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HEALING AT THE SPEED OF LIGHT®

K151816

Aug 19, 2015

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

RE:

Submission Number: K151816

510k Premarket Notification
TLC 2000

Theralase Inc.
1945 Queen Street East
Toronto, Ontario
M4L 1H7
Canada

Phone: 416.699.5273
Fax: 416.699.5250

Contact: Mr. Roger Dumoulin-White

Email: rwhite@theralase.com

To Whom It May Concern:

We are responding to your eCopy Hold Letter dated 08/18/2015 regarding submission number K151816 and have enclosed a replacement eCopy flash drive.

We apologize for this inconvenience.

This eCopy is an exact duplicate of the paper copy.

Theralase Inc. is requesting market clearance for their TLC2000 Laser System for use as an adjunctive treatment for knee pain therapy in accordance with 21 CFR 807.81. Devices of this type have been classified as Class II (performance standards) medical devices according to 21 CFR 890.550. Evidence to support the substantial equivalence to a predicated device is included in this submission.

44

The information contained herein is deemed confidential and the protection afforded to such confidentiality by application of laws and federal regulations is hereby claimed.

Your prompt response and affirmative reply to this Premarket Notification is greatly appreciated. Should you have any questions regarding this submission please do not hesitate to contact me.

Mr. Roger Dumoulin-White
President and CEO
Theralase Inc.

K151816

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Aug 13, 2015

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Silver Springs, MD 20993-0002

RE:

Submission Number: K151816

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Contact: Mr. Roger Dumoulin-White

Email: rwhite@theralase.com

To Whom It May Concern:

We are responding to your eCopy Hold Letter dated 07/06/2015 regarding submission number K151816.

We have reviewed the letter and have determined that the list of errors is due to hidden files resident on the flash drive. We apologize for this inconvenience. We have taken precautions to ensure that there are no hidden files on the included replacement flash drive.

All files are saved as pdf files which can be opened by Adobe Reader Version 9.5.

We ask that the original hard copy and eCopy submission be replaced with the hard copy and eCopy of this 510(k) submission. This eCopy is an exact duplicate of the paper copy.

28

Theralase Inc. is requesting market clearance for their TLC2000 Laser System for use as an adjunctive treatment for knee pain therapy in accordance with 21 CFR 807.81. Devices of this type have been classified as Class II (performance standards) medical devices according to 21 CFR 890.550. Evidence to support the substantial equivalence to a predicated device is included in this submission.

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Mr. Roger Dumoulin-White
President and CEO
Theralase Inc.

1945 Queen Street East, Toronto, Ontario M4L 1H7, Canada
•416.699.5273 •1.866.843.5273 •www.theralase.com

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June 26, 2015

K151816

FDA CDRH DMC
JUL 06 2015
Received

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

RE: 510k Premarket Notification
TLC 2000

Theralase Inc.
1945 Queen Street East
Toronto, Ontario
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Enclosed herein is the original hard copy and one electronic copy (eCopy) of the 510k Notification submission. This eCopy is an exact duplicate of the paper copy.

The information contained herein is deemed confidential and the protection afforded to such confidentiality by application of laws and federal regulations is hereby claimed.

1945 Queen Street East, Toronto, Ontario M4L 1H7, Canada
•416.699.5273 •1.866.843.5273 •www.theralase.com

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A copy of the Medical Device User Fee Cover Sheet and the payment verification are enclosed for your information. These documents have been sent to the appropriate division of the Department of Health and Human Services as required.

Your prompt response and affirmative reply to this Premarket Notification is greatly appreciated. Should you have any questions regarding this submission please do not hesitate to contact me.

Mr. Roger Dumoulin-White
President and CEO
Theralase Inc.

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Aug 13, 2015

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Mr. Roger Dumoulin-White
President and CEO
Theralase Inc.

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(b)(4)Proprietary Information

[redacted]

Appendix 1 – Medical Device User Fee Cover Sheet

Form Approved: OMB No 0910-511 Expiration Date: January 31, 2010 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)Proprietary 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)	2. CONTACT NAME
Theralase Inc. 1945 Queen Street East Toronto, Ontario M4L 1H7, Canada	Roger Dumoulin-White
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.1 E-MAIL ADDRESS rwhite@theralase.com
	2.2 TELEPHONE NUMBER (include Area code) 416 699 5273
	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 416 699 5250

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/oc/mdufma

Select an application type:	3.1 Select a center
[x] Premarket notification(510(k)); except for third party	[x] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[x] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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/cdrh/mdufma for additional information)

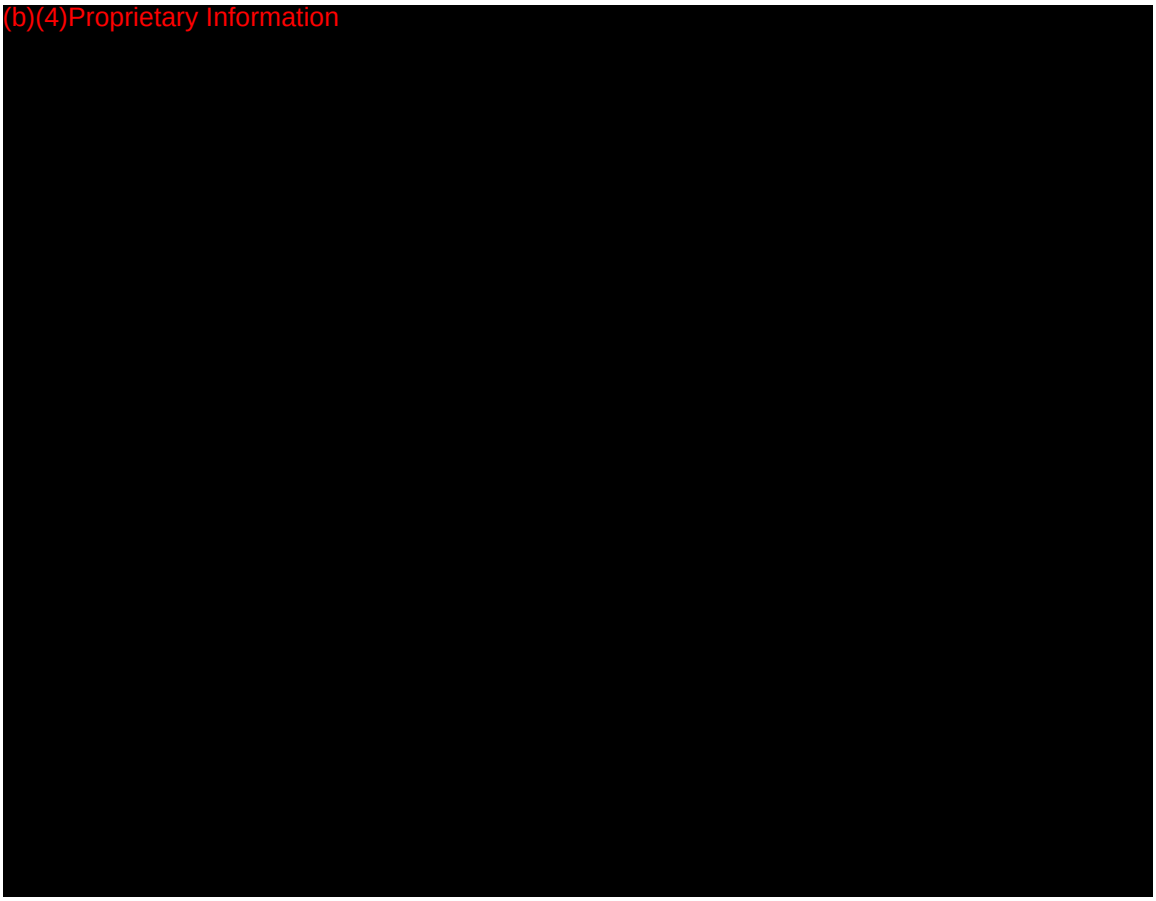
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. No

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] 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). No

Payment was not made using the Medical Device User Fee Cover Sheet Form 3601. Consequently, there is no MD number on the Medical Device User Fee Cover Sheet. However, the proof of payment information auto-reply is provided below.

(b)(4)Proprietary Information



Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of Adobe Reader for Windows®, Mac, or Linux® by visiting http://www.adobe.com/products/acrobat/readstep2.html.

For more assistance with Adobe Reader visit http://www.adobe.com/support/products/acrreader.html.

1.3 Class III Summary and Certification

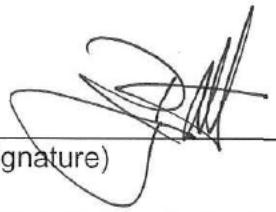
The TLC-2000 is Class II, Performance Standards, 21CFR Part 890.5500 – Infrared Lamp, Non-Heating. Consequently this section does not apply to the TLC-2000 product.

1.4 Financial Certification Statement

This section is not applicable to this submission as there were no clinical studies commissioned.

Premarket Notification Truthful And Accurate Statement
[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President and CEO of Theralase Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Roger Dumoulin-White
(Typed Name)

August 15, 2015
(Date)

K151816
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Premarket Notification 510(k) Statement

(As Required By 21 CFR 807.93)

I certify that, in my capacity as President and CEO of Theralase Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

(Signature of Certifier)

Roger Dumoulin-White
(Typed Name)

August 13, 2015
(Date)

K151816
*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Pending

Device Name
TLC-2000 Therapeutic Medical Laser System

Indications for Use *(Describe)*
The Theralase TLC-2000 Therapeutic Medical Laser System is indicated for adjunctive use in the temporary relief of pain associated with knee disorders. An average power setting of 40 mW is used with a treatment time of 1 minute per location. There are seven locations around the knee, three each lateral and medial. The seventh location is on the posterior of the knee at midline of the popliteal fossa.

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

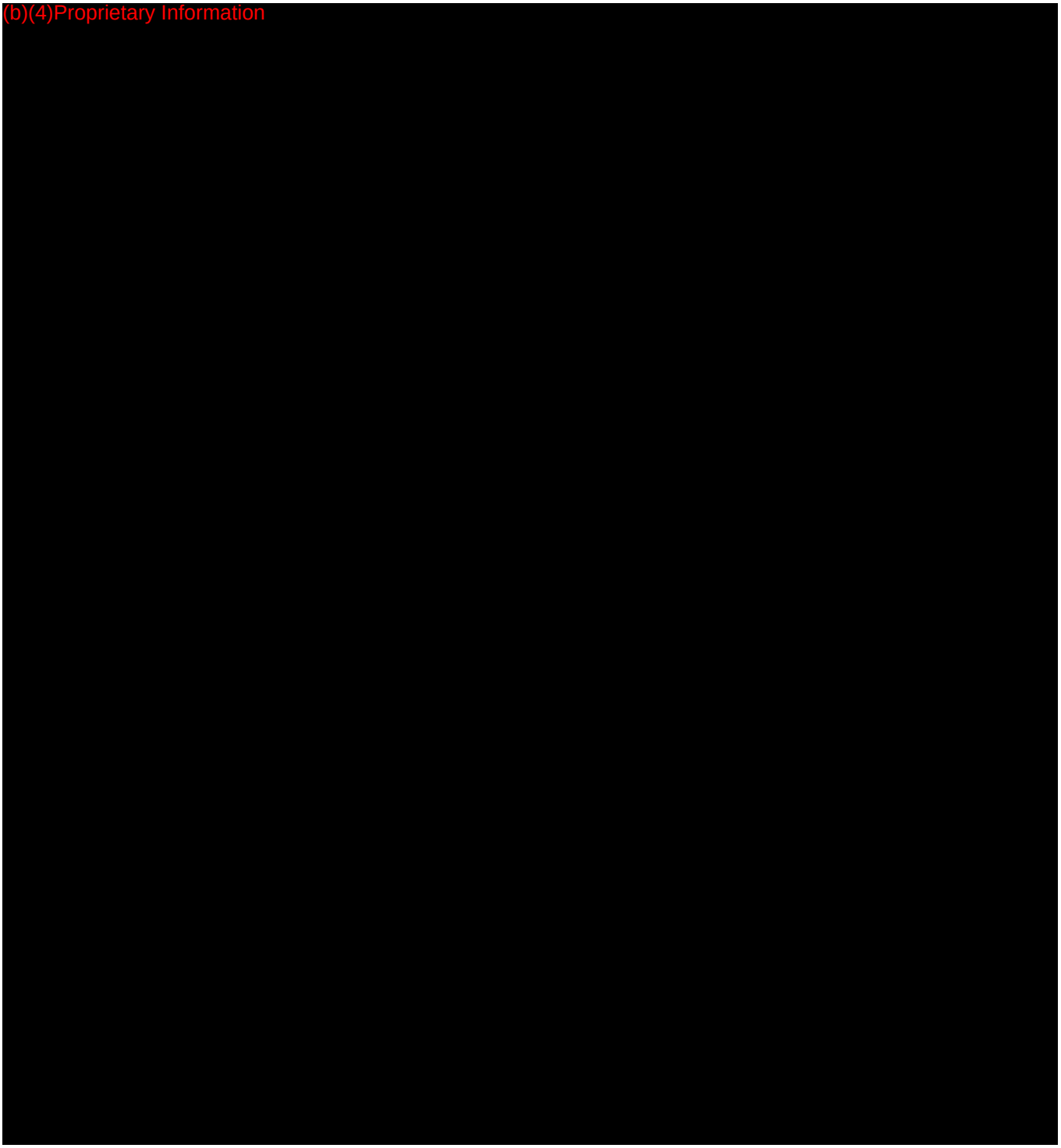
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

1.8 Product Description

The Theralase™ TLC-2000 Therapeutic Medical Laser System is a Class 3B medical laser system and is indicated for use for adjunctive use in the temporary relief of pain associated with knee disorders. The Theralase™ TLC-2000 Therapeutic Medical Laser System is comprised of the following components:

(b)(4)Proprietary Information



The power pack only supplies power to the probe(s) and incorporates the necessary safety measures for laser equipment the emergency stop, key switch and remote shunt. The probes are controlled by Theralase software resident on the tablet computer. The practitioner selects the knee pain diagnosis and the Theralase software transmits the correct power level and time settings for the knee pain protocol to the probe(s). Communications between the tablet and the probe(s) is via a wireless Blue Tooth link. (b)(4)Proprietary Information [redacted] The TLC-2000 laser probes are used in direct contact with tissue in order to inject photons of light (b)(4)Proprietary Information [redacted] non-invasively and drug-free into tissue.

The external power supply is a medically approved power supply. The input voltage range is 100 240 VAC with a frequency range of 47 73 Hz. The power supply connects to the AC source with a medically approved ac cord.

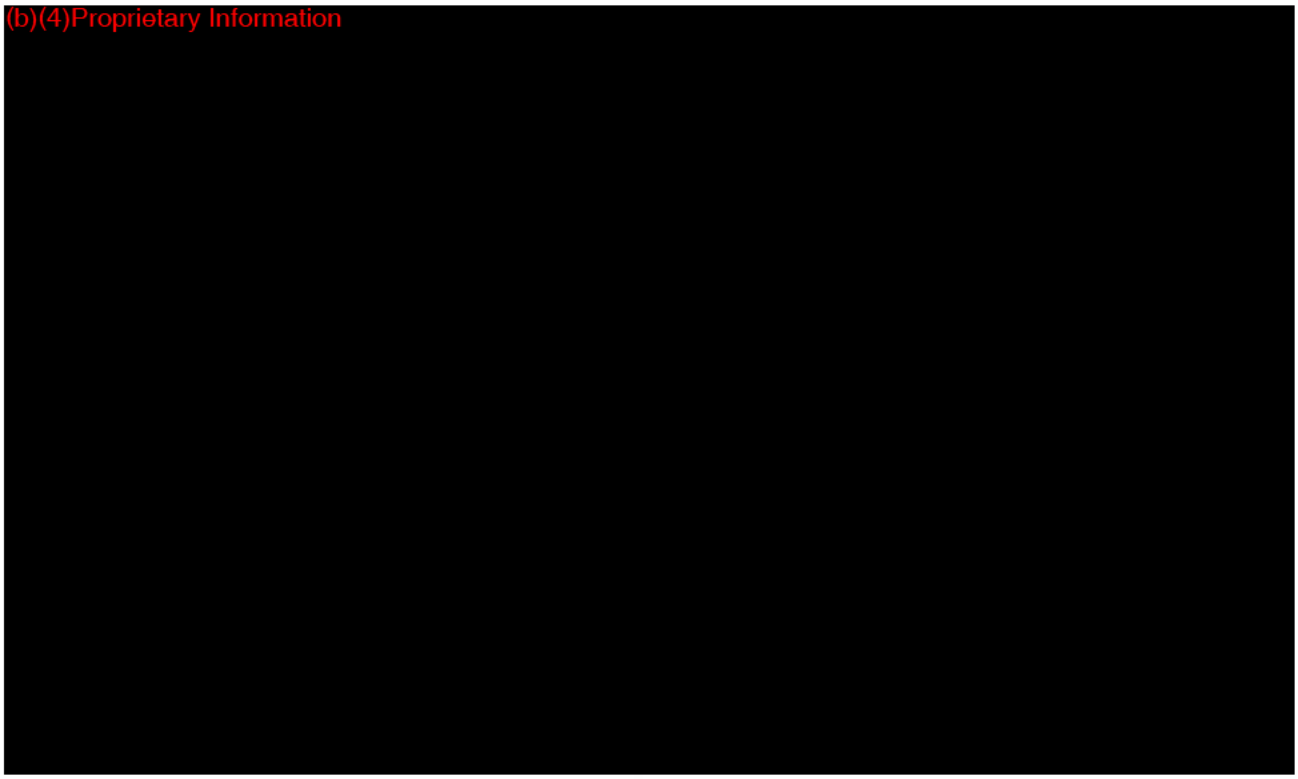
The system is supplies with the Operations Manual, Pain Management Manual, safety glasses and a carrying case.

The Operations Manual is attached as Appendix A to this submission.

Section 1.9 Declaration of Conformity and Summary Reports (FORM FDA 3654)

The TLC2000 Laser System is designed to comply with the Federal Food and Drug Administration's Code of Federal Regulations 21 CFR 1010 and 21 CFR 1040 and other applicable federal and state performance standards and regulations. The Company declares that the technical information provided within this submission is in conformance with the following consensus standards:

(b)(4)Proprietary Information



Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60825-1: Safety of Laser Products, Part 1: Equipment Classification and Requirements

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#12-273	
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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60825-1: Safety of Laser Products, Part 1: Equipment Classification and Requirements

CONFORMANCE WITH STANDARD SECTIONS*

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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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

IEC 60601-1:2012 Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-76	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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SUMMARY REPORT TABLE

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Add page

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

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

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2:2007 Medical Electrical Equipment, General Requirement for Safety. Electromagnetic Compatibility

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-1	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-1-2:2007 Medical Electrical Equipment, General Requirement for Safety. Electromagnetic Compatibility

CONFORMANCE WITH STANDARD SECTIONS*

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

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.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-2-22:2007 Medical Electrical Equipment, Part 2, Particular Requirements for the Safety of diagnostic and Therapeutic Laser Equipment.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#12-208	
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

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 60601-2-22:2007 Medical Electrical Equipment, Part 2, Particular Requirements for the Safety of diagnostic and Therapeutic Laser Equipment.

CONFORMANCE WITH STANDARD SECTIONS*

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		

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

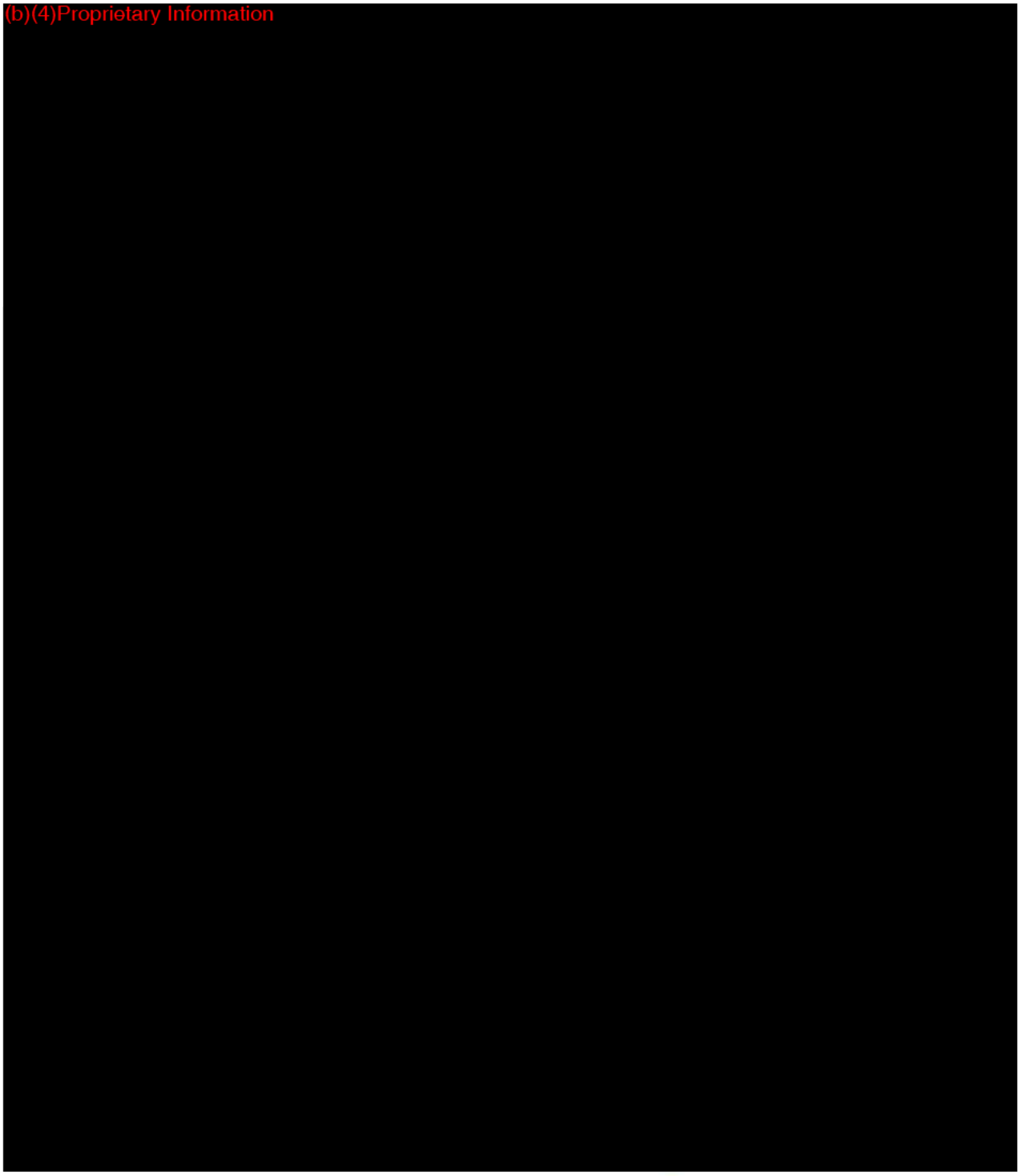
Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

2.1 Device Description

a) THE TLC-2000 SYSTEM

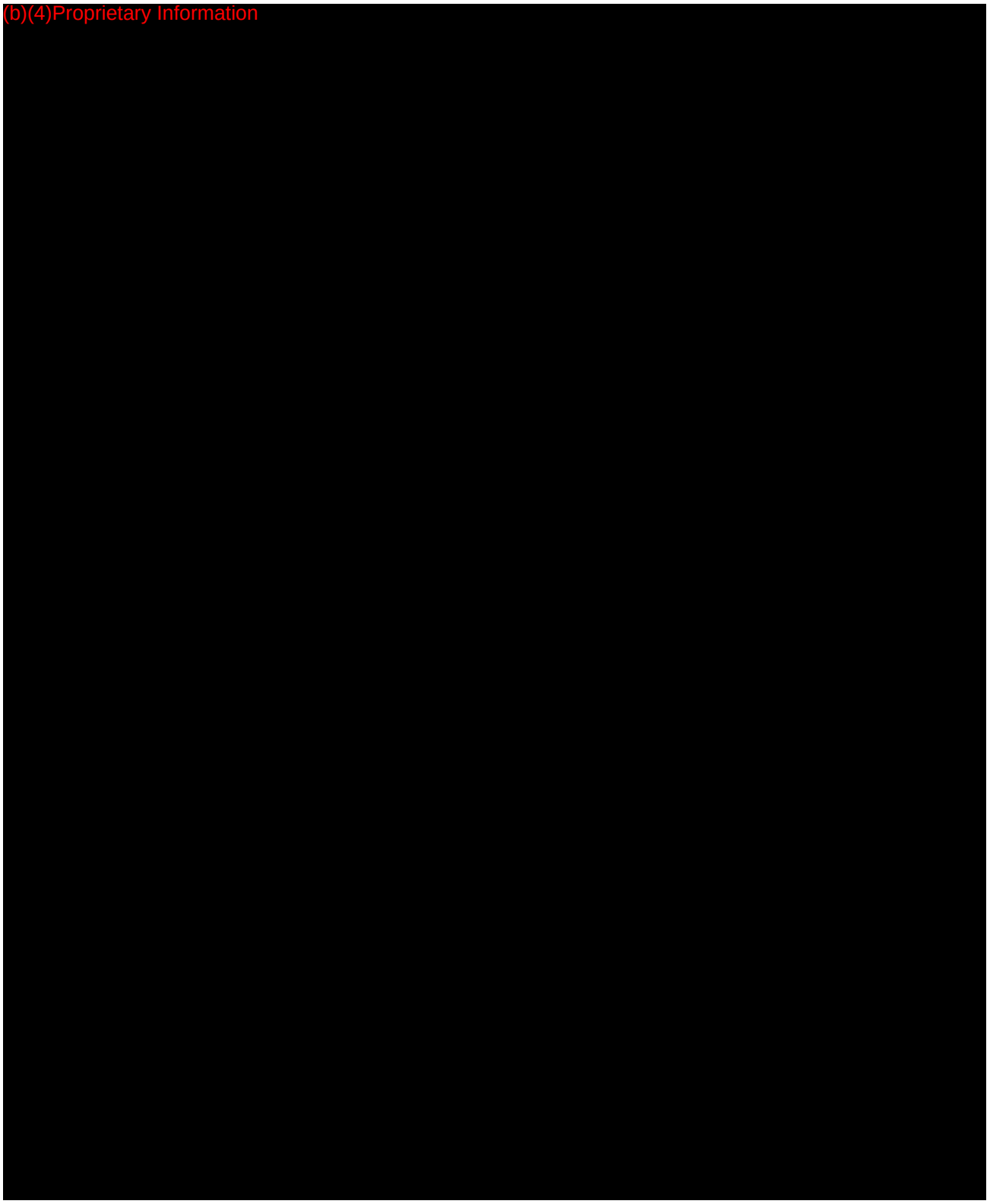
(b)(4)Proprietary Information



System Component Description:

The Probe:

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

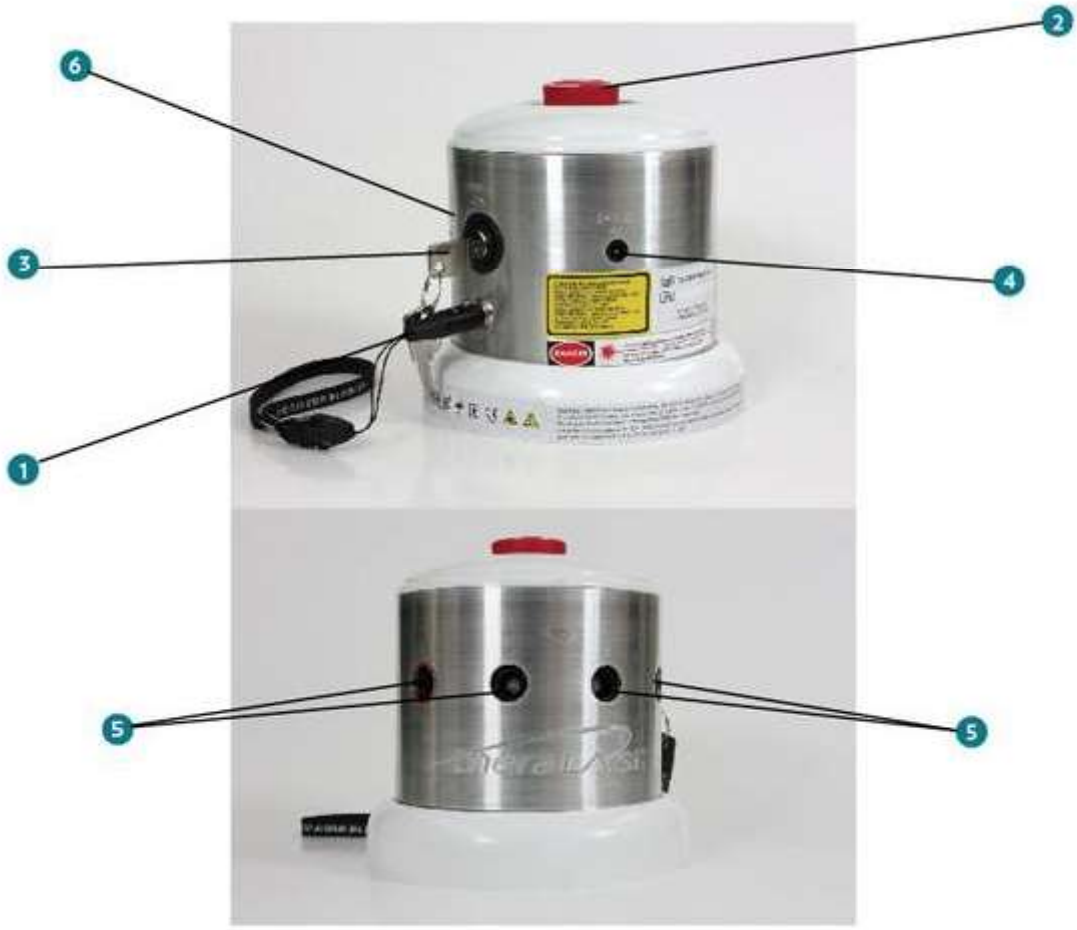
The Tablet:

1 Power On
2 Charging Port
3 USB Port
4 Release Button
5 Touch Pad

The tablet is a windows based computer running Windows 8.1 operating system. The tablet has a Blue Tooth 4.0 radio and WiFi. The tablet has a 10.1" touch screen and a detachable keyboard. The Theralase application software is loaded on the tablet when supplied with the system.

(b)(4)Proprietary Information

The Power Pack:



1 Remote Interlock
2 Emergency Stop
3 Key Switch
4 Power Input
5 Probe Power Ports
6 Power In / Power Out LED indicators

The power pack has the electronics which provide the operating voltages for the probe. The power pack contains the necessary safeties in the form of an emergency stop switch, a remote interlock and a key operated on/off switch. There are four ports available to connect up to four probes.

(b)(4)Proprietary Information

[redacted]

The Power Supply:

The power supply is a medically approved universal, 100 240 VAC input voltage rating at 47/63 Hz, power supply. The output is 24 volts DC for the power pack. A medically approved ac power cord is included.

b) ACCESSORY COMPONENT DESCRIPTIONS

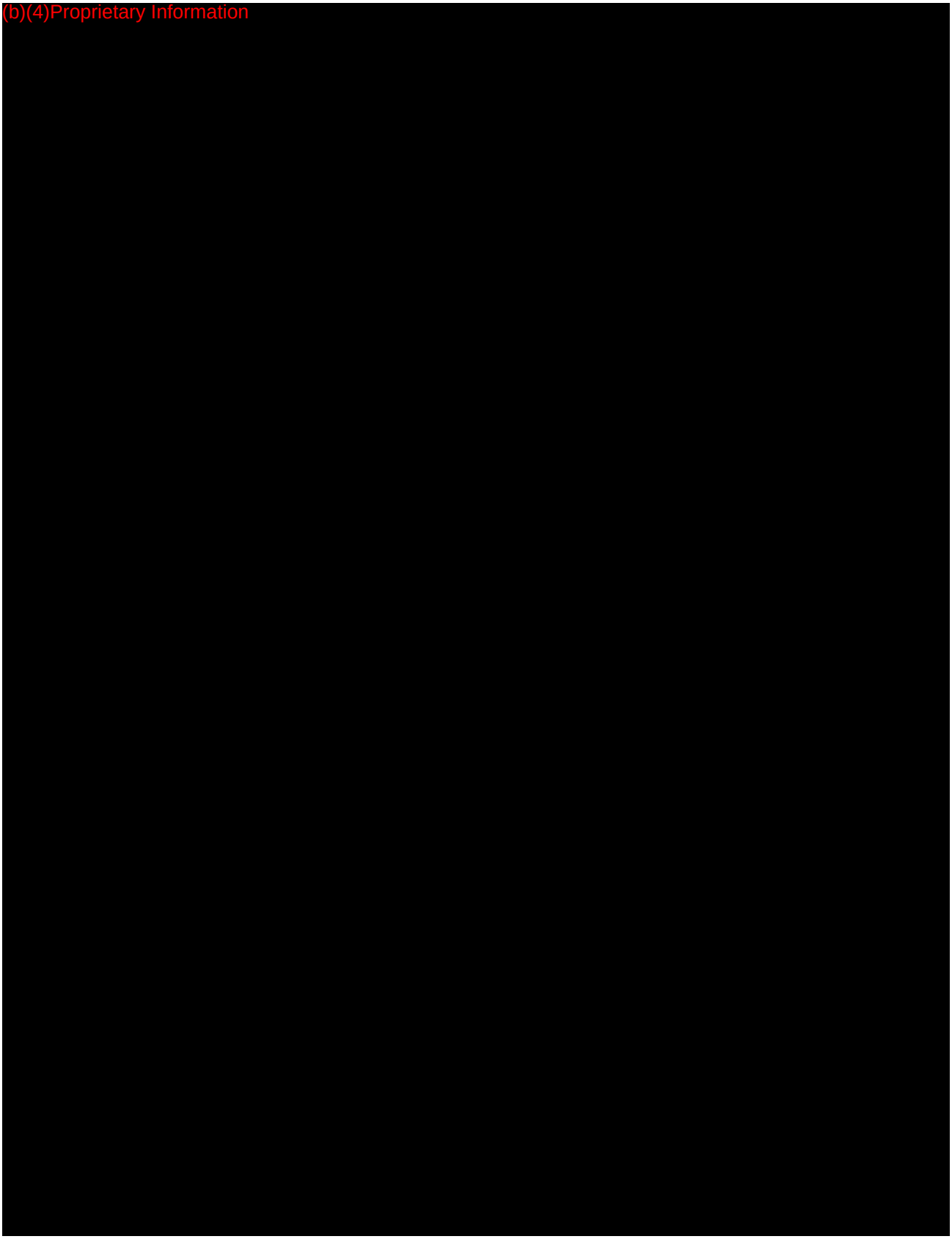
Safety eyewear:

Supplied with the system are two sets of standard, TLC-901 laser safety glasses one pair for the clinician and one pair for the patient. These laser safety glasses are provided for viewing diffused laser light only and are not for direct viewing of the laser output.

(b)(4)Proprietary Information

c) Specifications

(b)(4)Proprietary Information

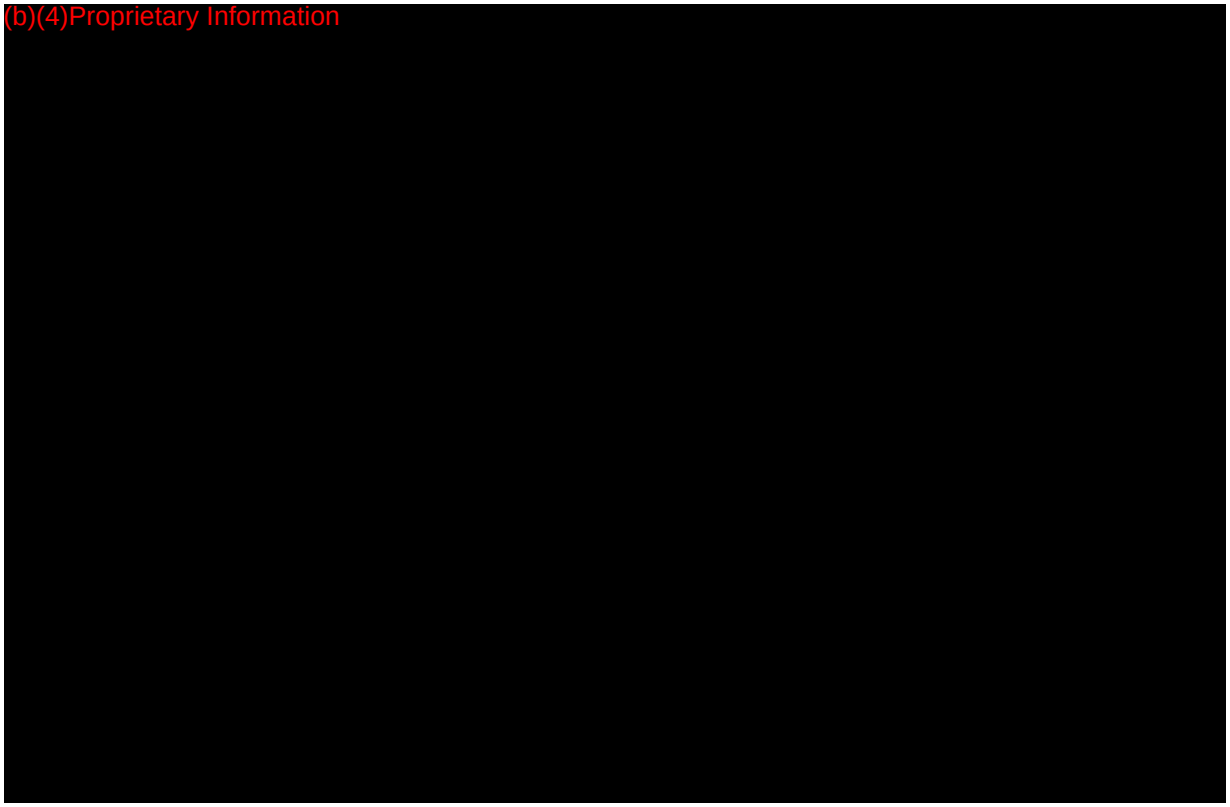


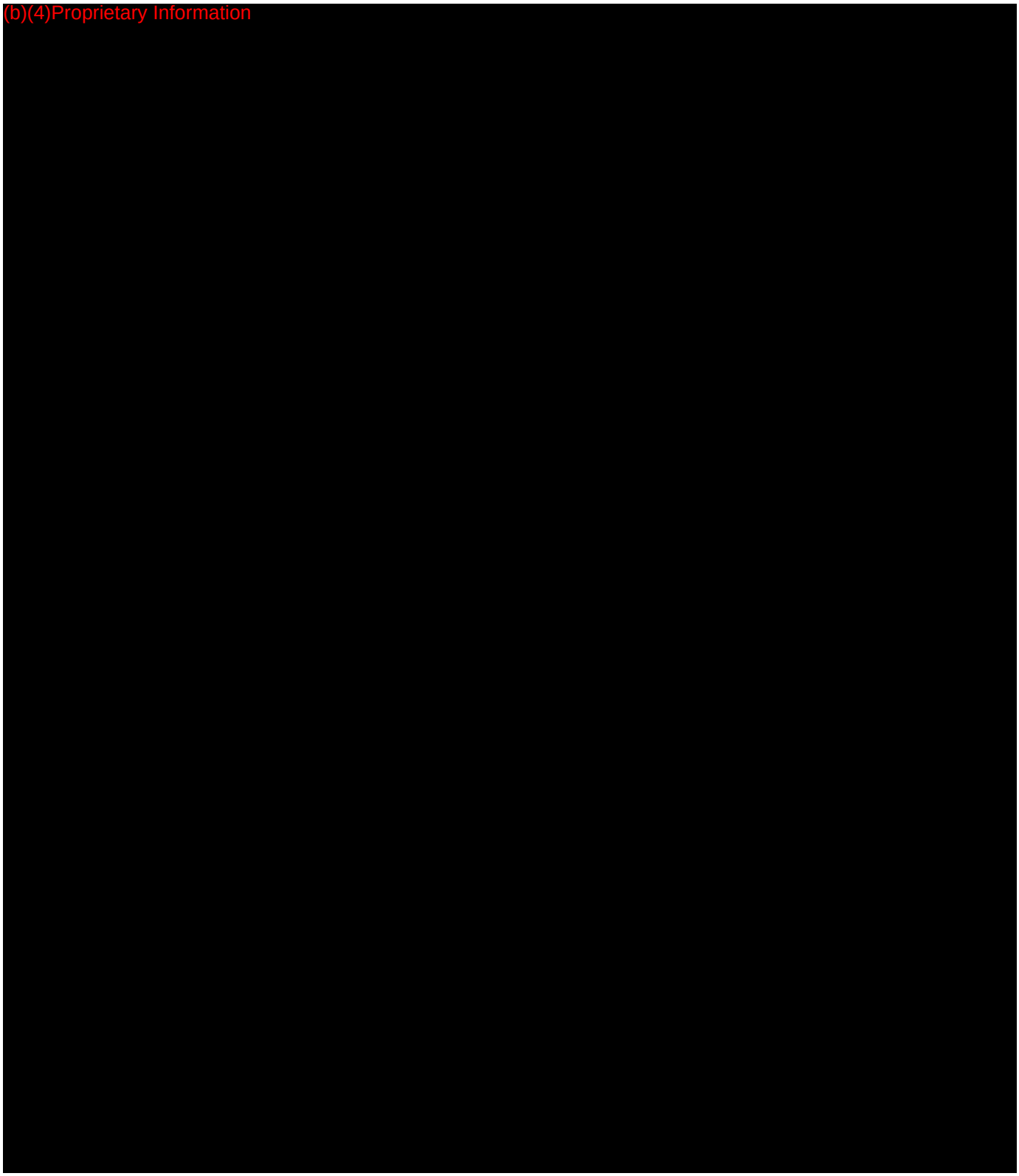
d) Intended Use of the TLC-2000

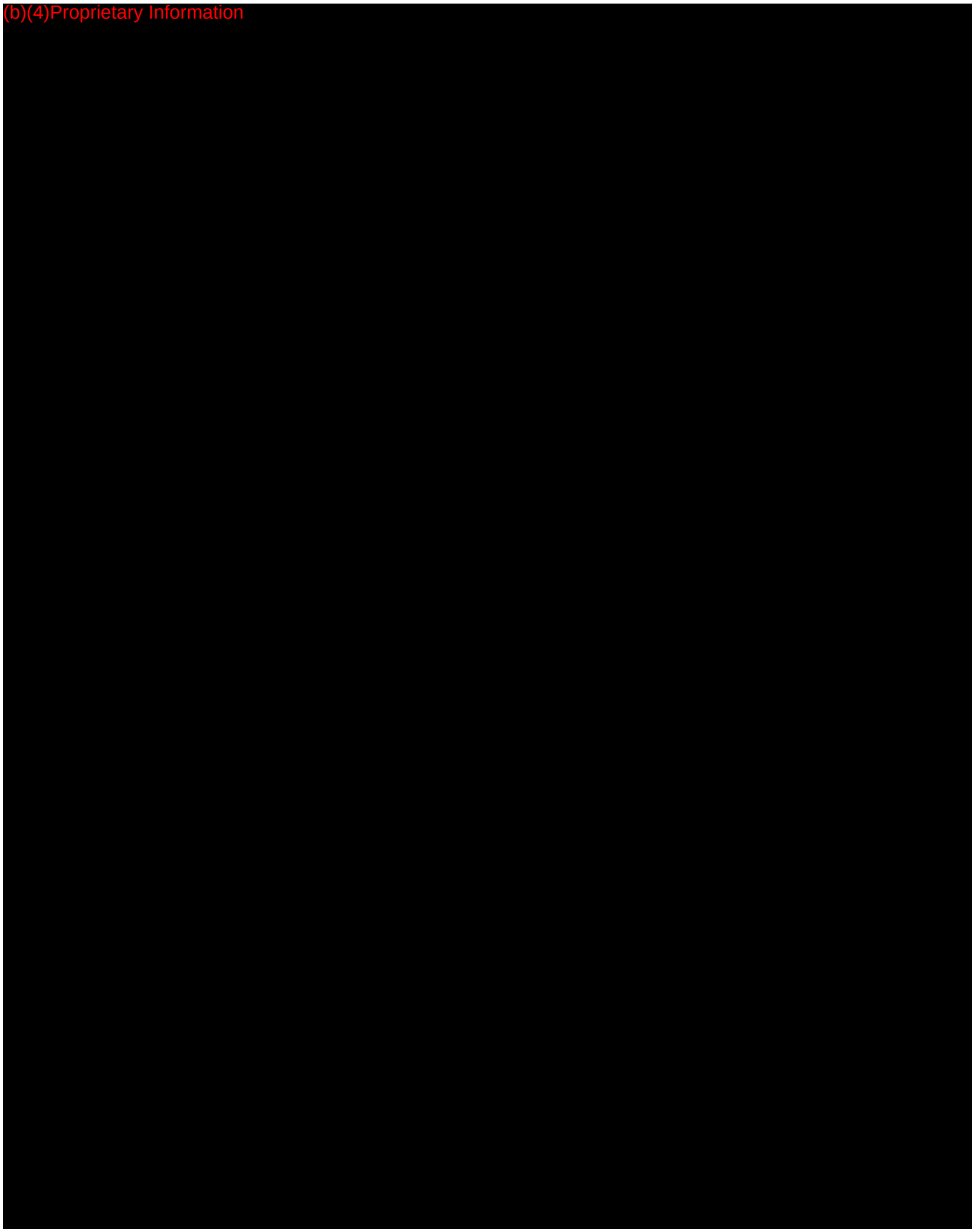
The TLC-2000 therapeutic medical laser probes are used for adjunctive use in the temporary relief of pain associated with knee disorders. The technology of Low Level Laser Therapy (LLLT) is designed as a non-invasive and non-toxic therapeutic treatment. The TLC-2000 laser probes are used in direct contact with tissue in order to inject photons of light (b)(4)Proprietary Information non-invasively and drug-free into tissue.

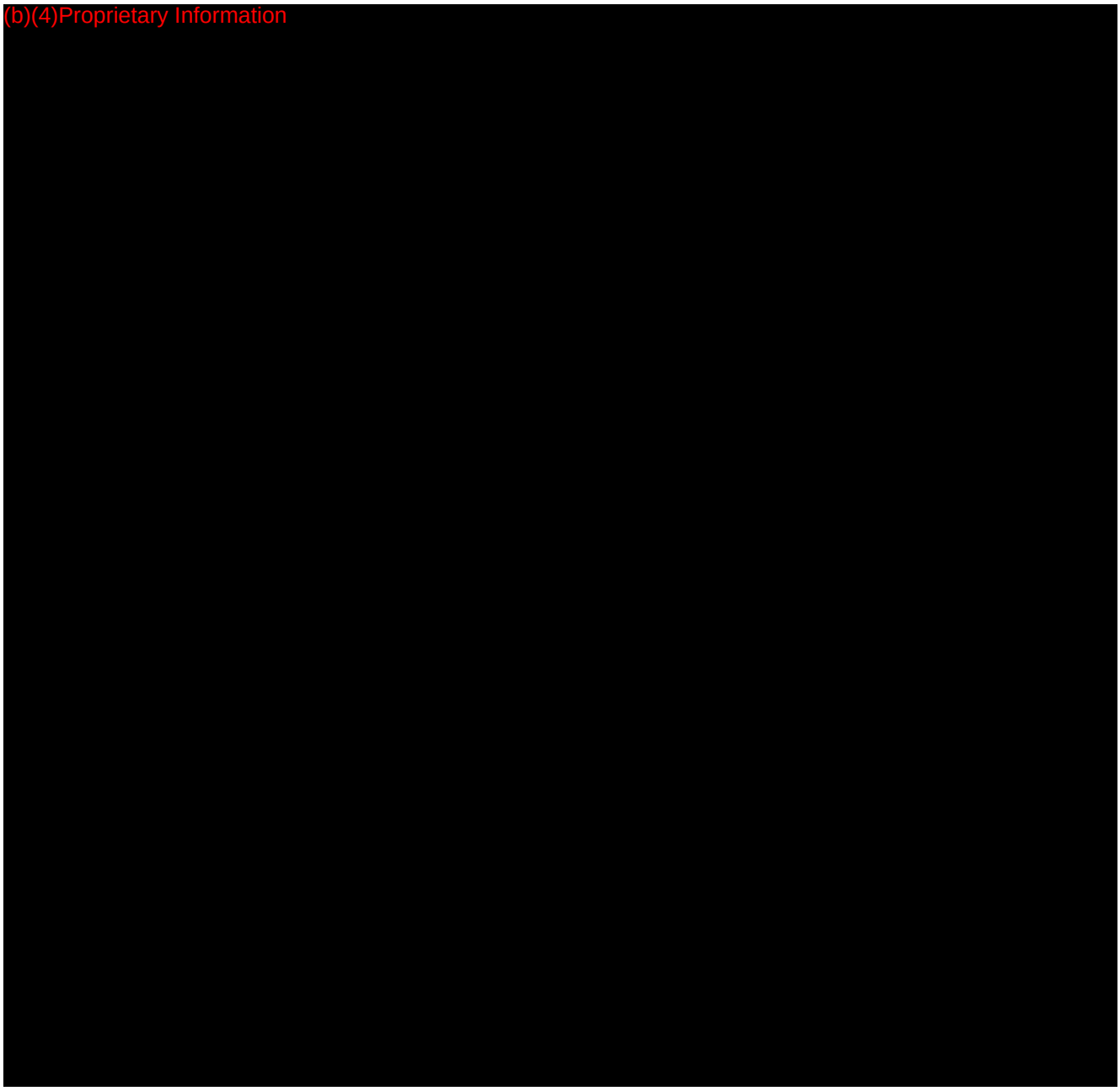
e) Principles of operation

(b)(4)Proprietary Information









2.2 Safety

There are no known significant safety or adverse effects reported in the literature from the use of Low Level Laser Therapy (LLLT). During the past ten years the predicate device has been on the market, there hav been no significant adverse effects reported from the use of the predicate device, the Theralase TLC-1000 Therapeutic Medical Laser System. As the new device, the Theralase TLC-2000, is comprised of the same materials, the same wavelengths and same physical design and number of laser diodes, no significant adverse effects are expected from the use of the new device.

However, following is a list of potential incidents that may occur during laser treatment:

1. Eye pain, retina or other ophthalmic damage may be noted if the laser beam is pointed directly at or into the eye for prolonged periods of time. Laser safety glasses, absorbent for the 905 nm wavelength, must be worn during all treatment sessions by both the subject and the health care professional(s).
2. Transient redness at the treatment site
3. Swelling at or near the area of laser irradiation
4. Tingling or itching
5. Temporary paresthesia

The FDA has classified bio-stimulation laser for pain attenuation as a non-significant risk device (HSS Publican 92-4159 IDE Manual, page 34). There are no greater risks associated with the use of LLLT than with any other treatment modality generally accepted for the treatment of knee disorders. The potential benefit of pain relief, decreased inflammation, increased function and improved quality of life may out-weigh any temporary adverse effect that may be observed from the use of the non-invasive Low Level Laser Therapy.

Over the past decades, an abundance of research studies, both *in vitro* and *in vivo*, have been conducted in laboratory and clinical environments. The vast majority of these studies report clear evidence that low level laser irradiation alters the cellular processes in a non-thermal and wavelength specific manner. Review of this literature does not reveal significant risks to study subjects and no unusual or adverse effects were reported during the clinical research conducted in which the predicate device was used.

The TLC-2000 is manufactured in an ISO 9001:20085 and ISO 13485:2003 compliant manufacturing facility in compliance with International ISO 9001 quality standard programs and the FDA Quality Systems Regulations (cGMP) 21 CFR Part 820.

The TLC-2000 sysem is tested and verified to meet all output technical specifications via 100% final quality control procedures.

The TLC-2000 System has been certified to the following safety standards:

(b)(4)Proprietary Information

2.3 Engineering Documentation

The Theralase TLC-2000 Therapeutic Medical Laser System is comprised of two parts that are manufactured by Theralase the laser probe and the power pack. [redacted] (b)(4)Proprietary Information

[redacted]

2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

	Update: 20/02/2015			NAME	DATE
	Update:		DRAWN	JACK LIN	12/09/2014
	Update:		CHECKED		
			ENG APPR.		
			Q.A		

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 1 OF 10

2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

[redacted]

	Update: 20/02/2015			NAME	DATE
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	Update:		CHECKED		
			ENG APPR.		
			Q.A		
			[redacted]		

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 2 OF 10

2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

[redacted]

	Update: 20/02/2015		NAME	DATE
	Update:	DRAWN	JACK LIN	12/09/2014
	Update:	CHECKED		
		ENG APPR.		
		Q.A		

[redacted]

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 3 OF 10

2.3.1_Controller Board Schematic

Left blank intentionally

Update: 20/02/2015		NAME	DATE
Update:	DRAWN	JACK LIN	12/09/2014
Update:	CHECKED		
	ENG APPR.		
	Q.A		

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 4 OF 10

2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

	Update: 20/02/2015			NAME	DATE
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	Update:		CHECKED		
			ENG APPR.		
			Q.A		

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 5 OF 10

2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

		NAME	DATE
Update: 20/02/2015	DRAWN	JACK LIN	12/09/2014
Update:	CHECKED		
Update:	ENG APPR.		
	Q.A		

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 6 OF 10

2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

		NAME	DATE
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Update:	CHECKED		
Update:	ENG APPR.		
	Q.A		

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 7 OF 10

2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

[redacted]

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		ENG APPR.			
		Q.A			
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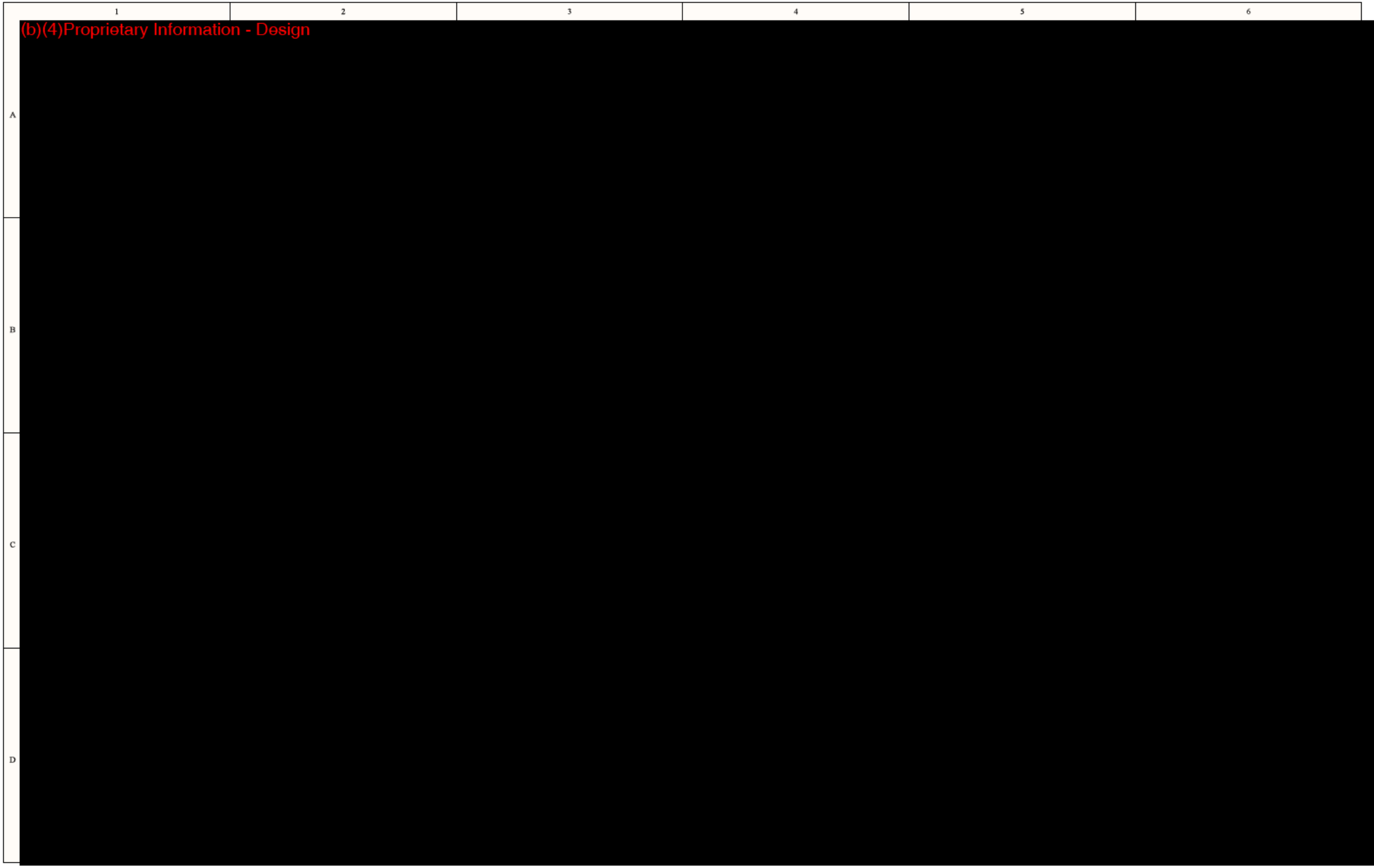
					SHEET 8 OF 10

2.3.1_Controller Board Schematic



2.3.1_Controller Board Schematic

(b)(4)Proprietary Information - Design

[redacted]

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			Q.A		
			[redacted]		

Schematic, TLC2000

Controller

SIZE	NUMBER	REV
B	500-0002.	R4

SHEET 10 OF 10

2.3.2_Controller Board PCB

REVISION RECORD			
LTR	ECO NO:	APPROVED:	DATE:

(b)(4)Proprietary Information - Design

[redacted]

THERALASE TECHNOLOGIES INC

ASSEMBLY – PRIMARY SIDE

PROD: TLC2000 CONTROLLER REV4
DATE: Feb 19 2015
No. of PCB LAYERS: 6

COMPANY: theraLASE

TITLE: PCB Assembly TOP Controller
TLC 2000

DRAWN:	DATED:	CODE:	SIZE:	DRAWING NO:	REV:
Rick Anderson	Feb 17, 2015		A	900-0002-RX	
CHECKED:	DATED:				
RELEASED:	DATED:				

SCALE: Scale SHEET: 1 OF 1

CAM350 V 10.1.0 : Thu Feb 19 14:08:52 2015 - (Untitled) : ASP-600-0002-R4.pho

REVISION RECORD			
LTR	ECO NO:	APPROVED:	DATE:

(b)(4)Proprietary Information - Design

COMPANY: TheraLase

THERALASE TECHNOLOGIES INC
ASSEMBLY - SECONDARY SIDE
PROD: TLC2000 CONTROLLER REV4
DATE: Feb 19 2015
No. of PCB LAYERS: 6

TITLE: PCB Assembly Bottom Controller
TLC 2000

CODE:	SIZE:	DRAWING NO:	REV:
	A	900-0002-RX	

DRAWN:	DATED:
Rick Anderson	Feb 17, 2015
CHECKED:	DATED:
RELEASED:	DATED:

SCALE: Scale SHEET: 1 OF 1

CAM350 V 10.1.0 : Thu Feb 19 14:08:52 2015 - (Untitled) : ASS-600-0002-R4.pho

(b)(4)Proprietary Information - Design

SIZE	QTY	SYM	PLATED	TOL
	434	+	YES	+/-.003
	6	X	YES	+/-.003
	5	⊡	YES	+/-.003 TO BE FILLED
18	29	◇	YES	+/-.003
27.56	6	⋈	YES	+/-.003
28	42	A	YES	+/-.003
31.5	14	B	YES	+/-.003
35	1	C	YES	+/-.003
40	2	D	YES	+/-.003
43	5	E	YES	+/-.003
47.24	2	F	YES	+/-.003
125.98	4	G	YES	+/-.003
35.43	2	H	NO	+/-.003

THERALASE TECHNOLOGIES INC
DRILL GRAPHICS
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

Refer to : PCB-600-0002-R4.DOC for Fabrication Notes

NOTE: ALL VIA-IN-PAD (13Mils dia.) TO BE FILLED WITH NON CONDUCTIVE MATERIAL AND PLATED OVER

CAM350 V 10.1.0 : Thu Feb 19 14:08:52 2015 - (Untitled) : DRL-600-0002-R4.pho

(b)(4)Proprietary Information - Design

[redacted]

THERALASE TECHNOLOGIES INC
LAYER 1 – PRIMARY SIDE
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

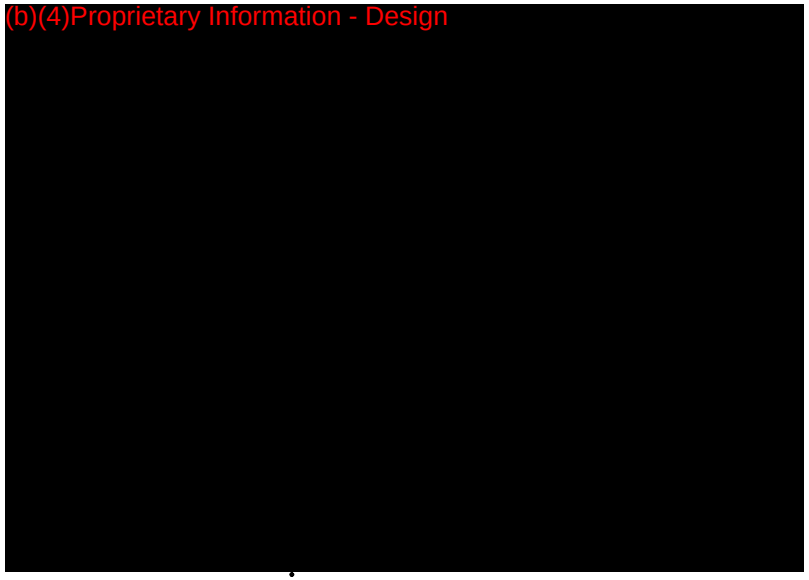
CAM350 V 10.1.0 : Thu

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
LAYER 2 - GND
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
LAYER 3 - SIG1
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

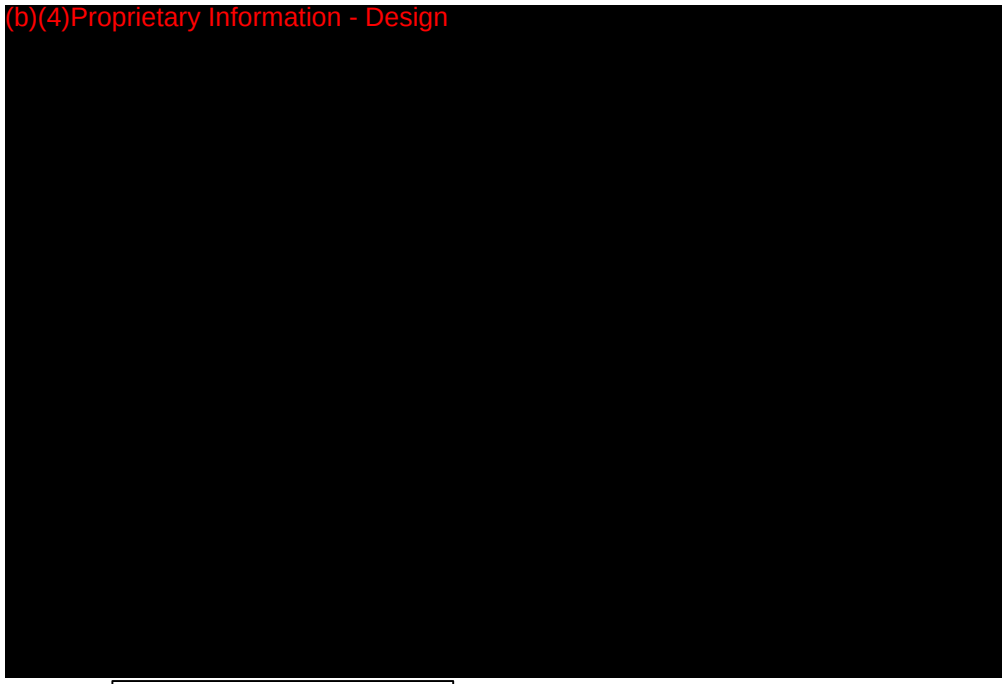


THERALASE TECHNOLOGIES INC
LAYER 4 – SIG2
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
LAYER 5 - PWR
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

(b)(4)Proprietary Information - Design



THERALASE TECHNOLOGIES INC
LAYER 6 – SECONDARY SIDE
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

(b)(4)Proprietary Information - Design

[redacted]

THERALASE TECHNOLOGIES INC
SOLDER MASK – PRIMARY SIDE
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

CAM350 V 10.1.0 : Thu Feb 19 14:08:52 2015 - (Untitled) : SMP-000-0002-R4.pho

(b)(4)Proprietary Information - Design

[redacted]

THERALASE TECHNOLOGIES INC

SOLDER MASK – SECONDARY SIDE

PROD: TLC2000 CONTROLLER REV4
DATE: Feb 19 2015
No. of PCB LAYERS: 6

CAM350 V 10.1.0 :

THERALASE TECHNOLOGIES INC
SOLDER PASTE - PRIMARY SIDE
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

CAM350 V 10.1.0 : Thu Feb 19 14:08:52 2015 - (Untitled) : SPP-600-0002-R4.pho

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
SOLDER PASTE – SECONDARY SIDE
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
SILKSCREEN – PRIMARY SIDE
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
SILKSCREEN – SECONDARY SIDE
PROD: TLC2000 CONTROLLER REV4 DATE: Feb 19 2015 No. of PCB LAYERS: 6

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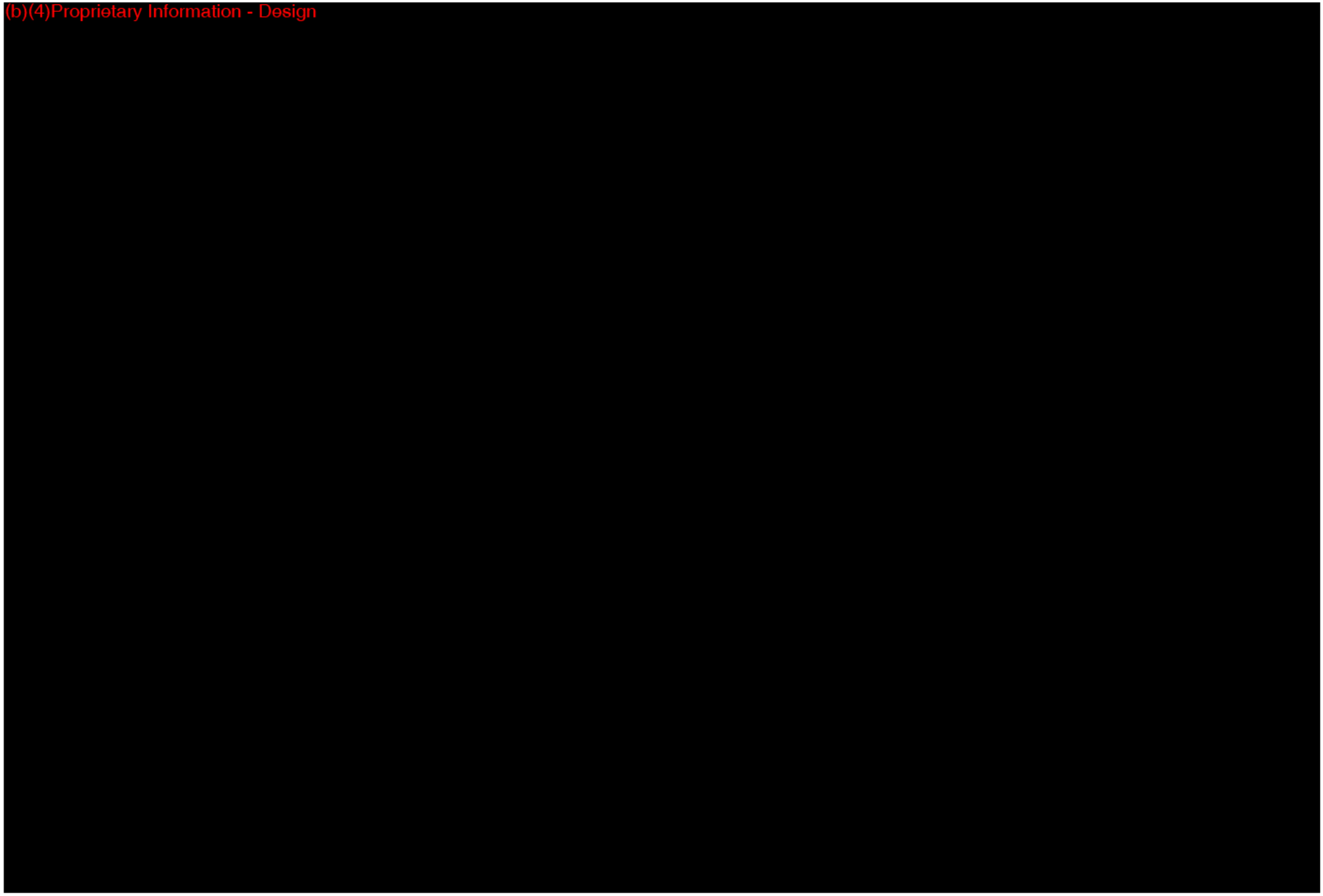
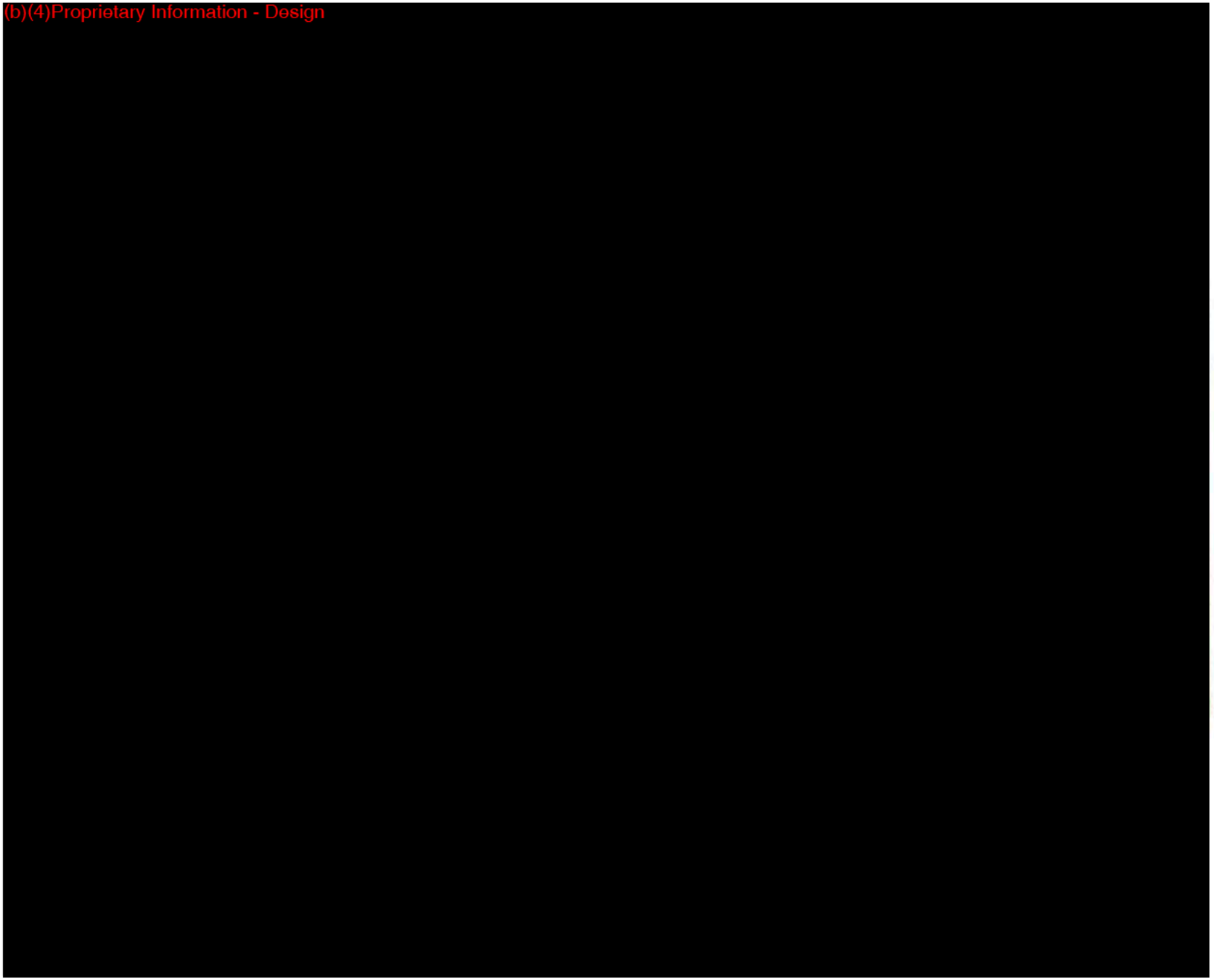


2.3.5_Controller Board Bottom Picture



2.3.6_Display BlueTooth Schematic

(b)(4)Proprietary Information - Design

(b)(4)Proprietary Information - Design

	Update: 26/10/2014			NAME	DATE
	Update:		DRAWN	JACK	26/10/2014
	Update:		CHECKED		
			ENG APPR.		
			Q.A		

[redacted]

Schematic, TLC2000

TFT Display_Bluetooth

SIZE	NUMBER	REV
B	500-0014	R2

SHEET * OF *

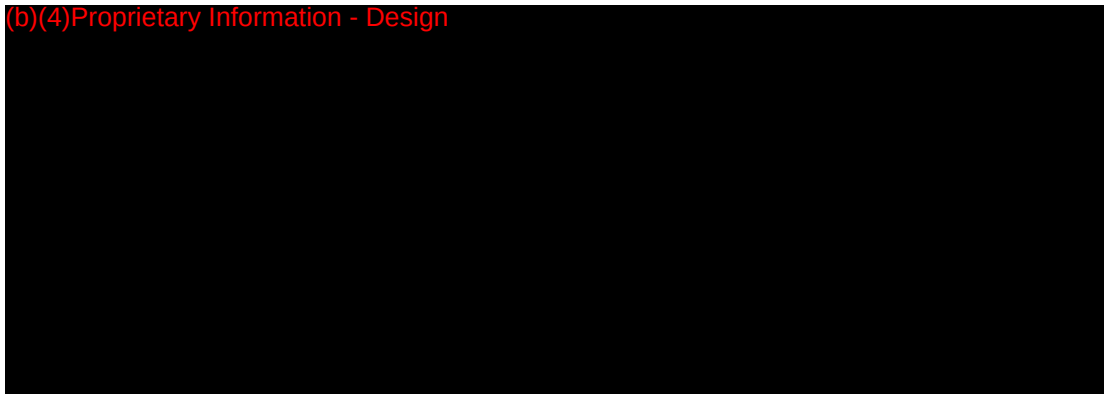
(b)(4)Proprietary Information - Design

SIZE	QTY	SYM	PLATED	TOL
12	46	+	YES	+/-0.003
35.43	2	◇	YES	+/-.003
39.37	3	X	NO	+/-.003

THERALASE TECHNOLOGIES INC
DRILL GRAPHICS
PROD: TLC2000 TFT-Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

Refer to : PCB-600-0014-R3.DOC for Fabrication Notes

(b)(4)Proprietary Information - Design

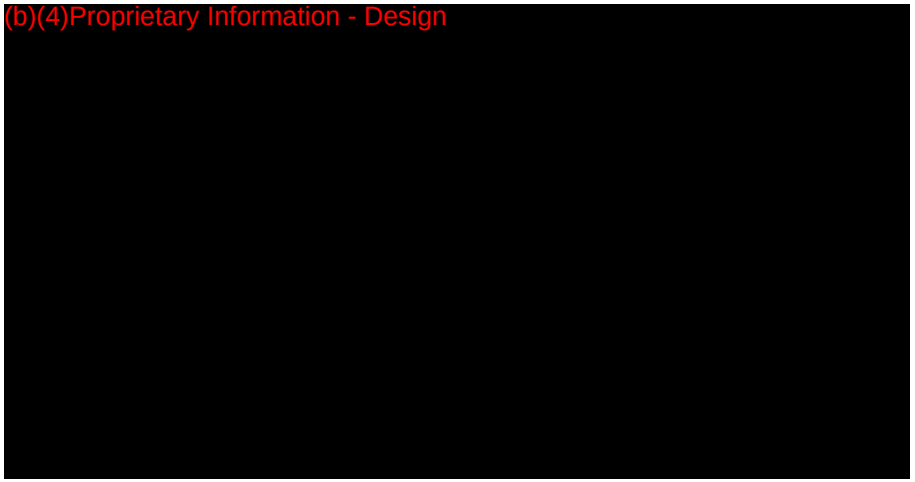


THERALASE TECHNOLOGIES INC
LAYER 1 – PRIMARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
LAYER 2 – SECONDARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

(b)(4)Proprietary Information - Design



THERALASE TECHNOLOGIES INC
SOLDER MASK – PRIMARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

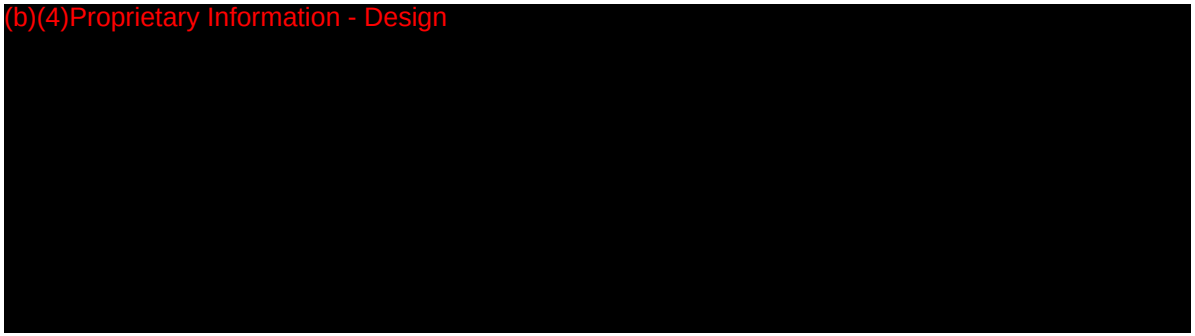
(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
SOLDER MASK – SECONDARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
SOLDER PASTE – PRIMARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

(b)(4)Proprietary Information - Design



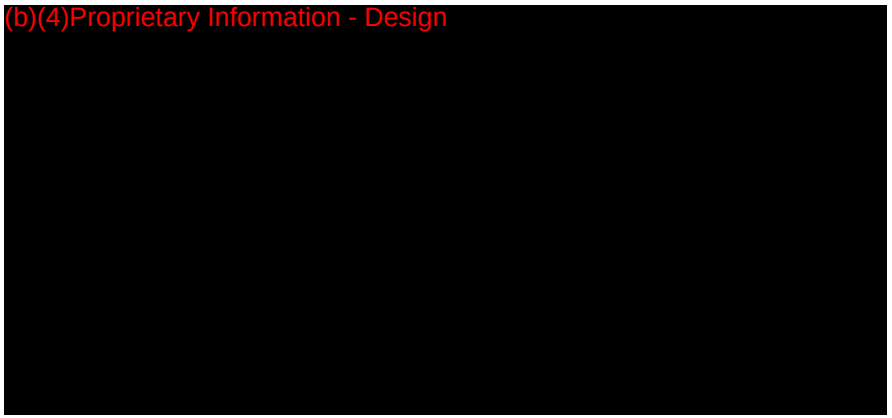
THERALASE TECHNOLOGIES INC
SOLDER PASTE – SECONDARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

(b)(4)Proprietary Information - Design

THERALASE TECHNOLOGIES INC
SILKSCREEN – PRIMARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

2.3.7_Display BlueTooth PCB

(b)(4)Proprietary Information - Design

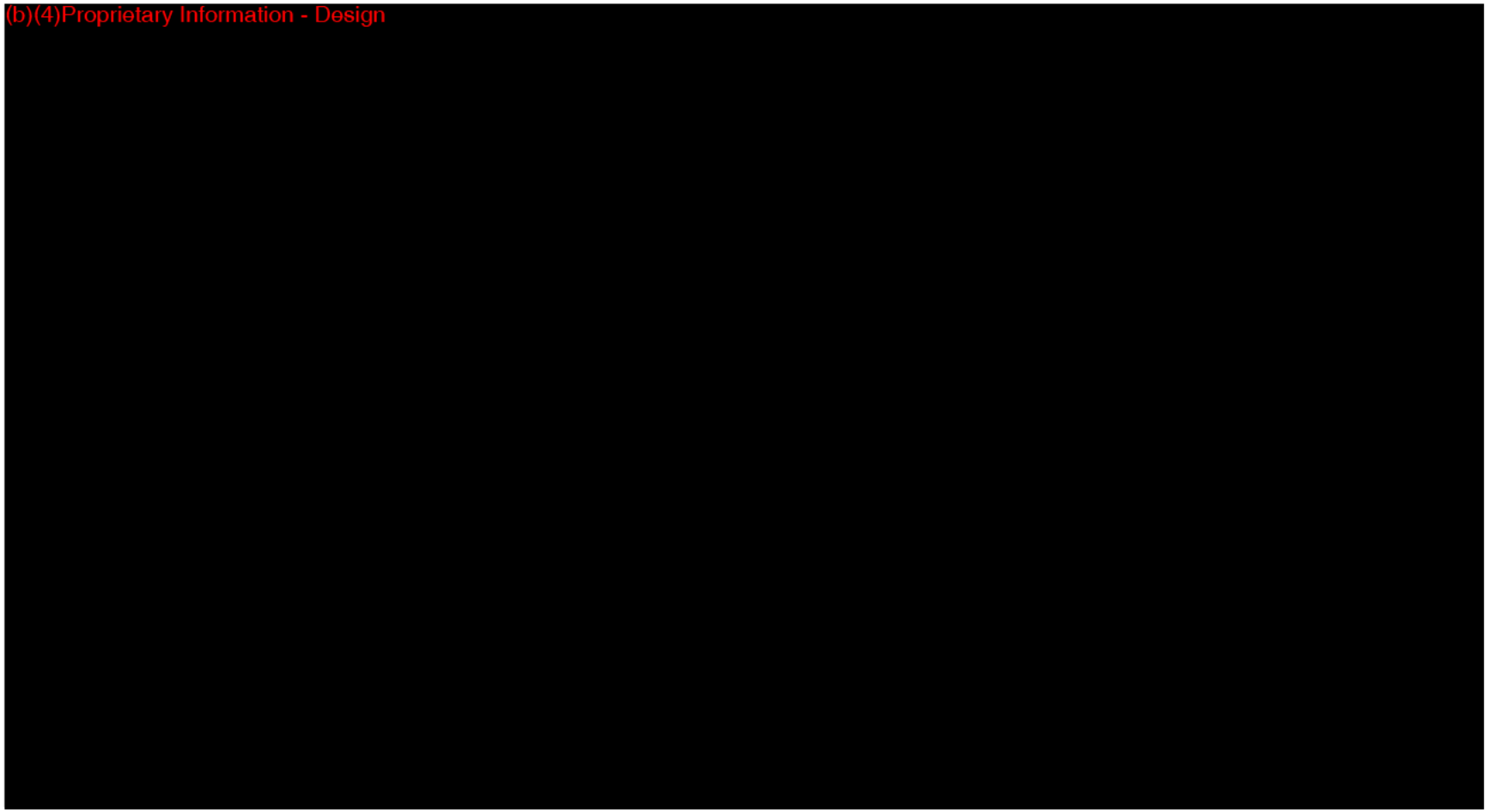


THERALASE TECHNOLOGIES INC
SILKSCREEN – SECONDARY SIDE
PROD: TLC2000 TFT–Display Bluetooth REV3 DATE: Feb 4, 2015 No. of PCB LAYERS: 2

CAM350 V 10.1.0 : Wed Feb 04 11:00:59 2015 - (untitled) : SSS-600-0014-R3.pho

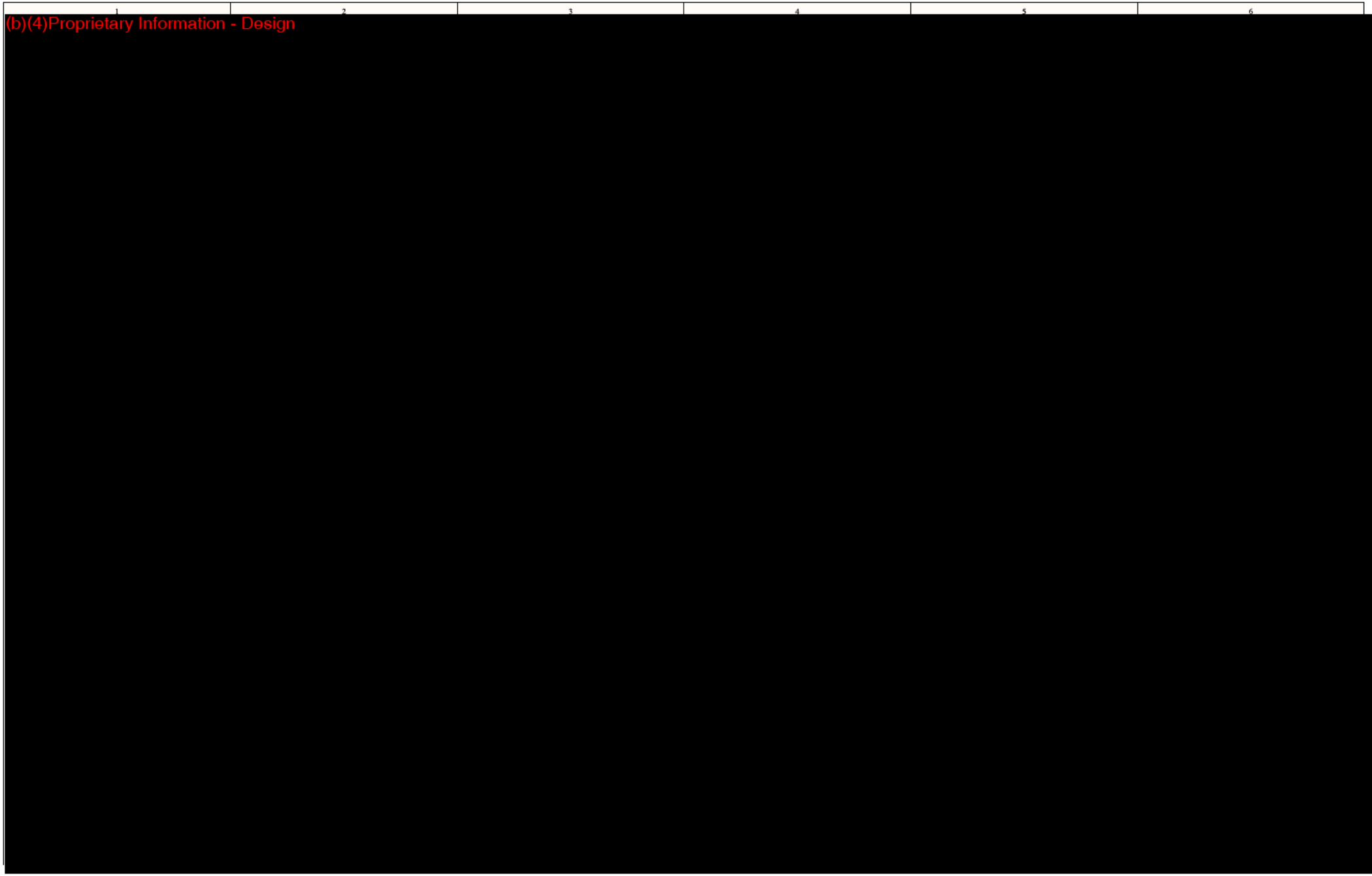
2.3.7_Display BlueTooth PCB

2.3.8 - Display blue-tooth top picture



2.3.9 - Display blue-tooth bottom picture

2.3.10_Laser Driver Schematic



2.3.10_Laser Driver Schematic

(b)(4)Proprietary Information - Design

[redacted]

DRAWN	Qing Zhang	10-11-2014
CHECKED		
ENG APPR.		
Q.A		

TITLE

Schematic Laser Diode Driver

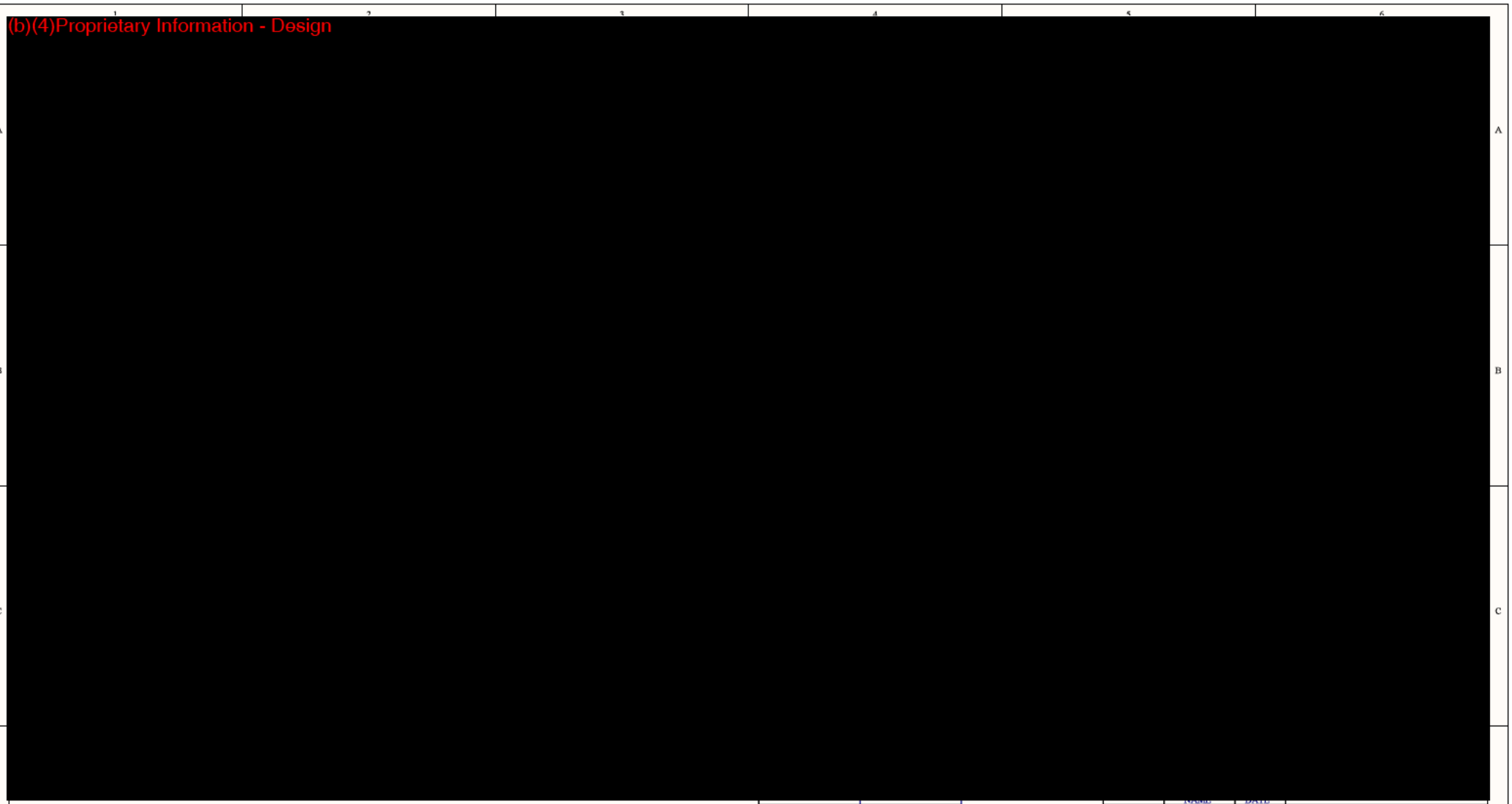
Cannot open file C:\Users\Public\Documents\Altium\AD14\Templates\logo_theralase.bmp

SIZE	NUMBER	REV
B	500-0003-R3	R3

SHEET 2 OF 3

2.3.10_Laser Driver Schematic

(b)(4)Proprietary Information - Design



	NAME	DATE
DRAWN	Qing Zhang	11-11-2014
CHECKED		
ENG APPR.		
Q.A		

Cannot open file C:\Users\Public\Documents\Altium\AD14\Templates\logo_theralase.bmp

