K130702

Airsonett AIRSONETT AB, Metallgatan, SE-262 72 Ängelholm, Sweden

510(k) SUMMARY

JUL 2 3 2013

Submitter: Airsonett AB
Metallgatan
SE-262 72 Angelholm
Sweden
+46 431 402470

Contact Information: Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432 USA
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

Submission Date: March 15, 2013

Device Name and Classification: Airsonett, version AIR-4, Class II
21 CFR 880.5045
Product Code: FRF

Equivalent Device Identification: Airsonett Airshower Air-3, K081062, BREATHE EASY (Models AD and CD) by RespirAid Ltd (K981841)

Device Description:

Airsonett is based on the Temperature controlled Laminar Airflow (TLA) technology. The air from the room enters the Airsonett and passes a filter that captures allergens and other particles. The filtered air is cooled to slightly below the ambient room temperature and is supplied with a low velocity from the air supply nozzle. Since the filtered air is slightly cooler, and therefore heavier than the surrounding air, the filtered air will descend slowly from the air supply nozzle by means of gravity in a laminar manner (non-turbulent). This descending colder air counteracts the body convection, displaces the allergen load in the breathing zone and thus dramatically reduces the level of inhalant allergens for the patient all through the night.

Air is drawn in through the air intake at the floor level and through the **HEPA filter**. A silent **Blower** (fan) brings airflow through the filter. The air is directed through the **Cooler/Heater** and divided into a cool respectively warm air flow. The cool air flow is directed through the **Air guidance arm** (neck) and out through the **Airshower** (Air Supply Nozzle). The Airshower can be altered in height, by adding/removing and combining the neck parts, to adapt to different types of environments. The warm air flow is directed to the **Warm air outlet**. On its way to the outlet the air flow passes the electronics and transports away the extra heat produced by the electronics.

Airsonett is based on a microprocessor controlled supervisory system. This system controls the device behaviour by measuring temperatures, controlling thermoelectric modules and fan unit, monitoring user interaction as well as management of internal timers to keep track of the total ontime for the system and time since last filter change. The control functions (Front Panel Board) and power distribution function (Power Electronics Board) are allocated on two separate circuit boards,

Intended Use: The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

Comparison Table:

Element of Comparison	**Subject Device**	**Claimed SE Device**
Product	Airsonett AIR-4	Airsonett Airshower Air-3, (510(k) Number K081062)
Manufacturer	Airsonett AB	Airsonett AB
Type of Medical Re-circulating Air Cleaner	Mobile Air Filtration system	Mobile Air Filtration system
Intended use	The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.	The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.
Type of device	Over the counter use	Over the counter use
Labeling	**Airsonett AIR-4**	**Airsonett Airshower Air-3**
Product Description	Housing Unit	Housing Unit
	Air Inlet and Treated Air Outlet	Air Inlet and Treated Air Outlet
	Blower	Blower
	HEPA filter	HEPA filter
	Air Warming Unit	Air Warming Unit
	Air Cooling Unit	Air Cooling Unit
	Adjustable Air Guidance Arm	Adjustable Air Guidance Arm
	Control Panel	Control Panel

Element of Comparison	Subject Device	Claimed SE Device
	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.
Power Requirements	115-230V~ (60-50Hz), 1.7-1.0A	115 V-230V~ (60-50Hz), 1.7-1.0 A
Standard	IEC 60601-1	IEC 60601-1
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h
Air Quality in treated air envelope (referred as clean zone in Appendix 1.2)	Filtration efficiency 99.5% of particles Ø ≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and -Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3	Class 100-1000 according to FED STD 209E
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour
Sound Level	≤38 dB(A)	~38 dB(A)

Element of Comparison	Subject Device	Claimed SE Device	Previous 510(k) SE Device for Airsonett Airshower Air-3
Manufacturer	Airsonett AB	Airsonett AB	RespirAid Ltd.
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h	20-40 m^3/h
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour	400-600 changes per hour

Summary of Testing:

Listing of standards applied

- IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2, Third edition, 2007, Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance; Electromagnetic Compatibility – Requirements and tests.

