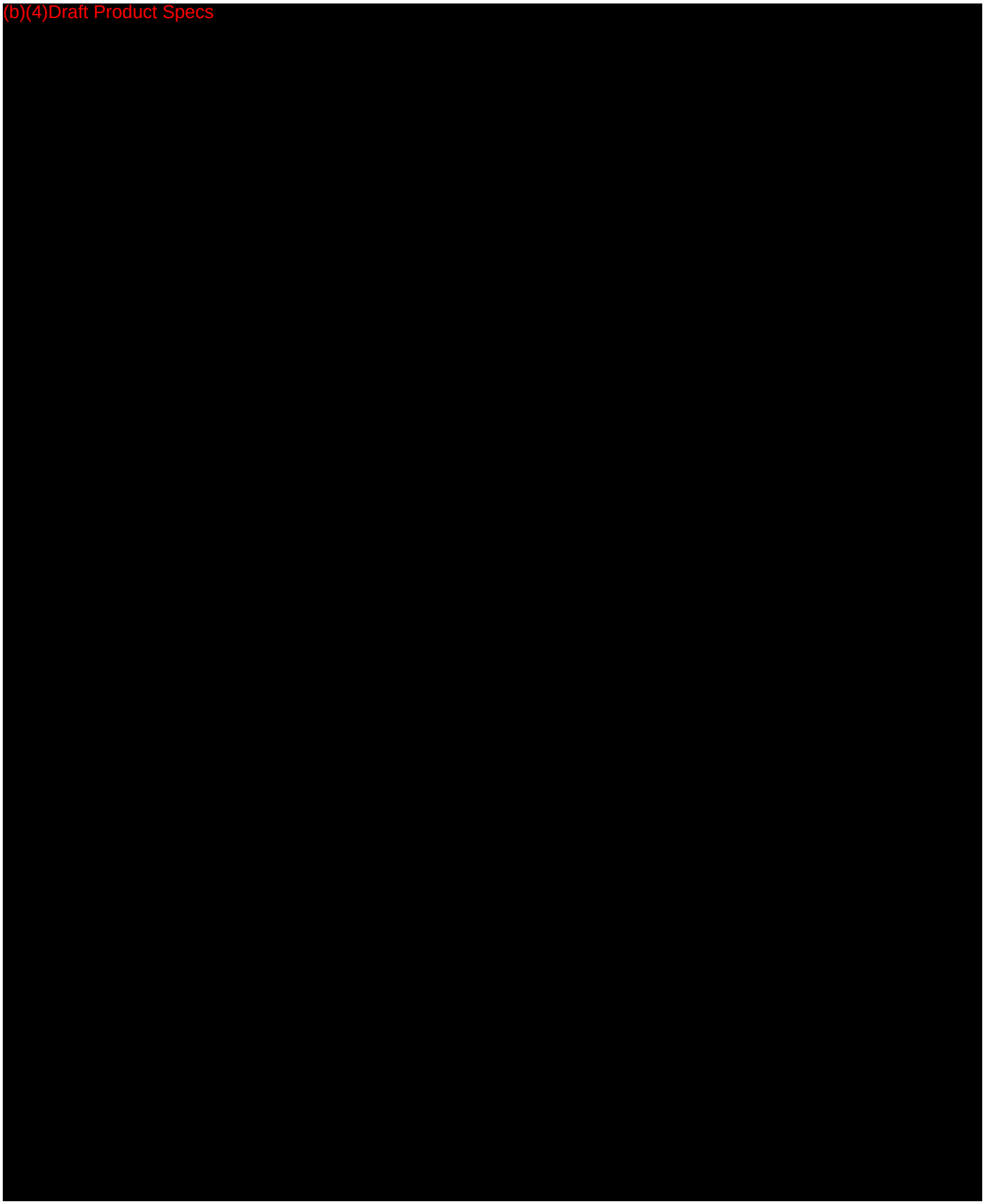

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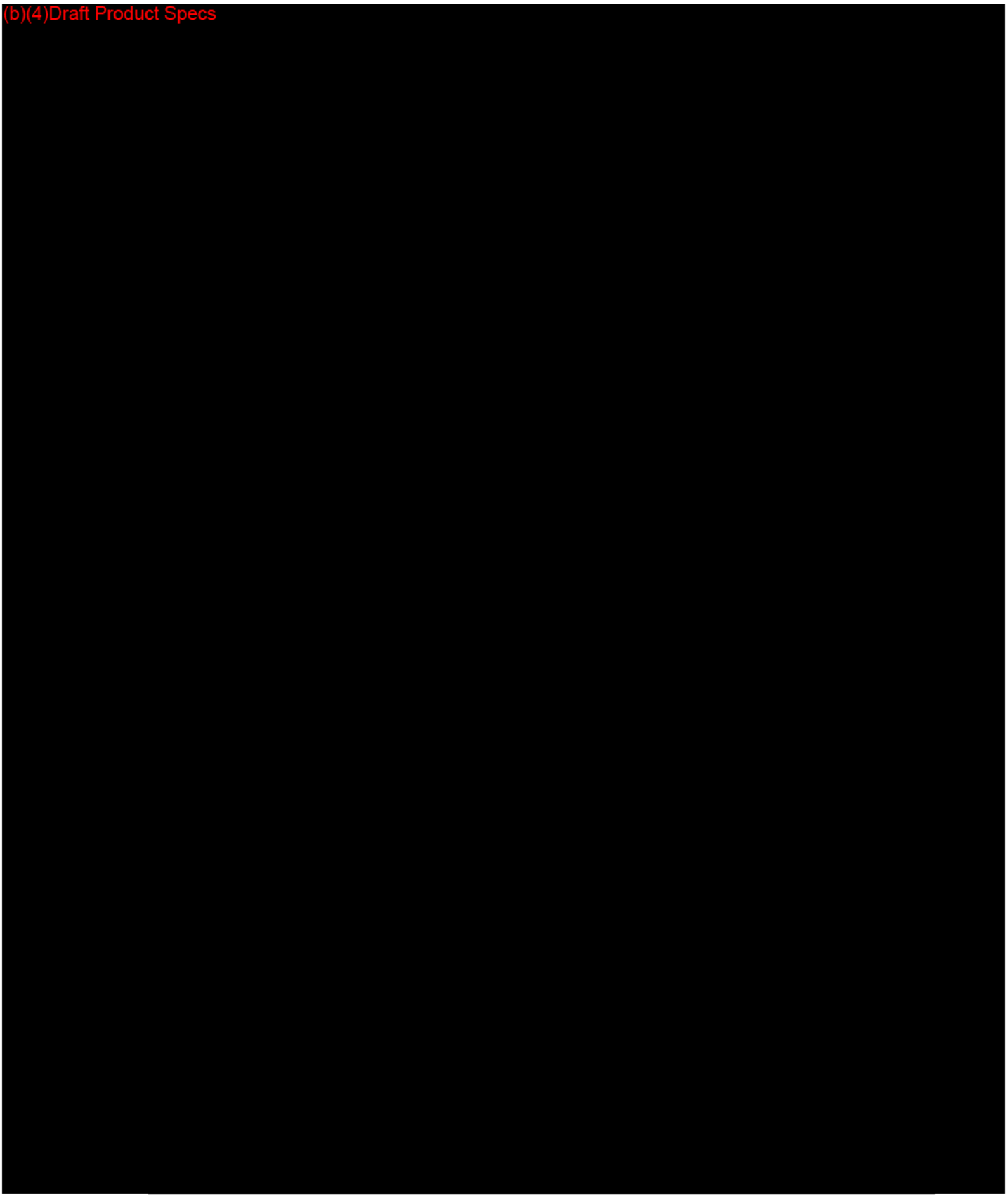

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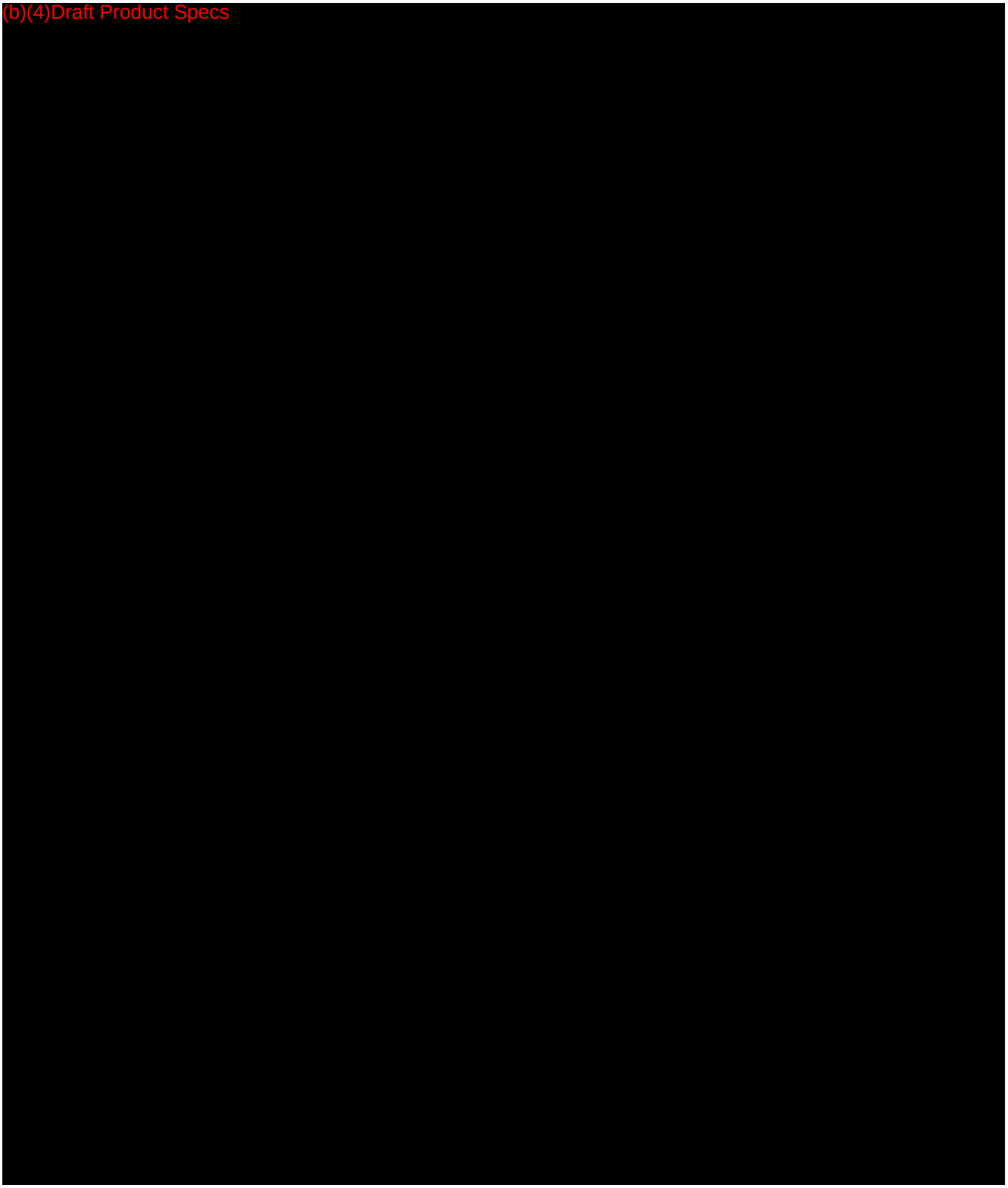

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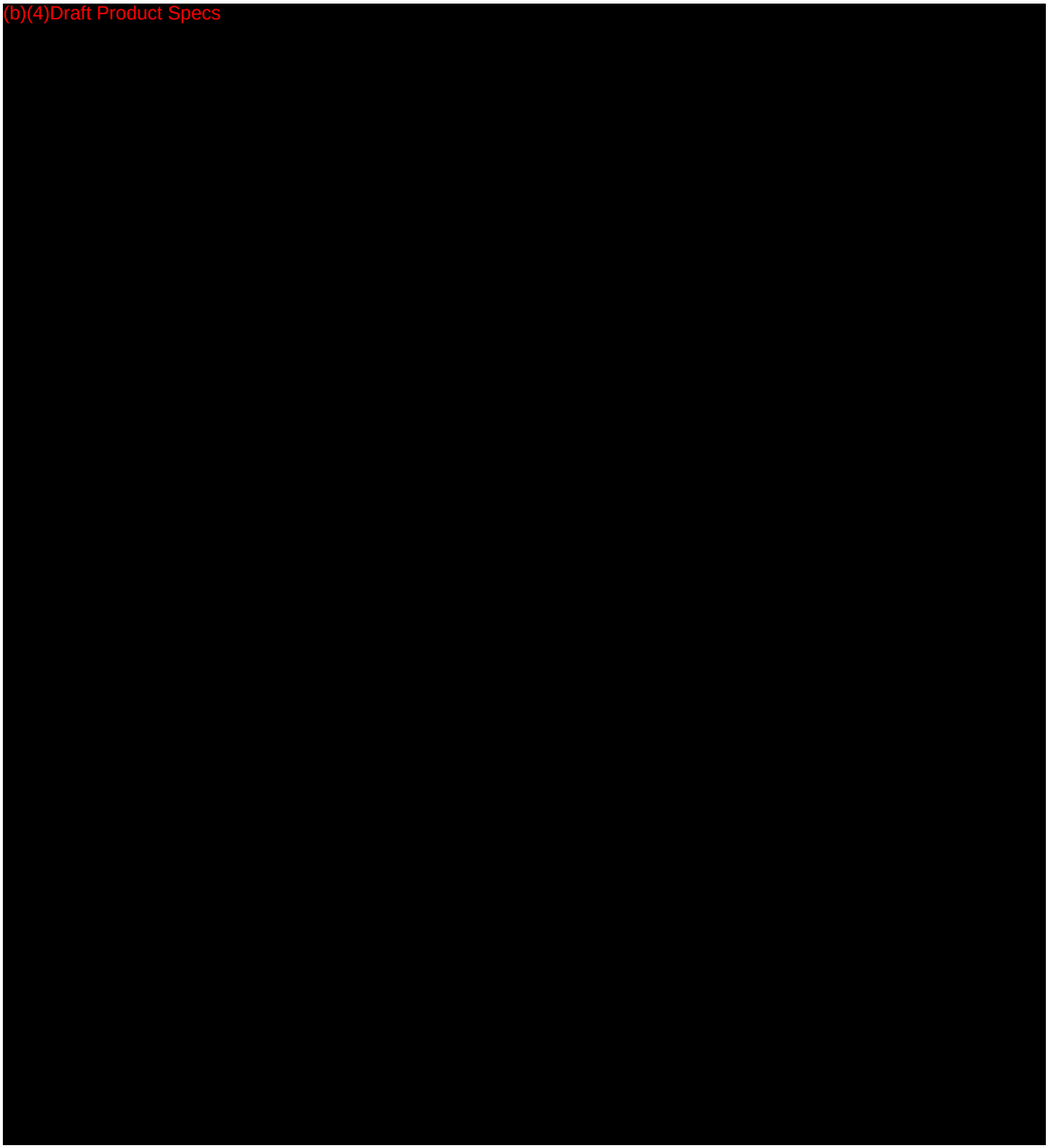

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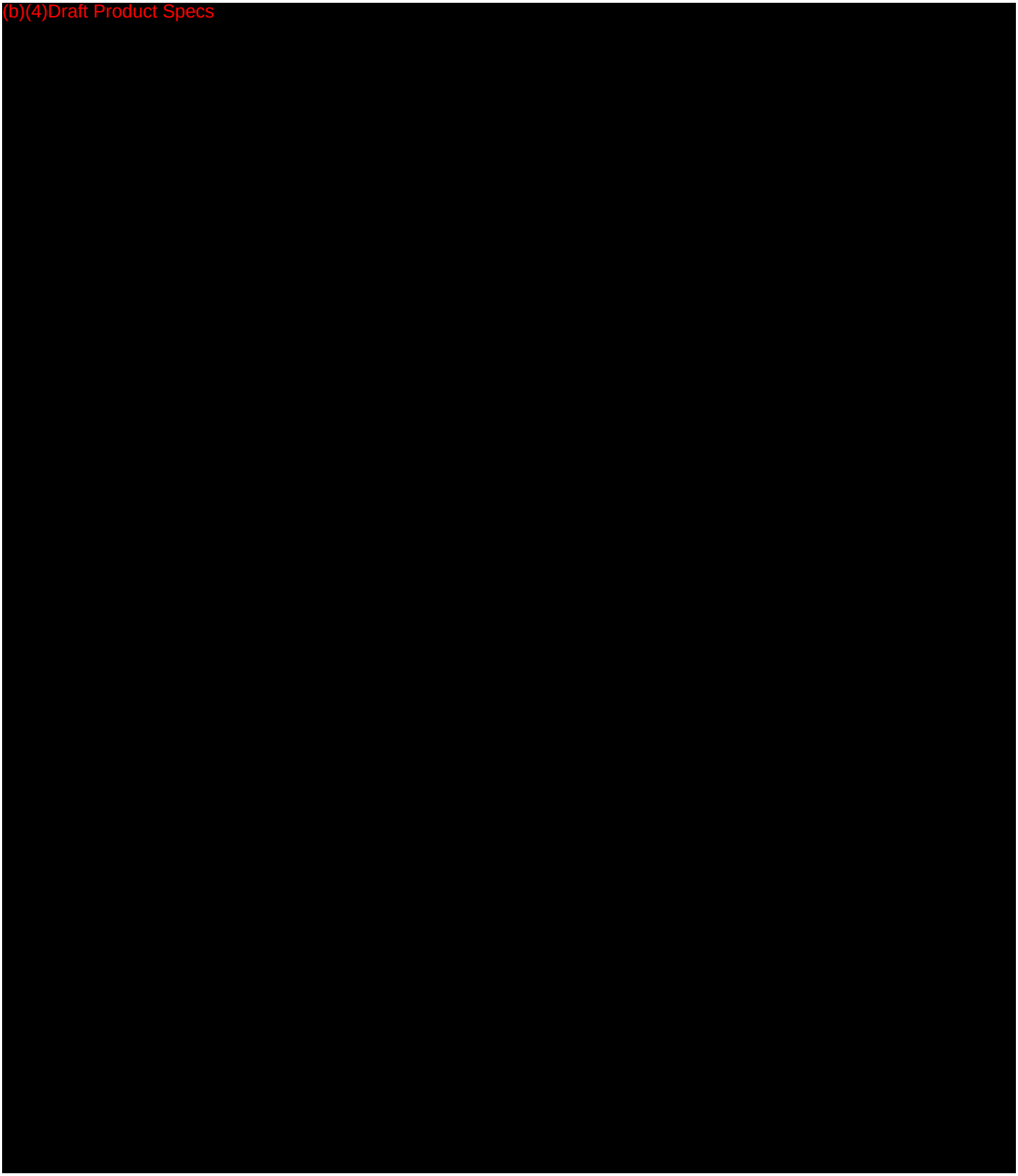

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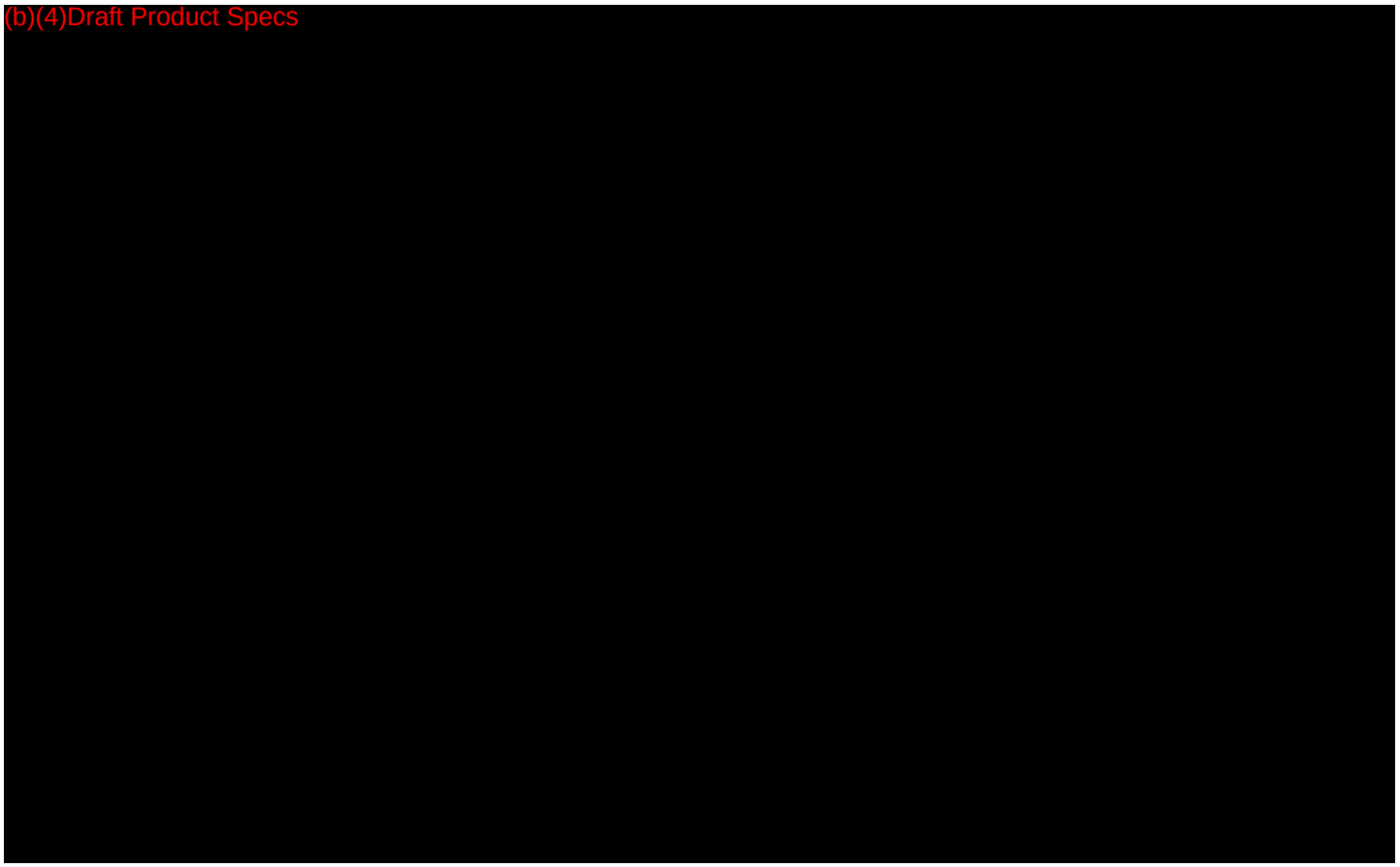

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Chapter 9 General Information

1 Introduction

This section provides a simple introduction to CT, or Computed Tomography, for people with no detailed physics or medical diagnostic education.

1.1 System Components

The system components are also described in the User Manual.

1.2 Emergency Stop

Emergency Stop procedures are described in the Safety chapter.

1.3 CT Description

Computed tomography (CT) is a medical imaging method employing tomography created by computer processing. Digital geometry processing is used to generate a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images taken around a single axial of rotation. The word "tomography" is derived from the Greek tomos (slice) and graphein (to write). Computed tomography is known as computed axial tomography (CAT or CT scan).

CT produces a volume of data, which can be manipulated, through a process known as windowing, in order to demonstrate various bodily structures based on their ability to block the X- ray/Röntgen beam. Although historically the images generated were in the axial or transverse plane, orthogonal to the long axis of the body, modern scanners allow this volume of data to be reformatted in various planes or even as volumetric (3D) representations of structures.

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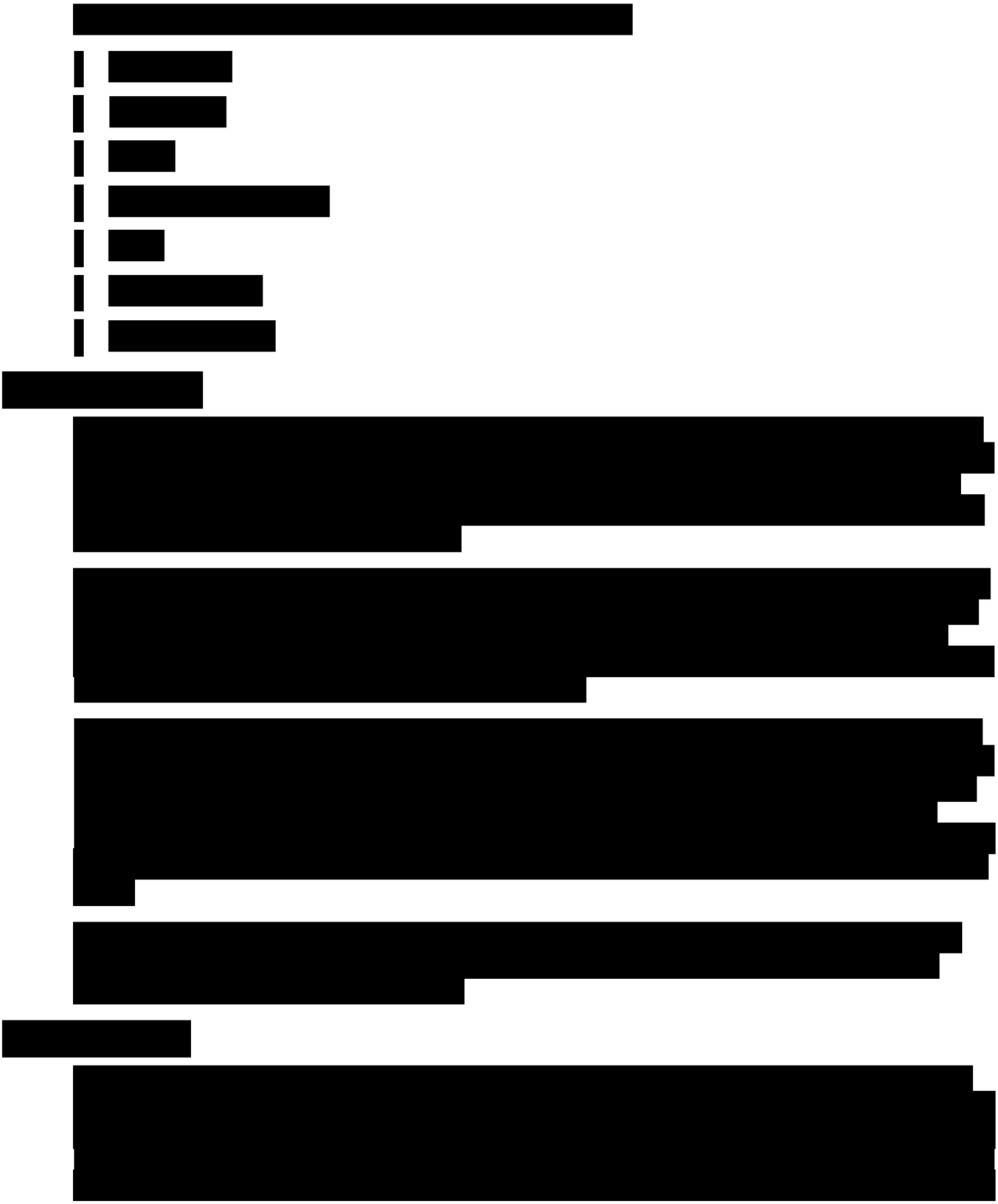

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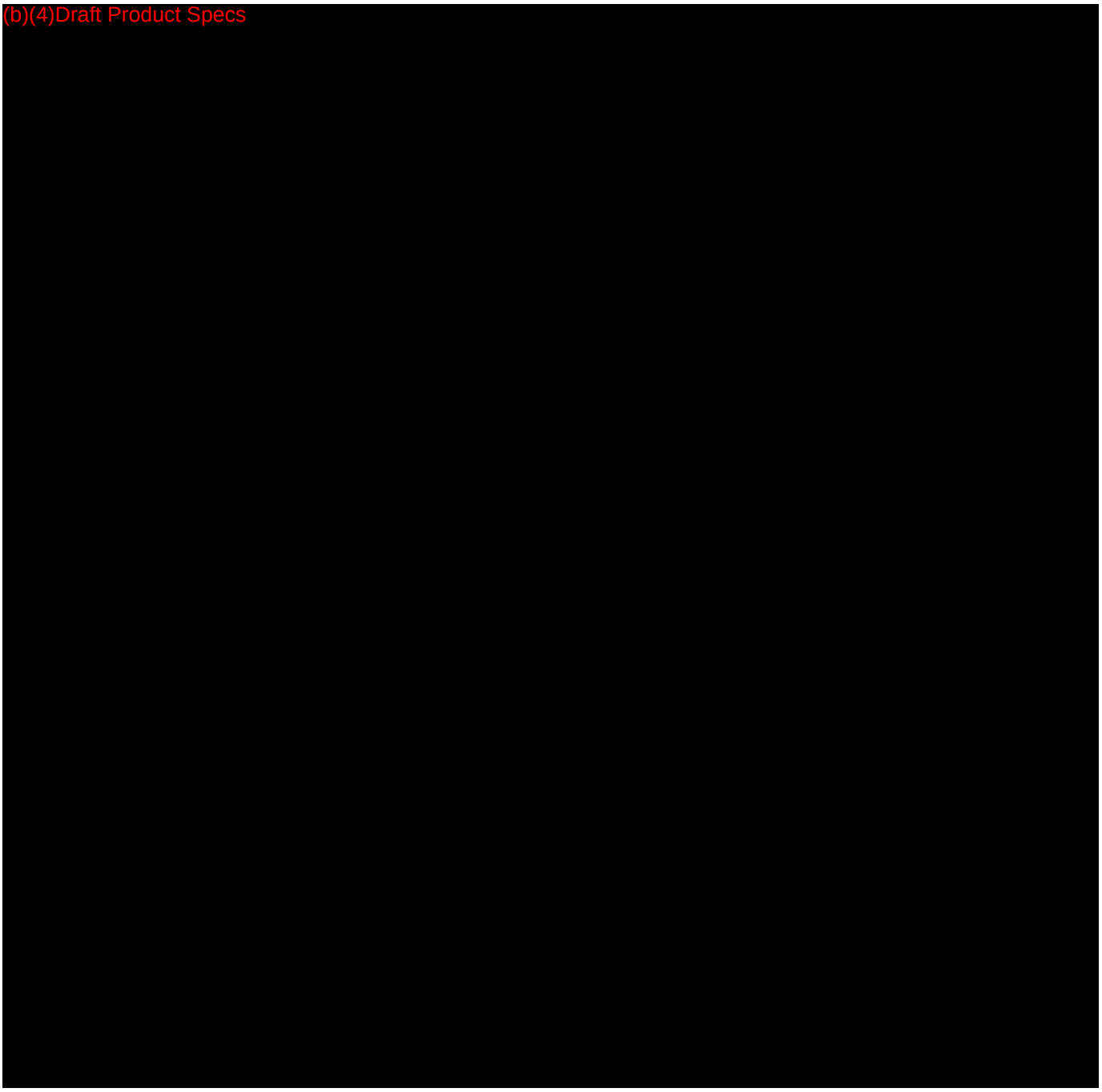

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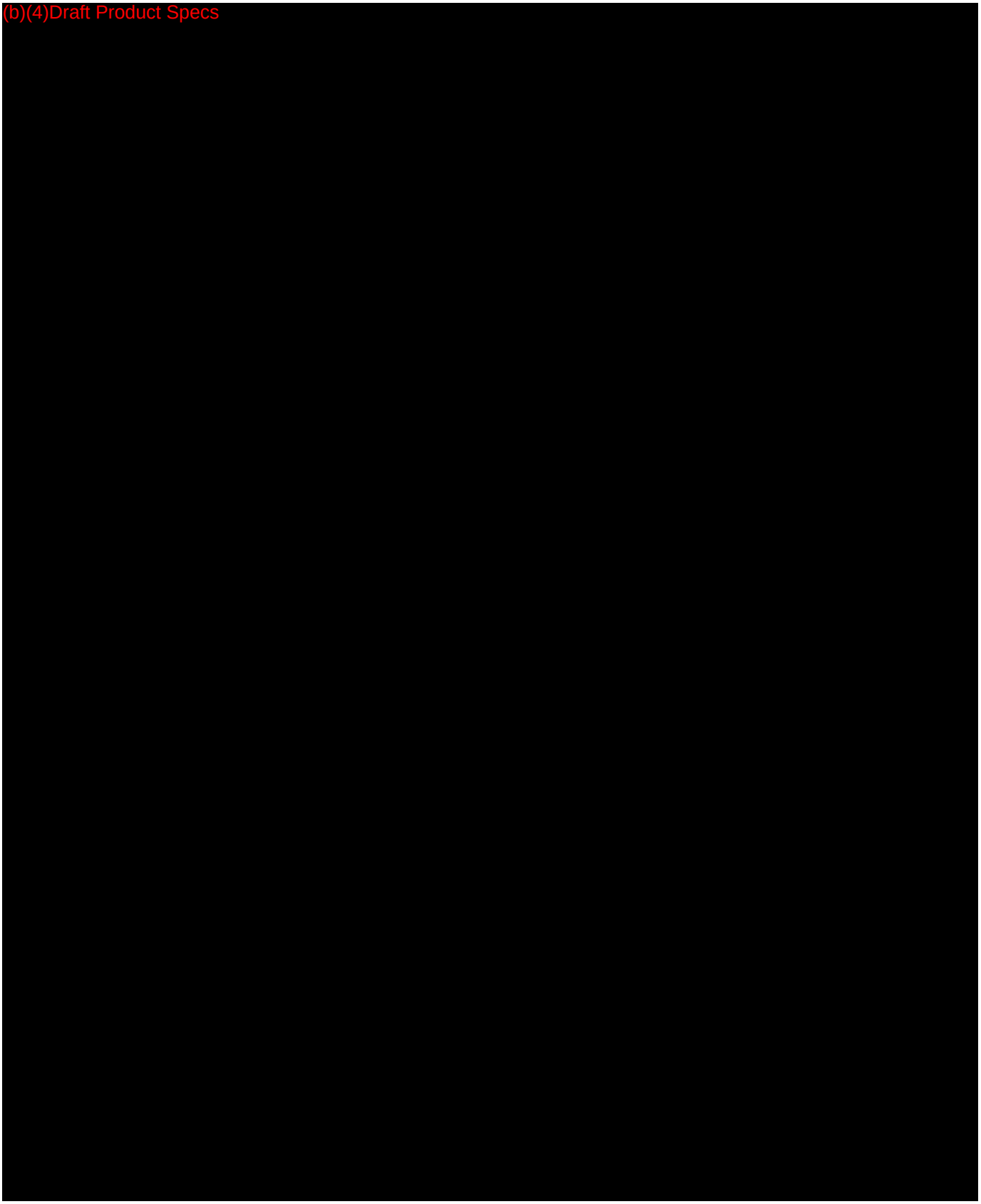

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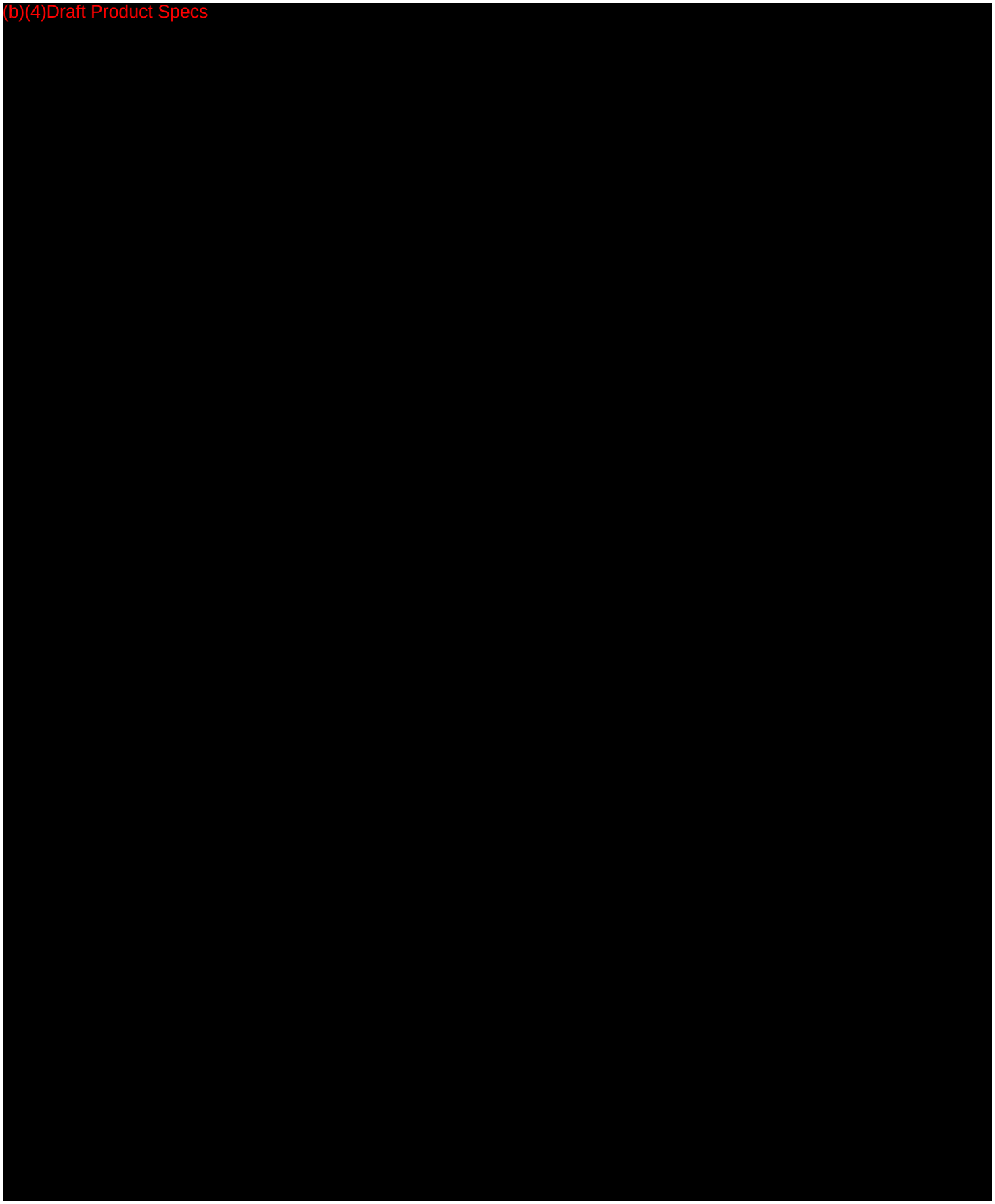

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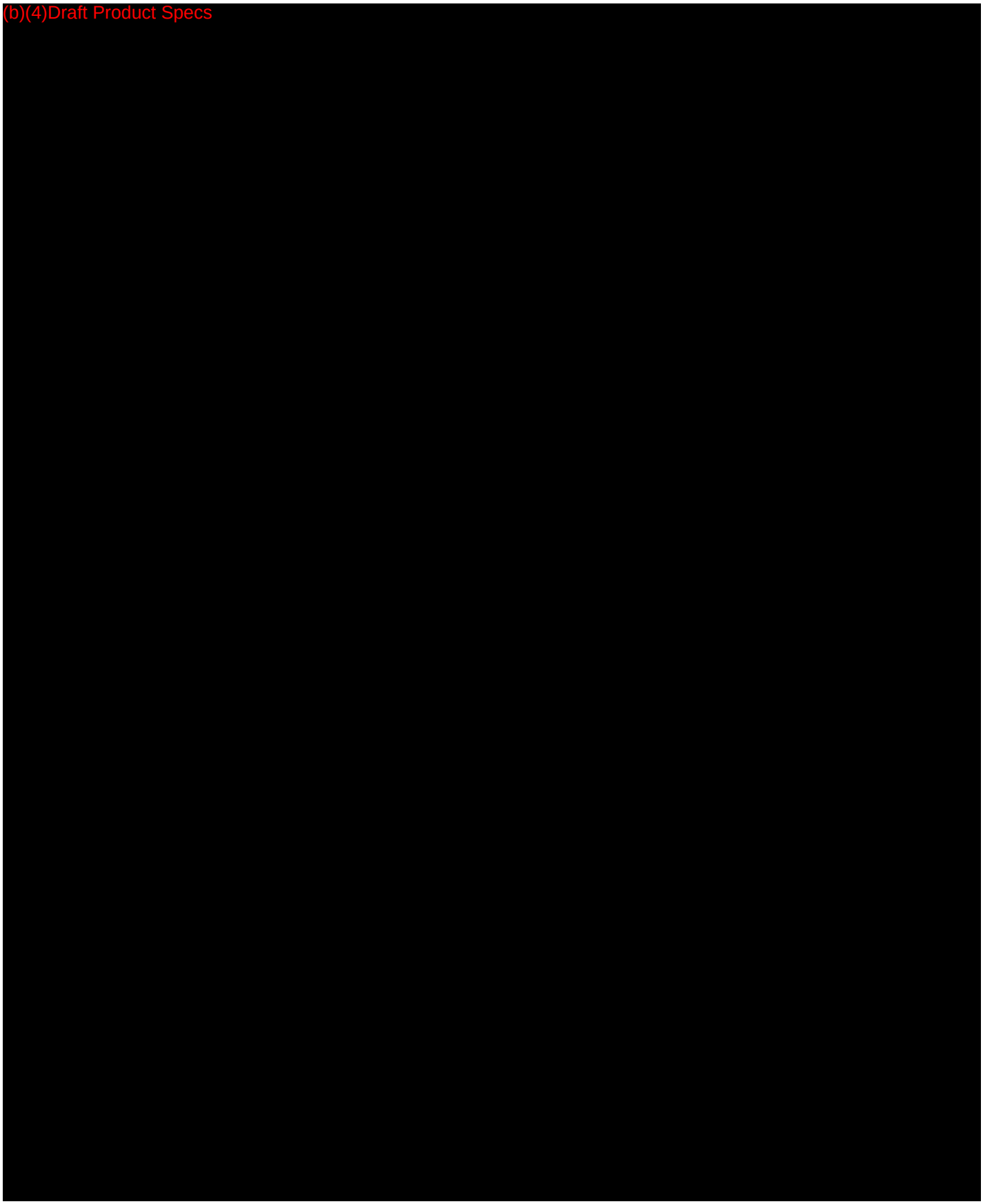

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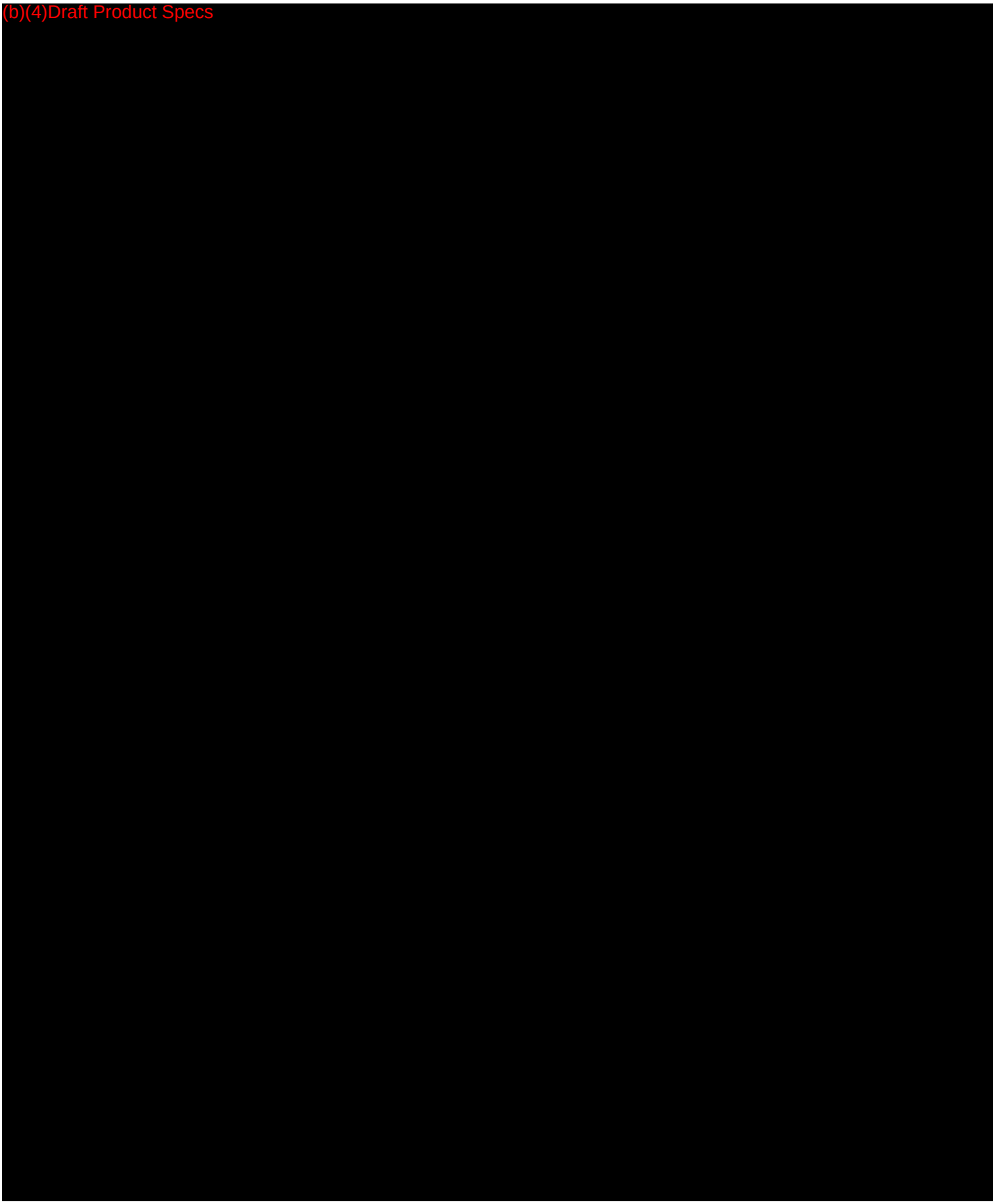

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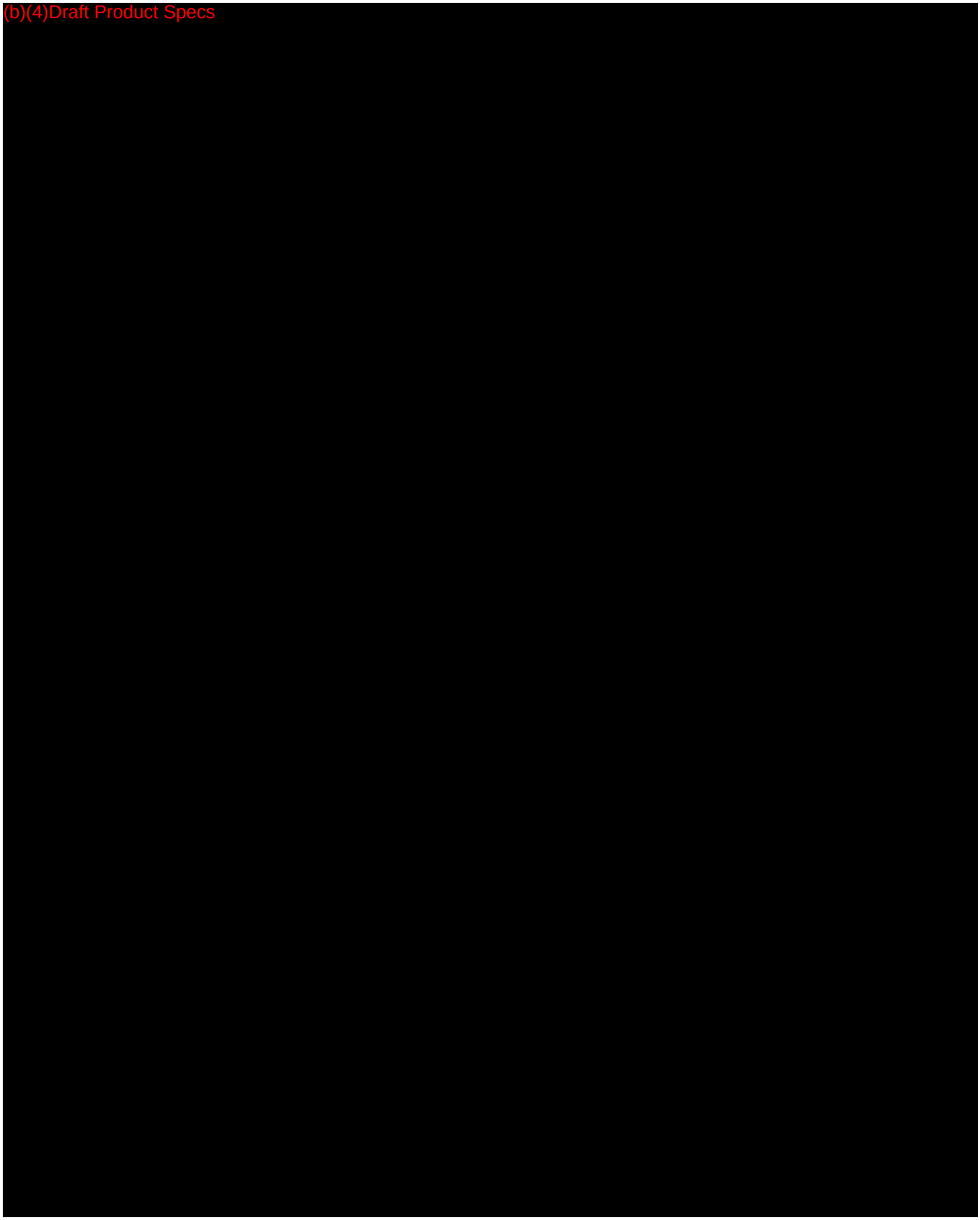

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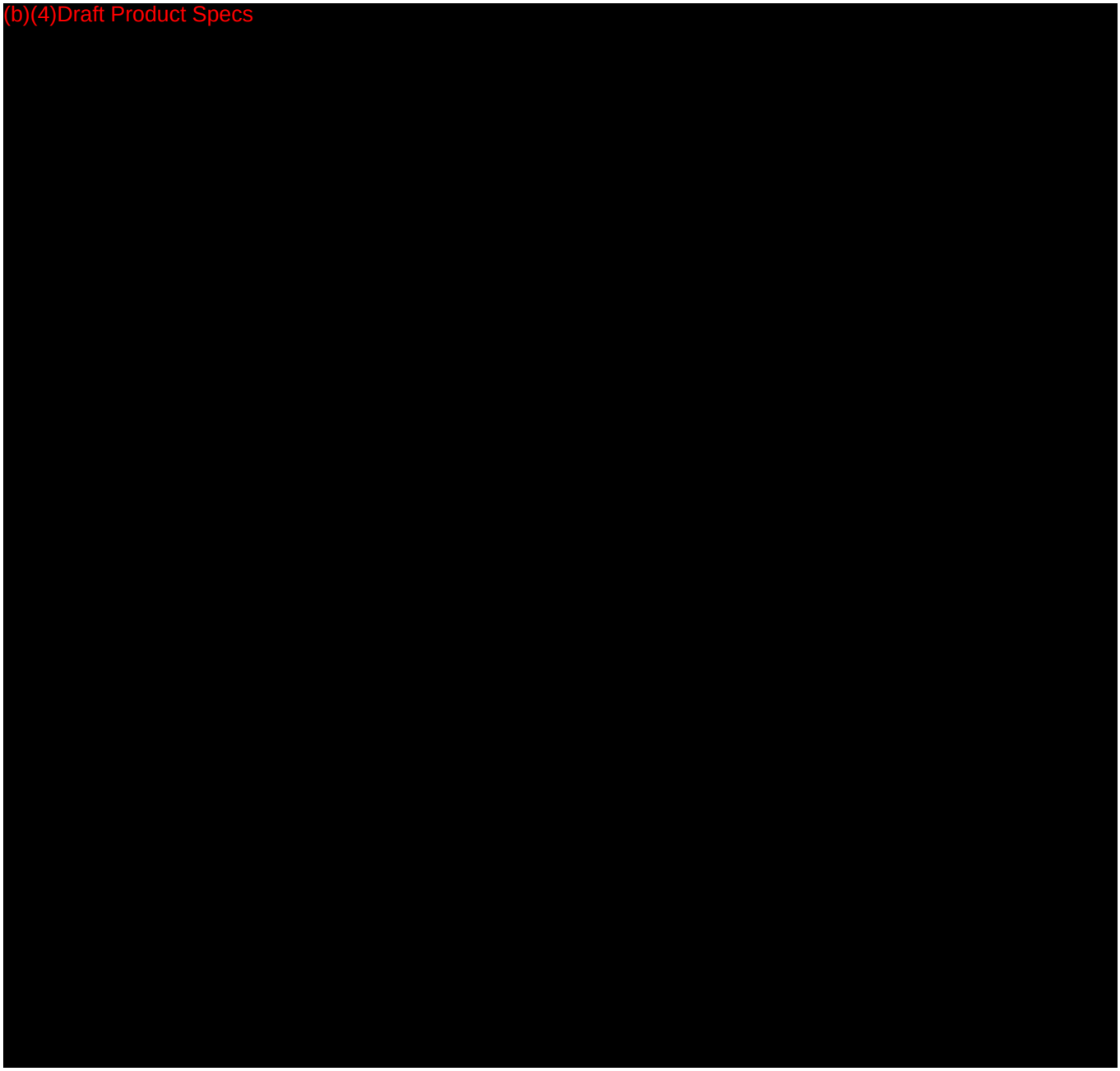

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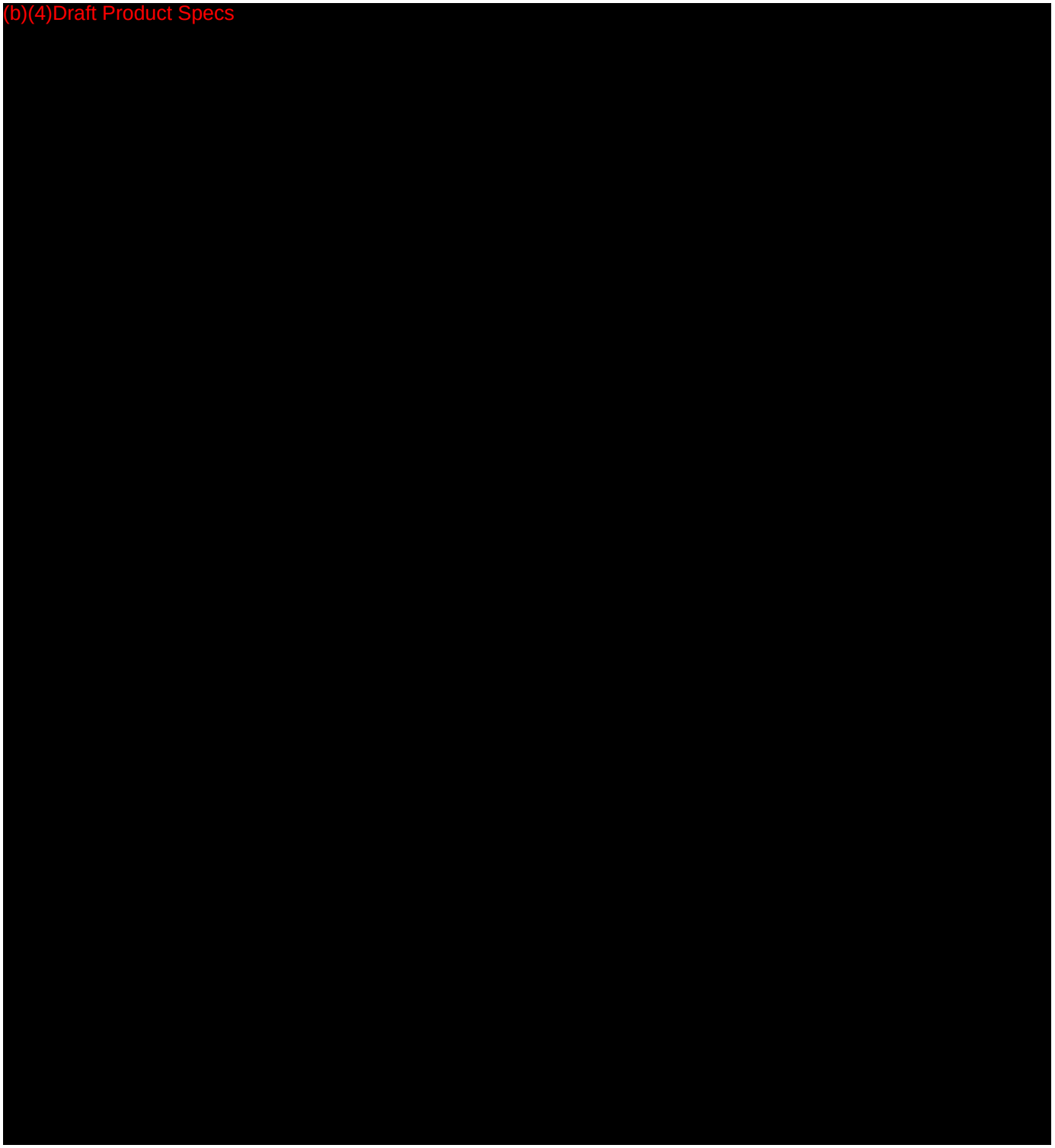

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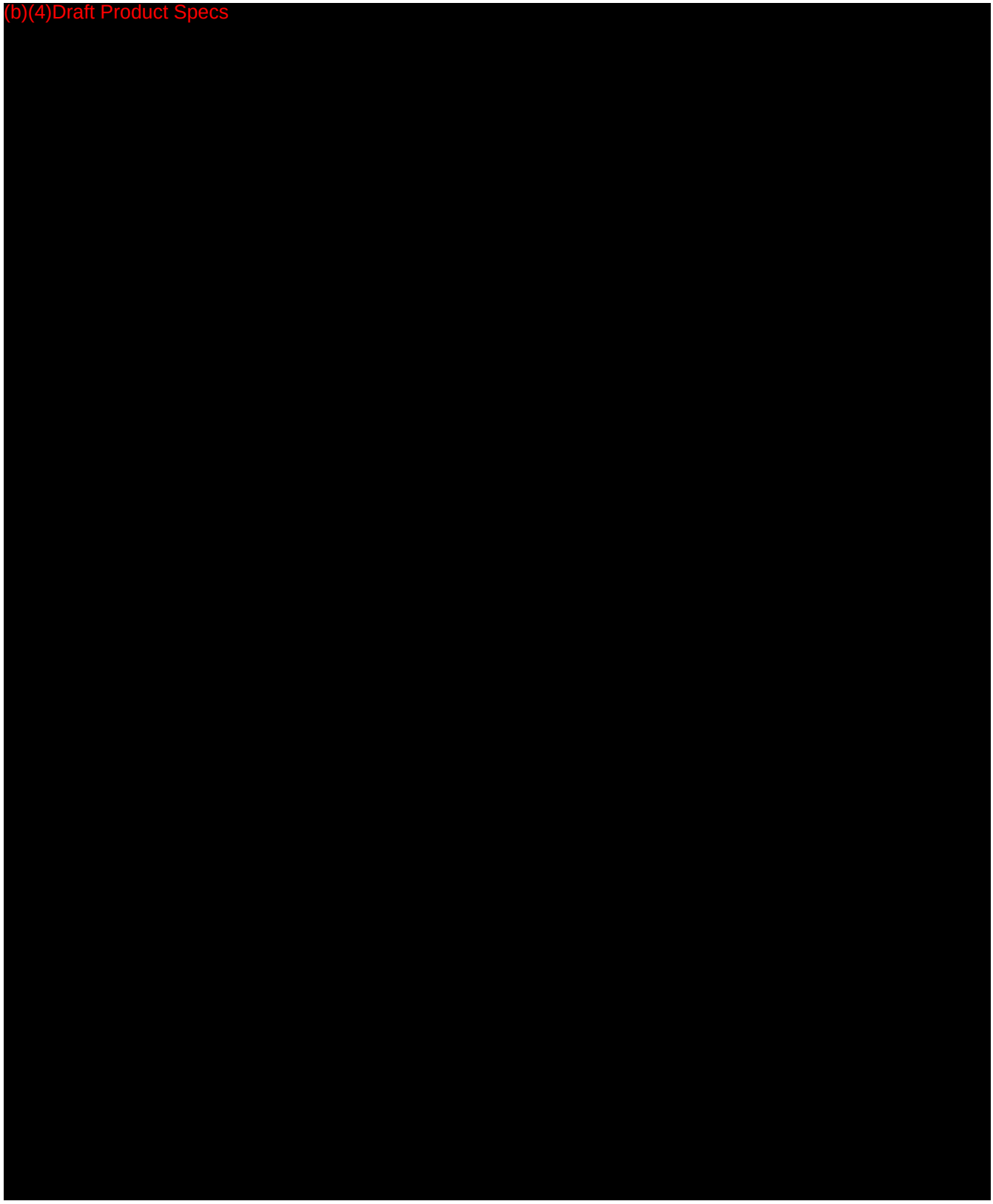

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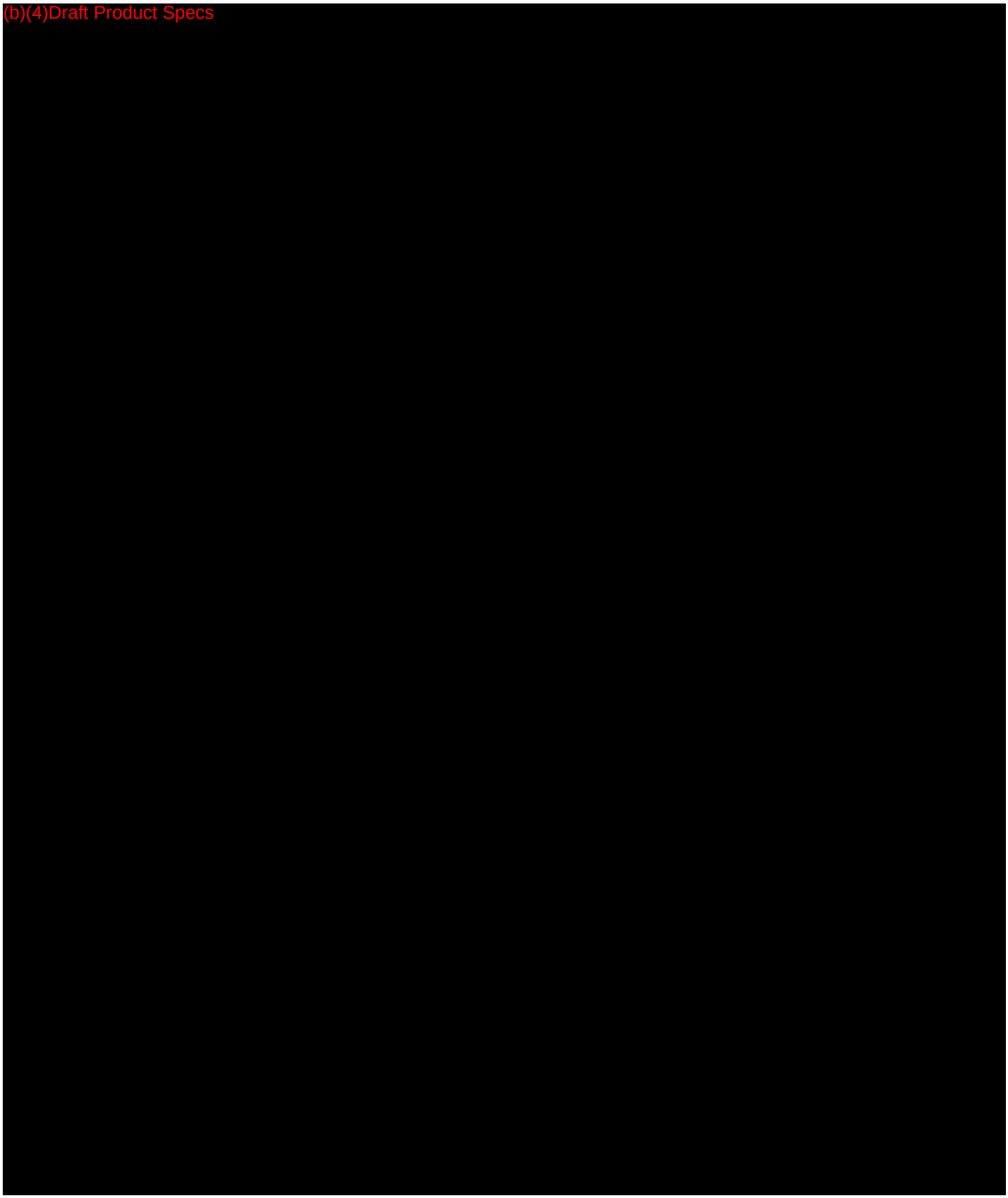

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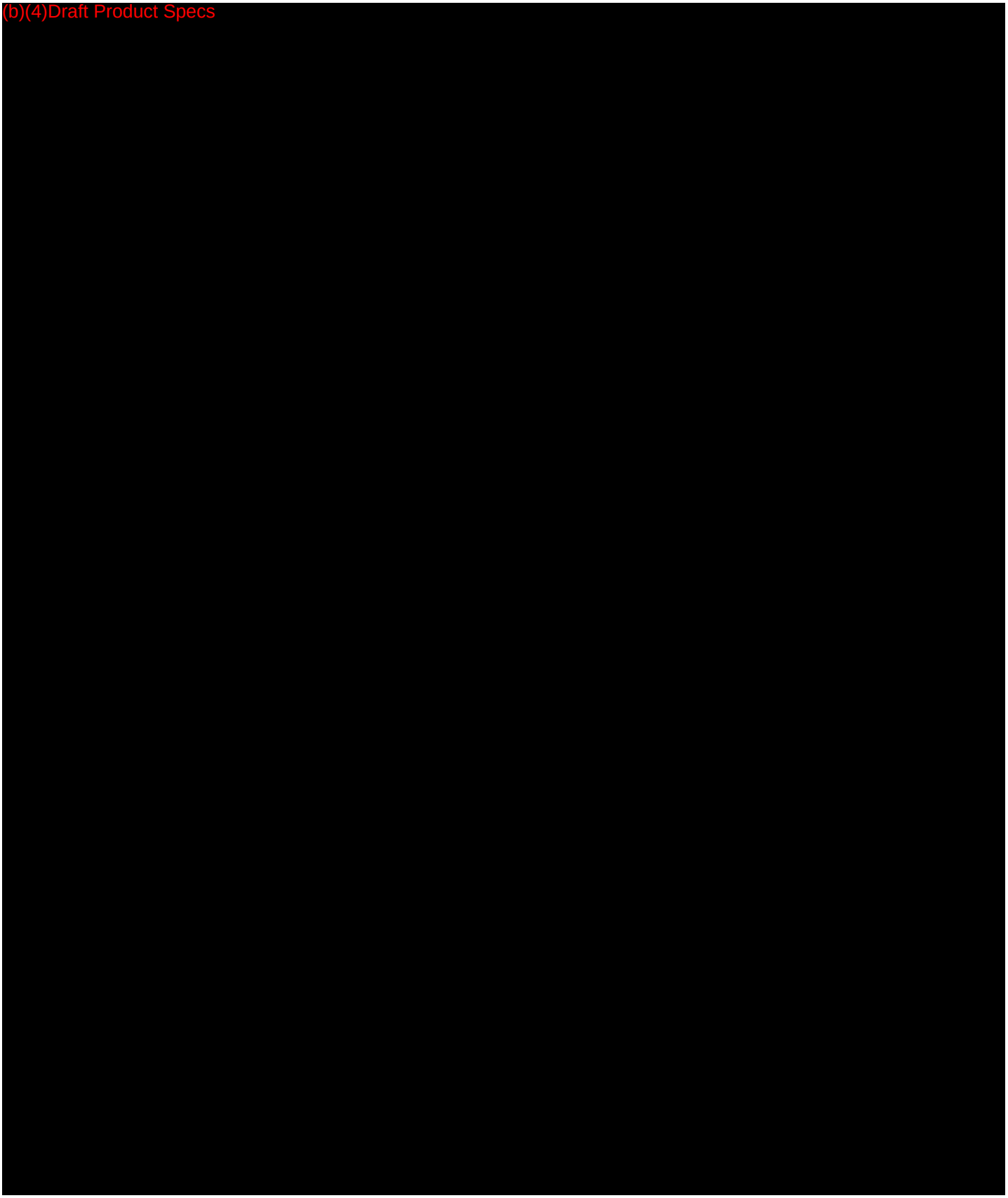

In addition to the user-specified ECG-based mA modulation, the system will also modulate the

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The Discovery™ CT870 system reconstructs axial and continuous images of 512 x 512 pixels.

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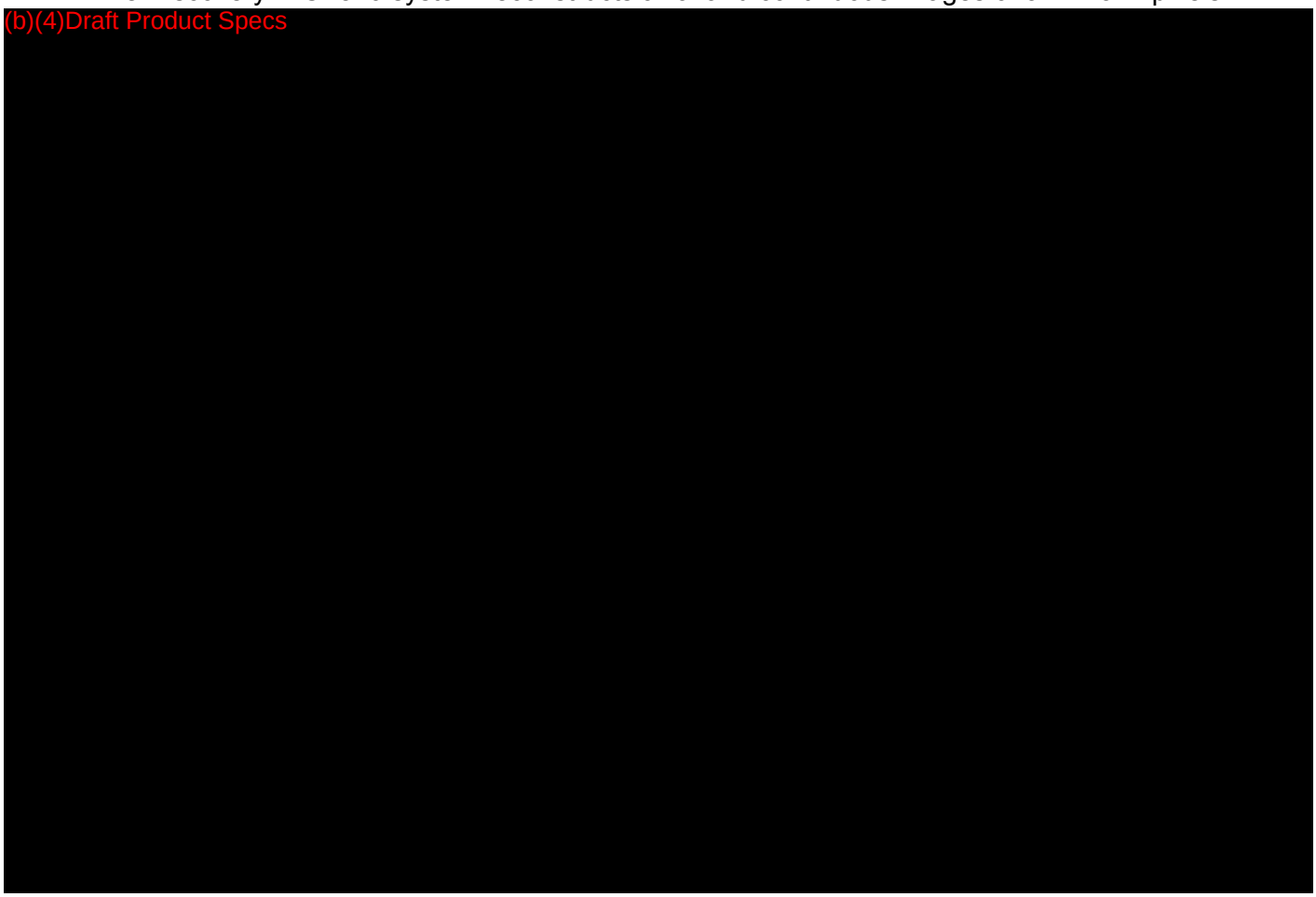

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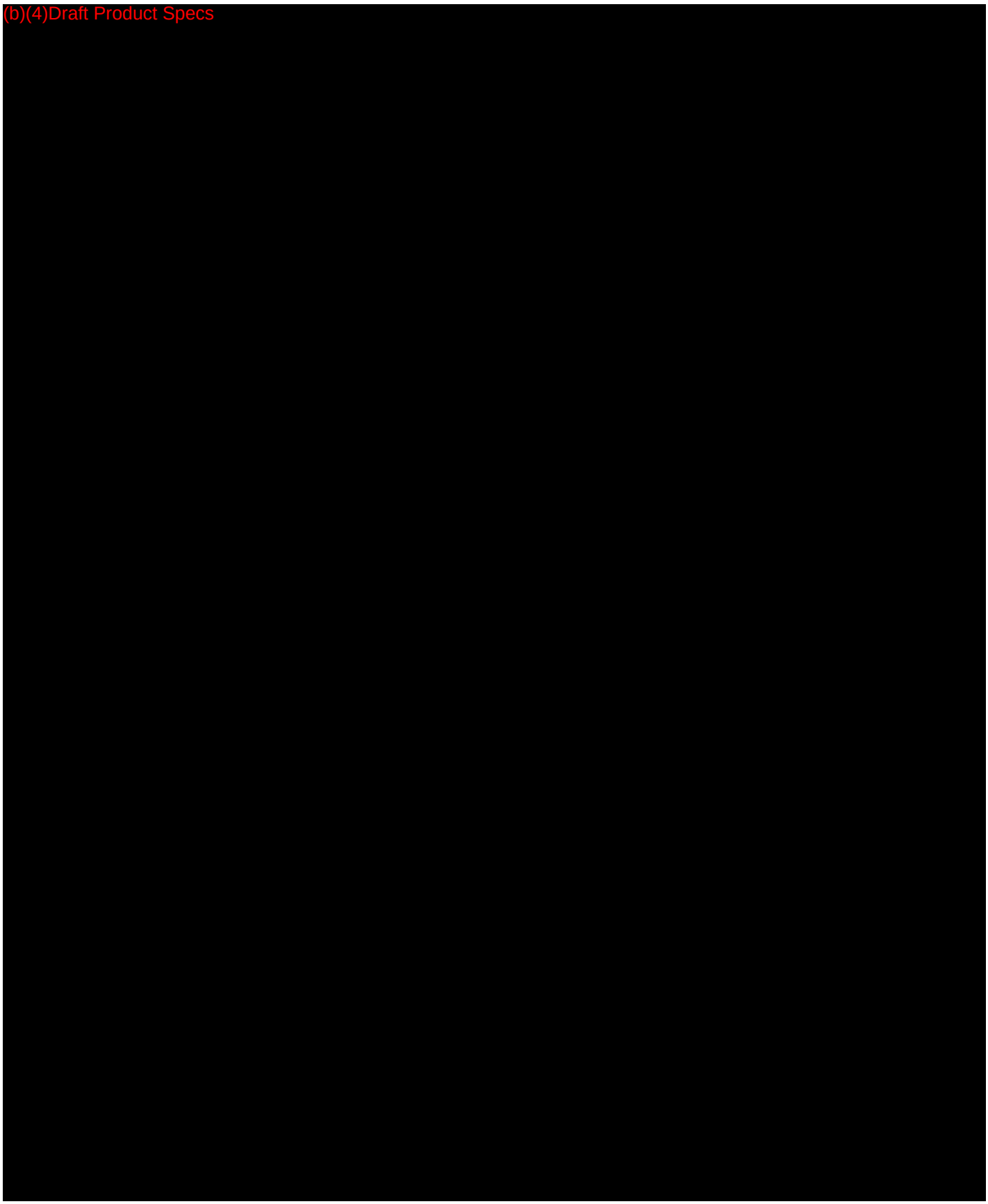

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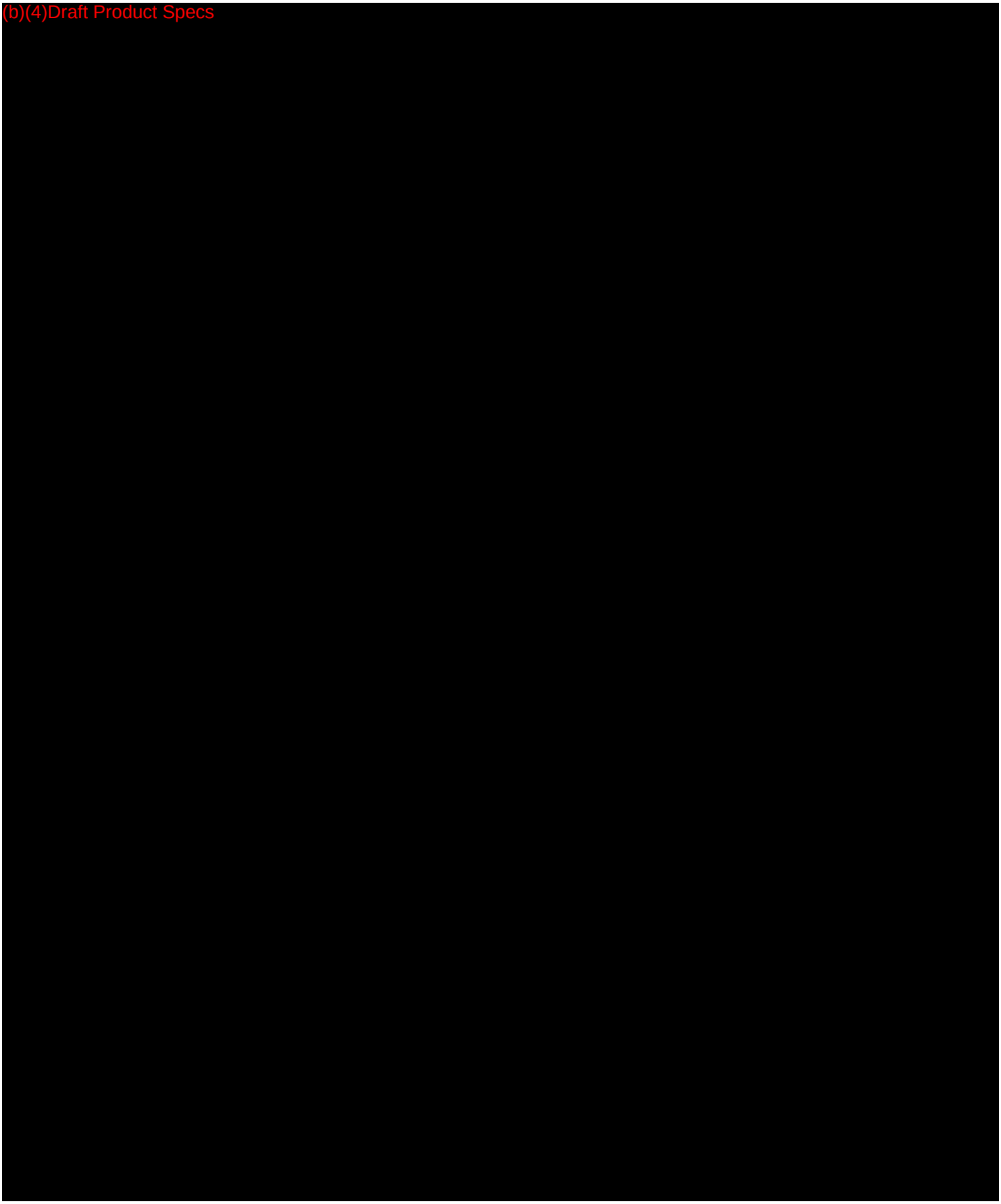

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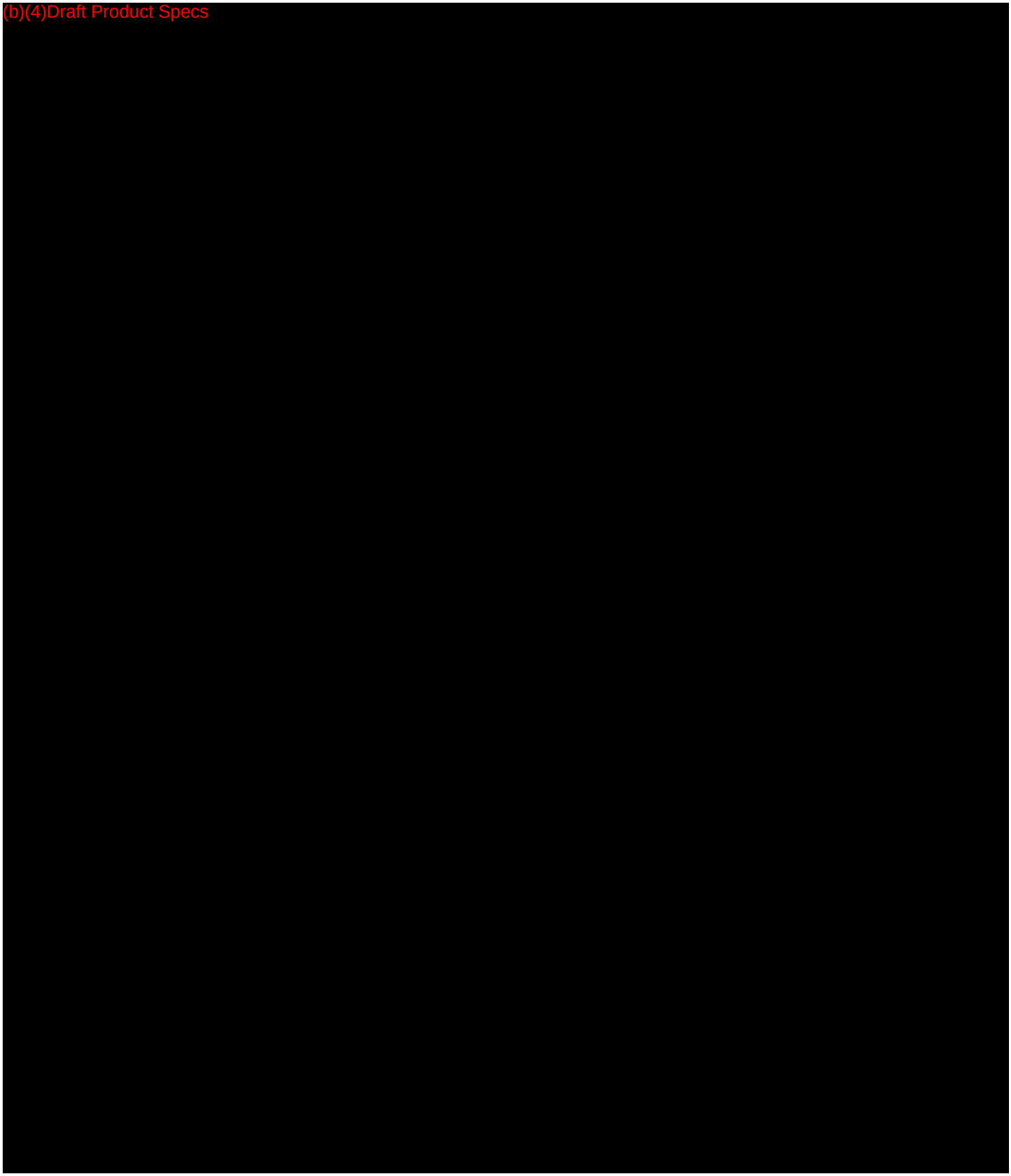

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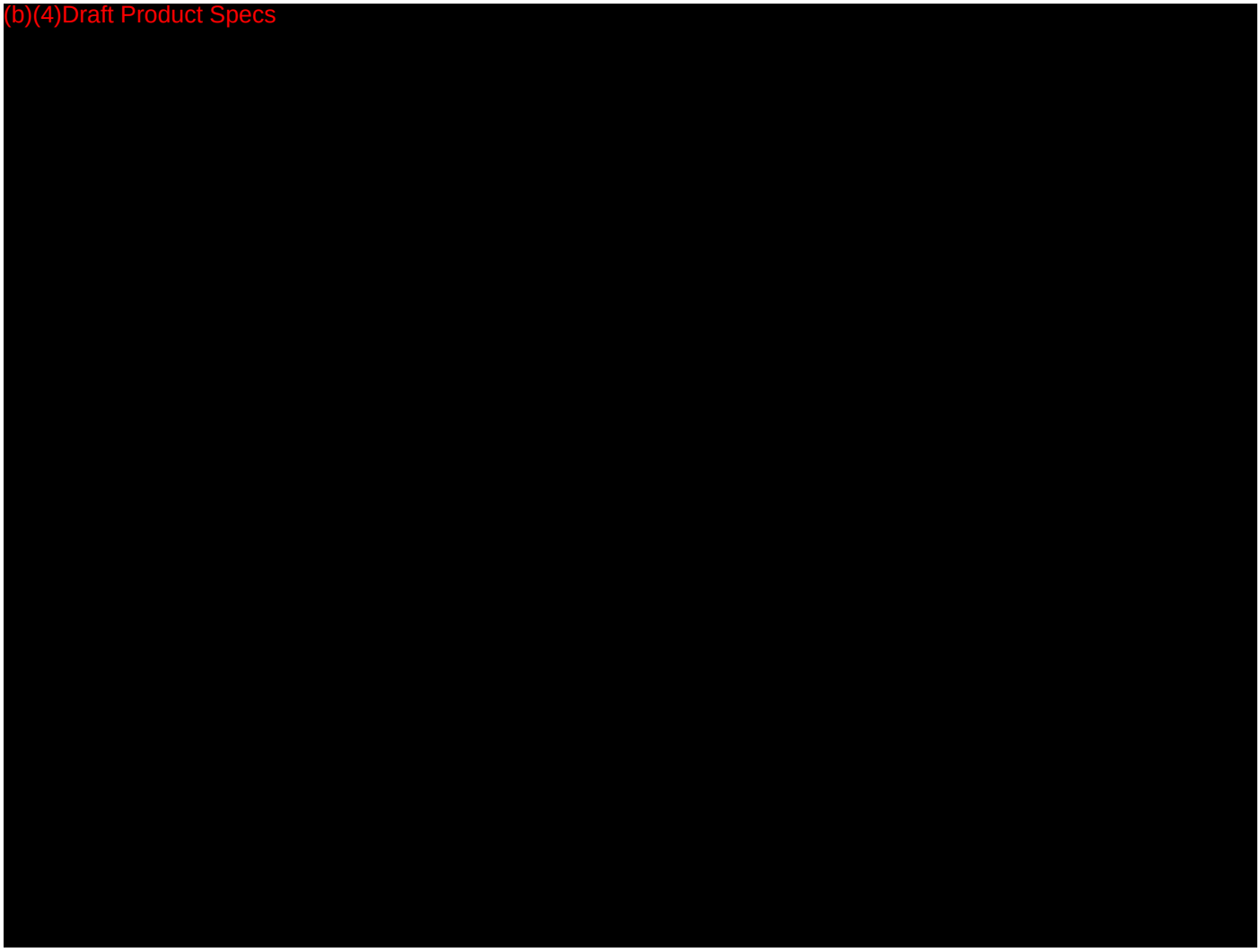

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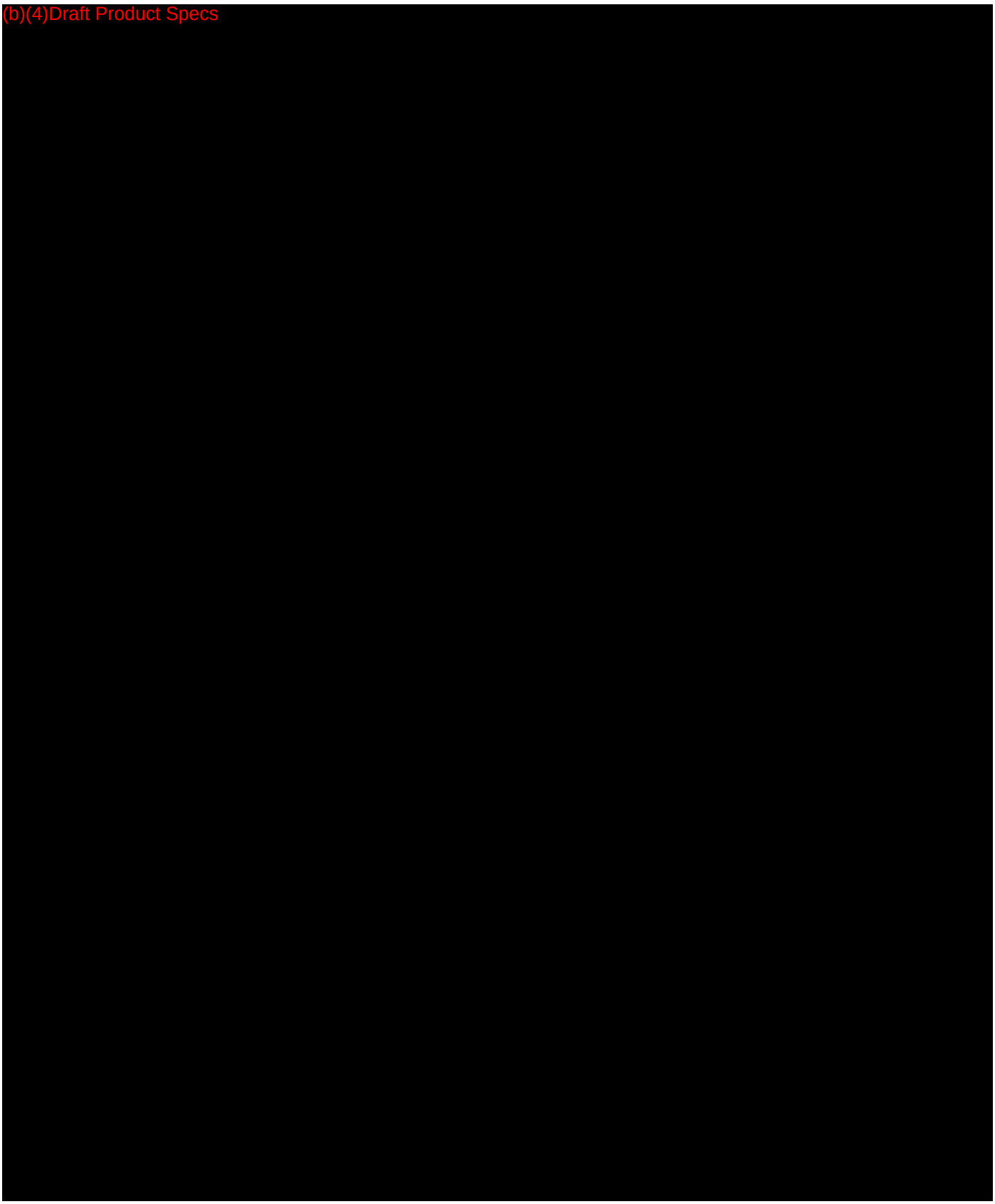

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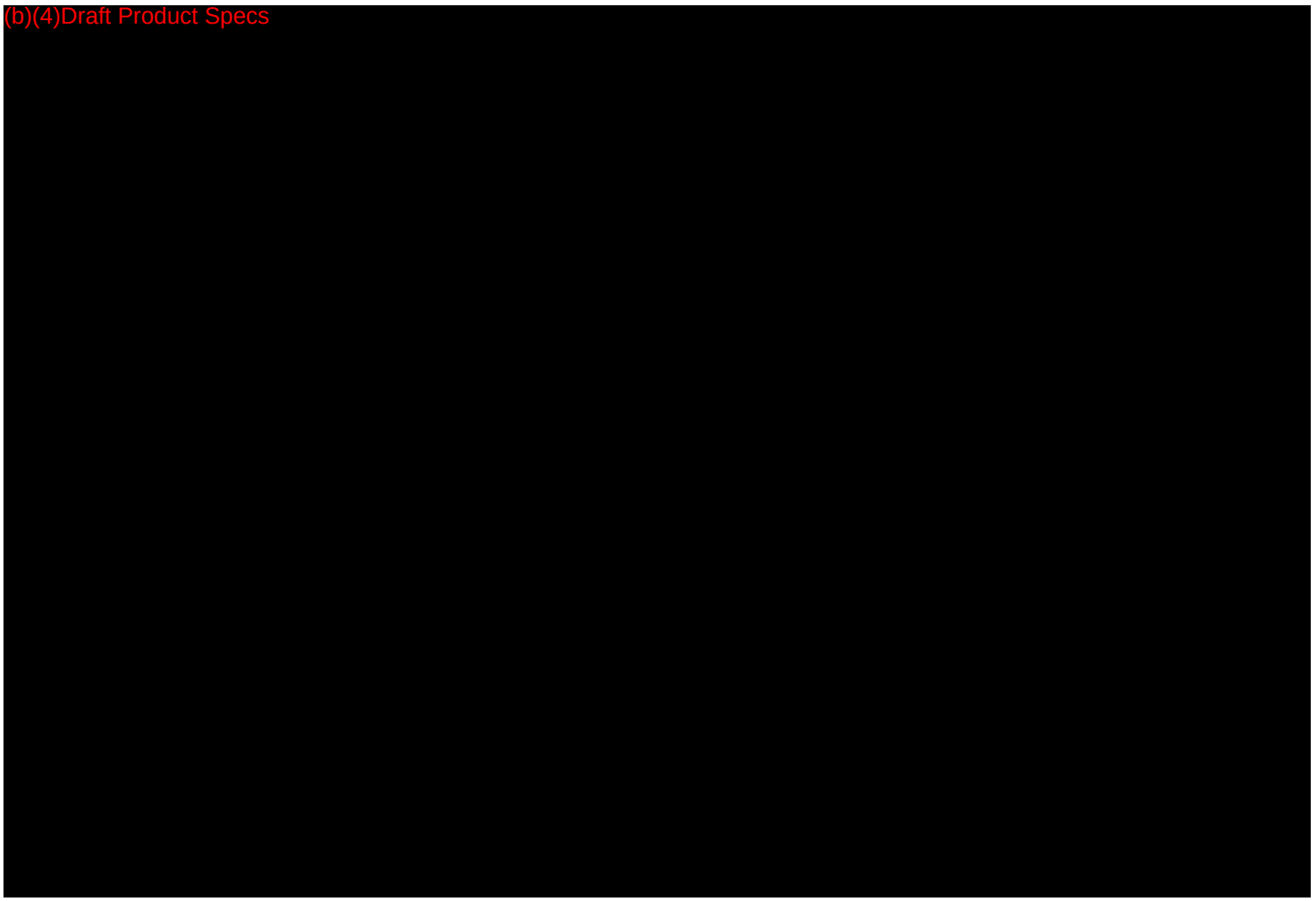

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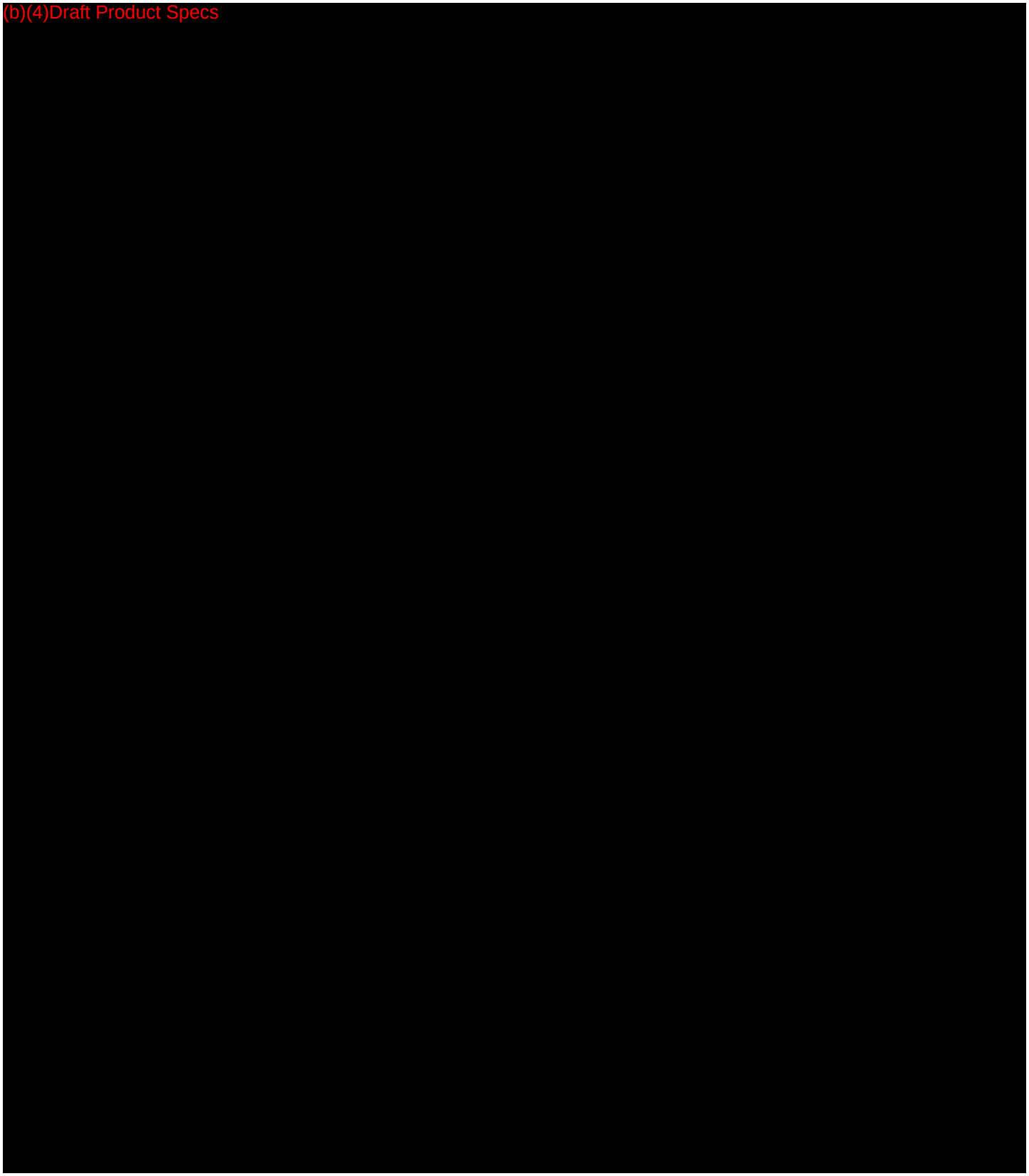

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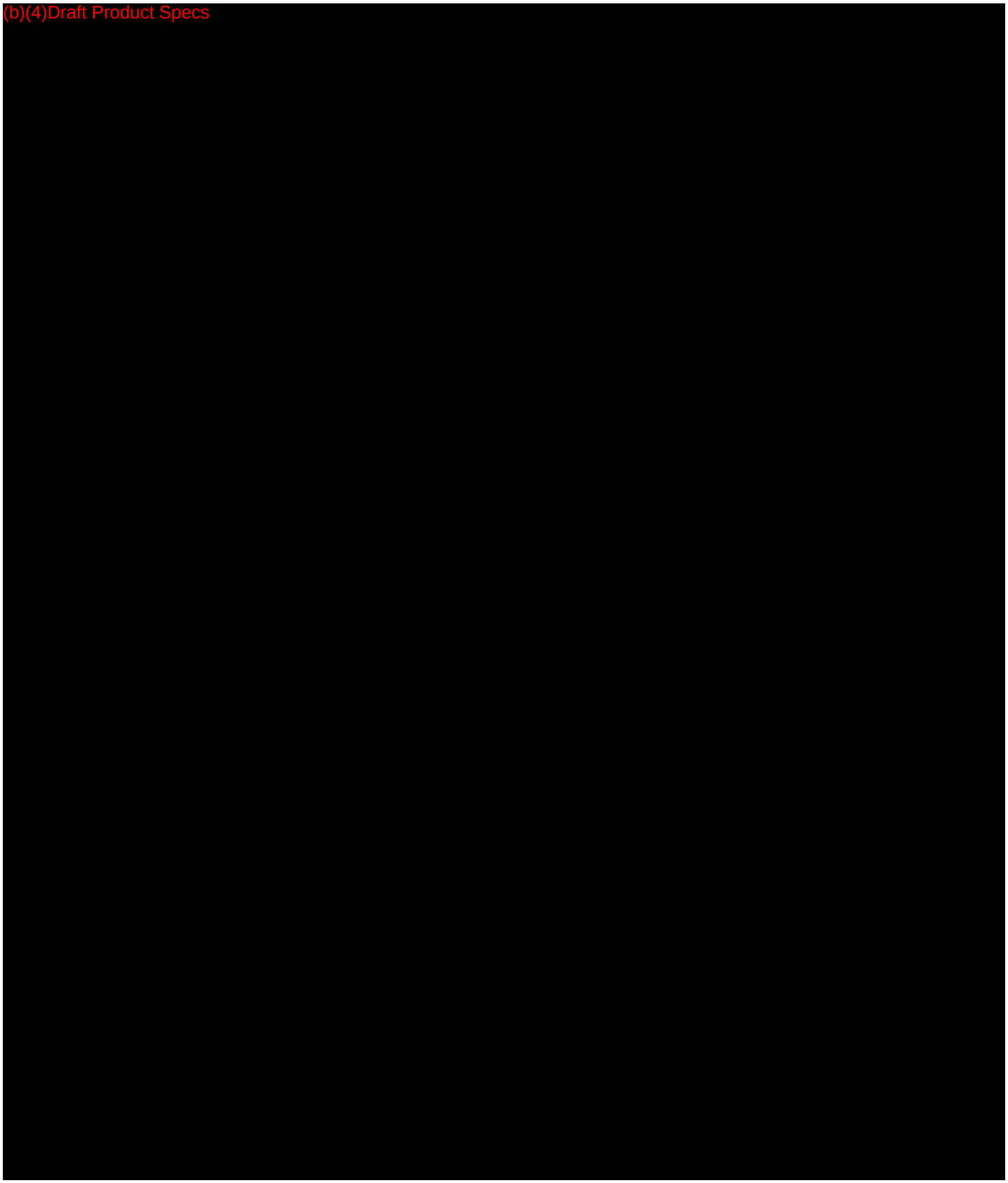

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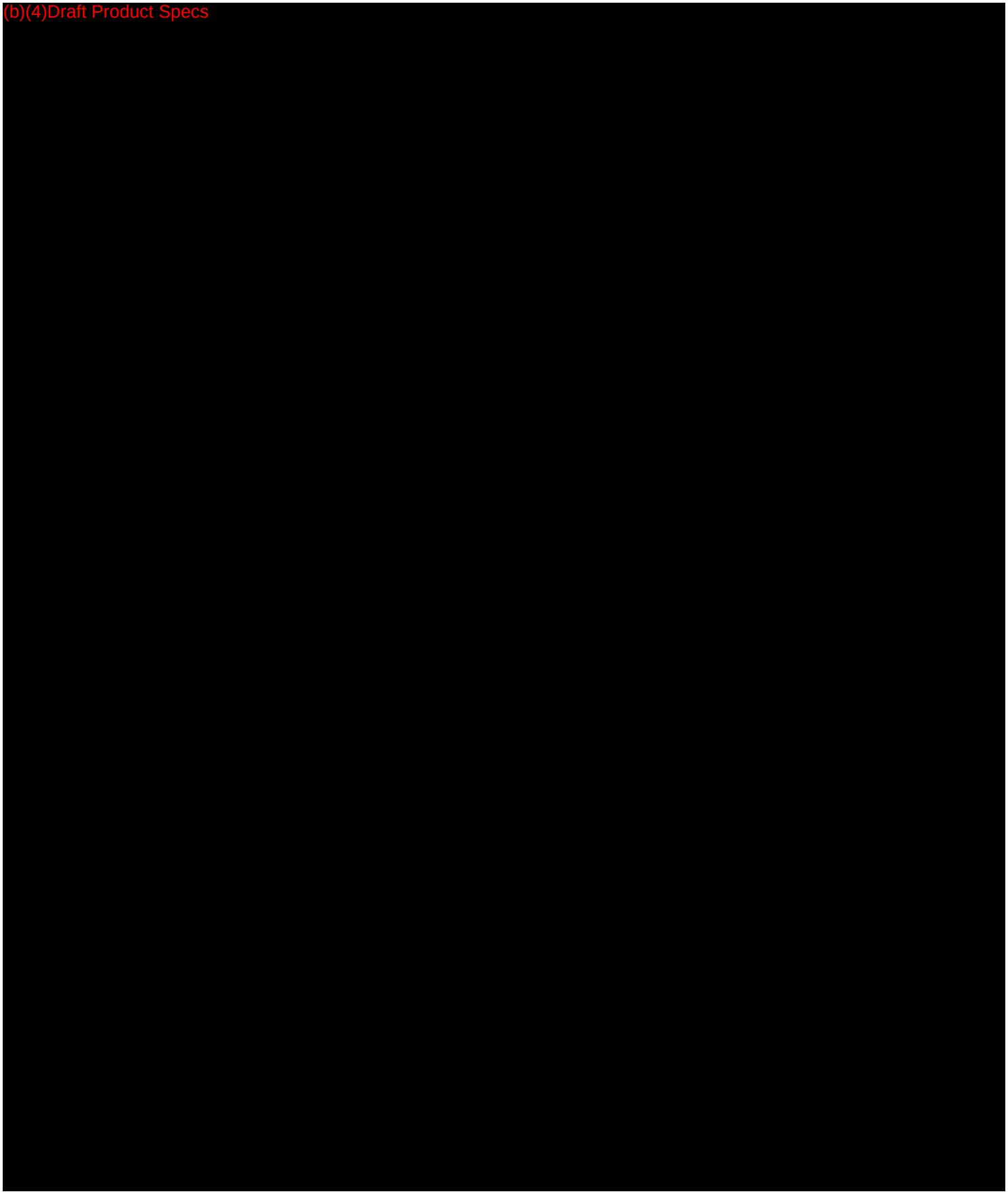

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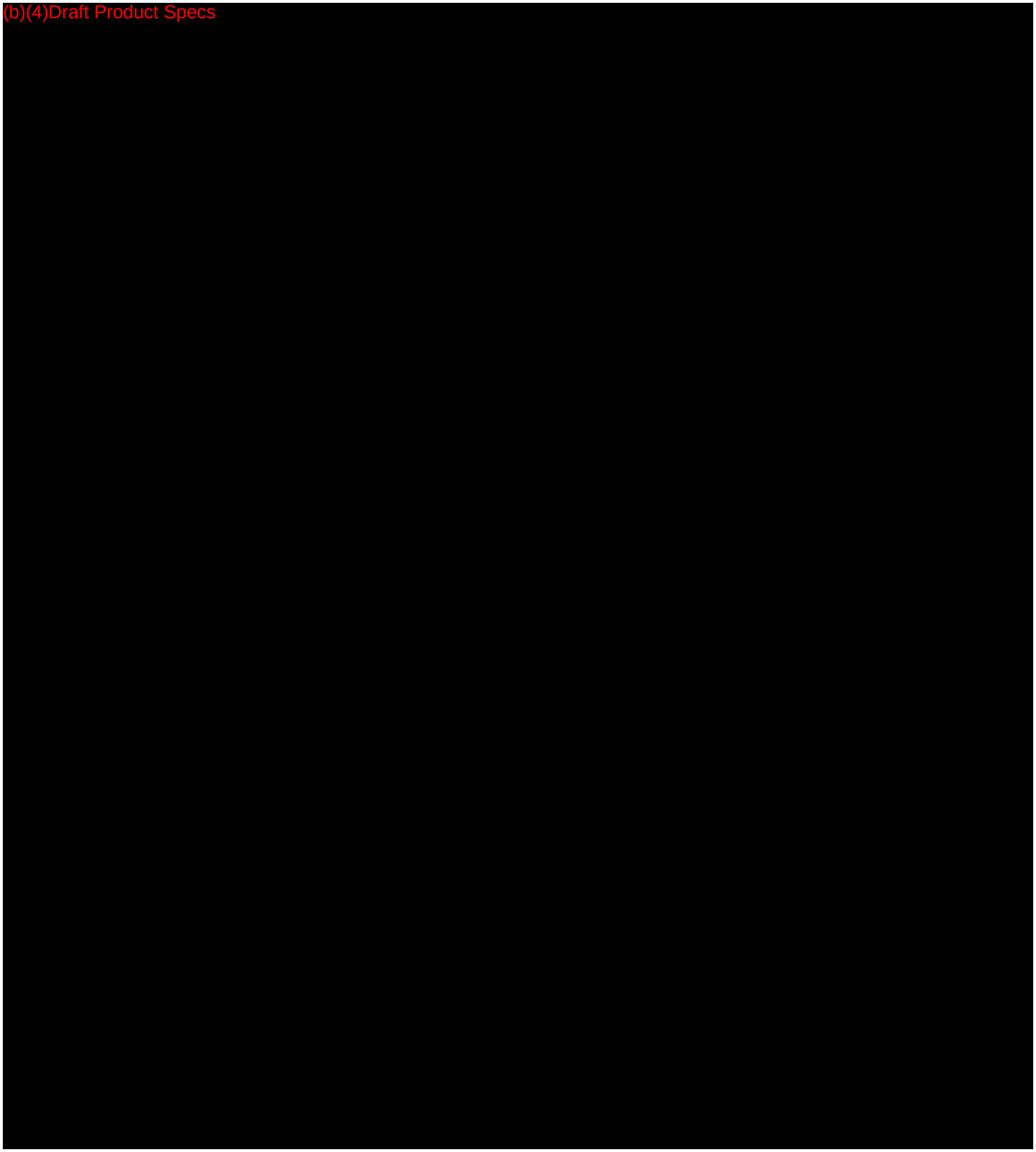

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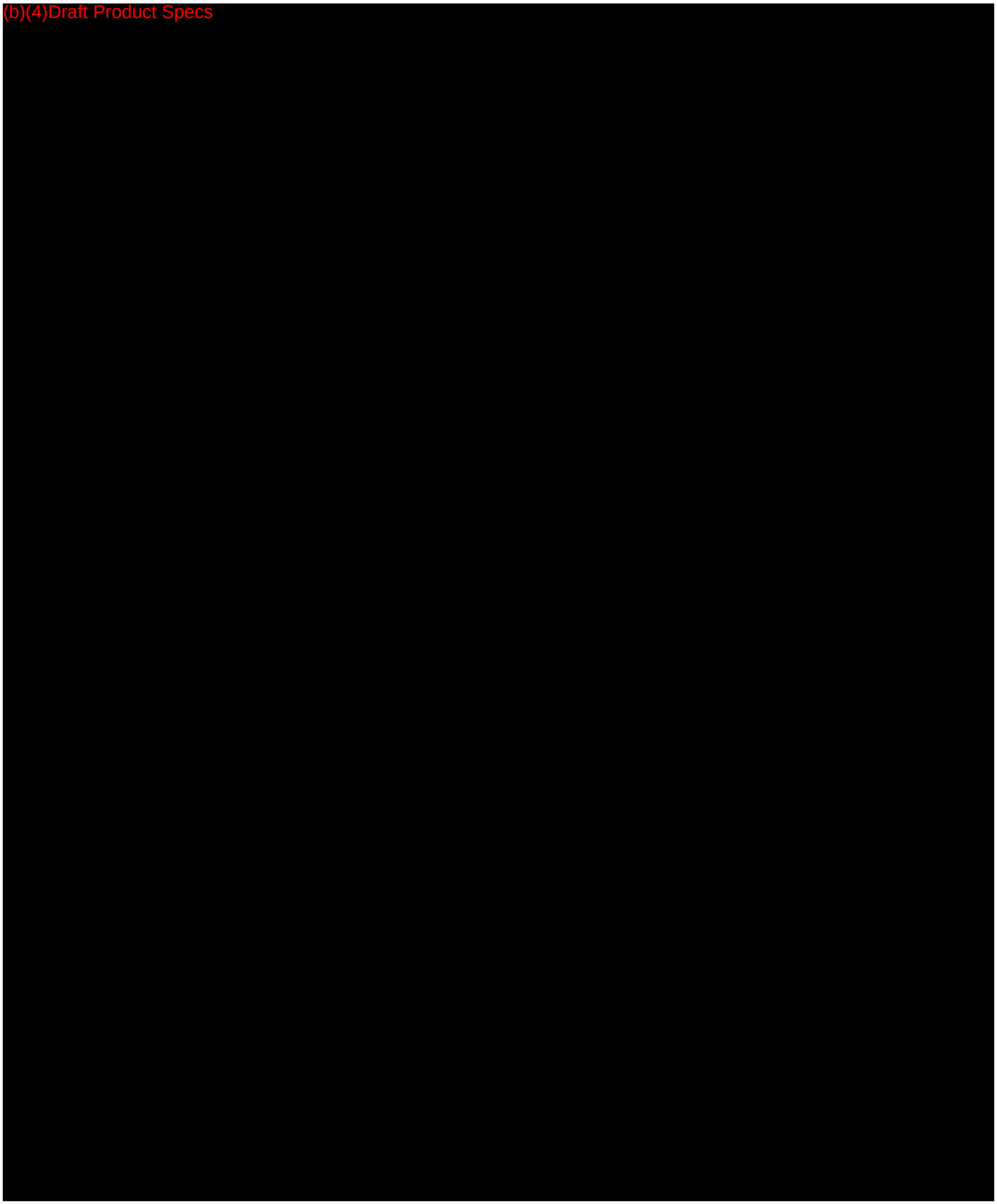

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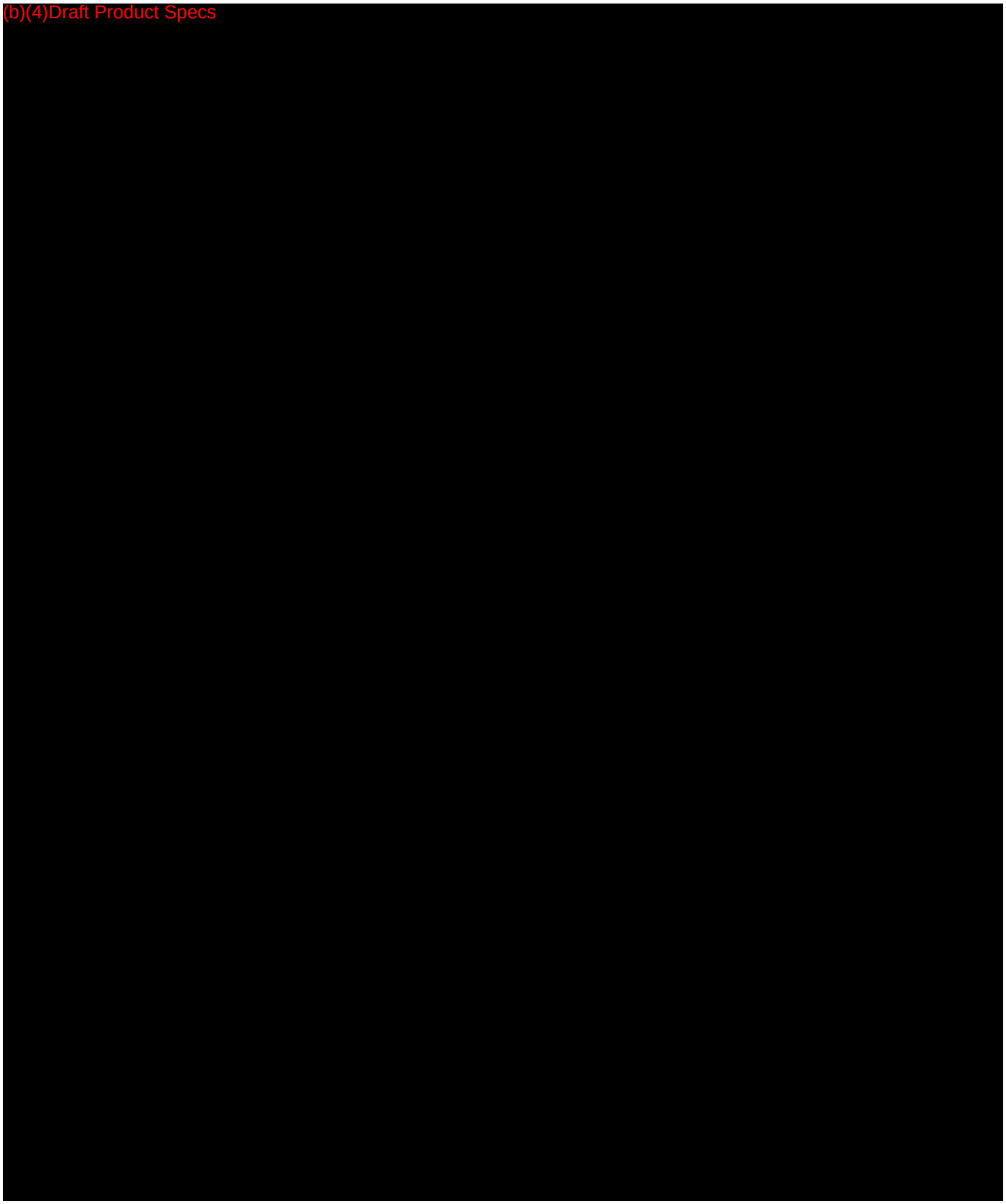

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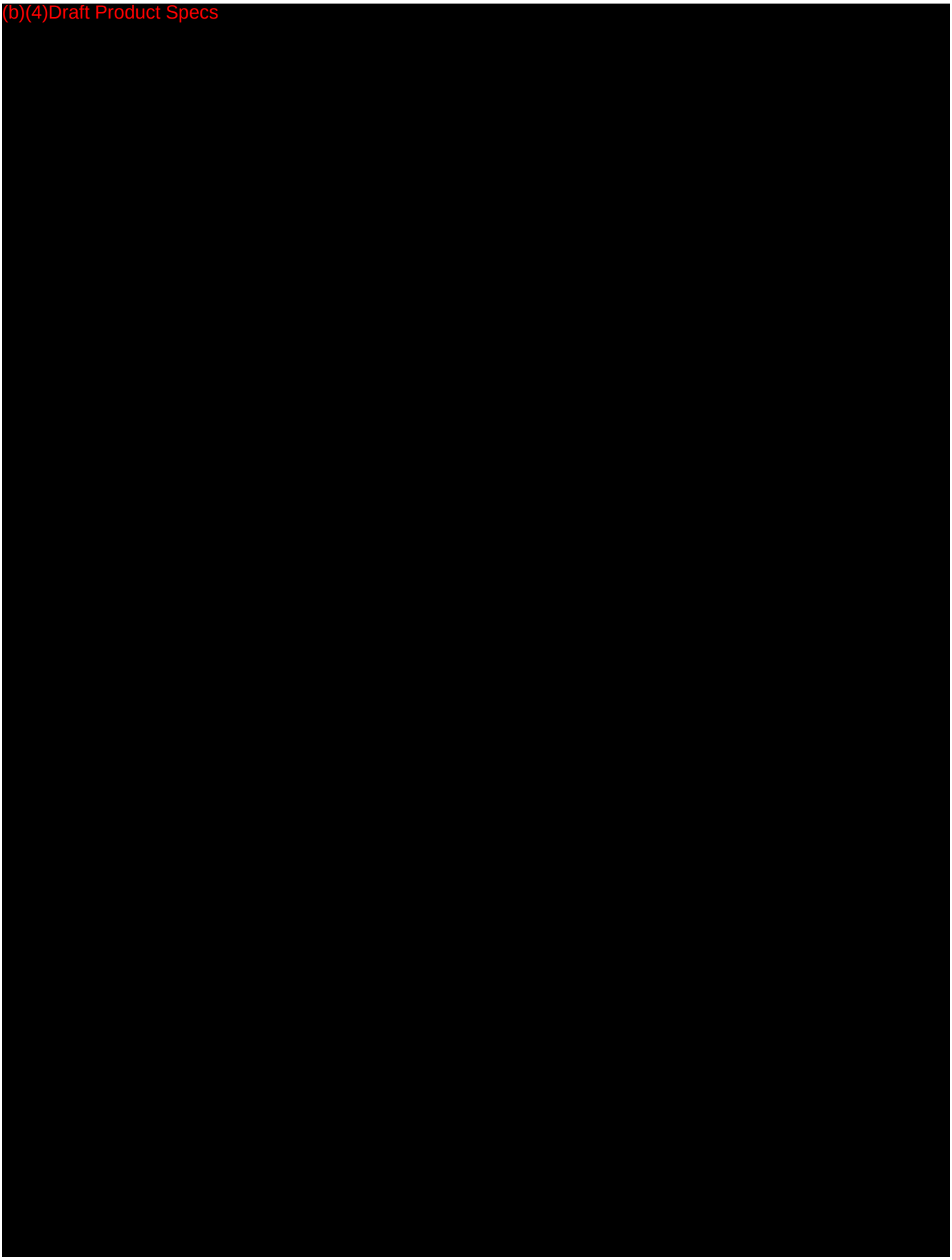

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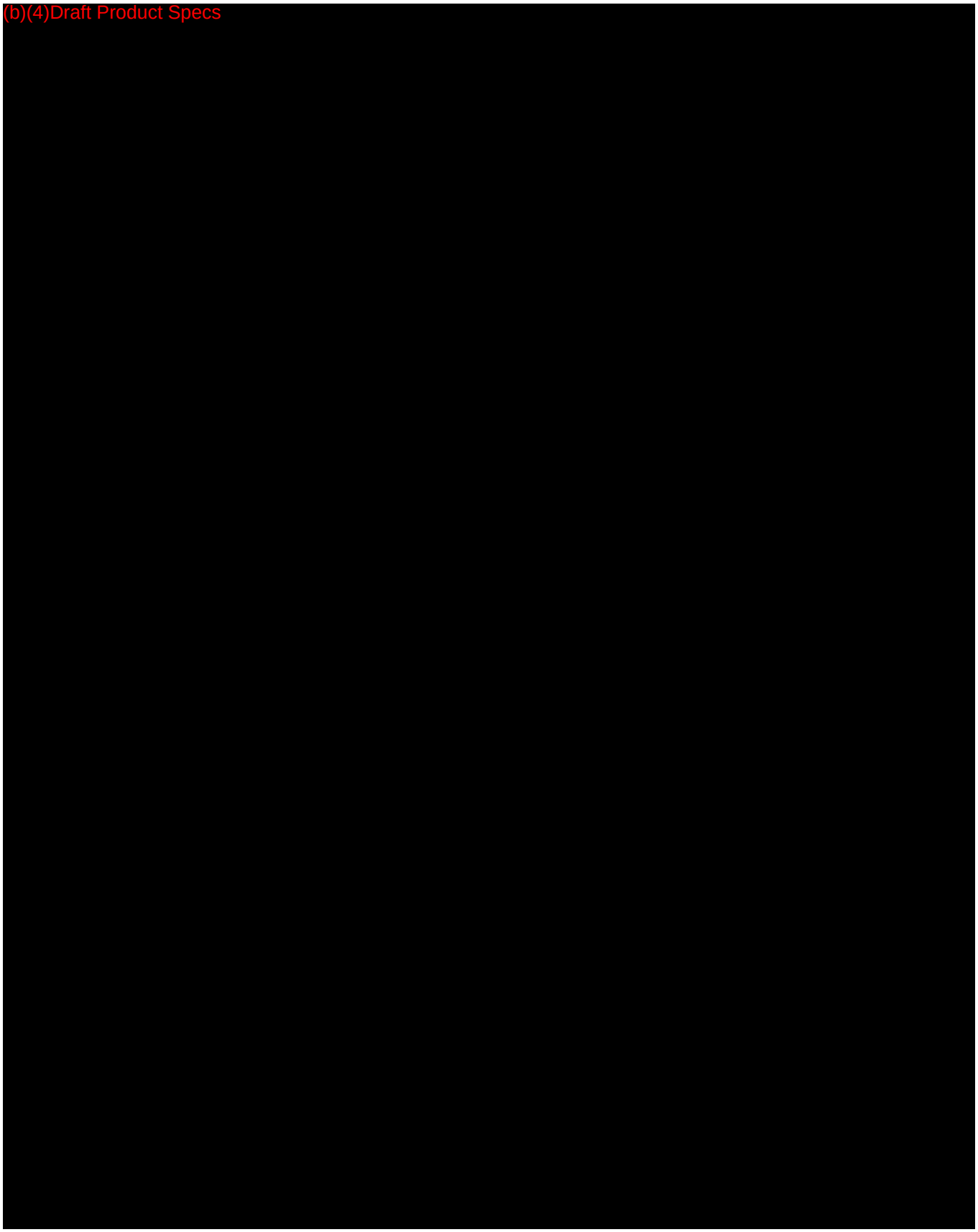

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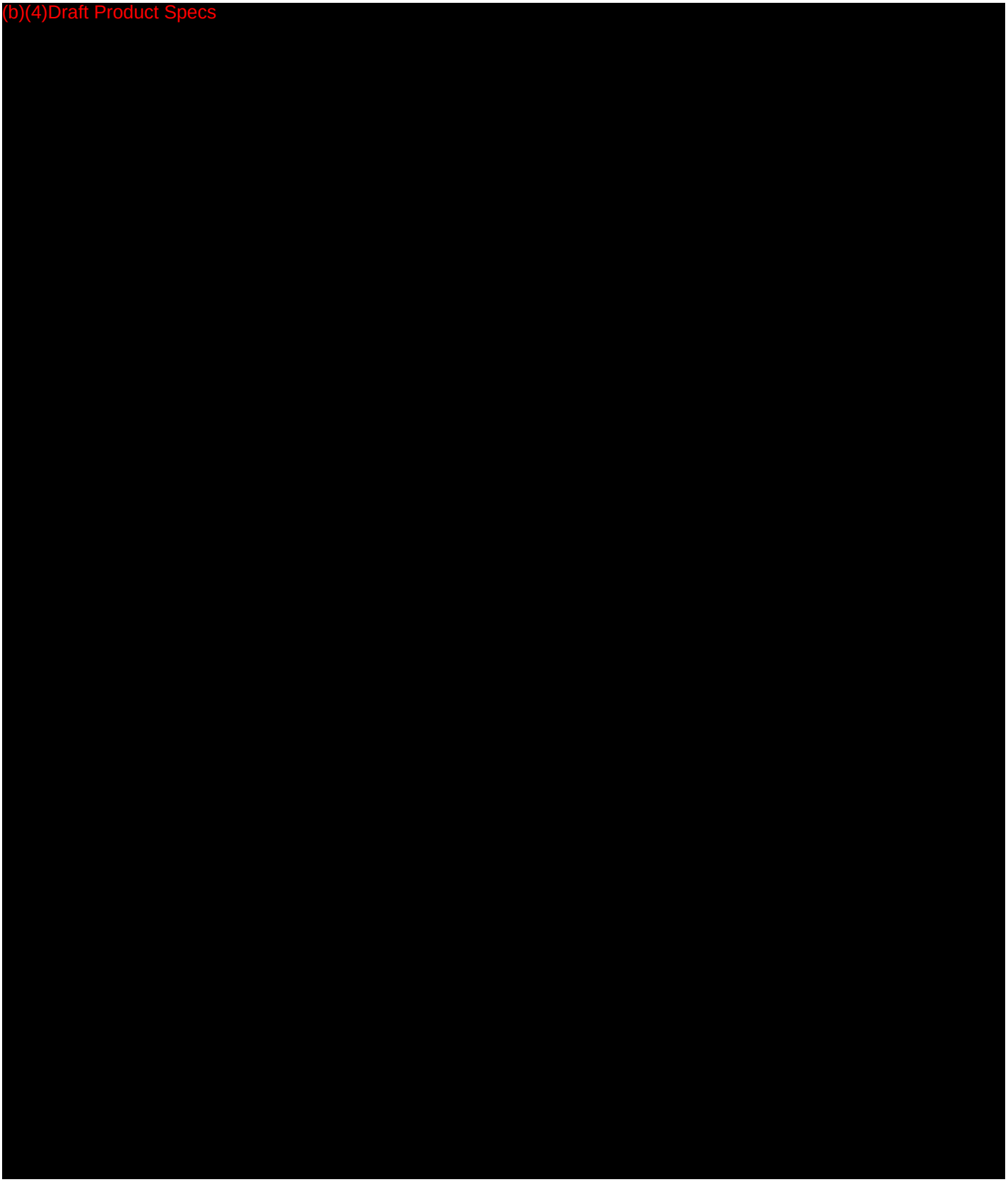

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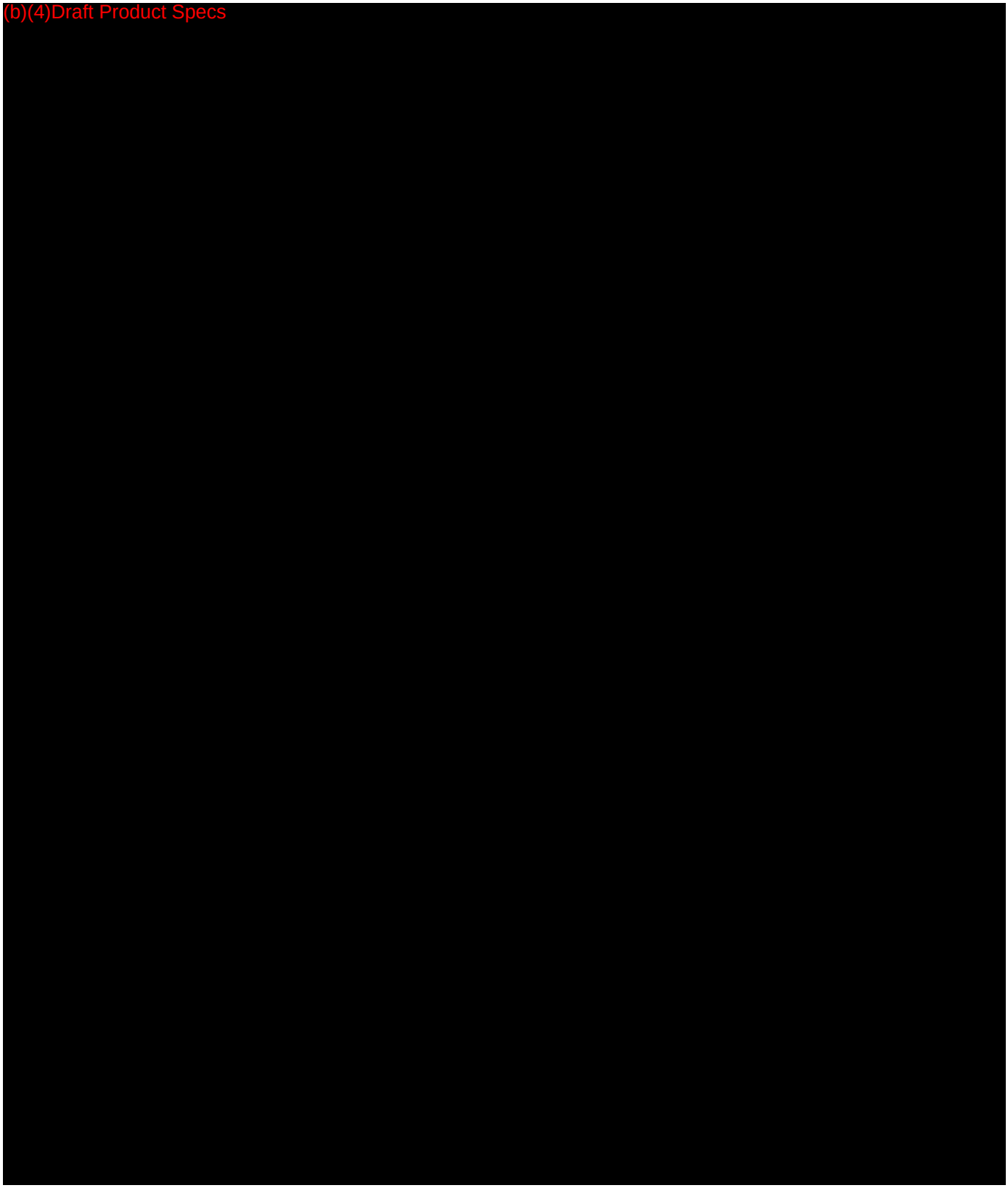

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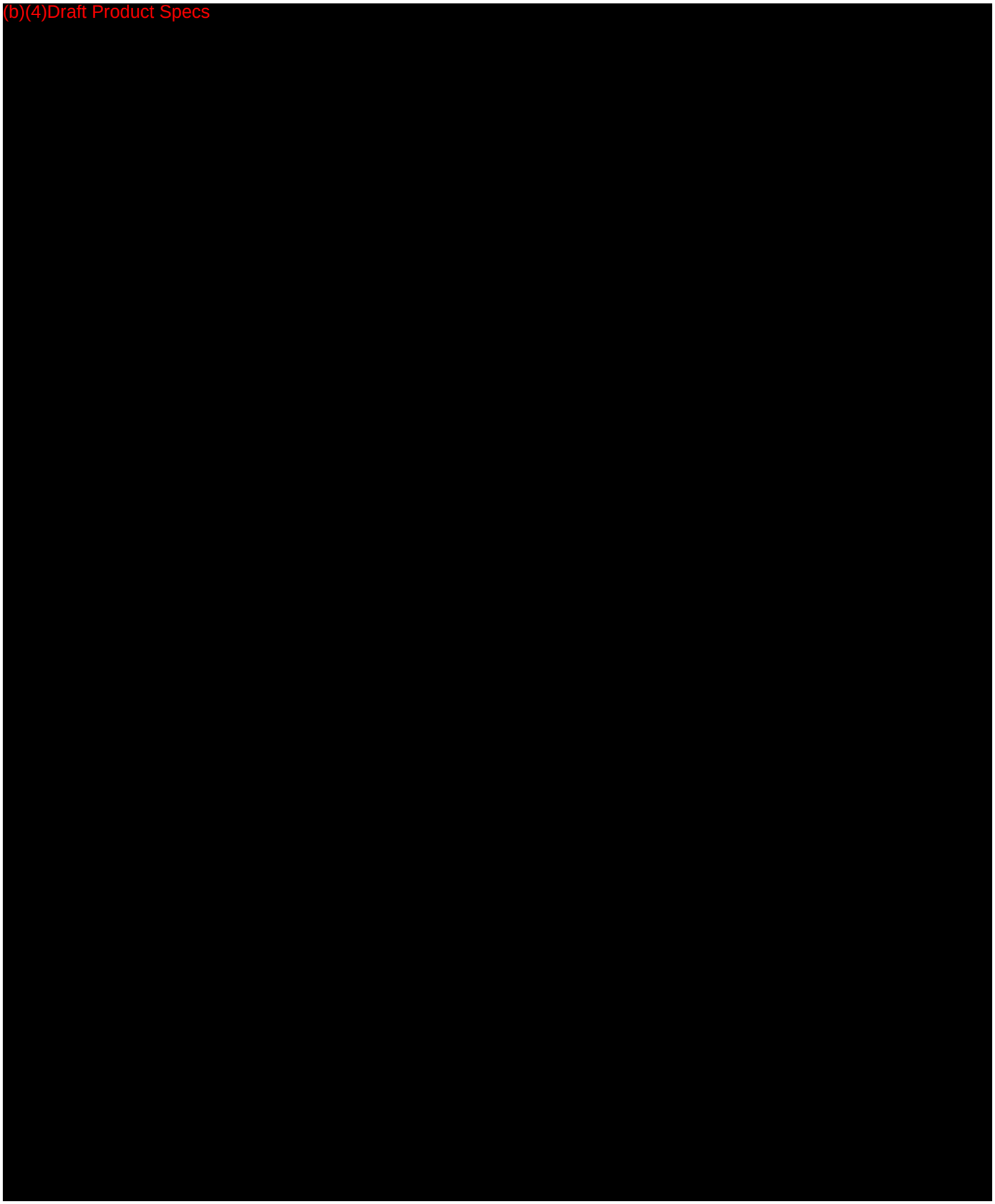

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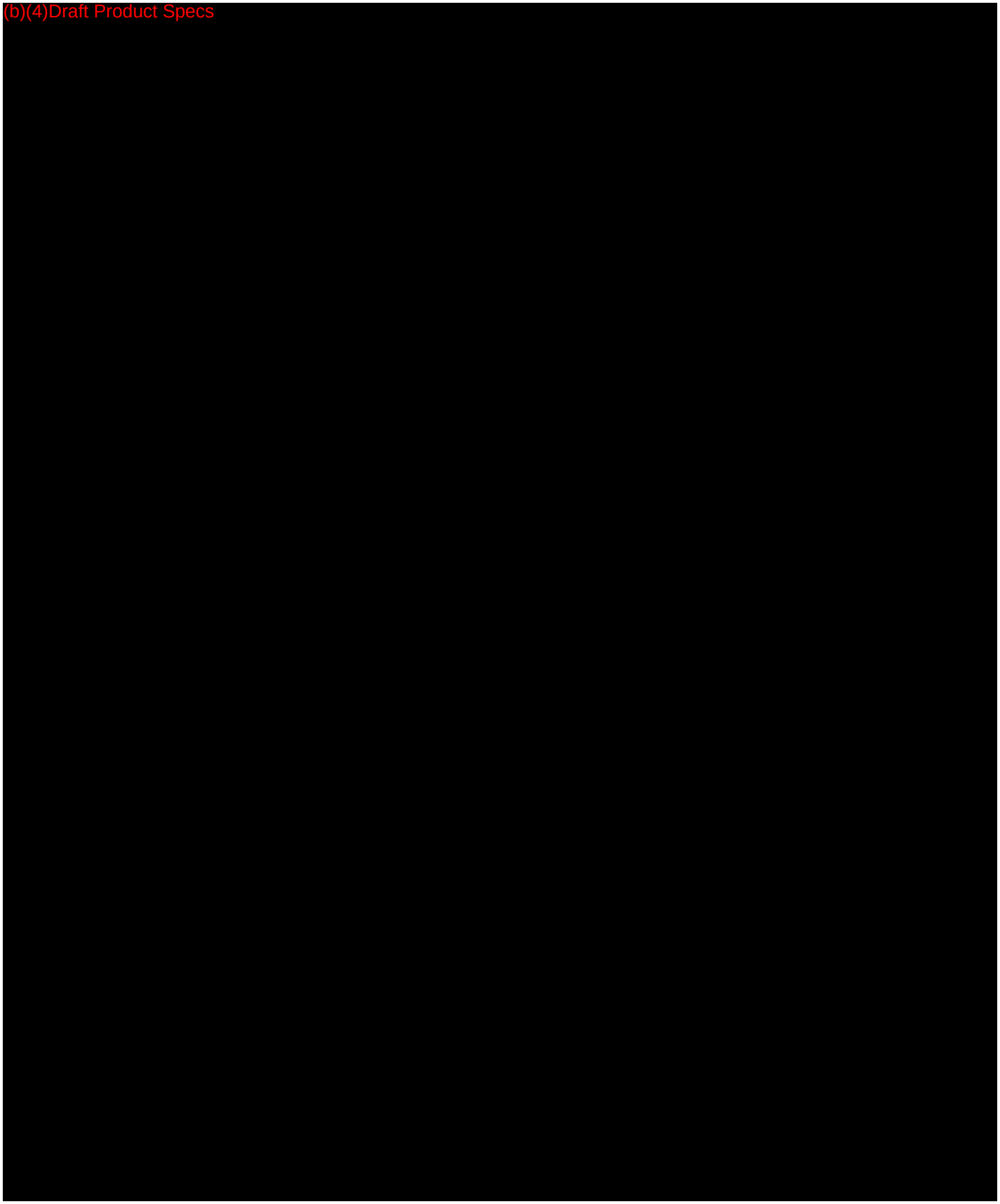

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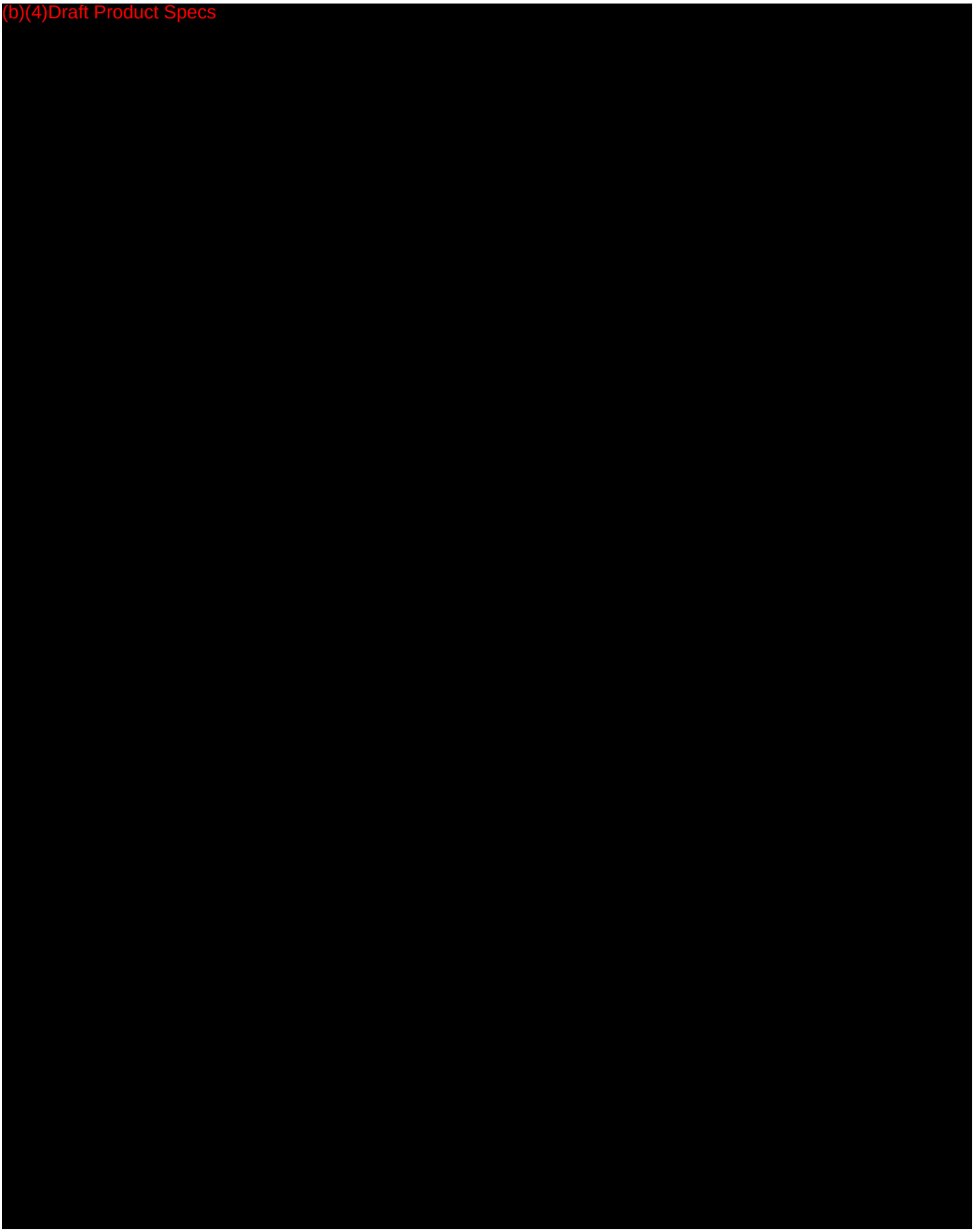

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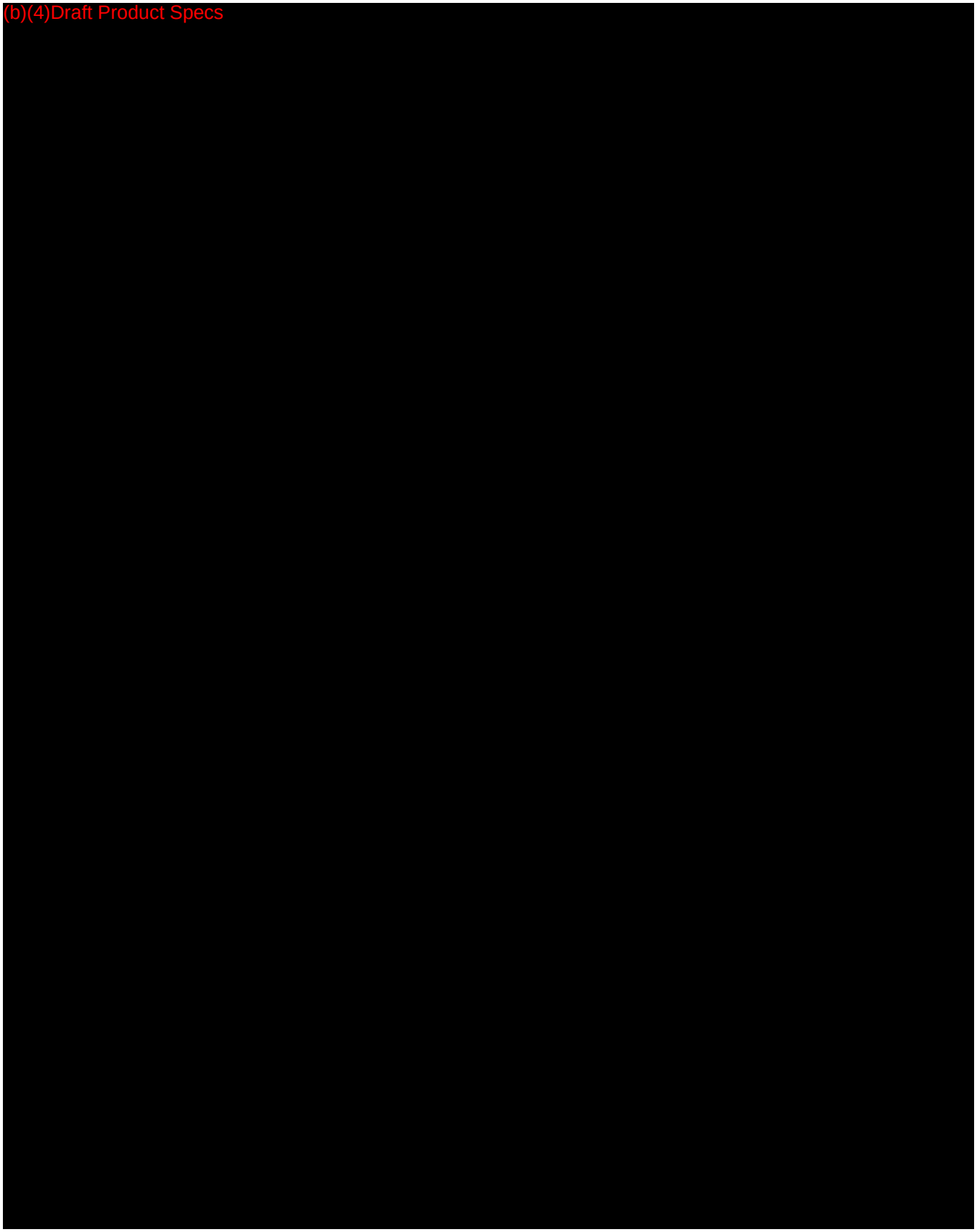

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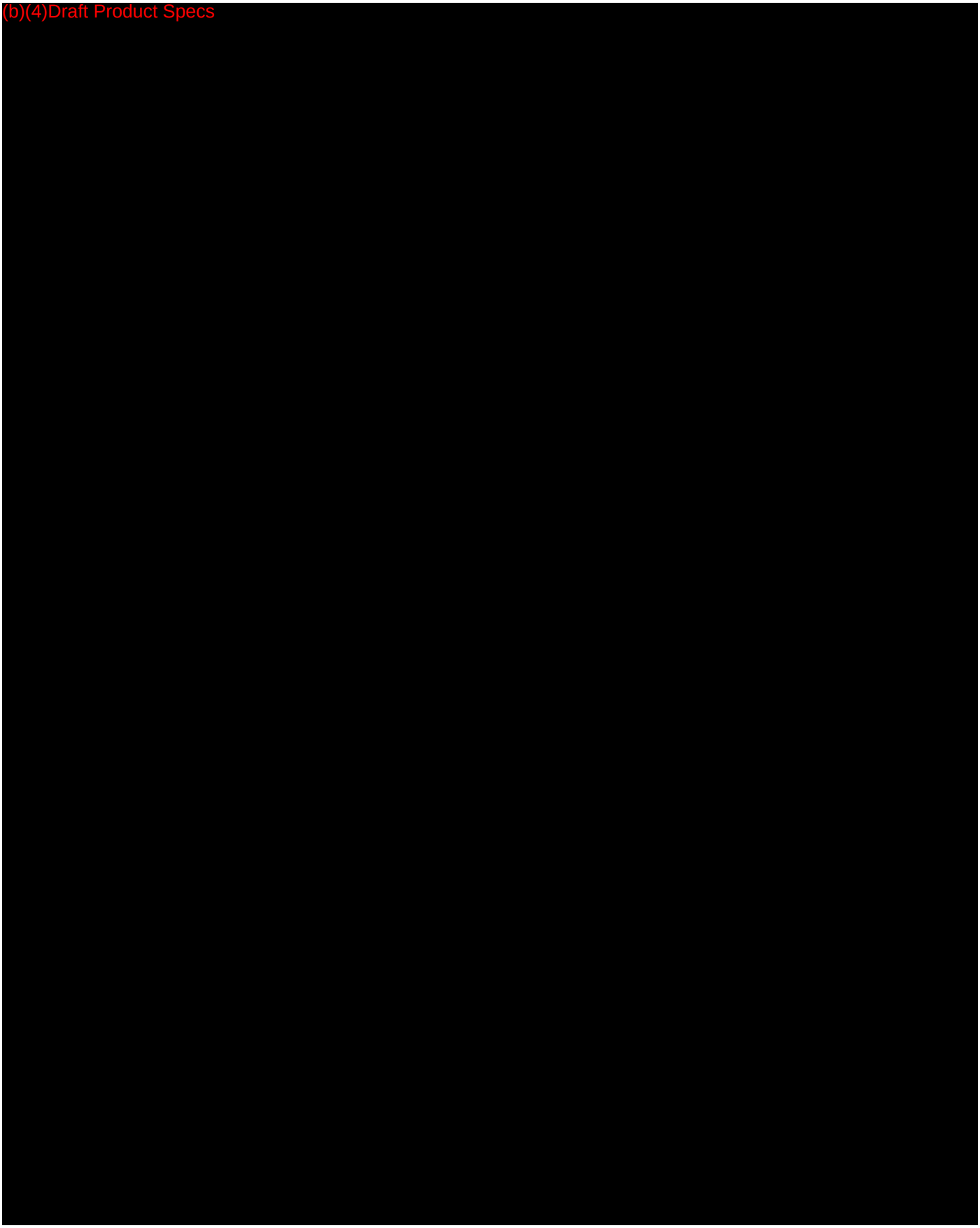

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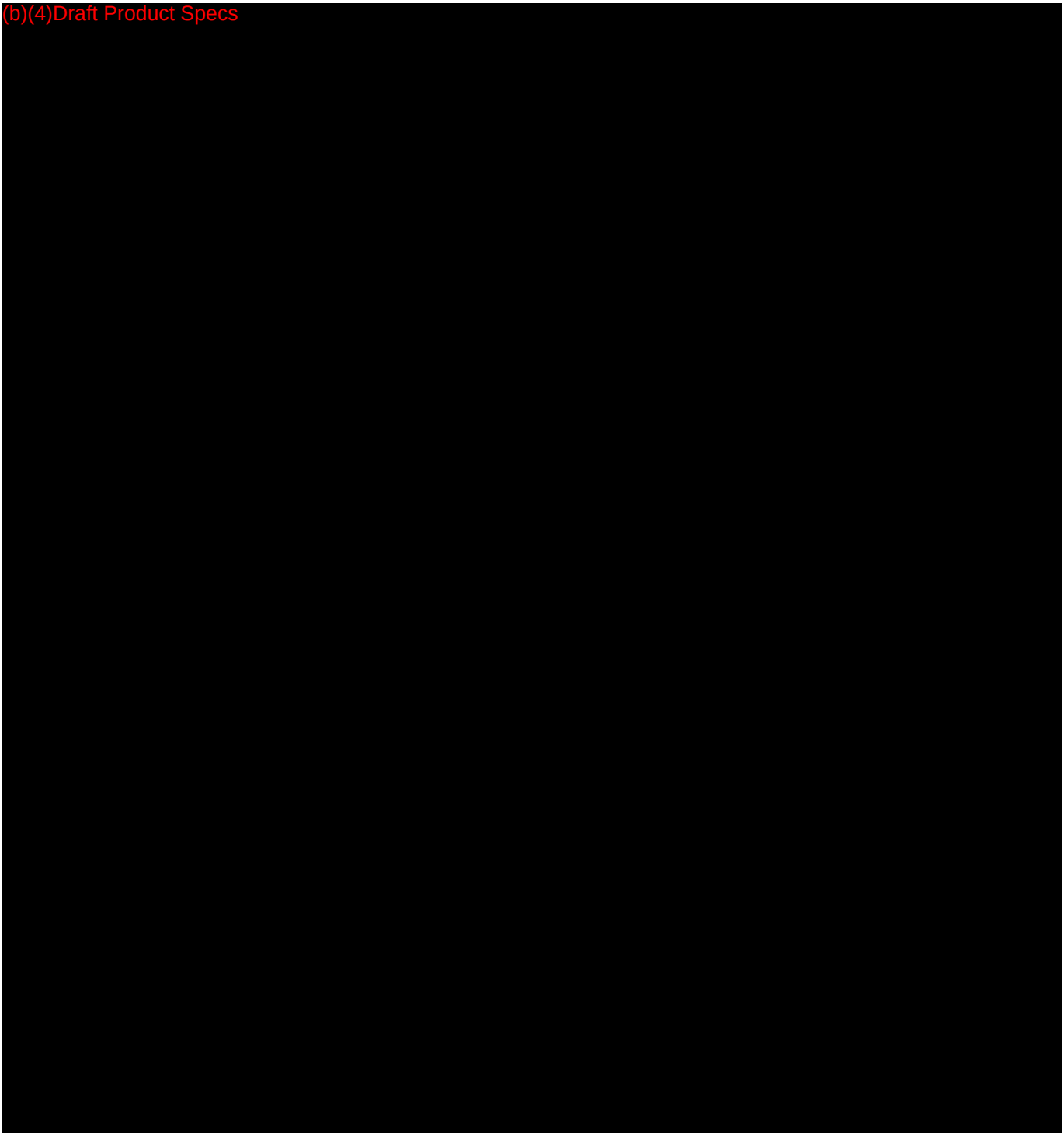

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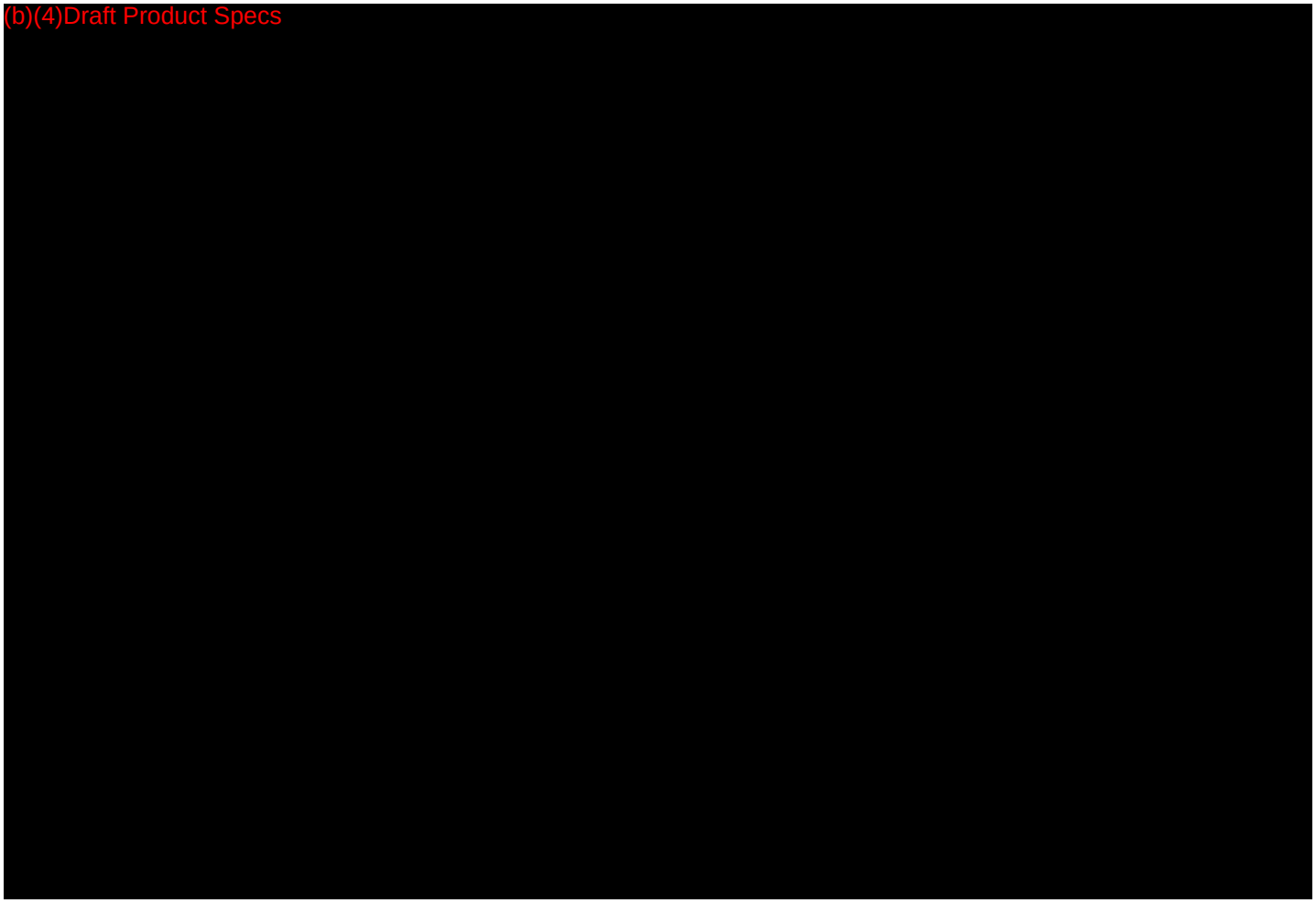

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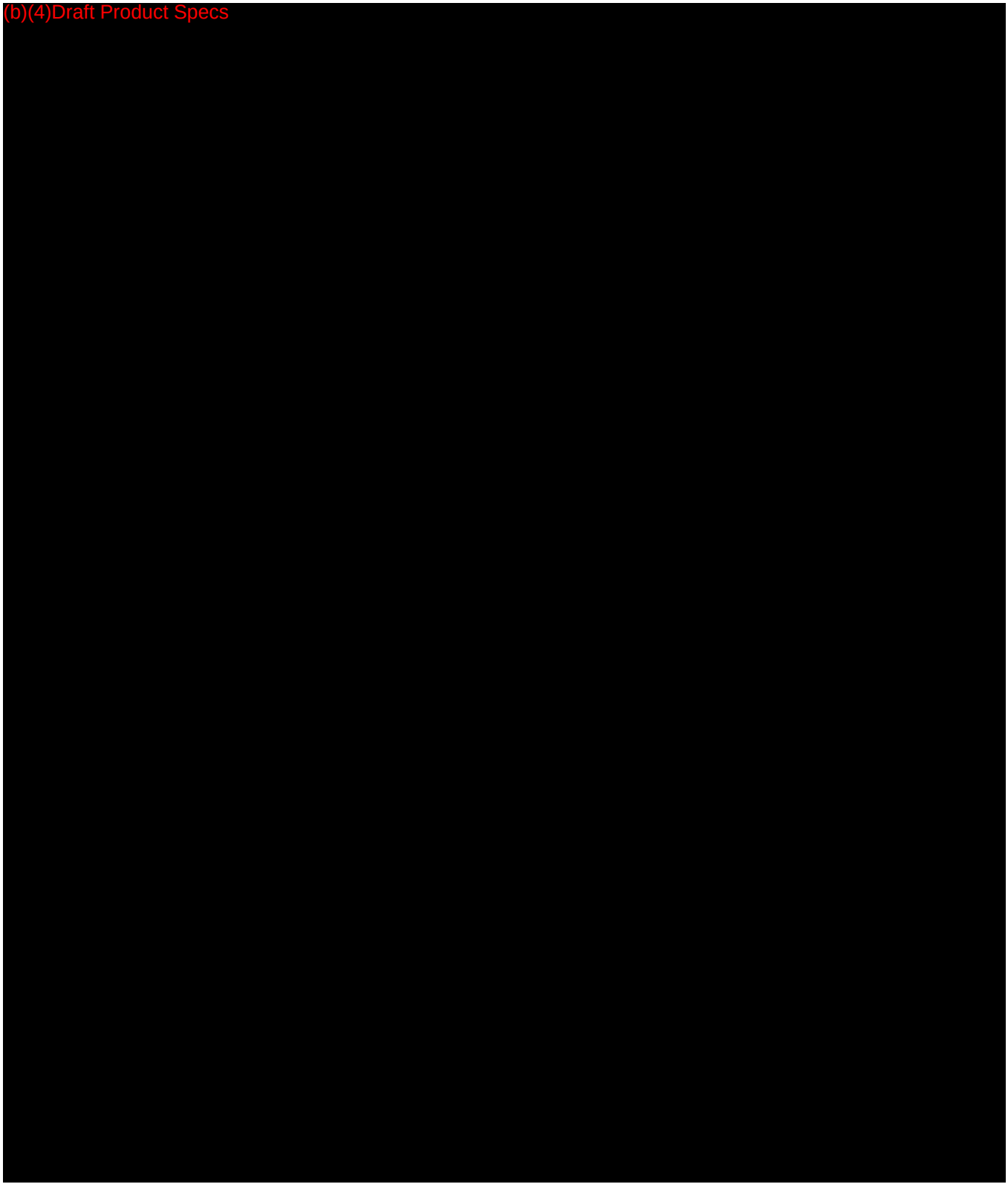

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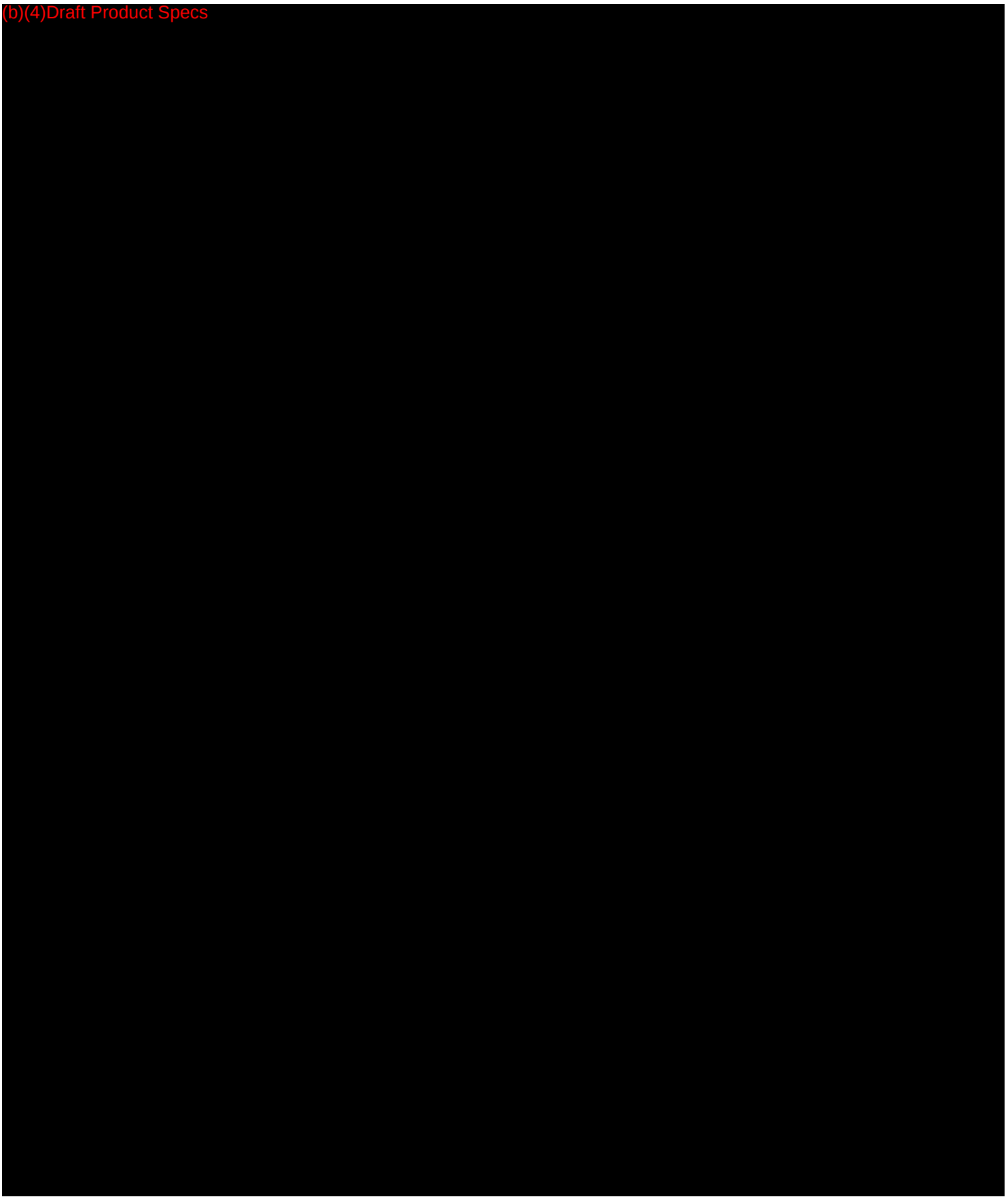

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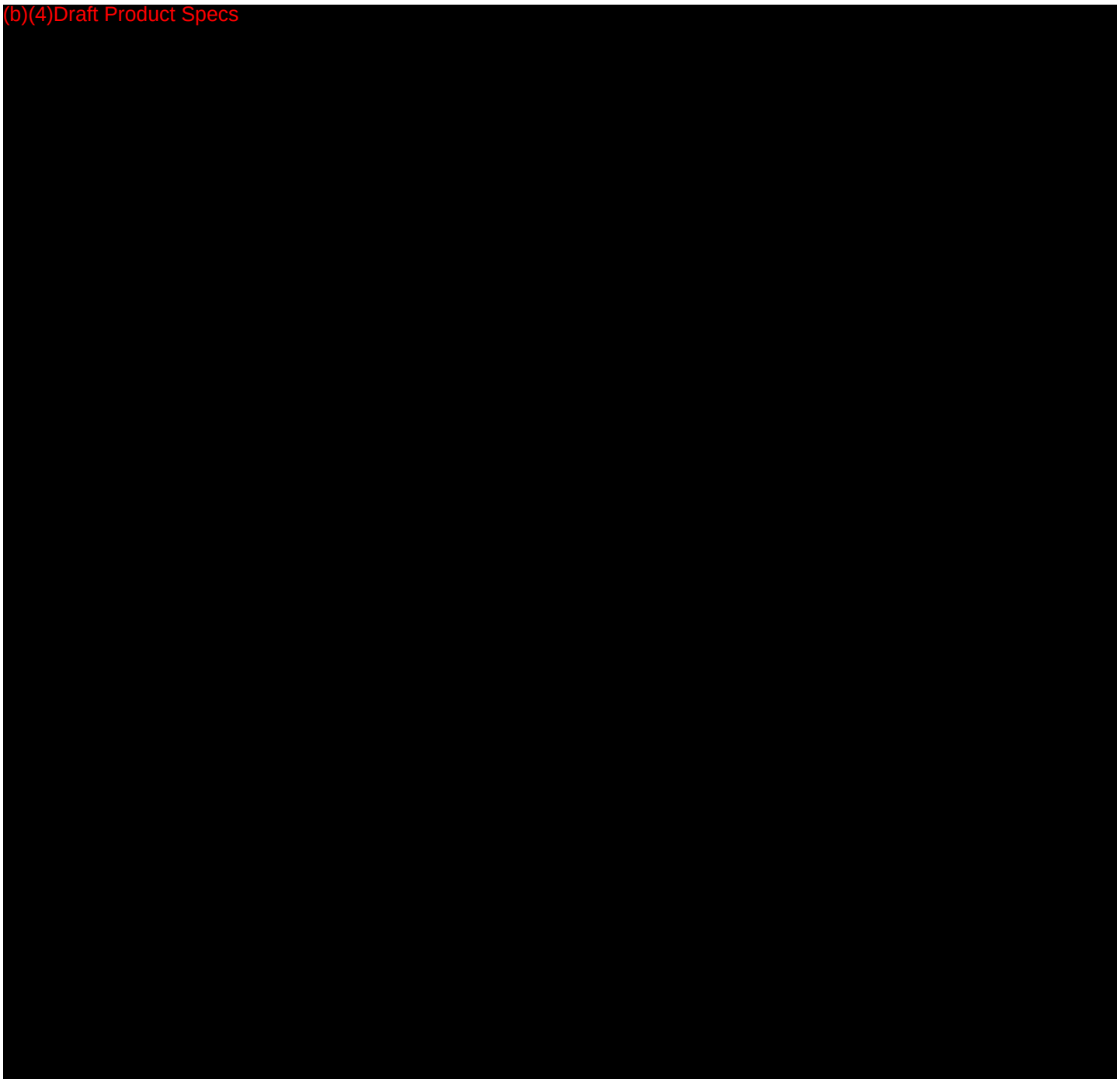

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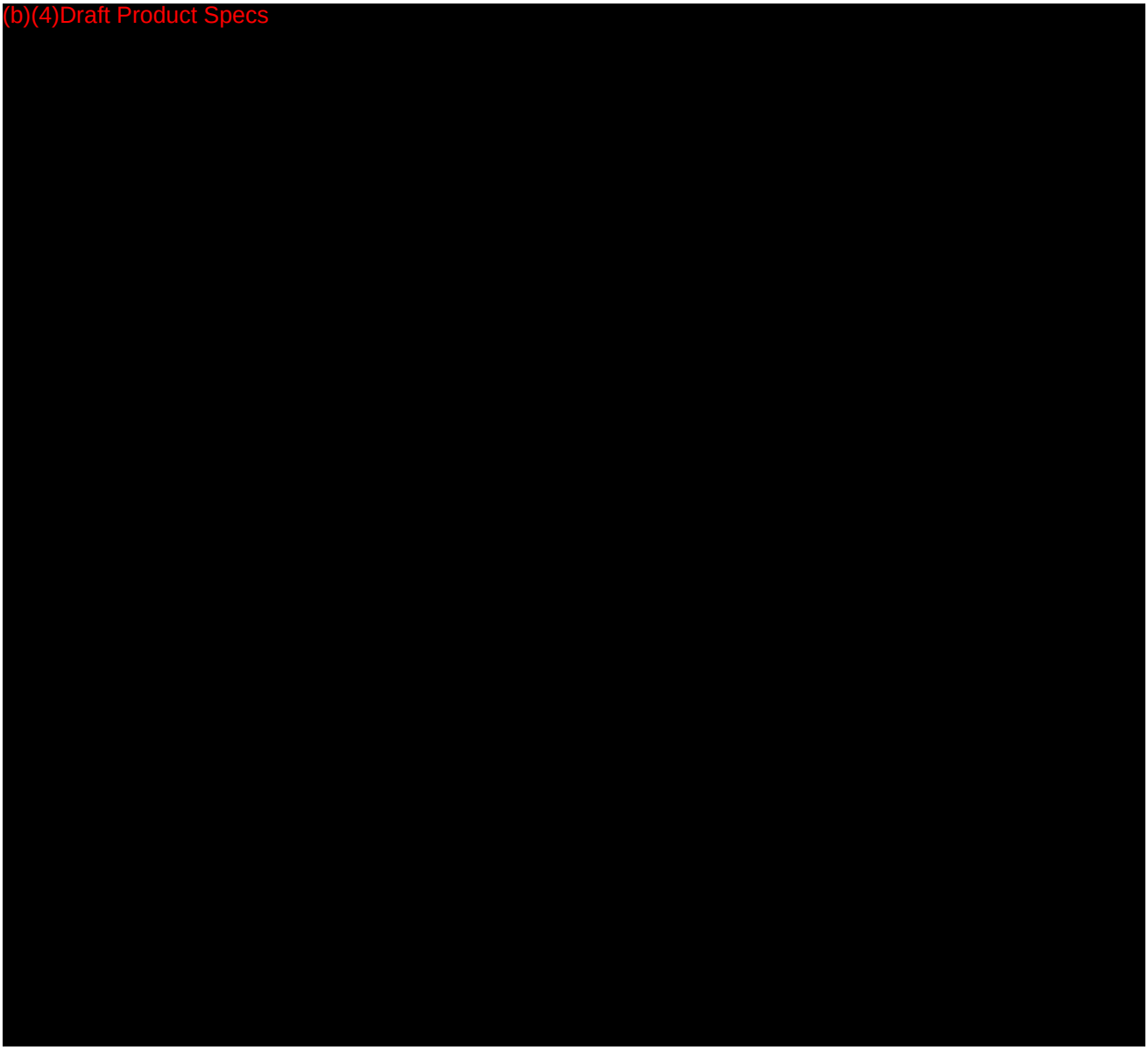

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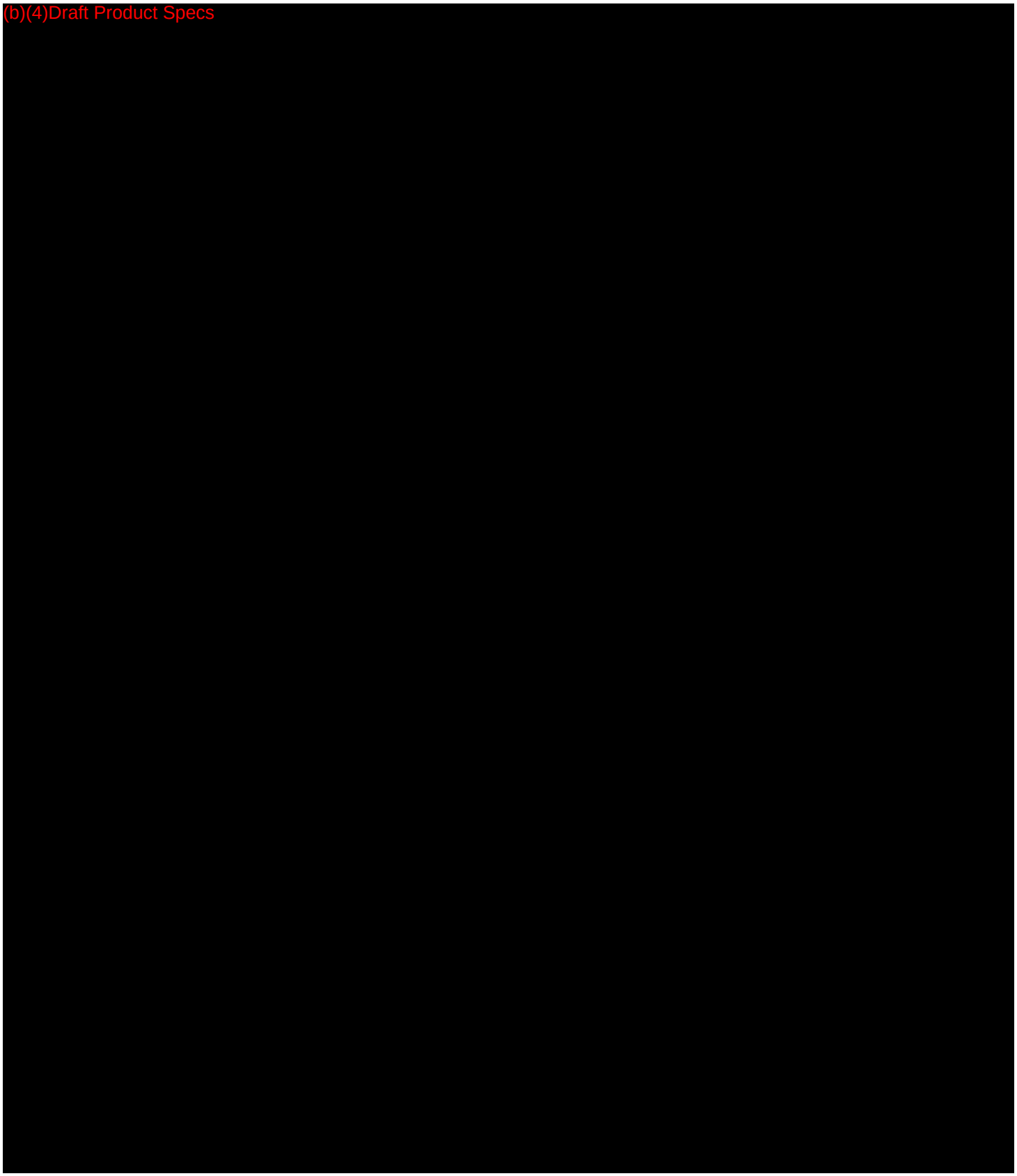

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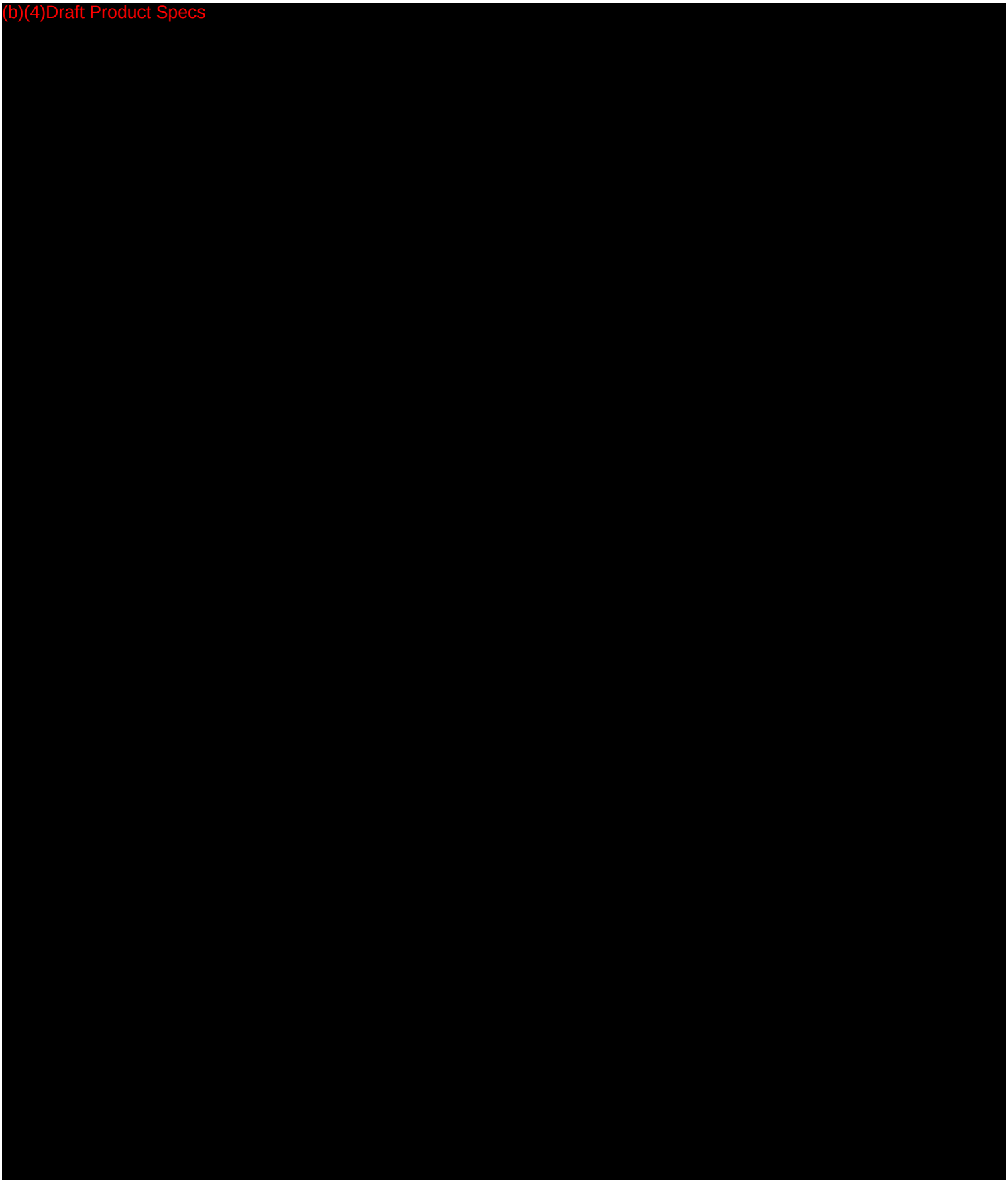

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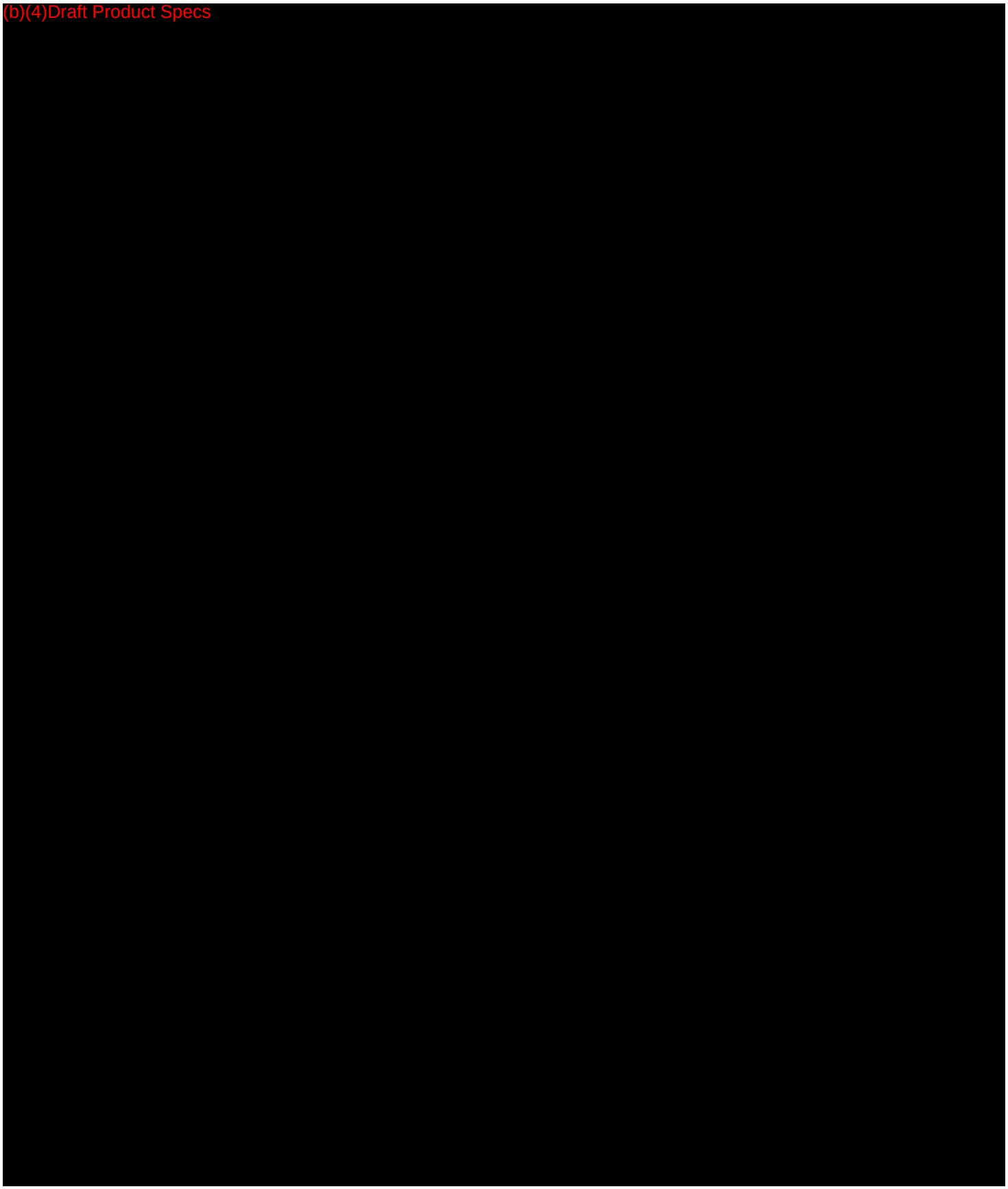

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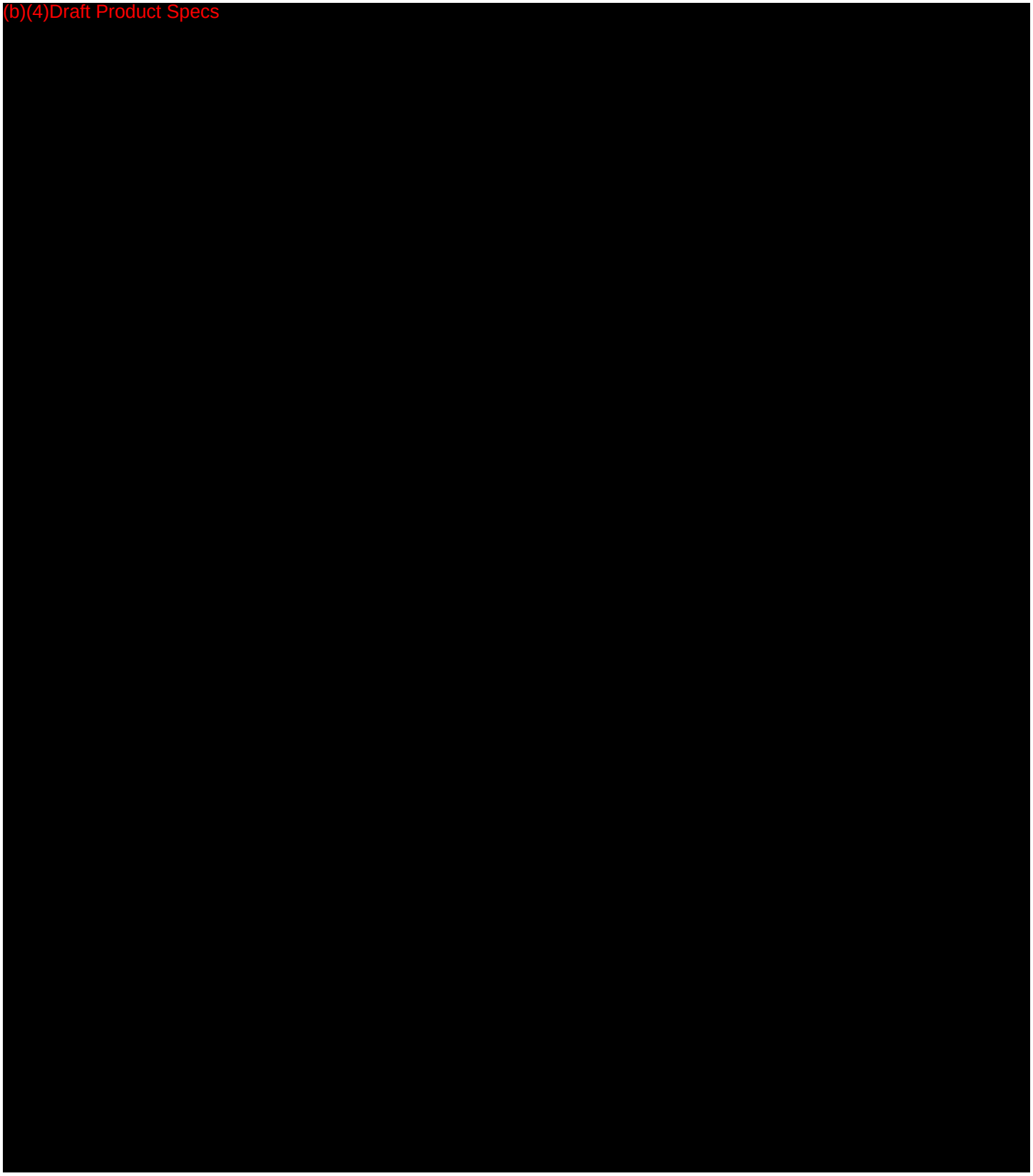

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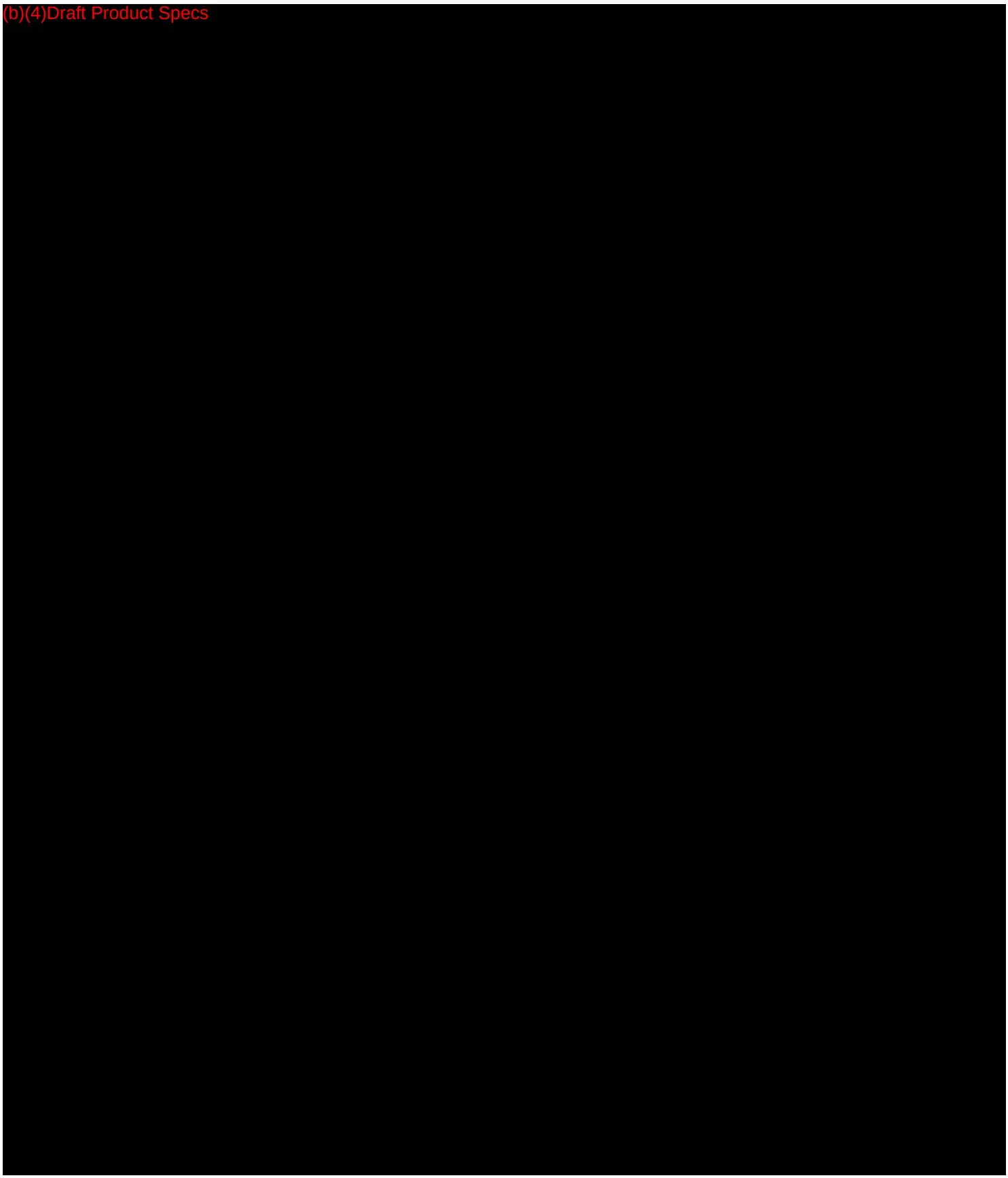

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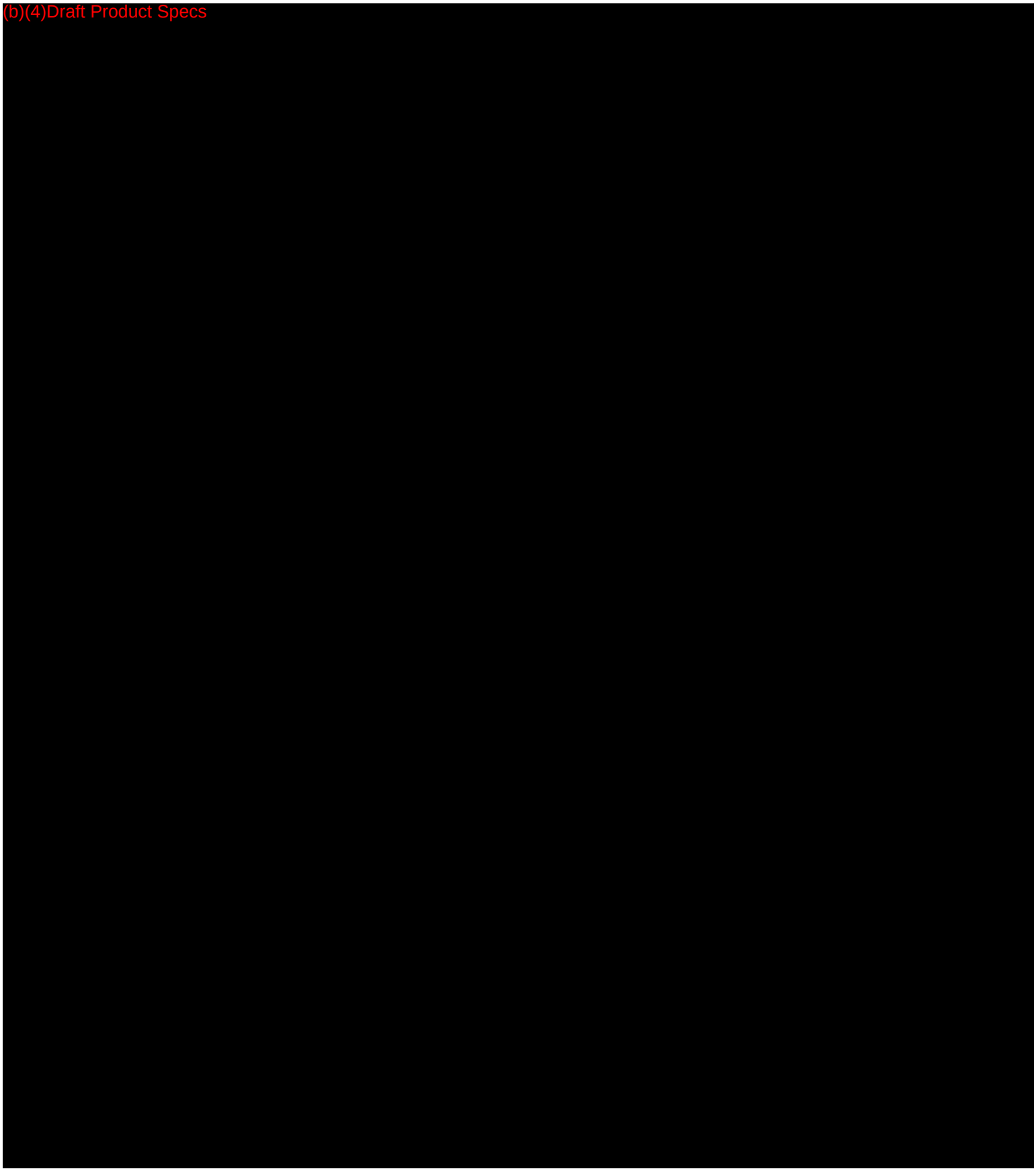

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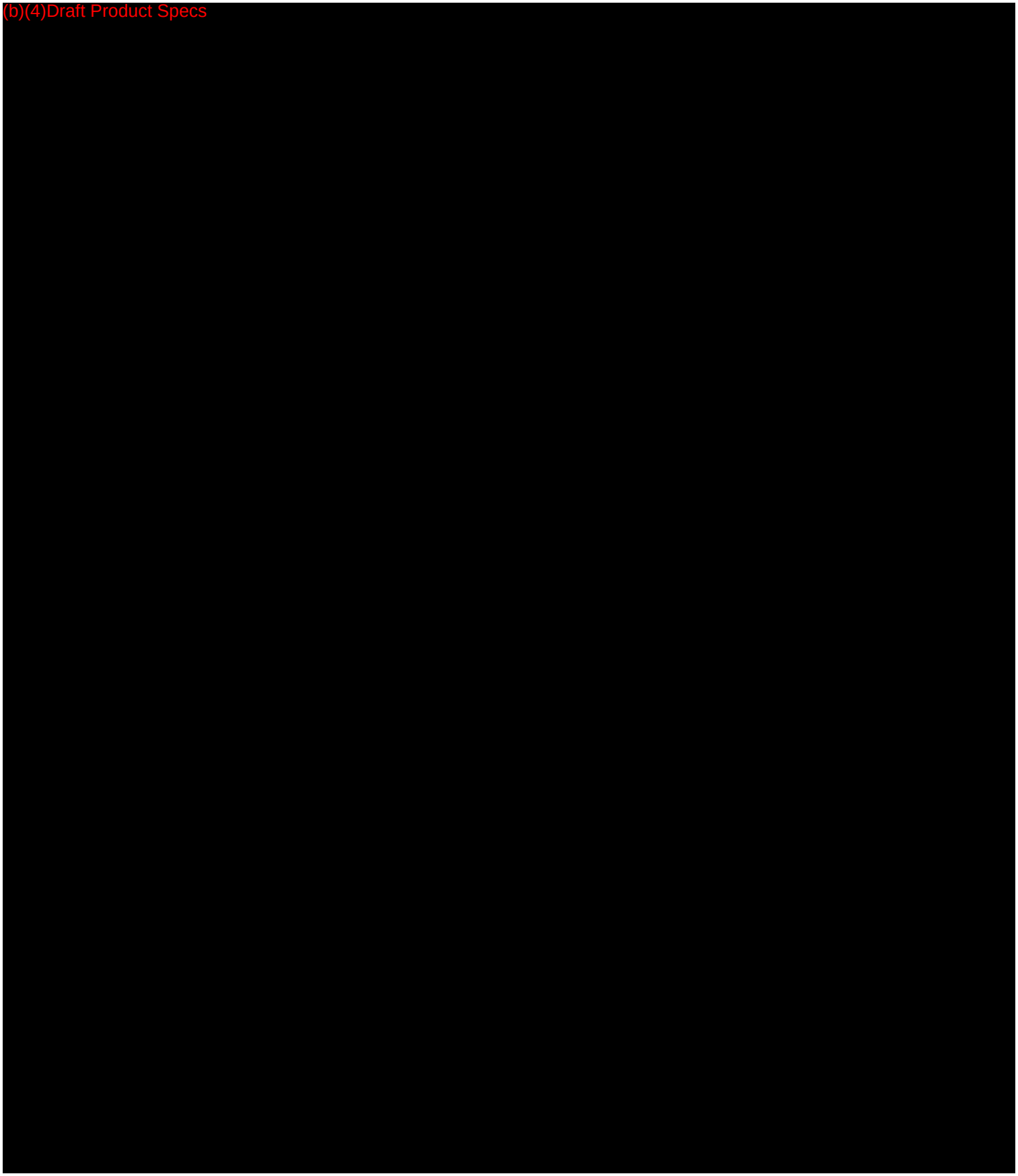

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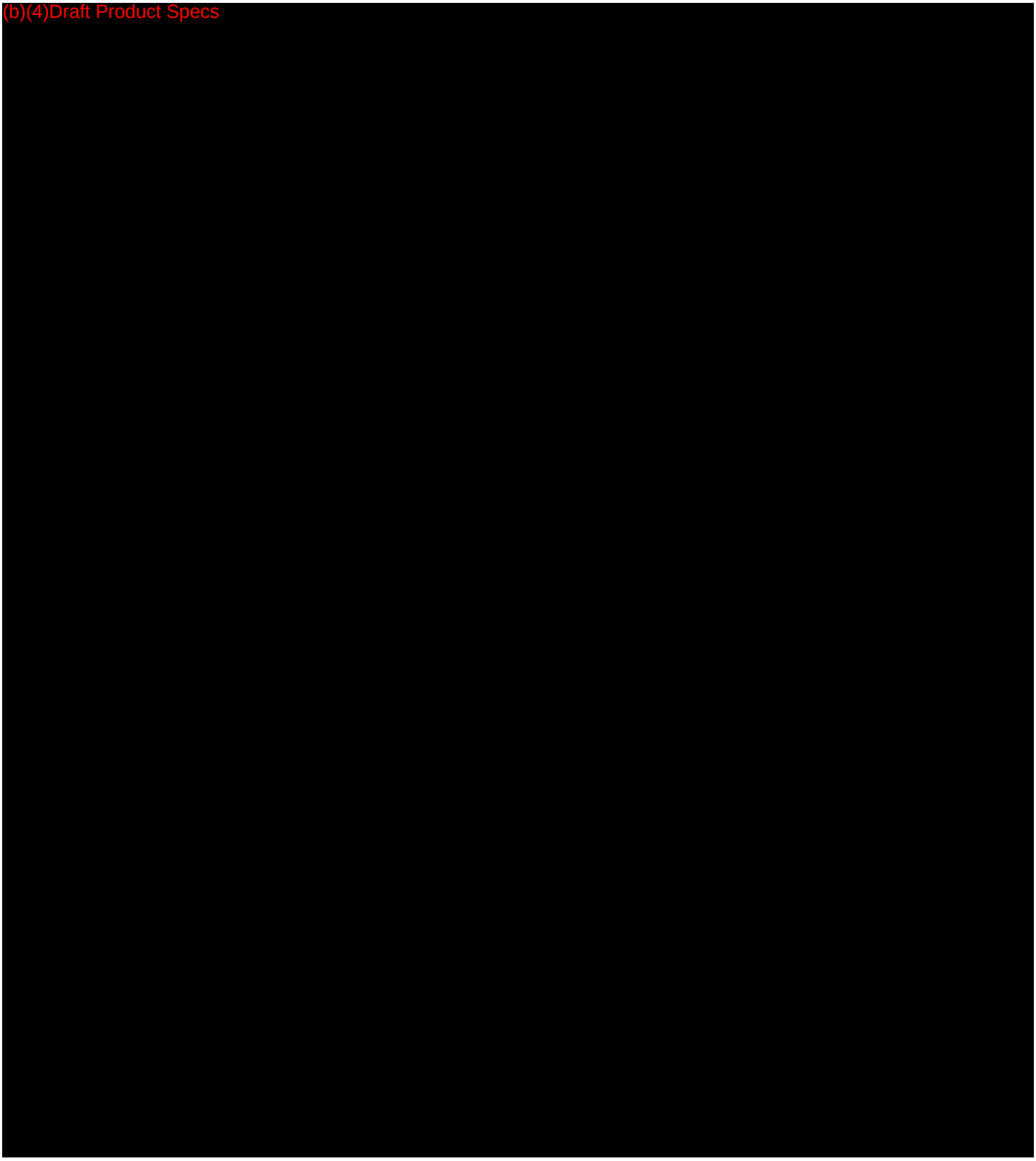

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Appendix A Abbreviations

1 Abbreviations

Table 1: Abbreviations

Abbreviations	Acronym
AW	Advantage Workstation
CFR	Code of Federal Regulations
cm	Centimeter
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DAS	Data Acquisition System
DFOV	Display Field of View
DICOM	Digital Imaging and Communication in Medicine
DLP	Dose Length Product
ECG	Electro cardiogram
EMC	Electro-magnetic Compatibility
EMI	Electro-magnetic Immunity
FDA	Food and Drug Administration
FWHM	Full Width Half Maximum
FWTM	Full Width Tenth Maximum
HU	Hounsfield Units
HV	High Voltage
IEC	International Electro-technical Commis-sion
ISO	Iso-center
IV	Intra-venous
kg	Kilogram
kV	kilo-volts
kW	kilo-watts
LCD	Liquid Crystal Display
lb	Pound
LCD	Low Contrast Detectability
mA	milli-amps
MD	Material Density
MDC	Main Disconnect Control
mGy	Milligray
ml	Milliliter

Abbreviations	Acronym
mm	Millimeter
MPR	Multiplanar Reconstruction
ms	millisecond
MTF	Modulation Transfer Function
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
PDU	Power Distribution Unit
PM	Planned Maintenance
PMMA	Poly-methyl methacrylate
QA	Quality Assurance
QEF	Quality Equivalent Filtration
QSR	Quality System Regulation
ROI	Region of Interest
SATA	Serial Advance Technology Attachment
SCIM	Scan Control Intercom Module
SFOV	Scan Field of View
SSP	Slice Sensitivity Profile
UL	Underwriters' Laboratories
WL	Window Level
WW	Window Width

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Attachment 13B

Revolution CT User Manual

Discovery™ CT870
User Manual

OPERATING DOCUMENTATION

5480385-1EN
Revision 1

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Revision History

Revision	Date	Reason For Change
1	4/13/13	Release for ME program milestone.
1	10/25/13	Release for 510K / VE program milestone.

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Table of Contents

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Chapter 1 User Information

1 Introduction

Anyone who operates this system should have received prior training before they attempt to scan patients. This training should include medical and X-ray education, If necessary, additional training is available from a GE Applications Specialist. Contact your institution's GE Healthcare sales representative for additional information about further safety and operational training. This manual does not provide medical explanations, but it does suggest potential applications for some of the software features. It describes potential safety problems and how to avoid them.

Everyone who uses this equipment must read and understand all instructions, precautions and warnings. Procedures and safety precautions described in the Safety chapter should be read periodically.

This manual is originally written in English.

Do not use the equipment if a known safety problem exists. Call your local service provider and have the system repaired.

2 User Documentation

Description

The user documentation is designed for safe and effective use of the system, and is divided into the following parts:

1. **User Manual**: This manual contains all the user information required to operate the scanner in a safe and proper manner.
2. **Technical Reference Manual**: This manual contains safety information and specifications related to dose and image quality performance of the system. The manual is intended to assist with quality assurance testing and planned maintenance to ensure system performance.
3. **Application Tips and Workarounds**: This manual details workaround information for software and system information.

3 GE Approved Accessories

With each use, check all accessories for damage and remove them from service if damaged or cracked. Use only GE approved equipment together with this system.

The following approved accessories were shipped with the system:

Table 1: GE Approved Accessories Types and Models

Type	Manufacturer/Model
Cardiac Trigger Monitor	IVY 7800 IVY CTM-400 IVY 3150–B
Respiratory Monitor	Varian 1.7
Partial UPS	Eaton Powerware 9355-15-14GE
External Hard Drive	Seagate FreeAgent 1 TB USB 2.0 Seagate FreeAgent 2 TB USB 2.0/3.0
Bar Code Reader	Honeywell 1300 g
Patient contrast injector: For Enhanced Xtream Injector Option	Nemoto Dual Shot Alpha (CiA425 Class IV)/GE 5328195 Nemoto Dual Shot GX (CiA425 Class IV) Medrad ISI900 (for Stellant D) (CiA425 Class I and Class IV)/GE 5335919

- Patient comfort and workflow accessories such as the cradle pad, cradle extender, patient arm board, catheter bag holder, table tray, and IV pole attached to the cradle.
- Patient positioning accessories including Axial and Coronal head holders, positioning straps, and pads.
- System quality assurance accessories including imaging phantoms and phantom holder.

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Chapter 2 Regulatory Information

1 Applicable Regulations and Standards

The system is classified as a Class I, IPX0 equipment, not suitable for use in the presence of a flammable anaesthetic mixture with oxygen or nitrous oxide. It is rated for continuous operation with intermittent loading. No sterilization is applied. The patient table cradle and patient support accessories are considered Type B applied parts.

This product complies with the requirements of the following regulations and standards:

Code of Federal Regulations, Title 21, Part 820 — Quality System Regulation

Code of Federal Regulations, Title 21, Subchapter J — Radiological Health

Federal U.S. law restricts this device for sale by or on the order of a physician.

GE Medical Systems is ISO 9001 and ISO 13485 certified.

The Discovery CT870 system complies with IEC 60601-1:2005, ES60601-1, EN60601-1:2006.

- All portions of the Discovery CT870 system are suitable for use in the patient environment.
- The system should be used only with GE approved equipment.

The Discovery CT870 system complies with radiation protection in accordance with IEC 60601-1-3:2008.

The Discovery CT870 system complies with IEC 60601-2-28. X-ray source assembly Performix HDw Tube Unit Assembly IEC 60601-2-28 (1993).

The Discovery CT870 system complies with IEC 60601-2-28. X-ray tube assembly Performix HDw Tube Unit Assembly IEC 60601-2-28:2010.

The Discovery CT870 system complies with IEC 60601-2-44. CT SCANNER Discovery CT870 System IEC 60601-2-44:2009

2 Product Description

2.1 Intended Use of the System

The system is intended for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

2.2 Indications for Use of the System

The system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver , kidney, pancreas, etc.. The system may acquire data using Axial, Cine, Helical, Cardiac , and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results

The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

2.3 Contraindications

None known.

3 Product Manufacturer

This section lists the manufacturer of the Discovery™ CT870 product.

Table 1: Discovery™ CT870 Product Manufacturer

Model Name	Manufacturer (*) Manufacturing Site	Manufacturer Address
Discovery™ CT870	GE Medical Systems	3000 N. Grandview Blvd. Waukesha, WI - 53188, USA

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Chapter 3 Safety

1 General Safety Guidelines

This chapter provides information about safety precautions and procedures. It is important for you to read and understand the contents of this chapter so the correct precautions and procedures are followed. This manual should be kept near the scanner desktop for easy access.

United States Federal Regulation 21CFR 801.109

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

- This product was designed and manufactured to ensure maximum safety of operation. It should be operated and maintained in strict compliance with the safety precautions, warnings and operating instructions contained herein, and in any other documentation specific to the product.
- The system has been designed to meet all the safety requirements applicable to medical equipment. However, anyone attempting to operate the system must be fully aware of potential safety hazards.
- The manufacturer or vendor of the equipment makes no representation, however, that the act of reading this manual renders the reader qualified to operate, test or calibrate the system.
- The owner should make certain that only properly trained, fully qualified personnel are authorized to operate the equipment. A list of authorized operators should be maintained.
- This manual should be kept at hand, studied carefully and reviewed periodically by the authorized operators.
- Unauthorized personnel should not be allowed access to the system.
- Do not leave the patient unobserved at any time.
- Become familiar with the functional hardware so that you can recognize serious problems. Do not use the system if it appears damaged or fails. Wait for qualified personnel to correct the problem.
- Abbreviations used in the operator manuals can be found in this manual.
- If the product does not operate properly or if it fails to respond to the controls as described in this manual, the operator should:
  - First ensure the safety of the patient.
  - Next ensure the protection of the equipment.
  - Evacuate the area as quickly as possible in any potentially unsafe situation.
  - Follow the safety precautions and procedures as specified in this manual.

  - Immediately contact the local service office, report the incident and await further instructions.

- The images and calculations provided by this system are intended as tools for the competent user. They are explicitly not to be regarded as a sole incontrovertible basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system.
- Understand the product specifications, system accuracy, and stability limitations. These limitations must be considered before making any decision based on quantitative values. In case of doubt, please consult your sales representative.
- Do not block the ventilation ports of the electronic equipment. Always maintain at least 6 inches (15 cm) clearance around the ventilation ports to prevent overheating and damage to the electronic hardware.
- The supplier will make available on request circuit diagrams, component parts lists, descriptions, calibration instructions which will assist the user's appropriately qualified technical personnel to repair those parts designated to be repairable.

2 Safety Conventions

This manual addresses three safety classifications:

DANGER

THE MOST SEVERE LABEL DESCRIBES CONDITIONS OR ACTIONS WHICH RESULT IN A SPECIFIC HAZARD. YOU WILL CAUSE SEVERE OR FATAL PERSONAL INJURY, OR SUBSTANTIAL PROPERTY DAMAGE IF YOU IGNORE THESE INSTRUCTIONS.

WARNING

THIS LABEL IDENTIFIES CONDITIONS OR ACTIONS WHICH RESULT IN A SPECIFIC HAZARD. YOU WILL CAUSE SEVERE PERSONAL INJURY, OR SUBSTANTIAL PROPERTY DAMAGE IF YOU IGNORE THESE INSTRUCTIONS.

CAUTION

This label applies to conditions or actions that have potential hazard. You may cause minor injury or property damage if you ignore these instructions.

This manual uses pictures, or icons, to reinforce the printed message. It uses the corresponding international symbol or icon next to the danger, warning or caution message. For example, the upright hand with the lightning bolt across it warns of electrical hazards.

3 Symbols and Warning Labels

3.1 Symbols

This chapter uses the international symbol or icon along with the danger, warning or caution message.

Table 1: Symbols Used in Labeling

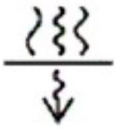
Symbol	Description
	Alternating current
	3 Phase alternating current
	Protective earthing point
	ON / Power ON
	OFF / Power OFF
	Input power
	Output Power
	Type B applied part
	Functional earth ground

Symbol	Description
	Electrical shock hazard
	Caution or warning
	Hand Pinch
	Radiation
	Maximum Weight Capacity
	Emergency Stop

Symbol	Description
	ETL Mark: Proof of product compliance (electrical, gas and other safety standards) to North American safety standards. Authorities Having Jurisdiction (AHJs) in 50 states and Canada and retailers accept the ETL classified/and recognized as proof of product safety..
	The system shall conform to applicable requirements of 21CFR Subchapter J
	WEEE: This symbol indicates that when the end-user wants to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	CE Mark: Manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.

Table 2: Symbols Used in Labeling

Symbol	Description
Made for	Indicates the manufacturer (responsible design owner)
Made by or by	Indicates the manufacturing Location
	Refer to instruction manual/booklet Attention, consult accompanying documents
	Pushing prohibited

Symbol	Description
	IEC Manufacture location label
	Date of manufacture
	Serial number
	Catalog number
	X-Ray filtration (Al Equivalent Filtration)
	Minimum filtration
	Laser symbol
	Extra large focal spot
	Large focal spot

Symbol	Description
	Small focal spot

3.2 Equipment Warning Labels

The following Warning Labels are used on the equipment:

3.2.1 Laser Warning Labels

Illustration 1: Warning labels located at the bottom of the gantry cover (Reference 21CFR 1040.10 (g)(4))

CAUTION
LASER RADIATION
DO NOT STARE INTO BEAM
CLASS 2 LASER PRODUCT

CAUTION
Laser Radiation
Do Not Stare into Beam
635, 670nm Laser Diode

1 Milliwatt Maximum Output

Class II Laser Product

Illustration 2: Labels on the front of the gantry (Reference 21CFR 1040.10 (h))

[redacted]

CAUTION
LASER APERTURE
Do not stare into beam

Illustration 3: Labels on the front of gantry, rear of table, back of PDU, back of Scanner Desktop, and side of System Cabinet.

[redacted]

CAUTION
Avoid Injury. Read and understand information in manuals before operating product.

3.2.2 X-ray Warning Labels

Illustration 4: Label located on Scanner Desktop (Reference 21CFR 1020.30 (j))

[redacted]

WARNING
THIS X-RAY UNIT MAY BE DANGEROUS TO PATIENT AND OPERATOR UNLESS SAFE EXPOSURE FACTORS, OPERATING INSTRUCTIONS AND MAINTENANCE SCHEDULES ARE OBSERVED.
TO BE USED BY AUTHORIZED PERSONNEL ONLY.

3.2.3 Table Warning Labels

Illustration 5: Pinch warning label located on the table

[redacted]

WARNING

FINGER PINCHING CAN CAUSE PHYSICAL INJURY. KEEP FINGERS AWAY FROM THIS AREA BEFORE OPERATING THE SWITCH FOR CRADLE OUT.

Illustration 6: Weight limit warning label located on the table

[redacted]

WARNING

AVOID INJURY. DO NOT EXCEED TABLE MAXIMUM CAPACITY OF 227 KG (500 LB).

3.2.4 Power Distribution Unit (PDU) Warning Labels

Illustration 7: PDU move warning on back of PDU

[redacted]

WARNING

PDU CAN MOVE AND DAMAGE CABLES. DO NOT LEAN ON OR MOVE WHEN CONNECTED TO POWER.

Illustration 8: PDU move caution on back of PDU

[redacted]

CAUTION

PDU can move and damage cables. Do not lean on or move when connected to power.

Illustration 9: WEEE Label

[redacted]

3.2.5 Scanner Desktop Labels

Illustration 10: Label on reading manuals before operating

[redacted]

CAUTION

Avoid Injury. Read and understand information in manuals before operating product.

Illustration 11: WEEE Label

3.2.6 External Accessory Labels

Illustration 12: IV pole warning label on leg of IV pole

WARNING

DO NOT LOAD MORE THAN 4.5 KG OR 10 POUNDS. VERIFY THAT EXTENSION COLLAR IS SECURELY TIGHTENED BEFORE USE.

Illustration 13: Table tray warning label on leg of table tray

WARNING

DO NOT LOAD MORE THAN 9 KG OR 20 POUNDS.

Illustration 14: Axial head holder caution

CAUTION

Accessory may fall and cause injury if not latched to cradle. Make sure that accessory is latched to underside of cradle. Excessive weight can break accessory and cause injury. Do not load more than 34 kg or 75 pounds.

Illustration 15: Axial head holder warning

WARNING

FALL HAZARDS ACCESSORY MAY FALL AND CAUSE INJURY IF NOT LATCHED TO CRADLE. MAKE SURE THAT ACCESSORY IS LATCHED TO UNDERSIDE OF CRADLE. EXCESSIVE WEIGHT CAN BREAK ACCESSORY AND CAUSE INJURY. DO NOT LOAD MORE THAN 34 KG OR 75 POUNDS.

Illustration 16: Coronal head holder caution

CAUTION

Do not hit the accessory against the gantry. Patient injury or equipment damage could result.

Illustration 17: Coronal head holder warning

WARNING

DO NOT HIT THE ACCESSORY AGAINST THE GANTRY. PATIENT INJURY OR EQUIPMENT DAMAGE COULD RESULT. ACCESSORY MAY FALL CAUSE INJURY IF NOT LATCHED TO CRADLE. MAKE SURE THAT ACCESSORY IS LATCHED TO UNDERSIDE OF CRADLE. EXCESSIVE WEIGHT CAN BREAK ACCESSORY AND CAUSE INJURY. DO NOT LOAD MORE THAN 34 KG OR 75 POUNDS.

4 Radiation Safety

(Reference 21CFR 1020.30 (h)(1)(i))

4.1 X-Ray Protection

WARNING

IMPROPERLY USED X-RAY EQUIPMENT MAY CAUSE INJURY. READ AND UNDERSTAND THE INSTRUCTIONS IN THIS BOOK BEFORE YOU ATTEMPT TO OPERATE THIS EQUIPMENT. IF YOU FAIL TO FOLLOW SAFE X-RAY PRACTICES OR IGNORE THE ADVICE PRESENTED IN THE MANUAL, YOU AND YOUR PATIENT RISK EXPOSURE TO HAZARDOUS RADIATION.

Authorized Users

This equipment incorporates a high degree of protection against X-ray radiation outside the useful beam. But this equipment cannot substitute the essential requirement that every user must take adequate precautions to prevent the possibility of any person carelessly, unwisely, or unknowingly exposing themselves or others to radiation.

Everyone having anything to do with X-ray equipment must receive proper training and become fully acquainted with the recommendations of the National Council on Radiation Protection and Measurements and the International Commission on Radiation Protection.

NCRP reports are available from:

NCRP Publications

7910 Woodmont Avenue

Room 1016

Bethesda, Maryland 20814

WARNING

EVERYONE HAVING ANYTHING TO DO WITH X-RAY EQUIPMENT MUST TAKE ADEQUATE STEPS TO ENSURE PROTECTION AGAINST INJURY.

All persons authorized to use the equipment must understand the dangers posed by X-ray exposure so that they can prevent any injury or damage that may result from such exposure. GE Healthcare urges you to use protective materials and devices to prevent any injury or damage from X-ray exposure.

4.2 General Radiation Safety

WARNING

NEVER SCAN A PATIENT WITH UNAUTHORIZED PERSONNEL IN THE SCAN ROOM. WARN VISITORS AND PATIENTS ABOUT POTENTIAL FOR HARM IF THEY FAIL TO FOLLOW INSTRUCTIONS.

WARNING

NEVER CALIBRATE, TEST THE SYSTEM, OR WARM THE TUBE WITH PATIENTS OR PERSONNEL PRESENT IN THE SCAN ROOM WITHOUT ADEQUATE RADIATION SAFETY PRECAUTIONS BEING UTILIZED.

- Stay behind a lead screen or lead glass shield during each X-ray exposure.
- Use technique factors prescribed by the radiologist or diagnostician. Use a dose that produces the best diagnostic results with the least X-ray exposure.
- Amber indicator lights on the gantry display panel, and rear of the gantry, illuminate during X-ray exposure.

WARNING

USE OF CONTROLS OR ADJUSTMENTS, OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN, MAY RESULT IN HAZARDOUS RADIATION EXPOSURE.

4.3 Scans Acquired at the Same Tomographic Plane

IEC standard 60601-2-44:2009, clause 203.107 states that you must be warned when scans are acquired at the same tomographic plane, i.e. same scan location. The need for the warning is to make users aware of the potential dose that can be given to the patient when acquiring scans at the same table location.

When acquiring scans in this mode:

- Utilize the dose information displayed on the *Scan Settings* screen. The dose information displayed is covered in the next section, $CTDI_{vol}$.
- An optional DICOM Structured Report (SR) Dose Report is saved in Series 997.
- Use proper techniques for the application and anatomy you are scanning.

A warning message is posted when [Confirm] is selected for the following scan types:

Axial scans with zero table increment (interval)

WARNING

THIS SERIES CONTAINS ONE OR MORE GROUPS WITH MULTIPLE SCANS AT THE SAME TOMOGRAPHIC PLANE, I.E. SAME LOCATION.
DO YOU WANT TO CONTINUE?

After reading the message, if you wish to continue with the scan, click [Continue], otherwise click [Cancel].

WARNING

PROLONGED EXPOSURE TO X-RAY IN ONE SPOT MAY CAUSE REDDENING OR RADIATION BURNS. USERS MUST BE AWARE OF THE TECHNIQUES USED AND EXPOSURE TIME TO ENSURE SAFE OPERATION.

4.4 Geometric Dose Efficiency

A warning message is posted when the Geometric Dose Efficiency in the Z-direction is less than 70%. Geometric Dose Efficiency is a measure of how much of the X-ray beam in the Z-direction is used by the system.

WARNING

THE FOLLOWING GROUPS IN THIS SERIES CONTAINS GEOMETRIC EFFICIENCY IN THE Z DIRECTION OF LESS THAN 70%: IMAGES 1-12,13-28.

NOTE: Images 1-12, 13-28 is an example of a location where Geometric Efficiency in Z is less than 70%.

4.5 Backup Timer Indicator

The system has backup timers that terminate the X-ray if it remains on longer than the prescribed scan time.

A warning message is posted when a scan is stopped by the backup timer.

Illustration 18: Backup Timer Warning Message

WARNING

BACKUP TIMER STOPPED SCAN. X-RAY STAYED ON LONGER THAN PRESCRIBED.

To continue scanning, press **Resume**.

4.6 Starting Scans from the Scan Room

Start Scan buttons are located on the right and left panels of both the front and rear gantry.

Illustration 19: Start Scan Button

If you want to stand by the gantry and start the scan, you can press **Start Scan** after you have confirmed the prescription and the table has been moved to the start location. Once the tube has reached the exposure speed, the button flashes green for 30 seconds and then times out.

Press the solid green **Start Scan** button again to bring the system back to the ready to scan state.

4.7 $CTDI_{vol}$

As you setup the scan parameters from the ViewEdit screen, the Dose Information area at the upper right of the scan monitor contains updated dose information. This dose information is based on a measurement of the CTDI or CT Dose Index, which is the current standard for CT dosimetry and performance. By using a measurement called $CTDI_{vol}$, a single value is provided to estimate the relative dose for an exam.

The $CTDI_{vol}$ is a weighted average measurement in a reference phantom. This dose is expressed in milliGrays. For additional information on specific $CTDI_{vol}$ doses and their calculations, refer to your Technical Reference manual.

The DLP or Dose Length Product is the product of the $CTDI_{vol}$ and the scan length for a group of scans. This number can be summed over the entire exam to give an estimate of the total dose. The value is expressed in milliGray centimeters.

The Projected Series DLP shows the DLP that would result from scanning the current group or groups.

The Accumulated Exam DLP displays the total exam DLP up to the current point in time. Scout dose is not included in the DLP totals since standards for reporting scout dose are not yet defined. Scout dose is generally a very small part of the exam.

The dose information updates when technique values such as kV, mA, scan time, slice thickness, and scan field of view are changed.

Dose information is saved as a screen save image in Series 999 upon selecting End Exam. Series 997 contains the DICOM Dose Structured Report.

5 Implantable Device Safety

WARNING

CT SCANS MAY CAUSE INTERFERENCE WITH IMPLANTED OR EXTERNALLY WORN ELECTRONIC MEDICAL DEVICES SUCH AS PACEMAKERS, DEFIBRILLATORS, NEUROSTIMULATORS AND DRUG INFUSION PUMPS. THE INTERFERENCE COULD CAUSE OPERATIONAL CHANGES OR MALFUNCTION OF THE ELECTRONIC MEDICAL DEVICE.

5.1 Recommendations prior to scanning

- If practical, try to move external devices out of the scan range.
- Ask patients with neurostimulators to shut off the device temporarily while the scan is performed.
- Minimize the X-ray exposure to the electronic medical device.
- Use the lowest possible X-ray tube current consistent with obtaining the required image quality.
- Do not scan directly over the electronic device for more than a few seconds.

  NOTE: For procedures such as CT Perfusion or CT Interventional scans that require scanning over the electronic medical device for more than a few seconds, attending staff should be ready to take emergency measures to treat adverse reactions if they occur.

5.2 Recommendations after scanning

- Have the patient turn the device back on if it had been turned off prior to scanning.
- Have the patient check the device for proper functioning, even if the device was turned off.
- Advise the patient to contact his or her healthcare provider as soon as possible if the patient suspects their device is not functioning properly after a CT scan.

NOTE: Recommendations from FDA Preliminary Public Health Notification: Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning date July 14, 2008.

WARNING

THIS SYSTEM IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS ONLY. THIS SYSTEM MAY CAUSE RADIO INTERFERENCE OR MAY DISRUPT THE OPERATION OF NEARBY EQUIPMENT. IT MAY BE NECESSARY TO TAKE MITIGATION MEASURES, SUCH AS REORIENTING OR RELOCATING THE SYSTEM OR SHIELDING THE LOCATION.

6 Electrical Safety

DANGER

ELECTRICAL SHOCK HAZARD. AVOID ALL CONTACT WITH ANY ELECTRICAL CONDUCTOR. DO NOT REMOVE OR OPEN SYSTEM COVERS OR PLUGS. INTERNAL CIRCUITS USE HIGH VOLTAGE CAPABLE OF CAUSING SERIOUS INJURY.

AN ELECTRICAL HAZARD MAY EXIST IF ANY LIGHT, MONITOR, OR VISUAL INDICATOR STAYS ON AFTER THE SYSTEM IS SHUT DOWN. TO PREVENT POSSIBLE INJURY, TURN OFF THE MAIN POWER SUPPLY WALL SWITCH, AND CONTACT YOUR SERVICE OFFICE IMMEDIATELY.

DANGER

NO USER SERVICEABLE PARTS. REFER SERVICE TO QUALIFIED SERVICE PERSONNEL. ONLY ALLOW PEOPLE WHO KNOW THE PROPER PROCEDURES, AND USE OF THE PROPER TOOLS, TO INSTALL, ADJUST, REPAIR, OR MODIFY THE EQUIPMENT.

TO GUARANTEE SAFE, RELIABLE EQUIPMENT PERFORMANCE, PREPARE THE SITE ACCORDING TO GE HEALTHCARE REQUIREMENTS. IF YOU HAVE ANY QUESTIONS ABOUT THESE REQUIREMENTS, CONTACT GE HEALTHCARE.

FUSES BLOWN WITHIN 36 HOURS OF BEING REPLACED MAY INDICATE MALFUNCTIONING ELECTRICAL CIRCUITS WITHIN THE SYSTEM. HAVE THE SYSTEM CHECKED BY QUALIFIED SERVICE PERSONNEL, AND DO NOT ATTEMPT TO REPLACE ANY FUSE. THIS INCLUDES MAKING SURE THE EQUIPMENT IS CONNECTED TO A SUPPLY MAINS WITH A PROTECTIVE EARTH.

DANGER

INFORMATION ON INTERNAL GANTRY COMPONENTS IS PROVIDED FOR USER EDUCATION. THE GANTRY CONTAINS DANGEROUS VOLTAGES AND MOVING PARTS.

TO PREVENT ELECTRICAL SHOCK OR CRUSHING INJURIES, DO NOT REMOVE COVERS OR ENTER THE GANTRY. ONLY TRAINED, QUALIFIED SERVICE PERSONNEL MAY REMOVE GANTRY OR OTHER EQUIPMENT COVERS.

DANGER

ELECTRICAL FIRE. CONDUCTIVE FLUIDS THAT SEEP INTO THE ACTIVE CIRCUIT COMPONENTS OF THE SYSTEM MAY CAUSE SHORT CIRCUITS THAT CAN RESULT IN ELECTRICAL FIRES. THEREFORE, DO NOT PLACE ANY LIQUID OR FOOD ON ANY PART OF THE SYSTEM.

To avoid electrical shocks or burns caused by the use of the wrong type of fire extinguisher, make sure that only fire extinguishers approved for use on electrical fires are used.

Surplus lengths of power cords or other cables from mobile accessory units that may be used during patient scanning should be stored in safe and isolated areas. For example: Excess cable may be wound in a figure eight and stored at the base of the stationary equipment. This minimizes signal interference and protects cables from damage due to traffic.

CAUTION

The accessory receptacles located on the Scanner Desktop are not for general use. Verify the accessory power requirements do not exceed the labeled ratings of the receptacles.

CAUTION

The accessory receptacles located on the scanner desktop are not for general use. The combined power consumption of the accessories should not exceed 960 watts.

CAUTION

Included power cord is only to be used when connecting GE approved accessories to the gantry or scanner desktop.

A CT System combined with GE approved accessories complies with the IEC 60601-1 standards related to safety and performance of medical electrical systems. Refer to the standard for more information.

- Do not connect electric devices to the CT System that are not approved by GE. It may create increased electrical leakage current and there is possibility of electric shock.
- The manufacturer is not responsible for any interference caused by using other than recommended interconnect cables or by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the users' authority to operate the equipment.
- The Scanner Desktop, LCD monitors and media tower are intended to be powered by the CT System using cables provided. Do not connect these devices to power sources other than the CT system (for example, wall outlets, or other electrical equipment). It may create increased electrical leakage current and there is possibility of electric shock.
- Note that some external powered equipment may only be connected by a signal cable to GE equipment (for example, a network hub). A separation device (for example, an isolated power supply) is required for equipment that is powered by a different power source.

Power Indicator Light Locations

Component	Indicator Light Location
Gantry	Indicator Locations: Gantry control buttons backlight, Gantry indicator/regulatory display and service panel 120VAC LED.
	System ON: gantry control panel backlighting, service panel 120VAC LED will be lit and Indicator display/ regulatory will display table vertical position.
	Shutdown: On the Indicator display the crescent moon will be statically lit (no flashing).
Power Distribution Unit	Indicator Location: PDU light at the front.
	System ON: The light indicator will be ON.
	Shutdown: The light indicator will be ON.
Scanner Desktop	Indicator Locations: Monitors Power ON/OFF buttons lights, Scanner Desktop/NIO Cabinet power on/off light located at the front.
	System ON: The light indicators will be ON.
	Shutdown: The light indicators will be ON.
RSCB	Indicator: Standby Button Light.
	System ON: The button light will be ON.
	Shutdown: The button light will be flashing.
System Cabinet (Image Generation)	Indicators: System Cabinet provides a green light to the service personal to indicate is energized. SDA computer and disks and Image Generation computer front panel Power ON/OFF lights.
	System ON: The light indicators will be ON.
	Shutdown: The light indicators will be ON.
SYS ON light	Indicator: Optional light, customer provided, it indicates that the PDU is energized (A1 breaker is ON).
	System ON: SYS ON light ON.
	Shutdown: SYS ON light ON.

7 Fire Safety

DANGER

THIS DEVICE IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OR IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

8 Mechanical Safety

8.1 General Mechanical Safety

WARNING

DO NOT USE THE TABLE BASE AS A FOOT REST. YOU COULD ENTRAP AND INJURE YOUR FOOT WHILE LOWERING THE TABLE. DO NOT PLACE YOUR HANDS BETWEEN THE TABLE BASE AND THE TABLE SIDE PANELS.

8.2 Patient Positioning

DANGER

DO NOT PLACE A PATIENT ON THE TABLE WEIGHING MORE THAN THE UPPER LIMIT OF 500 POUNDS. THIS COULD CAUSE THE TABLE TO FAIL AND THE PATIENT COULD FALL.

Illustration 20: Warning label located on table

WARNING

AVOID INJURY DO NOT EXCEED THE MAXIMUM CAPACITY OF 227 KG (500 LB).

CAUTION

Temporal sampling may be degraded due to changes in timing for the table to move from location to location if proper positioning methods are not followed. Make sure that the patient is securely positioned on the table and their arms are not allowed to drag on the table or allow clothing, sheets or blankets to get caught causing a table move problem.

CAUTION

When using the external laser alignment light for patient positioning purposes, be aware that the patient's elevation may be slightly lower with the cradle extended than with the cradle fully retracted. This is because the cradle may bend slightly under a patient's weight. This difference should be taken into consideration for applications where patient position information is critical, such as Treatment Planning. To minimize these effects, after using the external laser alignment system to position the patient, advance the patient to the CT scan plane. Turn on the CT alignment lights to determine if they line up with the markers on the patient. If necessary, compensate for the bend in the cradle by elevating the table. When the CT alignment lights line up with the markers, set the landmark for the scan using the Internal laser alignment light.

WARNING

WHEN USING PATIENT POSITIONING ACCESSORIES AND STRAPS, MAKE SURE THERE ARE NO AREAS WHICH MIGHT CAUSE A PINCH POINT OR INTERFERE WITH PATIENT TUBING OR IV.

WARNING

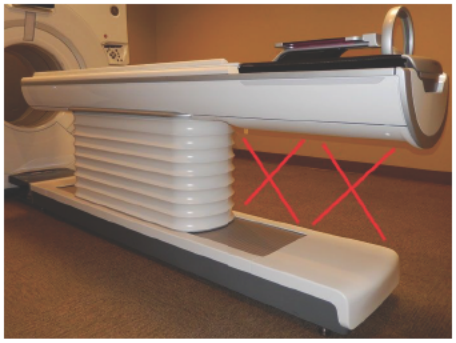
CHECK TO MAKE SURE THE POWER INJECTOR HAS ENOUGH IV TUBING TO ALLOW FREE MOVEMENT OF THE CRADLE. MAKE SURE THE UNIT ITSELF DOES NOT INTERFERE WITH TABLE TRAVEL. ENSURE EXCESS TUBING LENGTH IS SECURED TO THE TABLE TOP. DO NOT LOOP ADDITIONAL IV TUBING IN THE PATIENT'S FINGERS.

Check the length of all patient health lines (IV tubing, oxygen line, etc.) and make sure they accommodate cradle travel. Position these lines so they cannot catch on anything within the patient vicinity or between the table and gantry during cradle travel.

WARNING

THE PATIENT POSITIONING STRAPS PROVIDED WITH THE SYSTEM DO NOT SUPPORT THE FULL WEIGHT OF THE PATIENT. PATIENT POSITIONING STRAPS SHOULD BE USED TO AID IN PATIENT POSITIONING AND ARE NOT MEANT TO FULLY RESTRAIN THE PATIENT.

Illustration 21: Table



CAUTION

If the table is lowered with anything in the designated area below the table, the table could be damaged along with the equipment or object under the table.

WARNING

TO PREVENT PINCHING OR CRUSHING OF THE PATIENT'S EXTREMITIES, KEEP THE PATIENT'S HANDS AND FEET AWAY FROM THE EDGE OF THE MOVING TABLE TOP/CRADLE AND ITS SURROUNDING EQUIPMENT, OR BETWEEN TABLE BASE AND SIDE PANELS OF THE TABLE. TAKE SPECIAL CARE WHEN POSITIONING PHYSICALLY LARGE PATIENTS.

WARNING

TO PREVENT PINCHING OR CRUSHING OF THE PATIENT, WATCH THE PATIENT AND EQUIPMENT CAREFULLY AT ALL TIMES DURING TABLE MOVEMENT. IF UNWANTED MOTION OCCURS OR MOTION DOES NOT STOP, PRESS THE EMERGENCY STOP SWITCHES ON THE SCANNER DESKTOP OR GANTRY.

WARNING

THE HEAD HOLDER MAY CRACK, POSSIBLY INJURING THE PATIENT'S HEAD OR NECK, IF THE PATIENT TRIES TO BRACE HIMSELF OR HERSELF ON THE HEAD HOLDER DURING POSITIONING. THE HEAD HOLDER AND CRADLE EXTENDER ARE ONLY DESIGNED TO SUPPORT 75 POUNDS (34 KG). ASK THE PATIENT TO MOVE UP INTO THE HEAD HOLDER OR MANUALLY HELP THE PATIENT INTO POSITION.

CAUTION

Use of any cradle extension accessories such as the table extension, head holder, coronal head holder, and phantom holder are not accounted for in the table gantry interference matrix. Therefore, additional care needs to be taken to closely monitor any table up/down, in/out or gantry tilt movement to avoid contact of the extended accessory with the gantry.

CAUTION

Care should be taken to ensure the patient positioning straps, patient clothing, or other material will not be caught during table motion.

CAUTION

The patient head holder or table extender should be adequately secured to ensure stability. If they are not secured properly, degradation of image quality may result due to introduced motion of the head holder or table extender.

8.3 Gantry Air Inlets

The operator must inspect both the left and right gantry air inlets to make sure they not being blocked before operating the CT system and during operation. The system receives cooling air through the air inlets. Blocking the air inlets leads to a reduction in air flow and potentially overheating of the system. [The minimum distance to any object blocking the flow shall be 75 mm (3 inches).] Critical objects are jackets, robes, lab coats, bed sheets, pillow cases, covers or blankets that can get sucked into the air inlet and provide an excellent blockage and seal for air flow, despite initial proper spacing. Also paper sheets can get sucked into the air inlet and get stuck in front of the filter. For proper inspection, the operator should be able to clearly see the air filter through the opening of the air inlet.

Illustration 22: Gantry Air Inlets (right side shown)

(b)(4)Draft Product Specs

9 Emergency Devices and Emergency Egress

(Reference 21CFR 1020.33 (f)(2)(ii))

9.1 Emergency Devices

The system has two types of Emergency buttons:

1. **Emergency Stop** — When pressed, all table and gantry motions are halted, generation of X-rays is stopped, laser alignment lights are turned off. The system aborts any data acquisition in progress, and attempts to save all data acquired prior to the abort. Use the Emergency Stop button for patient related emergencies.
2. **System Emergency Off Button** — When pressed, the power to all system components is removed, stopping all table and gantry motion and generation of X-rays. The system aborts any acquisitions in progress, and data obtained prior to the abort can become corrupt or lost. Use the System Emergency OFF button for catastrophic emergencies, such as fire or earthquake.

CAUTION

If you press the Emergency Stop or Emergency OFF buttons during a scan, the system will abort the data acquisition.

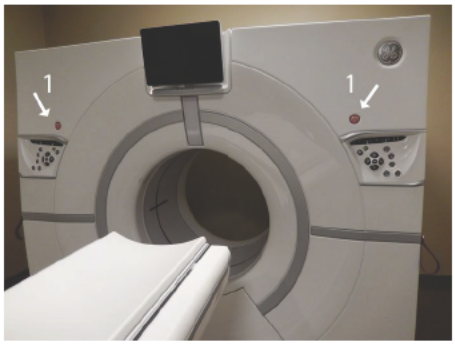
9.1.1 Emergency Stop

NOTE: Every operator should take a few minutes to locate the Emergency Stops on their system before scanning the first patient.

The system has five **Emergency Stop** buttons:

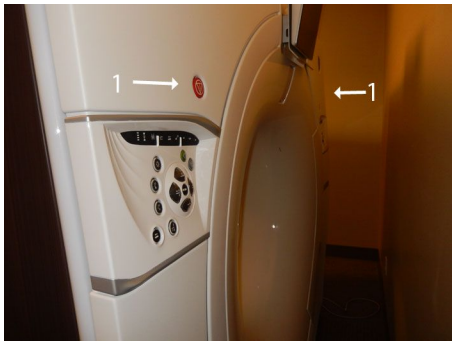
- Two on the front cover of the gantry.

Illustration 23: Front cover of gantry



- Two on the rear cover of the gantry.

Illustration 24: Rear cover of the gantry



- One on the Scan Control Interface.

Illustration 25: Scan Control Interface

Number	Description
1	Emergency Stop Button

Press an **Emergency Stop** button in the event of a patient related emergency or if the cradle, table or gantry starts to move unexpectedly.

- Once an **Emergency Stop** button is pressed, the **Reset** gantry control button, on the gantry control panel, flashes about once every two seconds.
- Press the **Reset** gantry control button to restore power to the gantry and table.

When Emergency Stop is applied, the maximum stopping distance of the moving cradle is 10 mm.

Emergency Stop Button Symbols

Emergency Stop buttons may be accompanied by one of the symbols below.

9.1.2 System Emergency OFF Buttons using Main Disconnect Control

In the event of a fire, flood, earthquake, or any other catastrophic emergency, all power to the system should be turned off. Pressing the **System Emergency OFF** button (red, circular button located on the wall) immediately removes all power to the system by removing power to the Main Disconnect Control (MDC). Because the system has no time to save data, or shutdown in an orderly fashion, pressing the **System Emergency OFF** button can corrupt system files or result in loss of patient data.

The facility designer determines the quantity and locations of the Emergency OFF buttons. GE recommends placing an Emergency OFF button near the doorway of every room in the system scan suite. Ask your supervisor to show you the location of all the Emergency OFF buttons in the system suite. Follow facility guidelines to report an emergency.

Reset the Emergency OFF Button

1. Press the Start button on the Main Disconnect Control.

   Power to the Power Distribution Unit (PDU), scanner desktop and system electronics will be restored.

2. Press the Reset gantry control button on the gantry panel.

   Power to the gantry drives, X-ray system, and table drive will be restored.

CAUTION

The x-ray and Drive power is disabled. Please walk into the scan room and press the Reset button on the Gantry Control Panel.

9.2 Emergency Patient Care During X-ray ON

- Press **STOP SCAN** to abort X-ray and stop gantry/table movement.
- Press **PAUSE SCAN** to pause scanning after the current scan completes.
- During an exam, the system pauses between scans if you Press any button on the control panel other than the alignment lights. It stops X-ray if you Press the same button(s) during a scan.
- Select **Resume** on the screen to continue the exam.

9.3 Emergency Egress

System operation may be stopped due to power failure or a safety event (something coming into contact with the collision sensors), or the system may be halted by the operator in response to emergency conditions.

The cradle unlatch button should only be used in emergency egress situations.

To safely remove the patient:

1. Press the Cradle Release gantry control button or the Emergency Stop button to disengage the clutch.
2. Pull the cradle to its out position, using the Cradle Lip or Cradle Handle.
3. Assist the patient off the table.

10 Laser Safety

(Reference 21CFR 1040.10 (h) 21CFR1020.33 (g)(4))

A laser alignment light system is available in order to accurately define the patient scan region.

From the gantry controls, press the laser alignment light to toggle all laser alignment lights on/off and to move the gantry components from the park or idle position to the alignment lights position. Alignment lights are used to establish landmark locations. Three alignment lights are displayed: axial, sagittal and coronal. Align the laser lights with the desired anatomical reference. A poorly positioned and centered patient can impact the mA values calculated for AutomA/SmartmA.

The laser alignment light switch is provided as an alternative to beam attenuators.

Press the Internal and External Landmark buttons to establish the table's reference point when positioning the patient. This reference point is normally the anatomic reference point used when positioning the patient. For example, if the patient's anatomic reference point is the sternal notch, then the sternal notch would be centered to the laser alignment light.

- For Internal Landmark, the gantry displays a table location of 0 mm. This sets the zero point for which S and I scan locations are centered around.
- For External Landmark , the gantry displays a table location approximately 240 mm from the internal landmark, depending on table characterization.

A landmark must be set before you click Confirm. At Done Scanning, the landmark is cleared. For scan setup details, see the Set up and position the patient procedure.

WARNING

THE LASER BEAM CAN CAUSE EYE INJURY.

- **TELL ALL PATIENTS TO CLOSE THEIR EYES BEFORE YOU SWITCH ON THE ALIGNMENT LIGHTS.**
- **INSTRUCT YOUR PATIENTS TO KEEP THEIR EYES CLOSED UNTIL YOU TURN OFF THE ALIGNMENT LIGHTS.**

NOTE: Closely monitor infants and infirm patients, and prevent them from accidentally staring into the beam.

WARNING

THE DETECTOR AND DAS ROTATE TO POSITION THE ALIGNMENT LIGHTS OVER THE LASER PORTS.

- Keep your hands away from the gantry opening.
- Make sure the gantry covers are in place.
- The indicator on the gantry display panel lights when you turn ON the alignment lights.

- Warning labels regarding laser safety are provided on the gantry, as described in the Warning Labels and Symbols section.

Maintenance

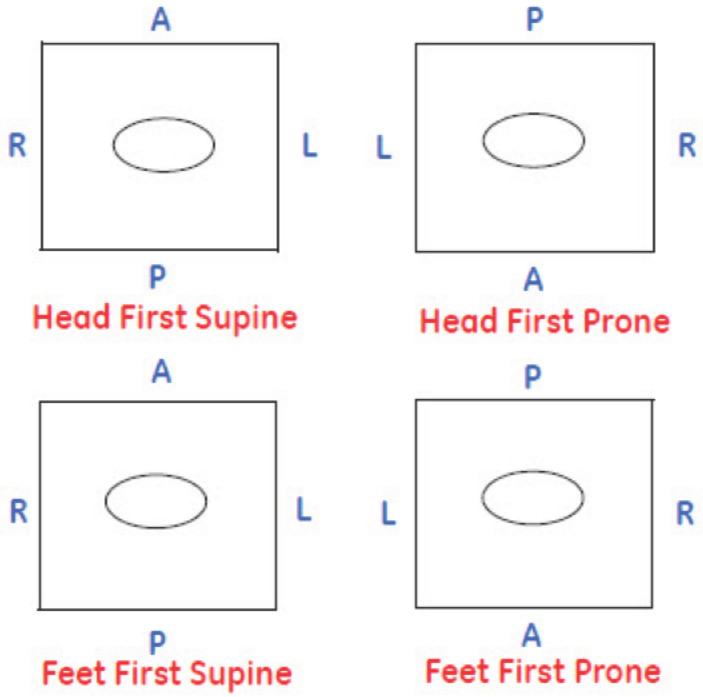
- Laser alignment lights do not require user maintenance.
- Qualified service personnel must inspect the lights periodically to assure proper alignment.

11 Reconstructed Image Orientation

CAUTION

GE CT image reconstruction is in an orientation viewing from the patient's feet. The reconstructed orientation is the orientation the image is installed in the image data base and is the orientation images are networked with to a remote viewing station.

Illustration 26: Patient Orientation



The patient position information stored in the image header correctly reflects the orientation (RAS) information for the patient. Viewing applications will correctly reflect Right (R), Left (L), Anterior (A) and Posterior (P) of the patient.

The reconstructed image orientation may differ from preferred anatomical viewing presentation in which the patient's Right is on the viewers Left and patient's Left is on the viewers Right. For example, when the patient is scanned Head First and Prone the patients's Left is on the viewer's Left and the patient's Right is on the viewer's Right. The image presentation will need to be modified to display preferred anatomical viewing. Some viewing stations may not have the capability to flip the image presentation, but if the capability exists, you must use display tools such as Flip to change the presentation of the image.

Some remote viewing stations may have the capability to set default viewing protocols. This is another tool that can be used to set an anatomical viewing presentation.

Post processing applications automatically orient images in anatomical viewing orientation. These applications create axial images in anatomical viewing presentation. Please see Auto Applications

(Option) for more information. The system also provides the capability to create Gray Scale Presentation State Objects (GSPS) to flip the image orientation.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE IF PATIENT ORIENTATION HAS BEEN CHANGED OR DOES NOT MATCH AFTER START OF EXAM.

12 Data Safety

CAUTION

Incorrect data entries or procedures could result in misinterpretation or misdiagnosis.

WARNING

ATTENTION - DISK SPACE LOW SOFTWARE PROBLEM DETECTED WITH DISK SPACE. PLEASE COMPLETE WHAT YOU ARE CURRENTLY DOING, THEN PERFORM SYSTEM SHUTDOWN. INFORMATION REGARDING WHICH DISK PARTITION(S) ARE FULL CAN BE OBTAINED FROM THE SYSTEM GESYSLOG IN /VAR/ADM.

WARNING

DO NOT LOAD ANY NON-GE APPROVED SOFTWARE ONTO THE COMPUTER.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE IF THERE IS A FAILURE DURING THE ARCHIVE OF PATIENT DATA.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE IF THERE IS A FAILURE DURING THE NETWORK TRANSFER OF PATIENT IMAGE DATA.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE WHEN EXPECTED IMAGE SPACE REQUIRED TO STORE IMAGES FROM PRESCRIBED RECONSTRUCTION IS INSUFFICIENT.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE WHEN EXPECTED DISK SPACE REQUIRED TO STORE SCAN DATA FROM THE PRESCRIBED EXAM IS INSUFFICIENT.

WARNING

MISSING SLICES HAVE BEEN INTERPOLATED TO MAKE REFORMATTED IMAGES.

CAUTION

When entering Patient ID information the system may contain multiple instances of the same Patient ID. Multiple schedule records can be due to multiple procedures being ordered under separate accession numbers or New and Completed records in the Patient schedule for the same Patient ID. When entering the Patient ID verify that the correct Accession number and Exam Description selected is what is desired. Scanning with an incorrect accession number may cause problems reconciling exams on a PACS system. Please see the Scheduling Patients chapter for more information.

NOTE: The Patient Schedule chapter is in the User Manual.

CAUTION

When comparing GE CT images with other images, consult the DICOM Conformance Statement for the details on the DICOM Image Position, Frame of Reference UID and Slice Location values stored.

CAUTION

Some annotation values are stored in private DICOM elements. When viewing images on a remote station these annotations values may not be visible on the image. Consult the DICOM Conformance Statement for information on private DICOM data fields.

CAUTION

Attention! The table landmark has changed. This changes the location of all scans you have prescribed. Double check all scan locations before you start scanning.

WARNING

THE SYSTEM POSTS A WARNING MESSAGE PRIOR TO THE MODIFICATION OF ANY EXISTING PATIENT DATA BY THE USER.

13 Application Specific Safety Topics

13.1 Axial and Helical Scanning

WARNING

HELICAL SCANNING HAS THE INHERENT ABILITY TO PRODUCE ARTIFACTS WHEN SCANNING HIGHLY SLOPED ANATOMY (E.G. PEDIATRIC OR ADULT HEADS). FACTORS WHICH WORSEN THIS EFFECT ARE: FASTER TABLE SPEEDS AND THICKER IMAGE THICKNESS. IN SOME CASES THESE ARTIFACTS COULD BE MISTAKEN FOR A HEMORRHAGE NEAR THE CRANIUM, OR A THICKENING OF THE SKULL.
TO REDUCE THE OCCURRENCE OF THESE ARTIFACTS, YOU MAY PRESCRIBE SLOWER TABLE SPEEDS AND/OR THINNER SLICES (SUCH AS 2.5 MM) DURING HELICAL SCANS NEAR THE VERTEX OF A PEDIATRIC OR ADULT HEAD.

WARNING

IT HAS BEEN DOCUMENTED IN RADIOLOGY LITERATURE THAT AN ARTIFACT MAY OCCUR IN THE CHEST THAT BEARS THE DOUBLE MARGIN OF THE GREAT VESSELS, WHICH EMULATES A DISSECTION OF THE VESSEL DURING 0.4 - 1.0 SECOND SCANS. THIS CAN OCCUR IN AXIAL OR HELICAL SCANS. IF YOU HAVE SCANNED AXIALLY WITH A 0.4 – 1.0 SECOND ROTATION TIME AND OBSERVE THIS PHENOMENON, RE-SCAN THE AREA WITH A GATED SCAN, IF AVAILABLE ON YOUR SYSTEM, OR USE ANOTHER DIAGNOSTIC MEANS TO DISTINGUISH BETWEEN POTENTIAL ARTIFACT OR PATIENT PATHOLOGY.

13.2 Cardiac Imaging

CAUTION

A patient with any of the conditions list below may require additional attention. If patients are scanned with these conditions, the software may not be able to detect the R-Peaks and the images therefore may be produced as ungated segment images: - Patient with multiple pre-contractions or extra systole (e.g. PVC,PAC) - Patients with persistent or extreme arrhythmia - Patients with bi-ventricular lead (dual chamber) pacemakers

CAUTION

ECG signal clarity and integrity must be confirmed prior to performing ECG-gated acquisitions. Items which may require adjustments of equipment settings or positioning, or patient set-up include: -External Interference - Atypical Patient ECG (e.g. elevated T-Waves, low ECG amplitude or signal strength) - Suboptimal Patient Connection ECG lead placement should follow recommended guidelines to optimize results. If the ECG lead becomes disconnected during the scan, or the heart rate drops below 30 BPM, the images will be reconstructed as non-gated segment images. This is done to avoid inaccuracy of the z-location of images where necessary.

CAUTION

Patient motion, respiration, beat-to-beat variability of heart rate, heart motion, or significant change in heart rate over the scan duration could cause an ECG gated acquisition to have degraded image quality. It is important to explain to the patient the pattern of breathing instructions to expect, the warm feeling that can be felt from the contrast injection and to position the patient comfortably such that the arms will not move with respect to the body during the scan. Heart rate information and phase location will be updated to indicate any movement of trigger locations since heart rate and phase values are calculated based on time between consecutive triggers and are not diagnostic values.

CAUTION

Ensure the ECG patches are not past expiration date and that the gel on the pads is still moist for proper conduction of the ECG signal for successful gating.

CAUTION

There is a possibility that the ECG signal may not be detected by the scanner due to improper lead placements, or a lead falling off during the scan. It is important to place new leads on the patient before the scan. Make sure the leads are attached properly, and use only GE recommended ECG leads. It is important to confirm ECG trace clarity before the scan.

CAUTION

If during the scan the heart rate drops significantly lower than the prescribed heart rate, there is a potential for gaps in the gated image location. To avoid image location gaps, a non-gated image is reconstructed for the period where the patient heart rate dropped below the expected or confirmed heart rate at the start of the exam. A non-gated image may have more motion and may not be reconstructed at the prescribed phase.

CAUTION

Manual edits of the ECG gating waveform may be performed retrospectively in some ECG gated exams as long as scan data exists on the console. Images can be reconstructed with user modified gating triggers and the original gating information can be retrieved after edits have been made.

CAUTION

The report cursor shows the voxel value nearest to the center location of the report cursor in the original loaded slices.

CAUTION

The formats and image quality of exported electronic films are not suitable for diagnostic purposes. Image quality may be degraded by data compression techniques used to export electronic films.

WARNING

CURVED AND LUMEN REFORMATION CAN INTRODUCE DISTORTIONS IN THE SHAPE OF OBJECTS.

13.3 CT Integrated Cardiac Module

WARNING

THE CT INTEGRATED CARDIAC MODULE IS FOR USE SOLELY IN ACQUIRING CT IMAGES USING CARDIAC GATING/TRIGGERING, NOT FOR PHYSIOLOGICAL MONITORING. THE PATIENT'S CURRENT CONDITION MAY NOT BE REFLECTED, RESULTING IN IMPROPER EMERGENCY TREATMENT.

14 Application Software Safety

CAUTION

Do not initiate a QuickSnap if the system is actively collecting data with X-ray on.

CAUTION

Do not initiate an IQ Snap while the system is actively scanning or reconstructing data.

15 Accuracy of Measurements

This section includes information on accuracy of measurements used when reviewing images.

15.1 Measure Distance for Axial, Helical, and Cine Images

CAUTION

Measure error using the straight line distance graphic is ± the largest voxel dimension.

CAUTION

Note that the measurements are accurate only if the trace segments are longer than the slice interval.

15.2 Measure Distance for Scout Images

Accuracy of measurements for scout images in the “X” direction varies with object thickness and distance from ISO center in the “Y” direction. Note the orientations of the “X” and “Y” in Illustration 27 below assume a scout scan plane of 0 degrees. If the scout plane is rotated, then the “X” and “Y” orientation changes accordingly.

- For measurements of anatomy in the “X” direction that are at ISO center (“Y”):

  The measure error using the straight line distance graphic is less than 5 % of the measured distance plus 2 mm.

- For measurements of anatomy in the “X” direction that are NOT at ISO (“Y”):

  The measure error using the straight line distance graphic is less than 5 % of the measured distance plus 2 mm plus 3 % of measured distance per centimeter from ISO.

- For measurements of anatomy in the “Z” direction:

  Measure error using the straight line distance graphic is less than two times the image pixel size.

Illustration 27: Scout Scan Plane

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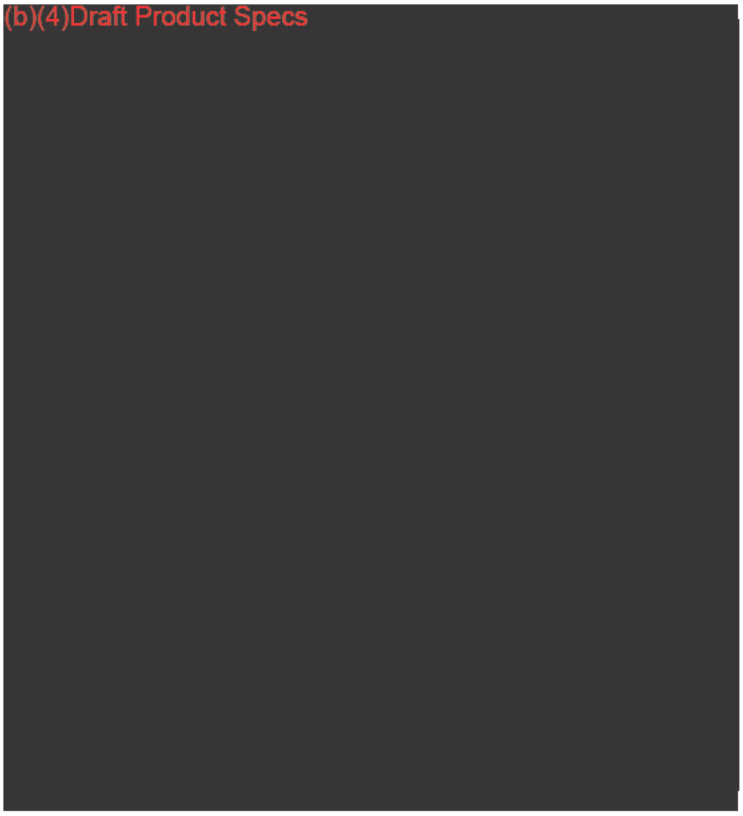

Number	Description
1	ISO center
2	Y-axis
3	X-axis
4	Z-axis
5	x-ray tube focal spot
6	scan plane
7	patient table

15.3 Measure Angle

CAUTION

Measurement accuracy using the angle graphic is equal to the displayed angle value ± 10 degrees for an angle measured between segments which are five times larger than the image pixel size. Accuracy improves as the length of the segments increases.

15.4 Voxel Dimensions

CAUTION

The image set resolution, that is, the dimensions of the voxels (volume elements) that constitute the image set, is determined by the size of the field-of-view, the matrix size, and the inter-slice distance. Ideally, voxels should be isotropic (with the same dimensions along all three axes). That is, the inter-slice distance should be the same as the voxel dimension in the acquisition plane. In practice, however, considerations such as patient irradiation dose levels will usually lead to the choice of a larger inter-slice distance. Be aware that details with dimensions in the order of or less than the inter-slice distance cannot be identified or measured with any degree of reliability.

15.5 ROI

CAUTION

Area measurement accuracy using a region of interest graphic (rectangle, smooth curve, ellipse or free draw) is equal to the displayed area ± the perimeter of the region multiplied by (largest voxel value)^2/2. Mean and standard deviation values for the intensity of the pixels in the region are also affected by this accuracy. If the ROI is rotated, the area measurement can vary up to 5 %. Region of interest statistics are based on the pixels INSIDE the graphic defining the region.

CAUTION

CT Numbers are NOT absolute; misdiagnosis is possible. System and patient variables may affect CT Number accuracy. If you rely solely upon CT numbers without taking variables into consideration, you could misdiagnose an image.

15.6 CT Number

(Reference 1020.33 (j)(1), 1020.33 (j)(2))

Besides anatomic location and area, each CT pixel also represents a CT number, which in turn indicates tissue density.

An image pixel represents a three dimensional volume, or voxel. It represents anatomy with a location, an area, and a pixel (density) value. The system flattens the 0.625, 1.25, 2.5, 3.75, and 5 mm scan thickness into a two dimensional screen image. If a pixel represents a variety of tissues, the system averages the contents to produce an averaged, rather than accurate, pixel value. Uniform tissues (within the voxel) produce fairly accurate pixel values.

CT pixel shading shows relative density. Denser materials weaken X-ray and produce whiter pixels. (Assumes Inverse Video OFF)

Reformat displays non axial planes created from contiguous pixels extracted from multiple images. 3D locates similar pixel values within contiguous images, and generates a mathematical model to produce images that appear three dimensional. BMD samples pixel values to estimate bone or tissue density.

Reconstruction assigns one value to every image pixel. CT uses pixel values of -32767 to +32767. MR uses pixel values of +16,000. The screen pixel translates the assigned value into one of the 256 shades of gray. Vary the gray scale window width and level to select anatomy for display. Window Width determines the quantity of gray pixel values. Window Level selects the center Window Width pixel value.

Example: Two windows may contain identical widths of 100 values, but display completely different anatomy, because one has a level of -100 and the other has a level of 150.

15.6.1 CT Number Mean and Standard Deviation

- An ROI averages the values of the enclosed pixels, and displays the resulting **Mean** value.
- **Standard Deviation** describes the difference between the minimum and maximum ROI value.
- A large ROI provides a larger, more accurate statistical sample than a small ROI.

The system provides, using the image display software, the capability to draw and edit rectangular and elliptical regions of interest (ROI), with the ability to calculate and report the mean value and standard deviation of the image pixel data contained within the ROI and the area of the ROI.

It also provides the capability to draw and edit a circular region of interest, with the ability to calculate and report the mean value, standard deviation, minimum, maximum and area (mm^2) of the image pixel data contained within the ROI.

15.6.2 CT Number Accuracy

CT Number of water: 0 HU ± 5 HU

CT Number of air: –1000 HU ± 10 HU

16 Accessory Safety

WARNING

DO NOT CONNECT ACCESSORIES OR OTHER ITEMS THAT ARE NOT APPROVED AS PART OF THE SYSTEM. DO NOT USE ACCESSORIES FROM OTHER MODALITIES.

WARNING

NONE OF THE ACCESSORIES SUPPORT THE FULL WEIGHT OF A PATIENT. IF YOU SIT, STAND, OR OTHERWISE APPLY EXCESSIVE PRESSURE TO THESE DEVICES, THEY COULD BREAK OR COME OFF THE CRADLE AND MAY CAUSE INJURY. IF AN ACCESSORY BREAKS, USE CAUTION WHEN PICKING IT UP AND DO NOT CONTINUE TO USE IT.

CAUTION

Using accessories which are not GE approved accessories might affect dose and image quality.

WARNING

ACCESSORIES LIKE ARM BOARDS AND CATHETER BAG HOLDERS ARE NOT SECURED TO GANTRY AND MAY INTERFERE WITH GANTRY IF NOT POSITIONED PROPERLY.

16.1 Monitor Safety

CAUTION

For a two-monitor configuration it is necessary to check the monitor calibration regularly to ensure images are displayed identically on both monitors.

16.2 IV Pole Safety

Care should be taken in the amount of weight placed on the pole. Ensure that the pole is tightened prior to use.

WARNING

THE IV POLE MAY BEND WHEN EXCESSIVE WEIGHT IS PLACED ON THE POLE. ENSURE NO MORE THAN 4.5 KG OR 10 LB IS PLACED ON THE IV POLE.

WARNING

ENSURE THAT THE IV POLE EXTENSION COLLAR IS TIGHTENED PRIOR TO USE TO PREVENT THE POLE HEIGHT FROM COLLAPSING.

Illustration 28: IV Pole Load Limits

CAUTION

Do not load more than 4,5 kg or 10 pounds. Verify that extension collar is securely tightened before use.

16.3 Table Tray Safety

Care should be taken in the total weight of objects that are placed on the tray.

Illustration 29: Tray Load Limits

WARNING

THE MAXIMUM ALLOWABLE WEIGHT PLACED ON THE TABLE TRAY IS 9KG OR 20 LBS.

WARNING

OBJECTS THAT MAY BE SUSCEPTIBLE TO TIPPING SHOULD BE STRAPPED DOWN WITH THE VELCRO™ STRAP PROVIDED.

16.4 Systems With Metal-Free Cradles and Accessories

CAUTION

Prevent damage to metal-free accessories! Carefully examine the metal-free clasp assembly on the accessory and the catch on the cradle before attempting to attach the accessory for the first time.

Illustration 30: Accessory Load Limit

CAUTION

Accessory may fall and cause injury if not latched to cradle. Make sure that accessory is latched to underside of cradle.

16.5 Power Injector Safety

CAUTION

The injector and the system are operated independently after the Start Scan button is pressed. When you want to stop both the system and the injector, use the Stop Scan button on the Scan Control Interface and the stop injector function on the injector system.

17 Maintenance and Cleaning

- To guarantee safe, reliable equipment performance, the site must be prepared according to GE Healthcare requirements, as specified in the Pre-Installation Manual.
- There are no user serviceable parts in this system. The product should be installed, maintained, and serviced by qualified service personnel according to procedures laid down in the product service manuals.
- The system in whole or in part should not be modified in any way without prior written approval by GE Healthcare.
- Keep the equipment clean. Remove body fluids and/or IV spills to prevent a health risk and damage to internal parts. Clean the equipment with any of the following approved cleaning agents. Follow cleaning agent manufacturer instructions. Apply with cloth or supplied cleaning agent wipes:
  - Warm water and soap mixture (mix 1 gallon of water with 0.5 teaspoon of dish washing soap)
  - Common household bleach, diluted 10:1
  - Sani-cloth HB
- Also, use dry cleaning for electronic components.
- Do not clean the connectors on the cables for ECG, respiratory equipment, etc. If you need to clean them contact GE Service.
- Planned maintenance must be carried out regularly to ensure safe operation of the equipment.
- For user maintenance of the system and performance tests, refer to the maintenance and calibration information in the Technical Reference Manual.

Environmental Concerns

This symbol indicates that the waste of electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

18 Hazardous Substances

The X-ray Tube Assembly contains potentially dangerous materials but does not present any danger as long as it is neither opened nor disassembled.

WARNING

DO NOT DISCARD THE X-RAY TUBE ASSEMBLY AMONG INDUSTRIAL WASTE OR DOMESTIC GARBAGE.

WARNING

A DAMAGED X-RAY TUBE ASSEMBLY SHOULD NOT BE DISPATCHED THROUGH THE NATIONAL POSTAL SERVICE.

The X-ray Tube Assembly contains the following potentially hazardous materials:

- Lead: Lead salts are toxic and their ingestion may cause serious problems. The manipulation/ handling of lead is subject to regulations.
- Oil: Univolt 54 and Crosstrans 206 mineral oil are not toxic, but the prevailing environmental regulations should be observed for their disposal or recuperation. For example, it is forbidden to dispose of these oils in the wastewater or sewage system or in the natural environment.

Your local GEMS field service will advise you on the suitable means of disposal of equipment.

The X-ray Tube Assembly to be discarded should be forwarded to the GEMS Service network, and it will be disposed of in a GEMS recycling center.

Precautions

Take all the necessary precautions for the personnel handling the recovery or destruction of X-ray Tube Assemblies, and in particular against the risks due to lead.

These personnel must be informed of the danger involved and of the necessity to observe the safety measures.

19 System Performance

CAUTION

Upon system startup, when an unrecognized X-ray tube is detected, the system displays the following notification to the operator: Attention An unrecognized X-Ray tube has been installed on the system. - GE cannot assure that system performance will conform to specifications. Advisory messages will be posted to the operator about an unrecognized tube during tube warm-up, during Fast Calibration, and in the dose report.

CAUTION

Prior to the start of tube warm-up, when an unrecognized X-ray tube is detected, the system displays the following notification to the operator: Attention An unrecognized tube has been installed on the system. Tube Cooling algorithms are designed specifically for GE tubes and the performance of the system cannot be guaranteed. Warning Scans may have been taken within the last two hours. Warmup scans may cause subsequent cooling delays. Note: Tube warmup will run in Autoscan mode.

WARNING

SCANS MAY HAVE BEEN TAKEN WITHIN THE LAST TWO HOURS. WARMUP SCANS MAY CAUSE SUBSEQUENT COOLING DELAYS. NOTE: TUBE WARMUP WILL RUN IN AUTOSCAN MODE.

CAUTION

Prior to the start of fast calibration, when an unrecognized X-ray tube is detected, the system displays the following notification to the operator: Attention An unrecognized tube has been installed on the system. Fast Calibration techniques are designed specifically for GE tubes and GE cannot guarantee that the performance of the system will meet specifications with an unrecognized tube.

CAUTION

Prior to confirmation of a scan prescription, when an unrecognized X-ray tube is detected, the system displays the following notification as a part of the pre-scan dose information to the operator: Unrecognized tube -- Dose not validated by GE.

CAUTION

When an unrecognized X-ray tube is detected, the system displays the following notification as a part of the post-scan dose report to the operator: Attention Unrecognized tube in use. The reported dose information is calculated based on empirical observations of systems with GE tubes. GE cannot assure the accuracy of reported dose information for any configurations that include tubes other than GE tubes.

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Chapter 4 Read Me First

1 About This Manual

This section explains the purpose and design of this user manual. It provides information on the purpose, prerequisite skills, organization, format, and graphic conventions used throughout the manual.

The guide does not identify components or features that are standard or purchasable options. If a feature or component included in the manual is not on your system, it is either not available on your system or your site has not purchased the option.

1.1 Notices

The following notice symbols are used to emphasize information that is considered important, requires special notice, or includes helpful troubleshooting tips.

NOTICE

Notice indicates information where adherence to procedures is crucial or where your comprehension is necessary to apply a concept or effectively use the product.

NOTE: Note provides additional information that is helpful to you. It may emphasize certain information regarding special tools or techniques, items to check before proceeding, or factors to consider about a concept or task.
Troubleshooting tips provide information that allow you to investigate the resolution of some type of problem, locate the difficulty, and make adjustments to solve the problem.

1.2 Purpose of this guide

This user guide is written for health care professionals and technologists to provide the information they need to properly operate the system. The guide is intended to allow you to understand the system components and features and to use the system to its maximum potential. The guide is does not teach imaging or clinical diagnostics.

This user guide should be kept with the equipment. Review the procedures and safety precautions, as needed. It is important for you to read and understand the contents of this guide before attempting to use the system.

This user guide is originally written in English.

1.3 Prerequisite skills

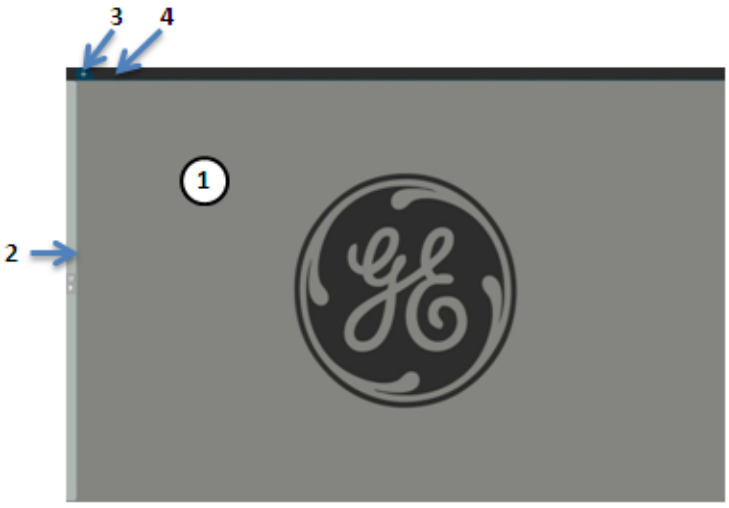
The operator profile may be limited to registered CT technologists certified by national registries, state licenses, or organizational certification; physicians with or without specific training in radiology; physicists or other personnel trained to operate the equipment.

This guide is not intended to teach imaging. You will need to have sufficient knowledge to perform the diagnostic imaging procedures within your modality.

2 Scan Display

The scan monitor is divided into four areas.

Illustration 1: Scan Monitor



Number	Description
1	Scan control display
2	Patient Schedule drawer
3	Add New Patient
4	Patient Tab area

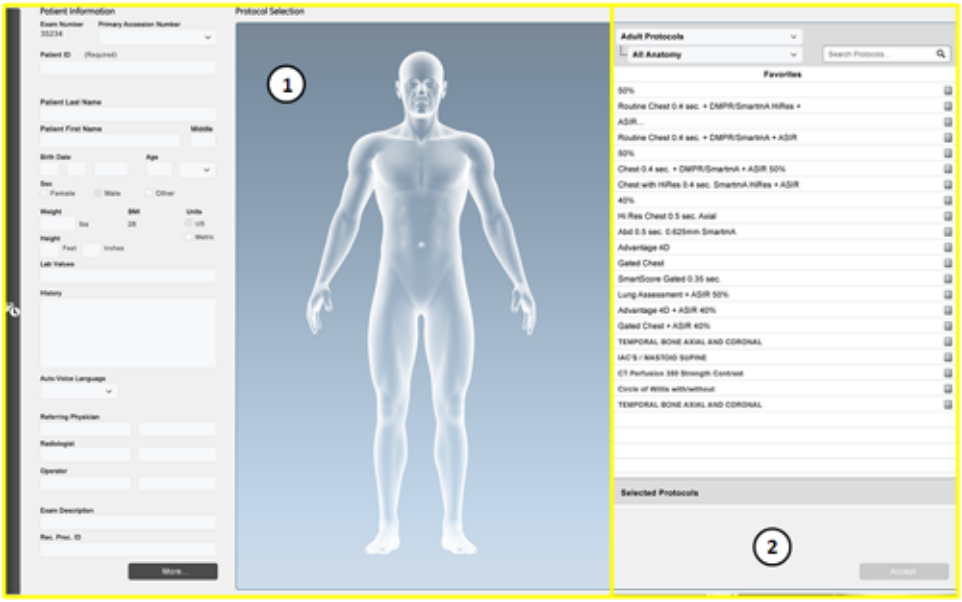
Table 1: Scan function icons

Icon	Description
	**New Patient** Starts a new patient and opens the *New Patient* menu. Once the patient information is completed and the protocol is selected, the *scan setup* interface displays.
	**Patient Schedule** Opens *patient schedule* to pre-program patient information or retrieve patient information from Digital Imaging and Communications in Medicine (DICOM) or Hospital Information System/Radiology Information System (HIS/RIS).

2.1 New Patient

Click the [New Patient] icon to launch the New Patient screen. It is divided into two areas.

Illustration 2: New Patient screen



Number	Description
1	Patient Information area
2	Protocol Selection area

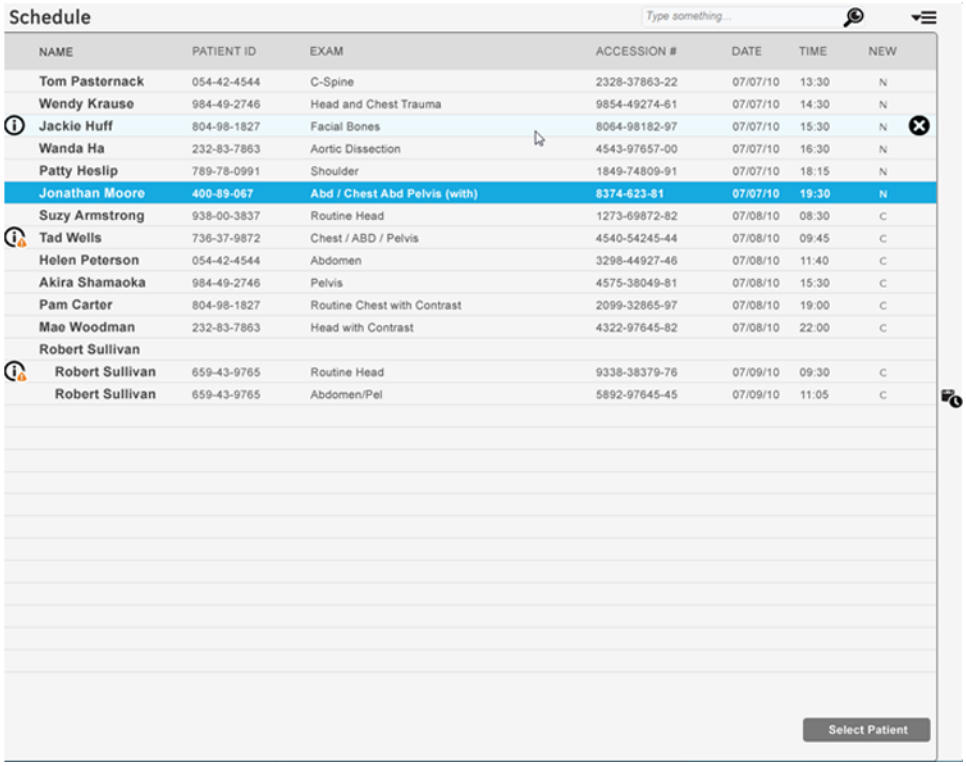
2.2 Patient Schedule

Illustration 3: Patient Schedule - Closed Zone

Click the [Patient Schedule] icon to open the *Patient Schedule* drawer.

Illustration 4: Patient Schedule - Open Zone

Illustration 5: Patient Schedule



2.3 Scan Setup screen

When an exam is in process, the *Scan Setup* screen displays the following. It is divided into three areas.

Illustration 6: Scan Setup screen

Number	Description
1	Patient Position Functions
2	Scan Settings. Here you adjust scan parameters. It also displays the real time scan progress information.
3	Displays multiple types of contents. typically, dose information is displayed in this area. It may also display real-time information when the active application requires it.

3 Image Display

The image display monitor contains 4 areas.

Illustration 7: Image Display Screen (right monitor)

Number	Description
1	Icons and System Status Area
2	Reconstruction and Image Processing Task List
3	Image Viewports
4	File Manager

3.1 Icons and System Status Area

The Icons and System Status Area displays the date, time, available disk space, tube status, system utilities icon, mode icon, and system messages.

Illustration 8: Icons and System Status Area

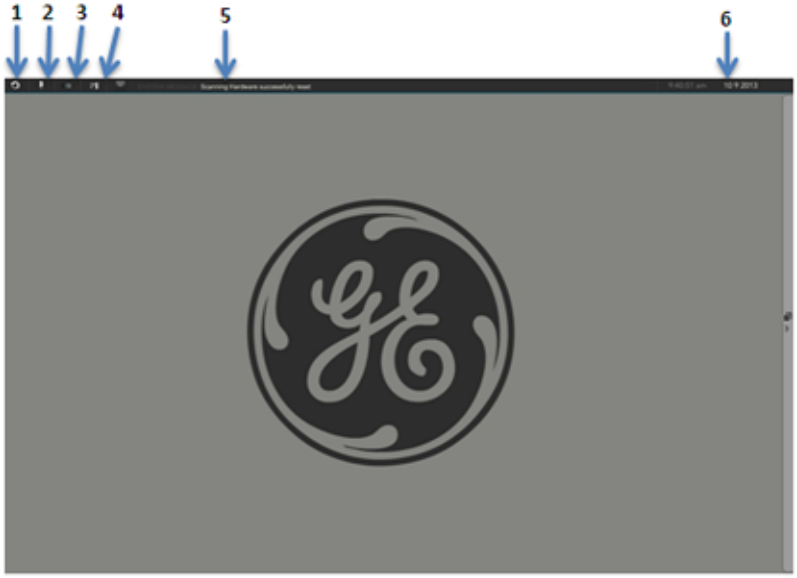
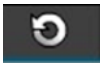
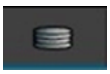


Table 2: Modes and System Status Icons

Number	Description
1	 **Mode Icon** Dropdown selection that contains the following: • Scanning Mode • Service Mode • Preferences • User Information • Protocol Management • Auto-Voice Management • Auto Gating Configuration • kV Assist Management • Access Controls (includes Dose Check Management) • System Lock • Start Up and Shut Down
2	 **Tube Status** The tube icon provides information and functions in response to the current state of the scanner x-ray tube.
3	 **Available Disk Space** Communicates the amount of available disk space on the system. A warning level is set to alert the user of low disk space. **NOTE:** We recommend that you remove images when the image space falls below 1,000 images. This ensures that there will be enough disk space for acquiring and reconstructing images. Do not remove images while scanning, restoring, or receiving images.

4	 **System Utilities** This feature encapsulates all the necessary user maintenance calibration routines and other utility functions for a particular scanner within a drop down menu: • Tube Warm Up • Daily Calibration • Scanner Utilities • Check Security • UNIX Shell – Left • UNIX Shell – Right • Quick Snap • Anon Pat Level • General Recon Queue • Network Queue • Archive Queue
5	**System Messages** Click on the message to see a list of system messages.
6	**Date and Time** The current date and time information.

3.2 Reconstruction and Image Processing Task List

This reconstruction and post processing task list offers the ability to define additional image processing tasks during the scan process, including Recons, manual and automatic reformats, in one central place. It also allows the monitoring of both the creation and transfer of those image sets.

Illustration 9: Reconstruction and Image Processing Task List Zone

3.3 Image Viewports

Viewports are displayed on both the left and right monitors. The two viewports on the left are dedicated to the scanning process, whereas the four viewports on the right are used in image-processing.

Illustration 10: Image Viewports Zones

3.4 File Manager

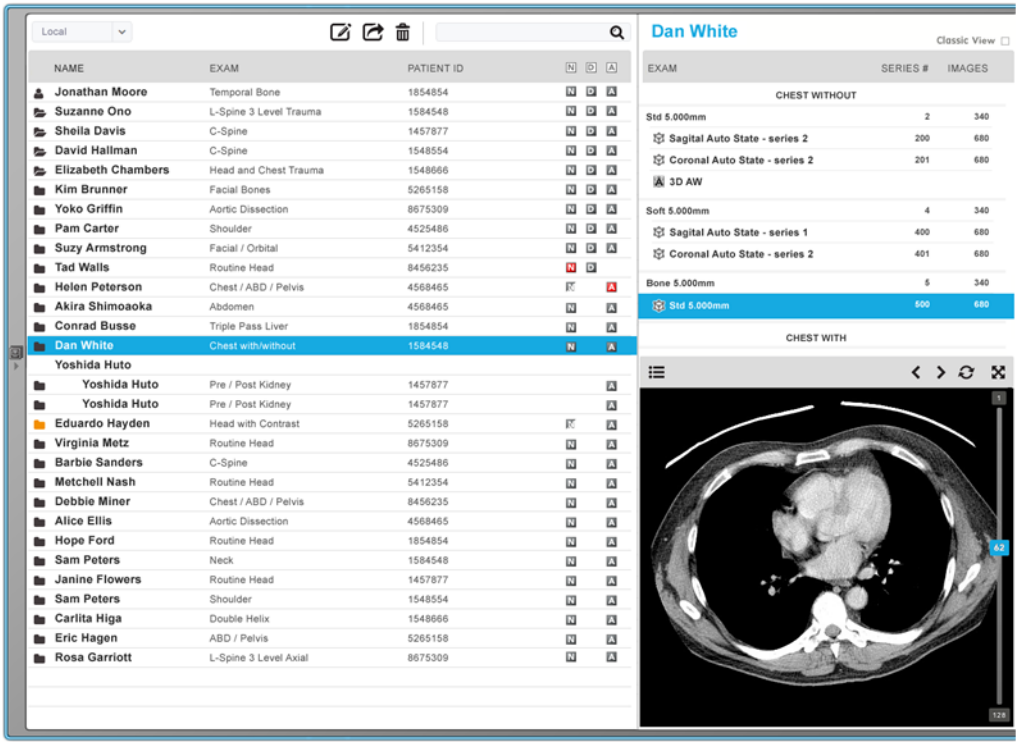
The File Manager serves three main functions: exam organization and status, access to files, and opening an exam.

Illustration 11: File Manager - Closed Zone

Click the [File Manager] icon to open the File Manager browser. Select an exam/series/images from the patient list and click to launch the session tab.

Illustration 12: File Manager - Open Zone

Illustration 13: File Manager



4 User Interface Conventions

4.1 Select items from a list

4.1.1 Single item

Click the item.

4.1.2 Multiple contiguous items

Click a start point in the list, press <Shift>, click an end point in the list, and all items between start and end are selected.

4.1.3 Multiple non-contiguous items

- Press and hold <Ctrl> and click each item.
- The <Close> or <X> button also closes a screen without executing the actions or implementing parameters.

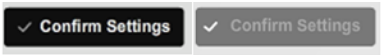
4.2 Cancel

The [Cancel] button closes a screen without executing the actions or implementing parameters described on a screen.

4.3 Button appearance

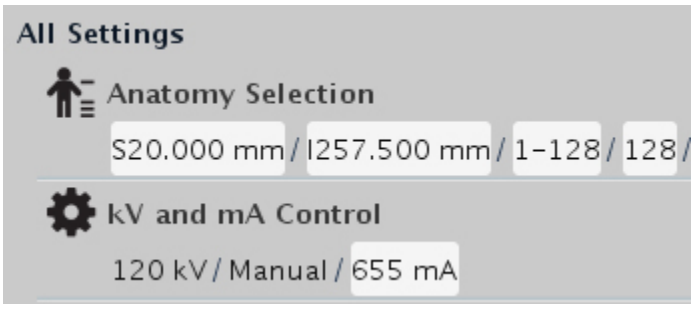
Buttons that are gray are not active. In the illustration below, the right button is not active.

Illustration 14: Active and Inactive Buttons



Settings that are updated, either by the system or by the user, appear in white. Text fields that cannot be changed are not underlined.

Illustration 15: White Text Field Indicating an Updated Value



For updated settings that are invalid, the background is highlighted white with a red outline and the settings collection is flagged with an alert icon to visually notify the user that this parameter is invalid. The [Confirm Settings] button is also disabled.

4.4 Pop-up windows

Pop-up windows may require an acknowledgement by clicking [OK] or [Accept] to close the window.

4.5 Mouse controls

For mouse control details, see Chapter 8, Section 2.9, Operate the mouse controls .

5 System Troubleshooting Tips

- Complete all portions of Fast Cal. This assures that the Air calibration and generator calibrations are up to date on the system.
- Scan aborts may occur during Axial or Helical scanning. Always be aware of the scan progress during an Exam and select Resume as soon as it is posted to continue.
- In general, wait for a screen transition to take place before making another selection. Switching desktops before the user interface is displayed can result in the wrong screen displayed on the desktop.
- If the scanner desktop becomes unresponsive for several minutes, click the [Mode] button and select [Shutdown] menu from the drop down to restart the system. If you cannot select [Shutdown], turn off the scanner desktop power switch, wait 10 seconds, then turn the console power switch back on.
- Contact your service representative, if you see the message: “Attention – High Speed Disk Performance Degraded.” Scan disk array has encountered a hard drive failure. The system is functional, but if another hard drive fails you will lose scan data. Please contact GE service to have the disk array repaired as soon as possible."

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Chapter 5 Pediatrics and Small Patients

1 Overview

GE Healthcare strongly suggests reducing radiation dose to ALARA (As Low As Reasonably Achievable) in all patients, especially pediatric and small patients, whenever it is determined that a CT scan is necessary. CT is an extremely valuable tool for diagnosing injury and disease, but its use is not without risk. This chapter discusses the importance of minimizing the radiation dose in small patients and children consistent with ALARA principles.

2 Radiation Exposure

2.1 Radiation exposure sensitivity

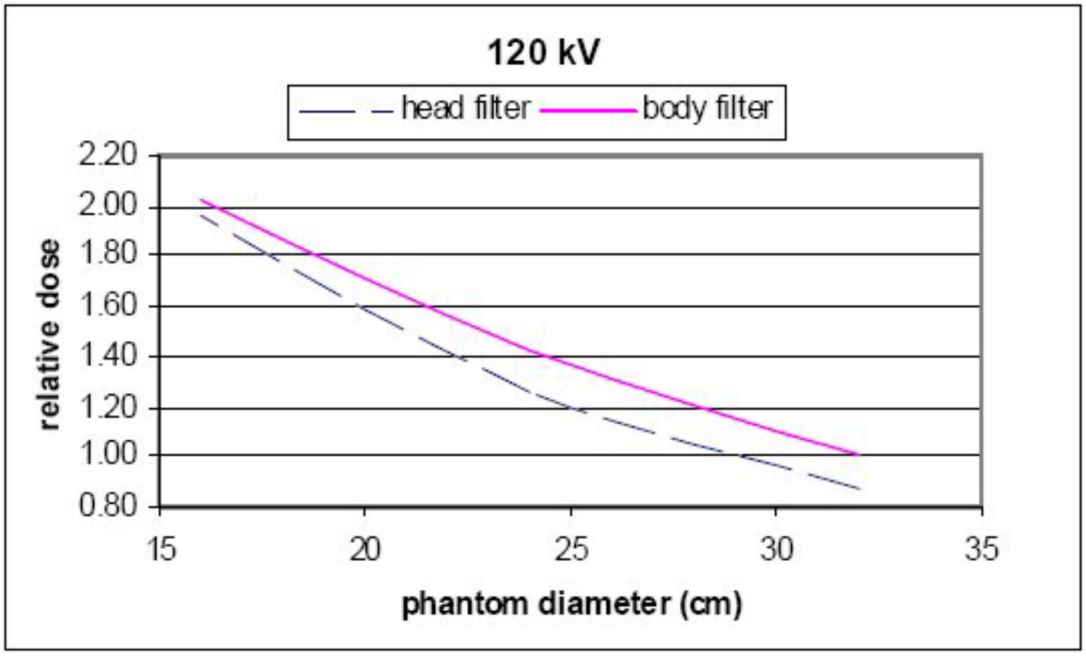
Radiation exposure is a concern in both adults and children. However, children are more sensitive to radiation than adults and have a longer life expectancy. Radiation risk is higher in young patients, as they have more rapidly dividing cells than adults. The younger the patient, the more sensitive they are. Using the same exposure parameters on a child as used on an adult may result in larger doses to the child. There is no need for these larger doses to children, and CT settings can be adjusted to reduce dose significantly while maintaining diagnostic image quality.

The National Cancer Institute and The Society for Pediatric Radiology developed a brochure, *Radiation Risks and Pediatric Computed Tomography: A Guide for Health Care Providers*, and the FDA issued a Public Health Notification, *Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients* dated November 2, 2001, that discuss the value of CT and the importance of minimizing the radiation dose, especially in children. These documents can be accessed at http://www.fda.gov.

2.2 Dose reporting considerations

It is widely understood and accepted that adult techniques should never be applied to small patients or pediatrics since smaller objects have higher dose at the same technique. The chart below illustrates the sharp increases in relative dose as the part scanned gets smaller in size using the same technique.

Illustration 1: Relationship between dose and phantom size for head and body filters at 120 kV. Similar curves are obtained for the 70, 80, 100, and 140 kVs.



Another consideration about dose is since it is not possible to characterize dose given to individual patients, the CT dose indices are provided to help make relative comparisons. These dose index

values can be used to compare CT systems and to help select appropriate operating conditions for scanning. However, it is important to recognize that the dose reported by these indices is inversely proportional to phantom size (see the above chart). This means that for the same scan technique, smaller phantoms (patients) will produce a higher absorbed dose than larger phantom (patients). Therefore, it is critical to remember that the body filter uses the 32 cm CTDI phantom and the head filter uses the 16 cm CTDI (Computed Tomography Dose Index) phantom for dose reporting purposes (CTDIvol is displayed in the *Dose Information* area on the *ViewEdit* screen). The table below indicates the phantom size used for calculating dose for each SFOV (Scan Field Of View).

In other words, when looking at the actual absorbed dose to the patient, understand that the dose may be higher than reported if the part scanned is smaller than the phantom tested. Keep this in mind when adjusting scan parameters to fit patients who are smaller than the phantoms tested.

Table 1: CTDI phantom used dose report based on SFOV type

SFOV type	CTDI phantom
Ped Head	16 cm phantom
Ped Body	
Small Head	
Head	
Small Body	32 cm phantom
Medium Body	
Large Body	
Cardiac Small	
Cardiac Medium	
Cardiac Large	

2.3 Minimize pediatric and small patient doses

There are several steps that can be taken to reduce the amount of radiation that pediatrics and small patients receive from CT examinations. Everyone shares the responsibility of minimizing CT radiation dose. Use the following suggestions for minimizing unnecessary doses.

2.3.1 Perform only necessary CT examinations

Is CT the most appropriate study? This important communication between the patient's physician and the radiologist is essential in determining the need for the CT examination. The indications and the appropriate technique to be used should be reviewed by the radiologist prior to every scan including the patient’s number of previous scans, reasons for the scan, and consideration of other effective lower dose modalities. In all circumstances, the expected benefits of the scan must always exceed the overall risk.

2.3.2 Scan only the organ or anatomical region indicated

Limit scan coverage to cover only the organ or anatomical region of the body indicated to avoid unnecessary exposure.

2.3.3 Minimize multi-phase contrast CT examinations

Scan only one series if possible.

- CT studies with and without contrast material are not always needed.
- Multiphase imaging may double or triple the dose and may not add diagnostic information to the study.
- If multi-phase studies are needed, use a lower dose technique for the non-contrast series compared to the contrast series and limit the scan only to the organ or anatomical region indicated.

2.3.4 Properly center all patients in the gantry

Center all patients in the gantry to allow the bow tie filters to deliver dose where it is needed and filter more where it is not.

- This is especially important using automatic exposure control techniques such as AutomA, SmartmA, and Organ Dose Modulation to further reduce unnecessary radiation exposure.
- Patients not properly centered may be under or over exposed to radiation if the table height is set too high or too low.

2.3.5 Lower mA settings for chest and bone imaging

Consider using a lower mA setting and higher Noise Indexes if AutomA is used for chest and bone imaging. Higher resolution/dose imaging is typically unnecessary for these types of studies where there is high inherent contrast between the structures being imaged.

2.3.6 Scan signal-to-noise

Limit the highest quality images requiring the highest radiation dose to very specific indications such as angiography or visualizing small subtle lesions. Studies with higher noise may be just as diagnostic and require lower dose.

2.3.7 Consider using in-plane Bismuth shields

Use in-plane Bismuth shields to reduce the patient dose.

- Recent studies have shown dose reductions to sensitive organs, such as breast tissue in females, the thyroid, and eyes without significantly affecting image quality.
- If used with AutomA, they should be put in place after the scout scans are acquired to reduce technique overcompensation.

2.3.8 Use pediatric positioning accessories

Use papoose boards and neonatal immobilizers, as needed, with certain patients.

- These accessories are sometimes helpful to secure the patient and keep the patient still.
- Results in less patient motion and therefore, less repeated exams.

2.3.9 Make a kid friendly environment

Help pediatric patients feel less scared.

- Put pictures of animals on the wall or ceiling.
- Use stuffed animals.
- Play games.
- Depending on the patient age, explain the procedure so they know what to expect when they enter the scan room. This will aid in patient cooperation and potentially less repeat studies and dose due to patient motion.

3 Pediatric and small patient scans

3.1 Optimize pediatric protocols for your facility

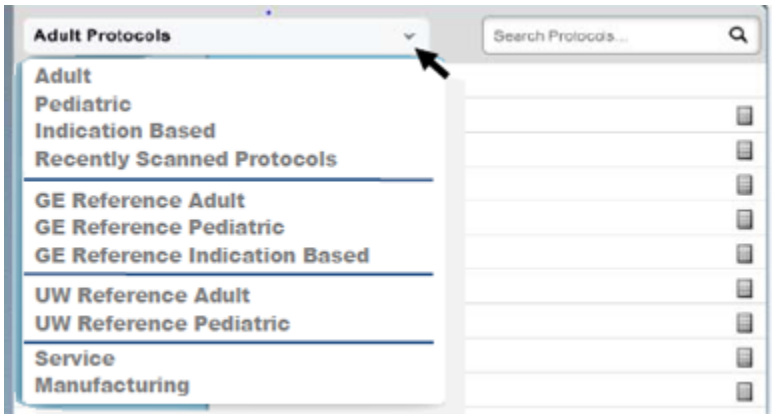
Work with your team of radiologists, medical physicists, and CT technologists to evaluate techniques that may reduce radiation dose and still provide adequate diagnostic information. In addition to the recommended protocols installed on your system and suggestions in this manual, these websites offer excellent sources of additional information on how to optimize scanning protocols:

- American College of Radiology (ACR): http://www.acr.org/
- Society of Pediatric Radiology (SPR): http://www.pedrad.org/
- National Cancer Institute (NCI): http://www.nci.nih.gov/aboutnci
- Image Gently: http://www.imagegently.com/
- FDA website: http://www.fda.gov/

3.2 Pediatric protocols

The Pediatric Protocol area was designed to help facilitate protocol selection for pediatric patients by providing age based protocol areas for Head, Orbit, and Miscellaneous and color coding system for Neck, Upper Extremity, Chest, Abdomen, Spine, and Pelvis. It is highly recommended to place and select pediatric protocols from the pediatric selector based on age, height, and weight. By entering the pediatric patient's weight in the *Patient Information* screen, the system automatically selects the appropriate color code area for the anatomical area selected.

Illustration 2: Protocol Category screen



3.3 Color Coding for Kids Protocol Selection

Based on the Broselow-Luten Pediatric System, the Color Coding for Kids system was developed to help you select the correct pediatric CT protocol. The system divides the protocols into nine color zones based on height and weight, and incrementally increases scan technique as the patient’s size increases. This arrangement of protocols assists you in reducing the variations in

pediatric protocol selection. If the patient weight is unavailable, a Broselow-Luten Tape can also be used to obtain the weight based on the length.

Once you select the Pediatric selector, the Pediatric *Protocol List* displays. Next to the name of the protocol a color icon along with the zone number will be indicated. The notes area of the protocol selector will display the zone ranges for weight and length, color name and the weight/color zone number.

NOTE: Weight-specific protocols are enforced for all anatomical areas except *Head*, *Orbit*, and *Miscellaneous*. Protocols in the *Head* and *Orbit* categories are usually defined based on patient age as opposed to patient weight/height.

Illustration 3: Pediatric Protocol Category screen

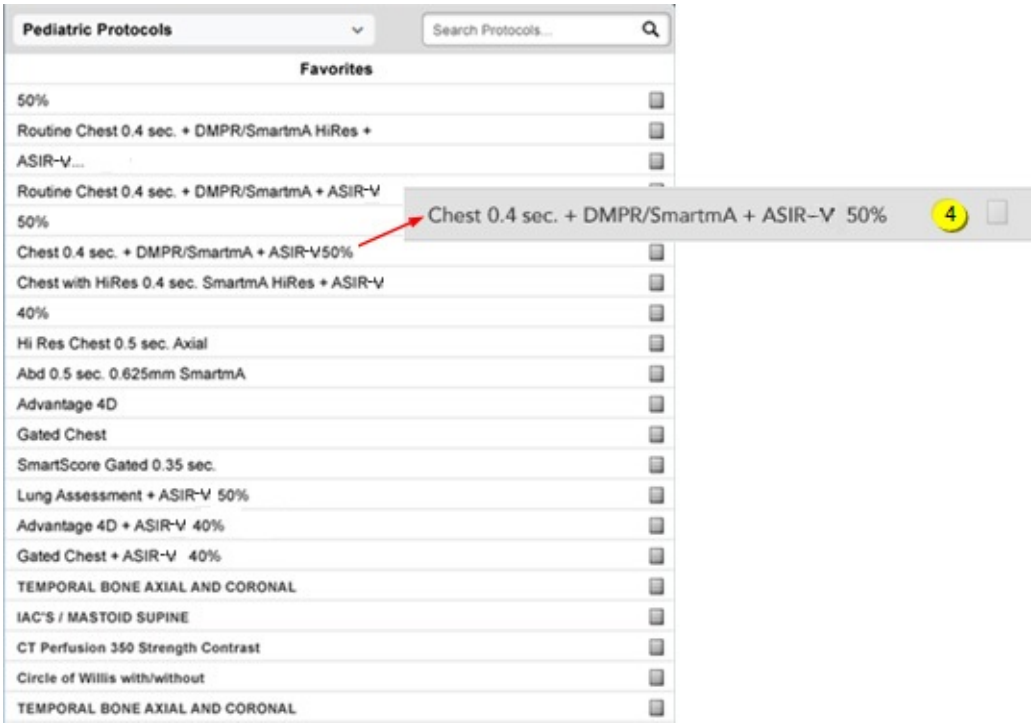


Table 2: Color codes

Zone number	Zone color	Zone weight (lb)	Zone weight (kg)	Zone length (cm)
1	Pink	13.2 to 16.5	6.0 to 7.5	59.5 to 66.5
2	Red	16.5 to 20.9	7.5 to 9.5	66.5 to 74.0
3	Purple	20.9 to 25.4	9.5 to 11.5	74.0 to 84.5
4	Yellow	25.4 to 32.0	11.5 to 14.5	84.5 to 97.5
5	White	32.0 to 40.8	14.5 to 18.5	97.5 to 110.0
6	Blue	40.8 to 49.6	18.5 to 22.5	110.0 to 122.0
7	Orange	49.6 to 69.5	22.5 to 31.5	122.0 to 137.0

Zone number	Zone color	Zone weight (lb)	Zone weight (kg)	Zone length (cm)
8	Green	69.5 to 89.3	31.5 to 40.5	137.0 to 150.0
9	Black	89.3 to 121.3	40.5 to 55	--

3.4 Set up a pediatric or small patient exam

Use this procedure each time you start a new patient exam for a pediatric patient. It is recommended that you complete the patient information setup before you get the patient on the table to reduce patient table time. The data can also be input by using *Patient Schedule* or a bar code reader.

1. From the scan monitor, click the *Patient Schedule* drawer icon.
   - The *Patient Information* screen displays the new *Exam Number*.
   - The maximum *Exam Number* is 49,999, which is reset by your Field Engineer.
2. From the *Patient Information* area, type data into the appropriate fields.
   - Press <Enter> to advance to the next field. Alternatively, use the mouse to navigate to each field.
   - Patient ID and Operator Name are a required field. If the patient does not have an identification number, type ***?*** or the word ***trauma***.
3. Click [Pediatric].
4. From the *Pediatric Protocol Selection* screen, click an anatomical area.
   - With the patient's weight entered, the system automatically selects the appropriate pediatric color code area for the anatomical area selected.
   - Use the arrows to scroll through the list.
   - Click a protocol from the list to download the scan parameter values.
5. From the *Pediatric Protocol Category* screen, select the weight/length category based on the size of your patient or verify the correct Color category has been selected if you entered a weight.
   - The protocols in the selected color code are then displayed accordingly.
   - The default weight/color selector displays the patient weight entered on the *Patient Information* screen, or the last weight/color selection (if no patient information was entered).
   - There is no default protocol for Pediatric areas *Neck*, *Upper Extremity*, *Chest*, *Abdomen*, *Spine*, *Pelvis*, and *Lower Extremity*.
   - If you enter a patient weight on the *Patient Information* screen and select a color/weight that is not consistent with the entered information, an error message displays. You must acknowledge that you have chosen a protocol that does NOT match the patient size.

6. Proceed with the Acquire a Scout scan procedure.

3.5 Adjust pediatric and small patient scan parameters

Use the following guidelines for adjusting individual exposure parameters by patient.

3.5.1 Adjust the parameters by size, age, weight, height, and indications

Use pediatric protocols based on the age, weight, height, and indications to avoid over exposure.

- Recommended pediatric color coded protocols are installed on the system and are arranged in colors according to height and weight for easy selection.
- These protocols should be considered as a baseline. It is strongly encouraged that you work with your radiologist and medical physicist to determine the lowest possible dose at the image quality desired.
- Consider the diameter of the part being scanned as a final determination before scanning. For instance, the part may be smaller or larger than what is indicated by the weight of the patient.

3.5.2 Consider decreasing the kV

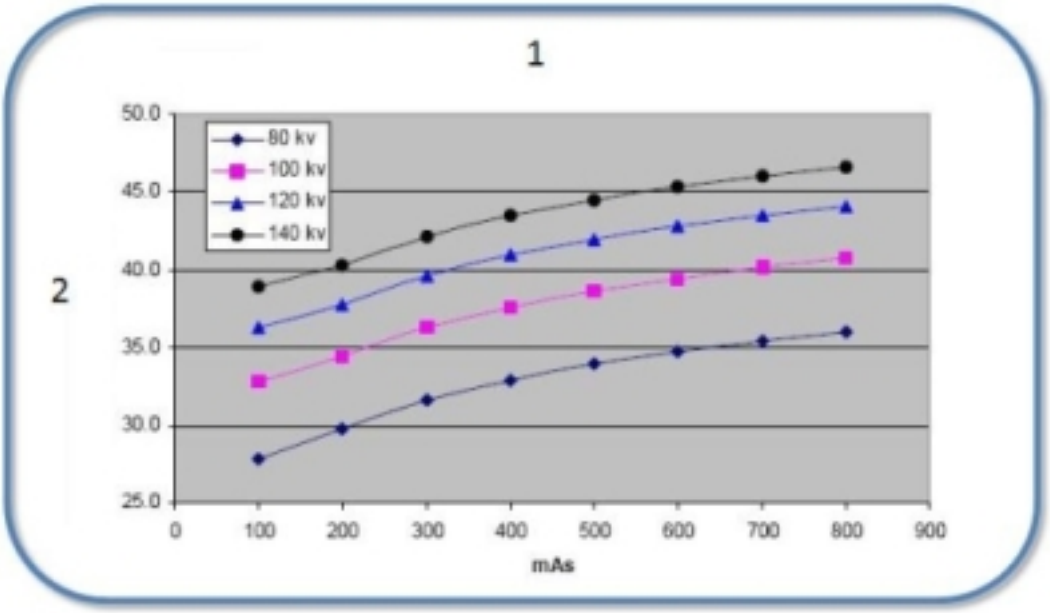
Decrease the kilovoltage to 70, 80 or 100 kV for smaller patients.

- A decrease in kV should not be done without increasing the mA to maintain noise levels and contrast to noise ratios.
- Lower kV selections increase HU values. Therefore, increase the window width for viewing images to maintain a similar appearance.
- Since lower kV selections lower X-ray penetration, it is important to not use low kV selections on too large of a patient, which can potentially result in compromised image quality. Work with your radiologist and medical physicist to establish low kV protocols and patient size limits.
- Refer to CTDI Dose Values and Adjustment Factors in the *Dose and Performance* chapter of the *Technical Reference Manual* as a guide for making adjustments to mAs for changes in kV in a protocol.
- For example, consider a protocol with a technique of 120 kV, 70 mA, Medium Body SFOV. As a starting point, in order to maintain $CTDI_{vol}$ while changing the kV, the technique could be adjusted as follows for pediatric patients:
  - 340 mA at 70 kV

- 215 mA at 80 kV
- 110 mA at 100 kV
- 70 mA at 120 kV
- 50 mA at 140 kV

- To assure sufficient X-ray penetration, the following chart is intended as a relative guide to the maximum patient diameter that can be scanned based on a kV and mA's selection. It does not indicate a recommended technique factor (that is generally higher) since the technique factor also depends on the image quality needed for the diagnostic task.

Illustration 4: Maximum patient diameter guide for low kV selection (1) and Lateral Patient Diameter in cm (2)



3.5.3 Center the patient properly when using AutomA

Properly center the patient. This is critical with AutomA.

- Double check and verify the table height is centered to the patient.
- Raise or lower the table as needed before taking the scouts.
- After the scouts are taken and prescription is done, verify the mA table calculations before confirming the scan.
- Make sure minimum mA and maximum mA values are set appropriately.
- See *Set the mA* procedure in the Scan chapter.

3.5.4 Increase the pitch

Increase the pitch.

- Increasing the pitch decreases the amount of radiation needed to cover the region indicated, usually without compromising the diagnostic quality of the scan.
- Increasing pitch from 1.0 to 1.375:1 decreases dose by a factor of about 27%.

3.5.5 Use Small SFOV Filters

Use the smallest SFOV whenever possible, depending on the exam and size of the patient.

- Matching the appropriate SFOV bowtie filter to the size of the patient ensures the dose is delivered where it is needed, and filtered where it is not needed.
- Small SFOV supports DFOVs up to 32 cm in diameter.
    - ***Ped Head*** SFOV supports DFOVs up to 32 cm in diameter and uses IBO processing to correct for beam hardening effects. It is particularly useful for infants 18 months or less in age.
    - ***Small Head*** SFOV should be used for patients from 1.5 years old to 10 years old.
    - ***Ped Body*** SFOV supports DFOV's up to 32 cm in diameter.
    - Both the Ped Body and Ped Head SFOVs are limited to 42 kW. This limits the maximum mA possible to 350 at 120 kVp.

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Chapter 6 Large Patient

1 Overview

CT is an extremely valuable imaging tool for diagnosis of injury and disease. In the radiology community, it is widely understood that very large patients (> 300 lb / 136 kg) are a challenge for imaging due to the increase of the X-ray attenuation in this patient population. The degree of X-ray attenuation in these large patients may degrade image quality as the patient size increases using the same scan technique as used for normal sized patients (< 300 lb (136 kg)). The system allows patients with weights up to 500 lb (227 kg).

This section presents the concepts necessary to successfully scan large patients.

2 Large Patients

2.1 Scanning large patients

2.1.1 Perform only necessary CT examinations

Is CT the most appropriate study? This important communication between the patient's physician and the radiologist is essential in determining the need for the CT examination.

The indications and the appropriate technique to be used should be reviewed by the radiologist prior to every scan including the patient’s number of previous scans, reasons for the scan, and consideration of other effective modalities. In all circumstances, the expected benefits of the scan must always exceed the overall risk.

2.1.2 Patient weight and patient size

There are multiple factors that need to be taken into consideration when prescribing a protocol for large patients besides weight such as height, muscularity, and body habitus. It is essential to remember that the maximum table loading weight is 500 lb (227 kg).

The patient's transverse dimension of the anatomical area being scanned is another important factor of a larger patient exam because of system hardware imaging requirements of an air gap and design limitations of a CT system.

The distance between the edge of gantry bore and the patient's body surface must be more than 5 cm to prevent blockage of the reference channels. If the maximum diameter of the patient is beyond the imaging capability of the 50 cm SFOV, the image quality can be degraded due to partial reference channel blockage. CT scanners expect an air gap around the imaged object and when the reference channel does not see air, this may cause degradation of image quality. If the diameter of the patient in all directions is beyond the imaging capability of the 50 cm SFOV, the image quality may be severely degraded and may not be useful for diagnosis if there is full reference channel blockage.

2.1.3 Properly position large patients in the gantry

Body straps may be useful with certain patients. These accessories are sometimes helpful in making the patient more round as opposed to elliptical, and in securing the patient to prevent contact with the gantry as they move through. Once the patient is positioned on the table, move the patient in and out of the gantry to make sure they are able to be safely moved through the gantry during the exam.

Properly centering the patient is essential to minimize image quality degradation. The bowtie filter provides maximum X-ray intensity through the center and 90% less X-ray at the edge of the SFOV. The Large Body bowtie filter (Large SFOV) should be used since it has the largest field of unattenuated X-ray. When possible, center the anatomy of interest in the center of the gantry to take advantage of the increased X-ray intensity.

Additionally, a correctly centered patient is essential when using automatic exposure control techniques such as AutomA and SmartmA to reduce unnecessary radiation exposure. If patients are not properly centered when using automatic exposure control, the mA selected by the system may be inadequate or may be greater than required compared to when the positioning is correct.

Often in order to fit a large patient safely in the gantry for imaging, a lower table position than desired is necessary. In these situations where the patient is miscentered, the use of AutomA and SmartmA is not recommended.

2.2 Guidelines for adjusting individual exposure parameters by patient

2.2.1 Adjust parameters

The aim of adjusting imaging parameters is to improve the image quality by increasing the amount of X-ray quantum energy received by detector. We strongly encourage you to work with your radiologist and medical physicist to determine the appropriate dose for the image quality desired. Each large patient should be evaluated individually to determine appropriate imaging parameters.

2.2.2 High kV

It is important to use higher kilovoltage selections on the very large patient. Using 140 kV is recommended for large patients because it provides higher X-ray penetration of anatomical structures being imaged. On the other hand, higher kV selections can decrease HU (Hounsfield Unit) values so the window width for viewing the images may need to be decreased to maintain a similar appearance.

2.2.3 mA adjustment

The reasonable use of scan technique with AutomA and SmartmA on a large patient can reduce patient dose effectively. However, significant differences may exist between the selected noise index and the image standard deviation when a very large patient provides insufficient detector signal (or prevents sufficient detector signal). In this case, electronic noise sources can become the dominant image noise source vs. X-ray noise. Under these conditions, special projection data dependent filters are applied at various threshold levels to help preserve image quality.

For more information on AutomA and SmartmA please refer to *AutomA/SmartmA* and *SmartmA* in the Scan Parameters section.

NOTE: If the size of the large patient section is beyond 50 cm SFOV, AutomA and SmartmA technique are not recommended since noise and mA prediction may not always be reliable. Manual mA is recommended.

2.2.4 Lower pitch / slow rotation time

Decreasing the pitch and rotation time will allow more mA to be delivered over the area of interest without compromising the diagnostic quality of the anatomical area scanned; however, this will be at the expense of extending the exposure time for the acquisition.

2.2.5 Scan Type

Compared to the Helical scan type, the Axial scan type provides a greater opportunity to increase mAs to achieve improved image quality for large patients but at the compromise of the total exam scan time.

NOTE: Using lower pitches, slower rotation times, or axial instead of helical with large patients to improve image quality, comes at the cost of longer scan times which means longer breath holds.

Consider the following to offset increasing acquisition times beyond the patient's capability to hold their breath:

- If multi-phase studies are needed, use lower dose techniques for the non-contrast series compared to the contrast series and limit the scan to only the organ or anatomical region indicated.
- Break the imaging range into multiple groups to match patient's breath-hold capability.

2.2.6 Increase slice thickness

Generally speaking, thicker slice images can provide lower noise than thinner slice images for the same dose. Consider using 1.25 or 2.5 mm slice thickness with 50% overlap as opposed to 0.625 mm slices for areas with large anatomical structures when reformats may be needed.

2.3 Radiation exposure and dose reporting

It is well known that normal weight adult techniques should not always be applied to large patients since this will likely decrease the image signal-noise ratio for the acquisition due to inadequate exposure. Generally speaking, higher radiation exposure is usually used for very large patients to improve image quality to compensate for dose attenuation.

It is critical to remember that the body filter only uses the 32 cm CTDI phantom for dose reporting purposes (CTDIvol displayed in the *Dose Information* area on the *Scan Settings* screen and the Dose Report). In other words, when looking at the actual absorbed dose for the large patient, understand that the dose may be lower than reported if the part scanned is larger than the phantom tested. Keep this in mind when adjusting scan parameters to fit patients who are larger than the phantoms tested.

NOTE: You have to balance between image quality level for diagnosis and responsibility for the delivery of higher radiation doses for larger patients, especially in abdomen and pelvis exams.

Chapter 7 Dose Check

1 Overview

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.
Attention: Consult accompanying documents.

For dose measurements and calculations, refer to the Discovery CT870 Technical Reference Manual, Dose and Performance chapter.

1.1 Introduction

Dose Check alerts you when the estimated dose index is above the limit set by the operating group, practice, or institution. Dose Check complies with the NEMA XR-25 standard.

Dose Check creates awareness of the dose index of the prescribed scan, and launches a notification if the dose index is above the limit. The notification is set at a level above routine or normally expected doses, but not so high as to pose a significant risk to the patient. Depending on patient size or imaging requirements, it may be appropriate to scan at a value above the Notification Value (NV).

Notification Values are not necessarily the same as the published Diagnostic Reference Values (DRLs). However, these may be consulted as a guide to determine the appropriate NV for your site and patient population. Because routine scanning does involve a range of applicable techniques due to patient sizes and imaging needs, another consideration on where to set the notification level will be the frequency in which your practice would want it posted.

Dose Check also issues an alert when the accumulated dose index would exceed the institution's established range. GE has pre-populated the system-level Alert Value (AV) at 1000 mGy $CTDI_{vol}$ in accordance with the FDA November 8, 2010 letter to MITA.

Dose Check should be incorporated into your department's Quality Assurance (QA) processes to assure that scan protocols are defined with the "as low as reasonably achievable" (ALARA) parameters, and to vary examination protocols to take into account patient body habitus. The feature provides for audit capability and tracking when Notification and Alert Values are exceeded and the capability to output the protocols on the system and the associated NVs entered for them.

Dose Check provides the following:

- Checks against a Notification Value and issues an alert if the estimated dose for the scan is above your limit.
- Checks against an Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters.
- Defines Alert Values for Adult and Pediatric imaging with an age threshold.

- Audit logging and review.
- Protocol Change Control.

1.2 Protocol Considerations

Before using Dose Check, the site physicist, and/or radiation safety officer in collaboration with the radiologist, should understand the current dose levels of site scanning protocols and the maximum dose limit at the site's clinical practice. Using this information, an appropriate starting point for the Notification Value for each protocol and system Alert Value should be set.

Guidance from such bodies as the American College of Radiology (ACR), US Food and Drug Administration (FDA), European Union (EU), International Commission on Radiological Protection (ICRP) and American Association of Physicists in Medicine (AAPM) may be useful in determining Notification and Alert values. The AAPM Working Group on Standardization of CT Nomenclature and Protocols has published a list of reference Notification values based on anatomical location. These can be found at www.aapm.org.

1.3 Terminology

Notification Value

The dose value that is the site typical dose level for each scan group. NV can be checked by $CTDI_{vol}$, DLP, or both. This value should be set to an average value of all patient sizes that will be imaged using the scan protocol. When setting the NV value consideration should be given to an appropriate upper limit for the NV value to take into account the percentage of exams that you would normally expect the value to be exceeded. Scans that exceed NV values will be logged.

Alert Value

The dose value in which specific authorization is needed to continue with a scan that exceeds this value. AV can be checked by $CTDI_{vol}$, DLP, or both.

Dose Check Administrator

A user role that has the authorization to enable Notification and Alert level checking.

Dose Check AV Exceeding User

A user which has authorization to exceed AV values during scanning.

Protocol Change Control

Requires user authorization to accept protocol parameters.

2 Set the Dose Administrator Role

2.1 Overview

NOTE: Refer to the Data Privacy chapter for instructions on setting local users, an enterprise server, and defining local or enterprise groups.

The Dose Check Administrator role is assigned at the group level. Users assigned to a group with Dose Check Administration Role will be able to enable Dose Checking, set Alert Values (AV) and set Alert Value (AV) Age Threshold. It is recommended that only one user who has been given authority after a discussion with the Radiologist, Physicist, and department management be assigned to the Dose Check Administration group.

2.2 Set the Dose Administrator Role

1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].
3. Click [User Admin. Tool]
4. From the *EA3 Administration* screen, enter your ***Username*** and ***Password***.
5. Click the *Local Users* tab.
6. From the *Local Users* tab, click [Add Local User].
7. From the *Add User* screen, enter the following:
   - A unique User ID
   - Full Name
   - Password
   - Confirm Password
8. Click [Add User].
9. Click the *Groups* tab.
10. From the *Groups* tab, click[Add Local Group].

    NOTE: Alternately, the system can be configured for Enterprise groups if Enterprise authentication has been enabled. Refer to the Data Privacy chapter for information on configuring Enterprise authentication.

11. From the *Add Local Group* screen, type a unique group name.
12. Click [Add Group].
    - The group is highlighted in the *Local Groups* list.
    - All information and buttons in the center panel refer to the highlighted group.
13. To change a groups role, select *Dose Check Administrator* and click [Apply Roles].

- A green label confirms the applied roles.
- An error message box displays if it is unsuccessful.

3 Set the AV Exceeding User Role

NOTE: Refer to the Data Privacy chapter for instructions on setting local users, an enterprise server, and defining local or enterprise groups.

3.1 Overview

The AV Exceeding User role is assigned at the group level. Users assigned to a group with AV Exceeding User role will be able to approve scanning when an AV value has been exceeded. We recommend that only one user be assigned to the AV Exceeding User group after having discussions with the radiologist, physicist and department managers.

3.2 Set the AV Exeeding User Role

1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].
3. Click [User Admin. Tool].
4. From the *EA3 Administration screen*, enter your ***Username*** and ***Password***
5. Click the *Local Users* tab.
6. From the *Local Users* tab, click [Add Local User].
7. From the *Add User* screen, enter the following:
   - A unique User ID
   - Full Name
   - Password
   - Confirm Password
8. Click [Add User].
9. Click the *Groups* tab.
10. From the *Groups* tab, click [Add Local Group].

    NOTE: Alternately, the system can be configured for Enterprise groups if Enterprise authentication has been enabled. Refer to the Data Privacy chapter for information on configuring Enterprise authentication.
11. From the *Add Local Group* screen, enter a unique group name.
12. Click [Add Group].
    - The group is highlighted in the Local Groups list.
    - All information and buttons in the center panel refer to the highlighted group.
13. To change a group's role, select *Dose Check AV Exceeding User* and click [Apply Roles].

- A green label confirms the applied roles.
- An error message displays if it is unsuccessful.

4 Configure the System for Dose Check

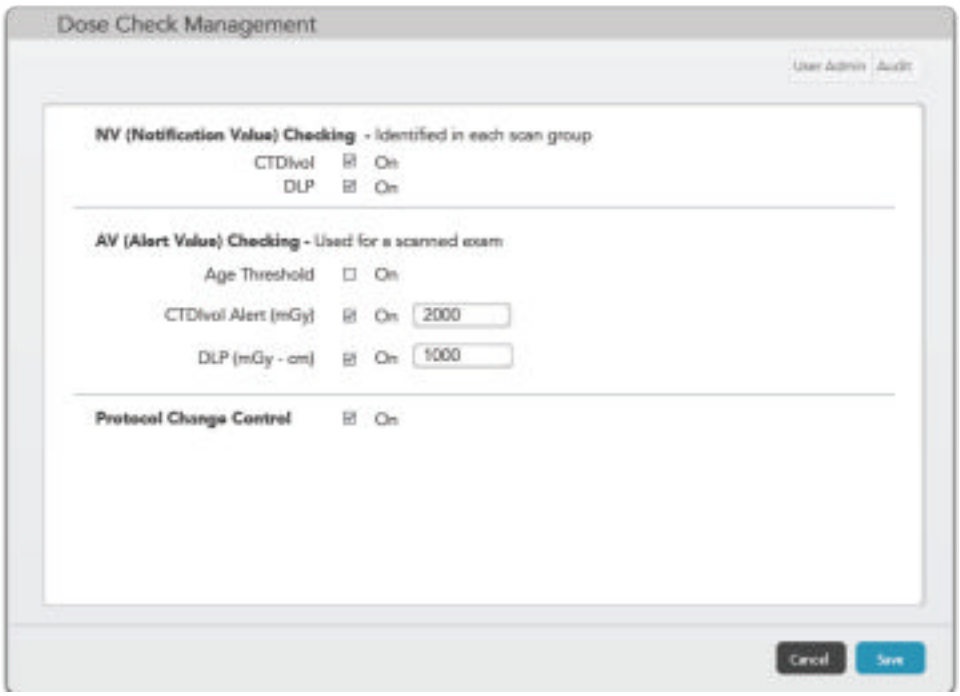
4.1 Overview

Use this procedure to configure the system for Dose Checking by Notification Value (NV) Checking and Alert Value (AV) Checking. You must have one user assigned to a group with the Dose Administrator role to confirm Dose Check settings.

4.2 Configure the System for Dose Check

1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].

Illustration 1: Dose Check enabled



3. Set checking for NV (Notification Value) Checking.
   a. In the *NV (Notification Value) Checking* area, click [$CTDI_{vol}$] and/or [DLP].
   b. Enter a value for *$CTDI_{vol}$* and/or *DLP*.
      - The range for NV is 0 to ≤ the value set for *AV*.
      - Or, you can enter ***N*** to indicate no checking.

   NOTE: The system default for NV checking is $CTDI_{vol}$ *On* and DLP *Off*. The GE reference protocols will not contain any NV values.
4. Set checking for AV (Alert Value) Checking.
   a. In the *AV (Alert Value) Checking* area, click [$CTDI_{vol}$] and/or [DLP].

b. Enter a value for *$CTDI_{vol}$* and/or *DLP*.

- The maximum AV value for $CTDI_{vol}$ is 2,000 mGy.
- The maximum AV value for DLP is 400,000 mGy-cm.
- The system default is AV checking by $CTDI_{vol}$ *On* with a value of 1,000 mGy. DLP checking *Off* with a value of 0 mGy-cm.

NOTE: The Alert Value should be determined by the site's radiologist and physicist.

5. Click [Save].

5 Configure the AV by Age Threshold

5.1 Overview

Use this procedure to configure the system for Dose Checking by AV (Alert Value) Checking by Age Threshold. You must have one user assigned to a group with the Dose Administrator role to confirm Dose Check settings.

AV (Alert Value) Checking by Age Threshold allows the user to set AV values for Adult and Pediatric age ranges.

AV (Alert Value) is based on the following criteria:

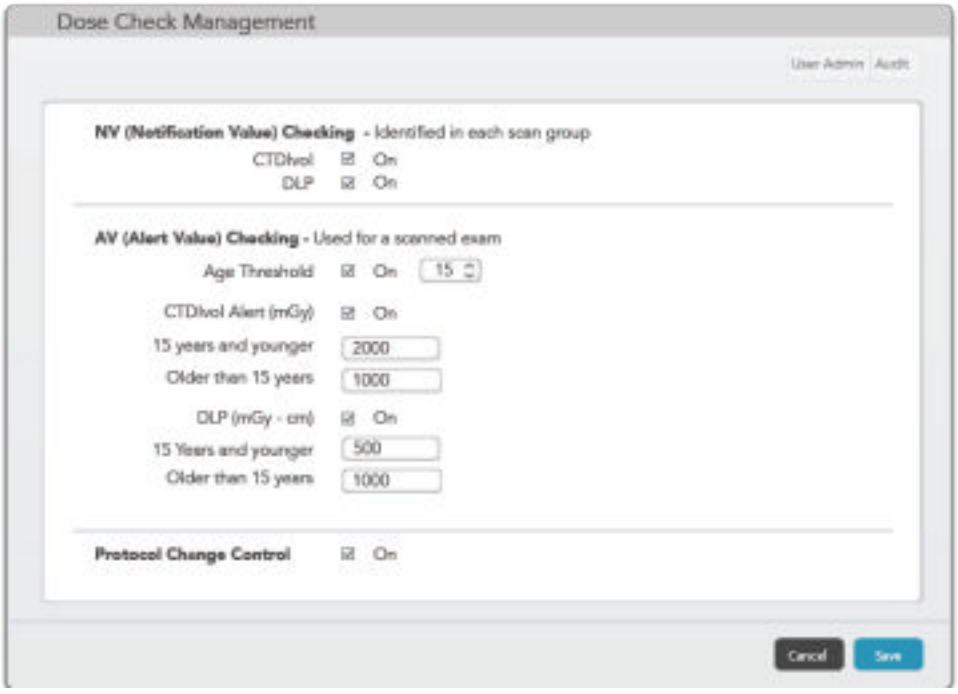
- Age value in New Patient.
- If no age value is present, then the system defaults to the higher age range.

During protocol management, the AV (Alert Value) under *Age Threshold* is always used if it is prescribed.

5.2 Configure the AV by Age Threshold

1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].

Illustration 2: AV (Alert Value) Checking by Age Threshold "On"



3. In the *AV (Alert Value) Checking* area, click [Age Threshold].
4. Enter the patient's age.

5. Enter a value for *$CTDI_{vol}$* and/or *DLP*.
   - The maximum AV (Alert Value) for $CTDI_{vol}$ is 2,000 mGy.
   - The maximum AV (Alert Value) for DLP is 400,000 mGy-cm.
   - The system default is AV (Alert Value) Checking by $CTDI_{vol}$ *On* with a value of 1,000 mGy. When DLP checking is *Off*, the value is 0 mGy.
   - The value must be lower than the Adult AV (Alert Value).
6. Click [Save].