TITLE

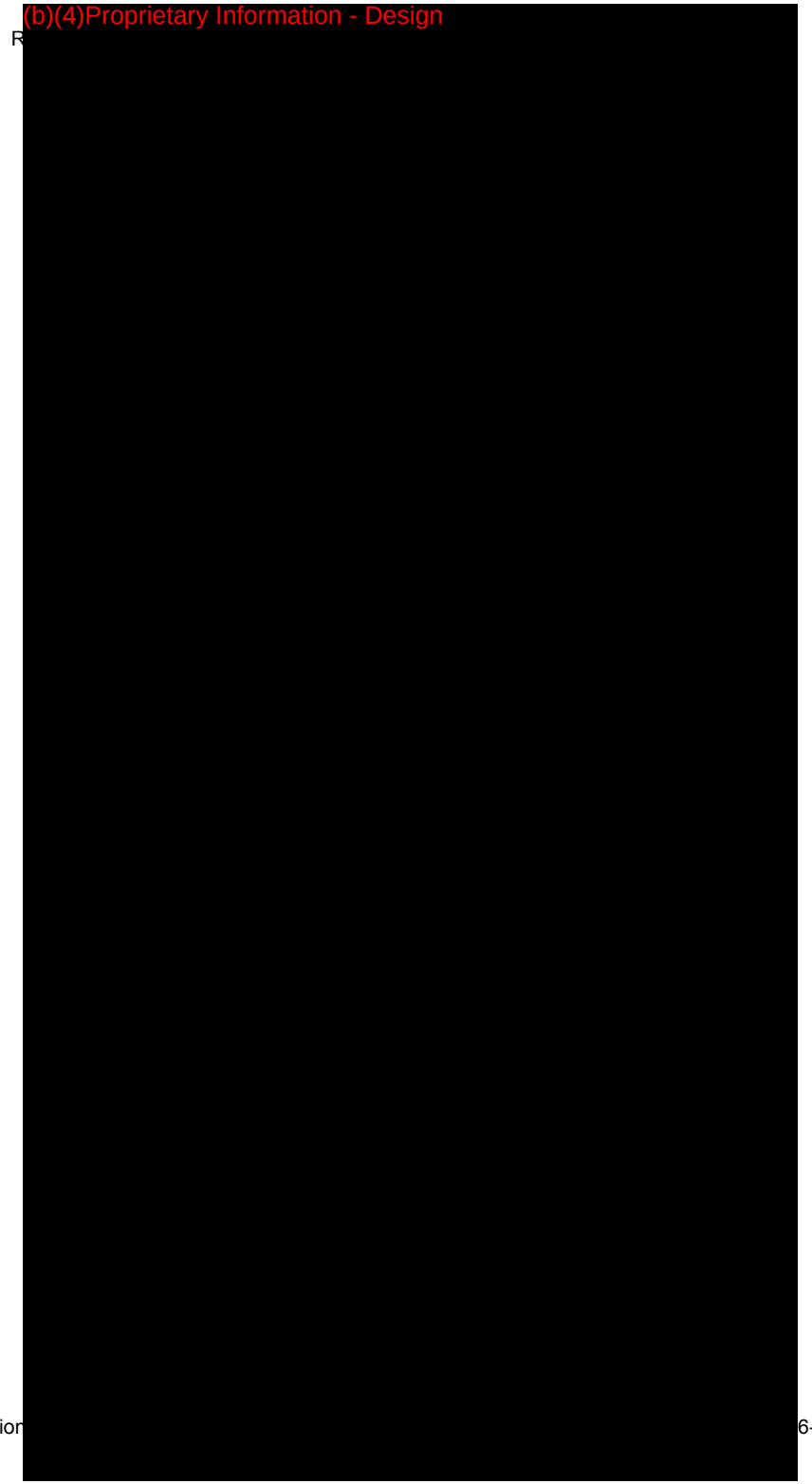
Schematic Laser Diode Driver

SIZE	NUMBER	REV
B	500-0003-R3	R3

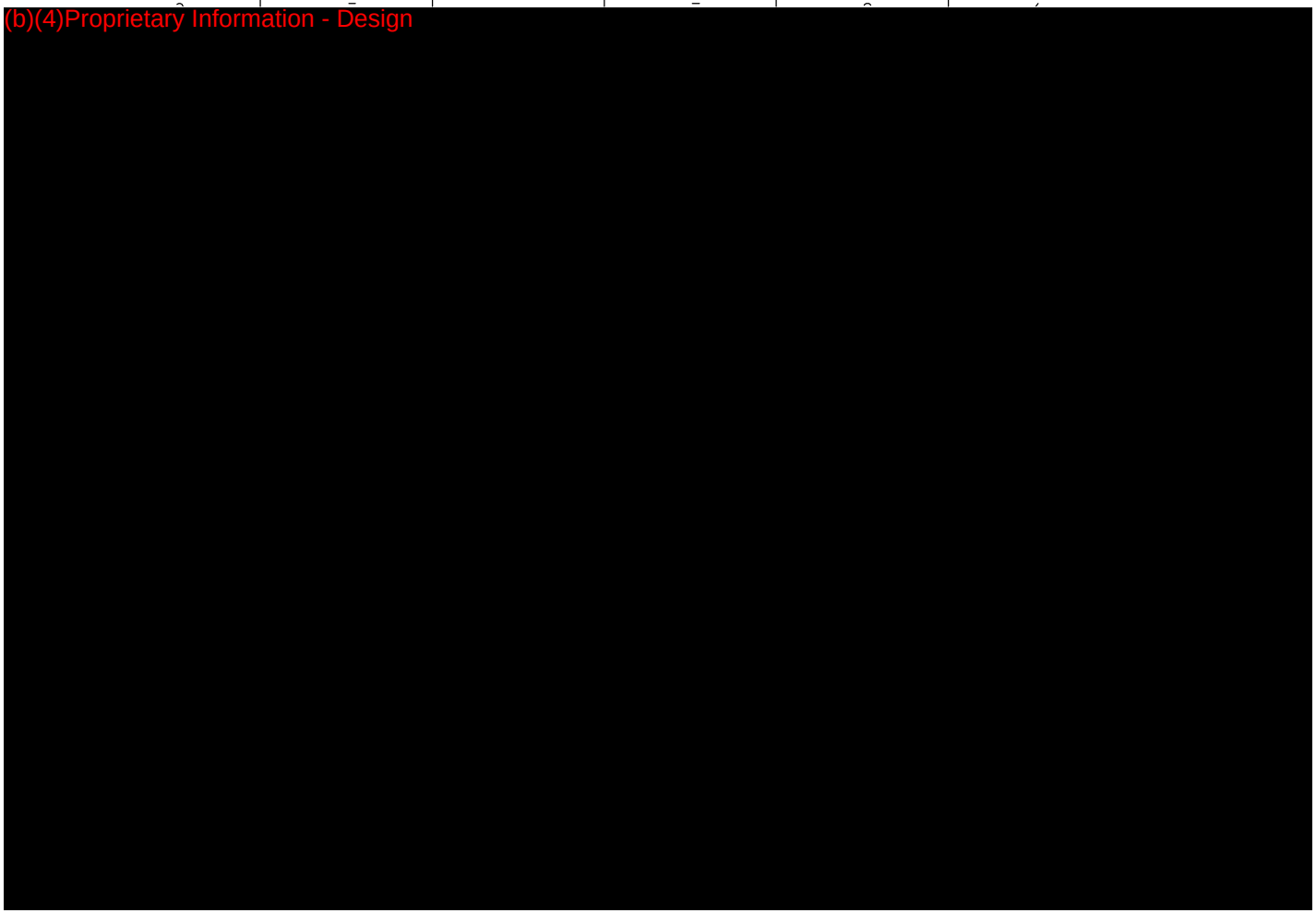
SHEET 3 OF 3

2.3.10_Laser Driver Schematic

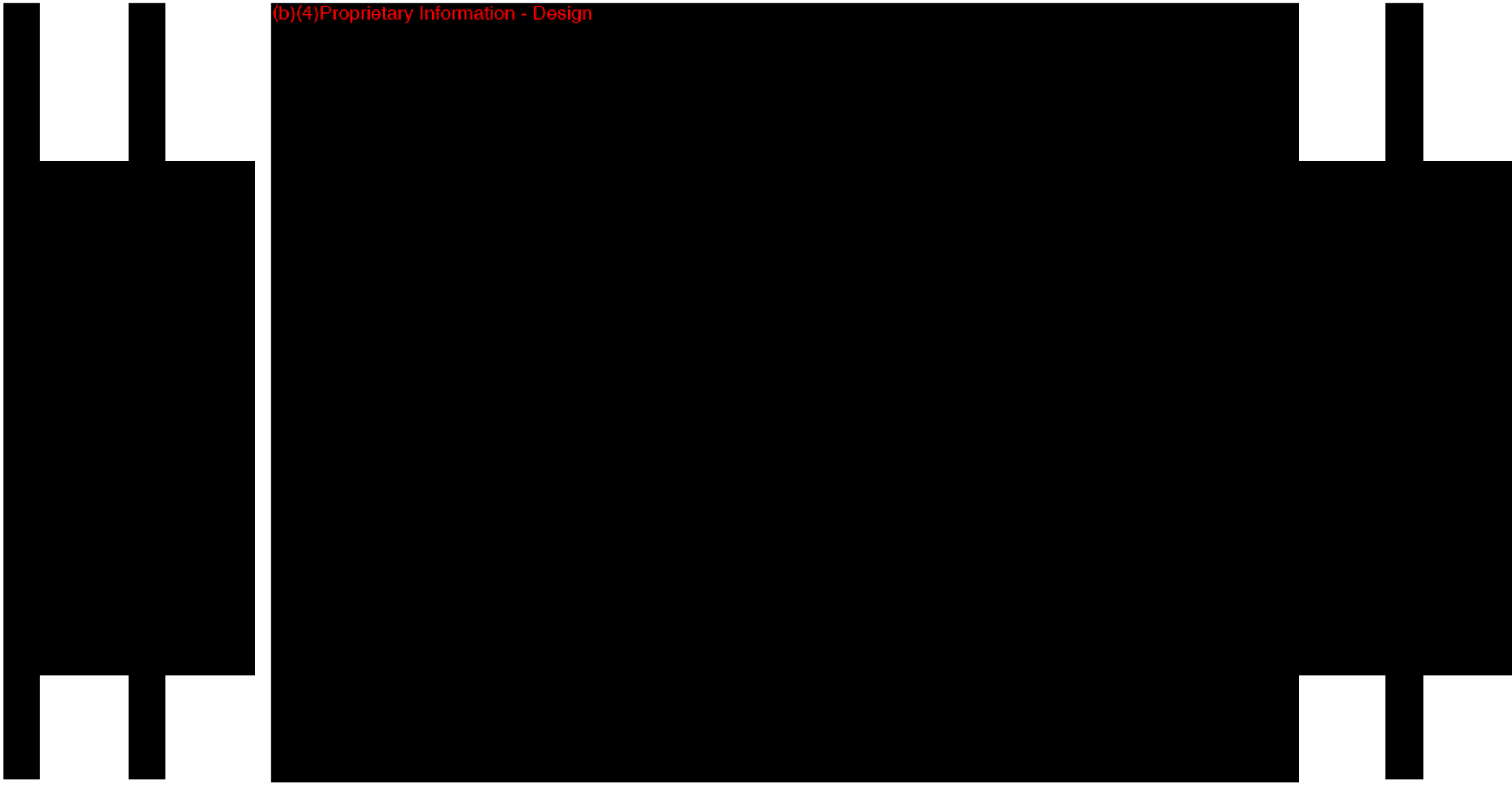
(b)(4)Proprietary Information - Design



2.3.11_Laser Driver PCB

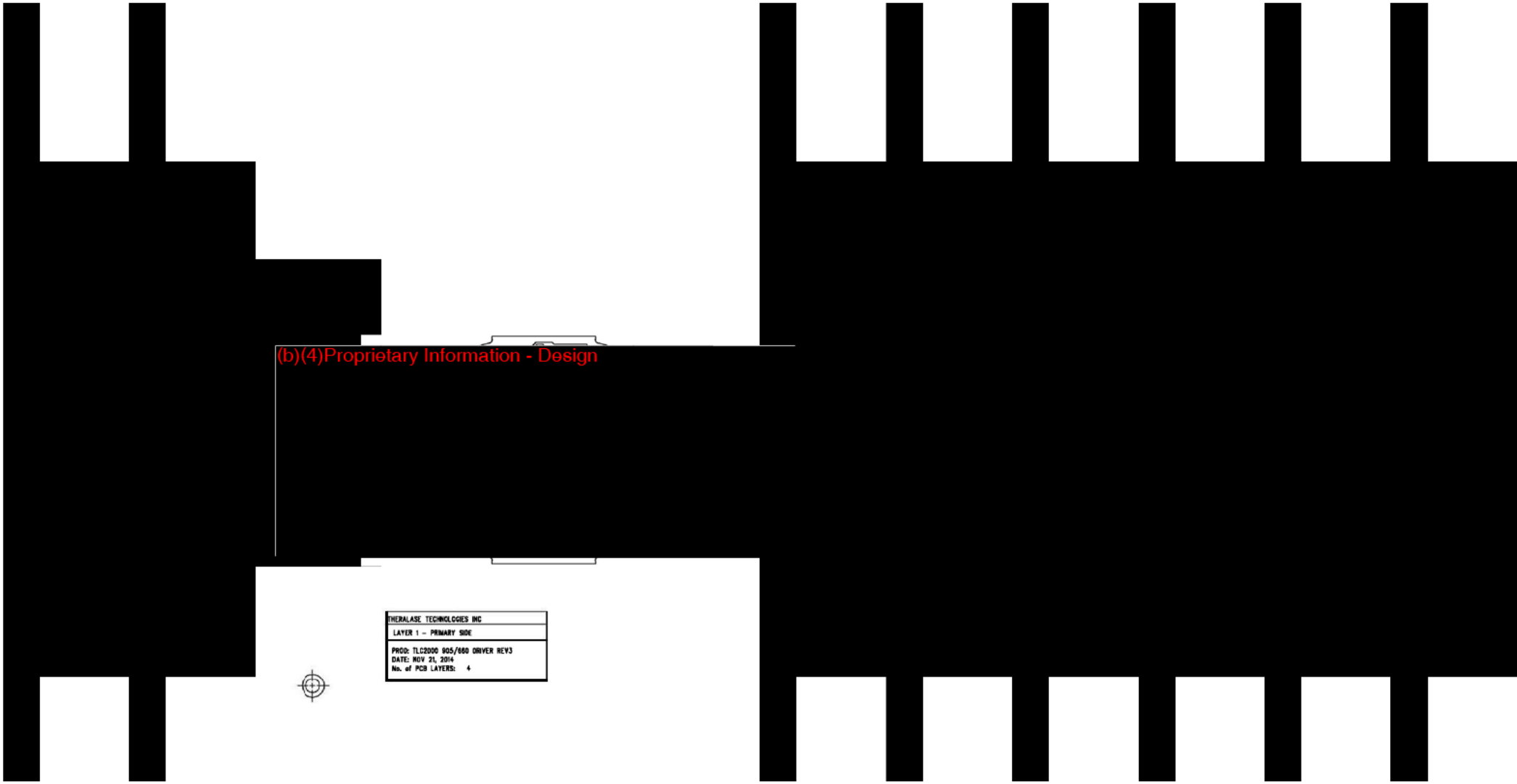


2.3.11_Laser Driver PCB

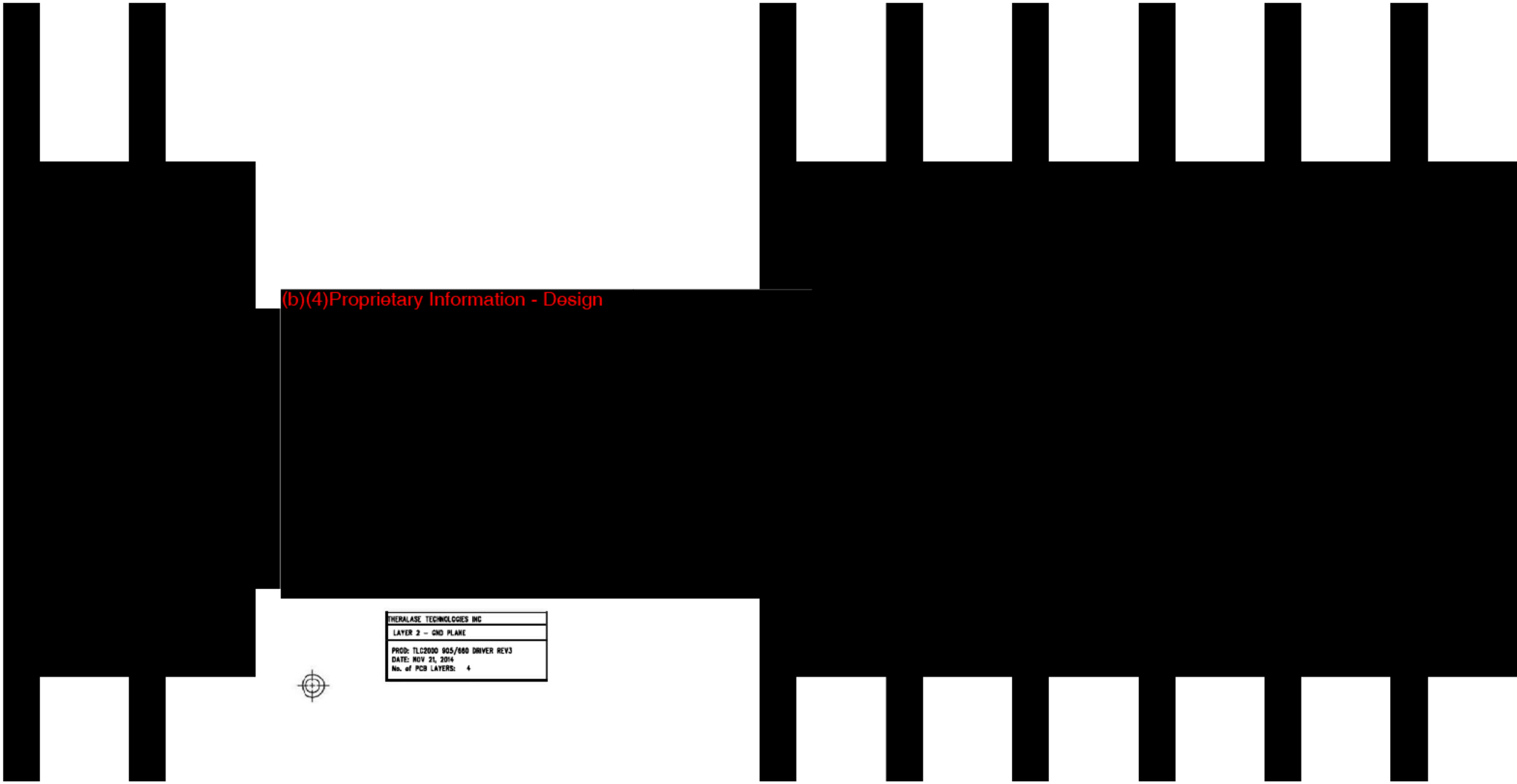


2.3.11_Laser Driver PCB

2.3.11_Laser Driver PCB

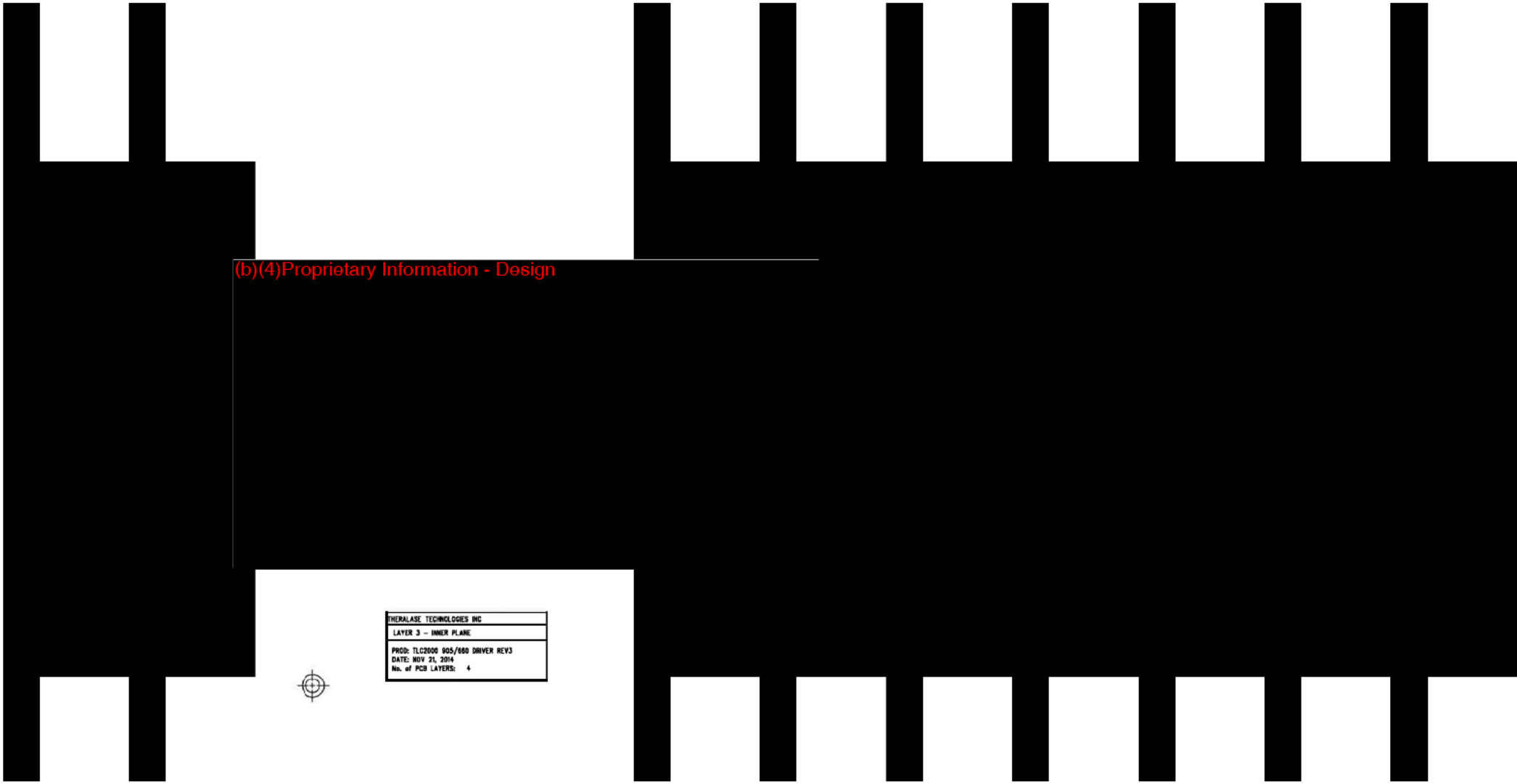


2.3.11_Laser Driver PCB



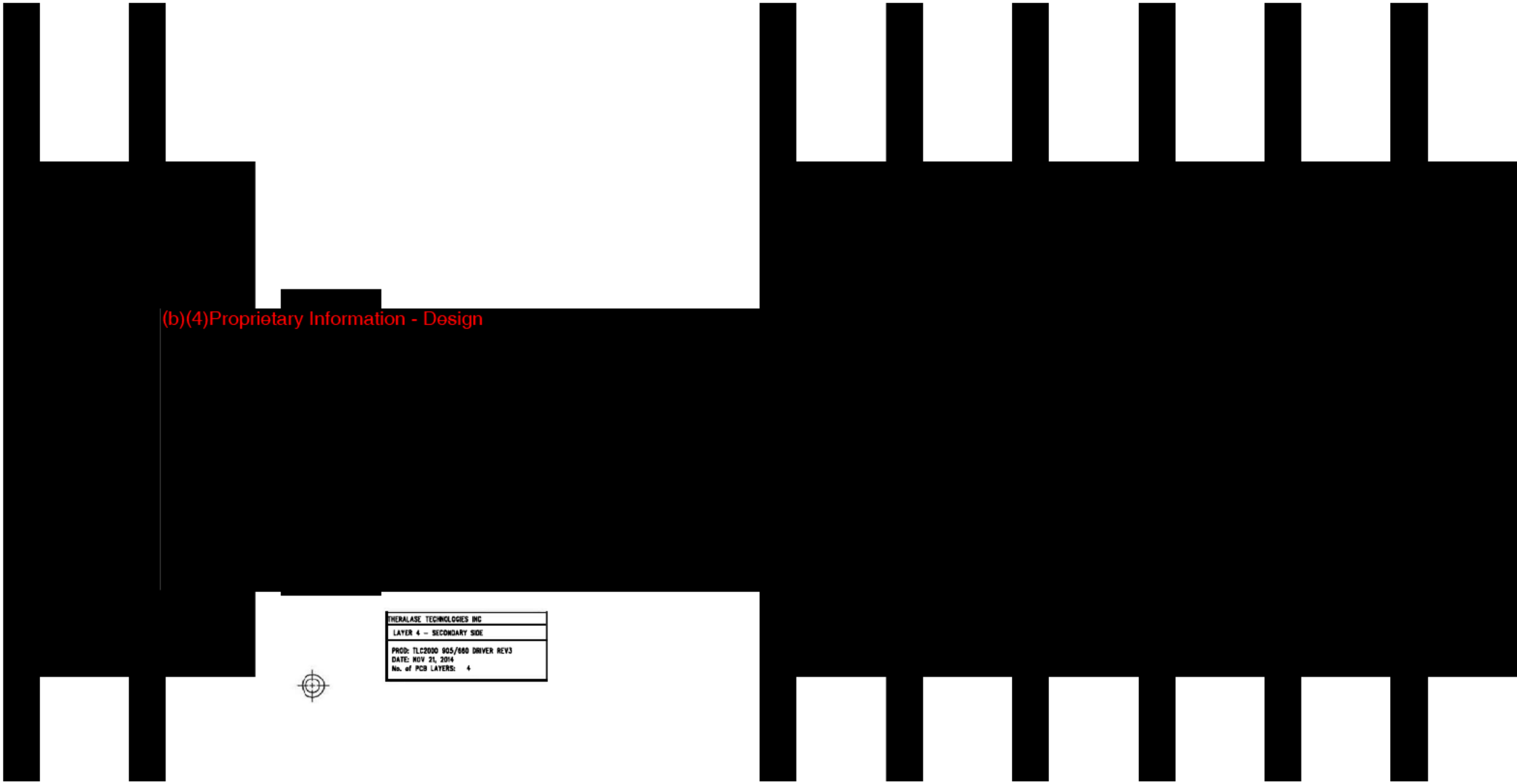
2.3.11_Laser Driver PCB

(b)(4)Proprietary Information - Design

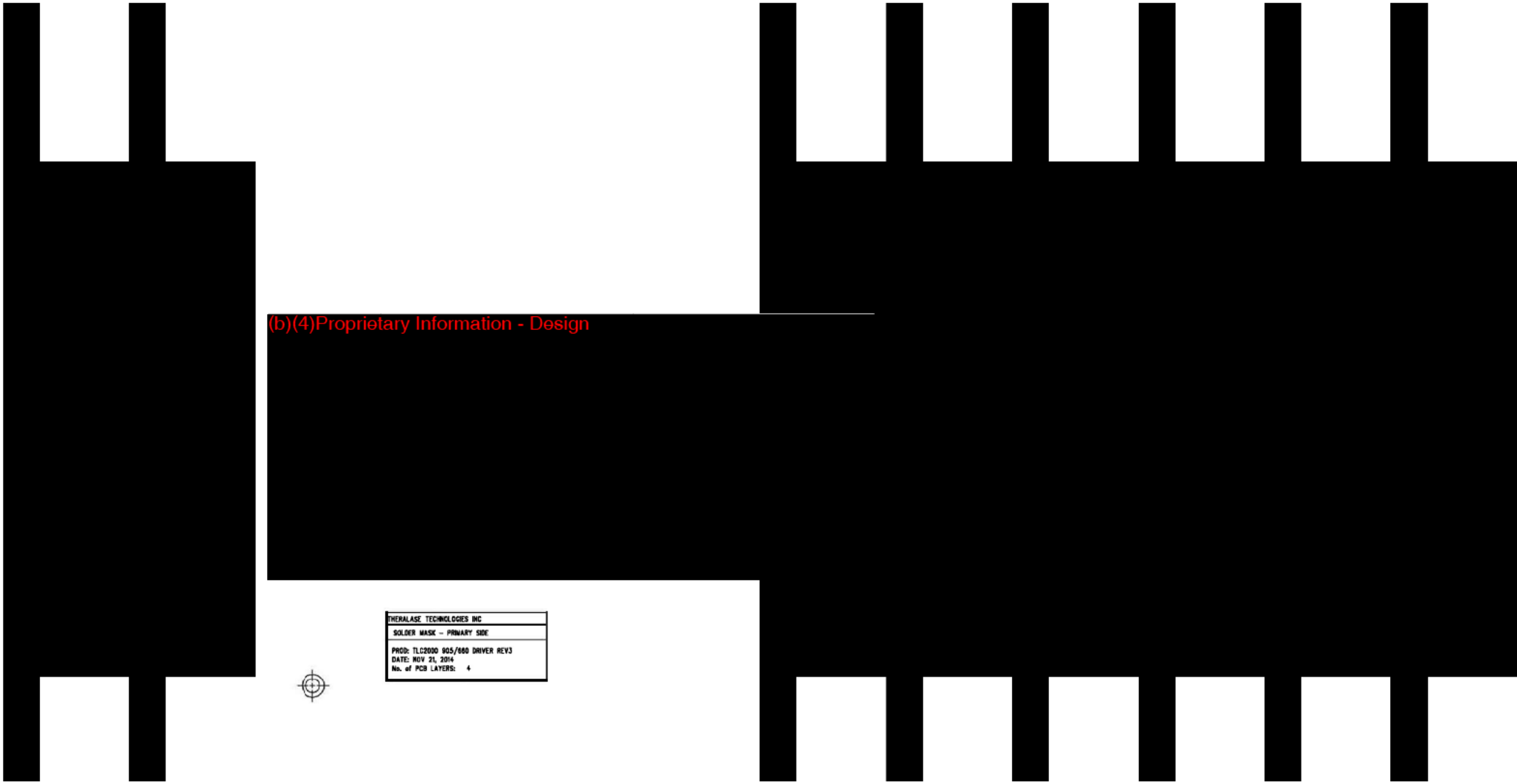


2.3.11_Laser Driver PCB

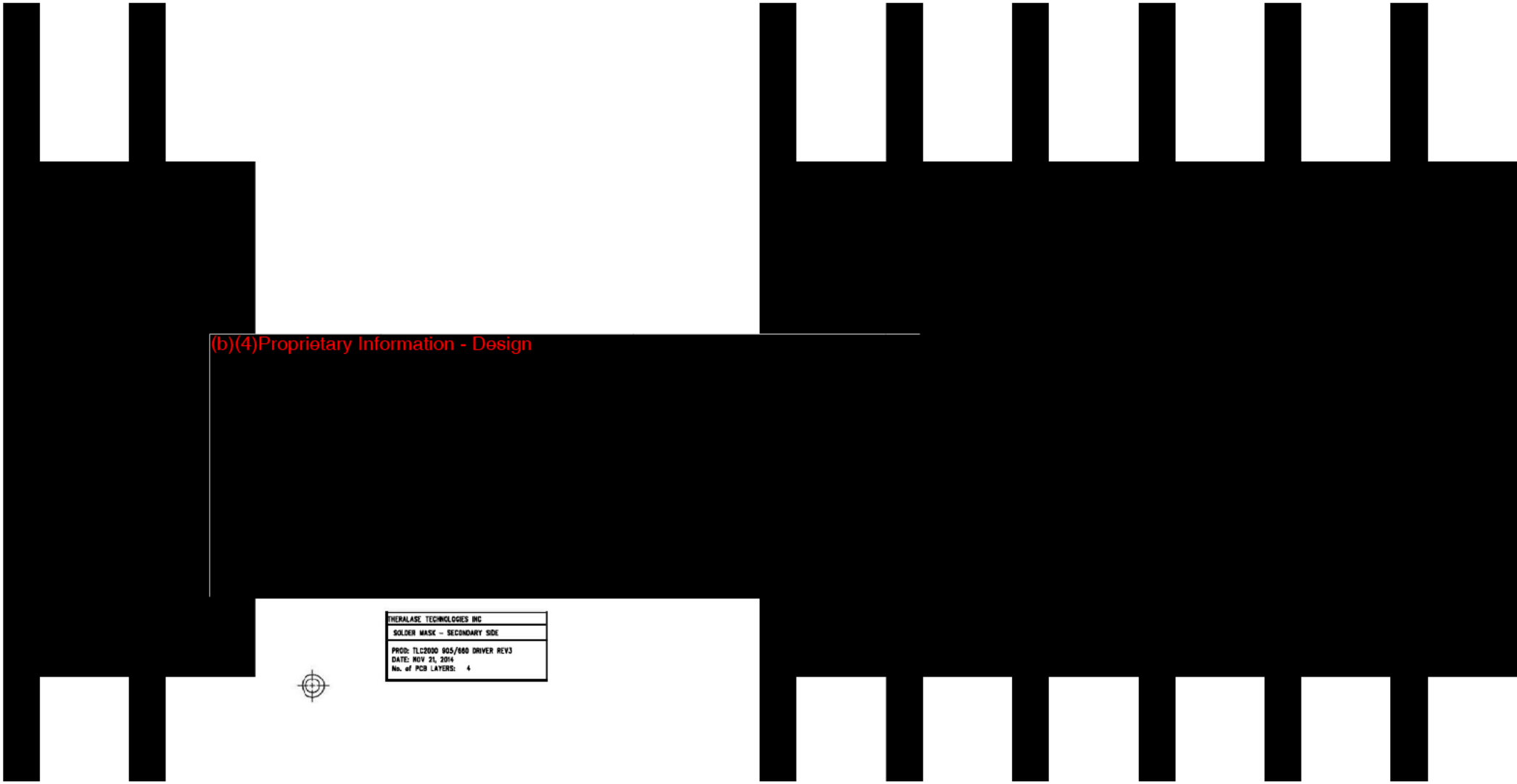
(b)(4)Proprietary Information - Design



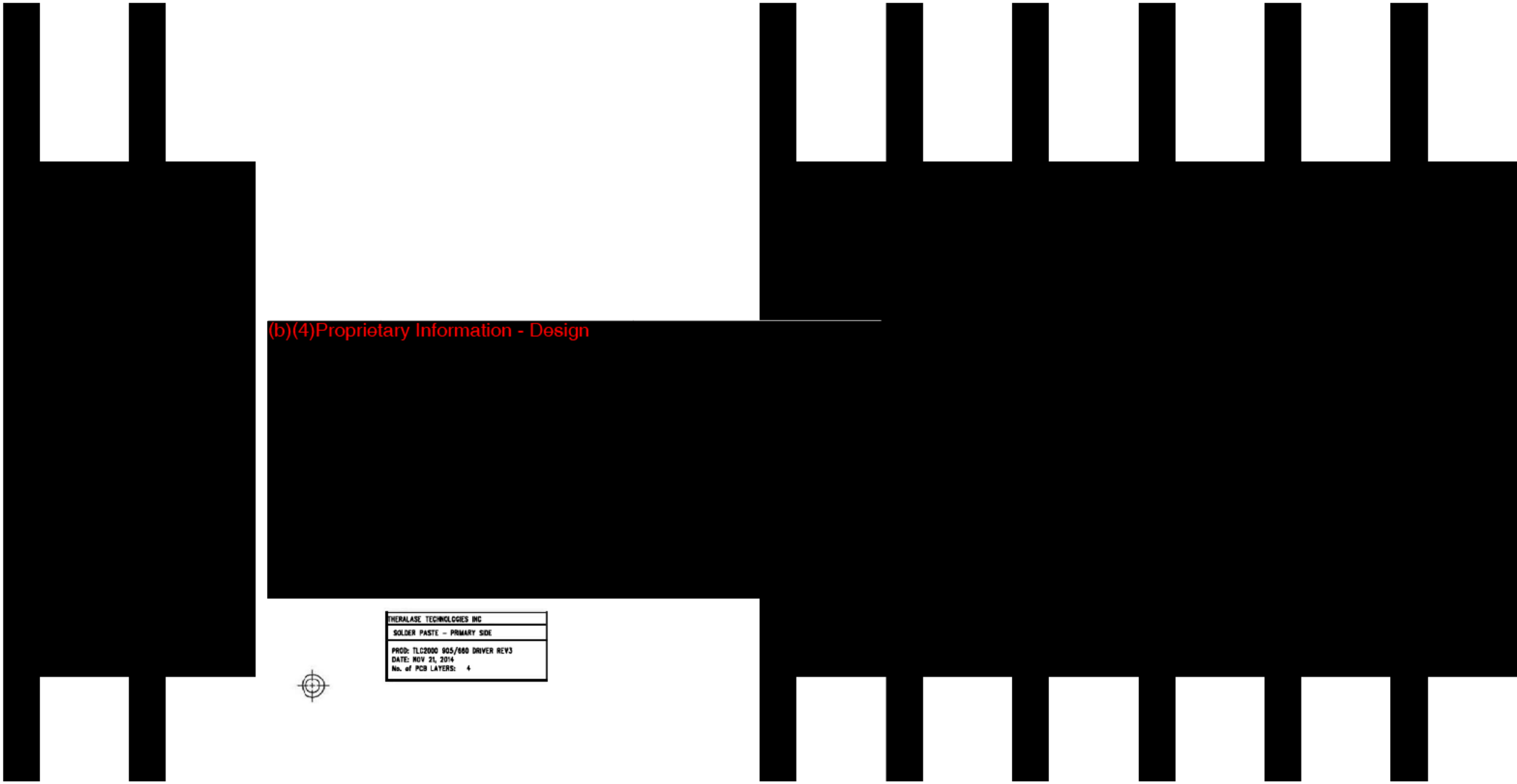
2.3.11_Laser Driver PCB



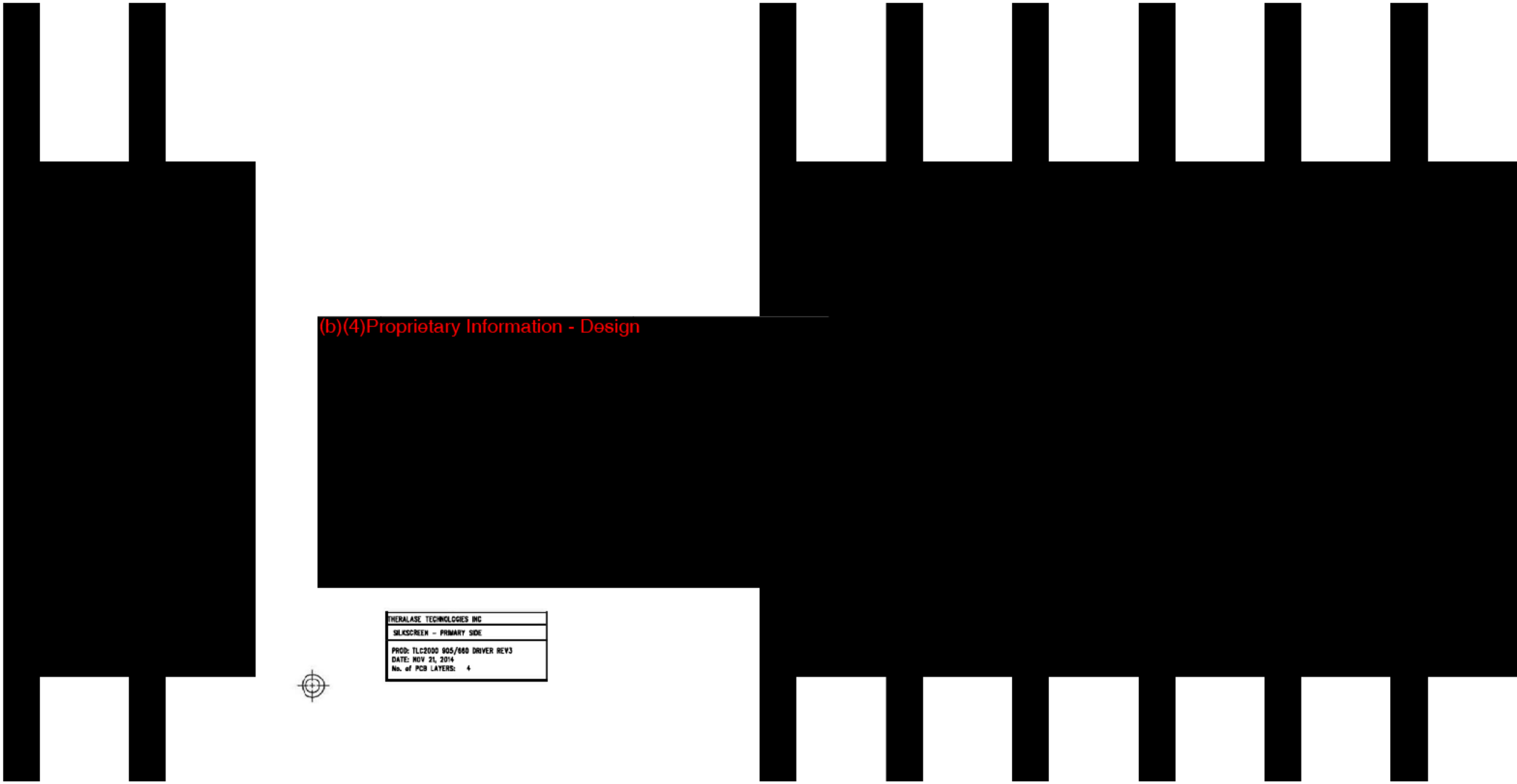
2.3.11_Laser Driver PCB



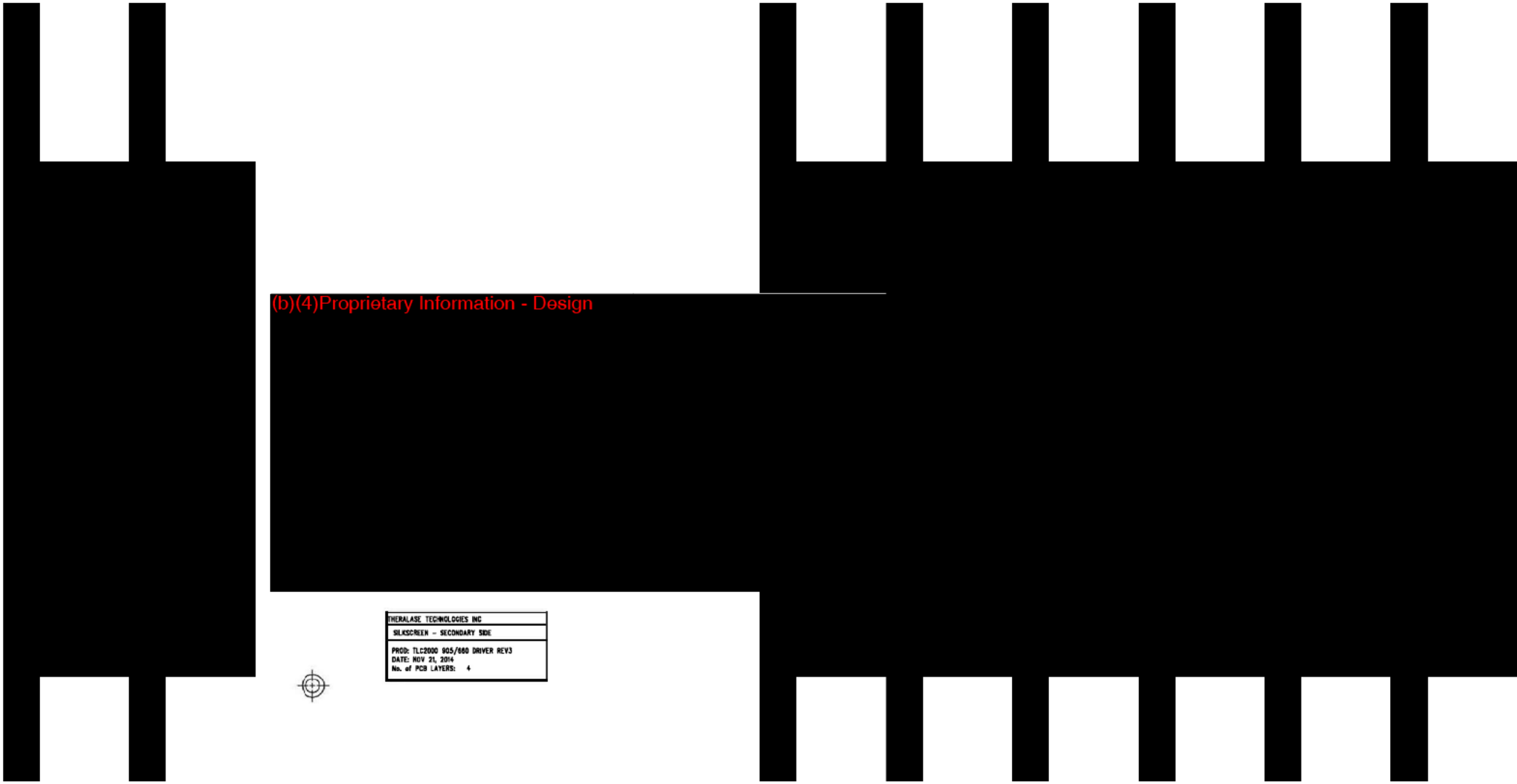
2.3.11_Laser Driver PCB



2.3.11_Laser Driver PCB



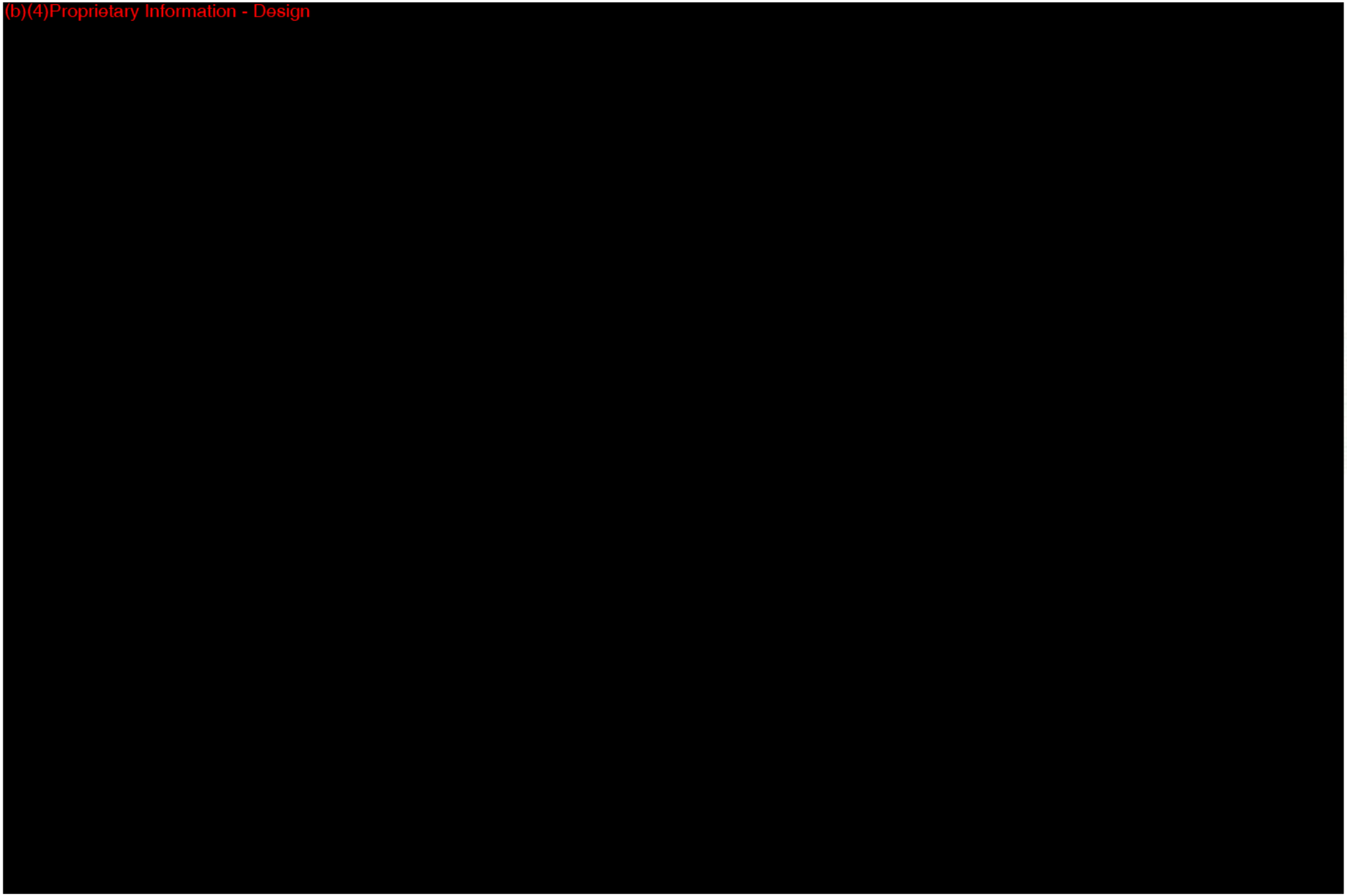
2.3.11_Laser Driver PCB



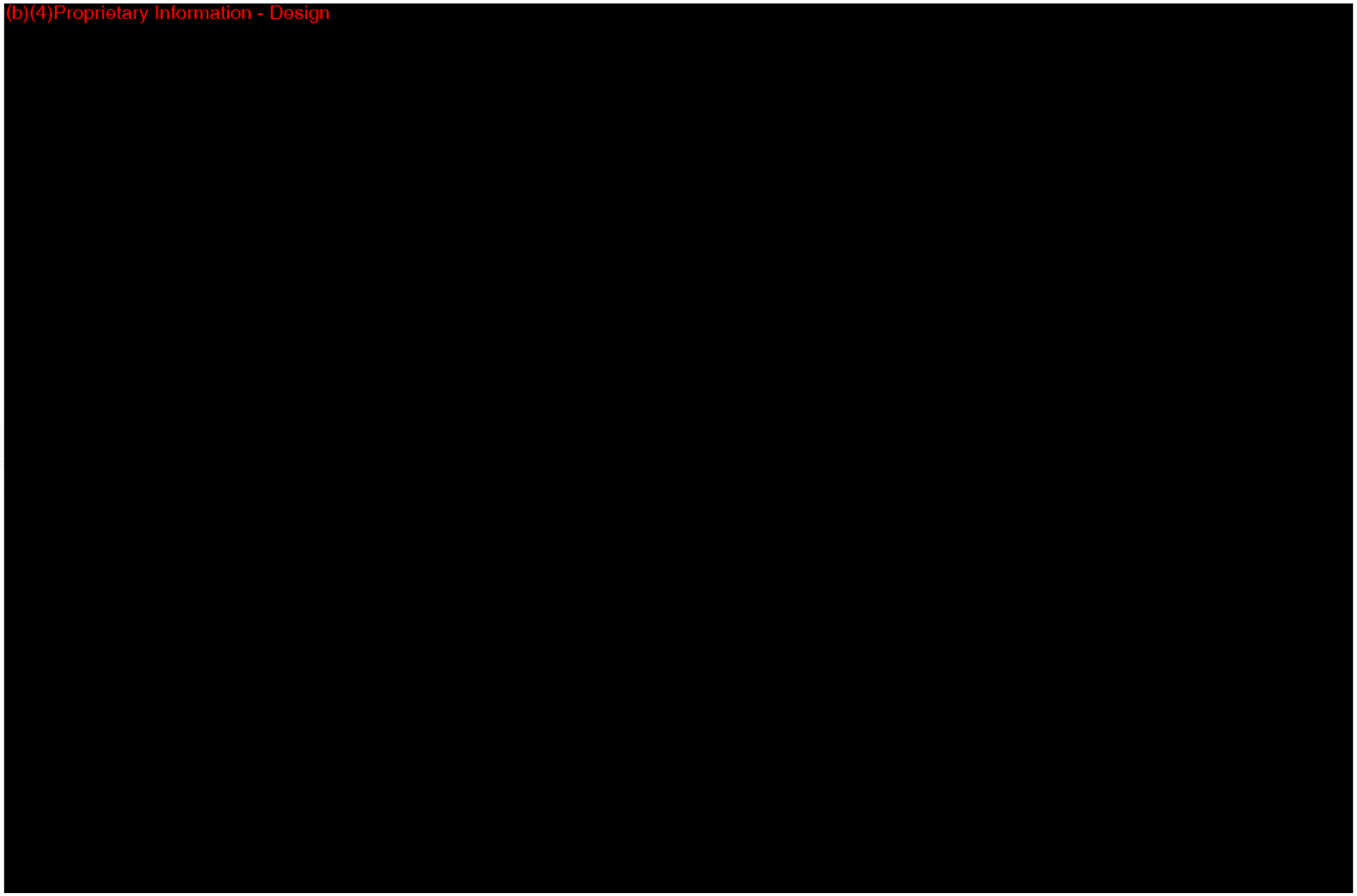
[redacted]

(b)(4)Proprietary Information - Design

[redacted]



2.3.13_Laser Driver Bottom Picture



2.3.14_Power Pack Schematic

REVISION RECORD			
LTR	ECO NO:	APPROVED:	DATE:

THERALASE TECHNOLOGIES INC
ASSEMBLY – PRIMARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

DRAWN: Rick Anderson	DATED: Mar 10, 2015	COMPANY: theraLASE			
CHECKED:	DATED:	TITLE: TLC 2000 BATTERY PACK BOARD Assembly Drawing – Primary			
RELEASED:	DATED:	CODE:	SIZE: A3	DRAWING NO: 900-0005-RX	REV: RX
		SCALE:		SHEET: OF	

REVISION RECORD			
LTR	ECO NO:	APPROVED:	DATE:

(b)(4)Proprietary Information - Design

DRAWN: Rick Anderson	DATED: Mar 10, 2015	
CHECKED:	DATED:	
RELEASED:	DATED:	

COMPANY: TeraLase

TITLE: TLC 2000 BATTERY PACK BOARD
Assembly Drawing – Secondary

CODE:	SIZE:	DRAWING NO:	REV:
	A3	900-0005-RX	RX

SCALE: SHEET: OF

2.3.15_Power Pack Pcb

2.3.15_Power Pack Pcb

[redacted]

(b)(4)Proprietary Information - Design

[redacted]

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
2	31	+	YES	+/-.003
3	31	X	YES	+/-.003
[illegible]	[illegible]	[illegible]	YES	+/-.003
[illegible]	[illegible]	[illegible]	YES	+/-.003
21.5	42	[illegible]	YES	+/-.003
42	19	[illegible]	YES	+/-.003
[illegible]	2	[illegible]	YES	+/-.003
25.85	5	[illegible]	YES	+/-.003
[illegible]	1	[illegible]	YES	+/-.003
[illegible]	4	[illegible]	NO	+/-.003
71	1	[illegible]	NO	+/-.003

THERALASE TECHNOLOGIES INC

DRILL GRAPHICS

PROD: TLC2000 BATTERY PACK (600-0005-R3)
DATE: Mar 10, 2015
No. of PCB LAYERS: 2

Refer to : PCB-600-0005-R3.DOC for Fabrication Notes
NOTE: ALL VIA-IN-PAD (13Mils dia.) TO BE FILLED WITH NON CONDUCTIVE MATERIAL AND PLATED OVER.

2.3.15_Power Pack Pcb

(b)(4)Proprietary Information - Design

[redacted]

[redacted]

THERALASE TECHNOLOGIES INC
LAYER 1 – PRIMARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

2.3.15_Power Pack Pcb

THERALASE TECHNOLOGIES INC
LAYER 2 – SECONDARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

2.3.15_Power Pack Pcb

(b)(4)Proprietary Information - Design

[redacted]

[redacted]

THERALASE TECHNOLOGIES INC
SOLDER MASK – PRIMARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

2.3.15_Power Pack Pcb

(b)(4)Proprietary Information - Design

[redacted]

[redacted]

THERALASE TECHNOLOGIES INC
SOLDER MASK – SECONDARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

2.3.15_Power Pack Pcb

(b)(4)Proprietary Information - Design

[redacted]

[redacted]

THERALASE TECHNOLOGIES INC
SOLDER PASTE – PRIMARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

2.3.15_Power Pack Pcb

(b)(4)Proprietary Information - Design

[redacted]

[redacted]

THERALASE TECHNOLOGIES INC
SILKSCREEN -- PRIMARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

2.3.15_Power Pack Pcb

THERALASE TECHNOLOGIES INC
SILKSCREEN -- SECONDARY SIDE
PROD: TLC2000 BATTERY PACK (600-0005-R3) DATE: Mar 10, 2015 No. of PCB LAYERS: 2

2.3.15_Power Pack Pcb

(b)(4)Proprietary Information - Design

(b)(4)Proprietary Information - Design

2.3.17_Power Pack Bottom Picture

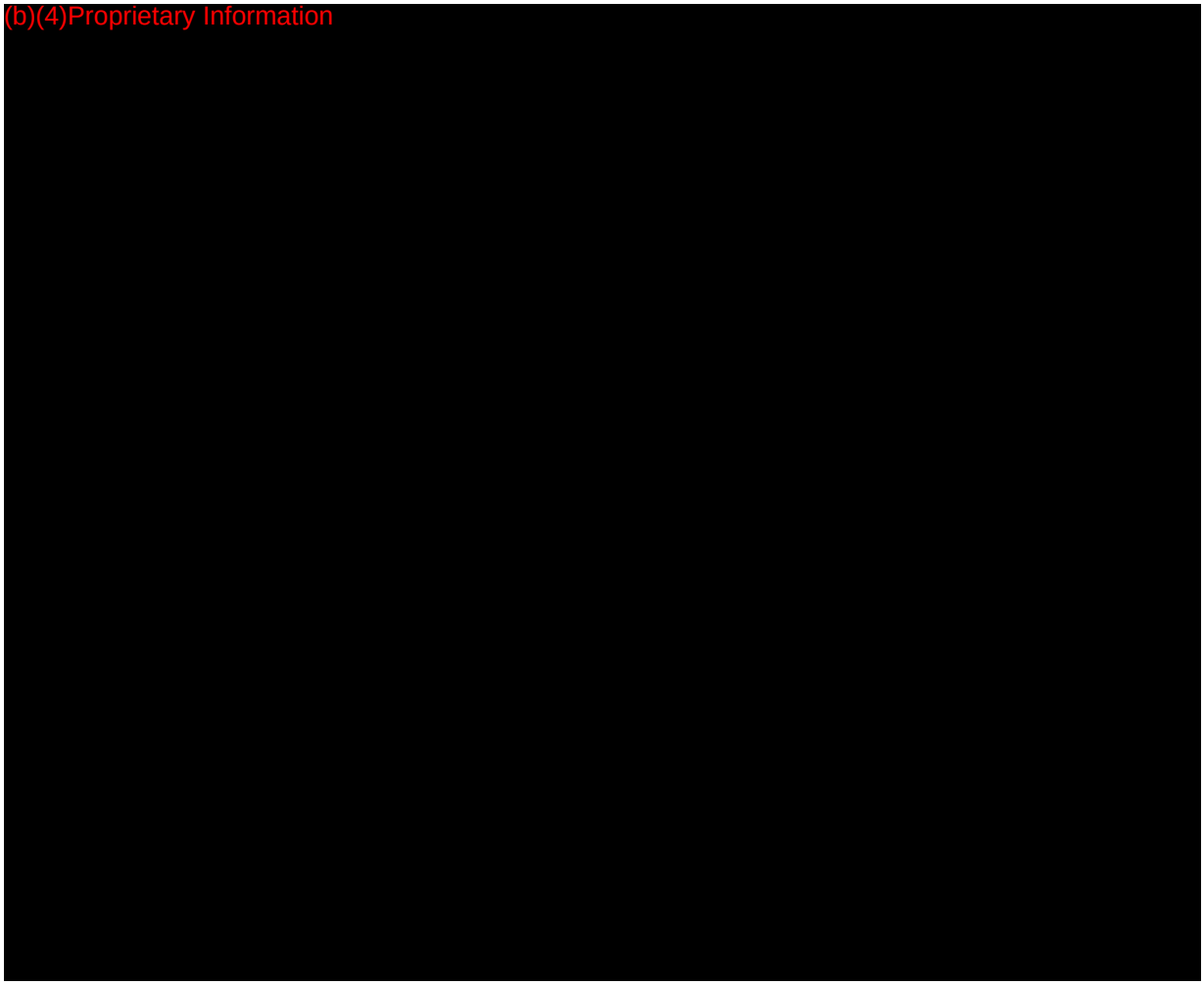
(b)(4)Proprietary Information - Design

2.4 Sterilization:

This section of the FDA submittal is not applicable to the Theralase TLC 2000 product as the product is not sold in a sterile condition and is not meant for a one time use. The probe is meant for repeated uses and can be cleaned and disinfected using a cloth moistened with 70% alcohol after each use.

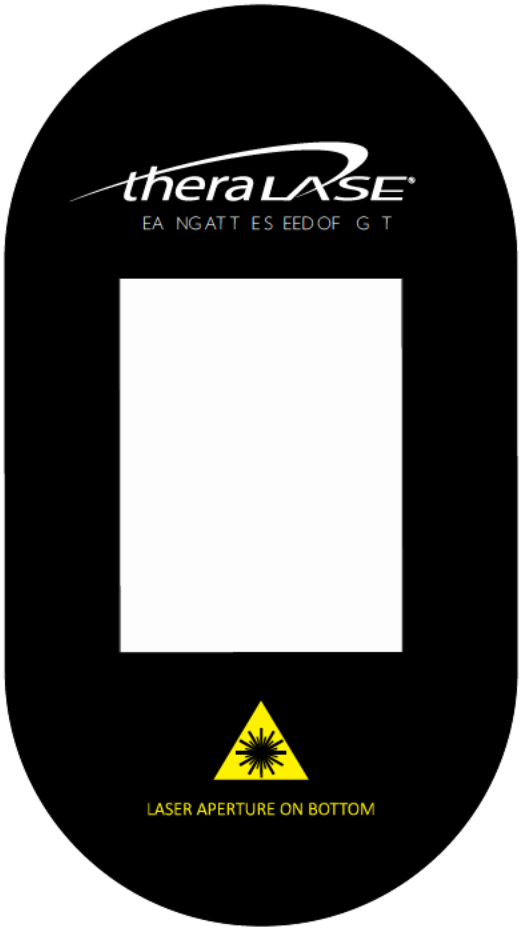
2.5 Biocompatibility and Toxicity

(b)(4)Proprietary Information



(b)(4)Proprietary Information

Probe Top Label



Lab Warning Sign TLC-2000

theraLASE®
Healing at the Speed of Light®

PAIN MANAGEMENT PROTOCOL MANUAL

Table of Contents

Clinical Information

Practical Advice for the Use of Low Level Laser Therapy

Cleaning the skin with isopropyl alcohol will diminish any reflection of the laser beam by the tissue surface due to natural oils.

(b)(4)Proprietary Information

[redacted]

Treatment Basics

General Protocols

(b)(4)Proprietary Information

[redacted]

Note:

- Certain pharmaceuticals are light sensitive and laser irradiation may increase or decrease their effectiveness in the body.
- Ask your patients about the sensations they experience during and after treatments. It will provide you with valuable knowledge of treatment protocols and treatment efficacy to apply in future treatments.

Acute / Sub-acute / Chronic Cases:

(b)(4)Proprietary Information

[redacted]

Indications

1) All tissue structures: epidermis, dermis, subcutaneous fat, muscle, tendon, bone and ligaments in the knee joint may be treated with a therapeutic laser for bio-stimulative rehabilitative purposes.

2) Metal pins, metal plates, plastics and pacemakers are not contraindicated.

3) Use clear plastic wrap, cellophane or translucent / transparent bandage types to protect a wound site resident in the knee area prior to laser treatment.

Contraindications

1) Do not treat the abdomen of a pregnant woman.

2) Do not treat any types of neoplasia, cancer or cancerous lesions, (benign or malignant).

Cautions in the use of Laser Therapy

1) Never point the laser in the direction of any person's eyes.

2) Do not treat endocrine glands such as the pancreas and the thyroid.

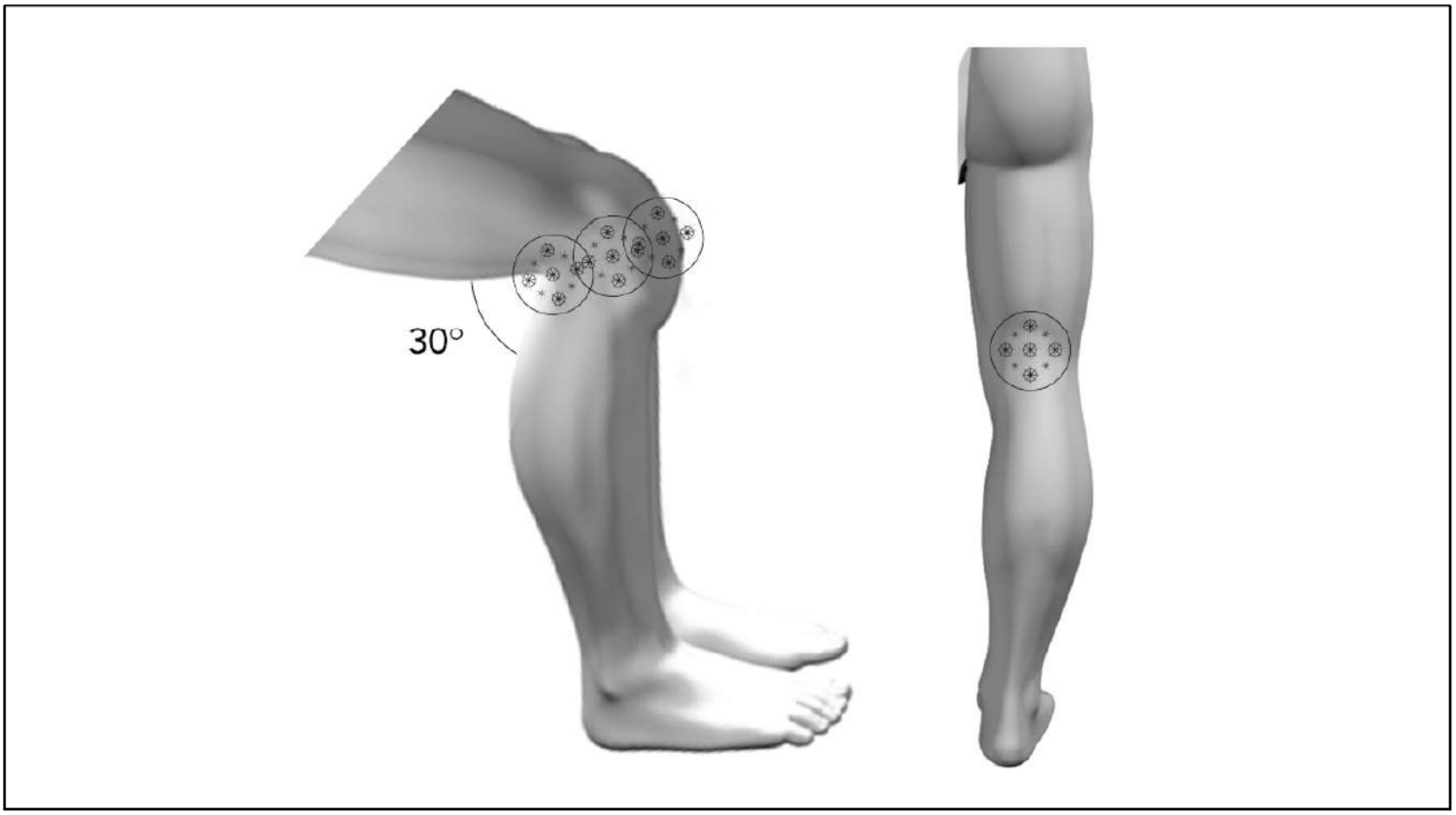
3) For a new patient or a patient who may be light sensitive, spot test the laser on an area of tissue to determine if they are adversely sensitive to laser treatment.

4) If a patient is currently prescribed photosensitive medicine, NSAIDS, steroids or corticosteroid medicine, allow 2 weeks as a wash out period prior to laser treatment. If a wash out period is not possible, reduce the laser power to ½ of the recommended power indicated and increase with each treatment as the patient reliance on photosensitive medicine, NSAIDS, steroids or corticosteroid medicine reduces.

5) Start treatment at the most painful area first and follow the treatment specifics. Treat surrounding tissue next.

(b)(4)Proprietary Information

Treatment Specification: 001 KNEE PAIN
Knee Pain



Treatment Protocol:

TLC-000 Treatment Record	001 KNEE PAIN
Number of Treatment Points	7

Treatment Program:

Frequency	3 per week
Total Visits	12

Treatment Settings:

Power	40
Time	1:00
Energy (Joules)	2.4 J

Treatment Details:

(b)(4)Proprietary Information

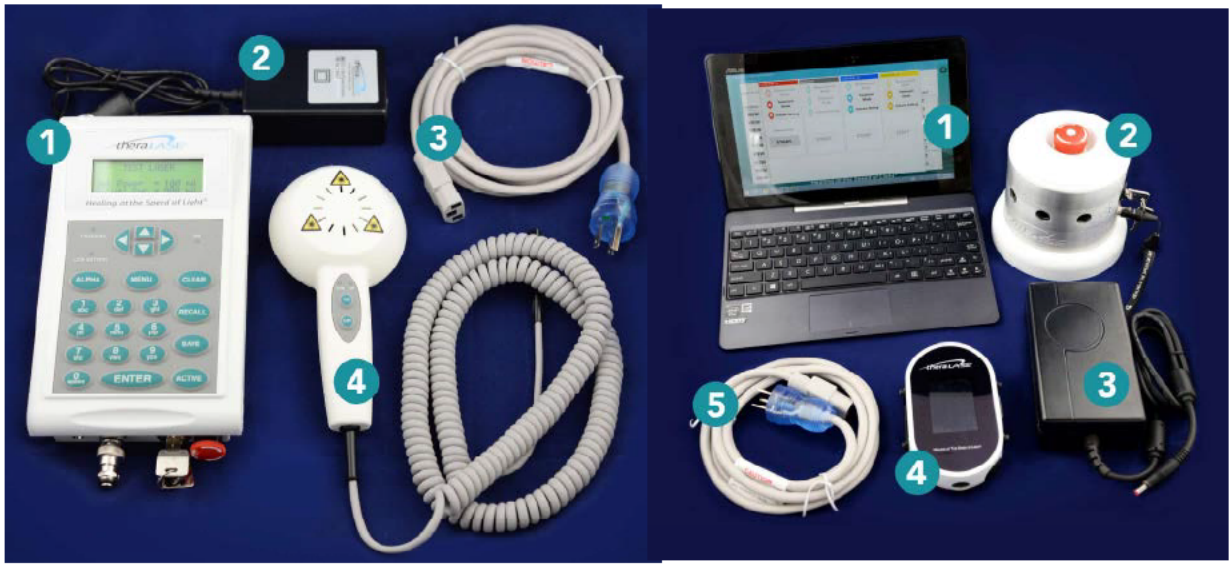
2.8 Advertising and Promotional Material

There are no promotional or advertisement materials available at this time.

3.1 Substantial Equivalence

The new product, the TLC-2000 is a Class 3B therapeutic medical laser. It is a new design based on the design of the predicate product, the TLC-1000, also a Class 3B laser. The TLC-1000 product is manufactured and for the past ten years has been sold in Canada under the Canadian Medical Devices License 65816 and has been sold in the United States under a 510(K) Premarket Submission Number K050342.

The TLC-2000 is a more modern approach where the practitioner saves patient diagnosis and treatment protocol information on a tablet computer. (b)(4)Proprietary Information [redacted]



Predicate Device: TlC-1000

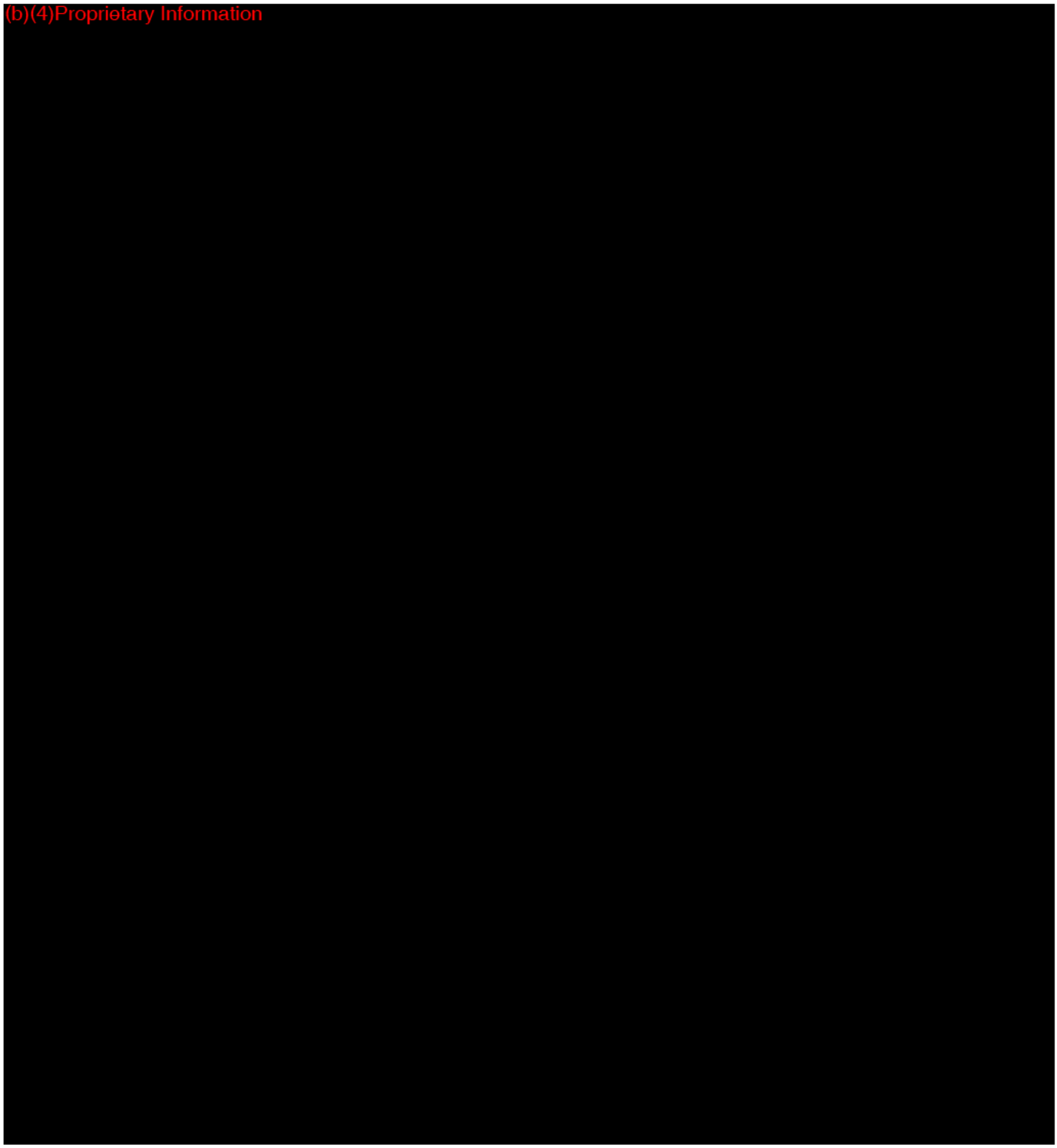
As shown above clockwise from the left:

1. The Controller
2. The Power Supply
3. The Medical AC Cable
4. The Probe

New Device: TLC-2000

As shown above clockwise from top left:

1. The Tablet Computer
2. The power Pack
3. The Power Supply
4. The Probe
5. The Medical AC Cable



Substantial Equivalence Table

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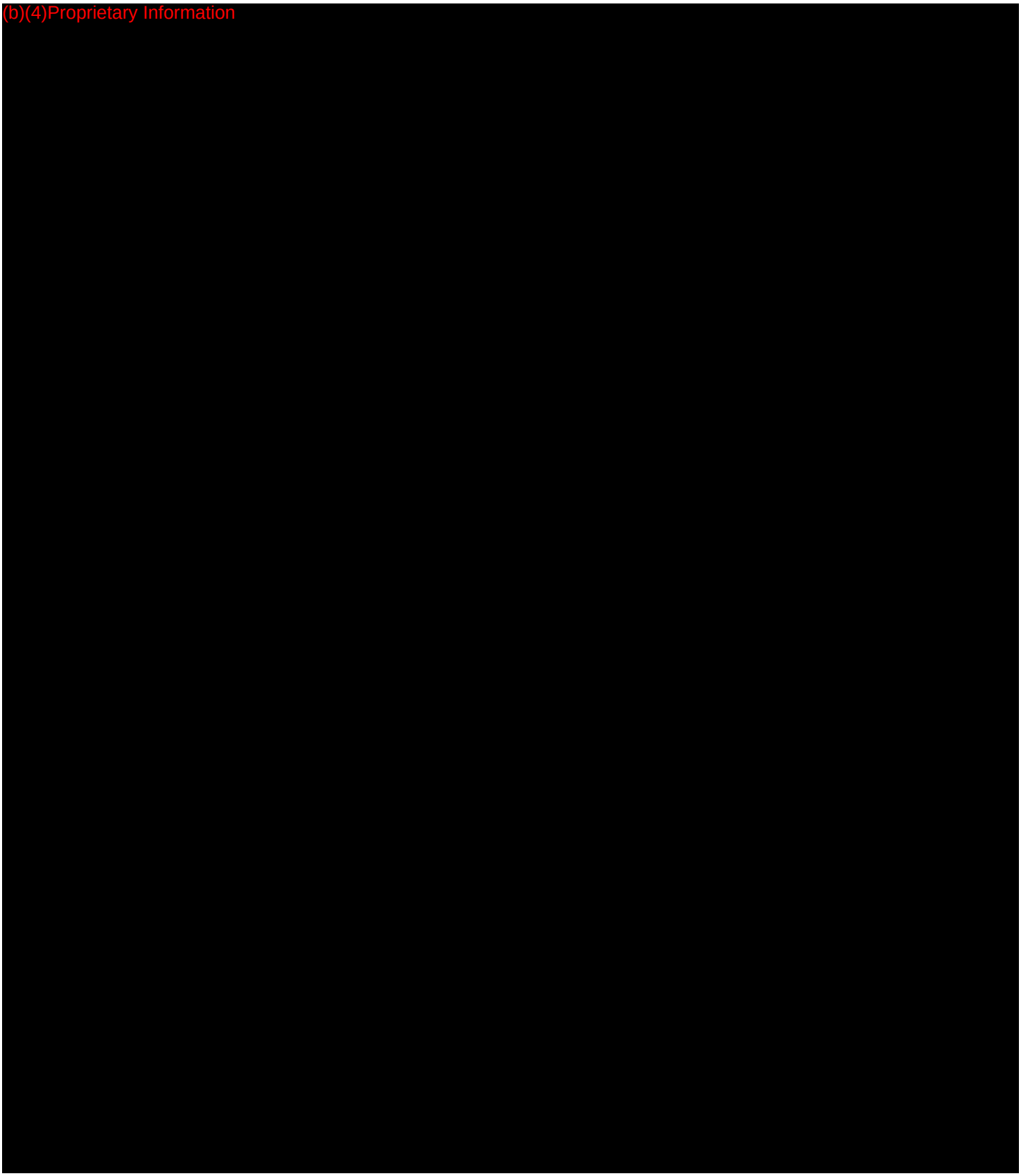

Substantial Equivalence Table ... Cont'd

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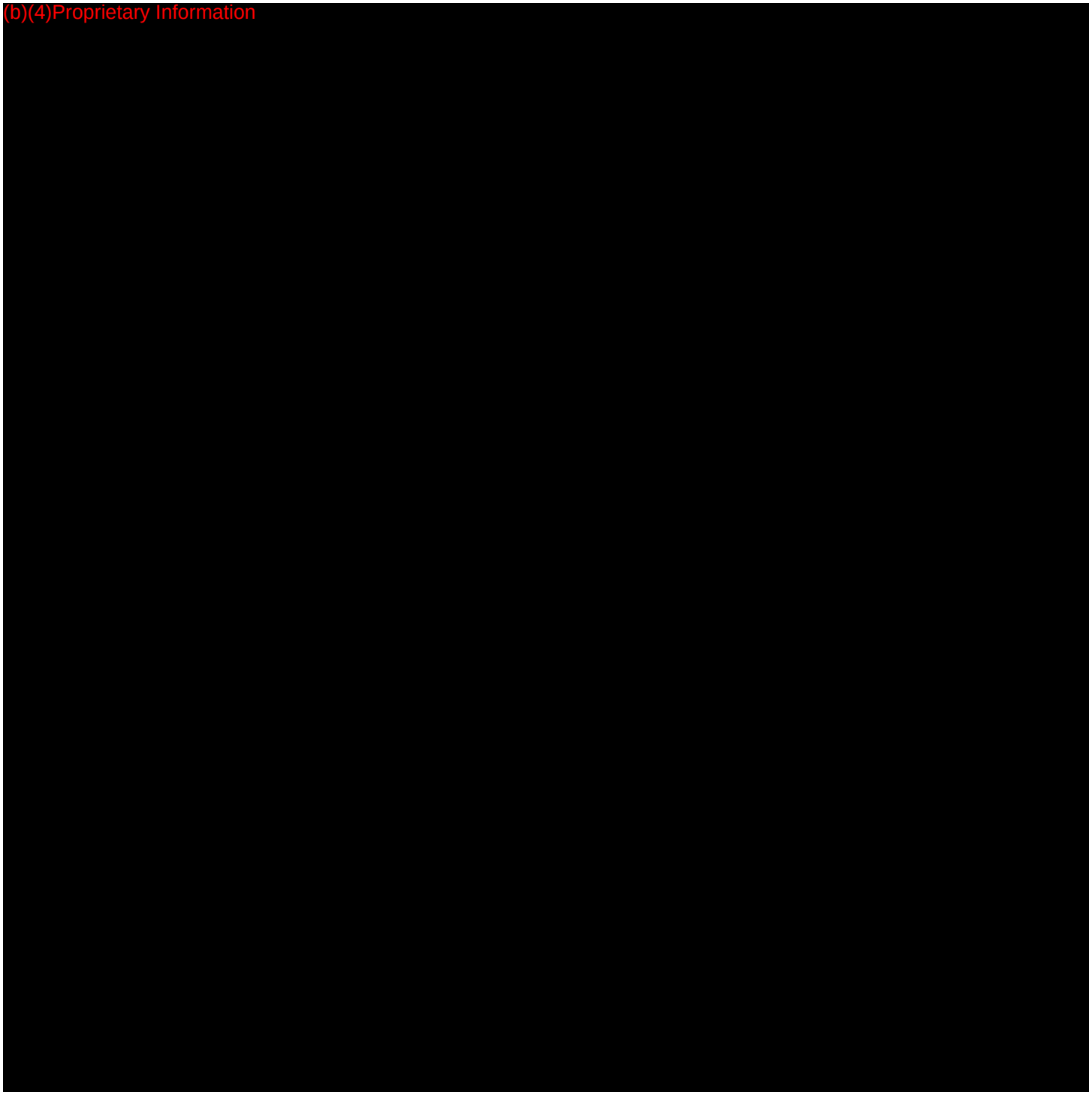

The main differences between the predicate Theralase TLC-1000 and the new device, Theralase TLC-2000 Medical Therapeutic Laser Systems are:

1. the additional safeties resulting from the newer laser standard:

(b)(4)Proprietary Information

2. higher power:

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3. the tablet software and database:

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4. Power measurement:

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(b)(4)Proprietary Information

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Software Verification and Validation Report

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(b)(4)Proprietary Information-Verification Report

(b)(4)Proprietary Information-Verification Report

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2 Software Requirements

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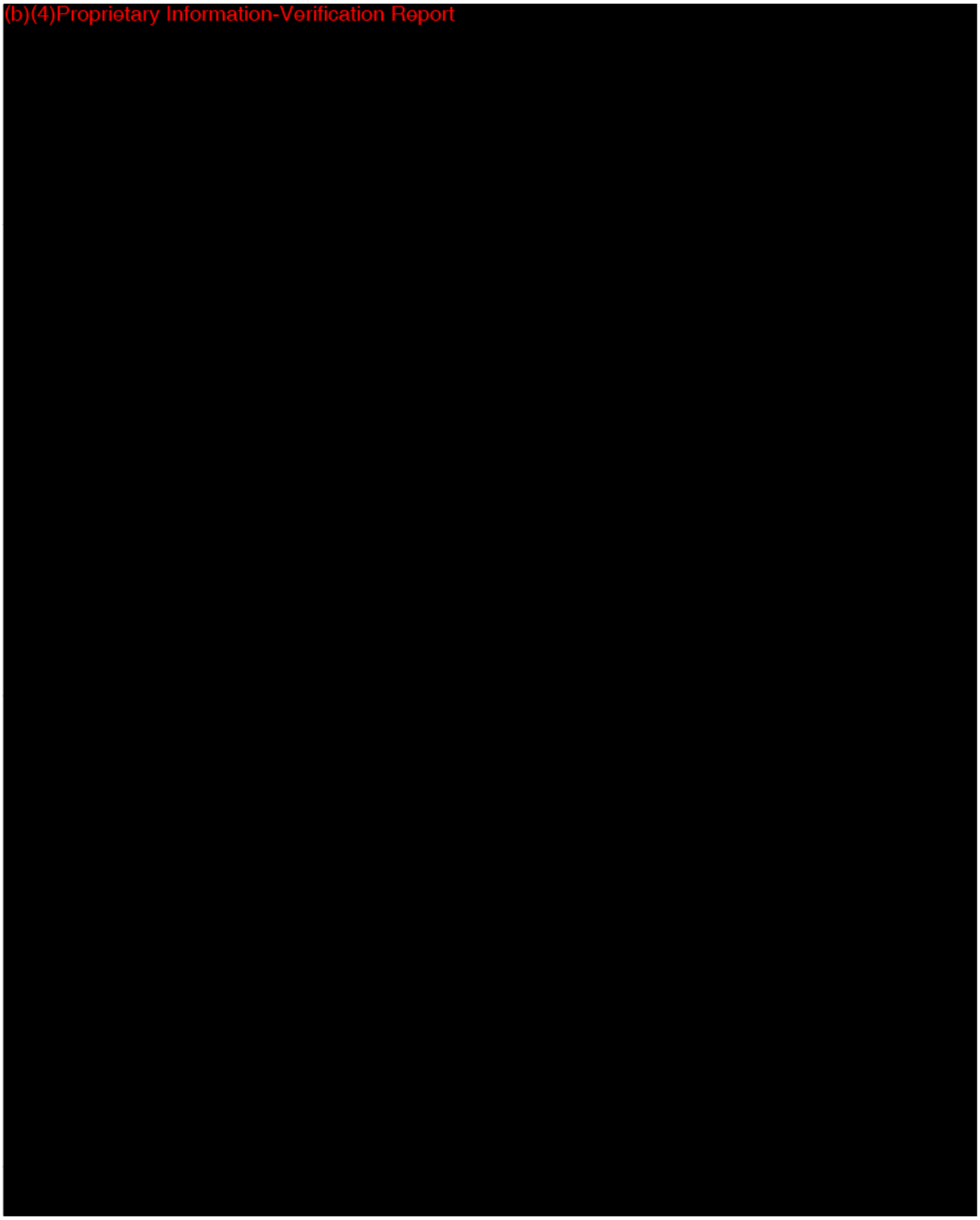

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3 Software Verification

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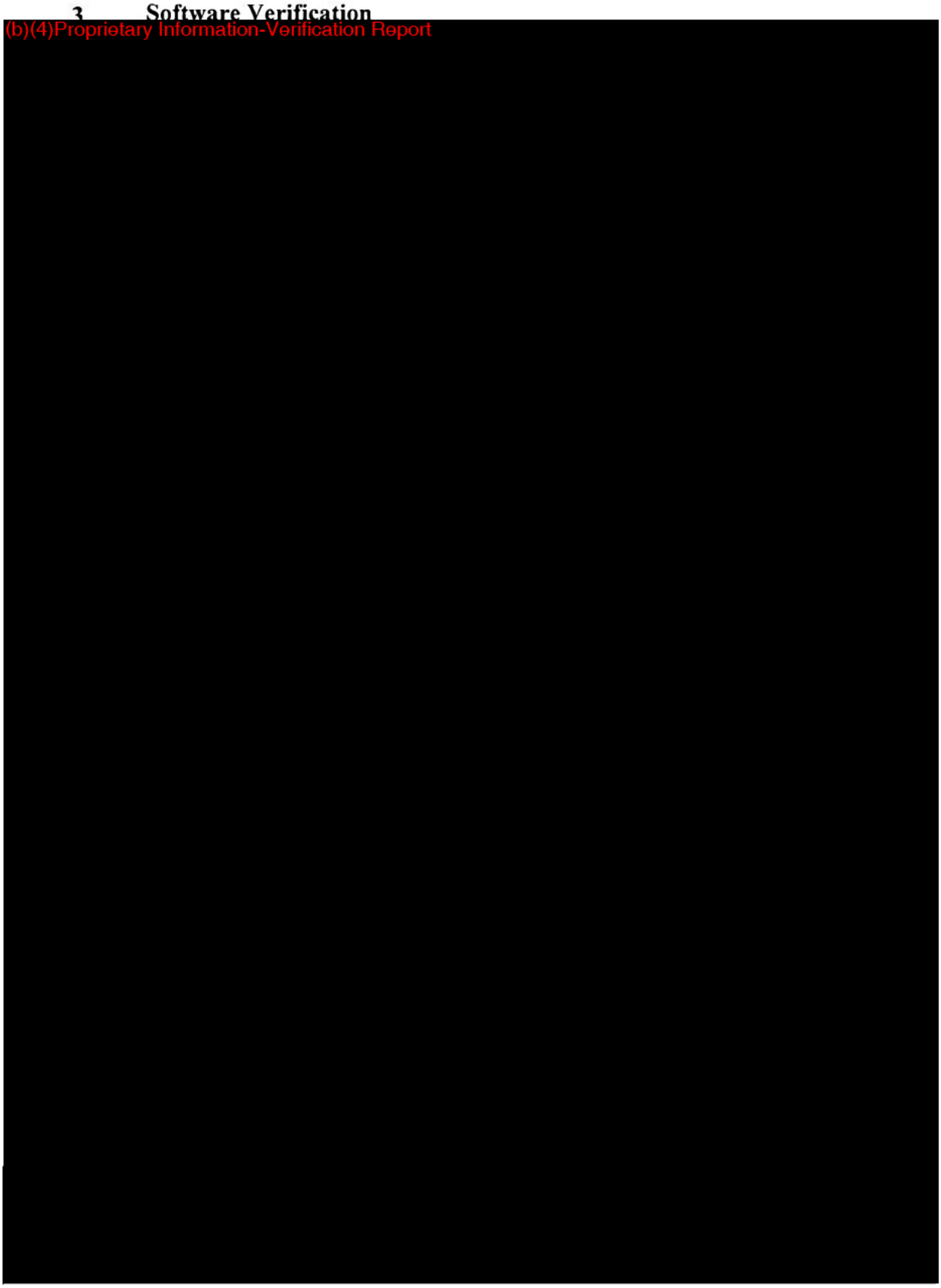