Performance Tests

Study endpoint	**Description of Test**	**Acceptance criteria**	**Conclusion**
Air quality in treated air envelope (clean zone)	Efficiency test results of filter.	Filter Filtration efficiency ≥99.5% of particles with size Ø≥0.5µm	Conforms with filtration efficiency ≥99.5%.
	Particle cleanliness of clean zone of Airsonett AIR-4. Test method: Laser counter of particles Ø≥0.5µm/ft^3 air flow over 1 minute.	Clean zone Filtration efficiency ≥99.5% of particles with size Ø≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and - Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3.	Conforms with filtration efficiency ≥99.5%. ⇨ Class 1000 according to FED STD 209E and Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3. AIR-4 is equivalent or better than previous version AIR-3, with regard to Air quality in treated air envelope (clean zone).
	Particle cleanliness of clean zone of Airsonett AIR-4.	Stability of the clean zone shall be preserved. Filter efficiency shall be preserved.	The stability of the clean zone is preserved and the filter does not deteriorate on efficiency over a normal working life.
Temperature difference between supply air and ambient air	The cooler/heater unit has been individually tested against temperature sensors to calibrate and verify the temperature difference between supply air and ambient air.	Temperature difference between supply air and ambient air: ≥0.75°C (1.35 degrees F).	Conforms with temperature difference between supply air and ambient air: ≥0.75°C (1.35 degrees F).

Conclusion: Airsonett AIR-4 is substantially equivalent to Airsonett Air-3 and Breathe Easy regarding technology, intended use and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 23, 2013

Airsonett, AB
C/O Ms. Constance G. Bundy
C.G. Bundy Associates, Incorporated
435 Rice Creek Terrace, North East
FRIDLEY MN 55432

Re: K130702
Trade/Device Name: Airsonett, Version AIR-4
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: II
Product Code: FRF
Dated: July 1, 2013
Received: July 2, 2013

Dear Ms. Bundy:

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

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

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

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

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

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Airsonett AIRSONETT AB, Metallgatan, SE-262 72 Ängelholm, Sweden

INDICATIONS FOR USE

510(k) Number (if known): k130702

Device Name: Airsonett, version AIR-4

Indications For Use:

The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.07.23 14:26:39 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: k130702

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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FRIDLEY MN 55432

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Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

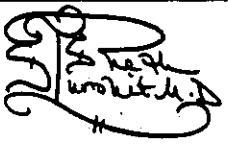
Full Submission Number: K130702

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Shani Smith
Branch Chief Sign-Off	Elizabeth Claverie-Williams
Division Sign-Off	 Tejashri Purohit-Sheth, M.D. Clinical Deputy Director DAGRID Tejashri S. Purohitsheth -S 2013.07.23 14:28:51 -04'00'

Template Name: K1(A) – SE after 1996

Airsonett AIRSONETT AB, Metallgatan. SE-262 72 Ängelholm, Sweden

INDICATIONS FOR USE

510(k) Number (if known): K130702

Device Name: Airsonett, version AIR-4

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130702

K130702

Airsonett AB
Angelholm, Sweden

March 15, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAR 15 2013
Received

Re: Traditional 510(k)

Device: Airsonett AIR-4
Classification: 21 CFR 880.5045, Class II
General Hospital
Product Code: FRF

As required, Airsonett is submitting two copies of this Premarket Notification. One copy is paper and one copy is an eCopy. The eCopy is an exact duplicate of the paper copy.

NOTE: There are no clinical data included in this submission. Therefore, Form 3674 is not included.

Any questions regarding this submission should be directed to Constance Bundy, Consultant to Airsonett AB.

Regards,

Constance G. Bundy

Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432 USA
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

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435 Rice Creek Terrace NE
Fridley, MN 55432 USA
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. 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)
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)

AIRSONETT AB
435 Rice Creek Terrace NE
Fridley mn 55432
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Constance Bundy
2.1 E-MAIL ADDRESS
cgbundy@live.com
2.2 TELEPHONE NUMBER (include Area code)
763-5741976
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

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

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

3.1 Select a center
[X] CDRH
[ ] CBER

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

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

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

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/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.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

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

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

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4) Constance C. Bundy 05-Mar-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

TABLE OF CONTENTS

Appendices

COVER LETTER

510(k) Type: Traditional

Device Common Name: HEPA Filtration system

Submitter: Airsonett AB
Metallgatan
SE-262 72 Angelholm
Sweden
+46 431 402470

Contact: Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace
Fridley, MN 55432
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

Confidentiality: Confidentiality is claimed for those documents marked as such

Classification Regulation: 21 CFR 880.5045

Class: II

Panel: General Hospital

Product Code: FRF

Associated Documents: None

Basis for Submission: New device

Note: This submission does NOT include clinical data. Therefore, Form 3674 has not been included.