6 Configure for Protocol Change Control

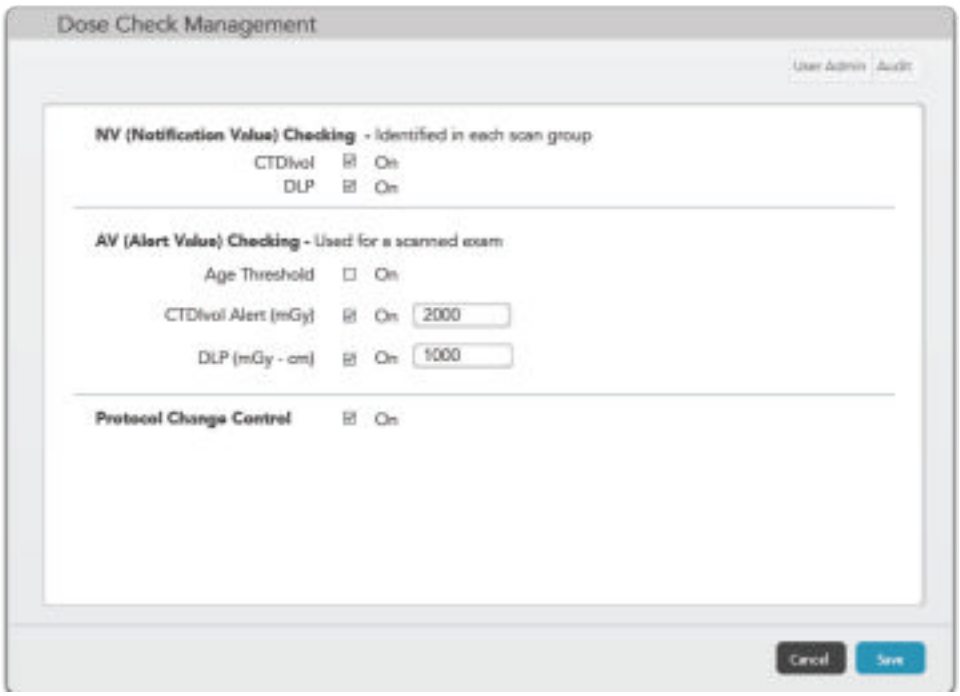
6.1 Overview

Use this procedure to configure Dose Check for Protocol Change Control (PPC). You must have one user that is assigned to a group with the Dose Administrator role to enable Protocol Change Control.

6.2 Configure for Protocol Change Control

1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].

Illustration 3: Protocol Change Control "On"



3. In the *Protocol Change Control* area, click the checkbox to *On*.
4. Click [Save].

7 Build Protocols Using Protocol Change Control

7.1 Overview

Use this procedure to build protocols with PCC. When PCC is enabled, the system requires an authorized user to accept protocol parameter updates.

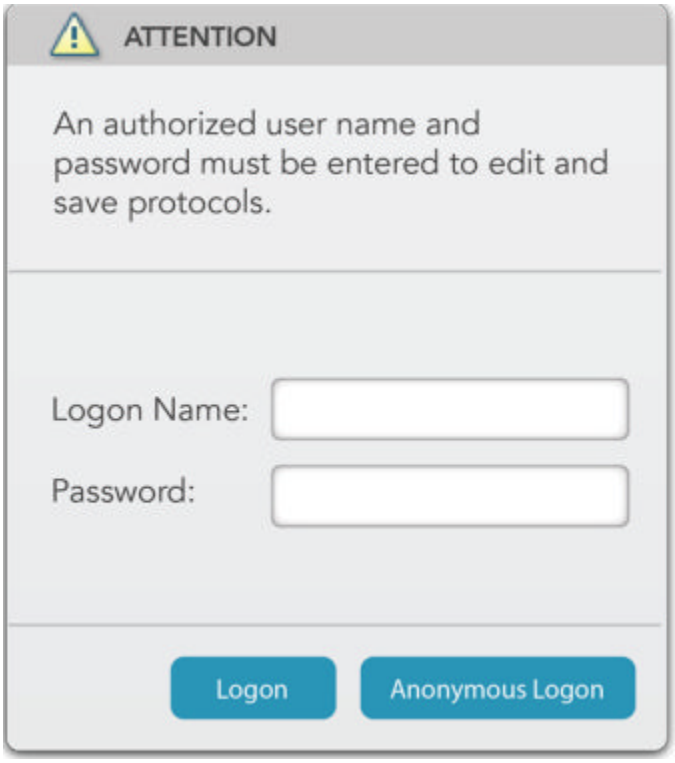
An authorized user can be determined by one of two ways.

- HIPAA is enabled and the currently logged in user has Standard User Role.
- If HIPAA is not enabled, when Protocol Management is selected, the user will be presented with an authorization screen.

7.2 Build Protocols Using Protocol Change Control

1. From the scan monitor, click the [Mode] icon.
2. Click [Protocol Management].

Illustration 4: Protocol Change Control Authentication screen



3. In the *Logon Name* field, enter ***your user name***.
4. In the *Password* field, enter ***your password***
5. Click [Logon].

8 Build Protocols with Notification Values

8.1 Overview

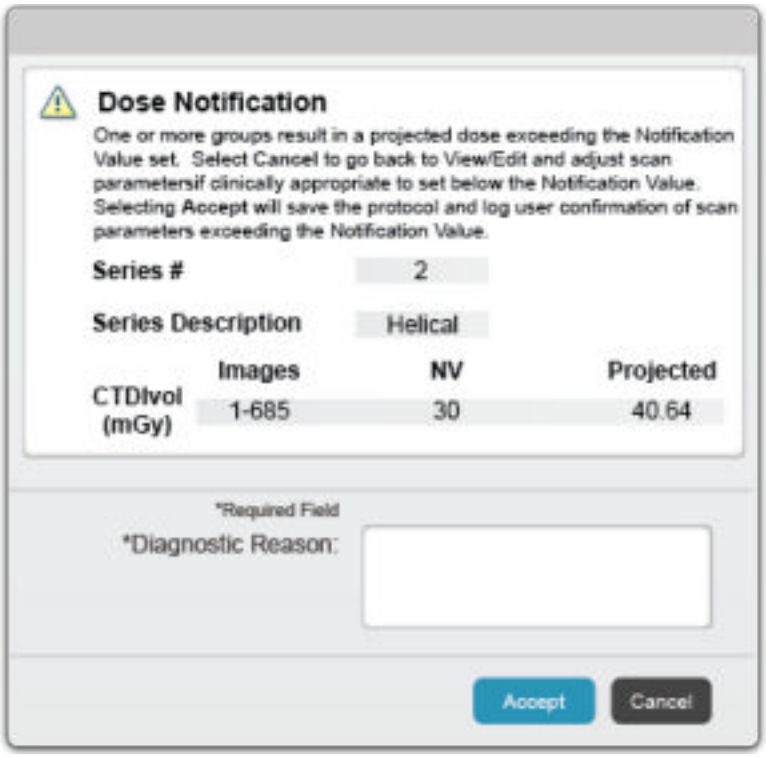
Use this procedure to set NV (Notification Values) in user protocols. NVs can only be set in Protocol Management.

8.2 Build Protocols with Notification Values

1. From the scan monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. On the *Protocol Selection* screen, click [Adult] or[Pediatric].
4. On the *User* selector, click an anatomical area.
5. In the *Anatomical* area, select a protocol.
6. Click the series task to go to the first non-scout series in the protocol.
7. From the *Dose Information* area, click [Setup].

   The Info screen is displayed.
8. Enter the *$CTDI_{vol}$* or *DLP NV* value by group.
9. Click [Info] to return to the *Dose Information* display.
10. Click [Accept] to save the protocol parameters.
    - The system compares all the $CTDI_{vol}$ and DLP values in the scan groups to the entered NV value.
    - The protocol parameters will not be accepted until the NV value is no longer exceeded or the user has entered a Diagnostic Reason for continuing to accept the scan parameters exceeding the NV value.

Illustration 5: Warning NV exceeded



- Saving a protocol with a dose level exceeding an NV demands a high degree of consideration. In most cases, you will click [Cancel] to go back to adjust the parameters. If there is a clinical reason to save a protocol exceeding an NV, enter the diagnostic reason.

11. Click in the *Diagnostic Reason* field
12. Enter the reason for scanning exceeding the NV value (maximum 64 characters).
13. Click [Confirm] to accept the Diagnostic Reason.
14. Click [Accept] to accept the protocol scan parameters.

NOTE: Viewing/exporting Protocol Summary in Audit Tool should be done after protocols are saved, not during editing.

9 Build Protocols with Notification Values by Factor

9.1 Overview

Use this procedure to set the Notification Values (NV) in user protocols for all scan groups by a factor. For example, if the $CTDI_{vol}$ in a scan group were 5 and a factor of 1.5 was entered, the new NV value for the group would be 7.5.

- Values can by entered in increments of 0.1.
- Values must be > 0.
- The maximum value is 10.

9.2 Build Protocols with Notification Values by Factor

1. From the scan monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. On the *Protocol Selection* screen, click [Adult] or [Pediatric].
4. On the *User* tab, click an anatomical area.
5. In the *Anatomical* area, select a protocol.
6. Click the series task to go to the first non-scout series in the protocol.
7. From the *Dose Information* area, click [Setup].
8. Click *NV $CTDI_{vol}$ DLP*.

   The *NV Setting Column Edit* screen displays.
9. In the *Factor* field, type the desired factor for $CTDI_{vol}$ and/or DLP.
10. Click [Accept] to return to the *Dose Information* display.

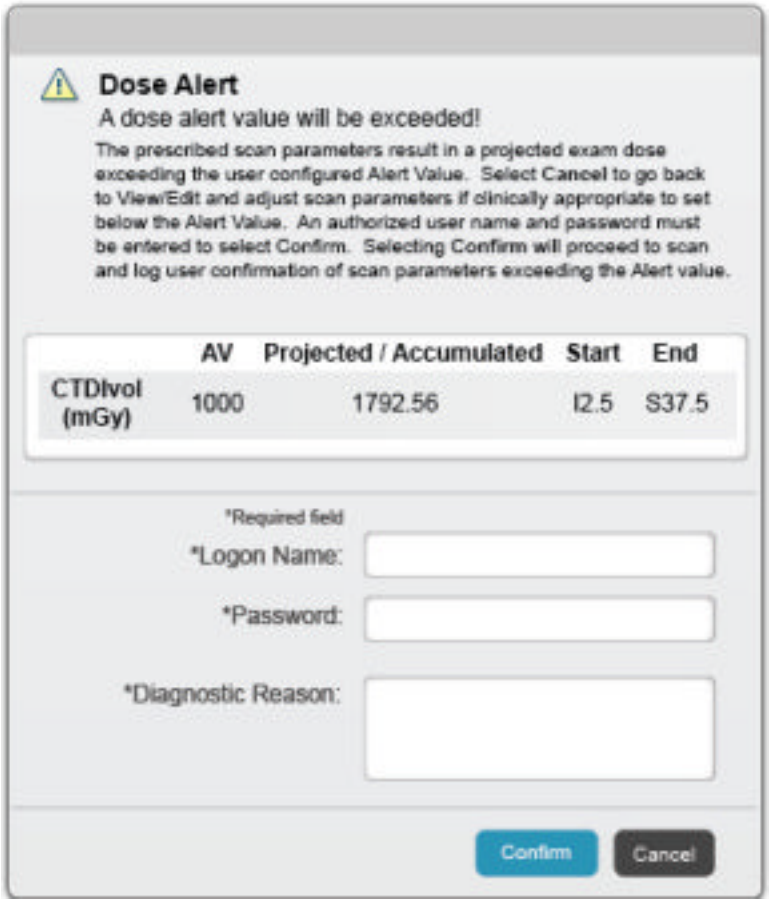
10 Scan Using Alert Value Checking

10.1 Overview

Use this procedure to scan using AV (Alert Value) Checking.

The $CTDI_{vol}$ or DLP value will be highlighted when the estimated dose for the protocol exceeds the AV value set for the system.

Illustration 6: AV (Alert Value) exceeded in dose



Adjust the scan parameters for the series in which the AV value is exceeded to adjust the dose below the prescribed AV value. If the AV value is still exceeded when [Confirm] is selected, a confirmation message will be posted. The scan cannot be confirmed until the AV value is no longer exceeded or a user with a Dose Check AV Exceeding user role has authorized the scan.

Performing a scan exceeding an AV value demands a high degree of consideration for appropriateness. Therefore, in most cases, you will click [Cancel] to go back to adjust parameters. However, if there is a true diagnostic need to perform a scan exceeding an AV value, then enter the diagnostic reason.

10.2 Scan Using Alert Value Checking

1. Type the ***logon name***.

2. Type the ***user password***.
3. In *Diagnostic Reason*, enter the reason the scan is exceeding the AV value. The maximum number of characters is 64.
4. Click [Confirm] to proceed to scanning.

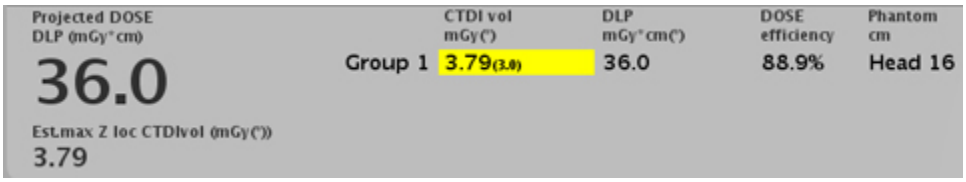
11 Scan Using Notification Value Checking

11.1 Overview

Use this procedure to scan using NV (Notification Value) Checking.

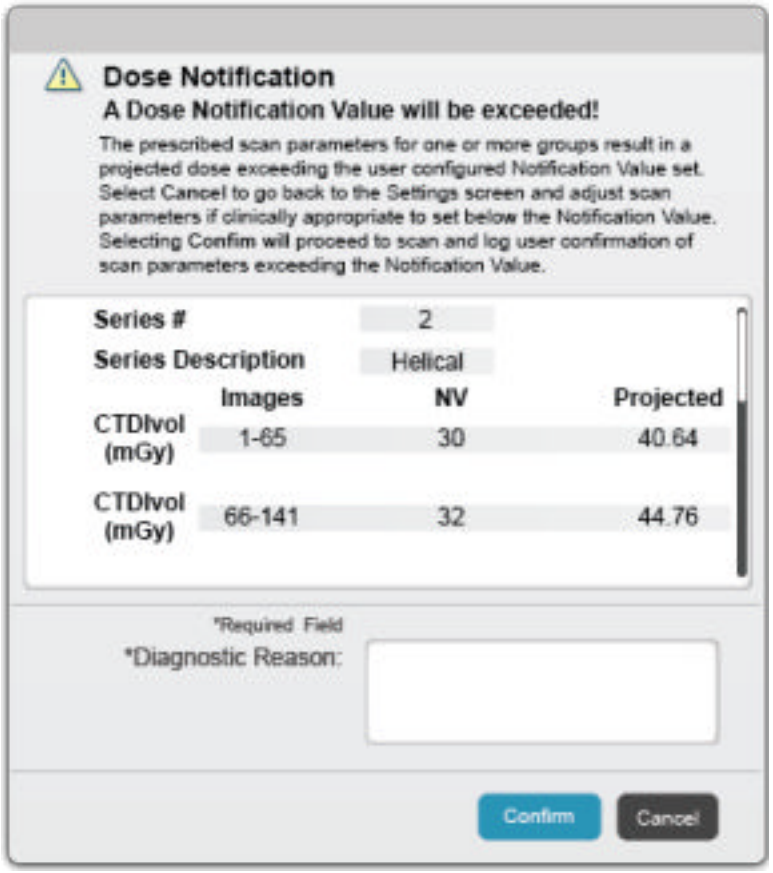
The $CTDI_{vol}$ or DLP value will be highlighted when the estimated dose for a scan group exceeds the NV value set for each scan group.

Illustration 7: NV exceeded in Dose Display



Adjust the scan parameters for the scan group in which the NV is exceeded to adjust the dose below the prescribed NV. If the NV is still exceeded when [Confirm] is selected, a confirmation message will be posted. The scan can not be confirmed until the NV is no longer exceeded or you have entered a Diagnostic Reason for continuing the scan with exceeding the NV.

Illustration 8: Warning NV Exceeded



11.2 Scan Using Notification Value Checking

1. In *Diagnostic Reason*, enter the reason the scan is exceeding the NV value. The maximum number of characters is 64.
2. Click [Confirm] to proceed to scanning.

12 Use the Dose Audit Tool

12.1 Overview

The Dose Audit Tool provides:

- Dose Check Log detailing exams which exceeded NV or AV values.
- Protocol Summary for protocol NVs.
- Export to save Dose Check Log data to media.

12.2 Display a Dose Check Log

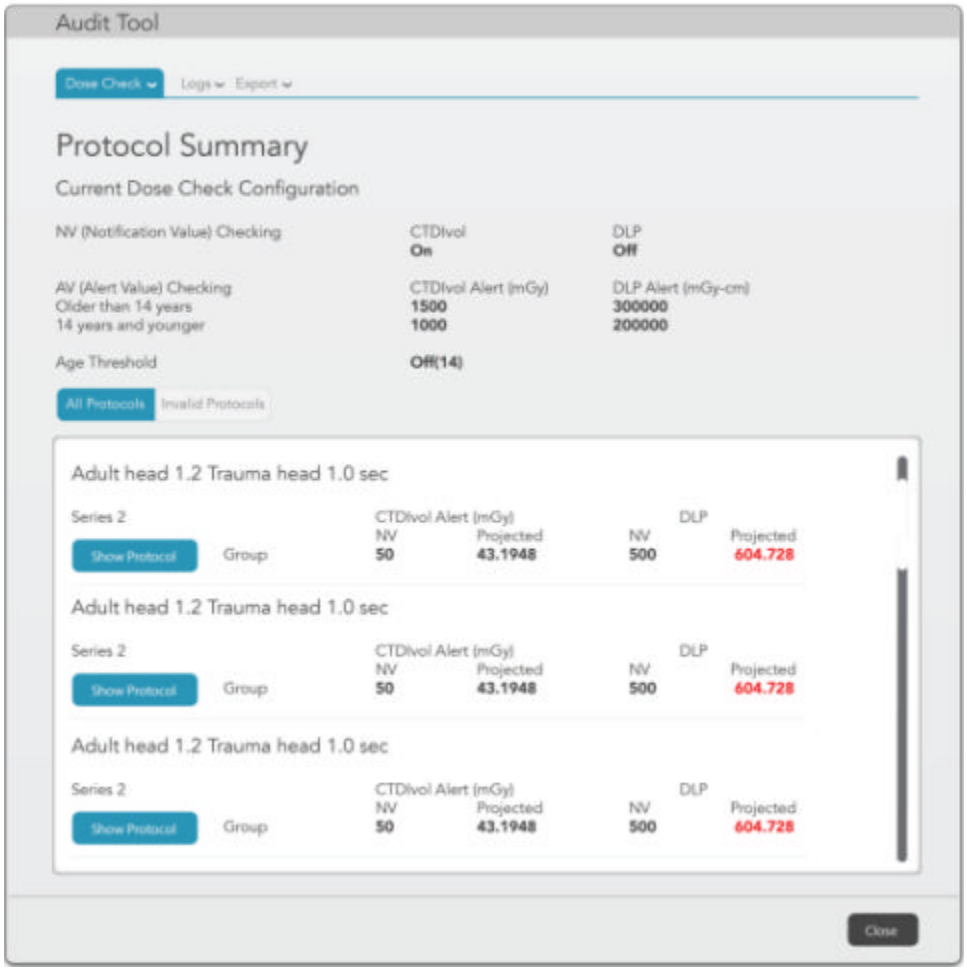
1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].
3. On the *Dose Check Management* screen, click [Audit Tool].
4. From the Dose Audit Tool, click [Log List].
5. On the Log List, select the desired log and click [OK].

   If the log data approaches the maximum size, the system posts a message directing you to export the log data.

12.3 Display the Protocol Summary

1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].
3. On the *Dose Check Management* screen, click [Audit Tool].
4. In the *Protocol Summary* area, click [All Protocols] or [Invalid Protocols].

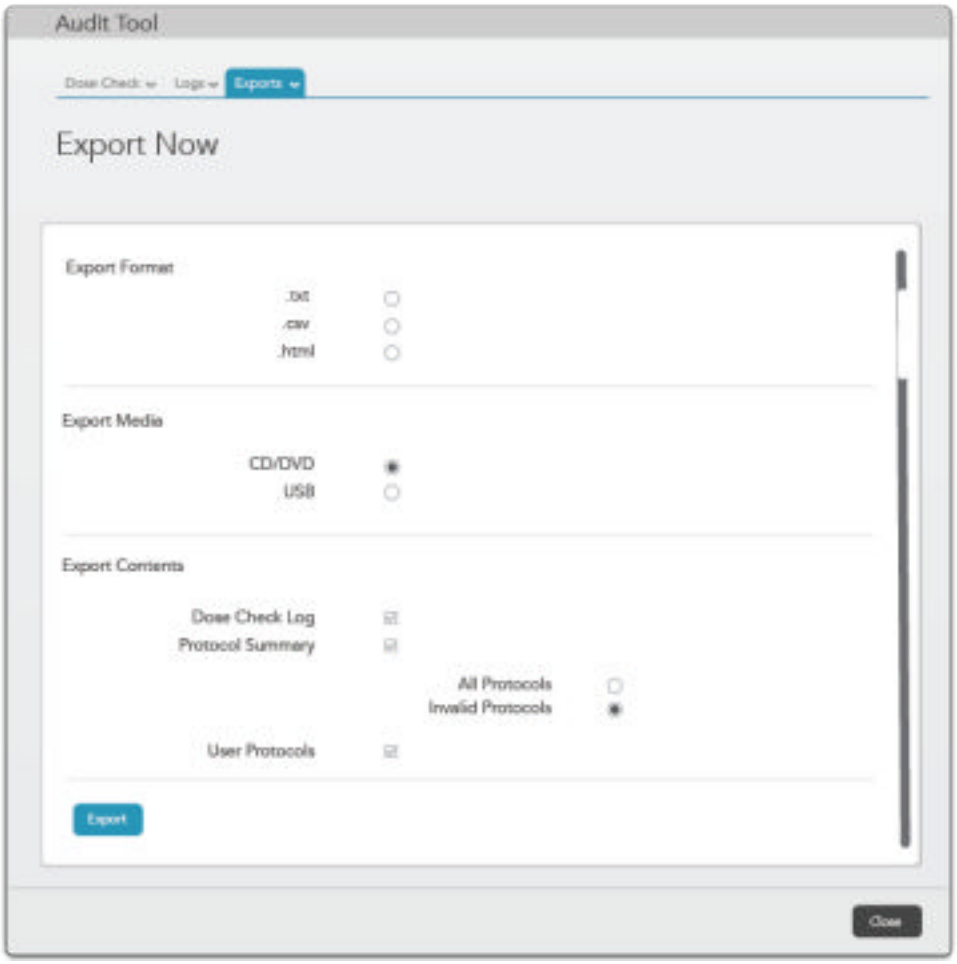
Illustration 9: Protocol Summary Invalid Protocols



12.4 Export Dose Check Log Data

1. From the scan monitor, click the [Mode] icon.
2. Click [Dose Check Management].
3. Insert CD-R media in the DVD RW drive or insert USB media in the USB port of the media tower.
4. On the *Dose Check Management* screen, click [Audit Tool].
5. From the Dose Audit tool, click [Export] to open the Select Export Options screen.

Illustration 10: Select Export Options screen



6. In the *Export Media* area, click [CD/DVD] or [USB].
7. In the *Export Contents* area, click one or more of the following: *Dose Check Log*, *Protocol Summary*, or *User Protocols*.

   If *Protocol Summary* is selected, click [All Protocols] or [Invalid Protocols].
8. Click [OK].

Chapter 8 Equipment

1 Overview

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

This section helps you to become familiar with your CT system, including the system components and hardware.

2 Scanner Desktop

The scanner desktop includes the components described below.

Illustration 1: Scanner Desktop

Number	Description
1	Media Tower
2	Scan monitor
3	Display monitor
4	Scan Control Interface and Keyboard
5	Mouse
6	Computer

Your system may include the Media Tower. This is a DVD-RW drive, which writes to DVD-RAM bare media, DVD-R, and CD-R. See *Remove DVD RAM cartridge* for instructions on using this equipment.

Illustration 2: Media Tower

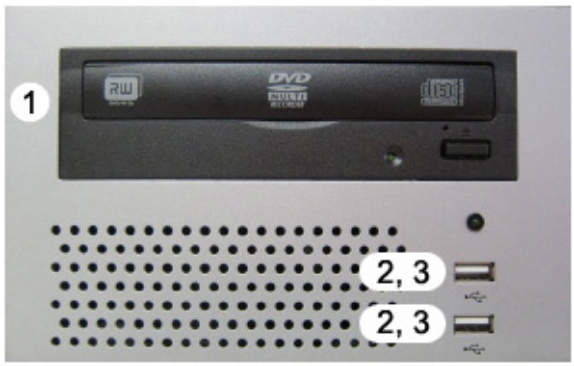
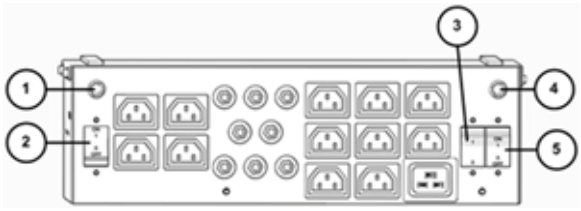


Table 1: Scanner Desktop

Number	Description
1	**Digital Video Disk Read/Write (DVD-RW) drive** This is a DVD-RW drive, which writes to DVD-RAM bare media, DVD-R, and CD-R. • Use the CD/DVD option and the DVD-RW drive to write and restore from CD-R or DVD-R. • Use the Data Export option to save information to CD-R. • Use to save ECG traces. • Use to access the electronic copies of the operator documentation. • Use to Export Protocols. • Use to save scan files, protocols, and service files to DVD-RAM bare media.
2	**USB Connection** Located in lower-right corner of the media tower. The CD/DVD/USB recognizes Hard Disk Drive (USB drive) or USB key (Flash memory) with VFAT format. It does not recognize any hardware with extension 3 format. • Supports connecting a USB media storage device to save or restore scan files. • Only one USB for saving scan data can be connected at a time. • The Bar Code Reader may be connected to one of the USB ports. • The storage device should have a minimum size of 4 GB.
3	**Connections for service computer functions** Located on the front of the Scanner Desktop and front of the PMT tower. • The Service Security Access Key connection to the system uses one of the USB ports on the front of the PMT tower. • The Service key should always be removed prior to any software reboot if left in by your local service. • The service ports on the front of the computer chassis include an Ethernet connection and USB port. The Ethernet port is for service laptop connection to the system. The USB port can be used for external storage device connection but suggested location is the PMT tower USB ports. Intended use is only for trained service personnel.

Number	Description
4	**Computer power on/off switch** Located on the back of the computer chassis as Item #2 below (item #1 is the Scanner Desktop power indicator). • Use to Turn off/on the computer if system functions are not accessible at the scanner desktop controls. • Use to completely Power Off the computer chassis. 

2.1 Computer

The system uses a PC computer running Linux operating system. The system includes system, image and scan data disks and stores up to 700,000 512^2 images and with one terabyte for scan data files. The computer is usually located under the Scanner Desktop.

2.2 Reconstruction hardware

The reconstruction engine provides advanced processing capabilities for reconstructing routine imaging modes.

2.3 Monitors

The system includes two monitors, a scan monitor and a display monitor.

Illustration 3: System Monitors

Number	Description
1	Scan monitor
2	Display monitor

NOTICE

When powering on, it takes 30 minutes for the monitors to reach their set brightness and contrast levels. During this time, do not make any adjustments to the brightness or contrast levels.

NOTE: If you leave your system on overnight, you should turn off the monitors to minimize burn-in.
If a monitor experiences burn-in, turn off the monitor and leave it off for the same duration as caused the burn-in.

Adjust the time-out period for the screen saver to activate, by setting the *Screen Saver Time* through *Preferences* under the *Mode* menu.

2.4 Scan Control Interface and Keyboard

The Scan Control Interface and keyboard consist of an alphanumeric keyboard, 10-key number keypad, buttons specific to initiating scan and communication with the patient.

Illustration 4: Scan Control Interface and Keyboard

Table 2: Scan Control Interface Buttons

Number	Button	Function	Description
1		**Emergency Stop**	In the event of an emergency, pressing emergency stop will stop all table and gantry motions, as well as any X-ray exposure in progress.
2		**Exposure indicator**	Illuminates when an exposure is taking place.
3		**Start Scan**	The Start Scan indicator flashes green once the tube has reached exposure speed. Press the button to start the scan. Start Scan will flash for 30 seconds before timing out. Press **Start Scan** button again to bring the system back to the ready state.

Number	Button	Function	Description
4		**Pause Scan**	Pauses scanning, once the current scan is completed. You can resume the scan by clicking [Resume] from the *Scan Settings* screen.
5		**Stop Scan**	Immediately stops the scan. You can resume the scan by clicking [Resume] from the *Scan Settings* screen.
6		**Move to Scan**	The indicator flashes green for three minutes, indicating that the system is ready to advance the cradle to the start position. Press **Move to Scan** to advance the cradle to the start location.
7		**Stop Move**	Stops cradle motion in/out. Click [Resume] from the *Scan Settings* screen to resume the scan.
8		**Cradle Home**	Moves the cradle to the home position.
9		**Talk**	Press **Talk** and speak towards the intercom to communicate with the scan room. The green LED (next to button) lights when **Talk** is pressed.
10		**Volume Control (autovoice to gantry)**	This dial controls the autovoice volume to the patient. An upward adjustment of the dial increases the volume while a downward adjustment of the dial decreases the volume. The dial has numbers indicating what volume level you have set. The green LED lights when autovoice is playing.
11		**Volume Control (operator to patient)**	This dial controls the volume of the operator's voice to the patient. An upward adjustment of the dial increases the volume while a downward adjustment of the dial decreases the volume. The dial has numbers indicating what volume level you have set.
12		**Volume Control (patient to operator)**	This dial controls the volume of the patient's voice to the operator. An upward adjustment of the dial increases the volume while a downward adjustment of the dial decreases the volume. The dial has numbers on it indicating what volume level you have set.
13		**Filming Keys**	The <F1> - <F4> function keys can be used for filming to the Manual Film Composer.

2.5 Film keys - F1 through F4, F12

The <F1> through <F4> function keys can be used for filming to the Manual Film Composer.

Table 3: Film function keys

F key	Description	Translated text
F1	Film Image	
F2	Film Screen	
F3	Film MID	
F4	Print Series	

2.6 Preset W/L keys – F5 through F11

The <F5> through <F11> function keys are used to apply preset Window Width and Window Level (W/L) values in the following applications: Image Viewer, Floating viewport, and Reformat. The W/L values are defined from the Viewer User Prefs.

Table 4: Preset W/L function keys

F key	Description	Translated text
F5	Previous	
F6	Abdomen	
F7	Head	
F8	Lung	
F9	Mediastinum	
F10	Spine	
F11	Vertebrae	

2.7 Page Up/Page Down keys

Illustration 5: Page up and down keys

Use the <Page Up> and <Page Down> to review the next and prior images in a viewport.

2.8 W/L control keys

Illustration 6: Arrow Keys

Use these keys to change the W/L settings for images in a viewport. The Up/Down keys increase/decrease the window level and the Left/Right keys decrease/increase the window width.

2.9 Operate the mouse controls

The three-button mouse is used to make selections on the scan and display monitors.

Illustration 7: Mouse Buttons

Table 5: Mouse Actions

Number	Mouse Action	Description
1	**Left-click**	Click the left mouse button.
2	**Right-click**	Click the right mouse button.
3	**Middle-click**	Click the middle mouse button.
	Click and drag	Click and hold the left mouse button while moving the mouse.
	Right-click and drag	Click and hold the right mouse button while moving the mouse.
	Middle-click and drag	Click and hold the middle mouse button while moving the mouse.
	Double-click	Click the left mouse button twice in rapid succession.
	Triple-click	Click the left mouse button three times in rapid succession.

3 Gantry

3.1 Gantry display

There are two gantry displays: the primary display and the secondary display. The gantry primary display shown below provides gantry and table status information as described in the following table.

Illustration 8: Gantry Primary Display

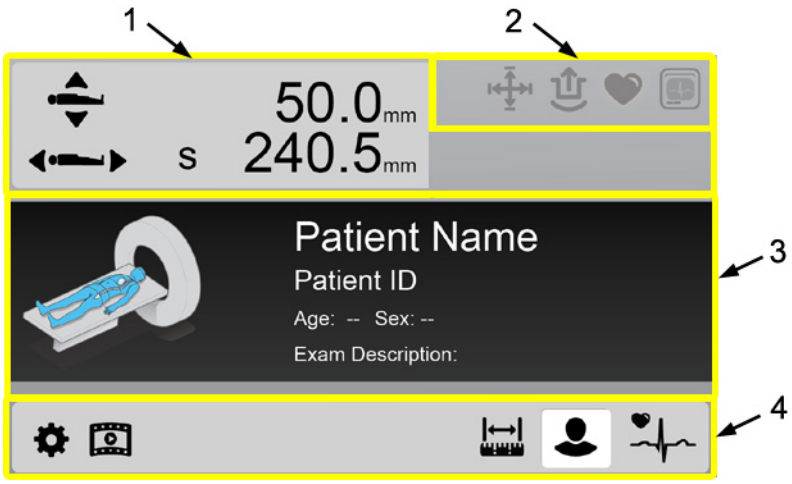
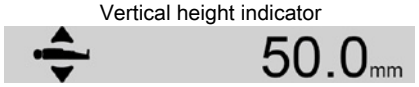
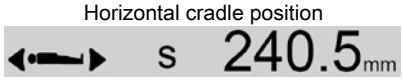
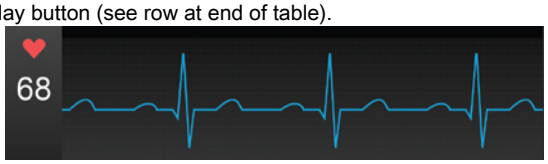


Table 6: Gantry Primary Display Components

Number	Component	Description
1	**Patient Orientation/Entry Area**	Displays information related to the position of the table. This information is used in the scan room while positioning the patient.
	Vertical height indicator 	The Vertical Height indicator displays the vertical height of the table in relation to ISO center.
	Horizontal cradle position 	The Horizontal Cradle Position displays the position of the cradle based on the established an atomic reference of the patient. This reference is established using the internal or external landmarks. The number is preceded by an S if the position is superior to the reference point or an I if the position is inferior to the reference point.
	Scannable Range 	Shown when *Scannable Range* is selected via the Menu area display button. Stays until user hides the scannable range information with another button press, Landmark is pressed, or longitudinal motion occurs. Table Travel Limits displayed are calculated based on a limit and collision matrix that takes into consideration the table height and landmark location on the cradle.
2	**Status Indicator Area**	Displays information related to connection of accessories (ECG, respiratory gating), positioning interference, and cradle unlatch. This information is used in the scan room while positioning the patient.

Number	Component	Description
	Collision indicator 	The Collision light illuminates when there is a possibility that the table, cradle, and gantry could collide. There are elevation collision sensors on the front and rear table covers. The collision sensors are active during table elevation. The light also illuminates if there is ten pounds of resistance during cradle motion in/out or when reaching the travel limits of the table, cradle, and gantry motion. In the case of interference, you may need to raise or lower the table, determine if resistance is being caused by any patient restraints, accessories, or by the patient.
	Cradle unlocked indicator 	The Cradle Unlocked indicator illuminates indicating the cradle is unlocked. When the cradle is unlocked, it is free floating.
	Internal ECG indicator 	The Internal ECG indicator is lit when an internal ECG gating signal is seen by the scanner.
	External ECG indicator 	The External ECG indicator is lit when an external ECG gating signal is seen by the scanner.
3	**Patient Exam Information Area** or **ECG Area** (Not shown above)	Shown when *Patient/Exam Information* is selected via the Menu area display button (see row at end of table).  Shown (see example above) when *ECG* is selected via the Menu area display button (see row at end of table).
4	**Menu Area**	Displays user selectable menu items. Navigate this area using the Back/Enter/Forward buttons on the Gantry Controls panel.
	Settings 	The Settings menu item is used to change the following: • ECG settings • Display brightness setting • Background color selection • Screen saver selection
	Movie 	The Movie menu item is used to display explanatory movies and slideshows.

Number	Component	Description
	Scannable Range 	The Scannable Range menu item is used to display scannable range information in the Patient Orientation/Entry Area.
	Patient/Exam Information 	Select to display Patient/Exam information in the *Patient/Exam Information – ECG* area.
	ECG 	Select to display ECG information in the *Patient/Exam Information – ECG* area.

The gantry secondary display shown below provides gantry and table status information as described in the following table.

Illustration 9: Gantry Secondary Display

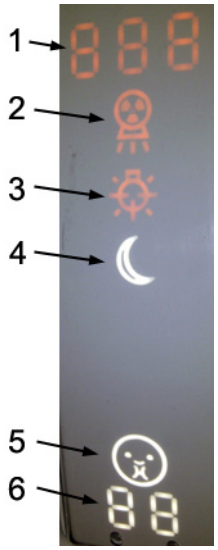
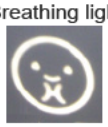


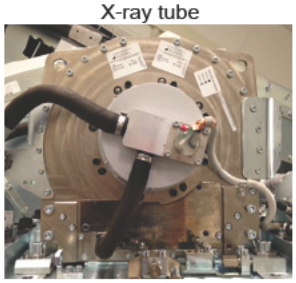
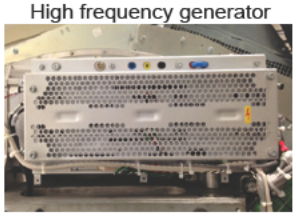
Table 7: Gantry Secondary Display

Number	Description	Description
1	Prep delay timer 	Displays the delay time before a scan starts.

2	Exposure indicator 	The Exposure Indicator illuminates when an exposure is taking place.
3	Laser light indicator 	The Laser Light Indicator illuminates when the laser alignment light is on.  **CAUTION** **For patient safety, it is important to have patients close their eyes anytime the laser alignment light is on.**
4	Sleep mode indicator 	(Feature not available yet.)
5	Breathing light 	The face blinks to let the patient know they will need to hold their breath. The total breath hold time is shown to let them know for how long. This prepares them for the upcoming breath hold. The face turns solid during the breath hold and the numbers start counting down. The illuminated face turns off when the timer gets to 0.
6	Elapsed breath hold time 	Elapsed breath hold time in seconds

3.2 Internal components

Table 8: Internal Components

Component	Description
X-ray tube 	The PerformixTM HDw x-ray tube assembly can operate up to 103kW. The anode heat capacity of the tube is 5.5 million heat units (MHU).
High frequency generator 	The high frequency generator is composed of the stationary inverter and the high voltage tank. Together the inverter and tank can provide 103kW of power with the PerformixTM HDw x-ray tube assembly. The high frequency generator provides control for the focal spot and fast kVp switching to support HiRes imaging.

Component	Description
Detector 	**Gemstone™ Clarity Detector and Collimator** Features a unique 3-dimensional post patient collimator to ensure HU uniformity and to minimize scatter / beam hardening artifacts associated with wide coverage systems. Provides 160mm coverage, 512 slices from 256 detector rows in the Z direction. The 256 rows are 0.625 mm in the Z direction. Each signal can be collected from an individual detector row. The Gemstone scintillator material is created from garnet gemstones fused with a rare earth phosphor composition.
Slip Ring 	Slip Ring provides data communication path from Detector/DAS to the Recon Interface Board from there to the Scan Data Acquisition disk.

3.3 Gantry and console interfaces

If your system has connections for GE approved accessories, the figures and tables below show where to connect these accessories (refer to the GE Approved Accessories list found in the Safety chapter).

3.3.1 Left rear plug-in panel

Illustration 10: Left Rear Plug-in Panel

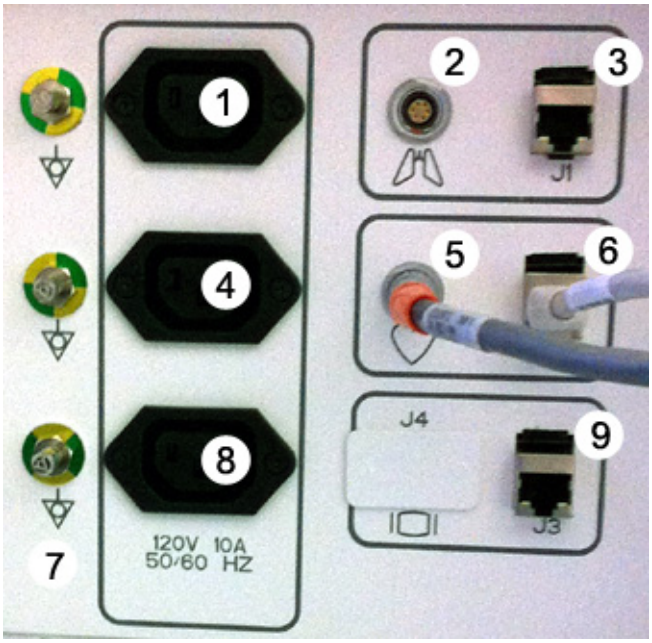


Table 9: Left Rear Plug-in Panel Components

Number	Description
1	Respiratory gating power connection
2	Respiratory gating trigger connection
3	Respiratory gating Ethernet connection
4	Cardiac gating power connection
5	Cardiac gating trigger connection
6	Ethernet connection for ECG monitor
7	Ground
8	Power connection (spare)
9	Ethernet connection (spare)

3.3.2 Console AC power box

Illustration 11: Console AC Power Box

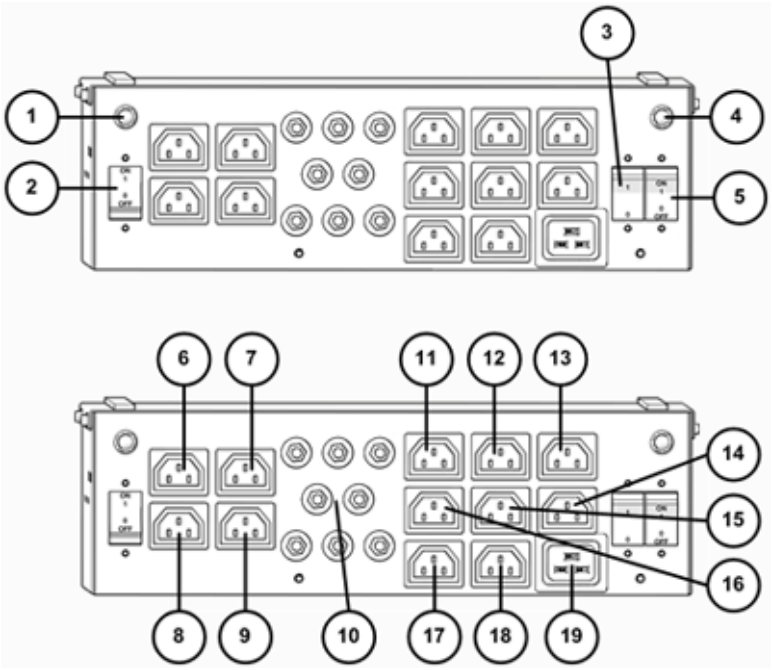


Table 10: Console Rear Plug in Panel Components

Number	Description
1	Power Indicator - Scanner Desktop internal components
2	Circuit Breaker / Switch - Scanner Desktop internal components
3	Circuit Breaker / Switch - Optional GEHC supplied motorized Scanner Desktop table
4	Power Indicator - Accessories
5	Circuit Breaker / Switch – Accessories
6	AC Power Outlet – Peripheral Media Tower
7	AC Power Outlet – Monitor (Prescription)
8	AC Power Outlet – Monitor (Display)
9	AC Power Outlet – Scan Room Monitor (Optional)
10	Accessory Grounds
11	AC Power Outlet – RPM_1
12	AC Power Outlet – RPM_2
13	AC Power Outlet – Injector_1 (see Note)
14	AC Power Outlet – Injector_2 (see Note)
15	AC Power Outlet – Injector_3 (see Note)
16	AC Power Outlet – Injector_4 (see Note)
17	AC Power Outlet – Spare
18	AC Power Outlet – Spare

Number	Description
19	AC Power Outlet – Optional GEHC supplied motorized Scanner Desktop table
NOTE:	Gantry and console outlets should not be used for the MedRad injector components or ISI900. A separate grounding cable should be attached between the injector and the CT system.

[redacted]

CAUTION

These receptacles are not for general use. The RPM power consumption should not exceed 720 Watts. The Injector power consumption should not exceed 780 Watts.

[redacted]

DANGER

INFORMATION ON INTERNAL GANTRY COMPONENTS IS PROVIDED FOR USER EDUCATION. THE GANTRY CONTAINS DANGEROUS VOLTAGES AND MOVING PARTS. TO PREVENT ELECTRICAL SHOCK OR CRUSHING INJURIES, DO NOT REMOVE COVERS OR ENTER THE GANTRY. ONLY TRAINED, QUALIFIED SERVICE PERSONNEL MAY REMOVE GANTRY OR OTHER EQUIPMENT COVERS.

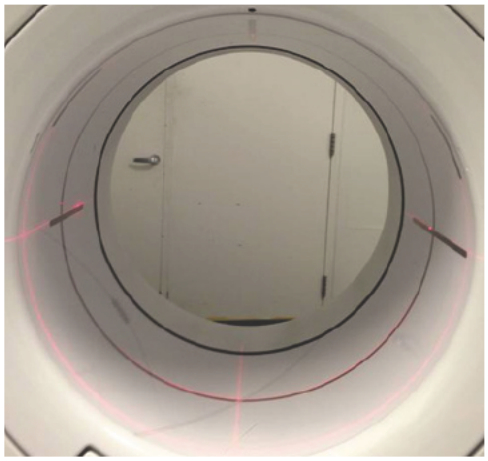
3.4 Operate the gantry controls

Gantry controls are described in the table, below.

Illustration 12: Gantry Controls

Table 11: Gantry Controls

Number	Icon	Function	Description
1		**Start Scan**	If you want to stand by the gantry and start the scan, you can press **Start Scan** after you have confirmed the prescription and the table has been moved to the start location. Once the tube has reached the exposure speed, the button flashes green for 30 seconds and then times out. Press the **Start Scan** button again to bring the system back to the ready to scan state.
2		**Stop Scan**	• Stops the prep display and X-ray exposure. • Halts all gantry and table motions.
3		**Cradle In**	Moves the cradle into the gantry.
4		**Table Up**	Moves the table up.
5		**Cradle Out**	Moves the cradle out of the gantry. Cradle In or Out can be used to move the patient to the scan location after clicking confirm. Cradle In or Out LED flashes for three minutes before it times out.
6		**Table Down**	Moves the table down.
7		**Fast Speed**	When pressed simultaneously with Table Up/Down or Cradle In/Out, speeds up the movement.

Number	Icon	Function	Description
8		Laser Alignment Light	Press to toggle all laser alignment lights on/off and to move the gantry components from the park or idle position to the alignment lights position. Alignment lights are used to establish landmark locations. Three alignment lights are displayed: • Axial, divides anatomy into superior and inferior sections. • Sagittal, divides the anatomy into right and left sections. • Coronal, divides anatomy into anterior and posterior sections.  **CAUTION** **For patient safety, always have patients close their eyes anytime the laser alignment lights are on.** The sagittal, coronal, and transverse alignment lights are within ±1 mm of the gantry coordinate system (x, y and z-axis) centered at gantry iso center. NOTE: The laser alignment light switch is provided as an alternative to beam attenuators.
9		Internal Landmark	Press to establish the table's reference point when positioning the patient. This reference point is normally the anatomic reference point used when positioning the patient. For example, if the patient's anatomic reference point is the sternal notch, then the sternal notch would be centered to the laser alignment light. • For **Internal Landmark**, the gantry displays a table location of 0 mm. This sets the zero point for which S and I scan locations are centered around. • For **External Landmark** , the gantry displays a table location approximately 240 mm from the internal landmark, depending on table characterization. A landmark must be set before you click **Confirm settings**. At Done Scanning, the landmark is cleared. For scan setup details, see the Set up and position the patient procedure.
10		External Landmark	

Number	Icon	Function	Description
11		**Cradle Lock/Release**	Press once to unlock the table cradle, which makes it so you can freely move the table with your hands. Use it to move the patient out of the gantry in an emergency. Press a second time returns the cradle to the locked position and the landmark is maintained.
12		**Table Home**	Press to simultaneously move the cradle out of the gantry. Once the cradle has been removed from the gantry, the table begins to lower to its lowest limit.
13		**E-Stop Reset**	Flashes white about once every two seconds when E-stop has been activated. Restores power to the gantry and table.
14		**Breathing Lights Demo**	Press to demonstrate the breathing light and countdown time to the patient. Refer to Table 7 for breathing lights description.
15		**Accent Lights On/Off**	Toggles accent lights on/off.
16		**Bore Lighting Intensity Up**	Increases the bore lighting intensity.
17		**Bore Lighting Intensity Down**	Decreases the bore lighting intensity.
18		**Back**	Moves to next (left) selectable area on the Gantry Primary Display. If more than one row, moves left and then up and left.
19		**Enter**	Selects highlighted menu item on the Gantry Primary Display.
20		**Forward**	Moves to next (right) selectable area on the Gantry Primary Display. If more than one row, moves right and then down and right.

3.5 Cardiac trigger monitor

3.5.1 Integrated cardiac trigger monitor

For cardiac gated exams that require the cardiac trigger monitor, use the Integrated Cardiac Module that is connected to the cradle.

Illustration 13: Integrated Cardiac Module

Table 12: Integrated Cardiac Module Components

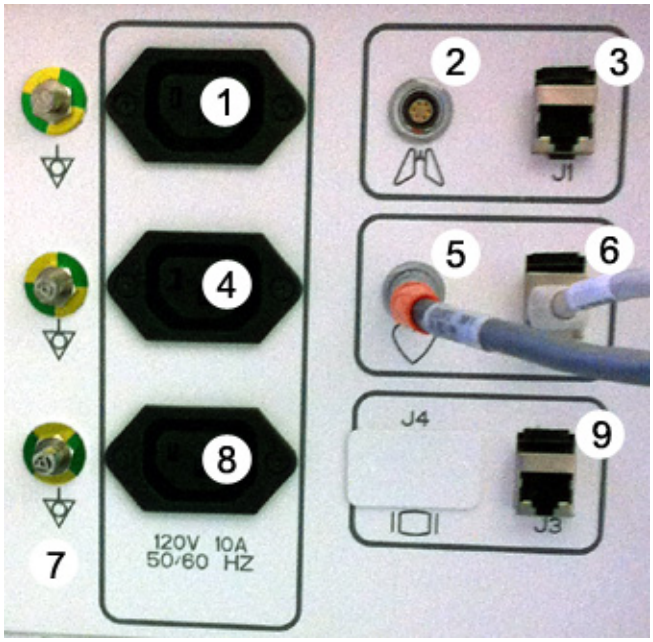
Number	Components	Description
1	Functional Ground	Connected to the ground cable that connects to the cable retractor below the cradle.
2	Network Interface Cable	Connected to the RS-422 communication cable that connects to the cable retractor below the cradle.
3	6-Pin AAMI ECG Patient Cable Connector	Connection used for the 4-lead patient cable.
4	4-Lead ECG Simulator	Connection used for the 4-leads when the simulator mode is required.
5	Annunciator LEDs	POWER (Green LED) – Indicates that power is applied to the Cardiac Module. COMMUNICATION (Yellow LED) – Flashes when the Cardiac Module is transmitting and receiving data. STATUS (Yellow LED) – Flashes when is operating normally.
6	Respiratory connector	Connection used for the Respiratory hose into this connector
7	Light Pipe	Light for room ambient.

3.5.2 External cardiac trigger monitor

If using the External ECG monitor (IVY 7800) instead of the ICM, follow the steps below:

1. Locate the gantry's left-rear plug-in panel.

Illustration 14: Left Rear Plug-in Panel



2. Plug the power connection for the cardiac trigger monitor into the electrical connection port (4).
3. Connect the coaxial cable to the connection port above the heart (5).

   NOTE: Do not loop the cable. This could introduce noise into the ECG trace.
4. Connect the Ethernet cable from the cardiac trigger monitor to the port labeled *Monitor* (6).
5. On the Gantry Display *Menu Area*, select Settings → ECG Settings to select the External ECG as the primary cardiac device. The External ECG can also be selected from the Console user interface.

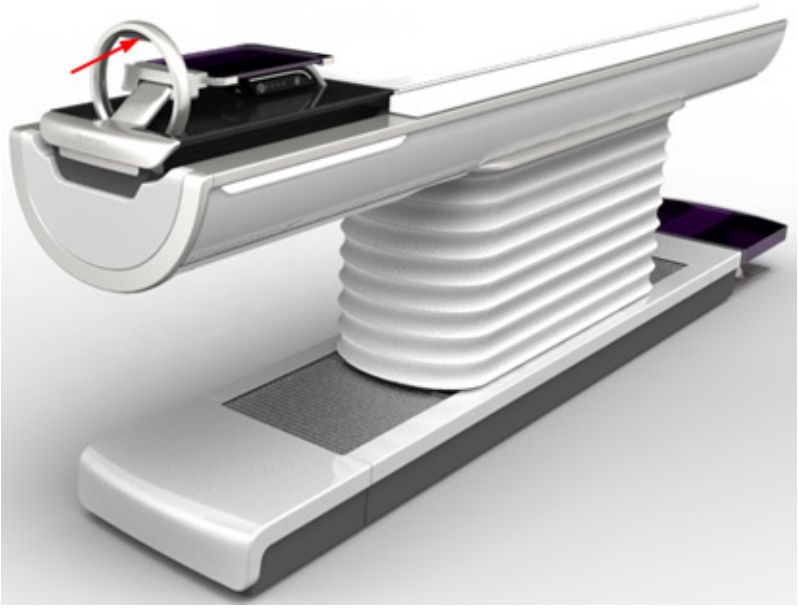
4 Table

The table has a weight limit of 500 pounds (227 kg) with an incremental accuracy of ±0.25 mm. The vertical range of the table is 49 to 103 cm. The scout view range is 1,900 mm and the scan range is 2,000 mm with cradle extender.

When interruption of Supply Mains occurs, the maximum stopping distance of the moving cradle is 220 mm.

To safely remove the patient in an emergency egress situation, grab and squeeze the Cradle Handle release switch. Continue to squeeze the Cradle Handle release switch while pulling the cradle to its out position.

Illustration 15: Patient Table Cradle Release Handle Switch

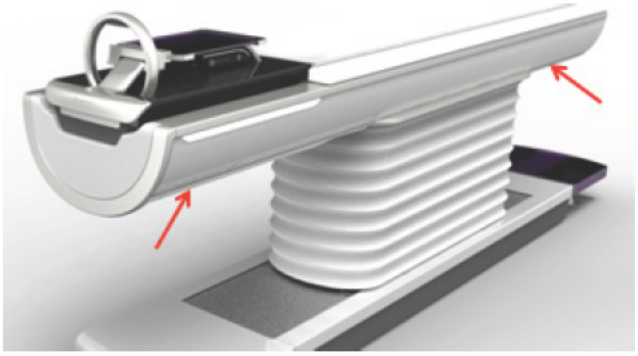


4.1 System operation and limitations that reduce the risk of collision with the patient

- The range of table motion is limited to prevent a collision between the table cradle and the gantry. The system will maintain a 25 mm clearance between the table cradle and the gantry.
- The system design minimizes gaps between moving covers and structures so that fingers cannot get into the gap.
- Operator controlled table motion requires continuous activation of gantry controls.
- Emergency stop controls are readily available that stop motion within 10 mm.
- The table motion is force limited to 200 N as a protective measure to reduce the risk of entrapment and pinching.
- The gantry employs covers to protect the patient against rotating parts, and provides cover interlocks to inhibit gantry rotation when the covers are open.

- Sensors are located beneath the table to detect collision and stop motion.

Illustration 16: Table Collision Sensor Locations



Sensors are located underneath the front and back of the table. These sensors indicate where there is potential for collisions with items such as wheel chairs or stretchers. When a sensor is touched, table and gantry movement stops immediately. In this event, clear the area and continue positioning the table.

There is a mark on the cradle for maximum scannable range.

CAUTION

If the table is lowered with anything in the red X area, as indicated in the figure below, the table could be damaged along with the equipment or object under the table.

Illustration 17: Restricted Area Below Table

CAUTION

Use of any cradle extension accessories such as the table extension, head holder, coronal head holder, and phantom holder are not accounted for in the table gantry interference matrix. Therefore, additional care needs to be taken to closely monitor any table movement to avoid contact of the extended accessory with the gantry.

4.2 Use the Load/Unload foot pedals

The Load and Unload pedals adjust the table up and down and in and out of gantry. The Load and Unload pedals are always active.

- The Load pedal moves the patient table up to a height of 99 cm and moves the cradle into the gantry.
- While the Unload pedal is pressed, it moves the patient table out of the gantry and moves the cradle to the full out home position, and then lowers the table to a minimum height of 49 cm.

To move the patient into the gantry, press and hold the **Load** pedal.

To move the patient out of the gantry, press and hold the **Unload** pedal until the table is at a suitable position to remove the patient from the table.

4.3 Patient comfort and accessories

4.3.1 Cradle pad

Attach the cradle pad to the velcro on top of the cradle.

To remove the cradle pad, pull the pad loose from the cradle velcro.

4.3.2 Cradle extender, Axial and Coronal head holders

To attach these accessories to the table:

1. Align the accessory tongue with the pocket at the end of the cradle.
2. Keep fingers clear of the cradle.
3. Push the tongue all the way into the pocket until it latches into place.
4. Rubber shims may have been installed on the head holder or foot extender to give it a tighter fit. Please take care when latching the accessory to make sure that it is completely latched. Push the latch forward until you hear a click. Verify that the latch is fully latched.

To remove these accessories from the table:

- Pinch the two L-shaped parts together and pull the accessory out of the cradle.
- An alternate method is to apply a light force to the catch towards the cradle, pinch the L-shaped catch together, and pull accessory out of the cradle.

4.3.3 Cradle extender pad

Attach the cradle extender pad to the velcro on top of the cradle extender.

To remove the cradle extender pad, pull the pad loose from the cradle extender velcro.

4.3.4 Patient arm board

To attach the patient arm board to the table, slide the accessory tongue under the cradle pad.

To remove the patient arm board from the table, pull the accessory tongue from under the cradle pad.

4.3.5 Catheter bag holder

To attach the catheter bag holder to the table, slide the accessory tongue under the cradle pad.

To remove the catheter bag holder from the table, pull the accessory tongue from under the cradle pad.

4.3.6 Table tray

To attach the table tray to the table:

1. Fit the legs of the tray-support form into the holes at the rear of the table.
2. Place the tray on top of the support form.
3. Use the strap to secure objects that might tip.

NOTE: Do not place the cardiac trigger monitor on the tray. The tray's weight limit is 19.8 pounds (9 kg).

To remove the table tray from the table:

1. Remove any straps used to secure objects.
2. Remove the tray from the top of the support form.
3. Remove the legs of the tray-support form from the holes at the rear of the table.

4.3.7 IV pole

To attach the intravenous (IV) pole to the table:

1. Insert the IV pole into the hole at the rear of the table or into the table tray.

   The maximum weight that can be attached to the IV Pole is 10 pounds (4.5 kg).
2. Tighten the extension lock to secure the pole.

To remove the intravenous (IV) pole from the table:

1. Loosen the extension lock that secures the pole.
2. Remove the IV pole from the hole at the rear of the table or from the table tray.

4.3.8 Positioning straps

To attach positioning straps:

1. Slide the bead end into the positioning track on the cradle.
2. Attach the velcro end to the patient anatomy.

To remove positioning straps:

1. Remove the velcro end from the patient anatomy.
2. Slide the bead end out of the positioning track on the cradle.

5 Hardware Components

5.1 Components

Pre-Patient Collimator

The collimator contains two independently controlled blades. The motion of the blades provides continuously variable beam thickness and Z-axis position. The collimator also has three bow-tie beam filters that filter and shape the beam to optimize dose and image quality.

Gemstone Clarity Detector

Features a unique 3-dimensional post patient collimator to ensure HU uniformity and to minimize scatter / beam hardening artifacts associated with wide coverage systems. Provides 160 mm coverage, 512 slices from 256 detector rows in the Z direction. The 256 rows are 0.625 mm in the Z direction. Each signal can be collected from an individual detector row. The Gemstone scintillator material is created from garnet gemstones fused with a rare earth phosphor composition.

5.2 Coverage

The Axial Detector Coverage/Beam Collimation for the 512-slice system are 5, 40, 80, 120, 140, and 160 mm beam collimation/detector coverage (0.625 mm).

Table 13: Images per Rotation

Slice Thickness (mm)	Detector Coverage (mm)					
	5	40	80	120	140	160
5	1i	8i	16i	24i	28i	32i
2.5	2i	16i	32i	48i	56i	64i
1.25	NA	32i	64i	96i	112i	128i
0.626	NA	64i	128i	192i	224i	256i
0.626z	NA	128i	256i	384i	448i	512i

5.3 Axial interval

The interval is equal to the number of images per rotation times the beam collimation, e.g., in the 256 x 0.625 mode, 256 images are generated, each 0.625 mm thick for a total of 160 mm of coverage protection. For collimation greater than 40 mm, a slight overlap is applied when the acquisition contains multiple table locations.

5.4 Helical pitch, scan mode, and collimation

Scan modes for helical are expressed in terms of pitch. Helical pitch is defined as the ratio of table travel per rotation in millimeters divided by the beam collimation. Previous systems expressed scan modes with names and defined pitch as table travel per rotation in millimeters divided by the detector row width.

For example: 55/40 mm = 1.375: 1 (Table Speed (55) divided by the Beam Collimation (40 mm) equals a Pitch of 1.375.

Table 14: Beam Collimation

Detector Configuration	Beam Collimation	System
64 × 0.625	40.0 mm	64

The following pitches are available:

- 0.5:1 interleaved helices
- 0.9:1 interleaved helices
- 1.375:1 interspaced helices

Interleaved helices minimize helical artifact and give the best detail. Interspaced helices have more interpolated data and increased helical artifact when compared to interleaved mode. Using interspaced helices compared to interleaved helices will provide lower dose.

5.5 Detector configuration

Parameter selections in the Coverage Collection determine the detector configuration.

5.5.1 Axial

The parameters selected to set the detector coverage (detector configuration) determine the slice thickness and speed.

- Beam Collimation or detector coverage allows selection of 5, 40, 80, 120, 140, and 160 mm.
- Axial slice thickness choices range from 0.625 to 5.0 mm thick.
- Number of images per rotation is equal to the detector coverage divided by the slice thickness.
- Rotation Speed can be adjusted to optimize acquisition time. Rotation Speeds are 0.4, 0.5, 0.8 and 1.0 seconds.

5.5.2 Helical

There are five main parameter selections for helical.

- Detector Coverage determines the beam collimation, 40.0 mm, in the Z direction.
- Helical Thickness determines the primary and secondary reconned image slice thickness.
- Slice thickness choices range from 0.625 mm to 5.0 mm.
- Pitch/Speed determines the speed of the table per gantry rotation. There are two pitch selections with associated table speed.
- Rotation Time determines the speed the gantry rotates in 360°.

6 Power Distribution Unit

The Power Distribution Unit (PDU) supplies power to various parts of the system including gantry components, table and operator console. On the front of the PDU are controls to indicate that power is on, a push button to turn power on/off to the gantry and table, and an Emergency Stop button.

Illustration 18: PDU Controls

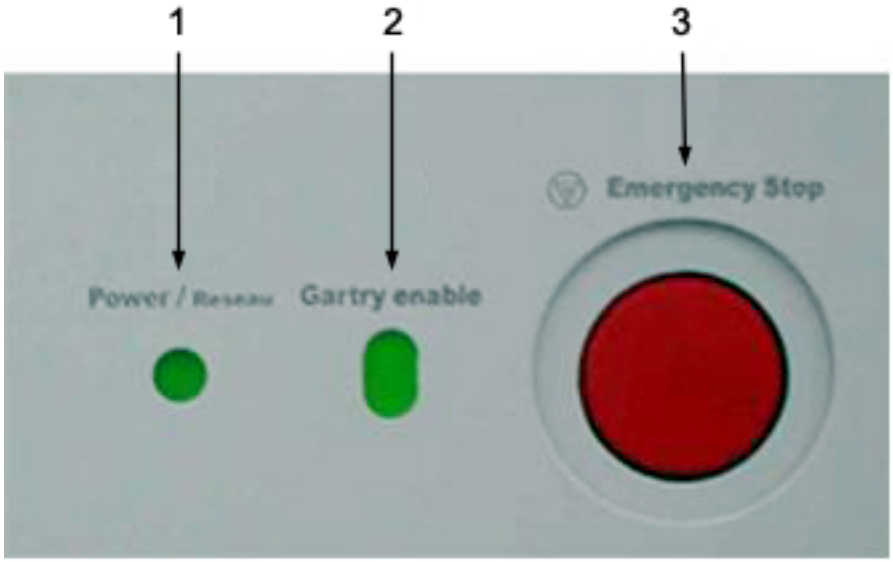


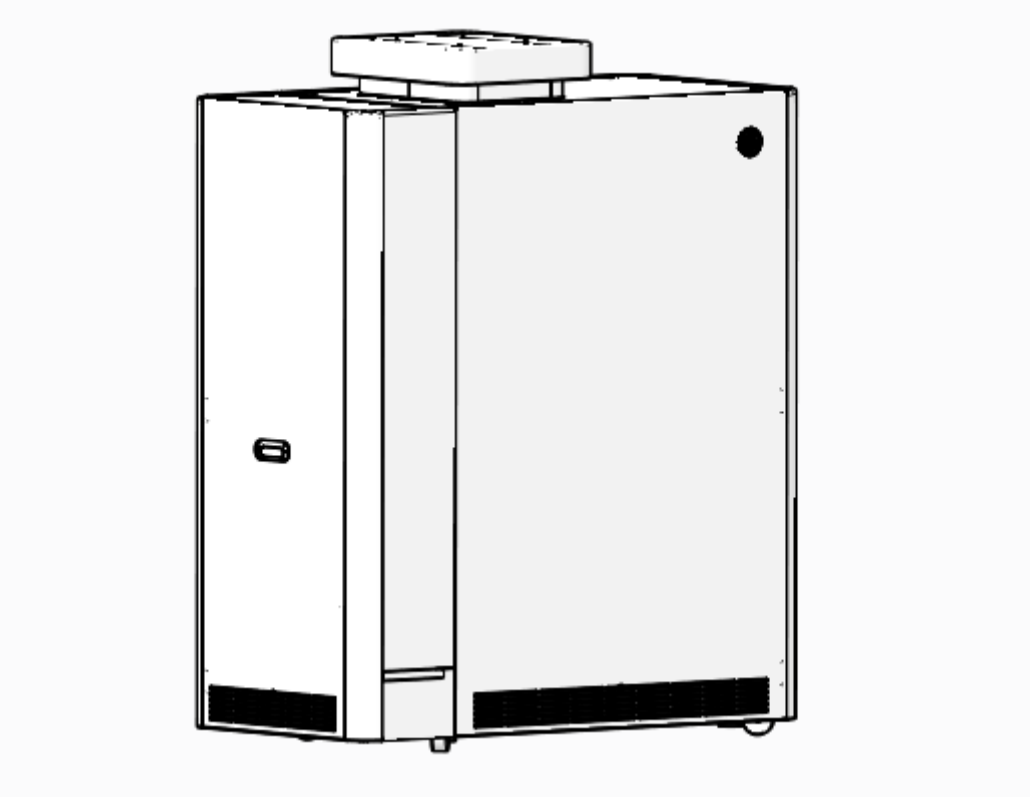
Table 15: PDU Controls

Number	Function	Description
1	Power	Indicates power is On/Off to the unit
2	Gantry enable	Enables/disables power to the gantry and table
3	Emergency Stop	Use the Emergency Stop to stop all table and gantry motions. X-ray is stopped, and laser alignment lights are turned off. The cradle and base are also unlatched. The system aborts any data collection acquisition in progress and attempts to save any data acquired.

7 System Cabinet

The System Cabinet contains the acquisition and image generation compute hardware along with supporting electronics. This cabinet supplies interfaces between the Scanner Desktop and the Gantry, allowing for acquisition control, raw data storage, and image generation process.

Illustration 19: System Cabinet



8 X-ray Tube and Generator

8.1 X-ray tube

- The Performix™ HDw X-ray tube assembly provides expanded mA capabilities for the small, large, and GSI focal spots.
- The tube supports normal and Hi Resolution imaging modes. Heat capacity is 6.8 MHU.
- 80 kW peak power (large spot, 0.3 second exposure, 120 kV, Non-Hi-Res Mode)
- 49 kW peak power (small spot, 0.3 second exposure, 140 kV, Non-Hi-Res Mode)

8.2 Generator

Provides bias voltages to the X-ray tube that controls width, length, and position of the focal spot on the target.

Table 16: mA range by kVp, Focal Spot size, and Scan Type

Scan Mode	kV	Small Focal Spot	Large Focal Spot
Normal	70	10 to 250	255 to 375
	80	10 to 580	NA*
	100	10 to 490	495 to 720
	120	10 to 405	410 to 665
	140	10 to 350	355 to 570
Hi-Res	70	10 to 250	255 to 375
	80	10 to 425	430 to 580
	100	10 to 340	345 to 545
	120	10 to 280	285 to 455
	140	10 to 240	245 to 390
* The large focal spot capability overlaps with the small focal spot capability and they are equivalent.			

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Chapter 9 Startup and Shutdown

1 Overview

This section describes how to turn the system on and off and how to log in to the system. It includes quality control information to verify that your system is operating properly.

For optimal performance, you should restart your system at least once every 24 hours. It is recommended to shutdown and startup the system at least once per week.

For power consumption savings it is recommended to shutdown your system at the end of the last shift.

2 System Startup and Shutdown

2.1 Prepare the system

- Clean the accessories and check for damage.
- Check and remove dried contrast agent from:
  - Scan window (around the gantry opening)
  - Table extension and cradle surfaces — especially the patient restraint plastic channels on the table
  - Accessories (Head holders, pads and cushions, etc.)
- Check supplies.

2.2 Login/Logout

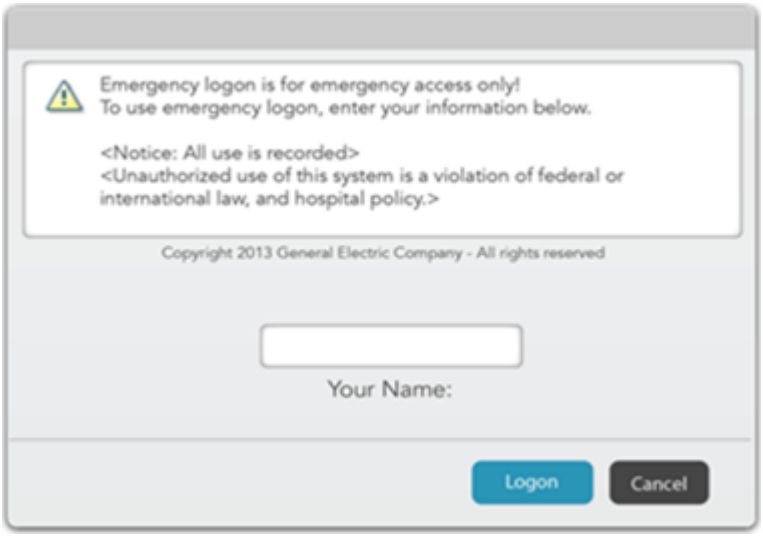
When enabled, the login feature requires you to log into the system to record the operator of record and for System Access. Use of the system login depends on whether or not your site is connected to a central, user repository. Sites with networks are referred to as enterprise systems, others are referred to as standalone systems. This feature can be used with enterprise or standalone systems.

Logging off does not prohibit other users from logging in. Logout is designed to protect patient privacy. It is not intended to stop approved users from logging in. When you log back in after a logout, the system returns to a non-scanning state.

2.2.1 Logon screen

The *Logon* screen displays when you reboot the system or when someone has logged out when System Access is enabled.

Illustration 1: Logon screen

Element	Description
Logon Name	Enter your system Login Name. Your administrator can set up a unique Logon Name for you through your hospital Enterprise system.
Password	Enter your password. The password is assigned by the system administrator.
Emergency Logon	Launches the Emergency Logon screen when System Access (EA3) is enabled. It does not require an ID or password on your Enterprise system. **Illustration 2: Emergency Logon screen** 
Logon	Click to logon.
Cancel	Quit the login procedure.

2.2.2 Login

If System Access is enabled, use the following procedures to log in and out of the system.

1. From the *Logon* screen, enter ***your login name***.
2. Enter ***your password***.

   If you do not have a valid account, click [Emergency Logon]. The *Emergency Logon* screen opens. Logging on does not require an ID or password.

   Otherwise, click [Logon].

2.2.3 Logout

1. From the display monitor, click the [Mode icon]  .
2. Click [Shutdown].
3. From the popup menu, click [Logout User], and then click [OK].

NOTE: Logging out does not keep others from logging in. Logout is for patient privacy, not to prevent approved users from logging in. When you log back on, the system returns to your last known state.

2.3 Start up the system

NOTICE

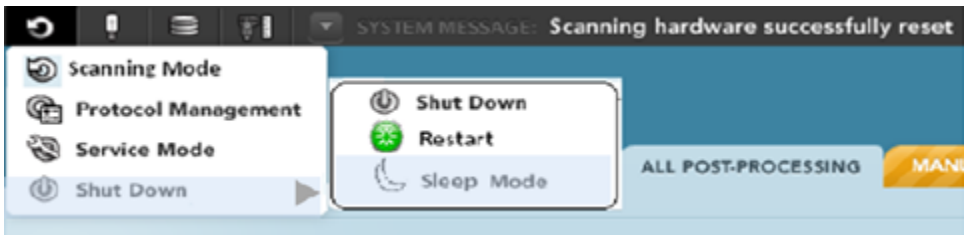
After a power interruption, wait two minutes before turning on power to the Main Disconnect Control.
Do not reboot the system with a USB device connected.

NOTE: SmartID verifies the tube ID at start up. If the tube ID verification fails, attention screens display indicating that the X-ray tube is not recognized. You can continue scanning; however, you need to contact your service representative. Hi Res is disabled when a non-GE tube is installed.

2.3.1 Routine daily startup when the system was not shut down

1. From the right monitor, click the [Mode icon] .
2. From the popup menu, select [Shut Down].
3. From the pop-up menu, select [Restart].

Illustration 3: Shut Down menu



4. Click [OK].

NOTE: The restart process might be able to preserve the thermal state of the detector.

2.3.2 Routine daily startup from system shutdown

If the system is in shutdown state (the operator console is turned off and the moon icon on the Gantry Indicator display is lit), push the power on button on the scan control interface to start up the system.

Illustration 4: Scan control interface power on button

NOTE: If the computer does not start, check the power switch on the back of the computer.

2.3.3 Start up from power off

If the power was turned off to the entire system (the Main Disconnect Control A1 Power Panel breaker is turned off), follow these steps:

1. Turn on power to the Main Disconnect Control.

   NOTE: If the computer does not start, check the power switch on the back of the computer.

2. Press <Reset> on the gantry controls to allow table and gantry motions.
3. Check the console screen for messages that require your attention. Follow the on-screen instructions.

2.3.4 System start-up failures

If the system fails to startup completely, toggle the power switch on the back of the computer cabinet.

2.4 Shut down or restart the system

Shut down and start up the system at least once a week for optimum system performance.

2.4.1 Considerations

- The system provides a visual indication when it is entering into shutdown.
- If the system is already shut down, the power button on the scan control interface flashes, the computer is turned off, and the moon symbol on the gantry is lit.

NOTICE

Moving the system into shutdown state will lose the thermal state of the detector.

2.4.2 Shutdown process

1. Close any open study.
2. Remove any USB devices before rebooting or shutting down.

   NOTE: If a save/restore of scan data is in progress, wait for the process to complete, exit *Recon Management*, and remove the USB device. If the system shuts down unexpectedly while a USB drive is connected, remove the USB drive and restart the system.

3. From the right monitor, click the [Mode icon]  .
4. From the Mode menu, click [Shutdown].
5. Check the console screen for messages that require your attention. Follow the on-screen instructions.

6. Confirm the shutdown request.
7. The system indicates when it is entering the shutdown state.

2.4.3 Restart process

The restart process may save the thermal state of the detector.

1. From the right monitor, click the [Mode icon]  .
2. From the Mode menu, click [Restart], and then click [OK].
3. Confirm the restart request.
4. The system indicates when the restart is complete.

3 Daily Quality Assurance

In order to assure consistent image quality, establish and maintain a regular quality assurance program.

3.1 Tube warm-up

The system operates most efficiently within certain parameters. These parameters are established by warming up the tube using a preset group of exposures. When you perform a tube warm-up at least once per 24 hour period and at any system prompt, the tube warm-up reduces the possibility of artifacts and may aid in prolonging the life of the tube.

Once every seven days, a beam quality check will be performed when you run a tube warm-up. A message displays asking you to remove any obstructions from the beam. When you start the scan, a series of air scans are taken followed by the tube warm-up scans.

3.2 Calibration

3.2.1 Daily calibration

The system requires that all kV and mA settings be with specific ranges. These ranges are established and maintained by performing air calibrations. These calibrations are performed as part of the daily system preparation following a tube warm-up procedure.

Daily calibration (Fast Cal) must be performed every 24 hours to maintain image quality.

The daily calibration performs several automatic checks:

- The system confirms the gantry is in balance.
- The system confirms that the scan window is clean. The scan window must be kept clean. Dirt, contrast material, and other matter could corrupt the calibration files.

  If the scan window is not clean the system prompts you to clean it. If this happens, clean the scan window, and click [Retry] to repeat the scan window check or click [Continue] to go on with the Fast Cal without repeating the check.

The number of tube warm-up scans depends on the current temperature of the tube.

The system finishes the Fast Cal procedure by performing the actual Fast Cal air scans.

3.2.2 Full system calibration

Full system calibrations are normally performed by a qualified engineer following a tube change or as part of preventive maintenance.

3.2.3 Non-GE X-ray tube

When the system is configured to use a non-GE tube or if the tube is unrecognized by the system, the system will alert you during system start-up, tube warm-up, and fast calibrations that a non-GE X-ray tube is detected in the system configuration. System configurations with non-GE X-ray

tubes will be noted in the Dose Report. A notification about using a non-GE X-ray tube will also display in protocol selection and management.

NOTE: If the system has an unrecognized X-ray tube:

- The performance of the system cannot be guaranteed.
- Warm-up scans may cause subsequent tube cooling delays. The tube warm-up will run in Autoscan mode.
- Fast calibration techniques are designed specifically for GE tubes and GE cannot guarantee that the performance of the system will meet specifications with an unrecognized tube.

3.3 Daily QA workflow

1. If the system has not been restarted in the last 24 hours, restart the system.
2. From the scan monitor, click the [System Tools and Calibration] icon .
3. Select and run *Tube warm-up*.
4. Once the tube warm-up is complete, click the [System Tools and Calibration] icon , and then select and run *Fast Cal*.
5. Perform a QA scan.

3.4 Tube warm-up

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

The system operates most efficiently within certain parameters. These parameters are established by warming up the tube using a preset group of exposures. When you perform a tube warm-up at any system prompt, the tube warm-up reduces the possibility of artifacts and may aid in prolonging the life of the tube.

- Every seven days, a beam quality check is run to check the integrity of the X-ray beam. You will be prompted to make sure the beam is clear. The beam quality check increases the amount of time it takes for the tube warm-up process. With the beam quality check, the tube warm-up takes about 3.5 minutes instead of about 80 seconds.
- SmarTube™ warm-up optimizes system scanning performance by including an indication of the temperature state of the tube. Operating the system in the green zone will maximize the tube life.
- The tube state is indicated by the [Tube] icon . If the tube temperature is out of its scanning range, messages appear next to the icon indicating the condition of the tube.

Table 1: Tube icon colors

When the tube icon is:	The tube is:	And you should:
Gray	At normal scanning temperature	Proceed with scanning
Blue	Too cold	Click the message next to the Tube icon, and then click [Begin warm-up routine].
Gray on red background	Warming up	Wait for the warm-up to complete before scanning. The message next to the Tube icon shows how long you will need to wait.
Orange on red background	Too hot	Wait for the tube to cool down. The message next to the Tube icon shows how long you will need to wait.

Illustration 5: Tube icon when tube is at normal scanning temperature

Illustration 6: Tube icon when tube requires warm-up

Illustration 7: Tube icon while tube is warming up

Illustration 8: Tube icon when tube is too hot

- For the best care of your tube, never skip the tube warm-up. Perform the warm-up when the system notifies you to do so. The time to warm up the tube is calculated to put the system in to the optimal operation state as quickly as possible.
- To avoid delays in scanning, check the tube state before moving patients into the scan room.
- The system will notify you if the tube ID verification fails (an unrecognized tube has been installed on the system). Follow the message instructions. Tube cooling algorithms are designed specifically for GE tubes and the performance of the system cannot be guaranteed.
- Perform a cold tube warm-up after two hours of non-use. The warm-up takes about 80 seconds. Scan within 30 minutes of the tube warm-up. Failure to perform the tube warm-up may result in serious tube and system damage and will reduce the maximum mA possible. The system will warn you regarding the reduced mA due to a canceled or skipped tube warm-up. The following table shows the limits on mA for each focal spot size.

For this size focal spot:	The maximum mA if the warm-up is skipped or canceled is:
Small	165 mA
Large	330 mA
XLarge	370 mA

Acceptable mAs (mAs = mA × Rotation time) can be achieved by changing rotation times as needed.

- If the detectors are cold due to an A1 Power Panel (Breaker) being off, turn the system on and wait two hours before performing a tube warm-up. This allows the detectors to return to their operating temperature.

1. Clear the gantry area of all objects. Any obstruction in the gantry may lead to artifacts in scanned images.
2. From the scan display, click the [System Tools and Calibration] icon and then click *Tube Warmup*.

   Alternatively, click the [Tube] icon and then click [Begin warm-up routine].

   A message warns that scans may have been taken in the last two hours.
3. Click [Accept & Run Tube Warmup].
4. Click [OK] at the Beam Obstruction alert window. The Beam Obstruction message opens only if the system is running a Beam Quality Check.

   NOTE: Refer to the Safety chapter regarding using non-GE tubes.
5. Press [Start Scan].
6. The system returns to the *Daily Prep* menu when the tube warm up is completed. Click [Quit] to exit the *Daily Prep* screen.

3.5 Run Fast Calibrations

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

- If the detectors are not at operating temperature, a message will indicate when the detectors will be at operating temperature.
- If there is a large shift in room temperature (± 10 degrees), perform a Fast Cal to maintain optimum IQ. Once the room temperature has stabilized, perform another Fast Cal.
- The system will notify you if it has been more than 24 hours since the last Fast Cal was run.
- If you experience a scan abort with resumes during Fast Cal, notify your Service Engineer.
- The system will notify you if an unrecognized tube has been installed on the system. Fast Calibration techniques are designed specifically for GE tubes and GE cannot guarantee that the performance of the system will meet specifications with an unrecognized tube. Tube Warmup will run in AutoScan mode.

1. Clear the gantry of any objects or personnel. Any obstruction in the gantry may lead to artifacts in scanned images.
2. Click [Fast Calibration]. The system automatically performs a gantry balance check (approximately 2 minutes).
3. Press [Start Scan]. Respond to all messages that appear during the calibration (approximately 15 to 20 minutes). Execute any necessary actions indicated in the messages.
    - If the system detects a dirty scan window (which may be caused by a beam obstruction, something in the gantry, contrast, dirt, or other matter on the scan window), a message displays. Clean the scan window and click [Retry].
    - The following automated calibration check procedures occur: warm-up, interconnectivity map scan, and Fast Cal air scans. Read the screen messages for calibration status.
4. When Fast Cal is complete, the system returns to the Daily Prep menu. Click [Quit] to exit the Daily Prep screen.

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Chapter 10 Patient Scheduler

1 Overview

Use *Patient Scheduler* to preprogram patient information and protocols in advance of the patient's arrival. At scan time, select a patient from the created list, enter the patient ID number, enter the accession number or use the optional bar code reader to open the patient's information. Patient information can be easily added or deleted from this list.

See the Patient Information fields table to view the limits for each entry in Patient Information.

With the ConnectPro option, you can retrieve critical patient information from your HIS/RIS using a DICOM connection and then send this information to your Patient Schedule. Connect Pro requires a HIS/RIS system and PACS.

2 Patient Scheduler

2.1 Connect Pro

ConnectPro retrieves critical patient information from your HIS/RIS using a DICOM connection and then sends this information to your Patient Scheduler. The patient information from HIS/RIS is referred to as the Modality Worklist.

Connect Pro can be customized to fit your department's needs by using filters to pull only the information of interest. It can collect more than standard patient demographic information; for example allergies, pregnancy status, medical alerts, etc.

2.2 Performed Procedure Step

Performed Procedure Step (PPS) is part of the Connect Pro option that requires a HIS/RIS system and PACS. It communicates to PACS and HIS/RIS after a procedure is complete. It improves the transfer of data to PACS because it can provide a complete message when all data has been transferred. The browser in Image Works has a PPS column that lists the PPS status of each exam. There are three states of exam status:

- **COMP** ends the exam and PPS. You can annotate an image or add a series, such as a screen save, but you should not edit the patient information. If you edit the exam (through Edit Patient Data), the exam is no longer recognized by the HIS/RIS system as the exam it requested. This status annotates the exam as COMP.
- **DISC** notifies the HIS/RIS that you are aborting the PPS. Use this only if the images you acquired were unacceptable or were not for the correct patient. This status annotates the exam as DISC.
- **DEFER** does not end PPS. You can still post-process and edit the patient information. If you edit the exam (through Edit Patient Data), the exam is no longer recognized by the HIS/RIS system as the exam it requested. Selecting PPS from the browser menu bar displays a window and allows you to Complete or Discontinue the PPS on the patient. This status annotates the exam as INPR.

2.3 New and completed records

In the patient schedule there is a column labeled *Status*. In the Status column, an *N* or a *C* is listed next to each patient entry.

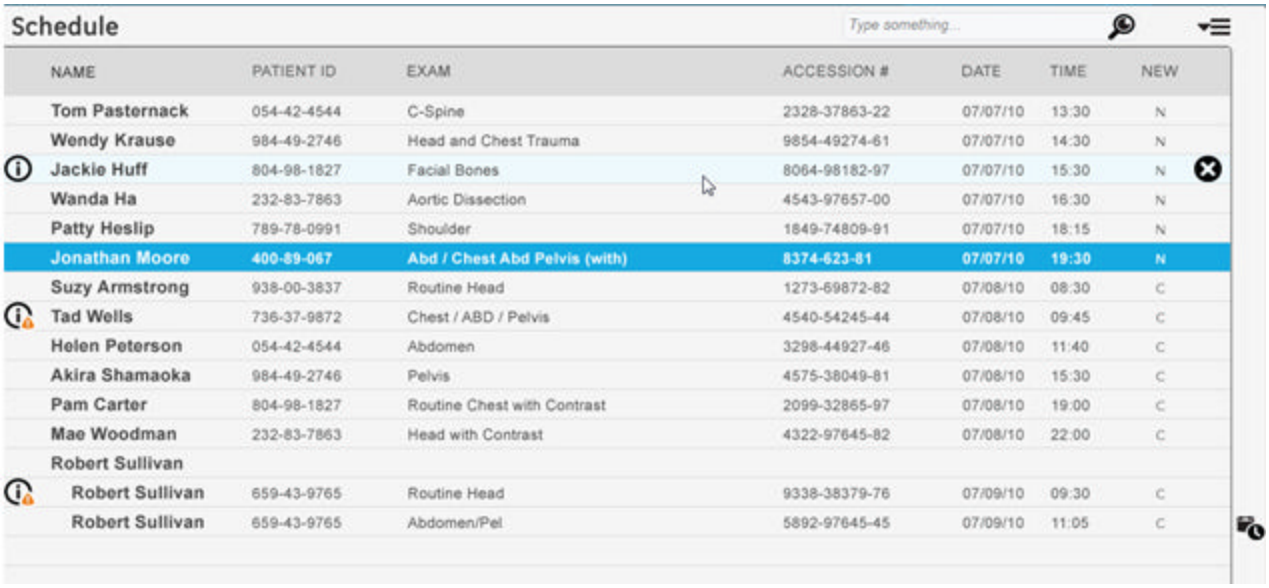
- **N** indicates the record is incomplete or is a new record. These are records for patient studies that are scheduled in Patient Schedule, but are not yet completed.
- **C** indicates the record is completed.

NOTE: When accessing patient information with Connect Pro you should only have new records in your schedule list. Having completed records may cause scanning a patient with the wrong accession number. To clear completed records; from the Connect Pro preferences, set *Delete Completed Exams* to 0 days. This setting assures that completed records are not added to the schedule list.

2.4 Schedule screen

Click the *Patient Scheduler* drawer to display the *Schedule* screen.

Illustration 1: Schedule screen

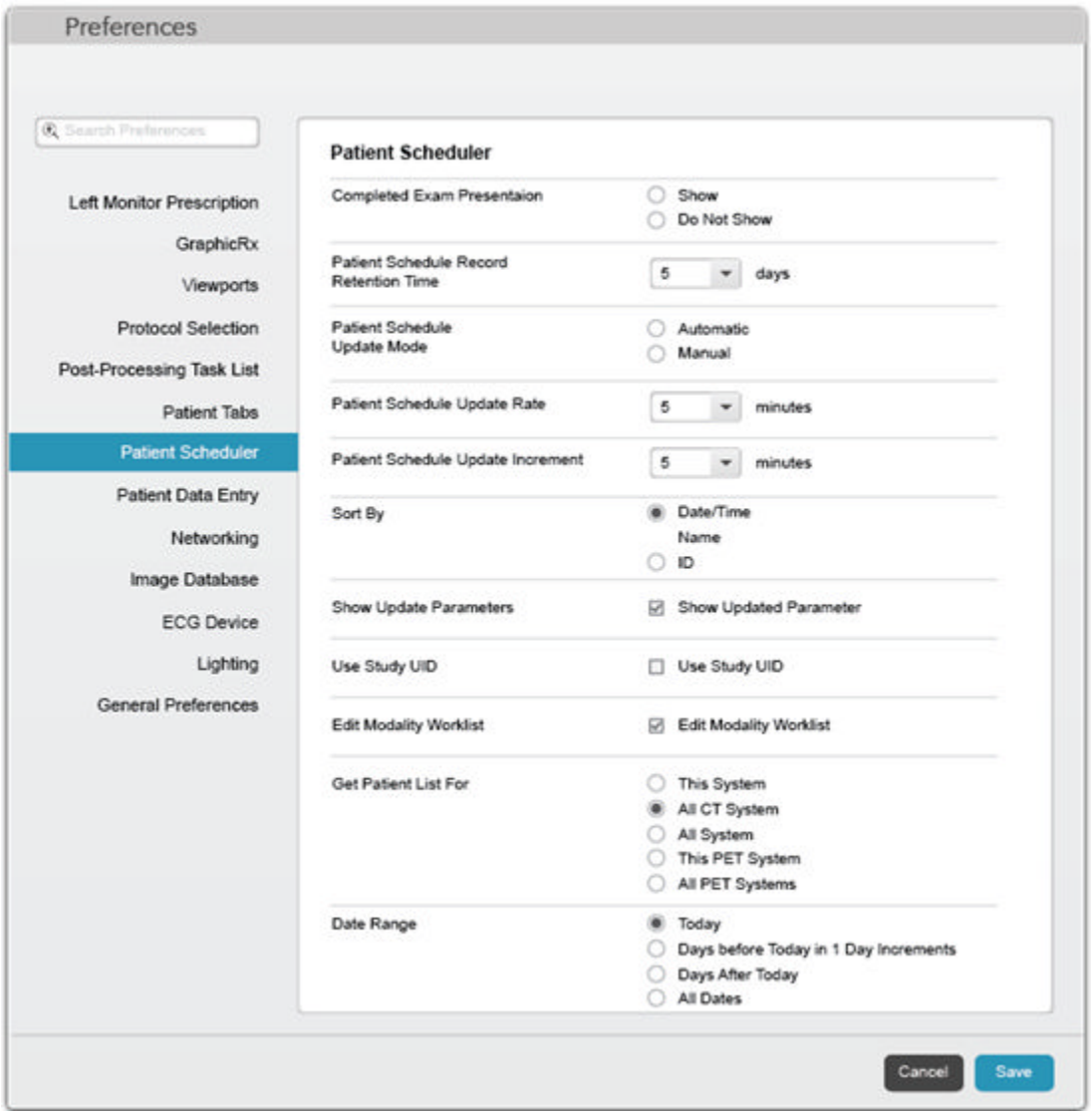


Element	Description
Quit	Closes the *Schedule* screen.
Select Patient	Select the patient for the scan.
Info Icon Caution Info Icon	Patient information such as allergies, pregnancy status, and medical alerts. This information is pulled from the HIS/RIS using a DICOM connection.
Add Patient	Opens the *Patient Scheduler* information screen, where you can enter the patient's information and add the number of a specific protocol.
Edit Patient	Edit patient information in the *Patient Scheduler*.
Delete Selected	Deletes selected patients from the list.
Delete All	Deletes all the patients from the list.
Update	Opens *Update Parameters* screen.
Requested Proc ID, Accession Number, Patient Name, Patient ID	Additional ways to populate the Patient Scheduler.
Continue Update	Applies the criteria chosen and updates the Patient Scheduler.
Cancel Update	Closes the Update Parameters screen without saving any new selections.

2.5 Patient Scheduler Preferences screen

From the Display monitor, select Mode from the drop-down menu.

Illustration 2: Patient Scheduler Preferences screen



Element	Description
Completed Exam Presentation	*Show* or *Do Not Show* completed exams.
Patient Schedule Record Retention Time	Set the number of days after which you would like to delete completed exams. The valid range is 0 to 30 days, and the default is 3 days. A completed record is not added to the Patient Schedule if the number of days is set to 0.
Patient Schedule Update Mode	Select *Automatic* or *Manual* for Patient Schedule updates.
Patient Schedule Update Rate	Set the frequency for checking for Patient Scheduler updates.
Patient Schedule Update Increment	Set the frequency for checking for Patient Scheduler updates.
Sort By	Sort the schedule by date/time, name, or patient ID.
Show Update Parameters	Selecting this option shows the update screen every time the system starts to automatically update. This allows you to edit the update parameters, if desired.
Use Study UID	Selecting this option uses a study instance Unique Identifier (UID) from HIS/RIS.

Edit Modality Worklist	Selecting this option allows you to edit any patient information from HIS/RIS.
Get Patient List For	*This System* Populates the Patient Scheduler for the current scanner you are on. *All CT Systems* Populates the Patient Scheduler for all of the CT systems on the HIS/RIS connection. *All Systems* Populates the Patient Scheduler for all the systems on the HIS/RIS connection.
Date Range	Populates the Patient Scheduler from the defined date range. Use the month/day/year format.

2.6 Add a patient to the schedule manually

To manually add a patient to the Patient Schedule, follow these steps:

1. From the scan monitor, click the [Patient Scheduler] drawer.
2. From the *Schedule* screen, select Add Patient from the drop-down menu.
3. From the *Schedule Patient* screen, complete all relevant fields.
   - Entered weights may be automatically rounded up to the next odd pound as weights are stored as kilogram units then converted back to pounds.
   - If you are using Exam Split with Hard Exam Split mode to add a patient, you must enter an exam description.
   - Enter the number of the specific protocol under *Protocol Number*.
   - Entering the date and time in appropriate fields lets you sort the Patient Schedule by scheduled times.
4. Click [Save] to add the patient to the schedule.

2.7 Edit a patient in the schedule

NOTE: You can not edit patient records from HIS/RIS if *Edit Modality Worklist* is not selected on the *Patient Scheduler Preferences* screen.

1. From the scan monitor, click the [Patient Scheduler] drawer.
2. From the *Schedule* screen, select a patient.
3. Select Edit Patient from the drop-down menu.
4. Edit the patient information.
5. Click [Save].

2.8 Delete a patient from the schedule

1. From the scan monitor, click the [Patient Scheduler] drawer.
2. From the *Schedule* screen, select patients to be removed.
3. Select [Delete Selected] from the drop-down menu.

   Alternatively, choose one of the following options:

- Select [Delete All] to remove all the patients from the list.
- Click [Delete All Completed] to remove all the completed patients, those marked with ***C***.

4. Click [OK] to confirm.

2.9 Update the patient schedule

To update the patient schedule using the ConnectPro option and *Modality Work List*, follow these steps:

1. From the scan monitor, click the [Patient Scheduler] drawer.
2. From the *Schedule* screen, select [Update].
3. From the *Update Parameters* screen, select one of the following options from the *Get Patient List* to populate the schedule from your HIS/RIS.
   - Select *This System* to pull the patient schedule for the current scanner.
   - Select *All CT Systems* to pull the patient schedule for all of the CT systems on the HIS/RIS connection.
   - Select *All Systems* to pull the patient schedule for all the systems on the HIS/RIS connection.
4. Enter values for the *Date Range*.
5. Enter a Requested Procedure ID, accession number, patient name or ID to narrow the search. These are optional fields.
6. Click [Continue Update] to continue or click [Cancel Update] to exit and make no changes.

2.10 View more patient information on the schedule

Use this feature with the Connect Pro option to view other valuable information about a patient such as allergies, pregnancy status, and medical alerts. This information is pulled from the HIS/RIS using a DICOM connection.

1. From the scan monitor, click the [Patient Scheduler] drawer.
2. From the *Schedule* screen, select a patient.
3. Click the [Info]  icon. The screen is populated from your HIS/RIS.

   If there is a caution for the patient, you will see the [Caution Info] icon  .
4. Click [Cancel] to close the *More Information* screen.

2.11 Set patient scheduler preferences

To set your preferences for the Patient Scheduler for items such as sort order and deletions of completed exams, follow these steps.

1. From the Display monitor, select the Mode icon, then select *Preferences*.
2. Select *Patient Scheduler* on the *Preferences* screen.
3. From the *Patient Scheduler Preferences* screen, complete fields as needed.
   - *Update Schedule Automatically:* If you have Connect Pro, click [Yes] to update the schedule at the update rate selected.
   - *Sort By:* Click the [Date/Time], [Name] , or [ID] sort option.
   - *Show Update Parameters:* If you have Connect Pro, click [Yes] to display the Update Parameters screen every time the system starts to automatically update.
   - *Patient Schedule Record Retention Time*: Set a number of days (0 to 30) to delete exams. Set the value to 0 when the schedule is updated from a HIS/RIS system so that completed exams are not added to the patient schedule. This eliminates the selection of completed accession being selected causing patient reconciliation issues on a PACS system.
   - *Use Study UID*: If you have Connect Pro, click to use a study instance Unique Identifier (UID) from HIS/RIS.
   - *Edit Modality Worklist*: If you have Connect Pro, click to be able to edit any patient information from HIS/RIS.
   - Set *Get Patient List For*.
   - Set *Date Range*.
4. Click [Save].

2.12 Select a patient from the schedule

Use this procedure to select a patient from the Patient Schedule to begin an exam.

1. Click the [Patient Scheduler] icon.
2. From the Patient schedule list, select the desired patient and click [Select Patient].
   - The *Patient Information* screen fields are populated.
     - Multiple records for the same patient can be selected.
     - Multiple records must be selected in order to use Exam Split.
   - If more than one record with the same Patient ID is found in the Patient schedule list a dialog message displays. To avoid having multiple Patient Records with the same Patient ID, set the Delete Completed Exams preference to zero. This will ensure that only new records are in the Patient Schedule list.
3. If a protocol is not tied to the patient, select a protocol. The system displays the first series.
4. Click [Accept]. The system displays the scan series tasks in the protocol.

2.13 Check a patient's status

To check the patient’s status, follow these steps:

1. From the scan monitor, click the [Patient Scheduler] drawer.
2. View the *Status* column.
   - N – New Record or Not Completed
   - C – Completed
3. Click and drag the scroll bar to browse through the list.

Chapter 11 Scan

1 Overview

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

Considerations

- If you encounter a message that you need to remove images to be able to scan the current series, first remove images to create space for scanning.
- In general, if a scan fails and a request to Resume is posted, click [Resume] to continue. Click [Resume] again if the first action fails. If scan still fails to restart, shutdown and Restart the system.

2 Scan Theory

2.1 Dose Deterministic Effects

There is the possibility that in normal use, the patient could be exposed to radiation dose levels of 1Gy $CTDI_{100\ (peripheral)}$ or above, at which deterministic effects may occur. Management of the high radiation dose is critical to maintain radiation safety. The available scan settings concerning radiation dose, air kerma, air kerma rate, radiation quality, and image quality include: mA, kV, scan time, detector coverage, and SFOV.

The table below provides the scan duration in seconds required to meet 1Gy $CTDI_{100\ (peripheral)}$ at 200 mA exposure at same scan location. This table assumes 200 mA and provides scan time as a practical example for an average patient. The product of the scan time shown and 200 mA yields the mAs required to result in deterministic effects. Note that for each kV / Aperture / SFOV combination in the table, any mA and scan time combination that meets or exceeds the equivalent mAs of this table can also result in deterministic effects of radiation. For obese patients, the mA may be larger than the practical example shown in the table, and the resulting mAs should be used to determine the exposure to the patient.

Table 1: Dose Deterministic Effects

Duration of Axial scan(s) at 200 mA required to meet 1Gy $CTDI_{100\ Peripheral}$																
SFOV		Small Head			Head			Small Body Cardiac Small			Medium Body Cardiac Medium			Large Body Cardiac Large		
CTDI100 (mGy)		25.815			30.05			14.33			16.965			16.07		
CTDI Phantom		16cm			16cm			32cm			32cm			32cm		
Focal Spot		XL	L	S	XL	L	S	XL	L	S	XL	L	S	XL	L	S
70	160	NA	175.4	173.6	NA	146.0	144.4	NA	291.0	285.8	NA	239.5	237.3	NA	290.8	288.1
	120	NA	183.1	181.1	NA	152.4	150.7	NA	320.4	314.1	NA	258.9	253.7	NA	311.1	308.1
	80	NA	185.1	181.5	NA	152.4	154.1	NA	344.8	344.8	NA	278.6	281.6	NA	338.2	341.9
	40	NA	168.4	168.4	NA	138.7	138.7	NA	317.2	317.2	NA	256.3	256.3	NA	311.1	311.1
	5	NA	109.4	118.6	NA	90.6	98.3	NA	204.6	221.8	NA	165.3	179.2	NA	200.7	217.6
80	160	NA	115.3	114.1	NA	100.1	99.0	NA	188.3	184.9	NA	157.4	155.9	NA	181.7	180.1
	120	NA	120.3	119.0	NA	104.5	103.3	NA	207.3	203.2	NA	170.1	166.7	NA	194.5	192.5
	80	NA	121.6	121.6	NA	104.5	105.6	NA	223.1	223.1	NA	183.1	185.1	NA	211.4	213.7
	40	NA	110.7	110.7	NA	95.1	95.1	NA	205.2	205.2	NA	168.4	168.4	NA	194.5	194.5
	5	NA	71.9	77.9	NA	62.1	67.4	NA	132.4	143.5	NA	108.7	117.8	NA	125.5	136.0
100	160	NA	63.0	62.4	NA	53.9	53.3	NA	101.6	99.8	NA	86.1	85.3	NA	93.8	92.9
	120	NA	65.8	65.1	NA	56.3	55.6	NA	111.9	109.7	NA	93.0	91.2	NA	100.4	99.4
	80	NA	66.5	66.5	NA	56.3	56.9	NA	120.4	120.4	NA	100.1	101.2	NA	109.1	110.3
	40	NA	60.5	60.5	NA	51.2	51.2	NA	110.8	110.8	NA	92.1	92.1	NA	100.4	100.4
	5	NA	39.3	42.6	NA	33.5	36.3	NA	71.5	77.5	NA	59.4	64.4	NA	64.8	70.2
120	160	39.9	40.4	39.9	34.3	35.0	34.7	64.0	64.0	62.9	54.1	55.1	54.6	57.1	58.2	57.6

Duration of Axial scan(s) at 200 mA required to meet 1Gy $CTDI_{100\ Peripheral}$															
SFOV		Small Head			Head			Small Body Cardiac Small			Medium Body Cardiac Medium			Large Body Cardiac Large		
CTDI100 (mGy)		25.815			30.05			14.33			16.965			16.07		
CTDI Phantom		16cm			16cm			32cm			32cm			32cm		
Focal Spot		XL	L	S	XL	L	S	XL	L	S	XL	L	S	XL	L	S
	120	41.7	42.1	41.7	36.2	36.6	36.2	69.8	70.5	69.1	58.9	59.5	58.4	62.2	62.2	61.6
	80	42.6	42.6	42.6	36.6	36.6	37.0	75.9	75.9	75.1	64.1	64.1	64.8	67.6	67.6	68.4
	40	38.7	38.7	38.7	33.3	33.3	33.3	69.8	69.8	69.8	58.9	58.9	58.9	62.2	62.2	62.2
	5	24.1	25.2	27.3	20.7	21.8	23.6	44.7	45.0	48.8	37.5	38.0	41.2	39.9	40.1	43.5
140	160	28.5	28.8	28.5	24.5	25.0	24.8	45.7	45.7	44.9	38.4	39.1	38.7	39.6	40.4	40.0
	120	29.8	30.1	29.8	25.8	26.1	25.8	49.8	50.3	49.4	41.8	42.2	41.4	43.2	43.2	42.8
	80	30.4	30.4	30.4	26.1	26.1	26.4	54.2	54.2	54.2	45.4	45.4	45.9	47.0	47.0	47.5
	40	27.7	27.7	27.7	23.8	23.8	23.8	49.8	49.8	49.8	41.8	41.8	41.8	43.2	43.2	43.2
	5	17.2	18.0	19.5	14.8	15.5	16.9	32.0	32.2	34.9	26.6	27.0	29.2	27.7	27.9	30.2

2.2 CT Perfusion

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

NOTE: Refer to the accompanying documents.
See the Discovery CT870 Technical Reference Manual, Dose and Performance chapter for information on dose measurements and calculations.

2.2.1 Purpose of CT Perfusion

CT perfusion studies are used to assess delivery and perfusion of blood in an organ and/or its tissues. Such studies are valuable for evaluating blood supply to neoplastic and non-neoplastic tissue (including normal and ischemic tissue). In particular, CT perfusion imaging allows the evaluation of cerebral ischemia or of the extent of angiogenesis associated with a tumor. CT perfusion should be performed only for a valid medical reason and with the minimum radiation dose necessary to achieve an adequate exam. Use of perfusion scans in children should be particularly reviewed for clinical impact and justified. Pediatric patients are more radiosensitive than adults and have a longer post-exam life expectancy, so particular attention should be paid to displayed CTDIvol when modifying protocols.

CT perfusion imaging relies on the linear relationship between CT attenuation, expressed in Hounsfield Unit (HU) and represented in a particular pixel of an image, versus the amount of iodinated contrast material perfusing the corresponding region of tissue attenuating the X-rays. Dynamic CT scanning enables the calculation of perfusion parameter maps, e.g., anatomic images where the pixel value represents mean transit time, blood flow, blood volume, and permeability maps depending upon the post-processing model used.

Scan technique parameters (e.g., kV, mAs) for CT perfusion studies should be set at values lower than those used for routine diagnostic scanning of the same anatomical area. Perfusion imaging involves visualization of temporal changes in iodine enhancement, rather than resolution of small or subtle anatomical detail. The post-scan software processing of the data is relatively insensitive to the increased noise levels; hence perfusion scans do not require use of the same radiation levels. In general, lower kV improves visualization of iodine contrast and consequently allows use of lower radiation doses. Lower kV settings are therefore recommended to be used as long as sufficient image quality for perfusion post-processing can be obtained. Body perfusion imaging of obese patients, for example, may be an application that requires use of higher kV values. Users should carefully review the manufacturer's reference perfusion protocols, which reflect the recommended kV, mA, and scan time for a typical perfusion acquisition. Additional guidance may be obtained from professional societies, regulatory agencies, educational textbooks, or peerreviewed literature. The AAPM provides a set of reasonable scan protocols for CT brain perfusion imaging that is freely available via its public webpage. See the recommended readings.

Because CT perfusion requires specialized post-processing software, a CT perfusion acquisition should not be performed unless this software is readily available to the institution. All users should be trained in both CT perfusion acquisitions and post-processing and should follow professional society perfusion practice guidelines. Before any changes are made to the manufacturer's reference protocols, both a radiologist and medical physicist familiar with CT perfusion should be

consulted. Changes in protocol and the reason for the changes should be communicated to the radiologic technologist. Any changes to the protocols should be evaluated with respect to the image quality (less than diagnostic level), temporal sampling and radiation dose of the manufacturer's original reference perfusion protocols. It is essential that all users understand that CT perfusion images will be much noisier than images of the same body region acquired for most other diagnostic purposes, and that this level of image quality is sufficient for the calculation of perfusion parameters.

2.2.2 Components of a CT Perfusion Study

Assessment of tissue perfusion for stroke includes a diagnostic quality non-contrast brain exam, an optional CT angiogram of the circle of Willis that may include the carotid arteries, and a CT perfusion exam. It may also include apost-contrast CT scan of the brain for assessment of residual lesion enhancement. In the assessment of tumors, a noncontrast scan for localization of the area of interest is often done prior to the CT perfusion exam.

In all cases, the CT perfusion exam should have technique factors that are lower than those used for the other components of the study (e.g., the non-contrast, post-contrast, and angiogram scans). Specific acquisition times for the perfusion exam depend on the post-processing algorithm used, but in all cases the exam must be performed over a relatively long period of time (typically 40 to 50 seconds and potentially up to 3 minutes; consult model-specific user manual and radiologist) in order to measure the time dependent physiologic process of blood flow through the brain. Since the scan location is fixed, the same anatomy is irradiated repeatedly during this scan time. Scan times are also affected by the concentration, volume, and rate of delivery of the contrast agent.

The lenses of the eyes are more radiosensitive than the skin. Scanning through the orbits should be avoided, if possible, by the use of patient positioning. Consult the medical physicist to ascertain appropriate deterministic thresholds across the body.

2.2.2.1 Body perfusion considerations

Perfusion scanning of the torso, typically referred to as body perfusion CT, is not currently performed as frequently as head perfusion scans. It is essential to refer to manufacturers' reference protocols (if provided) and to involve a radiologist and medical physicist familiar with the principles and techniques for body CT perfusion imaging, as well as communicate with the radiologic technologist. Because of the higher attenuation of the torso, body perfusion scans may require a higher kV than head perfusion scanning. Again, the image quality obtained should be noisier than most conventional body CT scans, as the post-processing algorithm is able to extract the needed time attenuation information from the noisy data set. Respiratory motion is an important consideration in body perfusion CT, and methods to limit diaphragmatic motion during the scan, or realign anatomic regions after the scan using registration algorithms should be used to minimize errors introduced from the movement of the tissue of interest during the course of the perfusion scan. In the rare event that a body perfusion scan would be performed in a pediatric patient, sedation in small children may be required.

2.2.2.2 Perfusion acquisition types

Some perfusion scans are performed in a continuous exposure mode, in which the table does not move and the X-rays are turned on over the entire scan period. This provides the highest degree of temporal sampling; however, such temporal sampling may not be required for a particular

application. This acquisition mode delivers the highest dose to the patient, since the X-ray beam is always on.

Other techniques and recommended protocols may include a mode where the table does not move but the X-rays are alternately turned on intermittently during the scan (such as Axial with an ISD). This method can be used to reduce the dose if the temporal sampling rate remains adequate for the post processing software which requires a minimum temporal sampling of 3.2 seconds.

Other types of data acquisitions are axial and helical “shuttle modes”, which are specially designed for perfusion scanning and can extend the coverage of tissue imaged, thus dispersing the dose over a wider area and decreasing peak skin dose. In both cases the temporal sampling rate is reduced for any specific anatomic location compared with continuous and intermittent exposure modes where the table remains stationary. The user must ensure that the sampling frequency remains adequate for the post-processing software, which requires a minimum temporal sampling of 3.2 seconds.

The temporal sampling rate varies based on the scan type selected for the acquisition and can affect the total dose for the acquisition. lists the scan types that can be used for acquisition of perfusion data.

Table 2: Perfusion data acquisition scan types

Scan Type	Coverage	Temporal Sampling Rate	Acquisition/Dose considera-tions
Axial	40, 80, 120, 160 mm	2.0 s	Limited coverage Lower dose due to intermittent scanning

Communication of should be conveyed by the facility to the radiologist, qualified medical physicist and radiologic technologist.

The exam duration for tumor perfusion, whether in the head or body, needs to extend over a longer time interval than a general perfusion scan, starting prior to the arrival of the contrast bolus and include a period of approximately 3 to 3.5 minutes to adequately support the collection of data for the computation of permeability maps. Initially, the temporal sampling rate must be the same as that used for stroke protocols in order to adequately measure the first passage of contrast material through the region. Subsequently, sparser sampling can occur, with temporal intervals ranging from 5 to 20 seconds. This reduces dose by decreasing the number of exposures.

2.2.2.3 Scan parameter effects on dose

2.2.2.3.1 kV effects on dose

The effect on dose from kV is non-linear. Holding all other parameters constant, changing from 80 kV to 120 kV will result in approximately a two- to four-fold increase in dose.

NOTICE

Attention: consult accompanying documents.
See the Discovery CT870 Technical Reference Manual for more details.

2.2.2.3.2 mA effects on dose

mA and mAs have a linear effect on dose. Holding all other parameters constant, doubling the mA or mAs will double the dose.

NOTE: The effects of kV and mA or mAs on dose are multiplicative. For example, a three-fold increase in dose that occurs from increasing kV combined with a two-fold increase in dose from doubling the mA will result in a six-fold increase in overall dose.

2.2.2.4 Considerations for peak skin dose

The highest radiation dose accruing acutely at a single site on a patient's skin, referred to as the "peak skin dose," is an important parameter in assessing risk of erythema (skin reddening) and epilation (hair loss). The necessity for repeated scanning of the same location over extended times results in skin doses that can be higher than those associated with routine CT applications. Factors that influence these doses include kV, mA, scan time, perfusion acquisition type, and table movement, if any, during the perfusion acquisitions. As with patient dose, lower kV settings are recommended and should be used as appropriate to achieve appropriate image quality for perfusion evaluation with respect to image noise based on body size, region scanned, and scanner type. In all cases, you should refer to the manufacturers' reference perfusion protocols as they reflect the appropriate kV, mA, and scan times for typical perfusion acquisitions. Additional guidance may be found at professional society and/or regulatory websites. See the recommended readings.

2.2.2.5 Required image attributes for perfusion imaging

The purpose of a CT perfusion series is to assess tissue perfusion and delivery of blood to the organ and/or tissues of the organ; the acquisition parameters are different from those needed for routine low contrast CT imaging applications. The acceptable noise level in CT perfusion is typically higher than that for acquisitions routinely used in diagnostic imaging. Automatic exposure control should not be used unless the manufacturer's reference perfusion protocol employs it. Protocols should be adjusted accordingly for patient age, injection rate, injection volume, and exam type (stroke versus tumor evaluation and head versus body).

CT perfusion scans need to acquire data over a sufficiently long duration to accommodate the transit time associated with the physiological process of the contrast bolus moving through the vascular system. The acquisition duration for a stroke study must cover the time from prior to the arrival of the contrast material bolus through the approach of the venous signal to baseline. This duration is directly dependent on the volume of contrast material injected, the rate of injection, and the patient's cardiac output. If contrast material volumes or injection rates change from exam to exam, the scan duration will need to be adjusted accordingly. Consult the perfusion post-processing software manual for more detailed imaging and CT perfusion information.

2.2.2.6 Contrast injection considerations

As the iodine concentration of contrast material decreases, contrast material volume or flow rate may need to be adjusted to deliver the required enhancement. You should pay close attention to the shape of the bolus, follow the bolus with saline, and use an injector capable of delivering the required injection rates.

The contrast injection rate should be determined by referring to the applicable section of this user manual, contrast agent labeling, and in consultation with a physician. Special consideration should be given for children due to their smaller size.

2.2.2.7 Other considerations and references

Due to the necessity to obtain data over an extended time period in order to calculate relevant perfusion parameters, repeated scanning of the same location is required. As a result, CT perfusion acquisitions produce peak skin doses higher than those associated with routine diagnostic CT imaging. Deterministic effects (e.g., tissue reactions such as skin reddening and hair loss) are a dose-threshold phenomena that can appear with peak skin doses > 2 Gy. As with all CT scanning, the $CTDI_{vol}$ value displayed on the operator console should always be confirmed prior to the scan. For CT perfusion without table motion, the value of $CTDI_{vol}$ tends to over estimate the actual peak skin dose by approximately a factor of two (see reference to Bauhs below). User manuals may contain an informative section that describes means for conversion of the displayed $CTDI_{vol}$ or dose profile to an estimated phantom peripheral dose, which may serve as an estimate for peak skin dose. A typical CT perfusion study should not result in a console-displayed $CTDI_{vol}$ of more than 1,000 mGy. Care should be taken and consideration given prior to rescanning a patient within a short time with a perfusion acquisition for the same anatomy due to concerns about reaching a cumulative peak skin dose value greater than the deterministic threshold for skin injury.

Sites should have a Quality Assurance (QA) program for oversight and review of any protocol changes. As with other scan types, the $CTDI_{vol}$ for a CT perfusion acquisition is recorded in both the DICOM screen capture and the DICOM CT dose structured report and should be used for QA follow up for all scanning.

Additional information on CT perfusion may be obtained in the user manuals for the CT perfusion post-processing software, from the ACR practice guide for CT perfusion, and from the AAPM website that contains reference perfusion protocols as well as other perfusion related information (please visit FDA Web site for documents related to radiation dose quality assurance).

All the reference protocols provided within the software of this system, including those for CT perfusion, are included in the Applications Protocol document supplied with the system. This document provides a concise description of each scanning series within the protocol, technique factors, and dose information for each.

2.2.2.8 Recommended reading

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7. Nabavi, DG, A Cenic, RA Craen, AW Gelb, JD Bennet, R Kozak, and T Lee. 1999. “CT assessment of cerebral perfusion: Experimental validation and initial clinical experience”, Radiology 213 : 141-149.
8. J. A. Bauhs, T. J. Vrieze, A. N. Primak, M. R. Bruesewitz, and C. H. McCollough, 2008, "CT dosimetry: comparison of measurement techniques and devices," Radiographics Vol. 28, pp. 245-253.
9. ACR-ASNR-SPR Practice Guideline for the Performance of Computed Tomography (CT) Perfusion in Neuroradiologic Imaging at American College of Radiology website
10. AAPM CT Scan Protocols website

2.3 Total Exposure Time

The Total Exposure Time is automatically set by the system and is determined by the number of images and type of scan. This setting can only be changed by resetting one of the other factors. The Total Exposure Time is useful for determining breath hold times and contrast injection timing.

- For helical scans, the displayed Total Exposure Time is exactly what is shown. The Total Exposure Time lists the X-ray on time only and does not reflect any ISD applied.
- For axial scans, when calculating breath hold times, the ISD for each scan must be added to the Exposure Time displayed to reflect the total amount of time the patient would need to hold his/her breath.

2.4 Automatic Exposure Control

Patients come in all shapes and sizes. For the purpose of achieving a desirable image quality with a scan technique that reflects the patient's size and shape, there are several approaches to employing automatic and manual mA setting modes of CT operation. These approaches are designed to adjust the X-ray output of the system according to the X-ray attenuation presented by a patient's anatomy. For example, the patient's weight or Body Mass Index (BMI) may be used as a guide to set a fixed mAs for the acquisition. Alternatively, some measure of patient thickness or girth, such as anterior-posterior (AP) thickness, lateral width, or patient circumference can be used as a basis to choose an appropriate fixed mAs value, i.e., a value that yields an image adequate for diagnosis with a patient dose as low as reasonably achievable. However, these methods have at least two inherent limitations. First, as they produce a fixed mAs value, they do not adjust for differences in body-region thickness and associated variation in X-ray attenuation along the patient length and/or around the patient circumference. Second, the use of weight, thickness or circumference is an incomplete surrogate for X-ray attenuation, which is one of the most relevant physical parameters affecting image quality and which depends on the elemental composition and density of human tissue as well as on its shape and thickness.

Automatic Exposure Control (AEC), on the other hand, is designed to adjust the scanner radiation output to meet a desired, pre-set level of image quality/noise criterion by empirically assessing the patient's attenuation and automatically modulating the mA accordingly. AEC can provide a desired level of image quality/noise at a lower patient dose than would be possible with a fixed scanner radiation output. In general, CT systems may accomplish AEC in two ways:

1. Modulating the mA dynamically during scanning in the X-Y and/or Z dimensions to adapt to variations in the patient's attenuation.
2. Adjusting the mAs to a fixed value based on measurement and calculation of the patient's overall attenuation: the mAs is constant during scanning, but its value has been quantitatively determined so as to yield an average pre-set level of image noise.

Most AEC systems operate as described in list item number 1 above. Discussion of AEC, hereafter, applies to these types of systems unless otherwise indicated.

2.4.1 How AEC works

On the basis of a patient's attenuation, AEC sets mA values as the X-ray tube rotates around the patient. The technology uses knowledge about the scanner's imaging chain and the measured attenuation of the patient to appropriately adjust mA values in order to achieve the desired, constant image noise/quality criterion.

Larger patients typically require scanning at a higher mAs than the mAs used for smaller patients. Similarly, thicker projections (e.g., laterally through the shoulders versus AP through the shoulders) typically require more mAs to achieve the same resultant image noise/quality criterion. Finally, anatomy with greater attenuation (e.g., abdomen or pelvis compared to the lungs) requires more mAs to achieve the same image noise/quality criterion.

2.4.2 Adaptation to anatomy

As patient attenuation changes throughout the course of the scan, either rotationally around the patient or along the length of the patient, AEC is designed to adjust dynamically the mA for each

body part and projection. If the attenuation does not change, AEC sets the mA at a constant value that is appropriate for the overall patient thickness and that achieves the desired image noise/quality criterion.

2.4.3 When to use AEC

AEC technology has the greatest impact when the portion of the patient being scanned has non-uniform size, shape, or density. In these cases, AEC adjusts scanner radiation output to the changing anatomy and modulates the mA in the Z-direction (along the patient) and/or in the XY-direction (around the patient). Even though AEC is used, before scanning the operator must still select scan parameters, including AEC parameters, which provide a desired image noise/quality criterion. Scan parameters including AEC parameters must be chosen to carefully balance patient radiation dose and image performance.

Even when the patient's anatomy has consistent size, shape, and density throughout the planned scan range, AEC technology chooses the appropriate exposure settings to achieve the image noise/quality criterion requested by the user.

When bismuth or other shields are considered for use in the planned scanned range, consult the system user manual for specific information.

2.4.4 When not to use AEC

AEC might not be available for all scanning modes or on all scanners. When AEC is available, if users do not understand the relationship between AEC parameters, image noise, and dose, AEC should not be used. Also, if the patient cannot be centered in the scanner, AEC is not recommended because the attenuation calculations used for AEC are designed with the assumption that the patient is centered in the gantry. Finally, if there is any question, radiologic technologists should always consult their medical physicist and radiologist to ensure that proper exposure techniques are used.

2.4.5 AEC does not guarantee reduction of radiation doses in all patients

The use of AEC does not always result in dose reduction, especially when compared to a fixed mA/mAs protocol. For example, when providing the desired image noise/quality criterion setting for a large patient, AEC might appropriately increase the scanner radiation output as compared to that for an average-sized patient. For most examinations of average-sized or small patients, and for the same image noise/quality criterion settings, AEC use will result in the same or lower $CTDI_{vol}$ as that of a fixed mA/mAs protocol. (However, a larger patient would appropriately require more fixed mA than for a smaller patient.)

NOTE: Radiologic technologists must be fully aware that proper patient centering is critical for accurate AEC function. Improper patient centering can result in an exposure that is either too high or too low to achieve the desired image noise/quality criterion. Note that proper patient centering can be more challenging for smaller pediatric patients, and so special care should be taken.

2.4.6 Effect of AEC control setting

For a given patient, changing the image noise/quality criterion setting in AEC will affect the patient dose: asking for lower image noise/higher image quality criterion will result in more dose to the

patient as the Noise Index value is decreased (made smaller). In contrast, asking for higher image noise/lower image quality criterion by increasing (make larger) the Noise Index value will result in less dose to the patient.

2.4.7 AEC considerations of patient size, shape, composition, and age

For a given AEC image noise/quality criterion setting, larger patients and more attenuating body regions may result in a higher scanner radiation output. Smaller patients and less attenuating body regions may result in a lower scanner radiation output.

While AEC can be an effective dose-reduction tool for pediatric patients, special care should be taken with this patient group. The GE Healthcare online education module available on the Image Gently website describes issues to consider when using our AEC features with pediatric patients.

2.4.8 Dynamic AEC scanning

When a scanning protocol contains multiple X-ray tube rotations at the same table location, the effect on patient dose of incorrect selection of protocol settings will be multiplied by the number of rotations. For such protocols, operators must take extra care when setting manual mAs or AEC parameters to achieve the desired level of image noise/quality criterion. For example, in perfusion scanning, the image noise can often be much higher (yielding a lower dose) than for routine diagnostic scanning of the same region because the primary application of perfusion scan data is for quantitative analysis and characterization of perfusion parameters rather than for diagnostic visualization. The manufacturer's reference protocol provides an indication as to whether use of AEC is or is not recommended with these scan modes.

2.4.9 How to tell if the dose has changed

For every patient, and any time AEC settings are changed, in order to confirm a correct level of scanner radiation output for that patient's size and exam protocol, users should examine the predicted $CTDI_{vol}$ and DLP displayed prior to performing the scan, as a step in operator confirmation of system settings. When a large patient is scanned at a particular setting of image noise/quality criterion, the $CTDI_{vol}$ and DLP will be higher than for a smaller patient at the same AEC settings. Predicted $CTDI_{vol}$ and DLP values are displayed on the scanner's dose display on the user interface prior to confirmation of settings for scanning. After scanning, the values are updated to reflect the average of the actual mAs values used in the scan and are displayed on the user interface as well as recorded in the DICOM secondary screen capture and DICOM radiation dose structured reports.

2.4.10 Summary

AEC is a versatile and powerful tool designed to tailor the scanner's radiation output to each patient based on the patient's size, age, shape and attenuation and the user's requested level of image noise/quality criterion. AEC technology uses measured patient attenuation values to adjust the mA dynamically in order to achieve the requested level of image noise/quality criterion. However, AEC settings must be chosen with the same care used to choose all other parameters that affect radiation dose to the patient. Before the scan parameters are confirmed, careful attention must be paid to $CTDI_{vol}$ and DLP displayed on the user interface; scanner radiation output associated with the prescribed protocol must be checked and confirmed prior to scanning. Used properly, AEC is a key technology to help ensure that the appropriate radiation dose is used for every patient.

2.4.11 AEC Messaging

User notification messages will be seen in *Scan Settings* and in Protocol Management when the scan mode is changed from or to an Automatic Exposure Control mode. Messages will be seen for the following changes:

- From Manual mA to AutomA/SmartmA mode
- From AutomA/SmartmA to Manual mA mode
- From Manual mA or AutomA/SmartmA to Cardiac Modulation mA mode
- From Cardiac Modulation mA to Manual mA or AutomA/SmartmA mode
- From Manual kV to kV Assist mode
- From kV Assist to Manual kV mode
- From ODM to Manual mA mode
- From ODM to SmartmA or AutomA mode
- From ODM to Cardiac Modulation mA mode

2.5 Slice Thickness Reference Noise Index and Noise Index Values

The Noise Index (NI) is a parameter that corresponds to the relative noise in the image. A higher Noise Index means the images will contain more noise and will be obtained with lower mA and/or kV, and therefore lower dose. A lower Noise Index means the images will contain less noise and will be obtained with higher mA and/or kV, and therefore higher dose.

The Noise Index is the operator input parameter for AutomA that controls the X-ray output within the bounds established by the operator settings for minimum and maximum mA. Any value between 1 and the maximum Noise Index value can be entered for the Noise Index when building a protocol.

For the GE reference protocols that use AutomA, the Noise Index is based on the slice thickness defined in the protocol. If the slice thickness defined in the protocol is 5 mm and is changed to 0.625 mm, the Noise Index will adjust according to the equation in Section 2.6.1.4, AutomA FAQs.

If AutomA is enabled for a manual mA GE reference protocol or user defined protocol, the Noise Index will be populated based on the slice thickness defined in the protocol, and the protocol category (anatomical area). If the slice thickness is changed from the original value of 0.625 mm to a slice thickness of 5 mm, the Noise Index will change. For example, a protocol with NI = 7 for 0.625 mm slice thickness gives approximately the same dose as NI = 2.47 for 5 mm slice thickness. The Noise Index should always be reviewed and adjusted as needed by the user to match the clinical image quality needed for the specific examination.

For procedures where lower mA and higher noise may be appropriate you should ensure that the Noise Index value is adjusted. For example, if a GE reference protocol or a user-defined protocol is selected and altered by enabling AutomA (not recommended by GE for brain perfusion). The Noise Index used in the Automatic Exposure Control calculation to define the x-ray output should be updated to match the individual exam type and clinical need.

The Noise Index, which is updated when the slice thickness is changed, affects X-ray output (dose). The Noise Index should always be reviewed and modified, if needed, to meet the clinical need, taking into consideration the user preference for image quality. Only the Min mA, Max mA, Noise Index, kV and patient attenutation affect machine mA output (dose) when using AutomA/ SmartmA.

The higher the Noise Index value, the lower the overall mA that is required. Resulting images are noisier with lower mA values. The lower the Noise Index value, the higher the overall mA that is required. Resulting images have less noise.

2.6 AutomA/SmartmA/ODM

2.6.1 AutomA

2.6.1.1 AutomA background

A significant factor in the quality of a CT image is the amount of X-ray quantum noise contained in the scan data used to reconstruct the image. Most technologists know how the choices of X-ray scan technique factors affect image noise. Noise decreases approximately inversely with kV and noise decreases with the inverse square root of the mAs and slice thickness. For example, increasing the mA from 50 to 200 (a factor of 4) will decrease quantum noise by a factor of 2 (the square root of 4). Quantum noise also increases with increasing helical pitch; however, the exact relationship is dependent on the details of the helical reconstruction process.

The most significant factor that influences the quantum noise in the scan data is the X-ray attenuation of the patient section being scanned. The X-ray attenuation is related to the size and tissue composition of the patient.

Illustration 1: Example small patient (120 kVp, 1.25 mm, 0.5 s axial) with factor of 5 noise increase (simulated): 1 = SD 8 @ 640 mA, 2 = SD 40 @ 25 mA

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For a given fixed scan technique, the quantum noise varies by about a factor of 5 from the smallest to the largest patients attenuation. Illustration 1 shows an example of a five times noise increase simulated for a small patient. With a fixed mA scan protocol, the technologist must select the mA using a qualitative estimate of the patient attenuation. This may be accomplished using the patient's weight, diameter measurements, body mass index, or with qualitative visual classification. Because these methods provide very rough X-ray attenuation estimates and do not account for attenuation changes within the patient region being scanned, the technologist must use a high enough technique margin to avoid the possibility of compromising the diagnostic quality of the images. Since dose is inversely related to the square of the noise, many patients are likely to be receiving more dose than necessary for the required diagnostic quality using such manual methods.

GE's AutomA and SmartmA features form part of a suite of Automatic Exposure Control (AEC) features that enable substantial patient dose reduction, while maintaining diagnostically acceptable image quality. Specifically, AutomA is an automatic tube current modulation feature that can make necessary mA adjustments much more accurately than those estimated for the

patient, and thereby can obtain a more consistent desired image noise in spite of the wide range of patient size. Since image noise variability is substantially reduced, a significant overall patient dose reduction is possible with proper scan parameter selection.

AutomA, or mA modulation in the patient z-axis, adjusts the tube current in the z-axis to maintain a user selected quantum noise level in the image data. It regulates the noise in the final image to a level desired by the user. AutomA is the CT equivalent of the auto exposure control systems employed for many years in conventional X-ray systems. The goal of AutomA is to make all images contain similar X-ray quantum noise independent of patient size and anatomy.

The AutomA tube current modulation is determined from the attenuation and shape of scout scan projections of the patient acquired just prior to CT exam sequence.

SmartmA, or mA modulation as a function of the X-ray tube rotation angle, has a different, but related objective to AutomA. SmartmA adjusts the tube current to minimize X-rays over angles that have less importance in reducing the overall image noise content. In anatomy that is highly asymmetric, such as the shoulders, X-rays are significantly less attenuated in the anterior-posterior (AP) direction than in the lateral direction. Thus, the overwhelming abundance of AP X-rays can be substantially reduced without a significant effect on overall image noise.

Angular modulation was first introduced on GE single slice scanners in 1994.[1,2]

2.6.1.2 AutomA theory

AutomA is an Automatic Exposure Control system that employs Z axis tube current modulation and is available on all GE Multislice CT scanners. A Noise Index parameter allows the user to indicate the level, or a so-called index of X-ray noise that will be present in the reconstructed images. Using a single patient scout exposure, the CT system computes the required mA to be used based on the selected Noise Index setting and the attenuation of the patient being scanned. The Noise Index value will approximately equal the standard deviation in the central region of the image when a uniform phantom (with the patient's attenuation characteristics) is scanned and reconstructed using the standard reconstruction algorithm.

Illustration 2: Example noise variation with fixed mA and mA variation with AutomA and a Noise Index setting

Number	Description
1	6.5 HU to 10.5 HU Noise variation in Z with 500 mA
2	Medium to small patient,120 kv, 5 mm, 0.5 seconds
3	AutomA profile in Z for 12.5 Noise Index, AutomA, SmartmA

The system determines the tube current using the patient's scout projection data and a set of empirically determined noise prediction coefficients. The scout projections contain density, size, and shape information as a function of the patient habitus in the z-direction. The total projection attenuation (projection area) contains the patient density and size information, while patient shape information, i.e. oval ratio, an estimate of the eccentricity of the patient habitus as a function of z, is contained within amplitude and width information derived from the scout projection data. These patient characteristics determine how much X-ray will reach the detector for a specified technique and hence predict the image standard deviation due to X-ray noise for the standard reconstruction algorithm.

To predict the image noise at a given z-position, the projection area and oval ratio are obtained from the patient's scout. The expected X-ray noise for the reference technique (reference noise)

is then derived as a function of the projection area and oval ratio from the scout using polynomial coefficients that were determined by a least squares fit of the noise measurements from a set of phantoms representing a clinical range of patient sizes and shapes.

Knowing the reference noise and the difference between the reference technique and the user selected prescribed technique, the mA required to obtain the prescribed Noise Index is calculated using well known X-ray physics equations. That is, the noise is inversely related to the square root of the number of photons and the number of photons is proportional to the slice thickness, slice acquisition time, and mA. In the GE AutomA design, adjustment factors for helical pitches are also incorporated in the calculation to account for noise differences that scale between helical selections and the axial reference technique.

2.6.1.3 References

[1] L. Kopka and M. Funke, "Automatically adapted CT tube current: Dose reduction and image quality in phantom and patient studies," Radiology 197 (P), 292 (1995)

[2] D. R. Jacobson, W. D. Foley, S. Metz, and A. L. Peterswen, "Variable milliampere CT: Effect on noise and low contrast detectability," Radiology 210(P), 326 (1996)

2.6.1.4 AutomA FAQs

What suggestions do you have for a new AutomA user?

- If you are not familiar with the concept of Noise Index, you can use the GE reference protocols that have AEC enabled. As a general starting point, use the standard deviation from an acceptable image for approximation of a Noise Index, or consult the literature until you find the highest Noise Index value that provides acceptable diagnostic quality. Experiment by scanning some phantoms with different Noise Index values to gain some confidence. A 30 cm diameter water phantom or a 35 cm diameter low density polyethylene phantom have an attenuation similar to the average adult abdominal patient.
- It is important to review the image quality that is obtained with the prescribed Noise Index to optimize the user's maximum and minimum mA range and Noise Index values accordingly. The maximum mA value set by the user sets the maximum allowed mA, or clipping mA value.
- You should also check the mA table on the scan set up screen to see what mA is actually being used. If you see that it is frequently at the maximum mA range, and you have determined that you require lower noise in your images than you are currently obtaining, consider increasing the Noise Index if more noise can be tolerated in your reconstructed images without compromising the diagnostic value, or increase the maximum mA limit if it is not at the maximum limit of the X-ray generator.
- If you normally reconstruct images with thin sections for 3D reformatting and thicker slices for axial viewing it is important to understand that the first prospective reconstructed slice thickness is used for calculating AutomA. Generally you would want to set the Noise Index for the thicker slice images. For example, you might want a Noise Index of 10.0 for 5 mm thick images for viewing but you may also want 0.625 mm slices for 3D reformatting. If you prescribe the 0.625 mm slice recon first, followed by the 5 mm recon, AutomA will calculate the mA needed to obtain an image noise of 10 for the 0.625 mm slices since it is prescribed first. In this case, to avoid excessively high mA and high dose, you need to readjust the Noise Index

using the following approximation. Please note that the following equation is to be used as a starting point, with the actual Noise Index for thin slices likely to vary from the exact solution given by this equation:

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Example:

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Why is the standard deviation I measure in the image different than the Noise Index I selected for the scan?

- There are many factors that can account for this. But, first consider that the prescribed Noise Index causes the tube current to be adjusted so that the system projects a similar X-ray intensity through the patient to the detector. Hence it regulates the X-ray noise or quantum noise in the scan projection data. The noise in the image depends on additional factors within the image reconstruction chain, including, but not limited to, the selection of reconstruction algorithms, reconstructed slice thickness selection (if different than your prospective selection), and the use of image space filters. In addition, it is very difficult to make standard deviation measurements on patient data since the standard deviation is affected by small CT number variations of the heterogeneous anatomy and by patient motion or beam hardening artifacts. Even with uniform phantoms, standard deviation measurements will produce some variability in measured results because of the inherent nature of quantum statistics.
- Another situation that can cause significant differences between the selected Noise Index and the image standard deviation is when very large patients provide insufficient detector signal. In these cases, electronic noise sources can become the dominant image noise source instead of X-ray noise. In these cases at various threshold levels, special projection data dependent filters begin to be applied to help preserve image quality. These filters on the projection data affect the noise properties of the reconstructed image. The highest kV is recommended when excessively large patients need to be scanned.
- Another factor is how well the patient is centered in the SFOV. Image noise can increase significantly if the patient is mis-centered. This occurs because the bowtie filter projects maximum X-rays intensity at isocenter since this is the region of maximum attenuation if the patient is centered. If the patient is mis-centered, there are fewer X-rays projected to the thickest part of the patient, and hence image noise will increase. The optimum strategy is to find the highest Noise Index sufficient for the clinical task and let AutomA select the mA without using significant constraints.

Will I get a dose reduction when I use AEC?

AutomA will use a patient exposure that depends on the Noise Index you select and the size of the patient you are scanning. If, you do not obtain a dose reduction over a population of patients,

you may have selected a lower Noise Index than you really need, resulting in, on average, higher mA values than fixed mA protocols. One strategy to avoid using more exposure is to set the max mA parameter to the same level as your fixed mA protocols, capping the maximum patient exposure to the same level as your fixed mA protocol. Hence, AutomA will never be allowed to use more exposure then previously employed. However, image noise will increase in regions where the mA is limited by the max mA selection and the IQ will degrade with increasing patient size. The optimum strategy is to find the highest Noise Index sufficient for the clinical task and let AutomA select the mA without using significant mA limits.

Why do my images seem noiser with AutomA?

- AutomA will produce an X-ray intensity to maintain the prescribed Noise Index. Thus, if images appear noisier when AutomA is employed, the user may need to use a lower Noise Index. This may be the case if the user finds that the average mA employed for the population of patients in question using AutomA is generally lower than your previous fixed mA protocols. This situation indicates that the user is using lower dose and hence higher noise levels would be expected.
- Certain patient images may also be noisier than your experience suggests. For example, your experience tells you to expect significantly lower noise in thin patients than obese patients. Since AutomA makes the image noise approximately the same for all patients, you may have to re-learn what to expect. What is most important, is to find the highest Noise Index that allows you to make a confident diagnosis for the clinical problem since this results in the lowest patient dose.
- If you desire somewhat lower noise in small patients, you may want to create Small, Nominal, and Large patient protocols. You can use a slightly lower Noise Index for the small patients and a slightly higher Noise Index for large patients.
- A conditional noise limiting strategy you can employ, is to increase the low mA range parameter. If you find that images are generally not acceptable to you below some minimum mA value, then you may set this value as the low mA range limit. This will prevent AutomA from using lower mA values than you desire. Note, however, that this defeats the purpose of AutomA and causes the image noise to decrease below the selected Noise Index and thereby increases the dose.
- Yet another possibility for higher noise than you might expect is if you are looking at multiple reconstructed images that have thinner slices than the prospective scan Rx slice thickness. AutomA uses prospective slice thickness as a factor when the mA table is generated. You need to be sure the Noise Index is set for the first prospective image based on image thickness you will use for axial image viewing (see the first FAQ). This caveat applies equally for fixed mA as well as AutomA scanning.
- Higher noise images can also occur when patients are not well centered in the scan field of view. The bowtie filter attenuation increases with distance away from isocenter. Hence the thickest part of the patient should be approximately centered in the scan field of view. Otherwise image noise will increase since the patient thickness adds to the bowtie filter thickness. This is especially important for highly asymmetric anatomy such as through the shoulders. Again, this effect is no different with AutomA than with fixed mA.

- Recognize also that there are some obese patients that exceed the capabilities of the tube and generator to satisfy the selected Noise Index. This is also no different than fixed mA scanning. For such obese patients, one strategy is to select a higher kV setting when possible.

Why is the mA annotated on the image sometimes slightly different than the mA I see in the mA table?

The mA displayed on the image is determined by measuring the generator mA during the scan and averaging the measured result over the total number of views used to reconstruct the image. The number of views used to produce the image may be more than one gantry rotation for a helical scan. Hence the annotated value is a combination of the mA table values that depends on how many views from each rotation were used for the image. In addition, the generator is automatically adjusting the filament current to account for changing conditions during the scan to keep the mA within the desired tolerance of the commanded mA table. For example, this is why you may see an mA value of 41 in the image where the mA table indicated 40.

I understand that noise in the image changes with reconstruction parameter selections, but why is the noise sometimes different when I retro reconstruct the same scan data at a different display FOV?

When you select a reconstruction algorithm, the system may sometimes re-adjust the actual filter kernel. This readjustment will change the image standard deviation. This will happen if the display field of view selection exceeds a certain size and is especially apparent with higher resolution algorithms such as bone and edge. The change in kernel is required when the DFOV selection makes the pixel size too large to support the intended spatial resolution. This characteristic is independent of AutomA. In the CT870 system, the AEC feature has been characterized to automatically adjust the exposure according to the user-prescribed display FOV of the primary image reconstruction.

Does AutomA require two scout images in order to function correctly?

No, all AEC features (AutomA, SmartmA, ODM, and kV Assist) are designed to require only one scout acquisition.

2.6.2 SmartmA

SmartmA adjusts patient exposure as a function of X-ray tube angle as the tube rotates around the patient. For each scan rotation in Z, the system calculates an mA for the lateral and anterior-posterior patient axes from an estimation of the ratio of patient attenuation through the long and short axes, respectively.

Patient exposure for a SmartmA scan is reduced when compared to a similar scan employing AutomA. This is shown in Illustration 3 which illustrates the mA as a function of rotation angle for AutomA and smartmA of a uniform oval shaped phantom. The image on the left shows the AutomA and SmartmA mA profiles as a function of X-ray tube angle, with an accompanying reduction in overall patient exposure.

While the SmartmA mA table simply specifies two different mA values per rotation, corresponding to the mA in the anterior-posterior direction and in the lateral direction, i.e. at 0, 180° and 90° and

270° degrees, respectively, the actual mA is continually varying in a smooth fashion between the specified mA values as a function of X-ray tube angle to the patient, as shown in Illustration 3.

Illustration 3 shows a sample SmartmA mA profile as a function of gantry rotation for a uniform oval polyethylene phantom with the same prescribed Noise Index using (blue) AutomA and (orange) SmartmA modes of Automatic Exposure Control (AEC). The reduction in patient exposure enabled by SmartmA is clearly seen in both images as a function of X-ray tube angle compared to the patient exposure illustrated by the AutomA profile. The expected mA reduction range when using SmartmA depends on the size and shape of the patient, and on the prescribed Noise Index, with a greater reduction expected for a relatively larger and more asymmetric patient, when a relatively low Noise Index is prescribed. The mA ramp up time is about 100ms.

Illustration 3: Modulation example

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2.6.3 Organ Dose Modulation (ODM)

Organ Dose Modulation (ODM) builds on the SmartmA feature to enable even further patient dose reduction. By reducing the mA exposure profile as a function of the X-ray tube angle, radio-sensitive organs towards the anterior surface of the patient, such as the eyes, breasts and thorax, can be further protected.

By modulating the X-ray tube current as a function of X-ray tube angle, ODM enables targeted reduction of the X-ray tube current towards the anterior surface of the patient, providing enhanced dose reduction to radio-sensitive organs of the patient while maintaining overall image noise.

In a similar way to other AEC features, the effectiveness of ODM is impacted by patient centering. To realize the expected dose reduction, the patient should be positioned in the center of the SFOV.

2.7 kV Assist

There is growing interest in optimizing the tube voltage, kV, to minimize the radiation dose of a CT scan. Lowering the kV has a significantly higher impact on the dose than lowering the mA, but kV also has a very complex interaction with other scan technique and image quality factors. The optimization of kV and mA parameters and image quality factors are also clinical task dependent.

- Lowering kV with a constant mA level will lower the radiation dose and can increase the image contrast in certain clinical tasks. It will always significantly increase the image noise.
- Lowering the kV with AutomA can increase the image contrast in certain clinical tasks and will keep the image noise constant. It will have very little effect on the radiation dose.

Careful optimization of the kV and mA (or NI) settings can maintain or improve image quality while reducing radiation dose in the context of specific clinical tasks.

When a tube voltage is selected, the desire is to pick the optimal tube voltage for the particular patient and clinical task, based on some criterion. This optimization could be performed, for example, in order to lower the amount of radiation dose associated with a CT scan, or to decrease the amount of contrast agent delivered to the patient or to improve image quality in terms of image contrast. For kV Assist, the goal is to optimize the tube voltage for radiation dose reduction. In order to understand how the tube voltage can be optimally selected, it is beneficial to examine the background of the impact of kV on CT imaging.

2.7.1 kV Assist background

Two significant factors that impact the quality of a CT image are the amount of X-ray quantum noise and of X-ray contrast (either from contrast agent administered to the patient or from tissues in the patient) in the scan data used to reconstruct the image. One key CT image quality factor is the Contrast-to-Noise Ratio (CNR). CNR gives an indication of how well structures can be seen through the image noise. CNR can be improved by increasing the contrast between structures, lowering the noise level, or both. If one assumes that only a single tube voltage will be used, these factors simplify to noise. For example, historically many CT scans have been performed at 120 kV. In that case, the behavior of how image noise, and therefore CNR, is impacted by X-ray scan technique factors can be understood from the description of AutomA. In this case where a particular tube voltage is used, the use of AutomA allows the scanner to adjust the tube current for the patient size and tissue composition in order to obtain a more consistent image noise.

In a more general look at X-ray scan technique factor setup, the behavior of image noise and contrast becomes more complicated. In this case, the quality is impacted not only by the number of X-rays that reach the detector, but also by their energy. This is impacted by what X-rays the system generates (how many [tube current] and at what energies [tube voltage]), and how much they are attenuated (patient size and composition). The selection of the tube voltage is related to the desired image contrast because, for some materials, the amount of X-ray stopping power varies greatly with the energy of the X-ray. The selection of the tube current is related to the desired image noise, but it must be noted that it is also greatly impacted by the tube voltage selection. For example, the number of X-rays produced at 100 mA at 80 kV is approximately three times less than the number produced at 120 kV. AutomA, for example, compensates for this once you select the tube voltage, but does not aid in tube voltage selection.

The selection of tube voltage in combination with tube current is important because the goal of technique setup is to pick the parameters that give the desired image quality at the lowest radiation dose. The behavior of both the image quality and the radiation output of the scanner is directly impacted by both the tube voltage and tube current selection. To help compensate for patient size and tissue composition without impacting the clinical workflow, an assisted approach for kV selection has been integrated into the scanner under the name kV Assist.

kV Assist is a tube voltage selection feature that can suggest the optimal kV based on the attenuation of the Scout image, and thereby provide a consistent desired image quality despite the wide range of patients. This feature works in conjunction with both AutomA and Manual mA in order to adjust the Noise Index/mA as needed once the kV is selected.

Because the selection of kV and mA may result in differences in the image appearance relative to historical techniques, WW and WL should be adjusted in order to optimize the image display. WW/WL adjustment based upon the selected kV can be enabled by the user to optimize contrast to noise and image quality for image viewing.

2.7.2 kV Assist theory

The selection of the tube voltage has a large impact on the number of X-rays that are used and their energy. Higher energy X-rays have greater penetrating power, but provide less image contrast. Lower energy X-rays have lower penetrating power, but provide more image contrast. Some materials, such as iodine, have a large change in X-ray attenuation with energy (and therefore have a large change in the resulting image contrast). For example, the image contrast in an iodine region in an average sized phantom could be approximately 1.6 times higher at 80 kV than 120 kV, and 1.2 times higher at 100 kV than 120 kV. Other materials, such as water, have little change in X-ray attenuation with energy (and therefore have little change in the resulting image contrast).

For the materials that do produce greater image contrast at different tube voltages, the resulting image quality may be improved if the noise is kept constant when the tube voltage is lowered. This is based on the impact that the CNR has on image quality.[1,2] Therefore, you could maintain the image noise at a lower tube voltage with improved image contrast, in order to improve the CNR. Alternatively, you could maintain the image noise and reduce the amount of contrast agent (if relevant) in order to maintain the CNR. A third option is to increase the image noise in order to maintain the CNR while reducing the radiation dose to the patient. kV Assist takes this third approach (while preventing excessive noise increases) in order to maintain image quality while reducing the radiation dose. For the example above (with contrast at 80 kV ~ 1.6 times contrast at 120 kV), maintaining the CNR could be achieved with a 60% and 20% increase in noise at 80 and 100 kV, respectively. This would result in significant dose reduction.

For many cases, maintaining the CNR of a particular material may not be clinically acceptable. Instead, both CNR and overall image noise should be taken into account.[3] kV Assist balances the consideration of CNR and image noise based on your selection of clinical task and Dose Savings.

kV Assist will take into account the patient size information from the Scout, the initial/baseline kV and the initial/baseline Noise Index/mA as the starting point, along with the user preference parameters for the selection of kV. The recommendation from kV Assist will be a consistent set of parameters affecting the scanning of the images.

- kV
- mA/NI – to meet CNR for clinical task
- WW/WL adjustment based upon the selected kV can be enabled by the user to optimize contrast to noise and image quality for image viewing. WW/WL should be optimized for image viewing based on the kV and mA.

kV Assist determines the recommended technique based on the baseline protocol, the scan conditions, and the level of $CTDI_{vol}$ savings configured by the user for kV Assist.

kV Assist will optimize the scan parameters based on the selected clinical mode.

In each mode, the system determines the patient size from the scout projection data. This is used in conjunction with a reference protocol (i.e., the X-ray scan technique factors that would be used without kV Assist) to determine the expected amount of image contrast for the relevant materials. The system then determines the Noise Index/tube current needed to provide the proper balance between CNR and image noise at each of the tube voltages. The combination of tube voltage and Noise Index/tube current that results in the lowest $CTDI_{vol}$ at the desired image quality is then selected. Note that the tube voltage with the lowest $CTDI_{vol}$ may not be selected for some patient sizes and applications in order to maintain the desired image quality (e.g., in order to avoid situations where potential image artifacts could occur).

The Dose Savings setting of the scan gives you the ability to fine tune the balance between CNR and image noise.

2.7.3 Image Display

Images of the same anatomy scanned with different tube voltages appear different. This is expected, because of the description above regarding Contrast-to-Noise Ratio changes. For example, images obtained with X-ray scan technique factors set by kV Assist could be brighter in areas (due to increased contrast) and noisier (due to increased noise). Even though similar information is present in the image, the change to the image appearance could be distracting. In order to minimize this change, kV Assist also provides the option for the system to modify the protocol's reference WW and WL (i.e., the WW and WL that would be used without kV Assist for an average patient).

2.7.4 kV Assist FAQs

What suggestions do you have for a new kV Assist user?

- If you are not familiar with the concept of Noise Index (image noise), see AutomA/SmartmA. In order to become familiar with kV Assist's impact on images, you can experiment by scanning different phantoms (ones that include regions of contrast are most appropriate for evaluating the modes based on contrast agent enhancement). Start with the normal Dose Savings level and increase or decrease as needed to meet your clinical needs.
- Review the image quality that is obtained with the kV and Noise Index/mA selected to optimize the settings.

Why is the kV with the lowest $CTDI_{vol}$ not always the recommended kV?

Based on the mode and the size/composition of the patient, kV Assist may not recommend some tube voltages that could result in degradation in image quality.

What if a message states that no kV is possible?

The situation where no kV is possible can occur for several reasons, including:

- The NI in the reference protocol could be too low, which requires more tube current than is achievable at any kV. Check the Noise Index and the mA table.
- The kV range could be limited to kV stations that require more tube current than is achievable. Check the Noise Index and the mA table.

What if the dose reduction results from kV Assist are not as large as I would like?

If the image quality away from the reference technique is better than required and the dose reduction is lower than desired, you can increase the Dose Savings level for a given mode. If the Dose Savings is already set to the maximum value, you can move to the next stronger mode. For any scans, you can always select Manual kV Mode to fine tune the technique.

What if the images produced by kV Assist appear too noisy?

If the image quality away from the reference technique is lower than required, you can decrease the Dose Savings level for a given mode. If the Dose Savings is already set to the lowest setting, you can move to the next weaker mode. For any scans, you can always select Manual kV Mode to fine tune the technique.

How are mA limits for AutomA adjusted if kV Assist is configured to adjust the mA limits as needed?

kV Assist will scale the mA limits at each kV in order to achieve the same minimum / maximum scanner radiation output as at the baseline kV (up to the system limits). Because of the interaction of tube voltage and tube current, this will result in higher mA limits at lower kV stations and lower mA limits at higher kV stations.

How will the behavior of kV Assist differ between mA limit configurations?

If kV Assist is configured to not adjust mA limits, the selection of lower kV stations may be restricted. This can occur because of the interaction of tube voltage and tube current, which dictates that higher mA values are needed when scanning at a lower kV. If the mA limit is not adjusted by the system, it is more likely that the higher mA values needed at a lower kV would fall above the mA limit. The actual system performance will depend on the mA limits set, as well as the patient size and kV Assist mode.

How do mA limits affect kV Assist selection of kV?

If an AutomA scan prescription for a given patient would result in mA values falling below the minimum mA limit, the mA values are adjusted to always fall above the minimum limit (i.e. clipped). The kV may still be selected by kV Assist (with the dose calculation determined by the clipped mA values). If a scan prescription for a given patient would result in mA values exceeding the maximum mA limit, the mA values are adjusted to always fall below the maximum limit. In this case, kV Assist

would not recommend this kV since the resulting image quality could be suboptimal. In this case, you can still select Manual kV Mode to select the kV and perform the scan if deemed appropriate.

What if I do not want to view head images at 70 kV?

In addition to the impact of kV Assist Mode and Dose Savings level on kV selection, there may be clinical situations in which you wish to lock out a kV or range of kV stations. The range of kVs used for kV optimization are dependent upon user selected kVs set in the protocol.

2.7.5 References

[1] W Huda, EM Scalzetti and G Levin, “Technique Factors and Image Quality as Functions of Patient Weight at Abdominal CT.” Radiology (2000), 217(2): 430-435.

[2] JM Boone, EM Geraghty, JA Seibert and SL Wooten-Gorges, “Dose Reduction in Pediatric CT: A Rational Approach.” Radiology (2003), 228(2): 352-360.

[3] L Yu, H Li, JG Fletcher and CH McCollough, “Automatic Selection of Tube Potential for Radiation Dose Reduction in CT: A General Strategy.” Medical Physics (2010), 37(1): 234-243.

3 Exam Workflow

3.1 Exam Workflow Concepts

3.1.1 Positioning a patient

Before placing patients in the system each day, the accessories that may be used during the day while scanning should be inspected such as the head holder, table extension, patient positioning sponges and straps to make sure they are in good working condition.

Positioning pads and straps should be inspected and cleaned to prevent possibility of artifacts being introduced due to foreign matter such as contrast on the surfaces of these items. Do not use accessories that maybe broken or torn.

Make sure patients are comfortable as possible on the table or in the head holder. Use positioning sponges and pads along with positioning straps to aid in the positioning of the patient to help them hold the position needed to complete the exam. If patients are comfortable, they will be able cooperate and hold still during the exam. If arm support or catheter bag hanger is used make sure they are placed securely on the table to support the arm or hold the catheter bag.

Monitor the location of the arm support or catheter bag holder to prevent any collisions with the gantry. Make sure any sheets, blankets and patient clothing or gowns are not allowed to get caught as the table is moving. Use the positioning straps to help contain these items so they are not loose or hanging off the cradle. Make sure to explain the procedure to the patient so they understand what is going to happen and what to expect. This will reduce incidences of patient moving because they are surprised by the position they are put in the gantry or the movement of the table.

3.1.2 Using protocols

All parameters for scanning a patient can be set up in a protocol. This saves you time when prescribing scan parameters for each patient. When a new patient is to be scanned, type in the patient information and choose a protocol. The protocol may be adjusted on a per patient basis without permanently altering the original set of parameters. Once the parameters are set and the prescription is confirmed, scanning can begin.

See *Protocols* for more information.

3.1.3 Using contrast

When Intravenous (IV) contrast is to be used, make sure the injector or syringes of contrast are set up before performing the localizer (scout) scan. The *Contrast* settings collection on the *Scan Settings* screen must be selected. When the icon is selected, there is a “+C” annotation on the images next to the image number, indicating that IV contrast was used for that exam.

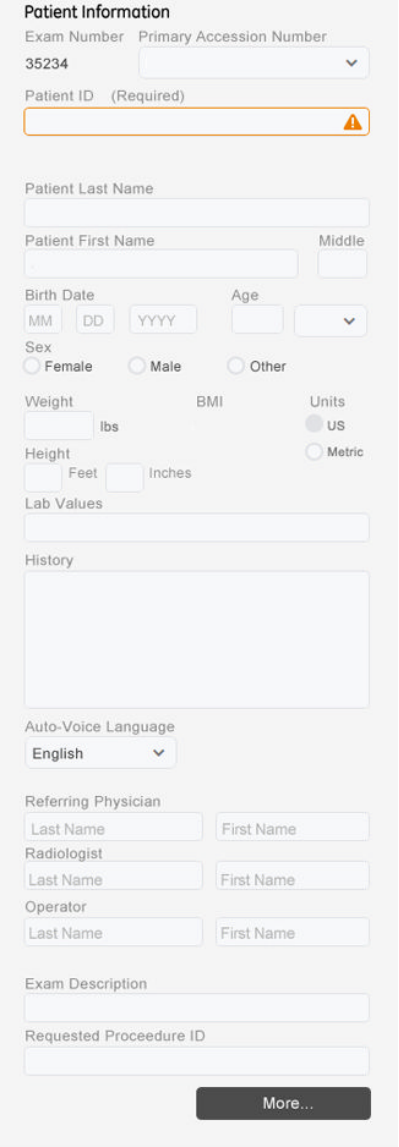
See *Enter contrast descriptions* for more information.

3.2 Exam Workflow Screens

3.2.1 Patient Information screen

From the scan monitor, open the *Patient Scheduler* drawer or click [+] to view the scan screens.

Illustration 4: Patient Information screen

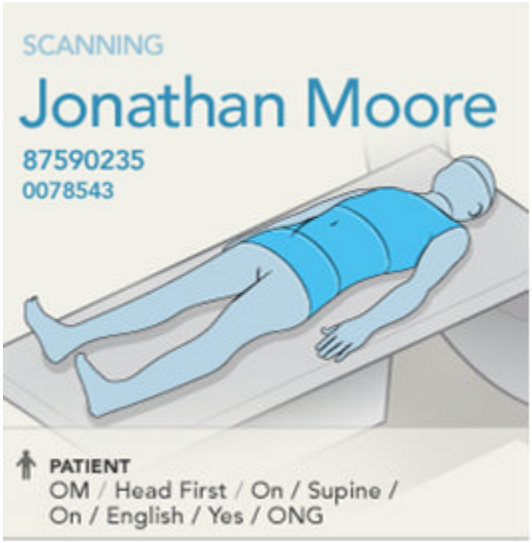


See *Set up the patient's information* procedure for character limits on each field.

3.2.2 Patient Position area

The Patient Position area is on the *Scan Settings* screen.

Illustration 5: Patient Position area



Element	Description
Anatomical Reference Point	Choose one of the preset center points or designate with a two letter abbreviation your center or 0 point. This should be set the same as your scout images.
Patient Position	Set the proper patient position by placing the cursor at the head or feet of the model and click to change the head first/feet first orientation. Place the cursor over the abdominal area or base of the table of the model and click to rotate the model in 90° increments.

3.2.3 Scan Settings screen

The *Scan Settings* screen is an area on the *Scan Setup* screen. The contents of the *Scan Settings* screen changes depending on the active application.

Illustration 6: Scan Settings screen (for illustration only)

Scan Task functions available on the Scan settings screen	
Element	**Description**
Done Scanning	Ends data acquisition for the exam.
Duplicate Series	Right click on the Series task you wish to duplicate.
Confirm Settings	Takes you out of the prescription preview mode so you can begin a scan. Confirm is not available if the patient has not been landmarked or if invalid parameters exist on the *Scan Settings* screen.
Close Exam	Closes the patient exam session.
Add Group	Right click from the Group task where you wish to add an additional Group.
Delete Group	Right click from the Group task you wish to delete.

3.3 Exam Workflow Procedure

This workflow provides an overview of a patient scan, from setup to image management.

1. Set up and position the patient.
2. Set up the patient's information.

3. Acquire a Scout scan.
4. Acquire the scan data.
   a. Set the Scan Parameters.
   b. Adjust the Graphic Rx.
   c. Set the Timing Parameters.
   d. Set the Recon Parameters.
   e. Apply any additional scan features.
   f. Enter contrast descriptions.
   g. Start the scan.

      Check the following before you confirm:

      i. Start/End locations for each recon
      ii. Direction of scans
      iii. mA table for AutomA or SmartmA

   h. Repeat a series, if necessary.
5. Close the exam.
6. View the images.
7. Manually archive the images.
8. Manually network the images.

3.3.1 Set up and position the patient

Prepare the scan room before bringing in the patient. Make sure that you have all the necessary supplies and accessories. If you will be using IV contrast, set up the injector or syringes before running the scout scan.

1. Attach the head holder or foot extender to the end of the cradle towards the gantry, if needed.
2. Press and hold the **Unload** table foot pedal to adjust the table height for transferring the patient onto the table.

   The cradle moves to home and to a minimum height of 49 cm.
3. Transfer the patient to the table.
   - Make sure to follow the manufacturer's directions for use of a protective table slicker when scanning, otherwise artifacts may appear in images.
   - Blocked reference channels can cause image artifacts. Make sure that there are no blankets, clothing, tubing, or straps hanging down below the table when scanning. Keep items wrapped close to the table by using the patient restraint straps.
4. Press and hold the **Load** table foot pedal.

- The table moves up to a height of 210 mm and the IMS advances the table and cradle into the gantry.
- Release the foot pedal when the patient is properly positioned. Use the gantry controls to further adjust the position.

5. Make the patient comfortable and immobilize as needed. Connect body straps to the cradle and wrap them around the patient.
   - When using 40 mm detector coverage for head scans, verify that the patient's head is completely in the head holder. If the patient is not fully in the head holder, light and dark images may appear on the image.
   - When using 40 mm detector coverage for head scans on the table top, make sure the head is not positioned over the connection point of the cradle extender. The head must be completely on the cradle.
   - Use the head holder straps to immobilize the patient's head.
   - Make sure items such as blankets and straps are not hanging off the table or allowed to touch or be dragged through the gantry during the scan, otherwise artifacts may appear in the images.
6. If needed, attach the IV pole.
7. Use the following gantry controls to refine the patient's position:

Table Up		Table Down	
Cradle In		Cradle Out	

NOTE: If it is not possible to move the table down:
- Check to make sure there is nothing blocking the table or gantry path.
- Check the message log for collision sensor errors, which prevent downward movement.
- Resolve any issues and press the table up/down buttons.
- If the problem persists, contact your service representative.

8. From the gantry controls, press the <Laser Alignment Light> button  to turn on the two laser lights: internal and external (axial, sagittal, and coronal). Align the laser lights with the target anatomical reference.

   Do not position the patient with the laser lights in his eyes.

9. From the gantry controls, press the <Internal Landmark> button or the <External Landmark> button. You can not select *Confirm Settings* until after you've pressed a landmark button.
   - The landmark sets a known anatomical reference for the radiologist to correlate anatomy.
   - The landmark sets the zero location. When scanning towards the patient's head, you are scanning superior to the zero location. When scanning towards the patient's feet, you are scanning inferior to the zero location. You should set the zero location to known anatomy. For example, when scanning a head, the landmark or zero location is typically the orbital meatal line.
   - A landmark or zero reference point is required before you scan a patient. It can be set before or after you click [New Patient].
   - When using the external laser alignment light to position the patient, be aware that the patient's elevation may be slightly lower with the cradle extended than with the cradle fully retracted. The cradle may bend slightly under the patient's weight. Take this difference into consideration for applications where patient position is critical, such as treatment planning. To minimize these effects, after positioning the patient using the external laser alignment, advance the patient to the CT scan plane. Turn on the CT alignment lights to determine if they line up with the markers on the patient. Compensate for the bend in the cradle by elevating the table. When the CT alignment lights line up with the markers, reset the landmark for the scan using the Internal laser alignment light.
10. From the Scan Control Interface, set volumes with the <Patient-to-Operator> and <Operator-to-Patient >, or <AutoVoice> communication controls. Press the <Talk> control to test the volume levels.

Patient-to-Operator volume communication control	Operator-to-Patient communication control	AutoVoice communication control	Talk control
			

3.3.2 Set up the patient's information

Use this procedure from the CT operator console, each time you start a new patient exam. Set up the patient information before you get the patient on the table. This reduces the amount of time the patient has to be on the table, possibly in a difficult position. When entering the patient information, the only field required for scanning is the patient ID. This task describes how to manually input the data. The data can also be input by using Patient Scheduler or a bar code reader.

1. From the scan monitor, open the *Patient Scheduler* drawer.
   - The *Patient Information* screen displays the new Exam Number.

- The maximum Exam Number is 49,999, which will be reset by your Field Engineer.
- If the information is entered from an RIS system, these areas support up to 64 characters. If the patient is edited or manually entered then the character limits are described in the following table.

Table 3: Patient Information fields

Field name	Parameters
Accession Number	up to 16 characters
Patient ID*	up to 16 characters
Patient Name*	up to 32 characters
Sex	M or F
Birthdate	Months, Weeks, Days
Age	Years, Months, Weeks, Days
Weight	Kilograms or Pounds
Height	Feet, Inches, or Centimeters
Reference Physician*	up to 32 characters
Radiologist	up to 32 characters
Operator	up to 3 characters
History	up to 60 characters
Exam Description	up to 22 characters
Protocol Number	up to 5 characters
Req. Proc. ID	up to 16 characters
Date	Exam Date Month, Day, Year
Time	Exam Time Hour, Minute

2. From the *Patient Information* screen, enter data into the appropriate fields.
   - Press [Enter] to advance to the next text field, or, use the mouse to navigate to each field.
   - The cursor must be within the *Patient Information* screen for the input to be accepted.
   - Patient ID is a required field. If the patient does not have an identification number, enter ***?*** or the word ***trauma***.
   - Once an identification number has been assigned, you can edit exam information using Edit Patient after Close Exam.
   - Set *Delete Completed Exams* to zero when Patient Information is updated from the HIS/RIS. This assures that completed accession numbers are not inadvertently selected for a second scanning. This could cause patient reconciliation issues on the Picture Archiving Communications System (PACS).
   - Digital Imaging and Communications in Medicine (DICOM) users must enter the patient name in the following manner: last name, first name, middle name separating each by a caret (^). For example: Doe^John^M.

- Enter the patient date in the format: Month: 12, Day: 22, Year: 1987. Two-digit years can be entered if the birth year is 2000+. Birth dates can only be entered for the past 150 years. The format for date entry depends on your system settings: MM/DD/YYYY, YYYY/MM/DD, DD/MM/YYYY.
- Patients in Japan may know their birth date only by emperor reign year. Configure the birth date fields to yyyy/mm/dd date format and enter the reign year in the year field. For example, enter ***S26***, if your patient was born in the 26th year of Showa's reign, which corresponds to 1951. The Era codes are Heisel (H), Showa (S), Taisho (T), Meiji (M). The system stores the converted birth year in the birth date field on the New Patient and Patient Schedule screens and in the image header.
- If needed, select items from any of the stored *Preset Selection* values: *Referring Physician, Radiologist, Operator, Exam Description* and click [OK].

3. After entering patient information, select a desired protocol category, and then search for a protocol using one of the following methods. Select the desired protocol(s) and then click [Accept].
   - Select a protocol from the Favorite list
   - Select an anatomical region and then select a protocol
   - Search directly for a protocol in the *Search Protocols* field, and then select a protocol
4. Proceed to *Acquire a scout*.

3.3.2.1 Enter patient information with the bar code reader

The patient information must be in the Patient Scheduler list before you use the bar code reader.

Bar Codes fail to read if the HIS/RIS system the bar code is created on has a different language keyboard than the CT system. For example, if your CT system has a French language keyboard then your HIS/RIS must have a French language keyboard. If it is not possible to have the same language keyboard on each system, then manually enter the Accession or Patient ID number or select the desired patient from the Patient Scheduler list to display the patient information on the *New Patient* screen.

NOTE: The Exam Description will be truncated to 22 characters when imported from a HIS/RIS system. The Study description field (0008, 1030) in the DICOM header is mapped to the Exam Description field on the *Schedule Patient* and *Patient Information* screens.

1. From the scan monitor, open the *Patient Scheduler* drawer or click [+].
2. To populate the fields on the *Patient Information* screen, aim the reader at either the Accession number or the Patient ID bar codes on the patient requisition.
3. Select desired protocol(s) and begin the exam.

3.3.2.2 Modify the Patient Information presets

Use these procedures to modify the *Preset* fields on the *Patient Information* screen. The Presets are saved across software loads from the saved *System State*.

From the Mode drop down menu on the right monitor, select [Preferences]. From the *Preferences* screen select [Patient Data Entry]. Click any of the preset fields or click [Add New] and type in the desired text field. Click [Save].

- Referring Physician
- Radiologist
- Operator
- Exam Description

Change an item on the list

1. From the *Preset fields* screen select the item you want to change.
2. Enter the information in the text field.
3. Press <Enter>.

Add an item to the list

1. From the *Preset fields*, click [Add New], and then enter new information in the text field.
2. Click [Save].

Delete an item from the list

1. From the *Preset fields* screen select the item you want to delete.

   The item is displayed in the text field
2. Click [Delete].

3.3.3 Acquire a scout

Use this procedure to acquire a scout from which you can prescribe the scan locations.

1. Confirm that the orientation of the patient matches the orientation of the patient in the *Patient Position* area of the *Scan Settings* screen.
   - Click the picture of the patient on the body to change the Head/Feet first orientation.
   - Click the picture of the patient on the table or above the body to rotate the body at 90° increments.
2. From the *Scan Settings* screen, confirm the start/end locations, kV, mA, and AutoVoice (if applicable).
   - To change a parameter value, click the field and enter a value. Plus (+) can be used for S values and Minus (-) for I values for entry using the ten key pad.
   - Technique factors are set low (120 kV and a low mA are common), since these scans are normally only used for planning purposes.
3. Set the *Scout Plane* to designate the type of scout to acquire.

- 0 = 12 o'clock, 90 = 3 o'clock, 180 = 6 o'clock, or 270 = 9 o'clock
- *Graphic Rx* is only available if the scout has been acquired at 0, 90, 180, or 270.

4. Click [WW/WL] and type desired values in the field and click [OK].
5. When performing a gated exam, set up the patient monitor and check the status of the [Gating] icon to verify that the system is receiving the ECG monitor signal.
   - Click [On] to enable gating.
   - If the ECG signal has not been detected, the system displays a message to check the connection. Check that all ECG leads are connected to the patient and that the monitor power is on. See Cardiac patient prep for more details.
6. On the left monitor, click the [Confirm Settings] button.
7. Press <Move to Scan>.
   - The button illuminates on the Scan Control Interface and flashes green, indicating you need to press <Move to Scan>.
   - If you need to stop table movement, press <Stop Move>.
8. Press <Start Scan>.
   - If you need to stop the scan, press <Stop Scan>.
   - If you need to pause the current scan, press <Pause Scan>.
     - This finishes the current scan, then pauses the next scan. Click <Resume> when you are ready to scan.
     - In Axial scans, the scan stops after the next scan.
     - In Helical scans, the entire scan is completed. Use <Stop Scan>; not <Pause Scan>.
9. Repeat the previous two steps to acquire the second scout scan.
10. Proceed to *Set the scan parameters* to acquire the scan data.

3.3.4 Adjust the Graphic Rx

Follow the steps below to adjust the graphic prescription and set up a scan series. If your protocol is set up correctly, you may not have to make many changes. You can just adjust the graphic lines representing the series and confirm.

1. Press and hold <Shift> and click and drag the center X to position the graphic lines over the anatomy you want to cover.
   - The slices are represented as a group of lines on the scout image. The start location is demonstrated with a solid square in the middle of a line. The end location is demonstrated by an open square box in the middle of a line.
   - The X allows you to move the lines up and down on a lateral scout, as well as from side to side on an Anterior/Posterior (A/P) scout.

- By moving the lines, you are adjusting the start and end locations, and the Right Anterior Superior (RAS) coordinates.
- If you change the landmark after the scout has been taken, Graphic Rx will not let you to change A/P centers on lateral Scout. Since the landmark changed, a new Scout should be acquired so Graphic Rx can be used.
- Clicking the X moves the slices in the slice direction only.

2. Click and drag the solid box to the starting position.
3. Click and drag the empty box to the ending position.

   Press <Shift> and simultaneously click and drag either the solid or empty box to adjust both the starting and ending locations at the same time.
4. Click and drag the diamond key to set the Display Field of View (DFOV) equally around the center of the DFOV.

   Alternatively, press <Shift> and simultaneously click and drag the diamond key to adjust the DFOV and the R/L or A/P center on the selected side.
5. From the Graphic Rx viewport, right-click, and choose an option to show or hide the slices.
   - Click [Hide Slices] to show a transparent area of coverage with no slice lines displayed.
   - Click [Show Slices] to show a line for each image reconstructed.
6. From the Graphic Rx viewport, right-click, and choose an option to review the irradiated area.
   - For helical acquisitions, the full X-ray irradiated area is shown for all groups using a pair of magenta lines that are the length of the SFOV.
   - For multiple groups, Graphic Rx supports Hide/Show Irradiation Lines. After you close Graphic Rx and re-enter, the irradiation lines default on.
7. Review the Graphic Rx values on the *Scan Settings* screen to make sure they are correct.
8. Proceed to *Set the scan parameters*.

3.3.5 Enter contrast descriptions

Use this procedure to enter contrast descriptions for the scan if you are using Intravenous (IV) or Gastro-Intestinal (GI) contrast.

NOTICE

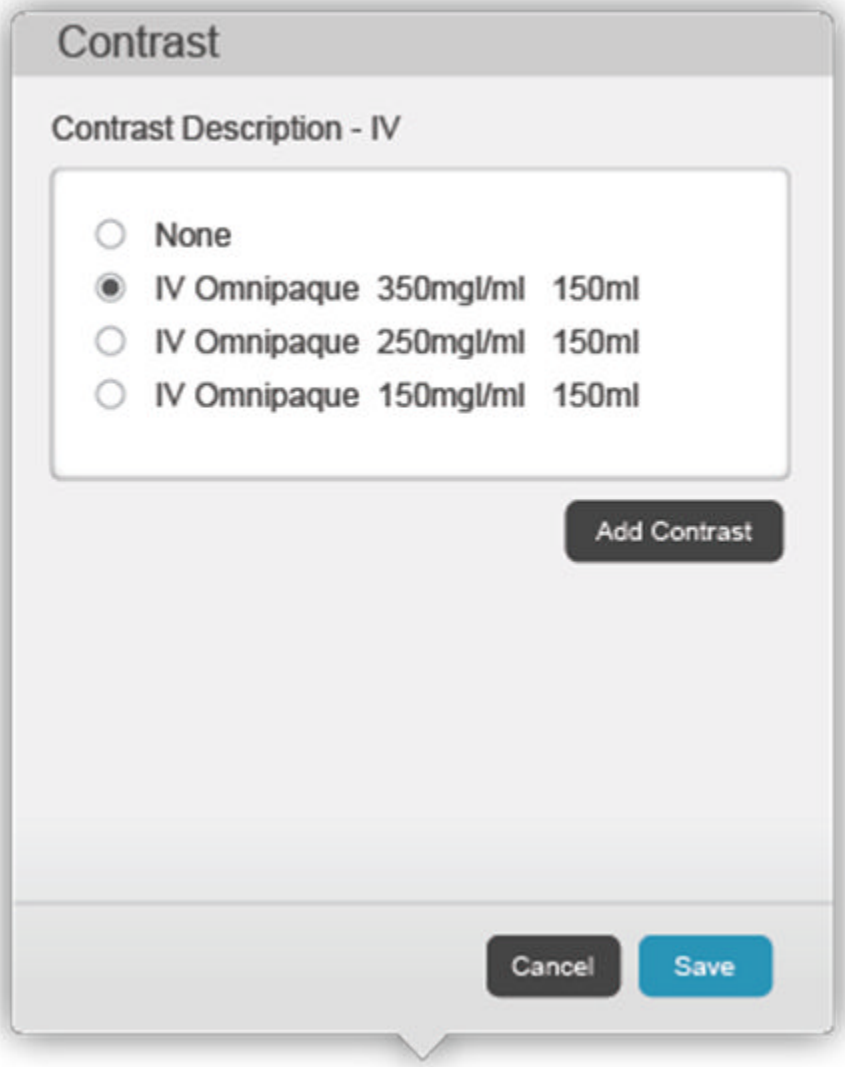
When IV contrast is to be used, make sure the injector or syringes of contrast are set up before running the localizer (scout) scan. The IV Contrast icon must be selected.

3.3.5.1 Selecting a Preset

1. Open the Contrast Settings collection. This will open the collection as shown in Illustration 7.
2. Select the preset applicable to the scan you are doing. See Section 3.5.2 if the value you want is not available.

3. Click [Save].

Illustration 7: Open Contrast Settings Collection

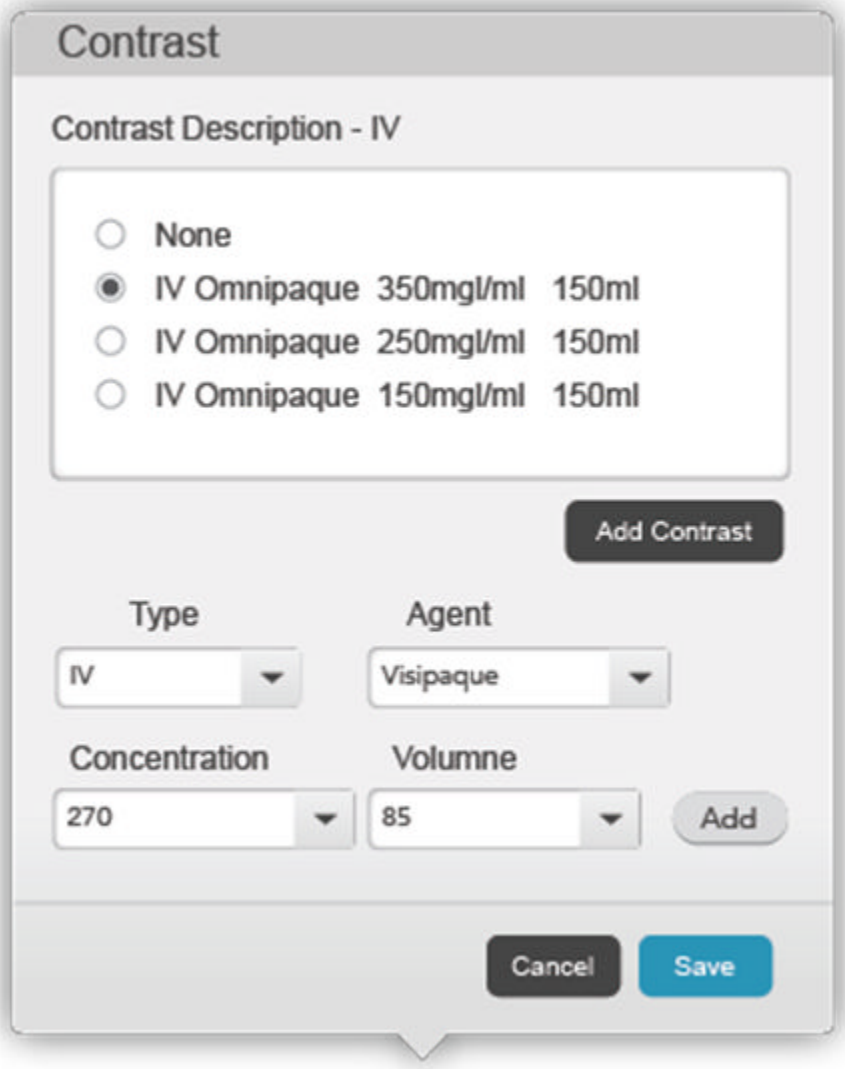


3.3.5.2 Adding a preset

1. Click the [Add Contrast] button as shown in Illustration 7. This will open a screen giving you the ability to specify the new preset as shown in Illustration 8.
2. Select the Type: “IV” or “Oral”.
3. Enter the name of the agent.
4. Enter the concentration.
5. Enter the volume.
6. Click [Add].

7. Return to the Section 3.5.1 instructions to select the contrast preset just added.
8. Note that presets may be removed by hovering over the preset in which case an “x” will appear (refer to Illustration 7). Clicking on this x removes the preset from the list.

Illustration 8: Adding a Preset



NOTE: When contrast is selected, a “+c” annotation displays on the images next to the image number, indicating that IV contrast was used for that exam.

3.3.6 Start the scan

Use this procedure to start a scan.

1. Review the following items for every acquisition before confirming to scan:
   a. Start/End locations for each recon

b. Direction of scans

c. mA table for AutomA or SmartmA

2. To start a scan, click the [Confirm Settings].
3. Press <Move to Scan>.
4. Deliver breathing and table move instructions, as needed.
5. Press <Start Scan>.

Considerations

- Press <Stop Scan> to stop scans between multiple helical groups and do not press <Stop Move>.
- Scan aborts may occur during Axial or Helical scanning. Always be aware of the scan progress during an Exam and select [Resume] to continue.
- Scan may fail to confirm posting a message that not enough image space exists, even though the image space shown in the Feature Status Area indicates there is enough space. This is due to the fact that images are stored on the system disk in more than one partition. Remove consecutive exams to free up image space for confirm to proceed.

NOTE: If you encounter the message that you need to delete images to be able to scan the current series, first remove images to create space for scanning, next if Scouts have not been taken, end the exam and start anew exam. However, if scouts have been acquired, use Revisit Protocol and prescribe the series again.

3.3.7 Duplicate a series

Use this procedure to duplicate a series that has already been scanned.

On the *Scan Settings* screen, right click on the series to be duplicated in the task list.

NOTE: The Prep Delay for group 1 is set to zero.

3.3.8 Stop a scan

3.3.8.1 Abort a scan in progress

Use this procedure to abort the X-ray and stop the gantry and table movement.

1. From the Scan Control Interface, press <Stop Scan>.
2. Click <Resume> from the *Scan Progress* screen to resume the scan.

3.3.8.2 Pause a scan in progress

Use this procedure to pause the current scan. This finishes the current scan, and then pauses the next scan.

1. From the Scan Control Interface, press <Pause Scan>.
2. Click [Resume] from the *Scan Progress* screen to resume the scan.

3.3.8.3 Emergency stop scan, electronics, and x-radiation

Use this procedure in the event of a patient related emergency or if the cradle, table, or gantry starts to move unexpectedly.

1. From the Scan Control Interface or gantry, press <Emergency Stop>.

   All table and gantry motions, and X-ray exposure are stopped.

2. On the gantry, press <Reset> to clear the Emergency Stop.

NOTE: For helical scans, you need to evaluate each situation. <Pause Scan> will not stop a helical scan in progress. The scan will complete and the system will stop and not scan any additional groups. <Stop Scan> will stop a helical scan. [Resume] will resume the helical scan from the point it was stopped.

3.3.9 Close the exam

When an exam is completed, click [Done Scanning].

4 Scan Parameters

See the *Scan parameters workflow* for procedures on how to set the following scan parameters.

4.1 Scan Type

The Scan Type is set in the *Scan Type* collection.

4.1.1 Hi Res

Hi Res mode provides the capability to acquire 2.5 more views using deflection of the X-ray beam in both non-cardiac and cardiac acquisitions. The additional views can be used to improve image quality to reduce aliasing, improve off center imaging, or improve resolution. Normal algorithms can be used; however, they will not improve resolution in the image. The HD reconstruction algorithms can enhance the inherent resolution in Hi Res mode acquisitions for DFOV less than 25 cm. The Hi Res algorithms have a two appended or HD prefix added to the algorithm name. Hi Res Mode may be useful when a large DFOV is used and targeting to a smaller DFOV is desired.

NOTE: Hi Res mode is available in the following modes.

- Axial – 40, 80, 120, 140, 160 mm detector coverage
- Helical
  - 0.516:1 pitch 40 mm detector coverage
  - 0.984:1 pitch 40 mm detector coverage
- Cardiac Axial – 40, 80, 120, 140, 160 mm detector coverage

Hi Res acquired images are annotated with HR in the lower-left annotation area of the image.

4.1.2 Axial

Axial scanning is the traditional “step and shoot” method of acquiring data. The X-ray tube and Data Acquisition System (DAS) expose and rotate one 360° loop. The table and patient move a preset distance (interval) and the process is repeated.

4.1.3 Cine

Cine is a method of scanning that uses full or partial rotations of the gantry while gathering input from one location over time. You may set the acquisition in groups expanding the time to be scanned. This is especially beneficial when determining the function of anatomy and physiology (i.e., hemangioma).

4.1.4 Helical

Helical or spiral scanning is a method of acquiring images in a continuous data set. The X-ray tube and DAS expose and rotate continuously through 360° while the patient is passed through the area of exposure at a set rate of movement depending on the rotation time and helical pitch. The information gathered is then reconstructed into images of the prescribed slice thickness and interval.

4.1.5 Cardiac Axial

See the Cardiac chapter.

4.1.6 Rotation Times

Rotation time is a parameter that can be adjusted for patient size and applications. For scanning an average sized patient for an abdominal study, the 0.5 second rotation time may provide adequate mAs for image quality. For a larger patient you may need to use the 0.8 second rotation time. Both studies would be completed using sub-second rotation times because of the flexibility in having the various rotation times.

- Axial – 0.4 s, 0.5 s, 0.8 s, 1.0 s
- Cine – 0.4 s, 0.5 s, 0.8 s, 1.0 s
- Helical – 0.4 s, 0.5 s, 0.8 s, 1.0 s
- Cardiac Axial – 0.28 s, 0.35 s

4.2 Scan Type screen

On the *Scan Settings* screen, click [Scan Type] to display the *Scan Type* screen.

Illustration 9: Scan Type screen

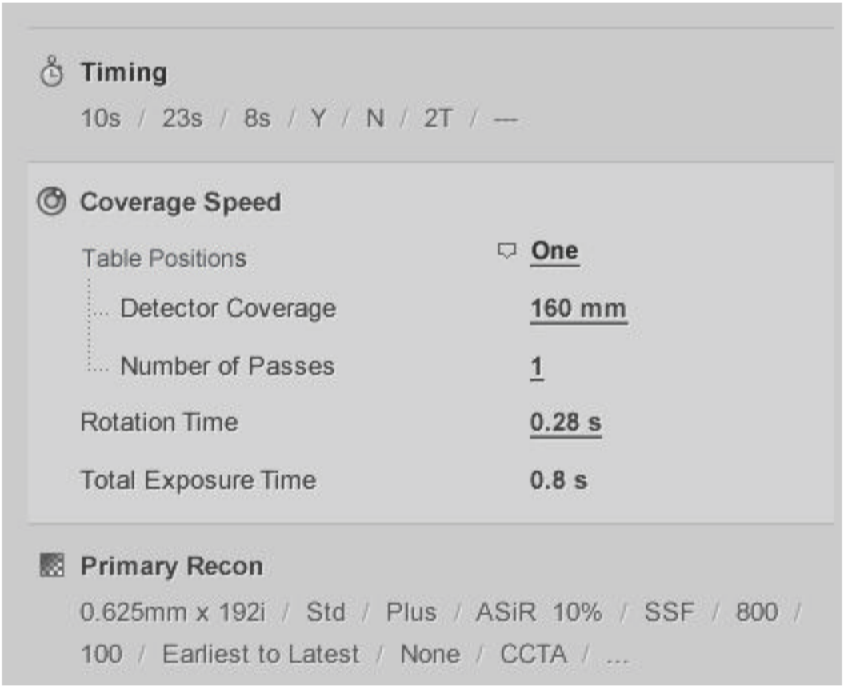
Element	Description
Hi Res Mode	Enables and disables the Hi Res mode. Hi Res is compatible with Axial, Helical, and Cardiac scan types.
Scan Type	Enables one of the following scan types: Axial, Helical, Cine, or Cardiac.

Cardiac Mode	Enables the Cardiac modes. The cardiac modes are only available if the Cardiac scan type is selected.
Rotation Time	The available rotation times depend on the scan type selected. See Rotation Time.

4.3 Coverage Speed screen

On the *Scan Settings* screen, click [Coverage Speed] to display the *Coverage Speed* screen.

Illustration 10: Coverage Speed screen



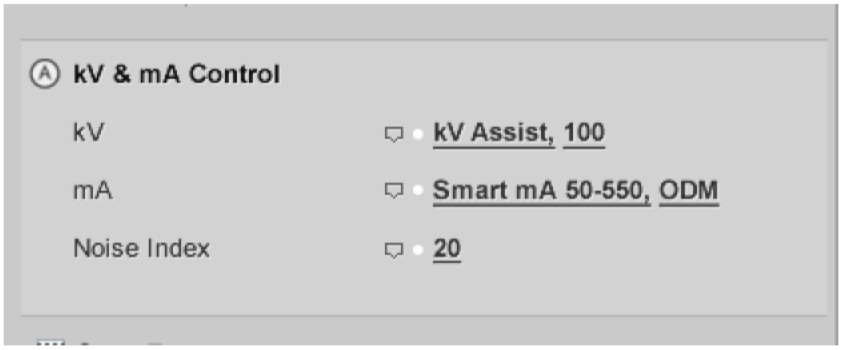
Element	Description
Detector Coverage	See also Detector Configuration. Axial • 5.0 mm • 40 mm • 80 mm • 120 mm • 140 mm • 160 mm Helical 40 mm beam
Pitch and Speed	• 0.516:1 pitch (40 mm detector coverage) • 0.984:1 pitch (40 mm detector coverage) • 1.375:1 pitch (40 mm detector coverage)

Rotation Time	• Axial – 0.4 s, 0.5 s, 0.8 s, 1.0 s • Helical – 0.4 s, 0.5 s, 0.8 s, 1.0 s • Cardiac Axial – 0.28 s, 0.35 s
Coverage Time	The coverage time determines the total duration of the scan.

4.4 kV and mA Control

On the *Scan Settings* screen, select the *kV and mA Control* collection to display kV, mA and Noise index settings.

Illustration 11: kV and mA Control collection



4.4.1 kV Control

On the *Scan Settings* screen, select [kV] on the *kV and mA Control* collection to display the kV

Manual kV Mode

By selecting Manual kV mode, the user can enter a kVp value for each prescribed scan group.

When building protocols, make sure that a reasonable and appropriate kVp level is selected for the Manual kV selection even if the protocol is designed to employ an AEC scan mode. This is done to ensure that a reasonable kVp setting is used for the diagnostic scan in the event that kV Assist is disabled.

kV Assist kV Mode

When kV Assist mode is selected the system will adjust kV and NI/mA based on the patient attenuation from the scout, the system kV Assist configuration, and the protocol's clinical task, baseline kV, kV range, mA mode, and mA setting or mA range and Noise index.

See the Protocol section for further details on setting up kV assist in the protocol.

4.4.2 mA Control

On the *Scan Settings* screen, select [mA] on the *kV and mA Control* collection to display the mA.

4.4.2.1 Manual mA Mode

The user can enter a mA value for each prescribed scan group in Manual mA mode.

When building protocols, make sure the Manual mA value field is populated with a reasonable mA entry, even if the protocol will use AutomA, in case AutomA is turned off when in Manual mA Mode.

4.4.2.2 AutomA Mode

When AutomA Mode is selected, the mA on the *Scan Settings* screen is annotated with the mA range prescribed for the scan group.

When possible, the kV setting for the scout should be taken using the same kV used for the Axial or Helical scan.

The system uses the patient attenuation data collected from the most recent scout scanned for the exam, the patient habitus, the prescribed Noise Index, and other settings in the mA table to determine the mA to be used for the acquisition. The user can view the predicted mA values for each rotation of the acquisition by accessing the mA table. The Patient Orientation and Patient Position for the series must match the scout. If there is no scout or the patient orientations do not match, AutomA will be disabled.

The mA table will indicate when one or more scan rotations are at the maximum or minimum mA value specified for the prescribed scan. This is to notify the user to check the parameters to ensure the acquisition will provide the expected results.

NOTE: Even if you are using AutomA, the Manual mA field should be filled in with a reasonable value in case AutomA should be inadvertently disabled.

4.4.2.3 mA Max and mA Min

Allows the user to enter values to specify a minimum and maximum mA range for AutomA and SmartmA . The mA Max value sets the maximum allowed, or clipping mA value. This mA value can also determine the focal spot size. The mA Max value can be used to limit the system to a small focal spot. You need to enter the correct mA value for the focal spot you wish to use based on Table 4.

Table 4: mA range based on focal spot and acquisition mode (Normal and Hi Res)

Scan Mode	kV	Small Focal Spot (mA)	Large Focal Spot (mA)	X-Large Focal Spot (mA)
Standard Res	70	10-250	255–375	NA
	80	10-580	NA	NA
	100	10-480	485–720	NA
	120	10-400	405–640	645–715
	140	10-345	350–550	555–610
High Res	70	10-250	255–375	NA
	80	10-415	420-580	NA
	100	10-335	340–535	NA

Scan Mode	kV	Small Focal Spot (mA)	Large Focal Spot (mA)	X-Large Focal Spot (mA)
	120	10-280	285–445	NA
	140	10-240	245-380	NA
Cardiac Standard Res	70	10-250	255–375	NA
	80	10-580	N/A	NA
	100	10-490	495-720	NA
	120	10-405	410-665	670-740
	140	10-350	355-570	575-635
Cardiac High Res	70	10-250	255-375	NA
	80	10-425	430-580	NA
	100	10-340	345-545	NA
	120	10-280	285-455	NA
	140	10-240	245-390	NA

4.4.2.4 Noise Index

Noise Index is an indication or index of the level of reconstructed image noise requested for the diagnostic imaging task being performed. As the Noise Index increases, the required exposure, i.e. mA and / or kV level, decreases and image noise increases; conversely overall image noise levels decrease and the required patient exposure increases with a decrease in the prescribed Noise Index. The user can specify the Noise Index in the Noise Index field. The Noise Index field is enabled only when the user enables one of the AEC features. A change in prescribed Noise Index necessarily adjusts dose to the patient, which is viewable at the bottom center of the screen in the dose display area. Patient dose will be decreased or increased as the Noise Index is accordingly increased or decreased.

4.4.2.5 Cardiac Modulated mA

See the *Cardiac* chapter for detailed information on Cardiac AEC.

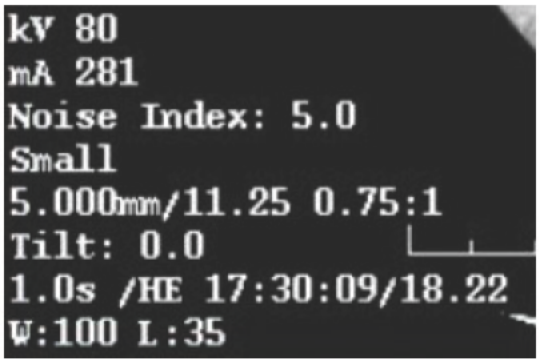
4.4.2.6 SmartmA

When SmartmA is enabled on the *Scan Settings* screen, the mA is annotated with the tilde symbol (~), indicating that SmartmA is selected.

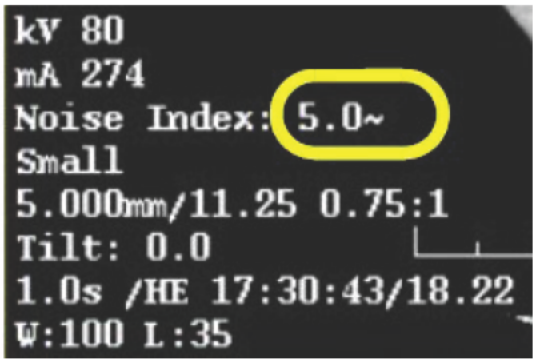
Images reconstructed from a SmartmA enabled scan are annotated with a tilde symbol (~) next to the Noise Index, as shown in Illustration 12.

Illustration 12: Image annotation

1



2



Number	Description
1	AutomA
2	SmartmA

NOTE: AutomA and SmartmA are disabled if the patient orientation does not match the Scout orientation. The system will inform and instruct users that Patient Orientation or Patient Position has changed from the previous series, and that AEC features have been disabled. The user can choose to re-acquire a new scout image, to re-orient the patient to be consistent with the orientation of the previous scout, or to confirm the manual mA setting that has become active in the event the AEC features are disabled.

The following message will be displayed if AutomA is disabled:

CAUTION

ATTENTION

Your patient orientation has changed from the previous series. Please verify or change orientation if needed. AutomA has been disabled. It can be enabled again once patient orientation matches that of the last scout series.

NOTE: Only manual mA values can be entered until the patient orientation matches the Scout orientation.

4.4.2.7 ODM

1. On the *mA Control* screen, the user can enable the ODM feature by selecting *ODM* mode.

Table 5: ODM selections

Element	Description
[mA mode] Button	Enables or disables the ODM feature. When enabled, up to three locations within the scan range can have ODM applied, with the locations specified either graphically on the scout image or by the start and end locations of the applied ODM regions in the appropriate Start and End Location text boxes.

Start Location / *End Location*	Displays start and end location of the ODM region. When the ODM feature is enabled, a set of empty Start and End Location entry fields are created by default.
Add or Delete an ODM region	By default, one set of empty Start and End Location entry fields are created. The number of ODM regions can be increased by clicking the region selection option. The maximum number of ODM regions is three. The regions cannot overlap with each other.
mA Table Information	A visual indicator shows scan rotations where ODM is applied. (A) anterior, (P) posterior, (L) left of the patient, (R) right of the patient Scan rotations where ODM is applied have an accompanying drop in the applied mA in the (A) anterior direction when compared to the (P) posterior direction. If the Patient Orientation changes from, Head First to Feet First, then the positions of (L) and (R) are reversed. ODM can be set in Protocol Management.

2. On the scout image, the prescribed ODM region is displayed in white and is inactive when the scan prescription is being adjusted by the user. When active, the ODM region is filled in and the scan prescription region is colored white and inactive.

   On the Localizer, the ODM region is displayed in white.

Illustration 13: ODM region on a scout image

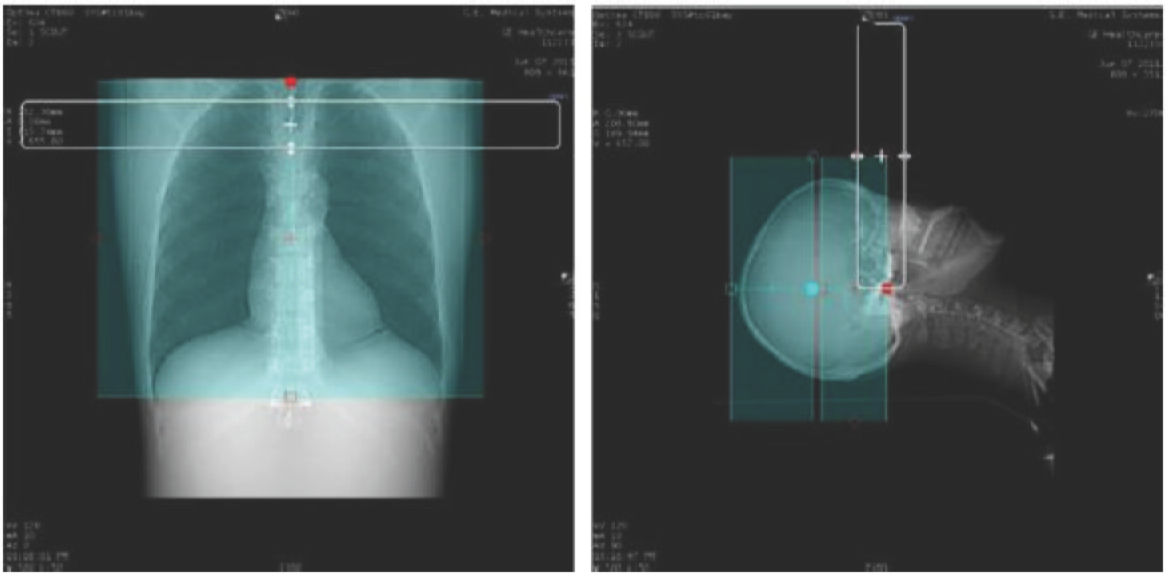
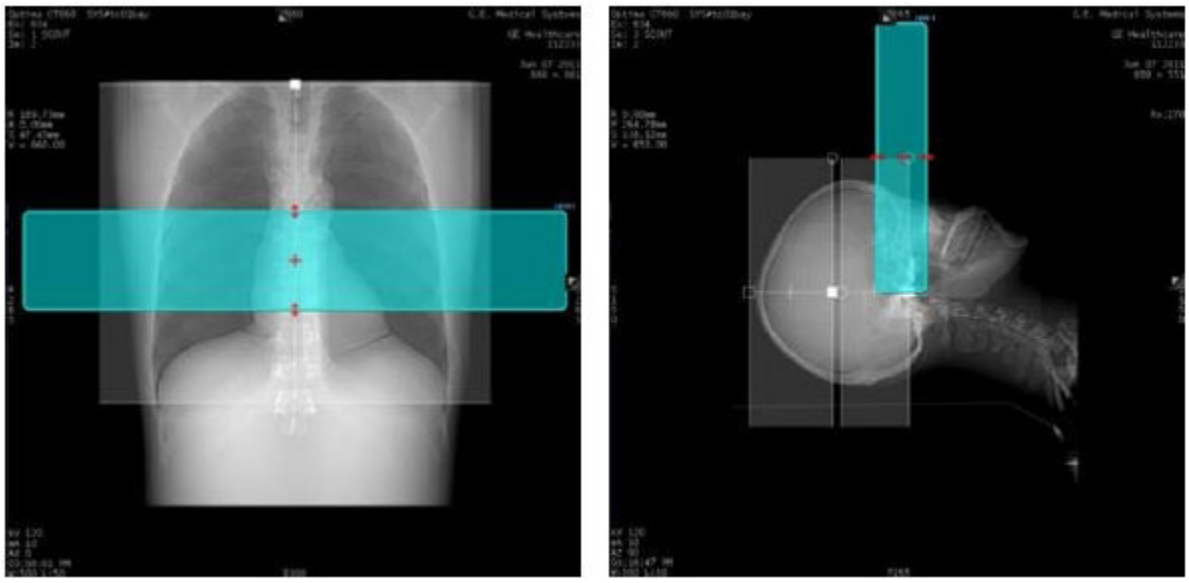


Illustration 14: ODM region enabled



NOTE: The ODM region can be moved only in the Z-direction, not for A-P or R-L direction.

3. When ODM is enabled for a scan, it will be indicated in the *kV and mA Control* collection. ODM will be set in one or more locations in the scan group. It does not mean all the rotations in the scan group have ODM applied.

   NOTE: SmartmA is ON when ODM is enabled.

   ODM is available with standard Axial, Helical or Cine scanning modes.

   ODM is not available for Cardiac scan types.

   ODM is not available for scan groups which are not compatible with AEC scan modes.

   If ODM is enabled and the scan type is modified to a state which is not valid for ODM, the system will notify the user.

   The following message will be posted when there is a change in ODM:

   NOTICE

   Attention: One or more ODM regions will not be applied to prescribed scan groups. Check ODM prescriptions, and ensure SmartmA is enabled and Scan Types are valid.

Image Annotation

To indicate that an image was generated within a scan region where ODM is enabled, a visual indicator is added after the Noise Index value.

4.5 Scan parameters workflow

Use this procedure to set the scan parameters according to your patient's size and the anatomy you are scanning. These parameters determine the image quality you achieve. Always make sure

you remove any objects that may cause artifacts. Review the scout image to view objects that might cause artifacts.

4.5.1 Considerations

- If the patient orientation is different from the previous scan, the following message is seen, *"Your patient orientation has changed from the previous series. Please verify or change orientation if needed."*
- If the landmark has changed, the following message is seen, *"The table landmark has changed. This changes the location of all scans you have prescribed. Double check all scan location before you start scanning."*

1. From the *Scan Settings* screen, select any scan task in the protocol.

   If you are building a protocol, selecting the desired or next scan task moves you around in the protocol.

2. Make sure the orientation of the patient is the same as the scout.
   - If necessary, click the picture of the patient to change the patient position.
   - There may be times that you change the patient's position from the way that the protocol was built. In that case, you have to change the patient's orientation on the screen each time you advance to the next series.
   - You can also build the protocol with Copy Patient Orientation and Patient Position, Anatomical Reference.
3. Choose the *Scan Type*.
   - For an Axial or Helical scan, see the *Technical Reference Manual* for information about the scan parameters.
   - For a Hi Res scan, see *Acquire a Hi Res scan*.
   - For a Cardiac scan, see *Select a Cardiac scan*.
4. Set the start and end locations.
   - To graphically set the locations, see *Adjust the Graphic Rx*.
   - To explicitly set the locations, see *Set the Start and End locations*.
   - To set a specific number of images, see *Set a specific number of images*.
5. Choose the *Coverage Speed* options.
6. Set the *Image Interval*.
7. Set the *SFOV*.
8. Set the *kV*.
9. Set the *mA*.
10. Proceed to the *Set the Timing parameters* procedure.

4.5.2 Choose the Scan Type

Use this procedure to choose a Scan Type to specify how the scan data is acquired.

1. On the *Scan Settings* screen, click [Scan Type].
2. For Hi Res Mode, click [On] in combination with the Axial, Helical, or Cardiac mode to produce images with improved resolution in the x and y directions.
   - Hi Res mode is supported to enable collection of more views in x/y direction to support increased resolution using HD algorithms or improvement in IQ as a result of having more views, such as for off-center DFOV imaging.
   - The standard set of reconstruction algorithms are compatible with Hi Res acquisitions, however, the inherent resolution will be reduced to match non Hi Res acquisitions.
   - The Hi Res modes supported include the following:
     - Axial – 40, 80, 120, 140, 160 mm detector coverage
     - Helical

       0.516:1 pitch 40 mm detector coverage

       0.984:1 pitch 40 mm detector coverage
     - Cardiac Axial – 40, 80, 120, 140, 160 mm detector coverage
3. From the *Scan Type* screen, choose the desired Scan Type.
   - Click [Axial] for a step and shoot method.
     - Routine head studies typically use axial scans acquired with a 1 second rotation time.
     - Hi-Res chest studies may use axial scans acquired with a sub-millimeter (0.625 mm) slice.
   - Click [Helical] for a continuous table movement method.
     - A wide range of exam types use helical scans.
     - To stop a scan between multiple helical groups, press <Stop Scan> not <Stop Move>.
   - Click [Cine] when one location needs to be scanned over a period of time, such as for hemangioma studies.

     Full is continuous exposure that supports table movement equal to the beam collimation or no table movement, where the scan is taken at one table position.
   - Click [Cardiac] to help freeze motion of the heart and vascular structures with a helical-gated or cine-gated scan.

     If the scan type is changed from another scan type, the mA value automatically updates. Review it to be sure it is acceptable.
4. Click a [Rotation Time].
   - Axial – 0.4 s, 0.5 s, 0.8 s, 1.0 s

- Cine – 0.4 s, 0.5 s, 0.8 s, 1.0 s
- Helical – 0.4 s, 0.5 s, 0.8 s, 1.0 s
- Cardiac Axial – 0.28 s, 0.35 s

5. Click [OK].

4.5.3 Set the start and end locations

Start and End Locations are set in millimeters superior to, and/or inferior from, the anatomical reference point. The locations designate the points of anatomy to be scanned. The easiest way to set the Start and End locations for a scan is to turn on Show Localizer and adjust the scan range graphically. If specific locations are known, use this procedure designate the beginning and end points of the anatomy to be scanned.

1. On the *Scan Settings* screen, click [Start Location].
2. Type a beginning point.
   - The numbers must be preceded by the correct designation of “S” for superior (towards the head) from the centering point, or “I” for Inferior (towards the feet).
   - Plus [+] can be used for superior and minus [-] for inferior.
3. Click [End Location].
4. Type an end point.
   - The numbers must be preceded by the correct designation of “S” for superior (towards the head) from the centering point, or “I” for Inferior (towards the feet).
   - Plus [+] can be used for superior and minus [-] for inferior.

4.5.4 Set a specific number of images

The *Number of Images*, which set automatically by the system, is determined by the combination of Start and End Location, Slice Thickness, and Image Interval. Use this procedure if you require a specific number of images for the scan prescription.

1. On the *Scan Settings* screen, click [No. of Images].
2. Type the desired value.

   The system automatically adjusts the end location.

4.5.5 Choose the Coverage Speed options

Use this procedure to set the Coverage Speed options for detector coverage, image slice thickness, pitch, table speed, and rotation speed.

1. On the *Scan Settings* screen, click [Coverage Speed].
2. On the *Coverage Speed* screen, choose the slice thickness for the detector coverage.
3. Choose the slice thickness.

- Beam collimation:
- The smaller the slice thickness, the more technique you need to use. The thinner the slice thickness, the higher the noise will be in the slice. Adjust protocol factors to provide desired image quality and noise level for the acquisition.
- A thinner slice provides better detail. However, contrast resolution will be decreased.

4. Choose the pitch and speed for the Helical mode.
   - The pitch is the table travel in millimeters per rotation divided by the beam collimation.
     - 4 Row Interleaved provides a 40 percent mAs reduction, and is 1.5 to 3 times faster than single slice helical and has minimal helical artifacts, but interleaved pitch 0.5:1 provides only one third of the coverage compared to interspaced mode.
     - 4 Row Interspaced provides data acquisition 2 to 6 times faster than single slice helical, but requires more interpolation, more helical artifact, and only a 20 percent mAs reduction.
   - In the helical mode, the helical pitches include 0.531:1, 0.984:1, and 1.375:1.
5. Choose the images per rotation for Axial and Cine modes.

Table 6: Images per Rotation

Slice Thickness (mm)	Detector Coverage (mm)					
	5	40	80	120	140	160
5	1i	8i	16i	24i	28i	32i
2.5	2i	16i	32i	48i	56i	64i
1.25	NA	32i	64i	96i	112i	128i
0.625	NA	64i	128i	192i	224i	256i
0.625z	NA	128i	256i	384i	448i	512i

   - The choice for one determines the choices for the other. Some combinations are not allowed.
   - The choice for number of images determines the beam collimation and slice thickness. Some combinations are not allowed.
   - The choices you make for thickness and images per rotation determine the available reconstruction thicknesses.
6. Note the coverage time and coverage speed.
7. Click [Apply].

NOTE: The coverage time shown in the *Coverage Speed* screen does not account for breath hold and breathe times that have been prescribed in the protocol.

4.5.6 Set the Image Interval

The Image Interval is for helical scans only and is automatically set to match the slice thickness by the system. For Axial or Cine scan type, the interval is set to equal the detector coverage. The interval value can be increased but not decreased. If the interval is greater than the detector coverage, the gap is between each rotation of data, not between the slices. This is known as contiguous (back to back) scans. Use this procedure to set an Image Interval if you want a contiguous, overlapped, or spacing (skip) in the scan prescription.

1. On the *Scan Settings* screen, click [Interval].
2. Type an interval value in mm.
   - In the Helical mode, the table moves in mm per rotation, while exposing the patient.
     - The image interval defaults to equal the slice thickness.
     - The maximum interval is twice the slice thickness.
     - The interval can be less than or greater than the slice thickness.
   - In the Axial mode, the interval or spacing defaults to the equal number of images per rotations multiplied by the slice thickness.
     - The interval for axial scanning can be zero, equal to, or greater than the width of the detector configuration. Typical intervals used are 40 mm.
     - Axial interval with skip refers to a gap between scan groups. This can be useful, for example, when performing a survey exam, such as a high resolution chest exam.
   - In the Cine mode, for an interval greater than zero, scans are created at several locations and the end location changes.
     - The usual interval is equal to the beam collimation.
     - You can change the interval when setting up Primary Recons.
   - IQ Enhance is compatible with 0.625 mm and 1.25 mm slice thicknesses. Interval for acquisitions with IQ Enhance must be equal to the slice thickness (0.625 mm or 1.25 mm) or an overlap of 50% (0.312 mm or 0.625 mm).

4.5.7 Set the Scan Field of View

The Scan Field of View (SFOV) determines how much anatomy is scanned. Use this procedure to select a SFOV that covers the anatomy of interest. The SFOV should always be larger than the circumference of the patient, regardless of what part is being imaged.

1. On the *Scan Settings* screen, click [Anatomy Selection].
2. Choose an SFOV.
   - Click [Ped Head] to image infants 18 months or less in age. It allows you to enter up to a 32 cm DFOV and is limited to 42 kW. It has a special processing to correct for beam hardening effects.

- Click [Ped Body] to image to image infants 18 months or less in age. It allows you to enter up to a 32 cm DFOV and is limited to 30 kW.
- Click [Small Head] to image small heads up to 32 cm. It has a special processing to correct for beam hardening effects.
- Click [Head] to image adult heads up to 32 cm. It has a special processing to correct for beam hardening effects.
- Click [Small Body] to image small bodies, extremities that are centered middle of the gantry and the QA phantom. It allows you to enter up to a 32 cm DFOV.
- Click [Large Body] to image most adult body work. If you measure the anatomy that you are scanning and it measures over 30 cm, you need to use the large SFOV. It allows you to enter up to a 50 cm DFOV.
- Click [Cardiac Small], [Cardiac Medium] or [Cardiac Large] for cardiac studies.

NOTE: Image reconstruction includes native reconstruction to reduce artifacts from beam hardening.

4.5.8 Set the kV

Use one of the following procedures to set the kV for the imaging study.

4.5.8.1 Manual kV

Use this procedure to manually prescribe the kV.

1. On the *Scan Settings* screen, click [kV mA Control].
2. Select a kV value. Typical applications are listed below.
   - Click [70] kV for pediatric imaging.
   - Click [80] kV for Bone Mineral Densitomery and Perfusion imaging in the brain and pediatric imaging.
   - Click [100] kV for pediatric and small patient imaging.
   - Click [120] kV for routine imaging of the chest, abdomen, and pelvis areas.
   - Click [140] kV for imaging the posterior fossa, thick areas, and heavy patients.

4.5.8.2 kV Assist

Acquire a scan with kV Assist

See the Protocols chapter for information about kV Assist.

Use this procedure to prescribe a scan with kV Assist.

1. Select a protocol and verify the Manual kV, Noise Index/AutomA or Manual mA, Slice Thickness, Rotation Time, Pitch, SFOV, and WW/WL values are acceptable.

2. Specify the Clinical Task for the study.
3. From the kV and mA Control collection set the kV mode to [kV Assist].
4. Optional: To further refine the amount of dose savings for the mode selected, select a Dose Savings option.
5. Select [Optimize WW/WL] to adjust the protocol's reference WW and WL based on the expected change in image contrast and noise.
6. Review the resulting kV, Noise Index or Manual mA and WW/WL values to ensure they are acceptable.

4.5.9 Set the mA

Use this procedure to set the mA for the scan prescription.

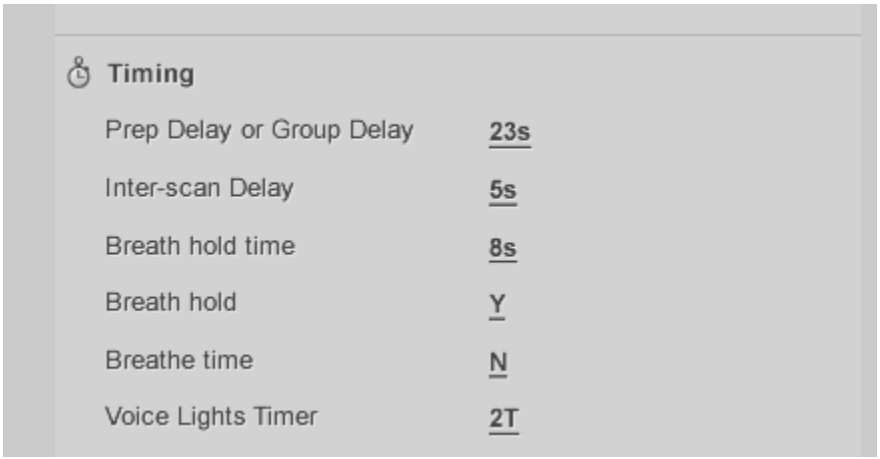
1. On the *Scan Settings* screen, click [kV and mA Control].
2. On the *kV and Control Settings* screen, choose an mA mode.
   - Set mA mode to [Manual mA] for manual mA and enter an mA value.
   - Set mA mode to [AutomA] to enable mA modulation in the Z-direction.
     - Select a Noise Index value that provides acceptable diagnostic quality. As the Noise Index increases the required mA decreases and image noise increases. The optimum strategy is to find the highest noise index sufficient for the clinical task and let AutomA select the mA without using significant constraints. Use a slightly lower noise index for small patients and a slightly higher noise index for large patients.
     - Enter a Min and Max value, which constrains the mA range used during the scan.
     - Select [SmartmA] to enable mA modulation in the XY-direction.
   - For cardiac scans, see guidelines for *AEC with Cardiac Modes*.
3. Select [Apply].
4. Review: From the scan monitor, select [Adjust] to view the calculated Z or X and Y values.
   - This can only be done at the time of scan set up and not in Protocol Management.
   - The system will display an indication when one or more rotations are at the Min mA or Max mA value specified for AutomA. If the system indicates this condition, check the scan parameters to ensure the acquisition will provide the expected results.

5 Timing Parameters

5.1 Timing Parameters screen

From the *Scan Settings* screen, click the [Timing] icon to display the Timing parameters screen.

Illustration 15: Timing Parameters screen



5.2 Timing parameters workflow

Use this procedure to set up the timing parameters in the scan prescription. The patient's condition has a significant effect on timing. Make sure that you know how long the patient can hold her breath. This helps when working with AutoVoice.

It is important to use injection delays. You can only inject once and you must get it right the first time. Different anatomy enhances at different rates. Check with your radiologist for the right injection delays.

1. From the *Scan Settings* screen, click the [Timing] icon.
2. If you need an injection delay, on the *Timing* screen set a Prep Delay time.
   - The range is 0 to 300 seconds for the first group and 600 seconds for any additional groups.
   - AutoVoice automatically sets Prep Delay time based on message length and Preset Delay Time set for the Voice, Lights, Timer selection.
3. If scanning in the Axial mode, set an Interscan Delay time.
4. For breath hold scans, set a Breath Hold time and set a Breathe Time, as needed.
5. Set the Voice/Lights/Timer options.
   - Multi-language selection in 9 languages are available for selection for system preset AutoVoice messages 1, 2, or 3.
   - ○ Preset Delay Time sets a delay from the time the message ends until the X-ray turns on. This is helpful for patients who need a longer time to follow breathing instructions.
6. To start the scan, click the [Confirm Settings] icon.

5.2.1 Set a Prep Delay time

The Prep Delay establishes how long the system waits before turning the X-ray on for a given group of scans. Use this procedure to set a Prep Delay time for giving contrast with a timed delay.

NOTE: The minimum Prep Delay may be affected by parameter choices: SFOV, Rotation Time, Pitch, and Start Location prescribed relative to the prior group. The system updates the group delay at *Scan Settings* to meet system requirements. Please check the system message bar on the right monitor before scanning.

1. From the *Scan Settings* screen, click the [Timing] collection icon.
2. In the *Timing* collection, click [Prep Delay].
3. Type a scan delay time in seconds.

NOTE: The system starts to acquire the scan after you press <Start Scan> and the Prep Delay time counts down to zero.
Start the injection at the same time as starting the scan to insure accuracy of when the intravenous (IV) bolus arrives in the appropriate anatomy.

The Prep Delay will be set to zero upon [Resume] after <Stop Scan> or <Pause Scan> is selected during the Prep Delay countdown.

5.2.2 Set the Interscan delay time

When the scan type selected is Axial, the Interscan Delay (ISD) becomes available. ISD allows time for the table to move the correct amount of millimeters that is set for the Image Interval. It can also be used for tube cooling by extending the time between exposures and allowing the heat to dissipate. Follow these steps to set an Interscan Delay time for an axial scan prescription.

1. From the *Scan Settings* screen, click the [Timing] collection icon.
2. In the *Timing* collection, click [Inter-scan Delay].
3. Type a scan delay time, in seconds, between each Axial scan. The valid range is 1 to 300 seconds.

   Typically, the ISD is set at 1 to 1.7 seconds so the exam is done as quickly as possible.

NOTE: ISD is not available with Helical types.

5.2.3 Set a Breath Hold Time

The Breath Hold parameter is the amount of time, in seconds, that your patient will hold her breath. Breath Hold, along the Breathe Time parameter, automatically divides all of your prescribed scans into Breath Hold scanning clusters. Use this procedure to set a Breath Hold time for how long the patient must hold her breath for each exposure.

1. From the *Scan Settings* screen, click the [Timing] collection icon.
2. In the *Timing* collection, click [Breath hold].
3. Type a value, in second, for how long the patient needs hold his breath.

- [Breath hold] and [Breathe time], can be used in conjunction in order to cluster scans within a group.
- The valid range for Breath Hold is N (None) or 1 to 120 seconds for Axial scans and 1 to 60 seconds for Helical scans.
- The valid range for Breathe Time is N (None) or 1 to 60 seconds.
- For better registration of the patient's anatomy, use a longer Breath Hold time.
- It is important that you practice with your patient to determine how long he can hold his breath.
- Typical Breath Hold times are 10 to 12 seconds.

NOTE: The coverage time shown on the *Coverage Speed* screen does not account for breath hold times that have been prescribed in the protocol.

5.2.4 Set a Breathe Time

Breathe Time is the amount of time, in seconds, you allow your patient to breathe in between breath hold clusters. Follow these steps to set a Breathe Time to allow the patient to breathe normally between breath holds.

1. From the *Scan Settings* screen, click the [Timing] collection icon.
2. In the *Timing* collection, click [Breathe time].
3. Type a value, in seconds, for how long you want to have the patient to breathe between groups of scans.
   - [Breath hold] and [Breathe time], can be used in conjunction in order to cluster scans within a group.
   - The valid range is N (None) or 1 to 60 seconds.
   - It is important that you practice with your patient to determine how long she can hold her breath.
   - Typical Breathe Times are 10 to 12 seconds.
   - If there is IV contrast being injected, it is important to consider the appropriate length of this delay and its effect on patient comfort. Make sure that the patient can breathe, but do not make the time gap between breaths too long otherwise you could lose the IV contrast.

NOTE: The coverage time shown on the *Coverage Speed* screen does not account for breath hold times that have been prescribed in the protocol.

6 Recon Parameters

Review and change Recon parameters from the *Scan Settings* screen on the scan monitor for Primary Recon and from the Image Display screen Reconstruction and Image Processing task list on the image monitor for Secondary Recons.

6.1 General Recon Parameters descriptions

6.1.1 Recon Type

Available Primary Recon Types are Quality Control, Normal, Hi Res, and Cardiac.

Quality Control images (QC) are reconstructed immediately after data acquisition. These images can be used to check that the anatomy of interest has been covered and the contrast enhancement is appropriate for the clinical need. QC images are not intended to be used for diagnosis.

Hi Res reconstruction algorithms provide the capability to select reconstruction algorithms that enhance the inherent resolution in Hi Res mode acquisitions or use the additional views to reduce aliasing artifacts, improve off-center DFOV imaging, and decrease streaking from dense structures. The algorithms that have a HD prefix added to the algorithm name provide increased resolution for DFOV of 25 cm or less. The normal algorithms can be used, which will not provide improved resolution but may be useful when large DFOV is used followed by a targeted reconstruction smaller DFOV, reducing aliasing and view spacing artifact.

6.1.2 Axial Plus and CINE Plus Recon Modes

The system provides a Plus recon mode for Axial and CINE scan types.

This mode is only available on Secondary Recons, can be optionally combined with ASiR-V, and is only available for collimations greater than or equal to 40mm.

Image annotation will identify this recon mode with a "+" sign near the Recon Type selected.

6.1.3 Cardiac Axial Plus Recon Mode

See Cardiac chapter.

6.1.4 Full and Plus Recon Modes for Helical scan types

The system provides the ability to manage dose, slice profile, and helical artifact through the Full and Plus recon modes.

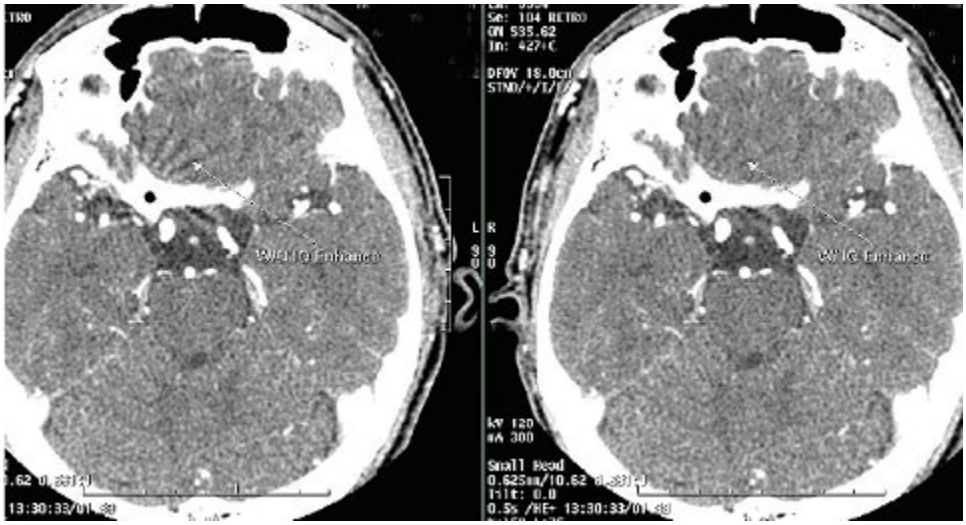
- Full mode provides a thinner slice profile but requires 10 to 15% more mA than Plus mode with equal image noise.
- Plus mode has up to a 20% wider slice profile than Full, but requires 15 to 20% less mA with equal noise. At the same mA, Plus mode provides reduced image noise.
    - Reduction of helical artifacts can be seen with Plus mode.
    - Plus mode uses additional views of data to reconstruct an image.

- When acquiring images in Plus mode, exposure time increases slightly to assure that enough views are collected to reconstruct all image locations prescribed.

6.1.5 IQ Enhance for Helical scan types

IQ Enhance is a special reconstruction process that can be prescribed to minimize artifacts commonly occurring in thin slice helical acquisitions. If you select the Helical scan type, IQ Enhance is available on the *Primary Recon* and *Secondary Recon* screens, if the slice thickness is 0.625 mm or 1.25 mm. The interval for these slice thicknesses must be equal to the slice thickness (0.625 or 1.25) or one half the slice thickness (0.312 or 0.625).

Illustration 16: Image Enhance images



An "*E*" displays on the image next to the annotation for recon algorithm to indicate IQ Enhance is enabled for the acquisition.

NOTE: IQ Enhance is not compatible with Axial or CINE scan types or cardiac gated acquisitions.

6.1.6 Flip and Rotate

The reconstructed orientation of an image can be changed from the default mode in Recon by selecting one of the following flip/rotate options on the *Primary Recon* and *Secondary Recon* screens.

- None
- FLR (Flip Right/Left)
- FTB (Flip Top/Bottom)
- FLR/FTB (Flip Right/Left and Top/Bottom)

NOTE: Flip/Rotate options can not be selected for images being acquired in the decubitus patient positions.

NOTE: Flip/Rotate options are only available after service checks that the viewing stations will display the data correctly.

6.1.7 Copy Forward

Copy Forward provides the capability to define a set of parameters:

- Orientation
- Start and End Locations
- Interval
- DFOV
- R/L Center
- A/P Center

To be copied from Primary Recon and into one or more Secondary Recons (two through ten).

Typing a **D** or **d** (duplicate) into parameter text boxes applies Copy Forward.

Where Copy Forward has been used in Secondary Recons for the Start and End Locations, the system keeps the range equal to that of the Primary Recon (Recon 1).

To copy the Patient Position and Patient Orientation, click the *Patient Settings* collection and select to copy Patient Position and Patient Orientation.

When the protocol is used in a New Patient exam at scan time, the fields where Copy Forward has been defined will be identified with "*C*" just to the right of the setting.

To override Copy Forward, click in the text box and type the desired parameters.

6.1.8 Primary Recon parameters workflow

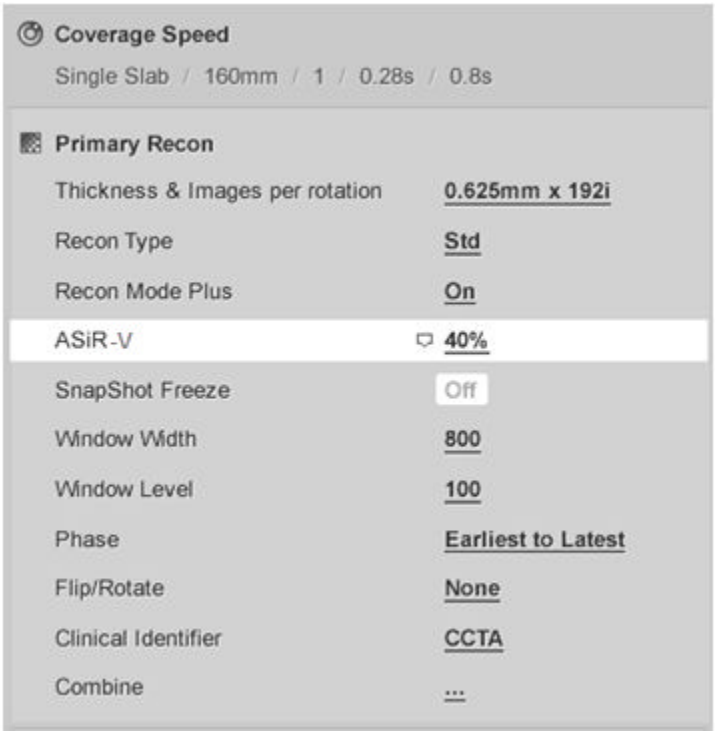
Most of the recon parameters are set from the protocol and from the adjustments that you made with the graphic lines on the scouts. When setting the recon factors, it is important to know what you are specifically looking for. If you are looking for fractures, you would want to use a different set of parameters than if you were looking for a mass.

6.2 Primary Recon Collection

From the *Scan Settings* screen, click on the *Primary Recon* settings collection title or icon to open it.

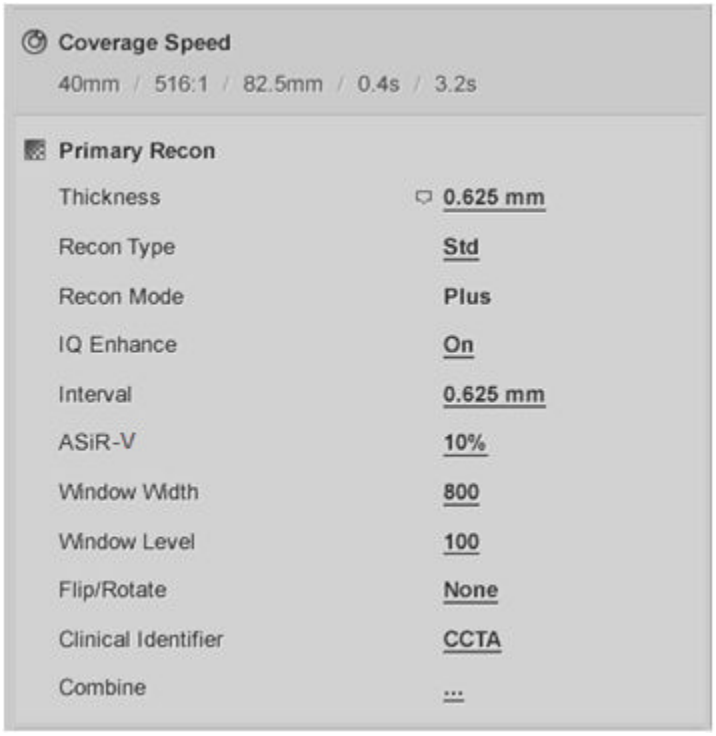
In general, settings collections can be opened by clicking the setting collection title or icon.

Illustration 17: Primary Recon Collection - Axial



Element	Description
Thickness & Images per rotation	Image thickness and the number of images created with each Axial rotation.
Recon Type	Reconstruction algorithms.
Recon Mode	Additional reconstruction image adjustments.
ASiR-V	See ASiR-V section for more information.
SnapShot Freeze	Only available for Cardiac Axial. See Cardiac chapter.
Window Width	Window Width/Level can be defined for the different groups.
Window Level	Window Width/Level can be defined for the different groups.
Flip Rotate	See Section 1.6.
Phase	Only available for Cardiac Axial, see Cardiac chapter

Illustration 18: Primary Recon Collection – Helical



Element	Description
Thickness	Image thickness.
Recon Type	Reconstruction algorithms.
Recon Mode	Additional reconstruction image adjustments.
IQ Enhance	See Section 1.5.
Interval	Image interval.
ASiR-V	See ASiR-V section for more information.
Window Width	Window Width/Level can be defined for the different groups.
Window Level	Window Width/Level can be defined for the different groups.
Flip Rotate	See Section 1.6.

6.3 Primary Recon parameters and workflow

Most of the recon parameters are set from the protocol and from the adjustments that you made with the graphic lines on the scouts. When setting the recon factors, it is important to know what you are specifically looking for. If you are looking for fractures, you would want to use a different set of parameters than if you were looking for a mass.

NOTE: For Primary Recon: Display Field of View (DFOV), R/L Center, and A/P Center are adjusted from the *Anatomy Selection* collection, located on the *Scan Settings* screen on the scan monitor.

6.3.1 Set the Display Field of View, DFOV

Follow these steps to enter a DFOV that covers the anatomy of interest. This allows you to target a particular piece of anatomy for display and determines how much of the SFOV is reconstructed into an image. Within the DFOV, an image center must be set with the R/L Center and A/P Center.

1. From the *Scan Settings* screen, click the *Anatomy Selection* collection title or icon.
2. Click [DFOV].
3. In the field, enter the value of the patient's measurements.
   - Measure the patient at the widest point and add 2 cm. This shows all the anatomy and the soft tissue around the anatomy.
   - If an R, L or A, P value is more than half of the DFOV, then the R/L, A/P image annotation does not display on the images. For example, if the DFOV is 10 cm and the R value is 56 mm then the image annotation displays *R*. Use a R-L or A-P value that is less than half of the DFOV in mm to avoid this.
   - The minimum DFOV is 5.0 cm.
   - The maximum DFOV depends on the selected SFOV.

NOTE: Alternatively, set the DFOV graphically. On the Show Localizer image, click and drag the diamond handles to increase or decrease the DFOV. The system automatically updates the value in the feature area.

6.3.2 Set the R/L Center coordinates

Follow the steps below to set the R/L Center parameter, which allows you to define the DFOV center of the image in the Right/Left directions relative to iso-center of the SFOV. This is useful for minor adjustments to imperfections in centering the patient on the table or if an offset structure such as the spine or kidney is what you want centered. If large adjustments are needed, then you should consider repositioning the patient on the table.

1. From the *Scan Settings* screen, click the *Anatomy Selection* collection title or icon.
2. Click [R/L Center].
3. To find the coordinates, place the mouse over the Show Localizer Anterior/Posterior (AP) scout image and look at the Right (R) and Left (L) readout at the bottom of the image.

   Continuous Report Cursor in Exam Rx Display Preferences must be turned on.
4. In the text edit field, type an **R** or **L** prefix and the R/L center coordinates, in millimeters.
   - The range of values can be from 0 to one-half the SFOV (e.g. Head SFOV is 32 cm so the maximum offset R/L is 16 cm or 160 mm). Typically, you would not want the offset to exceed one-half the DFOV or the resulting image does not show a right or left marker; it does show markers as R-R or L-L.
   - Entering a value other than zero off centers the image in the right and left axes of the patient.

- Plus <+> can be used for R values and Minus <-> for L values for faster data entry using the ten key pad.

NOTE: Alternatively, the R/L Center may be set graphically by using the X annotation on the AP scout image reference lines. Press and hold <Shift>, and then click and drag the X to center over the area of interest.

6.3.3 Set the A/P Center coordinates

Use this procedure to set the *A/P Center* parameter, which allows you to define the DFOV center of the image in the Anterior/Posterior directions relative to the SFOV. This is useful for minor adjustments to imperfections in centering the patient on the table or if an offset structure such as the spine or kidney is what you want centered. If large adjustments are needed, then you should consider repositioning the patient on the table.

1. From the *Scan Settings* screen, click the *Anatomy Selection* collection title or icon.
2. Click [A/P Center].
3. To find the coordinates, place the mouse over the Show Localizer lateral scout image and look at the Anterior (A) or Posterior (P) readout at the bottom of the image.

   Continuous Report Cursor in Exam Rx Display Preferences must be turned on.
4. In the field, type and Enter ***A*** or ***P*** prefix and the A/P Center coordinates, in millimeters.
   - The maximum offset for A/P Center is one half the SFOV from isocenter selected (e.g. Head SFOV is 32 cm so the maximum offset A/P is 16 cm or 160 mm).
   - Entering a value other than zero off centers the image in the anterior and posterior axes of the patient.
   - Plus <+> can be used for A values and Minus <-> for P values for faster data entry using the ten key pad.

NOTE: Alternatively, the A/P Center may be set graphically by using the X annotation on the lateral scout image reference lines. Press and hold <Shift>, and then click and drag the X to center over the area of interest.

6.3.4 Set the Recon Type

Use this procedure to set the Recon Type to designate the algorithm used for reconstruction of the images.

1. From the *Scan Settings* screen, click the [Primary Recon] collection icon.
2. Click [Recon Type].
3. Select the appropriate algorithm for the primary or first reconstruction.
   - The algorithms from left to right increase spatial resolution and decrease low contrast detectability.
   - Selections include:

Smooth, Soft, Stnd, Detail, Lung, Bone, Bone+, Edge, and Chest

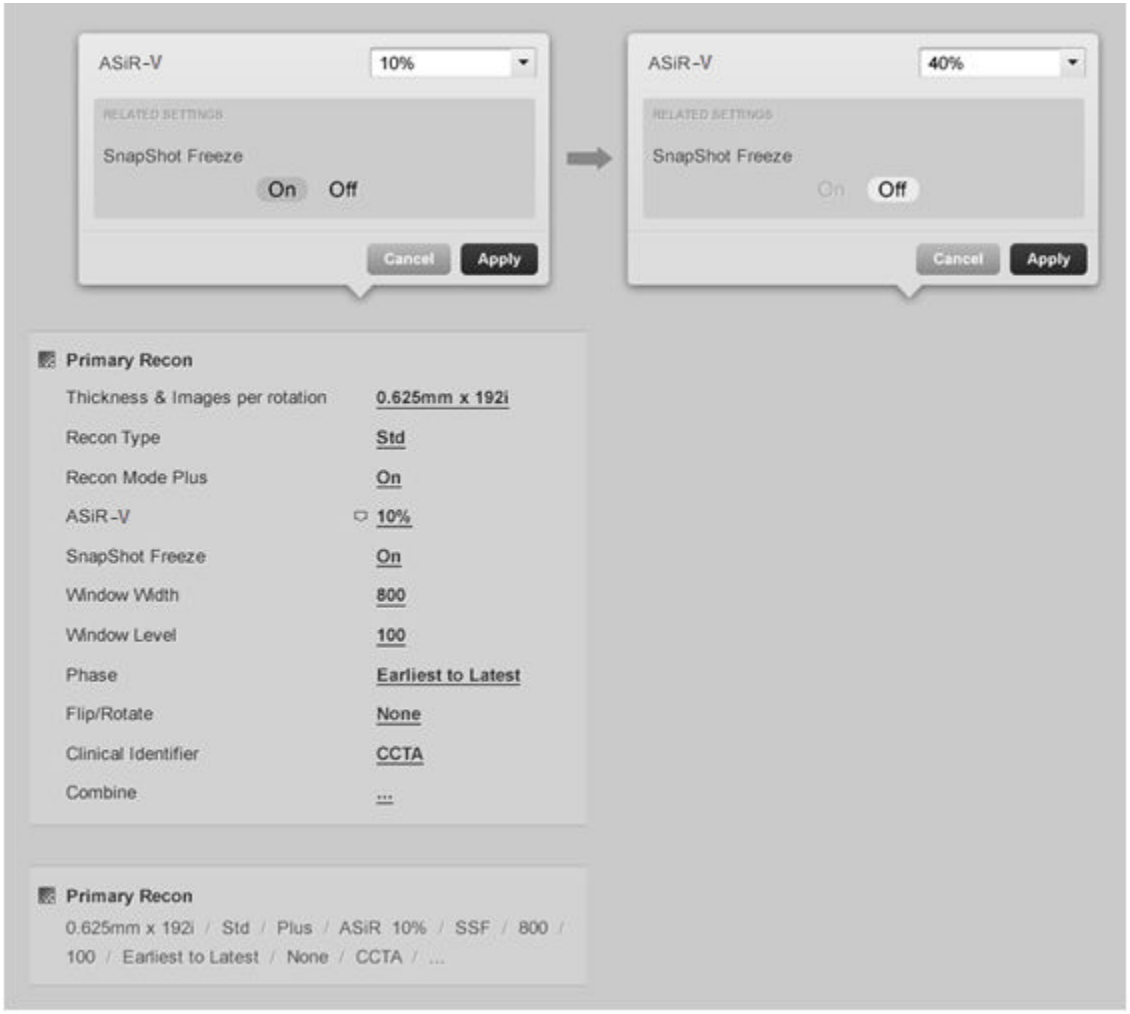
- Click [Soft] for tissues with similar densities, but not useful for un-enhanced scans.
- Click [Stnd] for routine exams, e.g., chest, abdomens, and pelvis scans.
- Click [Lung] for interstitial lung pathology.
- Click [Detail] for post myelograms, where hybrid tissue detail and bone edges are important.
- Click [Bone] for high resolution exams and sharp bone detail.
- Click [Bone Plus] for sub mm detailed head work. It can be used for any study that normally used the bone algorithm, but is very useful in cases where the Edge algorithm was used. This is because the Bone Plus algorithm has no reconstruction penalty and is very close in standard deviation to Edge.
- Click [Edge] for small bone work in the head, as well as high resolution scans.
- Click [Chest] for mediastinum and lung detail studies. It provides soft tissue resolution and contrast when viewing the images in a soft tissue/mediastinal W/L1 and high resolution of the lung tissue when viewing the images in a lung W/L.

4. If Hi Res mode is enabled, select a higher resolution algorithm that has similar characteristics to the non-Hi Res algorithms.
   - HD Stnd
   - HD Lung
   - HD Detail
   - HD Bone
   - HD Bone Plus
   - HD Ultra
   - HD Edge
5. If Cardiac Hi Res mode is enabled, select a higher resolution cardiac algorithm that has the same characteristics as the non-Hi Res cardiac algorithms.
   - HD Soft
   - HD Stnd
   - HD Lung
   - HD Detail
   - HD Stnd Plus
   - HD Detail Plus

- HD Edge

6.3.5 Recon Options for Axial, Cardiac Axial, and CINE scan types

Illustration 19: Recon Options screen progression for Axial scan types



For Axial scan types, the Recon Mode is set to *Full* by default.

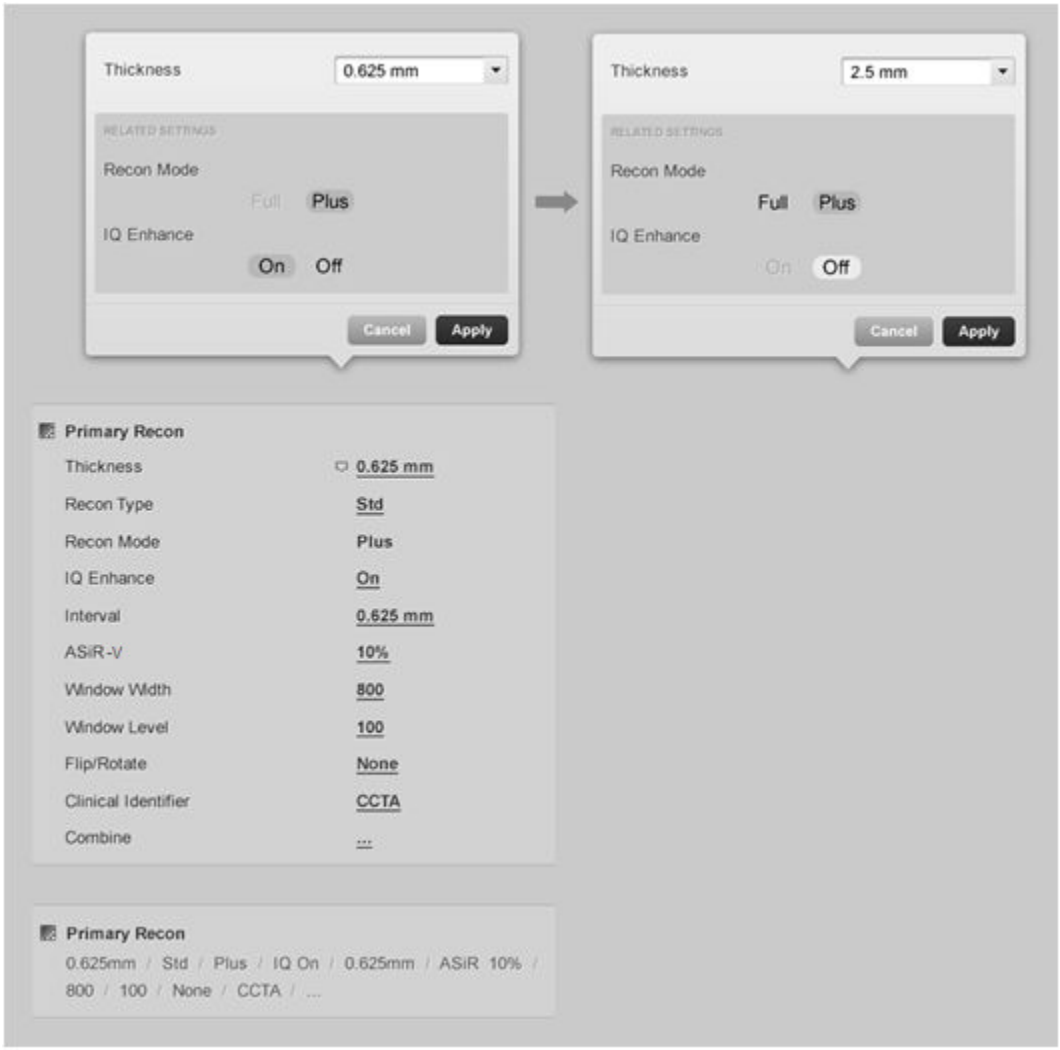
To adjust the Recon Mode, open the *Primary Recon* settings collection and click *Recon Mode* to select the Plus option [On] or [Off].

SnapShot Freeze and Phase for Cardiac Axial

See the Cardiac chapter.

6.3.6 Set Recon Options for Helical scan types

Illustration 20: Recon Options screen progression for Helical scan types



6.3.6.1 Recon Mode Full or Plus

To adjust the Recon Mode, open the *Primary Recon* settings collection and click *Recon Mode* to select either [Full] or [Plus].

NOTE: Plus Recon mode is not annotated on the Series Text Page.

Full mode is not allowed with 0.625 mm slice thickness at either 0.984:1 pitch or 1.375:1 pitch.

6.3.6.2 IQ Enhance

To adjust IQ Enhance, open the *Primary Recon* settings collection and click *IQ Enhance* to select either [On] or [Off].

IQ Enhance is used to minimize helical artifacts seen in helical thin slice images.

IQ Enhance is allowed with both 0.625 mm and 1.25 mm slice thickness, and the image interval can either be 50% or 100% of the slice thickness.

IQ Enhance annotation is added to the left side of the image.

6.3.7 ASiR-V for all scan types

To enable ASiR-V and select an ASiR-V level in percentage, follow the steps below.

1. Open the *Primary Recon* settings collection.
2. Click *ASiR-V*.
3. Select the desired ASiR-V percentage level and click [Apply].

6.3.8 Window Width and Window Level for all scan types

1. To adjust Window Width, Window Level, or both, open the *Primary Recon* settings collection.
2. Click on *Window Width* and type the desired value in the text edit field.
3. Click on *Window Level* and type the desired value in the text edit field.

6.3.9 Flip and Rotate for all scan types

1. To adjust Flip and Rotate, open the *Primary Recon* settings collection.
2. Click on *Flip / Rotate* and choose the desired selection.

   To flip or rotate the image in recon so the image will be reconstructed in the orientation desired for viewing, select one of the following options:

   - FLR (Flip Right/Left)
   - FTB (Flip Top/Bottom)
   - FLR/FTB (Flip Right/Left and Top/Bottom)

The Flip/Rotate option is turned off when software is delivered. A service representative can enable Flip/Rotate once you are sure that remote viewing stations display the flipped and rotated images correctly.

Images are annotated with:

- FI: LR
- FI: TB
- FI: Rotate 180

All Flip/Rotate annotations display on the left side of the image when prescribed in recon.

NOTE: Flip/Rotate and non-Flip/Rotate images can not be mixed in the same series.

NOTE: If Flip/Rotate in Recon and Continuous Cursor are enabled on a system, the RAS coordinates displayed on the left side of the image have the Flip/Rotate annotation intermixed with the RAS information. If Flip/Rotate was not applied to the image, there is a blank space in between the RAS information.

6.4 Secondary Recon Parameters

The system allows you to have up to nine additional secondary reconstructions of your scan groups that uses all or any portion of a group or across groups to change several of the reconstruction parameters.

These parameters for Axial scan types include:

Element	Description
Thickness & Images per rotation	Image thickness and the number of images created with each Axial rotation.
Recon Type	Reconstruction algorithms.
Recon Mode	Additional reconstruction image adjustments.
ASiR-V	See ASiR-V section for more information.
SnapShot Freeze	Only available for Cardiac Axial. See Cardiac chapter.
Window Width	Window Width/Level can be defined for the different groups.
Window Level	Window Width/Level can be defined for the different groups.
Flip Rotate	See Section 1.6.
Phase	Only available for Cardiac Axial, see Cardiac chapter

These parameters for Helical scan types include:

Element	Description
Thickness	Image thickness.
Recon Type	Reconstruction algorithms.
Recon Mode	Additional reconstruction image adjustments.
IQ Enhance	See Section 1.5.
Interval	Image interval.
ASiR-V	See ASiR-V section for more information.
Window Width	Window Width/Level can be defined for the different groups.
Window Level	Window Width/Level can be defined for the different groups.
Flip Rotate	See Section 1.6.

These parameters may be automatically copied from the first prospective reconstruction.

Rather than relying on creating additional reconstructions post scan for additional data sets, you are able to create these sets prospectively. This frees the operator from sitting at the console, directly contributes to increased productivity, and reduces the opportunity for error.

Secondary reconstructions are assigned sequential series numbers based on the series they are prescribed in, e.g., in the scenario where Series 2 has three additional secondary reconstructions, these are listed in the task list display indented from the original series. These reconstructions become Series 3, 4, and 5 in the exam.

To add a Secondary reconstruction, from the display monitor select the drop down selection on the right of the recon task, in the Reconstruction and Image Processing task list, select Duplicate Recon or select Add Recon for a particular series. Follow the primary reconstruction workflow to set the reconstruction parameters.

A reformat step can also be added on secondary reconstructions. Refer to the Display Applications chapter.

6.4.1 Graphic Retro

Graphic Retro provides the capability to graphical prescribe your retrospective reconstructions using an existing Axial plane image as a reference image.

6.4.2 Overlapped Axial Recon mode

The system supports the reconstruction of overlapped data from Axial scan type 40, 80, 120, 140, 160 mm detector coverage. The reconstruction of overlapped axial data can improve reformatted data. The interval cannot be adjusted.

Images reconstructed with the 0.625 Z recon mode will be annotated with a Z in the upper-left area of the images.

Illustration 21: Image annotation for Overlapped Axial Recon mode

6.4.3 Secondary Recon Slice Thickness

- Axial:
  - 5 mm detector coverage — 5.0 mm
  - 40 mm detector coverage — 0.625 mm, 0.625 z, 1.25 mm, 2.5 mm, 5.0 mm
  - 80 mm detector coverage — 0.625 mm, 0.625 z, 1.25 mm, 2.5 mm, 5.0 mm
  - 120 mm detector coverage — 0.625 mm, 0.625 z, 1.25 mm, 2.5 mm, 5.0 mm
  - 140 mm detector coverage — 0.625 mm, 0.625 z, 1.25 mm, 2.5 mm, 5.0 mm
  - 160 mm detector coverage — 0.625 mm, 0.625 z, 1.25 mm, 2.5 mm, 5.0 mm

- CINE:
  - 40 mm detector coverage — 0.625 mm, 1.25 mm, 2.5 mm, 5.0 mm
  - 80 mm detector coverage — 0.625 mm, 1.25 mm, 2.5 mm, 5.0 mm
  - 120 mm detector coverage — 0.625 mm, 1.25 mm, 2.5 mm, 5.0 mm
  - 140 mm detector coverage — 0.625 mm, 1.25 mm, 2.5 mm, 5.0 mm
  - 160 mm detector coverage — 0.625 mm, 1.25 mm, 2.5 mm, 5.0 mm
- Helical:

  40 mm detector coverage — 0.625 mm, 1.25 mm, 2.5 mm, 3.75 mm, 5.0 mm
- Cardiac Axial:
  - 40 mm detector coverage — 0.625 mm, 2.5 mm
  - 80 mm detector coverage — 0.625 mm, 2.5 mm
  - 120 mm detector coverage — 0.625 mm, 2.5 mm
  - 140 mm detector coverage — 0.625 mm, 2.5 mm
  - 160 mm detector coverage — 0.625 mm, 2.5 mm

7 AutoVoice

AutoVoice provides recorded breathing instructions to your patient and pre-message with SmartPrep. This allows for consistent breathing instructions, which assists in more precise timing during an exam. Your system also comes equipped with microphones at the console and gantry for communication with the patient.

The system has three, pre-recorded message sets in nine selectable languages that cannot be deleted. You can also record up to 17 additional messages for each language.

The default language for AutoVoice is set by service in Reconfig. The default language can be set to:

- English Male
- English Female
- Japanese
- French
- German
- Spanish (European)
- Spanish (Latin America)
- Italian
- Korean
- Chinese

7.1 AutoVoice workflow

Use the AutoVoice feature to provide automated breathing instructions to your patients.

1. Set the AutoVoice language. Add an AutoVoice language if necessary.
2. Record an AutoVoice message.
3. Change AutoVoice preset delay.
4. Delete an AutoVoice message, if necessary.

7.2 Set the AutoVoice language

Use this procedure to set the language for AutoVoice.

1. From the Patient Orientation Area (on the Scan Settings screen), click [Language].
2. Select the desired AutoVoice language from the dropdown list. This selection will apply to all AutoVoice selections for the exam.

7.3 Add an AutoVoice Language

Use this procedure to add a user AutoVoice language.

1. From the right monitor, click the Mode icon  .
2. Click [AutoVoice Management].
3. To add a language, click the AutoVoice Management context drop down menu and then select [Add Language].
4. Type the desired name for the language. The Language Name is saved only if a message is recorded and [Save] is clicked.

7.4 Set the Voice/Lights/Timer options

Use this procedure to set the Voice/Light/Timer settings so that the system will automatically give the breathing instructions to the patient according to the Breath Hold, Breathe Time, and Total Exposure Time. If the Total Exposure Time is less than the Breath Hold time, the system uses only the time needed for the exposure. The Light and Timer features are visible on the gantry if these features are selected for use.

1. From the *Scan Settings* screen, click the [Timing] icon.
2. On the *Timing* screen, click [Voice Lights Timer].
3. Select the commands you want to use for breathing instructions.
   - Three prerecorded voices are available in nine languages.
   - You can record additional voice instructions. See *Record an AutoVoice message*.
   - You can set an AutoVoice preset delay.
   - You can choose breathing lights and/or a timer.
4. Turn on [Lights], [Timer], or both.
5. View the color indicator to review your selections.
6. Click [OK].

7.5 Change the AutoVoice preset delay

The Preset Delay adds a delay between the completion of the Pre-scan message and X-ray on. This delay can be set per protocol. Use this procedure to set the preset delay before the AutoVoice message is played.

1. From the *Scan Settings* screen, click[Voice Lights Timer].
2. On the pop-up screen, click the time next to *Preset Delay Time*.
3. On the *Preset Delay* screen, click to select the delay time.

   The valid range is 0 to 7 seconds.

4. Click [OK].

8 Additional Scan Features

8.1 Add or delete a group

The following procedures can only be used during a scan.

8.1.1 Add a group

Use this procedure to insert another set of images following the prior group with all of the same factors, except for the Start and End locations within the same series.

From the *Scan Settings* screen, right-click on the last task in the series.

- Each time you click [Add Group], a new group is added.
- The start location of the new group is automatically set contiguous to the end of the prior group.
- The end location is determined by the number of slices, slice thickness, and image interval.

8.1.2 Delete group

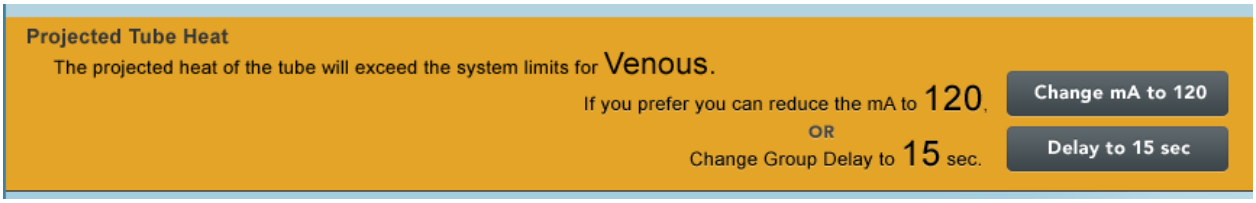
To remove an entire group from a series, follow these steps.

1. Right-click on the group you want to delete.
2. Click [Delete Selected Group].

8.2 Optimize technical parameters

If the system cannot complete the entire scan prescription with the technical parameters that you have selected, an Optimize message bar appears just above the Projected Dose display.

Illustration 22: Optimize message bar with mA and Group Delay options



At this point, you can select the choice that is most reasonable for your patient exam.

1. On the Optimize message bar, select a parameter that is best for your prescription.
    - Only one parameter (Up Front Delay, mA, or Group Delay) has to change for the scan to continue.
    - Up Front Delay is the time before you can proceed with scanning.
        - This parameter can be changed by the amount shown in the [Delay] button selection.
        - The [Start Scan] button is not active until the Up Front Delay time expires.
    - The mA parameter can be changed to what displays in the [Change mA] button selection.

- If you choose to reduce mA, you may be reducing image quality.
- Make sure that you always use enough mA to get the best image quality.

- The Group Delay parameter can be changed to what displays in the Delay button selection.
- Adjust the Prep delay based on instructions for Voice/Lights/Timer.
- If multiple groups are prescribed, the Optimize screen updates for each group, allowing you to make choices for each group.
- Once you have made choices that satisfy the system without compromising image quality, a message displays that tube cooling is no longer needed.

2. Click the [Confirm Settings] icon to start the scan.

8.3 Optimize patient dose

For years GE has followed the *As Low as Reasonably Achievable* (ALARA) principle in helping our customers optimize dose. GE has provided many tools to help the clinician minimize dose while achieving clinically diagnostic image quality.

GE CT is a proven leader in delivering dose efficiency in every scanner category. GE has achieved this position through a "total system" approach. The following features are some of the features that contribute to our "total system" approach and affect patient dose. Not all features are available on each system.

8.3.1 Pediatric Protocols

The pediatric protocols are based upon a child's size, age, and weight and tailor the dose or treatment to the size of the patient.

The Head and Orbit categories are age based. The rest of the categories are height and weight based protocols.

8.3.2 AutomA/SmartmA

AutomA/SmartmA modulates X-ray tube mA to account for specific patient anatomy based on data gathered from the scout image. You input the desired image quality (Noise Index) and the system adjusts the mA to achieve this within the bounds of the inputted minimum and maximum mA.

8.3.3 Organ Dose Modulation (ODM)

By modulating the x-ray tube current as a function of x-ray tube angle, Organ Dose Modulation (ODM) enables targeted reduction of the x-ray tube current towards the anterior surface of the patient, providing enhanced dose reduction to radio-sensitive organs of the patient while maintaining overall image quality.

8.3.4 AEC with Cardiac Modes

AutomA modulates X-ray tube mA to account for specific patient anatomy based on clinical task and data gathered from the scout image. You input the desired image quality (Noise Index) and the system adjusts the mA to achieve this within the ECG-based mA profile.

8.3.5 SmartHelical

SmartHelical is integrated into all GE CT systems. It decreases image noise as measured by pixel standard deviation.

8.3.6 Advanced Artifact Reduction (AAR)

A filter that significantly reduces streaking artifacts when highly absorbent objects are in the field of view, e.g., large shoulders. AAR is automatically enabled as needed.

8.3.7 Adaptive Statistical Iterative Recon (ASiR-V)

The next generation ASiR-V is a reconstruction technology that may allow for reduced mA in the acquisition of diagnostic images thus, enabling the physician to reduce the patient dose depending on the clinical task, patient size, anatomical location, and clinical practice.

8.3.8 kV Assist

kV Assist provides capability for adjustment of kV and NI/mA based on clinical task of the protocol and patient size, in order to optimize patient dose.

8.3.9 Auto Gating Configuration

Auto Gating uses the Scout to evaluate patient attenuation to calculate patient size and a kV/mA table for selection kV, mA, SFOV, and ASiR-V level for the protocol.

8.3.10 Dose Reports

$CTDI_{vol}$, DLP , Dose Efficiency are displayed during scan prescription and provides patient dose information. The CTD_{Ivol}, DLP, and phantom size used to calculate dose are automatically saved once you end the exam. The Dose Report is saved as a DICOM Secondary Screen Capture in Series 999. This series can be filmed, archived, and networked after the scan is completed.

DICOM Structured Dose Report generates a CT Dose Report, which can enable tracking of dose for the patient by the hospital radiation tracking system/RIS/HIS.

8.4 View the Dose Report

$CTDI_{vol}$, DLP, and Dose Efficiency are displayed during scan prescription to provide patient dose information.

8.4.1 Prerequisites

Before DICOM Structured Dose Report is turned on, confirm that your PACS or other receiving station supports structured reports.

Contact your service representative to enable DICOM SR Dose Report.

8.4.2 Dose Report Generation

Upon closure of the exam:

- The $CTDI_{vol}$, DLP, and Phantom size used to calculated dose are automatically saved.

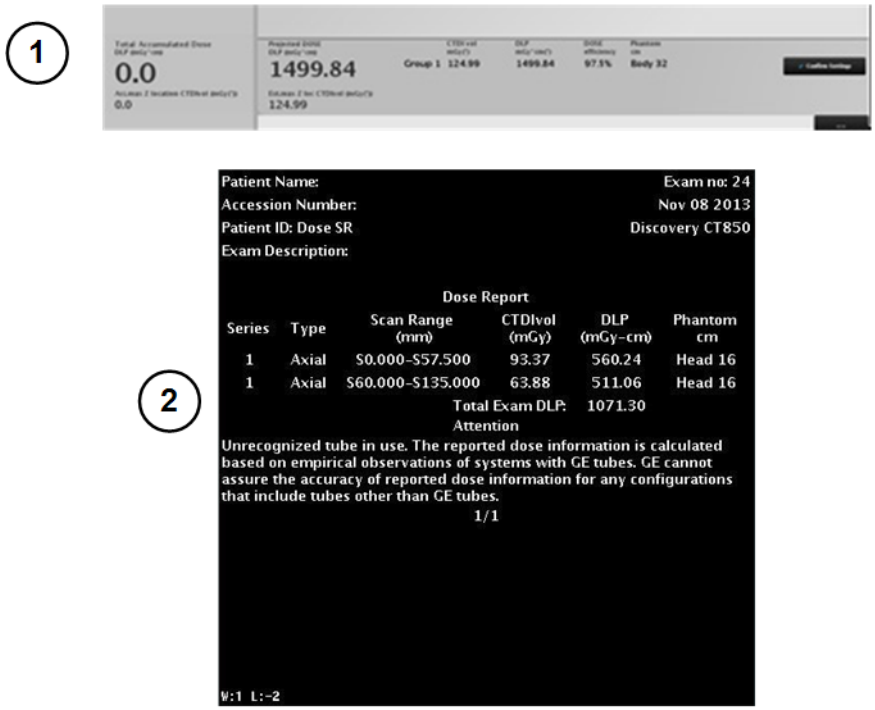
- DICOM Structured Dose Report generates a CT Dose Report which can enable tracking of the patient's dose information with the hospital radiation tracking system/RIS/HIS.
- The DICOM SR Dose Report is saved as part of the patient's exam in Series 997. It can be configured to either a Radiation Dose SR SOP or an Enhanced SR SOP.

  The DICOM SR Dose Report cannot be opened on the scanner. It can be reviewed and printed using the Reporting Tool on the Advantage Windows workstation or any station that can read a DICOM Structured Report. It cannot be saved to DVD or CD on the Advantage Workstation (AW) system (4.4 or lower).
- The Dose Report is saved as a secondary capture image in series 999. It can be filmed, archived, and networked after the scan is completed.

  NOTE: If Edit Patient is performed on an exam, the Dose Report and Dose SR report will be excluded from the Edited Patient Information due to the format of these files.

8.5 Dose Information

Illustration 23: Dose Information



Number	Description
1	Dose on Scan screen

2	Dose Report

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Chapter 12 Scan Applications

1 Overview

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

The following applications can be applied in Scan. If an application is not available, it may not be included with your system options.

2 ASiR-V

2.1 ASiR™-V Theory

ASiR-V is a reconstruction technique designed to reduce pixel-noise standard deviation in clinical images while preserving the structure details in the image. The ASiR-V noise reduction technique may let you reduce the X-ray dose, while maintaining acceptable image noise levels, or it can be used to improve images with an unacceptable level of noise.

Reconstruction of ASiR-V images involves defining the level of noise reduction desired for the parameters used for various applications. Image reconstruction is a blending of the original image and a percentage of an image with 100% noise reduction. There are 10 blending levels available which are simply the amount of noise reduction based on the maximum of the 100% image reconstructed with the original image data. It is expected that confidently selecting the optimal amount of noise reduction and integrating the reduction in dose will require some adapting on how this reconstruction technique works.

The software does not make the noise level changes or mA adjustment automatically. These changes need to by calculated and set by the user.

Before using ASiR-V, the site Physicist, in collaboration with the Radiologist, should conduct image quality evaluations with varying degrees of ASiR-V and difference scan techniques, both at routine dose and decreased dose. This should be done using your site's preferred method and phantoms. Using this information, an appropriate starting point for ASiR-V level and diagnostic scanning techniques can be incorporated into your site's User Protocols.

A general guideline for parameter step adjustment is:

Dose Reduction increments of about 20% ASiR-V level increments of 10%.

Whether ASiR-V is used for dose reduction or image quality improvement, parameter settings should be made in steps and then reviewed for diagnostic image quality until the desired clinically appropriate image quality is achieved.

2.2 ASiR-V Image annotation

ASiR-V level and mode are annotated on the image with text that defines the mode and level. The annotation is displayed in the upper-right corner of the image next to the Recon Type.

The annotation format is as follows:

- AR - ASiR-V mode
- 10% - 100%, which is the percentage of the 100 percent ASiR-V image that was blended with the original to reduce the noise in the ASiR-V images.

For example, AR60 denotes ASiR-V reconstruction mode with 60% of the 100% ASiR-V was blended with the original image.

NOTE: ASiR-V annotation information is not displayed in Advantage Workstation (AW) applications on the operator console.

2.3 Acquire a scan

Use this procedure to acquire data where ASiR-V noise reduction reconstruction will be used. ASiR-V is a reconstruction technique designed to reduce pixel-noise standard deviation in clinical images while preserving the structure details in the image. The ASiR-V noise reduction technique may let you reduce the X-ray dose, while maintaining acceptable image noise levels, or it can be used to improve images with an unacceptable level of noise. ASiR-V is prescribed in 10 percent increments for 10 percent to 100 percent. ASiR-V mode is annotated AR xx.

Keep the following in mind when selecting an ASiR-V recon mode: ASiR-V is not compatible with any of the real time interactive image modes such as SmartPrep.

Scan with ASiR-V

1. Prescribe the scan.
2. To enable ASiR-V and select an ASiR-V level in percentage open the Primary Recon settings collection by clicking the Primary Recon title or icon. Click [ASiR-V].
3. Select the desired ASiR-V percentage level and click [Apply].

   If you want to use ASiR-V to maintain image quality but reduce dose, from the kV and mA Control settings collection, reduce mA or increase noise index value.
4. Start the scan.

3 Direct Multi Planar Reformat (DMPR)

Direct Multi Planar Reformat (DMPR) allows you to move from the usual 2D image review mode to a prospective 3D image review mode in the axial, sagittal, coronal, and oblique planes. You can also automatically create batch reformats using predefined reformat protocols and network reformatted images to selected reading locations, reducing total exam time and increasing productivity.

DMPR displays images in anatomical orientation where anterior is at the top, posterior is at the bottom, right is on the left and left is on the right. For example, if you have a data set where the patient was scanned prone, the image display is automatically set to this orientation.

Reformat protocols can be applied in three ways:

- Automatically – the reformat protocol is defined before the scan takes place and runs as the scan is acquired.
- Semi-automatically – the reformat protocol is defined before the scan takes place but requires manual prescription of the slices before it is run.
- Manually – the reformat protocol is defined after the scan is acquired.

No matter how reformats are applied, they appear in the Reconstruction and Image Processing Task List (RIPTL).

DMPR allows for:

- visualization of multi-planar volumes
- creation of multi-planar reformat batch images
- visualization of multi-planar batches
- filming of multi-planar batch images
- networking of multi-planar batch images
- archiving of multi-planar batch images

Applications of DMPR include:

- fast review of scan prescription
- combined with AutoView for trauma imaging and automated multiplanar reformat protocols
- surgical planning assessment of trauma
- CT angiography
- as a supplement for other diagnostic information

To combine groups, the following parameters must be identical within each group:

- Slice Thickness
- Interval
- SFOV
- DFOV
- Scan Type
- Rotation Speed
- Image center
- Algorithm
- ASiR-V Level

Once the recon and multi-planar reformat batch images are created, the Reconstruction and Image Processing Task List (RIPTL) allows you to select and view image sets.

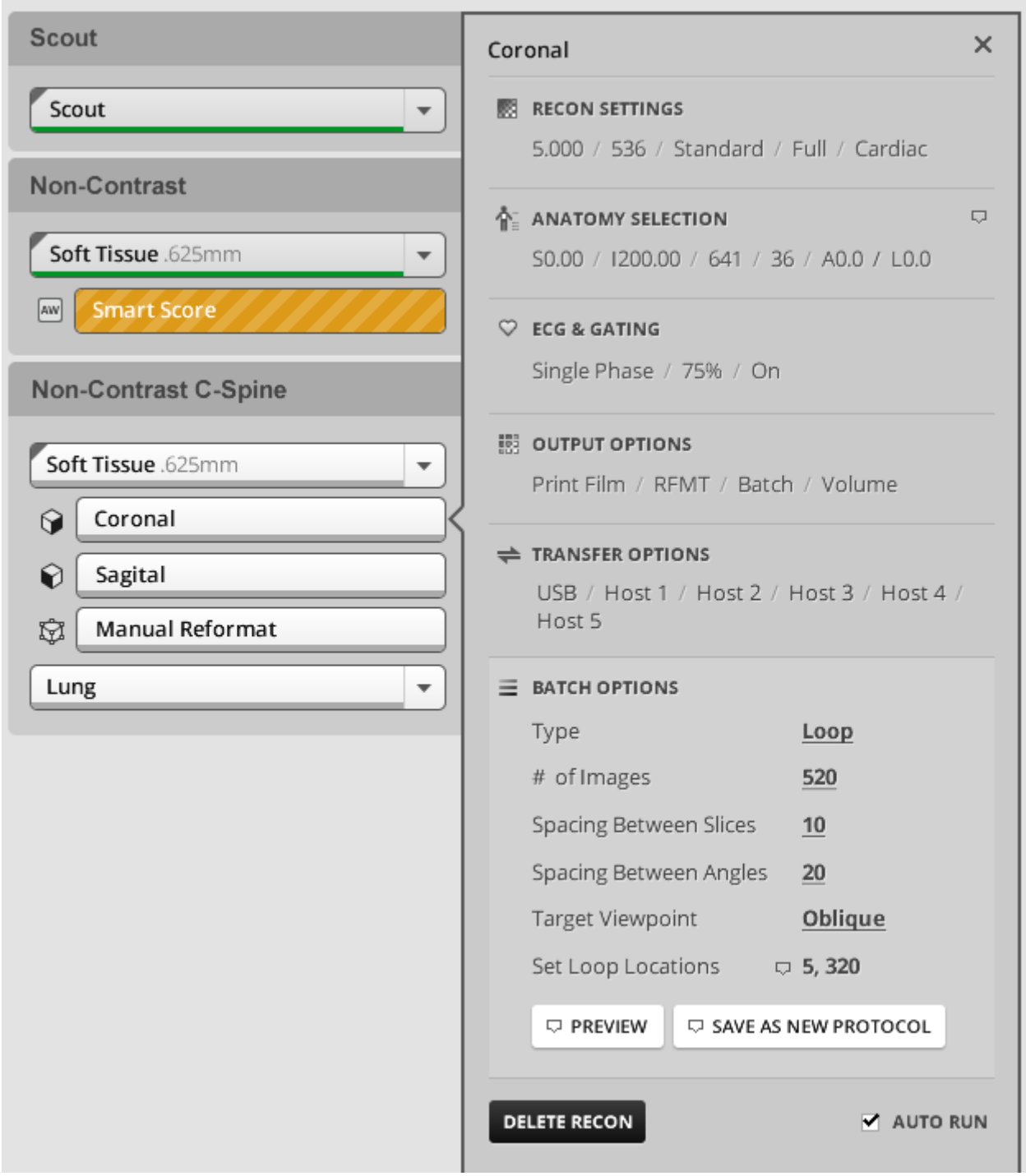
Considerations

- Each group must be contiguous to be able to be combined with the prior group in a DMPR session. DMPR can be prescribed with primary and secondary recons. DMPR reformats are limited to 2,000 images. Additional reformat protocols can be added from the File Manager.
- Any scans acquired after scanning has completed on the original scan group using Add Group are not added to the DMPR session. Remember to include all of the desired coverage area in the original scan prescription.
- If the patient orientation is prescribed as Decubitus (right or left), you will observe that the Paging slider for the sagittal image will scroll images in DMPR coronal viewport and vice versa. This is because in Decubitus orientation, patient's sagittals and coronals are switched. Hence, the DMPR sagittal viewport contains the coronals from patient's reference axis, and the DMPR coronal viewport contains the sagittals from the patient's reference axis.
- Make sure the interval between groups is appropriate to support DMPR in secondary recons 2-10 if the slice thickness prescribed for the groups in primary recon 1 is different.

3.1 Reformat Tools panel

To display the Reformat Tools panel, select or create a reformat task from the Reconstruction and Image Processing task list.

Illustration 1: Reformat Tools panel



3.1.1 Icons

On the Reconstruction and Image Processing task list, icons identify the reformat type.

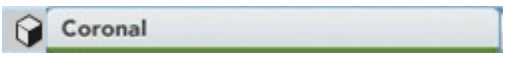
This icon:	Identifies this reformat type:
	Automatic or semi-automatic reformat
	Manual reformat

3.1.2 Reformat processing order

Automatic reformats are processed in top-down order. If a manual reformat is started while automatic reformats are running, the manual reformat has priority until it completes, at which point automatic reformats resume processing.

3.1.3 Processing and transfer status indicators

The processing and transfer status of reformats is shown by changing the field showing the reformat name.

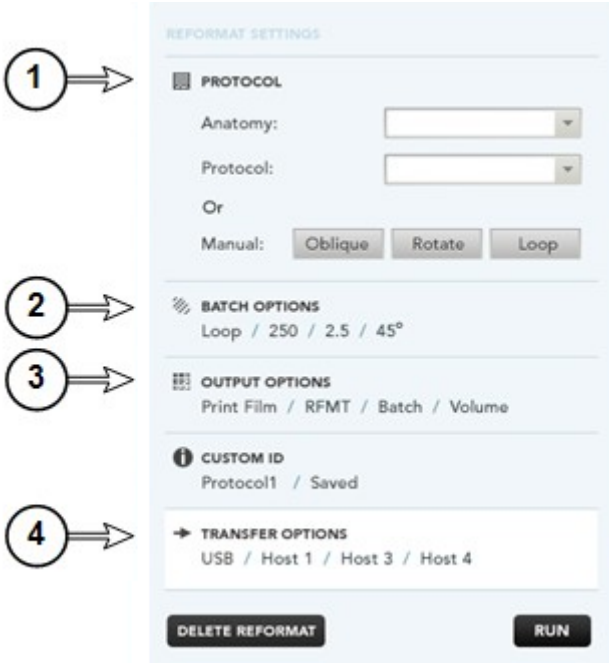
This indicator:	Means:
	Processing has not started
	Currently processing
	Completed processing
	Semi-automatic or manual reformat awaiting processing
	Transfer has been configured
	Transfer in progress
	Transfer complete

3.1.4 Reformat Settings panel

From the Reconstruction and Image Processing Task List, select a reformat to display the *Reformat Settings* panel.

NOTE: The settings for the reformat are contained in sections on the Reformat Settings panel. These sections are collapsible. When these sections are collapsed, the current settings for the reformat are shown on the collapsed panel.

Illustration 2: Reformat Settings panel



1	Protocol section (opened)	3	Output Options section (collapsed)
2	Batch Options section (collapsed)	4	Transfer Options section (collapsed)

3.1.4.1 Protocol settings

Table 1: Protocol settings

For this setting:	Select or set:
Anatomy	Select the anatomy for with the reformat. This setting affects the settings available in the Batch Options section.
Protocol	Select the protocol. This setting affects the settings available in the Batch Options section.
Manual buttons [Oblique], [Rotate], and [Loop Batch]	If you want a generic protocol, select the type of protocol using these buttons. Selecting one of these buttons clears the Anatomy and Protocol selections. [Oblique] – Produces sagittal, coronal, or off-axis (oblique) images from CT data. [Rotate] – Creates multiple images of an anatomical region by rotating around a single axis at a specified angle. This is used for vascular structures, such as pulmonary veins. [Loop batch] – Creates a cine image series. this is used to translate a curve or to rotate around a centerline.

3.1.4.2 Batch Options

The Batch Options change depending on the type of series being used in the reformat.

Table 2: Oblique settings

For this setting:	Select or set:
Type	This setting is read-only (set in the Protocol settings)
Number of images	Set the number of images to include in the reformat. This number updates based on slice thickness, slice interval, and the start and end locations.
Slice thickness	Set the slice thickness.
Interval	Set the slice interval.
FOV	Set the field of view
Tilt	Set the tilt.
Rendering Mode	Select the rendering mode.

Table 3: Rotate settings

For this setting:	Select or set:
Type	This setting is read-only (set in the Protocol settings)
Number of images	Set the number of images.
Angle between images	Set the angle between images.
Slice Thickness	Set the slice thickness.
FOV	Set the field of view
Rendering Mode	Select the rendering mode.

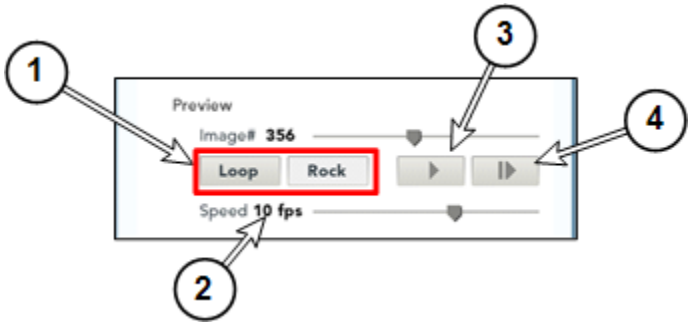
Table 4: Loop settings

For this setting:	Select or set:
Type	This setting is read-only (set in the Protocol settings)
Number of images	Set the number of images.
Set Start and Set End	Use buttons to set the start point and end point of the loop.
Target Viewpoint	This setting is read-only.

Preview tool

Before you save, film, or print a batch, you can preview what the batch will look like using the Preview tool in the Batch Options section of the Image Tools panel.

Illustration 3: Preview tool



1	Preview mode buttons	3	Play/Pause button
2	Preview speed selector	4	Click through images button

Save as New Protocol

After you make changes to the batch settings, you can save the changes to a new batch protocol. This new protocol appears in the list in the Protocol settings section.

You can categorize the new protocol by anatomy.

Illustration 4: Save as New Protocol

3.1.4.3 Output Options

Table 5: Output options

For this setting:	Select or set:
Save As	Select whether you want to save the output from the reformat as a reformat or as a screen save. In File Manager, a reformat is shown with an image type of RE-FORMAT. The image type for a screen save is shown as SCPT.
Batch Auto-View	If you want the reformat to automatically display in a batch view, check this box.
Volume Auto-View	If you want the reformat to automatically display in a volume view, check this box.
Series Description	You can enter a description for the series in this field. If you do not enter a description, the series will take the name of the pre-selected protocol. If you are not using a pre-selected protocol, the series will take the name “Processed Images”.

3.1.4.4 Transfer options

The Transfer options allow you to send the completed reformats to network hosts or to a USB drive.

Illustration 5: Transfer options

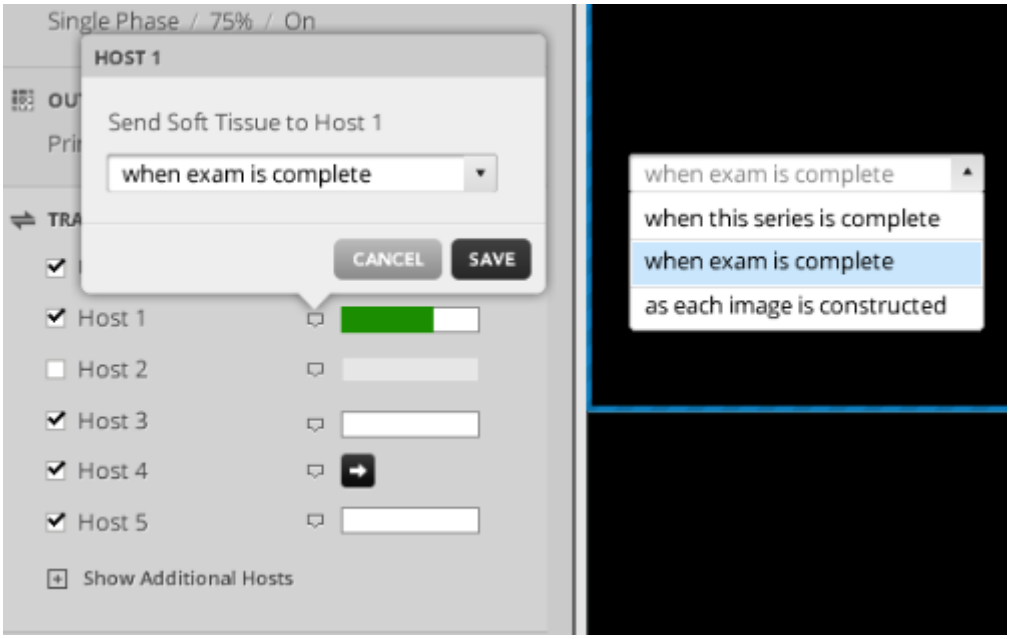


Table 6: Transfer options

For this setting:	Select or set:
Host name/USB boxes	Select the hosts/USB devices to which you want to send the reformat when it is complete.
Show Additional Hosts	If you have other hosts to select, open to select it from this list.
Send options anchored pop-over	Select the option corresponding to how you want to send the reformat.

3.1.4.5 Auto-Run/Run/Abort button

The Auto-Run/Run/Abort button is at the bottom of the Image Tools panel. This button takes on one of three states, depending on the state of the reformat.

When the button is in this state:	The reformat is in this state:	Clicking the button does this:
Auto-Run	The reformat is not running (you are editing the reformat).	If the button is grayed out, select the appropriate protocol from the Protocol section. Click the button to autorun the reformat after recon data has been acquired.
Run	The recon data is available, but the reformat has not been run.	Click the button to run the reformat. This button is grayed out if you have not selected a protocol or defined a batch reformat manually.

When the button is in this state:	The reformat is in this state:	Clicking the button does this:
Abort	The reformat is process.	Click the button to stop the reformat. If an automatic reformat is running and no images have been created, the reformat goes into manual mode, allowing you to modify the reformat and run it manually. If an automatic reformat is running and images have been created, the reformat is canceled and any images that have been created are available for view in the 2D viewer and will be an image series in File Manager. The reformat goes into manual mode, allowing you to modify the reformat and run it manually. For a manual reformat, the reformat is canceled and any images that have been created are available for view in the 2D viewer and will be an image series in File Manager. If you want to perform the reformat, you will need to add the reformat to the task list again.

3.2 Reformat planning

3.2.1 Automatic reformat

For an automatic reformat, no images are acquired before planning the reformat.

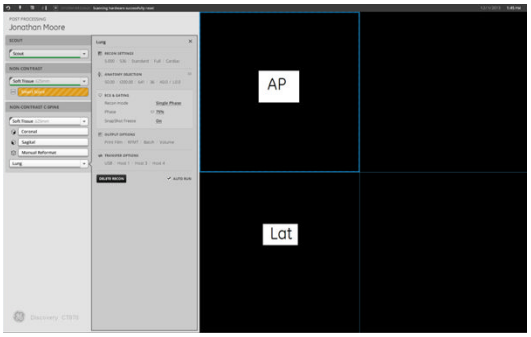
1. From the RIPTL, click reformat.
2. Select the protocol you want to use from the *Reformat Settings* panel.
3. Click the [Auto-Run] button.

3.2.2 Semi-automatic reformat

For a semi-automatic reformat, the scout images are available to plan the reformat.

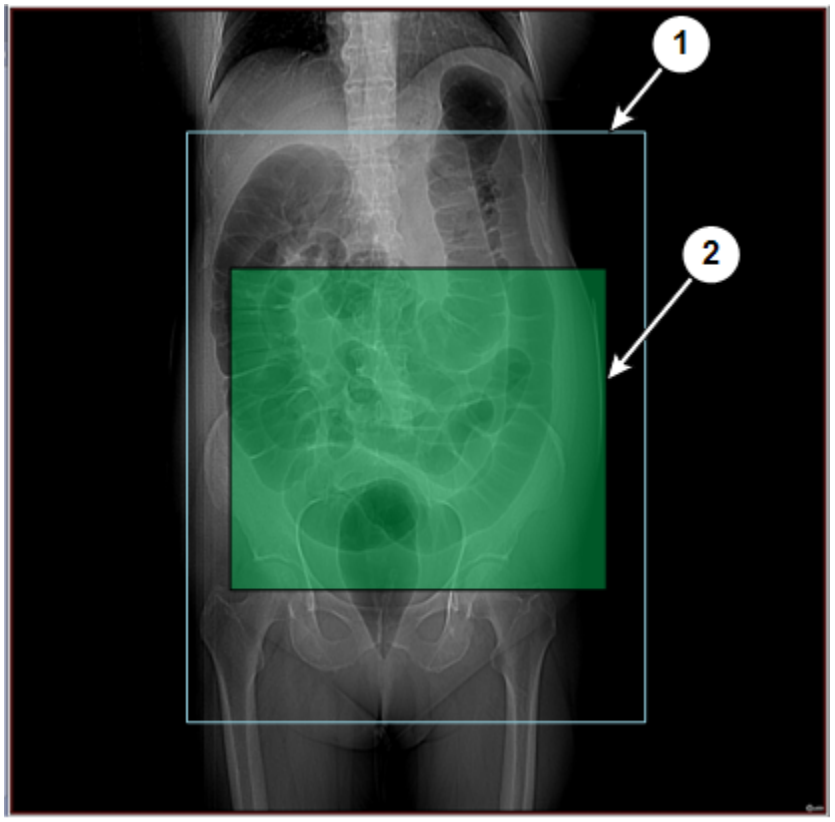
1. From the RIPTL, click reformat.
2. Select the protocol you want to use from the *Reformat Settings* panel. Adjust the settings for the protocol.
3. Scout images display in the upper left (AP) and lower left (lateral) viewports, displaying the GraphicRx lines of the acquisition reconstruction and the batch lines for the reformat batch.

Illustration 6: Scout image locations



4. Click [Auto-Run].
5. Adjust the location for the reformat on the scout image.

Illustration 7: Recon scan lines and graphic object



1	Boundaries of the graphic object for scan/recon. These boundaries update in real time based on the scan plan for scan/recon.	2	Oblique batch graphic object

3.2.3 Manual reformat

For a manual reformat, the recon data is available.

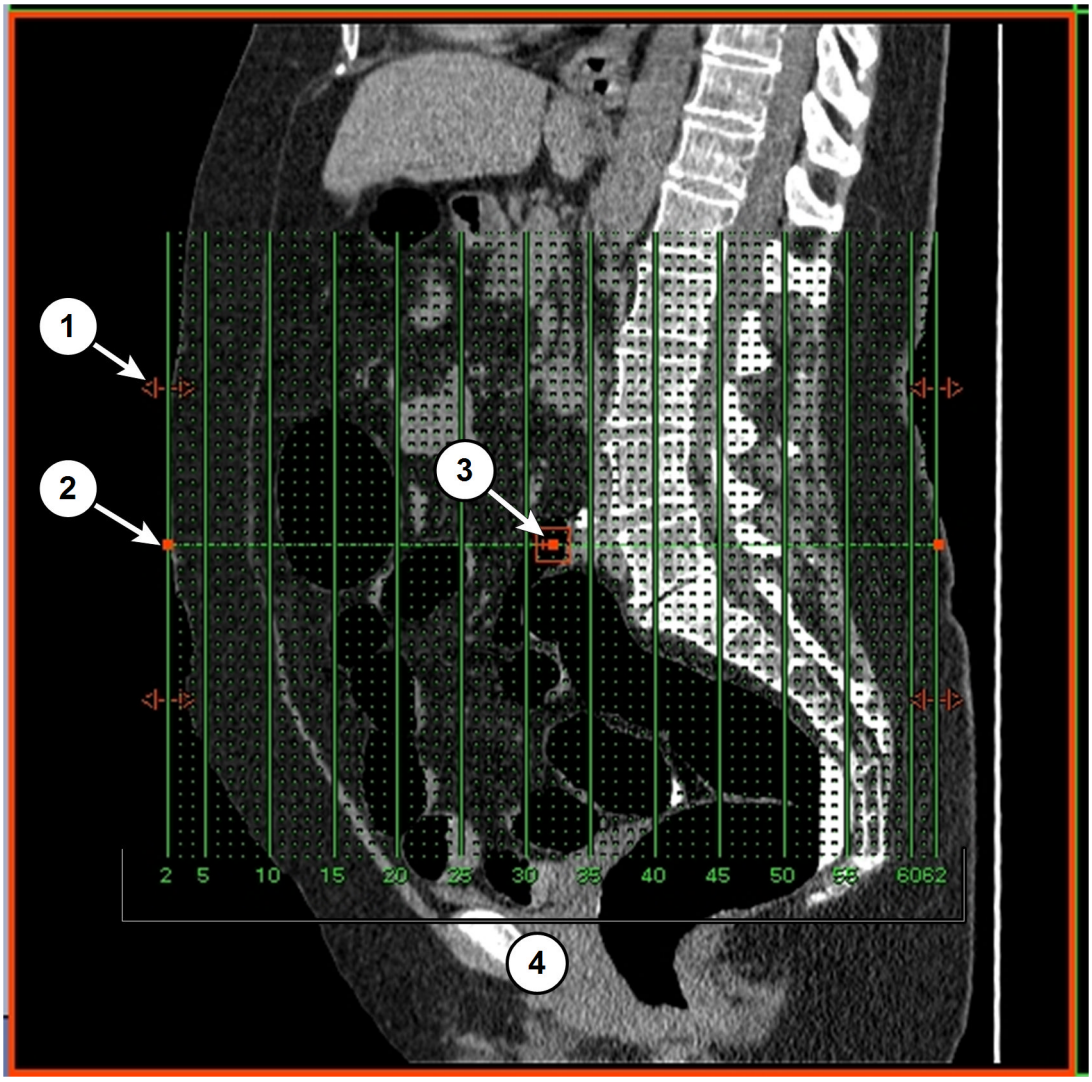
1. From the RIPTL, click reformat.
2. Select the protocol (or generic batch) you want to use from the *Reformat Settings* panel. Adjust the settings for the protocol.
3. The default reformat views appear in the viewports. If a protocol has been selected, batch lines appear on the views.
4. Click [Run].

3.2.4 Graphic object for oblique reformats

The graphic object used for planning an oblique reformat allows you to move the entire plan in the recon scan area, extend coverage in any plane, rotate the reformat angle.

This graphic object can be used on scout images for semi-automatic reformats, and any of the multiplanar volume views for manual reformats.

Illustration 8: Graphic object – oblique reformats

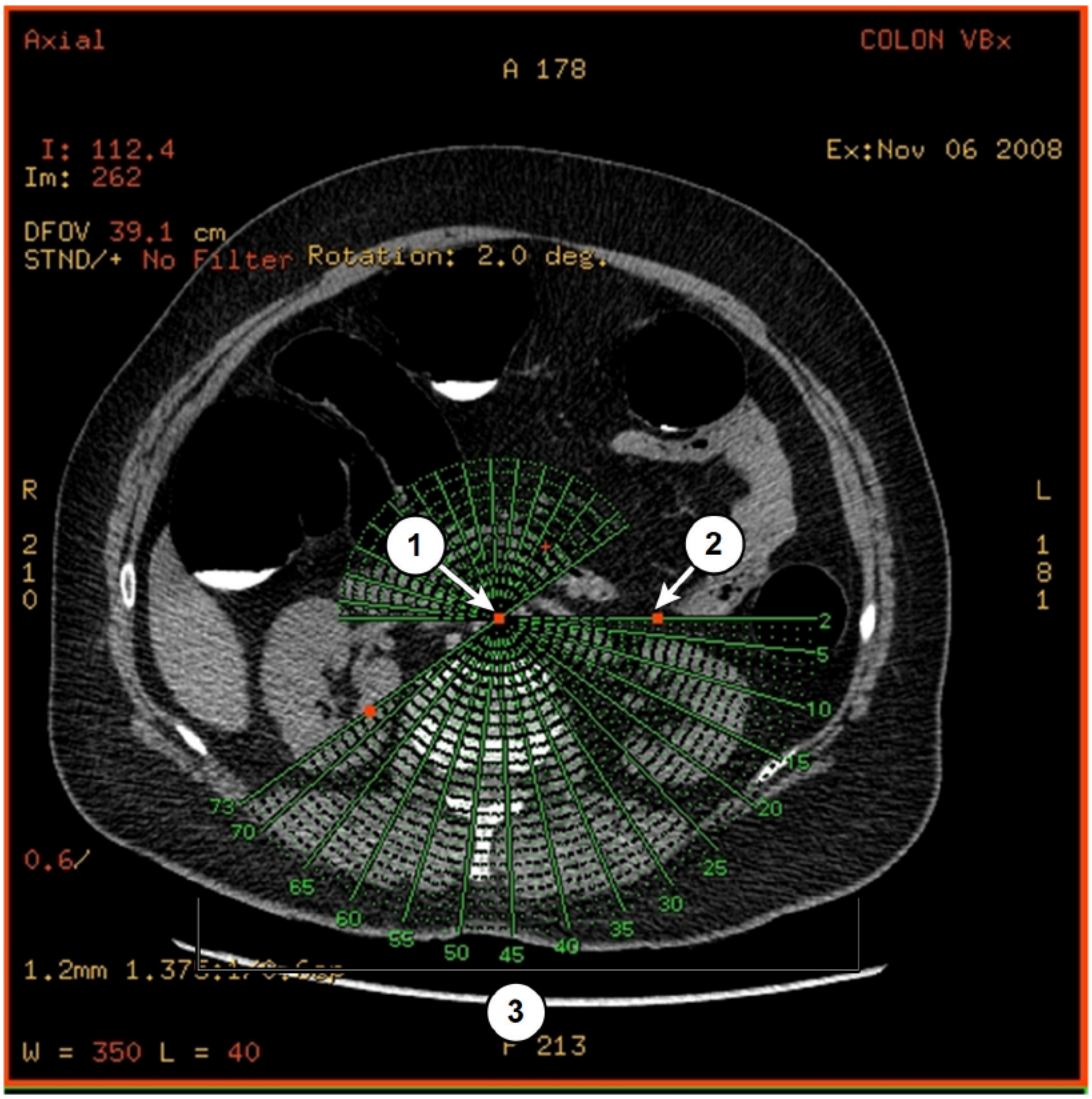


1	Handle to extend coverage in any plane	3	Handle to move the entire reformat plan
2	Handle to rotate the reformat angle	4	Numbers showing start and end of reformat

3.2.5 Graphic object for rotate reformats

The graphic object used for planning a rotate reformat allows you to move the entire plan in the recon scan area, change where the rotation will take place and where the start and end of the reformat will be.

Illustration 9: Graphic object – rotate reformats



1	Handle to move the entire reformat plan	3	Numbers showing start and end of reformat
2	Handle to change the placement of the rotate graphic object		

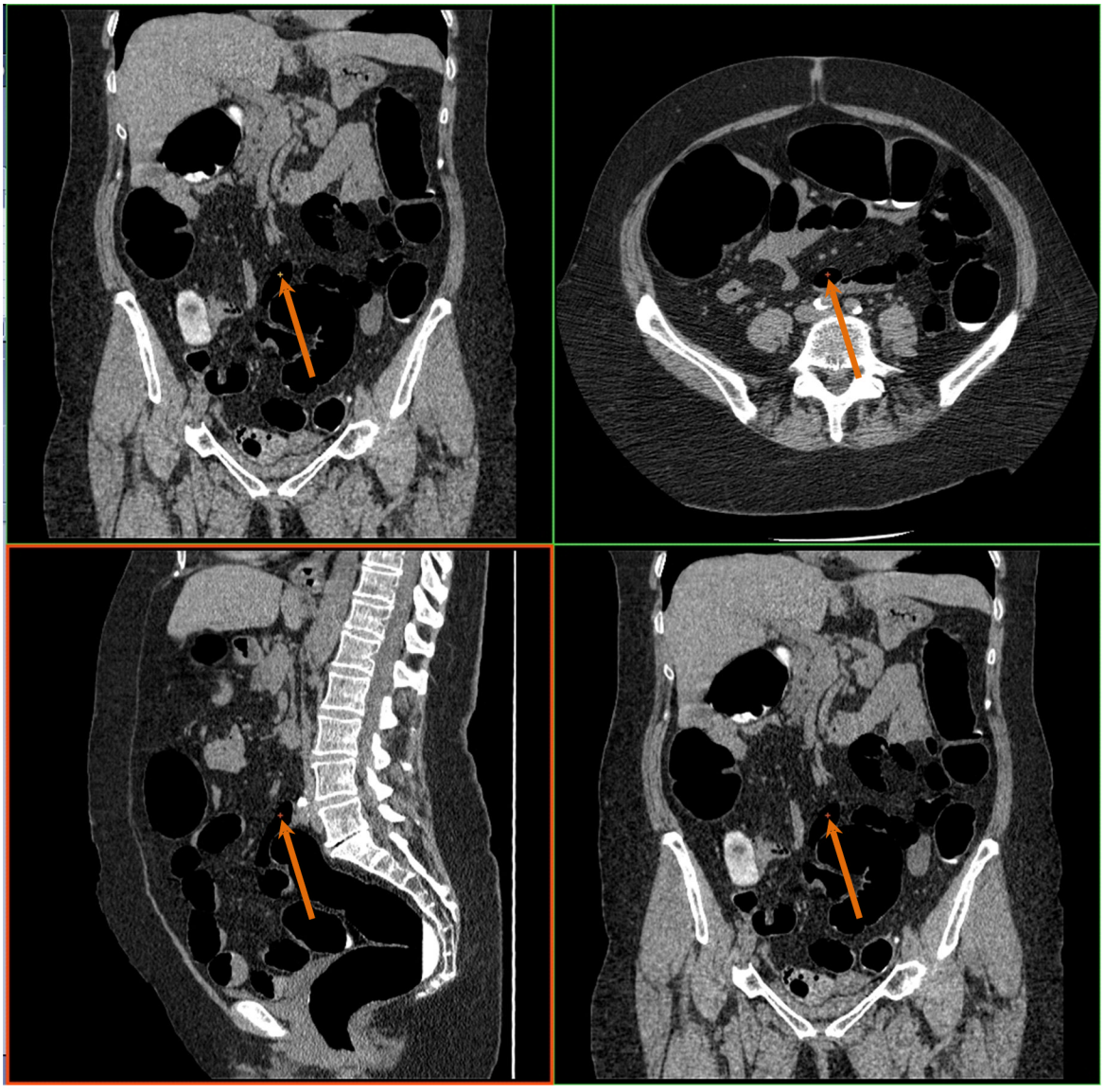
3.2.6 3D cursor

Use the 3D cursor to point to the same location in all viewports.

Place the 3D cursor by clicking a viewport and dragging the cursor into position, or you can move the mouse over an area and press the <Shift> key.

You can toggle the 3D cursor on and off by pressing the <C> key.

Illustration 10: 3D cursor (shown with arrows)



4 Exam Split

Exam Split gives you the capability to "split" a series of patient images into separate groups. These new smaller image groups can be networked to desired reading stations for multiple "reads" and multiple billings on select patient exams.

Using *Exam Split* allows for split images from a single acquisition and assign them to a Requested Procedure ID or accession number retrospectively. From the *File Manager* controls area using *Exam Split*, all the images of the scan will be loaded. You can also use the mouse to select a range of images to be sent to a specific exam procedure.

At scan time, all patient records that you want available to split must be selected from the *Patient Scheduler* when selecting [New Patient]. Your system is configured in one of two modes for *Exam Split:* virtual mode or hard mode. The configuration is dependent on the system you will send the images to review.

NOTE: *Exam Split* requires the Connect Pro option.

4.1 Virtual mode

Your remote station must support Performed Procedure Step (PPS) and Gray Scale Presentation State (GSPS). Images will be auto transferred to the remote station. In *Exam Split*, ranges of images are assigned to each accession number or procedure code and a GSPS object is created and transferred when selected.

4.2 Hard mode

Hard mode creates a new series of images for each accession number or procedure code ranges of images are assigned to. For this reason, images will not be auto transferred to the remote station. A GE Field Engineer will configure Exam Split based on input from your site IT and PACS administration.

4.3 Split exams with Patient Scheduler

Use the *Exam Split* option to split images from a single acquisition and assign them to a Requested Procedure ID or accession number retrospectively. The smaller image groups can be accessed at reading stations for multiple reads and multiple billings on select patient exams.

At scan time, all patient records that you wish to have available to split to must be selected from the *Patient Schedule* when selecting *New Patient*.

1. From the scan monitor, open the [Patient Scheduler] drawer.
2. From the *Patient Scheduler* screen, select the patient exams that you want to apply *Exam Split* once the images are reconstructed.

   A maximum of 15 procedures can be selected.
3. Click [Select Patient].

NOTE: If multiple accession numbers are selected, the last accession number selected is listed in the images header. The accession number is stored in a different DICOM field (0040, 0275) when multiple records are selected. Use *Exam Split* to send images to the PACS with the associated accession number for a particular procedure.

5 SmartPrep

SmartPrep™ allows intermittent monitoring of IV contrast enhancement in one particular section of anatomy that is in the area of interest. The contrast flow is monitored by low-dose scans until the contrast enhancement reaches the preferred point and the operator initiates the diagnostic scan or the Dynamic Transition level has been reached.

If SmartPrep is enabled for a series, the system cancels the AutoView display for any images in the recon queue when the SmartPrep series is started. These images are selected from the browser for review once they have been reconstructed. Only images from the series with SmartPrep and those after the SmartPrep series are displayed in AutoView viewport.

There are three phases to a SmartPrep scan.

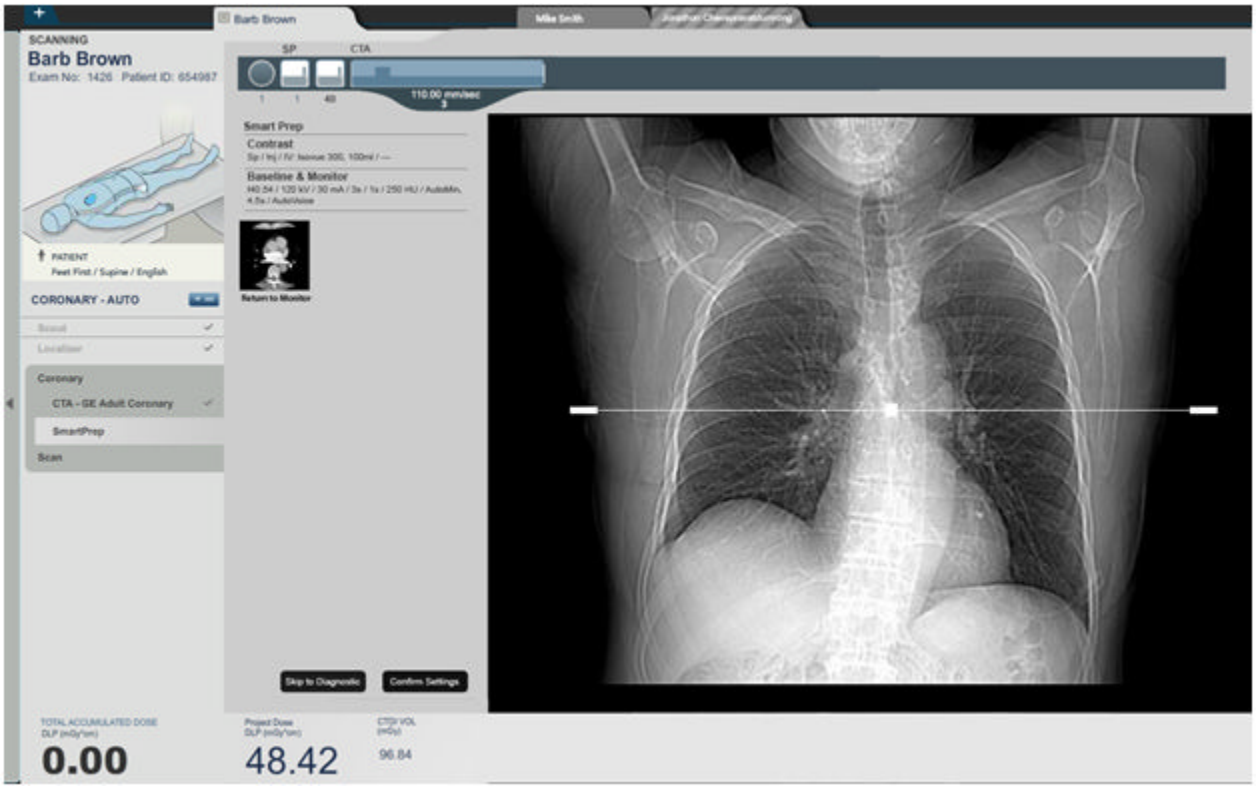
- **Baseline phase** — A single unenhanced image is acquired in the anatomy where the monitoring occurs and the Region of Interest (ROI) is established.
- **Monitor phase** — Uses the ROI defined in the baseline phase to display a graph that helps you determine the peak enhancement value. Up to 40 low-dose scans can be taken during the injection of IV contrast.
- **Scan phase** — Acquires the data based on the scan setup parameters. You start the scan when the contrast is at the peak on the curve or by when a preset Hounsfield value is reached.

Setting the SmartPrep parameters does not need to be done each time SmartPrep is used. The parameters can be included in any protocol using SmartPrep. The system holds the last values entered if SmartPrep is activated for an individual study. SmartPrep parameters allow for checking the contrast enhancement both visually and graphically.

5.1 SmartPrep Setup screen

Click on the *SmartPrep* task or this screen will be automatically displayed when the associated diagnostic scan is confirmed.

Illustration 11: SmartPrep Setup screen



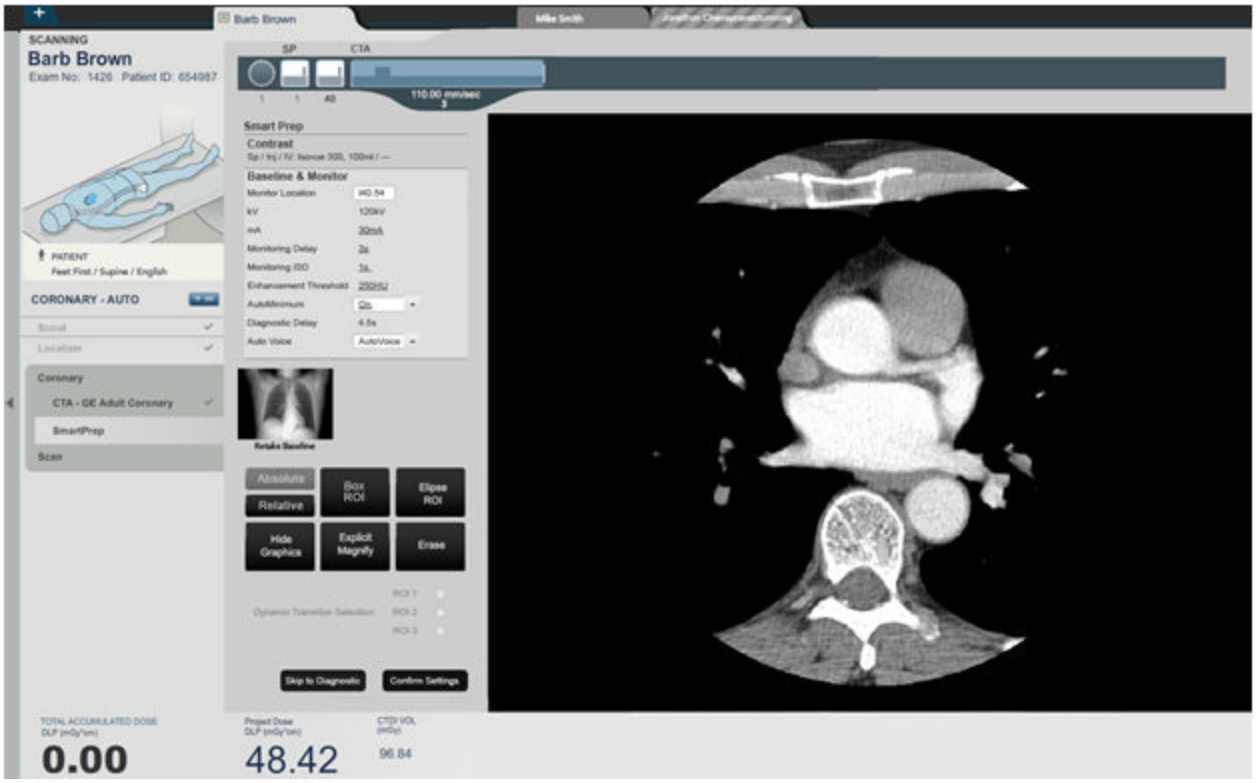
Element	Description
Scan Timeline	The Scan Timeline for SmartPrep is shown at the top of the viewport and includes a minimum of three sections and some number of delays: • **Delay** - Represented as a circle with the time of the delay shown underneath. • **SP Baseline** - First rectangular section under the SP label and represents the baseline scan. • **SP Monitor** - Second rectangular section and represents the monitor scan. The timeline represents a single monitor scan. As scans are taken, the timeline will fill and then clear for the next monitor scan. • **Diagnostic Scan** - Third rectangular section and represents the diagnostic scan for the SmartPrep series. When this is a multi-group series, a rectangular section will be shown for each group.
Scout Image	The last scout image taken at the current landmark is shown with a cut line that will allow the monitor location to be specified. Moving the cut line will correspondingly change the *Monitor Location* in the *Baseline & Monitor Collection*.

Settings Collections	The collections for the SmartPrep parameters are located just below the Scan Timeline. SmartPrep has two collections: • **Contrast Collection** - Allows contrast data to be specified for the study. The data included in this collection depends on whether the integrated injector is being used. The Type value on the Contrast Collection will be automatically set to SP (SmartPrep). See the Enter Constrast Description section in the Scan chapter for more information when the integrated injector option is not installed. • **Baseline and Monitor Collection** - Allows setup of the parameters controlling the Baseline and Monitor scans. See the Set up a Scan section in this chapter for more information.
Skip to Diagnostics	Skip the monitor phase and go directly into the diagnostic scan.
Confirm Settings	Continue to the step of taking the Baseline Scan.

5.2 Monitor Phase Setup screen

This screen is displayed after the baseline scan is completed.

Illustration 12: Monitor Phase Setup screen



Element	Description
Baseline Image	The baseline image is displayed allowing ROIs to be placed on the image.
Retake Baseline	Selecting the Retake Baseline will return to the *SmartPrep Setup* Screen.
ROI Tools	Used to put ROIs on the baseline image. 0-3 ROIs may be placed on the image.
Dynamic Transition Selection	Allows the selection for which ROI is to be used as the dynamic transition ROI. This can be none or any one.

5.3 Monitor Phase screen

This screen is displayed during the Monitor Phase.

Illustration 13: Monitor Phase screen

Element	Description
Baseline Image	The baseline image with the ROIs that have been set will display on the lower right hand side of the screen.
Monitor Image	The latest image from the monitor phase that corresponds to the image used to calculate the HU level on the Enhancement Chart and Enhancement Graph is shown in the lower right hand side of the screen. The ROIs that were set are shown on this image.
Enhancement Chart	The enhancement chart is shown on the left above the Pause and Begin Scan Now Buttons. This shows the relative HU level for each monitor scan in each ROI.
Enhancement Graph	The enhancement graph is shown on the right above the Pause and Begin Scan Now Buttons. The graph shows a line for the relative HU levels for each ROI over time. A horizontal line displaying the configured Enhancement Threshold is also provided.
Dynamic Transition	On the bottom row of the Enhancement Graph is a check box that allows Dynamic Transition to be disabled. This will only appear if an ROI has been designated as the transition ROI.
Real Time Information	At the bottom of the screen is the Real Time Information, showing Patient Handling, Scanning, and Injector Status information. The Injector Status information is only available when Integrated Injector is enabled.
Pause	Will pause the current monitor scanning. When paused, the options to Skip to Diagnostics, Resume, or Revisit Settings will be available.

Begin Scan Now	Whether or not Dynamic Transition is enabled, the Begin Scan Now button is available. Use this button to start the Diagnostic Scan.

5.4 Set up a scan

Use the following procedures to scan with SmartPrep, which allows intermittent monitoring of IV contrast enhancement in an area of interest. The contrast flow is monitored by low-dose scans until the contrast enhancement reaches the preferred point and the operator initiates the scan prescription when Dynamic Transition is OFF. When Dynamic Transition is ON, the system will automatically transition from Monitor phase to Scan phase when the contrast enhancement level for the Transition ROI reaches the Enhancement Threshold HU value.

Use this procedure to set up a SmartPrep series to acquire contrast-enhanced images with a bolus tracking technique.

Scan prescription

A SmartPrep prescription is a series with a SmartPrep task enabled. Only one SmartPrep task may be added to a series. If a Scout series is included in the study prior to the SmartPrep series, the Scout may be used to determine the monitor location. The series will contain the SmartPrep task and the prescription for the contrast enhanced scans to be taken when the contrast enhancement level is reached. These scans are referred to as the diagnostic scans.

1. Add a SmartPrep sub-step for a selected series using the *Scan Task List* Context Menu drop down selector. This will add the SmartPrep task to the end of the task list for the series.
2. If the diagnostic scan tasks are not confirmed, confirm the settings for these groups. After the last is confirmed, the SmartPrep Setup Screen will be displayed.
3. From the scout localizer on the display monitor, click and drag the slice line to define the Monitor location. Alternatively, type in the S/I location in the Monitor Location text field in the Baseline and Monitor Collection, for example, *S110*.
4. Expand the Baseline and Monitor Collection and enter the following values:
    - **mA** (range 10 to 100 in 10 mA increments), This is the mA used during the Monitor and Baseline Phases. Typically enter 40 mA for most studies. The system defaults to a low mA value, which keeps heat units to a minimum. The mA value can be adjusted depending on the patient size. The mA selected should be adequate to provide images that allow the detection of contrast but do not need to be of high diagnostic quality.
    - **kV** is a non-editable field and is the same as the value set for the first diagnostic scan. If this needs to be changed, go back to the Diagnostic scan task and change the settings there.
    - **Monitoring Delay** (0 to 60 seconds in 1-second increments) sets the time before monitoring scans begin. The time varies based on the anatomy being monitored.
    - **Monitoring ISD** (1 to 60 seconds in 1-second increments) sets the time between monitoring scans.
    - **Enhancement Threshold** (0 to 1,000 in steps of 1) sets the bar on the graph to monitor threshold enhancement. When Dynamic Transition is On, the Scan Phase starts

automatically when the HU value of the Transition ROI reaches the Enhancement Threshold. This is the magnitude of the change in HU level with respect to the HU level in the baseline scan.

- **Auto Minimum Delay** sets the Diagnostic Delay to the most minimum value possible, taking into consideration location of the monitor phase, start phase location, and AutoVoice pre-message length. When Auto Minimum Delay is set, the Diagnostic Delay value is read only. Use this to see the minimum delay value for your specific scan.
- **Diagnostic Delay**, (up to 60 seconds in one-second increments) typically set to the minimum value (automatic) for arterial studies and 10 seconds or longer for venous studies. The minimum value will be constrained to the time needed to move the table and play the auto-voice message. The minimum for scans without autovoice and small table moves (under 150 mm) will be around 2.5 seconds.
  - Allow enough time to deliver breathing instructions if AutoVoice is not being used.
  - The minimum time may vary if AutoVoice is turned on and depending on the monitor location relative to the start location.
- **AutoVoice Pre-message** is available if AutoVoice is prescribed in the Voice Lights Timer selection in Timing parameters. If AutoVoice is enabled for the series, the pre-message will be played as part of the diagnostic delay. The Diagnostic Delay will be increased to accommodate the length of the AutoVoice message.

5. Set the contrast settings. If the integrated injector option is enabled, see the Enhanced Xtream Injector section in this chapter. If the integrated injector option is not enabled, see the Enter Contrast Description section in the Scan chapter.
6. From the *SmartPrep Setup* screen, click [Confirm Settings].
7. Review and respond to the potential alert message that indicates that the projected dose efficiency had fallen below 70%.
8. Proceed to Acquire a scan without Dynamic Transition Section 5.1or Acquire a scan with Dynamic Transition Section 5.2.

5.5 Acquire a scan

There are two methods for acquiring a scan: without Dynamic Transition and with Dynamic Transition.

5.5.1 Acquire a scan without Dynamic Transition

To acquire contrast-enhanced images with a bolus tracking technique without Dynamic Transition, follow these steps:

5.5.1.1 Baseline phase

The Baseline phase acquires one non-contrast scan and allows you to establish an area to monitor contrast enhancement.

1. After the SmartPrep settings are confirmed, the Baseline scan is taken. After the Baseline scan is complete, the *Monitor Phase Setup Screen* is displayed.

2. Review the values on the *Scan Timeline* for the monitor and scan phases.
3. In the case that the baseline scan is not correct (for example if the patient moved or the scan location is not right), use the [Retake Baseline] button to return to Section 4.
4. If more than one baseline scan has been taken, use the page up / page down to scroll through the set of baseline scans to select the baseline image to use. The most recent will be the one displayed when this screen is entered. If a different image is selected, the scan parameters will automatically update to match the settings used for that scan.
5. Press [Move to Scan] to advance the table to the monitoring location.
6. Press [Start Scan].
7. Once the scan is complete, from the reconstructed image on the display monitor, click [Ellipse ROI] and place a maximum of three ROIs over areas of interest.

   For example, if scanning a liver, place an ROI in liver parenchyma away from vessels, if evaluating a vessel place the ROI over the vessel.

   Use, as needed, the zoom, roam, display normal, hide/show graphics, erase, or explicit mag (factor range: 0.5 to 2.0) from the SmartPrep display control panel.
8. Click [Confirm Settings] to continue to the Monitor Phase.
9. Review and respond to the alert message that indicates that multiple scans will be taken at the same location and that the projected Dose efficiency had fallen below 70%.

5.5.1.2 Monitor phase

The Monitor phase acquires images at the monitoring location during the delivery of intravenous iodinated contrast material and graphically displays the images, charts the enhancement thresholds, and clock with the time since monitoring began. Use the contrast graph, contrast table, and/or monitor images to determine when the diagnostic scan can begin.

1. After the Baseline scan settings are confirmed, the [Start Scan] button will begin to flash.
2. Simultaneously press [Start Scan] and start the IV contrast injection. A maximum of 40 monitoring scans are available. Move To Scan is typically not required since the last scan was at the baseline location.

   NOTE: If using an integrated injector, the step to start the IV contrast injection is not needed as the command will be sent by the scanner to the injector to start the injection.
3. The system waits the time set in the *Monitoring Delay* area and then begins acquiring images at the time set for the ISD. The total SmartPrep monitor scan time and Interscan Delay time between monitor images is displayed on the *Real Time Information* screen on the *Monitor Phase* screen.
4. View the information on the *Monitor Phase* screen to determine when to switch to the diagnostic scan phase:

   a. **Enhancement Graph**: Is only shown if at least one ROI was placed on the baseline image in the Baseline Phase. The x-axis displays time. The y-axis displays relative HU level - relative to the HU level in the ROI on the baseline scan. A separate line for each ROI is

shown on the graph with a point for each monitor scan. A horizontal line indicating the enhancement threshold that was set in the SmartPrep setup screen is also shown. This will allow a visual indication of when the level on an ROI reaches or exceeds this level.

b. **Enhancement Table**: Shows the same information as the Enhancement Graph, but in a tabular form.

c. **Baseline Image**: Shows the original baseline image with the ROI(s) on it.

d. **Monitor Image**: Shows the latest monitoring phase image also with the ROI(s) on it

5. Using the above tools, determine when the contrast level has reached a sufficient level to ensure that the contrast will be at an appropriate level to take the diagnostic scans. When this occurs, use the [Begin Scan Now] button to transition to the Scan Phase (Section 5.3).

5.5.2 Acquire a scan with Dynamic Transition

Use these steps to acquire contrast-enhanced images with a bolus tracking technique with Dynamic Transition.

5.5.2.1 Baseline phase

The Baseline phase acquires one non-contrast scan and allows you to establish an area to monitor contrast enhancement.

1. After the SmartPrep settings are confirmed, the Baseline scan is taken. After the Baseline scan is complete, the *Monitor Phase Setup Screen* is displayed.
2. Review the values on the *Scan* timeline for the monitor and scan phases.
3. Press [Move to Scan] to advance the table to the monitoring location.
4. Press [Start Scan].
5. In the case that the baseline scan is not correct (for example if the patient moved or the scan location is not right), use the Retake Baseline button to return to Section 4.
6. If more than one baseline scan has been taken, use the page up / page down to scroll through the set of baseline scans to select the baseline image to use. The most recent will be the one displayed when this screen is entered. If a different image is selected, the scan parameters will automatically update to match the settings used for that scan.
7. Once the scan is complete, from the reconstructed image on the display monitor, click [Ellipse ROI] and place a maximum of three ROIs over areas of interest.

   For example, if scanning a liver, place an ROI in liver parenchyma away from vessels, if evaluating a vessel place the ROI over the vessel.

   Use, as needed, the zoom, roam, display normal, hide/show graphics, erase, or explicit mag (factor range: 0.5 to 2.0) from the SmartPrep display control panel.
8. Select one of the ROIs to be used for the dynamic transition.
9. Click [Confirm Settings] to continue to the Monitor Phase.

10. Review and respond to the alert message that indicates that multiple scans will be taken at the same location and that the projected Dose efficiency had fallen below 70% and that Dynamic Transition is enabled.

5.5.2.2 Monitor phase

The Monitor phase acquires images at the monitoring location during the delivery of intravenous iodinated contrast material and graphically displays the images, charts the enhancement thresholds, and clock with the time since monitoring began. The contrast graph, contrast table, and/or monitor images can be used by the technologist to determine that the diagnostic scan can begin.

1. After the Baseline scan settings are confirmed, the [Start Scan] button will begin to flash.
2. Simultaneously press [Start Scan] and start the IV contrast injection. A maximum of 40 monitoring scans are available. Move To Scan is typically not required since the last scan was at the baseline location.

   NOTE: If using an integrated injector, the step to start the IV contrast injection is not needed as the command will be sent by the scanner to the injector to start the injection.
3. The system waits the time set in the *Monitoring Delay* area and then begins acquiring images at the time set for the ISD. The total SmartPrep monitor scan time and Interscan Delay time between monitor images is displayed on the *Real Time Information* screen on the *Monitor Phase* screen.
4. View the information on the *Monitor Phase* screen to determine when to switch to the diagnostic scan phase. In all the viewports with ROI information, the Dynamic Transition ROI will be visually distinct from the other ROIs.
   a. **Enhancement Graph**: Is only shown if at least one ROI was placed on the baseline image in the Baseline Phase. The x-axis displays time. The y-axis displays relative HU level - relative to the HU level in the ROI on the baseline scan. A separate line for each ROI is shown on the graph with a point for each monitor scan. A horizontal line indicating the enhancement threshold that was set in the SmartPrep setup screen is also shown. This will allow a visual indication of when the level on an ROI reaches or exceeds this level.
   b. **Enhancement Table**: Shows the same information as the Enhancement Graph, but in a tabular form.
   c. **Baseline Image**: Shows the original baseline image with the ROI(s) on it.
   d. **Monitor Image**: Shows the latest monitoring phase image also with the ROI(s) on it.
5. The system will auto-transition when the HU Enhancement level has been reached on the ROI selected as the transition ROI.
6. Using the above tools, monitor the progress of the contrast.
   a. If it looks like the dynamic transition will happen too early, uncheck the Dynamic Transition checkbox to disable this function. Note that once this is disabled, it cannot be re-enabled. Once this is done, the [Begin Scan Now] button must be used to transition as in the Acquire a Scan section.

b. If it looks like the dynamic transition will happen too late, use the [Begin Scan Now] button to transition to the Scan Phase.

5.5.3 Scan phase

The Scan Phase is the start of the actual Scan Prescription following the Monitor Phase.

1. After the [Begin Scan Now] button is clicked or Dynamic Transition has occurred, deliver the first breath hold instructions if Auto Voice Pre-Message is not turned on.
2. The system will:
   a. Move to the scan prescription start location (no need to press Move to Scan).
   b. Play the auto-voice message at the appropriate time if Auto Voice Pre-Message is turned on.
   c. Start the scan (no need to press Start Scan).
   d. Save an image of the last monitoring phase screen including the images, graphs, and table and save in series 99 for the study.
   e. Save the baseline image and monitoring images in series 200. If an extra monitoring phase was added, this will be in series 201.
3. When the scan is complete close the study by clicking [Done Scanning]. The Reports step is displayed. See the Reports section for more information on what is displayed.

6 Enhanced Xtream Injector

The Enhanced Xtream Injector provides synchronization of the start of the scan and the start of the contrast injector using the start scan button on the Scan Control Interface or the gantry controls. The Enhanced Xtream Injector also allows setting of the contrast injector parameters within the CT scan protocol and creation of an Injector Report at End Exam of what was completed. The system and injector are operated independently after the start button is pressed on the system.