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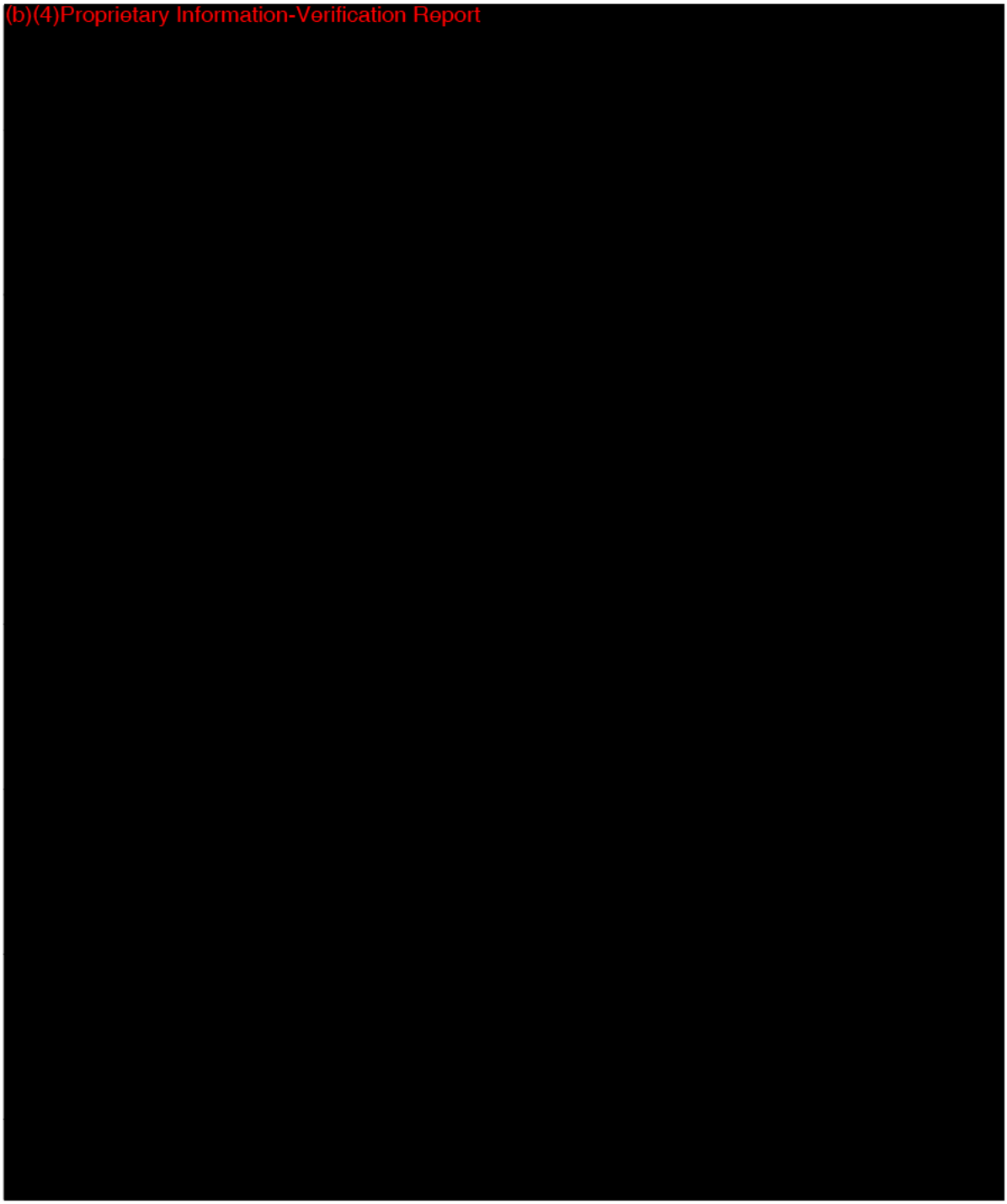

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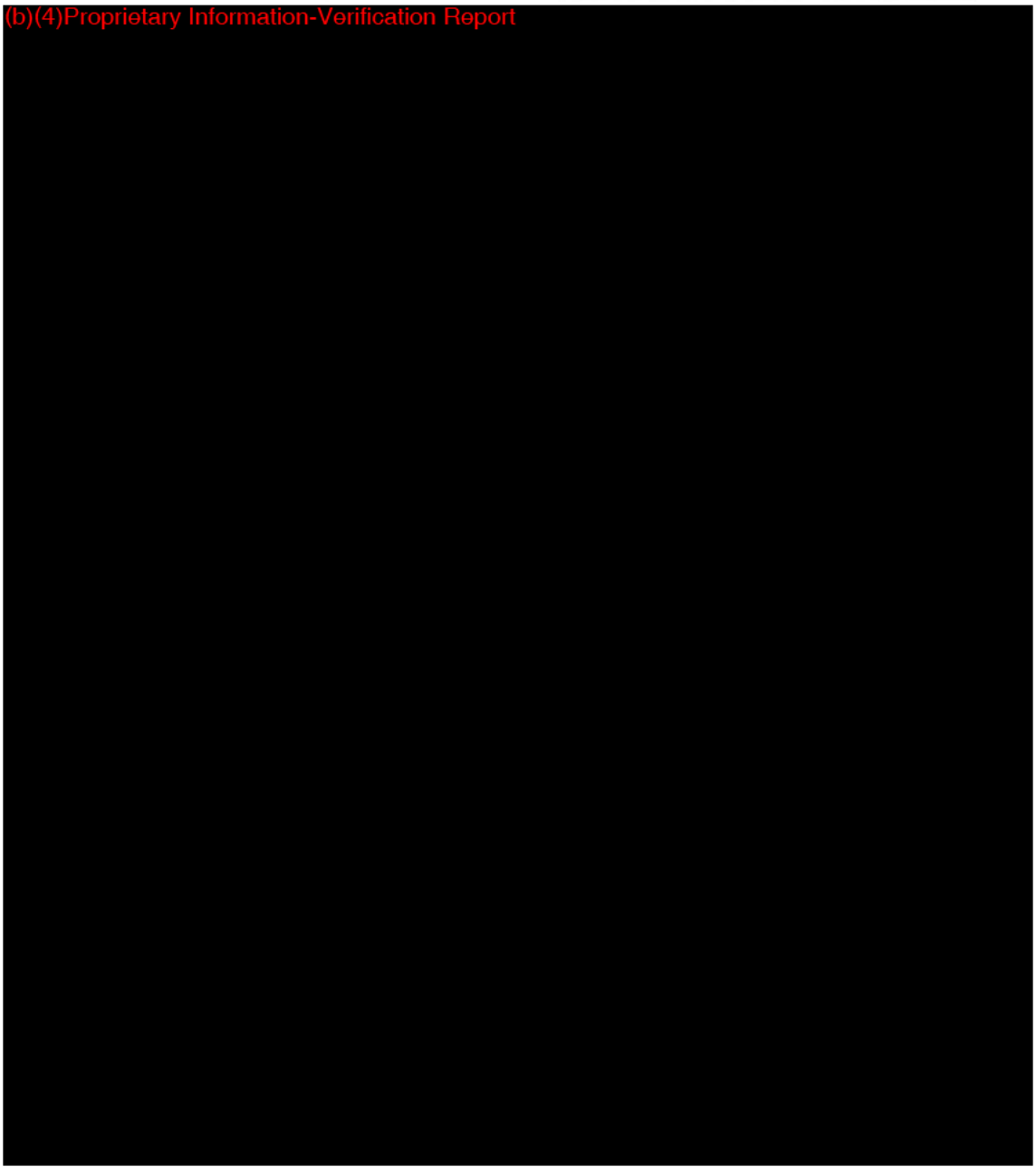

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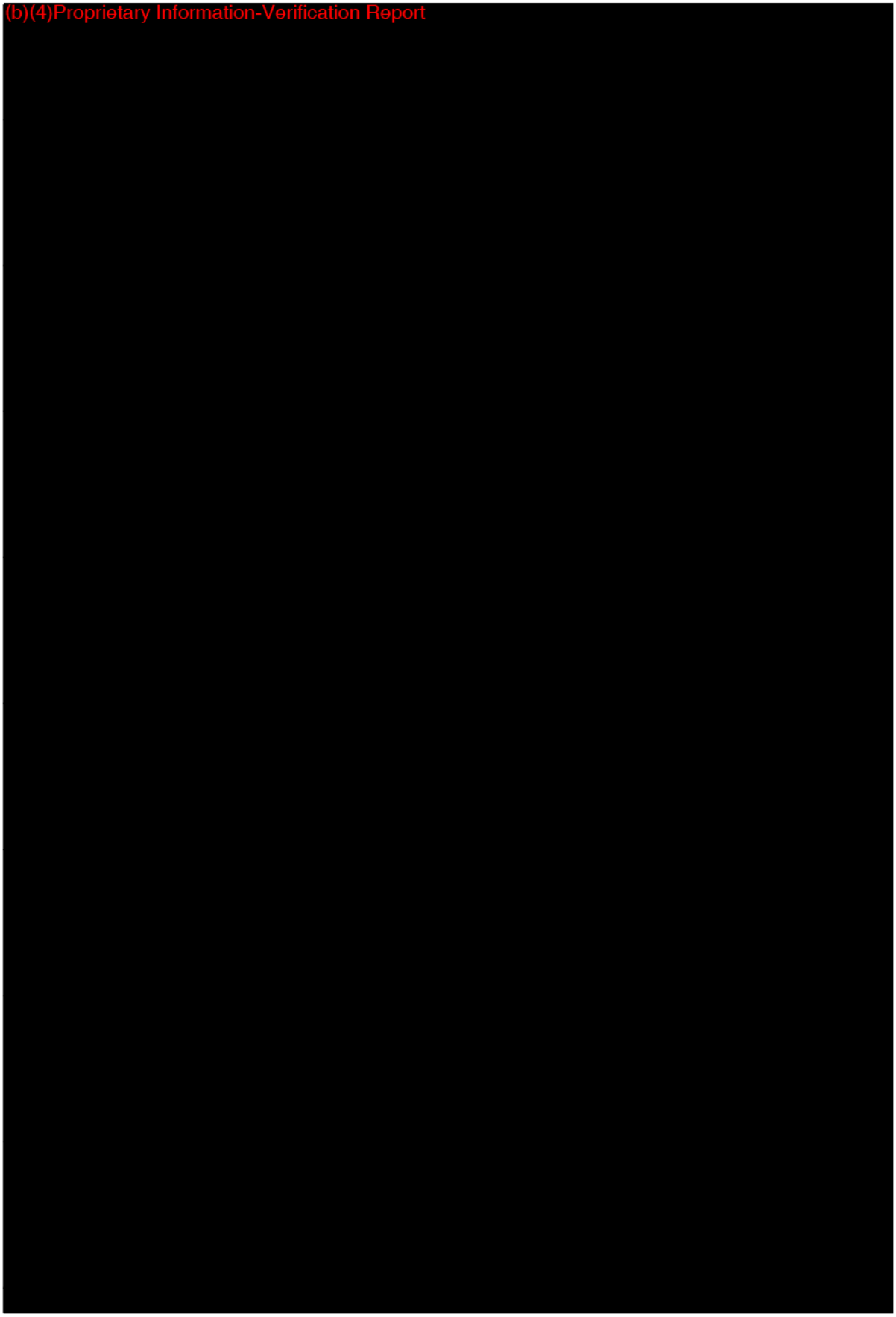

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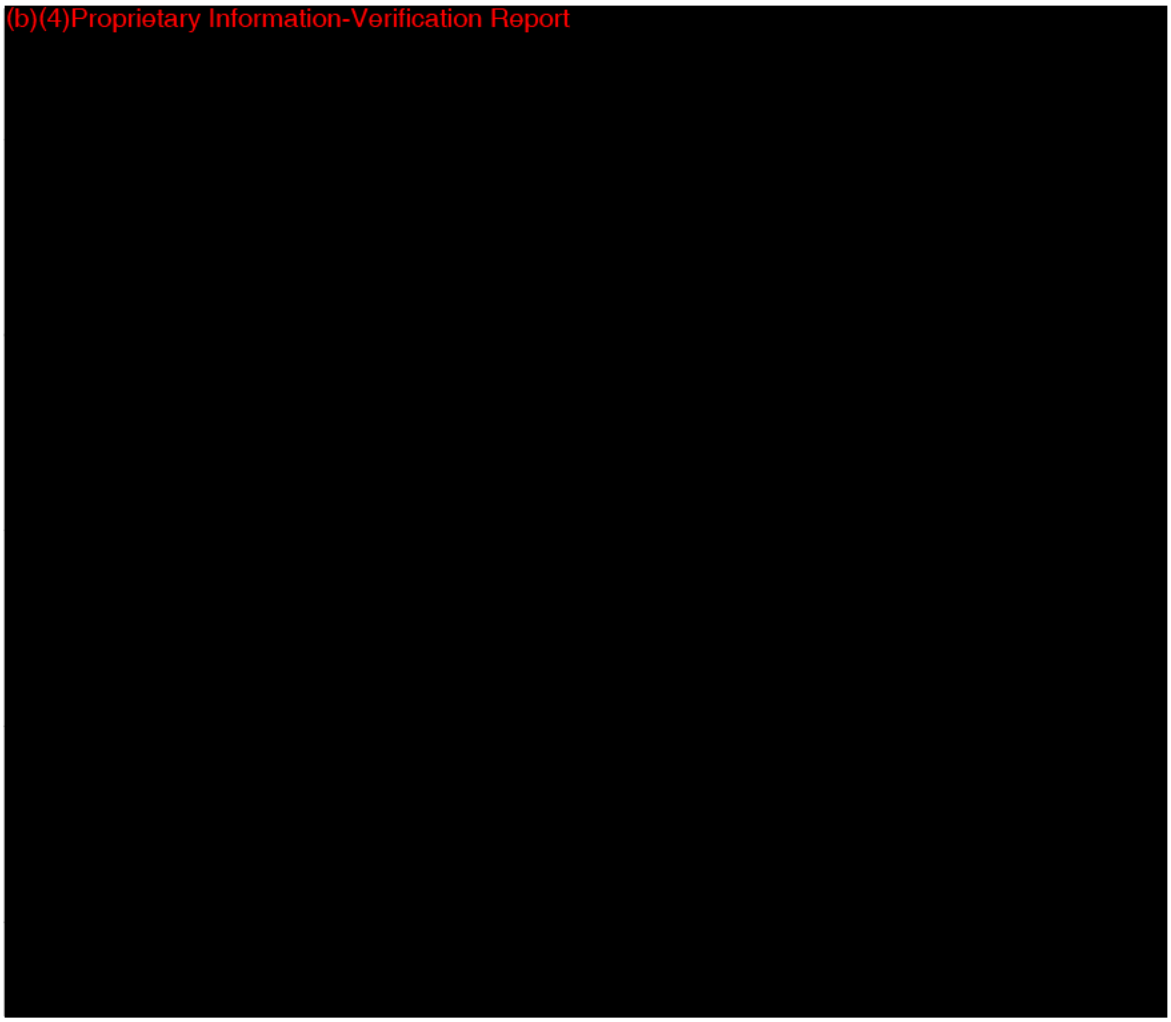

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5 System acceptance test

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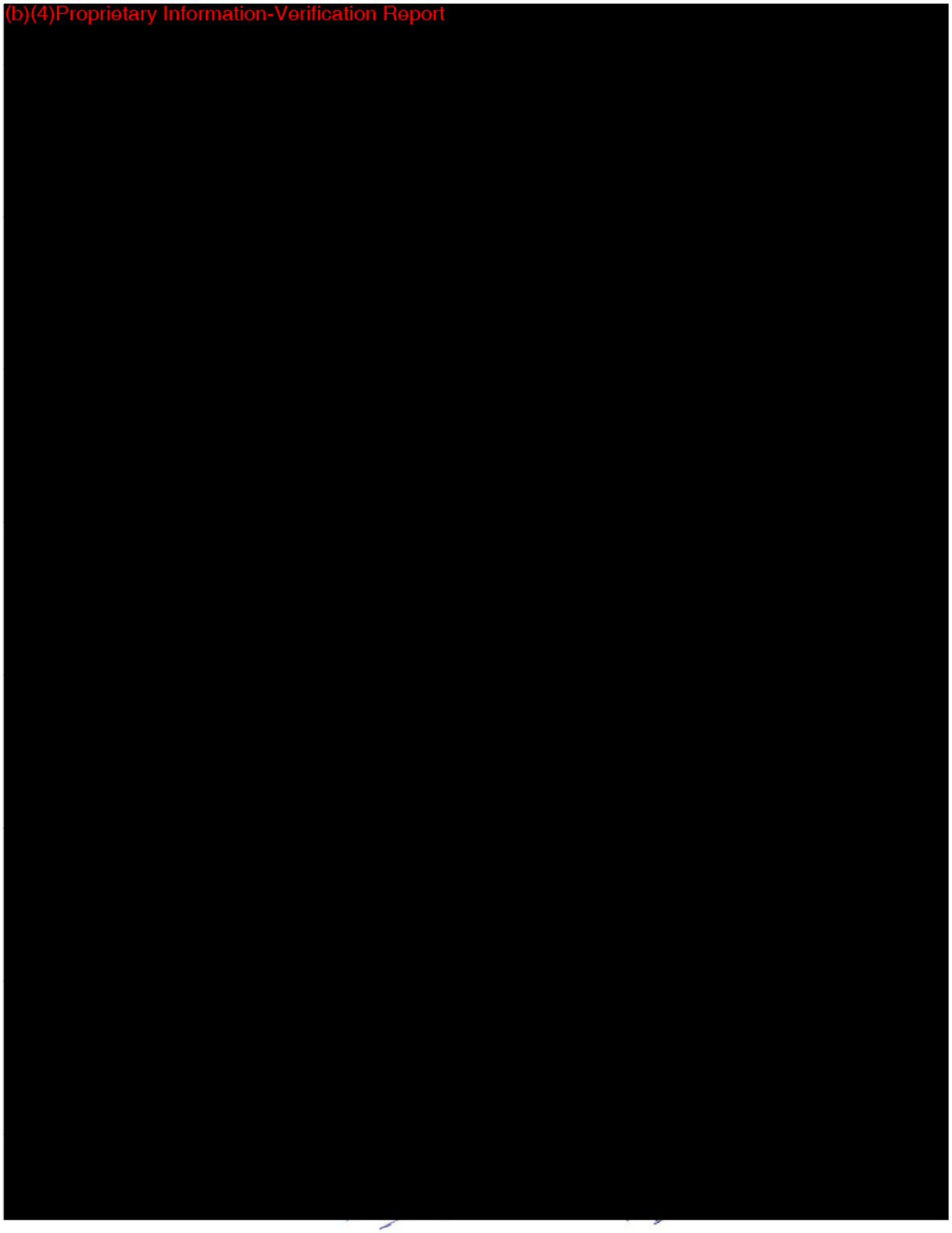

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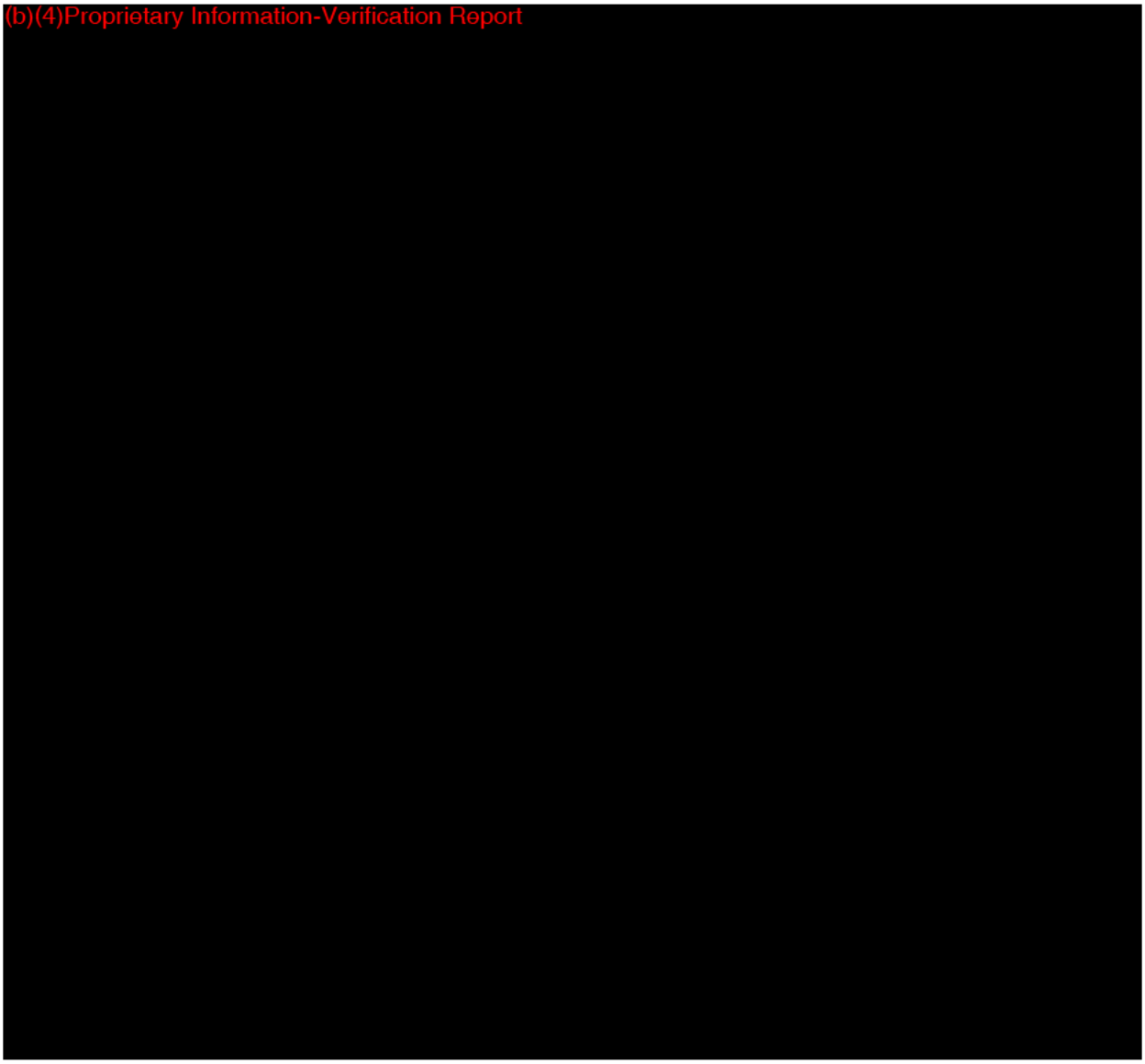

Risk Management Plan

Product Description:	Therapeutic Laser
Product Series:	TLC-2000
Date of Analysis:	January 13, 2015
Document Number	2914

1) Risk Management Plan

This risk management report is performed on the Theralase TLC-2000 Therapeutic Laser (TLC-2000) for the purpose of investigating the risk of the device. This analysis was planned at the beginning stage of the device design, initial manufacture of device and throughout the life of the device on an annual basis. Main methods and procedures we selected herewith are referred to EN ISO 14971:2007 and EN 60601-1 Edition 3 in regarding the European Medical Device Directives (MDD) on the safety and Performance of the product.

Roger Dumoulin-White, President & CEO and Qing Zhang, Senior Design Engineer have collaborated to compile the risk management plan. Mr. Dumoulin-White is the founder of Theralase Inc. and is well versed in the design, manufacture and application of therapeutic medical lasers. Mr. Zhang is an experienced electronics design engineer who is well versed in the design and manufacture of Theralase therapeutic medical laser systems.

The Theralase TLC-2000 therapeutic medical laser system is designed and manufactured by Theralase Inc. utilizing this risk management plan to minimize risk, maximize safety and efficacy for our customers.

The phases of the life cycle of the Theralase TLC-2000 therapeutic medical laser system covered by the risk management plan include: design, manufacture and post-production usage.

Verification of design changes or process changes to the Theralase TLC-2000 therapeutic medical laser system to minimize risk is completed by Qing Zhang and Roger Dumoulin-White to assess their success in minimizing risk.

The Quality Manager is responsible for all phases of the risk management plan.

Risk that could harm the patient, because bodily injury or death is unacceptable. Risk that prevents operation of the product is acceptable.

(b)(4)Proprietary Information-Verification Report

2) Risk Analysis Procedure

a) Intended Use / Intended Purpose and Identification of Characteristics Related to the Safety of the Medical Device

(b)(4)Proprietary Information

(b)(4)Proprietary Information

[redacted]

3) Estimation of the Risk(s) for each Hazard

See completed FMEA summary below.

3) Risk Evaluation

Risks to be reduced include:

Zero. All risks have been reduced to acceptable levels.

4) Risk Control

a) Option Analysis

Risks have been reduced by:

a. Inherent safety by design
b. Protective Measures in the medical device itself
c. Information for safety

b) Implementation of Risk Control Measures

All risk control measures have been fully implemented per the attached FMEA summary below.

c) Residual Risk Evaluation

No residual risks exist as all risk control measures are in place and all risks have been reduced to acceptable risk levels.

d) Risk / Benefit Analysis

Not required. All risks have been reduced to acceptable risk levels.

e) Other Generated Hazards

Not required. All risks have been reduced to acceptable risk levels.

f) Completeness of Risk Evaluation

Completed per the attached FMEA summary below.

5) Overall Residual Risk Evaluation

No residual risks exist as all risk control measures are in place and all risks have been reduced to acceptable risk levels.

6) Post Production Information

(b)(4)Proprietary Information

7) Failure Mode and Effects Analysis (FMEA) Document Summary

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(b)(4)Proprietary Information

Severity Evaluation Criteria:

(b)(4)Proprietary Information

8) Usability Verification Plan and Report

a. Inputs to the USABILITY SPECIFICATION

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Medical Purpose

The TLC-2000 multiple laser probes are used in direct contact with tissue in order to inject photons of light (b)(4)Proprietary non-invasively and drug-free into tissue.

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Part of body or type of tissue applied to or interacted with

The TLC-2000 multiple laser probes are used in direct contact with tissue depending on what the injury is. Consult protocol manuals for correct placing of the probes on patient.

Intended Operator

Trained medical practitioner or staff under medical practitioner's guidance and who has taken training on how to use the medical device.

Application

Environment:

- Hospital
- Medical Clinic

Conditions of Visibility:

- Ambient Luminance – 100 to 500 lux
- Viewing Distance – 20 cm to 1 metre
- Viewing Angle – orthogonal ± 20°

Physical:

- Voltage - 100 to 250 vac
- Temperature – 0 to 25°C
- 0 to 100 % RH non-condensing

(b)(4)Proprietary Information

b. Primary Operating Function

(b)(4)Proprietary Information

[redacted]

- Audible indication on Probe to notify user that the laser is on
- Visible indicator lights to show the power pack is plugged in to the external power supply properly

Resulting Hazardous Situations and Harms

(b)(4)Proprietary Information

Preliminary review of the User Interface concept

1. Interchanging Probes:
   - Probe cable input into probe and power pack clearly identified
   - Cable connector locks into place and is clearly identified showing location of mating connector
   - Clear instructions in operator / user manual and quick reference guide

   Conclusion: No Issues

2. Reading Display:
   - Fonts and colours clearly legible from 20 cm to 1 meter
   - Operating instructions for each option clearly identified in Operator / User manual and Protocol manual

   Conclusion: No Issues

3. Setting Up / Preparing for Use:
   - Easy to assemble / disassemble
   - Set-up included in Quick Reference Guide
   - Detailed operating instructions in operator / user manual and on training DVD

   Conclusion: No Issues

4. (b)(4)Proprietary Information

5. Cleaning:
   - Easy to clean surfaces with Isopropyl Alcohol wipes and swabs
   - Surface finishes are smooth eliminating areas that trap dirt

   Conclusion: No Issues

6. (b)(4)Proprietary Information

d. Use Scenarios

The following use scenario has been performed.

Usability Specification :	Internal and / or Customer Specification Reference
Test Description :	From Specification clause description of test being undertaken
Acceptance Criteria :	Pass / Fail targets and Pass / Fail criteria
Test Result :	Pass or fail is recorded according to the acceptance criteria.

(b)(4)Proprietary Information

(b)(4)Proprietary Information

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TLC-1000
PAIN MANAGEMENT PROTOCOL MANUAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS.GOV@fda.hhs.gov or 301-796-8188

Table of Contents

Clinical Information

Practical Advice for the Use of Low Level Laser Therapy

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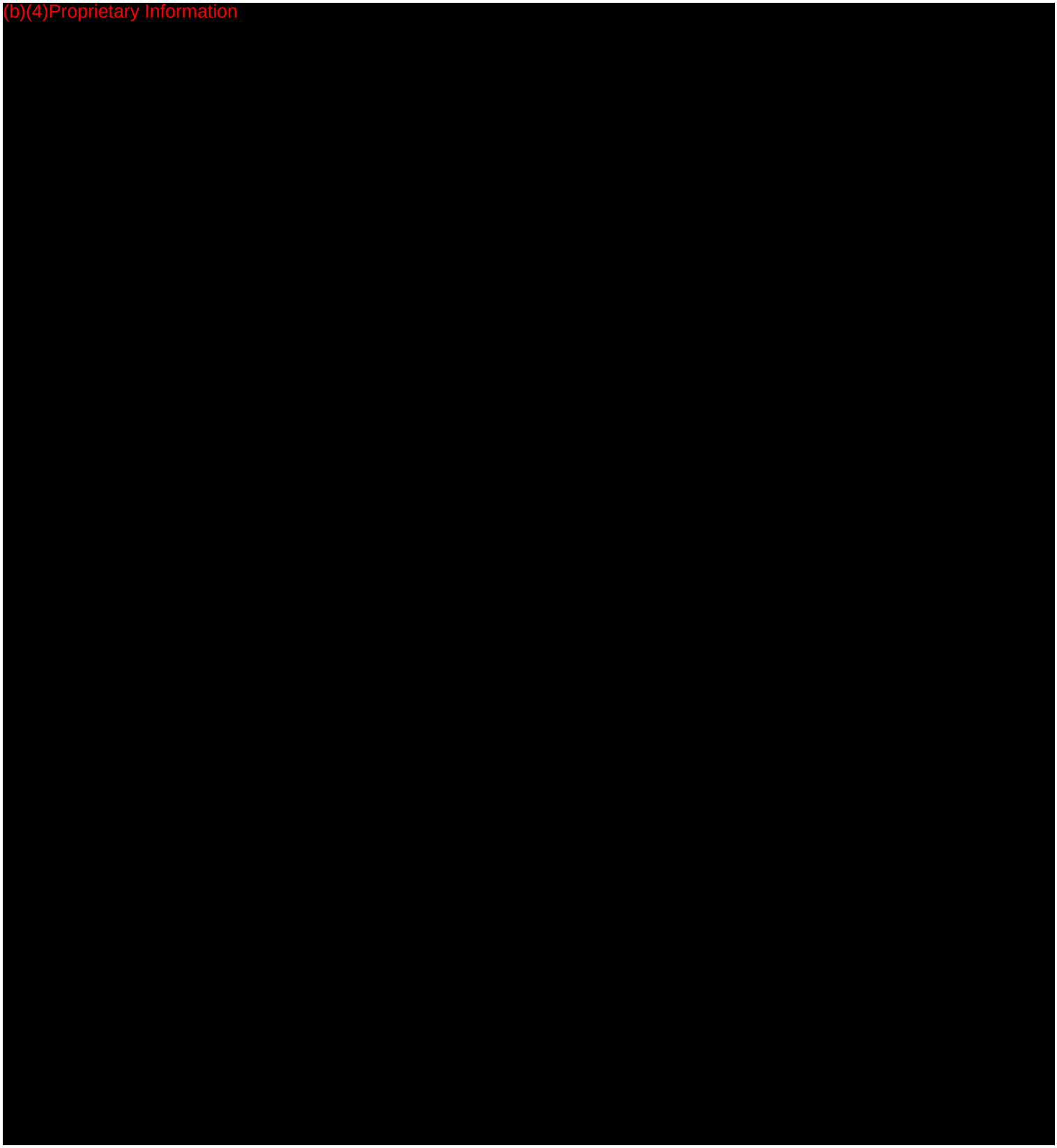

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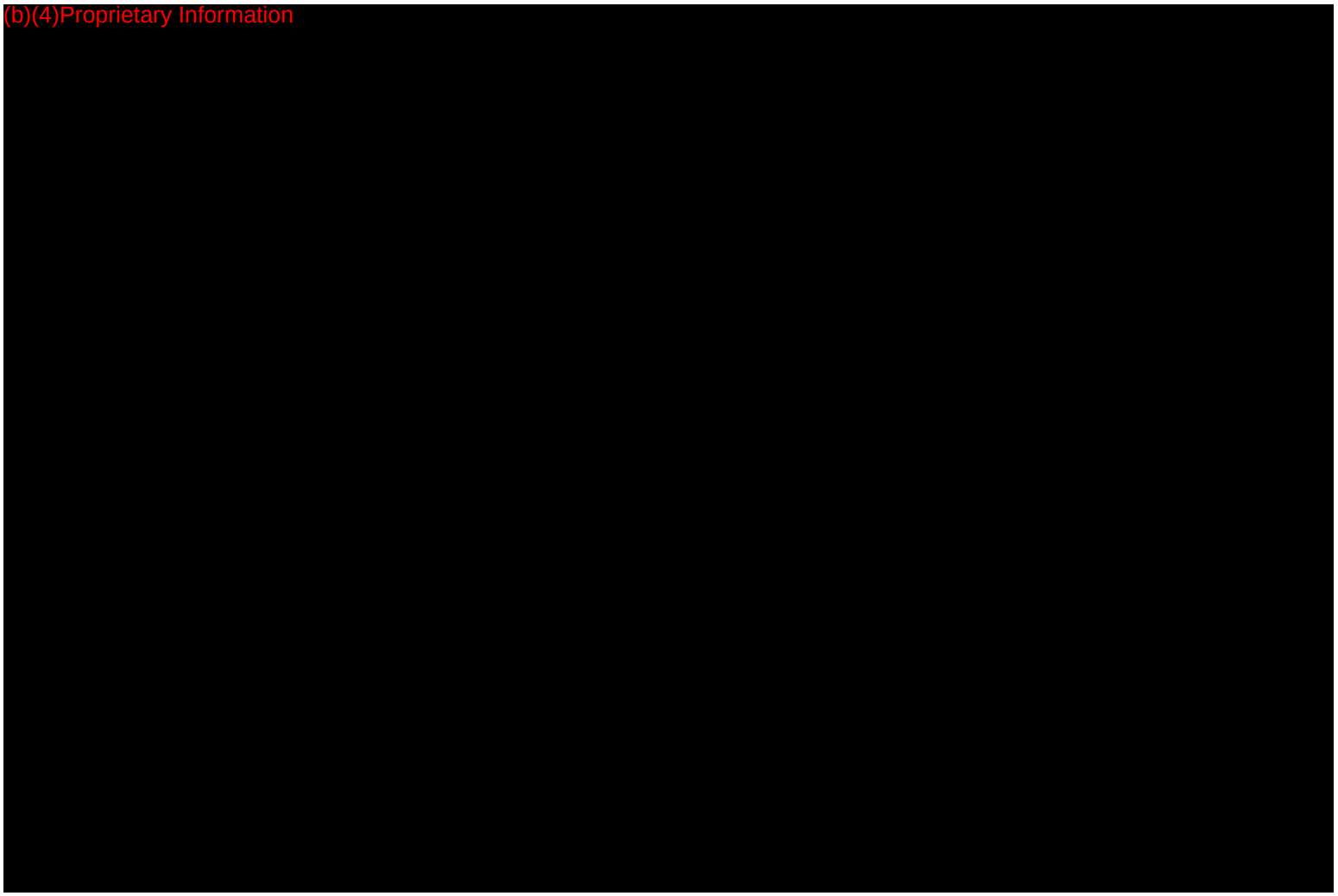
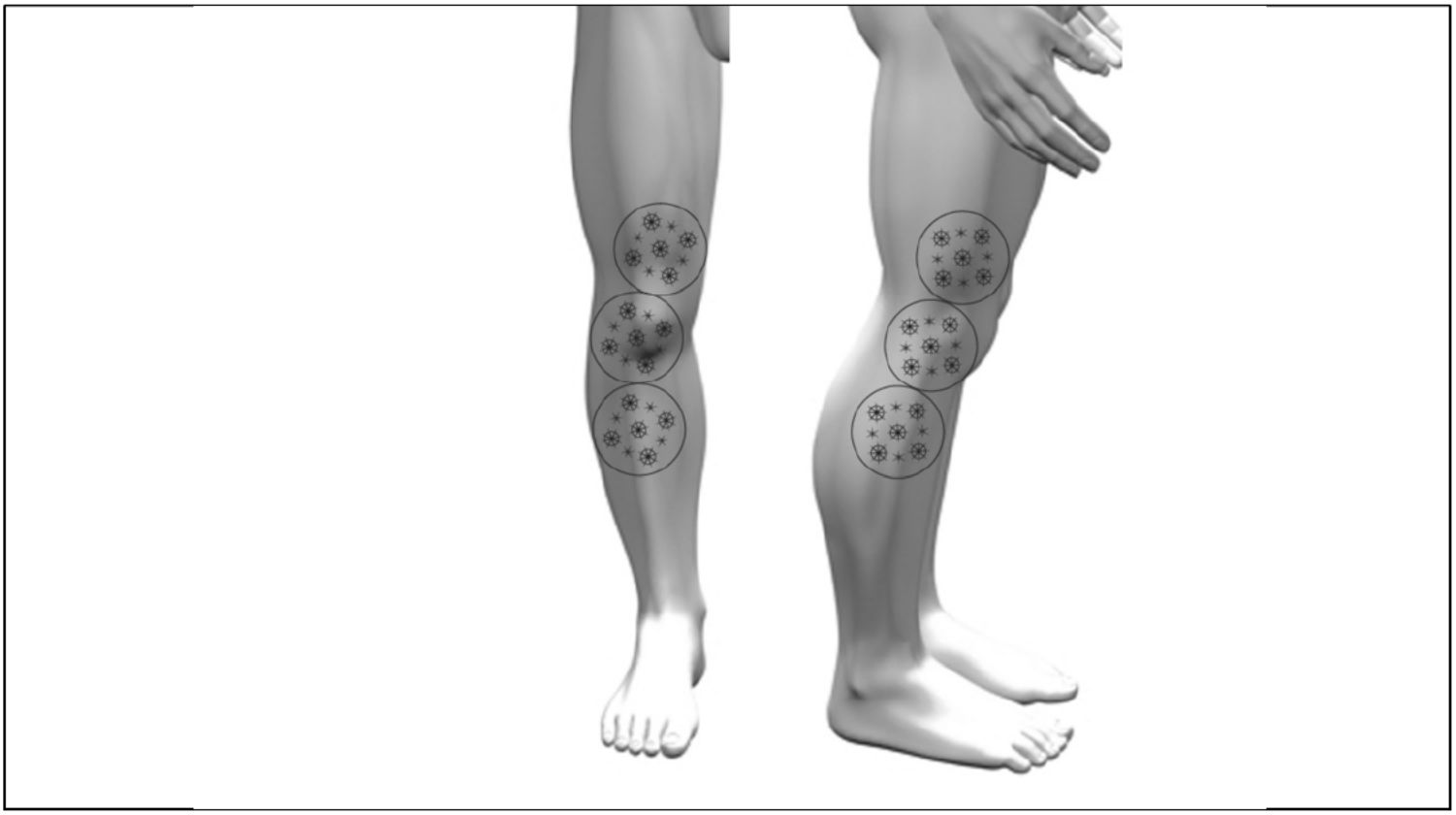


Treatment Specification: KNEE PAIN

Knee Pain



Treatment Protocol:

TLC-2000 Treatment Record	KNEE PAIN
Number of Treatment Points	6

(b)(4)Proprietary Information

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Treatment Details:

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TLC-1000
OPERATIONS MANUAL

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TLC-1000 Laser Controller Labels and Symbols

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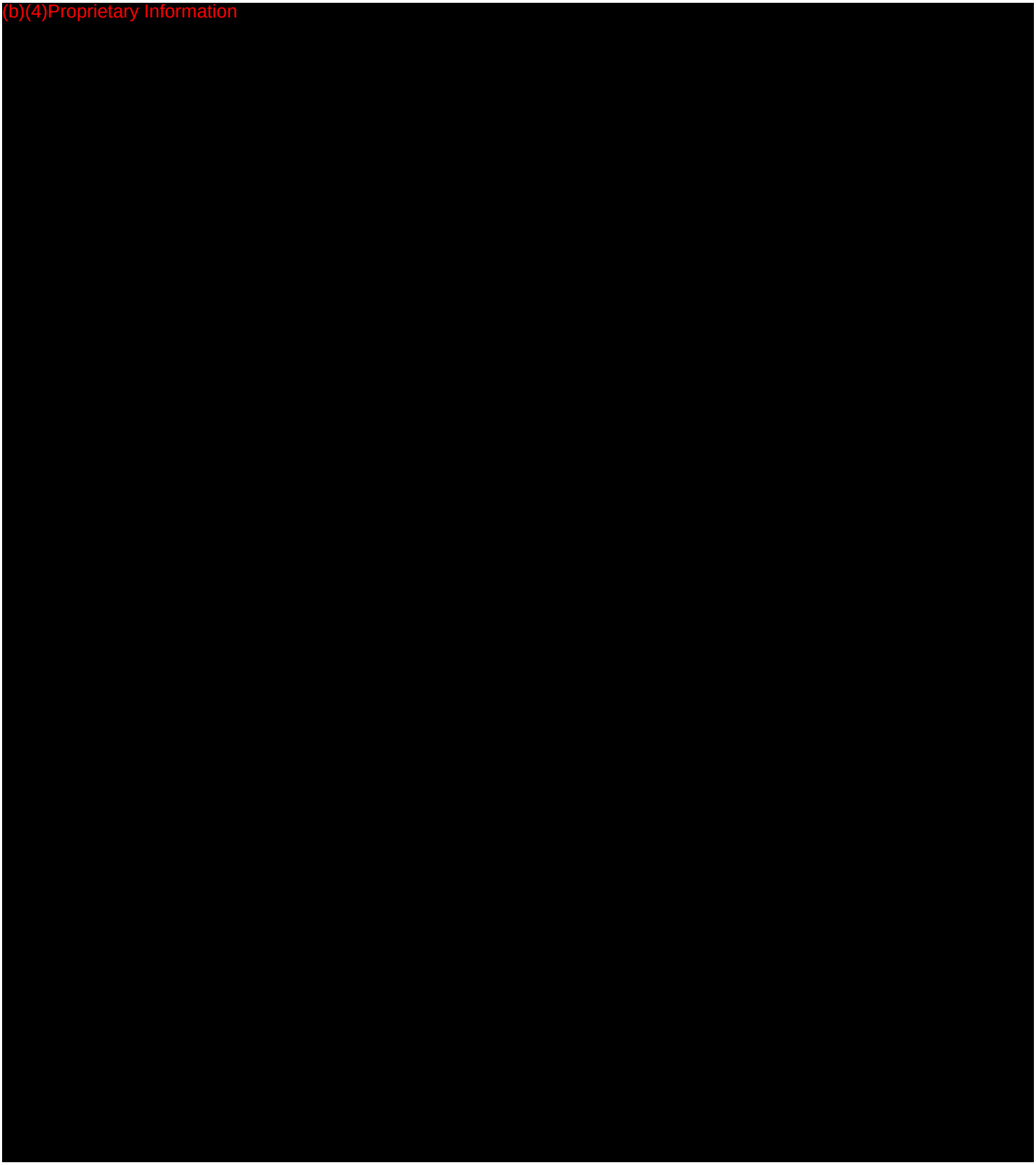

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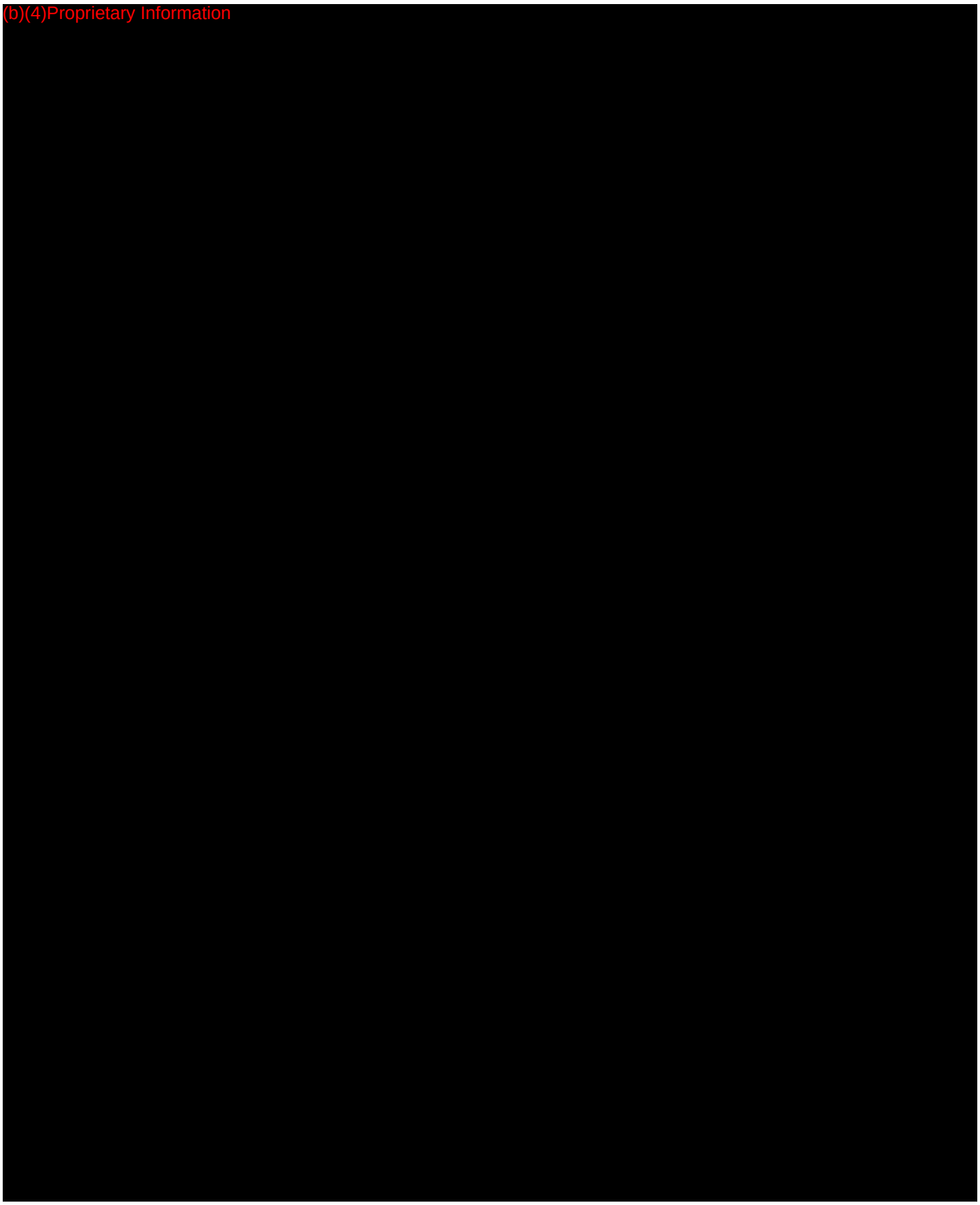

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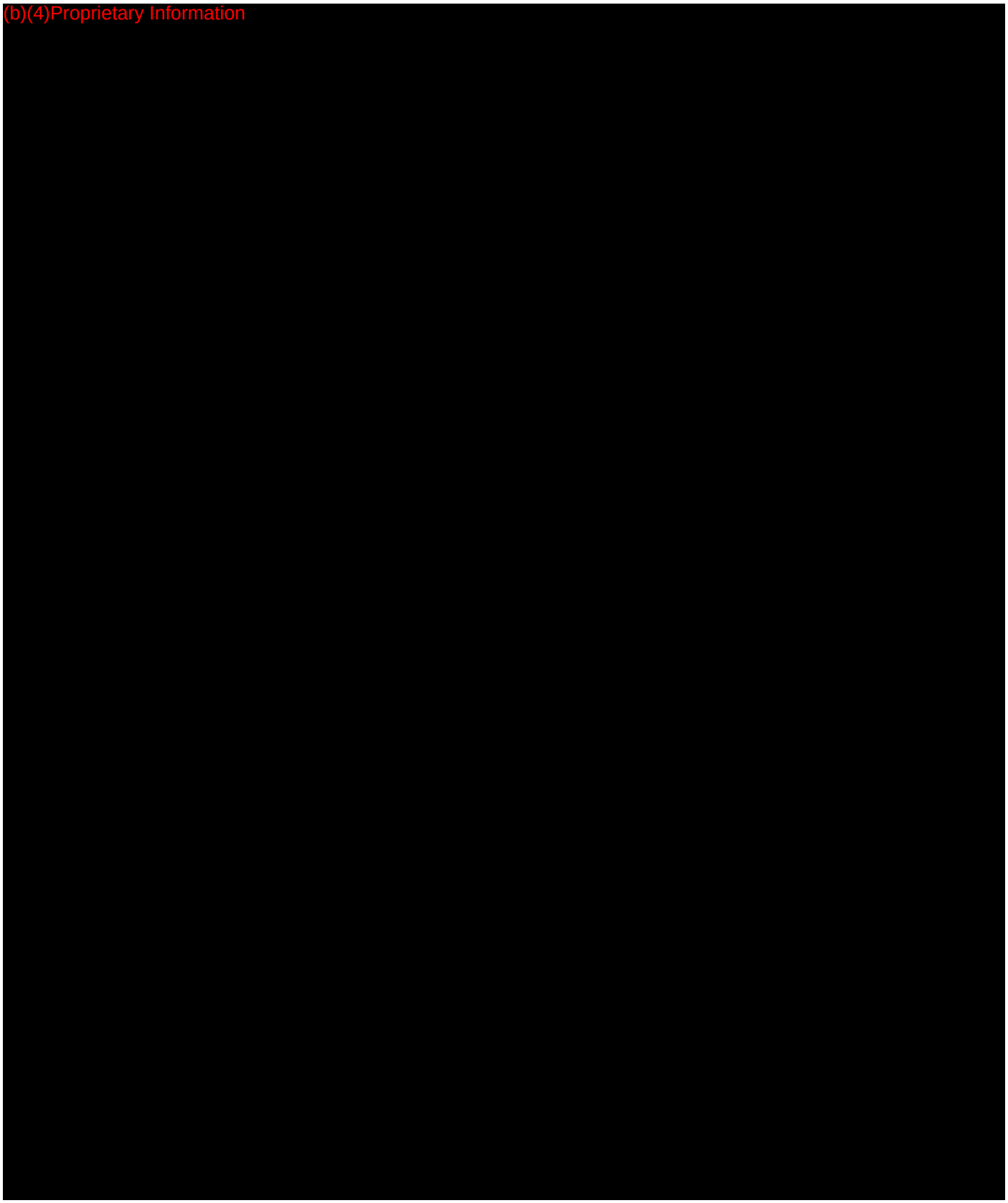

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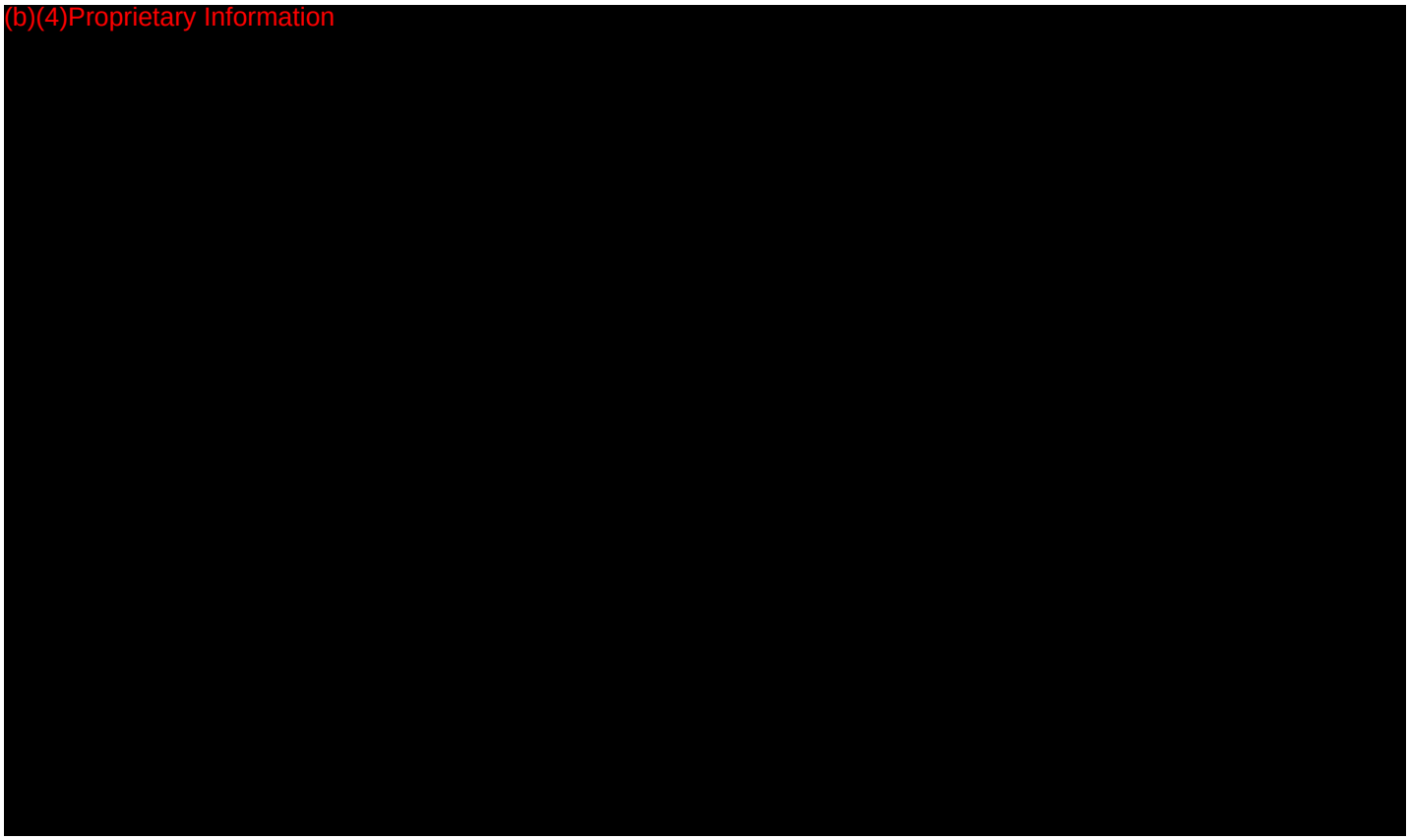

2. THERALASE TLC-1000 SERIES PRODUCT INFORMATION

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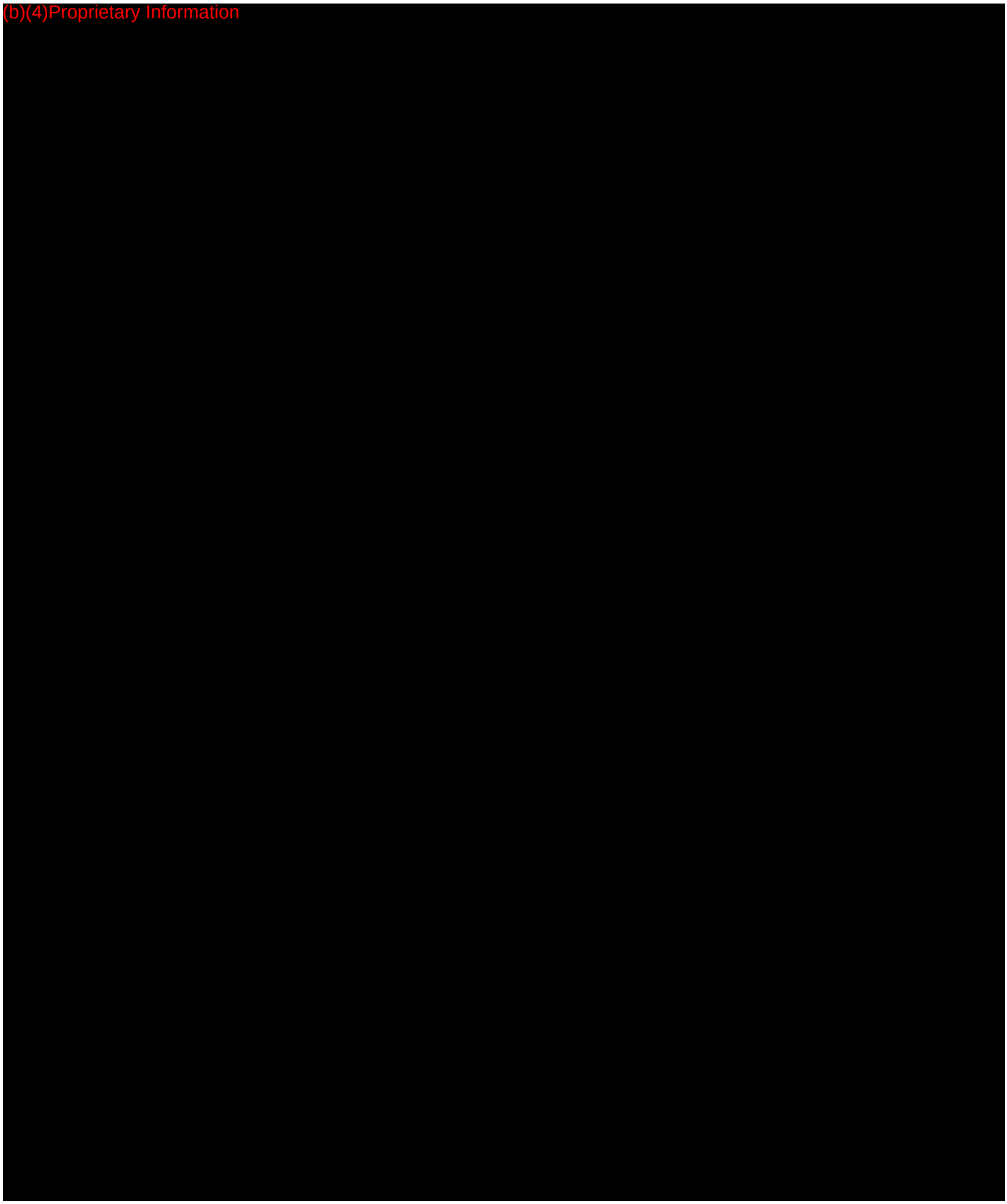

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The Multiple Laser Probe (TLC-900)

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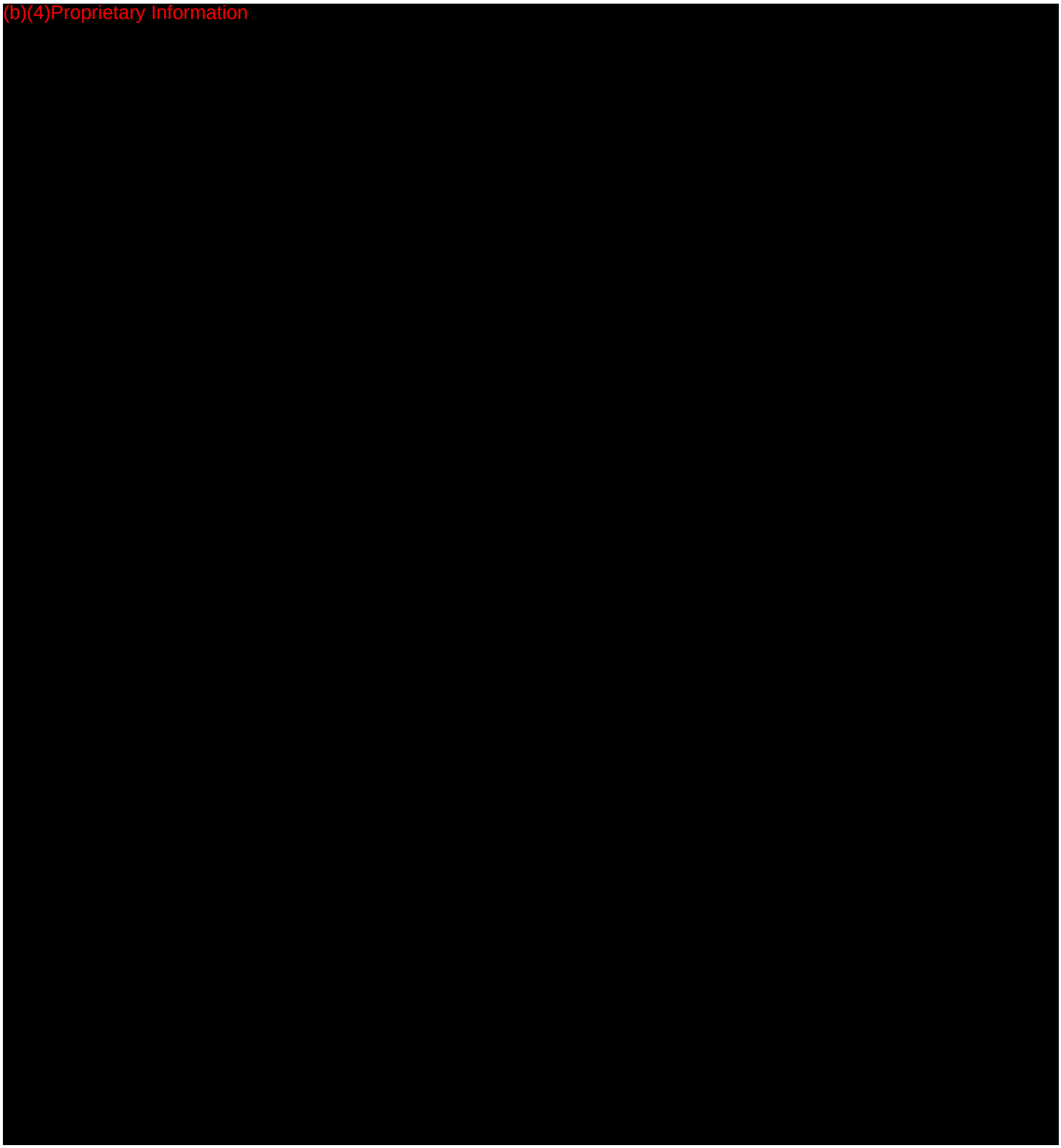

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Hard case for TLC-1000 system (part number: TLC-1200)

3. Start-Up Information

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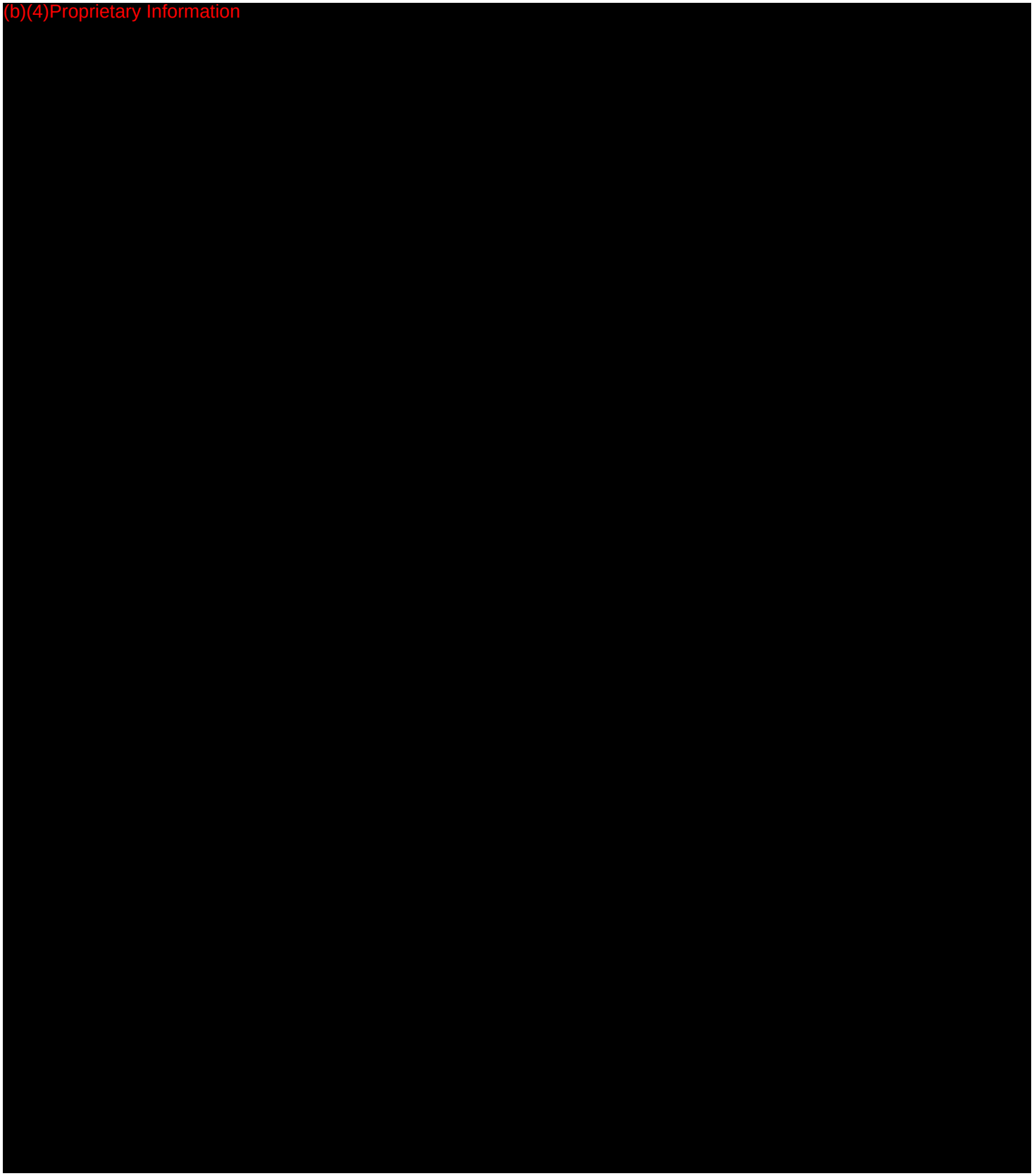

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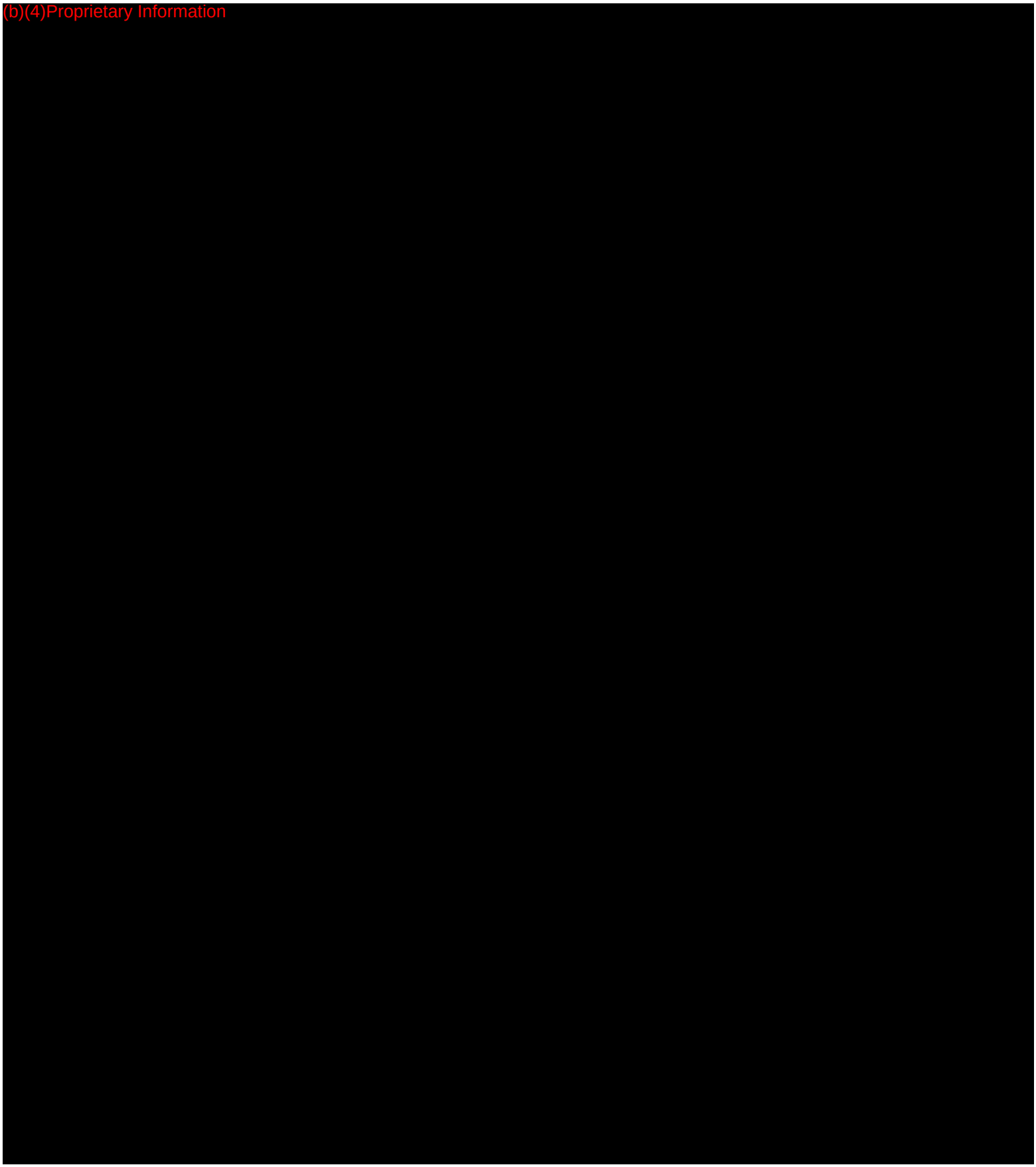

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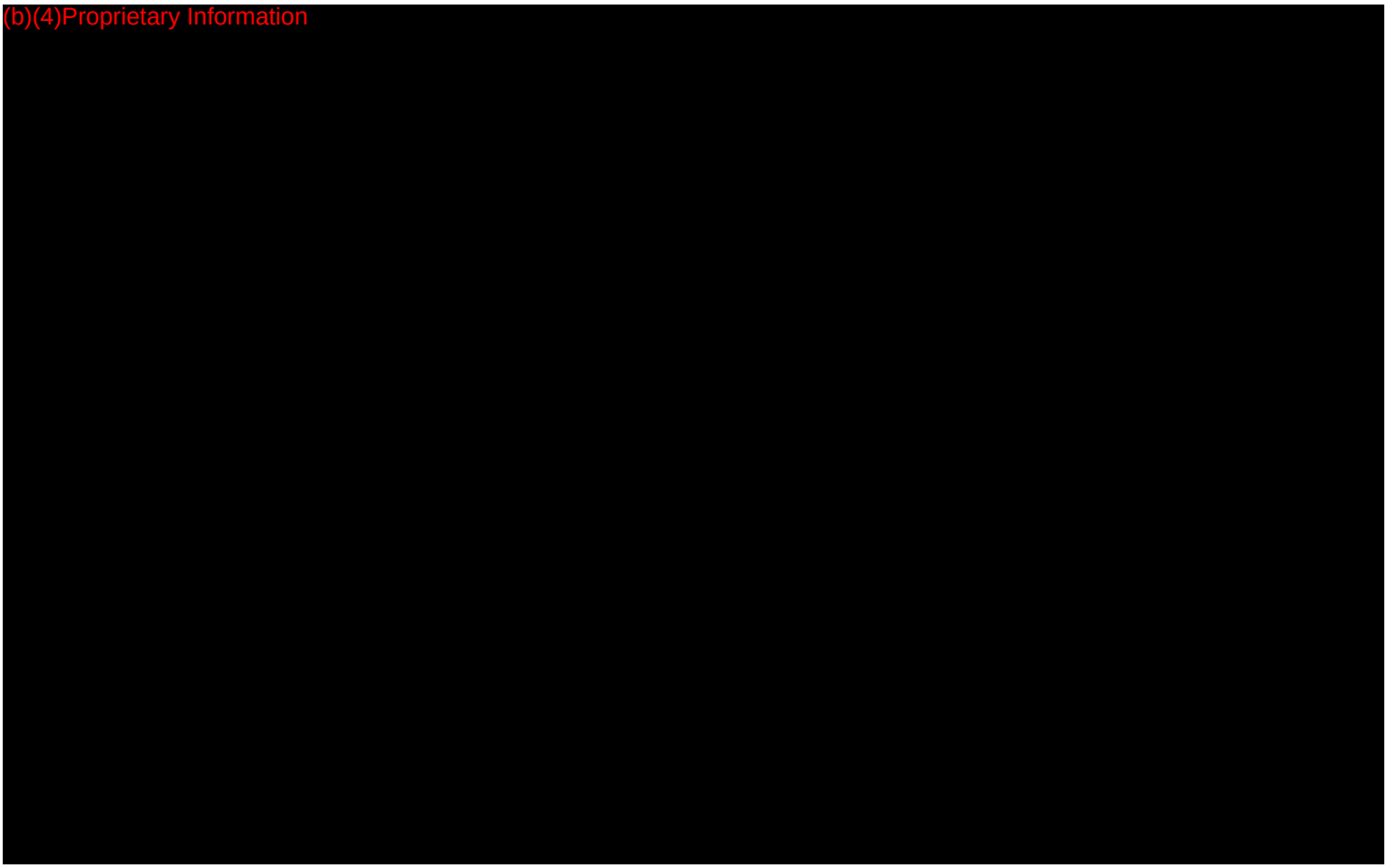

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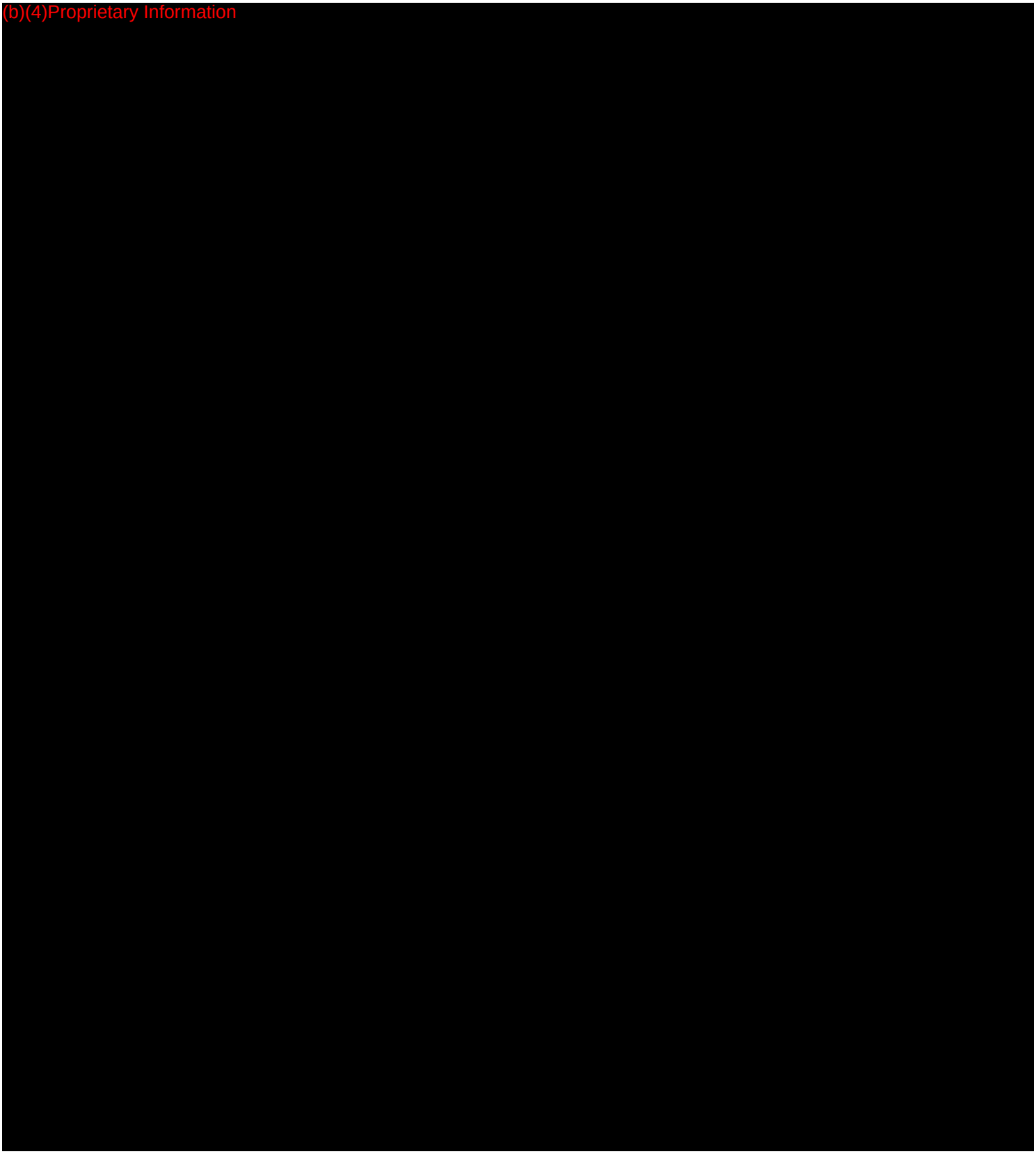

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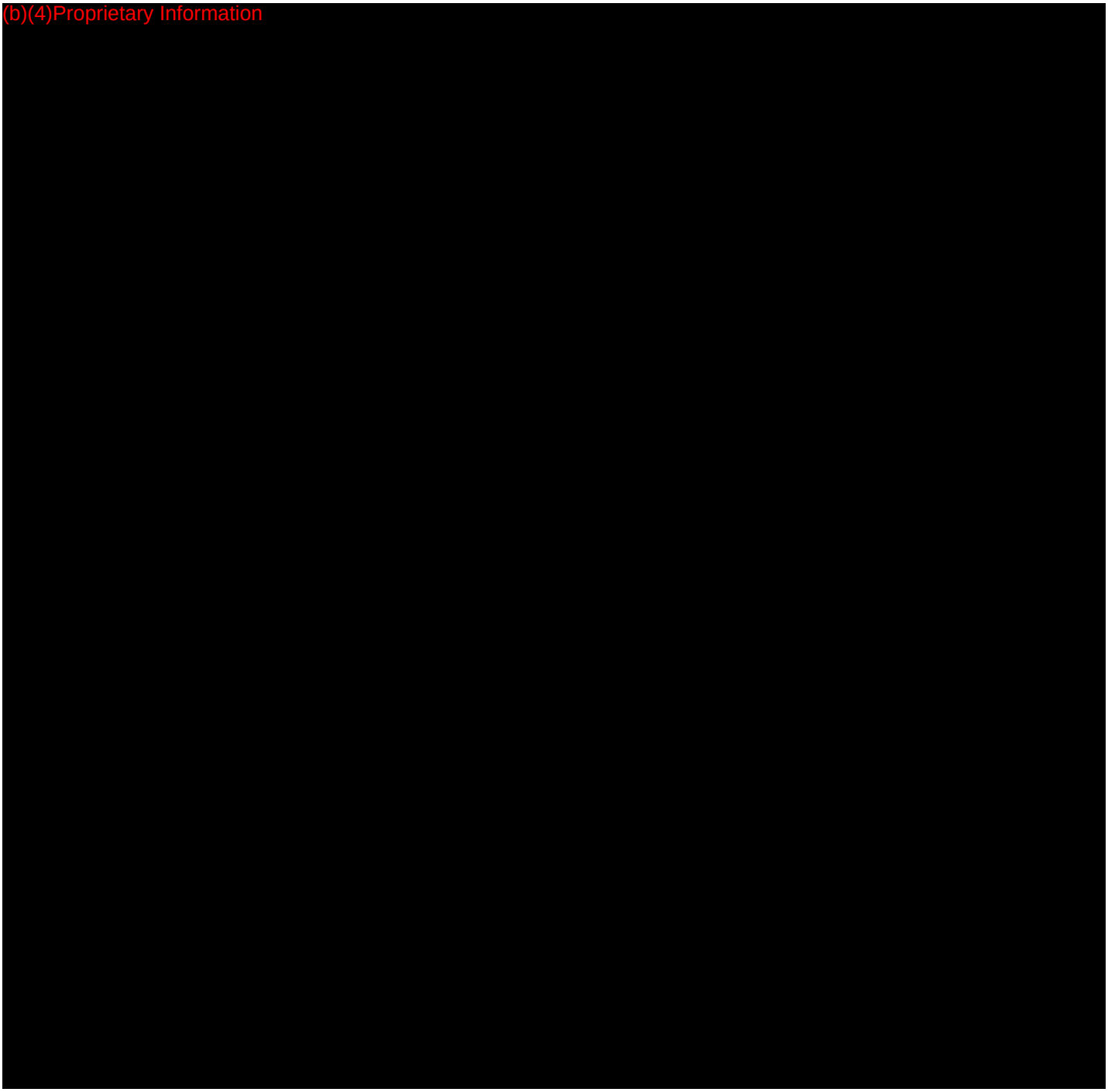

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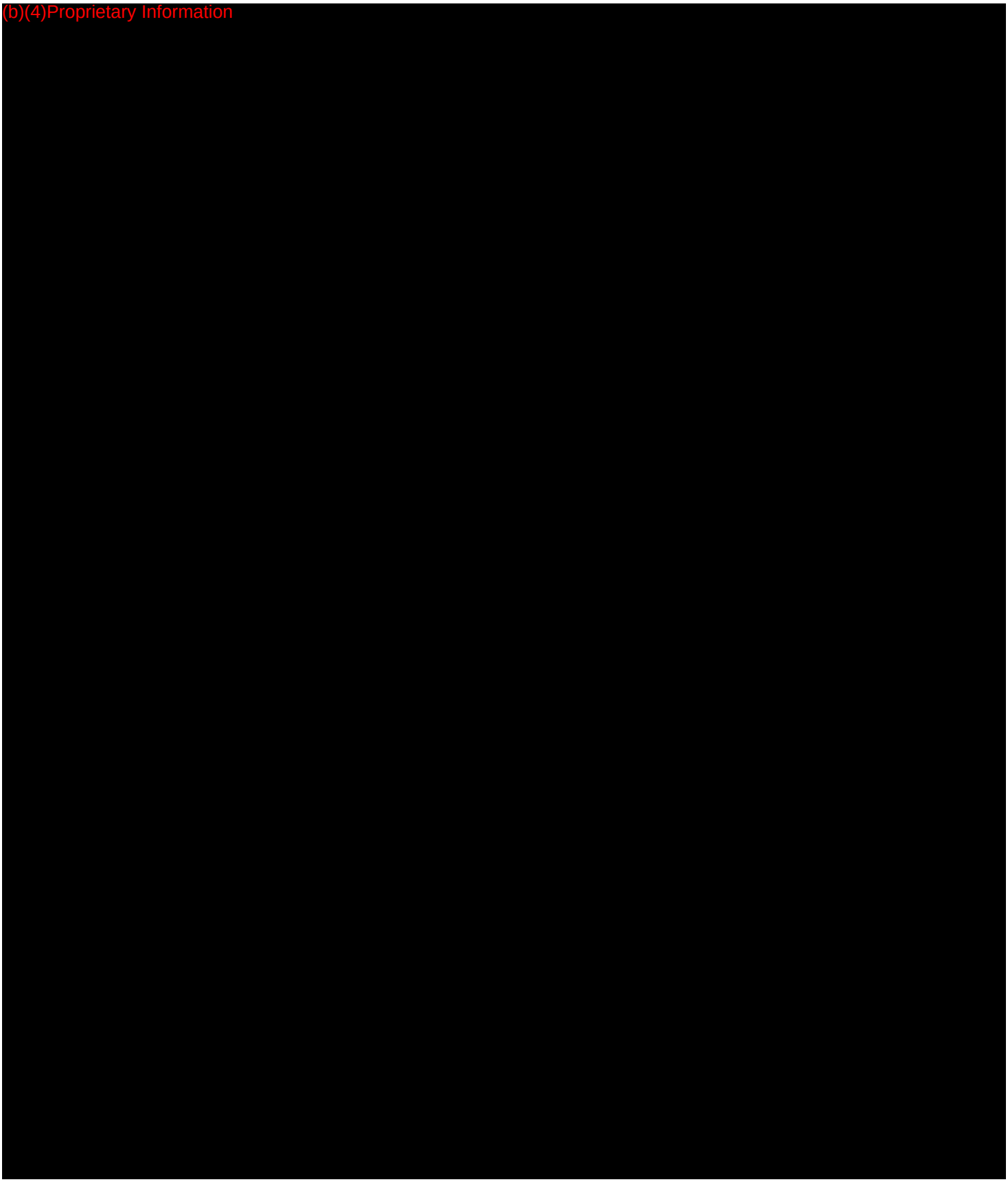

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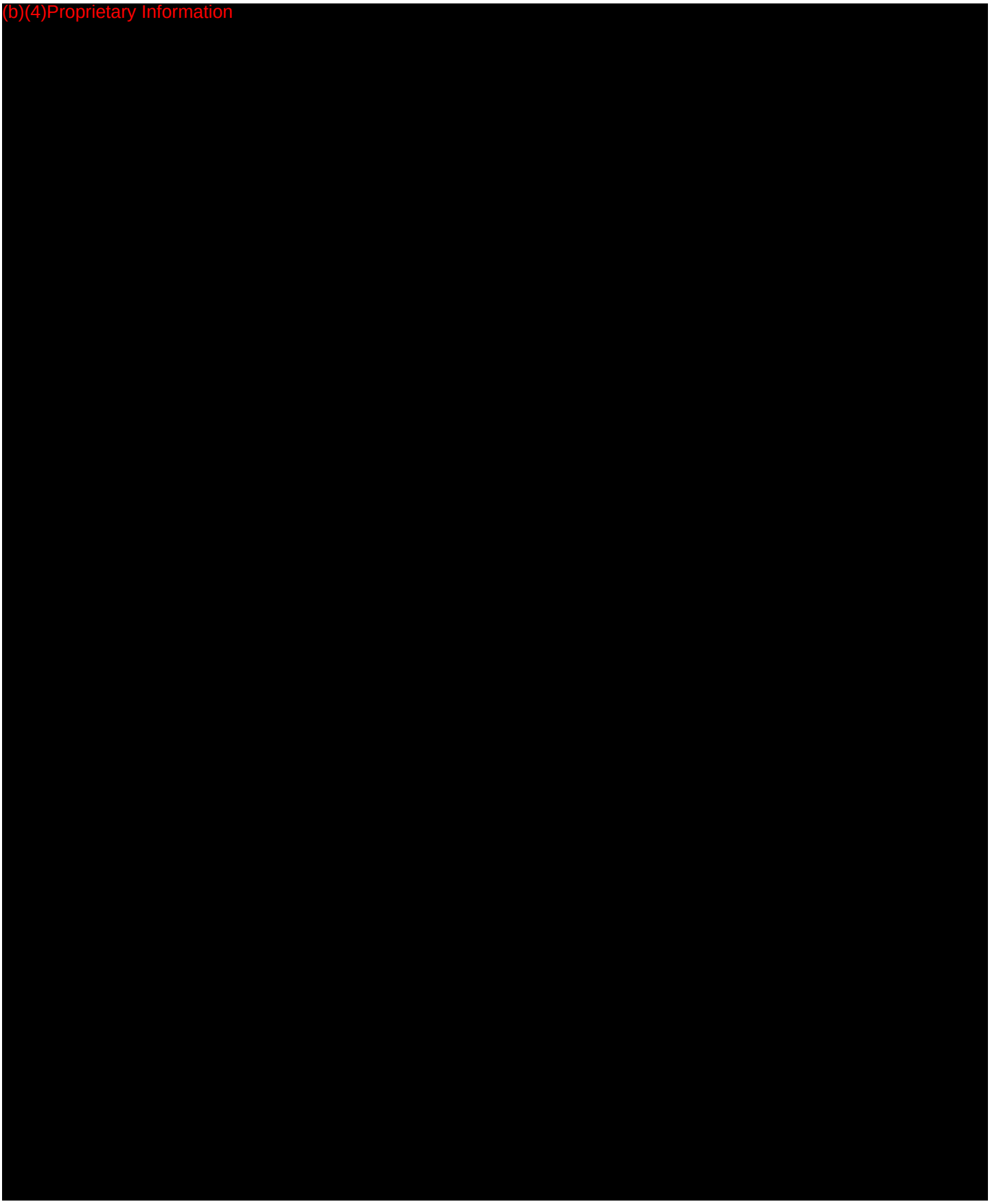

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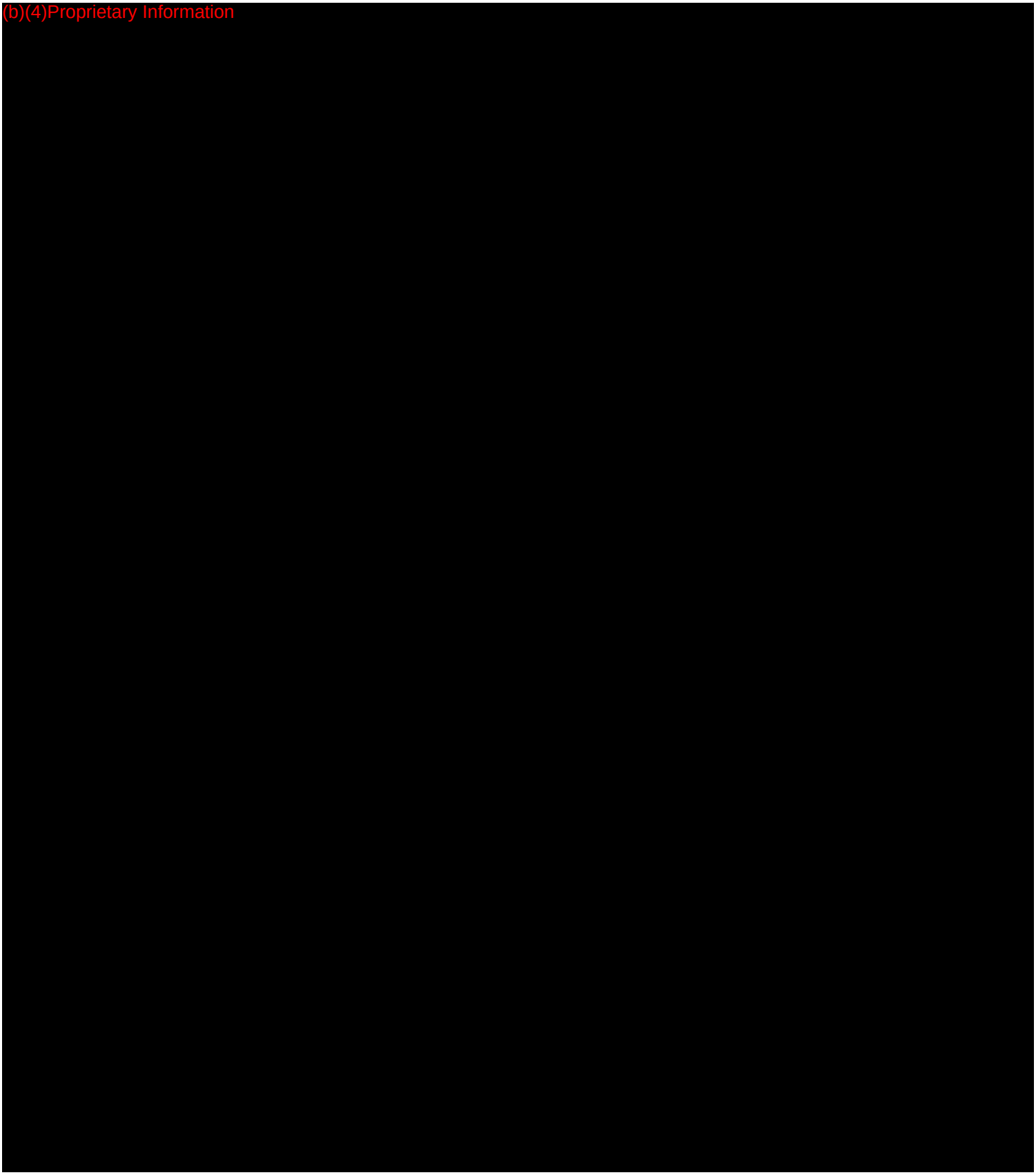

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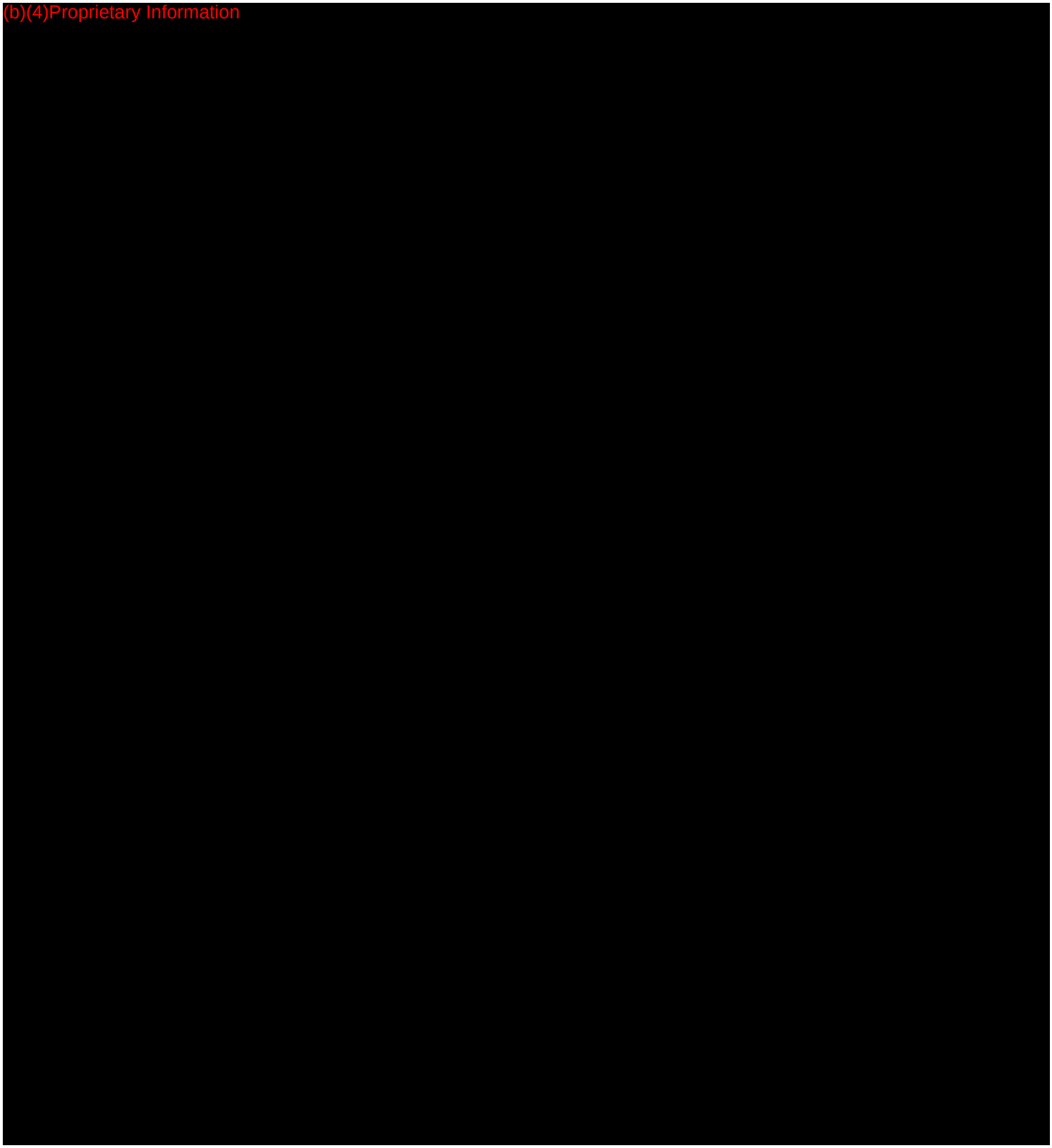