Design and Use of Device – Table

Question	Yes	No
Is the device intended for prescription use?		X
Is the device intended for over-the-counter use?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device? If yes, does this device require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Airsonett, version AIR-4

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

Submitter: Airsonett AB
Metallgatan
SE-262 72 Angelholm
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+46 431 402470

Contact Information: Constance G. Bundy
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Manufacturer	Airsonett AB	Airsonett AB
Type of Medical Re-circulating Air Cleaner	Mobile Air Filtration system	Mobile Air Filtration system
Intended use	The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.	The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.
Type of device	Over the counter use	Over the counter use
Labeling	**Airsonett AIR-4**	**Airsonett Airshower Air-3**
Product Description	Housing Unit	Housing Unit
	Air Inlet and Treated Air Outlet	Air Inlet and Treated Air Outlet
	Blower	Blower
	HEPA filter	HEPA filter
	Air Warming Unit	Air Warming Unit
	Air Cooling Unit	Air Cooling Unit
	Adjustable Air Guidance Arm	Adjustable Air Guidance Arm
	Control Panel	Control Panel

Element of Comparison	**Subject Device**	**Claimed SE Device**
	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.
Power Requirements	115-230V~ (60-50Hz), 1.7-1.0A	115 V-230V~ (60-50Hz), 1.7-1.0 A
Standard	IEC 60601-1	IEC 60601-1
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h
Air Quality in treated air envelope (referred as clean zone in Appendix 1.2)	Filtration efficiency 99.5% of particles Ø ≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and -Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3	Class 100-1000 according to FED STD 209E
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour
Sound Level	≤38 dB(A)	~38 dB(A)

Element of Comparison	**Subject Device**	**Claimed SE Device**	**Previous 510(k) SE Device for Airsonett Airshower Air-3**
Manufacturer	Airsonett AB	Airsonett AB	RespirAid Ltd.
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h	20-40 m^3/h
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour	400-600 changes per hour

Summary of Testing:

Listing of standards applied

- IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

- IEC 60601-1-2, Third edition, 2007, Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance; Electromagnetic Compatibility – Requirements and tests.

Performance Tests

Study endpoint	**Description of Test**	**Acceptance criteria**	**Conclusion**
Air quality in treated air envelope (clean zone)	Efficiency test results of filter.	Filter Filtration efficiency ≥99.5% of particles with size Ø≥0.5µm	Conforms with filtration efficiency ≥99.5%.
	Particle cleanliness of clean zone of Airsonett AIR-4. Test method: Laser counter of particles Ø≥0.5µm/ft^3 air flow over 1 minute.	Clean zone Filtration efficiency ≥99.5% of particles with size Ø≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and - Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3.	Conforms with filtration efficiency ≥99.5%. ⇨ Class 1000 according to FED STD 209E and Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3. AIR-4 is equivalent or better than previous version AIR-3, with regard to Air quality in treated air envelope (clean zone).
	Particle cleanliness of clean zone of Airsonett AIR-4.	Stability of the clean zone shall be preserved. Filter efficiency shall be preserved.	The stability of the clean zone is preserved and the filter does not deteriorate on efficiency over a normal working life.
Temperature difference between supply air and ambient air	The cooler/heater unit has been individually tested against temperature sensors to calibrate and verify the temperature difference between supply air and ambient air.	Temperature difference between supply air and ambient air: ≥0.75ºC (1.35 degrees F).	Conforms with temperature difference between supply air and ambient air: ≥0.75ºC (1.35 degrees F).

Conclusion: Airsonett AIR-4 is substantially equivalent to Airsonett Air-3 and Breathe Easy regarding technology, intended use and performance.

TRUTHFUL AND ACCURATE STATEMENT

DEVICE DESCRIPTION

Introduction

Airsonett is developed based on the discovery of high allergen exposure in the breathing zone when lying in bed

During night the concentration of indoor airborne allergens in the breathing zone is primarily generated from bed reservoirs (e.g. house dust mite and pet allergens) and is higher than the concentration of allergens in the ambient bedroom air [1]. The reason for the difference in concentration of allergens in the breathing zone and the room in general is the body convection; the air warmed by the body in the bed creates an airflow that rises due to the lower density of the warm air. The warm air transports the allergens present in the bedding towards the opening in the duvet where it rises and passes by the breathing zone. Airsonett effectively displaces the allergen rich body convection and dramatically reduces the level of inhalant allergens during sleep.

Principle

Airsonett is based on the Temperature controlled Laminar Airflow (TLA) technology. The air from the room enters the Airsonett and passes a filter that captures allergens and other particles. The filtered air is cooled to slightly below the ambient room temperature and is supplied with a low velocity from the air supply nozzle. Since the filtered air is slightly cooler, and therefore heavier than the surrounding air, the filtered air will descend slowly from the air supply nozzle by means of gravity in a laminar manner (non-turbulent). This descending colder air counteracts the body convection, displaces the allergen load in the breathing zone and thus dramatically reduces the level of inhalant allergens for the patient all through the night.