The supported injectors are CiA425 compliant and are compliant with the Class 4 injector as defined in CiA425. Only the Medrad Stellant D and Nemoto DualShot Alpha / DualShot GC/GXV injectors are supported. Connecting any other injector will disable the ability to use the integrated injector capabilities.

6.1 About Enhanced Xtream Injector

6.1.1 Indications for use

The Enhanced Xtream Injector option is designed to facilitate contrast-enhanced CT imaging by connecting the system with a compatible injector. When used, pressing one single start button at the system allows the user to start the CT scan synchronized with the injector.

The Enhanced Xtream Injector option is based on the protocol contained in the CiA425 standard and allows this injector to operate with multiple GE Medical Systems systems that have the modified software and hardware interface required for the CiA425 communication protocol built into them. This device is only the communication protocol and bus interface needed to communicate with a 510(k) cleared injector that is compatible with the CiA425 standard.

NOTE: This option is only the communication protocol and bus interface needed to communicate with a validated compatible OEM injector (availability may vary regionally).

6.1.2 Protocol considerations

Injection parameters can be included in scan protocols when the Enhanced Xtream Injector option is installed. Patient size and conditions should be taken into consideration for the parameters set in the protocol.

6.2 Enhanced Xtream Injector screen

From the Contrast collection, click [Injector On]. The injector parameters can be defined in Protocol Management.

Illustration 14: Enhanced Xtream Injector screen

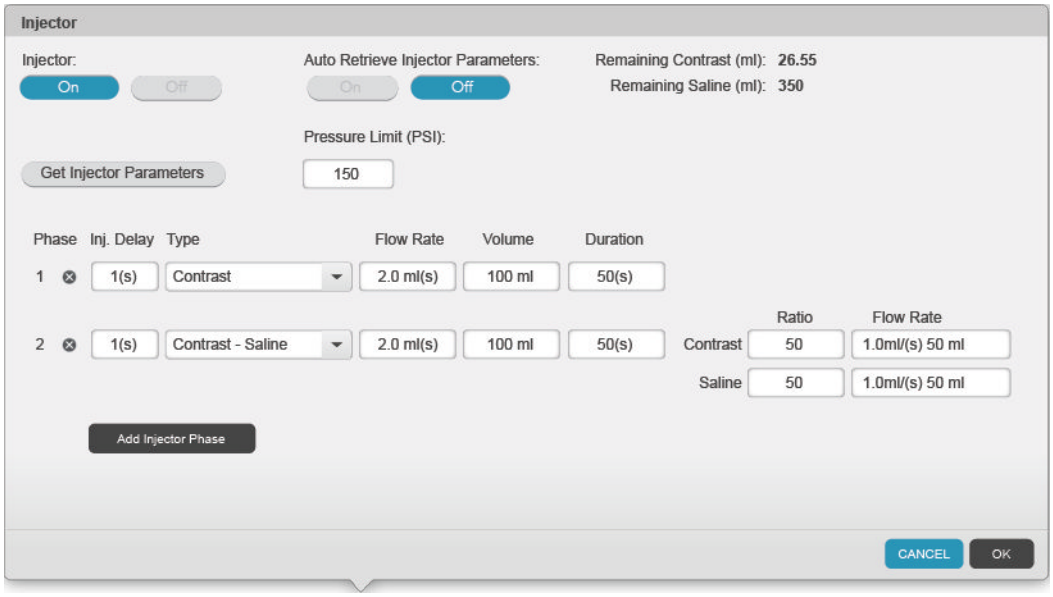
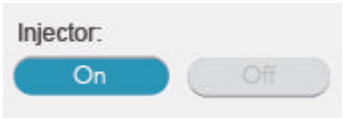
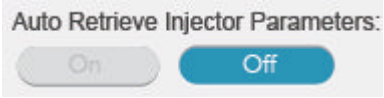
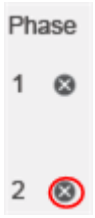


Table 7: Enhanced Xtream Injector screen

Icon name	Icon	Description
On/Off		The text fields and push buttons for parameter setting becomes sensitive when it turns to on.
Phase		Up to six phases are available depending on the injector. • **0** no delay prior to the injection of this phase. • **1 to max** — injection delay of the injector in seconds prior to the start of this phase. This is a timed pause. • *** Hold** • - the injection for this phase is started from the injector by pressing the start button. This is only valid for phases two through five.
Inj. Delay (s)		Injection delay can be set in increments of seconds.

Icon name	Icon	Description
Type		Allows type of injection selection.
Ratio (%)		Only available when *Contrast Saline* is selected in *Type*. The upper frame is for contrast, the lower frame if for Saline. The range is 1:99 and 99:1. When mixed phase is set from CT user interface, then the indication of ratio on *Injector Monitor* is dismissed. If you want to set the ratio on Injector Monitor, those buttons are displayed.
Pressure Limit		Ask GE service to set the unit for pressure: kPa, kg/cm2 or PSI The pressure limit value is converted and stored in kPa. When transferring this value between the system and the injector the pressure limit value may update due to rounding in the conversion back to PSI or kg/cm2.
Remaining Contrast Media Remaining Saline		The system displays the remaining volume of contrast media and saline.
Get Injector Parameters		The injector parameters pop up displays the parameters currently prescribed on the injector user interface.
Auto Retrieve Injector Parameters		If on, will retrieve the injector parameters from the injector system when transitioning to a task which has the injector enabled.
Add Phase		Adds a phase.
Delete Phase		Deletes a phase.
OK		Sends all parameters set on *Enhanced Xtream Injector* screen to the injector and closes the screen. If the injector has been armed, the injector will disarm when *Accept* is selected.

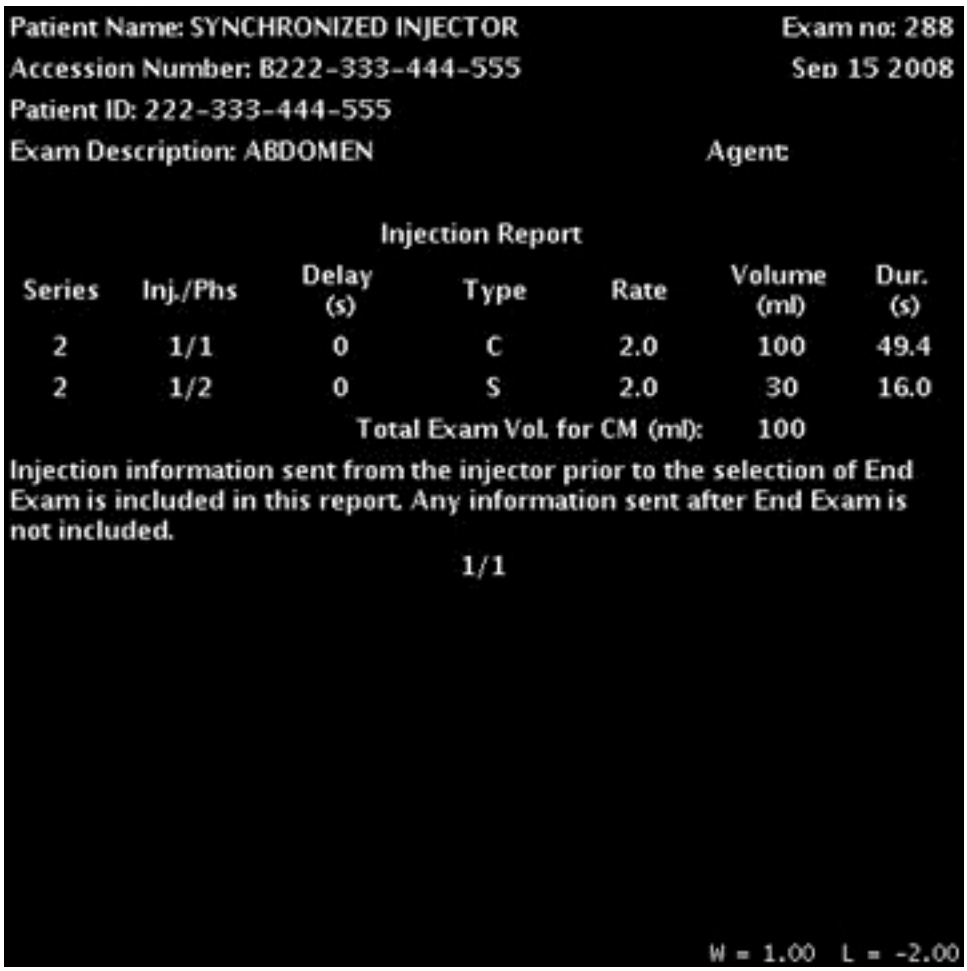
Icon name	Icon	Description
Cancel	CANCEL	Parameter values are not updated and remain at the values present when the pop up window is opened.

NOTE: There is no Xtream Injector button for Scout scans.

6.3 Contrast report

An Enhanced Xtream Injector contrast report detailing the contrast agent used, injection phase, delay, phase type, rate, volume, and duration is automatically saved when you select [Done Scanning]. The contrast report is saved as Series 996. It can be filmed, archived, and transmitted over a network. The values saved for rate, volume and duration are the actual values achieved by the injector, not the prescribed values.

Illustration 15: Enhanced Xtream Injector contrast report text page



NOTE: Selecting [Done Scanning] before the Injection Complete message posted on the injector may result in the Injector Report not being created.

6.4 Set up the Enhanced Xtream Injector

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

Before you start

- A cable from the injector must be connected to the gantry.
- Confirm that the injector is connected to the system and power is on.
- Setup the syringes.
- Prepare the Injector as described in the injector operator manual.

To set up the Enhanced Xtream Injector after the patient and the injector are prepared, follow these steps. Review the injector status messages.

1. Prepare the injector.
2. From the *Contrast Collection*, click [Injector].
    - If you have the Enhanced Xtream Injector option, then the *Enhanced Xtream Injector* screen opens.
    - The button turns on and synchronizes the start of the scan and injector.
    - IV contrast is automatically turned on when Xtream Injector is turned on.
3. Set the injector parameters on either the injector or the *Enhanced Xtream Injector* screen.

    From the *Enhanced Xtream Injector* screen, click [OK].
4. From the *Scan Settings* screen, set the scan parameters.
5. Click [Confirm Settings].
    - If there is an alert next to the Contrast Collection, check and resolve the injector parameters on the system or the Injector. *Confirm Settings* is only active when both the system and the injector are ready.
    - Complete any required fields and note the injector status information on the *Scan Progress* screen.
6. Press [Start Scan] to start the scan and injection.

NOTICE

If you stop the scan or the system aborts the scan the injector does not stop. If you stop the injector or the injector aborts, the system does not stop scanning.

If either of these scenarios occur, verify the remaining volume to be injected before resuming the injection or scan. You may need to update parameters on the Scan Settings screen.

NOTE: If you have the Enhanced Xtream Injector option, after you end the exam, a contrast report is saved as Series 996.

Chapter 13 Cardiac

1 Overview

Use this information to acquire and display cardiac images and Electrocardiogram/ Electrocardiograph (ECG) traces.

2 Cardiac Workflow

1. Prepare the patient.
2. Attach ECG electrodes to the patient.
3. Acquire a Scout scan.
4. Acquire a heart localizer scan (recommended, but optional).
5. Acquire a manual bolus timing scan, or utilize the SmartPrep feature in the next step.
6. Acquire a contrast enhanced cardiac scan.
7. Create new images from cardiac scan data.
   - *Primary Recons*

     Reconstruct basic cardiac scans; including Auto Gated or Manual Primary Reconstructions, which can be single phase or multi phase. Choices include: "center phase(s)" or "earliest to latest phase(s)".
   - *Secondary Recons*
8. Review reconstructed images.

2.1 Prepare the patient

Follow these steps to prepare the patient for the cardiac exam.

2.1.1 Exam prep instructions

Advise the patient of the following:

- Fast for four hours prior to exam.
- No caffeine 12 hours prior to exam.
- No cardiovascular exercise prior to the exam.
- Thoroughly explain all phases of the scan before you start the exam to keep the patient as calm as possible.

Administration of Beta Blockers and/or Sublingual Nitroglycern Spray can be used according to your site's policy.

Please refer to the Society of Cardiovascular CT Guidelines at www.scct.org for more patient preparation information.

2.1.2 Consent forms

If a consent form is required, review the form with the patient and get a signature.

2.1.3 Breathing instructions

Diagnostic cardiac images are dependent on the patient's heart rate during the data acquisition; a calm patient keeps the heart rate steady with a repeatable rhythm. Breathing instructions are therefore very critical to a successful cardiac scan.

Follow these breathing instruction guidelines:

- Deliver the same instructions for each series, starting with the scout scan.
- Program cardiac breathing instructions with AutoVoice to deliver consistent breathing instructions.
  - The voice instructions should be 10 seconds or longer so that the patient is breathed slowly.
  - Have three to five seconds of silence before you click the [Stop] recording button, after you say "take a breath in and hold it." This gives the patient enough time to hold his breath before the scan starts and for the heart rate to stabilize before the scan. This time prevents the patient from breathing in during the first several slices, which results in image motion.
  - The Preset Delay in AutoVoice can be used to program an additional one to seven seconds prior to X-ray on, as needed per each patient.
- The scan time for the contrast enhanced cardiac gated acquisition is approximately 1 second for a single scan location to cover the entire heart. The heart rate stabilizes two to seven seconds after a breath hold, therefore have the patient start the breath hold three to five seconds prior to X-ray exposure. Watch the ECG waveform display so that you can determine when the patient's heart rate stabilizes within the breath hold. Adjust your breath hold instructions to achieve as stable of a heart rate as possible during the contrast enhanced cardiac gated scan.
- Per your physician and site's policy, deliver two to four liters of oxygen via nasal cannula if the patient has difficulty holding his breath. This can help lower the heart rate.
- Practice the breathing instructions with the patient.

2.1.4 IV setup and contrast

- To conserve CT table time, setup the patient IV line outside the scan room.
- Explain the contrast injection and potential effects, even if the patient has had a previous contrast injection. Reassure the patient that what he feels during the injection is normal and to remain relaxed during the scan. An informed patient is a calm, less anxious patient.
- Have the injector loaded with contrast by a trained person authorized by your site. The total volume and contrast strength is site dependent.
  - For single-barrel injectors: load with contrast.
  - For dual-barrel injectors: load a syringe with contrast media and prepare a saline syringe.

2.2 Attach ECG electrodes to the patient

Use this procedure to attach electrodes to the patient for an ECG gated scan.

1. Bring the patient into the scan room.
2. Verify you have a signed consent form, if needed.
3. Transfer the patient to the CT table.
   - Position the patient supine, feet first.
   - Landmark the patient at the sternal notch.
4. Review the ECG trigger device status on the Gantry Display. Ensure the selected ECG trigger device is connected and active.

Display Icon	Description
	Internal ECG trigger device is selected.
	External ECG trigger device is selected.

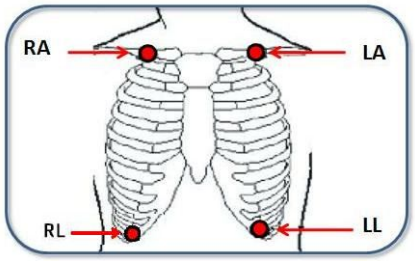
NOTE: You may change the selected ECG trigger device, internal or external, from the tool menu on the Gantry Display. See Section 2.1.2.

5. Place arms above patient's head and elevated by pillows or sponges.

   Do NOT place the arms flat on the table or on the gantry. This position can limit vessel flow and cause arm/shoulder motion. As the table moves into the gantry during the scan, it tends to cause the patient to arch his back raising the chest and thus causing incorrect registration artifacts.
6. With the patient's arms above his or her head, select RA and LA electrode placements over the clavicles. Do not place any electrodes over muscle, scar tissue, or hair for the following reasons:
   - **Muscle** — The ECG can pick up muscle electrical activity due to the above head arm position. Help the patient to relax his or her arms and reduce shoulder muscle fatigue.
   - **Scar tissue** — This is denser than normal tissue, which makes it difficult to get a good signal. If the patient has scar tissue in the shoulder area, then place the electrode out onto the patient's arm. In the chest area, place the electrode where there is no scar tissue.
   - **Hair** — Electrodes placed over a very hairy area do not allow good skin contact. If necessary, shave a four-inch square area for the electrode placement.
7. To remove any lotion or oils, gently scrub the electrode location with cotton gauze until the skin is a healthy pink. Do not use alcohol to prepare the electrode site.
8. With the patient in the scan position (arms above the head), apply the ECG electrodes and leads to the patient no more than 5 to 10 minutes before the scan. Follow these guidelines:

- Use GE recommended electrodes: Dyna/Trace1500 by ConMed. Electrode ordering information is found on the top of the IVY monitor or in the Integrated Cardiac Module (ICM) Operator Manual. Using other electrodes can result in gating errors that can lead to non-diagnostic images.
- Use electrodes made for short term monitoring (e.g. exercise monitoring). Do not use electrodes used for long term monitoring.
- Always use new ECG electrodes (radiotranslucent with silver/silver chloride) with a fresh gel pad. Dry or expired electrodes can result in poor signal conduction that can cause intermittent triggering.
- Keep the electrodes as far away as possible from the scan field of view.
- Place the two upper electrodes directly on the mid portion of the patient's clavicle. If needed to produce a better signal, move the electrodes towards the arms.
- Place the two lower electrodes at the bottom of the rib cage.

Illustration 1: Recommended four electrode placement



Electrode	Description
RA	US (white); EU (red)
LA	US (black); EU (yellow)
RL	US (green); EU (black)
LL	US (red); EU (green)

9. Review the ECG waveform. Ensure the patient's heart rate is within allowable system limits for scanning: 30 to 200 beats per minute.
   a. If the Internal ECG trigger device is selected and active, the user may display the ECG status area by selecting the ECG waveform icon using the back, forward and enter keys on the gantry.
   b. If the External ECG trigger device is selected and active, ECG waveform will be displayed on the external device only. It will not be displayed on the Gantry Display.
10. If the ECG waveform appears noisy and/or improper R-peak triggering occurs at any time prior to the diagnostic scan series, use the impedance measurement utility on the ECG trigger device to ensure proper electrode connection. See *Check Electrode Impedance*.

    Reposition any electrodes with poor electrode connection and then recheck the impedance value. After repositioning electrode(s), initiate another impedance measurement. Repeat process until all electrodes indicate successful impedance measurements.

11. Check the waveform. The more abnormal the waveform, the less chance for a successful cardiac exam. A calm patient keeps the heart rate steady with a repeatable rhythm. A significantly varying heart rate can result in non-diagnostic images. A low and stable heart rate typically allows a high quality study with low radiation dose.

Illustration 2: Normal waveform

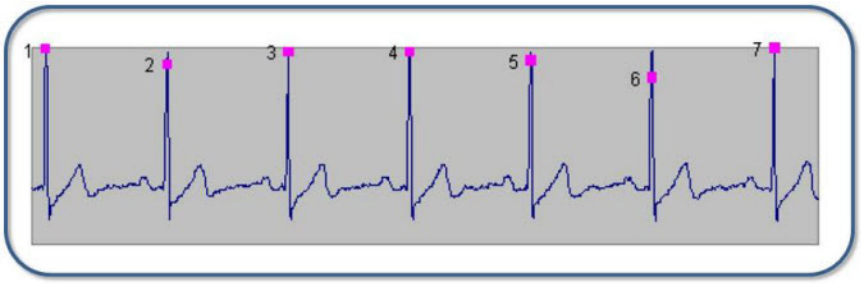


Illustration 3: Noisy ECG trace with extra trigger at #4

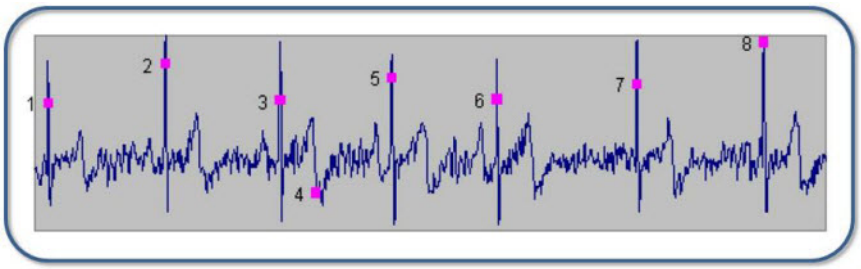


Illustration 4: Elevated T-wave causing double trigger

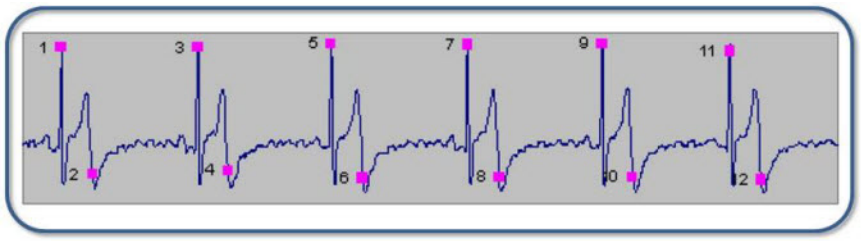
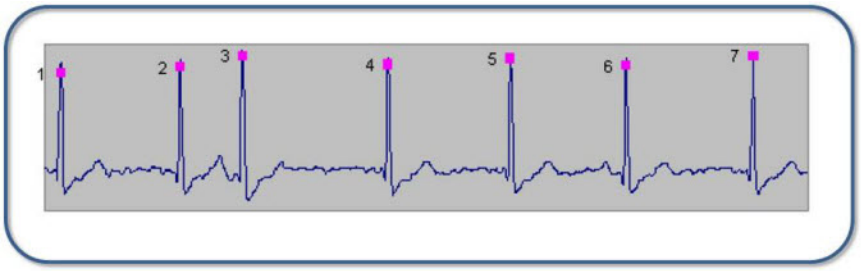


Illustration 5: ECG trace with a premature beat arrhythmia at trigger #3



12. Complete these activities to improve the ECG trace, if needed.
    - Check the cable connections.

- If the External ECG trigger device is selected, position it away from the table and gantry to minimize sensitivity to noise.
- Consider an alternative electrode placement: remove electrodes, prep the patient again, apply fresh electrodes, and repeat the impedance check.
- Check default electrode selection on the active ECG trigger device.

2.2.1 Adjust ECG Trigger Device Settings

2.2.1.1 User Console

The User Console allows the user to select an ECG Trigger Device, internal or external, and adjust the Internal ECG trigger device settings.

The Internal ECG trigger device settings that the user may edit include:

- Active Lead: lead I, lead II, lead III or auto
- ECG Waveform Filter: enabled or disabled
- ECG Simulator: enabled or disabled; if enabled, the heart rate is simulated
- ECG Waveform: gain level or auto
- Pacer Detection: enabled or disabled

1. Left click on the *Mode* drop down menu in the upper left corner of the image display and select *Preferences*.
2. In the Preferences utility, select *EKG device* and make any adjustments or changes.

2.2.1.2 Gantry Display

The Gantry Display allows the user to select a ECG Trigger Device, internal or external, and adjust the Internal ECG trigger device settings.

The Internal ECG trigger device settings that the user may edit include:

- Active Lead: lead I, lead II, lead III or auto
- ECG Waveform: gain level or auto
- Pacer Detection: enabled or disabled
- ECG Waveform Auto Display: enabled or displayed

1. Select the tool screen on the Gantry Display using the back, forward and enter keys on the gantry.
2. Select the ECG settings option on the Gantry Display tool screen using the back, forward and enter keys on the gantry.
3. Change the selected ECG trigger device and/or the Internal ECG trigger device settings using the back, forward and enter keys on the gantry.

NOTE: If the External ECG trigger device is selected, all other menu options are disabled. See accompanying user documents for External ECG trigger device operation.

2.2.1.3 External ECG Trigger Device

For information on the External ECG trigger device settings and how to change the device settings, see accompanying user documents for instructions.

2.2.2 Check Electrode Impedance

The user may initiate an ECG electrode impedance check from the CT system if the Internal ECG trigger device is selected. For information on checking electrode impedance using an External ECG trigger device see accompanying user documents for instructions.

Initiating Electrode Impedance Check

2.2.2.1 User Console

The User Console allows the user to initiate an impedance measurement, if the internal ECG trigger device is selected and active.

1. Right click on the ECG waveform in an active patient study.
2. Select *Test Electrode Impedance*.

2.2.2.2 Gantry Display

The Gantry Display allows the user to initiate an impedance measurement, if the internal ECG trigger device is selected and active.

1. Select the ECG settings option on Gantry Display tool screen.
2. Select *Test Electrode Impedance*.

2.2.2.3 Electrode Impedance Results

The system displays the electrode impedance measurement results on both the User Console and the Gantry Display. Measurements are displayed with a color indicating whether the measurement is within the allowed threshold. Green indicates a good electrode connection and red indicates a poor electrode connection.

2.3 Acquire a Scout scan

Use this procedure to acquire a scout scan series for the cardiac protocol.

1. From the scan monitor, open the *Patient Scheduler* drawer.
2. Select the patient to be scanned and click [Select Patient] , or double left click the desired patient from the list.
3. Enter the patient's information.
4. Start or connect the IV line to the contrast tubing.
5. Review the contrast effects with the patient.

6. If you have not already attached the electrodes to the patient, attach them.
   - For details see, Section 2.
   - Do not scan until you have an acceptable cardiac waveform and heart rate.
7. Secure both IV tubing and ECG cables. Make sure that the cables do not dangle from the table.

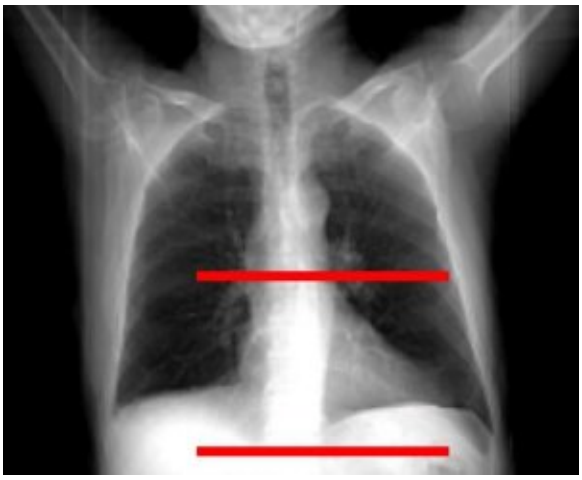
   ECG lead wire movement during the scan can result in a degraded signal.
8. Review breathing instructions with the patient.
9. From the *Protocol Selection* screen, select a cardiac protocol and click [Accept].
10. From the *Scan Settings* screen, click [Confirm Settings].
11. Press **Move to scan**.
12. Deliver the breathing instructions and table move instructions.
13. Press **Start Scan**.
14. Repeat Steps 11–13 to acquire an orthogonal scout.
15. Proceed to the Acquire a heart localizer scan procedure.

2.4 Acquire a heart localizer scan (optional, but recommended)

Use this procedure to acquire Axial images that can be used to determine the start and end locations for the heart scan, and to determine the location for the contrast bolus tracking scan.

1. From the *Scan Settings* screen, click [Continue].
2. Choose one of the following options:

Illustration 6: Heart localizer



   - **Option 1** — Gated localizer for calcium scoring
     1. Ensure that the scan mode is Cardiac Axial.

2. For calcium scoring recommended scan settings, see Section 3.4, Cardiac scan modes .
3. Adjust the position of the Graphic Rx region to fully cover the heart.

- **Option 2** — Ungated localizer
  1. Ensure the scan mode is Helical.
  2. Recommended settings: 120 kV, 0.4 seconds, 60 mA (100 mA for large patients), 1.375:1 pitch, 55 table speed.
  3. Position the localizer lines to cover just the heart, approximately from the carina to 2 cm below the apex of the heart.

3. Evaluate the ECG waveform for heart rate stability.
4. Click the [Confirm Settings] icon.
5. Press <Move to scan>.
6. Deliver breathing and table move instructions. Give the patient the same breathing instruction that they have practiced.
7. Press <Start Scan>.
8. Continue on the *Scan Settings* screen to one of the following procedures:
   - Acquire a manual bolus timing scan and acquire a contrast enhanced cardiac scan.
   - Acquire a contrast enhanced cardiac scan using SmartPrep.

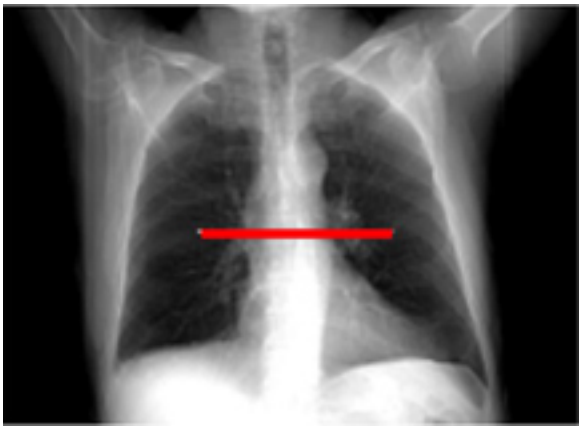
2.5 Acquire a manual bolus timing scan

Use this procedure to calculate the bolus timing of when to start the contrast injection to capture the arterial phase. Omit this step if SmartPrep will be used.

1. From the *Scan Settings* screen, click [Continue].

   Recommended settings: 120 kV, 1 rev/s, 50 mA, 5 s prep, 1 s ISD, 5 mm/1i
2. Place the localizer line one centimeter below the carina and just above the base of the heart, the optimal location to find the ascending aorta for a timed contrast injection.

Illustration 7: Localizer scan location for timed bolus injection

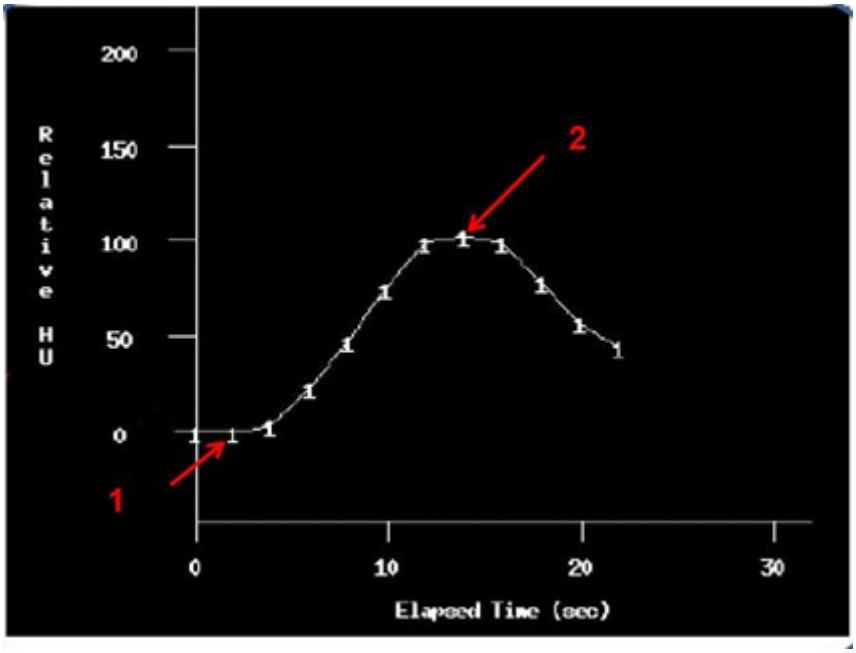


3. Evaluate the ECG waveform for heart rate stability.

   From the *Scan Settings* screen, check that the ECG is reported out in the *ECG and Gating* collection, or open the *Setting* collection and turn ECG Gating ON.

4. Click [Confirm Settings].
5. Deliver breath hold instructions identical to the instructions you will use for the cardiac gated series. See breathing instructions for more details.
6. Press <Move to scan>.
7. Start the injector.
   - If using the Integrated Injector option: The injector is started automatically when <Start Scan> is pressed.
   - If not using the Integrated Injector option: Simultaneously press <Start the Injector> and <Start Scan>.
8. Observe the heart rate during the scan.
9. Click the viewport with the reconstructed test bolus images. Review the images and identify the image with contrast in the ascending aorta.
10. From the image display, open the *Measure Tools* collection and select *MIROI*.
11. From the *MIROI Analysis* screen, select [Ellipse ROI].
12. Click and drag the ROI to the ascending aorta.
13. Size the ROI to fit completely inside the aorta.
14. Click [OK].
15. Use the graph to calculate the bolus timing.

Illustration 8: MIROI graph



Number	Description
1	first tick mark
2	pre-scan delay time

a. Count each tick mark to the peak of the curve.

b. Multiply the number of tick marks by two.

c. Add five seconds for prep group delay.

- This time represents the time it takes for the contrast once injected to reach the aortic root where the coronary arteries branch off (Time to Peak enhancement).
- If you use the GE reference protocol, image number one is at five seconds and the tick marks are two seconds apart, as shown in the graph.

d. Add three to four seconds to allow for filling of the distal coronary vessels. The minimum total time should be set to 24 seconds or greater.

In the example below, total time = 24 seconds. The value will be entered in the Prep Group Delay fields on the *Timing* collection on the *Scan Settings* screen, for the contrast enhanced cardiac scan.

- (7 tick marks × 2 = 14 seconds)
- (+5 for prep group delay = 19 seconds for peak enhancement time)
- (+4 for distal filling of vessels = 23 seconds)
- (+1 additional delay to make total delay 24 seconds or greater = 24 seconds)

NOTE: If total time >= 24 seconds, no additional delay is required.

16. Click [Continue] to proceed to the contrast enhanced cardiac scan.

2.6 Acquire a contrast enhanced cardiac scan

Use this procedure to acquire the contrast enhanced cardiac scan. This is the final scan before transferring the images to the Advantage Windows Workstation.

1. Confirm the ECG trace is strong and stable.
2. Select the SFOV: Cardiac Small, Cardiac Medium, or Cardiac Large SFOV. When a Cardiac SFOV is selected, dose is computed based on a 32 cm phantom.
   - *Cardiac Small DFOV* default is 25 cm; upper limit is 32 cm.
   - *Cardiac Medium DFOV* default is 25 cm; upper limit is 36 cm.
   - *Cardiac Large DFOV* default is 25 cm; upper limit is 50 cm.
3. Position the scan lines to cover the complete heart from approximately 1 cm superior to the left main coronary artery ostium to 1 cm inferior to the apex of the heart.
4. Confirm that a cardiac scan mode is selected.
5. Review the heart rate measurements made during the breath hold recording, and the ECG and Gating settings that were adjusted based on those measurements.
6. Review the ECG and Gating settings.
   - The data acquisition windows/parts indicate the portion or portions of the cardiac cycle that will be imaged.
   - When using Auto Gating, the acquisition windows/parts will change depending on the patient's heart rate during the most recent ECG recording during a breath hold.
7. Arrhythmia Management.
   - When using Auto Gating and an irregular heart rhythm is detected either during the last breath hold or during the previous few minutes, the system may scan the patient two times, to increase the likelihood of a clinically successful scan. The Auto Gating Profile determines if this setting is enabled or disabled, and the user has the ability to change this setting by disabling Auto Gating and changing the Instant Rescan setting.
   - This is indicated by a value of two scans.
   - This value can be changed after setting Auto Gating to “Off”. Change this value if it is not appropriate.
8. Enter the prep delay that you determined from the MIROI timing bolus scan. The typical prep delay time is Peak + 9 seconds.
9. The Primary Recon is the primary reconstruction for the scan series and may influence scan parameters. If needed, prescribe secondary reconstructions 2 through 10.

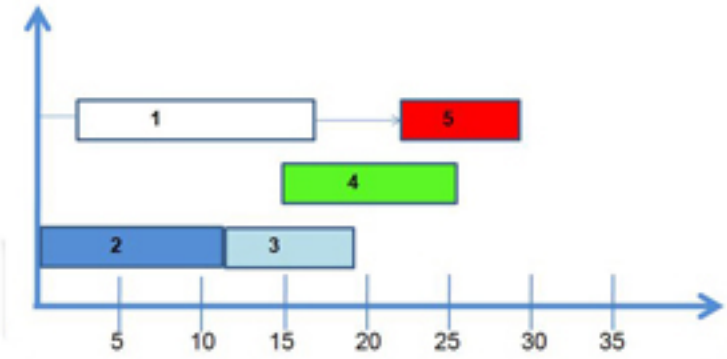
10. Click the *Contrast* collection, choose the *IV Contrast* setting, and enter the contrast description and amount.

    Alternatively, you may choose one of any preset items from the list. This is available in the *Contrast* collection.

11. Program the contrast injector.

    - The protocol used varies depending on the contrast type, patient size, and injector capability.
    - Consider adjusting the volume of contrast on the second phase to insure a six second range from the end of the contrast injection to the start of X-ray on. This delay time insures that if using saline, you are getting the advantage of the saline bolus in the right chamber. Start the scan too soon and you will not see enough saline flush through the SVC. Start the scan too late and you will completely flush out the right chambers.
    - The time delay from the end of the contrast injection (3) to the start of the scan (5) should not exceed six seconds.
    - Skip to the next step if SmartPrep is selected.

Illustration 9: Time delay



Number	Description
1	22 second prep delay
2	phase 1
3	phase 2
4	saline for ten seconds
5	X-ray on

12. See the *Scan Applications* chapter; *SmartPrep* section for more details.

    Typical SmartPrep parameters for cardiac scans:

    - mA = 40 to 60
    - Monitoring Delay = 10.0 seconds
    - Monitoring Inter-scan Delay (ISD) = 1 second produces an image every 1.7 seconds

- Enhancement threshold = 150
- Diagnostic Delay = Auto Minimum or desired delay time
- The minimum delay between Monitor and Scan phase is based on the Monitoring location relative to the start location for the Scan phase.

13. Arm the injector.
14. Click [Confirm Settings].
15. Give the patient the same breathing instructions as the previous series. See Section 1.3 for more details.
16. Press <Move to scan>.
17. Start the injector.
    - If using the Integrated Injector option: The injector is started automatically when <Start Scan> is pressed.
    - If not using the Integrated Injector option: Simultaneously press <Start the Injector> and <Start Scan>.

3 Cardiac Scan Parameters

Use these parameters to select Cardiac Scan Type and to review and setup Primary Recon and any Secondary Recon or Recons.

3.1 Scan Type

1. From the *Scan Settings* screen, open the *Scan Type* collection.
2. Select Cardiac Scan Type.
3. Click [Apply].

3.2 Primary Recon

From the *Scan Settings* screen, open the *Primary Recon* collection and make any changes as needed.

3.3 Secondary Recon

From the image monitor, Reconstruction and Image Processing Task List, you can edit, add, or delete Secondary Recons.

Right-click on an existing recon task or adding a new one opens the editing panel to the right of the task list.

Any needed recon setting changes can be made within the editing panel.

Prior to the scan, Primary and Secondary Recon allow the following options for cardiac phase selection: Center Phase(s), Earliest to Latest or Function.

After the scan, additional phase selection options are available. See Cardiac Secondary Recon for more details.

3.4 Cardiac scan modes

Cardiac Axial

- Use Cardiac Axial imaging for low dose cardiac or cardiovascular imaging when the system data acquisition timing will use the patient's ECG signal.
- Cardiac Axial imaging can acquire data at one or multiple cardiac phases or phase ranges within a single cardiac cycle.
- Cardiac Axial imaging can be used to simultaneously acquire images of cardiac function by imaging at a low dose throughout one complete cardiac cycle.
- Cardiac Axial imaging can be used to obtain images during consecutive cardiac cycles.
- Cardiac Axial imaging uses a patient's heart rate and heart rate variation to determine the patient-specific cardiac scan duration, providing robust acquisition of the cardiac phases that will be most useful for clinical assessment.

- Cardiac Axial imaging incorporates automatic adjustment of the system collimation to acquire low-dose cardiac scans within a single heartbeat, and to acquire larger scan ranges with automated, dose-optimized collimation with a minimum number of interscan table position boundarys.
- Cardiac Axial imaging is used for non-contrast calcium score scans.

  Recommended setting for calcium scoring (including Agaston, calcium volume, and calcium mass): 75% cardiac phase (acquisition window), 120 kV, 0.28 sec/rotation, 2.5 mm slice thickness, 160 mm coverage, Noise Index = 18, and 60% ASiR-V. This Noise Index corresponds to an average mA of 350 with an ASiR-V level of 60%.
- The system will support heart rates from 30 to 200 beats per minute, but imaging cardiac patients with arrhythmias, mechanical dysfunction, or higher heart rates may lead to images that are degraded because of motion, which may compromise diagnostic quality.

3.4.1 Anatomy Selection

The user sets the start and end location of the cardiac scan, either graphically or using a numerical entry. The system determines the minimum number of exposures and the smallest collimation or collimations that will cover the prescribed region to minimize both scan time and dose.

Hearts can typically be acquired using a single exposure. Scans that require the aortic arch or scans of coronary artery bypass graft (CABG) patients will typically require two exposures. In this case, the system also optimizes to place the entire heart within a large inferior-sided scan with a smaller superior-sided scan.

The user inputs the top and bottom of the region where imaging is required. The system generates scan prescription parameters that will cover these top and bottom locations out to the edge of the DFOV specified for the primary reconstruction. Additional image slices will also be reconstructed above and below these locations to the extent allowed by the geometry of the system. The first and last image locations are displayed, and these values can be indirectly changed by specifying where full field of view images are required.

3.4.1.1 Considerations

The advanced, wide coverage system is able to generate high temporal-resolution images throughout most of the imaged volume. Additionally, the system generates images with excellent spatial resolution but with increased susceptibility to motion artifact in the outer radial portions of several of the first and last images. For this reason, we recommend that the scanned region extend at least 1 cm beyond the heart in all directions.

3.4.1.2 Graphic Prescription (Graphic Rx)

Two graphic prescription modes are available: simple and detailed. The modes can be selected from a menu at the top of the Graphic Rx images. From the Graphic Rx, the user can use the scout to specify the required scan range, as well as the lateral extent of the primary reconstruction. When two orthogonal (e.g. A/P and Lateral) scouts are acquired, the graphic prescription remains synchronized.

Simple Mode:

- Purple lines indicate the location of the first and last images that will be generated. These images may have a relatively small field of view.
- A blue Graphic Rx box indicates the approximate location of the image region that will have optimal temporal resolution across the full DFOV for the primary image reconstruction.

Detailed Mode:

- Purple lines indicating the location of the first and last images that will be generated. These images may be relatively small.
- A blue Graphic Rx hexagon, or series of hexagons, indicates the image regions that have optimal temporal resolution.

Handles are available near the top and bottom of the blue Graphic Rx region. Adjust the location of these handles to indicate the locations where you require full field of view images. The system then determines the smallest available scan range that will cover this request, which will be reflected by the position of the blue region and the purple lines.

Additionally, the user can enter a numerical value for the S/I location in the start or end scan field. The value that you enter is where you require a full field of view image. The system will compute and display the location where it will generate the first or last image.

3.4.2 Scan Overlap

The system applies a small amount of overlap when scanning neighboring regions. The amount of overlap is controllable from the GraphicRx toolbar.

- Minimum overlap will generate images with some susceptibility to motion artifacts in the middle to outer region of axial slices near the table position boundary. The minimum overlap has the highest dose efficiency.
- Medium overlap will generate images with some susceptibility to motion artifacts in the outer region of axial slices near the table position boundary. This is the pre populated setting in the GE Reference protocols.
- Full overlap will generate images with optimal temporal resolution, and hence, minimal susceptibility to motion artifacts throughout the axial slices near the table position boundary. The increased overlap results in a higher dose scan than Minimum or Medium overlap.

3.4.3 Single Table Position

When the Single Table Position setting (see *Coverage Speed*) is set to “One”, the system constrains the scan range to the maximum detector coverage.

3.5 Set the ECG and Gating settings

The ECG and Gating settings control the timing for when the scan data will be acquired.

When you select *ECG and Gating* from the *Scan Settings* screen, the screen that displays will depend on the scan type selected.

- The heart icon on the gantry display indicates the monitor is connected with the gantry.
- The instantaneous BPM heart rate is shown on the console and monitor.
- If the heart rate does not display and a lead off message is displayed, follow these guidelines:
  - Check Gating box to view the ECG trace on the scan monitor.
  - Check electrode placement. Consider an alternative placement to improve the cardiac signal.

If necessary to reestablish communication with the Internal ECG trigger device, it can be restarted from the Service Options.

3.5.1 Auto Gating

When Auto Gating is enabled, the system uses the heart rate measurements from the most recent breath hold recording with the Auto Gating Profile table, to automatically prescribe the data acquisition timing. The ECG recording that is used for Auto Gating is indicated by a white dot next to the name of the recording, to the immediate right of the ECG trace window. Similar white dots are next to the settings that are specified by the Auto Gating feature.

- Turn Auto Gating “Off” to allow manual changes to any of the settings that are specified by the Auto Gating feature.
- Turn Auto Gating “On” to reapply the settings determined by the heart rate measurements and the Auto Gating Profile, removing any manual changes that may have been made to a setting.

The Acquisition Windows below set the desired areas of the cardiac cycle to be imaged and thus determine the overall exposure time of the scan(s). The kV and mA Control settings determine the mA values as a function of the heart cycle and thus determine the dose of the scan(s).

3.5.1.1 Gating Based On

This setting shows the ECG recording and the associated average heart rate.

When no ECG recording exists, the values for parameters normally specified by the Auto Gating feature come directly from the scan protocol definition.

The user cannot change the Auto Gating Profile at this point in the workflow. If a different Auto Gating Profile is desired, you must switch to a scan protocol that uses the desired Auto Gating Profile.

3.5.1.2 Acquisition Window, Part 1

This setting directs the system to acquire data so that an image may be generated at the specified cardiac phases or times. For background information about R-wave, R-wave to R-wave, and % phase, see the *Cardiac Phase Background* section below.

While preparing to acquire scan data, after each R-wave is detected, the system predicts the heart rate of the upcoming beat to be the same as the last previously measured regular beat. The system begins to acquire scan data from about half a rotation before the first required phase or time, continuing to acquire scan data until about half a rotation after the last required phase or time. For

example, at a gantry rotation time of 280 ms and a real-time predicted heart rate of 60, corresponding to an R-wave to R-wave time of 1000 ms, an Acquisition Window of 75% would result in scan data acquisition from about 610 ms (= 1000 * 75% - 280/2) to about 890 ms (= 1000 * 75% + 280/2).

The system sets the minimum data acquisition so that SnapShot Freeze images can be generated for at least one cardiac phase.

Although scan data is acquired for a duration of at least one complete rotation, the temporal resolution is, on average, half of the gantry rotation time (e.g. 140 ms when the gantry rotation time is 280 ms). The additional data is used for the outer few slices, and for image quality improvements throughout the volume. The tube current (mA) is modulated to typically 20% for the outer views, so that the additional image information can be provided with minimal increase in patient dose.

A range can be specified (e.g. 70% – 80%), indicating that the system should acquire data so that all phases in the range can be reconstructed, assuming that the actual heart rate variation is within the limits specified by the HR Variation Allowance parameter (described below).

A time value is used to specify an absolute time after the R-wave. For example, a value of 250 ms will acquire scan data centered 250 ms after an R-wave, which may be useful, for example, for imaging patients prior to electrophysiology procedures.

The phases or times to be acquired are shown graphically in the Acquisition Window and Heart Rate widget.

Allowed values for the acquisition window are from 0 to 300%, or from 0 to 1000 ms. A typical value is 75%, typically corresponding to mid diastole. Values greater than 100% are for phases to be acquired from the following beat, most commonly used for Acquisition Window, Part 2 or Part 3.

Set the mA value for this acquisition window to a percentage of the value specified in the kV and mA Control setting. Lower values reduce dose, but will also increase the amount of noise in the images. The mA value set here is the 100% level for Acquisition Window, Part 2 or Part 3 below.

If acquiring data for multiple purposes (coronary, function, etc.), Coronary Assessment acquisitions should be prescribed in Acquisition Window, Part 1.

Widen for SnapShot Freeze (SSF)

Set the Widen for SnapShot Freeze gating parameter to “On” to ensure that the system will acquire sufficient data to support SnapShot Freeze processing at all of the prescribed phases or times.

For example, if *Acquisition Window, Part 1* is 70%-80% and the Widen for SSF gating setting is enabled, then as long as the heart rate is within HR Variation Allowance of the predicted heart rate, the system will be able to generate images to support SnapShot Freeze processing at 70%, 80%, and all phases in between.

Applying this parameter to a part of the Acquisition Window can result in a slightly larger data acquisition window. To reduce patient dose, this parameter should not be applied to the part or parts of the Acquisition Window that will not be used for coronary assessment.

3.5.1.3 Acquisition Window, Part 2

A second data acquisition window can be used to acquire additional cardiac phases during the same heart cycle used for *Acquisition Window, Part 1*.

For example, a value of 45%, or a range of 45% -50%, would acquire scan data near the end of systole.

A range of 0 -100% would acquire scan data to generate all phases of the cardiac cycle, which may be useful for functional assessment of the heart. A significantly lower mA value, such as 20%, significantly reduces the tube current except where higher tube current is required by other acquisition windows. Wide reconstructed slices, such as 2.5 mm instead of the 0.625 mm typically used to assess coronaries, reduces the amount of increased noise that otherwise would be seen in functional images.

A range of 60% -150% would acquire data from early diastole (60%) through the end of diastole (100%) and continuing to the end of systole in the following beat (150%). Phases reconstructed every 10% would then show an entire heartbeat, and would allow an ejection fraction calculation based on an end-diastolic measurement followed by the subsequent end-systolic measurement.

Allowed values for the mA % are 10% to 100%. A typical value is 100%, indicating that the system use the mA value specified in the *Scan* chapter, *mA Control* section.

For additional details, see the *Cardiac Modulated mA* section in this chapter and the *Scan* chapter, *mA Control* section.

3.5.1.4 Acquisition Window, Part 3

A third data acquisition window can be used to acquire additional cardiac phases during the same heart cycle used for *Acquisition Window, Part 1*.

For example, if *Acquisition Window, Part 1* is used to acquire 75%, and *Acquisition Window, Part 2* is used to acquire 45%, then *Acquisition Window, Part 3* can be used to acquire functional images from 30% -120%. When combined with a lower mA, such as 20%, this allows the acquisition of functional images for relatively little additional dose.

Allowed values are the same as for *Acquisition Window, Part 2*. Allowed values for the mA % are 10% to 100%.

3.5.1.5 HR Variation Allowance

The phases acquired within the Acquisition Window are only accurate to the extent that the real-time predicted heart rate is close to the actual heart rate. The HR Variation Allowance ensures that the prescribed phases will be acquired as long as the heart rate, in beats per minute, does not jump by more than the HR Variation Allowance value.

For example, if the HR Variation Allowance is 3 BPM, and the real-time predicted heart rate is 60 BPM, then the system will ensure that the prescribed phases will be acquired so long as the actual

heart rate during the beat when data is being acquired is between 57 (= 60 – 3) and 63 (= 60 + 3) BPM.

A typical value will be the heart rate variation measured during the previous breath hold.

For very low heart rates, such as below 50-55 BPM, it may be possible to reduce this value when doing mid-diastolic (e.g. 75%) imaging, as the quiescent duration is long enough that acquisition of the exact prescribed phase may not be required.

Allowed values are 0 to 20 BPM.

3.5.1.6 Instant Rescan

Turning “On” Instant Rescan causes the system to apply the scan prescription on two nearly consecutive beats. While doubling the dose, having two acquisitions increases the chances that at least one of the scans will be diagnostic, using the same contrast injection.

A typical value is “Off” for patients in normal sinus rhythm (i.e. a relatively steady heart rate with no or very few pre-ventricular contractions or other irregular beats). A value of “On” may be used for patients with irregular beats during the prior breath hold, or with multiple irregular beats over the previous several minutes, indicated by red tick marks on the ECG history below the ECG trace.

Turning “On” Instant Rescan turns on Single Table Position Acquisition and sets the Scan Interval to “0” and the Total Scans to 2.

3.5.1.7 Adaptive Gating

Adaptive Gating tells the system to avoid scanning during beats that are immediately after an early beat. The system will delay the exposure due to early beats at most two times during a scan group.

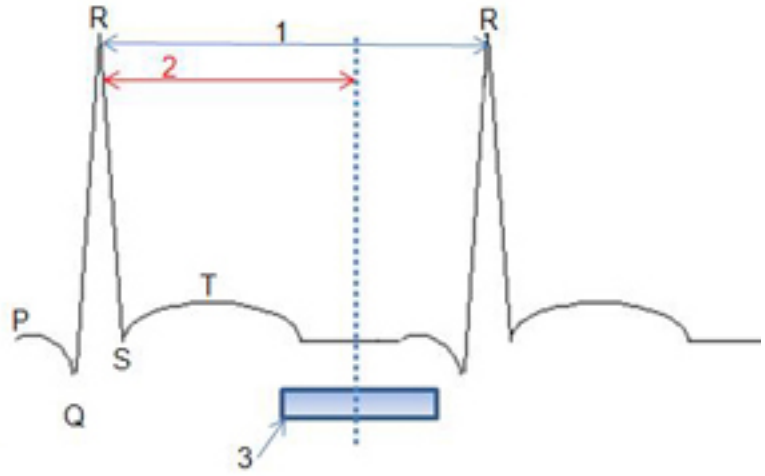
Adaptive Gating is typically turned on when functional information is desired, as the beat after an early beat will not typically be representative of the patient’s cardiac function, or when it is important to avoid or reduce incorrect registrations between neighboring images acquired with multiple table positions.

Set Adaptive Gating to “Off” to allow scanning during compensatory, or unusually long beats which may occur immediately after early beats.

3.5.1.8 Cardiac Phase Background

Use this information to learn about cardiac phases.

Illustration 10: ECG waveform:



Number	Description
1	R-wave to R-wave interval
2	R-peak 75 percent default
3	Reconstruction window

- *Systole*, cardiac contraction, is from R-peak to T-wave.
- *Diastole*, cardiac relaxation, is from T-wave to R-peak.

R-wave to R-wave interval

The R-wave to R-wave interval is the time from the R-peak of one heart cycle to the R-peak of the next heart cycle. The R-peak is used to predict where the targeted phase for reconstruction occurs and then acquire/reconstruct images at that period of time during the heart cycle.

Phase Location (R-Peak Delay (%))

The cardiac phase location is defined as a period in time in the cardiac cycle. The Acquisition Window Range setting (2) controls when the CT system will acquire data. Data is acquired so that images can be reconstructed at all of the specified phases. (3) Refers to the center of the reconstruction window in terms of a percentage distance between any two successive R-peaks given from the ECG.

The cardiac phase location is defined as the time interval from the R-wave to the center of the reconstruction window (3). It is usually desirable to reconstruct images at the phase that has the least amount of cardiac motion. The phase location can be changed to identify where the least amount of cardiac motion occurs. For lower heart rates, the most common location is in the middle of diastole, typically around 75 percent, but as heart rate increases or varies this location may change. It is not uncommon for higher heart rates to have better image quality at the end of systolic portion, typically around 45 percent.

3.5.2 Coverage Speed

3.5.2.1 Detector Coverage (mm)

The detector coverage of the scan, or of the series of scans, is shown. To edit a value in a multi-table position scan, first split the group into individual scans, then change the detector coverage to the desired value. Note that this will disable the automatic determination of the detector coverage based on your numerically or graphically specified end location.

3.5.2.2 Single Table Position

When Table Positions is set to “One”, the feature restricts the system to acquiring data at a single axial location. When the system cannot fully cover the user-prescribed scan region, at the field of view specified in the primary reconstruction, an alert will be displayed by the Anatomy Selection scan start and end parameters, indicating that the scan range has been restricted by the Coverage Speed: Table Positions: One. To allow a larger scan range with multiple table positions, change the value to “One or more”.

3.5.2.3 Number of Passes

The number of times that the system runs the prescription defined in the *Anatomy Selection* and *ECG and Gating* settings. For example, changing the value from 1 to 2 will result in two passes, and will double the patient dose.

This parameter is useful for generating multiple passes of a region, such as for viewing the dynamic changes in contrast.

NOTE: When Instant Rescan is enabled, either by the user or by the Auto Gating feature, the number of passes will be two. When Instant Rescan is changed from enabled to disabled, the Number of Passes will be one.

3.5.2.4 Time Between Images

The system adds a delay between each pass so that generated images will separated by this amount of time. When the acquisitions are ECG gated, the system attempts to generate images that are within one-half of an R-wave to R-wave interval (i.e. half of a heartbeat), or less, of the specified time.

3.6 Display an ECG Trace on the operator console

The ECG Trace component is displayed near the top of the scan monitor. It shows the real-time heart rate, recent min and max heart rates, the ECG Trace, the procedure duration, user-selectable jump points to show the live ECG or one of up to three breath-hold ECG recordings. Immediately below the ECG waveform is a history of the ECG over the previous five minutes. The left triangle allows the history to be expanded, showing the heart rate relative to a nominal target. Red tick marks display times when irregular beats were detected. Blue squares indicate times when ECG statistics were measured during a breath hold. The statistics of the last recording, indicated by a white dot, are used to set the Auto Gating parameters. Clicking anywhere in the history or expanded history causes the strip to jump to the ECG Trace at that point. Click on "Live" to return to the live ECG.

When Auto Gating is “On”, scan settings in the *ECG and Gating* collection are automatically updated when a patient breath-hold ECG is recorded. These settings are indicated by a white dot, and are highlighted when an update occurs.

The ECG Trace is automatically displayed on the *Scan Settings* screen when an ECG-gated scan mode is selected.

For scan modes that are not ECG-gated, the ECG Trace is displayed when the *ECG* option is "*On*" in the [Gating and ECG] collection. Note this can be preset for each series in a protocol.

Place the cursor in the *ECG Trace* viewer, right-click to display the *Statistics* menu.

- Select Reset Statistics to reset or clear the current statistics if the patient's HR has changed. This step may be desired if there has been a change in the patient's heart rate or if a modification of the electrodes or leads has caused changes to the waveform.
- Select Preferences to open the *Stats Preferences* screen. From the Stats Preferences screen, select values for any of the following options:
    - Stats Window to define the moving window of time during which the heart rate statistics are calculated (Min, Avg, Max). Heart rate is a real time heart rate. Minimum HR is the minimum heart rate detected within the time frame you specify. Maximum HR is the maximum heart rate detected with the time frame you specify. Average HR is the heart rate averaged within the time frame you specify. The default is 30 seconds and the allowable range is five to 60 seconds.
    - Show/Hide Statistics to set an on/off preference for every exam. This setting is different from the right mouse menu *Show/Hide* option that turns off the statistics for just the current exam.
    - Click [Apply].

4 Cardiac Modulated mA

The goal of Cardiac AEC modulation with cardiac modes, similar to AEC modulation for non-cardiac modes, is to deliver a patient exposure that is appropriate to the combination of the patient attenuation and the diagnostic imaging task. In AEC with Cardiac modes, the advantages of patient-specific exposure modulation control, and the scanning and image reconstruction techniques unique to cardiac imaging mode combine to enable low dose cardiac imaging of the patient.

Similar to other AEC-related scan modes, a scout of the patient is initially obtained when using AEC with Cardiac modes. The AEC feature then uses the patient attenuation information extracted from the scout and combines this unique information with the user-prescribed scan parameters contained in the protocol to derive an appropriate scan technique. Similar to standard AEC mode, a user-prescribed Noise Index is the scan parameter input that plays the major role in determining the final patient exposure solution derived by the feature. In general, a higher Noise Index results in a reconstructed image dataset with higher overall image noise but at a lower patient exposure; conversely, a lower Noise Index results in lower overall image noise but at the cost of generally higher overall patient exposure. The user must balance the competing requirements of image noise and patient dose to arrive at a Noise Index that accomplishes the diagnostic imaging task at a dose that is as low as reasonably achievable

In ECG-gated mA modulation for cardiac, the AEC algorithm determines the required peak mA of the exposure profile to satisfy the user requested Noise Index for the reconstructed image. The peak value is derived from the patient attenuation information extracted from the scout projections, combined with the user requested scan parameters. The AEC algorithm recognizes the fact that the user is in cardiac mode and adjusts the scan technique for an equivalent non-cardiac AEC scan to account for the unique challenges imposed by cardiac scan acquisition and reconstruction techniques.

See *Scan* chapter for detailed information on non-Cardiac AEC.

5 Auto Gating

Auto Gating is a feature designed to optimize ECG-gated acquisition settings based on an assessment of patient heart rate and variability, primarily focused on exams of the coronary arteries. A similar feature on CT750 HD is referred to as SnapShot Assist. The Auto Gating workflow provides the capability to record an ECG Trace during a breath hold to determine the acquisition settings best suited for the heart rate characteristics of the patient.

For example, at higher heart rates, systolic phases are usually preferred due to changes in cardiac motion. Auto Gating automatically uses heart-rate specific acquisition settings from predetermined look up tables.

A patient's heart rate can change over the course of a cardiac examination and result in suboptimal results if adjustments are not made prior to the diagnostic cardiac CT scan. A patient's heart rate should be assessed throughout an exam to watch for heart rate changes.

Consider the following factors that can impact a patient's heart rate during Coronary CT Angiography (CCTA). These factors should remain consistent between the practice breath hold and the gated cardiac exam to ensure that the pre-scan heart rate assessment is accurate.

- Breath hold technique — end inspiration, mid inspiration, suspended breathing, etc.
- Time delay after the breath hold command.
- Contrast — total volume, injection rate.
- Beta blockers — oral and or IV.
- Vasodilators — can lead to slight increase in heart rate.
- Patient aspects — sex, age, electrophysiological disease, cardiac function issues.

5.1 Auto Gating Acquisition Settings

Auto Gating generates suggested scan settings using the selected profile based on the patient's recorded ECG and selected Auto Gating profile (e.g., GE Adult Coronary). It uses the patient's recorded heart rate information to predict the heart rate behavior during a CCTA scan to optimize the parameters on a per-patient basis. You can acquire a recording automatically during scan acquisition (timing bolus, calcium scoring series, etc.) or manually during a practice breath hold.

No recommendations will be given under the following conditions:

- The ECG trace was recorded more than seven minutes prior to the cardiac scan.
- The ECG recording median heart rate is more than 30 BPM from the current ECG Trace real-time heart rate average.
- The heart rate range/variability measured is greater than 40 BPM.

See *Automatically record the heart rate during breath hold*.

See *Manually record the heart rate during breath hold*.

5.2 Auto Gating Configuration screen

From the display monitor, click the [Mode] icon, then click [Auto Gating Configuration] to display the *Auto Gating Configuration* screen.

The *Auto Gating Configuration* screen allows you to configure acquisition settings based on the patient's heart rate and variation. The bottom half of the screen lets you define scan settings for the selected Heart Rate and Variability categories in the top half of the screen.

Table 1: Auto Gating Configuration tab descriptions

Number	Name	Description
1	Profile and Profile Name area	• Profile allows you to select a User Profile, where you can define the parameters for heart rate and variability for the categories you want to set up. • Profile Name allows you to rename the 20 editable User Profiles.
2	Average (Median) Heart Rate / Max Beat to Beat HR Variation category table	The Average HR/Max Beat to Beat HR Variation interactive table allows you to create heart rate and variation categories.
3	Scan Parameters	The Scan Parameters area allows you to define the scan parameters for Cardiac Axial scans. See *Scan Parameters*.
4	Maximum HR	Allows you to set the maximum heart rate range for the category table. The maximum heart rate is 200.
5	Define Irregular Beat Settings	Opens the Irregular Heart Beat Override and Irregular Beat Override Parameters windows. See Irregular Heart Beat Override.
6	Save	Saves parameter changes.
7	Exit	Closes the screen.

5.2.1 Scan Parameters

The title bar of the *Scan Parameters* area updates to inform you of the exact boundaries selected in the *Average Heart Rate/Max Beat to Beat HR Variation* category table.

Cardiac Axial

Table 2: Cardiac Axial parameters

Name	Description
Acquisition Window	The Acquisition Window defines the phases of the cardiac cycle that will be acquire during the scan, and the relative mA (%) that will be applied for each part of the cardiac cycle. Acquisition Windows can be defined in R-R % or ms offset from prior R-peak.
Heart Rate Variation Allowance	HR Variation Allowance, in BPM, defines the additional X-ray on interval that will be applied to the scan to accommodate a possible discrepancy between the predicted heart rate and the actual heart rate when the system is acquiring data.
Adaptive Gating	A feature used to avoid scanning during the beat immediately after an irregular (short) beat. The system continuously monitors the R-peak Triggers in real time. If the system detects an irregular beat, the system pauses and avoids scanning during the subsequent beat. The system then resumes scanning when the ECG trace returns to normal.

Widen for SSF	This setting directs the system to acquire data so that an image may be generated at the specified cardiac phases or times. For background information about R-wave, R-wave to R-wave, and % phase, see the *Cardiac Phase Background* section below.

5.2.2 Irregular Heart Beat Override

The [Define Irregular Beat Settings] button opens the Irregular Heart Beat Override window. It is based on the number of irregular beats in the recorded trace and/or in the stats window of the live real-time trace.

- Recorded - activates the Irregular Heart Beat mode when irregular heart beats are detected during the user activated breath hold recording of the heart rate.
- Live - activates the Irregular Heart Beat mode when irregular heart beats are detected during the live ECG.

If the number of irregular heart beats are above the defined range, a severe alert message will be displayed to the user. If the number of irregular heart beats fall within the defined range, settings are provided in the Irregular Beat Override Parameters area. "Recorded" should remain selected, otherwise irregular beats detected during the recorded ECG will be ignored and the standard scan settings would be provided based on heart rate and variability.

5.3 Automatically record the heart rate during breath hold

Auto Gating requires an ECG waveform to be recorded during patient breath hold in order to provide profile feedback. Use this procedure to automatically record the patient's heart rate and variability during the Scout, Timing Bolus, Calcium Scoring (Smart Score), or other CT scan series if you have not built recording of a trace into the protocol.

A recording of at least three seconds is required to gather enough data for evaluation of heart rate and variability. The breath hold duration for the scan must be at least as long as the Breath Hold Recording Length setting or no recording will be saved.

1. From the *Scan Settings* screen, click [Gating] to open the ECG Trace Viewer.
2. Right-click in the ECG viewer and select *Record Preferences*.
    - Adjust the *Breath Hold Recording Length*. Valid recording lengths are 3 to 15 seconds.
    - The system will apply the Breath Hold Delay time and AutoVoice Command message that is prescribed in AutoVoice.
        - If no message is selected, an AutoVoice message will not be played and you will need to provide manual breathing instructions.
        - The breathing commands should be the same as given for the contrast enhanced scan.
    - Select *Record trace in this series*.
3. Click [Apply].

5.4 Manually record the heart rate during breath hold

Auto Gating requires an ECG waveform to be recorded during patient breath hold in order to provide profile feedback. Use this procedure to manually record the patient's heart rate and variability in the case when other compatible series with breath holds cannot be used or the patient heart range has changed significantly.

This method may be useful when SmartPrep will be used instead of a Timing Bolus to initiate the scan at optimal contrast enhancement. You may also initiate a practice breath hold recording when patient heart rate changes or any time prior to the contrast enhanced scan.

A recording of at least three seconds is required to gather enough data for evaluation of heart rate and variability. The breath hold duration for the scan must be at least as long as the Breath Hold Recording Length setting or the recording will not be saved.

1. From the *Scan Settings* screen, click [Gating] to open the ECG Trace Viewer.
2. Right-click in the ECG viewer and select *Record Preferences*.
    - Adjust the *Breath Hold Recording Length*. Valid recording lengths are 3 to 15 seconds.
    - The system will apply the Breath Hold Delay time and AutoVoice Command message that is prescribed in AutoVoice.
        - If no message is selected, an AutoVoice message will not be played and you will need to provide manual breathing instructions.
        - The breathing commands should be the same as given for the contrast enhanced scan.
    - Select *Record trace in this series*.
3. Click [Apply].
4. Click [Record].
    - The selected AutoVoice message plays, giving pre-message breathing instructions.
    - When recording is completed, AutoVoice plays the post-message breathing instructions.
5. Click *Recorded* to review the recorded trace.

NOTE: If a patient's heart rate characteristics have changed, use the Record button to re-record the heart rate during breath-hold and generate new suggested scan settings.

6 Cardiac Secondary Recon

6.1 Reconstruct basic cardiac scans

Use this procedure to reconstruct cardiac images with different settings than what was prospectively prescribed.

- Cardiac Axial acquisitions allow reconstruction during a portion of the R-to-R interval. The amount of data acquired is controlled by cardiac phases prescribed in the acquisition.
- See *Create new images from scan data* for retrospective management details.

1. From the display monitor, right click the primary recon task in the Reconstruction and Imaging Processing Task List (RIPTL) and select *Add Recon*.
2. The screen displays all of the scan parameters available for the secondary reconstruction.
3. Optional:

   Type the Retro Start and Retro End locations that fall within the range of the selected group. Add an ***S*** (+) or ***I*** (-) prefix to the location.
4. Optional:

   Click *Thick (mm)* and enter a thickness that populates all groups.

   - If you only need to change the thickness of one group, or only one of multiple groups, select the thickness area for that group.
   - The original detector configuration at which the patient was scanned affects how you can change the slice thickness. The thickness in black is available for reconstruction.
5. Optional:

   Click *Interval* and enter an interval that populates all groups.

   If there is only one group in which you wish to change the interval, or only one of multiple groups, you may select the interval area for that group.
6. Optional:

   Click *DFOV* and type a DFOV value.

   The system defaults to the DFOV used for scan acquisition.
7. Optional:

   Click *R/L Center* and select an individual or all groups (top button). Type an offset value. Use one of the following methods to determine the off-set value:

   - From the *Recon* tab, click [N] under the Graphic Retro column to display the Graphic Retro control panel on the display monitor. The cursor can be used to determine DFOV and R/L and A/P centers.
   - Place the real time cursor in an image and view the image's upper-left corner for the RAS coordinates.

- Click [List/Select] and select the exam and series from which you want to take the R/L values. The series values are displayed in the browser menu.

8. Optional:

   Click *A/P Center* and enter an offset value.

9. Optional:

   Click *Recon Type* and select the algorithm.

10. From the *ECG and Gating* settings collection, click the Recon mode for the phase prescription method.

    This allows you to select the phases of the cardiac cycle from which images are created.

    - Single Phase: enter a single % or ms value to be used for reconstruction.
    - Multi-phase: enter a range of % or ms values to be used for reconstruction.
    - Center Phase(s): A reconstruction will occur at the center of the acquisition window(s).
    - Earliest to Latest: A multi-phase reconstruction will adapt to the available data acquired at a user-defined increment.
    - Function: A multi-phase reconstruction over one heart cycle will be reconstructed at a user-defined increment.

    The manual options, Single Phase and Multi-phase, for defining the reconstruction timing relative to the cardiac cycle, are only available after the scan has been acquired.

    A typical phase prescription is 70 to 80% in 5% intervals, which is applied to all available heart cycles during X-ray on.

11. In *ECG and Gating* settings, select the mode (Single, Multi-phase, etc.) and enter the desired phase(s) for reconstruction.

    - %R displays standard phase percent reconstruction
    - +ms displays absolute millisecond reconstruction
    - -ms displays reverse absolute millisecond reconstruction

12. For Multi-phase, enter the *Start* phase, *End* phase, and *Interval* to reconstruct.

    - The recommended reconstruction phases using percentage recon are 70 percent to 80 percent with a 5 percent increment.
    - If you are acquiring a functional imaging exam for ejection fraction and wall motion, prescribe phases from 5 to 95 in phase increments of 10 percent and consider reconstructing the data with a 2.5 mm thickness.

13. Click [Save] to close the Phase Selection dialog box.

NOTE: A DICOM compliant ECG trace image is automatically saved after each primary and secondary image reconstruction request. These traces are saved in a dedicated Series labeled as 599.

6.2 Interactive ECG Editor

Use these procedures to visually interact with cardiac reconstruction timing relative to the ECG trace. This allows you to adjust gating information such as R-peak trigger time and reconstruction timing relative to the ECG trace.

Considerations

- On the ECG trace DICOM secondary capture image generated with each recon, the following two texts are overlapped: *Series Description* and *Not Intended for Diagnostic Use*. Only use the secondary capture image as a record of the trace used to generate images - it is not to be used for diagnostic purposes.
- If the accession number is not in the image header, it may cause the series to be listed as a separate exam. If so, reconcile the exam on the PACS.

1. Select a patient and exam for Recon and Image Processing, this will open the exam on the image monitor.
2. Select the Series desired for reconstruction.
3. Make edits to R-peak triggers or reconstruction timing on the ECG trace.

Table 3: ECG Editor screen

Number	Description
1	Heart rate statistics are displayed: minimum, maximum, average heart rates and number of irregular beats.
2	Secondary reconstructions parameters are displayed: start phase, end phase, and interval.
3	The trigger point on the ECG Trace for each R-peak is displayed, as well as the X-ray On interval, and the image reconstruction timing when images will be generated.
4	Click the [Save] icon to save your modified trigger locations with exam information.
5	Click the [Restore] icon to restore the original ECG Trace information for the acquisition.
6	Click the [Measure icon] to measure, in msec, the distance between two defined points on the waveform. Place the cursor on the trace and click and drag right or left.
7	Click the [Magnify] icon or the [Minimize] icon to magnify or minimize the ECG waveform.
8	Click and drag the navigation bar to view the selected portion of the waveform.

6.3 Graphically adjust reconstruction timing

Use this procedure to move or reposition image reconstruction timing within a single heart cycle.

6.3.1 Method 1

Place the cursor over the recon location and click, drag, and drop to the new location.

The annotation in the reconstruction location indicates the % or ms where images will be reconstructed.

6.3.2 Method 2

1. Place the cursor over the recon window you wish to move, and right-click *Position Image Recon Timing*.
2. Type and Enter the location as + or - milliseconds.

   The recon timing for selected heart cycle moves to the new location.
3. Click [OK].

6.3.3 Method 1 and 2

For all cardiac scan types, the recon window cannot be moved outside of its current R-to-R interval.

6.4 Insert, delete, or move an R-peak trigger

Use this procedure if gating issues occur during the scan or if the system does not trigger accurately at the R-peak of the ECG trace.

- Insert, remove, or move a trigger to normalize a heart cycle when a trigger occurs at an unwanted location. This can be due to abnormal ECG waveform patterns, external noise interference, and low amplitude trace.
- Remove image reconstruction location from one or more heart cycles to improve image quality when an arrhythmia is present in the scan.

1. Open a prior ECG gated scan series in Reconstruction and Image Processing on the image monitor.
2. To insert a trigger, place the cursor anywhere on the ECG trace where you want to insert it and right-click *Insert Trigger*.

   An additional trigger will display on the ECG trace.
3. To delete a trigger point on the ECG trace and to normalize the heart cycle, place the cursor on the trigger and right-click *Delete Trigger*.
4. To move a trigger, place the cursor over the trigger and click and drag it to the new location.

6.5 Remove recon during a heart cycle

Use this procedure to remove an image reconstruction location from one or more heart cycles.

1. Place the cursor on an image recon location in the ECG Editor, and right click *Delete Image Recon Window*.
2. The ECG trace updates, the recon location is no longer be visible, and the data from that heart cycle is not included in the image reconstruction.
3. Click [Confirm] to reconstruct the images.
4. Review the images created using the ECG editing process. Editing the trace changes the reconstruction using the original scan data.

6.6 Display secondary recon images

Use this information to view secondary reconstructed cardiac images. The following information is for the default numbering system. If you want a new series number assigned, click [New Series].

6.6.1 Single Phase image set

Secondary Cardiac Axial — Series 104 (100 + original series #)

6.6.2 Multi-phase image set

When retro reconstructing a multi-phase (MP) data set to the acquired slice thickness the series numbers are as follows if the original series number is 4.

- Secondary Cardiac Axial — Series 504 (500 + original series #)
- If images are Secondary Reconstructed with a thicker slice, the series number has an additional 50 added on.

6.6.3 Cardiac image annotation

SSCIN (Secondary Cardiac Axial — single sector image)

6.6.4 Edited cardiac image annotation

Image where the ECG trace has been edited, are annotated with an E placed before the scan type, e.g. E/SSCIN.

E/SSCIN (Secondary Cardiac Axial — single sector image)

7 SnapShot Freeze

The SnapShot Freeze (SSF) feature can be utilized to reduce coronary artery motion artifacts that may occur in cardiac exams. SSF is an available recon option with cardiac axial scanning, for both Hi Res and non-Hi Res acquisition modes.

When SSF reconstruction is selected, a special 3-phase image series is generated for subsequent motion correction processing on the AW workstation (or AW Server) with the CardIQ Xpress Process application.

SSF is prescribed at a specified target phase location appropriate for coronary imaging. In the case of higher heart rate exams, you may, for example, wish to prescribe SSF at both a 75% R-to-R target phase (mid-diastole) as well as a ~45% R-to-R target location (approximate end-systole).

All Cardiac Axial scan acquisitions are inherently SSF compatible, meaning that for at least the target phase location corresponding to the center of the acquisition window, SSF is available. However, when prescribing an acquisition with a given phase range (70-80% R-to-R for example), if coronary motion correction is also desired across this full phase range, ensure that Widen for SSF is explicitly enabled as part of the scan Acquisition Window prescription (Otherwise, in the example above, SSF recon may only be available at the 75% phase location.).

Constraints

SnapShot Freeze is not available with the following:

- Cardiac Axial PLUS mode reconstruction
- 0.625 Z , overlapped reconstruction
- DFOV < 15cm

Considerations

- Appropriate cardiac target phase selection (mid-diastole and/or end-systole) is essential for optimal performance.
- Ensure a sufficient acquisition phase range for the anticipated SSF target phase(s). For ease of use, utilize the Widen for SSF checkbox within Auto Gating.
- For a single-beat/single-table position acquisition, position the heart well within the wide-coverage Cardiac Axial scan.
- For an acquisition series that requires more than one axial scan location given clinical coverage needs (perhaps a bypass graft assessment for example), ensure that the native coronaries are well within the coverage of one axial scan to prevent having a higher motion vessel near an axial scan boundary.
- Avoid an excessive image noise level. Select the appropriate kV / mA technique (using the AEC Noise Index parameter) for optimal performance, and utilize ASiR-V as needed.
- Select a recon kernel that is appropriate for coronary imaging.

- Poor contrast opacification of the coronary vessels (low / non-uniform HU enhancement from poor/missed bolus, venous contamination, etc.) can result in sub-optimal SnapShot Freeze motion correction.
- Streak artifacts from surgical clips, pacemaker lead wires, etc., in close proximity to the coronaries, can result in sub-optimal SnapShot Freeze motion correction.
- Utilize targeted reconstruction to maximize pixel resolution; however the prescribed DFOV should allow for at least 2 cm of tissue between the edge of the DFOV and the heart. Do not “over-zoom”.
- As SnapShot Freeze targets coronary motion, for an acquisition series with a scan range significantly longer than the heart itself, select only the axial scan location(s) containing the heart to streamline subsequent SSF motion correction processing.
- Millisecond-based phase prescription and the ECG Editor are fully compatible with SnapShot Freeze. Utilize as needed.

7.1 Prescribe SnapShot Freeze for a Primary Recon

Use this procedure to prescribe SnapShot Freeze for a Primary Recon to reduce motion in the coronary vessels.

1. From the scan monitor, on the *Scan Settings* screen, open the *Anatomy Selection* collection to adjust the DFOV, A/P Center offset, and R/L Center offset as needed.
    - The DFOV has to be at least 15 cm.
    - The prescribed DFOV should allow for at least 2 cm of tissue between the edge of the DFOV and the heart.
2. From the scan monitor, on the *Scan Settings* screen, open the *Primary Recon* collection.
    - Adjust Thickness & Images per rotation as needed.
    - ASiR-V can be turned “On” by clicking the selection, choosing an ASiR-V level in %, and then clicking [Apply].
    - Adjust any other parameters as needed.
    - Select SnapShot Freeze to “On”.
3. The Primary Recon series can be prescribed to automatically transfer for SnapShot Freeze motion reduction processing on the AWWS or AW Server with CardIQ Xpress processing, with the Transfer Options settings collection for the Primary Recon available in the Reconstruction and Image Processing task list on the image monitor.

7.2 Prescribe SnapShot Freeze for a Secondary Recon

Use this procedure to prescribe SnapShot Freeze for a Secondary Recon to reduce motion in the coronary vessels.

1. From the image monitor, Reconstruction and Image Processing task list, select the appropriate Secondary Recon (prescribed as part of the protocol) or add a Secondary Recon using [Add a Recon].
2. Click on an existing Secondary Recon task or add a new one to open the editing panel to the right of the task list.
    - Adjust Thickness & Images per rotation as needed.
    - ASiR-V can be turned “On” by clicking the selection, choosing an ASiR-V level in %, and then clicking [Apply].
    - Adjust any other parameters as needed.
3. Open the *Anatomy Selection* collection to adjust the Recon Start location, Recon End location, DFOV, A/P Center offset, and R/L Center offset as needed.
    - The DFOV has to be at least 15 cm.
    - The prescribed DFOV should allow for at least 2 cm of tissue between the edge of the DFOV and the heart.
4. Open the *ECG and Gating* collection.
    - Select SnapShot Freeze to “On”.
    - Select Phase Type as needed.
    - Select Phase percent or percents as needed and click [Apply].
5. The Secondary Recon series can be prescribed to automatically transfer for SnapShot Freeze motion reduction processing on the AWWS or AW Server with CardIQ Xpress processing, with the Transfer Options settings collection for the Secondary Recon available in the Reconstruction and Image Processing task list on the image monitor.

Chapter 14 View Images

1 Overview

The File Manager application has a variety of display tools and feature a large viewing area to display images.

Considerations

- If a power failure occurs during a prospective image reconstruction, any images reconstructed prior to the power failure are not displayed in the browser/patient list and are not saved in the database. Type an exam/series/image number in the Accelerator Line, and then select another exam from the browser to refresh it. There may be a slight delay. If this action fails, reboot the system. If that fails, use retro recon to generate the images. There is no need to rescan the patient.
- In general, wait for a display action to complete before entering another command.
- Many of the view image tasks can be executed through type-in commands. See Acceleration commands for a list of commands.
- The Image Type column on the Patient List indicates the following:

  kV: Single Energy Image

2 View Images Concept

The File Manager application has a variety of display tools and a large viewing area to display images.

2.1 Image setup

2.1.1 File Manager

The File Manager function lists the exams stored on the console. This list is known as the *browser*. The browser is broken down into examinations, series, and images.

- The exam listing includes the exam number, patient name, date, description of the exam, modality image format, Performed Procedure Step (PPS) information, and the archive status by exam.
- The series area lists the series that comprise the exam. The series number is listed here, as well as the scan type, a description, the modality from which the images come, PPS information, and the manufacturer of the system.
- The image list contains information related to images that comprise the selected series. The list includes image numbers, table location, thickness and spacing, gantry tilt, Right Anterior Superior (RAS) coordinates, Scan Field of View (SFOV), Display Field of View (DFOV), Resolution, Matrix size, Mid scan time in seconds, and Archive status. This function provides a list of all the exams on the system disk available for viewing.

2.1.2 Paging

Paging lets you to view images at up to 45 frames per second. This function is good for viewing scans taken at the same location with contrast to track flow or with motion such as flexing an elbow. There are two viewing choices in Paging: Temporal and Spatial.

- *Temporal* displays the images in a loop from start to end locations.
- Spatial goes from the starting location to the ending location, then from the ending location to the starting location, and repeats the sequence.

2.1.3 Image Viewer and Floating Viewport

The Image Viewer and Floating Viewport are located on the File Manager desktop. This is the place from which you can view images. All of the routine display functions are located here. The difference between the Image Viewer and Floating Viewport is a few functions. The Image Viewer has all the same functions as the Floating Viewport.

2.1.4 Performed Procedure Step

Performed Procedure Step (PPS) is used with a Hospital Information System/Radiology Information System (HIS/RIS) and Picture Archiving Communications System (PACS) with Connect Pro. It communicates to PACS and HIS/RIS that you have completed a procedure. It improves transfer of data because it can provide a complete message when all data has been transferred. The browser has a PPS column that lists the PPS status of each exam.

- COMP — completed
- DISC — discontinued and it cannot use PPS again.
- INPR — in progress.

2.2 Display area

The display area can be divided into several viewing areas that are called *viewports*.

Viewports on the left monitor are used during the scanning process. Viewports on the right monitor are used during post-processing.

Table 1: Left Monitor (Scanning) Viewports

These viewports:	Are used for:
Scout Acquisition viewports 	These viewports display scout images as they are acquired. The acquired scout images alternate between these viewports. By default, the most recent scout image appears in the bottom viewport. You can configure which viewport displays the most recent image. You can select next or previous series to see different series in the exam.
Auto-View viewport 	The Auto-View viewport displays the primary recon or quality control image being acquired in real-time as each image is being reconstructed. You cannot page through these images. Quality control images are displayed in this viewport as they are created. This allows you to ensure the images being acquired are adequate, without having to wait for a full reconstruction to complete. QC images are marked “QC/Quality Check”.
Navigation viewport 	In the Navigation viewport, you can page through any images in the primary reconstruction of the scan that is currently being acquired or was just acquired. As in the Auto-View viewport, images are added to this viewport as soon as they are reconstructed, but the viewport does not automatically page to the new images. Quality control images are displayed in this viewport if they are acquired, but as diagnostic images are reconstructed they replace the QC images in the viewport. QC images are marked “QC/Quality Check.”

Table 2: Right Monitor (Image) Viewports

These viewports:		Are used for:
Pagable auto-view viewports		The pagable auto-view viewports display recon and reformat images created during post-processing.
Recons	Reformats	

These viewports:		Are used for:
		By default, the top viewport autoviews images are they are being reconstructed, and the bottom viewport auto-views reformat images. You can set up the behavior of these viewports when you set up the protocol, or you can configure their behavior through the recon or reformat setup screens. These viewports display only if you are not running some other task like reformat or volume viewer.
Navigation viewports		When not being used as pagable auto-view viewports, all of the viewports on the right monitor are navigation viewports. In these viewports, you can load and navigate through any finished recon/reformat image set from the post-processing list.

2.2.1 Navigation Viewport

While reconstruction is active and you have an Auto View port selected with Auto Link, the lower-right viewport autgomatically displays the first image of the series currently being reconstructed. The viewport is annotated with “AL” on the bottom-right corner of the image to indicate that Auto Link is active. All display features and next/prior can be used with Auto Link.

2.2.2 Primary viewport

A viewport becomes active or receives primary focus by clicking on it. At that point, the border around the image turns blue. When a viewport has received the primary focus, you can choose List/Select and choose which exam you want to view. Also, you can window level, magnify, and perform other image manipulation functions without effecting other images currently displayed on the screen.

2.2.3 Secondary viewport

When you click on another viewport it becomes active and the border turns blue. The previously active viewport has secondary focus, indicated by a yellow border. These two viewports are linked together. A change in one viewport is reflected in the other. For example, changing the window width and window level in the primary viewport duplicates the change in the secondary focused viewport. To return to a single viewport, double click on the viewport of interest.

2.2.4 Floating viewport

Floating viewports allow you to load any exam, series, or image. They are not tied to any particular location on the display, and can be resized. Floating viewports stay above everything else on the display.

There can be only one floating viewport at a time, but it can display multiple series. See Section 3.8, Compare exams, series, or images .

2.3 Double-size viewports

Any viewport can be expanded to double-size by clicking the [Expand] icon  on the hover menu for the viewport.

To return the viewport to its normal size, click the [Contract] icon  .

Double-size viewports contain additional controls that allow you to manipulate and annotate images.

2.4 Image manipulation

2.4.1 Gray Scale Enhancement

Gray Scale Enhancement (GSE) is a display feature that changes the slope and gamma curve of an image. It can be used in head studies to improve the bone/brain interface, which helps with gray/white matter differentiation. There are three levels of GSE: G1, G2, and G3. G1 applies the least amount of enhancement and G3 applies the most. When a filter is applied, the images are annotated with G1, G2, or G3 just above the vertical tick mark scale on the right side of the image.

2.4.2 Image filters

There are several different display enhancement filters available in the File Manager desktop.

The Edge Enhancement filters sharpen the image and are useful for filming bone windows. There are six levels of Edge Enhancement: E1, E2, E21, E22, E23, and E3. E1 applies the least amount of enhancement and E3 applies the most. When these filters are used, the image is annotated with E1, E2, E21, E22, E23, or E3.

The Lung Enhancement filter is designed specifically to use when filming lung windows. When the Lung Enhancement filter is applied, the image is annotated with the word Lung.

There are also five Smoothing filters, S1, S11, S2, S22, and S3, which are used when filming soft tissue windows to decrease the appearance of noise in an image or enhance low contrast areas. S1 applies the least amount of smoothing and S3 applies the most. When these filters are used, the images is annotated with S1, S11, S2, S22, or S3.

2.4.3 DICOM Gray Scale Presentation State object

DICOM Gray Scale Presentation State (GSPS) is a DICOM object which saves a range of images, WW, WL, roam, zoom, image flip, and graphic annotations such as image annotation and measurement graphics. This object is then sent to a review station along with the source images. When the object is viewed, images are presented in the form that was displayed on the scanner. GSPS object can only be viewed on systems that support DICOM GSPS objects.

2.5 Graphics, Text Pages, and Commands

2.5.1 Screen Save

Screen Save is an electronic photograph of an image. Screen Save saves everything that is on the image in primary focus. This includes zoom, cursors, measurements, flip, or annotation. You

can use Screen Save to save images when anatomy or pathology has been measured. The screen saved images are listed on the patient list browser as series number 99, and called SSave for the series type. When a screen saved image is displayed, the window width and window level can be changed, but information cannot be removed.

2.5.2 Accelerator commands

The Accelerator Line, also known as the Command Line, lets you enter text commands that can be shortcuts to various display functions that are usually accessed through menu selections. Typing these commands can act as a shortcut to opening additional menus to access a function.

2.5.3 User Preferences

User Preferences is only available on the File Manager desktop. You can choose customized settings for annotation, tick marks, grid, right-mouse button use, series binding, and window/level presets. You may choose to apply your selections for the present exam only, or you can save your selections as the system default.

3 Image Display

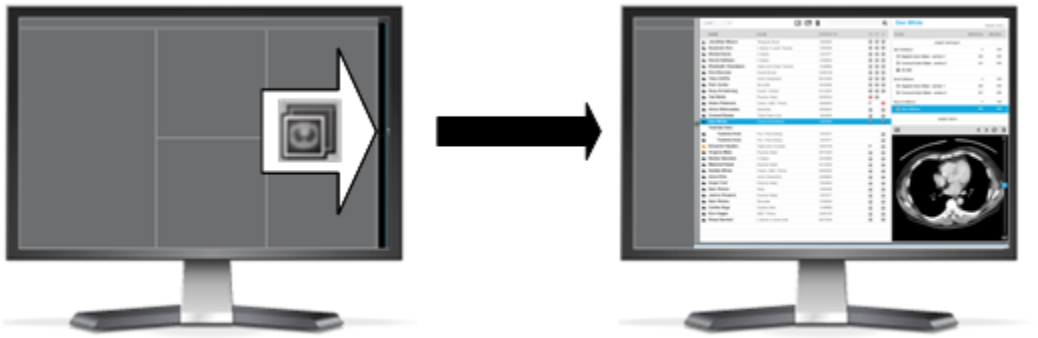
3.1 Open File Manager

To open File Manager to access browser applications, follow the steps below. This procedure uses Image Viewer and Floating Viewport as an example.

File Manager is always accessible on the right monitor.

1. On the right (display) monitor, click the File Manager “drawer”. (You do not have to click the File Manager icon – just click the drawer that is labeled with the [File Manager] icon .

Illustration 1: Opening File Manager



2. From the Exam List, double-click the exam you want to view. The exam opens in a patient session tab, and the File Manager drawer closes.

Illustration 2: Sections of the File Manager Drawer

1	Controls area	3	Series list
2	Exam list	4	Image display/Image list

3.2 Display images

[redacted]

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

1. From the display monitor, open the File Manager drawer.
2. From the Exam list, double-click the exam you want to display. If there is more than one exam for a patient, the exams appear in a list under the patient's name in the Exam List.

   Alternatively, click the Select Patient icon to the left of the patient's name, or right-click the exam and then click [Open Exam in Tab.]
3. Hover over the Viewport image selection button next to the image set you want to view. The button enlarges to show the viewports. Click the viewport into which you want to load the image set.

NOTE: By default, if you load the same image set into multiple viewports, the viewports will page separately. If you select the viewports before paging (click on the viewports to select them), they will page together.

3.3 Sort the patient list

To help you find examinations and patient data quickly, you can sort the patient list by any of the columns in the list.

Click on a column heading to sort by that column. For example, to sort by Patient ID, click the heading for the *Patient ID* column.

NOTE: Changes to the sort order are retained, even after a reboot.
You can change the order of columns (except for the *Name* column) by clicking and dragging the column headings.

3.4 Set which Patient List columns to display

By default, the columns that appear in the Patient list are:

- Patient name
- Exam Description
- Patient ID
- Scan data available flag
- Exam networked flag
- Exam Archived flag
- Examination date

Other columns that you can display include:

- Exam ID
- Accession Numbers
- Referring physician
- Patient name in ideographic form (available in certain regions)
- Filmed flag
- • PPS flag (available for sites with PPS)

Right-click on any column heading (except for the Networked flag heading) to select which columns to display.

3.5 Select an exam, series, or image

Use the following procedures to select images for display.

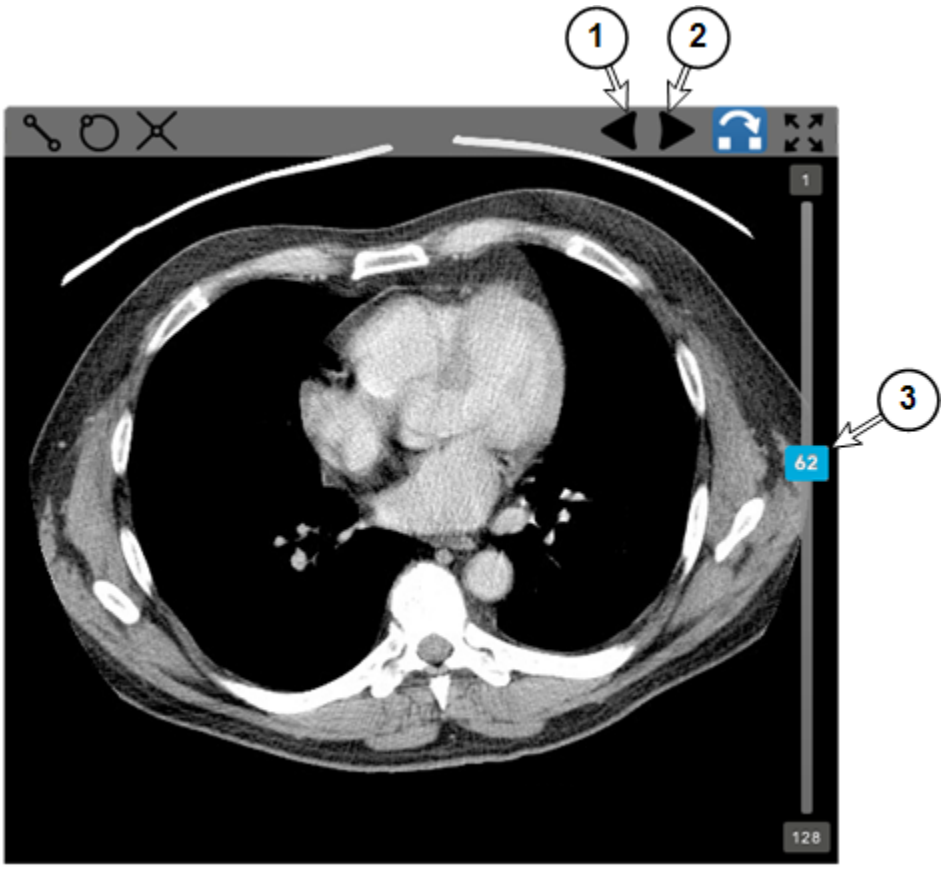
3.5.1 Navigation viewport

1. From the display monitor, open the File Manager drawer.
2. From the Exam list, select the patient name.
3. The Series list shows the series for the selected patient. Select the series you want to view.
4. The series loads into the Navigation viewport.
5. Hover your cursor over the Navigation viewport. Controls appear at the top of the viewport, and a scroll bar appears at the right of the viewport, indicating the image in the series that is being displayed.

   By default, the middle image in the series is displayed. To scroll through the images in the series, click and drag the slider on the scroll bar.

   To go to the previous or next series in the exam, click the [Next] or [Previous] icons.

Illustration 3: Navigation viewport controls



1	Previous series icon	3	Images scroll bar – click and drag to show the images in the series
2	Next series icon		

3.5.2 Keyboard

Hover your cursor over a viewport to activate the keyboard controls for that viewport. If you are not hovering over a viewport, the selected viewport is active. If you have more than one selected viewport, all selected viewports are affected by the keyboard commands.

Table 3: Keyboard commands for viewports

This key:	Does this:
Right arrow <→>	Increases the window width
Left arrow <←>	Decreases the window width
Up arrow <↑>	Increases the window level
Down arrow <↓>	Decreases the window level
Page up <PgUp>	Displays the previous image in the series
Page down <PgDn>	Displays the next image in the series
<F1> through <F4>*	Filmer keys
<F5>	Return to previous W/L
<F6> through <F11>	Window/Level presets
Control-s <Cntrl-s>	Saves the currently displayed image as a screen capture
*Hovering over a viewport does not affect the function of these keys.	

3.5.3 Accelerator Line

The Accelerator Line lets you review the next and prior images in a viewport. See *Type an Accelerator command*.

- Enter an image number, with no prefix, and the image displays in the upper-left viewport. For example, type ***1*** and press <Enter>.
- Enter ***e*** and the exam number to recall a specific exam.
- Enter ***s*** and the series number to recall a specific series.
- Enter ***e# s# i#*** to view a specific exam, series and image. For example, e7854 s2 i47 displays exam 7854, series 2, image 47. Note that there is a space between each number. You can also skip the prefixes and type 7854 2 47 to display the information.
- Enter ***ns*** for next series or ***ps*** for prior series.
- Enter ***ne*** for next exam or ***pe*** for prior exam.

3.6 Selecting viewports

Use this procedure to select viewports.

1. Click a viewport to select it. (Loading an image into a viewport also makes it selected.) Any mouse drag or click in a viewport will also select it.)
    - A blue border around a viewport indicates it is active.

- If no other viewports are selected, manipulations done in this viewport do not affect any other viewports.

2. To select additional viewports, Control-click (<Ctrl> key + left click) them.
   - Any manipulations done in either the primary or secondary viewport will also take effect in the other viewport.
   - Any offsets between viewports when they are selected are maintained. For example, if one viewport is displaying image 5 of a series and another viewport is displaying image 30, the difference is maintained while paging through images (if you page to image 10 in the first viewport, you will page to image 35 in the second viewport).

3.7 View images in a cine loop

Use this procedure to view images in a cine loop, which is useful for tracking flow in same-location scans taken with contrast or with motion such as flexing an elbow.

1. Open an exam in File Manager.
2. Load the series you want to view into a viewport.
3. From the viewport control panel, click [Analyze], and then click the [Cine] icon.
4. In the Cine area, click the [Play] icon  , which uses all the default settings. Alternatively, make selections from the Cine area.

   NOTE: The system automatically changes the image format to 1-on-1.

To do this:	Use this setting:	Icon:
Define the range of slices in the cine display	Check [Play All] to play all of the images in the series, or click [Play Range] and enter the image numbers in the *From* and *To* fields.	
Define the image interval	Typically, leave this value set to 1 (the default value). When displaying a multi-phase series in cine, enter the number representing the number of phases in the image range.	
Select a viewing mode	Click the [Loop] icon to view the series from start to end, then from start to end. For example, if there are 20 images in the series, the images display 1-20, 1–20, 1-20, and so on. Click the [Rock] icon to view the series from start to end, and then end to start. For example, if there are 20 images in the series, the images display 1-20, 20-1, 1-20, and so on.	Loop icon  Rock icon 
Play the cine loop forward and backward	Click the [Play] icon to play the cine loop.	Play icon 
Pause the cine loop	Click the [Pause] icon.	Pause icon 
Go to the end of the cine loop	Click the [End] icon.	End icon 

To do this:	Use this setting:	Icon:
Go to the beginning of the cine loop	Click the [Beginning] icon.	Beginning icon 
Step forward through the cine loop, one image at a time	Click the [Step Forward] icon.	Step Forward icon 
Step backward through the cine loop, one image at a time	Click the [Step Backward] icon.	Step Backward icon 

NOTE: To change the series, load the new series into the viewport.

3.8 Compare exams, series, or images

To compare exams, series, or images, open a floating viewport.

1. Select the first exam in File Manager.
2. In File Manager, right-click the exam(s) or series of interest you want to compare from the Series list, and then click [Open in floating viewport].

   Alternatively, you can right-click on any viewport where the exam or series is already loaded, and then click [Floating Viewport].
3. Check the *Side-by-side* box on the floating viewport.

   The exams and series you selected appear side-by-side, in a grid. Just as with single viewports, you can page through each exam/series individually, or you can select the viewports you want to page together. (Control-click to select more than one viewport.)

3.9 View a reference image

Use this procedure to show the image from which the primary image was prescribed in small viewport within the image.

NOTE: If you execute a screen save is with a reference image on, the reference image is saved with the same W/L as the main image, regardless of the W/L displayed on the reference image.

1. Click on the viewport to which you want to apply a reference image.

   The viewport display must be 512^2 x 512^2 or larger for the reference image to display.
2. From the viewport control panel, click [Reference Image].
3. Select an option for displaying the reference image:
   - Click [All On] when using Print Series with Reference image to insure that the reference image is filmed.
   - Click [Selected On] to only display a reference image on the primary viewport.
   - Click [All Off] or [Selected Off] to remove the reference image.

4 Image Manipulation

4.1 Display normal

Use this procedure to restore an image to its original size and orientation. This feature removes all filters, magnification factors, orientation changes, and graphics.

1. From the viewport control panel, click [Display].
2. Click the [Display Normal] icon .

4.2 Use edge and smoothing filters

The edge and smoothing filters enhance anatomical structure without additional reconstruction time The edge enhancement filters sharpen the image. The smoothing filters decrease the appearance of noisy images or enhance low-contrast areas when filming soft tissue.

4.2.1 Considerations

- Smoothing and edge filters are not additive. Only one filter may be applied to an image at a time. Applying a new filter negates the previously applied values.
- A new series is not created for the filtered images.
- Filters are applied to image data only.

4.2.2 Applying filters

1. From the viewport control panel, click [Analyze], and then click [Apply Filters].
2. Select a filter type.
   - Click [E1], [E2] or [E3] for edge enhancement.
   - Click [LU] for lung enhancement.
   - Click [S1], [S2] or [S3] for smoothing.
3. To turn off the filters, click [None] for the filter type.

   Alternatively, click the [Display] menu and then click the [Display Normal] icon .

4.3 Flip/rotate images

Use this procedure to change the orientation of a displayed image.

1. From the viewport control panel, click [Display].
2. Click the icon corresponding to how you want to reorient the image.

To reorient the image in this direction:	Click this icon:
Flip the image top-to-bottom	

To reorient the image in this direction:	Click this icon:
Flip the image left-to-right	
Rotate the image 90° to the left (counterclockwise)	
Rotate the image 90° to the right (clockwise)	

3. To return the image to its normal orientation, click the [Display] menu and then click the [Display Normal] icon  .

4.4 Apply Gray Scale Enhancement

Use this procedure to improve the brain/bone interface and improve low contrast structures in the brain such as gray/white matter. There are three levels of Gray Scale Enhancement (GSE), G1, G2 and G3. G1 applies the least amount of enhancement and G3 applies the most. The GSE filter selected is applied to all images in the series.

1. From the viewport control panel, click [Analyze], and then click [Apply Filters].
2. Under *Gray Scale Enhancements*, click [G1], [G2] or [G3].
3. To turn off GSE, click [None] for the filter type.

   Alternatively, click the [Display] menu and then click the [Display Normal] icon  .

4.5 Create and view GSPS objects

The gray scale presentation state is a DICOM object which saves a range of images along with the image state and graphic annotations. The GSPS object can be displayed on the CT scanner or on a remote host that supports DICOM GSPS.

4.5.1 Create a GSPS object

1. In a viewport, modify the image using any of the following features:
   - Window Width and Window Level
   - Roam
   - Zoom
   - Flip
   - Rotate
   - Graphics such as ROI, measure distance, and image annotation
2. From the viewport control panel, click [Export/Film], and then click [Save State].

   The GSPS object will be saved as series 10,000 for the current exam.

4.5.2 View a GSPS object

1. Select the GSPS object in File Manager.
2. Right-click the GSPS object, click [Open With], and then click [Image Viewer].
3. Use the menu to change the viewer format.
4. Click [+] to view additional GSPS objects in the series.

4.6 Magnify or minify an image

To zoom in (magnify) or zoom out (minify) an image, right-click and drag the image in a viewport.

NOTE: You can configure the mouse controls. See See User Preferences for more information.

4.7 Apply a matte

Use the matte procedure to eliminate unwanted information on or around an image. There are two types of matte: rectangular and elliptical. The size of the matte can be easily adjusted.

4.7.1 Place a matte

From the viewport control panel, click [Measure], and then click the [Ellipse ROI] or [Rectangular ROI] icon.

The following table shows some shortcuts for placing mattes.

To do this:	Type or click:
Place an elliptical matte	There are two shortcuts: • Select the [Ellipse ROI] icon from the viewport hover menu. • Type **`ematte`** in the Accelerator line and then press <Enter>.
Place a rectangular matte	Type **`rmatte`** in the Accelerator line and then press <Enter>.

To propagate the matte to all images in the series, type **`prop a`** in the Accelerator line and then press <Enter>.

4.7.2 Move, resize, hide, or delete a matte

1. To resize the matte, click and drag the blue cross hairs in the upper-left corner of the matte.
2. To move the matte, click and drag anywhere outside the matte.
3. To delete or hide the matte:
   a. From the viewport control panel, click [Measure].
   b. To remove the matte, click [Erase Graphics].
   c. To hide the matte, click [Hide Graphics].

   NOTE: To remove all graphics from a viewport, you can click [Display] and then click the [Display Normal] icon  .

4.8 Move images within a viewport

You can reposition images in a viewport for filming or viewing. All images in the series will be moved.

Hold down the Control (<Ctrl> key), and right-click in the viewport, and drag the image to the desired position.

NOTE: You can configure the mouse controls. See User Preferences for more information.

4.9 Inverse the video display

To invert the video display between black/white and white/black:

1. In the viewport control panel, click [Display.]
2. Click the [Setup] icon.
3. Click the [Inverse gray] color map.
4. To restore the viewport to the normal color map, click the [Gray (none)] color map.

4.10 Adjust the W/L

Use one of the following methods to adjust the W/L to control the image brightness and contrast.

4.10.1 Accelerator Line

1. Place the cursor on any viewport.
2. To change the window width, type: ***ww 500*** or any desired value.
3. To change the window level, type: ***wl 250*** or any desired value.

4.10.2 Keyboard

1. Place the cursor over any viewport.
2. Press and hold or repeatedly tap the up/down arrow keys to increase/decrease the window level.
3. Press and hold or repeatedly tap the left/right arrow keys to decrease/increase the window width.

Illustration 4: Arrow keys

4.10.3 Function keys

You can use the <F5> - <F11> function keys to apply preset W/L values in ImageWorks, Exam Rx and Reformat. The W/L values are defined from the Viewer User Prefs.

1. Press <Shift> and one of the function keys (F5 through F11) to program a preset W/L.
2. Press one of the function keys (<F6> through <F11>) to activate the preset window.
3. Press [F5] to reset the window level to the previous setting.

Illustration 5: Function keys

4.10.4 Mouse

1. Place the cursor over any viewport.
2. To adjust only the window's width, middle-click and drag the mouse:
   - to the right to widen the window width (make the image gray).
   - to the left to narrow the window width (make the image more black and white).
3. To adjust the window level, middle-click and drag the mouse:
   - up to darken the image.
   - down to brighten the image.
4. Middle-click and drag diagonally to change both the window width and the level.

5 Measurements

5.1 Measure a density reading

Use these procedures to obtain information on areas of anatomy and pathology.

1. From the viewport control panel, click [Measure].
2. From the *Measure* menu, choose the [Rectangular ROI], [Ellipse ROI] or [Trace ROI].

   NOTE: The Ellipse ROI button is also available from the hover menu bar which appears when you hover your cursor over a viewport.
3. Position the cursor on the image and click to deposit the insertion point.
   - For Trace ROI, move the solid blue box to the start point. Press and hold <Shift>, and then click and drag to define the area for the trace.
   - For Rectangular ROI or Ellipse ROI, click and drag on the small box in the upper-right corner of the ROI to resize or click the ROI number and drag to a new location.
4. Click [Erase Graphics] to erase all annotation.

5.2 Add a grid

Use these procedures to place a grid (matrix) over the primary image to measure anatomy or pathology on an image.

1. From the viewport control panel, click [Display], and then click the [Grid] icon.
2. Click and drag the center point of the grid to move it.
3. To remove the grid, click the [Grid] icon again .

5.3 Measure distance

Use these procedures to activate a measure tool to obtain information, distances, and areas of anatomy or pathology. Up to three measurement statistics can be displayed on a single image.

1. From the viewport control panel, click [Measure].
2. Click the [Measure Distance] icon.

   NOTE: You can click the [Measure Distance] icon from the viewport hover bar, which displays when you hover your cursor over a viewport.
3. Click and drag either end point of the start and end locations to adjust the line segment size.
4. From the Accelerator line, type ***tpr*** and press <Enter> to view a text page ROI.
   - This is useful when more than three measurements are on a viewport.
   - You can film or screen save Text page ROI.
5. Click the [Erase Graphics] icon to erase all display objects.

5.4 Report a cursor

Use this procedure to display cursor statistics and Right Anterior Superior (RAS) coordinates for a single pixel.

1. From the viewport control panel, click [Measure].
2. Click the [Report Cursor] icon.

   NOTE: You can click the [Report Cursor] icon from the viewport hover menu, which displays when you hover your cursor over a viewport.

3. Click [Report Cursor] again to turn it off.

6 Graphics, Text Pages and Commands

6.1 Type an Accelerator command

The Accelerator Line lets you enter command-line instructions for various functions that apply to all active viewports.

1. To view a list of all available commands, type ***?*** in the *Accelerator Line* and press <Enter>.
2. To enter a command, type the command and press <Enter>.
   - The command is applied to all selected viewports. As next and prior images are selected, the command applies to those images.
   - Image selection from the Accelerator Line does not function if the primary viewport contains an MIROI plot or Report Pixels chart. Use List Select to display a new image.
   - No text is entered in the *Accelerator Line* if the cursor is positioned over the *Film Composer*.

The table below lists available commands with descriptions and their applicable applications.

Table 4: Accelerator commands

Command / Description	GRx	Image Viewer
ac Applies custom annotation to the image displayed as defined by *Display Preferences* settings.	X	X
af Restores full annotation to the image displayed.	X	X
agp <on/off> <N> -where N is a group number Restores full annotation to the image displayed. agp <on/off> <N> -where N is a group number. With this feature, you can selectively turn off or on specific image annotations on the screen. The N number corresponds to the annotation in the customize setting for annotation in User Preferences. For example, to turn off right marker, type agp off 10. You can type more than one number at a time.	X	X
an Removes all annotation from the image displayed.	X	X
ang Creates an angle type measurement cursor by explicitly describing the end points of the lines that make up the cursor.		X
ap Applies partial annotation to the image displayed as defined by *Display Preferences* dialogue box on Exam Rx screen.	X	X
arrow <on> or <off> Displays or removes an arrow cursor from a text annotation box for user annotation.		X
blank Removes image from the selected viewport, similar to a user text page.		
dist A measure distance line will appear on the screen.		X
e <examination number> The desired exam number as indicated on the system disk.		X

Command / Description	GRx	Image Viewer
e <exam number> s <series number> i Exam, series, and image numbers as indicated on the system disk .		X
eag Removes all graphics from the selected image.		X
eg Removes selected graphics from the selected image.		
el Creates an ellipse type measurement cursor.		X
ematte Displays an elliptical black matte or mask around the image. Size is adjustable with the mouse by a left click and drag on the blue crosshair. Position is adjustable by a click and drag on the edge of the matte.		X
fac Applies custom annotation to the images filmed as defined by *Display Preferences* dialogue box on Exam Rx screen.		X
faf Restores full annotation to the images being filmed.		X
fagp <on/off> <N> -where N is a group number With this feature, you can selectively turn off or on specific image annotations for filming. The N number corresponds to the annotation in the customize setting for annotation in *User Preferences*. For example, to turn off right marker, type fagp off 10. You can type more than one number at a time.		X
fan Removes all annotation from the images being filmed.		X
fap Applies partial annotation to the images being filmed as defined by *Display Preferences* dialogue box on Exam Rx screen.		X
fi <filter name> filter names: e1; e2; e21; e22; e23; e3; lung; (for edge enhancement) s1; s11; s2; s21; s3; (for smoothing filters) and off Apply/remove edge enhancement and smoothing filters on selected images. Edge enhancement filter names are, from least sharpening to most: e1, e2, e3, lung; smoothing filters are named s1, s2, s3. Entering the command fi e1 applies the least image sharpening,; entering fi lung applies the most. For example: fi e1, fi e2, fi e3, fi lung, fi s1, fi s2, fi s3, fi off.	X	X
flr Flips the image horizontally.	X	X
ftb Flips the image vertically.	X	X
fo <rows>< columns> For example: fo 4 3 Formats the display screen as specified by rows and columns. The above example displays images across the screen in four rows and three columns, or common twelve-on-one.		X
freehand Displays a small solid blue box that can be used to draw a freehand trace for an ROI. You must click and drag the box to where you would like to start the trace. Then select the blue box while holding Shift on the keyboard and move the mouse cursor around the screen to draw the trace.		X
gse <filter name> filter names: g1; g2; g3; off Gray scale enhancement increases the apparent contrast of the image without changing the window/ level settings. Useful for enhancing low contrast structures. For example: gse g1, gse g2, gse g3, gse off).	X	X

Command / Description	GRx	Image Viewer
grid <on> or <off> (Displays or removes a ruled grid on the image.	X	X
hg Hides all graphics on the selected image. The undo function is show graphics.		X
i <image number> Image number: the desired image number from within the displayed series. For example: i 27.	X	X
inv Reverses the blacks and whites on the image.		X
mmg Turns the right mouse button drag action into zooming (magnification) of the image.		X
mmr Turns the right mouse button drag action into scrolling (pan, roam) of the image.	X	X
mmz Turns the right mouse button drag action into zooming (magnification) of the image.	X	
ne Displays the first image of the next exam in the selected viewport, next determined by the sort function applied to the *List Select* browser.		X
ns Displays the first image of the next series from the displayed exam in the selected viewport.		X
no Restores the image display to display normal mode: removes all zoom, filter, pan, annotations etc. applied to the viewport. Displays the image from the disk as created.	X	X
nori Takes reference image off of selected image.		X
noria Takes reference image off all images.		X
noxr Removes cross-reference lines from the image display.		X
pa [<start> <end>] [<rate>] Activates cine paging. For the start and end values, enter the first and last images you want to page thru. For rate, enter the number of images per second to page through, with the maximum being 60.		X
pi <interval> Allows you to set the interval for paging. The pa command must be used prior to setting paging interval.		X
pia <interval> Allows you to set the interval for paging. The pa command must be used prior to setting paging interval.		X
pe Displays the first image of the previous exam in the selected viewport, previous determined by the sort function applied to the *List Select* browser.		X
pm <spatial/temporal> Allows you to change the mode for paging. Selecting temporal will display the images in a loop mode. Spatial will display images in a back-and-forth mode.		X
pp Sends the entire current display screen to the film composer and sets the film composer format to that of the current display format.		X

Command / Description	GRx	Image Viewer
prs Opens the print series dialogue box for the selected viewport, which is in turn satisfied by mouse commands. By specifying options in the print series box, a sequence of images maybe sent automatically to the printer, or current print jobs may be canceled by the operator. Desired image parameters must be set before calling the print series command — zoom, window level, annotations etc. cannot be altered after the print series dialogue box is opened.		X
ps Displays first image of the previous series of the displayed exam in the selected viewport.		X
prop <range> range: a= all images in series; s = series; i = image range (1-15) For example,: prop a or prop i 1-15) Displays selected graphics on the specified images. The “i” is lower case sensitive. In the first example, the graphic displays on all images called into the viewport until cleared by another command (such as erase graphics) or a different series is displayed in the viewport. In the second example, the graphic is applied only to images 1 through 15 in the current series.		X
quit Closes the Viewer application.		X
rc Displays (reports) current mouse cursor location in pixel coordinates, and a single pixel ROI reading.		X
rect Creates a rectangle measurement cursor. Used for ROI.		X
ri Puts a reference image on the selected image.		X
ria Puts a reference image on all images.		X
rl Rotates the image 90 degrees counterclockwise.	X	X
rmatte Displays a rectangular, black matte or mask around the image. You can adjust the by clicking and dragging the blue cross hairs. You can adjust the position is by a clicking and dragging the edge of the matte.		X
rp Opens a Report Pixels dialogue box, and displays an ROI box cursor on the image. You can move the dialogue box by clicking and dragging. You cannot resize the box. Once in position, click [OK] in the dialogue box to create a pixel report consisting of density values for individual pixels within the area delineated by the box cursor.		
rr Rotates the image 90 degrees clockwise.	X	X
rs Reset image to initial display parameters. It does not reset the W/L.		X
s <series number> Series number: the selected series number from within the displayed exam.		X
sb <on> <off> Turns series binding on or off. With series binding on, the next image is defined as the next image in the entire exam; at the end of any particular series, the next image is the first image of the next series. At the end of the exam, a ‘next’ command will loop back to the first image of the exam. With series binding off, at the end of a particular series, a ‘next’ command will loop back to the first image of the current series.		X
scnsave Captures the selected image exactly as it is displayed, and creates a new image with a series number of 99 on the system disk that includes all graphics and display factors applied to the image and/or viewport at the time of capture.		X

Command / Description	GRx	Image Viewer
sg Shows, or re-displays all graphics on the selected image which were hidden with the hide graphics command.		X
siw Applies default window width and level setting to the display.	X	X
spline Places a small, open blue box for creating a trace. Position the blue box where you want the trace to start. Then hold down the <Shift> key and click the left mouse to deposit points. All the points will connect to create a trace.		X
ss [<first image> <last image>] Saves the image orientation, W/L values, graphics, and filter and GSE values of a range of images that you can set. Typing ss by itself will save settings for the entire series. A GrayScale Presentation State Object is also created and saved to the data base.		X
te Displays text page for the exam in the primary viewport.		X
tm <on> or <off> Displays or removes horizontal tick marks (rulers) only, along the border of the image.	X	X
tmv <on> or <off> Displays or removes vertical tick marks (rulers) only along the border of the image.	X	X
tpr Displays a text page for the image in the primary viewport which lists all the ROI cursors and their statistics.		X
ts Displays text page for the exam/series in the primary viewport.		X
ua Displays specified text in a user annotation field on the image.		X
up Displays the *User Preferences* screen.		X
utp Removes image from the selected viewport, creating a blank viewport for user annotation or graphics.		X
wl <level> Applies specified window-level setting to the display.	X	X
ww <width> Applies specified window-width setting to the display.	X	X
xr <series number> <image set>: <interval> Series number: an appropriate series number to be cross-referenced. image set: a consecutive group of image numbers within the series. interval: the interval of images to be filmed: two equals every other image, three equals every third image, etc.		X
xra <series number> <image set>: <interval> Used to add additional cross-referenced groups or series to a scout which already has a cross-reference on it. series number: an appropriate series number to be cross-referenced. image set: a consecutive group of image numbers within the series. interval: the interval of scan plane lines to be displayed: two equals every other image, three equals every third image, etc.		X
zo <factor> Factor: magnification factor Magnifies the image by the factor specified. For example, zo 1.5 displays the image one and one half times larger than its display size.		X
factor: magnification factor Magnifies the image by the factor specified.	X	

6.2 Annotate an image

Use this procedure to add annotation to your images, which allows you to comment for labeling purposes or draw attention to a specific area of interest.

NOTE: An active user annotation graphic does not film the box or arrow that is displayed on the screen.

1. Click on the viewport you want to add annotation.
2. From the viewport control panel, click the [Annotate Tools].
3. Click the [Annotation] icon.
4. Move the mouse to the selected viewport and enter the text.
   - To move the annotation, click on the blue box and drag.
   - To move the end of the line, click and drag the arrowhead.
   - To remove the line, click and drag it into the box.
5. Click the [Annotation] icon to add another annotation.
6. [Click the Erase Annotation] icon  to remove the primary (blue) annotation or click [Erase All] to remove all annotation.

6.3 View an exam or series text page

Use this procedure to view patient and scan parameter information.

1. From the viewport control panel, click [Export/Film Tools].
2. Click [Exam Page] to view information about the exam or [Series Page] to view information about the series.
3. Click [Manual Film] to send to the Film Composer.
4. Click [Screen Save] to save the displayed information to series 98.
5. Use arrow keys to navigate between multiple pages.
6. Click [Quit].

6.4 Hide, show, or remove graphics

Use this procedure to temporarily remove added annotation and graphic objects on an image then re-display them.

1. To hide measurements, such as ROIs:
   a. From the viewport control panel, click [Measure].
   b. Click [Hide Graphics].

c. To remove measurements, click [Erase Graphics.]

2. To hide annotations:

   a. From the viewport control panel, click [Annotate].

   b. Click [Hide Annotations].

   c. To remove annotations, click [Erase Annotations].

6.5 Save an image screen

Use the *Screen Save* tool to take a snapshot of a viewport. The image is saved to series 99 as series type SSAVE. The images can be archived and networked, and W/L and zoom are still adjustable. However, these images have post processing restrictions, and any annotation on the image cannot be removed once the screen has been saved.

NOTE: Screen Save images are not PPS aware. Images created in Reformat, 3D, and Navigator are not PPS aware. Image types INPR is posted in the PPS column in the browser even though PPS is not enabled.

1. From the viewport control panel, click [Export/Film Tools].
2. Click [Save Screen].

   NOTE: Alternatively, you can use the Accelerator Line. Type ***scnsave***, and then press <Enter>.

6.6 Cross-reference images on a scout

Use this feature to view lines on the scout image representing previously scanned locations.

In the Accelerator Line, type **`xra <series number> <image set>:<interval>`**, where:

- **`series number`** is an appropriate series number to be cross-referenced
- **`image set`** is a consecutive group of image numbers within the series
- **`interval`** is the interval of scan plane lines to be displayed. 2 equals every other image, 3 equals every third image, and so on.

For example, if you wanted to display lines showing previously scanned locations for the third series, images 1 through 20, with the lines appearing on every third image, you would type: **`xra 3 1-20:3`** into the Accelerator Line, and then press <Enter>.

7 User Preferences

7.1 Set annotation preferences

To customize the default font size and the level of Film and Image Viewer image annotation, follow these steps:

1. Click the [Mode] icon , and then click [Preferences].
2. On the *Preferences* screen, click [Viewports].
3. In the *Image Annotation Viewers* and *Image Annotation Film* sections of the screen, select [No Annotation], [Partial annotation], [Full annotation] or [Custom annotation] for either or both the screen and film area.

   If you click [Custom Annotation], select the specific annotations you want displayed, and then click [OK].
4. To view parameters in a larger font, click [Customize Large Font] and select the specific annotation group to enlarge.
5. Click [Save].

7.2 Set grid preferences

To customize the default grid's appearance, follow these steps:

1. Click the [Mode] icon , and then click [Preferences].
2. On the *Preferences* screen, click [Viewports].
3. Scroll down to the *Grid* section of the screen.
4. Select the parameters you want for the grid display.
   a. Click [On] or [Off] to set matrix line display.
   b. Click [Dotted] or [Solid] to set line style.
   c. Type in numeric values for *grid spacing, tick spacing* and *tick length*.
5. Click [Save].

7.3 Set mouse preferences

To customize the behavior of mouse buttons:

1. Click the [Mode] icon , and then click [Preferences].
2. On the *Preferences* screen, click [Viewports].
3. Under *Mouse Preferences*, use the drop-down menus to set the mouse behavior for the left, middle, and right mouse buttons.
4. Use the drop-down menus to set the mouse behavior for the Control-left, Control-middle, and Control-right mouse buttons.

5. Click [Save].

7.4 Set series binding preferences

To set the default series binding, follow the steps below.

1. Click the [Mode] icon , and then click [Preferences].
2. On the *Preferences* screen, click [Viewports].
3. Scroll to the *Series Binding* section.

   Check the [Series Binding On] box to make series binding the default for viewports.
4. Click [Save].

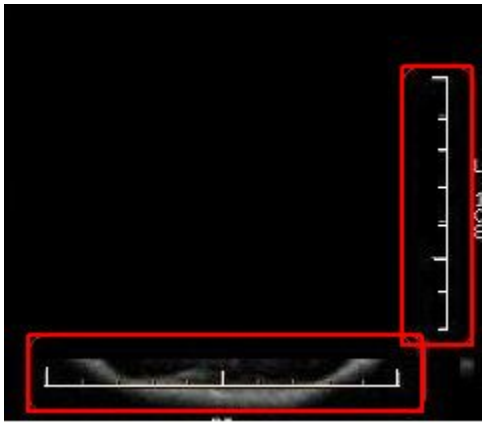
7.5 Set tick mark preferences

To define the default tick mark display, follow these steps:

7.5.1 Preferences

1. Click the [Mode] icon , and then click [Preferences].
2. On the *Preferences* screen, click [Viewports].
3. Scroll down to the *Tick Marks* section.
4. Select how you want tick marks to display in viewports. Choices are:
   - Vertical & Horizontal
   - Vertical
   - Horizontal
   - None

Illustration 6: TIck marks: vertical and horizontal



5. Click [Save].

7.5.2 Accelerator Line

On the Accelerator Line, type (not case sensitive):

- ***TMV ON*** or ***TMV OFF*** to turn on or off the vertical tick marks.
- ***TMH ON*** or ***TMH OFF*** to turn on or off horizontal tick marks.
- ***TM ON*** or ***TM OFF*** to turn on or off both horizontal and vertical tick marks.

7.6 Set W/L preset preferences

To set the W/L preset values, follow the steps below. See the *Adjust the W/L* procedure for details on applying W/L.

1. Click the [Mode] icon  , and then click [Preferences].
2. On the *Preferences* screen, click [Viewports].
3. Scroll down to the *Window Width/Window Level Presets* section.
4. Each shortcut key (function key) for W/L is set to a particular value. You can change the names of the presets for these shortcut keys, and change the default window width and window level for them.
5. Click [Save].

Chapter 15 Display Applications

1 Overview

NOTICE

The following display applications can be used with scanned images.

Add/Subtract

Direct Multi Planar Reformat (DMPR)

Exam Split

2 Add/Subtract

Considerations:

- Add/Subtract can process a maximum of 1,000 images. To select a range of images, select the first image in the range, hold the shift key and select the last image in the range.
- Add/Subtract images are displayed in the series type column as either processing pairs (Proc) or combination (Comb).
  - **Proc** is the result of processing pairs of images that have identical locations in the patient's body. Proc series can be used like any other series of acquisition images, i.e., geometrical measurements, reformatting, 3D reconstructions, etc.
  - **Comb** is the result of a combination of images having different locations in the patient's body. The absolute anatomical coordinates accompanying Comb series are not accurate and therefore only relative geometrical measurements (i.e., distance, angle, or area) made within a resulting image are accurate.

2.1 Add/Subtract basic terminology

Term	Definition
Image addition	Adds image intensity values pixel by pixel and is useful for adding thin slices together to get a thicker slice.
Image subtraction	Subtracts image intensity values pixel by pixel and is useful to evaluate contrasted vessels. **NOTE:** Patient movement and breathing between the images can affect the quality of the subtraction.
Maximum pixel value extraction	Locates maximum image-intensity values pixel by pixel. This is useful for contrasted vessels or calcifications.
Minimum pixel value extraction	Locates minimum image intensity values pixel by pixel. Useful when evaluating soft tissue.
Binding Series	Creates a new series consisting of copies of selected images from one or more existing series. Useful if you have images in two separate series and want them in one series to perform 3D or Reformat. **NOTE:** Save State information is not maintained in the new series generated with Binding Series.
Accept negative pixels	Allows negative pixel values in the resulting image, otherwise all negative pixel values are set to zero.
Proc series	Images appear in the *series list type* column if the images in the series are the result of processing pairs of images that have identical locations in the patient. Proc series can be used like any other series of acquisition images, i.e., geometrical measurements, reformatting, 3D reconstructions, etc.
Comb series	Images appear in the *series list type* column if the images in the series are the result of a combination of images having different locations in the patient. The absolute anatomical coordinates accompanying Comb series (shown both in the browser and on the displayed images) are not accurate. Only relative geometrical measurements (i.e., distance, angle, or area) made within a resulting image are accurate.
Ratio slider	When both [Select Set] buttons are used during addition or subtraction, equal weighting is applied to the two pixels in each pair. You can change that with the *Ratio* slider.

2.2 Add/Subtract and Image Combination screen

On the right side of the window, click [Add/Subtract] to open the *Add/Subtract* screen.

Illustration 1: Add/Subtract screen

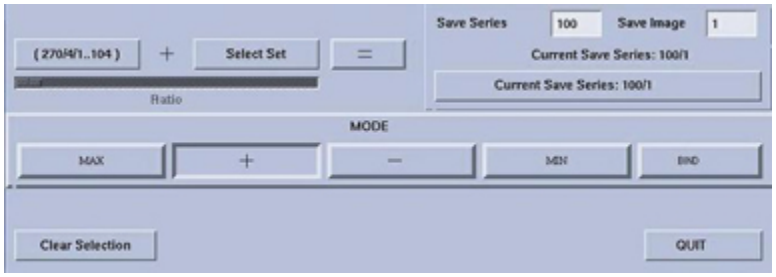
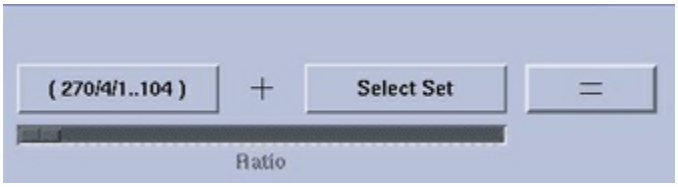


Illustration 2: Image Combination area



Element	Description
Select Set (1)	Defines the first image set.
Select Set (2)	Defines the second image set.
Equal (=)	Runs the process and generates the new images.
Ratio slider	Adjusts the pixel weighting ratio between the two sets. The slider is only available during addition and subtraction when both *Select Set* buttons are selected.
Save Series	Displays the current series and starting image number of the saved series. By default, images resulting from subsequent operations are added onto the end of the same series unless you click [New Save Series]. **Illustration 3: Save Series area** 
New Save Series	Places images resulting from subsequent operations into a new series in the *Patient List*. If you do not select this option, the images are saved in the current saved series.

Mode

Illustration 4: Mode buttons

Button	Description
Max	Creates a new series that finds the highest corresponding signal intensity values in the selected set or sets of images.
Plus (+)	Creates a new series that adds the image intensity values of the selected image sets.
Minus (-)	Creates a new series that subtracts the image intensity values of the selected image sets.
Min	Creates a new series that finds the lowest corresponding signal intensity values in the selected set or sets of images.
Bind	Creates a new series that consists of copies of the selected images from one or more existing series.

Accept Negative Pixels

Allows negative pixel values in the images. If not enabled, all negative pixel values are set to zero. This operation is useful on pre- and post-contrast studies of the same slice location.

Clear Selection

Clears the values associated with the [Select Set] buttons.

2.3 Add/subtract images

To create a new image set, for example add thin slices together or subtract pre/post contrast series, follow the steps below. Processed images will be annotated with the date.

1. In the Controls Area of the File Manager, click the [Add/Subtract Images] icon .
2. Select the images.
   - If one set is selected, each operation produces one resulting image.
   - If two sets are selected, images in the two sets are paired according to physical location in the patient's body. Unpaired images are ignored.
3. On the *Image Combination* screen, click the left [Select Set].
4. If you are adding/subtracting two sets of images, select the second set of images, and click the right [Select Set].
   - By default, equal weighting is applied to the pixels in each pair, but you can use the *Ratio* slider to change the weighting values .
   - Drag the slider to the left to increase the pixel weighting of the images on the left Select Set button. Drag the slider to the right to increase the pixel weighting of the images on the right Select Set button.
5. Click [+] or [-].

6. For subtraction, click [Accept Negative Pixels] unless you want the negative pixel values set to 0 in the resulting image.
7. Typically, use the system provided series number.
8. Click [=] (equal sign) to generate the images in the exam defined by the left Select Set button.
9. To repeat the add/subtract procedure with a new series number and description, click [New Save Series].

2.4 Bind series

To combine images from different series to create a new series, follow the steps below. Processed images will be annotated with the date.

1. In the Controls Area of the File Manager, click the [Add/Subtract Images] icon .
2. Select the images.
3. On the Image *Combination* menu, click the left [Select Set].
4. Click the right [Select Set].
5. Click [Bind].
6. Use the system-provided series number, or enter a new series description and number in the *Save Series* field.
7. Click [=] to generate the images in the exam defined by the left [Select Set] button.
8. To repeat the add/subtract procedure with a new series number and description, click [New Save Series].

2.5 Create images with min/max values

To create a new image using only the minimum or maximum CT numbers, follow the steps below. The resulting images are annotated with the day on which the addition/subtraction was performed.

1. In the Controls Area of the File Manager, click the [Add/Subtract Images] icon .
2. Select the images.
3. On the *Image Combination* menu, click the left [Select Set].
4. Click [Min] (minimum) or [Max] (maximum).
5. Typically, use the system-provided series number.
6. Click [=] (equal).
7. Optional: Click [New Save Series] to repeat the add/subtract procedure with a new series number and description.

3 Direct Multi Planar Reformat (DMPR)

Direct Multi Planar Reformat (DMPR) allows you to move from the usual 2D image review mode to a prospective 3D image review mode in the axial, sagittal, coronal, and oblique planes. You can also automatically create batch reformats using predefined reformat protocols and network reformatted images to selected reading locations, reducing total exam time and increasing productivity.

DMPR displays images in anatomical orientation where anterior is at the top, posterior is at the bottom, right is on the left and left is on the right. For example, if you have a data set where the patient was scanned prone, the image display is automatically set to this orientation.

Reformat protocols can be applied in three ways:

- Automatically – the reformat protocol is defined before the scan takes place and runs as the scan is acquired.
- Semi-automatically – the reformat protocol is defined before the scan takes place but requires manual prescription of the slices before it is run.
- Manually – the reformat protocol is defined after the scan is acquired.

No matter how reformats are applied, they appear in the Reconstruction and Image Processing Task List (RIPTL).

DMPR allows for:

- visualization of multi-planar volumes
- creation of multi-planar reformat batch images
- visualization of multi-planar batches
- filming of multi-planar batch images
- networking of multi-planar batch images
- archiving of multi-planar batch images

Applications of DMPR include:

- fast review of scan prescription
- combined with AutoView for trauma imaging and automated multiplanar reformat protocols
- surgical planning assessment of trauma
- CT angiography
- as a supplement for other diagnostic information

To combine groups, the following parameters must be identical within each group:

- Slice Thickness
- Interval
- SFOV
- DFOV
- Scan Type
- Rotation Speed
- Image center
- Algorithm
- ASiR-V Level

Once the recon and multi-planar reformat batch images are created, the Reconstruction and Image Processing Task List (RIPTL) allows you to select and view image sets.

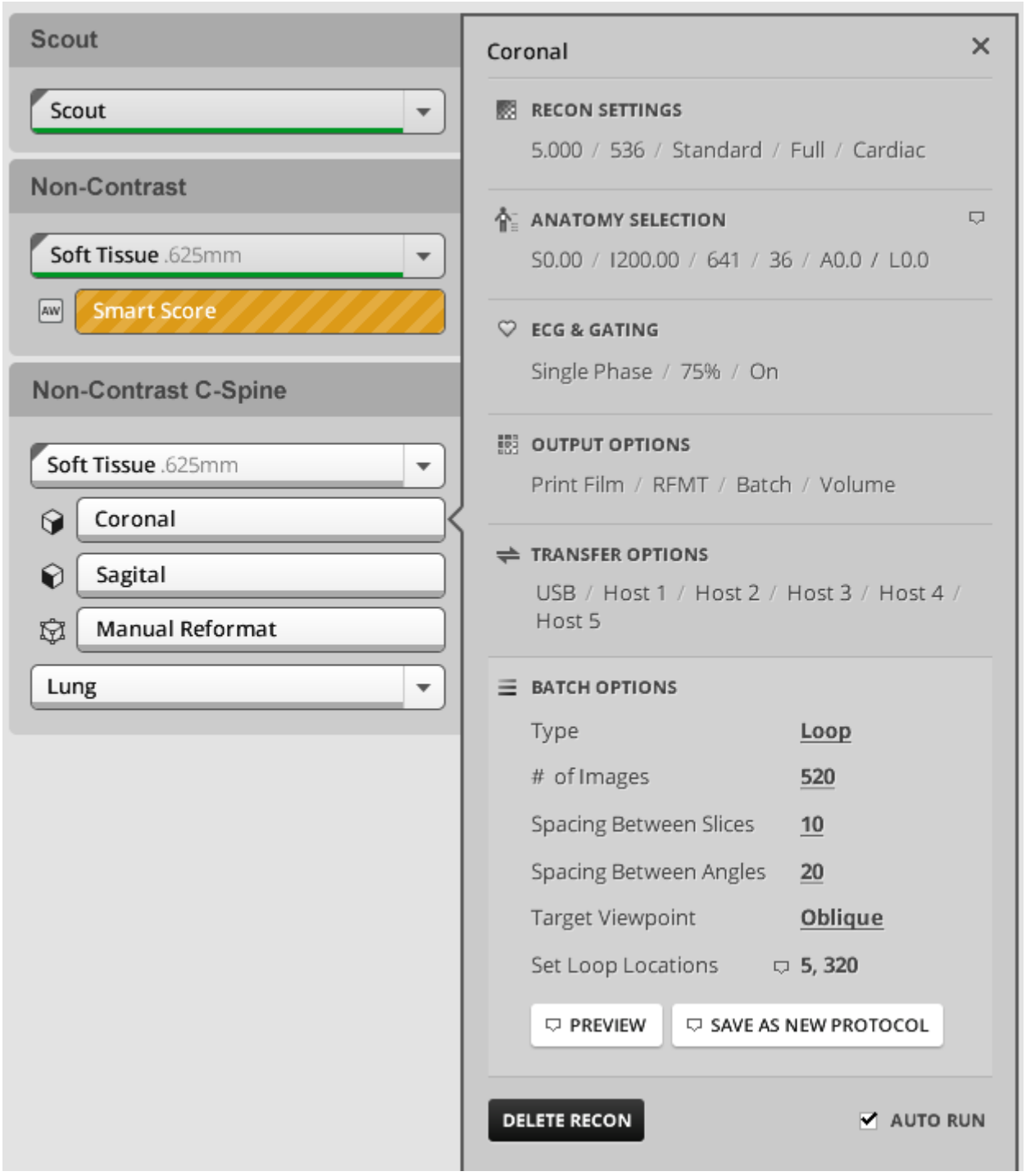
Considerations

- Each group must be contiguous to be able to be combined with the prior group in a DMPR session. DMPR can be prescribed with primary and secondary recons. DMPR reformats are limited to 2,000 images. Additional reformat protocols can be added from the File Manager.
- Any scans acquired after scanning has completed on the original scan group using Add Group are not added to the DMPR session. Remember to include all of the desired coverage area in the original scan prescription.
- If the patient orientation is prescribed as Decubitus (right or left), you will observe that the Paging slider for the sagittal image will scroll images in DMPR coronal viewport and vice versa. This is because in Decubitus orientation, patient's sagittals and coronals are switched. Hence, the DMPR sagittal viewport contains the coronals from patient's reference axis, and the DMPR coronal viewport contains the sagittals from the patient's reference axis.
- Make sure the interval between groups is appropriate to support DMPR in secondary recons 2-10 if the slice thickness prescribed for the groups in primary recon 1 is different.

3.1 Reformat Tools panel

To display the Reformat Tools panel, select or create a reformat task from the Reconstruction and Image Processing task list.

Illustration 15: Reformat Tools panel



3.1.1 Icons

On the Reconstruction and Image Processing task list, icons identify the reformat type.

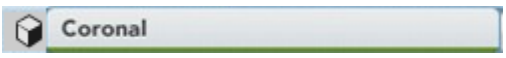
This icon:	Identifies this reformat type:
	Automatic or semi-automatic reformat
	Manual reformat

3.1.2 Reformat processing order

Automatic reformats are processed in top-down order. If a manual reformat is started while automatic reformats are running, the manual reformat has priority until it completes, at which point automatic reformats resume processing.

3.1.3 Processing and transfer status indicators

The processing and transfer status of reformats is shown by changing the field showing the reformat name.

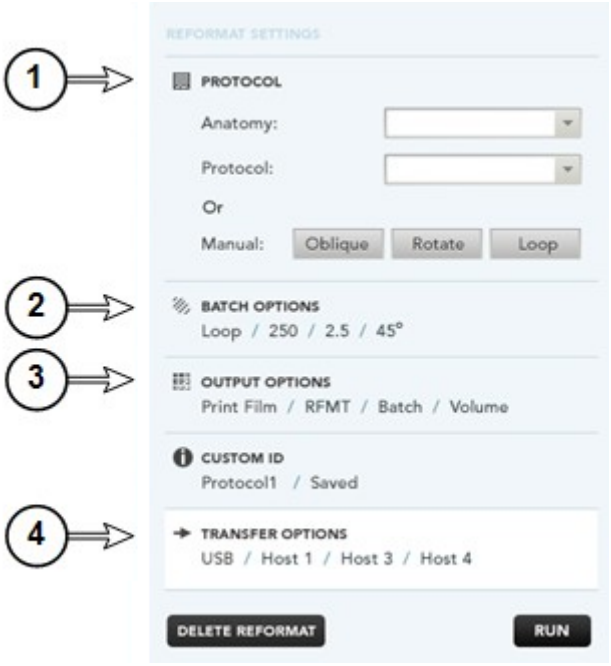
This indicator:	Means:
	Processing has not started
	Currently processing
	Completed processing
	Semi-automatic or manual reformat awaiting processing
	Transfer has been configured
	Transfer in progress
	Transfer complete

3.1.4 Reformat Settings panel

From the Reconstruction and Image Processing Task List, select a reformat to display the *Reformat Settings* panel.

NOTE: The settings for the reformat are contained in sections on the Reformat Settings panel. These sections are collapsible. When these sections are collapsed, the current settings for the reformat are shown on the collapsed panel.

Illustration 16: Reformat Settings panel



1	Protocol section (opened)	3	Output Options section (collapsed)
2	Batch Options section (collapsed)	4	Transfer Options section (collapsed)

3.1.4.1 Protocol settings

Table 1: Protocol settings

For this setting:	Select or set:
Anatomy	Select the anatomy for with the reformat. This setting affects the settings available in the Batch Options section.
Protocol	Select the protocol. This setting affects the settings available in the Batch Options section.
Manual buttons [Oblique], [Rotate], and [Loop Batch]	If you want a generic protocol, select the type of protocol using these buttons. Selecting one of these buttons clears the Anatomy and Protocol selections. [Oblique] – Produces sagittal, coronal, or off-axis (oblique) images from CT data. [Rotate] – Creates multiple images of an anatomical region by rotating around a single axis at a specified angle. This is used for vascular structures, such as pulmonary veins. [Loop batch] – Creates a cine image series. this is used to translate a curve or to rotate around a centerline.

3.1.4.2 Batch Options

The Batch Options change depending on the type of series being used in the reformat.

Table 2: Oblique settings

For this setting:	Select or set:
Type	This setting is read-only (set in the Protocol settings)
Number of images	Set the number of images to include in the reformat. This number updates based on slice thickness, slice interval, and the start and end locations.
Slice thickness	Set the slice thickness.
Interval	Set the slice interval.
FOV	Set the field of view
Tilt	Set the tilt.
Rendering Mode	Select the rendering mode.

Table 3: Rotate settings

For this setting:	Select or set:
Type	This setting is read-only (set in the Protocol settings)
Number of images	Set the number of images.
Angle between images	Set the angle between images.
Slice Thickness	Set the slice thickness.
FOV	Set the field of view
Rendering Mode	Select the rendering mode.

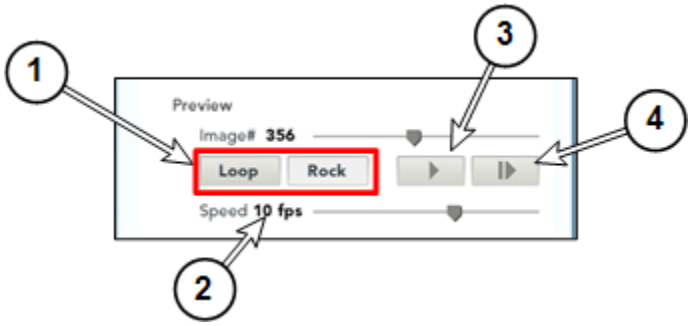
Table 4: Loop settings

For this setting:	Select or set:
Type	This setting is read-only (set in the Protocol settings)
Number of images	Set the number of images.
Set Start and Set End	Use buttons to set the start point and end point of the loop.
Target Viewpoint	This setting is read-only.

Preview tool

Before you save, film, or print a batch, you can preview what the batch will look like using the Preview tool in the Batch Options section of the Image Tools panel.

Illustration 17: Preview tool



1	Preview mode buttons	3	Play/Pause button
2	Preview speed selector	4	Click through images button

Save as New Protocol

After you make changes to the batch settings, you can save the changes to a new batch protocol. This new protocol appears in the list in the Protocol settings section.

You can categorize the new protocol by anatomy.

Illustration 18: Save as New Protocol

3.1.4.3 Output Options

Table 5: Output options

For this setting:	Select or set:
Save As	Select whether you want to save the output from the reformat as a reformat or as a screen save. In File Manager, a reformat is shown with an image type of RE-FORMAT. The image type for a screen save is shown as SCPT.
Batch Auto-View	If you want the reformat to automatically display in a batch view, check this box.
Volume Auto-View	If you want the reformat to automatically display in a volume view, check this box.
Series Description	You can enter a description for the series in this field. If you do not enter a description, the series will take the name of the pre-selected protocol. If you are not using a pre-selected protocol, the series will take the name “Processed Images”.

3.1.4.4 Transfer options

The Transfer options allow you to send the completed reformats to network hosts or to a USB drive.

Illustration 19: Transfer options

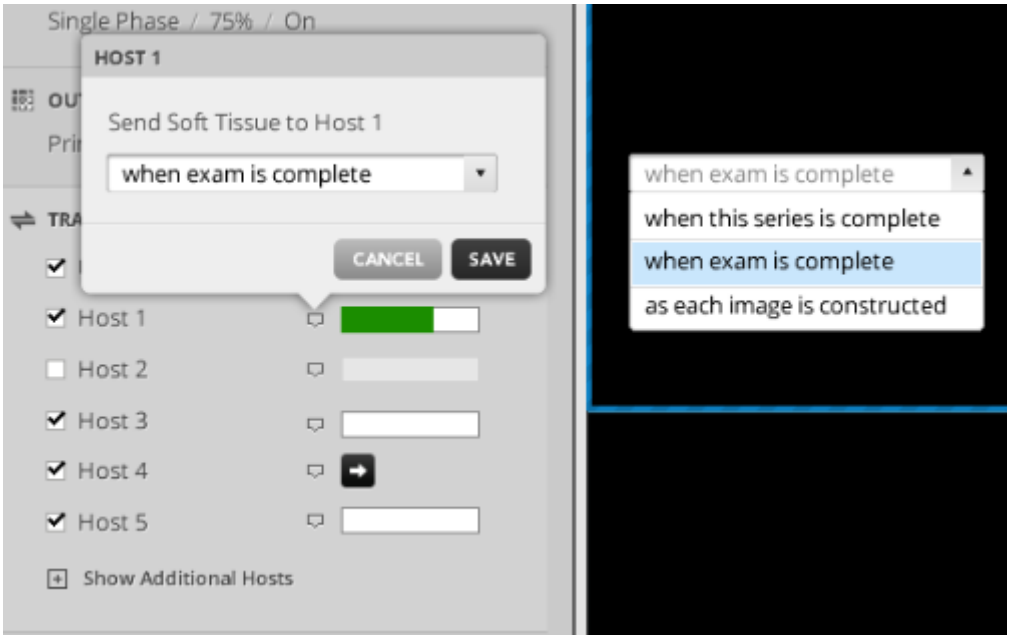


Table 6: Transfer options

For this setting:	Select or set:
Host name/USB boxes	Select the hosts/USB devices to which you want to send the reformat when it is complete.
Show Additional Hosts	If you have other hosts to select, open to select it from this list.
Send options anchored pop-over	Select the option corresponding to how you want to send the reformat.

3.1.4.5 Auto-Run/Run/Abort button

The Auto-Run/Run/Abort button is at the bottom of the Image Tools panel. This button takes on one of three states, depending on the state of the reformat.

When the button is in this state:	The reformat is in this state:	Clicking the button does this:
Auto-Run	The reformat is not running (you are editing the reformat).	If the button is grayed out, select the appropriate protocol from the Protocol section. Click the button to autorun the reformat after recon data has been acquired.
Run	The recon data is available, but the reformat has not been run.	Click the button to run the reformat. This button is grayed out if you have not selected a protocol or defined a batch reformat manually.

When the button is in this state:	The reformat is in this state:	Clicking the button does this:
Abort	The reformat is process.	Click the button to stop the reformat. If an automatic reformat is running and no images have been created, the reformat goes into manual mode, allowing you to modify the reformat and run it manually. If an automatic reformat is running and images have been created, the reformat is canceled and any images that have been created are available for view in the 2D viewer and will be an image series in File Manager. The reformat goes into manual mode, allowing you to modify the reformat and run it manually. For a manual reformat, the reformat is canceled and any images that have been created are available for view in the 2D viewer and will be an image series in File Manager. If you want to perform the reformat, you will need to add the reformat to the task list again.

3.2 Reformat planning

3.2.1 Automatic reformat

For an automatic reformat, no images are acquired before planning the reformat.

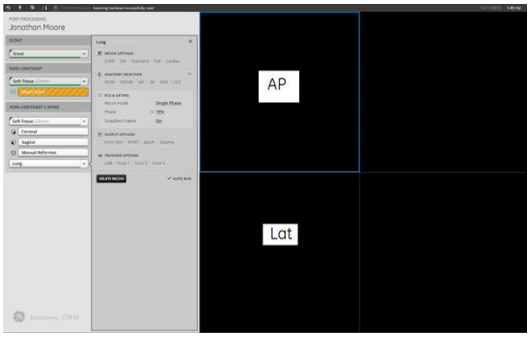
1. From the RIPTL, click reformat.
2. Select the protocol you want to use from the *Reformat Settings* panel.
3. Click the [Auto-Run] button.

3.2.2 Semi-automatic reformat

For a semi-automatic reformat, the scout images are available to plan the reformat.

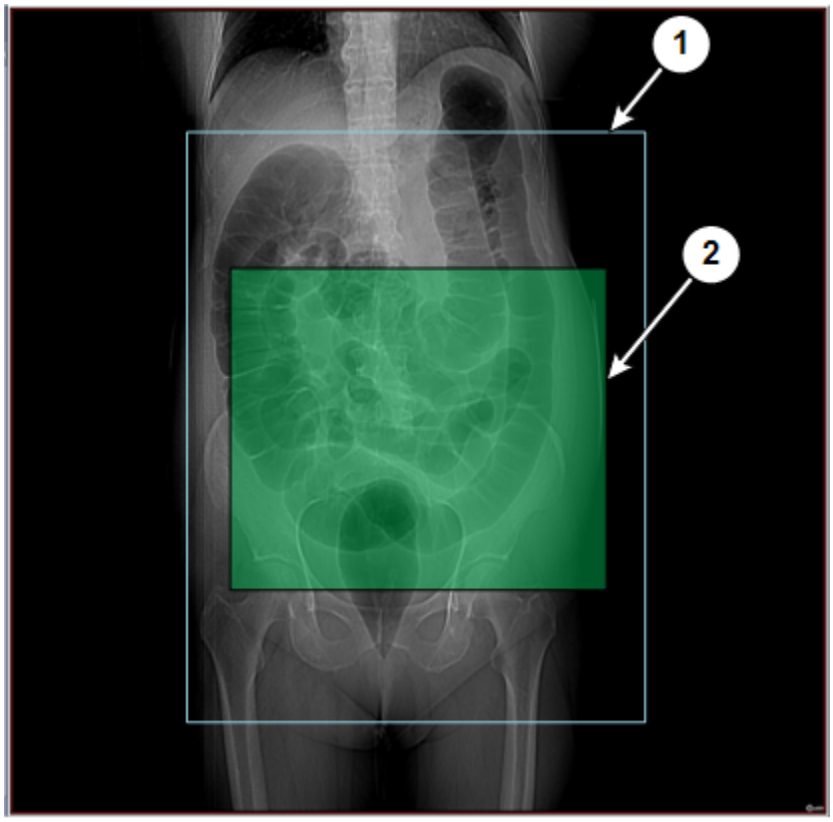
1. From the RIPTL, click reformat.
2. Select the protocol you want to use from the *Reformat Settings* panel. Adjust the settings for the protocol.
3. Scout images display in the upper left (AP) and lower left (lateral) viewports, displaying the GraphicRx lines of the acquisition reconstruction and the batch lines for the reformat batch.

Illustration 20: Scout image locations



4. Click [Auto-Run].
5. Adjust the location for the reformat on the scout image.

Illustration 21: Recon scan lines and graphic object



1	Boundaries of the graphic object for scan/recon. These boundaries update in real time based on the scan plan for scan/recon.	2	Oblique batch graphic object

3.2.3 Manual reformat

For a manual reformat, the recon data is available.

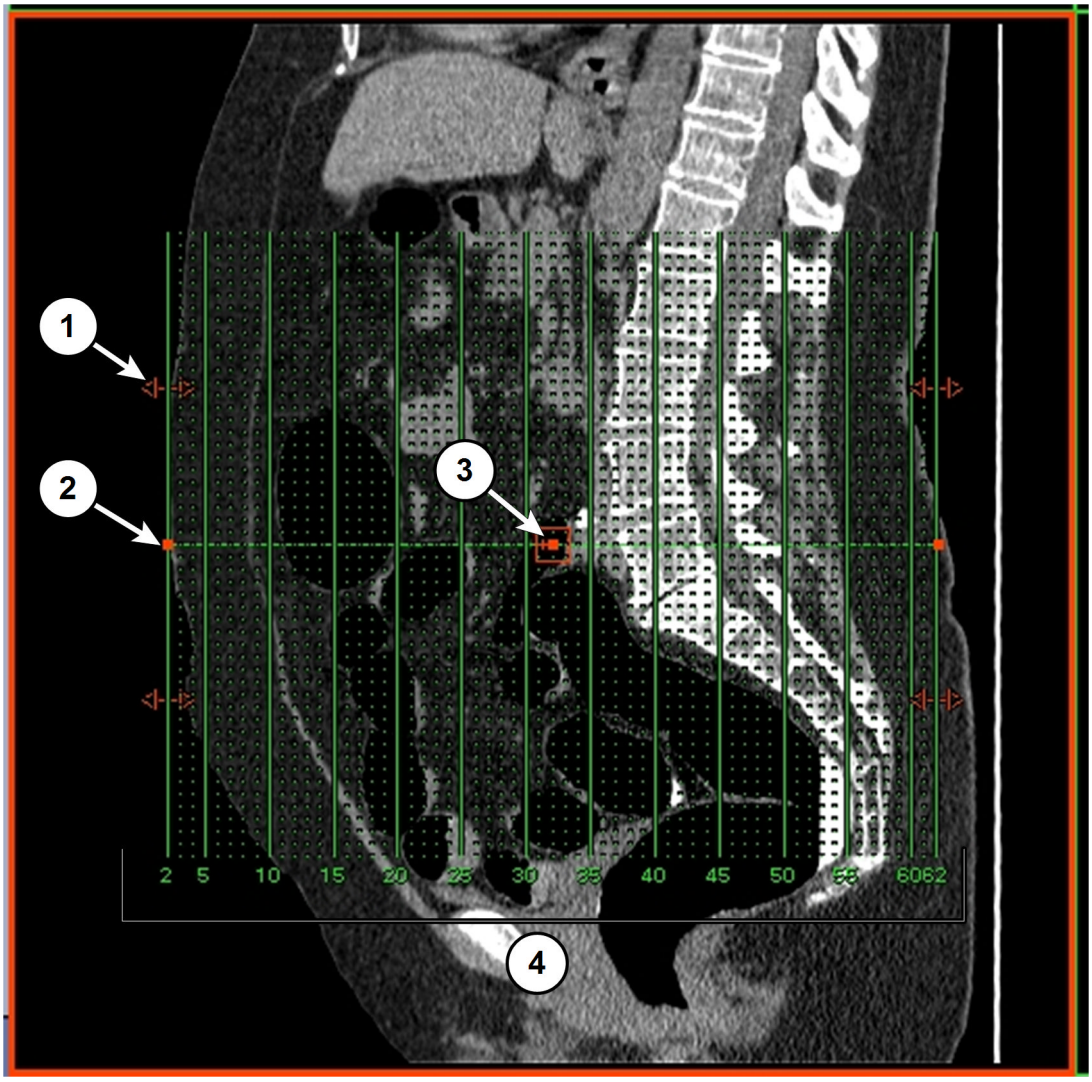
1. From the RIPTL, click reformat.
2. Select the protocol (or generic batch) you want to use from the *Reformat Settings* panel. Adjust the settings for the protocol.
3. The default reformat views appear in the viewports. If a protocol has been selected, batch lines appear on the views.
4. Click [Run].

3.2.4 Graphic object for oblique reformats

The graphic object used for planning an oblique reformat allows you to move the entire plan in the recon scan area, extend coverage in any plane, rotate the reformat angle.

This graphic object can be used on scout images for semi-automatic reformats, and any of the multiplanar volume views for manual reformats.

Illustration 22: Graphic object – oblique reformats

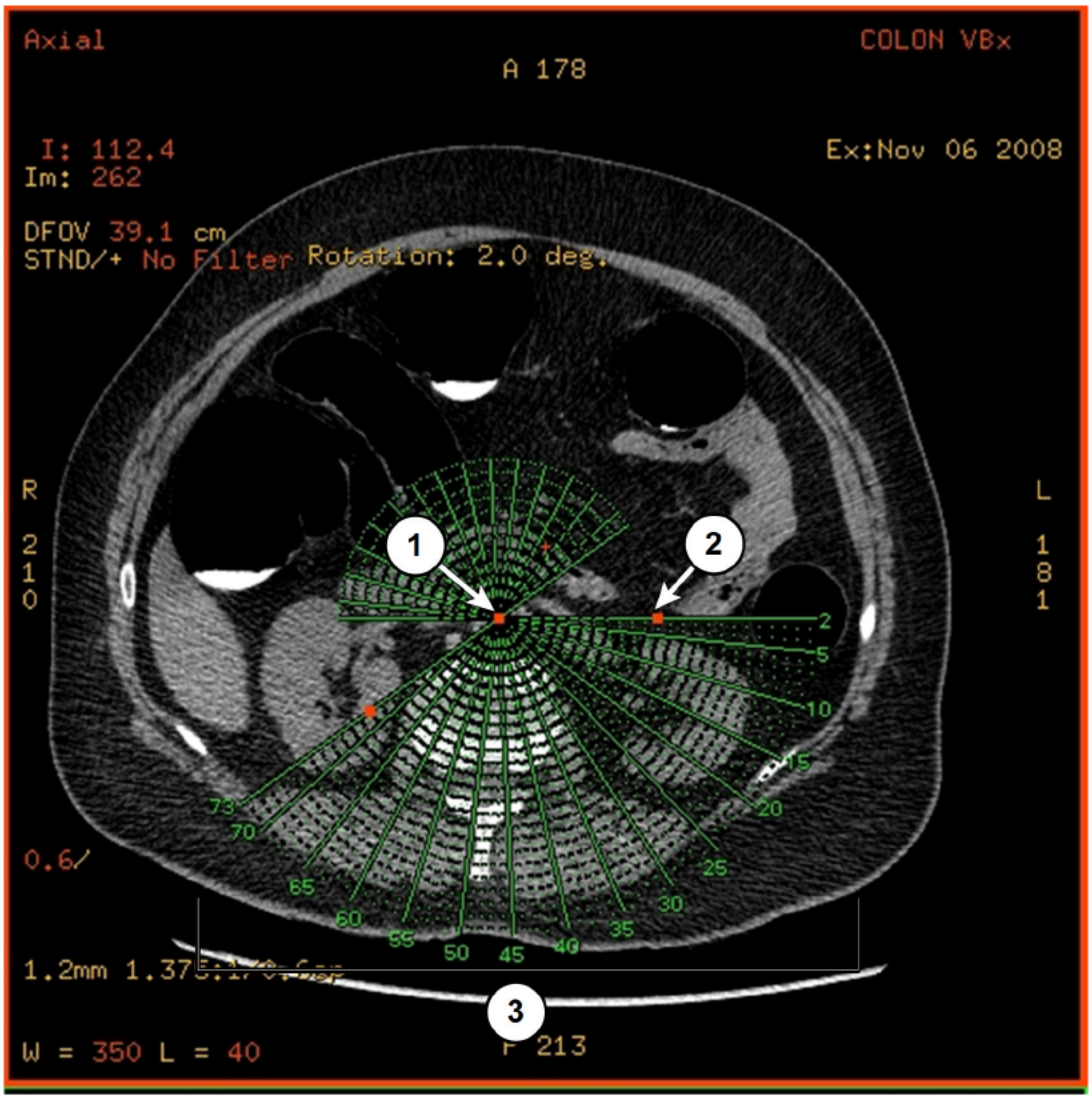


1	Handle to extend coverage in any plane	3	Handle to move the entire reformat plan
2	Handle to rotate the reformat angle	4	Numbers showing start and end of re-format

3.2.5 Graphic object for rotate reformats

The graphic object used for planning a rotate reformat allows you to move the entire plan in the recon scan area, change where the rotation will take place and where the start and end of the reformat will be.

Illustration 23: Graphic object – rotate reformats



1	Handle to move the entire reformat plan	3	Numbers showing start and end of re-format
2	Handle to change the placement of the rotate graphic object		

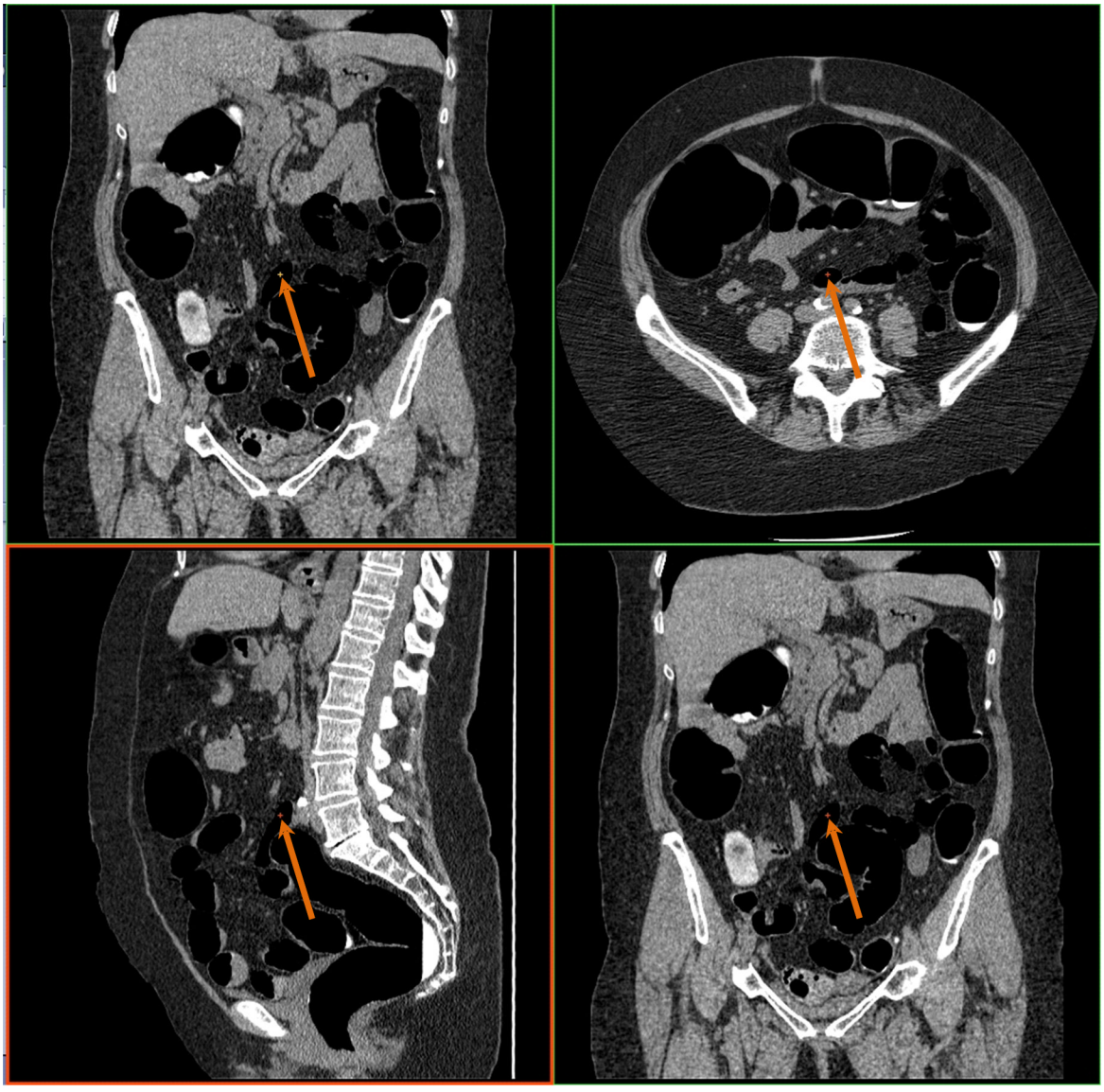
3.2.6 3D cursor

Use the 3D cursor to point to the same location in all viewports.

Place the 3D cursor by clicking a viewport and dragging the cursor into position, or you can move the mouse over an area and press the <Shift> key.

You can toggle the 3D cursor on and off by pressing the <C> key.

Illustration 24: 3D cursor (shown with arrows)

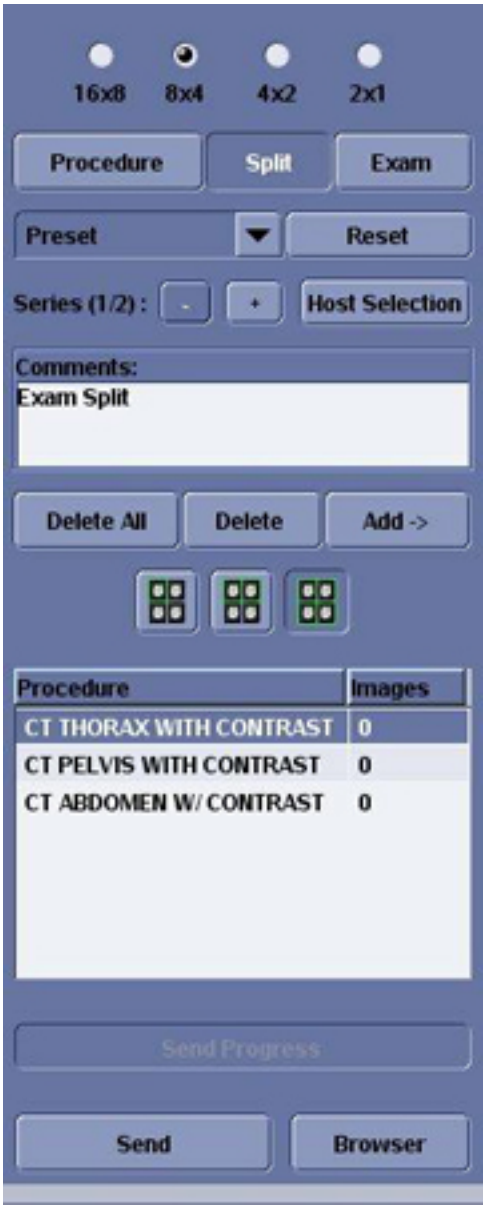


4 Exam Split

4.1 Exam split screen

From the Controls Area of the File Manager, click the [Exam Split] icon  .

Illustration 15: Exam Split screen



Screen Element	Description
Procedure/Split/Exam	Displays a list of Requested Procedure IDs or Accession Numbers for a patient.
W/L presets	Allows selection from a Preset menu and to Reset the W/L to the last selected values.

Comments	Add a comment that is attached to the file you have selected to split.
Delete All/Delete/Add	After selecting a range of images, click an option to set your primary port display.
Procedure	Lists Requested Procedure ID or Accession numbers.
Send	Saves your selections and sends the files to the selected host.
Browser	Cancels your selection, ends the Split Exam session, and returns you to the browser.

4.2 Split exams when the scan is completed

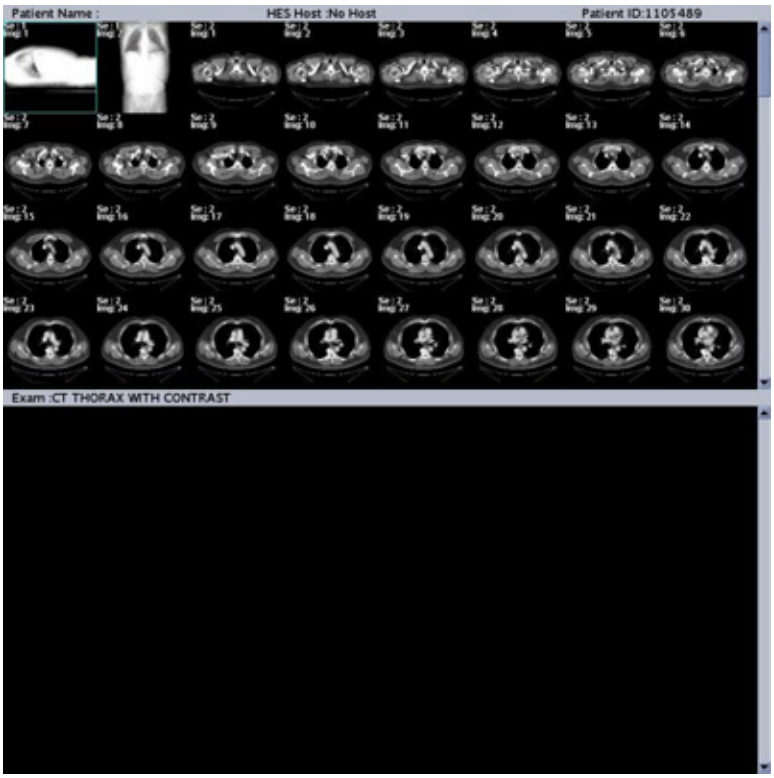
Use this procedures to split a series into separate groups that can then be used for multiple reads and billing. Exam Split is only available if your system has ConnectPro.

1. Complete an exam where multiple Requested Procedure ID or Accession Numbers have been selected.

   All Patient records that you wish to split, must be selected from the *Patient Schedule* when you selected [New Patient]. You cannot add procedures after the exam is ended.

2. From the browser, click the exam you wish to split.
3. From the Controls Area of the File Manager, click the [Exam Split] icon  .
4. Select the series to split.
5. From the list of applications, click [Exam Split].
   - The *Exam Split* menu appears with the selected images displayed in the upper viewports. The system may display every image or skip some images depending on the total number of images selected.
   - If the exam you selected does not have Multiple Procedures, a dialog message is posted and Exam Split exits.
6. From the *Exam Split* screen, click first image, press <Shift>, and click the last image to set the range of images to be grouped together per procedure code.

Illustration 16: Example of the first slice highlighted for Exam Split range selection procedure



7. From the *Procedures* list area, select a procedure that reflects the procedures selected from Patient Schedule.
8. From the *Exam Split* control panel, click [Add].

   Add select images to the procedure.
9. Adjust the W/L as needed in the exam area of the display.

   To adjust the W/L use either the W/L Presets on the *Exam Split* control panel or use the mouse.
10. From the *Exam Split* control panel, click [Host Selection].

Illustration 17: Host Selection

11. Select the receiving host and click [Save].

12. From the list of procedures on the *Exam Split* control panel, select the procedures you wish to send to the host and click [Send].
    - To select multiple procedures, press and hold <Shift> while selecting procedures.
    - For systems configured for VES, send exams prior to splitting and it sends GSPS objects.
    - For systems configured as HES, images are sent after splitting and sends a new series.

Chapter 16 Reformat

1 Overview

Use the Reformat software, launched from File Manager, to display and manipulate Reformat data sets.

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

1.1 Indications for use

Volume Viewer is a medical diagnosis software that allows the processing, review, analysis, and communication of 3D reconstructed images and their relationship with originally acquired images for CT, MR, X-ray Angio, and PET scanning devices. The combination of acquired images, reconstructed images, annotations, and measurements performed by the clinician are intended to provide to the referring physician clinically relevant information for diagnosis, surgery, and treatment planning.

1.2 User profile

As with any medical imaging process, only qualified personnel should use this equipment. You must be aware of the limitations of the basic imaging modality and of ensuing image processing. This includes understanding the limitations of the initial series acquisition, image processing technology used, and image display methods.

1.3 Requirements for Reformat

Certain requirements need to be met before you can perform reformat.

- A valid image set for reformat must have the same:
  - Matrix size
  - Display center
  - Orientation
- Four or more images must be selected before selecting *Reformat*.
- Tilt acquisitions are not supported for right and left decubitus patient orientation.
- You cannot have two images with identical locations.
- Spacing must be less than 10 mm.
- The image set can only include axial, sagittal, or coronal images.
- Different Display Field Of Views and Gantry Tilts can be loaded, however you have to select between different sources of images to view them. The source annotation is located in the

upper-left corner of the image. You can change between sources by clicking on the red annotation.

1.4 Considerations

- If *Volume Viewer* hangs, simultaneously press <Alt> and <X> to clear the issue.
- If a message is displayed indicating images are too far apart or failed to build a reformat model for series with a large number of images, wait several seconds and launch *Reformat* again. When the series has a large number of images, the system may not have identified how many images are in the series before *Reformat* tries to start.
- *Reformat* does not include the slice location for axial images. If axial slice location is needed, generate the images in DMPR or generate secondary recons of the data.

2 Reformat

Reformatting allows you to define and display cross-sections of a 2D stack or 3D volume of image data that are oriented differently from the original acquisition images.

A baseline view is a basic axial, coronal or sagittal view. Of these, the acquisition view displays the images in the acquisition plane of the original image set, the other two are the corresponding orthogonally reformatted views. They can be moved to show any location in the 3D volume, but remain aligned parallel to the three main axes of the Right Anterior Superior (RAS) coordinate system. An oblique view is a plane reformatted view that can be both moved and rotated to any location and orientation within the 3D volume.

If a feature of interest extends beyond a single plane, standard baseline or oblique view reformatting cannot show the entire feature no matter how you position the oblique plane. To create a single view that includes the entire feature, use curved reformatting to create a curved cross-section.

2.1 Open Reformat

1. From the File Manager, select the desired exam / series / images to reformat.
   - To select a subset of images, press <Shift> and simultaneously click the first and last image.
   - To select specific images, press <Ctrl> and simultaneously click individual items.
2. From the File Manager Applications icons, click [Reformat].
   - An oblique, axial, sagittal, and coronal are displayed in the four viewports.
   - *My Tools* tab can be customized to display any display icons. Therefore, the instructions in this chapter are for accessing a particular icon from the tab on which it originated. On your system, the icon may be on your *My Tools* tab.
3. Change the view type by selecting a view type from the red annotation.

2.2 Use the Reformat Image Controls

The Image Controls display when you start *Reformat*.

Illustration 1: Image Control area

Click an icon on the top row to set the action of the left mouse button when placed over the image. Changing the selection in the Image Control area updates the on-view Mouse Modes menu selection.

The icons can be in one of three states:

1. Selected (depressed)
2. Unselected (light blue)
3. Unavailable (grey)

2.2.1 Rotate freehand or page images

1. Click the [Page/Rotate] icon  to activate a freehand rotation or to page through images.
2. Click and drag to rotate 3D/Oblique views and page axial/sagittal/coronal views.

   No rotation handle is displayed on 3D/Oblique views when this mode is selected.

2.2.2 Zoom (magnify) images

1. Click the [Zoom] icon  to activate zoom mode.
2. Click and drag to zoom the image in or out.

2.2.3 Roam (pan) images

1. Click the [Roam] icon  to activate a roaming mode.
2. Click and drag the image to move it up and down and left and right (only applicable if the image has been zoomed in).

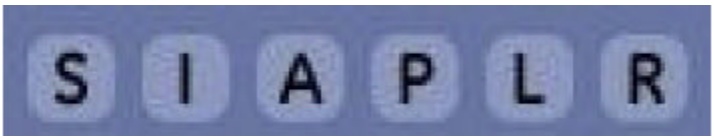
2.2.4 Select objects

Click the [Select] icon  to activate the selection mode.

2.2.5 W/L images

1. Click the [W/L] icon  to activate the W/L mode.
2. Click and drag over an image to adjust the window width (left-right motion) or the window level (up-down motion).

2.2.6 Change the image orientation

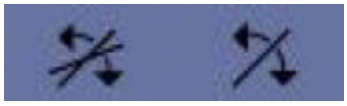


Click an image orientation icon to change the plane or a 3D or oblique reformat image.

Table 1: Orientation controls

Button	Description
S	Superior
I	Inferior
A	Anterior
P	Posterior
L	Left
R	Right

2.2.7 Activate the Oblique mode



The [Multi Oblique Mode] button (left) displays three oblique planes defined by three adjustable color axis (orange, green, blue).

1. Adjust any axis to update the two other oblique planes.
2. Click again to deactivate the *Multi Oblique* mode, which keeps the orientations defined in oblique viewports.

The [Single Oblique Mode] button (right) displays a line cursor in *Reformat*, which is used to define a new plane.

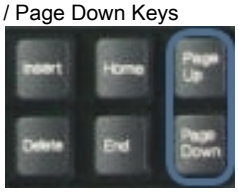
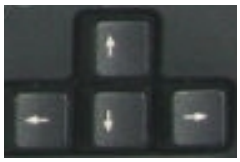
1. Set the function of one viewport to *Oblique*.
2. Make another viewport primary and then click the [Single Oblique Mode] button.

   A solid yellow line appears, which represents the plane of the Oblique reformat.
3. Place the cursor on the solid yellow line and click and drag it to tilt the yellow line to the desired plane.

2.3 Use the keyboard shortcuts

Illustration 2: Keyboard

Table 2: Keyboard shortcuts

Indicator/Key	Description
Film keys	Press <F1> - <F4> for manual filming with the *Manual Film Composer*.
Preset Window Width/Window Level Keys	Press [F5] - [F11] for preset Window Width and Window Level.
Page Up / Page Down Keys 	Press these keys to scan through the images in a viewport.
Window Width / Window Level Control Keys 	Press these keys to change the WW/WL settings for images in a viewer. The Up/Down arrow keys increase/decrease the window level, respectively. The Right/Left arrow keys increase/decrease the window width, respectively.
Tab	Press <Tab> to swap between image control modes.
Space Bar	Press the <Space Bar> to show/hide the *MyTools* palette.
Ctrl Key + moving the mouse	Press <Ctrl> and simultaneously move the mouse to page through the slices.
Shift	Press <Shift> to place the cursor at the mouse location.
Shift + click and drag	Press <Shift> and simultaneously click and drag to draw a trace line as you move the mouse.
Alt	Press <Alt> and click to edit a trace area.
Alt + s	Press <Alt> and <s> simultaneously to save the image as you name it.

2.4 Use the right-click functions

Place the cursor over the viewport and right-click to display the on-view menu. Move the cursor down the menu until your choice is selected. Not all choices are available under all conditions.

Table 3: Right-click menu selections

Menu Selection	Description
Save	**Save Image** - saves the image as a DICOM image. **Save Image As** - saves the image and assigns it a description. **Save Screen** - saves all images displayed on the screen as DICOM images.
Display Properties	**Hide 3D cursor** - removes the 3D cursor from the screen. Toggles back with Show 3D cursor. **Reference image** - displays a small reference image showing the plane orientation and position of the current image. **Lock orientation** - locks image orientation (3D and 2D oblique only). It is not possible to change the orientation with the mouse in the locked view. **Center on cursor** - centers the image on the cursor. **Center on FOV** - centers the image on the FOV. **Center on object** - centers the image on an object (useful after segmentation).
Annotations	**No Annotation** - hides all annotations including the right and left markers. **Partial Annotation** - hides or shows part of the image annotations (scan parameters). **Custom Annotation** - shows the annotations that have been checked in the Annotation tab of the Display panel. **User Graphics** - shows only the user graphics (including measurements and annotations). **Full Annotation** - shows all annotations. This option is available when full annotations are not shown.
Trace	When a trace has been defined with the Display Trace tool, this option is available. **Create trace** - create a trace on the image. **Clear last point** - deletes the last point deposited. **Clear trace** - deletes all points. **Lock cursor to trace** - locks the 3D cursor on the trace.
Mouse Modes	Sets the action of the left mouse button. The active mode is indicated by "->" sign.
Enlarge	Changes the view to Full Screen.
Reset Pointer	Returns the object back to the center of the viewport. Use this tool if there are blank viewports.
ROI	The cursor must be centered on an active ROI to view this menu. **Delete ROI** - deletes the active ROI. **Delete all ROIs** - deletes all ROIs. **Edit ROI's label** - allows you to change the ROI's label. There is a maximum of 10 characters. **Duplicate** - duplicates the active ROI. **Hide/Show Statistics** - hides or shows the ROI statistics.

3 Display

In most respects, a 3D display view is like any other view. You can adjust window width and level as required, zoom, and scroll the image. You can add text annotations and change the color of the displayed object. In theory, you can also perform measurements or define and perform a scalpel cut on a 3D view since you can mark points and create traces on it. In practice, this is highly inadvisable, because on the 3D view you have no indication how deep into the 3D object the 3D cursor is located, and the result may not be at all what you wanted or expected.

A 3D view is different in that it displays an image of the 3D model (which may consist of one or more 3D objects), and that you can manipulate this 3D model.

On a 3D view, you can:

- Rotate and tilt the 3D model in all directions.
- Define one or more cut planes and display the 3D model with part of it removed, showing a cross section of the model at the location of the cut plane.
- Place a spherical shutter (mask) on the view to show only an essential part of the model, with the remainder masked out.
- Use colors, in particular to distinguish merged 3D models in merged 3D views.
- Extract a 3D object or volume of interest from the original 3D models using the Segment tools.

3.1 Annotation

There are two types of annotation:

- *System annotation* which is automatically supplied by the system and is always displayed in the same place. The type and amount of annotation displayed can be modified but not moved.
- *User annotation* which is annotation you add. This annotation can be text or measurements and can be placed anywhere on the viewport.

Text annotation

You can add notes and comments directly on the views, and use a marker with the annotation to point out anatomical features. User text annotations can be edited, moved or deleted as necessary. When images are saved, any annotations shown on the images are saved with them.

Preset annotation

Preset annotations are those which have already been created and saved for future use. These annotations can consist of text or text with measurement annotations. The preset measurement annotations vary depending on the current protocol. In addition to the supplied default annotations supplied, you can create and save annotations.

Measurement annotation

You can create and view various measurements (voxel value, distance, angle, area, volume) on the views. Like text annotations, they can be moved, deleted or edited as necessary.

3.2 ROI

The Region of Interest (ROI) tools exist in 2D and 3D. Several shapes are available to measure a region of interest in any view plane/volume: circle, elliptic, rectangle, and cubic for 3D ROIs. You can use the ROI tools to obtain information, volumes, areas and statistics of anatomy or pathology. The ROI tools allow you to:

- measure the pixel intensity value at a specific point on the image
- display the area or volume
- display the mean, standard deviation and minimum and maximum pixel values within the ROI

In order to perform measurements on an image that can be expressed in absolute values (mm), the image must be calibrated, i.e. the relationship between image pixels and true anatomical distance in the patient's body (the scale factor) must be known. For images such as CT and MR this information is automatically recorded during image acquisition and stored with the image. Measurements on such images can therefore be expressed directly in mm, using the patient-based Right Anterior Superior (RAS) coordinate system.

3.3 Modify active (red) annotation

All active (red) annotations on the image indicate adjustable fields. Red Numerical values can also be adjusted with left/right-click to decrease/increase values. Other red annotations can be modified selecting options from a menu. The selections vary based on the application launched and the selected view.

Illustration 3: Active annotation

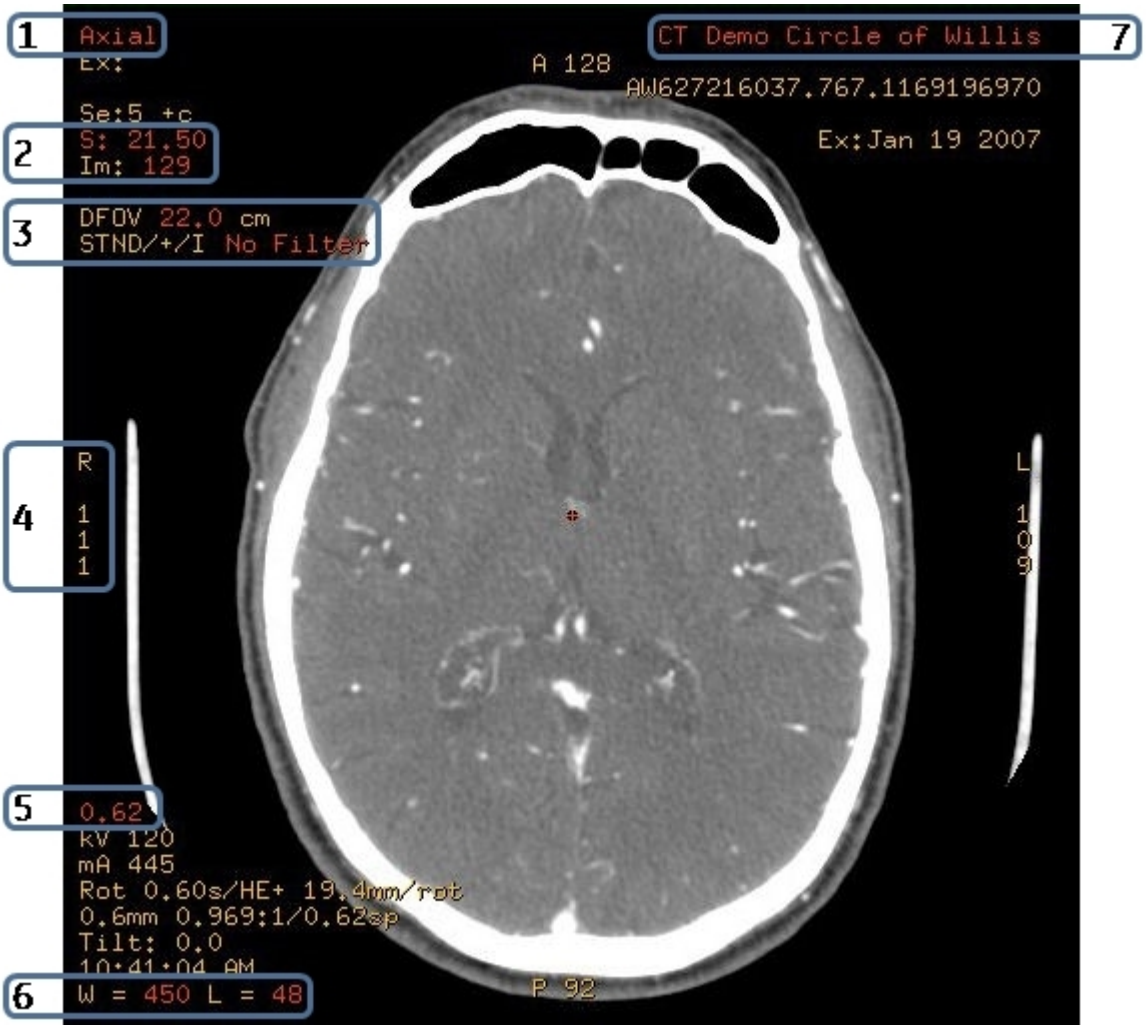


Table 4: Active annotation

No.	Annotation	Description
1	Plane or View Type	Right-click and select a view type from the menu to change the plane or select a 3D model. The type of view displayed in each of the four views of the viewing area is determined by the selected protocol. During image processing, you can change the view at any time using the active annotations.
2	Scan Location Image Location	Middle-click and drag horizontally to scroll through the images or click to increment and right-click to decrement an image at a time. Alternatively, you can use the left and right arrow keys on the keyboard to move through the image set. Scan location is not available on 3D views.
3	DFOV	Middle-click the drag horizontally to real-time magnify the image or click to increment and right-click to decrement the mag factor. The maximum zoom factor (ratio between acquisition DFOV and actual DFOV) is 8.0. You cannot increase the DFOV beyond the original value, unless the height of the stack of images (number of images × slice thickness) is larger than the DFOV. In that case, you can zoom up to the height of the stack of images (zoom factor < 1.0).

No.	Annotation	Description
	Image Filter	Smooth 1 to 3, Edge 1 to 3, and Lung filters are 2D display filters and are available only on Axial, Sagittal, Coronal, and Oblique viewports. Smooth 3D Plus is a 3D anisotropic filter that smoothes the whole volume. It can be applied on any 2D or 3D viewport. **NOTICE** **The filter effect is purely visual and any statistics performed on a filtered image will be performed on original volumes (non filtered).** **NOTE:** CT Filters can be applied on thick slabs only when rendering is set to "Average".
4	Image Roam	Click and move the image within the viewport.
5	Slice Thickness	Middle-click and drag horizontally to real-time change the slice thickness or click to increment and right-click to decrement the slice thickness (2D images).
6	Window Width and Window Level	Middle-click and drag vertically and horizontally to real-time change the W/L. Alternatively, move the mouse over the annotation and type in a new value or right-click to display the W/L Preset menu. To modify the W/L of the reference images, middle- click and hold on the reference image and move the mouse.
7	Patient Name	Click or right-click and select *Show* or *Hide* to show/hide the patient name.

3.4 Review Controller screen

The *Review Controller* screen contains display short cuts. The image selection sliders can appear on the left or the right side of the image.

Illustration 4: Review Controller

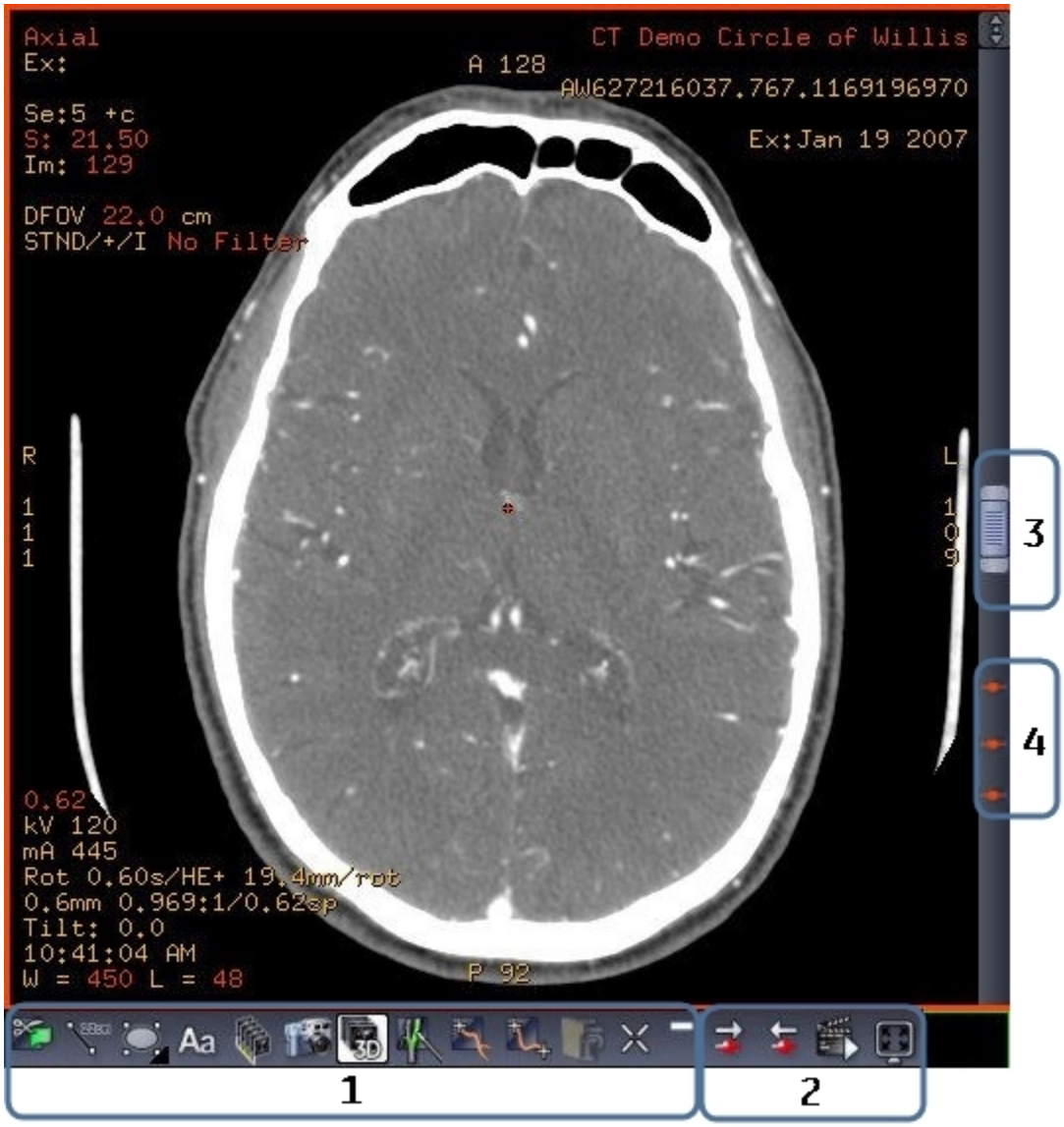


Table 5: Review Controller functions

No.	Function	Description
1	My Tools Palette	The icons in this area of the Review Controller are based on the Display tools you have moved to My Tools tab. As you add or delete tools from My Tools tab, the Review Controller updates.

No.	Function	Description
2	Review Control Tools 	Click the Next ROI and Prior ROI to navigate between deposited ROIs and report cursors. Click the Movie icon to switch to phase browsing. Click the Enlarge icon view an image full screen. Click it again to restore the initial display. When the mouse mode is set to Page/Rotate, Zoom, or Pan, it is also possible to double-click a view to enlarge it.
3	Paging Direction/Speed 	a = Click and drag either side button to change the Thickness of the MIP image. Slice thickness adjustment is not available on 3D views. b = Click and drag the middle slider to page through the image set. To page, you can also press <Ctrl> and click and drag the mouse up and down.
4	Bookmarks 	Allows you to navigate to an image that has a graphic.

3.5 Display tab

The *Display* tab contains the following tools.

Illustration 5: Display tab

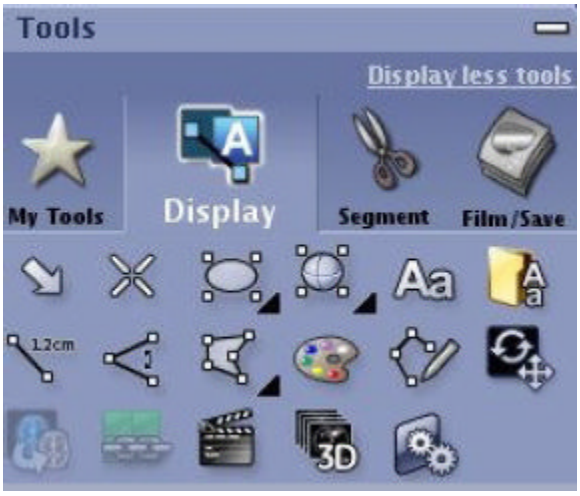
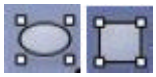


Table 6: Display icons

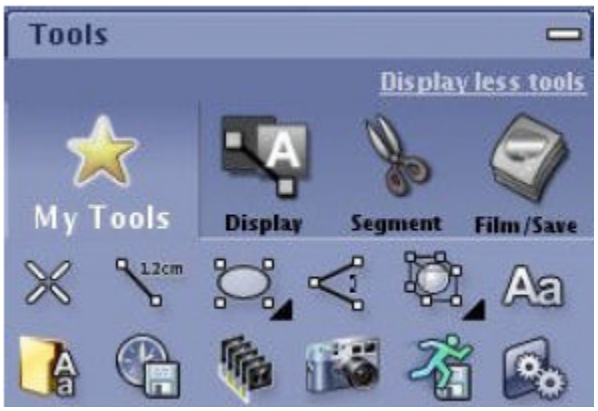
Icon	Description
Arrow Tool 	Deposits an arrow on the screen. Click and drag the end of the arrow to re-size and rotate it. Click and drag anywhere on the arrow to move it.
Report Cursor 	Deposits a point on the viewports to display a RAS coordinate and vector ROI at the current cursor position.
2D ROIs 	Displays statistics as average, minimum and maximum voxel values, standard deviation, and area within the 2D ROI.
3D ROIs 	Displays statistics as average, minimum and maximum voxel values, standard deviation, and volume within the 3D ROI. The 3D color ROI provides the ability to colorize voxels inside the ROI based on ranges of voxel value. Additional Statistics such as volume can be calculated for each colored area. (Click the arrow in the lower-right corner of the button to select the 3D Box ROI, the 3D Color ROI, or the Spherical ROI.)
Annotate 	Opens the Annotate control panel, which allows you to use predefined annotations on the views or create new annotation. Many of the options are linked to measurement tools. For example, the Distance Annotation allows you to link an annotation with a measurement (e.g., Stenosis: xx.x mm).
Preset Annotation 	Opens the Preset Annotation control panel, which allows you to place preset annotations on an image.
Measure Distance 	Opens the Measure Distance control panel, which allows you to perform measurements on an image.
Measure Angle 	Opens the 2D Angle control panel, which allows you to deposit thee points on an image.
Measure Area 	Opens the Area control panel, which allows you to deposit points around a region of interest. Right-click to convert to ROI or display results.
Measure Volume 	Opens the Volume control panel, which allows you to deposit a point to obtain a volume measurement.
Set Color 	Opens the Set Color control panel, which allows selection of a color map or custom color to apply to non-VR viewports.
Trace 	Opens the Trace control panel, which allows you to create and manipulate a curved reformation, a Profile, or an X-Section.

Icon	Description
Rotate/Translate 	Opens the Rotate/Translate control panel, which you can set rotation by degree and direction and translation by distance.
Integrated Registration 	Integrated Registration is not supported on the CT console.
Link/Unlink 	Opens the Link/Unlink control panel, which allows you to unlink multiple volumes to allow manual registration adjustment.
Cine 	Opens the Cine control panel, which allows you to automatically page through all of the slices of a single phase series or control a 4D Cine of multiphase series.
MPR/3D 	Opens the MPR/3D control panel, which guides you through the creation of 3D or multiplanar image views. From this panel you can adjust slab thickness and select render modes such as MIP, Average, MinIP, and Volume Rendering.
Display Options 	Opens the Display Options panel, which allows you to set display preferences for viewed images.

3.6 My Tools tab

Open *Reformat* and then click [My Tools] to view the My Tools tab. My Tools palette is a customizable tools palette, where you can place the most frequently used tools. It is recommended to group the tools together so they are easily accessed. Unlike the other tabs, this tab cannot be hidden. See the Display tab for a description of the available tools.

Illustration 6: My Tools tab



3.6.1 View Tools

- Click [More Tools] to switch to an Advanced mode, where you have access to all the tools grouped under tabs.
- Click [Display Less Tools] to switch to the Basic mode, where some tools are stacked.

3.6.2 Remove a tool

To remove a tool, drag and drop the tool outside the palette and right-click the tool and select *Remove from My Tools*.

3.6.3 Add a tool

To add a tool, go to the tab where to tool to add is, then drag and drop it to the My Tools palette or right-click the tool and select *Add to My Tools* (for example to add annotations preset tool go to Display tab).

3.6.4 Move or hide the palette

The My Tools tab can be floated anywhere in the interface. Click and drag the top part of the tab to move it. Press the <space bar> to show or hide at a mouse location.

3.7 Color Map Table screen

When you draw a colored ROI, a Color Bar displays on the left side of the viewport. Click the Color Bar to open the *Color Map Table* screen.

Illustration 7: Color Map Table: Statistics tab

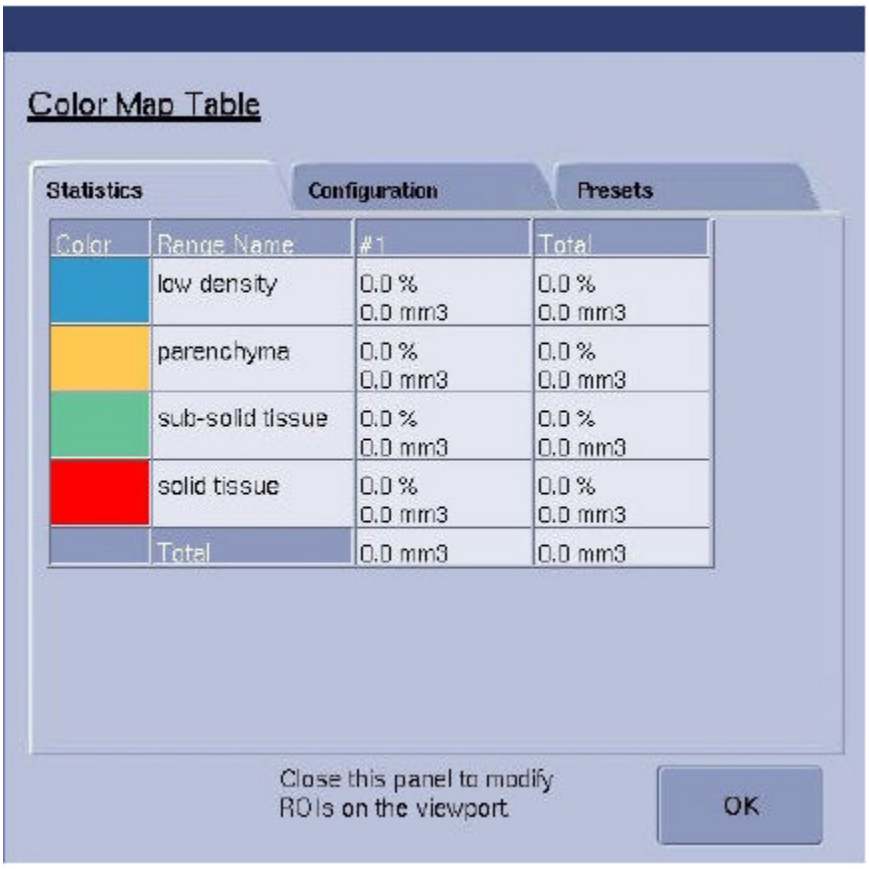


Table 7: Statistics selections

Function Name	Description
Color Range Name	Displays the color, name, and range of values assigned to each defined color. These settings can be changed on the Configuration tab.
Percentages	The percentage and area of each Volume of Interest (VOI) corresponding to each color-coded Look Up Table (LUT) range. Areas of an image can be made to display discrete LUT values by placing an LUT ROI on the image.

Illustration 8: Color Map Table: Configuration tab

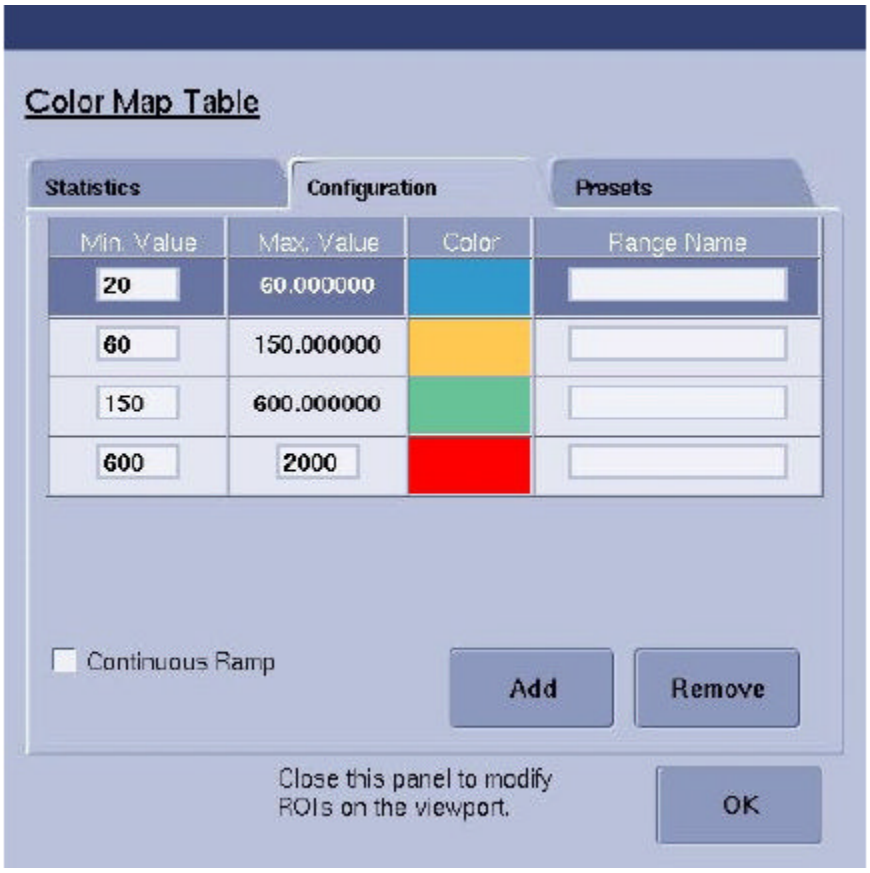


Table 8: Configuration selections

Function Name	Description
Min. / Max Values	Defines the range for Min. / Max values. Type in the text field to change the values.
Color	Click a color block to display the *New Color* screen from which you can change the shade of the selected color.
Range Name	Defines the name of the color range. Type in the text field to change the color range name.
Continuous Ramp	Displays LUT values as a continuous ramp of colors. Statistics are not available in the continuous mode.

Illustration 9: Color Map Table: Presets tab

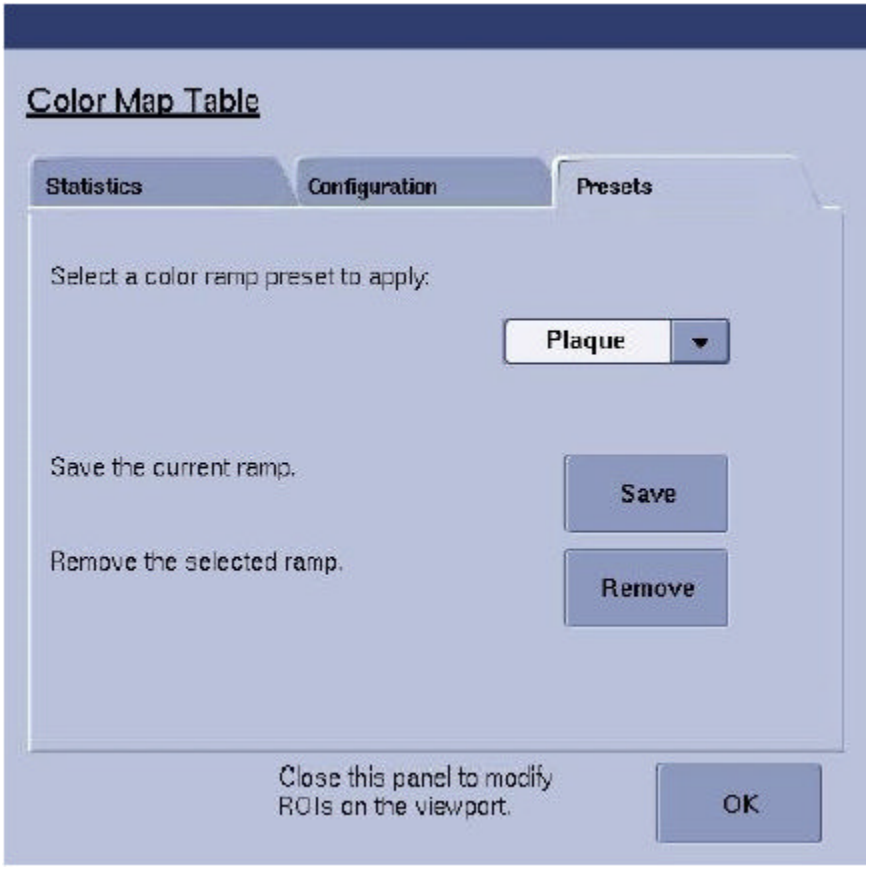


Table 9: Presets selections

Function Name	Description
Color Map Presets	Lists presets for particular diagnostic investigations: Plaque, Emphysema, MonoColorCT and Perfusion.
Save	Adds a new color ramp.
Remove	Deletes a user created color ramp.

3.8 ROI Preferences screen

From the *Review Controller*, click the [ROI] icon to display the *ROI Preferences* screen.

Illustration 10: ROI Preferences screen

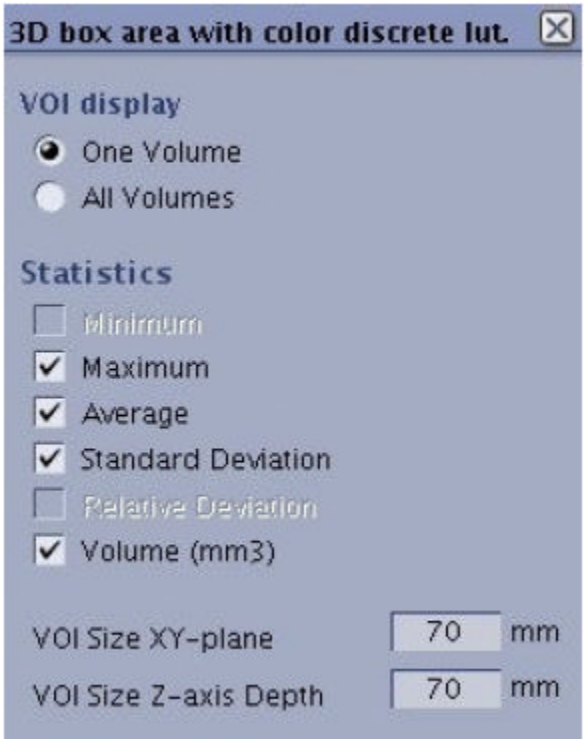


Table 10: ROI selections

Function Name	Description
VOI Display	Sets the display of the Volume of Interest (VOI) on one or all viewports for 3D images. • **One Volume** displays the VOI on only the viewport on which the VOI was placed. • **All Volumes** displays the VOI and statistics on all viewports.
Statistics	Allows any combination of minimum, maximum, average, standard deviation and volume values.
Size	Type in a height, width and depth. There is no depth for the sphere ROI. This will become the default size of the ROI, but it can be modified directly on the image.

3.9 Annotate an image

Use this procedure to add specific and unique annotation to an image or apply a pre-set annotation that is saved on your system.

1. Open *Reformat*.
2. Click the *Display* tab.
3. Click the [Annotate] icon  .
4. On the *Annotate* screen, click the annotation type (simple, linked, or measure).
5. Place the cursor on the image and click to deposit the cursor and default text.

6. Enter new text in the Annotation text screen.

3.10 Save preset annotation

Use this procedure to add a custom pre-set annotation to the *Preset Annotation* list.

1. Open *Reformat*.
2. From the *Display* tab, click the [Annotate] icon  .
3. On the *Annotate* screen, type text in the *Annotation Text* field.

   The preset name automatically fills in with part of the text from the annotation text field.
4. Change the preset name.
5. Select the text.
6. Press <Backspace>.
7. Type in a new name.
8. Click [Use for other anatomy] if you want the annotation available for other anatomies or [Use for other protocol] if you want the annotation available for other protocols.
9. Click [Save as preset] to add annotation to preset annotation list.

3.11 Measure

Use these procedures to activate a measure tool to obtain information, distances, and areas of anatomy or pathology.

1. Open *Reformat*.
2. Click the *Display* tab.
3. Follow one of the measure procedures below.

3.11.1 Measure distance

1. Click the [Measure Distance] icon 

.
2. Make one selection for each menu choice.
   - Measure:
     - Projection (2D): to view the length of the projection. When used in 3D images, the measurement will correspond to the projected red distance in the plane of the screen.
     - From Volume (3D): to view the true distance in the 3D volume. Endpoints can be positioned at different depths in the volume. Rotate 3D volumes to check the exact position.
   - Display:

- On one slice: to view the measurement on only one slice.
- On all slices: to view the measurement on all slices.
- On one viewport: to view the measurement on only one viewport.
- On all viewports: to place a measurement on different slices or volumes of a multi-phase scan at the same time.

○ Along:

- Straight line: to deposit the first and second point.
- Curve: to measure along a curve by depositing multiple points on the image. Right-click to validate the curved line.

3. Click an image at the start of measurement.
4. Move cursor to end point of measurement and click.
5. Click and drag the squares to adjust the points.
6. View the measurement results.

3.11.2 Measure angle

1. Click the [Measure Angle] icon  .
2. Click an image three times to deposit three points.
3. Click and drag the squares to adjust the points.
4. View the measurement results.

3.11.3 Measure area

1. Click the [Measure Area] icon  .
2. Click an image to deposit points.
3. Click and drag the squares to adjust the points around the region of interest.
4. Right-click to display the measurement results.

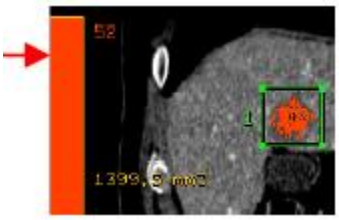
3.11.4 Measure volume

1. Click the [3D ROI] icon  .
2. Click an image to deposit the 3D ROI on an object of interest.
3. Click any of the corners to size the volume.
4. View the area measurement results.

3.12 Manage Colormaps

Use this procedure to manage Colormaps on reformatted images.

1. Open *Reformat*.
2. Click the *Display* tab.
3. Click the [3D ROI with color] icon  .
4. Click the image to deposit the ROI.
5. Click the color ramp displayed on the left side of the image to open the *Color Table* screen.



6. Click the *Statistics* tab to view range percentages for each color.
7. Change the values of the ROI on the viewport.
   a. Click the *Configuration* tab to change the values of the ROI on the viewport.
   b. Click a value in the *Min Value* column, and type a new value.
   c. Click a value in the *Max Value* column and type a new value.
   d. Click a *Range name* column text box to type a name.
8. To change a color in the color ramp, select a color in the *Color* column.
   a. From the Select new color screen, drag the cursor over a color on the color wheel.
   b. View the Current selected color.
   c. Click [Apply].
9. To add or remove a color in the color ramp, click [Add] or [Remove].
10. Click the *Presets* tab to load and save Colormap presets.
11. Click [Save] to save setting adjusted in the *Configuration* tab.
12. To load a color map preset, select the color ramp preset from the menu.
13. Click [OK].

3.13 Add an ROI

Use this procedure to add an ROI on an image to obtain information, volumes, areas, and statistics of anatomy or pathology. The ROI allows you to:

- measure the pixel intensity value at a specific point on the image
- display the area or volume
- display the mean, standard deviation, and minimum and maximum pixel values within the ROI

1. Open *Reformat*.
2. Click the *Display* tab.

Illustration 11: ROI tools

3. Select the desired ROI tool.

   3D color ROI is available one color MR or multi-color CT.
4. Define your preferences on the ROI panel.
   a. Choose an ROI propagation option.
      - Select One Volume to view the ROI on only the viewport on which the ROI is displayed.
      - Select All Volumes to view the ROI and statistics on all viewports.
   b. Select one or more Statistic options to view any combination of minimum, maximum, average, standard deviation and area (2D) or volume (3D).
   c. Explicitly adjust the size of the ROI.
      - For 2D ROIs, type a diameter in the Vertical and Horizontal Diameter fields.
      - For 3D VOIs, type a VOI size for the XY-plane and Z-axis depth.
      - The sphere VOI does not have a depth entry.
5. Click the desired anatomy to deposit the ROI.
6. Click and drag an ROI corner to adjust the size.
7. View the ROI measurements.
8. To hide the ROI statistics, click on the edge of the ROI to make it active, then right-click the center of the ROI, and select *Hide Statistics*.

NOTE: To delete the ROI, right-click on the ROI and select *Delete ROI*.

4 View Types

The following table contains the available view types in *Reformat* and their function.

Table 11: View Types

View Type	Function
3D	Displays the volume in 3D with different rendering. Default rendering is high density MIP. Other modes are available from the rendering mode red annotation.
Volume Rendered (VR)	Displays the volume in 3D color rendering.
Axial	An image plane representing a cross-sectional slice of anatomy.
Sagittal	An image plane dividing the body into left and right portions.
Coronal	An image plane through the body, dividing it into anterior and posterior portions (lengthwise).
Oblique	An image plane that has been tilted through the body rather than following the long axis. It can look like a axial image.
Oblique 3D	A 3D image plane created by defining points along an anatomical feature.
Curved	An image plane created by defining points along an anatomical feature.
Profile	A graph showing CT number intensity across a location.
Histogram (3D data)	A graph showing the percentage of occurrence and numerical statistics of each voxel intensity value in an object and total object volume. It also determines boundaries around a class of similar voxel intensities and can highlight pixel values. Statistics are not valid for 2D data.
X Section	A histogram (graph) showing the percentage of occurrence and numerical statistics, and area calculations in a user-defined surface area on a reformatted slice. It also determines boundaries around the class of similar pixel intensity values in this area.

4.1 Create a Curved view

Use this procedure to display a reformat of a curved, complex view of tortuous vessels or organs. The curved view does not need to lie along a single orthogonal or oblique plane but can follow anatomical lines.

1. Open *Reformat*.
2. In one of the viewports, right-click on the view type active annotation and select [Curved].
3. On an axial, sagittal, or coronal image, press and hold <Shift> as you deposit points along the anatomy.
4. As you trace, the curved image updates automatically in the curved reformat viewport.

4.2 Create an X Section Histogram view

A histogram graph shows the percentage of occurrence of each voxel value, either in a user-defined surface area on a reformatted slice (cross-section histogram) or in the entire 3D object (volume histogram). It also determines boundaries around the class of similar voxel intensities.

1. Open *Reformat*.

2. In one of the viewports, right-click on the view type active annotation and select Histogram or X Section.
   - If you select a view type of histogram, you will immediately view a volume histogram which includes the entire 3D model. No other action is required. Place the cursor on the voxel reference line and hold <Shift>. The image displays the range of voxel class boundary lines by highlighting them in green.
   - If you select a view type of X Section, the view will display *Undefined* histogram until you start to define the trace.
   - Both the volume and cross-section histograms contain the same information with the exception of the name and measurement units. Cross-section histograms show total area, while volume histograms show the total volume for the entire object without cut planes.
3. For a cross-section (X Section) histogram, in the viewport containing the anatomy of interest, press <Shift> and simultaneously click the image to deposit points on the area of interest to create a trace.

NOTE: The histogram values and statistics are those of the current 3D model, not those of the original exam. If the 3D model contains only a given range of voxel values, only voxels within that range will appear in the histograms. Statistics and computed values of surface area or volume displayed on the histograms are subject to the same accuracy limitations as other on-view measurements. This tool can be used for cross-section and volume measurements of specific anatomic features if the feature to be measured can be clearly defined by a range (class) of voxel values.

4.3 Create an MPVR view

Use this procedure to create an Multi-Projection Volume Reformation (MPVR) view. This type of thick slab reformatted image is often used to see vessels in Computed Tomography Angiography (CTA) scans.

1. Open *Reformat*.
2. Click the red annotation in the upper-left corner of the viewport and select 3D or MIP render mode. The selections available are dependent on the view type.

   MIP is used most often in CTA models to demonstrate the most intense voxels.
3. Click the [Oblique Mode] icon .
4. Click and drag the yellow line on the image.
5. Place the cursor over the red thickness annotation to do one the following options.
   - Type the desired thickness and press <Enter>.
   - Middle-click and drag to the desired thickness.

4.4 Create a Profile view

A profile graph shows the voxel value along a 3D trace (profile). This allows you to analyze the voxel value distribution of a 3D object in various ways, as an aid in setting up 3D processing (e.g., thresholding).

1. Open *Reformat*.
2. Select the *Profile Layout* preset, if available.
3. In one of the viewports, right-click the view type active annotation and select Profile.
4. On an axial, sagittal, or coronal image, press and hold <Shift> as you deposit points along the anatomy.

   As you trace, the profile view displays the pixel intensity along the trace.
5. On the profile view:
   - The horizontal axis is the position in millimeters along the trace and the vertical axis is the pixel intensity values as a function of that position.
   - Press <Shift> to display the pixel intensity from the location of the 3D cursor. Click and drag the white line to move it, which in turn, moves the cursor on the image.
   - View the displayed statistics.

5 Volume Render

Volume Rendering uses the concept of Opacity. For different density levels, each voxel transmits a certain amount of light, which is reflected on the following voxel, and only the residual light reaches the following layer. The resulting image is the total sum of the reflection from each layer of tissue through which the light has passed. The effect of using Volume Rendering on a dataset is that it makes highly opaque objects more visible and at the same time it makes less opaque objects more transparent.

Illustration 12: Opacity curve: Ramp up (A), Lower threshold (B), Upper threshold (C)

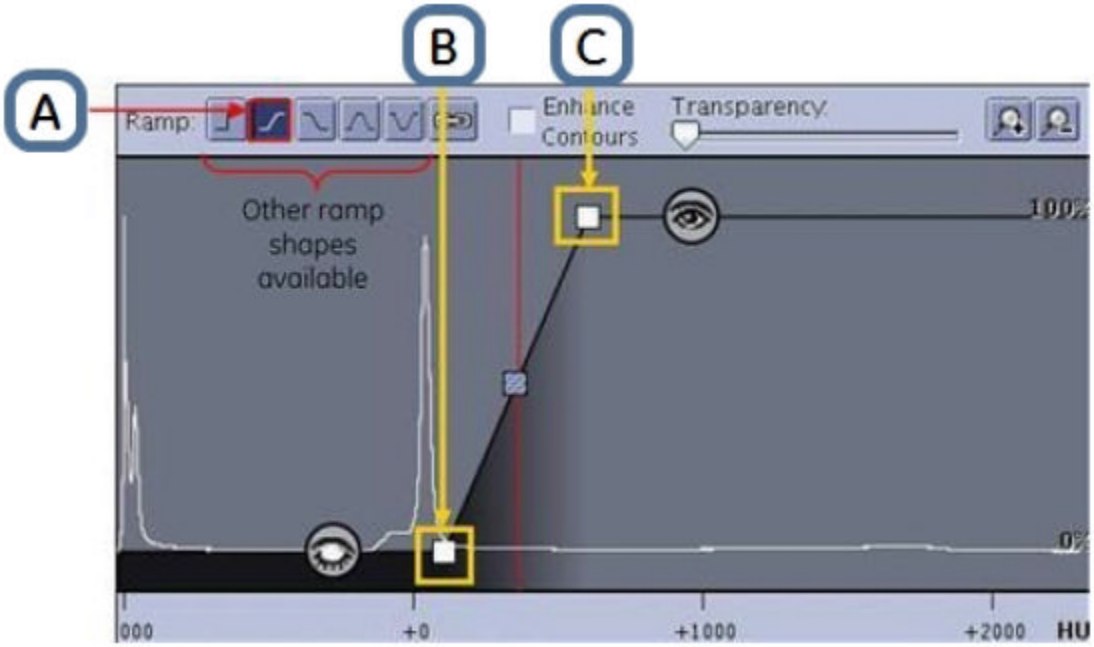


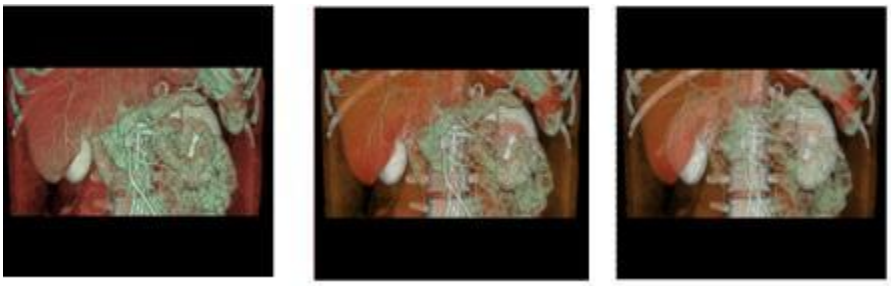
Illustration 13: Left = Structures presenting density value associated with high opacity reflect light: they are visible. Right: = Structures presenting density value associated with low opacity transmit light: they are translucent.

5.1 Up ramp VR adjustments

- To decrease background noise, increase the value of the lower threshold.
- To increase visualization of soft tissues structures, decrease the value of the lower threshold.
- Max opacity can be reduced: structures become more translucent.

Threshold Values constant: (50 to 800); Opacity values are changed.

Illustration 14: Opacity Values: Left = 100%; Middle = 50%; Right = 25%



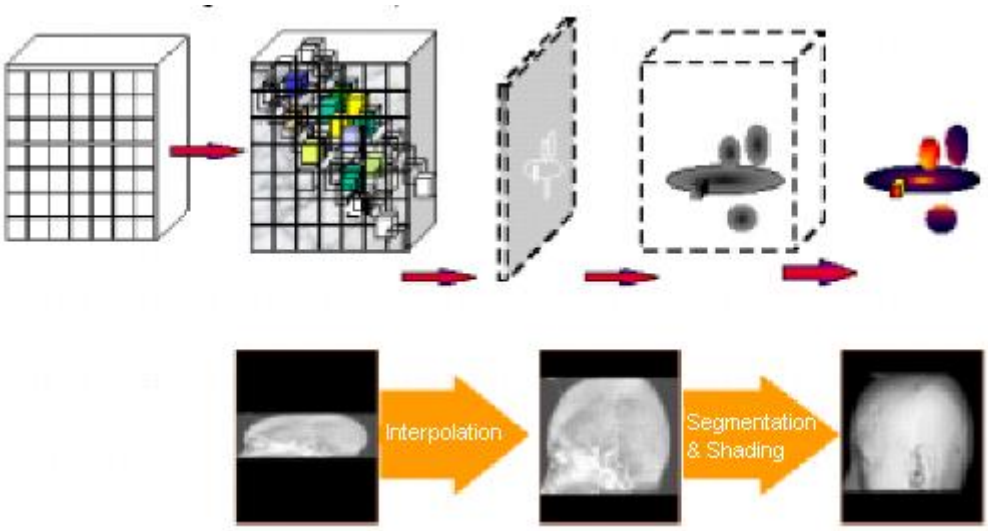
Opacity Values constant: (100); Threshold values are changed.

Illustration 15: Threshold Values from left to right: (-200 Low Threshold); (-100 Low Threshold); (0 Low Threshold); (50 Low Threshold); (100 Low Threshold)

5.2 Surface rendering

Surface Rendering is similar to Volume Rendering except that it first separates the Volume of Interest (VOI) from the original data set and then it creates the rendered image.

Illustration 16: Surface Rendering



5.3 Render modes

The Render modes consist of Volume Rendering, HD MIP, MIP, Min IP, Ray Sum, and Integral.

Table 12: Render modes

Mode	Function
Volume Rendering	Exists only if the model was built using volume mode and is used to display the surface of a model.
HD MIP	Displays the model using the High Definition Maximum Intensity Projection mode. The mode is identical to the MIP mode as described below, except that image definition is greater but the system speed is slower.
Weighted MIP	Displays MIP rendering enhancing front voxels and fading voxels in the back.
MIP	Displays the model using the Maximum Intensity Projection mode. In this mode, the density of each point on the screen is the maximum density along a line perpendicular to the screen.
Min IP	Displays the model using the Minimum Intensity Pixel mode. In this mode, the density of each point on the screen in the minimum density along a line perpendicular to the screen.
Ray Sum	Displays the model by summing the model's intensity along lines perpendicular to the screen. This mode simulates conventional radiography images.
Integral	Displays only the surface of the model, but the density of each surface point is equal to the sum of densities along a shallow depth below the displayed surface point.

5.4 VR Presets screen

From *Reformat*, click the *VR* tab and *VR Presets* to display the VR Presets screen.

Illustration 17: VR Presets screen

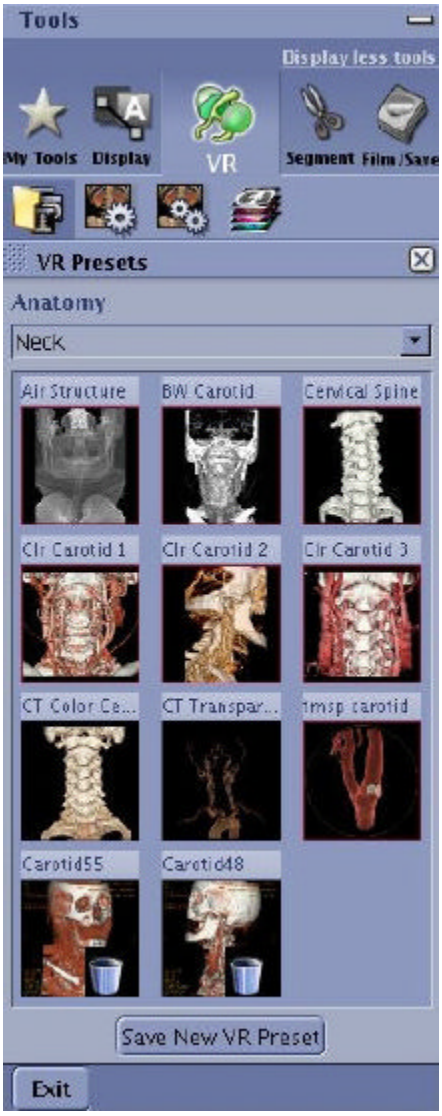


Table 13: VR Presets selections

Function Name	Description
VR Preset icons	The VR presets are provided for each anatomical category. When selected, the VR preset applies to the active VR view (red border).
Save New VR Preset	Saves the current settings as a new VR preset.
Trash icon 	Deletes a user defined VR preset.

5.5 VR Settings screen

From the desktop, click the *VR* tab and *VR Settings*.

Illustration 18: VR Settings screen

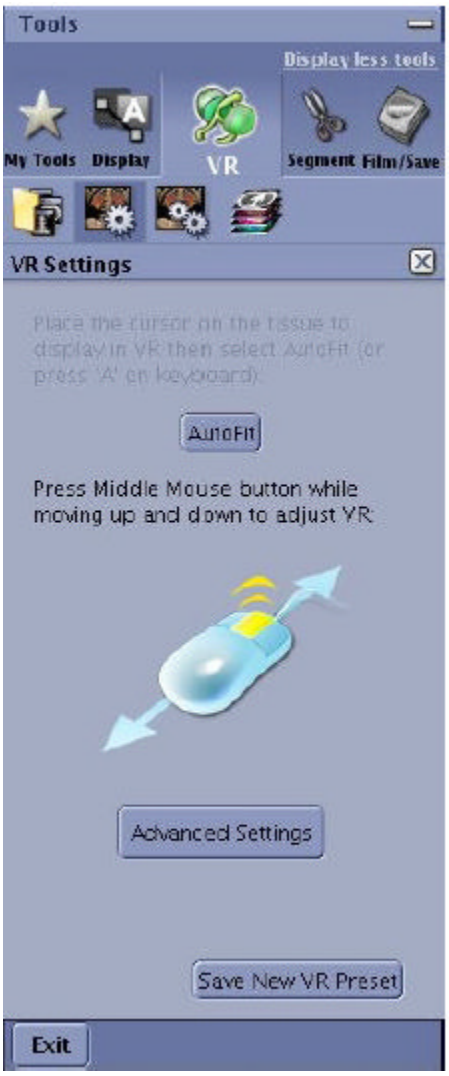


Illustration 19: Advanced VR Settings screen

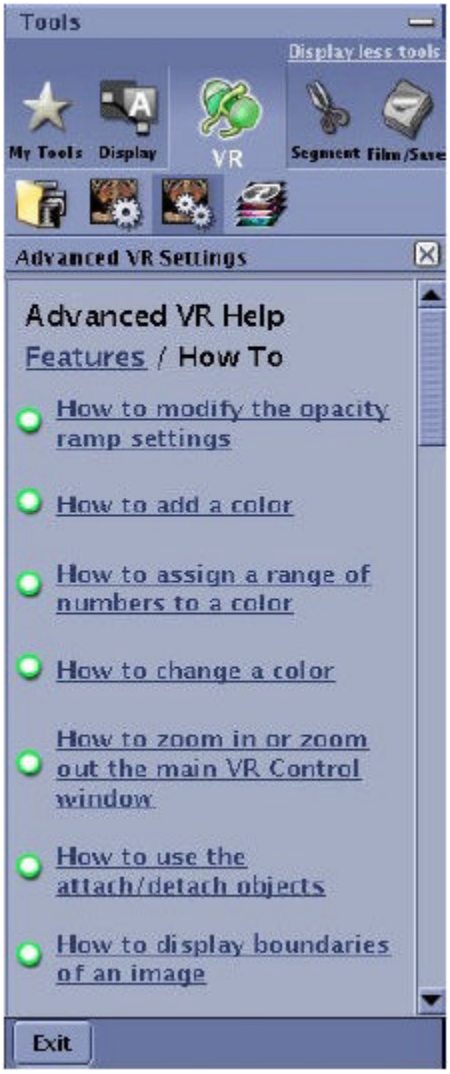


Table 14: VR Settings selections

Function Name	Description
Auto Fit	Automatically fits VR parameters to display the structure under the 3D cursor.
Advanced Settings	Displays the advanced VR settings screen, which provides Volume Render help topics.
Save New VR Preset	Saves the current settings as a new VR preset.

5.6 VR Controls screen

From the desktop, click the *VR* tab and *Advanced VR Settings* to display the *VR Controls* screen.

Illustration 20: VR Controls screen

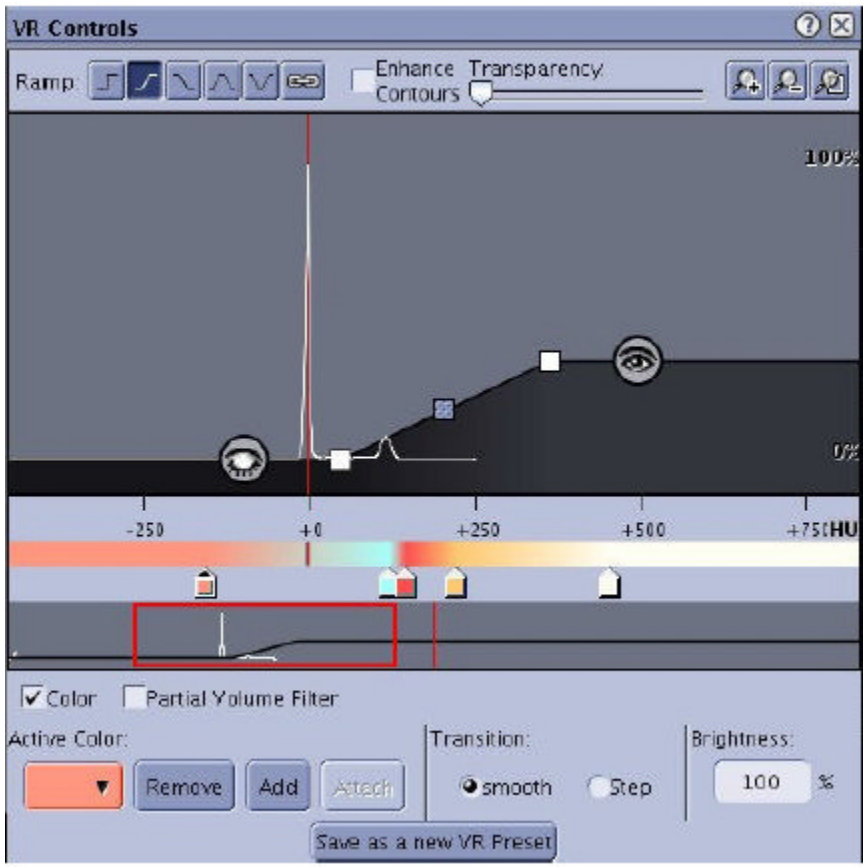


Table 15: ROI selections

Function Name	Description
Ramp	Defines the opacity curve shape. • *Step:* surface type rendering displaying structures with high voxel values. • *Ramp-up:* displays structures with high values typically vessels and bone. • *Ramp-down:* displays structure with low values typically airways. • *Plateau:* displays structures within a given range. • *Valley:* use with cut plane to create endo-luminal view. • *Attach mode:* used to apply multiple plateau ramps attaching colors to ranges of voxel values.
Enhance Contours	Enhances boundaries of structures. This is useful to display vessels or orthopedic cases.
Transparency	Makes internal objects transparent and makes objects boundaries more visible.
Zoom	Zoom in or out to modify the range of voxel values displayed.
Histogram	Displays the voxel distribution (number of voxels per voxel value) in the image. Peaks correspond to voxel values that are highly represented in the image.
Vertical Red Line	Represents the numerical value of the voxel at the location of the 3D cursor. Moving the 3D cursor on the image will change the location of the red line.

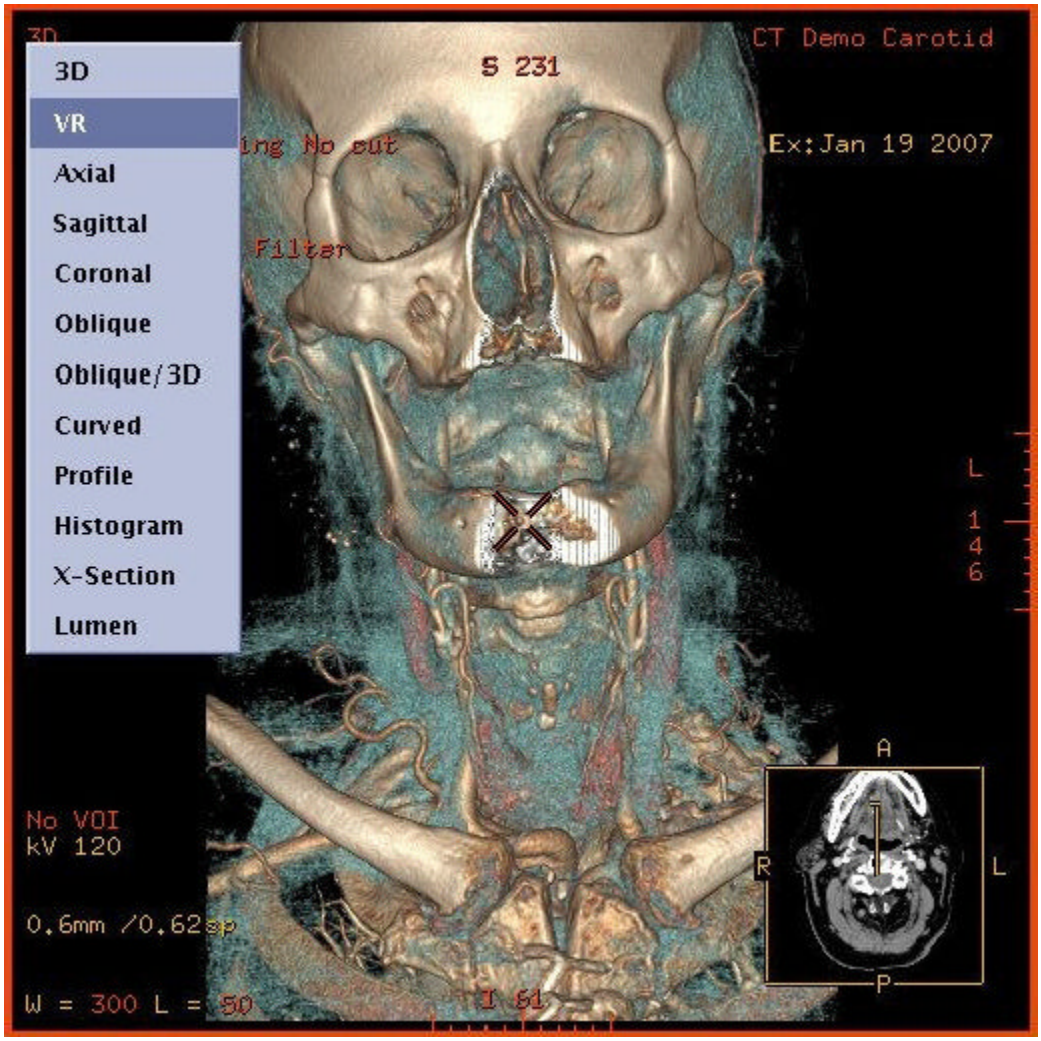
Function Name	Description
White box	Represents the Opacity Threshold values. When using Ramp-up shape: • Drag the lower white box to the right to remove soft tissue from an exam to modify the maximum opacity of voxels. • Click the upper white box at the top of the ramp and drag up or down to modify the opacity of all visible voxels.
Blue Box	Allows you to shift the whole ramp. Click and drag the solid blue box on the ramp to change the upper and lower values of the ramp.
Red Box	Represents the scale of voxel values. Click and drag the box left or right to shift the display. • Zoom in or out with the Zoom icons upper-right corner. • Right-click the main control to return to the original zoom.
VR Ramp	Represents the voxel opacity in the VR images as a function of the voxel values. It means that voxels with identical value will have the same opacity.
Color	Activates the color. An unchecked box displays the VR in black and white.
Partial Volume Filter	Attenuates the partial volume by associating partial volume voxels with adjacent voxels that represent the more opaque object. It improves the visibility of structures that would otherwise be hidden by partial volume voxels and improves the color coding of voxels in color mode.
Active Color	Use to select the active color. Click the square color button below the ramp (the triangle above the color gets black). Click Active Color to change the color.
Transition	• Smooth: shaded transition from one color to the next. • Step: all voxels inside the value range display the same color. When Step is selected small white diamonds indicating range borders display. Click the diamonds to adjust precisely range of values that are assigned to each color.
Brightness	The amount of light displayed in the model. Type in a value greater than 100 to increase the light in the model.

5.7 Display a VR image

Use these steps to display a Volume Render image and the VR tab on the Tools screen.

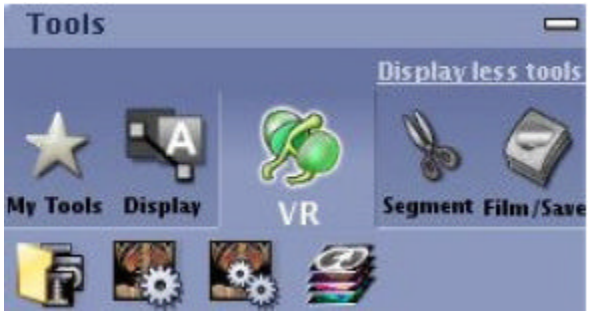
1. Open *Reformat*.
2. Right-click the View Type active annotation and select *VR*.

Illustration 21: View Type active annotation



3. From the Tools section, click the *VR* tab.

Illustration 22: Reformat Tools: VR tab



5.8 Attach/detach objects

1. Display a VR image.

2. Click the [Advanced VR Settings] icon  .

   Read the Advanced VR Help on the tab for more information.

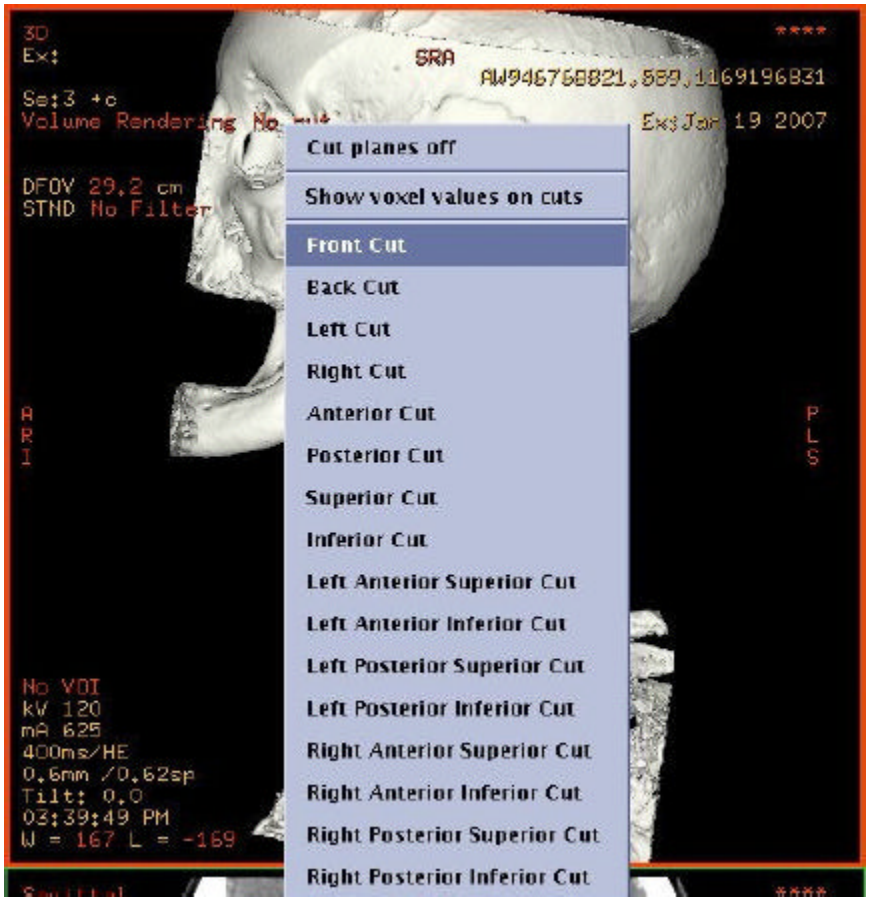
3. From the VR Controls screen Active Color area, select an active color.
4. From the Ramp area, click the [Attach Mode] icon 
5. From the Active Color area, click [Attach].
6. Click and drag the colored box at the top of the ramp to adjust the opacity of the colored voxels.
7. Repeat the steps to attach additional colors.

5.9 Cut planes

When structures of interest are hidden on a 3D or VR view, use cut planes to display them prominently.

1. Display a VR image.
2. On a reformatted image, move the 3D cursor to the location of where you want the cut plane reference point.
3. Right-click the *No Cut* active annotation and select a plane to cut the 3D view.
4. Rotate the view to 3D view to display structures of interest in cut area.
5. Select Cut planes off to deactivate.

Illustration 23: Cut planes menu on 3D VR view



5.10 Work with colors

Use the following procedures to apply colors to your images.

1. Display a VR image.
2. From the Tools section, click the [Advanced VR Settings] icon
3. View the VR Controls screen.

Illustration 24: Advanced VR Settings screen

5.10.1 Add colors

1. Place the 3D cursor on the anatomy of interest.
2. From the Active Color area, click [Add].

5.10.2 Assign a range of colors

1. Select *Color*.
2. From the *Transition* area, select [Step].
3. Click and drag the colored boxes to adjust the colors to the desired value.

5.10.3 Change a color

1. Select *Color*.
2. From the Active Color menu, select a color or click *More Colors* to display the color wheel.
3. Optional: On the color wheel, click and drag the circle to the desired color.
4. Click [Done].

5.11 Autofit

Use this procedure to refine the VR opacity in an image.

1. Display a VR image.
2. From the VR tab, click the [VR Settings] icon 
3. Place the 3D cursor on the anatomy of interest in any multi-planar view.
4. From the VR Settings panel, click [AutoFit] or press <A>.
5. Middle-click and drag the mouse up and down to refine the VR opacity.
6. Click [Save New VR Preset] to save the setting as a new VR preset.

Illustration 25: AutoFit on a vessel (top); AutoFit on the trachea (bottom)

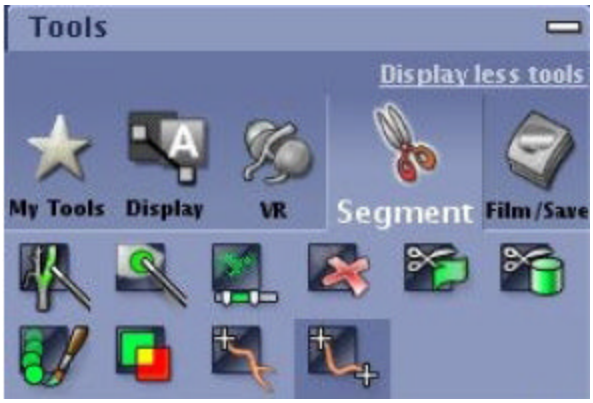
Autofit on a vessel (top). Autofit on the trachea (bottom).

5.12 Create a multi-VR object

You can merge multiple objects into a multiple VR model into a single view or model to perform more complex VR views with multiple object segmentation and visualization.

1. Open *Reformat*.
2. From the Tools section, click the *Segment* tab.

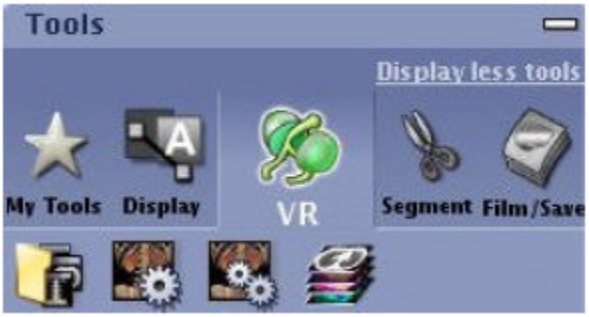
Illustration 26: Segment tab



3. Click the [Auto Select] icon  .
4. Select the desired structure.
   - **Small Vessels** - segments vessels below a 5 mm diameter.
   - **Any Structure** - segments vessels greater than a 5 mm diameter and soft tissues growing from a seed point.
   - **Bones** - segments bony structures growing from a seed point.
5. Click [Add].
6. Click [Yes] to clear the upper-left viewport.
7. From any 2D view, click and hold on the object you want to add.

   A green filter will fill the object while this object is being reconstructed in the upper-left viewport.
8. In a viewport, right-click and select *Mouse Modes* > *Left Mouse: Selection*.
9. Drag the VR viewport and drop it on the viewport of the isolated object where the message, *Drop here to reassign views* displays.
10. From the Tools section, click the *VR* tab.

Illustration 27: VR tab



11. From the VR tab, click the [Multi Objects] icon  .
12. On the Multi-Object panel, hover over the objects.

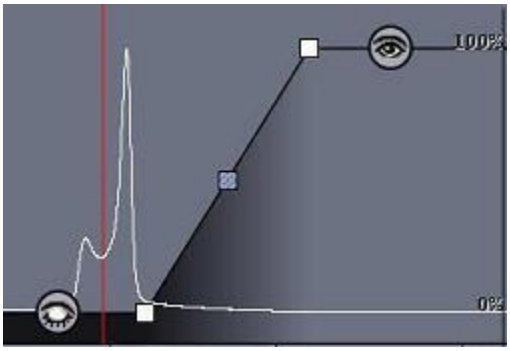
    The corresponding object appears in the left window.
13. Select an object to adjust its transparency.
14. Click the [Eye] icon to hide or show the corresponding object on the active viewport.

5.13 Modify the opacity ramp

1. Display a VR image.
2. From the VR tab, click the [Advanced VR Settings] icon 

   Read the Advanced VR Help for more information.
3. From the VR Controls screen, perform any of the following functions in the Transparency area to modify the opacity ramp.
   - Click and drag the white boxes left or right to independently modify the upper or lower range of the ramp.
   - Click and drag the lower white box to the right to remove soft tissue or noise from an image.
   - Click and drag the white box at the top up or down to modify the overall opacity of the rang. This affects the opacity of all visible voxels.
   - Click and drag the blue box left or right to change the upper and lower values applied to the ramp.

Illustration 28: VR Controls: Transparency area



5.14 Zoom in/out

1. Display a VR image.
2. From the VR tab, click the [Advanced VR Settings] icon 

   Read the Advanced VR Help for more information.
3. From the VR Controls screen, click and drag the red box in the lower window (which represents the scale of voxel values displayed) left or right to shift the display.
4. Click a Zoom icon to zoom in and out of the image.
   -  Zoom In
   -  Zoom Out
   -  Zoom Display - Displays a red mask for you to define a range of interest.
5. Right-click to return to the original histogram range.

6 Segment

To display a specific feature within the image, you can define what part of the exam data should be visible, and what part should not. The main Segment tools include:

- *Threshold:* To extract a region of interest by selecting a range of voxel values that represents a specific tissue or anatomical feature.
- *Scalpel:* To perform cuts in the 3D volume to define the region of interest.
- *Paint:* To mark the region of interest with colored paint and then display only this region.
- *Auto Select:* To select an object and add it on or remove it from the selected view.

The process of removing structures is sometimes referred to as *volume segmentation* because the 3D volume is segmented, or split, in two parts: the volume of interest that is currently displayed, and the remainder that is removed from view.

After volume segmentation, the displayed part of the 3D model consists of one or more 3D objects. A 3D object is a part of the 3D model that is separate from other parts. Two 3D objects are separate if there is at least one voxel width of empty space between them.

Sometimes two seemingly separate objects still act as one, because they are still connected somewhere by a bridge of voxels. It is also possible that a seemingly single object turns out to consist of two or more parts, separated by narrow gaps. The tools on the *Advanced Processing* screen can help you to deal with these effects.

6.1 Segment tab

The *Segment* tab contains *Advanced Processing* tools used to refine segmented objects or combine them using Boolean operations. Before using the tools, perform an initial segmentation with any of the Segment tools.

When a tool is clicked, a control panel for that tool displays.

Illustration 29: Segment tab

Table 16: Segment selections

Function Name	Description
Auto Select 	Allows you to select an object and add or remove it from the selected view.
Auto Contour 	Click the center of the structure or use the click and drag method to define a diameter. Adjust contour if needed. Accept and Measure. Click Auto Contour icon again to initiate a new contour.
Threshold 	Opens a screen from which you extract a region of interest by selecting a range of voxel values that represents a specific tissue or anatomical feature.
Remove Object 	Opens a screen from which you remove or keep isolated objects or display removed structures.
Scalpel 	Cut outside or inside region - Opens a screen from which you cut the 3D volume, split an object into separate object, define a volume of interest or remove part of the 3D volume.
Paint on Slices 	Opens a screen from which you trace contours on the baseline (axial, sagittal and coronal) views, to outline and mark the region of interest on the slices that intersect the region.
Quick Paint 	Quick Paint Opens a screen from which you paint with an adjustable sphere-shaped cursor on reformatted slices to define the volume of interest.
Advanced Processing 	Opens the Advanced Processing screen that consolidates many advanced segmenting processes.
One Click AVA 	The One Click AVA button is activated with VesselIQ Xpress licenses and allows vessel tracking in one click.
Two Click AVA 	The Two Click AVA button is activated with VesselIQ Xpress licenses and allows vessel tracking in two clicks.

6.2 Scalpel control panel

From the *Segment* tab, click the [Scalpel] icon  to display the Scalpel control panel.

Illustration 30: Scalpel control panel

Table 17: Scalpel selections

Function Name	Description
Cut Inside	Click and drag around the object of interest and then click the appropriate button to either cut inside or outside the trace. The trace may appear either red or green.
Cut Outside	Saves the current settings as a new VR preset.
Cut On Trace	Applies the cut along the trace.
Clear	Clears the latest trace.
Cut Depth	Allows changing the Scalpel from a restricted depth defined by the text field or an Infinite depth.
Undo	Undoes the last operation performed. If the view on which the last operation was performed is changed, the possibility of undoing the last operation is permanently lost.
Keep Object	Keeps all the voxels that are attached to the object of interest under the cursor.

6.3 Advanced Processing panel

From *Reformat*, click the *Segment* tab and then click [Advanced Processing]. Advance Processing consolidates many processes: dilate, erode, filters, subtraction methods, close gaps/open bridges, close holds, and extract surface.

Illustration 31: Advanced Processing panel

Table 18: Advanced Processing selections

Function Name	Description
Size in Voxels	Determines the number of layers you want to add or remove. Change the value by using the slider or by typing in a value.
Dilate	Add one or more layers (20 maximum) of voxels to the surface of the current 3D objects. This feature can restore voxels that were removed by operations like thresholding, erosion, or opening bridges.
Erode	Removes one or more layers (20 maximum) of voxels from the surface of the current 3D objects.

Close Gaps	Fills in the gaps and connects the adjacent features. Adjacent features in the 3D volume that appear to consist of a single object may be composed of more than one 3D object when you try to use *Keep Object* or *Remove Object*. This can be caused by the presence of narrow gaps, often only a few voxels in size, that separate the features. This mostly occurs when using thresholding to define a feature of interest, when the threshold setting is marginal. You can try to modify the threshold setting or alternatively use *Close Gaps* to fill in the gaps and connect the adjacent features. You set the size in voxels of the gaps you want filled in. This function resembles the *Dilate* function, but only gaps up to the specified size are filled in; the rest of the objects are not dilated. This function consists of performing a dilation followed by an erosion. Since erosion does not totally remove the voxels added by dilation, some small gaps or holes are filled in. A closing size of N is obtained by N dilations followed by N erosions. This means that small gaps or holes having one of their X, Y, or Z dimensions less than 2N are filled in. For example, a closing size of 3 is obtained by three dilations followed by three erosions. This means that small gaps having one of their three dimensions less than six are filled in. *Open Bridges* describes the opposite function.
Open Bridges	Removes residual bridges and separates adjacent features in the 3D volume. You set the size in voxels of the bridges you want removed. This function resembles the Erode function, but only the bridges up to the specified size are eroded. This function consists of an erosion followed by a dilation. Since dilation does not totally restore the voxels removed by erosion, some fine structures remain eroded. An opening size of N is obtained by N erosions followed by N dilations. Fine structures having one of their X, Y, or Z dimensions less than 2N are removed. For example, an opening size of 3 is obtained by three erosions followed by three dilations. Fine structures having one of their three dimensions less than six are removed. *Close Gaps* describes the opposite function.
Close Holes	Resets any such inner holes to the original voxel values. When using thresholding, this can result in holes appearing inside the 3D volume (i.e., closed spaces inside the 3D volume where the voxel value is outside the selected range). By default, the voxel value inside such inner holes will be set to the same value as the outside of the 3D volume (empty space). If you have used the *Scalpel* or *Paint* tools to remove part of the 3D model, any holes enclosed within the 3D volume resulting from these operations will also be re-filled when you use this feature.
Extract Surface	Removes all data from the inside of the current 3D objects, leaving only the surface. Since the inside of the objects no longer contain any data, little if any further processing is possible. Use this function to speed up the display after you have fully defined your region or objects of interest; e.g., during rotation or batch filming, or to modify 3D shading. Enter a surface thickness of at least 2 to guarantee connectivity information for any further operations such as selecting or removing objects. With a value of 1, the result appears visually correct, but the surface is too thin to be considered as one or more coherent objects.
Intersection	Intersection keeps only the voxels that exist in the same location in both objects. The values of the resulting voxels are those of the original object in the primary view.
Set Addition	*Set Addition* keeps all the voxels that exist in either of the objects. If a voxel belongs to both objects, its value in the primary view is kept. Use *Set Addition* to combine structures obtained using different processing tools. For example, you may need different tools and settings to process a vessel from the left side of the patient and another vessel from the right side. By treating the two vessels separately and storing the results in the *Save/Recall* panel, you can optimize the processing for each side. *Set Addition* keeps all the voxels that exist in either of the objects. If a voxel belongs to both objects, its value in the primary view is kept. Use *Set Addition* to combine structures obtained using different processing tools. For example, you may need different tools and settings to process a vessel from the left side of the patient and another vessel from the right side. By treating the two vessels separately and storing the results in the Save/Recall panel, you can optimize the processing for each side. After recalling both from the *Save/Recall* panel in two separate views, the set addition operation allows you to join and display them as a single object.

Set Subtraction	*Set Subtraction* removes all the voxels in the primary view that also exist in the secondary view. In other words, the secondary view is subtracted from the primary view. Using a set operation on the data from two 3D models results in a single object (3D model). As an example, you can start by using thresholding to select the entire hip bone structure and store the result in the *Save/Recall* panel. Next, isolate and select only the femur (using paint or scalpel) and store the result separately. Subtracting the femur from the complete bone structure may now allow you to see the extent of a hip bone fracture that was obscured by the femur. This is different from the merge operations, which allow you to display more than one 3D model at the same time and show their spatial relation by means of cut planes and different levels of transparency. Merge operations are strictly a display feature; they do not combine the separate 3D models.
Filter Floaters	*Filter Floaters* allow you to remove small residual objects in the 3D model that can appear after thresholding, usually resulting from noise in the original image set.
Undo	*Undo* becomes active after you have performed an action.
Keep Object	Place the cursor over pixels representing the pixel intensities you want to keep. *Keep Object* keeps all pixels with the selected intensity; all other pixels are discarded.

6.4 Combine segmented objects

Use this procedure to combine 3D segmented objects together.

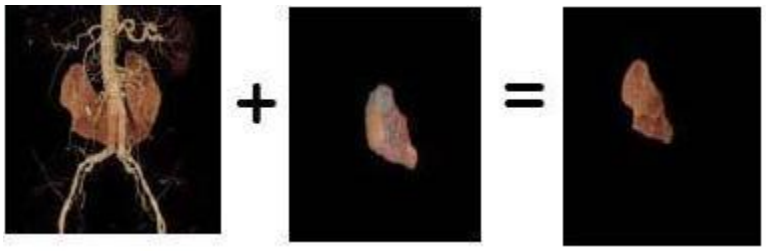
1. Open *Reformat*.
2. Select and view the images to be used for combining objects.

   All objects must originate from the same master volume.
3. From the Tools section, click the *Segment* tab.
4. Perform segmentation to generate objects to combine using any segmentation technique (*Threshold, Auto Select, Paint*, etc.).
5. Display objects to combine in separate views.
6. In a viewport, right-click and select *Mouse Modes > Left Mouse: Selection*.
7. Double-click to isolate first view of interest.
8. Single-click to isolate second view of interest.
   - Views of interest display red and green borders. Other views should not have color borders.
   - To adjust red and green borders, click the view to set red, the other view will turn green.
9. Select an operation (results of the operation display in the red views).
10. Click the [Advanced Processing] icon.
11. From the Advanced Processing panel, perform one of the following functions.
    - Click the [Subtraction] icon  to remove all the voxels in the primary view that also exist in the secondary view.

      Before subtracting, make sure the borders of the view are displayed as: Red - Green = Red.

- Click the [Intersection] icon  to keep only the voxels that exist in the same location in both objects.

- Click the [Addition] icon  to keep all the voxels that exist in either of the objects.



6.5 Paint On Slices

Use this procedure to draw contours of the structure of interest on different slices. The volume to keep will be interpolated based of the defined contours.

1. Open *Reformat*.
2. From the Tools section, click the *Segment* tab.
3. From the Segment panel, click the [Paint On Slices] icon  .
4. Move the 3D cursor to the edge of the feature of interest.
5. Optional: Click [Edge Attraction] to automatically refine the drawn contours, adjusting them to nearby structure edges.
6. Press <Shift> and click to deposit the cursor.
7. Click and drag the 3D cursor to define the area.

   When the mouse button is released, the first and last points connect.

8. Move to the next slice on which you want to paint.
   - It is not necessary to define contours on every slice.
   - The contours interpolates to the intermediate slices.
9. Repeat the process until your reach the last slice containing the structure to contour.
10. Click [Apply].

6.6 Add/Remove anatomy with Auto Select

Use this procedure to automatically remove anatomy from reformatted images.

1. Open *Reformat*.
2. From the Tools section, click the *Segment* tab.
3. From the Segment panel, click the [Auto Select] icon  .
4. Select a tool for segmenting.
   - Click [Small vessel] for vessels less than 5 mm. Click once to fill and track vessel.
   - Click Any Structure for vessels greater than 5 mm or soft tissue. Click and hold until area of interest is filled.
   - Click [Bones] to segment bones.
   - Click [Pick from VR].
5. Click [Add] or [Remove] depending on the desired outcome.
6. Scroll through the axial images at minimum slice thickness.

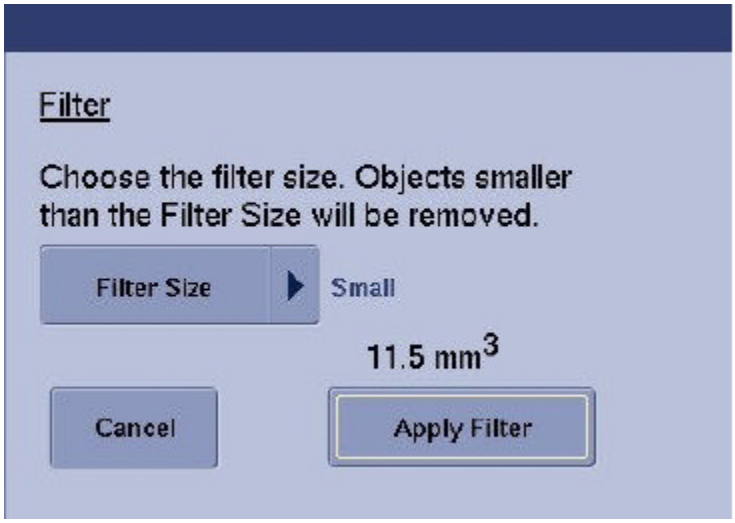
   If any vessels are contoured in green, put the cursor on the missing vessel in the 2D view and click and hold until the area of interest is filled.
7. Repeat steps to complete all missing vessels.

6.7 Remove floaters

Filter Floaters removes small residual objects in the 3D model that can appear after thresholding, usually resulting from noise in the original image set.

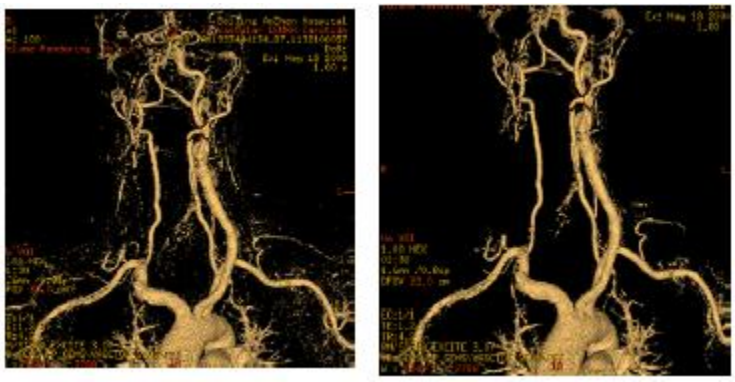
1. Open *Reformat*.
2. Perform a segmentation.
3. From the Tools section, click the *Segment* tab.
4. From the Segment panel, click the [Advanced Processing] icon. 
5. Click the view of interest and click [Filter Floaters].

Illustration 32: Filter screen



6. From the Filter screen, click [Filter Size] and select a filter size.
   - Small
   - Medium
   - Large
   - Custom
7. Click [Apply Filter] to remove objects smaller than the filter size.

Illustration 33: Left = no filter; Right = filter applied



6.8 Threshold an image

Use this procedure to threshold the image and keep only voxels within a specified range of value.

1. Open *Reformat*.
2. From the Tools section, click the *Segment* tab.

3. From the Segment tab, click the [Threshold] icon  .
4. Select the desired image from which you want to threshold.
5. From the Threshold panel, use one of the following methods to adjust the threshold range of voxel values.
   - Click and drag the Min. and Max. Threshold sliders.
   - Type a minimum and maximum value in the Min. and Max. fields.
   - Click [Bone] or [Air] to apply preset threshold values.
6. Click [Apply Threshold] to display only the part of the 3D volume with voxel values inside the set range.
7. To further refine segmentation, select the object on the viewport and choose to remove or keep the object.
   - Click [Remove Object] to remove all voxels connected to the object.
   - Click [Keep Object] to remove all objects not connected to the object.

7 Batch Film

The Batch function allows you to rapidly set up a set of regularly spaced images, preview the set as an animated sequence (batch loop) and film and save it.

7.1 Batch types

A batch can be one of the following types:

- *Parallel oblique batch:* a series of parallel oblique slices along a common center line
- *Radial oblique batch:* a series of oblique slices generated radially around a common axis
- *3D batch:* a series of 3D images obtained by rotating a 3D object around an axis
- *Batch loop:* a series of 3D images obtained by rotating a 3D object in a continuous mode

  A batch loop allows you to rotate the 3D model, to adjust the display speed and to stop it in any position. You can select the number of views making up the loop, the FOV to use, etc. A batch image set can be viewed step-by-step or as a batch loop. It can be filmed, and/or saved on the image disk as a new series in the exam. To set up a batch you typically start with a batch protocol. A default batch protocol is provided for each of the three types of batches. You can use these as a starting point for your own custom batch protocols which you can save and re-use.

7.2 Batch protocol

To set up a batch you typically start with a batch protocol. A default batch protocol is provided for each of the three types of batches. You can use these as a starting point for your own custom batch protocols which you can save and re-use.

A batch protocol defines:

- Batch mode: oblique or rotation.
- Number of views and spacing between views (mm or degrees).
- Spacing between views.
- Display field of view.
- Slice thickness (and render mode for thick slices).
- Output mode: this can be preview only, film, archive, film + archive, filmer images or filmer movies. If you select film mode, you can also define the film layout.

When creating and saving your own custom batch protocol, you have two options:

- Add it to the list of existing batch protocols for the current loading/processing protocol.
- Combine it with the current loading/processing protocol to create a new loading/processing protocol. Create a custom multiple-batch protocol by combing two or more batch protocol setups.

7.3 Preview, film, or save a batch

Once you have defined the batch, you can:

- Preview the resulting batch as an animated sequence (batch loop). The controls allow you to set the display rate (frames per second), to pause and restart the sequence, and to move through the set step-by-step.
- Film the batch, i.e., send image set to a hardcopy device such as a laser camera. The format (image layout on the film) is defined in the batch protocol or can be selected in the *Modify Batch* panel.
- Save the batch on the image disk of the workstation. A new series is created in the current exam and can be used later for viewing and/or processing.

7.4 Film/Save tab

The *Film/Save* tab contains the following selections.

Illustration 34: Film/Save tab

Function Name	Description
Batch	Creates rotation, loop or oblique batch images based on your prescription.
Movie	Creates a comprehensive movie including different rotations, zoom and pan of the volume.
QTVR	Not applicable in reformat.
Quick Export	Exports in a single click a batch of rotations of a 3D view or a full batch of contiguous images for 2D images. **NOTE:** Video Export does not work on the Operators Console.
Save Image	Saves selected image with user-selected format.
Save State	Saves current status of Volume Viewer (3D Model, displays, ROIs) as an additional series of the exam. A One-Touch protocol entitled *Save State* will appear in the *Application* field providing the ability to restore Volume Viewer State.
Save/Recall	Opens a clipboard where you can drag and drop objects for temporary storage within the current Volume Viewer session.
Film/Save options	Opens a clipboard where to drag and drop objects to store temporarily within current Volume Viewer session.

7.5 Batch screen

Click the *Film/Save* tab and then click [Batch] to display the *Batch* screen.

Illustration 35: Batch screen — Loop tab

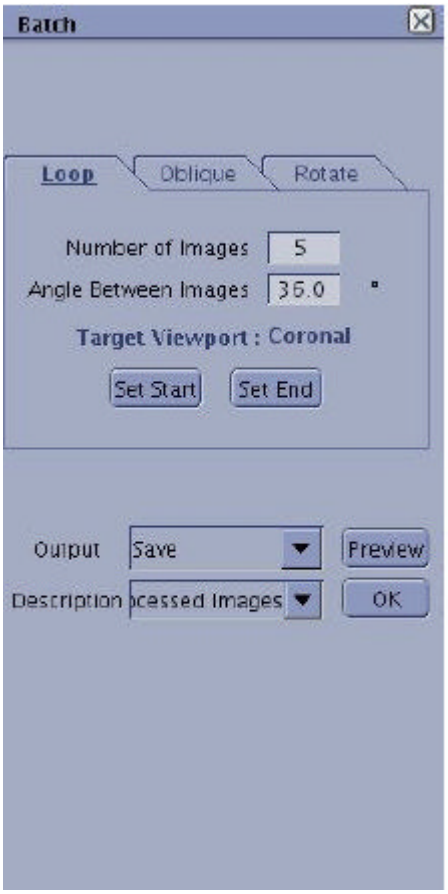


Illustration 36: Batch screen — Oblique tab

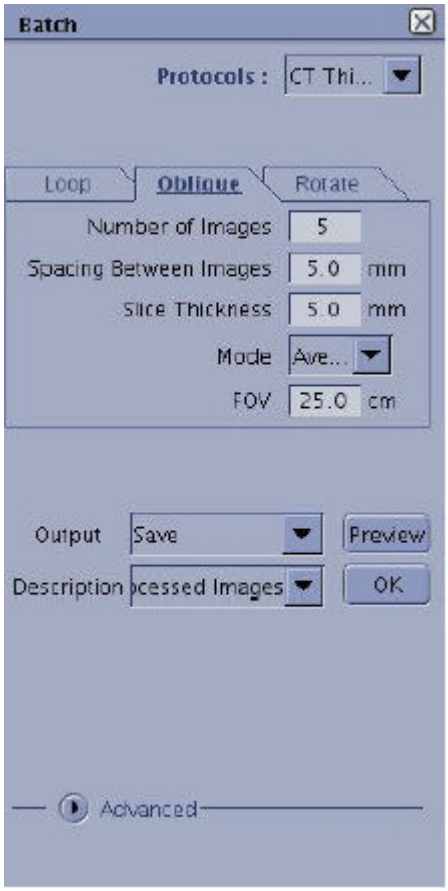
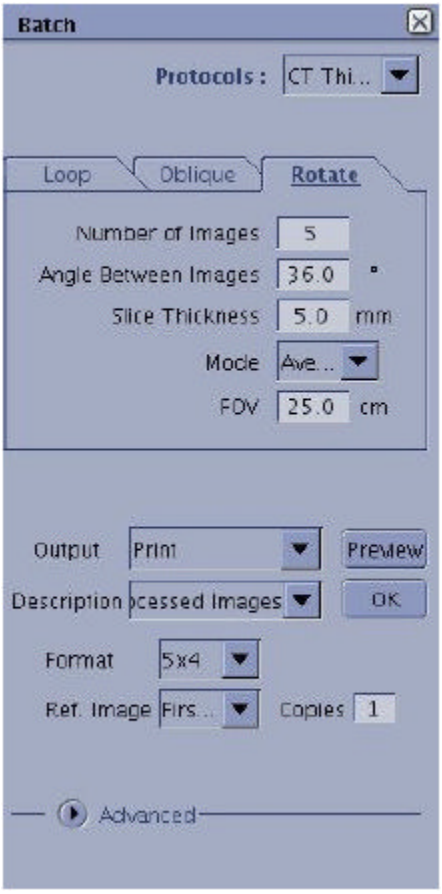


Illustration 37: Batch screen — Rotate tab

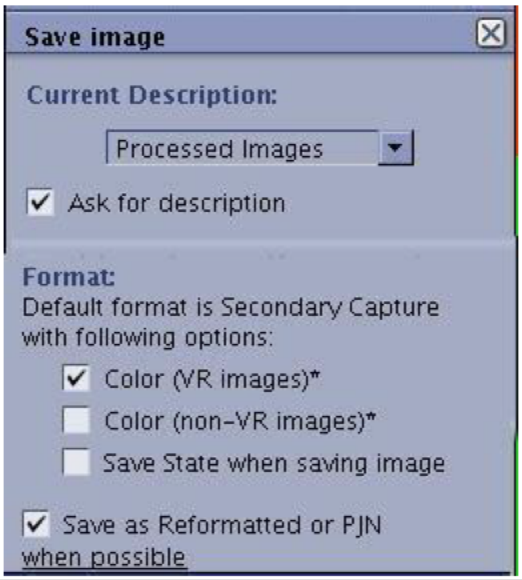


Function Name	Description
Prescription mode	• *Oblique* displays a set of lines to define the reformat planes. • *Rotation* defines projection planes. The defined planes rotate 180°. • *Loop* defines the first and last slices of your projection planes that can be set to any degree of rotation. The displayed values are those of the current protocol and can be modified. The text fields change depending on the mode you select (oblique, rotation or loop).
Copies	Appears only if *Print* or *Print & Save* are selected as an Output mode. Enter a value in the text field.
Output Modes	• Print allows filming of the projection images and makes the [Format] and [Reference Image] buttons available. Select a film format and select the film that you want the reference image to appear on. • Save creates a new series in the browser. The series type is determined from the *Film/Save Options* screen. Note that if *Color Save* has been turned on from the *Film/Save Options* screen, the projections will be saved as SSAVE images even if Rfmt is selected as the image type. Screen saves cannot be filtered or measured. • Filmer Images drops all generated images into the filmer (AW only). • Print/Save allows for both filming the generated images and saving a new series to the browser. • Filmer Movie drops the generated images in the filmer as a movie to be exported as mpeg or avi image type.

Format	Appears only if Print or Print & Save are selected as an Output mode. The Format menu allows you to make a format selection.
Reference Image	Appears if Print or Print & Save are selected as an Output mode. Select which film you want the reference image to appear on: the first film, all films, or no film. The reference image is the first image of a rotation that has the following items displayed on it: number of views, rotation degrees, and the direction arrows icon.
Preview	Displays the planes in a movie prior to filming or saving the images.
OK	Saves and previews the images simultaneously. If Save or Print & Save is the selected as output mode, a new series is created in the Patient List.
Advanced	Lets you add a new batch step for oblique or rotation. Click the arrow button and set the parameters as desired.

7.6 Save Image screen

Illustration 38: Save Image screen

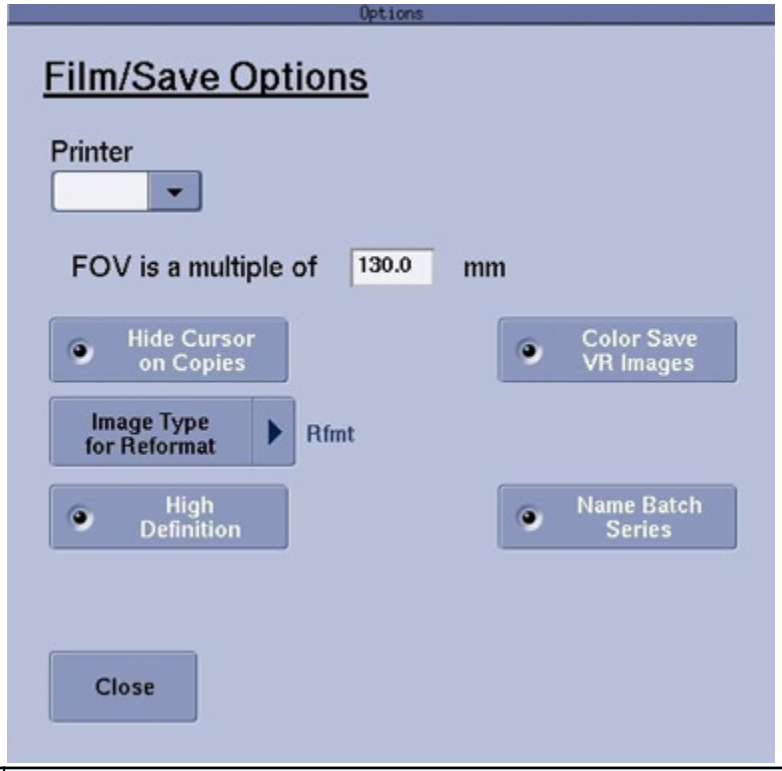


Element	Description
Current Description	Choose either an existing description from the drop-down box, or be prompted to enter a new description before saving. Each new description gets stored in the drop-down box.
Format	• *Format Color (VR images)* saves the image as a volume rendered color image. Leave it unchecked to save it as black and white. • *Color (non-VR images)* saves the images as color. Window Level and Width of color images cannot be modified. • *Save State* saves current status of Volume Viewer (3D Model, displays, ROIs) at the same time as saving the image. This Saved State can be used later on to restore Volume Viewer State. • *Save a Reformatted or PJN when possible* saves the image as a reformatted or screen save image whenever possible. • Reformatted and projection images can be used for further measurements and loading. Saving as reformatted is possible for axial, sagittal, coronal, oblique images and thick slabs except for volume rendering and X-ray or nuclear med images. • Color and Save state options are not compatible with Reformatted DICOM format and cannot apply to images saved as Reformatted. Uncheck this option to benefit from Color and Save State capabilities.

7.7 Film/Save Options screen

Click the *Film/Save* tab and then click [Film/Save Options] to display the *Film/Save Options* screen.

Illustration 39: Film/Save Options screen



Function Name	Description
Select Printer	Printer options are displayed in the menu. Note that the camera selected from this menu can be different from the camera selected from the Film Composer.
Current Batch Description	Allows you to a Patient List series description name for the saved series. Select *Ask for description when...*
FOV is a multiple of	Enter a multiple by which the FOV is changed when clicking on the red DFOV annotation. For example, if the FOV is set to 130, the FOV is adjusted as a multiple of 130 – 6.5 mm/13 mm/26 mm. It is not possible to set the DFOV higher than the acquired FOV or lower than a DFOV of 8 mm.
Format	• [Color Save (non-VR Images)] - saves non-Volume Rendered images in color. • [Color Save (VR Images)] - saves Volume Rendered images in color. • [Hide Cursor on Copies] - hides or shows the cursor on the saved or filmed image. • [High Definition] - films images along the Z direction in high definition.

Image Type for Reformat	When saving reformatted images, you can select the image type. The image type determines functions that can be performed on the image and how the annotations are stored. SCPT: • Allows W/L adjustments of saved images. • Saves only annotation (system or user entered) that is currently visible on the view. These annotations are part of the image: they can no longer be edited or deleted. Reformatted: • Allows W/L adjustments, measurements, and filtering of saved images. • Automatically saves all system annotations with the view, even if they are hidden at the moment that you save the image. However, the user annotations (text and measurements) are saved only if they are shown at the moment that you save the image.

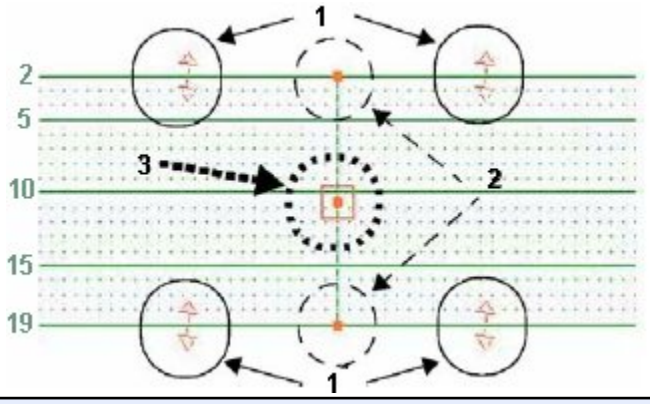
7.8 Set up a batch oblique

Use Batch Oblique to define a set of oblique planes adjusting settings (range, angle, position) from a grid on a reference image.

1. Open *Reformat*.
2. From the Tools section, select the *Film/Save* tab.
3. From the Film/Save tab, click the [Batch] icon.
4. From the Batch panel, click the view to be used as the reference image.
5. Click the *Oblique* tab to display a grid used to define the oblique planes.
6. Type a value for the Number of Images, Spacing Between Images, Slice Thickness, Mode (Average, MIP, MIN, VR), and FOV.
7. Select the desired output mode from the menu.
   - Choose Print to send generated images to the default printer (setup the Format and the display of a Reference Image).
   - Choose Save to save generated images in a new series in the browser.
   - Choose Print/Save to film the generated images from a default printer and save them in a new series.
8. Click [OK].

   The Spacing between views and slice thickness can be set independently of each other creating a gap, contiguous or overlapped images.

Illustration 40: Oblique tool



Number	Description
1	Add slice handle
2	Tilt handle
3	Move handle

7.9 Batch film images

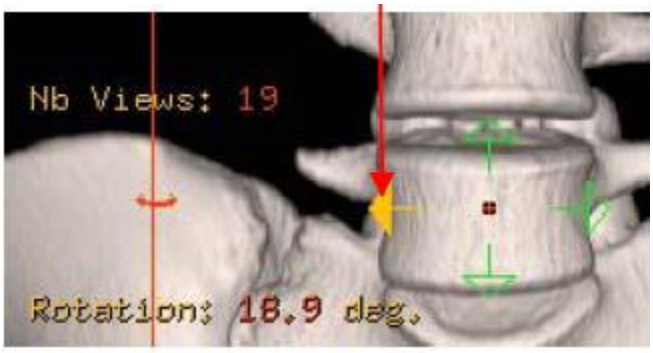
Use this procedure to set up a batch rotation of images to film/save.

1. Open *Reformat*.
2. From the Tools section, click the *Film/Save* tab.
3. From the Film/Save tab, click the [Batch] icon.
4. From the Batch panel, click the [Rotate] tab.

7.9.1 Rotate 360° 3D images

1. Click the appropriate arrow to indicate rotation direction.

Illustration 41: Rotation direction



2. Type in the number of images or angle between images in the appropriate field.

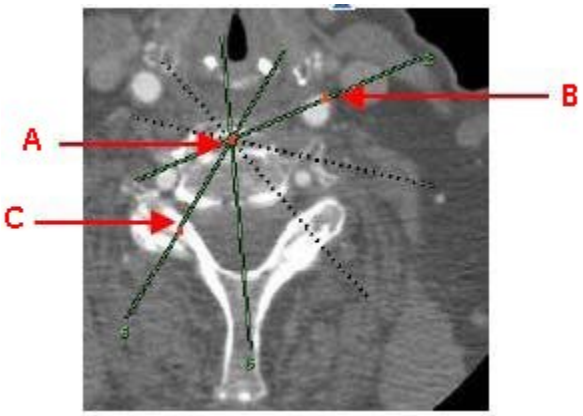
   Modifying one of these parameters updates the other.
3. Type in the *FOV*.

4. Select the desired output mode from the menu.
   - Choose Print to send generated images to the default printer (setup the Format and the display of a Reference Image).
   - Choose Save to save generated images in a new series in the browser.
   - Choose Print/Save to film the generated images from a default printer and save them in a new series.
5. Click [OK].

7.9.2 Radial planes on 2D views

1. From the Protocols menu, select *Fan*.
2. Adjust the center of radial slices (A), first radial plane location (B), and the number of radial planes (C) on the 2D reference image.

Illustration 42: Radial prescription



3. Enter the Number of Images, Spacing between Images, Slice Thickness, Rendering Mode, and FOV.
4. Select the desired output mode from the menu.
   - Choose Print to send generated images to the default printer (setup the Format and the display of a Reference Image).
   - Choose Save to save generated images in a new series in the browser.
   - Choose Print/Save to film the generated images from a default printer and save them in a new series.
5. Click [OK].

7.10 Save a curved parallel plane or rotating curve batch

Use this procedure to set up a Loop batch for a curved parallel plane or rotating curved batch.

1. Open *Reformat*.
2. From the Tools section, click the *Film/Save* tab.

3. From the Film/Save tab, click the [Batch] icon.
4. From the Batch panel, click the [Loop] tab.
5. Prescribe one of the following.
    - For a curved parallel plane batch:
        - Scroll to the first image to be saved and click [Set Start].
        - Scroll to the last image to be saved and click [Set End].
    - For a rotating curved batch:
        - Adjust the angle of the first image from the Angle active annotation on the curved viewport and click [Set Start].
        - Set the angle of the last image and click [Set End].
6. Type the number of images to be saved.
7. Press <Enter>.
8. To save the new series, set Output to Save.
9. Click [OK].

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Chapter 17 Data Management

1 Overview

The *File Manager* allows you to manage your acquired images. This section contains information on how to save, restore, delete, and network images using the File Manager. It also includes procedures on how to make an anonymous patient and edit patient data.

The File Manager has four sections:

- A *Controls Area*, which allows you to select databases, search databases, and access functions that you can use on exams.
- The *Exam List*, which shows the exams in the selected database. Status information for exams is also provided here.
- The *Series List*, which shows the series and image information for the exams selected in the Exam List. Status information for series and images is provided here.
- A *navigation viewport*, which shows images you select from the Series List.

2 File Manager

To open File Manager to access browser applications, follow the steps below. This procedure uses Image Viewer and Floating Viewport as an example.

File Manager is always accessible on the right monitor.

On the right (display) monitor, click the File Manager “drawer”. (You do not have to click the File Manager icon – just click the drawer that is labeled with the [File Manager] icon .

Illustration 1: Opening File Manager

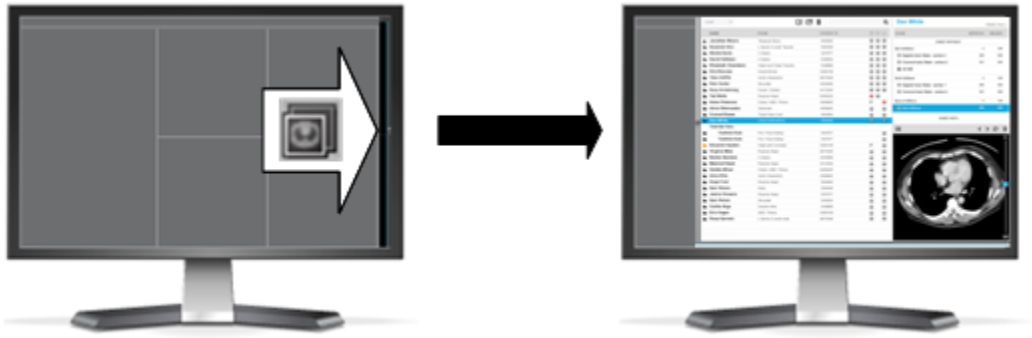


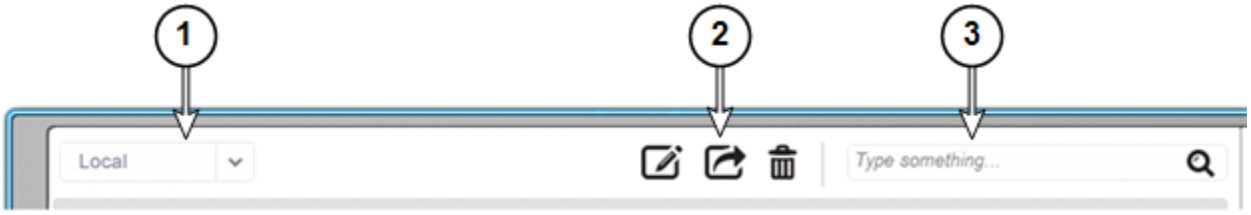
Illustration 2: Sections of the File Manager Drawer

1	Controls area	**3**	Series list
2	Exam list	**4**	Image display/Image list

2.1 Controls area

The controls area of the File Manager has a set of controls that allow you to change the source database, search the database, and launch applications.

Illustration 3: Controls area of the File Manager



1	Source menu – select the database you are using	**3**	Search box – typing a string of characters in this box will search for that string in any of the search-able fields of the source database
2	Applications – this configurable area gives you shortcuts to launching applications		

2.1.1 Source Menu

The Source menu controls the contents of the Patient List and displays the host database or archive to which you are currently connected. The default source list is the Local data base of your scanner.

2.1.2 Search box

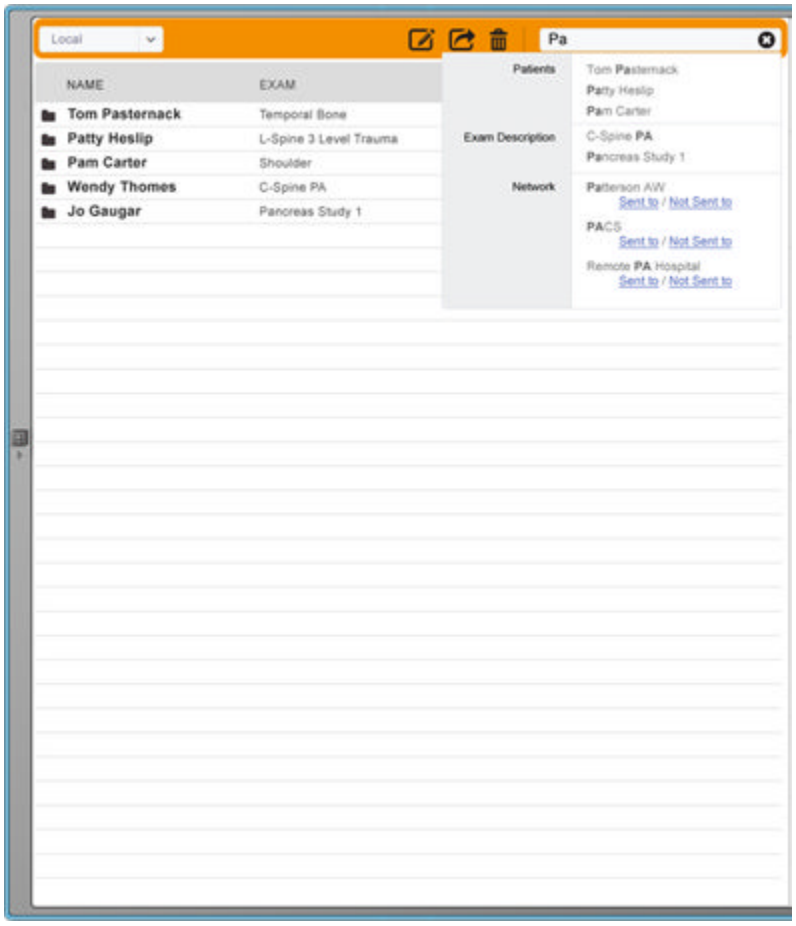
To help you find an exam, you can type a character string to find into the search box.

When you type a character string into the search box, the system searches:

- patient names (in any part of the name)
- patient IDs
- exam IDs
- exam description
- network locations

Search results appear in the exam list. The exam list changes color to indicate that you are looking at a filtered list.

Illustration 4: Filtered exam list



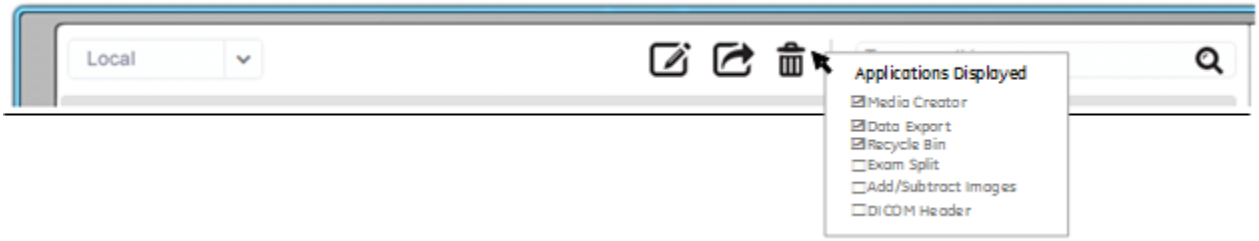
To remove the filter, click the [Close] icon in the search box. The filter is also removed if you close the File Manager, or if you choose a different source database.

2.1.3 Application icons

The controls area has a configurable set of application icons. The applications available depend on the options purchased for your system. Additionally, if your system has been configured to have a Recycle Bin, the Recycle Bin icon is available for display.

To change the icons that are displayed in the control area, right-click in the control area and select the icons you want to display. Up to seven icons can be displayed.

Illustration 5: Control area icon selection



2.1.4 Recycle Bin

If your system has been configured to have a Recycle Bin, you can display the Recycle Bin icon in the control area.

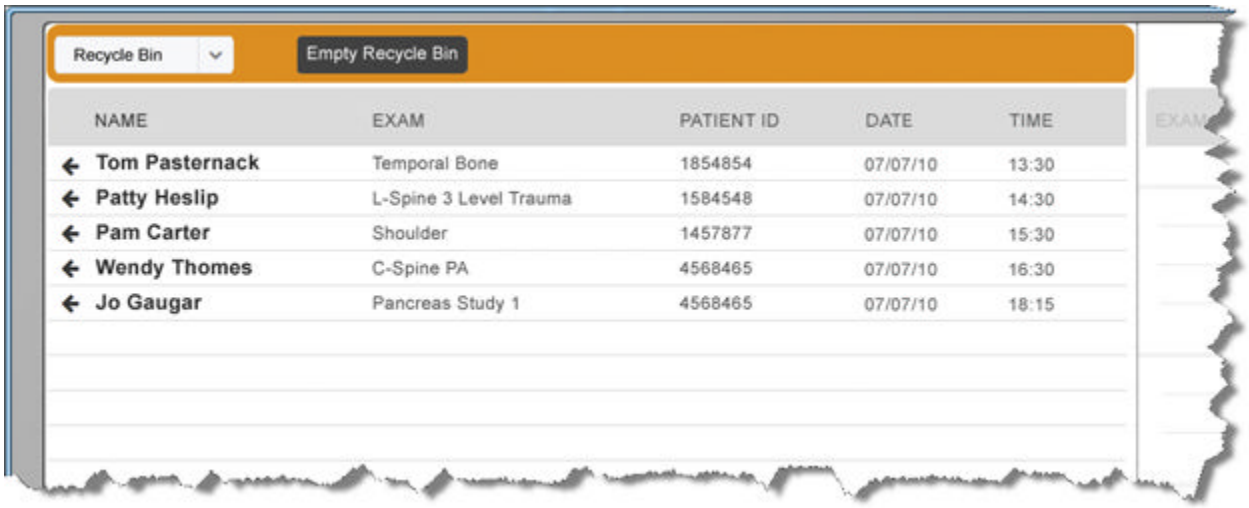
The Recycle Bin icon indicates how full the Recycle Bin is.

Table 1: Recycle Bin status icons

This Recycle Bin icon:					
Indicates:	The Recycle Bin is between 0% and 12% full	The Recycle Bin is between 13% and 37% full	The Recycle Bin is between 38% and 62% full	The Recycle Bin is between 63% and 88% full	The Recycle Bin is between 89% and 100% full

To see the contents of the Recycle Bin, click the [Recycle Bin] icon.

Illustration 6: Recycle Bin

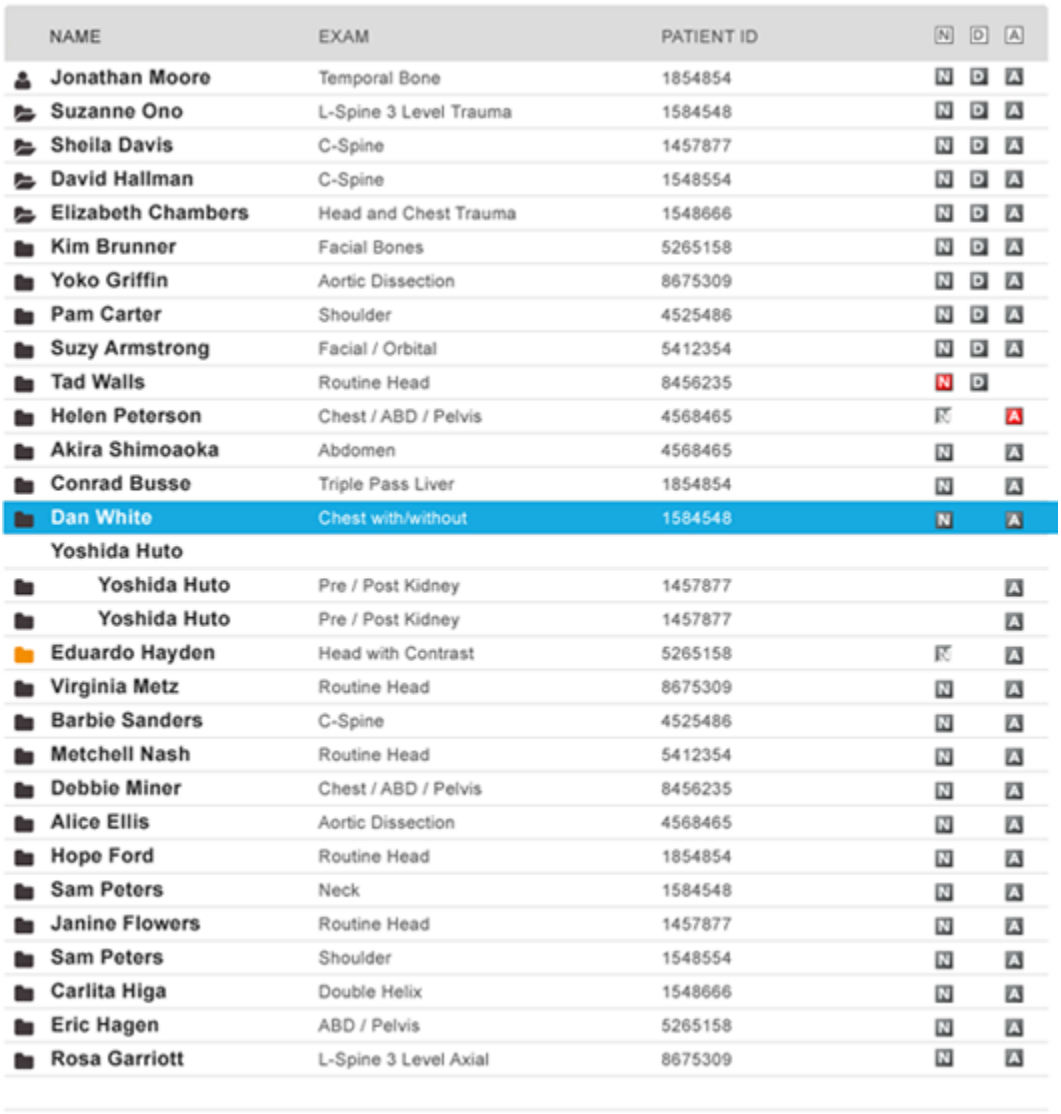


To perform this action:	Do this:
Restore an exam from the Recycle Bin	Right-click the exam and then click [Restore]
Delete an exam from the Recycle Bin	Right-click the exam and then click [Delete]
Delete all exams from the Recycle Bin	Click [Empty Recycle Bin]

2.2 Exam list

The exam list shows the exams stored in the source database.

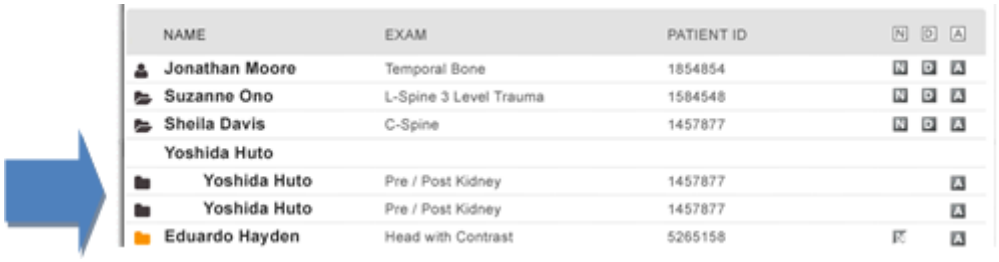
Illustration 7: Exam list



NAME	EXAM	PATIENT ID	N	D	A
Jonathan Moore	Temporal Bone	1854854	N	D	A
Suzanne Ono	L-Spine 3 Level Trauma	1584548	N	D	A
Sheila Davis	C-Spine	1457877	N	D	A
David Hallman	C-Spine	1548554	N	D	A
Elizabeth Chambers	Head and Chest Trauma	1548666	N	D	A
Kim Brunner	Facial Bones	5265158	N	D	A
Yoko Griffin	Aortic Dissection	8675309	N	D	A
Pam Carter	Shoulder	4525486	N	D	A
Suzy Armstrong	Facial / Orbital	5412354	N	D	A
Tad Walls	Routine Head	8456235	N	D	
Helen Peterson	Chest / ABD / Pelvis	4568465			A
Akira Shimoaoka	Abdomen	4568465	N		A
Conrad Busse	Triple Pass Liver	1854854	N		A
Dan White	Chest with/without	1584548	N		A
Yoshida Huto					
Yoshida Huto	Pre / Post Kidney	1457877			A
Yoshida Huto	Pre / Post Kidney	1457877			A
Eduardo Hayden	Head with Contrast	5265158			A
Virginia Metz	Routine Head	8675309	N		A
Barbie Sanders	C-Spine	4525486	N		A
Metchell Nash	Routine Head	5412354	N		A
Debbie Miner	Chest / ABD / Pelvis	8456235	N		A
Alice Ellis	Aortic Dissection	4568465	N		A
Hope Ford	Routine Head	1854854	N		A
Sam Peters	Neck	1584548	N		A
Janine Flowers	Routine Head	1457877	N		A
Sam Peters	Shoulder	1548554	N		A
Carlita Higa	Double Helix	1548666	N		A
Eric Hagen	ABD / Pelvis	5265158	N		A
Rosa Garriott	L-Spine 3 Level Axial	8675309	N		A

When there are multiple exams for the same patient, the exams are shown under the patient's name as shown in the following illustration.

Illustration 8: Exam list – multiple exams for same patient



NAME	EXAM	PATIENT ID	N	D	A
Jonathan Moore	Temporal Bone	1854854	N	D	A
Suzanne Ono	L-Spine 3 Level Trauma	1584548	N	D	A
Sheila Davis	C-Spine	1457877	N	D	A
Yoshida Huto					
Yoshida Huto	Pre / Post Kidney	1457877			A
Yoshida Huto	Pre / Post Kidney	1457877			A
Eduardo Hayden	Head with Contrast	5265158			A

2.2.1 Columns in the Exam list

By default, the following columns are displayed:

- Exam tab status
- Patient name (in the format configured for the system) (last name, first name or first name last name).
- Exam description
- Patient ID
- Scan data available flag
- Exam networked flag
- Exam archived flag
- Examination date

You can configure the Exam list to display these additional columns:

- Exam ID
- Accession number
- Referring physician
- Examination time
- Patient name in ideographic form (certain locations only)
- Filmed flag
- PPS flag – this flag is displayed if PPS commands have been sent (available only at sites where PPS has been configured)

See Section 2.4 for information about configuring, arranging, and resizing the columns displayed in the Exam list.

2.2.1.1 Exam status column

The first column of the Exam list shows icons representing the status of exams.

Table 2: Exam list status icons

This icon:	Indicates:
	The exam is for the patient currently on the table. To bring the exam tab to the front, click the icon or double-click the exam.
	The exam is open in a tab, but the patient is not on the table. (For example, the patient scan is complete and the patient is no longer on the table, but you are performing image processing tasks.) To bring the exam tab to the front, click the icon or double-click the exam.

This icon:	Indicates:
	The exam is closed. To open the exam, click the icon or double-click the exam. The tab will show the scan task list and the dose report, and the current state of image processing. No images will be displayed.
	Image processing is not completed, but the tab for the exam is closed. If the exam was aborted before image processing was complete, you can reopen the exam and continue with image processing.
	Image processing had an error and the tab for the exam is closed. You can reopen the exam and fix the error.
	The exam is being pulled from a remote network host, a DVD, or USB media.
	Pulling the exam from a remote host failed. Click this icon to open the network queue manager.

2.2.1.2 Raw Data column

The Raw Data column indicates whether scan data is still available on the console for the exam, allowing additional reconstructions to take place. If the data is available, the Raw Scan Data icon  is shown in the Raw data column.

NOTE: The icon changes depending on the language used in the user interface.

2.2.1.3 Network Status icons

The Network Status column shows the network state of exams.

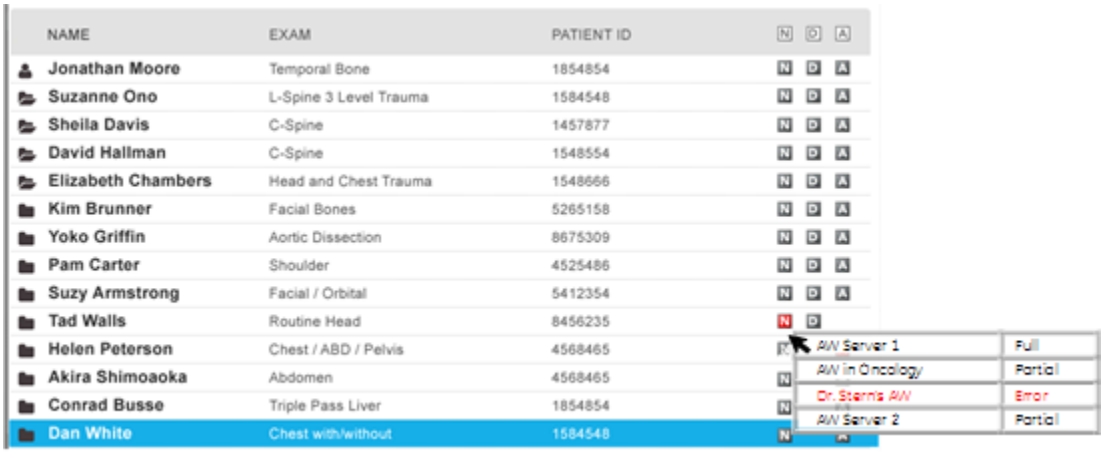
Table 3: Network Status icons

This icon:	Indicates:
No icon	The exam has not been networked.
	All series in the exam have been networked.
	A network transfer is in progress for the exam.
	There was an error when attempting to network the exam. The icon will display if there is an error in transferring to any network location. Click the icon to open the network queue manager.
	The exam has been partially networked. (One or more series in the exam have been networked.)

NOTE: The icons change depending on the language used in the user interface.

Hovering over a network status icon displays a pop-up list showing the destinations to which the exam was networked. The list is limited to 10 destinations.

Illustration 9: Network destinations pop-up list



Destinations to which there has been a network error are shown in red.

For partially networked exams, see the network status flags in the Series list for information about where the series in the exams are networked.

2.2.1.4 Archive Status icons

The Archive Status column shows the archive state of exams.

Table 4: Archive Status icons

This icon:	Indicates:
No icon	The exam has not been archived.
	An archive is in progress for the exam.
	All series in the exam have been archived.
	The exam has been partially archived. (One or more series in the exam have been archived.)
	There was an error while attempting to archive the exam. If the archive is a network archive, click the icon to open the network queue manager.

NOTE: The icons change depending on the language used in the user interface.

2.2.1.5 PPS column

If the PPS column is displayed, the PPS icon  appears when PPS is completed for an exam.

2.2.1.6 Filmed Status icons

The Filmed Status column shows if exams have been filmed.

Table 5: Filmed Status icons

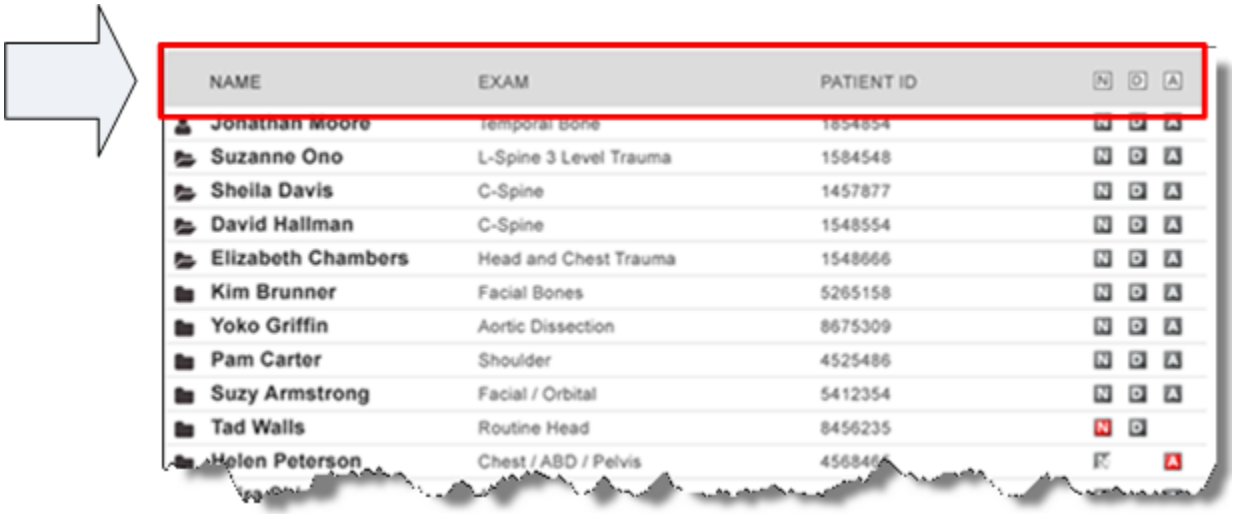
This icon:	Indicates:
No icon	The exam has not been filmed.
	All series in the exam have been filmed.
	The exam has been partially filmed. (One or more series in the exam have been filmed.)
	There was an error while attempting to film the exam. Click the icon to display the film queue manager.

NOTE: The icons change depending on the language used in the user interface.

2.2.2 Sorting the Exam List

You can sort the Exam List by any displayed column. Click a column heading to sort the list by that column.

Illustration 10: Exam list column headings



2.2.3 Deleting exams

To delete an exam, right-click the exam in the Exam List and then click [Delete Exam]. Alternately, you can select the exam and then press the <Delete> key.

The system asks you to confirm that you want to delete the exam.

You can delete more than one exam at a time. Shift-click exams to select a contiguous list of exams, or Control-click to select exams one-by-one.

When you delete an exam, the system checks to see if the Recycle Bin is full (if the Recycle Bin is configured on the system). If the Recycle Bin has enough space, deleted exams are moved to the Recycle Bin.

If there is not enough space in the Recycle Bin to hold the deleted exams, the system warns you that the exams will be permanently deleted and asks you to confirm that you want to delete the exams.

If the system does not have a Recycle Bin configured, the system warns you that the exams will be permanently deleted and asks you to confirm that you want to delete the exams.

NOTE: There are some conditions that prevent you from deleting exams:

- The exam is for the patient on the table
- The exam is open in a tab
- The exam has open processing
- Networking or archiving for the exam is in process

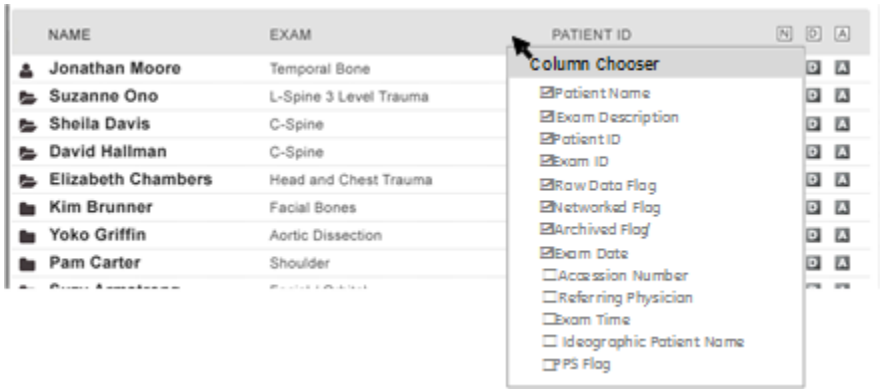
If you try to delete an exam that has any of the above conditions, the system displays a message informing you why the exam cannot be deleted.

2.2.4 Configuring the Exam List

2.2.4.1 Choosing which columns to display

You can change which columns are displayed in the Exam List. Right-click on any column heading (except the Network column), and select the columns you want to display from the pop-up list.

Illustration 11: Exam List – choosing columns to display



2.2.4.2 Changing the width of columns

To change the width of columns in the Exam List, click and drag the right edge of the column heading.

NOTE: You cannot change the width of columns that show only icons.

2.2.4.3 Changing the order of columns

You can change the order of the columns in the Exam List by clicking and dragging the column headings.

The first column (Exam Status) cannot be moved.

Illustration 12: Exam List – changing column order

2.2.5 Keyboard shortcuts

The following shortcuts apply when working with the Exam List:

- The <Delete> key deletes the selected items. The system will prompt you to confirm any deletions.
- Simultaneously press <Ctrl> and <A> to select all items in the Exam List.
- To select a contiguous range of items, select the first item, press <Shift>, and then select the last item.
- To select a non-contiguous range of items, select the first item, press <Ctrl>, and then select the rest of the items you want to select.

2.3 Series list

The Series List shows the series and image information for exams in the database. It appears on the right side of the right monitor. When you select an exam in the Exam List, the Series List updates to show the Final Dose Report and all series associated with the exam.

If you select a series that contains images from the Series List, the images are previewed in the viewport directly below the Series List.

2.3.1 Nested and Classic views

There are two ways of viewing the Series List.

The default, or nested view, reflects the nested tasks in the Reconstruction and Image Processing Task List. Scan series headers indicate the scan series the images are associated with. The series types are indicated by icons.

Illustration 13: Series List in nested view

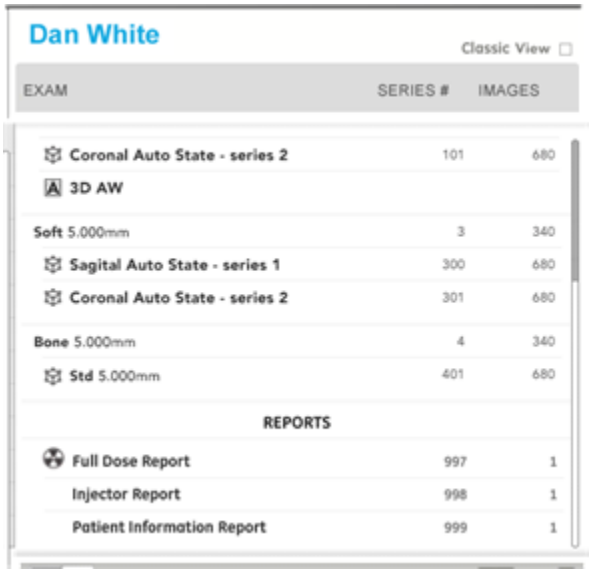


Table 6: Series type icons (nested view)

This icon:	Indicates:
	Reformat in any plane.
	Image or file created by an AW application.
No icon	Any other type of image or file (scout, straight recon, screen captures, GSPS, DICOM SR, and so on).

The classic view of the Series List sorts the series in an exam by the series number, although you can sort the columns by any of the columns. The series types are indicated with text labels instead of icons.

Illustration 14: Series List in classic view

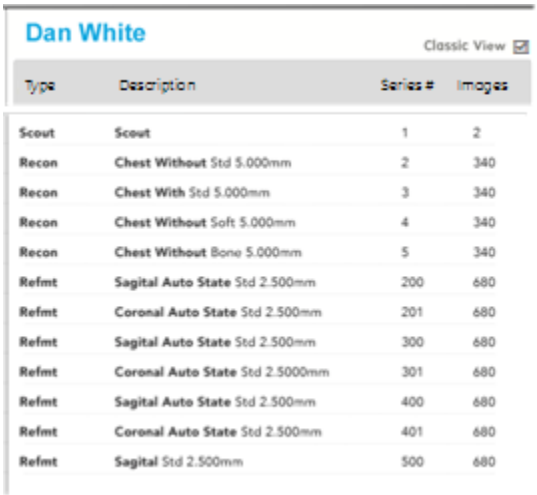


Table 7: Series labels (classic view)

This label:	Indicates:
SCOUT	Scout: acquired scan data that can be viewed, W/L, measured, and so on.
PROSP	Prospective: acquired scan data that can be viewed, W/L, measured, and so on.
COMB	Combined: result of a combination of image data that can be W/L. Produced by Add/Sub from images at different locations.
SSAVE	Screen Save: screen capture data that can be W/L. Produced by the Viewer, 3D, and Reformat applications. Dose Report: generated by each exam if Dose Report is enabled on the system. $CDTI_{vol}$, DLP, and Dose Efficiency displays during scan prescription and provides patient dose information.
PROC	Processed: post-processed data that can be W/L and measured. Produced by Add/Sub from images at the same location.
REFMT	Reformat: post-processed data that can be W/L, filtered, and measured.
3D	Three-dimensional: post-processed data that can be W/L. Produced by Volume Analysis.
SR	Structured Report: generated by each exam if Structured Dose Report is enabled on the system. A CT Dose Report can enable tracking of dose for the patient by the hospital radiation tracking system/HIS/RIS.
GSPS	Gray Scale Presentation State: produced by the Viewer to be used in conjunction with the original series to capture presentation information (W/L, flip, rotate, zoom). It can be networked to review stations that support this DICOM type.
RETRO	Retrospective: reconstructed data post-scan.

To switch to the classic view, check the [Classic View] box. To switch back to the nested view, uncheck the [Classic View] box.

NOTE: The nested view is not available for exams stored in remote locations, on CDs or DVDs, or on USB drives. (The nested view requires DICOM data that is not available from remote locations.)
The nested view cannot be sorted. If you click a column header in the nested view, the Series List is displayed in the classic view.

2.3.2 Series List columns

By default, the Series List has the following columns:

- Series type
- Series name
- Series number
- Number of images

Additional columns you can display in the Series List include:

- Networked
- Archived
- Filmed

- Modality (available in nested view only)

  See Section 3.5 for more information about changing which columns are displayed in the Series List.

2.3.3 Sorting the Series List

You cannot sort the Series List in the nested view. If you click a heading in the nested view, the Series List displays in the classic view.

By default, the classic view sorts by series number. To sort on a different column, click the column heading.

Illustration 15: Series List classic view column headings

2.3.4 Deleting series and images

To delete a series or image, right-click the item in the Series List and then click [Delete Series] or [Delete Image]. Alternately, you can select the item and then press the <Delete> key.

The system asks you to confirm that you want to delete the item.

You can delete more than one item at a time. Shift-click items to select a contiguous list of items, or Control-click to select items one-by-one.

When you delete a series or image, the system checks to see if the Recycle Bin is full (if the Recycle Bin is configured on the system). If the Recycle Bin has enough space, deleted items are moved to the Recycle Bin.

If there is not enough space in the Recycle Bin to hold the deleted items, the system warns you that the items will be permanently deleted and asks you to confirm that you want to delete the items.

If the system does not have a Recycle Bin configured, the system warns you that the items will be permanently deleted and asks you to confirm that you want to delete the items.

2.3.5 Configuring the Series List

2.3.5.1 Choosing which columns to display

You can change which columns are displayed in the Series List classic view. Right-click on any column heading, and select the columns you want to display from the pop-up list.

2.3.5.2 Changing the width of columns

To change the width of columns in the Series List classic view, click and drag the right edge of the column heading.

2.3.5.3 Changing the order of columns

You can change the order of the columns in the Series List classic view by clicking and dragging the column headings.

2.3.6 Keyboard shortcuts

The following shortcuts apply when working with the Series List:

- The <Delete> key deletes the selected items. The system will prompt you to confirm any deletions.
- Simultaneously press <Ctrl> and <A> to select all items in the Series List.
- To select a contiguous range of items, select the first item, press <Shift>, and then select the last item.
- To select a non-contiguous range of items, select the first item, press <Ctrl>, and then select the rest of the items you want to select.

2.4 Scan Data Manager

Scan data

During a scan, x-rays pass through the patient's anatomy with each rotation of the gantry and strike the detectors. The signal from the detectors is converted to an analog signal that is then captured as part of the scan file. This is the scan data (or raw data). The scan data contains all of the information gathered during an exposure.

Lock scan data

As patient exams and scans are performed on the system, the raw scan data is saved to a database. By default, the scan data from the earlier scans is deleted to make room for the data from newer scans. However, it may be necessary to retain (lock) the scan data for reconstruction at a later time or perform additional reconstructions.

Unlock scan data

Once scan files are no longer needed, you can unlock them so they can be overwritten with new data. Unlocked scan data files are overwritten as the system requires space for new scan data files.

Delete scan data

If you are sure you no longer need scan data files, you can delete them directly. These files will be removed from the system and will be unavailable (unless they have been saved).

Save scan data

You can save scan data to DVD or USB media if scan data needs to be retained for an indefinite time or sent elsewhere for diagnostic review.

Scan data may be saved to DVD-RAM media or to a USB hard drive.

Saved scan data can be restored back to the system database for later reconstruction.

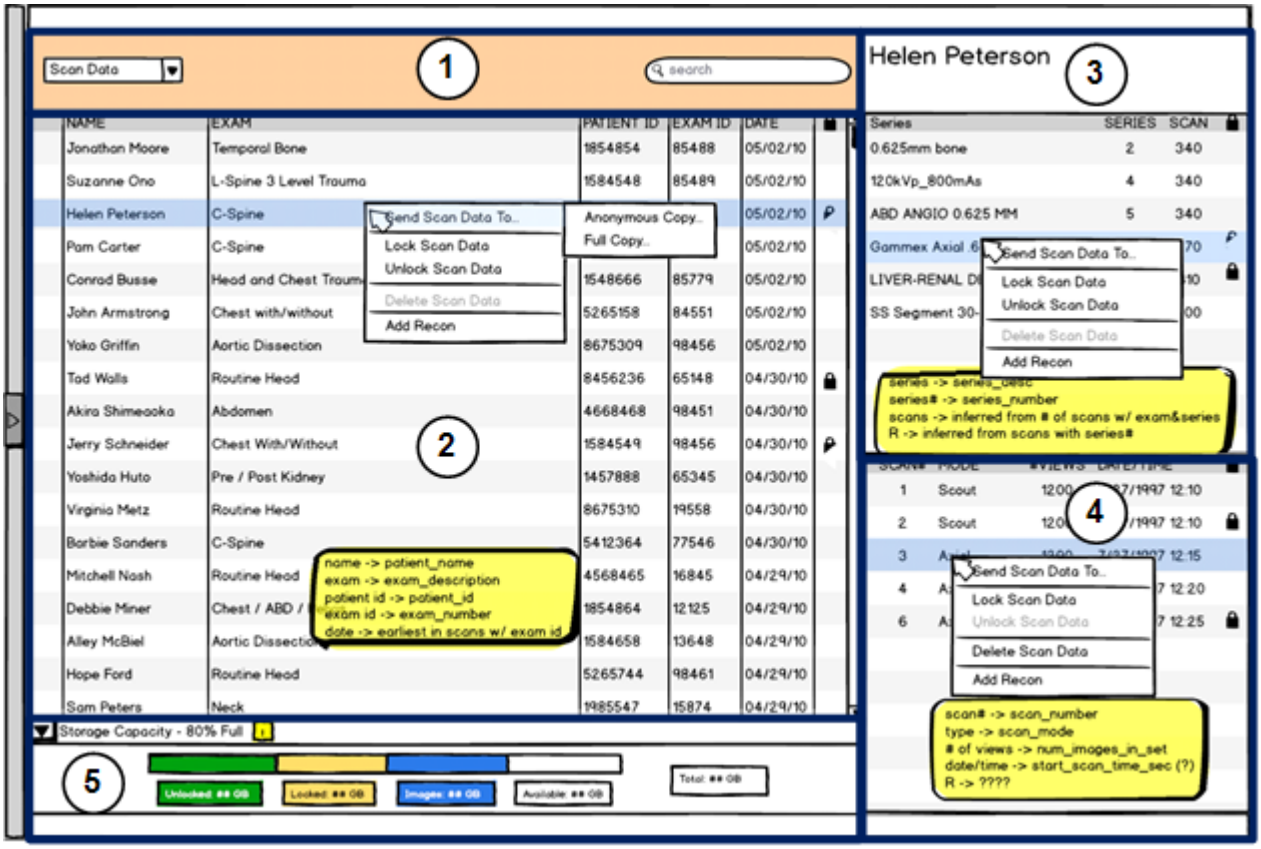
NOTE: Only scan data from a Discovery CT870 system can be restored on a Discovery CT870 system.
The system overwrites the oldest scan files on the system when restoring scan data. If you have several files to restore, lock the scan files as they are restored to make sure the system does not overwrite them.

Scan Data Manager

The Scan Data Manager allows you to manage scan data, allowing you to store it, archive it to external media, and open scan data to create additional reconstructions.

From the File Manager, select [Scan Database] from the *Source* menu.

Illustration 16: Scan Data Manager screen



1	Controls area	**4**	Group Information
2	Scan Data Exam list	**5**	Storage Capacity Chart
3	Series list		

2.4.1 Controls area

The Controls contains the Source menu and a search box. Selecting anything other than Scan Data from the Source menu will close the Scan Data Management screen. You can type a search string into the Search box to find exams (this is like searching for exams in the File Manager).

2.4.2 Exam List

The Exam List contains a list of exams for which there is scan data available. This list works similarly to the Exam List in the File Manager.

There is a Locked status column that indicates which exams (or partial exams) have been locked against automatic deletion.

Table 8: Locked column status flags

This flag:	Means:
Blank (no flag)	The exam is unlocked and will be deleted when the system requires space for data from new scans.

This flag:	Means:
	The scan data for the exam is locked against automatic deletion.
	Part of the exam scan data has been locked against automatic deletion.