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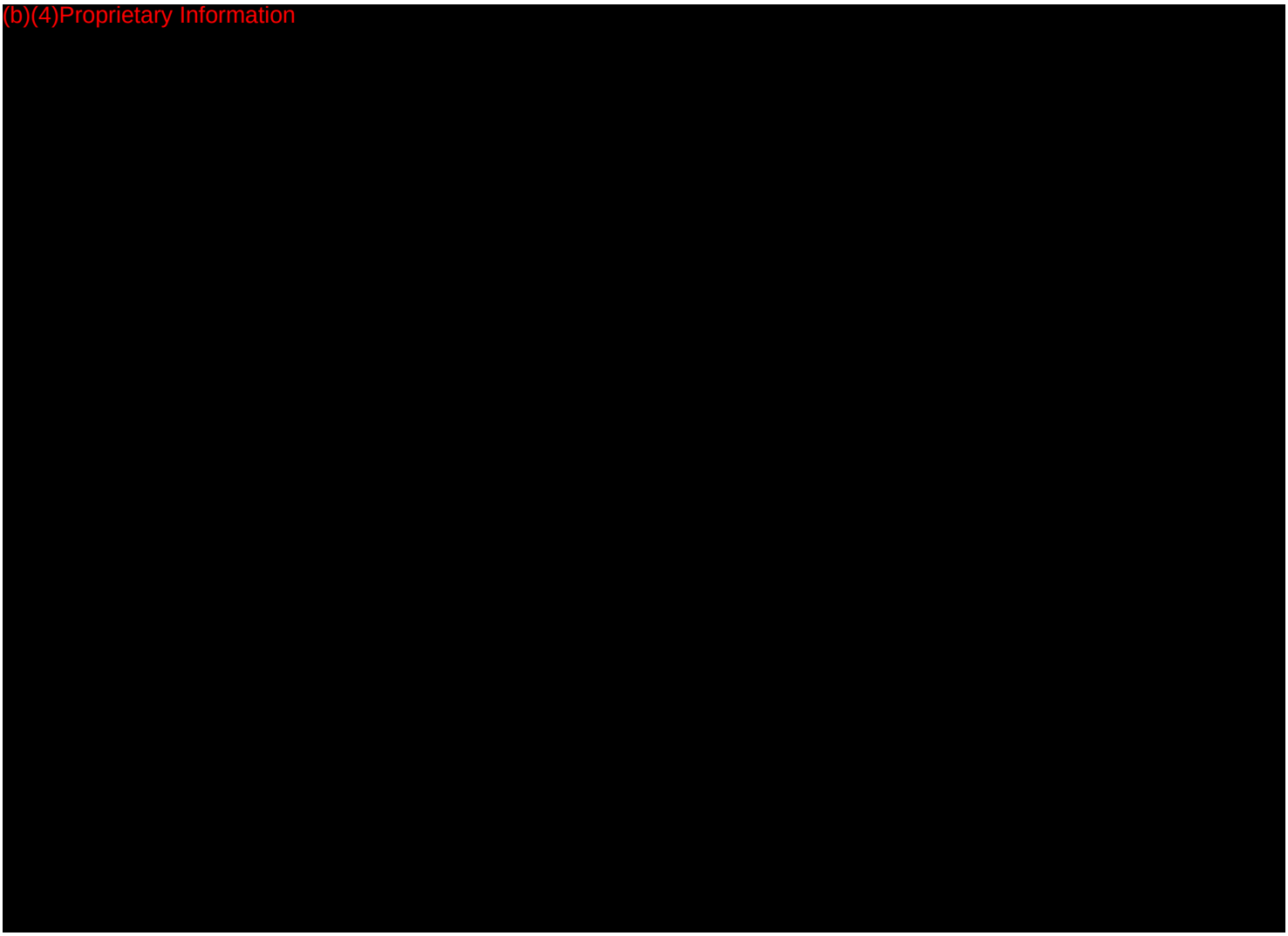

6. Laser Exposure Level Calculations

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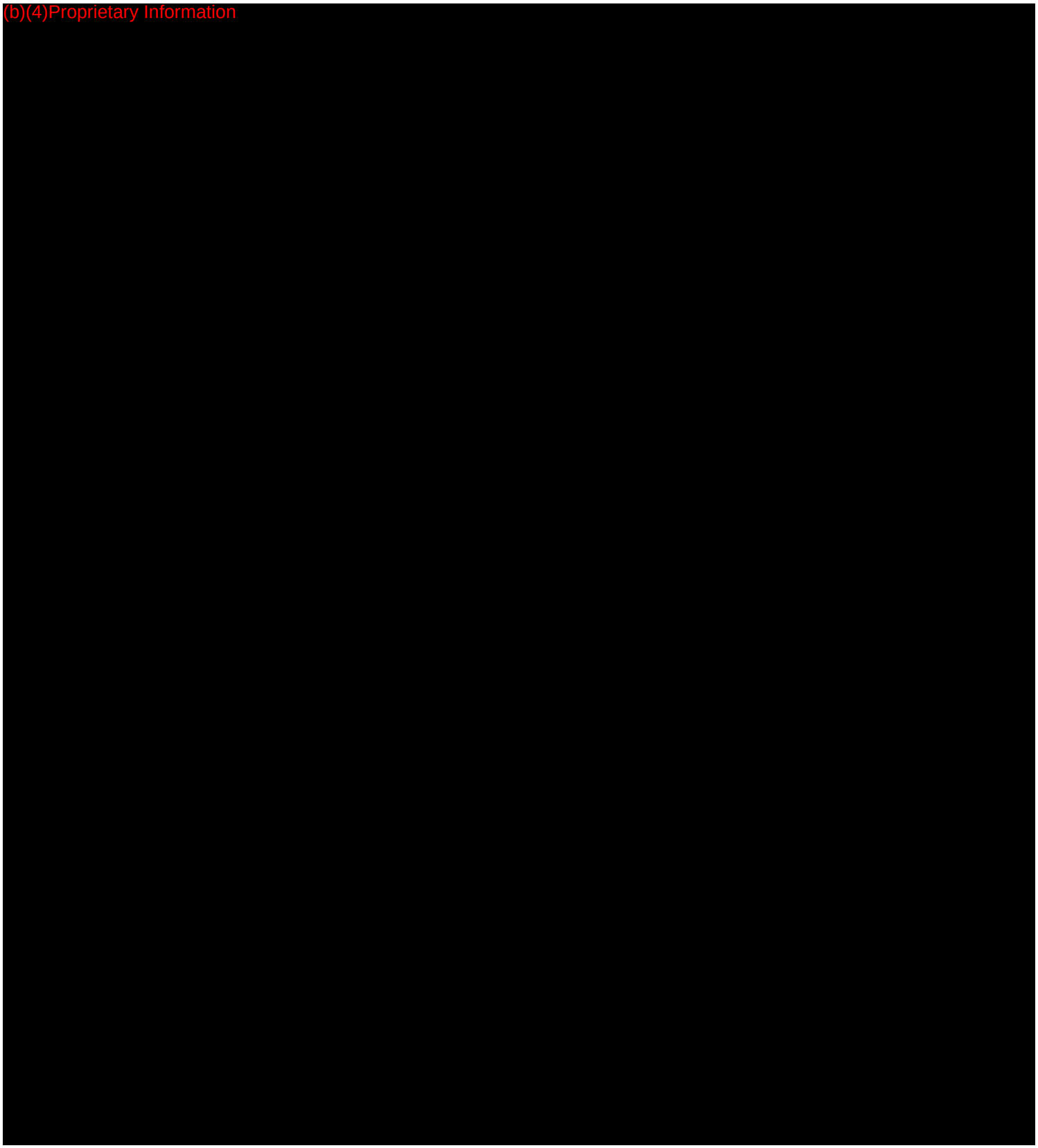

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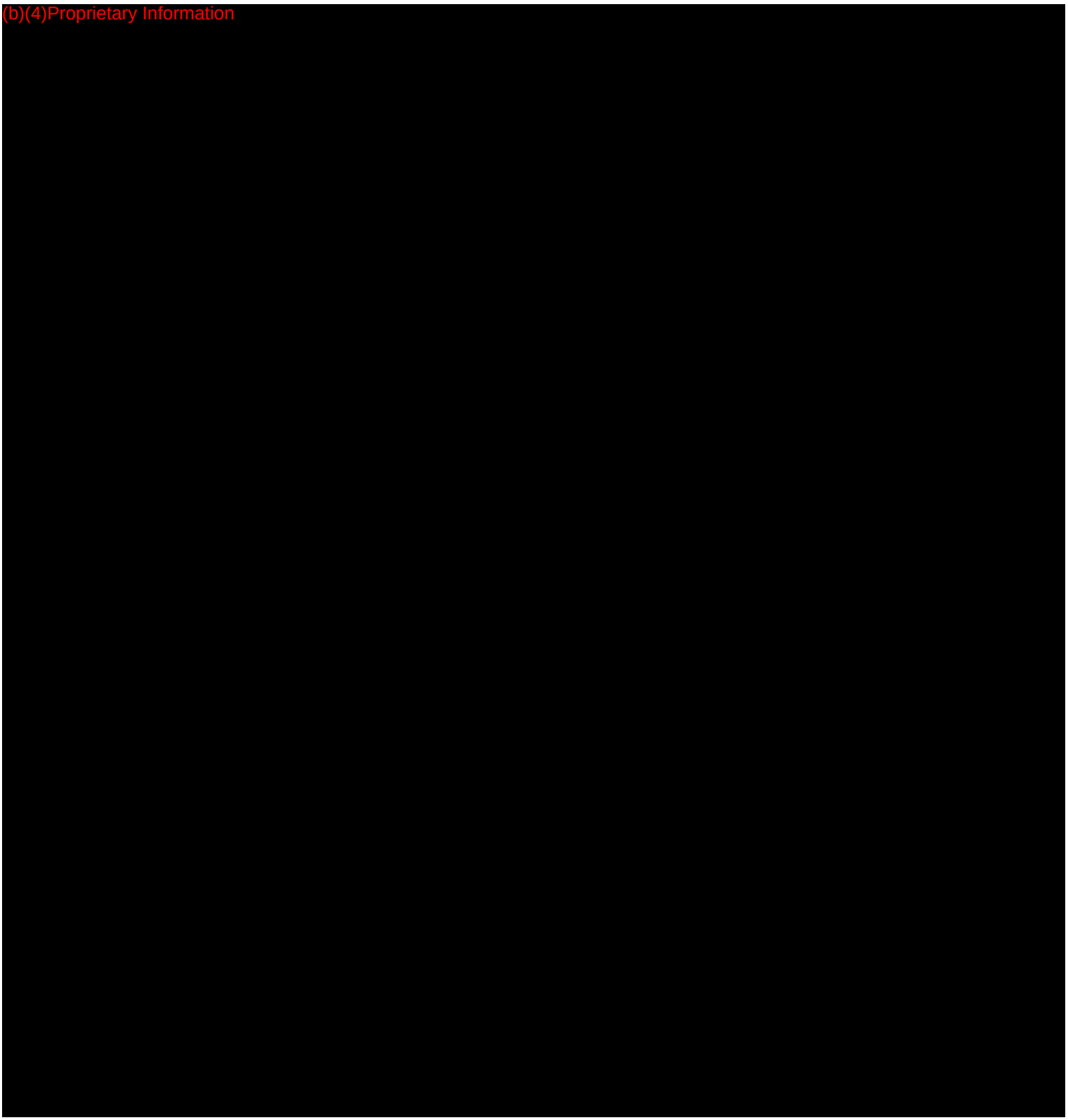

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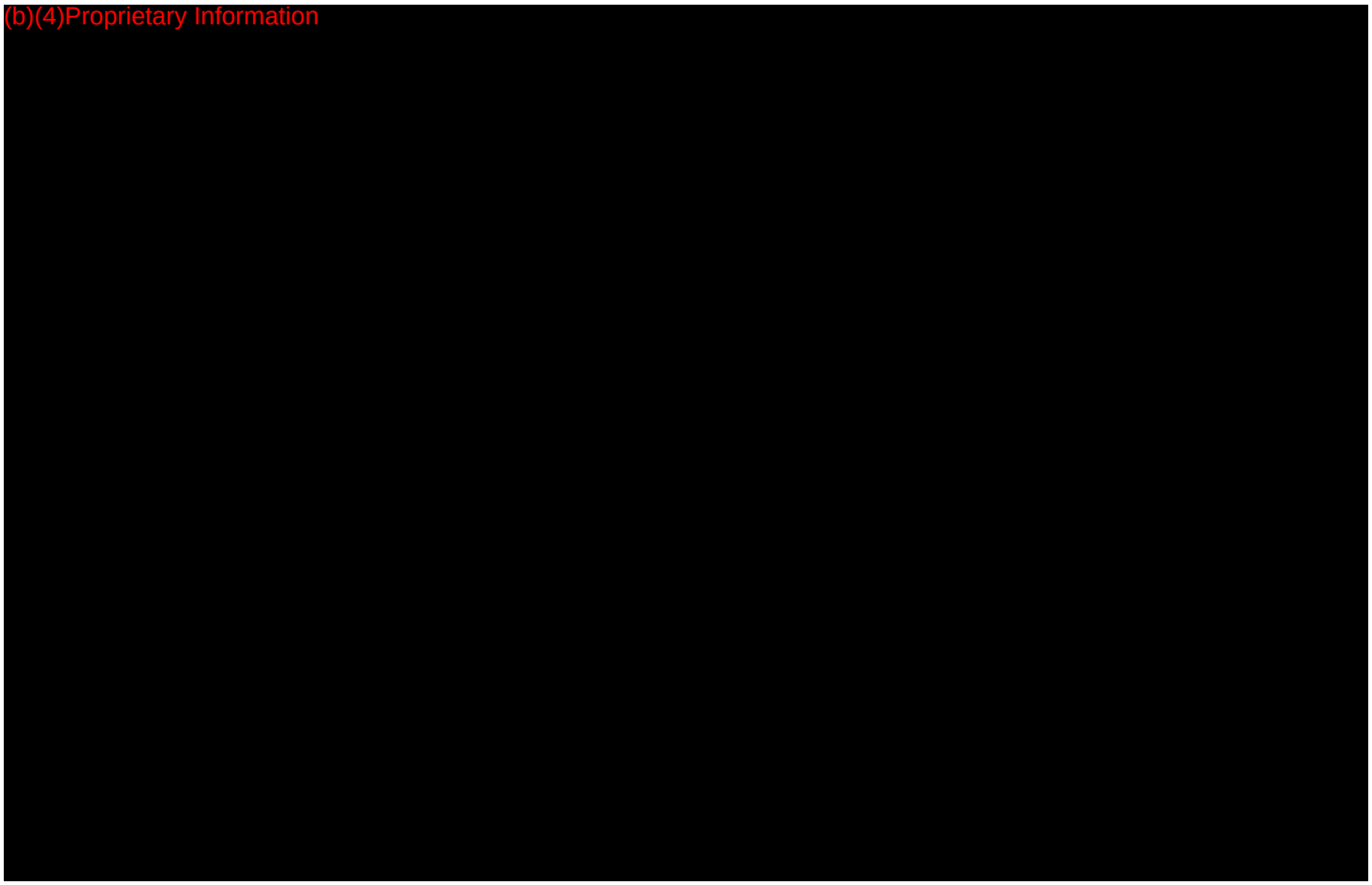

7.Electro Magnetic Compatibility Information

In accordance with clause # 5.2.x of EN 60601-1-2.

Interconnecting Cables

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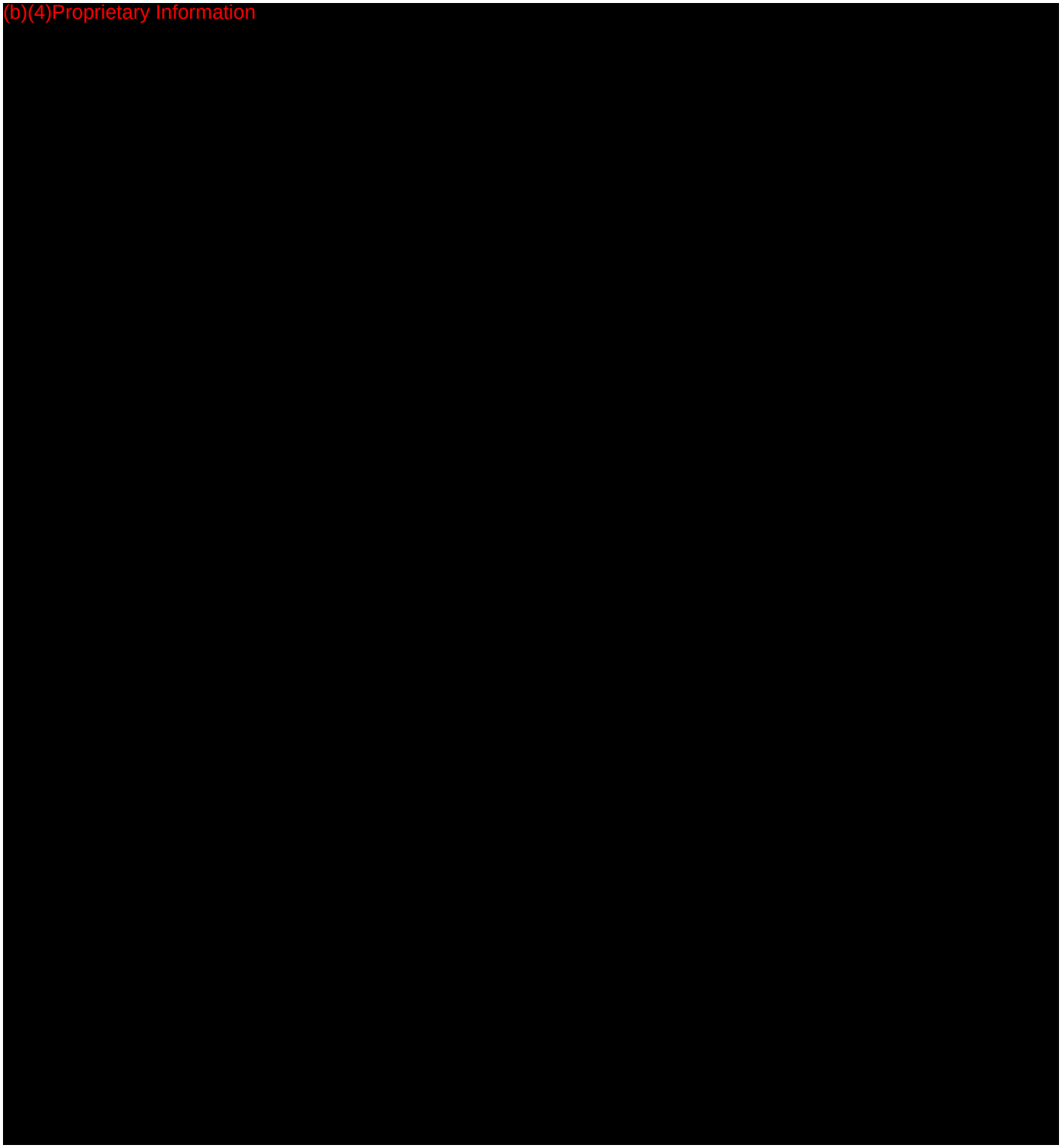

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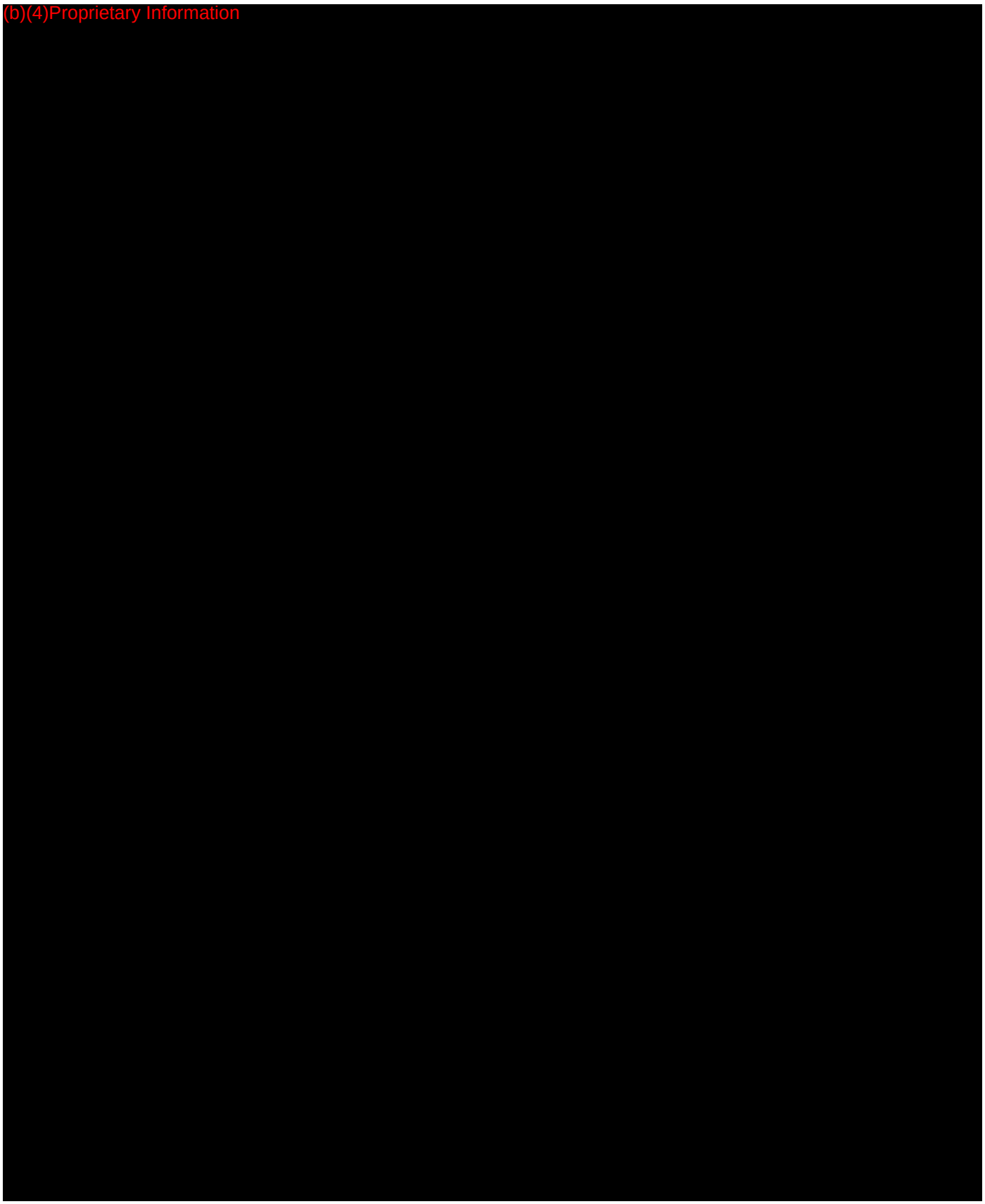

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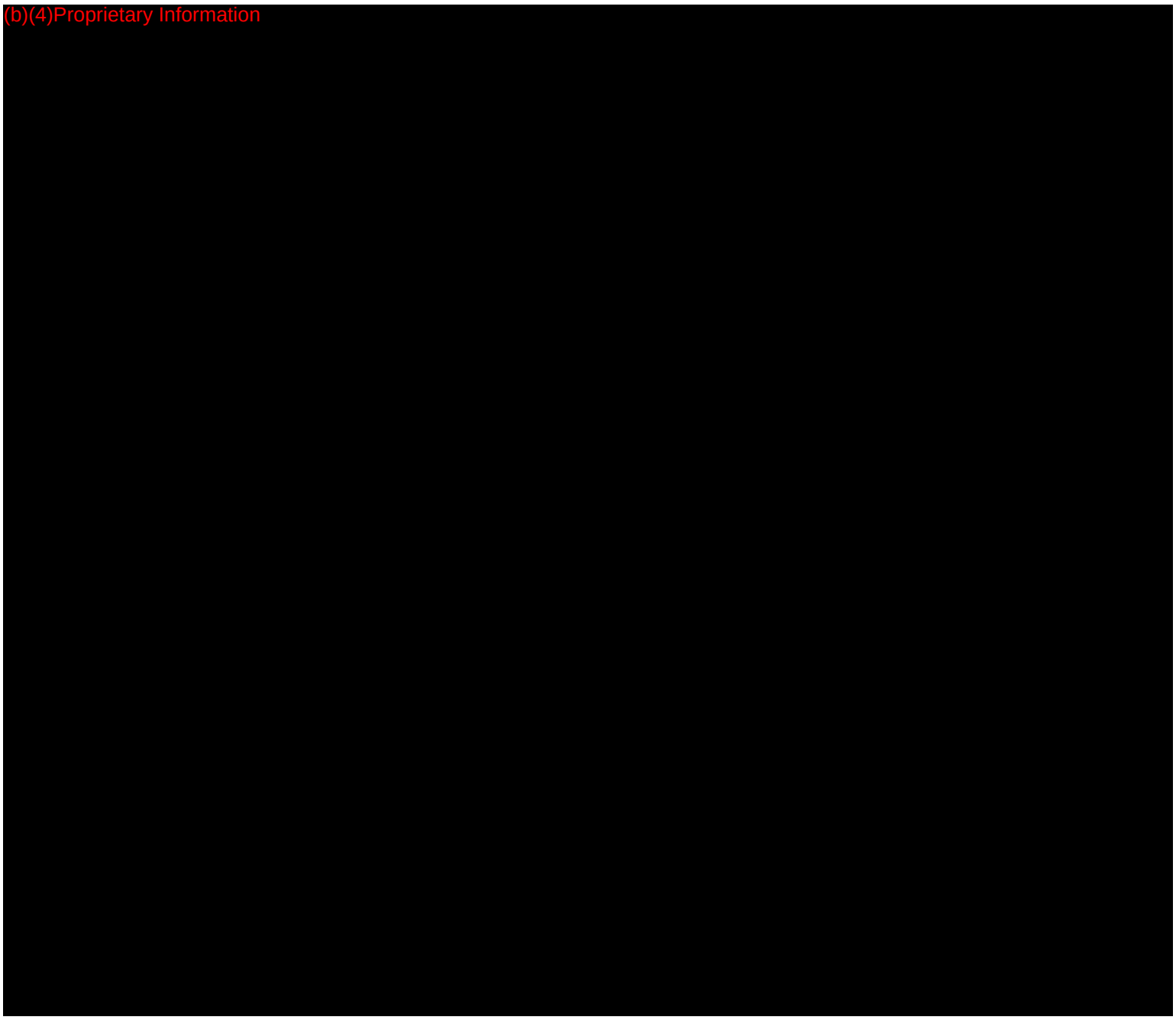

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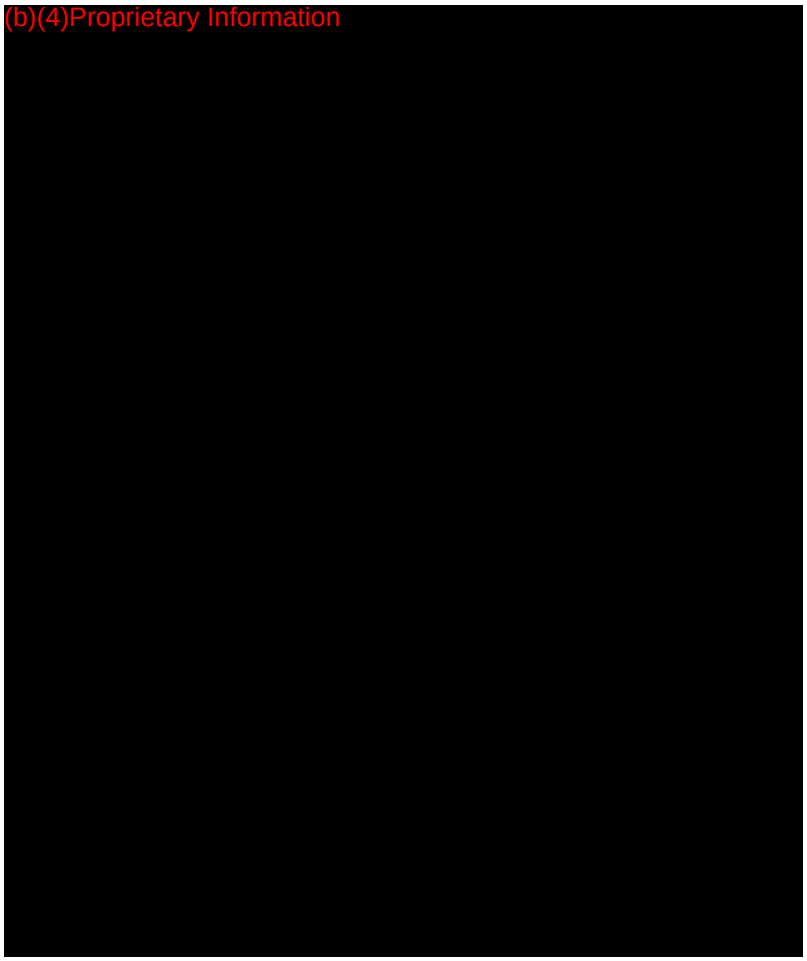

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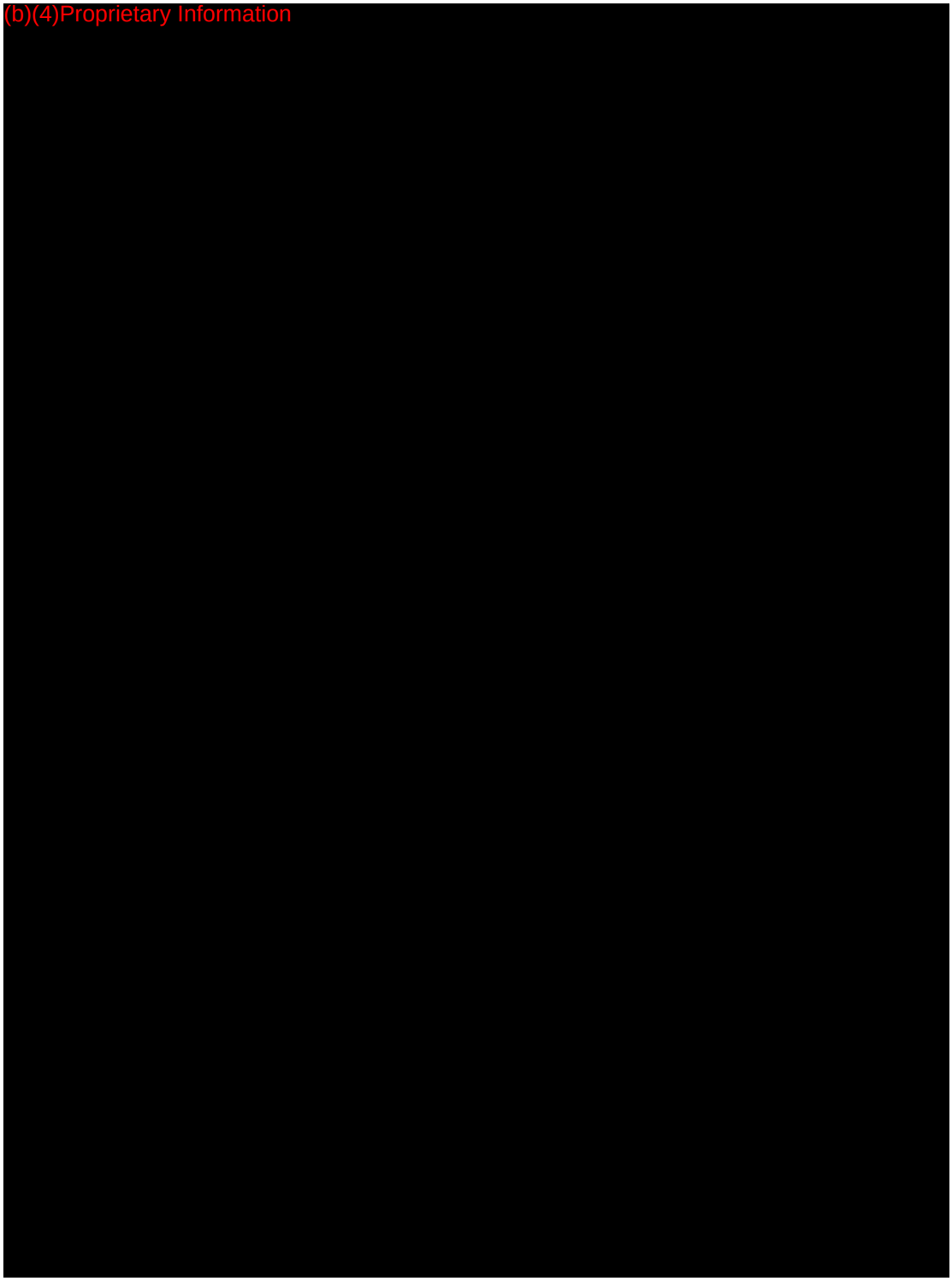
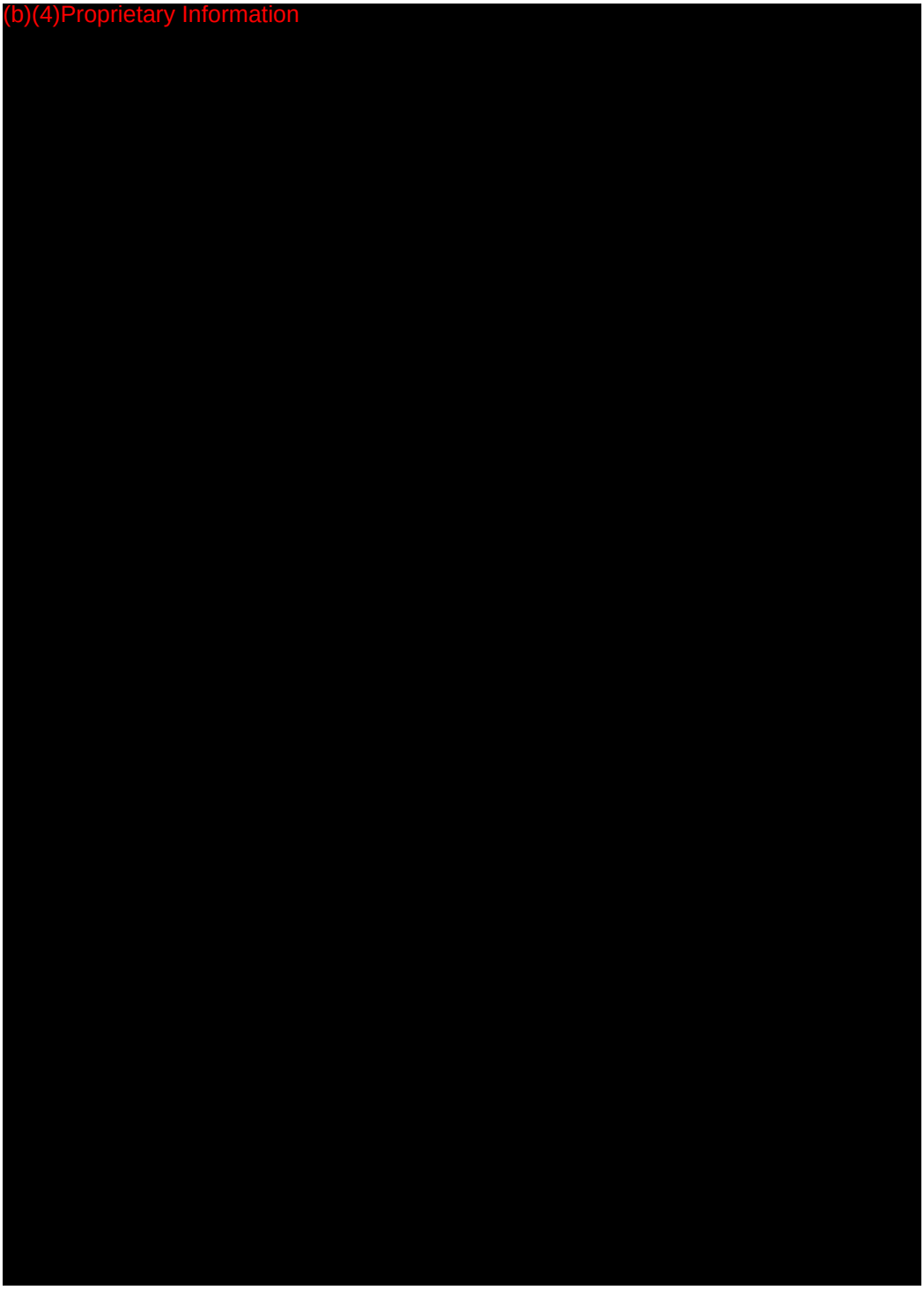




theraLASE®
Healing at the Speed of Light®

TLC-2000
OPERATIONS MANUAL

TABLE OF CONTENTS

1. Safety Information – Please Review Before Using the Theralase System

The Theralase™ TLC-2000 therapeutic laser is a Class 3B medical laser and as such is a potential hazard for direct and indirect viewing of the laser light.

The Theralase TLC-2000 system as mentioned earlier is composed of four main components; the tablet computer, the Power Supply, the Power Pack and the Laser Probes. The Laser Probes are the applied parts of the system. Safety and safe use of the product are indicated both visually by the use of labels as well as equipment features. These will be detailed below.

NOTE: IT IS IMPORTANT TO BE WELL AWARE OF ALL THESE SAFETY DETAILS PRIOR TO USING THE EQUIPMENT.

NOTE: In Canada, the device is to be installed and operated according to the requirements of the following standard: CSA - Z386-14 Safe Use of Lasers in Health Care.

Labeling and an Explanation of Symbols

TLC-2002 Power Pack

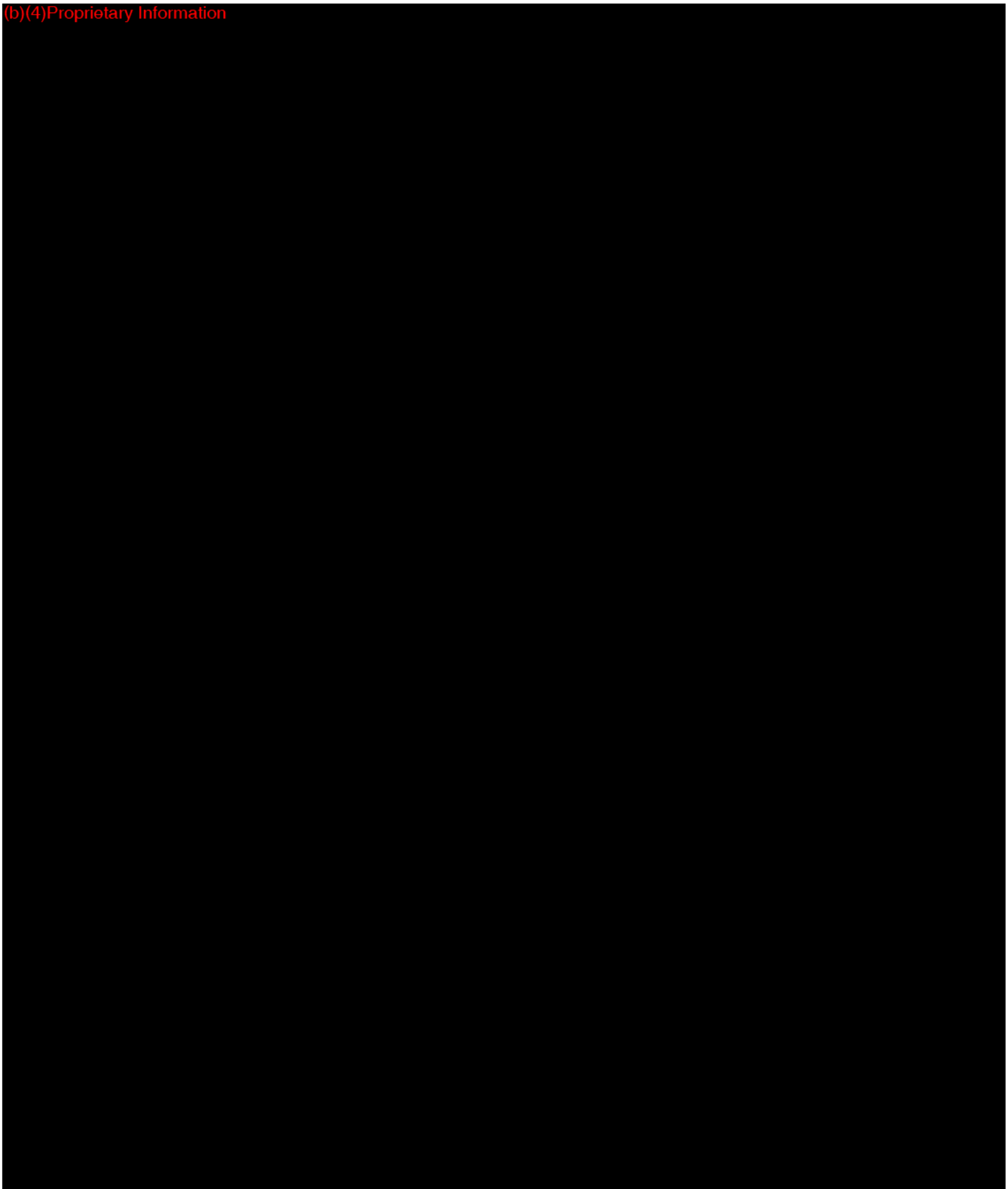
TLC-2000 Laser Probe

TLC-2003 Power Supp y

F gure Locat on of the safety symbo s on the Thera ase TLC-2000 System

TLC-2000 LASER CONTROLLER LABELS AND SYMBOLS

(b)(4)Proprietary Information



KEY EQUIPMENT SAFETY FEATURES

HARDWARE

In addition to the safety signs placed on each of the elements of the Theralase™ system, key safety features are built into the TLC-2000 Power Pack and Tablet software as well. These are illustrated below.

Figure 3. Safety Features

1. Emergency Stop: This button shuts down the entire laser system immediately when pressed.

2. ON/OFF Key Switch: This is the main on / off switch for the laser system. When not in use, the keys can be placed in a safe location to prevent unauthorized use of the equipment.

3. Remote Interlock Connector: The Remote Interlock Connector is a connector that may be removed for disconnecting the mains power.

4. Laser Probe: The Laser Probes are the applied parts of the system. The Probe cannot operate the laser diodes unless a laser protocol has been received from the tablet software.

5. Tablet Software: Even if the Key Switch is left in the system with the Remote Interlock Connector in place and the Laser Probe(s) turned on, there is yet another security feature in place. The Laser Probe(s) cannot emit laser light unless treatment data has been received from the Theralase software on the tablet. To login into the operating system the Theralase TLC-2000 application software requires a username and password to operate.

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OPERATIONAL SAFETY

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

(b)(4)Proprietary Information

Please note that Theralase™ supplies Laser Safety Eyewear with all of its products and can be contacted directly at 1-866-The-Lase (1-866-843-5273) for additional sets if required. Order (Part #: TLC-901) directly from Theralase™ Inc. for all additional laser eyewear needed. The laser eyewear is for diffuse viewing of laser light only.

The Theralase™ TLC-2000 laser output is athermic. Laser diode package cases may warm up slightly during treatment giving a feeling of warmth to a laser treatment. Under no circumstances should the patient experience a very hot or burning sensation during treatment. If this occurs, discontinue the treatment immediately and contact Theralase™ Inc. for service.

Observe the safeguards as put forward below. The Theralase™ TLC-2000 therapeutic medical laser is a sophisticated medical device and as such should only be handled by experienced medical practitioners suitably trained in its use.

PRECAUTIONS

- Make sure that the area to be treated is free from any substance that reflects or prevents penetration of the laser beam. It is recommended that areas to be laser treated are cleansed, prior to treatment.
- Operate the laser in a well-illuminated area, as the pupils of the eye are smaller and not as easily damaged.
- Operate the laser in an area free from mirrors or polished metal surfaces to prevent accidental reflections.
- Operate the laser in a segregated area with a sign posted:

(b)(4)Proprietary Information

Operate the laser probes in direct contact and perpendicular to the tissue being treated.

Align laser probes to the area to be treated before commencing laser treatment.

SAFETY WARNING

- The TLC-2002 Laser Power Pack is designed to operate with TLC-2001 Laser Probes only. A maximum of four TLC-2001 Laser Probes may be connected to the TLC-2002 Power Pack at any one time.
- The Theralase™ TLC-2000 laser and all attachments are not designed to be protected from water intrusion and should never be used wet or in the accompaniment of water. If the laser system becomes wet or immersed in water, thoroughly dry the laser system and allow 48 to 72 hours in a warm environment to fully dry prior to use. If problems persist, contact Theralase™ Inc. for service.
- The Theralase™ TLC-2000 laser and all its attachments should not be used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- The Theralase™ TLC-2000 laser and all attachments are not suitable for use in the presence of strong electromagnetic field or other electrical interference.
- The Theralase™ TLC-2000 laser and all attachments are designed as an integral system and use of parts other than the recognized accessories or parts can degrade the performance of the Theralase™ TLC-2000 laser and may result in hazardous radiation exposure.

WARNING:
No Modification of This Equipment is Allowed

WARNING:
To Avoid Risk of Electrical Shock, This Equipment Must Only Be Connected to a Supply Mains With Protective Earth.

DISCLAIMER INFORMATION

The TLC-2000 therapeutic laser system is a medical device and is sold to healthcare practitioners as a tool for the rehabilitation of their patients. The TLC-2000 therapeutic laser system and attachments are utilized to assist in the alleviation of their patient's symptoms. The TLC-2000 therapeutic laser system is not promoted as a cure for any patient ailments.

The information contained in this manual is for reference only and does not preclude the practitioner from using proper judgement in the rehabilitation of their patients.

It is the practitioner's sole responsibility to decide if laser therapy is indicated for their specific patient's rehabilitation.

The treatment protocols detailed in this manual are for reference only and are not promoted as the only protocol available to the practitioner.

2. THERALASE TLC-2000 SERIES PRODUCT INFORMATION

The TLC-2000 Therapeutic Laser System is used in the adjunctive treatment of knee pain.

The TLC-2000 laser probes are used in direct contact with tissue in order to inject photons of light (b)(4)Proprietary Information (b)(4)Proprietary Information non-invasively and drug-free into tissue.

PRODUCT OVERVIEW AND TECHNICAL DESCRIPTION

The Theralase™ TLC-2000 series of products is comprised of four main components

- The Tablet Computer with Theralase software (p/n TLC-2004)
- The Power Supply (p/n TLC-2003)
- The Laser Probe(s) (p/n TLC-2001)
- The Power Pack (p/n TLC-2002)

The Power Pack only supplies power to the Laser Probe(s). The Laser Probes are controlled by Theralase software resident on the Tablet. Under software control the Laser Probes operate in a patient treatment mode with the power level and time based on the protocol resident in the tablet software. Communications between the Tablet and the Laser Probe(s) is via a wireless Blue Tooth® link (b)(4)Proprietary Information (b)(4)Proprietary Information

(b)(4)Proprietary Information

(b)(4)Proprietary Information

THE LASER POWER PACK (TLC-2002)

The Theralase™ TLC-2000 laser system Power Pack (TLC-2002) is shown below. The Power Pack consists of an aluminum case with a plastic top and bottom. There is a separate plastic stand that the bottom of the Power Pack fits into. There are four ports to accommodate up to four TLC-2001 Laser Probes.

Laser Probe Port | Unit ON Indicator | Laser Probe Power ON Indicator

Remote Interlock Connector | Emergency (E-STOP) Switch | Key Switch

Figure 5. The TLC-2000 system Power Pack (TLC-2002)

The Theralase™ TLC-2000 laser system and all attachments are rated as Class 1 ME equipment, type BF and are equipped with Class 3B lasers.

Details regarding the safe use of the TLC-2000 system components are detailed in section 2 and operation of the unit in sections 3 and 4.

The top of the unit has an emergency STOP button (red button with white arrows), a key switch for switching the unit off and being able to lock the unit from unauthorized use, an interlock switch and a green ON LED. A further detail of these items as well as their operation is detailed in section 2.

The following are the detachable parts for the TLC-2000:

Power Supply: TLC-2003 Power Supply (+24 VDC, 4.2 A)
Laser Probe: TLC-2001 Laser Probe

WARNING: PLEASE DISCONNECT POWER SUPPLY BEFORE SERVICING

The Power Supply (TLC-2003)

The TLC-2003 is a universal power supply – the input voltage range is 100VAC to 240VAC, 47 to 63 Hz, meaning that it can be safely used anywhere in the world. The TLC-2003 power supply is able to power the TLC-2002 Power Pack.

Plugs in to main AC line via power cord (TLC-155)

Power output: Voltage: +24 VDC
Current: 4.0 A

Power supply TLC-2003 plugs in to the Power Pack - TLC-2002

Figure 7. TLC-2003 Power Supply and associated Line Cord

With the proper cord set the TLC-2003 can be plugged in anywhere in the world. The cord set (TLC-155) supplied with the Theralase™ TLC-2003 power supply is a hospital grade 115 to 120 VAC, 50 to 60 Hz approved cord set. This is built to a North American standard and was chosen to work in Canada and the United States.

Some of the key features of the TLC-2003 Power Supply include

100-240 VAC Universal Input
In Case IEC320
Single Output up to 101 Watts
Outputs Regulated with Low Ripple
Meets Safety Agency Requirements
Complies with EMC/EMI Regulations
CE Compliant
Impact Resistant Polycarbonate Enclosure

CAUTION:

• Use only the TLC-2003 Power Supply (+24 VDC, 4.2 A) to power the TLC-2002 Power Pack. This is the only Power Supply approved to be used with the TLC-2000 laser system.

• Outside of North America, the proper international cord set must be specified and purchased from Theralase® Inc. or purchased separately for the country of preference.

LASER PROBES (TLC-2001)

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Figure 10. Top and Bottom view of the Laser Probe (TLC-2001)

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CAUTION

The Laser Probe Cover should be placed over the lens area when not in use.

Connecting/Disconnecting the Laser Probes (TLC-2001) to the Power Pack (TLC-2002)

All the Laser Probes feature a very simple medical grade push-pull cable connector. This consists of a cable with a plug assembly on each end and a printed circuit board-mount receptacle assembly in the Power Pack and the Laser Probe.

Assurance of proper mating is provided by keying. The key(s) of the cable plug assembly are designated by an arrow on the plug and must align with the key of the receptacle assembly.

Figure 11. Probe Assembly illustrating the key

The cable plug assembly must be properly aligned with the receptacle assembly, and then inserted until the latches engage the receptacle assembly. There should be no need to force the connector into the receptacle. To ensure proper mating, there must be an audible "click". Refer to Figure 12.

Figure 12. Mating the Connectors – Cable Plug Assembly Key is aligned with Receptacle key

The connectors must be unmated by first gently sliding the housing subassembly away from the receptacle assembly – see Figure 13 and then pulling the entire connector out. PLEASE hold the main body and DO NOT pull the cable.

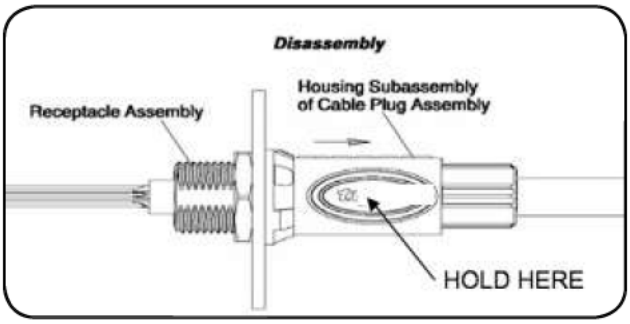

Figure 13. Un-mating the connected assembly

ACCESSORIES

Accompanying the TLC-2000 system, in addition to the above main items, will be two sets of laser safety goggles (TLC-901).

Safety Eyewear:

Two sets of laser safety goggles (part #: TLC-901) are supplied by Theralase as standard accessories. These laser safety goggles are provided for viewing of diffused laser light only and are not indicated for direct viewing of the laser output.

It is highly recommended that both the practitioner and the patient wear laser safety eyewear during laser therapy treatment.

Figure 14. Theralase supplied Laser Safety Eyewear

Optical Density **("O.D.")** is the scientific term to describe a material's ability to block light of a certain wavelength. It is a logarithmic formula, where the higher the O.D. value, the better the material blocks light. For example, an O.D. of 1 means the material will allow 10% of the light penetrate the eyewear at a particular wavelength.

O.D.	Light Penetration	Light Absorption

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(b)(4)Proprietary Information

[redacted]

CAUTION:

Use only Theralase™ Inc. supplied laser safety eyewear or laser safety eyewear that meets or surpasses the above noted optical densities at the above-specified wavelengths

NEVER POINT A LASER TOWARDS A PERSON'S EYES UNDER ANY CIRCUMSTANCES

Figure 14. Hard case for TLC-2000 system (part number: TLC-1200)

CONTRAINDICATIONS IN THE USE OF LASER THERAPY:

1. Do not treat the addomen of a pregnant woman.
2. Do not treat any tpes of neoplasia, cancer or cancerous lesions (benign or malignant).

CAUTIONS IN THE USE OF LASER THERAPY:

1. Never point the laser in the direction of any person's eyes.
2. Do not treat endocrine glands such as the pancreas and the thyroid.
3. For a new patient or a patient who may be light sensitive, spot test the laser on an area of tissue to determine if they are adversely sensitive to laser treatment.
4. If a patient is currently prescribed photosensitive medicine, NSAIDS, steroids or corticosteroid medicine, try to allow 2 weeks as a wash out period prior to laser treatment. If a wash out period is not possible, reduce the laser power to 1/2 of the recommended power indicated and increase with each treatment as the patient reliance on photosensitive, NSAIDS, steroids or corticosteroid medicine reduces.
5. Start treatment at the most painful area first and follow the treatment specifics. Treat surrounding tissue next.
6. Under no circumstances should the patient feel anything more than a slight warming effect. If the patient feels hot sensations, pain or burning, STOP LASER TREATMENT IMMEDIATELY and check laser equipment. If laser probe head is hot to the touch, call immediately for service. Detailed contact information is provided in Section 5 - Maintenance and Service, of this manual.
7. Under no circumstances over-treat an individual as over-treatment may lead to bio-inhibition of tissue structures.

3. START-UP INFORMATION

A detailed description of the individual system components

The Power Pack (TLC-2002)

The TLC-2002 Power Pack provides power to each TLC-2001 Laser Probe. The probes ports, numbered 1 to 4 are the same electrical output. A TLC-2001 Laser probe should always be connected to location #1 first, then #2, etcetera.

Figure 16. A detailed look at the Power Pack

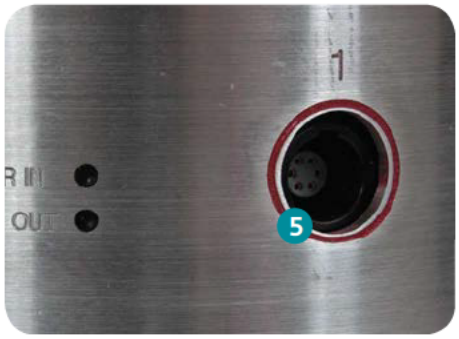
1. Remote Interlock Connector The Remote Interlock Connector is capable of disconnecting the TLC-2001 Laser Probe(s) from main power when removed. To remove, press the button on the connector and pull the Remote Interlock Connector straight out. Main power is now disabled and no action will restore it until the Remote Interlock Connector is replaced. To replace, insert straight into the matching receptacle.

2. Emergency Stop This button shuts down the entire laser system immediately when pressed, disabling mains power.

NOTE: Depressing the Red Emergency Stop Button immediately disables the laser system. Operation may be resumed by rotating the Red Emergency Stop Button 1/4 of a turn to the right and allowing it to "pop out" again.

3. Key Switch This is the main on / off switch for the laser system. When the key is turned to the left, the system is off, disabling mains power. When the key is turned ¼ turn to the right, the system is on. The key can only be removed when in the OFF position.

TLC-2003 Power Supply input



Connection to the TLC-2001

4. Power Supply Input Input for black DC adapter cord from the TLC-2003 Power Supply. When the DC adapter is connected the TLC-2000 Power Pack may be operated directly from an AC wall outlet.

Caution: Use only the TLC-2003 Power Supply for the Theralase™ system.

5. Probe Power Ports Power supply ports for up to four (4) TLC-2001 Laser Probes (High Density 6 pin medical grade connector).

6. Power IN LED This LED is illuminated only when the external power supply is connected and the key switch is in the ON position, the Remote Interlock Connector is installed and the Emergency Stop is not activated.

7. Power OUT LED This LED is illuminated only when both of the internal power supply voltages to the probes are good.

Note: The TLC-2001 Laser Probes will not function if this LED is OFF.

The PROBE

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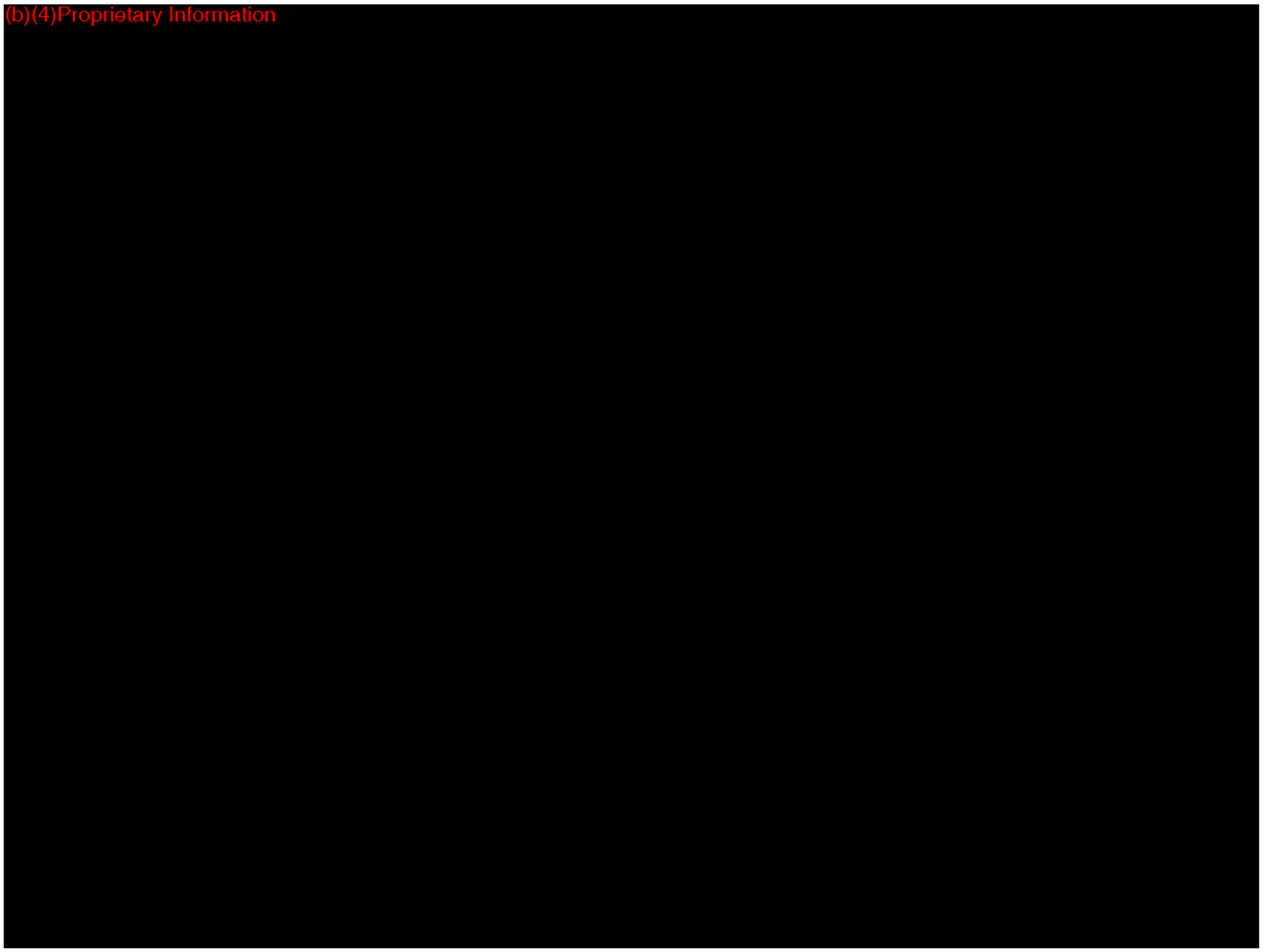

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THE TABLET (TLC-2004)

The Tablet comes with the Theralase® software already installed and the keyboard and touch screen together. The touch screen can be separated from the keyboard if desired. There is a pop up touch screen keyboard; however, it may be easier to input data using the attached keyboard. With the keyboard attached, selections can be made using the cursor or the touch screen.

When delivered, the Tablet has an administrator username and password. It is recommended that the system be configured for new passwords and user names. Refer to the section Setting Username and Passwords in the Administrator Menu section for this procedure.

The Tablet is shipped with the manufacturer's user manual and software license card. Refer to those documents for additional information.

Figure 16. A detailed look at the tablet

1. Power On Hold this button down for two (2) seconds until the touch screen turns on.

2. Charging Port Plug the micro USB connector from the charger into this port to power the tablet from AC voltage.

3. USB Port Plug the Blue Tooth® USB stick into this port.

4. Release Button Press this button to separate the keyboard and the touch screen.

5. Touch Pad Use this pad to control the cursor and make selections by moving your finger over the surface of the touch pad. Press the lower left corner of the touch pad to make a selection.

SET-UP PROCEDURE

1. Unpack the contents of the case and identify each of the pieces as outlined in the figure below.

Identify the following components of your TLC-2000 system:

1. Tablet computer (TLC-2004)
2. Tablet power supply and cable
3. Power Supply (TLC-2003)
4. Medical AC power cable
5. Power Pack (TLC-2002)
6. Laser Probe(s) 1 to 4 (TLC-2001)
7. Probe cable(s) 1 to 4
8. Straps
9. Safety Eyewear

Figure 20. TLC-2000 system components

Set the TLC-2002 Power Pack on a steady surface and ensure the key switch is in the "off" position. Make all connections as shown below and read the following set of instructions BEFORE operating the system.

(b)(4)Proprietary Information

Figure 20. How the TLC-2000 system connects together

2. Connect the 120 VAC hospital grade line cord (TLC-155) into the TLC-2003 Power Supply (or approved Hospital Grade cord set for country of use) and then connect the TLC-2003 power supply into the power input located on the Power Pack.

3. Connect the Laser Probe(s) (TLC-2001) to the Power Pack (TLC-2002) by inserting the medical grade push-pull connector to mate with the receptacle in the Laser Probe port.

Important Note: Port 1 **MUST** be used for one of the Laser Probes. Detailed instructions on how to connect the Laser Probe to the Power pack is given in section 3. Leave the Laser Probes turned OFF.

Note: Connect the Laser Probe(s) to the Power Pack **PRIOR** to switching the Power Pack ON.

4. Connect the Tablet power supply to the mirco USB connector on the Tablet and plug into a 120 VAC source. The power supply is universal and will need a plug adaptor for 240 VAC.

5. Open the Tablet and turn it on. Then log on to the operating system with the supplied username and password.

6. Select the TLC-2000 icon and enter the username and password to start the application.

Note: There is a user name and password for the Tablet computer and also for the TLC-2000 software.

7. At this point the Welcome screen should be displayed with icons for the actions.

8. Turn on the Power Pack by:
    a. Turning the Emergency Stop switch a quarter turn clockwise to allow it to "pop" out
    b. Inserting the Remote Interlock Connector into its receptacle on the front panel of the Power Pack until it locks firmly into place
    c. Turn the Key Switch 90° to the right

9. At this point the Power Pack Power IN and Power OUT LEDs should illuminate.

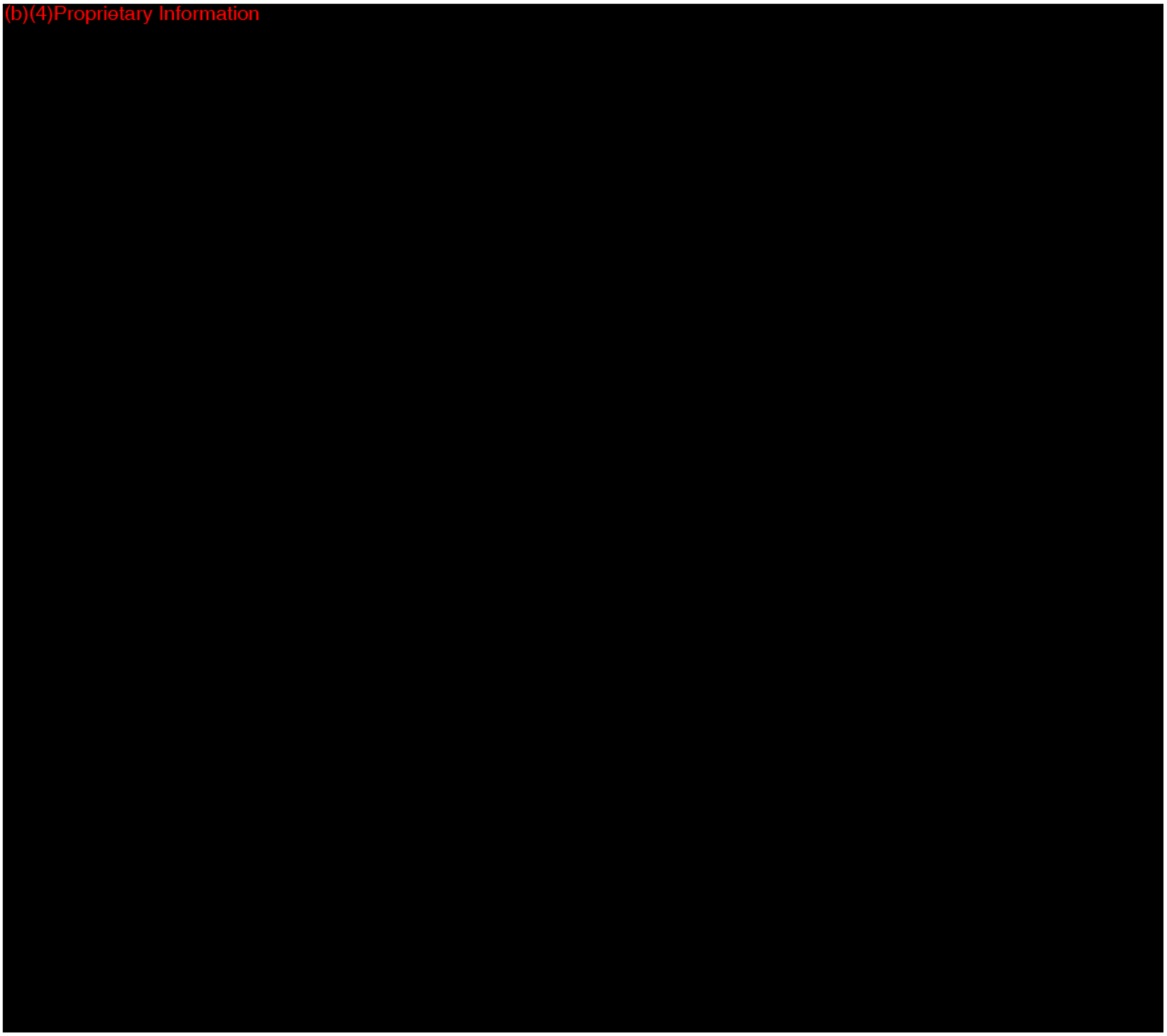
10. The system components are now set up and ready to be used.

REMINDER:

The Theralase software must be operating with patient data in the database BEFORE the Laser Probes will emit laser light.

4. SYSTEM OPERATION OVERVIEW

(b)(4)Proprietary Information



Stop Procedure

The Laser Probe may be turned off during operations by either of the following means:

1. Slide the switch on the Laser Probe to the OFF position.

2. Press the STOP button on the Tablet software

3. Press the Red Emergency Stop Button to stop Laser Probe operation and disable the mains power to the TLC-2000 laser system. Laser operation can only be re-started by turning the E-STOP switch a quarter turn clockwise to allow it to "pop" out.

4. Turn the on / off power key switch to the left ¼ turn to stop laser operation and to disable the mains power to the TLC-2000 laser system.

The Key Switch or Remote Interlock Connector may now be removed if desired to disable the laser system from unauthorized operation.

Note: Even if the Key Switch is left in the system and the Remote Interlock Connector is in place, the security password must be known to enable laser operation; thereby, providing a 3 step security protocol to prohibit laser use by unauthorized personnel.

Overview of the Menu

(b)(4)Proprietary Information

PRACTITIONER TAB

(b)(4)Proprietary Information

(b)(4)Proprietary Information

ADMINISTRATOR TAB

(b)(4)Proprietary Information

System Operation in Detail

COMMON OPERATIONS

Turning On the Tablet:

Turn on the tablet by pressing and holding the power on button on the lid of the tablet for two (2) seconds. Keep it pressed until the screen starts.

(b)(4)Proprietary Information

Turning the Tablet OFF

To turn the tablet OFF, swipe the screen in a Right to Left motion from the right hand edge of the screen. A vertical menu will be displayed. (To close the vertical menu, swipe the screen in a Left to Right motion.) Touch the Settings Icon to display the settings menu. Touch the power icon and select SHUT DOWN from the pop up window.

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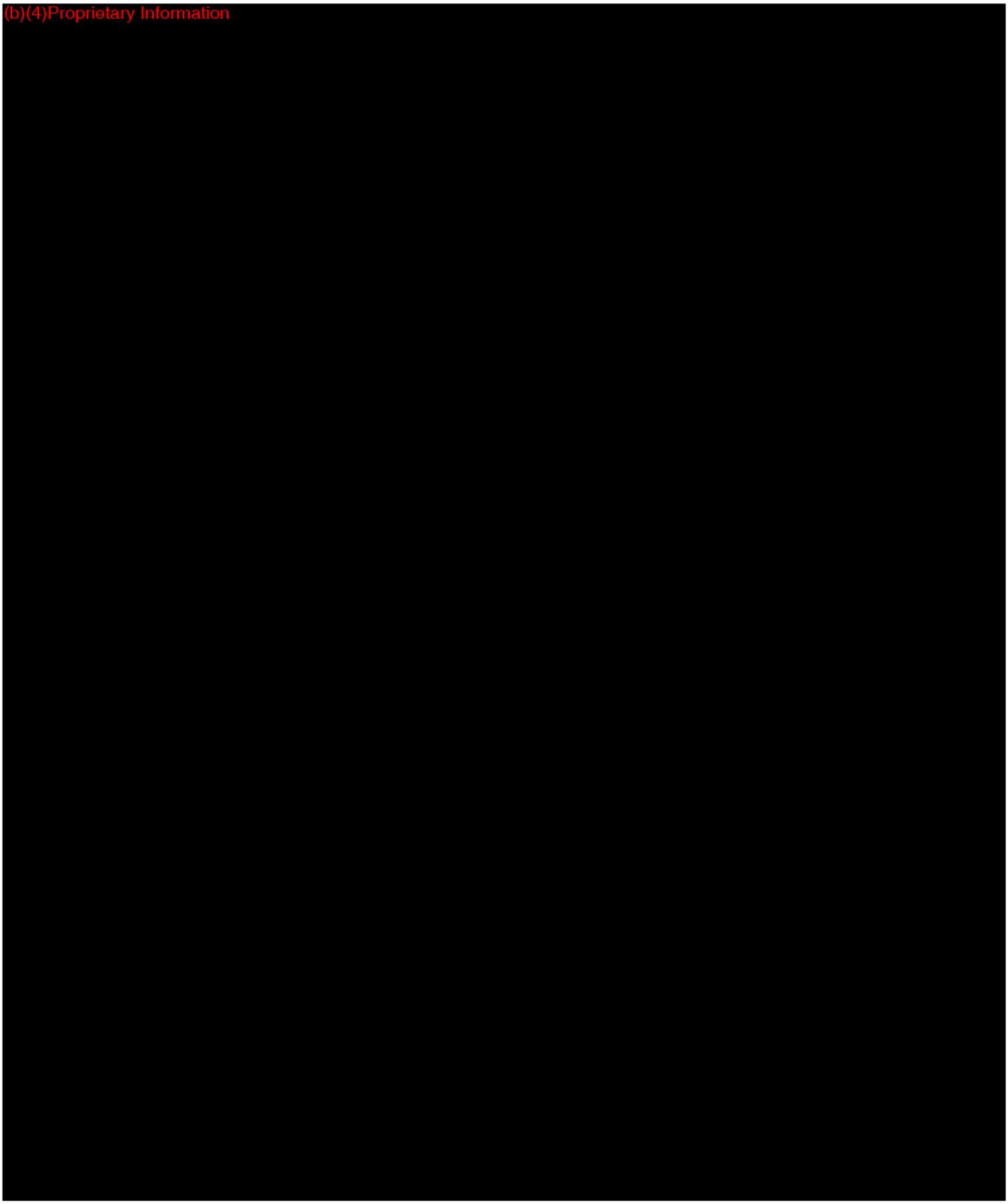
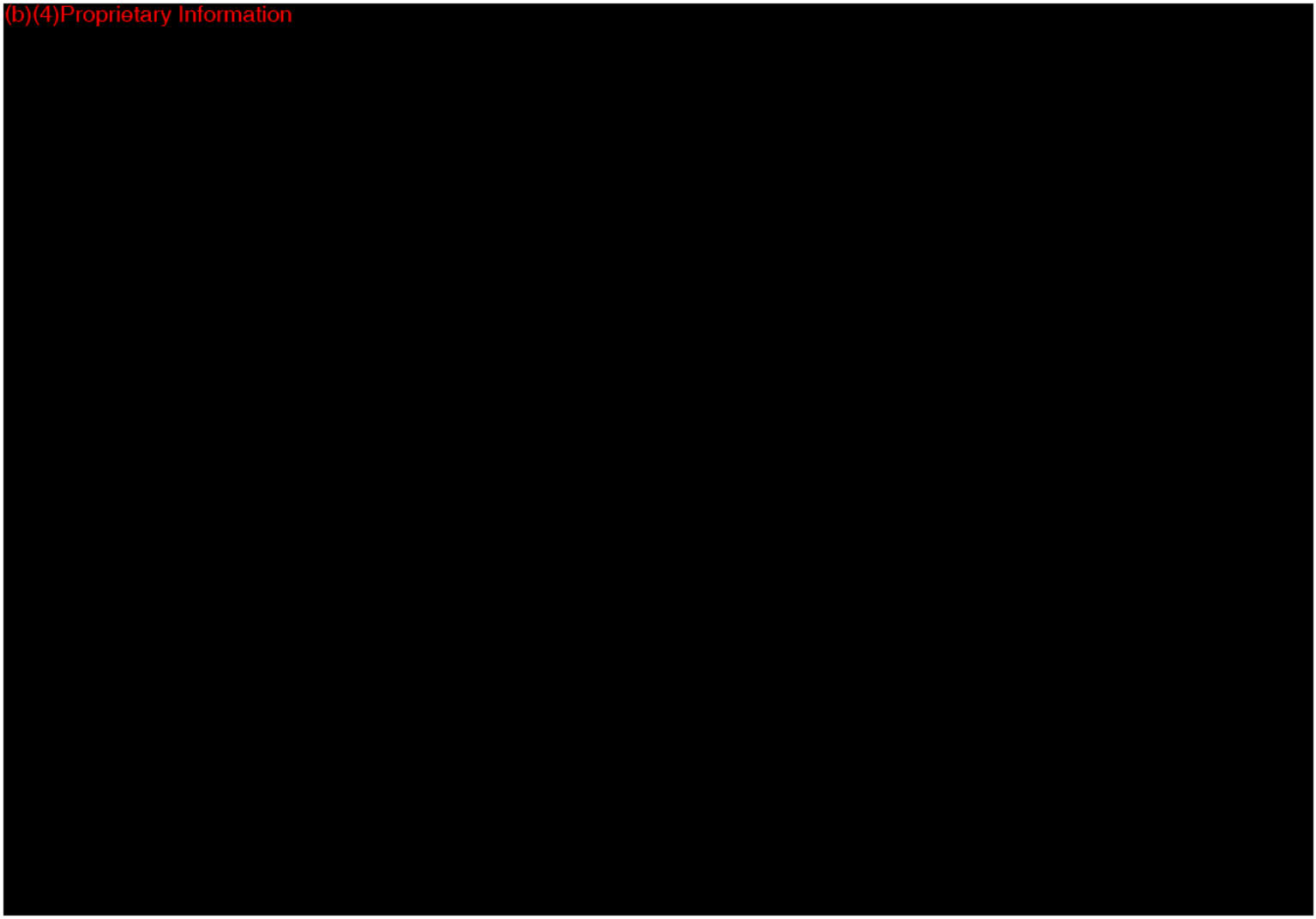


Advanced Operations

How to Create Custom Protocols

(b)(4)Proprietary Information



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WARNING MESSAGES

(b)(4)Proprietary Information

5. Maintenance and Service

This section deals with maintenance and serviceability of the Theralase™ system by the end user. If further detailed service of your laser system is required, contact Theralase Inc directly for assistance. Detailed contact information is supplied at the end of this section.

Inspection and Cleaning

PRE AND POST TREATMENT

(b)(4)Proprietary Information

[redacted]

WEEKLY

Follow the stop procedure in the basic operation section of this manual. Remove the key from the power pack. Disconnect the Laser Probe(s) and power input to the Power Pack. Carefully clean each of the TLC-2001 Laser Probes with isopropyl alcohol swabs being careful not to immerse the Laser Probe heads. Remove the lense cap and immerse a Q-tip into isopropyl alcohol and rotate in the laser aperture carefully to avoid damaging the laser diodes.

MONTHLY

Follow the stop procedure in the basic operation section of this manual. Remove the key from the power pack. Disconnect the Laser Probe(s) and power input to the power pack. Inspect the laser diodes for cracks or chips in the glass. A visible chip in the glass, a crack in the glass or a missing glass mandates replacement of the laser diode. Contact Theralase immediately for replacement of the defective / damaged laser diode.

PREVENTIVE MAINTENANCE SCHEDULE

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Transport

Remove the key from the main power switch and store in a safe location. Disassemble the laser system, carefully packing all components and taking special care with the laser probe assembly. In packing and unpacking the apparatus, be careful not to twist or kink the probe cable(s) too sharply to prevent damage to the probe cable assembly. Ensure proper storage of the Laser Probesto avoid laser diode damage. If you damage your laser diodes, please notify Theralase™ Inc. immediately for service / replacement. (The laser system should be kept within 0 to 40°C, 500 hPa to 1068 hPa and 0 to 80% relative humidity during transport).

Caution:

Calibration must only be performed by Theralase™ Inc. or by trained personnel possessing the proper knowledge and test equipment. Contact Theralase™ Inc., if after testing, software indicates maintenance of the laser diodes is required.

Calibration/Repair of the Laser Verification Unit

Calibration or repair of the real-time Laser Probe Cover is not a process that can be performed in the field. There are no user serviceable parts in the probe. In the event, if such a situation does arise, it is recommended to call Theralase Customer Support at 1-866-843-5273 or email service@theralase.com for detailed instructions on how to best handle this condition.

Service of Laser Diodes

The TLC-2000 therapeutic medical laser system contains no user serviceable parts. If the laser diodes require maintenance then contact the factory and return the system for service.

Product Warranty

(b)(4)Proprietary Information

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Environmental Considerations

This product contains electronic components and as such is considered e-waste and must be disposed of responsibly. Do not dispose of this product with waste destined for landfill or incineration. This product must be recycled according to local laws & regulations. At the end of this product service life, estimated to be 10 years, the product can be returned to Theralase for disposal.

Theralase Customer Service Contact Information

Please note the following contact info for Theralase Customer service. When sending your system in, it would be advisable to make a copy of your checklist (see Section 2) and attach this to your package. Describe the issue that your therapeutic laser system is experiencing and the customer service department will instruct you on the recommended service / replacement parts for your equipment.

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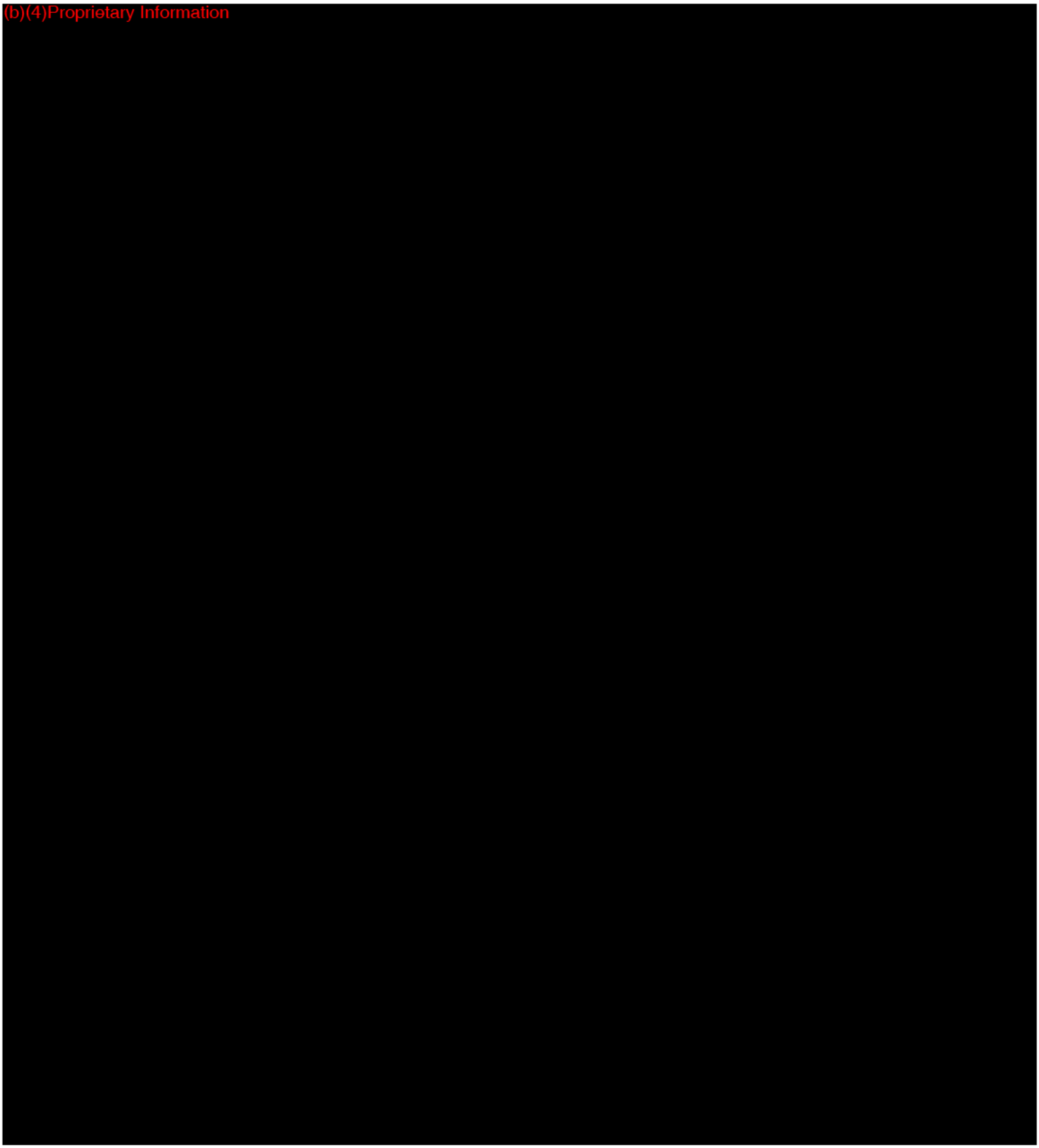

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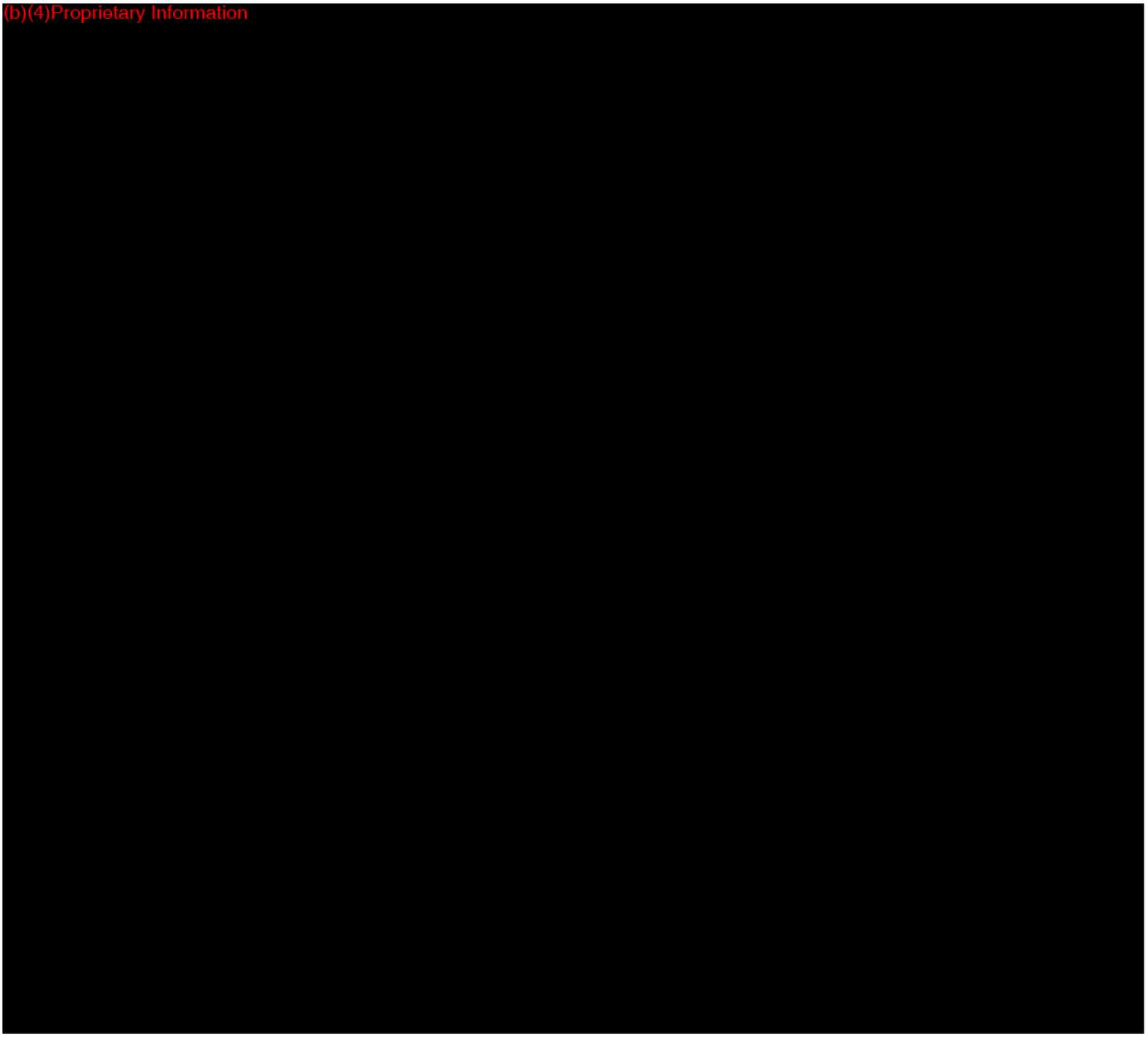

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510(k) Safety and Efficacy

Theralase Inc.

TLC-2000 Therapeutic Medical Laser System

June 19, 2015

I. General Information

Device Generic Name: TLC-2000 Laser

Trade Name: TLC-2000 Therapeutic Medical Laser System

Device Classification: Class II, Performance Standards
21CFR Part 890.5500 Infrared Lamp, Non-heating

Product Code: NHN

Applicant Name and Address: Theralase Inc.
1945 Queen Street East
Toronto, Ontario
M4L 1H7
Canada
Phone: (1) 416.699.5273
Fax: (1) 416.699.2250

510(k) Number: Pending

II. Device Description:

The TLC-2000 Therapeutic Medical Laser System is a non-heating lamp as defined in 21 CFR 890.5500. The TLC-2000 System is a precision medical device consisting of a hand held portable multiple laser probe (b)(4)Proprietary Information [redacted] a tablet computer and a power supply.

III. Indications for Use:

The TLC-2000 Therapeutic Medical Laser System is indicated for adjunctive use in the temporary relief of pain associated with knee disorders.

IV. Contraindications and Warnings:

A. Contraindications:

- Direct irradiation of the eyes Class 3B lasers are potentially harmful to the retina, although retinal damage is highly unlikely from exposure to the laser beam of the TLC-2000 Laser when used as directed in the Operator`s Manual and under normal use by a licensed healthcare practitioner.

- Pregnancy The Laser is contraindicated for use in the near vicinity or over the pregnant uterus.

- The TLC-2000 is a symptomatic treatment, and its use is contraindicated where analgesia may mask progressive pathology, and should not be used where the practitioner would normally avoid the use of any analgesia in order to retain the beneficial aspects of pain.

B. Warnings

- Refer to the warning messages in the TLC-2000 Therapeutic Medical Laser Operator`s Manual in Appendix C.

V. Alternative Procedures or Practices

The primary alternatives for the use in treating chronic or acute knee pain include the use of TENS, steroids, non-steroidal anti-inflammatory drugs (NSAIDs) and barbiturated drugs (known to be addictive and relatively toxic).

VI. Adverse Events

There are no known safety or adverse effects reported in the literature from the use of Low Level Laser Therapy. There were no adverse effects reported by the principal investigators during the course of the clinical study that was performed for the predicate device.

The potential incidents, although the likelihood of occurrence is extremely rare, may include: eye pain, retina or other ophthalmic damage if the laser beam is pointed directly at or into the eye for prolonged periods of time; transient redness at the treatment site; swelling at or near the area of laser irradiation; tingling or itching and/or temporary paresthesia.

VII. Efficacy

The TLC-2000 Therapeutic Medical Laser System utilizes the very same protocol, for the temporary relief of pain associated with knee disorders, as the predicate device and therefore the clinical study results for the predicate device can be applied to the new device.