References

1. J.Y. Lau, J.K. Sercombe, E.R. Tovey. Characterisation of personal Der p 1 exposure from upper bedding, when placed in a clean environment Journal of Allergy and Clinical Immunology Vol. 115, Issue 2, Supplement, Page S94

Device Description

1.1. **Schematic description**

Air is drawn in through the air intake at the floor level and through the **HEPA filter**. A silent **Blower** (fan) brings airflow through the filter. The air is directed through the **Cooler/Heater** and divided into a cool (blue arrows) respectively warm (red arrows) air flow. The cool air flow is directed through the **Air guidance arm** (neck) and out through the **Airshower** (Air Supply Nozzle). The Airshower can be altered in height, by adding/removing and combining the neck parts, to adapt to different types of environments. The warm air flow is directed to the **Warm air outlet**. On its way to the outlet the air flow passes the electronics and transports away the extra heat produced by the electronics (Fig 1-3).

Fig 1. Airsonett

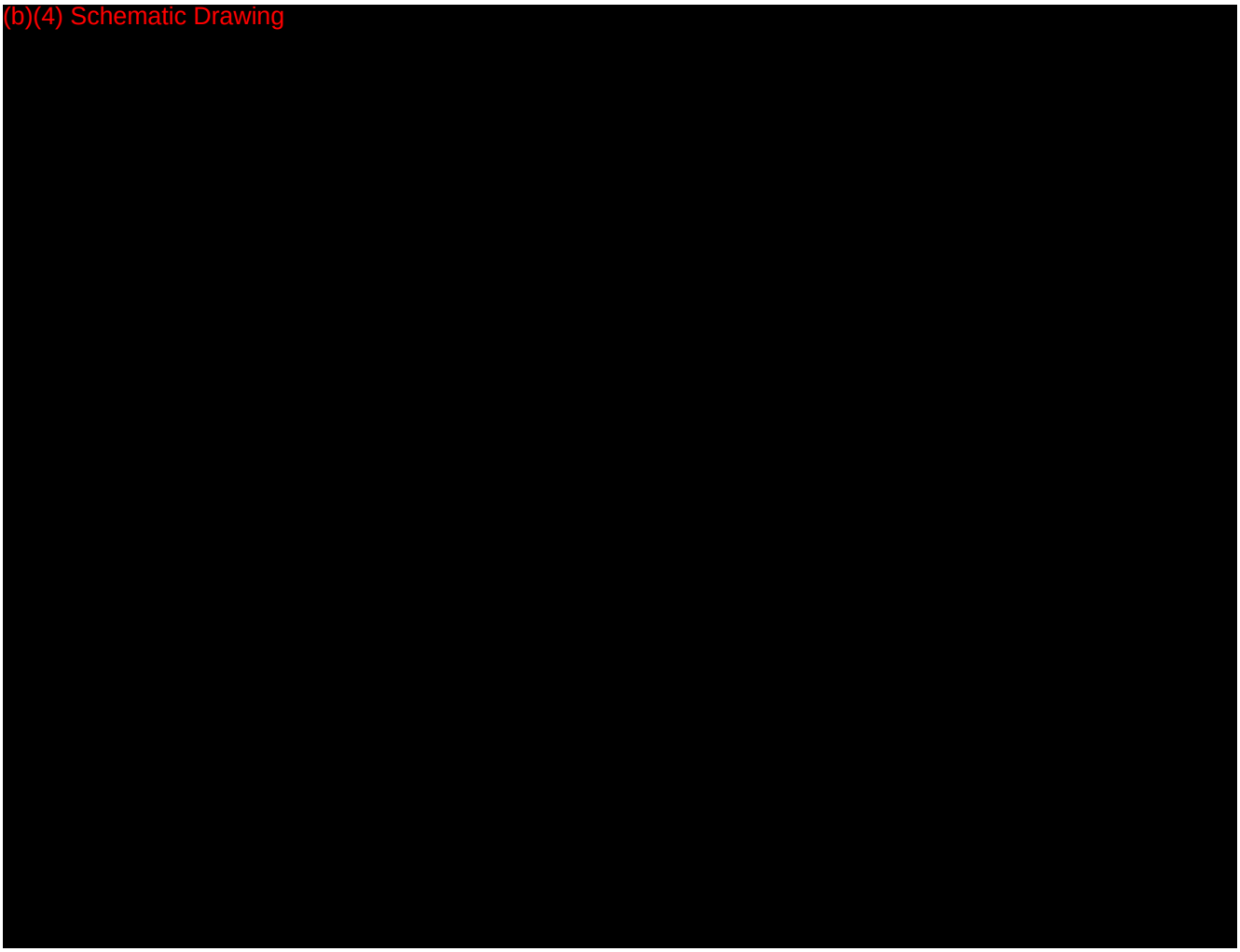
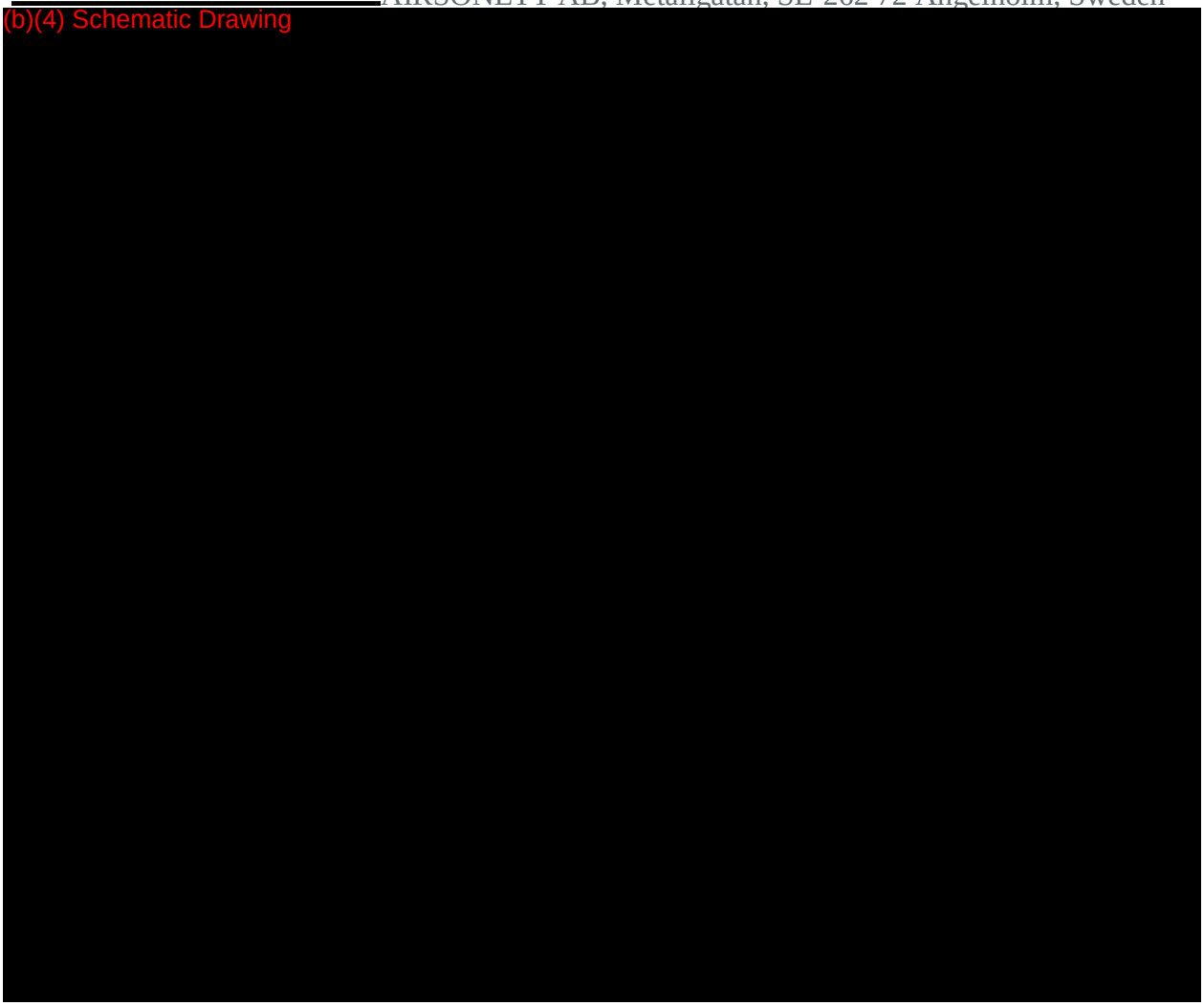


Fig 2. Airsonett - Schematic Air flow/function description

(b)(4) Schematic Drawing



1.2. **HEPA filter**

The filter for capturing allergens from e.g. cat, dog, house dust mite, pollen and mould spores is a HEPA-filter (High Efficiency Particulate Air filter) with filtration efficiency ≥99.5% of particles with size Ø≥0.5µm (this is the relevant particle range covering most indoor aeroallergens). The dimensions of the filter are 300x425x150 mm (11.8x16.7x5.9 in). It is a compact filter with a very tightly pleated filter material to provide a large filter area. The large filter area permits a low pressure fall over the filter during operation of Airsonett, and thereby enabling low energy consumption of the fan and low noise and still maintaining required air flow out through the Airshower. Airsonett indicates time for exchanging filter. Airsonett and filter is designed for enabling easy and correct exchange of filters. See also Appendices 1.1-1.2.