2.4.3 Storage Capacity chart

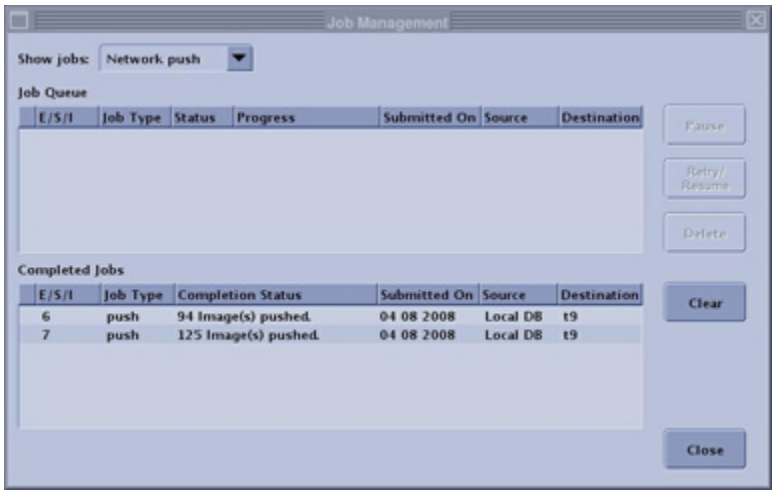
The Storage Capacity chart at the bottom of the Scan Data Manager screen shows system storage statistics. It displays the amount of scan data that is locked and cannot be deleted, the amount of scan data that is unlocked, the amount of space occupied by reconstructed images and other miscellaneous files, and the amount of free space on the system.

Use the chart to see how much space is available for new scan acquisitions and to help prevent the accumulation of unnecessary files that will prevent the system from scanning.

3 Job Management Screen

From the right monitor, click the [Scanner Utilities] icon and then click [Network Queue] to open the Job Management screen.

Illustration 17: Job Management Screen



Jobs Menu

Illustration 18: Jobs Menu

The Show jobs menu filters the list of Registered jobs and Completed jobs displayed in the tables. The selections include:

- All jobs
- All PPS jobs (only for sites with PPS, HIS or RIS systems)
- All Network jobs
- All Archive jobs
- Network push
- Network retrieve
- Archive record (Not Applicable)

- Archive restore (Not Applicable)
- Remote archive

Job Queue

The Job Queue area displays the list of registered jobs as defined from the *Show All Jobs* menu.

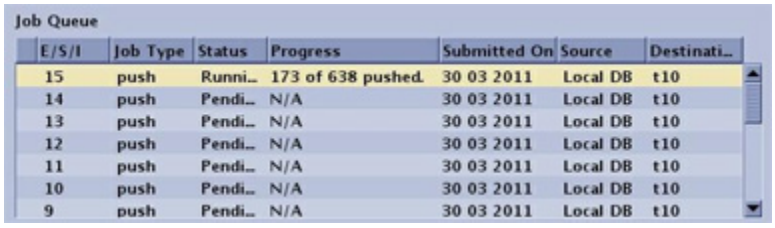
Click and drag the edges of each title in the menu bar to expand or contract the field.

Click a title in the menu bar to sort the list.

The job status types include:

- Paused — indicates that stops the progress of a transmission
- Failed
- Running — indicates the job is active

Illustration 19: Registered Jobs

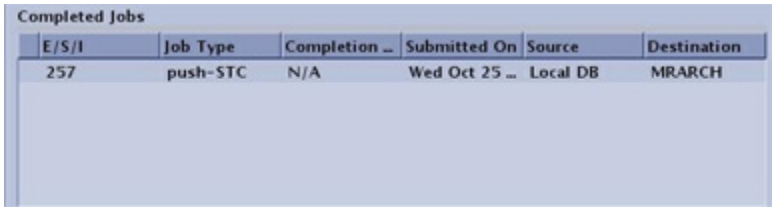


Completed Jobs

The Completed Jobs area displays when a successful transfer is completed the job is listed. The most recent job is listed at the top of the list.

Click [Clear] to remove all jobs from the Completed Jobs list.

Illustration 20: Completed Jobs



Queue Controls

- Click [Pause] to place the selected items in the list into a paused state. To resume the job, select the item and click [Resume/Retry].
- Click [Resume/Retry] to initiate the job of the selected items in the list.

- Click [Delete] to remove a transmission from the Registered Jobs list. A pop-up requires your confirmation for deletion.
- Click [Clear] to delete all items from the Completed Jobs list.

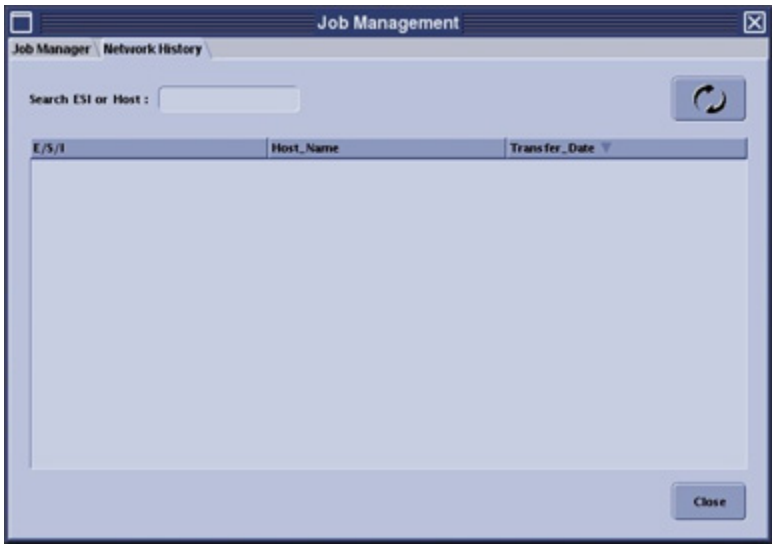
See Section 4.6, View the Backlog/Queue.

Network History

The Network History tab lists the jobs that have been transferred. The entries are listed by how the job was queued for transfer, i.e., by exam, series, or image.

See Section 4.8, Check the Network History.

Illustration 21: Network History



4 Archive/Network

Archive

An archive device is a network device set up as an archive destination by your service personnel. When an image is archived, the icon in the Archive column of the Exam List and Series List indicates that it has been archived. The archive flag does not display when an image is saved to a CD or DVD.

There are two methods of archiving. You can manually archive images, which allows you to save only those specified by you. You can also automatically archive images. In this case, all exams are auto archived upon scan completion.

The archive and network status columns on the Exam List and Series List contains information regarding archive or network status.

When saving images to a remote archive device such as a PACS, items queued to be saved to the device will be listed in the Job Management screen.

The archive status is displayed in the Job Management screen and in the status area of the screen.

Network

Networks link image acquisition systems and workstations together, providing a way to quickly and easily transfer images between your scanner, remote workstations, and other image acquisition systems. You may view images that are supported by your scanner from any station, or view images from other stations networked to your scanner.

You can network images between your system and any DICOM compatible device. Images transferred from your system can be automatically networked upon reconstruction or manually networked upon your initiation. You may also get images from another networked device. Before networking images, check to see that there is enough room on the receiving system's disk to accommodate the images being transferred.

Network status information is displayed on the Job Management window in the *Feature Status* area.

NOTE: Images cannot be sent to an IRIX-based CT system.

Archive/Network queues: Job Management

The archive and network queues are viewed from the Job Management screen. When you choose to view an archive or network job, the queues provide a snapshot of the status of the archive or network tasks occurring on the system. You are able to pause, resume, and delete the archive and network tasks.

The Job Management screen also provides a history of archive and network events. The list allows you to check and verify that an exam, series or image has been sent to an archive or network node. If an entire exam or series has been selected, only one transfer is executed and one entry is displayed in the queue. If specific series or images have been selected, a separate transfer is

executed and a separate entry is displayed for each selection. When saving images to a remote archive device such as a PACS, items queued to be saved remotely will be listed in the Archive Queue under the Remote archive list.

NOTE: After a system crash or reboot, check the queue status and restart, if necessary. The restore and save queues are maintained even after a shutdown has been performed.

4.1 Configure a host

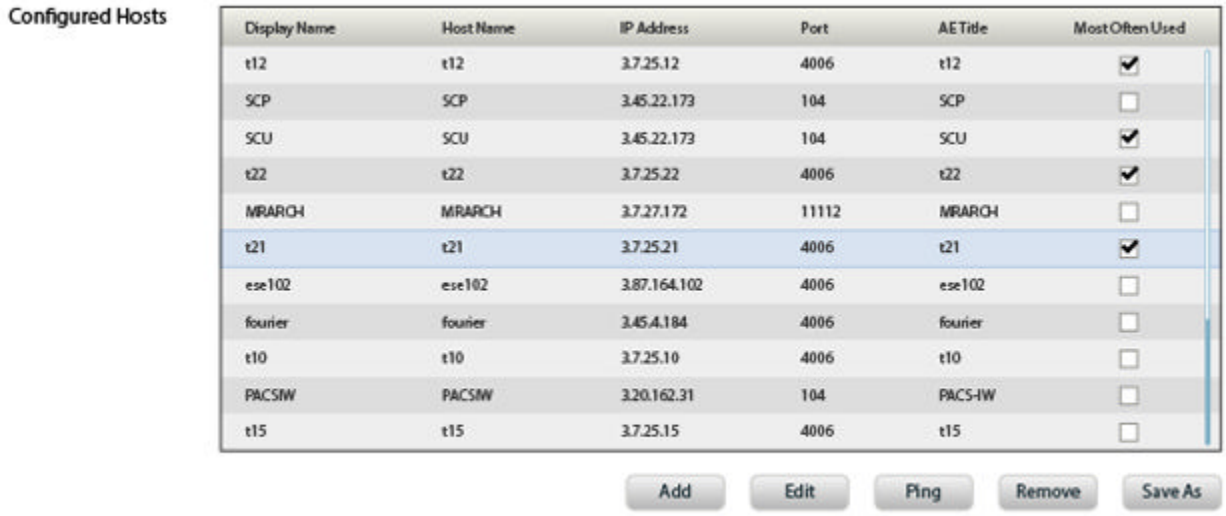
Network host configuration takes place in the Network Preferences screen. To display Network Preferences:

1. Click the [Mode] icon , and then click [Preferences].
2. On the *Preferences* screen, click [Networking].

Configured Hosts

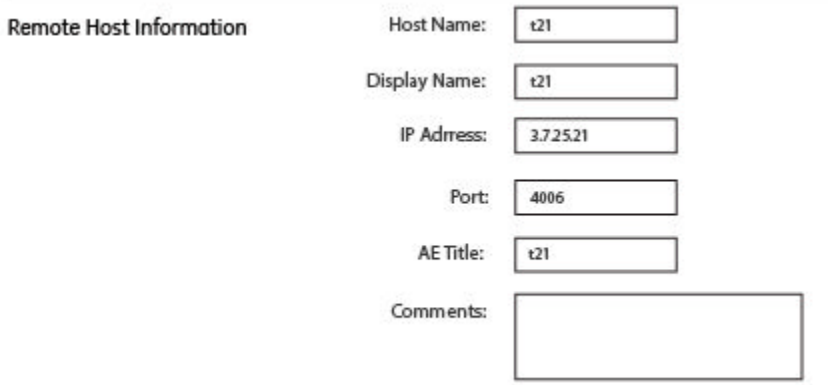
The *Configured Hosts* area lists of all the archive and network nodes. See *Configure a host*.

Illustration 22: Configured Hosts list



Remote Host Information

Illustration 23: Remote Host Information



- **Host Name:** The name given to the network node of the currently selected node. This name is typically entered by the service engineer.
- **Display Name:** The name that is shown in both the source menu and Archive and Network destinations.
- **IP Address:** The location of the node within the network. You must enter the IP1 address correctly or the connection can not be made. Your service engineer can help you determine the IP address.
- **Port:** A predetermined number that is specific to the type of host and the protocol used. Your service engineer can provide you with this number.
- **AE title:** This title is provided by the service engineer.
- **Comments:** A space to enter text that is associated with the selected node.

Archive Node Settings

Select the Archive Node option to place the selected node in the Archive destinations. Only devices or nodes that have this option checked can be used as an archive device. Not all hosts can be used as archive nodes (for example, another CT system cannot be used as an archive node, but a PACS system can be used as an archive node).

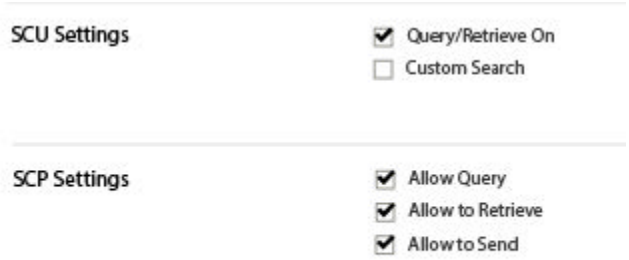
To be a successful archive node, the node must meet certain DICOM requirements so that when the data is transferred from the host system to the node, the DICOM handshake can be successful. This is not necessary for networking images. The same handshake is not required.

Illustration 24: Archive Node Settings box

SCU and SCP Services

The Services area contains settings for SCU and SCP.

Illustration 25: Services Area



In the *SCU Settings* area:

- Select *Query Retrieve* to ping and retrieve images from the currently selected node.
- Select *Custom Search* to filter the patient list of the selected node. When you select the current node from the Source menu, the Filter Data window automatically appears.

In the *SCP Settings* area:

- Select *Allow Query* to give the currently selected remote node the ability to retrieve from your host system.
- Select *Allow to Retrieve* to give the currently selected remote node the ability to query your host system.
- Select *Allow to Send* to give the currently selected remote node the ability to send to your host system.

Save

Click *Save* to save the settings for the currently selected node.

4.2 Source list

The configured remote networks can be viewed by clicking on the *Source* list in the Exam List, or by viewing the *Configured Hosts* list in networking preferences.

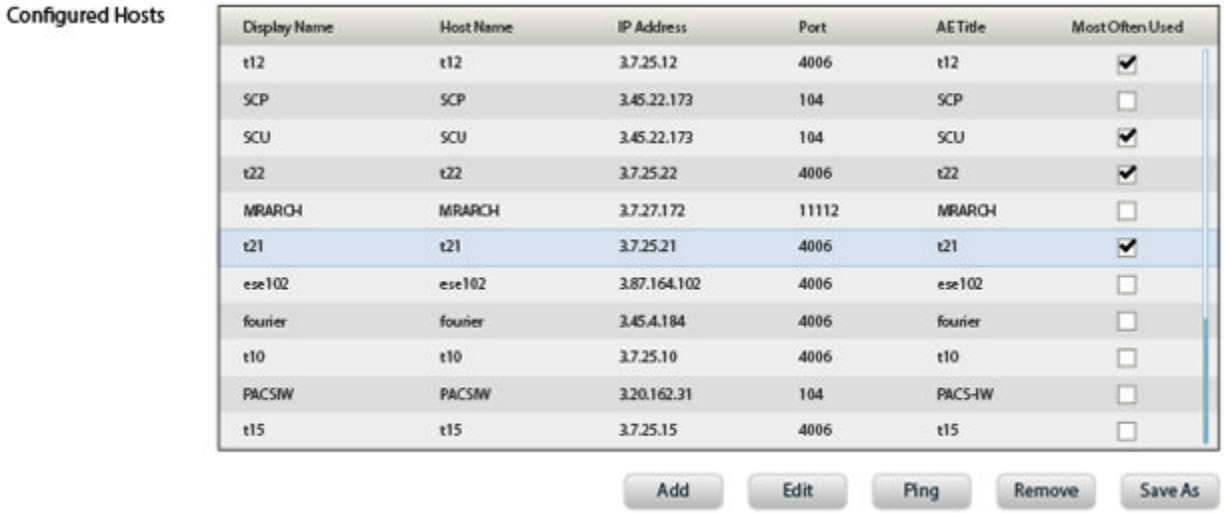
Source Menu

The Source menu displays the configured network hosts. The Exam List displays the exams from the selected source.

Configured Hosts List

For details, see Section 1.

Illustration 26: Configured Hosts list



4.3 Configure a Host

Use these steps to configure, ping, or delete an archive node or network host.

1. Click the [Mode] icon , and then click [Preferences].
2. On the *Preferences* screen, click [Networking].

Add or Edit a Host

1. From the *Configured Hosts* list, click [Add].
2. In the *Remote Host Information* area, complete all fields.
3. If the host is an archive, check the [Archive Node On] box.
4. In the *Services* area, select your options.
5. Click [Save] to save the settings for the currently selected node.
6. Click [OK].

Remove Nodes from the Configuration Host List

1. From the *Configured Hosts* list, select the node you want to remove.
2. Click [Remove].
3. Click [Yes] at the confirmation prompt.

Ping a Remote Host

1. From the *Configured Hosts* list, select the node you want to ping.
2. Click [Ping].

3. Click [OK] to the message prompt.

   If a failure occurs, read the prompt to help determine the cause of the failure.

Most Often Used

If you have a large number of hosts, you can designate the hosts you use most often by checking the Most Often Used box for those hosts. This will put those hosts first in the list when you are selecting hosts for sending and receiving exams, series, and images.

4.4 Local DB Retrieve Exams, Series, or Images

Use these steps to restore exams, series, or images to your system from a remote host.

1. On the right monitor, open the File Manager.
2. From the [Source] menu, select the remote Archive host.
   - If the host is not available, a message appears. Read the message and click [OK].
   - The host must be configured to receive a query. Check the SCP Settings on the Configure Network Hosts window to verify that all the SCP settings have been checked (Allow to query, Allow to retrieve, Allow to send).
3. To find the exam you want to restore:
   a. In File Manager, enter a search string into the *Search* box.

      The filtered Exam List displays.

   b. To return to the non-filtered Exam List, click the close icon in the Search box.
4. From the Exam List, select the exam you want to retrieve.

   If you are selecting series or images, select them from the Series List.

   NOTE: You can select more than one exam, series, or image. Shift-click to select a contiguous list, or Control-click to select items one-by-one.

   You cannot retrieve series or images from different exams in the same transfer. Select the series or images you want to retrieve from an exam, start the retrieval, and then transfer the series or images from the other exam.
5. To retrieve exams, click the [Get Exam] icon  . Alternatively, right-click the exam and then click [Get Exam].

   To retrieve series, right-click the series and then click [Get Series].

   To retrieve images, right-click the images and then click [Get Images].
6. The selected items transfer to your system.

   The system indicates that exam transfers are taking place with an animated icon next to the exams. The system status bar shows the progress of the transfer. You can check the status of the transfer using the Job Management screen.

- Jobs are performed on a first-come, first-served basis.
- When the data has been transferred to the local database, the Archive flag is set for the transferred data.
- When the data has been successfully transferred to a network host, the Networked flag is set for the data.
- Hover the cursor over the Archive or Networked flag to see more information.

NOTE: If there is an error in retrieving an exam, it will be indicated in the local Exam List with a red icon. Click the icon to open the Job Management screen.

4.5 Manually Send Exam, Series or Images

Follow these steps to send an exam, series, or image to a an archive or network host as an alternative to auto archive.

1. On the right monitor, open the File Manager.
2. From the Exam List, select the exam, series, or images you want to send.

   If you are selecting series or images, select them from the Series List.

   NOTE: You can select more than one exam, series, or image. Shift-click to select a contiguous list, or Control-click to select items one-by-one.

   You cannot send series or images from different exams in the same transfer. Select the series or images you want to retrieve from an exam, start the retrieval, and then transfer the series or images from the other exam.
3. To send to a non-archive host, right-click the selected item, click [Send Exam To] (or [Send Series To] or [Send Image To], and then click the host name.

   The data transfer process begins.
4. To send to an archive, right click the selected item and then click [Archive Exam] (or [Archive Series], or [Archive Image]). If there is more than one archive available on your network, select the archive.
5. View the Job Management window or the archive and network status in the Feature Status area to view the state of the images as they are transferred to the archive or network host.
   - Jobs are performed on a first-come, first-served basis.
   - When saving images to a remote archive device such as a PACS, items queued are performed on a first-come, first-served basis.
   - When the data has been successfully transferred to an archive device, the Archive flag is set for the data.
   - When the data has been successfully transferred to a network host, the Networked flag is set for the data.
   - Hover the cursor over the Archive or Networked flag to see more information.

4.6 View the Backlog/Queue

Follow these steps to view a backlog of archive or network activity or to delete an archive or network job.

1. From the right monitor, click the [Scanner Utilities] icon and then click [Network Queue] to open the Job Management screen.
2. From the *Job Management* window, click [Show Jobs] and select an option to refine the lists.
3. From the Registered Jobs list, select the jobs you would like to change.
   - Click an individual item.
   - Press <Shift> and simultaneously click the first and last item.
   - Press <Ctrl> and simultaneously click individual items.
4. Choose one of the following job actions:
   - Click *Pause* to pause the selected items.
   - Click [Retry/Resume] to initiate the job for the selected items.
   - Click *Delete* to remove a transmission from the queue. A message confirms the deletion.
   - Click [Clear] to delete Completed Jobs from the list.
5. 6. Click [Close].

Delete Jobs from the Completed Jobs List

1. From the right monitor, click the [Scanner Utilities] icon and then click [Network Queue] to open the Job Management screen.
2. From the *Job Management* window, click [Clear] to remove the selected jobs from the list.
3. Click [Close].

4.7 Eject (Detach) Media

To make sure a removable media device is in a safe state, it need to be ejected (detached) before you remove it from the system.

Follow these steps to eject (detach) a CD, DVD, or USB drive.

1. Insert a CD, DVD, or USB drive into the appropriate drive.
2. Check the Archive/Network backlog to verify that all image transfer from the device is complete.
3. From the File Manager, click the [Eject] button (next to the Source list at the top of the File Manager).
4. The system asks which device you want to eject. Select the device, and then click [Eject].
5. The system displays a message when it is safe to remove the device.

6. In the case of DVD and CD drives, the drive will open. If you have ejected a USB device, unplug the USB device.

4.8 Check the Network History

1. From the right monitor, click the [Scanner Utilities] icon and then click [Network Queue] to open the Job Management screen.
2. From the *Job Management* window, click the *Network History* tab.
3. In the log, locate the network history that you want to view.

   Entries are listed how the job was queued for transfer. If by Exam, then only the exam number is listed. If by Series, then the exam and series are listed. If by Image, then the exam, series, and image are listed.
4. Enter a specific exam, series or image number into the *Search ESI* or *Host* field.

   The history file opens for all matches to the exam, series or images.
5. Click the [Refresh] icon

   to update the network history log.
6. Click [Close].

4.9 Workarounds

When archiving images, consider the following and use the workarounds as necessary.

- Images archived on an Advantage Windows system may fail to restore on the system. Use Network to transfer images from the Advantage Windows to the system.
- After restoring an exam, series, or images that already exist on the system disk, you will not see a message window indicating that the images are restored or that they already exist. If you have restored images, and do not see a confirmation that they have been restored, verify that the files do not already exist on the system disk.
- If the system is unable to read the media, remove the write protect and see if the system is able to recover the media to access the data.

5 CD, DVD and USB Interchange

CD, DVD and USB interchange is used to write or recall images from a Compact Disc-Recordable (CD-R) or Digital Versatile Disc-Recordable (DVD-R) in a Digital Imaging and Communications in Medicine (DICOM) format. CD/DVD/USB cannot be selected as the default archive device. Exam, series, or images will not be marked as archived. A DICOM viewer is stored on the media so the images can be viewed on a personal computer.

Only CD -R or DVD -R media can be used for CD/DVD/USB Interchange. For CD-R, write speed should be at least 4X and storage size of 700 MB. The media is write once and all selections must be queued at the same time. Approximately 7,000 images can be stored to a 4.7 GB DVD-R.

In order to view the information placed on media using CD/DVD/USB interchange, the PC must running Windows XP, Windows Vista, or Windows 7 operating system and containing Java 1.5 or higher versions. The first time the reader of the Interchange media tries to access the data, the security setting in Advanced Settings on the PC must be set to "Allow active contents from CDs to run on My Computer." A log file is created on the PC used to read the media, which tracks the reading of the media to record issues for troubleshooting. The log file is limited to six files and overwrites data once the limit is reached.

NOTE: CD/DVD/USB interchange is available for writing DICOM images onto the compatible media listed in Table 9. It is not considered a method for long-term image storage.

NOTE: If your field engineer is trying to load this option, it is listed in the options list as *Copy Composer*.

Media and Device Requirements

The following table lists the recommended CD-R and DVD-R manufacturers that have been qualified by GE Healthcare. Other high-quality CD-R and DVD-R media may also work, but GEHC has qualified only the media types shown below.

Table 9: Recommended media

CD-R	DVD-R
Sony 650 - 700 M CD-R	Verbatim 4.7 GB 4X Commerical
	Maxwell 4.7 GB 1X-4X
	Sony 1X-4X Compatible 4G
	TDK 4.7 GB Commerical

Pay attention to the following declarations about media and operation requirements when you use CDs and DVDs.

- Only supports single layered CD-R and DVD-R media. No other media types are supported, including but not limited to DVD-RW.
- Dual layered CD-R and DVD-R media are not supported.
- Only supports 700 MB single layer CD-R media.

- Only supports 4.7 GB single layer DVD-R media.

Pay attention to the following considerations about USB devices:

- USB devices can be flash drives or USB hard drives which use external power.
- By DICOM standards, the format of USB device must be VFAT.
- There are no USB capacity limitations.
- You can erase data from the USB device with your PC.
- Before writing to the USB device, the system checks the USB capacity and the size of the data being written.

Operation Requirements

Pay attention to the following operation requirements for CD/DVD/USB interchange.

- Only supports single-write session. Multi-session mode is not supported.
- Cannot append write data to media that has already been written.
- CD/DVD/USB interchange is NOT INTENDED for archive or backup purposes! These features make only “temporary copies” for interchange purposes. GEHC requires cartridge media for archive like MOD or future solutions. GEHC will not “recover” any interchange media (it should just be burned again if necessary using patient data restored from authorized/provided archive media).
- It is advised to not write to CD/DVD/USB interchange media during a scan operation.
- It is advised to not open post-processing applications requiring high computer usage while writing to CD/DVD/USB.

5.1 Media Creator

From File Manager, click the [Media Creator] icon  .

Illustration 27: Media Creator Window

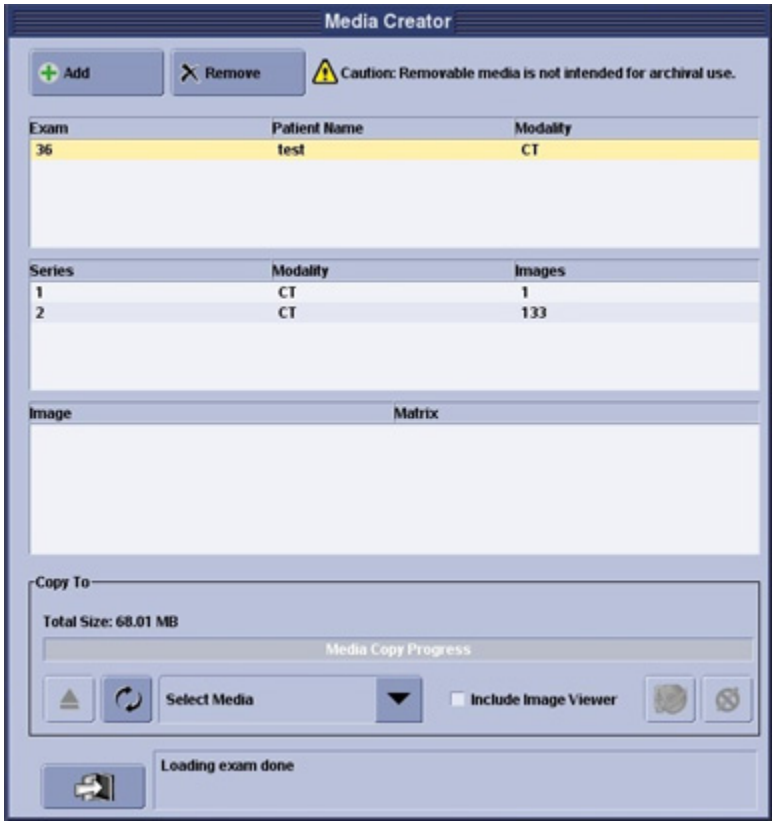


Table 10: Media Creator selections

Icon	Name	Description
	Add	When an exam is selected in the Exam List, click Add to add it to the exam to the list. Select a single or multiple series and click Add to add the selected series to the list.
	Remove	Click to delete selected items in the list.
	Eject	Click to eject the CD or DVD from the drive. Eject also makes it safe to detach a USB device from the drive.
	Refresh	Click to update the contents of Select Media menu.
	Media menu	Displays the CD/DVD drives and USB drives.

	Include Image Viewer	When selected, a Viewer is saved with the image to the identified device (CD/DVD or USB).
	Disk Capacity	The Total Size display shows the size of the items that have been added to the list. It updates as you add more items.
	Stop	Click to halt the copy process.
	Close	Click to close the Media Creator screen.

5.2 How to Handle CDs and DVDs

Recordable CDs (CD-R) are more sensitive to damage than conventional CD-ROMs that you may be familiar with. Follow the handling suggestions below.

NOTICE

To avoid image loss, never touch the recording surface of a recordable CD (CD-R). Handle the disk only by the outer edge or central hole. Do not place the CD face down on a hard surface. Fingerprints or scratches will make the disk unusable.

- Store the disc in a protective case. Proper storage helps protect the data from damage due to scratches on the disc surface.
- Do not leave the disc in direct sunlight or in a hot, humid environment. These conditions can warp and damage the disc.
- Use only a felt tip permanent pen when labeling. Write only on the clear, inner diameter of the disk (or the printed area of a CD-R). Never use a ballpoint or hard point pen. Do not use adhesive labels.
- Use a soft, lint-free cloth to remove spots, dust, or fingerprints from the disc. Always wipe from the center to the outside edge of the disc. Do not wipe the disc in a circular motion.
- Do not use any chemical-based cleaners. These can damage the disc.
- Do not use the CD/DVD/USB interchange program to permanently store your data. If the CD/DVD/USB is damaged there is no recovery of the data.

5.3 Save Images

NOTICE

Please refer to the Safety section for important safety information regarding the use of the equipment and software on this system.

Use these steps to save images from your system to a CD, DVD or USB device.

You can record DICOM image data to either a blank, compatible CD/DVD that is placed in the CD/DVD read/write external drive or to a USB device inserted into one of the USB ports. If saving to CD/DVD, once you close the drawer with the CD/DVD in it, wait until the CD/DVD drive light turns off. This is an indication that the CD-R or DVD-R is spinning up to speed.

- Data on a CD-R, DVD-R and USB can be recorded only in a single session. All image data that you want to record must be selected beforehand. The data will be recorded in a single pass. It is not possible to add data on a CD-R or DVD-R.
- Image data can also be recorded in Portable Document Format (PDF) or HTML format by using the Data Export function.
- You cannot load images on a USB device that already has data stored on it. If you attempt this, the system informs you that if you continue, it will erase the data from the USB device. It is advisable to use only USB devices that have no data on them.
- Do not connect two USB devices at the same time for save/restore of scan data.
- The following information will be displayed for CT images: Hospital Name, Patient Name, Date of Birth, Acquisition Date, Exam/Series/Image information, Anatomical Reference, Slice Location, DFOV, Recon Algorithm, Series Description, kV, mA Noise Index Values, Pitch, Rotation Time, Tilt, Slice Thickness, Scan Time of Day, RAS coordinates, and WW/WL values.

1. From File Manager, click the [Media Creator] icon  .
2. From the Media Creator screen , select the media type from the Media menu.

   If you opened the Media Creator screen before you inserted a device into a drive, click the Refresh icon

   to update the Select Media menu.

Illustration 28: Media Menu

3. To save a Viewer with the images, select Include Image Viewer.

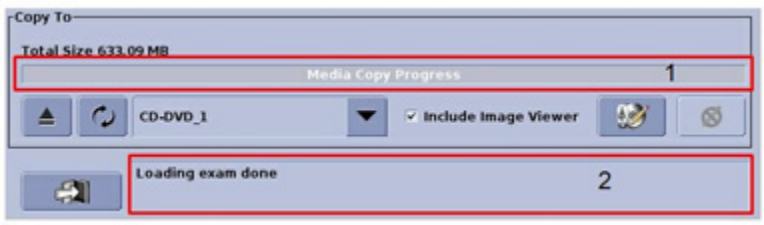
   If you do not select Include Image Viewer, you will not be able to view the images on a PC or laptop. The purpose of saving the images without the Viewer is to transport them to another compatible system.

Illustration 29: Include Image Viewer Option

4. Select the desired exams or series from the File Manager.
   - Click an individual item.
   - Press and hold <Shift> and click the first and last item.
   - Press <Ctrl> and simultaneously click individual items.
5. From the Media Creator screen, click Add.
   - The selected exam/series/images are added to the Media Creator list.
   - The Total Size display updates as more exams/series/images are added to the list. Toggle Include Image Viewer on/off to see updated Total Size display.
   - A message displays if the size of the exams/series/images exceeds the space on the CD/DVD or USB device.
   - You cannot add the same exam to the screen more than once. A message displays that you have entered the same patient more than once. Remove one of the exams.
6. Clear exams or series from the Media Creator list.
   a. From the Media Creator screen, select the series and/or exams you wish to clear.
      - Press <Ctrl> and simultaneously click individual items to remove non-contiguous items on the list.
      - Press <Shift> and simultaneously click the first and last item to remove contiguous items on the list.
   b. Click [Remove].
7. Click the [Copy] icon

   to start the recording process.
   - Do not begin recording until all desired series have been added to the list. You cannot record more data to the CD-R or DVD-R once you have started the recording process.
   - The progress bar (1) and message bar (2) displays messages indicate the progression of the copy activity.

Illustration 30: Progress Bar and Message Area



- Error prompts may appear if the media is damaged, if the media is not blank or the files are too large for a single media, etc.
- The progress bar displays 100% and a message appears in the message area when recording is completed.
- Very large data sets can take a very long time (more than one hour) to copy to CD. If you change your mind about copying the files to CD/DVD, you can quit copying and start it over at a time more convenient. Click [Quit] to cancel the copy process and upon clicking [OK] to the confirmation prompt, the copy process is stopped and the Media Creator screen closes. An alternative is to click [Cancel].

8. Once the recording is finished, click the [Close] icon

.

- If you click Close before the save process has completed, a confirmation prompt appears. If you confirm the Close, then the save process is canceled.
- The [Stop] icon

stops burning data.

9. From File Manager, click the [Media Creator] icon  .

   View the progress bar to note if the burning process is finished.

10. When the contents have been burned to the media, a message posts in the Message area. It is now safe to remove the CD/DVD or USB.

11. Click the [Eject] icon

to remove the media from the drive.

- The CD/DVD drive automatically opens when the CD/DVD save is finished. Only click Eject to stop the CD/DVD save process.

- Removing the USB device without ejecting it can results in errors that may require the device to be reformatted.
- Do not remove the USB device during copy process. Make sure you first Stop the copy process before you remove the device from the drive.

5.4 Restore Images

Follow the steps below to restore images from a CD, DVD or USB device to your system.

1. Place a CD-R or DVD-R in the CD/DVD external drive or place a USB device into one of the USB drives. Wait until the drive light turns off, which is an indication that the CD-R or DVD-R is spinning up to speed.
2. From the File Manager [Source] menu, select the drive that has the CD, DVD, or USB.
3. From the File Manger, select the exam, series or images to restore.
   - Click an individual item.
   - Press <Shift> and simultaneously click the first and last item.
   - Press <Ctrl> and simultaneously click individual items.
4. To retrieve exams, click the [Get Exam] icon  . Alternatively, right-click the exam and then click [Get Exam].

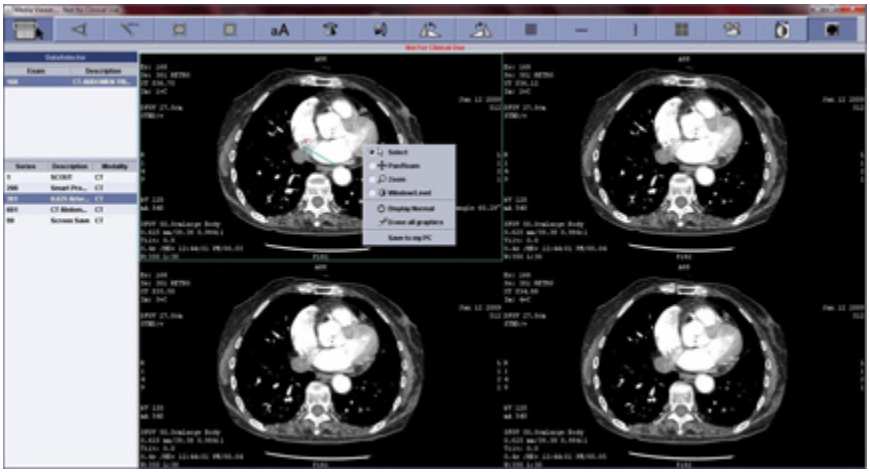
   To retrieve series, right-click the series and then click [Get Series].

   To retrieve images, right-click the images and then click [Get Images].
5. To view the restore process status, see the Section 4.6, View the Backlog/Queue procedure.
6. After the restore process completes, click the [Eject] icon (next to the [Source] list in File Manager).

5.5 View Images on a PC

The Media Viewer is automatically loaded onto a CD-R or DVD-R that is burned from the CD/DVD/USB program. Follow these steps to view images from a CD or DVD. The PC must be running Windows XP, Windows Vista, or Windows 7 with Java 1.5 or higher.

Illustration 31: Media Viewer



1. Load a recorded CD-R or DVD-R into the drive of your PC or laptop

   The CD Viewer automatically launches. If an Auto Play window displays, click Run CDViewer.exe.

2. Click [Accept] to the license agreement.
3. From the DataSelector, select an exam and wait until the data is loaded.

   Your PC or laptop must contain Java run time environment as JRE1.5_14 or higher version. If not, the Java, bundled with the application, is installed on demand.

4. Select a series to view.
5. Use the Media Viewer image controls, located at the top of the Media Viewer, to manipulate the images.

Table 11: Media Viewer Image Controls

Icon	Description
	Adds an angle measurement on the selected viewport.
	Adds a line measurement on the selected viewport.
	Adds an ellipse ROI on the selected viewport.
	Adds a rectangle ROI on the selected viewport.
	Hides/Shows a grid on the selected viewport.

	Hides/Shows a horizontal tick mark for all viewports.
	Hides/Shows a vertical tick mark for all viewports.
	Adds user annotation on the selected viewport.
	Erase All Graphics (right-click menu), removes all the Graphics (ROIs, User Annotation, Grid) from the selected viewport.
	Flips the image left to right on the selected viewport.
	Flips the image top to bottom on the selected viewport.
	Rotates the image counter-clockwise by 90° on the selected viewport.
	Rotates the image clock-wise by 90° on the selected viewport.
	Zoom (right-click menu), selects the left mouse drag operation as zoom.
	Roam (right-click menu), selects the left mouse drag operation as roam.
	Window/Level (right-click menu), selects the left mouse drag operation as window/level.
	Display normal (right-click menu), resets image operations on the selected viewport.
	Viewer format adjusts viewport format.
	Turns the screen annotation off/on.
	Inverts Grayscale for selected viewport.
	Starts cine or movie.
	Stops cine or movie.

Save to my PC	Right-click menu item, exports the image of the selected viewport to the local system in JPEG/ PNG format.
	Hides/Shows the DataSelector panel.

5.6 Remove DVD RAM Cartridge

Use this procedure to remove media from a DVD RAM cartridge for use in the Peripheral Media Tower equipped with a single DVD multimedia drive.

- For use with Operator Console utilizing a single bay Peripheral Media Tower (DVD-Multimedia drive only).
- DVD-Multimedia drives cannot accept cartridge type DVD-RAM media. Use the following procedure for removing the DVD-RAM media from the cartridge if so equipped.
- Handle bare DVD-RAM media with care. Do not touch the recording surface. Fingerprints, dirt, dust and scratches on the recording surface can destroy previously recorded data and prevent recording of additional data.
- If required, use only approved CD/DVD media disk cleaning solution (not supplied) to clean any disks that become contaminated with fingerprints, dirt, and dust. Do not use alcohol, antistatic, or other cleaning solutions.
- Take care with placing bare DVD-RAM media without cartridge.
- Always return a DVD-RAM media to its cartridge for storage.

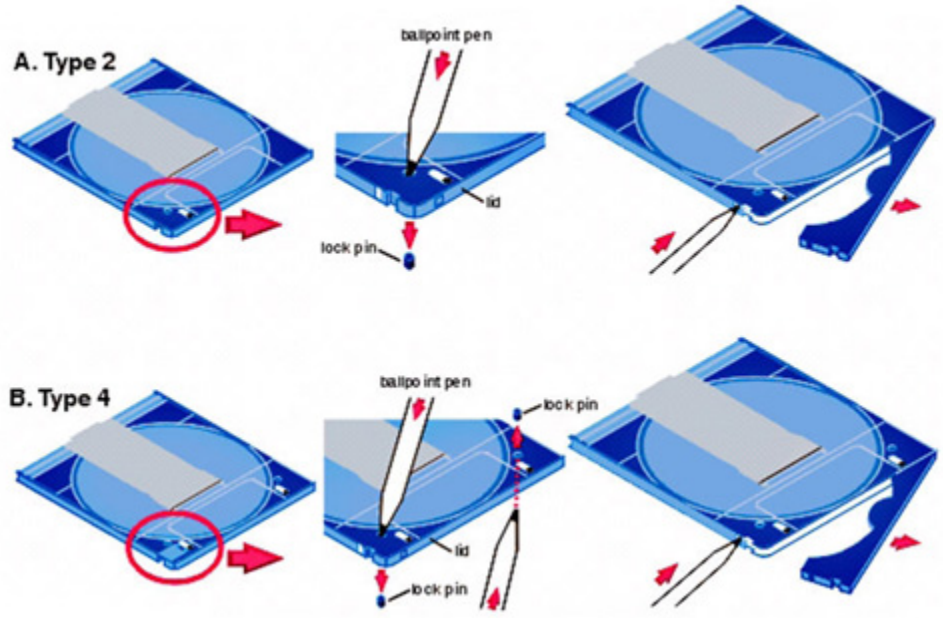
NOTE: In the case of double-sided DVD-RAM media, take care to insert the media back into cartridge with the same orientation as it was removed. If media is inserted upside down, any labeling on the cartridge will not be consistent with data on the disk.

Follow the procedure and precautions outlined below to remove the disc from the cartridge.

1. Remove the disc.
   a. Push and remove the cartridge-locking pin with a sharp-tipped object, such as a ballpoint pen.
   b. Open the cover by pushing the sharp-tipped object into the gap on the left-front side of the cartridge.
2. Do not touch the recording surface. Fingerprints, dirt, dust and scratches on the recording surface can destroy previously recorded data and prevent recording of additional data.
3. Open the cover with care. If you damage the cover, you may not be able to close it again.
4. Use a felt-tipped marker to write on the label. Never stick a new label on a disc.
5. Clean dirty discs only with the special DVD-RAM disc cleaner and cleaning fluid (not included).
6. Always return a disc to its cartridge for storage.

7. Make sure the printed side of the shutter and the printed side of the disc is facing the same side when returning the disc to its cartridge. Also, note the setting of the write-protect tab.
8. Place bare DVD-RAM media back in cartridge for storage.
9. Close cartridge lid once DVD-RAM media is fully inserted into cartridge.

Illustration 32: DVD RAM Removal



6 Data Export

Data Export allows you to store images on a CD-R or USB device, or export images via File Transport Protocol (FTP) as JPEG, PNG, AVI, MPEG, or MOV formats.

The files can only be burned to a CD-R and only one report can be burned at a time. Once a CD-R has been burned, you cannot add more reports at a later time. It is not a rewritable process.

The JPEG, PNG, AVI, MPEG, or MOV images can be viewed from a PC or laptop with a Windows 2000 or XP operating system using Internet Explorer 5.5 or later.

There are two tabs on the Data Export window:

- *Compose* tab — allows you to define the compression factor, annotation level, W/L, zoom, scroll, and output format for the series you want to export.
- *Export* tab — allows you to view a list of all the examinations and series you have in the Data Export program.
    - You can compose a series and then export it to either a CD or FTP site at a later date.
    - Examinations and series stay in the *Export* program until they are actively deleted.

6.1 Compose Tab

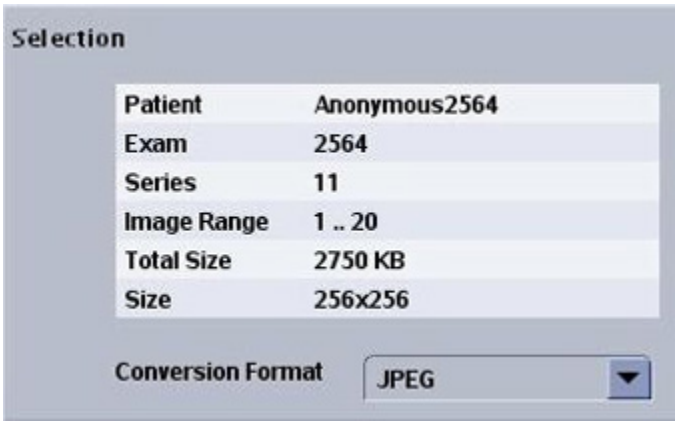
From the File Manger, click the [Data Export] icon .

Illustration 33: Compose Tab

Selection

Displays the patient name, exam and series number, the number of images in the series, the file size of the images with the current compression selection, and matrix size.

Illustration 34: Selection Area



Conversion Format

Click the *Conversion Format* menu to select the image format for the currently selected data set. Format choices include: JPEG, PNG, AVI, MPEG, and MOV. AVI, MPEG, and MOV are all movie-type formats. Choose the format that is compatible with the movie player on your PC or laptop.

Compression Factor and Image/Sec

Move the Compression Factor slider to choose a compression value for JPEG and MPEGs. The lower the number, the less the compression, the higher the image quality but the larger the file.

Select an Image/Sec rate for the movie play back speed. It is only applicable for MPEG, AVI, or MOV files.

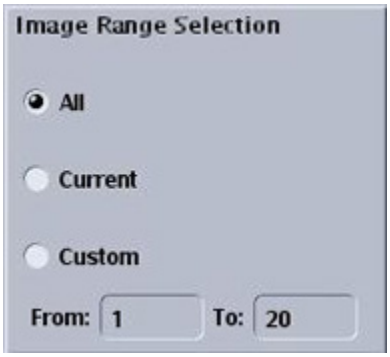
Illustration 35: Compression Factor and Image/Sec

Image Range Selection

In the Image Range Selection area, choose the images you want to place in the designated folder. For example, if you have a multi-phase series selected and all you want is the first phase in the MPEG, then select the range of images representing phase one of your data set.

The ability to select a subset of images from the selected series is particularly important if you plan to transfer the files via FTP rather than burn a CD.

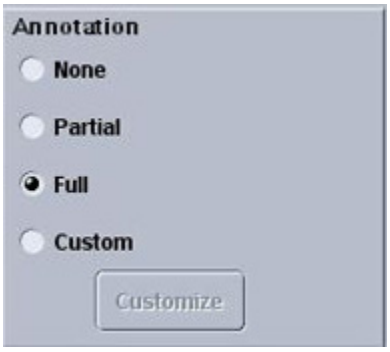
Illustration 36: Image Range Selection



Annotation

In the *Annotation* area, choose the level of annotation for the images: none, full, partial (a subset of the full annotation, or custom. Click [Customize] to turn on specific annotation fields.

Illustration 37: Annotation



Series + or -

Click Series [+] or [-] to navigate through a series within the exam.

Select *Propagate Image Operations* to apply the image manipulations (W/L, zoom, scroll) you have performed on all images forward from the currently displayed image within a series.

Illustration 38: Series Area

Play/Stop

Click [Play] to preview the MPEG, AVI, or MOV file.

Click [Stop] to quit playing the movie.

Image Viewport

The image viewport displays the current images by scrolling through them in a cine loop. Press <Page Up> and <Page Down> to scroll through the images.

Image Conversion

Illustration 39: Image Conversion

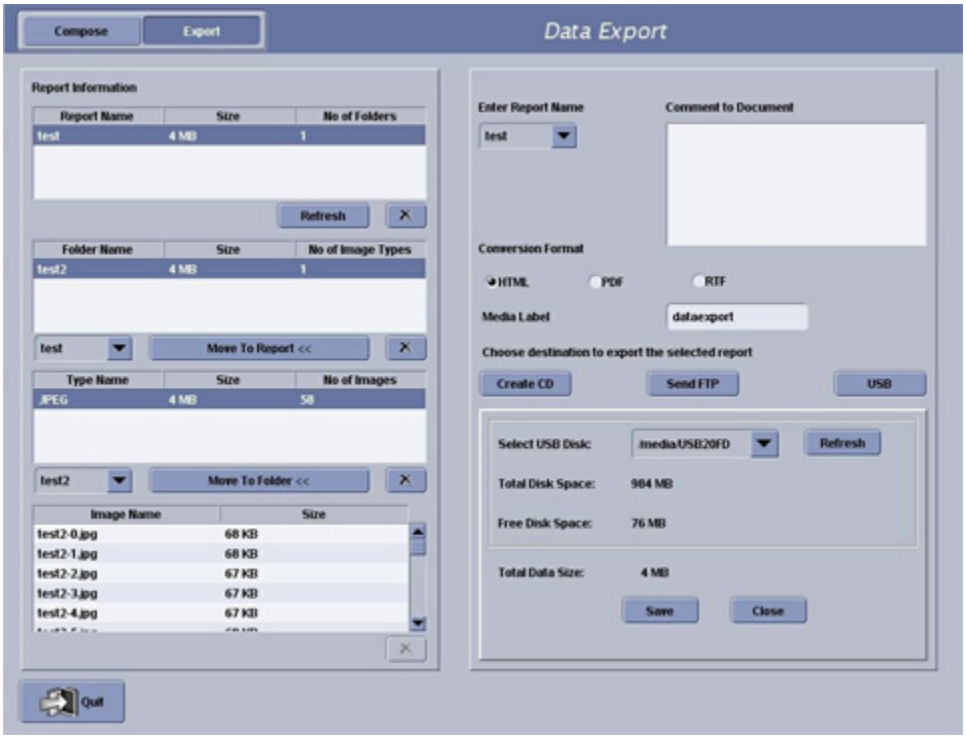
- In the *Report Name* menu field, select or enter a name to display at the top of the report. The name also appears in the Export Data list. Typically the patient's name and type of file are entered as the report name. There can be no spaces or characters other than alpha numeric.
- In the *Folder Name* menu field, select or enter the name of the folder where you want to file the report name. From the *Export* tab, you can view the data listed within each folder. The data within a folder is sorted by file type. For example, if you added 10 JPEGs from the T1 series and 20 JPEGs from the T2 series you will see a list of 30 JPEGs in that folder. If you want these JPEGs separated, you must place them in separate folders.
- Select *Save Preferences* to save the changes you have made on Data Export screen.
- Select *Anonymous* to have the patient's name replaced with Anonymous and the exam number when the iamges are added to the report.
- Click [Add to Report] to add the current data set to the report from which you can either burn the information to a CD-R or FTP it to an IP1 address. A Data Conversion progress window displays the status.
- Click [Cancel] if you want to stop the data conversion.

Illustration 40: Data Conversion Progress

6.2 Export Tab

From the File Manger, click the [Data Export] icon . Click the [Export] tab.

Illustration 41: Export Tab



Report Name List

Contains all the report names in the data base.

Click the [Delete] icon

to remove selected items from the list. Items remain on the list after you click Quit Data Export until they have been deleted through this method.

Illustration 42: Report Name List

Folder Name List

Identifies all the folders associated with the report name. Check the file size to make sure you can FTP the file or store it on a single CD-R.

Illustration 43: Folder Name List

Click [Move to Report] to move the selected item to a destination of your choice. For example, you can select an item in the Type list and add it to a particular folder in the Folder list. The folder size is listed.

Click the [Delete] icon

to remove selected items from the list. Items remain on the list after you click [Quit] until they have been deleted through this method.

Type Name List

Contains of all the file types within the selected folder. Keep in mind that the only items displayed in the list are the item types. If, for example, you added 20 T1 JPEG images to Folder 1 and then added another 20 T2 JPEG images to Folder 1, the number of JPEGs in folder 1 is 40. The quantity and size of each data type is listed.

Click the [Delete] icon

to remove selected items from the list. Items remain on the list after you click [Quit] until they have been deleted through this method.

Illustration 44: Type Name List

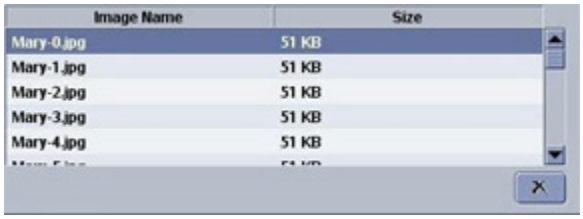
Image Name List

Contains of all the images within the selected file type.

Click the [Delete] icon

to remove selected items from the list. Items remain on the list after you click [Quit] until they have been deleted through this method.

Illustration 45: Image Name List



Enter Report Name

In the *Enter Report Name* field, select the report that you are going to export.

Type in a comment that appears on the report. Do not apply a carriage return when typing. The text will wrap automatically for the finished report.

Illustration 46: Report Name

Conversion Formats

In the *Conversion Format* area, choose a file type. Typically select HTML.

In the *Media Label* field, enter a name for the CD.

Illustration 47: Conversion Format

Media Type

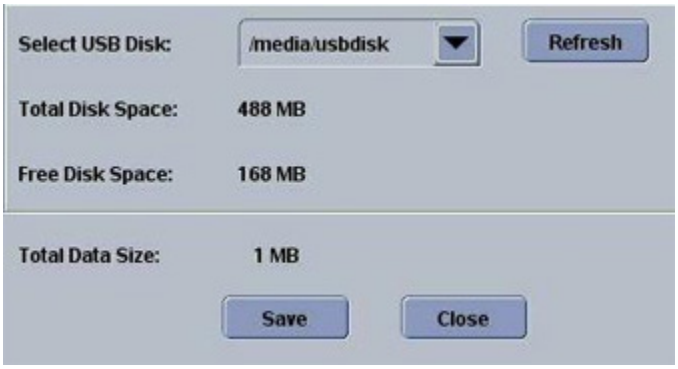
Select the media type to export the data as.

Illustration 48: Media Type Destination

Media information

This area of the Data Export tab changes based on the media selection.

Illustration 49: Media Information



Click the *Select USB Disk* menu to select a specific USB device if more than one device is inserted into the USB ports.

Click [Refresh] to update the Select USB Disk menu if you insert another USB device into a second port after you have opened the Data Export window.

The Total Disk Space, Free Disk Space, and Total Data Size fields provide information about the selected USB device. Verify that you have sufficient space on the device before you click Save.

Click [Save] to start the transfer process.

Click [Close] to close this area of the Data Export window.

FTP Selections

The User Name, Password, and IP Address fields are for the FTP destination site. Select *Save the Settings* to save only the target directory information. There must be a target directory at the IP address to successfully transfer files.

Illustration 50: FTP Selection Area

6.3 Compose a Report

1. From the File Manager, select the series you want to export.

   Only one series can be exported at a time.

2. From the File Manger, click the [Data Export] icon .

   Click Compose if it is not selected.

3. Review the images in the Compose image viewport.
   - Middle-click and drag to adjust the W/L.
   - Right-click and drag to adjust zoom factor.
   - Click and drag to scroll.
   - Press <Page Up> or [Page Down] to navigate through the images.
   - Click [Play] to view the images in a cine loop.

4. Click the *Conversion Format* menu and select an image format that is compatible with the movie player on your PC.

5. In the *Image Range Selection* area, choose the image range.

   If you want a subset of the images, select *Custom*, and then type the range in the text box.

6. Move the *Compression Factor* slider to select a value.

   The smaller the number, the higher the image quality and the larger the file size.

7. In the *Annotation* area, choose your desired annotation display format.

   If you want the patient name to be displayed as Anonymous with the exam number, select *Anonymous*.

8. Once you are satisfied with the image appearance (W/L, zoom, scroll), select Propagate Image Operations.

9. Enter a name for both the report and the folder (only use alpha numeric characters, no spaces).

10. Click [Add to Report].

    If you change your mind and decide not to add the data to the report, click Cancel from the progress bar screen.

11. To add another data set to the report, repeat these steps.

12. Click the *Export* tab to export the report (for details see *Export a Report*) or click [Quit] to exit Data Export.

6.4 Export a Report

This procedure assumes that you have composed a report in Data Export.

1. From the File Manger, select the series you want to export. Only one series can be exported at a time.
2. From the File Manger, click the [Data Export] icon  .
3. Click the *Export* tab.
4. From the *Export Report Name* list, select a report.
5. From the *Folder Name, Type Name*, and *Image Name* lists, select a data set.
6. Optional: Type a message in the *Comment* field. Do not press Enter, the system will adjust the text for the final report.
7. Choose a Conversion format, typically HTML.
8. To create a CD:
   a. Insert a compatible CD-R into the DVD-RW drive.
      - This is not the drive housed in the computer cabinet but rather the box that houses the CD/DVD drives located on the desk.
      - The only compatible media for Data Export is CD-R 700 MB with at least 4X write speed. DVDR is not supported. If a DVD-R is placed in the drive, the system will write to this media, but the integrity of the data cannot be guaranteed and the time for the system to recognize the media will be excessive.

   b. Carefully seat the media in the drive. Wait until the drive has sensed the media and the drive light goes off, then click [Create CD].

   c. Click [OK].

      When the CD writing step is completed, the CD ejects from the drive.

   d. Click [OK] to the CD Written Successful prompt.

9. To transfer a file via FTP:
   a. Click *Send FTP* to send the data to an IP address

   b. Complete all the fields on the FTP window and click [OK].

   c. Click OK to the Successful File transfer prompt.

10. To copy the data to a USB drive:
    a. Select a USB device.
    b. Click [Save].
11. Click [Quit].
    - Reports stay listed in the Export tab until you remove them.
    - Consider how long you will want to keep the file in the program based on if you need to burn another CD or file transfer the report again.

6.5 View a Report on a PC

1. Place the CD in the CD drive of a PC running Windows 2000 or XP.
2. If the report does not open automatically:
    - Click on the [My Computer] icon and open your CD or USB drive.
    - Click *INDEX* to open the file. The report opens in an Internet browser.
3. 3. When finished, select File > Close.
4. Remove the CD from the drive.

6.6 Delete Items

1. From the *Data Export* window , click the *Export* tab.
2. From the Export tab, select an item from Report, Folder, Type, or Image list.
3. Click the [Delete] icon

.
4. Click [Quit].

7 Patient Data

Removal of Patient Information

The Anonymous Patient feature assists you in removing patient identifiers by electronically removing certain exam information and replacing it with anonymous information. And Anonymous Patient can be created by exam, series, or image.

There are two modes available for you to remove patient identifiers: Full and Partial.

- Full mode removes most patient identifiers from an exam, image or series. However, the use of Full mode does not guarantee exams, series, or images will be rendered anonymous in compliance with applicable data privacy laws. You should review the exam, series, or image data processed by the feature to ensure compliance with applicable data privacy laws before sharing the information with third parties.
- Partial mode removes a subset of patient identifiers including, but not limited to, patient name, patient ID, patient date of birth, and patient age. Site name, exam, and series descriptions remain unchanged.

The level of annotation for Anonymous Patient is controlled by the Anonymous Patient Level in the Tool Chest. This is done after the patient has been scanned, thus you must enter a name when you start a new patient.

NOTE: Screen save images, such as Exam or Series text pages or Dose Report text pages are not anonymized, and are not included in the exam if anonymize by exam has been selected.

Table 12: Fields removed from exams, series, or images using Full or Partial Anonymous modes

Field	Full mode	Partial mode
Exam Number	ANON or ANONYMIZED	ANON or ANONYMIZED
Patient ID	ANON or ANONYMIZED	ANON or ANONYMIZED
Patient Name	ANON or ANONYMIZED	ANON or ANONYMIZED
Exam Description	ANON or ANONYMIZED	Shown
Series Description	ANON or ANONYMIZED	Shown
Birth Date	Removed	Removed
Age	Removed	Removed
Weight	Removed	Removed
Operator Name	Removed	Removed
Site Name	Removed	Shown
Sex	Blank	Blank
Referring Physician	Blank	Blank
Referring Physician	Blank	Blank

Anonymizing an exam is useful when:

- your radiologist wants to take the films to a conference
- you have scanned a test patient or volunteer and do not want the name displayed
- anytime you do not want the patient's name on the films (For example, films that are in a marketing display or in a trade show.)
- anytime you send images to GE

Edit Patient Information

Edit Patient allows you to edit certain patient information once the exam has been completed. You can only edit exams that were created on your system.

You cannot access Edit Patient if the exam you want to edit is currently in use. An exam is currently in use if New Patient, Network Send, Archive Save, 3D, Reformat, Denta Scan, Navigator, Image Viewer, or Floating Viewport is active. You cannot use Edit Patient if the exam displayed is in a free viewport. If you try to use Edit Patient when an exam is currently in use, which means the exam is on the archive, film, or network queue, an error message displays.

- Use Edit Patient during idle times in network receive, active recon, or archive restore. The system may hang if Edit Patient is started while the following operations are in progress:
  - Network Receive
  - Prospective or Retrospective reconstruction
  - Archive Restore
  - Film
- You cannot edit contrast or patient weight.
- Edit Patient will not update scan data files or completed patient information.
- If you edit an exam that has a saved 3D model, the 3D model is deleted from the exam. If you edit an exam and you have the 3D model selected when you select Edit Patient, you will not be able to edit the exam.
- There must be sufficient disk space available.
- All images should be reconstructed before editing. Scan data cannot be edited, only images. All remove images and post-processing (screen saves, reformat, 3D surface) should be done after editing. All images created before the edit do not contain the edited information.
- Any DICOM secondary screen captures such as Dose Report and SmartPrep screen saves and DICOM SR Dose Report will be deleted from the exam with Edit Patient Data.

Edit Patient Data Window

From the File Manager, right-click on the exam and then select [Edit Patient Info].

Illustration 51: Edit Patient Data Window

- If the text field is empty, click in the field, and enter the new data.
- If the field contains data, place your cursor in the field and select the text you want to change. Once selected, either press <Delete> or enter new data.
- If you make an error, you can reset the individual text box or all the text boxes. Click [Reset Selected Value] or [Reset All Values]. The Exam Number field cannot be edited.
- When entering data in the Birthdate field, the month, day, and year can be separated by a hyphen (-), forward slash (/), comma (,) or period (.). The year must contain four digits.

Edit Patient Data

Follow these steps to edit or add patient information.

1. From the Exam List in the File Manager, select the exam to be edited.
    - Only one exam number can be selected.

- The exam must be closed or ended.
- Exams can be edited multiple times.
- You can only edit exams that were created on your system.
- Edit Patient is not accessible if the exam you want to edit is currently in use. An exam is currently in use if New Patient, Network/Archive/Film queues, Save, 3D, Reformat, Denta Scan, Navigator, viewport, AutoFilm queue, Image Viewer, or Floating Viewport is active. An error message displays.
- To create a blank viewport, enter ***blank*** in the Accelerator Line.

2. Right-click on the exam and then select [Edit Patient Info].
3. At the alert window, click [Accept] to continue.
4. From the *Edit Patient Data* window, edit the text fields.
   - Click the text you want to edit and enter your changes.
   - The *Exam Number* field cannot be edited.
   - *Edit Patient* is not accessible if the exam is in use.
5. Click [Save] when you are satisfied with the changes. A confirmation window opens.
6. At the confirmation window, click [Accept].
   - A percentage countdown menu displays until *Edit Patient* is closed and the Patient Information Edit Log is updated.
   - It takes approximately two minutes to update a 100-image exam.
   - The original exam is replaced with the edited exam and is indicated by *e+1* in the description field. The number indicates how many times the exam has been edited.

Make a Patient Anonymous

Use this procedure to remove certain exam information and replace it anonymous information. An Anonymous Patient can be created by exam, series, or image. To set the annotation level to Full or Partial, see the *Set the anonymize patient annotation level* procedure.

1. From the File Manager, right-click on the exam and then select [Create Anonymized Copy].
2. Verify that there is enough disk space to create an anonymous patient exam.

   A progress bar displays the process's status.

Install a SMPTE Pattern

Follow these steps to install a SMPTE pattern to view BRH or quality assurance images. Once installed the images are in exam 1000, which can be selected from the Exam List. The patient Name is listed as SMPTE.

1. Click the [Mode] icon  .
2. Click [Service Mode].
3. Click [Install SMPTE Image].

Display a DICOM Header

Follow these steps to open a DICOM image header in a floating window. The window displays all image DICOM header information, including the DICOM tag, value, and description.

1. From the File Manager, select the exam.
2. From the *Series List*, select an image.
3. From the File Manager control area, click the [Image Header] icon.

   A window opens with the DICOM header information.

   NOTE: Refer to the DICOM Conformance Statement for Discovery CT870.

8 Manage Scan Data

8.1 Locking and unlocking scan data

You can lock scan data to prevent the system from automatically deleting it when it needs space for new exams and scans. When you are finished with the scan data from an exam or series, you can unlock it.

1. From the File Manager, select [Scan Database] from the *Source* menu.
2. In the Scan Data Manager, right-click the exam, series, or group you want to lock or unlock scan data.
3. To lock the scan data for the item, click [Lock Scan Data]. To unlock scan data, click [Unlock Scan Data].

8.2 Deleting scan data

You can delete scan data for an exam, series, or group.

1. From the File Manager, select [Scan Database] from the *Source* menu.
2. In the Scan Data Manager, right-click the exam, series, or group for which you want to delete scan data.
3. Click [Delete Scan Data].
4. The system asks you to confirm that you want to delete the scan data for the item. Click [Delete] to delete the scan data.

8.3 Sending scan data to USB or DVD

You can send scan data to a USB or DVD drive. You can send the full scan data, or an anonymized version of the data.

1. From the File Manager, select [Scan Database] from the *Source* menu.
2. In the Scan Data Manager, right-click the exam, series, or group for which you want to send scan data to USB or DVD.
3. Click [Send Scan Data].
   - If you want to send an anonymized version of the scan data, click [Anonymous Copy].
   - If you want to send the full scan data, click [Full Copy].

8.4 Add reconstruction

You can add a new reconstruction from the raw scan data.

1. From the File Manager, select [Scan Database] from the *Source* menu.
2. In the Scan Data Manager, right-click the exam, series, or group for which you want to add a new reconstruction.

3. Click [Add Recon].
4. The Reconstruction and Image Processing task list opens. The item you selected in the Scan Data Manager will be selected in the task list. Use the task list to create the reconstruction (as you would do after a scan).

   The Exam Summary page opens on the left monitor (as it does at the completion of a scan).

Chapter 18 Protocols

1 Overview

A protocol is a series of pre-programmed scan parameters used for imaging a particular part of the body. Protocols can be used for scanning, edited, viewed, copied, and saved with a different name to create a new user protocol, while preserving the original.

2 Protocols

A protocol must be selected in order to initiate the scanning sequence. Protocols are used as a basis for routine or established procedures. They save time by using preset established parameters. Once chosen for use, any protocol may have any parameters modified as needed for individual case purposes. The system comes with a set of GE Adult and GE Pediatric Reference Protocols that cover common types of examinations. You can use these protocols or modify them to fit particular clinical needs. Refer to known sources for techniques and dose information for viable parameters as proper techniques must be used to ensure image quality as well as patient safety.

2.1 Build protocols

Protocols are built using the *Protocol Management* feature. There are seven protocol categories:

- *Adult:* Category of protocols defined by your site for Adult patients. These protocols are custom protocols that your radiologist or physician likes to use.
- *Pediatric:* Category of protocols defined by your site for Pediatric patients. These protocols are custom protocols that your radiologist or physician likes to use.
- *Recently Scanned Protocols:* Category where a copy of the last 90 protocols reside exactly as they were used. These protocols can be copied and used but cannot be modified or deleted.
- *GE Reference Adult:* Category for a set of predefined protocols for Adult patients that cannot be modified but can be copied and used. These protocols are factory installed. They have been developed in collaboration with clinical partners to provide users with a convenient and clinical relevant starting point for tailoring your departmental protocols.
- *GE Reference Pediatric:* Category for a set of predefined protocols for Pediatric patients that cannot be modified but can be copied and used. These protocols are factory installed. They have been developed in collaboration with clinical partners to provide users with a convenient and clinical relevant starting point for tailoring your departmental protocols.
- *Service:* Category for protocols used by a service representative.
- *Manufacturing:* Category for protocols used by a manufacturing representative.

The protocols contain all of the scan parameters. There is space for 90 protocols in each of the 10 anatomical regions for adult protocols.

2.2 Use protocols

After entering the patient's information in the *New Patient* area, the operator chooses a protocol from one of the seven protocol categories (Adult, Pediatric, Recently Scanned Protocols, GE Reference Adult, GE Reference Pediatric, Service, or Manufacturing).

Once the protocol category is chosen, select an anatomical area and the desired protocol. Once the protocol is chosen and accepted, the scanning sequence is activated. All parameters for scanning a patient can be set up in a protocol. This saves time when prescribing scan parameters for each patient.

2.3 Edit protocols

Once a protocol is chosen, any parameter in the individual exam may be adjusted without affecting the established protocol. If an established protocol has a parameter or parameters you wish to permanently change, this can be done through the *Protocol Management* feature. If your system has been configured for EA3 Login, you must have permission to accept any changes in *Protocol Management*.

2.4 View protocols

Protocols can be viewed with the *Protocol Management* feature. Each series can be viewed, and scan values may be changed to see the effect on other values or other available options.

2.5 System options

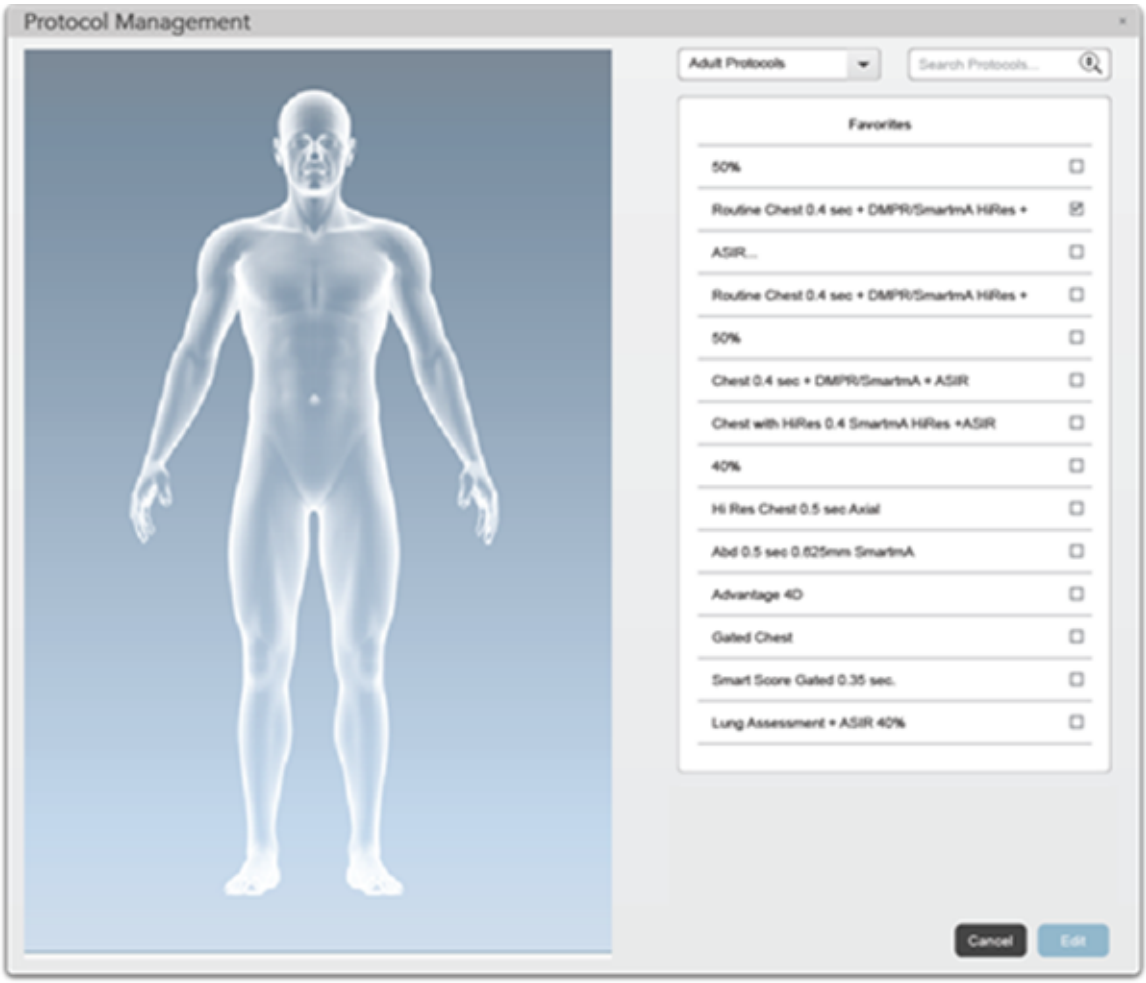
There are several option packages that may be purchased and installed on your system which include the setup of various protocols. You need to have some understanding of their functions if you are to use them in your protocols. These options include: Prospective Gating, Cardiac, and Auto Applications.

2.6 Protocol Selection screen

From the [Mode] icon, click [Protocol Management] to display the *Protocol Selection* screen.

Each protocol category contains 10 protocol groups. Each protocol group can contain up to 90 protocols.

Illustration 1: Protocol Selection screen in Protocol Management



2.6.1 Protocol numbers

The protocol numbering systems enable you to easily find a protocol based on a number convention. The first number indicates the protocol area you are using. The second number indicates which protocol you selected from that area.

- User area numbers: Adults = 1 to 10, Pediatrics = 11 to 20
- GE area numbers: Adults = 21 to 30, Pediatrics = 31 to 40

Enter the protocol number into the search field to narrow the protocol list to that specific protocol.

2.6.2 Anatomical Selector

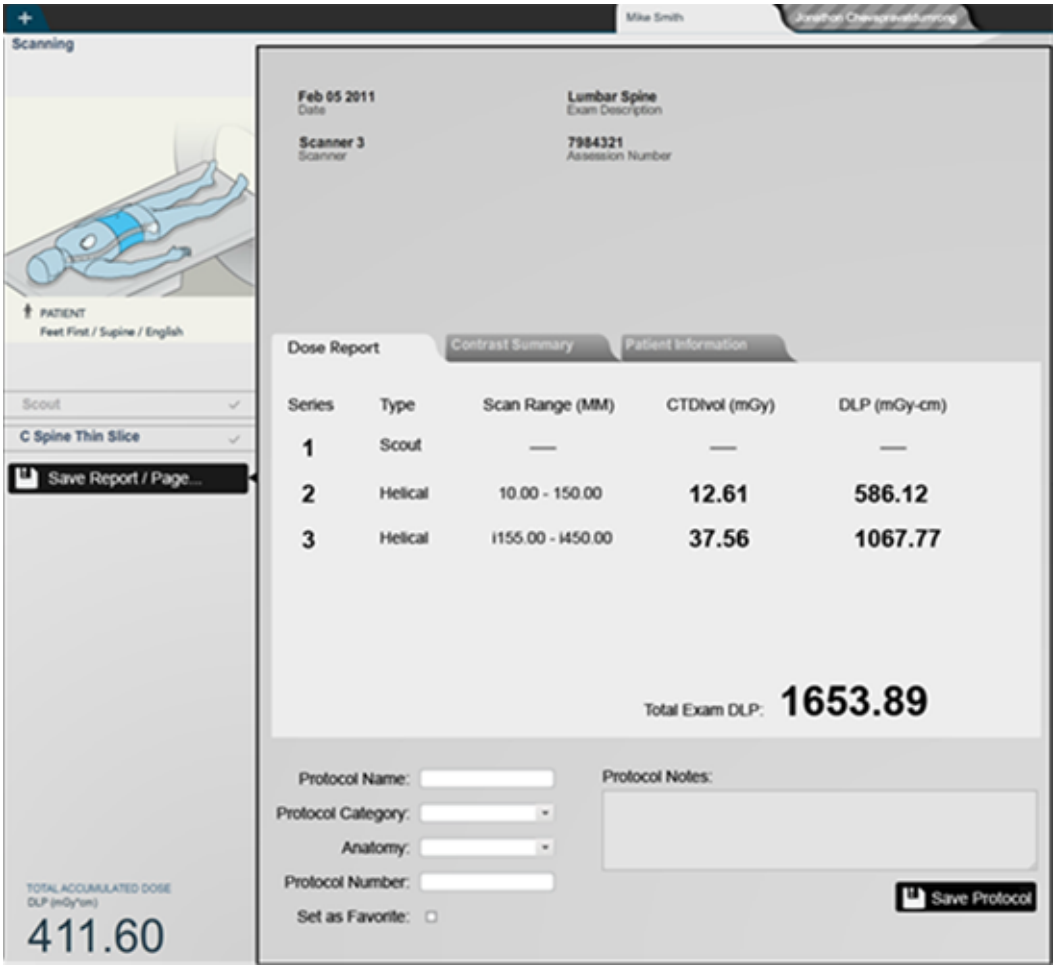
The *Anatomical Selector* area allows selection of a specific anatomical region in order to show only protocols related to that region.

2.7 Edit a protocol

Use this procedure to change the established user protocols on the system.

1. From the display monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. On the *Protocol Selection* screen, select the Protocol Category from the pull down.
   - There is space for 90 protocols in each of the Adult anatomical areas.
   - If you wish to edit Pediatric protocols, click [Pediatric].
   - For color coded Pediatric anatomical areas, there is space for 90 protocols in each of the different weight classifications. Head, Orbit, and Miscellaneous are not color coded.
4. Select an anatomical region.
   a. Scroll through the protocol list to find the desired protocol; or
   b. Use the search to find the desired protocol.
5. Select a protocol you wish to edit.
6. Click [Edit] if you are making changes to an existing protocol.
7. Modify the protocol parameters as needed.
8. Select [Save] to save the new parameters.
9. To save the edited parameters as a new protocol.
   a. Enter the desired protocol name.
   b. Select the protocol category from the pull down.
   c. Select the anatomy from the pull down.
   d. Select [Save].

Illustration 2: Protocol save screen



NOTE: Copy orientation and patient position is a feature that adjusts the patient orientation and position based on the prior series. For example, if the patient orientation and position is supine feet first, and the scout for the patient you are currently scanning, is prone, feet first, after the scout is acquired and next series is selected, the orientation and position values set in the protocol are automatically changed to the scout values.
Copy forward is a feature that allows you to duplicate the following scan parameters to any Secondary Recons (2 – 10) of the next series:

- Start/End
- Interval
- DFOV
- R/L and A/P centers

To activate copy forward, type **d** or **D** in the *Parameter* text field.

2.8 Add a protocol to Favorites

Use this procedure to add a protocol to a list of Favorites. Favorite protocols are protocols that are commonly used by a site.

1. From the display monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. On the *Protocol Selection* screen, select the protocol category from the pull down. The system will display a list of the most commonly used protocols for all body parts in this category.
4. As needed, click the desired anatomical body part to view that protocol list.
5. From the Anatomical Protocol list, right click the desired protocol and then click [Add to Favorites]. Repeat this procedure for each additional protocol to also be set as a favorite.

   Favorite protocols are displayed on the main protocol selection screen for each protocol category

2.9 Copy and paste a protocol

Use this procedure to copy protocols from the GE Reference Adult or GE Reference Pediatric category, or Adult or Pediatric category, into the Adult or Pediatric category. You can also copy a protocol within the User Adult or Pediatric category. A copied protocol can be used as a template to create different protocols with minor adjustments. Repeat the procedure for each additional protocol to be copied.

1. From the display monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. On the *Protocol Selection* screen, select a protocol category from the pull down.
4. As needed, click the desired anatomical body part to view that protocol list.
5. Select the protocol to be copied.
6. Right click and select [Copy].
7. Click the anatomical category to select the destination to paste the protocol.
8. Click on an empty protocol list number and then right click and select [Paste].
9. Rename the protocol, as needed.
   a. Click the protocol.
   b. Right click and select [Re-name] and then enter the new name.

2.10 Delete a protocol

Use this procedure to delete a protocol from your user defined list. This allows you to keep your protocol list current by deleting any unnecessary protocols.

NOTE: Only protocols in the *Adult* or *Pediatric* categories can be deleted.

1. From the display monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. On the *Protocol Selection* screen, select either the [Adult] or [Pediatric] protocol category.
4. As needed, click an anatomical category.
5. Select the protocol you want to delete.
6. Right click and select [Delete].
7. Click [OK] at the confirmation prompt.

3 AutoVoice

3.1 Record an AutoVoice message

The system has three pre-recorded voice message sets in nine selectable languages that cannot be deleted. Use this procedure to record up to 17 additional AutoVoice messages on your system (for each language).

1. From the display monitor, click the [Mode] icon.
2. Click [AutoVoice Management].
3. To record a message, select [Add message] from the drop down context menu.
    - The new message will be created with the AutoVoice message list for the selected language.
    - Every selection must have a name.
    - Title the name it so it is easily identifiable (i.e., Mary S. Inspiration), that way you know whose voice is being used and the content of the message.
4. Click [Pre-Message] next to the name you just entered.
5. Click [Record] button and begin message.
    - Click and hold [Record] until you are ready to begin your message. Normally, you are recording a pre-message first, e.g., “Take in a breath and hold it.” When you release the mouse button, the recording starts as indicated by the clock to the right of the button.
    - Begin your message right away.
    - Speak clearly toward the microphone located on the computer Scan Control Interface.
6. Click [Stop] button as soon as you finish speaking.
    - The total time of the message is displayed in the clock.
    - If you make a mistake, simply click [Stop] button and then repeat these steps.
    - Try to start and stop the recording as quickly as possible to avoid adding time to the beginning or end of a message.
7. Click [Post-Message].
8. Click [Record] button and begin your Post-Message.
9. Click [Save].
10. To hear a recorded message, click the selection's Pre- or Post- message and then click [Play] in the Message Management area.

3.2 Delete an AutoVoice message

It may be necessary to remove old or unwanted messages from the system as employees change or as different languages are required. Use this procedure to delete an AutoVoice message.

1. From the display monitor, click the [Mode] icon.
2. Click [AutoVoice Management].
3. On the *AutoVoice Management* screen, select the title of the message you want to delete.

   The three pre-recorded messages cannot be deleted.
4. Click [Delete message] from the drop down context menu.

4 kV Assist settings

4.1 Typical Clinical Tasks

Table 1: Typical Clinical Tasks

Typical Clinical Tasks	Scan Situation	Region of primary importance
CT Angiography (CTA)	iodinated contrast agents are used	enhanced tissue regions
Bone, non-contrast (BONE)	contrast agents are not used	bony regions
Soft Tissue, contrast-enhanced (C+)	iodinated contrast agents are used	both enhanced and non-enhanced tissue regions
Soft Tissue, non-contrast (C-)	contrast agents are not used	non-enhanced tissue regions

kV Assist recommendations for kV and NI/mA are optimized based upon typical clinical tasks or scanning and imaging conditions.

4.2 Dose Savings

The Dose Savings control gives the ability to fine-tune the balance between CNR and image noise. The Dose Savings adjustment can be set and saved for each protocol, to fine tune the Dose Savings per application. The adjustment of this parameter will primarily affect the mA/NI adjustment, but may also affect the kV selected. If even more or less Dose Savings is desired than can be achieved using the Dose Savings control, the baseline protocol values for kV, NI/mA may need to be adjusted for kV Assist to provide further changes for CNR and radiation dose.

In addition to the impact of Clinical Task and Dose Savings level on kV selection, there may be clinical situations in which the user wishes to lock out a kV or range of kV stations. This can be accomplished using the kV Range settings on the kV Control screen during protocol setup. For example, if the site does not want kV Assist to select 70 kV for head scans, the head protocol can be constructed with kV min = 80 kV and kV max = 140 kV. In this case, the kV Assist feature would only select kV settings of 80, 100, 120, or 140 kV.

One final consideration is that the site may not wish to deviate from their reference protocol unless there are substantial dose savings to be made. Because there are different preferences on what is substantial, an additional control (Minimum $CTDI_{vol}$ Adjustment) is provided in the kV Assist Configuration to set a minimum $CTDI_{vol}$ savings that must be met in order for a kV other than the baseline kV value to be suggested. For example, if the $CTDI_{vol}$ savings are less than a specified level, the site may not want to change the kV. This is handled appropriately by the kV Assist design.

4.3 Image display

Images of the same anatomy scanned with different tube voltages appear different. This is expected, due to Contrast-to-Noise Ratio changes. For example, images obtained with X-ray scan technique factors set by kV Assist could be brighter in areas (due to increased contrast) and noisier (due to increased noise). Even though similar information is present in the image, the change to the image appearance could be distracting. In order to minimize this change, kV Assist also provides the option for the system to modify the protocol's reference WW and WL (i.e., the WW and WL that would be used without kV Assist for an average patient).

Adjustment of the WW and WL (if selected in the protocol or scan) is based on the Clinical Task and kV Assist Dose Savings, as well as the reference WW and WL. In the case where image contrast is increased, the WL is adjusted to compensate for the brighter pixels. In the case where image noise is increased, the WW is adjusted to compensate for pixel variations. In addition, in order to provide the capability to fine-tune the display changes that are made (per scanner), an additional control is available in Protocol Management to set the strength of the WW and WL changes. Optimize WW/WL updates the window width and level values entered by the user.

4.4 mA Limits

When a scan is prescribed using AutomA, the scan setup uses limits for the min/max mA in order to allow the user to limit the range over which the system can modulate the mA. The maximum mA limit allows the user to restrict the maximum amount of radiation emitted from the system during the scan. Because of the interaction between tube voltage and tube current, however, the scanner output at a fixed mA value is very different between kV stations. This is especially important for kV Assist, since the scan kV may be different from the baseline kV in the protocol. This could result in very different behavior if the same mA limits are used.

For example, if you select a maximum mA limit of 440 mA at 120 kV, and then perform a scan at 80 kV (with the same 440 mA limit), the maximum mA output during the scan (at the maximum mA limit) could be 2-3 times lower than expected. This is equivalent in terms of maximum output to a scan at 120 kV with a mA limit of ~150-220 mA, which may not be the desired behavior. In order to prevent the user from having to perform this type of calculation manually in order to update mA limits when a new kV is used, kV Assist can be configured to automatically update the mA limits for the kV selected. In this case, the mA limits are set in order to achieve the same minimum / maximum scanner radiation output as at the baseline kV (up to the system limits). Alternatively, if the user prefers the same mA limits for all kV stations, kV Assist can be configured to not modify the mA limits.

Table 2: kV Assist Configuration parameters

Parameter	Description
Minimum $CTDI_{vol}$ Adjustment	Defines the amount of dose savings to be achieved before changing kV from baseline kV. Another way to look at it is - do not change the kV unless there is at least a specified amount of dose savings.
WW/WL Adjustment	Less, Normal, More sets the strength of adjustment in the WW/WL values when Optimize WW/WL is enabled.
mA Limits (AutomA)	Allows the system to change the minimum/maximum mA values as needed for the kV specified in kV Assist. Or, allows the system to operate within the minimum/maximum mA values specified for the protocol in AutomA for selection of kV in kV Assist.

4.5 Configure kV Assist adjustment factors

Use this procedure to set the configuration parameters, before using kV Assist.

1. From the scan monitor, click the [Mode] icon.
2. From the *Mode* drop down menu, click [kV Assist Management].
3. From the *kV Assist Configuration* screen, set the desired kV Assist adjustment factors.

a. Select the Minimum $CTDI_{vol}$ Adjustment.

b. Select the WW/WL Adjustment.

c. Select the mA Limits (AutomA).

- Allow system to change minimum/maximum mA values as needed for kV specified in kV Assist.
- Use the same minimum/maximum mA values (as specified within each protocol) for kV specified in kV Assist (default).

4.6 Build a protocol with kV Assist

Use this procedure to build a kV Assist enabled protocol and define the baseline Manual kV, Noise Index, or Manual mA values in the protocol.

1. From the scan monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. On the *Protocol Selection* screen, create a new protocol or select a protocol to edit.
4. Click [Edit] if you are making changes to an existing protocol.
5. Set the Scout parameters.
6. Select a Clinical Task.
7. Set the Axial scan parameters.
   a. On the Scan Settings screen, set the baseline parameters for Noise Index, mA, Slice Thickness, Rotation Time, Pitch, and SFOV.
   b. On the Scan Settings screen, open the kV and mA settings collection and then click [kV] and set the baseline Manual kV value.
   c. From the kV Control screen, click [kV Assist].
   d. Select a minimum and maximum kV value to define the kV Range.

      This selection allows the user to avoid using too low or too high of tube voltages.
   e. To further refine the mode, select a *Dose Savings* option.
   f. Select [Optimize WW/WL].
8. Continue with specifying the parameters for the series.
9. Verify the remaining parameters for the subsequent series in the protocol.
10. Save the protocol.

5 Auto Gating settings

5.1 Auto Gating workflow

Use this workflow to set up a cardiac protocol which uses Auto Gating.

1. Set up a User Profile using the Auto Gating Configuration.
2. Build a cardiac protocol using Auto Gating.

5.2 Set up a User Profile

5.2.1 Open Auto Gating Configuration

1. From the display monitor, click the [Mode] icon.
2. From the Mode drop down, click [Auto Gating Configuration].

   The *Auto Gating Configuration* screen displays heart rate ranges and scan settings for each range. These heart rate ranges and scan settings can be edited for the selected User Profile.
3. Select a *User Profile* from the *Profile* list.
   - *GE Adult Coronary* and *GE Adult Function* are the Profiles provided by the system that cannot be edited.
   - *User Profiles* can be edited and renamed. The initial configuration of the User Profile is the same as the *GE Adult Coronary* profile.
4. In the *Profile Name* text field, type a ***profile name***.
5. Click [Rename].

5.2.2 Set up the HR configuration

1. Define the Average Heart Rate / Max Beat to Beat HR Variation categories in the table.
   - To change the size of a table cell, click and drag the vertical or horizontal borders.
   - As you change the size of the cells in the table, the text in the Scan Setting Selections area updates to let you know what boundaries for the selected Average Heart Rate / Max Beat to Beat HR Variability category are selected.
   - As a category is selected in the *Average Heart Rate/Max Beat to Beat HR Variation* category table, the corresponding table cell highlights.
2. Define the ECG Gated Scan Settings.
3. Define the *Irregular Beat Override* settings.
   - Select *Recorded* and/or *Live* and define the limits.
   - Configuring a limit for Live causes Auto Gating to suggest the "Irregular Beat Override Parameters" if the number of Irregular Beats detected during the Live ECG monitoring is within the defined range.

- When the number of detected irregular beats falls into the Recorded or Live defined categories, the selected parameters for that category will override parameters in the Heart Rate / Variability Category table.

4. Click [Save].

5.3 Build a cardiac protocol using Auto Gating

Use this procedure to build a cardiac protocol using Auto Gating.

Considerations

Auto Gating Protocol Configuration Default Profile is set to GE Adult Coronary. Auto Gating automatically provides suggested settings based on the selection in the Default Profile in Auto Gating Protocol Configuration for any ECG-gated acquisition if an ECG recording has been done.

1. From the display monitor, click the [Mode] icon.
2. Click [Protocol Management].
3. From the *Protocol Selection* screen, click [Chest] and select an existing cardiac protocol.
4. Click [Edit] to add Auto Gating to an existing protocol.
   a. Select any series to have the heart rate automatically recorded during the acquisition.
   b. Click [Auto Gating].
   c. Select [On] and a default profile for the exam that will be used to provide Auto Gating scan settings.
   d. Select [On] to automatically record the ECG trace in the series or [Off] to not automatically acquire a recording.
   e. Click [Accept].
5. Verify the remaining parameters for the subsequent series in the protocol.
6. Save the protocol.

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Chapter 19 Data Privacy

1 Overview

Today, most countries have enacted data privacy laws to protect against the unauthorized access to and use of health information. Examples of global privacy laws are:

- Health Insurance Portability and Accountability Act (HIPAA)
- Directive 95/46/EC on Data Protection (the Data Protection Directive)
- Personal Information Protection and Electronic Documents Act (PIPEDA)

2 Data Privacy

2.1 Overview

GE Medical Systems has a longstanding reputation of providing customizable, clinical solutions to protect the privacy and security of your organization's unique clinical workflow, as well as your patient's confidentiality.

Please recognize the intended use of the product when determining how critical any privacy risk is, relative to patient care and safety. GE is very concerned with providing the best care to the patients, and in some cases we have determined that patient care is more important than the risk to privacy. In these cases we take every precaution to minimize privacy risk.

Security and Privacy are maintained across a Healthcare system. Any product that is placed into an uncontrolled environment will not be secure and cannot protect privacy. As we design scanners, we design them to be implemented in a "Secure Environment". A secure environment is based on multiple layers of security, a concept known as defense in depth. For example, a Best Practice that is gaining much attention places firewalls between departments, as well as at a DMZ, between all extranets, and the external Internet access point. In this example a radiology firewall may allow DICOM and HL7 traffic through, but no other protocols. These DICOM and HL7 protocols would be blocked at the DMZ and again at the Internet Firewall.

Data Privacy using EA3 requires you to log on to the scanner and log off when you are done scanning for a period of time. If you do not log off, the system will log you off and you will have to log back on. Data Privacy using EA3 contains the following permissions. You can have Administrative, GE Service, Standard User or Limited User. Standard User can perform scanning functions and modify protocols. Administrator can set up and delete users. Limited users can perform all scanning functions. GE Service can do all functions. You must have Administrative permission to add or delete users.

When you are adding users for local databases, certain rules apply. You must use the following guidelines:

- Users/Groups – Lower case letters and numbers only
- Users/ Groups – Can not start with a number
- Users/Groups – No limit on length
- Passwords – Must be at least one character long, no Null characters
- Passwords – Can contain uppercase letters, numbers and special characters

Administrator and Limited User permissions have different abilities when logging on. The Administrator permission can add users. The Standard User permission can scan and modify protocols in Protocol Management. The Limited User can only scan. Emergency User login has Limited User permission.

Data Privacy is an option that can be enabled or disabled by your Field Engineer through reconfiguration of your system.

2.2 Users and groups

Every person who has permission to use the system is a user. Users are set up by system administrators. These administrators may be IT personnel in an enterprise environment, or a site manager or lead tech in stand-alone environments. The administrator adds new users and assigns the users to a group, which dictates the level of privileges a person will have.

For example, a person named Sue Smith could belong to a group called technologists, radiologists, administrators, or any combination.

2.3 Groups and privileges

The group to which a person belongs has privileges. If you do not have an enterprise system, the assignment of group privileges is probably limited to those who have administrator privileges and those who do not. Additionally, permission for protocol edit may be assigned to groups. If your system is set up for enterprise login, your IT person or administrator use more of the features.

2.4 Open EA3

Use this procedure to open EA3 user interface.

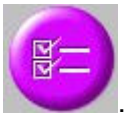
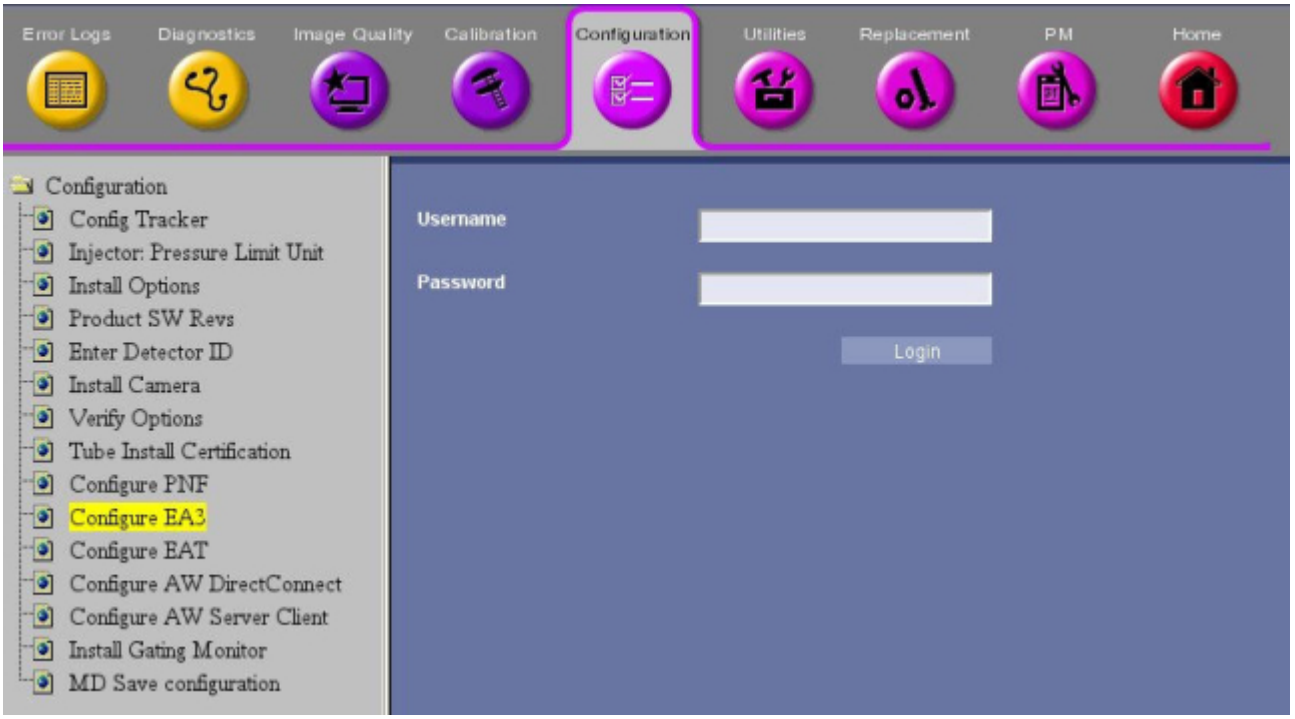
1. From the display monitor, click the [Mode] icon.
2. From the *Mode* menu, click [Service Mode]
3. From the *Service Mode* menu, click [Configuration] icon  .
4. From the *Configuration* list, select *Configure EA3*.

Illustration 1: Configuration menu

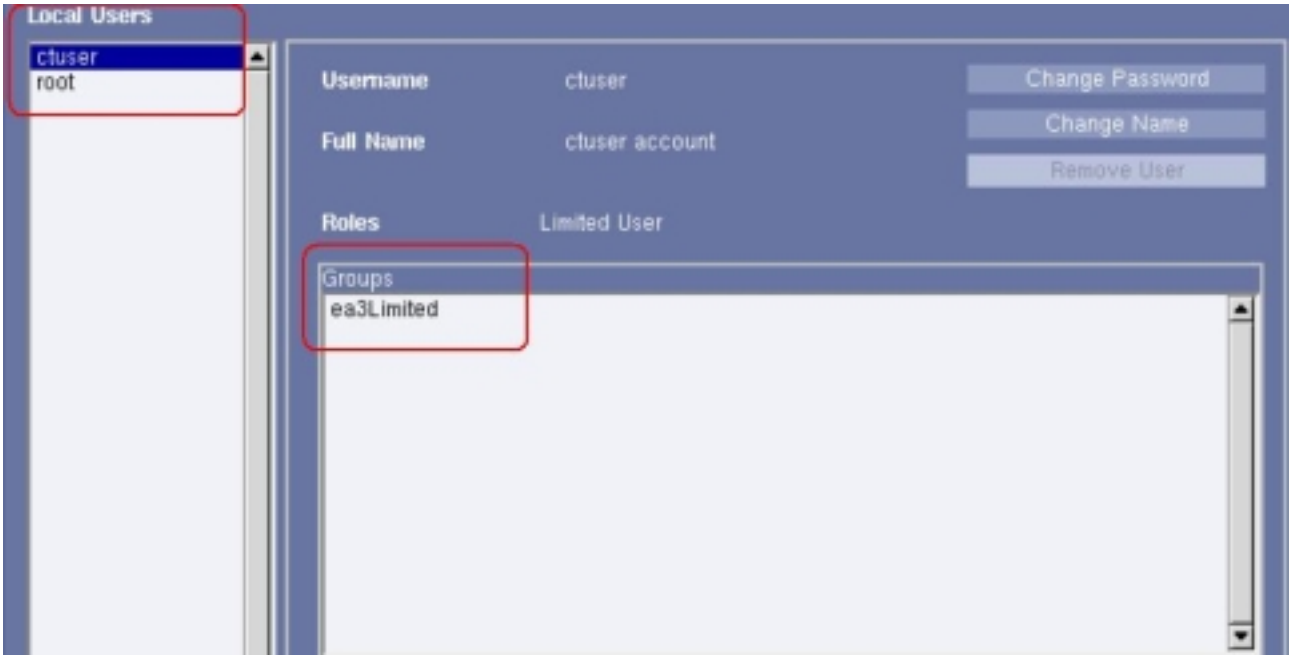


5. Type your ***username*** and ***password***.

   Consult your service engineer for user name and login.

6. Click [Login].
7. From the *Local Users* or *Group* tab, select a group or user.
   - Only one group and user can be in context at a time. If you choose multiple users, the system selects the top user in your selected list. Once a user or group is in context, you can make any necessary modifications to that user or group.
   - If there are no users or groups, then there no items in context. All of the buttons in the center panel are disabled until a user or group is added.

Illustration 2: Local User list and Group list



2.5 Configure local users

Use this procedure to add or remove users, change user group memberships, change user names, change user passwords, lock / unlock users, force users to change their password on next login, etc.

1. Open EA3.
2. From the *Local Users* tab, enter desired selections.
   - *Max Logon Attempts Before Lock* — the number of failed login attempts you can make before your account is locked for a certain number of minutes. When your account is locked, you cannot login, even if you provide the correct username/password combination. Either the specified time must elapse before you login again, or a user with an *ADMIN* role must login to the EA3 Administration component to unlock you. Locking only applies to local users. Enterprise user locking is managed by the enterprise server.

     If the administrator forcefully locks your account, the lock duration does not apply. You are locked until the administration unlocks you.
   - *Minimum Password Length* — the minimum length of a new password. If a password is below the minimum length already, setting this value has no effect on the password. For example, if your password is 8 characters, and someone changes the minimum password length to 10 characters, the 8 character password is still okay. However, next time you change your password, you must choose a password that is 10 characters or greater. The minimum password length feature only applies to local users. Password length restrictions for enterprise users are managed by the enterprise server.
   - *Lock Duration (Minutes)* — the number of minutes you stay locked if you become locked due to failed login attempts.

You can become locked in one of two ways.

3. Click [Apply Configuration] to accept your configuration changes. Alternatively, click [Restore Configuration] to undo any changes made that have not yet been saved.
   - If there was a problem with making the changes (such as an invalid value or a problem contacting the backend Servlet) an error message box appears with a description of the error.
   - If the changes are successful, then a brief message appears indicating that the changes were applied in a green label.

2.6 Add a local user

Use this procedure to add a local user.

1. Open EA3.
2. From the *Local Users* tab, click [Add Local User].
3. From the pop-up panel, type information for each of the following:
   - A unique user ID
   - Full Name
   - Password
   - Confirm Password
   - If an error occurs, a message box displays, and your changes are not committed to the database. Correct your errors and try again. Common errors include:
     - User name and password cannot be the same.
     - Password does not meet the minimum length requirements. Choose a longer password.
     - *Password* and *Confirm Password* box do not match. Make sure the passwords match.

Illustration 3: Add User screen

4. Click [Add User].

User restricted fields

Some fields and buttons on the *Local User* tab are not selectable under the following conditions. The following roles, users or groups have one or more of these criteria and they cannot be modified. Roles: limited user, standard user, GE service, administration. Users: root, ctuser, insite.

- *Permanent* — if a user is permanent, he can never be removed. When a permanent user is in context, the [Remove User] button is disabled.
- *Content Not Editable* — if a user is flagged as this, then their group memberships cannot be changed. When a 'content not editable' user is in context, the [Add To Groups], and [Remove From Groups'] buttons are disabled.
- *Password not changeable* — if a user is flagged as this, then the password cannot be changed, and the [Change Password] button is disabled.

2.7 Add a local group

Use these procedures to add a group.

1. Open EA3.
2. From the *Groups* tab, click [Add Local Group].
3. From the *Add Local Group* window, type and Enter a unique group name.

   If an error occurs, a message box displays, and your changes are not committed to the database. Correct your errors and try again. Common errors include:

   - Group name already exists in the database
   - Application session timeout

Illustration 4: Add Local Group

4. Click [Add Group].

   The group is highlighted in the *Local Groups* list box. All information and buttons in the center panel refer to the highlighted group.
5. To change a group's roles, select the *Roles* option boxes and click [Apply Roles].
   - A green label confirms the applied roles.
   - An error message box displays if it is unsuccessful.

2.7.1 Add memberships

1. Open EA3.
2. From the *Groups* tab, select a group in the *Local Groups* area.
3. In the *Group Members* area, click [Add Membership].

   A panel lists all the users that are eligible to be added to the selected group.
4. Select the users you want to add to the group.

   If no users are eligible to be added to this group, an error message displays.
5. Click [Add To Group].

2.7.2 Group restricted fields

Some fields and buttons on the *Group* tab are not selectable under the following conditions. The following roles, users or groups have one or more of these criteria and they cannot be modified. Roles: limited user, standard user, GE service, administration. Users: root, ctuser, insite.

- *Permanent* — if a group is permanent, it can never be removed. When a permanent group is in context, the [Remove Group] button is disabled.
- *Content Not Editable* — if a group is flagged as this, then its group memberships cannot be added or deleted. When a user belongs to a *Content Not Editable* group, the user cannot be removed or added from the group, therefore, the group name does not show up when you click [Remove From Group] or [Add to Group].
- *Password not changeable* — if a group is flagged as this, then the roles associated with that group cannot be changed. This property does not have a direct impact on what you can do on the *Local Users* tab.

2.8 Add an enterprise group

Use this procedure to add an enterprise group.

1. Open EA3.
2. From the *Group* tab, click [Add Enterprise Group].
3. From the *Add Enterprise Group* pop-up window, type and Enter a unique group name.

   If an error occurs, a message box displays, and your changes are not committed to the database. Correct your errors and try again. Common errors include:

   - Group name already exists in the database
   - Application session timeout

Illustration 5: Add Enterprise Group

4. Click [Add Group].
   - This action does not add an enterprise group, rather it provides EA3 the ability to manage roles for that group that already exist on the Enterprise directory server. For example, if you add a group *All Employees* as an *Enterprise* group to EA3, and assign that group with the *STANDARD* role, then any enterprise user that logs in through EA3 and belongs to the *All Employees* group has the *STANDARD* role.
   - You cannot manage the group memberships for Enterprise groups. This is managed by the directory server, not EA3. Therefore, whenever an Enterprise group is in context, both the [Add Membership] and [Remove Membership] buttons are blocked. This does not mean that no one belongs to the Enterprise groups, but rather that this is managed by the directory server and not EA3.
   - Once an enterprise group is added, it is automatically highlighted in the *Enterprise Groups* list box and it is *in context*. (A HIPAA term meaning that all information and buttons in the center panel refer to the selected user or group.)

2.9 Add or remove a user from a group

Use this procedure to add or remove groups listed in the *Groups* list.

1. Open EA3.
2. Select the *Local Users* tab.
3. In the *Local Users* area, select the user you want to modify.

   The groups that this user is currently a member are listed in the *Groups* area.
4. In the *Groups* area, click [Add To Groups] or [Remove From Groups].

Illustration 6: Groups

5. Select the group you wish to add remove for this user.
6. Click [Add Membership] or [Remove Membership].

Illustration 7: Add membership list

Illustration 8: Remove membership list

2.10 Change a user's full name

Use this procedure to change a user's name.

1. Open EA3.
2. From the *Local Users* tab, select a user.
3. Click [Change Name].
4. From the *Change Name* window, type a new name.

Illustration 9: Change Name

5. Click [Confirm Change].

2.11 Change a user's password

Use these procedures to change a user's password.

1. Open EA3.
2. From the *Local Users* tab, select a user.
3. Click [Change Password].
4. From the *Change Password* window, enter a password and confirm the password.

- A password can contain uppercase letters, numbers, and special characters.
- A password cannot contain the same characters/name as the login.
- An error message displays if the password does not meet the minimum length requirements. The minimum requirement are displayed in the *Minimum Password Length* field located in the top area of the *Local Users* tab. Change the password to an acceptable length.

Illustration 10: Change Password window

5. Click [Confirm Change] to accept the new password or [Cancel] to exit without changing your password.

Force a user to change password on next login

Use this procedure if you are an administrator to force a user to change his password.

1. From the *Local Users* tab, select a user.
2. From the bottom of the *Local Users* tab, select the *Change Password on Next Login* option.
3. Click [Apply Configuration].
   - The next time the user logs in, he will be required to enter a new password.
   - Once the new password is entered, the *Change Password on Next Login* option is de-selected.

2.12 Lock/unlock a user

Use this procedure to lock/unlock a user from login privileges.

1. Open EA3.
2. From the *Local Users* tab, select a user.
3. From the bottom of the *Local Users* tab, select the Locked toggle option.
   - When the *Locked* box is checked the user is locked from login even if he has a valid password.
   - If *Emergency User* is enabled on your system, the locked user can login as an *Emergency User*.

4. Click [Apply Configuration].

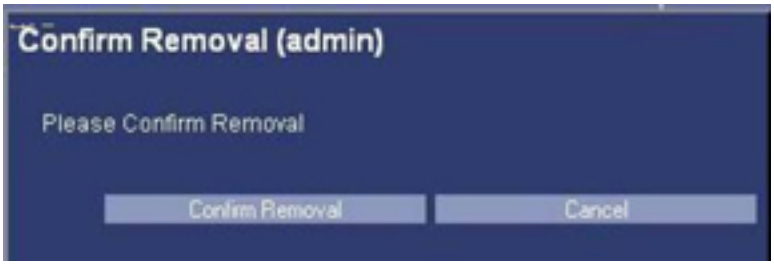
2.13 Remove a user, group, or membership

Use these procedures to remove items from the list.

2.13.1 Remove a user

1. Open EA3.
2. From the *Local Users* tab, select a user.
3. Click [Remove User].
4. From the *Confirm Removal* window, click [Confirm Removal].

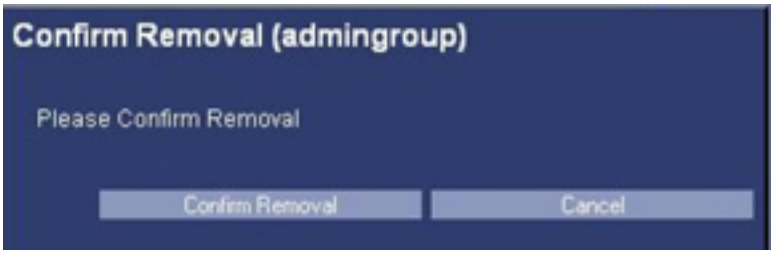
Illustration 11: Confirm Removal window



2.13.2 Remove a group

1. Open EA3.
2. From the *Group* tab, select a group.
3. Click [Remove Group].
4. From the *Confirm Removal* window, click [Confirm Removal].

Illustration 12: Confirm Removal window



2.13.3 Remove a membership

1. Open EA3.
2. From the *Group* tab, select a group.
3. Click [Remove Membership].
   - A panel lists all users that are eligible to be removed from the highlighted group. Select users you want to remove from the group.

- If no users are eligible to be removed from this group, an error message box displays.

4. Click [Remove From Group].

2.14 Configure EA3 properties

Use this procedure to configure EA3 application properties.

1. Open EA3.
2. From the *Applications* screen, enter the desired selections.
   - *Enable Authorization* — enable or disable authorization. If authorization is enabled, anyone logging in through EA3 (both local and enterprise users) must have a role. Anyone without a role is denied access, if authorization is turned on. The *User* role does not matter for logging into EA3, however, other EA3 client applications may restrict which roles can login.
   - *Emergency Logon Allowed* — enable or disable emergency access. If EA3 is used in GUI mode, this entry decides whether or not to display the [Emergency login] button. If this is disabled, emergency user access is prevented.
   - *Emergency Roles* — the roles assigned to the emergency user. The defaults allow an admin to assign a *Standard user* role, *Limited User* role, or both roles.
   - *Inactivity Timeout (minutes)* — The minutes that must elapse without any mouse/keyboard, etc. activity before a timeout is generated. When a timeout is generated, the EA3 logon screen is displayed. This value can be any positive integer, or it can be 0. If the value is 0, this indicates NO inactivity timeout; regardless of how much time has elapsed the system does not timeout.
   - *Display Last Logon Name* — enable or disable to display the username of the last user that has logged in on the EA3 logon screen.
   - *Administrator Message* — under certain circumstances / error conditions, the user of EA3 is asked to contact an administrator. This field allows the administrator to specify contact details for himself / herself and a custom message.
   - *Emergency Prompt* — the text that is displayed to any user logging in as emergency. The user is asked to enter information (usually their actual user name). This text appears in that prompt for information.
3. Click [Apply Configuration] to accept your configuration changes. Alternatively, click [Restore Configuration] to undo any changes made that have not yet been saved.
   - If there was a problem with making the changes (such as an invalid value or a problem contacting the backend Servlet) an error message box appears with a description of the error.
   - If the changes are successful, then a brief message appears indicating that the changes were applied in a green label.

2.15 Configure the Enterprise tab

Use this procedure to configure the properties necessary to make a connection to an Enterprise directory server (i.e., MSAD, Novell, etc.). The *Enterprise* tab is used by the site's IT1 or GE Service

personnel. It provides connectivity to the site's user database. If you do not have a network established in your hospital or clinic, this tab is not used.

1. Open EA3.
2. From the *Enterprise* tab, enter desired selections.
   - *Enable Enterprise Authentication* — login authorization. If it is unchecked, only local EA3 users can log in. If it is checked, both local users and enterprise EA3 users can log in and local EA3 user database is tried first.
   - *Cache Enterprise Users* — enables Enterprise users to be cached once they successfully login. If the Enterprise directory server is not available due to network or other issues the following scenarios occur:
     - If it is checked, a local record of an Enterprise user is kep and the you can login.
     - If it is unchecked, an *Enterprise* user is denied access.
     - Hashed passwords are cached, the actual password is not cached.
   - *Enterprise Authentication Latency (Seconds)* — the time the EA3 login process wait for a response from the Enterprise directory server. Often times, there is a network latency when connecting to servers, which is dependent on your network configuration. If the amount of time is reached without a response from the directory server, the EA3 login process returns a failed login. A value of 5 seconds is typically enough time to allow a properly configured directory server to respond, without causing undue user annoyance.
3. Modify properties in the lower two boxes of the *Enterprise* tab to make the Enterprise directory server connection.
4. Click [Apply Configuration] to accept your configuration changes. Alternatively, click [Restore Configuration] to undo any changes made that have not yet been saved.

2.16 Auto configuration

1. Open EA3.
2. From the *Enterprise* tab, click [Auto-detect Server Name].
   - The system searches for the Server Name of the directory server.
   - If the DNS allows service lookups, EA3 executes an auto-detection with the Enterprise Directory Server. If it cannot find the server, it is not an error. Continue with these steps to configure the Server.
3. In the *Server Configuration* text field, type the Server Name or IP address of the Enterprise directory server that EA3 should connect to.

   The system must either have DNS enabled or the system must have static information in a hosts file (i.e., /etc/hosts).
4. Select the Authentication type the directory server supports.

- If it is a Microsoft Active Directory Server, typically select Kerberos. If it is a Novell eDirectory Server, typically select LDAP. If you do not know, check with the owner of the directory server for information.
- If the enterprise server supports SSL connections, select the *'Use SSL'* option.
- If you use LDAP authentication without SSL, passwords are sent in the clear. This is not recommended. An alert is posted for this configuration. With kerberos and non-SSL, the authentication is encrypted, but the LDAP traffic is not.

5. Click [Test Connection] to test if the machine can connect to the directory server.
   - If the connection is successful, *CONNECTION OK* is displayed next to the [Test Connection] button.
   - If the connection is unsuccessful, *CONNECTION BAD* is displayed next to the [Test Connection] button.
   - If the connection is bad, then there is a problem connecting to the directory server. Check the following:
     - IP/server name
     - if system has DNS running
     - if the system can resolve the IP address / server name
   - Once the *Test Connection* procedure indicates that the connection is good.
6. Once the *Test Connection* is successful, select the type of directory server, either Microsoft Active Directory, Novell eDirectory, or another.
7. Click [Generate Defaults] to populate the *Realm Name*, *Format*, *DN*, *Login Attribute*, *First Name Attribute*, *Last Name Attribute*, and *Group Attribute* fields with default values for that directory server type.
   - If the directory type is MSAD, both the realm name and the DN are populated.
   - If the directory type is eDirectory, the realm name is left blank. If you are configuring a directory server that is not MSAD or Novell eDirectory, the configuration must be done manually. Get the correct LDAP property information from the owner of the directory server.
   - If this is a non-MSAD, non-eDirectory server, or is a server with a non-default configuration, manually change some properties, as needed.
8. Enter a ***username*** and ***password*** of a user that resides on the directory server.
9. Click [Login] and view the result information to see if the login is successful.
   - The First Name, Last Name, and any group memberships for the user are printed. If First Name, Last Name, or Group Memberships are not found, a warning is posted, which indicates that:
     - the LDAP properties are mis-configured (i.e., First Name Attribute, Last Name Attribute, and/or Group Attribute).

- the user does not have a First Name, Last Name, or any Group Memberships configured on the Enterprise directory server.

- If you get these warnings, talk with the owner of the directory server to verify you have everything set up correctly.
- If the test login succeeded and you are satisfied with the first name, last name, and group membership information, then your Enterprise directory server is properly configured.

10. Click [Apply Configuration] to accept your configuration changes. Alternatively, click [Restore Configuration] to undo any changes made that have not yet been saved.

2.17 Manual configuration

Use this information to connect to a directory server other than MSAD, Novell eDirectory, or any other system that has a custom configuration. The following LDAP definitions are for configuration properties that may need to be manually selected.

Format — set to *domain* or *dn*.

- *domain* is the 'MSAD' way of doing LDAP authentication (i.e <userId>@<realm name>).
- *dn* is the eDirectory, and most other directory servers use (i.e. loginAttribute=<userId>,<ldap base dn>) way of doing LDAP authentication. If you are connecting to a non-MSAD directory server, more than likely use *dn*.

DN — is the LDAP base DN of the LDAP server to which you are connecting. Typically this is the fully qualified domain name separated by a bunch of 'DC='. For example, if the fully qualified domain name of the directory server is 'example.com', it is likely that the DN is 'DC=example,DC=com'.

Login Attribute — is the LDAP attribute to be used for the unique user identifier, that is the user id to login. Set it to the unique identifier your server uses.

- On MSAD it is: *sAMAccountName*
- On eDirectory, it is typically: *cn*

First Name Attribute — is the LDAP attribute that is used for the user's first name.

Last Name Attribute — is the LDAP attribute that is used for the user's last name.

Group Attribute — is the LDAp attribute that is used to find group memberships for the user. On MSAD, it is 'memberOf'.

NOTE: EA3 finds all instances of this attribute (not just the first, like it does for other attributes). If a user belongs to more than one group, EA3 finds all memberships.

NOTE: Regarding LDAP parameter configurations, EA3 finds the first instance of the configured attribute for a user, except for Group Membership. If you configure the First Name attribute to be an attribute that is listed multiple times, EA3 assumes the first one found during an LDAP query is the correct First Name. For Group Membership, EA3 finds all instances of that attribute.

Save changes

No changes are saved to EA3 on a tab unless you click [Apply Configuration] before you navigate to another tab or click [Confirmation] on a popup panel. If there is more than one [Apply Configuration] button on a tab, click the one associated with the data you changed (the buttons are grouped with the data they manage in a bordered panel).

Click [Apply Configuration] or [Restore Configuration] and in 5 seconds a label appears indicating that the changes have or have not been saved, respectively:

- Enable Authorization
- Limited User
- Inactivity Timeout (Minutes)
- Emergency Prompt
- Apply Configuration

Chapter 20 System Management

1 Overview

Use these procedures for system management level functions.

Turn on/off extended CT numbers

Set the anonymize patient annotation level

2 Turn on/off extended CT numbers

Used this procedure to enable or disable extended CT number range.

1. Verify that the system is idle and all reconstructions are complete.
2. Click the [Mode] icon  , and then click [Preferences].
3. Click [Viewports].
4. Scroll through the Viewports preferences to find *Extended HU*. Click [On] to turn extended CT numbers on, or click [Off] to turn extended CT numbers off.

3 Set the anonymize patient annotation level

Patient de-identification or anonymizing an exam electronically removes certain exam information and replaces it with anonymous information. There are two levels to anonymizing patient information: Full and Partial.

Use this procedure to set the annotation level for patient anonymize.

1. Click the [Scanner Utilities] icon  , and then click [Anon Pat Level].
2. The system tells you what the current anonymize level is.
   - Click OK to change the patient anonymize level.
   - Click Cancel to keep the current patient anonymize level.
3. Set the desired level: **Full** or **Partial**.
   - Full mode is the most HIPAA-compliant mode.
   - ANON and the exam number are added to the Exam List.

NOTE: See Chapter 17, Patient Data for information about how to anonymize an exam, series, or image.

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Chapter 21 General Information

1 Introduction

This section provides a simple introduction to CT, or Computed Tomography, for people with no detailed physics or medical diagnostic education.

1.1 System Components

The system components are also described in the User Manual.

1.2 Emergency Stop

Emergency Stop procedures are described in the Safety chapter.

1.3 CT Description

Computed tomography (CT) is a medical imaging method employing tomography created by computer processing. Digital geometry processing is used to generate a three-dimensional image of the inside of an object from a large series of two-dimensional X-ray images taken around a single axial of rotation. The word "tomography" is derived from the Greek tomos (slice) and graphein (to write). Computed tomography is known as computed axial tomography (CAT or CT scan).

CT produces a volume of data, which can be manipulated, through a process known as windowing, in order to demonstrate various bodily structures based on their ability to block the X- ray/Röntgen beam. Although historically the images generated were in the axial or transverse plane, orthogonal to the long axis of the body, modern scanners allow this volume of data to be reformatted in various planes or even as volumetric (3D) representations of structures.

2 CT Operation Theory

The CT Scanner consists of the following subcomponents:

- X-ray source
- CT Detector
- Gantry
- Power Distribution Unit
- Table
- System Cabinet
- Scanner Desktop

2.1 X-ray Source

The source and detector components are housed on a gantry with a cylindrical patient bore. An X- ray tube that is part of the source subcomponent is housed on the rotating gantry, diametrically opposite to the detector. The high voltage generator is the second part of the X-ray source. It provides high voltage to the X-ray tube across the anode and the cathode, along with current to the filament, which is part of the cathode

The X-ray tube contains filaments, a cathode and an anode. The filament provides the electrons that create X-rays. The X-ray system generates a current that heats the filament until electrons start to “boil off” and break away from the filament. We refer to the filament current as “mA.” Increasing the mA increases the number of electrons that become available to make X-ray. Higher concentrations of electrons improve image resolution.

The X-ray system creates a high voltage, or kV, potential between the cathode and anode. The negative charge on the cathode repels the electrons that boil off the filament. The positive charge on the anode attracts the negatively charged electrons. The electrons strike the rotating anode target and displace electrons in the target material. This interaction creates heat and X-ray photons. The target rotates to help spread the heat over a larger area. Increasing the kV increases the electron strike speed, which in turn increases the intensity or “hardness” of the X-ray photon beam.

The X-ray tube's heat capacity and dissipation can determine the frequency and length of CT Exposures, or limit the mA. A Helical or Cine exposure can last up to 60 seconds and axial exposures last from 0.28 to 1.0 seconds.

2.2 CT Detector

The CT Detector is a wide coverage cone beam detector with multiple detector rows along the longitudinal plane. The Detector channels are arranged as an arc diametrically opposite to the X-ray tube on the rotating CT gantry. The detector consists of a scintillator that converts X-rays into light, diodes for light conversion into current and analog to digital converter that converts the current into digital signal. The Data Acquisition System (DAS) samples each detector cell up to about 2500

times per gantry rotation, amplifies and quantifies the current from the cells and transmits the resultant data to the scanner desktop.

256 rows = 256 unique physical cell locations in Z-axis Detector cell segregation in the Z-axis provides 3-D post-patient collimation.

2.3 Gantry

The stationary and rotating structure and drive system which controls the rotation and angular positioning of the Detector and X-ray Source.

Variable rotation scan speeds (0.28, 0.35, 0.4, 0.5, 0.8, 1.0 seconds per rotation).

2.4 Power Distribution Unit

The Power Distribution Unit, or PDU distributes power to the rotating gantry, patient table and the scanner desktop.

2.5 Table

The Table provides support and vertical/longitudinal motion of the patient relative to the CT scanner. The Table also mechanically houses and electrically interfaces to the integrated ECG unit. This subcomponent includes patient positioning and support accessories (pads, straps, poles, headholders) as well as foot pedals.

2.6 System Cabinet

The System Cabinet subcomponent provides pre-processing, image reconstruction, post-processing and scout image construction operations on data available from scan data management. It includes both the software and computer hardware for image generation and scan data acquisition.

2.7 Scanner Desktop

The Scanner Desktop provides the software user interface in the control room of the scanning suite for all system operations. It governs system operation and workflow until user confirms a scan prescription (resuming control after scan completes), and includes both the software and scanner desktop hardware.

Illustration 1: CT System Illustration

(b)(4)Draft Product Specs

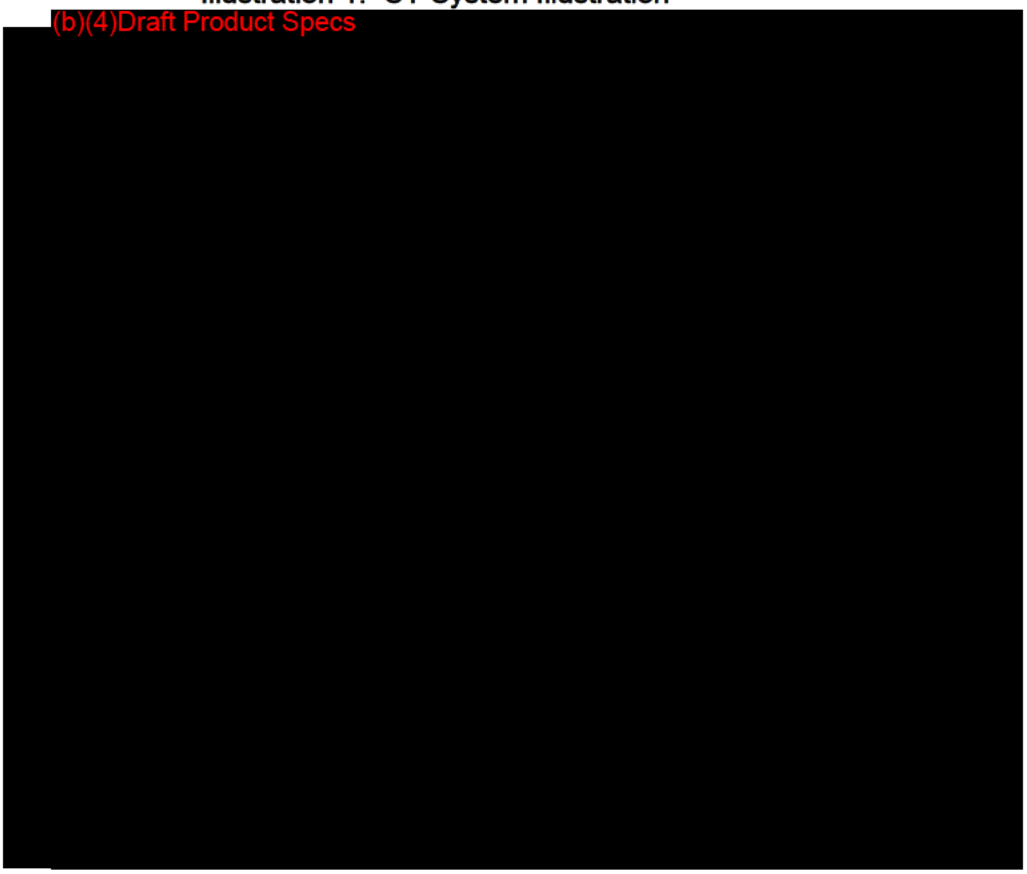


Table 1: CT System Description

Number	Description
1	X-ray must reach the detector's reference channels at the edges of the Scan Field of View (SFOV)
2	X-ray Tube
3	Centered Patient
4	Gantry Opening
5	Detector DAS

3 General Information

3.1 Gantry Coordinate System

X, Y, Z: Scanner gantry coordinate system:

- X=Tangent to circle of rotation.
- Y=Radial (from ISO toward tube focal spot).
- Z=Longitudinal (in/out of the scan plane).

Illustration 2: Gantry Coordinate System

(b)(4)Draft Product Specs

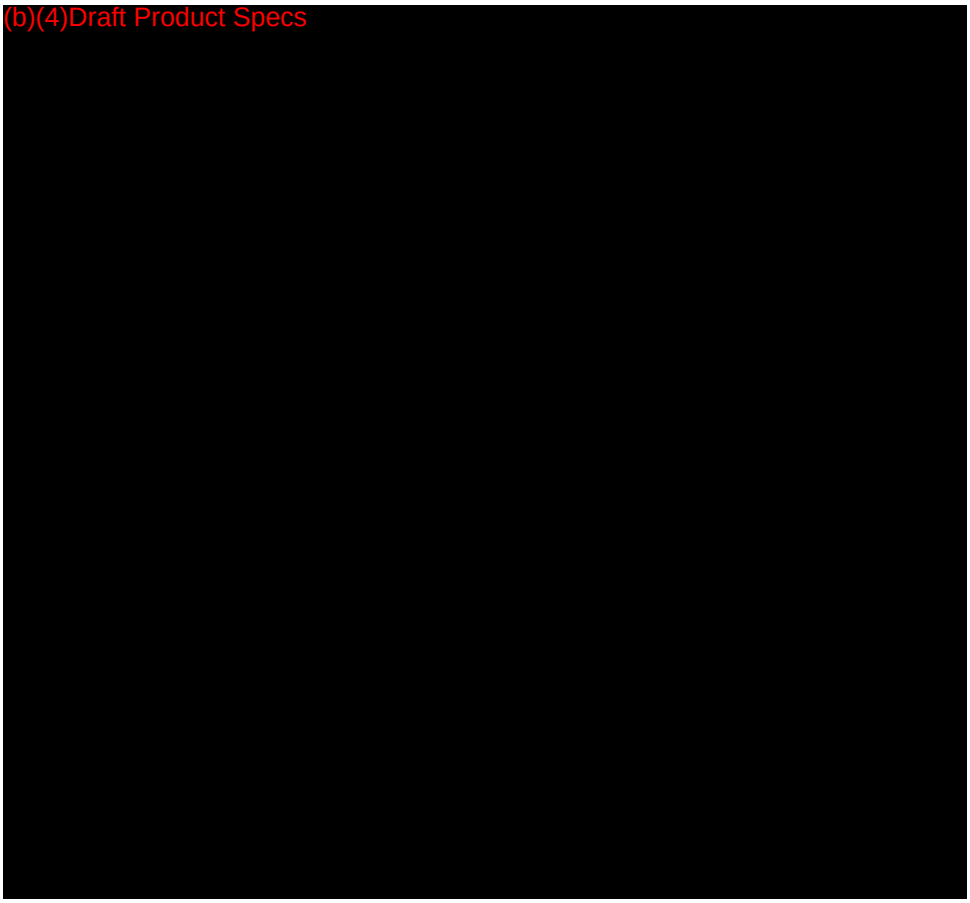


Table 2: Scanner Geometry

Parameter	
ISO Center Height	1026 mm
Focal spot to ISO Center	625.6 mm
Focal spot to detector	1097.6 mm
SFOV	500 mm
Gantry Bore Diameter	795 mm

3.2 Patient Scanning

Table 3: Table Scan Length

Scan	Scan Length (mm)
Scout Scans	2000 mm
Axial/Cardiac Scans	2000 mm
Helical Scans	> 1850 mm

NOTE: Helical scan range varies based on the helical pitch and gantry rotation speed selected.

Maximum patient weight capacity is 227 kg (500 lbs).

4 Network

4.1 Purpose of Discovery CT870 Scanner Connection to Network

The Discovery CT870 Scanner is intended to be connected to a network in order to support the following functionality:

- DICOM services to retrieve images from other DICOM-compliant machines
- DICOM services to push images to other DICOM-compliant machines
- DICOM services to query for images on other DICOM-compliant machines
- DICOM services to print images on DICOM complaint printers
- DICOM services to confirm that images have been permanently stored on a DICOM-compliant machine
- DICOM services to get DICOM modality worklist information from a remote hospital or radiology department information system computer
- DICOM services to allow a Modality Performed Procedure Step to be communicated to the Hospital/Radiology information system
- DICOM services to verify the remote DICOM system is connected properly to the scanner device
- Services to provide authentication and authorization against Enterprise directory servers

All of the above features are optional on the Discovery CT870 Scanner.

4.2 Network Interface Technical Specifications

Connection Name:	Hospital network port
Physical network connection type:	IEEE 802.3-1998 1000/100/10 BaseT Ethernet
Speeds and duplex modes supported:	10Mbps, 100Mbps, and 1Gbps half and full duplex Auto-negotiate
Default IP Address (from factory):	IP Address – 192.9.101.1 Subnet Mask – 255.255.255.0 Gateway – empty
IP addressing:	IPv4 static
QoS Support:	n/a

4.3 Network Information Flows Specifications

Flow Name	DICOM image retrieve
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Get a DICOM image or set of images from a network device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below

Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	CT Image Storage MR Image Storage Enhanced SR X-Ray Radiation Dose SR – CT Radiation Dose RT Structure Set Storage Positron Emission Tomography Image Storage
Ports (default)	4006
Traffic characterization and bandwidth requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency max	n/a

Flow Name	DICOM image push
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Send a DICOM image or a set of images to a network device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	CT Image Storage MR Image Storage Grayscale Softcopy Presentation Sate Storage Enhanced SR X-Ray Radiation Dose SR – CT Radiation Dose RT Structure Set Storage Positron Emission Tomography Image Storage
Ports (default)	4006
Traffic Characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency Max	n/a

Flow Name	DICOM image query
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Find a list of DICOM images from a network device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Study Root Query/Retrieve Information Model - FIND Study Root Query/Retrieve Information Model - MOVE
Ports (default)	4006
Traffic Characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency Max	n/a

Flow Name	DICOM Storage Commit
Network Connection on device	Hospital network port

Usage Type/Function/Purpose	Used to confirm that local DICOM images have been permanently stored on a remote DICOM device
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Storage Commitment Push Model SOP Class
Ports (default)	4006
Traffic Characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency Max	n/a

Flow Name	DICOM Modality Worklist Information
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Transfer patient information for HIS/RIS system to CT scanner
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Basic Modality Worklist Information Model – FIND SOP Class
Ports (default)	4006
Traffic Characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency Max	n/a

Flow Name	Modality Performed Procedure Step
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Send a report about a performed patient exam to the HIS/RIS system
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Modality Performed Procedure Step SOP Class
Ports (default)	4006
Traffic Characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency Max	n/a

Flow Name	DICOM Print
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Send a DICOM image to a DICOM printer
Licensed/optional/required	optional

Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Basic Grayscale Print Management Meta SOP Class Basic Color Print Management Meta SOP Class Print Job SOP Class Printer SOP Class
Ports (default)	4006
Traffic Characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency Max	n/a

Flow Name	Enterprise Authentication / Authorization
Network Connection on device	Hospital network port
Usage Type/Function/Purpose	Authenticate local user against Enterprise Server
Licensed/optional/required	optional
Communication Partner Device/IP Address/Network	Any network device supporting the DICOM application layer protocol(s) listed below
Middle Layer Protocols	TCP/IP
Application Layer Protocol and Encoding	Microsoft Active Directory / Novell eDirectroy
Ports (default)	3002, 3003, 3004, 6386
Traffic Characterization and Bandwidth Requirements	On demand, local user initiated. The bandwidth is dependent on the local site.
Latency Max	n/a

4.4 Required characteristics and configuration for network support of Discovery CT870 Scanner specifications

The network must meet the specific requirements above for all traffic flows associated with the subset of features, use cases and workflow required by the responsible organization's users.

In addition, the network must be "flat" (limited to a single IP broadcast domain).

4.5 Remote Host Parameters

The Network function has new enhancements to support DICOM networking. When adding or updating a remote list, there are some new parameters needed. All of the following information, except for Comments, needs to be provided in order to set up a remote host:

- The Host name to be entered is the name of the device. If the device is DICOM, the name must match exactly to the name given to the device.
- The Network address of the device is provided by the institution's network administrator.
- The Network protocol is DICOM. If the Discovery™ CT870 will be sending to this device, the device must be DICOM and the DICOM network protocol must be selected.
- The Port number is unique to the device. If the device is an Advantage Windows workstation or HiSpeed CT/i, X/i, or NX/i system, the number will be 4006.

- The AE Title is unique to the device. If the device is an Advantage Windows workstation or another GE Medical Systems system, the AE Title will be the same as the Host name.
- The Comment field allows you to input a comment.
- The Archive Node refers to the archiving responsibility of the device:
  - If Auto is selected, the CT system will automatically check to see if the device is a Storage Commitment Provider.
  - If Yes is selected, the device will be responsible for archiving images. When the device has received and saved the images, a notification message will be displayed on the scanner desktop and the Archive status for the exam will be “A” for archived.
  - If No is selected, the device will not be responsible for archiving.

  NOTE: The device must be a Storage Commitment Provider in order for remote archive node to function.
- Access to the local host refers to the device's ability to access the Discovery™ CT870. Select Yes if you want the device to be able to send to and/or query the Discovery™ CT870.
- The Custom search feature enables the Custom search dialog box to be automatically displayed when you select receive from the remote browser. If Yes is selected, the feature is enabled. If No is selected, the Custom search dialog box will not automatically be displayed. You can, however, get to the search feature once the remote browser is displayed, by simply selecting Search, on the remote browser.

4.6 Network Compatibility

The BrightSpeed Series, LightSpeed QX/i, Plus, Ultra, RT, RT^{16}, Xtra, Pro^{16}, Pro^{32}, VCT, Optima CT660, Optima CT520, Optima CT540, Optima CT580, Discovery CT590, Discovery™ CT750 HD and Discovery™ CT870 image formats are DICOM. This image format may only be transferred between systems using a DICOM network protocol. The receiving station must support DICOM receive for LightSpeed images to be transferred (send or receive) to it.

Use the following table for network compatibility. The table lists the network protocol to use and the features available for that system. The far left column lists the system the user is at (from).

Table 4: Network Compatibility

From	To			
	BrightSpeed Series, BrightSpeed Select Series, LightSpeed™ QX/i, Plus, Ultra, RT, RT16, Xtra, Pro16, Pro32/VCT. Discovery™ CT870, Discovery™ CT750HD, Optima CT660, Optima CT520, Optima CT540, Optima CT580, Discovery CT590	**HiSpeed CT/i**	**HiSpeed NX/i, X/i, or QX/i**	**3rd Party DICOM Station**
BrightSpeed Series, BrightSpeed Select Series, LightSpeed™ QX/i, Plus, Ultra, RT, RT16, Xtra, Pro16, Pro32/VCT. Discovery™ CT870, Discovery™ CT750HD, Optima CT660, Optima CT520, Optima CT540, Optima CT580, Discovery CT590	DICOM Query Send Receive	DICOM Query Send Receive	DICOM Query Send Receive	DICOM* Query** Send Receive**
HiSpeed CT/i	DICOM Query Send Receive	DICOM Query Send Receive	DICOM Query Send Receive	DICOM* Query** Send Receive**
HiSpeed FX/i, DX/I, LX/i	DICOM Query Send Receive	DICOM Query Send Receive	DICOM Query Send Receive	DICOM* Query** Send Receive**
3rd Party DICOM Station	DICOM Query Send Receive	DICOM Query Send Receive	DICOM Query Send Receive	DICOM* Query** Send Receive**

* Some 3rd party stations use the ODINA network protocol. In this case use DICOM protocol and port number 104.

** Query capability is available only if station is a query retrieve provider.

NOTE: LightSpeed™ VCT, LightSpeed™ Pro32, BrightSpeed based systems do not support Advantage Network Protocol.

Table 5: Advantage Windows Network Compatibility

From					
	AW 1.X	**AW 2.X**	**AW 3.X**	**AW4.X**	**BrightSpeed Series, BrightSpeed Select Series, LightSpeed QX/i, Plus, Ultra, RT, RT16, Xtra, Pro16, Pro32/VCT Select, VCT/ VCT XT or Discovery™ CT870, Discovery™ CT750HD, Optima CT660, Optima CT520, Optima CT540, Optima CT580, Discovery CT590**
BrightSpeed Series, BrightSpeed Select Series, LightSpeed QX/i, Plus, Ultra, RT, RT16, Xtra, Pro16, Pro32/VCT Select, VCT/ VCT XT or Discovery™ CT870, Discovery™ CT750 HD, Optima CT660, , Optima CT520, Optima CT540, Optima CT580, Discovery CT590	DICOM Send	DICOM Send	DICOM Send	DICOM Query Send Receive	DICOM Query Send Receive
AW 1.X	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive
AW 2.X	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive
AW 3.X	SdC Net V1 Query Send Receive	SdC Net V2 Query Send Receive	SdC Net V3 Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive
AW 4.X	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	SdC Net Query Send Receive	DICOM Query Send Receive

NOTE: Advantage Windows systems do not support Query Retrieve provider. Send images from the Advantage Windows to the BrightSpeed Series, LightSpeed™ QX/i, LightSpeed™ Plus, LightSpeed™ Ultra, LightSpeed™ Pro16, LightSpeed™ Pro32/VCT Select, LightSpeed™ VCT/VCT XT, Discovery™ CT870, Discovery™ CT750HD, Optima CT660, Optima CT580, Optima CT520, Optima CT540, Discovery CT590.

NOTE: Optima CT660, Optima CT520, Optima CT540, Optima CT580, Discovery CT590, Discovery™ CT870, Discovery™ CT750HD, LightSpeed Pro32/VCT Select, LightSpeed VCT/VCT XT, LightSpeed Pro16, LightSpeed16, Ultra, Plus, QX/i, BrightSpeed Series, or HiSpeed QX/i PC Based Systems do not support Advantage Network Protocol.

5 System Operational Modes

5.1 Overview

The system provides powerful data collection capability with following scan modes:

- Scout
- Axial
- Cine
- Helical
- Cardiac Axial

5.2 Scout

Scout imaging is used for anatomical location in conjunction with scan and recon prescription, to provide an anatomical cross-reference for axial images, and to provide quick feedback to the user as to the anatomy scanned. Scout supports the following features:

- Selectable kV (70, 80, 100, 120, 140 kV)
- Tube current limited to 250 mA with large focal spot
- Approximately 100 mm/sec table speed
- Detector coverage: 5 mm
- Scout orientation: 0, 90, 180, 270 degrees

5.3 Axial

Axial imaging features include:

- All kV and mA stations available, dependent on generator and tube limitations.
- Rotation speeds: 0.4, 0.5, 0.8, 1.0 second
- Detector coverage: 5, 40, 80, 120, 160 mm
- Variable image thickness selections: 0.625, 0.625z overlapped, 1.25, 2.5, and 5.0 mm
- Sample rates: 984 Hz-8571Hz
- Discovery™ CT870 can acquire up to 512 axial slices per rotation

5.4 Cine

Cine imaging features include:

- All kV and mA stations available, dependent on generator and tube limitations

- Maximum scan time: 60 seconds
- Rotation speeds: 0.4, 0.5, 0.8, 1.0 second
- Detector coverage: 5, 40, 80, 120, 160 mm
- Variable image thickness selections: 0.625, 1.25, 2.5, and 5.0 mm
- Sample rates: 984 Hz-8571Hz
- Discovery™ CT870 can acquire up to 512 axial slices per rotation

5.5 Helical Scans

Helical imaging features:

- All kV and mA stations available, dependent on generator and tube limitations
- Maximum scan time: 60 seconds
- Rotation speeds: 0.4, 0.5, 0.8, 1.0 second
- Detector coverage: 40 mm
- Variable image thickness selections: 0.625, 1.25, 2.5, 3.75, and 5.0 mm
- Sample rates: 984 Hz-6240 Hz
- Pitches: 0.516:1, 0.984:1, and 1.375:1

Helical Image Interval

The system has the ability to generate images at very small spacing and thereby exceed the number of native acquisition channels. When the scanner operates in a helical mode of data acquisition with its 64x0.625 mm detector configuration and a 1.375:1 helical pitch, images can be reconstructed spacings as small as 0.001 mm. The average number of slices (images) per gantry rotation is calculated by dividing the total number of reconstructed slices (images) by the number of rotations during the data acquisition.

5.6 Cardiac Axial

Cardiovascular imaging utilizes ECG-gating to target specific phases of the cardiac cycle, and a weighted reconstruction algorithm to increase temporal resolution. In this mode, projection data is acquired for at least one rotation, with an effective image temporal resolution of approximately half of the gantry rotation time.

Cardiac Axial acquisition is a prospectively ECG-gated scan mode, where the heart rate is monitored and the R-Peak triggers the acquisition of data for a specified range of phases in the cardiac cycle (using R-peak to R-peak phase percent or ms after R-peak). The system coverage of up to 160 mm at one table location is enough to cover many cardiovascular applications in a single scan. However, if more than one table location is required, the system will determine required collimations and table locations based on user specified scan range, scan field of view,

the primary recon display field of view (DFOV), and image offsets (A/P and R/L). The system also allows the user to control the amount of scan overlap based on user selection (min, medium, or full) to balance image quality and dose (see User Manual for description of these settings).

The Heart Rate Variation Allowance parameter (specified in BPM, typically based on the maximum beat to beat variation during a short breath-hold) can be used to increase the scan duration in order to ensure requested phases are acquired in the presence of heart rate variation. A low and stable heart rate will allow the shortest scan duration, which will minimize patient dose.

Cardiac Axial imaging features include:

- Scan speed of 0.28 or 0.35 seconds
- Compatible with Hi Res mode

  All kV and mA stations available, dependent on generator and tube limitations
- Compatible with Auto mA (See Automatic Exposure Control)
- Image thickness of 0.625 mm or 2.5 mm
- Reconstruction algorithms optimized to cardiac imaging

5.7 ECG-Modulated mA

5.7.1 Electrocardiograph Tube Current Modulation

Modulating tube current (mA) based on an electrocardiograph (ECG) signal is a technical innovation that significantly reduces radiation dose for cardiovascular imaging applications.The concept is based on the fundamental principles of cardiac CT imaging.

5.7.2 ECG-Modulated mA Theory

The motion of the heart has always been challenging for diagnostic imaging of the heart and surrounding areas. Motion can cause blurring and mis-registration artifacts in images. Heart motion increases with a patient's heart rate and for some heart rates there may not be one single optimal phase of the heart cycle which minimizes motion for all coronary arteries. For this reason, the CT system allows the user to set up a cardiac acquisition window with up to 3 independent parts for imaging different periods of the heart cycle. The user may specify phases of the heart cycle to acquire and the relative tube current level for each part of the acquisition window. The system responds to the patient's heart rate and modulates the tube current to acquire the cardiac phases requested by the user. This tube current modulation, in conjunction with prospective ECG gating of the X-ray exposure, allows the system to acquire the requested cardiac phases while minimizing dose to the patient. If Auto Gating is enabled, the system will automatically adjust the scan parameters based on the patient's heart rate and heart rate variability during scan prescription. This allows the system to intelligently respond to heart rate changes and optimize the scan parameters prior to acquisition.

The tube current utilized for cardiac acquisition window part 1 (100% mA) may be set by the user manually or automatically by the system (see Auto mA) based on the user specified Noise Index (NI).

In addition to the user-specified ECG-based mA modulation, the system will also modulate the tube current during each cardiac acquisition phase to minimize patient dose. Although projection data is acquired for a duration of at least one complete rotation, the temporal resolution is, on average, half of the gantry rotation time (e.g. 140 ms when the gantry rotation time is 280 ms). The additional projection data beyond 140 ms is used for the outer few slices, and for image quality improvements throughout the volume. The system typically modulates the tube current (mA) to 20% for the outer views, so that the additional image information can be provided with minimal increase in patient dose.

Example 1: Coronary Imaging for 75BPM Patient

Description: Acquire systolic and diastolic phases of the heart cycle

- Acq. Window Part 1: 70-80% R-to-R, 100% of specified mA (based on Auto mA or prescribed manual mA)
- Acq. Window Part 2: 40-50% R-to-R, 100% of specified mA

Illustration 3: Example 1

Example 1, dark grey indicates the approximate range of phases available for image recon at 100% mA; light grey indicates full range of phases available for recon, with increasing image noise as the recon phase moves further away from the 100% mA ranges at 40-50% and 70-80%

Example 2: Coronary + Functional Imaging for 60BPM Patient:

Description: Acquire low-noise coronary images at diastole and lower dose data for functional assessment over the full cardiac cycle.

- Acq. Window Part 1: 75% R-to-R, 100% of specified mA
- Acq. Window Part 2: 0-95% R-to-R, 20% of specified mA

Illustration 4: Example 2

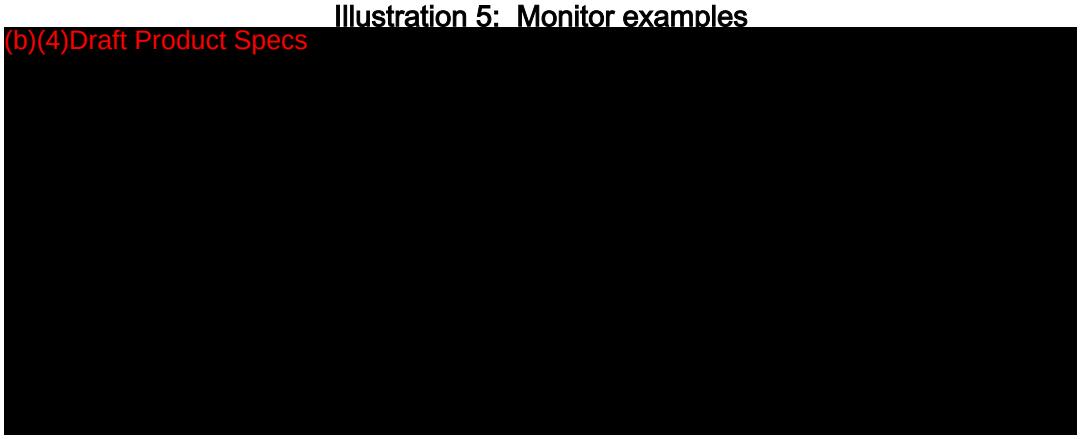
Example 2, dark grey indicates approximate range of phases available for image recon at 100% mA and 20% mA

In the event that the patient should experience a premature ventricular contraction (PVC) or other irregular heart rhythm, there is the possibility that low noise images could become shifted from the prescribed phases.

6 Image Display

The left monitor LCD has two viewports in a matrix of 512 x 512 picture elements, or pixels. The right monitor LCD displays a matrix of 1024 x 1024 pixels. The 1024 display can be further divided into up to 4 viewports of 512 x 512 pixels. Each pixel displays one of the 256 available shades of gray.

Illustration 5: Monitor examples



The Discovery™ CT870 system reconstructs axial and continuous images of 512 x 512 pixels. Images from other scanners may display 64, 128, 320, or 1024 pixel image matrices.

The amount of anatomy represented by each pixel equals the Display Field of View diameter in mm divided by the matrix width/height.

The system assigns a unique CT number value, originally called a Hounsfield Unit, to each pixel. The two dimensional pixel represents a three dimensional portion of patient tissue. The pixel value represents the proportional amount of X-ray beam that passed through anatomy and entered the detector.

6.1 CT Number

Image reconstruction supports two ranges of pixel CT Numbers, the "normal range" and an "extended range".

- Normal Range is -1024 to 3071
- Extended Range is -31743 to 31743

However, the system display supports pixels with a range of -32,767 to +32,767.

The system references CT number zero to water and CT number -1000 to Air. Lung and fat have negative pixel values and normally appear black. A CT number over 200 represents dense material like contrast agent, calcium, bone, and normally appears white.

Inverse Video reverses video white to black, but pixel values remain the same.

Variables that can affect CT Number accuracy:

- Partial volume effects of anatomy
- Scans acquired with IV or oral contrast agents
- X-ray tube deterioration
- Improperly calibrated system (poorly centered phantom, used wrong phantom, replaced current calibration files with extremely old Cal files)
- Beam hardening due to patient anatomy, especially bone.

To reduce CT Number variations:

- Warm up the X-ray tube whenever the system recommends it; make sure the tube design matches the software configuration parameters
- Center the patient anatomy of interest in the gantry opening. Select an SFOV that encompasses the patient.
- Acquire comparable images with similar scan and reconstruction choices.
- Maintain consistent table height throughout the exam.
- Test image quality on a regular basis to provide the numerical data to track system performance over time.

To decrease the potential for misdiagnosis:

- Use ROI to compare pathology to surrounding tissue
- Scan structures with slice thicknesses about one-half the thickness of the lesion or less.

Example: Prescribe scan thickness of 5 mm or less to scan a lesion with a 10 mm thickness. (Display an axial image and use the Measure Distance and ROI functions to determine the size of the pathology.)

Center ROI measurements over the midpoint of the pathology to minimize partial volume effects.

The mixture of tissue types, such as fat with tissue within the same voxel (a pixel with depth), varying patient sizes, differences between CT machines and X-ray tubes, all lead to CT number variance. In a well calibrated scanner, water has a CT number that ranges from -3 to +3. The CT number remains uniform across all kV settings. However, as the X-ray tube ages, kV decreases and pixel values become less dependable.

6.2 Pixels

The anatomic image consists of rows and columns of small, square, picture elements called pixels. The monitor displays 1,048,576 pixels in a matrix of 1024 horizontal rows of 1024 pixels. Add number of viewports selected for viewing to determine the number of pixels used for display in each viewport. The monitor pixel size remains the same, but the amount of anatomy the pixels represent varies with the scan and display field of view (SFOV & DFOV). A pixel also represents a specific anatomic area. The system identifies each two dimensional pixel by its location, area and value.

6.3 Pixel Coordinates

Describe pixel location two ways.

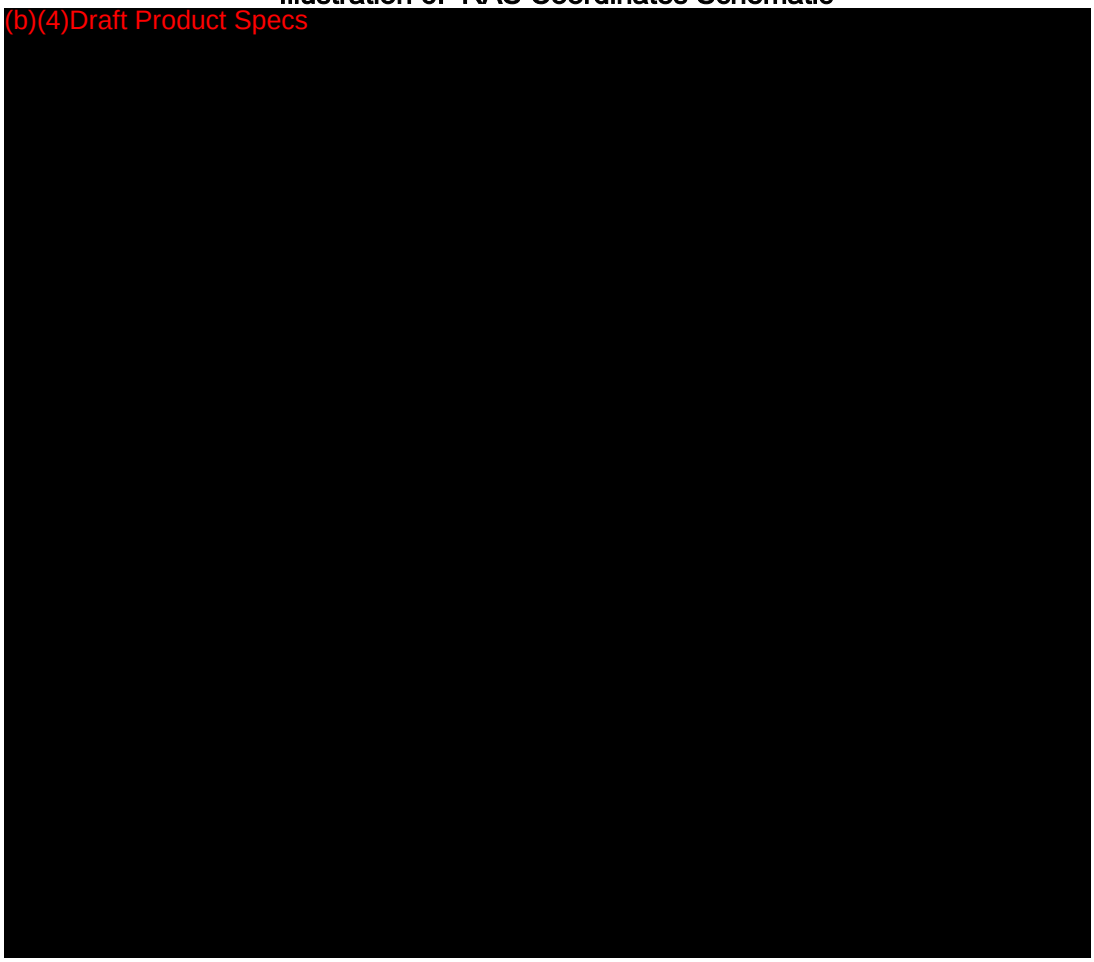
- Matrix Coordinates: Upper left pixel = (0,0);

  Lower right pixel = (511,511);

  Pixel in center of matrix = (255,255);

  Pixel ten columns to the right = (10,0)

Illustration 6: RAS Coordinates Schematic



NOTE: The illustration above represents a 512 x 512 matrix viewport.

- RAS: Anatomic distance from the center of the landmark slice

Target the image; decrease the DFOV diameter. Center the reconstruction on coordinates other than the SFOV center.

Magnifying and targeting can displace the central SFOV pixel from the central monitor pixel. Look at the DFOV coordinates and magnification annotation to find the SFOV center, or display the grid. The grid always appears over the pixel in the center of the DFOV Matrix (coordinate 255,255).

6.4 RAS Coordinates

These three distances in millimeters appear on the upper left of the viewport on which the mouse cursor is on, when Continuous Report Cursor is selected.

- The pixel with the R/L and A/P coordinates closest to zero, represents the SFOV center. The S/I coordinate always equals the table location at isocenter.
- Coordinates transition from R to L, A to P, and S to I, to show relationships between current location, landmark location, and isocenter.

Illustration 7: RAS Coordinates Schematic

Table 6:

Right:	Coordinate location falls to the patient's right of the mid-sagittal plane (right of isocenter)
Left:	Coordinate location falls to the patient's left of the mid-sagittal plane (left of iso-center)
Anterior	Coordinate location falls above the mid-coronal plane (above isocenter)
Posterior:	Coordinate location falls below the mid-coronal plane (below isocenter)
Inferior:	Scan location falls between the selected landmark and patient's feet
Superior:	Scan location falls between the selected landmark and patient's head

The DFOV and matrix determine pixel size.

A reconstructed pixel represents an area determined by dividing the Display FOV (in mm) by the reconstruction matrix, squared. You may magnify pixels up to eight times the reconstructed size, or minify them to one half size. The anatomic area represented by each monitor pixel decreases as the magnification factor increases; anatomic area/monitor pixel increases as the magnification factor decreases.

Table 7:

Pixel Size in millimeters	
DFOV in cm	512 x 512
5	0.10
10	0.20
15	0.29
20	0.39
22	0.43
25	0.49
30	0.59
35	0.68
40	0.78
45	0.88
50	0.98

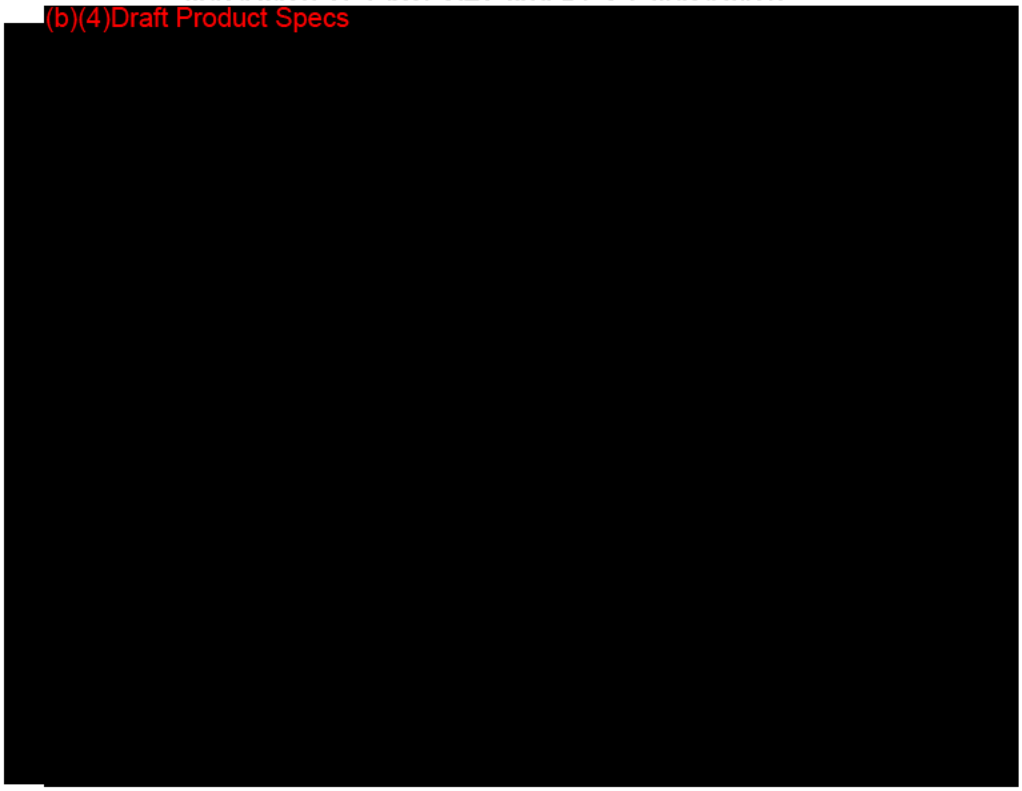
The DFOV determines the anatomic area imaged by a single reconstruction.

- Area equals pr^2 (Area = 3.14 x radius x radius)
- The 50 cm FOV has a 25 cm radius, so its area equals 1963 cm^2.
- The ROI or magnification factor determines the anatomic area covered by a magnified image.

Example: A monitor pixel represents 0.5 by 0.5 mm. Magnify pixel size by 2. Each monitor pixel now represents 0.25 by 0.25 mm of anatomy.

Illustration 8: Pixel Size and DFOV Illustration

(b)(4)Draft Product Specs



6.5 Pixels and CT Numbers

Besides anatomic location and area, each CT pixel also represents a CT number, which in turn indicates tissue density.

- An ROI averages the values of the enclosed pixels, and displays the resulting **Mean** value.
- **Standard Deviation** describes the difference between the minimum and maximum ROI value.
- A large ROI provides a larger, more accurate statistical sample than a small ROI.

An image pixel represents a three dimensional volume, or voxel. It represents anatomy with a location, an area, and a pixel (density) value. The system flattens the 0.625, 1.25, 2.5, 3.75, and 5 mm scan thickness into a two dimensional screen image. If a pixel represents a variety of tissues, the system averages the contents to produce an averaged, rather than accurate, pixel value. Uniform tissues (within the voxel) produce fairly accurate pixel values.

CT pixel shading shows relative density. Denser materials weaken X-ray and produce whiter pixels. (Assumes Inverse Video OFF)

Reformat displays non axial planes created from contiguous pixels extracted from multiple images. 3D locates similar pixel values within contiguous images, and generates a mathematical model to produce images that appear three dimensional. BMD samples pixel values to estimate bone or tissue density.

Reconstruction assigns one value to every image pixel. CT uses pixel values of -32767 to +32767. MR uses pixel values of +16,000. The screen pixel translates the assigned value into one of the 256 shades of gray. Vary the gray scale window width and level to select anatomy for display. Window Width determines the quantity of gray pixel values. Window Level selects the center Window Width pixel value.

Example: Two windows may contain identical widths of 100 values, but display completely different anatomy, because one has a level of -100 and the other has a level of 150.

6.6 Window Width

The system uses 256 gray shades to display 63,486 CT pixel values. The Window Width selection determines the number of CT values represented by each shade of gray. A narrow window assigns fewer pixels to each gray level than a wide window.

Example: WW = 256 System assigns one pixel value to each gray shade WW = 2560 System assigns ten pixel values to each gray shade.

6.7 Window Level

The Level equals the CT number value of pixel in the center of the Window Width range. The Level value receives the middle shade of gray. The system displays pixel values that fall between the center and upper window level as gray to off white. It displays pixel values that fall between the center and lower window values as gray to charcoal. When you change the level, the window width moves up and down the CT number line. The CT values change with Window Level, but the Window Width and number of pixels per gray level don’t change.

Inverse Video reverses display conventions. Dense or high numbers are portrayed as black rather than white.

7 Scout Based Attenuation Characterization

A patient's size, shape and density define the attenuation characteristics seen by the X-rays. An understanding of the desired image quality (noise and contrast) and the attenuation characteristics of the region being scanned can be used to determine the required scan technique factors (kVp and mA).

Automatic characterization of the patient's attenuation can enable a CT system to aid the user in determining the scan technique factors required to achieve the desired image quality. The scout image is a measurement of the distribution of the attenuation for the patient. This distribution of attenuation can be analyzed to give a metric of total attenuation (or patient size) and a metric of patient shape.

One size metric that can be used is Water Equivalent Diameter, Dw. This is the diameter of a uniform cylinder of water that gives the same total attenuation as the patient. Although Dw assumes a circular water object, patients are rarely circular. Most anatomical regions, however, can be approximated as ovals. Therefore, in addition to Dw, it is beneficial to have a shape metric to indicate how non-circular the anatomy is. One shape metric is the Oval Ratio, OR. The OR is the ratio of the major and minor diameters, with a value of 1 indicating a circle. Together, these two metrics can be determined at every location over the selected scan range of the patient to create a 3D characterization of the attenuation. This information can then be used by different applications, such as AutomA, Snapshot Assist and kV Assist.

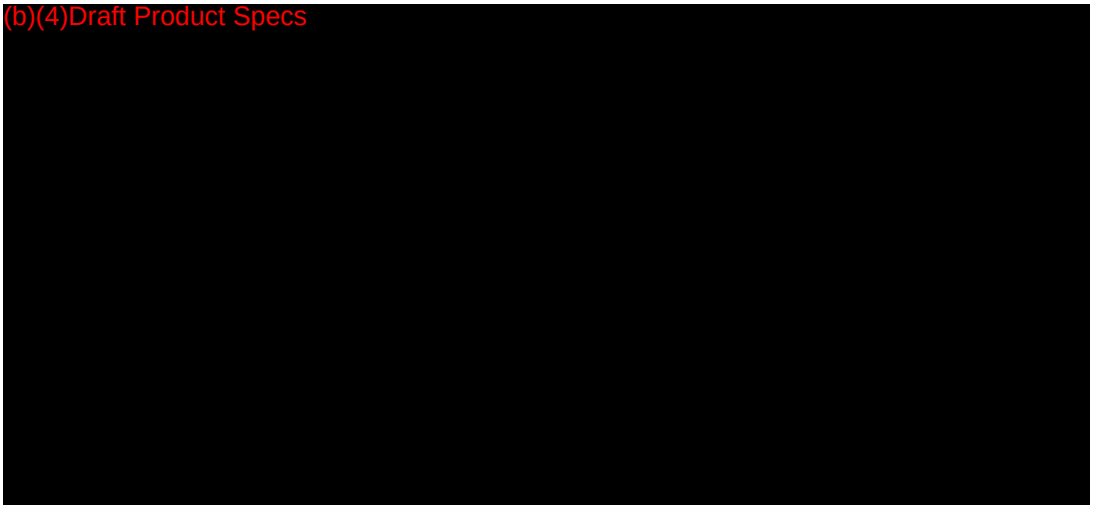
The following are some examples of phantom images and their representative Dw and OR characterizations:

- 35cm Polyethylene Phantom with Water Equivalent Diameter = 33.6cm (OR=1)

- 20x32cm Polyethylene Phantom shown with overlay indicating: Left - Water Equivalent Diameter = 33.6cm (OR=1) and Right - Ellipse based on Dw and OR (OR=1.58)(Please confirm Dw value for 20x32cm poly phantom – do not expect it to be same value as for 35cm poly phantom (compare captions 11-8 and 11-9).)

- Thorax Phantom shown with overlay indicating: Left - Water Equivalent Diameter = 22.1cm (OR=1) and Right - Ellipse based on Dw and OR (OR=1.08)

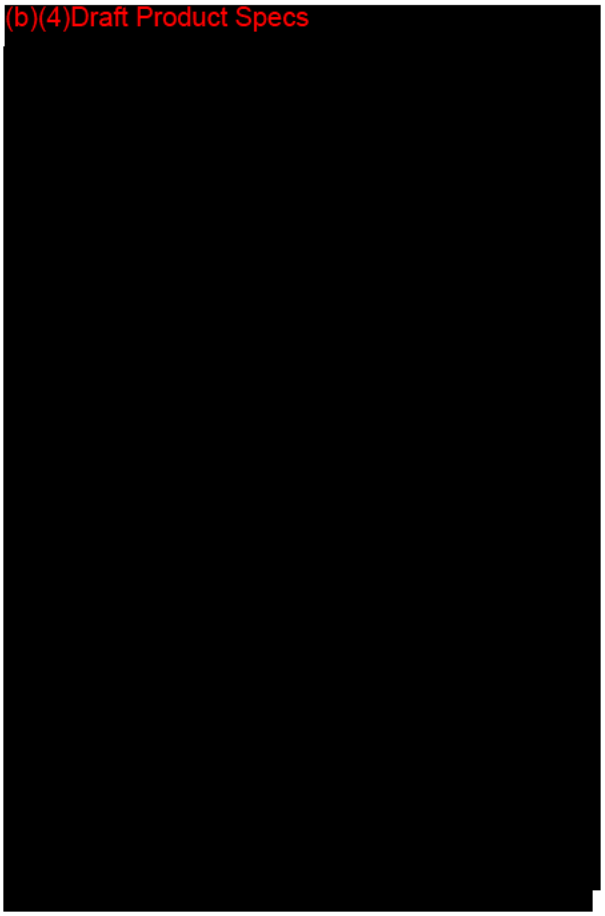
- Large Thorax Phantom shown with overlay indicating: Left - Water Equivalent Diameter = 33.8cm (OR=1) and Right - Ellipse based on Dw and OR (OR=1.14)



Since these metrics are dependent on the attenuation distribution, Dw and OR measurements can vary across the entire anatomical region. In an anatomical area like the abdomen, which contains little air pockets, the Dw is similar to the average physical diameter of the patient. But for an area like the chest, which contains the lungs, Dw may be significantly smaller than the average diameter.

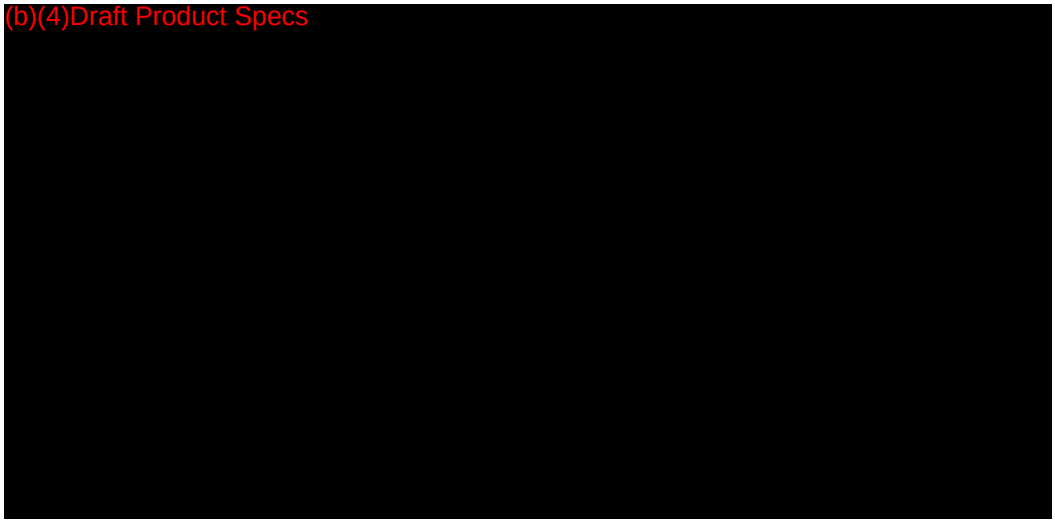
An example of this behavior can be seen in the figure below of a scout torso phantom with the measured Dw and OR at different locations.

- Scout of Torso Phantom in Lateral View (middle) with measured Water Equivalent Diameter (top) and (bottom) Oval Ratio Torso images from the scout are shown with their representative Dw and OR characterizations.



- Torso Phantom shown with overlay indicating: Left - Water Equivalent Diameter = 26.3cm (OR=1) and Right - Ellipse based on Dw and OR (OR=1.80)

- Torso Phantom shown with overlay indicating: Left - Water Equivalent Diameter = 25.6cm (OR=1) and Right - Ellipse based on Dw and OR (OR=1.24)



Unlike AutomA where there is mA modulation over the scan range in the z-direction based on patient size, applications like SnapShot Assist and kV Assist set parameters that do not modulate during the scan acquisition. SnapShot Assist calculates a median Dw from the specified scan range to translate it to a scout-attenuation BMI estimate based on the conversion detailed in Menke, Radiology 2005.

Appendix A Abbreviations

1 Abbreviations

Table 1: Abbreviations

Abbreviations	Acronym
AW	Advantage Workstation
CFR	Code of Federal Regulations
cm	Centimeter
CT	Computed Tomography
CTDI	Computed Tomography Dose Index
DAS	Data Acquisition System
DFOV	Display Field of View
DICOM	Digital Imaging and Communication in Medicine
DLP	Dose Length Product
ECG	Electro cardiogram
EMC	Electro-magnetic Compatibility
EMI	Electro-magnetic Immunity
FDA	Food and Drug Administration
FWHM	Full Width Half Maximum
FWTM	Full Width Tenth Maximum
HU	Hounsfield Units
HV	High Voltage
IEC	International Electro-technical Commis-sion
ISO	Iso-center
IV	Intra-venous
kg	Kilogram
kV	kilo-volts
kW	kilo-watts
LCD	Liquid Crystal Display
lb	Pound
LCD	Low Contrast Detectability
mA	milli-amps
MDC	Main Disconnect Control
mGy	Milligray
ml	Milliliter
mm	Millimeter

Abbreviations	Acronym
MPR	Multiplanar Reconstruction
ms	millisecond
MTF	Modulation Transfer Function
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology
PDU	Power Distribution Unit
PM	Planned Maintenance
PMMA	Poly-methyl methacrylate
QA	Quality Assurance
QEF	Quality Equivalent Filtration
QSR	Quality System Regulation
ROI	Region of Interest
SATA	Serial Advance Technology Attachment
SCI	Scan Control Interface
SFOV	Scan Field of View
SSP	Slice Sensitivity Profile
UL	Underwriters' Laboratories
WL	Window Level
WW	Window Width

Appendix B Units of Measure

1 Units of Measure

This appendix lists the units of measure used in this manual.

Table 1: New Patient/Patient Schedule

Data	Unit	Symbol
Weight	Kilogram	kg
Weight	Pounds	lb
Height	Centimeter	cm
Time	Days	d

Table 2: ScanRx Screen numeric indications

Data	Unit	Symbol
Height	Centimeter	cm
Rotation	Time Second	s
Slice Thickness	Millimeter	mm
Interval	Millimeter	mm
kV (Tube Voltage)	Kilovolt	kV
mA (Tube Current)	Milliampere	mA
Gantry Tilt	Degree	°
Total Exposure Time	Second	s
Prep Group	Second	s
ISD	Second	s
Breath Hold	Second	s
Breathe Time	Second	s
Cine Duration	Second	s
DFOV	Centimeter	cm
R/L Center	Millimeter	mm
A/P Center	Millimeter	mm
CTDIvol	Milligray	mGy
DLP	Milligray centimeter	mGy cm
Phantom Size	Centimeter	cm
Beam Collimation	Millimeter	mm
Helical Thickness	Millimeter	mm
Axial Thickness	Millimeter	mm
Retro Recon Thickness	Millimeter	mm

Table 3: SmartPrep Setting

Data	Unit	Symbol
Monitoring Delay	Second	s
Monitoring ISD	Second	s
Diagnostic Delay	Second	s
mA (Tube Current)	Milliampere	mA

Table 4: Enhance Xtream Injector Setting

Data	Unit	Symbol
Inj. Delay	Second	s
Flow Rate	Millilitere/Second	ml/s
Duration	Second	s
Pressure Limit	Pascal	Pa
Remaining Contrast Media	Millimeter	mm
Remaining Saline	Millimeter	mm

Table 5: AutoVoice and Breathing Lights Selection

Data	Unit	Symbol
Preset Delay Time	Second	s

Table 6: Routine Display Tools — List/Select

Data	Unit	Symbol
im Ctr S-I	Millimeter	mm
Thick	Millimeter	mm
Gantry	Degree	°
Im Ctr R-L	Millimeter	mm
Im Ctr A-P	Millimeter	mm
SFOV	Centimeter	cm
DFOV	Centimeter	cm
Midscan	Seconds	s

Table 7: Exam Pg / Series Pg

Data	Unit	Symbol
Height	Centimeter	cm
Weight	Kilogram	kg

Table 8: Display result on an image for Image Measurements - Ellipse ROI / Box ROI / Trace ROI

Data	Unit	Symbol
a (Area)	Square Meter	mm^2
Distance	Millimeter	mm
Angle	Degree	°

Table 9: Measure Angle

Data	Unit	Symbol
Angle	Degree	°

Table 10: DynaPlan screen numeric indications Data Unit

Data	Unit	Symbol
kV	Kilovolt	kV
mA	Milliampere	mA
Time	Second	s
Thk	Millimeter	mm
Tilt	Degree	°

Table 11: ImageWorks numeric indications

Data	Unit	Symbol
Im Ctr S-I	Millimeter	mm
Thick	Millimeter	mm
Gantry	Degree	°
Im Ctr R-L	Millimeter	mm
Im Ctr A-P	Millimeter	mm
SFOV	Centimeter	cm
DFOV	Centimeter	cm
Midscan	Seconds	s

Table 12: Denta Scan Control Panel

Data	Unit	Symbol
Shift Curve	Millimeter	mm

Table 13: Batch Control Panels for Reformat / 3D Data Unit

Data	Unit	Symbol
Spacing between images	Millimeter	mm
Slice Thickness	Millimeter	mm

FOV	Centimeter	cm
Angle between images	Degree	°

Table 14: Image Annotation numeric indications

Data	Unit	Symbol
DFOV	Centimeter	cm
kV	Kilovolt	kV
mA	Milliampere	mA
Thickness	Millimeter	mm
Rotation Speed	Second	s
L/R/A/P/S/I indication	Millimeter	mm

Appendix C Lexicon

1 Lexicon

For the CT technologist who operates multiple scanner models, perhaps from multiple manufacturers, the variability in names for important scan acquisition and reconstruction parameters can lead to confusion, reduced comfort and an increased potential for error. The intent of this CT terminology lexicon is to allow users to translate important CT acquisition and reconstruction terms between different manufacturers' systems.

The following tables provide the SABMI (Scout Adjusted Body Mass Index) terminology for GE and is a result of the AAPM CT Terminology working group. It identifies relevant from established lexicon (e.g., Radlex and DICOM) and other relevant literature published.

The AAPM website will provide updates when changes in standardization of terminology occur. Visit www.aapm.org, search CT Protocols, and select Lexicon for full listing of terminology across various manufactures of CT equipment.

The generic descriptions or terms in the first column are intended to orient the user to the relevant concepts; they are not consensus "preferred terms." The generic descriptions are not based on any single existing or pending terminology standard; however the references cited below were consulted in developing the generic descriptions.

A number of individuals and groups have advocated for terminology standardization in CT, including at a March 30-31, 2010 FDA (Food and Drug Administration) public meeting entitled "Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging" (transcripts available at the FDA website: www.fda.gov in Medical Devices). Participants proposed a cooperative effort among professional organizations (AAPM, ASRT, ACR, etc.), industry, and the FDA.

1.1 Scan acquisition and user interface basics

Table 1: Scan acquisition and user interface terms

Generic description	GE names
The portion of the user interface where scans are prescribed	Scan Settings
Other portions of the **user interface**, such as where reconstructed images are viewed	Patient tabs or File Manager
CT localizer radiograph (i.e. the scanned projection radiograph, often acquired by the CT system to allow the user to prescribe the start and end locations of the scan range)	Scout
Axial scan mode: Data acquisition while the patient table remains stationary; the table position may be incremented between X-ray exposures to collect data over a longer z axis range.	Axial
Helical or Spiral scan mode: Data acquisition while the patient table is continuously moving along the z axis.	Helical
Dynamic scan mode - single detector width: Data acquisition at multiple time points over the same anatomic location(s) while the patient table remains stationary; X-ray exposure can be continuous or intermittent	Cine or zero interval Axial
Dynamic scan mode - multiple detector widths: Data acquisition at multiple time points over the same anatomic location(s) while the patient table cycles back and forth between designated start and end locations in order image a region wider than the detector	Not used on this system
Interventional CT - Intermittent X-ray exposures	Not used on this system
Interventional CT - Continuous X-ray exposures	Not used on this system
Table increment (mm) per 360 degree rotation of the X-ray tube (axial scan mode)	Interval
Table feed per 360 degree rotation of the X-ray tube (helical scan mode)	Speed (mm/rot)
Field of measurement: Diameter of the circular region within the scan plane over which projection data are collected. Nominally equal to the diameter of the primary beam at isocenter in the axial plane.	Scan Field of View (SFOV, cm)
Tube current: Number of electrons accelerated across an X-ray tube per unit time, expressed in units of milliampere (mA)	mA
Tube current-time product: The product of tube current and exposure time per rotation, expressed in units of milliampere • seconds (mAs). In axial scan mode, this is equal to tube current × (scan angle ÷ 360) × rotation time. In helical scan mode, this is equal to tube current × rotation time.	Not used on this system

Generic description	GE names
Effective tube current-time product: In helical scan mode, this is the product of tube current and rotation time (expressed in units of milliampere • seconds (mAs) ÷ pitch)	Not used on this system
Tube potential: The electric potential applied across an X-ray tube to accelerate electrons towards a target material, expressed in units of kilovolts (kV)	kV
Pitch: Unitless parameter used to describe the table travel during helical CT; equal to table travel (mm) per gantry rotation ÷ total nominal beam width (mm)	Pitch
Automated patient instructions	AutoVoice

1.2 Dose modulation and reduction tools

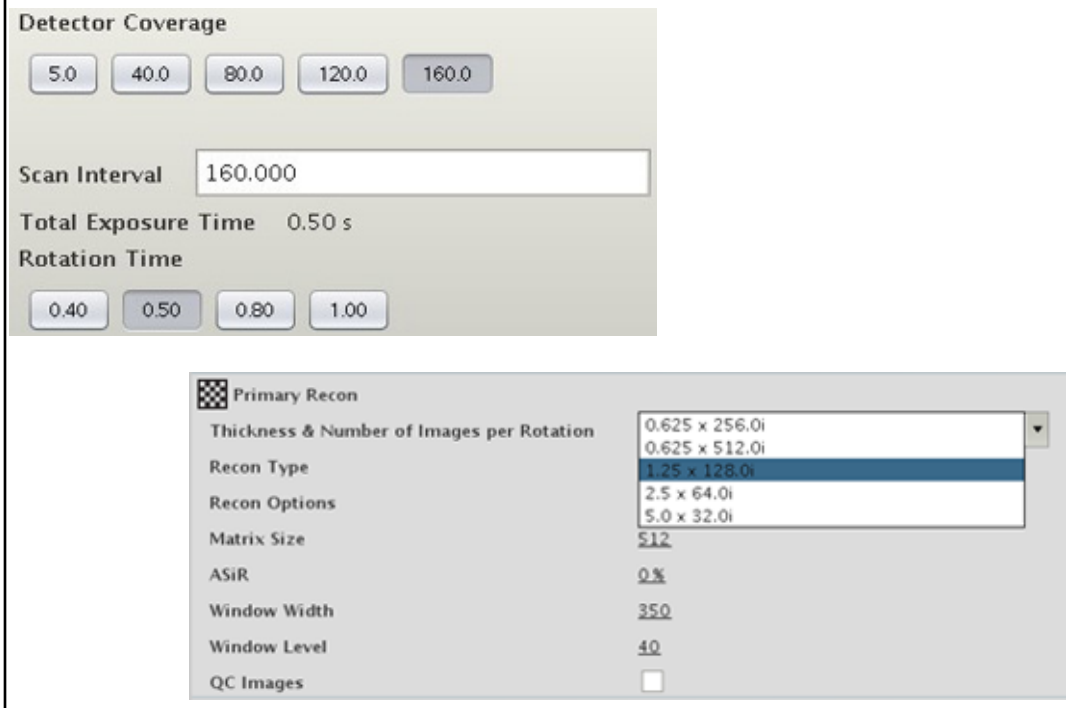
Table 2: Dose modulation and reduction tool terms

Generic description	GE name
Automatic exposure control (AEC): A scanner feature that automatically adapts the X-ray tube current to the overall patient size to achieve a specified level of image quality	Available in AutomA and SmartmA
Angular tube current modulation	Organ Dose Modulation
Longitudinal tube current modulation	AutomA
Angular and longitudinal tube current modulation	SmartmA (x, y, z)
ECG-based tube current modulation	Cardiac Modulated
Image quality reference parameter for AEC	Noise Index

1.3 Multi-slice detector geometry

Table 3: Multi-slice detector geometry terms

Generic description	GE name
Multi-slice detector array design	Fixed
Detector configuration	Detector Configuration

Generic description	GE name
Detector rows (N) and slice thickness (T) selection console screen image **Illustration 1: Detector Coverage and Slice Thickness** 	

1.4 Image reconstruction and display

Table 4: Image reconstruction and display terms

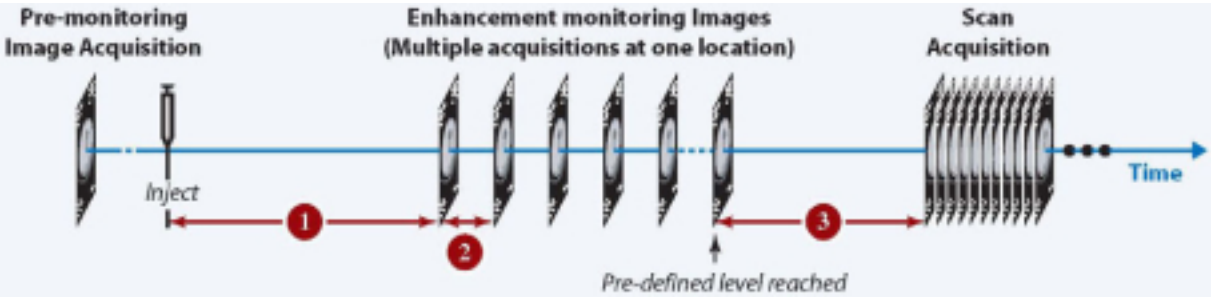
Generic description	GE name
Window width: Range of CT numbers (maximum - minimum) that are distributed over the viewable grey scale of the display device or film	Window Width
Window center: The CT number in the center of the viewable grey scale	Window Level
Reconstruction field of view: Width of the square region mapped to the reconstructed image matrix	Display Field of View (DFOV) (cm)
Prescribing the reconstruction parameters prior to scan acquisition	Primary and Secondary re-con
Prescribing the reconstruction parameters after scan acquisition	Post Scan Secondary re-con
Reconstruction property that determines sharpness or smoothness of image in the axial plane	Algorithm
Helical interpolation options to achieve a wider or narrower section sensitivity profile	Full (narrower) or Plus (wider) mode

Generic description	GE name
Nominal width of reconstructed image along the z axis	Thickness (mm)
Distance between two consecutive reconstructed images	Interval
Fast but lower-quality reconstructed images for rapid review of entire exam	Quality Check
Off-center reconstruction coordinates are called	RL Center; AP Center
Flip or rotate the image orientation is called	Flip/rotate
Image modifications to alter sharpness or smoothness (done in image space without reconstructing images)	Image Filters

1.5 Contrast media tools

Table 5: Contrast media tool terms

Generic description	GE name
Bolus tracking: Scanner feature to automatically initiate a prescribed axial, helical or dynamic scan when a threshold level of contrast enhancement is reached at a specified region of interest	Smart Prep
Test Bolus: Scan mode used to measure the contrast transit time using a small injection of contrast media	Take axial scans at zero table feed and process with MIROI
Time-attenuation curve (TAC): Graph of the contrast enhancement versus time	Smart Prep graph or MIROI graph
Threshold: CT number (HU) where bolus tracking tool will trigger the system to begin the scan	Transition ROI Threshold
Scanner feature used to quantitatively evaluate the TAC	MIROI (multiple image region of interest)
Monitoring delay: Time from injection to the start of monitoring scans (Time 1 in figure below)	Monitoring Delay
Monitoring interval: Time between consecutive monitoring scans to (Time 2 in figure below)	Monitor ISD (InterScan Delay)
Scan delay: Time from when threshold is reached and prescribed axial, helical or dynamic scan begins (Time 3 in figure below)	Diagnostic delay

Generic description	GE name
	

1.6 Multi-planar formats and 3D processing

Table 6: Multi-planar formats and 3D processing terms

Generic description	GE name
Reformatted image at an oblique plane (not an axial, coronal, or sagittal)	Oblique reformat
Saving images at various viewing angles about a volume or surface rendered object	Batch Loop
Saving images at various planes through a volume	Batch Reformat
Surface-rendered object	3D
Volume-rendered object	Volume Rendered image (VR)

1.7 Service and application tools

Table 7: Service and application tool terms

Generic description	GE name
X-ray tube warm up	Tube Warm-up (tube warm up)
Daily calibrations	Fast Cals (done in daily prep)
Application information	Learning Solutions or User Manual
Application support assistance	Insite or Ilinq

1.8 Workflow

Table 8: Workflow terms

Generic description	GE name
Scheduled (but not yet scanned) patient list is called	Patient Scheduler
Already scanned patient list is called	File Manager
User comments or text added to an image is called	User annotation
Filming tools are called	Not used on this system
Data page summarizing scan parameters, $CTDI_{vol}$ and DLP	Exam Text Page, Series Text Page, or Done SC
Sorting patient list	Click column to sort

1.9 References

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www.gehealthcare.com

Attachment 13C

Revolution CT Product Datasheet

Revolution CT

Uncompromised.

Introduction

GE's Revolution CT is a breakthrough that delivers uncompromised image quality & clinical capabilities through the convergence of coverage, spatial resolution, temporal resolution & dose performance – all in one. Until now, CT users had to compromise between systems that could only provide a subset of these capabilities. The Revolution CT delivers industry leading technical specifications for a premium CT system:

- ✓ 160 mm coverage Gemstone Clarity Detector
- ✓ 140ms temporal resolution (0.28s rot. Speed) + intelligent motion correction for 24 ms effective temporal resolution
- ✓ Best in class 0.23 mm spatial resolution
- ✓ 80 cm bore size

The system is designed to use less radiation dose than the previous generation product while maintaining the same superior level of image quality. Further, the fast speed of the scan could potentially reduce contrast volumes. The hardware platform is also capable of supporting Gemstone spectral imaging[1] and 0.2s[1] rotation speed. The system has been tested to withstand in excess of 75G's of acceleration forces at 0.2s rotation speed. Key technology enablers include:

- A unique image chain hardware and reconstruction for uncompromised image quality, overcoming the challenges of typical wide detector systems such as cone beam artifacts, HU uniformity, scatter & beam hardening artifacts, while improving dose performance
- The next-generation of iterative reconstruction technology, ASiR-V, designed to deliver ultra-low noise levels, improved low contrast detectability and may enable a reduction in dose[2] for all clinical applications
- Best effective temporal resolution enabled by 0.28 second rotation speed combined with intelligent motion correction for excellent cardiac imaging at any heart rate
- A wide 80 cm bore to image all patients, allow better patient positioning & access

Thanks to its innovative design, the Revolution CT delivers breakthrough clinical applications for all anatomies:

- 1-Beat High definition, motion free coronary images at any heart rate with intelligent motion correction
- 1-Beat, comprehensive cardiac assessment for every patient at low dose - coronaries, rest / stress perfusion & function
- 4D imaging capabilities for all anatomies enabled by whole organ acquisition to visualize vascular flow, organ motion or kinetic properties
- Dynamic, low dose perfusion studies up to 16cm for cardiac, neuro or body applications with no table motion, personalized coverage & sampling
- Ability to acquire Perfusion and CTA data from a single exam
- Dedicated HD cardiovascular and head / neck angio in a single low dose exam for comprehensive stroke workup
- Sub-second scans for typical trauma and pediatric sedation-free exams, enabled by wide detector and fast table speed at up to 300 mm/sec
- Rapid & comprehensive TAVI planning with dedicated protocols allowing ECG gated and non-gated acquisitions in a single exam

Revolution CT has been designed with future onsite hardware upgradability as a key goal to ensure longevity of the state of the art technology to help you continually provide best in class care to your patients.

Indications for Use

The Revolution CT Computed Tomography X-ray is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver, kidney, pancreas, etc. The system may acquire data using Axial, Cine, Helical, Cardiac and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results.

[1] Option. May be available in the future

[2] In clinical practice, the use of ASiR-V may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

*Option – may be available in the future

Revolution CT
Uncompromised.

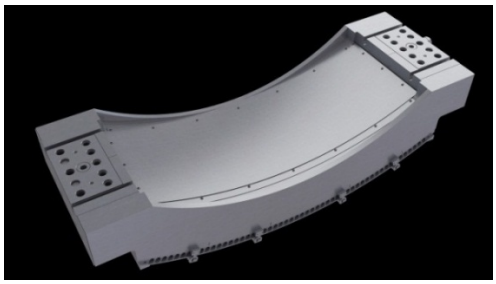
The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Gemstone Clarity Detector

The scanner features next generation "Gemstone Clarity" detector with ground breaking technology and also features Gemstone scintillator with the industry's best primary speed & afterglow specifications.

The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems. Combined with VHD reconstruction technology, the system delivers excellent image quality at full 160mm coverage to enable whole organ imaging. Further, the 3D Collimator reduces scatter to primary ratio by more than 50% compared to a 160mm system with a 1D post patient collimator.



The Gemstone Clarity detector also features a revolutionary ultra-low capacitance photo diode with new ASIC technology that redefines electronic noise at the quantum limit to less than 3 photons @ 120 keV (3100 electrons). The detector includes acquisition electronics which allow 4x faster bandwidth and 3x faster trigger rate than previous generations and reduces electronic noise by 25% and is 25% more dose efficient. This allows for unparalleled high definition imaging at full 160mm coverage & support for 0.2s[3] rotation speeds.

The detector also features a source side reference channel design to allow you to leverage the 80cm bore fully with 50 cm scan field of view while ensuring that neither the patient nor any patient attached equipment blocks the detectors X-ray reference channels.

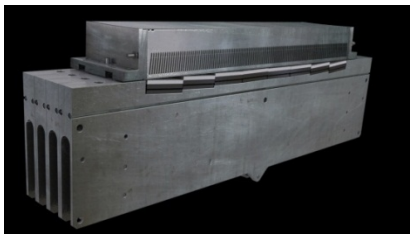
Gemstone Scintillator

The Gemstone Clarity detector enables high definition CT imaging with a revolutionary, extremely fast scintillator. The scintillator material is an isotropic ceramic with cubic structure – highly uniform and translucent. (Cubic structures offer better transparency to that of Gadolinium Oxysulfide (GOS) which has a hexagonal lattice).

The relative speed of the scintillator enables High Definition technologies such as High Resolution imaging capability, with less noise and the ability to perform fast kV switching.

- **Scintillator speed :** 0.03 µs (100 times faster than GOS)
- **Afterglow:** 0.001% - 4 times lower than GOS
- **Radiation damage:** 0.03% - 20 times less than GOS
- **Scatter to Primary Ratio** < 10%
- **Detection efficiency:** 98% @ 120 kVp

3D Collimator scatter reduction technology



Reduces scatter to primary ratio by more than 50% and results in significant improvement in image quality and reduction in beam hardening & metal artifacts.

Gemstone Clarity Data Acquisition Subsystem (DAS)

The Gemstone Clarity Data Acquisition Subsystem (DAS) features 3 times faster trigger rates capable of supporting features such as High definition imaging up to 2496 views per rotation and fast kV switching mode with 1968 views per rotation even at 0.2s[4] rotation speed.

Detector specifications	
z-Coverage/ 360° rotation	**16cm**
Number of slices	512 slices
Number of detector rows	256
Number of detector elements	212,992 cells with individual electronic / DAS channels for excellent data fidelity
Number of views	Up to 2,496 views per rotation
Electronic noise	Less than 3 photons noise (3100

[3] Option. May be available in the future

[4] Option. May be available in the future

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electrons)	
Effective analog to digital conversion range	> 2,000,000:1

VHD Reconstruction (Volume High Definition)

The system features state of the art image reconstruction technology designed to mitigate cone beam artifacts associated with wide coverage systems. In addition, the algorithm preserves temporal uniformity and provides excellent image quality at full 160mm coverage. It further reduces variation in iodinated contrast HU uniformity across the full 16cm Z coverage, typically caused due to heel effect. In addition, Multi Material Artifact Reduction (MMAR) technology utilizes material physics learning's from GSI in to single energy acquisition and in conjunction with 3D Collimator, reduces beam hardening artifacts due to iron, bone, metal & other dense objects.

Tube & Generator

Performix™ HDw X-Ray Tube

Performix HDw is a next generation anode-grounded, metal-ceramic x-ray tube The tube enables improved spatial resolution via dynamic in-plane focal spot deflection and independent control of the focal spot size in both X and Z-axis optimizing the focal spot to deliver consistent beam quality across the full 160mm Z-axis coverage, making it one of the most innovative CT tubes offered today. The design is optimized for exams requiring a large number of scans without tube cooling. It is powered by an onboard high frequency generator capable of ultra-fast kVp switching.

Ultra-fast kV switching generator

The new generator features 3 times faster rise & fall times for kV switching compared to previous generator. This would allow for more time to be spent at the target energy levels and result in better energy separation between the datasets acquired at different kV levels using fast kV switching.

Tube & Generator specifications	
Generator Maximum peak power	103 kW
Tube current range	mA: 10 to 740, 5mA increments
Tube voltage	kVp: 70, 80, 100, 120, 140
Thermal ratings	Efficient anode heat transfer and casing design eliminates inter-patient delays for demanding helical scans - Anode: Max anode heat content: 4.1 MJ (5.5 MHU) Max anode input power: 103kW - Housing: Max x-ray tube assembly heat content: 5.0 MJ (6.8 MHU) Max continuous heat dissipation: 3.0 kW
X-Ray Tube Housing Assembly	Anode-Grounded Technology • Nominal tube voltage: 140kVp • Leakage technique factor: 140 kV, 14.3 mA • Quality equivalent filtration: Min 3.9mm Al equiv at 75 kV
Tube insert focal spot	
Small Focal Spot (580 max mA)	- 1.0 x 0.7 per IEC 60336/2005
Large Focal Spot (720 max mA)	- 1.6 x 1.2 per IEC 60336/2005
X-Large Focal Spot (740 max mA)	- 2.0 x 1.2 per IEC 60336/2005
Target Angle	10.5 degrees

Performix HDw Tube License

The GE Performix HDw tube includes a standard license that automatically enables the use of tube dependent advanced applications. The use of a third party X-ray tube will require an additional license for the activation of these features.

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Gantry & Slipring

Revolution CT's gantry platform has been designed from ground up and tested to support rotation speeds as fast as 0.2s[5] / rotation. It also features a wide 80cm bore diameter to facilitate scanning larger patients and to ensure flexible access and patient positioning in the gantry. The slip ring is designed for transferring data at 40 Gbps. To ensure safe & reliable performance at these fast rotation speeds, the gantry platform features the following state of the art technology:

Whisper Drive system

Reduces audible noise during gantry rotation at 0.28s by more than 50% compared to a typical belt driven system rotating at 0.28s / rotation speed, thus improving patient comfort (69 dBA)

Contactless Slipring

Transfers power and data to and from the rotating side of the gantry (slip ring) to the stationary side through contactless RF technology. This eliminates carbon dust due to brush wear-out in typical CT systems thereby increasing the reliability of the system.

Fail-safe mounts

The gantry frame features redundant fail-safe mounts for all major components that is designed and tested to stringent standards to ensure safe and reliable operation even at 0.2s rotation speed.

Laser Alignment Lights

Define both internal and external scan planes to ± 1 mm accuracy. Activated any time during exam (with tube stationary)

Gantry displays and controls

- The Gantry features a large LCD that displays patient information and ECG data from the integrated ECG module. This display can also be configured to show patient informational videos, etc.
- Built-in **patient breathing lights** and countdown timer
- Cardiac gating indicator light
- Start scan button with countdown to X-ray on
- Scan plane toward front of gantry for improved positioning access
- Biopsy and interventional studies have been facilitated through a more streamlined gantry shroud, and bilateral table/gantry controls and gantry display that maximize maneuverability while working next to the gantry
- Flexible cable management system includes coordinated straps that can be attached to the gantry sides to keep cables connected to the gantry away from the floor and to reduce clutter

Gantry specifications	
Aperture	80 cm
Distance Focus to detector	109.7 cm
Distance Focus to isocenter	62.6 cm
Scan Field of View	50 cm
Rotation time	VariSpeed technology: 360° in 0.28 to 1.0 sec (Note : The hardware platform has been designed and safety tested for unprecedented rotation speeds up to 0.2s[6] / rotation)
Temporal Resolution	140ms cardiac temporal resolution; 24ms effective cardiac temporal resolution using SnapShot Freeze intelligent motion correction
Data chain bandwidth	40 Gbps

Table (Patient positioner)

Revolution CT features a next generation table capable of 300mm/s travel speed. This enables fast scanning for longer range anatomies.

The table has also been designed with 10x more stiffness to reduce deflection under heavy load and provide the best possible images even under heavy load conditions.

[5] Option. May be available in the future

[6] Option. May be available in the future

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Table specifications	
Vertical Range	50 cm to 100.1 cm
Vertical scannable range	73.1 cm to 100.1 cm
Elevation Speeds	15(±3) mm/s and 48(±3) mm/s
Horizontal Range	200 cm
Horizontal Scannable range (metal free)	• 200 cm in Axial • 185 cm in helical • 5 - 200 cm in scout
Horizontal speed	**Up to 300 mm/s**
Load capacity	**227 kg (500 lb)** maximum allowed with ± 0.06% positional precision over the entire scannable range.

The table features:

- Controls on gantry for elevation and cradle movement. Foot pedals on both sides of table for fast elevation. Cradle position controlled from OC for prescribed scans.
- Integrated ECG module with waveform and configuration through the gantry display
- Workflow hub area with a see through tray to give you the most flexibility in placing scanning related supplies, etc. without limiting visibility to the integrated ECG inputs
- IV Pole integrated at the foot-end of the table helps to prevent IV lines from becoming crossed and tangled, and helps keep lines in place during patient table travel

Operator console

The Revolution CT scanner desktop allows simultaneous scanning, image reconstruction, display, processing and analysis, as well as networking, archival and filming.

It features the new "Clarity Operator Environment" designed with your everyday needs in mind. The environment allows for more real time adaptive capabilities thus enabling improved timing with Smart Prep including automatically transitioning acquisition when the set HU threshold is reached. The benefits provided by the new interface include:

- Smart prescription workflow automates scan set up by recommending scan parameters specific to the patient based on scout attenuation and ECG information, in the case of cardiac, to enable consistent image quality & dose performance across scans, irrespective of the technologist expertise level
- Seamless multi-tasking through ability to have multiple patient sessions open with one active patient for acquisition and the rest for post-acquisition tasks
- "Plan ahead" task list as part of scan setup automates repetitive tasks such as reconstructions, image transfer, image processing, etc. without requiring technologist intervention
- Ability to prospectively prescribe multi planar reconstructions for anatomies such as spine as part of the protocol, thus automating the workflow seamlessly
- Clear status visibility across all automated patient tasks without any interaction enables you to focus on the primary task at hand
- Manage your patient flow better with the ability to prepare scan prescription for the next patient while the current patient is getting off the table
- Quickly select scan protocols through global search, anatomical selection or user specific favorites in the newly designed protocol management system
- Facilitates protocol consistency by controlling access to changes and simplifying inputs required
- Integration with AW allows prescribing automatic image processing steps to be performed on the AW / AW Server post acquisition
- Better dose awareness through clearly visible real time projected dose indicator for the selected protocol

Console specifications	
Host computer	• CPU: Dual Intel Six Core Xeon 2.66GHz 5650 Processors • RAM 48GB DDR3-1333MHz ECC DIMM
Total system storage	up to 700,000 512 images and with 1 TB for scan data files
Additional storage	USB 2.0 Port for External Hard Disk Drive Connectivity

Peripheral components

- 24in 1920x1200 Monitor
- 104-Key USB 2.0 Keyboard
- 3-Button USB 2.0 Mouse
- 3-Button USB 2.0 Trackball
- DVD-ROM, DVD-R, DVD-RW, DVD+R, DVD+RW, CD-ROM, CD-R, CD-RW, DVD+R DL

- 5.25in media
- 8.5 GB Double Sided DVD Media Capacity
- 16X DVD / 40X CD read speed
- Scan Control Interface

Image networking

- Exam Transfer up to 16 frames per second on dedicated 1 Gbit connection
- Standard auto-configuring Ethernet (UTP connection) - 1000/100/10 BaseT
- Direct network connection; multi-suite ethernet card not required for gateway out of suite
- Protocols supported:
  - DICOM network send (one IP address at a time) and receive, pull/query, and storage commitment push - InSite point-to-point
- **Data Export capabilities** to convert clinical images into PC-friendly formats like .jpeg, .mpeg, and .avi.

Smart Flow - Productivity & Workflow features

Simplified, automated scan prescriptions, personalized to the patient and easy-to-use reference protocols make the Revolution CT fast and efficient in patient set-up, prescription & scanning. The following features further help you streamline your workflow.

SmartStart™

- Gantry-mounted start scan button and countdown display,
- Facilitates single-technologist operation by allowing start of scan at the gantry, with a visual reminder of time until X-ray initiation

AutoScan™
Fully automates longitudinal table movement and start of each helical scan.

Auto SmartPrep

Provides software for real-time monitoring of contrast enhancement at a prescribed location & automatically transitions scan when the preset threshold is reached with a turnaround time of < 3 seconds with a table move of 150mm.

Prospective Multiple-Thickness Reconstruction

In addition to the initial reconstructed slice thickness, the operator has the option to prospectively specify up to 9 additional reconstructions from a single raw data set. These images can be reconstructed at any of the defined nominal slice thicknesses available for a given table speed and scan mode along with different reconstruction kernel options.

Queued Reconstruction

Requests will be processed continuously and simultaneously with other processes on the system including scanning. Prospective reconstruction will be prioritized over retrospective reconstruction.

Prospective & Retrospective Reconstruction

Operator may initiate full reconstructions at any table location in increments of 1/10 the image thickness; image thickness remains constant.

Reconstruction speed : Up to 55 frames per second

Retrospective Image Decomposition

The operator has the option to retrospectively decompose the original raw data set and reconstruct additional images at any of the defined nominal image thickness available for a given table speed and scan mode.

Exam Split

Allows multi-anatomical exams to be split in to separate anatomic sections.

Trauma Patient entry

Allows patient scans and image display/analysis without entering patient data before scanning.

Scan Modes

The Revolution CT system can perform virtually any clinical application due to its wide variety of scan modes.

Axial:

- Up to 160 mm of contiguous axial coverage acquired simultaneously with each 360° rotation, with the time between scans set by the user-selected interscan delay (ISD) or intergroup delay (IGD)
- Scans may be easily clustered in groups to allow multiple scans in a single breath hold
- Minimum scan-to-scan cycle time of < 2 seconds with table moves of ≤ 160 mm (any scan time) and < 1 second without any table move
- Flexible detector coverage & capability to mix collimations from 5 mm to 160 mm

Helical:

- Continuous 360° scanning @ up to 40mm collimation with constant table movement and no interscan delay
- Scans can be acquired in a wide variety of speeds

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Mixed mode scans:

- The system allows axial and helical scans or gated / un-gated axial scans to be mixed in a single series acquisition with very short delay of <= 1 second to cover larger than 160mm anatomy

Cine:

- Up to 160 mm of contiguous axial coverage acquired simultaneously with each 360° rotation
- Minimum scan-to-scan cycle time of < 2 seconds with table moves of ≤ 160 mm (any scan time) and < 1 second without any table move

Scout™:

- Single radiographic plane for scan localization and graphical prescription of prospective reconstruction;

  Extended range matches helical scannable range at 0.625mm slice thickness

High Definition Scan Modes: All supported scan modes listed above are also available in High Definition mode

Axial Scan parameters

The Revolution CT acquires 160 mm of axial coverage in one 360° rotation.

For each rotation of the gantry, the Revolution CT collects up to 160mm of scan data. There are varieties of reconstruction modes available for creating images from the multi-slice scan data. By using some of these reconstruction modes, scan data can be combined prior to image reconstruction to create slices with reduced partial-volume artifacts. This is particularly useful for posterior-fossa imaging.

Scan speed	
Routine	0.4 to 1.0 second full scans (360° acquisition);
Cardiac	0.28s
Scan technique	
kVp	70 to 140
mA:	10 to 740, 5mA increments
Focal Spot selection @120kVp	• Small spot for up to 405mA • Large spot for up to 665mA • X-Large spot for up to 740mA
Scan Plane Geometry:	Longitudinal positioning in 0.1 mm per slice increment. Gantry display in 0.5 mm increments.
Aperture	5mm to 160mm
Inter scan Delay (ISD)	Minimum of 1 second with no table movement. < 2 seconds with <= 160mm table move
Inter Group Delay (IGD):	Minimum IGD is the same as minimum ISD; also user-selectable.
Scan-to-Scan Cycle:	Minimum scan-to-scan cycle of 1 second possible for 0.5 seconds scan speed with minimum ISDs.
Maximum Scan Fields of View:	• 32cm for pediatric head & body, adult head and small body, small cardiac • 36cm for medium cardiac • 50cm for medium & large body, large cardiac

Scan with no table increments, contiguous image location, or skipped image locations are possible. Overlapped axial scans are not possible.

Axial image reconstruction

A variety of reconstruction kernels such as Standard, Bone, HD Standard, etc. are available with different contrast & noise characteristics

Number of reconstructed slices	Up to 512 slices per rotation
Reconstruction Matrix	512 x 512
Display Matrix	1024 x 1024
Display FOV	Freely variable center/off-center, prospective/retrospective target selection
CT Number Scale	-1024 to 3072 (normal range) and -31743 to 31743 (extended range)
Reconstructed slice widths	0.625mm to 5mm
Prospective multiple reconstruction (PMR)	Up to 10 sets of recons can be pre-programmed

Helical Scan parameters

The system supports helical mode imaging using beam collimation 64x0.625 with helical reconstruction increment as small as 0.1mm.

Scan speed	
Routine	Full 360° rotational scans in 0.4 to 1.0 seconds;
Pitch range	0.516:1 to 1.375:1
Scan technique	
kVp:	70 to 140

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mA:	10 to 740, 5mA increments
Focal Spot selection @120kVp	Small spot for up to 405mA Large spot for up to 665mA X-Large spot for up to 740mA
Reconstructed slice widths	0.625mm to 5mm
Max single acquisition time	60-second scan
Inter Group Delay (IGD):	1 second between adjacent helical scans
Maximum Scan Fields of View:	• 32cm for pediatric head & body, adult head and small body • 50cm for medium & large body

Scan with no table increments, contiguous image location, or skipped image locations are possible. **Helical image reconstruction**

A variety of reconstruction kernels such as Standard, Bone, HD Standard, etc. are available with different contrast & noise characteristics

Reconstruction Matrix	**512 x 512**
Display Matrix	1024 x 1024
Display FOV	Freely variable center/off-center, prospective/retrospective target selection
CT Number Scale	• 1024 to 3072 (normal range) • 31743 to 31743 (extended range)
Prospective multiple reconstruction (PMR)	Up to 10 sets of reconstructions can be pre-programmed
Helical Reconstruction Times	up to 55 fps
Minimum DFOV	5 cm
Minimum Pixel Size	0.0977 mm

Scout Scan parameters

ScoutView™ scans provide excellent detail for anatomical localization in conjunction with scan prescription.

Scan locations may be prescribed at the operator console either graphically (via mouse), or explicitly (keyboard entry) from a Scout scan.

Scan speed	
Aperture	5 mm effective aperture
Table speed	100 mm/s

Scan technique	
kVp	70 to 140
mA	10 to 250, 5mA increments
Orientation	AP, RLAT, PA, LLAT (preset);
Scout range	50 to 2000* mm Scouts longer than 1,000 mm are auto minified to fit the display
Max display FOV	50cm

Image Quality

The Revolution CT is a sub-millimeter isotropic CT scanner making it possible to leverage coronal and sagittal reformats. It preserves the industry leading spatial resolution of Discovery CT750 HD system.

The optimized x-ray source (focal spot shape & dynamics as well as reduced off focal radiation) allows for improved measurement methods to fully characterize the limiting resolution of the Revolution CT system design.

High Contrast Resolution

Helical Visual Measurement

Reformatted resolution is demonstrated on the Catphan™ High Contrast Resolution Insert Module CTP528:

0.35 ± 0.05mm voxel size is seen in the reformatted plane.

Spatial resolution

The Revolution CT detector provides high contrast spatial resolution.

Helical scan: Typical MTF is demonstrated on a 0.05mm tungsten wire and a 1.0mm x 0.025mm gold foil phantom for in-plane and z-plane, respectively:

Typical Hi-Res Algorithm Resolution		
MTF	X-Y lp/cm	Z lp/cm
50%	13	7.3
10%	18	12.2
0%	21.4	21.2

Axial scan: Typical in-plane MTF is demonstrated on a 0.05mm tungsten wire. In-plane Spatial Resolution Performance for full scan Axial and Cine Scans:

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Typical Hi-Res Algorithm Resolution	
MTF	X-Y lp/cm
50%	13
10%	18
0%	21.4

Low-Contrast Resolution

The Revolution CT Scanner preserves the superior Low Contrast Detectability (LCD) of Discovery CT 750 HD. This may allow for improved visualization of smaller low contrast structures.

LCD is measured on 8 inch (20cm) CATPHAN phantom, 5mm slice thickness, 0.30% (3HU) contrast using helical scan

Reconstruction Mode	Object Size	% Contrast (typical)	Dose level (mGy CTDIvol) 5 mm Slice
Standard Algorithm with ASiR-V	5mm	0.30%	8.8

Image Noise

Image Noise is demonstrated on a 20cm Water Phantom or the GE Quality Assurance Phantom for head protocols using helical technique.

Image Noise
0.45% ± 0.05% at 9.5 mGy CTDIvol with the Standard Reconstruction Algorithm, 5mm Slice Thickness at 0.516:1 helical pitch and ASiR-V

CTDI

Both high resolution and normal scanning modes: On CTDI Head and Body Dose Reference Phantoms:

$CTDI_{vol}$ in mGy/100 mAs (0.984:1 Pitch)	
Head	14.86
Body (large)	6.88

HU Accuracy

Iodine HU Accuracy	HU accuracy for iodinated contrast is significantly improved based on native physics modeling reconstruction technology. < 10 HU across 160mm z-coverage (< 3% variation)

Artifact reduction

Revolution CT's unique VHD reconstruction technology with Multi Material Artifact Reduction (MMAR) models system physics and incorporates material characteristics to significantly reduce typical artifacts such as beam hardening caused due to dense objects such as bone, iodine & metal. Further, it significantly reduces cone beam artifacts inherent to wide coverage systems.

Smart Dose technologies

GE Healthcare develops products based on the idea that both dose and image quality is important in providing quality medical care. To assist you in optimizing each CT exam for your patients, Smart Dose provides solutions to help you manage dose.

Dose reduction and optimization technologies

ASiR-V

Integrated advanced iterative reconstruction technology (ASiR-V) reduces noise, even at very low signal levels. This technology is designed to deliver reduced noise levels, improved low contrast detectability and may enable a reduction in dose[7] for all clinical applications.

Scout Based Technologies
Enables tailoring the x-ray beam to the patient being scanned. In order to use the optimal amount of dose to achieve the desired image quality, it is important to know the patient attenuation. This information can be generated by the scanner utilizing the scout data, which is then leveraged by our family of Scout Based Technology features:

3D Dose Modulation utilizing SmartmA* and AutomA
Volumetric knowledge prior to scanning allows you to personalize protocols and optimize dose for every patient – large and small. During the scan, real-time, 3D dose modulation helps deliver consistent image quality because it automatically accounts for the changing dimensions of your patients anatomy.

Organ Dose Modulation

Organ Dose Modulation (ODM) builds on the SmartmA feature to enable even further patient dose reduction. By reducing the mA exposure profile as a function of the X-ray tube angle, radiosensitive organs towards the anterior surface of the patient, such as the eyes, breasts and thorax, can benefit from enhanced dose reduction while the overall image noise is still maintained.

kV Assist
Makes it easy to select optimal kV settings for the patient being scanned. Recommends tube voltage and current to achieve the lowest dose while meeting desired image quality

[7] In clinical practice, the use of ASiR may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

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70 kV Scanning
70 kVp scan mode to enable low dose pediatric and small patient scans

ECG Automatic Gating

For cardiac applications, prospective ECG dose modulation automatically adjusts the mA to minimize the patient's exposure to X-rays – reducing dose outside the prescribed phase ranges. Up to 3 phase ranges can be selected within a heart cycle with different levels of mA. The peak mA is automatically determined based on noise index set by the user and patient attenuation information from the scout. The user can also select the % modulation outside the prescribed phase range. This provides clear images and allows you to reduce dose yet provides motion free, high quality images for functional and anatomical analysis within a heart cycle.

SmartTrack
Advanced hardware and software for X-ray beam tracking minimizes patient dose.

SmartBeam
Optimizes X-ray beam filtration independently for body, head, and cardiac applications.

Dose reporting

Dose Computation, Display & Reporting
CTDIvol (CTDI volume), DLP (Dose Length Product), and Dose Efficiency computation and display during scan prescription provide dose information to the operator.

Dose Reporting
Dose Reporting saves the CTDIvol, DLP, and phantom type in a DICOM Structured Dose Report and a secondary screen capture. Series and cumulative exam values are saved. Saved values can be networked, filmed and archived.

Dose Check
Provides the user with tools to help them manage CT dose in clinical practice and is based on the standard XR-25-2010 published by The Association of Electrical and Medical Imaging Equipment Manufacturers Association (NEMA).

Dose Check provides the following:
• Checking against a Notification Value if the estimated dose for the scan is above your site established value
• Checking against an Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters if the estimated dose exceeds the alert value
• The ability to define Alert Values for Adult and Pediatric with age threshold
• Audit Logging and Review capabilities
• Protocol Change Control capabilities

CT 4Kids
Dose-optimized procedure based protocols for pediatric imaging

Color Coding for Kids
Provides pediatric scan protocols based on the Broselow-Luten™ Pediatric System. This Color Coding system is incorporated into the protocol selection on the operator's console and is designed to facilitate pediatric emergency care and reduce medical errors.

Making advanced imaging routine & routine imaging advanced

Cardiac & Cardiovascular

1-Beat, High definition, motion free coronary images at any heart rate is enabled by a prospectively ECG-gated whole heart cardiac axial acquisition protocol that utilizes 160mm of high-definition coverage with 0.28s rotation speed and real-time control to complete the scan in a single beat to ensure robust, low dose and high definition cardiac imaging for all heart rates, with or without beta blockers

- SnapShot Freeze intelligent motion correction technology allows for 24ms effective cardiac temporal resolution, industries highest and results in motion free images
- For cardiac scan modes, Revolution CT provides best in class spatial resolution at 18.2lp/cm in z-direction and 14.8lp/cm in X-Y direction (measured at 2% MTF). This spatial resolution provides clear images to help the physician with tasks such as accurately quantifying stenosis in coronary and other vascular structures
- This scanning technique ensures IV contrast uniformity & temporal uniformity across the whole volume with the ability to prescribe up to 3 phases to acquire prospectively within a single beat

1-Beat, comprehensive cardiac assessment allows for acquiring motion free coronaries, rest or stress perfusion and functional data in a single beat, giving you a comprehensive assessment and potentially reducing the need for additional imaging tests. Integrated beam hardening reduction capabilities allows for accurate perfusion assessment. The ability to perform stress perfusion with motion free CCTA in a single exam can potentially reduce unnecessary dose by not requiring a rest perfusion exam in case no defects are found in the stress perfusion.

Dynamic Acquisition Modes

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The Revolution CT allows for whole organ dynamic perfusion acquisition with up to 16 cm of coverage, this allows perfusion acquisition of the heart, brain, liver, kidneys and other organ and tissues with uniform contrast along with integrated beam hardening reduction. The scanner also allows for a flexible aperture size and sampling rate during dynamic perfusion acquisitions, which is particularly beneficial in localizing anatomy of interest for brain and other perfusion acquisitions. This is enabled by selecting supported collimations between 5mm to 160mm for selecting the aperture size and selecting different sampling rate groups depending on the phase of the contrast. Typically a faster sampling rate when the contrast bolus is arriving in the tissue followed by a slower sampling during washout.

Revolution CT also allows for the ability to acquire a prospectively gated dynamic perfusion acquisition of the whole heart using up to 16 cm of coverage.

The scanner is also capable of **4D imaging** to acquire morphology and perfusion information from a single exam. This can help assess conditions such as congenital heart disease and visualize blood flow through vascular structures.

TAVI assessment
Dedicated TAVR protocols allow mixing of ECG gated cardiac axial acquisition with non ECG gated modes covering the 700mm anatomy in less than 10 seconds. Image processing application integration allows for seamless assessment of TAVI studies.

Calcium Scoring
The system also allows single beat acquisition for cardiac calcium scoring

Triple Rule Out™
The system allows for robust Triple Rule Out studies with motion free coronaries, PE & aorta evaluation in a single exam. The system can cover the entire thorax anatomy in under 3 seconds to provide contrast uniformity at low dose.

Smart Cardiac
The system has been designed to improve the robustness of cardiac exams for patients with high or irregular heart rates and in situations involving irregular heartbeats, arrhythmia, atrial fibrillations, PVC's, etc. The system can monitor and alert the user to these situations and also recommend turning on a challenging patient mode. This mode avoids scanning during an irregular beat and can further rescan during the next regular beat using the same contrast bolus.

Neurology

Comprehensive Stroke workup is enabled by one touch dynamic acquisition mode in Revolution CT. Very low mA acquisition with smart smoothing in image processing application results in accurate perfusion metrics at very low doses

The Revolution system is also capable of acquiring neuro perfusion and CTA of the brain in a single exam to enable comprehensive functional & anatomical assessment of the brain.

The system can also acquire cardiac function, CCTA and a head / neck angio in a single exam using a single contrast bolus to perform a comprehensive cardiovascular and neuro assessment using multi-volume scan mode.

Routine head scans can be performed in less than a second single rotation with excellent gray white matter and bone / brain interface separation. VHD reconstruction technology with integrated artifact reduction reduces beam hardening artifacts in the posterior fossa region.

Body & Oncology

Whole organ diagnosis & follow-up
Low dose, whole organ diagnosis & follow up of organs such as the liver, kidneys, pancreas, etc. is enabled by dynamic acquisition modes. The scanner can also acquire multiple images at the same location over time to provide a 4D view to assess vascular flow to these organs.

Fast body scans enabled by multi-volume 16cm acquisition with excellent image quality allows for reduced breath hold times and shallow breathing. Dose is minimized through the ability to select collimations between 5mm and 160mm personalized to each patient.

Emergency & Trauma

The system allows for robust Triple RuleOut™ acquisition for all patients providing 1-Beat, HD, motion free coronaries, PE & aortic dissection in a single exam covering the entire thorax in less than 3 seconds. ECG gating and mA modulation along with flexible collimations enable low dose acquisition personalized to the patient.

Split second scanning up to 16cm combined with fast table speed of 300 mm/s allows for ultra fast scanning, thus reducing the effect of breathing and other motion during the scan.

Custom scan modes that enable scanning multiple anatomical regions in a single exam combined with UI capabilities to prescribe multi planar reconstruction prospectively enables fast trauma scanning on this system.

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Pediatrics

Split second pediatric trauma acquisition of abdomen / pelvis is enabled by wide 16cm z-coverage, thus reducing the need for sedation and eliminating unnecessary repetition of scans in young children due to failed sedation, as is the case in 29%[8] of conventional exams, shown in a large trial.

70kV scan mode allows for minimizing dose to pediatric patients while preserving excellent contrast to noise ratio and image quality.

Musculo Skeletal Imaging

The Revolution CT can acquire high definition images of the bone with excellent detail & significantly reduced artifacts from metal objects such as screws and plates.

4D imaging mode can acquire kinetic studies to assess joint articulation up to 16cm coverage.

DICOM Conformance Standards

DICOM Interchange
Allows the saving of any image from the database, along with a PC viewer using Internet Explorer, to a CD-R or DVD-R without marking the exam/series or image as archived for exam transfer between stations that are not networked or pass along to referring physicians or patients.

For detailed information, please reference DICOM conformance statement.

- DICOM Storage Service Class
- Service Class User (SCU) for image send
- Service Class Provider (SCP) for image receive
- Service Class User (SCU) for storage commitment
- DICOM Query/Retrieve Service Class
- DICOM Modality Worklist
- DICOM Modality Performed Procedure Step
- DICOM Print

Image Networking
Exams can be selected and moved between the Revolution CT and any imaging system supporting the DICOM protocol for network send, receive and pull/query.

Image transfer time using DICOM protocols is > 16fps on a 1000baseT network.

(b) (4)

[8] British Journal of Anaesthesia, 84 (6), 743-8 (2000)

(b) (4)

Industry Standards

The Revolution CT complies with a wide variety of industry standards to facilitate more rapid adoption of features and performance improvements as the computing and medical imaging industry evolves.

Compatible Options

The following options are available on the Revolution CT and operator console. Some of these may be standard and some might require optional purchase. See Advantage Workstation (AW) product data sheet for list of available AW options.

Scanner & Operator console options
Automatic Exposure Control
5000 Image Series
Copy Composer/Interchange
Data Export
256 slice
High Definition Modes
0.28s rotation speed
ECG Viewer
Cardiac option
1-Beat cardiac
Integrated Cardiac MonitorConnect Pro
Exam Split
Direct MPR
SmartPrep
512i Overlap reconstruction
Operator console table
AW client access
CT Perfusion 4 Neuro
CT Perfusion 4 Multi-organ
Enhanced Xtream Injector Class IV
Tube License
NG2000 Table slickers
Bar code reader
Uninterruptible Power Supply
Supported Class IV injector

Standard, Selectable Items

(b) (4)

- NG Patient Positioning System
- Keyboard: English, French, German, Scandinavian, Danish, Dutch, Italian, Norwegian, Spanish, Swedish, Portuguese or International (with overlays for English, French, German,

Revolution CT
Uncompromised.

GE Healthcare
Milwaukee, USA - Fax: 1 262 544 3384
Tokyo, Japan - Fax: 81 425 85 5490
Paris, France - Fax: 33 1 30 70 94 35

Italian, Japanese, Mandarin, Portuguese-Brazil, Portuguese-European, Spanish, Korean, Estonian, Finnish, Hungarian, Lithuanian, Polish, Romanian, Slovakian, and Turkish)

- Cable Set
- ConnectPro HIS/RIS Interface with Performed Procedure Step)
- Operator console table with adjustable height

Warranty

The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

Regulatory Compliance

This product is designed to comply with applicable standards under the Radiation Control for Health and Safety Act of 1968.

This product complies with the performance standards of 21 CFR, sub-chapter J, and the applicable IEC 60601-1 series.

Laser alignment devices contained within this product are appropriately labeled according to the requirements of the Center for Devices and Radiological Health.

This product satisfies regulations regarding Electro-Magnetic Compatibility (EMC) and Electro-Magnetic Interference (EMI), pursuant to IEC-60601-1-2.

Revolution CT may not be available in all markets.

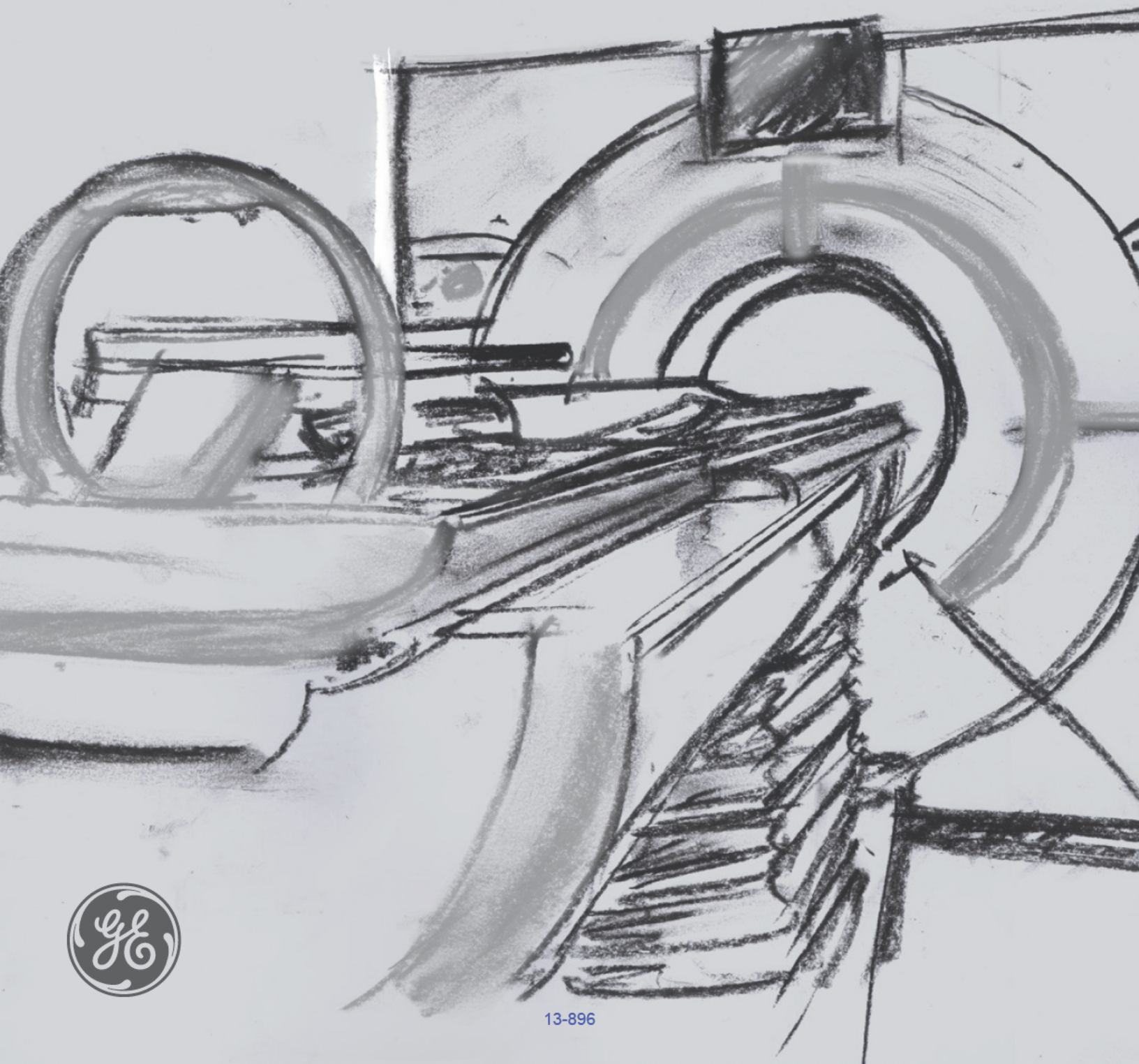
Attachment 13D

Revolution CT Sample Brochure

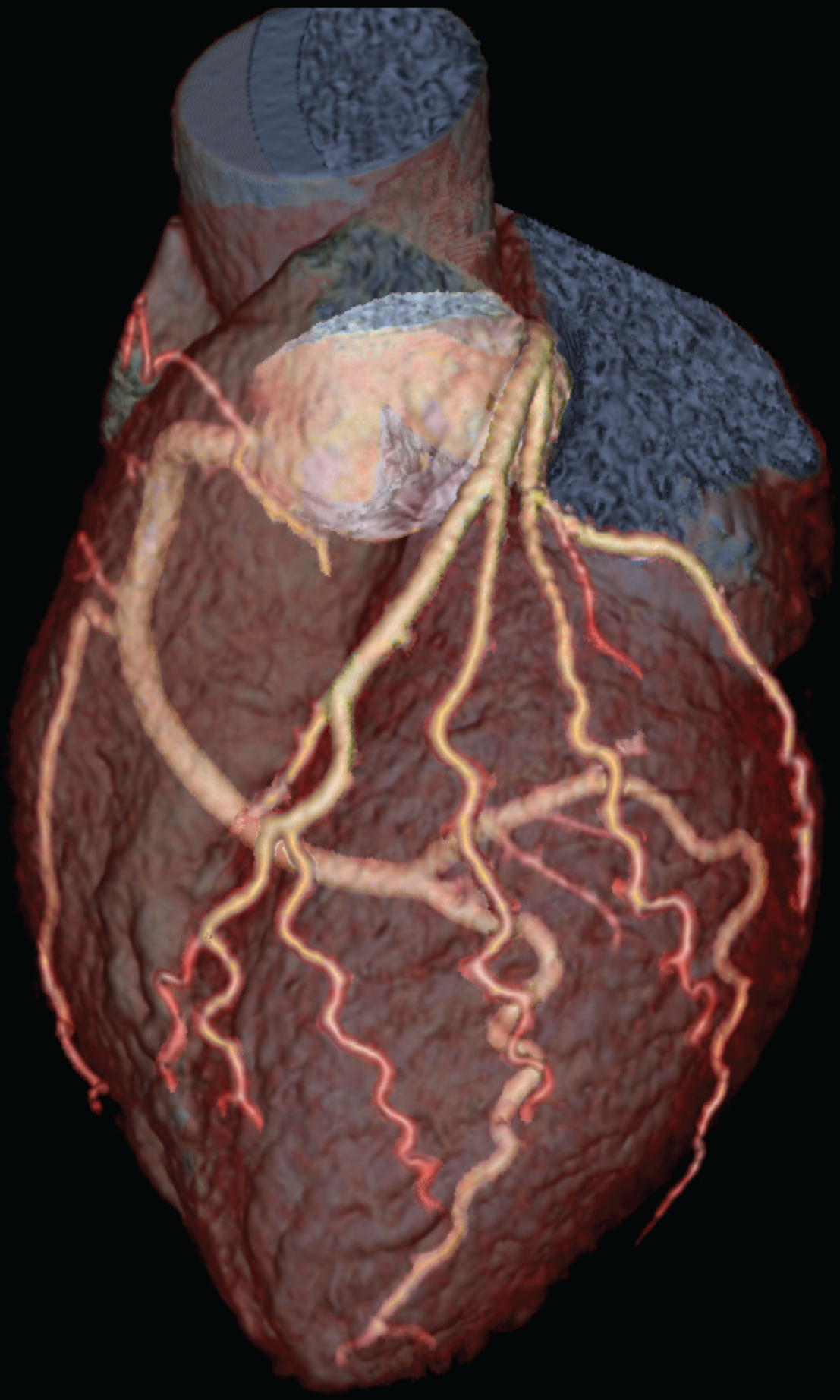
GE Healthcare

Revolution CT

Uncompromised.



13-896



13-897

WHERE THE ART OF INTUITION MEETS THE SCIENCE OF IMAGING.

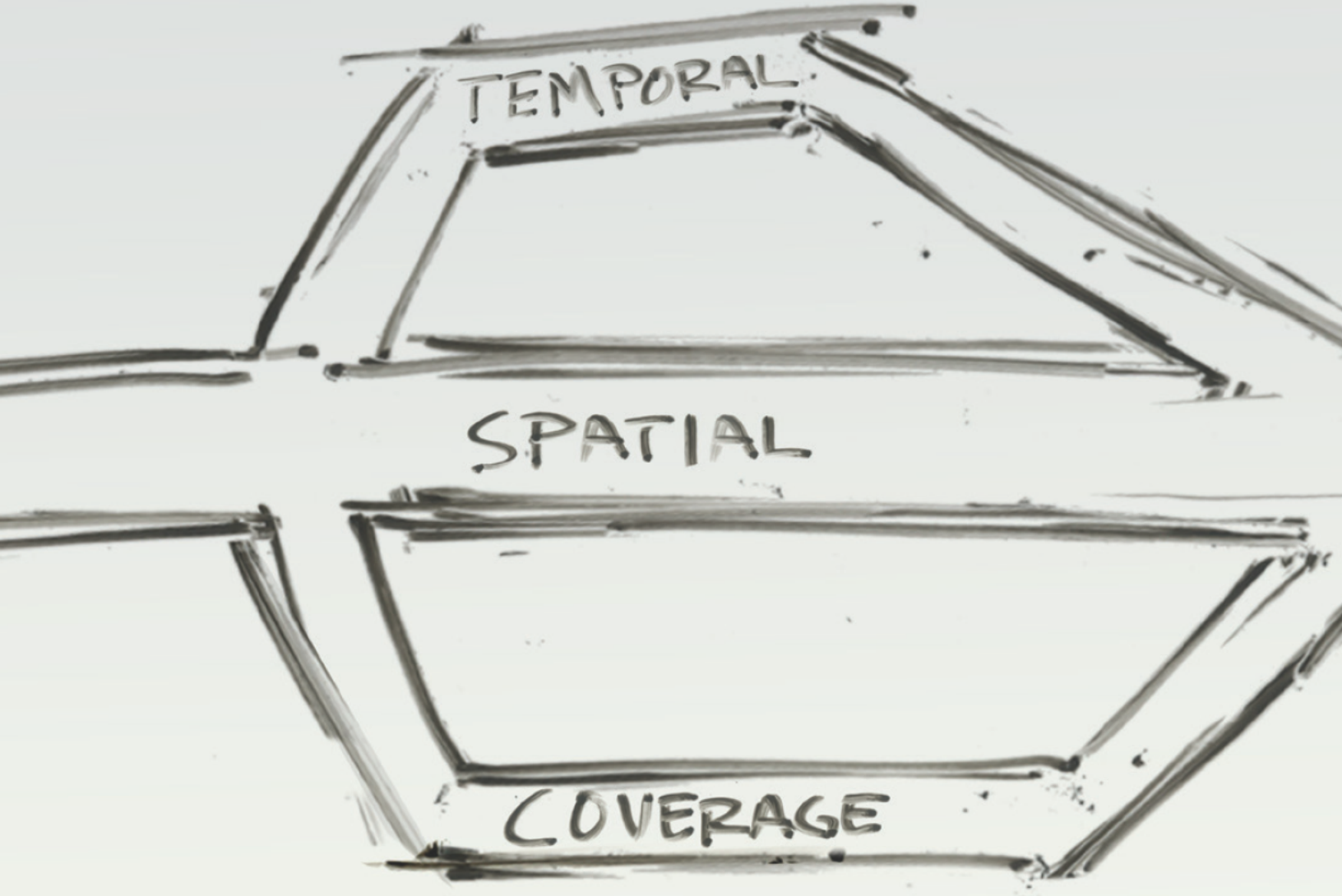
You leverage the art of your diagnostic intuition and the power of CT technology to convert black and white images into a confident diagnosis. To help you do this, we've developed a revolutionary CT platform that creates uncompromised images enabled by the latest technological and scientific advances. Images that may even be described as works of art.

Introducing Revolution CT. Where the art of intuition meets the science of imaging.

EVERY PATIENT'S NEED IS DIFFERENT.

Every day you face complex clinical challenges that require multiple tests to confidently diagnose and identify treatment strategy.

At the same time, the healthcare environment is more cost constrained and demands higher efficiency and productivity.



IT'S TIME FOR A REVOLUTION.

What if your CT could address the needs of all your patients, even the challenging ones?

What if your CT could help you deliver clinical excellence across all of your departments?

INTRODUCING REVOLUTION CT.

13-901

The CT that delivers uncompromised image quality and clinical capabilities through the convergence of coverage, spatial and temporal resolution – all in one.

It is the CT designed to help you deliver revolutionary and differentiated capabilities across all of your clinical areas.

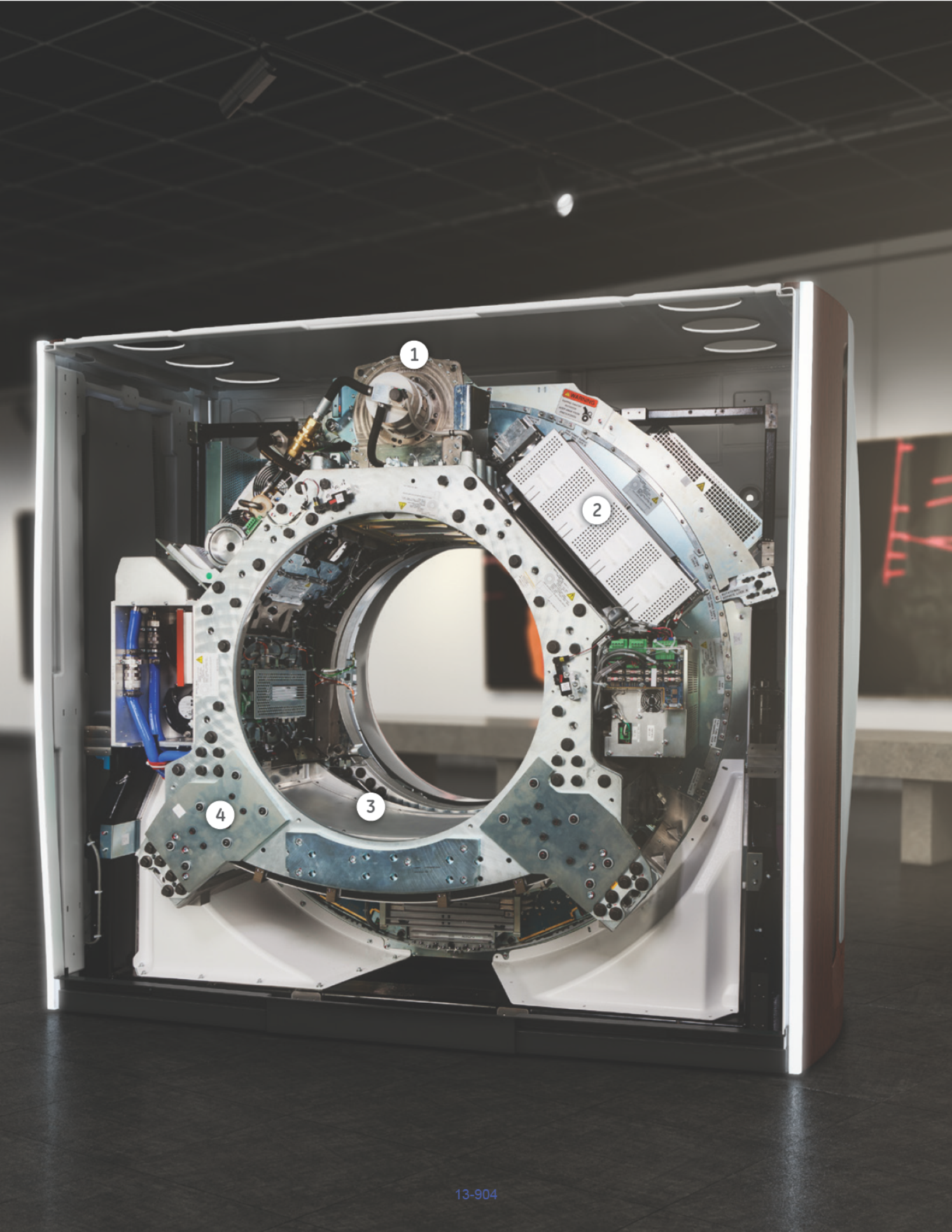
TECHNOLOGY ENGINEERED TO WOW.

The Revolution CT is redesigned from the ground up to deliver uncompromised image quality and clinical capabilities through the convergence of coverage, spatial and temporal resolution – all in one. It is engineered to provide technologies for whole organ coverage, best in class image quality and speed. The key technology enablers include:

A new imaging chain that leverages both hardware and VHD reconstruction technology for excellent image quality across the entire 160 mm of coverage.

All new gantry platform delivering 0.28 s rotation speed and tested to support up to 0.2 s. Combined with SnapShot* Freeze intelligent motion correction, Revolution CT delivers the best effective temporal resolution for routine cardiac imaging at any heart rate.

1. New Performix HDw tube
2. Ultra fast kV-switching generator
3. Gemstone* Clarity Detector
4. 0.2s ready gantry with Whisper Drive system and Contactless slipring


1
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NEXT GENERATION DETECTOR.

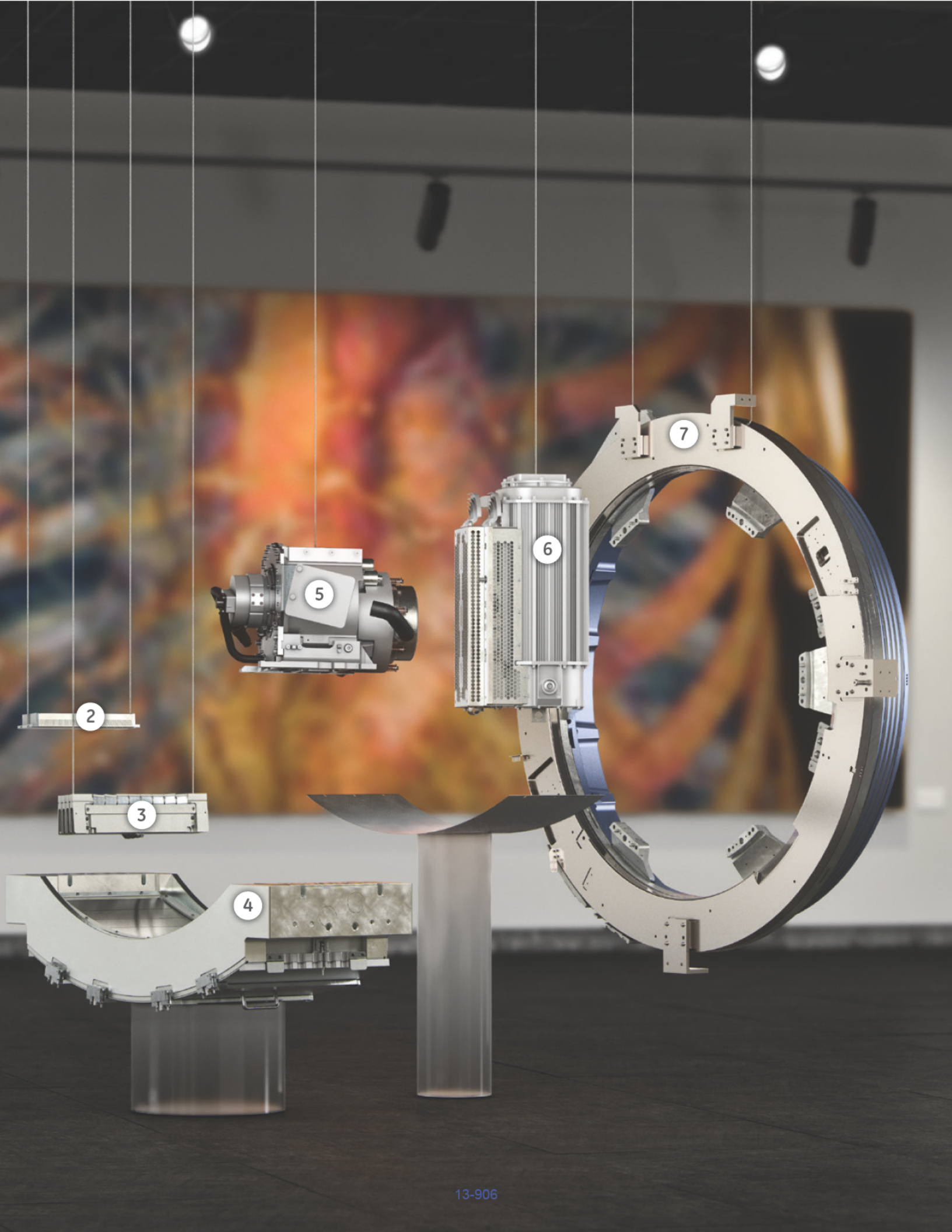
Revolution CT features the new Gemstone Clarity Detector with ground breaking technology to enable wide area coverage with best in class spatial resolution.

With the industry's fastest scintillator, the Gemstone Clarity Detector's industry leading sampling speed enables high definition and spectral imaging.

Wide area detectors can result in image artifacts that compromise quality. Revolution CT utilizes a unique focally aligned detector design to overcome limitations associated with wide coverage. Miniaturized detector modules make this design possible and because these streamlined modules reduce electronic noise, you get coverage and image quality with a 25 percent improvement in dose efficiency. That's uncompromised.

A proprietary 3D Collimator ensures IV contrast uniformity and minimizes scatter and beam hardening artifacts associated with wide coverage systems.

1. Gantry Display
2. 3D Collimator
3. Detector module
4. Gemstone Clarity Detector
5. Performix HDw tube
6. Ultra fast kV-switching generator
7. Contactless Slip ring and Whisper Drive system


2
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7

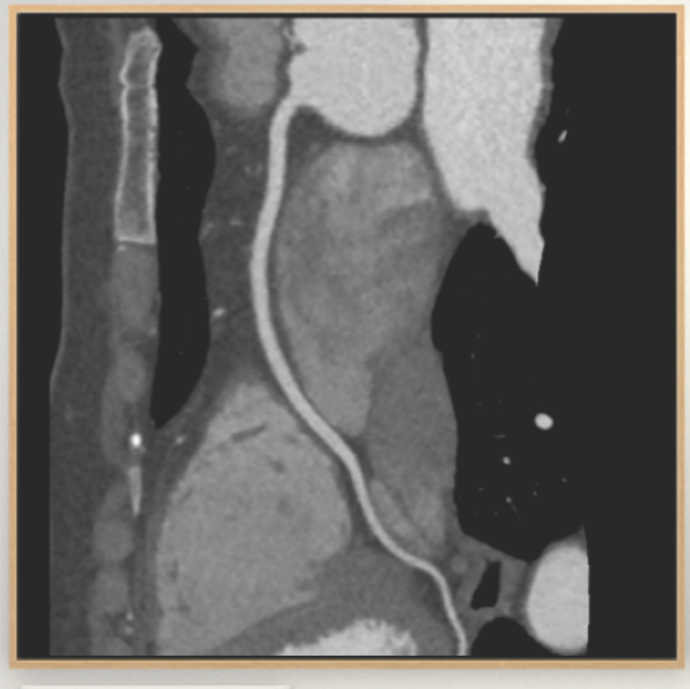
MAKING ADVANCED EXAMS ROUTINE AND ROUTINE EXAMS ADVANCED.

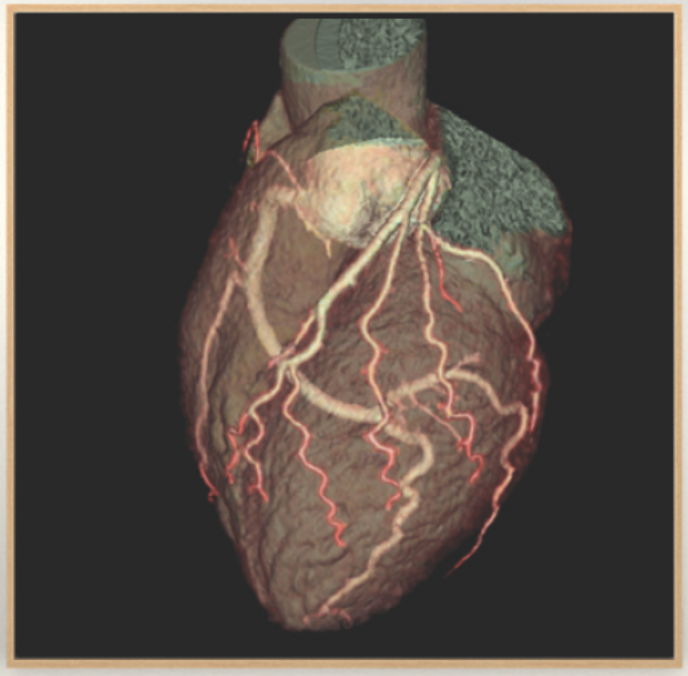
Thanks to its innovative design, Revolution CT will improve routine exams and enable you to deliver breakthrough clinical applications for all anatomies:

- Make your routine exams advanced with best in class 0.23 mm spatial resolution and built in artifact reduction.
- Capture the whole heart in a single beat, in high definition, with motion-free coronary images at any heart rate. One beat acquisition for calcium scoring, coronary imaging or comprehensive cardiac assessment can be achieved with or without beta blockers.
- Deliver rapid and precise TAVR planning at low radiation and contrast dose.
- Perform whole organ dynamic perfusion studies of the heart, brain, liver, kidneys and other organs and tissues with up to 16 cm of coverage with uniform IV contrast. Flexible collimation and sampling rate minimizes dose and is particularly beneficial in localizing anatomy of interest.
- 4D imaging for all anatomies to visualize vascular flow, organ motion or kinetic properties enabled by whole organ coverage.
- Deliver rapid and comprehensive trauma assessment thanks to the wide detector, fast table speed at up to 300 mm/sec and better access to patients through the wide 80 cm bore.

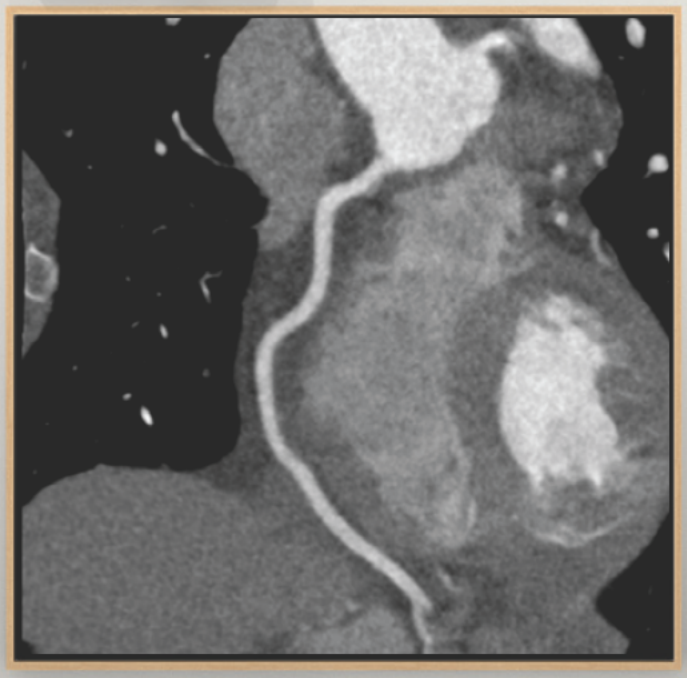
CARDIAC IMAGING.

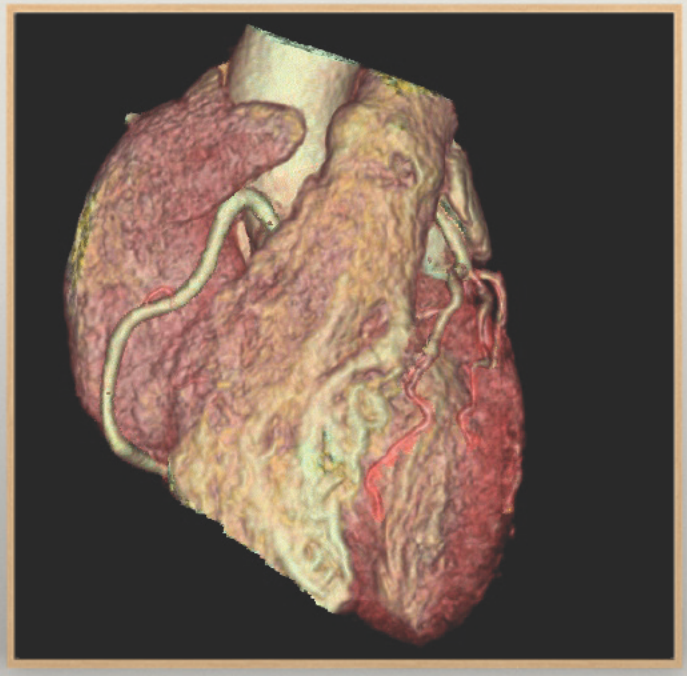
1-Beat, low dose, high definition, motion free coronaries.





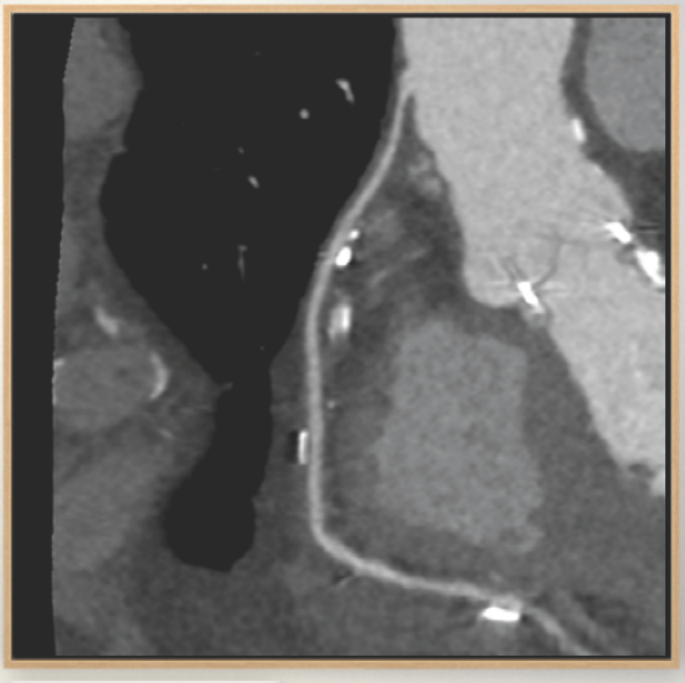
80 kV, 500 mA,
55 BPM, 23 BMI,
0.9 mSv

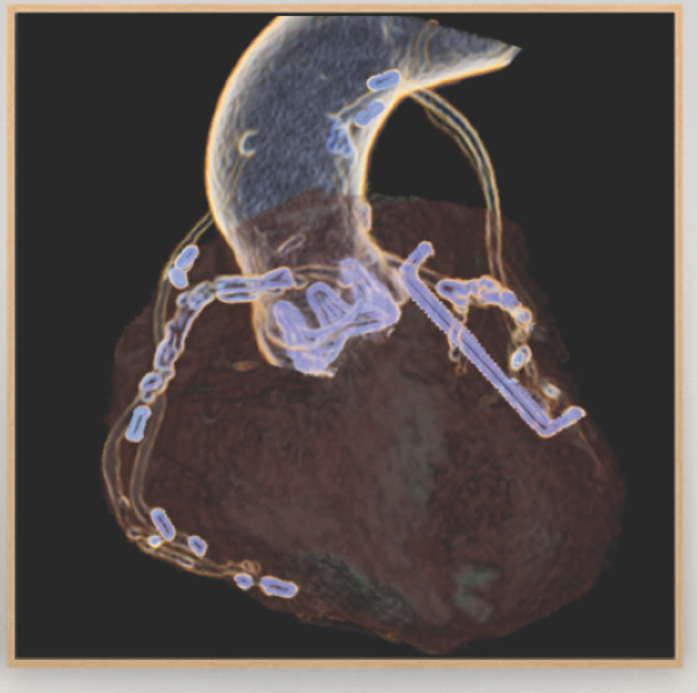




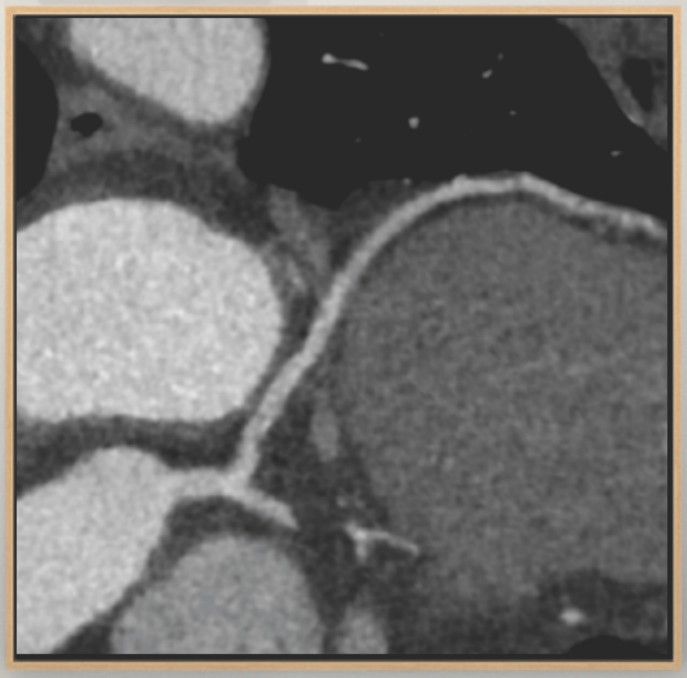
100 kV, 325 mA, 64 BPM,
29 BMI, 1.19 mSv, highly
irregular heart rate

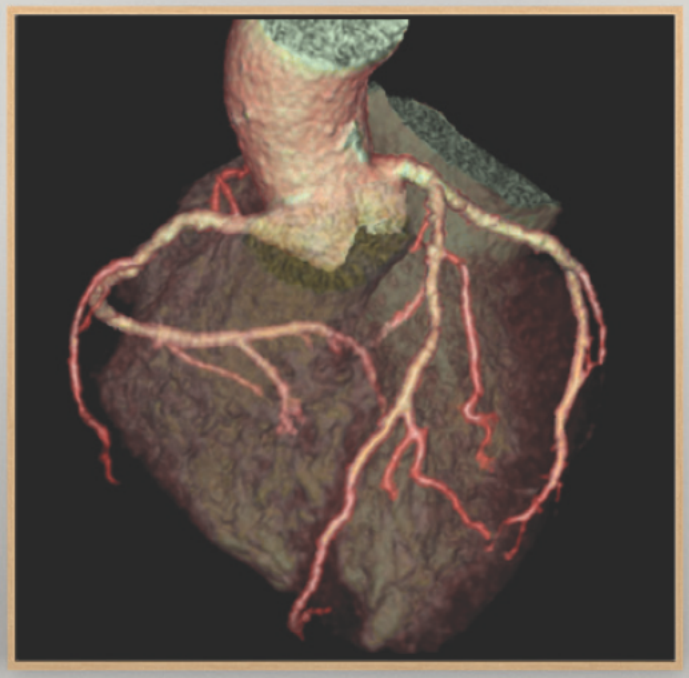
1-Beat, low dose, high definition, motion free coronaries – even with challenging patients.





100 kV, 400 mA,
79 BPM, 24 BMI,
3.2 mSv

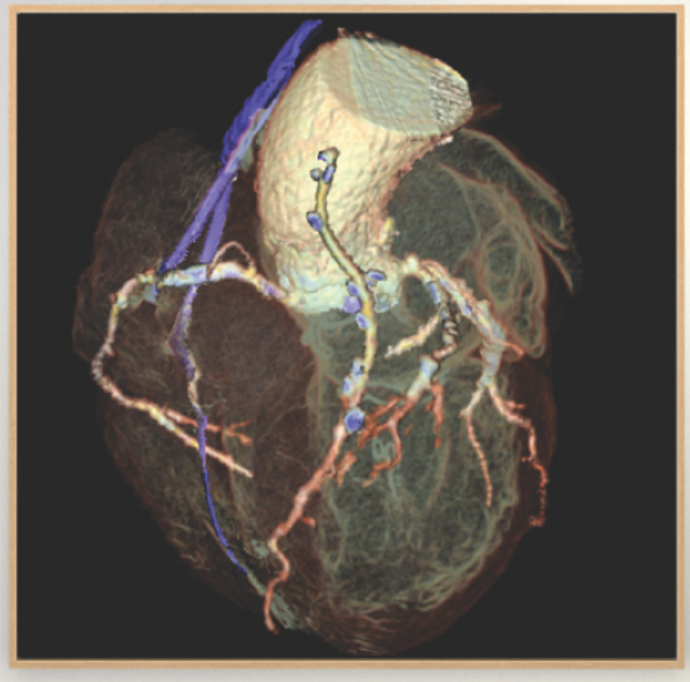


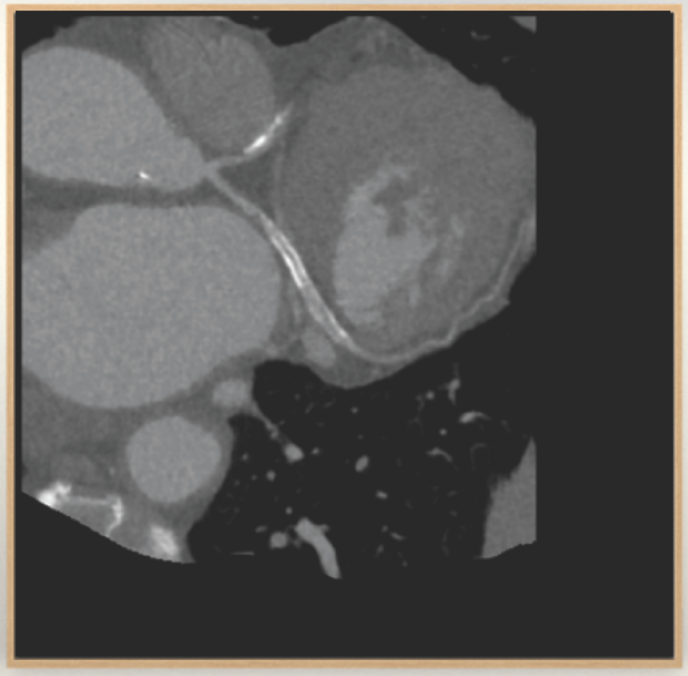


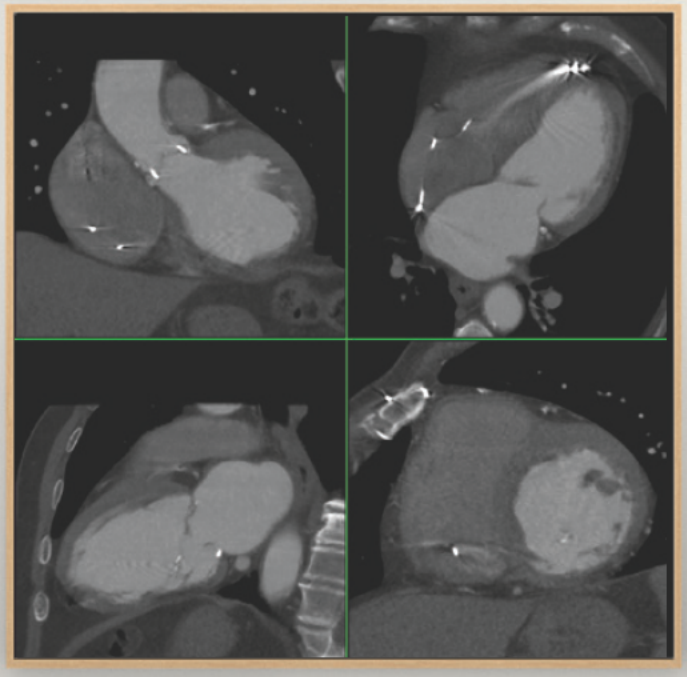
120 kV, 570 mA,
79 BPM, 42 BMI,
6.2 mSv

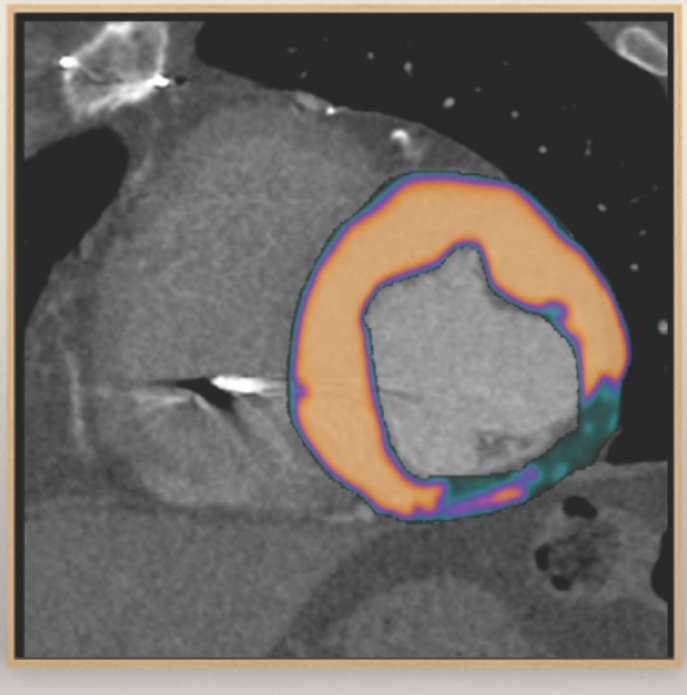
CARDIAC IMAGING.

Comprehensive cardiac assessment for every patient: coronaries, stress perfusion and function in one exam, one beat.



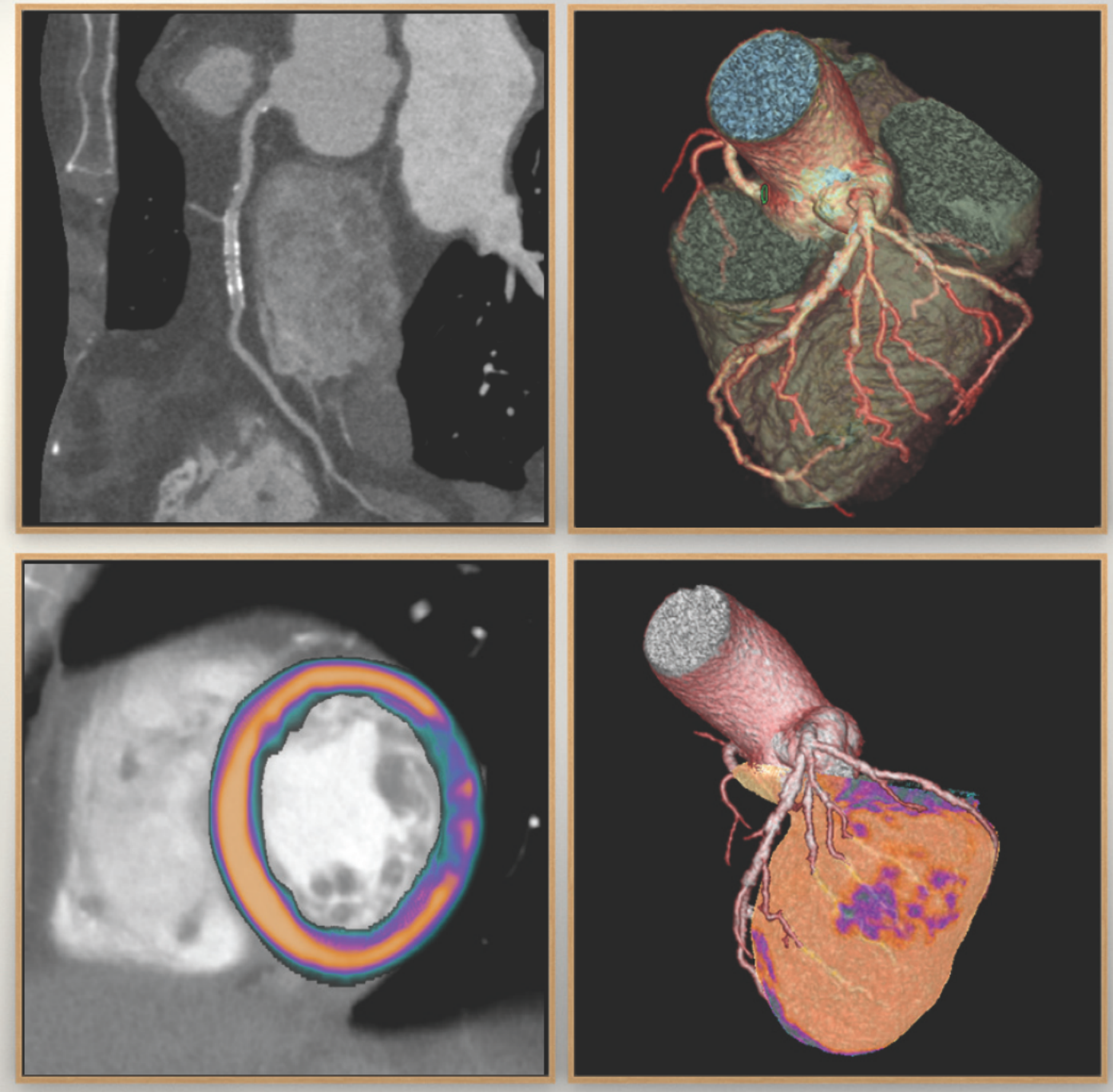






120 kV, 325 mA,
77 BPM, 28 BMI,
5.5 mSv

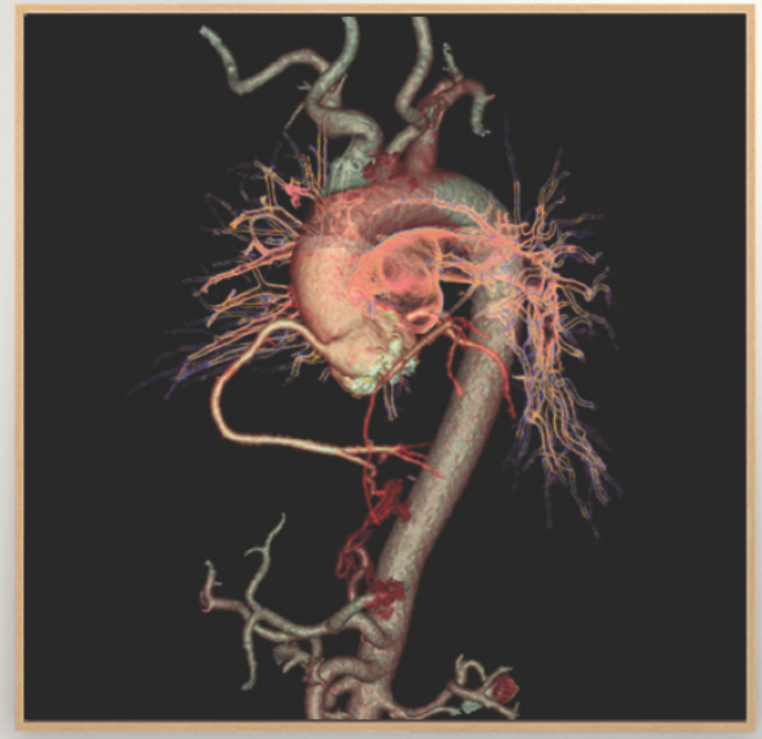
Comprehensive cardiac assessment for every patient: coronaries, myocardiac perfusion and function in one exam, one beat.

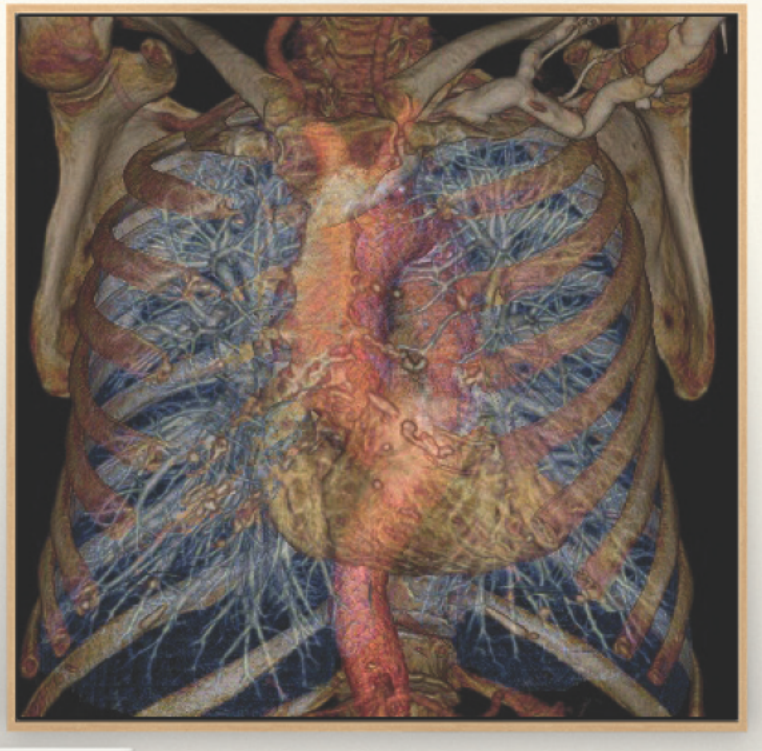


100 kV, 450 mA, 54 BPM, 28 BMI, 1.6 mSv

CARDIOVASCULAR IMAGING.

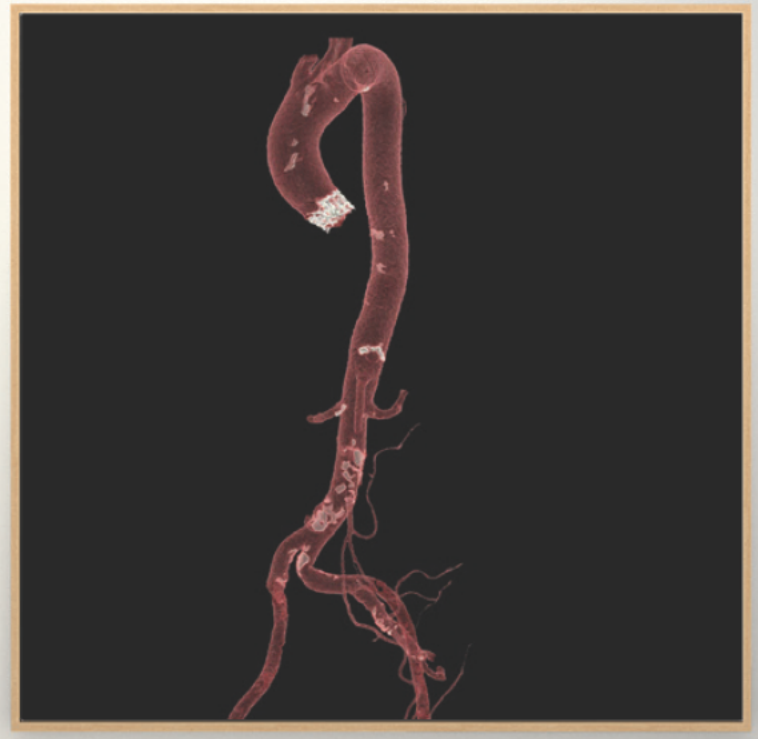
Robust, high definition TRO study for every patient with motion free coronaries at low dose and minimal breath hold.

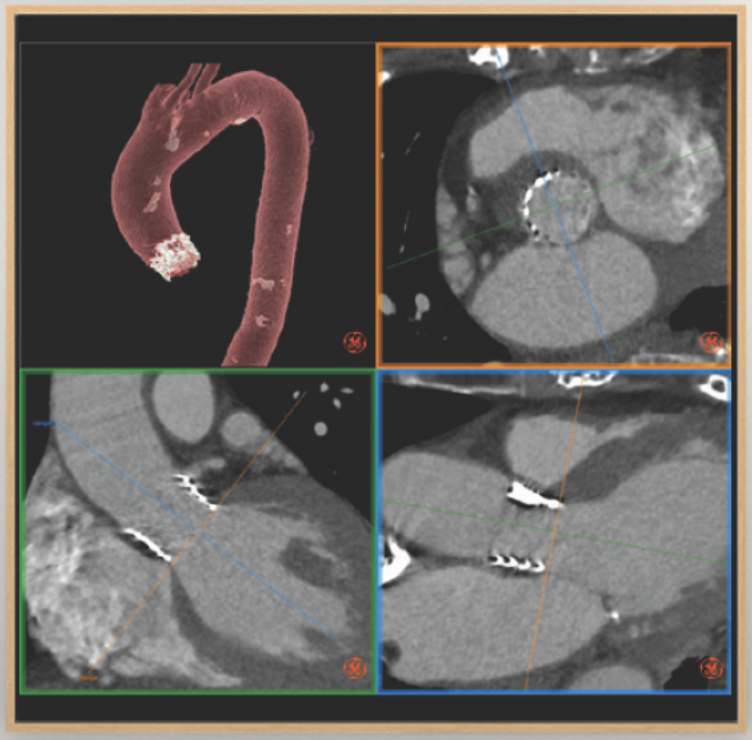




120 kV, 360 mA,
29 BMI, 65 BPM

Dedicated scan mode for rapid and precise TAVR planning delivering low radiation and contrast dose.

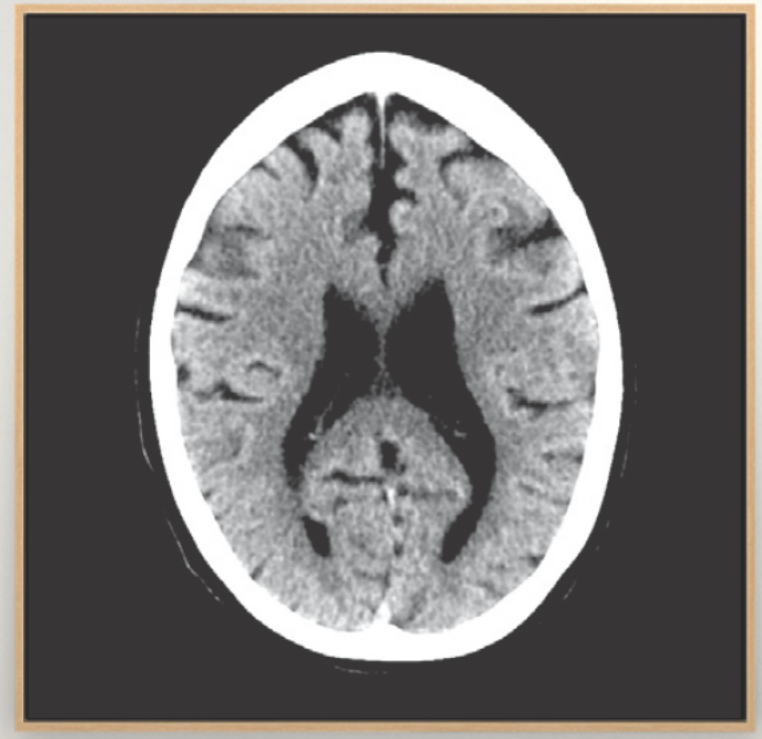




120 kV, 480 mA,
87 BPM

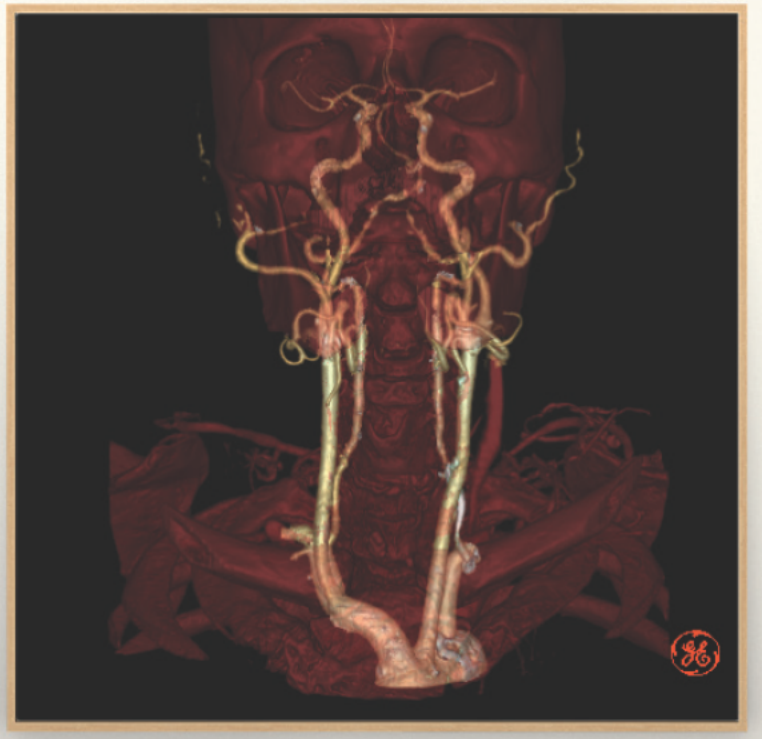
NEURO IMAGING.

Routine low dose head imaging in less than a second with significantly reduced artifacts.



140 kV, 250 mA, 1 s

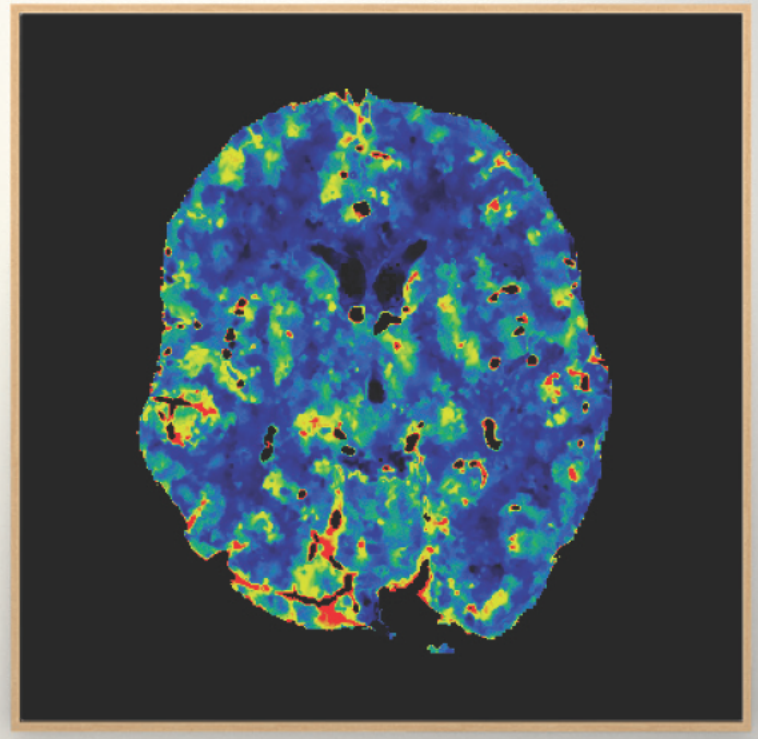
High definition CT angiography.

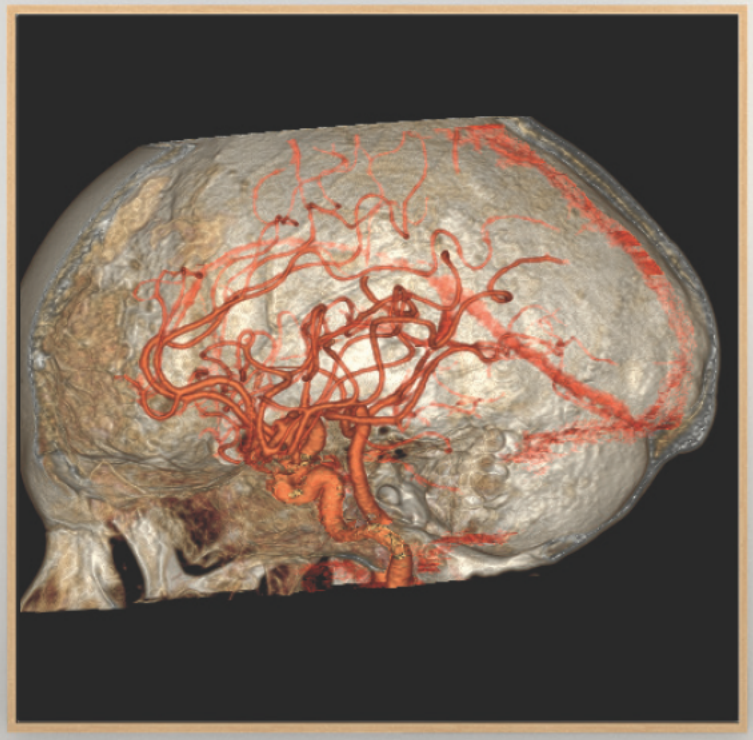


120kV, 400mA, 0.8 s

Rapid, comprehensive stroke assessment:

- One exam for whole brain perfusion and dynamic CTA at very low dose.
- Personalized coverage and sampling for low dose perfusion.

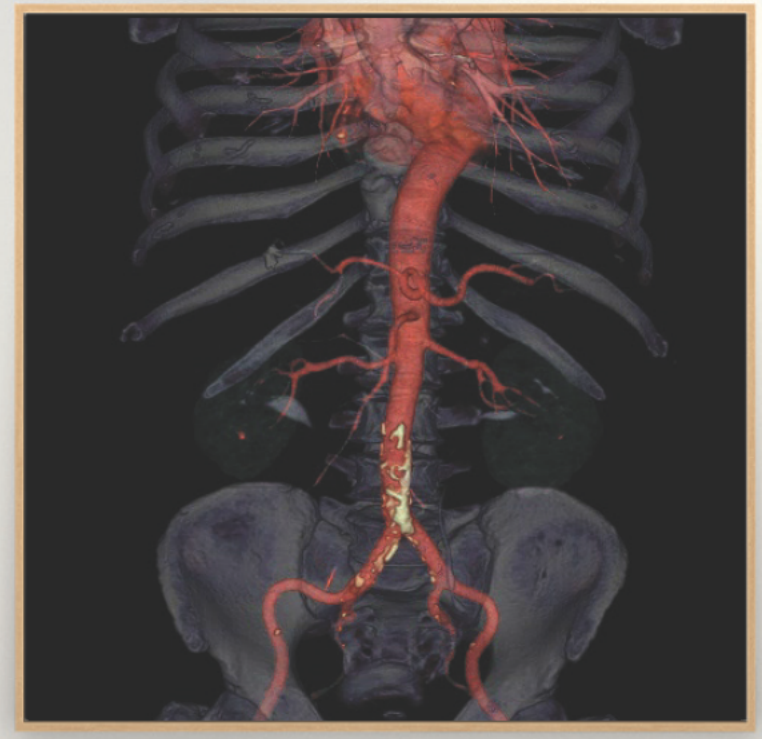




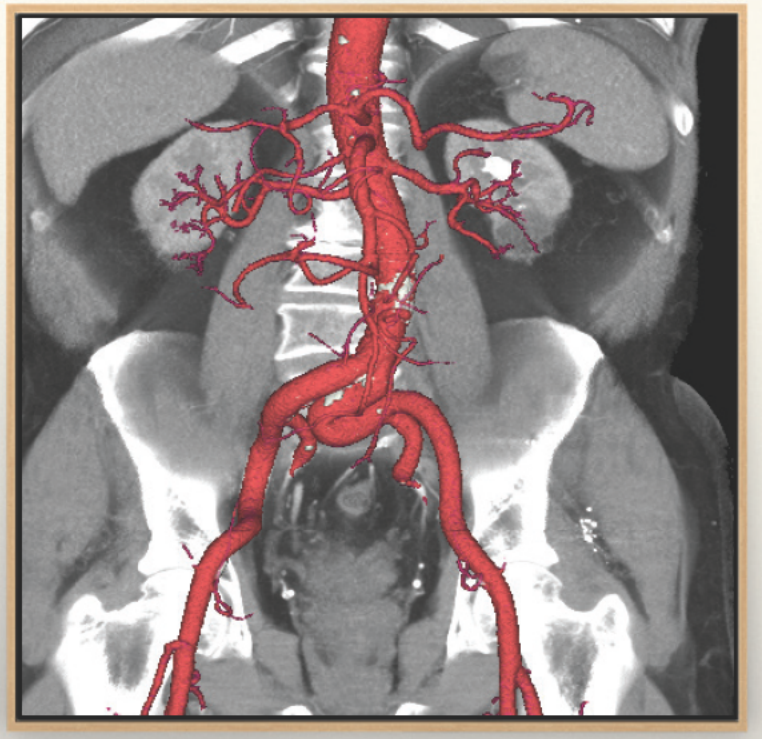
80 kV, 200 mA,
120 mm Coverage

BODY IMAGING.

Fast body scans with excellent image quality using multi-volume axial scanning with flexible collimation.

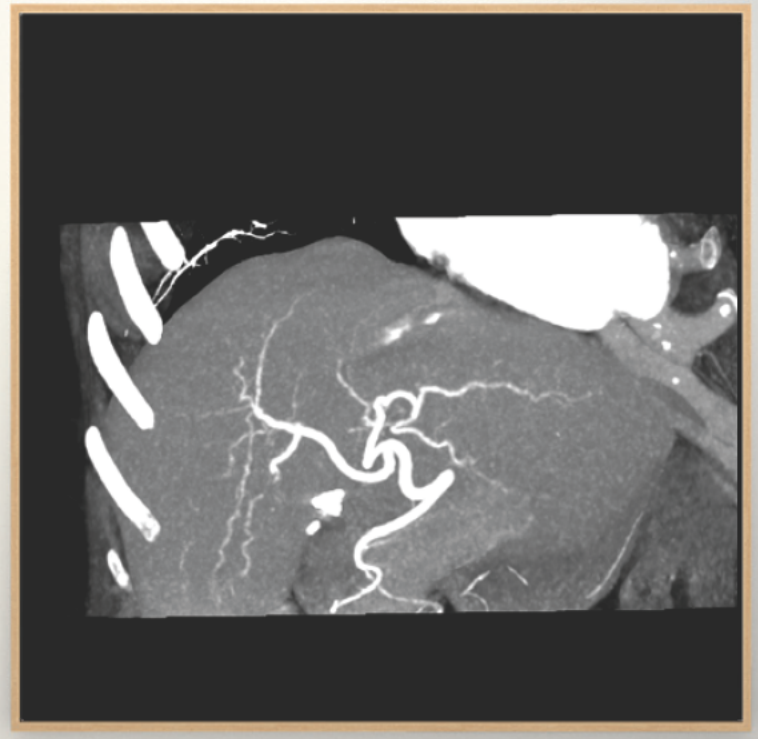


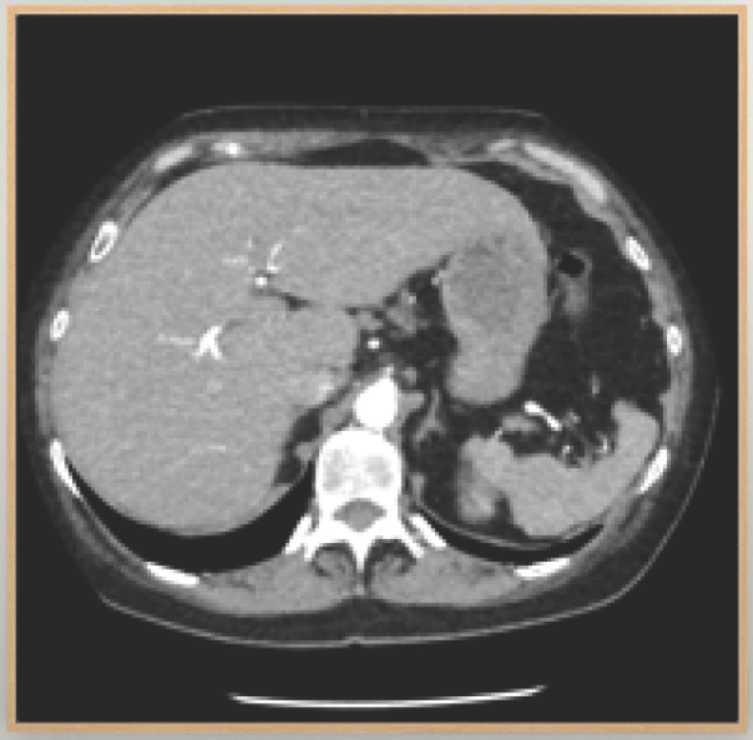
140 kV, 270 mA,
35 BMI



120 kV, 310 mA,
29 BMI

Dynamic imaging of the whole liver, kidneys and pancreas with variable sampling for perfusion and vascular flow analysis.

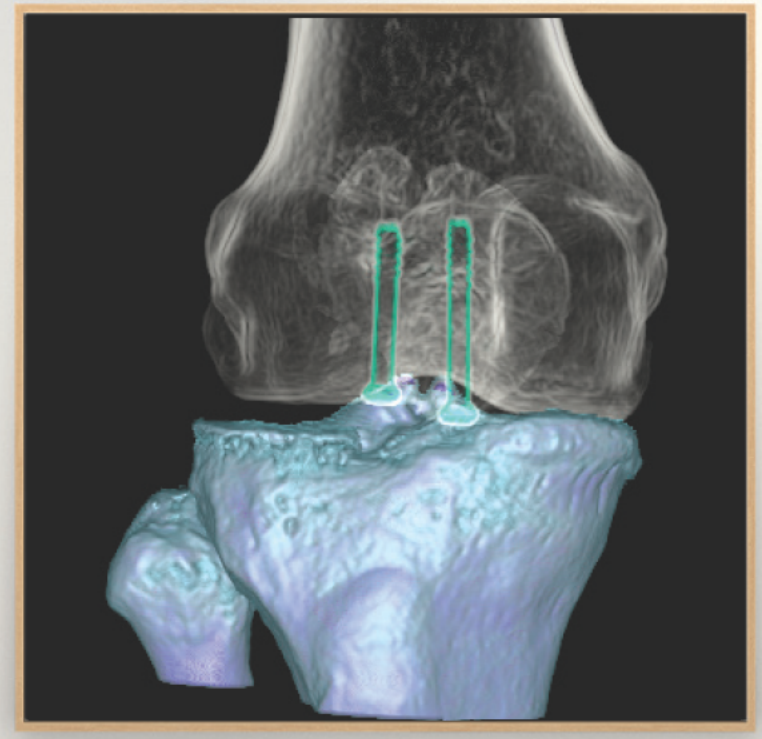




120 kV, 350 mA,
23 BMI

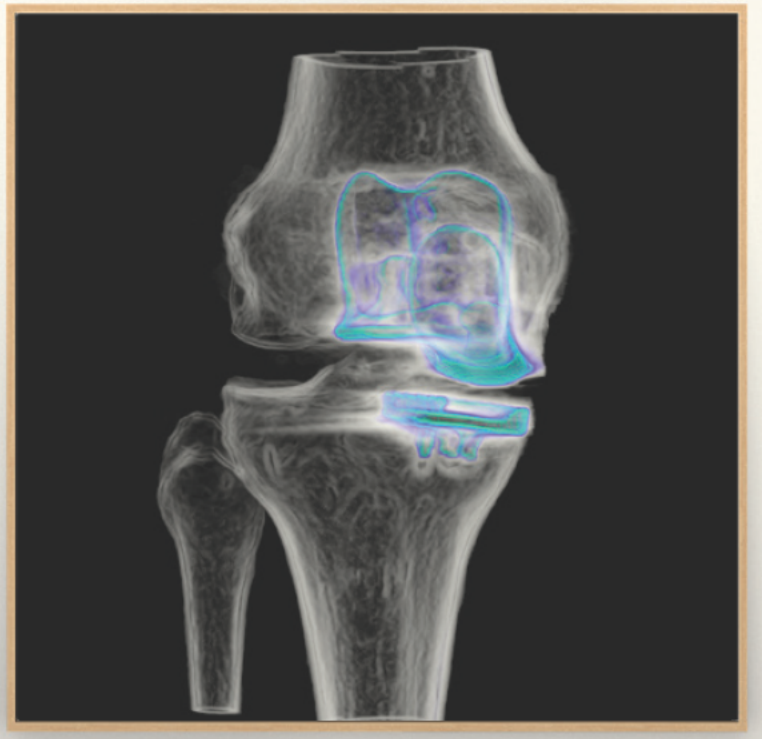
MUSCULOSKELETAL IMAGING.

High definition bone imaging.



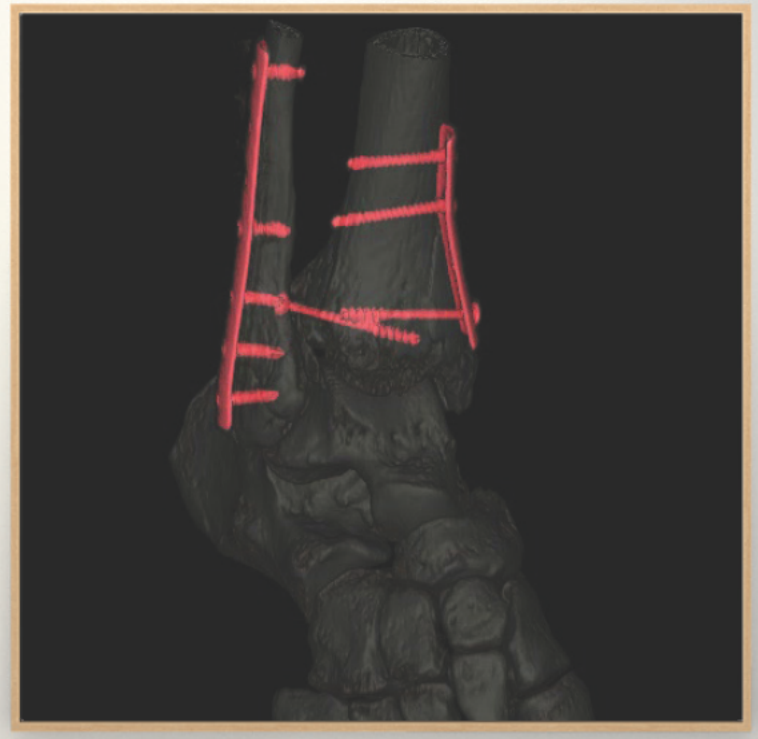
120 kV, 200 mA, 0.5 s

4D kinetic study to assess joint articulation through wide coverage dynamic imaging.

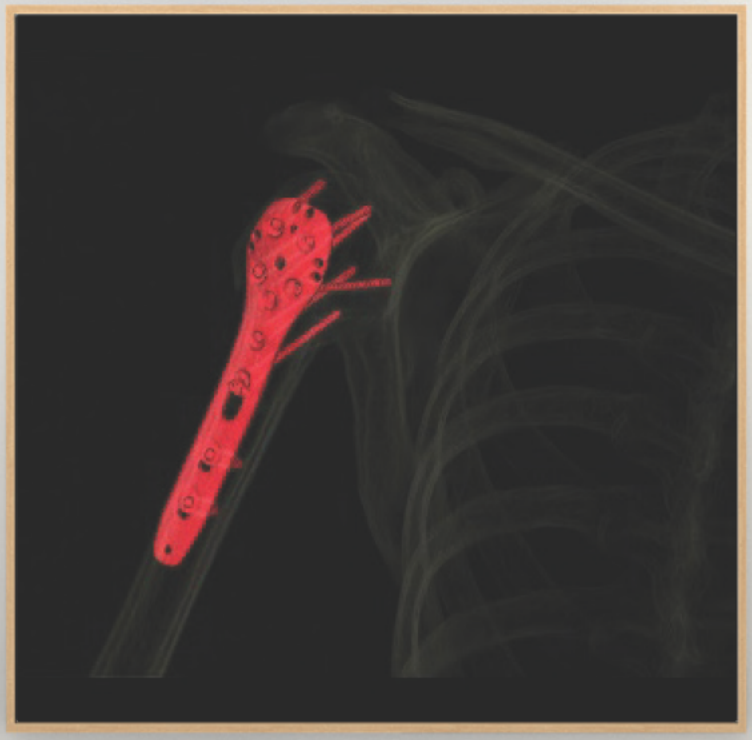


120 kV, 140 mA, Kinetic motion study

High definition bone imaging with significantly reduced artifacts from screws and metal.



120 kV, 220 mA,
0.5 s

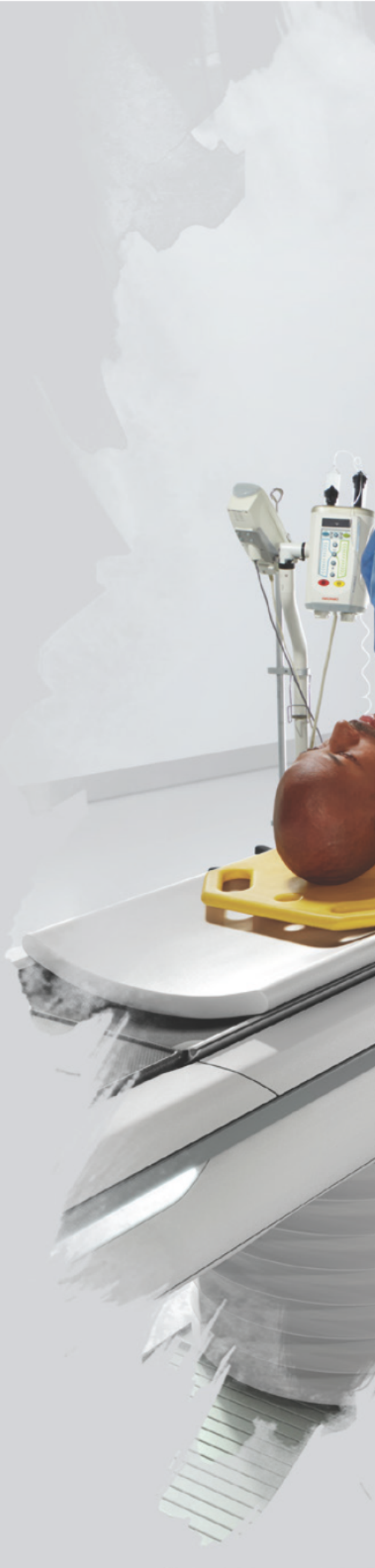


140 kV, 140 mA,
0.5 s

DESIGNED FOR RAPID TRAUMA ASSESSMENT.

Revolution CT is designed to deliver rapid, comprehensive trauma assessment through fast scanning, dedicated scan modes and review tools:

- Better access to patients through the wide 80 cm bore.
- Ultra-fast scanning enabled by up to 16 cm axial coverage combined with fast table speed of 300 mm/s thus reducing the effect of breathing and other motion during the scan.
- Custom scan modes that enable scanning multiple anatomical regions in a single exam.
- Real-time image reconstruction for instant access to images.
- User interface capabilities to prescribe multi planar reconstruction prospectively and to facilitate image review.




50.0
240.5
John Doe

ACHIEVE YOUR HIGHER CALLING BY DELIVERING BETTER CARE AT A LOWER DOSE.

Revolution CT features the latest Smart Dose technologies designed to help you acquire high quality images using lower doses of radiation, contributing to more accurate diagnoses and lower exposure for patients.

Integrated ASiR-V*
Reconstruction technology (ASiR-V) reduces noise, even at very low signal levels. This technology is designed to deliver reduced noise levels, improved low contrast detectability and may enable a reduction in dose[1] for all clinical applications.

Organ Dose Modulation
The system can also automatically modulate X-ray to reduce dose to radiation-sensitive organs and anatomical areas such as the eyes and the breasts without compromise to image quality.

Pediatric imaging
Minimize need for sedation and breath hold at very low dose in pediatric patients with less than one second whole abdomen and pelvis scanning.

70 kV scanning
Capability for low dose protocol, especially suitable for pediatric imaging.

[1] In clinical practice, the use of ASiR-V may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

PRIORITIZE THE PATIENT EXPERIENCE.

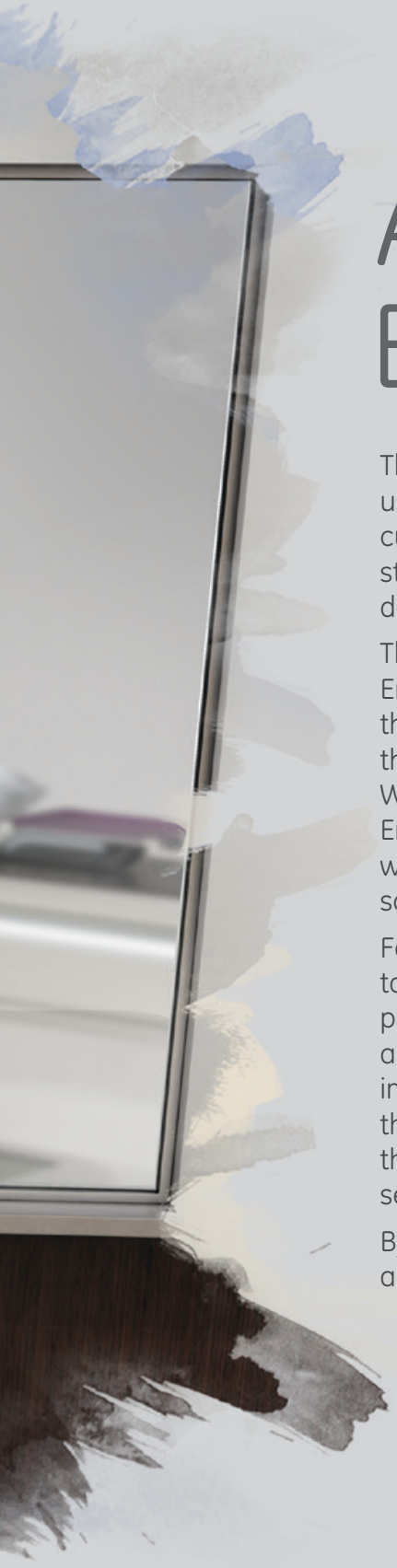
Revolution CT is meant to be symbiotic with its environment. Instead of being obtrusive, we utilized natural design elements so that it gently accentuates your senses. By giving more thought to the aesthetics, we're able to make your scan room feel less clinical and more inviting – lowering the anxiety for your patients.

It's all about the details:

- Natural wood grain panels.
- Soft ambient lighting throughout the system.
- Patient friendly bore pattern for more comfortable scanning experience.
- Whisper Drive gantry enables split second scan times while keeping the system powerfully quiet for patients.
- Low radiation and contrast dose, without compromising on image quality.

These details will help you redefine and prioritize the patient experience in CT.


50.0



A BETTER USER EXPERIENCE.

The Revolution CT is the fastest CT we've ever built. But what's the use of all that raw speed if your technologists still find it difficult and cumbersome to use every day? That's why we developed both a streamlined and user-friendly interface as a fundamental element in defining a better user experience.

The first thing worth noticing about the new Clarity Operator Environment and user interface is the design itself. We took cues from the various consumer devices you enjoy using every day and integrated them into a totally new, but yet familiar user interface experience. With the latest in Smart Flow technologies, the new Clarity Operator Environment will provide you with more intuitive, guided acquisition workflow to simplify scan setup and enable more consistency across scans, something all your technologists can benefit from.

For example, technologists have the ability to perform seamless multi-tasking by having multiple patient sessions open with one active patient for acquisition and the rest for post-acquisition tasks. It also allows the system to handle repetitive tasks such as reconstructions, image transfers and post processing with the ability to automate them through plan-ahead task lists. And we've emphasized dose awareness through a clearly visible, real-time projected dose indicator for the selected protocol.

By defining a better user experience for your technologists, we've allowed them to get back to what they do best, being with the patient.


GE Healthcare


50.0

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GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world.
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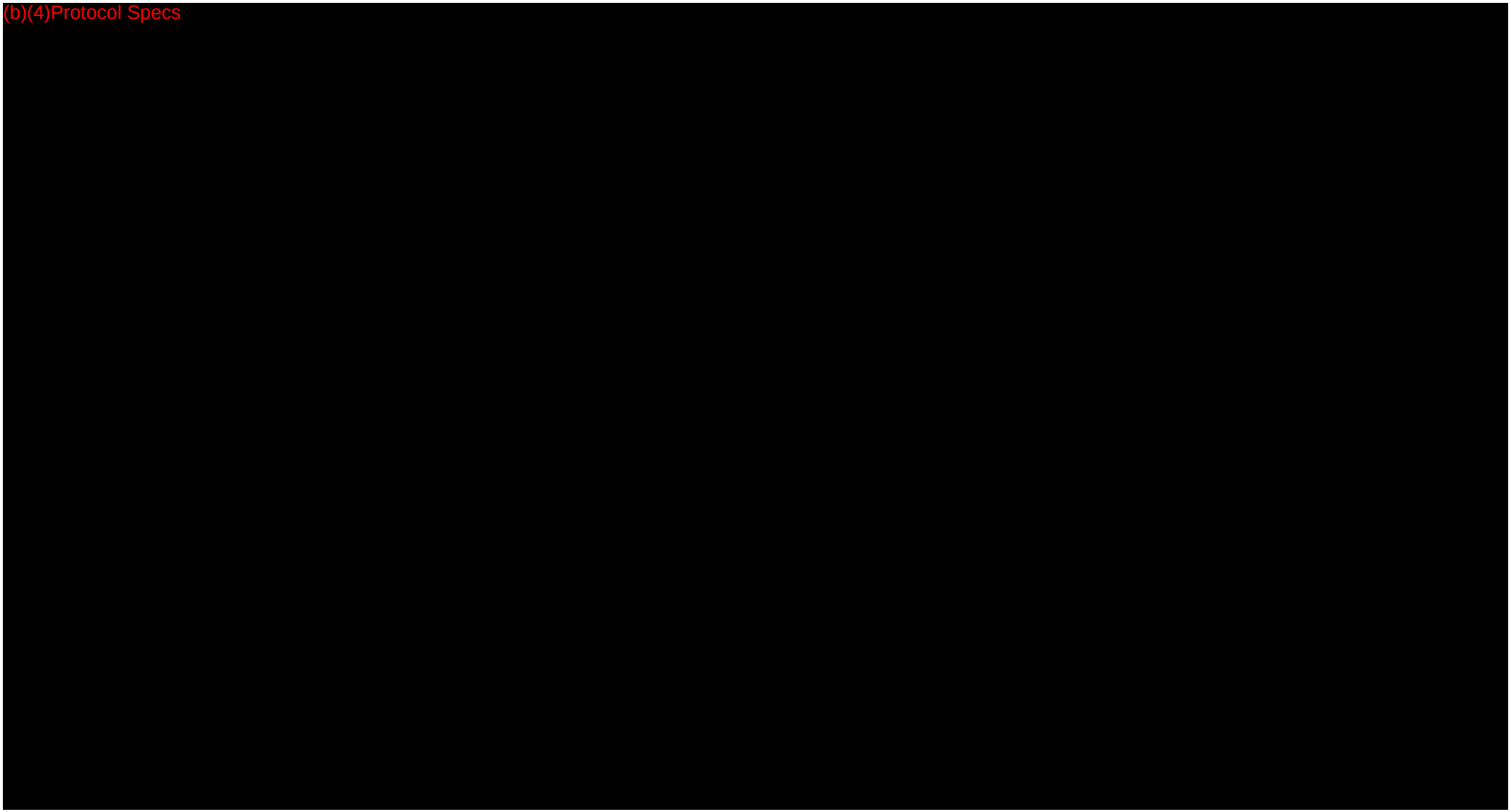
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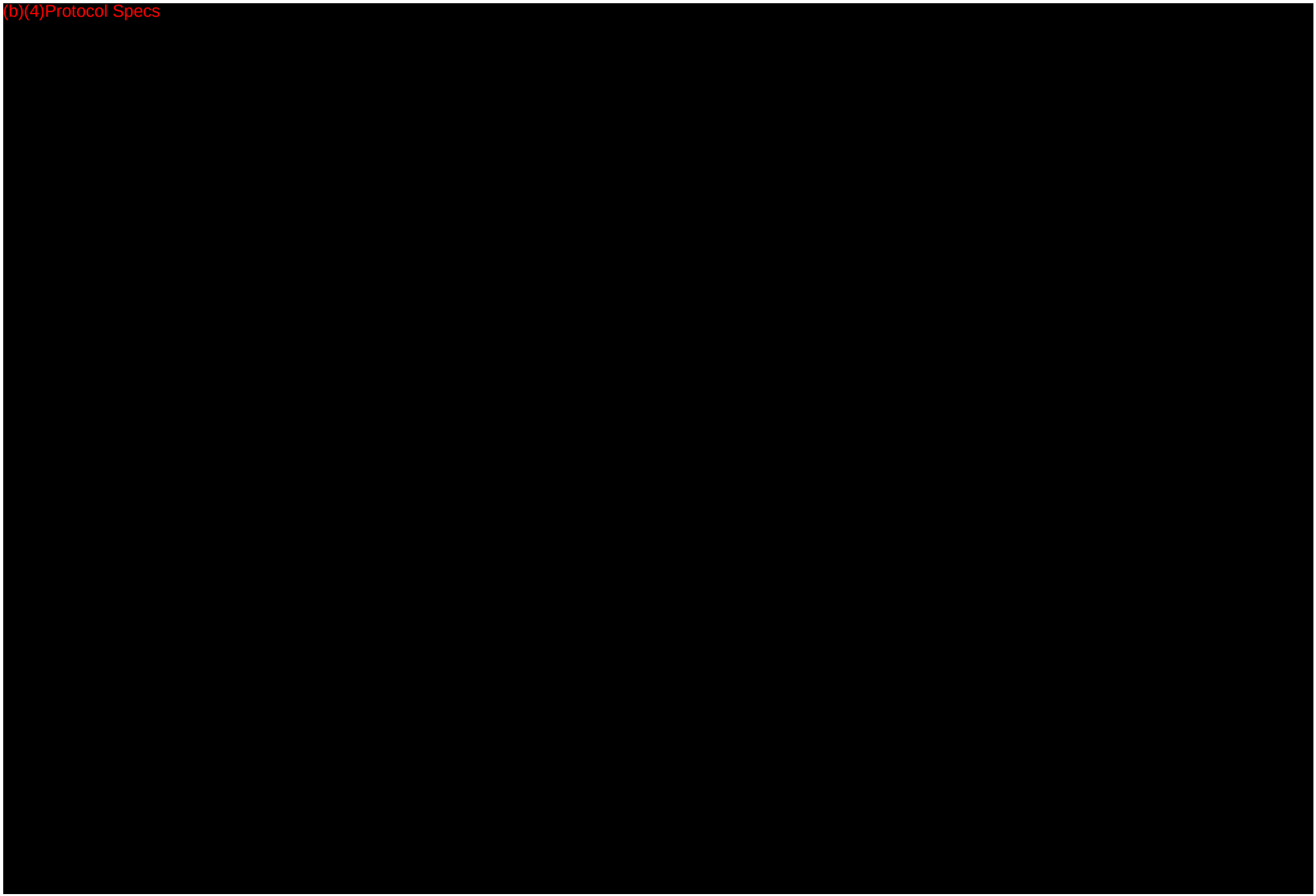

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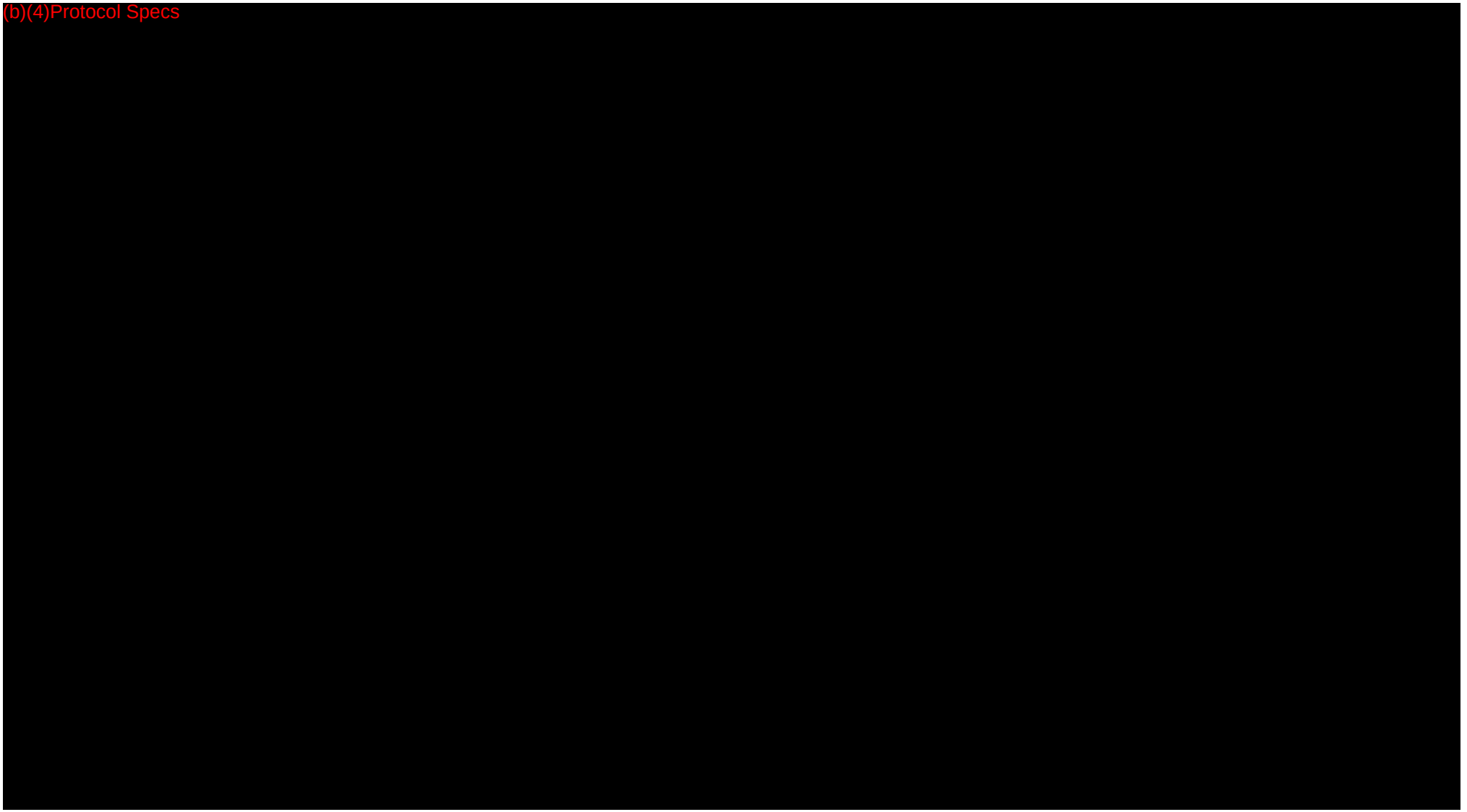

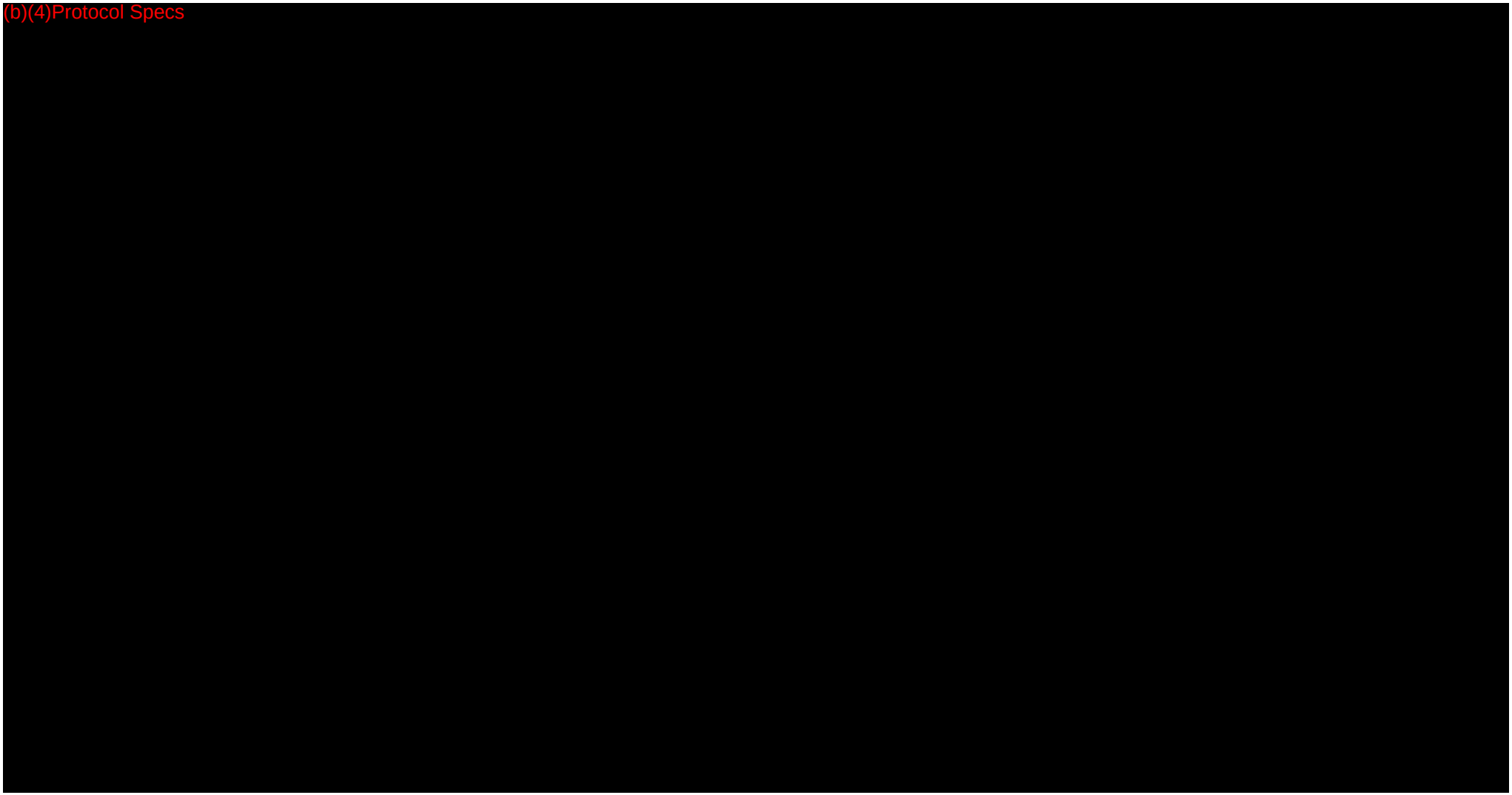
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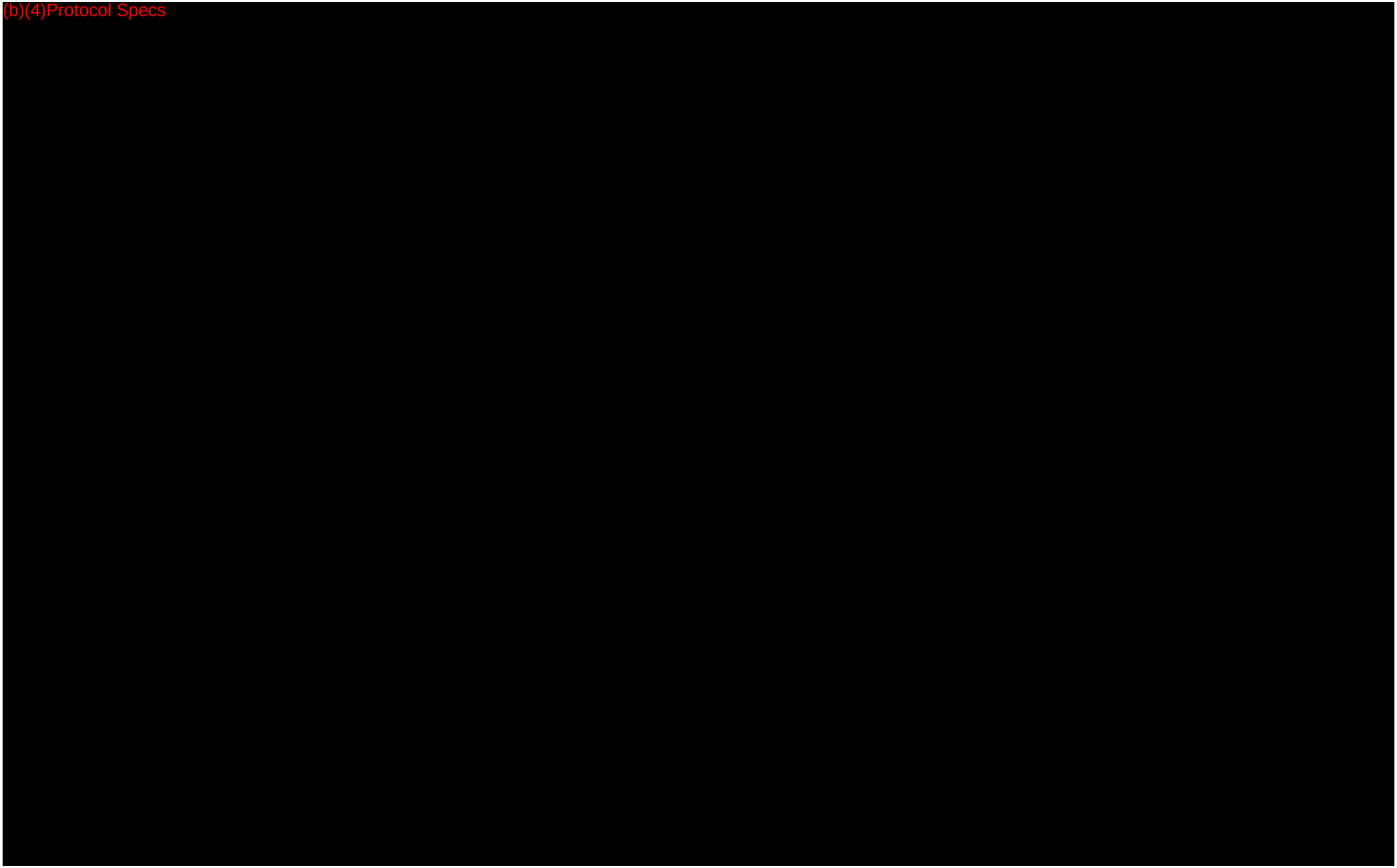
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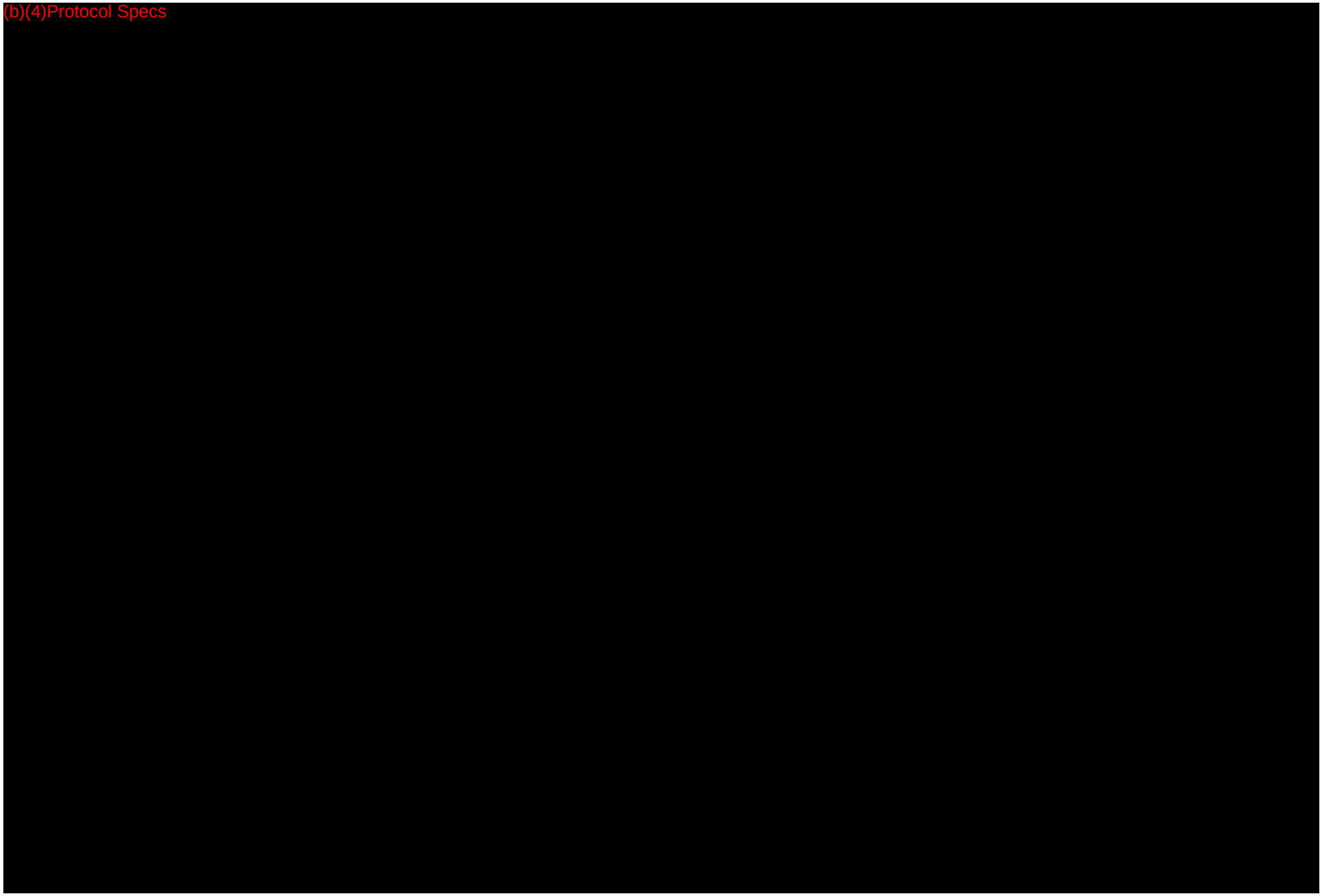

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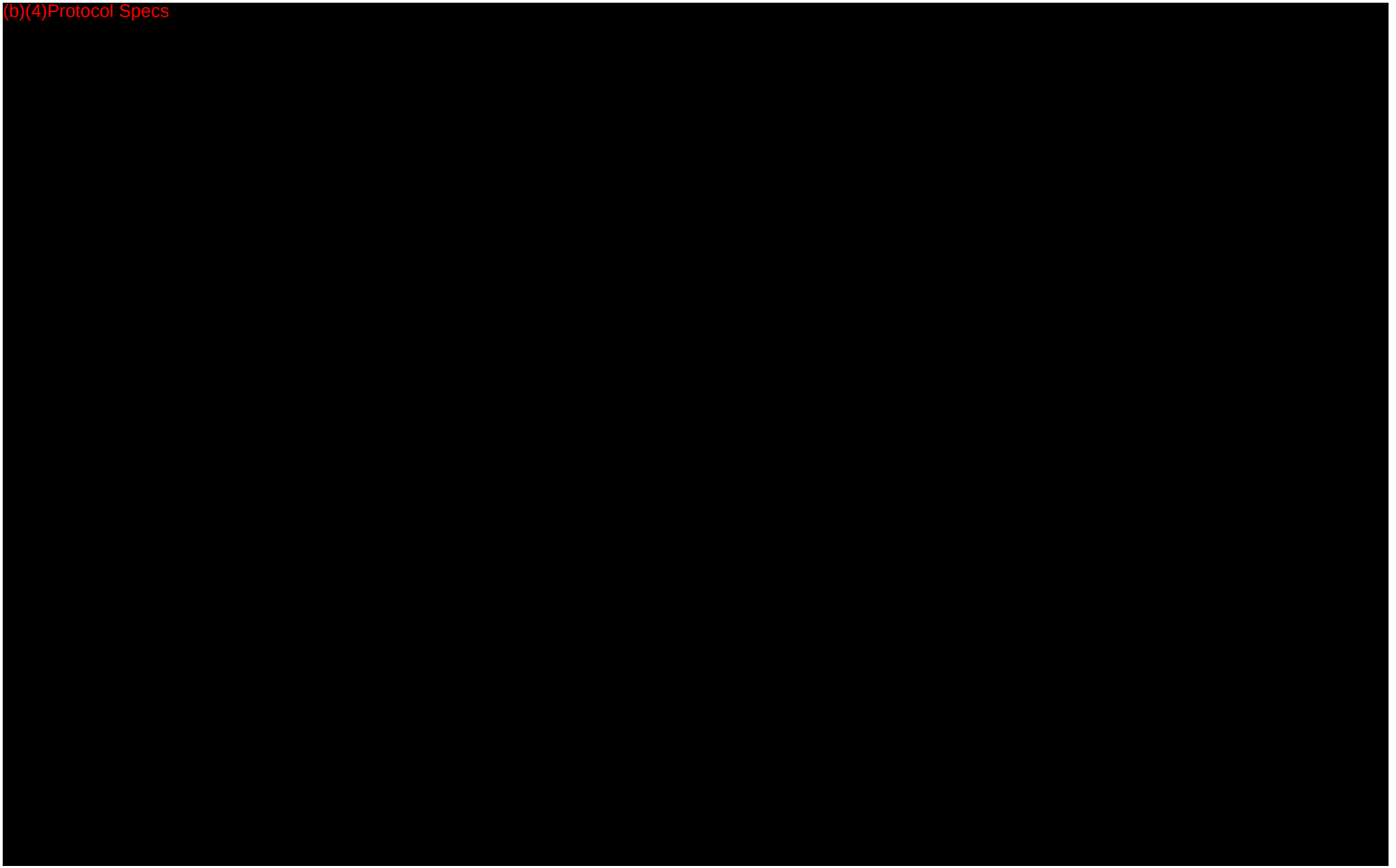
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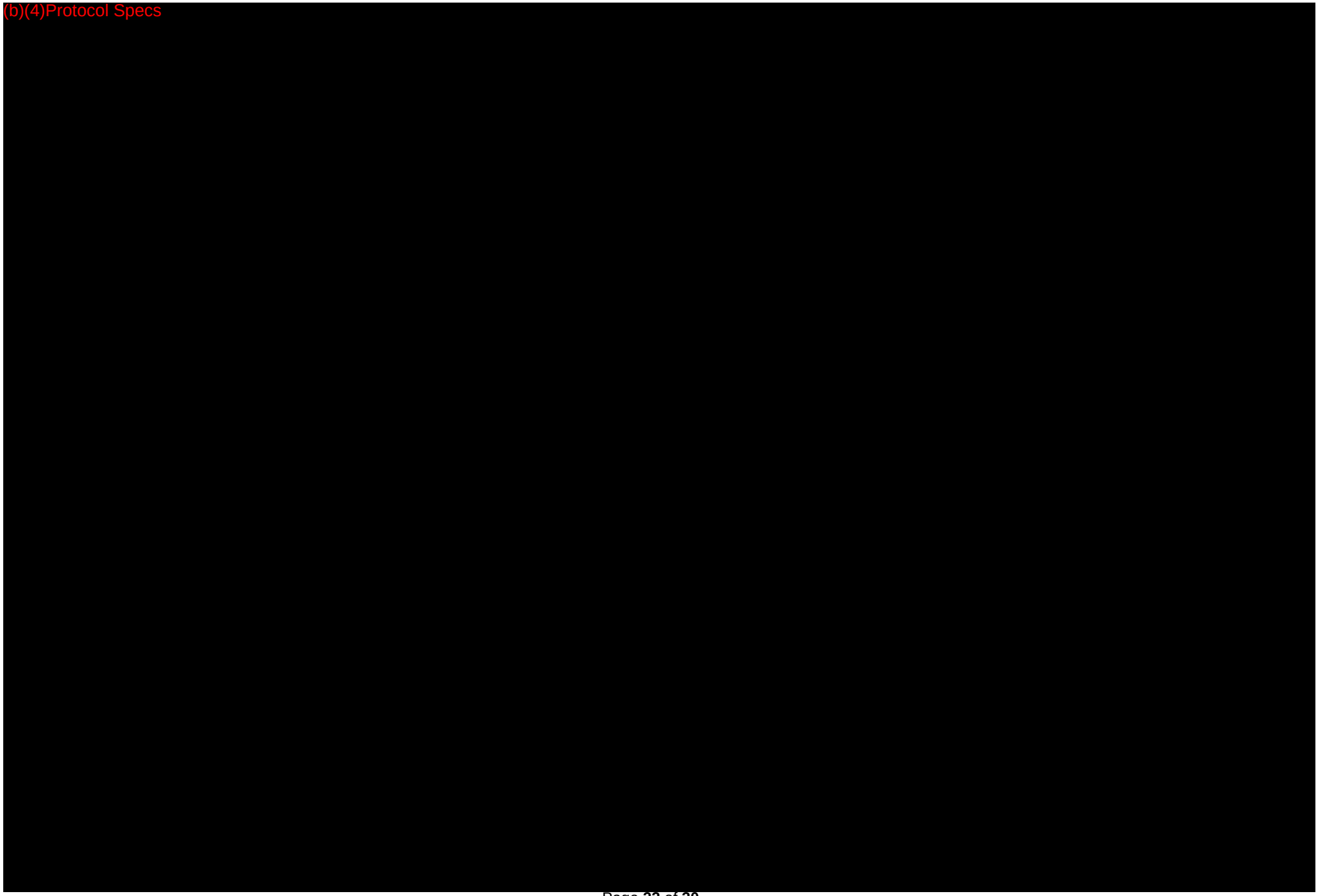
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Section 14: Sterilization and Shelf Life

Revolution CT

Not applicable:
This section does not apply, since the device is not sold as a sterile device and does not have a shelf life.