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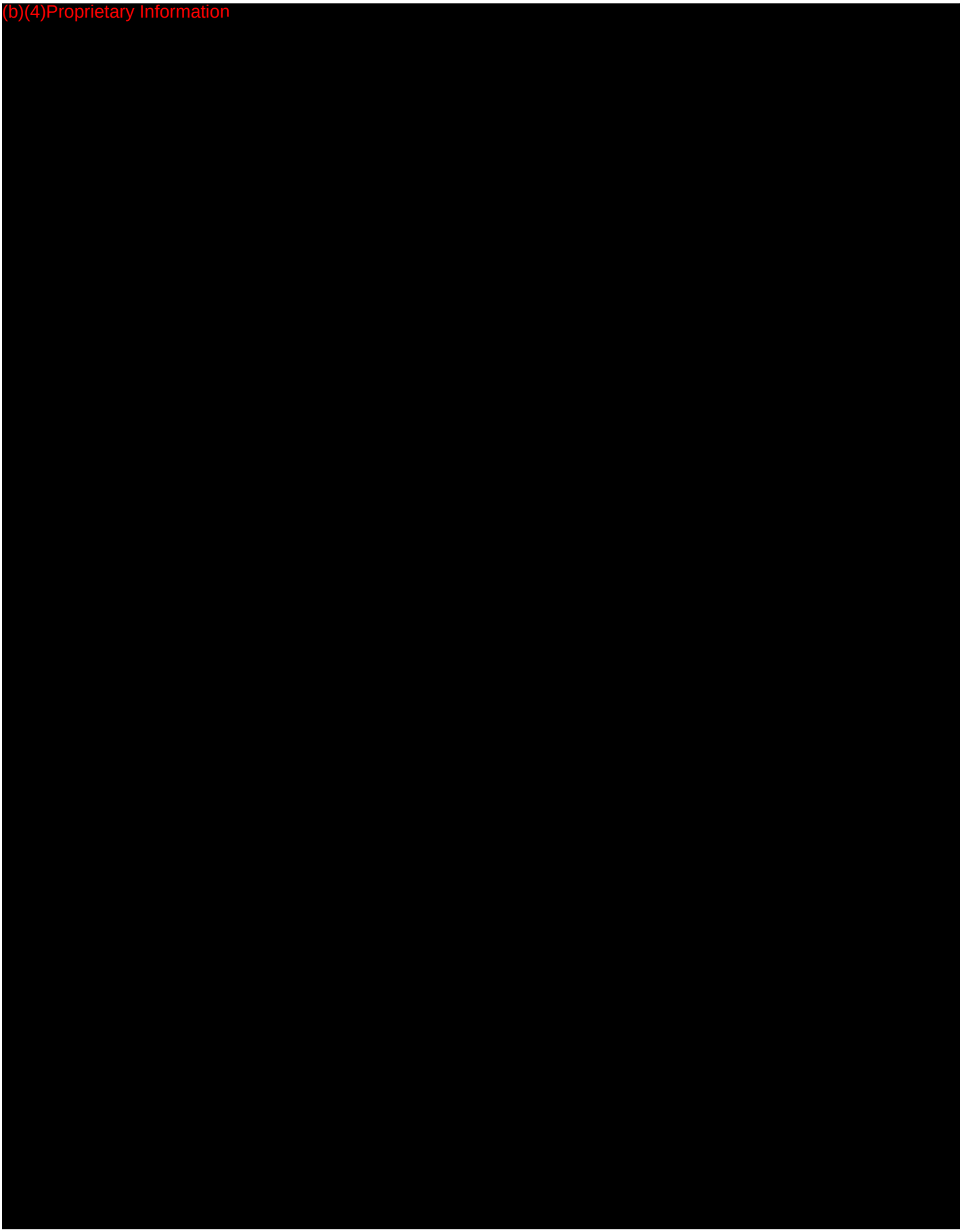

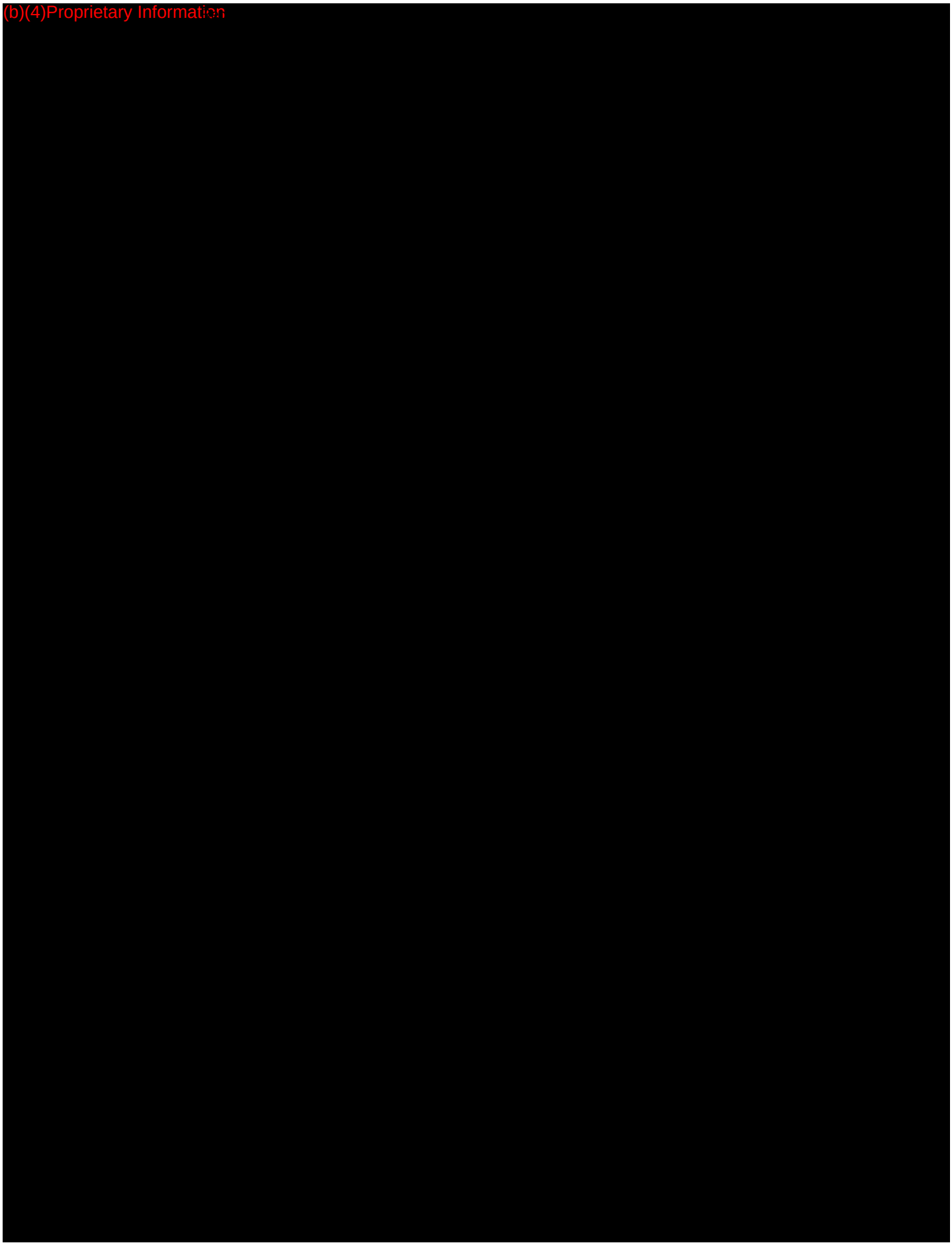

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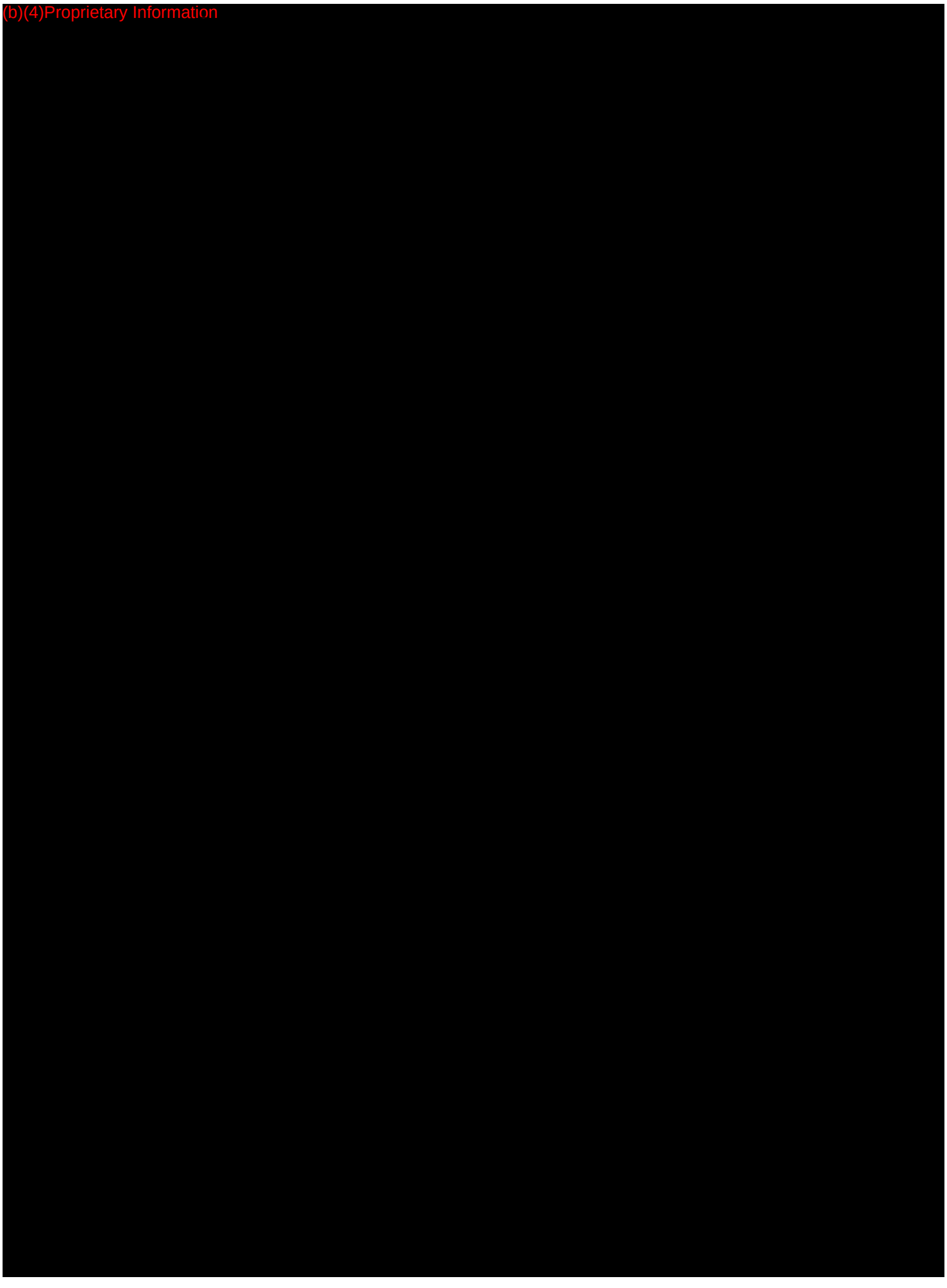

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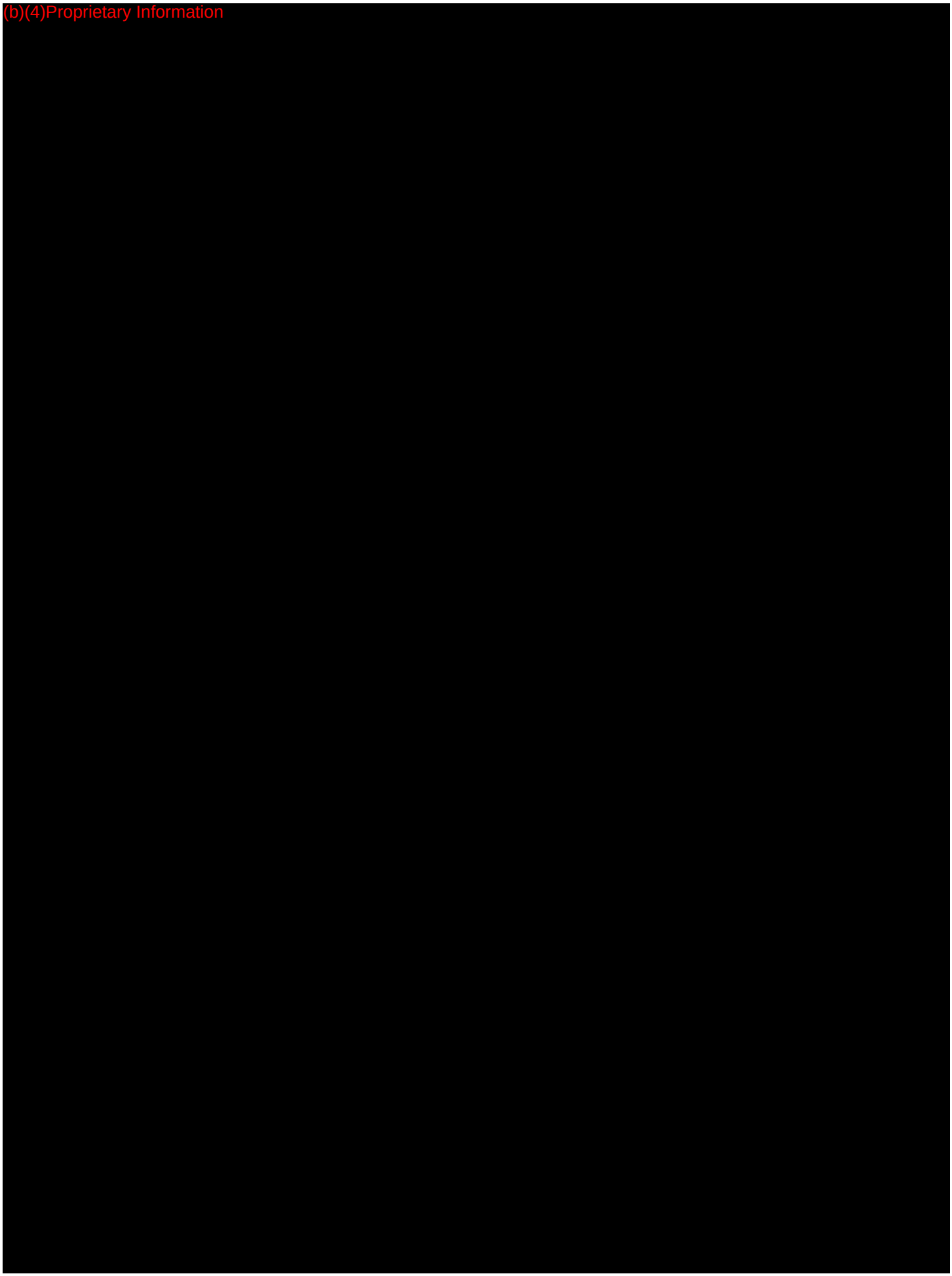

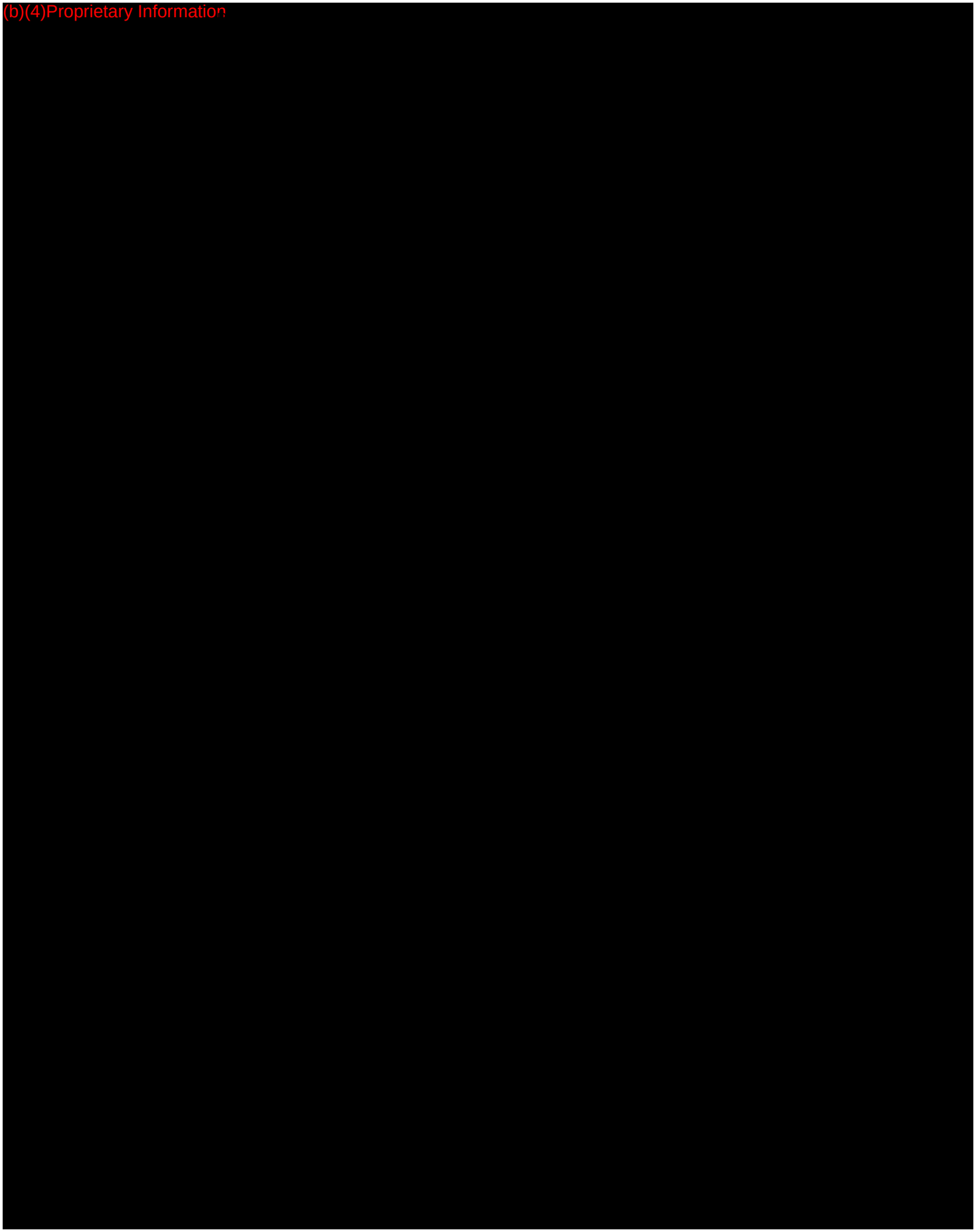

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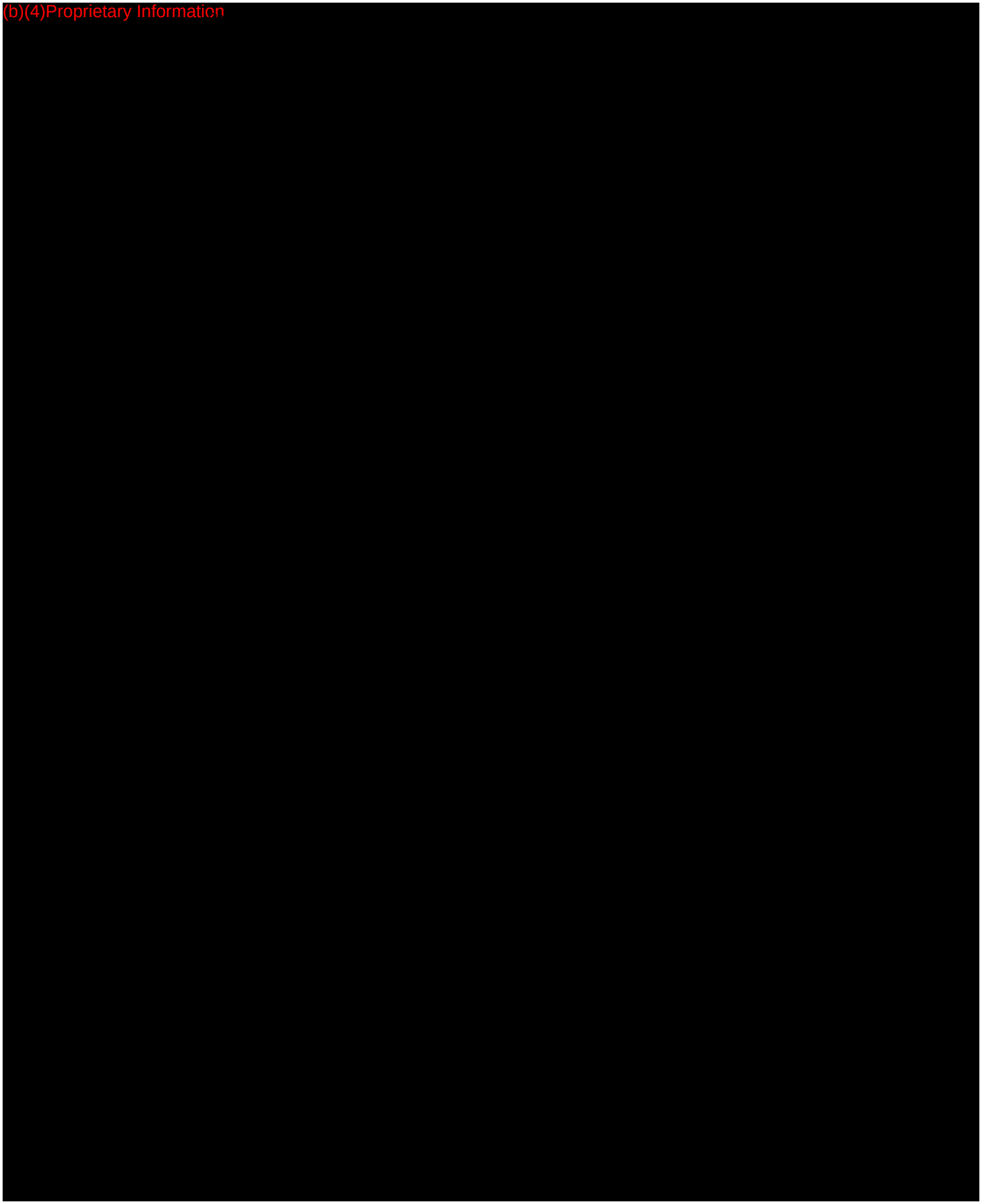

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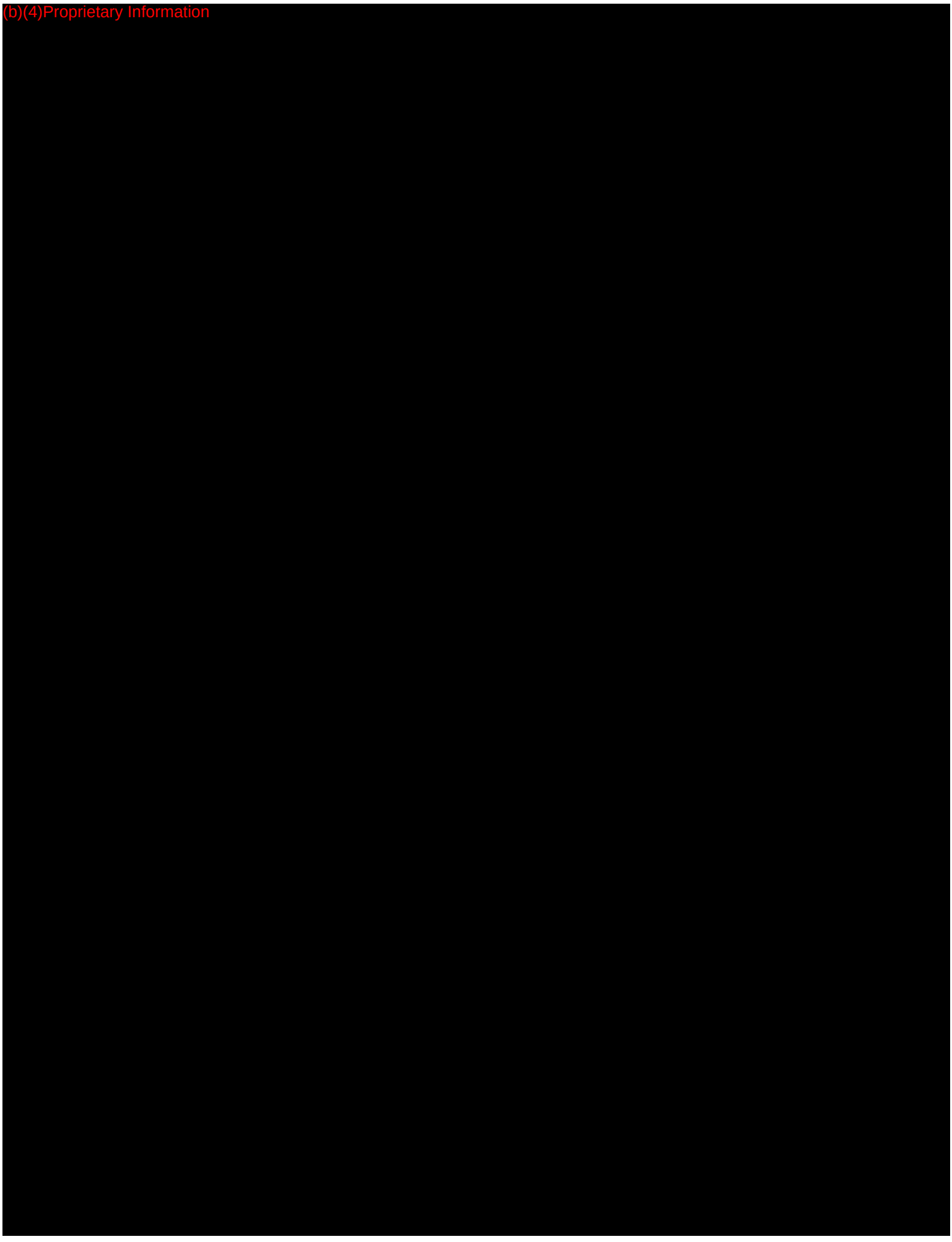

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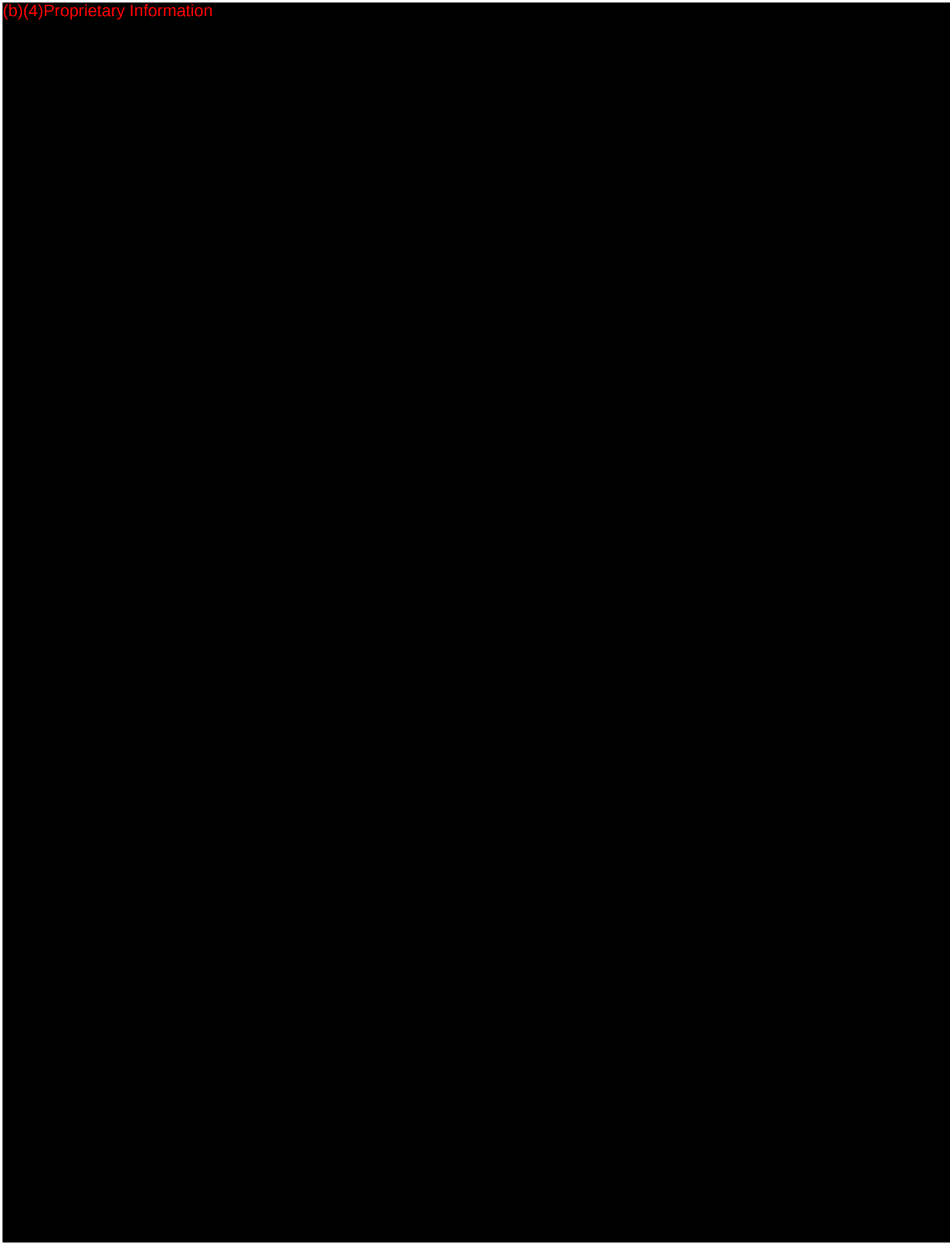

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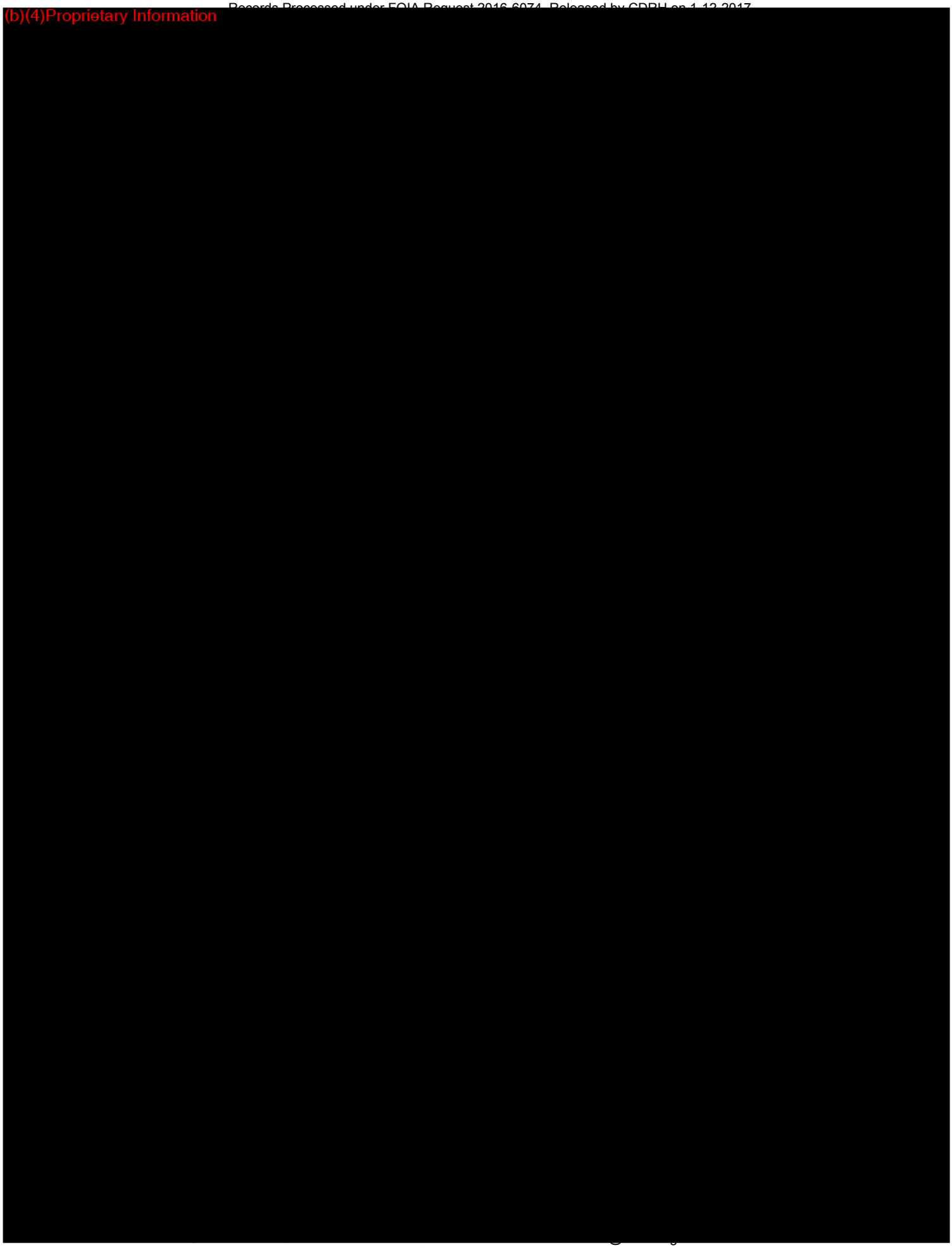

Annex A
(informative)

Biological evaluation tests

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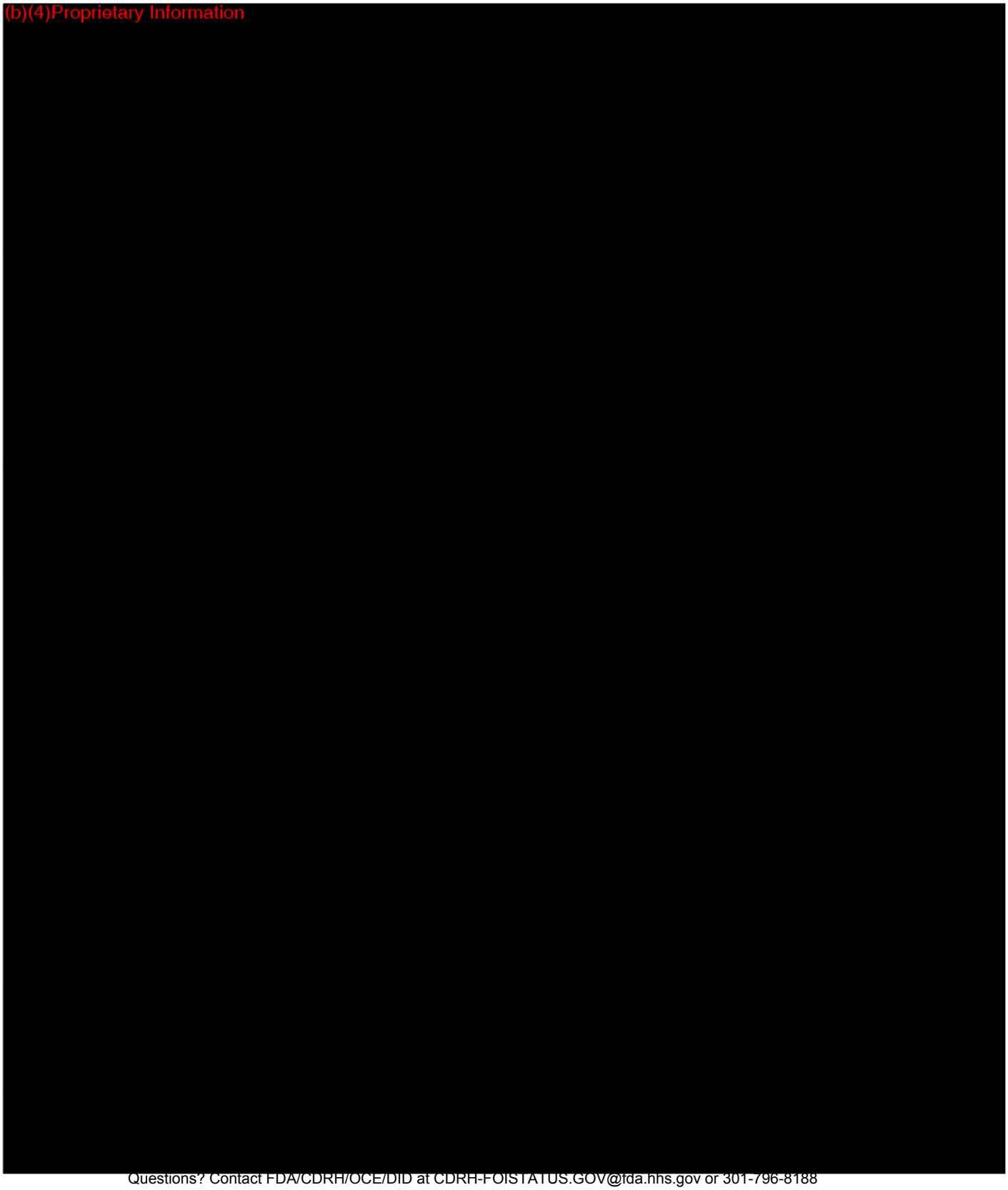

Engineering Test Report

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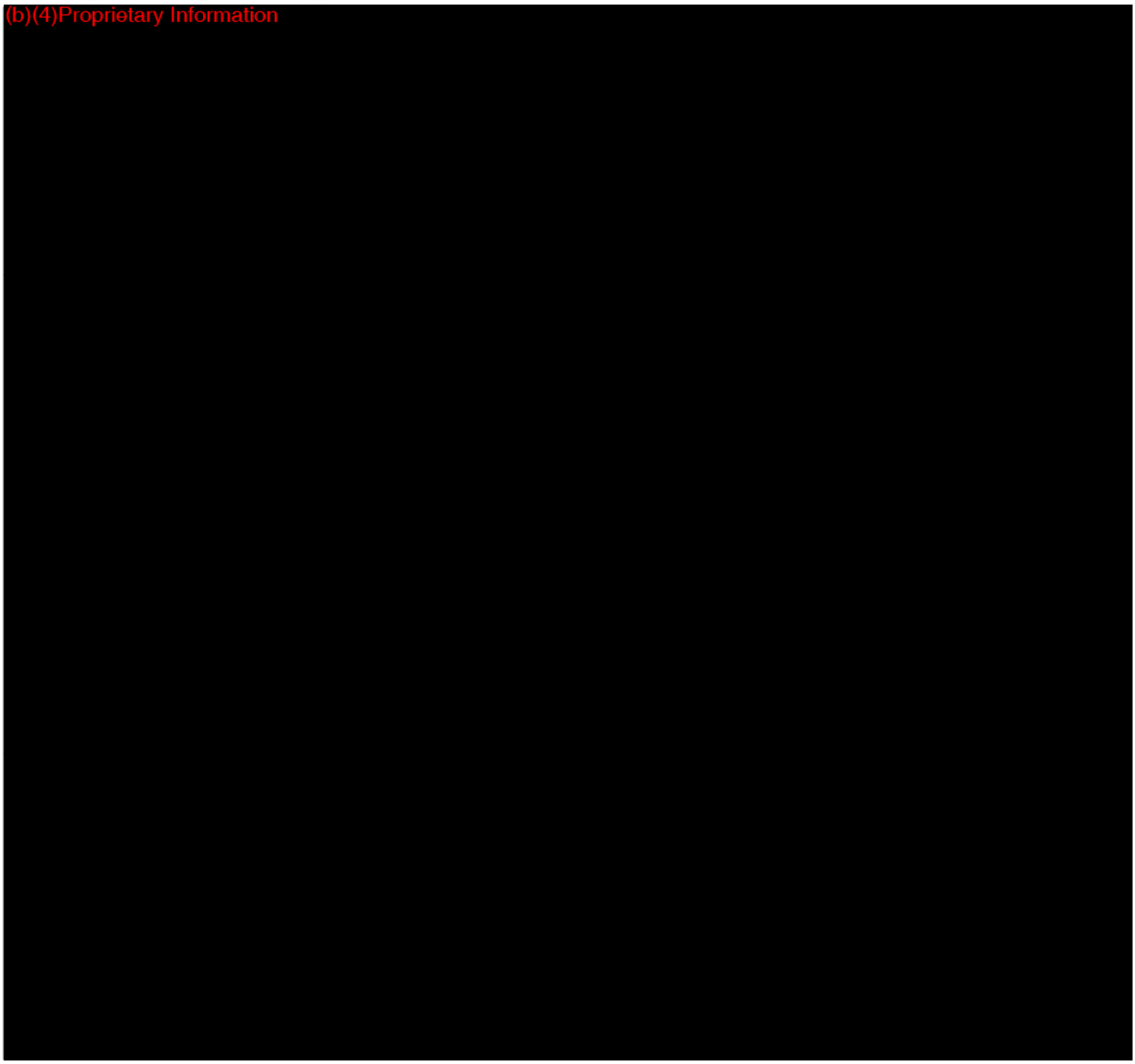

(b)(4)Proprietary Information **Test Results**

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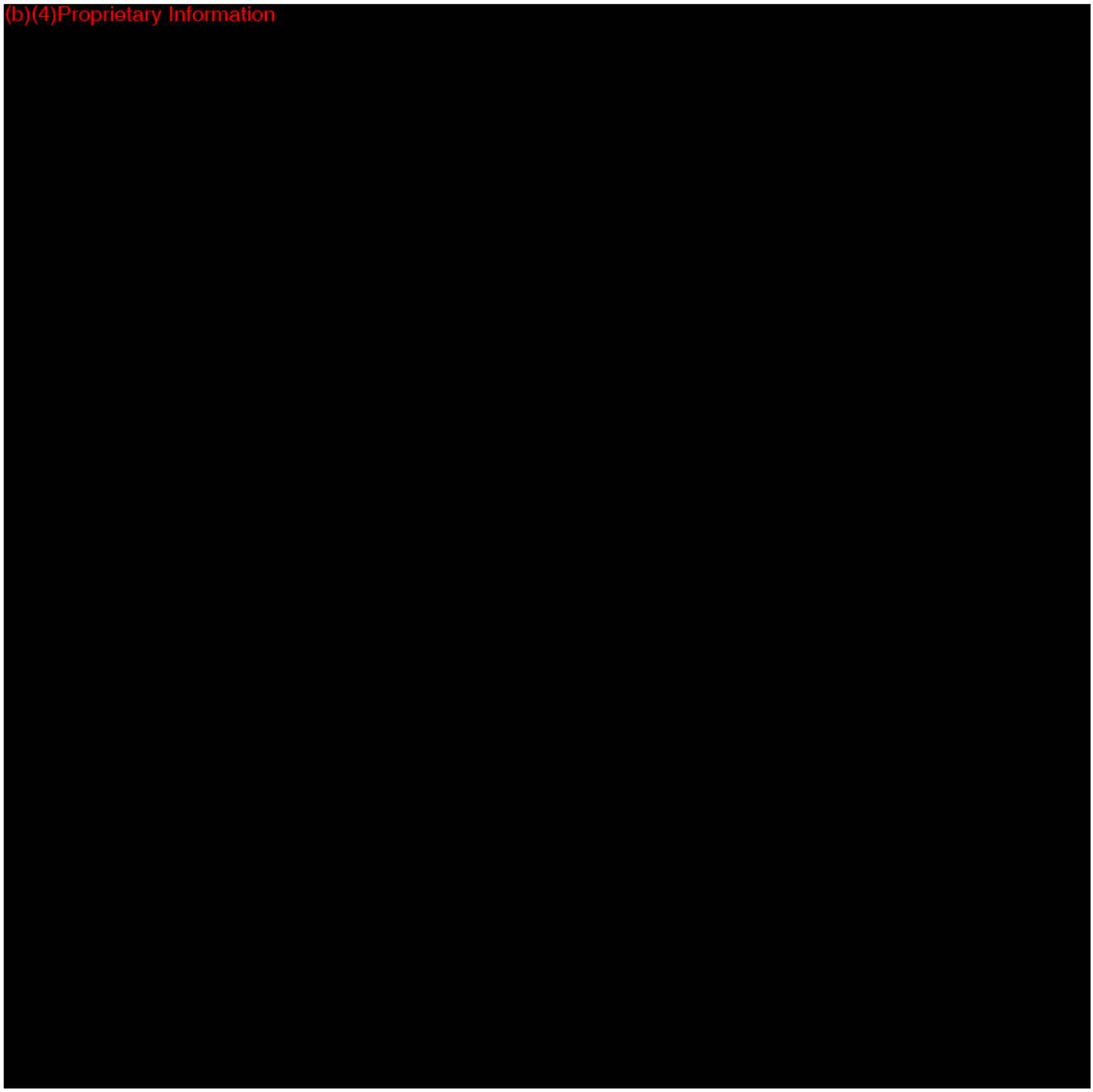

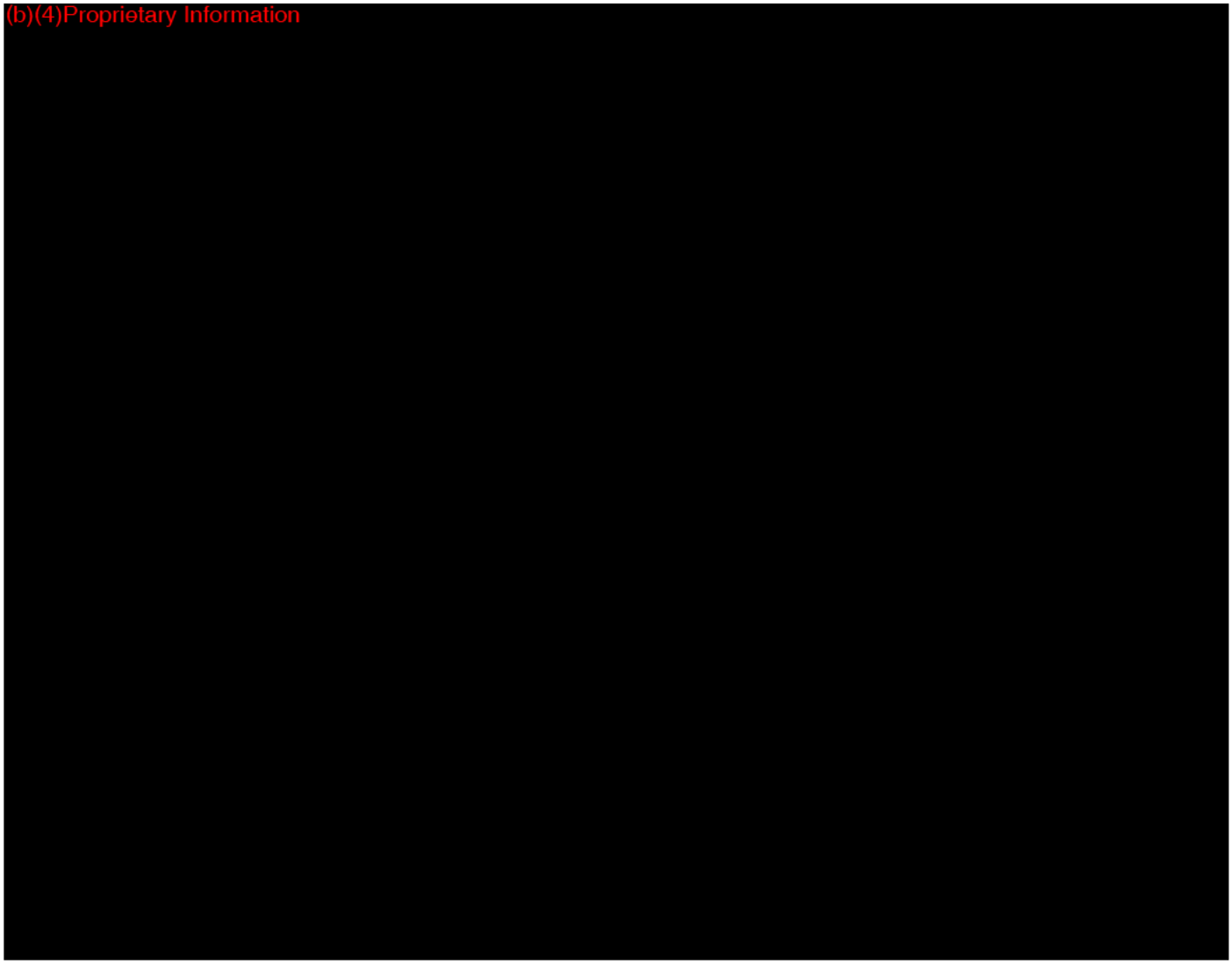

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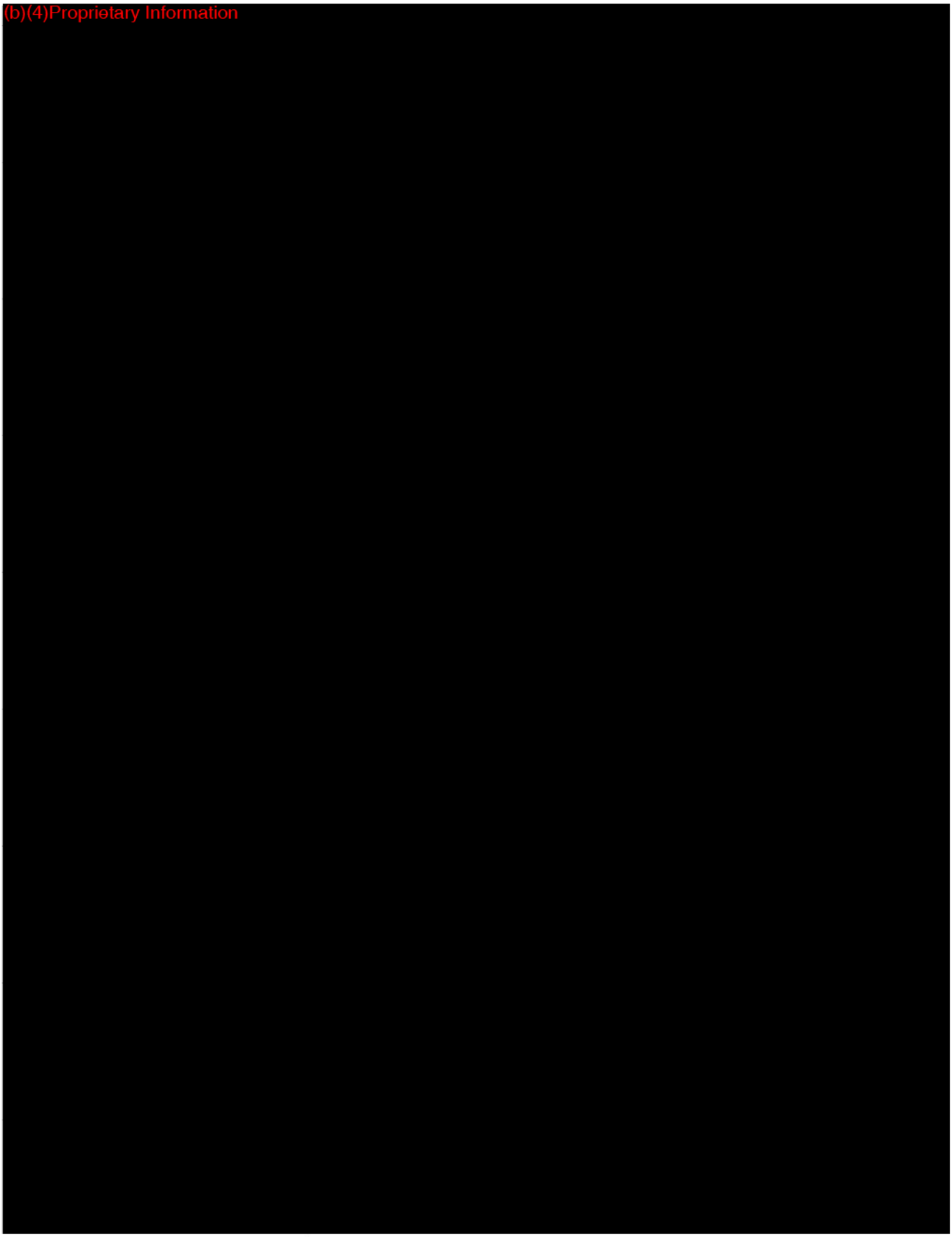

Wavelength Measurements

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System attempted to attach the file. Please look at attachments to open this file manually.

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theraLASE®
HEALING AT THE SPEED OF LIGHT™

TLC-2000 Thermal Tests

June 24, 2015

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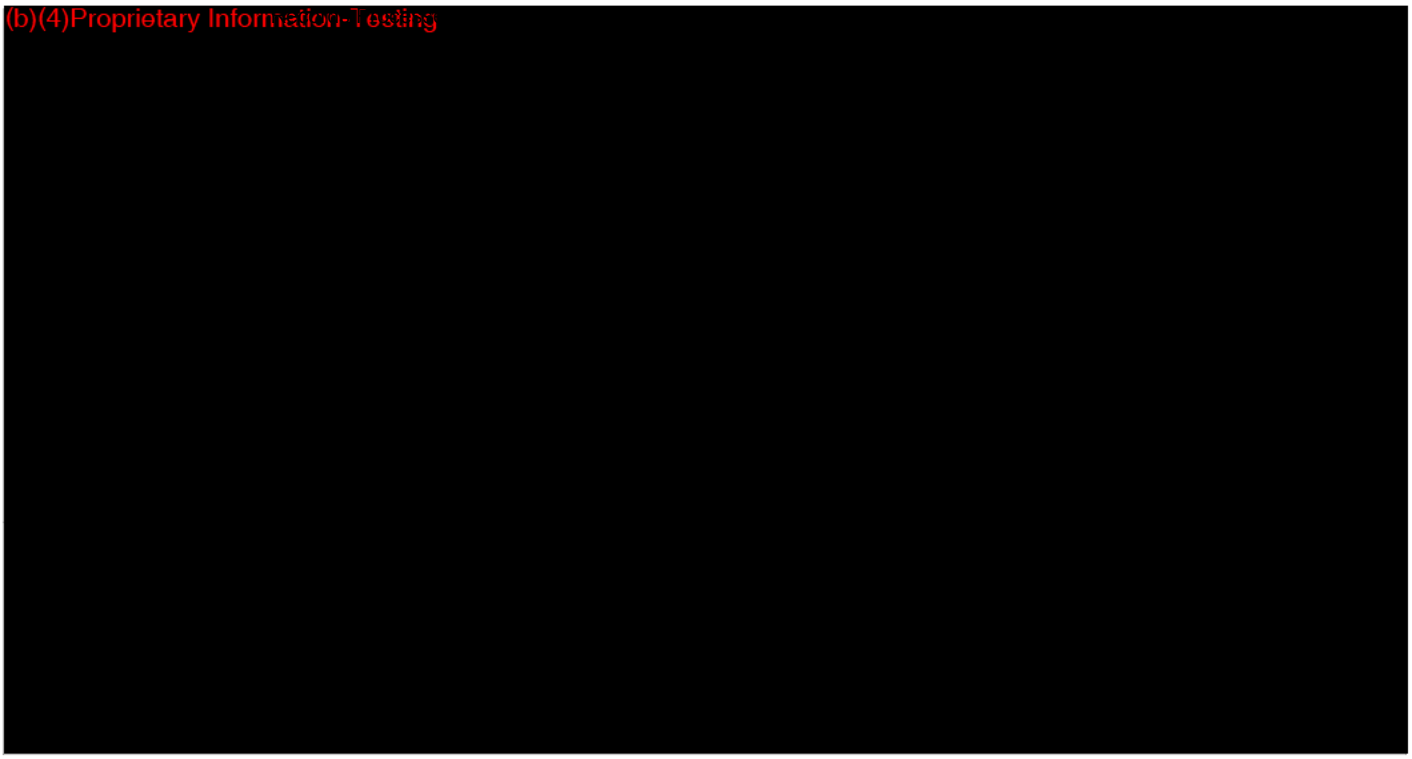

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Sampling Rate: 0.5
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Device Serial Number:
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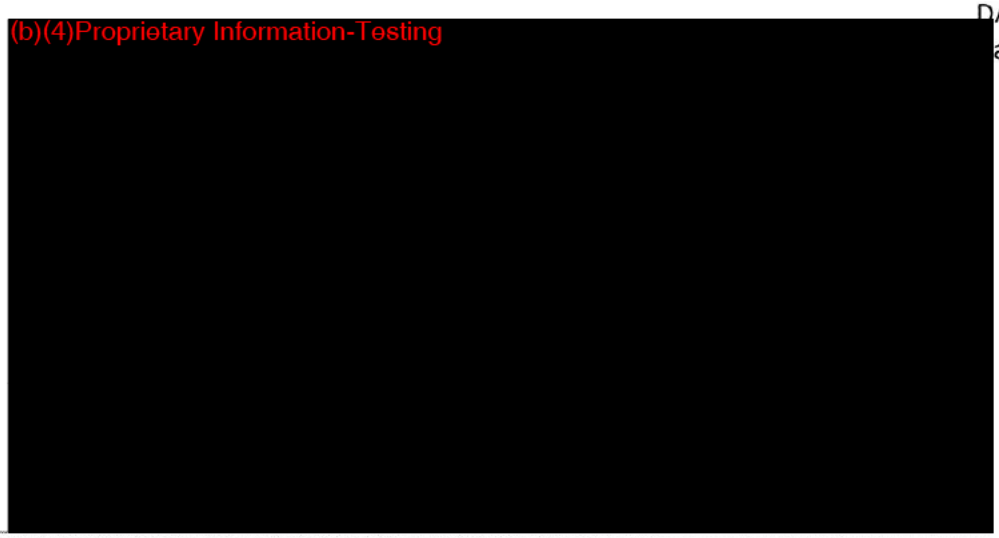

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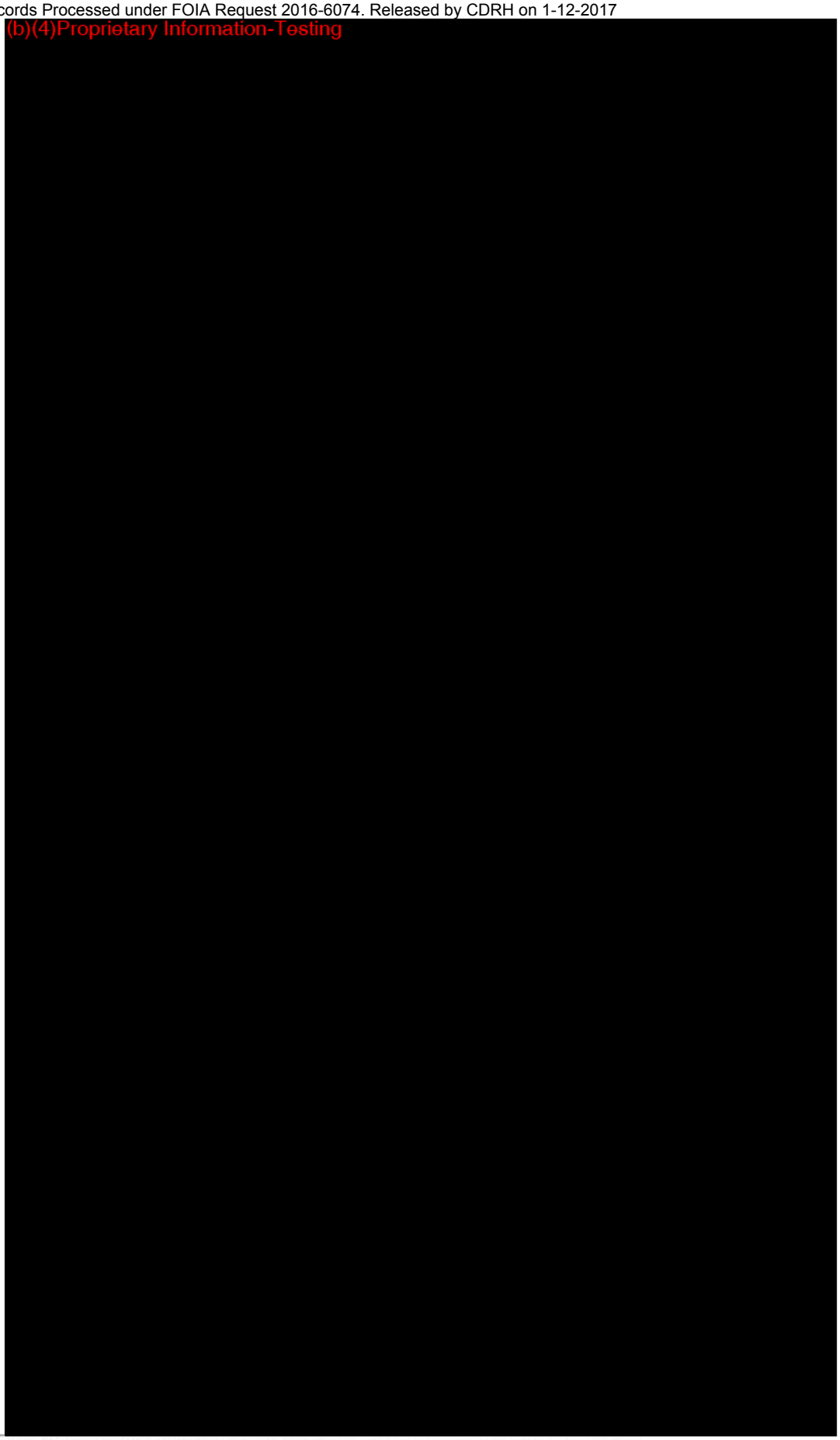

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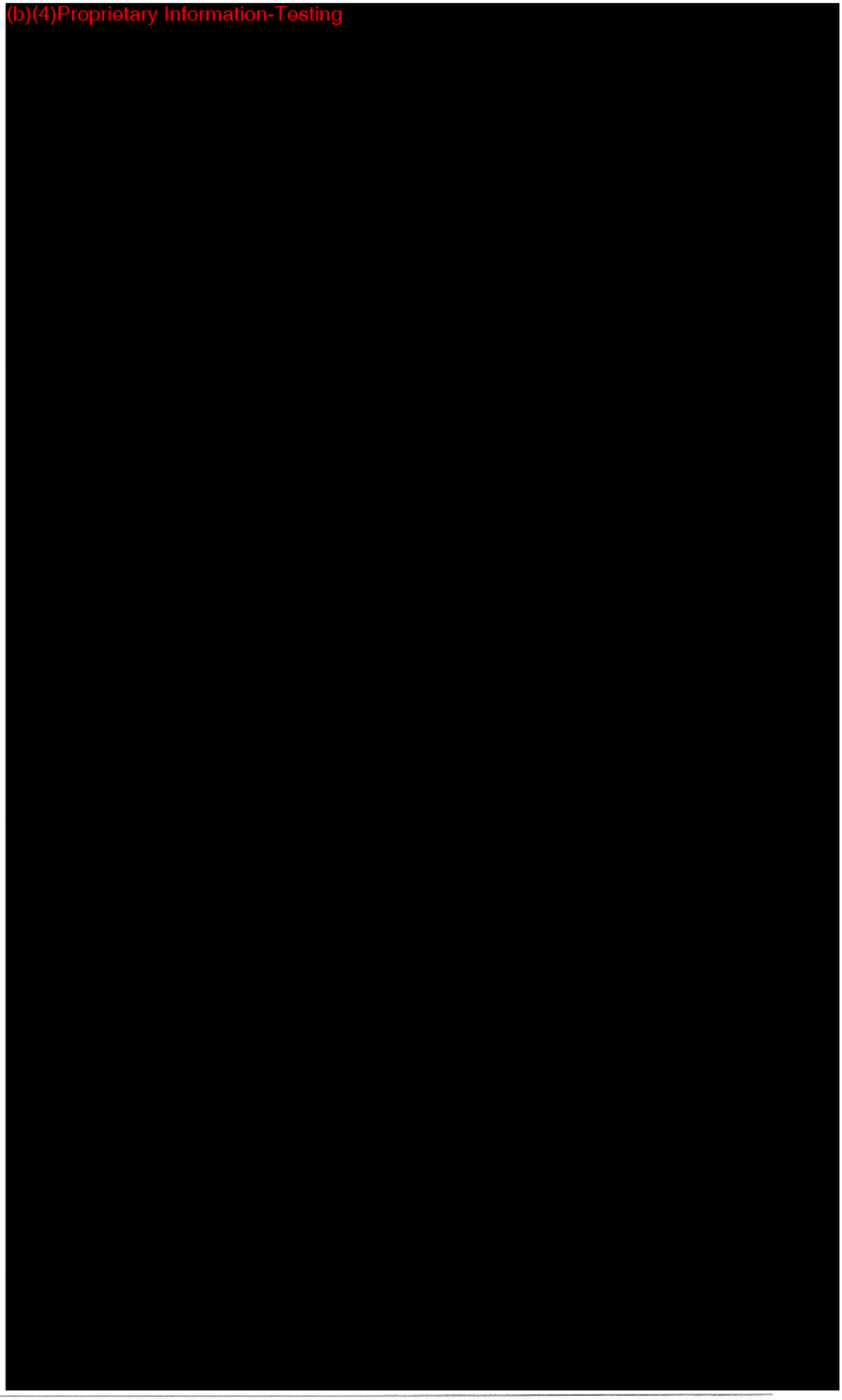

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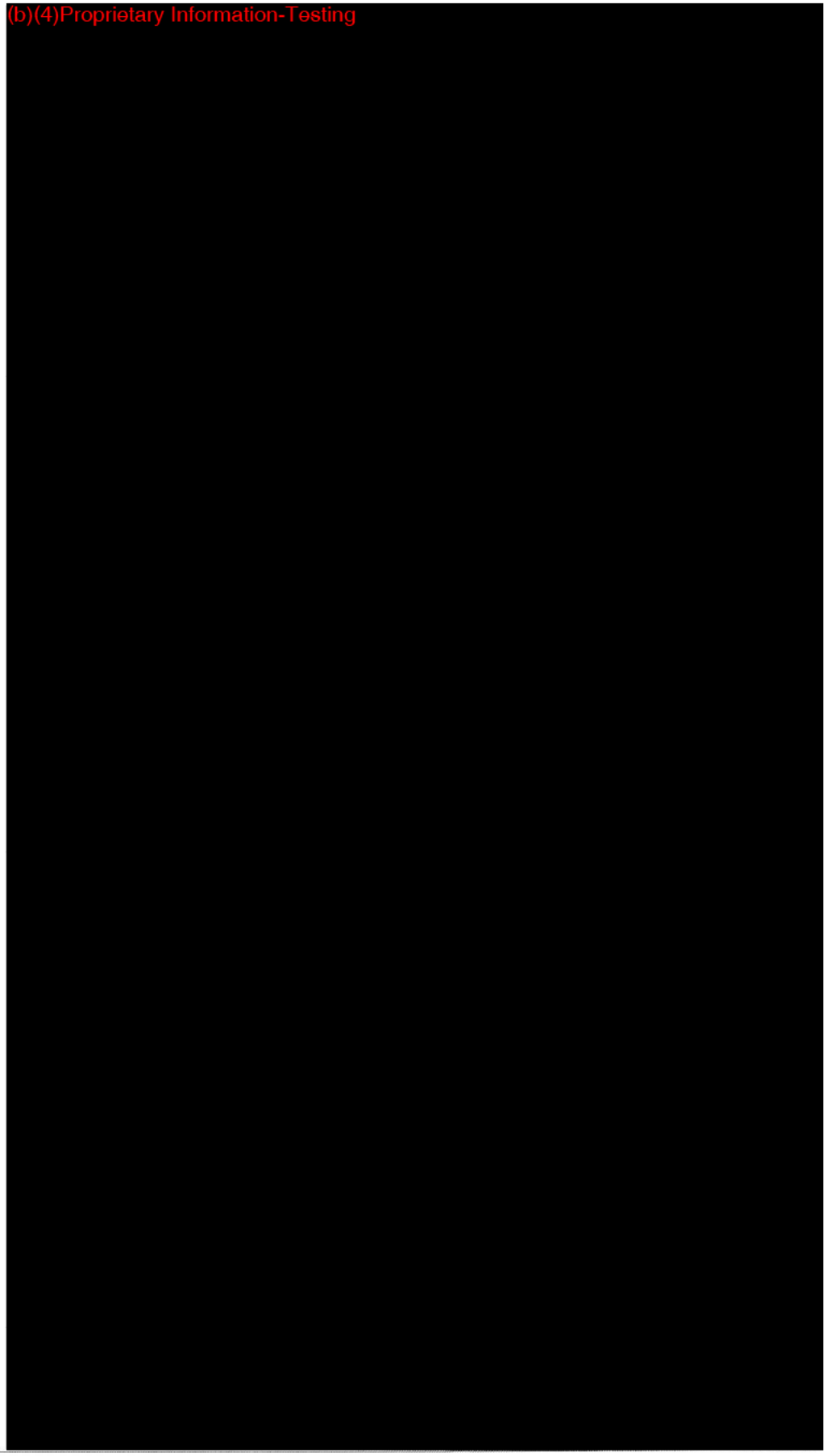

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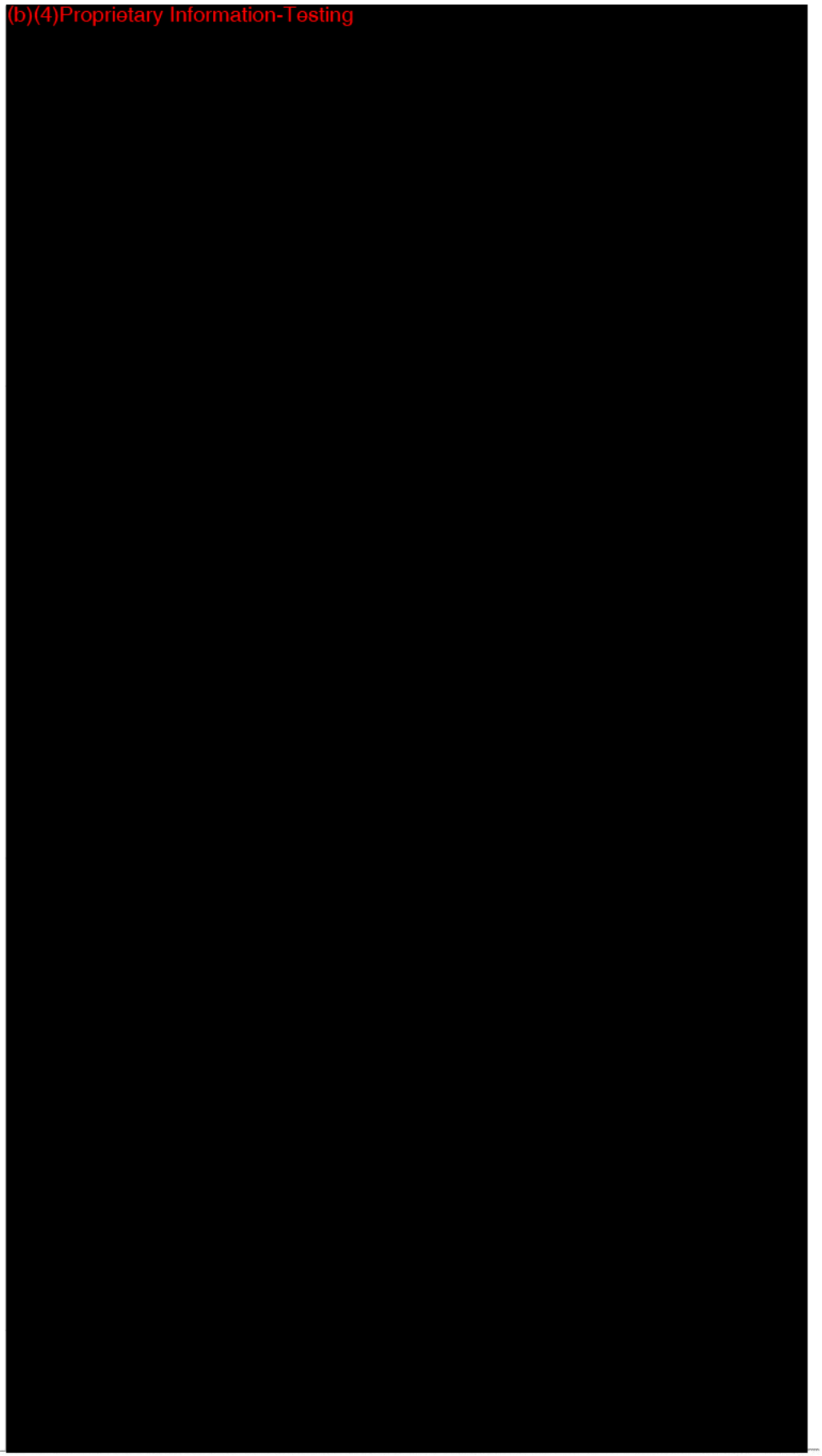

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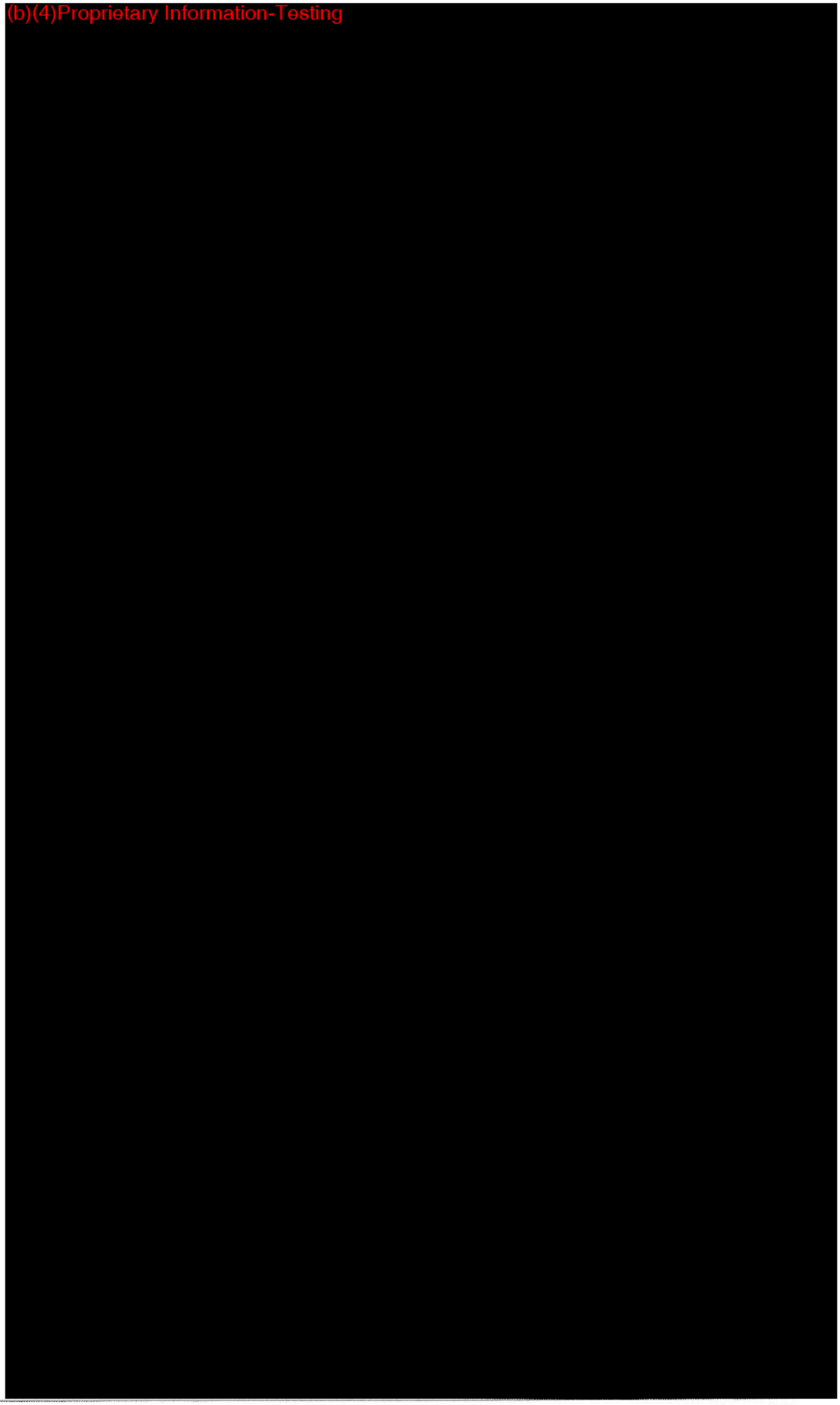

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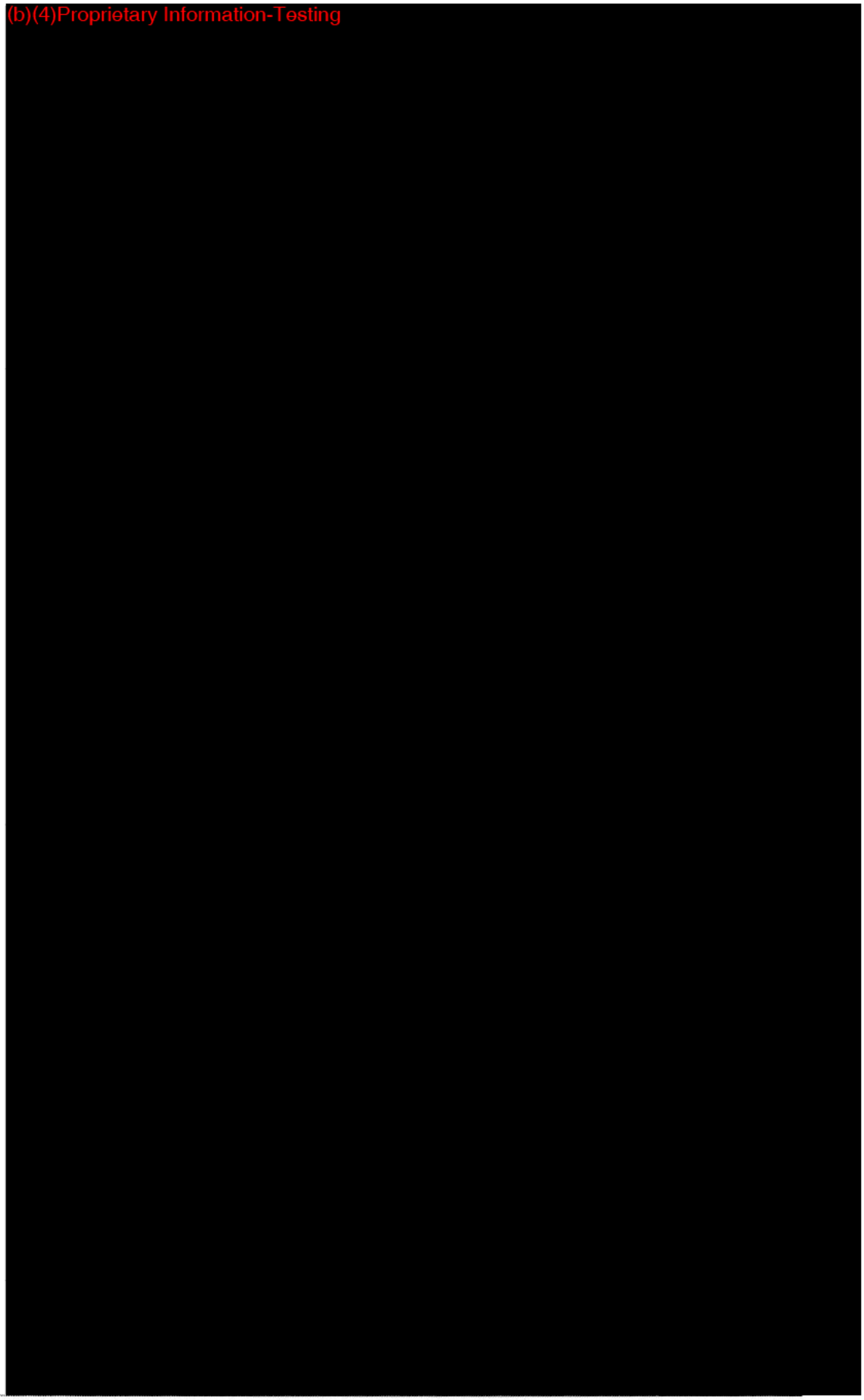

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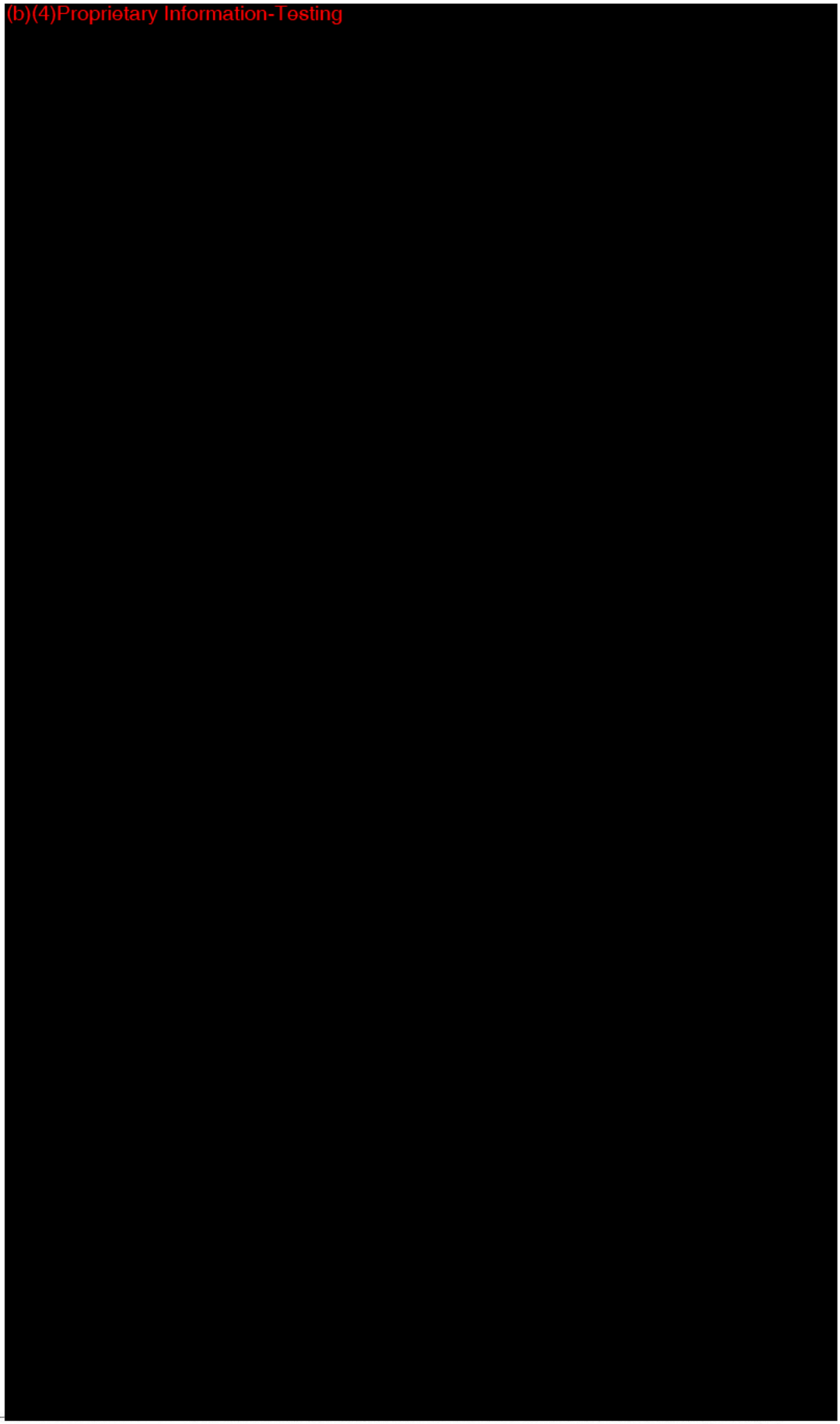

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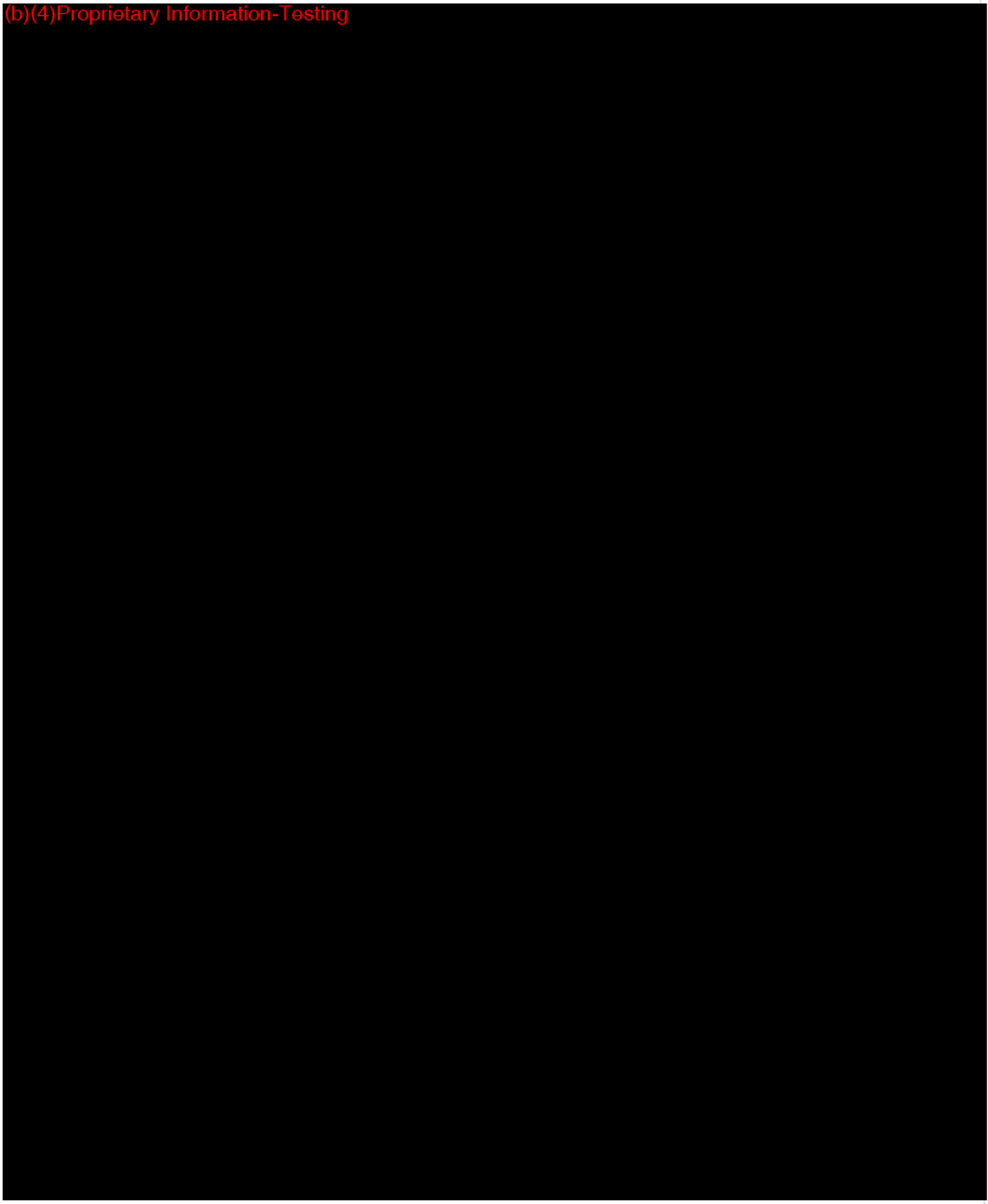

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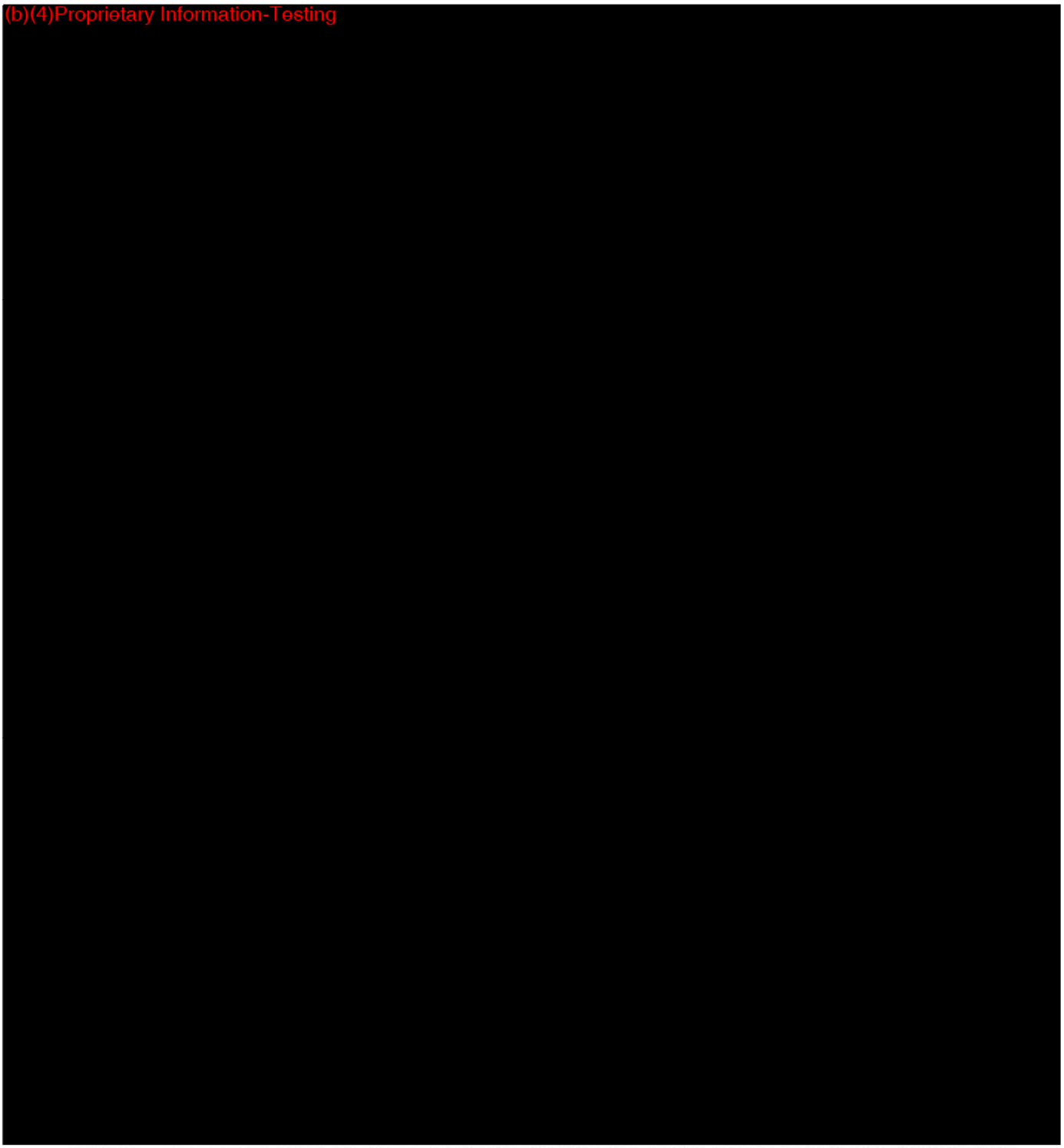
TLC-2000 Skin Temperature versus Power Level

(b)(4)Proprietary Information-Testing

Specification

(b)(4)Proprietary Information-Testing



Specification

(b)(4)Proprietary Information-Testing

Test Results

(b)(4)Proprietary Information-Testing

Observations:

(b)(4)Proprietary Information-Testing

Specification

Conclusion:

(b)(4)Proprietary Information-Testing

[redacted]

Usability Evaluation Report

TLC-2000 Therapeutic Laser System

Prepared by:

(b)(4)Proprietary Information-Testing

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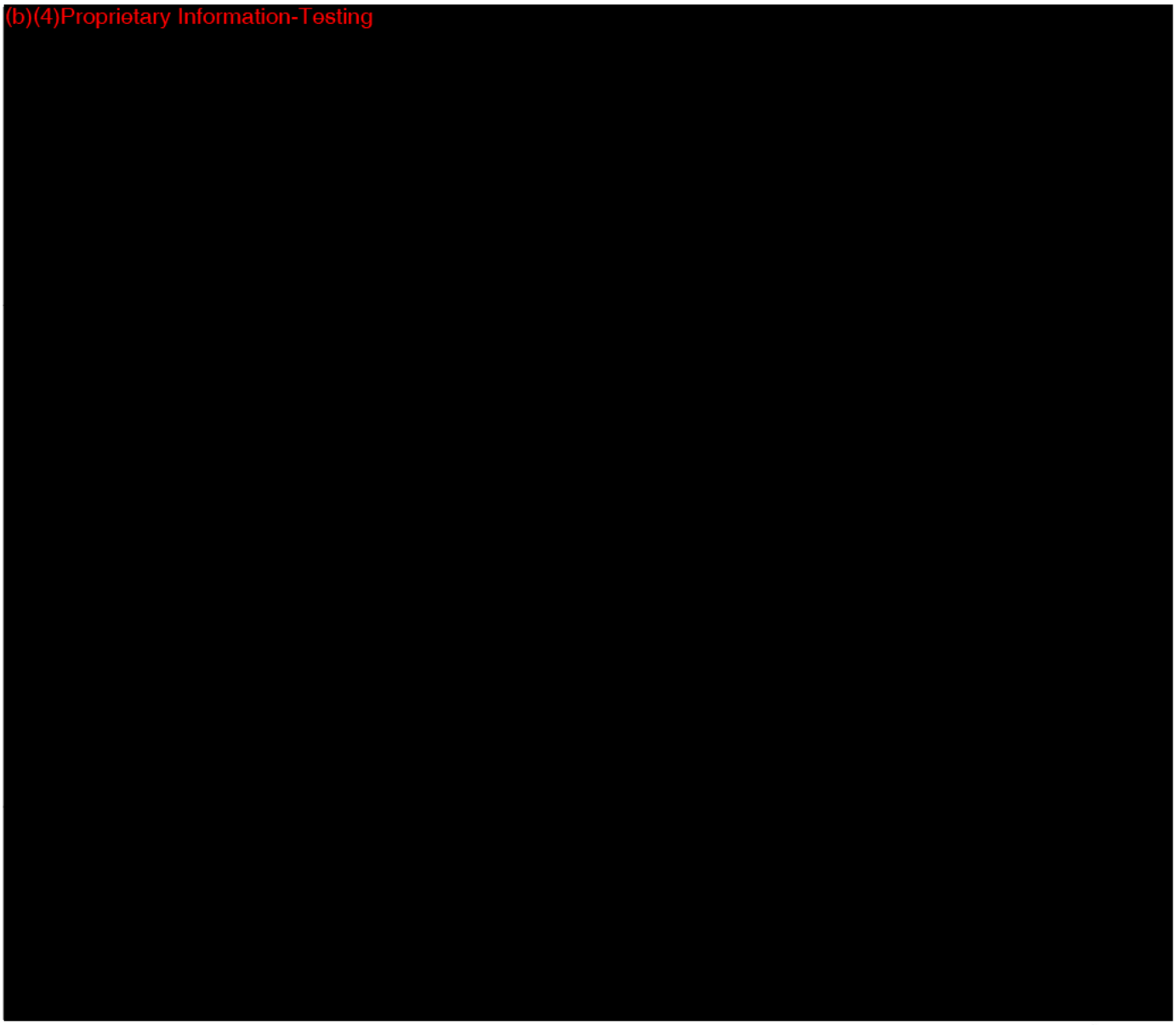
1.0 Medical Device