Fig 4a. HEPA filter

Fig 4b. Exchanging filter

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1.4. **Cooler/Heater Unit**

The cooler/heater unit consists of four heat sinks and two thermoelectric modules [TEC]. Each TEC is mounted between two heat sinks and "pumps" heat from one heat sink (cool side) to the other heat sink (warm side). Each heat sink consists of fins, the area that interacts with the air, and heat pipes that transfer the heat between the TEC and the fins, via blocks. The air from the fan is split in two parts, one part transporting away the heat from the warm side heat sinks and one part is cooled down by the cool side heat sinks. The thermo electric modules use approximately 80W of power at full cooling giving approximately 50W cooling effect of the air passing through the cool side heat sinks. The cooling effect of 50W is enough to cool the air ($90ft^3$/min, $150m^3$/tim) ca 1 C (1.8 F). The heat transported away on the warm side is then about 130W.

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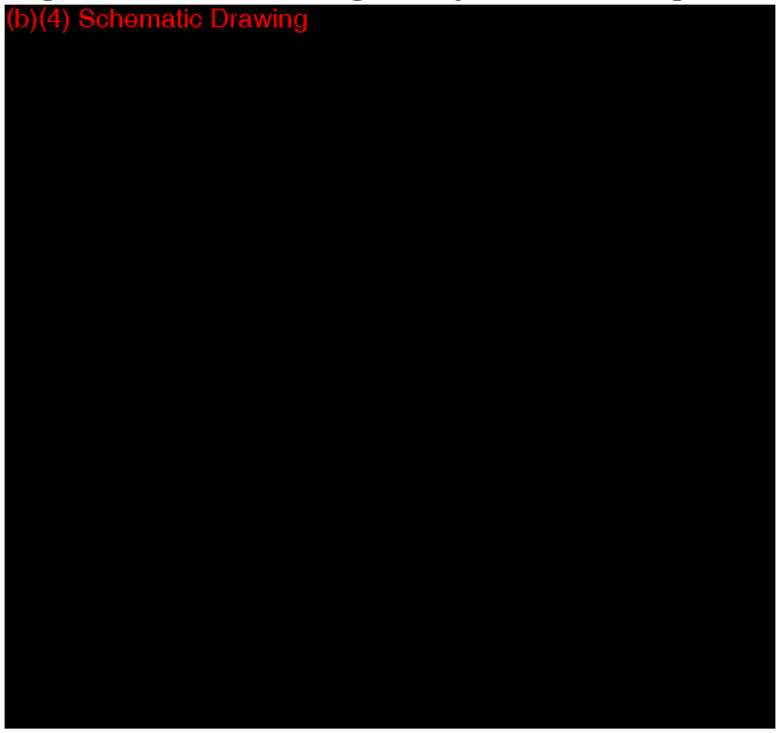
1.4.1. The function of the thermoelectric module

Thermoelectric modules are solid-state heat pumps that operate on the Peltier effect. A thermoelectric module consists of an array of p- and n- type semiconductor elements heavily doped with electrical carriers. The array of elements is soldered so that it is electrically connected in series and thermally connected in parallel. This array is then affixed to two ceramic substrates, one on each side of the elements (Figure 10).

Electrons can travel freely in the copper conductors but not so freely in the semiconductor. As the electrons leave the copper and enter the hot-side of the p-type, they must fill a "hole" in order to move through the p-type. When the electrons fill a hole, they drop down to a lower energy level and release heat in the process. Essentially the holes in the p-type are moving from the cold side to the hot side. Then, as the electrons move from the p-type into the copper conductor on the cold side, the electrons are bumped back to a higher energy level and absorb heat in the process. Next, the electrons move freely through the copper until they reach the cold side of the n-type semiconductor. When the electrons move into the n-type, they must bump up an energy level in order to move through the semiconductor. Heat is absorbed when this occurs. Finally, when the electrons leave the hot-side of the n-type, they can move freely in the copper. They drop down to a lower energy level and release heat in the process.

In summary, heat is always absorbed at the cold side of the n- and p- type elements. The electrical charge carriers (holes in the p-type; electrons in the n-type) always travel from the cold side to the hot side, and heat is always released at the hot side of thermoelectric element. The heat pumping capacity of a module is proportional to the current and is dependent on the element geometry, number of couples, and material properties.



1.5. **Electrical Hardware and Software**

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Fig 11. Block representation of Airsonett electronics.