Section 15: Biocompatibility

Revolution CT

Biocompatibility Evaluation

Risk analysis was performed on the Revolution CT accordance with (b)(4)Testing (b)(4)Testing Work Instruction and (b)(4)Testing Guideline. The risk analysis has the following elements:

- hazard identification,
- risk classification,
- risk control

Biocompatibility Risk Assessment Review was conducted which shows that the materials used in Revolution CT have a demonstrable safe history of use in a specified role and physical form that is equivalent to that of the device under design in accordance with Clause 4.1 of ISO 10993-1:2009.

(b)(4)Testing

(b)(4)Testing

The Revolution CT system, the predicate device Discovery CT750 and the cleared (b)(4)Testing . Additionally the Revolution CT is manufactured following the same GEHC QMS as the predicate device Discovery CT750 HD and (b)(4)Testing

Section 16: Software

Revolution CT

APPENDICES OF SECTION 16

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16.0. Software Checklist

This section was prepared in accordance with the FDA guidance document titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued May 11, 2005.

For subsection 16.12 "Off the Shelf Software, the "Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices" is followed.

For subsection "Cybersecurity", the FDA Guidance for Industry "Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software" is followed.

The documentation contained in this software section for the Revolution CT is submitted as "MODERATE" level of concern.

(b)(4)Testing

Software Documentation	Moderate Level of Concern	Special 510(k) Deliverable	Location in 510(k)
Level of Concern	A statement indicating the Level of Concern and a description of the rationale for that level.	Level of Concern	Section 16.1

Software Documentation	Moderate Level of Concern	Special 510(k) Deliverable	Location in 510(k)
Software Description	A summary overview of the features and software operating environment	A summary overview of the features and software operating environment with identification of changes to design	Section 16.2
Device Hazard Analysis	Tabular description of identified hardware and software hazards, including severity assessment and mitigations.	Implementation Risk Analysis for changes to design	Section 16.3
Software Requirement Specification	A complete SRS document	Software Requirements related to modification	Section 16.4
Architecture Design Chart	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts	Diagram with identification of changes related to modification	Section 16.5
Software Design Specification	Software Design Specification Document	Software Design Specifications related to modification	Section 16.6
Traceability Analysis	Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation testing.	Representative traceability for modification	Section 16.7
Software Development Environment Description	Summary of the software life cycle development plan including a summary of the configuration management and maintenance activities.	Summary of the software life cycle development. Including configuration management and maintenance plan document	Section 16.8

Software Documentation	Moderate Level of Concern	Special 510(k) Deliverable	Location in 510(k)
Verification, Validation and Documentation	Description of V & V activities at the unit, integration and system level. System level test protocol, including pass/fail criteria, and tests results.	Verification and Validation test plan, pass/fail criteria, and summary of results for the modification. Regression testing.	Section 16.9
Revision Level History	Revision history log, including the release version number and date	Revision history log including the release version number and date	Section 16.10
Unresolved Anomalies (bugs)	List of remaining software anomalies, annotated with an explanation of the impact on the safety and effectiveness, including operator usage and human factors	List of remaining software anomalies, annotated with an explanation of the impact on the safety and effectiveness, including operator usage and human factors	Section 16.11
Off-The-Shelf Software	List of the off-the-shelf software used in the modified device		Section 16.12
Cybersecurity	Assessment of off-the-shelf Software on Cybersecurity	Assessment of off-the-shelf Software on Cybersecurity	Section 16.13
Software Certification	Certification that the software information provided in this premarket notification is correct	Certification that the software information provided in this premarket notification is correct	Section 16.14

16.1. Software Level of Concern

The level of concern for the Revolution CT was determined to be MODERATE. The following describes how the level of concern was determined:

In accordance with the May 11, 2005 *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,* the evaluation of the level of concern for the Revolution CT is a result of the risk analysis performed. The determination of the level of concern is consistent with the definitions provided in this guidance.

Major - The level of concern is Major if a failure or latent design flaw could directly result in death or serious injury to the patient or operator. The level of concern is also 'Major' if a failure or latent flaw could indirectly result in a death or serious injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Moderate – The level of concern is Moderate if a failure of latent design flaw could directly result in minor injury to the patient or operator. The level of concern is also 'Moderate' if a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information of through the action of a care provider.

Minor – The level of concern is 'Minor' if failures or latent design flaws are unlikely to cause any injury to the patient or operator.

The severity and risk levels have been determined per the GEHC Global Risk Management Procedure.

Additionally, the following are answers to questions in the aforementioned guidance:

Level of Concern	
If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.	
1. Does the Software Device qualify as Blood Establishment Computer Software	(b)(4)Testing [redacted]
2. Is the Software Device Intended to be used in combination with a drug or biologic?	
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	
4. Prior to mitigations of hazards, could a failure of the Software Device result in death or serious injury, either to a	

Level of Concern	
patient or to a user of the device? Examples of this include the following:	(b)(4)Testing
a) Does the Software Device control a life supporting or life sustaining function?	
b) Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	
c) Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	
d) Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	

Level of Concern	
e) Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	(b)(4)Testing [redacted]
If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.	
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	(b)(4)Testing [redacted]
2. Prior to mitigations of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	
3. Could a malfunction of, or latent design flaw in, the Software Device lead to an erroneous diagnosis or delay in delivery of appropriate medical care that would likely lead to Minor Injury?	
If the answer to all of the questions in above are No, the Level of concern is Minor.	

Conclusion: The level of concern was determined to be **Moderate** for the Revolution CT

16.2. Software Description

The Revolution CT Software provides the user interfaces to the system users, such as technologists and service engineers. The software provides functionalities to prescribe scans, reconstruct the raw scan data, post process the image data and offers tools to review the image data . The software also allows networking the images to other review workstations and/or PACS systems.

Additionally, The Software communicates and controls the external peripherals, such as Cardiac Trigger monitor and Contrast Injector.

The CT software provides the computational software, services tools, and interfaces to provide for system installation, storage, configuration, management, and security, and software for run-time management of the CT scanner hardware. This also includes service connectivity and software download as well as providing the computer specific diagnostics and service tools.

The following picture shows a high level interaction of the Revolution CT software system to the users and other systems.

Figure 16.2.1 Revolution CT Software System Interaction View

Hardware platform

The Revolution CT system's software is deployed upon multiple hardware components. The scanner desktop software is hosted on an off-the-shelf Information Technology Equipment (ITE) computer(b) . The system cabinet houses two servers which host the Image Generation and Scan Data Acquisition software. The gantry and table house dedicated boards for Scan Control software. All of these are connected via network connections on a private subnets. There is a dedicated connection between the Data-Chain and Data-Acquisition System (DAS) that is used for transferring high-speed raw scan data.

The hardware qualification and verification is managed through the design control process.

Operating systems

(b)(4)Testing

Off-the- shelf software

Refer to section 16.12 for Off-the-shelf Software.

Intended operational Environment

The Revolution CT is typically used in radiological departments for diagnostic purpose by professional users. This remains the same as the predicate device Discovery CT750 HD as well as other similar CT devices marketed by GE Healthcare.

More information about the Revolution CT software is provided in 16.4 Software Requirement Specification and 16.5 Software Architecture.

16.3. Device Hazard Analysis

16.3.1. Overview of the Risk Management Process

Risk Management is the systematic application of management policies, procedures and practices to analyze, evaluate, control and monitor risk for the purpose of producing, delivering and maintaining safe products.

The GE procedure for Risk Management presents the methodology for making risk management decisions. It defines the minimum requirement for assessing the degree of risk associated with GE Healthcare products by identifying hazards, estimating the associated risk, evaluating, controlling and managing such risks in accordance with ISO/EN 14971 and IEC 60601. It [redacted] (b) (4)

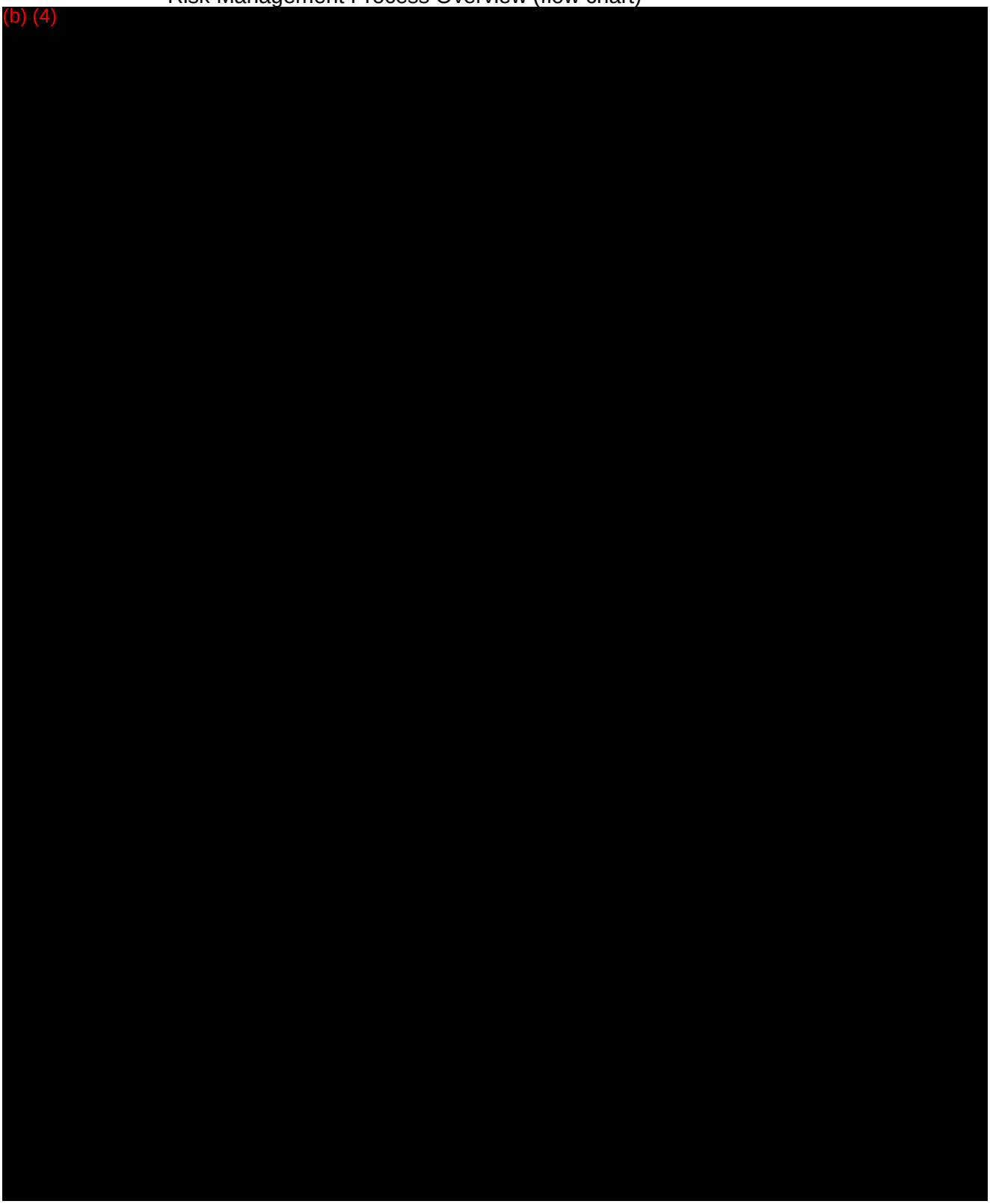
[redacted]

This procedure applies to all sites operating under the GE Healthcare Quality Management System. This is a comprehensive systemic approach to all medical devices from original design to obsolescence.

Risk Management is a lifecycle process that applies to the product from conception to obsolescence. This GE Healthcare Procedure also establishes the procedure for developing and maintaining a Risk Management File. The Risk Management File is initiated during product development and updated throughout the product life. The figure below depicts the Risk Management Process:

Risk Management Process Overview (flow chart)

(b) (4)



16.3.2. Device Hazard Analysis

The device hazard analysis was performed and the verification of the mitigations was completed on the Revolution CT System per the risk management process described above.

The risk management file will continue to be updated during the lifecycle of the product in accordance with GEHC Global Risk Management Procedure and ISO 14971 “Medical Devices Application of Risk Management to Medical Devices”. The risk analysis has the following elements:

- hazard identification,
- risk classification,
- risk control

(b) (4)

The extracted software related CMT is provided in appendix 16.3a.

(b) (4)

16.4. Software Requirements Specification

The Revolution CT software system is decomposed into 9 software subsystems (software items). Please refer to 16.5: Architecture for the details of decomposition.

16.5. Software Architecture

The Revolution CT Software architecture description can be found in the appendix 16.5a Revolution CT Software Architecture (b) (4)

16.6. Software Design Specification

The Software Subsystem Design Specifications (SSDS) pertaining to the software items referenced in Section 16.5 are provided in the following appendices:

16.7. Traceability Analysis

The following Figure 16.7.1 describes the entire traceability for the proposed device.

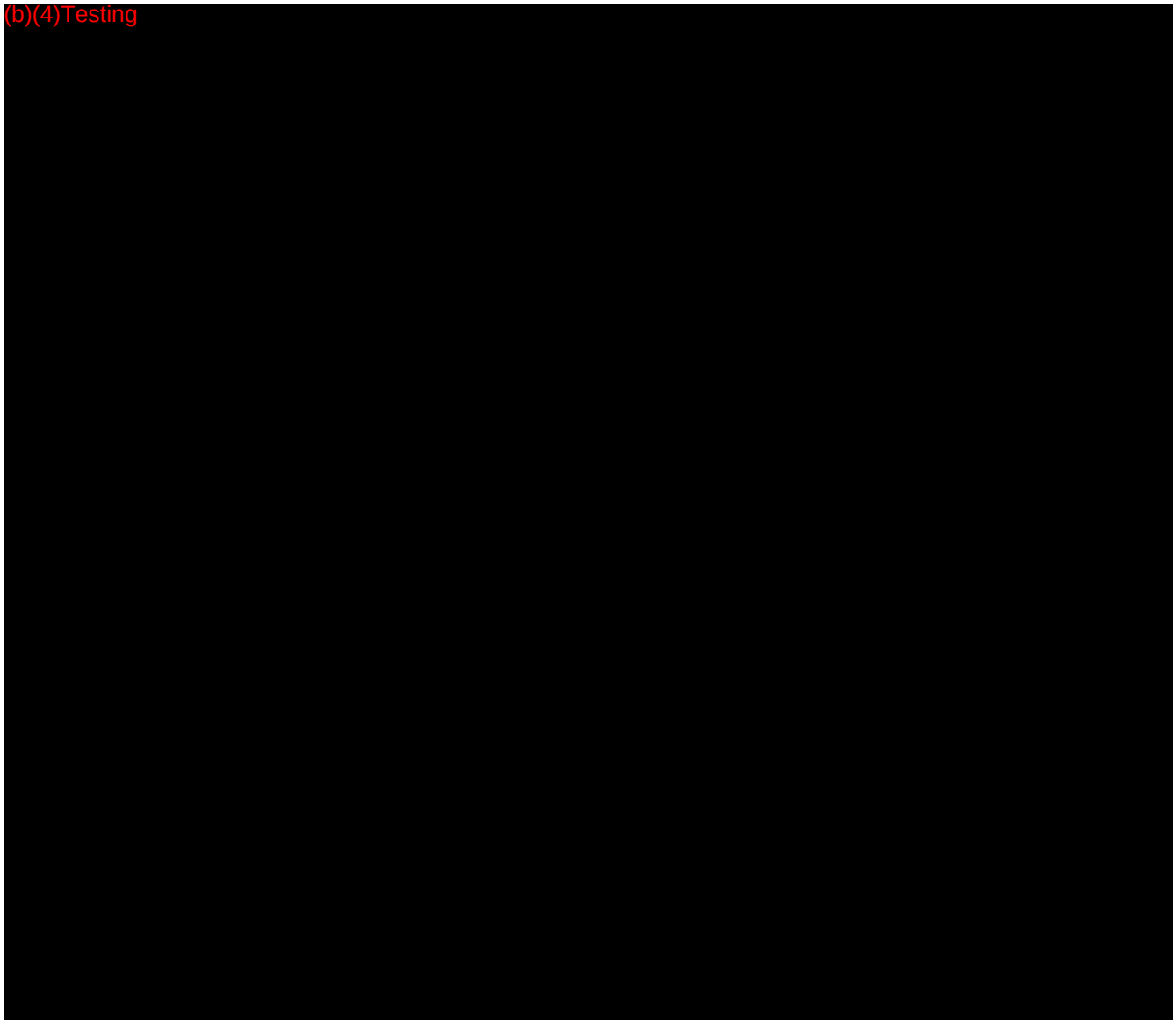
(b)(4)Testing

Figure 16.7.1: Traceability Strategy for Revolution CT

Note: documents denoted by the green colored boxes are provided in this 510(k) submission.

Software requirements, identified by their respective requirement IDs, are linked to their respective test IDs either directly or through child requirements. These linkages are captured in the trace reports together with the software verification summary reports provided in **Section 16.9**.

(b)(4)Testing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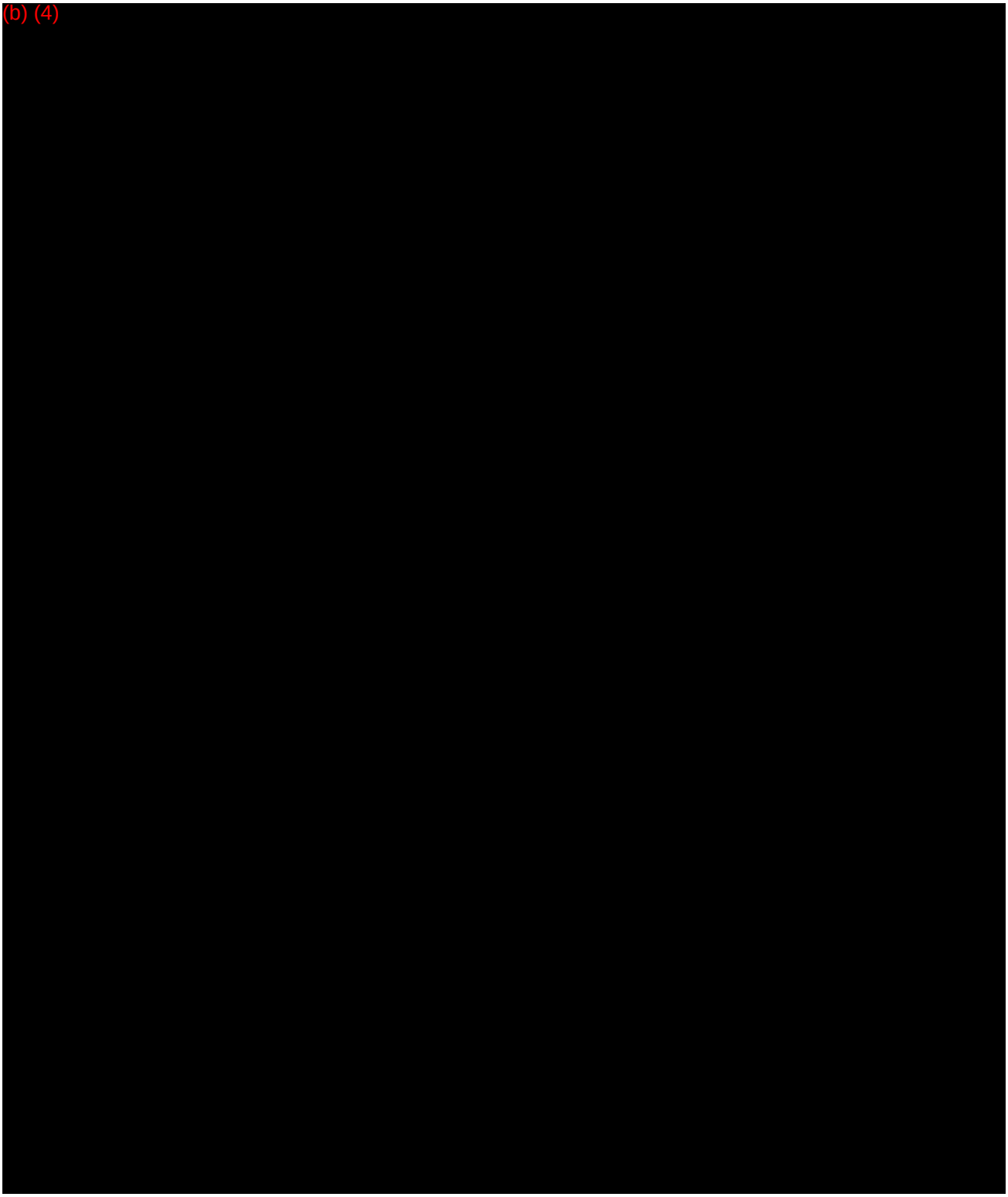
16.8. Software Development Environment Description

(b) (4)



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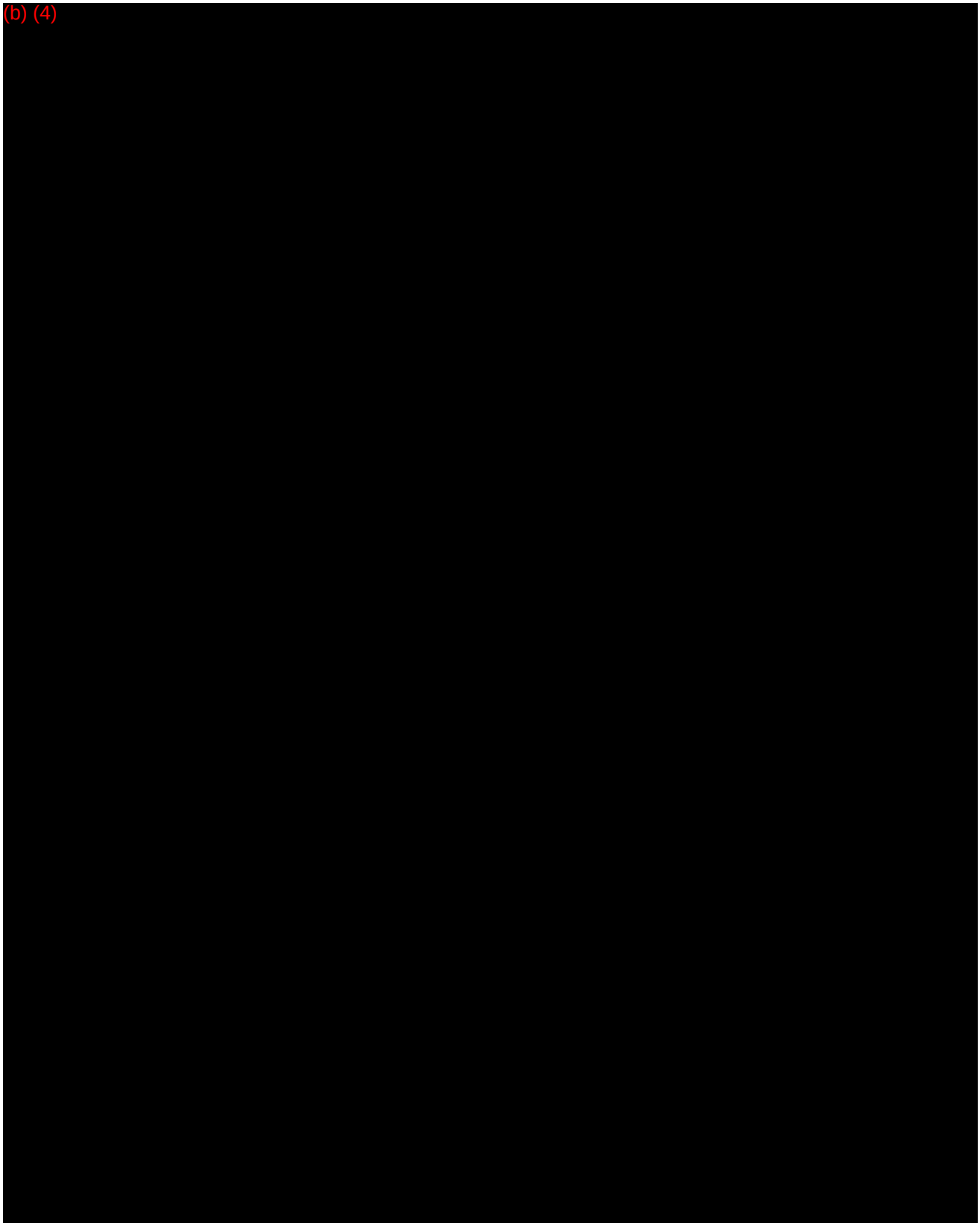

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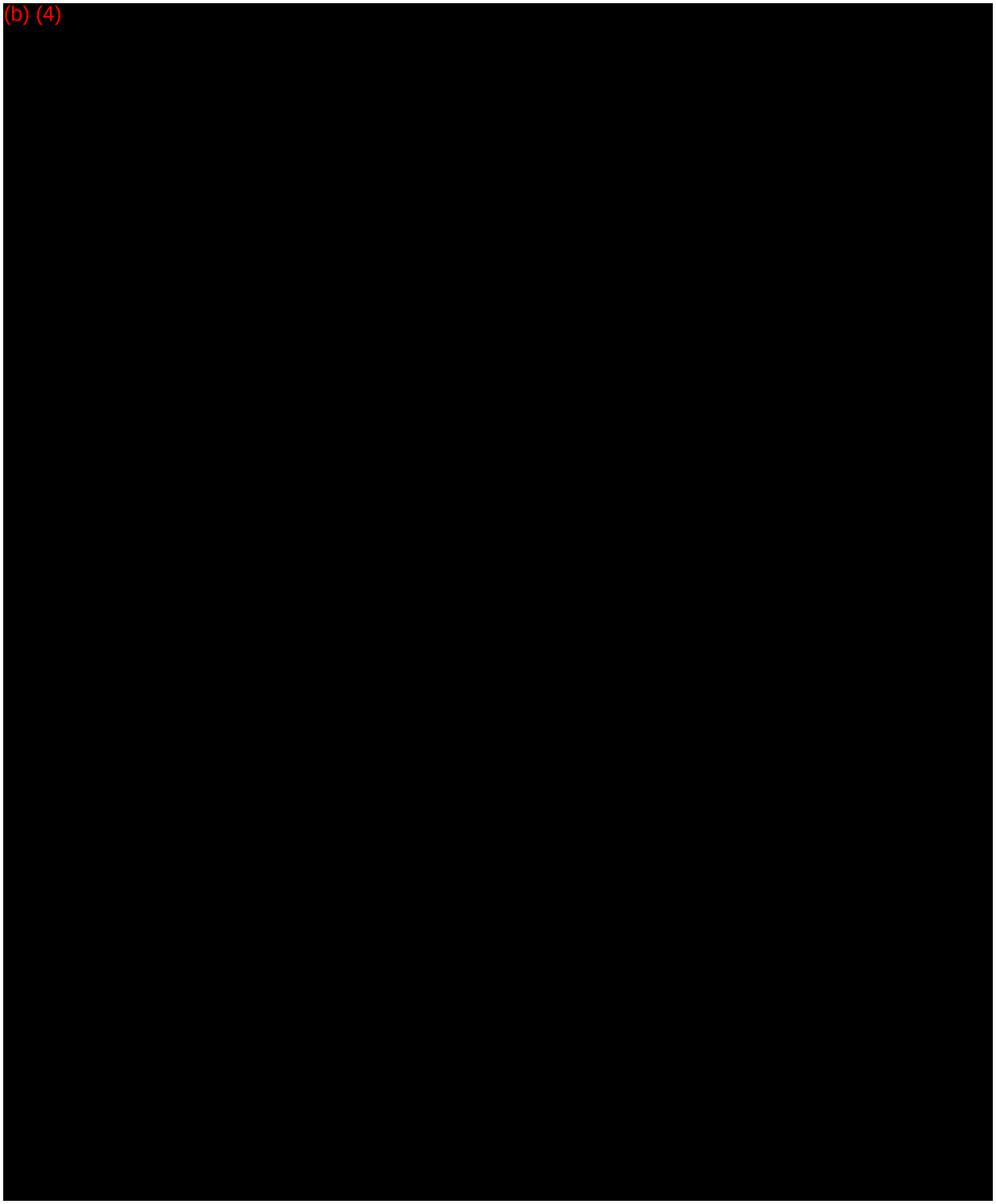
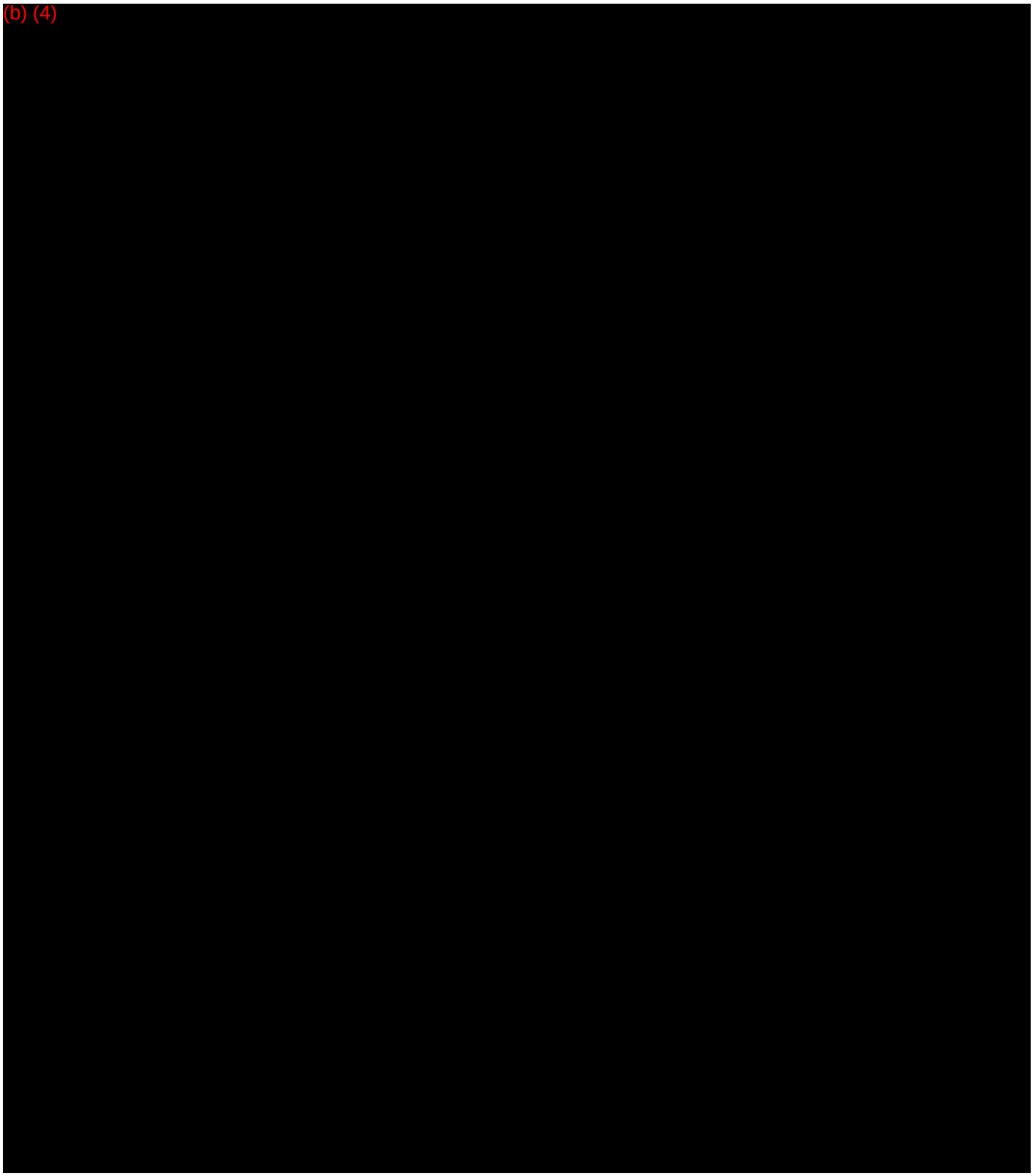


Software development in Revolution CT also follows the GEHC Software Development Life Cycle Process that is compliant to IEC 62304:2006

(b) (4)



The detailed software development procedures are described in the Software Development Lifecycle (SDLC) document (b) (4) [redacted]

16.9. Verification and Validation Documentation

Verification and Validation was concluded by GEHC to confirm substantial equivalence of safety and effectiveness to the predicate device.

This section summarizes the verification and validation activities for the Revolution CT software subsystems.

(b) (4)

[redacted]

Conclusion:

The design inputs requirements for the Revolution CT system were successfully tested. Applicable engineering testing as well external clinical evaluation demonstrated that the Revolution CT system meets design input and customer needs. The system performs in an equivalent manner to its predicate device the Discovery CT750 HD.

Reference the software subsystem test summary reports provided in this submission below:

(b) (4)

[redacted]

(b) (4)

16.10. Revision Level History

Throughout the product development cycle, the software checked into the version control system is build / rebuilt on an as-needed basis. At certain milestones within the development cycle (verification testing, validation testing), the source files are labeled in the version control system with a number related to this project. When the software is deemed suitable for release, this version of software will be officially released to manufacturing using the Quality Management System.

Below is a tabular view of this information with two major milestones of the development.

(b) (4)

The detailed content of each build label is in the Release notes (b) (4)

The final release number corresponding to the version that passed Verification and Validation testing and intended for commercialization is (b) (4)

16.11. Unresolved Anomalies

Problems are reported in a defect tracking system Clearquest as SPRs (System Problem Reports). All new problems are assessed by a Defect Review Board (DRB) to determine the problem's impact. Table 16.11.1 shows the criteria by which problems will be categorized for severity. (b)(4)

(b)(4)

The SPR resolution process for SPRs that are defects is shown in Figure 16.11.1. The defect tracking system is used to track the progress of the SPR through all these steps and is used to record the objective evidence required to show these steps were followed.

(b)(4)

All design defects found during the development and testing phases of the subject device have been reviewed and closed and there are no unresolved or unmitigated (b)(4)

(b)(4)

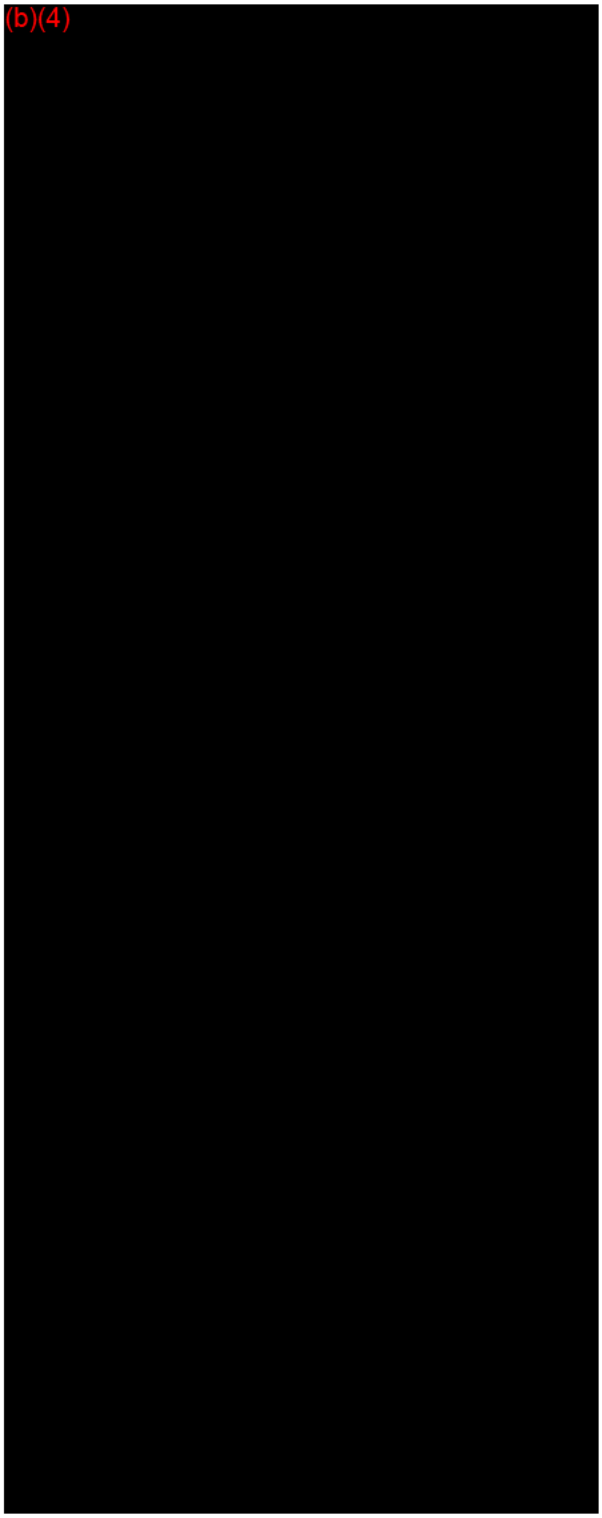


Figure 16.11.1 – SPR Resolution Process

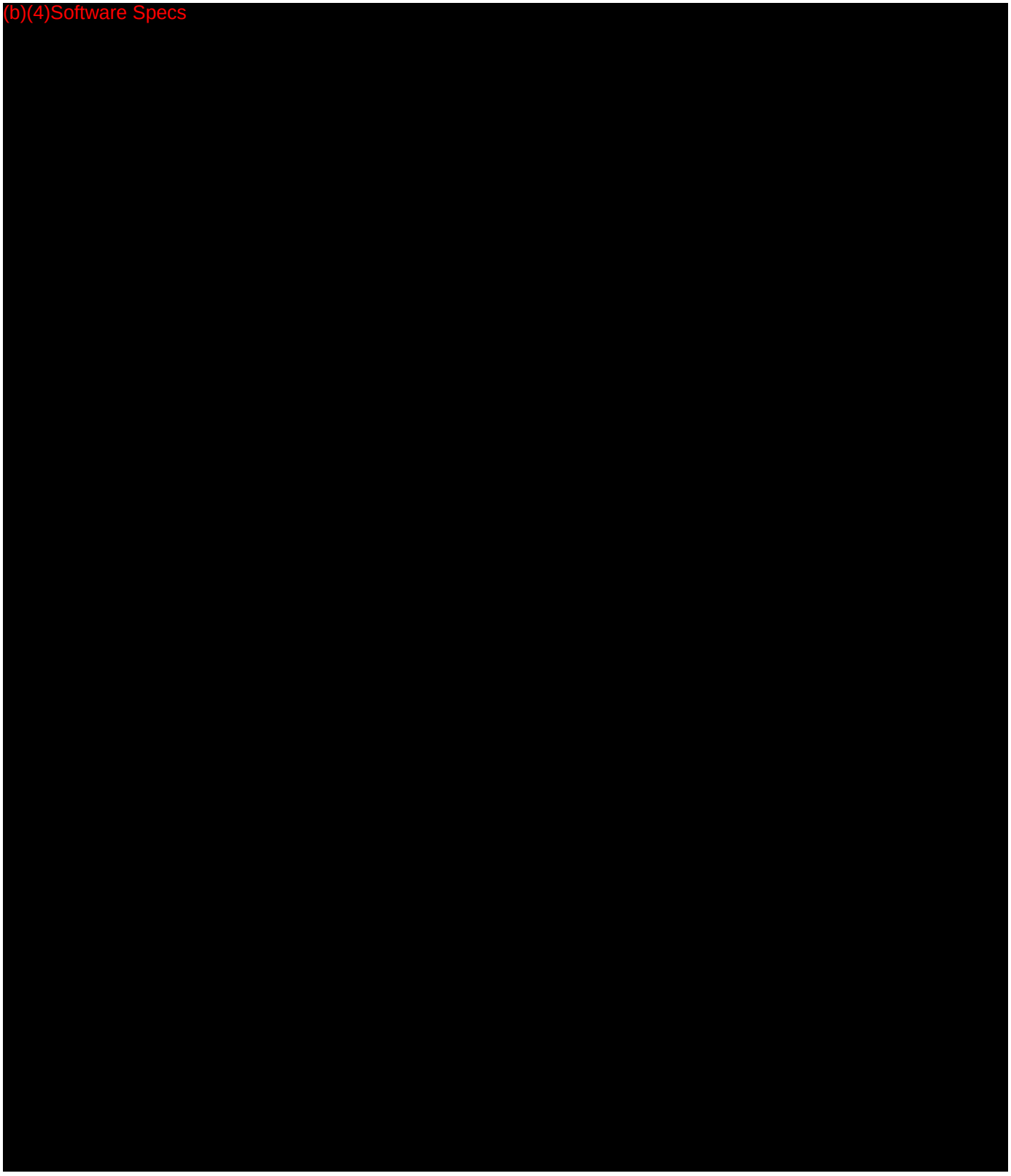
16.12. Off-The-Shelf Software

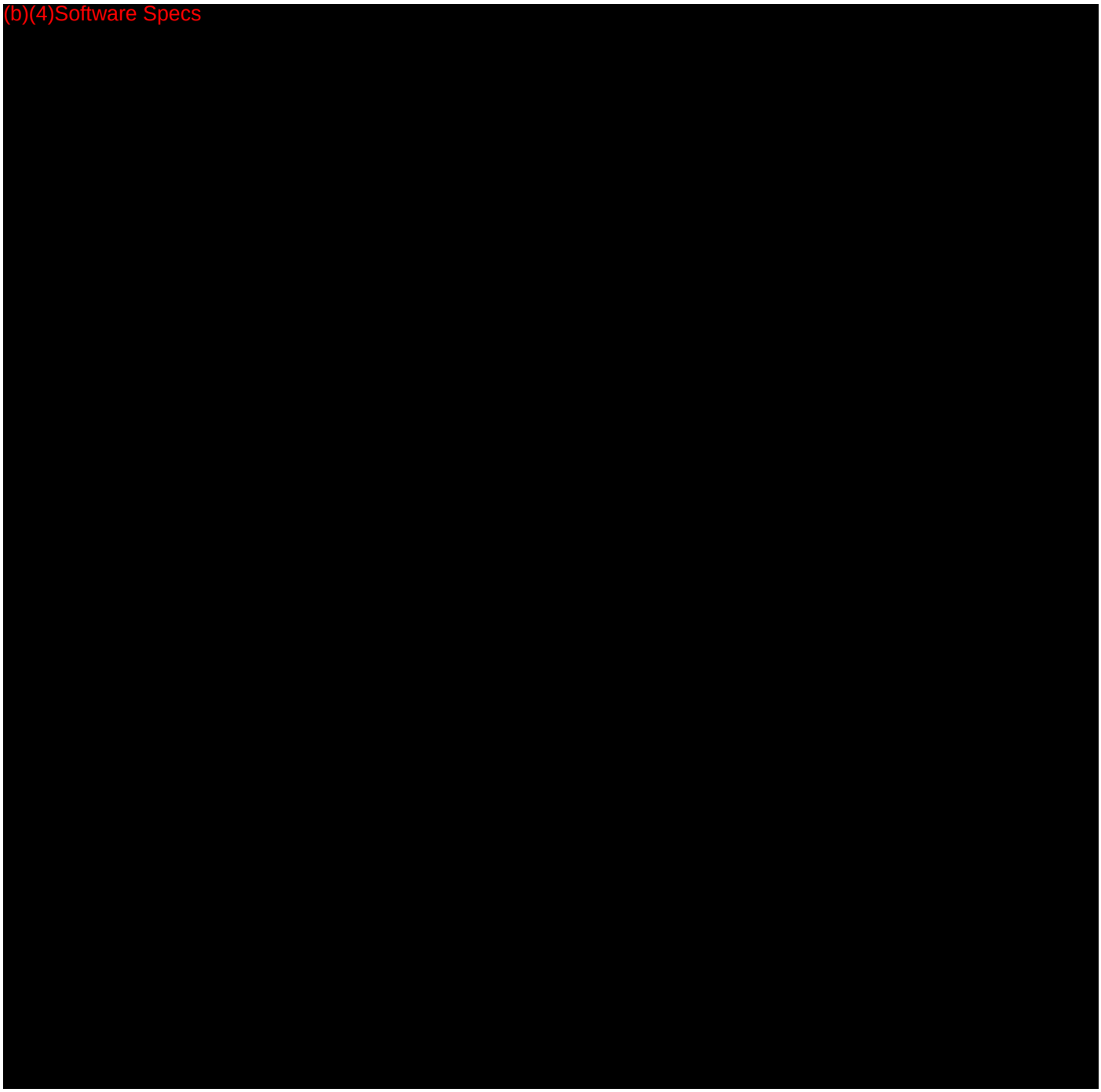
Some Off-the-Shelf (OTS) software components a.k.a. Software of Unknown Pedigree (SOUP) or 3rd Party software are used in Revolution CT developed by GE Healthcare.

(b)(4) [redacted] All SOUPs were verified via system and subsystem verification per the Software Development Lifecycle Procedure described in Section 16.8.

(b)(4) [redacted]

(b)(4)Software Specs

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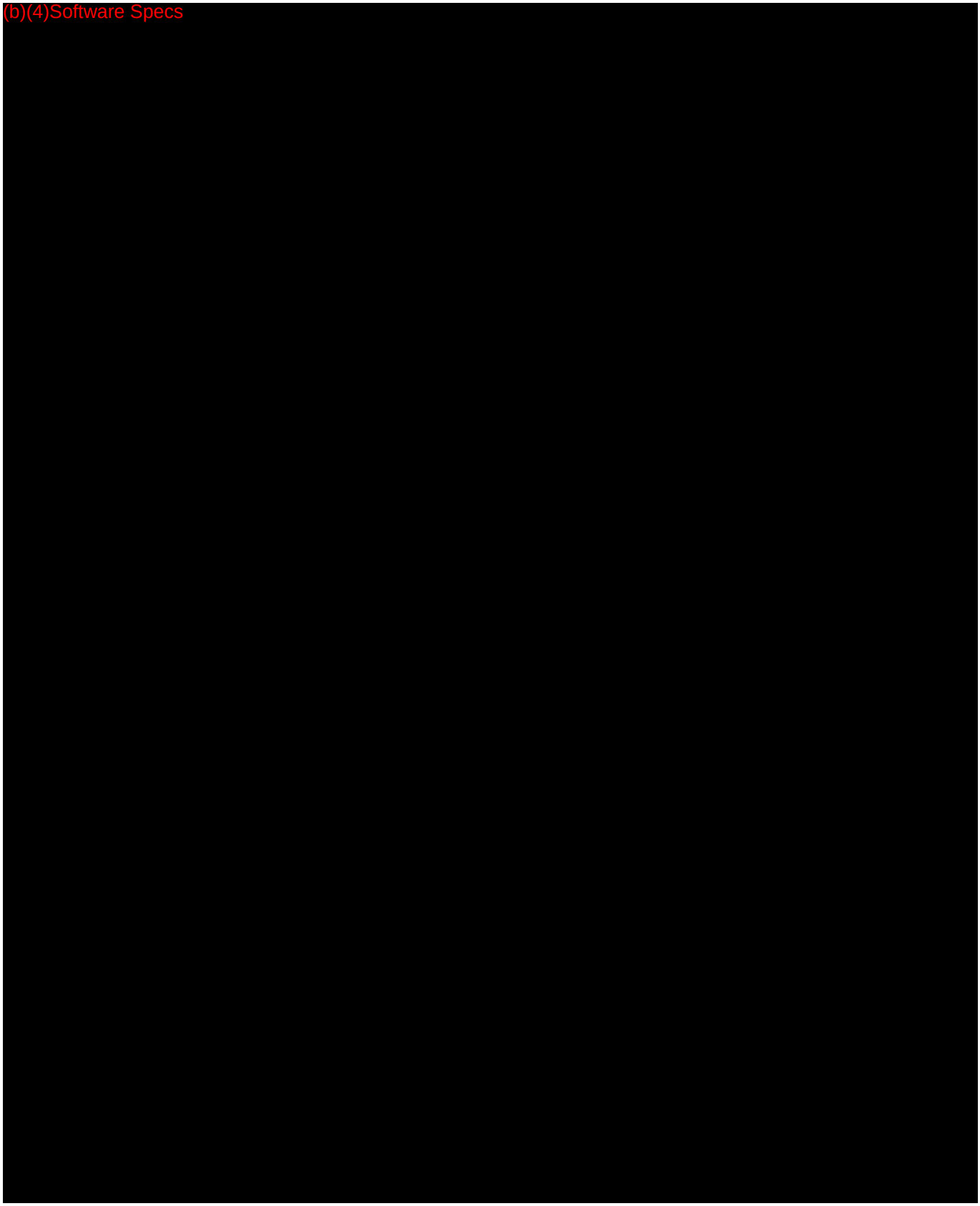

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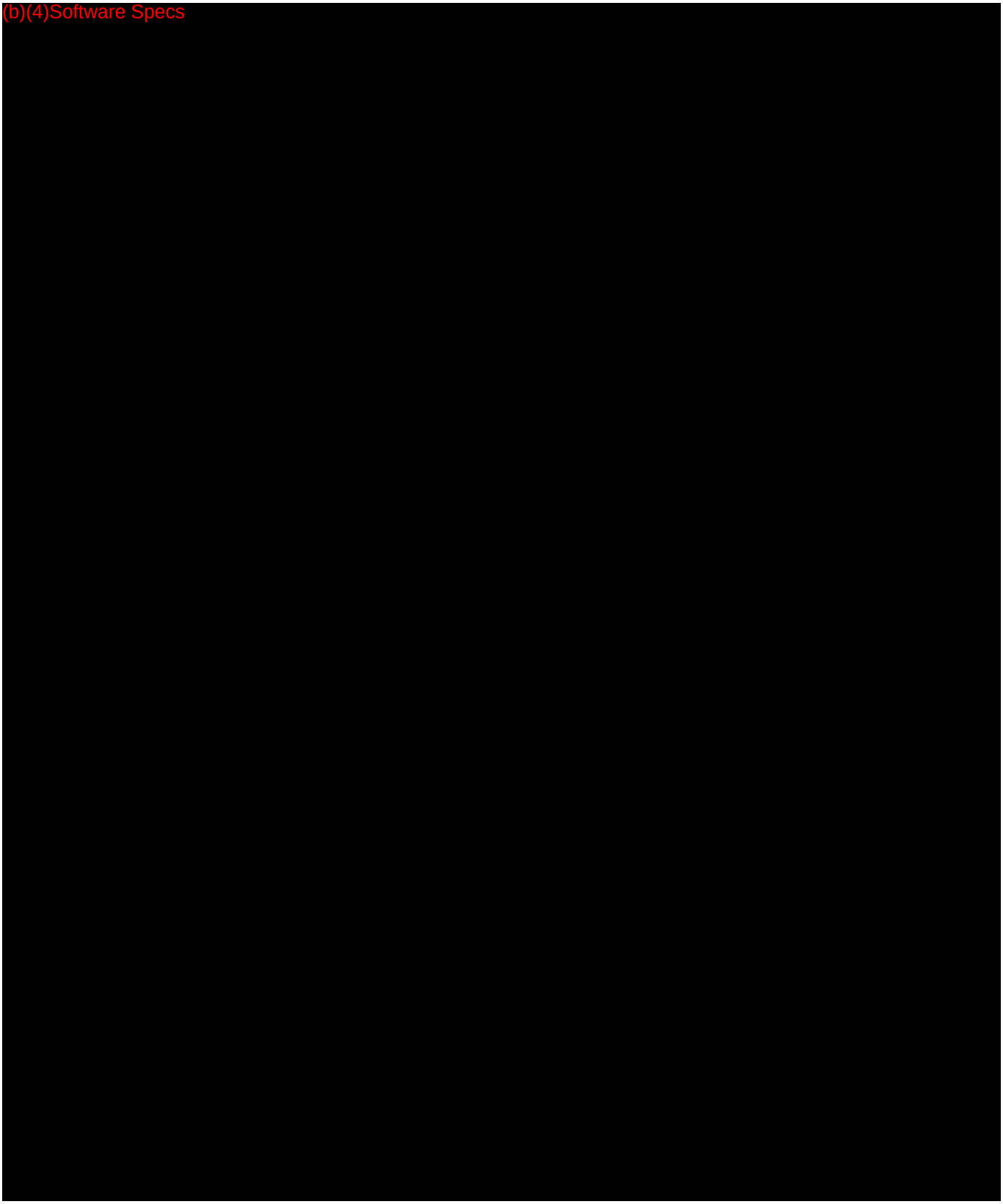

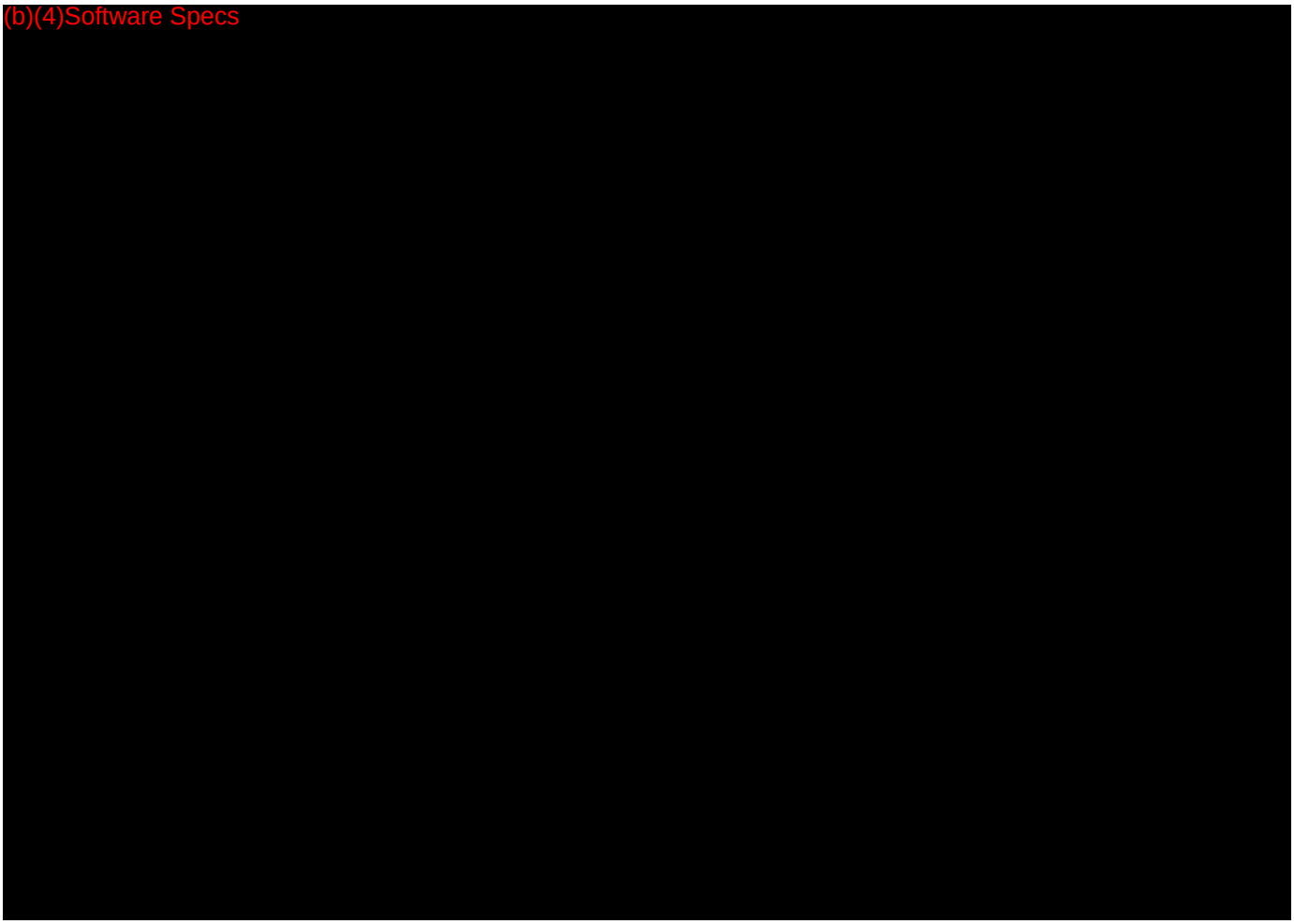
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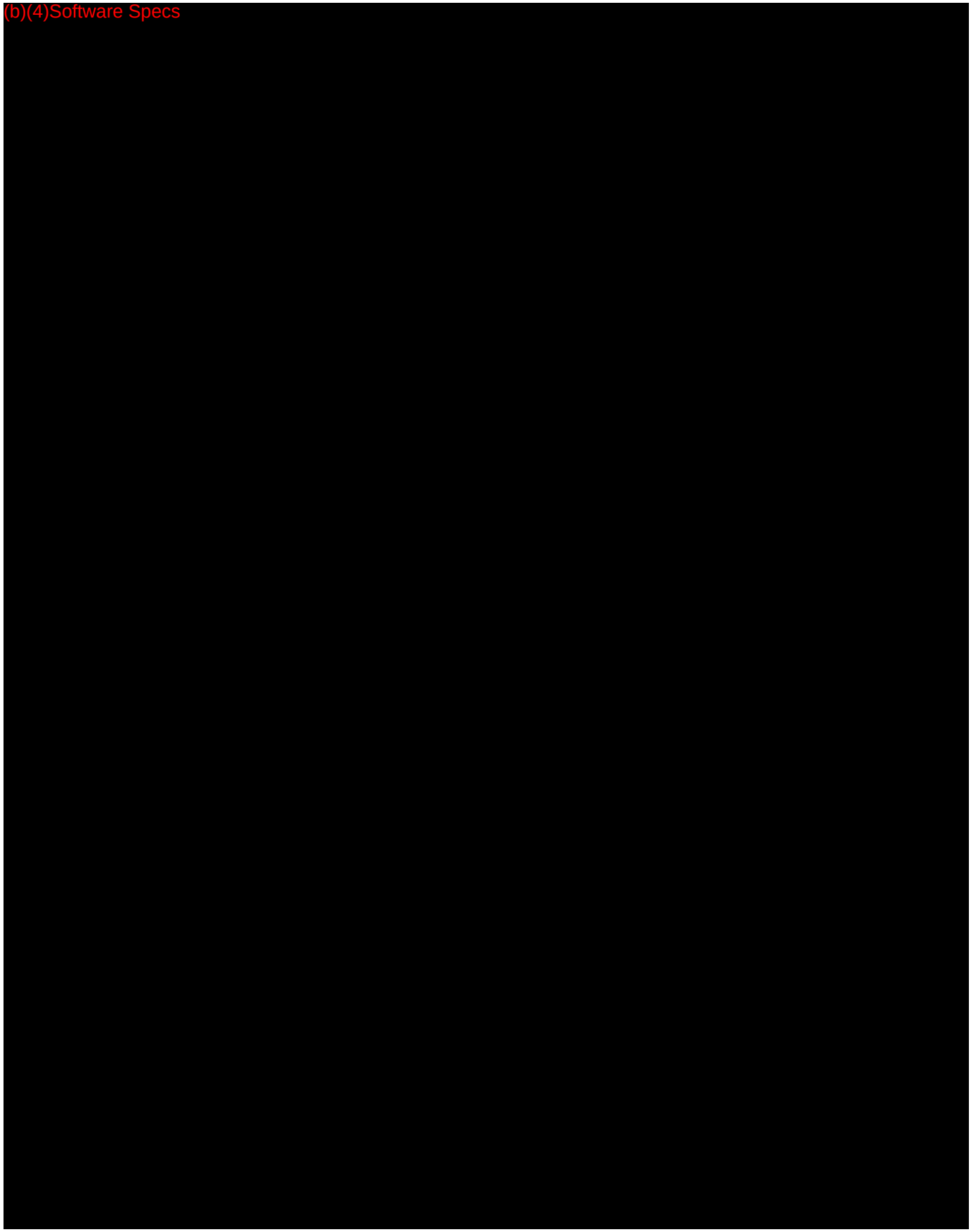

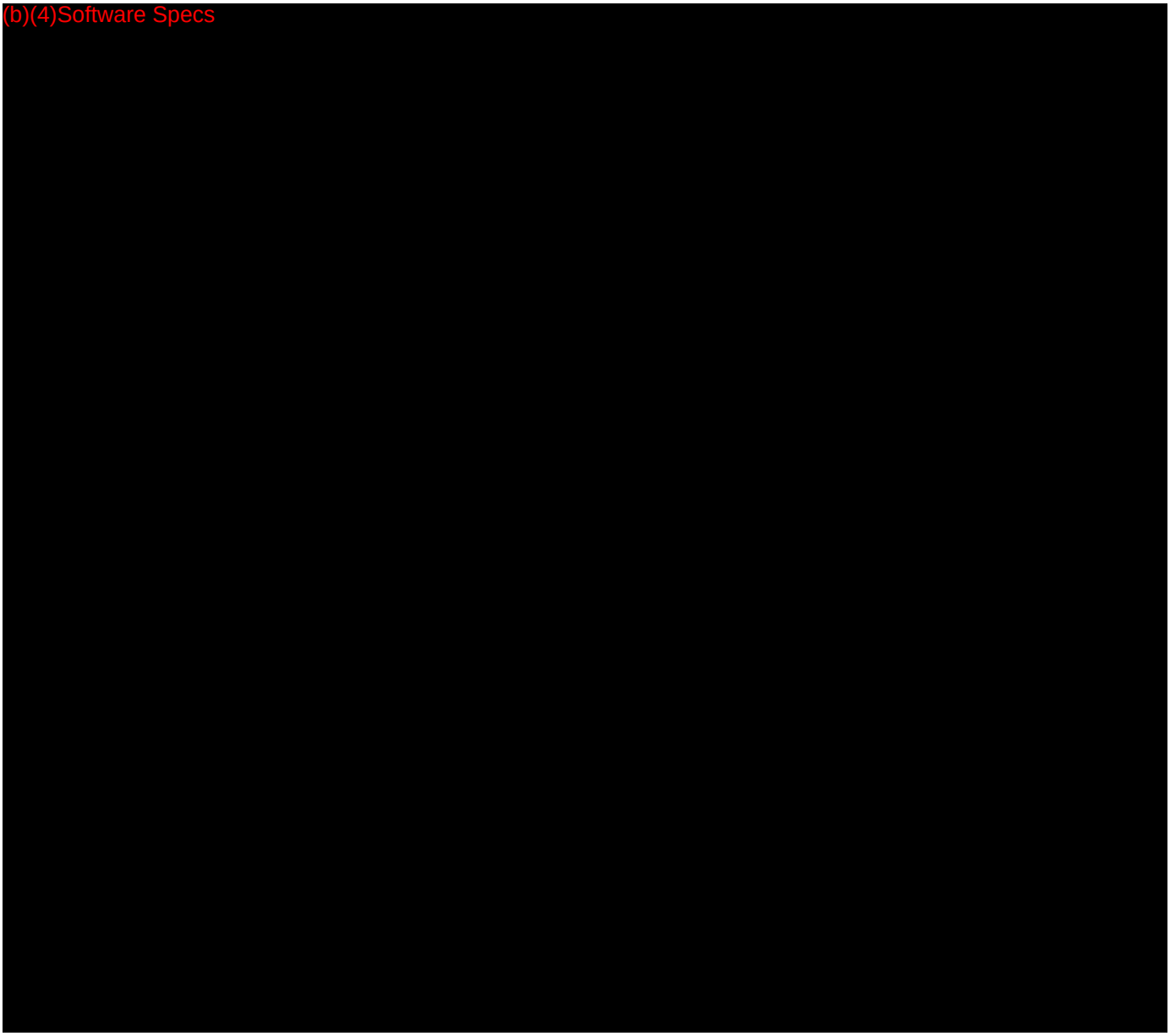
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16.13. Cybersecurity

This section is prepared in accordance with the FDA Guidance for Industry

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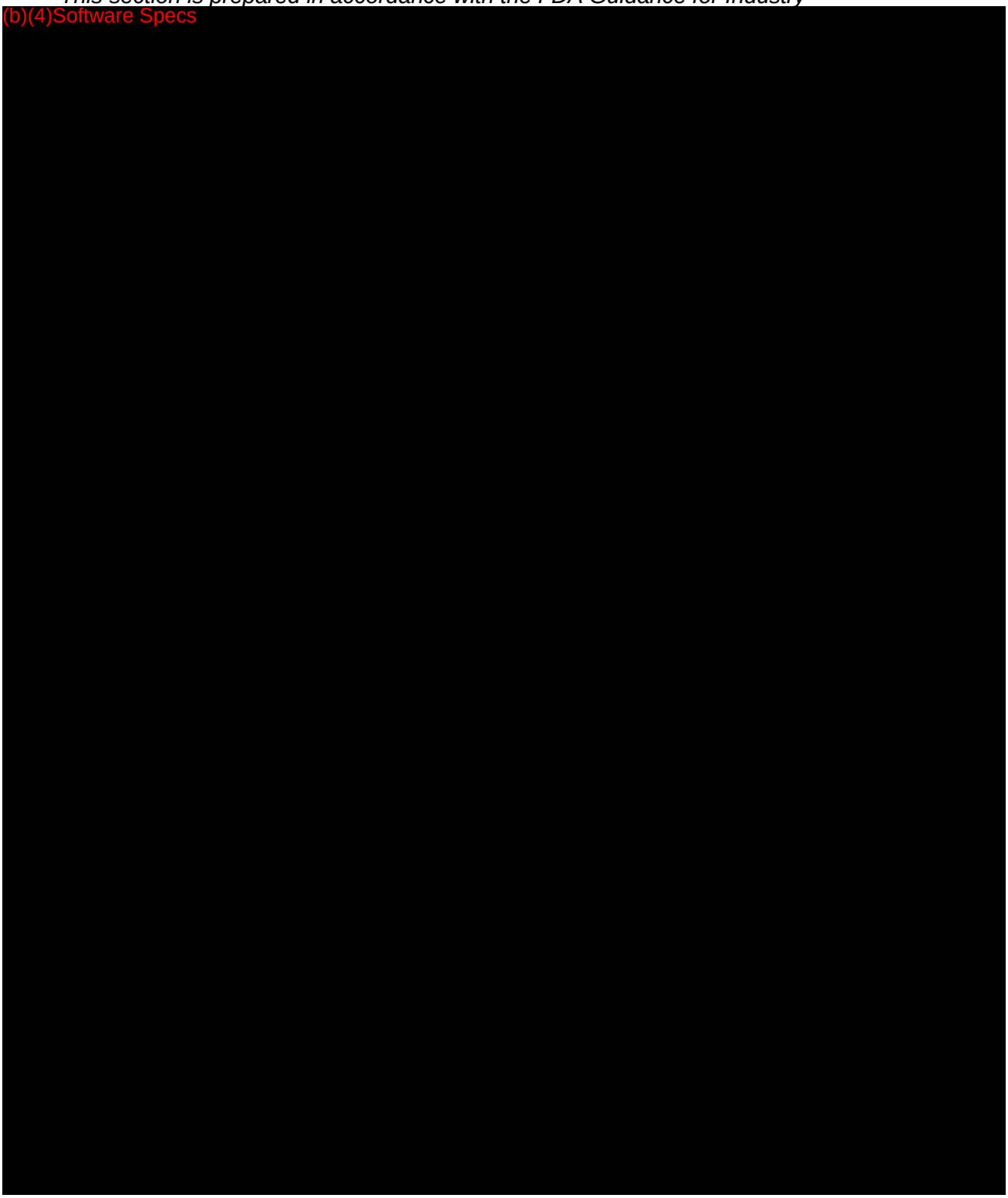

Conclusion:
Therefore, we conclude that the Cybersecurity vulnerability of the Revolution CT System due to the use of the OTS is minimized and GE Healthcare ensures the continued safe and effective performance of the subject medical device.

16.14. Software Certification

Software Certification

This certifies that the software information provided in this premarket notification is correct and that the established procedures and quality controls were and shall continue to be adhered to, and that the described process will be completed prior to release with acceptable results that demonstrate that the Revolution CT meets its required specifications.

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[redacted]

NOV - 4 - 2013

Date

GE Healthcare, GE Healthcare

Appendices for Section 16
Software

Revolution CT

Appendix 16.3a

Revolution CT Hazard Analysis and Control (Software CMT)

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Section 17: Electromagnetic Compatibility and Electrical Safety

Revolution CT

17.1 Summary of Electromagnetic Compatibility

17.2 Summary of Electrical Safety

17.1 Summary of Electromagnetic Compatibility

The Revolution CT system complies with IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests.

EMC testing for the Revolution CT was performed and completed in [redacted] (b)(4)Performance Testing Report

The Standards Data Forms for 510(k)s (FDA Form 3654) can be found in **Section 9**.

The Revolution CT is similar to GE Healthcare's Discovery CT750 HD and other current production CT systems with respect to electromagnetic compatibility [redacted] (b)(4)Performance Testing Report

17.2 Summary of Electrical Safety

The Revolution CT system complies with ANSI/AAMI ES60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance, IEC 60601-1, and applicable collateral and particular standards of the IEC 60601 series. These standards include many requirements associated with electrical safety, including requirements for enclosures and protective covers, separation, protective earthing, leakage current, dielectric strength, and operation under fault conditions.

Certification testing to these standards has been completed by an independent testing laboratory and final reports have been released to GE Medical Systems, LLC. The system Authorization to Mark (ATM) certificate that is provided by the NRTL is provided in **Section 9**.

The Standards Data Forms for 510(k)s (FDA Form 3654) can be found in **Section 9**.

The Revolution CT system is similar to the predicate device Discovery CT750 HD and other GE Healthcare's current production CT systems with respect to electrical safety. All current production systems are also compliant with the applicable standards of the 60601 series. Additionally, electrical safety testing is incorporated into the manufacturing and installation procedures of all GE Healthcare CT systems, as they are for Revolution CT and associated configurations.

Section 18: Performance Testing - Bench

Revolution CT

Section 18: Performance Testing - Bench

This section contains system verification report and summaries of additional bench performance evaluations conducted in support of this submission.

The performance evaluation testing used a variety of test methods, phantoms, and clinical datasets. Various mathematical, physics and statistical analysis were performed to demonstrate that each performance item was successfully verified and substantiated. The test report is provided in **Attachment 18A**.

System verification and simulated user scenario testing was conducted. This test report is provided in **Attachment 18B.**

(b)(4)Performance Testing Report

Revolution Performance Evaluation

Contributors	Role
(b) (6)	Senior Scientist, Physics & Image Quality
	Senior Scientist, Physics & Image Quality
	Manager, CT Detectors
	Principal Engineer, Physics & Image Quality
	Principal Engineer, Cardiac Imaging
	Senior Scientist, Physics & Image Quality
	Principal Engineer, Dose Management
	Principal Engineer, Cardiac Imaging
	Architect, Cardiovascular Applications
	Lead Engineer, Physics & Image Quality
	Principal Engineer, CT Mechanical
	Principal Scientist, Physics & Image Quality

(b)(4)Performance Testing Report

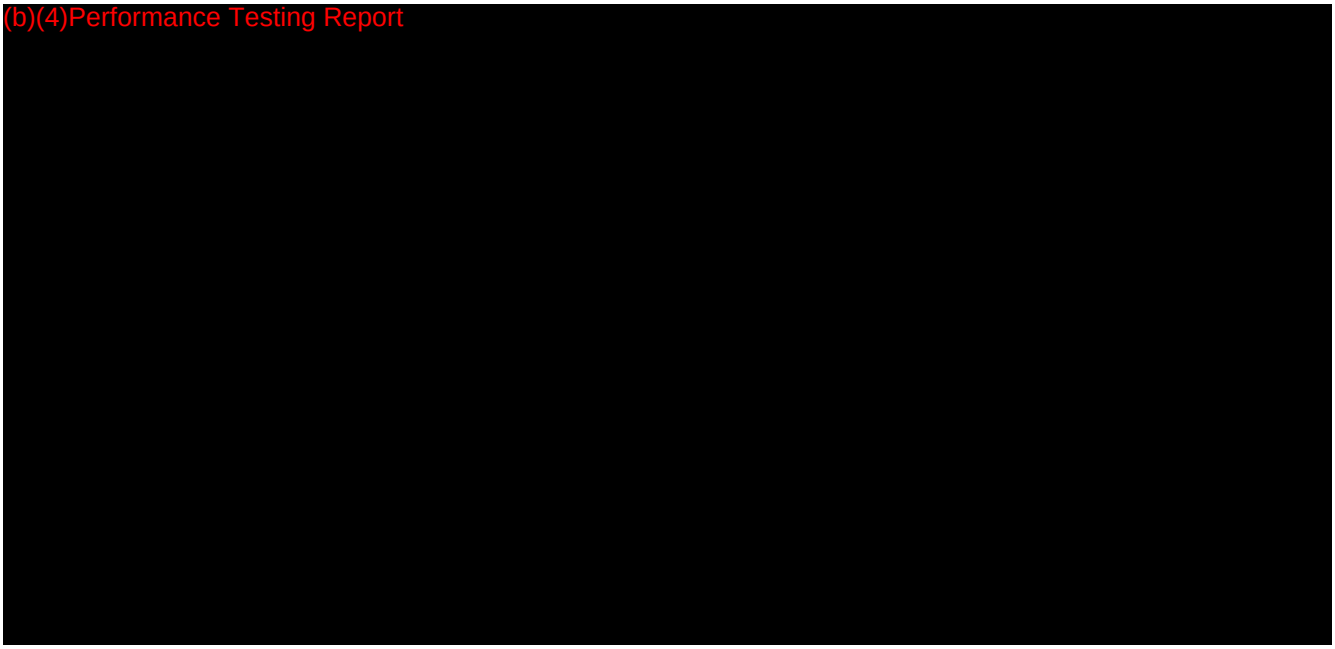


Table of Contents

1. Introduction

1.1 System Description

The GE Discovery CT870 HD shown below in Figure 1 is the next generation scanner in GE's line of Computed Tomography (CT) products. This scanner is also called the "Revolution" CT scanner.

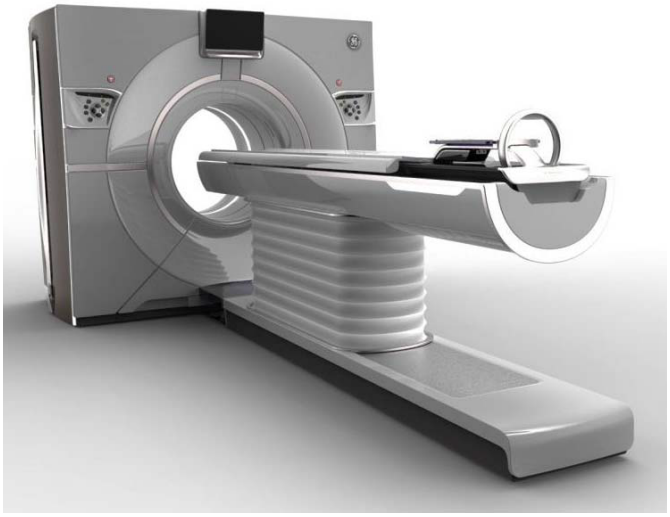


Figure 1: The new GE Discovery CT870 HD scanner, known internally as the Revolution CT scanner.

Revolution is designed as the first fully volumetric CT scanner to provide whole organ imaging capability for the full range of clinical applications with the same state-of-the-art image quality and dose performance as the (b) (4) scanner. With Revolution, the CT scanner has been redesigned from the ground up to resolve the major trade-offs occasioned by full organ imaging in a third-generation CT platform.

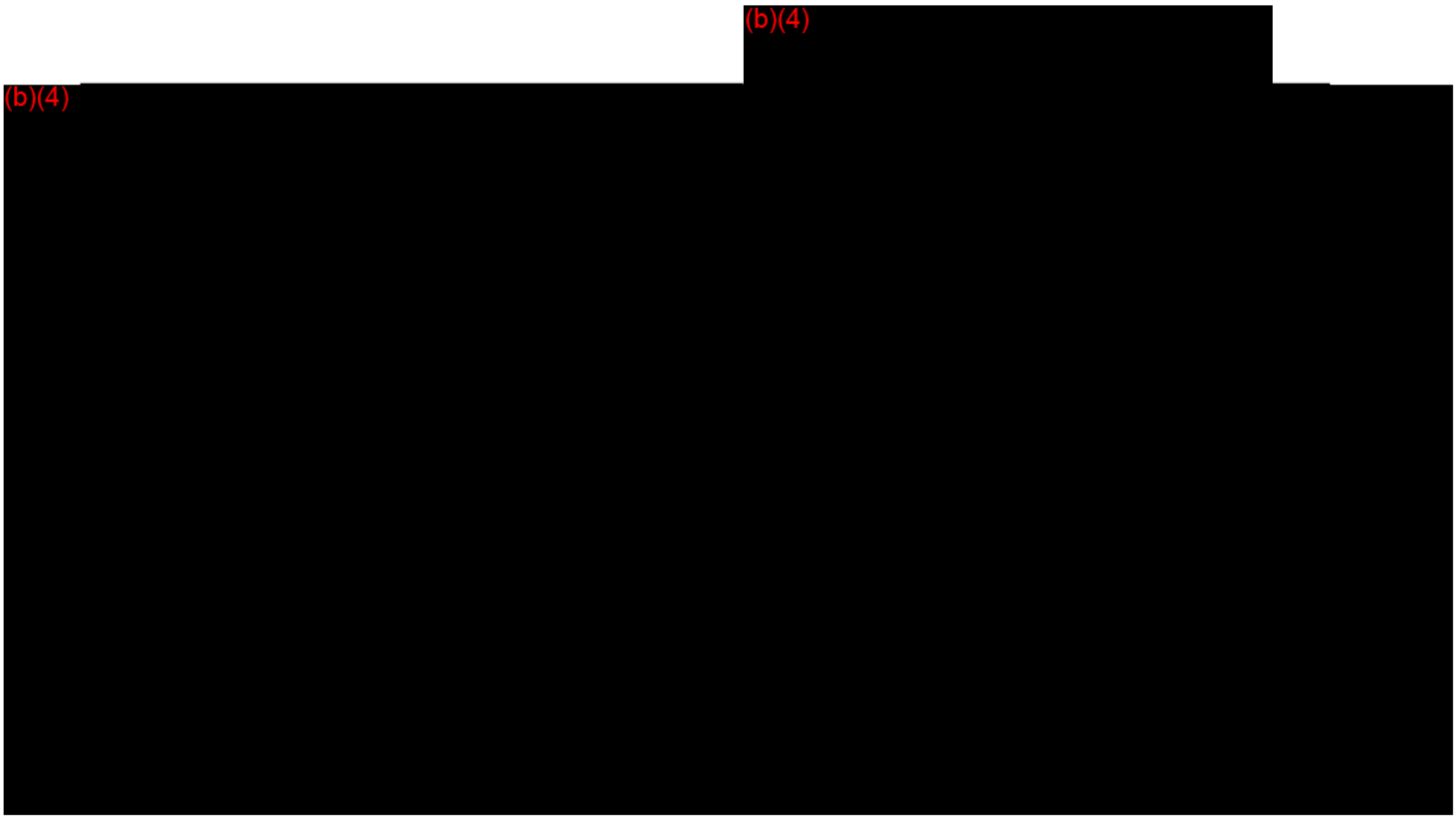
Revolution is built on the new Gemstone Clarity detector configuration, featuring 256 slices at 0.625mm row thickness and a full 160mm z-coverage. The Gemstone Clarity detector has (b)(4) for the ultimate in both z-coverage and spatial resolution across the full range of CT clinical applications, (b)(4) (b)(4). A longitudinal section of the detector is pictured in Figure 2. The detector features a modular design with a (b)(4) architecture where the (b)(4)

(b)(4)

(b)(4)

Gemstone Clarity is the next-generation of solid-state CT detectors using the Gemstone scintillator technology, which combines high light output, high stopping power, and low radiation damage, with the fastest primary speed and lowest afterglow in the industry to support extremely fast acquisition modes across the full spectrum of modern CT clinical applications. In Revolution, the Gemstone scintillator is coupled with (b)(4) for high speed data acquisition with sampling rates (b)(4) while limiting intrinsic noise at the quantum limit to the equivalent of (b)(4) for maximum signal fidelity.

(b)(4) the Revolution gantry, shown in Figure 3, has been completely redesigned with high specifications of strength and rigidity that support fast rotation speeds for acquisitions with high temporal resolution, while providing an 80cm bore opening to accommodate patients with positioning flexibility and in total comfort. With a (b)(4) center mount design that (b)(4) generated by the rotating components, the gantry and detector assembly is capable of supporting accelerations in (b)(4), which ensures reliable operation at today's 0.28 seconds per rotation, and can be extended to (b)(4)



On the rotating gantry, the new (b)(4) tube tailored for the wide angle geometry generates the X-ray beam for patient imaging. The system also features (b)(4) design to power the acquisitions and extract all the data (b)(4) at the fast trigger rates supported by the (b)(4) The (b)(4) features (b)(4) and up to (b)(4) of data bandwidth over 4 (b)(4) to transfer the acquired raw data to the stationary data storage and the image reconstruction engine.

In the wide cone-beam geometry of the new scanner, the sampling (b)(4) (b)(4) with the wide X-ray beam (b)(4) have been fully addressed by the (b)(4) advanced (b)(4) (b)(4) which has been designed specifically to (b)(4) (b)(4) on this new platform. Combined with (b)(4) (b)(4) (b)(4) this new (b)(4) provides (b)(4) handling of CT signal challenges to make reliable images.

The image reconstruction engine further (b)(4) (b)(4) for noise reduction and dose management in reconstruction. Finally, GE's (b)(4) echnology is supported on all cardiac acquisitions to (b)(4) of the reconstructed images when visualizing the coronaries.

1.2 Clinical Benefits

The Revolution scanner is indicated for head, whole body, cardiac and vascular Computed Tomography applications. It has been designed with expanded capabilities to avoid or eliminate the

Combining fast rotation speeds with large longitudinal coverage, ECG-gating, and a wider bore provides the ideal platform for imaging in particular, and the in general. A single axial acquisition over can cover the full heart in a single beat for robust imaging across a large range of heart rates, with consistent anatomical position, temporal uniformity, and contrast uniformity. Residual motion artifacts The comprehensive cardiac capabilities of the new system extend to a range of imaging situations, from all from a single exam. Wide coverage and fast scanning also make it easier) assessment.

The Revolution system is also designed to imaging situations. 4D imaging across all anatomies is enabled by whole organ acquisition over a specified period of time with or without ECG gating or respiratory gating to visualize . This is especially useful for cardio-vascular and oncology applications. Dynamic perfusion studies up to of anatomy in the brain, can be performed without requiring providing temporal and contrast uniformity

In oncology applications, wide coverage and fast acquisition speed may allow without requiring a breath hold when imaging organs, thereby providing easier patient access to state-of-the-art CT imaging. With the anatomy of interest covered , it is easier to visualize the when diagnosing lesions, monitoring tumor progression, and during follow-ups for treatment response. The entire chest can be covered in little time, which is important to assess , among other thoracic pathologies. Pediatric scanning and trauma assessment can also be performed more easily with the the full anatomical area, reducing the need for breath holds and possibly repeat scans

In general, the Revolution scanner is intended to manage the traditional challenges of CT acquisitions

Considering the above system description and potential clinical benefits, the following performance items are evaluated in Section 2.

2. Revolution Performance Evaluation

2.1 One-Beat Cardiac Imaging:

2.1.1 Performance item 1a: The Revolution system can cover the entire heart in less than one beat, providing IV contrast uniformity and temporal uniformity throughout the whole image volume.

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Whole Heart Coverage

(b)(4)

(b)(4)

(b)(4)

At 0.28 seconds per rotation, the Revolution scanner can easily image all patients in less than half a cardiac cycle for up to more than 100 beats per minute (1/0.28s * 60s / 2 > 100). Figure 4 and Figure 5 show some illustrations of different patient exams where the heart is covered more than adequately within one beat for potential coronary and functional assessment.

In conclusion, the Revolution scanner can cover the entire heart in less than one beat.

Contrast Uniformity

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In conclusion, the Revolution scanner provides excellent IV contrast uniformity throughout the whole image volume.

Temporal Uniformity

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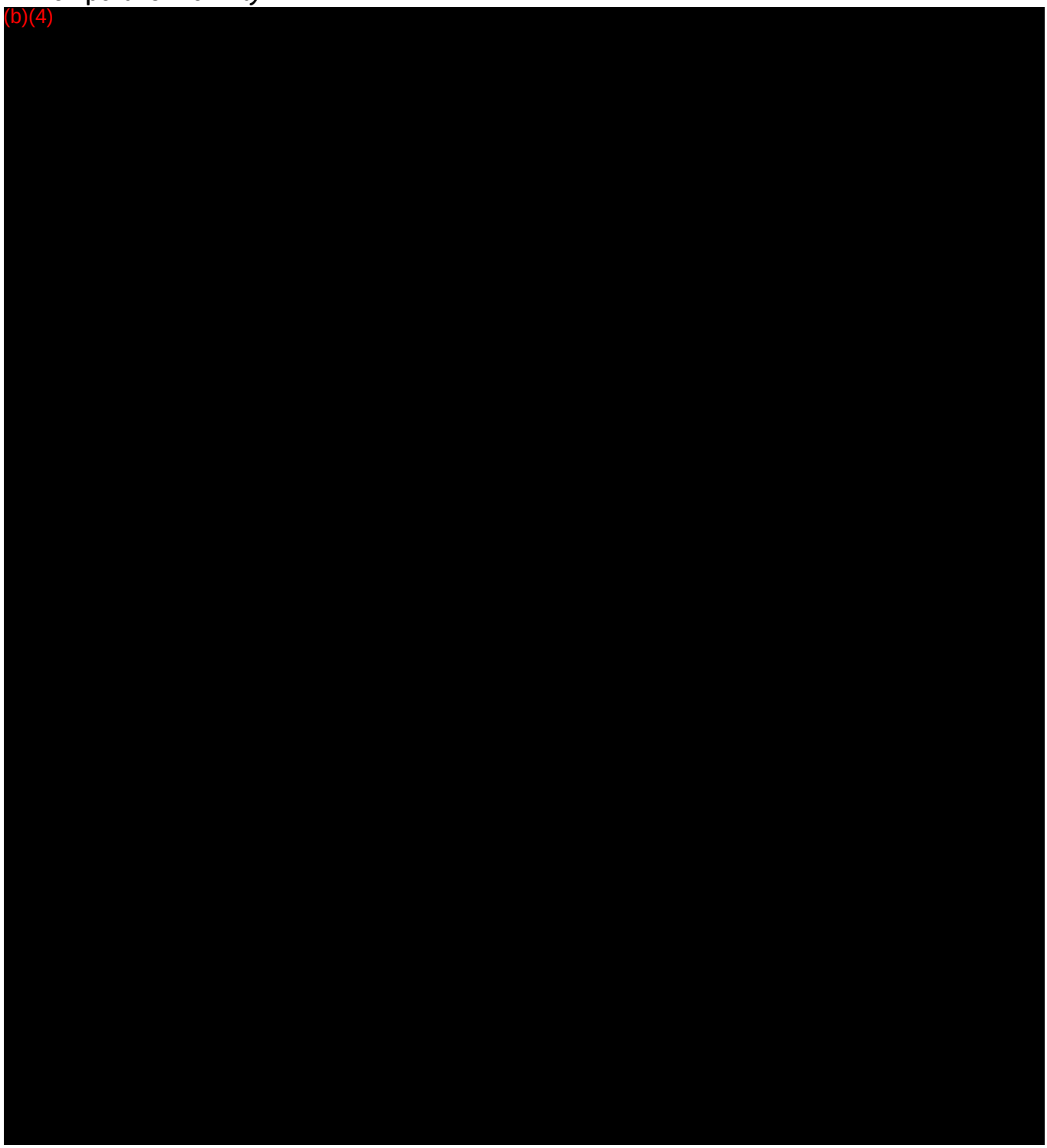

(b)(4)

In conclusion, the Revolution scanner provides excellent temporal uniformity throughout the whole image volume.

2.1.2 Performance item 1b: The Revolution system can provide a comprehensive cardiac exam with both functional and anatomical data in a single beat, enabling combined acquisitions of systolic and diastolic phases.

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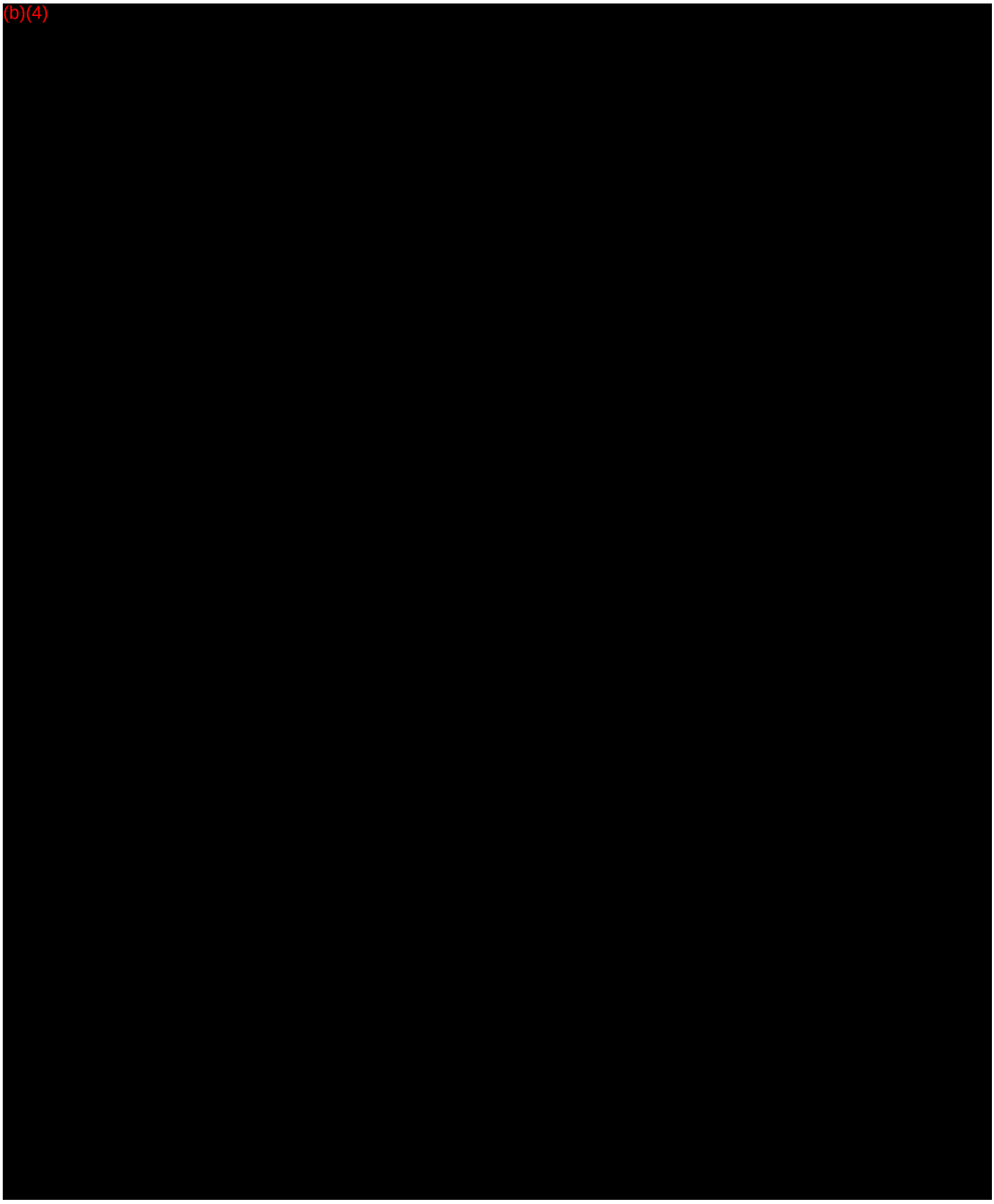

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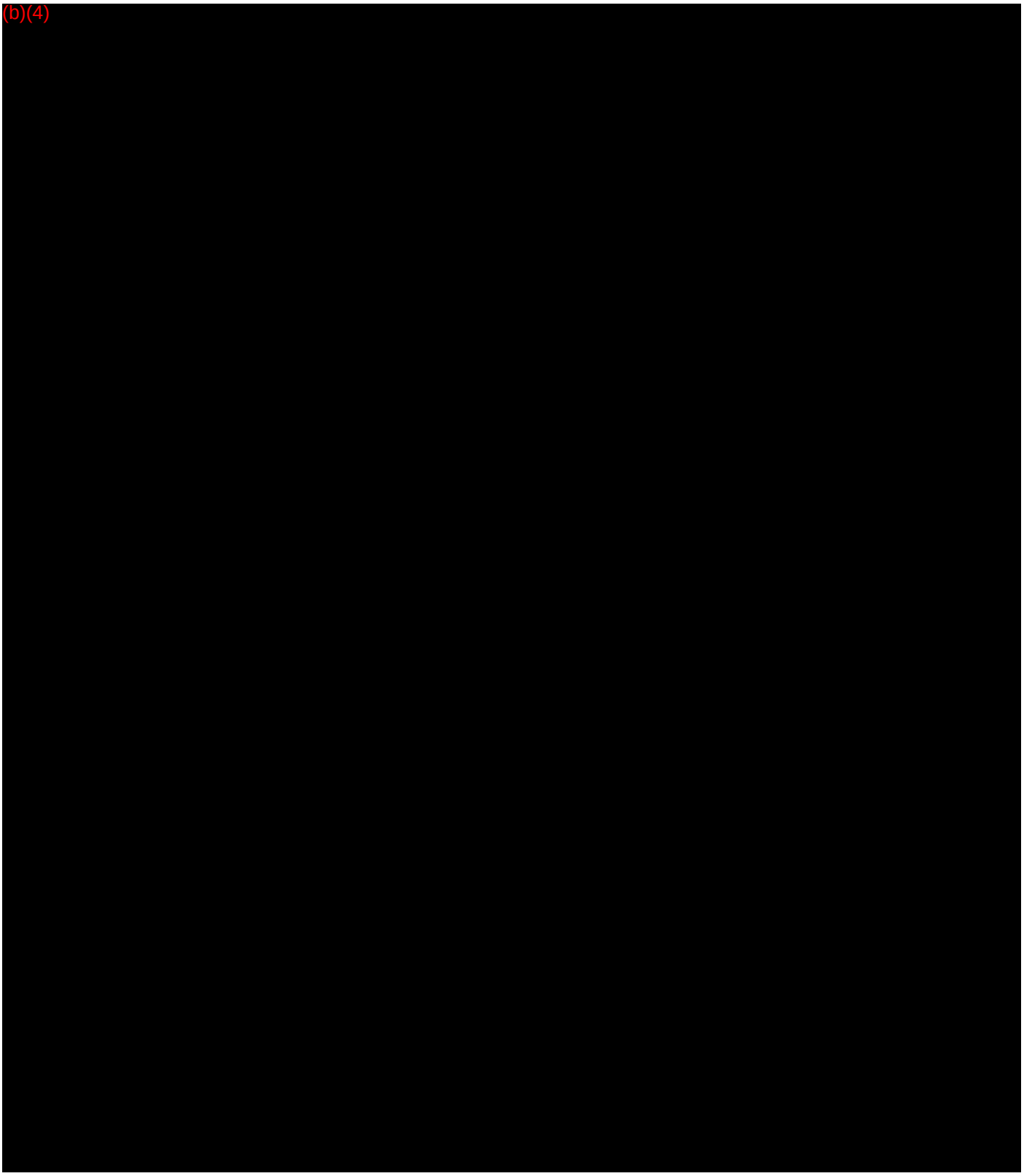

In conclusion, the Revolution system can provide a comprehensive cardiac exam with both functional and anatomical data in a single beat, enabling combined acquisitions of systolic and diastolic phases.

2.2 Cardiac Temporal Resolution:

2.2.1 Performance item 2a: The Revolution system can acquire images of the heart with 140 millisecond temporal resolution.

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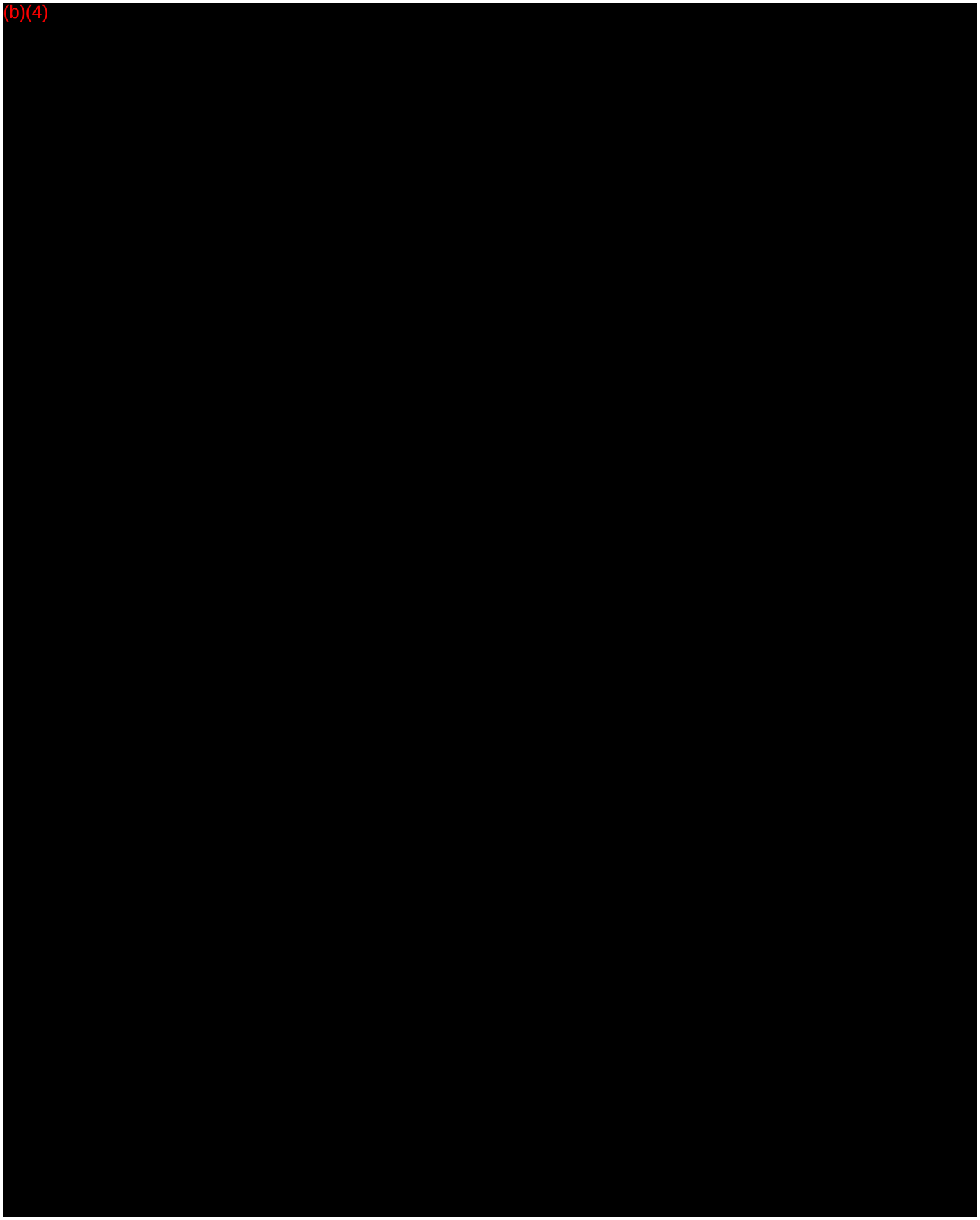

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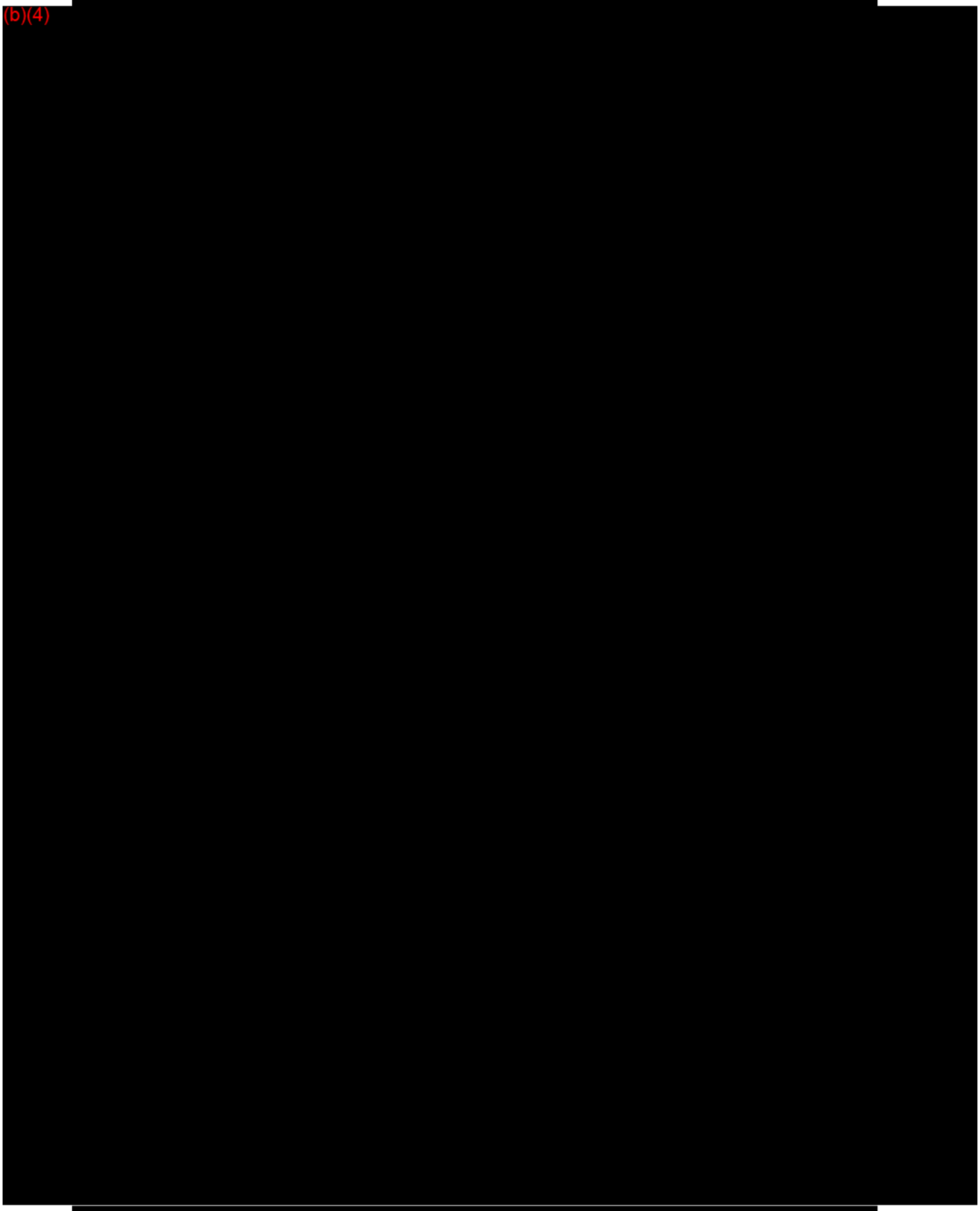

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In conclusion, the Revolution system can make images of the coronaries with (b)(4) effective temporal resolution with SnapShot Freeze.

2.2.3 Performance item 2c: The Revolution system can improve the robustness of cardiac exams for patients with high or irregular heart rates.

Robustness for Cardiac Imaging

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In conclusion, the Revolution system can improve the robustness of cardiac exams for patients with high heart rates.

Imaging Patients with Irregular Heart Rates

(b)(4)

In conclusion, the Revolution system can improve the robustness of cardiac exams for patients with irregular heart rates.

2.3 Radiation Dose:

2.3.1 Performance item 3a: The Revolution system can image the heart using less radiation dose than the Discovery CT750 HD scanner while maintaining image quality*.

** Image quality is defined as standard deviation of noise. Radiation dose is defined as CTDIvol and DLP. In clinical practice, a consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.*

Evidence

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Discussion

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Data Collection

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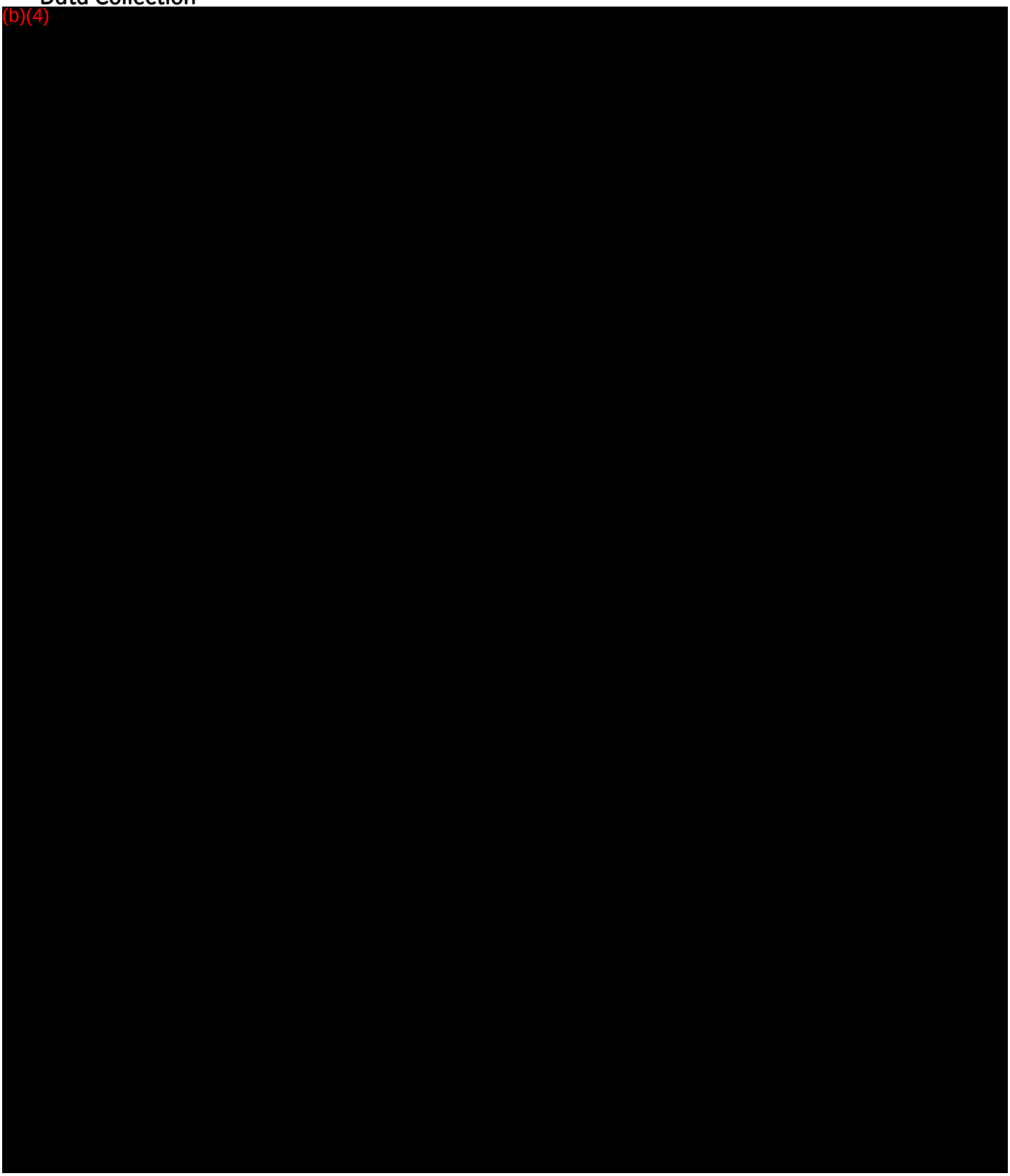

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In conclusion, the Revolution system can image the heart using less radiation dose than the Discovery CT750 HD scanner while maintaining image quality.

2.3.2 Performance item 3b: The Revolution system provides native iterative reconstruction technology which reduces noise levels and improves low contrast detectability compared to FBP, and may enable a reduction in dose*.

** In clinical practice, the use of ASiR-V may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.*

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Noise Reduction Potential

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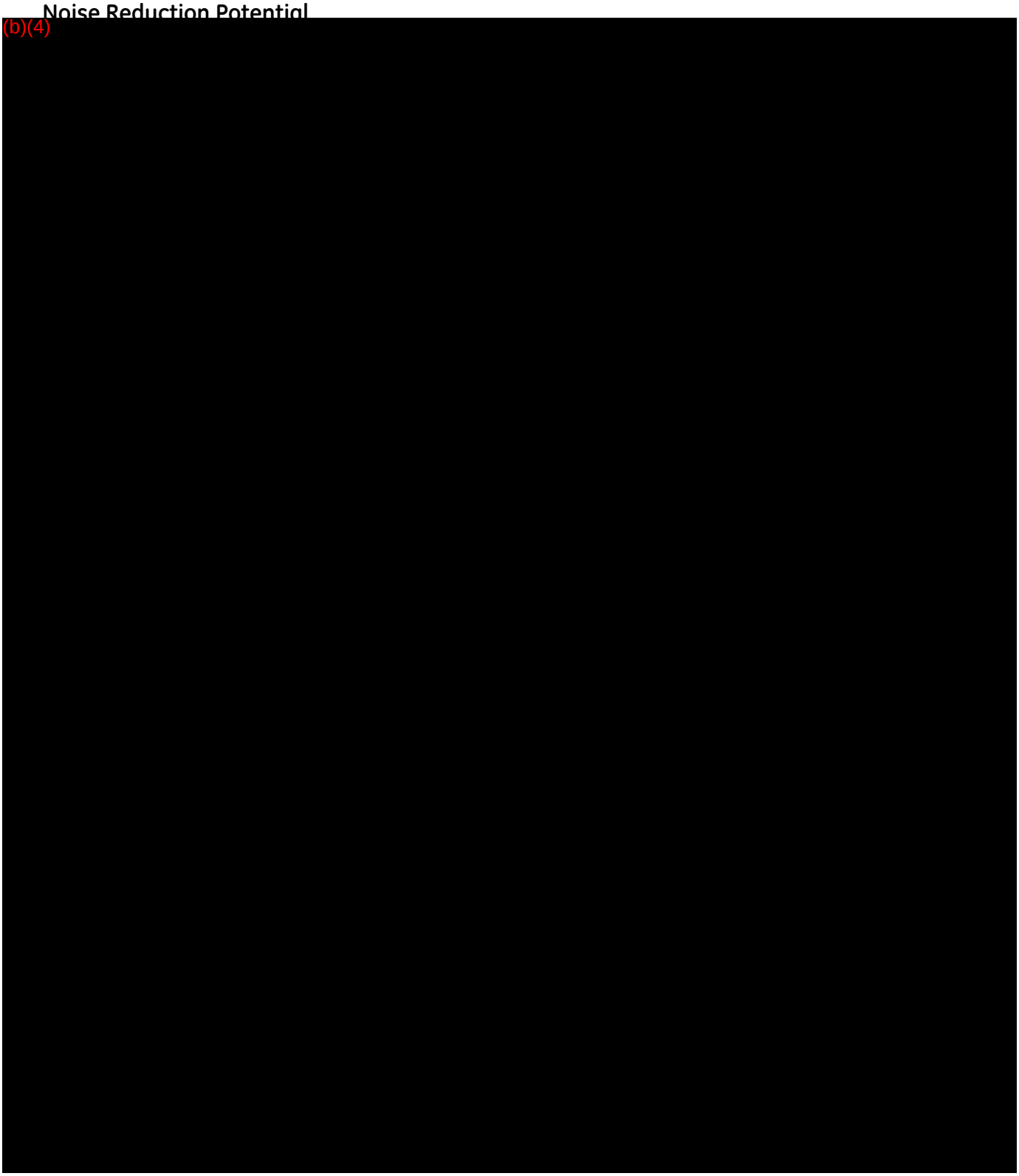

(b)(4)

In conclusion, the Revolution system provides native iterative reconstruction technology (ASiR-V) which reduces noise levels compared to FBP.

Dose Reduction Potential

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2.4 Cardio-Vascular and Thoracic Applications:

2.4.1 Performance item 4a: The Revolution system supports mixed acquisitions of the heart, aorta, and femoral arteries with ECG-gated axial scans and non-ECG-gated axial modes covering (b)(4) anatomy in less than (b)(4), and is integrated with post-processing applications for the assessment of (b)(4)

(b)(4)

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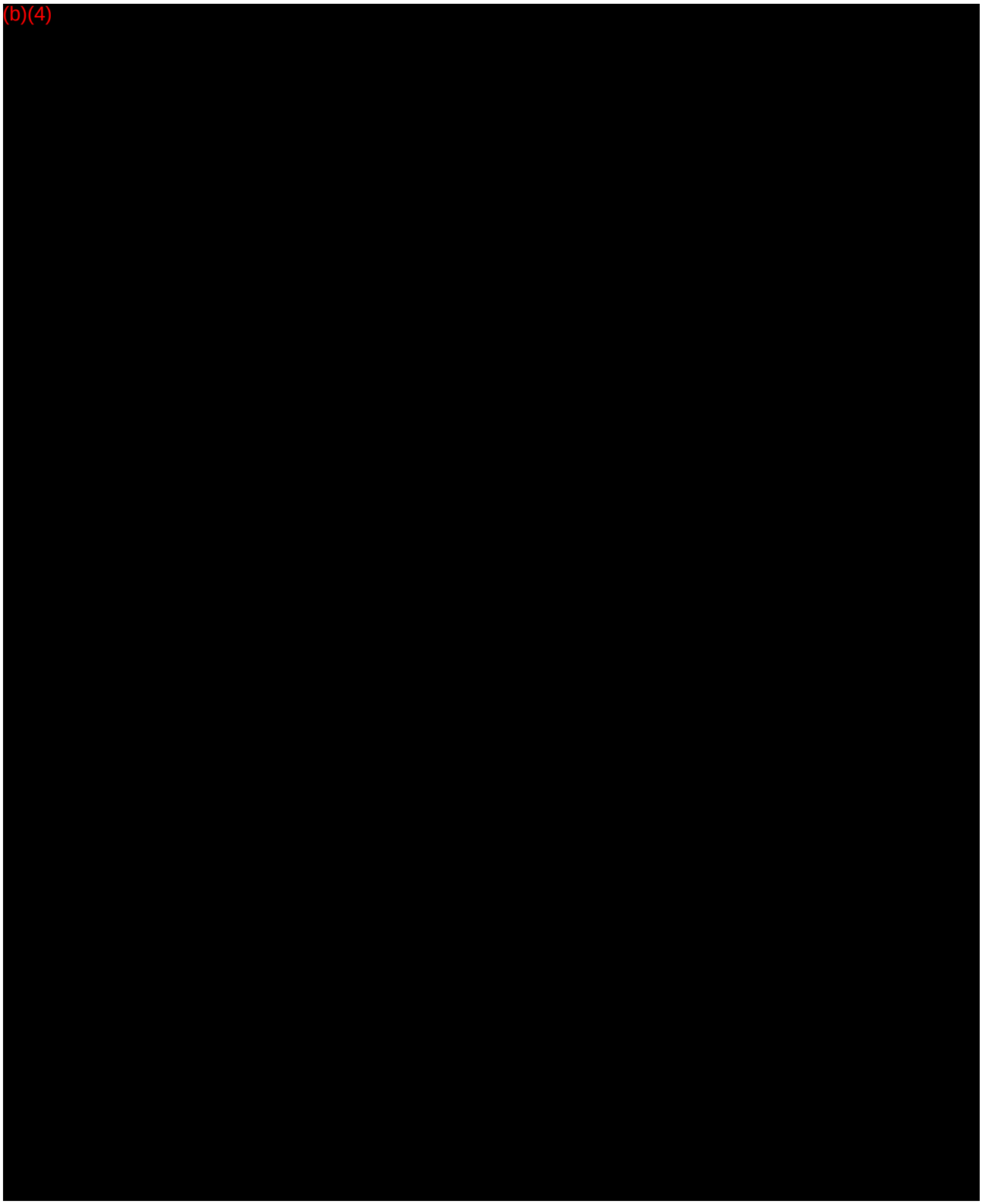

In conclusion, the Revolution system supports mixed acquisitions of the heart, aorta, and femoral arteries with ECG-gated axial scans and non-ECG-gated axial modes covering (b)(4) in (b)(4) and is integrated with post-processing applications for the assessment of (b)(4)

2.4.2 Performance item 4b: The Revolution system can cover the entire thorax in less than (b)(4) with ECG gating and makes images with high temporal and contrast uniformity at low dose.

(b)(4)

(b)(4)

In conclusion, the Revolution system can cover the entire thorax in (b)(4) with ECG gating and makes images with high temporal and contrast uniformity at low dose.

2.4.3 Performance item 4c: The Revolution system allows (b)(4) data acquisition for up to 16cm coverage for fast imaging of pediatric and trauma patients.

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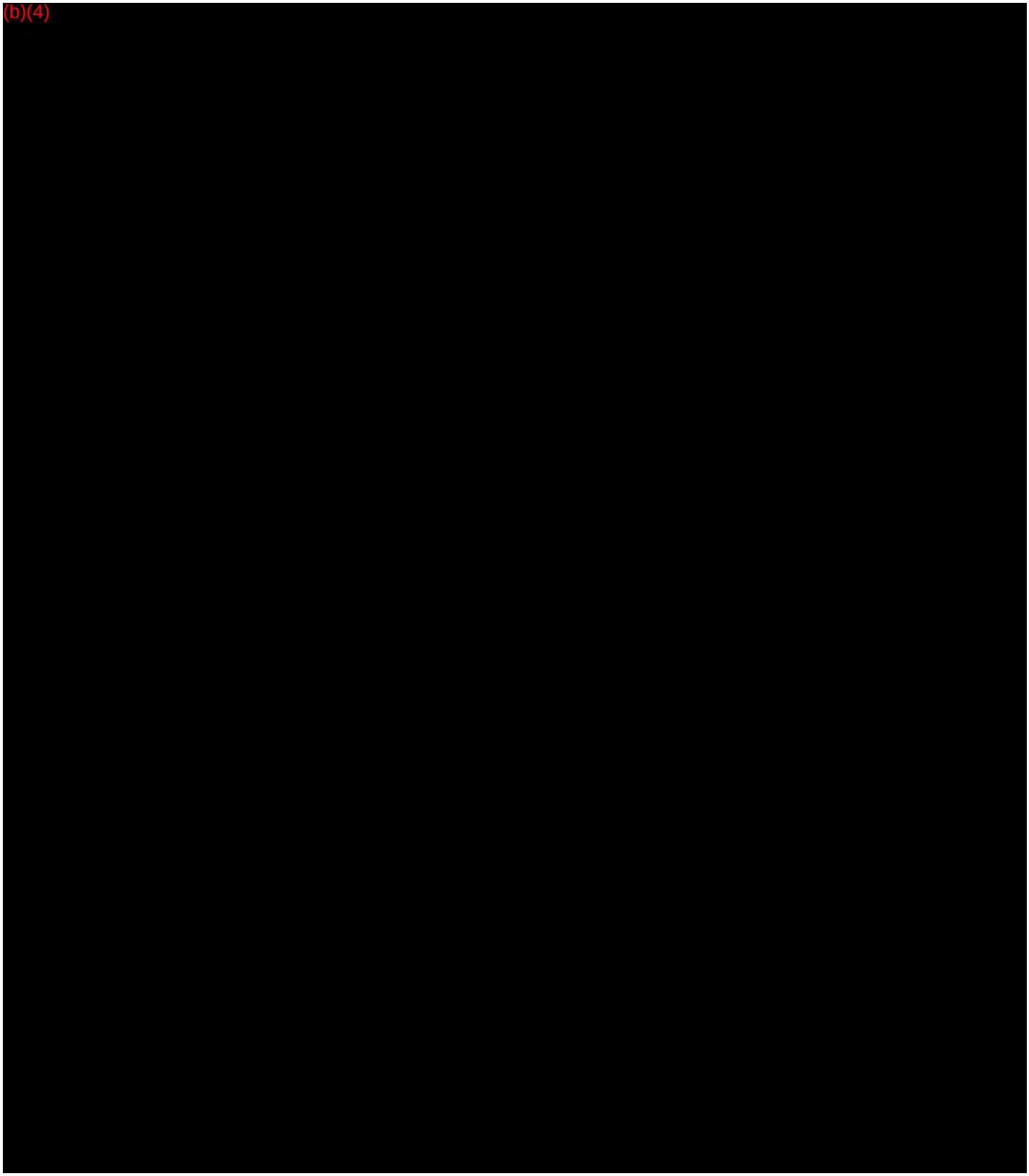

In conclusion, the Revolution system allows (b)(4) data acquisition for up to 16 cm coverage for fast imaging of pediatric patients.

Imaging of Trauma Patients

(b)(4)

In conclusion, the Revolution system allows (b)(4) data acquisition for up to 16 cm coverage for fast imaging of trauma patients.

2.5 Image Quality Performance:

2.5.1 Performance item 5a: The Revolution system significantly reduces cone-beam artifacts and improves quantitative uniformity for iodinated contrast down to within (b)(4) across the whole 160mm z-coverage.

Cone-Beam Artifact Reduction

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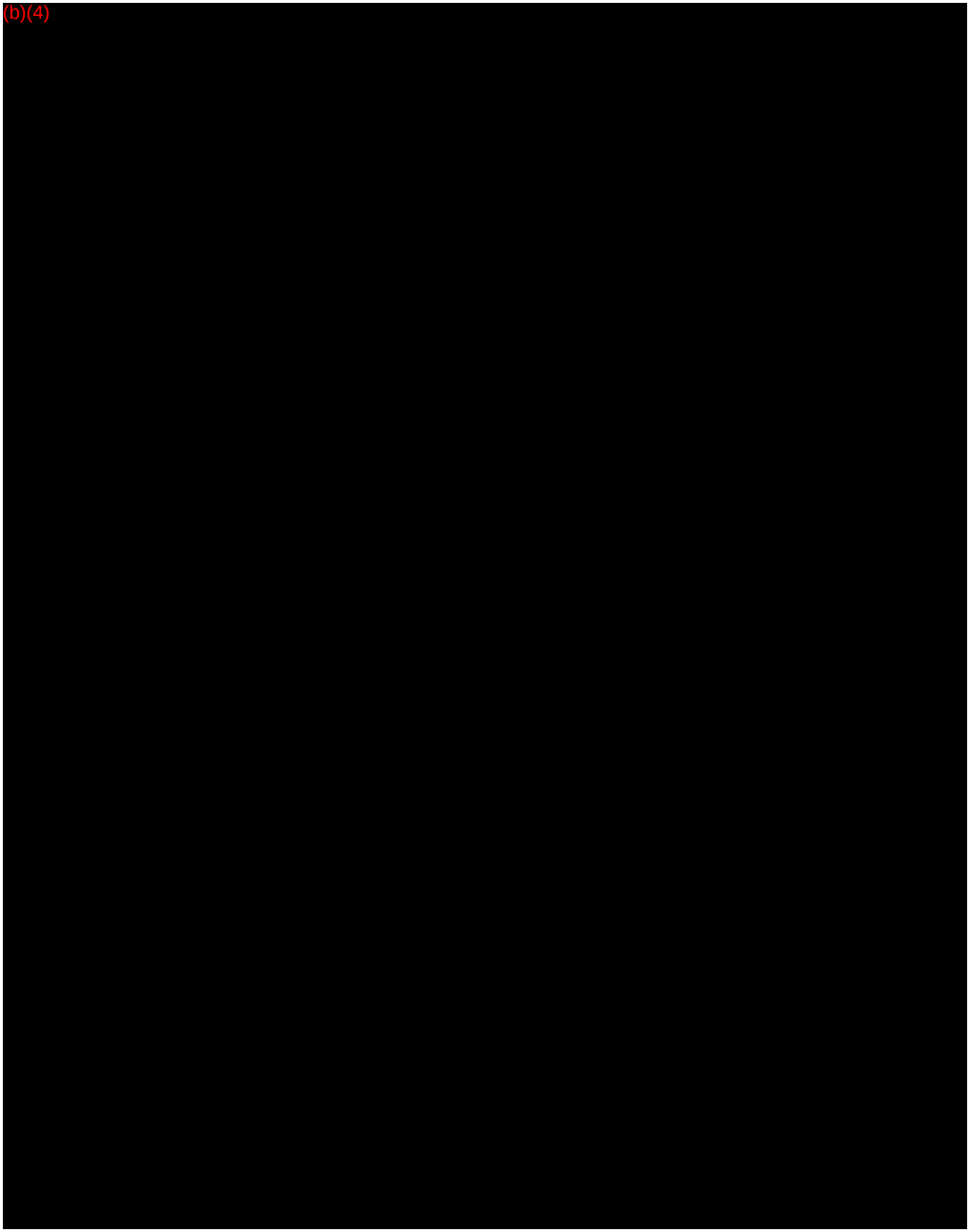

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In conclusion, the (b)(4) Reconstruction is designed to resolve the sampling (b)(4) associated with cone-beam (b)(4) in the wide-cone geometry of the Revolution scanner.

(b)(4)

Cone-Beam Artifacts in Non-Gated (Full Scan) Reconstruction

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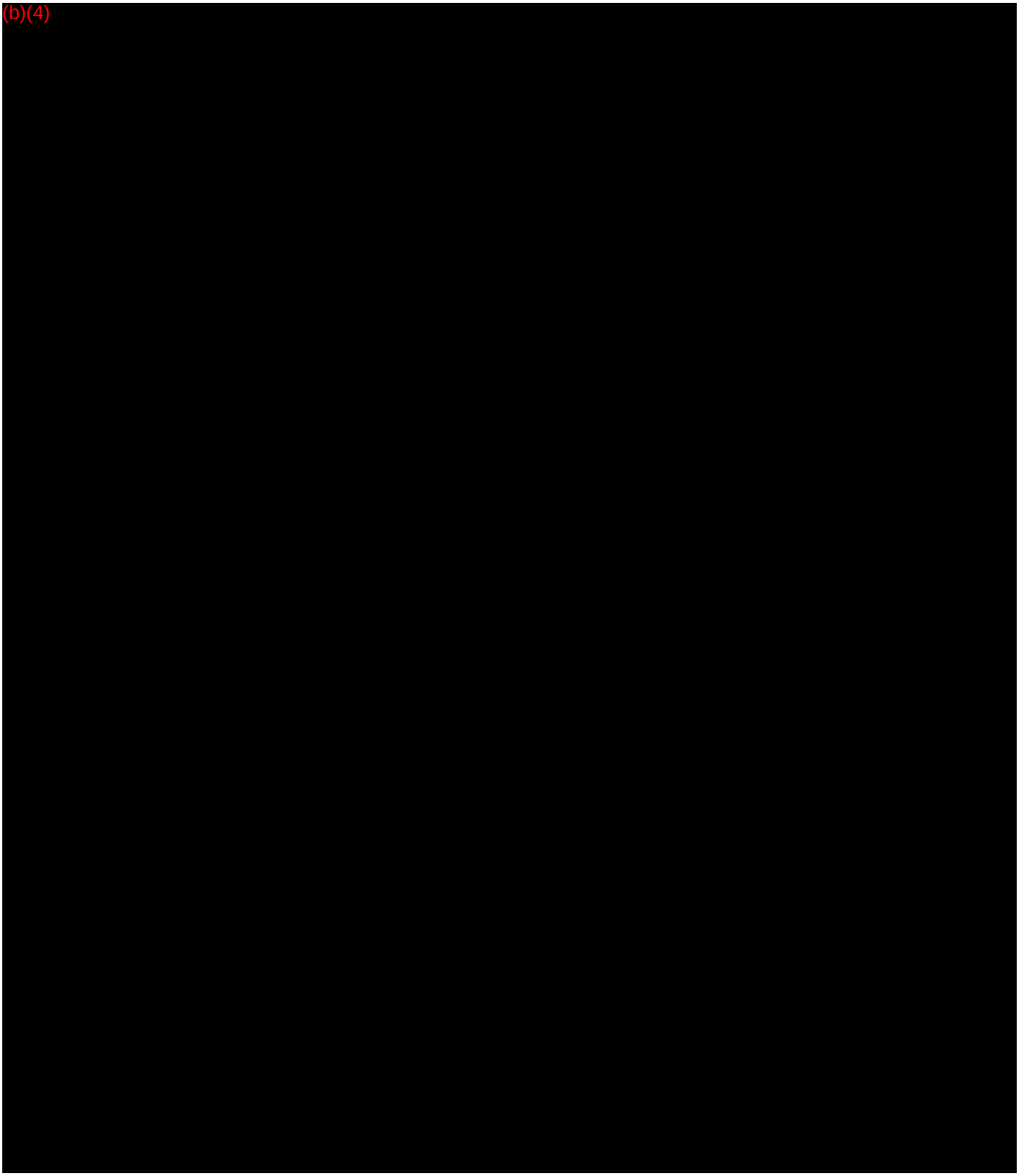

In conclusion, the Revolution system significantly reduces cone-beam artifacts for non-gated (b) (b)) acquisitions within the 160mm detector coverage.

Cone-Beam Artifacts in Gated (Half Scan) Reconstruction

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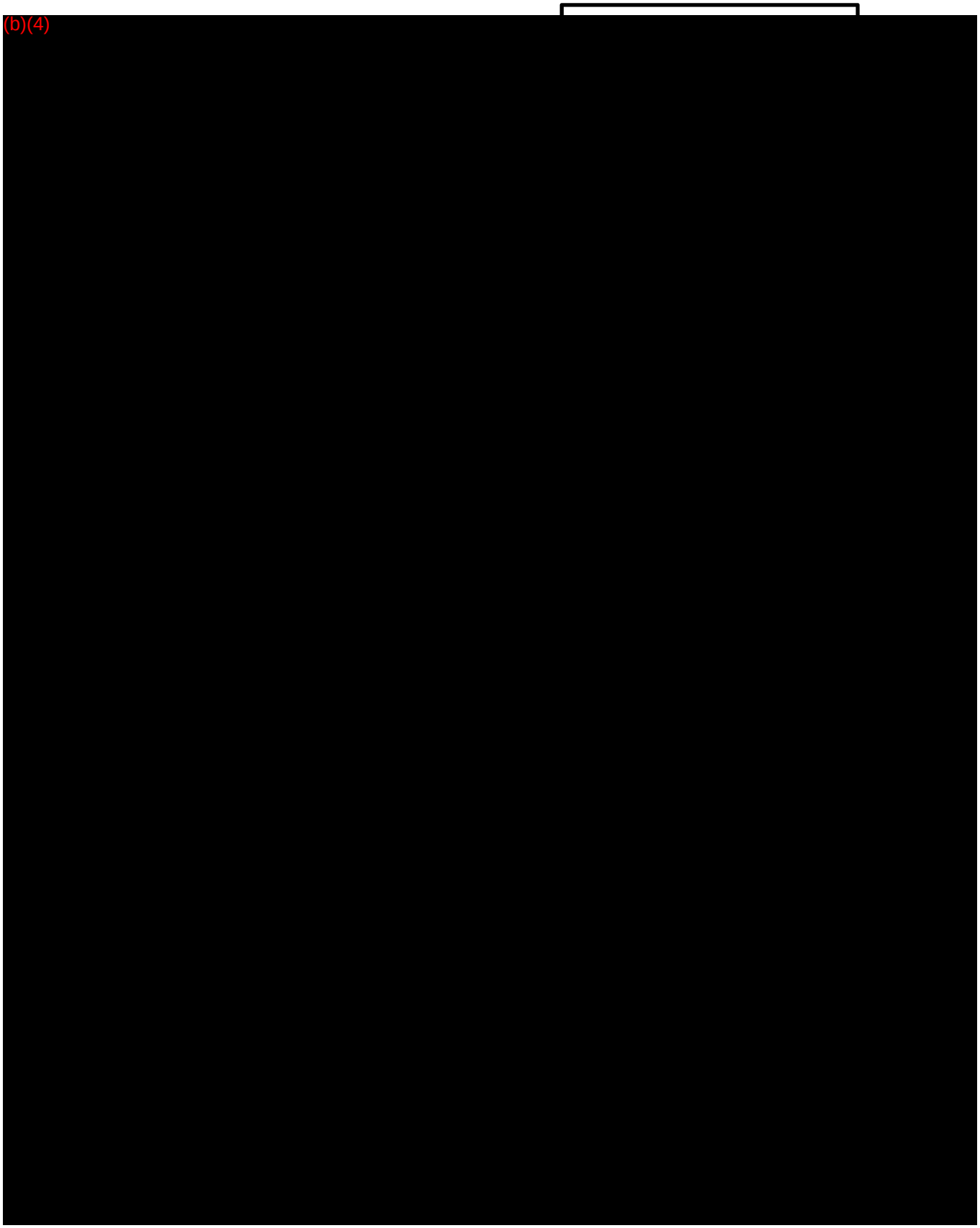

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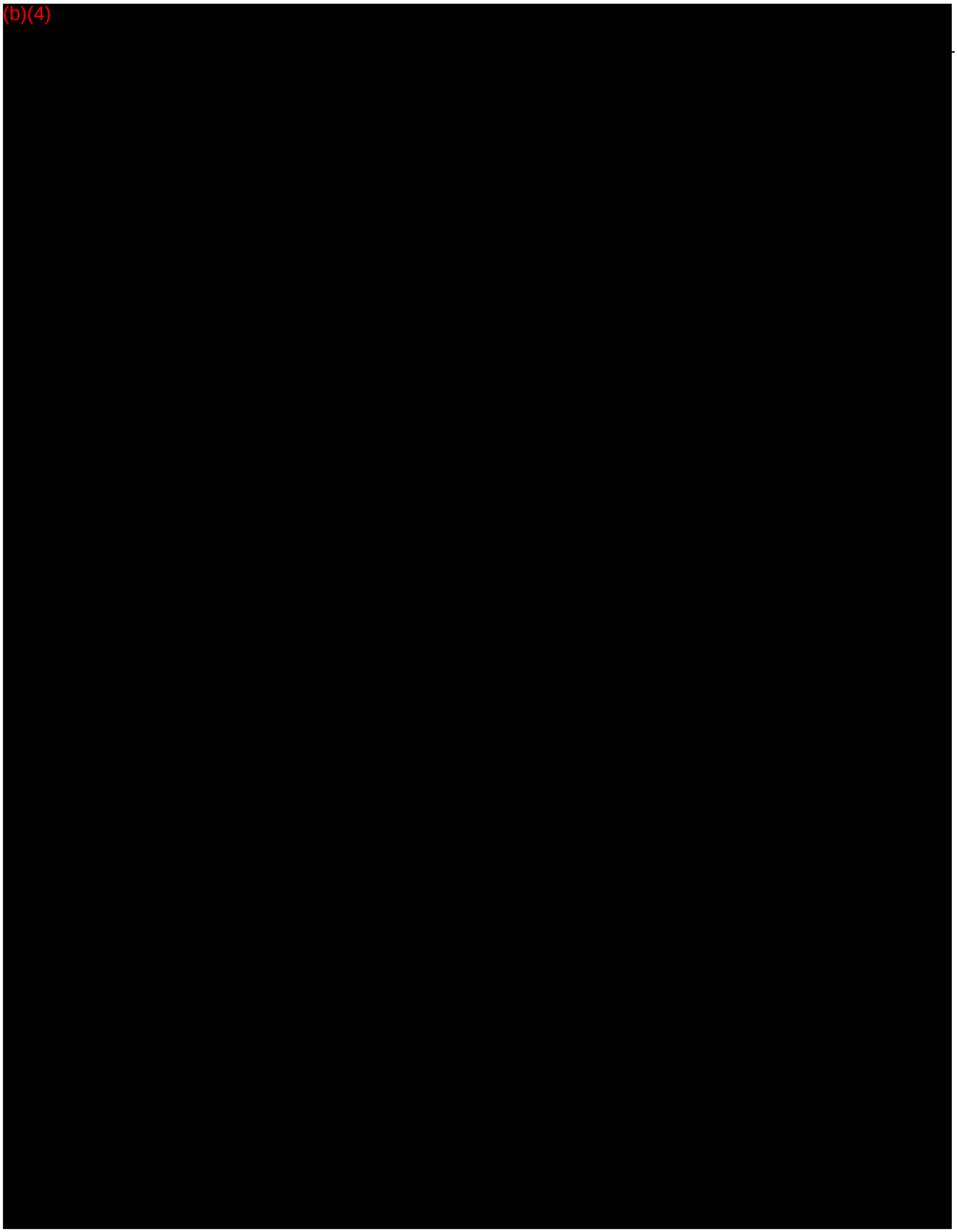

In conclusion, the Revolution system significantly reduces cone-beam artifacts for gated (b)(4) acquisitions within the 160mm detector coverage.

Quantitative Uniformity

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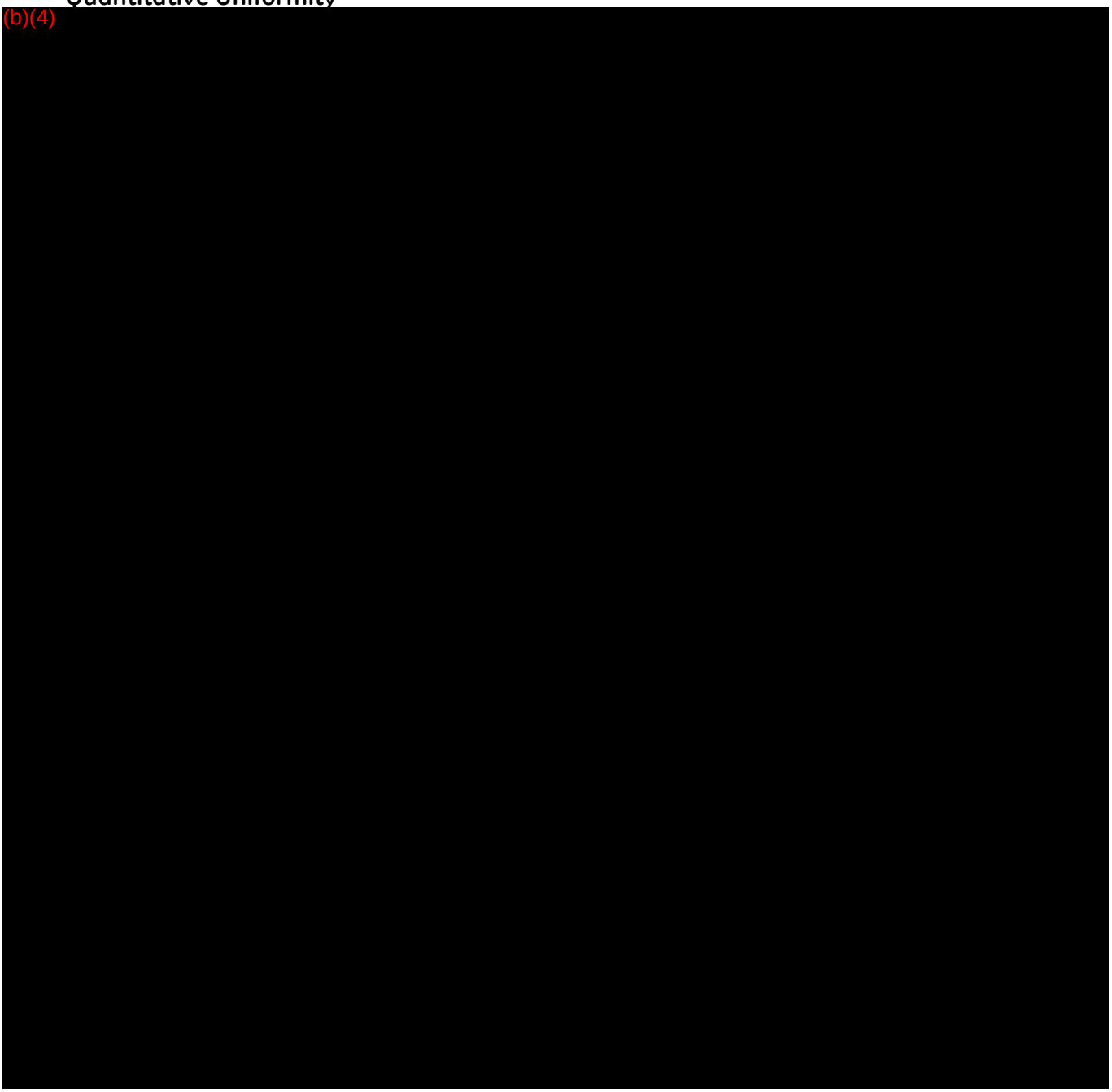
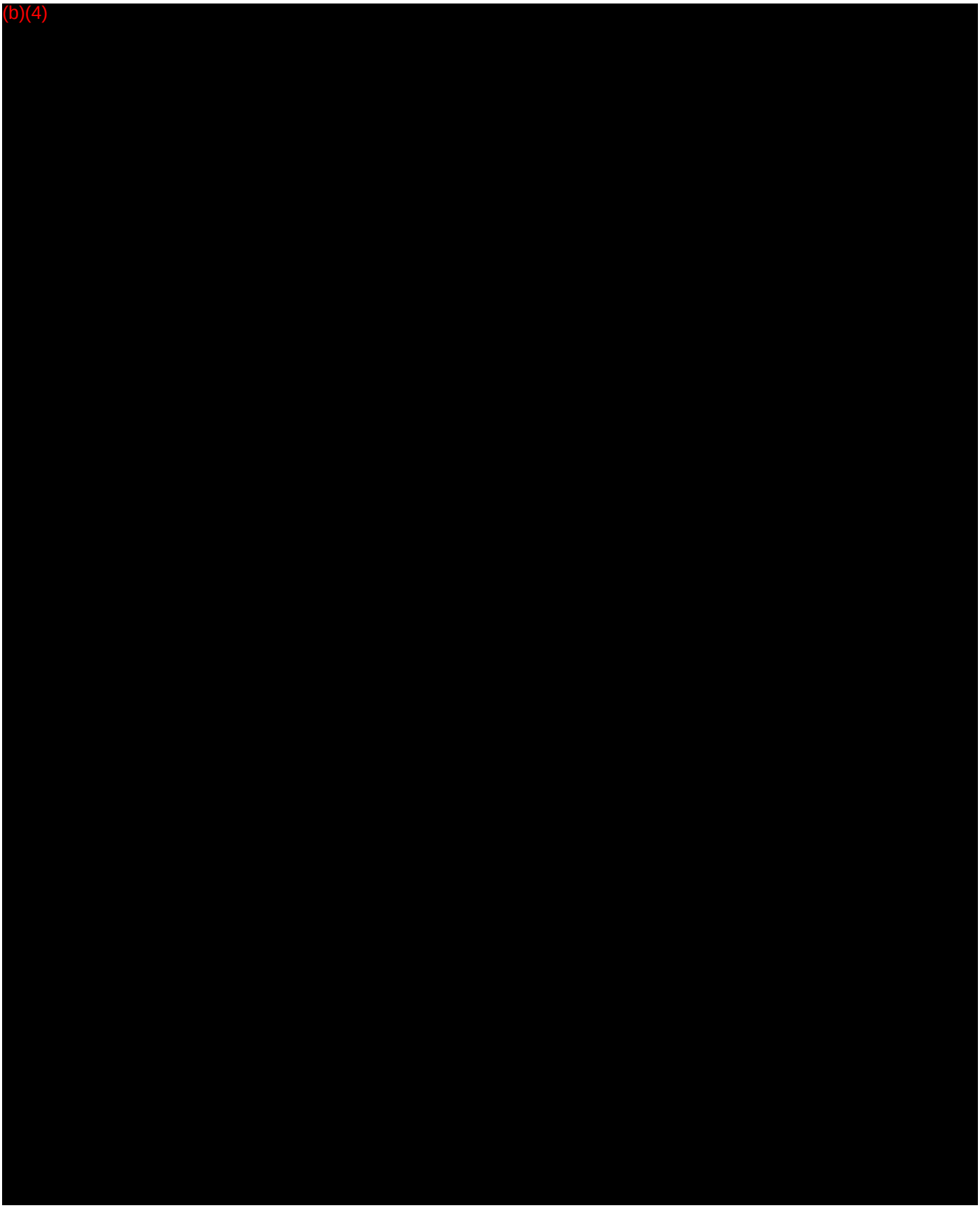


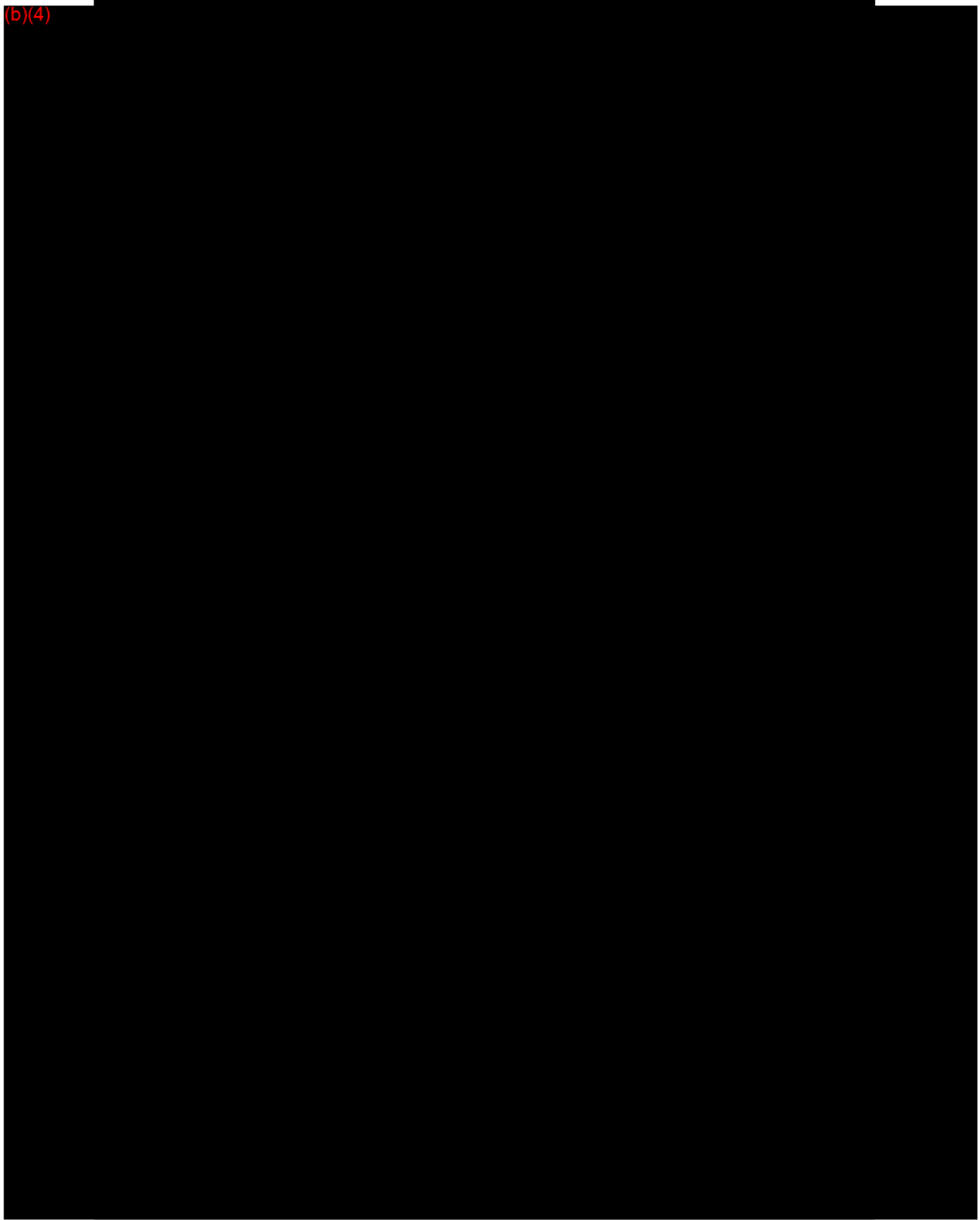
(b)(4)



(b)(4)

(b)(4)

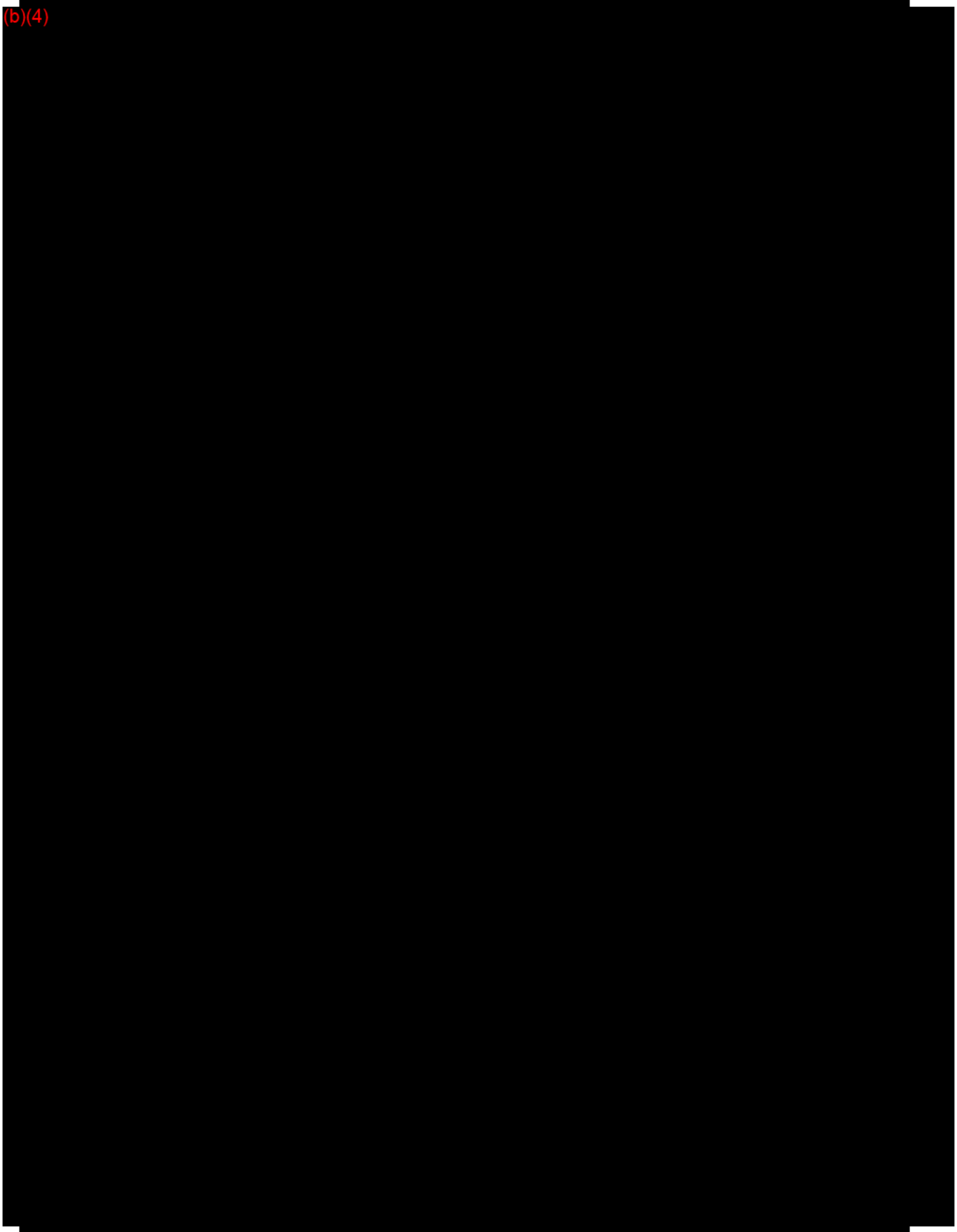
(b)(4)



MyWo
(b)(4)
Revisio

f 74

(b)(4)



(b)(4)

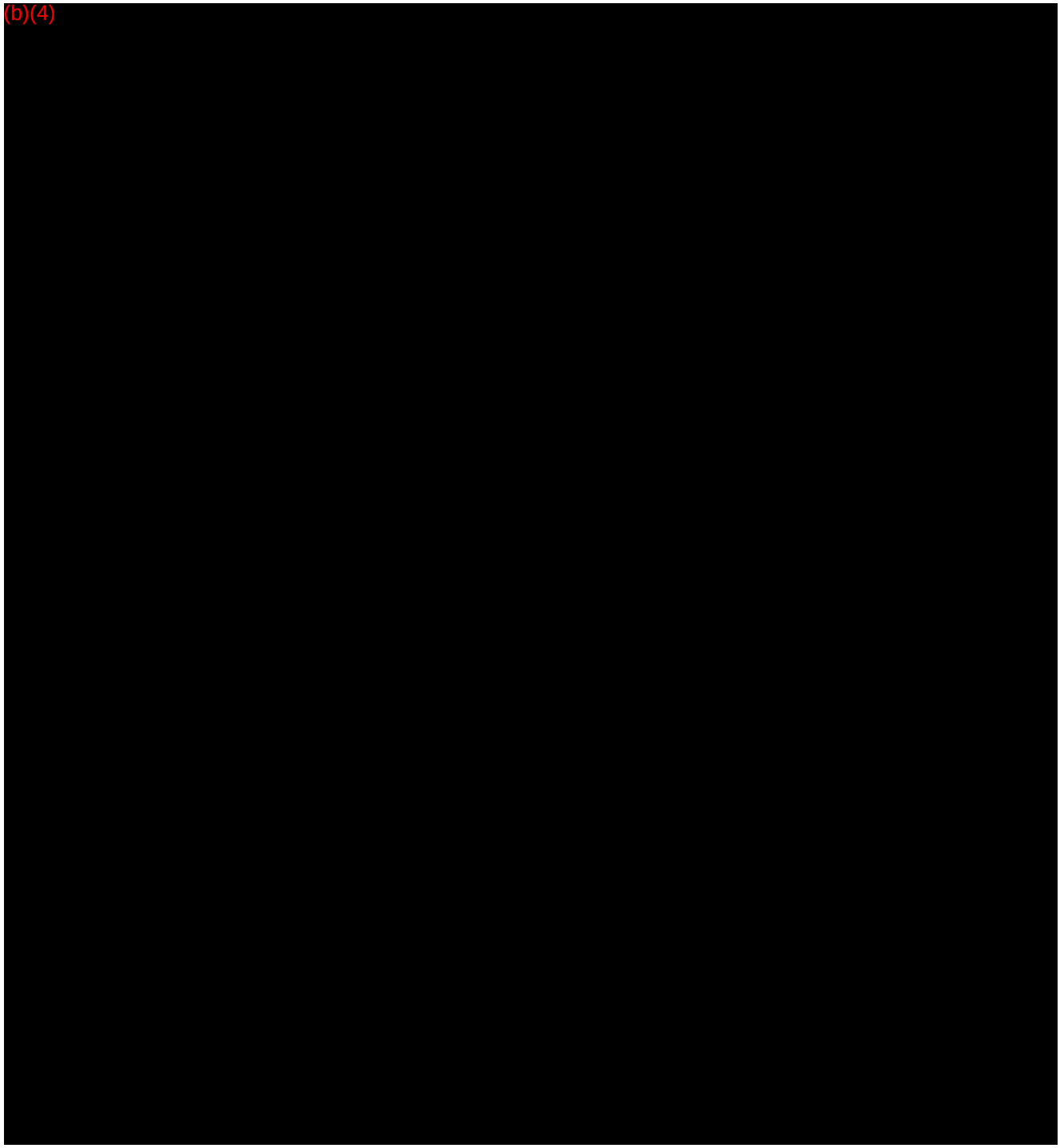
(b)(4)

[redacted]

In conclusion, the Revolution system provides native reduction of the X-ray scatter-to-primary ratio by (b)(4) across the imaging range.

Artifact Reduction

(b)(4)



(b)(4)

(b)(4)

(b)(4)

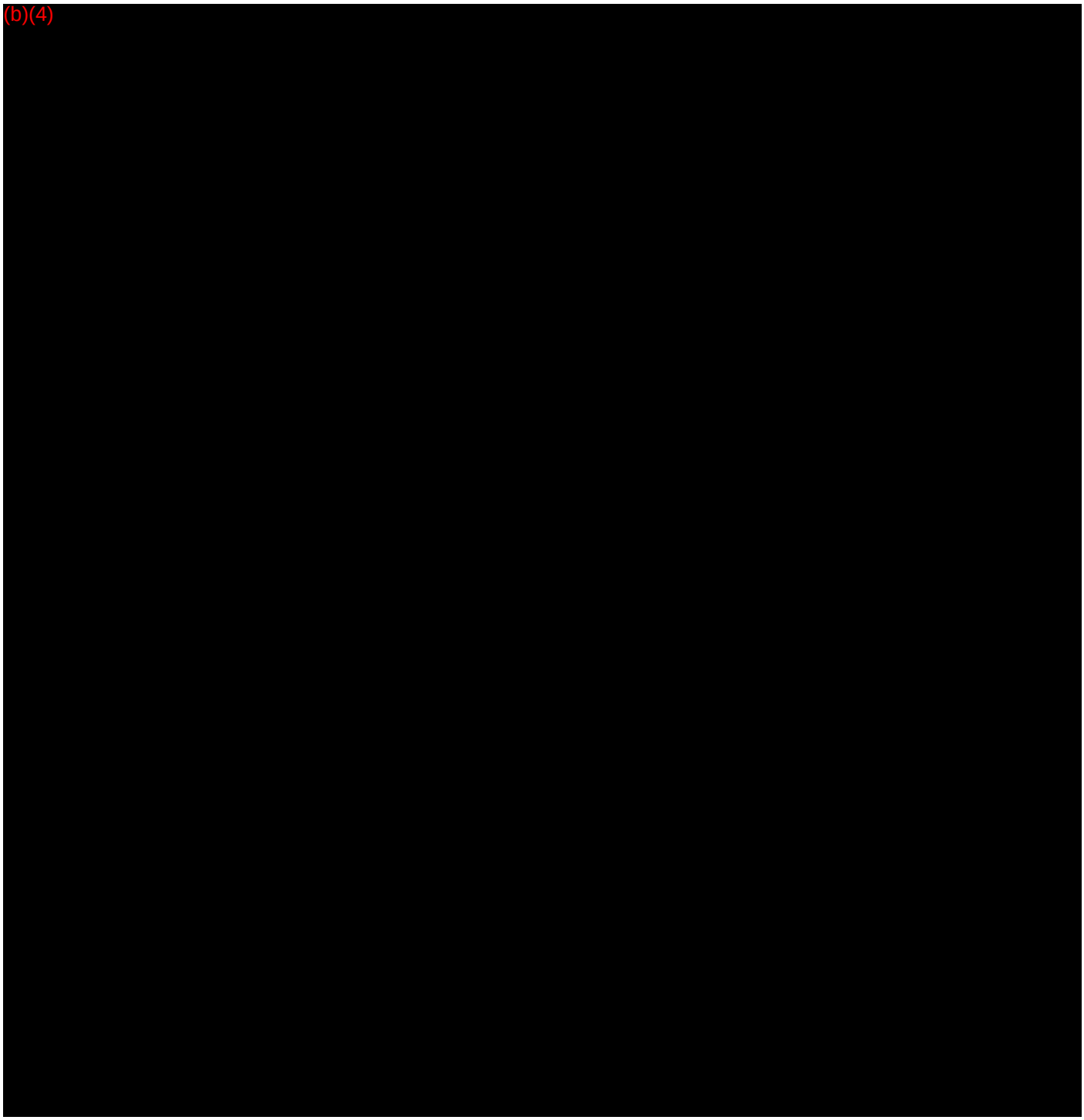
(b)(4)

(b)(4)

[redacted]

2.5.3 Performance item 5c: The Revolution system provides (b)(4) spatial resolution.

(b)(4)



(b)(4)

(b)(4)

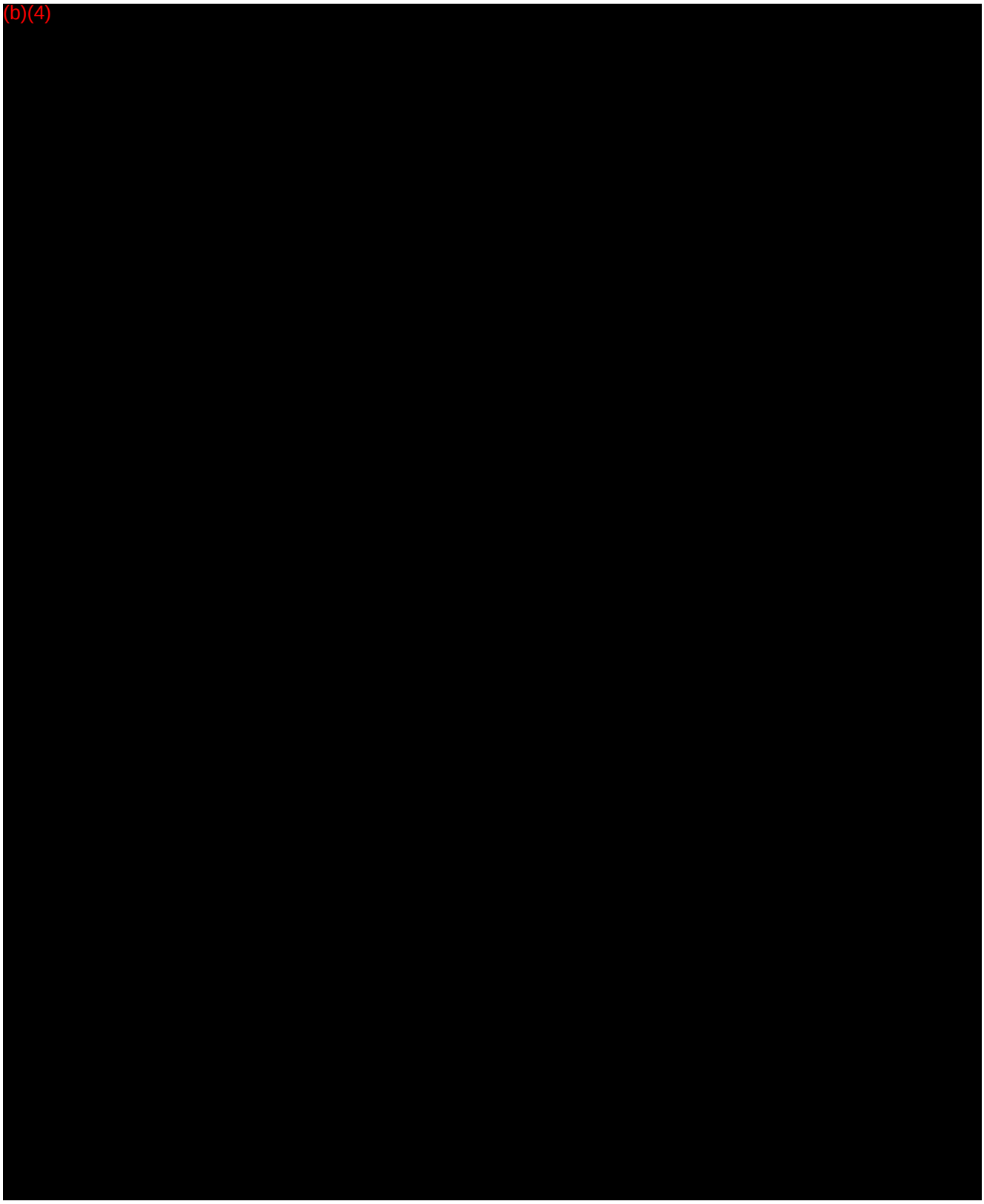
In conclusion, the Revolution scanner is capable of (b)(4) spatial resolution.

2.6 Platform Design:

2.6.1 Performance item 6a: The Revolution system has been designed and safety tested to rotate with speeds as fast as (b)(4) per rotation.

(b)(4)

(b)(4)



In conclusion, the Revolution system has been designed and safety tested to rotate with speeds as fast as (b)(4) per rotation.

2.6.2 Performance item 6b: The Revolution system includes detector acquisition electronics which allow (b) faster bandwidth and (b) faster trigger rate than previous generations, reduce electronic noise by (b)(4) and are (b)(4) dose efficient.

(b)(4)

Data Bandwidth

(b)(4)

In conclusion, the Revolution system includes detector acquisition electronics which allow (b) faster bandwidth than the Discovery CT750 HD scanner.

Trigger Rate

(b)(4)

In conclusion, the Revolution system includes detector acquisition electronics which allow (b) faster trigger rate than the Discovery CT750 HD scanner.

Electronic Noise

(b)(4)

In conclusion, the Revolution system includes detector acquisition electronics which can reduce electronic noise by (b) compared to the Discovery CT750 HD scanner.

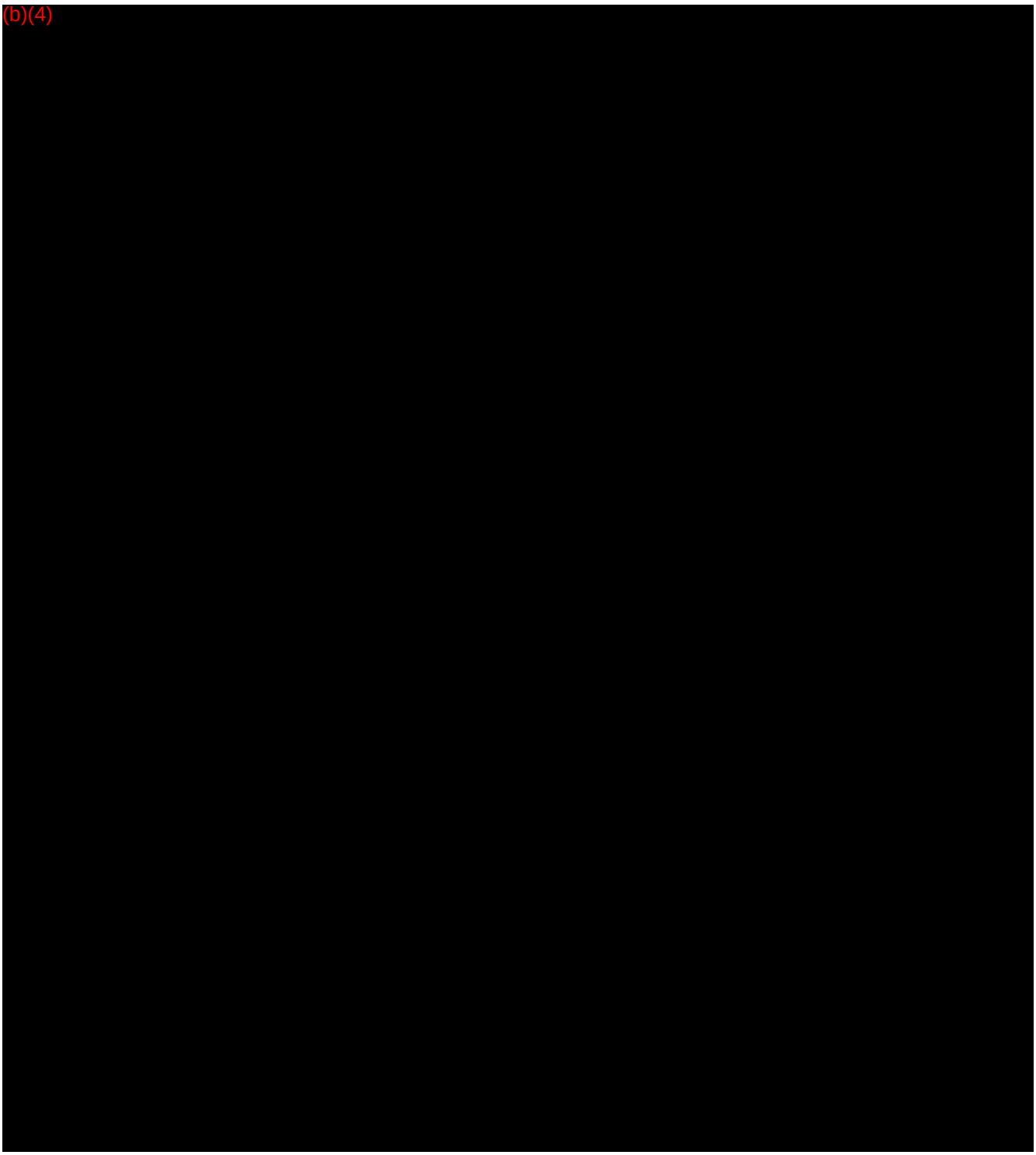
Dose Efficiency

(b)(4)

In conclusion, the Revolution system includes detector acquisition electronics which are (b)(4) dose efficient compared to the Discovery CT750 HD scanner.

[4] A larger projection measure (PM) is equivalent to higher attenuation, or a larger patient, by application of Beer's Law where PM = -ln(I / I_0) where I is the measured intensity and I_0 is the input flux.

References



(b)(4)

(b)(4)

Attachment B

Revolution System Verification and Simulated User Scenarios Testing Report

In the system verification report, each test set containing test cases traceable to system requirements and their final test status are presented. Tests were run in multiple rounds. (b)(4)

(b)(4)


Test Set
(b)(4)
(b)(4)

GE (b)(4) Design Verification and User Simulation Testing Report For Revolution VE Release

(b)(4)

(b)(4)

TABLE OF CONTENTS

1 Design Verification and Simulated User Testing Purpose and Scope

1.1 Purpose and Scope

(b)(4)

2 Traceability and Reference Documents

(b)(4)

◊ System Requirement Down trace Report DOC1317807 Rev 2

3 Sub-system Verification Results

(b)(4)

[redacted]

4 System Verification and (b)(4)

.

4.1 System Installation, Functionality, Performance and (b)(4)

(b)(4)

[redacted]

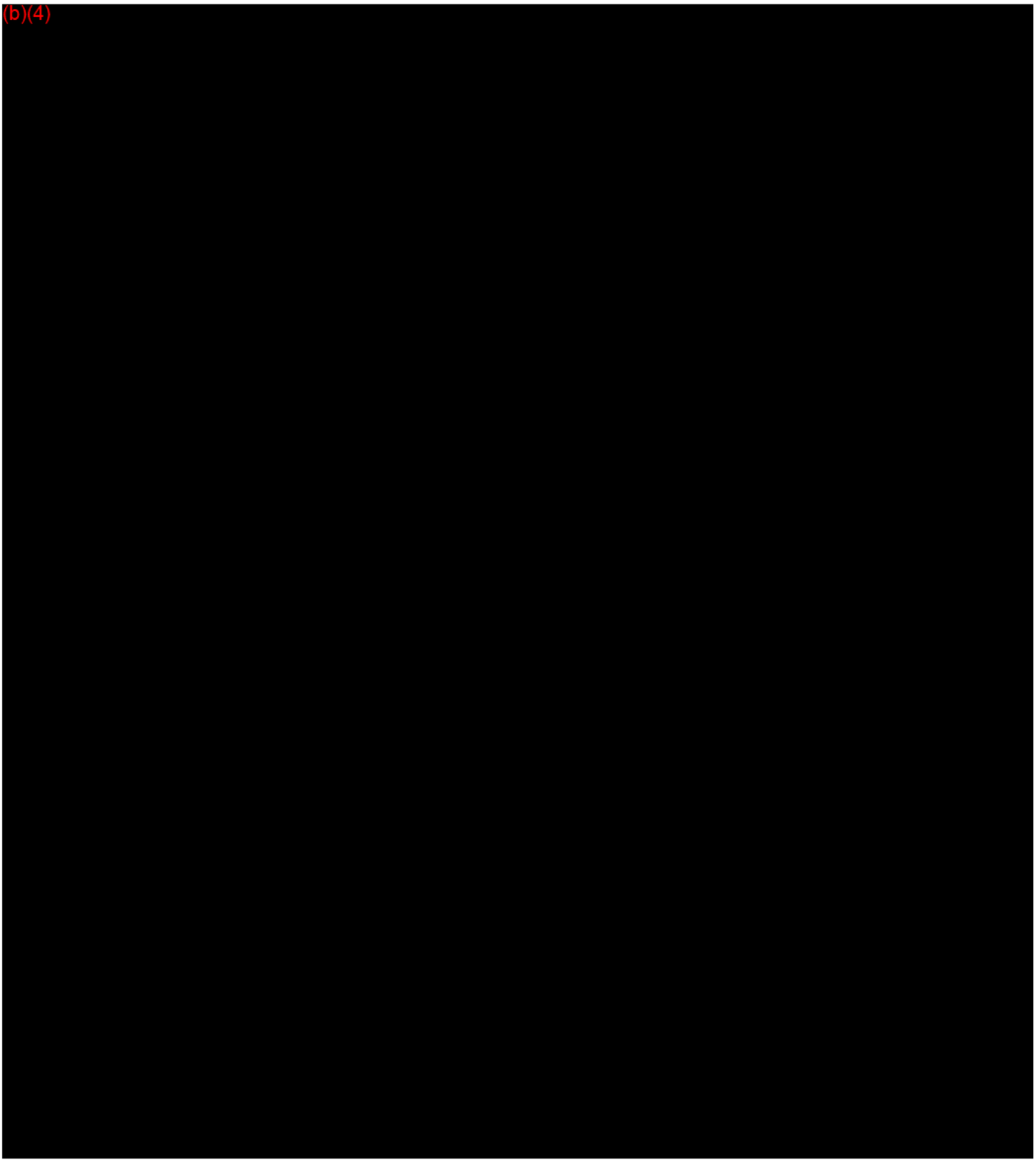
(b)(4)

4.1.3 Execution Summary

(b)(4)

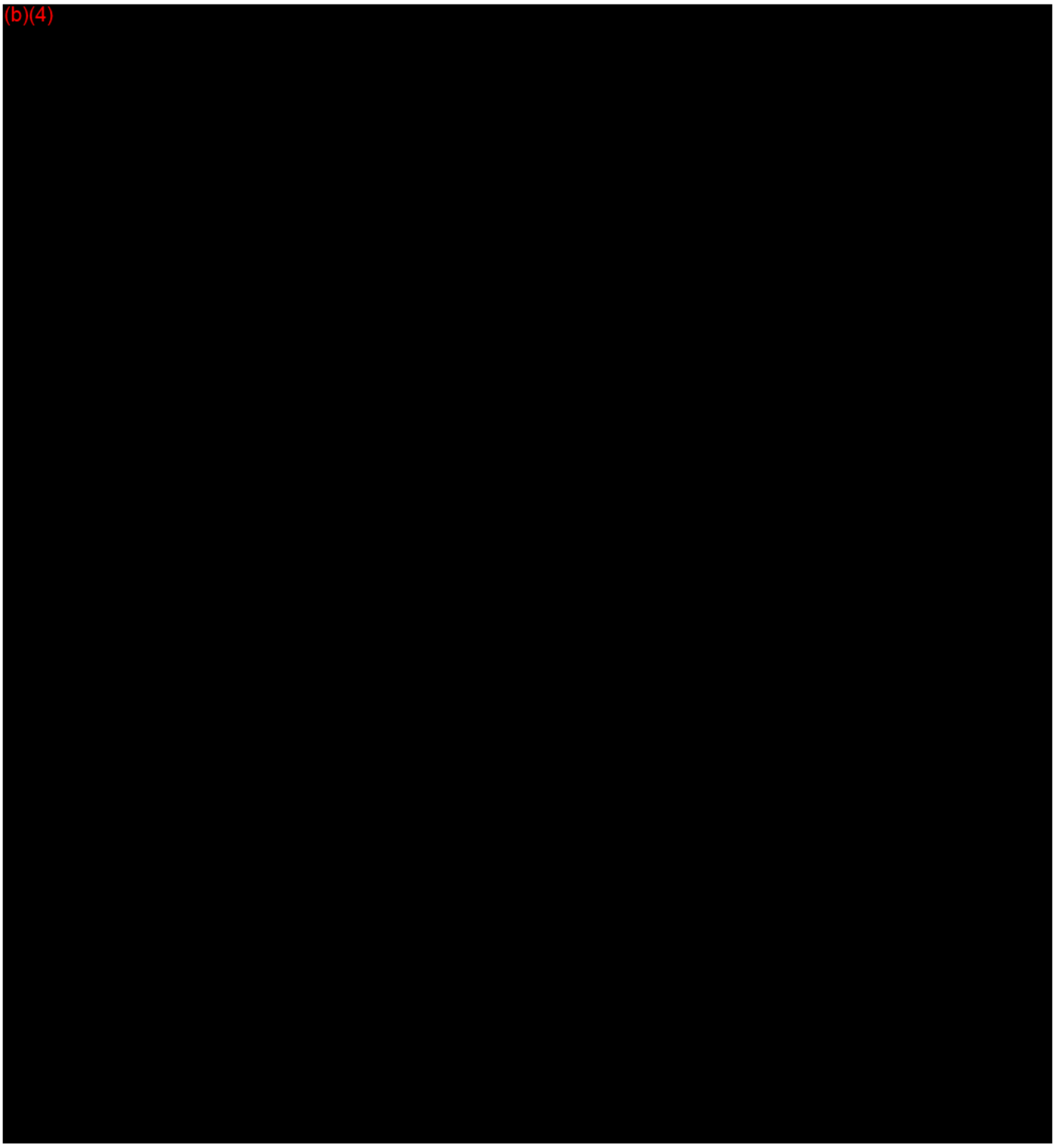
(b)(4)

(b)(4)



(b)(4)

(b)(4)



(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

4.2 Summary and Conclusion

All sub-system testing has been completed in accordance with the Software Verification Plan and the individual sub-system verification plan/steering guides.

All system testing has been completed in accordance with the GE(b)(4) Design Verification and Simulated User Testing Plan.

The(b)(4) Revolution product(b) meets the design input requirements allocated to the(b) release. The(b)(4) Revolution product(b) is safe and effective for the intended uses.

Section 19: Performance Testing - Animal

Revolution CT

This section is not applicable to this submission for the Revolution CT, the subject of this premarket submission because the Revolution CT system did not require animal studies and test results to support substantial equivalence.

Section 20: Performance Testing – Clinical

Revolution CT

Section 20: Performance Testing – Clinical

20.1 Introduction

This section contains the summary report of GE's clinical external evaluation of the Revolution CT **(Attachment 20B)**. This evaluation was intended to provide clinician feedback of the Revolution CT system and to generate sample clinical images for this 510k submittal. Given the prior clearances of similar CT devices, extensive global clinical use of CT scanning, and completed verification testing and engineering bench testing that have not raised new questions of safety or effectiveness s, the clinical evaluations performed were not formal clinical trials nor intended to answer safety and effectiveness questions relating to The Revolution CT.

Sample clinical data was collected from (b) subjects at one site: (b)(4) with the approval of appropriate ethics committee and in accordance with 21 CFR Parts 812, 50 and 56, as well as GE Healthcare's quality system's procedures for such evaluations.

These images were read by (b) board certified radiologists (see CV's in **Attachment D**) with expertise in different specialty areas. The images were categorized into the following types of scans:

- (b)(4)

Each image was read by (b) different and qualified radiologists who provided an assessment of diagnostic image quality and/or clinical acceptance for the particular clinical tasks

The full set of sample clinical images used for the assessment is being included in this submission in DICOM format in a flash drive that accompanies the paper copy submission. The DICOM files are placed under the "MISC FILES" folder per the FDA's eCopy Guidance. These DICOM images are only provided in the eCopy and not being provided in paper copy. An index of the images files is included in the Clinical Image Assessment Summary in **Attachment 20B.** These images were originally stored on (b) DVDs and that's why the image index references each image file location by DVD number. Per the FDA's eCopy guidance these image files in DVDs were compressed into the .zip files with each .zip file representing the original DVD data content.

Additionally the submission includes the Principal Investigator (b) (6) statement about the overall image quality which is being provided in **Attachment C,** as well as the CV's of all the radiologists who read the images in the evacuation which are being provided in **Attachment D.**

In conclusion, the image quality evaluation on sample clinical CT images demonstrated that diagnostic results were obtained in all cases. This sample data was representative of a wide range of anatomical coverage, patient indication, and serves to help demonstrate the performance of the Revolution CT for patient imaging.

Attachment A

FDA Form 3674

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Helen Peng

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
11/20/2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
3000N, Grandview Blvd, W1140, Waukesha, WI 53188

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 262 548 5091
(Fax) 262-364-2506

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Computed Tomography X-ray System

JAK Radiology (#90)

Class II Product

Revolution CT

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
(b) (6) Sign

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) (b) (6)
(Title) Clinical Affairs Project Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
3000 N Grandview BLVD, W427
Waukesha, WI 53188

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (b) (6)
(Fax) N/A

15. DATE OF CERTIFICATION
11/12/2013

Form FDA 3674 (3/12) (FRONT)

PSC Publishing Services (301) 443-6740 EF

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. **& 4.** - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. **& 14.** - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

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Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

Form FDA 3674 (3/12) (BACK)

Attachment B

Revolution CT Clinical Image Assessment Report

Revolution CT Clinical Image Assessment Summary Report

(b)(4) -RPT

CONTENTS

1 SCOPE

This document serves to summarize the results of an image quality evaluation of sample clinical CT images obtained on the GE Healthcare Revolution CT scanner. Clinical CT data was collected under the study protocol (b)(4) entitled "Clinical Evaluation for GE Revolution CT System" hereafter referred to as *Protocol*.

2 OVERVIEW

Sample clinical data (raw CT scan data and demographic data) were collected using the Revolution CT system under Ethics Committee approval and with Informed Consent at (b)(4) The system was placed at the Site under a non-significant risk IDE.

The subject population included those (b)(4) There were no inclusion or exclusion criteria requiring that the subject had specific pathology. The intent of the protocol was to obtain a sample set of clinical images across different patient populations, clinical scenarios, and scanning protocols/techniques. Patients were selected for potential recruitment to meet these needs. Any patient who met these criteria stated in the Protocol and who voluntarily signed the Informed Consent Form was recruited.

The Principal Investigator (PI) was responsible for patient selection and patient recruitment at the Site.

The raw CT scan data from these subjects were used by GE to create images. (b)(4) However, the images were evaluated by multiple readers for clinical acceptance and image quality. Each image set was reviewed by (b) readers who are qualified radiologists at different institutions in the United States of America.

3 RECRUITMENT SUMMARY

Data from (b) subjects were collected and considered for this image evaluation. The following table shows the gender distribution of the subjects recruited for this image assessment.

Table 1 - Summary of gender for subjects whose images were used in the evaluation

(b)(4)

As shown in *Table 2*, the mean age of the subjects was (b) years and the minimum and maximum ages were (b) and (b) years respectively.

Table 2 - Summary of ages for subjects whose images were used in the evaluation

(b)(4)

There were (b) subjects scanned using cardiac protocols, (b) subjects scanned using body (including extremity) protocols, and (b) subjects scanned using neuro protocols.

4 ASSESSMENT SUMMARY AND RESULTS

Each image set was reviewed by (b) readers who are qualified radiologists at different institutions in the United States of America. The readers evaluated images relevant to their expertise and experience (b)(4), and were blinded to results of the evaluations by the other readers.

(b)(4)

Each reader was a provided a "Task List" to complete. A Task was defined by:

- An Evaluation Target (b)(4)
- The relevant image set to evaluate, identified by subject ID, exam number(s), and series number(s)
- The Case Report Form (CRF) to complete.

(b)(4)

Case Report Forms were labeled Form A through Form H, and each contained different questions depending on the Evaluation Target relevant to that form.

(b)(4)

(b)(4)

In the subsections below, the results of the image quality evaluation are described. These results are organized according to the protocol category: (b)(4).

(b)(4)

4.1 (b)(4)

The BMI for the subjects scanned with cardiac protocols, and the radiation dose associated with those scans, are shown in *Figure 1*.

Figure 1 - Cardiac CT Dose and Subject BMI

(b)(4)

The results within each of these clinical Evaluation Targets are summarized below.

4.1.1 (b)(4)

(b)(4)

(b)(4) quality was scored

The median score for each case along with the minimum and maximum score (when they differ from the median score) are shown below in *Figure 3*.

(b)(4)

Figure 4 - Median IQ scores for CCTA images vs. average heart rate

(b)(4)

(b)(4) t. The results are summarized below in *Table 5.*

(b)(4)

4.1.3 (b)(4)

(b) subjects had scans yielding data from multiple phases of the cardiac cycle. Images from these multiple phases were evaluated using (b)(4)

4.1.4 (b)(4)

(b) subjects had an exam which included a (b)(4) The readers were asked to evaluate the (b)(4) o assess whether they were (b)(4) diagnostic quality to assess (b)(4). In (b)(4) readers indicated that the images were (b)(4) diagnostic quality to assess coronary (b)(4)

4.1.5 (b)(4)

(b)(4) The readers were asked to evaluate the overall image quality using (b)(4)

(b)(4)

All (b)(4) readers gave an overall image quality rating of ((Excelling Image Quality).

b

4.1.6 (b)(4)

(b)(4) evaluated for purposes of (b)(4)
(b)(4)

Additionally, the readers were asked (b)(4) image quality (b)(4) for their (b)(4)

(b)(4) rated the overall image quality as ((Excellent Image Quality) and confirmed that the image quality was (b)(4) process.

4.2 (b)(4)

(b)(4) subjects obtained CT scans for (b)(4) The description of these cases and associated (b)(4) results are described below in sections 4.2.1 and 4.2.2.

4.2.1 (b)(4)

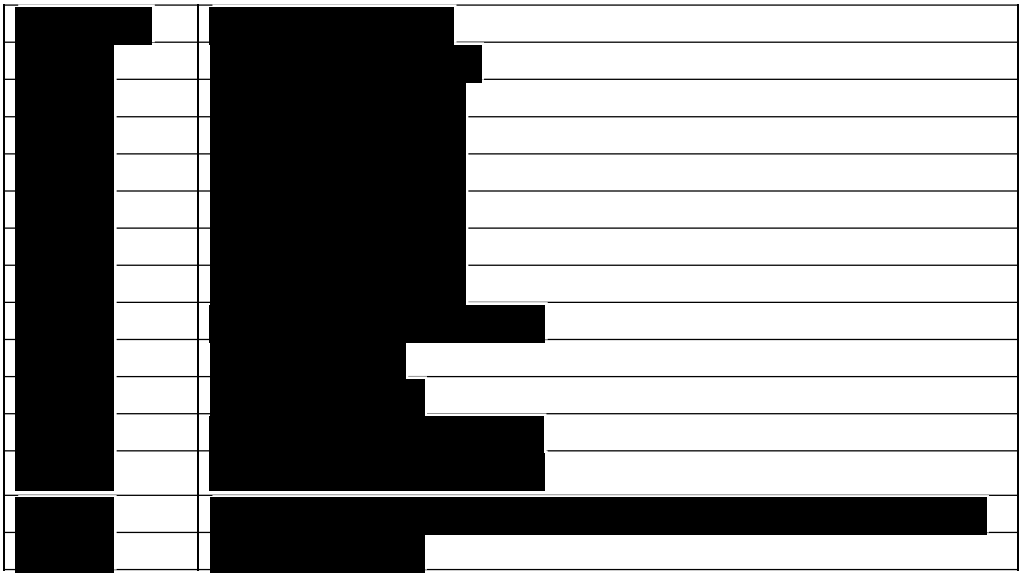
There were (b) subjects who underwent CT of the body. The (b) for the subjects imaged with body CT protocols, and the radiation dose associated with those protocols, are shown in *Figure 6*. DLP is plotted, which takes into account (b)(4) a subject received. (b)(4) demonstrates that the body CT data, and (b)(4) (b)(4), represent a diversity of clinical scenarios involving various subject sizes and radiation doses.

Figure 6 - (b)(4)

(b)(4) [redacted] The doses are within clinically appropriate ranges for these types of scans (with similar coverage and clinical target) and (b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]



[redacted]

[redacted]

The median score for each case along with the minimum and maximum score (when they differ from the median score) are shown below in *Figure 7*. (b)(4) [redacted]

Figure 7 - Overall IQ scores for general body images

These scores show that the body cases assessed in this evaluation all had diagnostic image quality, with every case receiving a [redacted] score indicating good or excellent image quality.

[redacted] to identify the body cases containing metal or other foreign objects [redacted] For these cases, the readers were asked, [redacted] to rate the appearance of metal artifact in the images from the Revolution CT system according to the following [redacted]

[redacted]

Figure 8 shows the distribution of scores across all readers for those cases in which metal or foreign objects were identified. [redacted]

Figure 8 - (b)(4)

4.2.2 (b)(4)

There were (b) subjects that were scanned with (b)(4). The radiation dose of these scans is shown in *Figure 9*.

DLP is plotted above, which takes into account [redacted] the complete set of scans a subject received. The doses are within clinically appropriate ranges for these types of scans (with similar coverage and clinical target) and [redacted]

The images from these [redacted] were assessed for overall image quality using [redacted]

[redacted]

The [redacted] score for each case along with the minimum and maximum score (when they differ from the median score) are shown below in *Figure 10*. [redacted]

Figure 10 - Overall IQ scores for [redacted]

These scores demonstrate that the [redacted] all had diagnostic image quality, with [redacted] receiving [redacted] scores indicating excellent image quality.

[redacted] identify which of the cases contained [redacted] For these cases, the readers were asked, [redacted] to rate the appearance of metal artifact in the images from the Revolution CT system [redacted]

[redacted]

Figure 11 shows the distribution of scores across all readers for those cases in which [redacted] were identified. [redacted]

Figure 11 - Histogram of (b)(4)

4.3 (b)(4)

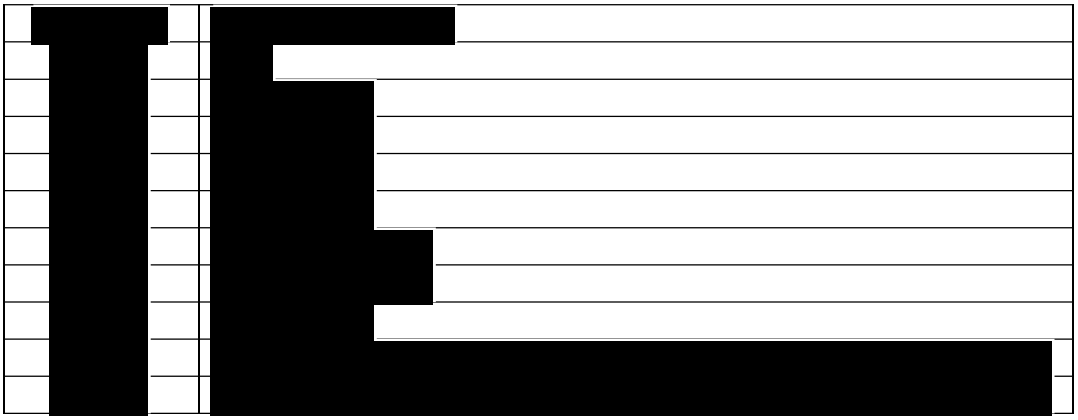
(b) subjects obtained CT scans for the (b)(4) (b)(4) The radiation dose (DLP) associated with the (b)(4) protocols used for this evaluation are shown in *Figure 12*.

Figure 12 - Plot of Neuro CT Exam DLP

DLP is plotted above, which takes into account [redacted] across the complete set of scans a subject received. The doses, including those for [redacted], are within clinically appropriate ranges for these types of scans (with similar coverage and clinical target) [redacted]

[redacted]

[redacted]



4.3.1 (b)(4)

There were (b)(4) sets which were assessed for (b)(4) (b)(4). Readers assessed these images using (b)(4) Overall image quality was scored (b)(4)

(b)(4)

The (b)(4) score for each case along with the minimum and maximum score (when they differ from the median score) are shown below in *Figure 13.* (b)(4)

(b)(4)

Figure 13 - Overall IQ scores for (b)(4)

These scores show that the (b)(4) cases assessed in this evaluation all had diagnostic image quality. Excellent image quality was indicated by the (b)(4) scores in (b)(4) cases.

(b)(4)

The (b)(4) score for each case along with the minimum and maximum score (when they differ from the median score) are shown below in *Figure 14.* (b)(4)

(b)(4)

Figure 14 – (b)(4)

The above chart demonstrates that the appearance of (b)(4) from the Revolution CT system (b)(4) or much better.

The readers were then asked to identify which of the cases contained (b)(4)

(b)(4) rate the appearance of (b)(4) the images from the Revolution CT system (b)(4)

(b)(4)

(b)(4)

Figure 15 - Histogram of (b)(4)

4.3.2 (b)(4)

(b) cases were assessed for (b)(4) using *Case Report Form* ***G***. (b)(4) (b)(4) generated using a commercially available software application (b)(4) The readers were asked if the information contained within the (b)(4) s was diagnostic. (b)(4)

(b)(4) .

4.3.3 (b)(4)

(b) cases were assessed for (b)(4) using *Case Report Form* ***H***. Readers (b)(4) images were (b)(4) or (b)(4) r assessment. In (b)(4)

The readers were then asked to identify which of the cases contained (b)(4) (b)(4) For these cases, the readers were asked, d (b)(4) (b)(4) to rate the appearance of (b)(4) in the images from the Revolution CT system (b)(4)

(b)(4)

5 IMAGES

All of the de-identified sample clinical CT images used for this image assessment are provided on electronic media in DICOM format for FDA review.

Table 8 – Catalogue of subject ID's and corresponding DVD media number(s)

(b)(4)

(b)(4)

(b)(4)

6 SUMMARY AND CONCLUSION

An image quality assessment was performed by (b)(4) on sample clinical CT images obtained from the Revolution CT scanner. (b)(4)

(b)(4) images were shown to have (b)(4) (b)(4) cases were all confirmed to have (b)(4) (b)(4) were (b) shown to have excellent image quality (b)(4)

(b)(4) cases were shown to have (b)(4)

All (b)(4)) were shown to have (b)(4) (b)(4) The appearance of (b)(4) was shown to be (b)(4) (b)(4) (b)(4) were acceptable for (b)(4) , and (b)(4) cases were (b)(4) e for (b)(4) .

The appearance of (b)(4) was shown to be (b)(4) (b)(4)

No (b)(4) were identified in any of the images. The sample data was representative of a broad range of clinical scenarios. Where relevant, these include (b)(4)

The results of this assessment demonstrate the performance of the GE Healthcare Revolution CT scanner for patient imaging.

Attachment C

Statement From (b) (6)

(b)(4)

[redacted]

October 2, 2013

GE Healthcare
3000 N. Grandview Blvd.
Waukesha, Wisconsin WI 53188

To Whom It May Concern:

I have reviewed a sample set of clinical CT images obtained on the GE Revolution CT system which features the 16cm detector and faster gantry rotation speed. These images were across various exam types that I believe are an adequate representation of overall clinical performance of this system. In my professional opinion, acceptable diagnostic results were obtained for all exams through an image quality assessment.

September 30th, 2013

(b)(4)

[redacted]

Attachment D

CVs of Radiologists

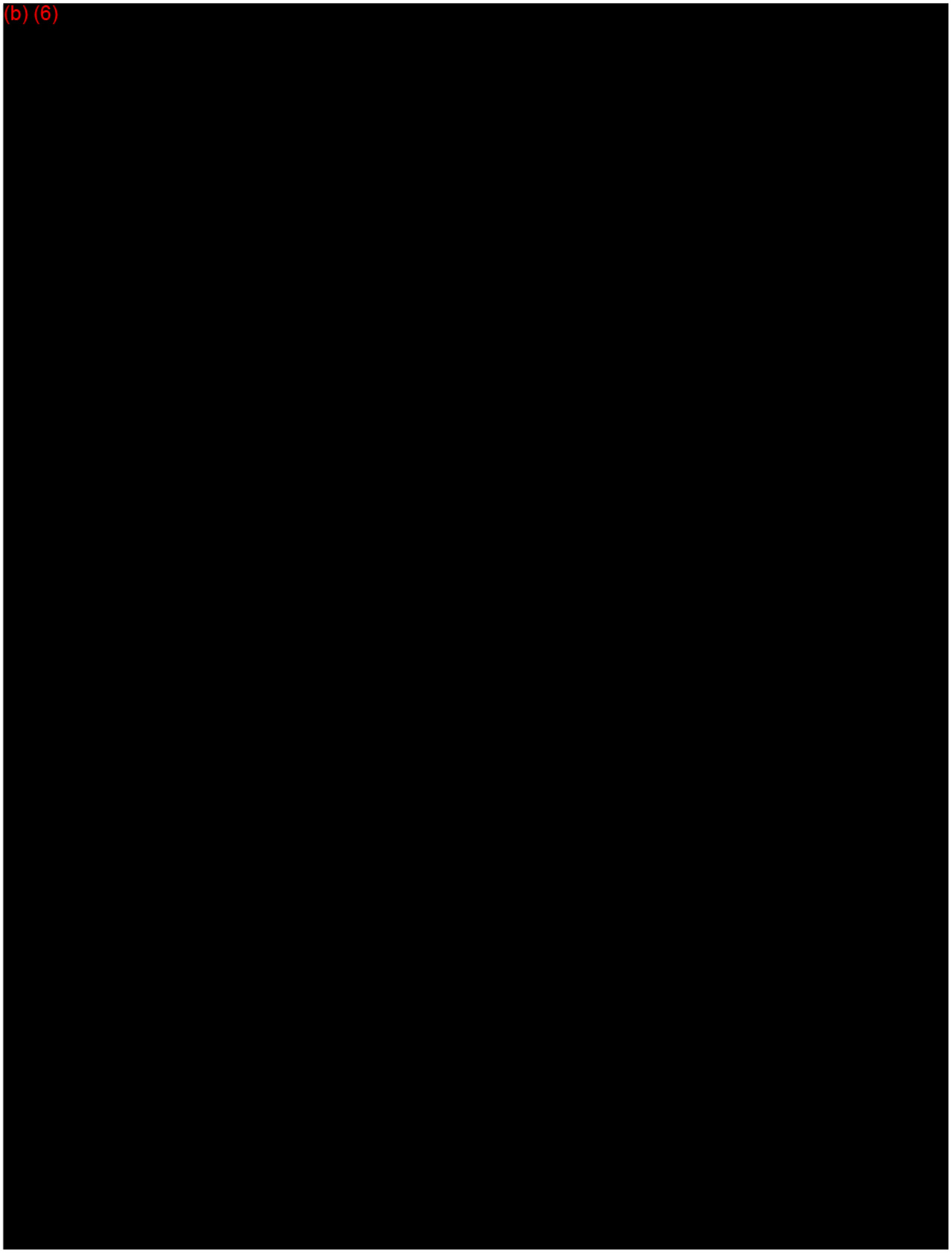
(b) (6) CV

Curriculum Vitae and Bibliography

(b) (6)

[redacted]

(b) (6)



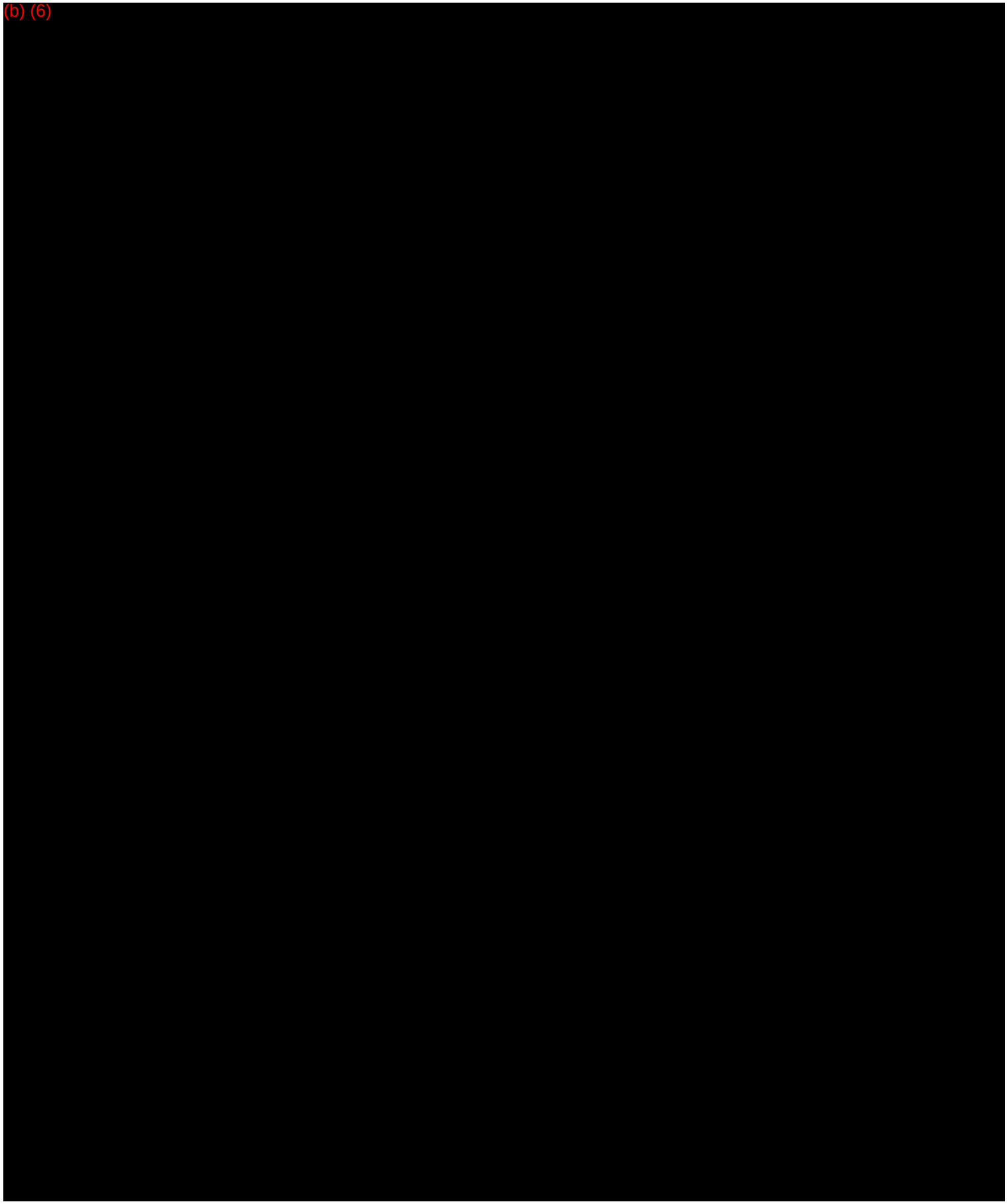
(b) (6) CV

(b) (6)

[redacted]

(b) (6)

(b) (6)



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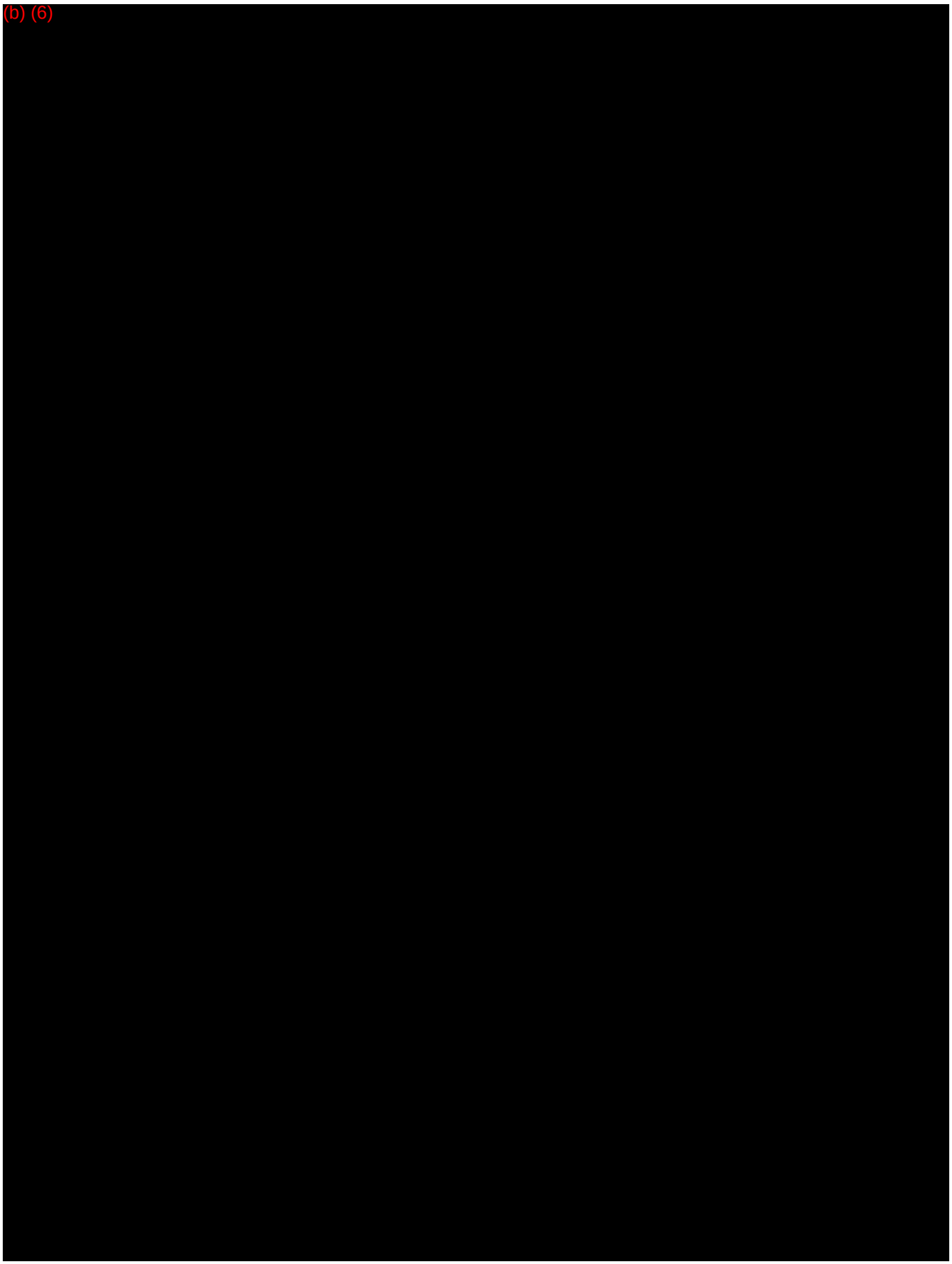

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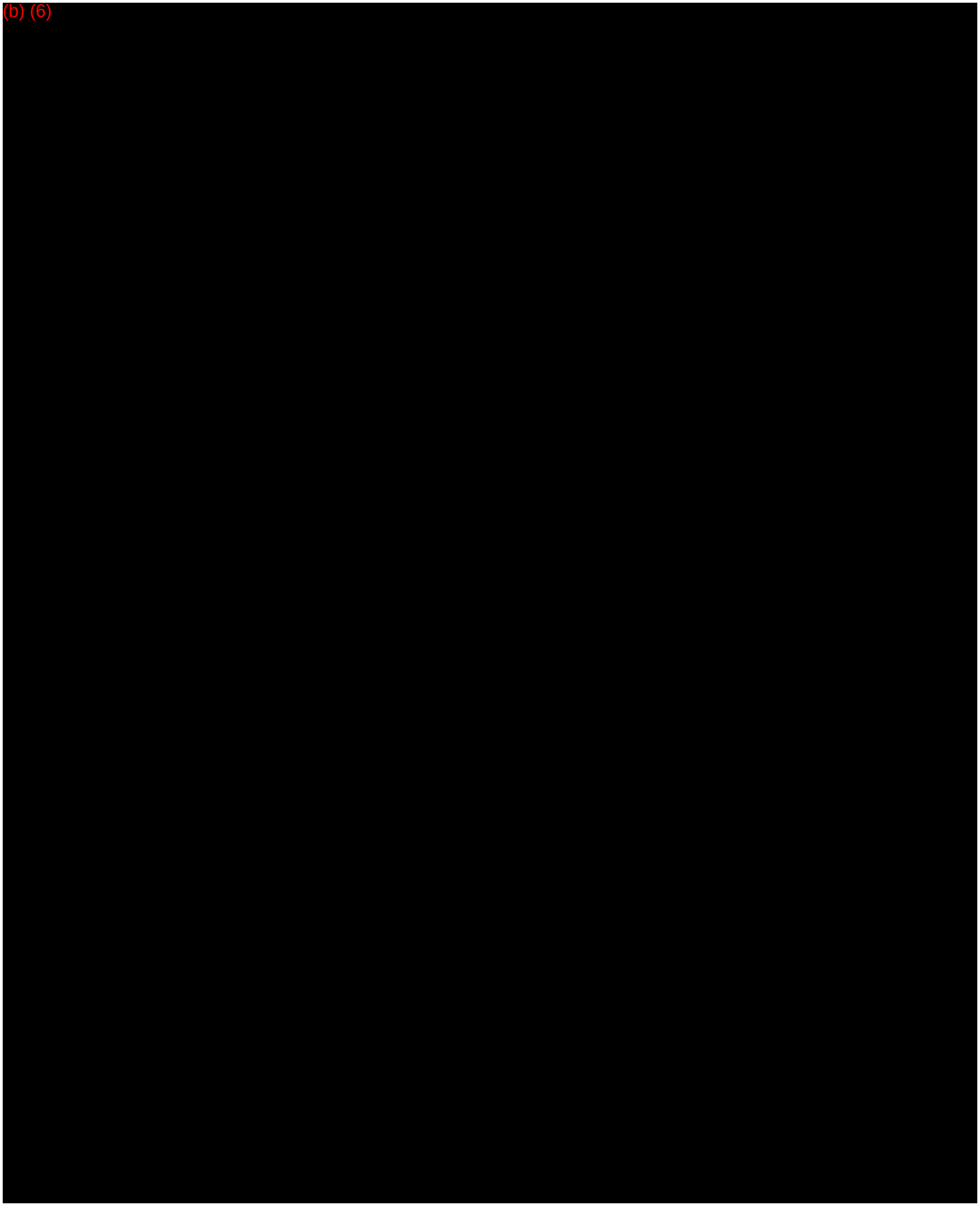

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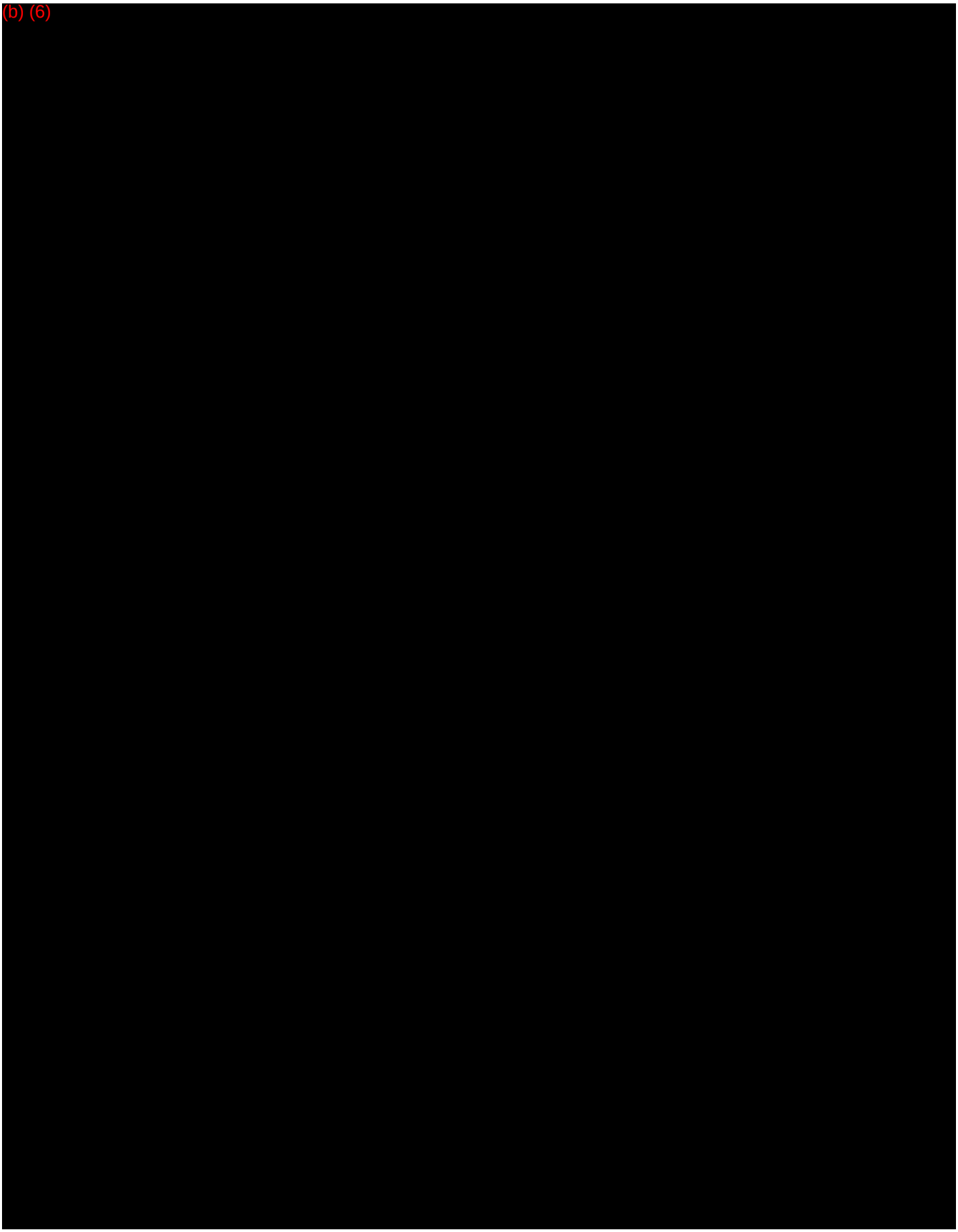

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(b) (6)

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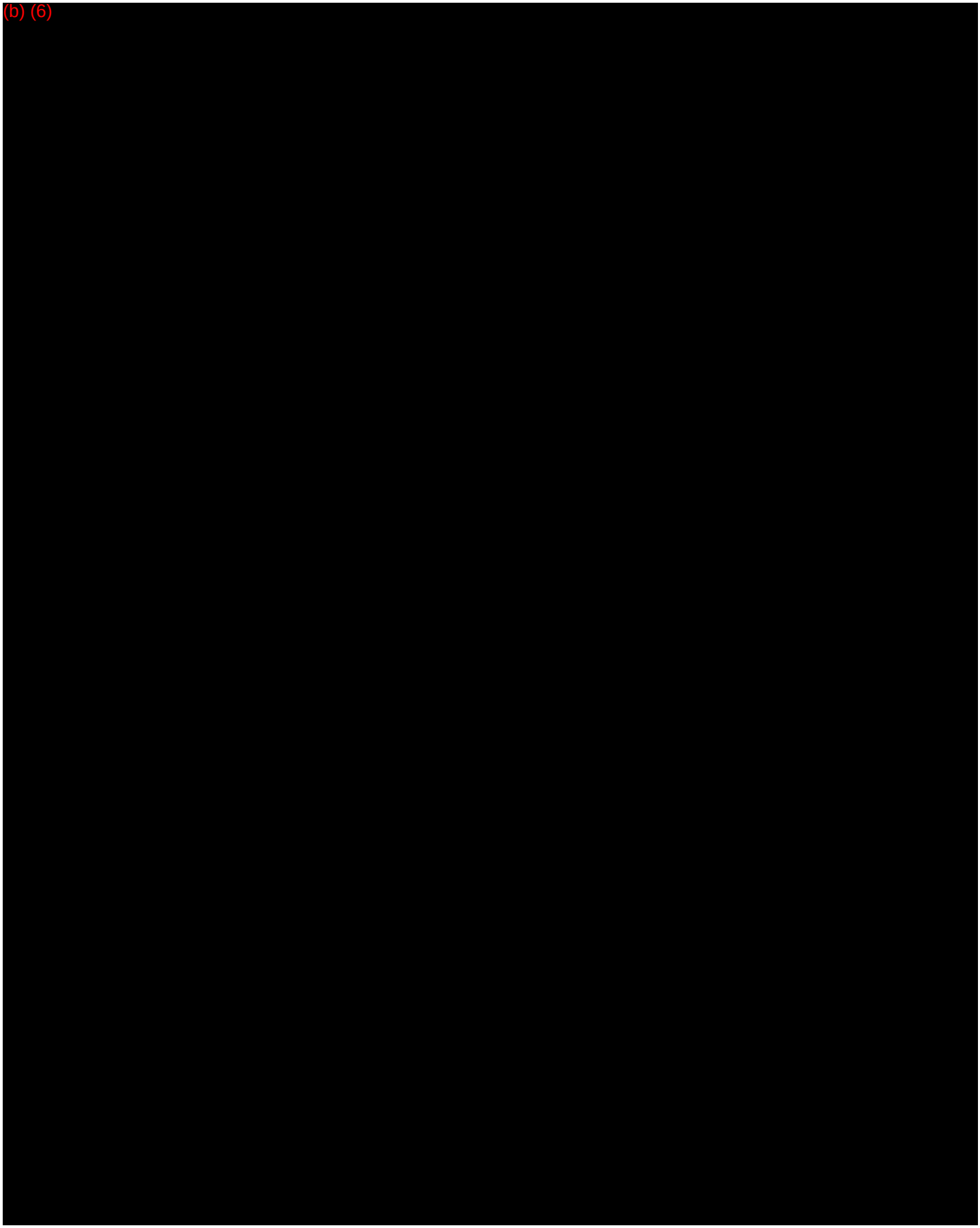

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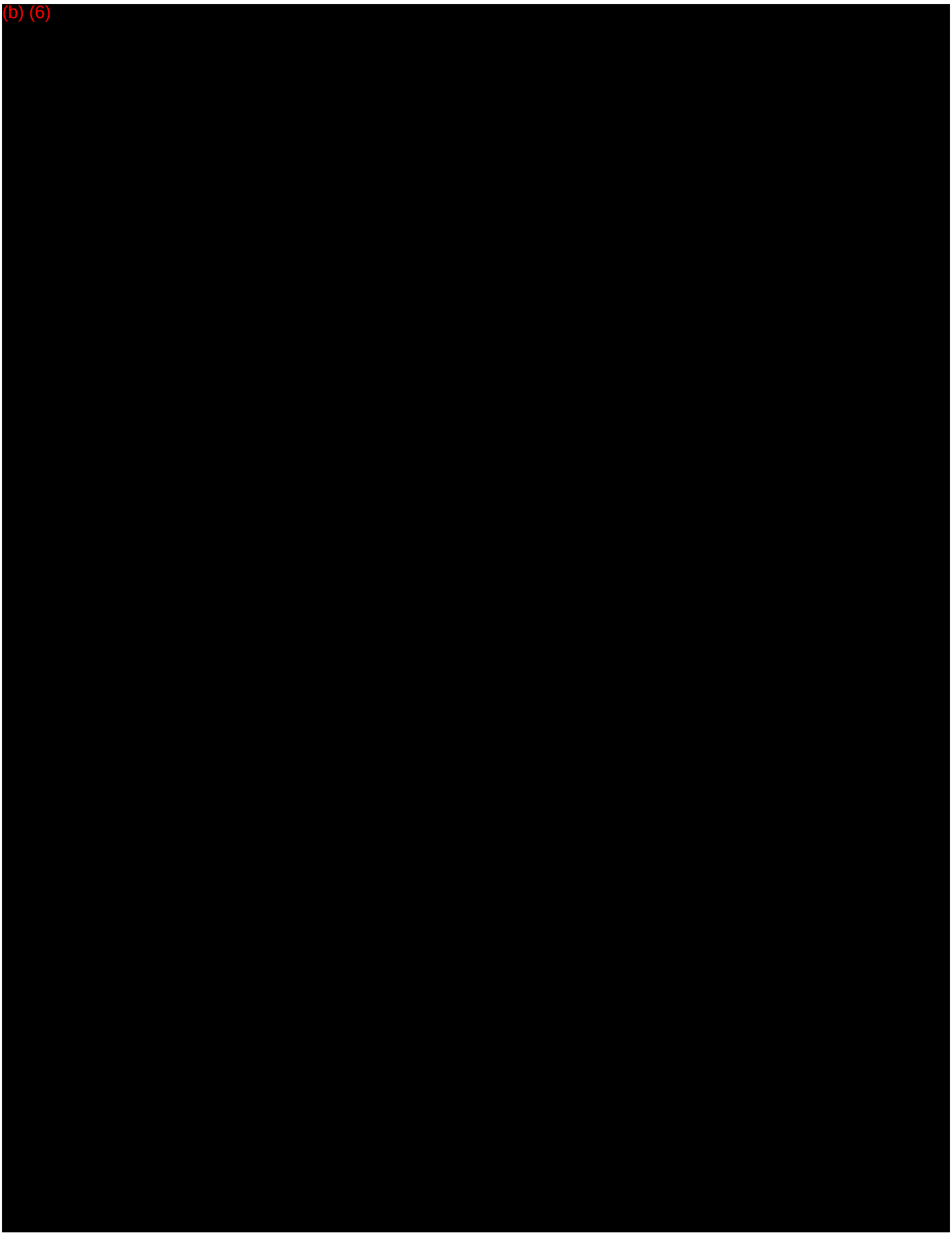

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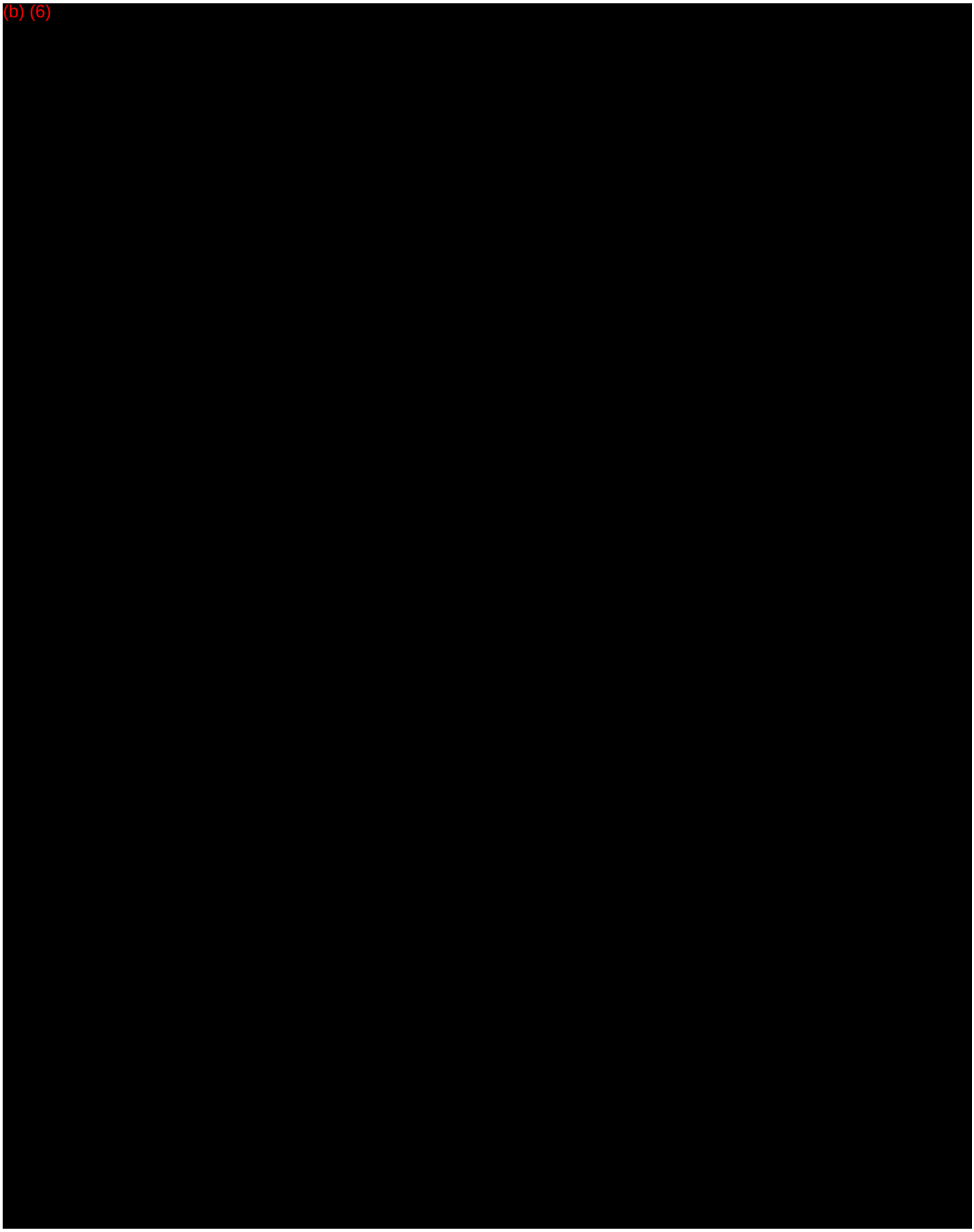

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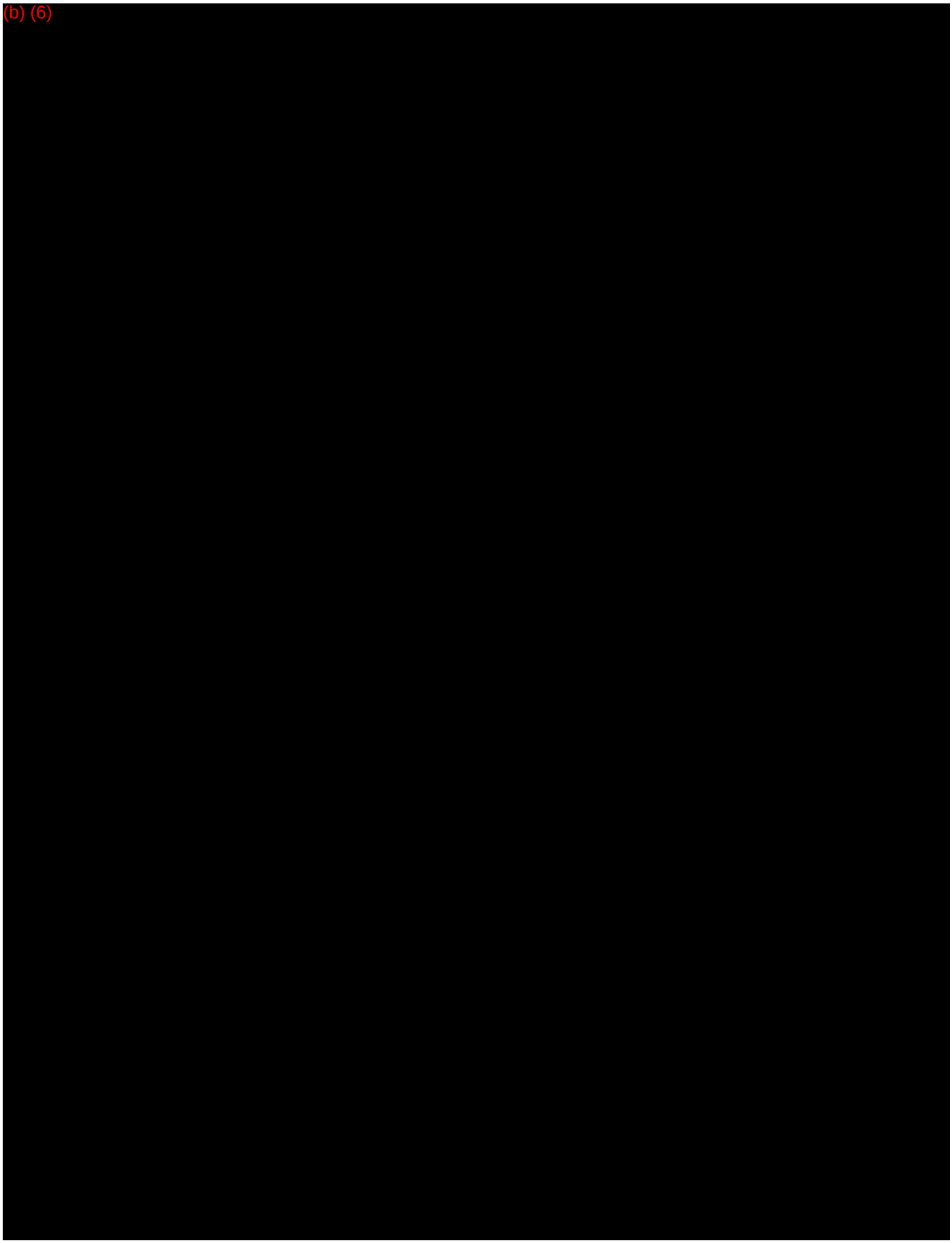

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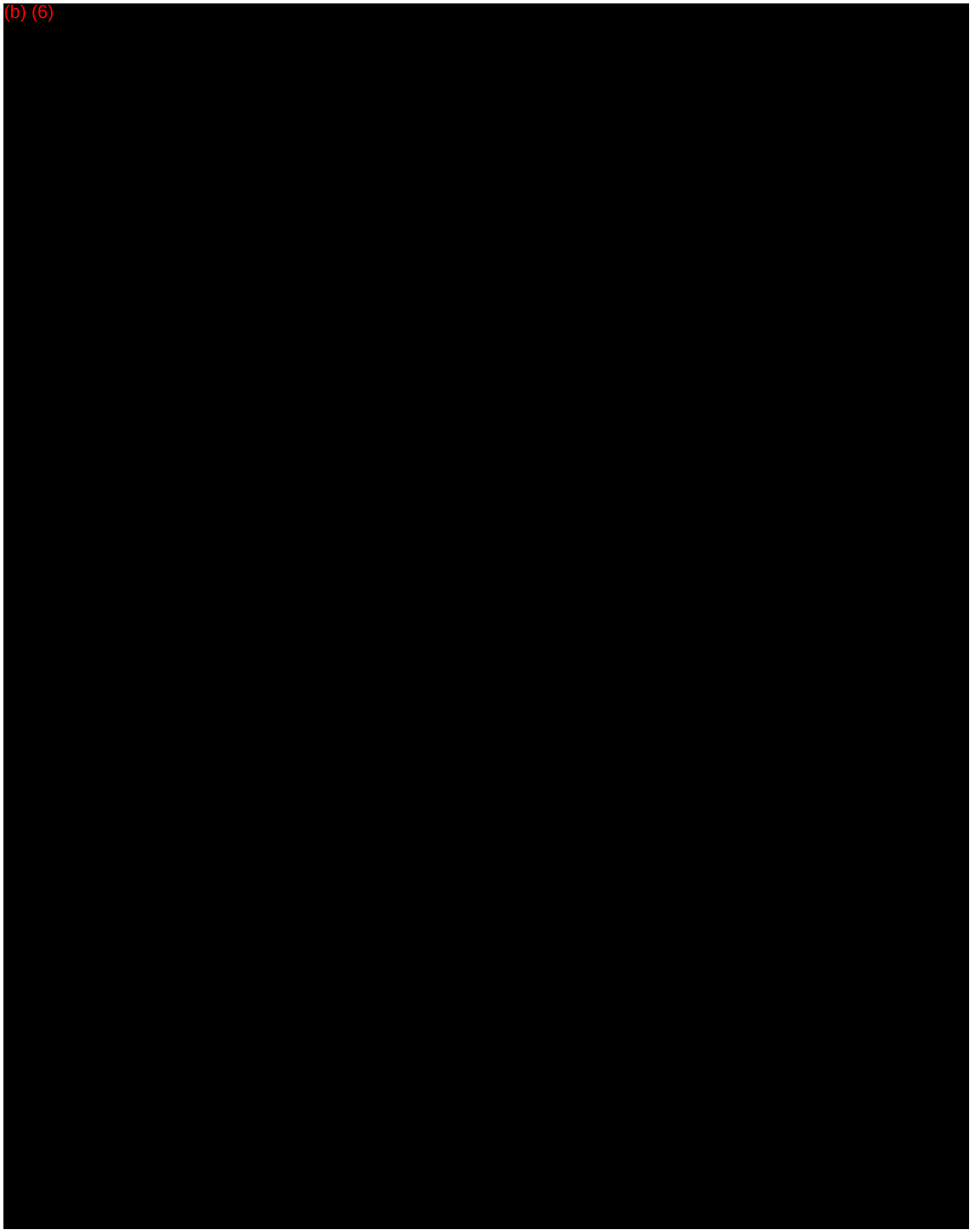

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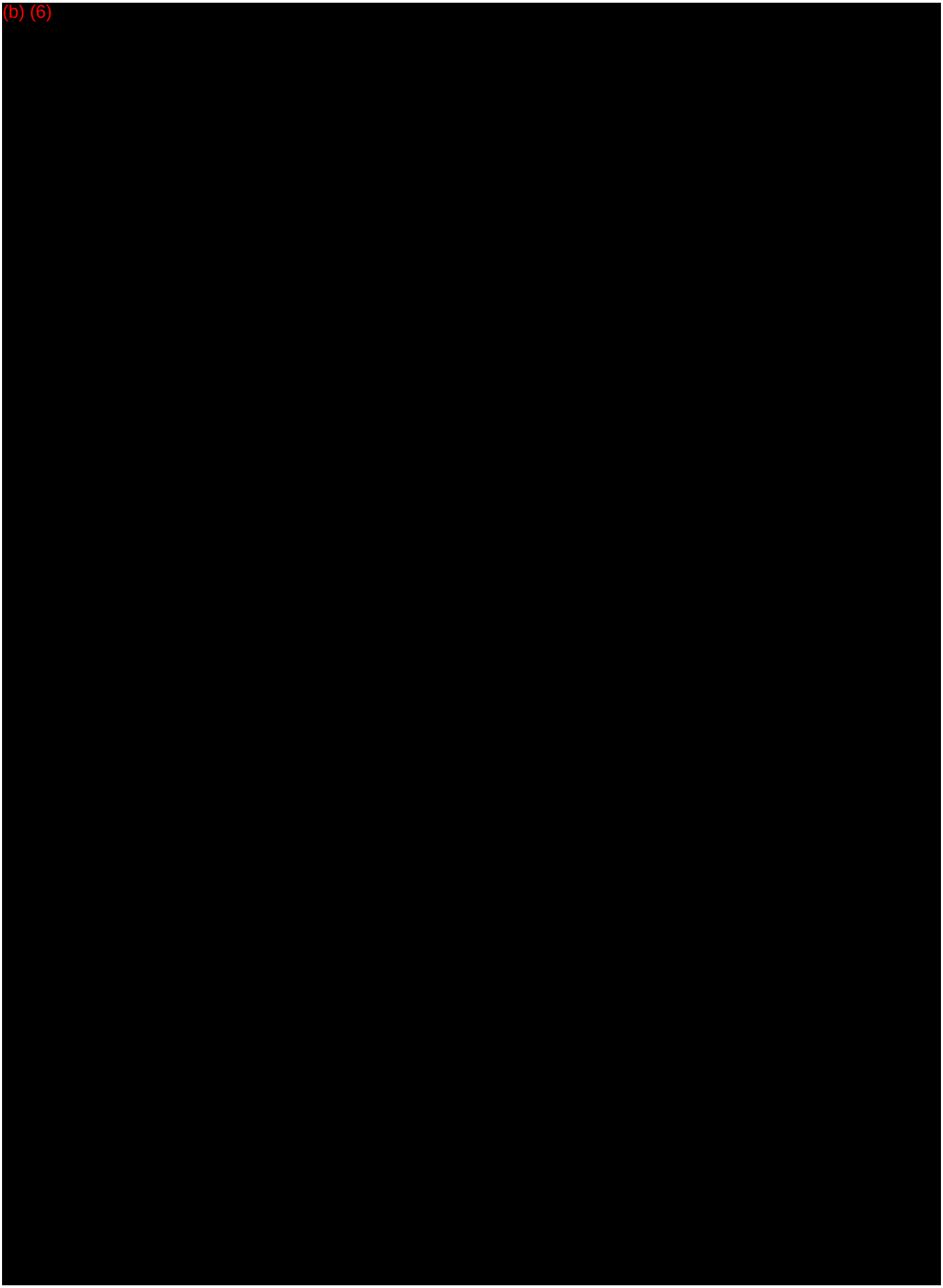

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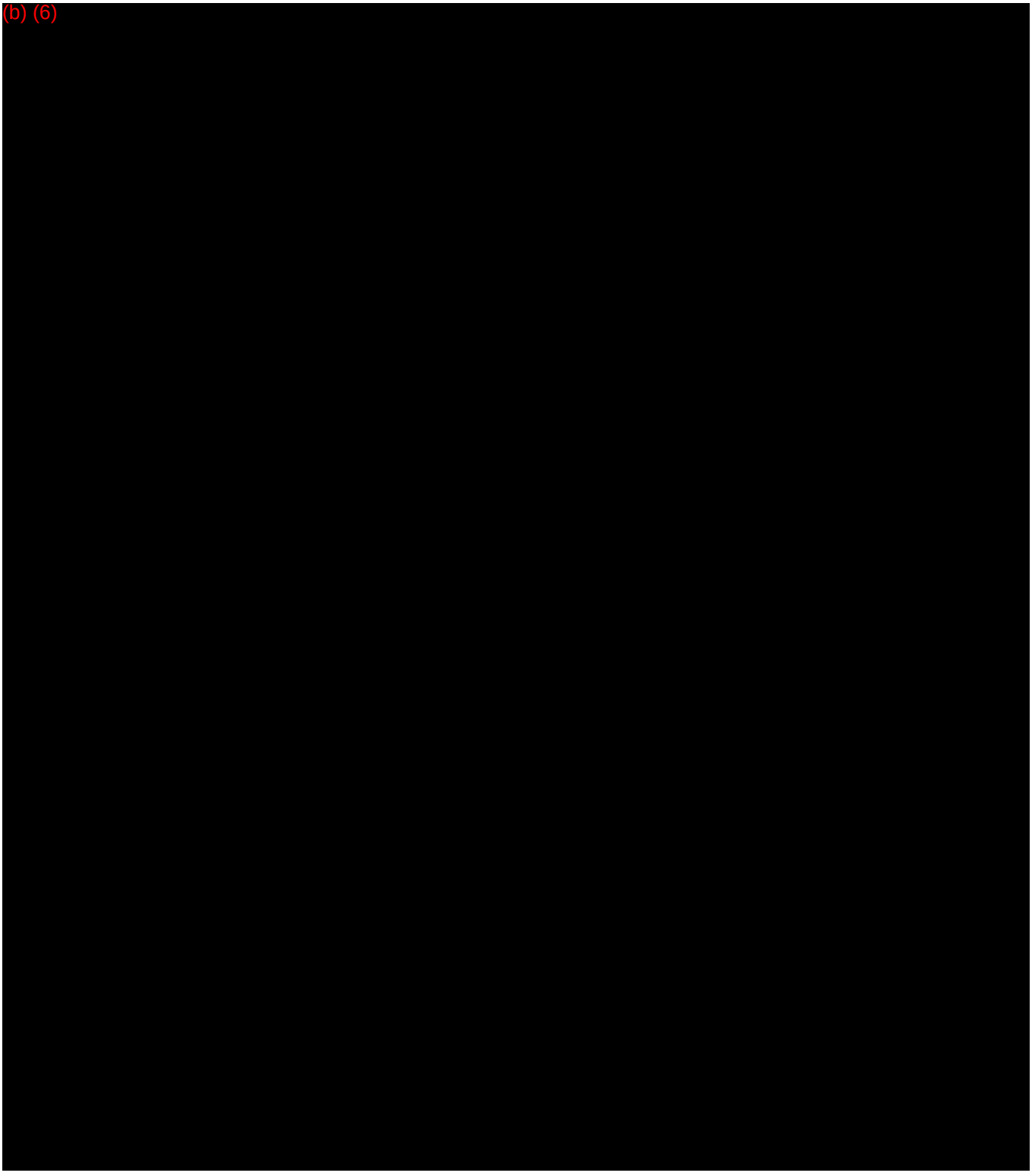

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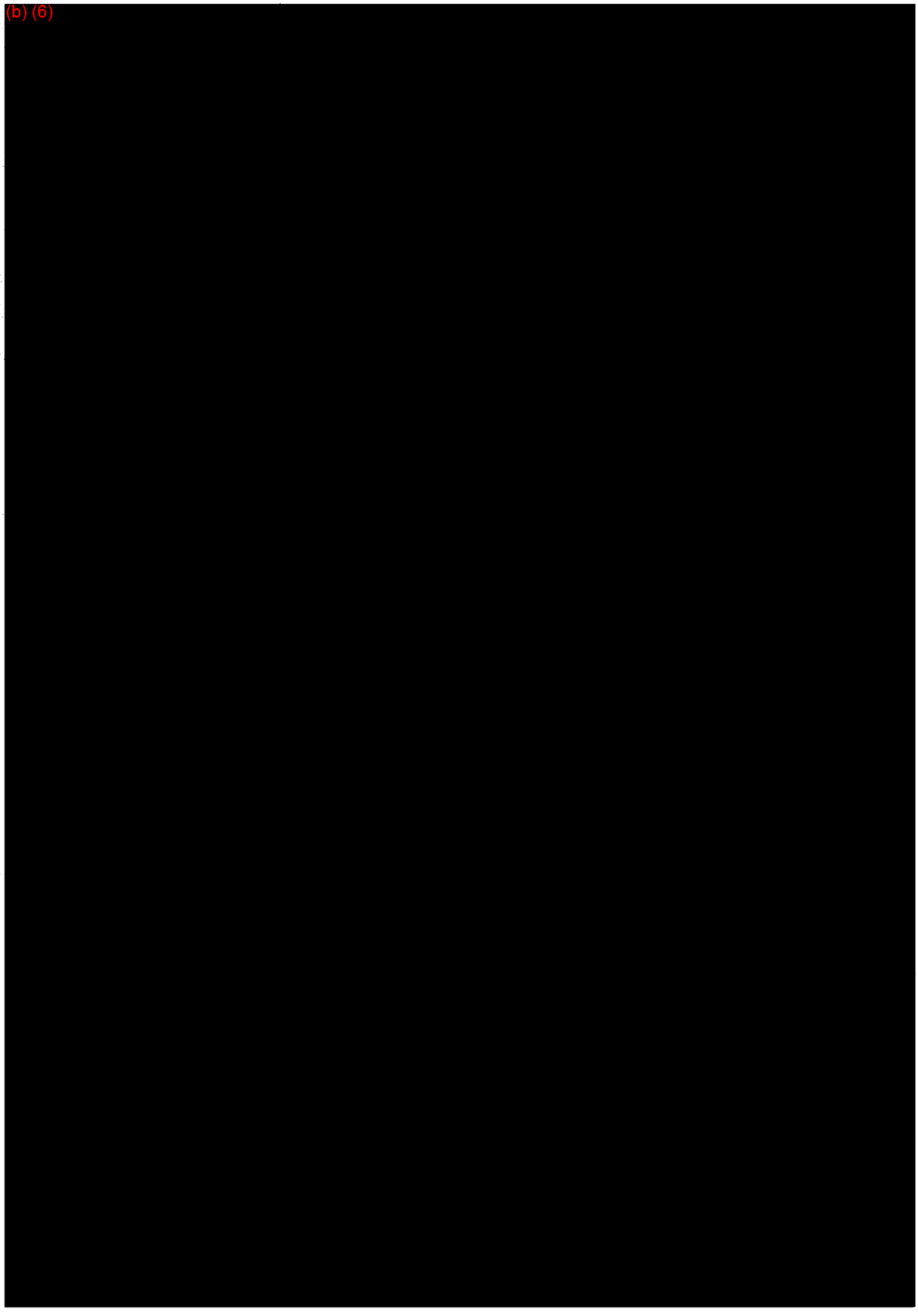
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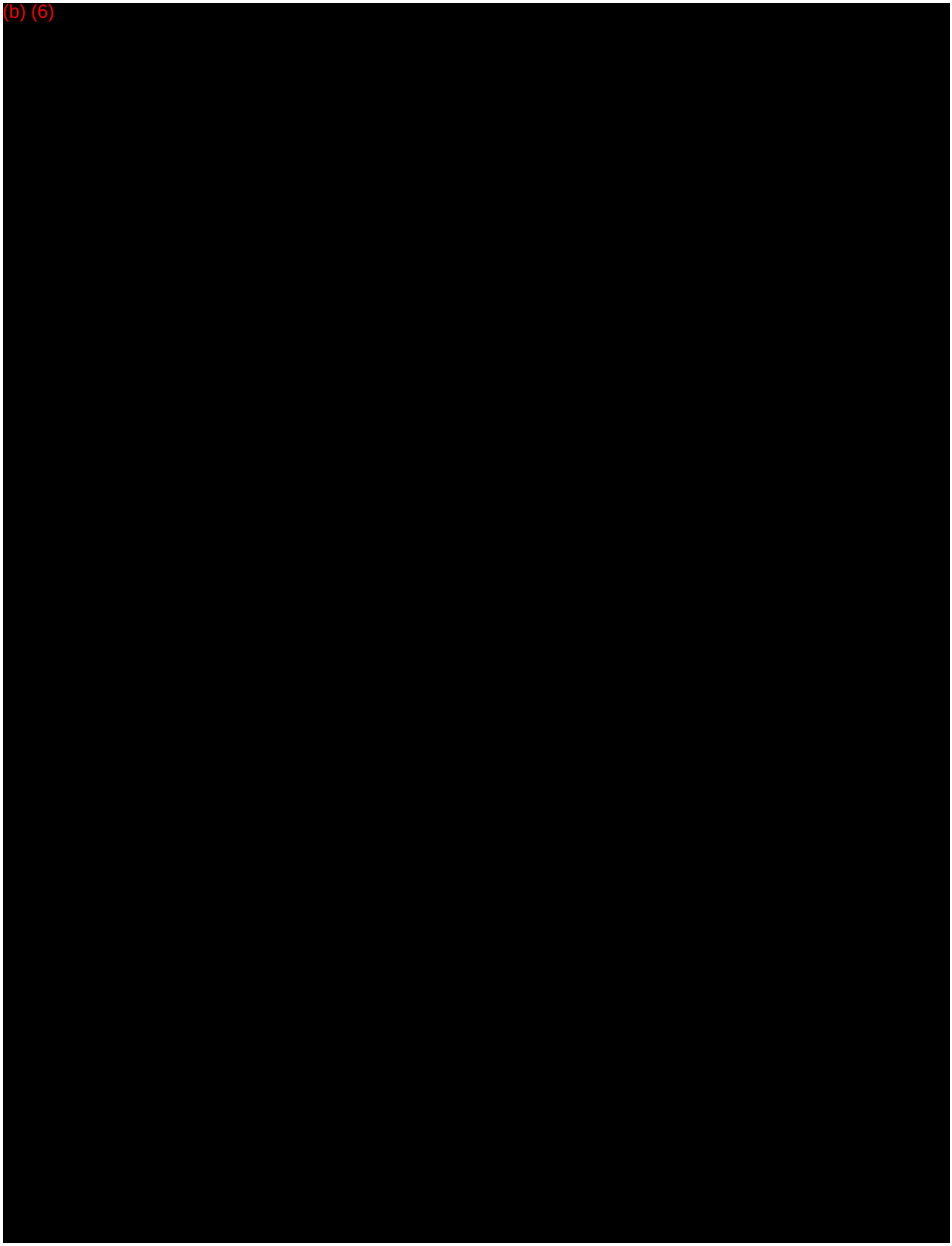

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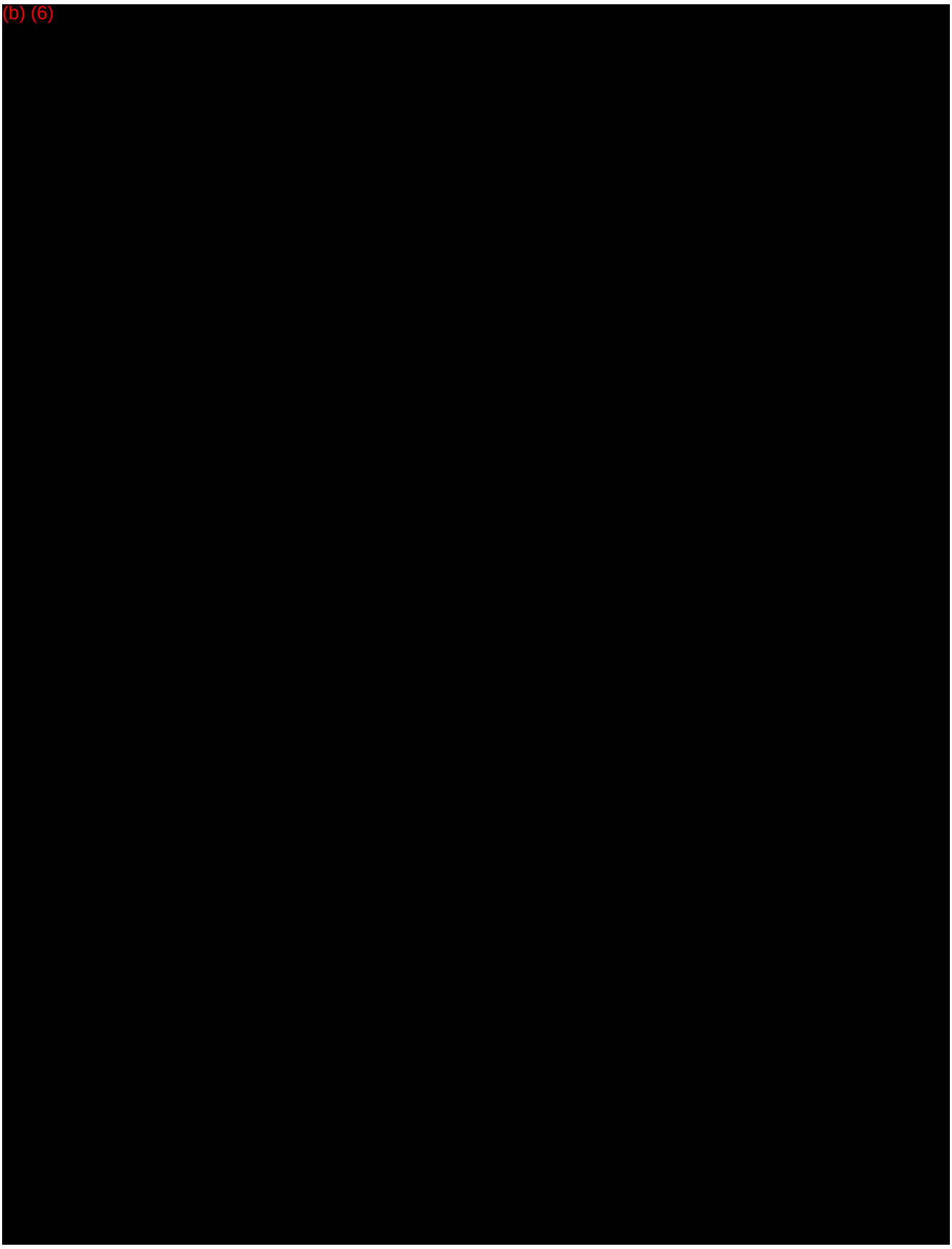

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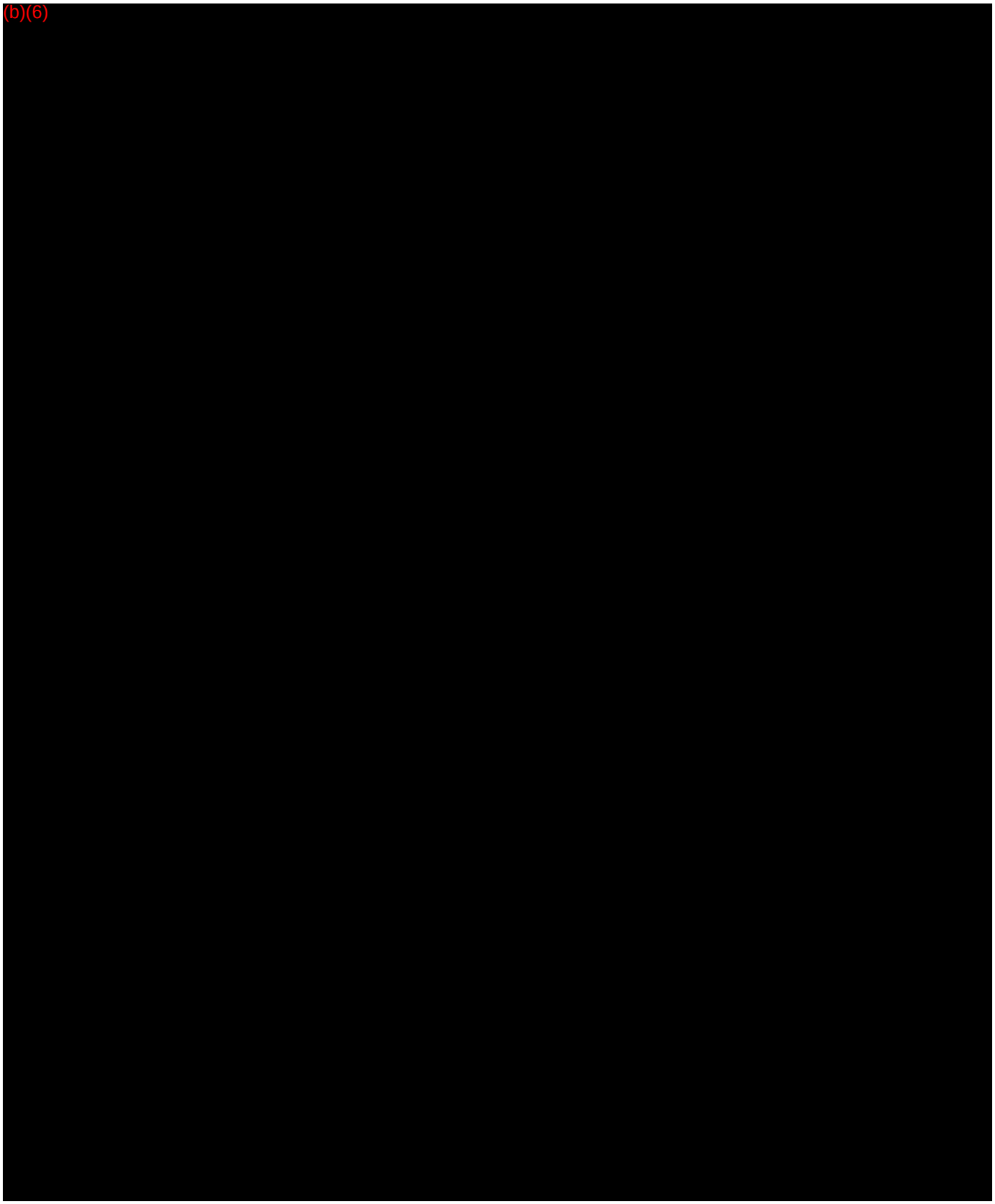

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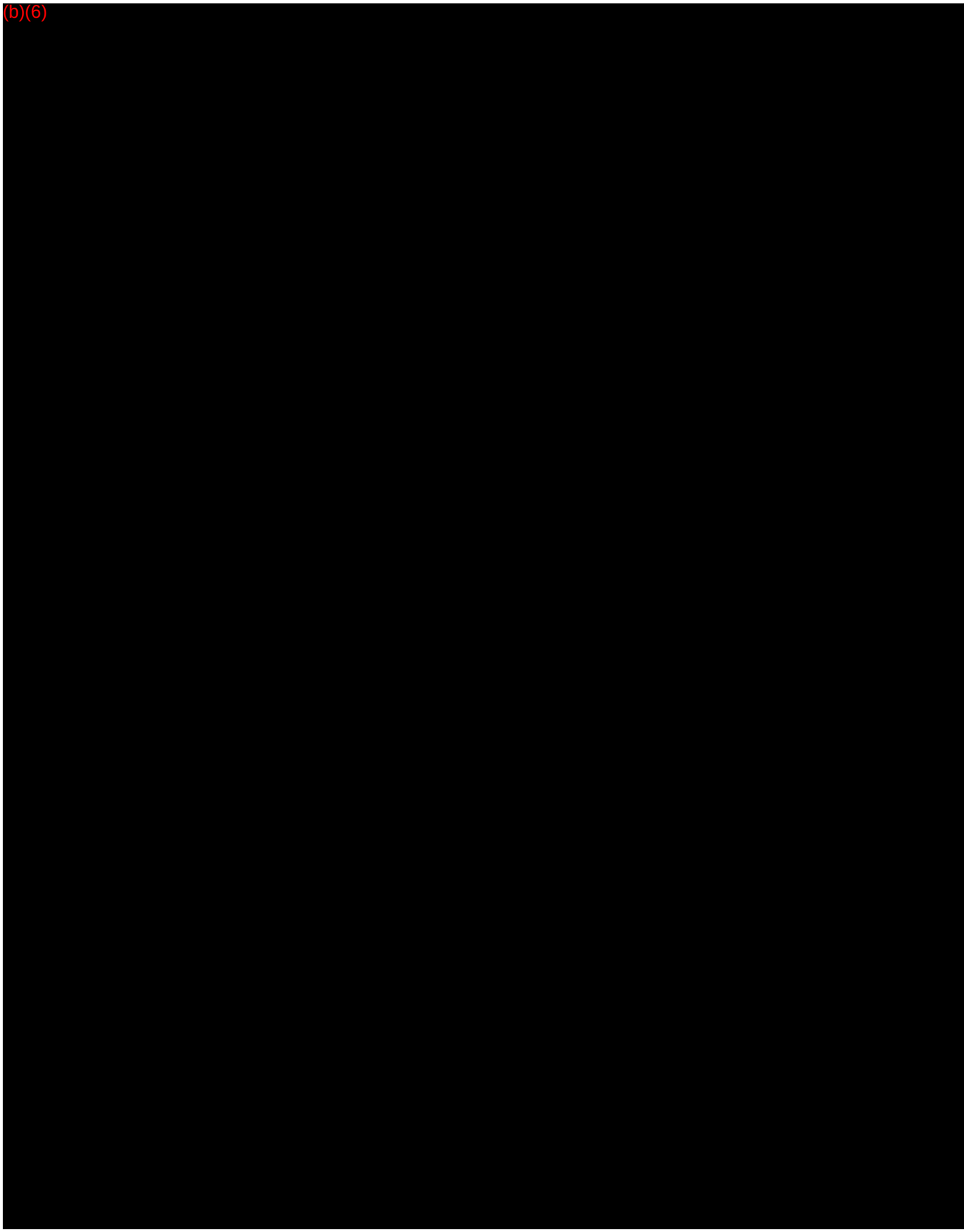

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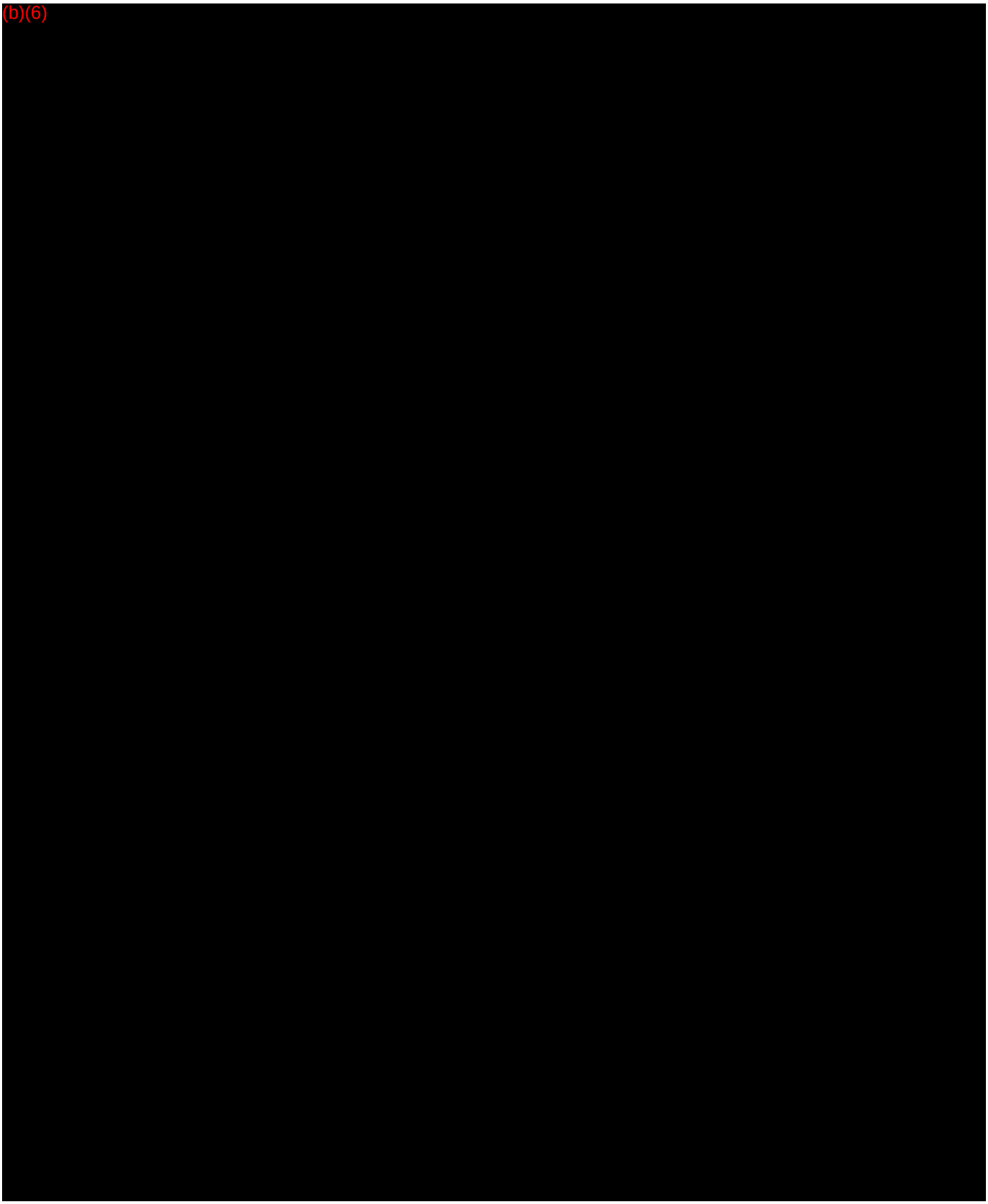

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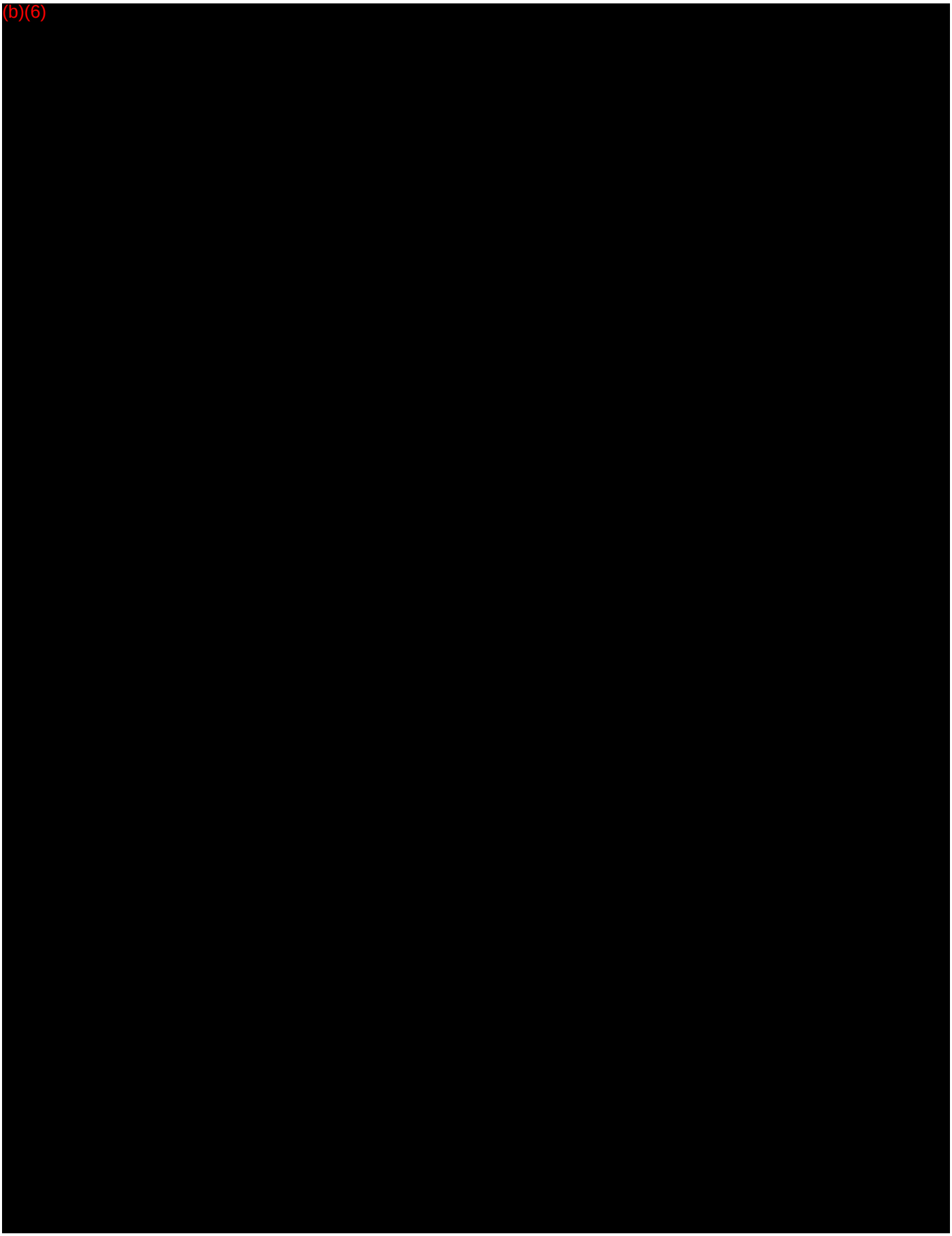

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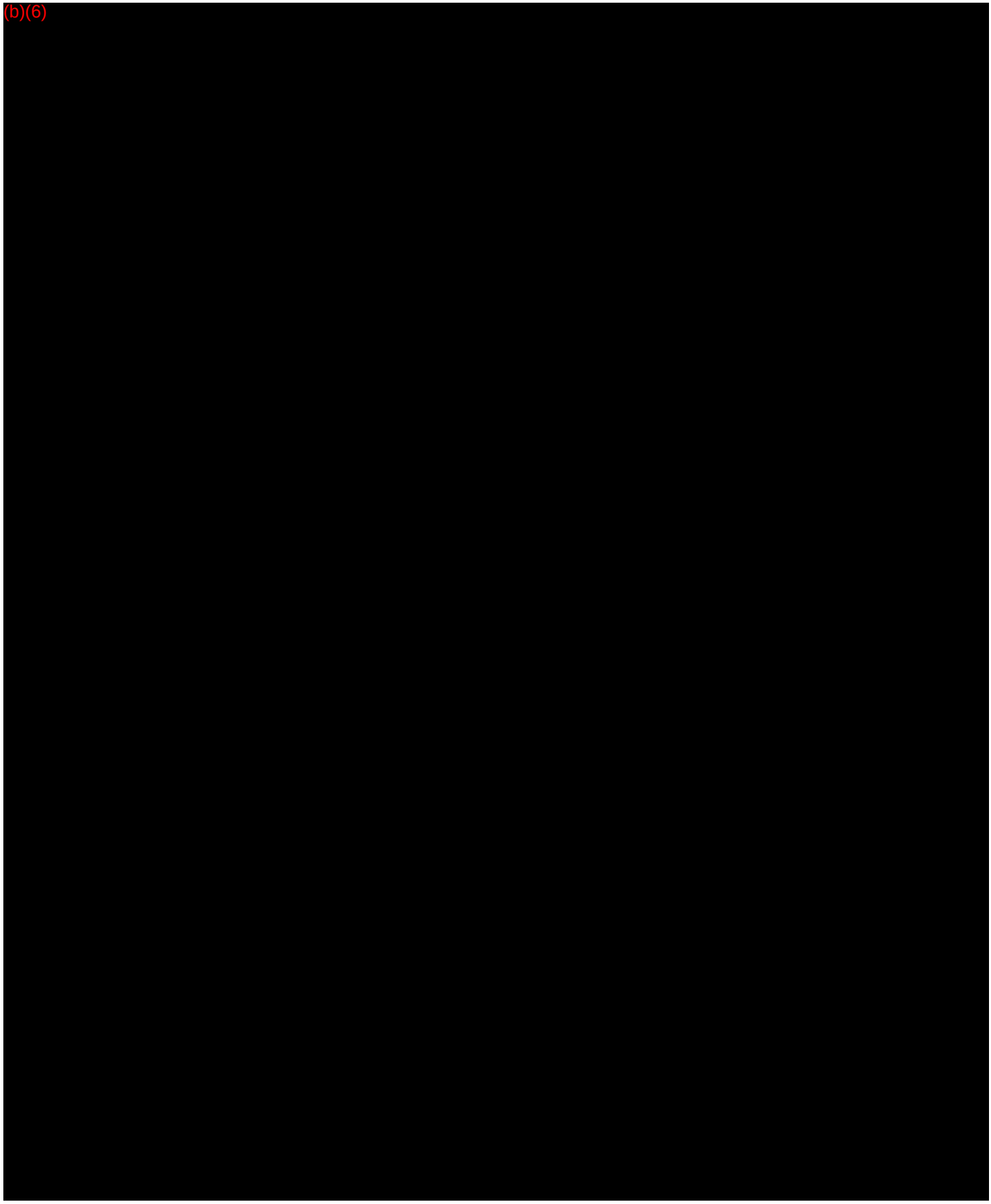

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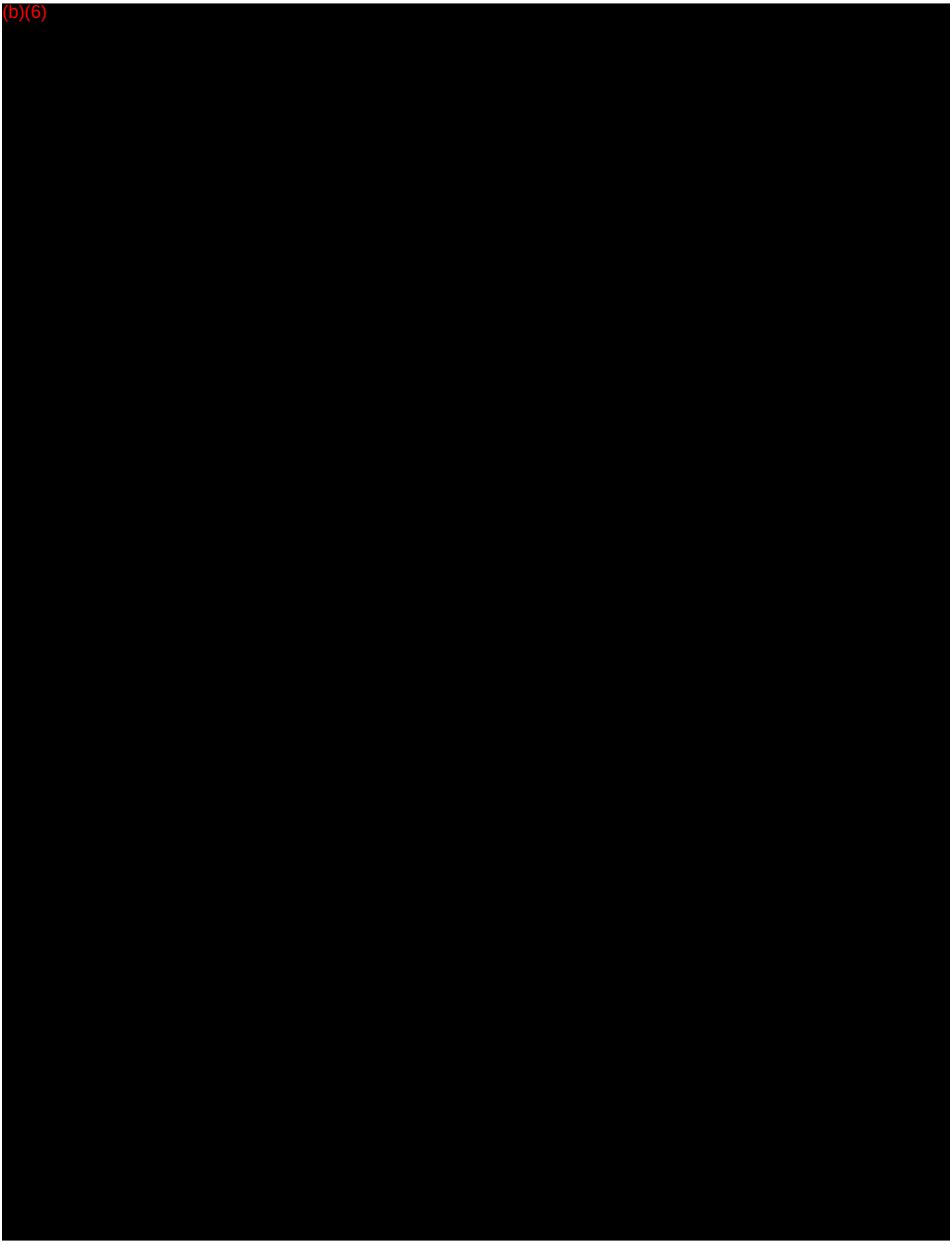

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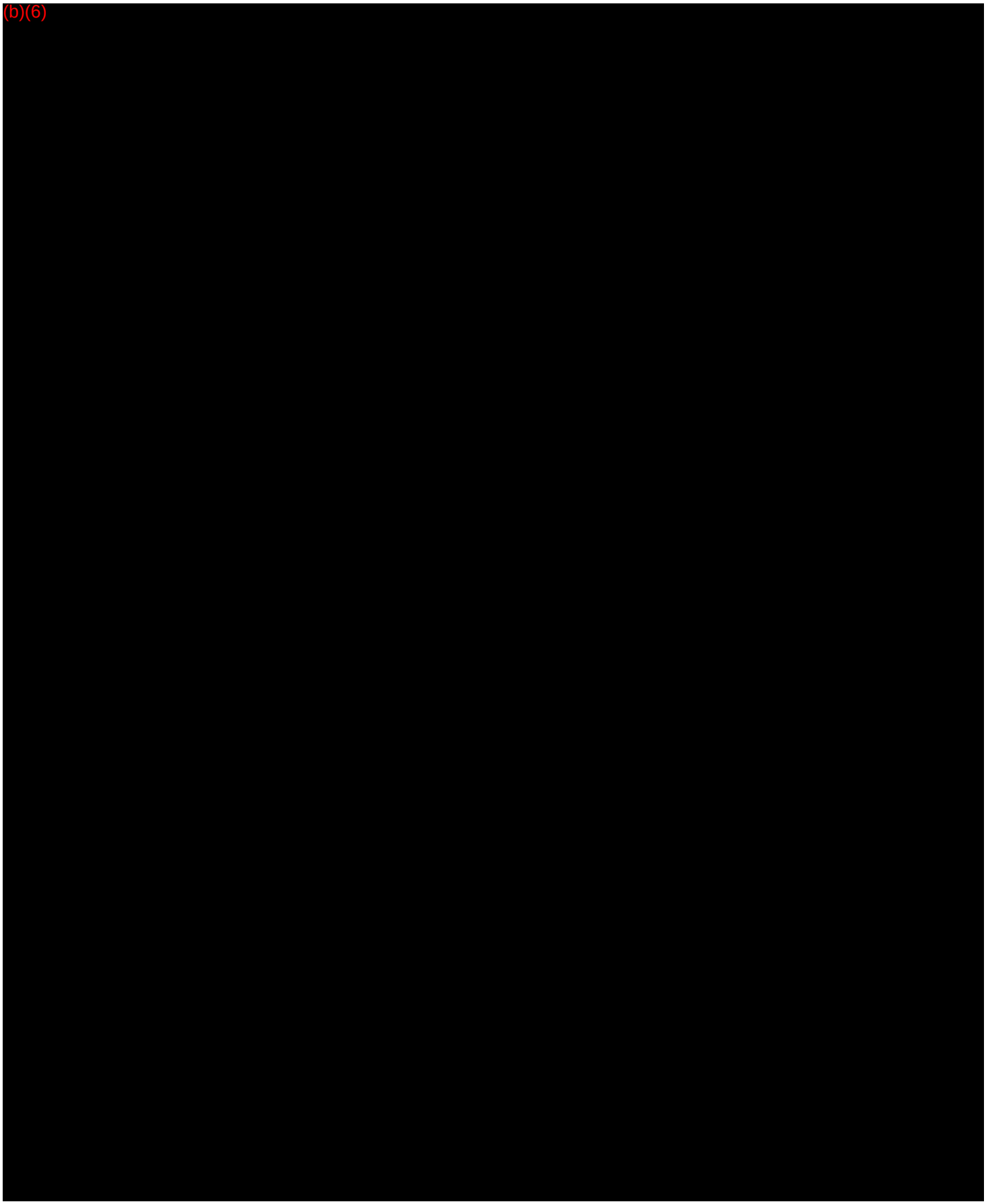

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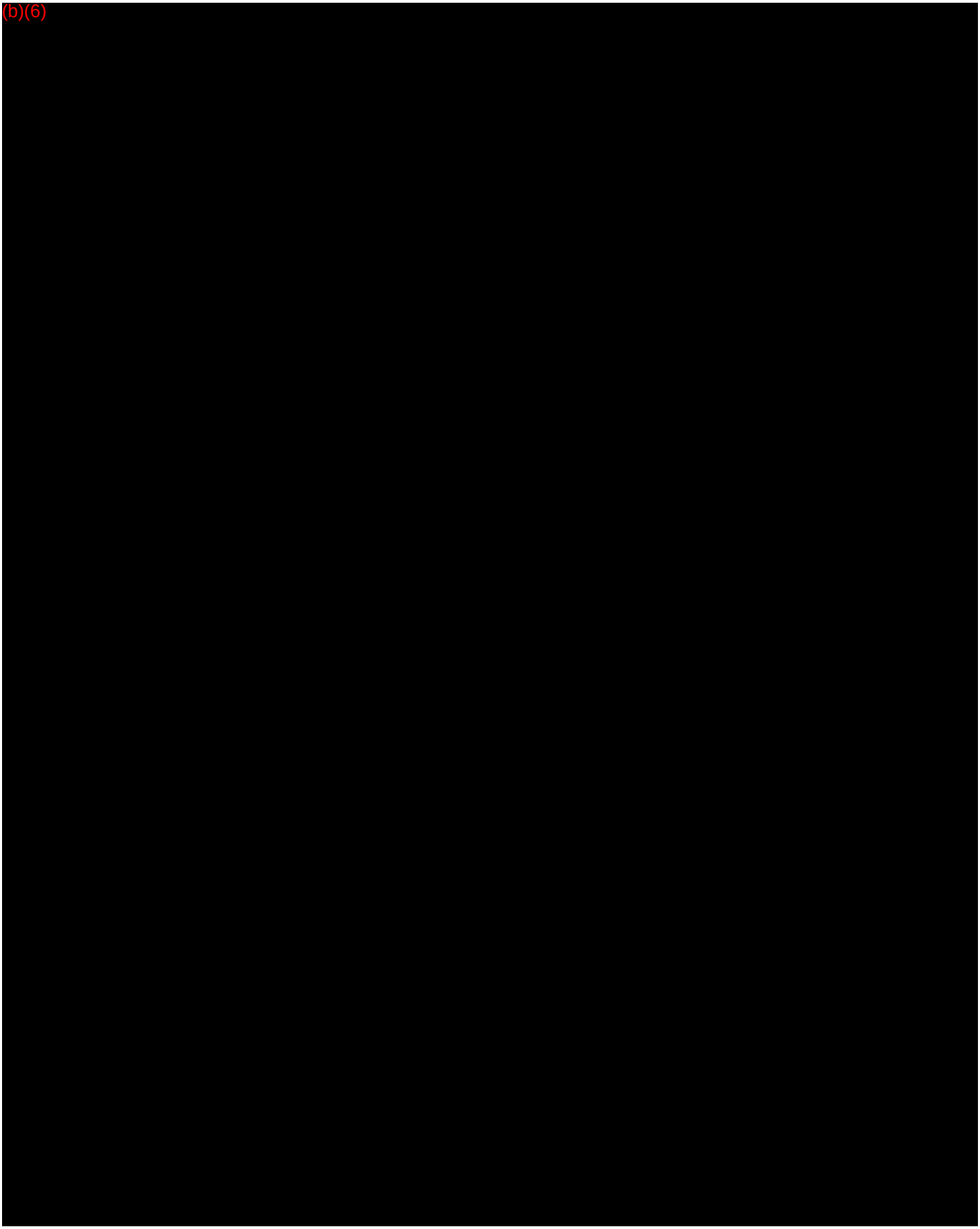

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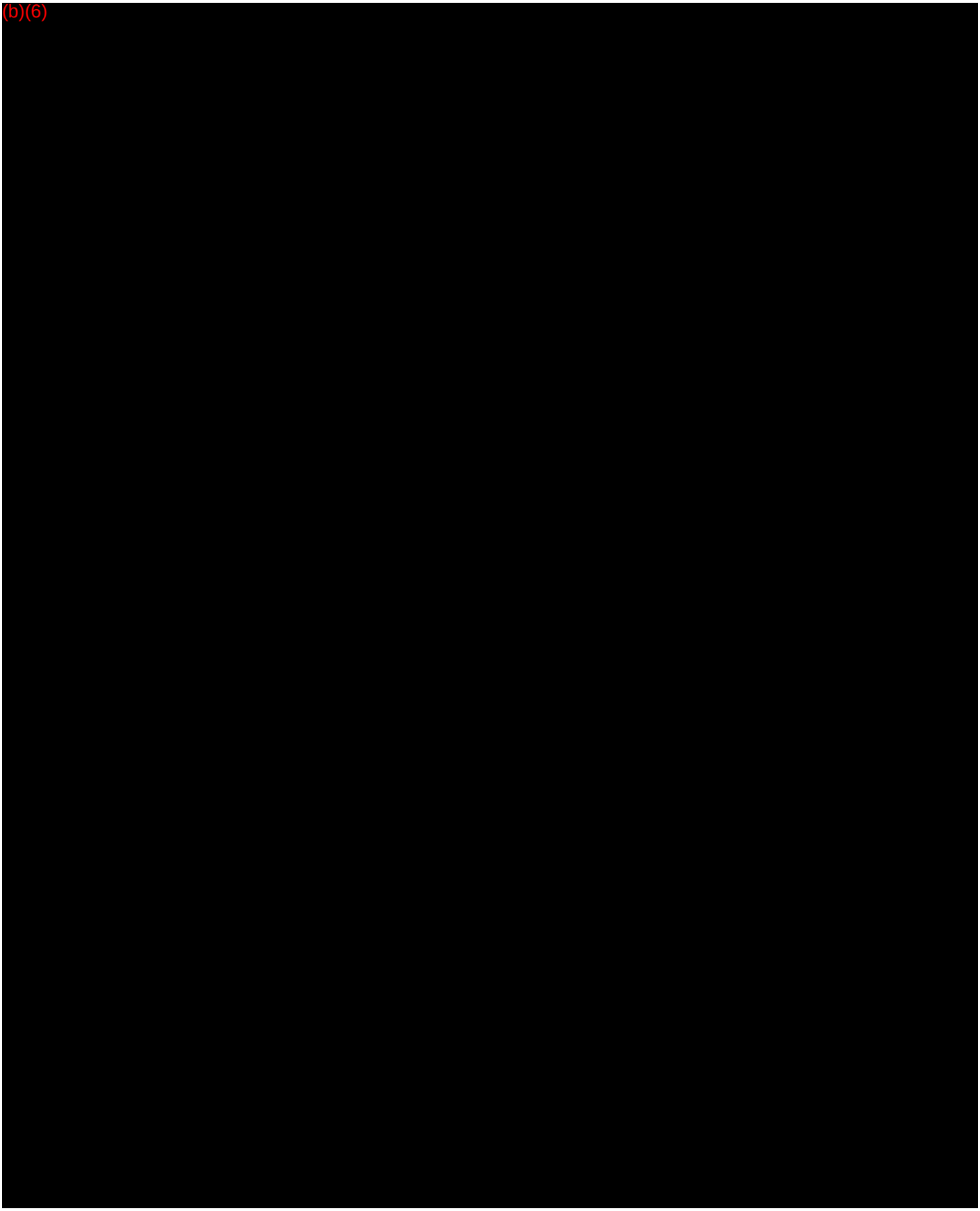

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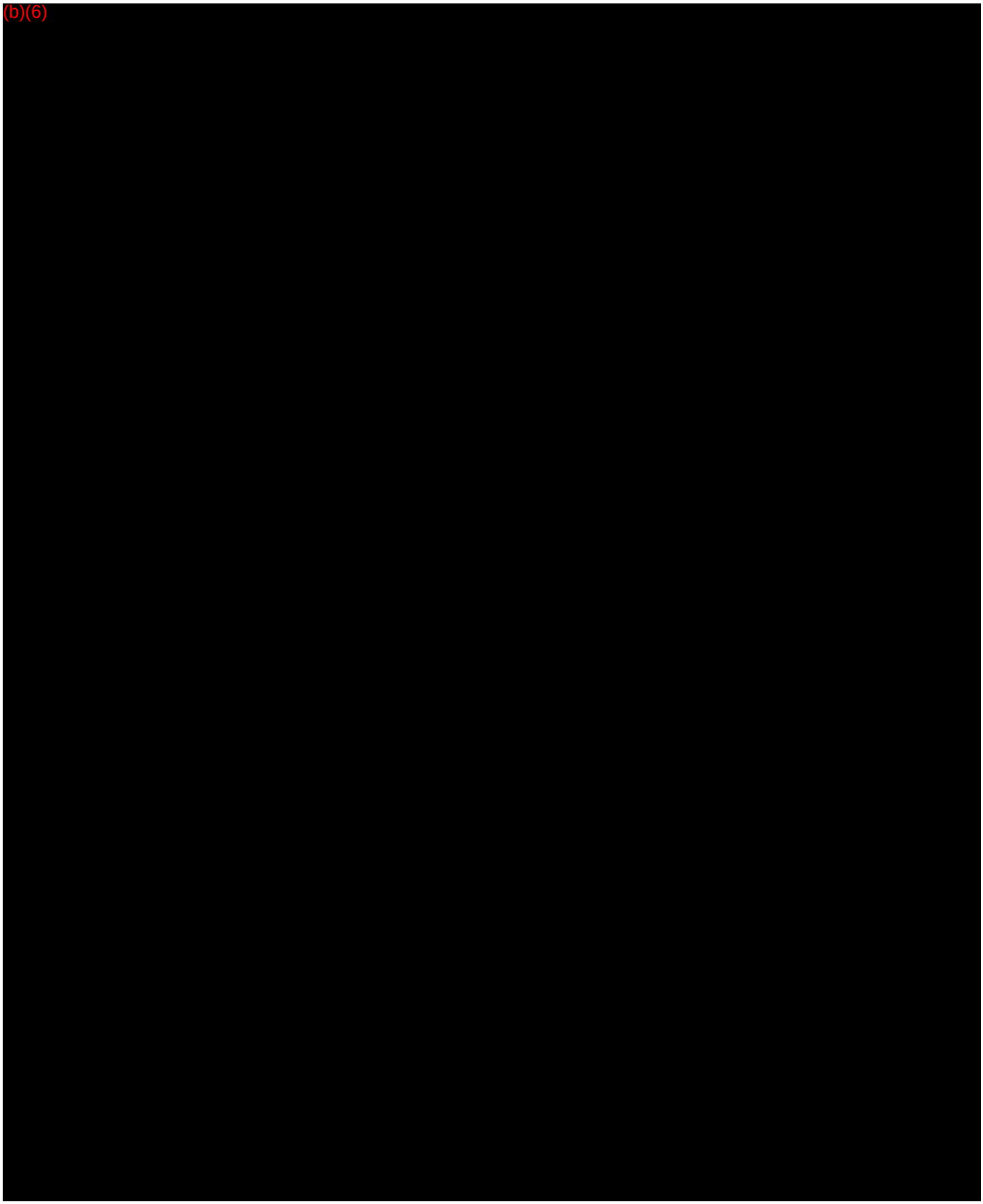

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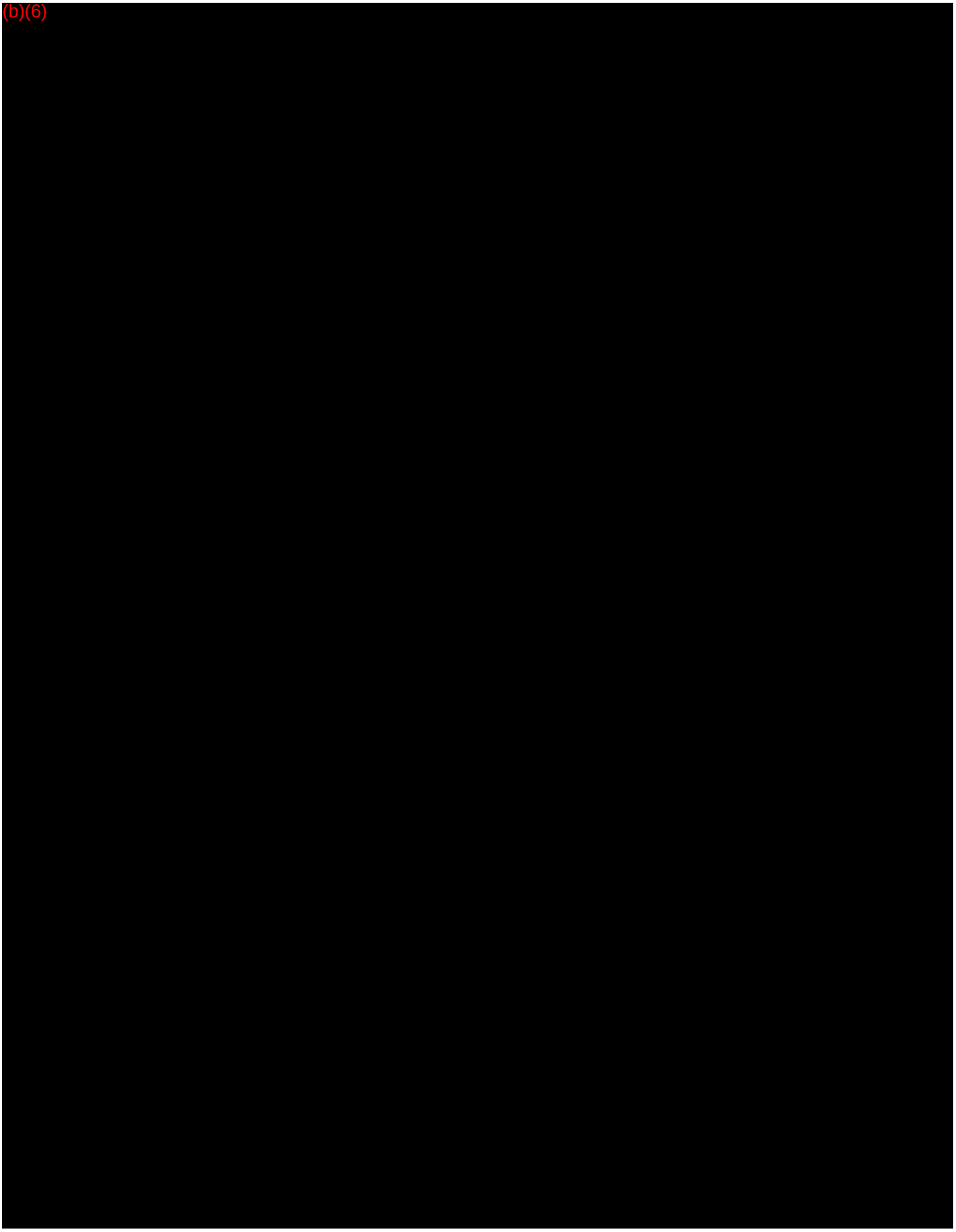

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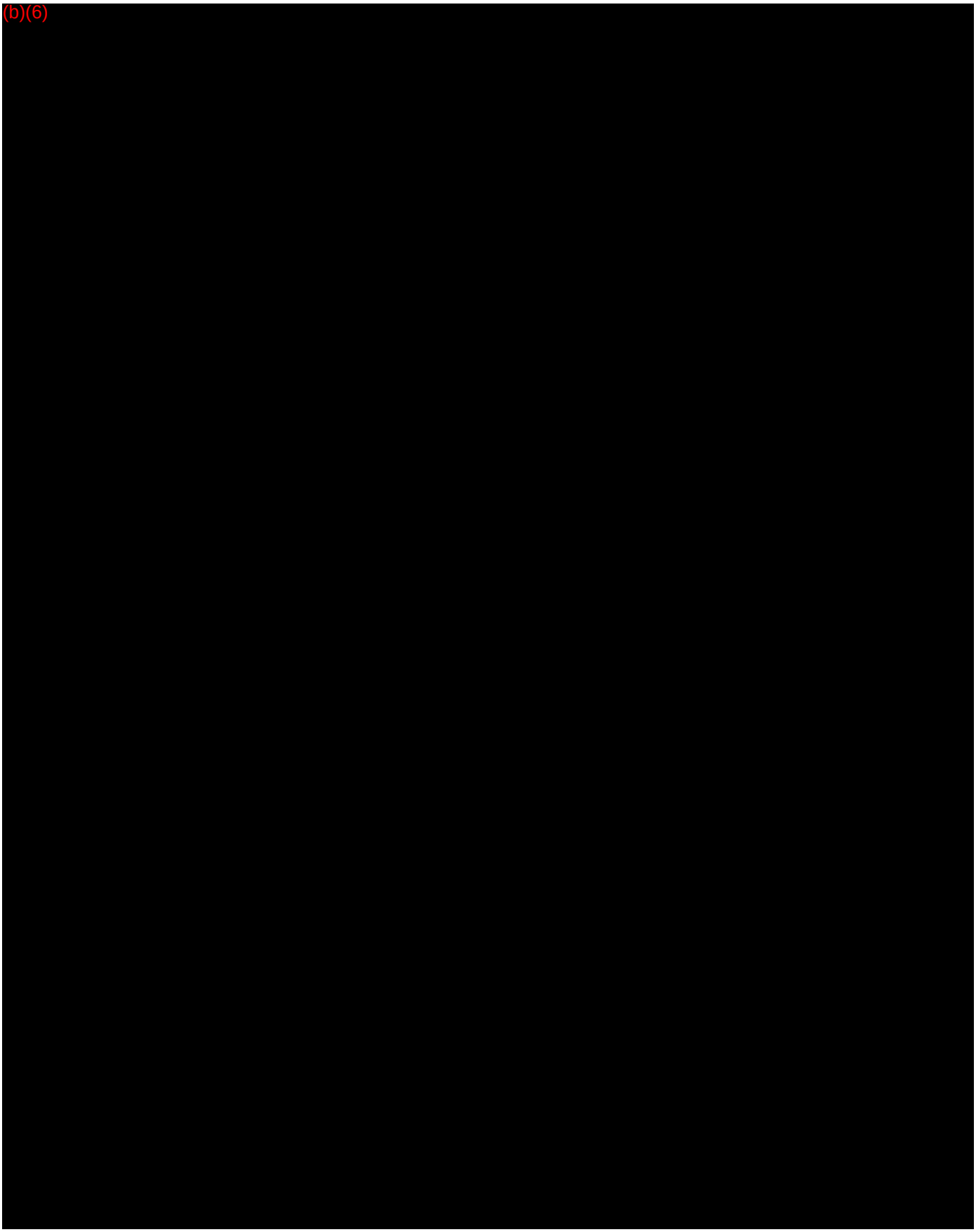

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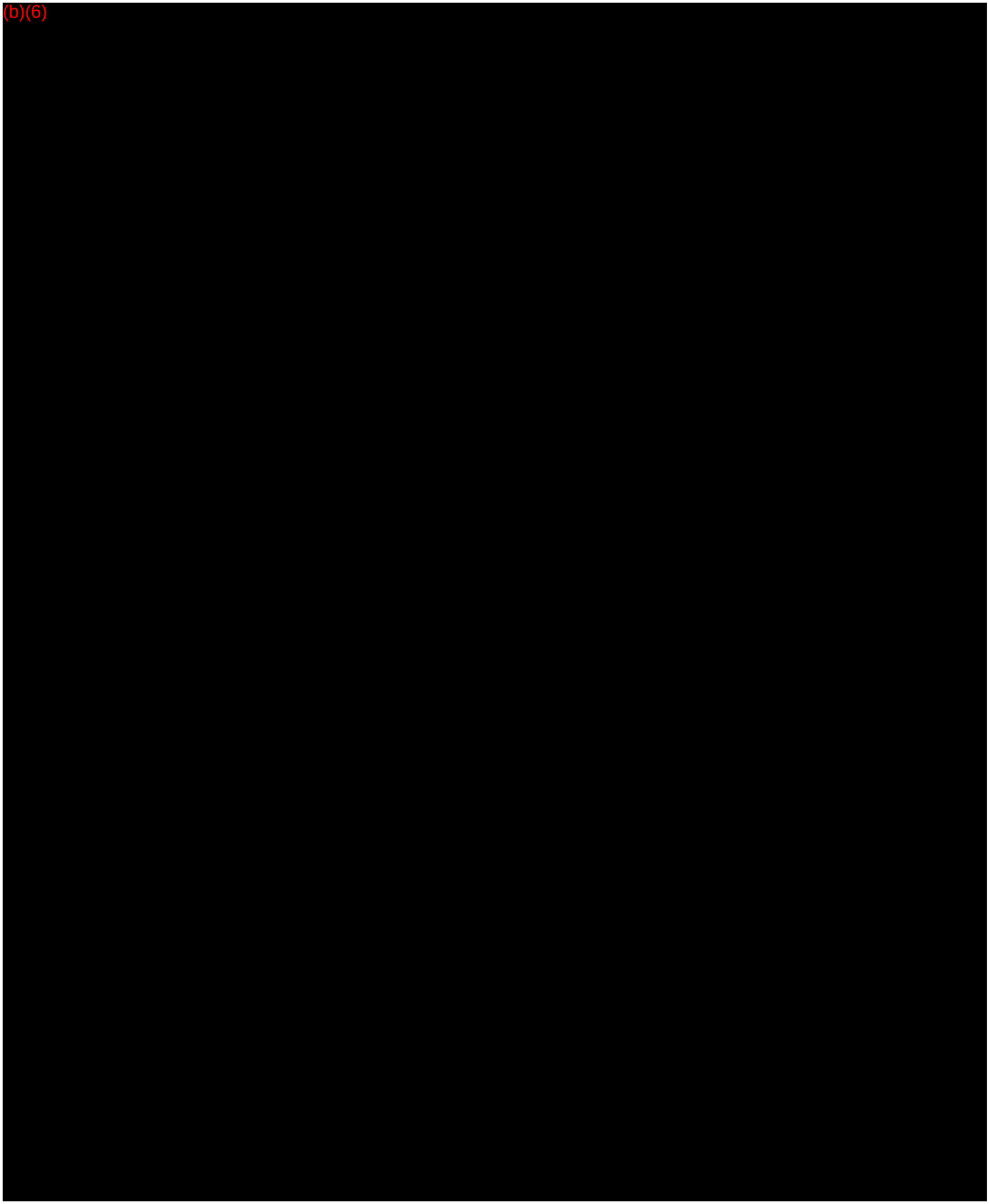

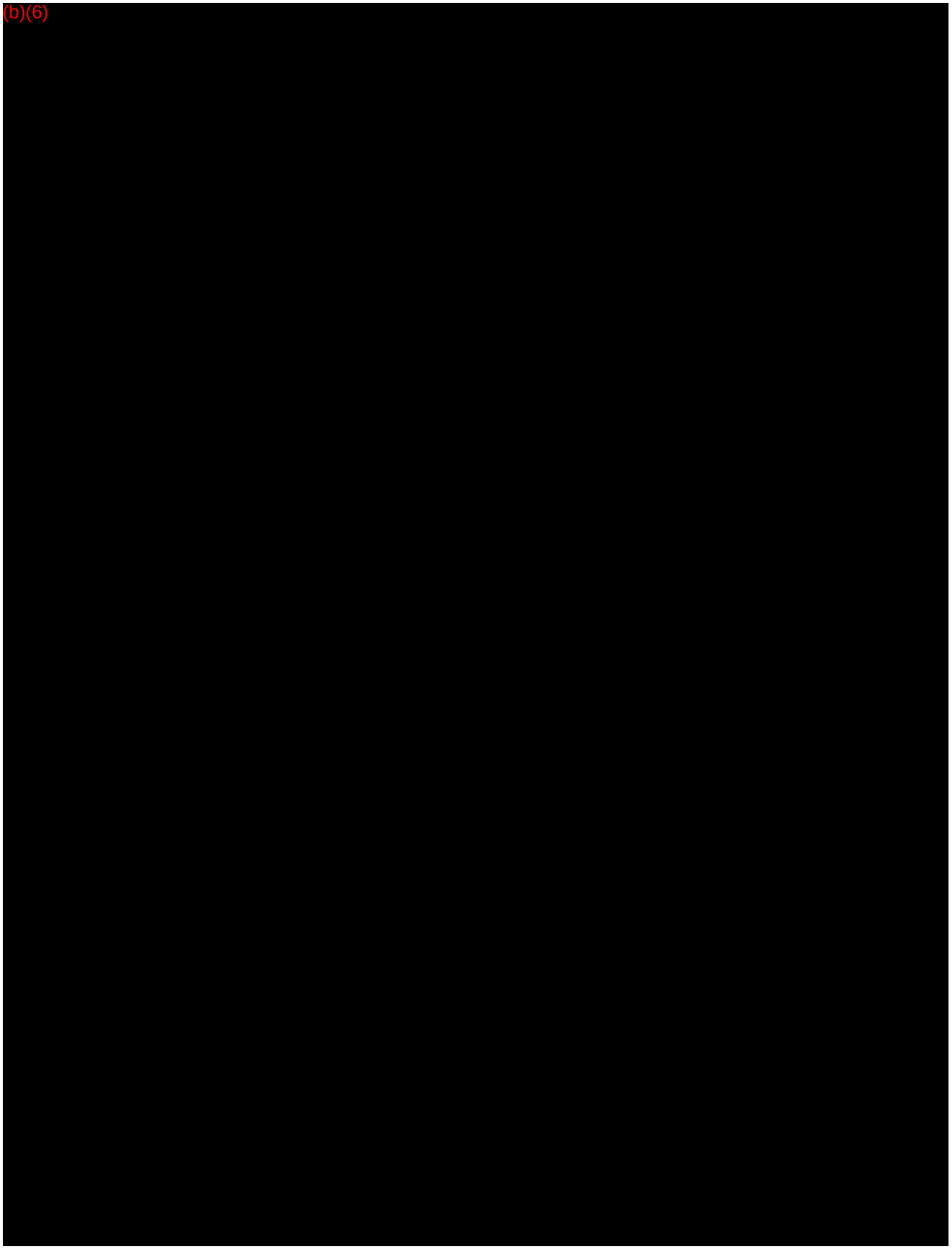
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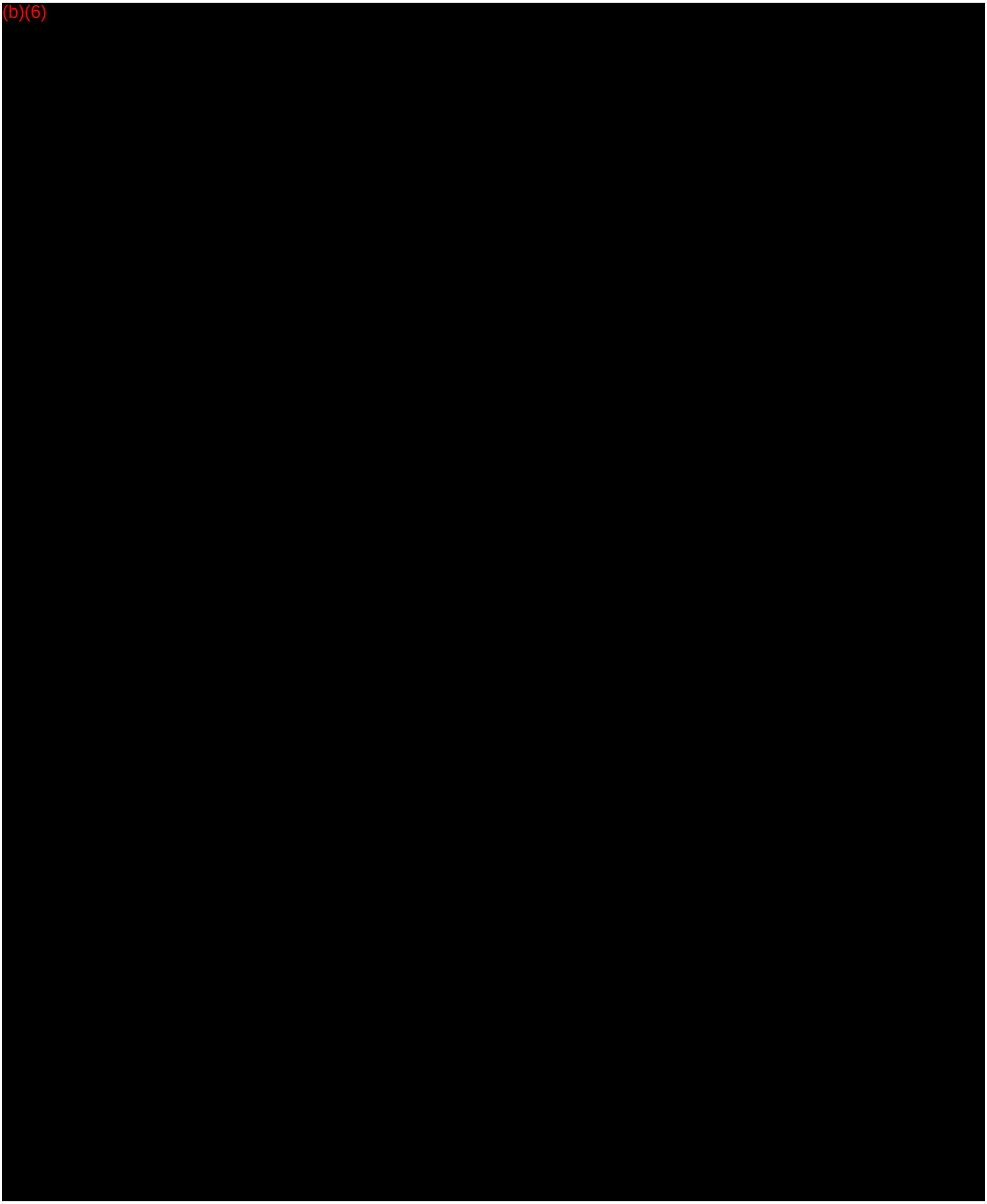

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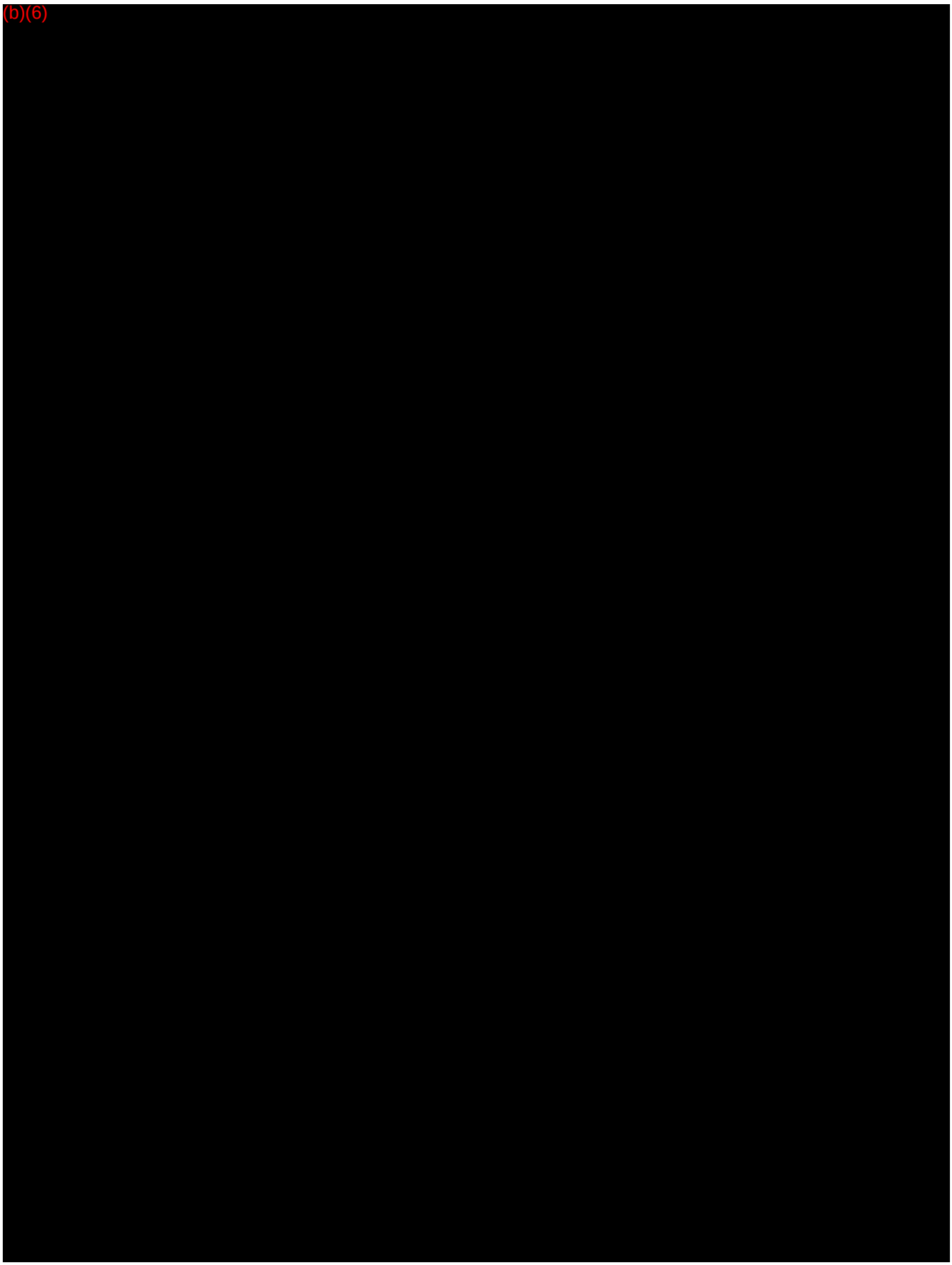

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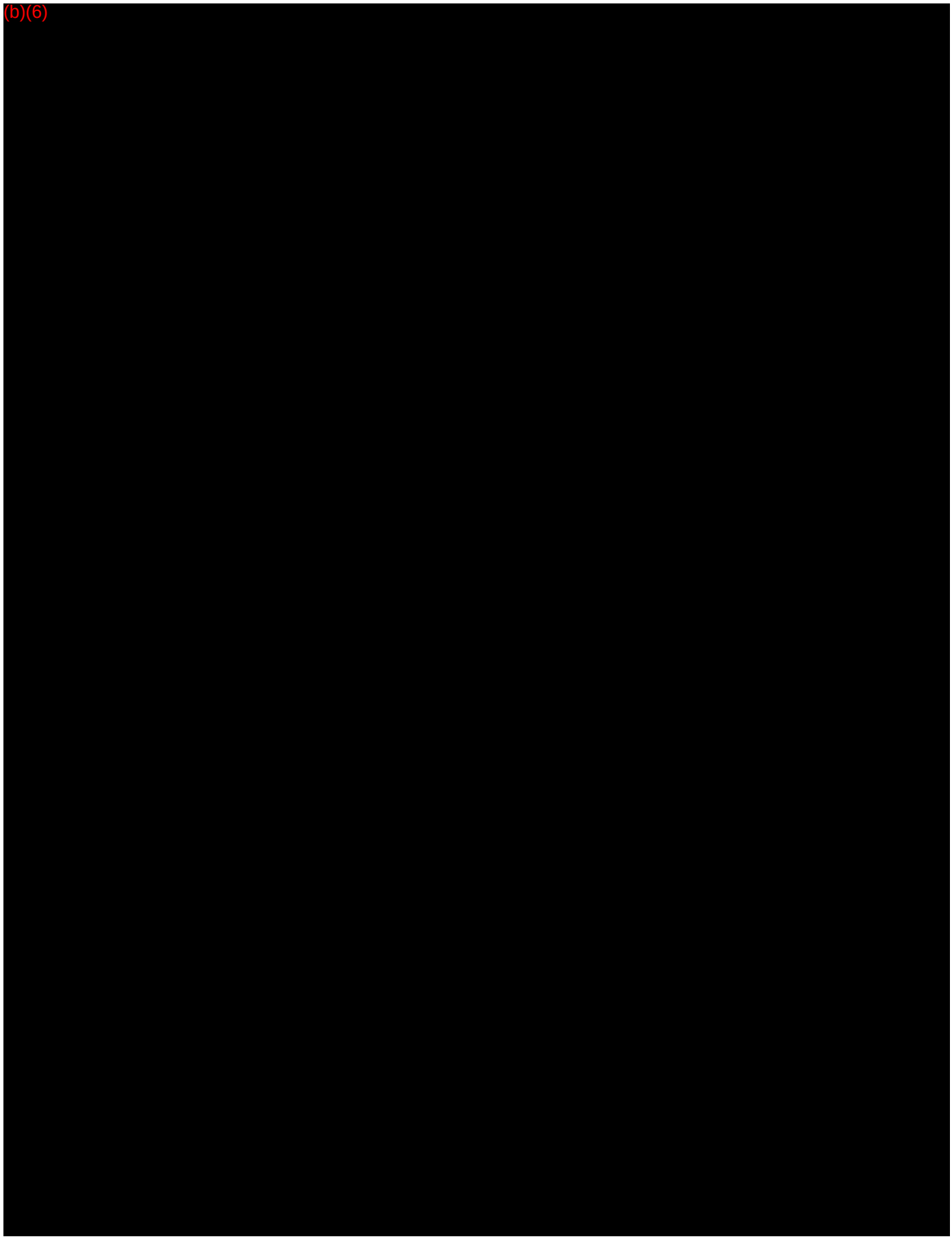

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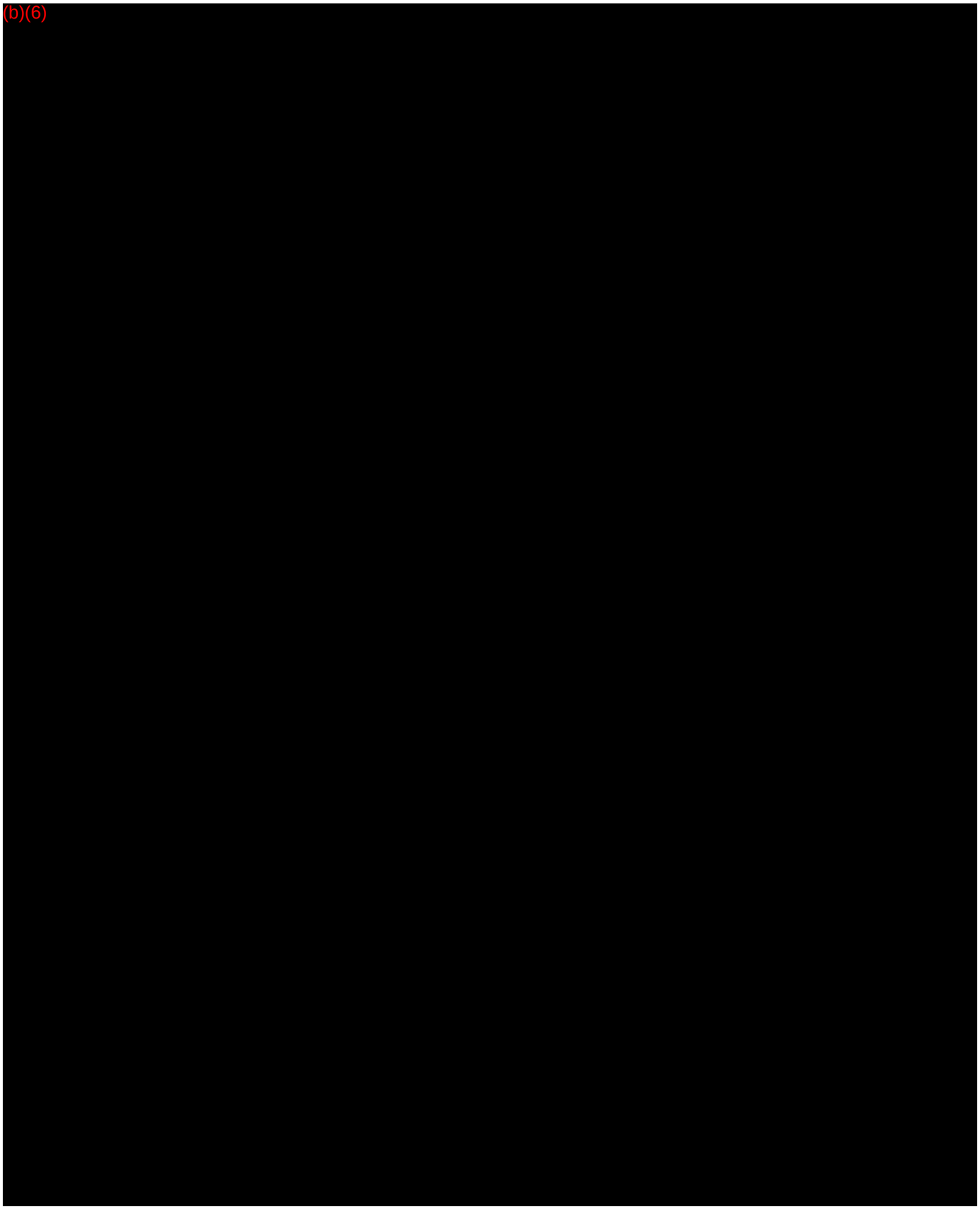