(b)(4)Proprietary Information-Testing



1.3 Medical Device Description

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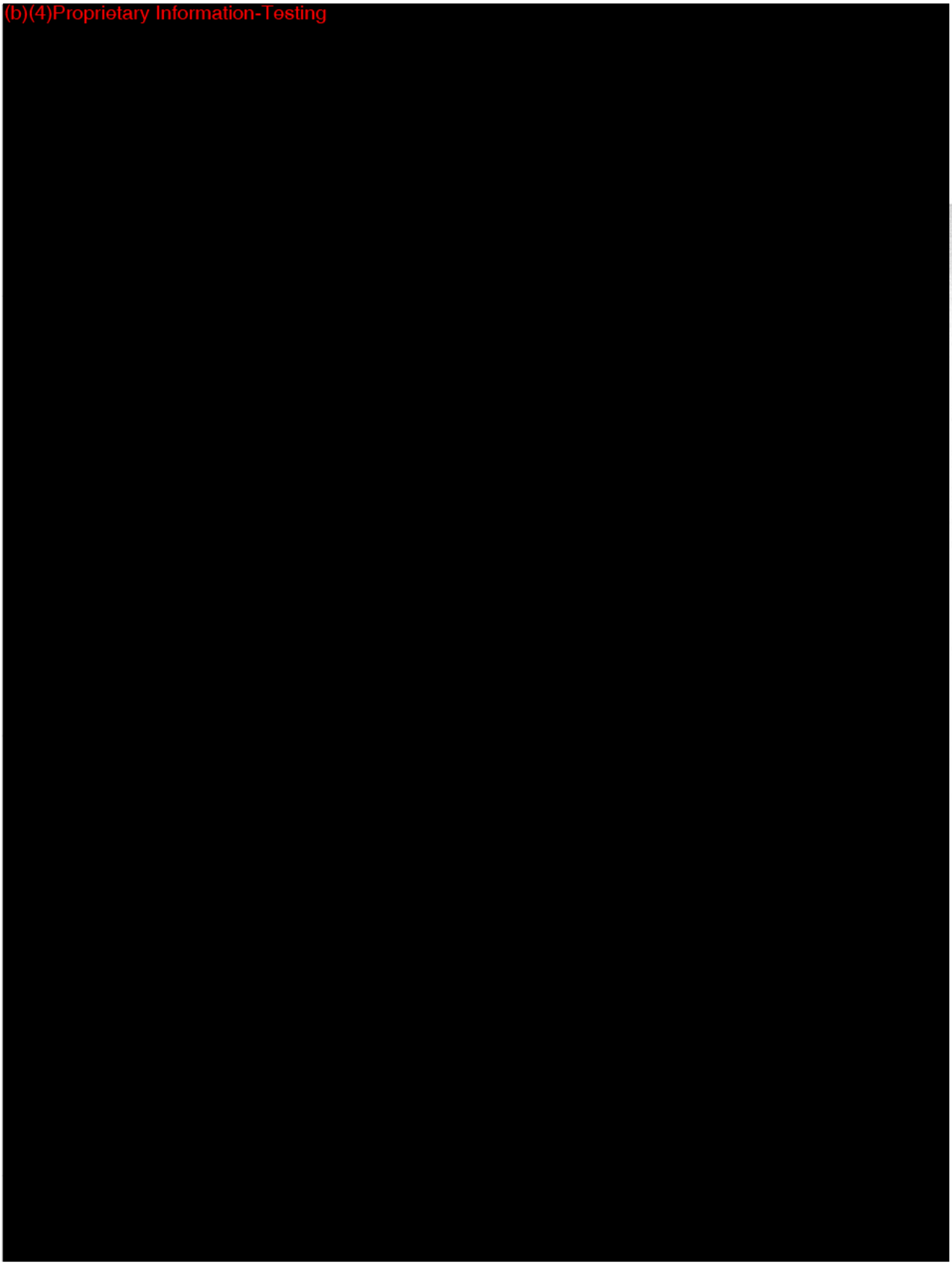

Laser Treatment Probe (TLC-2001):

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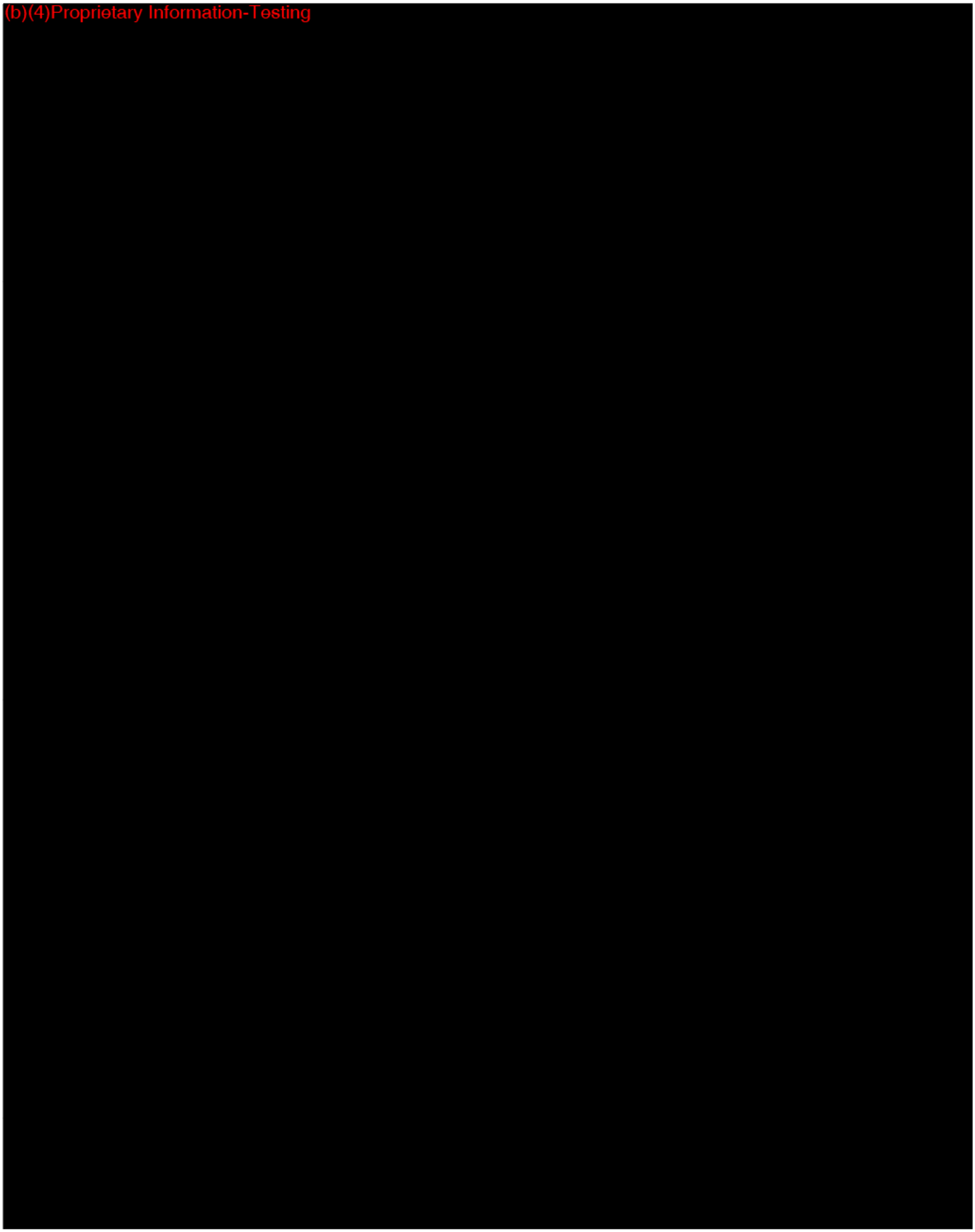


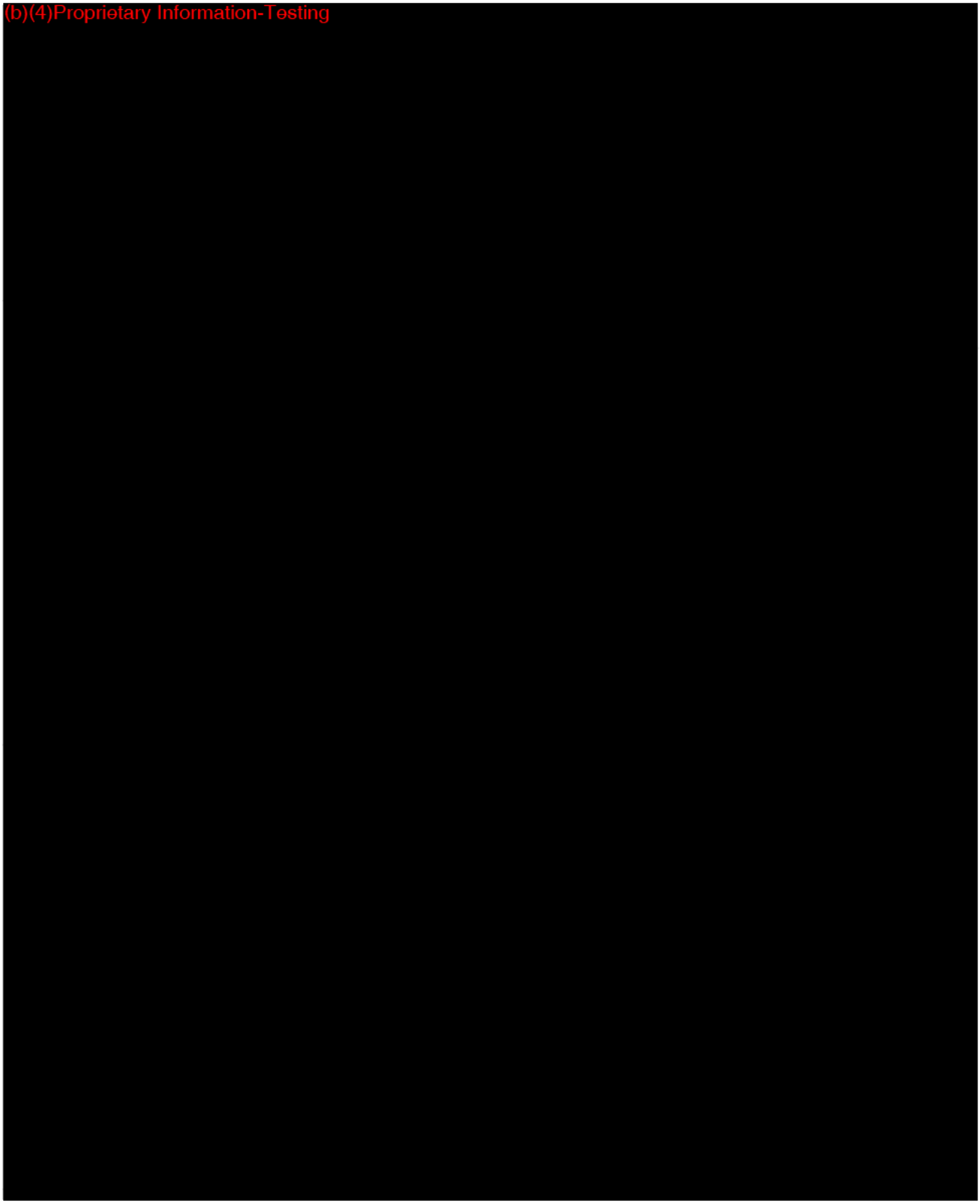
(b)(4)Proprietary Information-Testing

Tablet (TLC-2004):

(b)(4)Proprietary Information-Testing

Power Pack (TLC-2002):

(b)(4)Proprietary Information-Testing



The Power Supply (TLC-2003):

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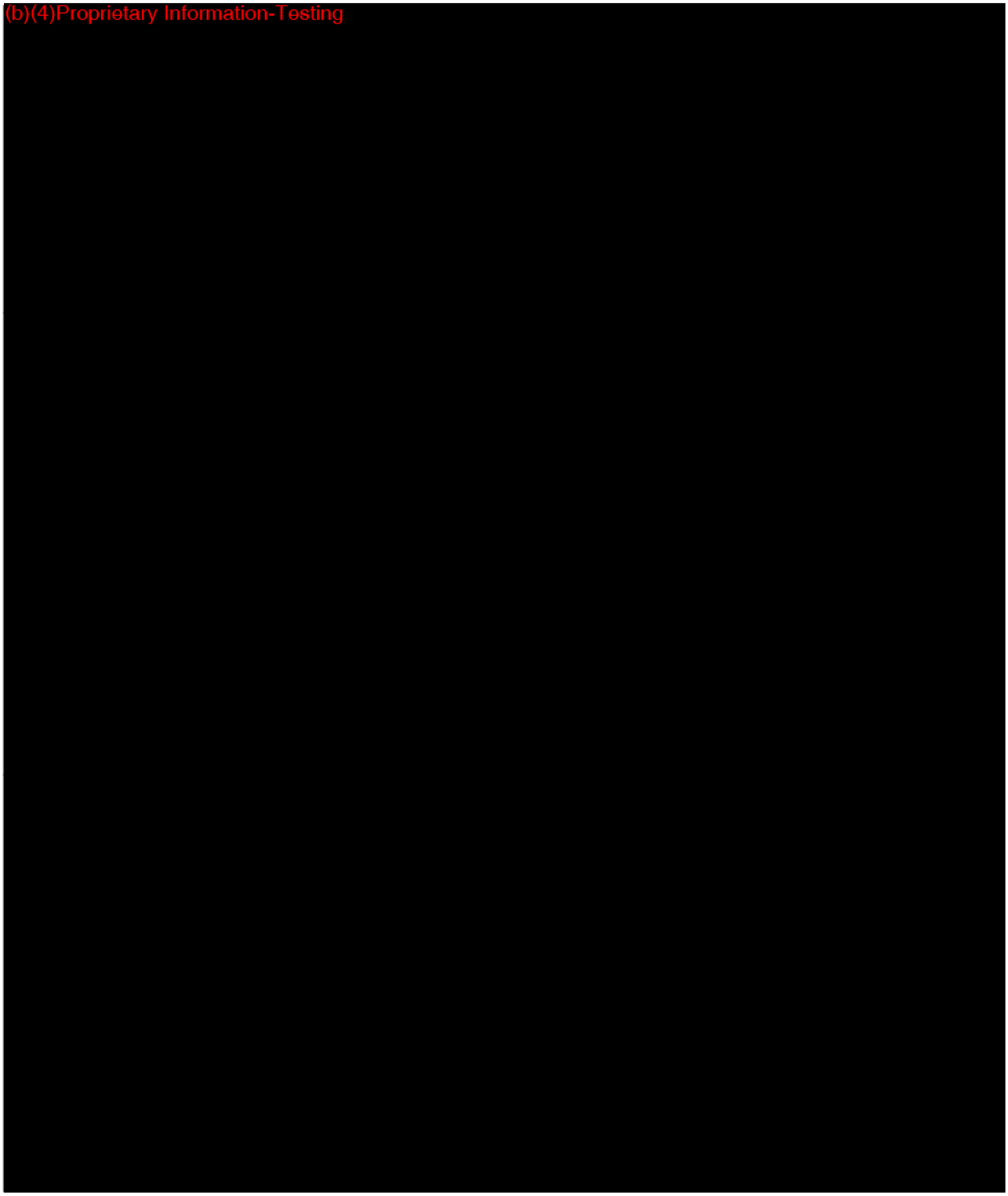

Specifications

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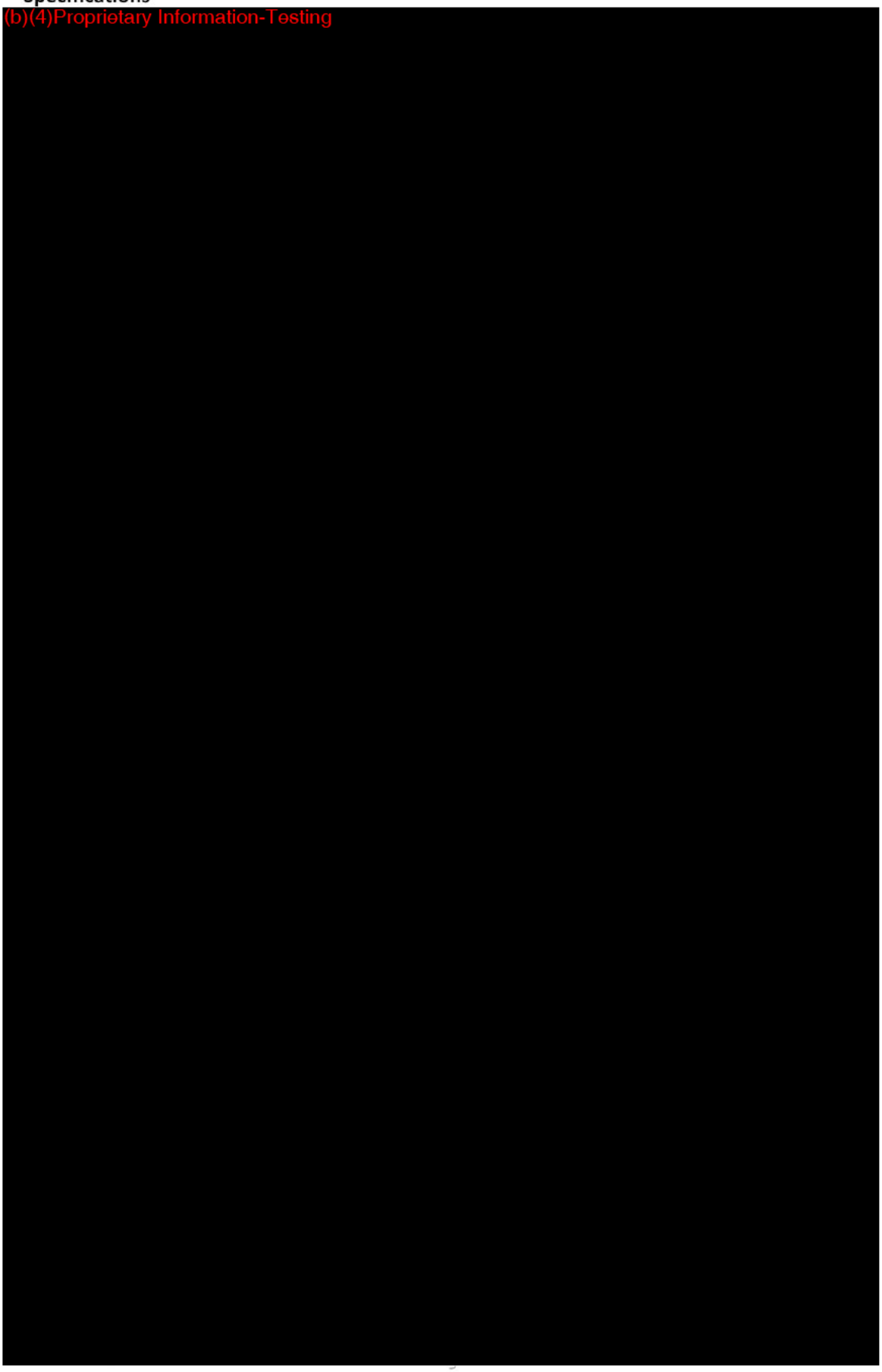

1.4 Intended Medical Use

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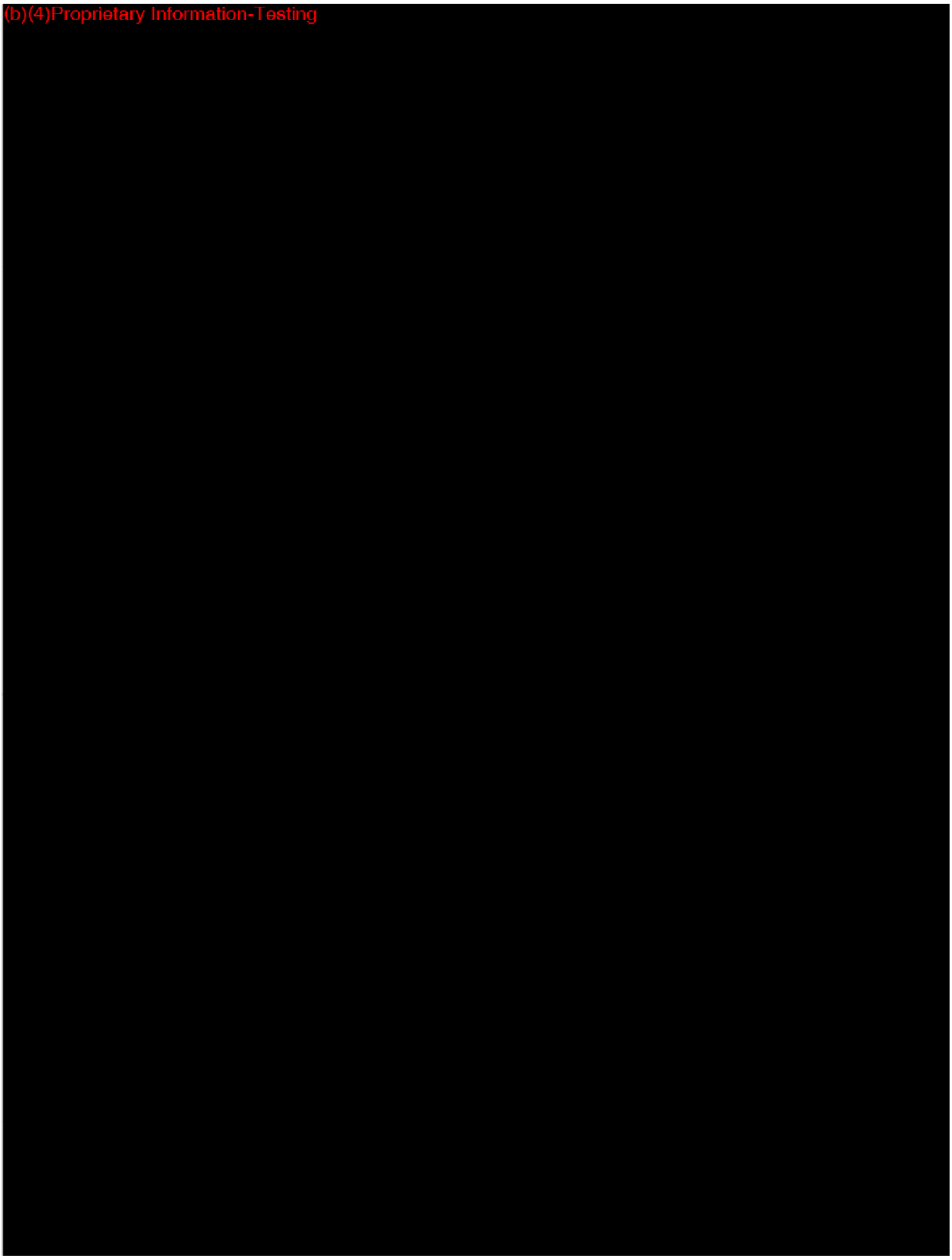

2.0 DUI

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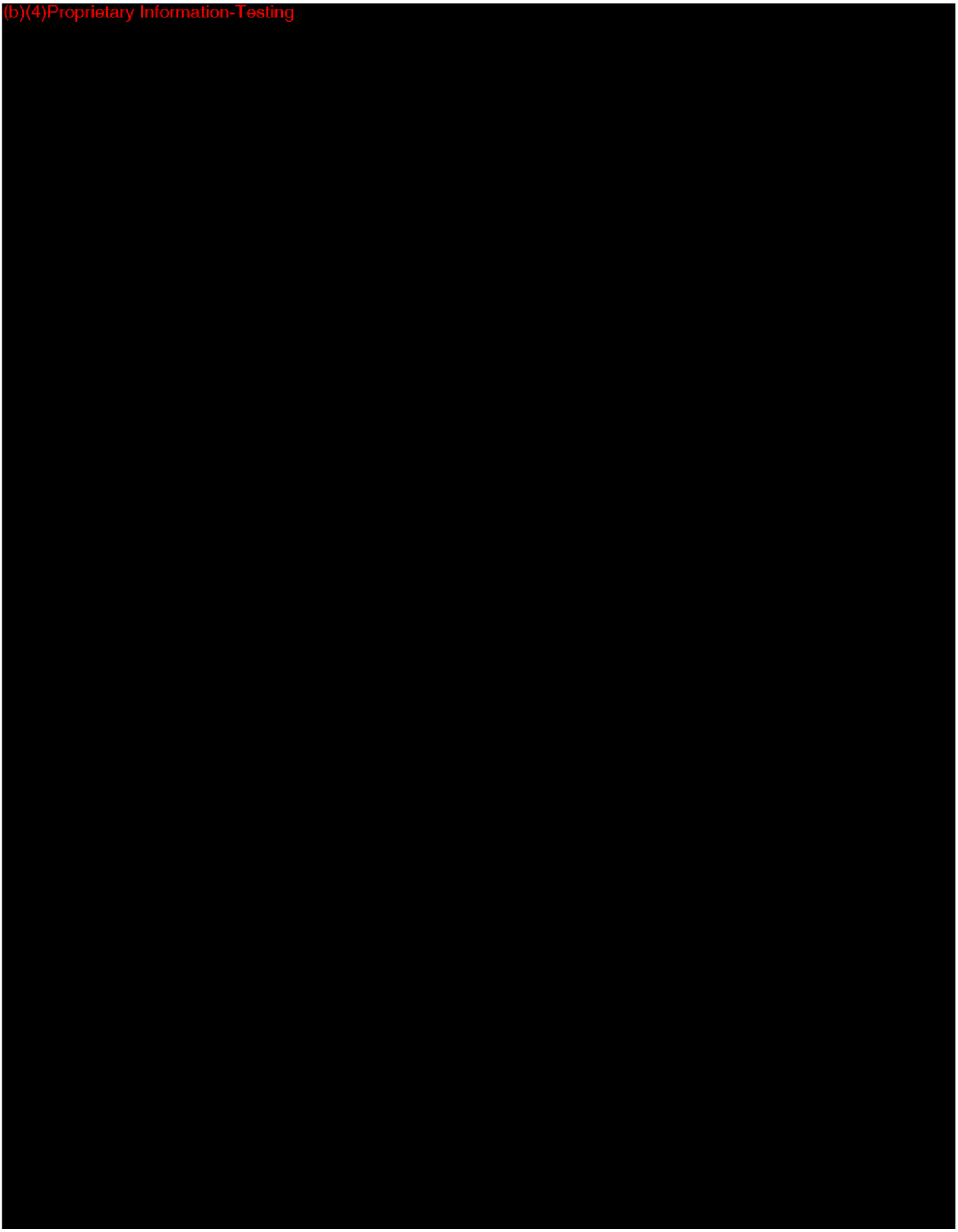
(b)(4)Proprietary Information-Testing



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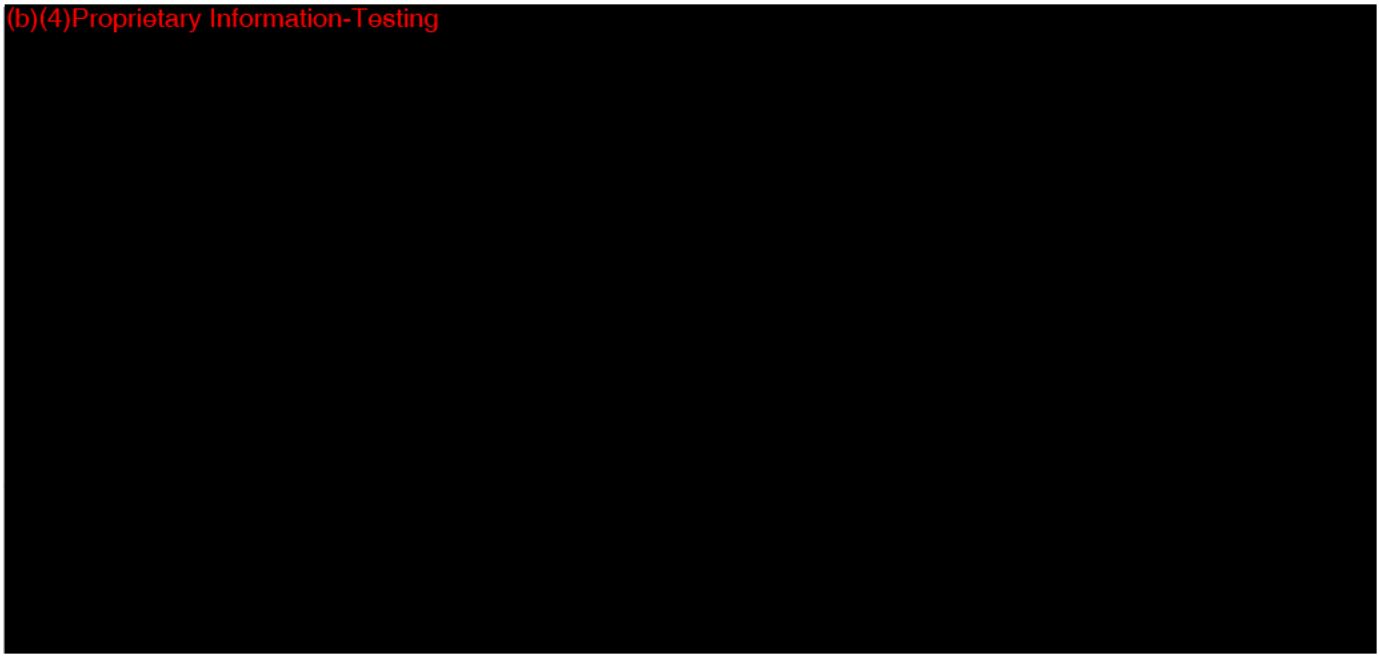

4.0 DUI Design

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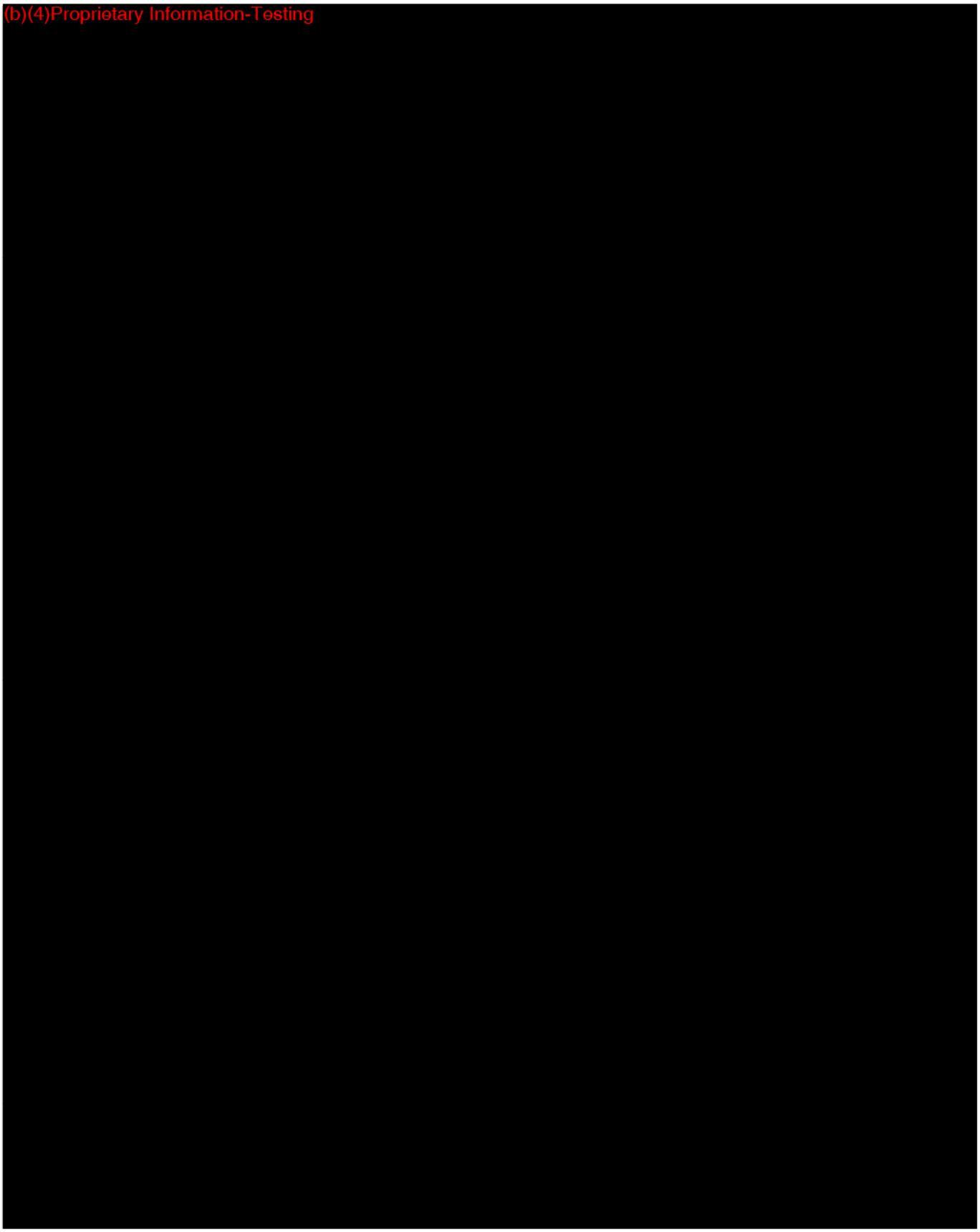
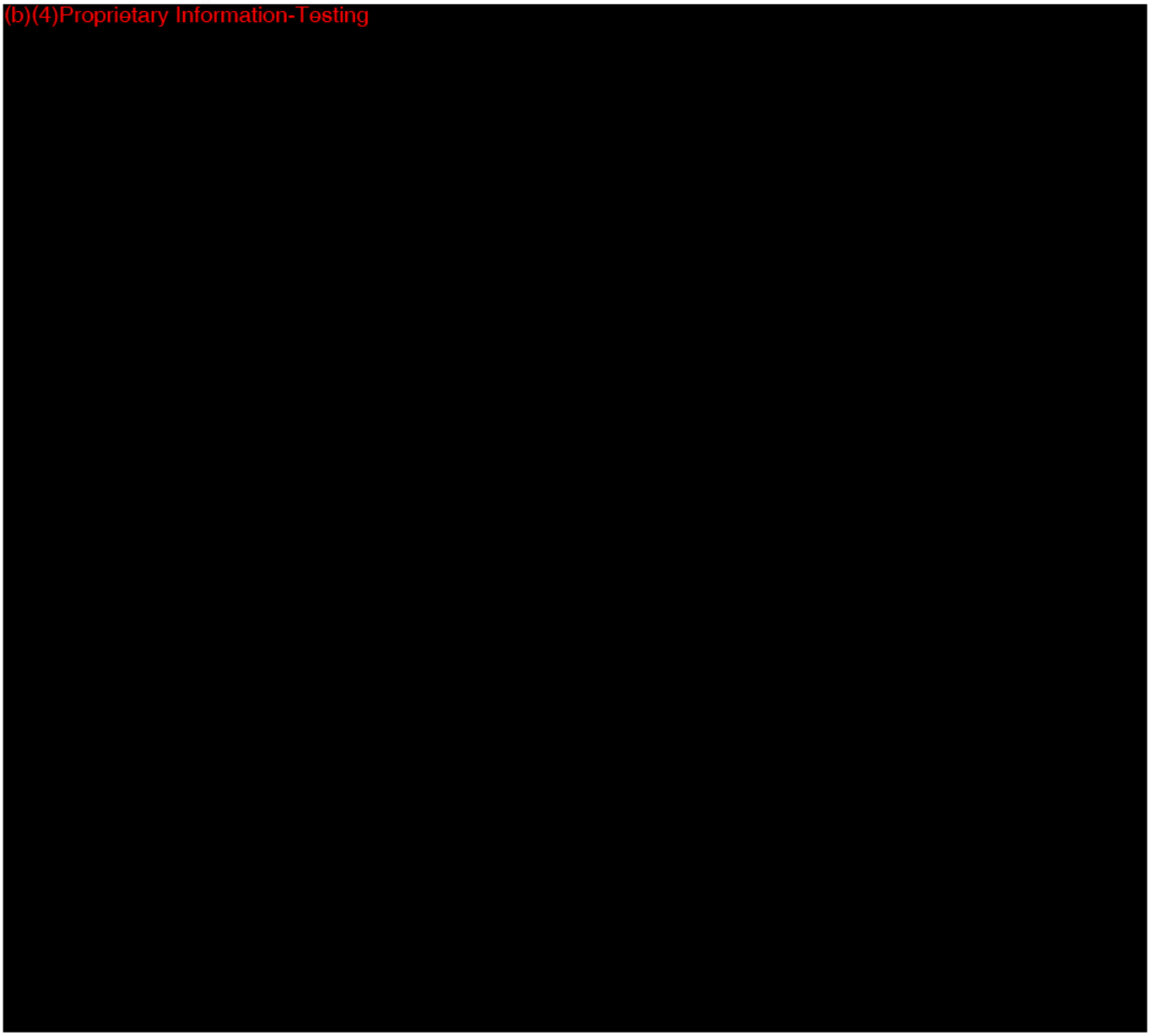


5.0 Evaluation Planning

(b)(4)Proprietary Information-Testing



6.0 Validation Testing

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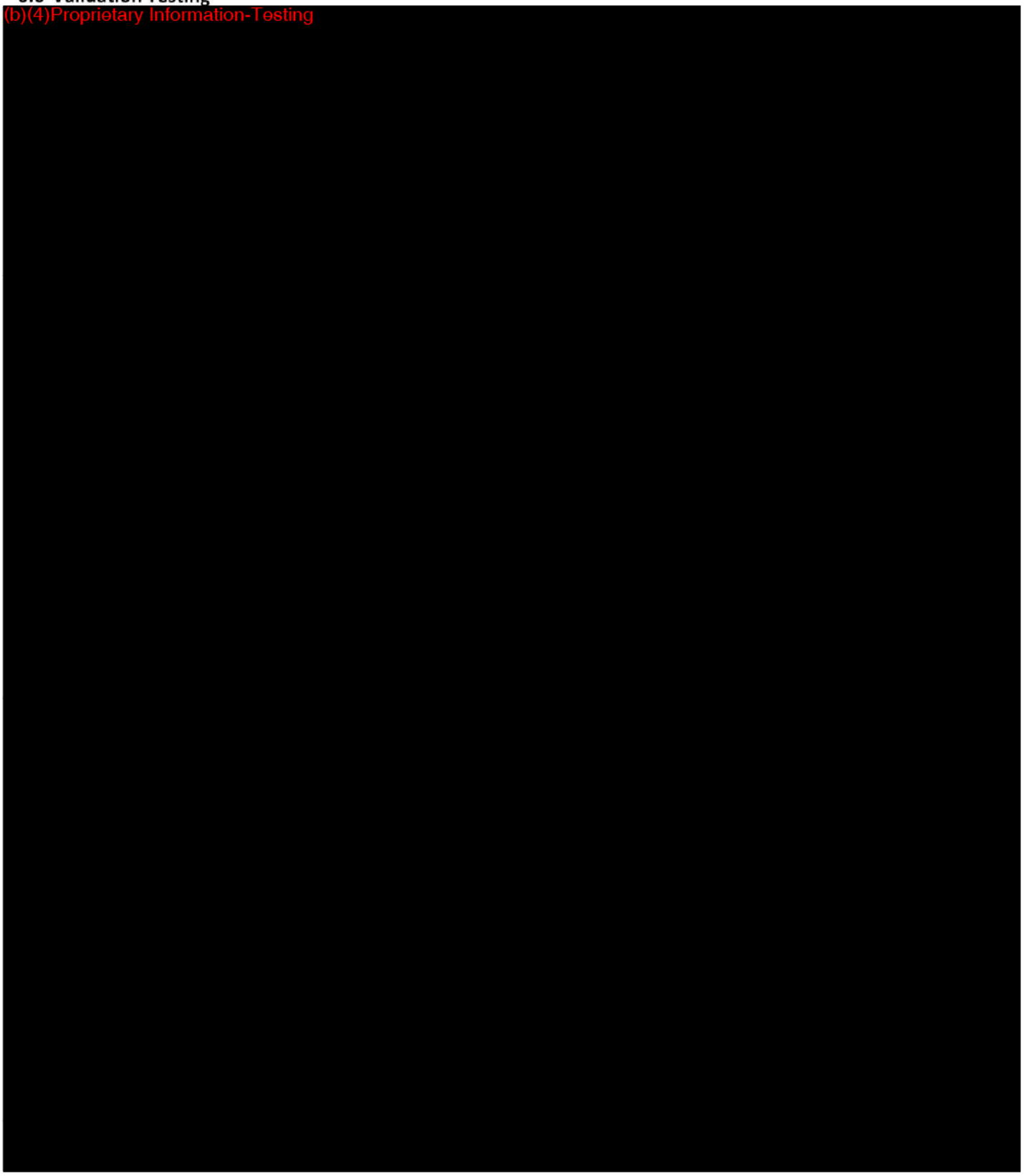

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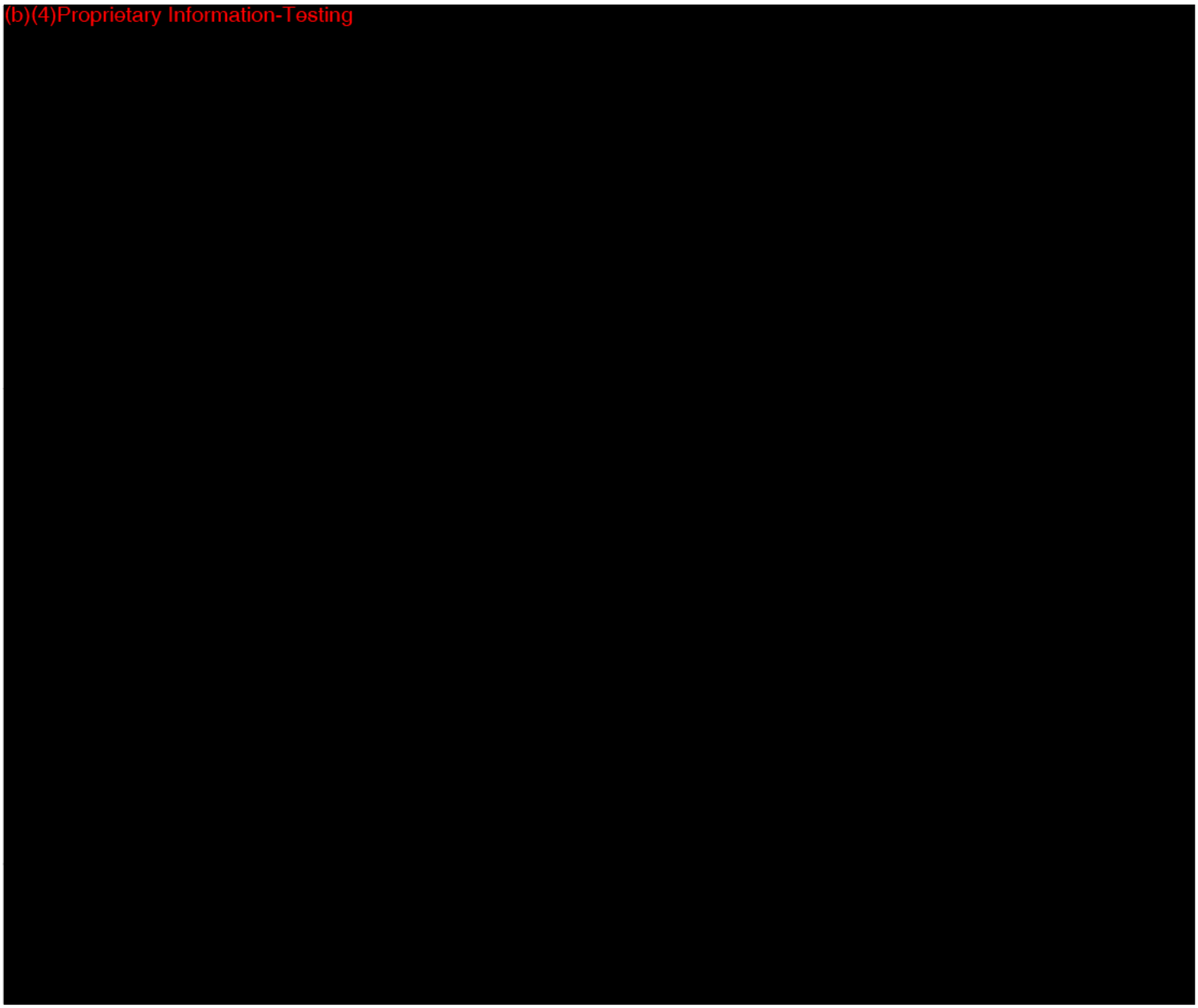

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October 29, 2015

K151816/S001

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10903 New Hampshire Avenue
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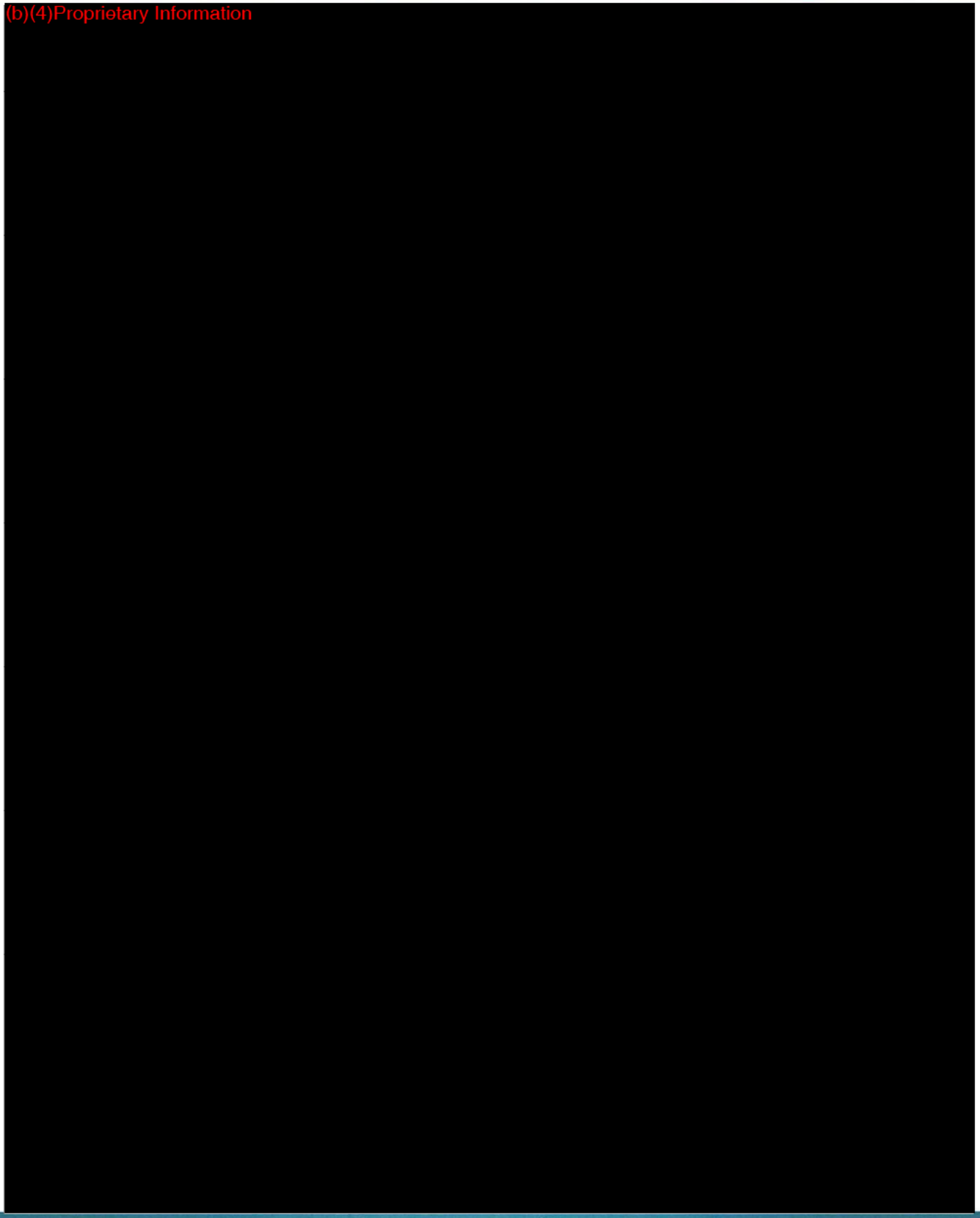

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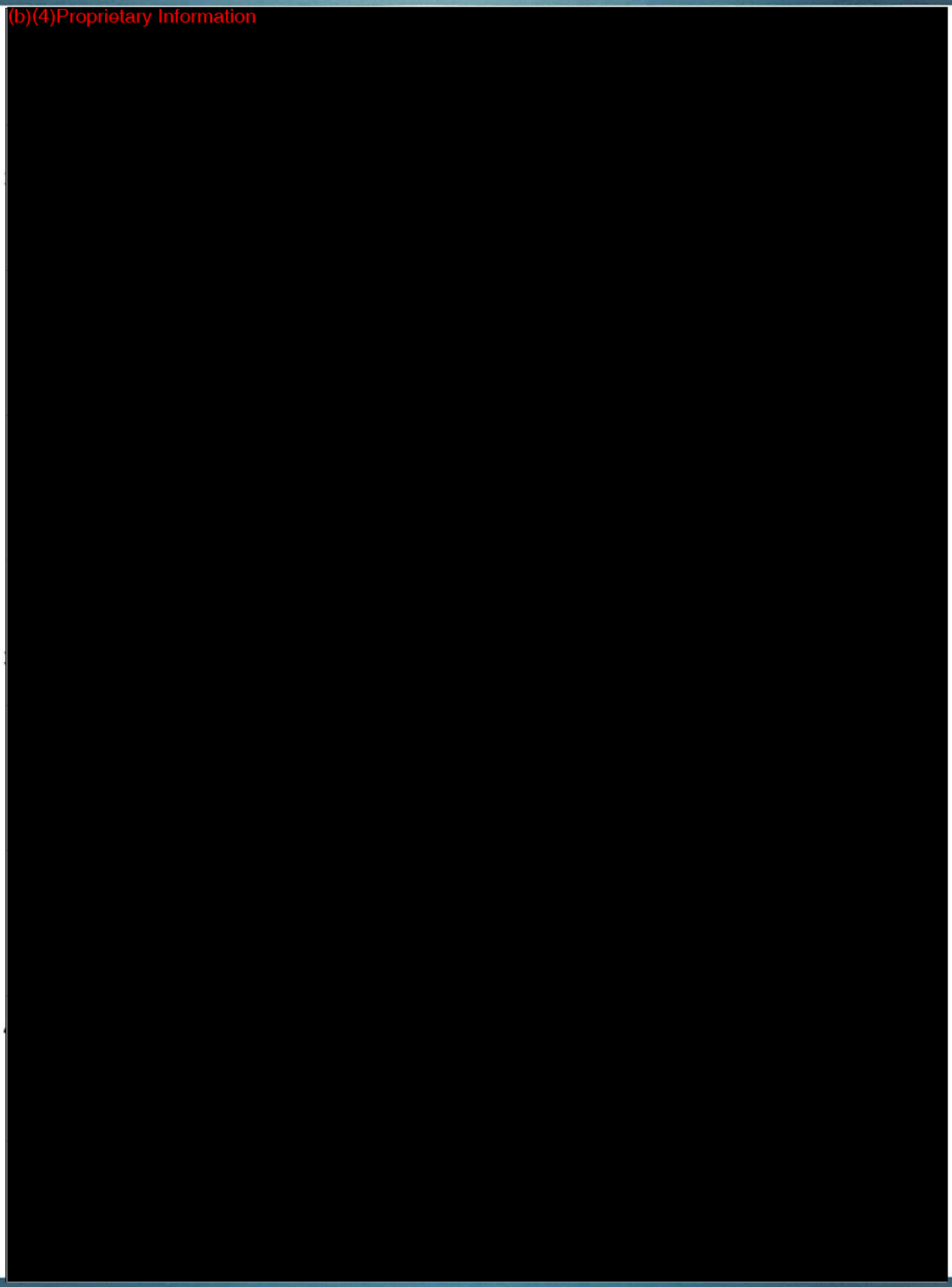

Please refer to the attached revised documents:

(b)(4)Proprietary Information

[redacted]

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(b)(4)Proprietary Information

[redacted]

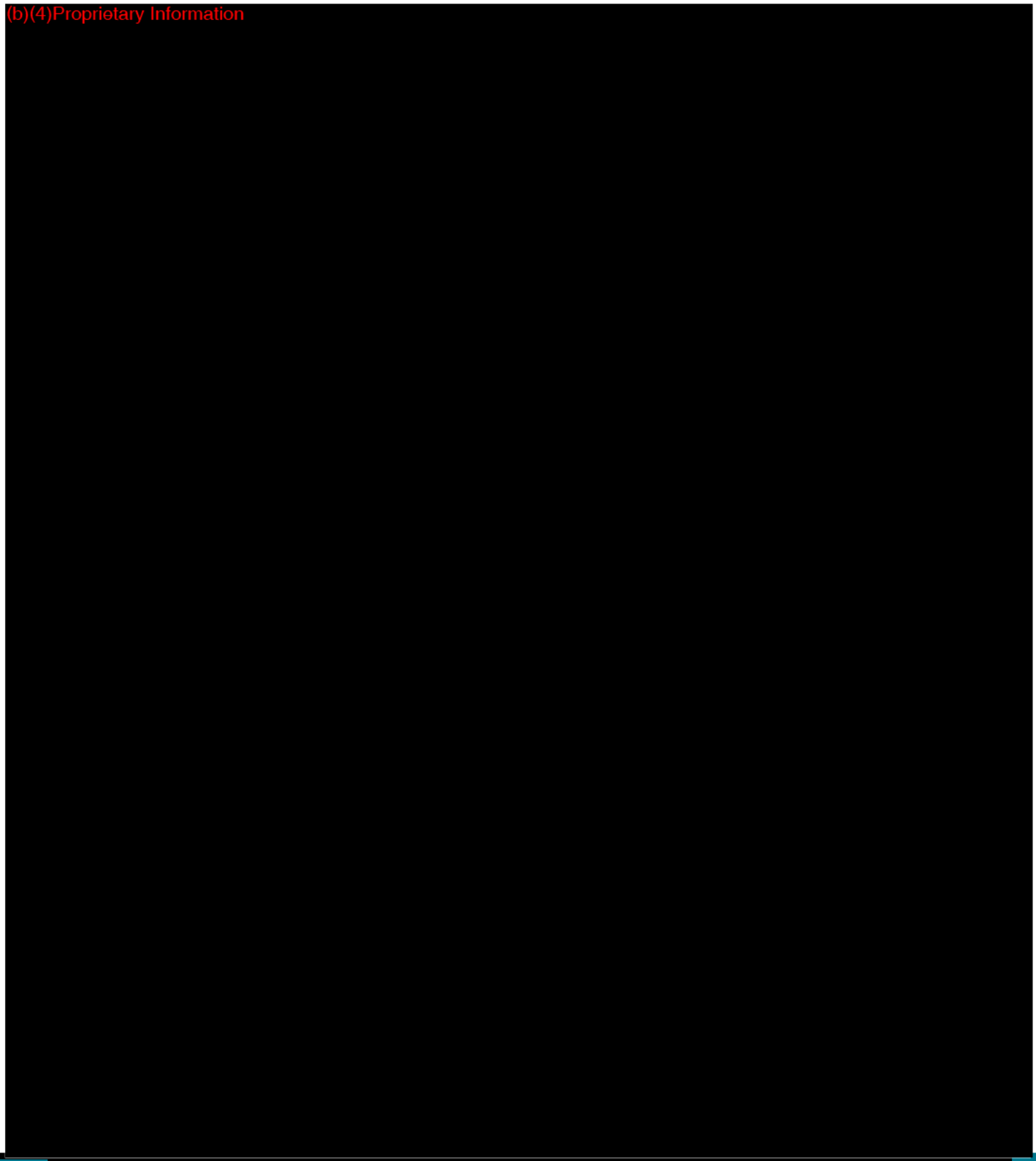
018_Instructions for Use
020_Substantial Equivalence
024_A_TLC2000 Operation Manual

(b)(4)Proprietary Information

[redacted]

Please refer to the attached revised documents:

(b)(4)Proprietary Information



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151816

Device Name
TLC-2000 Therapeutic Medical Laser System

Indications for Use *(Describe)*
The Theralase TLC-2000 Therapeutic Medical Laser System is indicated for adjunctive use in the temporary relief of pain associated with knee disorders with standard chiropractic practice.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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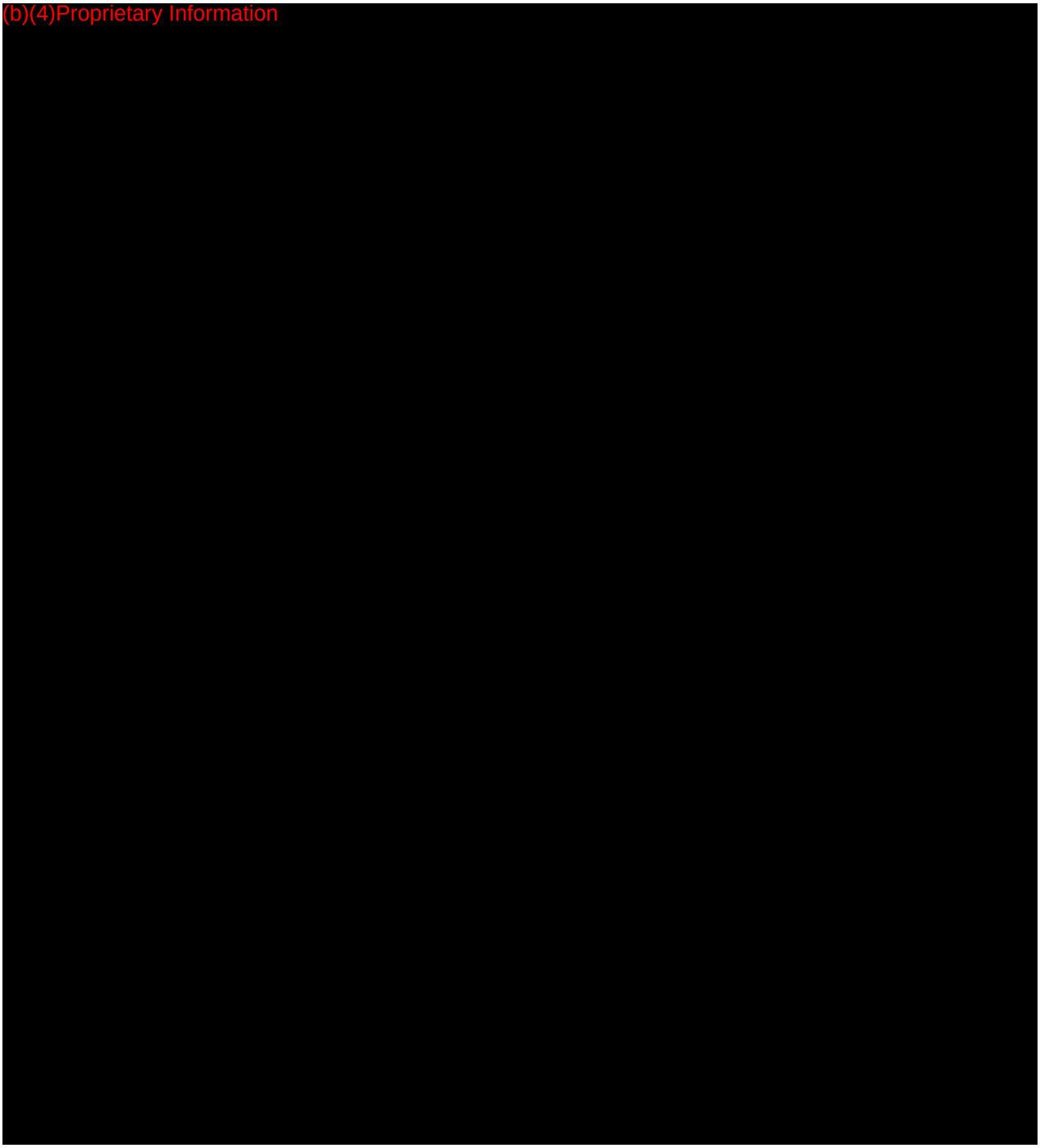
1.8 Product Description

The Theralase™ TLC-2000 Therapeutic Medical Laser System is a Class 3B medical laser system and is indicated for "Adjunctive Use in the Temporary Relief of Pain Associated with Knee Disorders with Standard Chiropractic Practice." The Theralase™ TLC-2000 Therapeutic Medical Laser System is comprised of the following components:

(b)(4)Proprietary Information



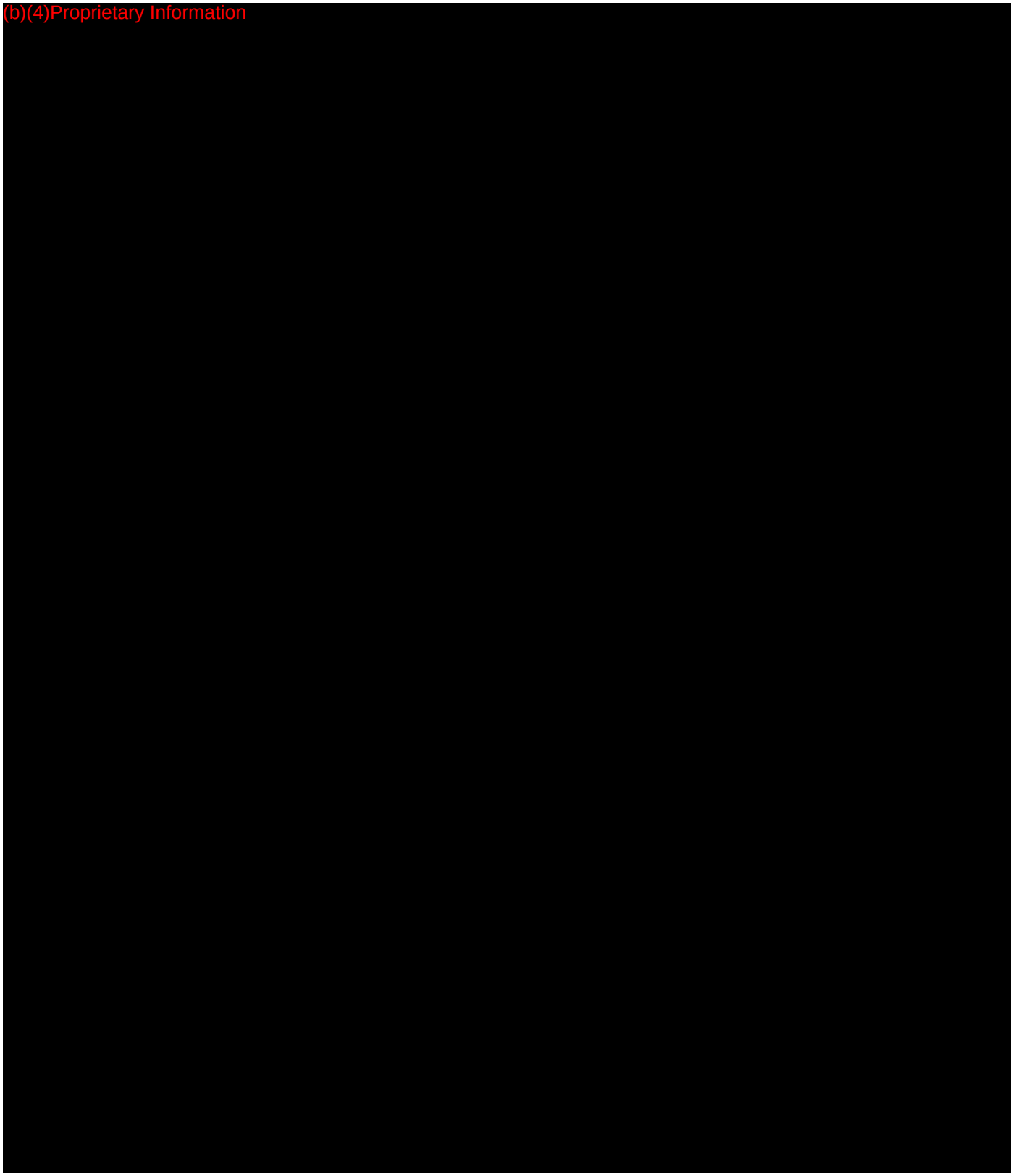
(b)(4)Proprietary Information

The external power supply is a medically approved power supply. The input voltage range is 100 240 VAC with a frequency range of 47 73 Hz. The power supply connects to the AC source with a medically approved ac cord.

The system is supplies with the TLC-2000 Operations Manual, Pain Management Protocol Manual, safety glasses and a carrying case.

2.1 Device Description

(b)(4)Proprietary Information



System Component Description:

The Probe:

1 Display
2 Display Window
3 Power On/Off Switch
4 Start/Stop Button
5 Laser Diode Aperture
6 Optodes
7 Probe Body
8 Strap Handles
9 Laser Output Window

The probe connects to the power pack with an 8 foot long cable. The probe has a color Liquid Crystal Display, power on/off switch and a treatment start/stop switch. The probe contains the (b) x [redacted] x [redacted] nm laser diodes and the circuitry to operate them. There is an

(b)(4)Proprietary Information

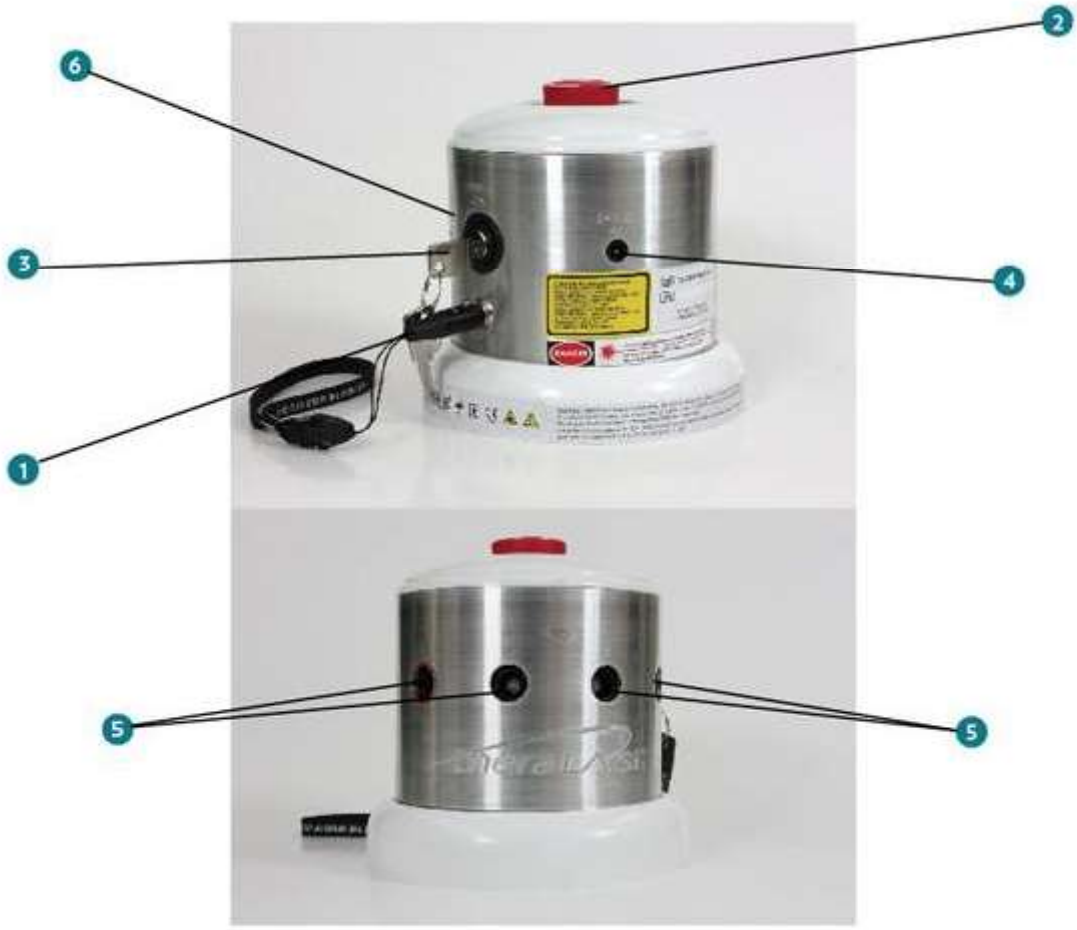
The Tablet:

1 Power On
2 Charging Port
3 USB Port
4 Release Button
5 Touch Pad

The tablet is a windows based computer running Windows 8.1 operating system. The tablet has a Blue Tooth 4.0 radio and WiFi. The tablet has a 10.1" touch screen and a detachable keyboard. The Theralase application software is loaded on the tablet when supplied with the system.

The Theralase TLC-2000 application software is used by the practitioner to enter patient data, to select the knee pain treatment protocol, which is indicated for Adjunctive Use in the Temporary Relief of Pain Associated with Knee Disorders with Standard Chiropractic Practice, to store patient treatment data and to transmit the treatment settings to the probe. For all data that is input, the software will display a verification window listing the data and ask the operator to confirm that all the data is correct before saving to the database.

The Power Pack:



1 Remote Interlock
2 Emergency Stop
3 Key Switch
4 Power Input
5 Probe Power Ports
6 Power In / Power Out LED indicators

The power pack contains the electronics which provide the operating voltages for the probe. The power pack contains the necessary safety systems in the form of an emergency stop switch, a remote interlock and a key operated on/off switch.

(b)(4)Proprietary Information

[redacted]

The Power Supply:

The power supply is a medically approved universal, 100 240 VAC input voltage rating at 47/63 Hz, power supply. The output is 24 volts DC for the power pack. A medically approved AC power cord is included.

b) ACCESSORY COMPONENT DESCRIPTIONS

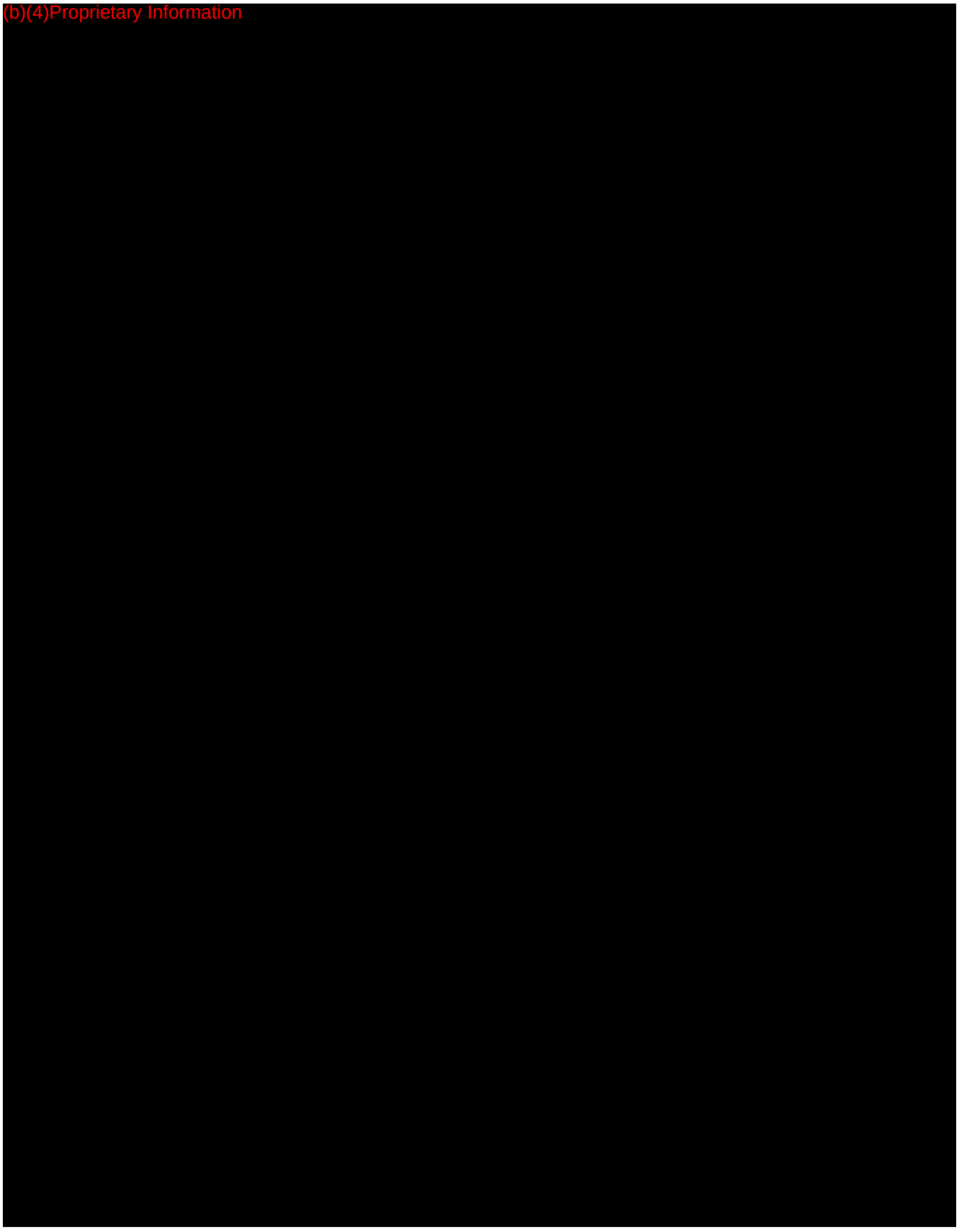
Safety eyewear:

Supplied with the system are two sets of standard, TLC-901 laser safety glasses one pair for the clinician and one pair for the patient. These laser safety glasses are provided for viewing diffused laser light only and are not for direct viewing of the laser output.

(b)(4)Proprietary Information

c) Specifications

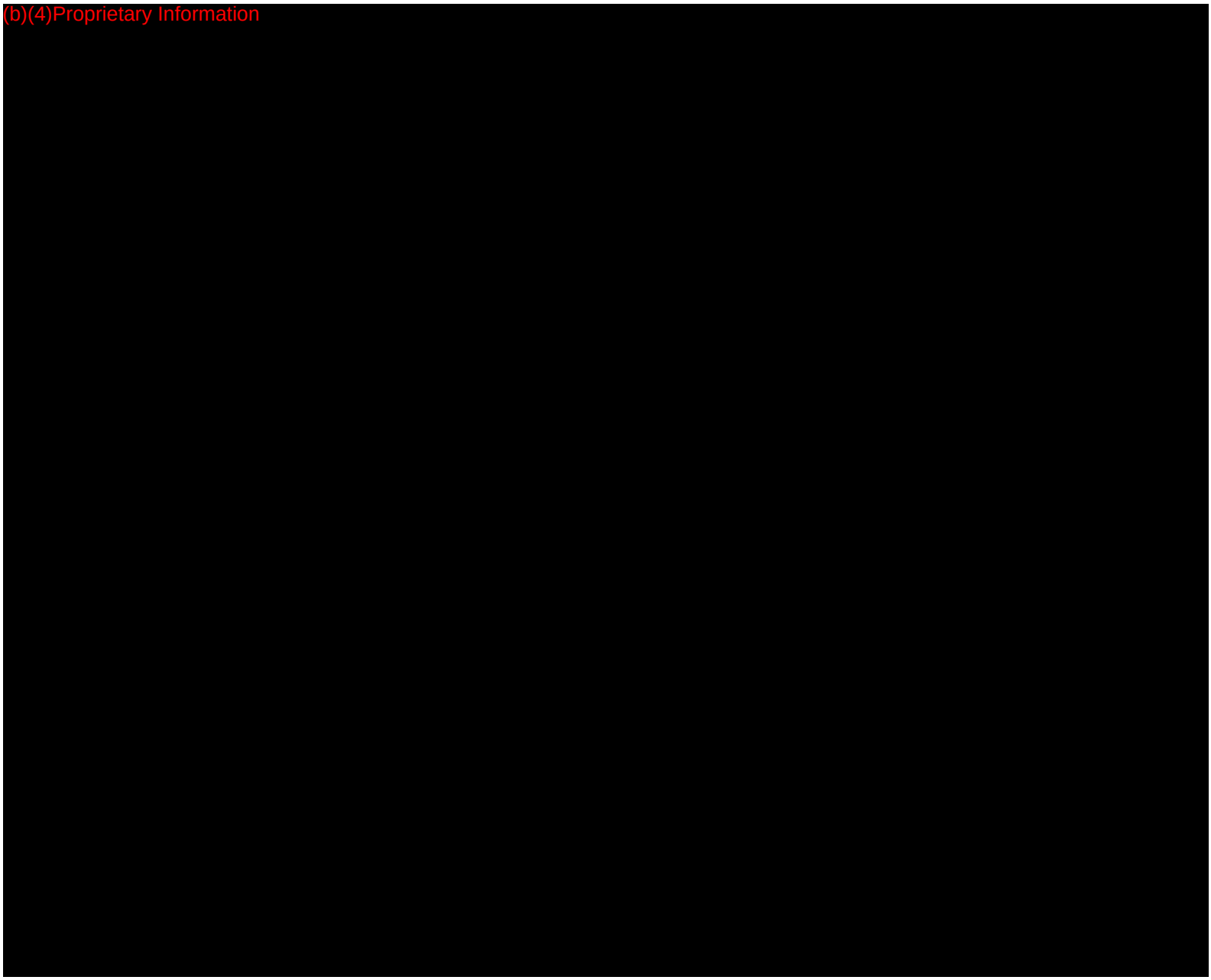
(b)(4)Proprietary Information



d) Intended Use of the TLC-2000

The TLC-2000 therapeutic medical laser system is indicated for Adjunctive Use in the Temporary Relief of Pain Associated with Knee Disorders with Standard Chiropractic Practice.

(b)(4)Proprietary Information



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TLC- 2000
PAIN MANAGEMENT PROTOCOL MANUAL

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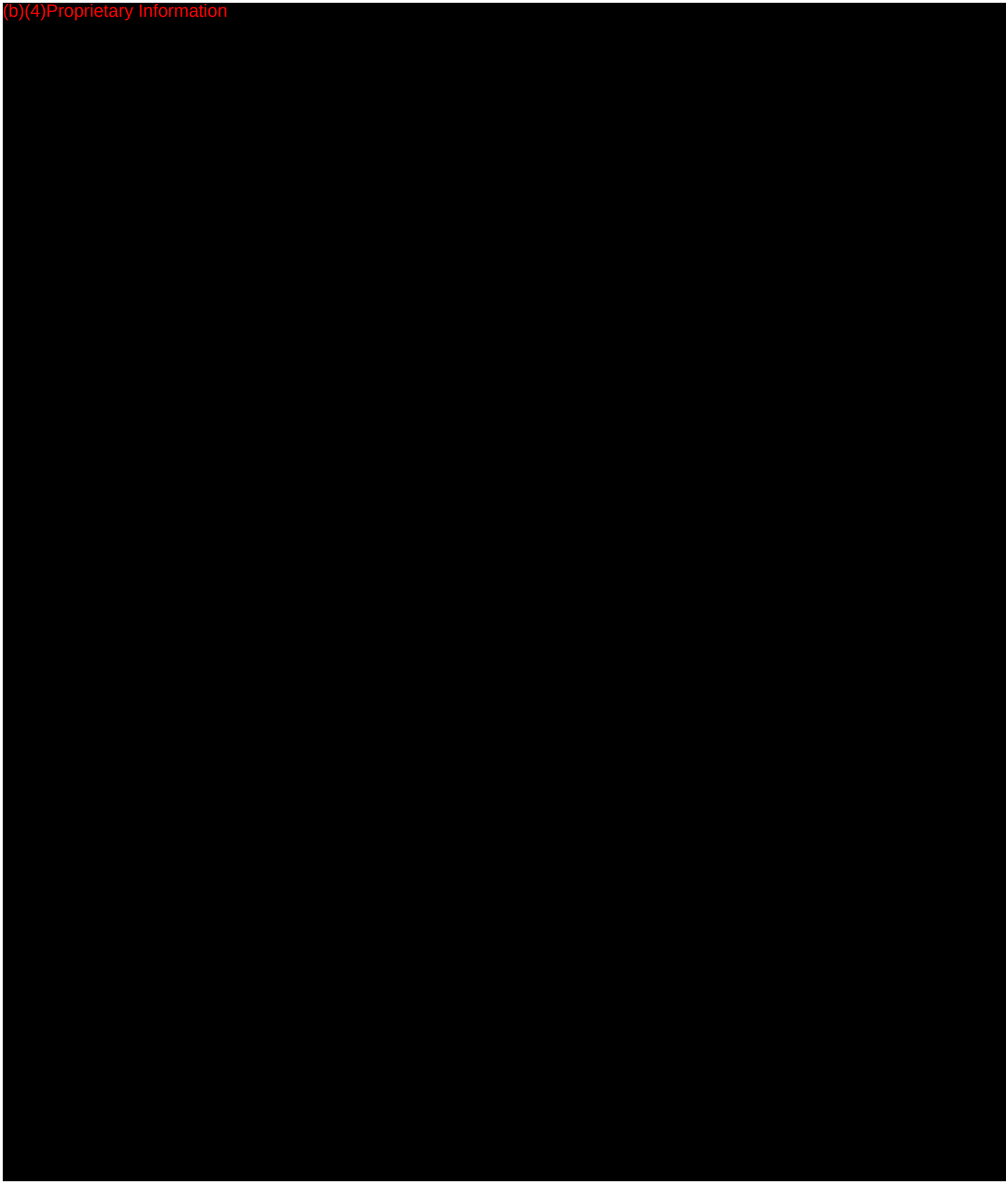
Clinical Information

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

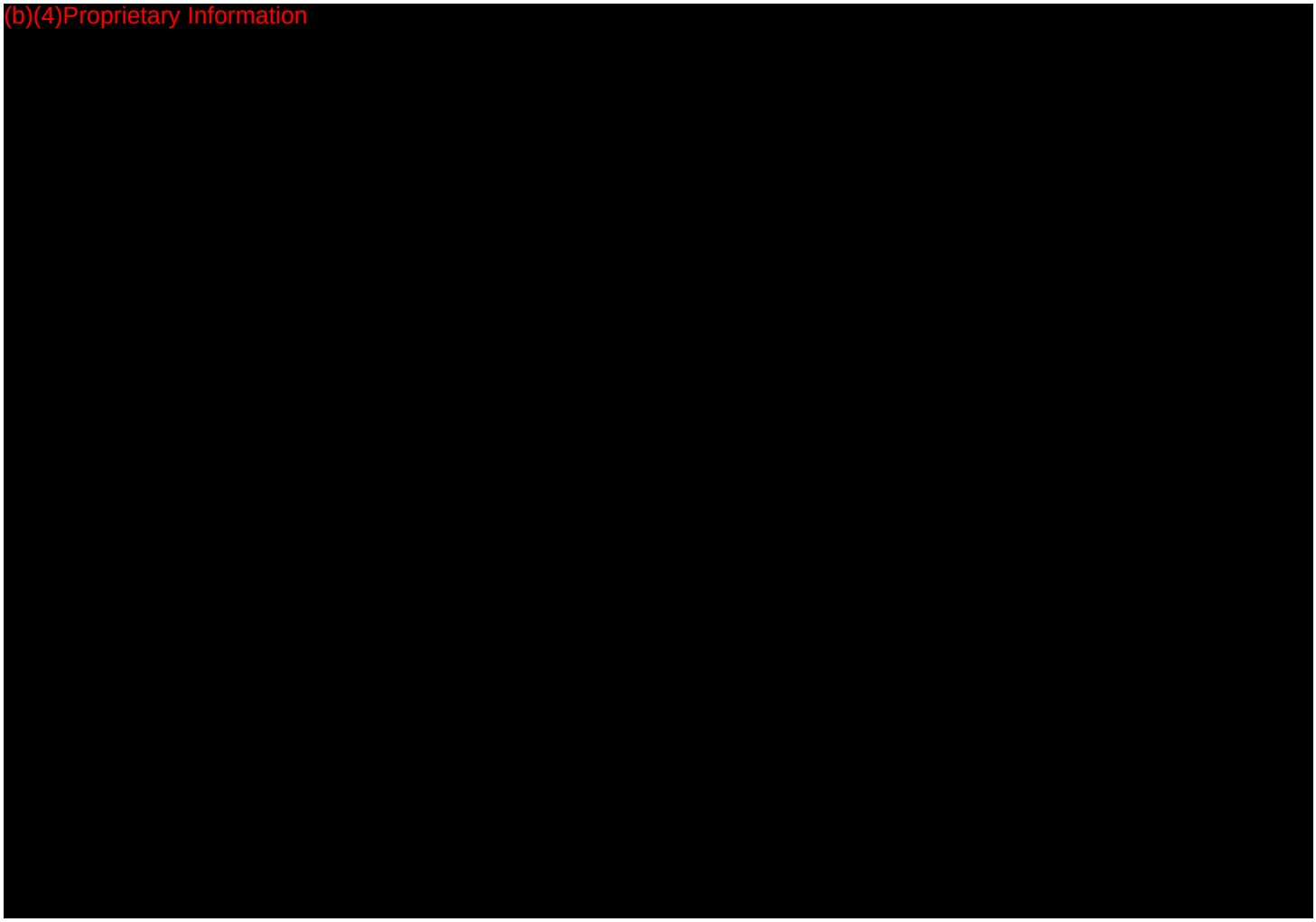
(b)(4)Proprietary Information



Operation Procedure (Knee Protocol)

Caution: The patient and the practitioner should always wear protective eyewear during laser operation.

(b)(4)Proprietary Information



Treatment Specification: 001 KNEE PAIN

Adjunctive Use in the Temporary Relief of Pain Associated with Knee Disorders with Standard Chiropractic Practice.

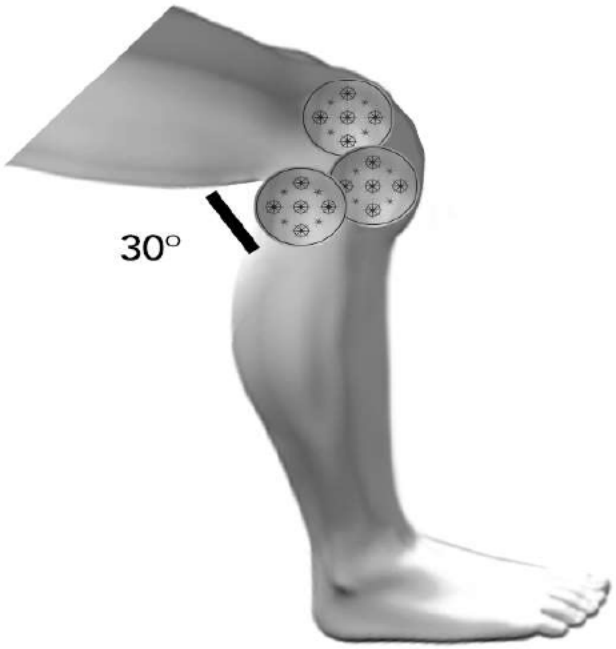


Figure 1

Treatment Protocol:

TLC-000 Treatment Record	001 KNEE PAIN
Number of Treatment Points	7

(b)(4)Proprietary Information

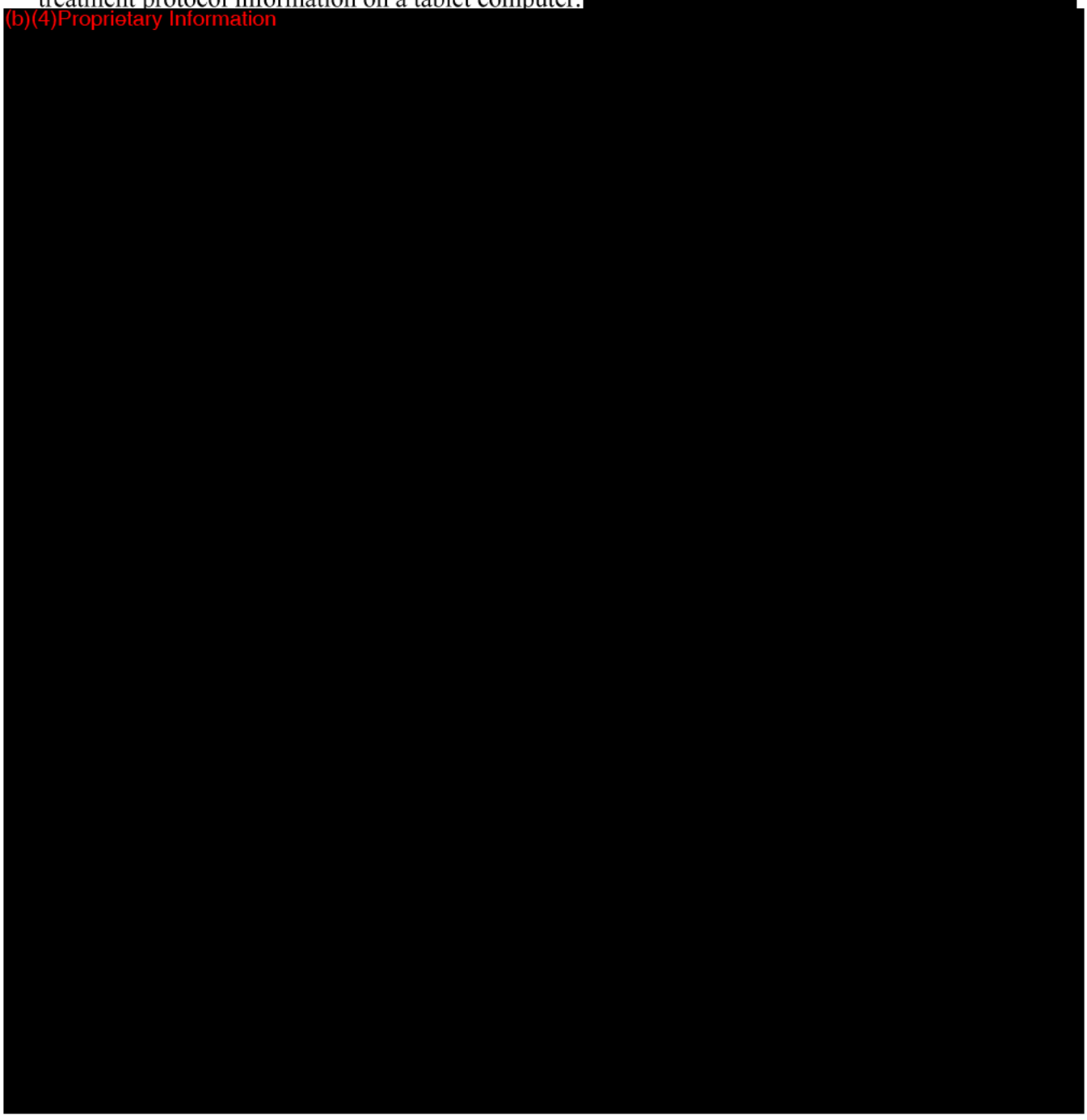
(b)(4)Proprietary Information

3.1 Substantial Equivalence

The new product, the TLC 2000 is a Class 3B therapeutic medical laser. It is a new design based on the design of the predicate product, the TLC 1000, also a Class 3B laser. The 1000 product is manufactured and for the past ten years has been sold in Canada under the Canadian Medical De ices License 65816 and has been sold in the United States under a 510(K) Premarket Submission Number K050342.