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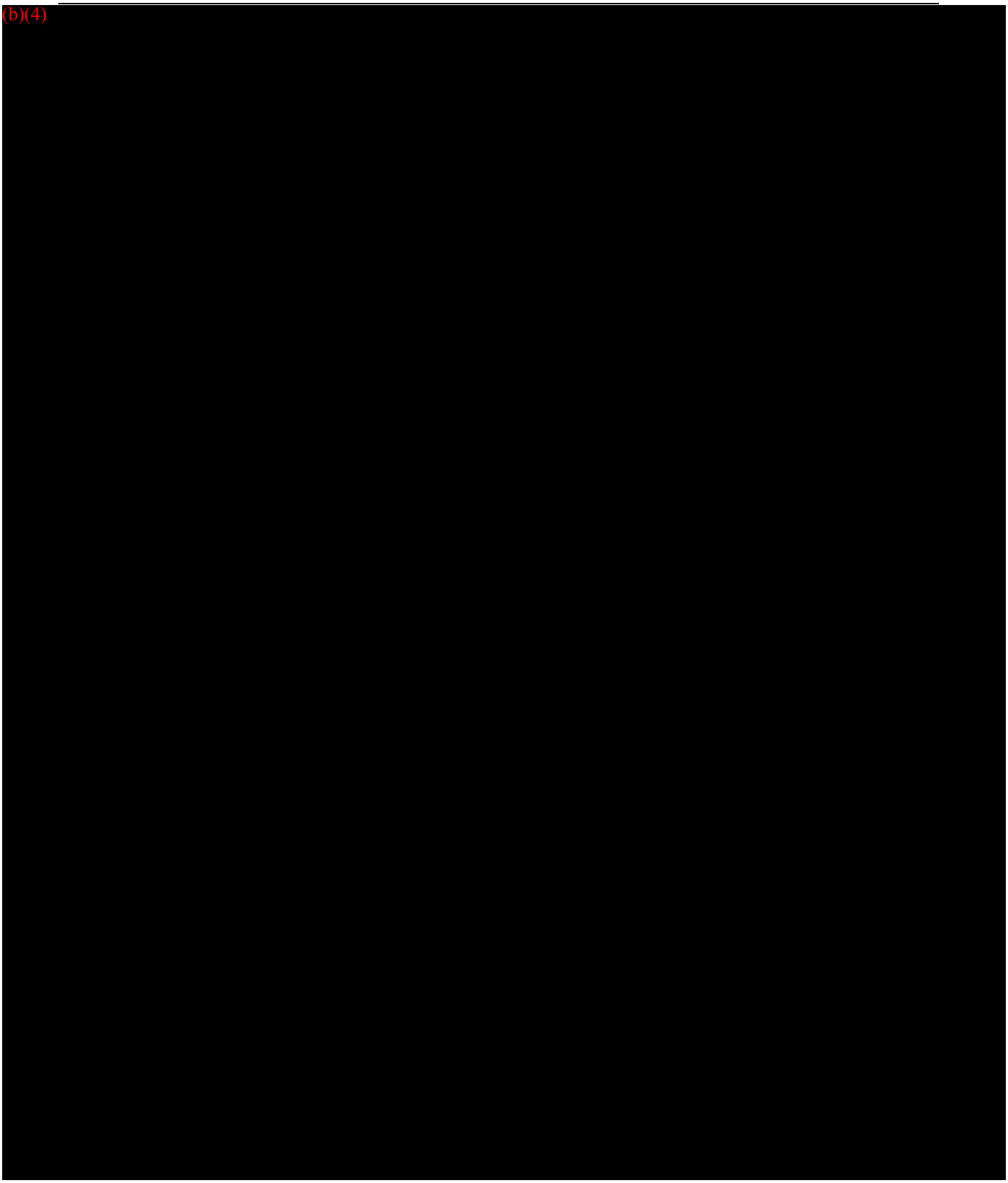

1.6. **Airshower**

The Airshower is an air supply unit for supplying air to premises in order to create therein a zone with clean air, whereby the temperature of the air supplied is lower than the temperature in the premises. Air resistance is provided inside the Airshower by an air permeable material providing air resistance, e.g. a porous foam of air filter type (detail 1 Figure 12) so that air entering the Airshower is evenly distributed to flow out into the ambient room through essentially all portions of an air discharge foam (detail 2 Figure 12). The outer air discharge material is adapted to sieve the discharged air for generating a continuous flow outside the air discharge unit. The features of the Airshower (the shape, the pressure drop in the inside material and the porosity of the outside material) allows for the velocity of the air coming out from the Airshower, to be reduced significantly after only about 6 inches (15 cm), enabling an air plume to be developed. The features of the Airshower, in combination with the cooler, and thereby heavier, discharged air, create a descending air plume wherein the gravity will be the dominating force after about 6 inches. Airsonett creates a distinct zone of clean air with a diameter of about 60 to 80 cm (24-31 inches) beneath the Airshower. Very little mixing with surrounding air takes place in the zone. Turbulences will be limited to only the edge zone where the discharged cooler air meets the ambient air.