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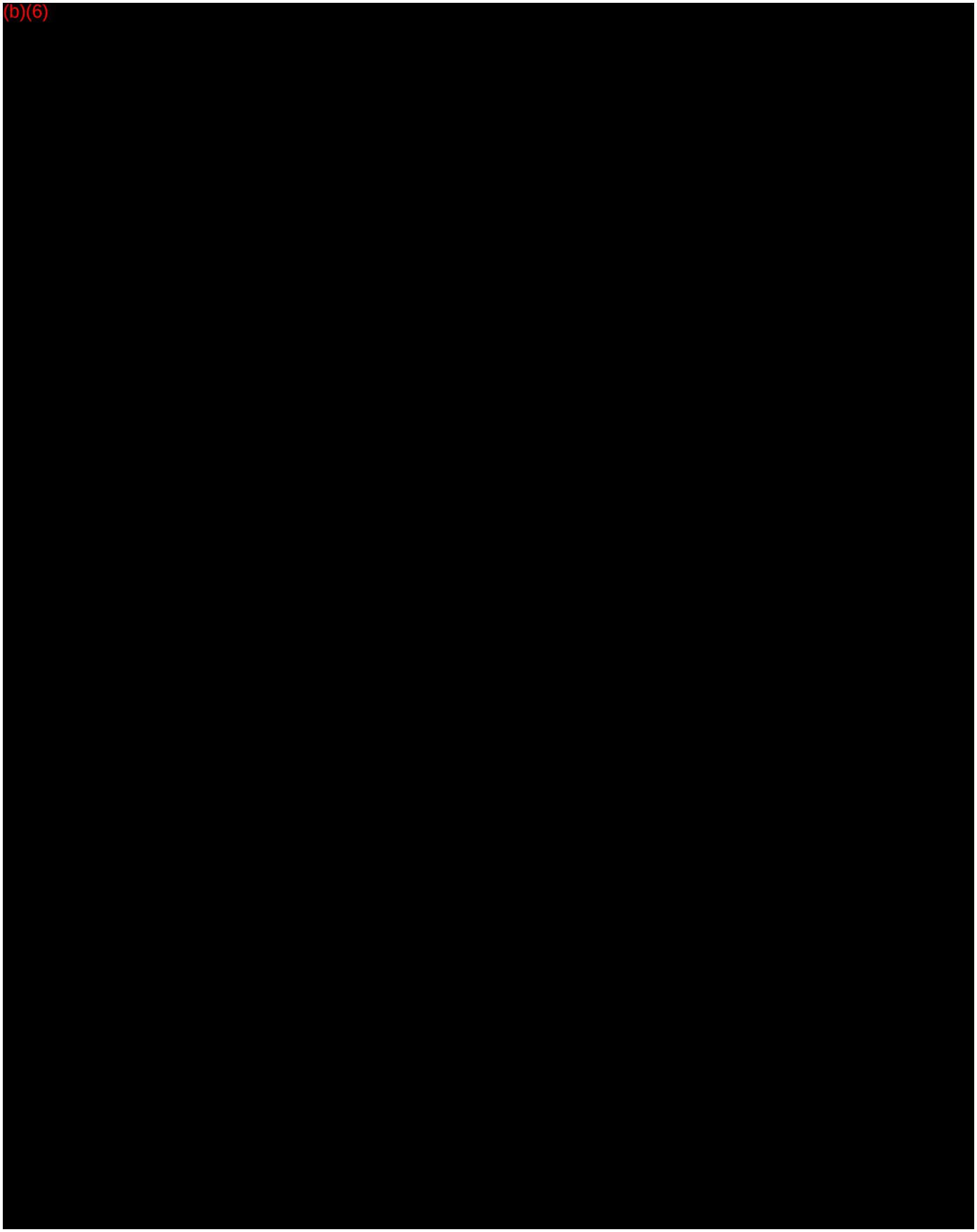

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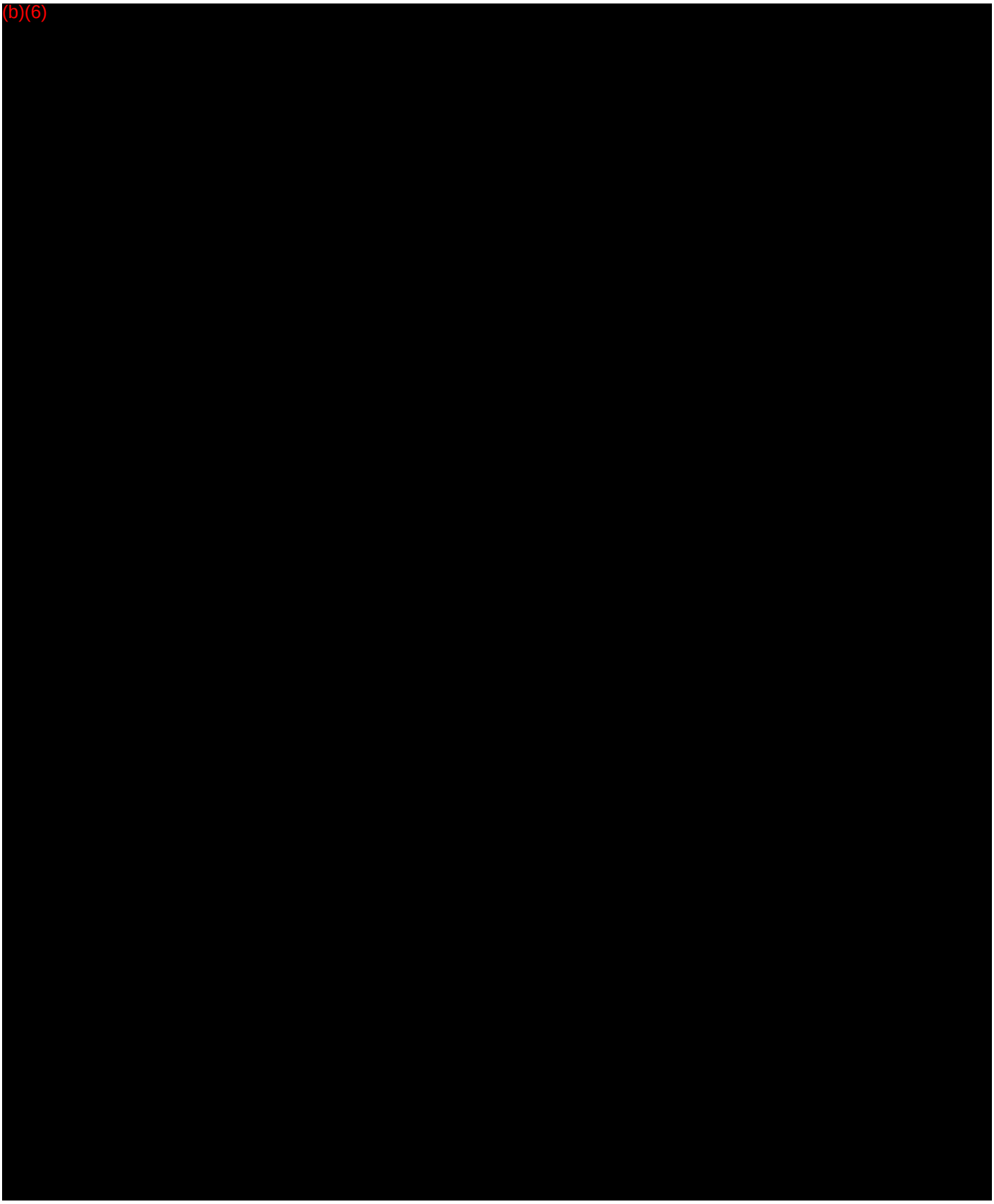

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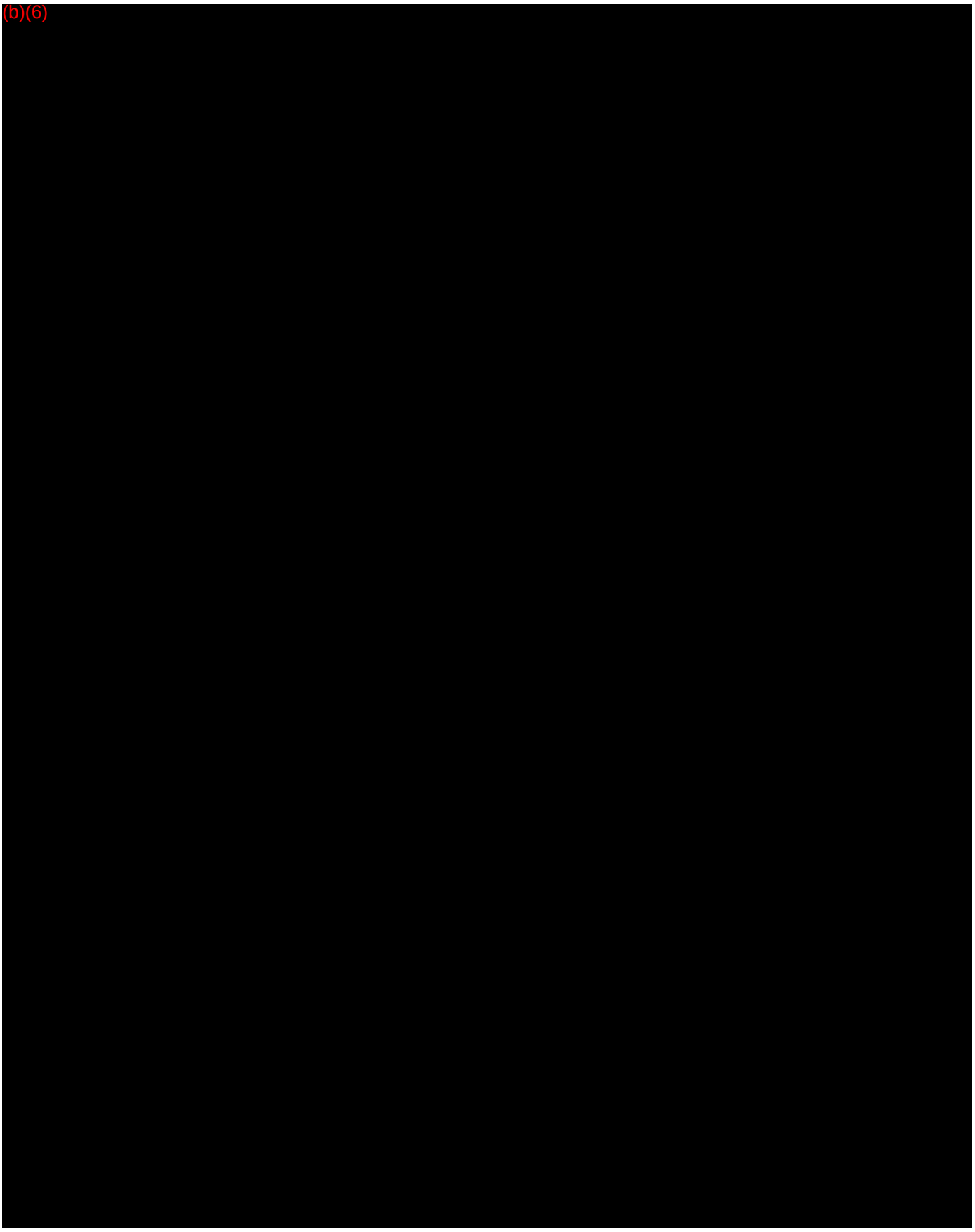

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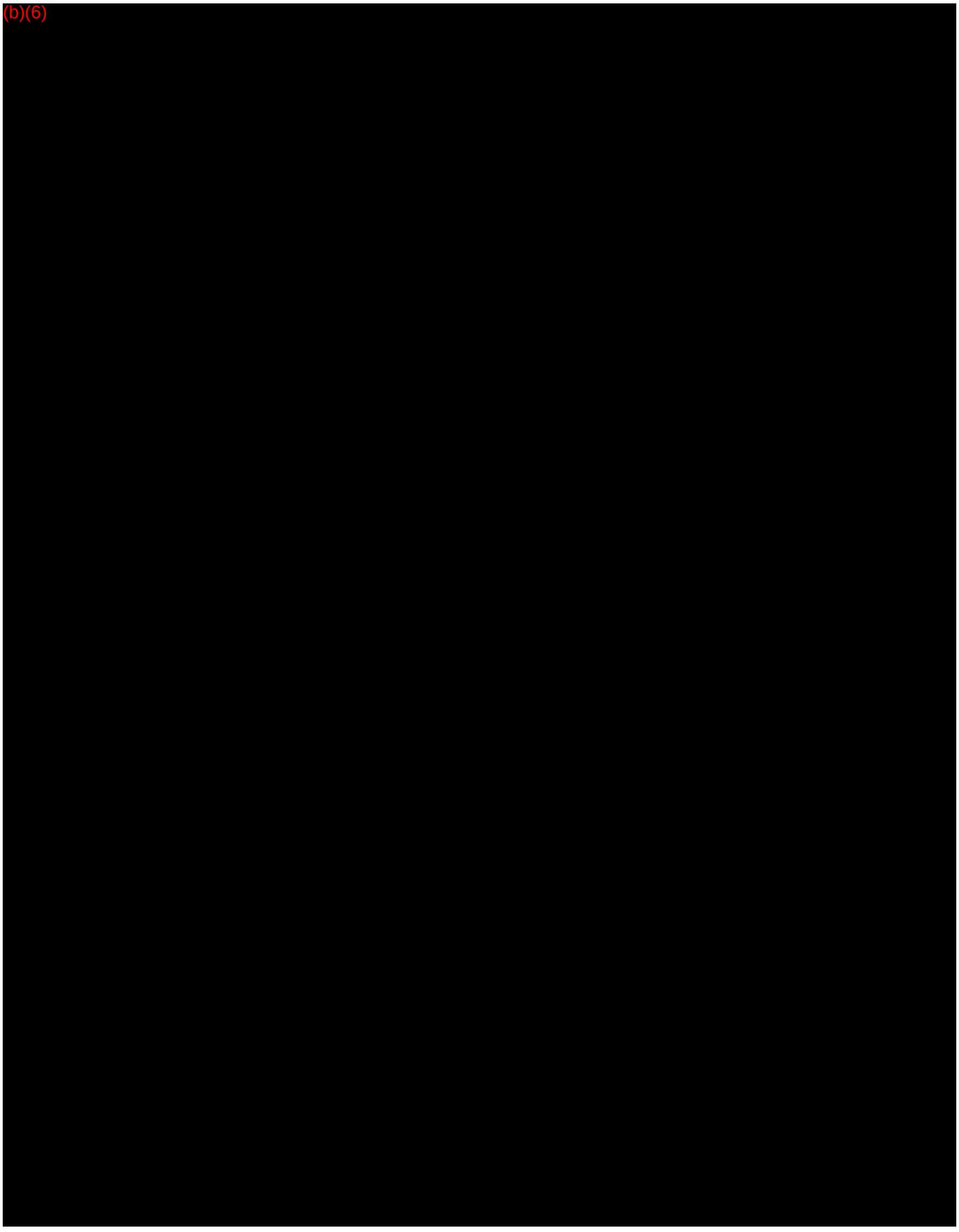

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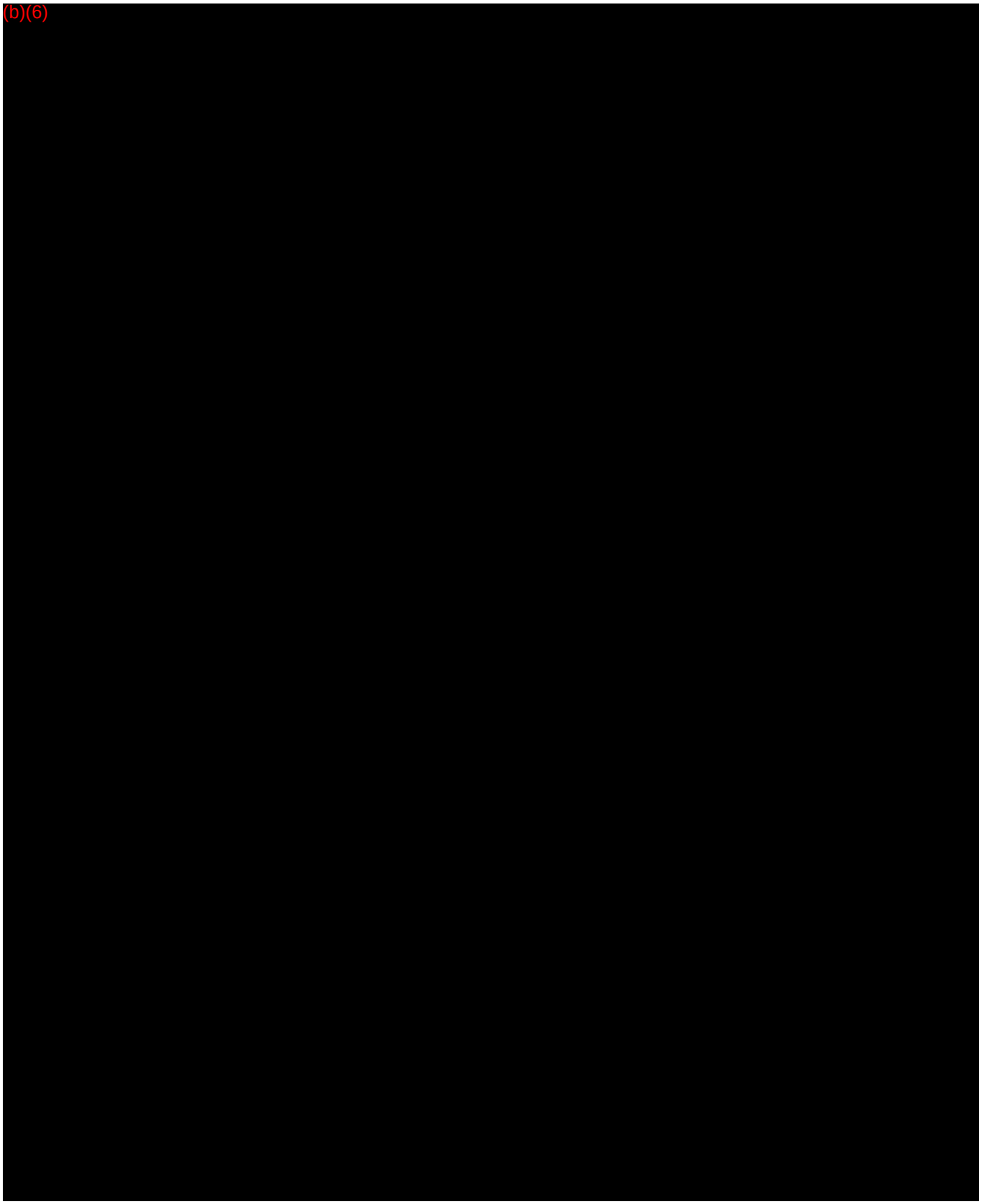

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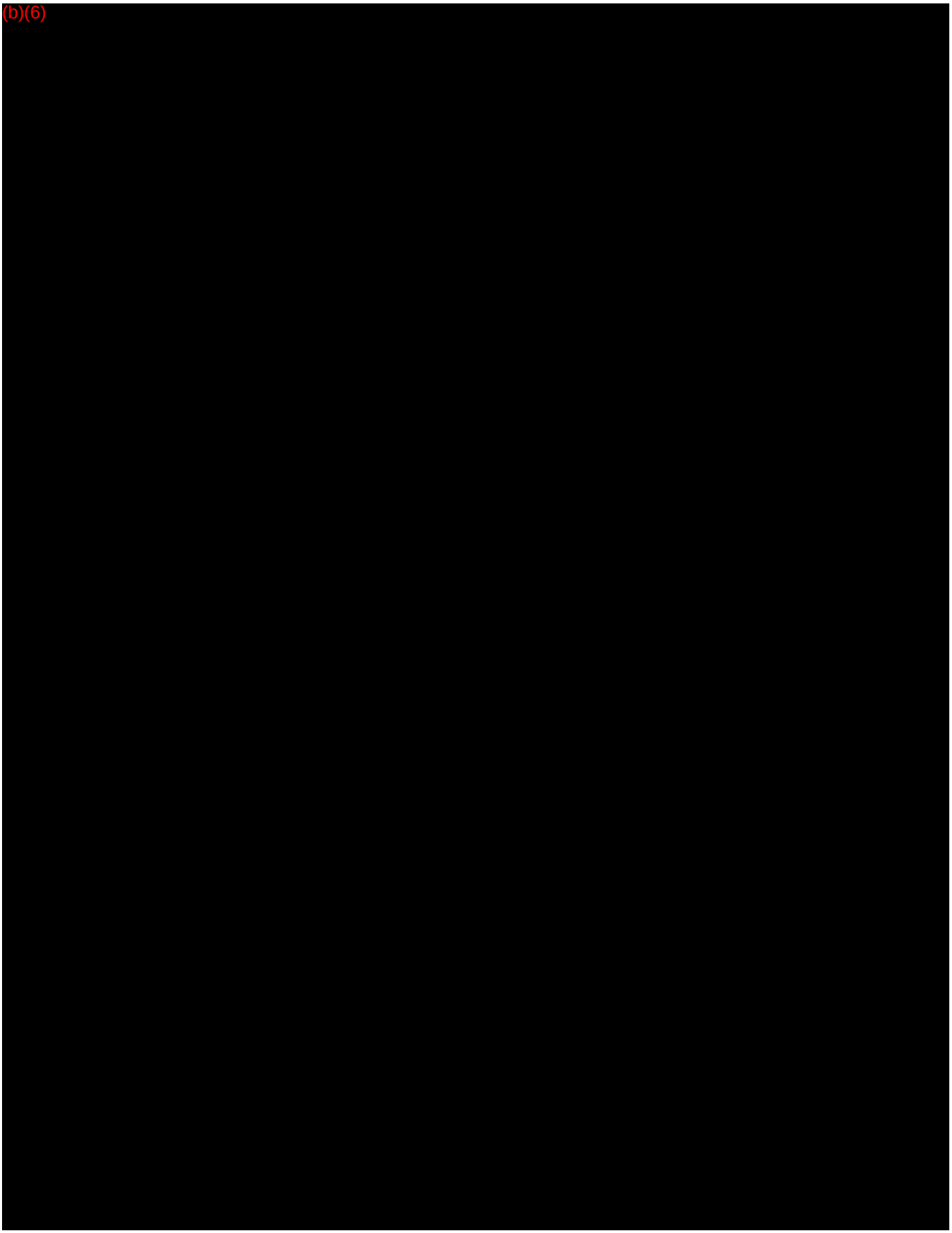

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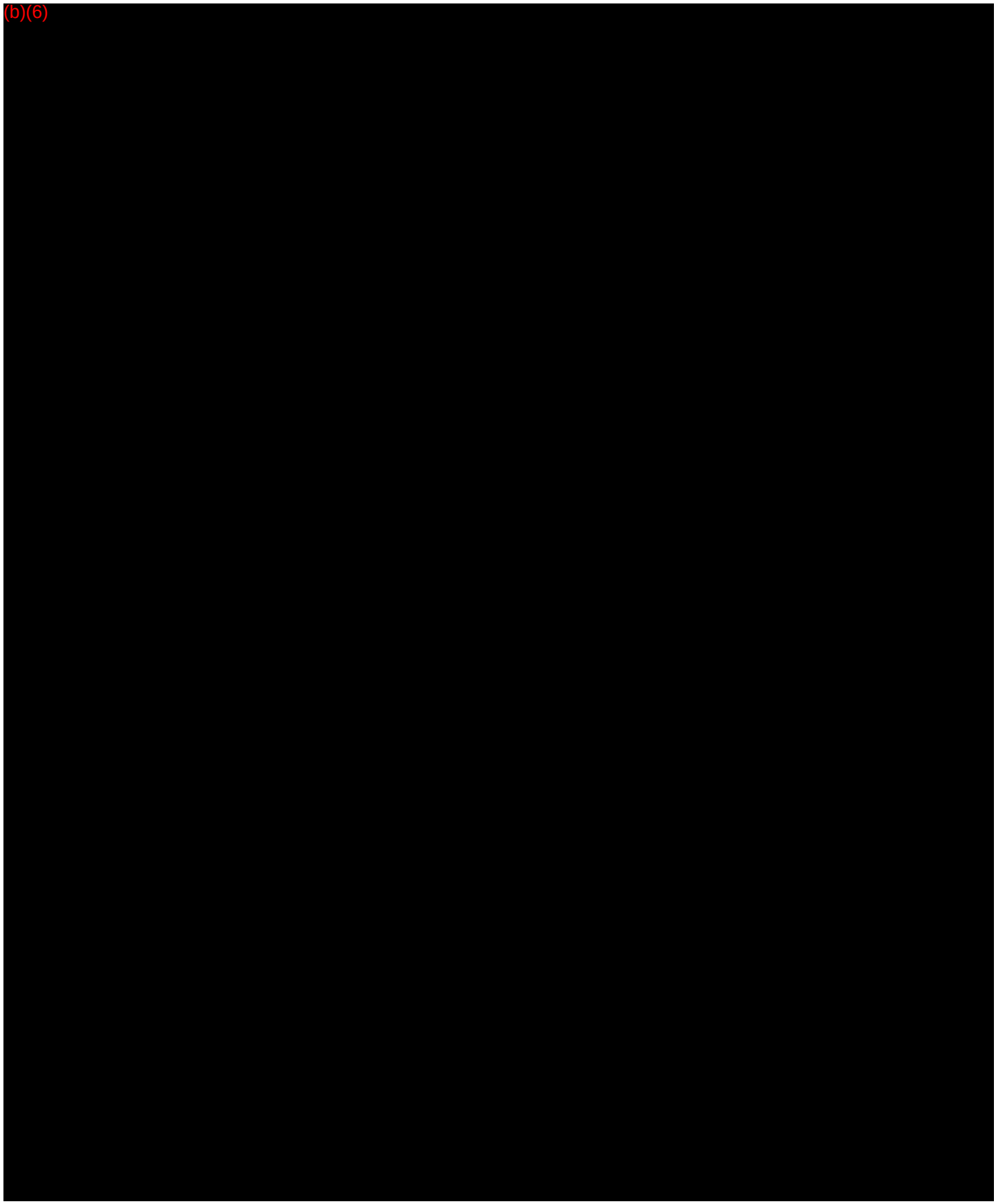
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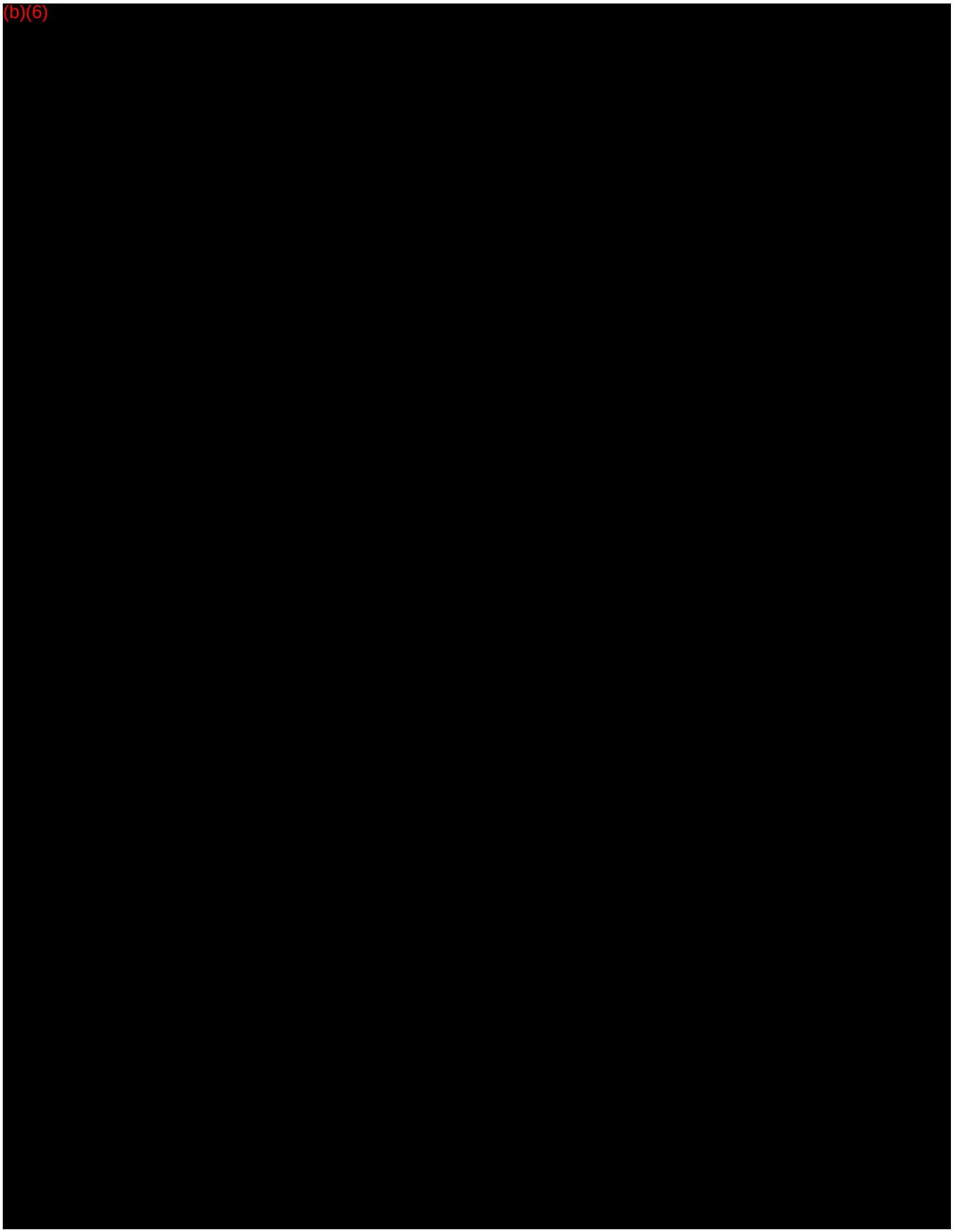

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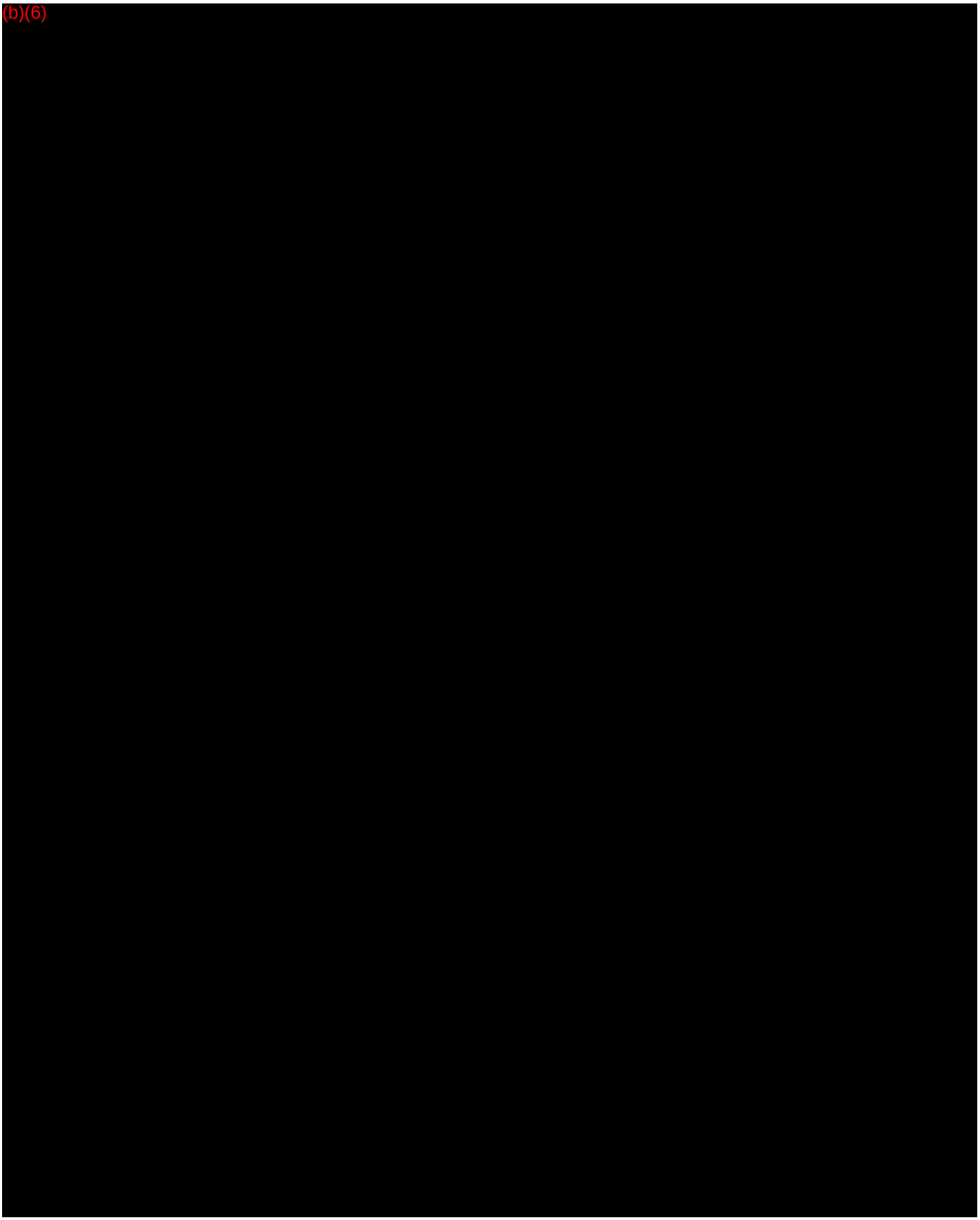

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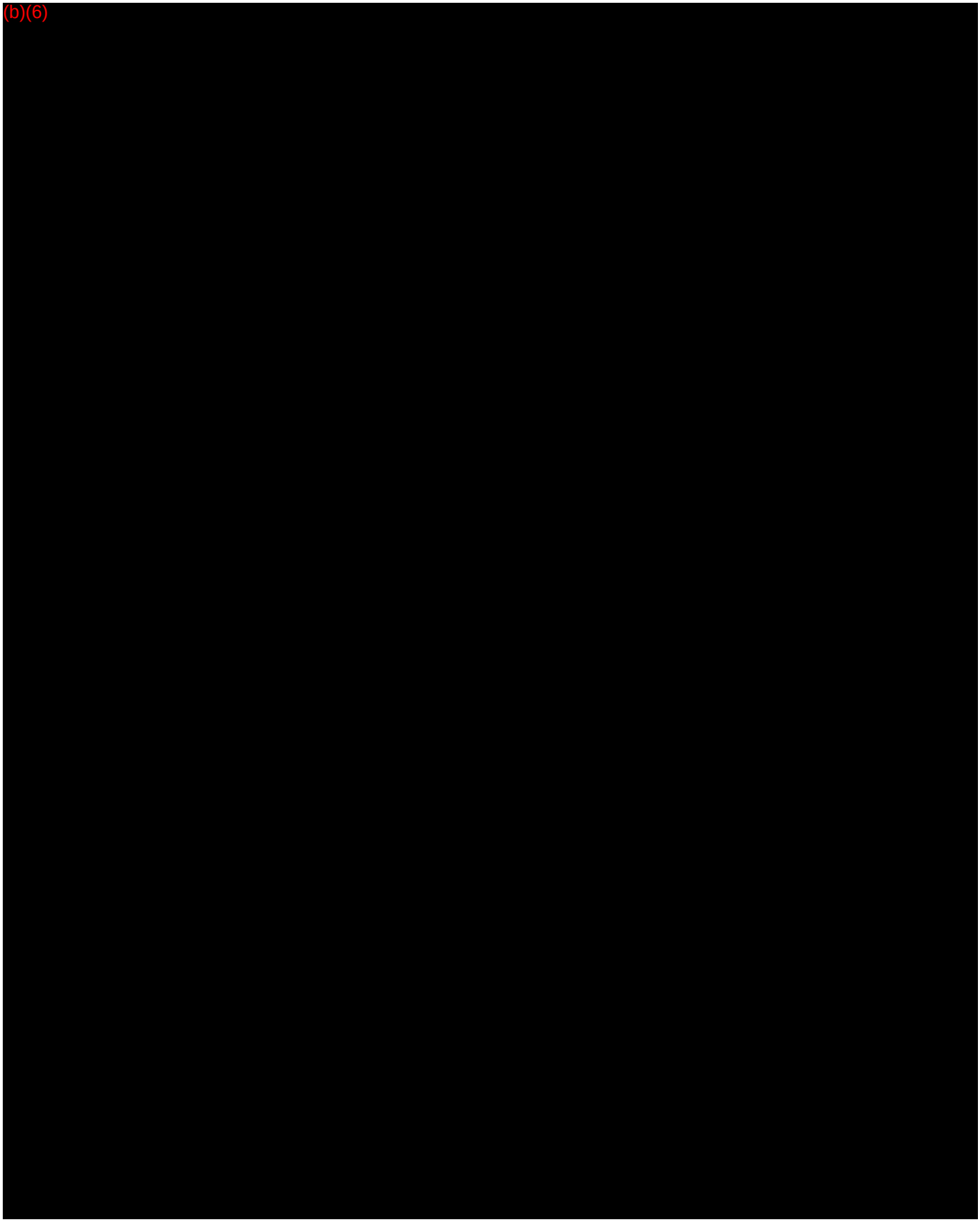

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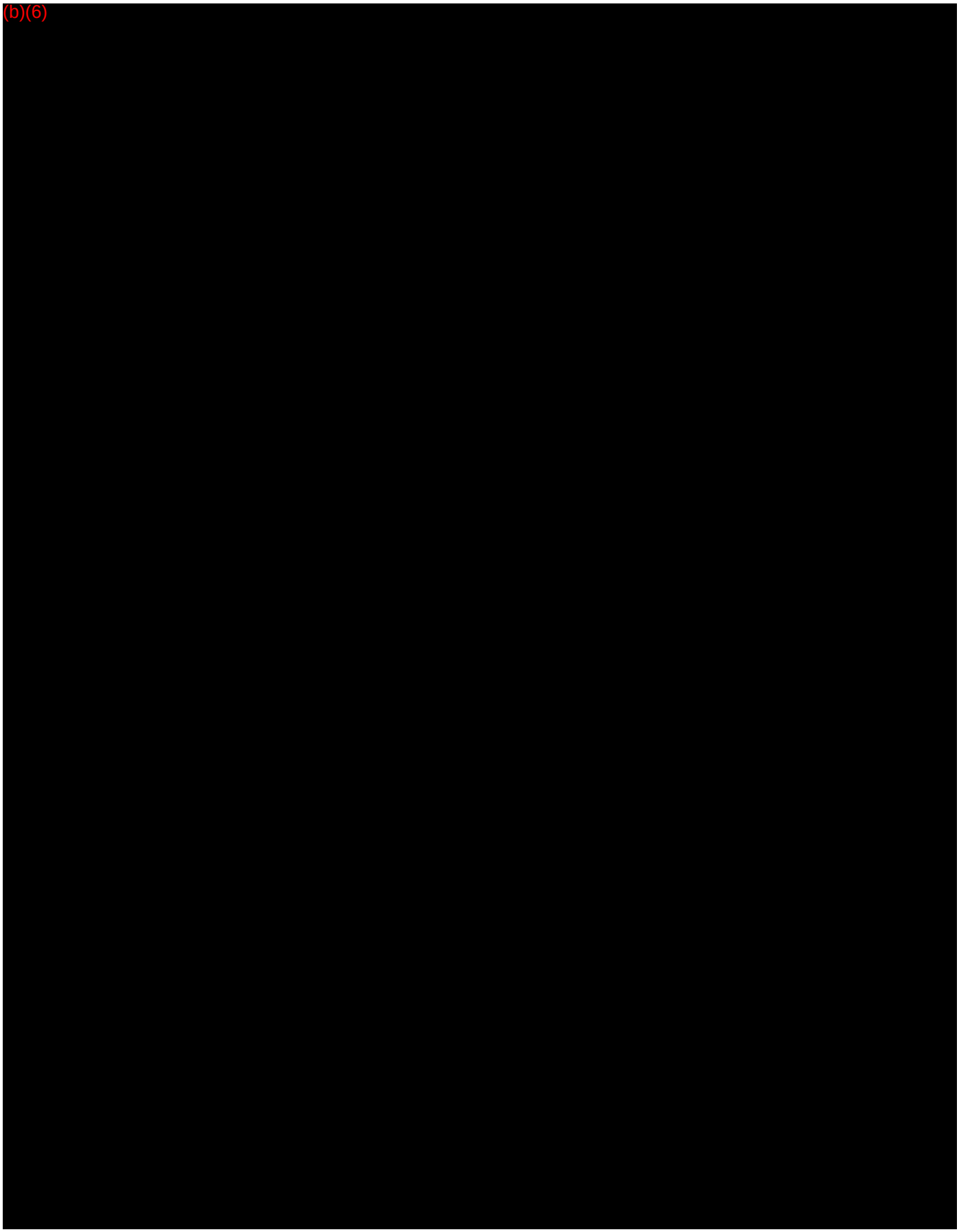

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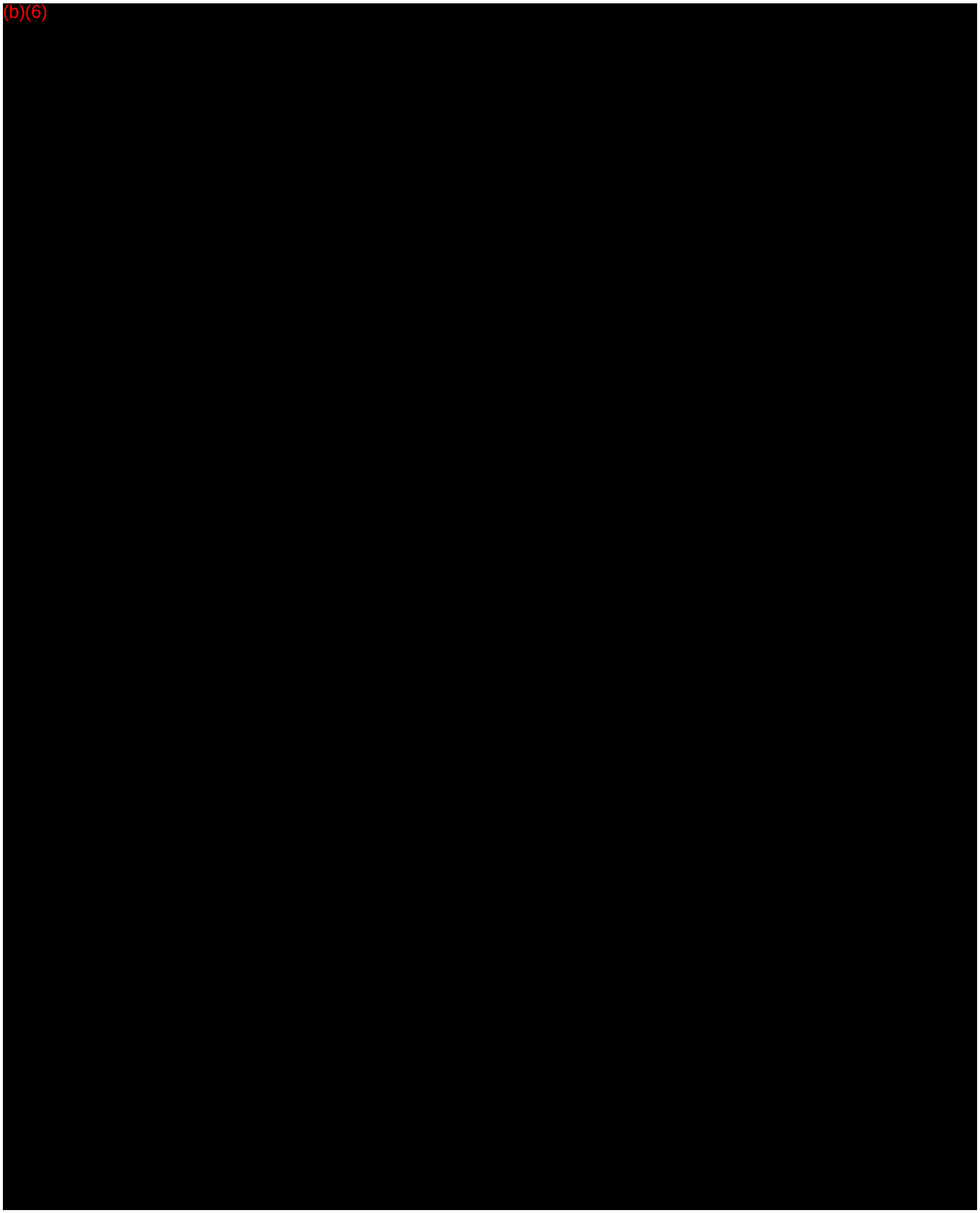

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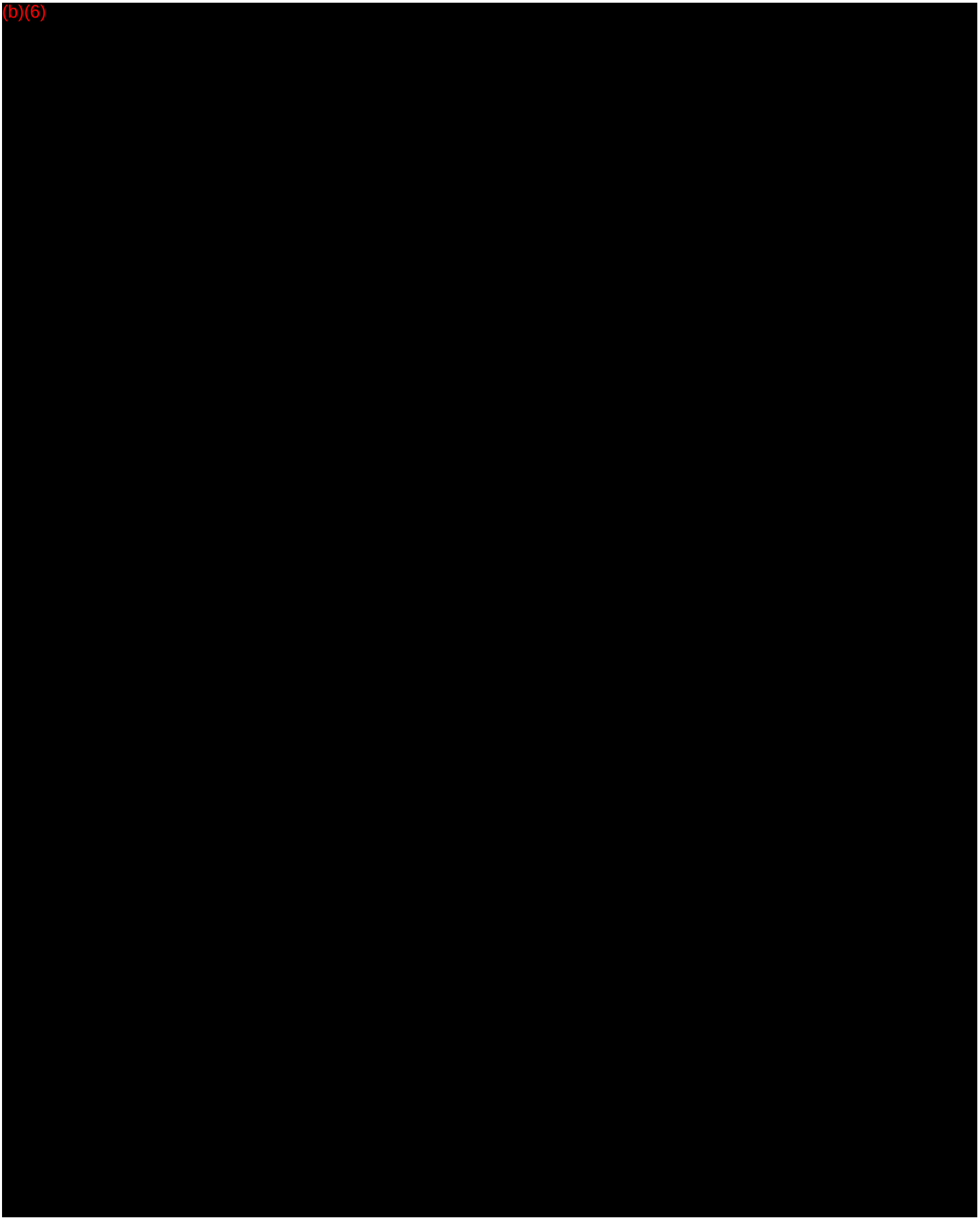

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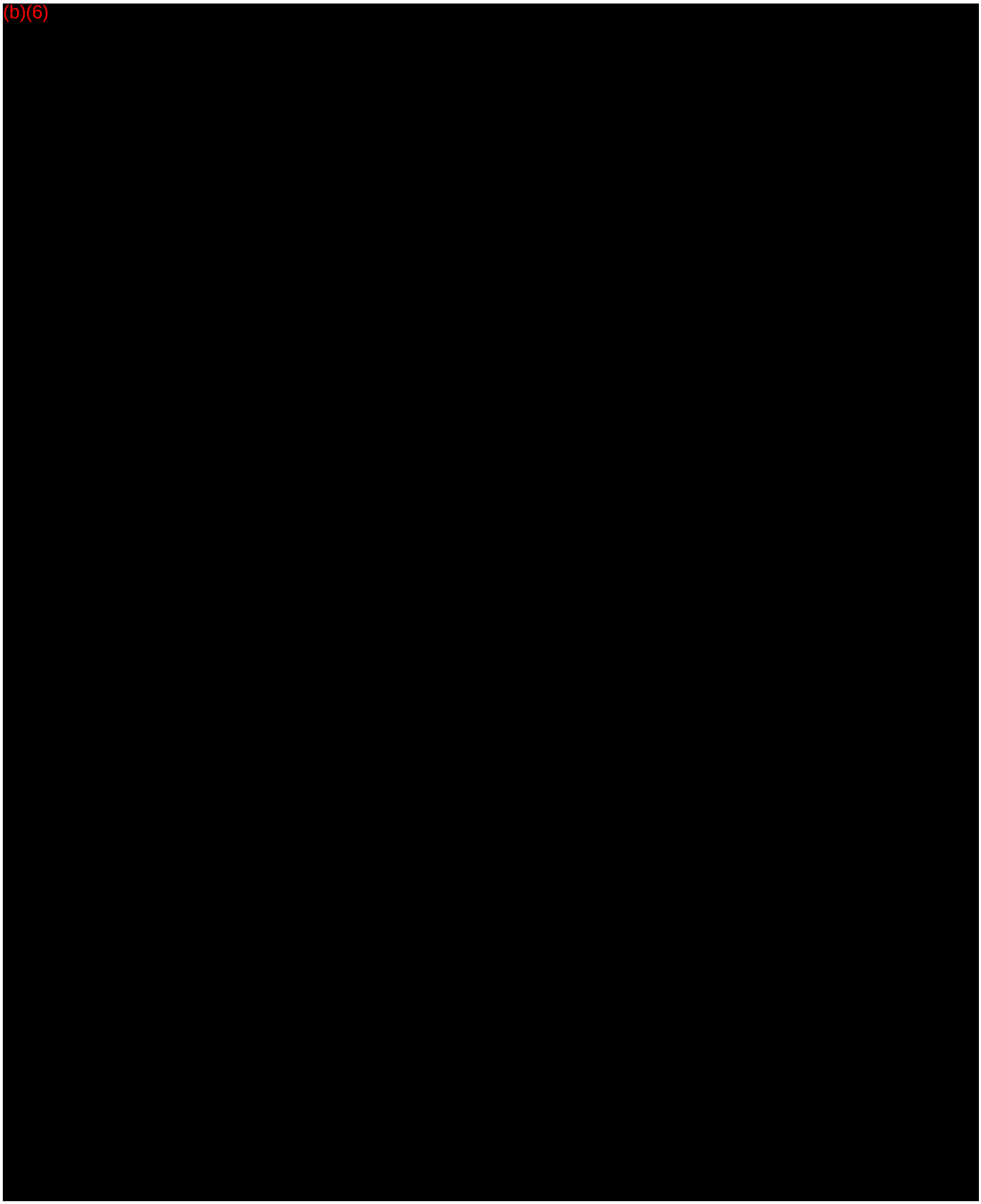

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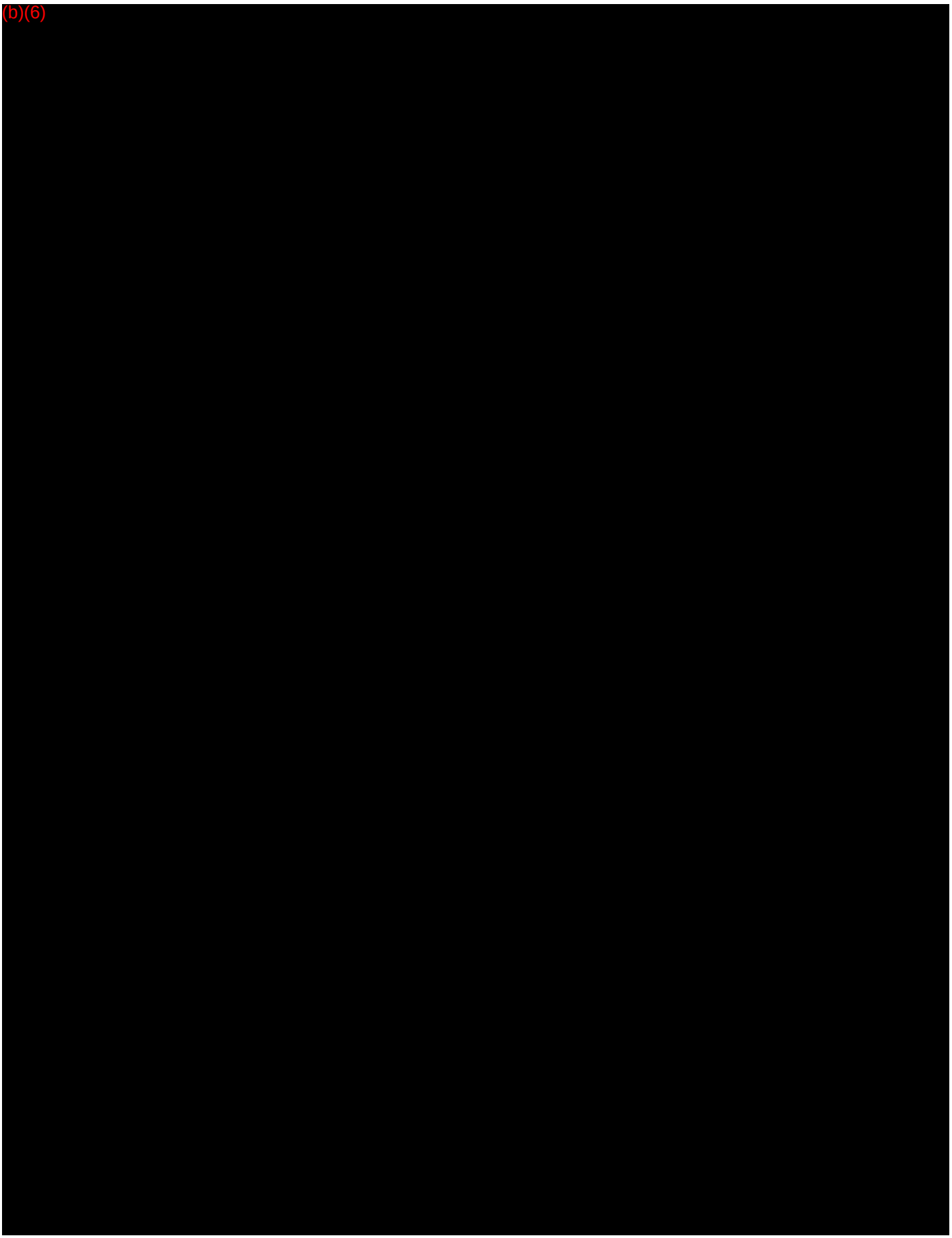

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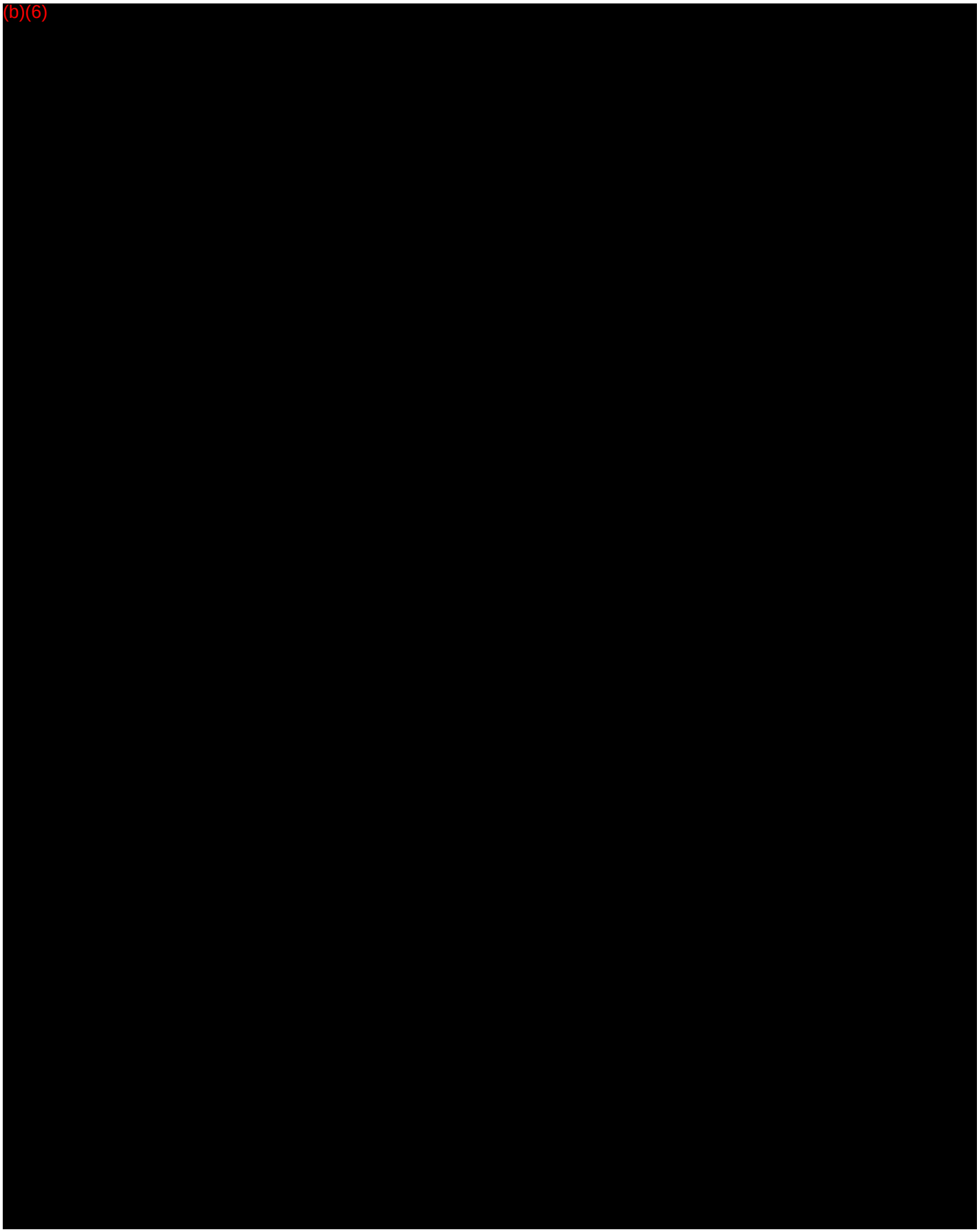

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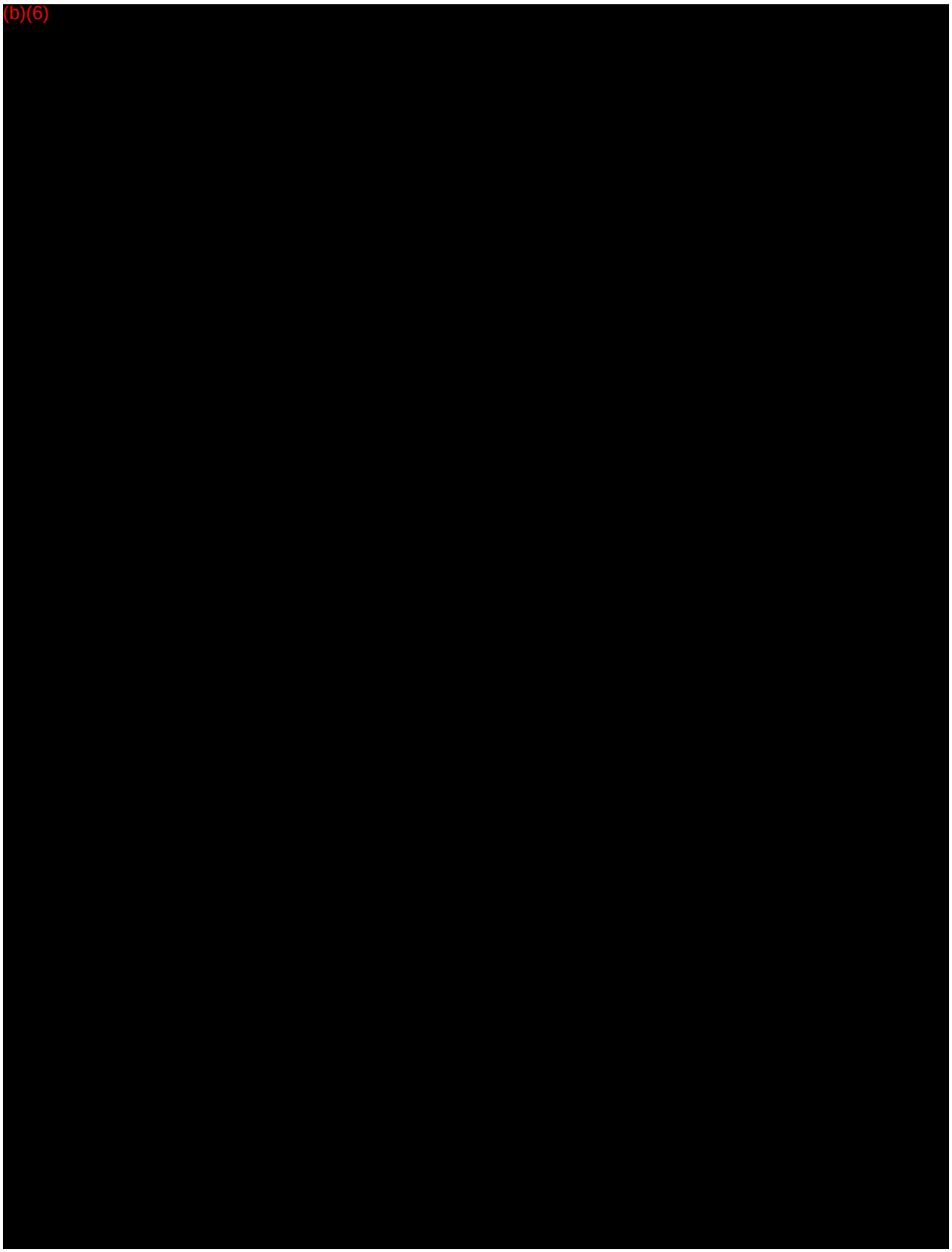

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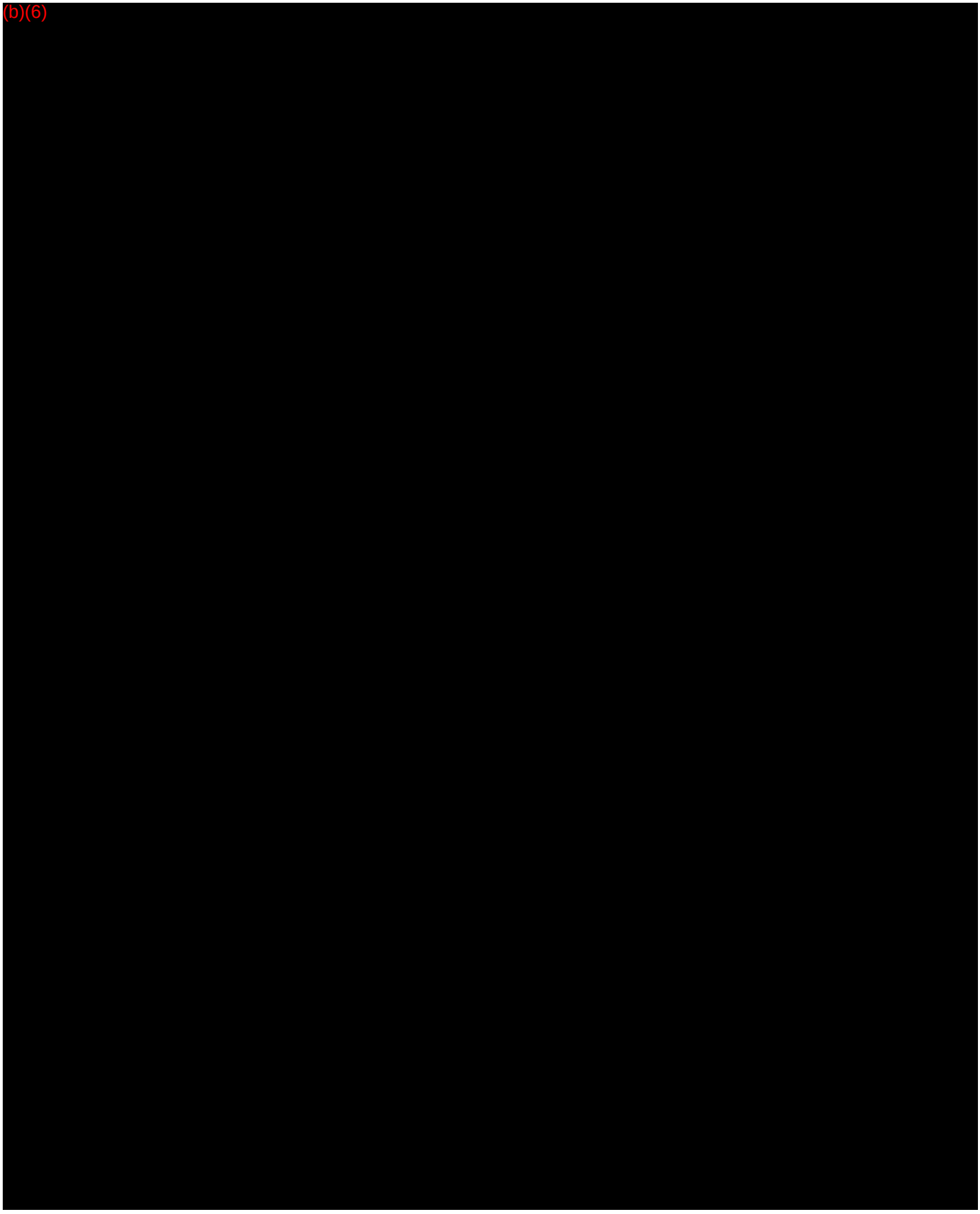

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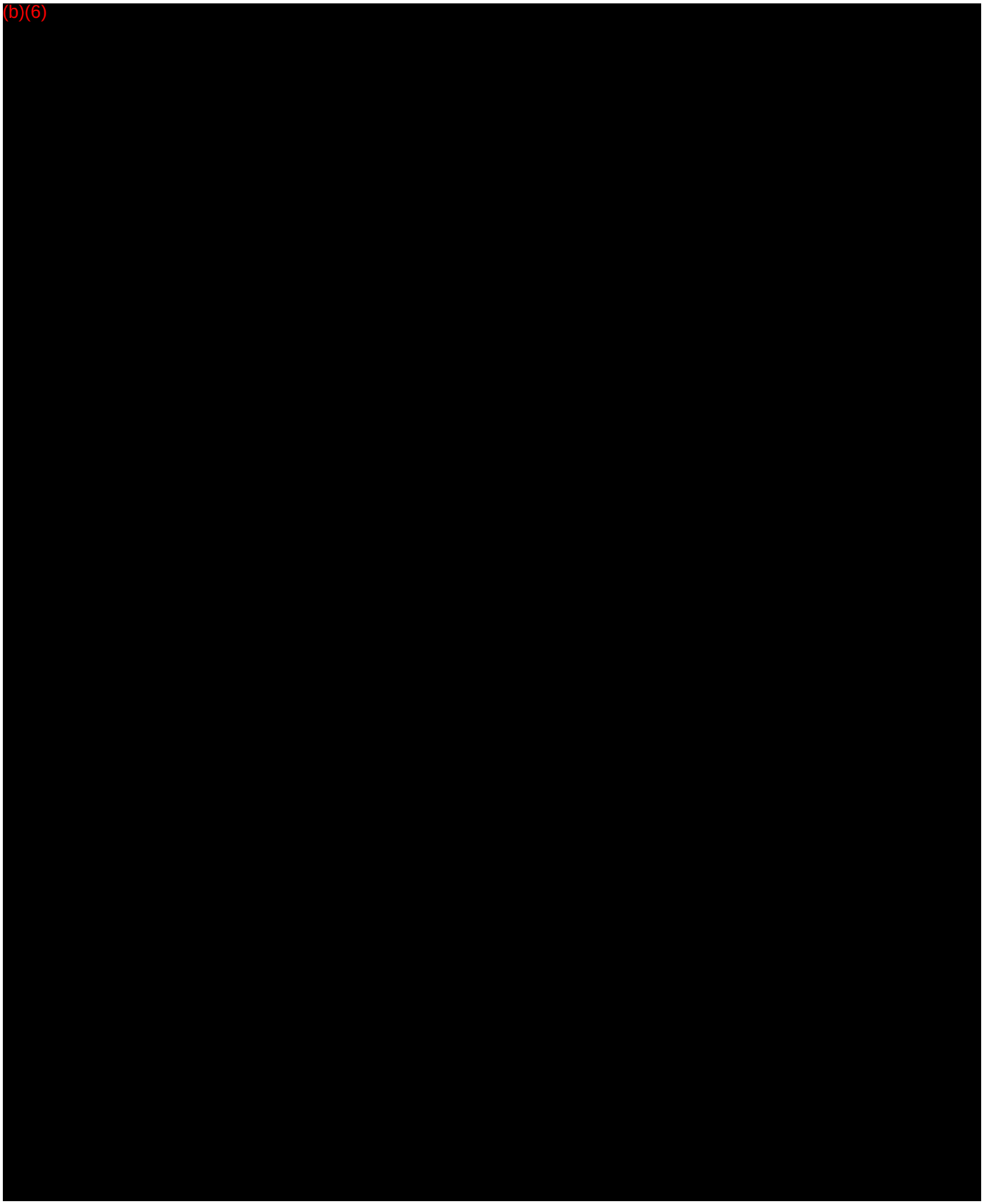

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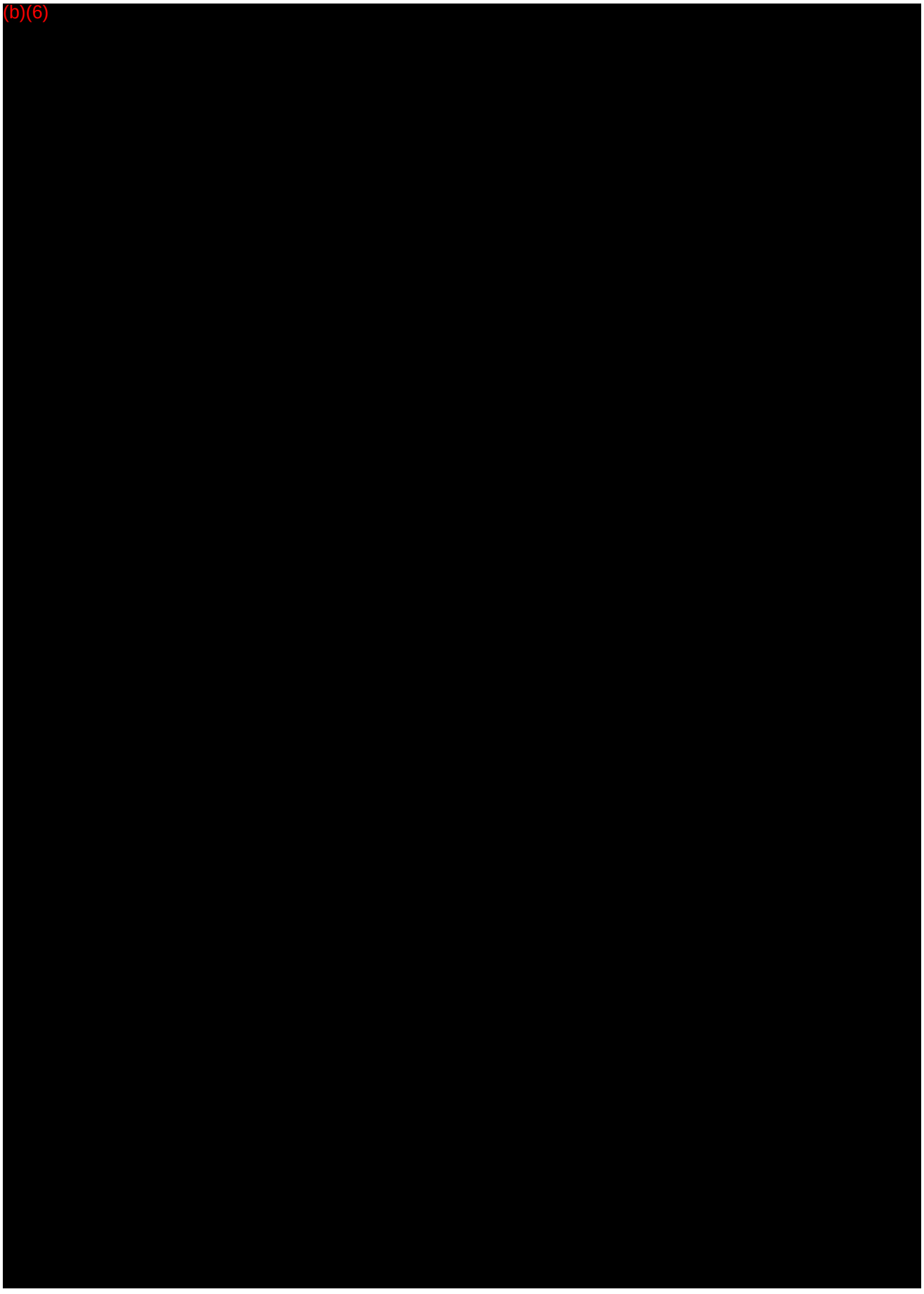

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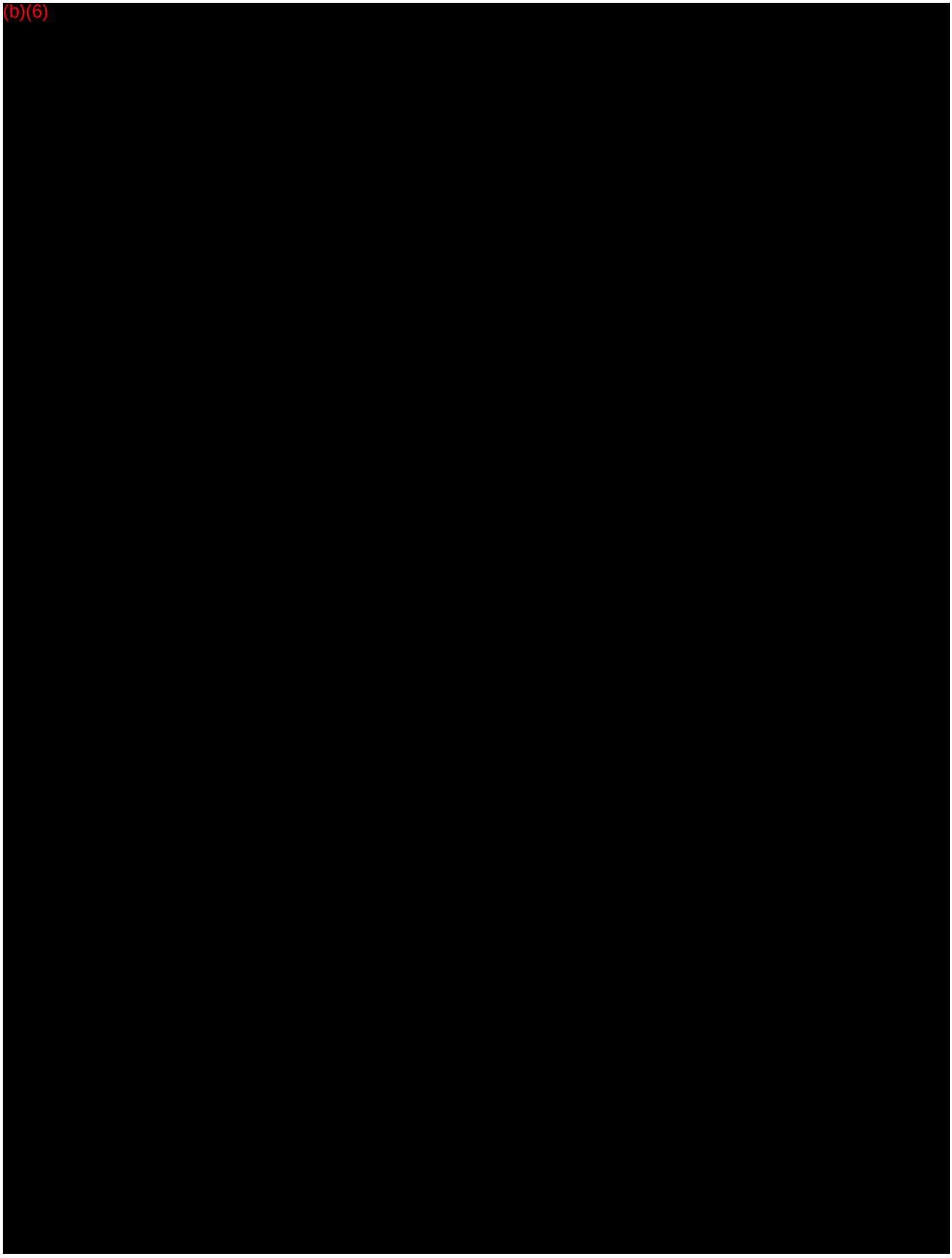

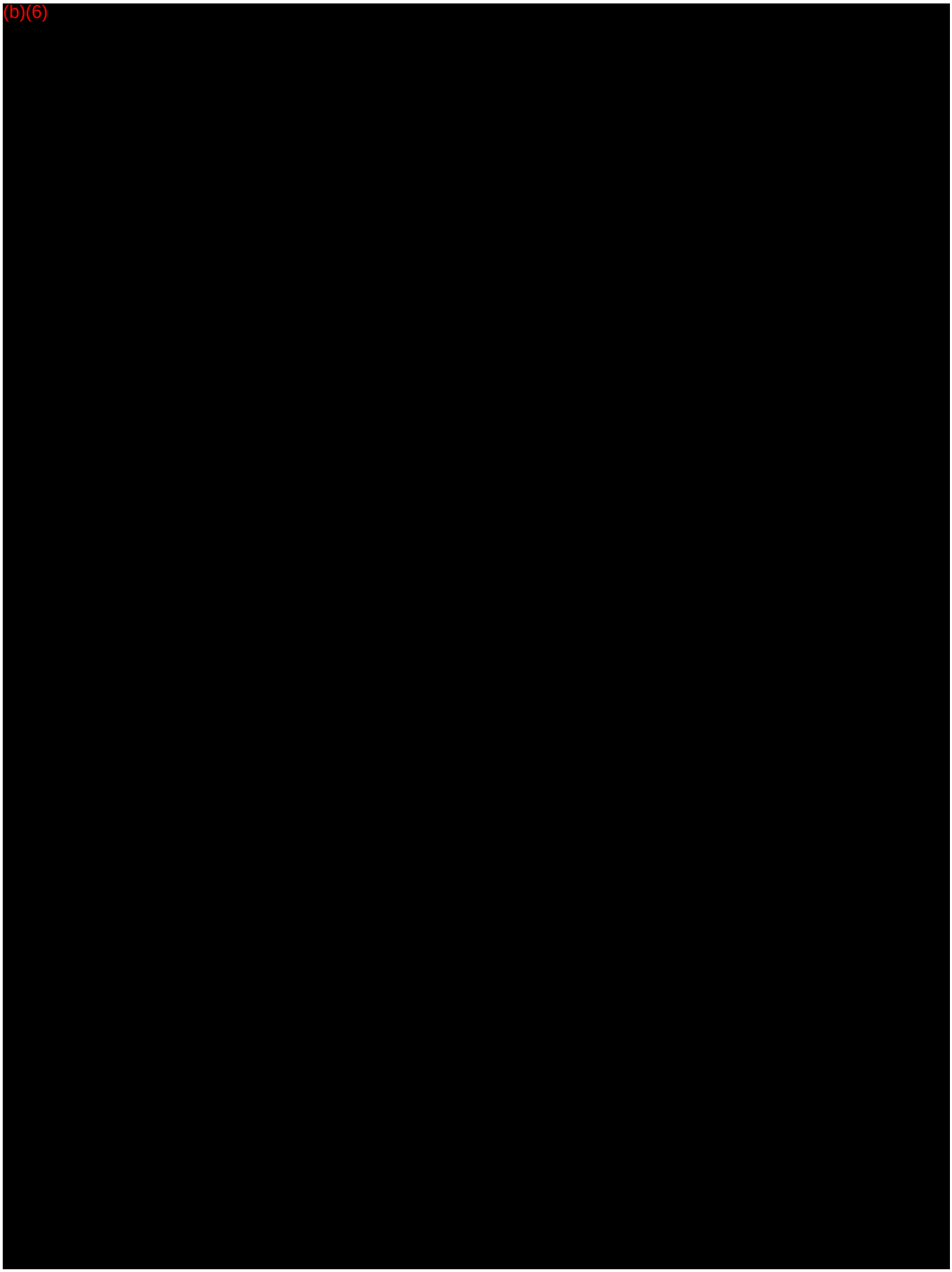
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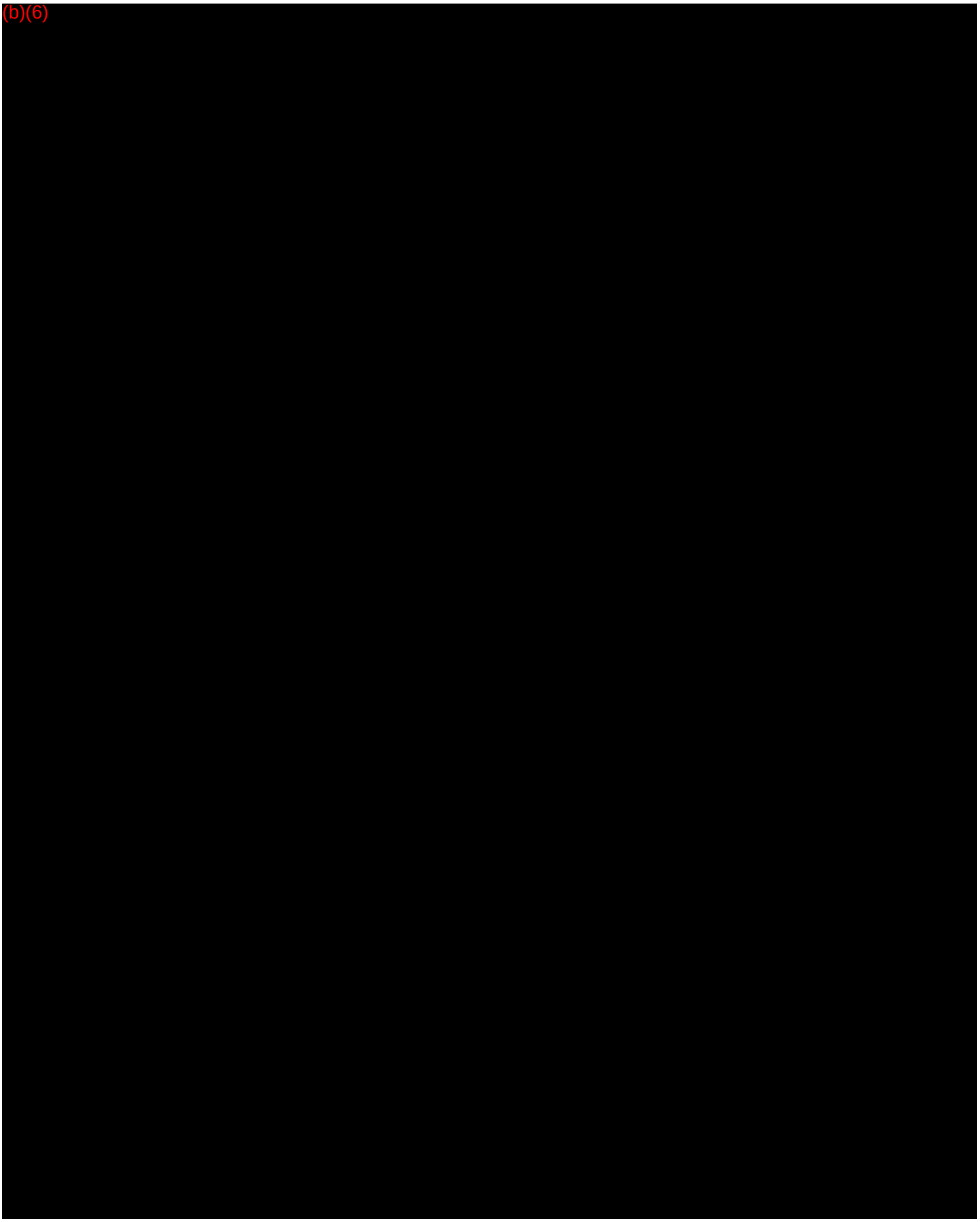

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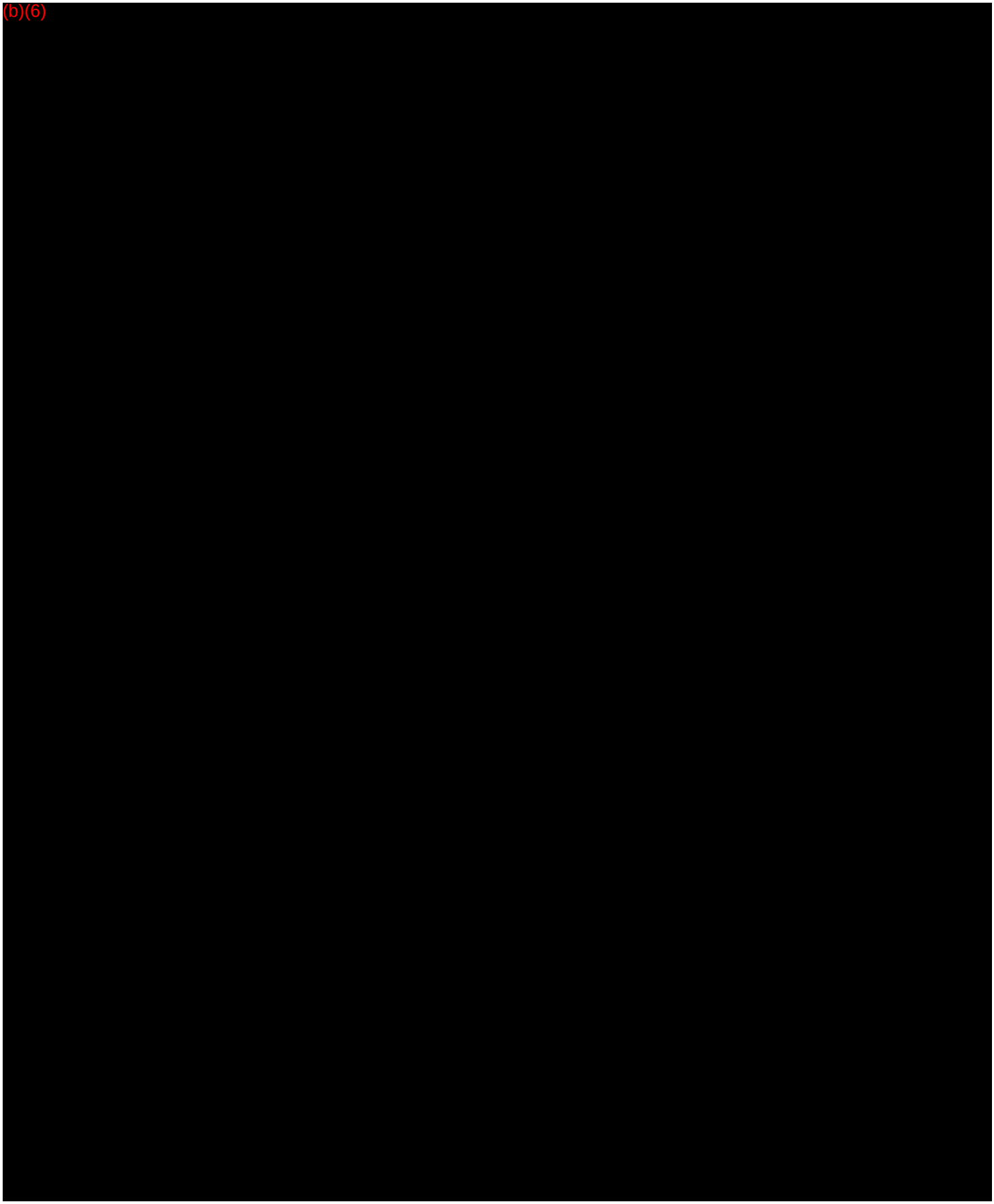

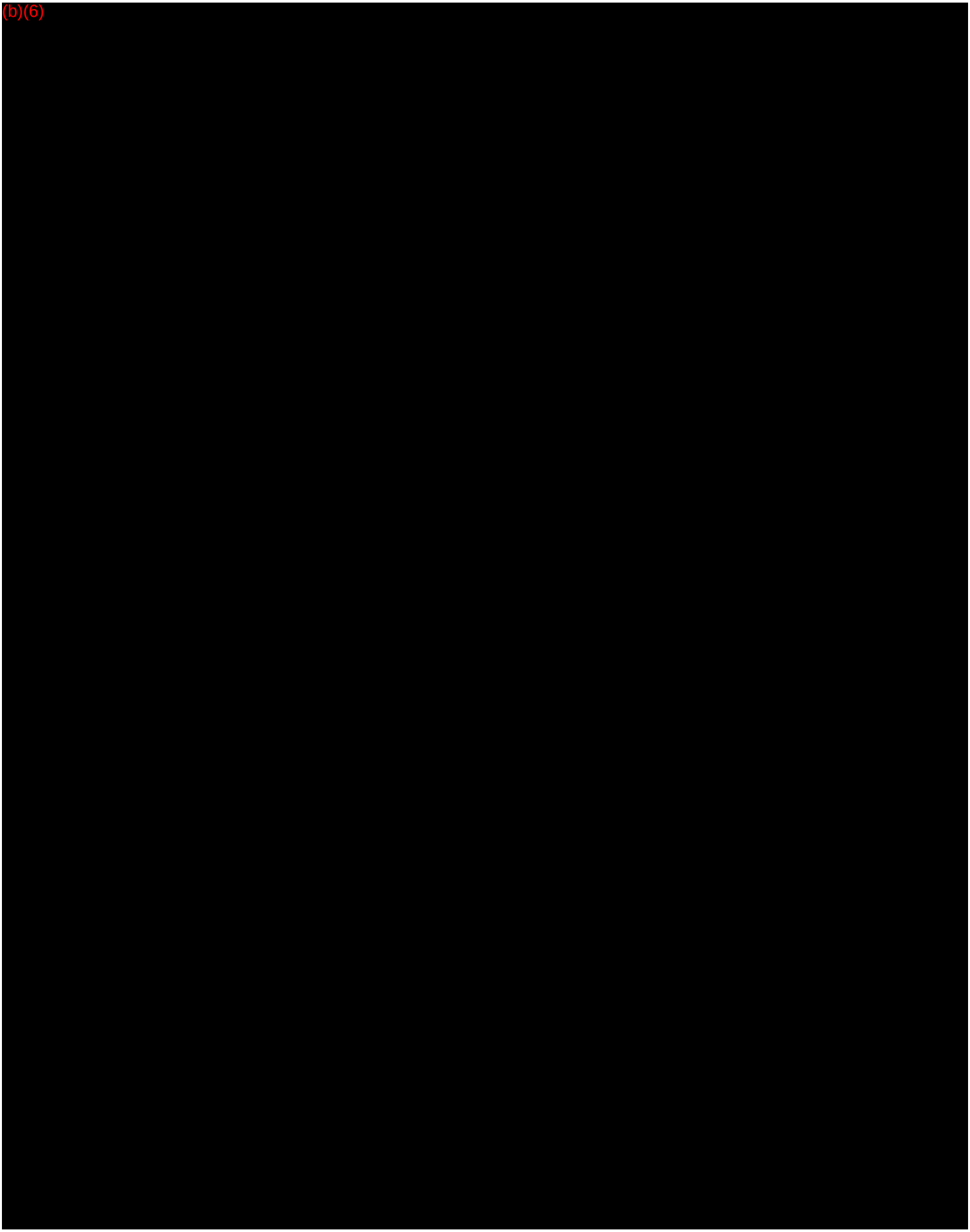
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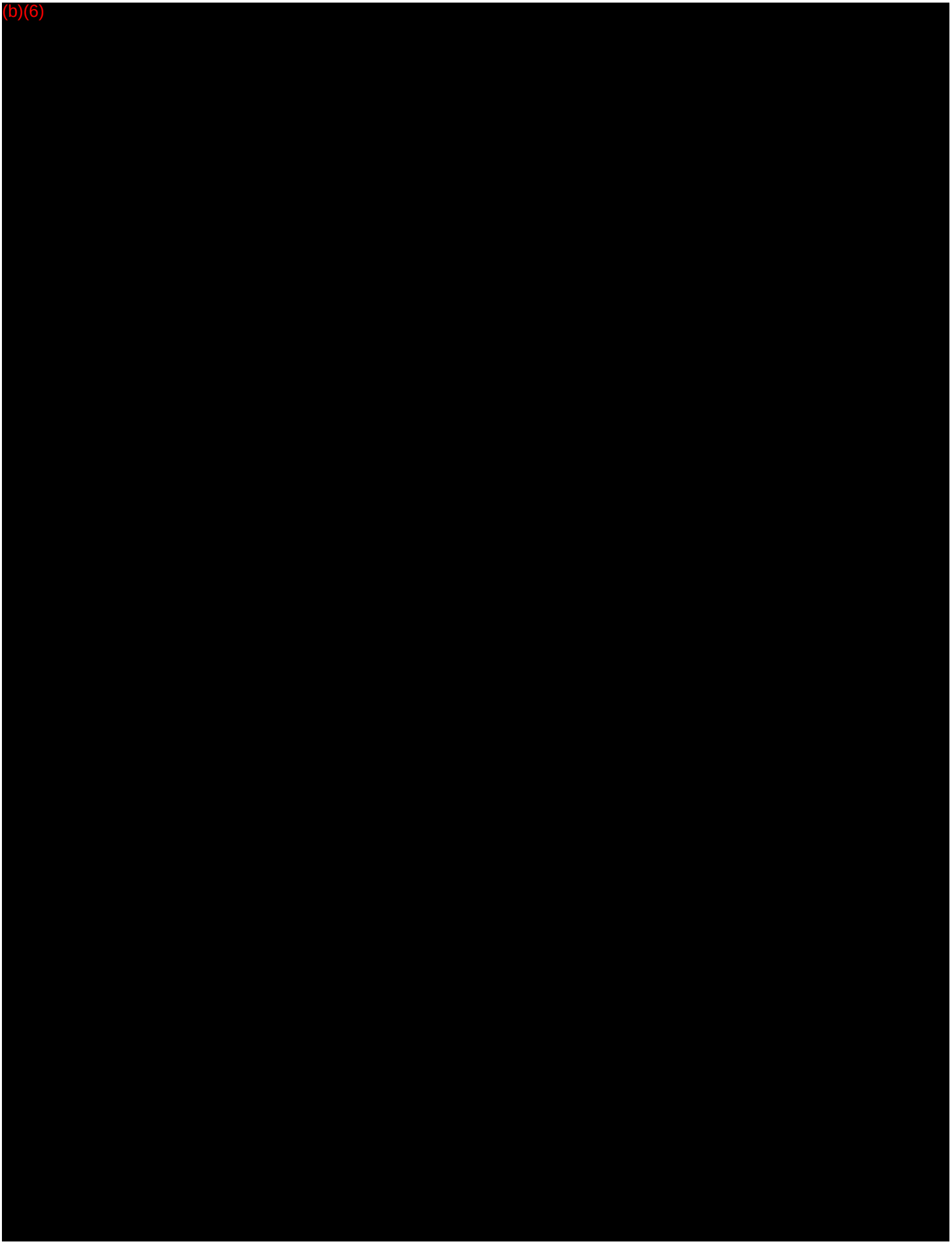

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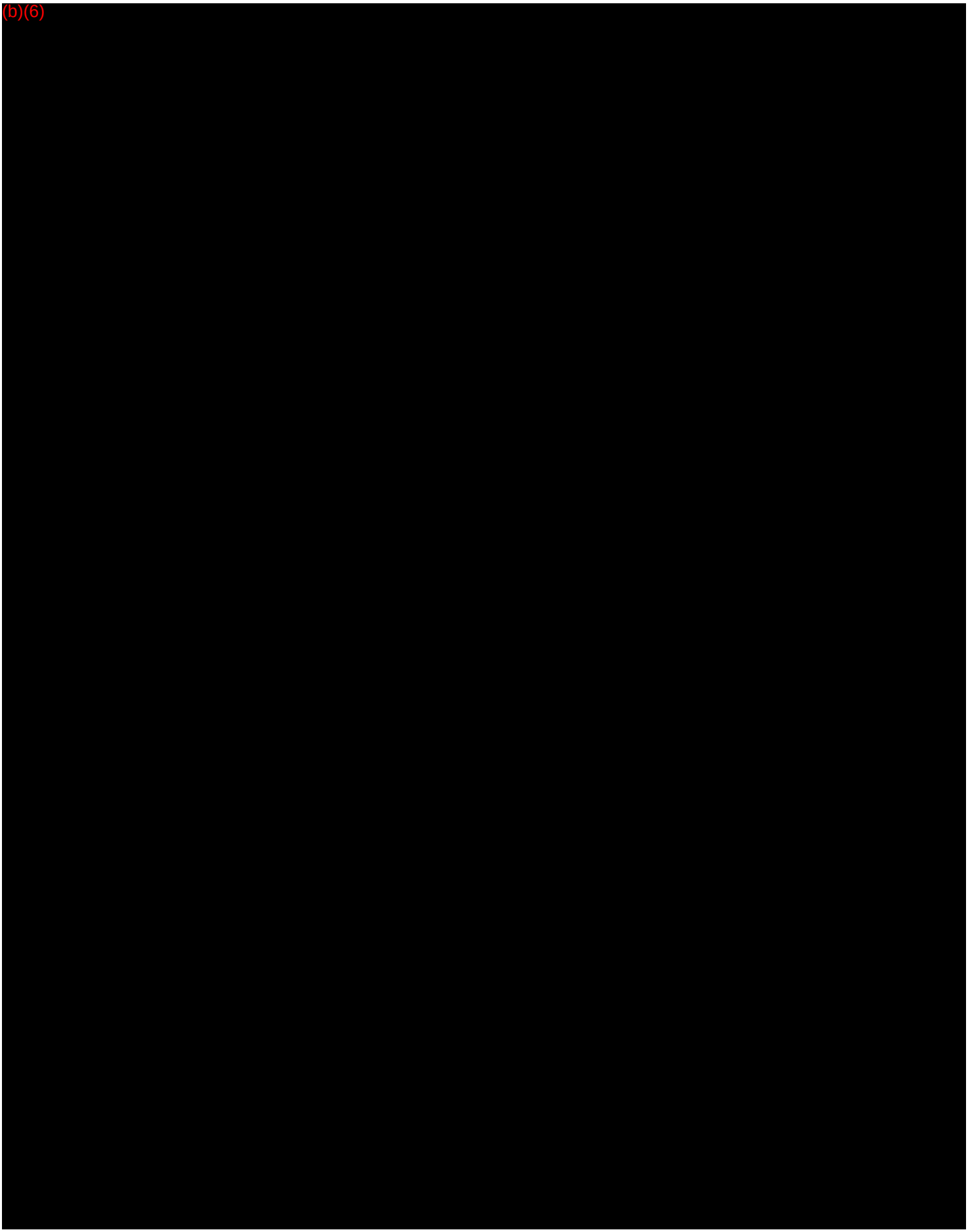

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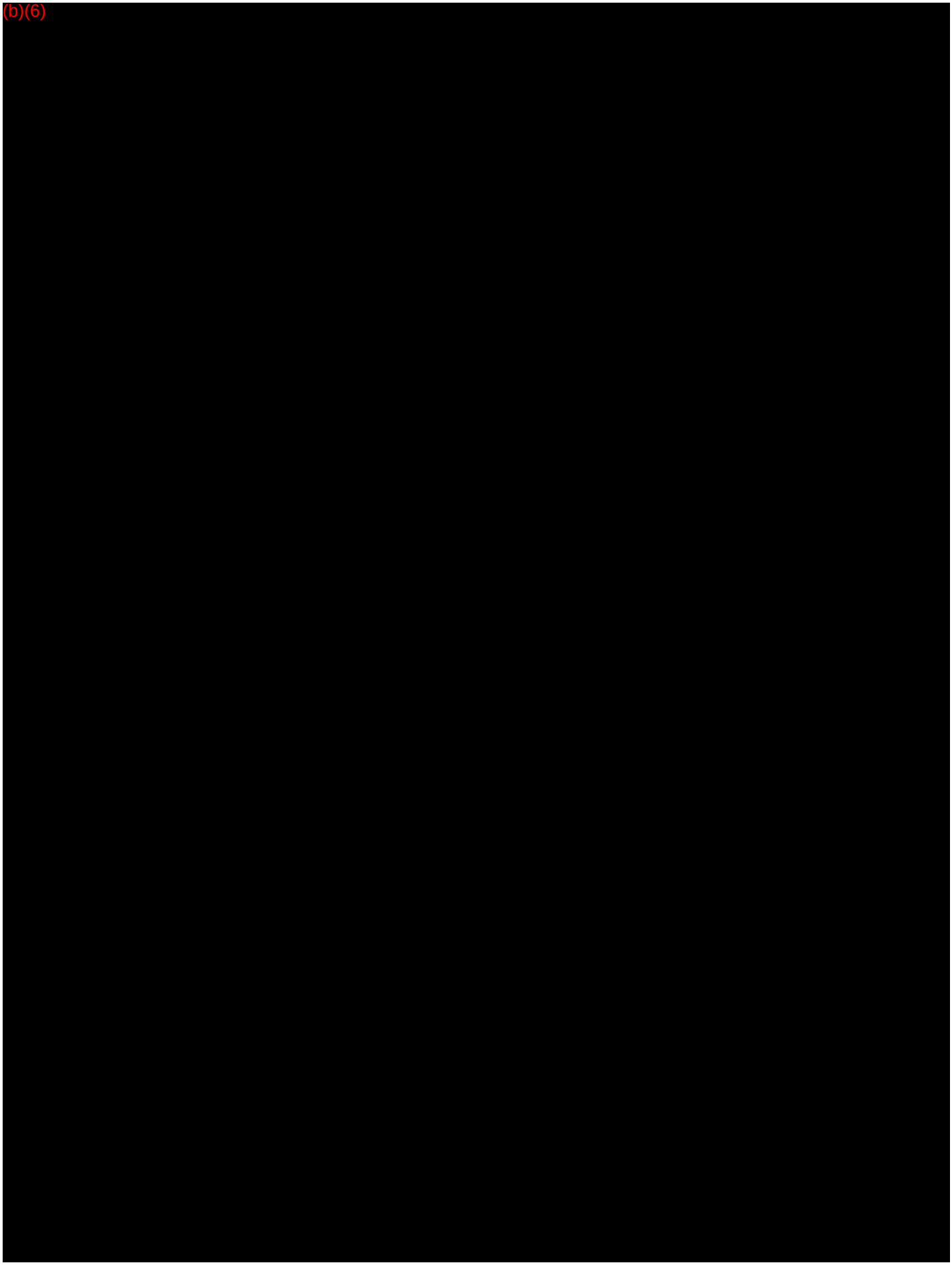

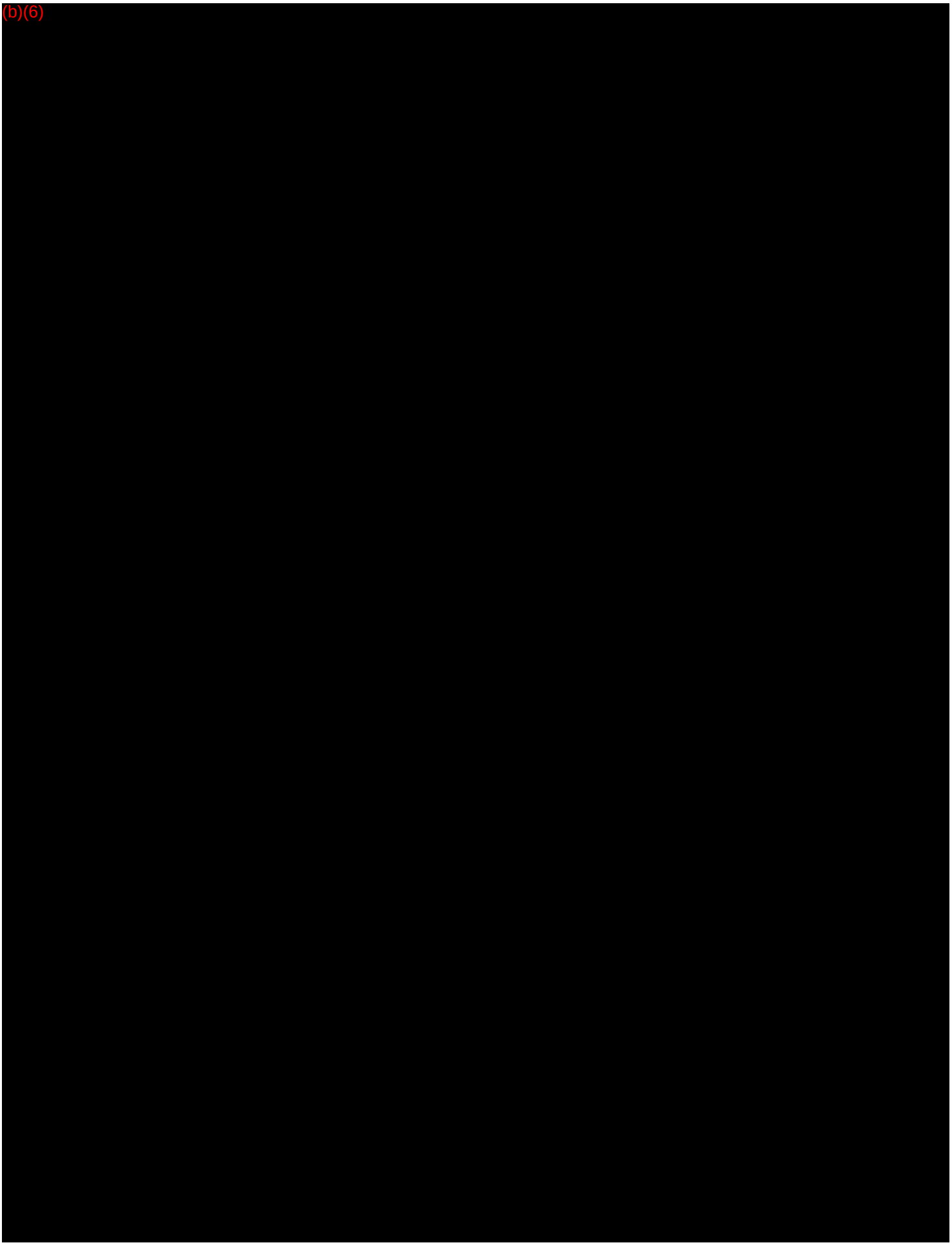
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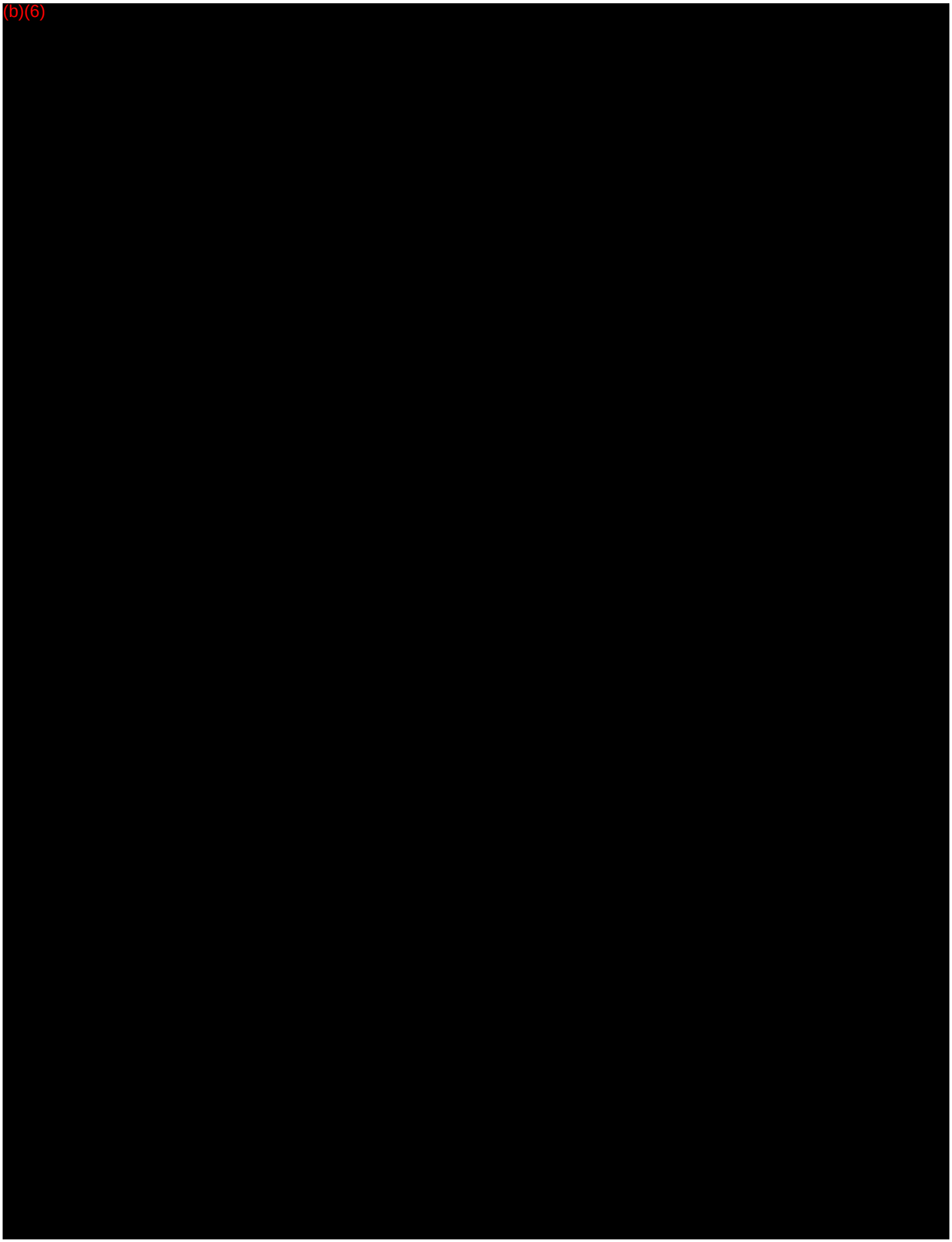
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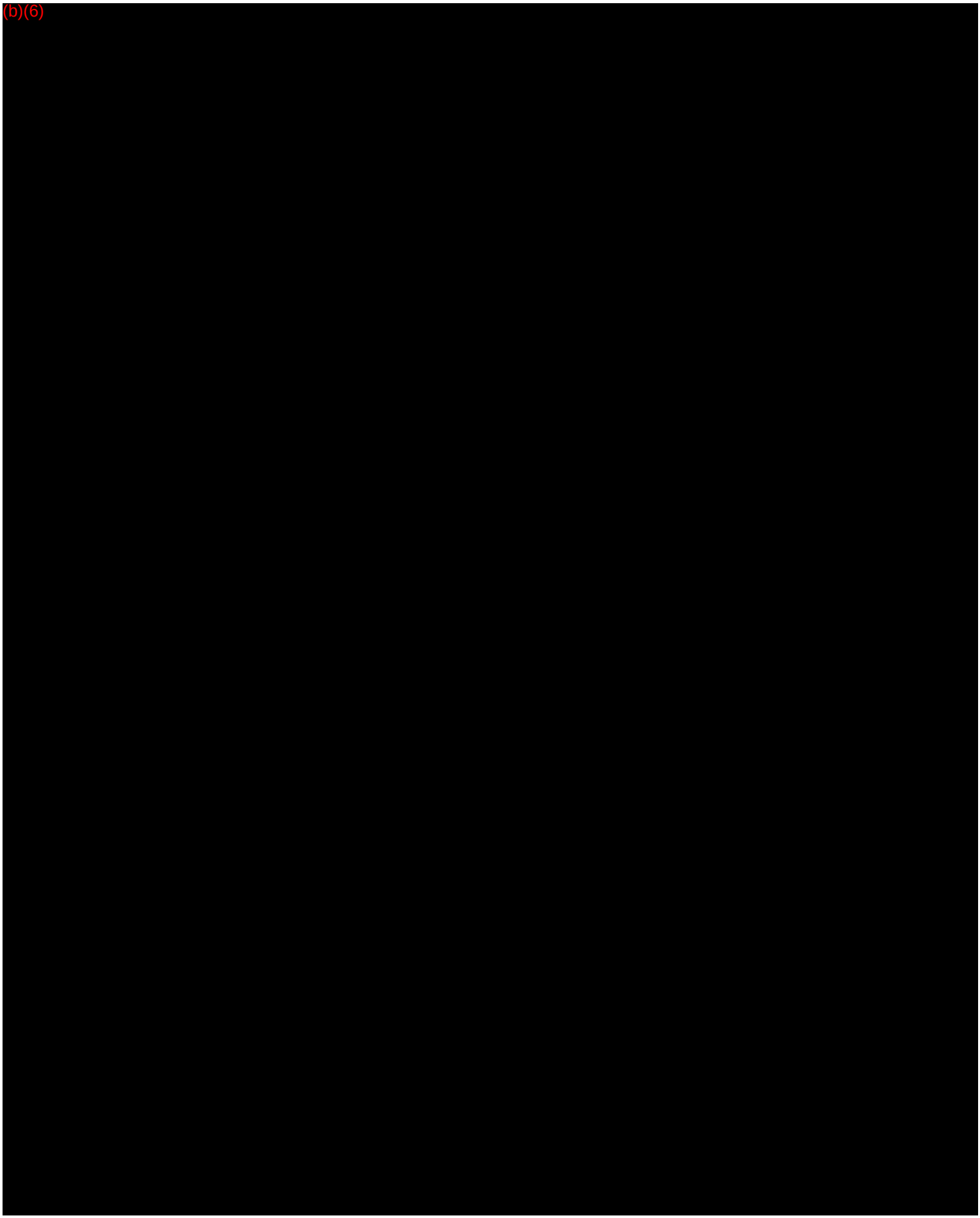

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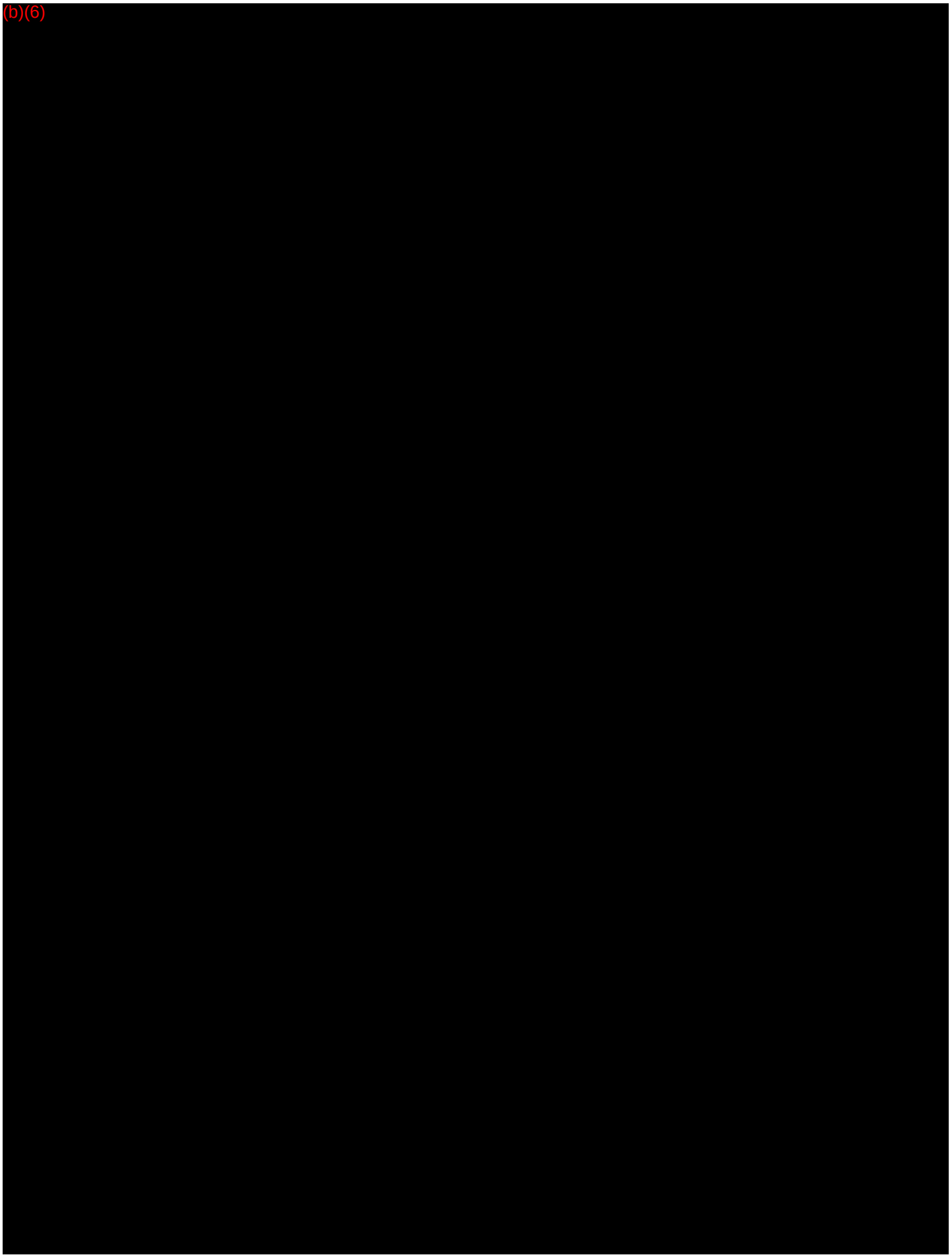
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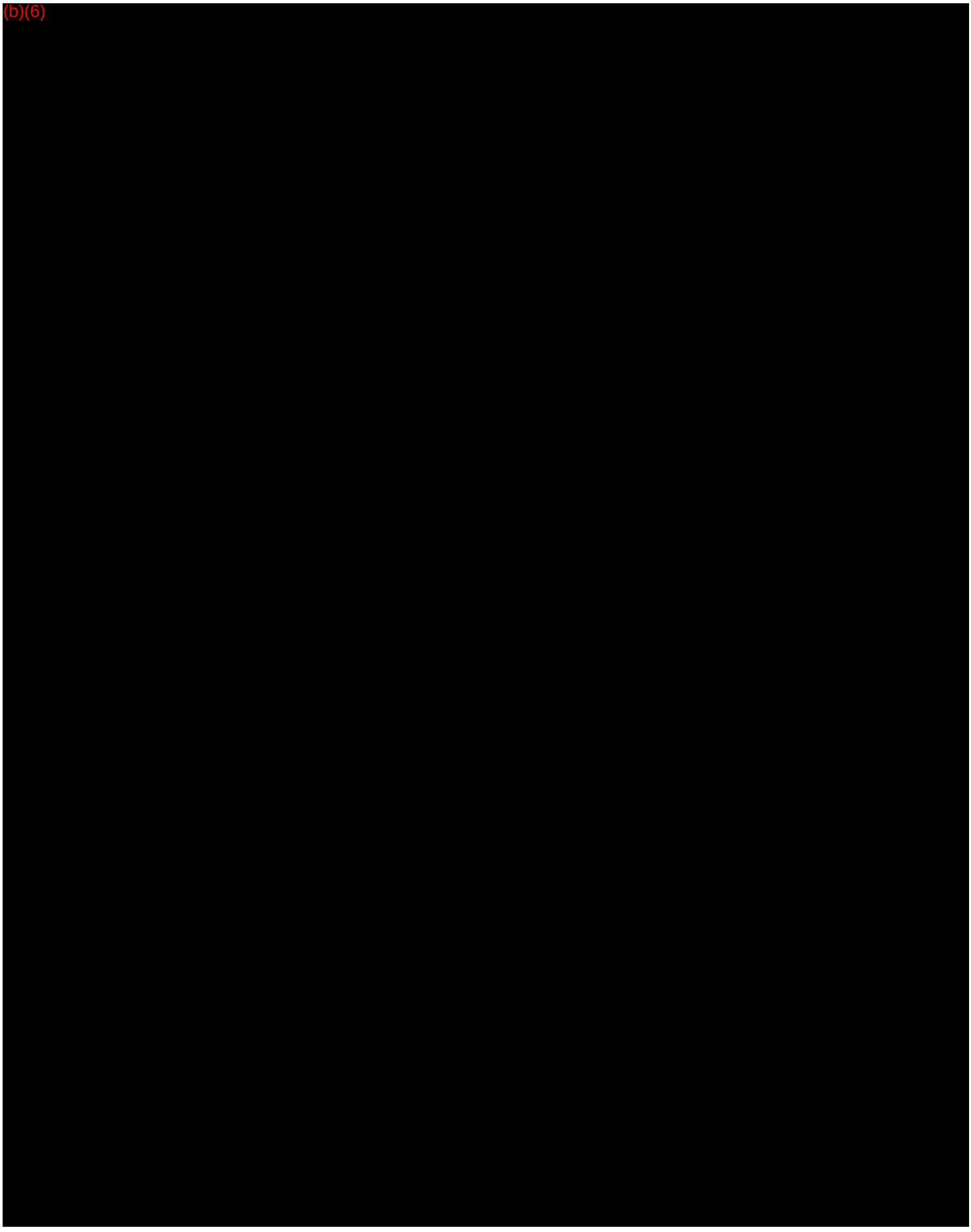
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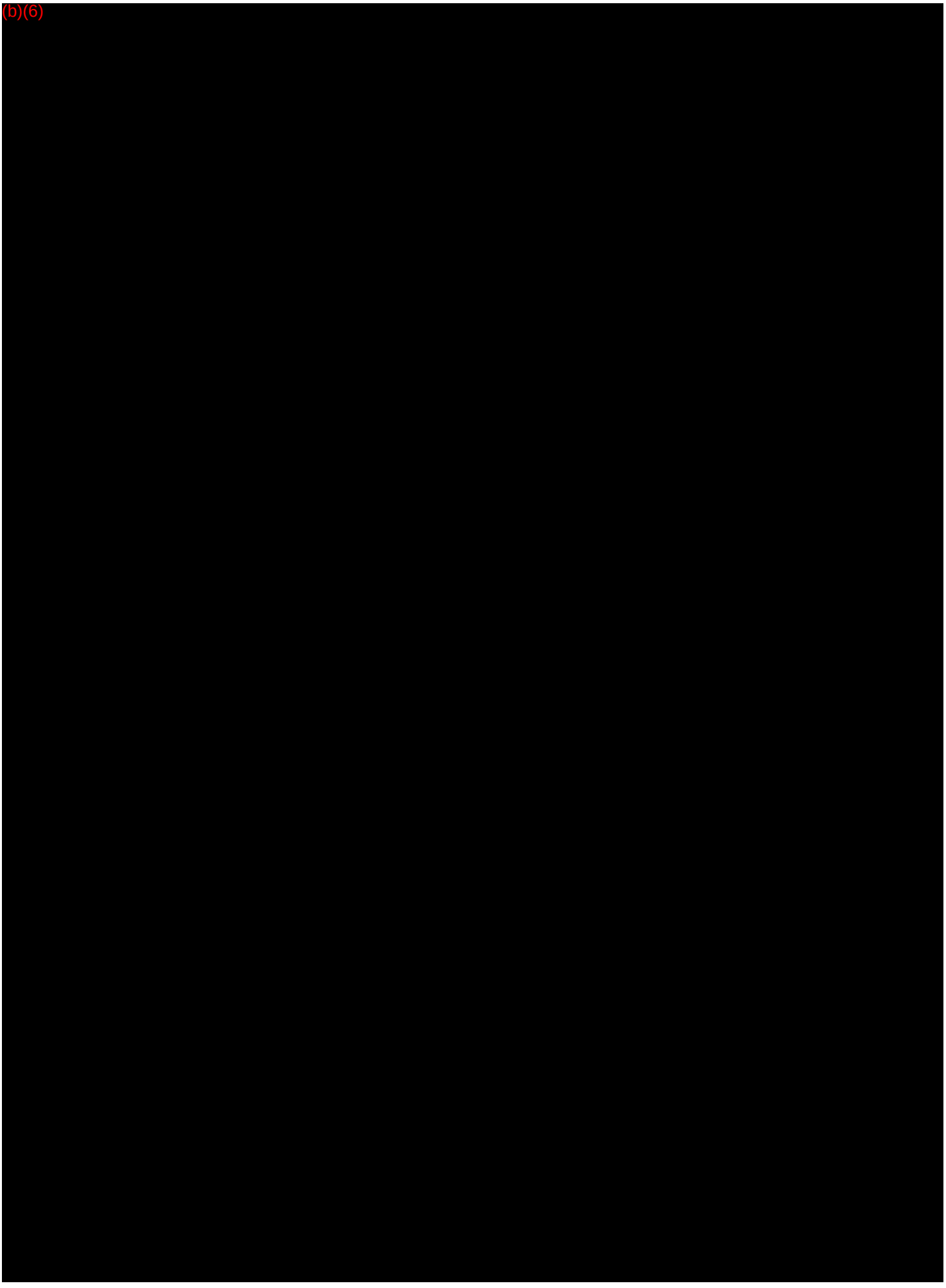
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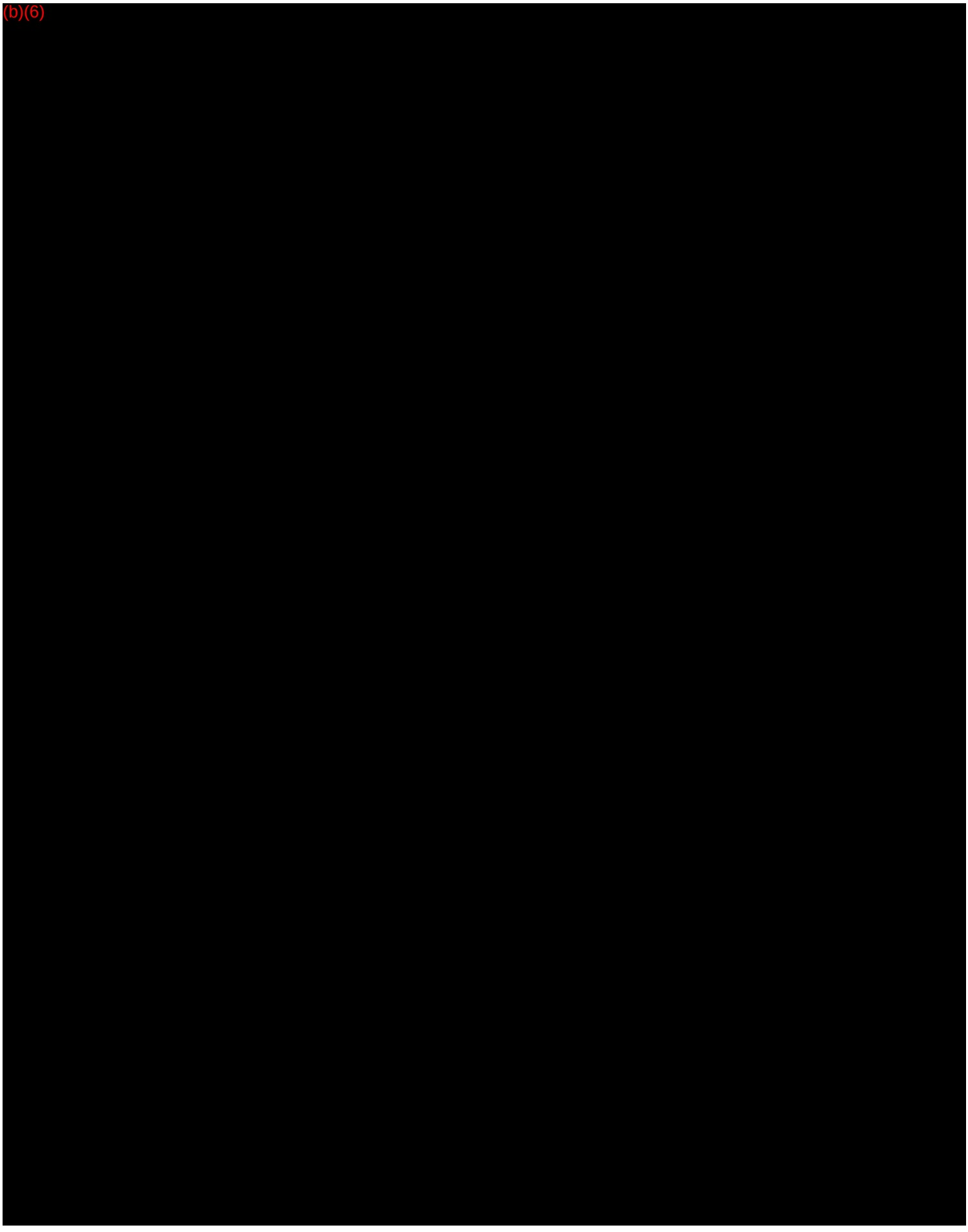

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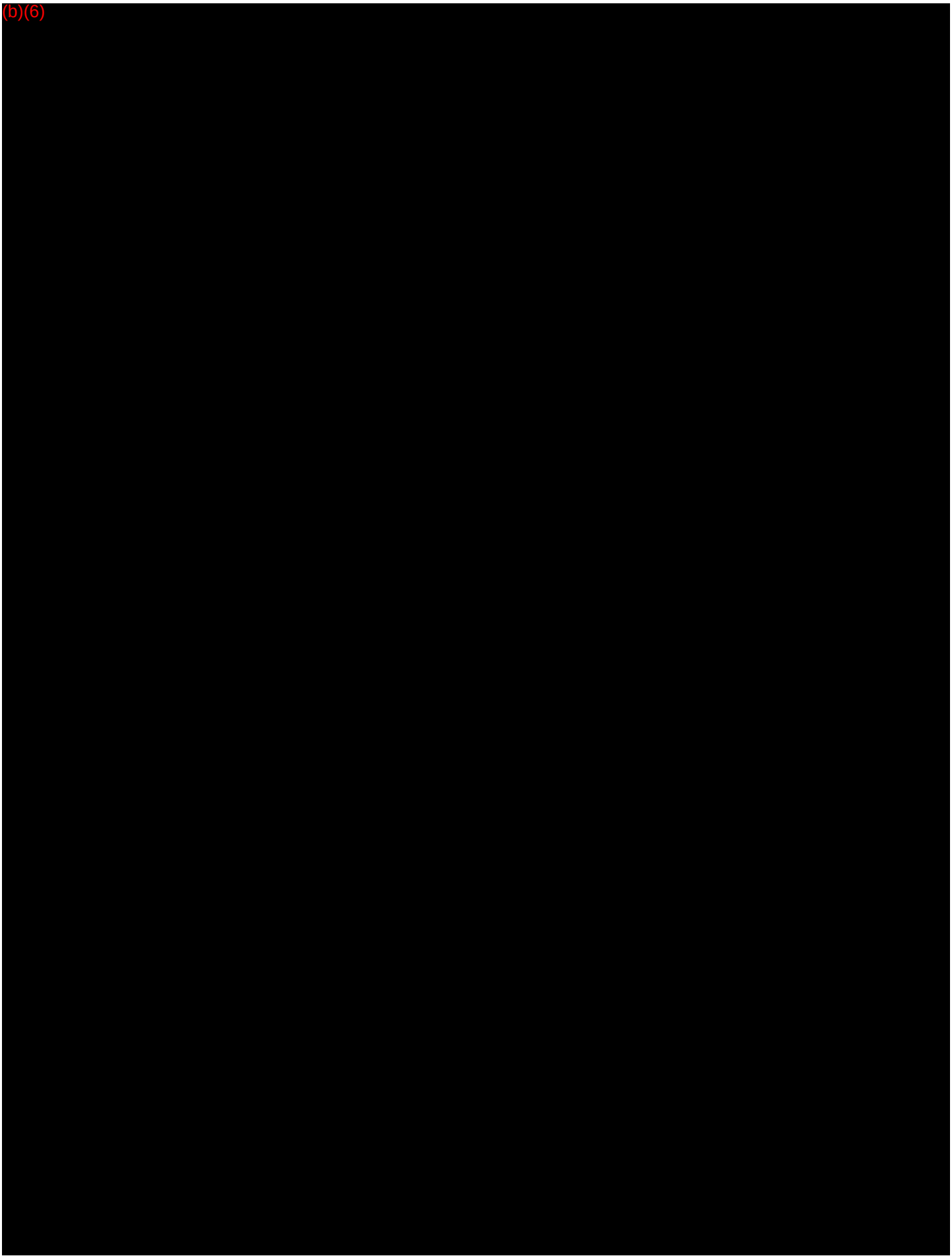

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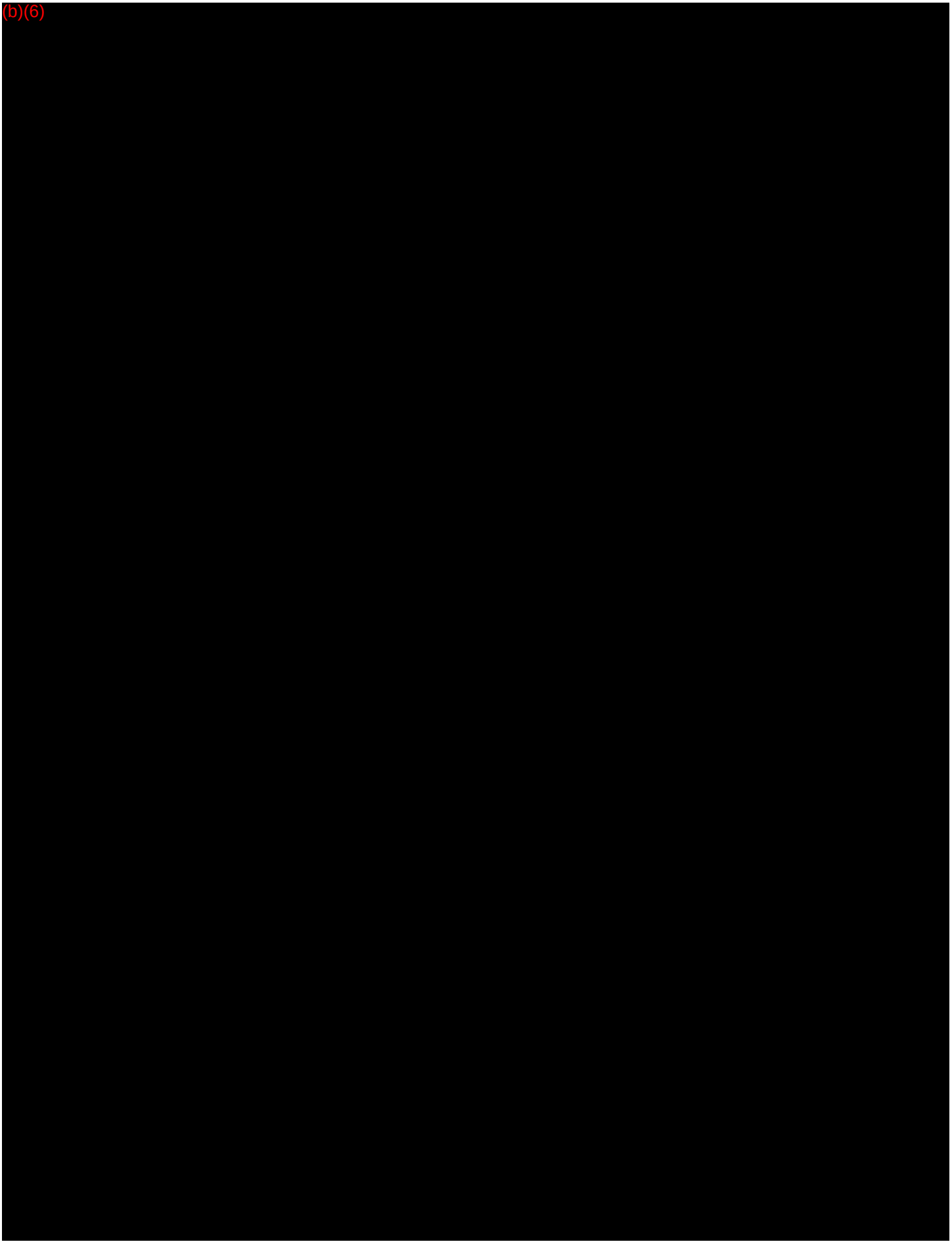
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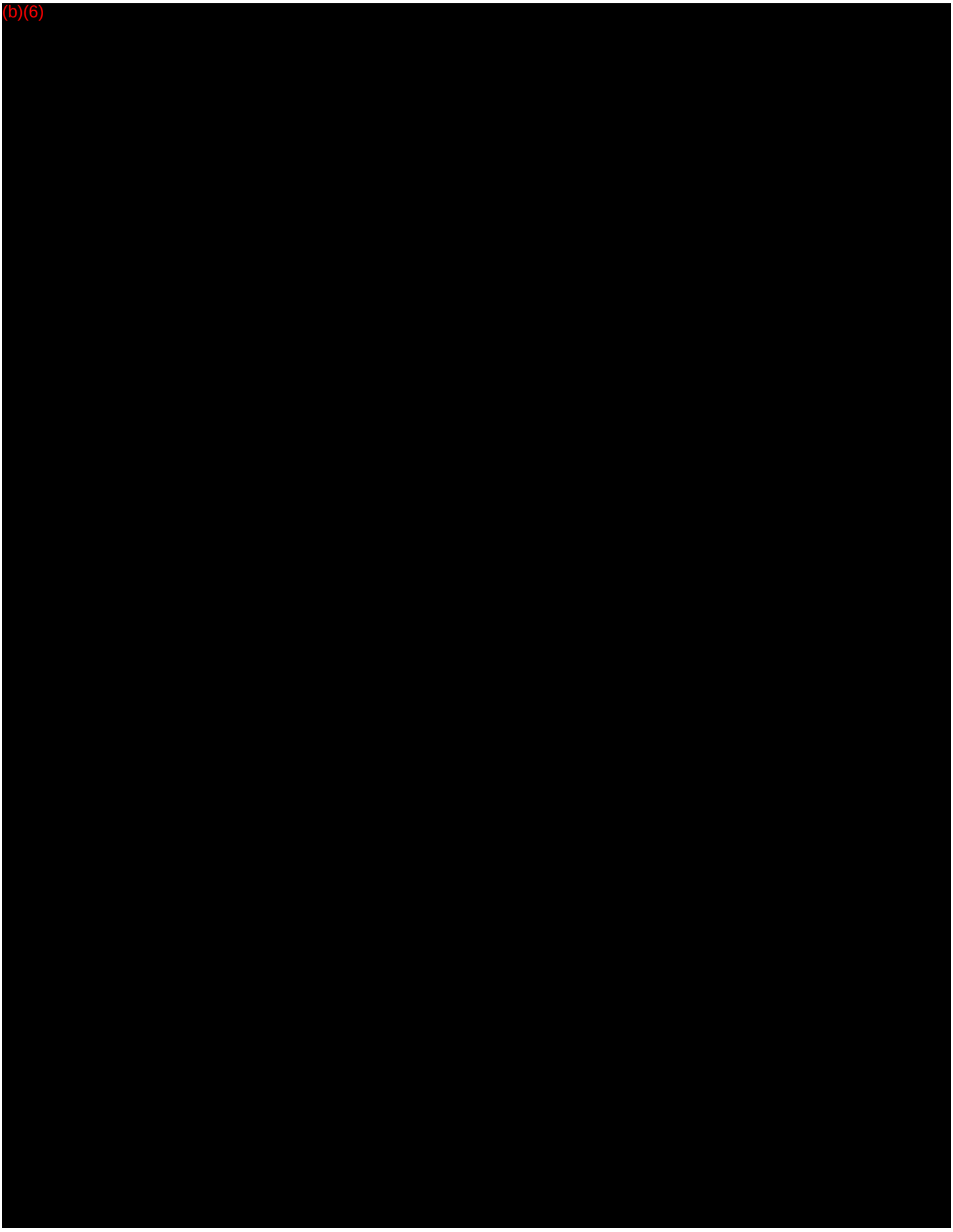
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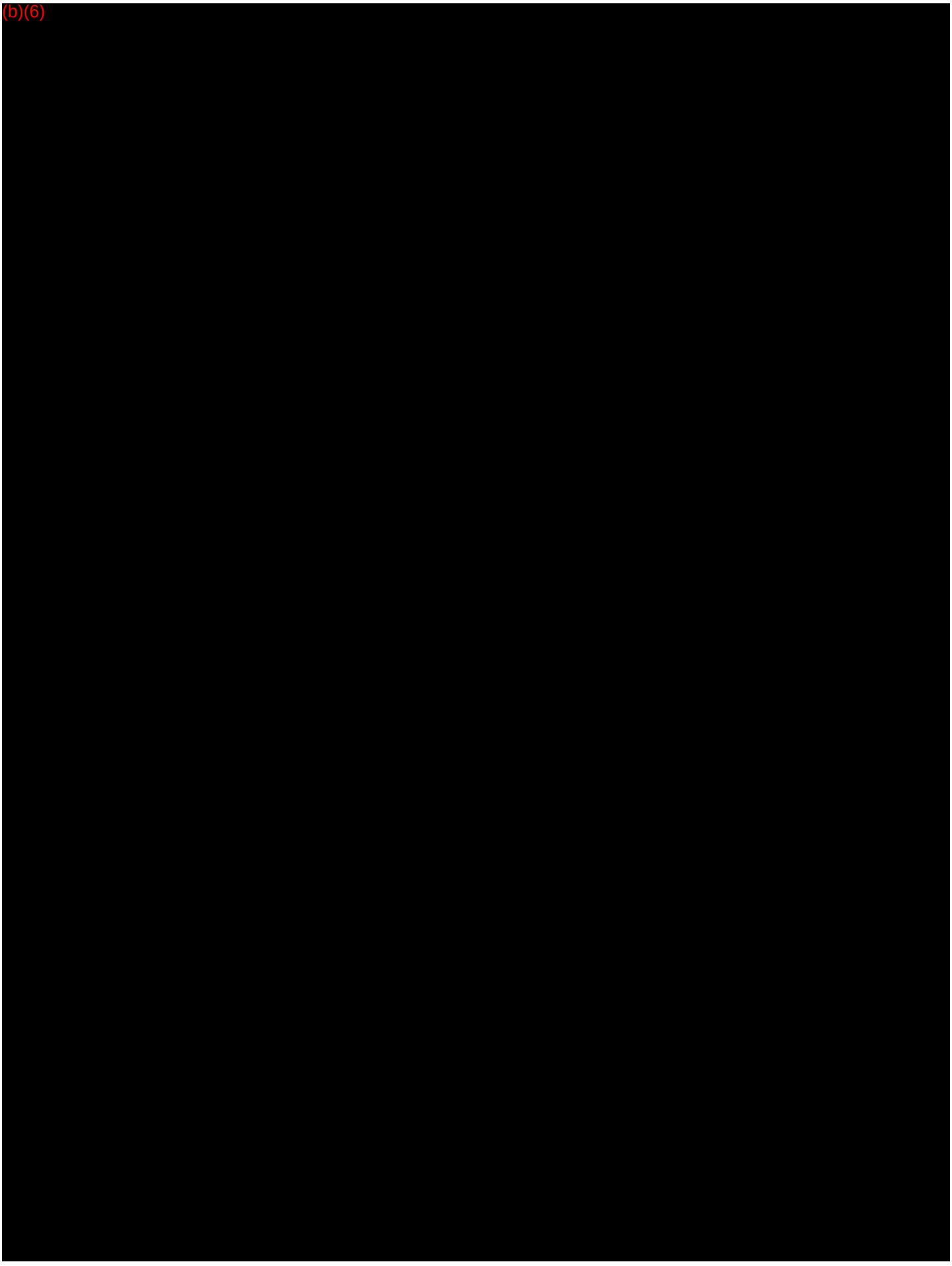

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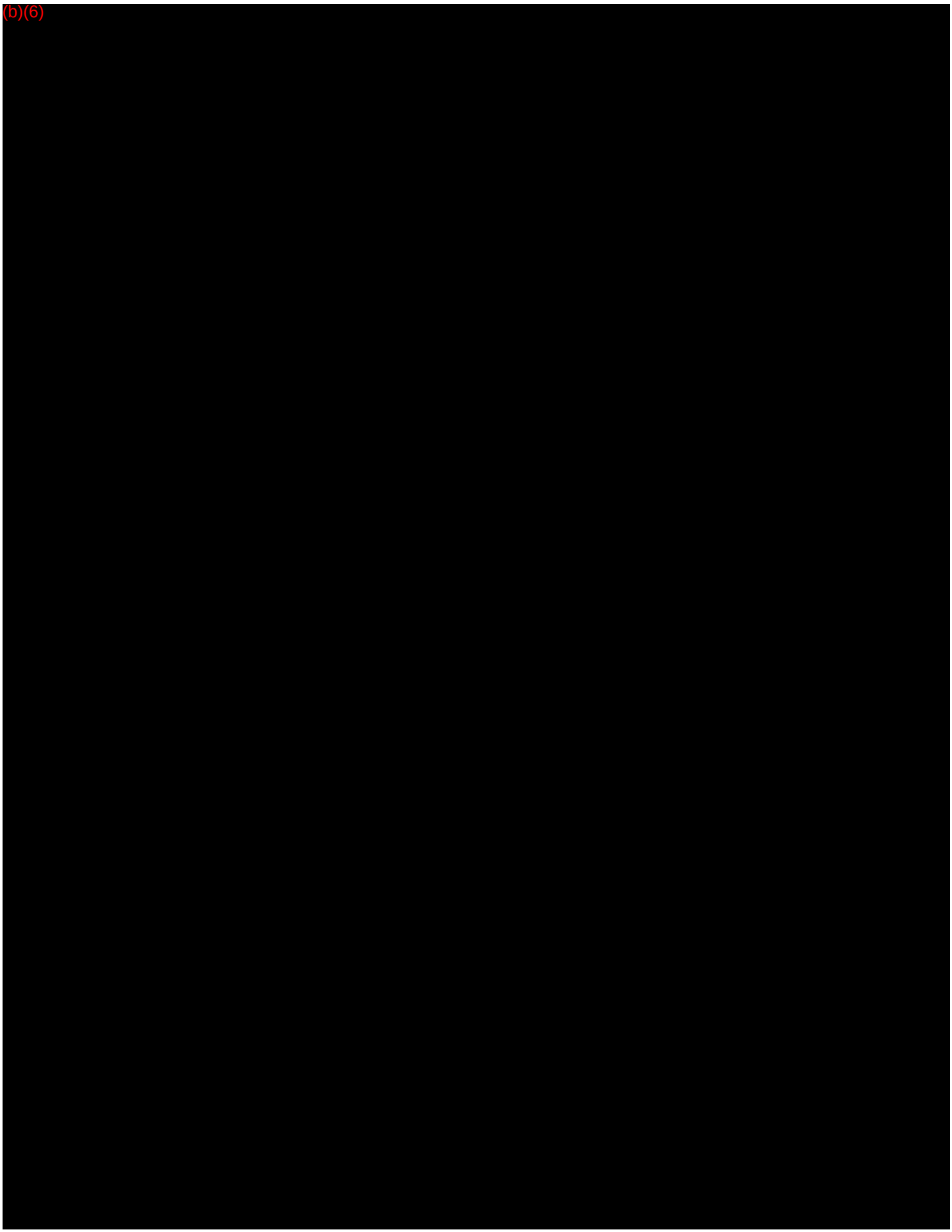

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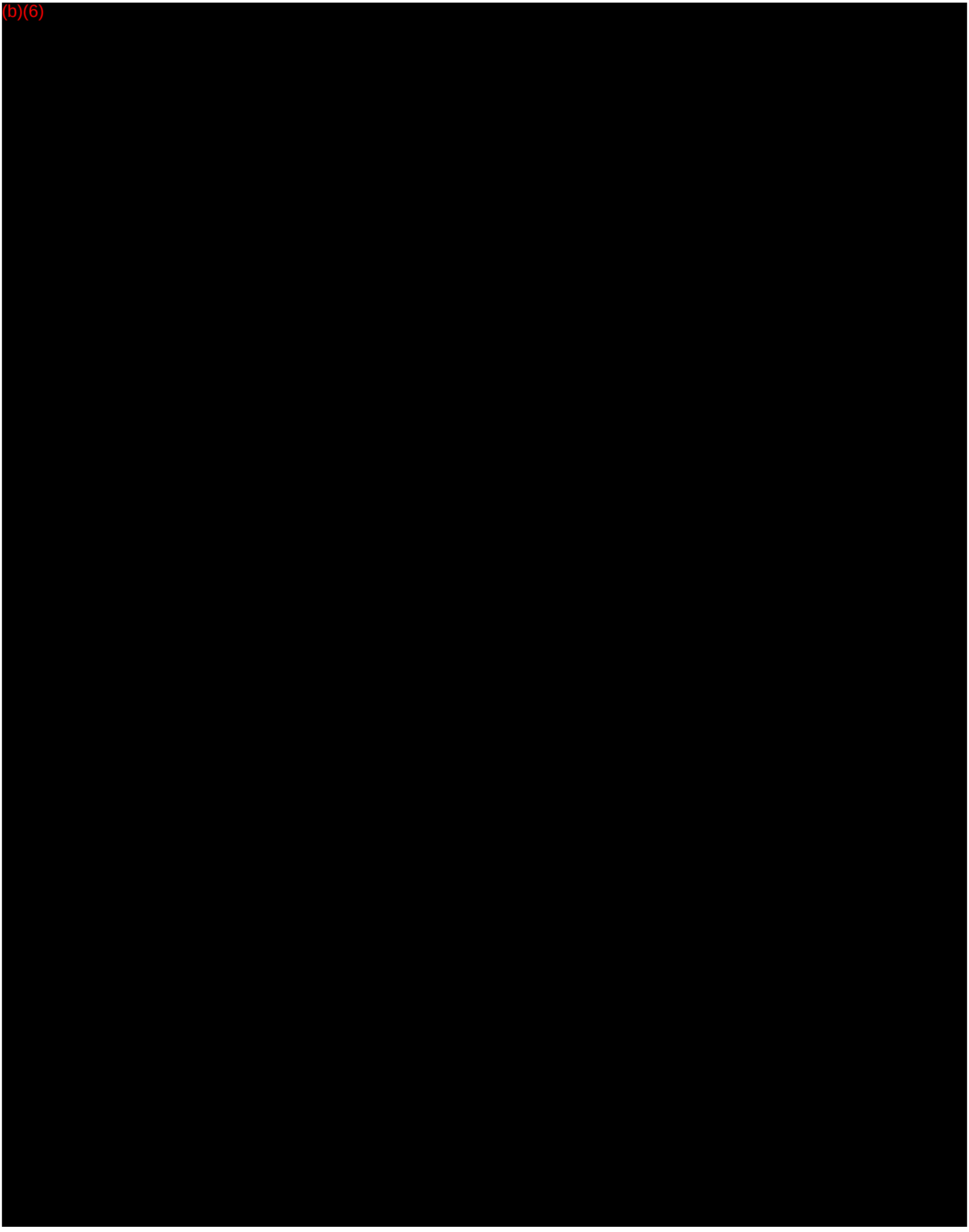
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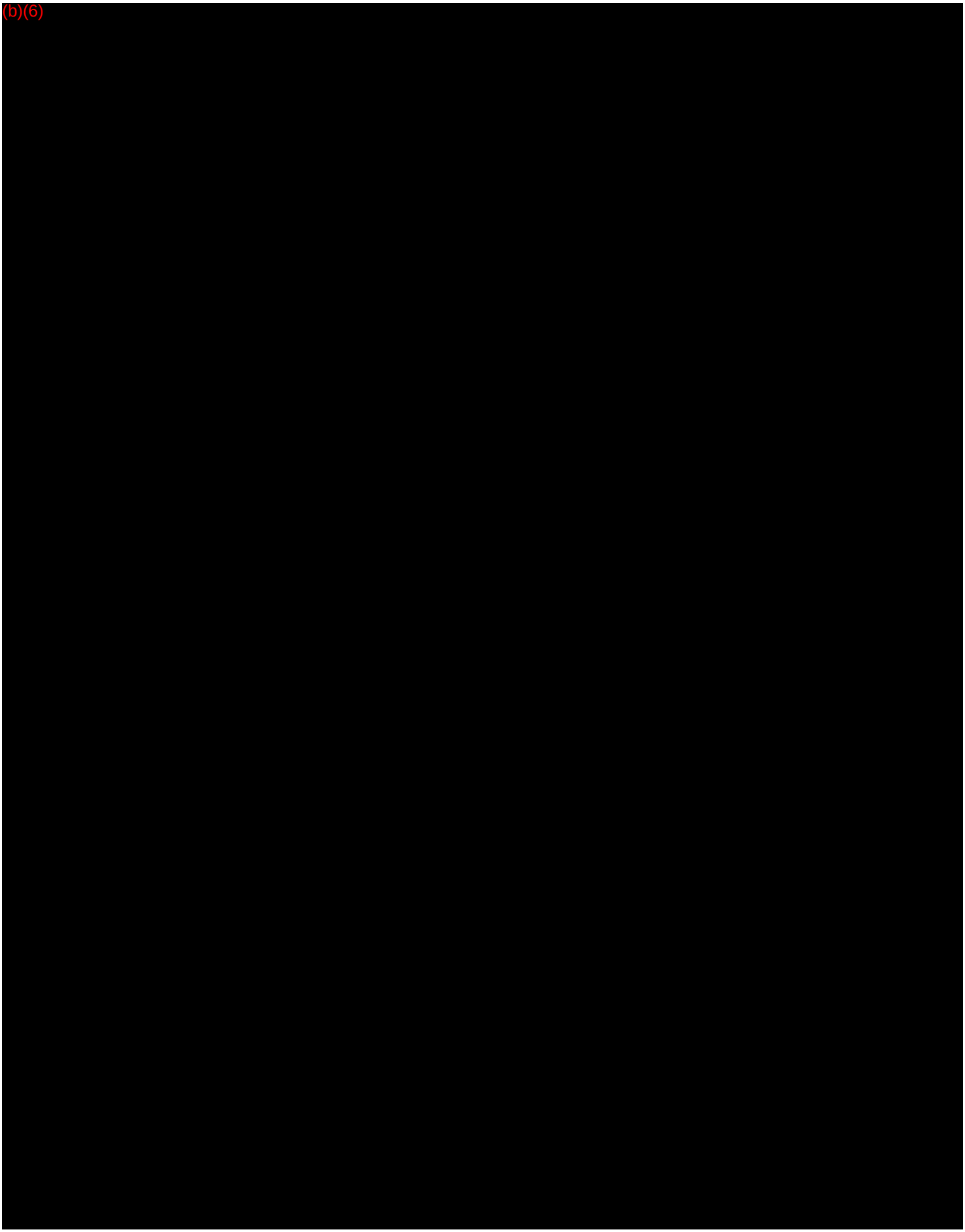
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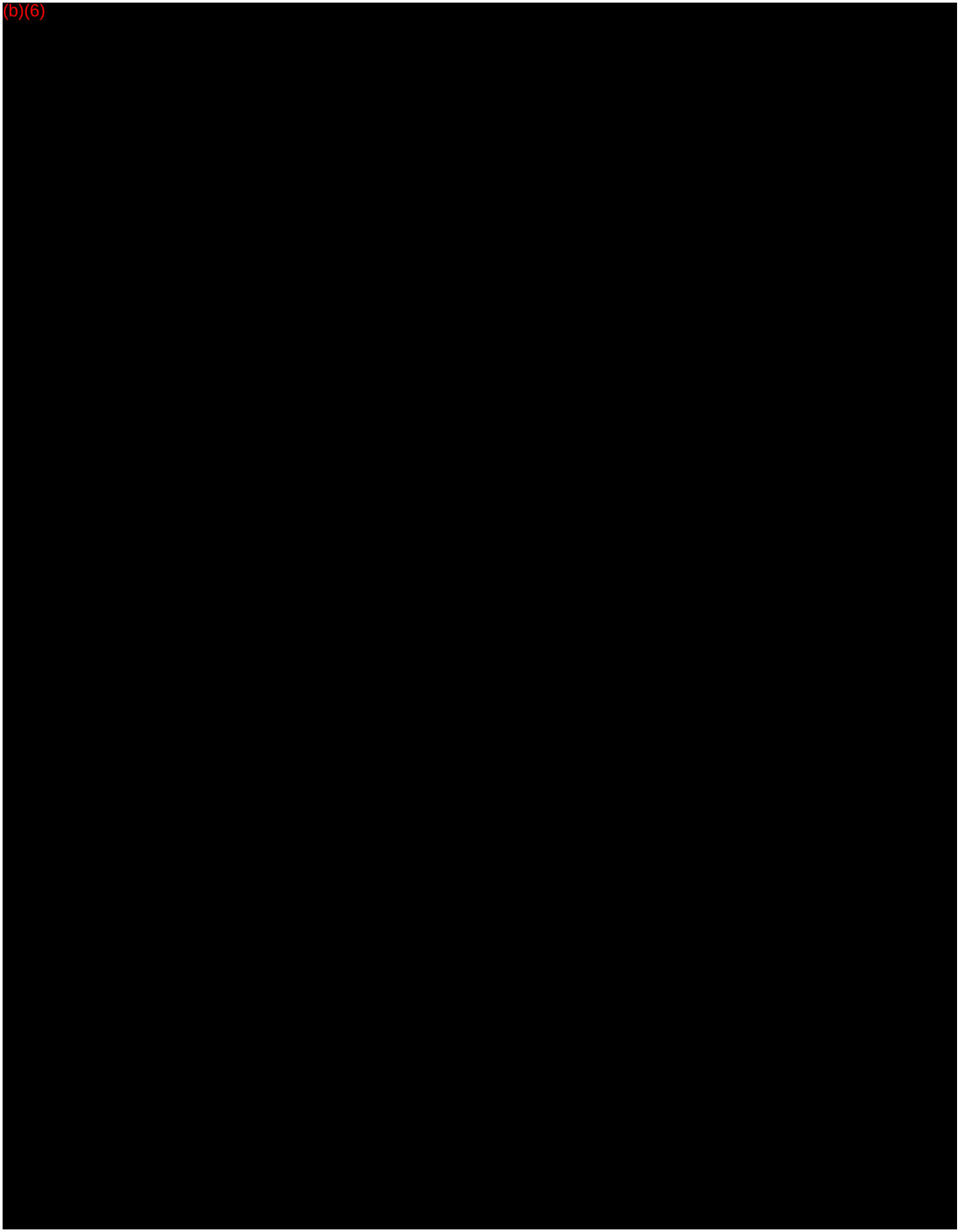
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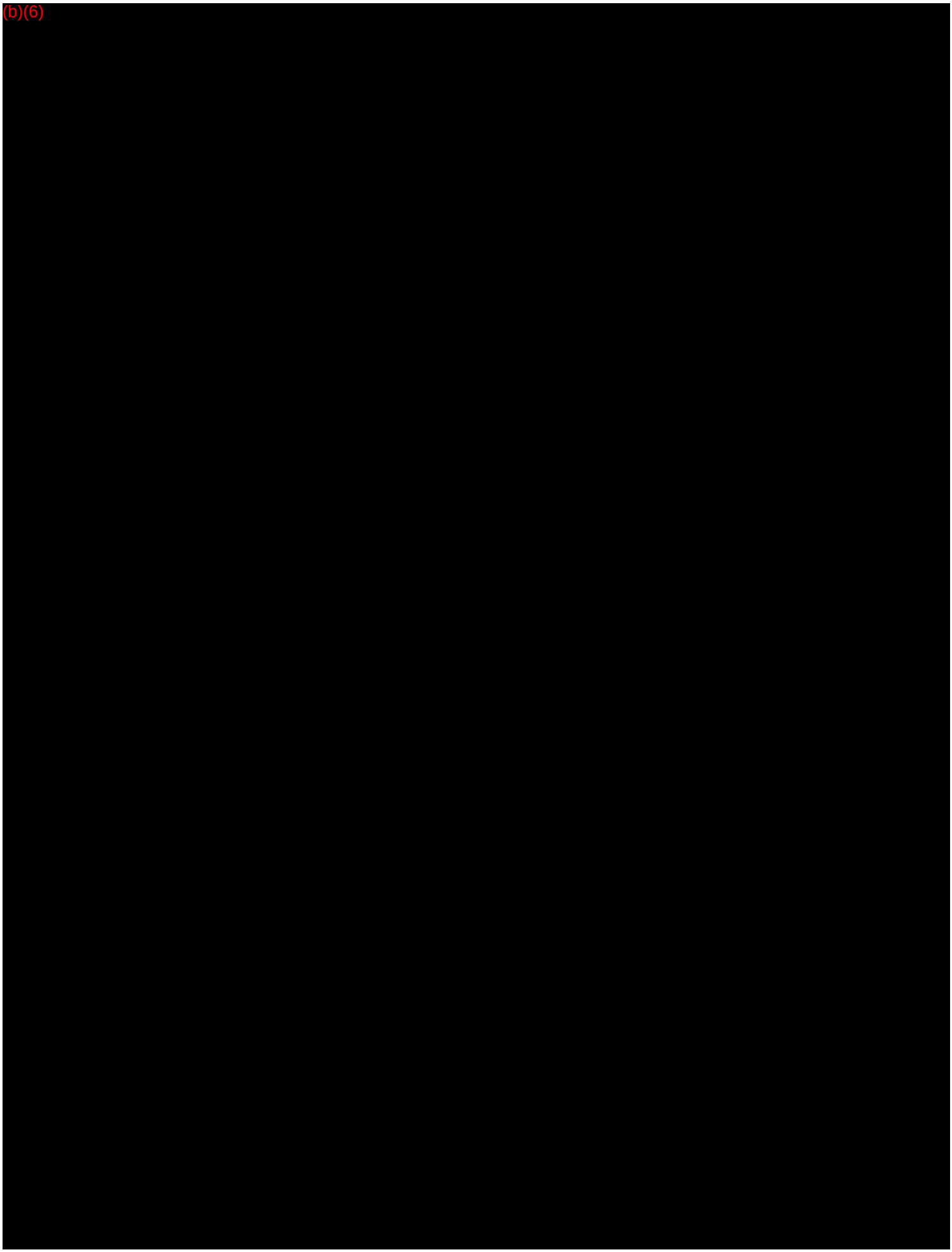
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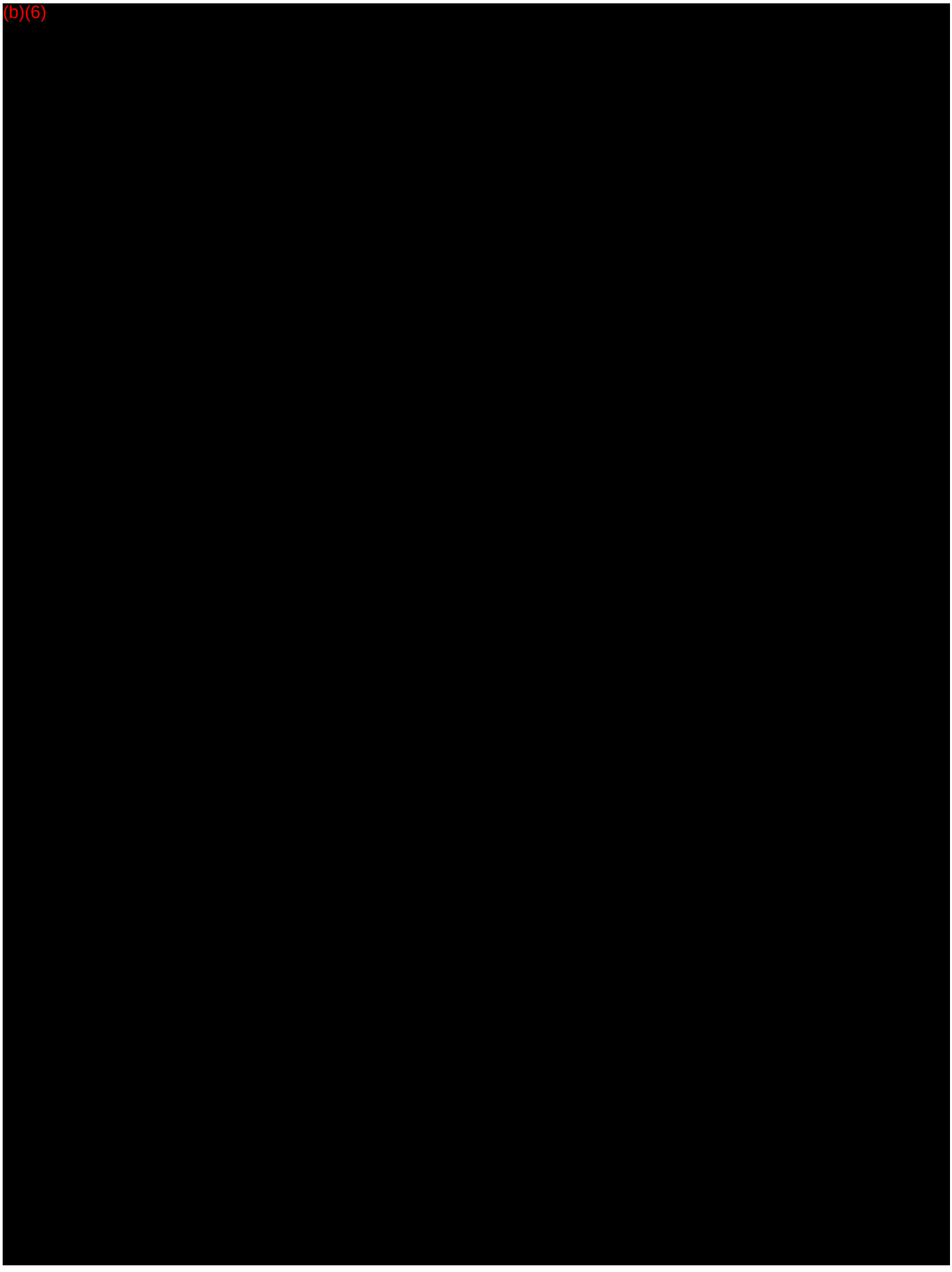

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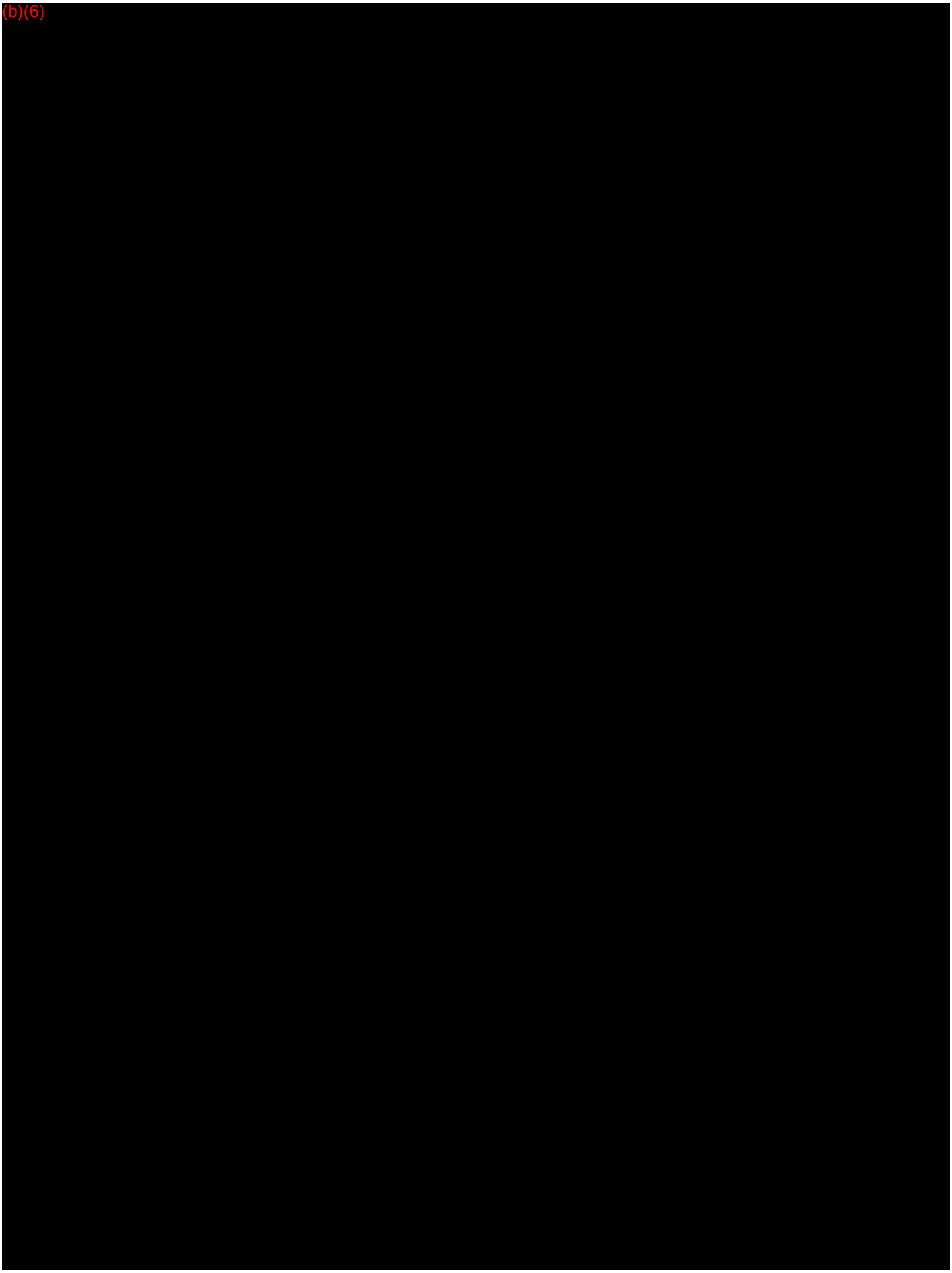

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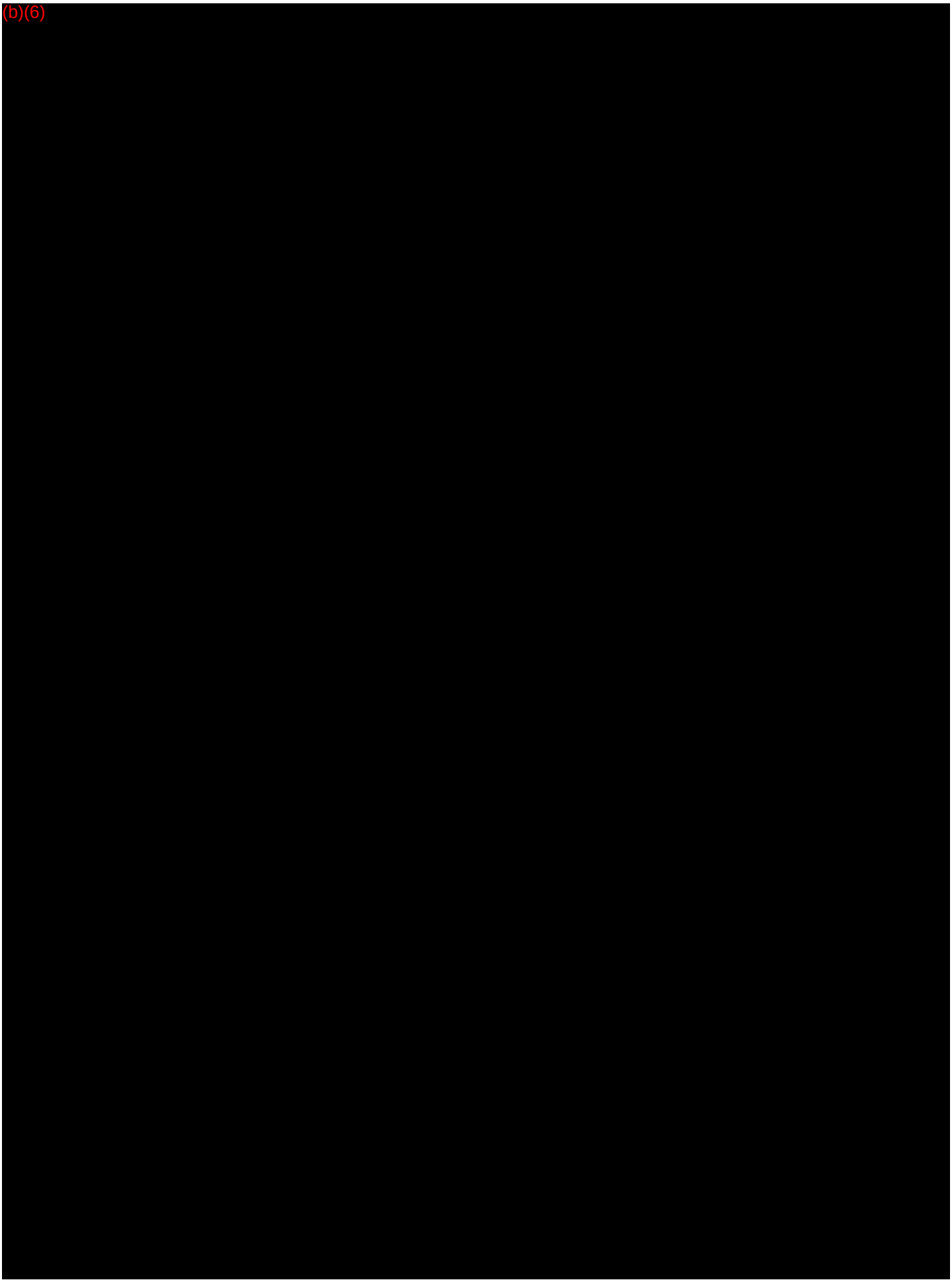
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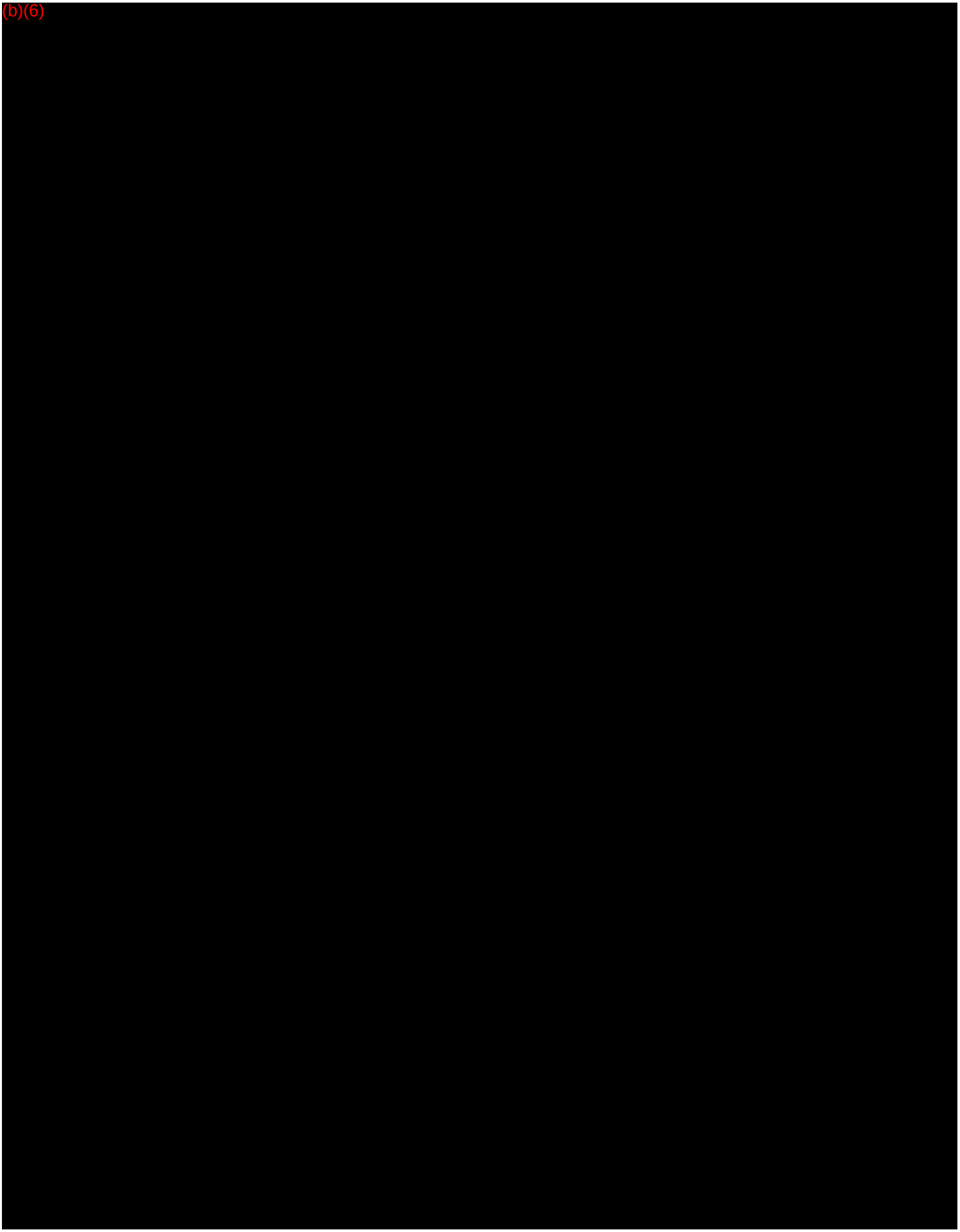
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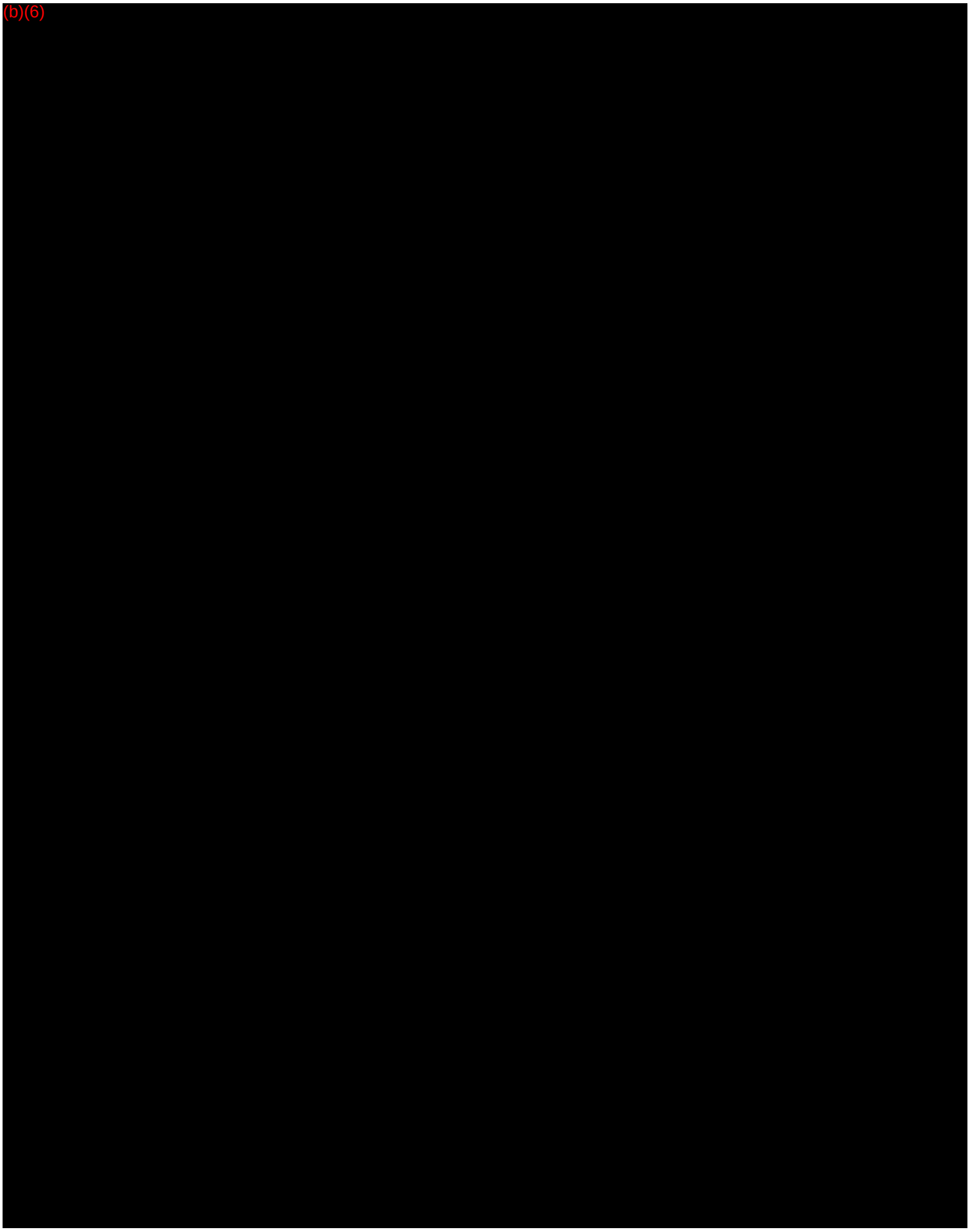
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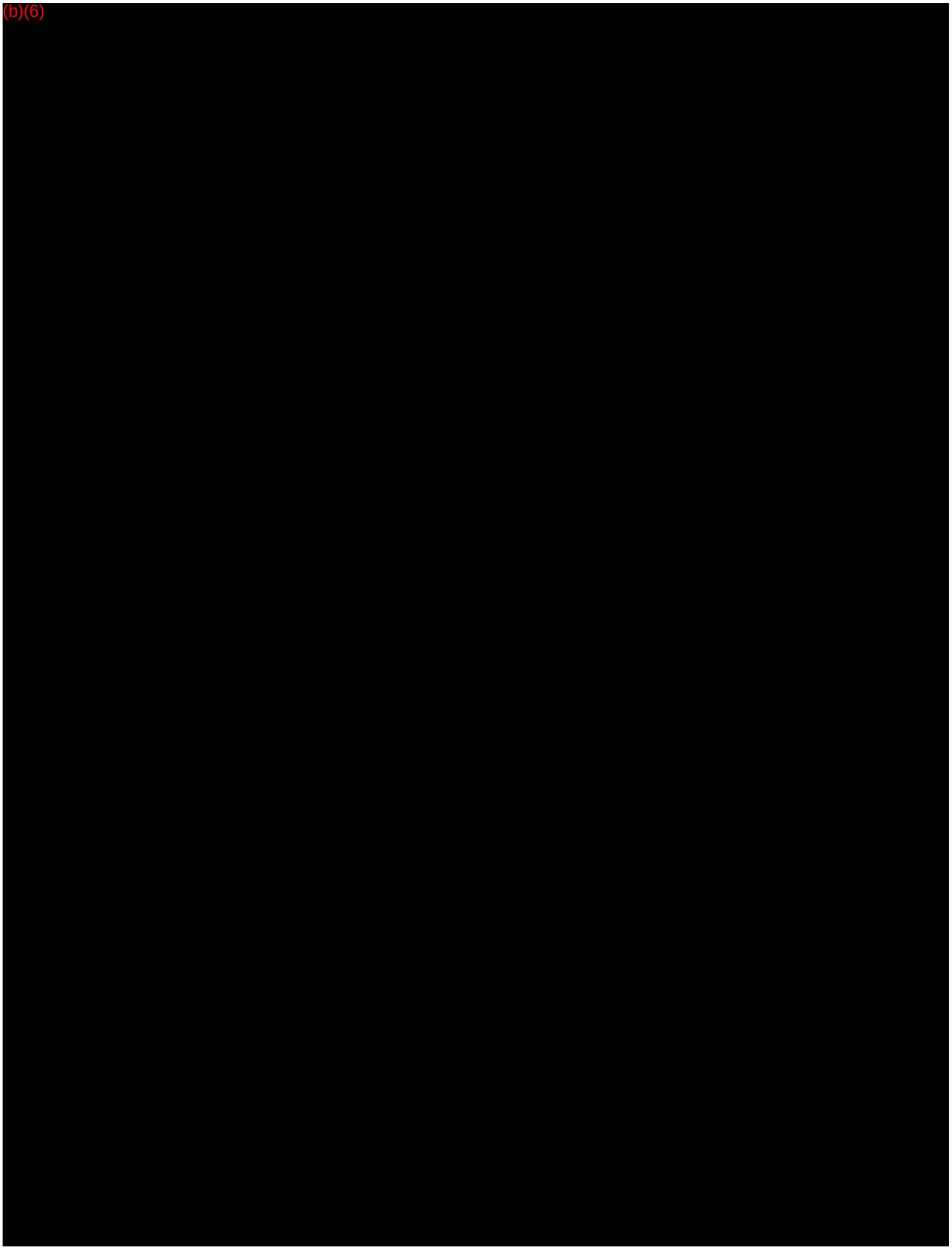

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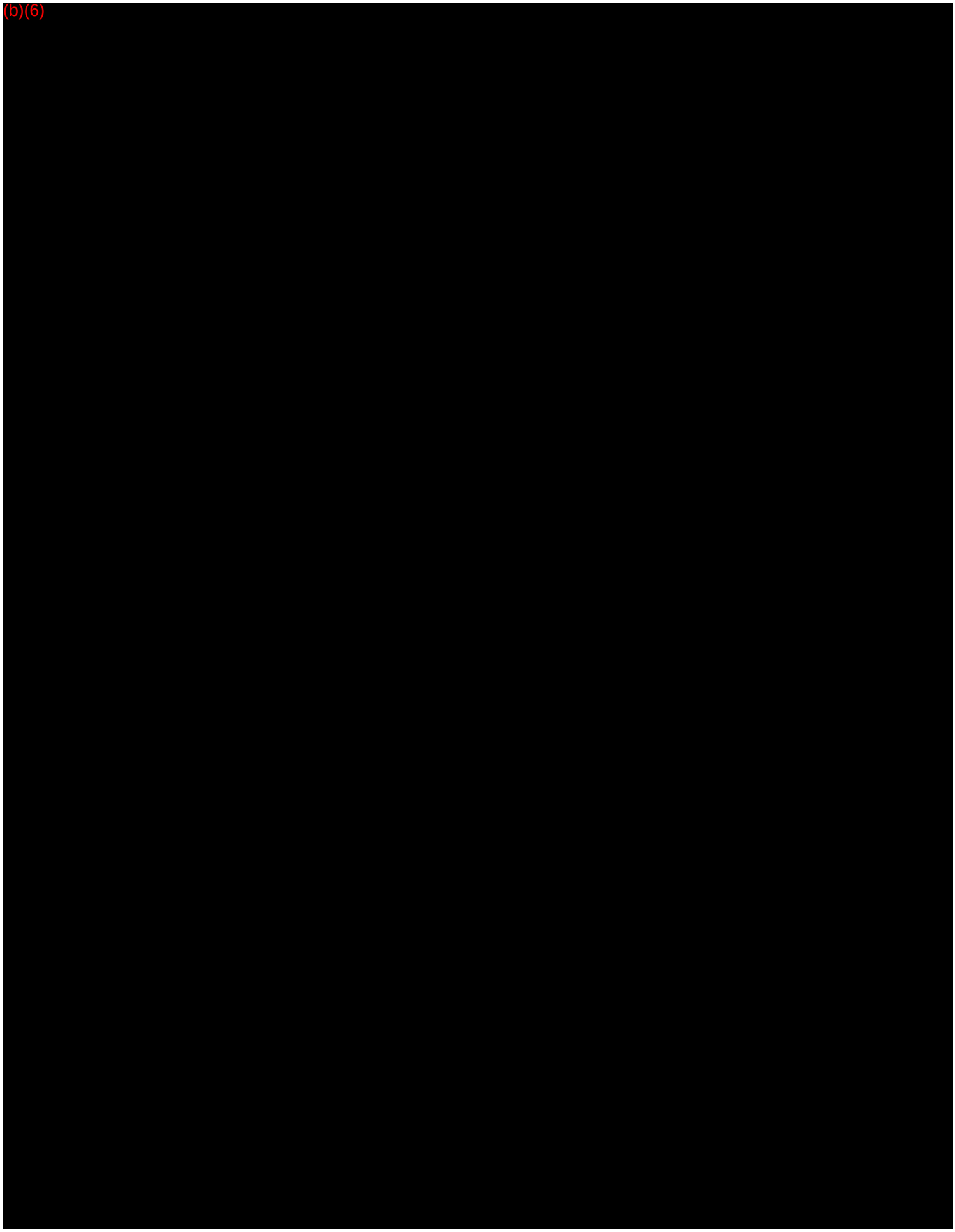

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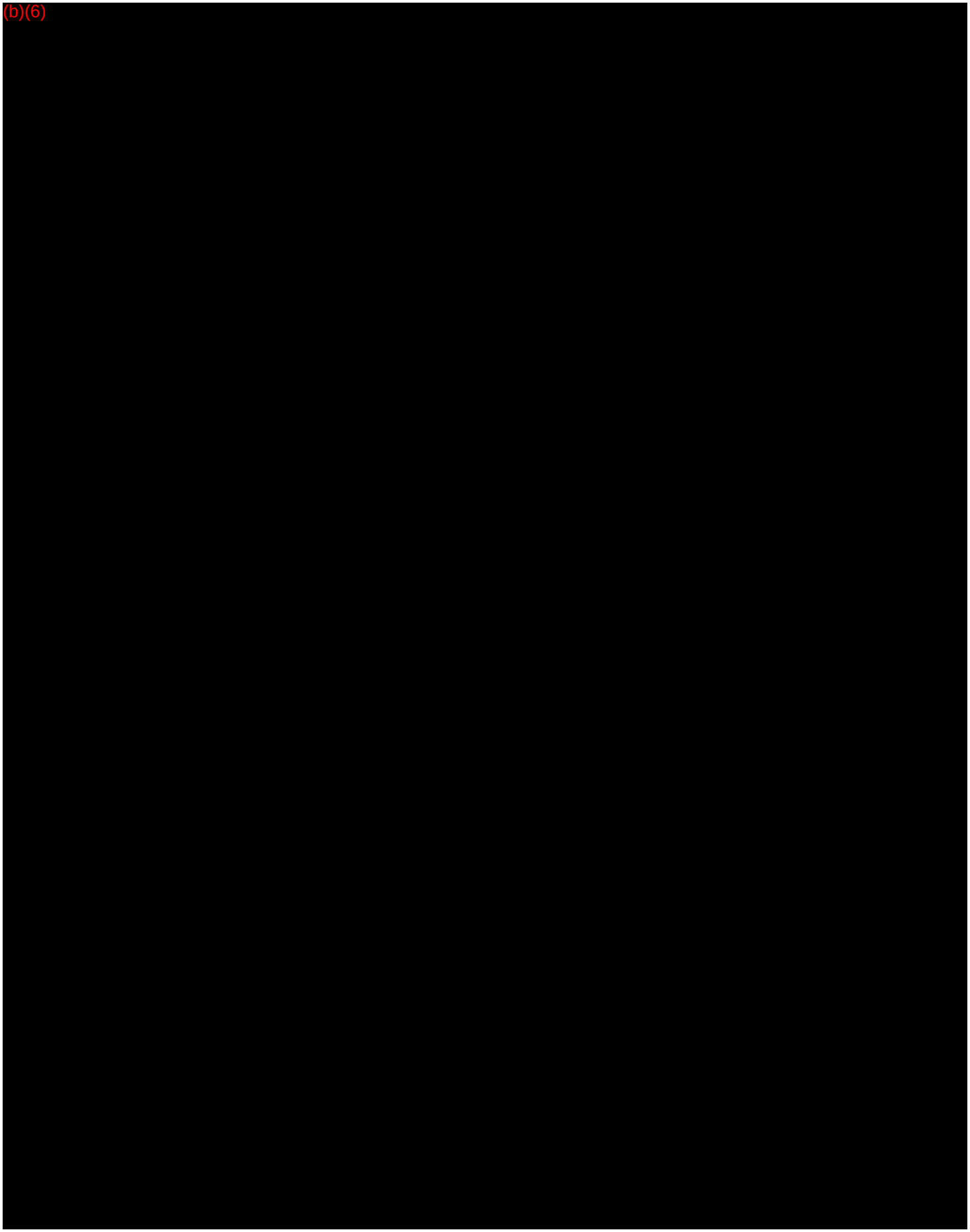

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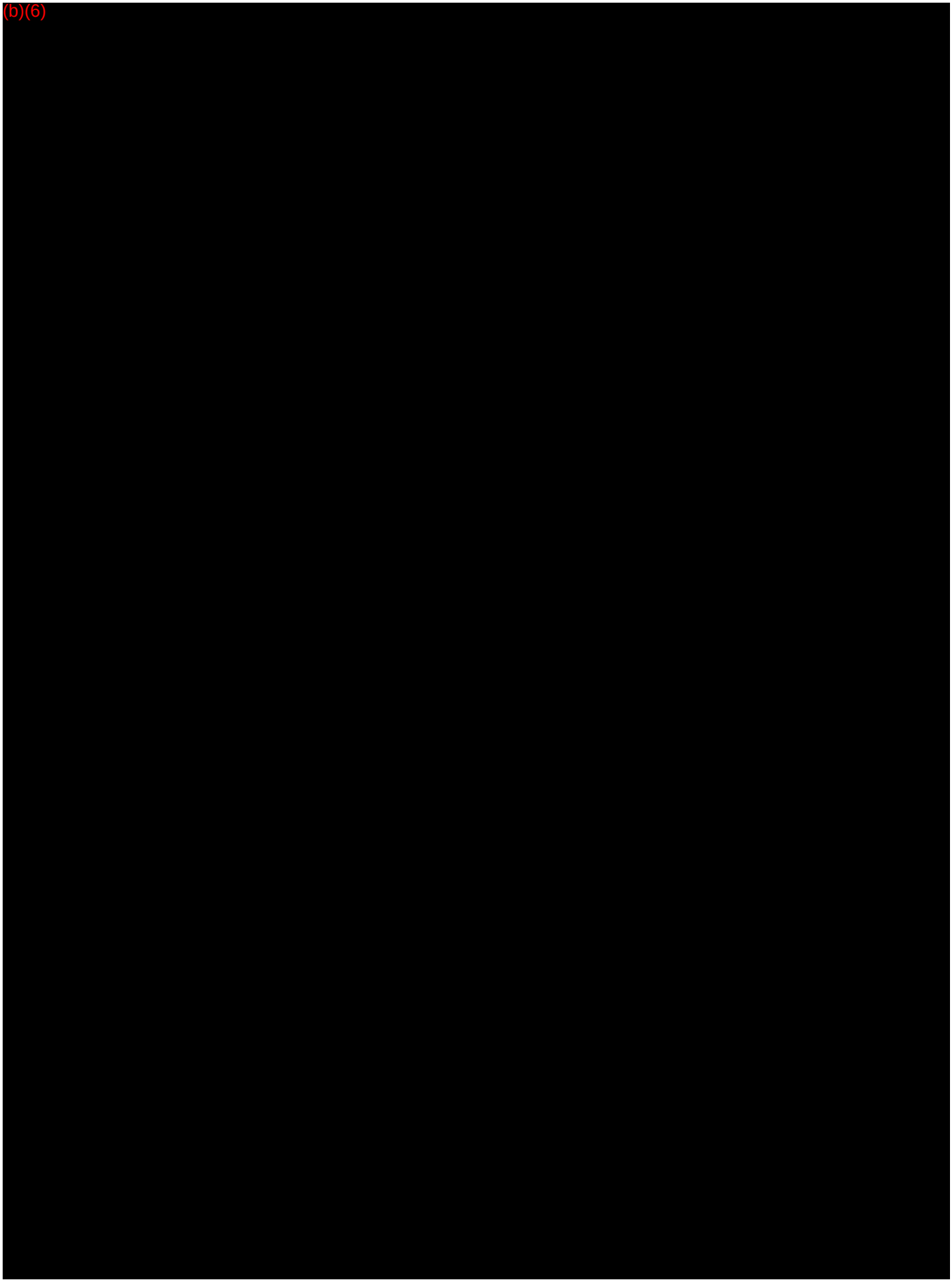
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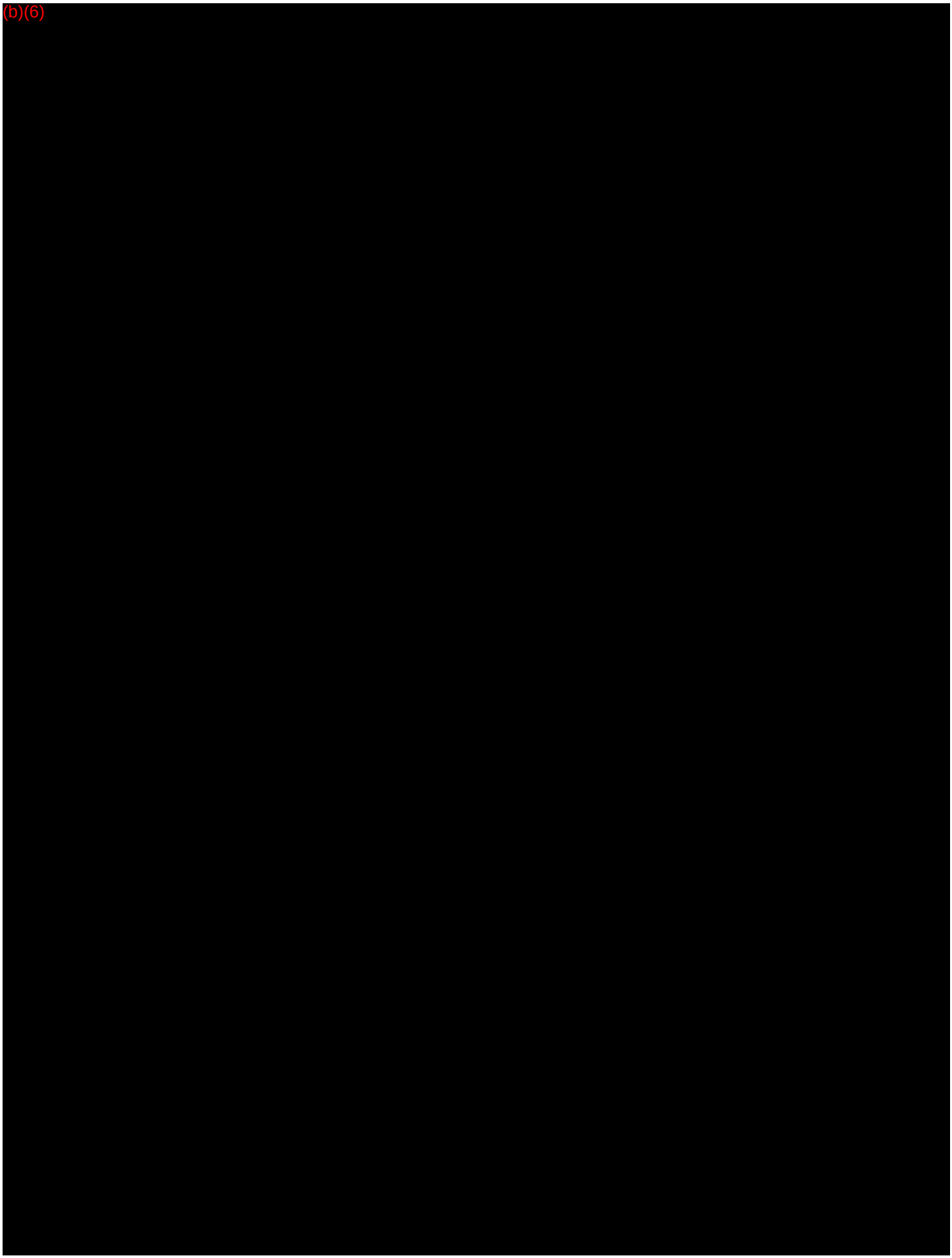

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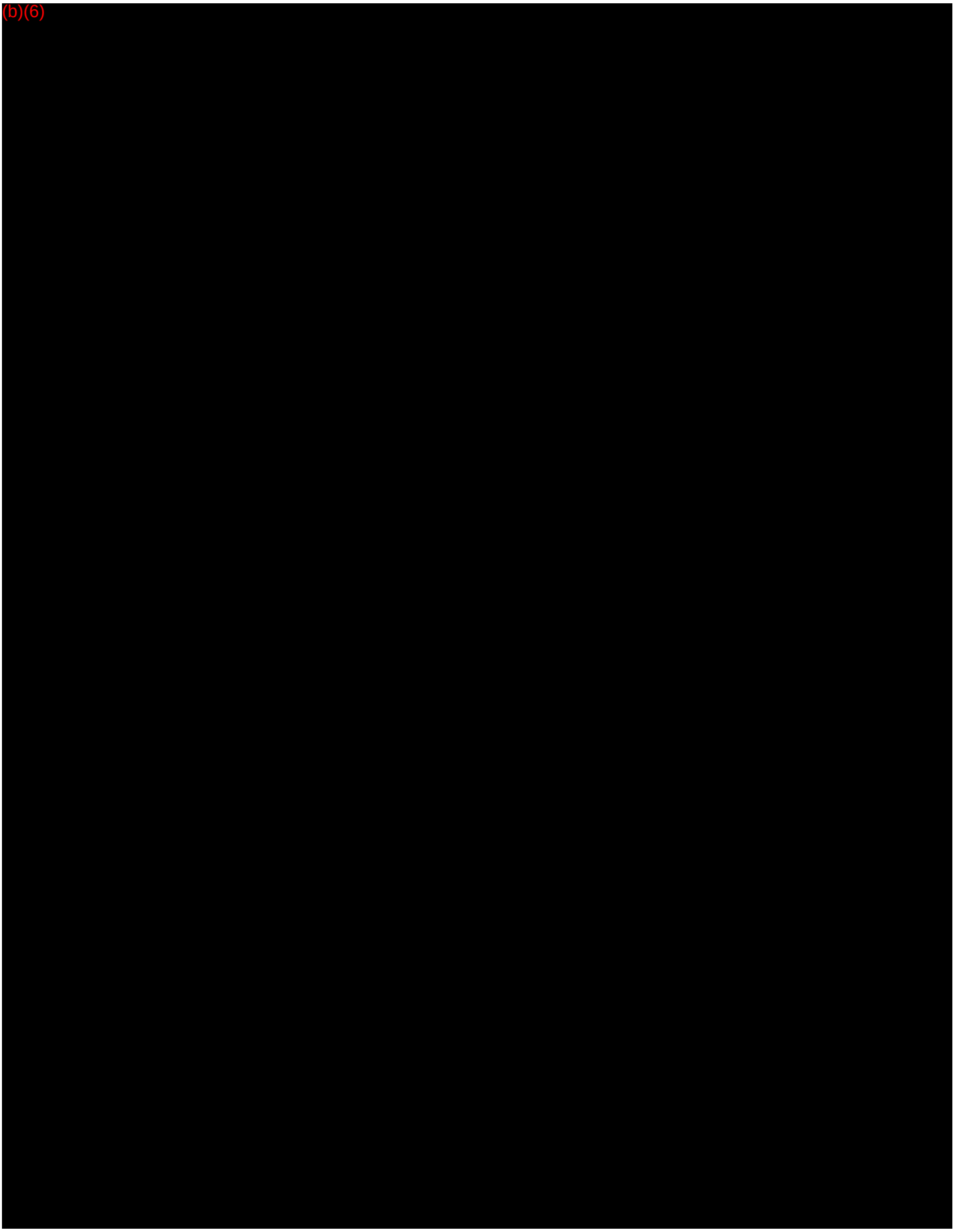

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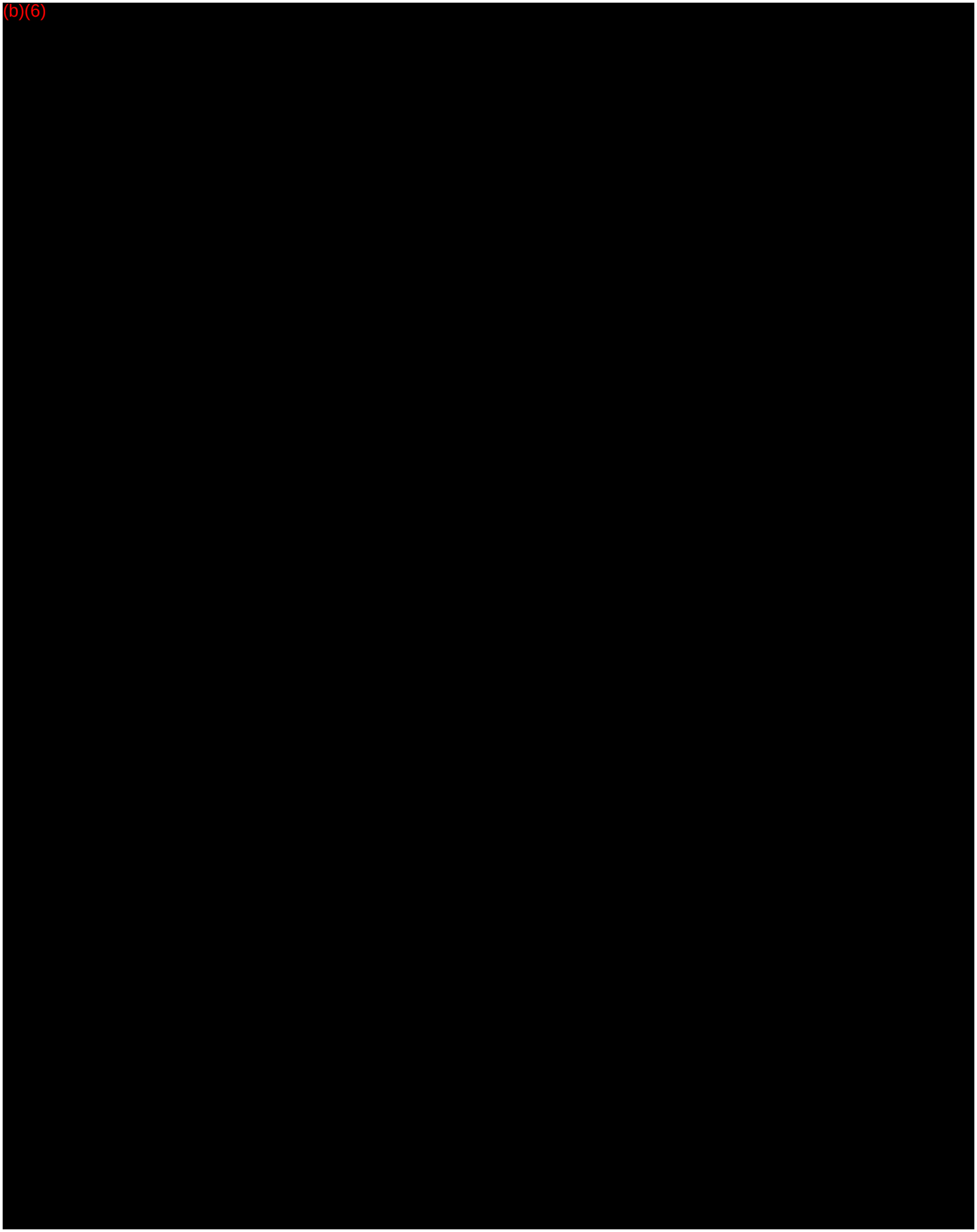
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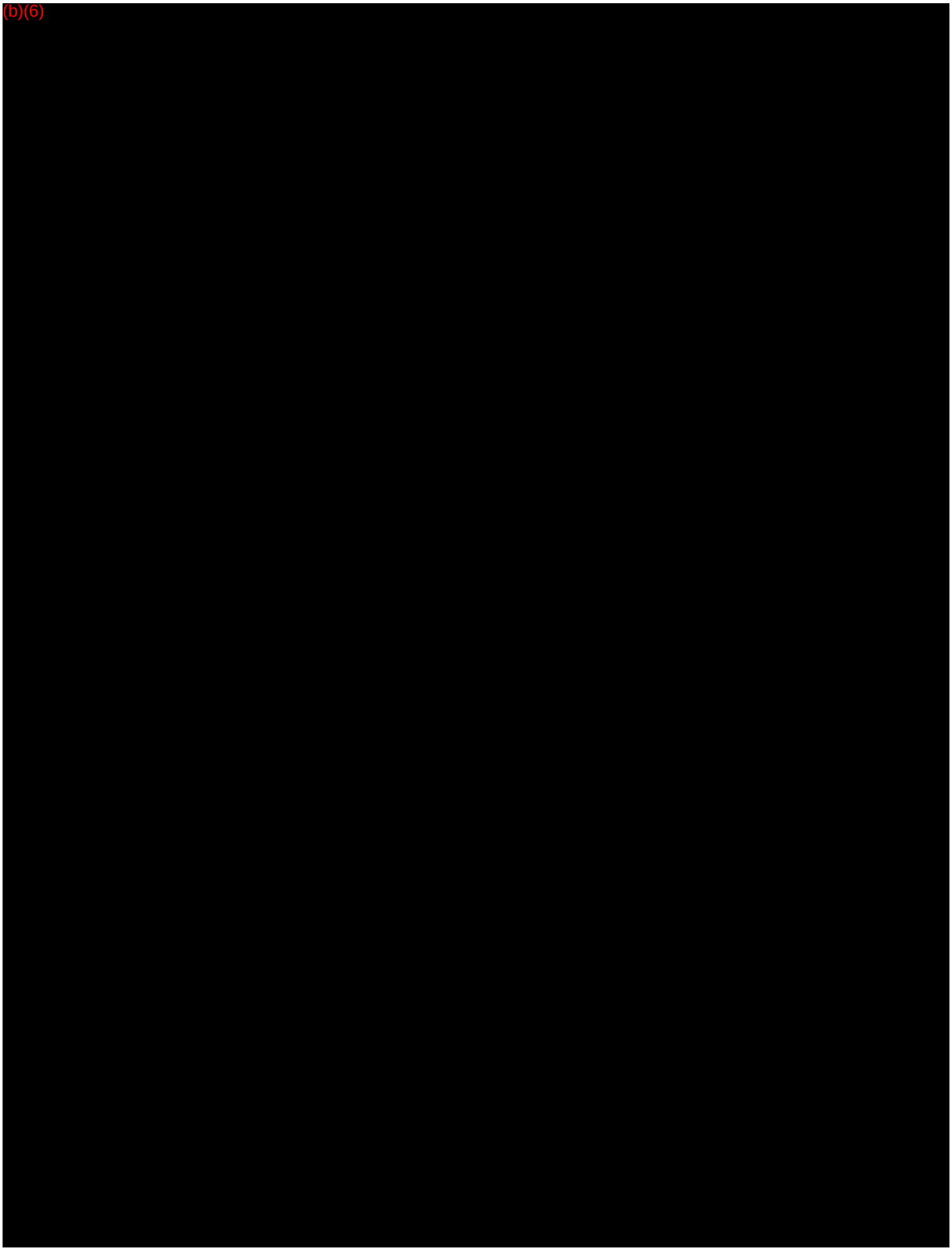
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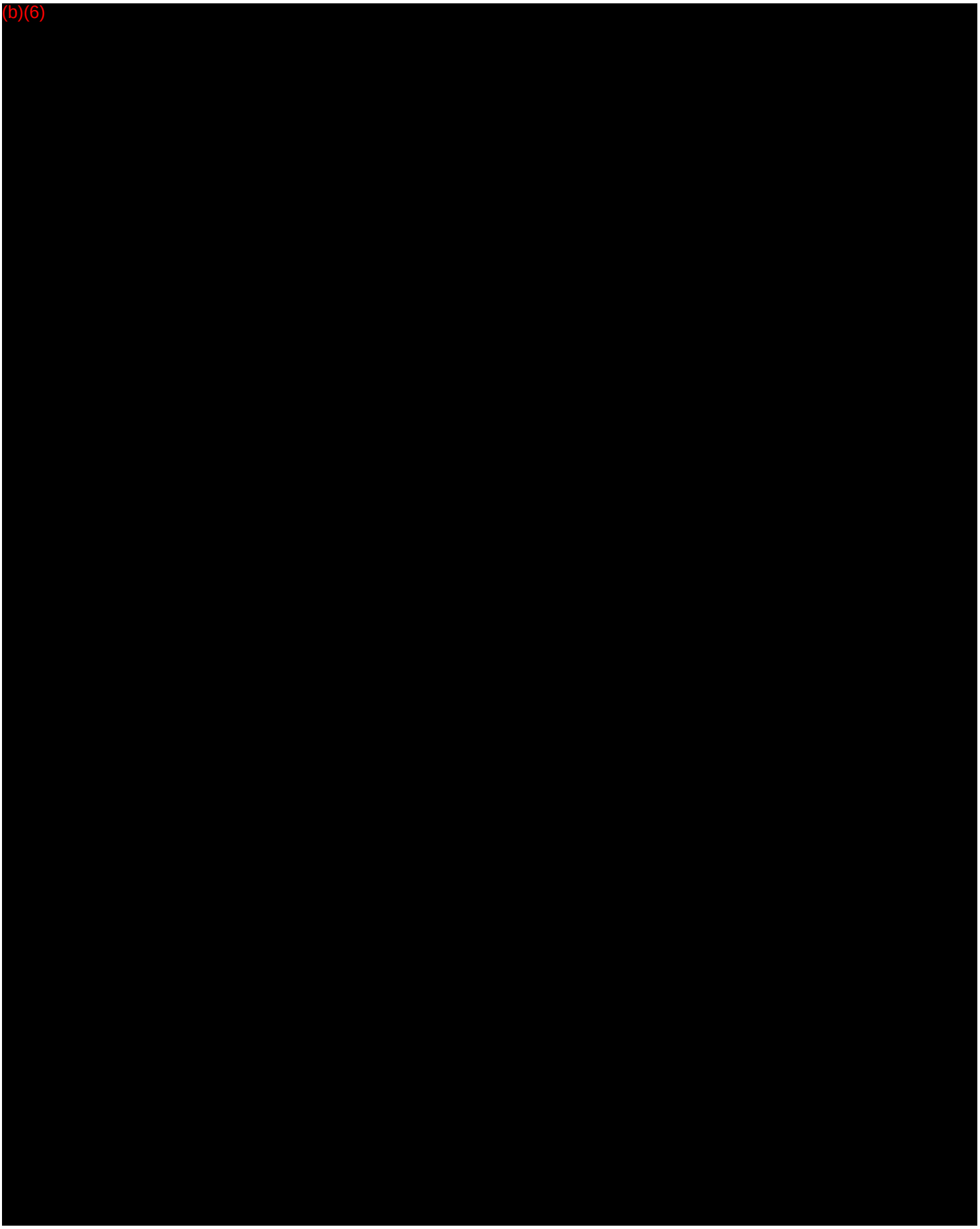


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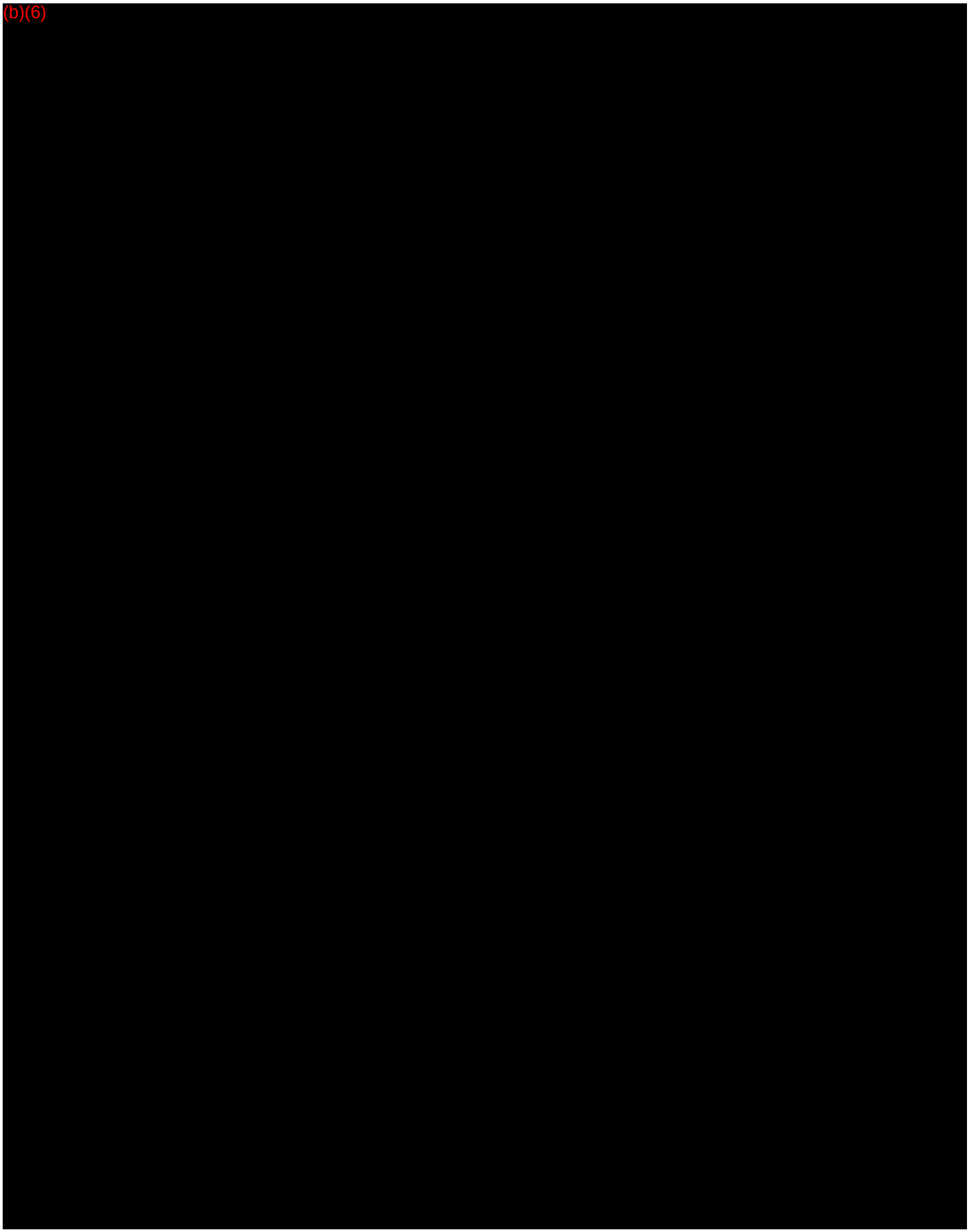

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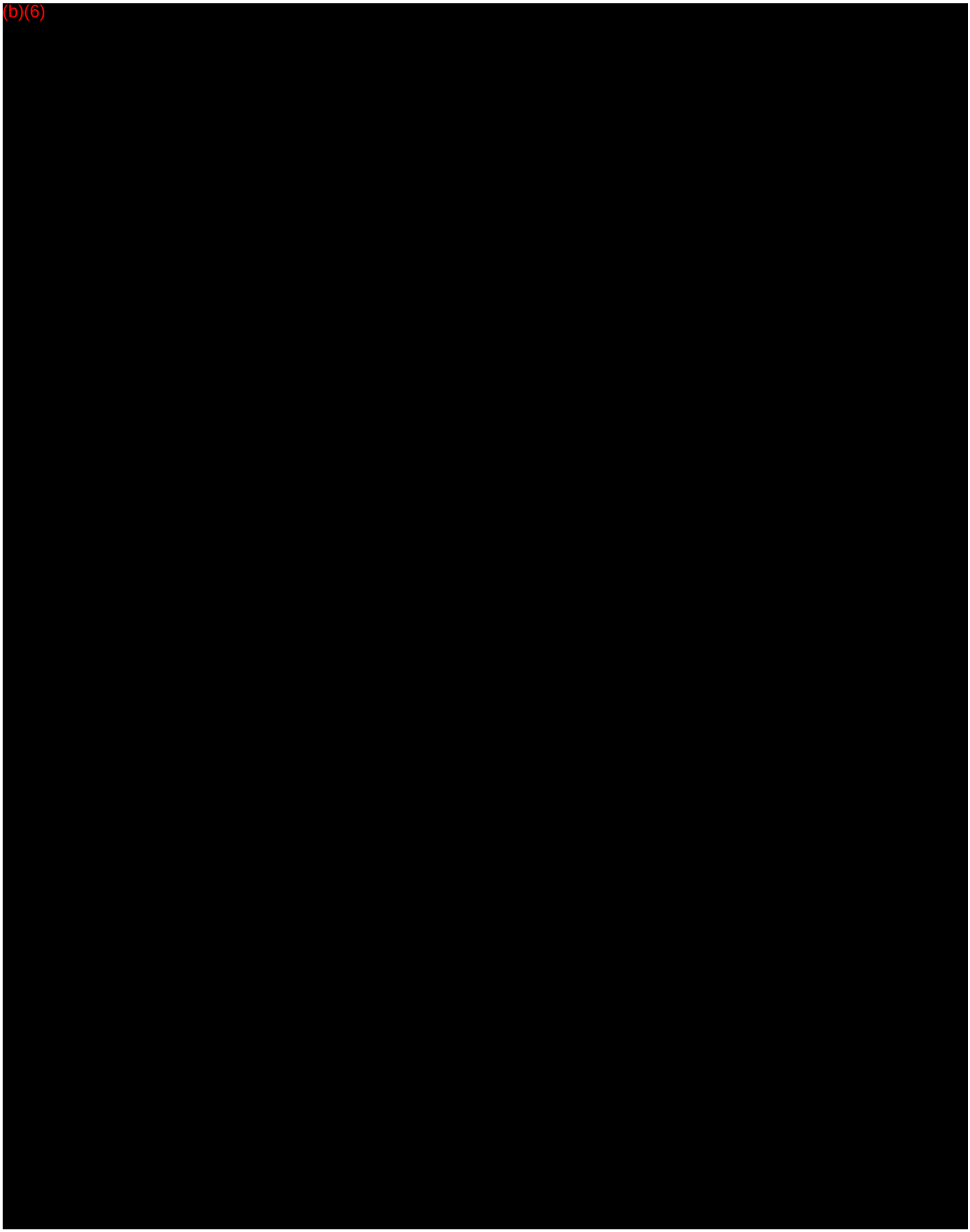

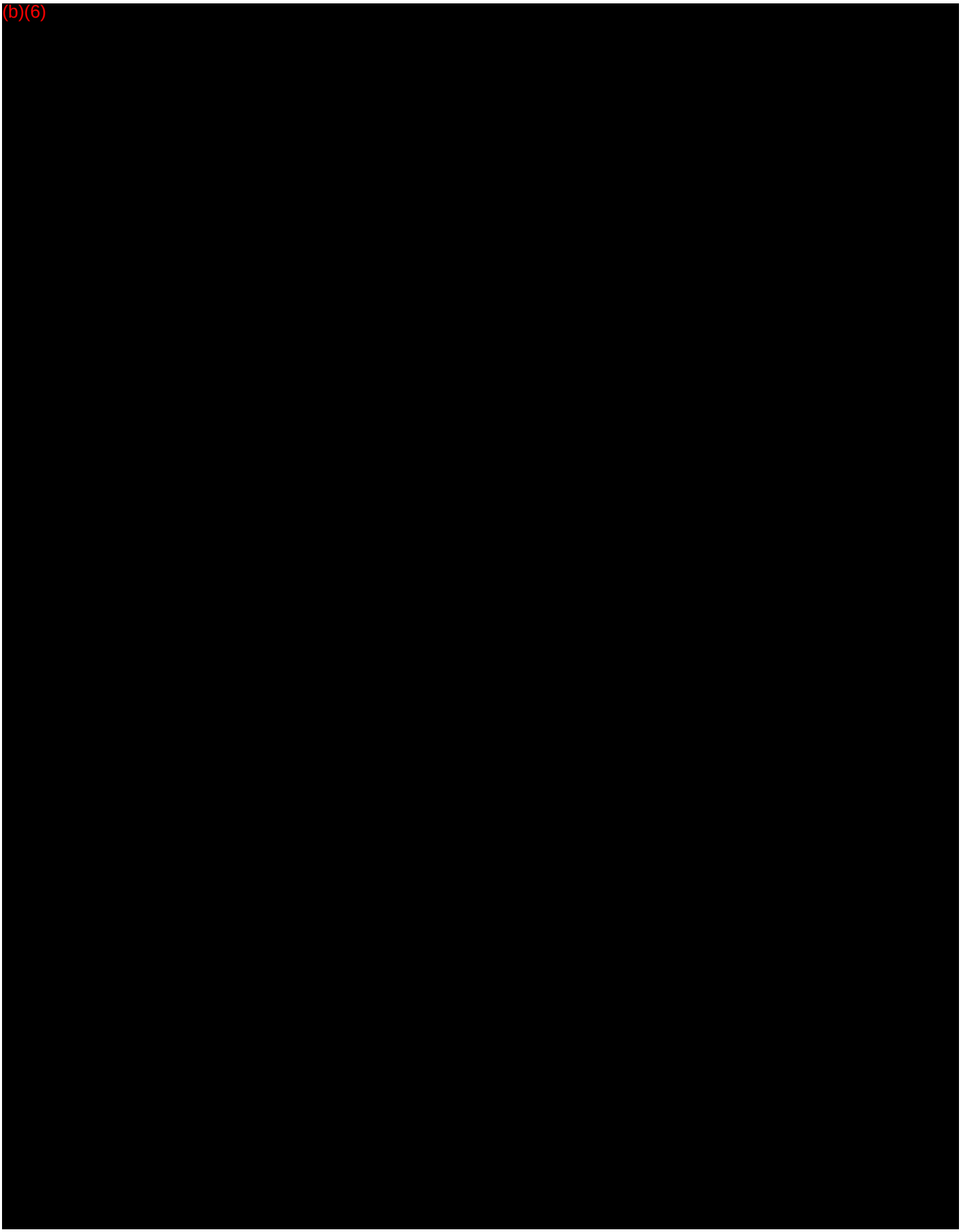
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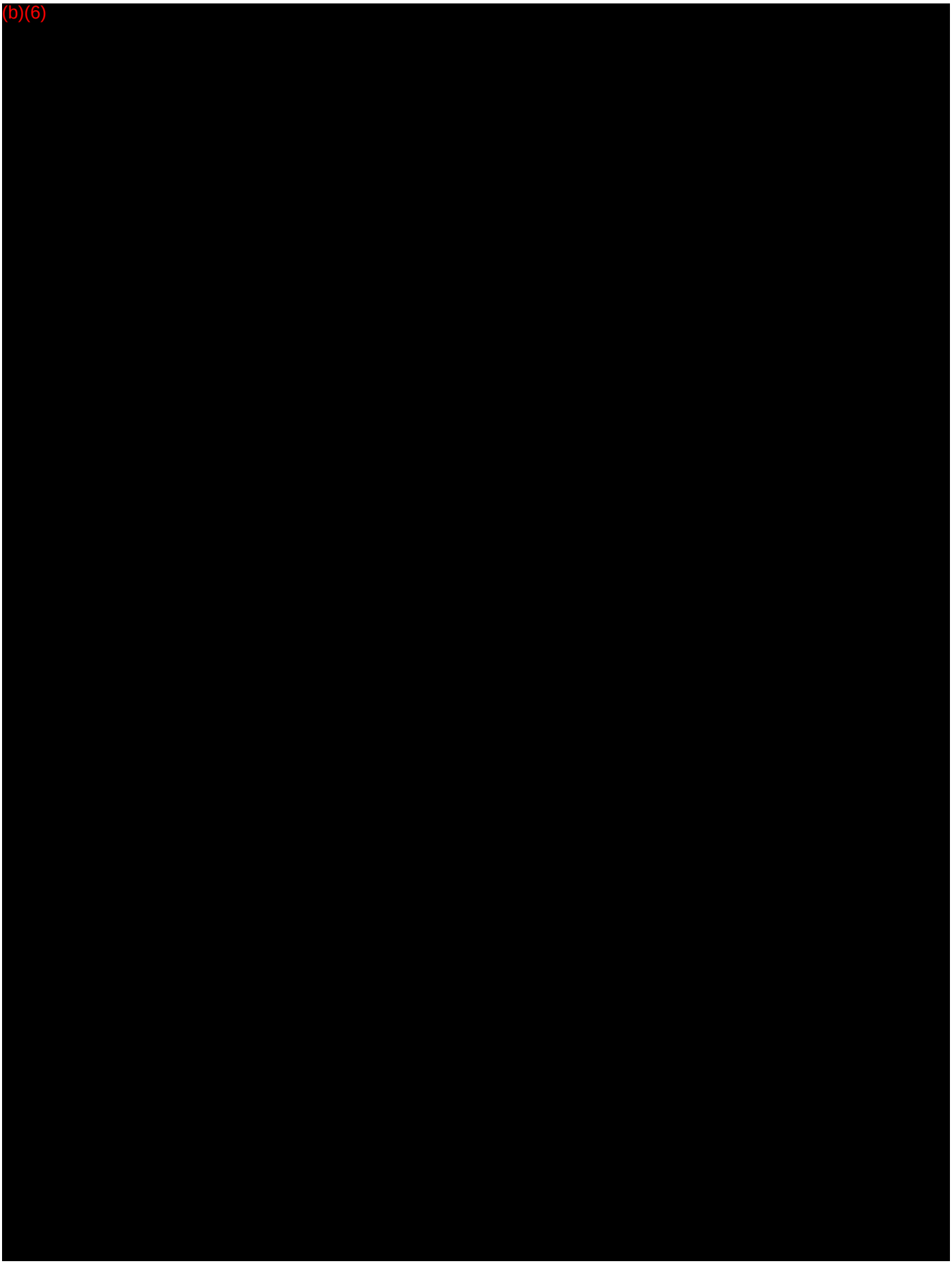

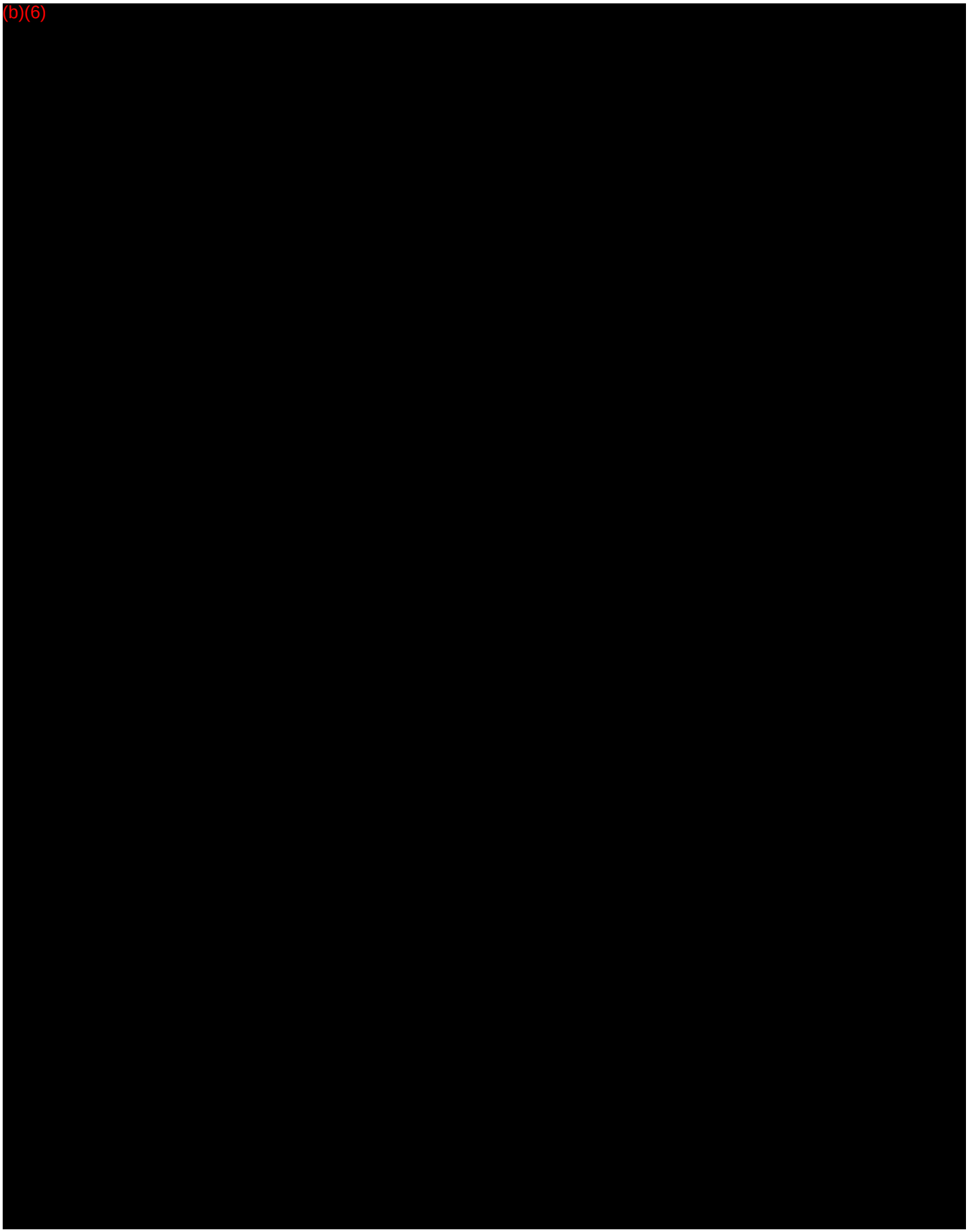
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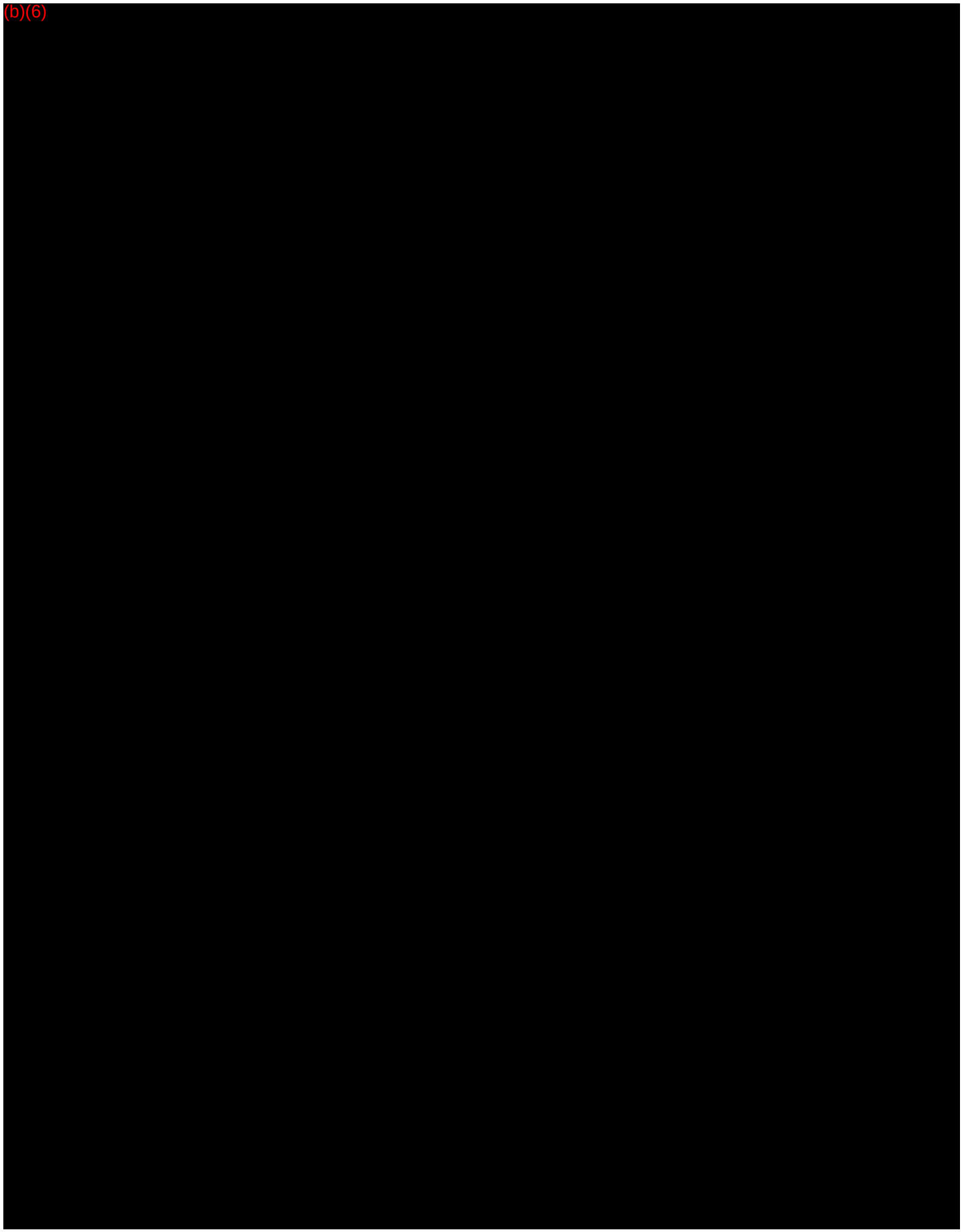
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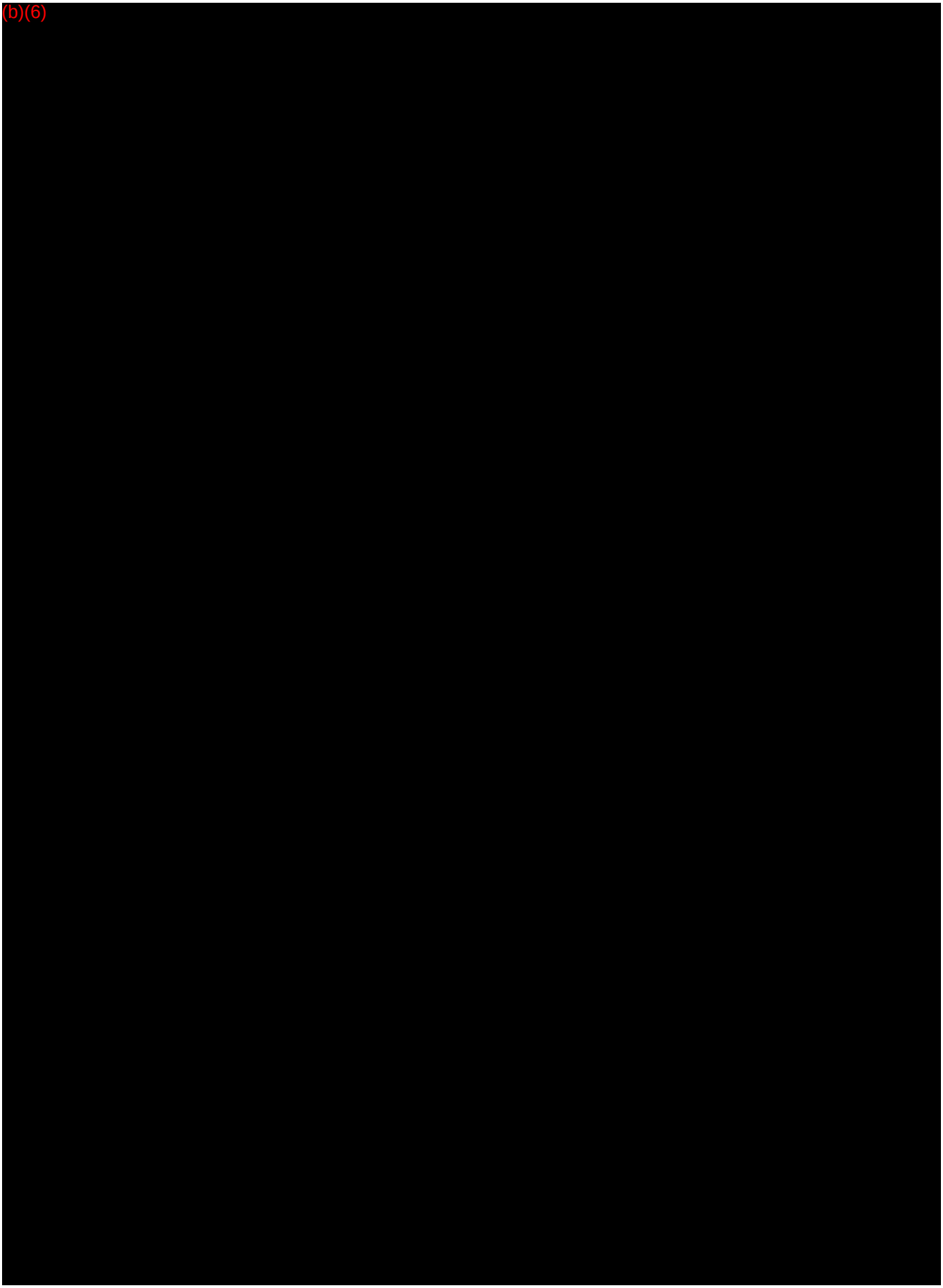
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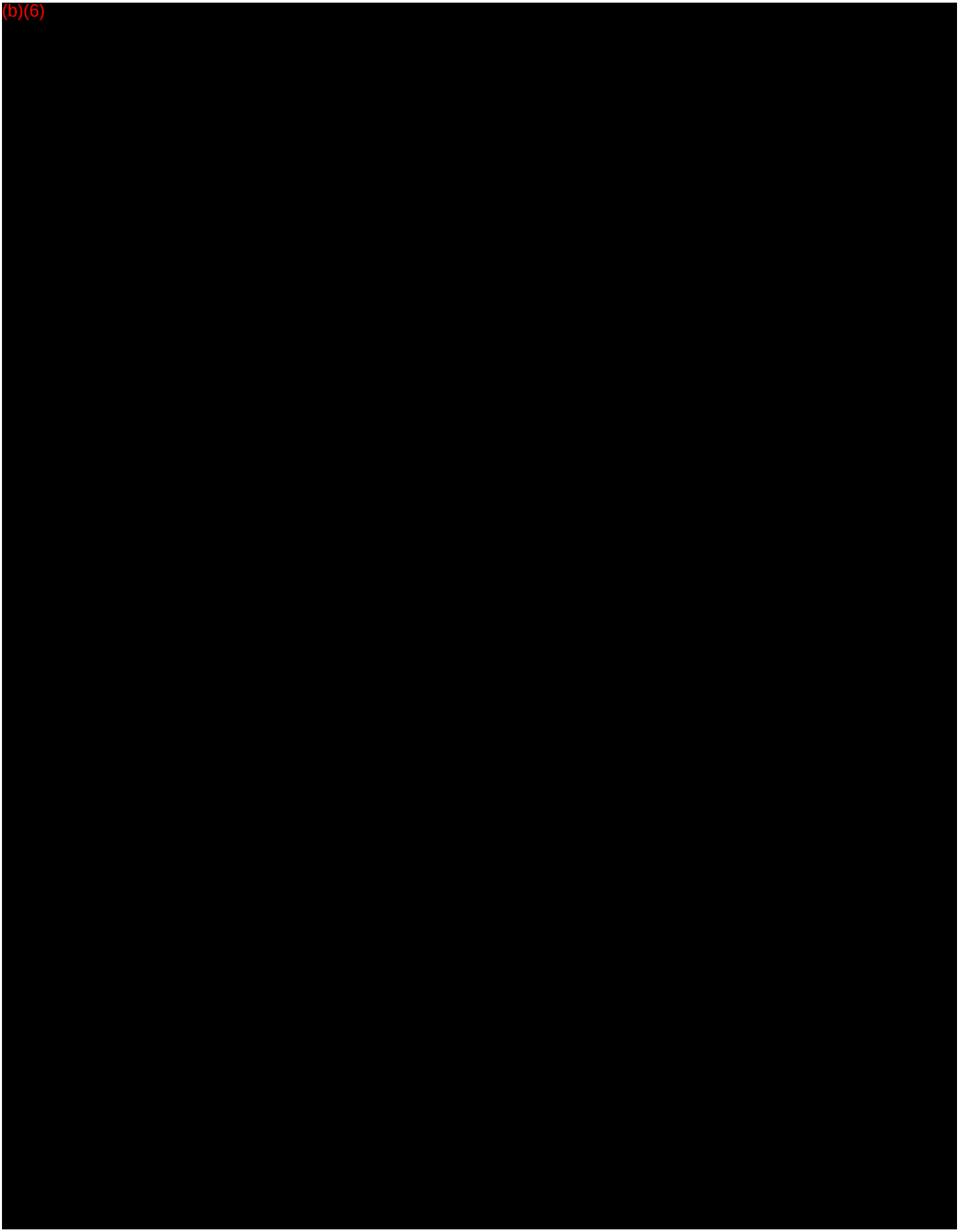
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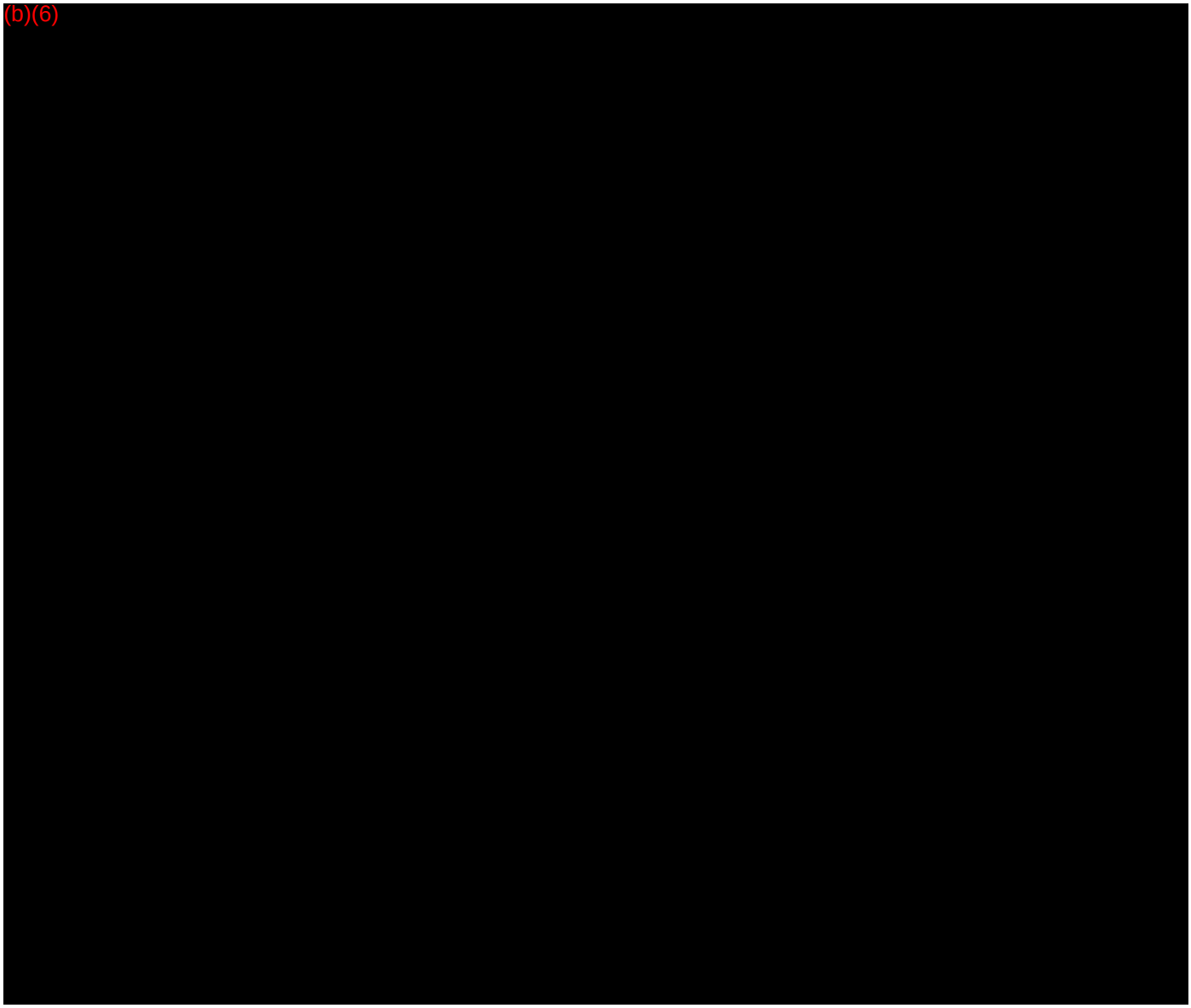
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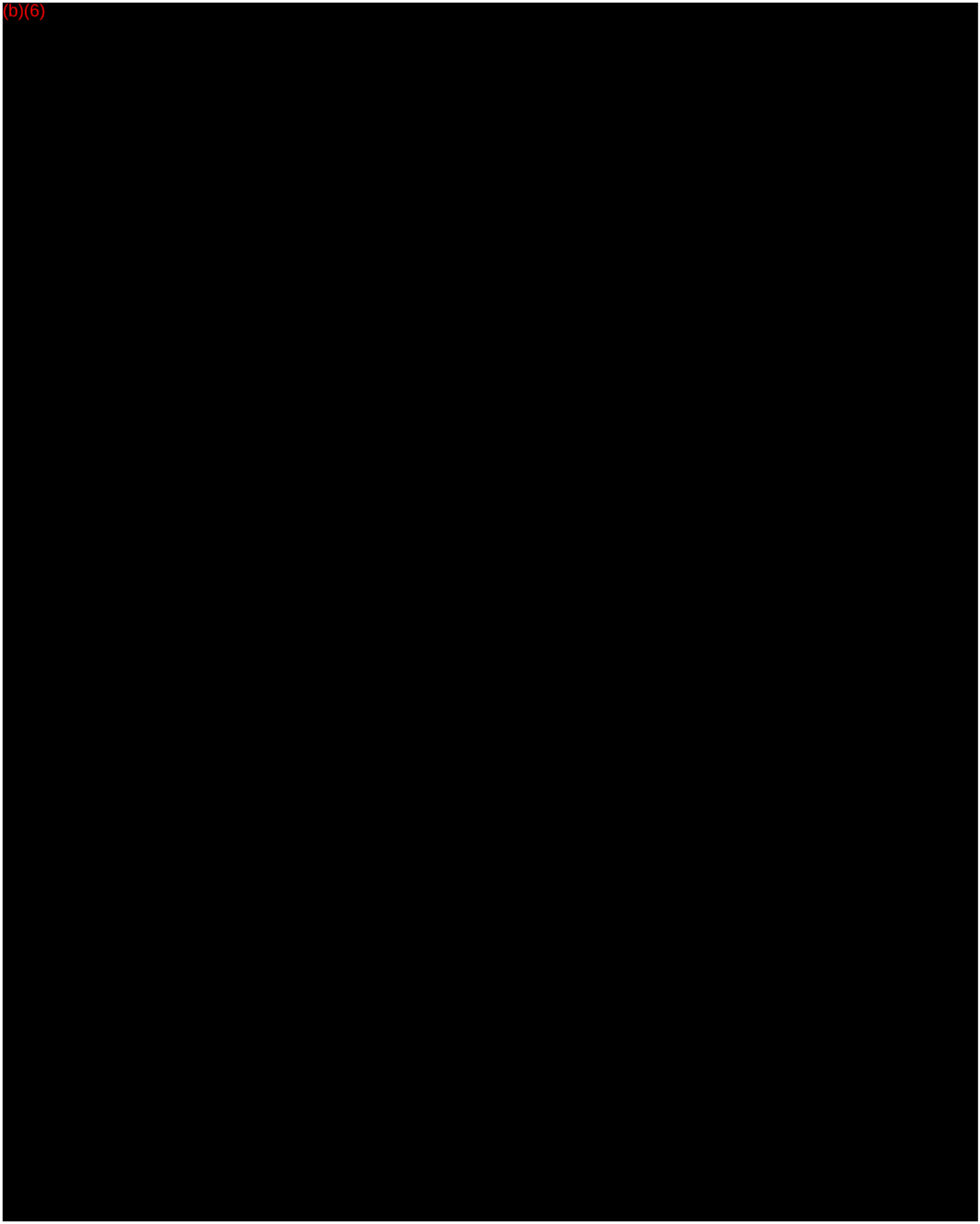

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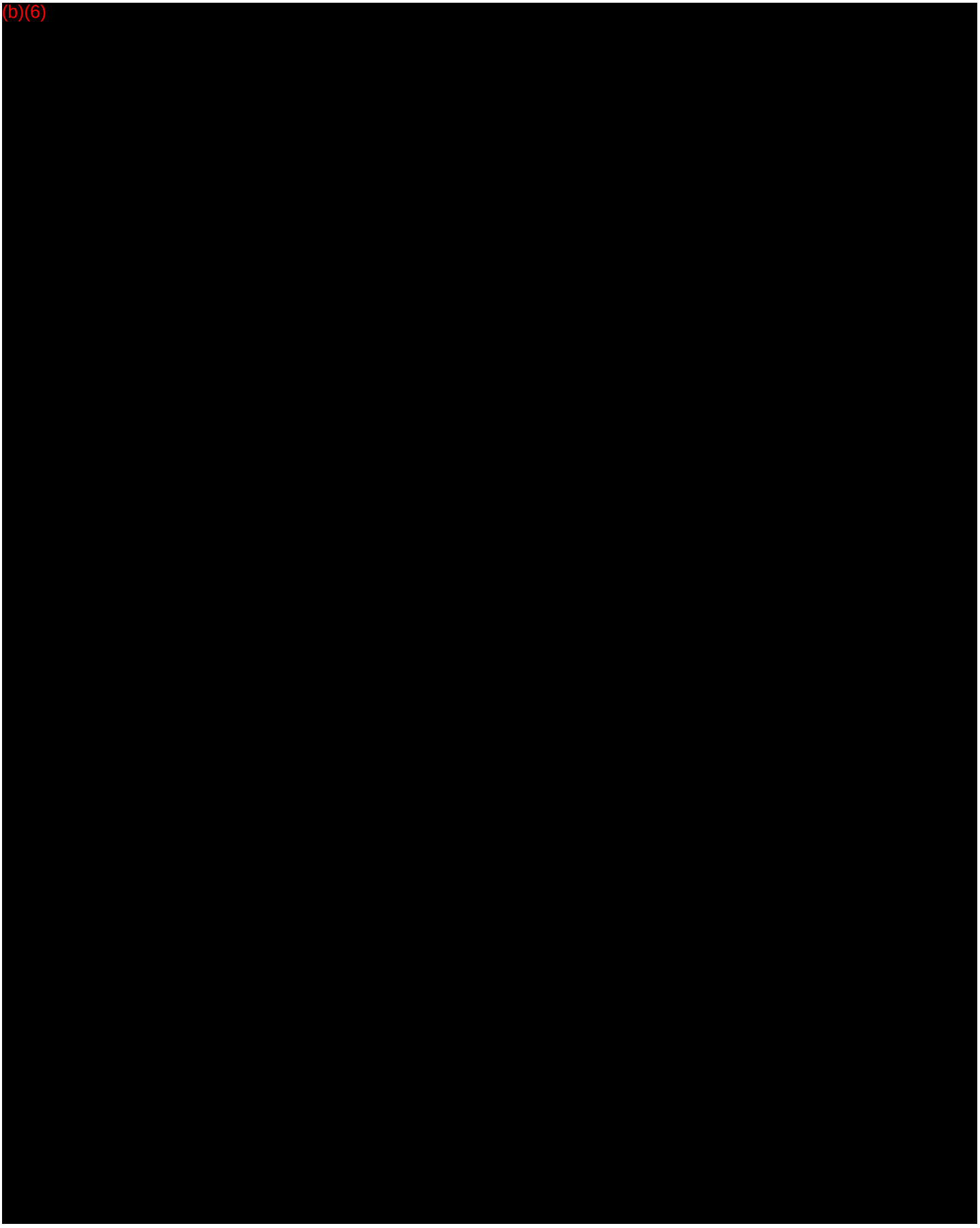

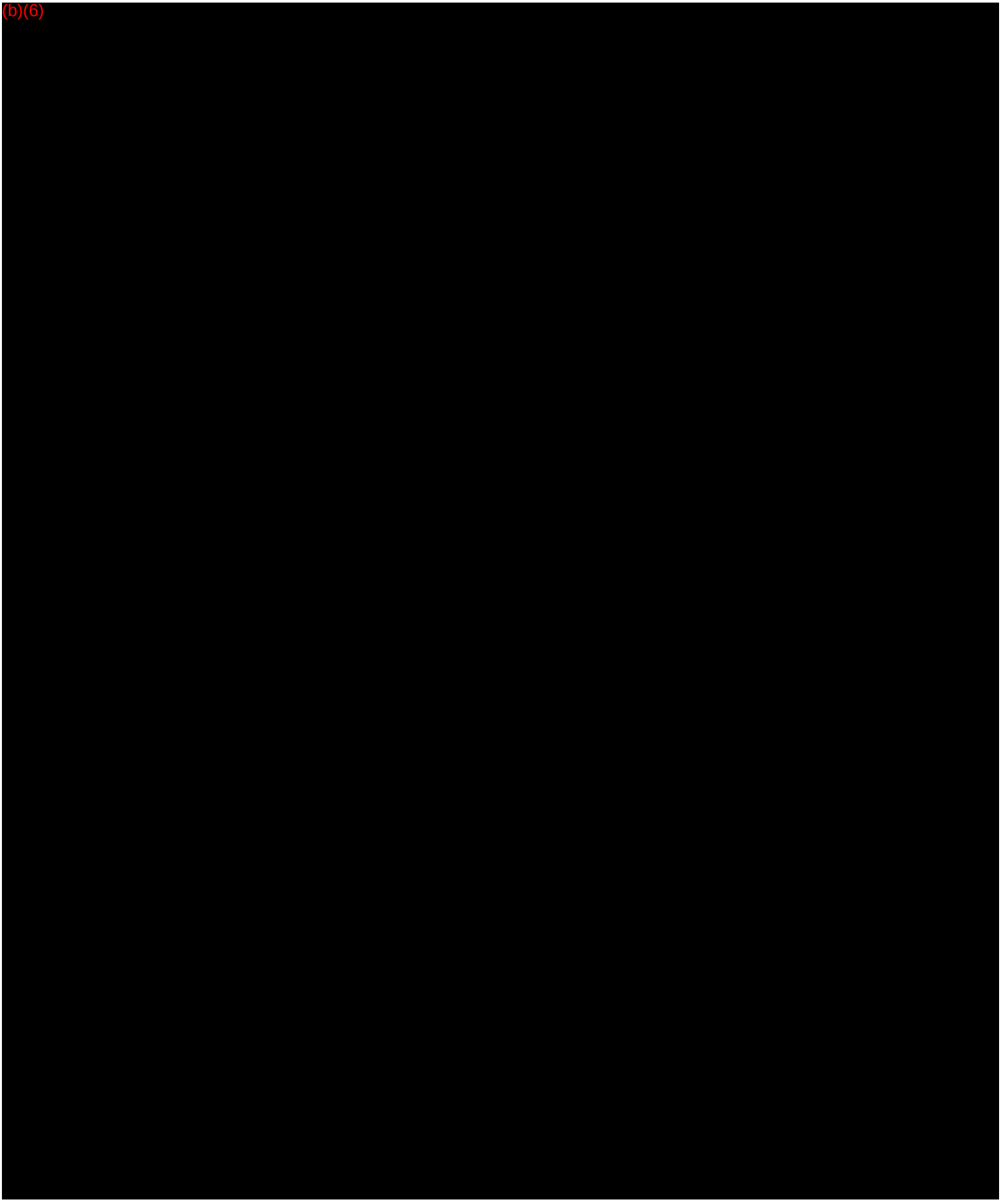
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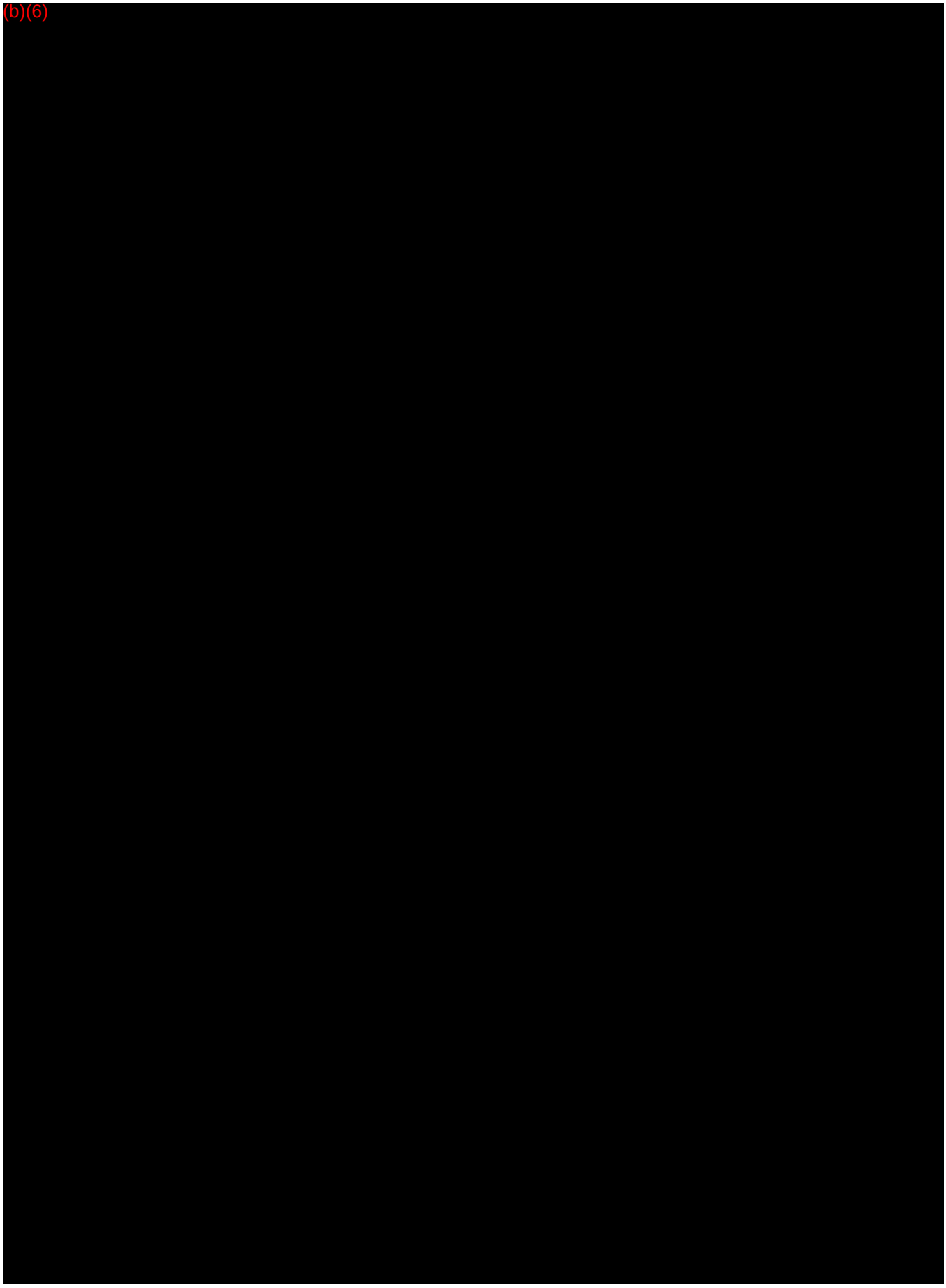
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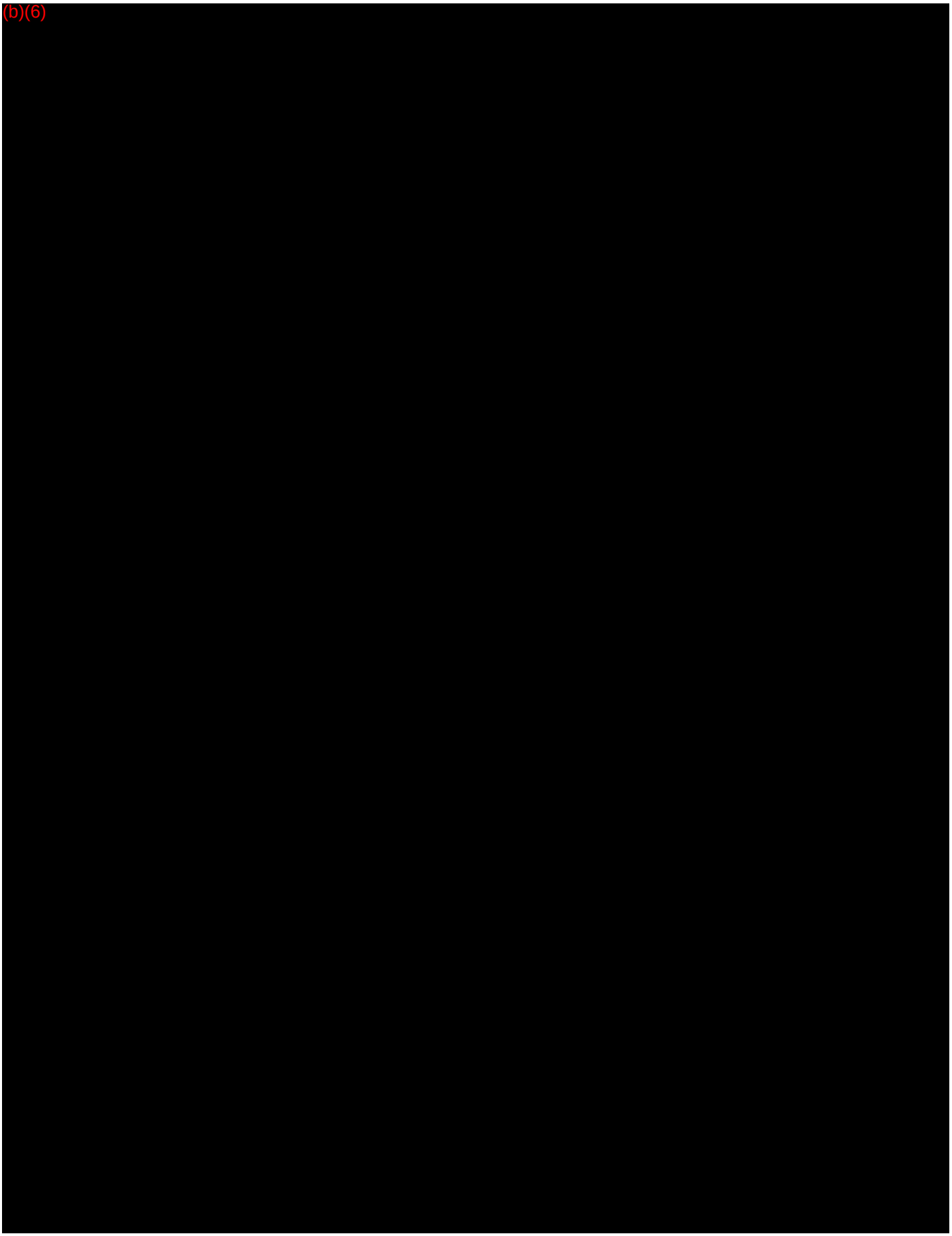
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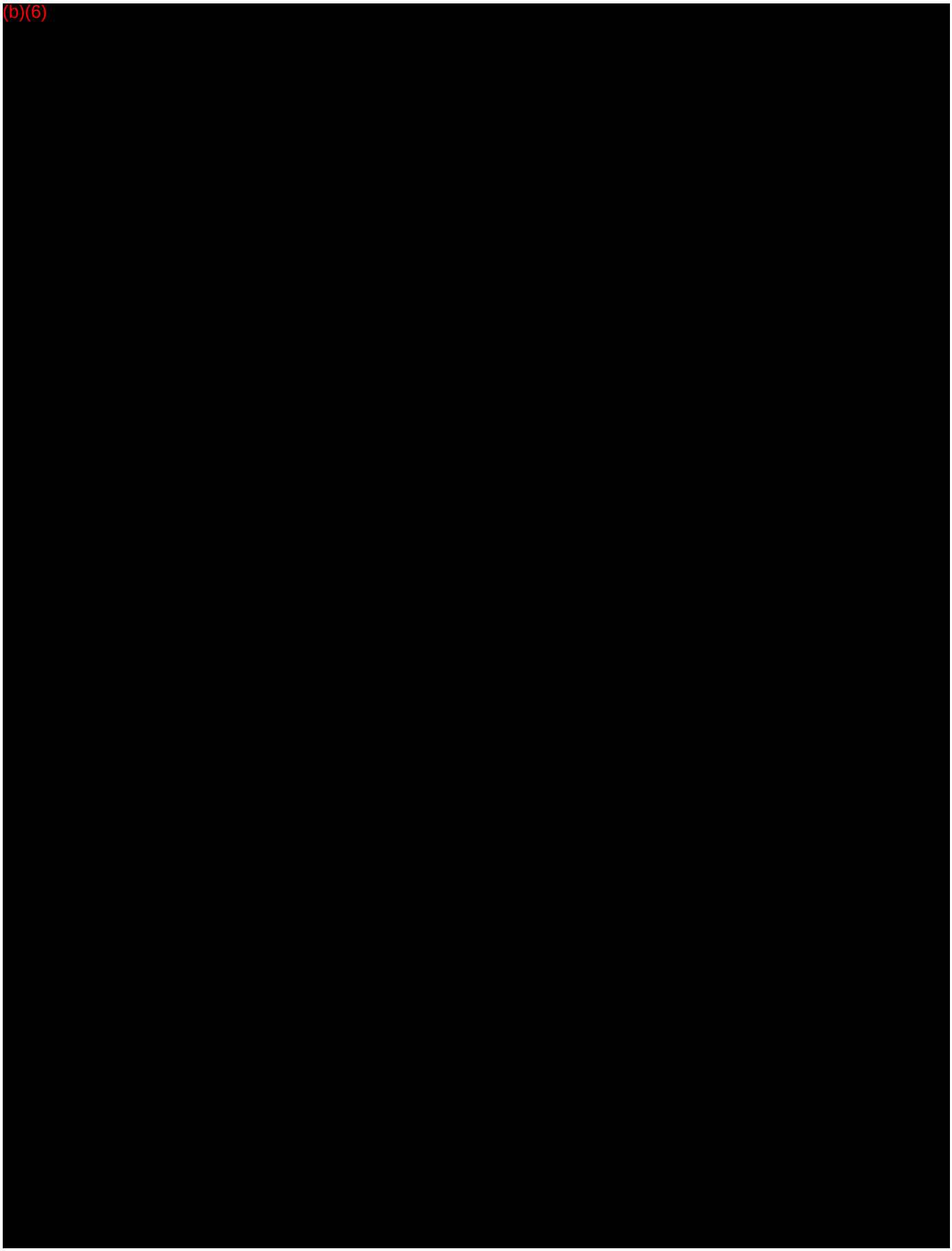
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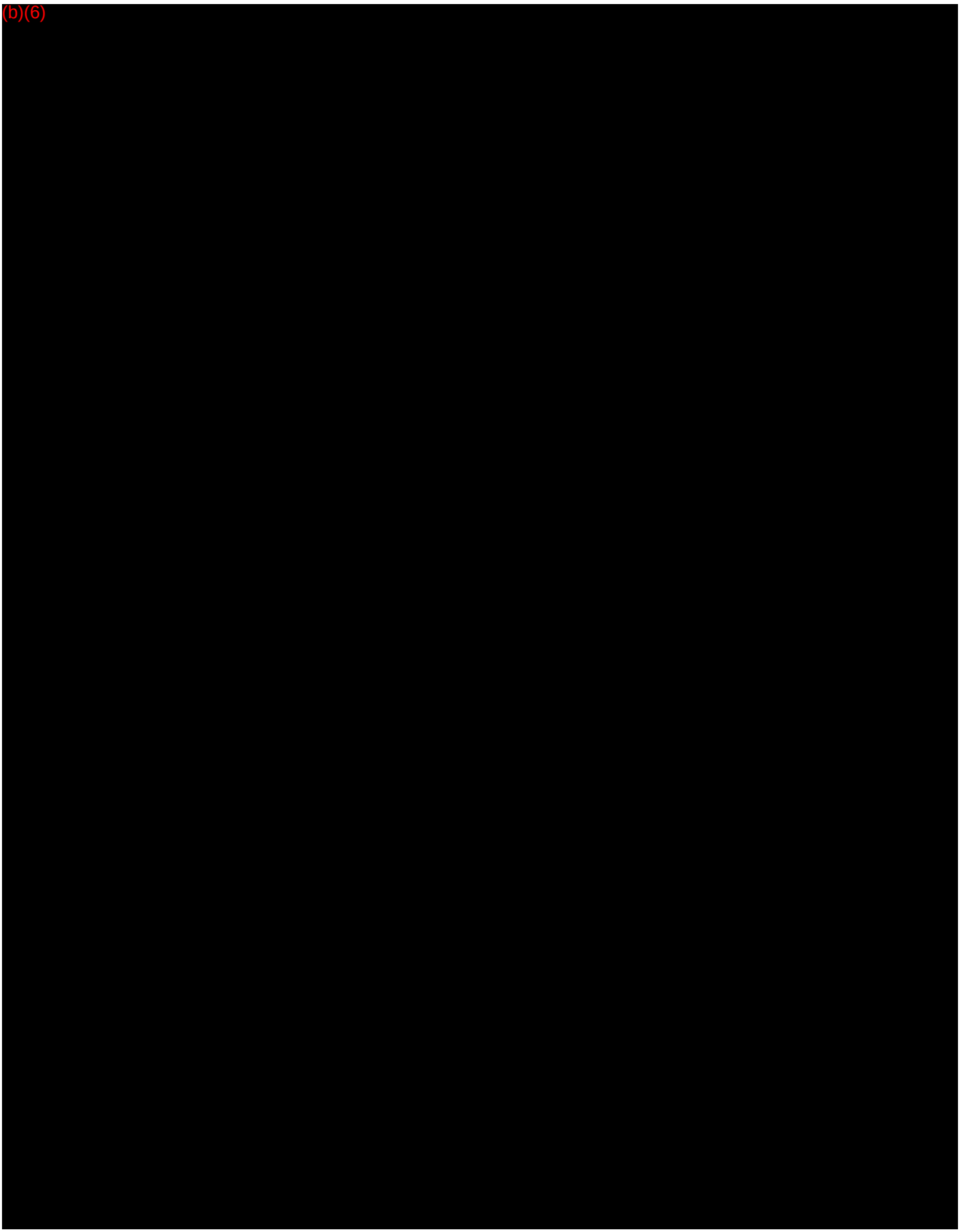

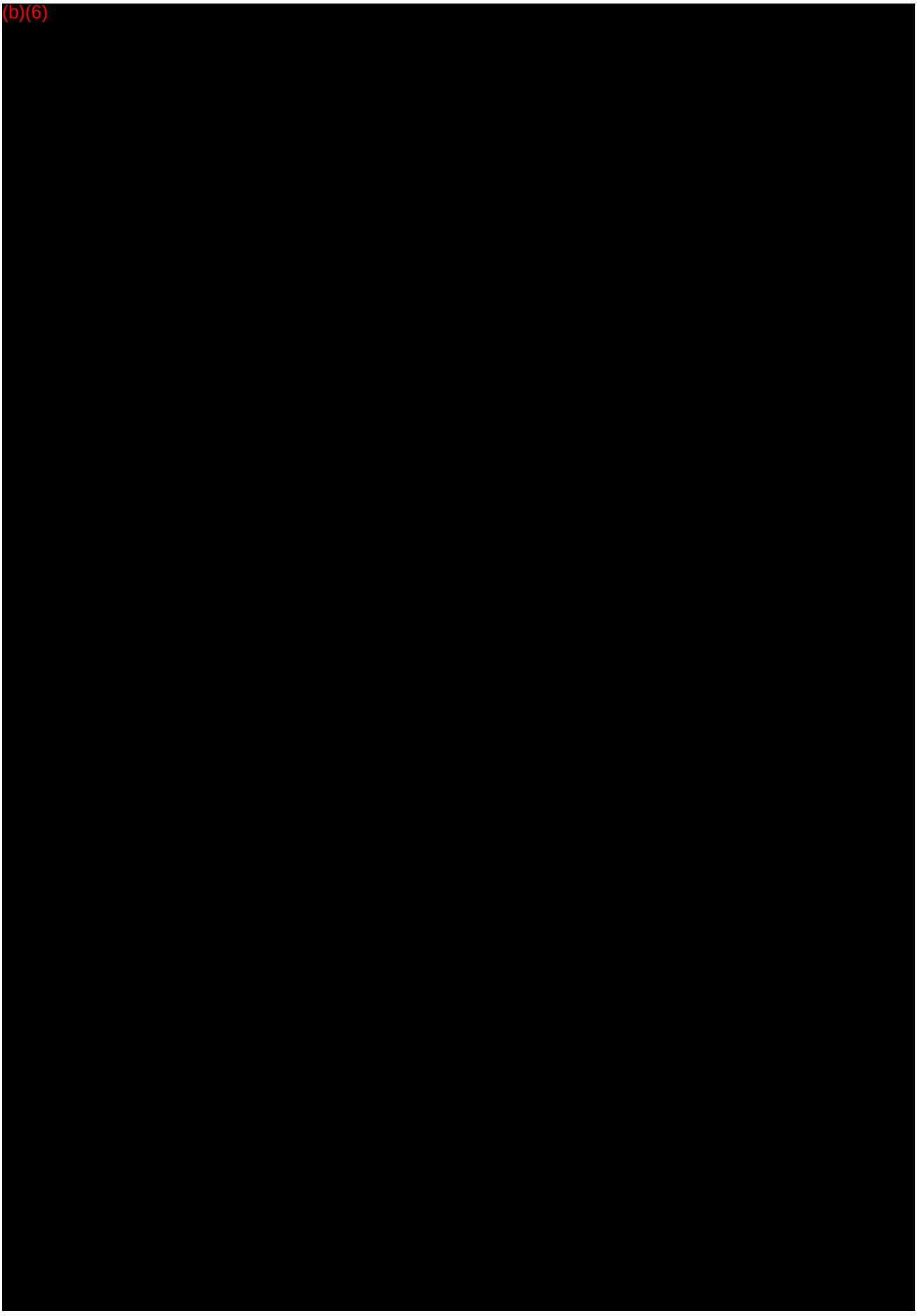
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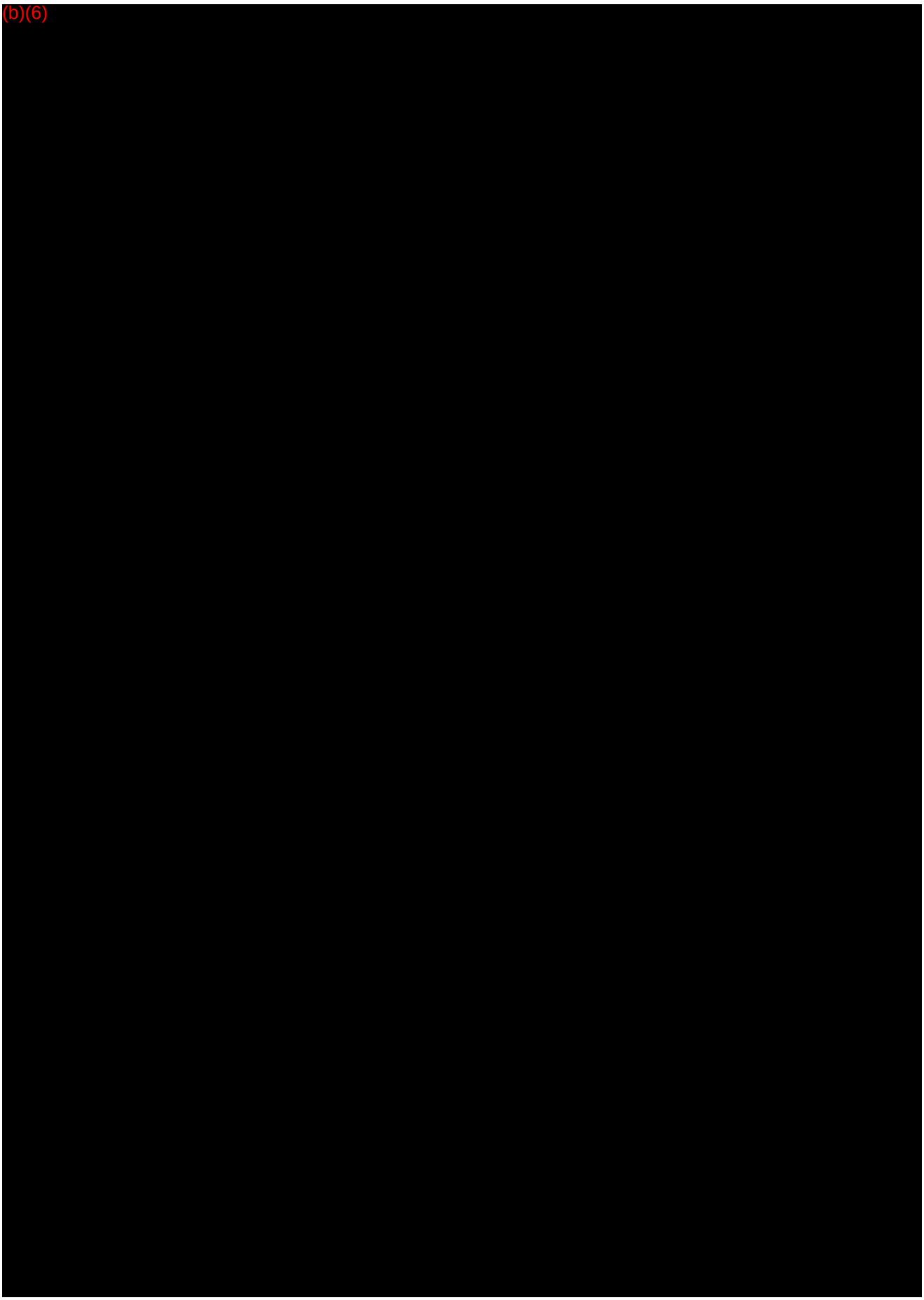

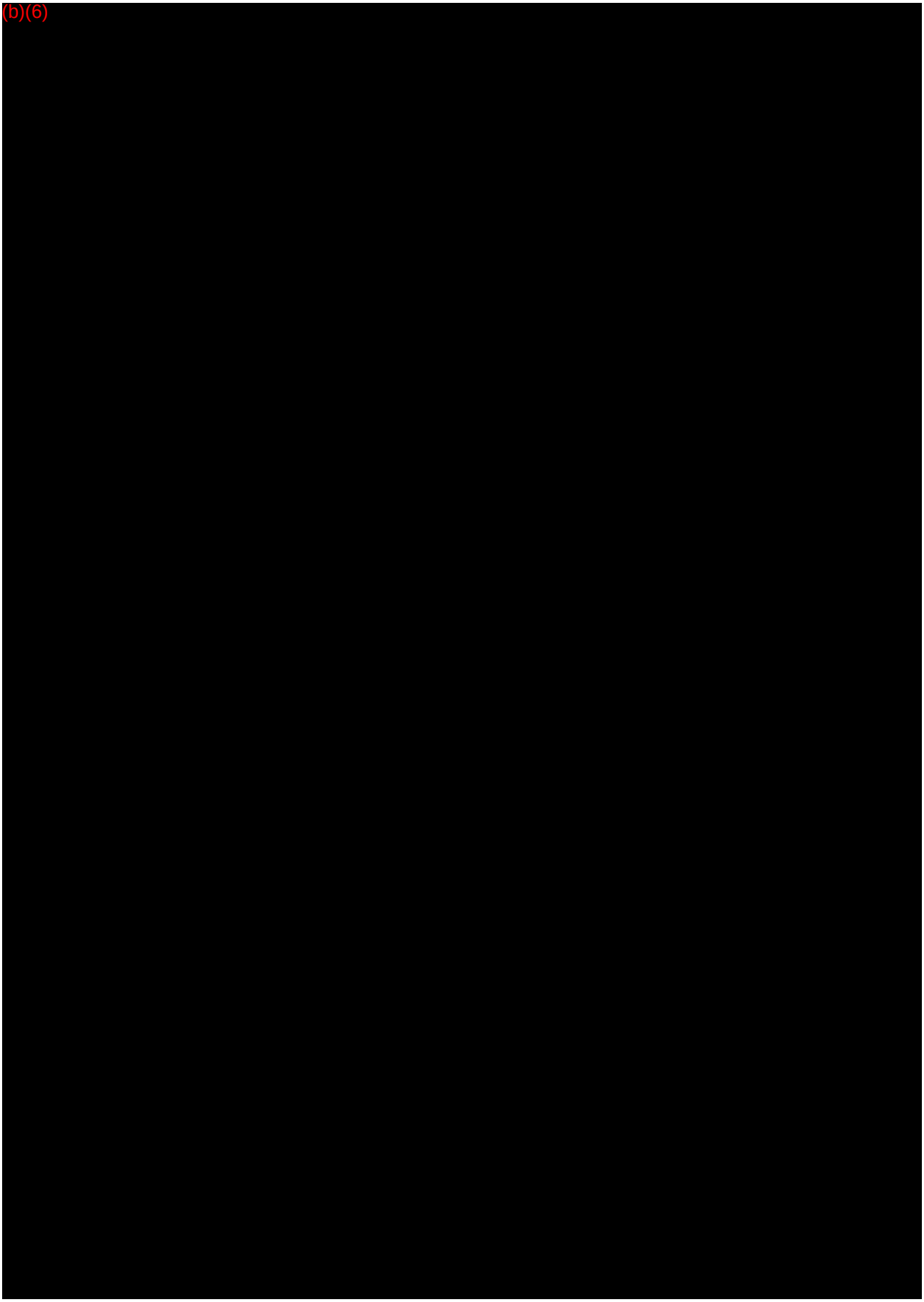
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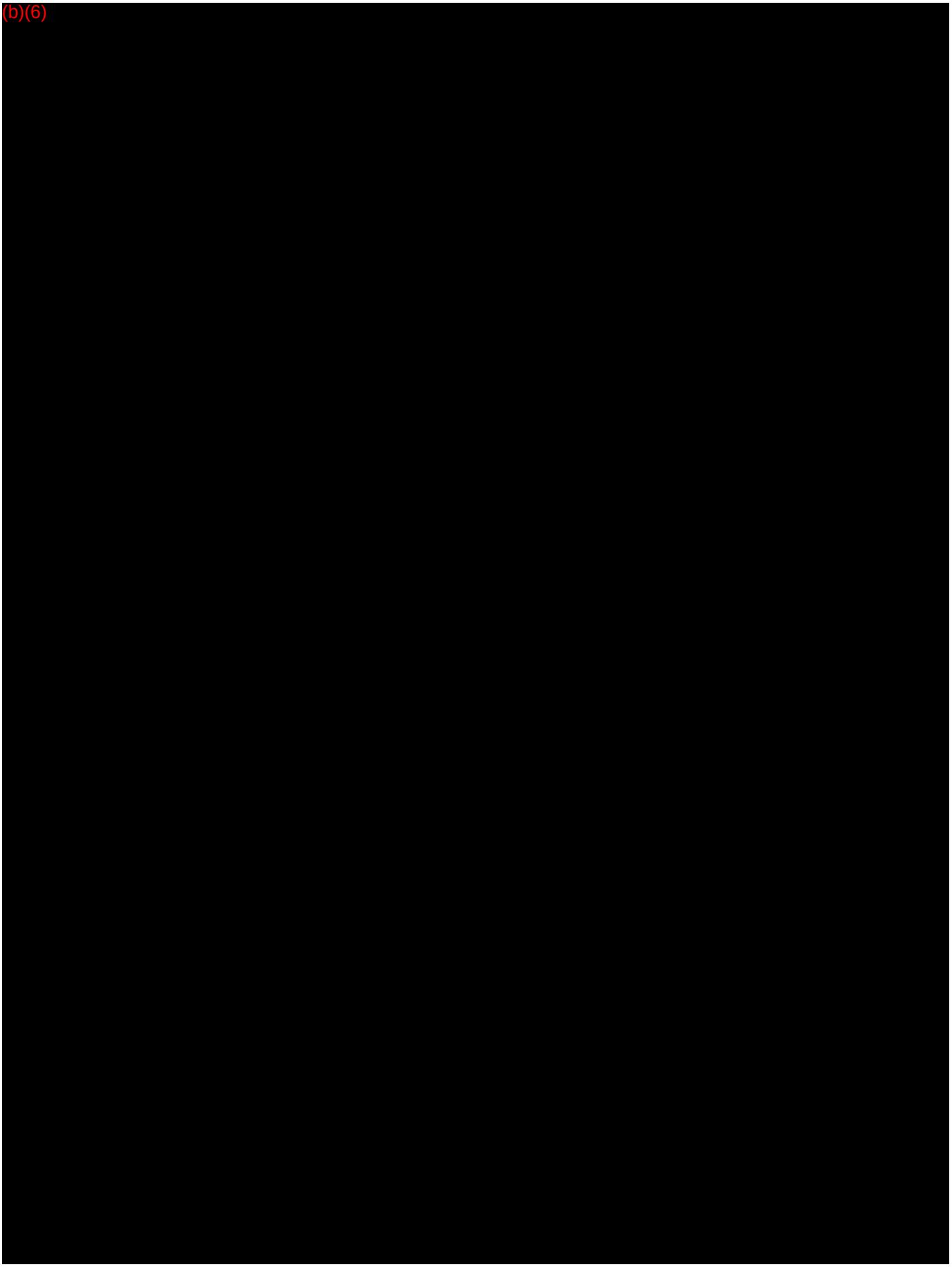

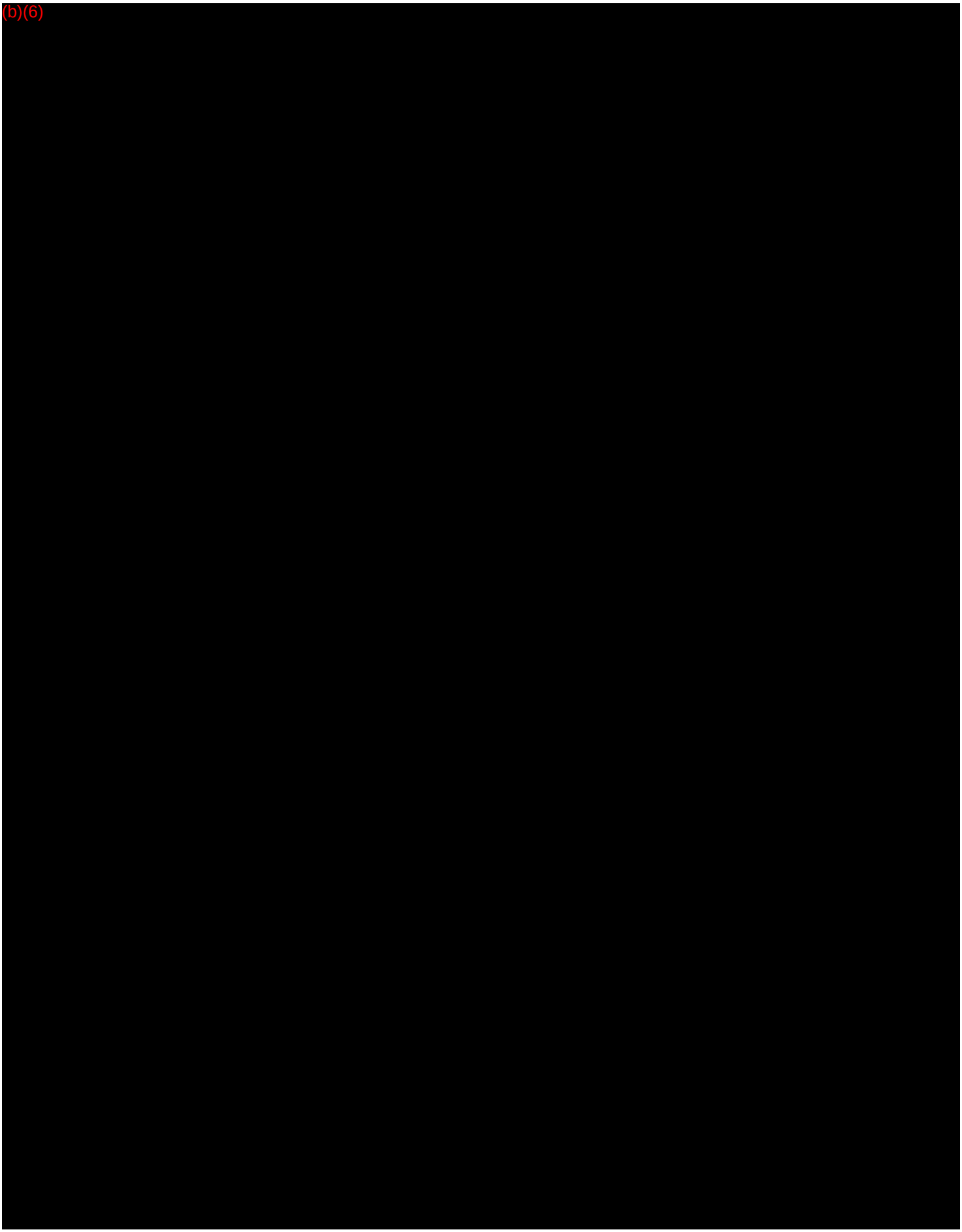
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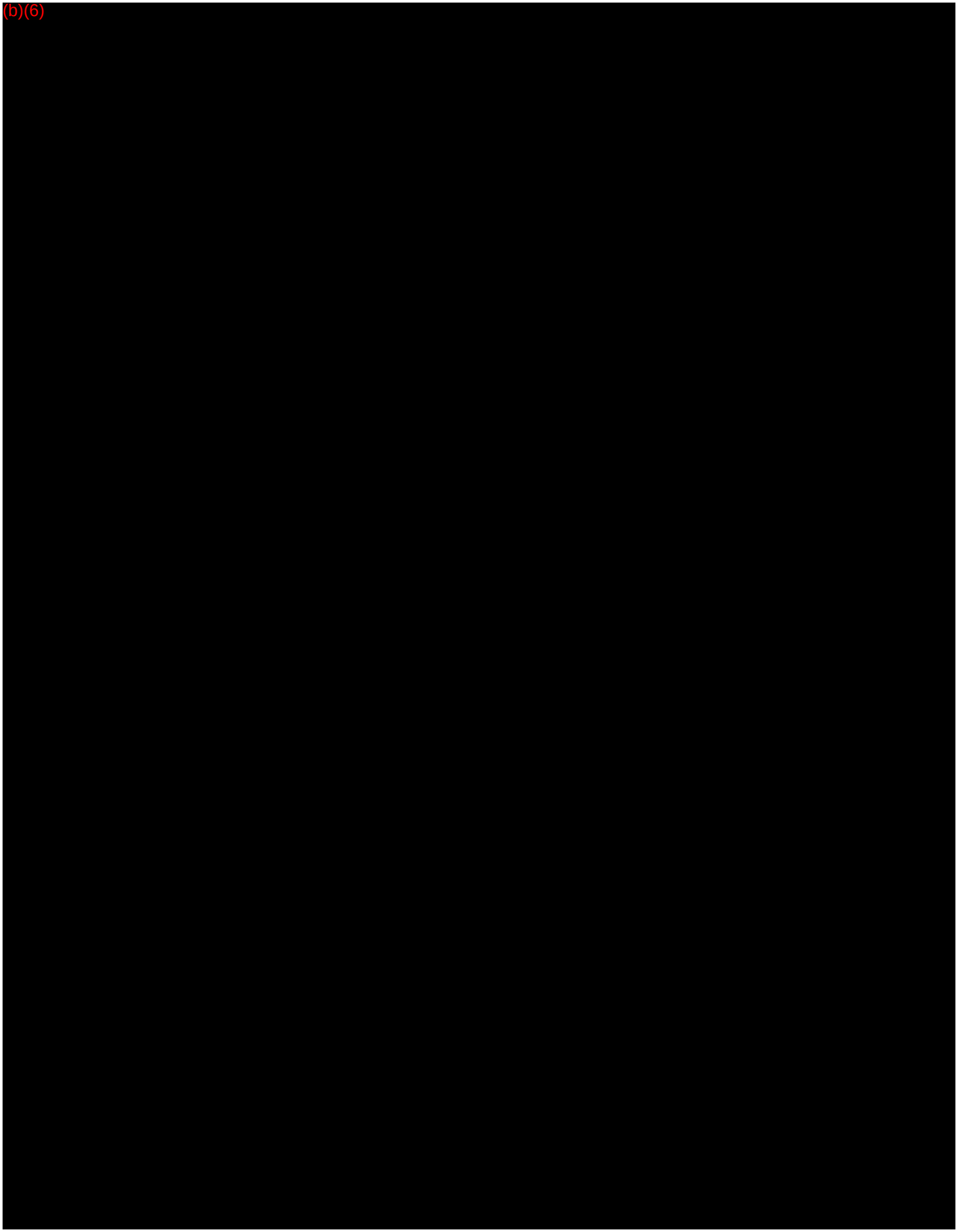
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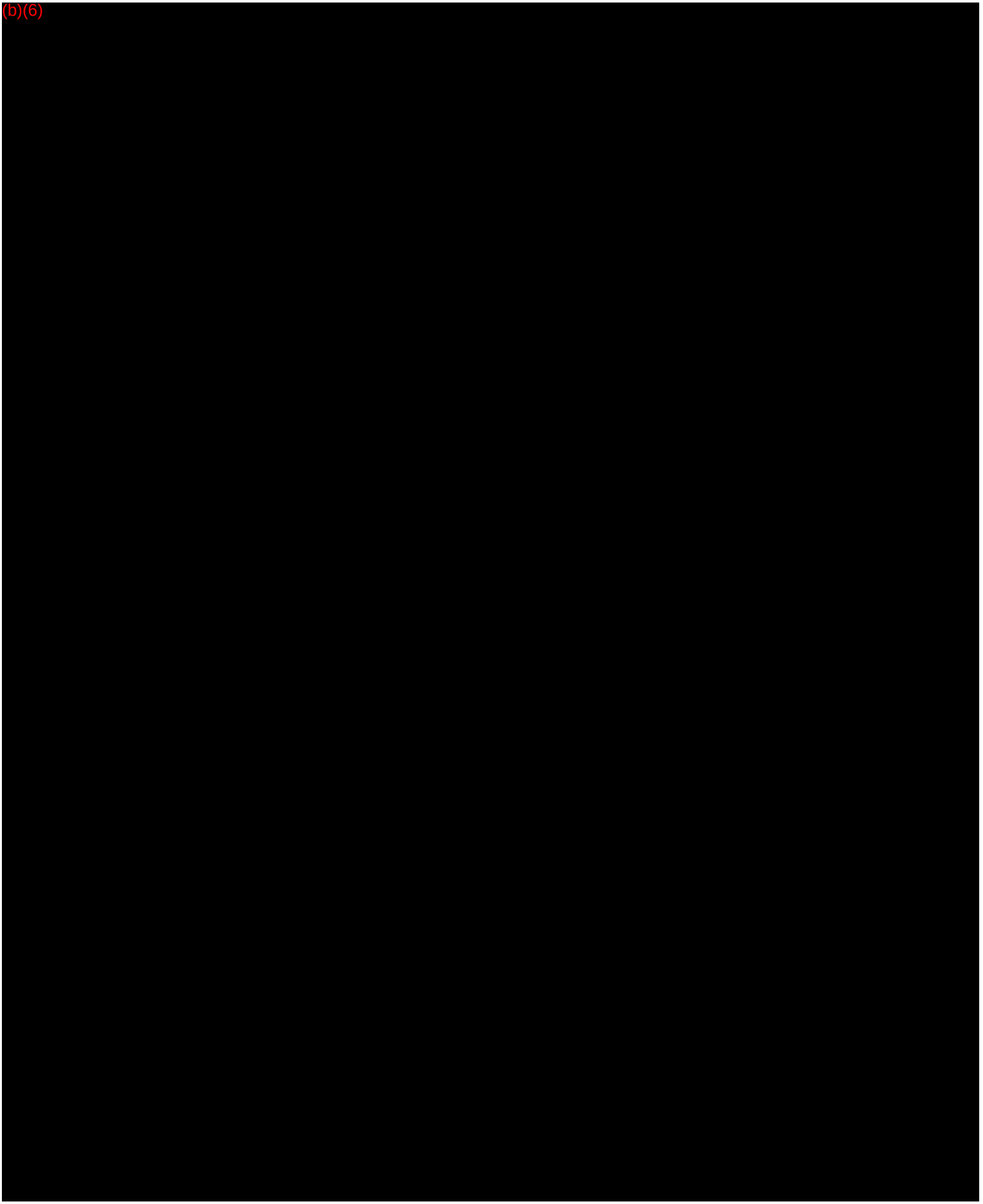
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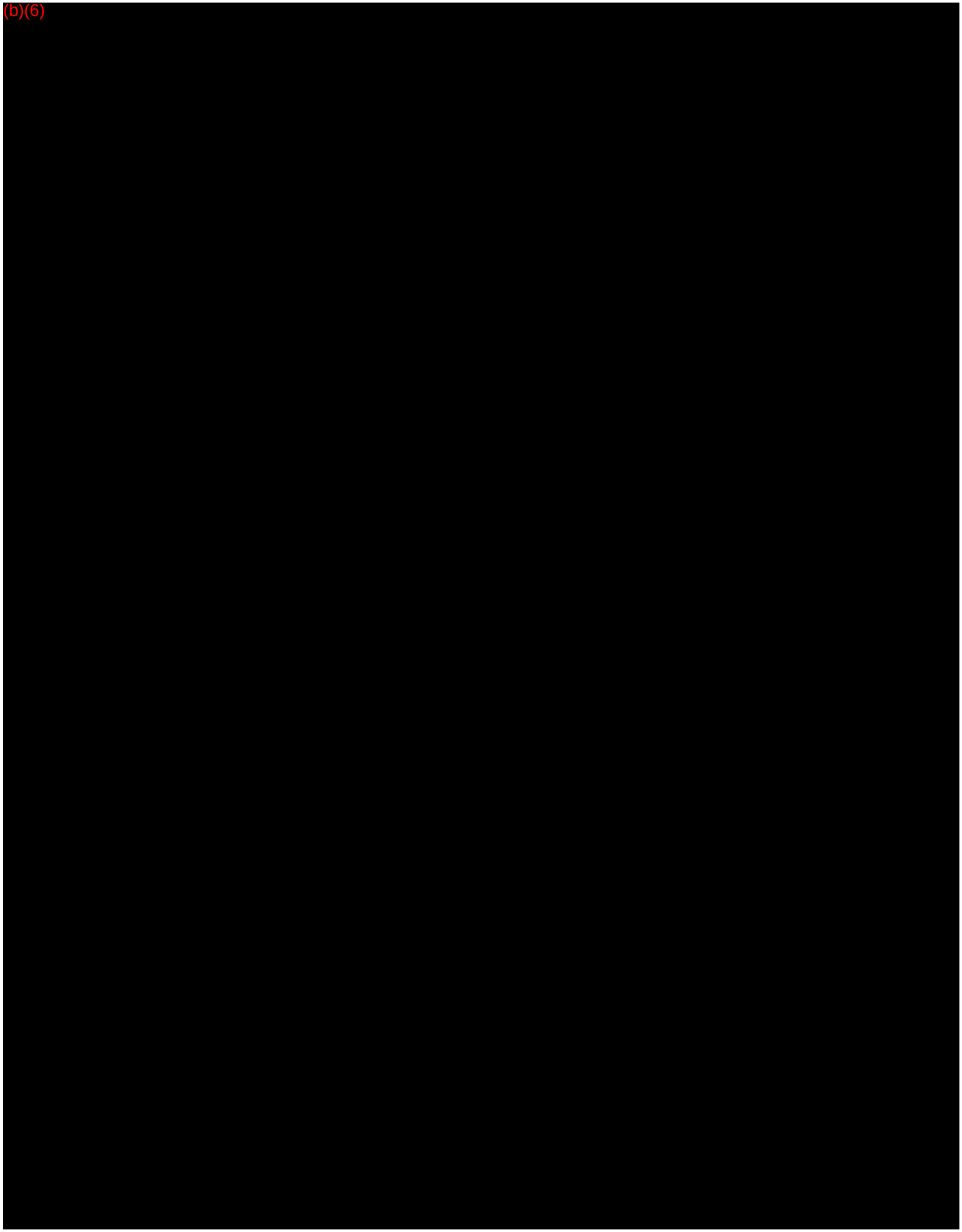
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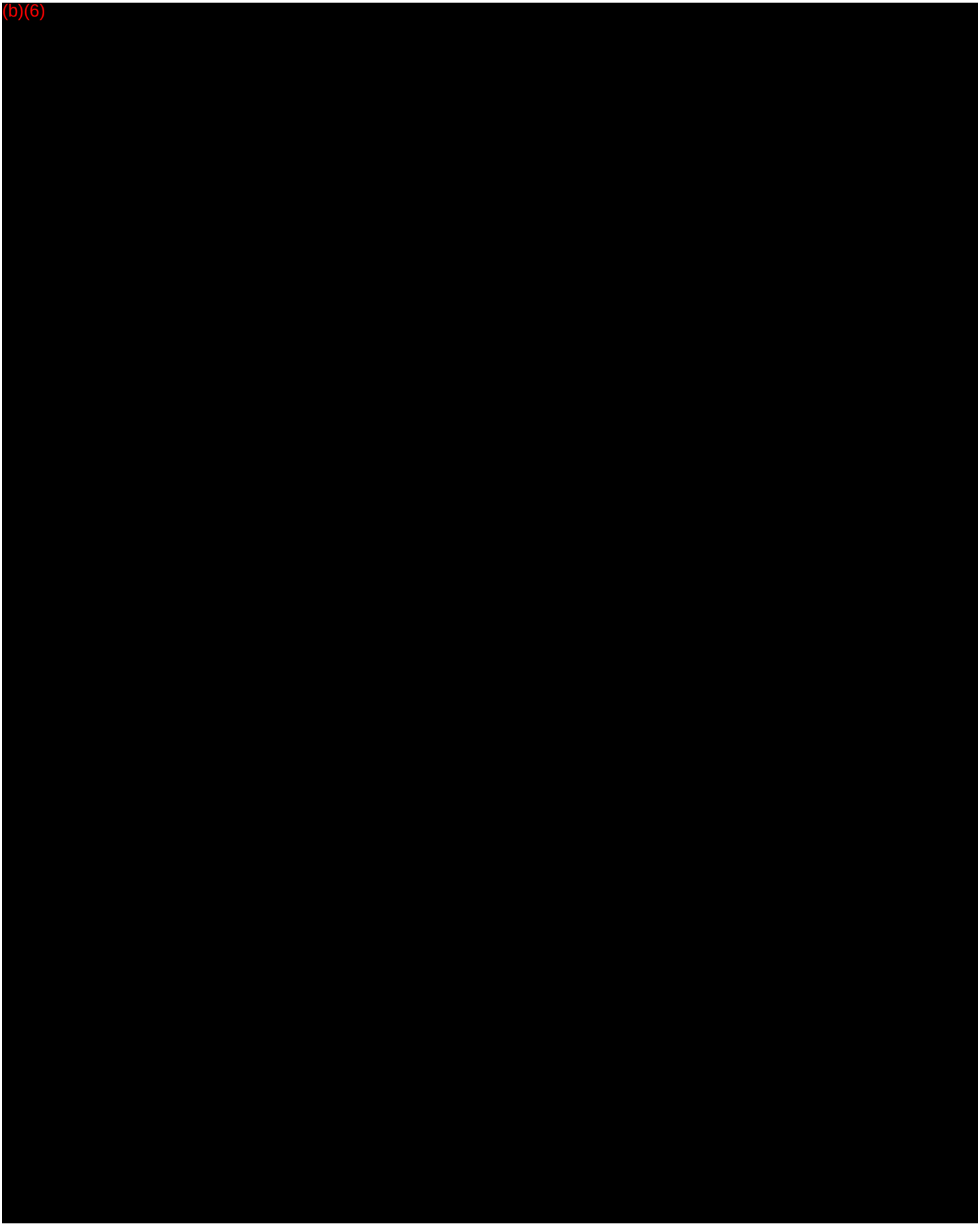
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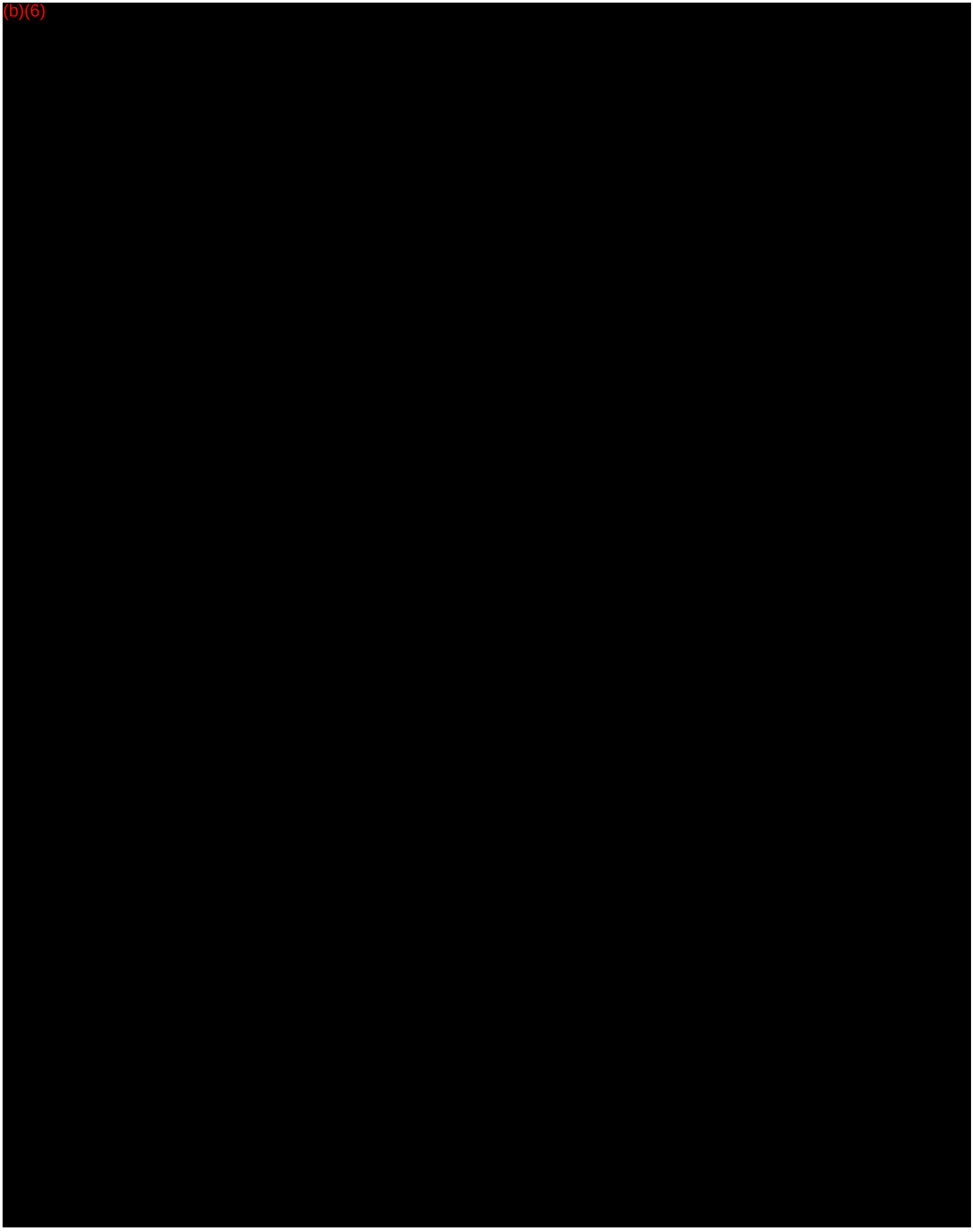
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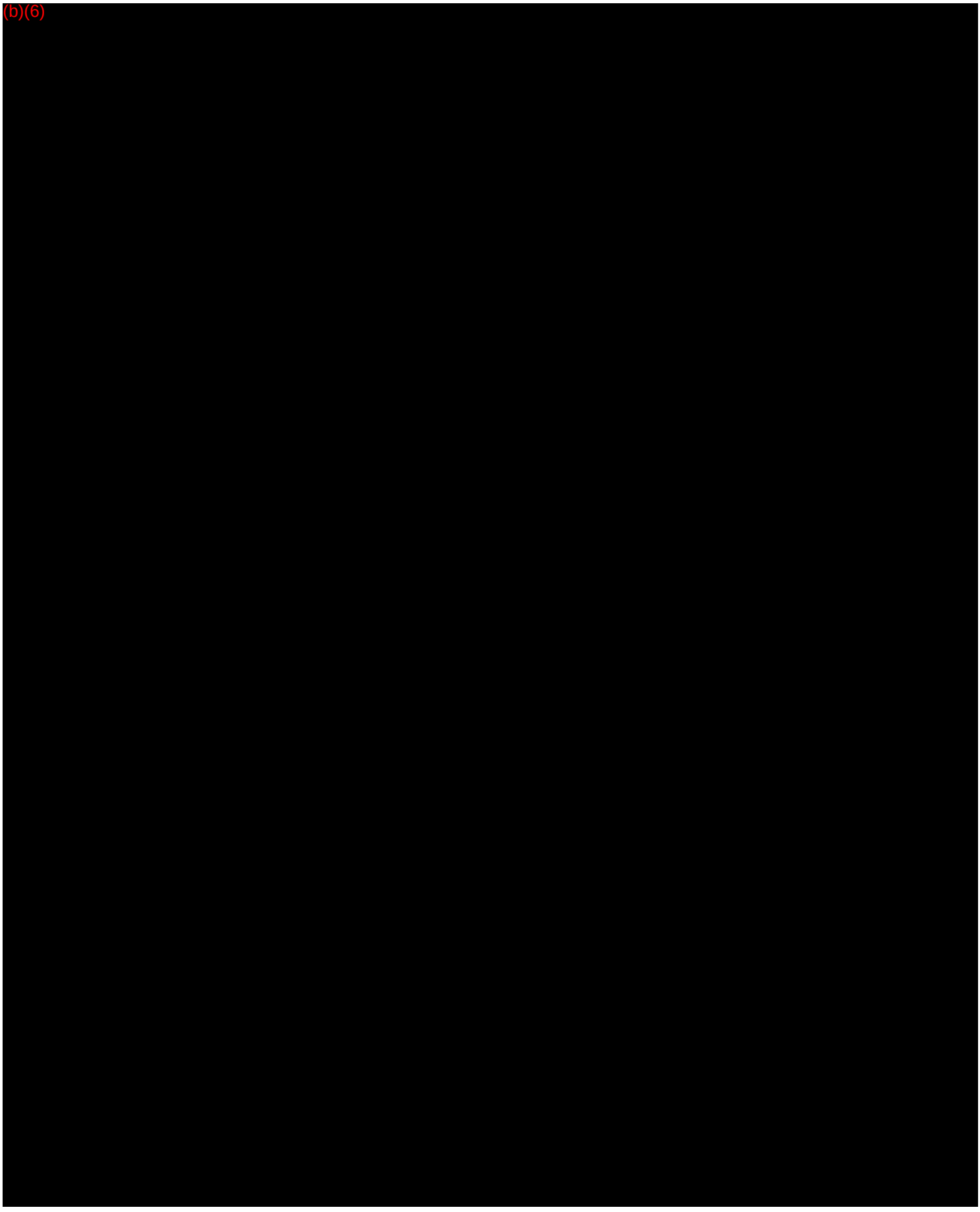

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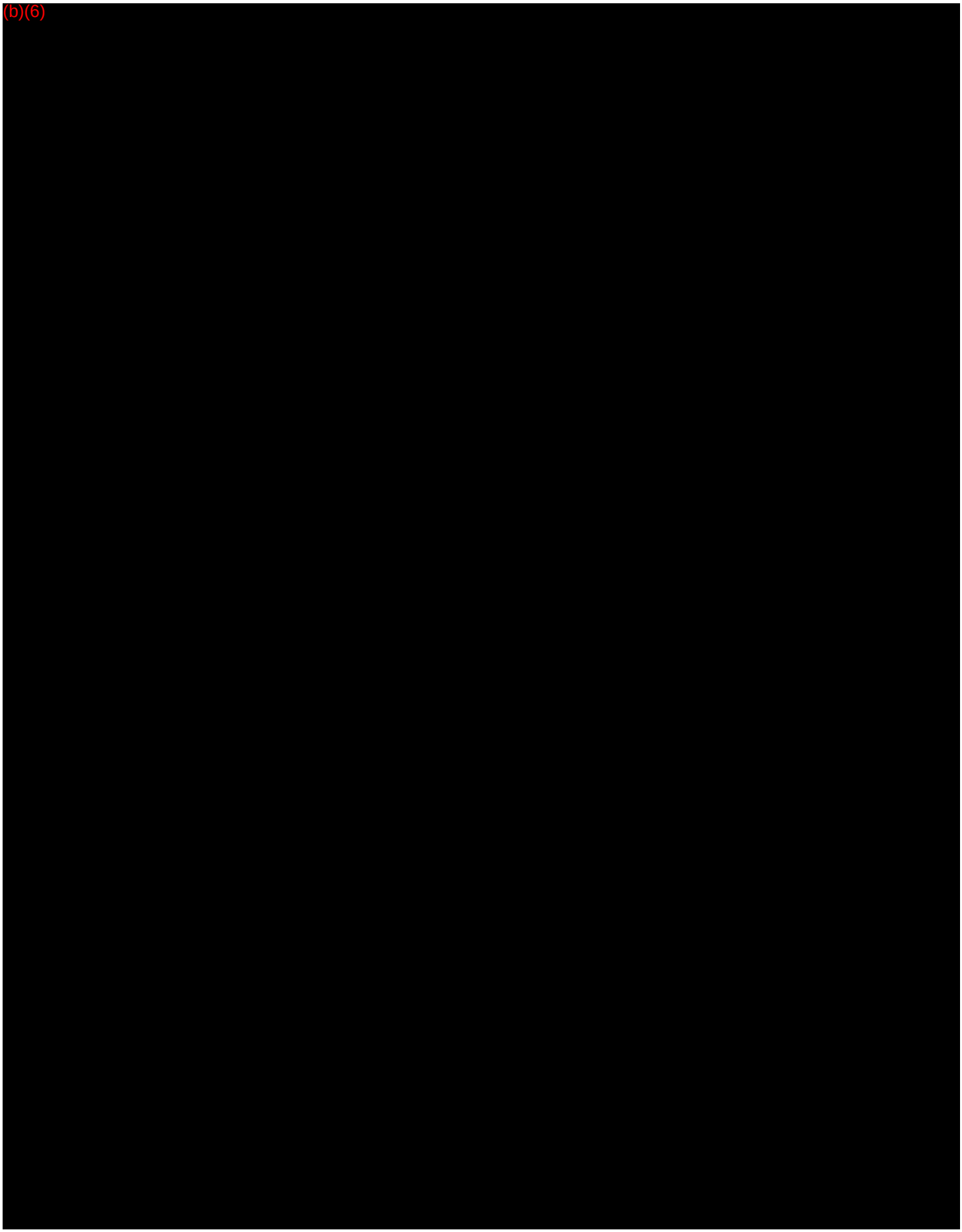

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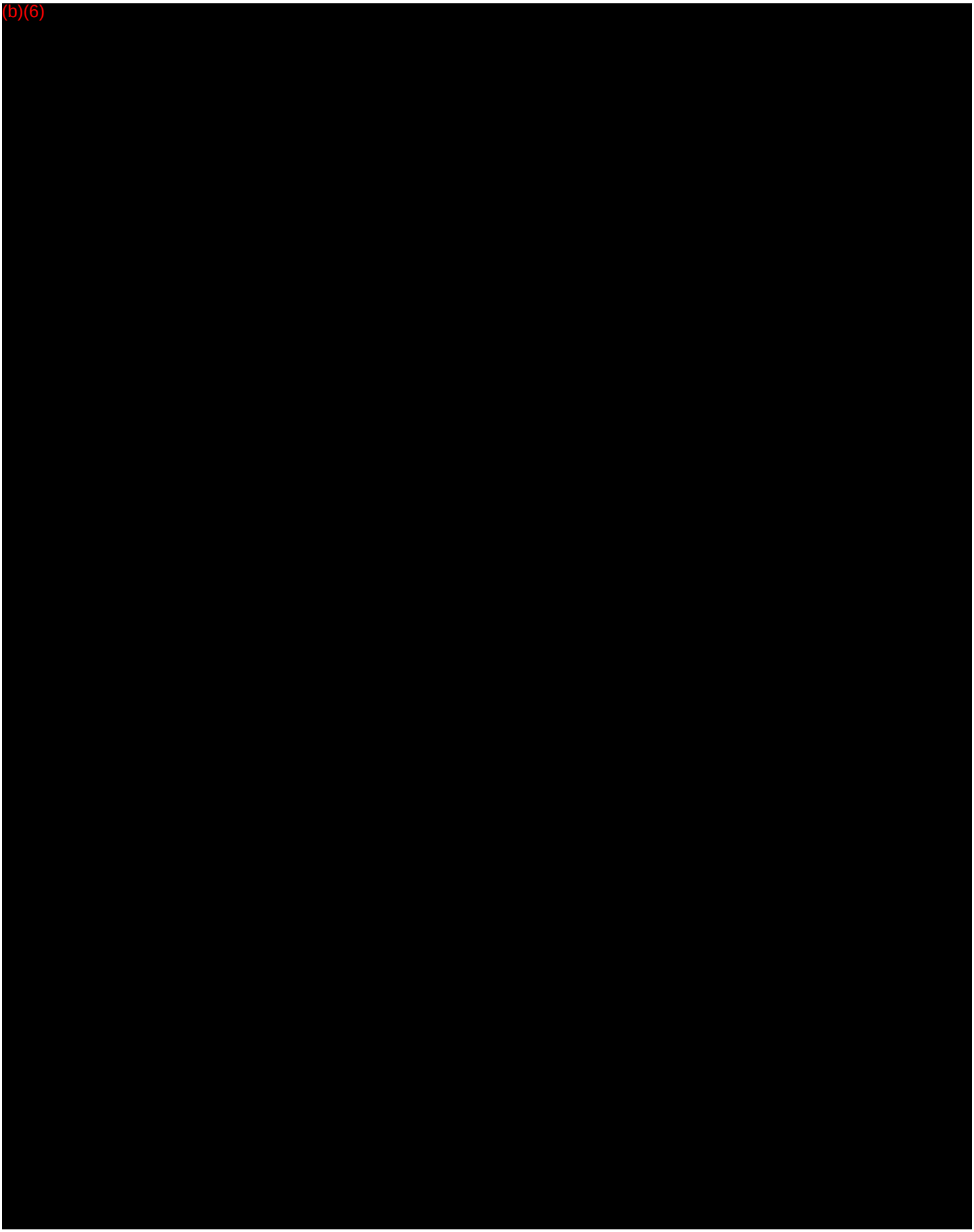
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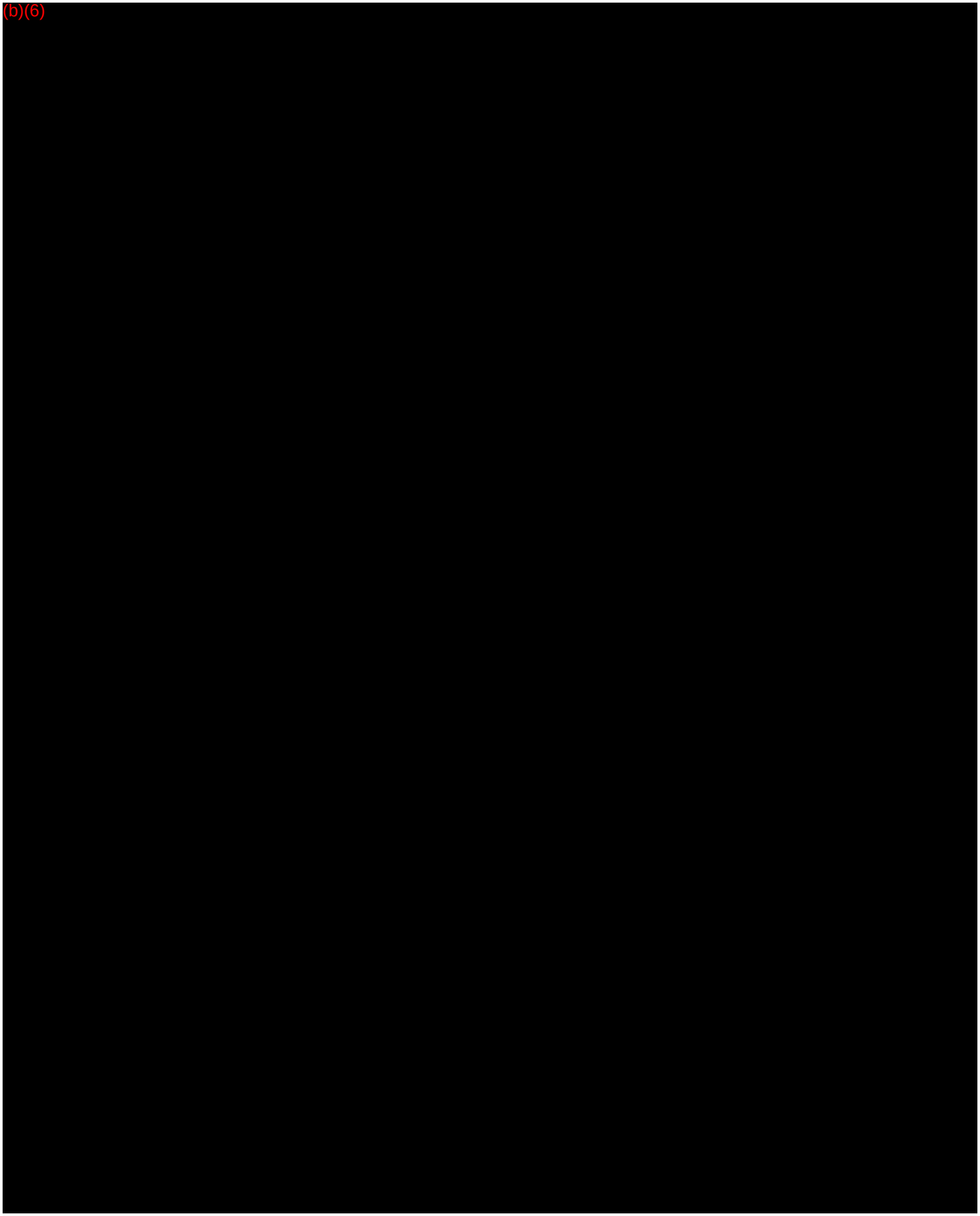
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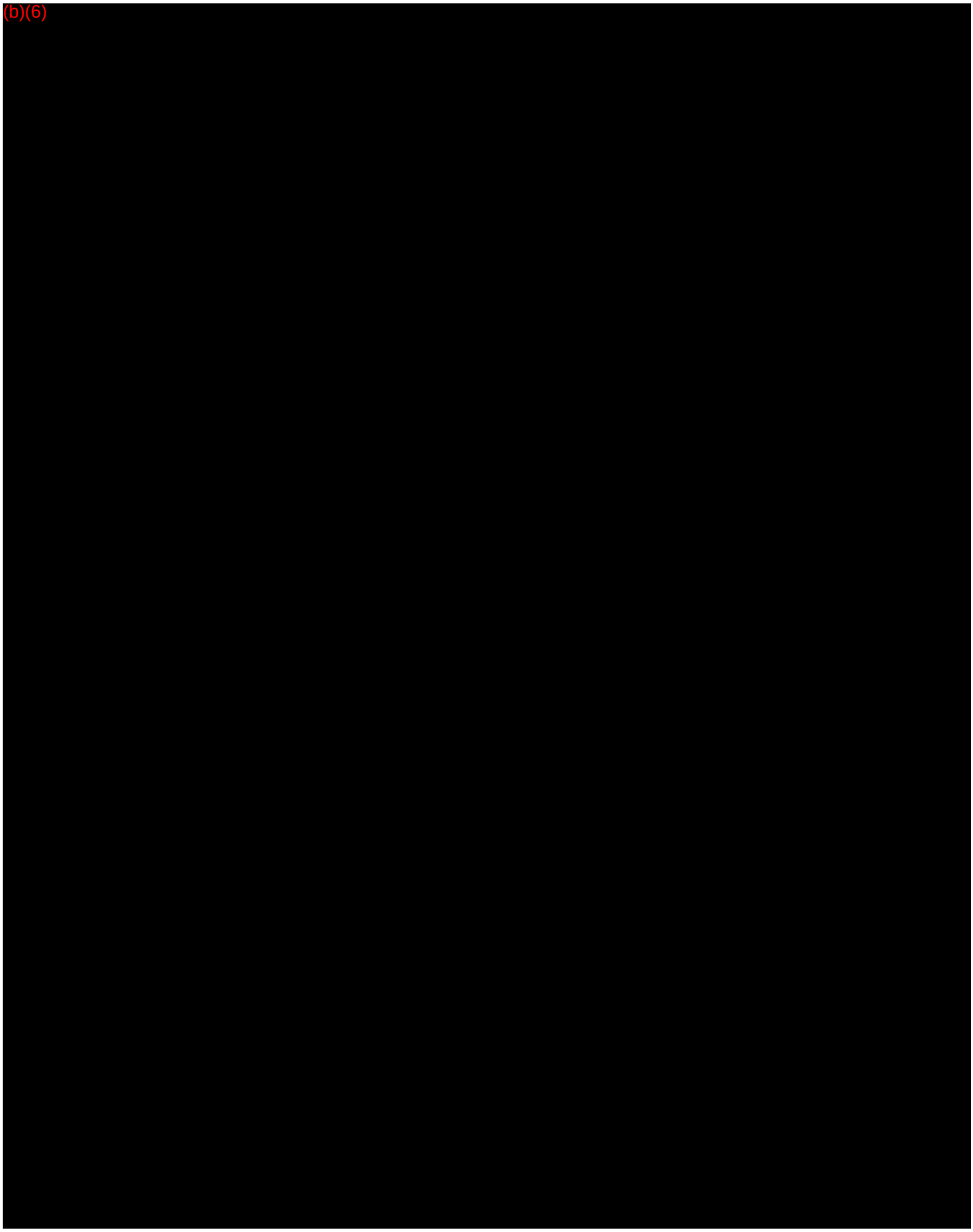
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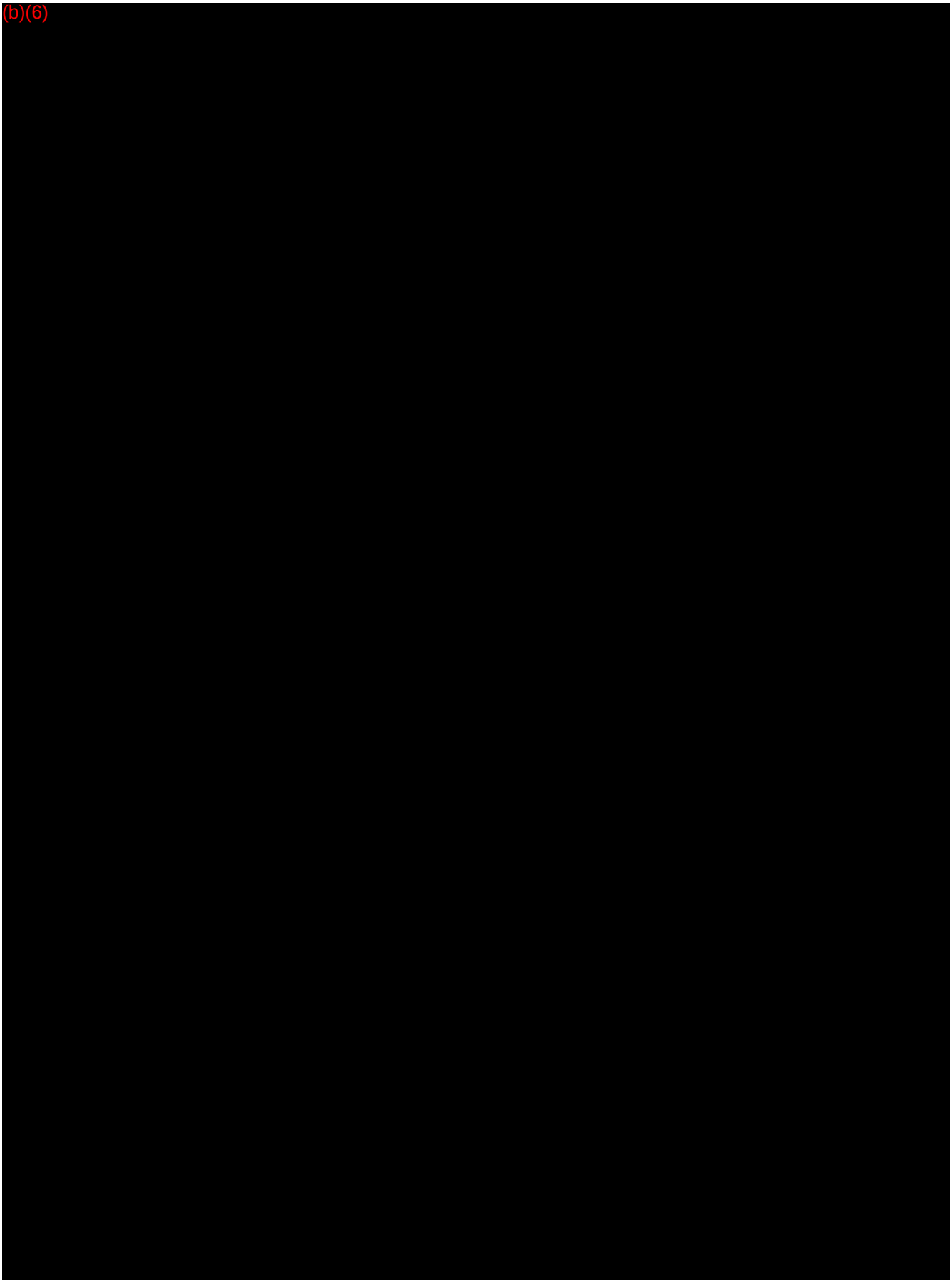