The TLC 2000 is a more modern approach where the practitioner sa es patient treatment protocol information on a tablet computer. (b)(4)Proprietary Information

(b)(4)Proprietary Information



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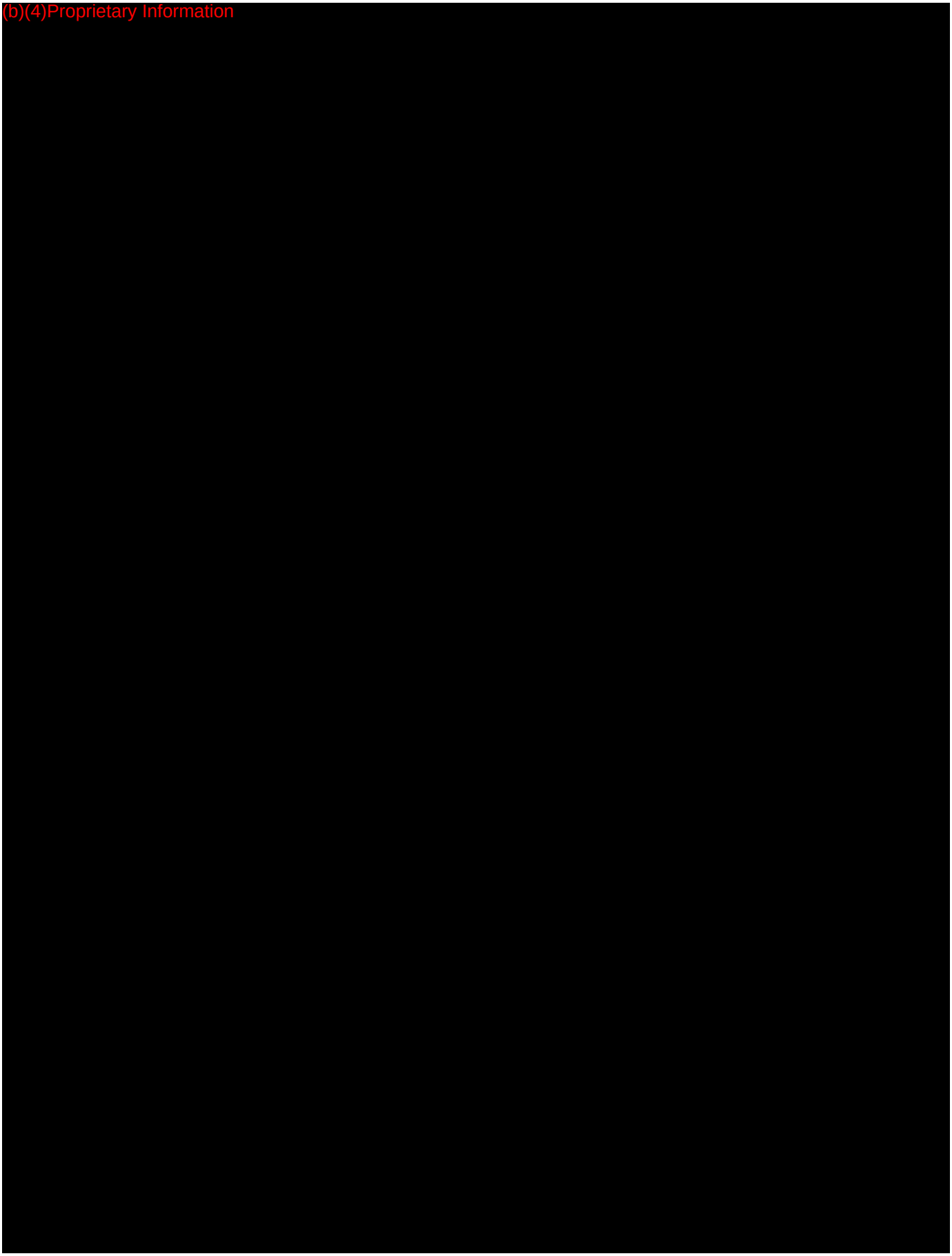

Substantial Equivalence Table

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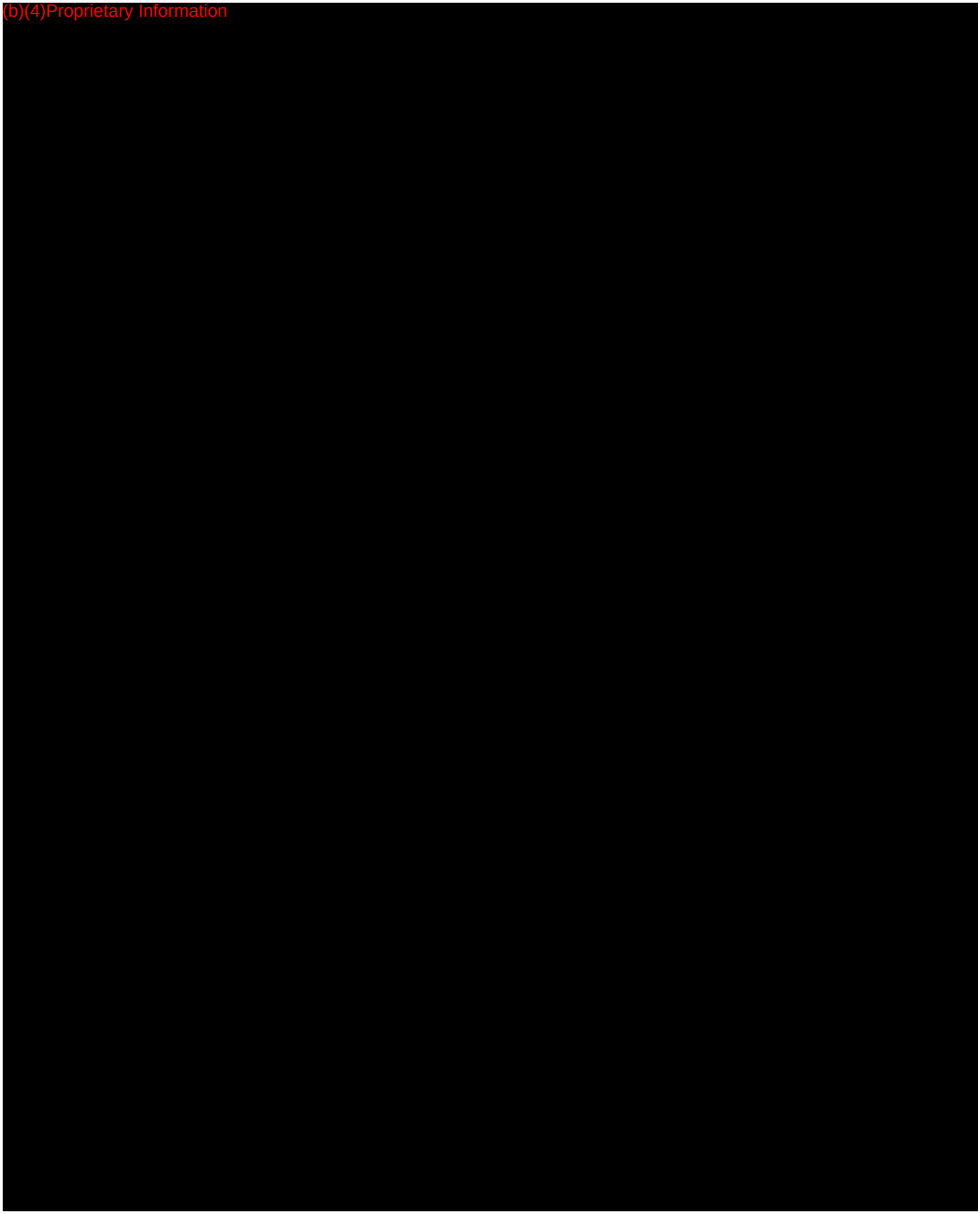

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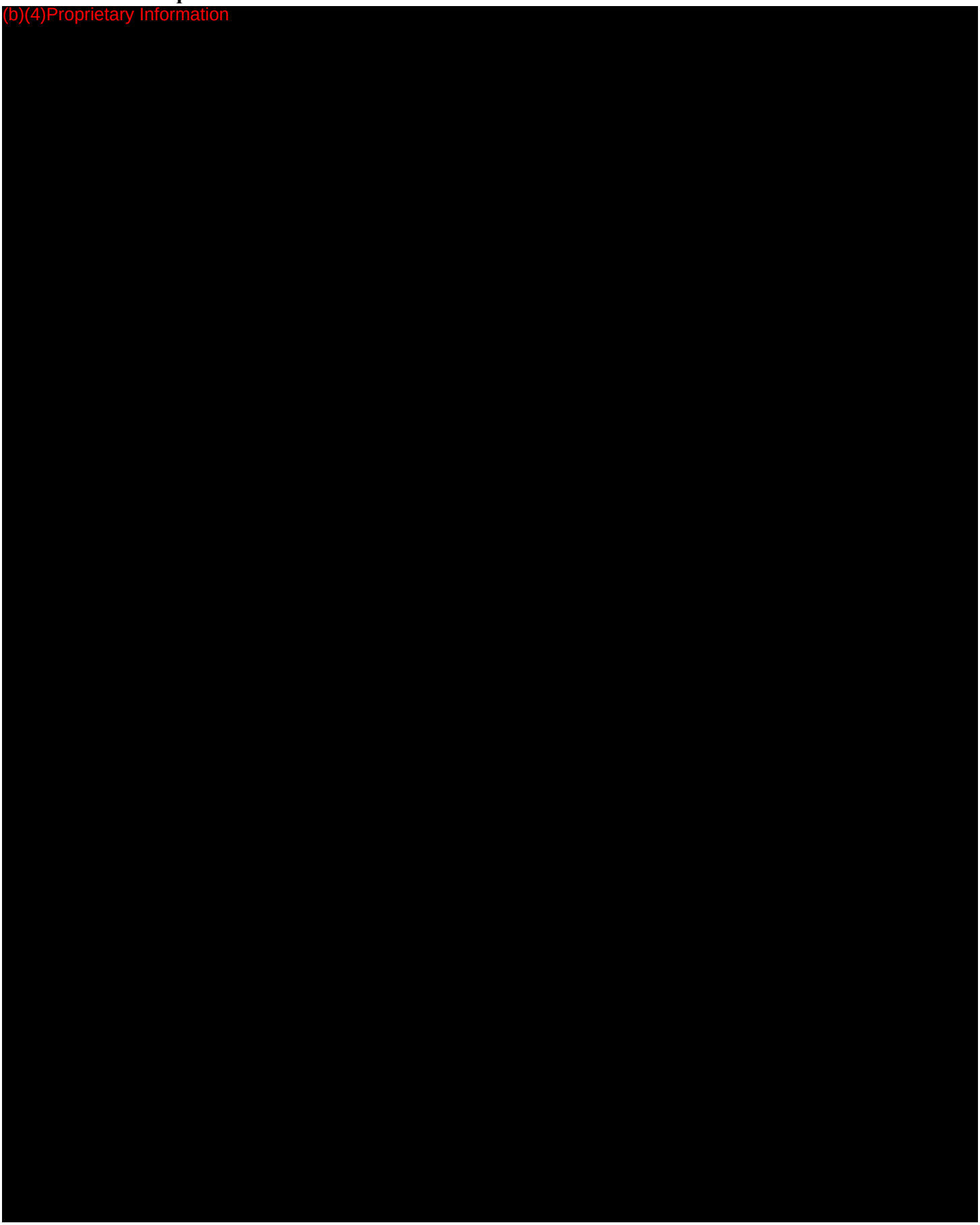

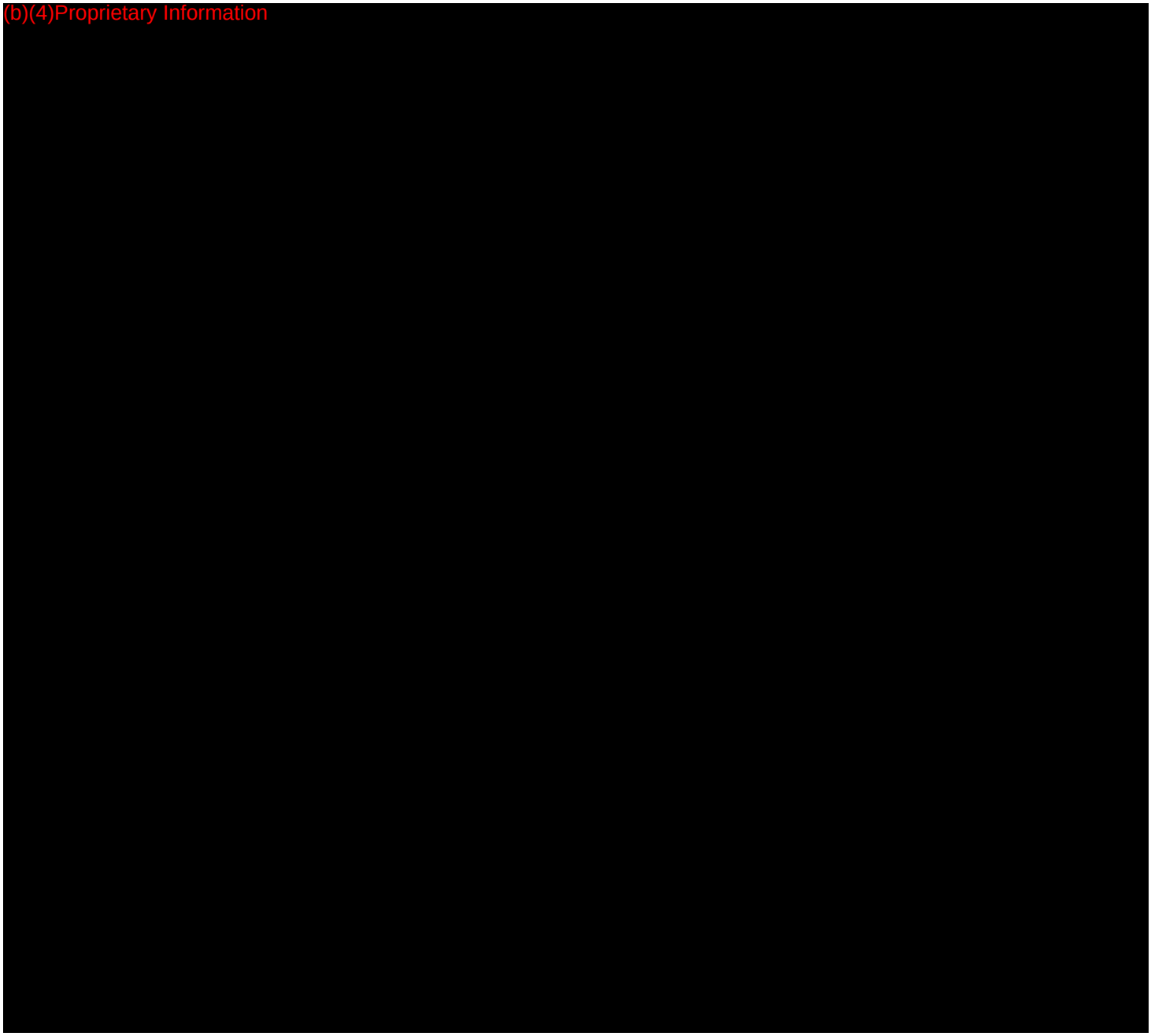

Conclusions: Substantial Equivalency

(b)(4)Proprietary Information

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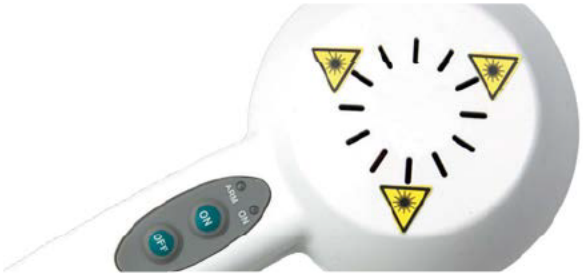

TLC-1000
PAIN MANAGEMENT PROTOCOL MANUAL

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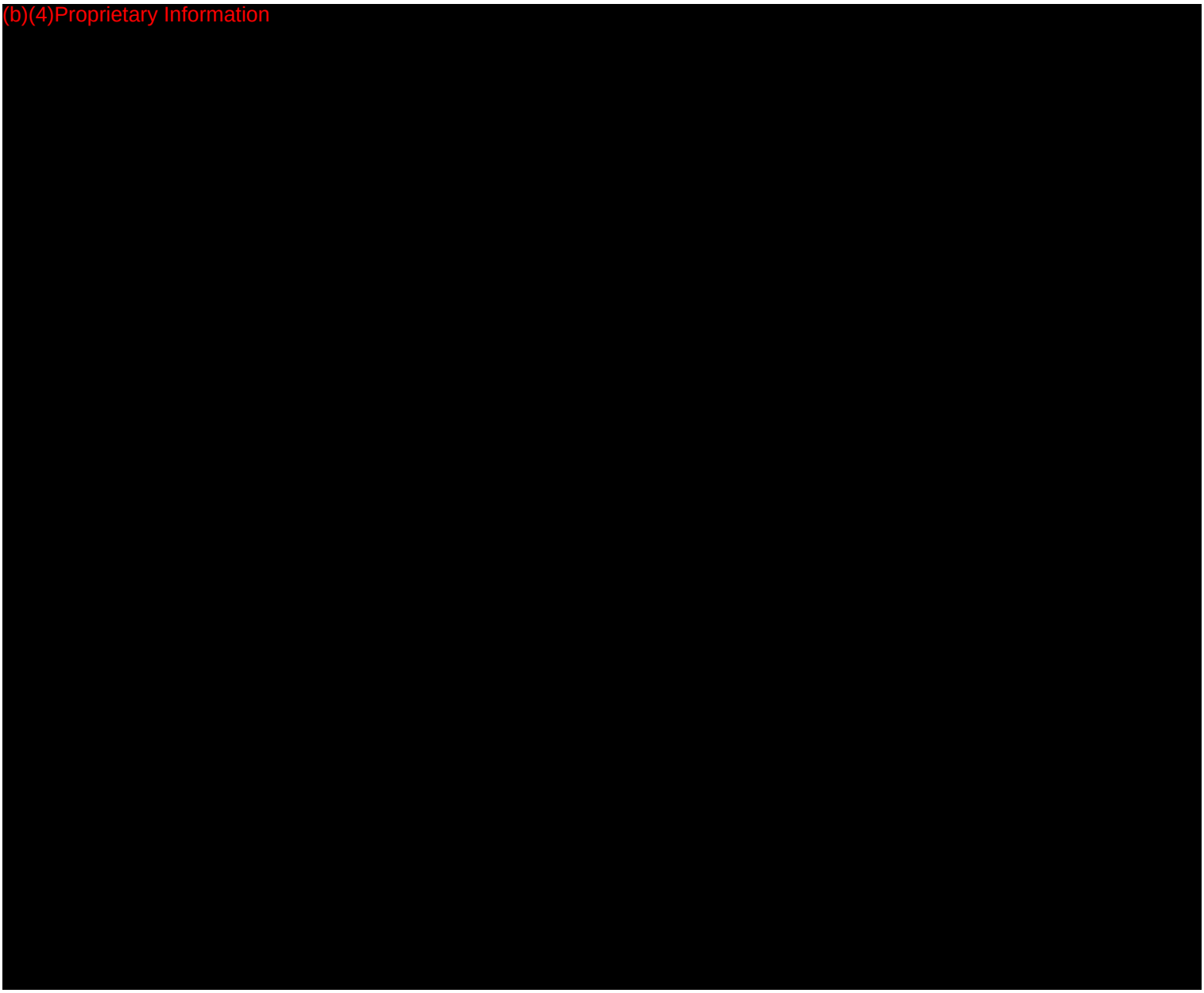
Clinical Information

Practical Advice for the Use of Low Level Laser Therapy

(b)(4)Proprietary Information



Cautions in the use of Laser Therapy

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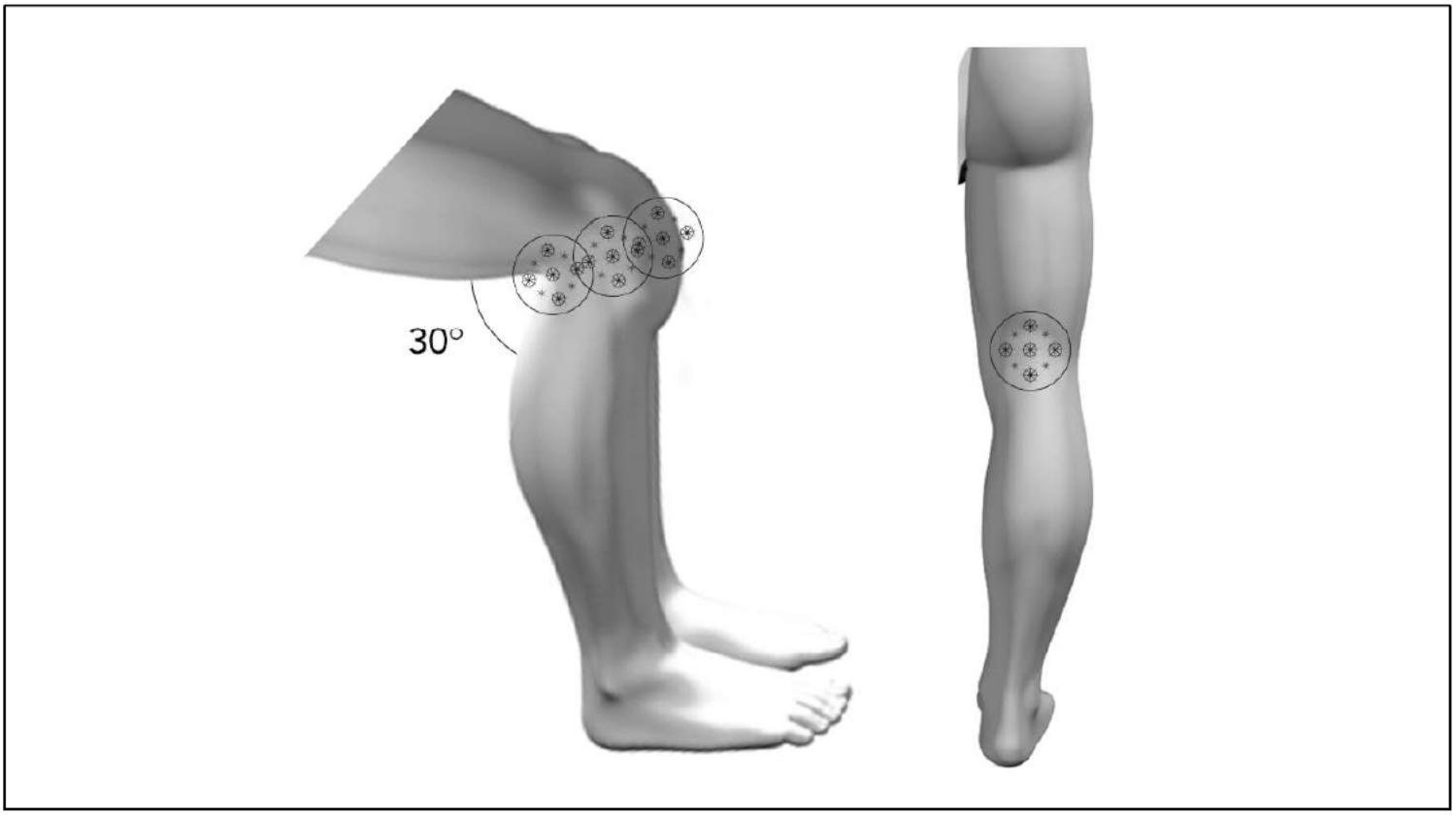
Treatment Specification: 001 KNEE PAIN
Knee Pain



Treatment Protocol:

TLC-000 Treatment Record	001 KNEE PAIN
Number of Treatment Points	7

(b)(4)Proprietary Information

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TLC-1000
OPERATIONS MANUAL

(b)(4)Proprietary Information

(b)(4)Proprietary Information

1. Safety Information – Please Review Before Using the Theralase System

The Theralase™ TLC-1000 therapeutic laser is a Class 3B medical laser and as such is a potential hazard for direct and indirect viewing of the laser light.

The Theralase™ TLC-1000 system as mentioned earlier is composed of three main components; the TLC-1000 Laser Controller, the Power Supply and the TLC-900 Multiple Laser Probe. Safety and safe use of the product are indicated both visually by the use of labels as well as equipment features. These will be detailed below. **IT IS IMPORTANT TO BE WELL AWARE OF ALL THESE SAFETY DETAILS PRIOR TO USING THE EQUIPMENT.**

(b)(4)Proprietary Information

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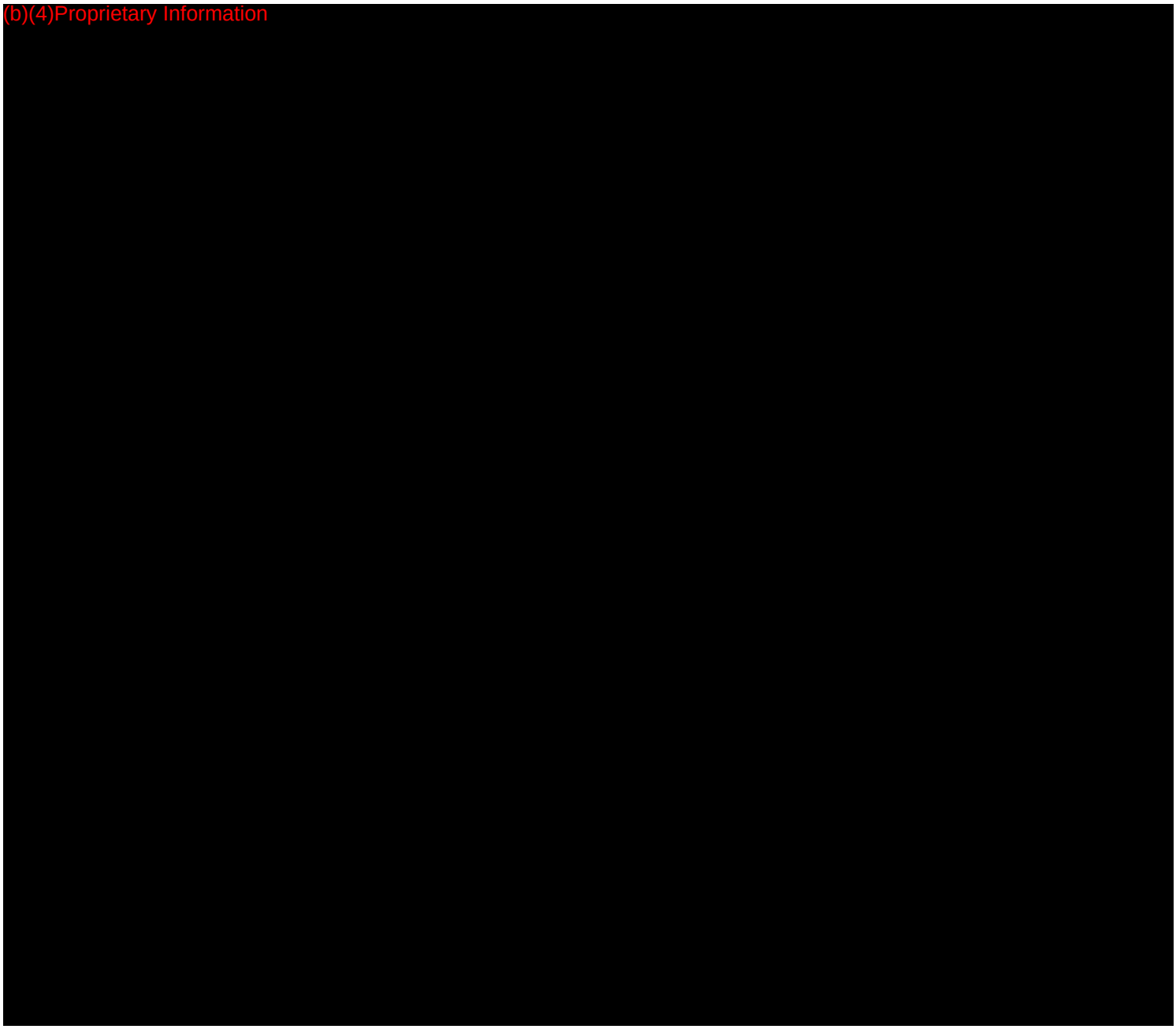
Operational Safety

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

(b)(4)Proprietary Information



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2. THERALASE TLC-1000 SERIES PRODUCT INFORMATION

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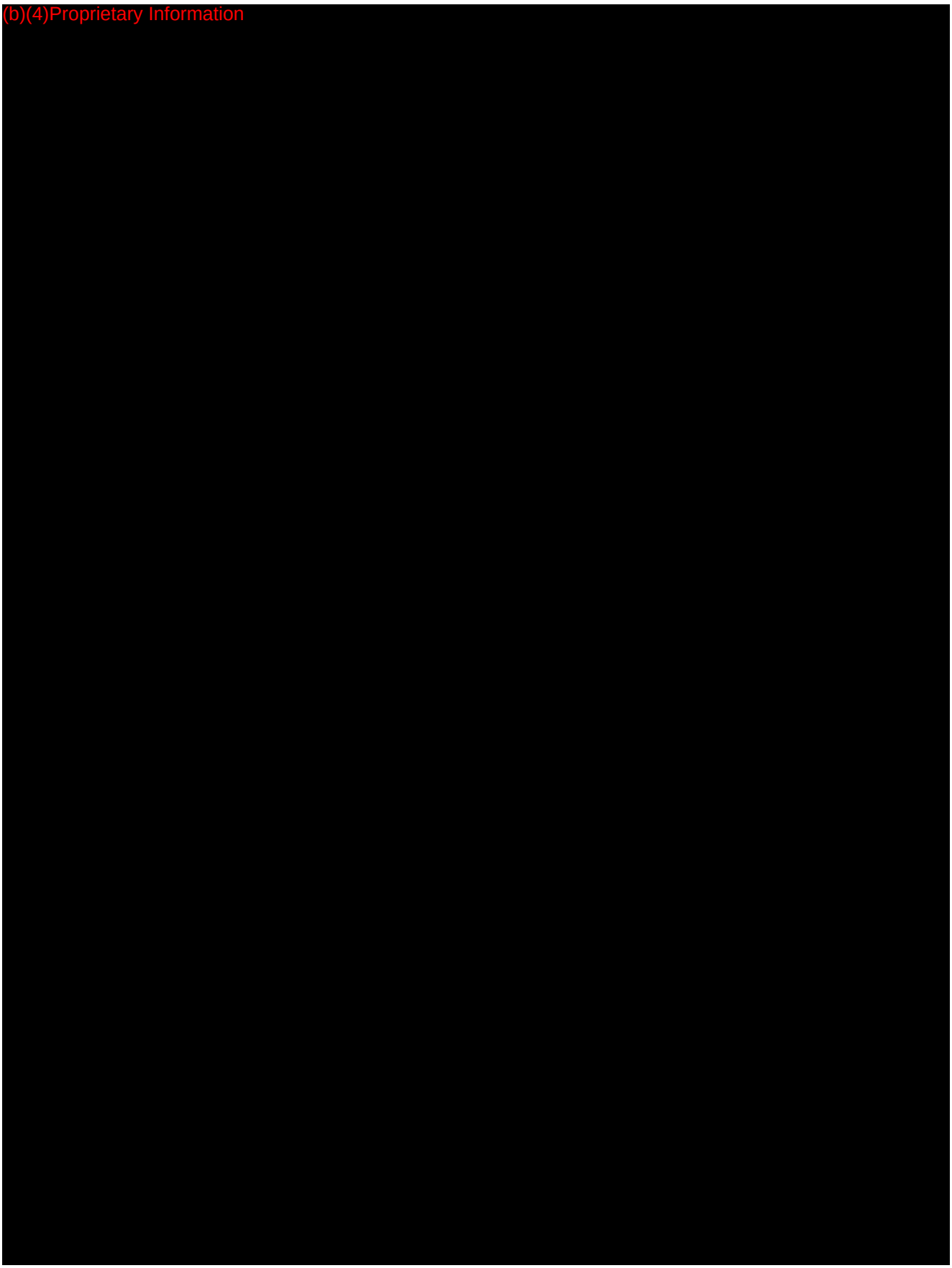

The Laser Controller (TLC-1000)

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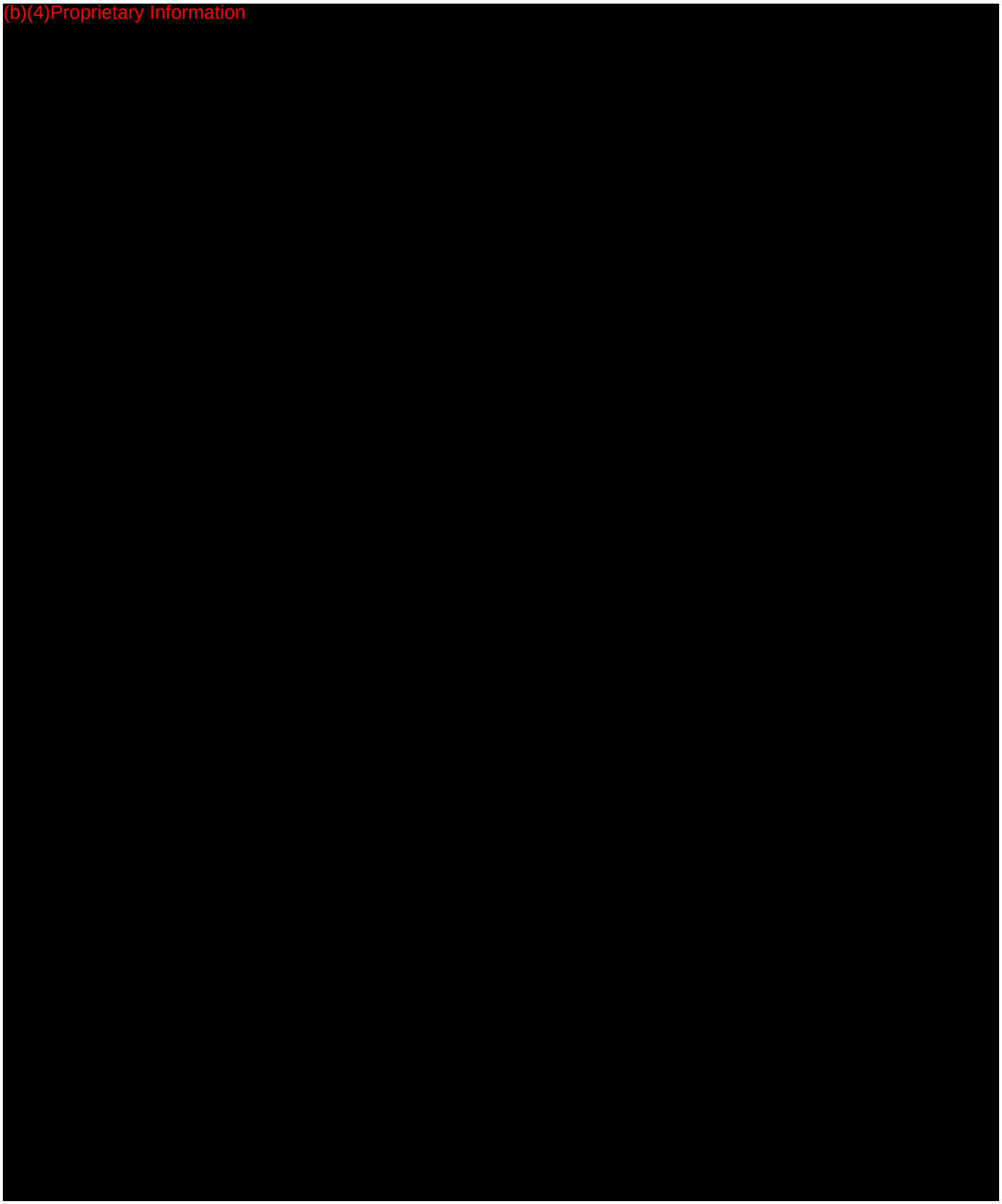

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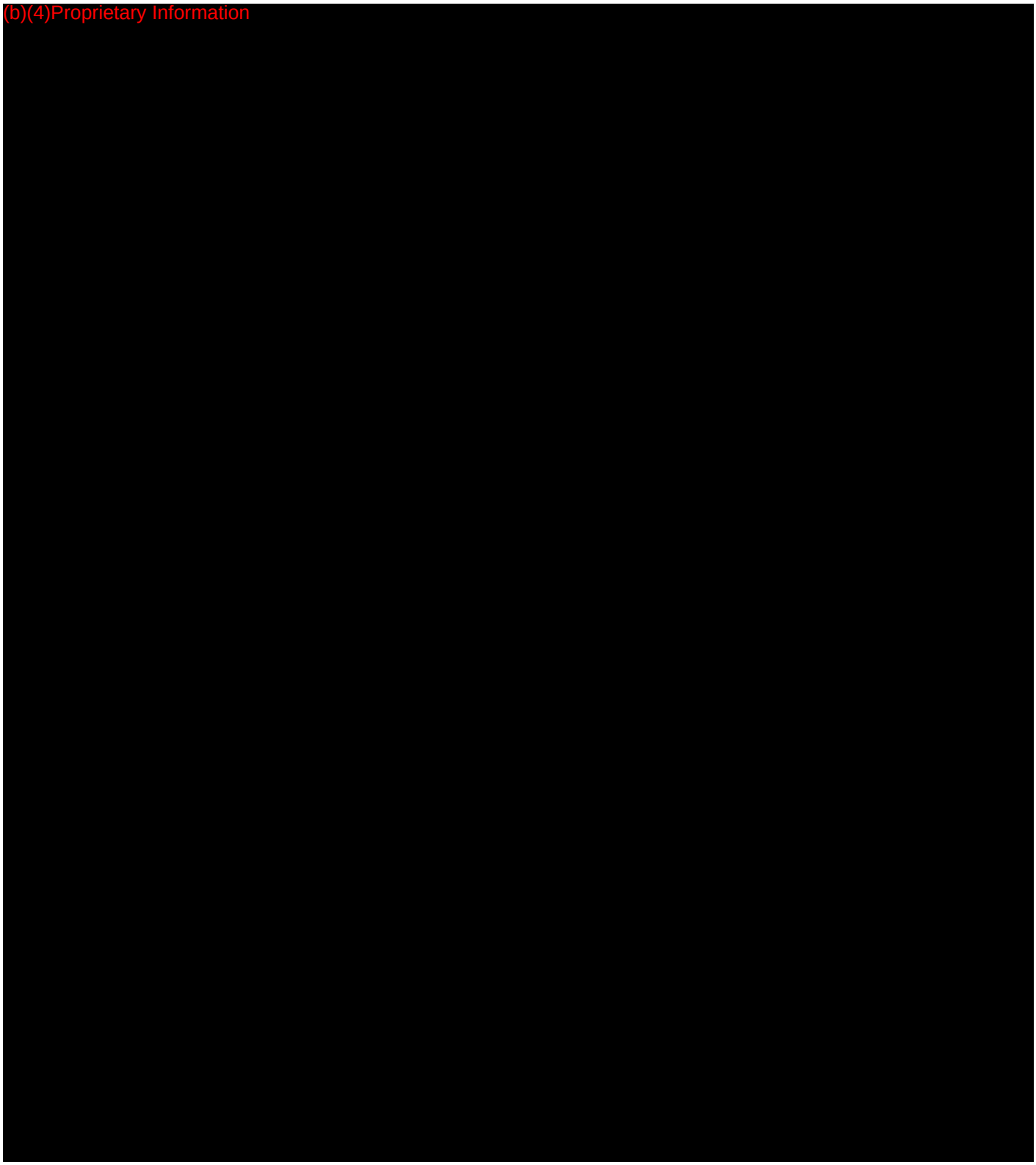
(b)(4)Proprietary Information

CAUTION:

- ***Use only the TLC-154 power supply (+24 VDC, 2.7 A) to power the TLC-1000 laser controller. This is the only power supply approved to be used with the TLC-1000 laser controller.***
- ***Outside of North America, the proper international cord set must be specified and purchased from Theralase™ Inc. or purchased separately for the country of preference.***

The Multiple Laser Probe (TLC-900)

(b)(4)Proprietary Information



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Hard case for TLC-1000 system (part number: TLC-1200)

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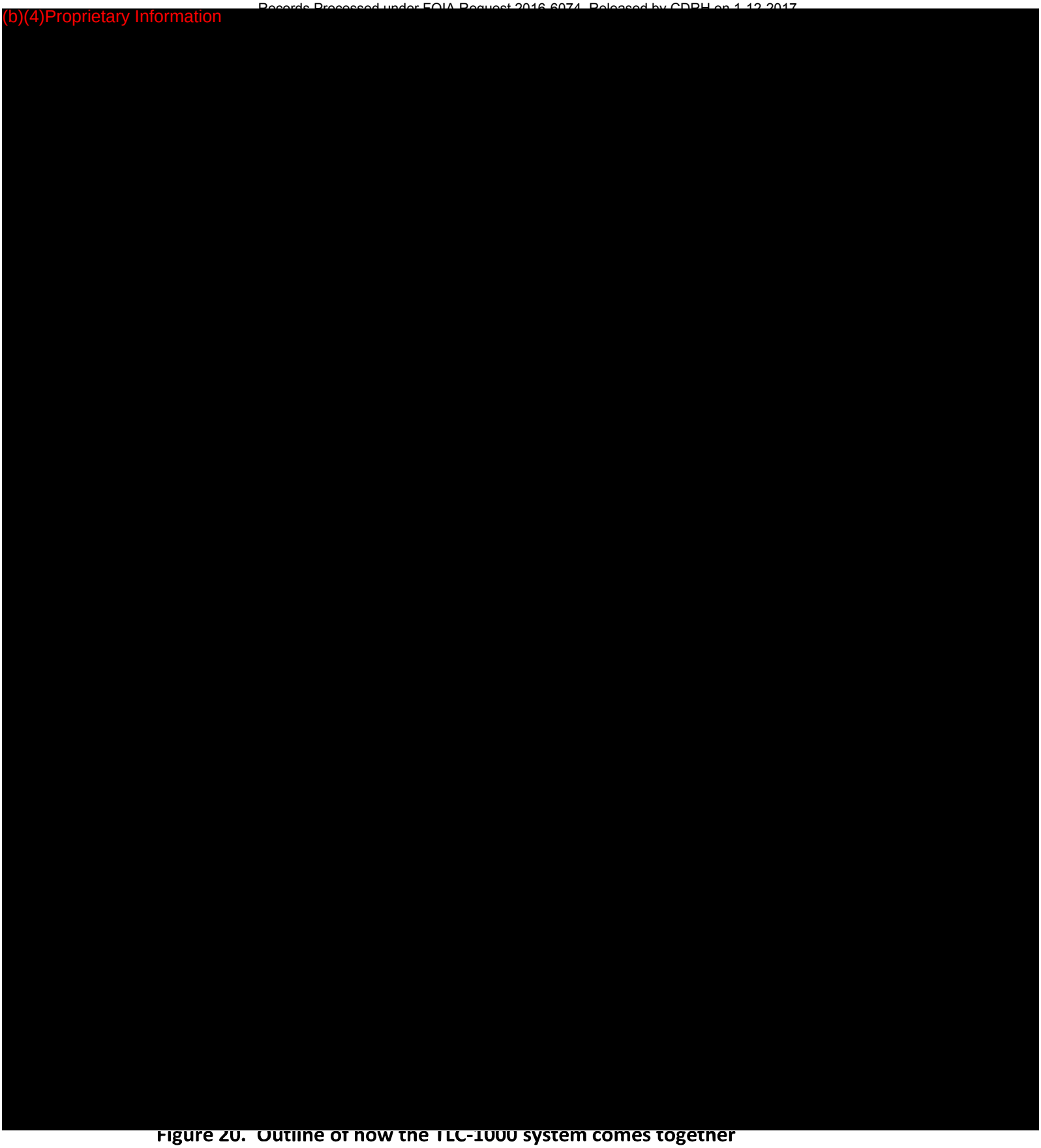

Figure 20. Outline of how the TLC-1000 system comes together

1. Unpack the contents of the case and identify each of the pieces as outlined in the figure above.

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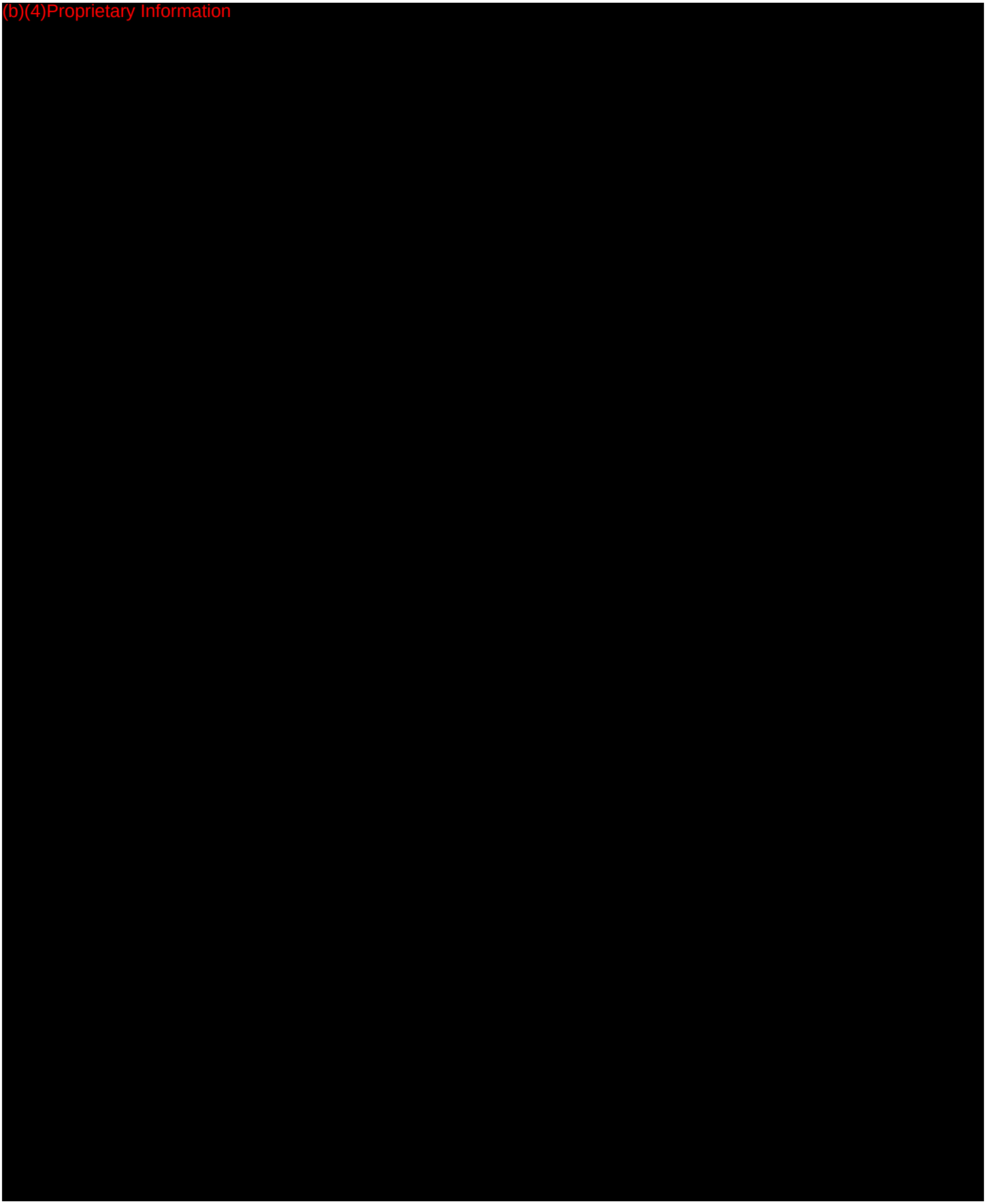

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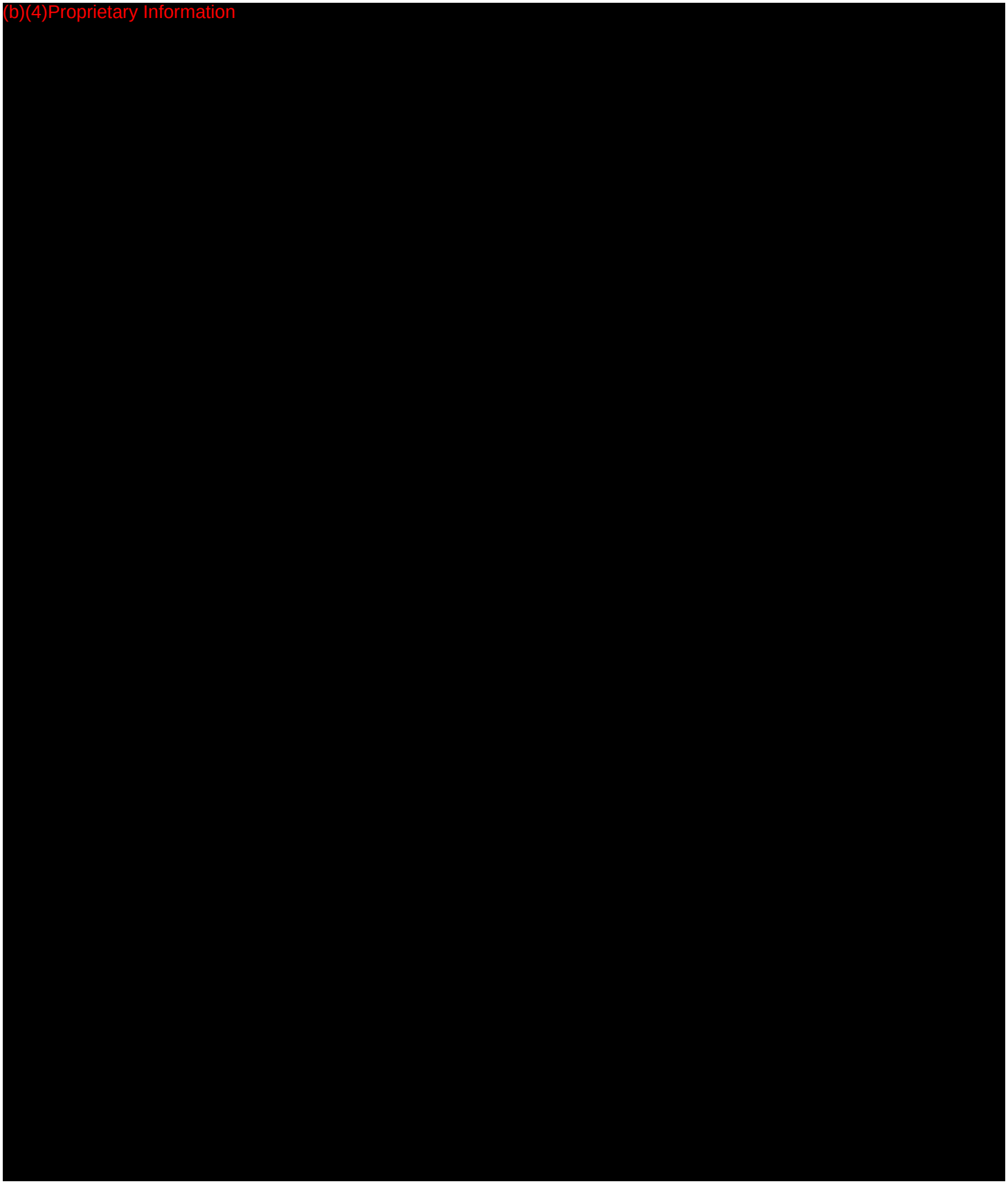

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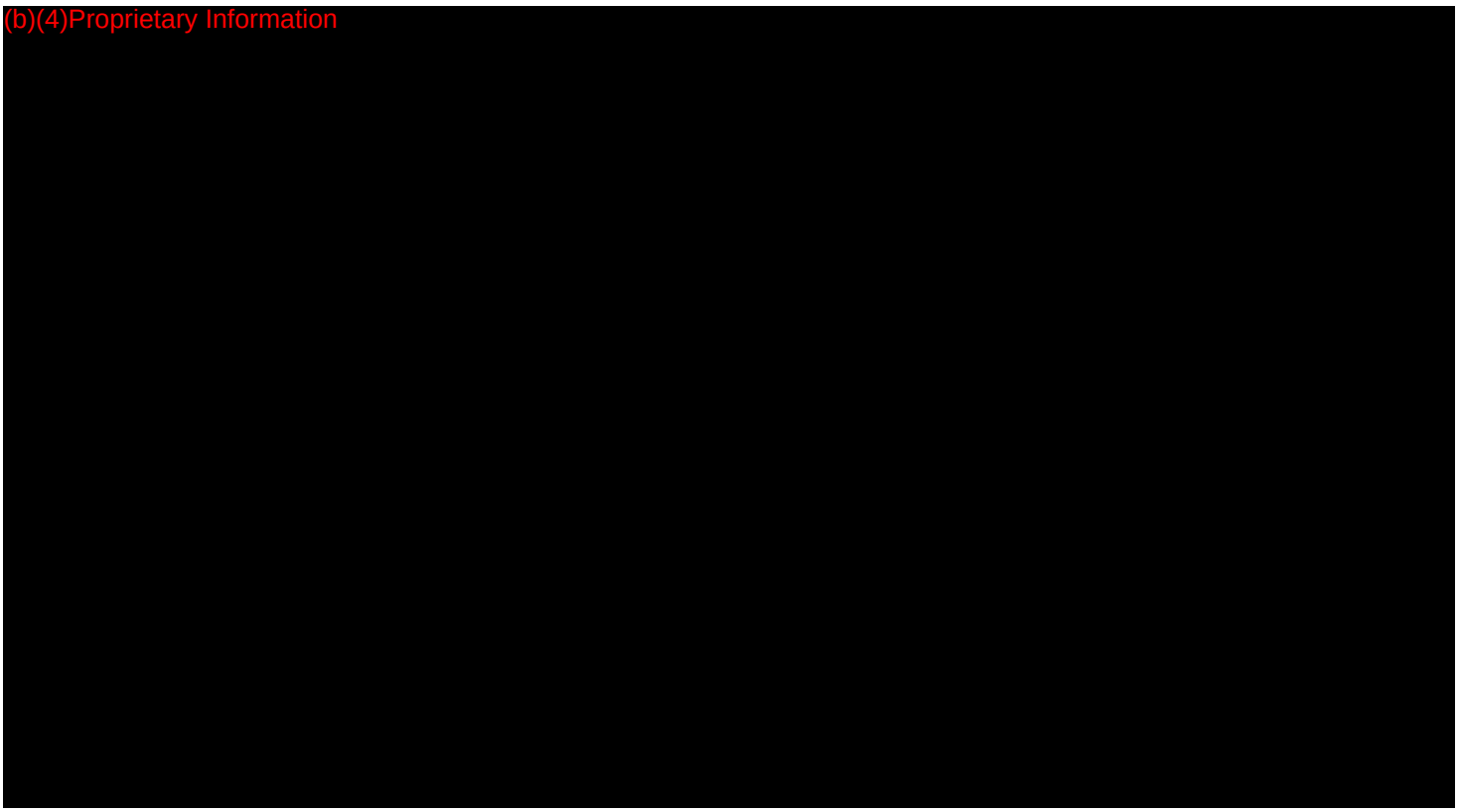

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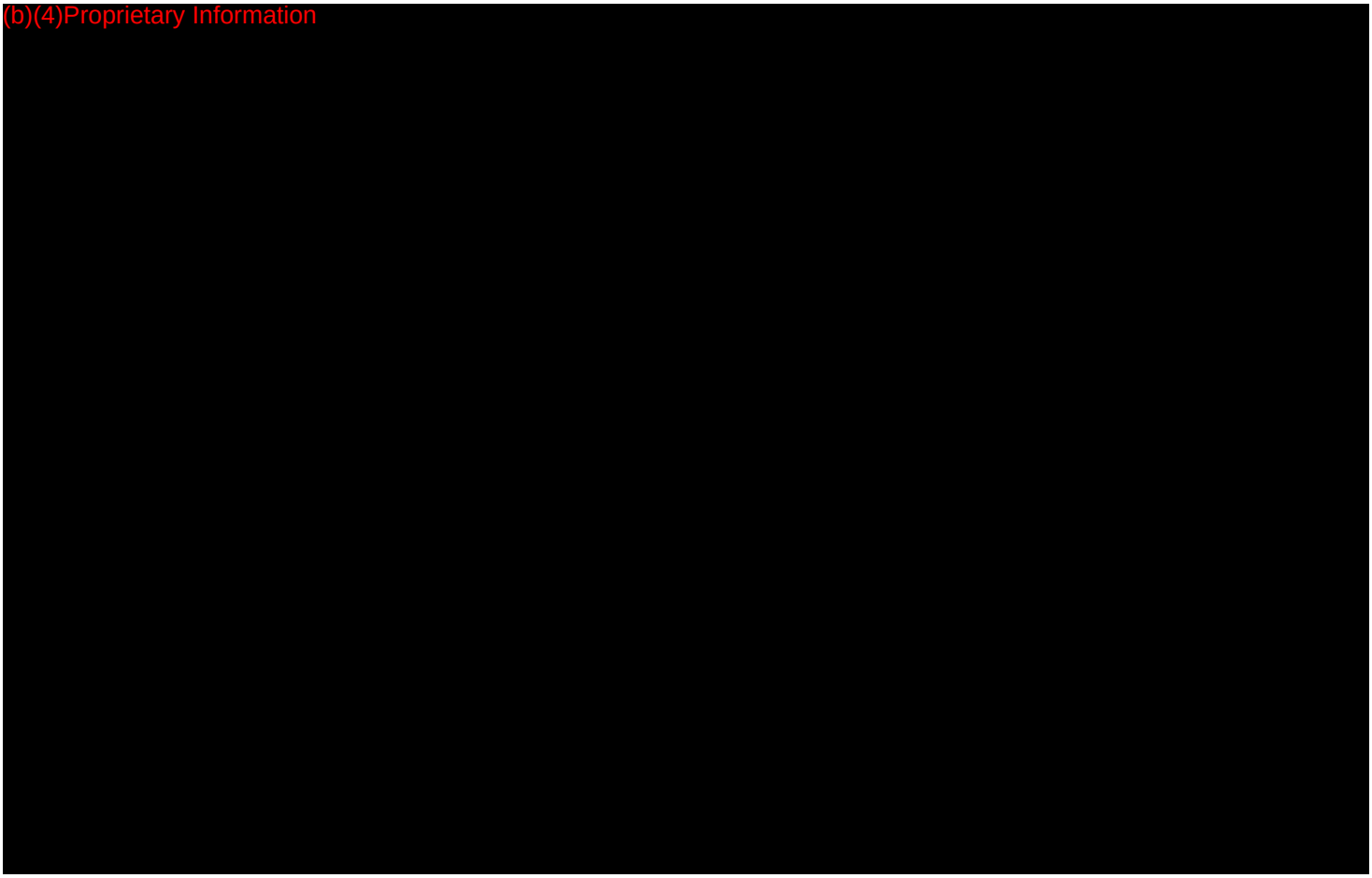

4. Operation Procedure (Knee Treatment Protocol)

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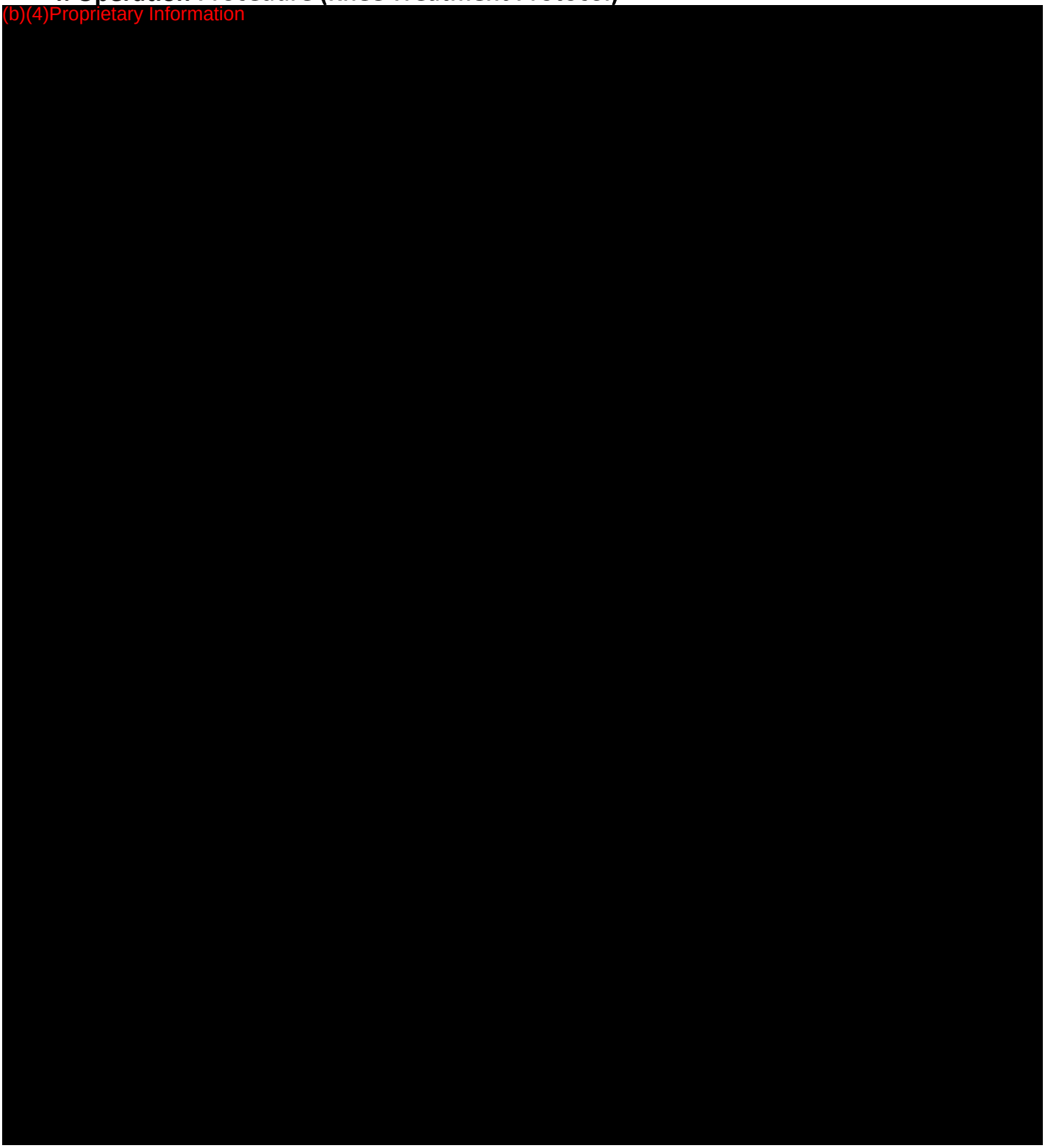

02 Options

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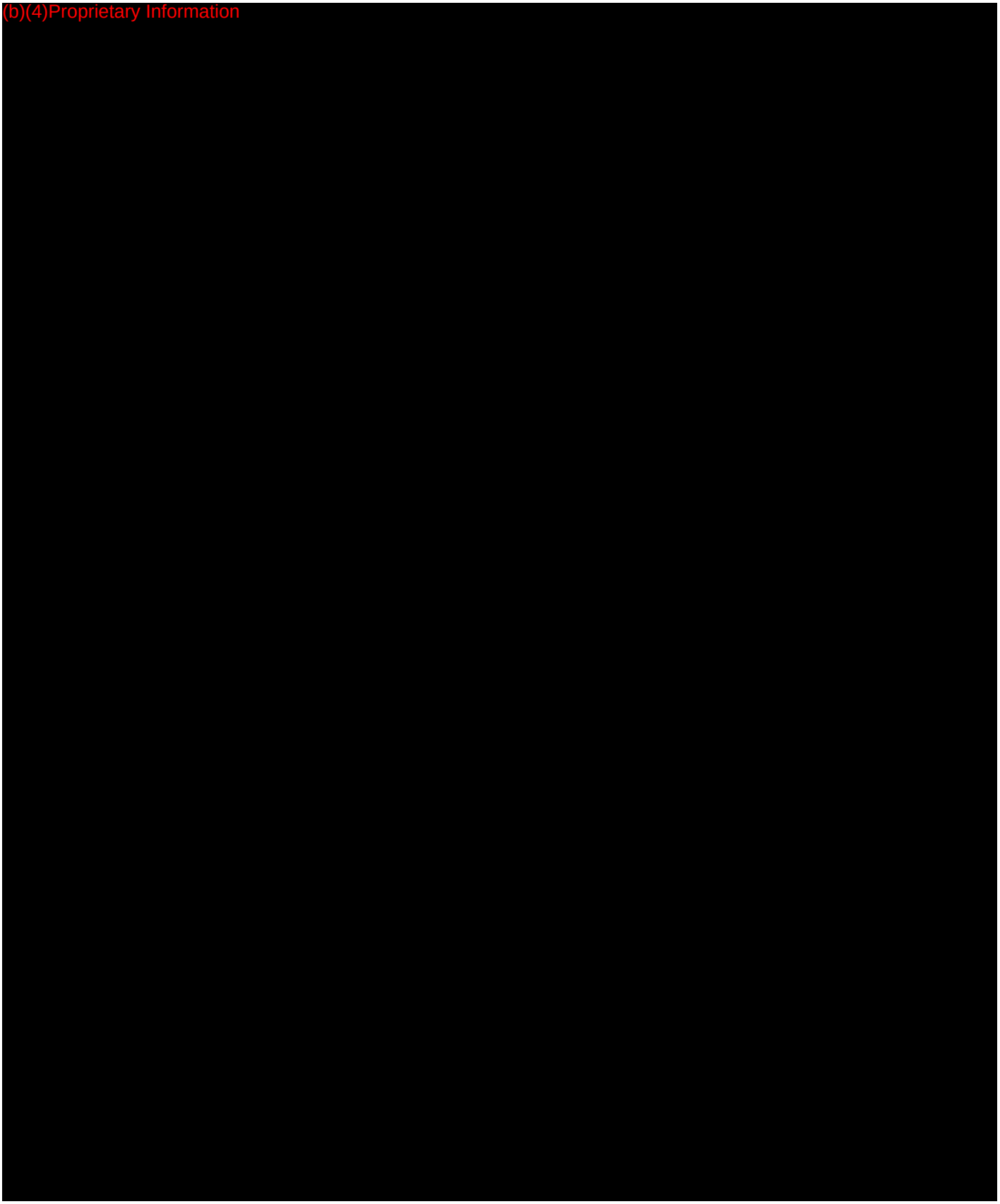

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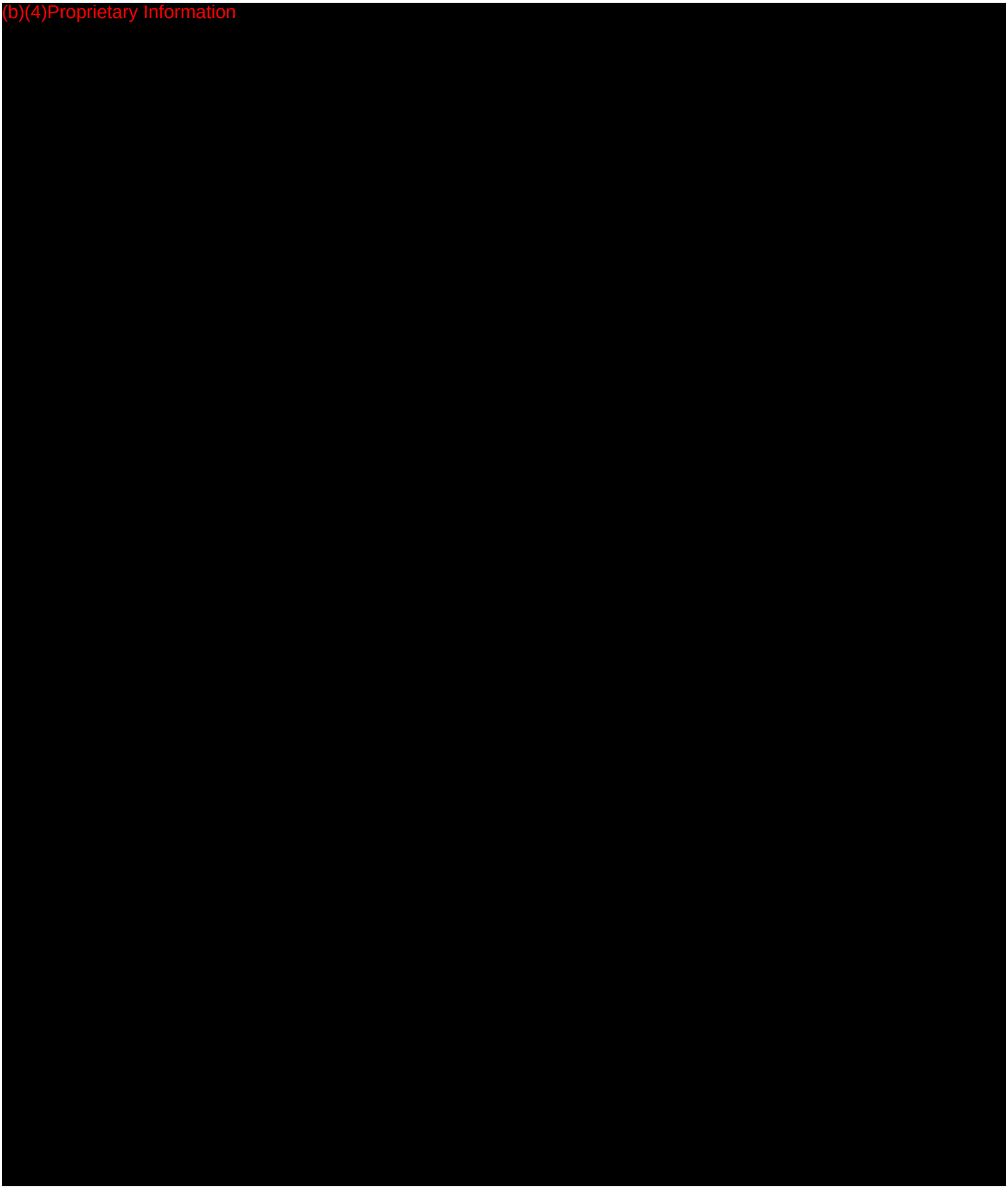

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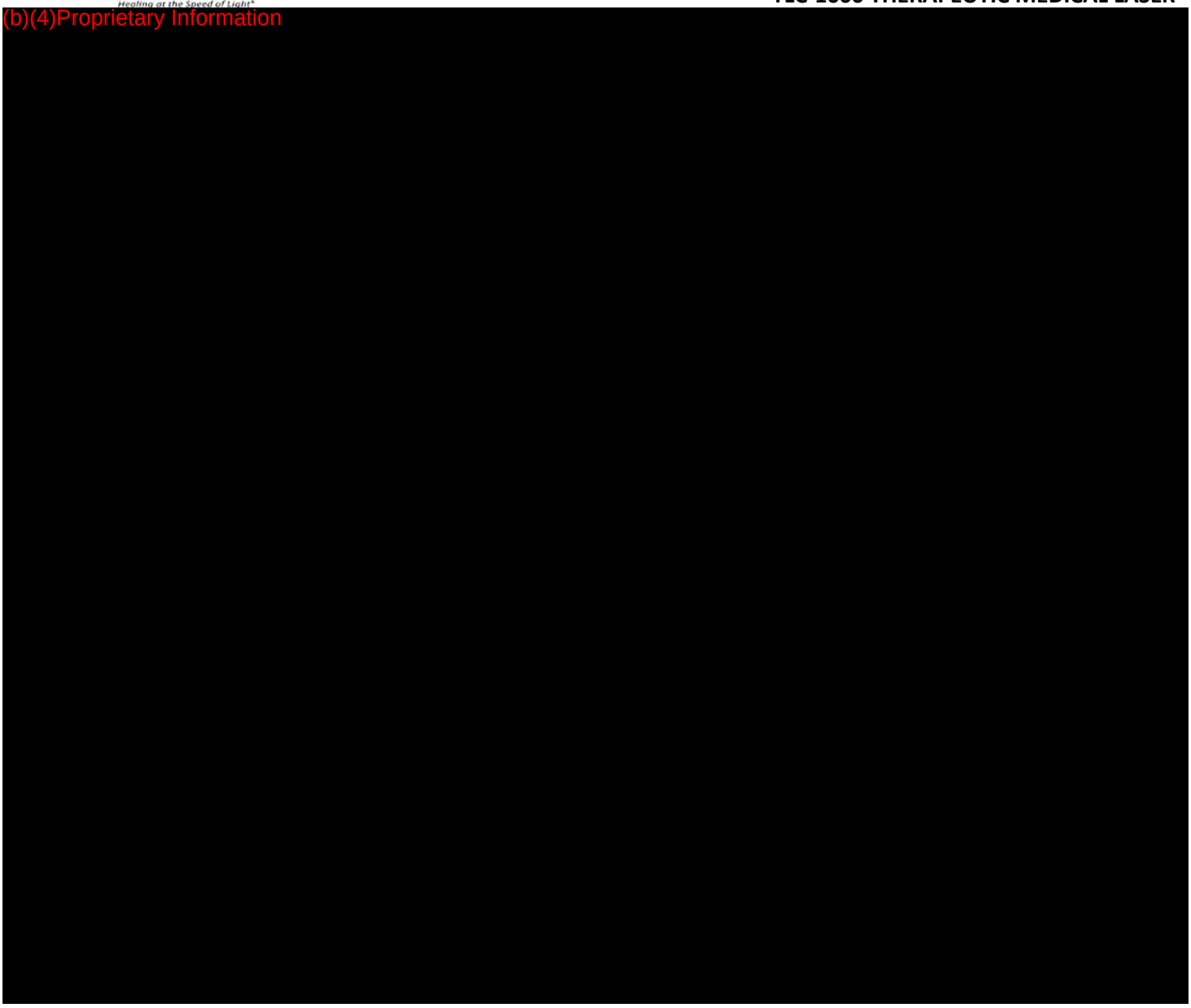

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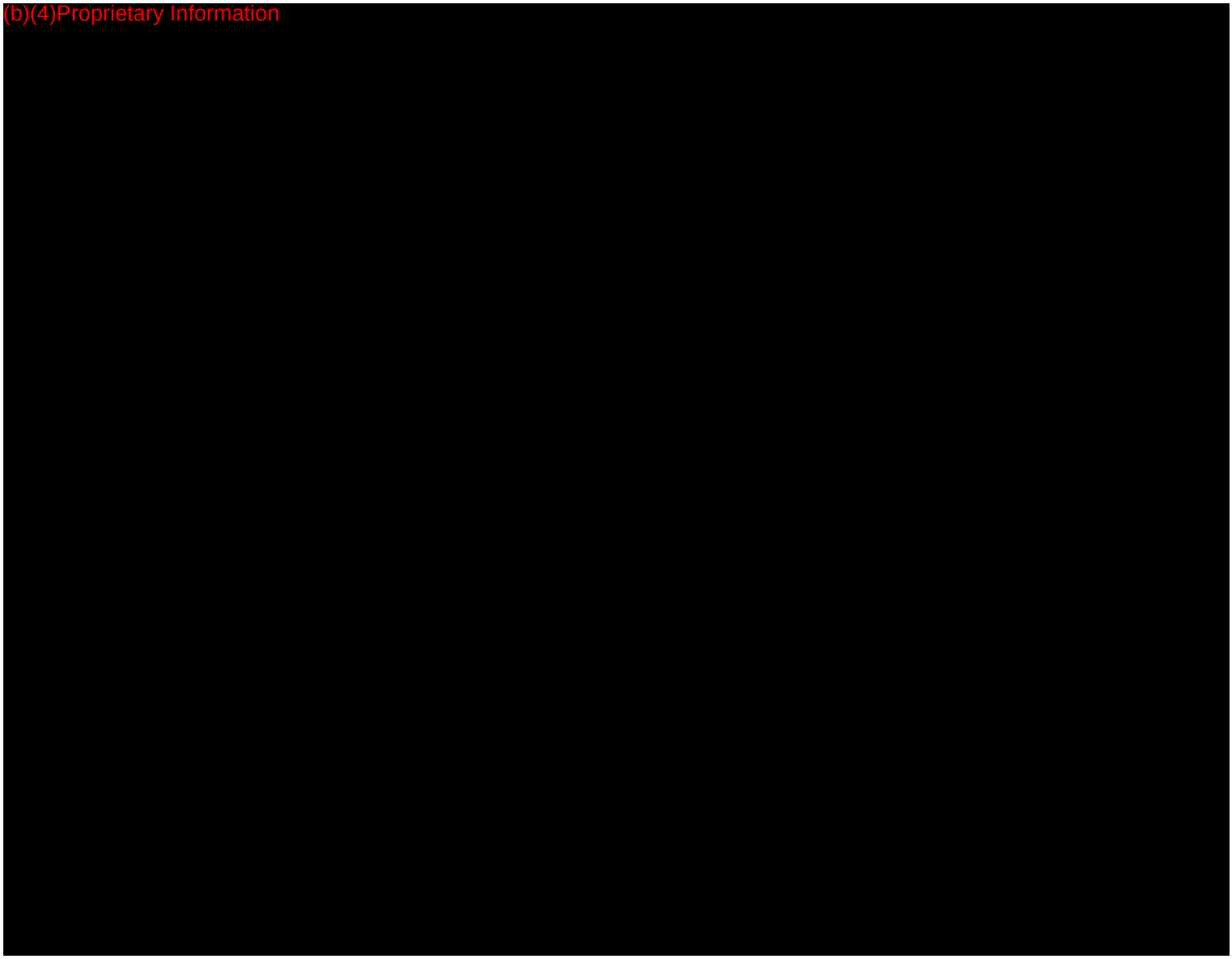

7.Electro Magnetic Compatibility Information

In accordance with clause # 5.2.x of EN 60601-1-2.

Interconnecting Cables

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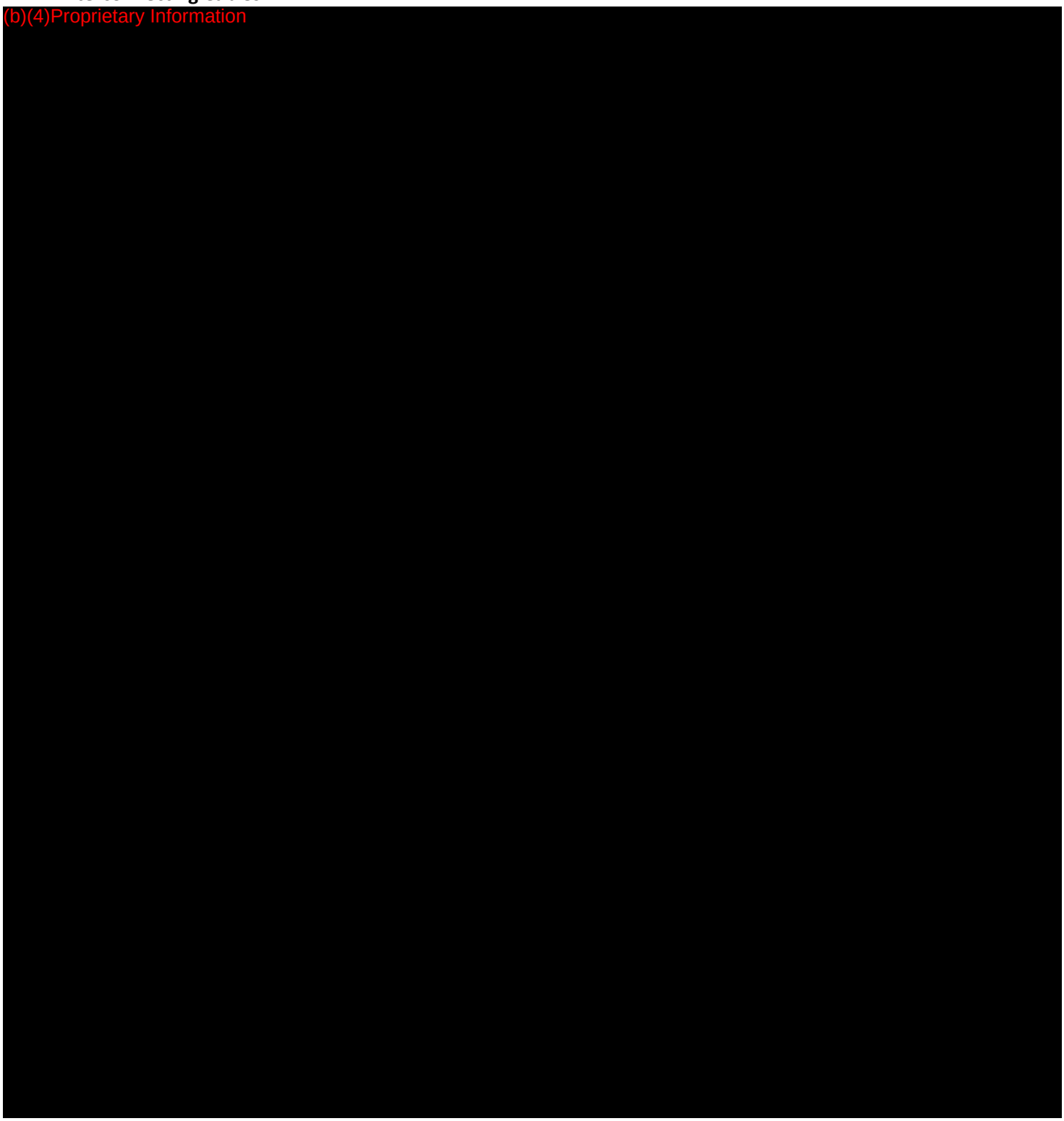

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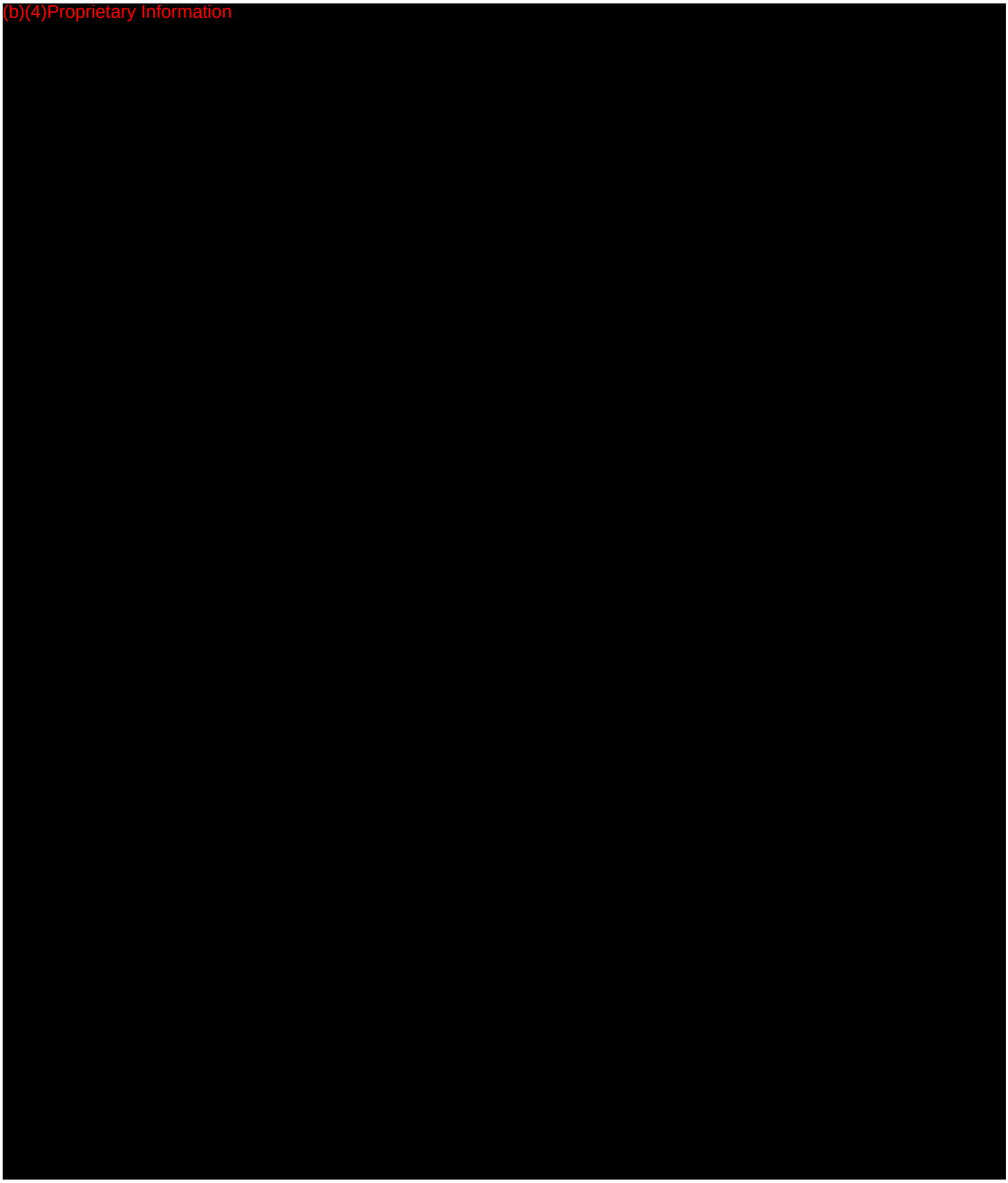

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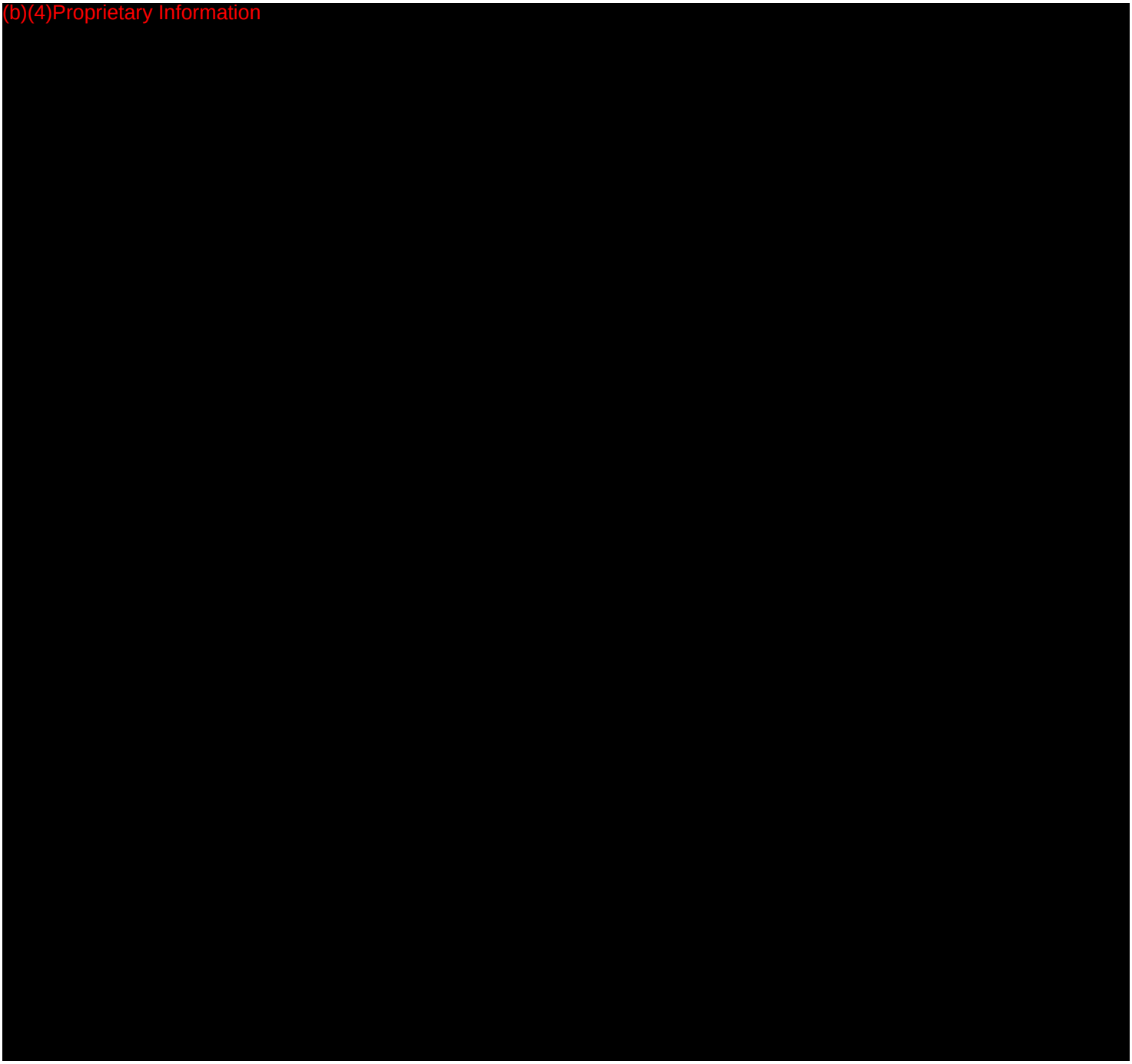

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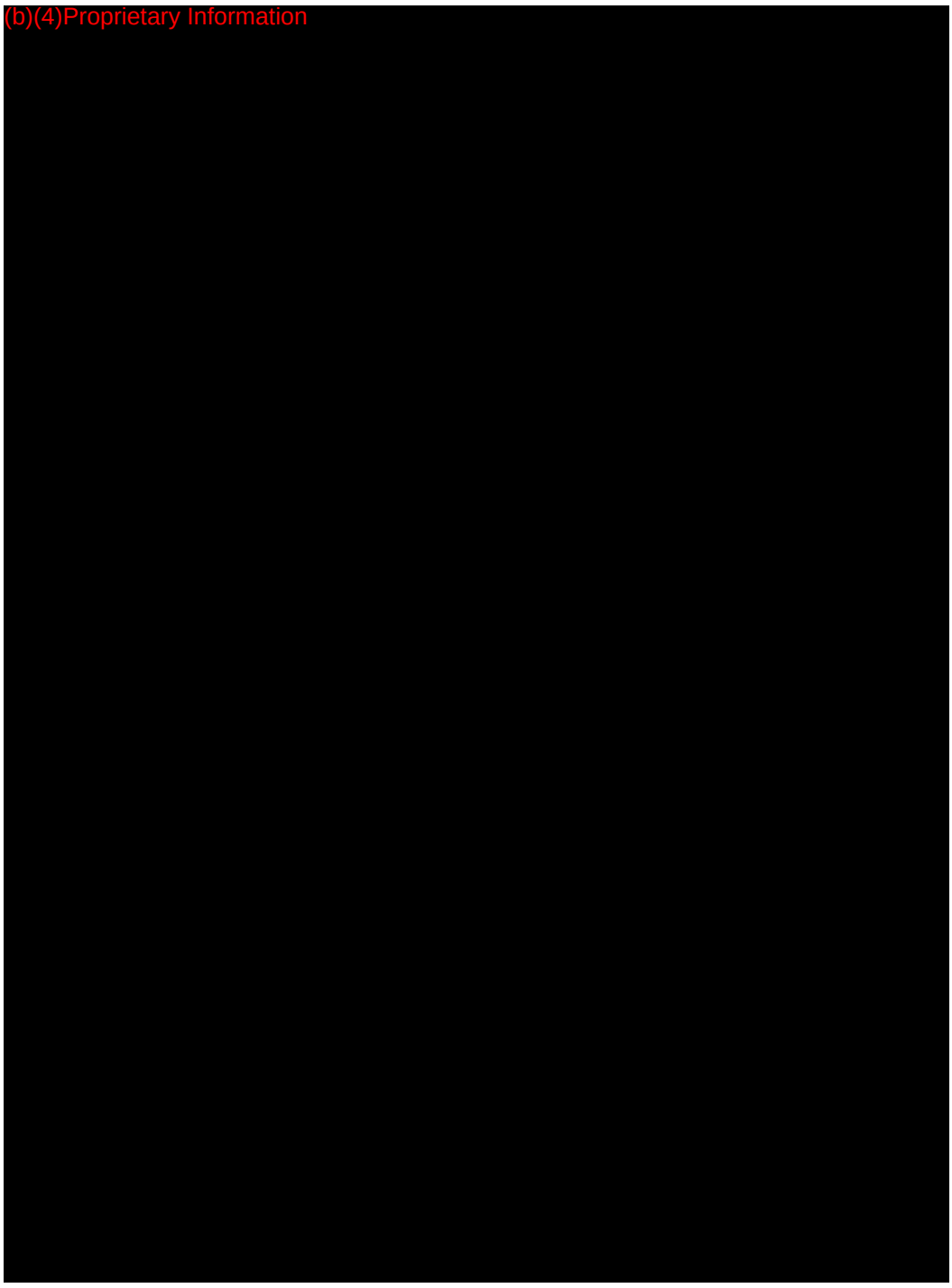

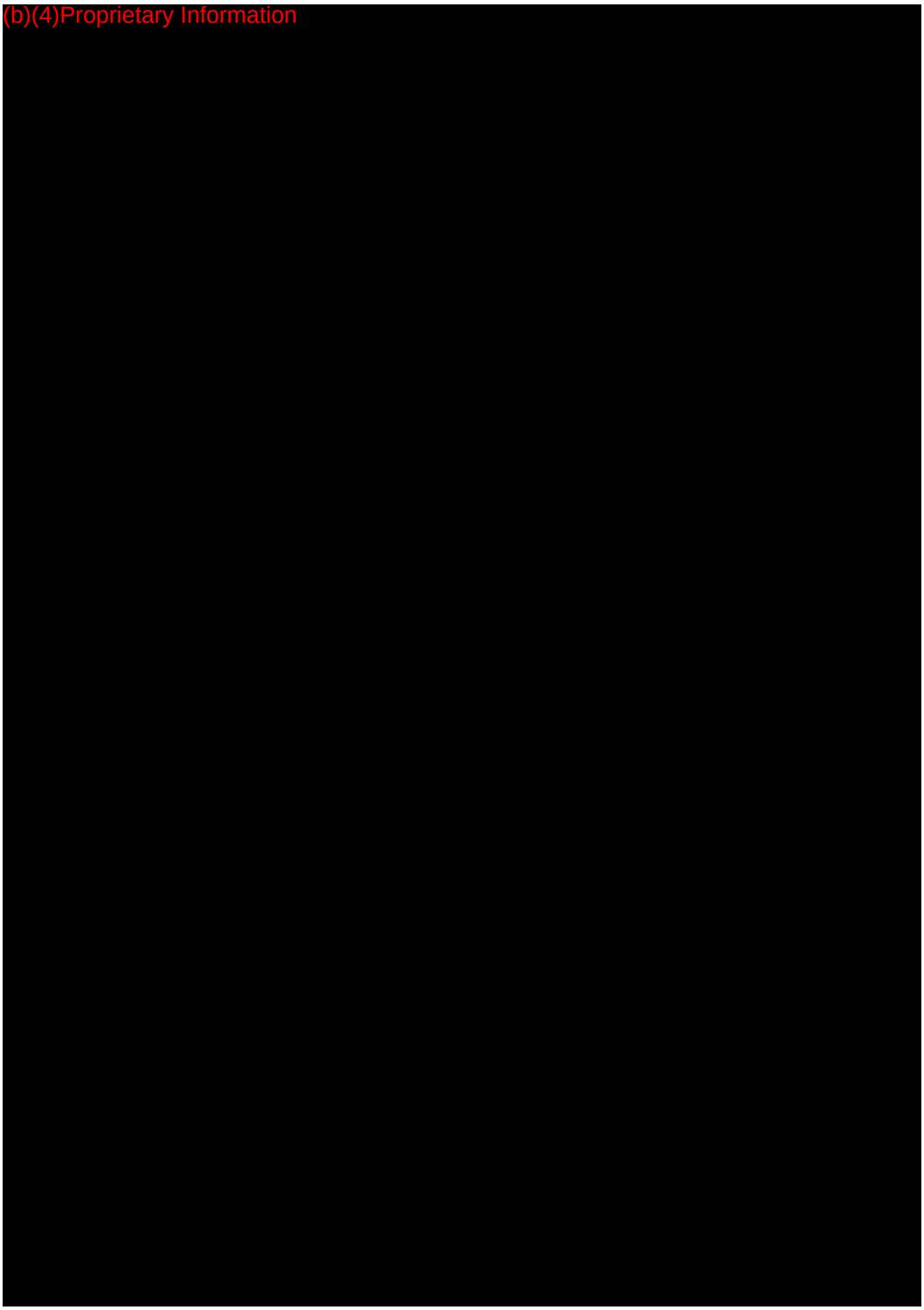

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Healing at the Speed of Light®

TLC-2000
OPERATIONS MANUAL

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1. Safety Information – Please Review Before Using the Theralase System

The Theralase™ TLC-2000 therapeutic laser is a Class 3B medical laser and as such is a potential hazard for direct and indirect viewing of the laser light.

The Theralase TLC-2000 system as mentioned earlier is composed of four main components; the tablet computer, the Power Supply, the Power Pack and the Laser Probes. The Laser Probes are the applied parts of the system. Safety and safe use of the product are indicated both visually by the use of labels as well as equipment features. These will be detailed below.

NOTE: IT IS IMPORTANT TO BE WELL AWARE OF ALL THESE SAFETY DETAILS PRIOR TO USING THE EQUIPMENT.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Labeling and an Explanation of Symbols

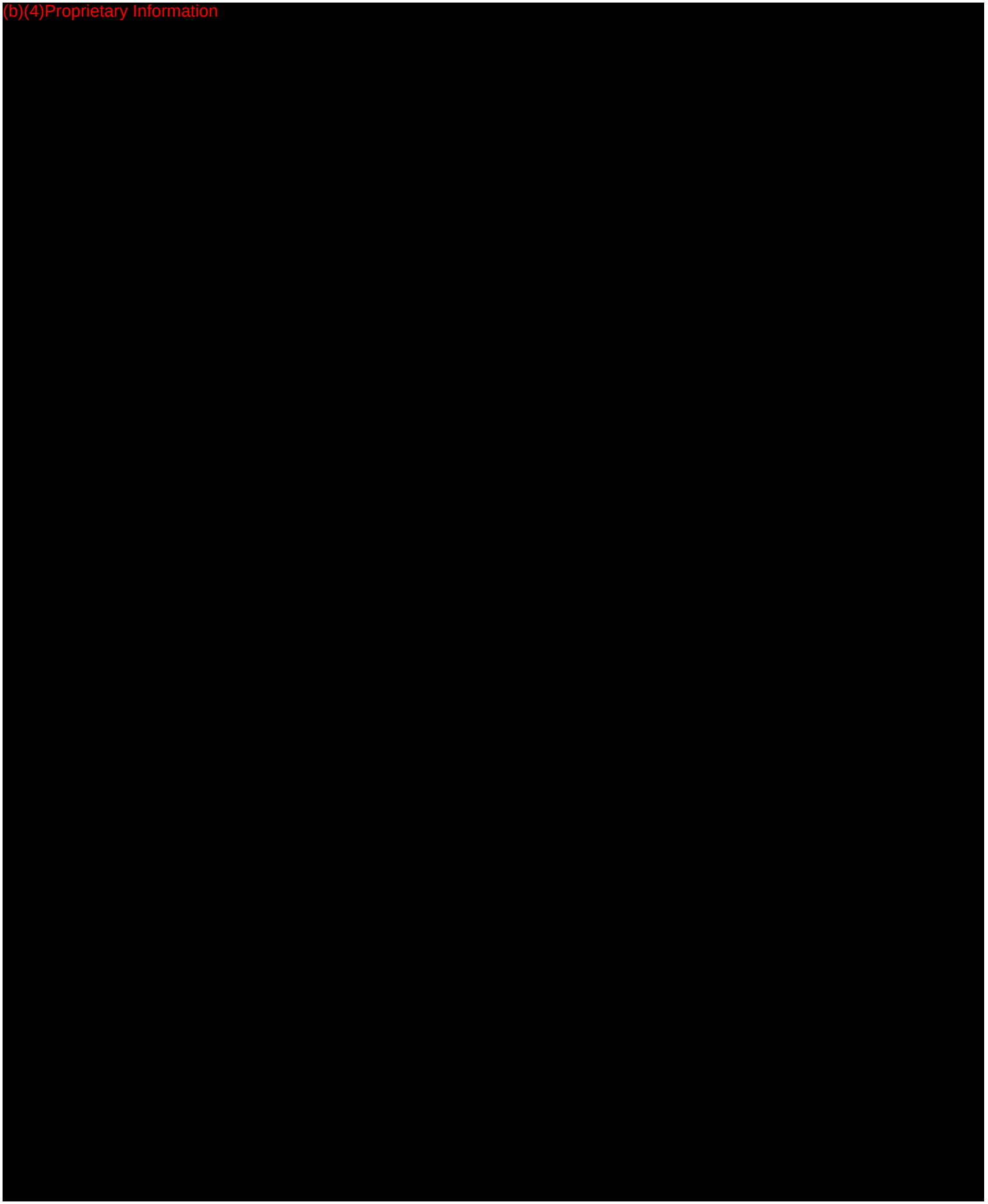
TLC-2002 Power Pack

TLC-2000 Laser Probe

TLC-2003 Power Supp y

F gure Locat on of the safety symbo s on the Thera ase TLC-2000 System

(b)(4)Proprietary Information



KEY EQUIPMENT SAFETY FEATURES

HARDWARE

In addition to the safety signs placed on each of the elements of the Theralase™ system, key safety features are built into the TLC-2000 Power Pack and Tablet software as well. These are illustrated below.

Figure 3. Safety Features

1. Emergency Stop: This button shuts down the entire laser system immediately when pressed.

2. ON/OFF Key Switch: This is the main on / off switch for the laser system. When not in use, the keys can be placed in a safe location to prevent unauthorized use of the equipment.

3. Remote Interlock Connector: The Remote Interlock Connector is a connector that may be removed for disconnecting the mains power.

4. Laser Probe: The Laser Probes are the applied parts of the system. The Probe cannot operate the laser diodes unless a laser protocol has been received from the tablet software.

5. Tablet Software: Even if the Key Switch is left in the system with the Remote Interlock Connector in place and the Laser Probe(s) turned on, there is yet another security feature in place. The Laser Probe(s) cannot emit laser light unless treatment data has been received from the Theralase software on the tablet. To login into the operating system the Theralase TLC-2000 application software requires a username and password to operate.

(b)(4)Proprietary Information

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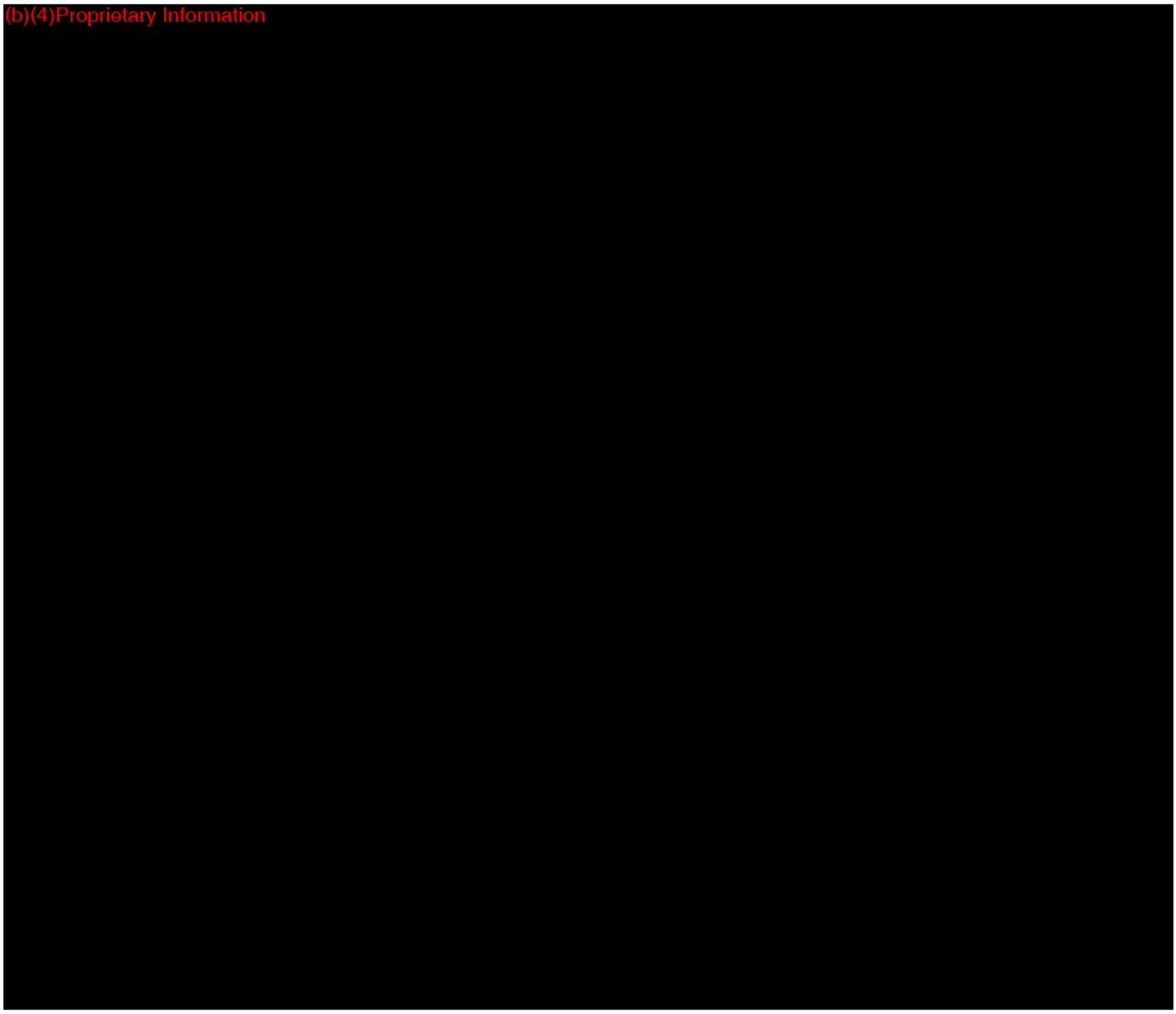
OPERATIONAL SAFETY

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

(b)(4)Proprietary Information



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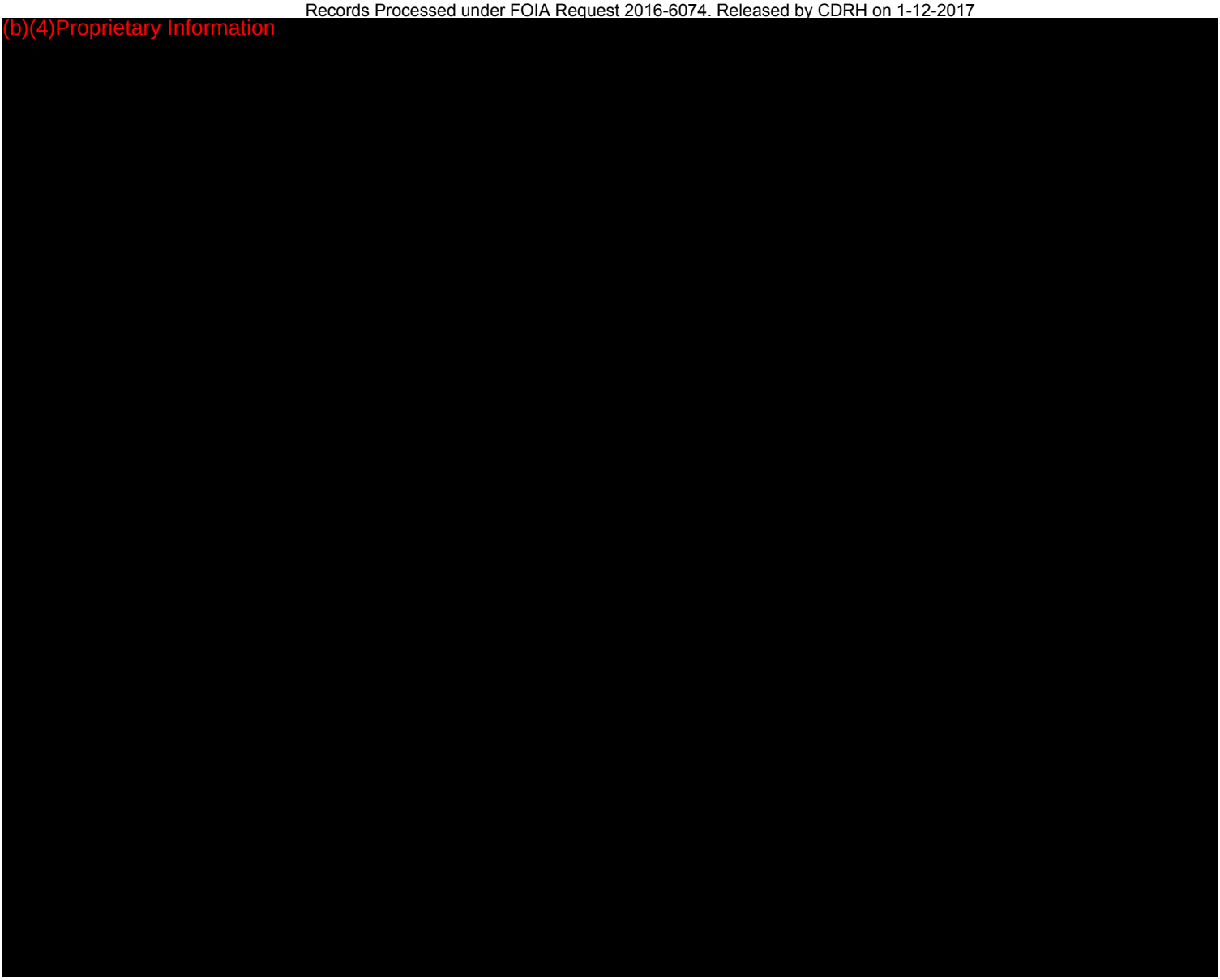


SAFETY WARNING

- The TLC-2002 Laser Power Pack is designed to operate with a TLC-2001 Laser Probe only.
- The Theralase™ TLC-2000 laser and all attachments are not designed to be protected from water intrusion and should never be used wet or in the accompaniment of water. If the laser system becomes wet or immersed in water, thoroughly dry the laser system and allow 48 to 72 hours in a warm environment to fully dry prior to use. If problems persist, contact Theralase™ Inc. for service.
- The Theralase™ TLC-2000 laser and all its attachments should not be used in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- The Theralase™ TLC-2000 laser and all attachments are not suitable for use in the presence of strong electromagnetic field or other electrical interference.
- The Theralase™ TLC-2000 laser and all attachments are designed as an integral system and use of parts other than the recognized accessories or parts can degrade the performance of the Theralase™ TLC-2000 laser and may result in hazardous radiation exposure.

WARNING:
No Modification of This Equipment is Allowed

WARNING:
To Avoid Risk of Electrical Shock, This Equipment Must Only Be Connected to a Supply Mains With Protective Earth.

DISCLAIMER INFORMATION

The TLC-2000 therapeutic laser system is a medical device and is sold to healthcare practitioners as a tool for the rehabilitation of their patients. The TLC-2000 therapeutic laser system and attachments are utilized to assist in the alleviation of their patient's symptoms. The TLC-2000 therapeutic laser system is not promoted as a cure for any patient ailments.

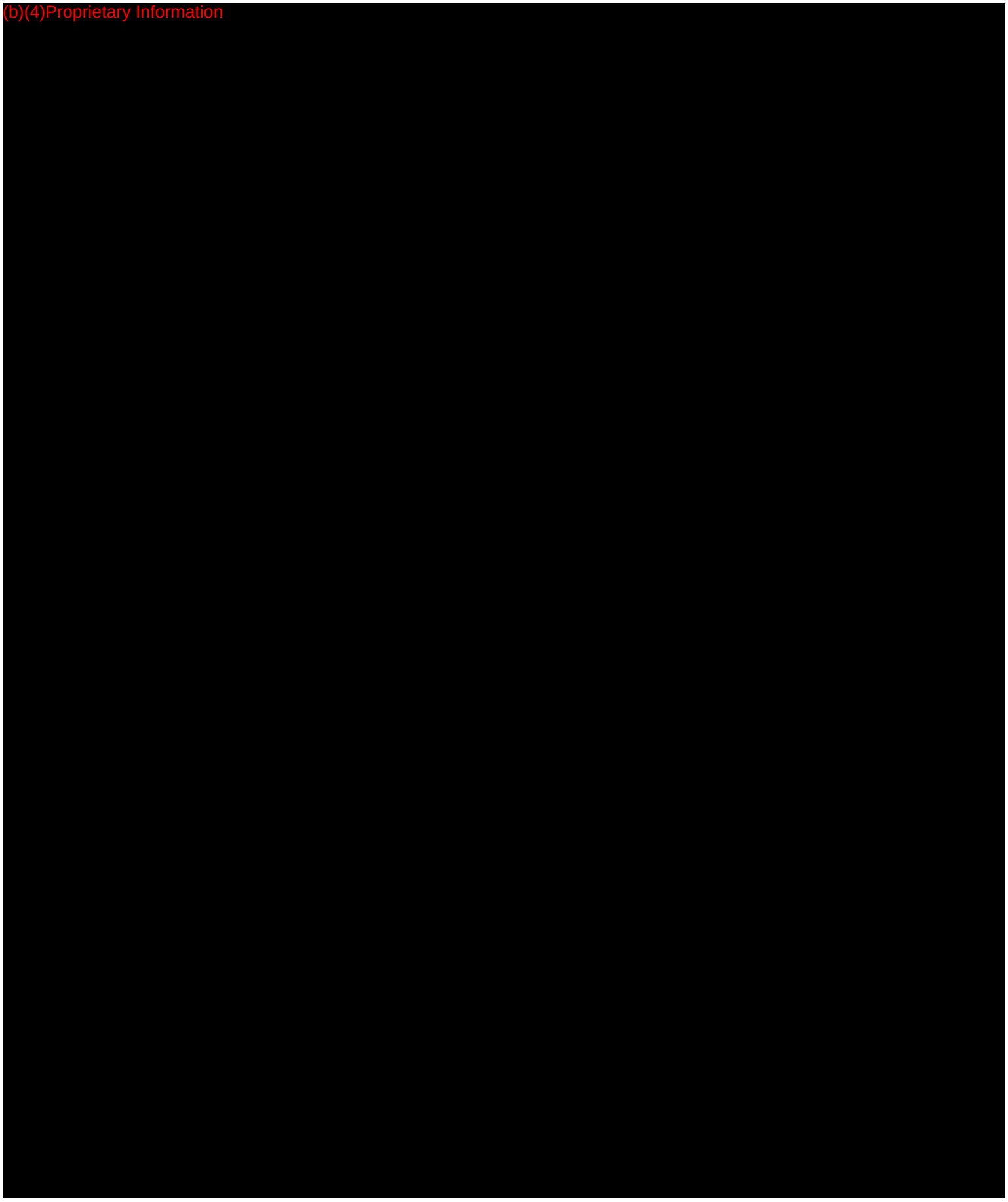
The information contained in this manual is for reference only and does not preclude the practitioner from using proper judgment in the rehabilitation of their patients.

It is the practitioner's sole responsibility to decide if laser therapy is indicated for their specific patient's rehabilitation.

The treatment protocols detailed in this manual are for reference only and are not promoted as the only protocol available to the practitioner.

The Theralase TLC-2000 Therapeutic Medical Laser System is
"Indicated for Adjunctive Use in the Temporary Relief of Pain Associated with Knee Disorders with Standard Chiropractic Practice."

(b)(4)Proprietary Information



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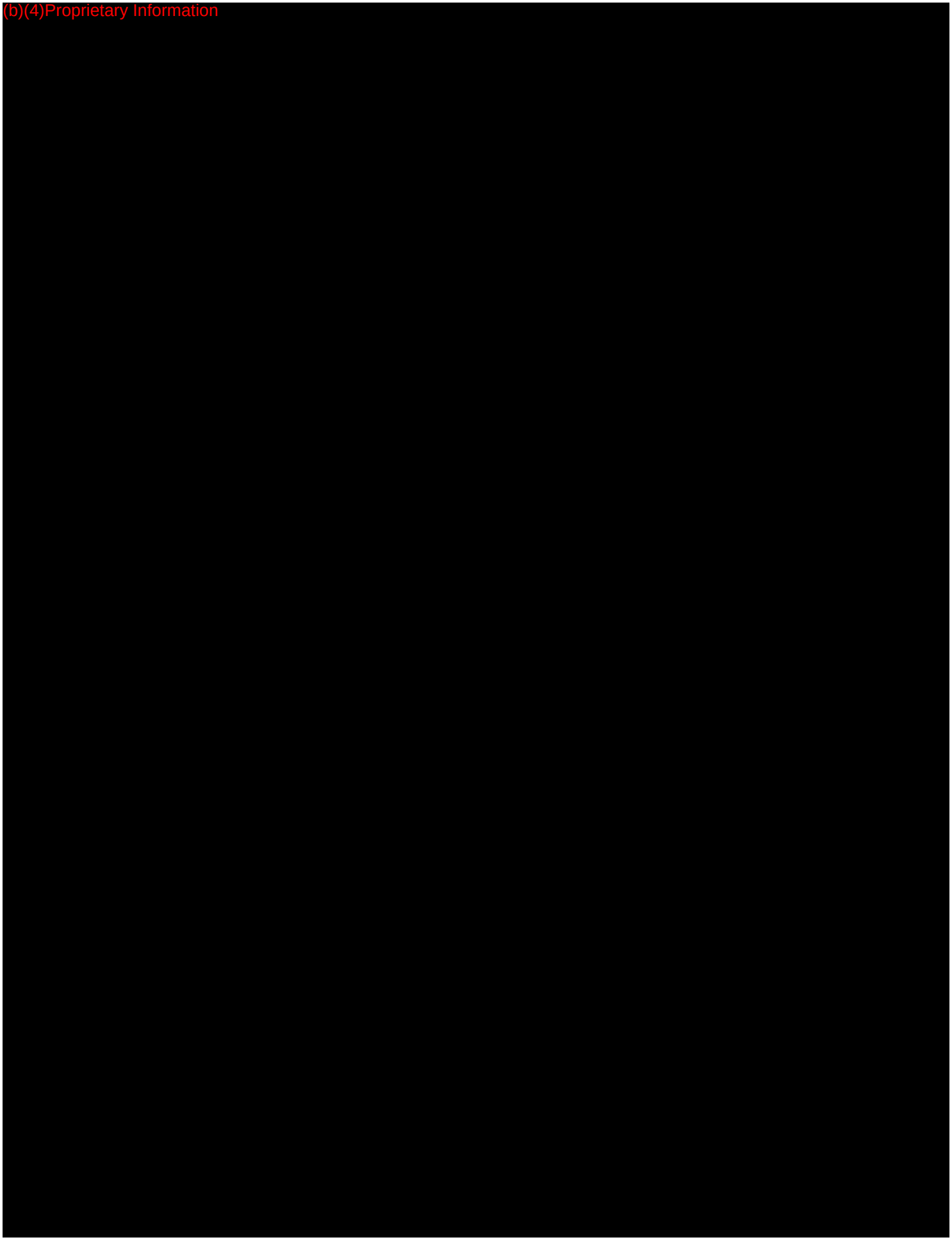

THE LASER POWER PACK (TLC-2002)

The Theralase™ TLC-2000 laser system Power Pack (TLC-2002) is shown below. The Power Pack consists of an aluminum case with a plastic top and bottom.

Laser Probe Port | Unit ON Indicator | Laser Probe Power ON Indicator

Remote Interlock Connector | Emergency (E-STOP) Switch | Key Switch

Figure 5. The TLC-2000 system Power Pack (TLC-2002)

The Theralase™ TLC-2000 laser system and all attachments are rated as Class 1 ME equipment, type BF and are equipped with Class 3B lasers.

Details regarding the safe use of the TLC-2000 system components are detailed in section 2 and operation of the unit in sections 3 and 4.

The top of the unit has an emergency STOP button (red button with white arrows), a key switch for switching the unit off and being able to lock the unit from unauthorized use, an interlock switch and a green ON LED. A further detail of these items as well as their operation is detailed in section 2.

The following are the detachable parts for the TLC-2000:

Power Supply: TLC-2003 Power Supply (+24 VDC, 4.2 A)
Laser Probe: TLC-2001 Laser Probe

WARNING: PLEASE DISCONNECT POWER SUPPLY BEFORE SERVICING

The Power Supply (TLC-2003)

The TLC-2003 is a universal power supply – the input voltage range is 100VAC to 240VAC, 47 to 63 Hz, meaning that it can be safely used anywhere in the world. The TLC-2003 power supply is able to power the TLC-2002 Power Pack.

Plugs in to main AC line via power cord (TLC-155)

Power output: Voltage: +24 VDC
Current: 4.0 A

Power supply TLC-2003 plugs in to the Power Pack - TLC-2002

Figure 7. TLC-2003 Power Supply and associated Line Cord

With the proper cord set the TLC-2003 can be plugged in anywhere in the world. The cord set (TLC-155) supplied with the Theralase™ TLC-2003 power supply is a hospital grade 115 to 120 VAC, 50 to 60 Hz approved cord set. This is built to a North American standard and was chosen to work in Canada and the United States.

Some of the key features of the TLC-2003 Power Supply include

100-240 VAC Universal Input
In Case IEC320
Single Output up to 101 Watts
Outputs Regulated with Low Ripple
Meets Safety Agency Requirements
Complies with EMC/EMI Regulations
CE Compliant
Impact Resistant Polycarbonate Enclosure

CAUTION:

• Use only the TLC-2003 Power Supply (+24 VDC, 4.2 A) to power the TLC-2002 Power Pack. This is the only Power Supply approved to be used with the TLC-2000 laser system.

• Outside of North America, the proper international cord set must be specified and purchased from Theralase® Inc. or purchased separately for the country of preference.

(b)(4)Proprietary Information

[redacted]

CAUTION

The Laser Probe Cover should be placed over the lens area when not in use.

Connecting/Disconnecting the Laser Probe (TLC-2001) to the Power Pack (TLC-2002)

The Laser Probe features a very simple medical grade push-pull cable connector. This consists of a cable with a plug assembly on each end and a printed circuit board-mount receptacle assembly in the Power Pack and the Laser Probe.

Assurance of proper mating is provided by keying. The key(s) of the cable plug assembly are designated by an arrow on the plug and must align with the key of the receptacle assembly.

Figure 11. Probe Assembly illustrating the key

The cable plug assembly must be properly aligned with the receptacle assembly, and then inserted until the latches engage the receptacle assembly. There should be no need to force the connector into the receptacle. To ensure proper mating, there must be an audible "click". Refer to Figure 12.

Figure 12. Mating the Connectors – Cable Plug Assembly Key is aligned with Receptacle key

The connectors must be unmated by first gently sliding the housing subassembly away from the receptacle assembly – see Figure 13 and then pulling the entire connector out. PLEASE hold the main body and DO NOT pull the cable.

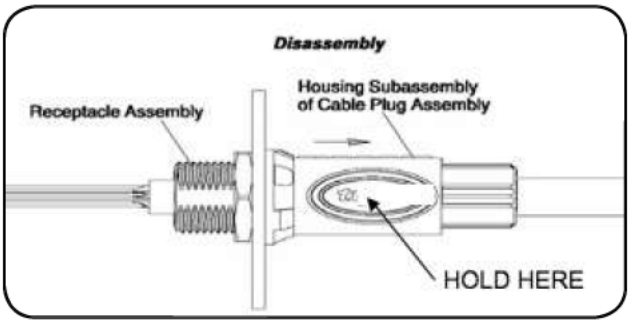

Figure 13. Un-mating the connected assembly

ACCESSORIES

Accompanying the TLC-2000 system, in addition to the above main items, will be two sets of laser safety goggles (TLC-901).

Safety Eyewear:

Two sets of laser safety goggles (part #: TLC-901) are supplied by Theralase as standard accessories. These laser safety goggles are provided for viewing of diffused laser light only and are not indicated for direct viewing of the laser output.

It is highly recommended that both the practitioner and the patient wear laser safety eyewear during laser therapy treatment.

Figure 14. Theralase supplied Laser Safety Eyewear

Optical Density **("O.D.")** is the scientific term to describe a material's ability to block light of a certain wavelength. It is a logarithmic formula, where the higher the O.D. value, the better the material blocks light. For example, an O.D. of 1 means the material will allow 10% of the light penetrate the eyewear at a particular wavelength.

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(b)(4)Proprietary Information

Therefore, using the Theralase™ approved laser glasses may result in the following levels of light being transmitted to the eye (assuming of course that the laser diode is directly in contact with the laser glasses and pointed at the eyes on the individual's face):

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CAUTION:

Use only Theralase™ Inc. supplied laser safety eyewear or laser safety eyewear that meets or surpasses the above noted optical densities at the above-specified wavelengths

NEVER POINT A LASER TOWARDS A PERSON'S EYES UNDER ANY CIRCUMSTANCES

Figure 14. Hard case for TLC-2000 system (part number: TLC-1200)

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3. START-UP INFORMATION

A detailed description of the individual system components

The Power Pack (TLC-2002)

The TLC-2002 Power Pack provides power to the TLC-2001 Laser Probe.

Figure 16. A detailed look at the Power Pack

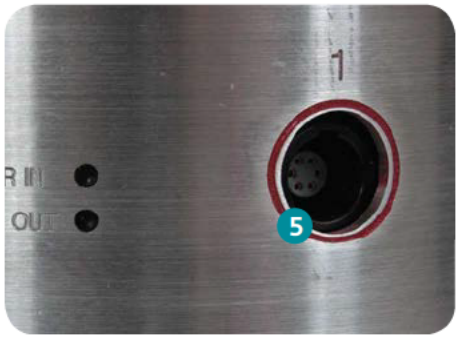
1. Remote Interlock Connector The Remote Interlock Connector is capable of disconnecting the TLC-2001 Laser Probe from main power when removed. To remove, press the button on the connector and pull the Remote Interlock Connector straight out. Main power is now disabled and no action will restore it until the Remote Interlock Connector is replaced. To replace, insert straight into the matching receptacle.

2. Emergency Stop This button shuts down the entire laser system immediately when pressed, disabling mains power.

NOTE: Depressing the Red Emergency Stop Button immediately disables the laser system. Operation may be resumed by rotating the Red Emergency Stop Button 1/4 of a turn to the right and allowing it to "pop out" again.

3. Key Switch This is the main on / off switch for the laser system. When the key is turned to the left, the system is off, disabling mains power. When the key is turned ¼ turn to the right, the system is on. The key can only be removed when in the OFF position.

TLC-2003 Power Supply input



Connection to the TLC-2001

4. Power Supply Input Input for black DC adapter cord from the TLC-2003 Power Supply. When the DC adapter is connected the TLC-2000 Power Pack may be operated directly from an AC wall outlet.

Caution: Use only the TLC-2003 Power Supply for the Theralase™ system.

5. Probe Power Port Power supply port for the TLC-2001 Laser Probe (High Density 6 pin medical grade connector).

6. Power IN LED This LED is illuminated only when the external power supply is connected and the key switch is in the ON position, the Remote Interlock Connector is installed and the Emergency Stop is not activated.

7. Power OUT LED This LED is illuminated only when both of the internal power supply voltages to the probes are good.

Note: The TLC-2001 Laser Probe will not function if this LED is OFF.

The PROBE

The Theralase TLC-2001 Laser Probe is shown below. A feature of the Laser Probe is the use of a heatsink to keep the probe cool during use. There are three different strap sizes provided with the Laser Probes to facilitate holding the probe on different aspects of the knee.

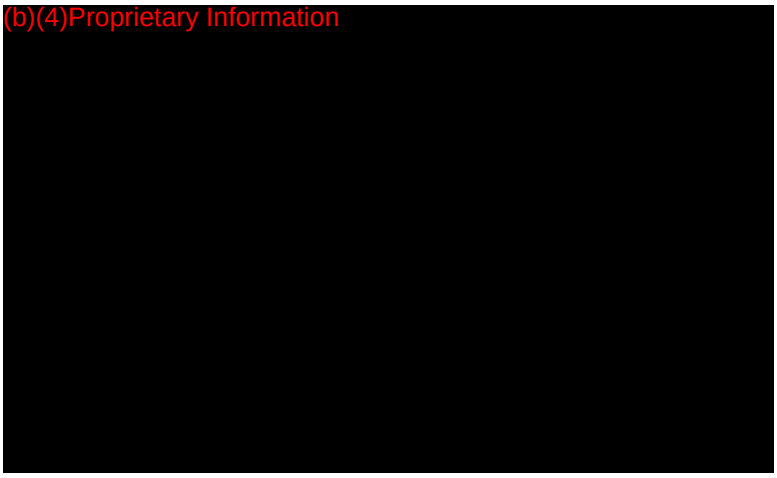


Figure 16. A detailed look at the Laser Probe (TLC-2001)

1. Display A 2.4" Liquid Crystal Display **("LCD")** is used to display the status of the Laser Probe (idle/armed, laser operation(on/off), BlueTooth® quality, laser treatment time, laser power, and Laser Probe error messages.

2. Display Window The display window is made from optically transparent acrylic plastic and can be cleaned with isopropyl alcohol.

3. Power On/Off Switch Slide this switch forward to turn on the Laser Probe. Slide the switch back to turn off the Laser Probe.

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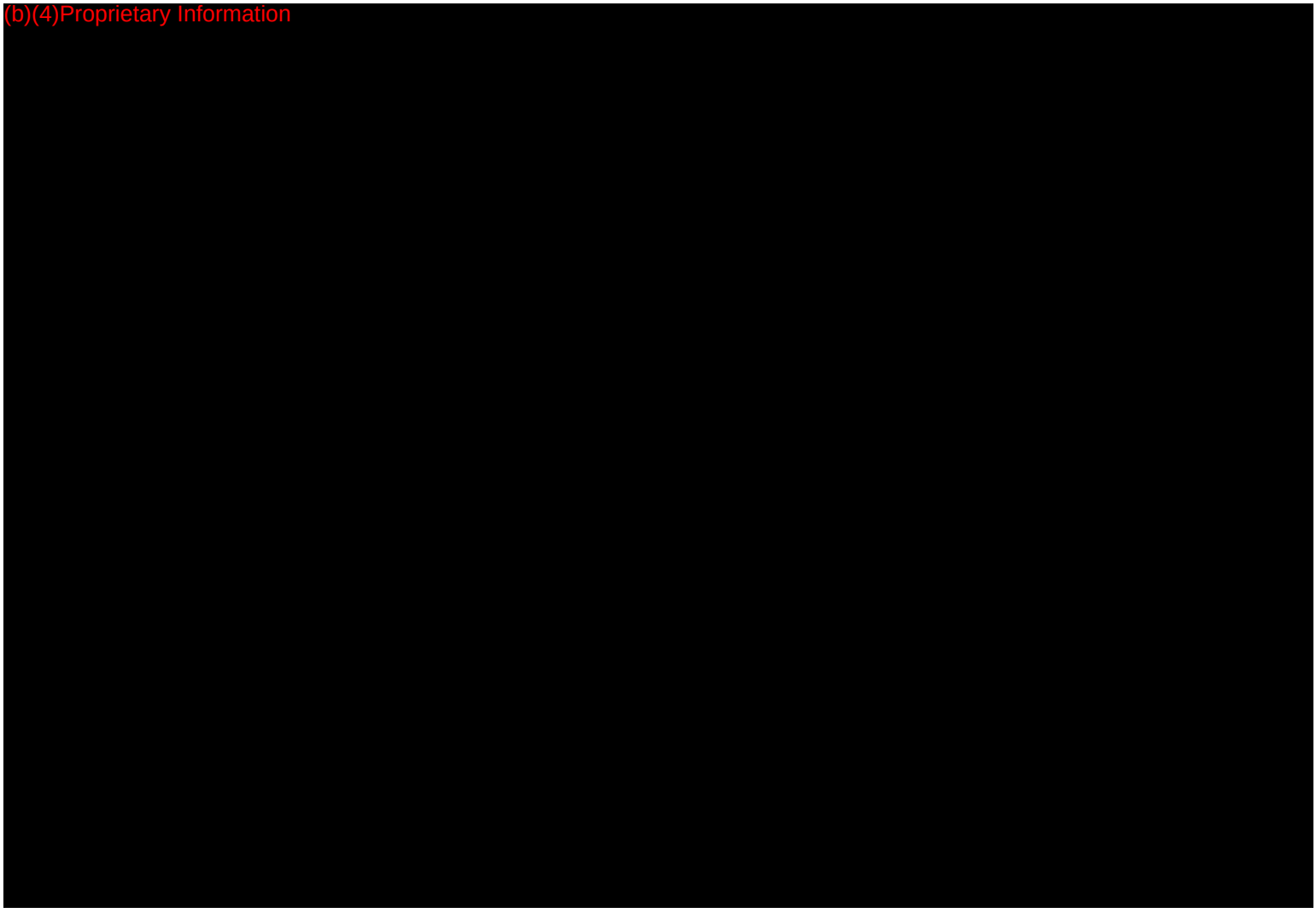
Caution: NEVER look directly into this area with the lasers on.

6. Laser Output Window The laser output window is an optically transparent acrylic plastic mounted to a ring. The window is removable by turning the ring left until it stops and lifting the ring straight off the probe. The window is coated to be scratch resistant. It keeps the lasers clean and can be wiped with isopropyl alcohol. Windows that become scratched should be replaced. Replacement windows can be ordered directly from Theralase.

(b)(4)Proprietary Information



THE TABLET (TLC-2004)

The Tablet comes with the Theralase® software already installed and the keyboard and touch screen together. The touch screen can be separated from the keyboard if desired. There is a pop up touch screen keyboard; however, it may be easier to input data using the attached keyboard. With the keyboard attached, selections can be made using the cursor or the touch screen.

When delivered, the Tablet has an administrator username and password. It is recommended that the system be configured for new passwords and user names. Refer to the section Setting Username and Passwords in the Administrator Menu section for this procedure.

The Tablet is shipped with the manufacturer's user manual and software license card. Refer to those documents for additional information.

Figure 16. A detailed look at the tablet

1. Power On Hold this button down for two (2) seconds until the touch screen turns on.

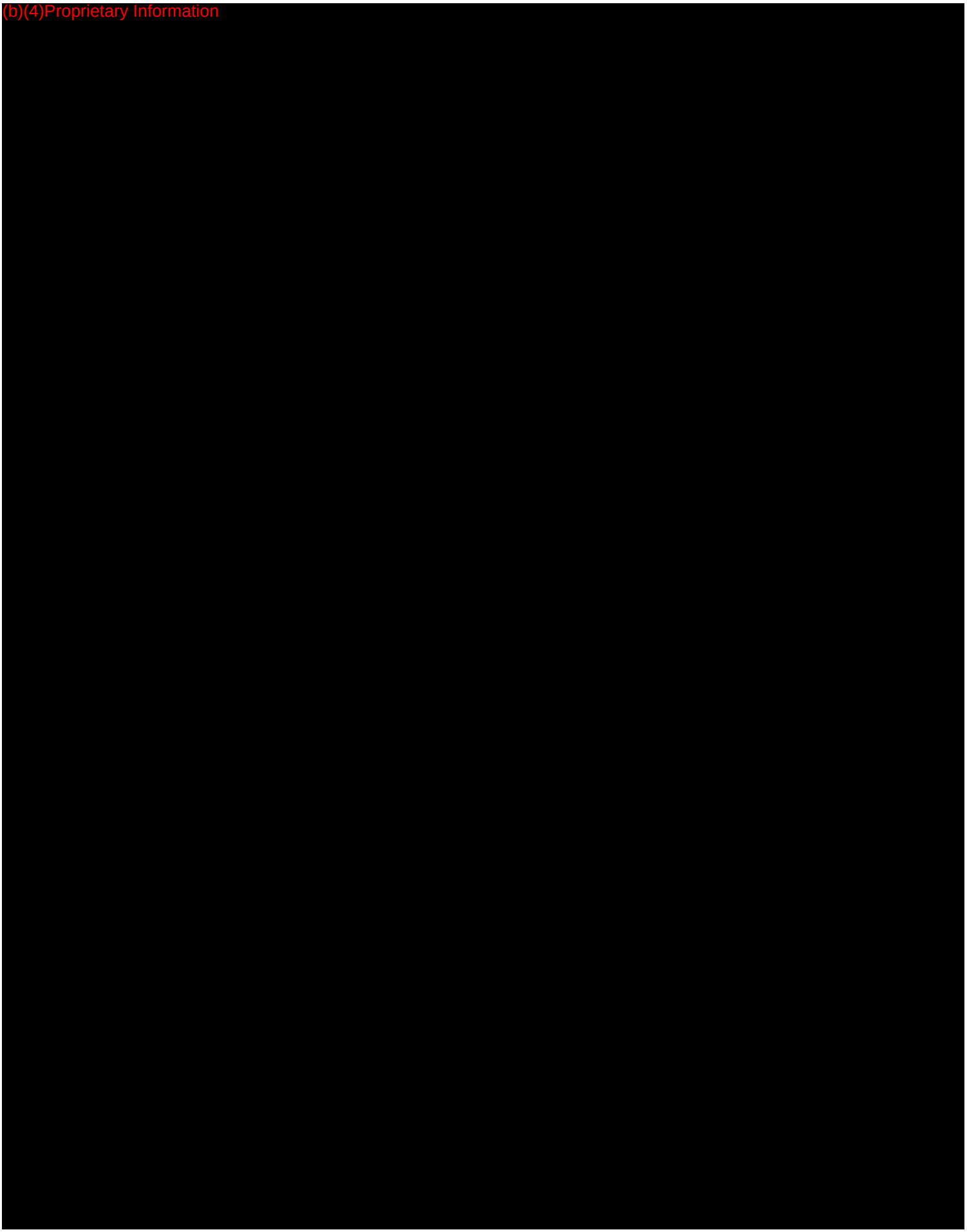
2. Charging Port Plug the micro USB connector from the charger into this port to power the tablet from AC voltage.

3. USB Port Plug the Blue Tooth® USB stick into this port.

4. Release Button Press this button to separate the keyboard and the touch screen.

5. Touch Pad Use this pad to control the cursor and make selections by moving your finger over the surface of the touch pad. Press the lower left corner of the touch pad to make a selection.

(b)(4)Proprietary Information



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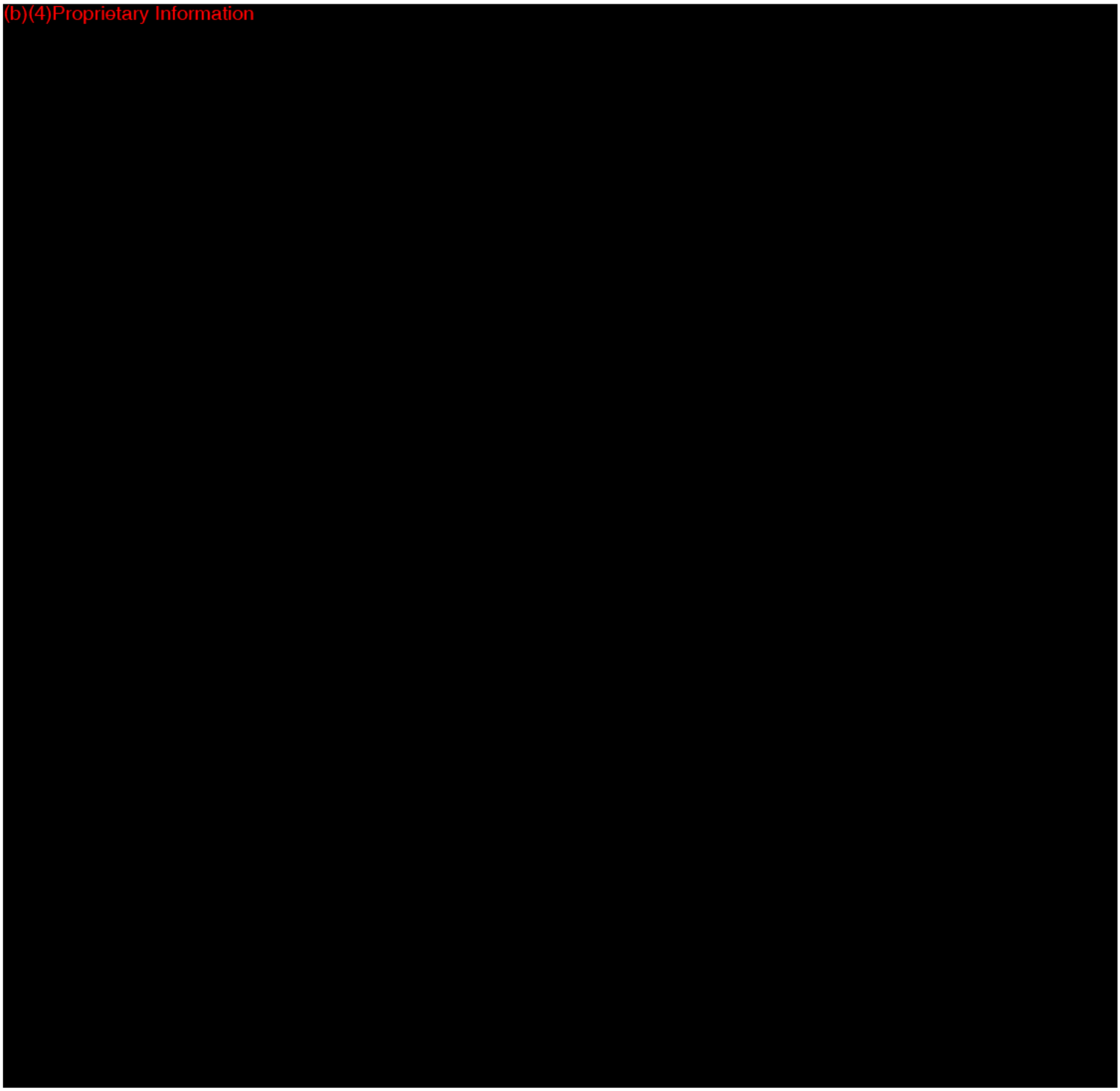
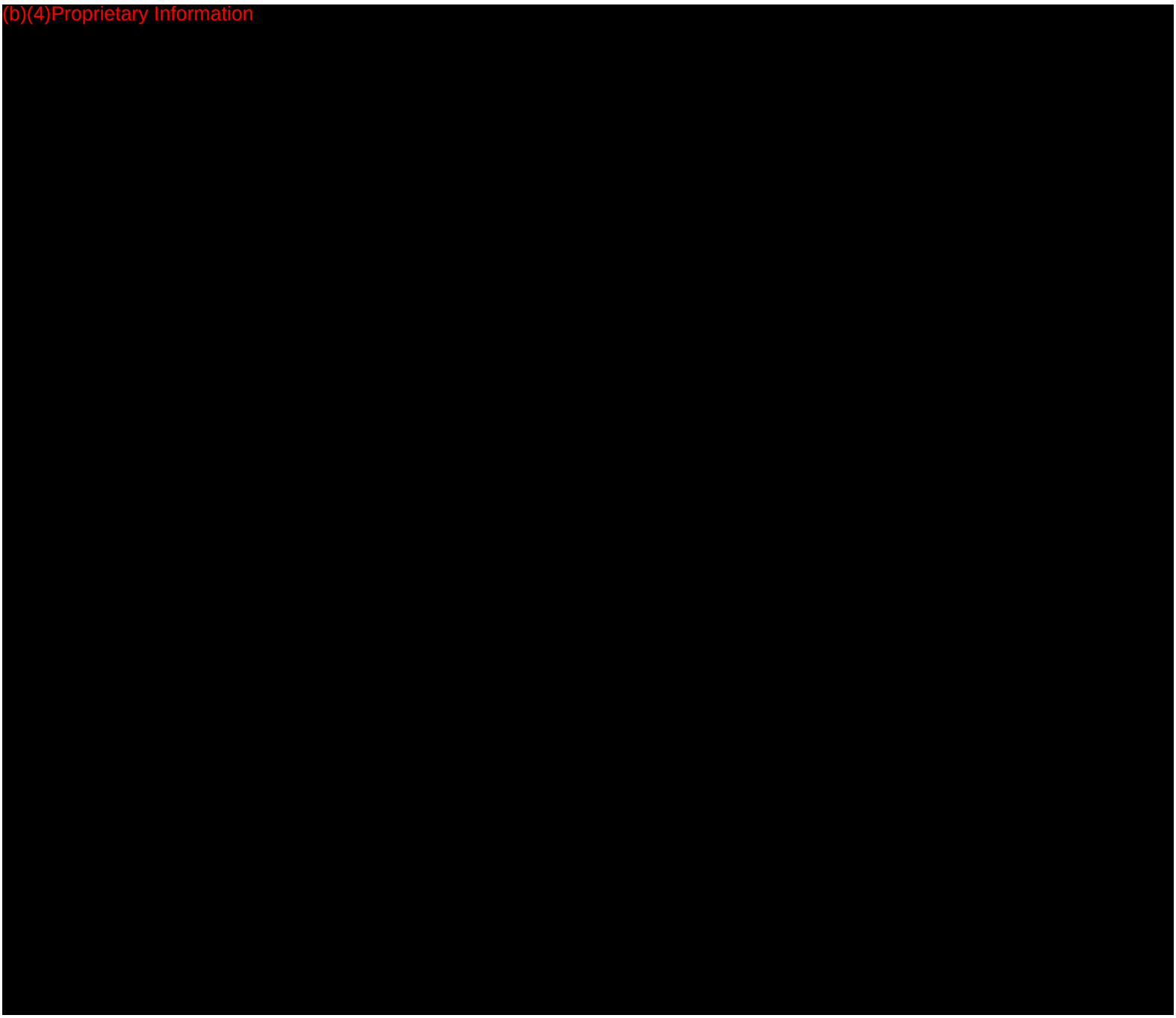


REMINDER:

The Theralase software must be operating with patient data in the database **BEFORE** the Laser Probe will emit laser light.

4. SYSTEM OPERATION OVERVIEW

(b)(4)Proprietary Information



Stop Procedure

The Laser Probe may be turned off during operations by either of the following means:

1. Slide the switch on the Laser Probe to the OFF position.

2. Press the STOP button on the Tablet software

3. Press the Red Emergency Stop Button to stop Laser Probe operation and disable the mains power to the TLC-2000 laser system. Laser operation can only be re-started by turning the E-STOP switch a quarter turn clockwise to allow it to “pop“ out.

4. Turn the on / off power key switch to the left ¼ turn to stop laser operation and to disable the mains power to the TLC-2000 laser system.

The Key Switch or Remote Interlock Connector may now be removed if desired to disable the laser system from unauthorized operation.

Note: Even if the Key Switch is left in the system and the Remote Interlock Connector is in place, the security password must be known to enable laser operation; thereby, providing a 3 step security protocol to prohibit laser use by unauthorized personnel.

Overview of the Menu

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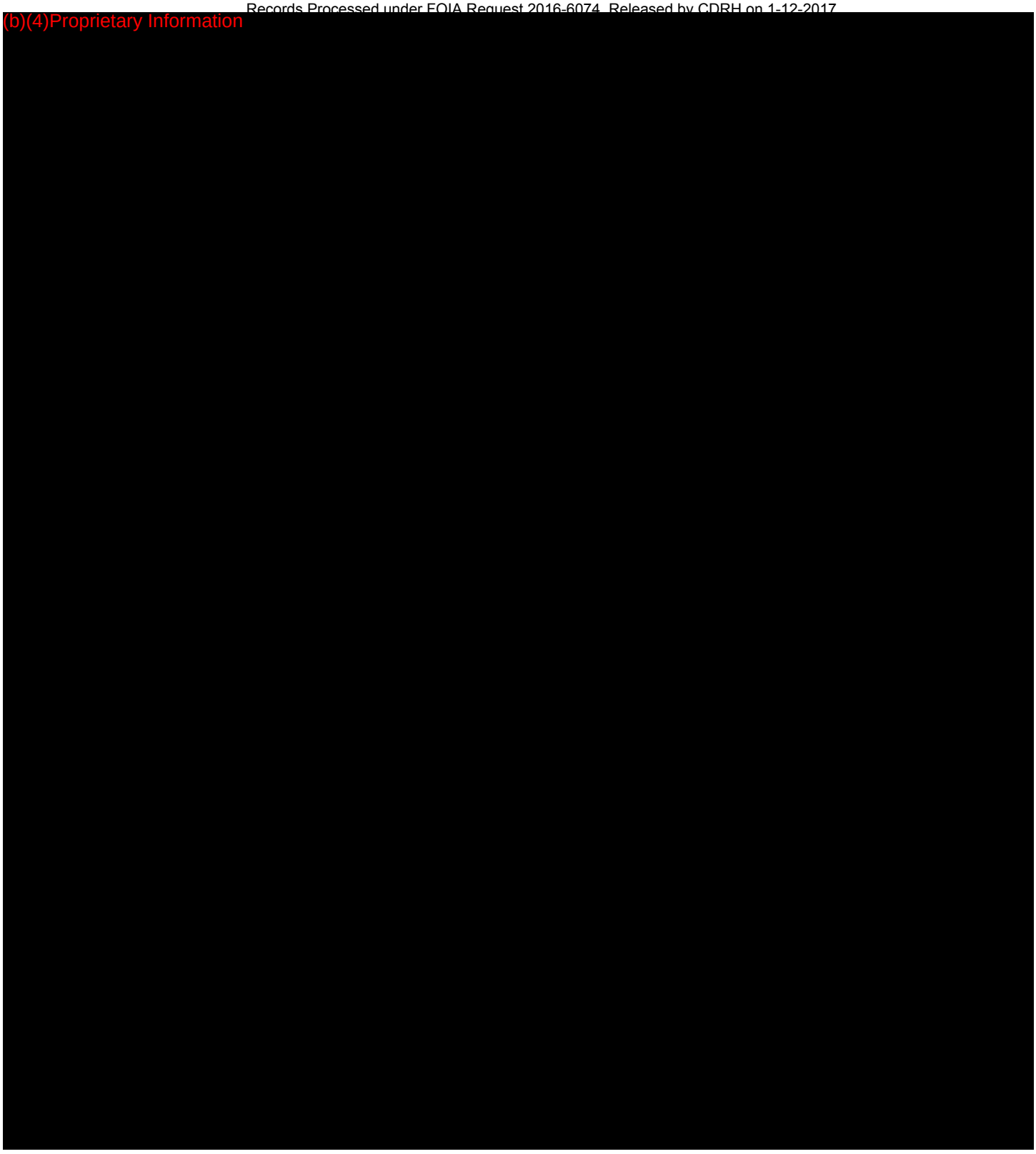
(b)(4)Proprietary Information

SYSTEM OPTIONS TAB

(b)(4)Proprietary Information

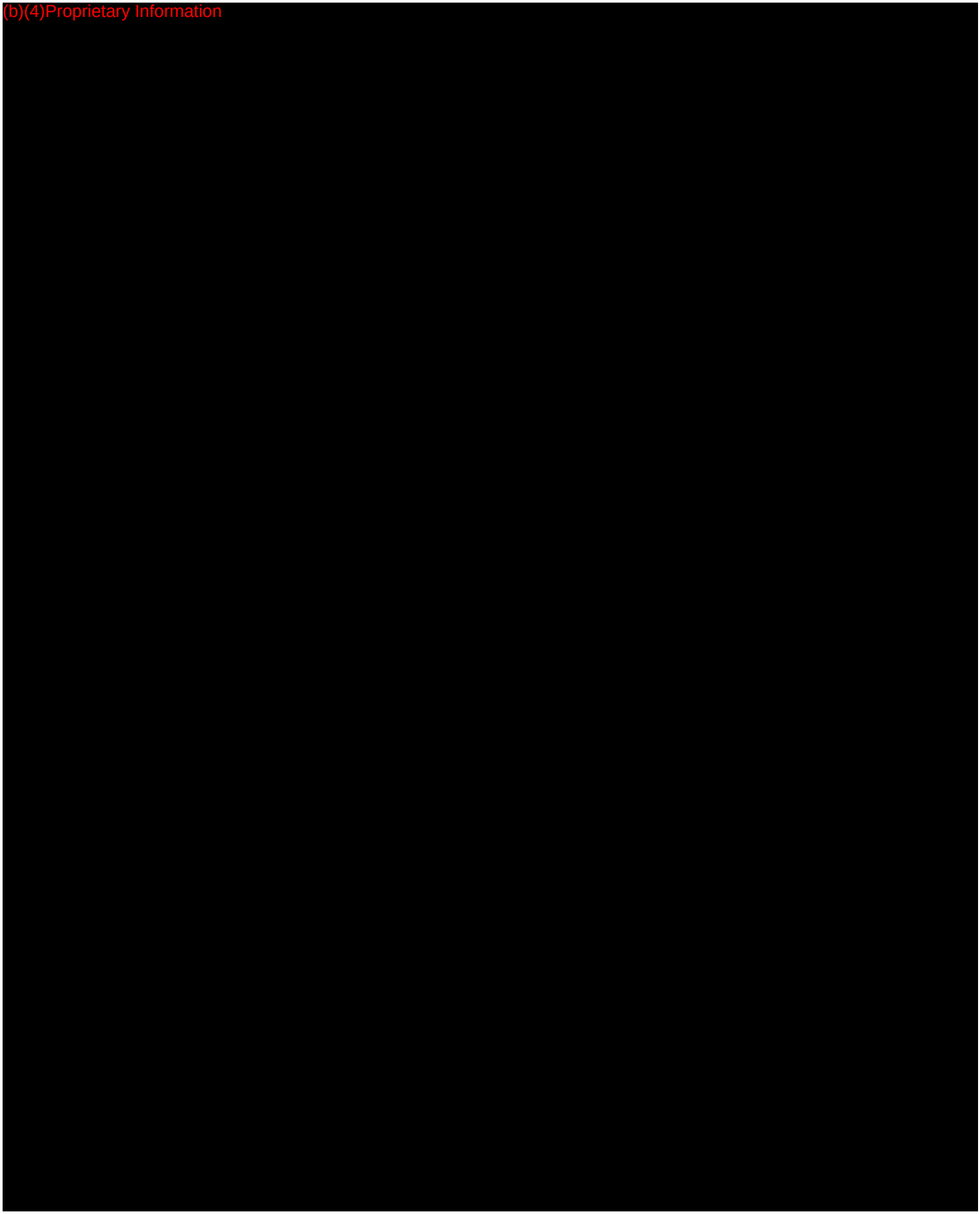
(b)(4)Proprietary Information



Turning the Tablet OFF

To turn the tablet OFF, swipe the screen in a Right to Left motion from the right hand edge of the screen. A vertical menu will be displayed. (To close the vertical menu, swipe the screen in a Left to Right motion.) Touch the Settings Icon to display the settings menu. Touch the power icon and select SHUT DOWN from the pop up window.

(b)(4)Proprietary Information



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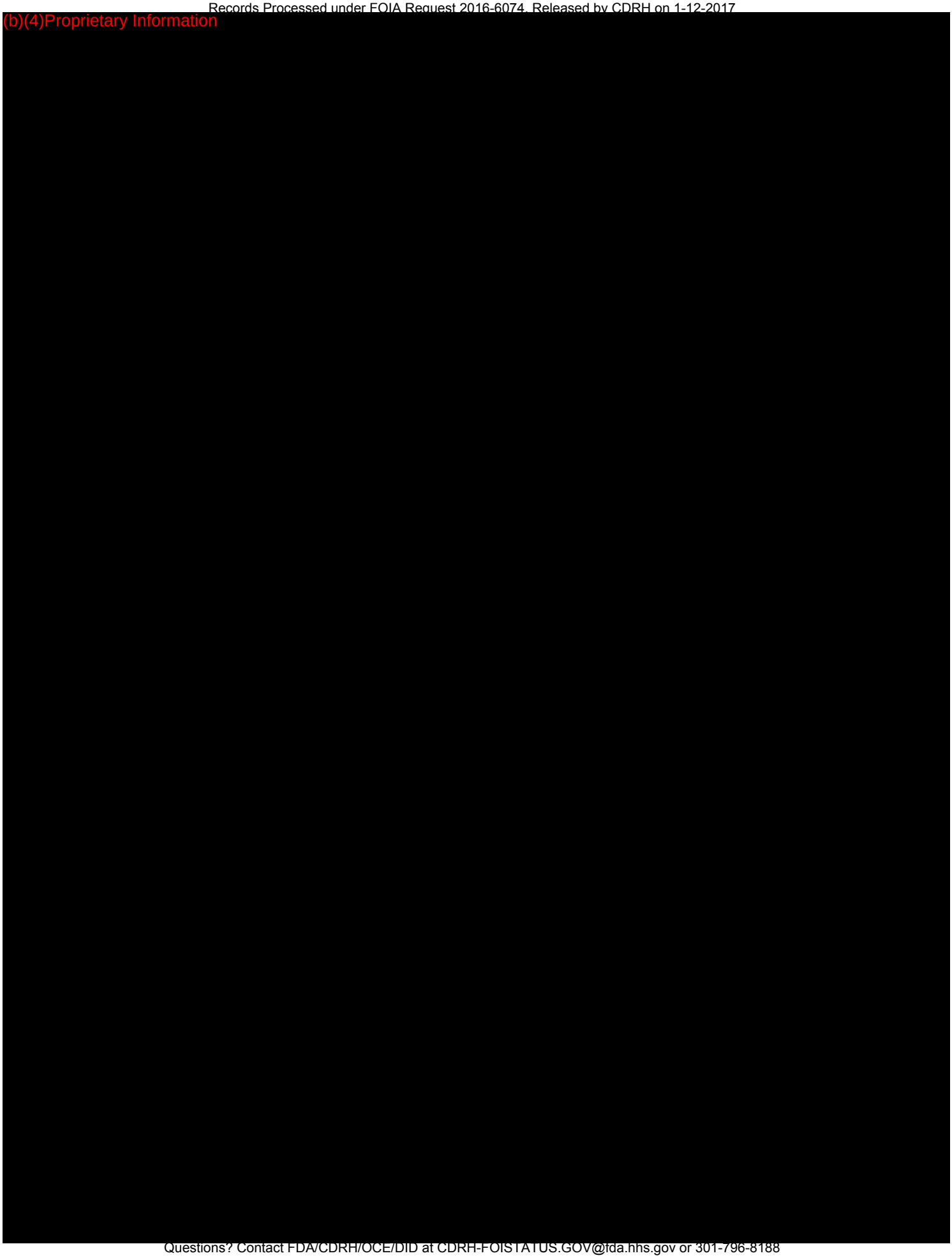

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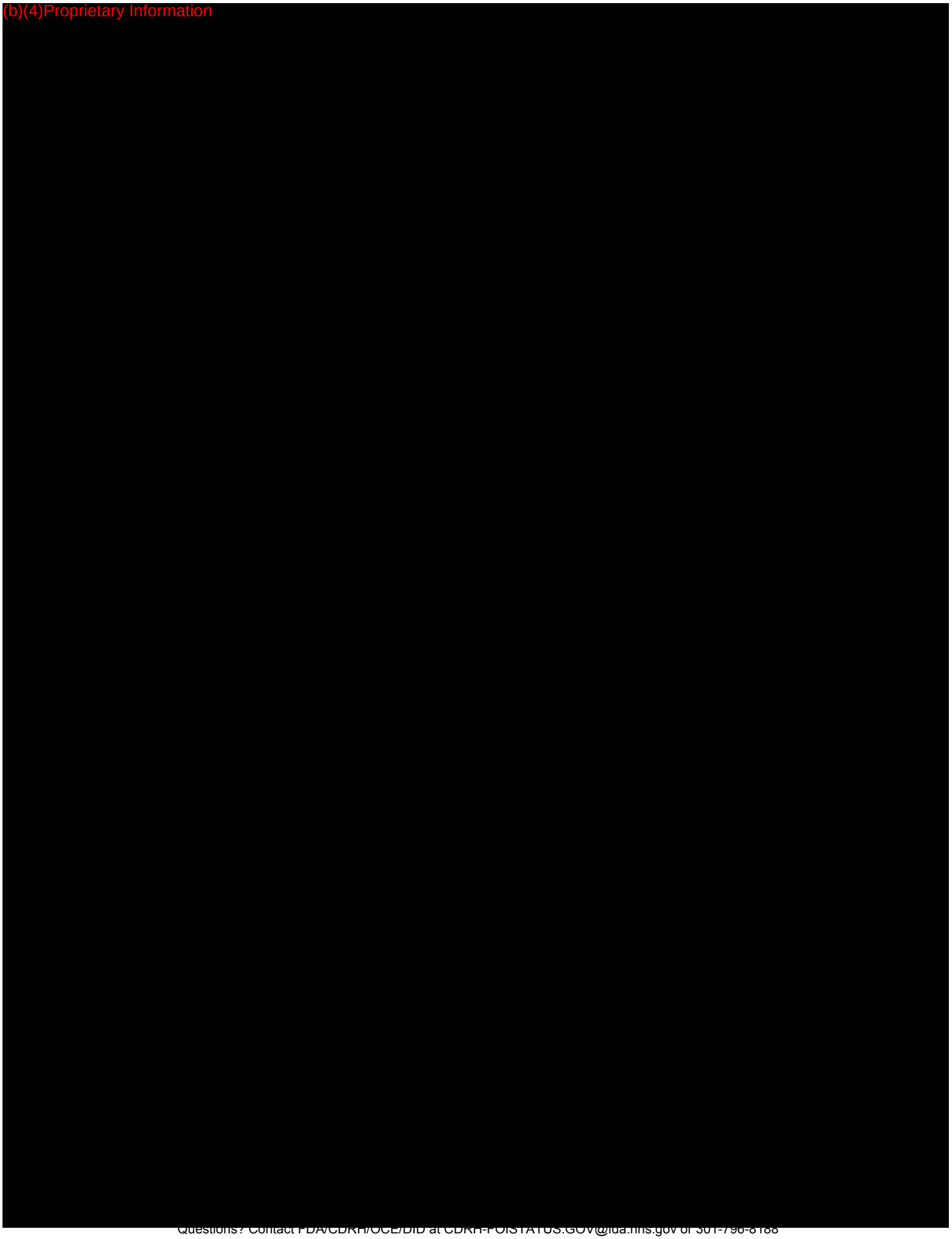

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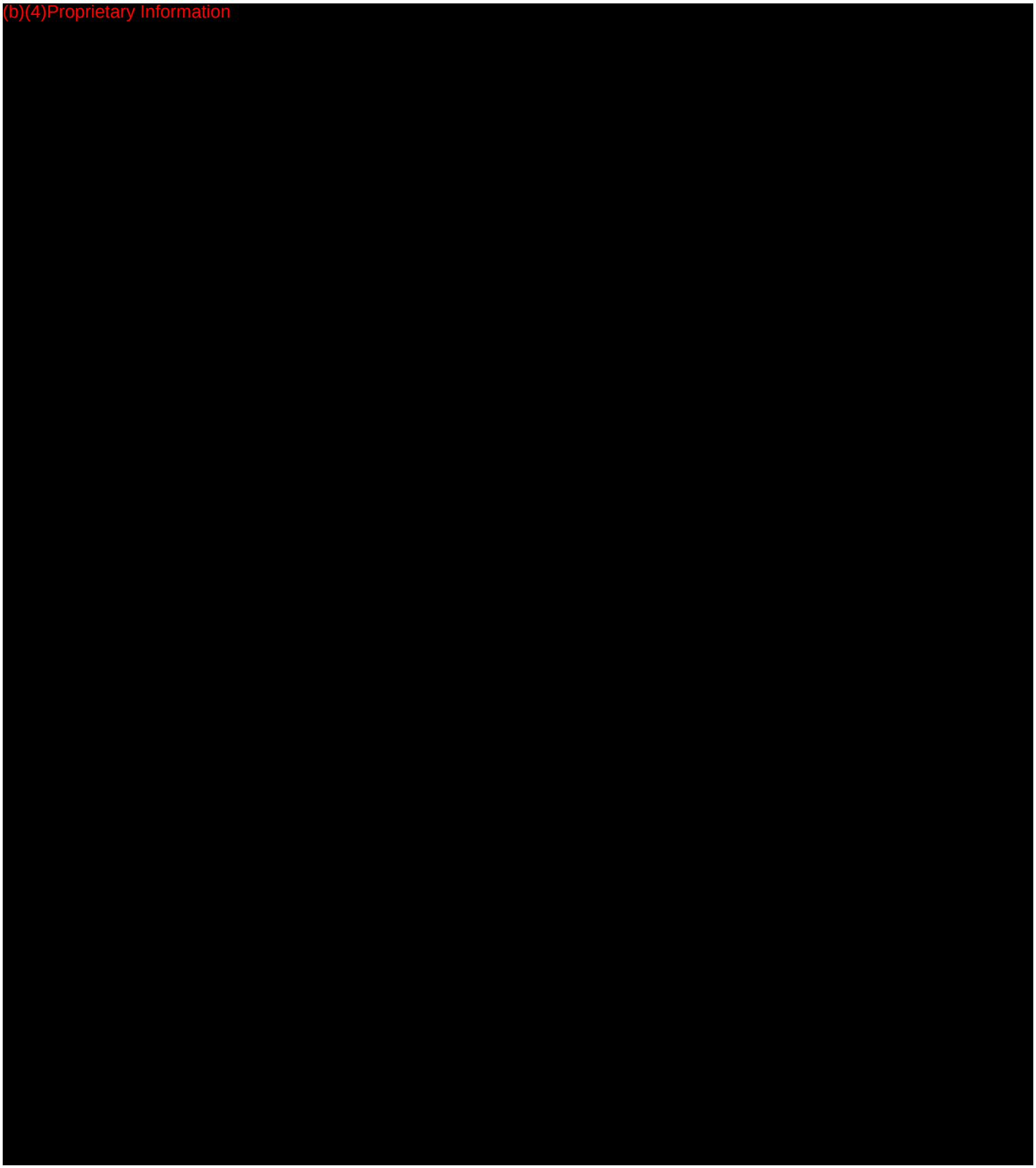
(b)(4)Proprietary Information



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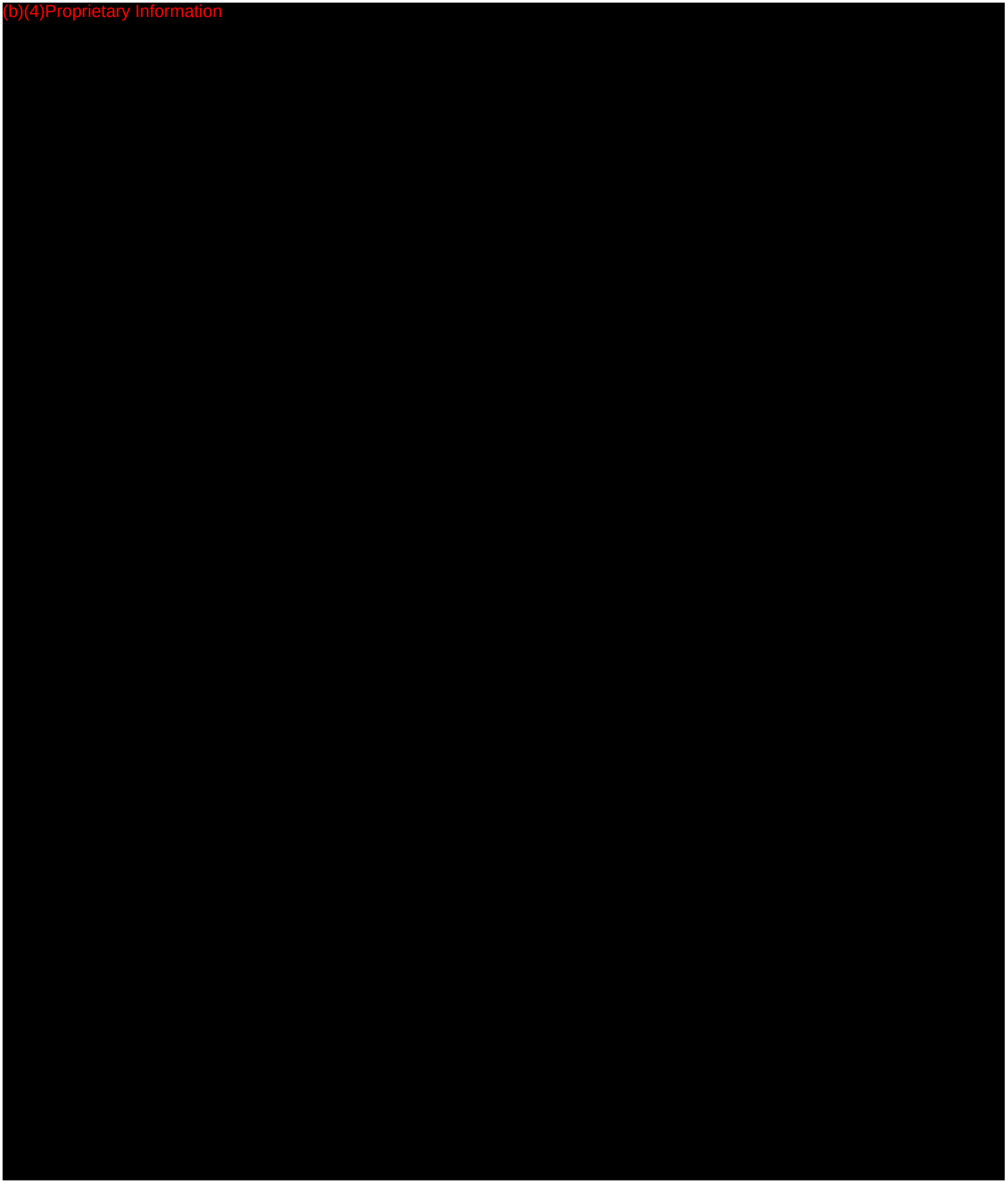

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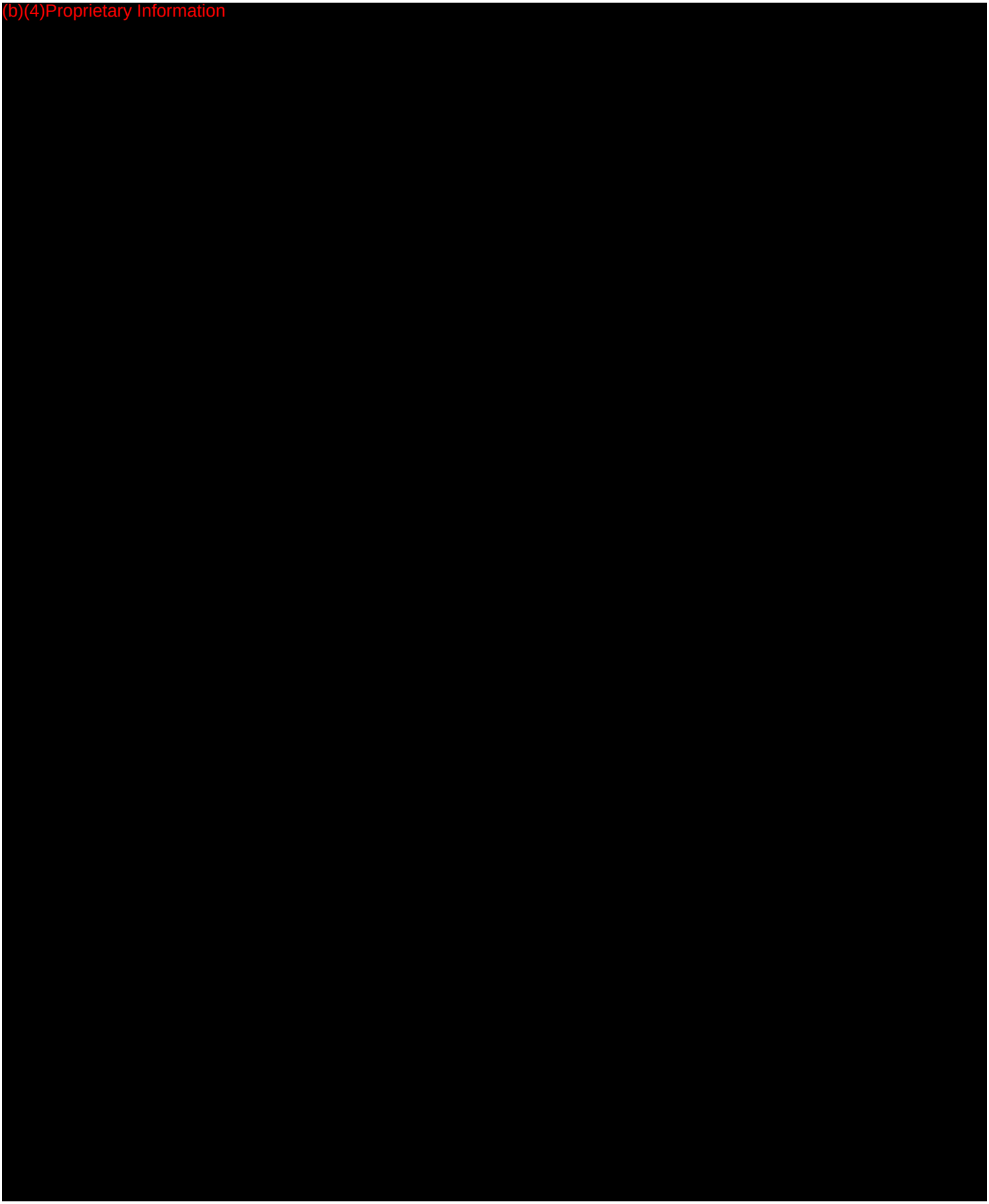

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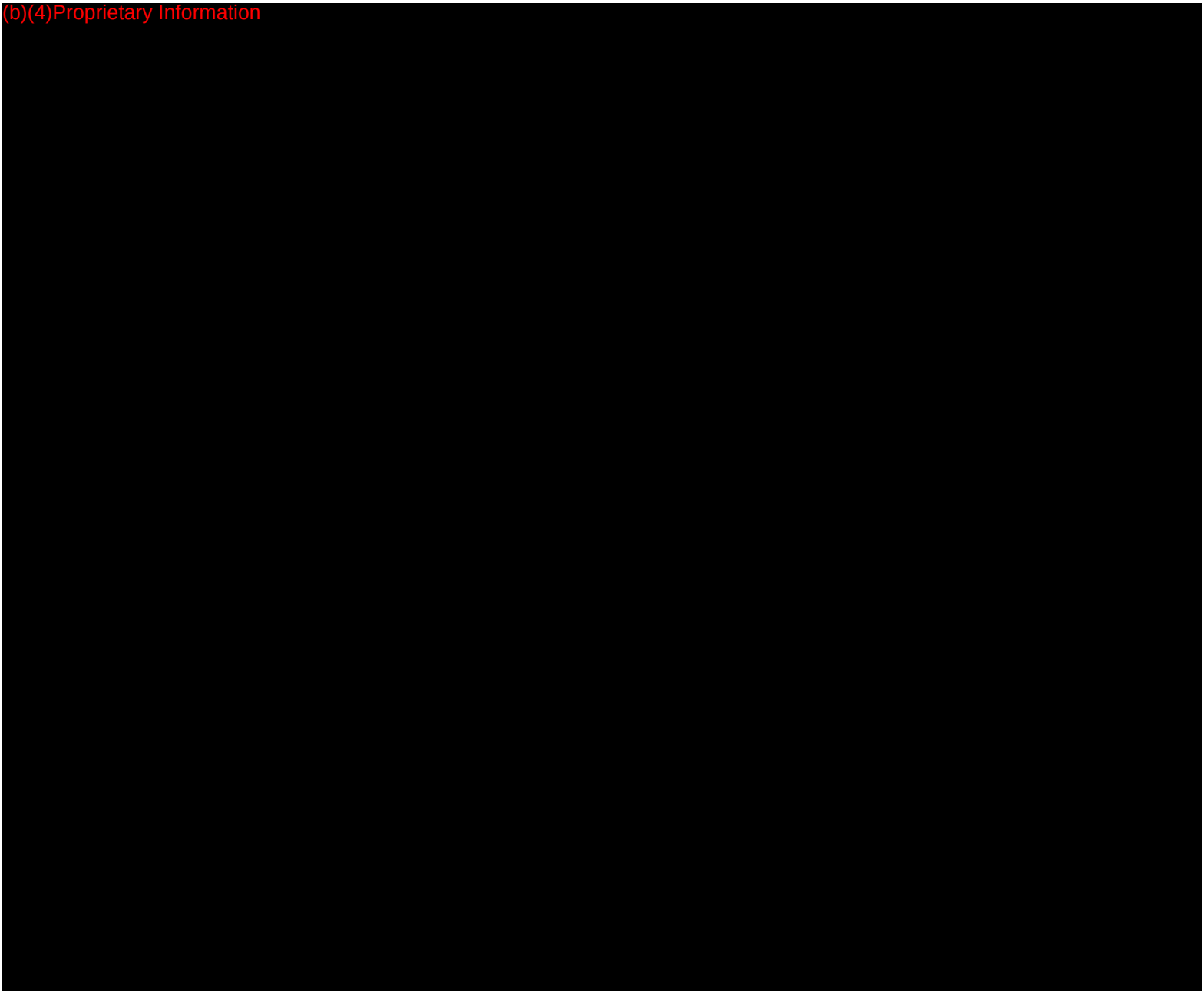
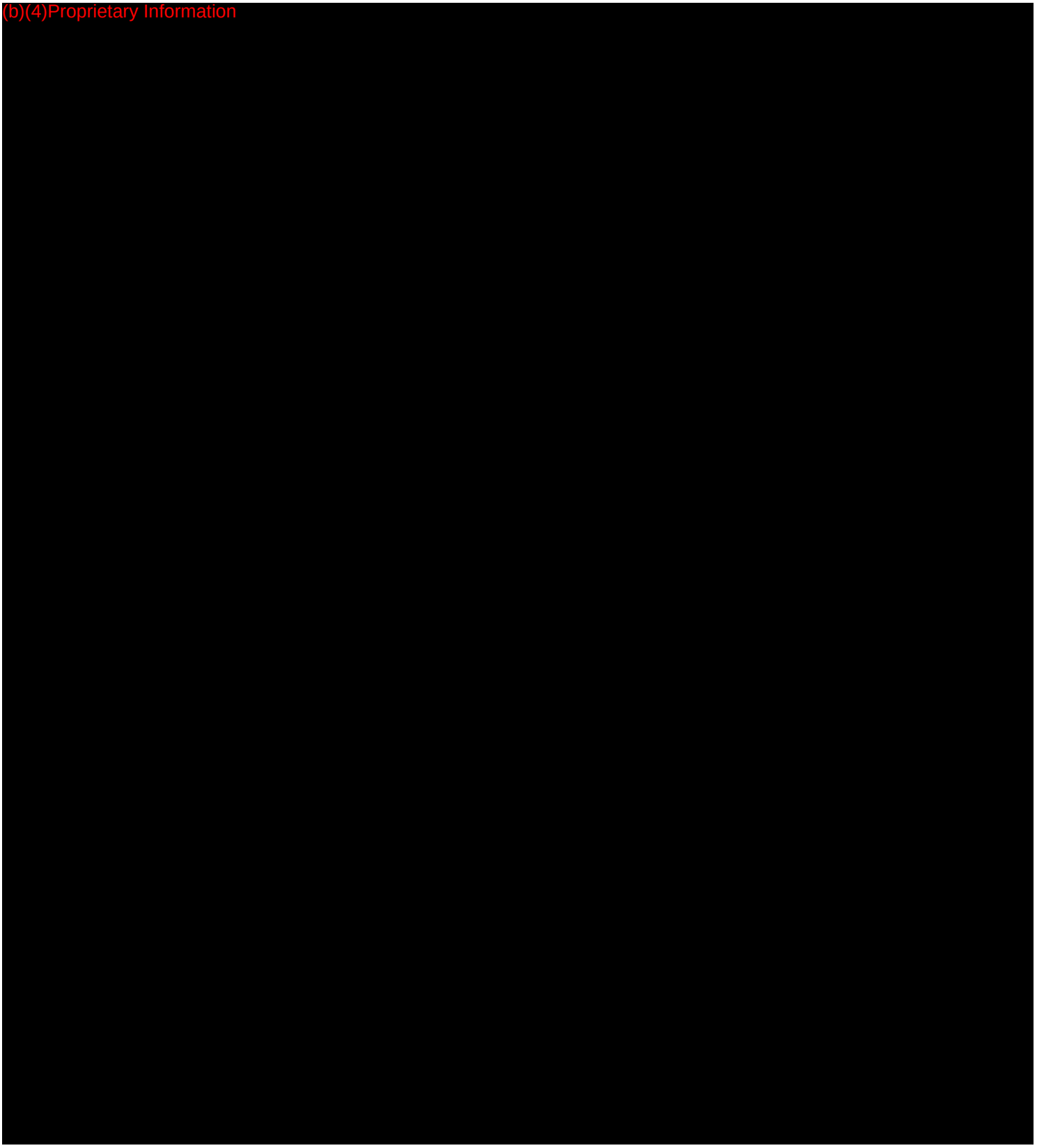


WARNING MESSAGES

(b)(4)Proprietary Information



5. Maintenance and Service

This section deals with maintenance and serviceability of the Theralase™ system by the end user. If further detailed service of your laser system is required, contact Theralase Inc directly for assistance. Detailed contact information is supplied at the end of this section.

Inspection and Cleaning

PRE AND POST TREATMENT

The probe should be cleaned with a 70% solution of isopropyl alcohol before and after treatments.

WEEKLY

Follow the stop procedure in the basic operation section of this manual. Remove the key from the power pack. Disconnect the Laser Probe and power input to the Power Pack. Carefully clean the TLC-2001 Laser Probe with isopropyl alcohol swabs being careful not to immerse the Laser Probe head. Remove the lense cap and immerse a Q-tip into isopropyl alcohol and rotate in the laser aperture carefully to avoid damaging the laser diodes.

MONTHLY

Follow the stop procedure in the basic operation section of this manual. Remove the key from the power pack. Disconnect the Laser Probe and power input to the power pack. Inspect the laser diodes for cracks or chips in the glass. A visible chip in the glass, a crack in the glass or a missing glass mandates replacement of the laser diode. Contact Theralase imme-diately for replacement of the defective / damaged laser diode.

(b)(4)Proprietary Information

Transport

Remove the key from the main power switch and store in a safe location. Disassemble the laser system, carefully packing all components and taking special care with the laser probe assembly. In packing and unpacking the apparatus, be careful not to twist or kink the probe cable too sharply to prevent damage to the probe cable assembly. Ensure proper storage of the Laser Probe to avoid laser diode damage. If you damage your laser diodes, please notify Theralase™ Inc. imme-diately for service / replacement. (The laser system should be kept within 0 to 40°C, 500 hPa to 1068 hPa and 0 to 80% relative humidity during transport).

Caution:

Calibration must only be performed by Theralase™ Inc. or by trained personnel possessing the proper knowledge and test equipment. Contact Theralase™ Inc., if after testing, software indicates maintenance of the laser diodes is required.

(b)(4)Proprietary Information

[redacted]

Product Warranty

(b)(4)Proprietary Information

[redacted]

Environmental Considerations

This product contains electronic components and as such is considered e-waste and must be disposed of responsibly. Do not dispose of this product with waste destined for landfill or incineration. This product must be recycled according to local laws & regulations. At the end of this product service life, estimated to be 10 years, the product can be returned to Theralase for disposal.

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Report Scope

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Summary

The results contained in this report relate only to the item(s) tested.

(b)(4)Proprietary Information - Testing

For testing dates, see "Testing Environmental Conditions and Dates".

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Test Results Summary

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Applicable Standards, Specifications and Methods

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Document Revision Status

Revision 0: April 20, 2015
First Release

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Definitions and Acronyms

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**	(b)(4)Proprietary Information - Testing
Product	**TLC-2000**	
Standard(s)	(b)(4)Proprietary Information - Testing	

Testing Facility

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Testing Environmental Conditions and Dates

Following environmental conditions were recorded in the facility during time of testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

[redacted] **Test Results Section**

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	[redacted]

[redacted]

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing)

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**	(b)(4)Proprietary Information - Testing
Product	**TLC-2000**	
Standard(s)	(b)(4)Proprietary Information - Testing	

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing)

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**	(b)(4)Proprietary Information - Testing
Product	**TLC-2000**	
Standard(s)	(b)(4)Proprietary Information - Testing	

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing)

(b)(4)Proprietary Information - Testing

Test Equipment List

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**	(b)(4)Proprietary Information - Testing
Product	**TLC-2000**	
Standard(s)	(b)(4)Proprietary Information - Testing	

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	IEC/EN 60601-1-2:2007 - (Ed3.0)

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**	(b)(4)Proprietary Information - Testing
Product	**TLC-2000**	
Standard(s)	(b)(4)Proprietary Information - Testing	

(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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(b)(4)Proprietary Information - Testing

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	[redacted]

(b)(4)Proprietary Information - Testing

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[redacted]

Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**
Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Standard(s)	(b)(4)Proprietary Information - Testing

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Standard(s)	(b)(4)Proprietary Information - Testing

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Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information - Testing

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Product	**TLC-2000**
Standard(s)	(b)(4)Proprietary Information -)

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Standard(s)	(b)(4)Proprietary Information - Testing

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Standard(s)	(b)(4)Proprietary Information - Testing

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Client	**Theralase Inc.**	(b)(4)Proprietary Information - Testing
Product	**TLC-2000**	
Standard(s)	(b)(4)Proprietary Information - Testing	

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Product	**TLC-2000**	
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