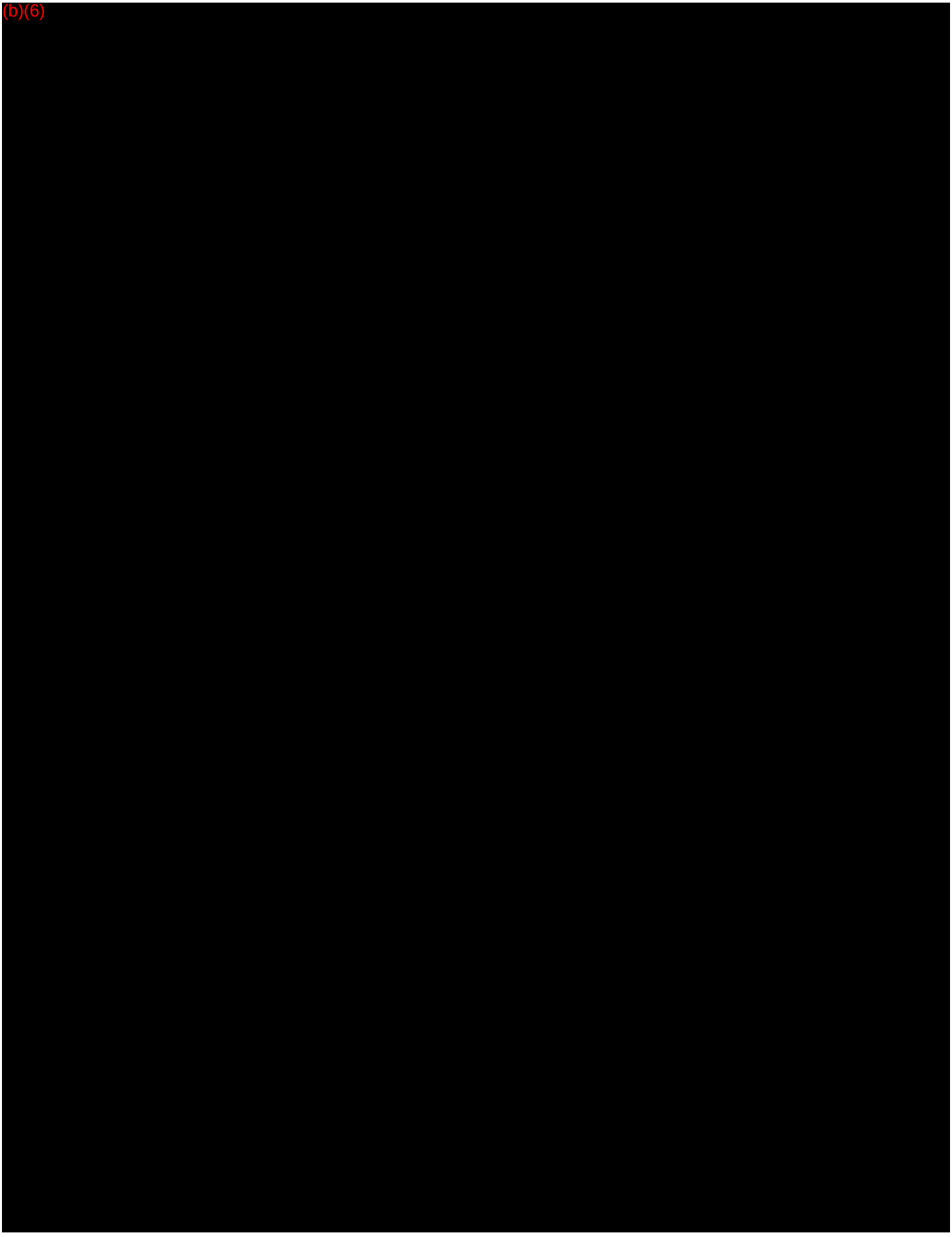
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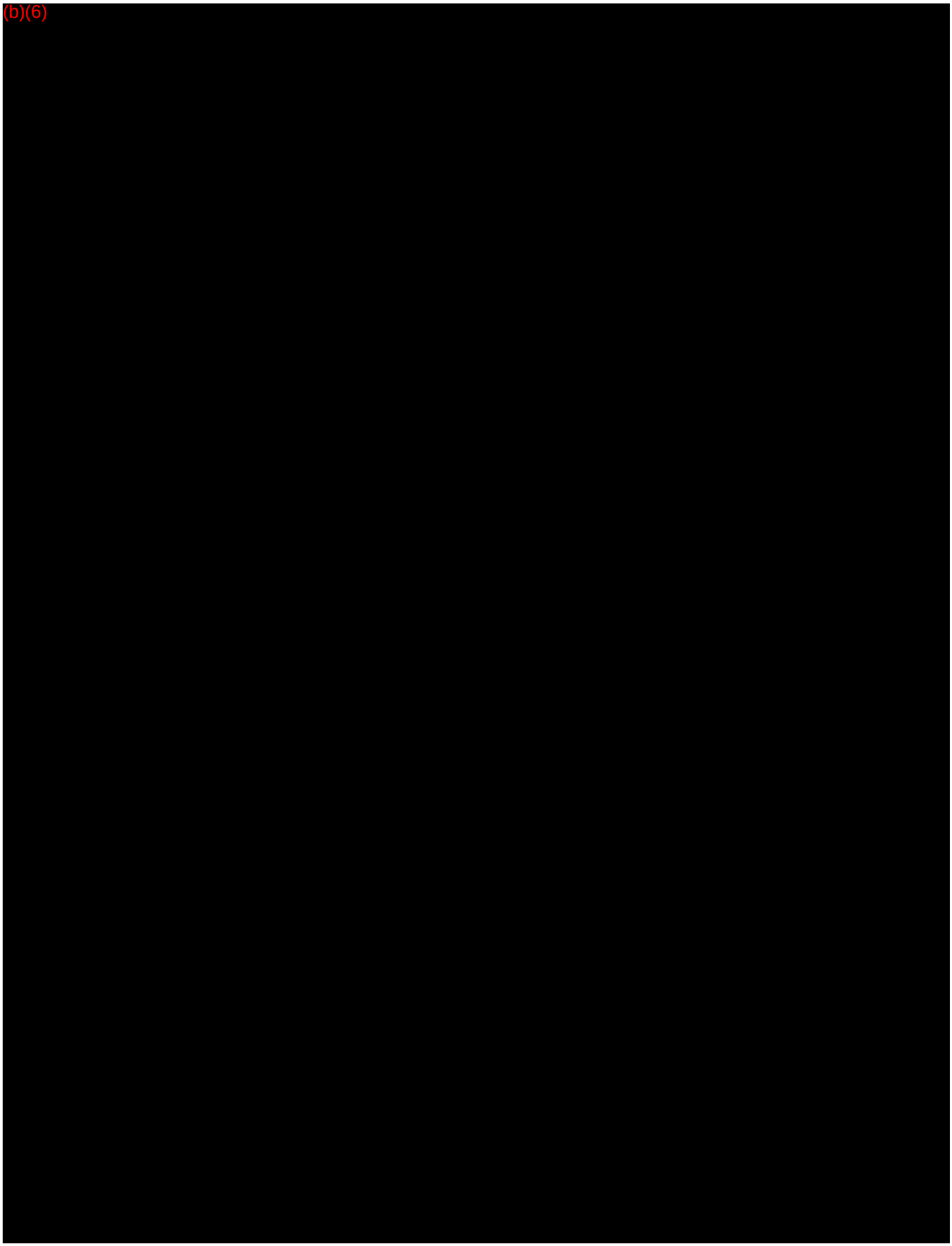
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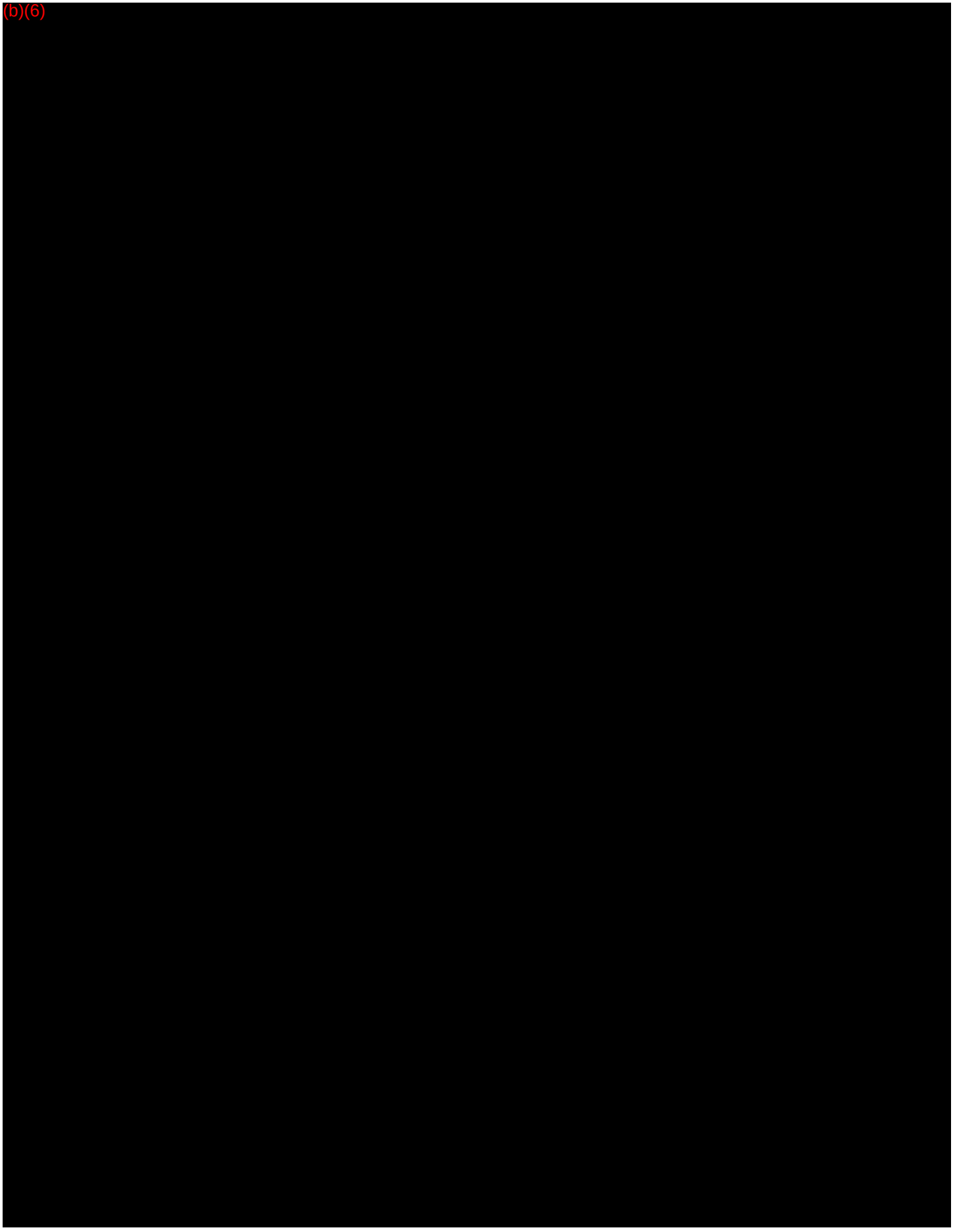
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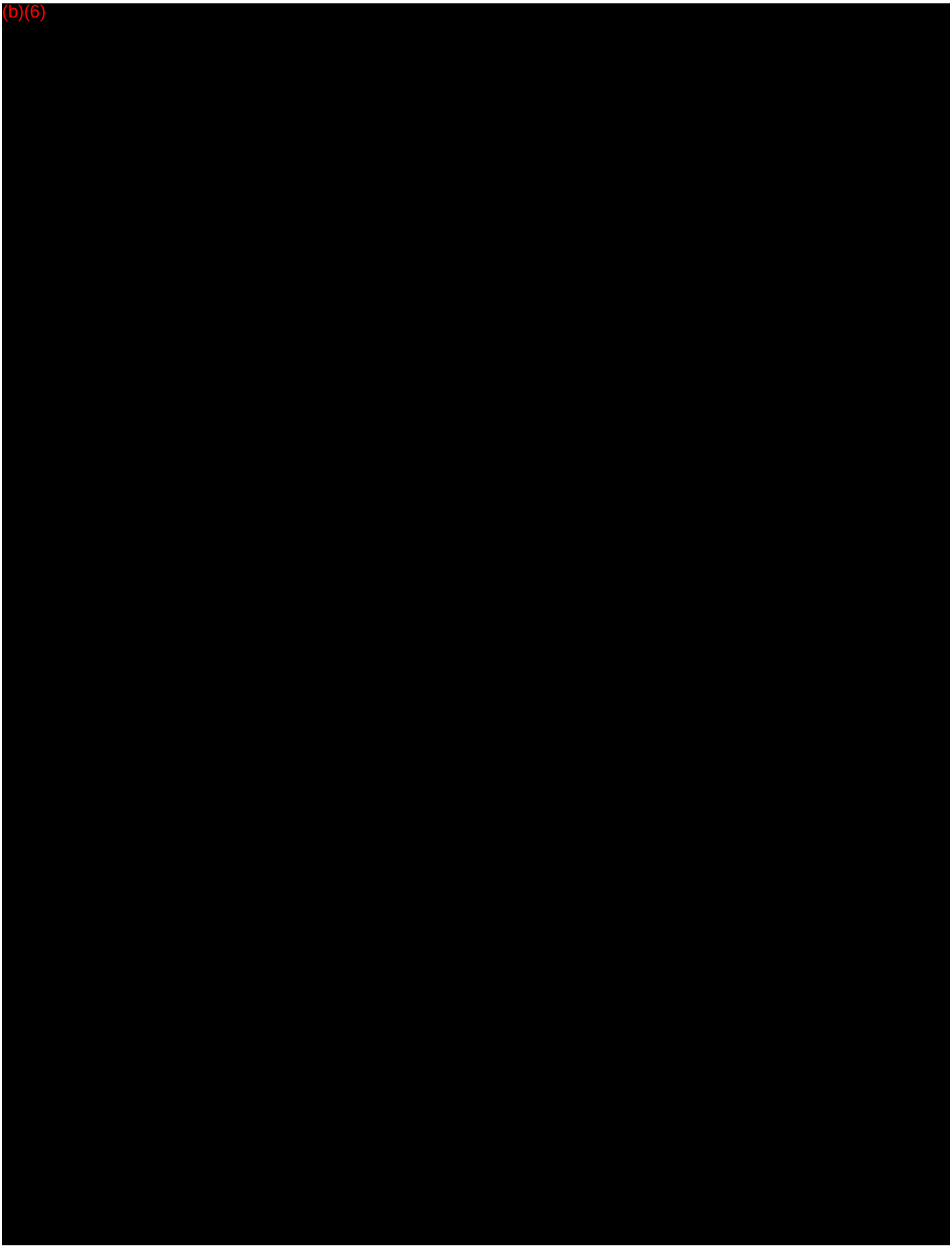

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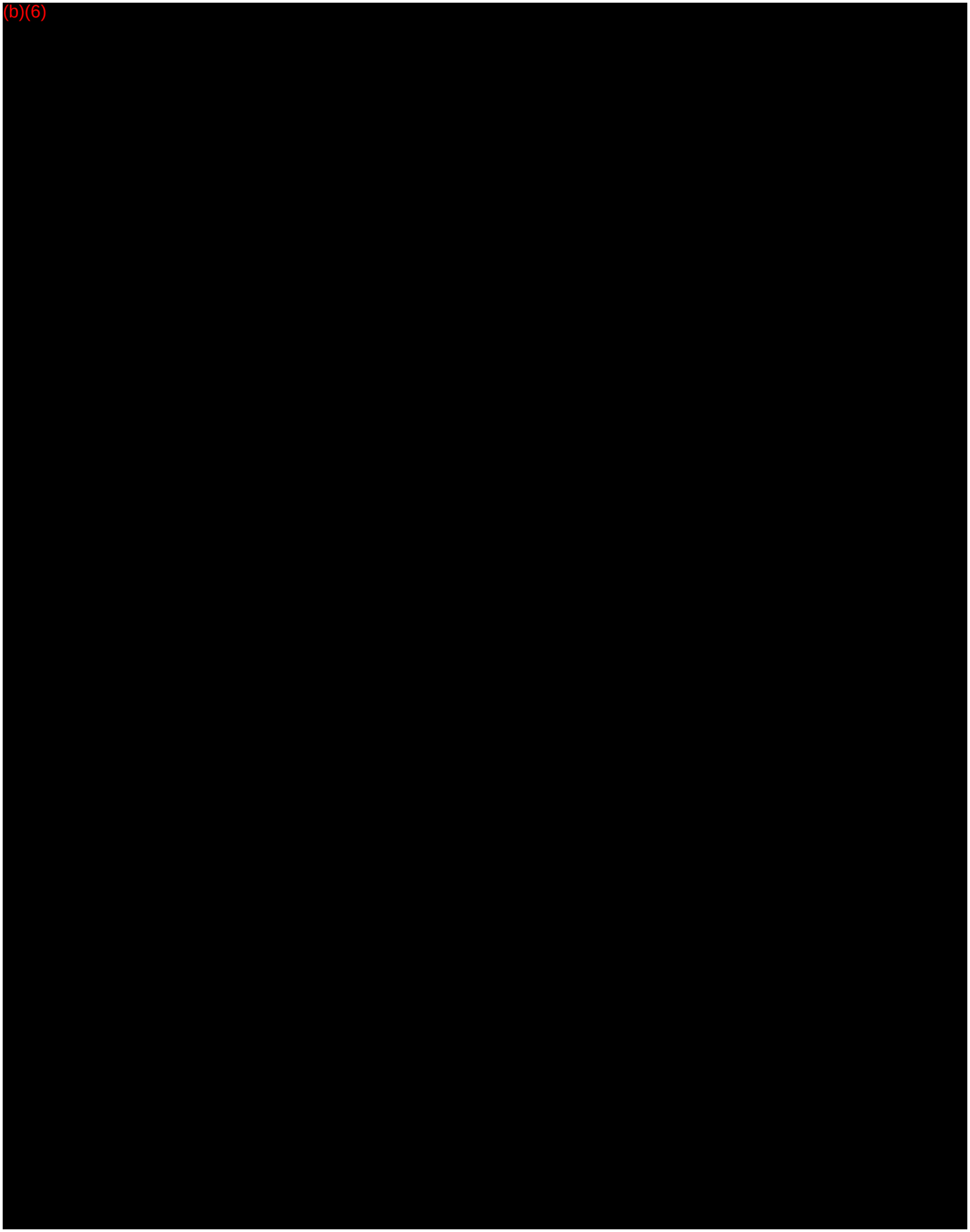
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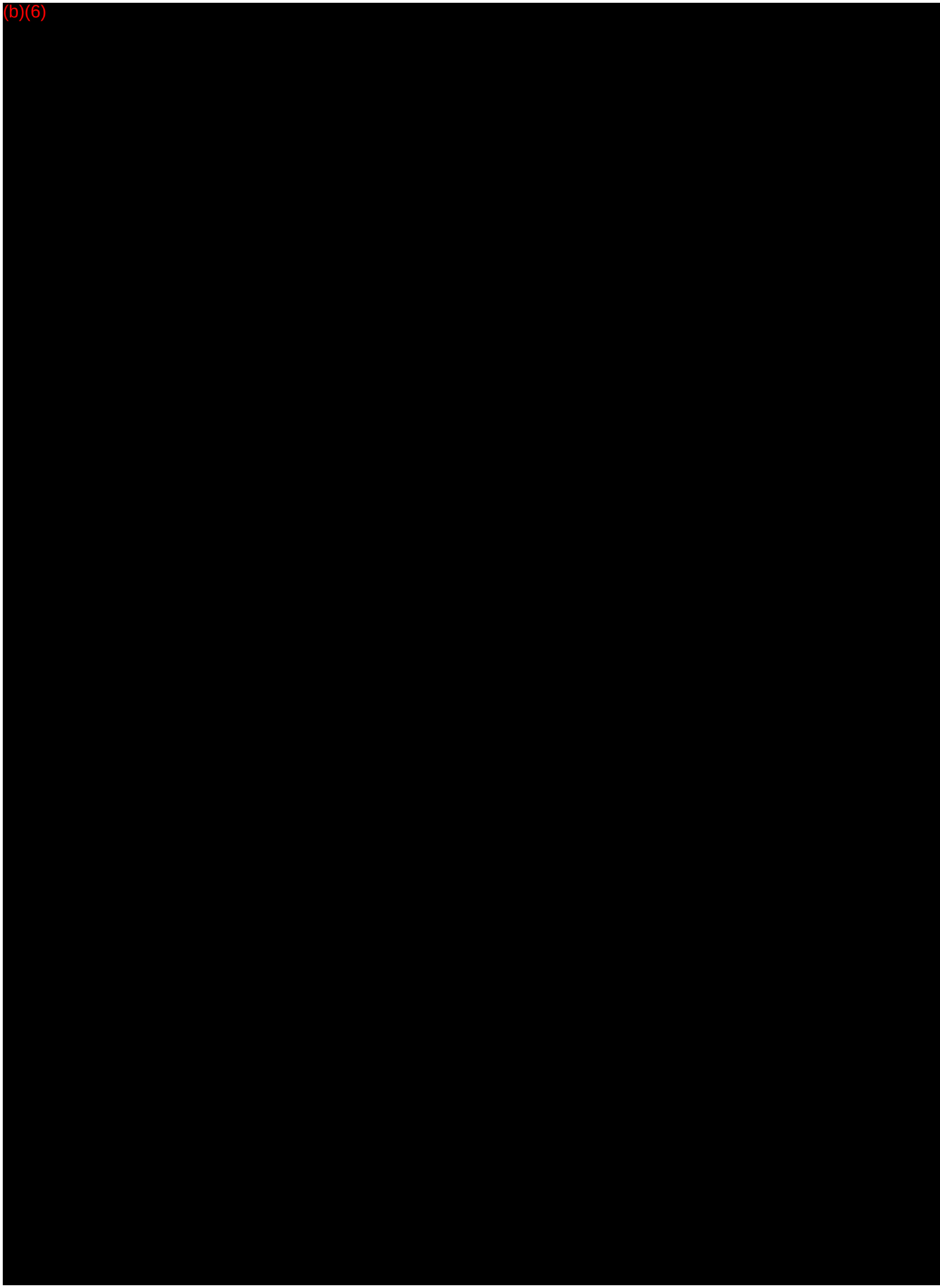
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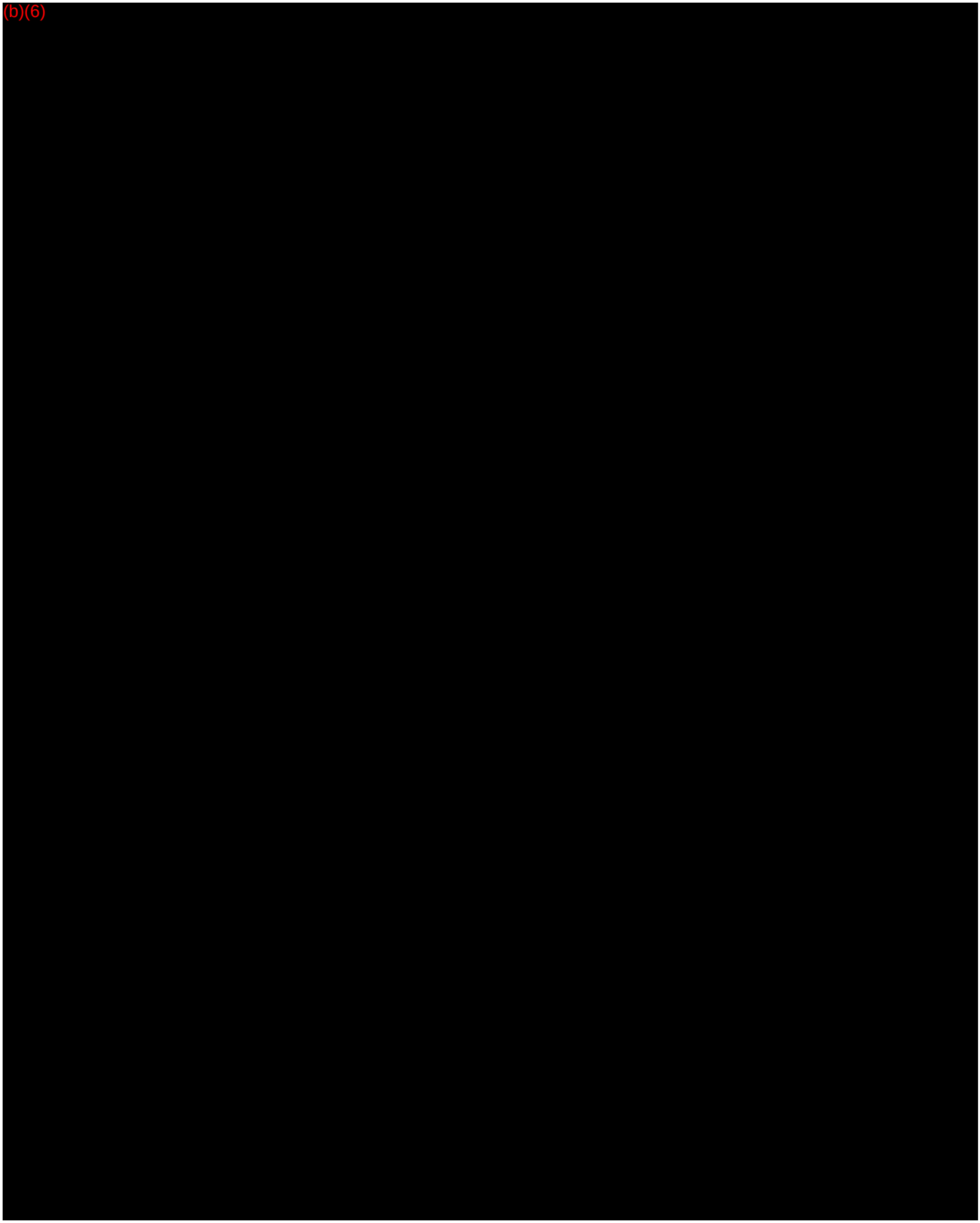
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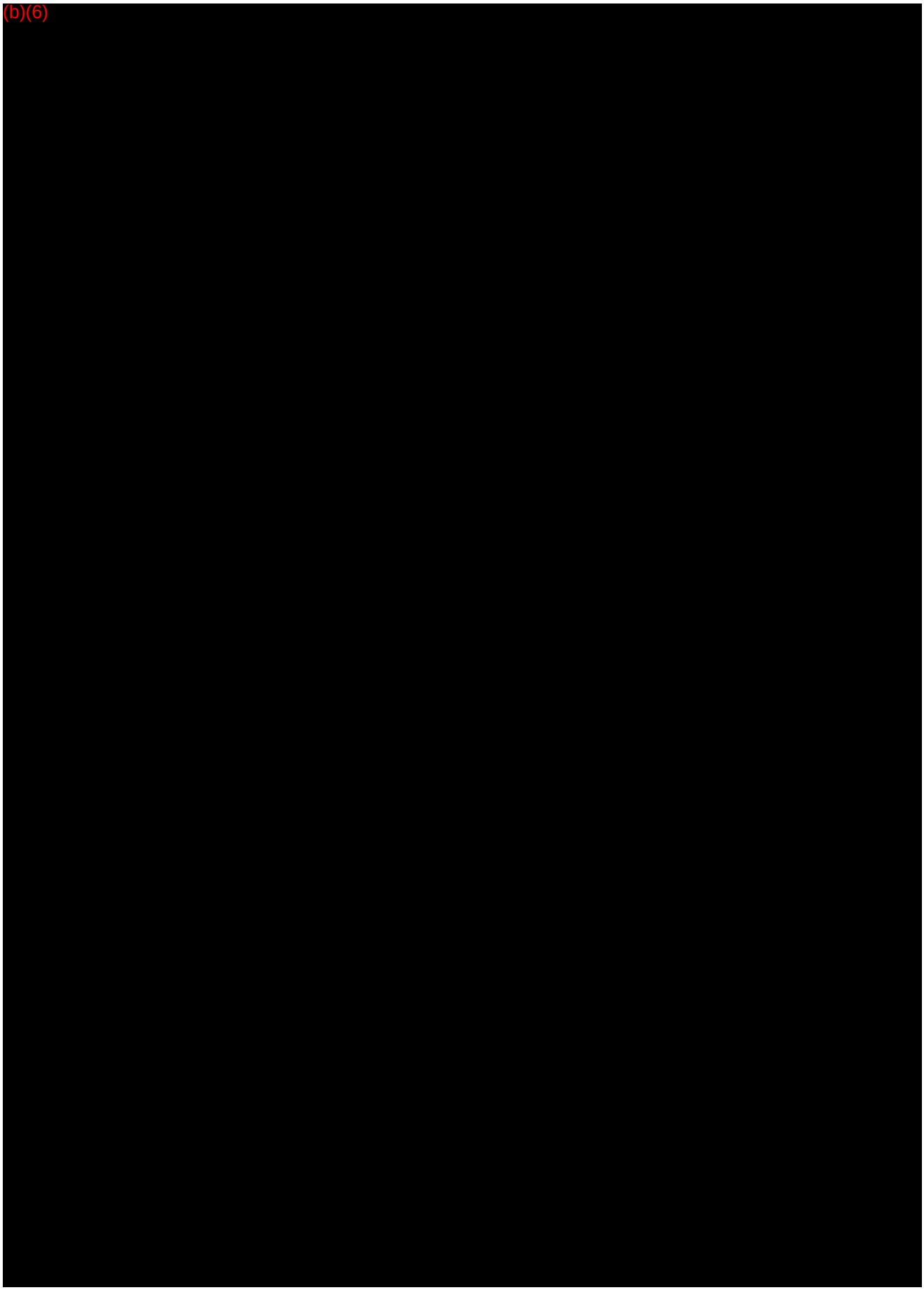
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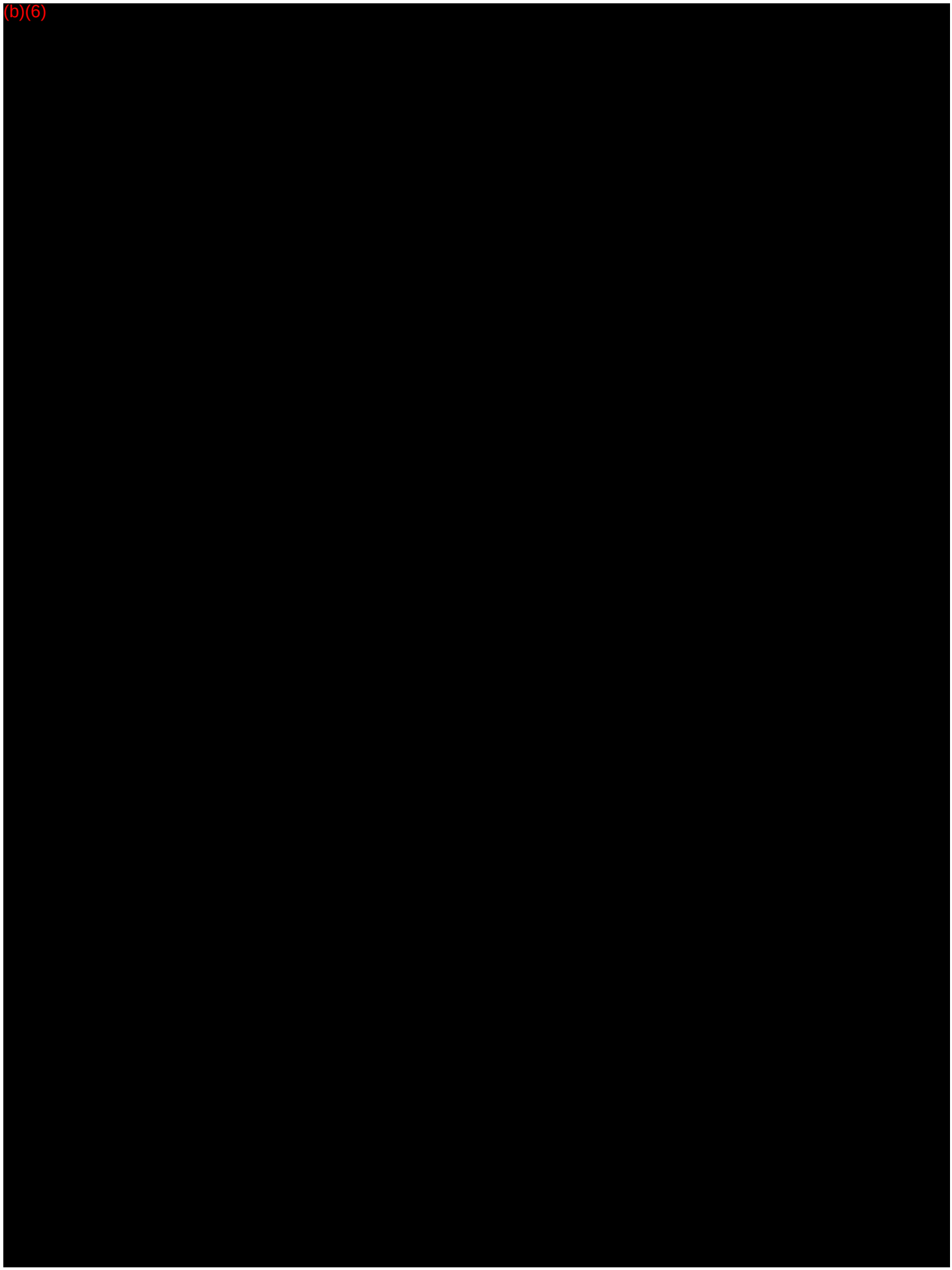

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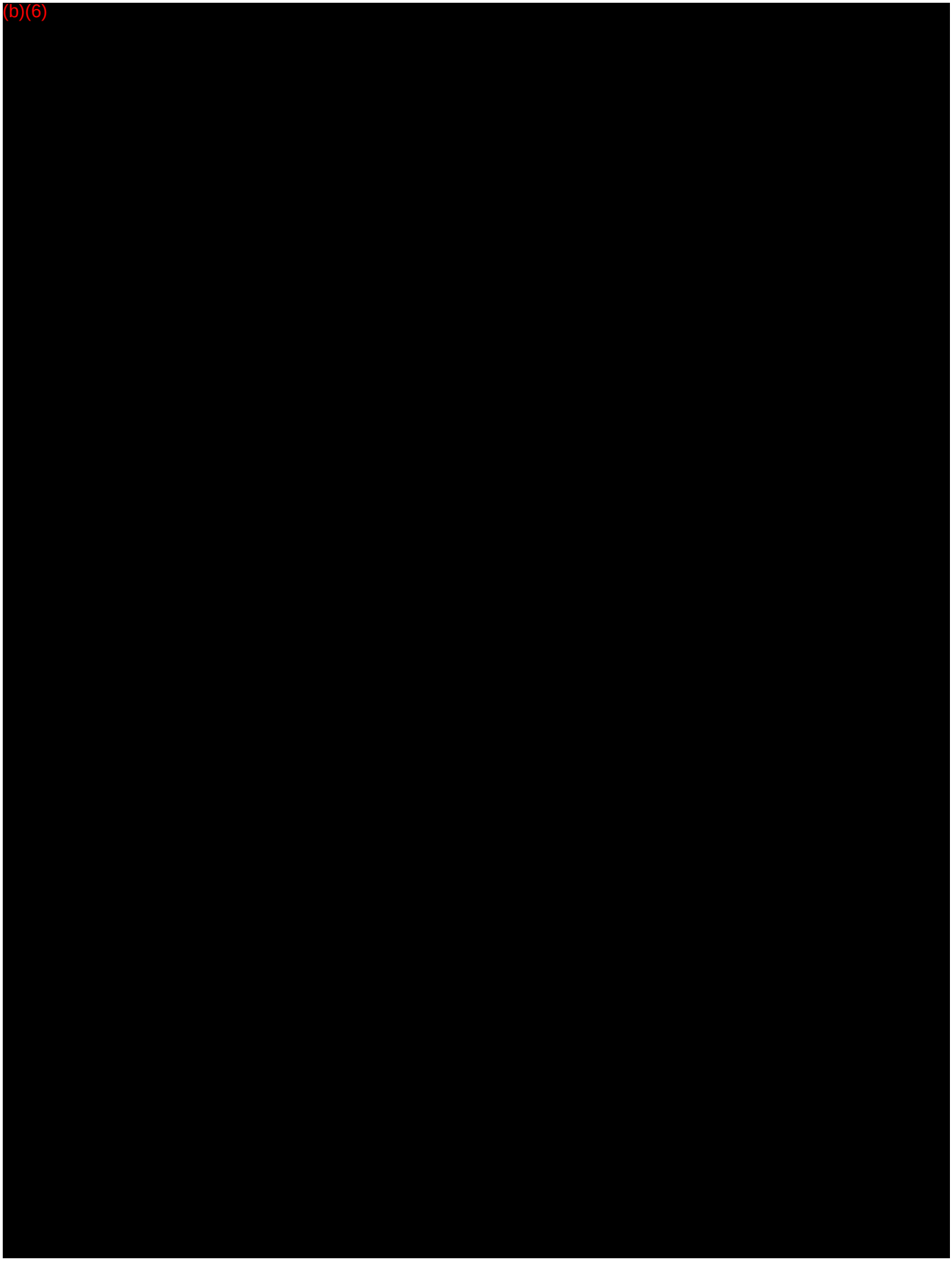

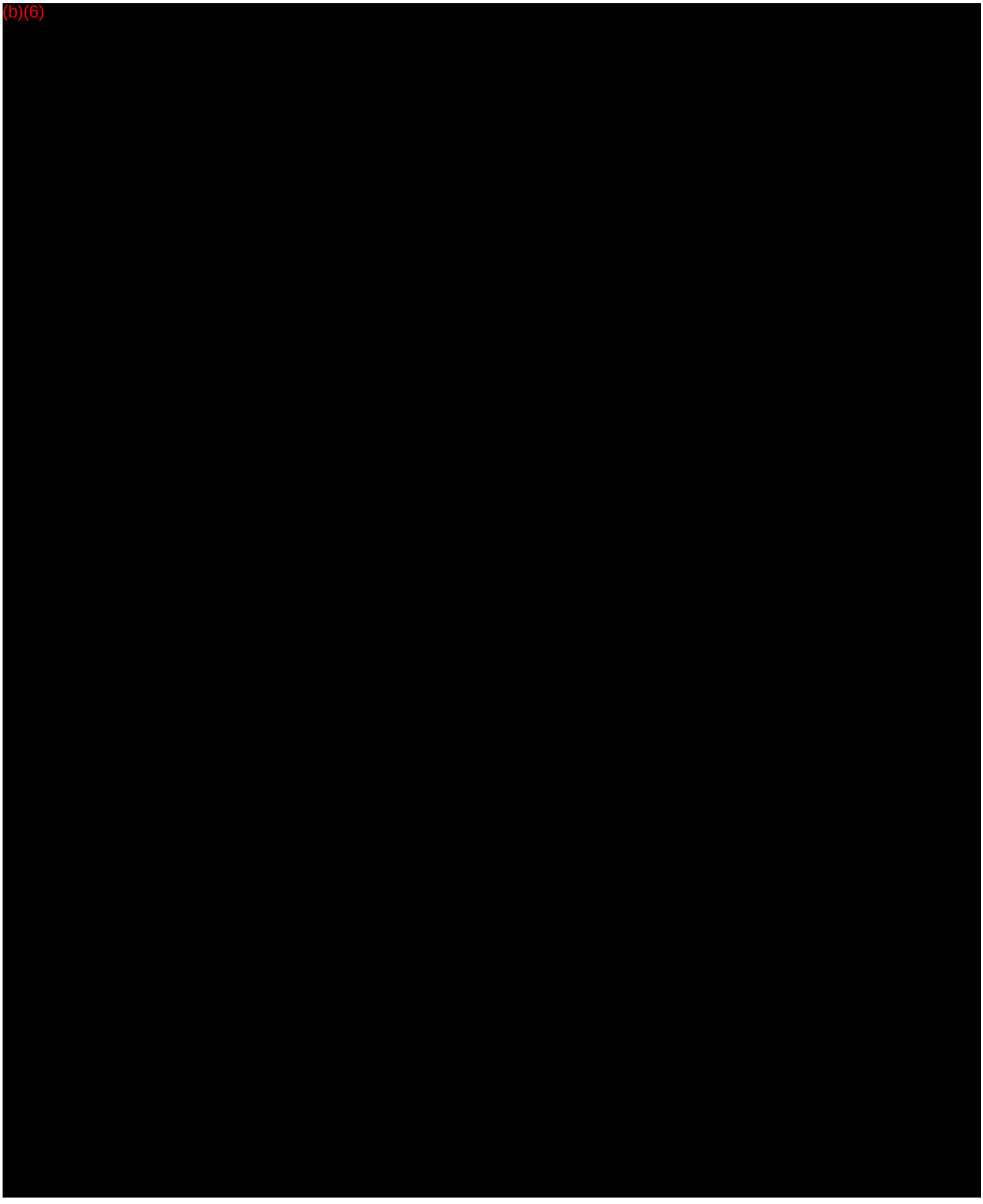
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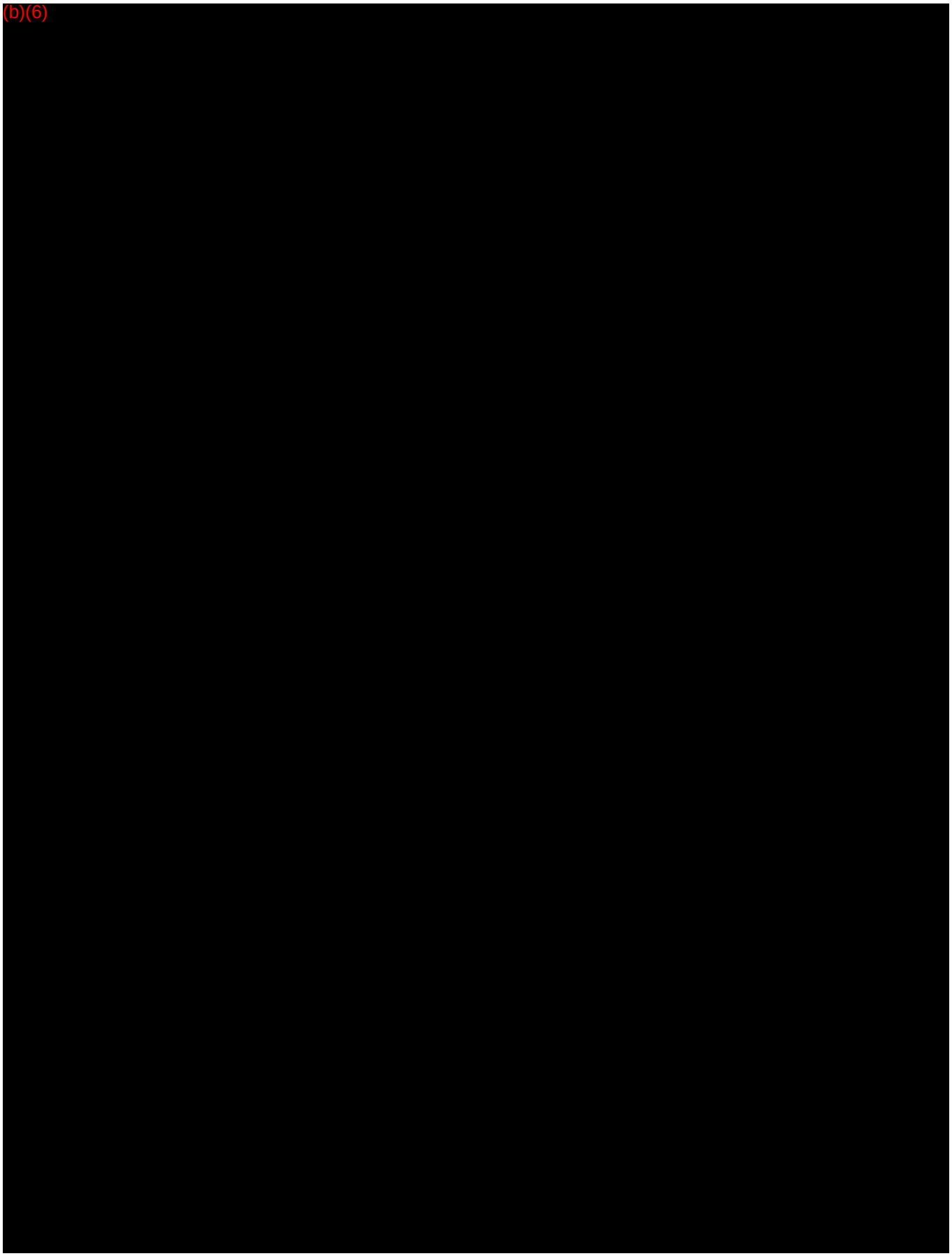

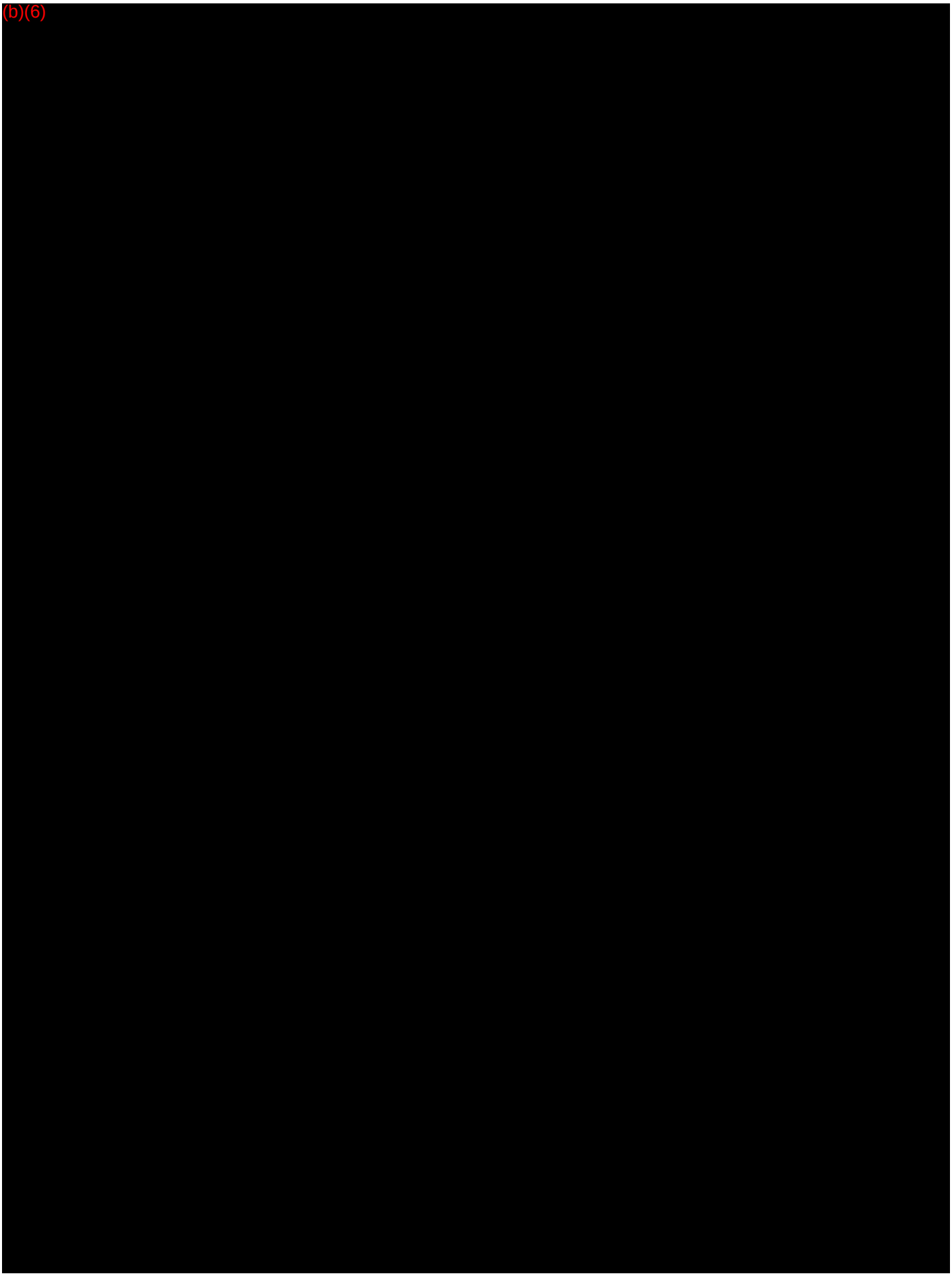
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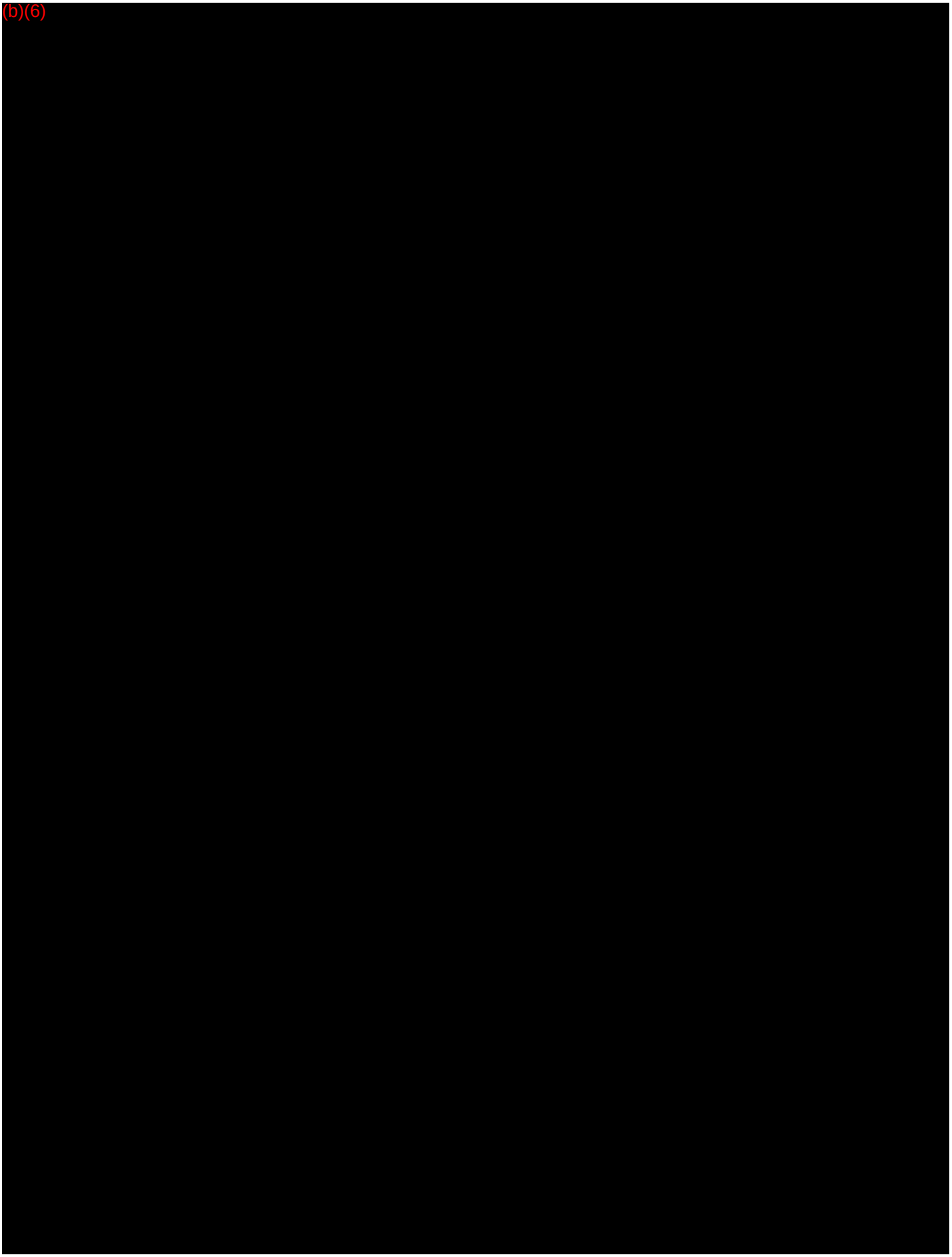

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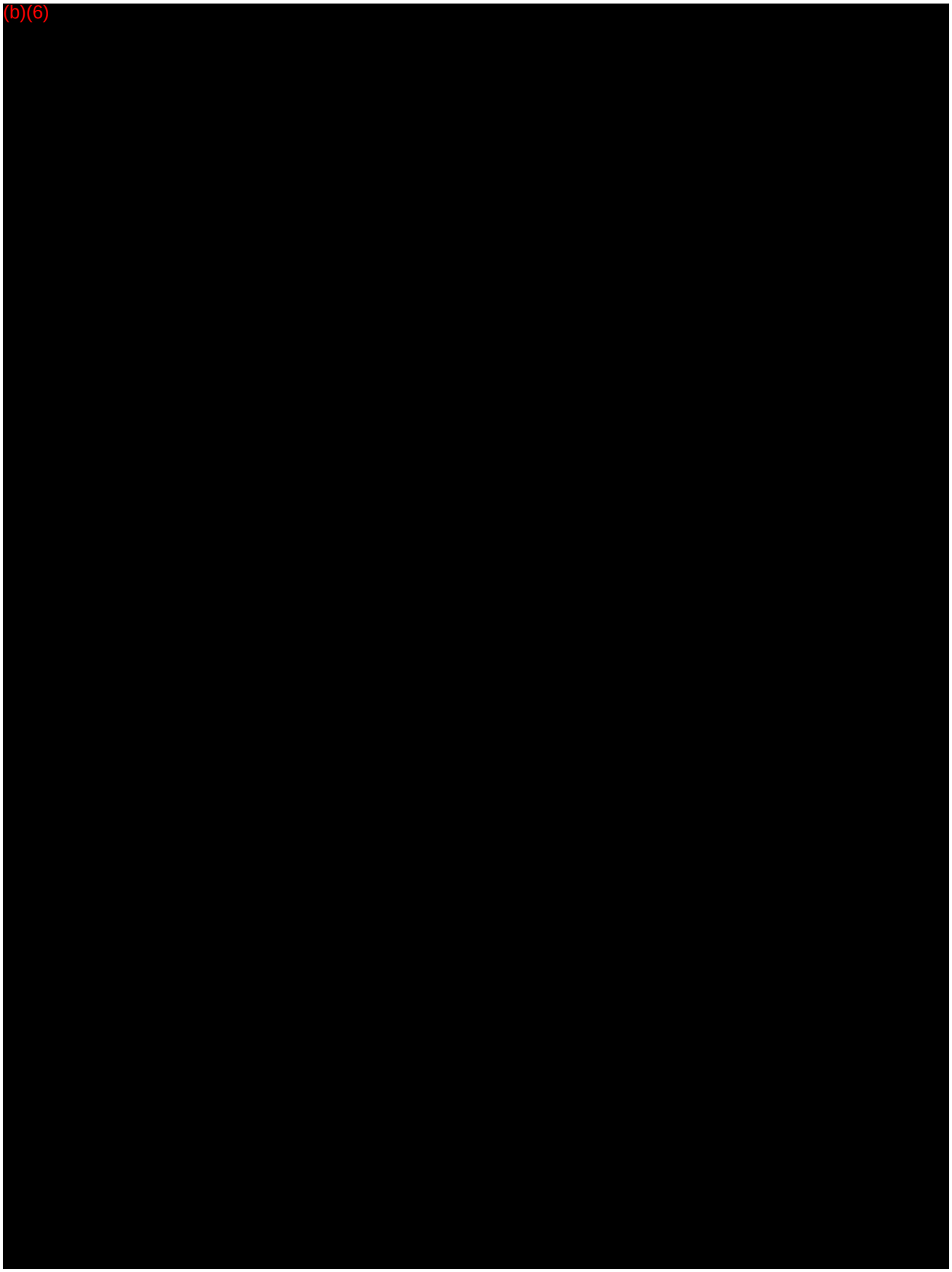
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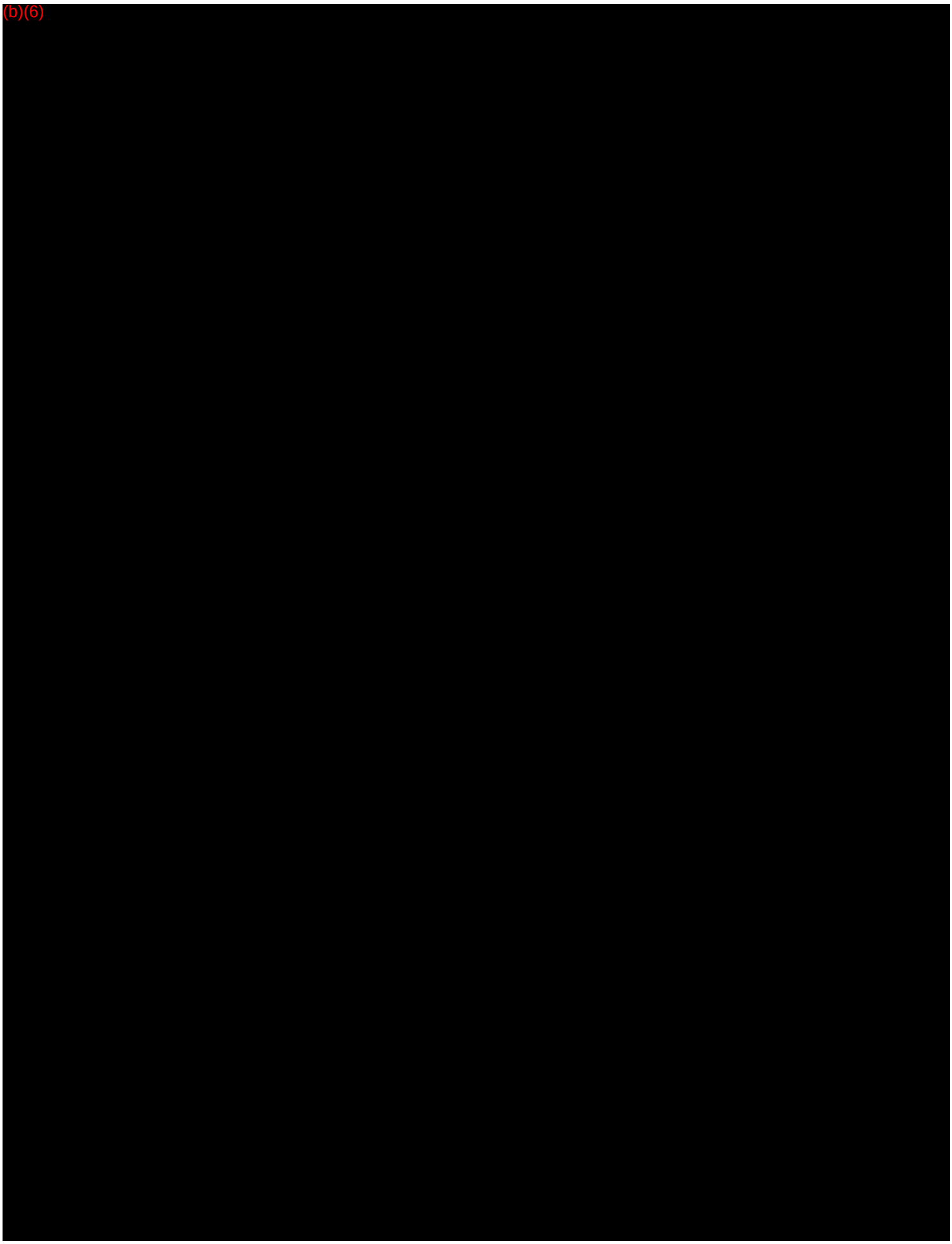
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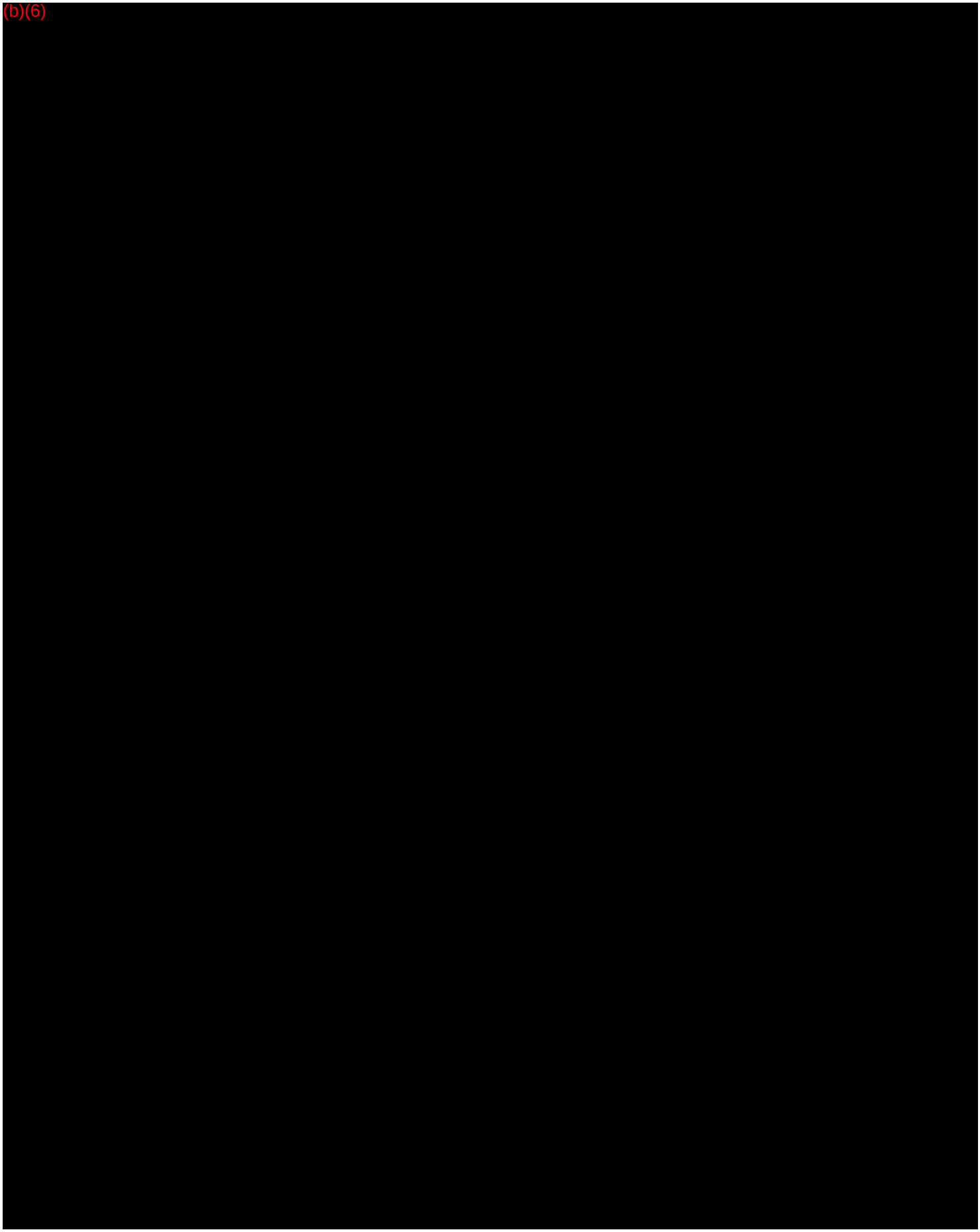
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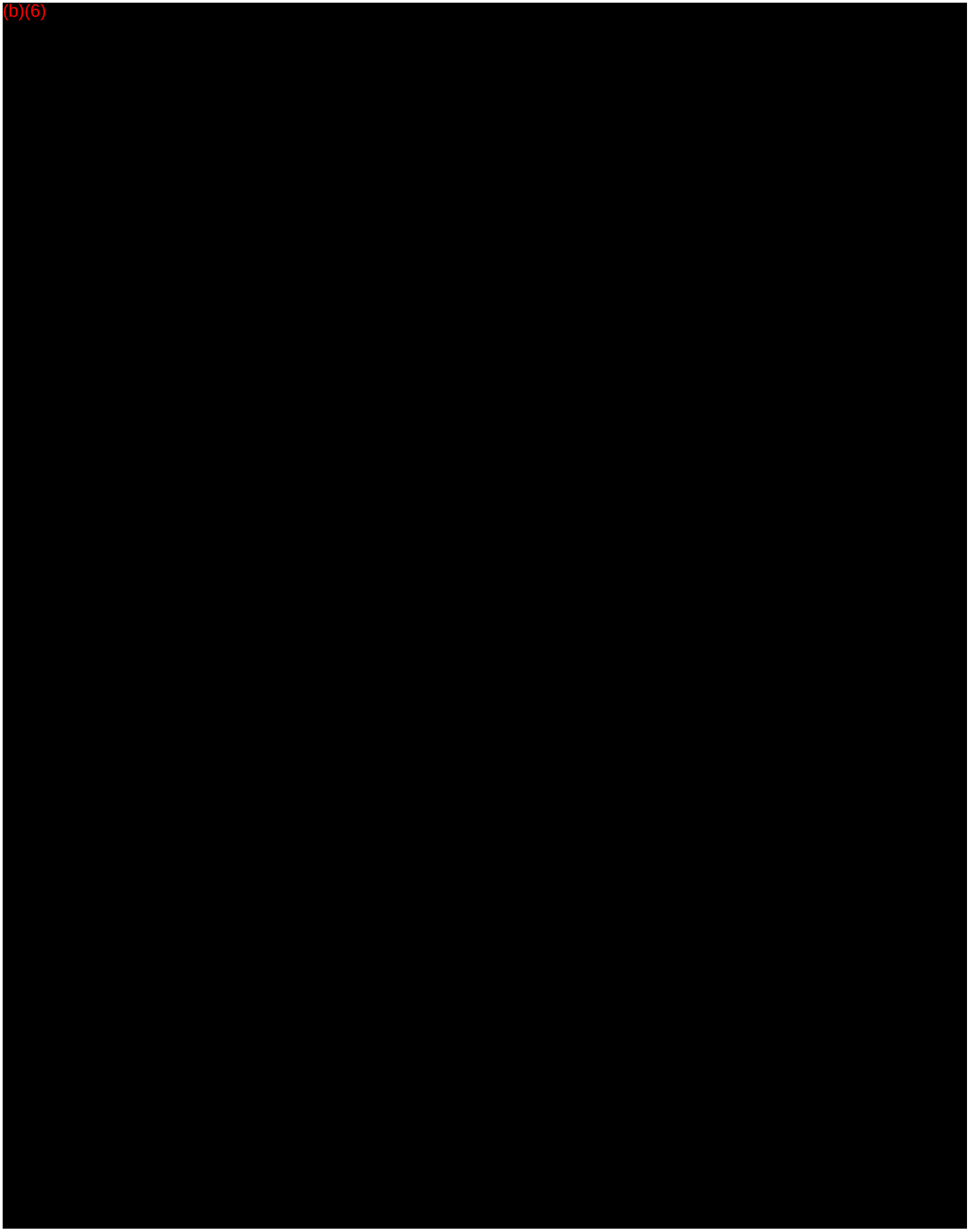

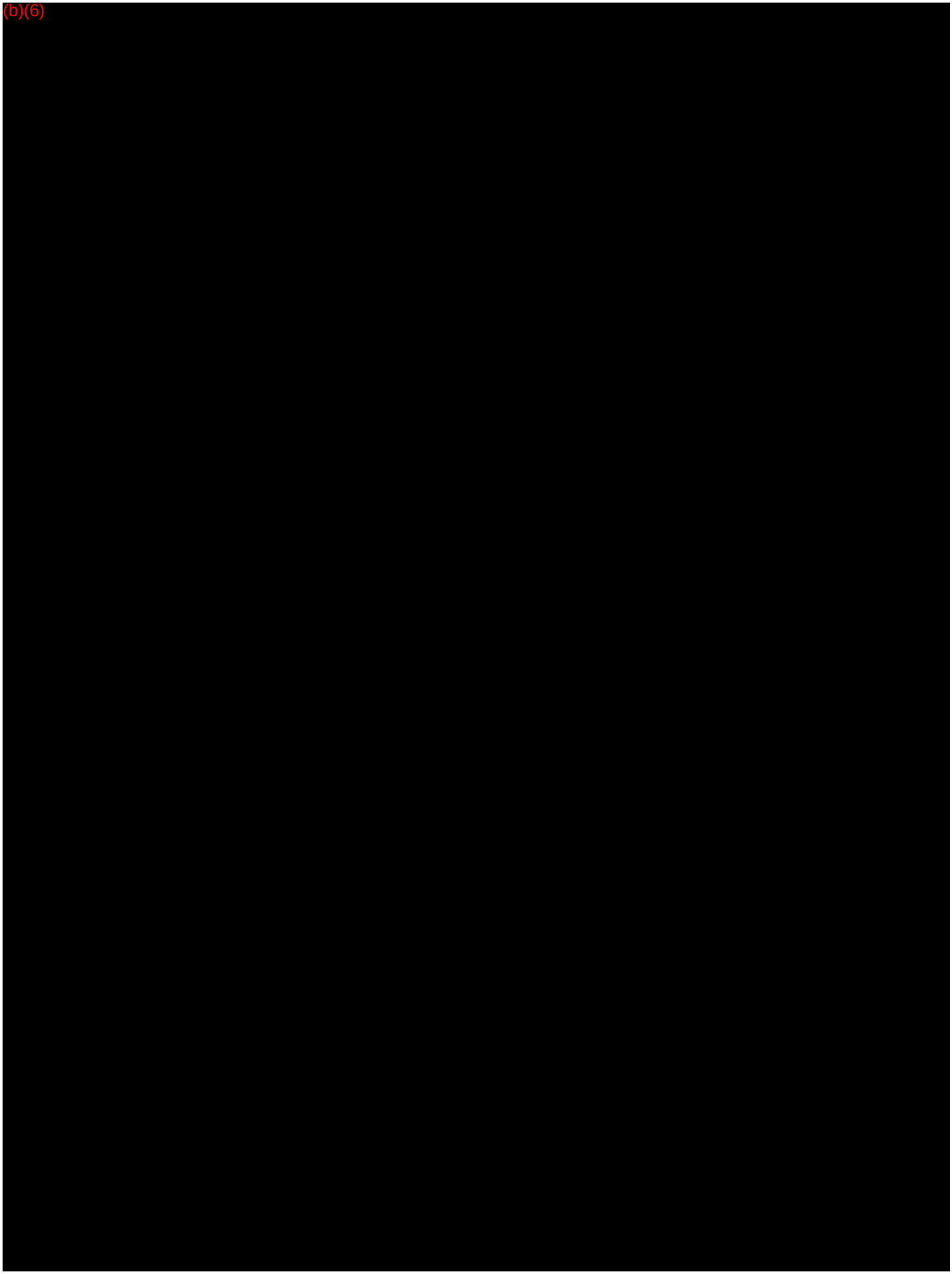
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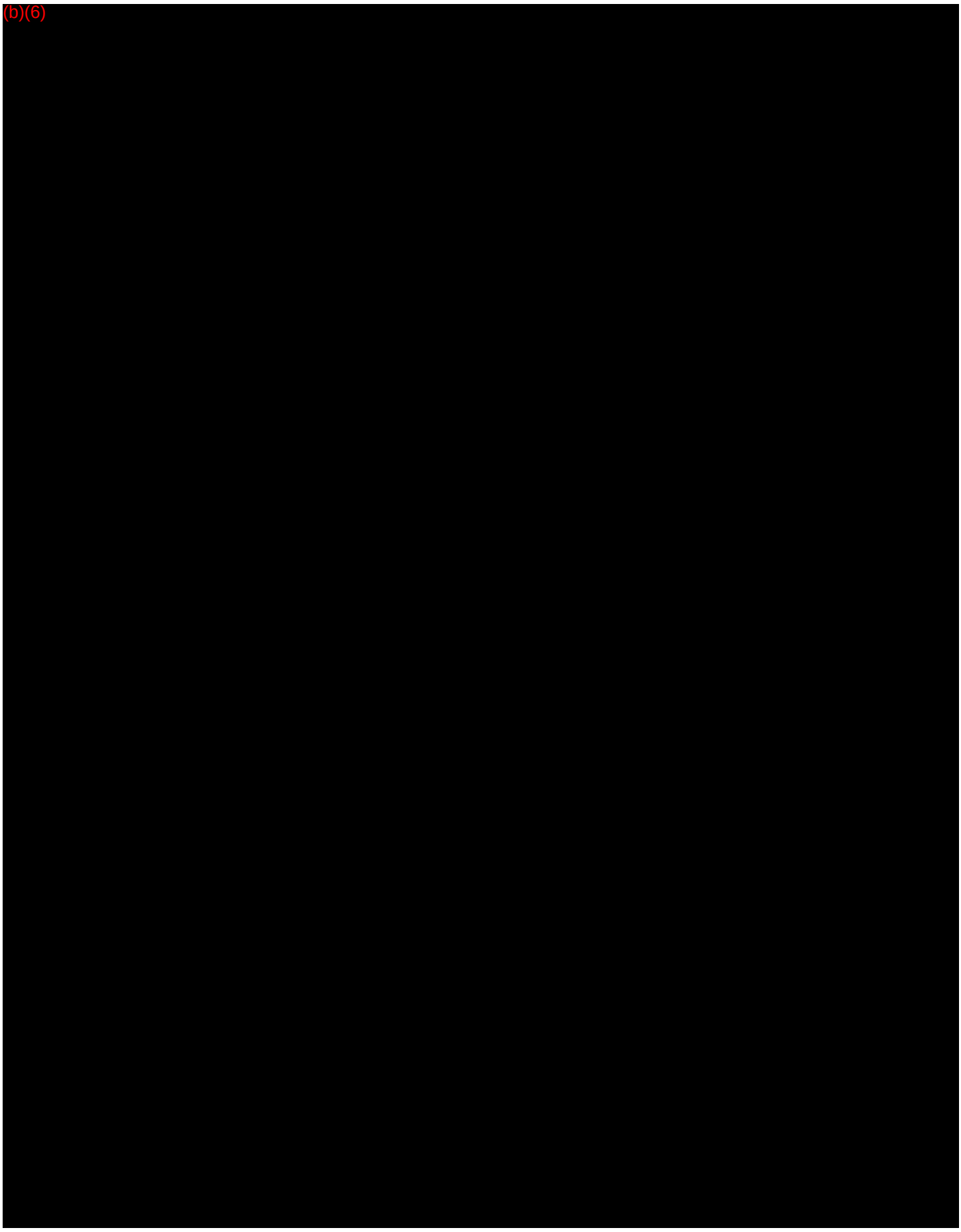

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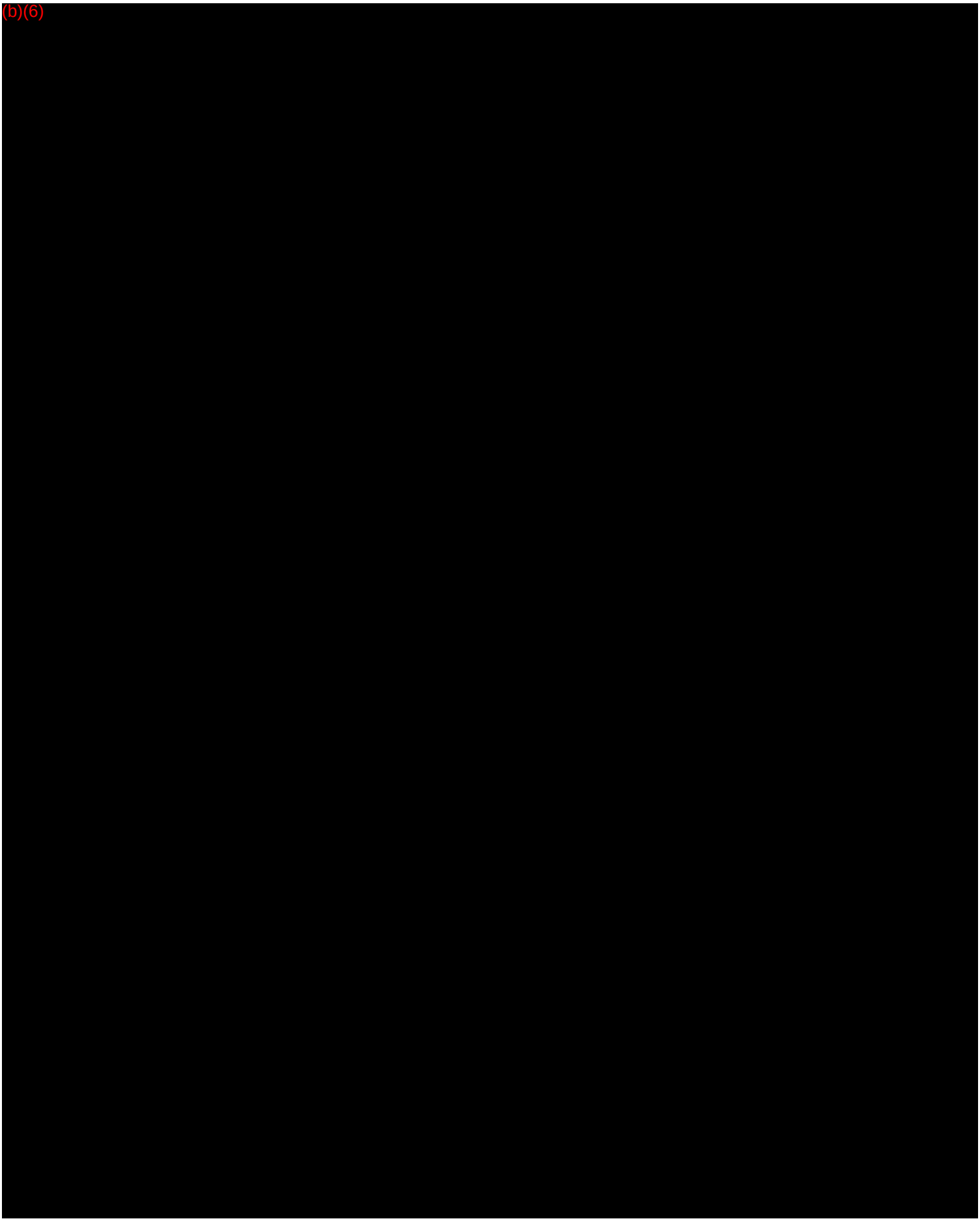
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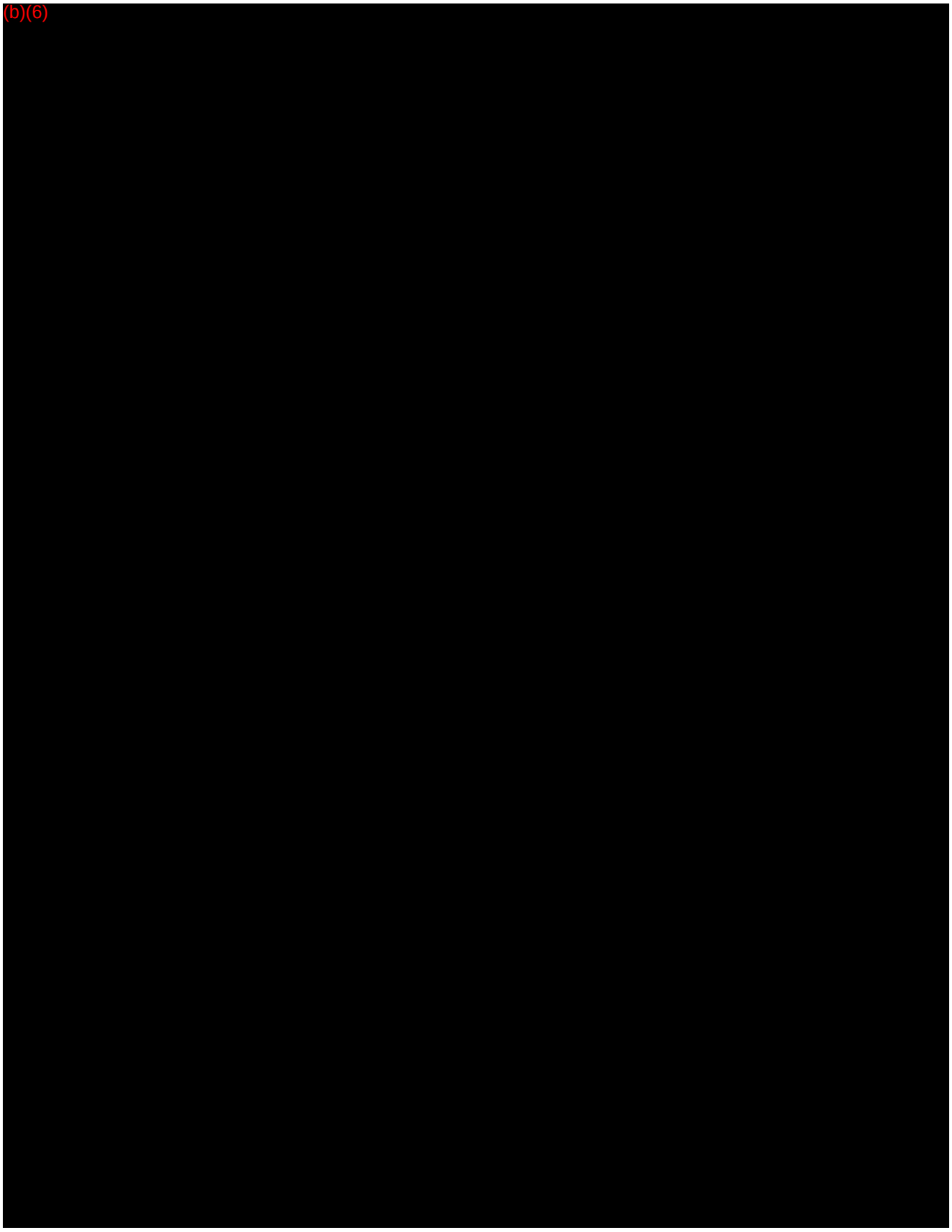

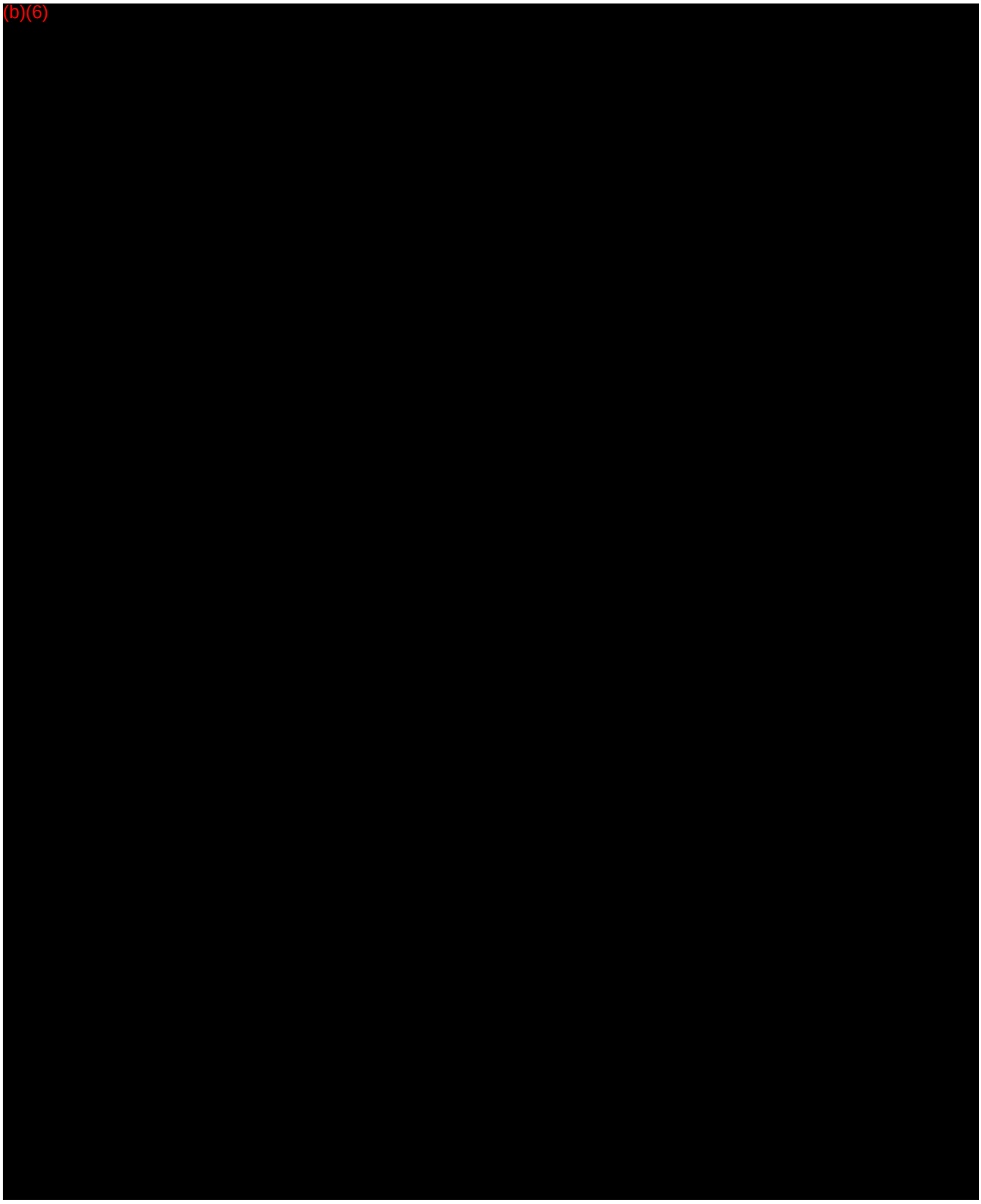
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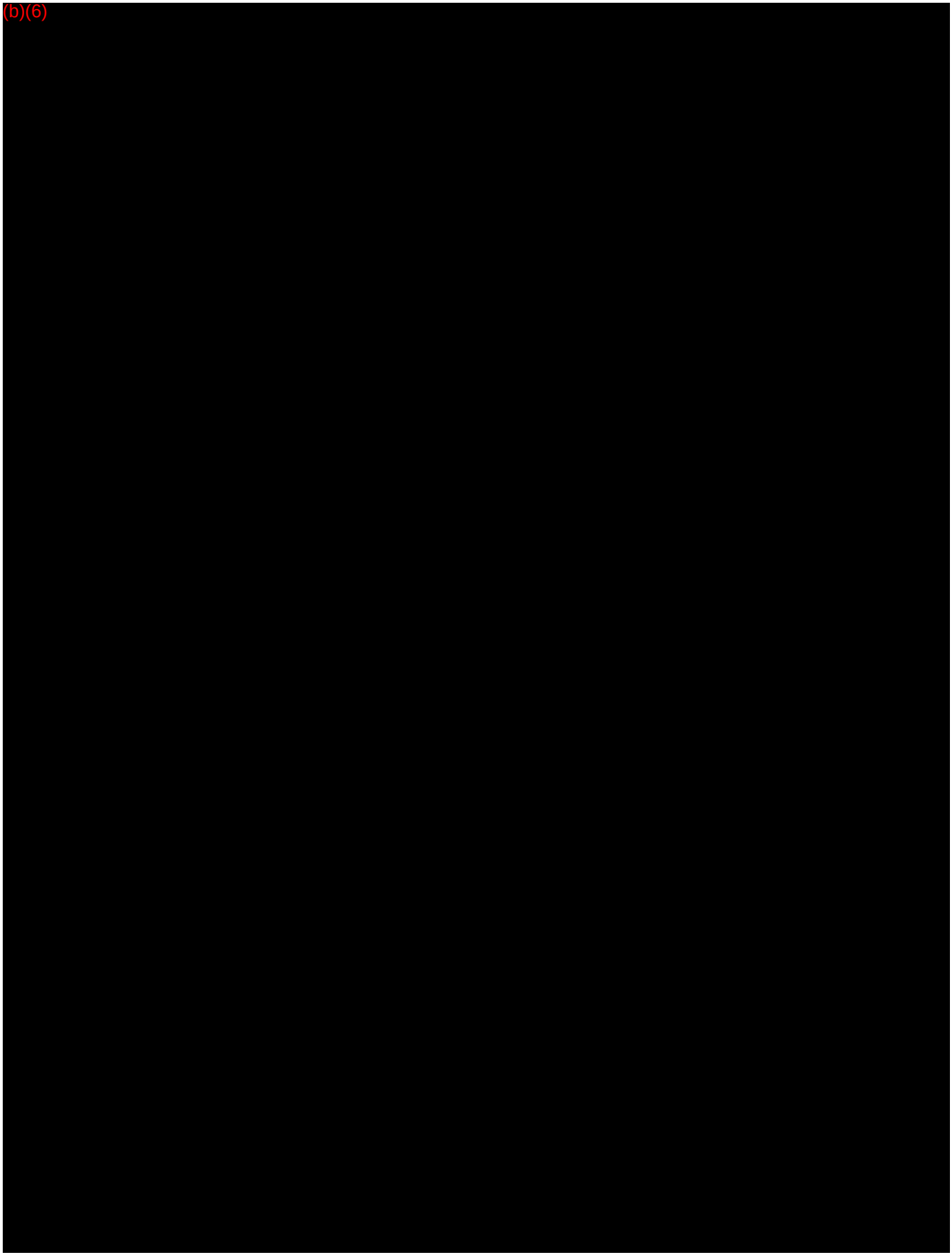

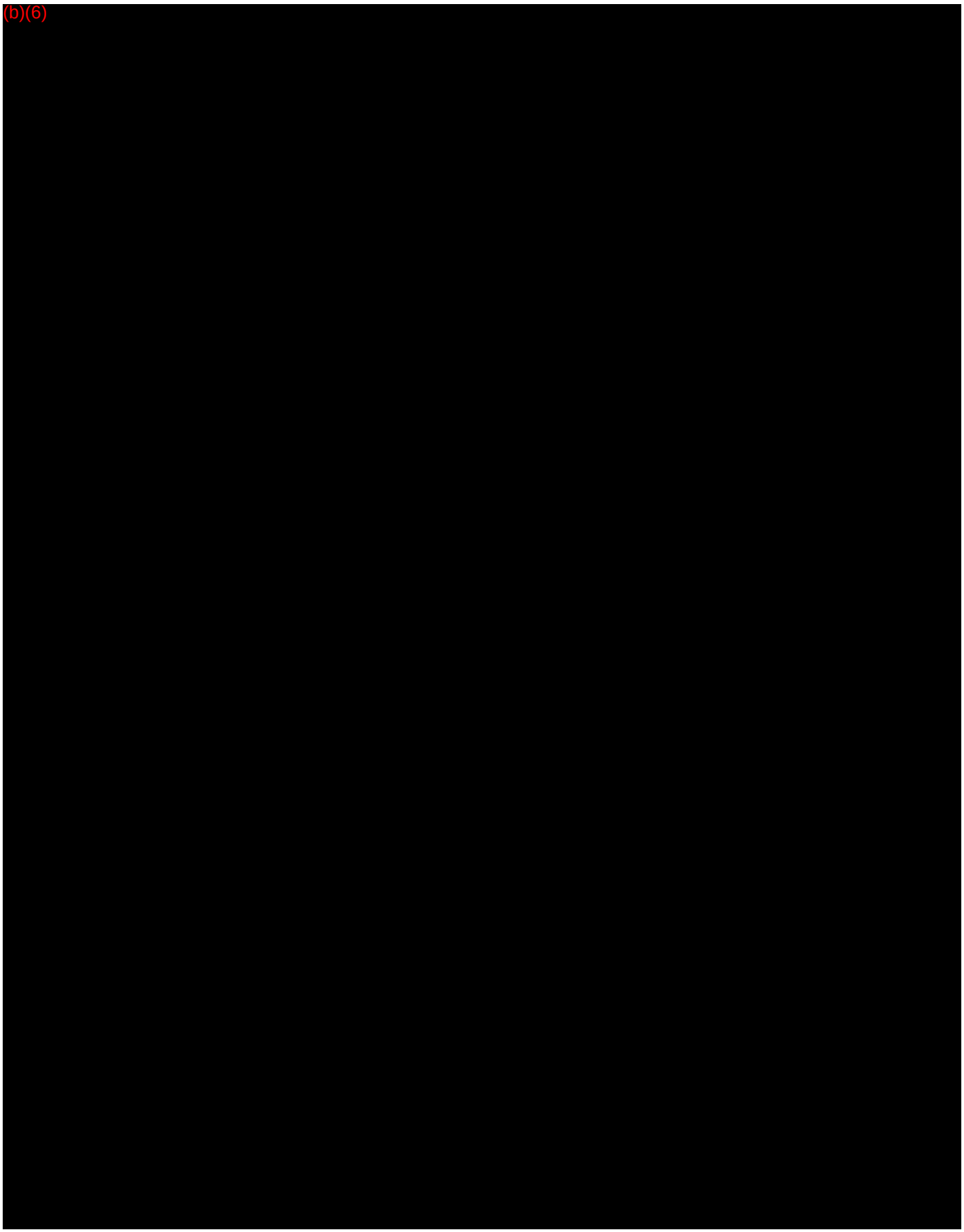
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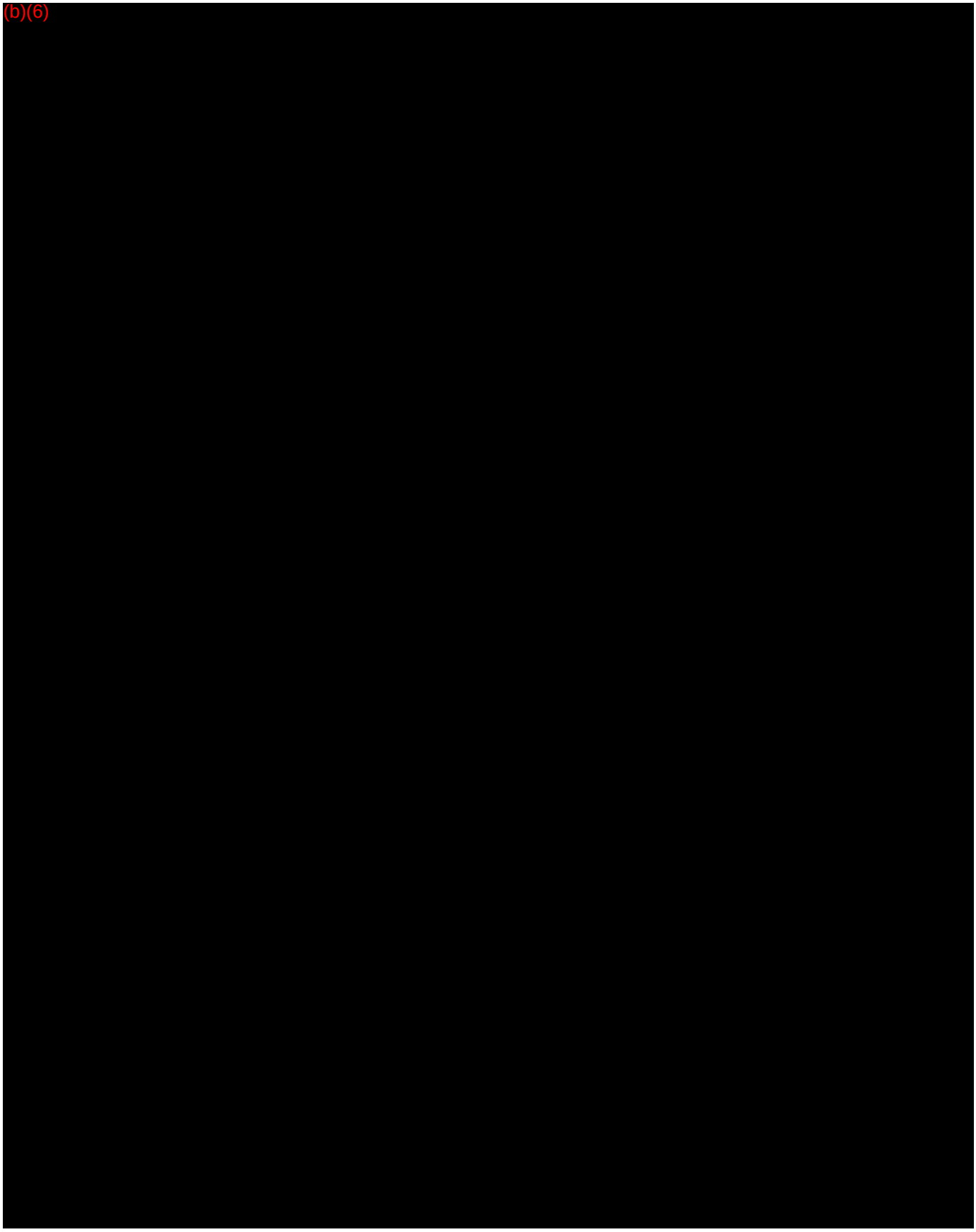
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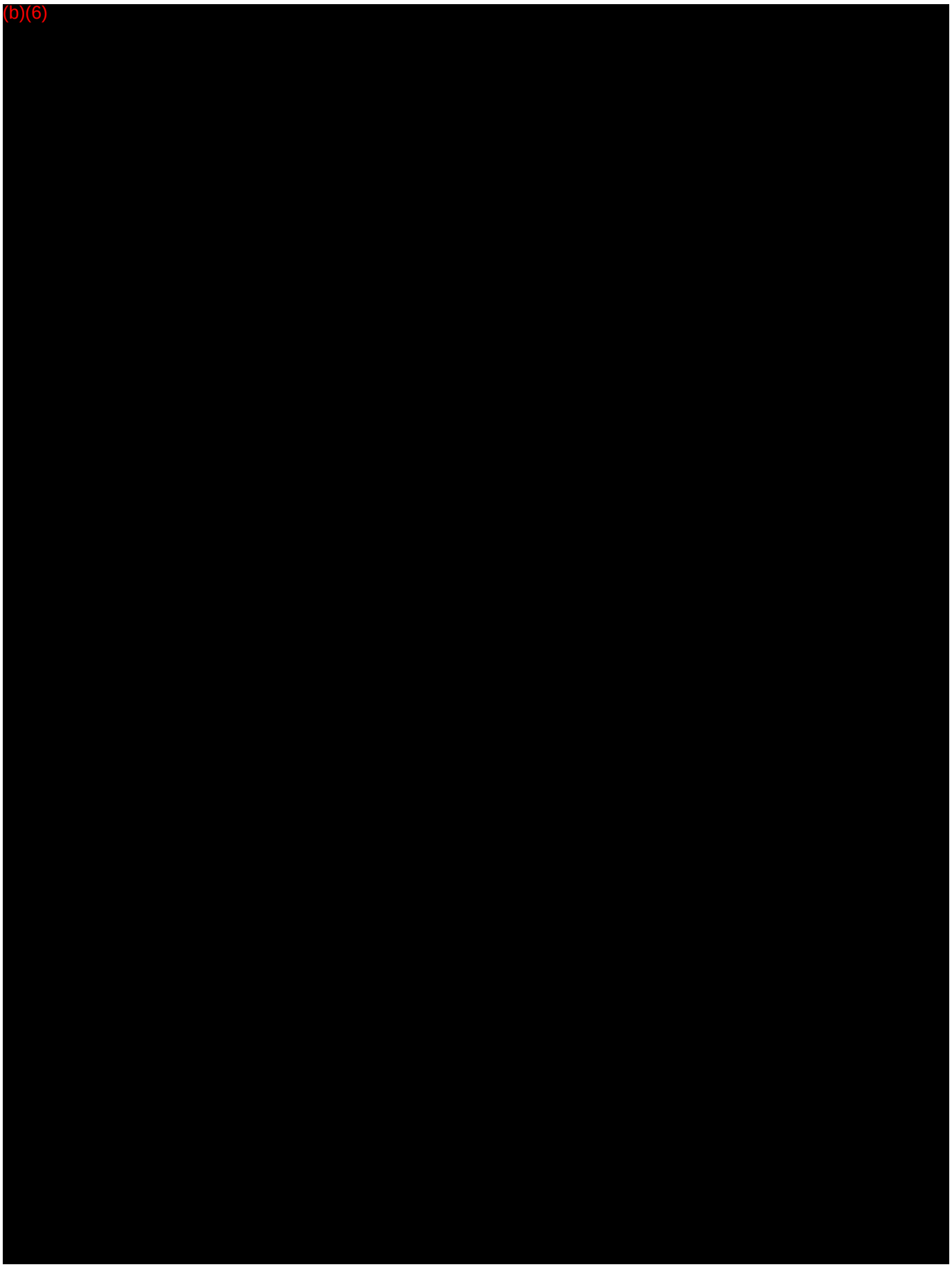
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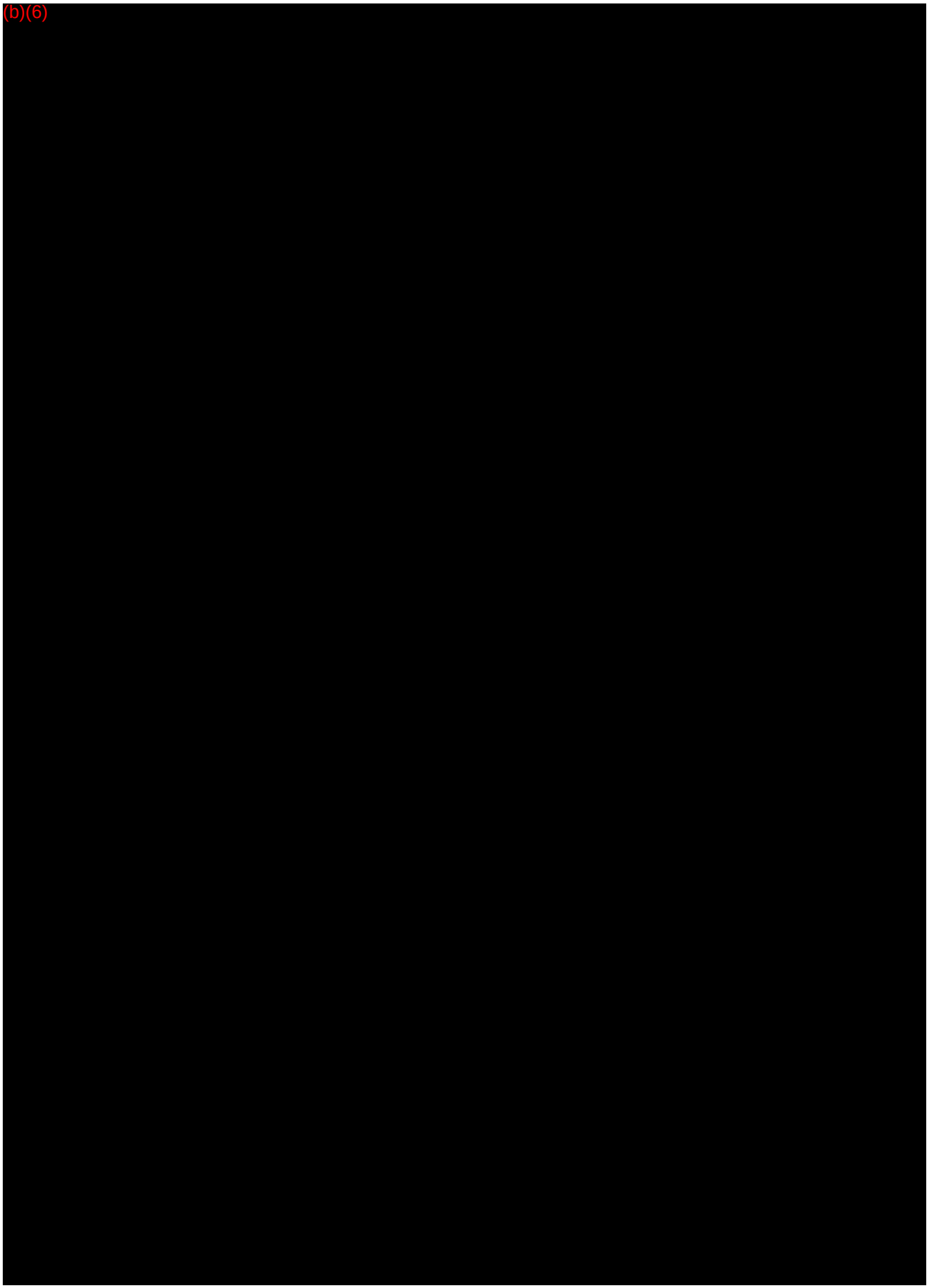
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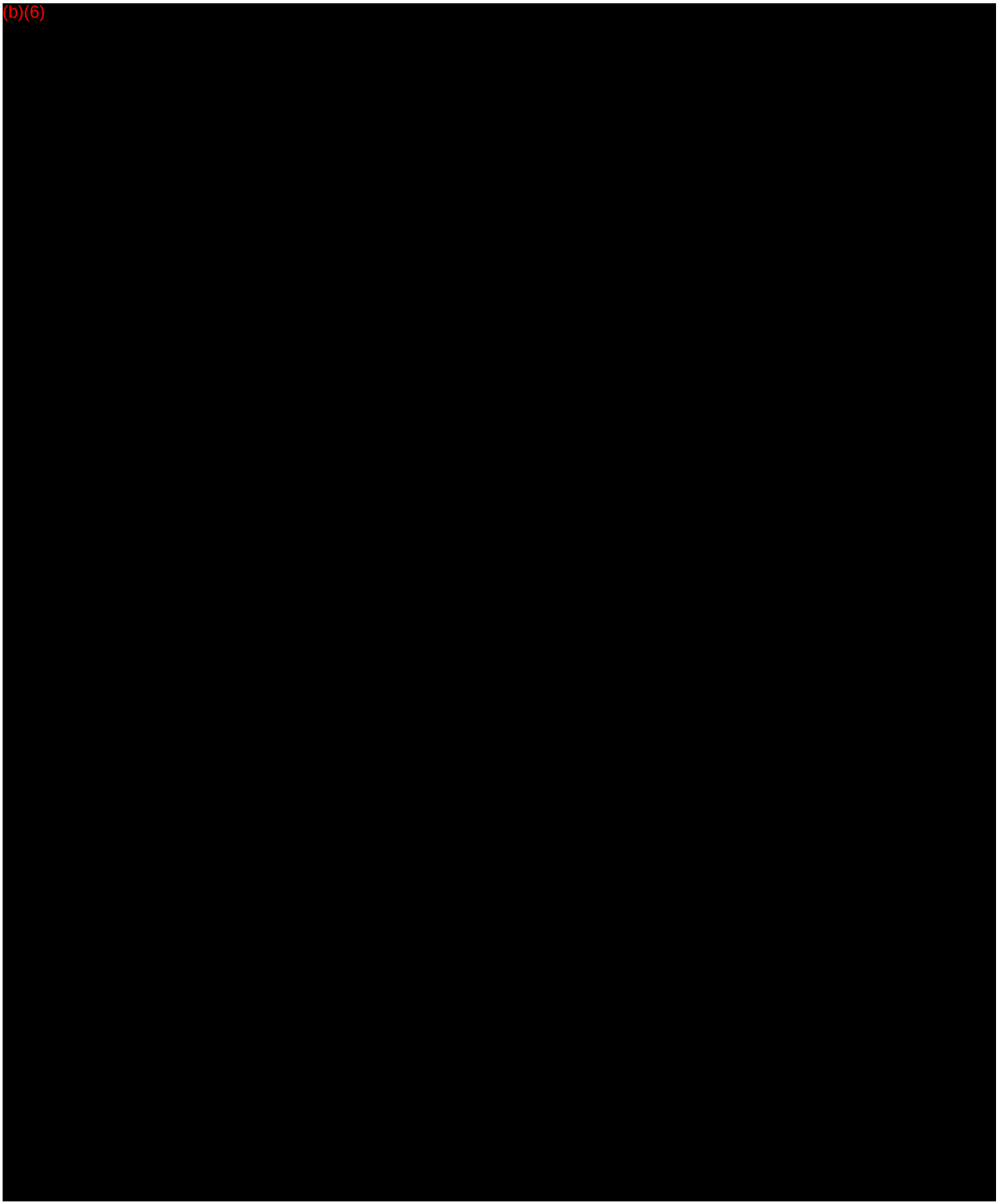

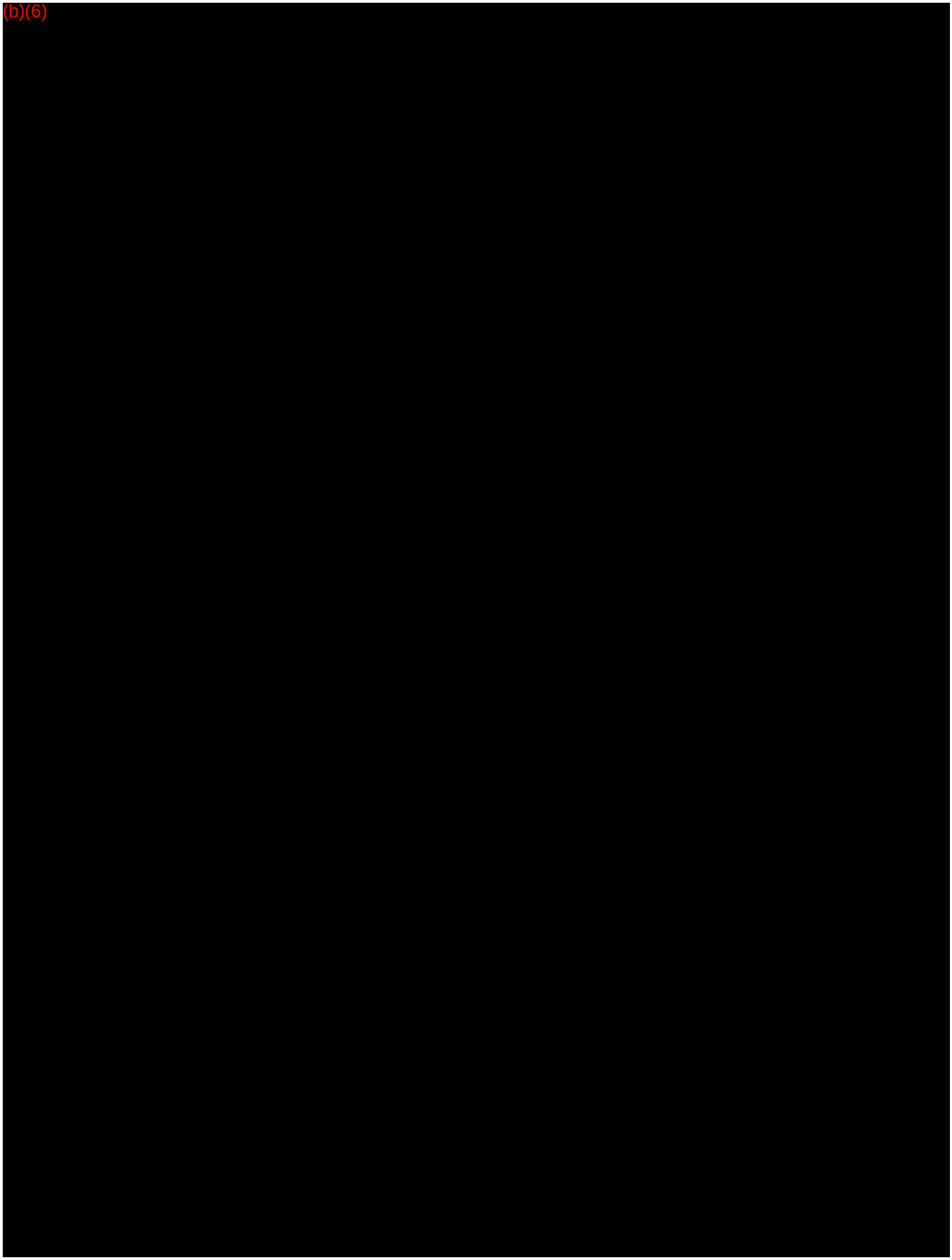
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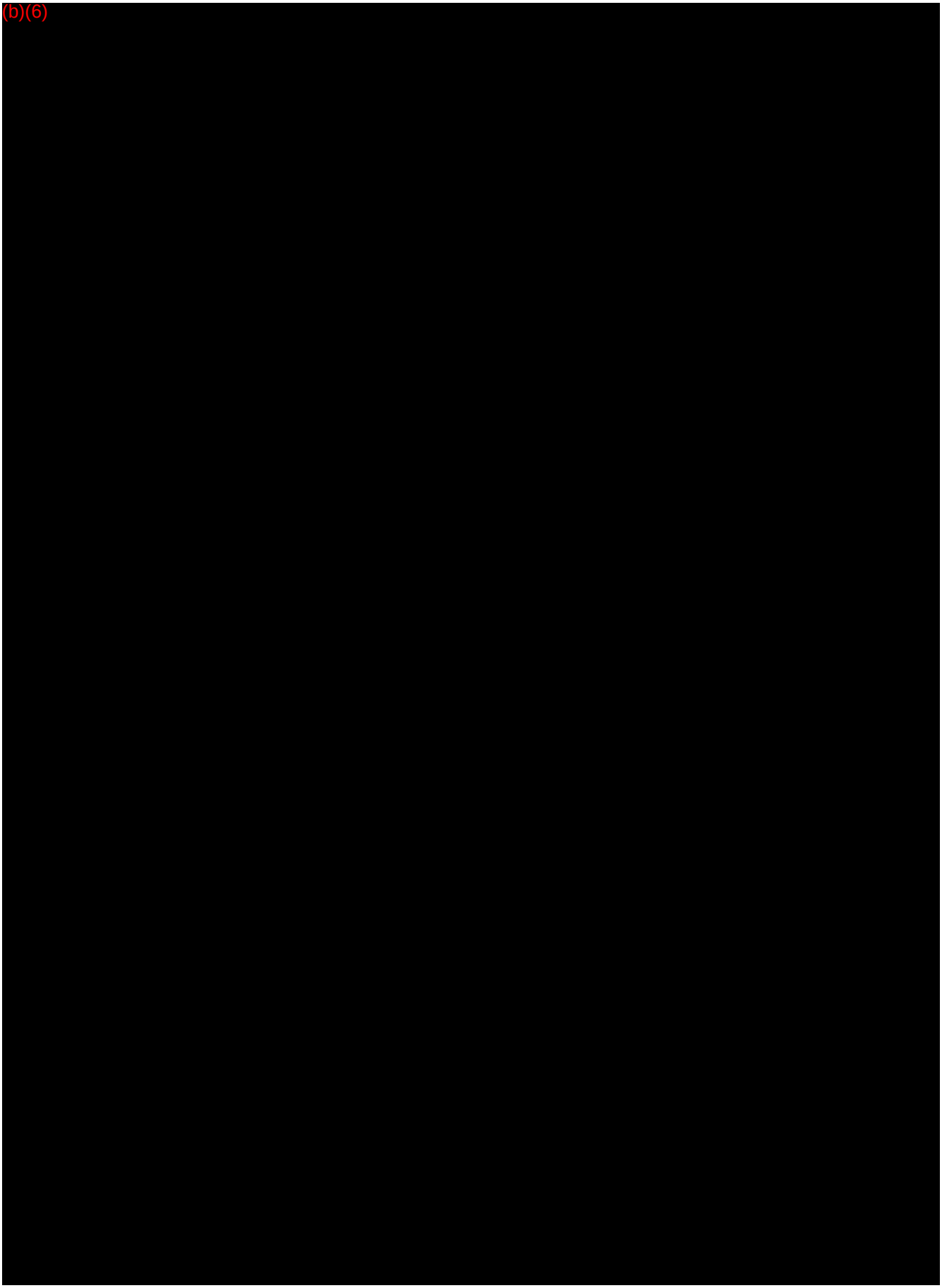

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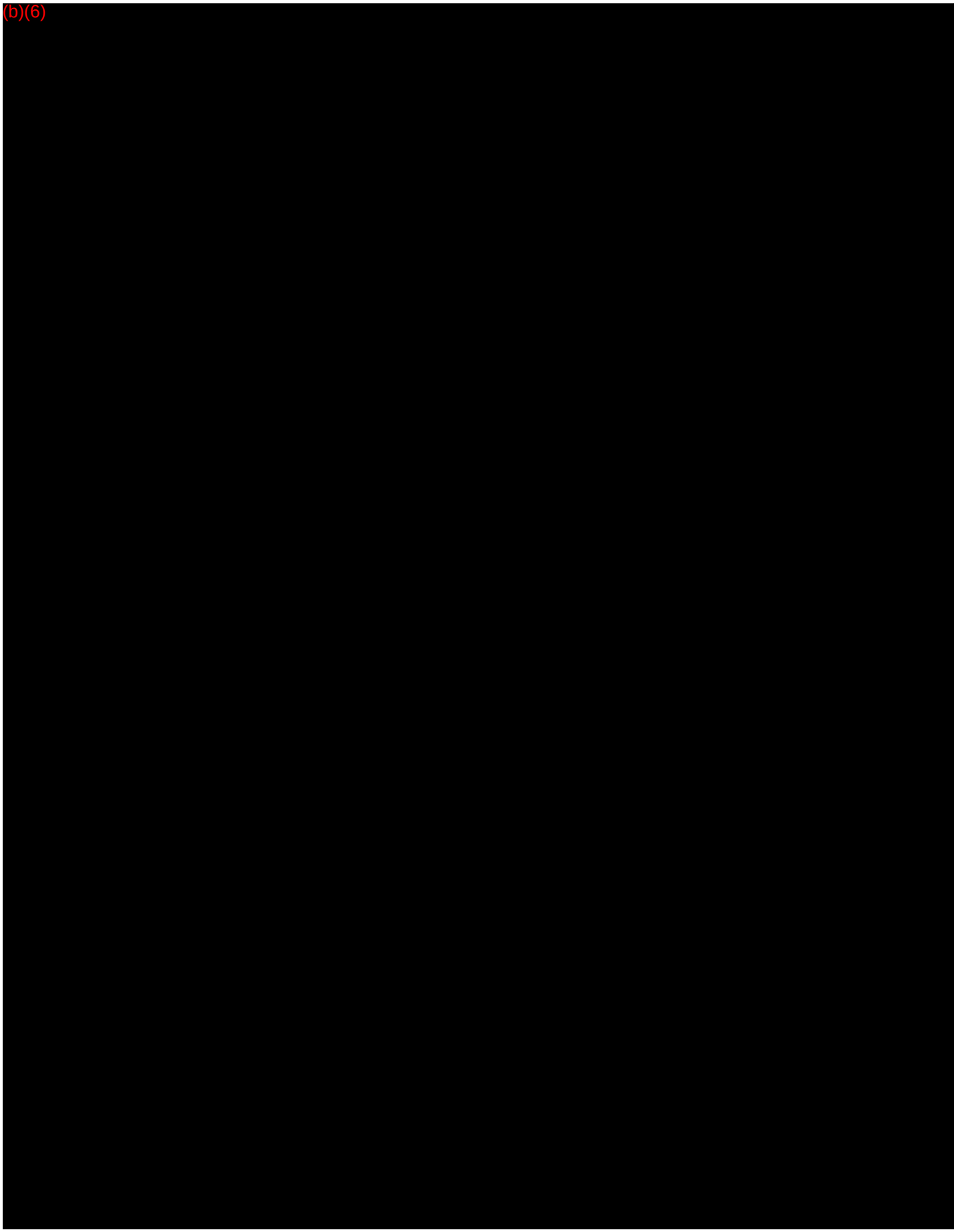

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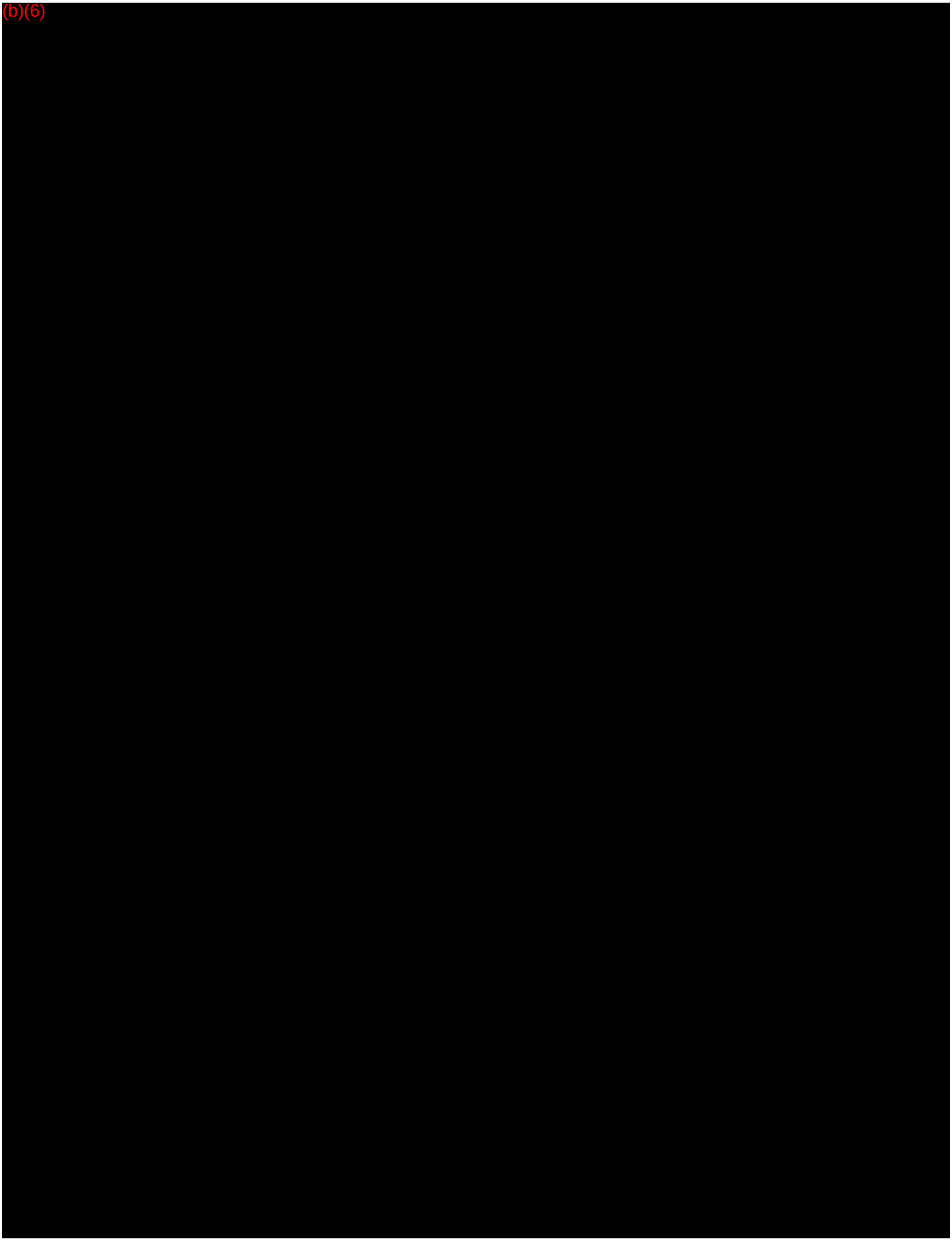
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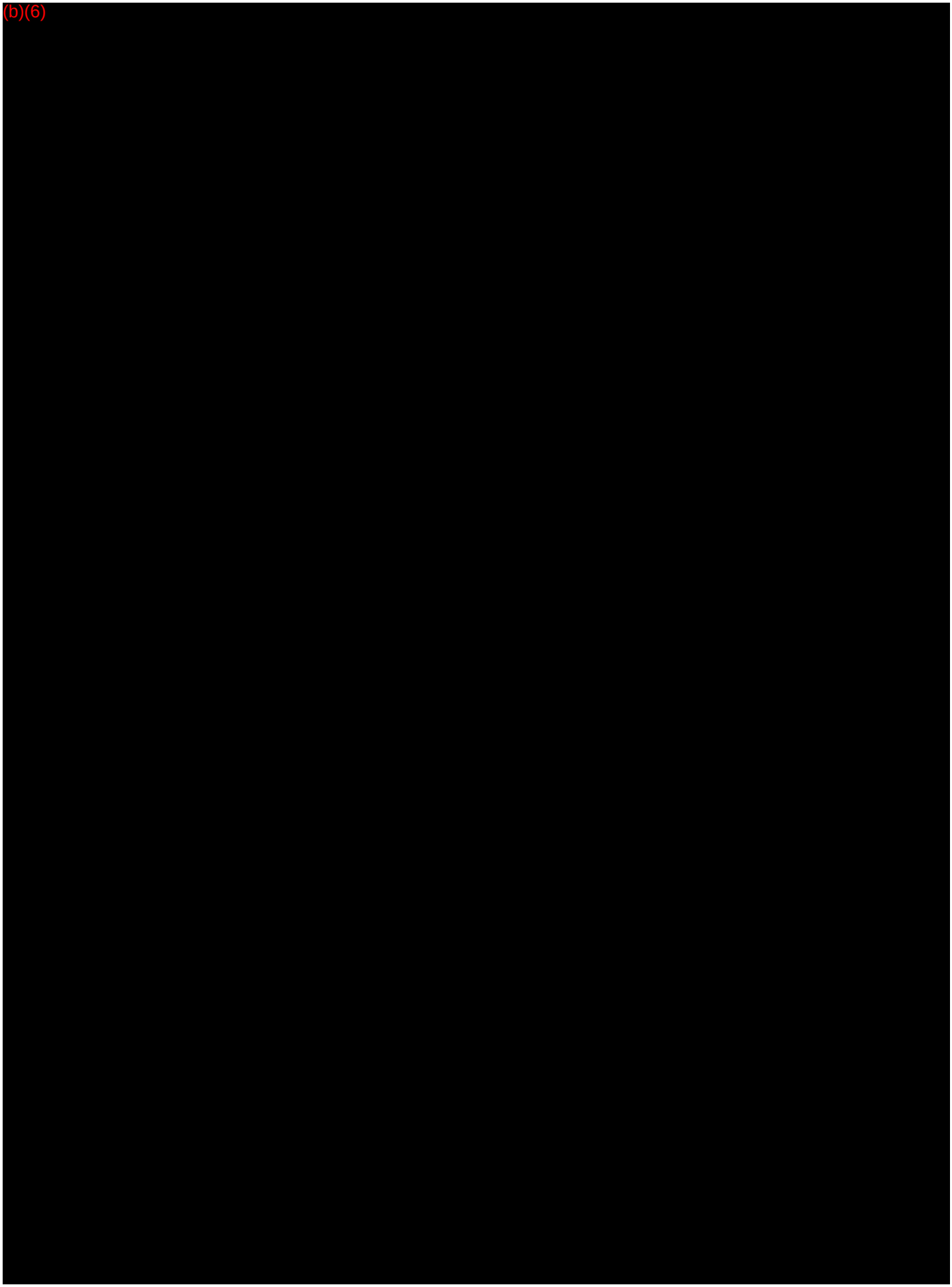

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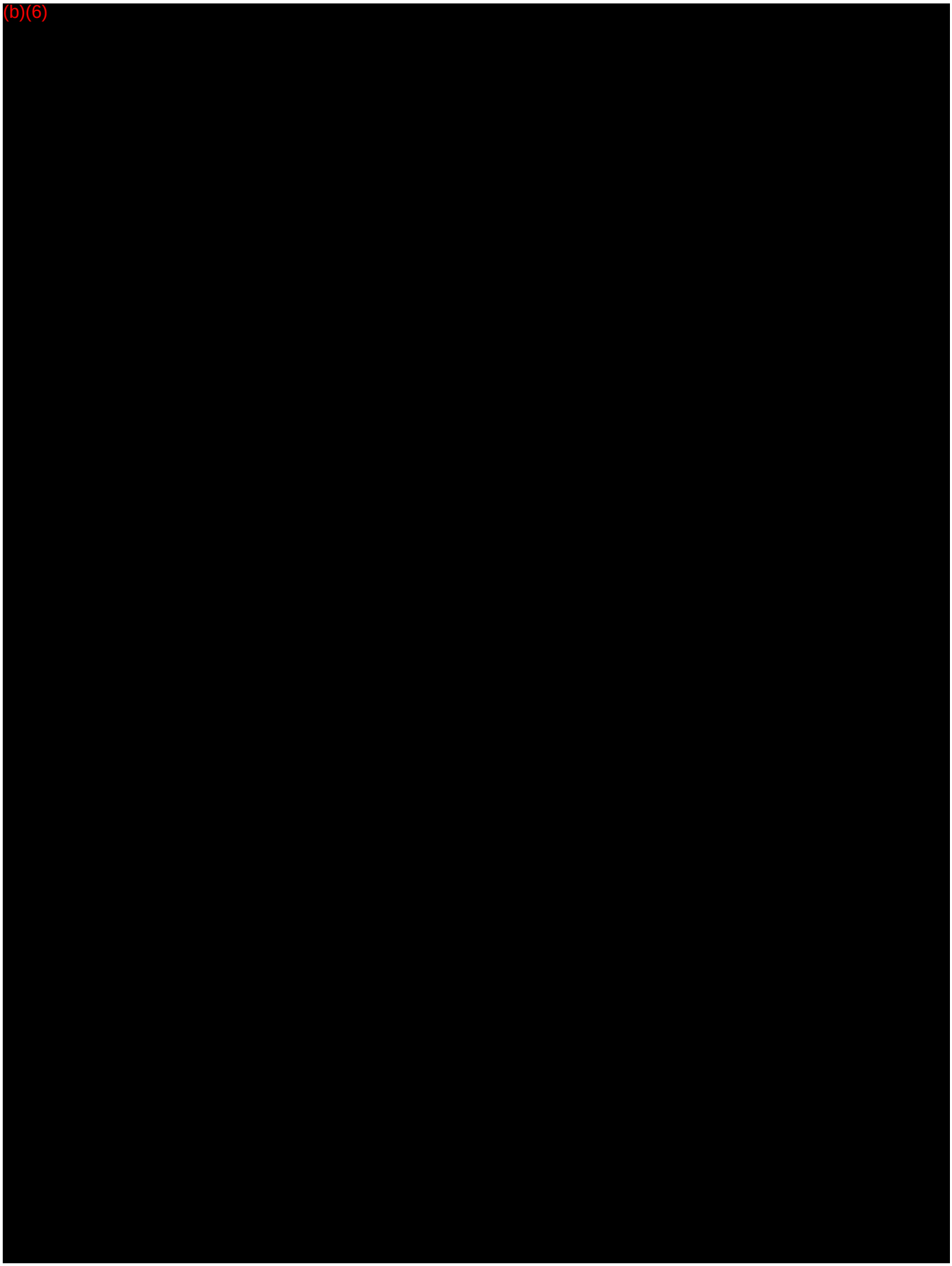

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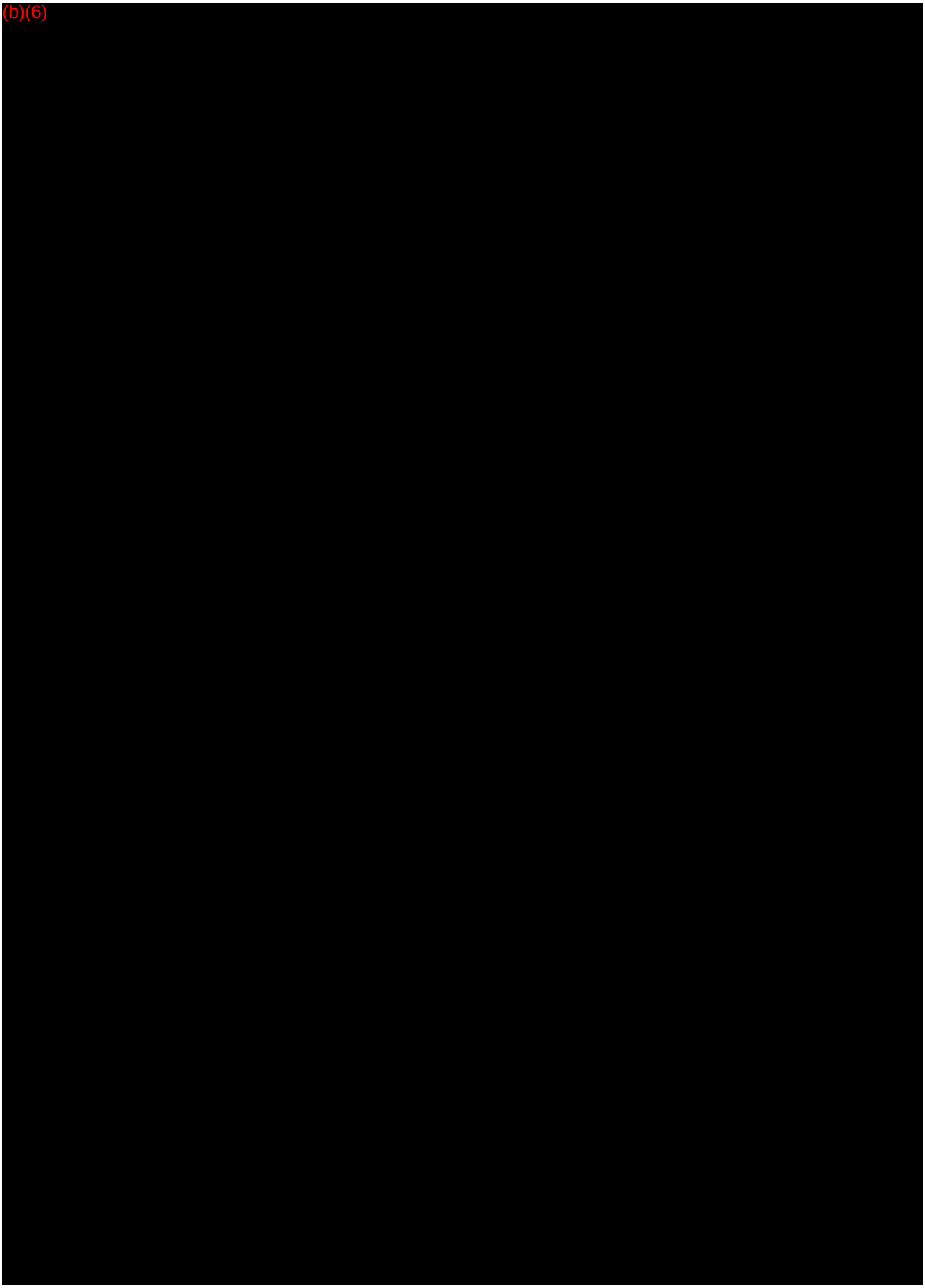

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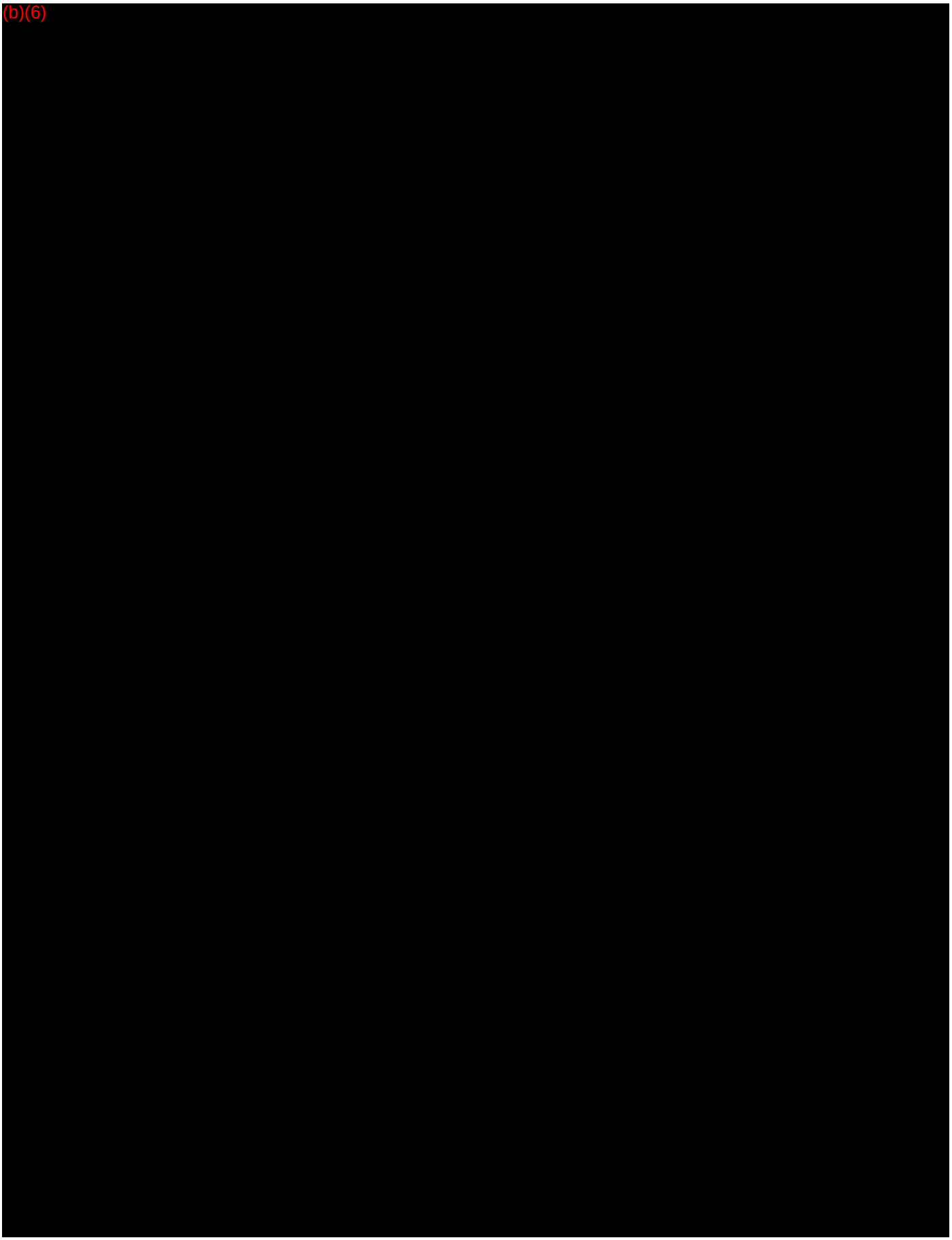
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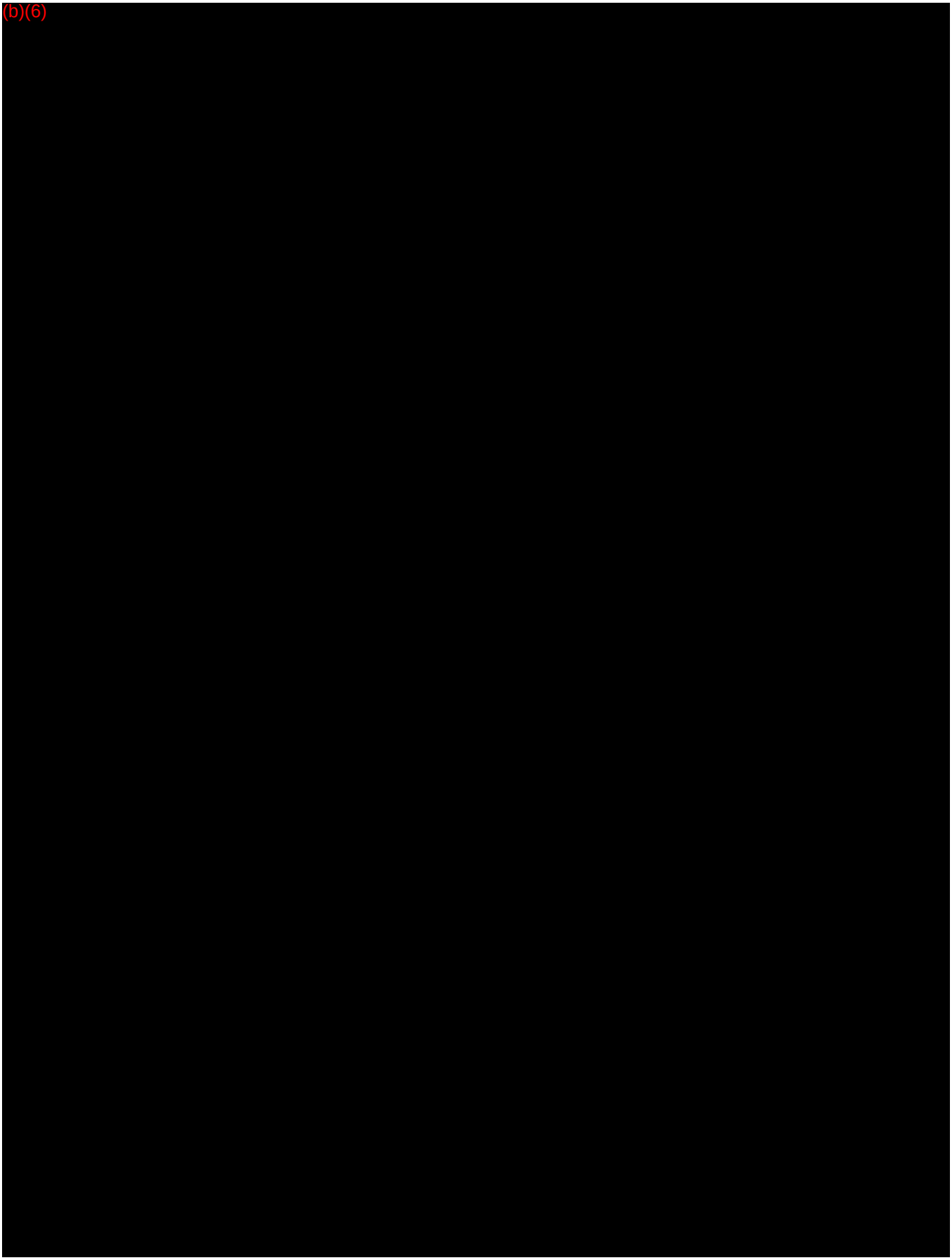
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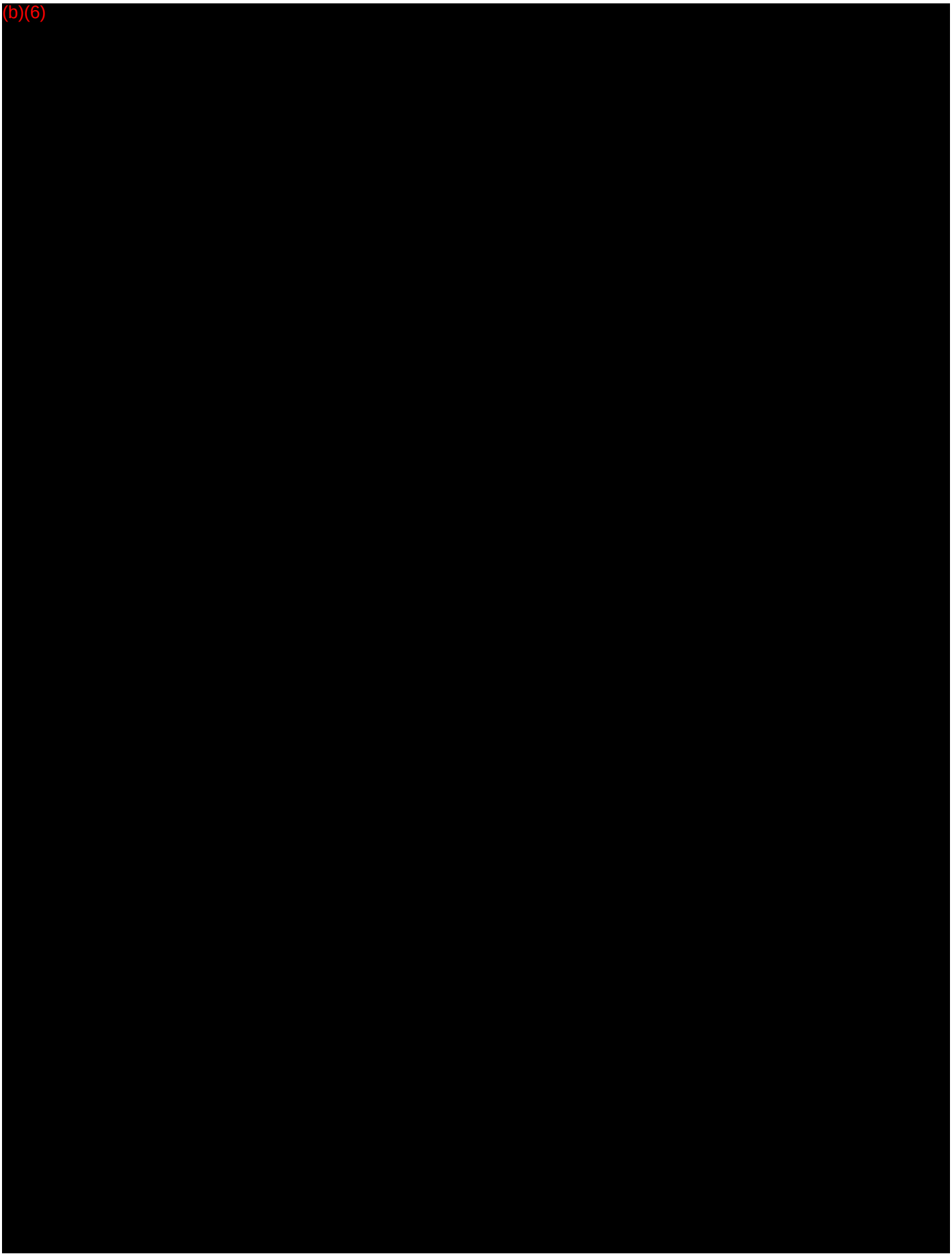

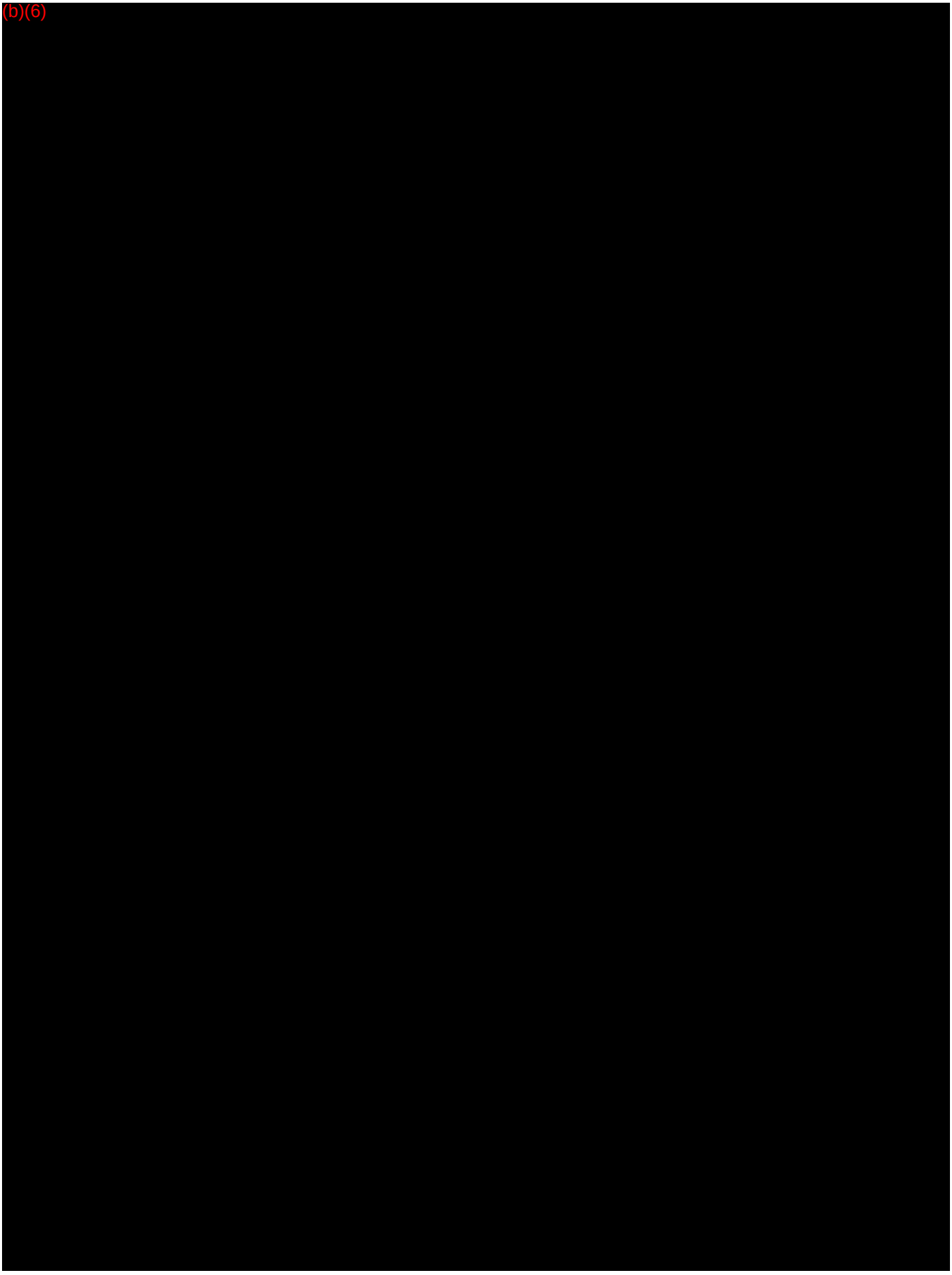
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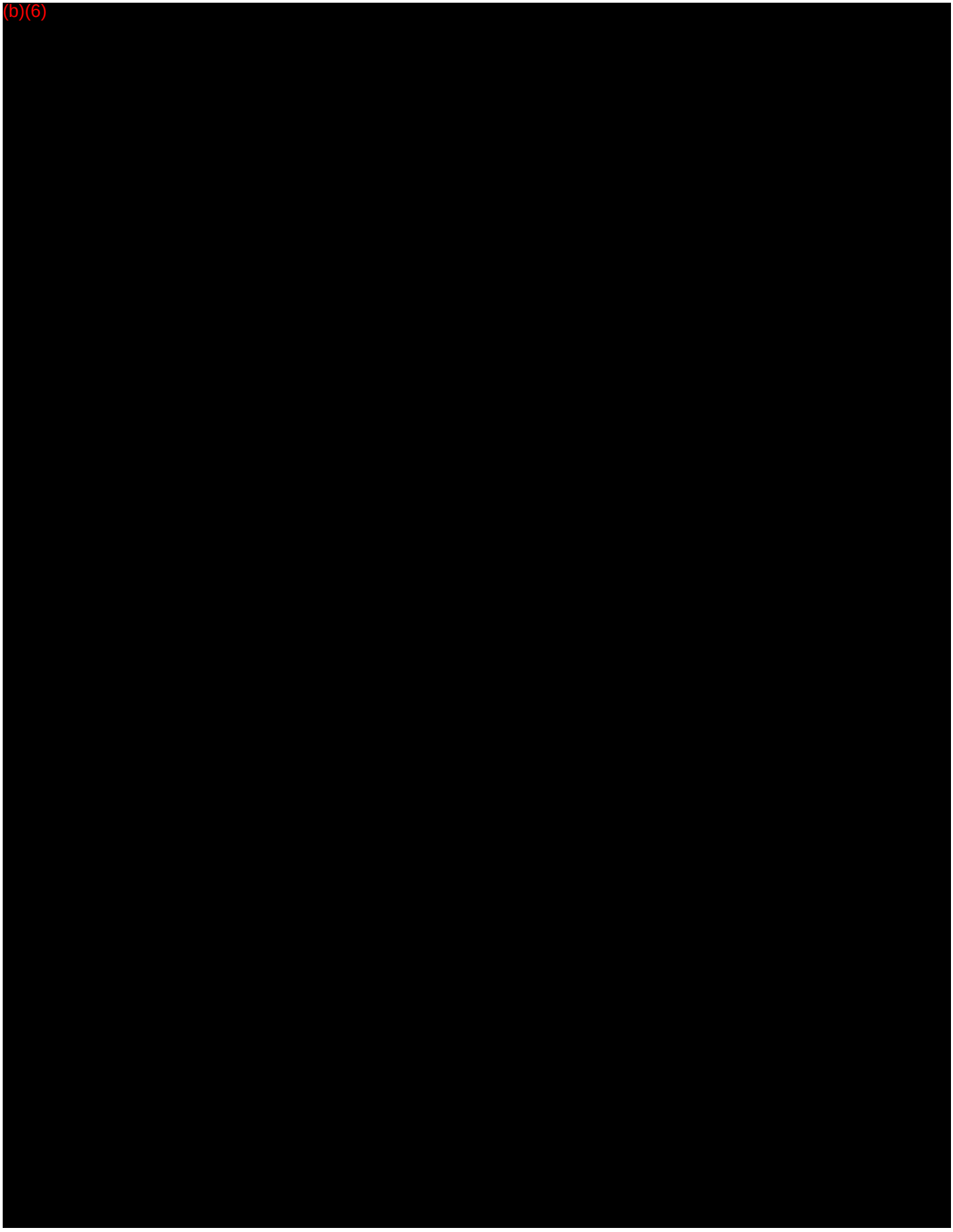

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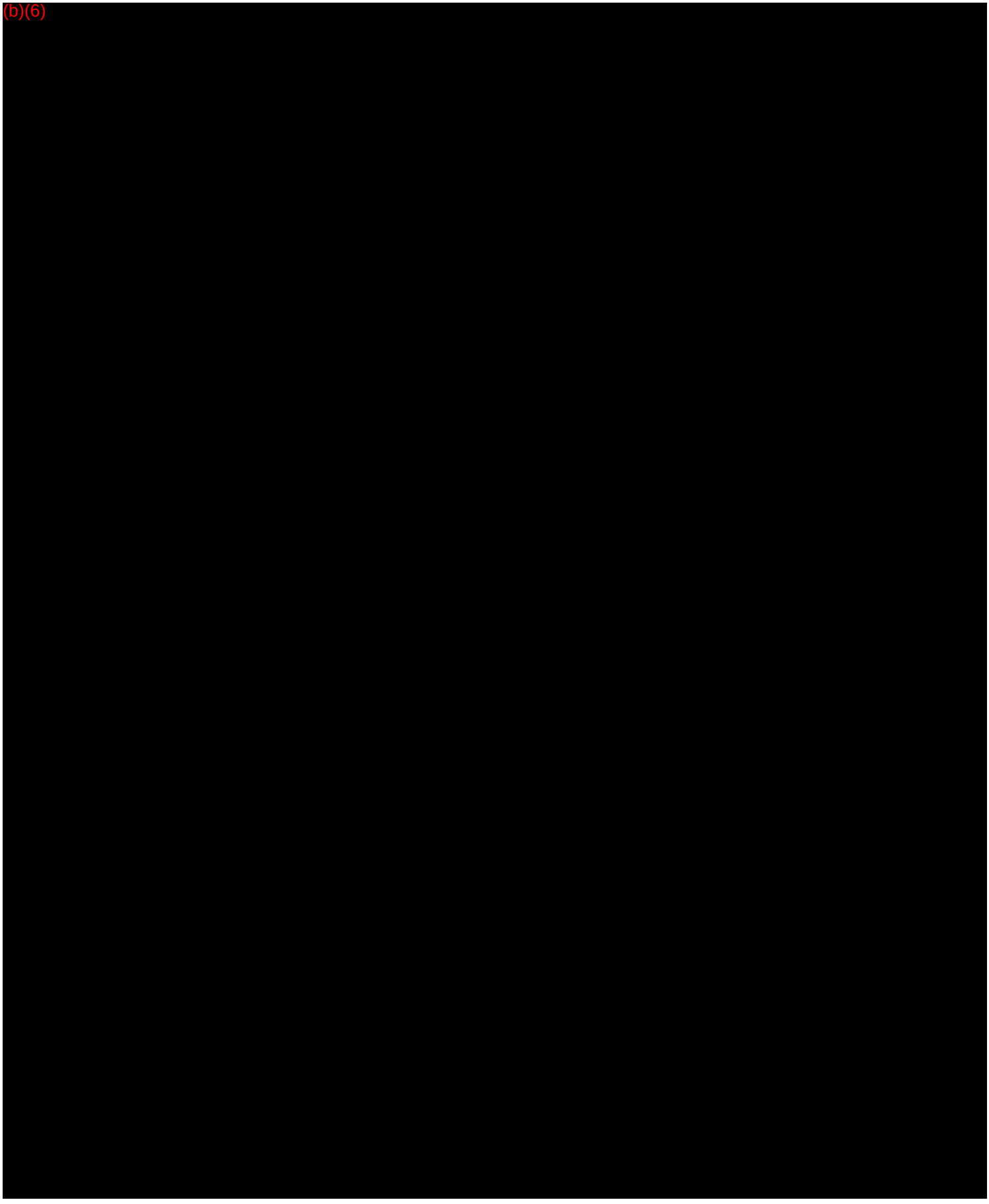

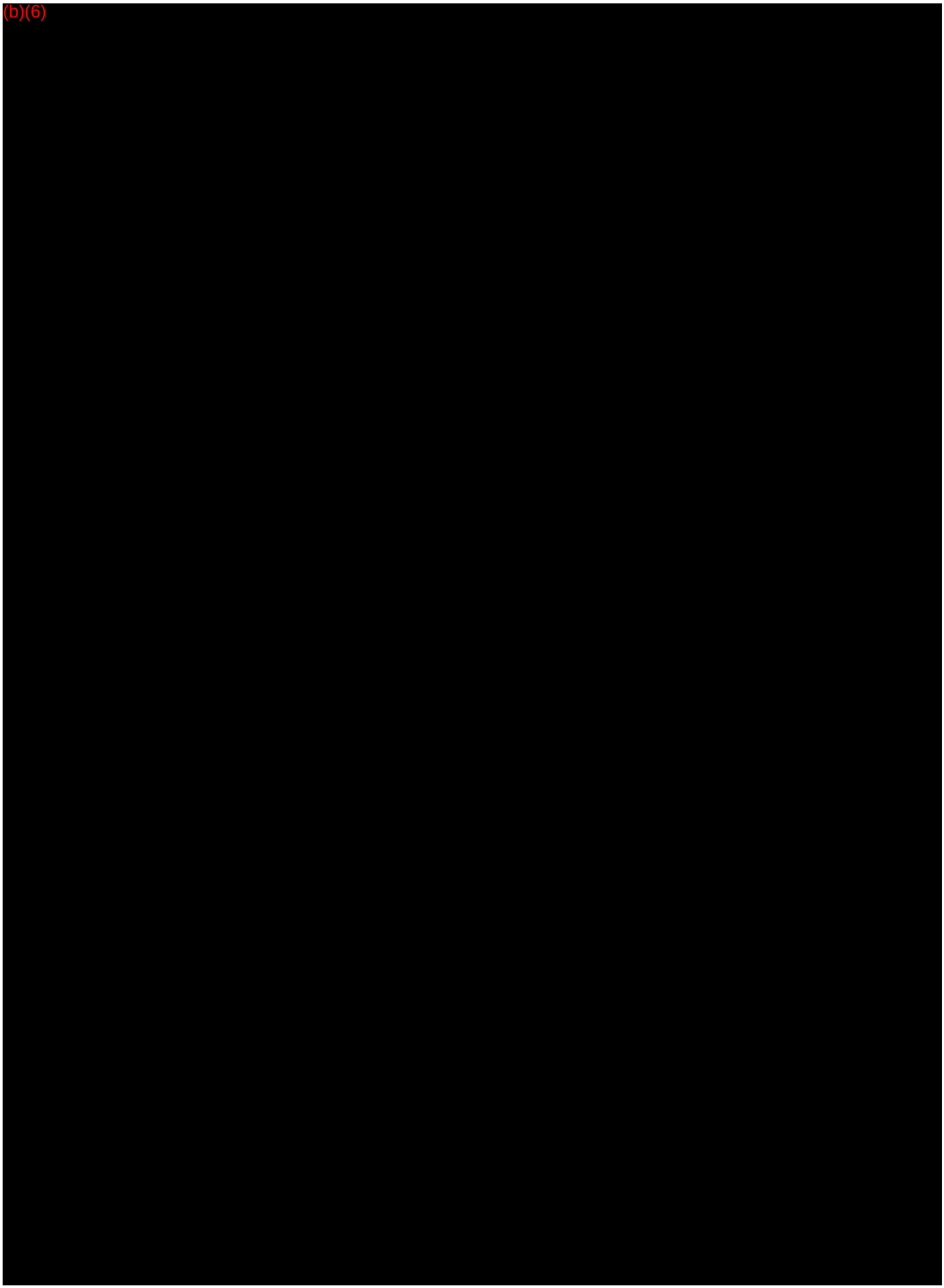
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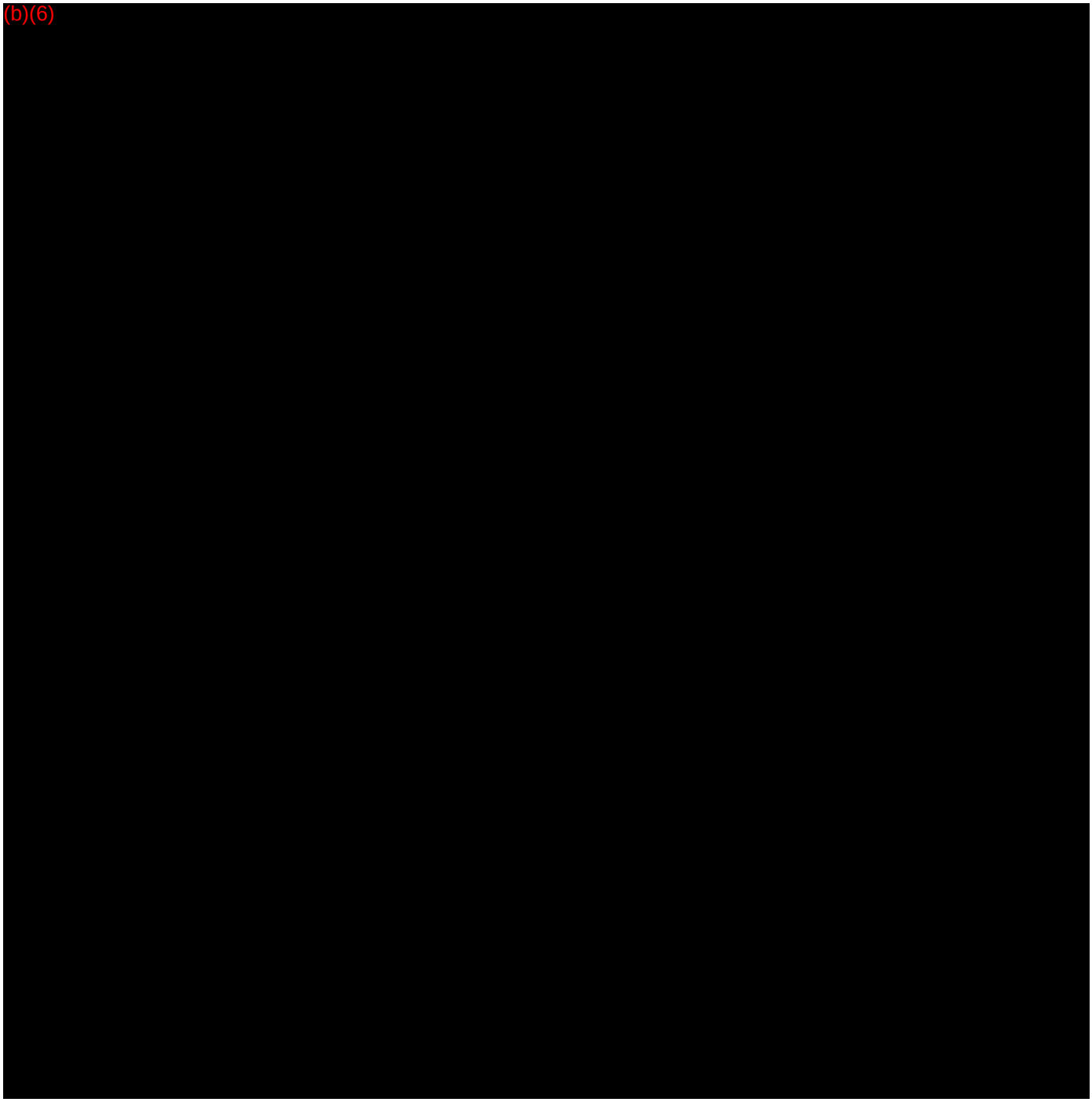
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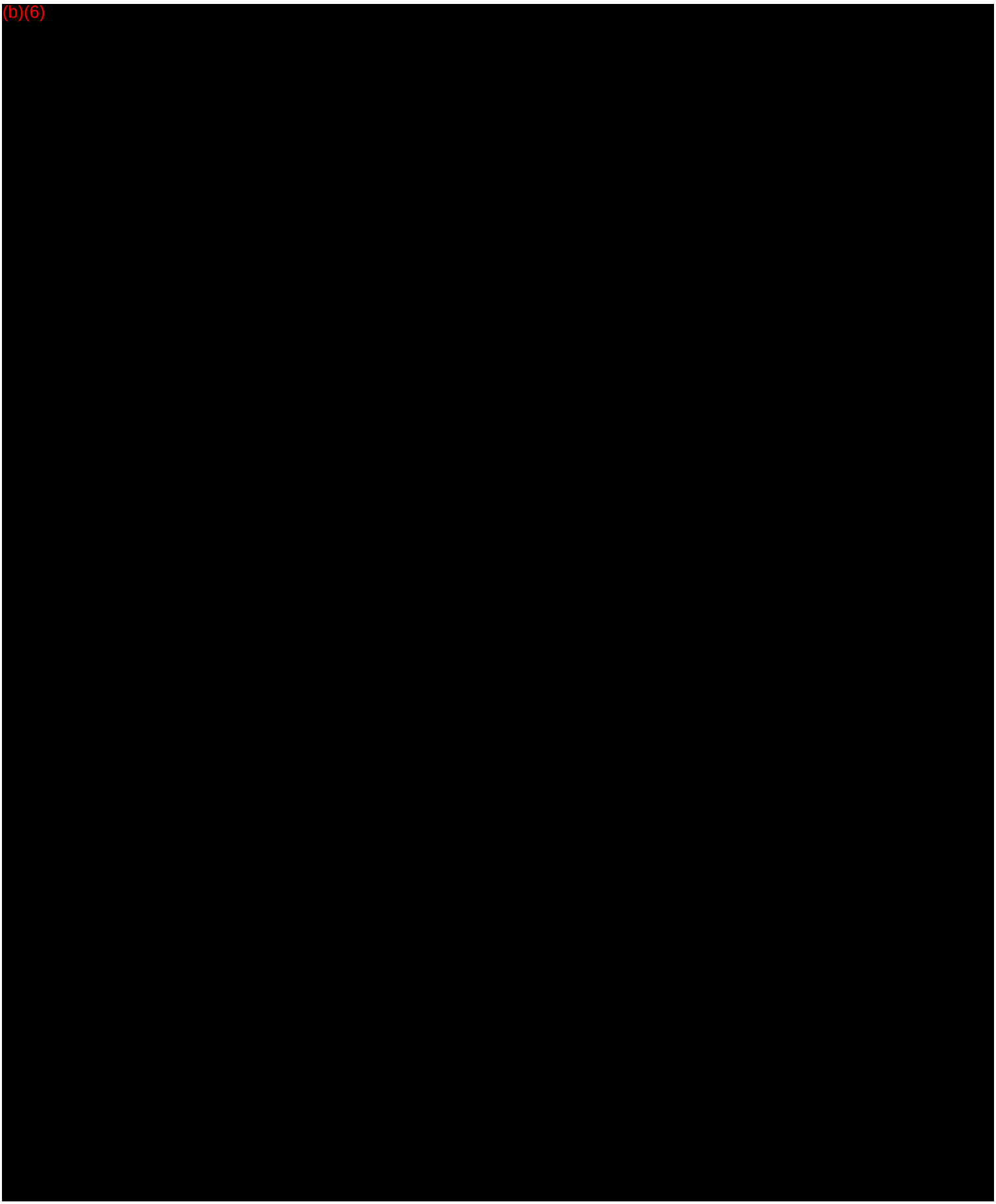

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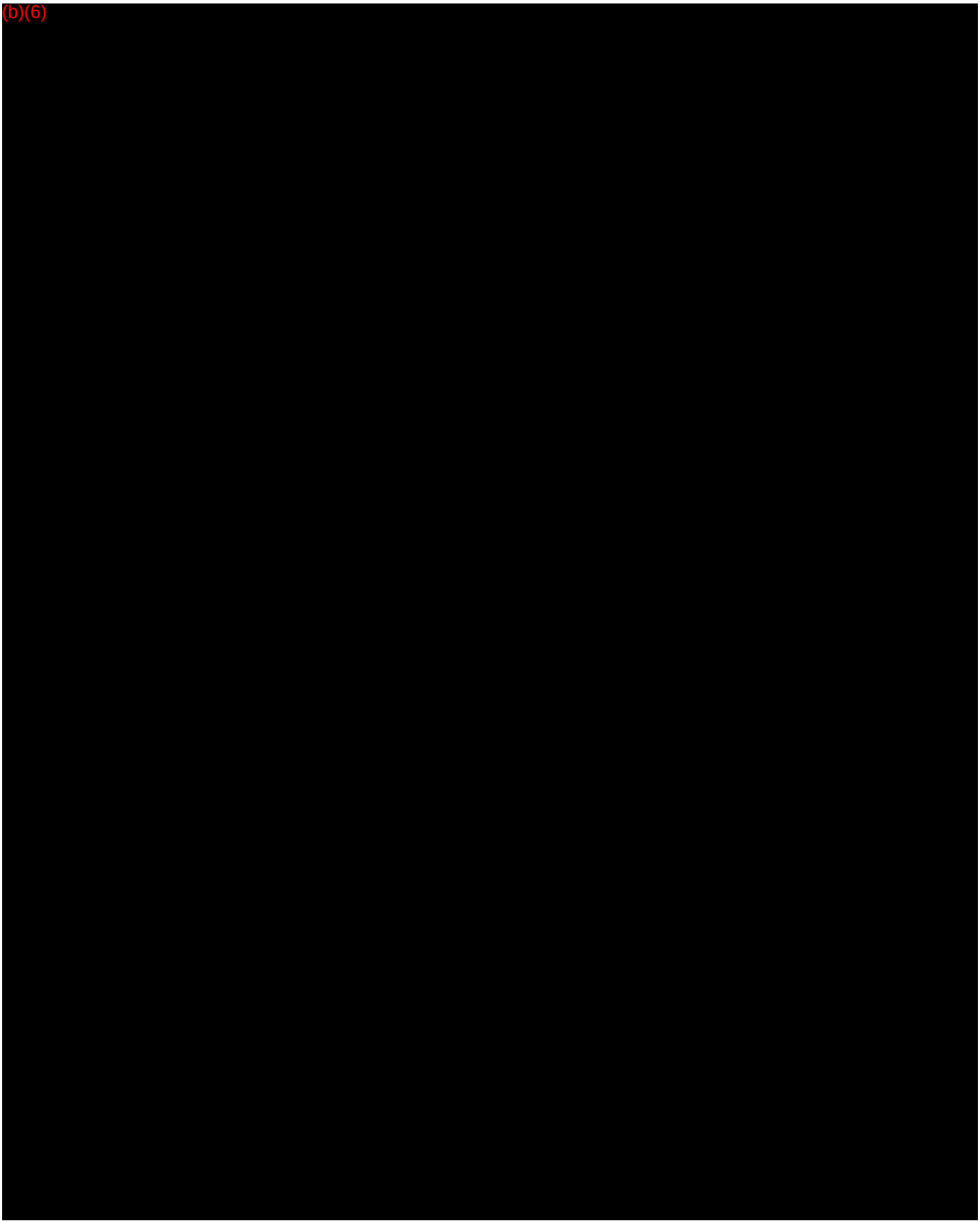

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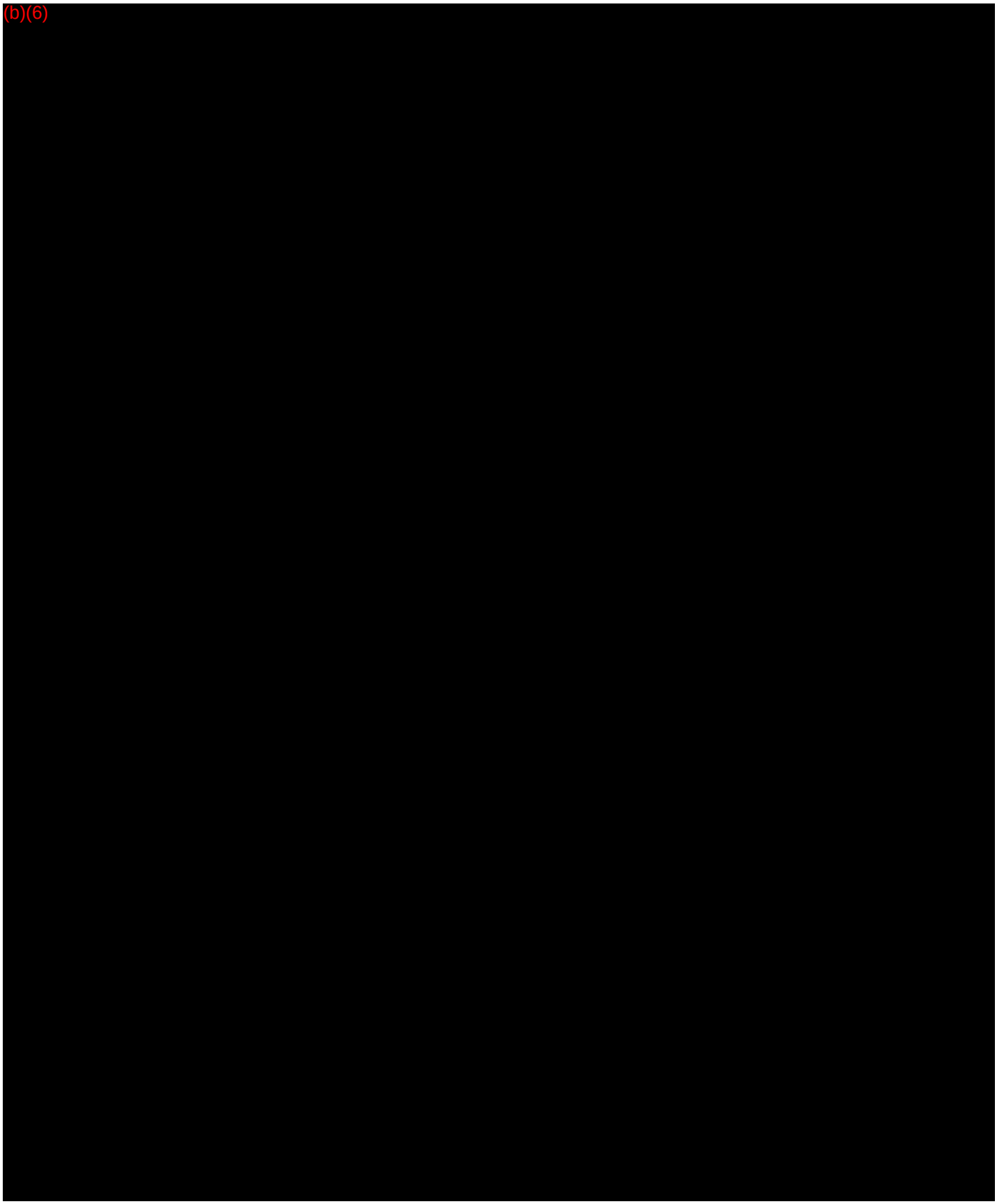

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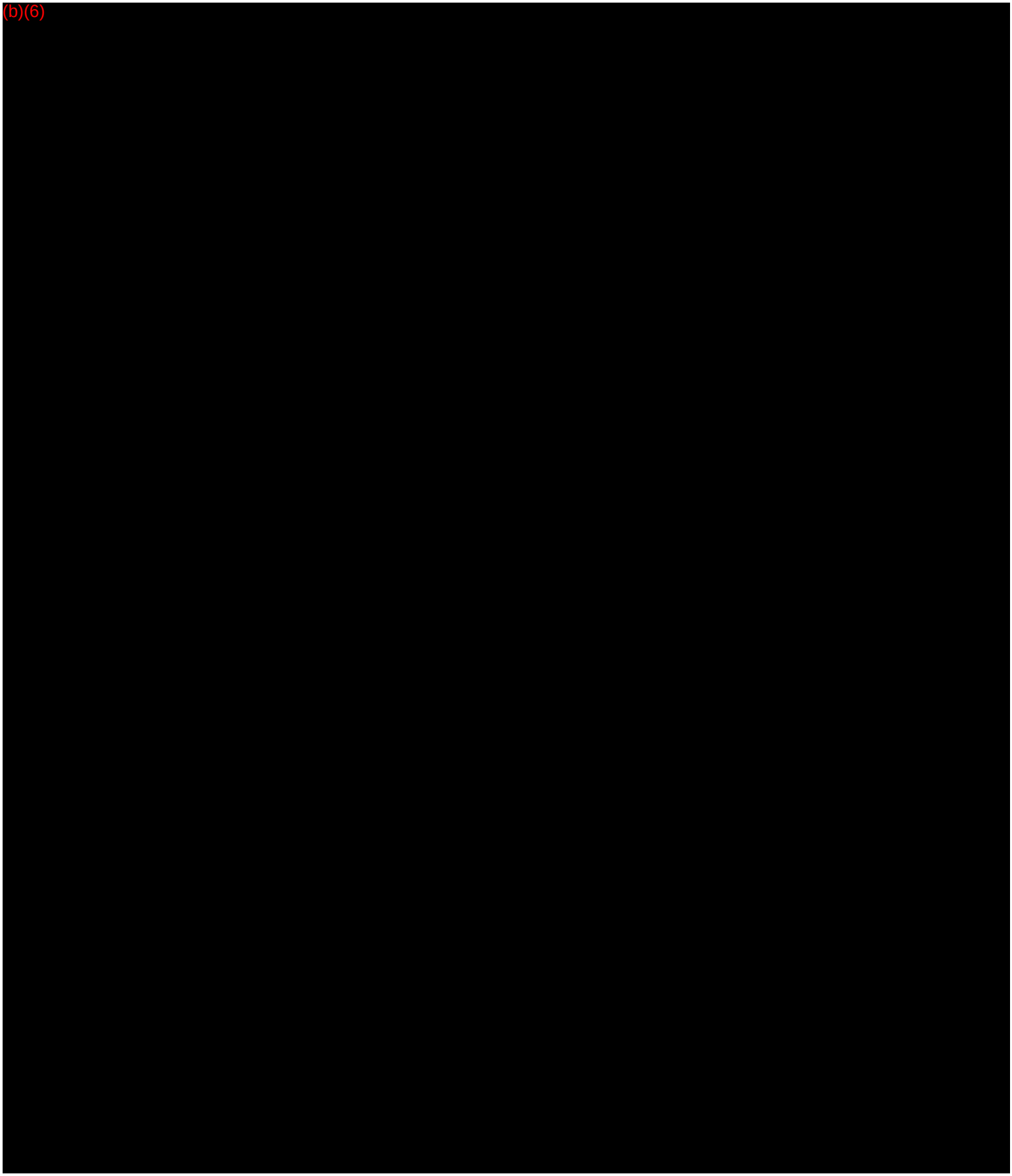

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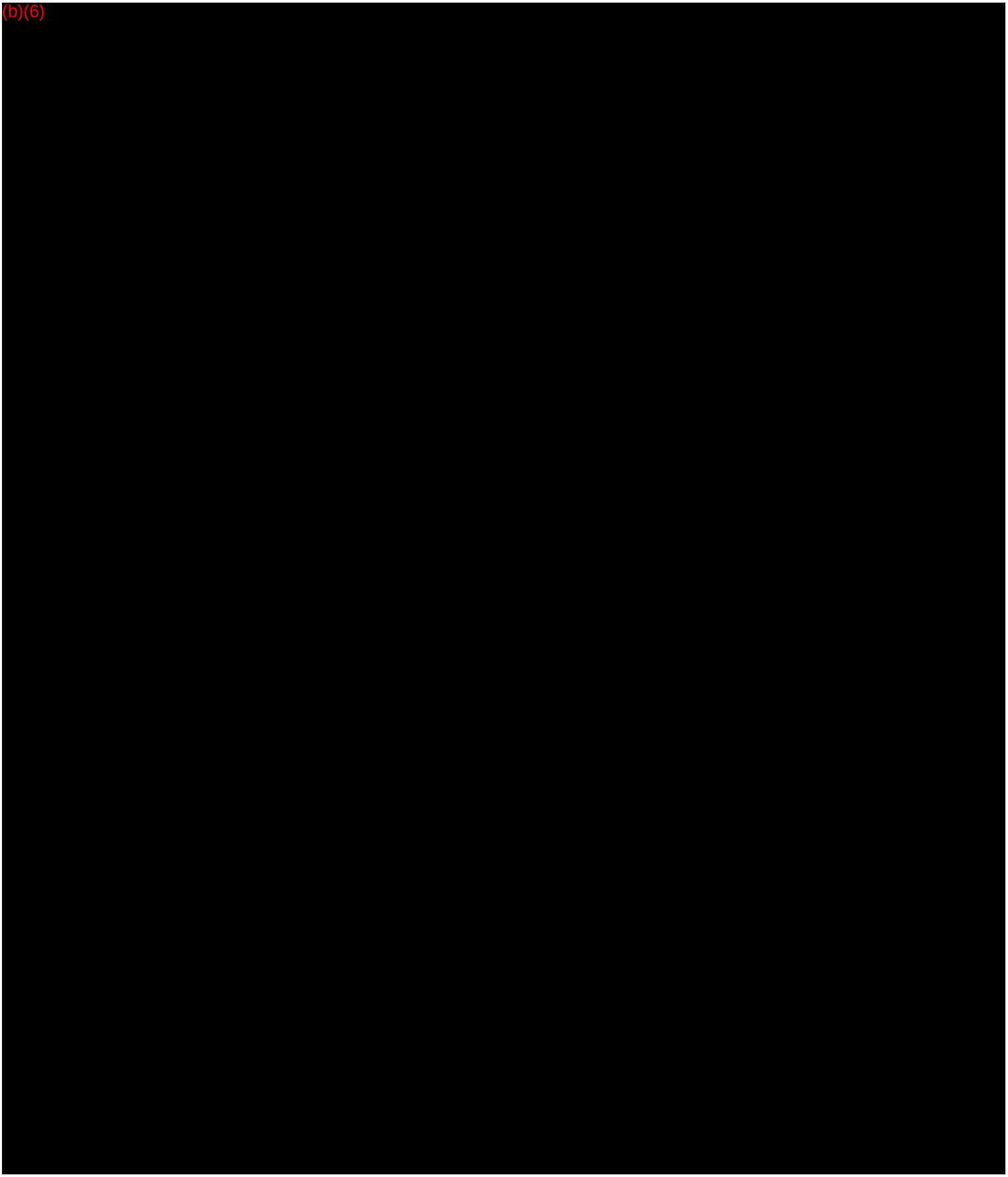

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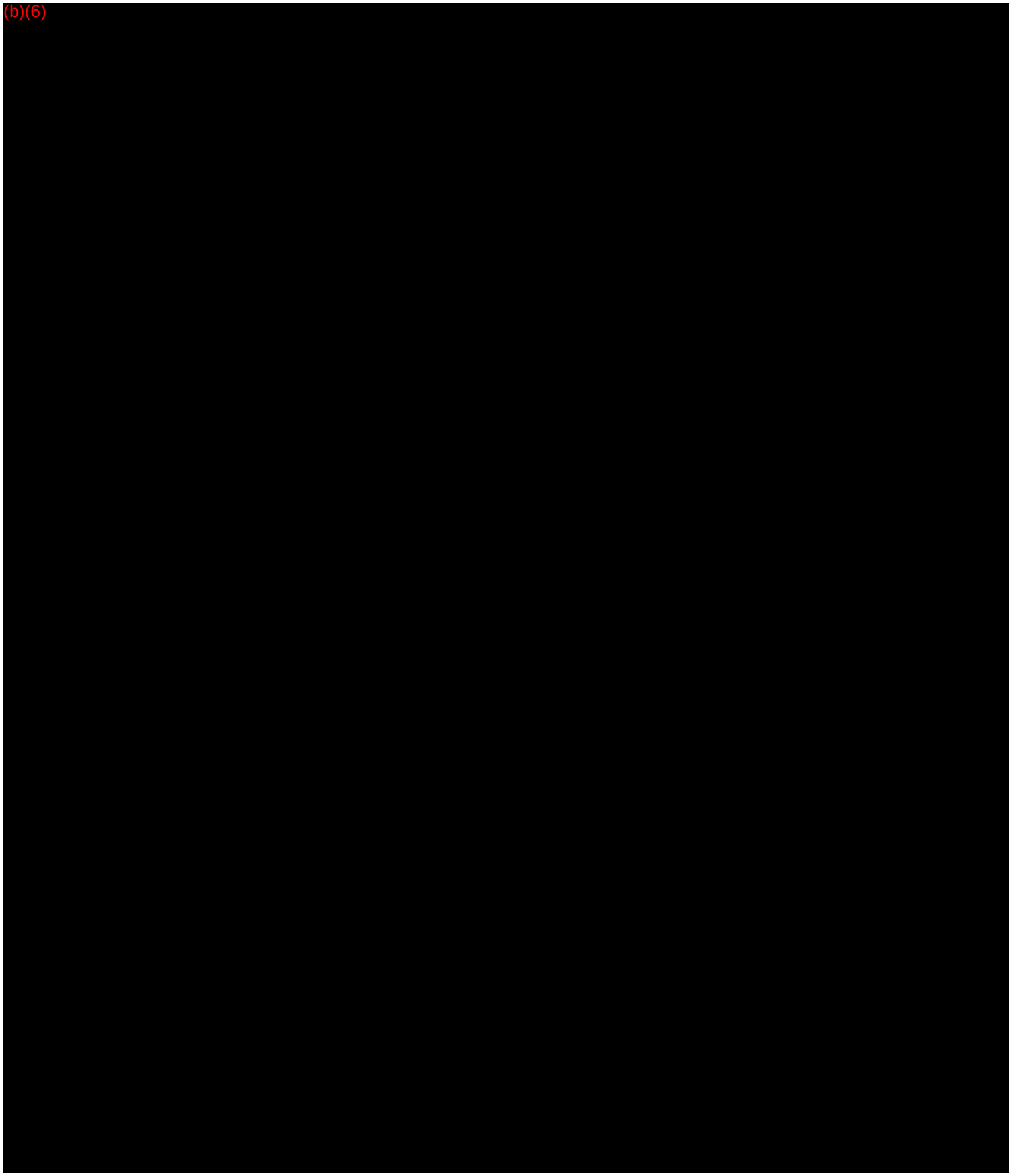

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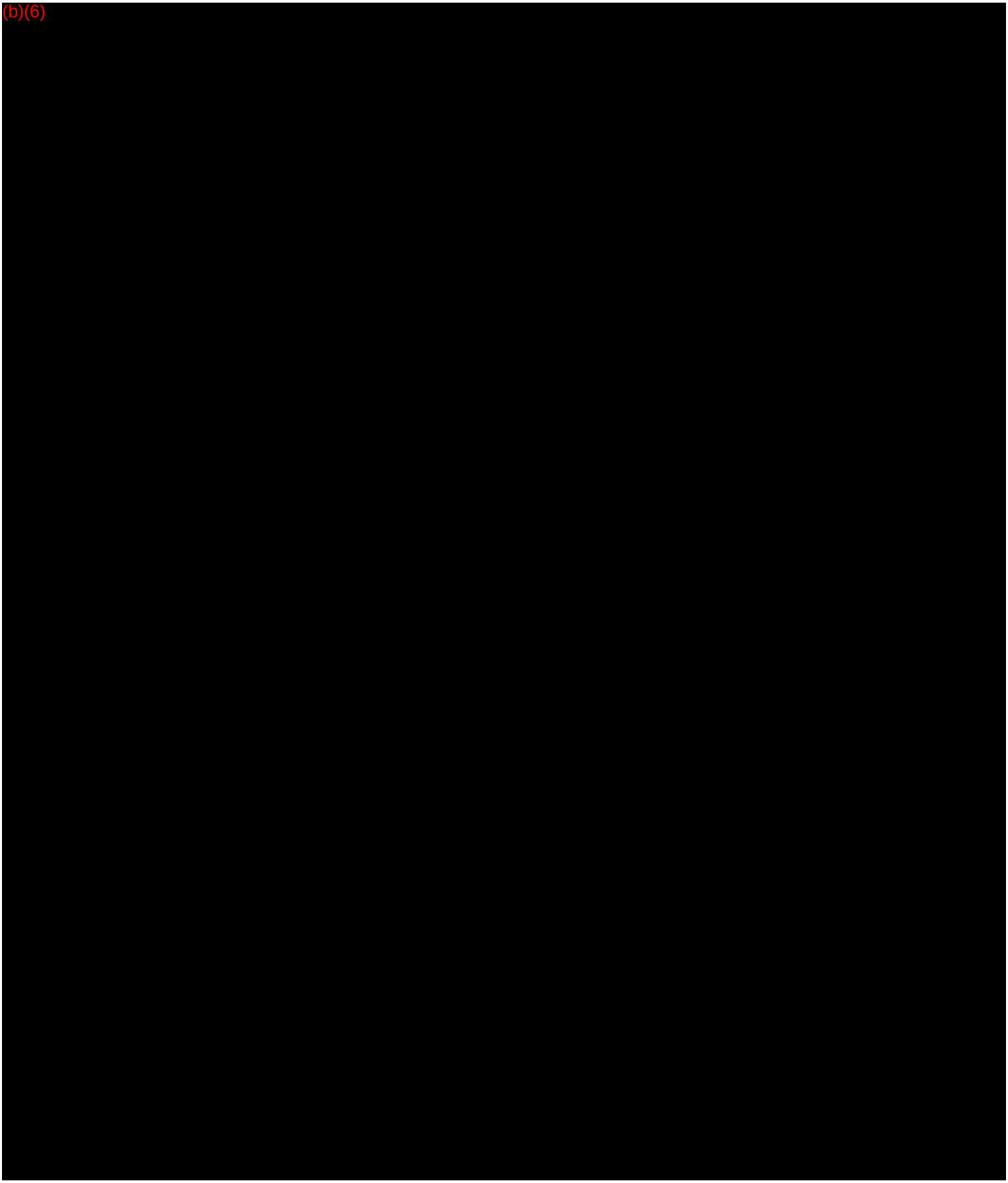

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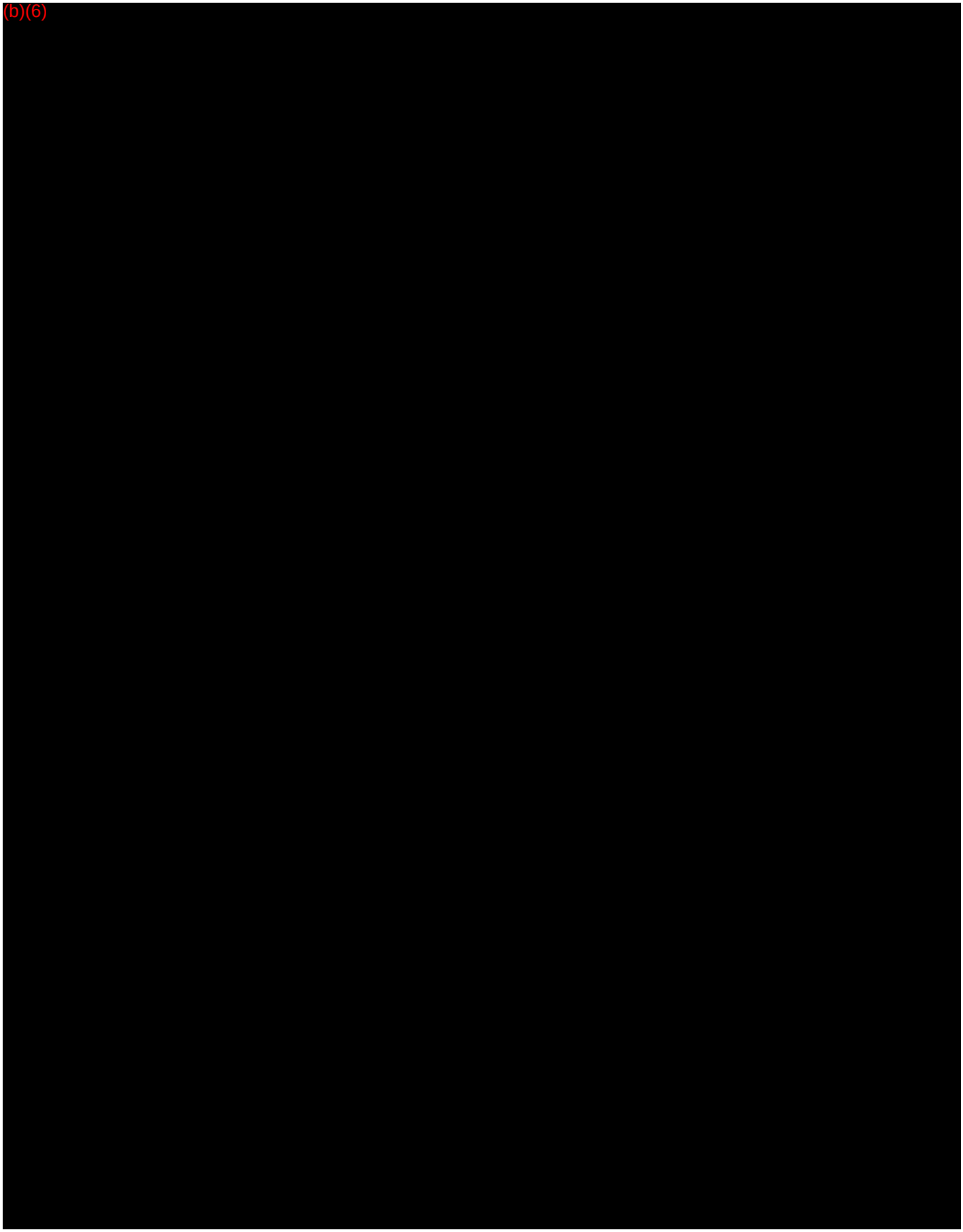

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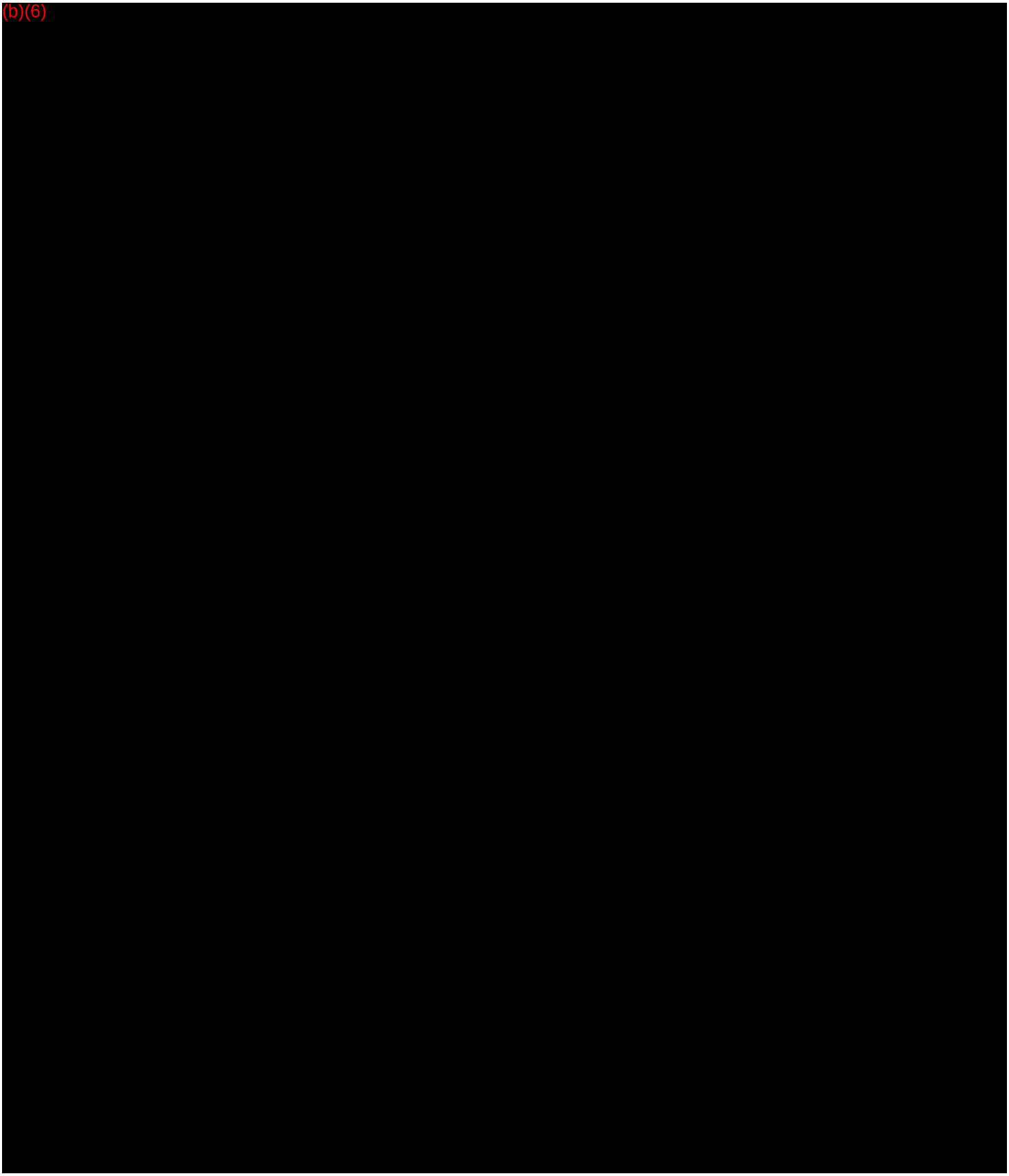

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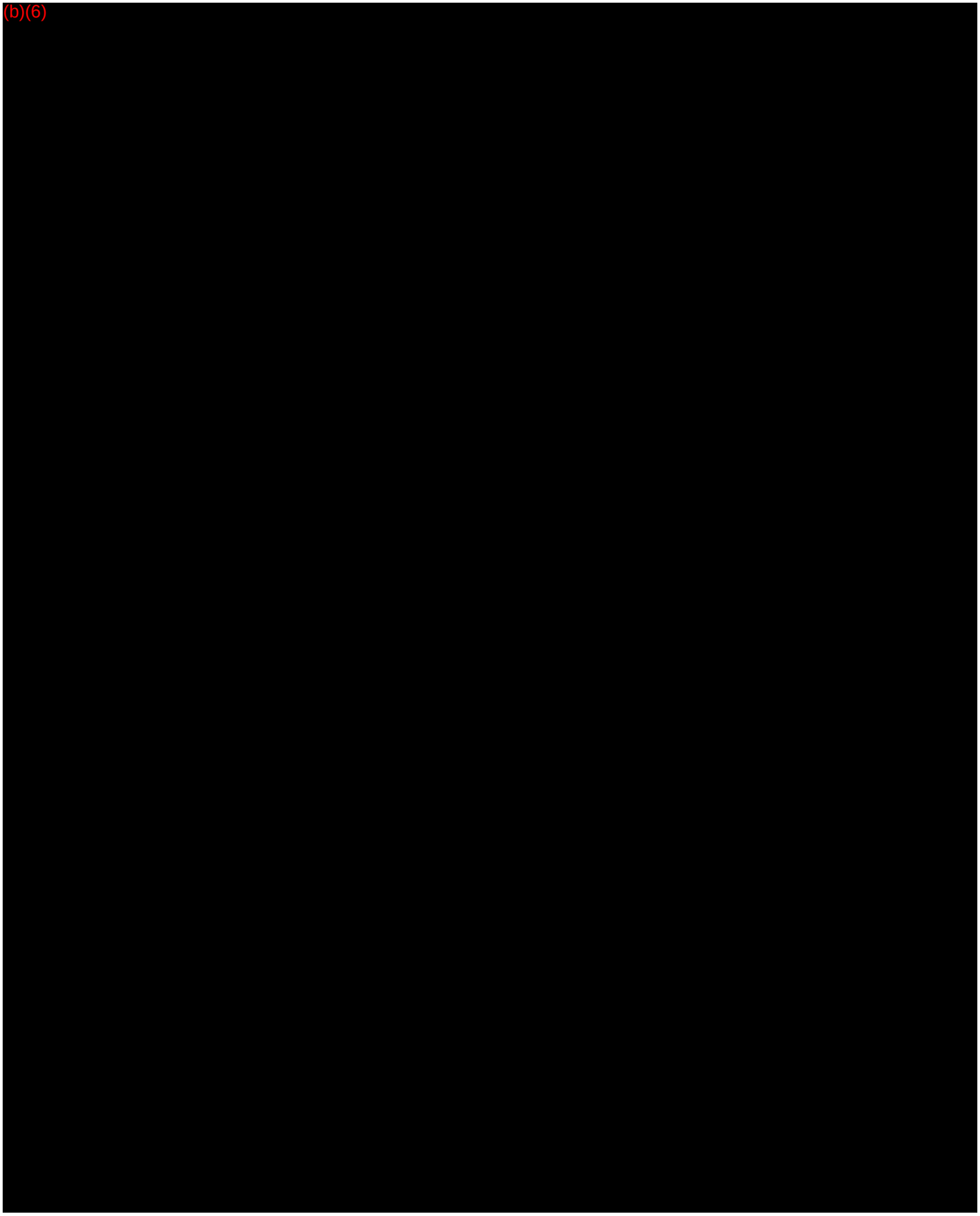

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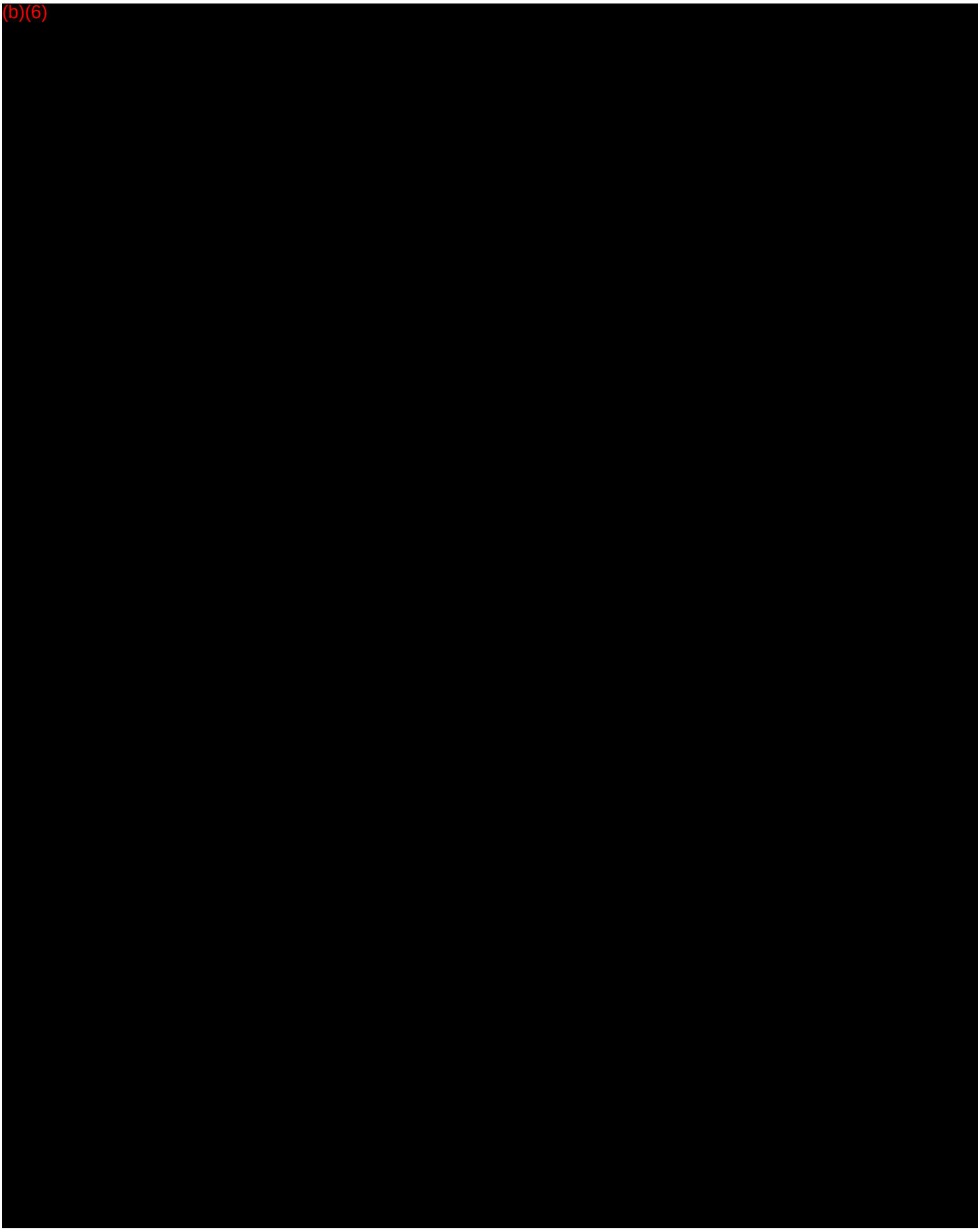

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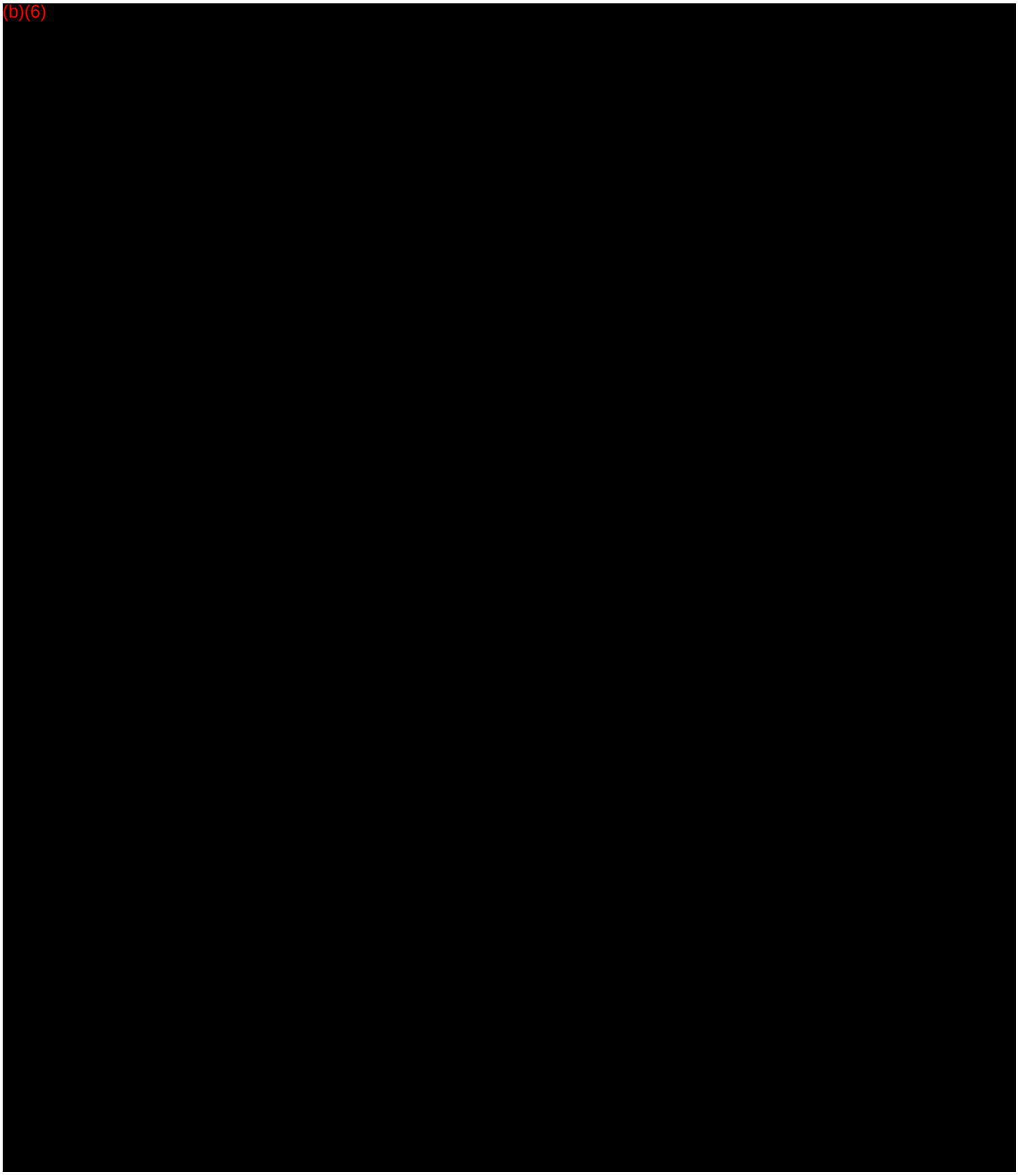

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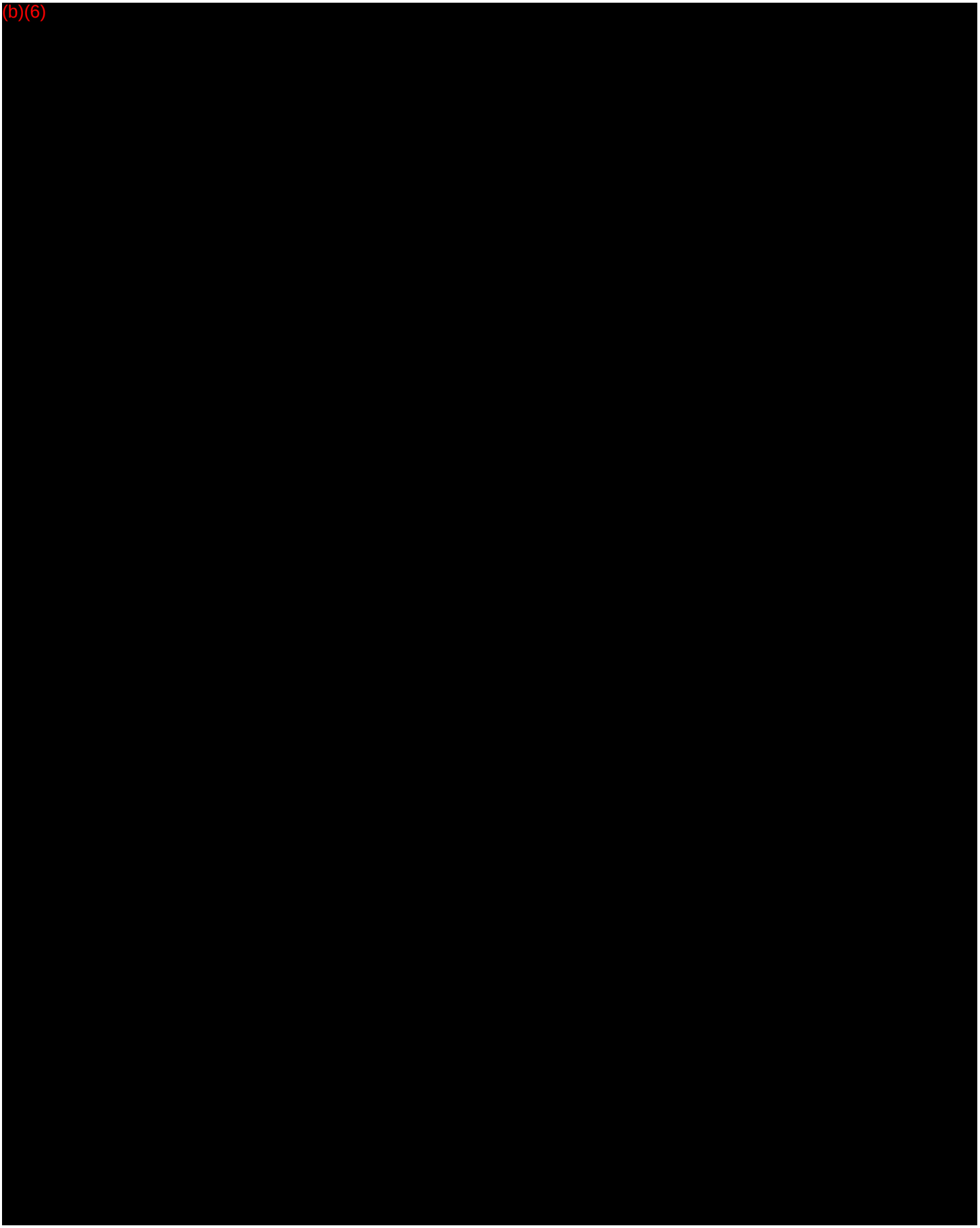

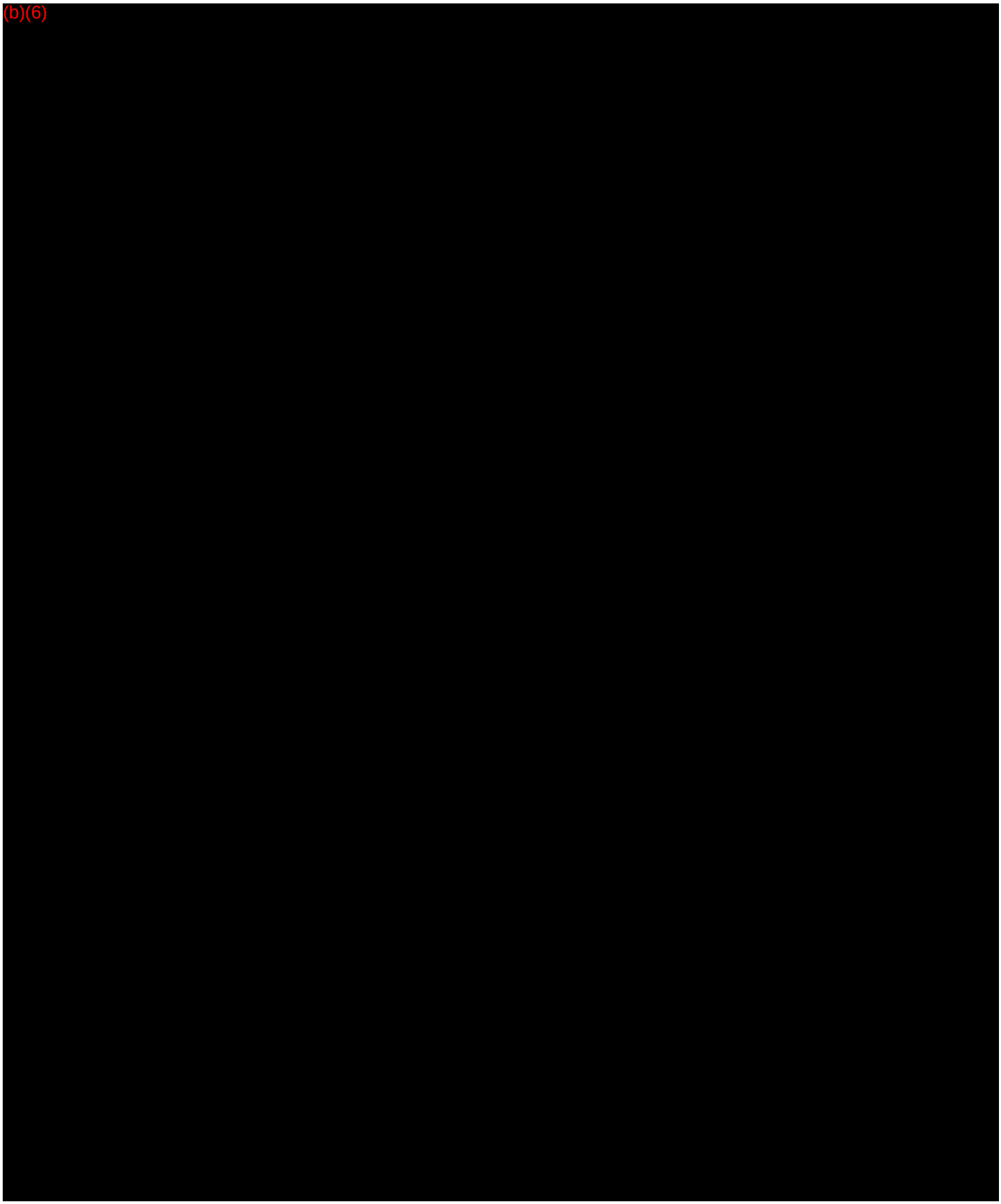
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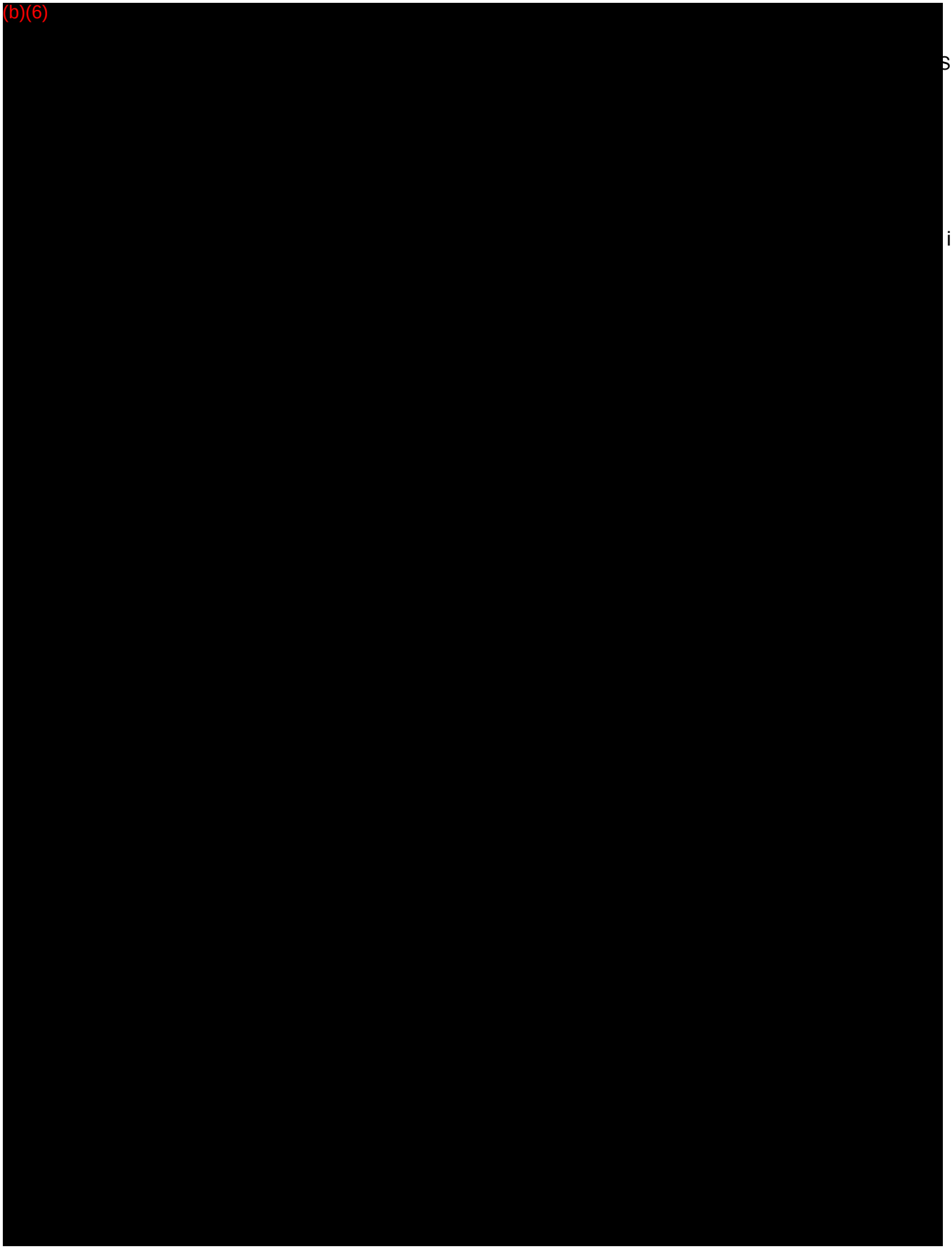
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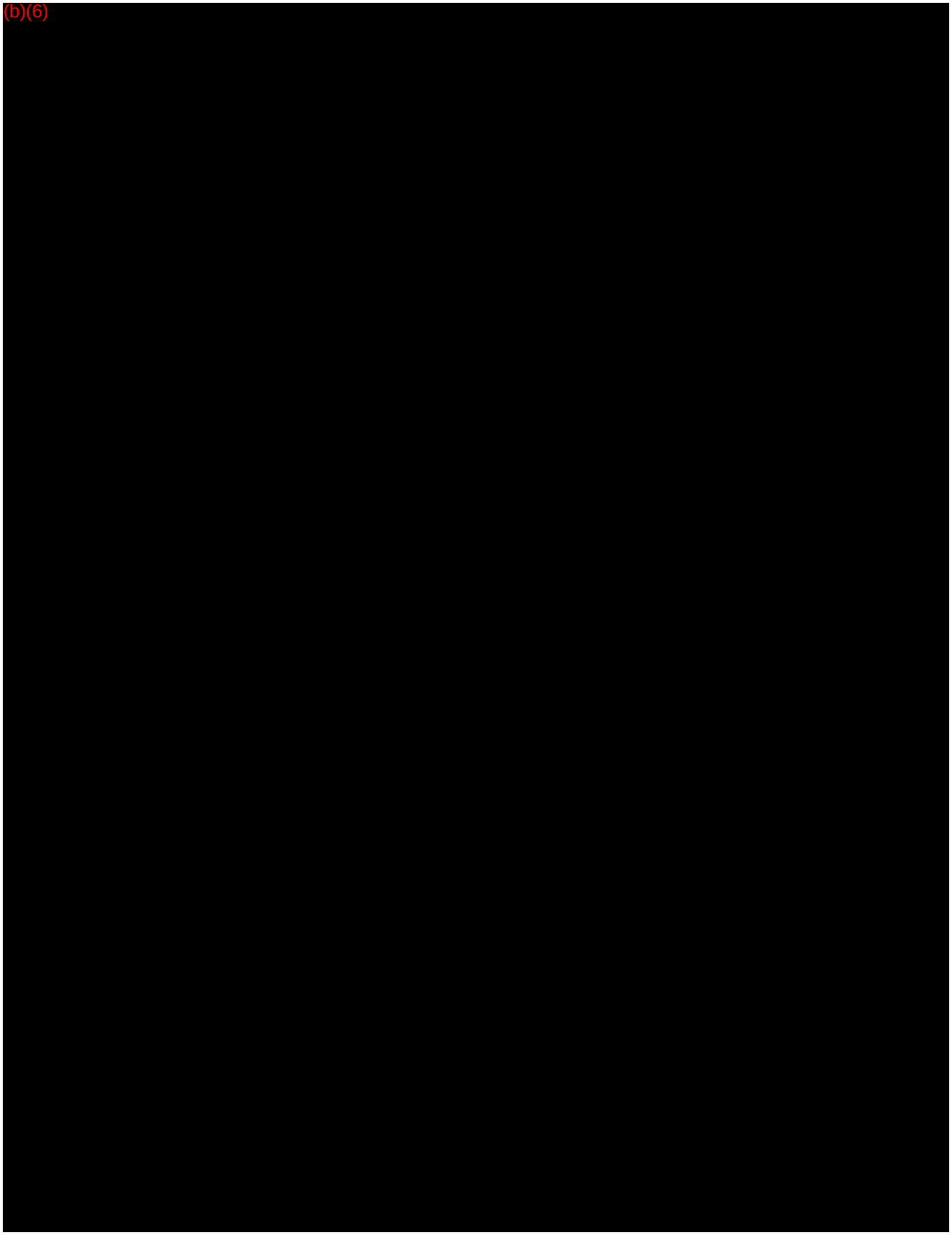

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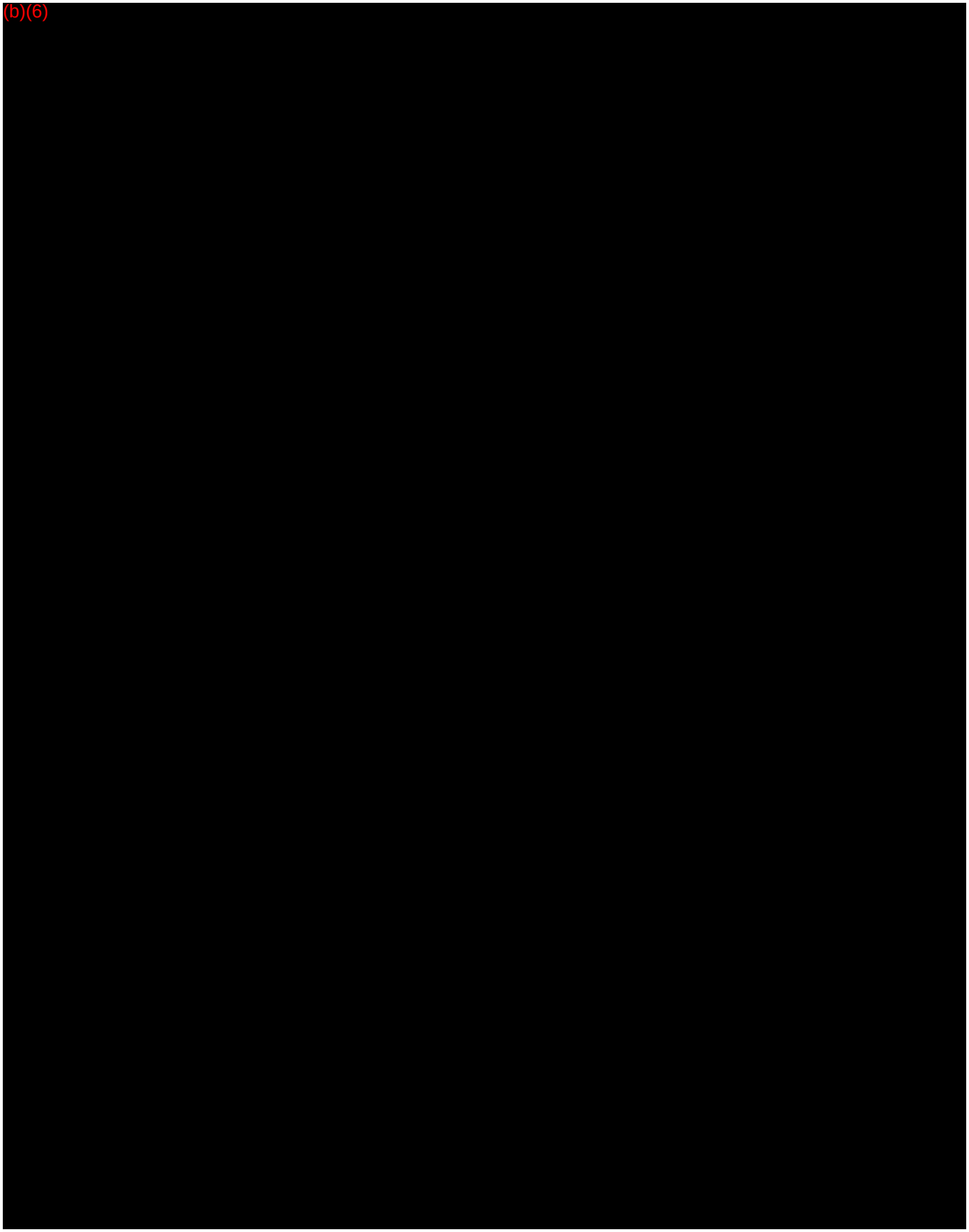

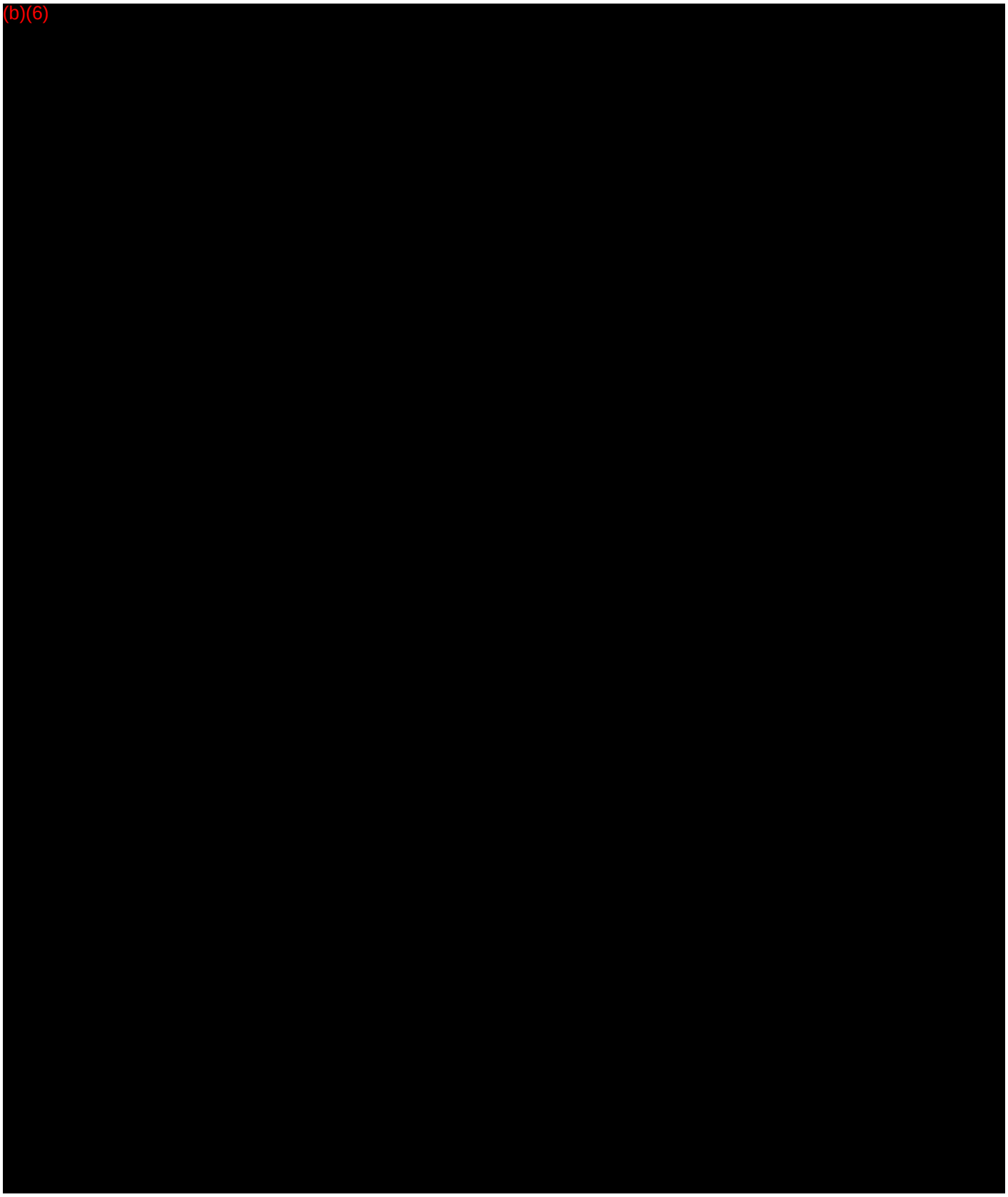
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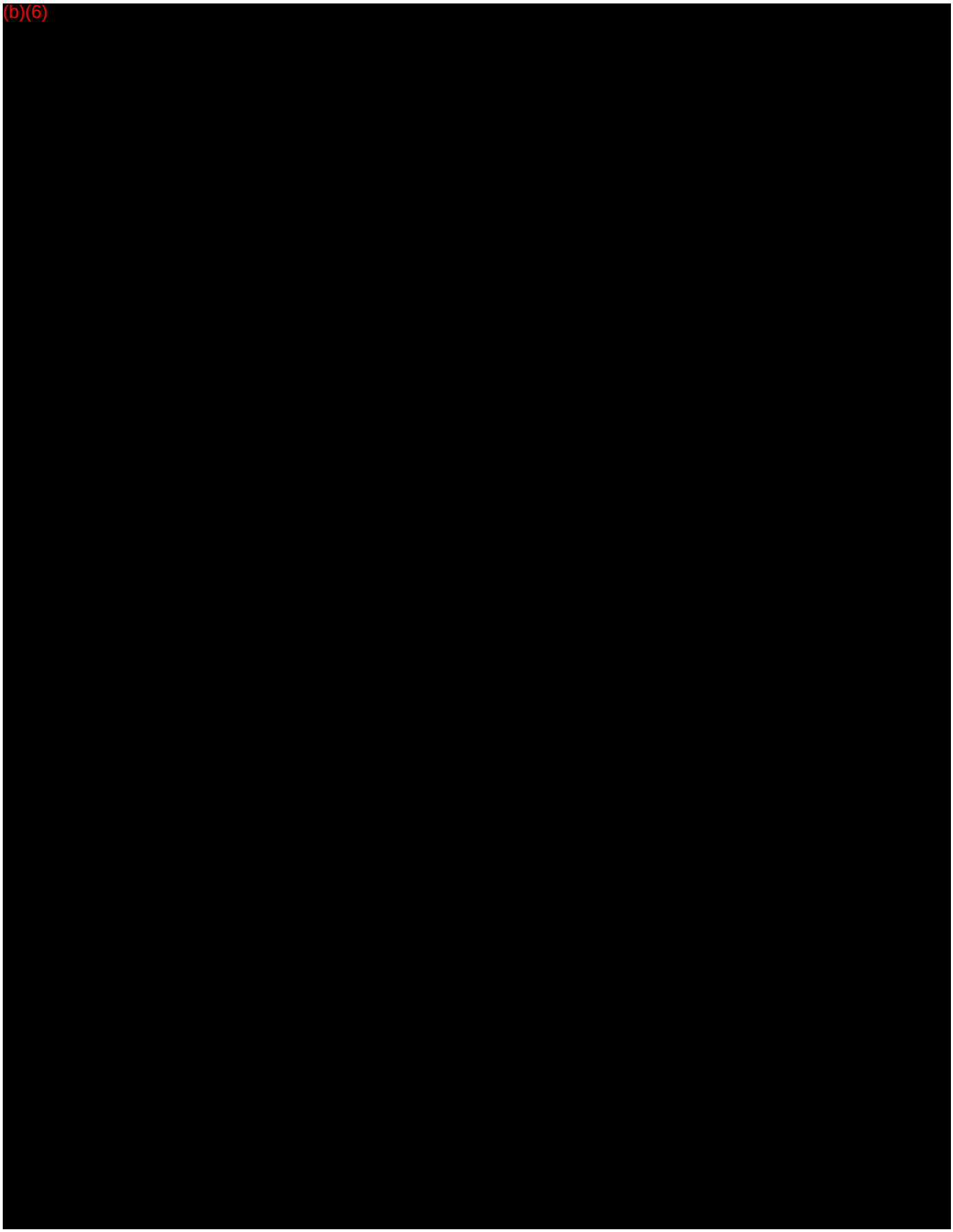

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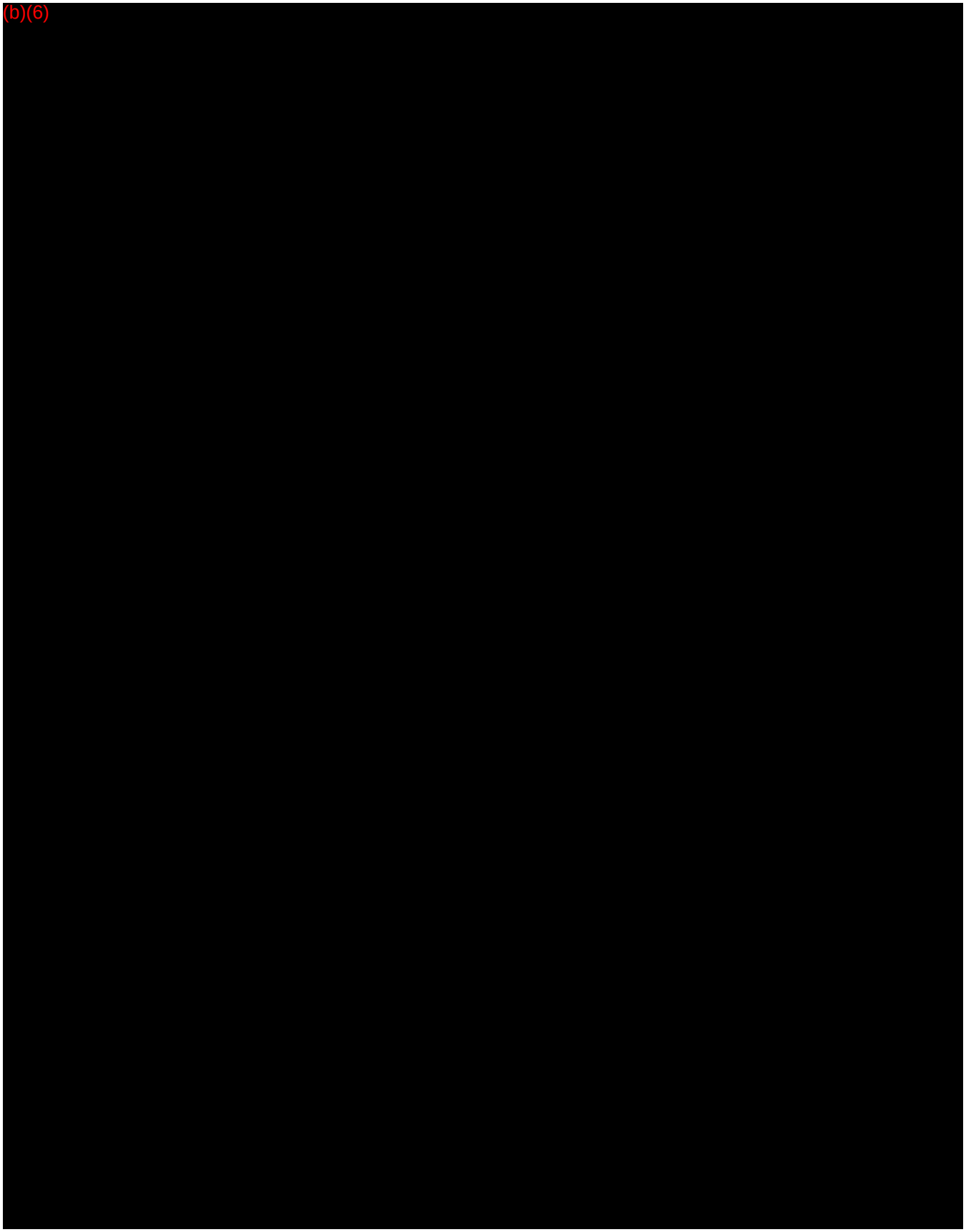

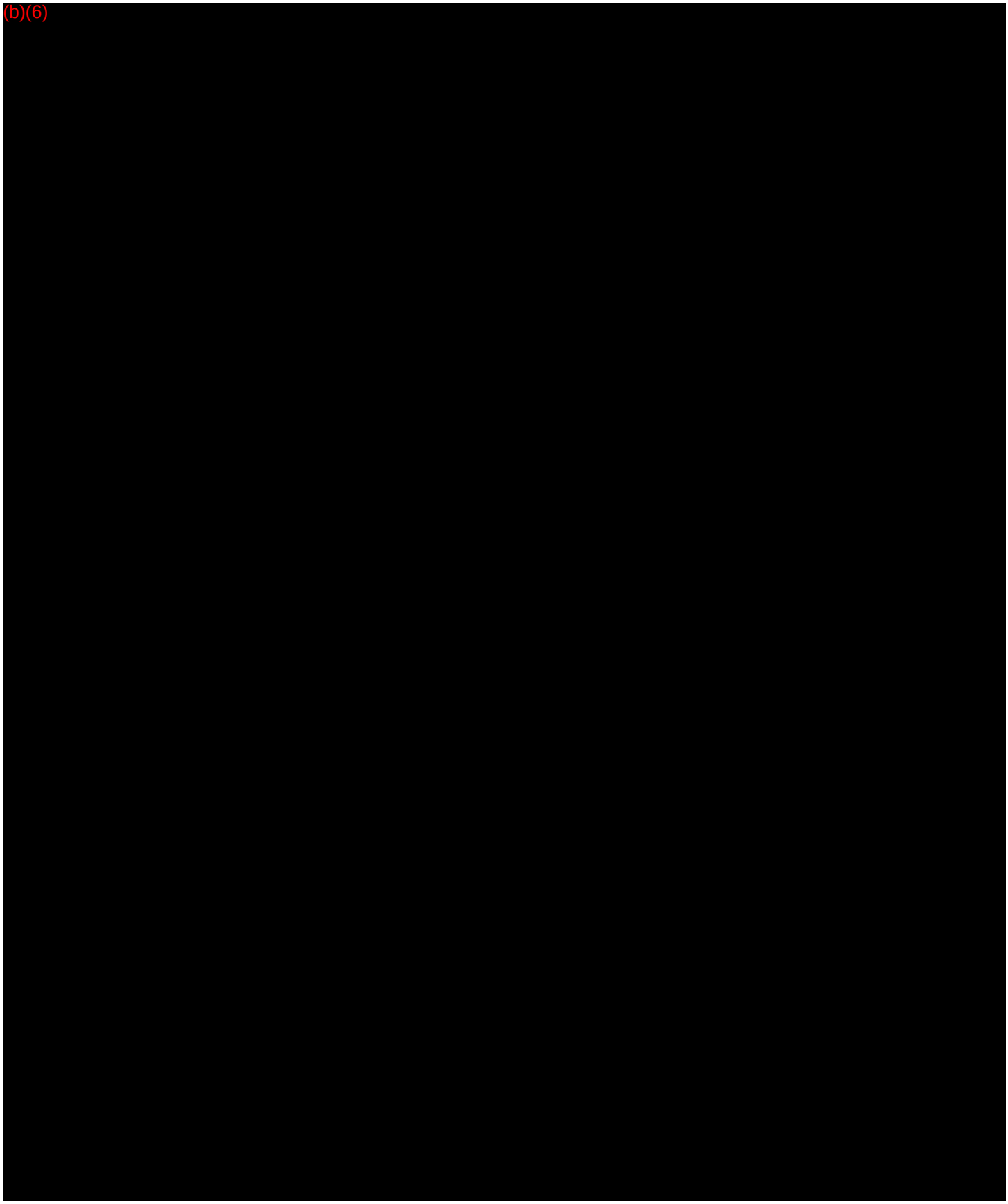
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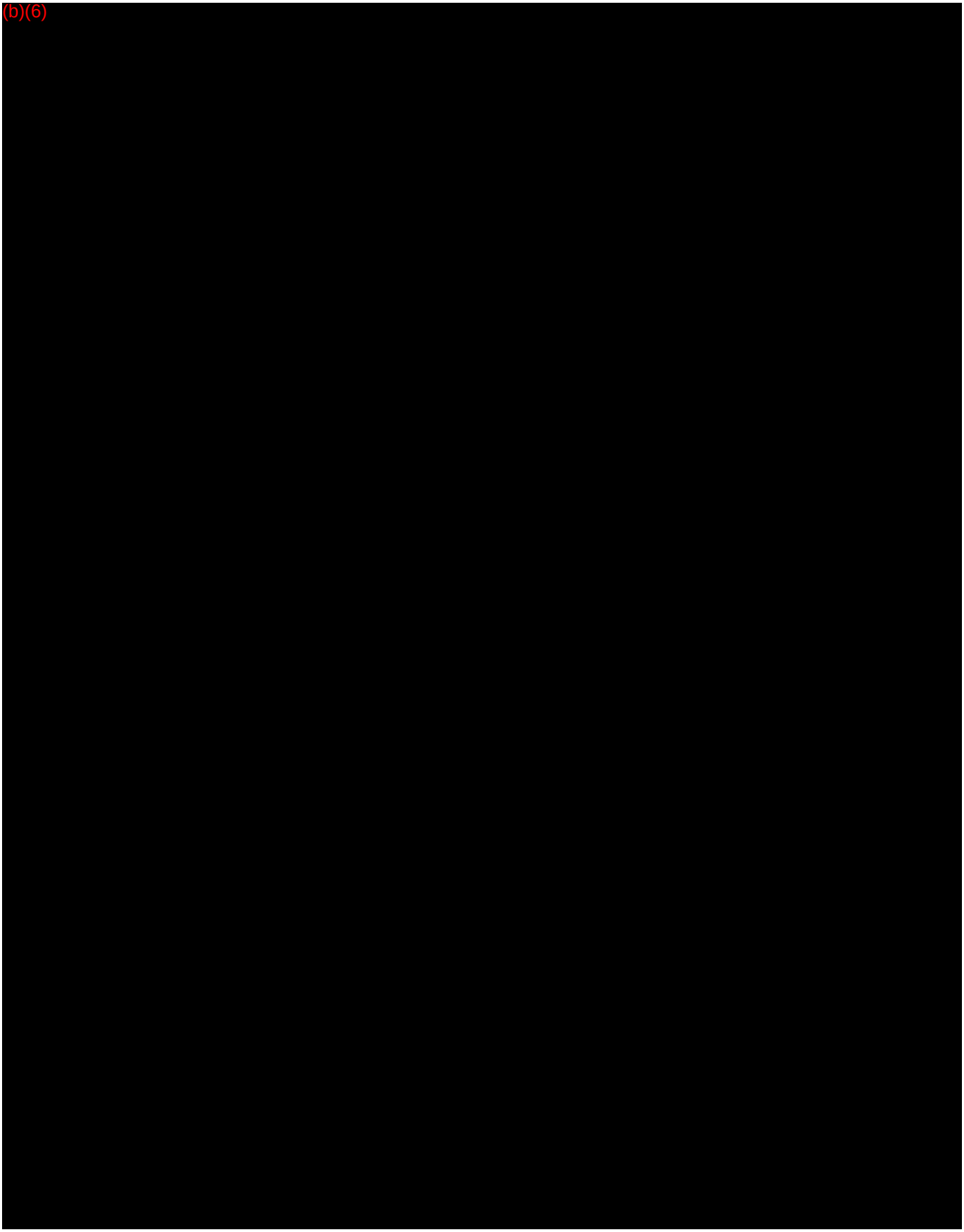

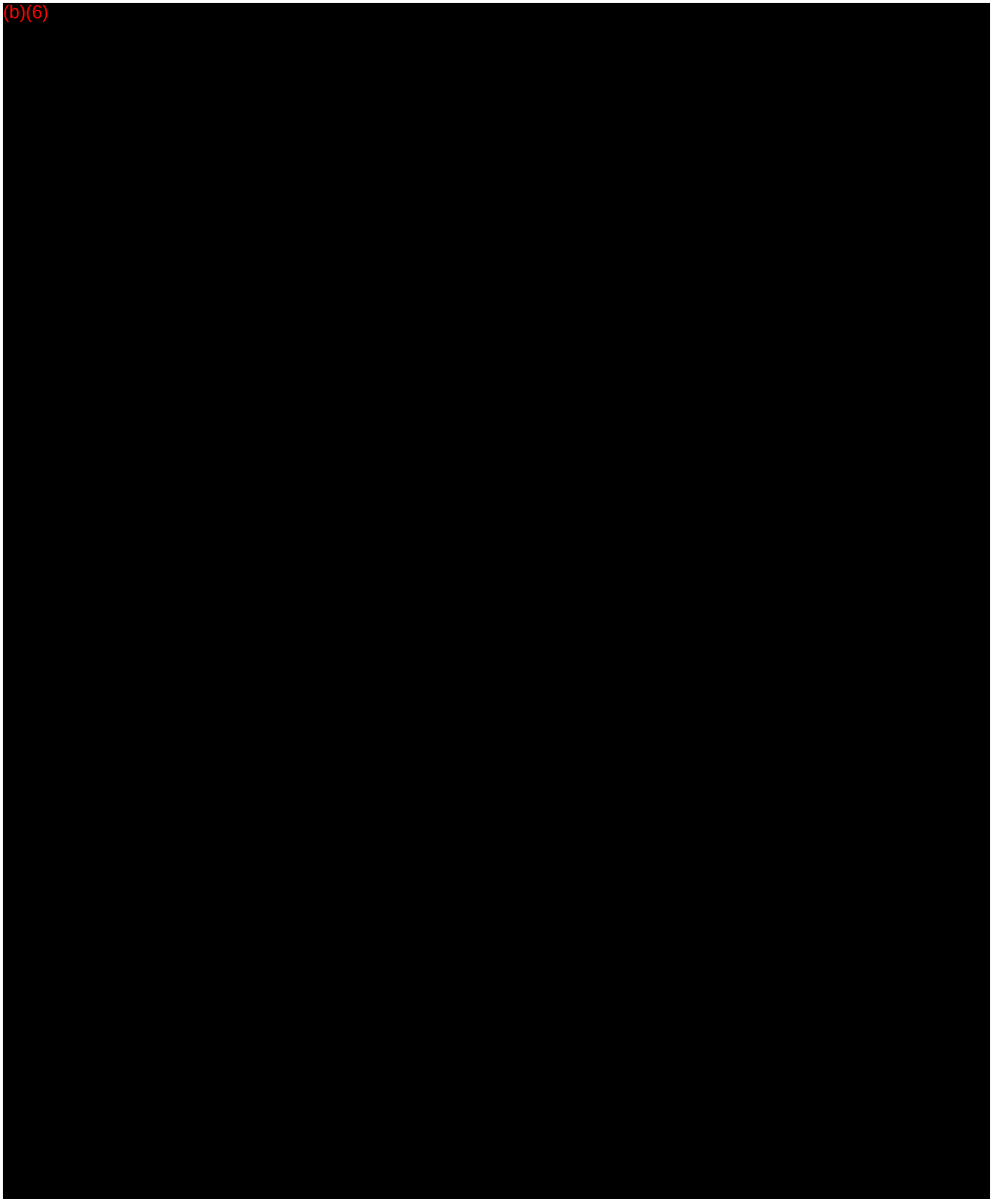
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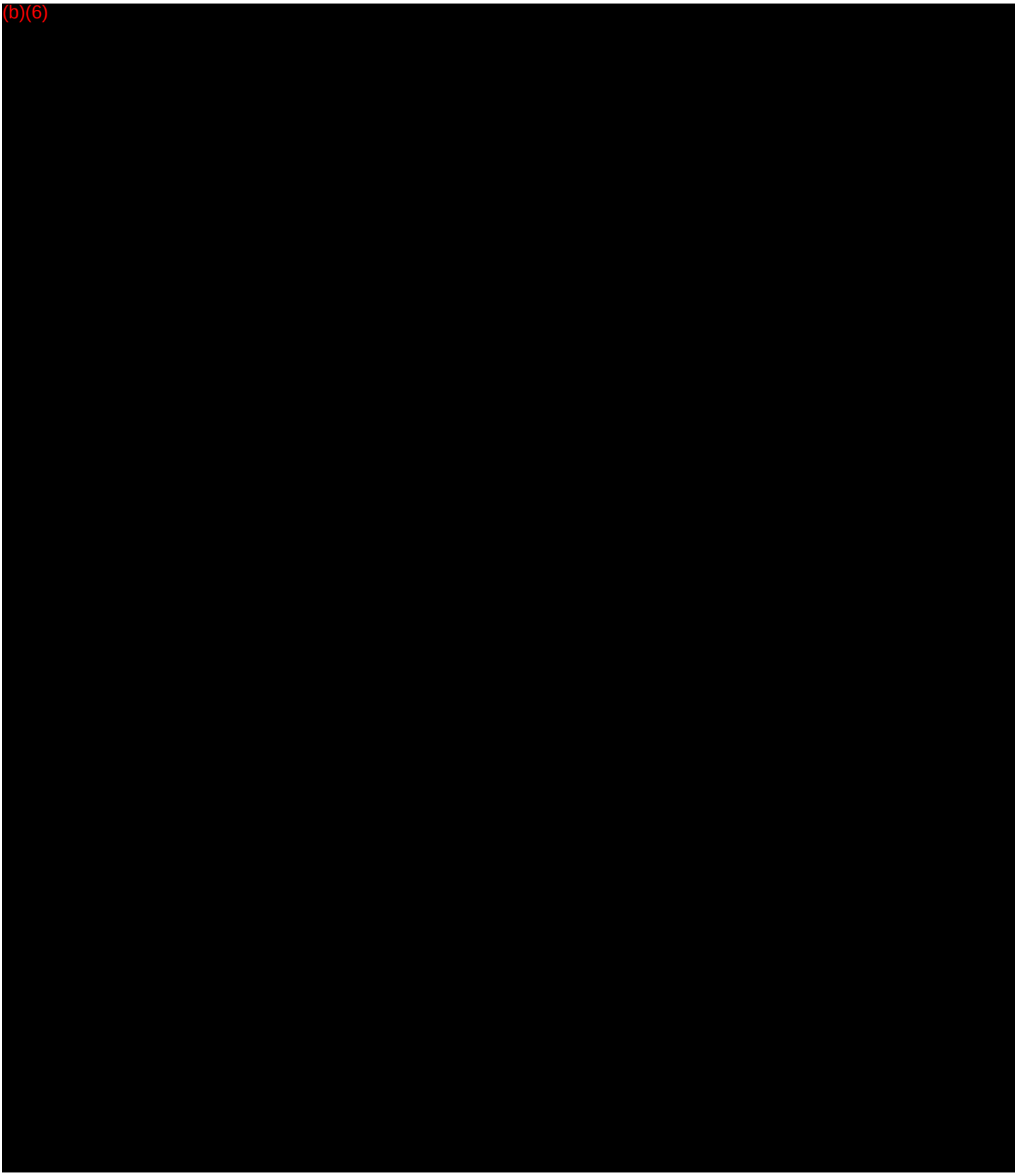

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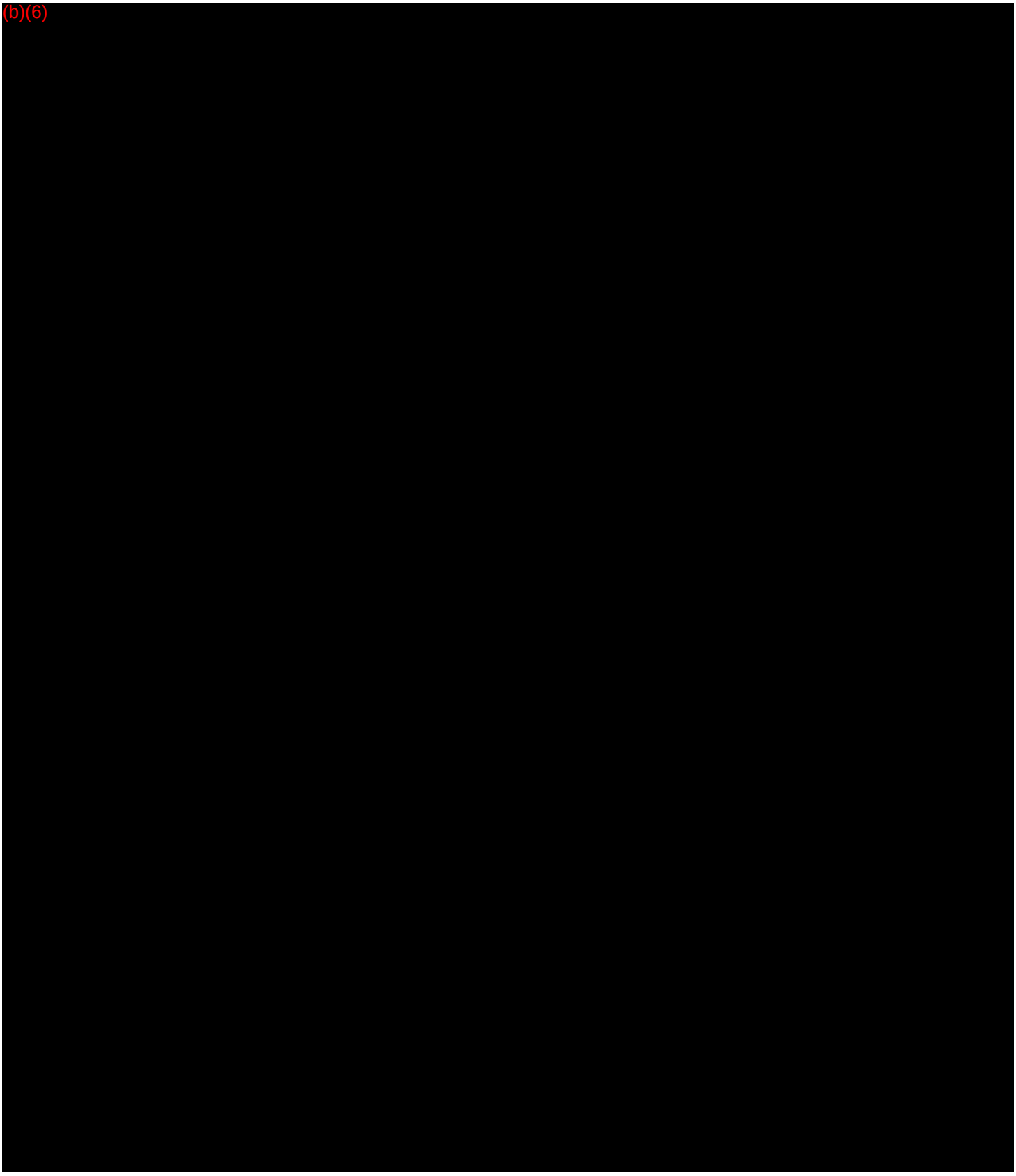

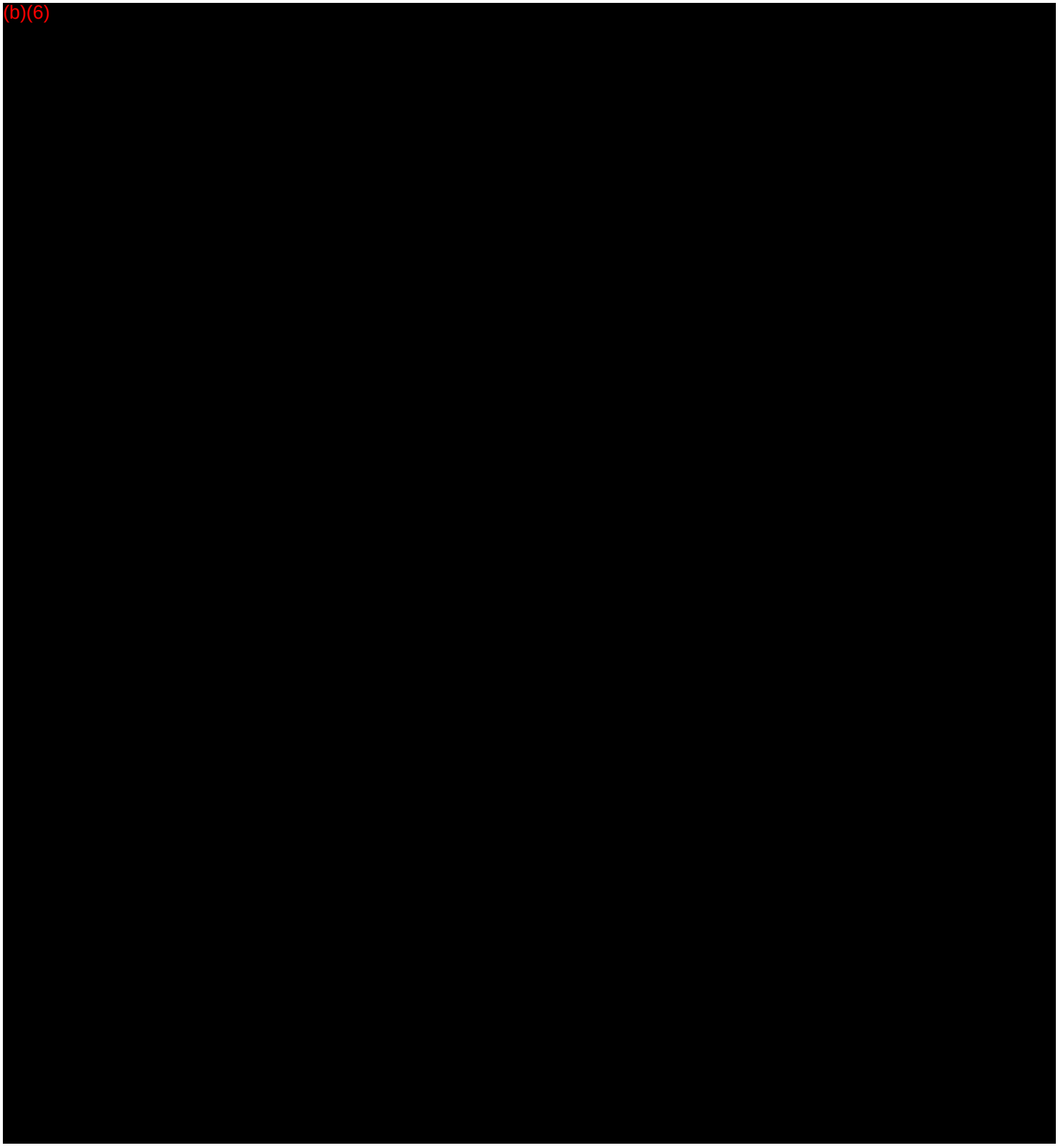
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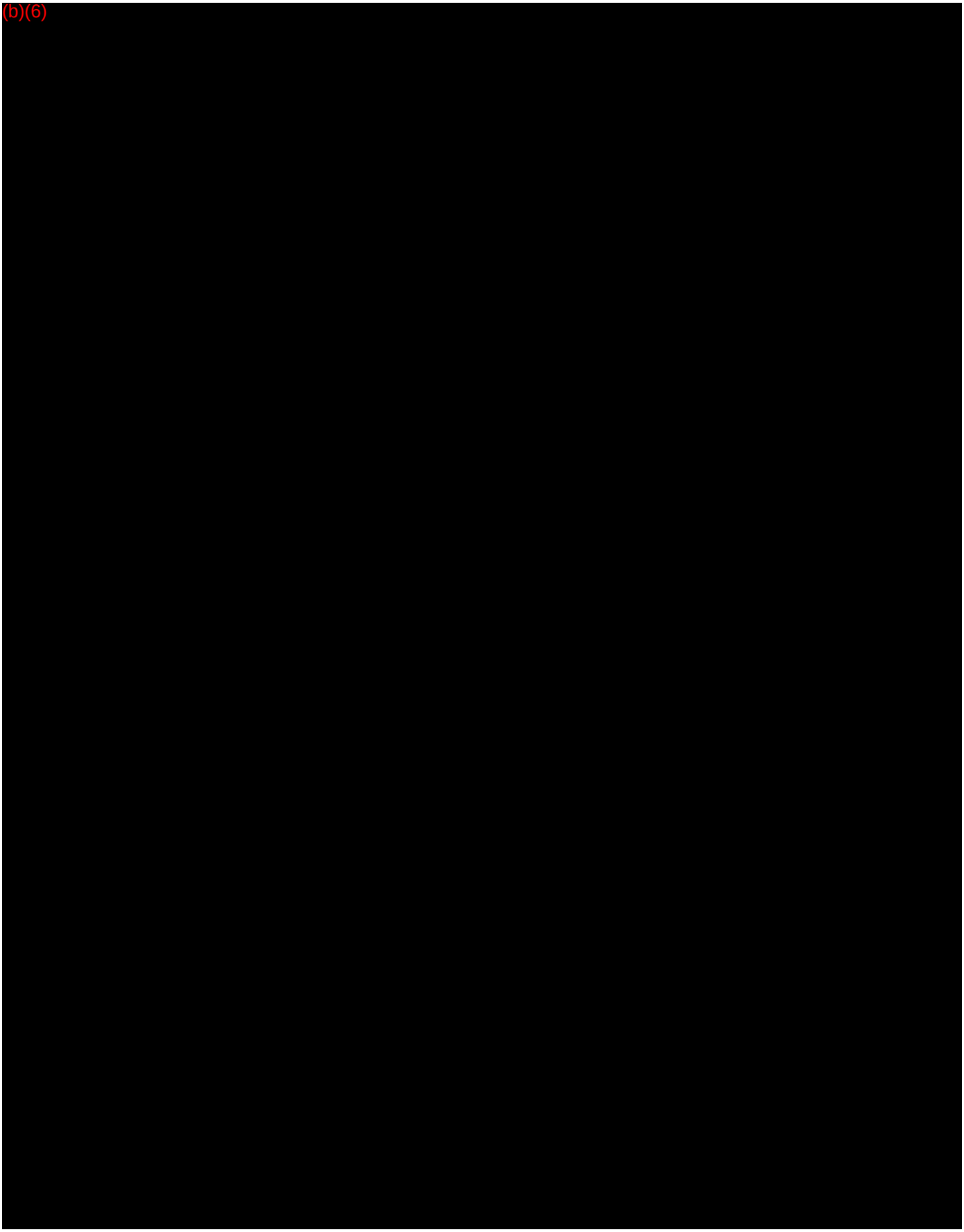

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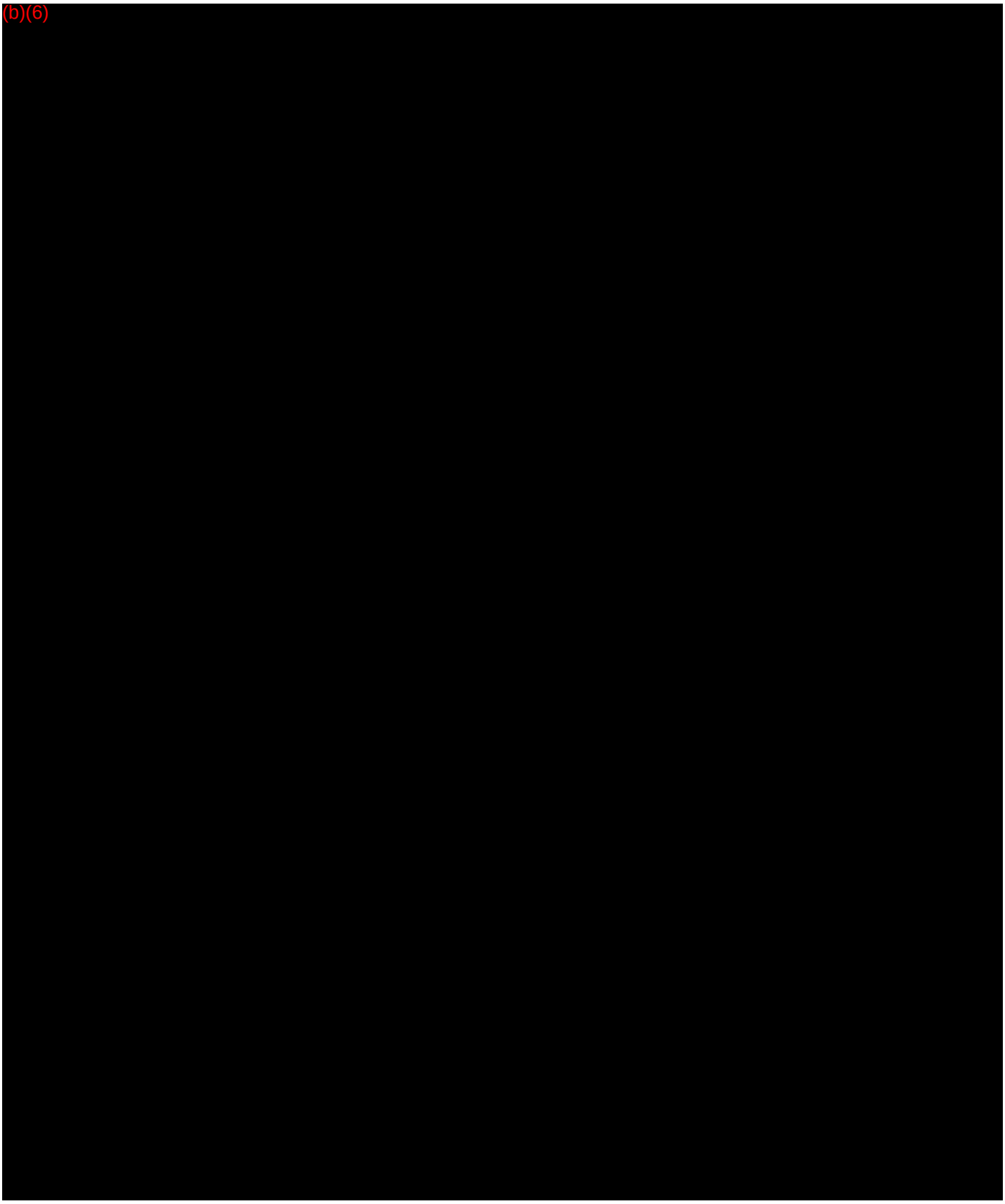

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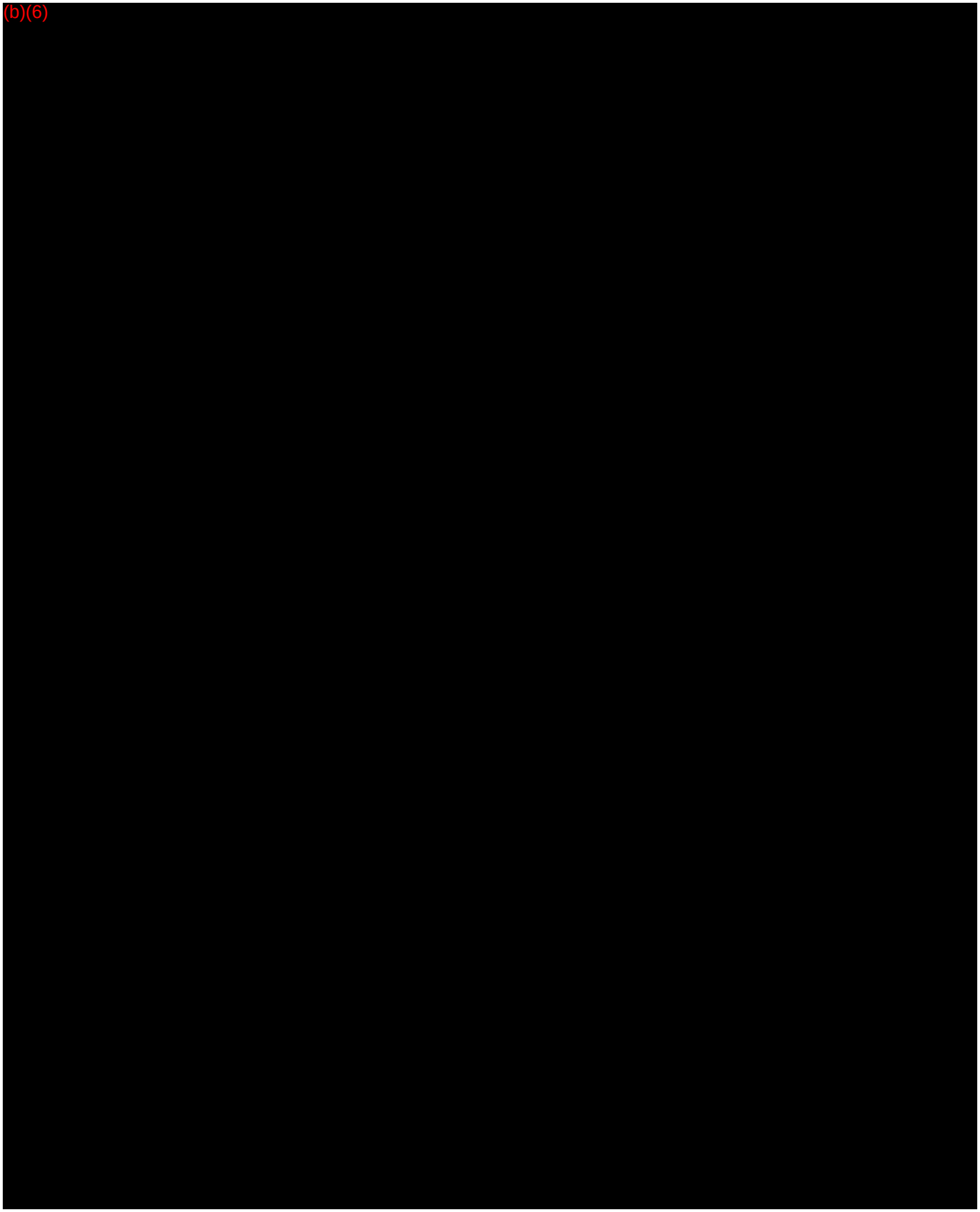

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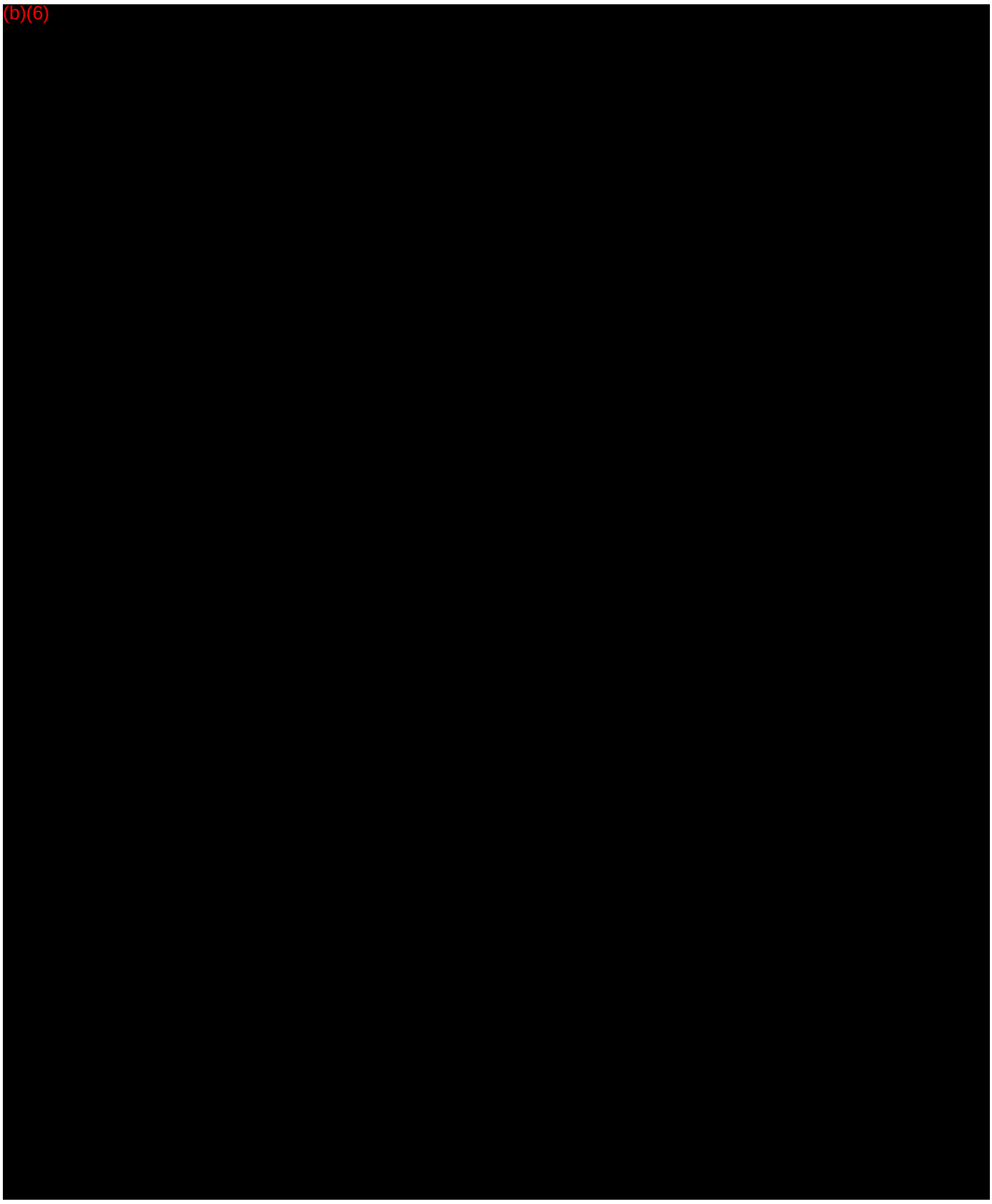

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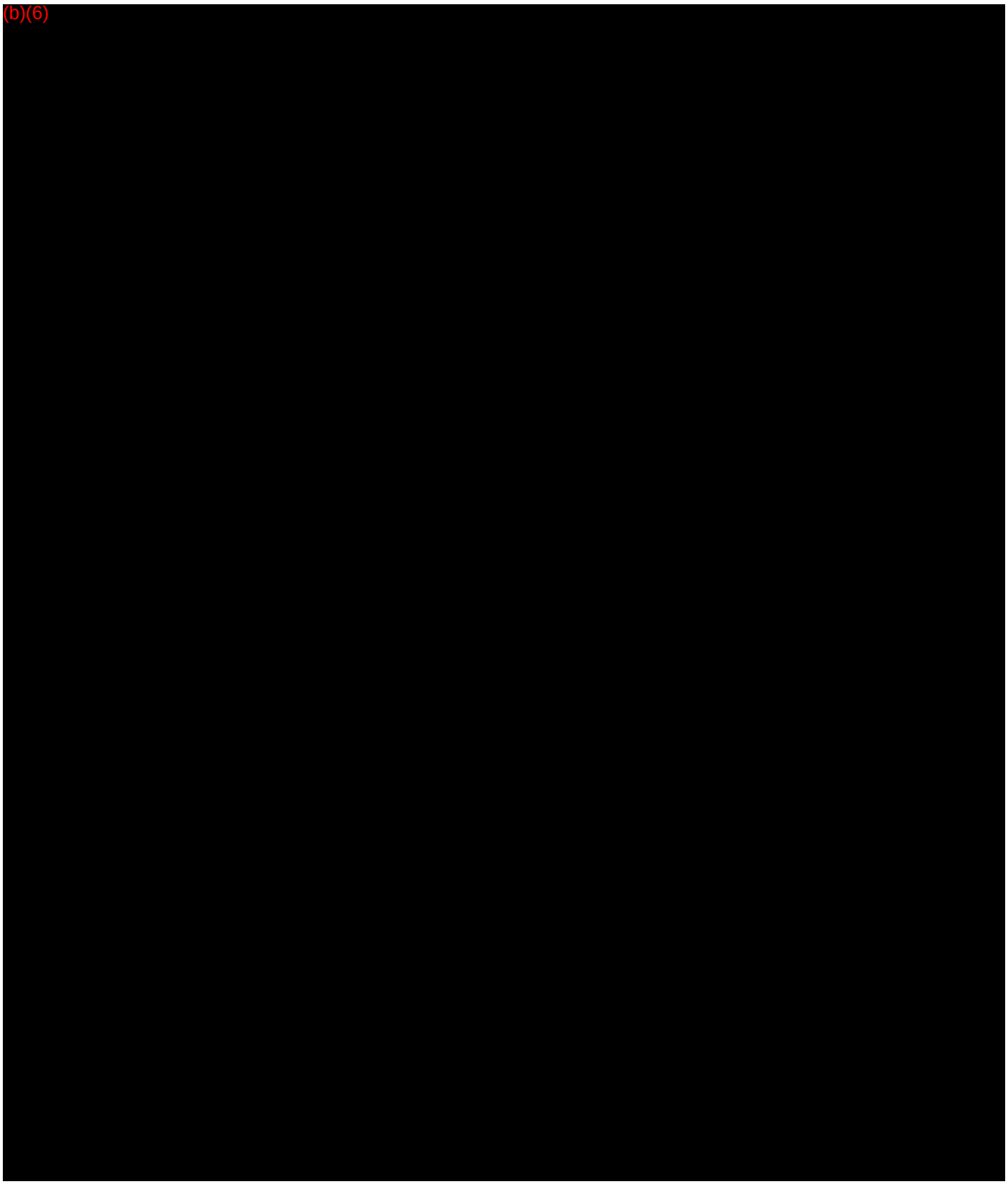

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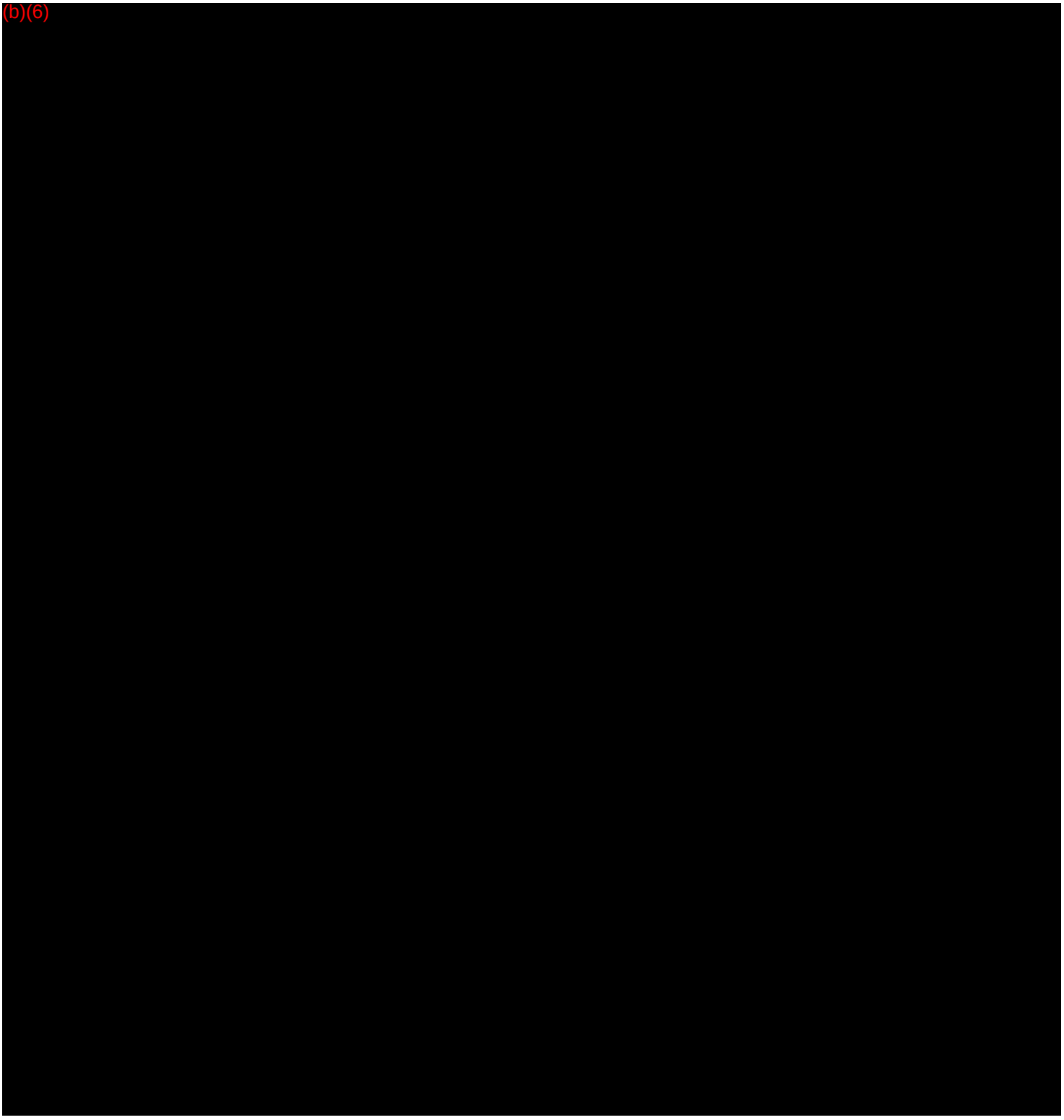

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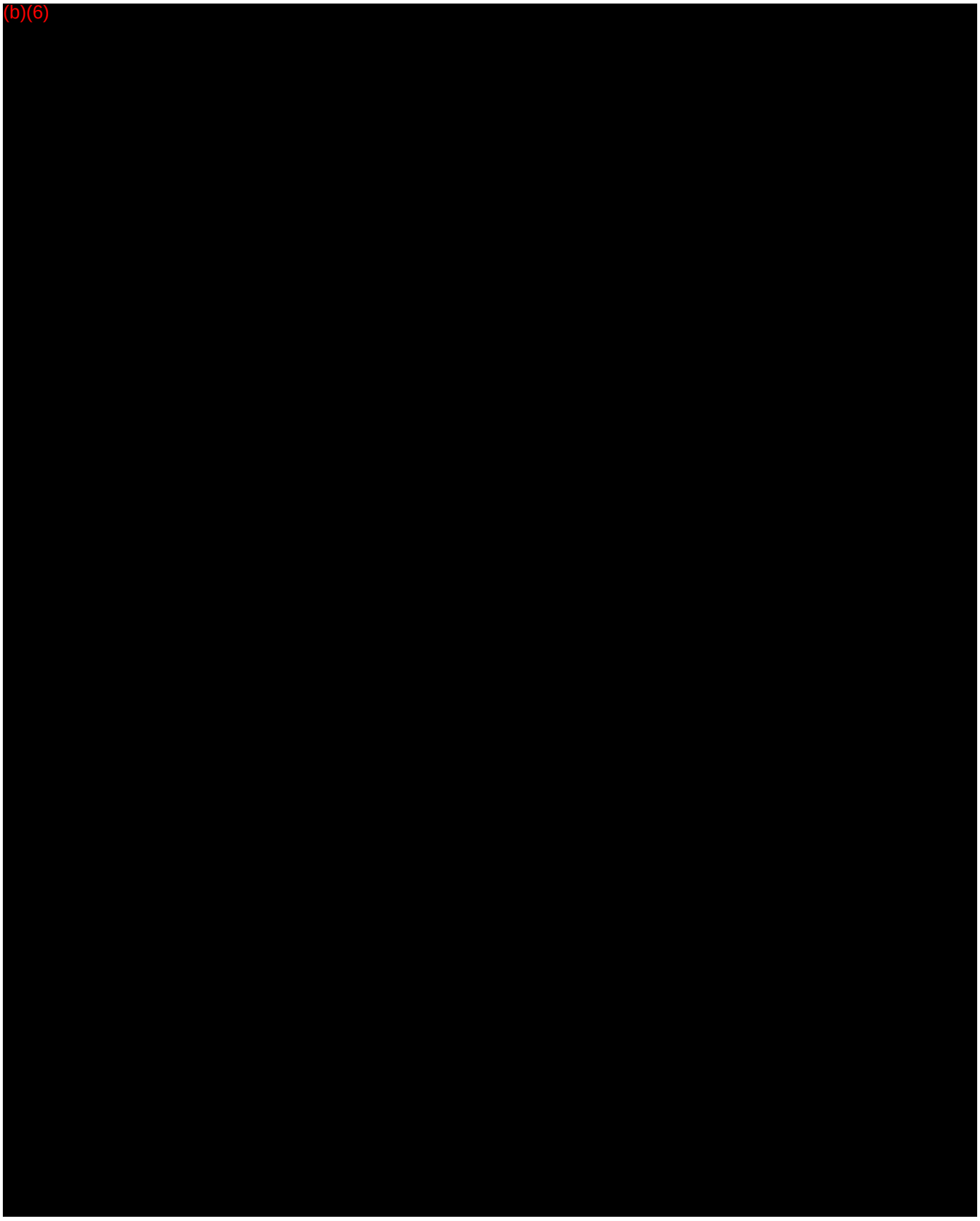

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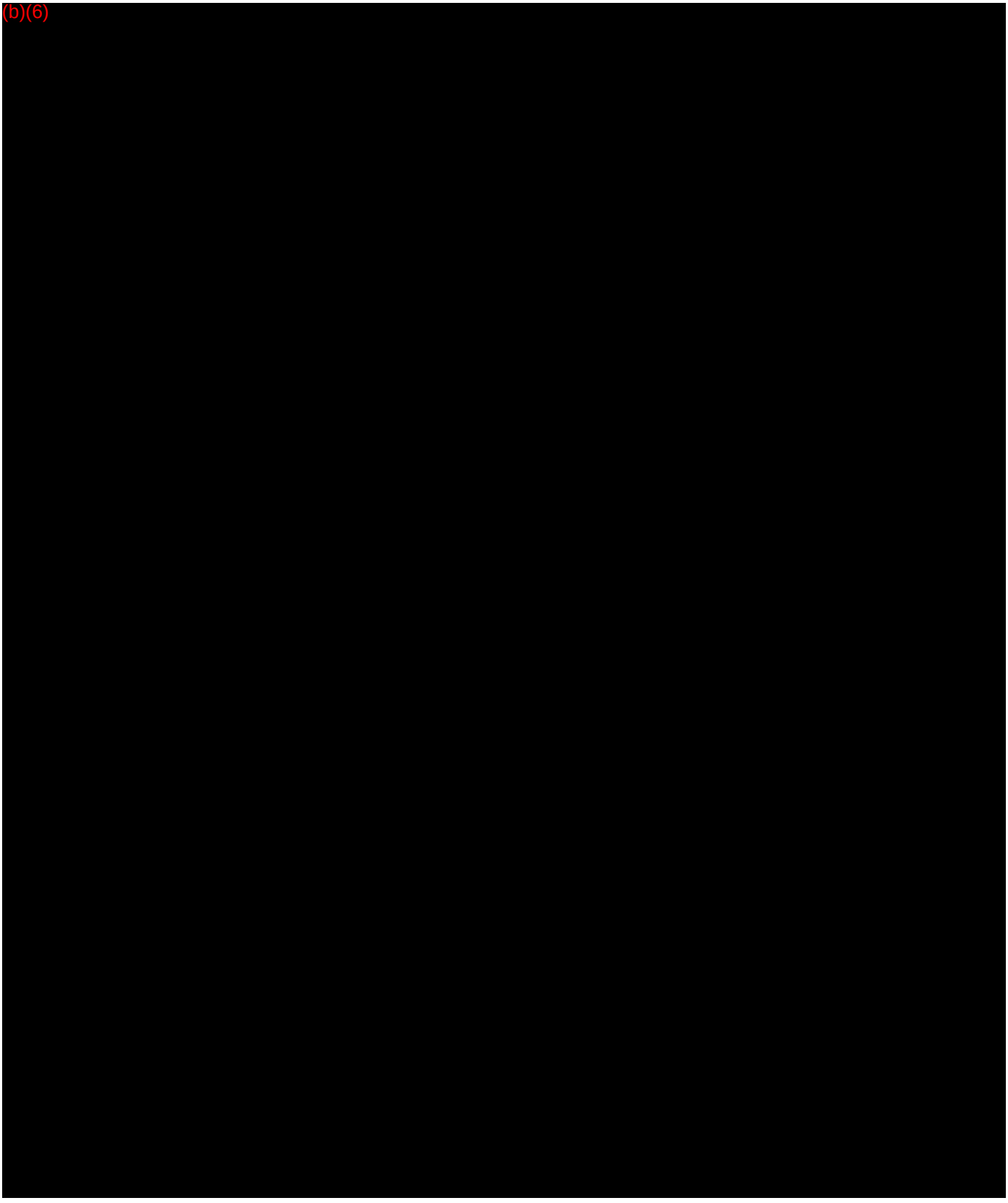

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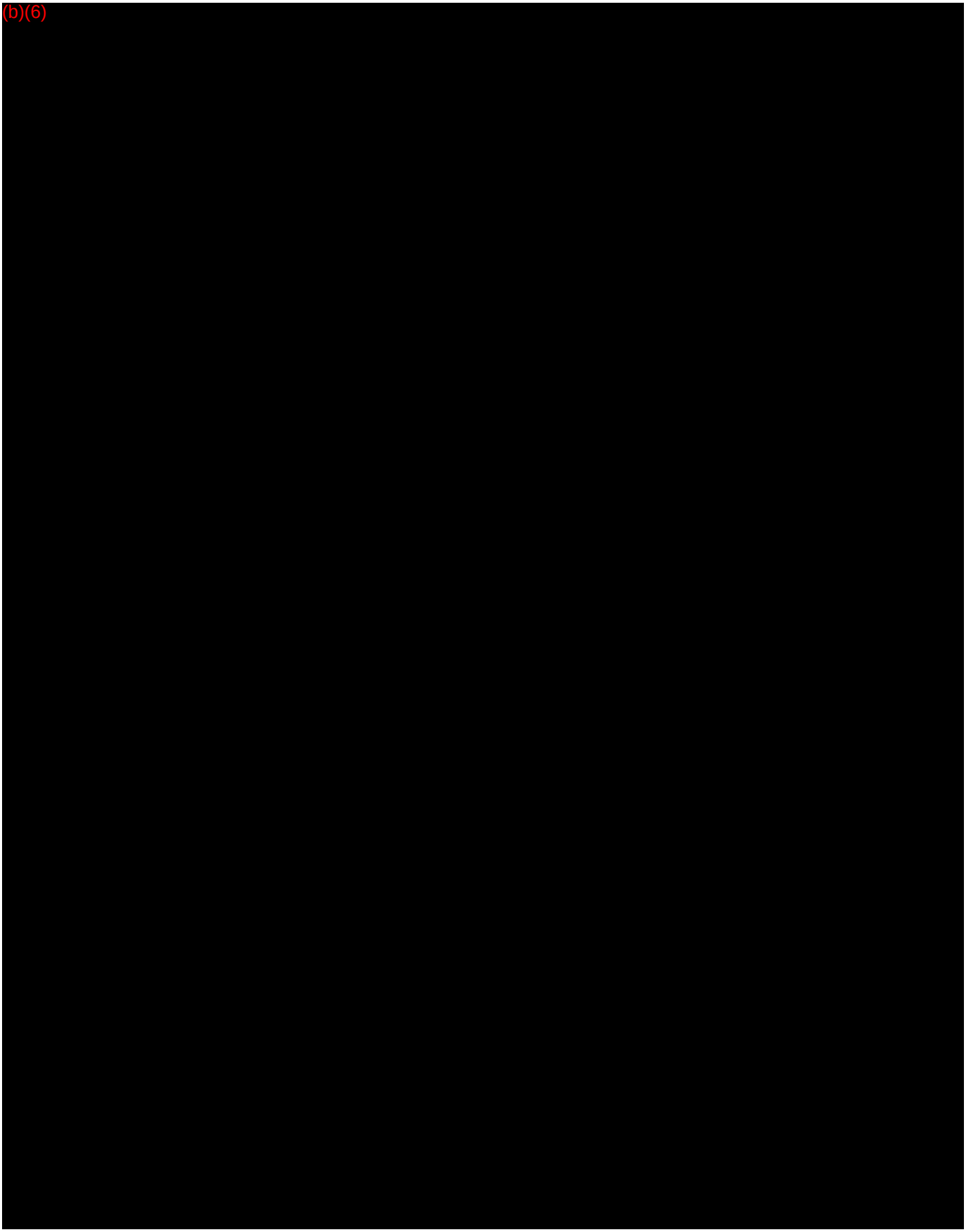

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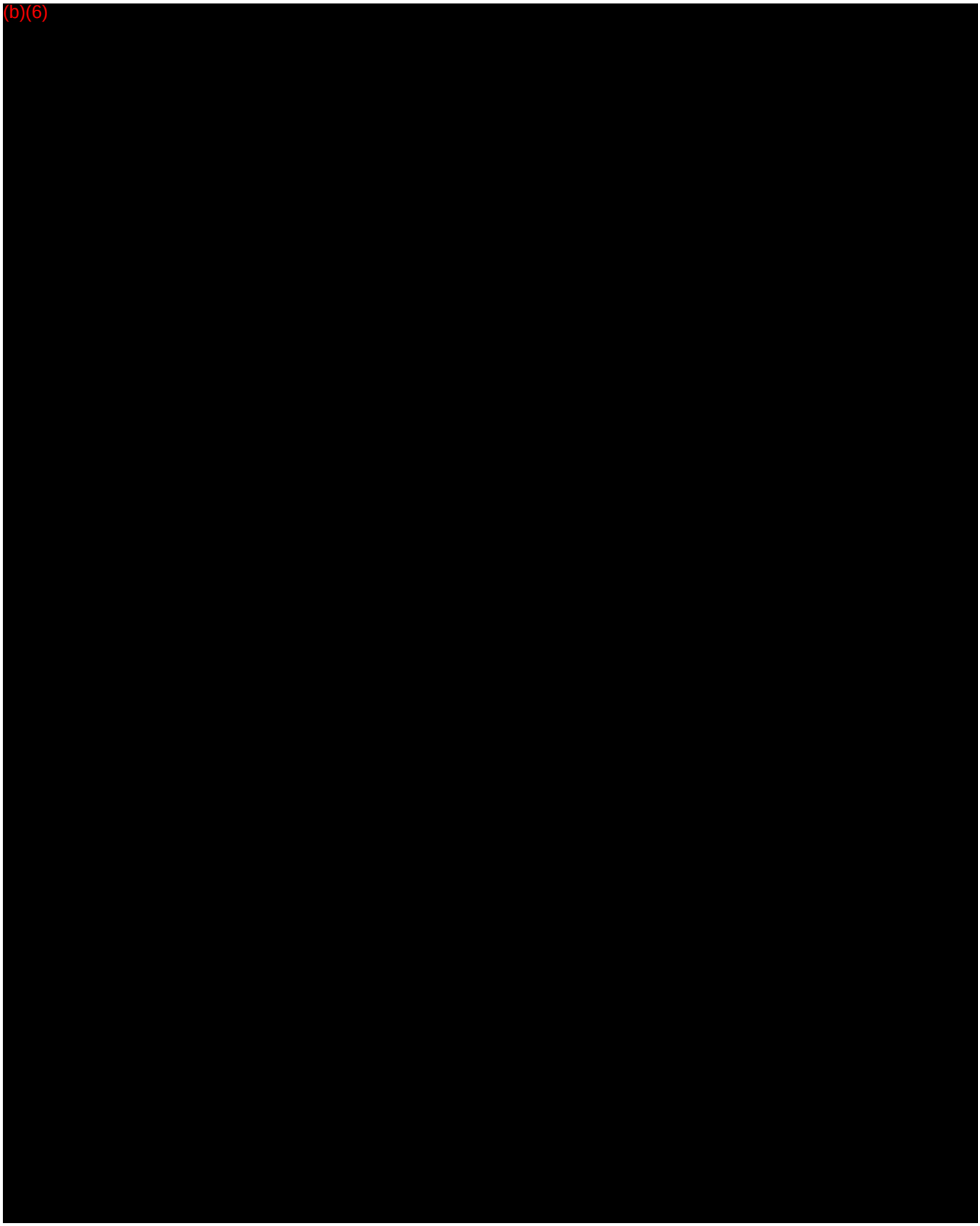

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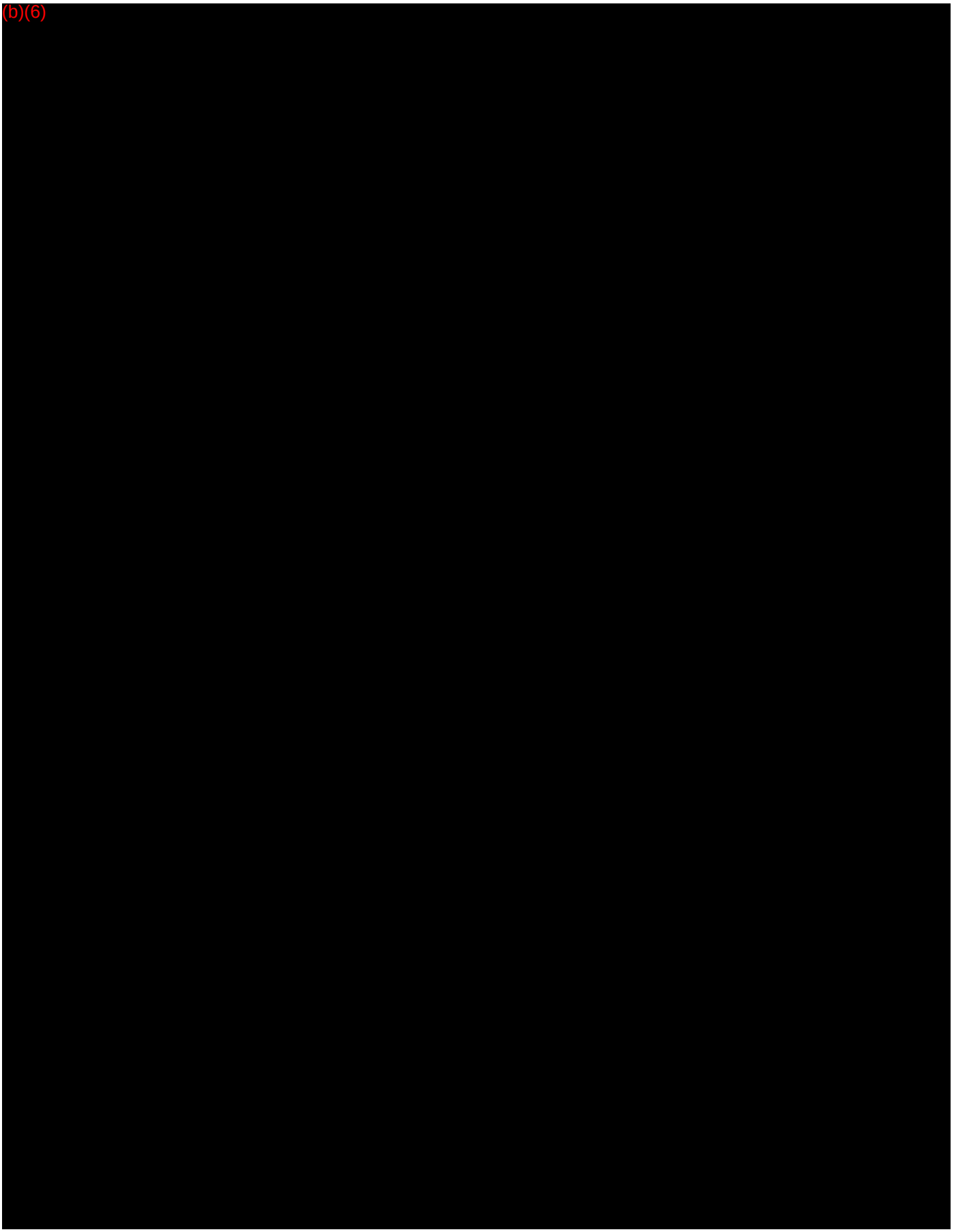

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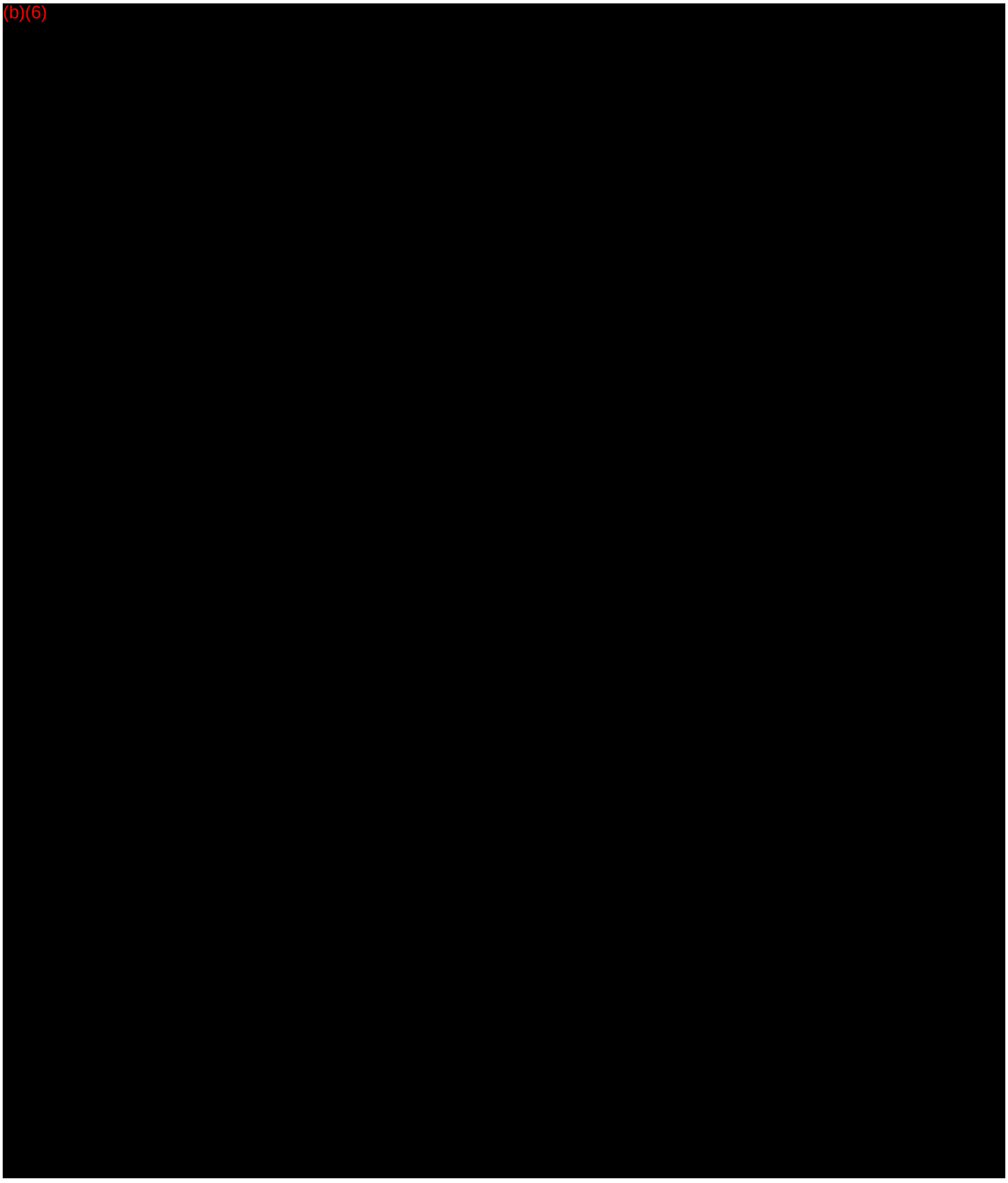

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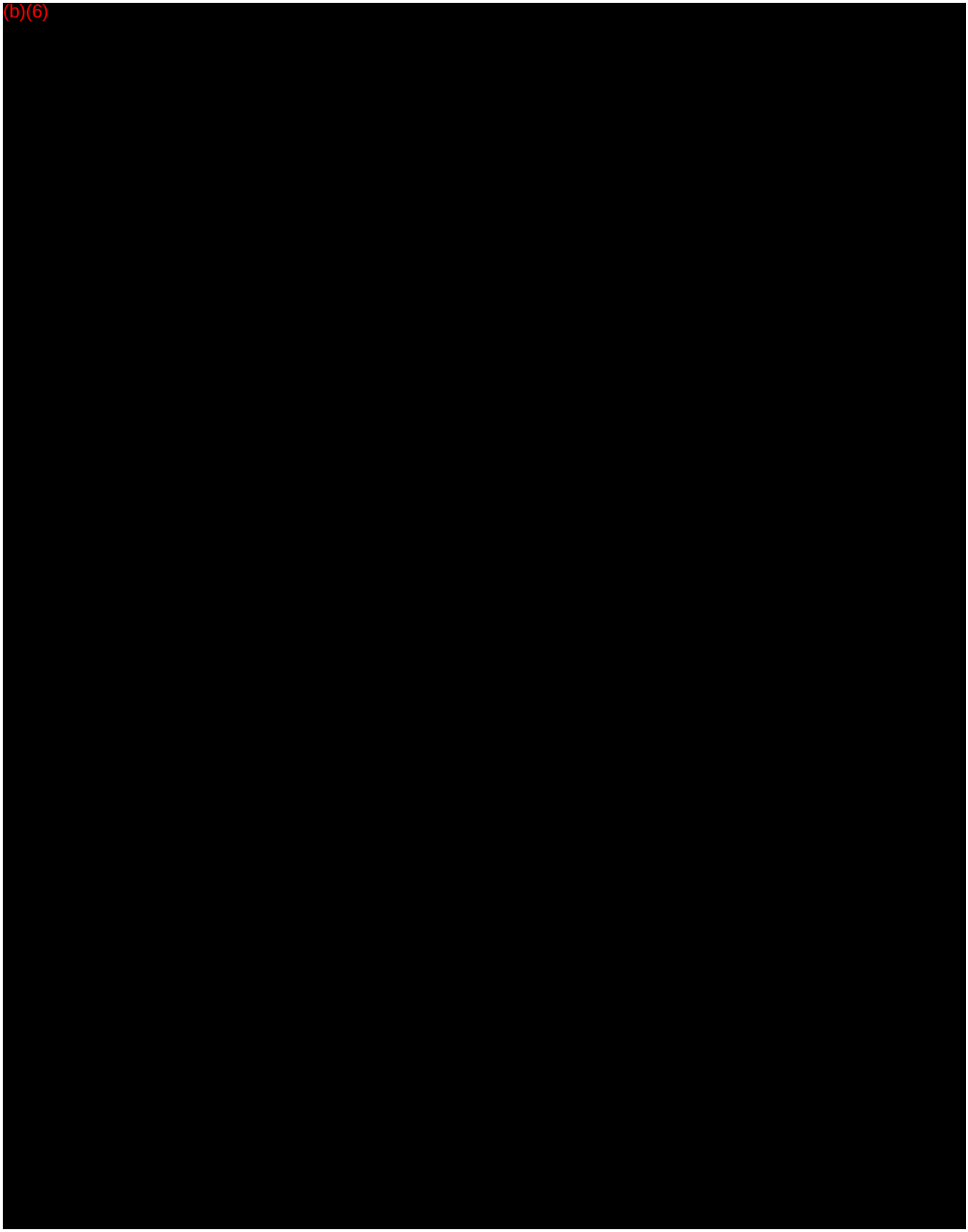

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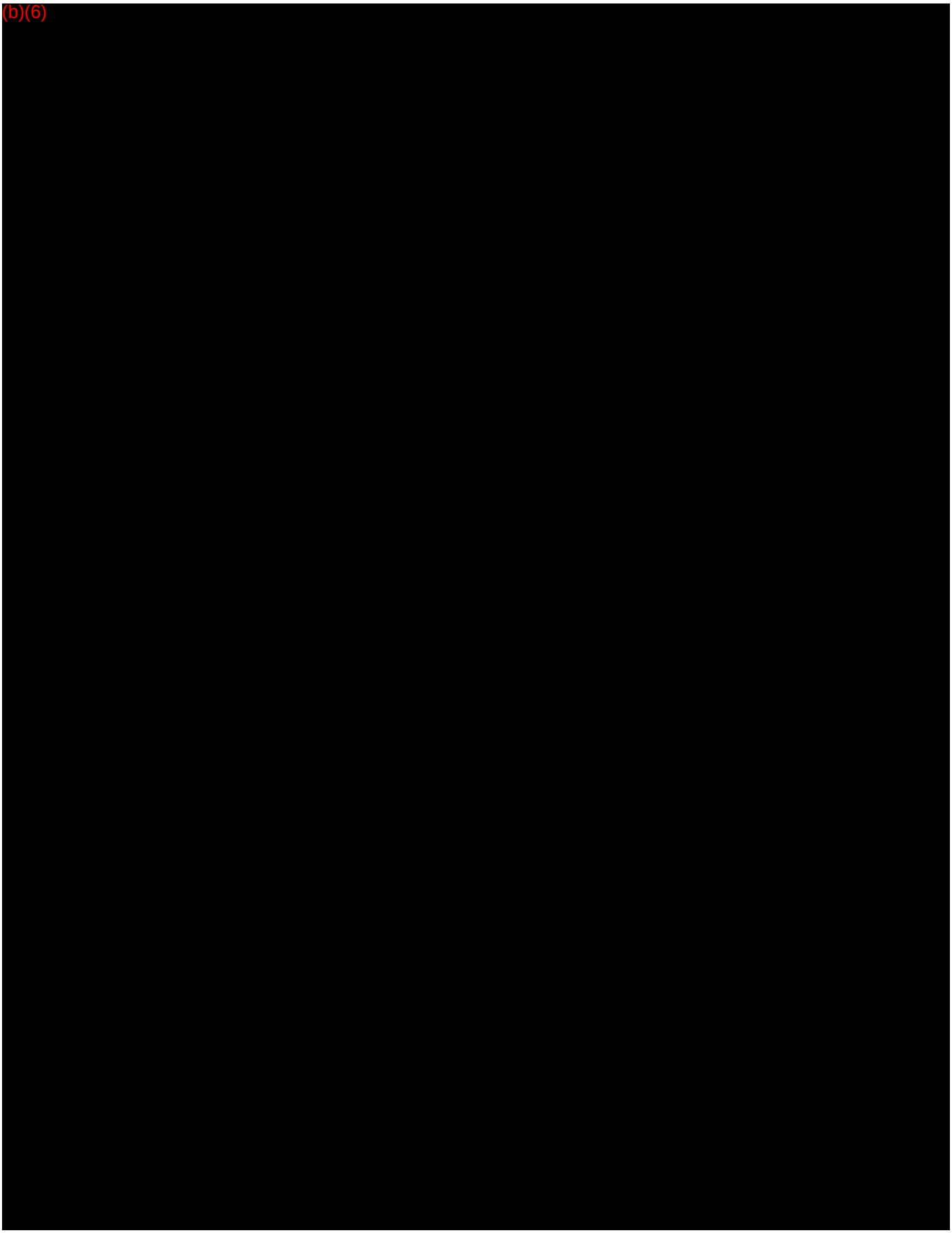

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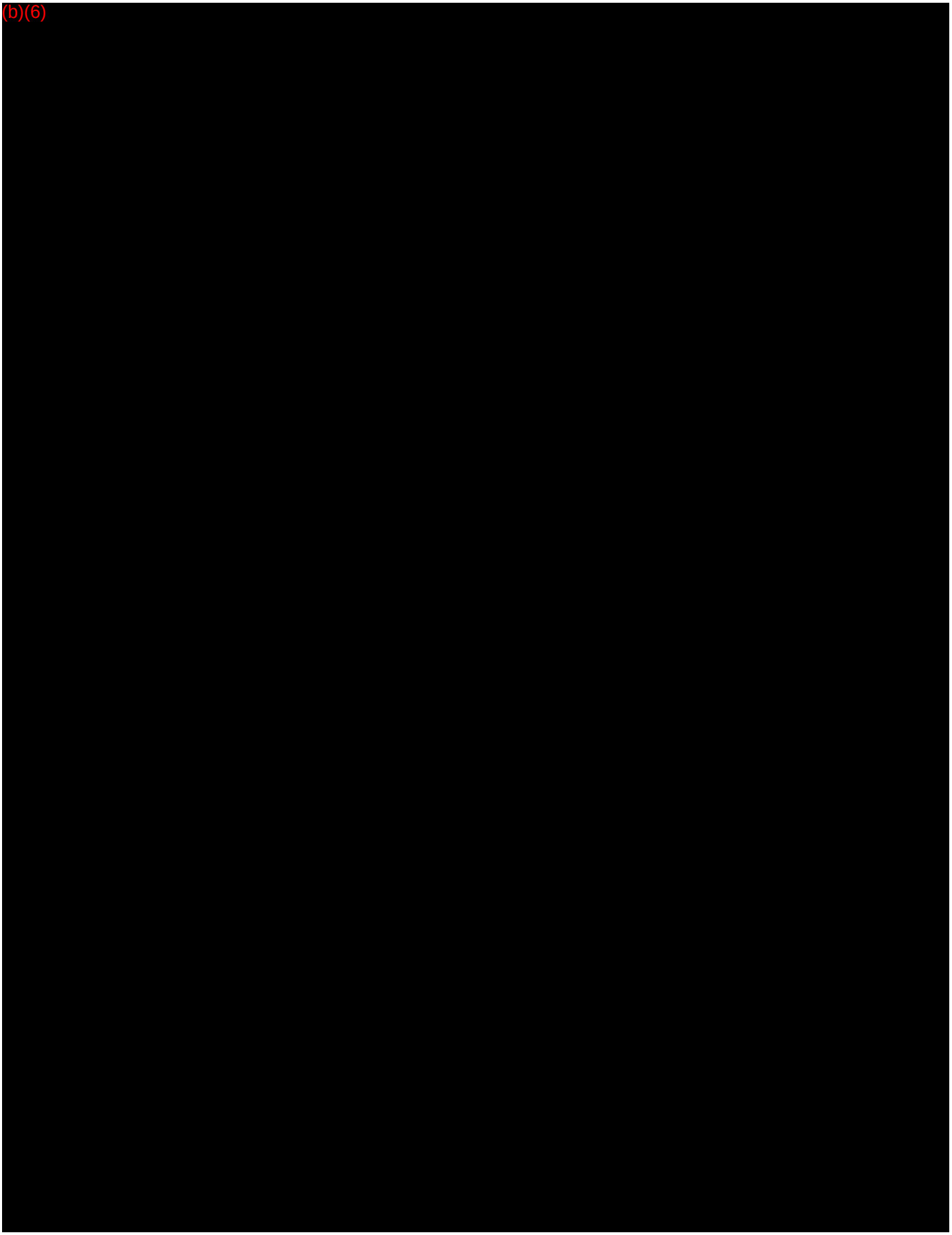

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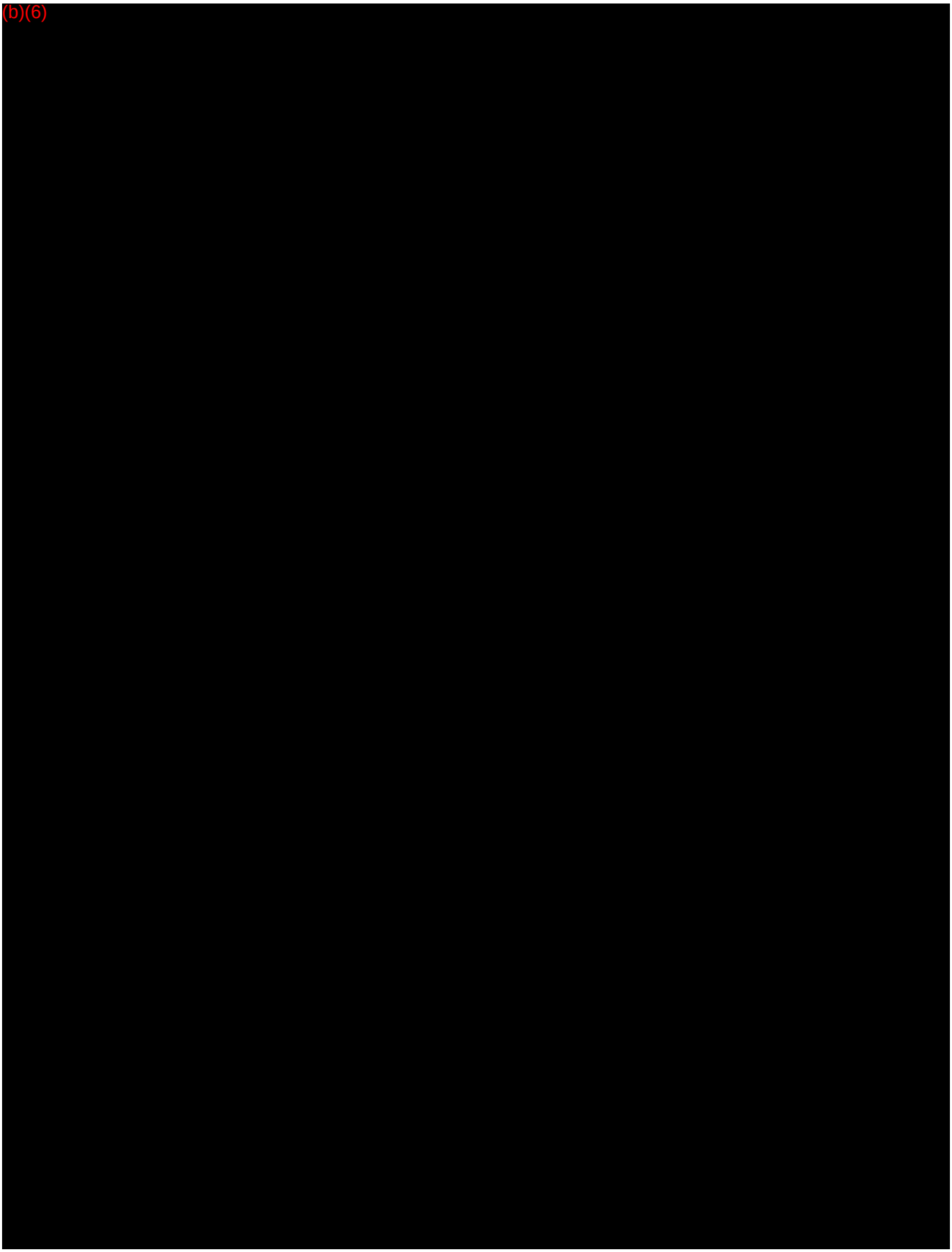

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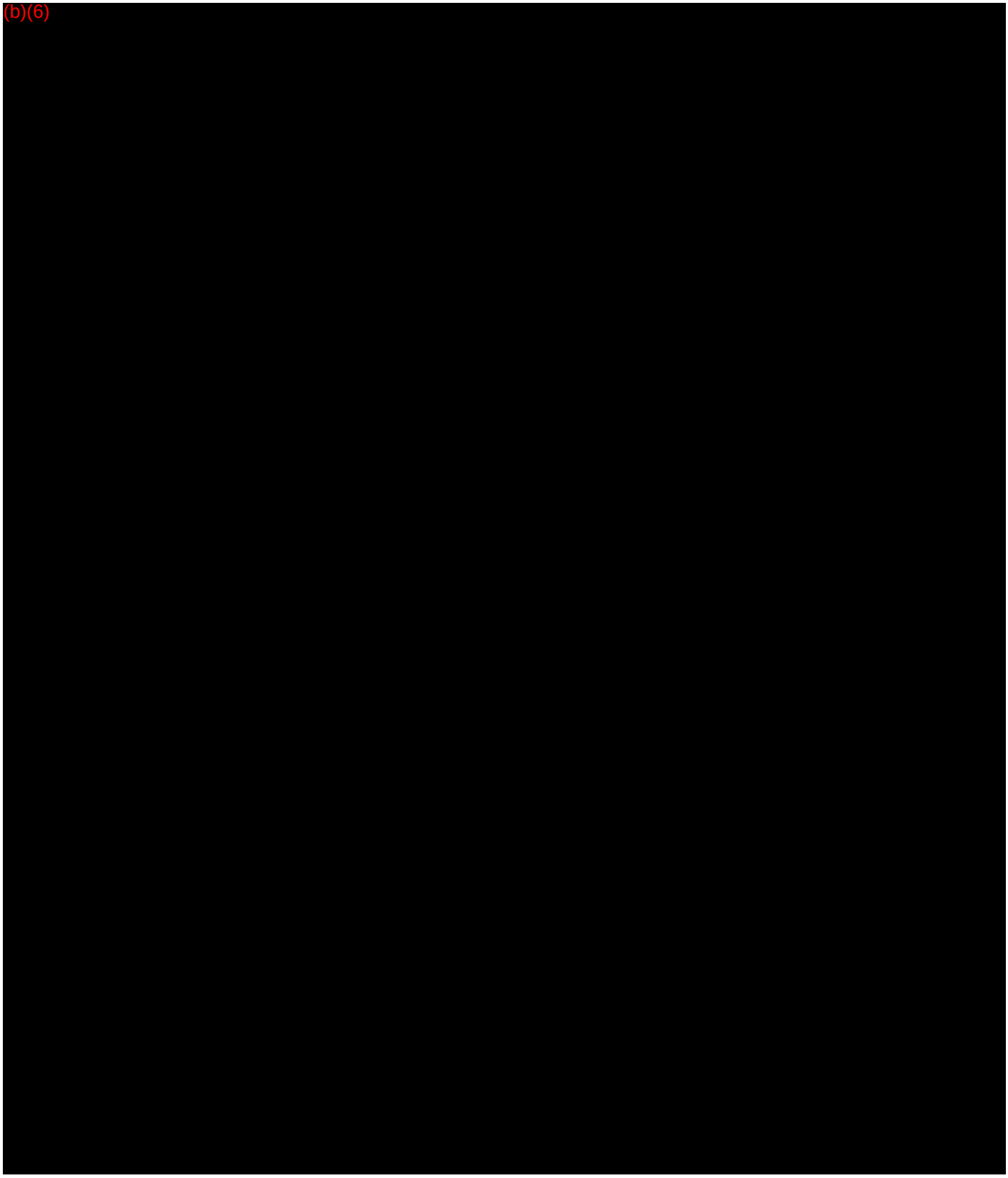

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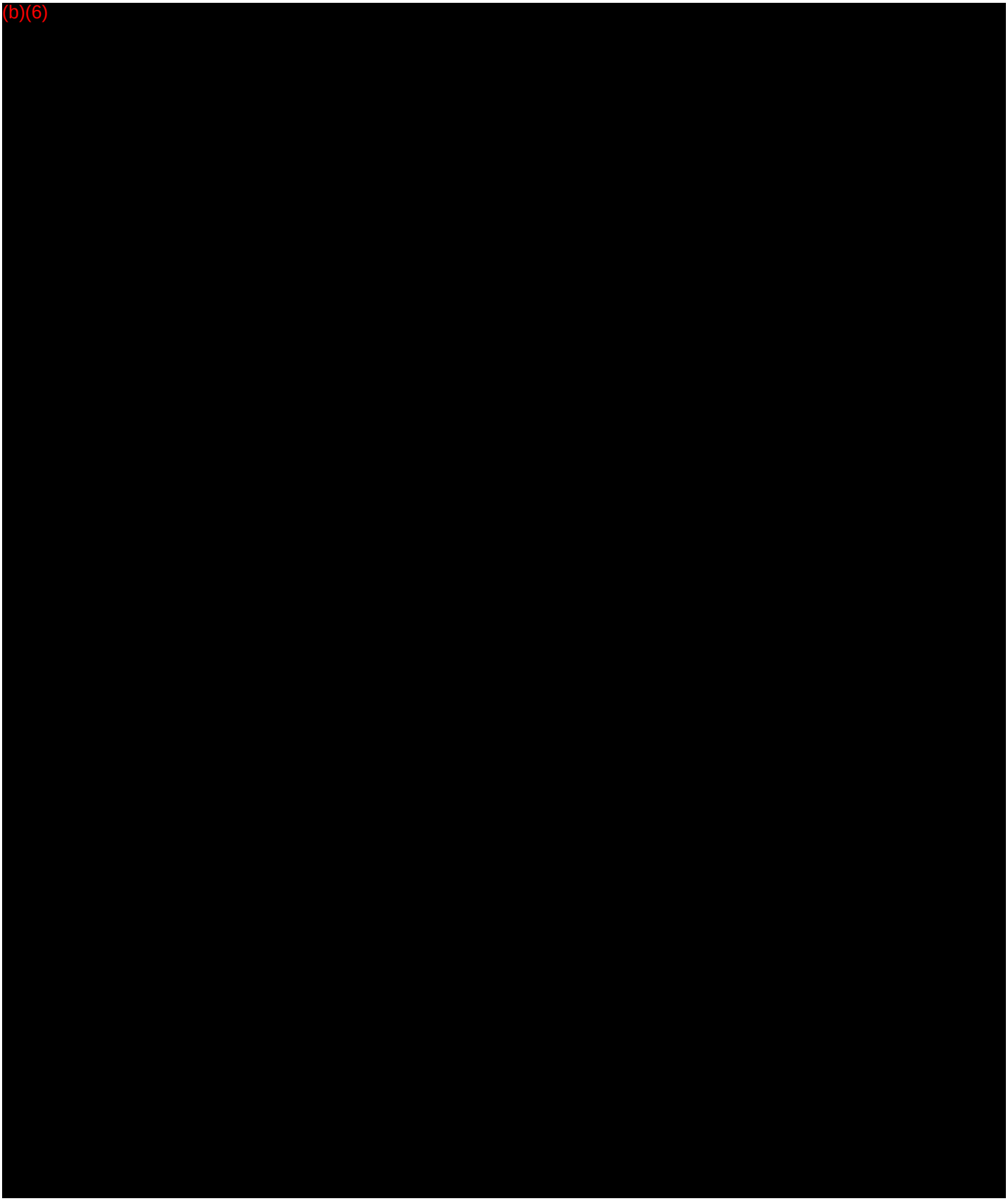

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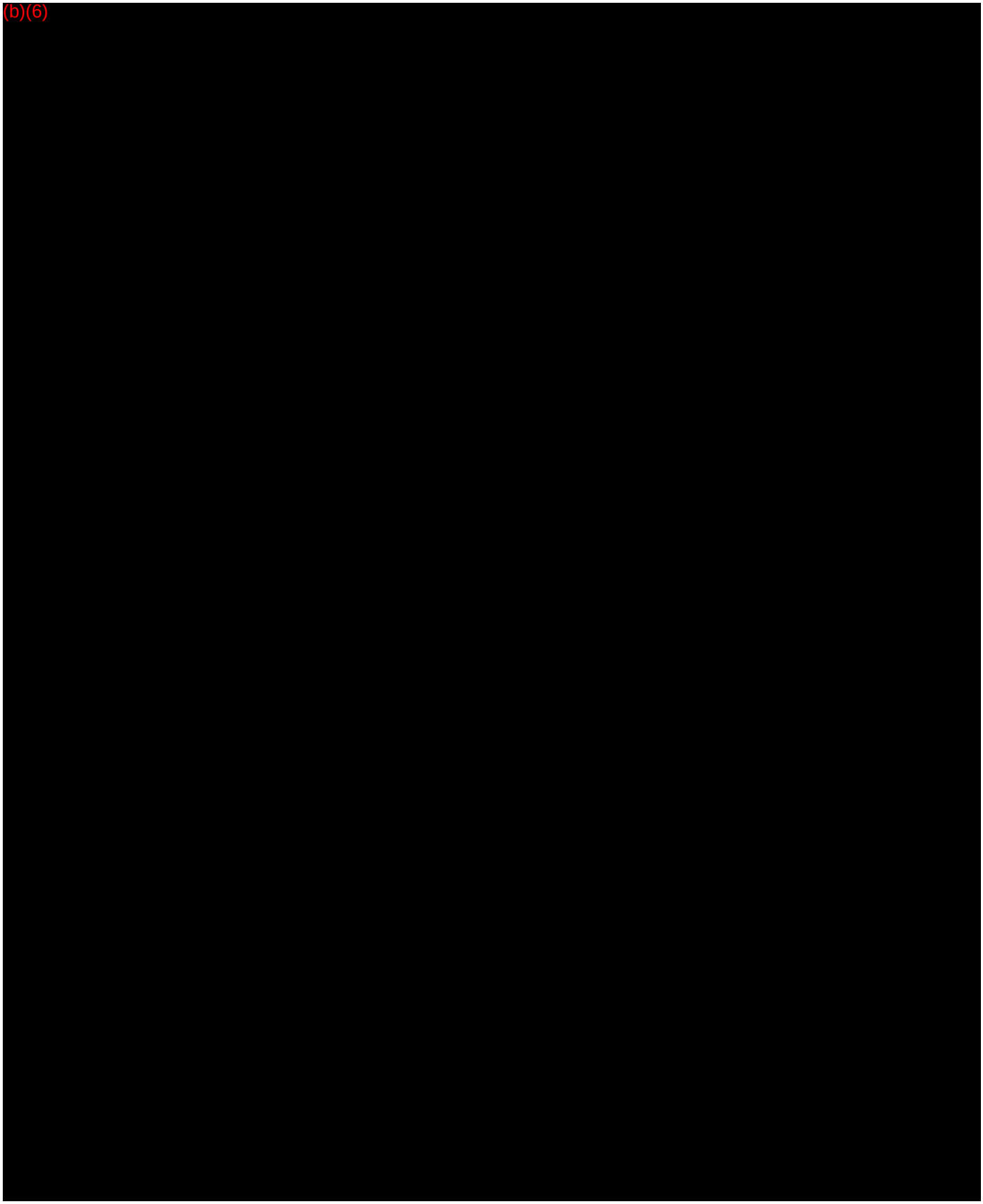

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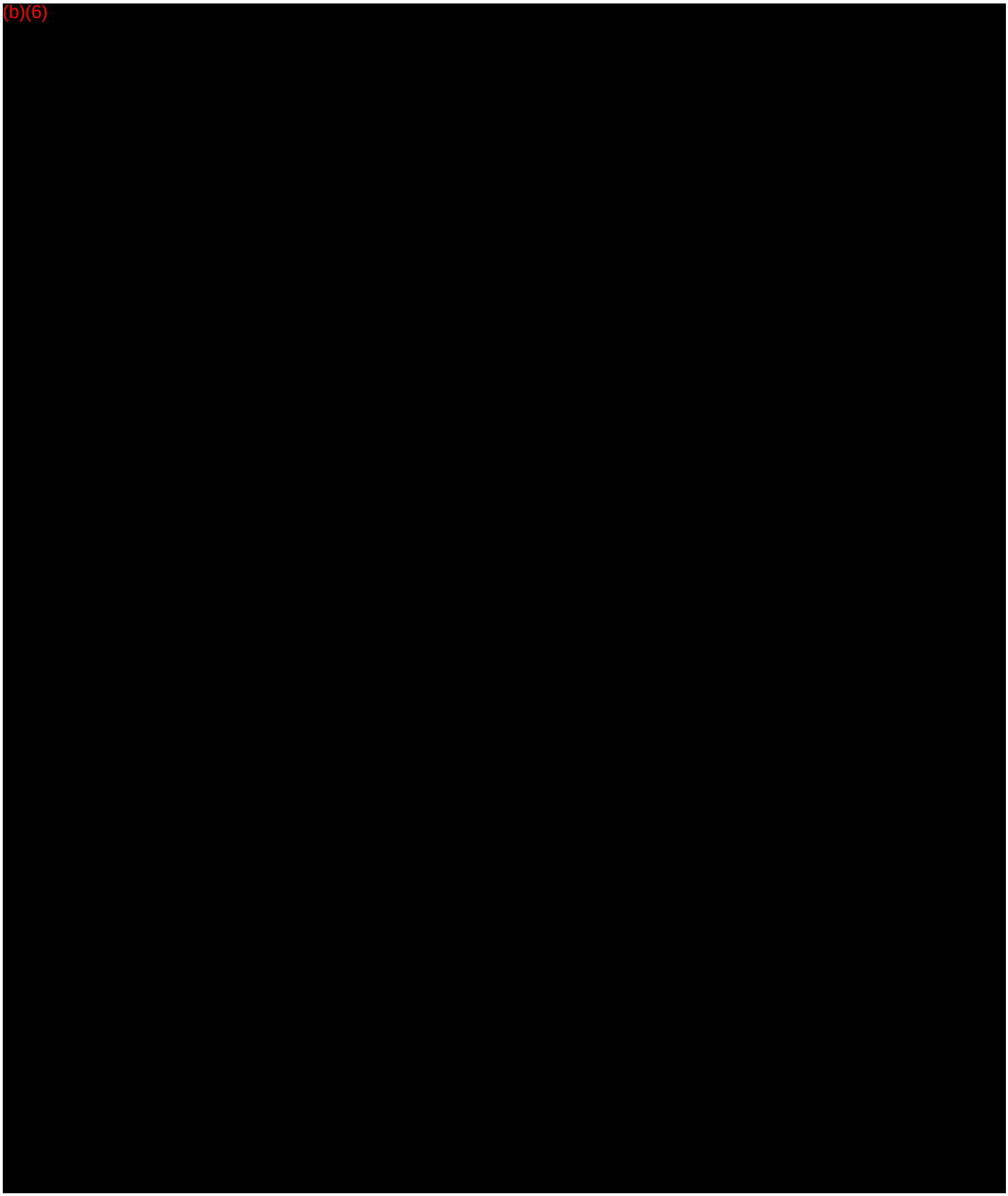

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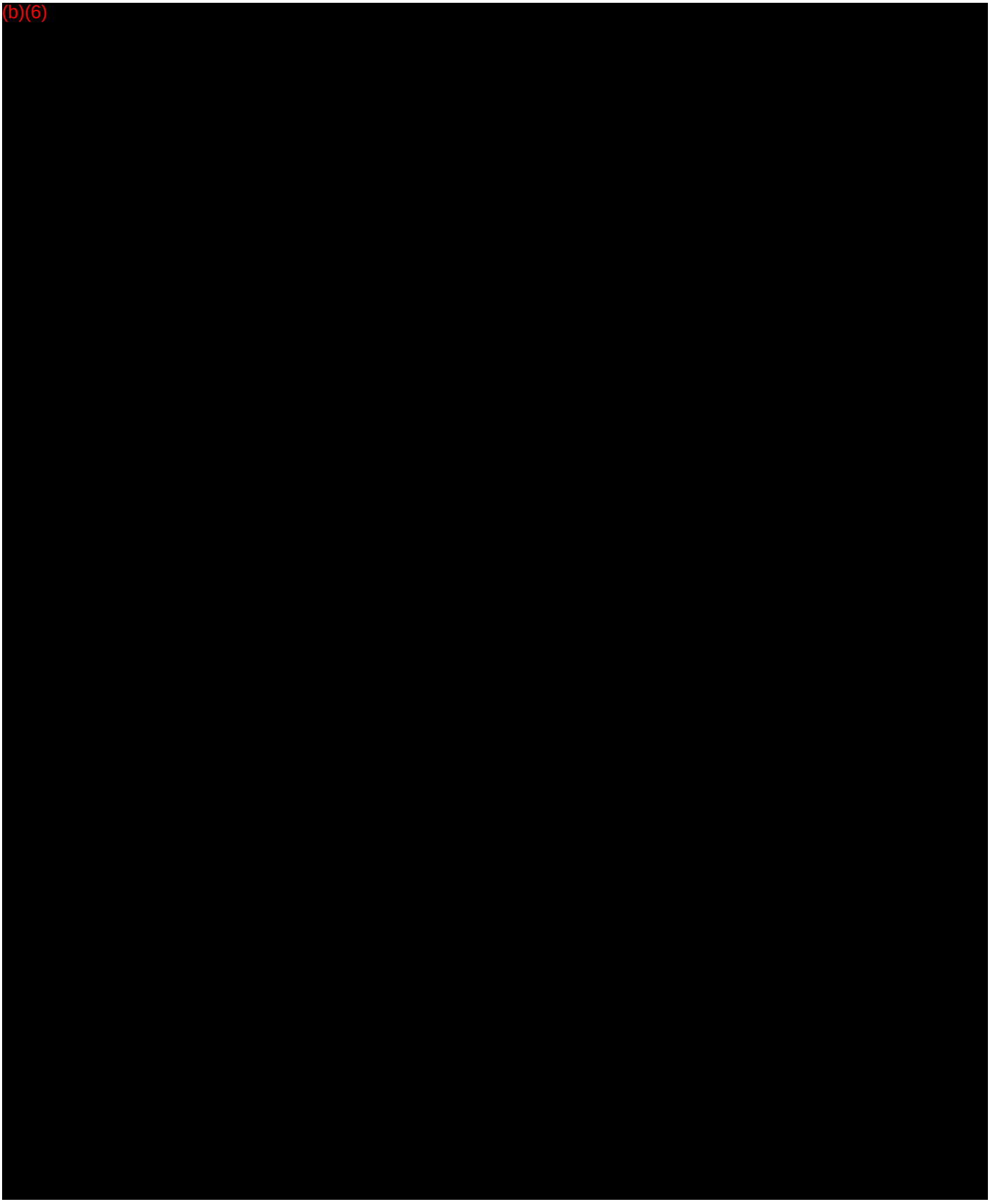

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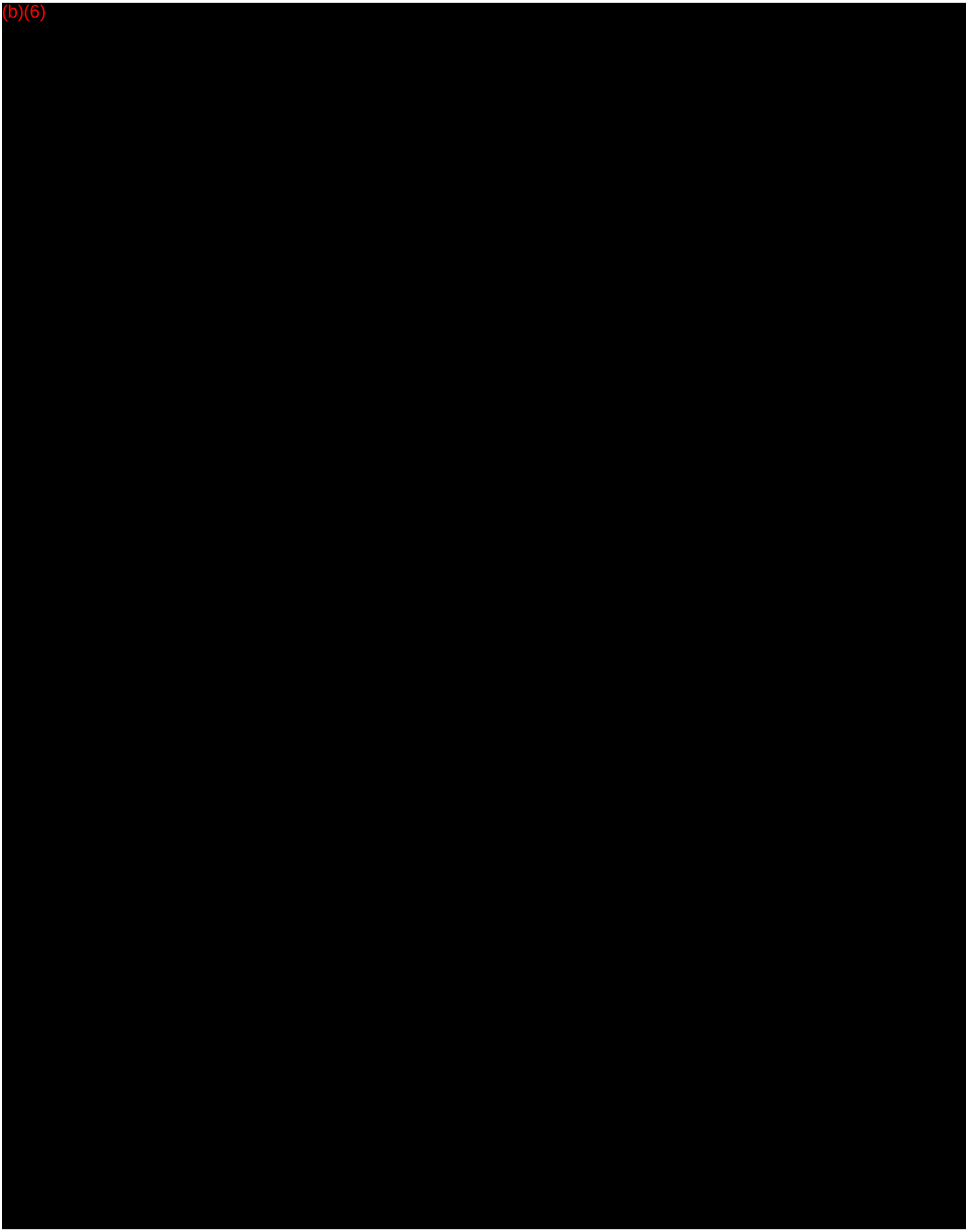

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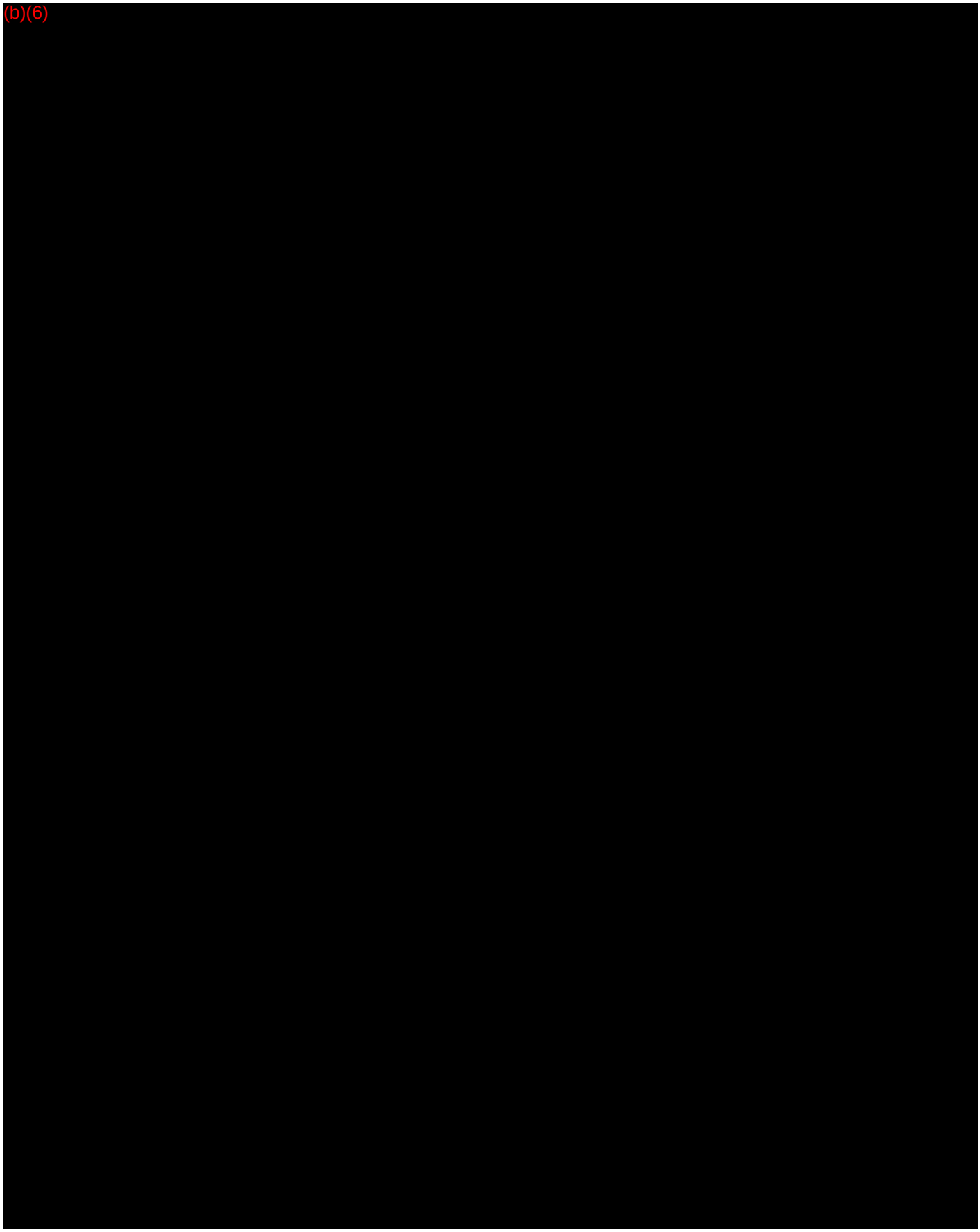

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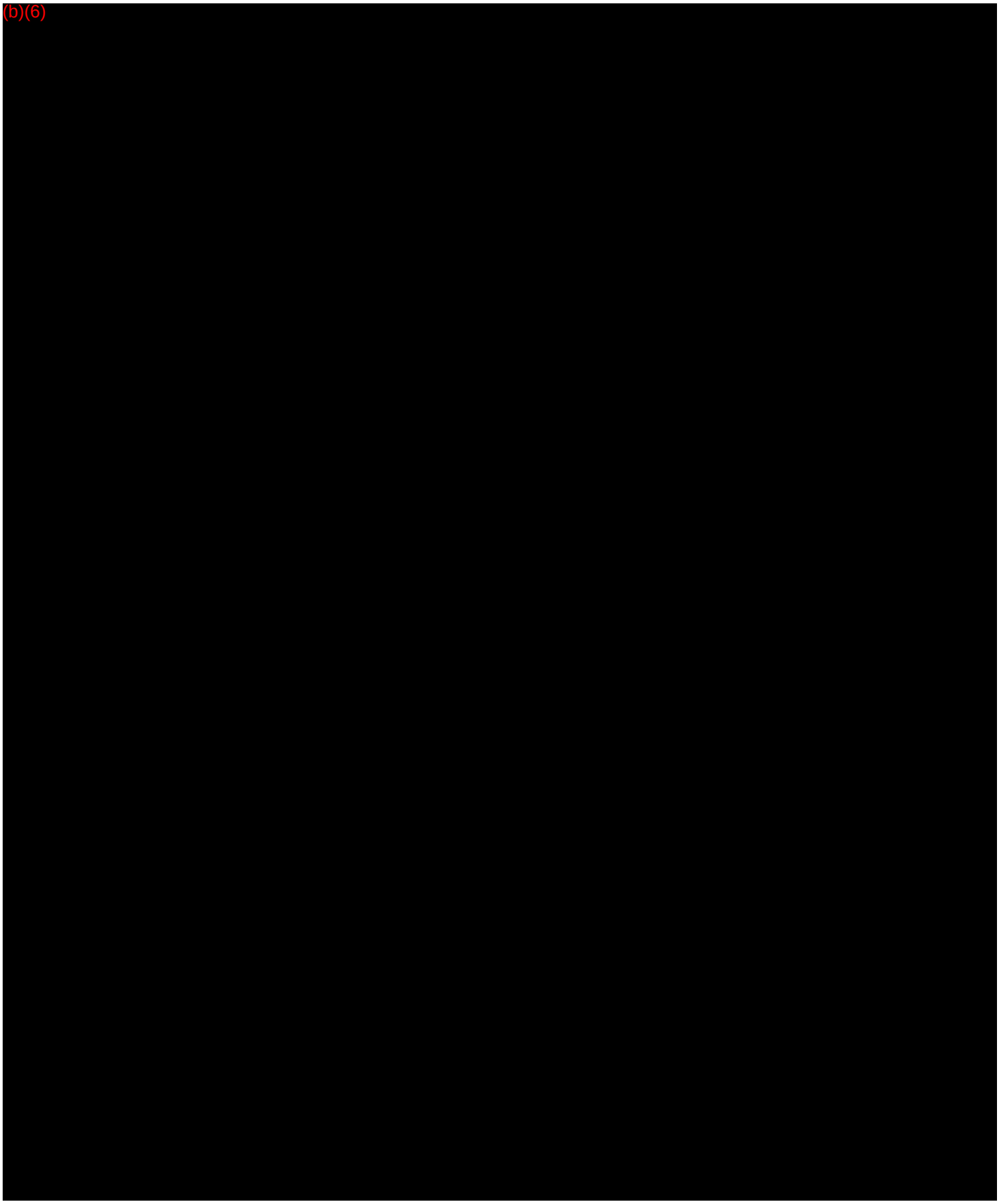

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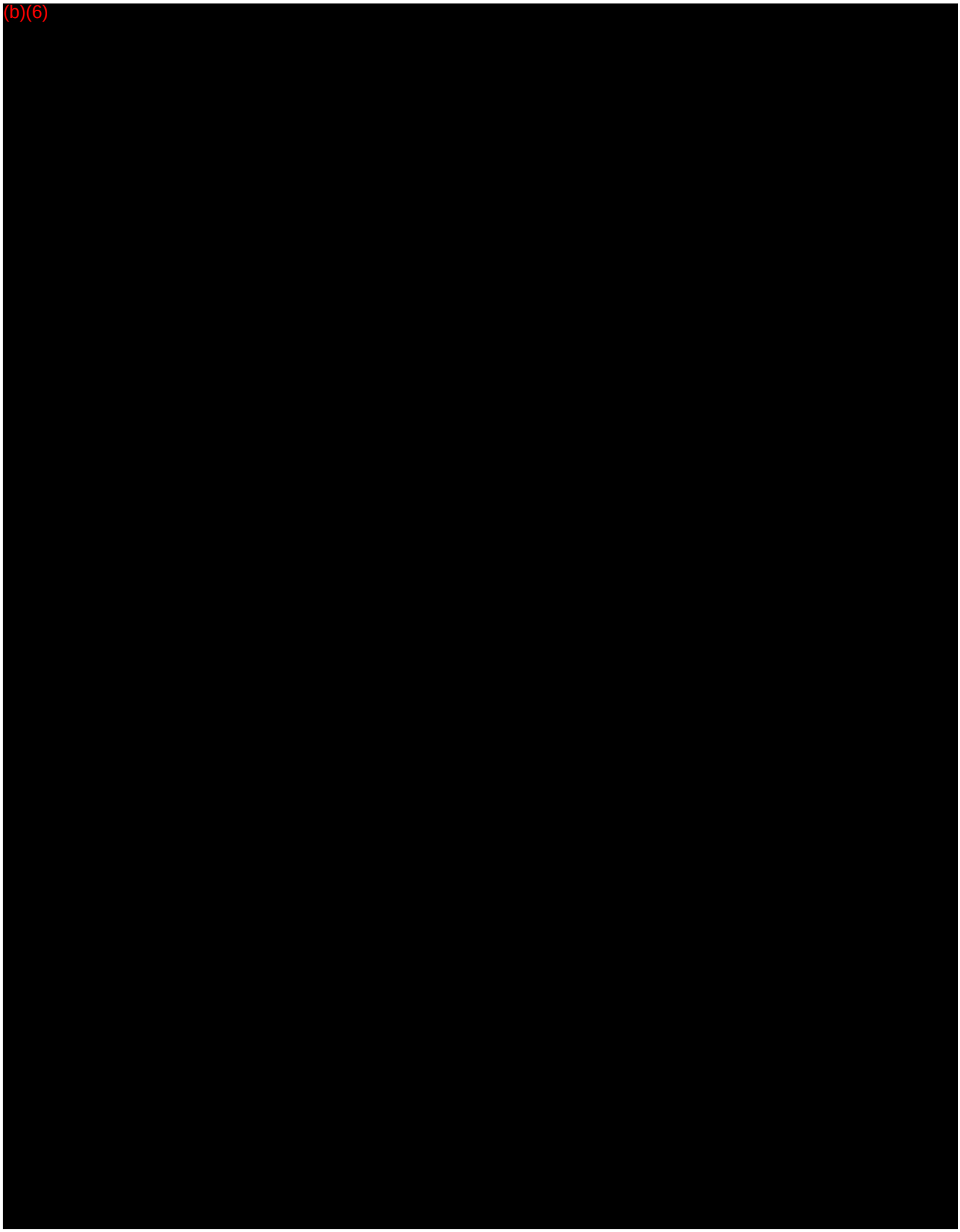

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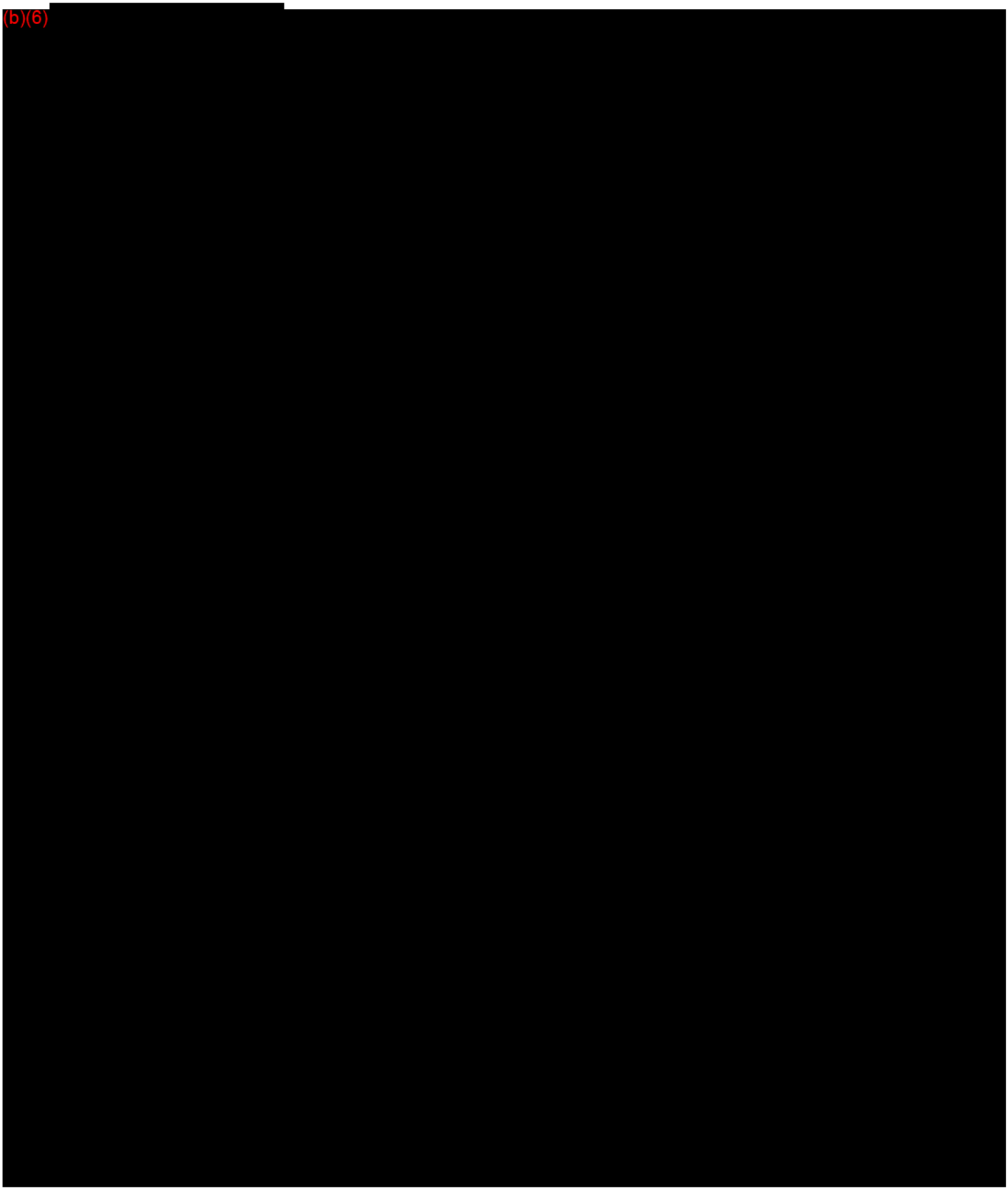

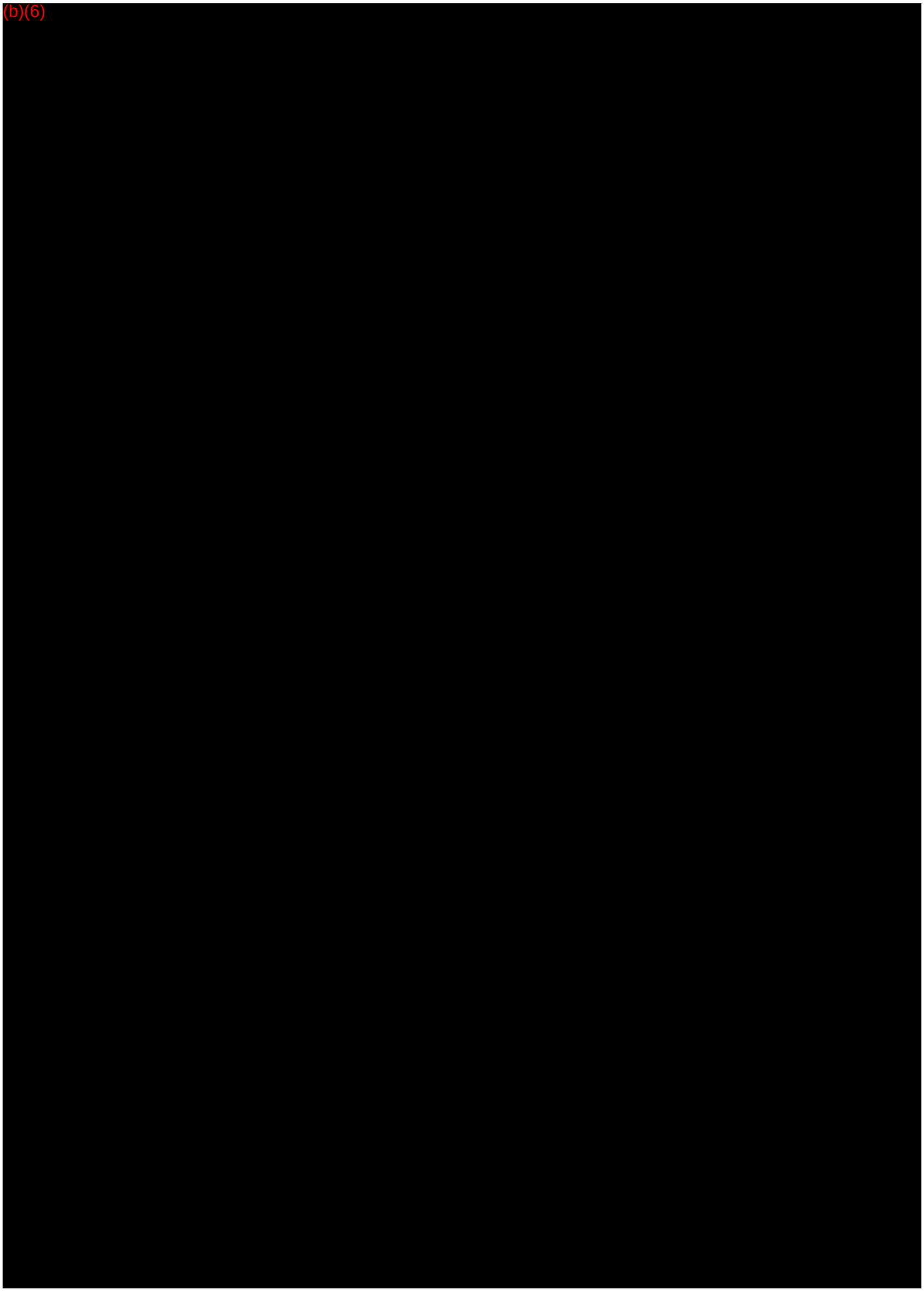
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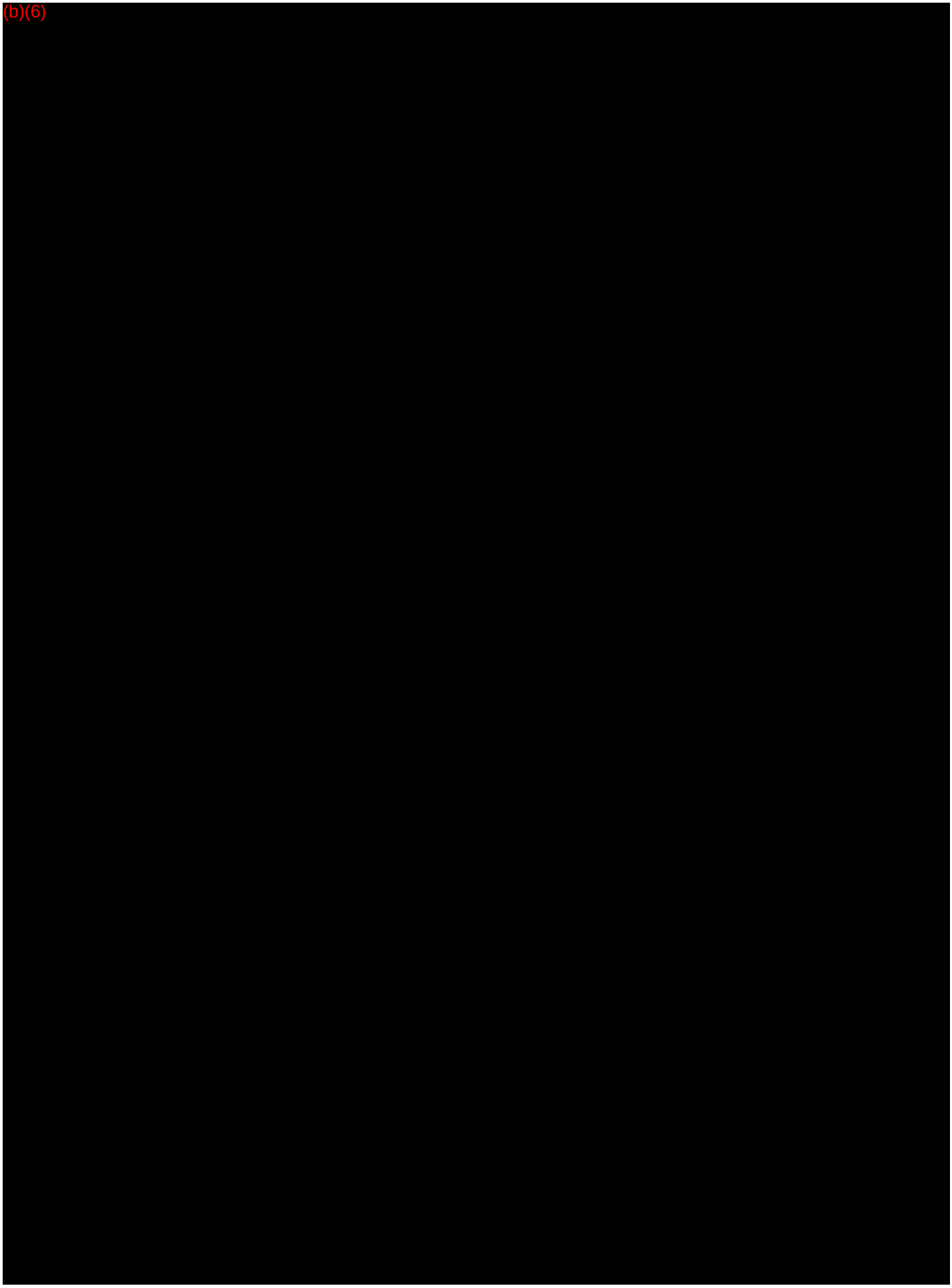
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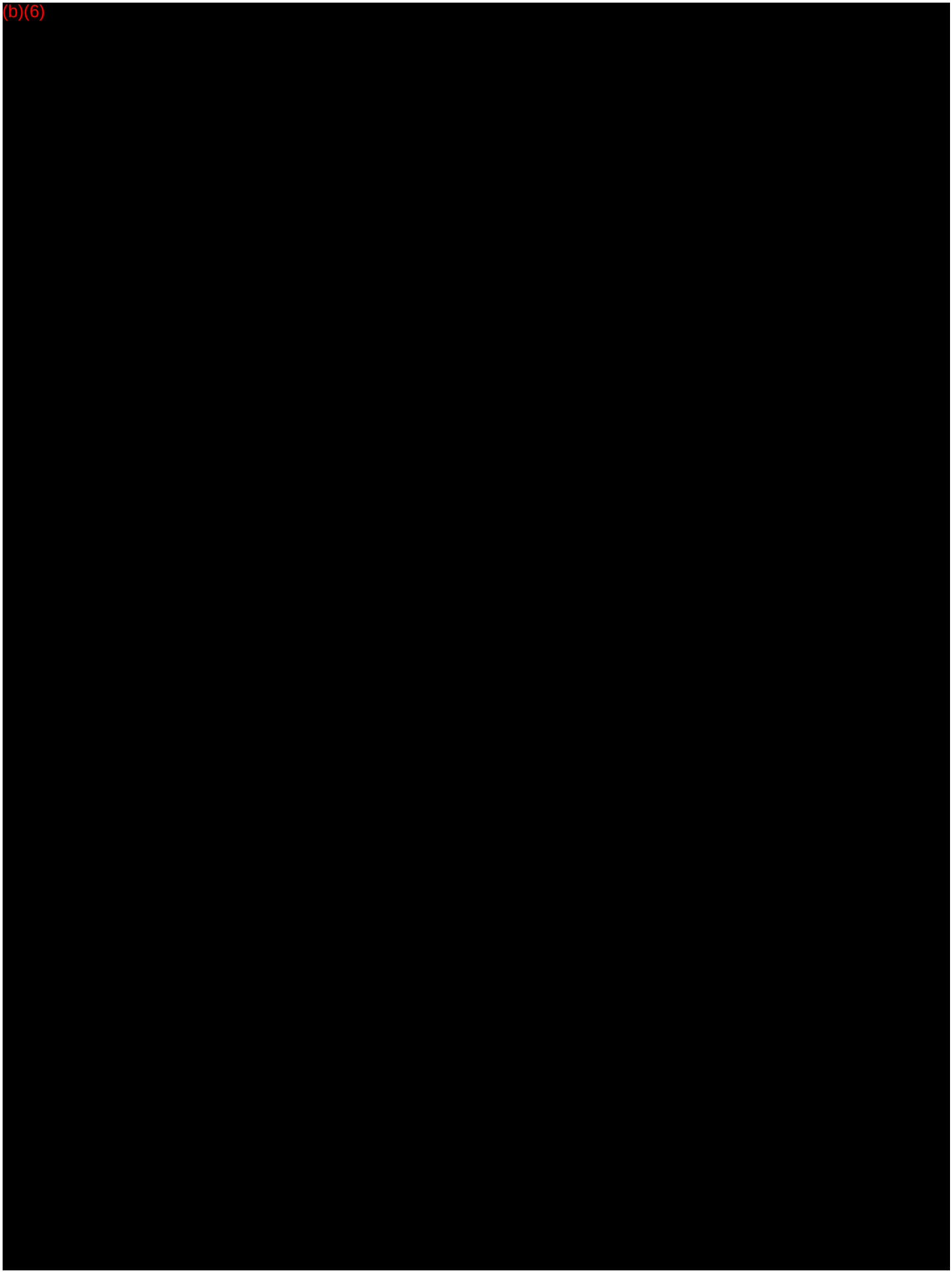
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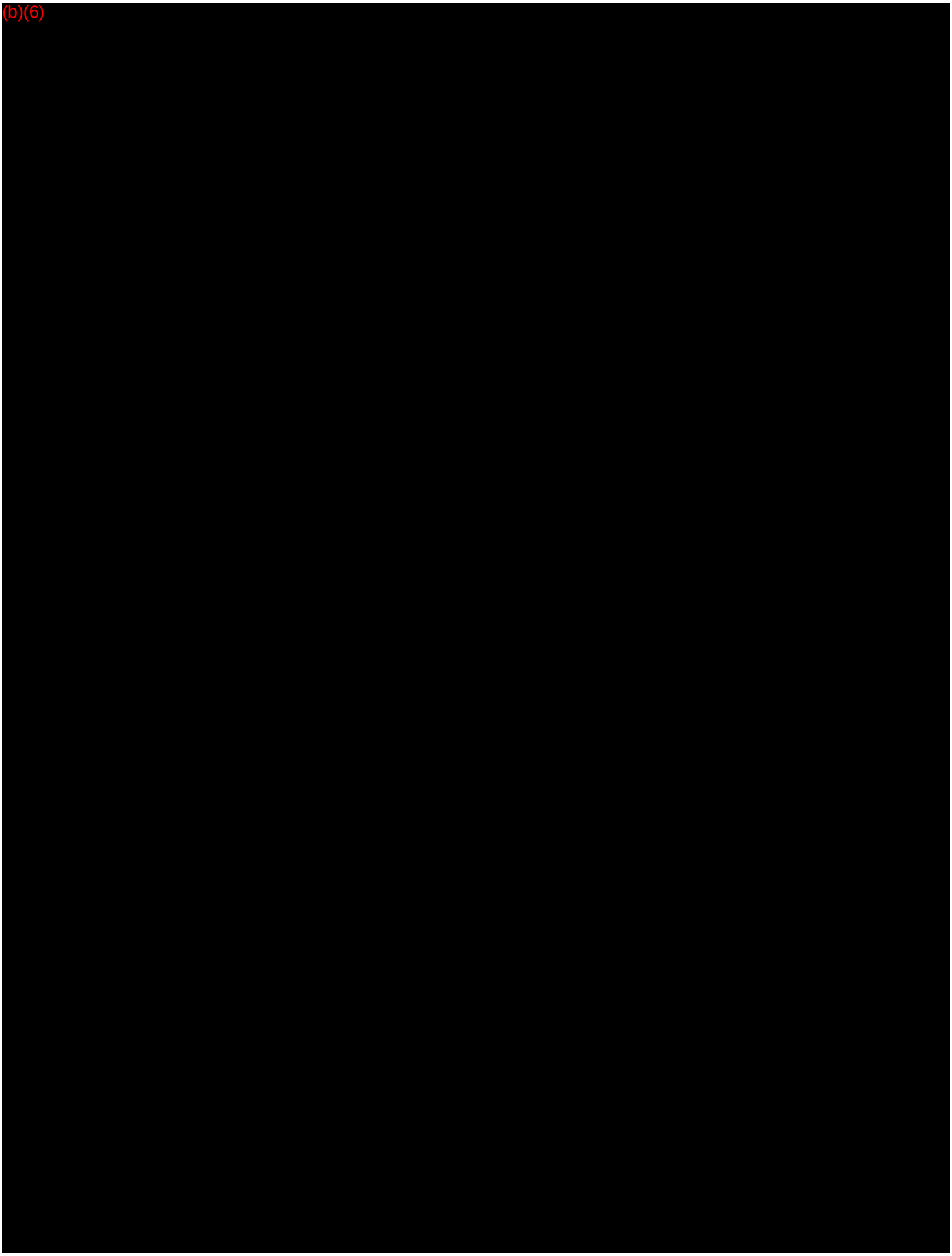
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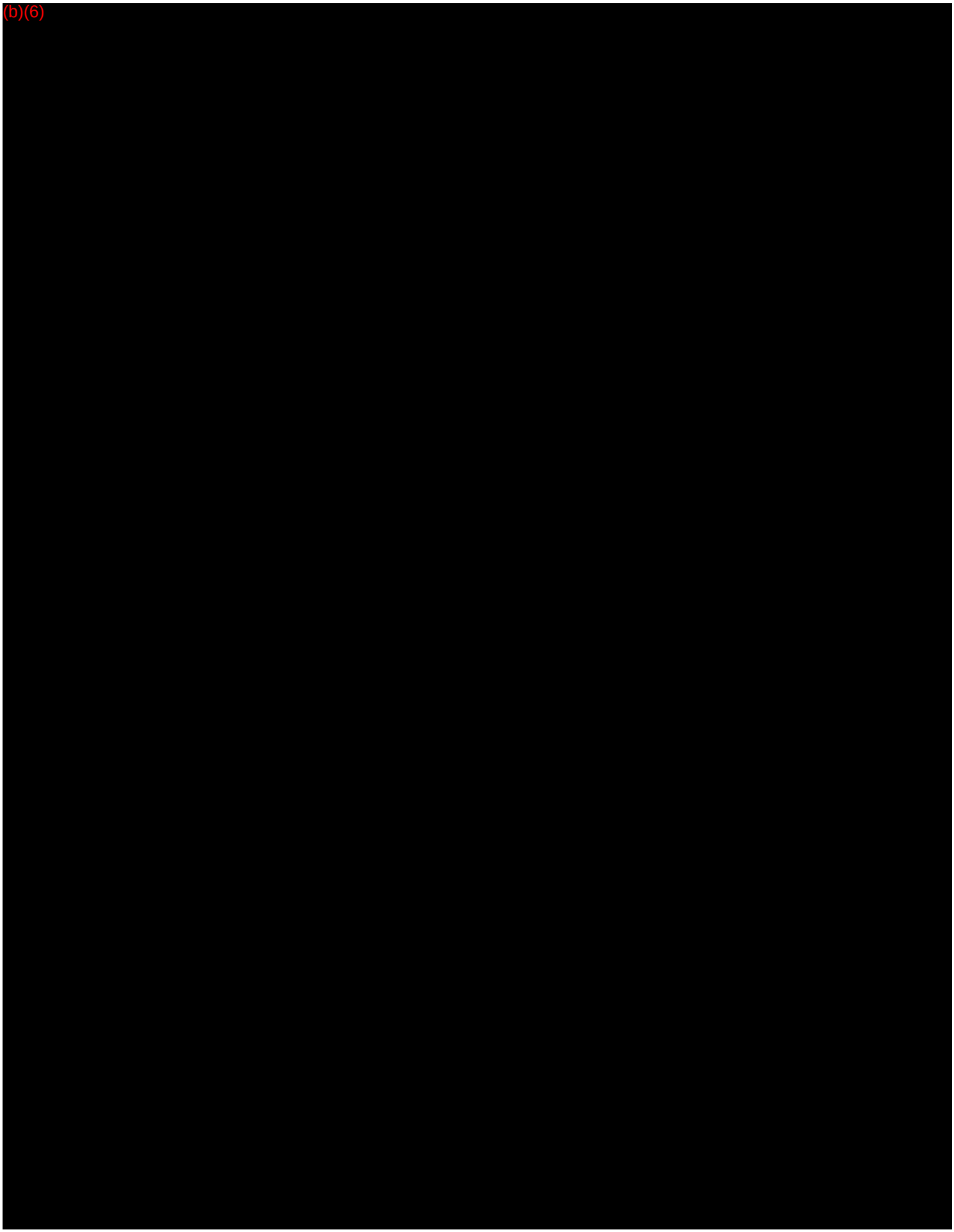

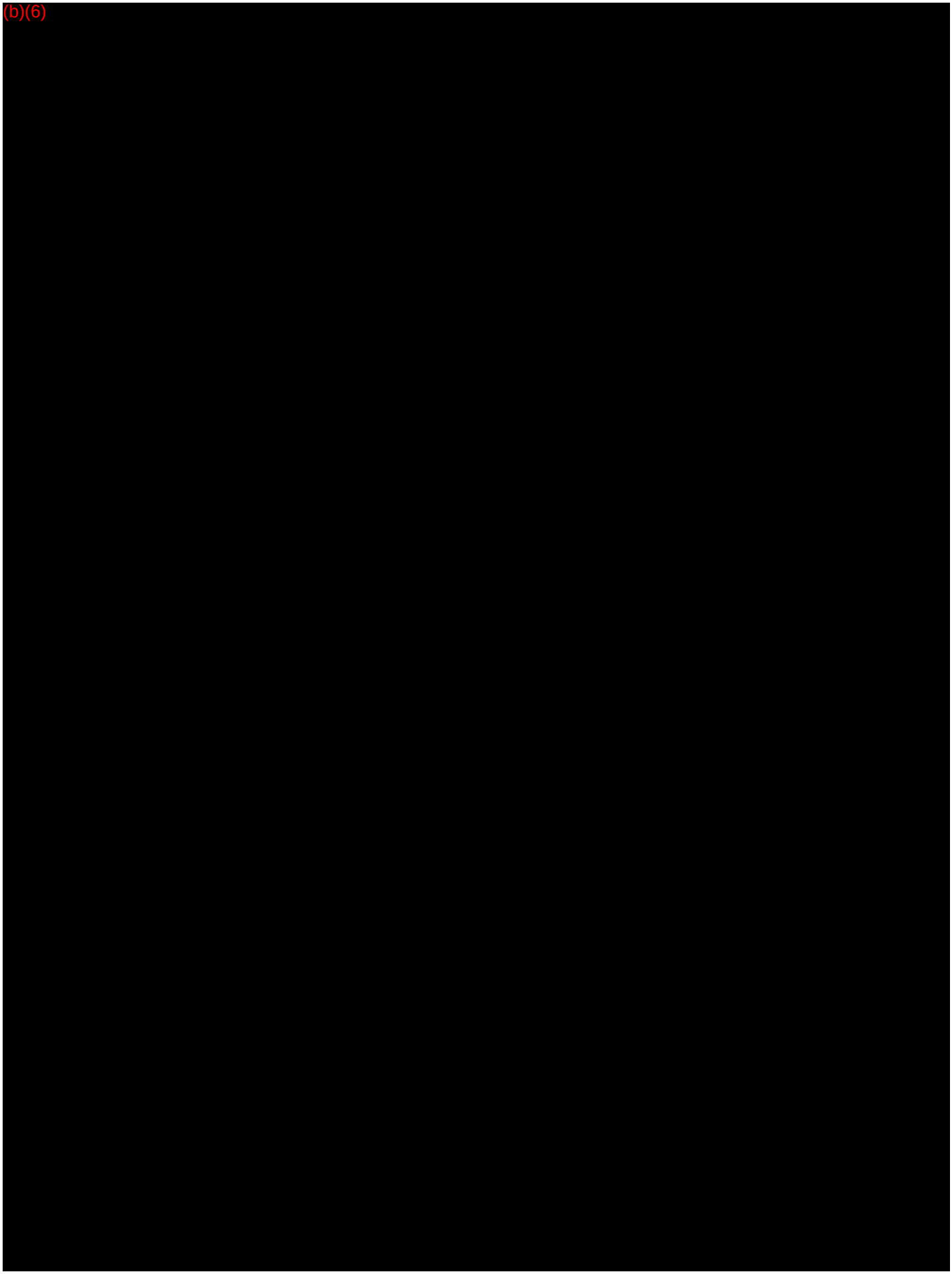
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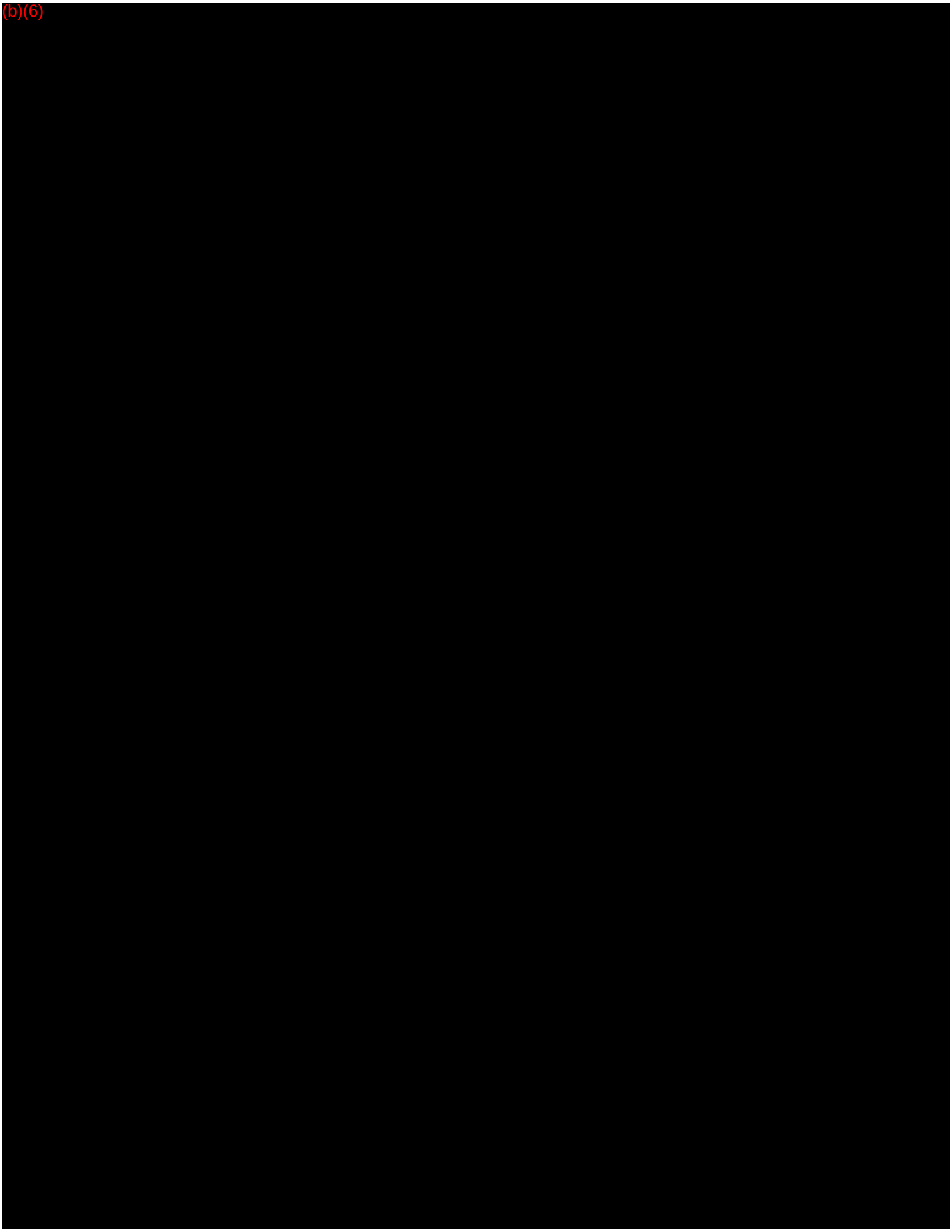
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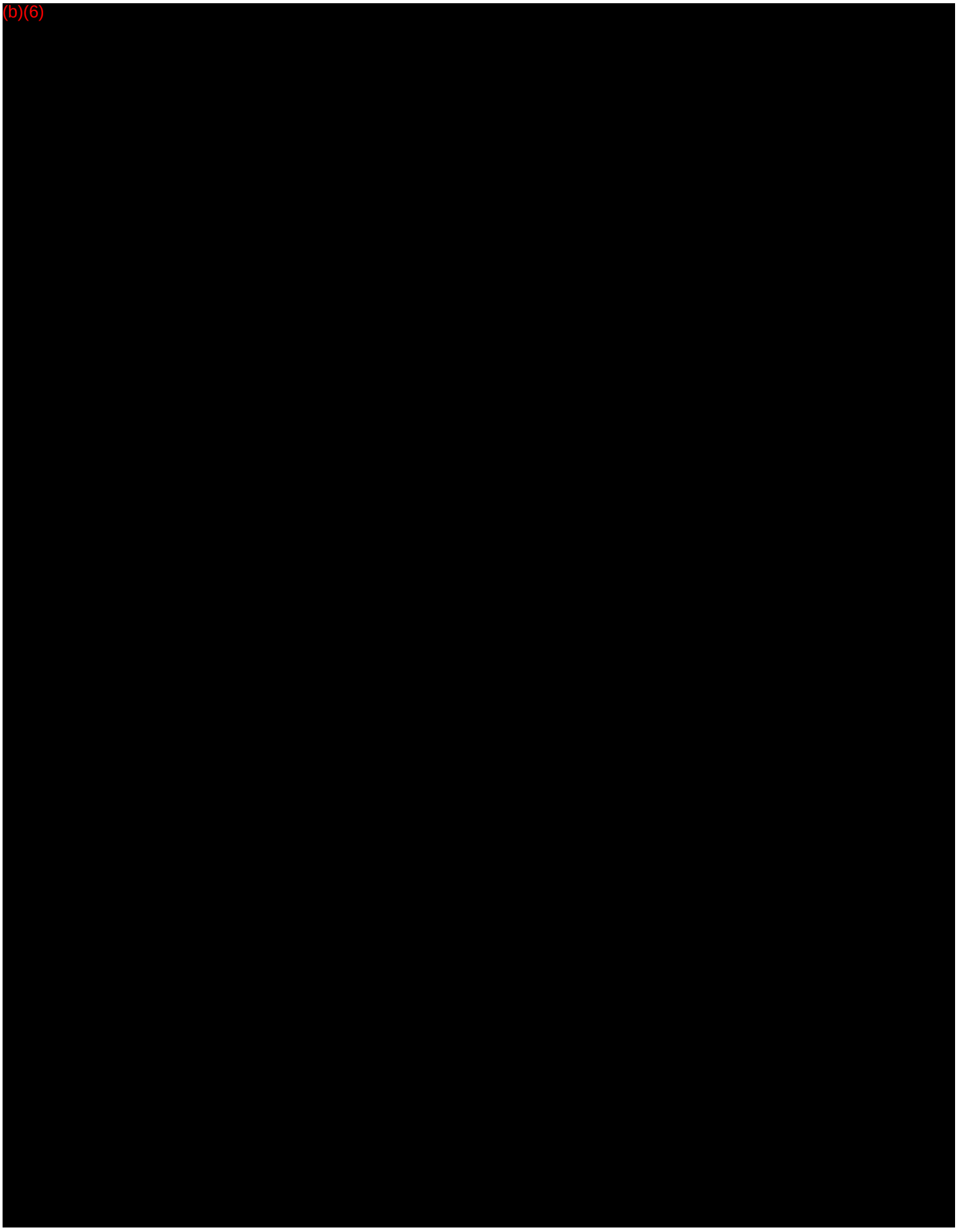
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Section 21: Other

Revolution CT

Section 21: Other

The following FDA guidance documents were used as references when preparing this 510(k) submission:

(b) (4)

K133705/S001

GE Healthcare

Response to RAI - K133705

Mr. William Jung

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAR 11 2014
Received

Date: March 10th, 2014

Subject: Additional Information for ~~K133750~~ K133705

Dear Mr. Jung:

Enclosed please find the additional information you requested in your email dated January 24, 2014 with regards to Revolution 510(K).

This response is provided in duplicate, with one paper copy and one eCopy. The eCopy is an exact duplicate of the paper copy.

GE appreciates the FDA's administrative and scientific review of the 510(K). We believe the information provided previously in the original submission as well as the additional information provided in this response has addressed FDA's concerns. Should you have any more questions please don't hesitate to ask me at the contact info below or Mr. Huy Doan at (b) (6) by email or (b) (6) by phone.

Sincerely,

Helen Peng
Regulatory Affairs Manager
GE Healthcare
Phone: (262) 424-8222
Email Hong.Peng@ge.com

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Response to FDA Questions on Revolution (K133705)

Mr. William Jung

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Date: March 10th, 2014

Subject: Additional Information for K133750

Dear Mr. Jung:

Enclosed please find the additional information you requested in your email dated January 24, 2014 with regards to Revolution 510(K).

This response is provided in duplicate, with one paper copy and one eCopy. The eCopy is an exact duplicate of the paper copy.

GE appreciates the FDA's administrative and scientific review of the 510(K). We believe the information provided previously in the original submission as well as the additional information provided in this response has addressed FDA's concerns. Should you have any more questions please don't hesitate to ask me at the contact info below or Mr. Huy Doan at (b) (6) by email or (b) (6) by phone.

Sincerely,

Helen Peng
Regulatory Affairs Manager
GE Healthcare
Phone: (262) 424-8222
Email Hong.Peng@ge.com

FDA Question #1

(b)(4) [redacted]

GE Response:

We removed the statement below in the device description:

(b)(4) [redacted]

The revised device description section is provided in Attachment A.

FDA Question #2

(b)(4) [redacted]

GE Response:

(b)(4) [redacted]

FDA Question #3

(b)(4) [redacted]

GE Response:

We believe that this statement is substantiated in the performance evaluation document, section 2.3 (pages 18-30 to18.35). However, we also added the definition of image quality in the product data sheet (page 1) as a footnote which reads:

(b)(4) [redacted]

The revised product datasheet is provided in Attachment B.

FDA Question #4

(b)(4) [redacted]

GE Response:

We agree with the FDA's approach.

FDA Question #5

(b)(4) [redacted]

(b)(4)

[redacted]

GE Response:

(b)(4)

[redacted]

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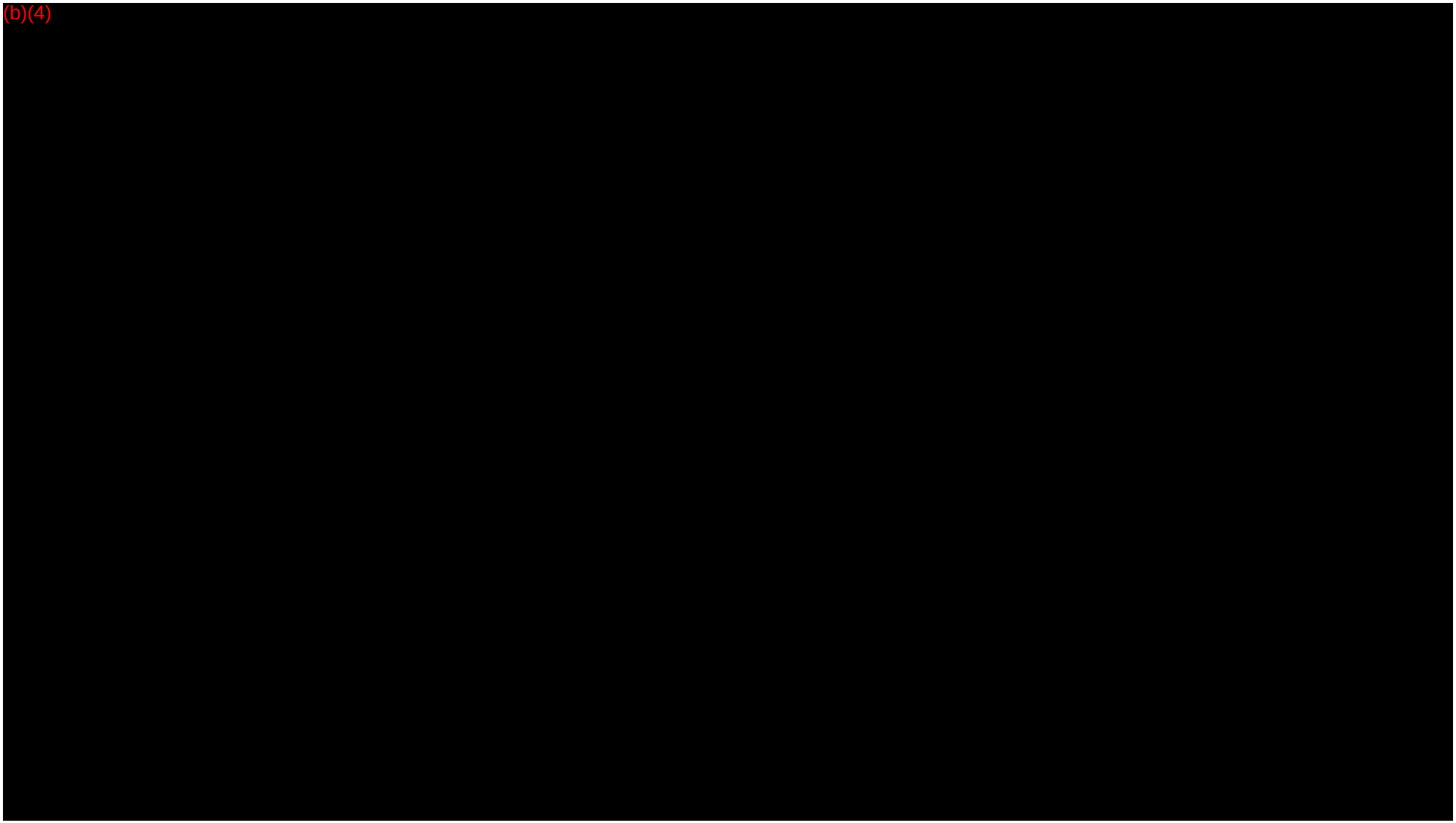

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FDA Question #6.

(b)(4)

GE Response:

(b)(4)

ID	Description	Type	Disposition
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ID	Description	Type	Disposition
(b)(4)			

ID	Description	Type	Disposition
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ID	Description	Type	Disposition
(b)(4)			

FDA Question #7.

(b)(4)

d. (b)(4)

[redacted]

GE Response:

(b)(4)

[redacted]

(b)(4)

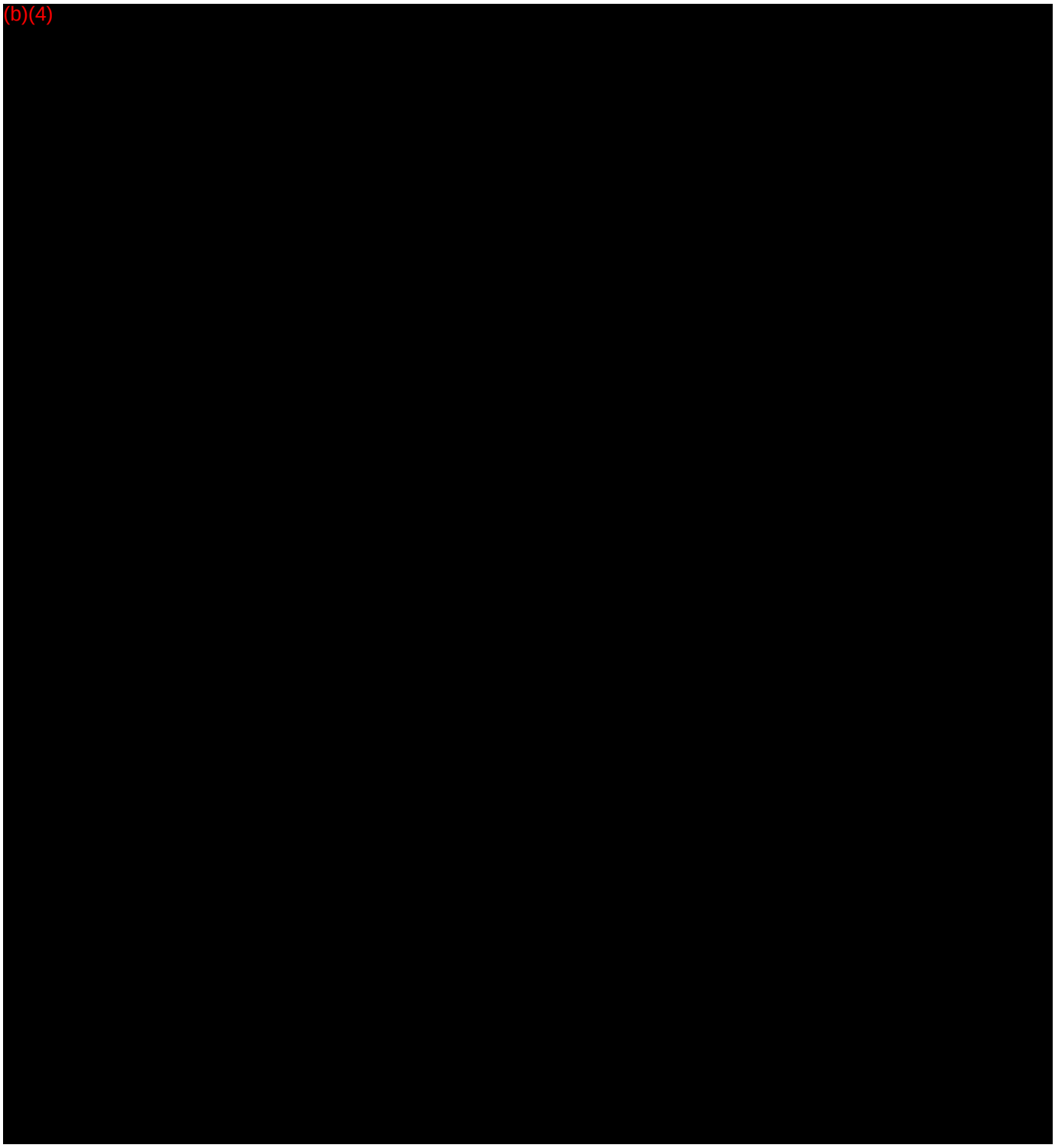
FDA Question #8

(b)(4)

GE Response:

(b)(4)

(b)(4)



8b. (b)(4)

(b)(4)

FDA Question #9

(b)(4)

GE Response:

(b)(4)

(b)(4)

[redacted]

FDA Question #10

(b)(4)

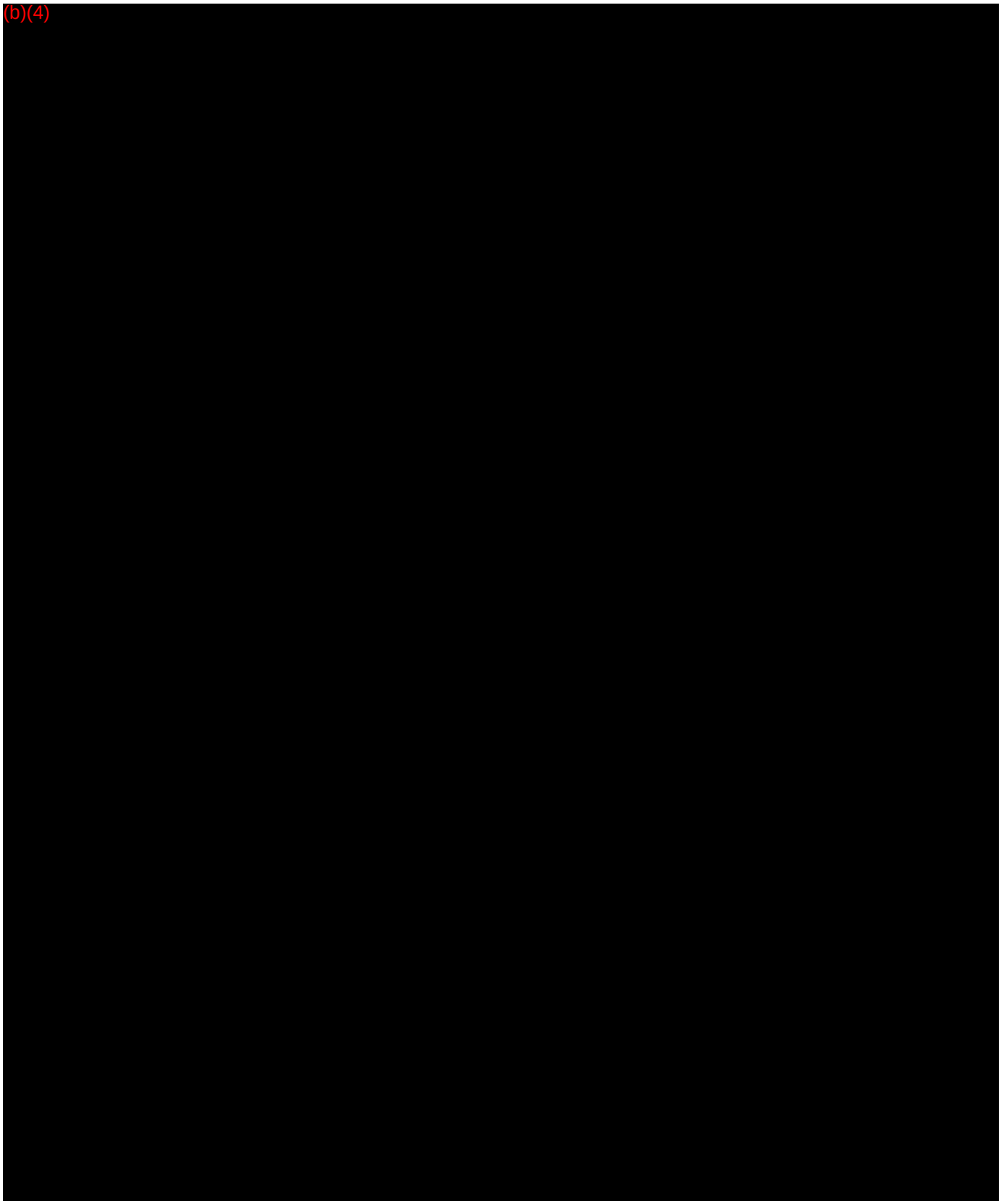
[redacted]

GE Response:

(b)(4)

[redacted]

(b)(4)



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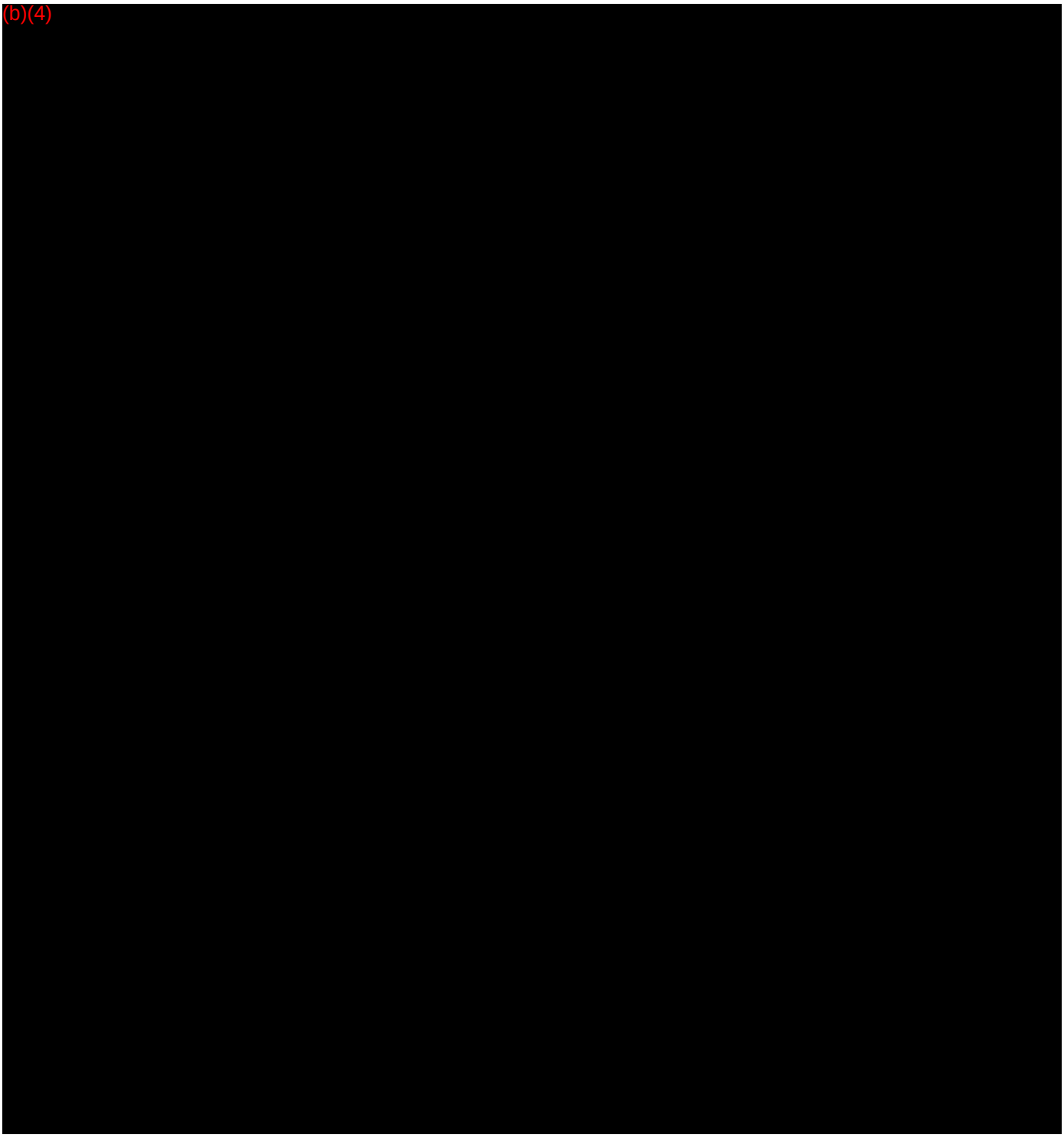

[1] Extended HU is a standard feature on the CT scanner by clicking the option in a text box on the left hand screen, and clicking “ok” to confirm and restart the image reconstruction application.

FDA Question #11

(b)(4)

[redacted]

GE Response:

(b)(4)

[redacted]

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FDA Question #12

(b)(4) [redacted]

GE Response:

(b)(4) [redacted]

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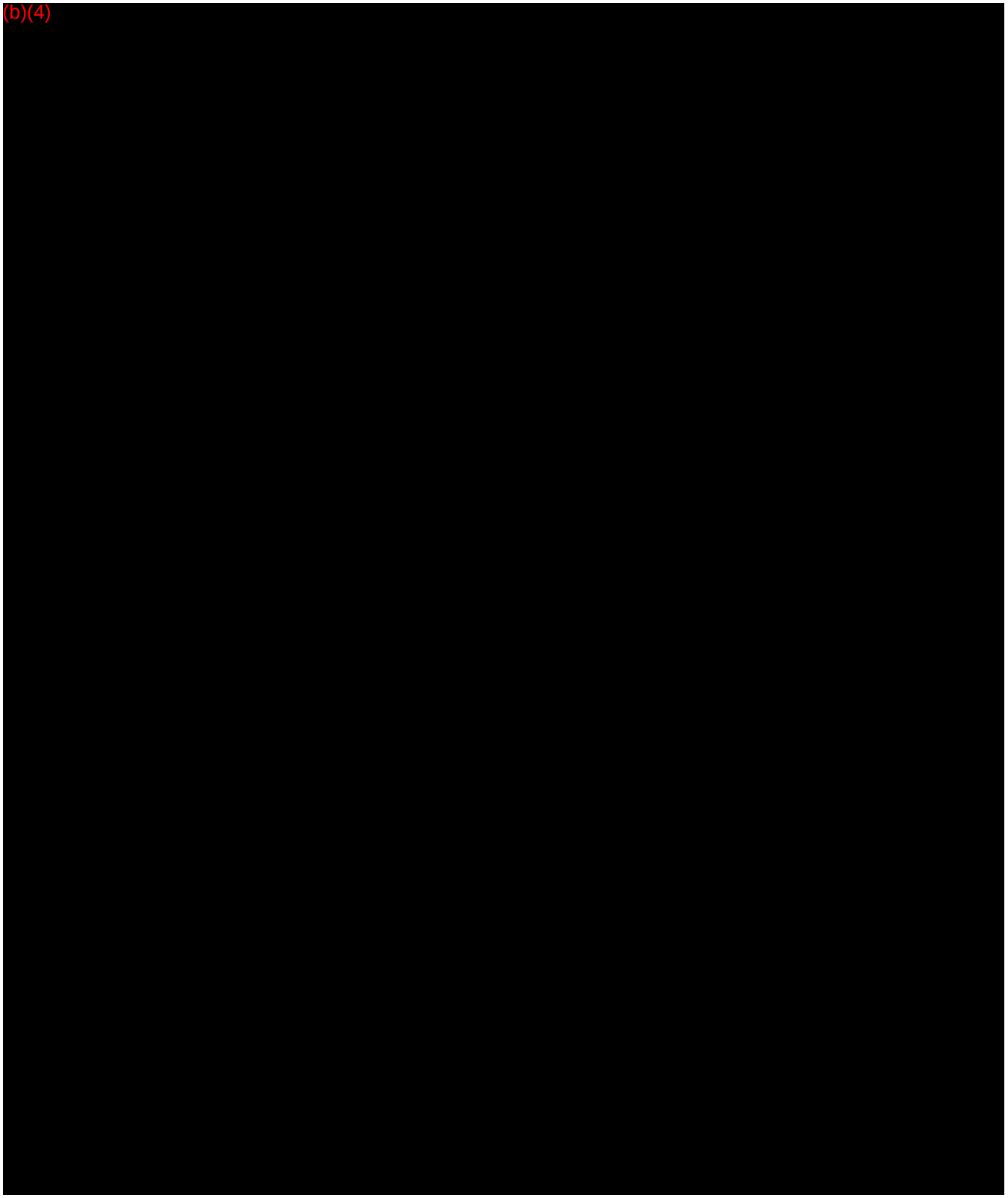

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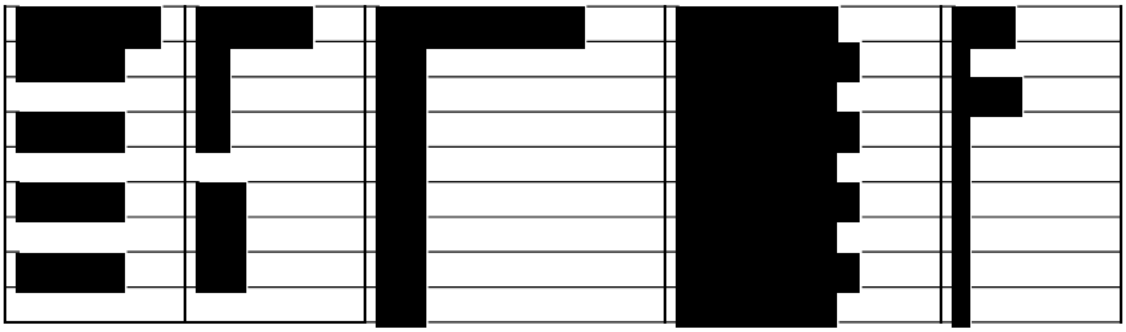

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[redacted] These images are as follows:

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FDA Question #13

(b)(4)

GE Response:

(b)(4)

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[redacted]

FDA Question #14

(b)(4)

[redacted]

GE Response:

(b)(4)

[redacted]

(b)(4)

These images are as follows:

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attachment F.

FDA Question #15

(b)(4)

GE Response:

(b)(4)

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(b)(4) [redacted]

[redacted]

[redacted]

[redacted] These images are as follows:

(b)(4) [redacted]

Attachments

Attachment A	(b)(4)
Attachment B	
Attachment C	
Attachment D	
Attachment E	
(b)(4)	
Attachment L	

SECTION 11

Device Description

Revolution CT

11.1 Product Description

The Revolution CT System is a general purpose, high premium, multi-slice CT Scanning system consisting of a gantry, a detector, power distribution unit (PDU), a table, a system cabinet, scanner desktop and associated accessories. It is designed as a powerful fully volumetric CT scanner to provide whole organ imaging capability for the full range of clinical applications with the same or better state-of-the-art image quality and dose performance as the GE (b)(4)

The following paragraphs describes briefly its main components.

Gantry

The system uses a rotating gantry with a cylindrical patient bore that houses the X-ray tube, the high voltage generator and detector. The Revolution CT system features a wide 80cm bore diameter to facilitate scanning larger patients and to ensure flexible access and patient positioning in the gantry. The X- ray tube which is part of the X-Ray source is housed diametrically opposite to the detector. The high voltage generator is the second part of the X-ray source. It provides high voltage to the X-ray tube across the anode and the cathode, along with current to the filament, which is part of the cathode.

The Tube focus to detector distance is (b)(4)
(b)(4)
one rotation in (b)(4) . It also has the capability to rotate (b)(4) seconds per rotation .

Linear attenuation of X-rays by the patient or object placed on the CT table in the gantry opening is measured at the detector as the gantry rotates around the object.

The Revolution CT system uses the **Performix™ HDw X-Ray Tube**. (b)(4)
(b)(4) The tube is (b)(4)
(b)(4) can be used for higher-resolution images, while the
(b)(4) operation at higher mA.

Detector

The CT Detector is a wide coverage cone beam detector with multiple detector rows along the longitudinal plane. The Detector channels are arranged as an arc diametrically opposite to the Xray tube on the rotating CT gantry. The detector consists of a scintillator that converts X-rays into light, diodes for light conversion into current and analog to digital converter that converts the current into digital signal.

The Data Acquisition System (DAS) samples each detector cell up to (b)(4) times per gantry rotation, amplifies and quantifies the current from the cells and transmits the resultant data to reconstruction engine. It consists of (b)(4) available input channels and operates at a sample rate (b)(4)

The detector is a full 160mm detector. It allows 256 rows of data to be collected at a time for both axial, helical, and Cine imaging. This allows 256 axial images to be generated in a single gantry rotation in the axial mode. The 256 rows of this detector are comprised of cell elements with an effective pitch of 0.625 mm at isocenter.. Each row consists of (b) detector elements used for imaging. resulting in (b)(4) total data elements.

In addition, the detector features a (b)(4) layout and a (b)(4) (b)(4) to minimize uniformity & scatter artifacts associated with wide coverage systems.

Patient Table

The Table provides support and vertical/longitudinal motion of the patient relative to the CT scanner. The Table also mechanically houses and electrically interfaces to the integrated ECG unit. This subcomponent includes patient positioning and support accessories (pads, straps, poles, head holders) as well as foot pedals.

The patient table has the capacity to hold up to (b)(4) distributed load with (b)(4) positional accuracy for a scannable range up to (b)(4) The table is capable of (b)(4) travel speed. This enables fast scanning for longer range anatomies.

Scanner Desktop

The Scanner Desktop (Operator Console) provides the software user interface in the control room of the scanning suite for all system operations. It governs system operation and workflow until user confirms a scan prescription (resuming control after scan completes), and includes both the software and console hardware.

The Scanner Desktop uses (b)(4) Information Technology Equipment class computer consisting of a (b)(4)

System Cabinet

The System Cabinet subcomponent provides (b) processing, image reconstruction, post processing and scout image construction operations on data available from scan data management. It includes both the software and computer hardware for image generation and scan data acquisition.

Transaxial images are generated using (b)(4) (b)(4) . The reconstruction engine is custom-designed for CT image generation. The scanner also can use (b)(4) .

Additional details about the Revolution CT Scanner can be found in the product data sheet as well as in the Operator Manuals found in **Section 13** of this submittal. Photographs of the product can be found in section 11.3 of this submittal.

11.2 Options and Accessories

The following peripheral devices, software options and accessories are designed and verified to work with the Revolution CT System.

- (b)(4)

The following are the software options of the Revolution CT:

- (b)(4)

Additional information concerning options and accessories associated with Revolution CT scanner can be found in the product data sheet included in Section 13 and in the Technical Reference Manual – Chapter 1 included in Section 13.

11.3 Product Photographs

A. (b)(4) Scanner System viewed from the end of the patient table.

(b)(4)

D. (b)(4) Patient Table

Revolution CT

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Introduction

GE's Revolution CT is a breakthrough that delivers uncompromised image quality & clinical capabilities through the convergence of coverage, spatial resolution, temporal resolution & dose performance – all in one. Until now, CT users had to compromise between systems that could only provide a subset of these capabilities. The Revolution CT delivers industry leading technical specifications for a premium CT system:

- ✓ 160 mm coverage Gemstone Clarity Detector
- ✓ Intelligent motion correction for 29 ms effective temporal resolution[1]
- ✓ Best in class 0.23 mm spatial resolution
- ✓ 80 cm bore size

The system is designed to use less radiation dose than the previous generation product while maintaining the same superior level of image quality[2]. Further, the fast speed of the scan could potentially reduce contrast volumes. The hardware platform is also capable of supporting Fast kV switching and 0.2s[3] rotation speed. The system has been tested to withstand in excess of 75G's of acceleration forces at 0.2s rotation speed. Key technology enablers include:

- A unique image chain hardware and reconstruction for uncompromised image quality, overcoming the challenges of typical wide detector systems such as cone beam artifacts, HU uniformity, scatter & beam hardening artifacts, while improving dose performance.
- Integrated advanced iterative reconstruction technology (ASiR-V) reduces noise, even at very low signal levels. This technology is designed to deliver reduced noise levels, improved low contrast detectability and may enable a reduction in dose[4] for all clinical applications.
- Best effective temporal resolution enabled by 0.28 second rotation speed combined with intelligent motion correction for excellent cardiac imaging at any heart rate
- A wide 80 cm bore to image all patients, allow better patient positioning & access

Thanks to its innovative design, the Revolution CT delivers breakthrough clinical applications for all anatomies:

- 1-Beat High definition, motion free coronary images at any heart rate with intelligent motion correction
- 1-Beat, comprehensive cardiac assessment for every patient at low dose - coronaries, rest / stress perfusion & function
- 4D imaging capabilities for all anatomies enabled by whole organ acquisition to visualize vascular flow, organ motion or kinetic properties
- Dynamic, low dose perfusion studies up to 16cm for cardiac, neuro or body applications with no table motion, personalized coverage & sampling
- Ability to acquire Perfusion and CTA data from a single exam
- Dedicated HD cardiovascular and head / neck angio in a single low dose exam for comprehensive stroke workup
- Sub-second scans for typical trauma and pediatric sedation-free exams, enabled by wide detector and fast table speed at up to 300 mm/sec
- Rapid & comprehensive TAVI planning with dedicated protocols allowing ECG gated and non-gated acquisitions in a single exam

Revolution CT has been designed with future onsite hardware upgradability as a key goal to ensure longevity of the state of the art technology to help you continually provide best in class care to your patients.

Indications for Use

The Revolution CT Computed Tomography X-ray is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission projection data from the same axial plane taken at different angles. The system has the capability to image whole organs in a single rotation. Whole organs include but are not limited to brain, heart, liver, kidney, pancreas, etc. The system may acquire data using Axial, Cine, Helical, Cardiac and Gated CT scan techniques from patients of all ages. These images may be obtained either with or without contrast. This device may include signal analysis and display

[1] Intelligent motion correction with SnapShot™ Freeze is designed to reduce blurring artifacts due to motion in coronary vessels that cannot be addressed by gantry speed alone. Providing up to a 6X improvement, while maintaining high spatial resolution, the reduction in motion artifacts is equivalent to a 0.058s Equivalent Gantry Rotation Speed with Effective Temporal Resolution of 29msec as demonstrated in cardiac phantom testing

[2] Image quality is defined as standard deviation of noise. Radiation dose is defined as CTDIvol and DLP. In clinical practice, a consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task

[3] Option. May be available in the future

[4] In clinical practice, the use of ASiR may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

equipment, patient and equipment supports, components and accessories.

This device may include data and image processing to produce images in a variety of trans-axial and reformatted planes. Further, the images can be post processed to produce additional imaging planes or analysis results.

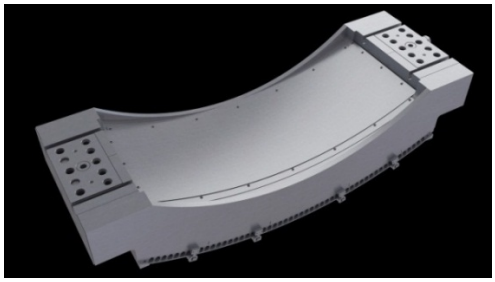
The system is indicated for head, whole body, cardiac, and vascular X-ray Computed Tomography applications.

The device output is a valuable medical tool for the diagnosis of disease, trauma, or abnormality and for planning, guiding, and monitoring therapy.

Gemstone Clarity Detector

The scanner features next generation "Gemstone Clarity" detector with ground breaking technology and also features Gemstone scintillator with the industry's best primary speed & afterglow specifications.

The Gemstone Clarity detector features a unique focally aligned layout of the detector sub-modules and a 3D collimator (post patient) to minimize scatter artifacts, ensure HU uniformity & reduce beam hardening artifacts associated with wide coverage systems. Combined with VHD reconstruction technology, the system delivers excellent image quality at full 160mm coverage to enable whole organ imaging. Further, the 3D Collimator reduces scatter to primary ratio by more than 50% compared to a 160mm system with a 1D post patient collimator.



The Gemstone Clarity detector also features a revolutionary ultra-low capacitance photo diode with new ASIC technology that redefines electronic noise at the quantum limit to less than 3 photons @ 120 keV (3100 electrons). The detector includes acquisition electronics which allow 4x faster bandwidth and 3x faster trigger rate than previous generations and reduces electronic noise by 25% which may improve image quality and reduce artifacts in low signal conditions as may be encountered in large patients. This allows for unparalleled high definition imaging at full 160mm coverage & support for 0.2s[5] rotation speeds.

The detector also features a source side reference channel design to allow you to leverage the 80cm bore fully with 50 cm scan field of view while ensuring that neither the patient nor any patient attached equipment blocks the detectors X-ray reference channels.

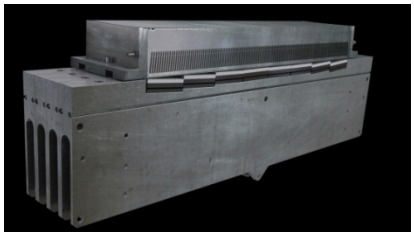
Gemstone Scintillator

The Gemstone Clarity detector enables high definition CT imaging with a revolutionary, extremely fast scintillator. The scintillator material is an isotropic ceramic with cubic structure – highly uniform and translucent. (Cubic structures offer better transparency to that of Gadolinium Oxysulfide (GOS) which has a hexagonal lattice).

The relative speed of the scintillator enables High Definition technologies such as High Resolution imaging capability, with less noise and the ability to perform fast kV switching that may enable applications such as dual energy acquisitions.

- **Scintillator speed :** 0.03 µs (100 times faster than GOS)
- **Afterglow:** 0.001% - 4 times lower than GOS
- **Radiation damage:** 0.03% - 20 times less than GOS
- **Scatter to Primary Ratio** < 10%
- **Detection efficiency:** 98% @ 120 kVp

3D Collimator scatter reduction technology



Reduces scatter to primary ratio by more than 50% and results in significant improvement in image quality and reduction in beam hardening & metal artifacts.

Gemstone Clarity Data Acquisition Subsystem (DAS)

The Gemstone Clarity Data Acquisition Subsystem (DAS) features 3 times faster trigger rates capable of supporting features such as High definition imaging up to 2496 views per rotation and fast kV switching mode with 1968 views per rotation even at 0.2s[6] rotation speed.

Detector specifications	
z-Coverage/ 360° rotation	**16cm**
Number of slices	512 slices

[5] Option. May be available in the future

[6] Option. May be available in the future

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Number of detector rows	256
Number of detector elements	212,992 cells with individual electronic / DAS channels for excellent data fidelity
Number of views	Up to 2,496 views per rotation
Electronic noise	Less than 3 photons noise (3100 electrons)
Effective analog to digital conversion range	> 2,000,000:1

VHD Reconstruction (Volume High Definition)

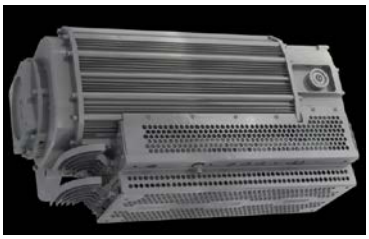
The system features state of the art image reconstruction technology designed to mitigate cone beam artifacts associated with wide coverage systems. In addition, the algorithm preserves temporal uniformity and provides excellent image quality at full 160mm coverage. It further reduces variation in iodinated contrast HU uniformity across the full 16cm Z coverage, typically caused due to heel effect. In addition, Multi Material Artifact Reduction (MMAR) technology utilizes material physics learning's from GSI in to single energy acquisition and in conjunction with 3D Collimator, reduces beam hardening artifacts due to iron, bone, metal & other dense objects.

Tube & Generator

Performix™ HDw X-Ray Tube

Performix HDw is a next generation anode-grounded, metal-ceramic x-ray tube The tube enables improved spatial resolution via dynamic in-plane focal spot deflection and independent control of the focal spot size in both X and Z-axis optimizing the focal spot to deliver consistent beam quality across the full 160mm Z-axis coverage, making it one of the most innovative CT tubes offered today. The design is optimized for exams requiring a large number of scans without tube cooling. It is powered by an onboard high frequency generator capable of ultra-fast kVp switching.

Ultra-fast kV switching generator



The new generator features 3 times faster rise & fall times for kV switching compared to previous generator. This would allow for more time to be spent at the target energy levels and result in better energy separation between the datasets acquired at different kV levels using fast kV switching.

Tube & Generator specifications	
Generator Maximum peak power	103 kW
Tube current range	mA: 10 to 740, 5mA increments
Tube voltage	kVp: 70, 80, 100, 120, 140
Thermal ratings	Efficient anode heat transfer and casing design eliminates inter-patient delays for demanding helical scans - Anode: Max anode heat content: 4.1 MJ (5.5 MHU) Max anode input power: 103kW - Housing: Max x-ray tube assembly heat content: 5.0 MJ (6.8 MHU) Max continuous heat dissipation: 3.0 kW
X-Ray Tube Housing Assembly	Anode-Grounded Technology • Nominal tube voltage: 140kVp • Leakage technique factor: 140 kV, 14.3 mA • Quality equivalent filtration: Min 3.9mm Al equiv at 75 kV
Tube insert focal spot	
Small Focal Spot (580 max mA)	- 1.0 x 0.7 per IEC 60336/2005
Large Focal Spot (720 max mA)	- 1.6 x 1.2 per IEC 60336/2005

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X-Large Focal Spot (740 max mA)	- 2.0 x 1.2 per IEC 60336/2005
Target Angle	10.5 degrees

Performix HDw Tube License

The GE Performix HDw tube includes a standard license that automatically enables the use of tube dependent advanced applications. The use of a third party X-ray tube will require an additional license for the activation of these features.

Gantry & Slipring

Revolution CT's gantry platform has been designed from ground up and tested to support rotation speeds as fast as 0.2s[7] / rotation. It also features a wide 80cm bore diameter to facilitate scanning larger patients and to ensure flexible access and patient positioning in the gantry. The slip ring is designed for transferring data at 40 Gbps. To ensure safe & reliable performance at these fast rotation speeds, the gantry platform features the following state of the art technology:

Whisper Drive system

Reduces audible noise during gantry rotation at 0.28s by more than 50% compared to a typical belt driven system rotating at 0.28s / rotation speed, thus improving patient comfort (69 dBA)

Contactless Slipring

Transfers power and data to and from the rotating side of the gantry (slip ring) to the stationary side through contactless RF technology. This eliminates carbon dust due to brush wear-out in typical CT systems thereby increasing the reliability of the system.

Fail-safe mounts

The gantry frame features redundant fail-safe mounts for all major components that is designed and tested to stringent standards to ensure safe and reliable operation even at 0.2s rotation speed.

Laser Alignment Lights

Define both internal and external scan planes to ± 1 mm accuracy. Activated any time during exam (with tube stationary)

Gantry displays and controls

- The Gantry features a large LCD that displays patient information and ECG data from the integrated ECG module. This display can also be configured to show patient informational videos, etc.
- Built-in **patient breathing lights** and countdown timer
- Cardiac gating indicator light
- Start scan button with countdown to X-ray on
- Scan plane toward front of gantry for improved positioning access
- Biopsy and interventional studies have been facilitated through a more streamlined gantry shroud, and bilateral table/gantry controls and gantry display that maximize maneuverability while working next to the gantry
- Flexible cable management system includes coordinated straps that can be attached to the gantry sides to keep cables connected to the gantry away from the floor and to reduce clutter

Gantry specifications	
Aperture	80 cm
Distance Focus to detector	109.7 cm
Distance Focus to isocenter	62.6 cm
Scan Field of View	50 cm
Rotation time	VariSpeed technology: 360° in 0.28 to 1.0 sec (Note : The hardware platform has been designed and safety tested for unprecedented rotation speeds up to 0.2s[8] / rotation)
Temporal Resolution	140ms cardiac temporal resolution; 29ms effective cardiac temporal resolution using SnapShot Freeze intelligent motion correction
Data chain bandwidth	40 Gbps

[7] Option. May be available in the future

[8] Option. May be available in the future

510(k) pending at FDA. Not available for sale in the United States. Not yet CE Marked, not available for sales in all regions

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Table (Patient positioner)

Revolution CT features a next generation table capable of 300mm/s travel speed. This enables fast scanning for longer range anatomies.

The table has also been designed with 10x more stiffness to reduce deflection under heavy load and provide the best possible images even under heavy load conditions.

Table specifications	
Vertical Range	50 cm to 100.1 cm
Vertical scannable range	73.1 cm to 100.1 cm
Elevation Speeds	15(±3) mm/s and 48(±3) mm/s
Horizontal Range	200 cm
Horizontal Scannable range (metal free)	• 200 cm in Axial • 185 cm in helical • 5 - 200 cm in scout
Horizontal speed	**Up to 300 mm/s**
Load capacity	**227 kg (500 lb)** maximum allowed with ± 0.06% positional precision over the entire scannable range.

The table features:

- Controls on gantry for elevation and cradle movement. Foot pedals on both sides of table for fast elevation. Cradle position controlled from OC for prescribed scans.
- Integrated ECG module with waveform and configuration through the gantry display
- Workflow hub area with a see through tray to give you the most flexibility in placing scanning related supplies, etc. without limiting visibility to the integrated ECG inputs
- IV Pole integrated at the foot-end of the table helps to prevent IV lines from becoming crossed and tangled, and helps keep lines in place during patient table travel

Operator console

The Revolution CT scanner desktop allows simultaneous scanning, image reconstruction, display, processing and analysis, as well as networking, archival and filming.

It features the new "Clarity Operator Environment" designed with your everyday needs in mind. The environment allows for more real time adaptive capabilities thus enabling improved timing with Smart Prep including automatically transitioning acquisition when the set HU threshold is reached. The benefits provided by the new interface include:

- Smart prescription workflow automates scan set up by recommending scan parameters specific to the patient based on scout attenuation and ECG information, in the case of cardiac, to enable consistent image quality & dose performance across scans, irrespective of the technologist expertise level
- Seamless multi-tasking through ability to have multiple patient sessions open with one active patient for acquisition and the rest for post-acquisition tasks
- "Plan ahead" task list as part of scan setup automates repetitive tasks such as reconstructions, image transfer, image processing, etc. without requiring technologist intervention
- Ability to prospectively prescribe multi planar reconstructions for anatomies such as spine as part of the protocol, thus automating the workflow seamlessly
- Clear status visibility across all automated patient tasks without any interaction enables you to focus on the primary task at hand
- Manage your patient flow better with the ability to prepare scan prescription for the next patient while the current patient is getting off the table
- Quickly select scan protocols through global search, anatomical selection or user specific favorites in the newly designed protocol management system
- Facilitates protocol consistency by controlling access to changes and simplifying inputs required
- Integration with AW allows prescribing automatic image processing steps to be performed on the AW / AW Server post acquisition
- Better dose awareness through clearly visible real time projected dose indicator for the selected protocol

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Console specifications	
Host computer	• CPU: Dual Intel Six Core Xeon 2.66GHz 5650 Processors • RAM 48GB DDR3-1333MHz ECC DIMM
Total system storage	up to 700,000 512 images and with 1 TB for scan data files
Additional storage	USB 2.0 Port for External Hard Disk Drive Connectivity

Peripheral components

- 24in 1920x1200 Monitor
- 104-Key USB 2.0 Keyboard
- 3-Button USB 2.0 Mouse
- 3-Button USB 2.0 Trackball
- DVD-ROM, DVD-R, DVD-RW, DVD+R, DVD+RW, CD-ROM, CD-R, CD-RW, DVD+R DL
- 5.25in media
- 8.5 GB Double Sided DVD Media Capacity
- 16X DVD / 40X CD read speed
- Scan Control Interface

Image networking

- Exam Transfer up to 16 frames per second on dedicated 1 Gbit connection
- Standard auto-configuring Ethernet (UTP connection) - 1000/100/10 BaseT
- Direct network connection; multi-suite ethernet card not required for gateway out of suite
- Protocols supported:
  - DICOM network send (one IP address at a time) and receive, pull/query, and storage commitment push - InSite point-to-point
- **Data Export capabilities** to convert clinical images into PC-friendly formats like .jpeg, .mpeg, and .avi.

Smart Flow - Productivity & Workflow features

Simplified, automated scan prescriptions, personalized to the patient and easy-to-use reference protocols make the Revolution CT fast and efficient in patient set-up, prescription & scanning. The following features further help you streamline your workflow.

SmartStart™

- Gantry-mounted start scan button and countdown display,
- Facilitates single-technologist operation by allowing start of scan at the gantry, with a visual reminder of time until X-ray initiation

AutoScan™
Fully automates longitudinal table movement and start of each helical scan.

Auto SmartPrep

Provides software for real-time monitoring of contrast enhancement at a prescribed location & automatically transitions scan when the preset threshold is reached with a turnaround time of < 3 seconds with a table move of 150mm.

Prospective Multiple-Thickness Reconstruction

In addition to the initial reconstructed slice thickness, the operator has the option to prospectively specify up to 9 additional reconstructions from a single raw data set. These images can be reconstructed at any of the defined nominal slice thicknesses available for a given table speed and scan mode along with different reconstruction kernel options.

Queued Reconstruction

Requests will be processed continuously and simultaneously with other processes on the system including scanning. Prospective reconstruction will be prioritized over retrospective reconstruction.

Prospective & Retrospective Reconstruction

Operator may initiate full reconstructions at any table location in increments of 1/10 the image thickness; image thickness remains constant.

Reconstruction speed : Up to 55 frames per second

Retrospective Image Decomposition

The operator has the option to retrospectively decompose the original raw data set and reconstruct additional images at any of the defined nominal image thickness available for a given table speed and scan mode.

Exam Split

Allows multi-anatomical exams to be split in to separate anatomic sections.

Trauma Patient entry

Allows patient scans and image display/analysis without entering patient data before scanning.

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Scan Modes

The Revolution CT system can perform virtually any clinical application due to its wide variety of scan modes.

Axial:

- Up to 160 mm of contiguous axial coverage acquired simultaneously with each 360° rotation, with the time between scans set by the user-selected interscan delay (ISD) or intergroup delay (IGD)
- Scans may be easily clustered in groups to allow multiple scans in a single breath hold
- Minimum scan-to-scan cycle time of < 2 seconds with table moves of ≤ 160 mm (any scan time) and < 1 second without any table move
- Flexible detector coverage & capability to mix collimations from 5 mm to 160 mm

Helical:

- Continuous 360° scanning @ up to 40mm collimation with constant table movement and no interscan delay
- Scans can be acquired in a wide variety of speeds

Mixed mode scans:

- The system allows axial and helical scans or gated / un-gated axial scans to be mixed in a single series acquisition with very short delay of <= 1 second to cover larger than 160mm anatomy

Cine:

- Up to 160 mm of contiguous axial coverage acquired simultaneously with each 360° rotation
- Minimum scan-to-scan cycle time of < 2 seconds with table moves of ≤ 160 mm (any scan time) and < 1 second without any table move

Scout™:

- Single radiographic plane for scan localization and graphical prescription of prospective reconstruction;

  Extended range matches helical scannable range at 0.625mm slice thickness

High Definition Scan Modes: All supported scan modes listed above are also available in High Definition mode

Axial Scan parameters

The Revolution CT acquires 160 mm of axial coverage in one 360° rotation.

For each rotation of the gantry, the Revolution CT collects up to 160mm of scan data. There are varieties of reconstruction modes available for creating images from the multi-slice scan data. By using some of these reconstruction modes, scan data can be combined prior to image reconstruction to create slices with reduced partial-volume artifacts. This is particularly useful for posterior-fossa imaging.

Scan speed	
Routine	0.4 to 1.0 second full scans (360° acquisition);
Cardiac	0.28s
Scan technique	
kVp	70 to 140
mA:	10 to 740, 5mA increments
Focal Spot selection @120kVp	• Small spot for up to 405mA • Large spot for up to 665mA • X-Large spot for up to 740mA
Scan Plane Geometry:	Longitudinal positioning in 0.1 mm per slice increment. Gantry display in 0.5 mm increments.
Aperture	5mm to 160mm
Inter scan Delay (ISD)	Minimum of 1 second with no table movement. < 2 seconds with <= 160mm table move
Inter Group Delay (IGD):	Minimum IGD is the same as minimum ISD; also user-selectable.
Scan-to-Scan Cycle:	Minimum scan-to-scan cycle of 1 second possible for 0.5 seconds scan speed with minimum ISDs.
Maximum Scan Fields of View:	• 32cm for pediatric head & body, adult head and small body, small cardiac • 36cm for medium cardiac • 50cm for medium & large body, large cardiac

Scan with no table increments, contiguous image location, or skipped image locations are possible. Overlapped axial scans are not possible.

Axial image reconstruction

A variety of reconstruction kernels such as Standard, Bone, HD Standard, etc. are available with different contrast & noise characteristics

Number of reconstructed slices	Up to 512 slices per rotation
Reconstruction Matrix	512 x 512
Display Matrix	1024 x 1024
Display FOV	Freely variable center/off-center,

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	prospective/retrospective target selection
CT Number Scale	-1024 to 3072 (normal range) and -31743 to 31743 (extended range)
Reconstructed slice widths	0.625mm to 5mm
Prospective multiple reconstruction (PMR)	Up to 10 sets of recons can be pre-programmed

Helical Scan parameters

The system supports helical mode imaging using beam collimation 64x0.625 with helical reconstruction increment as small as 0.1mm.

Scan speed	
Routine	Full 360° rotational scans in 0.4 to 1.0 seconds;
Pitch range	0.516:1 to 1.375:1
Scan technique	
kVp:	70 to 140
mA:	10 to 740, 5mA increments
Focal Spot selection @120kVp	Small spot for up to 405mA Large spot for up to 665mA X-Large spot for up to 740mA
Reconstructed slice widths	0.625mm to 5mm
Max single acquisition time	60-second scan
Inter Group Delay (IGD):	1 second between adjacent helical scans
Maximum Scan Fields of View:	• 32cm for pediatric head & body, adult head and small body • 50cm for medium & large body

Scan with no table increments, contiguous image location, or skipped image locations are possible. **Helical image reconstruction**

A variety of reconstruction kernels such as Standard, Bone, HD Standard, etc. are available with different contrast & noise characteristics

Reconstruction Matrix	**512 x 512**
Display Matrix	1024 x 1024
Display FOV	Freely variable center/off-center, prospective/retrospective target selection
CT Number Scale	• 1024 to 3072 (normal range) • 31743 to 31743 (extended range)
Prospective multiple reconstruction (PMR)	Up to 10 sets of reconstructions can be pre-programmed
Helical Reconstruction Times	up to 55 fps
Minimum DFOV	5 cm
Minimum Pixel Size	0.0977 mm

Scout Scan parameters

ScoutView™ scans provide excellent detail for anatomical localization in conjunction with scan prescription.

Scan locations may be prescribed at the operator console either graphically (via mouse), or explicitly (keyboard entry) from a Scout scan.

Scan speed	
Aperture	5 mm effective aperture
Table speed	100 mm/s
Scan technique	
kVp	70 to 140
mA	10 to 250, 5mA increments
Orientation	AP, RLAT, PA, LLAT (preset);
Scout range	50 to 2000* mm Scouts longer than 1,000 mm are auto minified to fit the display
Max display FOV	50cm

Image Quality

The Revolution CT is a sub-millimeter isotropic CT scanner making it possible to leverage coronal and sagittal reformats. It preserves the industry leading spatial resolution of Discovery CT750 HD system.

The optimized x-ray source (focal spot shape & dynamics as well as reduced off focal radiation) allows for improved measurement methods to fully characterize the limiting resolution of the Revolution CT system design.

Revolution CT

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High Contrast Resolution

Helical Visual Measurement

Reformatted resolution is demonstrated on the Catphan™ High Contrast Resolution Insert Module CTP528:

0.35 ± 0.05mm voxel size is seen in the reformatted plane.

Spatial resolution

The Revolution CT detector provides high contrast spatial resolution.

Helical scan: Typical MTF is demonstrated on a 0.05mm tungsten wire and a 1.0mm x 0.025mm gold foil phantom for in-plane and z-plane, respectively:

Typical Hi-Res Algorithm Resolution		
MTF	X-Y lp/cm	Z lp/cm
50%	13	7.3
10%	18	12.2
0%	21.4	21.2

Axial scan: Typical in-plane MTF is demonstrated on a 0.05mm tungsten wire. In-plane Spatial Resolution Performance for full scan Axial and Cine Scans:

Typical Hi-Res Algorithm Resolution	
MTF	X-Y lp/cm
50%	13
10%	18
0%	21.4

Low-Contrast Resolution

The Revolution CT Scanner preserves the superior Low Contrast Detectability (LCD) of Discovery CT 750 HD. This may allow for improved visualization of smaller low contrast structures.

LCD is measured on 8 inch (20cm) CATPHAN phantom, 5mm slice thickness, 0.30% (3HU) contrast using helical scan

Reconstruction Mode	Object Size	% Contrast (typical)	Dose level (mGy CTDIvol) 5 mm Slice
Standard Algorithm with ASiR-V	5mm	0.30%	8.8

Image Noise

Image Noise is demonstrated on a 20cm Water Phantom or the GE Quality Assurance Phantom for head protocols using helical technique.

Image Noise
0.45% ± 0.05% at 9.5 mGy CTDIvol with the Standard Reconstruction Algorithm, 5mm Slice Thickness at 0.516:1 helical pitch and ASiR-V

CTDI

Both high resolution and normal scanning modes: On CTDI Head and Body Dose Reference Phantoms:

$CTDI_{vol}$ in mGy/100 mAs (0.984:1 Pitch)	
Head	14.86
Body (large)	6.88

HU Accuracy

Iodine HU Accuracy	Improves quantitative uniformity of iodinated contrast down to within 10 HU (3 % variation) across the whole 160 mm z-coverage[9].

Artifact reduction

Revolution CT's unique VHD reconstruction technology with Multi Material Artifact Reduction (MMAR) models system physics and incorporates material characteristics to significantly reduce typical artifacts such as beam hardening caused due to dense objects such as bone, iodine & metal. Further, it significantly reduces cone beam artifacts inherent to wide coverage systems.

Smart Dose technologies

GE Healthcare develops products based on the idea that both dose and image quality is important in providing quality medical care. To assist you in optimizing each CT exam for your patients, Smart Dose provides solutions to help you manage dose.

[9] based on measurements using a phantom with an iodine-rod in a uniform water background

Revolution CT
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Dose reduction and optimization technologies

ASiR-V

Integrated advanced iterative reconstruction technology (ASiR-V) reduces noise, even at very low signal levels. This technology is designed to deliver reduced noise levels, improved low contrast detectability and may enable a reduction in dose[10] for all clinical applications.

Scout Based Technologies
Enables tailoring the x-ray beam to the patient being scanned. In order to use the optimal amount of dose to achieve the desired image quality, it is important to know the patient attenuation. This information can be generated by the scanner utilizing the scout data, which is then leveraged by our family of Scout Based Technology features:

3D Dose Modulation utilizing SmartmA* and AutomA
Volumetric knowledge prior to scanning allows you to personalize protocols and optimize dose for every patient – large and small. During the scan, real-time, 3D dose modulation helps deliver consistent image quality because it automatically accounts for the changing dimensions of your patients anatomy.

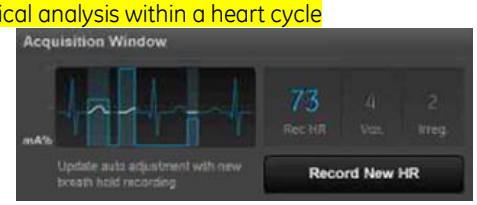
Organ Dose Modulation
Organ Dose Modulation (ODM) builds on the SmartmA feature to enable even further patient dose reduction. By reducing the mA exposure profile as a function of the X-ray tube angle, radiosensitive organs towards the anterior surface of the patient, such as the eyes, breasts and thorax, can benefit from enhanced dose reduction while the overall image noise is still maintained.

kV Assist
Makes it easy to select optimal kV settings for the patient being scanned. Recommends tube voltage and current to achieve the lowest dose while meeting desired image quality

70 kV Scanning
70 kVp scan mode to enable low dose pediatric and small patient scans

ECG Modulated mA

For cardiac applications, prospective ECG dose modulation automatically adjusts the mA to minimize the patient's exposure to X-rays – reducing mA, and thus dose, near the beginning and end of each prescribed phase range. Up to 3 phase ranges are selected within a heart cycle with different mA levels. The peak mA for the first phase range is automatically determined based on noise index set by the user. The user can also select the relative mA level for an optional second or third phase range, set as a percent of the mA level of the first phase range. This provides clear images and allows you to reduce dose yet provides motion free, high quality images for functional and anatomical analysis within a heart cycle



SmartTrack
Advanced hardware and software for X-ray beam tracking minimizes patient dose.

SmartBeam
Optimizes X-ray beam filtration independently for body, head, and cardiac applications.

Dose reporting

Dose Computation, Display & Reporting
CTDIvol (CTDI volume), DLP (Dose Length Product), and Dose Efficiency computation and display during scan prescription provide dose information to the operator.

Dose Reporting
Dose Reporting saves the CTDIvol, DLP, and phantom type in a DICOM Structured Dose Report and a secondary screen capture. Series and cumulative exam values are saved. Saved values can be networked, filmed and archived.

Dose Check
Provides the user with tools to help them manage CT dose in clinical practice and is based on the standard XR-25-2010 published by The Association of Electrical and Medical Imaging Equipment Manufacturers Association (NEMA).

Dose Check provides the following:
- Checking against a Notification Value if the estimated dose for the scan is above your site established value
- Checking against an Alert Value where the user needs specific authority to continue the scan at the current estimated dose without changing the scan parameters if the estimated dose exceeds the alert value
- The ability to define Alert Values for Adult and Pediatric with age threshold
- Audit Logging and Review capabilities
- Protocol Change Control capabilities

CT 4Kids
Dose-optimized procedure based protocols for pediatric imaging

Color Coding for Kids

[10] In clinical practice, the use of ASiR may reduce CT patient dose depending on the clinical task, patient size, anatomical location and clinical practice. A consultation with a radiologist and a physicist should be made to determine the appropriate dose to obtain diagnostic image quality for the particular clinical task.

Provides pediatric scan protocols based on the Broselow-Luten™ Pediatric System. This Color Coding system is incorporated into the protocol selection on the operator's console and is designed to facilitate pediatric emergency care and reduce medical errors.

Making advanced imaging routine & routine imaging advanced

Cardiac & Cardiovascular

1-Beat, High definition, motion free coronary images at any heart rate is enabled by a prospectively ECG-gated whole heart cardiac axial acquisition protocol that utilizes 160mm of high-definition coverage with 0.28s rotation speed and real-time control to complete the scan in a single beat to ensure robust, low dose and high definition cardiac imaging for all heart rates, with or without beta blockers

- Intelligent motion correction with SnapShot™ Freeze is designed to reduce blurring artifacts due to motion in coronary vessels that cannot be addressed by gantry speed alone. Providing up to a 6X improvement, while maintaining high spatial resolution, the reduction in motion artifacts is equivalent to a 0.058s Equivalent Gantry Rotation Speed with Effective Temporal Resolution of 29msec.[11]
- For cardiac scan modes, Revolution CT provides best in class spatial resolution at 18.2lp/cm in z-direction and 14.8lp/cm in X-Y direction (measured at 2% MTF). This spatial resolution provides clear images to help the physician with tasks such as accurately quantifying stenosis in coronary and other vascular structures
- This scanning technique ensures IV contrast uniformity & temporal uniformity across the whole volume with the ability to prescribe up to 3 phases to acquire prospectively within a single beat

1-Beat, comprehensive cardiac assessment allows for acquiring motion free coronaries, rest or stress perfusion and functional data in a single beat, giving you a comprehensive assessment and potentially reducing the need for additional imaging tests. Integrated beam hardening reduction capabilities allows for accurate perfusion assessment. The ability to perform stress perfusion with motion free CCTA in a single exam can potentially reduce unnecessary dose by not requiring a rest perfusion exam in case no defects are found in the stress perfusion.

Dynamic Acquisition Modes

The Revolution CT allows for whole organ dynamic perfusion acquisition with up to 16 cm of coverage, this allows perfusion acquisition of the heart, brain, liver, kidneys and other organ and tissues with uniform contrast along with integrated beam hardening reduction. The scanner also allows for a flexible aperture size and sampling rate during dynamic perfusion acquisitions, which is particularly beneficial in localizing anatomy of interest for brain and other perfusion acquisitions. This is enabled by selecting supported collimations between 5mm to 160mm for selecting the aperture size and selecting different sampling rate groups depending on the phase of the contrast. Typically a faster sampling rate when the contrast bolus is arriving in the tissue followed by a slower sampling during washout.

Revolution CT also allows for the ability to acquire a prospectively gated dynamic perfusion acquisition of the whole heart using up to 16 cm of coverage.

The scanner is also capable of **4D imaging** to acquire morphology and perfusion information from a single exam. This can help assess conditions such as congenital heart disease and visualize blood flow through vascular structures.

Scanning for TAVR planning
Dedicated TAVR protocols allow mixing of ECG gated cardiac axial acquisition with non ECG gated modes covering the 700mm anatomy in less than 10 seconds.

Calcium Scoring
The system also allows single beat acquisition for cardiac calcium scoring

Triple Rule Out™
The system allows for robust Triple Rule Out studies with motion free coronaries, PE & aorta evaluation in a single exam. The system can cover the entire thorax anatomy in under 3 seconds to provide contrast uniformity at low dose.

Smart Cardiac
The system has been designed to improve the robustness of cardiac exams for patients with high or irregular heart rates and in situations involving irregular heartbeats, arrhythmia, atrial fibrillations, PVC's, etc. The system can monitor and alert the user to these situations and also recommend turning on a challenging patient mode. This mode avoids scanning during an irregular beat and can further rescan during the next regular beat using the same contrast bolus.

[11] As demonstrated in cardiac phantom testing

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Neurology

Comprehensive Stroke workup is enabled by one touch dynamic acquisition mode in Revolution CT. Very low mA acquisition with smart smoothing in image processing application results in accurate perfusion metrics at very low doses

The Revolution system is also capable of acquiring neuro perfusion and CTA of the brain in a single exam to enable comprehensive functional & anatomical assessment of the brain.

The system can also acquire cardiac function, CCTA and a head / neck angio in a single exam using a single contrast bolus to perform a comprehensive cardiovascular and neuro assessment using multi-volume scan mode.

Routine head scans can be performed in less than a second single rotation with excellent gray white matter and bone / brain interface separation. VHD reconstruction technology with integrated artifact reduction reduces beam hardening artifacts in the posterior fossa region.

Body & Oncology

Whole organ diagnosis & follow-up
Low dose, whole organ diagnosis & follow up of organs such as the liver, kidneys, pancreas, etc. is enabled by dynamic acquisition modes. The scanner can also acquire multiple images at the same location over time to provide a 4D view to assess vascular flow to these organs.

Fast body scans enabled by multi-volume 16cm acquisition with excellent image quality allows for reduced breath hold times and shallow breathing. Dose is minimized through the ability to select collimations between 5mm and 160mm personalized to each patient.

Emergency & Trauma

The system allows for robust Triple RuleOut™ acquisition for all patients providing 1-Beat, HD, motion free coronaries, PE & aortic dissection in a single exam covering the entire thorax in less than 3 seconds. ECG gating and mA modulation along with flexible collimations enable low dose acquisition personalized to the patient.

Split second scanning up to 16cm combined with fast table speed of 300 mm/s allows for ultra fast scanning, thus reducing the effect of breathing and other motion during the scan.

Custom scan modes that enable scanning multiple anatomical regions in a single exam combined with UI capabilities to prescribe multi planar reconstruction prospectively enables fast trauma scanning on this system.

Pediatrics

Split second pediatric trauma acquisition of abdomen / pelvis is enabled by wide 16cm z-coverage, thus reducing the need for sedation and eliminating unnecessary repetition of scans in young children due to failed sedation, as is the case in 29%[13] of conventional exams, shown in a large trial.

70kV scan mode allows for minimizing dose to pediatric patients while preserving excellent contrast to noise ratio and image quality.

Musculo Skeletal Imaging

The Revolution CT can acquire high definition images of the bone with excellent detail & significantly reduced artifacts from metal objects such as screws and plates.

4D imaging mode can acquire kinetic studies to assess joint articulation up to 16cm coverage.

DICOM Conformance Standards

DICOM Interchange
Allows the saving of any image from the database, along with a PC viewer using Internet Explorer, to a CD-R or DVD-R without marking the exam/series or image as archived for exam transfer between stations that are not networked or pass along to referring physicians or patients.

For detailed information, please reference DICOM conformance statement.
- DICOM Storage Service Class
- Service Class User (SCU) for image send
- Service Class Provider (SCP) for image receive
- Service Class User (SCU) for storage commitment
- DICOM Query/Retrieve Service Class
- DICOM Modality Worklist
- DICOM Modality Performed Procedure Step
- DICOM Print

Image Networking
Exams can be selected and moved between the Revolution CT and any imaging system supporting the DICOM protocol for network send, receive and pull/query.

Image transfer time using DICOM protocols is > 16fps on a 1000baseT network.

Siting Requirements

Easy, convenient siting of the Revolution CT allows for installation in a space as small as 24.3m² (261 square feet) and fits in the same space as Discovery CT750 HD, thus eliminating the need for renovating the space.

[13] British Journal of Anaesthesia, 84 (6), 743-8 (2000)

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For siting requirements, see "Revolution CT Pre-Installation Manual"

Industry Standards

The Revolution CT complies with a wide variety of industry standards to facilitate more rapid adoption of features and performance improvements as the computing and medical imaging industry evolves.

Compatible Options

The following options are available on the Revolution CT and operator console. Some of these may be standard and some might require optional purchase. See Advantage Workstation (AW) product data sheet for list of available AW options.

Scanner & Operator console options

Base software:

Connect Pro
Exam Split
Direct MPR
SmartPrep
3D Dose Modulation
5000 image series
Copy composer
Data Export
ECG Viewer
AWE Connection
Xtream Recon (55 fps)
Scout based technologies (Snapshot Assist, kV Assist)

Standard Software Options

256 slice
High Definition
0.28s rotation speed
70 kV Scan modes
Volume Viewer
1-Beat cardiac
512i Overlap reconstruction
Dynamic Transition
Prospective Reformats
Organ Dose Modulation
Digital Tilt

Other options / accessories

Operator console table
CT Perfusion 4 Neuro
CT Perfusion 4 Multi-organ
Enhanced Xtream Injector Class IV
Tube License
NG2000 Table slickers
Bar code reader
Uninterruptible Power Supply
Supported Class IV injector

Standard, Selectable Items

The GE Performix HDw tube includes a standard license that automatically enables the use of tube dependent advanced applications. The use of a third party X-ray tube will require an additional license.

- NG Patient Positioning System
- Keyboard: English, French, German, Scandinavian, Danish, Dutch, Italian, Norwegian, Spanish, Swedish, Portuguese or International (with overlays for English, French, German, Italian, Japanese, Mandarin, Portuguese-Brazil, Portuguese-European, Spanish, Korean, Estonian, Finnish, Hungarian, Lithuanian, Polish, Romanian, Slovakian, and Turkish)
- Cable Set
- ConnectPro HIS/RIS Interface with Performed Procedure Step)
- Operator console table with adjustable height

Warranty

The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation.

Regulatory Compliance

This product is designed to comply with applicable standards under the Radiation Control for Health and Safety Act of 1968.

This product complies with the performance standards of 21 CFR, sub-chapter J, and the applicable IEC 60601-1 series.

Laser alignment devices contained within this product are appropriately labeled according to the requirements of the Center for Devices and Radiological Health.

This product satisfies regulations regarding Electro-Magnetic Compatibility (EMC) and Electro-Magnetic Interference (EMI), pursuant to IEC-60601-1-2.

Revolution CT may not be available in all markets.

GE Healthcare
Milwaukee, USA - Fax: 1 262 544 3384
Tokyo, Japan - Fax: 81 425 85 5490
Paris, France - Fax: 33 1 30 70 94 35

510(k) pending at FDA. Not available for sale in the United States. Not yet CE Marked, not available for sales in all regions

Introduction

Title

(b)(4) performances test procedure

Purpose

This document describes the detailed activities and acceptance criteria to assess GSI/ Fast kV performances

(b)(4)

Acronyms

(b)(4)

Design output

Introduction

The design output being verified is described in the following tables.
It shall be filled prior to any test.

The softwares embedded on the product are included in the BOM of the board they are installed on, and are also detailled in the table "software".

Revision and serial number of configuration used during test shall be filled by the tester.

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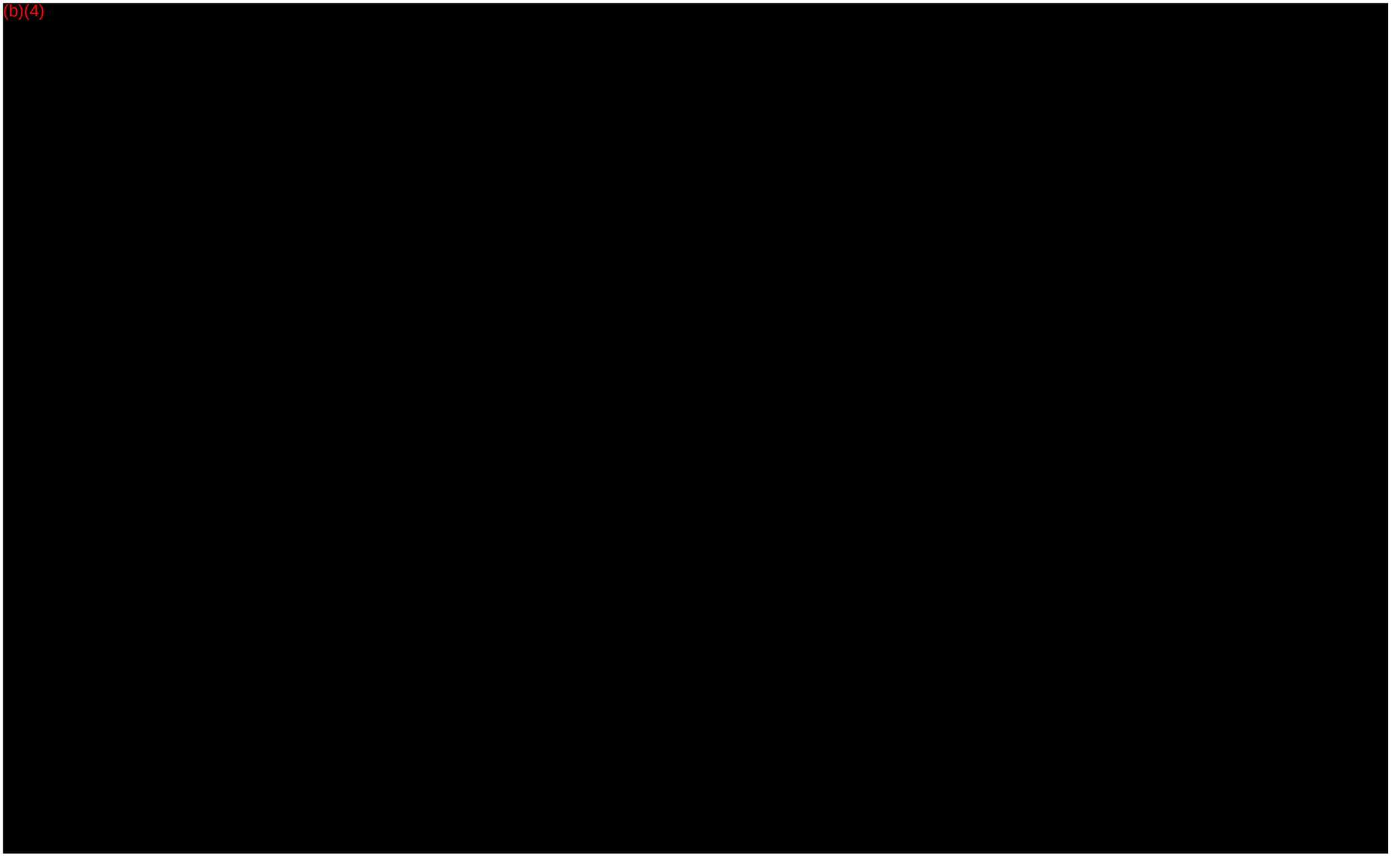

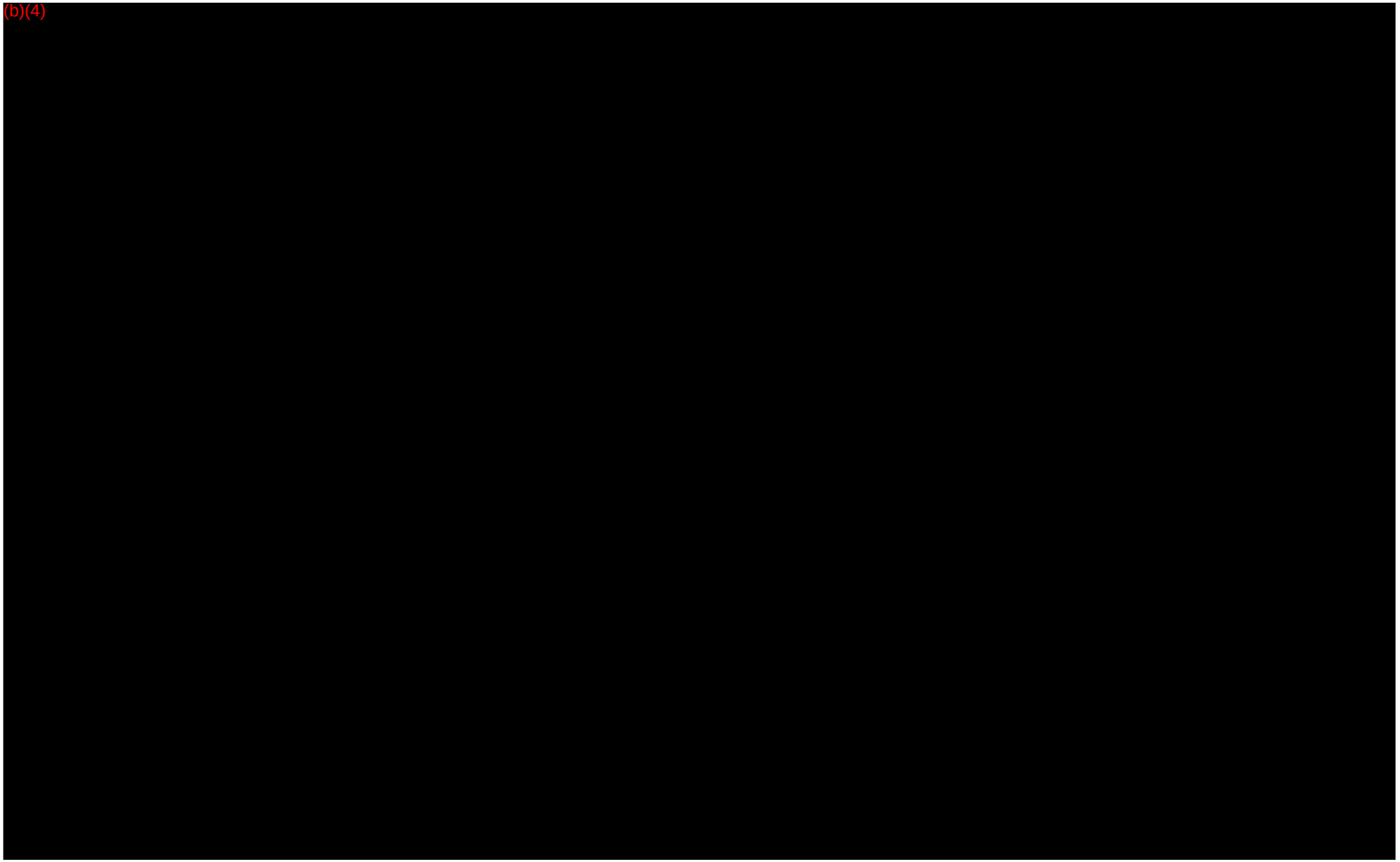

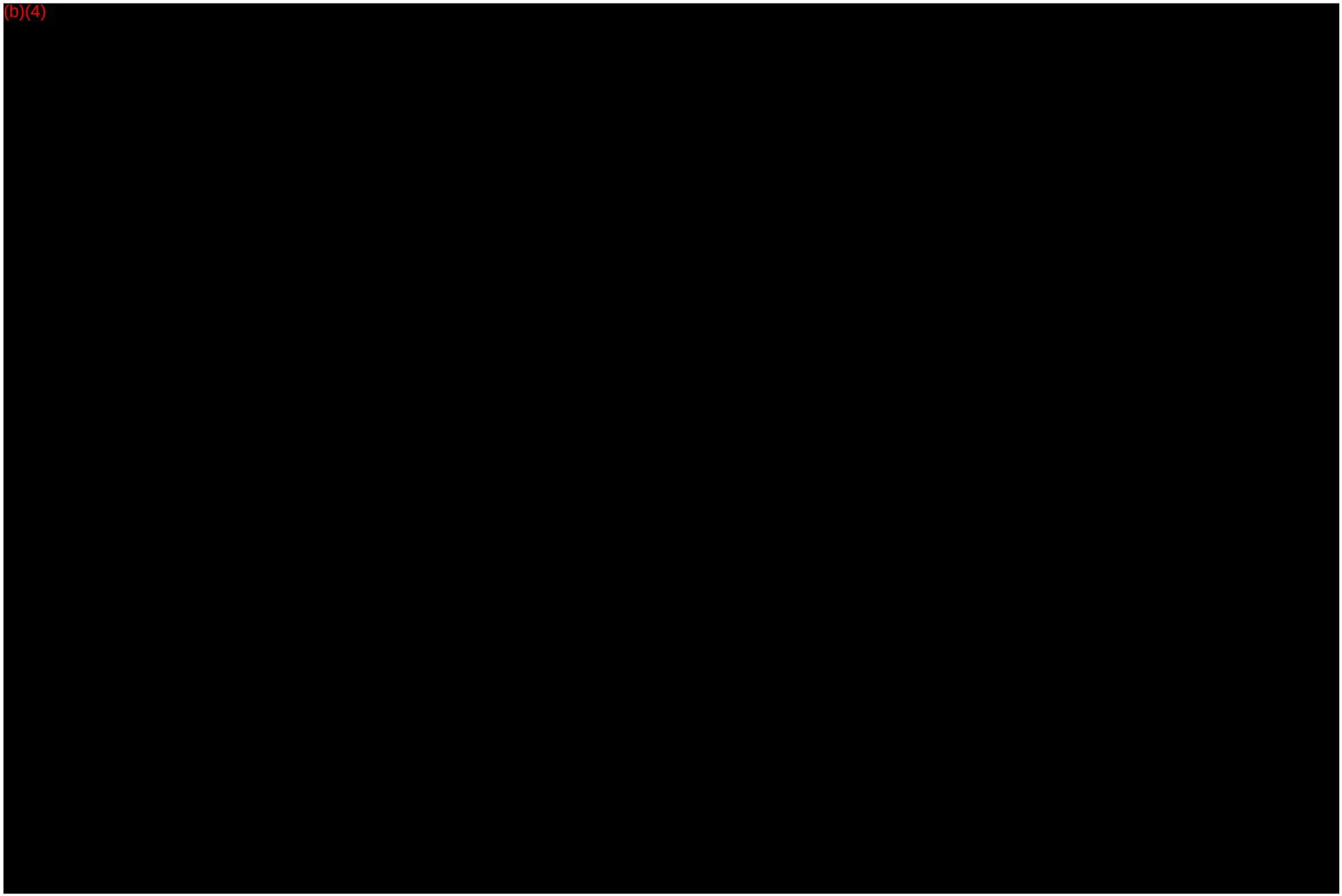

Introduction

Title

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Purpose

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Revolution (b)(4) Performance Description

Contributors	Role
(b) (6)	Senior Scientist, (b)(4) Technologies

(b)(4)

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1. Revolution Performance Description

1.1 (b)(4)

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In conclusion, based on the (b)(4) data, the (b)(4) that can be recommended by (b)(4) result in higher (b)(4)
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[redacted]

Clinical Data

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References

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[redacted]

GE Healthcare

Technical Publication

Discovery™ CT870

Software Version (b)(4) [redacted]

Application Tips and Workarounds

(b)(4) [redacted]

Revision 2

GE Medical Systems does business as GE Healthcare

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DAMAGE IN TRANSPORTATION

All packages should be closely examined at time of delivery. If damage is apparent write "Damage In Shipment" on ALL copies of the freight or express bill BEFORE delivery is accepted or "signed for" by a GE representative or hospital receiving agent. Whether noted or concealed, damage MUST be reported to the carrier immediately upon discovery, or in any event, within 14 days after receipt, and the contents and containers held for inspection by the carrier. A transportation company will not pay a claim for damage if an inspection is not requested within this (b) day period.

Call Traffic and Transportation, Milwaukee, WI (b)(4) immediately after damage is found. At this time be ready to supply name of carrier, delivery date, consignee name, freight or express bill number, item damaged and extent of damage. Complete instructions regarding claim procedure are found in (b)(4)

CERTIFIED ELECTRICAL CONTRACTOR STATEMENT

All electrical Installations that are preliminary to positioning of the equipment at the site prepared for the equipment shall be performed by licensed electrical contractors. In addition, electrical feeds into the Power Distribution Unit shall be performed by licensed electrical contractors. Other connections between pieces of electrical equipment, calibrations and testing shall be performed by qualified GE Healthcare Technologies personnel. The products involved (and the accompanying electrical installations) are highly sophisticated, and special engineering competence is required. In performing all electrical work on these products, GE will use its own specially trained field engineers. All of GE's electrical work on these products will comply with the requirements of the applicable electrical codes.

The purchaser of GE equipment shall only utilize qualified personnel (i.e., GE's field engineers, personnel of third-party service companies with equivalent training, or licensed electricians) to perform electrical servicing on the equipment.

IMPORTANT...X-RAY PROTECTION

X-ray equipment if not properly used may cause injury. Accordingly, the instructions herein contained should be thoroughly read and understood by everyone who will use the equipment before you attempt to place this equipment in operation. The General Electric Company, Healthcare Technologies, will be glad to assist and cooperate in placing this equipment in use.

Although this apparatus incorporates a high degree of protection against x-radiation other than the useful beam, no practical design of equipment can provide complete protection. Nor can any practical design compel the operator to take adequate precautions to prevent the possibility of any persons carelessly exposing themselves or others to radiation.

It is important that anyone having anything to do with x-radiation be properly trained and fully acquainted with the recommendations of the National Council on Radiation Protection and Measurements as published in NCRP Reports available from NCRP Publications, 7910 Woodmont Avenue, Room 1016, Bethesda, Maryland 20814, and of the International Commission on Radiation Protection, and take adequate steps to protect against injury.

The equipment is sold with the understanding that the General Electric Company, Healthcare Technologies, its agents, and representatives have no responsibility for injury or damage, which may result from improper use of the equipment. Various protective materials and devices are available. It is urged that such materials or devices be used.

OMISSIONS & ERRORS

Customers, please contact your GE Sales or Service representatives. GE personnel, please use the (b)(4) Process to report all omissions, errors, and defects in this publication.

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LEGAL NOTES

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REVISON HISTORY

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DISCOVERY CT870 (b)(4) – WORKAROUNDS

SCOPE

This manual is only applicable to systems with (b)(4) version software installed.

SYSTEM START UP

- The image database may fail to start up after a powerfail of the system. The image space in the status area will be blank. If this occurs, please call service.

SCAN

- In graphic Rx, click and drag of the mouse right/left on the Start or End handle will adjust the scan location. To avoid this, only use up and down movement when the Start or End handle is selected.
- Contrast Agent, Volume and Rate text cannot be deleted once entered into the preset list. When adding text be careful to enter the correct data.

DISPLAY

- Next/Prior with the page Up/Down key may fail to function in Exam Rx Display. Double click on the viewport to refresh page Up/Down functionality.
- Cross Reference fails to function when the browser contains original and anonymized exam. To avoid this, perform Cross Reference prior to anonymizing the exam.

RECONSTRUCTION

- Image space remaining does not update correctly on the status area. Don't let image space fall below 10,000 images. This will ensure there is room on the system disk to confirm scans and to install reconstructed images.
- Number of images per rotation is not being shown correctly in the image viewer for images reconstructed with overlap recon mode. Use the Image Browser to see the numer of images reconstructed.
- When Start and End locations are updated to less than the scan range in Retro Recon for Cardiac Axial, the number of images reconstructed is greater than the original scan range. Delete the images that are not needed from the Image Browser.

DATA EXPORT

- DVD is not a media type in the Export tab. Place DVD -R media in the CD/DVD drive and select CD as the media type to export to DVD –R

NETWORK

- The network transfer status indication in the image browser may be lost after a reboot of the system. Image transfer staus can be verified by checking for the images on the remote destination or by using the Job history from the Image Browser.

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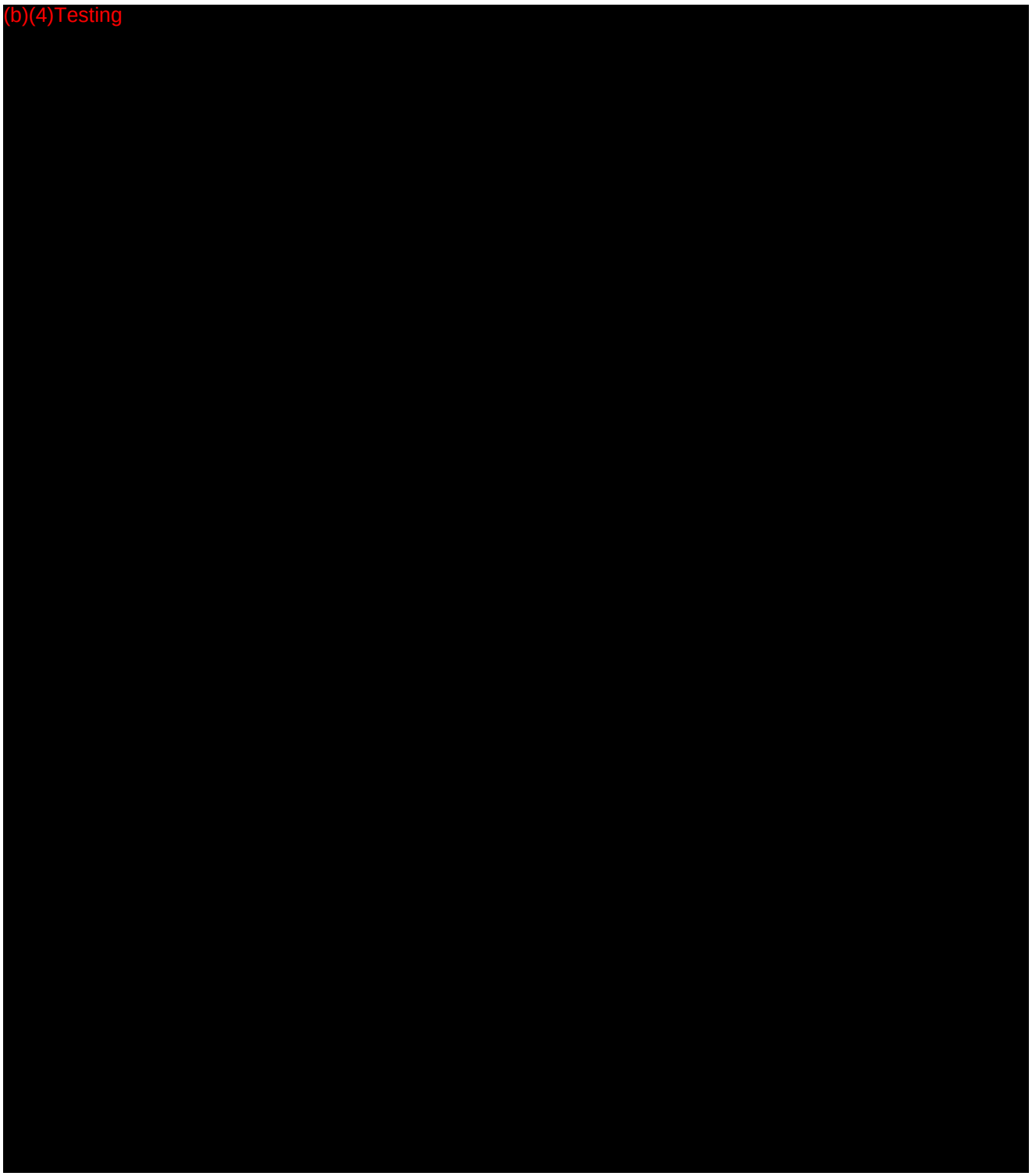
GE Medical Systems, a General Electric Company, going to market as GE Healthcare.
3000 N. Grandview Boulevard
Waukesha, Wisconsin 53188
USA

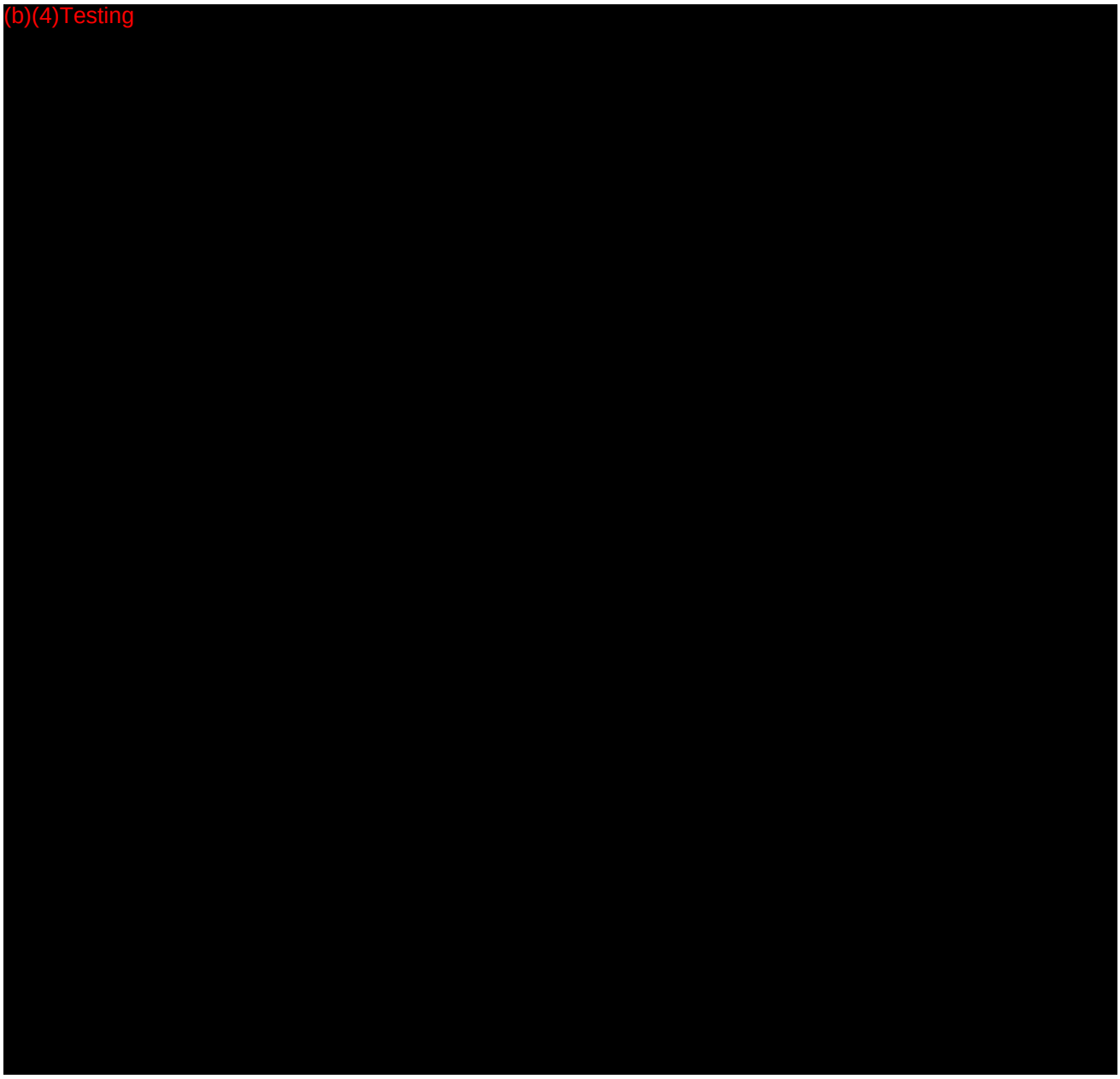
(b)(4)Testing **Testing**

Phantom: (b)(4)Testing

(b)(4)Testing



(b)(4)Testing



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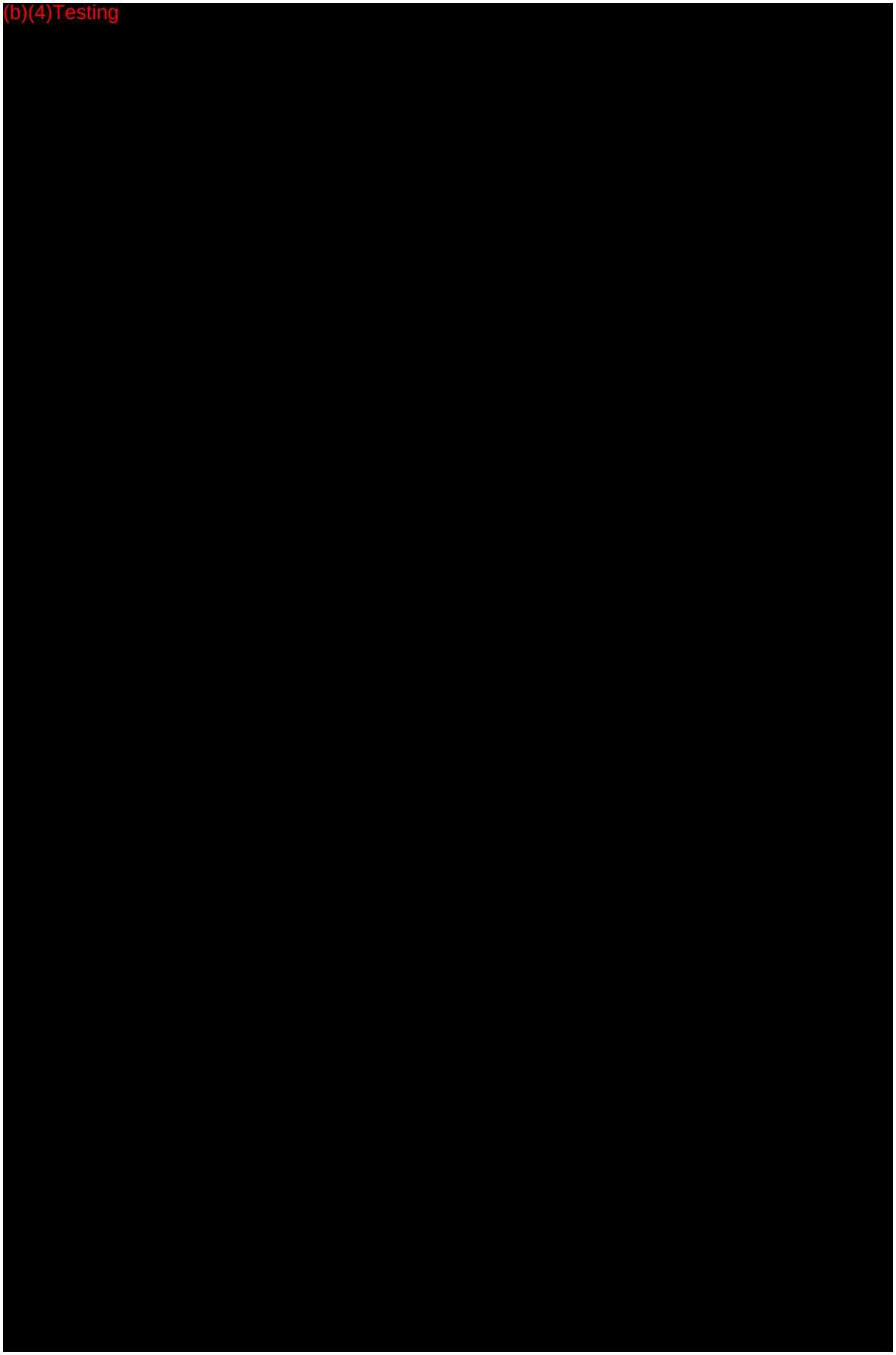

Conclusions: (b)(4)Testing

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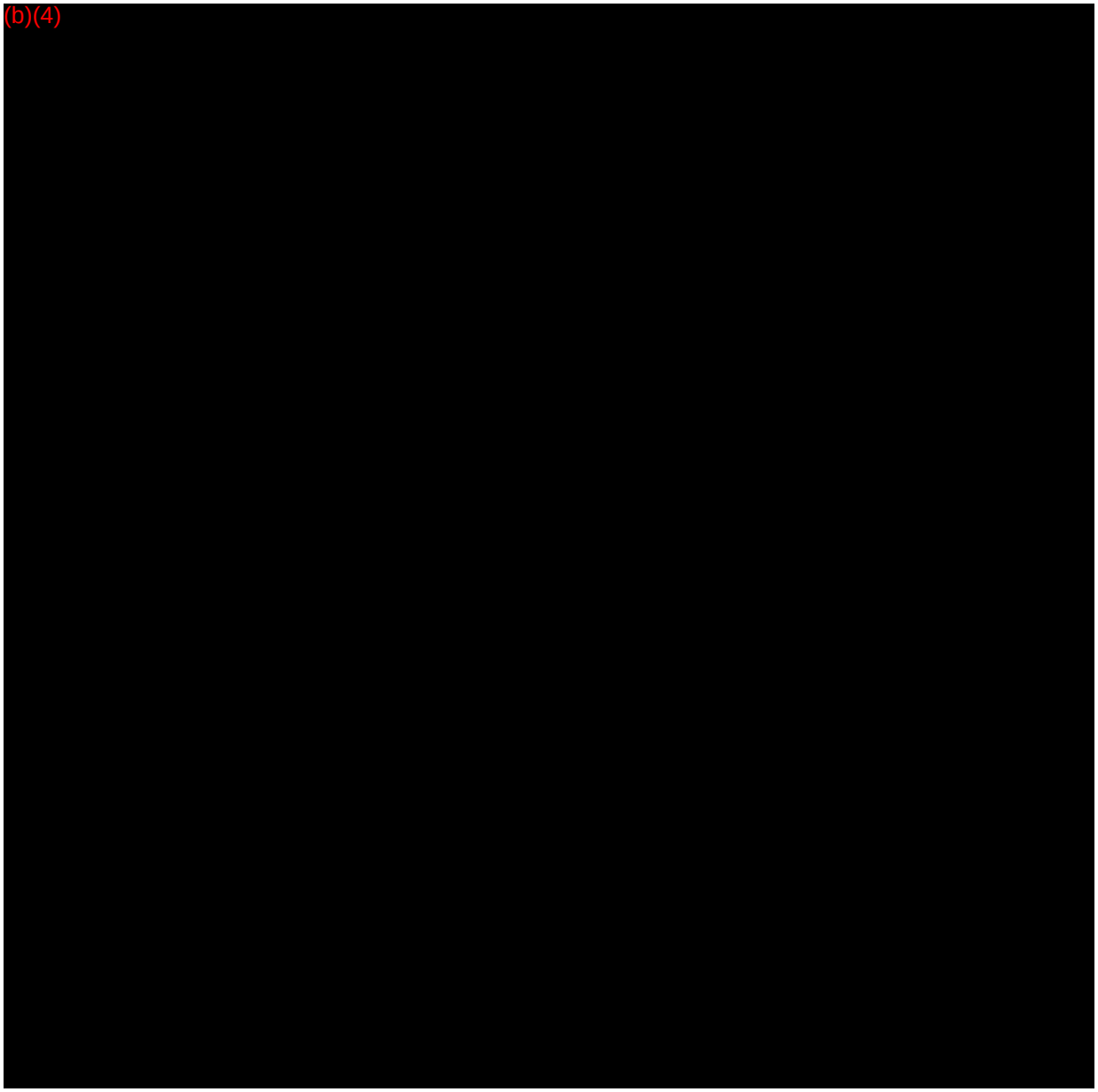

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Revolution Performance Evaluation

Contributors	Role
(b)(4)	

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1. Introduction

1.1 System Description

The GE Discovery CT870 HD shown below in Figure 1 is the next generation scanner in GE's line of Computed Tomography (CT) products. This scanner is also called the "Revolution" CT scanner.

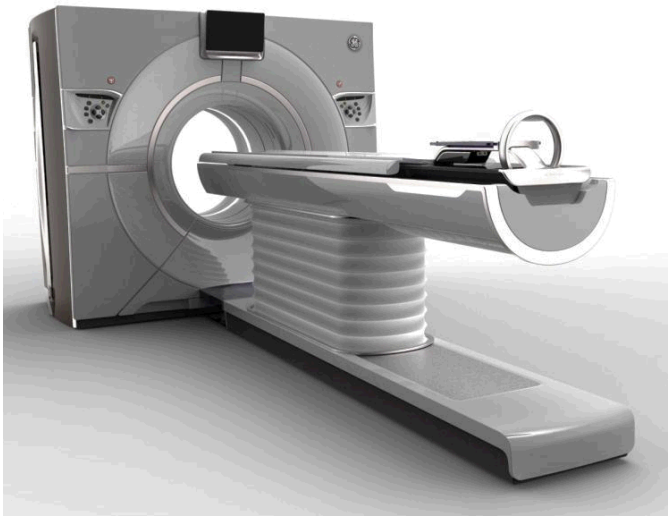


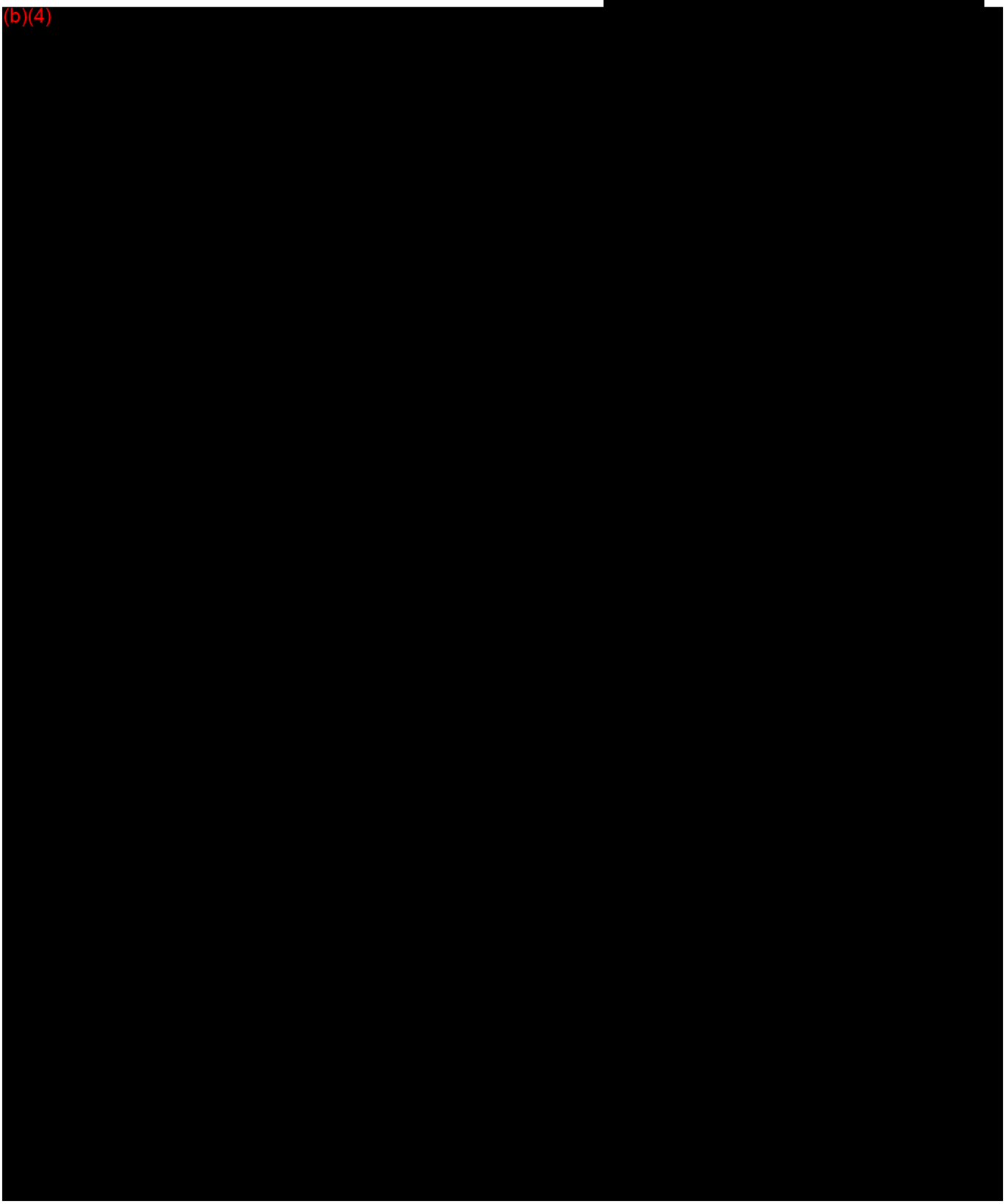
Figure 1: The new GE Discovery CT870 HD scanner, known internally as the Revolution CT scanner.

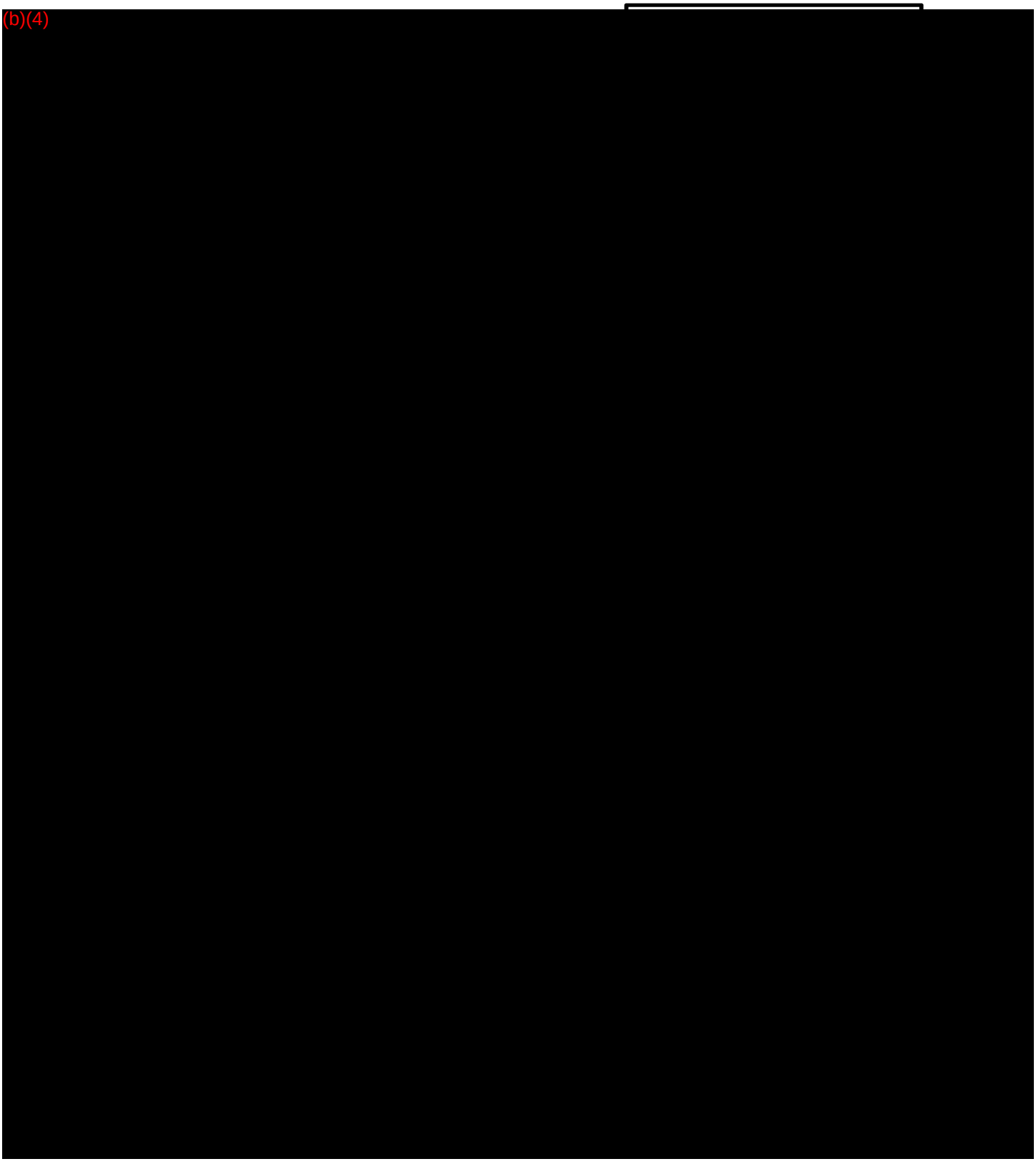
Revolution is designed as the first fully volumetric CT scanner to provide whole organ imaging capability for the full range of clinical applications with (b)(4) state-of-the-art image quality and dose performance (b)(4) . With Revolution, the CT scanner (b)(4)

(b)(4)

(b)(4)

(b)(4)





(b)(4)

[redacted]

(b)(4)

2. Revolution Performance Evaluation

2.1 One-Beat Cardiac Imaging:

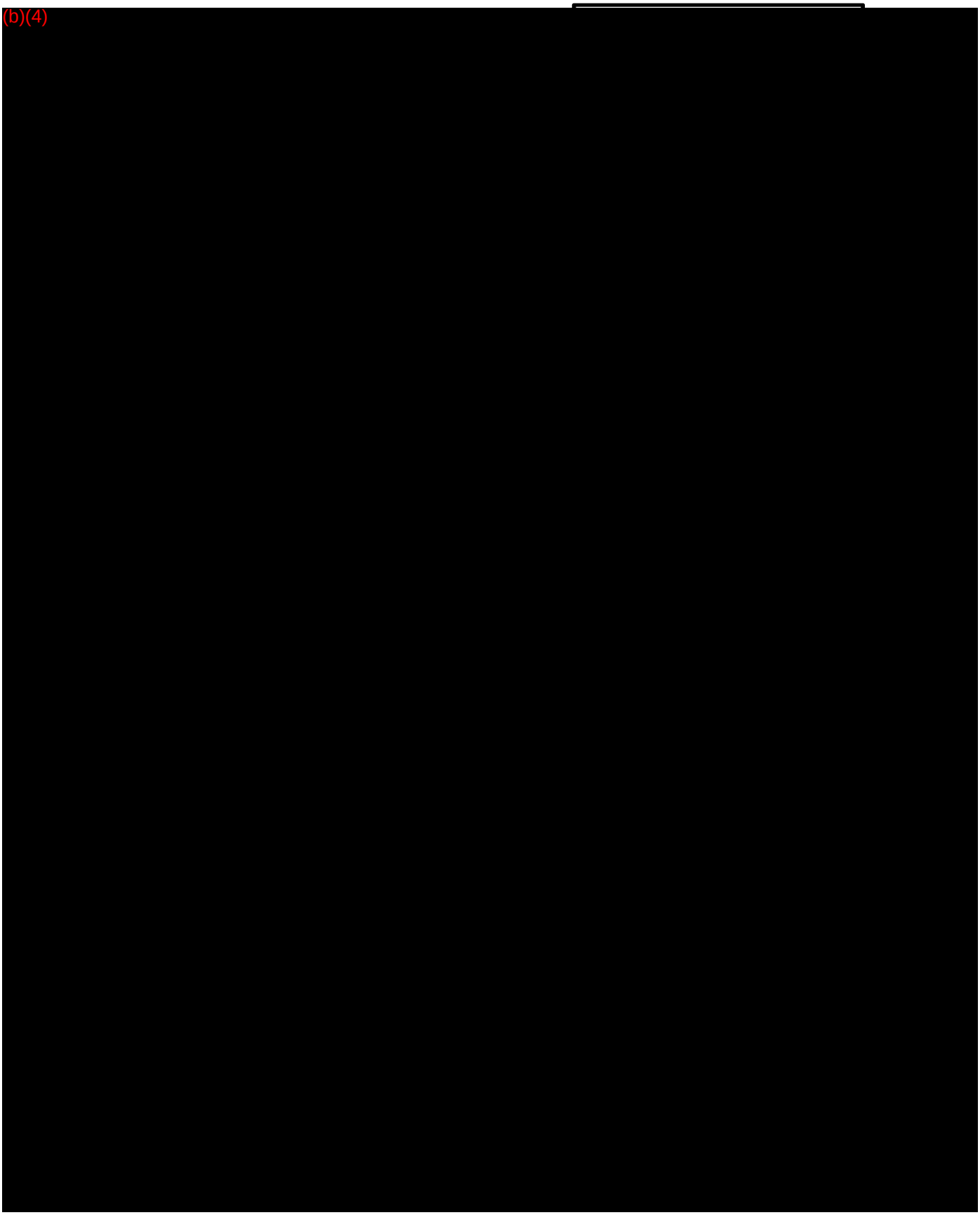
2.1.1 Performance item 1a: The Revolution system can cover the entire heart in less than one beat, providing IV contrast uniformity and temporal uniformity throughout the whole image volume.

(b)(4)

(b)(4)

Whole Heart Coverage

(b)(4)



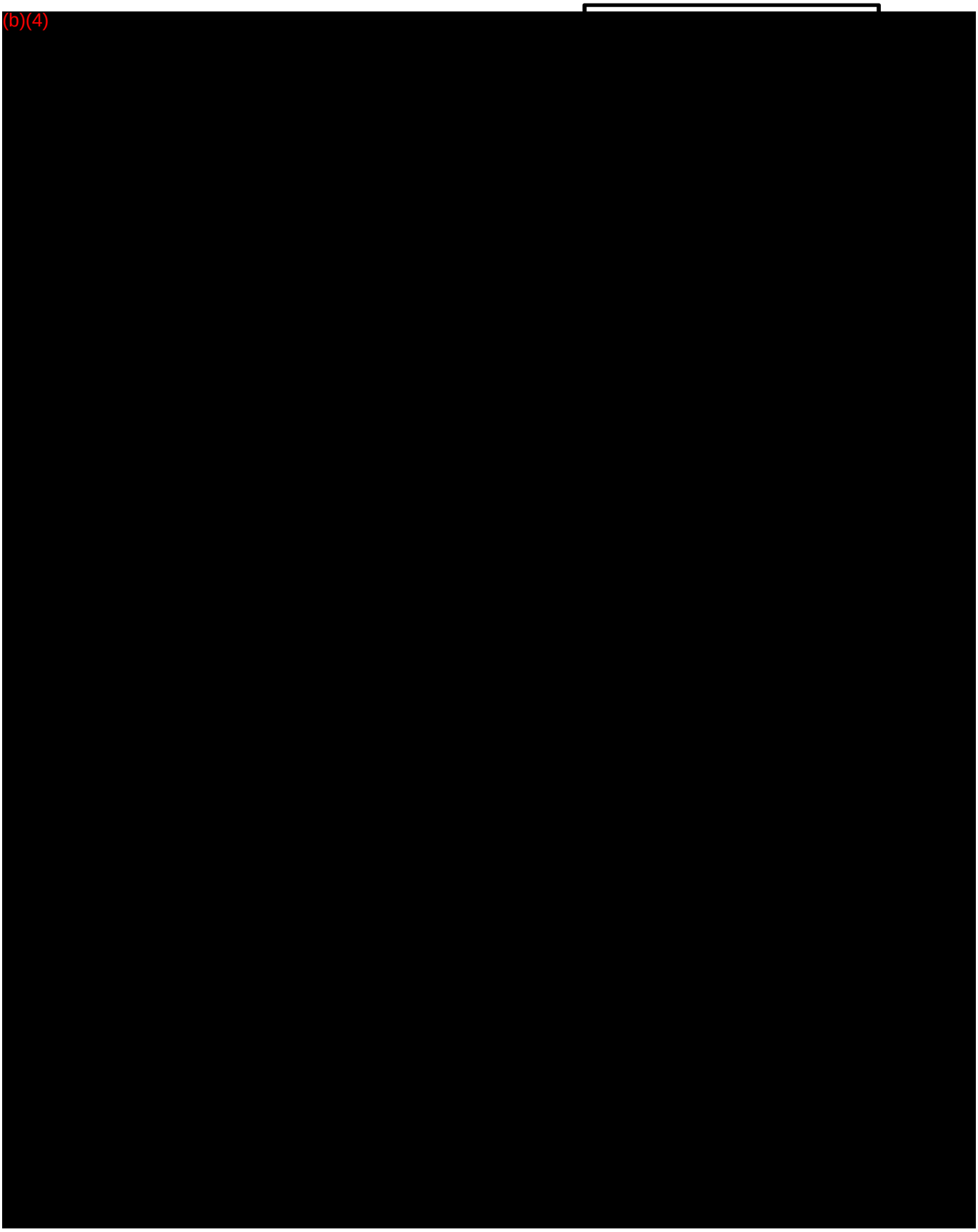
(b)(4)

In conclusion, the Revolution scanner can cover the entire heart in less than one beat.

Contrast Uniformity

(b)(4)

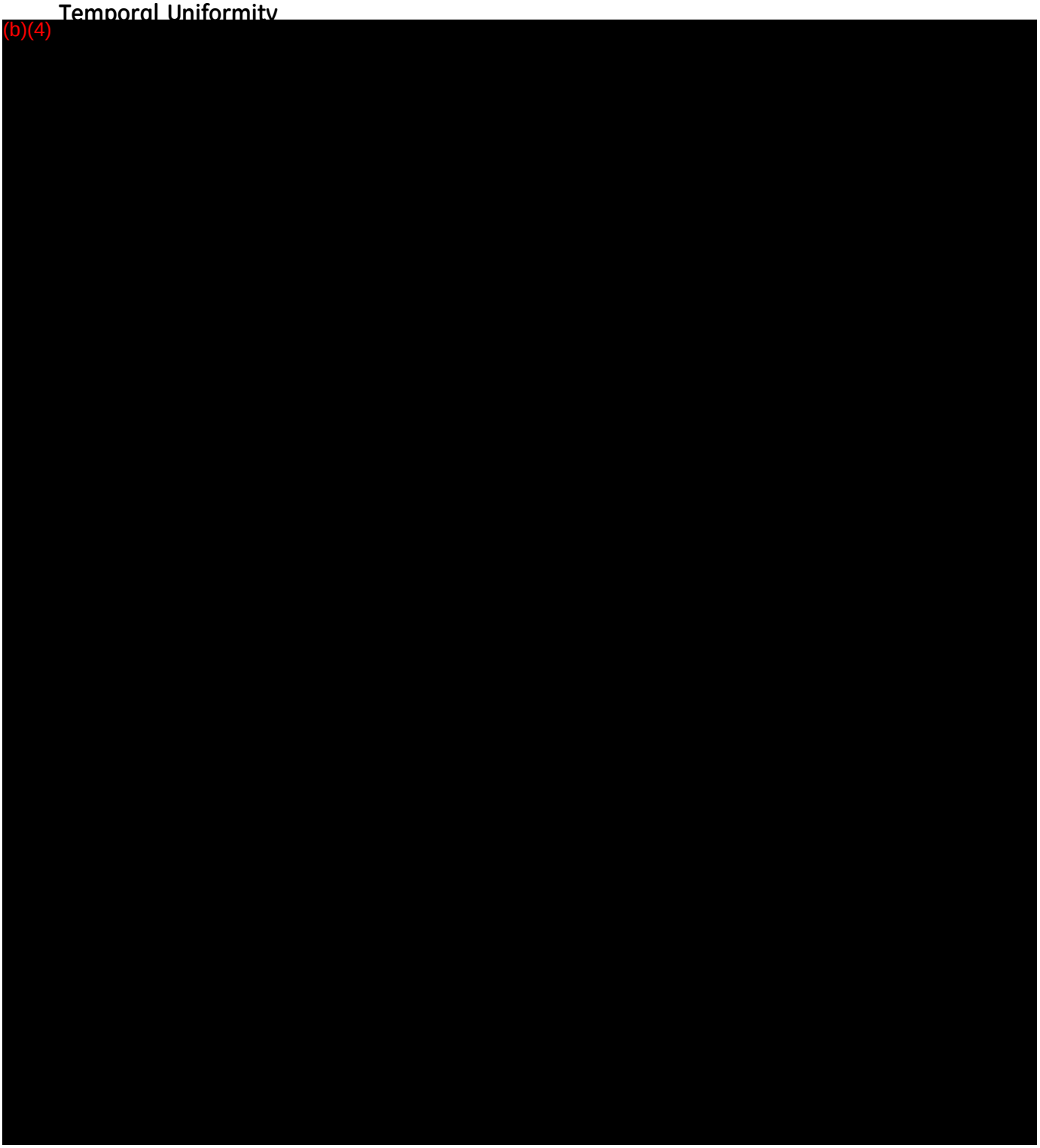
(b)(4)



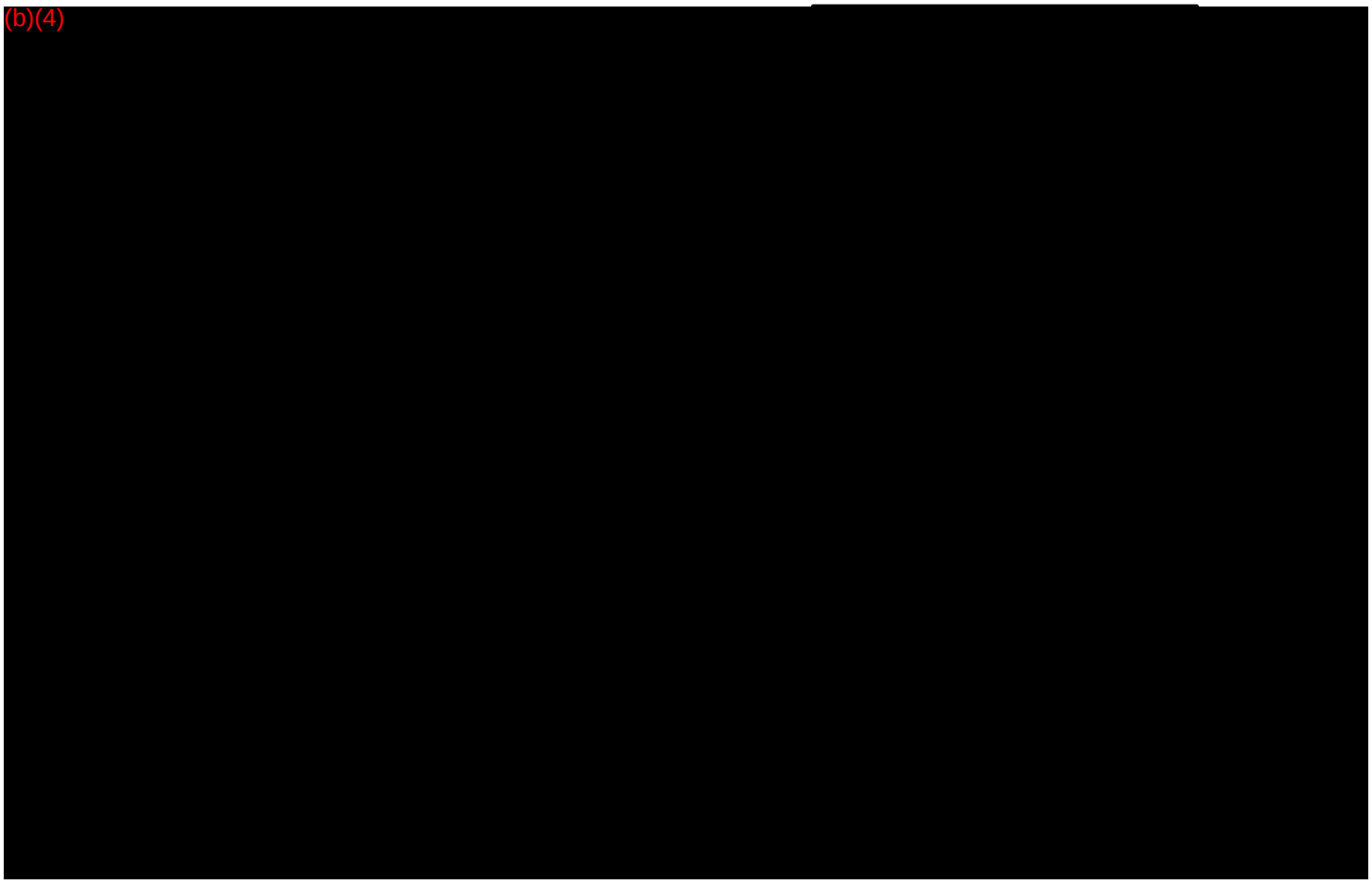
In conclusion, the Revolution scanner provides excellent IV contrast uniformity throughout the whole image volume.

Temporal Uniformity

(b)(4)



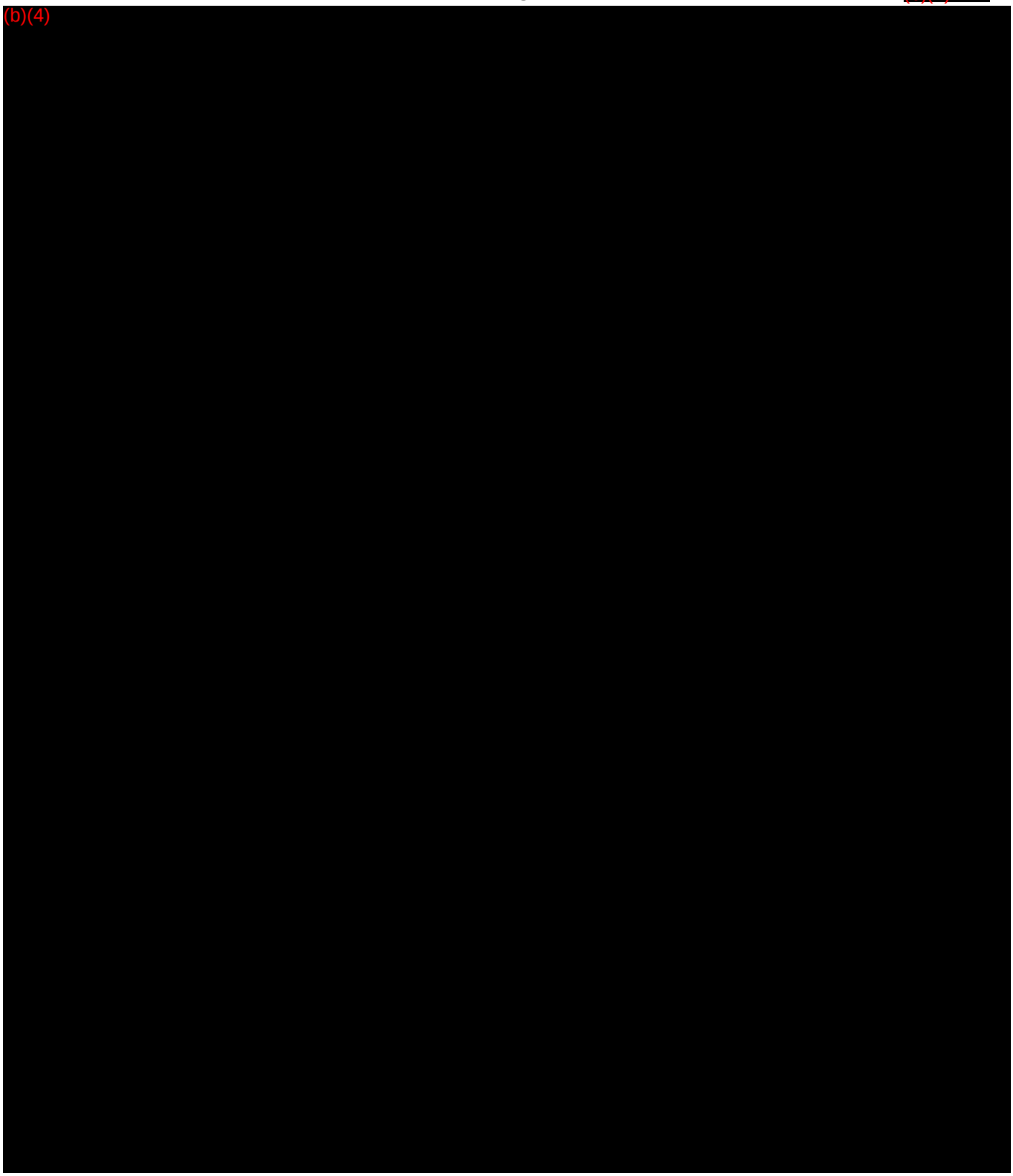
(b)(4)



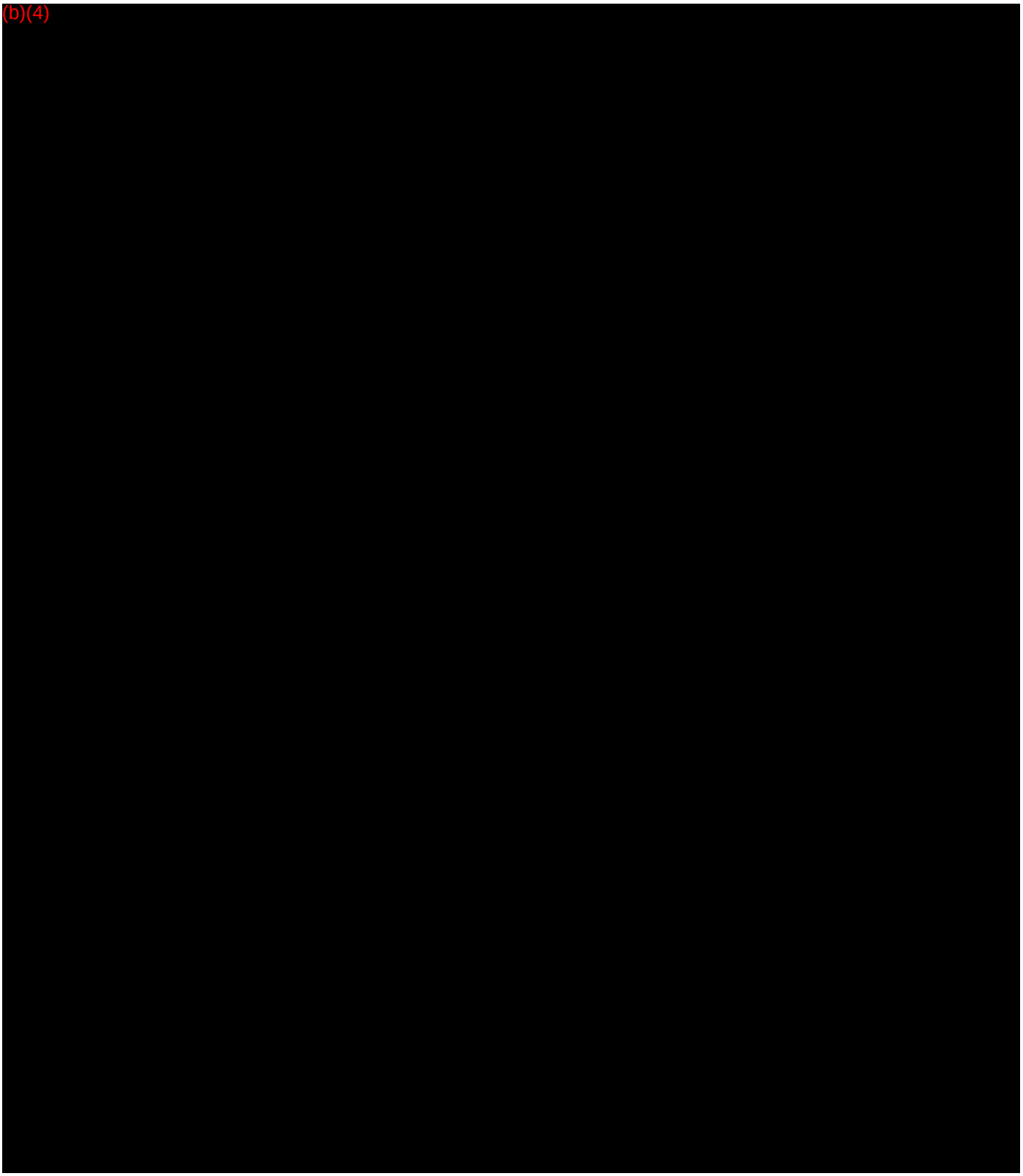
In conclusion, the Revolution scanner provides excellent temporal uniformity throughout the whole image volume.

2.1.2 Performance item 1b: The Revolution system can provide a comprehensive cardiac exam with (b)(4) in a single beat, enabling (b)(4) acquisitions of systolic and diastolic phases.

(b)(4)



(b)(4)



In conclusion, the Revolution system can provide a comprehensive cardiac exam with (b)(4) in a single beat, enabling (b)(4) acquisitions of systolic and diastolic phases.

2.2 Cardiac Temporal Resolution:

2.2.1 Performance item 2a: The Revolution system can acquire images of the heart with (b)(4) temporal resolution.

(b)(4)

(b)(4)

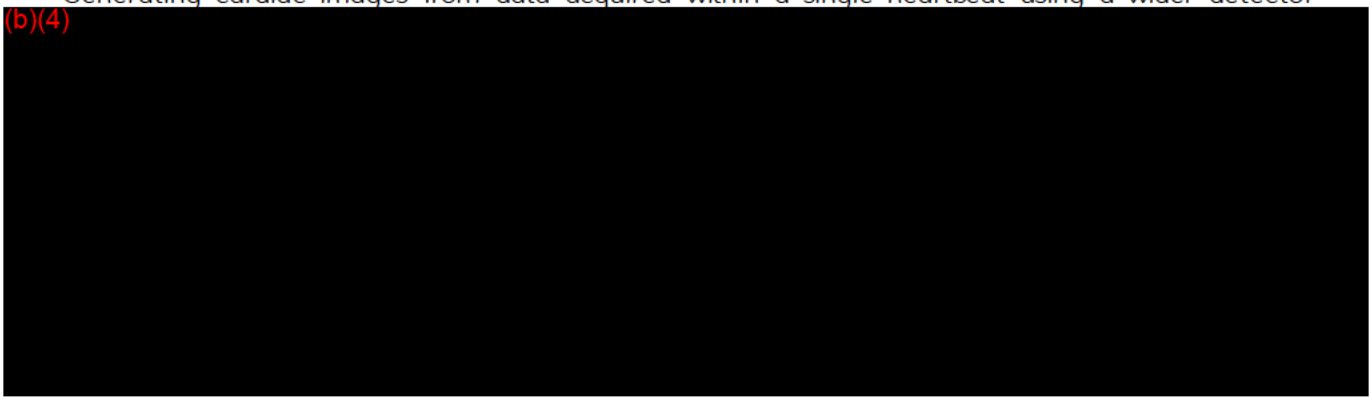
In conclusion, the Revolution system can acquire images of the heart with (b)(4) temporal resolution.

2.2.2 Performance item 2c: The Revolution system can improve the robustness of cardiac exams for patients with high or irregular heart rates.

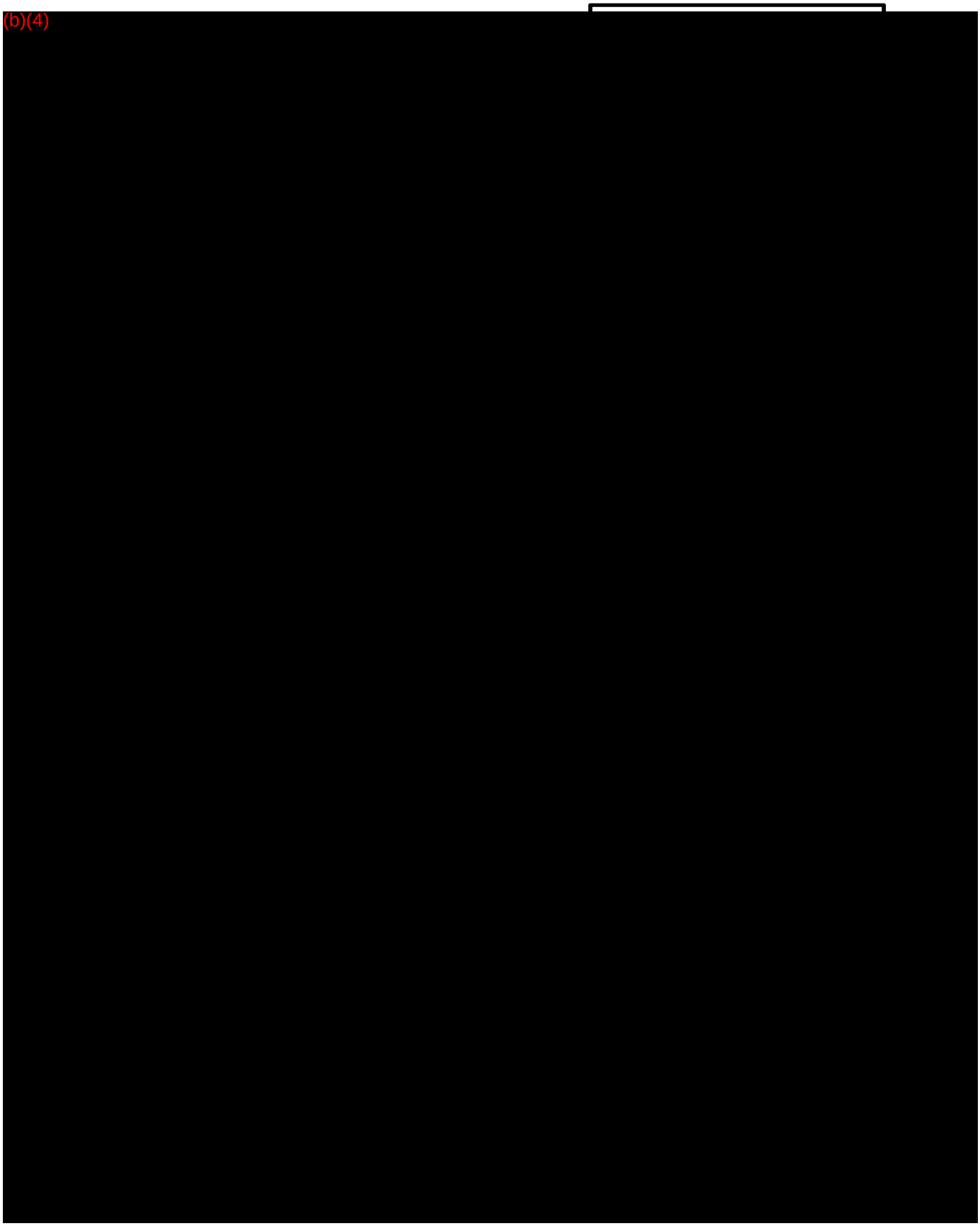
Robustness for Cardiac Imaging

Generating cardiac images from data acquired within a single heartbeat using a wider detector

(b)(4)



(b)(4)



(b)(4)

(b)(4)

In conclusion, the Revolution system can improve the robustness of cardiac exams for patients with high heart rates.

(b)(4)

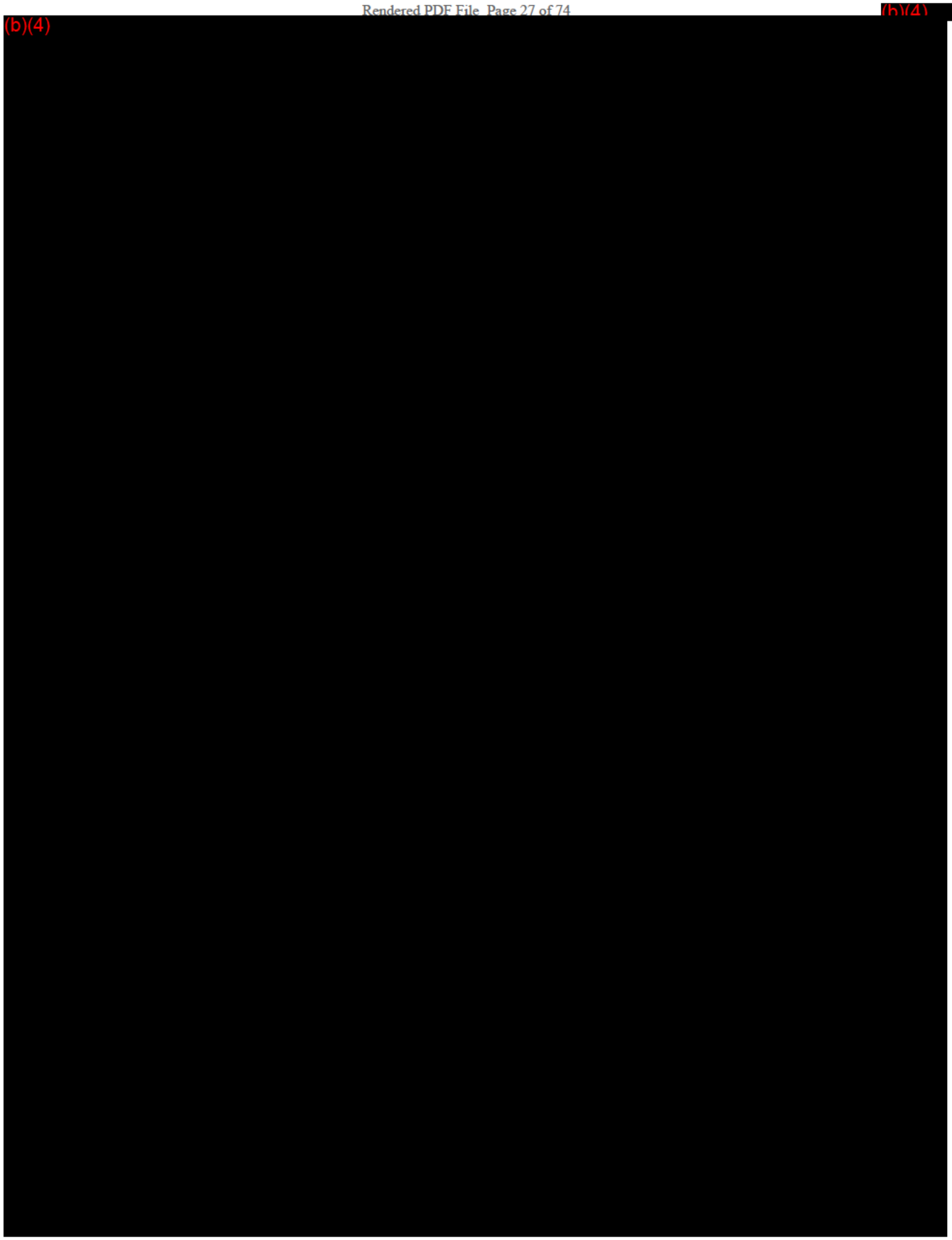
In conclusion, the Revolution system can improve the robustness of cardiac exams for patients with irregular heart rates.

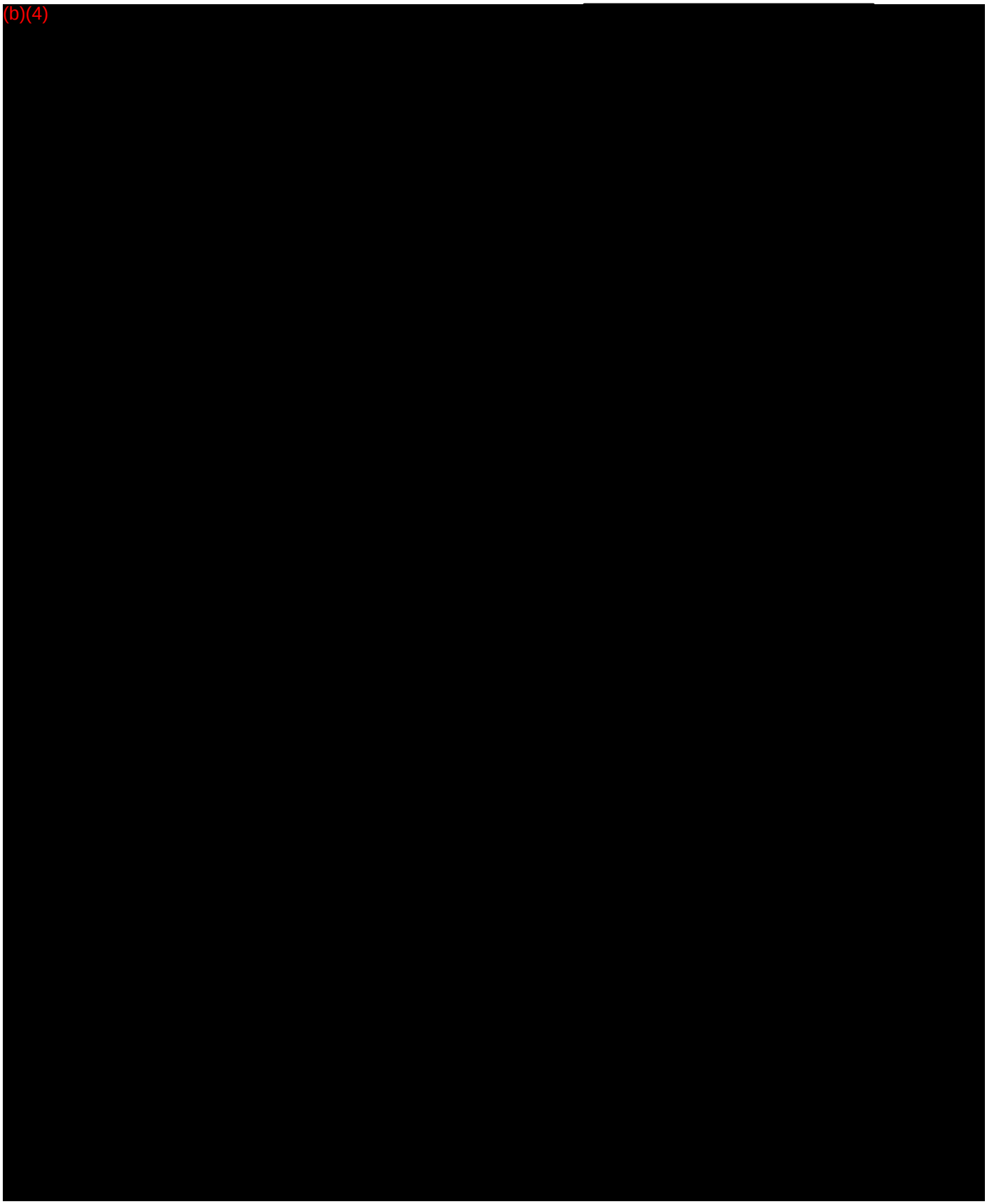
2.3 Radiation Dose:

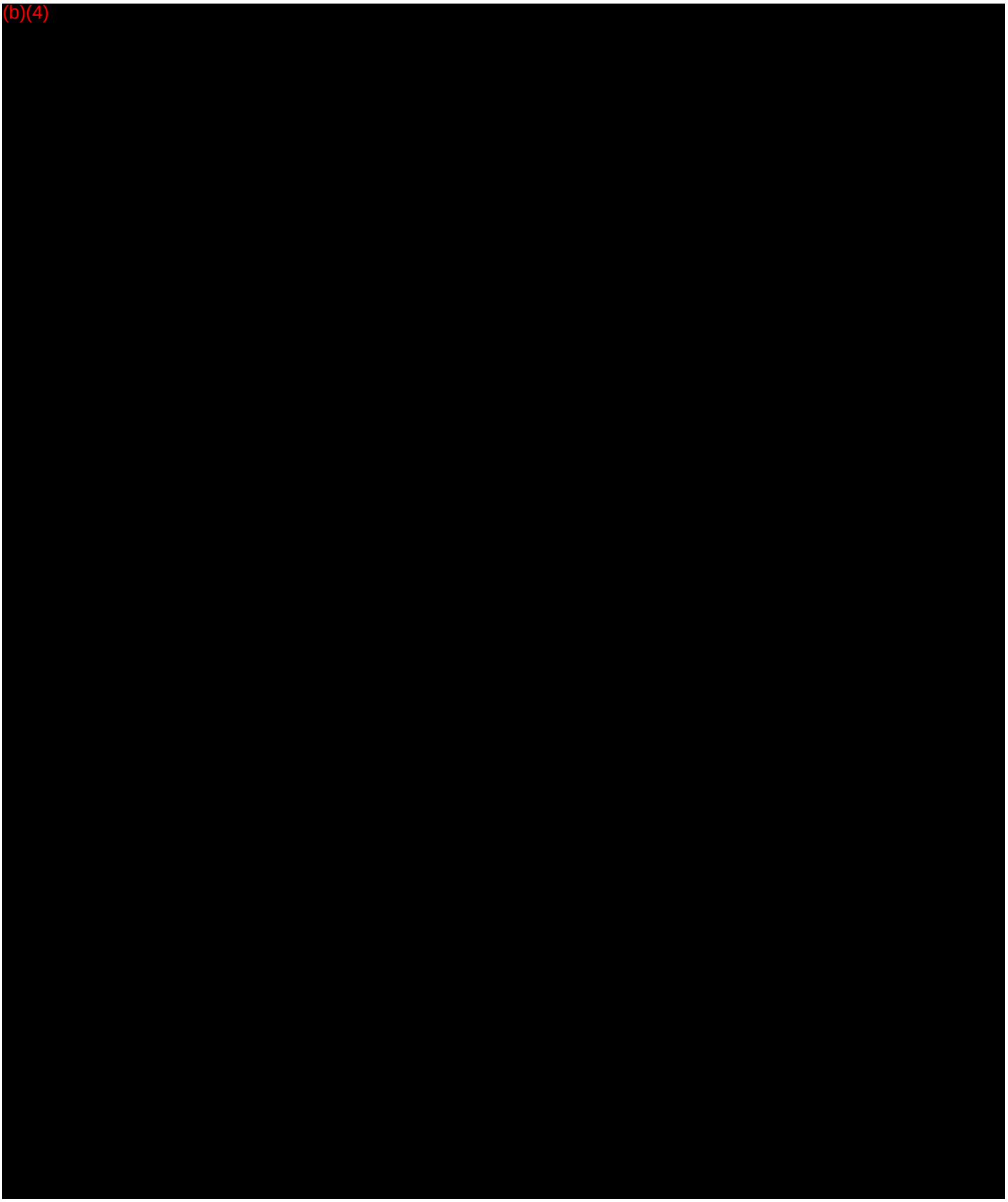
2.3.1 Performance item 3a: The Revolution system can image the heart using less radiation dose than (b)(4) while maintaining image quality*.

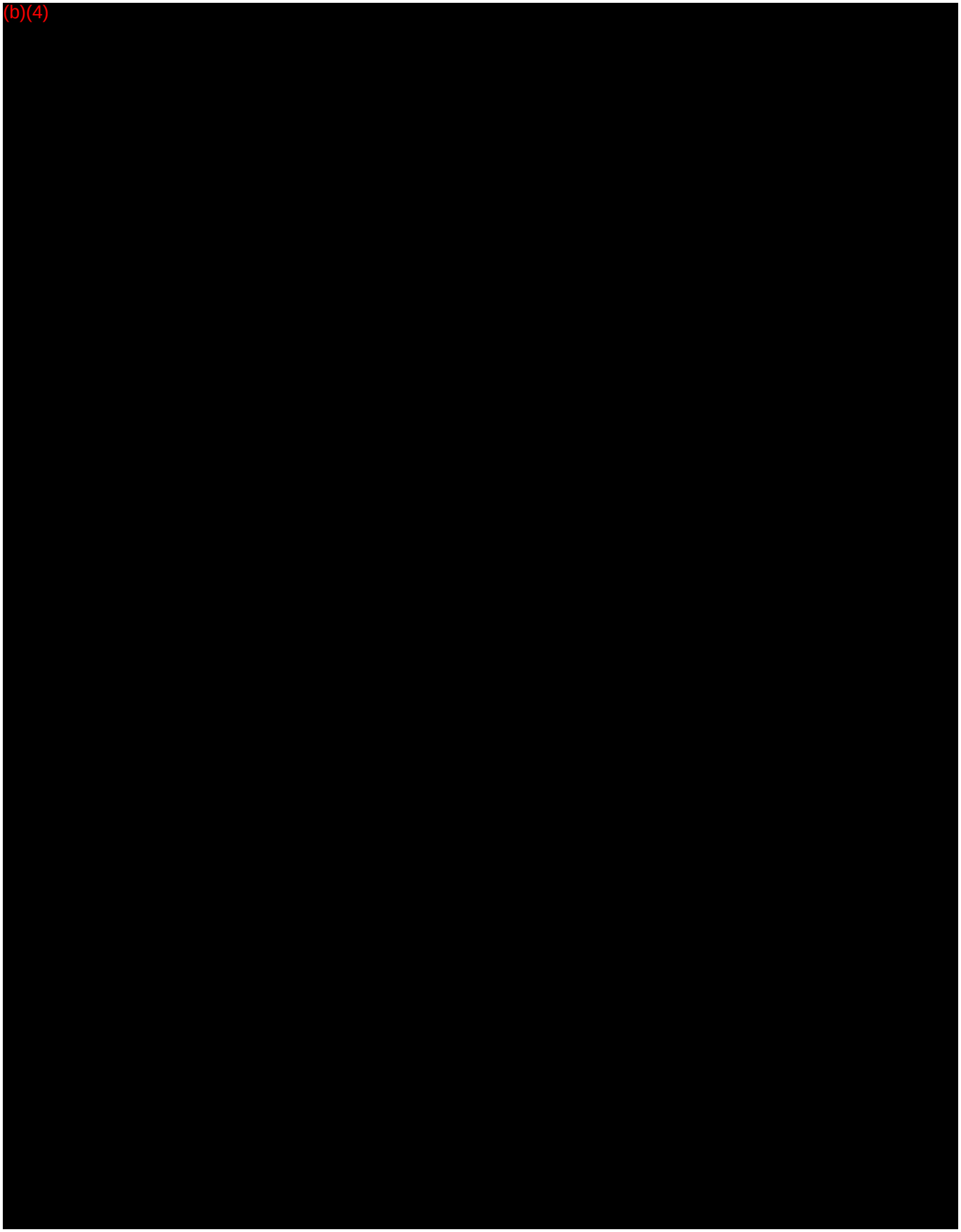
(b)(4)

(b)(4)







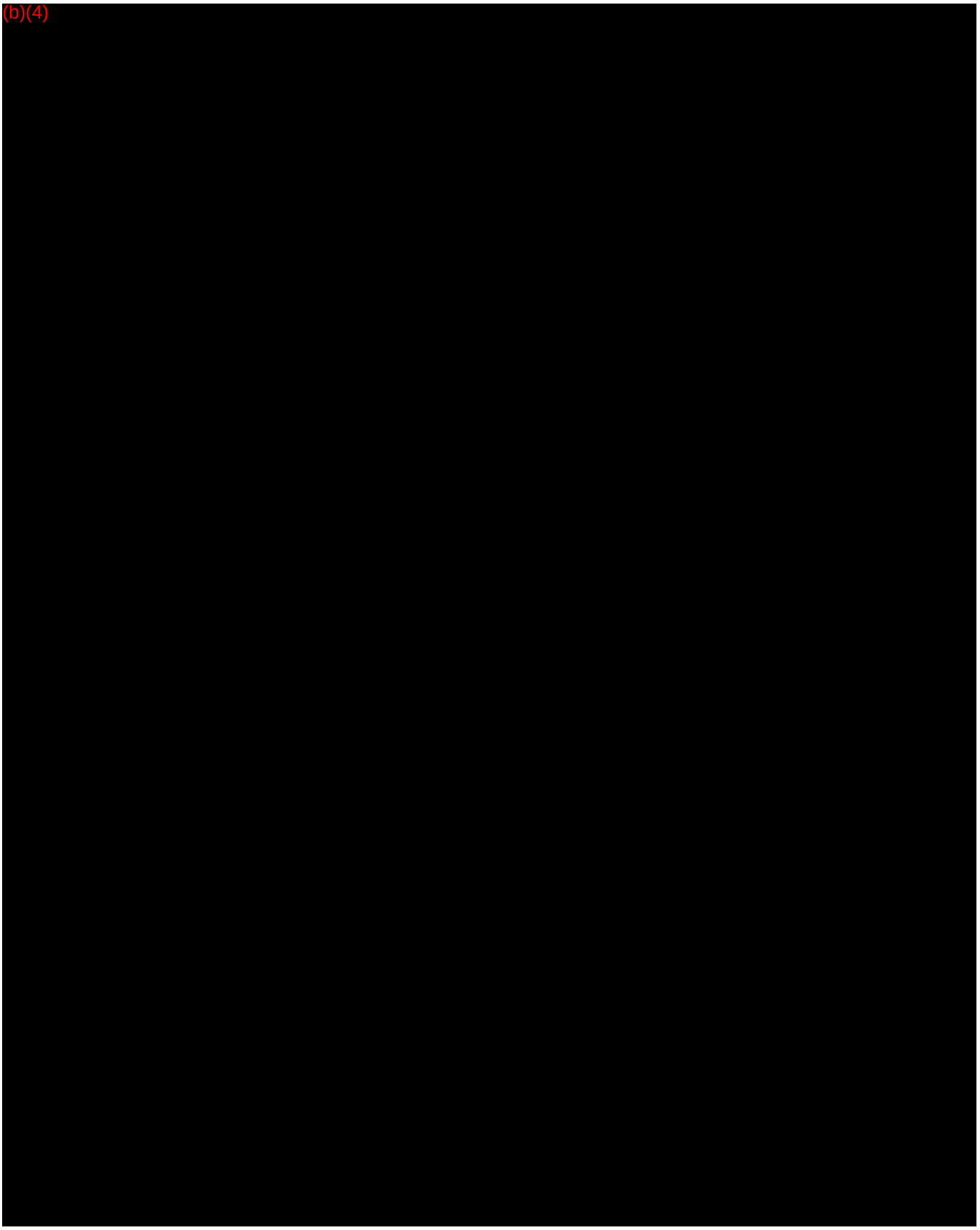


(b)(4)

In conclusion, the Revolution system can image the heart using less radiation dose (b)(4) r while maintaining image quality.

2.3.2 Performance item 3b: The Revolution system provides (b)(4) iterative reconstruction technology (b)(4) and (b)(4) compared to FBP, and may enable a reduction in dose*.

*(b)(4)

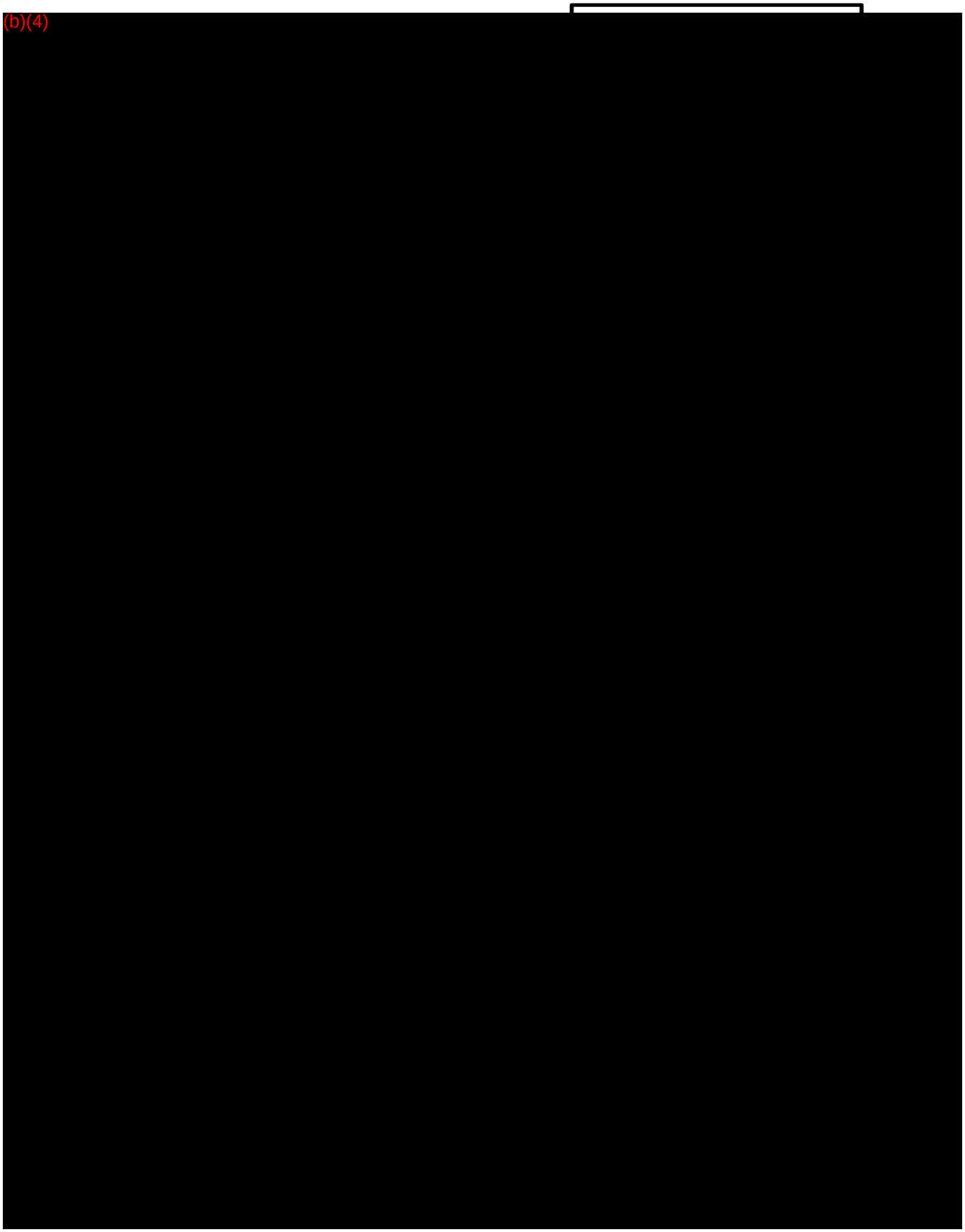


(b)(4)

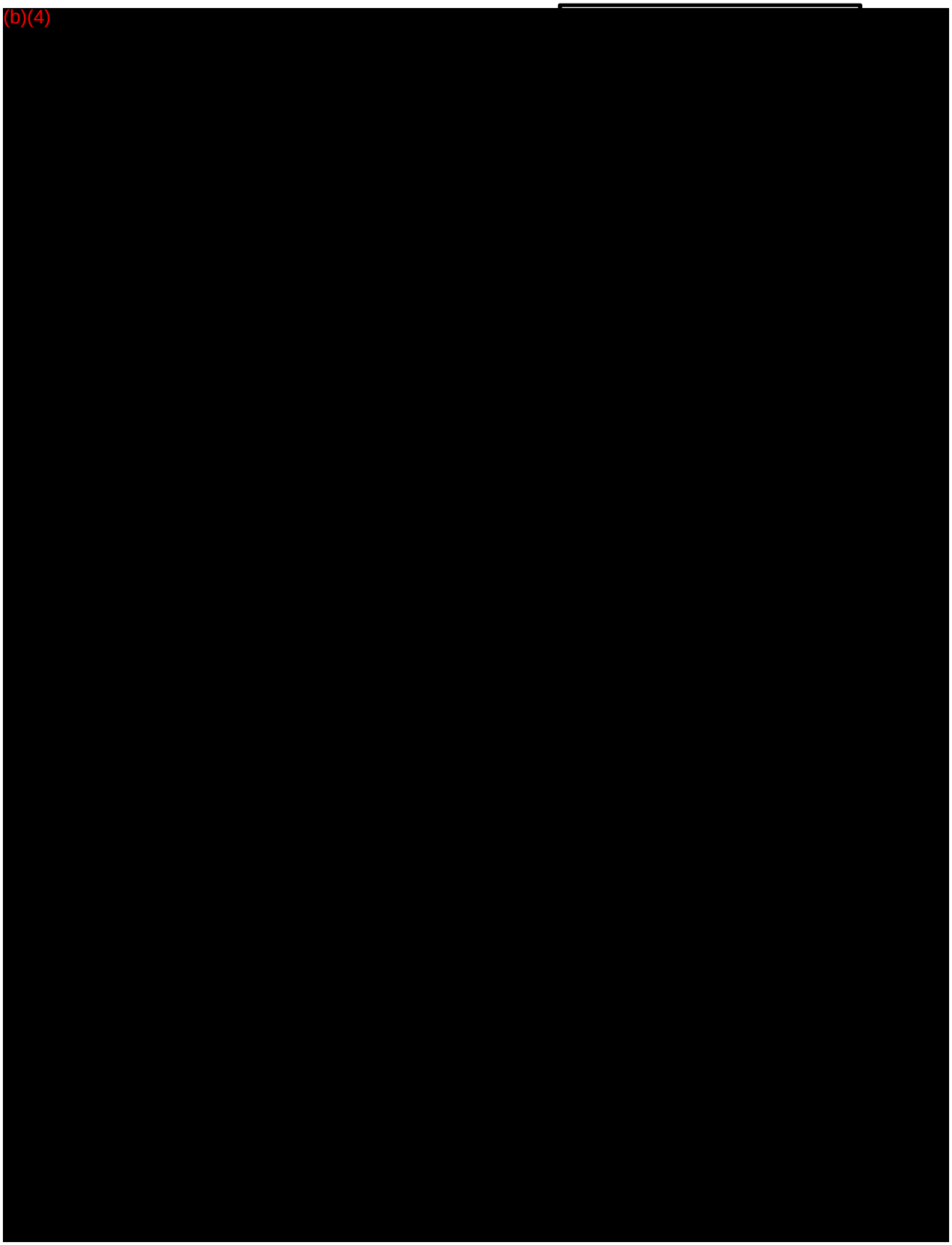
In conclusion, the Revolution system provides (b)(4) iterative reconstruction technology (b)(4) which reduces noise levels compared to FBP.

(b)(4)

(b)(4)



(b)(4)



(b)(4)

In conclusion, the Revolution system provides (b)(4) iterative reconstruction technology (b)(4) which may enable a reduction in dose compared to FBP.

(b)(4)

In conclusion, the Revolution system provides (b)(4) iterative reconstruction technology (b)(4) which may increase low contrast detectability compared to FBP.

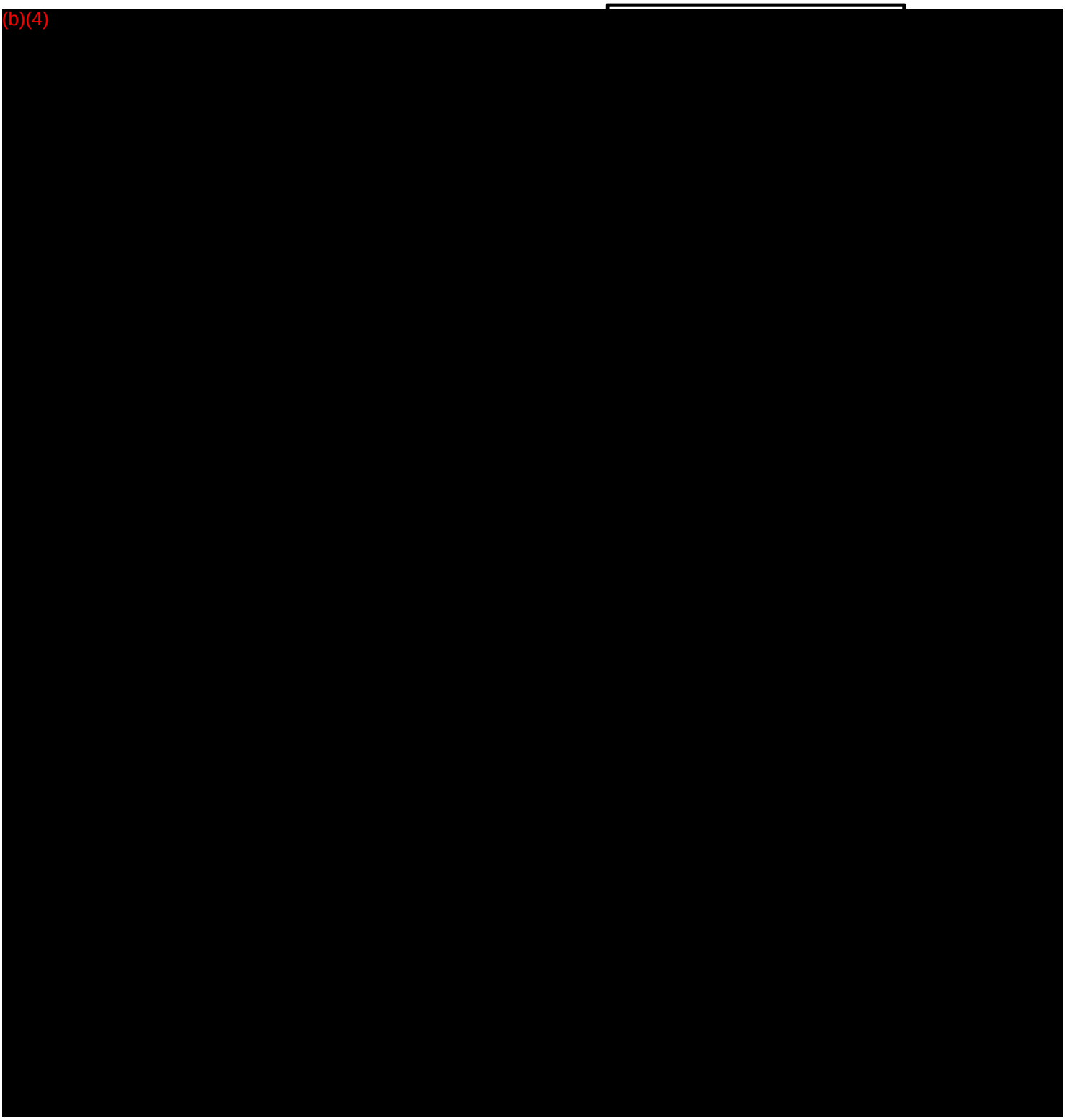
(b)(4)

2.4 Cardio-Vascular and Thoracic Applications:

2.4.1 Performance item 4a: The Revolution system supports (b)(4) acquisitions of the heart, aorta, and femoral arteries with ECG-gated axial scans and non-ECG-gated axial modes covering (b)(4) , and is integrated with post-processing applications (b)(4) .

(b)(4)

(b)(4)



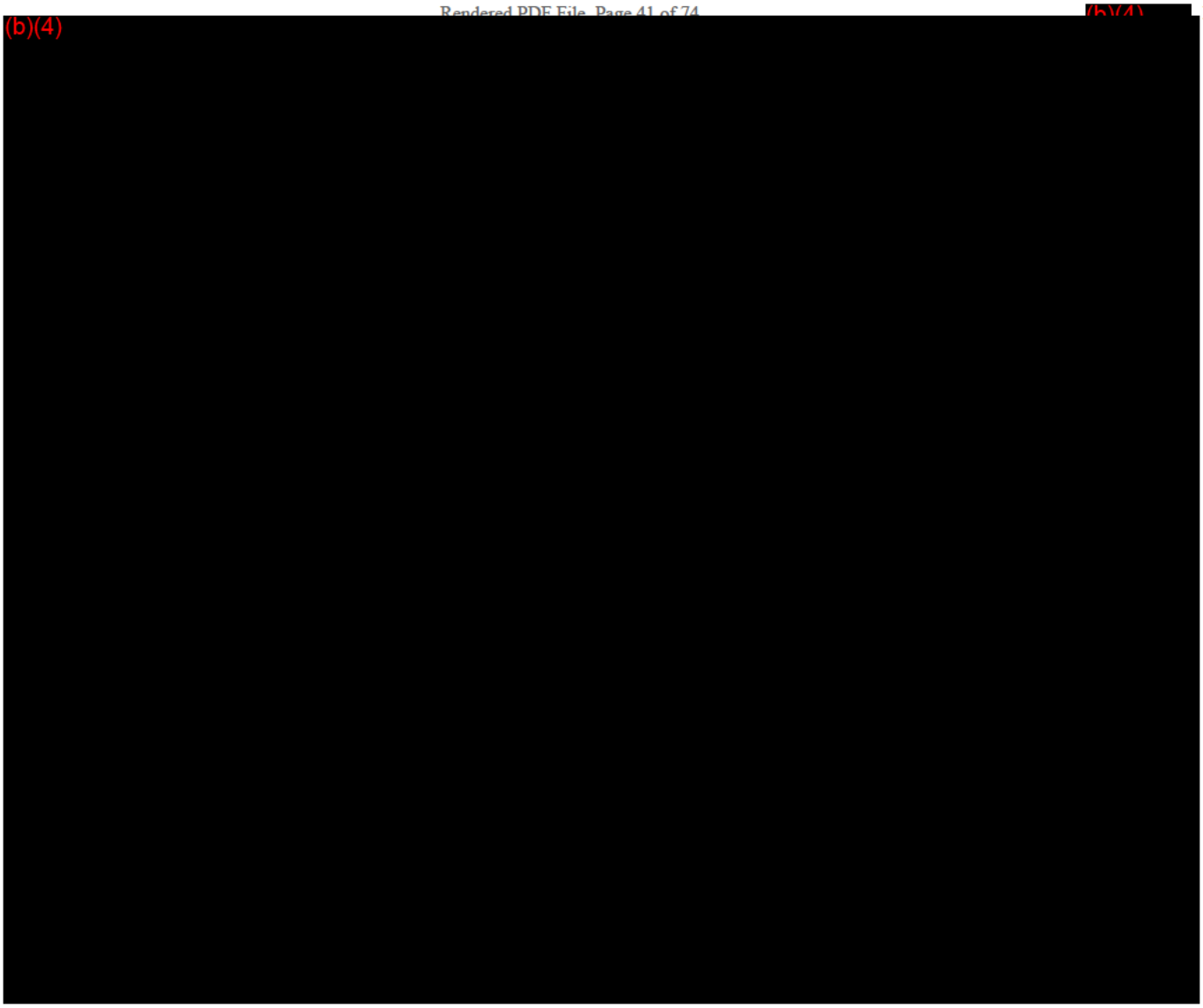
In conclusion, the Revolution system supports (b)(4) acquisitions of the heart, aorta, and femoral arteries with ECG-gated axial scans and non-ECG-gated axial modes covering (b)(4) , and is integrated with post-processing applications (b)(4)

(b)(4)

2.4.2 Performance item 4b: The Revolution system can cover the entire thorax in (b)(4) with ECG gating and makes images (b)(4) at low dose.

(b)(4)

(b)(4)



In conclusion, the Revolution system can cover the entire thorax in (b)(4) with ECG gating and makes images with (b)(4) at low dose

2.4.3 Performance item 4c: The Revolution system allows (b)(4) data acquisition for (b)(4) coverage for fast imaging of pediatric and trauma patients.

(b)(4)

(b)(4)

(b)(4)

In conclusion, the Revolution system allows (b)(4) data acquisition for (b)(4) coverage for fast imaging of pediatric patients.

(b)(4)

.

In conclusion, the Revolution system allows (b)(4) data acquisition for (b)(4) coverage for fast imaging of trauma patients.

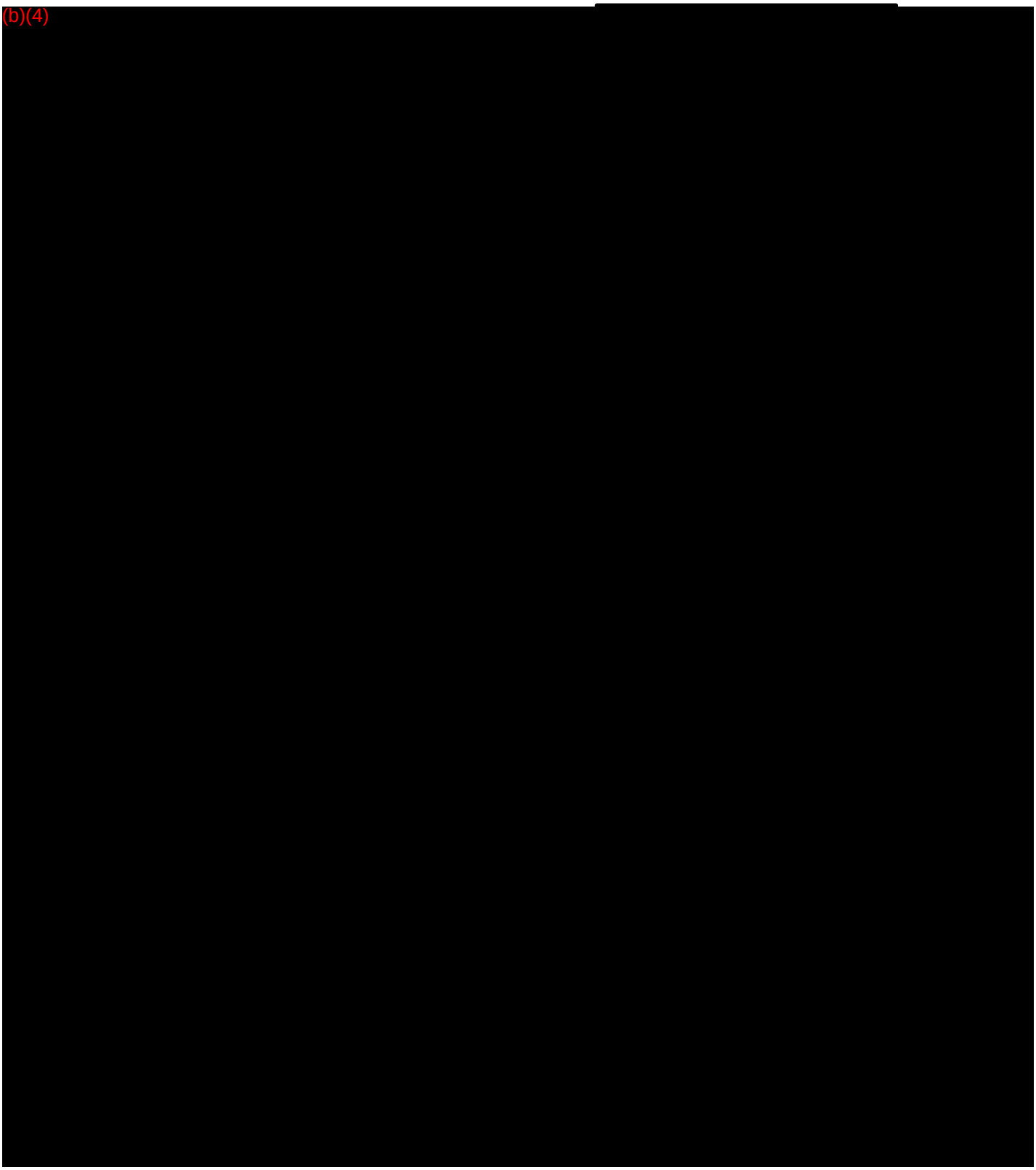
2.5 Image Quality Performance:

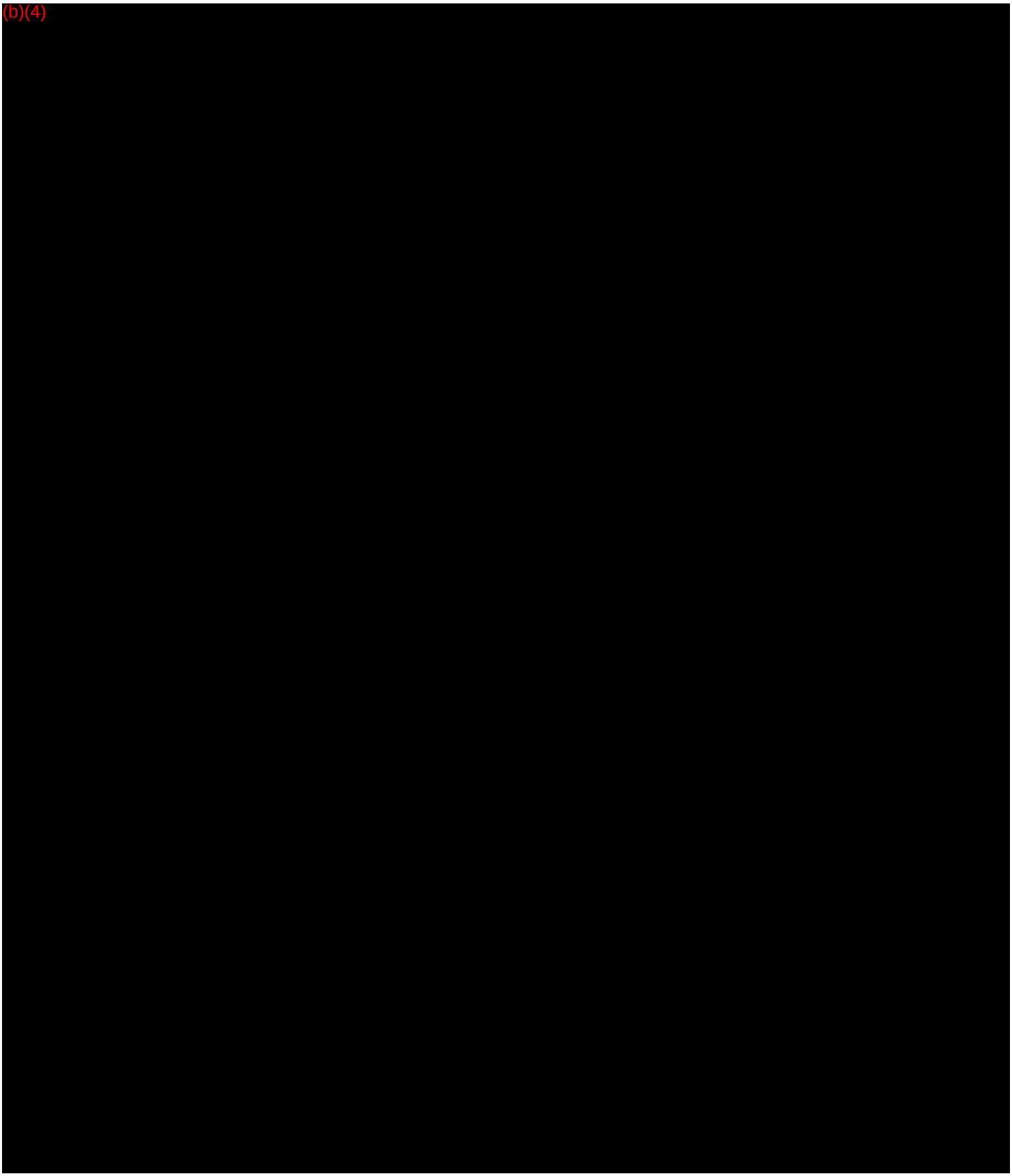
2.5.1 Performance item 5a: The Revolution system significantly reduces cone-beam artifacts and improves quantitative uniformity for iodinated contrast down to (b)(4)) across (b)(4) z-coverage.

(b)(4)

(b)(4)

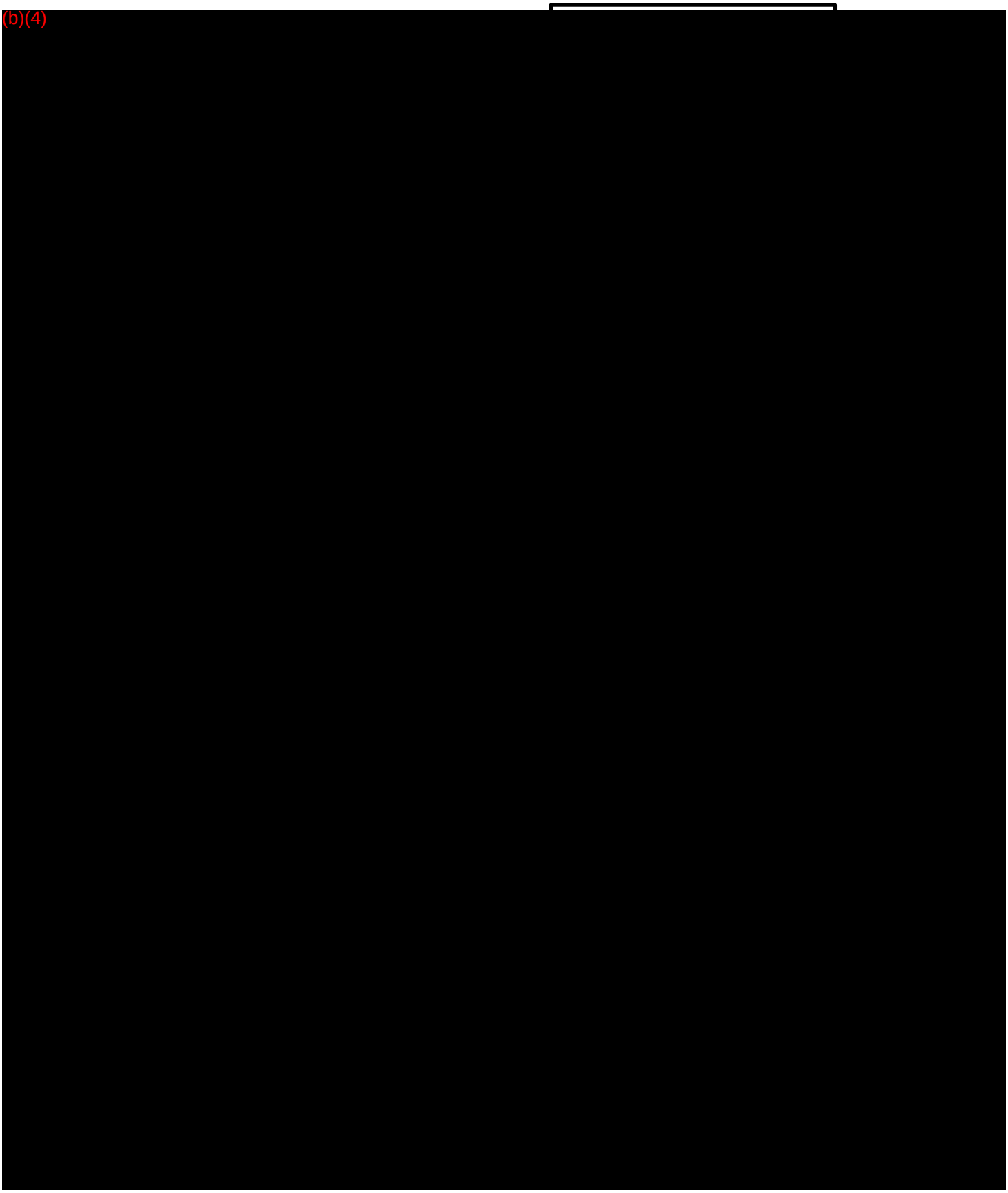
(b)(4)





(b)(4)

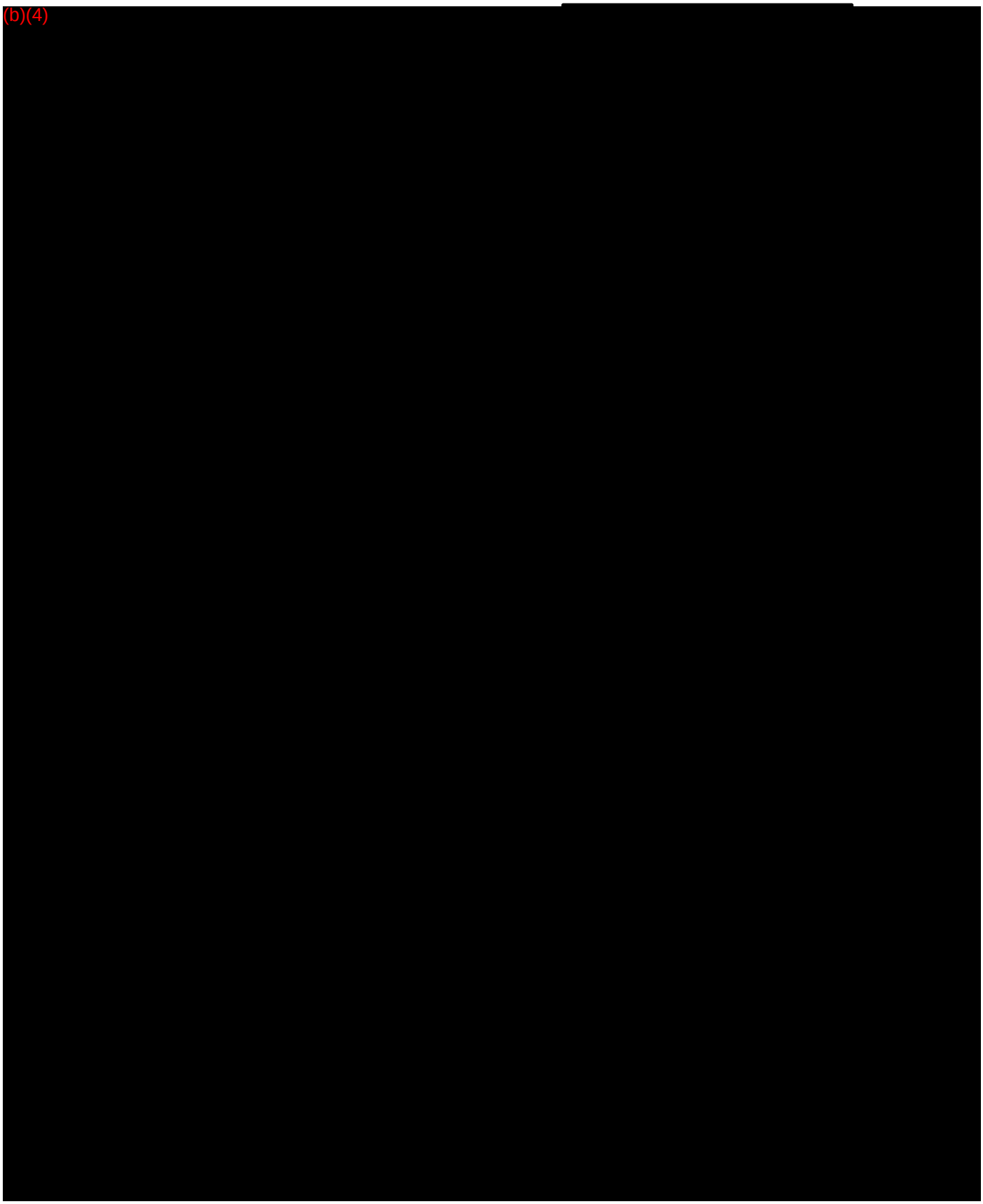
(b)(4)



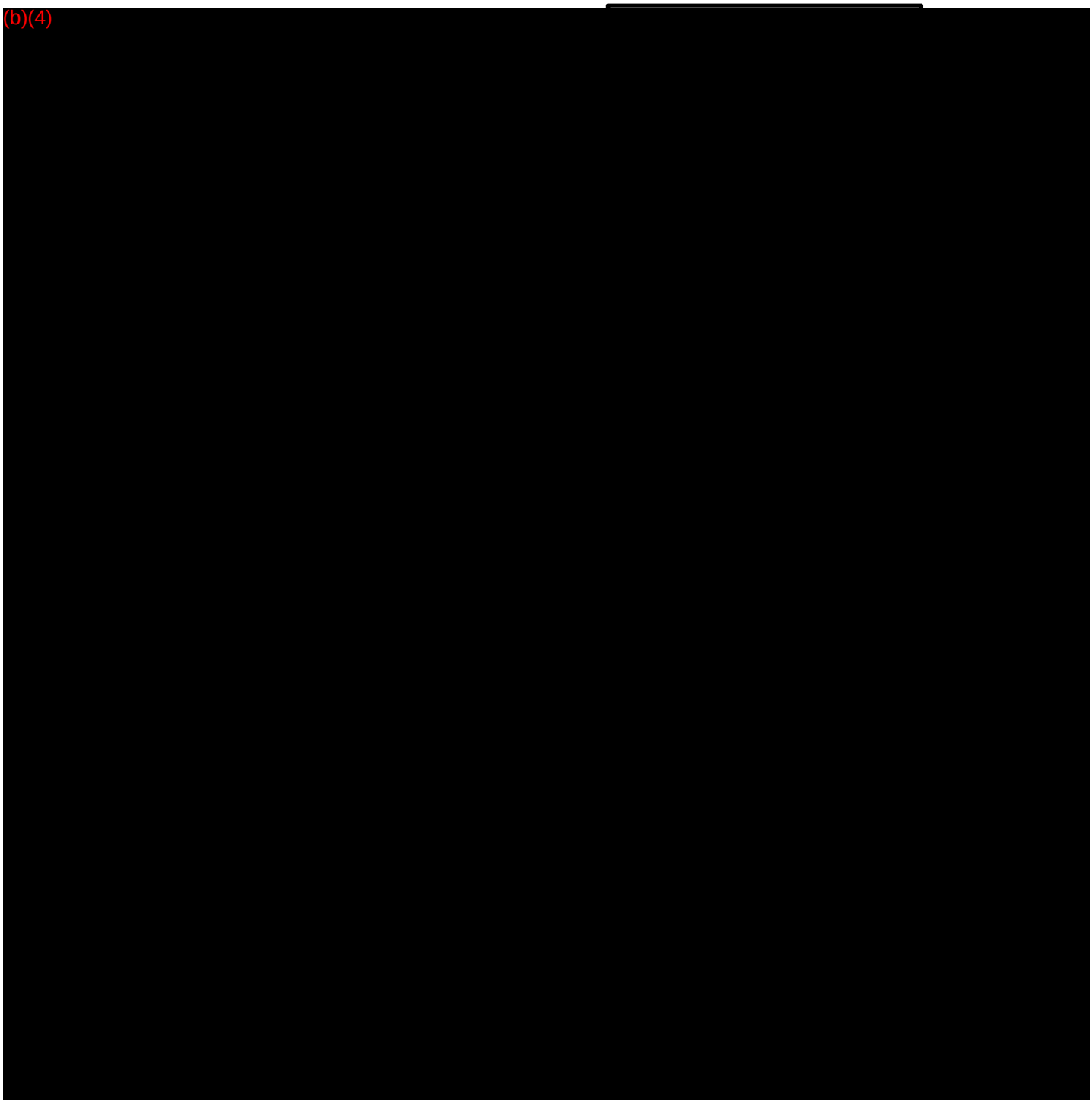
(b)(4)

[redacted]

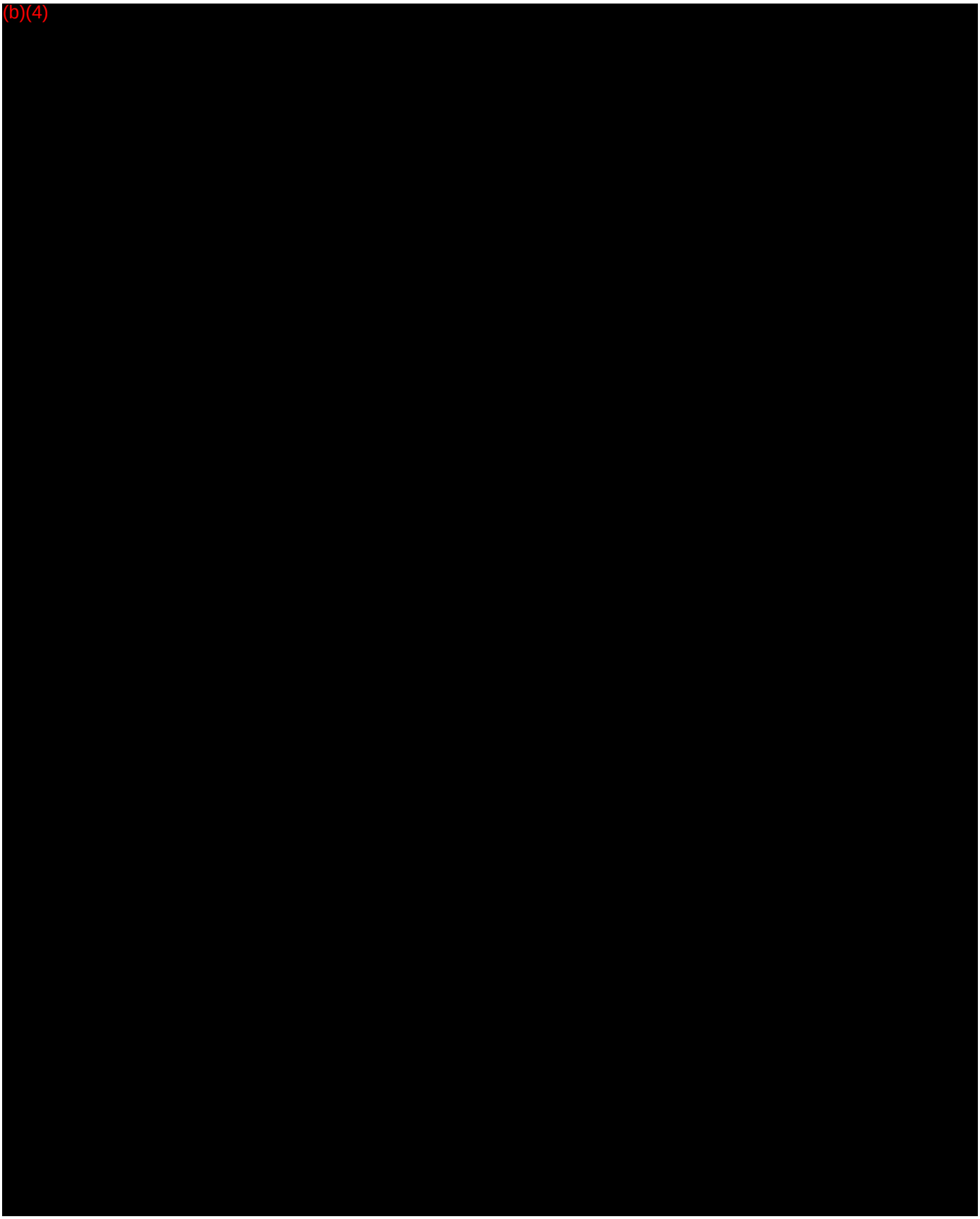
(b)(4)



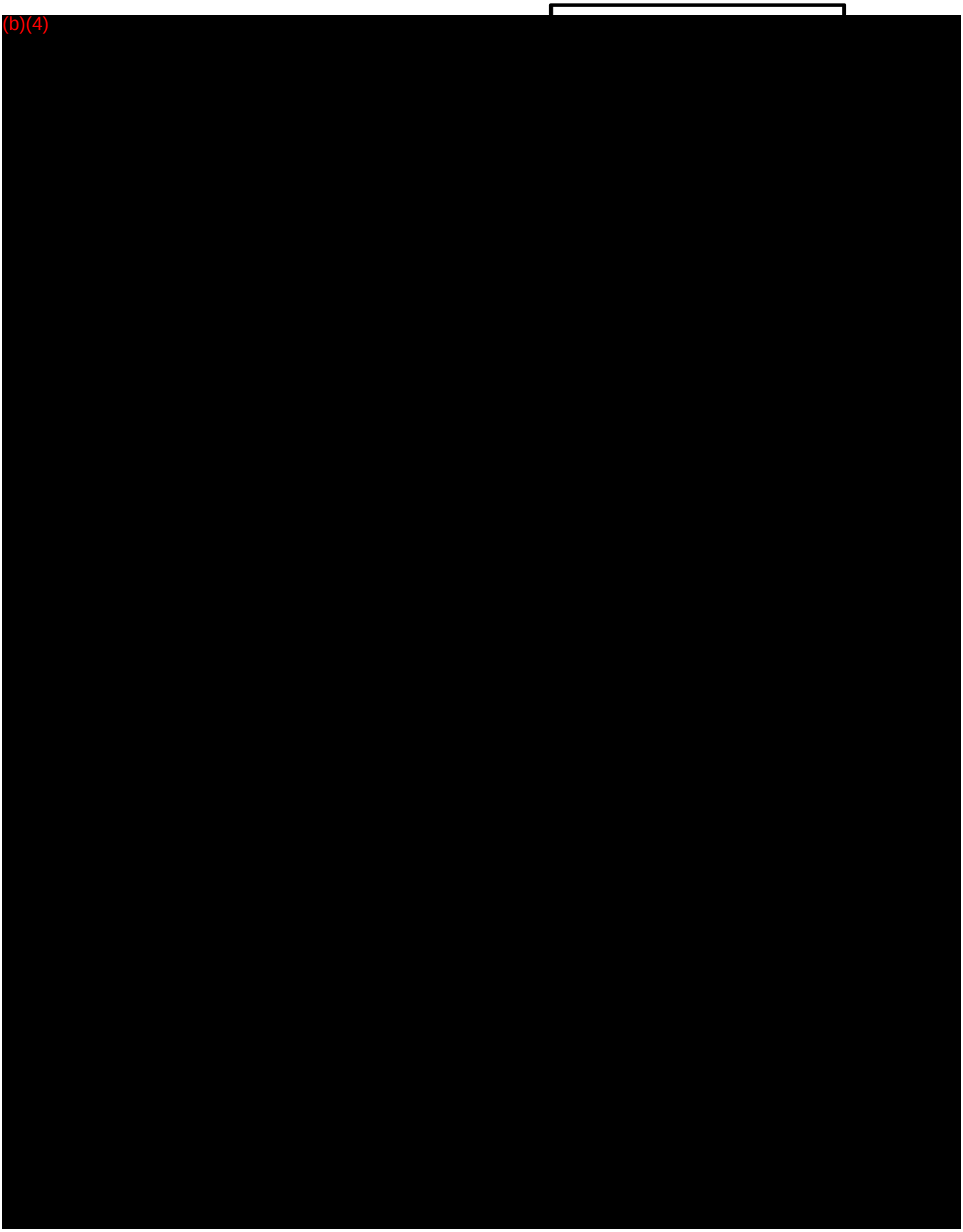
(b)(4)



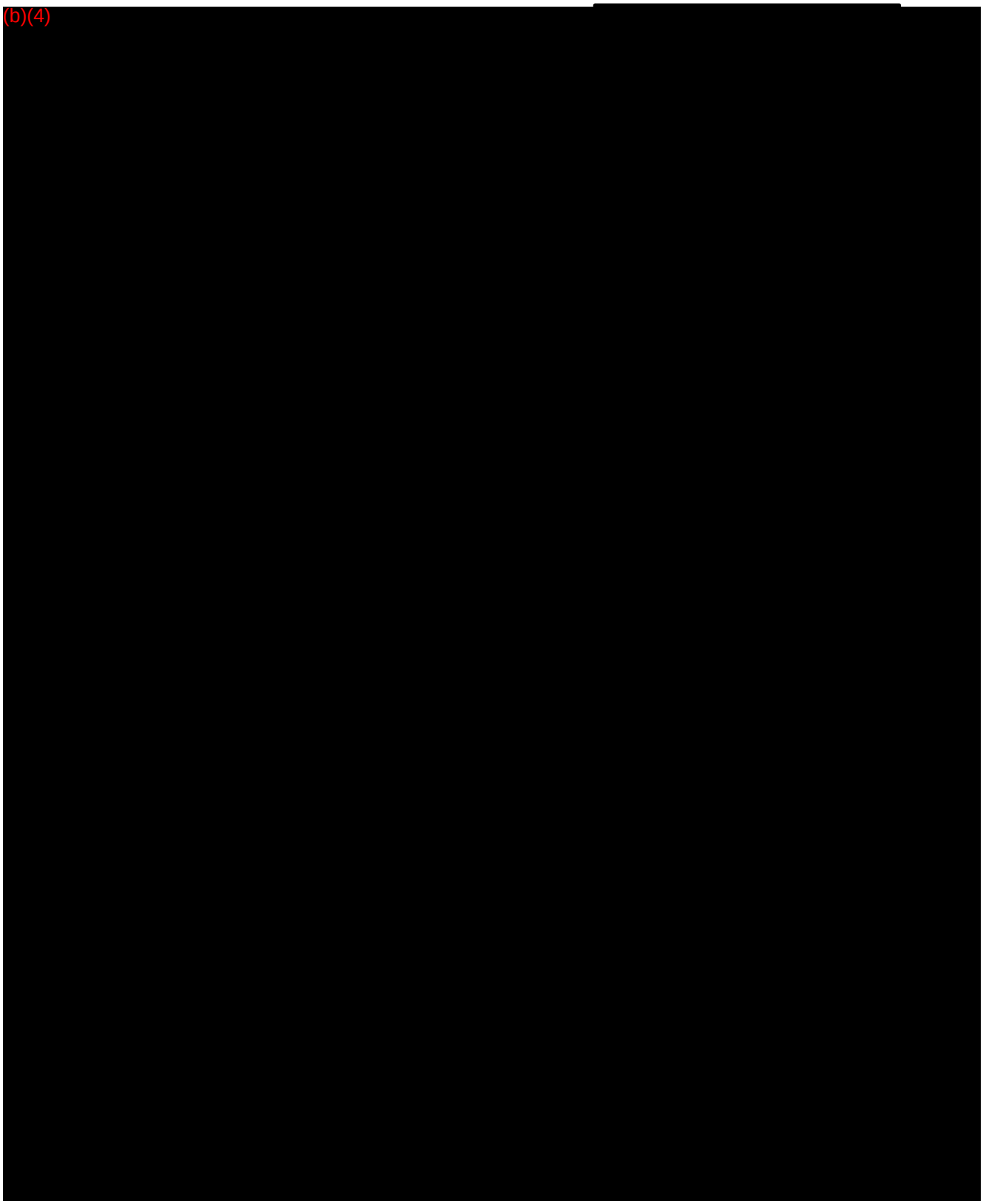
(b)(4)



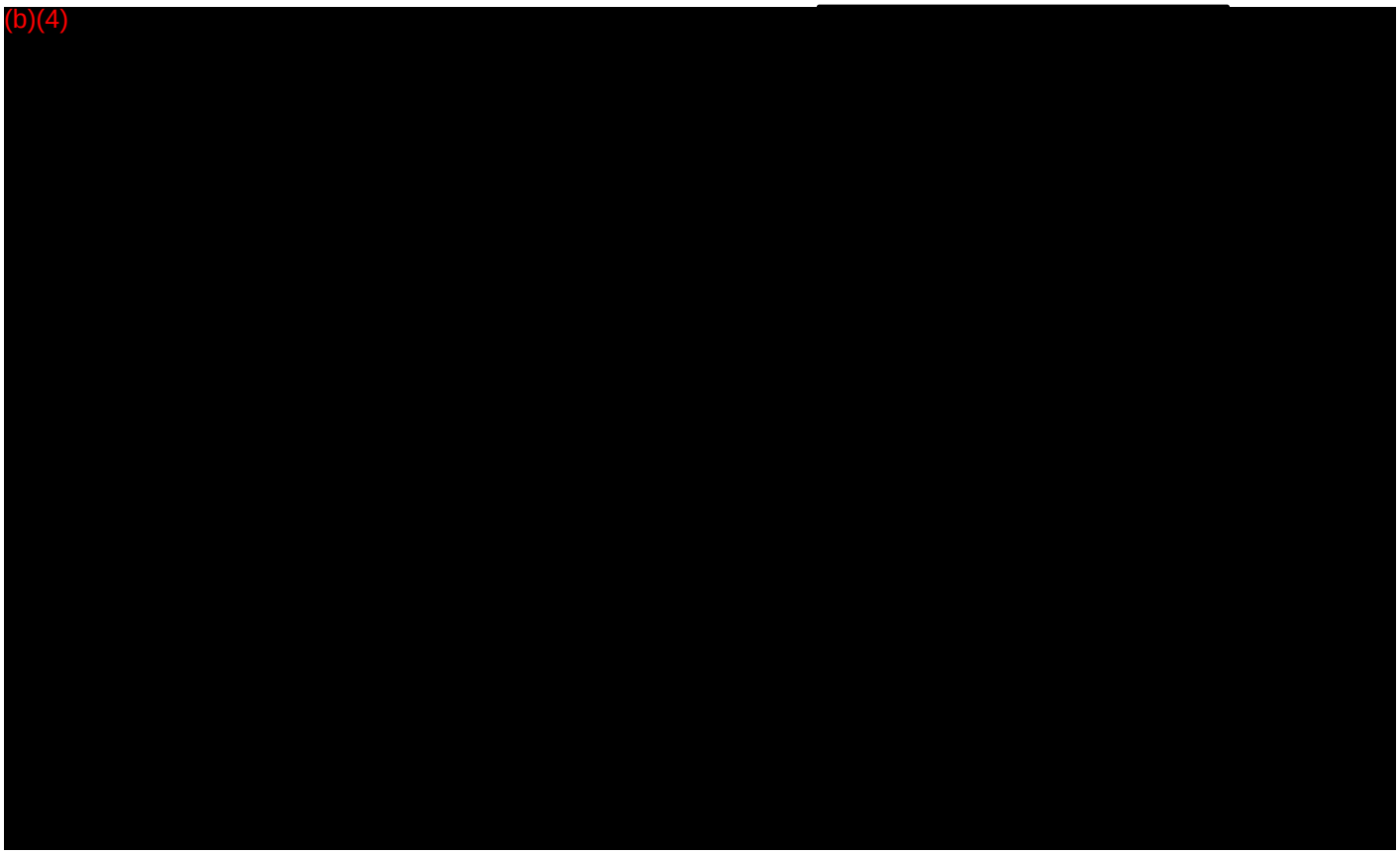
(b)(4)



(b)(4)



(b)(4)

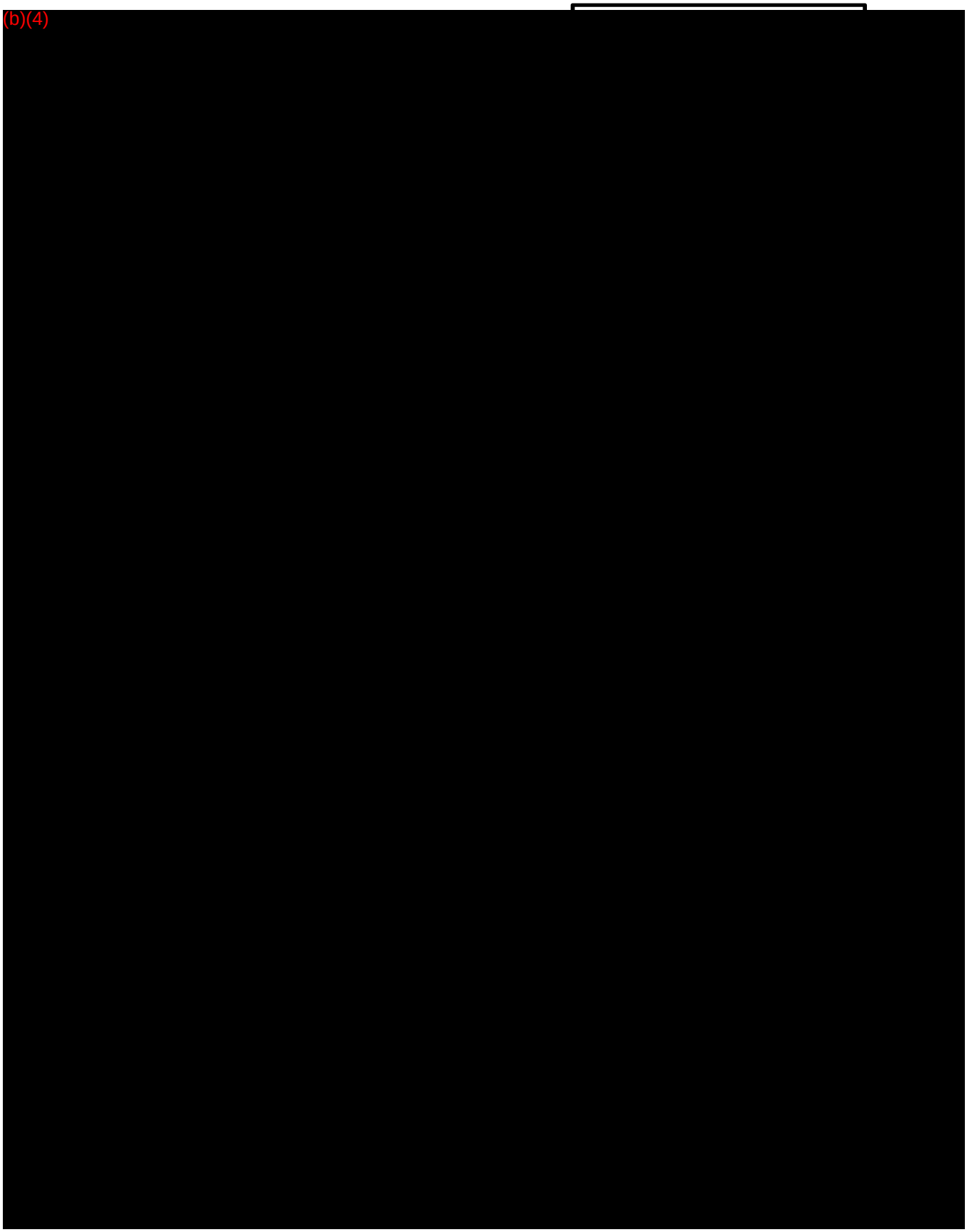


In conclusion, the Revolution system is capable of improving quantitative uniformity of iodinated contrast down to (b)(4) across (b)(4) z-coverage.

2.5.2 Performance item 5b: The Revolution system provides (b)(4) reduction of common CT artifacts due to (b)(4), reducing X-ray scatter-to-primary ratio (SPR) (b)(4) and reducing artifacts from (b)(4) and other (b)(4) objects.

(b)(4)

(b)(4)

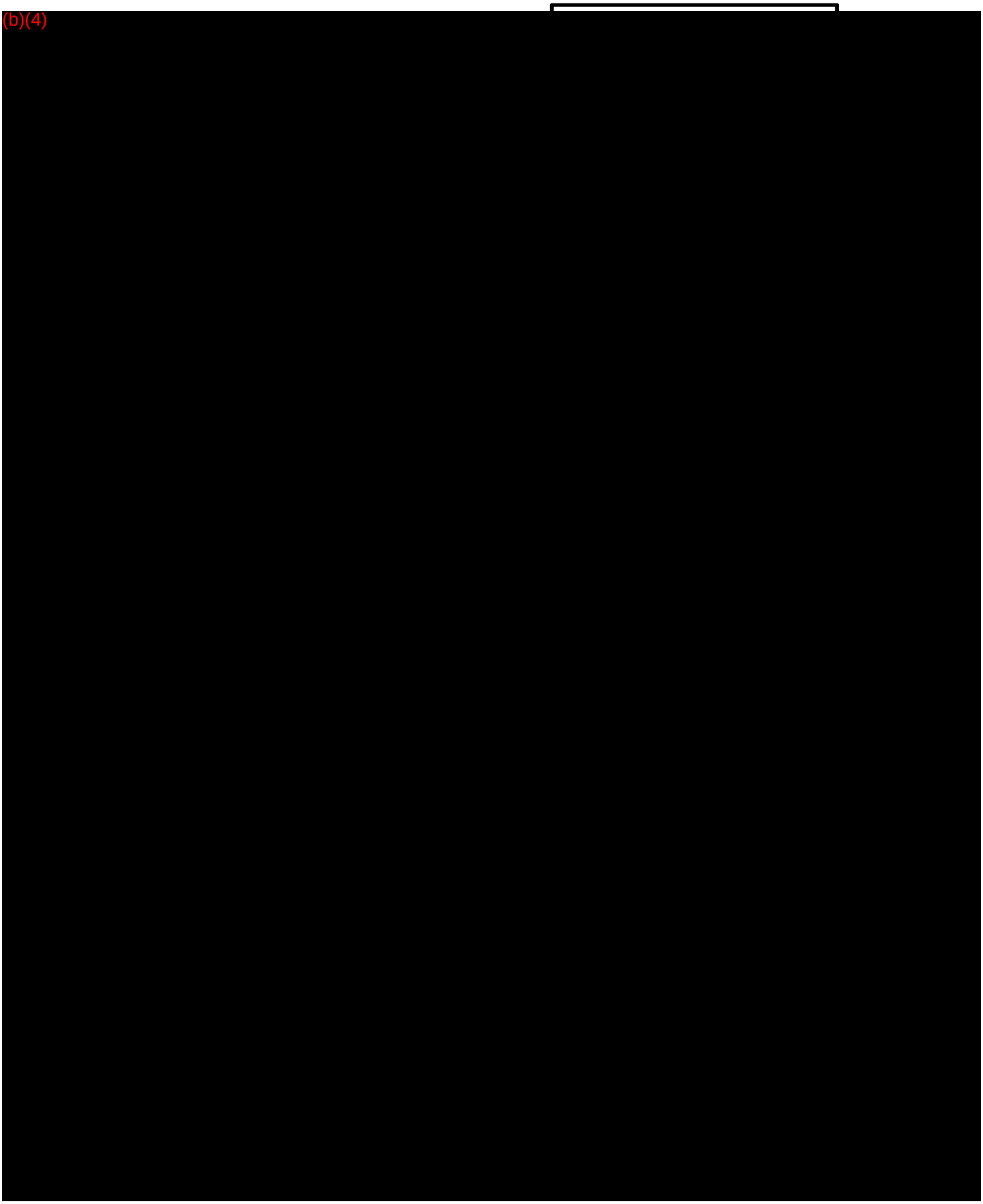


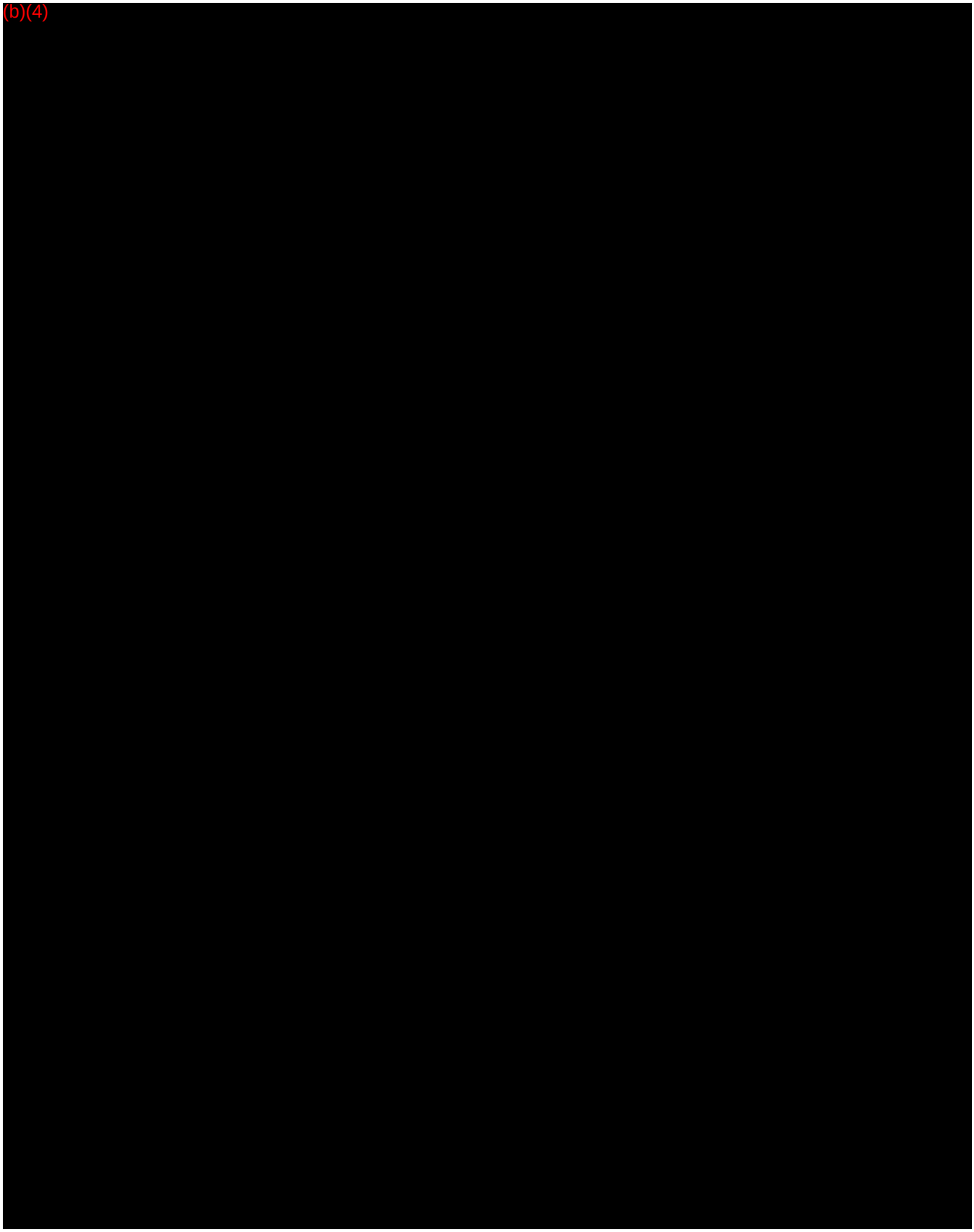
(b)(4)

In conclusion, the Revolution system provides (b)(4) reduction of the X-ray scatter-to-primary ratio (b)(4) across (b)(4)

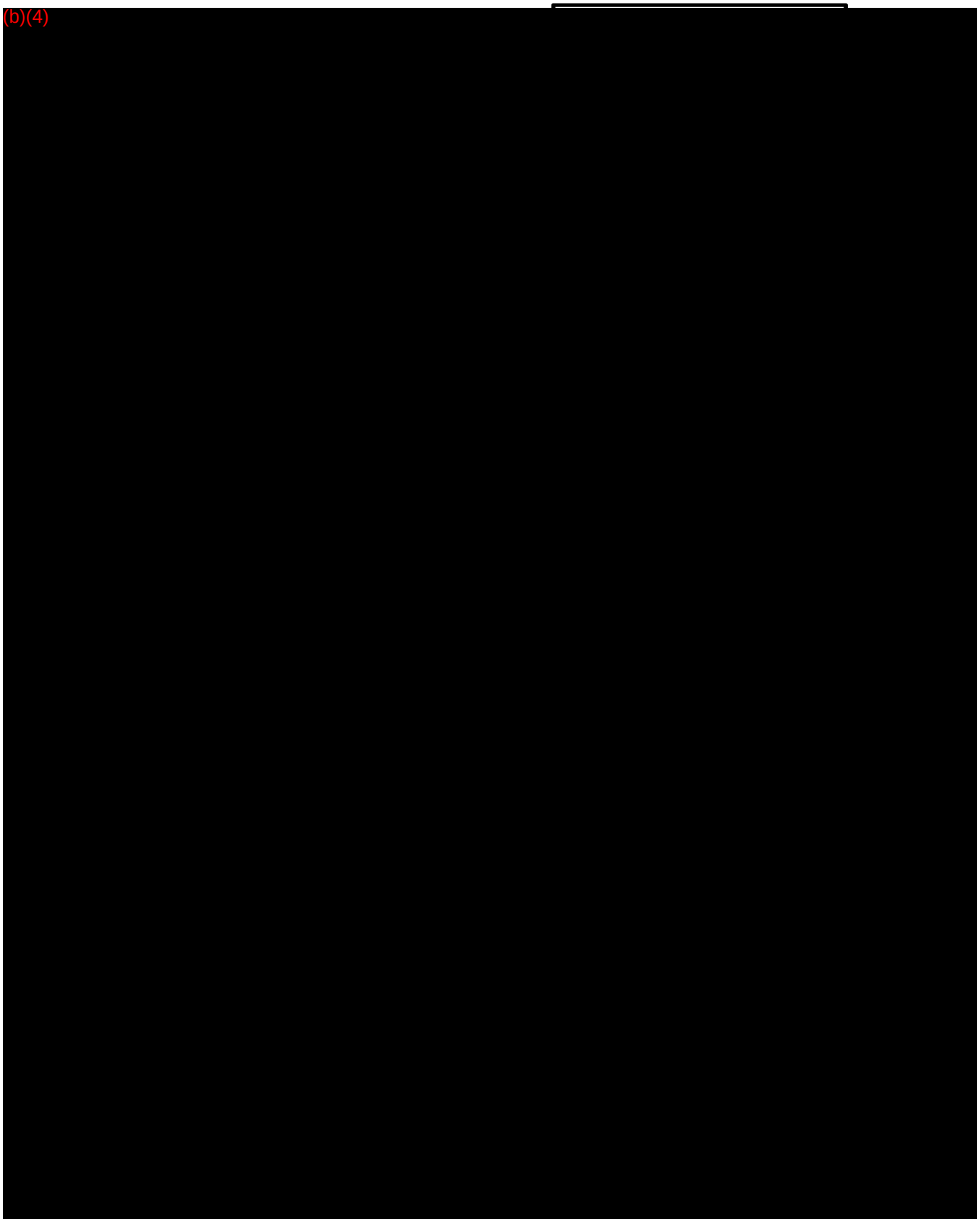
(b)(4)

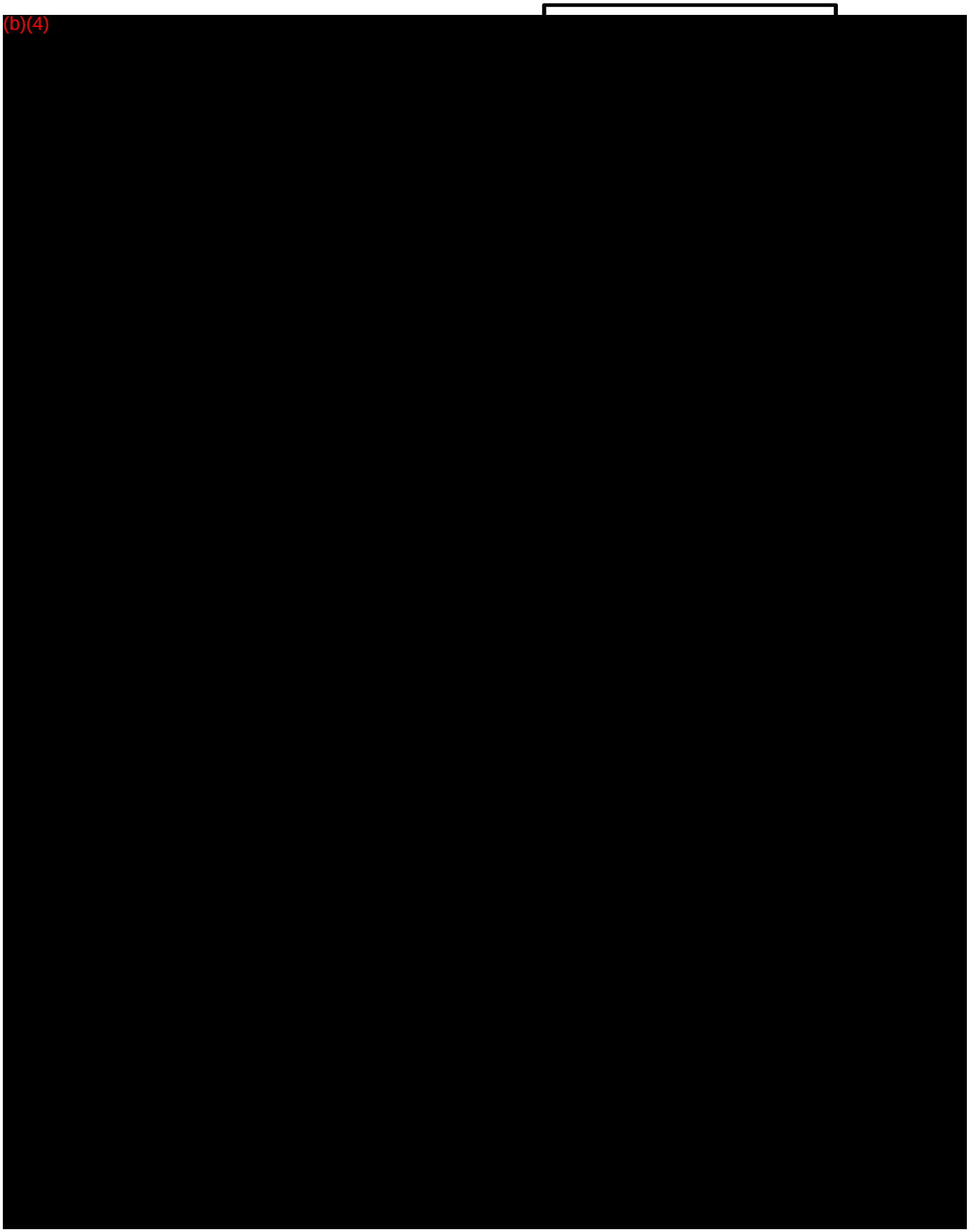
(b)(4)





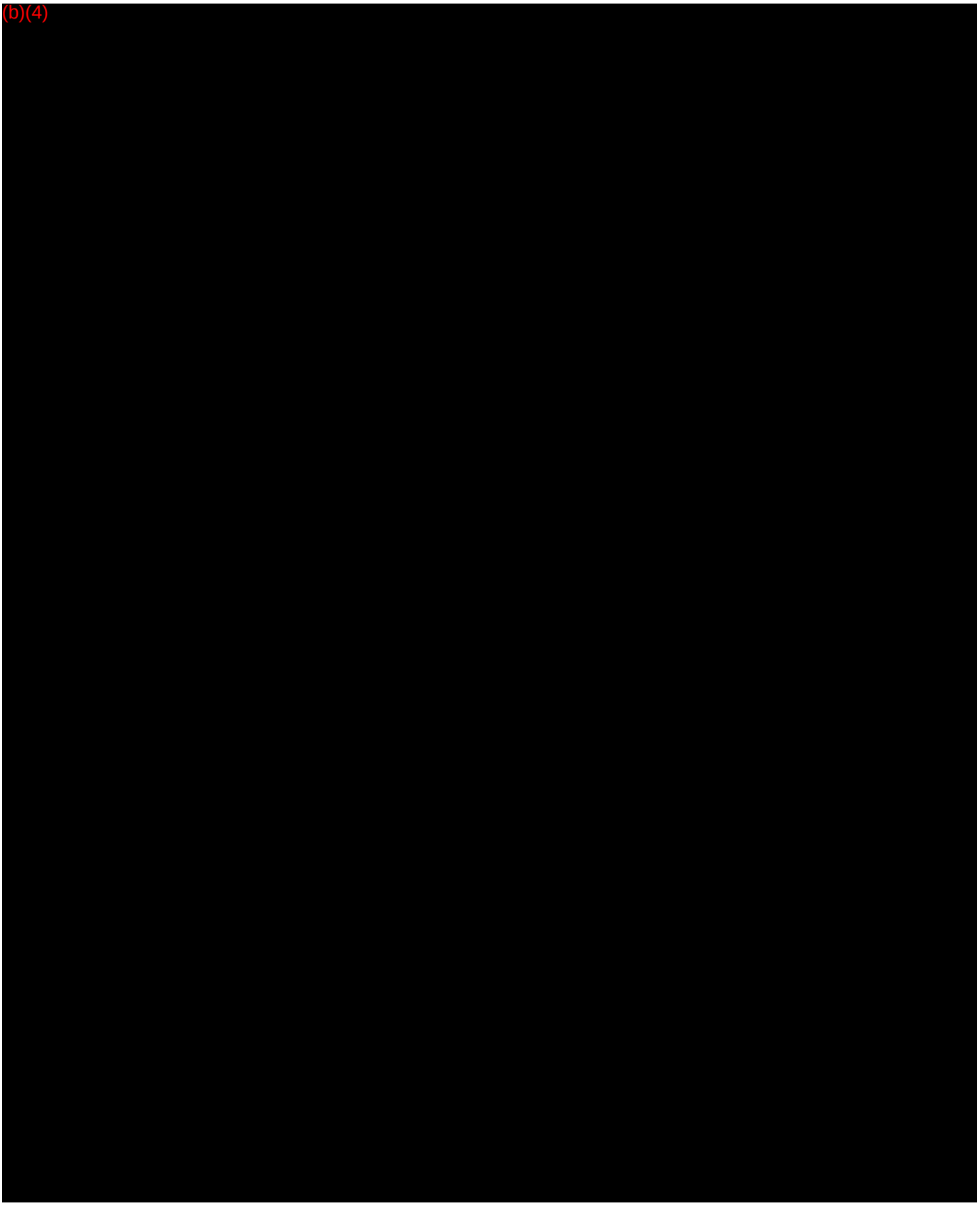
(b)(4)



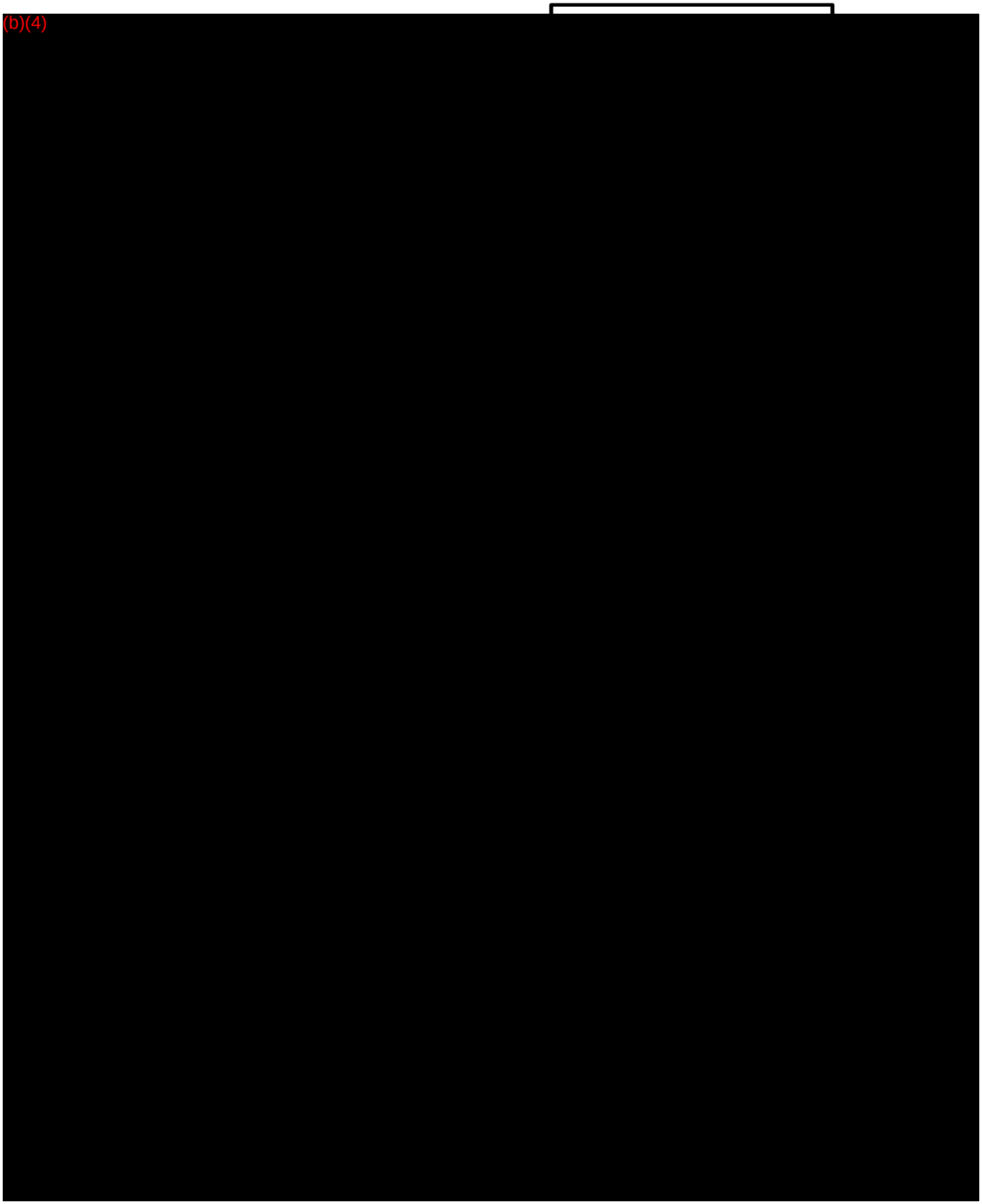


(b)(4)

In conclusion, the Revolution scanner can reduce (b)(4) and other (b)(4) objects.



(b)(4)



(b)(4)

In conclusion, the Revolution scanner is capable (b)(4) spatial resolution.

2.6 Platform Design:

2.6.1 Performance item 6a: The Revolution system has been designed and safety tested to rotate with speeds (b)(4) per rotation.

(b)(4)

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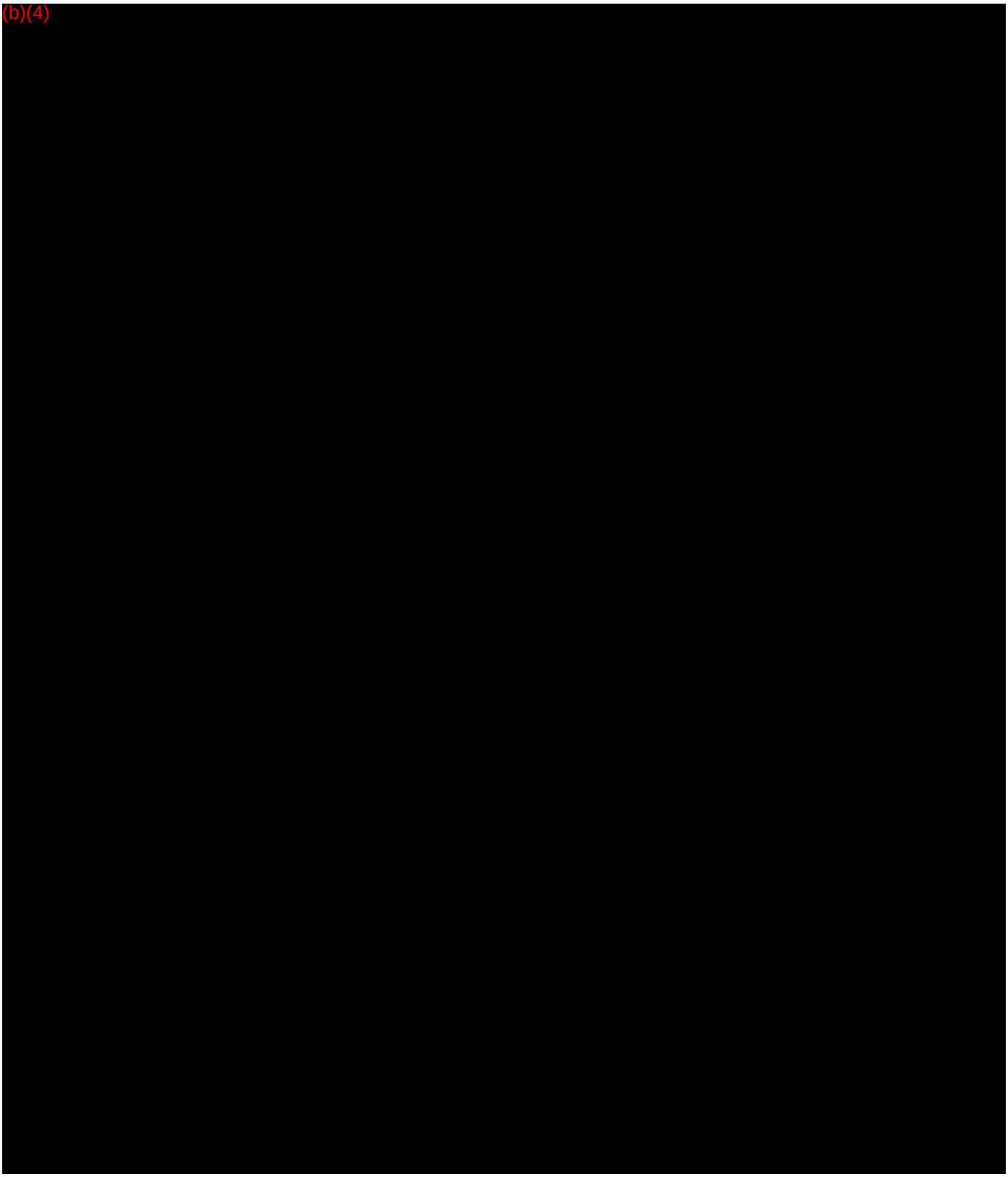
(b)(4)



In conclusion, the Revolution system has been designed and safety tested to rotate with speeds (b)(4) per rotation.

2.6.2 Performance item 6b: The Revolution system includes detector acquisition electronics which (b)(4) bandwidth (b)(4) faster trigger rate (b)(4) (b)(4) and reduce electronic noise (b)(4) which may improve image quality and reduce artifacts in low signal conditions as may be encountered when scanning large patients*.

(b)(4)

In conclusion, the Revolution system includes (b)(4) which (b)(4) bandwidth than (b)(4)

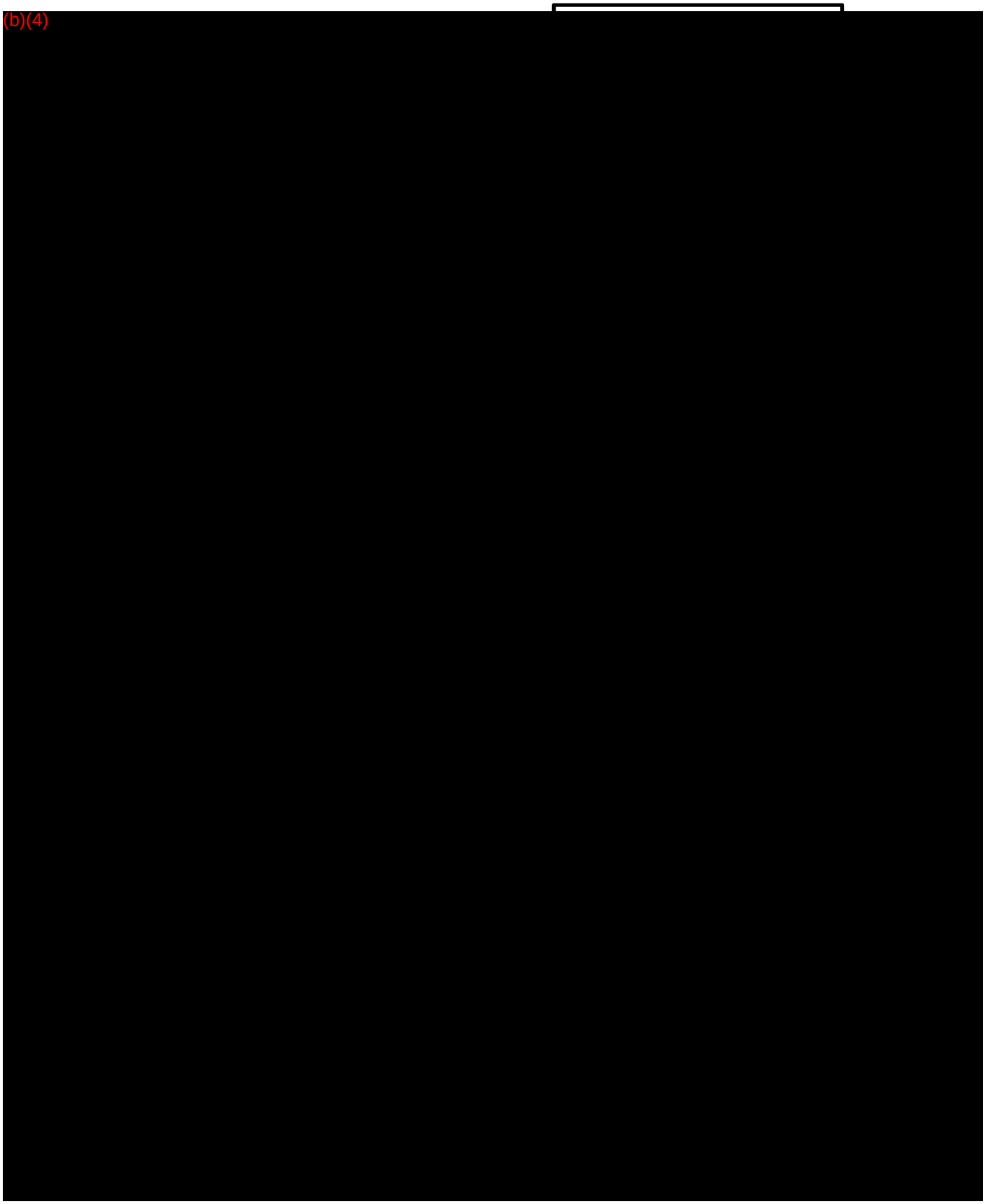
(b)(4)

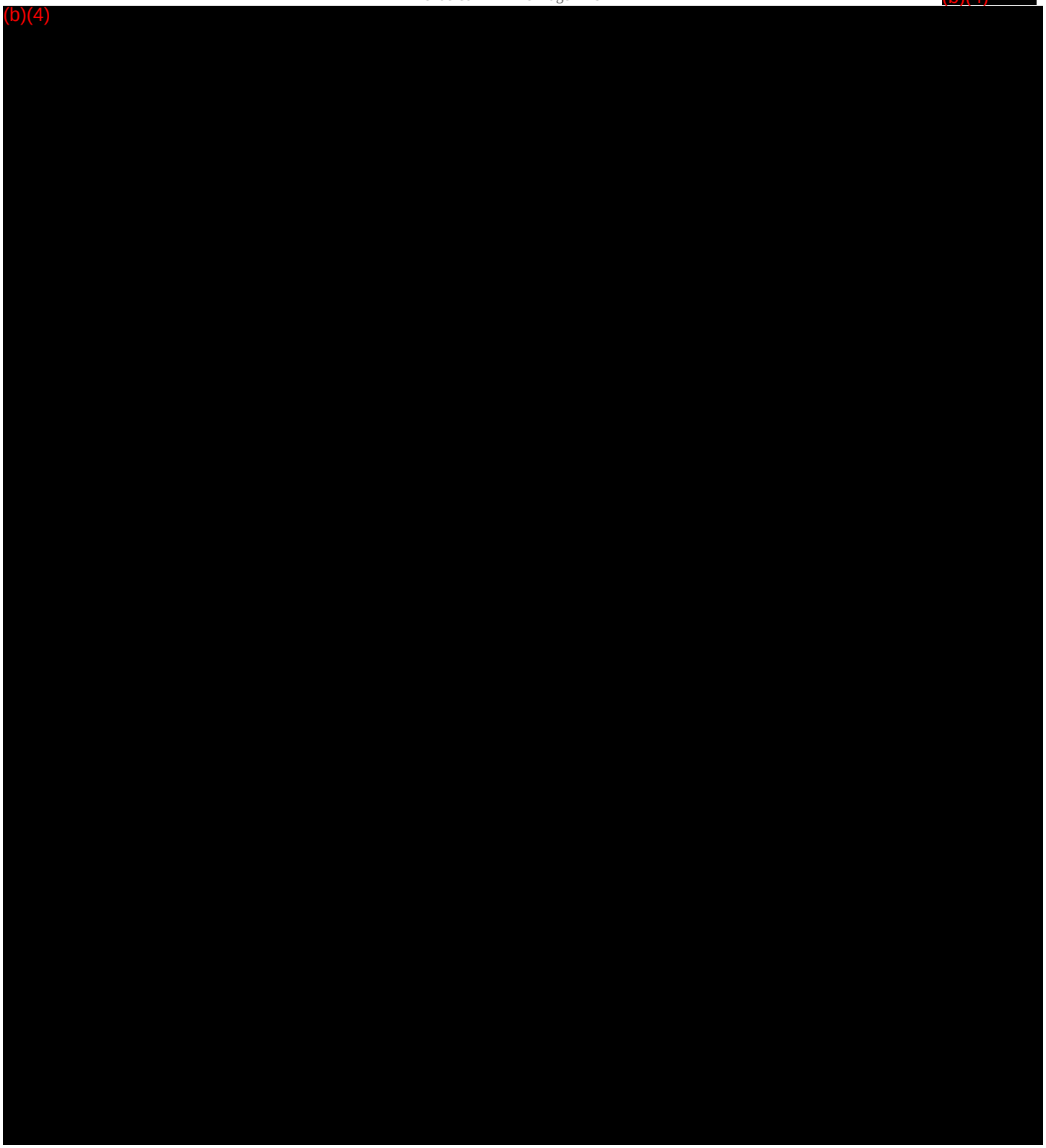
In conclusion, the Revolution system includes detector acquisition electronics which (b)(4) faster trigger rate than (b)(4) .

(b)(4)

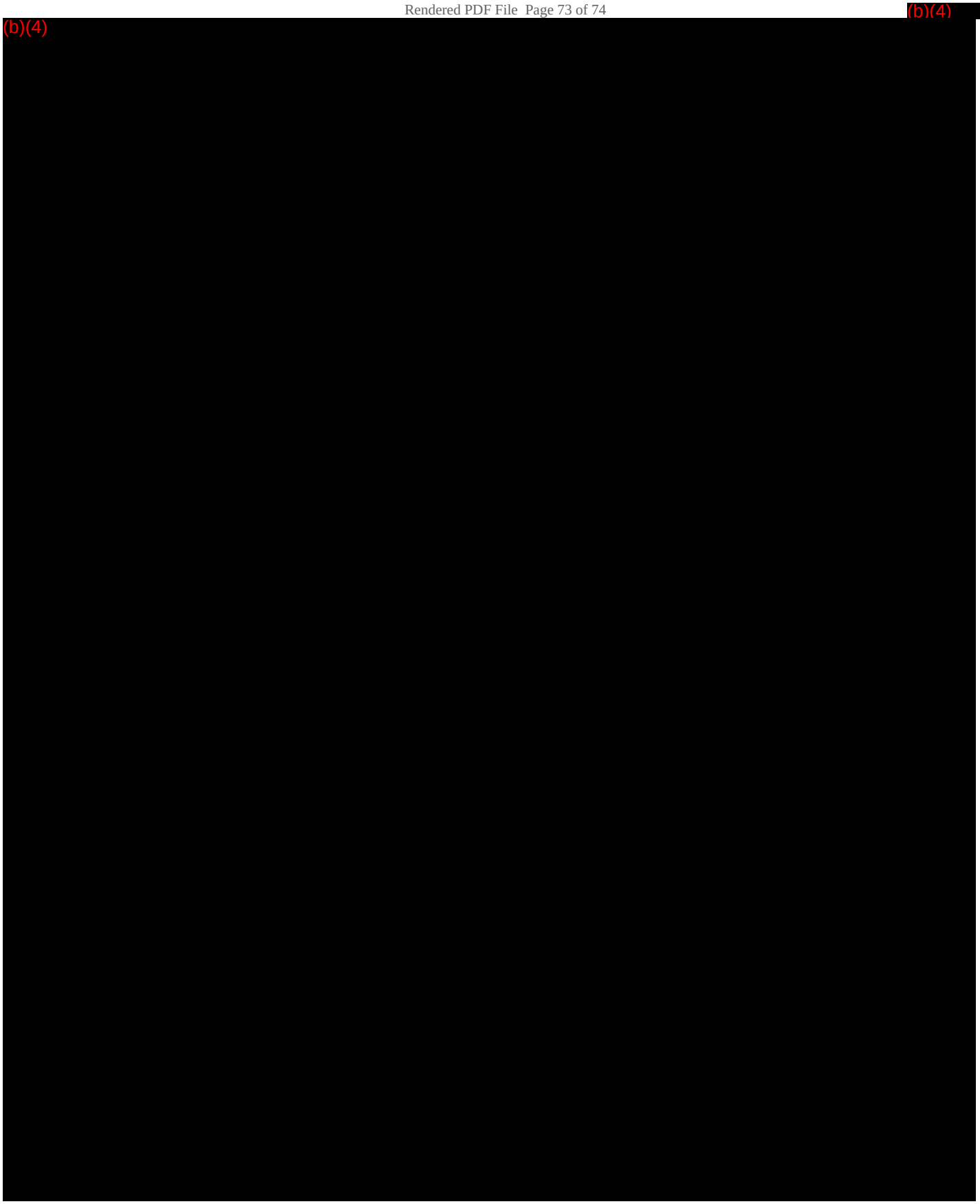
In conclusion, the Revolution system includes detector acquisition electronics which can reduce electronic noise (b)(4) compared to (b)(4)

(b)(4)





In conclusion, the Revolution scanner includes detector acquisition electronics that reduce electronic noise (b)(4) which may improve image quality and reduce artifacts in low signal conditions as may be encountered when scanning large patients.



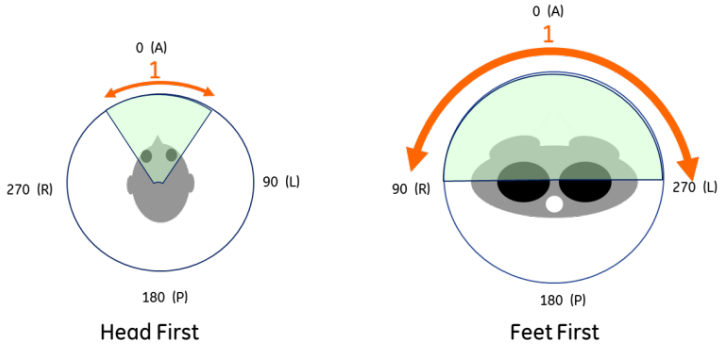
Organ Dose Modulation

Organ Dose Modulation (ODM) builds on the SmartmA feature to enable even further patient dose reduction. By reducing the mA exposure profile as a function of the X-ray tube angle, radiosensitive organs towards the anterior surface of the patient, such as the eyes, breasts and thorax, can be further protected.

By modulating the X-ray tube current as a function of X-ray tube angle, ODM enables targeted reduction of the X-ray tube current towards the anterior surface of the patient, providing enhanced dose reduction to radio-sensitive organs of the patient while maintaining overall image noise.

In a similar way to other AEC features, the effectiveness of ODM is impacted by patient centering. To realize the expected dose reduction, the patient should be positioned in the center of the SFOV.

Modulation example for ODM: 1=Tube current reduction area



The mA reduction rate on front side of the patient and the mA reduction tube angle are shown below.

For ODM mA reduction rate for ODM

(b)(4)

When patient is in prone position, the mA is reduced from table side as it is the direction of the front side of the patient.

Organ Dose Modulation (ODM) provides a mA modulation mode to optimize patient dose in the anterior/front direction of the patient where the most radiation sensitive organs are located while maintaining (b)(4) in other areas by (b)(4)) according to the X-Ray tube angle.

IMPORTANT: Please refer to the Safety section for important information regarding the use of the equipment and software of the system.

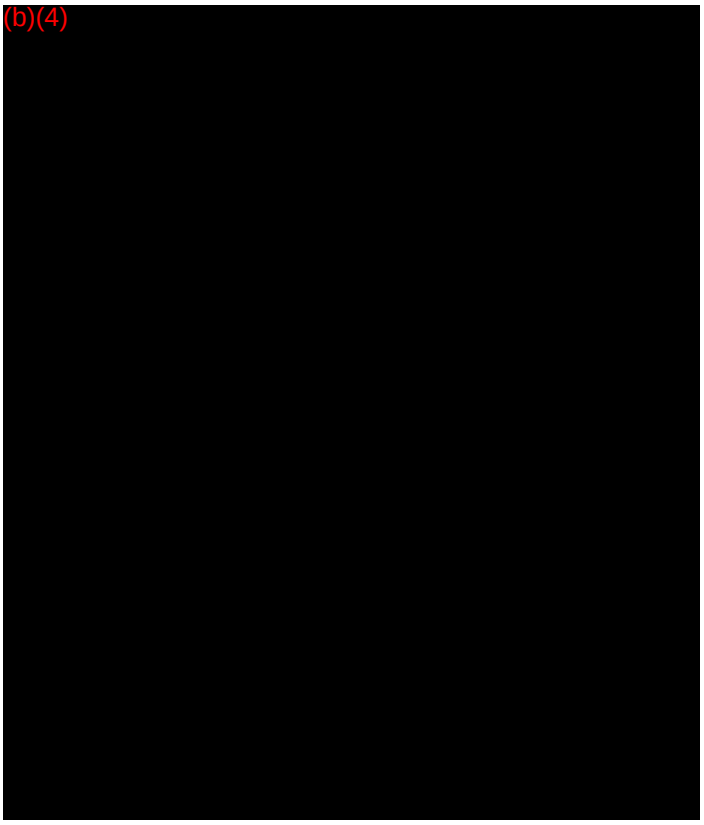
Attention: (b)(4) Organ Dose Modulation is impacted by patient centering. To realize expected dose reduction, the patient should be positioned in the center of the Scan-Field-of-View (SFOV).

Considerations:

- A Scout is required.
- mA mode selected should be SmartmA and ODM.
- ODM can be used for Axial, Cine and Helical scan type
- (b)(4)
- The mA modulation range for ODM is based on the (b)(4) for the acquisition.
- The mA modulation range follows the AP/front of the patient. Thus, the patient orientation on table will be used to define the tube angle range where mA modulation is applied for ODM.
- The maximum number of ODM locations (b)(4)
- The range of an ODM location is a minimum (b)(4) for Helical and (b)(4) for Axial or Cine (b)(4)
- ODM locations cannot (b)(4)
- ODM can be built into a protocol in Protocol Management.
- When a Scan Type is not compatible/invalid with ODM, the system posts an Attention popup with the message: (b)(4)

Organ Dose Modulation Screens

(b)(4)



Start/End

Displays start and end location of the ODM location entered explicitly or prescribed graphically.

Enable Location / Disable Location

To enable a location click in the box next to Loc 1, 2 or 3. To disable a location uncheck the box. Maximum number of ODM locations is (b)(4). ODM locations cannot (b)(4).

mA Table Information

The mA table displays the mA per rotation. An asterisk (*) indicates which scan rotations where OMD was applied along with the mA value in the A (anterior), P (posterior), L (Left), and R (right) of the patient. If the patient is Feet First then the position of Left and Right are reversed.

Scanning with Organ Dose Modulation

1. Select a protocol with valid scan type and perform the Scout scans.

2. On the scan settings screen, select kV mA Control collection and select mA mode SmartmA and ODM.

3. Check Location 1

4. Prescribe the location of the ODM location explicitly in the ODM prescription screen or graphically prescribe the location on the Localizer.

- Rt. Click on the localizer to graphically display the ODM location
- On the Localizer, inactive ODM locations are differently from active ODM locations.

Figure 3: Inactive ODM location displayed on the Localizer image.

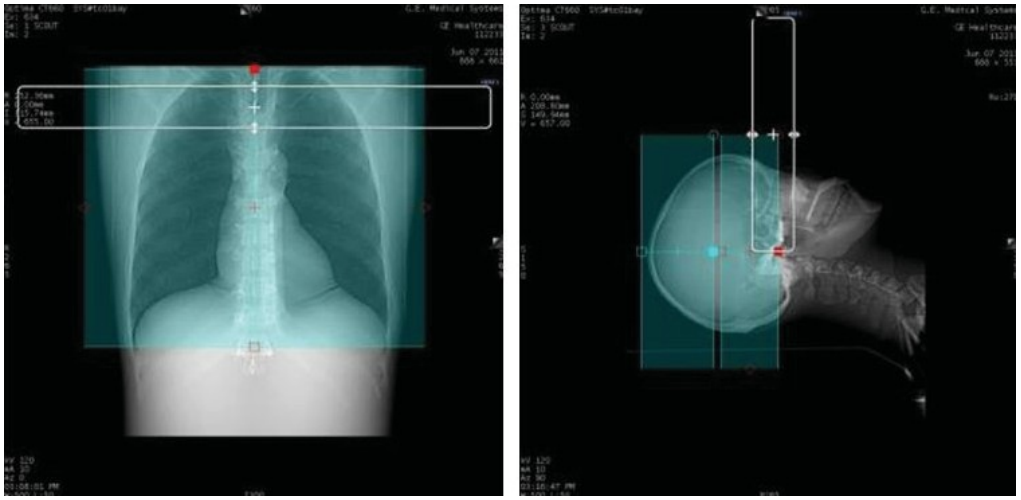
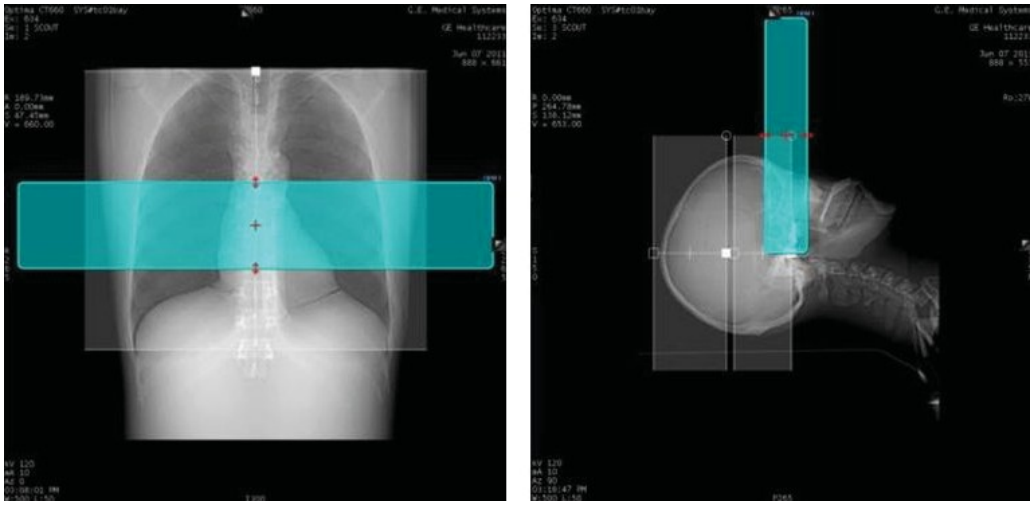


Figure 4: Enabled/active ODM Location



- ODM location can be moved (b)(4) It cannot be moved in (b)(4) .
- Minimum of (b)(4) for Helical and (b)(4) for Axial or Cine to maximum of the scan range. The mA modulation is applied across a full rotation. It cannot be prescribed across (b)(4) (b)(4)

5. When ODM is applied, the mA mode is listed as SmartmA and ODM in the kV and mA Control collection. This means ODM scan is enabled for one or more tube rotations in a scan group for the series. It does not mean all the rotations in the scan group have ODM applied.

Figure 5 scan settings screen with ODM enabled for the scan group

(b)(4)

[redacted]

6. Complete the scan prescription and scan.

Image Annotation

When an image is acquired within the ODM range, an asterisk mark (*) is added after Noise Index value.

(b)(4)

Building a protocol with Organ Dose Modulation

1. Go to Protocol Management

2. Select protocol you want to include ODM in. Ensure that the protocol contains a Scout series.

3. Add a scout series prior to the ODM series, if the protocol does not already contain a scout series.

3. On the scan settings screen, click ***kV mA Control***, select SmartmA and ODM.

4. Enable ODM Location by checking the box to add (b)(4) ODM locations.

4. Prescribe the start and end location of the ODM location explicitly in the ODM Information screen or prescribe graphically from the localizer.

5. Complete the rest of the scan prescriptions.

6. Accept and Save the protocol.

In the event that the patient should experience a premature ventricular contraction (PVC) or other irregular heart rhythm, there is the possibility that low noise images could become shifted from the prescribed phases.

5.8 SmartTrack

The purpose of SmartTrack (also known as z-axis tracking, or beam tracking) is to follow the focal spot so that we can keep the most uniform part of the X-ray beam and the narrowest possible beam on the detector to reduce dose and still avoid artifacts. The focal spot moves (b)(4) due to thermal changes in the tube and mechanical forces during gantry rotation. In order to maintain the narrowest possible beam, the system employs a (b)(4) control system called "Z-Axis Tracking". The (b)(4) control system uses (b)(4) data from the (to position the collimator cams in real time. Each blade is automatically and independently) adjusted for optimal beam performance[1].

(b)(4)