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1.7. **Warm Air Outlet**

The warm air flow from the warm side heat sinks is directed to the Warm air outlet. The warm air flow is evenly distributed to flow out through practically all portions of a perforated metal sheet by means of air resistance provided by porous material (e.g. foam of air filter type). The porous material is situated inside the perforated metal sheet. The form and free area of the perforated metal sheet (and porous material) is constructed to generate a low speed (low impulse) air discharge with very little mixing with the ambient air. The discharged warm air flow rises upwards in the room, due to its lower density, in a laminar manner without disturbing the laminar air flow from the Airshower (see Figure 13).

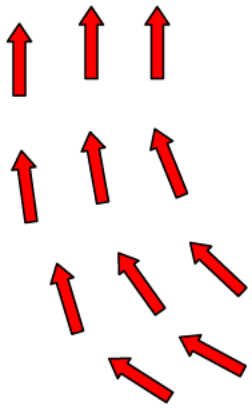

Fig 13. Air discharge from Warm air outlet

Substantial Equivalence

Element of Comparison	Subject Device	Claimed SE Device
Product	Airsonett AIR-4	Airsonett Airshower Air-3, (510(k) Number K081062)
Manufacturer	Airsonett AB	Airsonett AB
Type of Medical Re-circulating Air Cleaner	Mobile Air Filtration system	Mobile Air Filtration system
Intended use	The Airsonett AIR-4 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.	The Airsonett Airshower Air 3 is a Mobile Air Cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.
Type of device	Over the counter use	Over the counter use
Labeling	**Airsonett AIR-4**	**Airsonett Airshower Air-3**
Product Description	Housing Unit	Housing Unit
	Air Inlet and Treated Air Outlet	Air Inlet and Treated Air Outlet
	Blower	Blower
	HEPA filter	HEPA filter
	Air Warming Unit	Air Warming Unit
	Air Cooling Unit	Air Cooling Unit
	Adjustable Air Guidance Arm	Adjustable Air Guidance Arm
	Control Panel	Control Panel
	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.	Airsonett Airshower makes use of the Airshower characteristics and cools the air outflow; thereby using thermal stratification for guiding the air to a patient's breathing zone.
Power Requirements	115-230V~ (60-50Hz), 1.7-1.0A	115 V-230V~ (60-50Hz), 1.7-1.0 A
Standard	IEC 60601-1	IEC 60601-1
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h

Element of Comparison	Subject Device	Claimed SE Device
Air Quality in treated air envelope (referred as clean zone in Appendix 1.2)	Filtration efficiency 99.5% of particles Ø ≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and -Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3	Class 100-1000 according to FED STD 209E
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour
Sound Level	≤38 dB(A)	~38 dB(A)

The Airsonett is substantially equivalent to Airsonett Airshower Air-3 regarding technology, intended use and performance.
The Airsonett is also substantially equivalent to the claimed SE device in the 510(k) for Airsonett Airshower Air 3: Breathe Easy (510(k) number: K081062)

Element of Comparison	Subject Device	Claimed SE Device	Previous 510(k) SE Device for Airsonett Airshower Air-3
Manufacturer	Airsonett AB	Airsonett AB	RespirAid Ltd.
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h	20-40 m^3/h
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour	400-600 changes per hour

Discussion

Airsonett AIR-4 and the Airsonett Airshower Air-3 are substantially equivalent in Intended Use, technology and performance. Both devices are designed to remove particles from the air for medical purposes.
The Airsonett AIR-4 differs from the predicate device, AIR-3, in that

- the filter has been improved. The filter area of AIR-4 is larger than for AIR-3, enabling a larger filtration efficiency. The filtration efficiency of AIR-4 has been verified to be equivalent or better than the filtration efficiency of AIR-3, giving an equivalent Air Quality in treated air envelope.
- the software and hardware have been improved. AIR-4 has additional functions for improved usability, such as filter exchange control; the AIR-4 indicates in a display when filter shall be exchanged. The software of AIR-4 has been validated.

LABELING

Instructions for Use enclosed in Appendix 1.5.
Label of device as described below.

SOFTWARE

Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.	
1. Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)	No
2. Is the Software Device intended to be used in combination with a drug or biologic?	No
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	No
4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: a. Does the Software Device control a life supporting or life sustaining function?	No
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	No
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	No
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	No
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	No

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.	
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	No
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	No
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	No

The answers to all of the questions in Tables 1 and 2 above are No, thus the Level of Concern is Minor.

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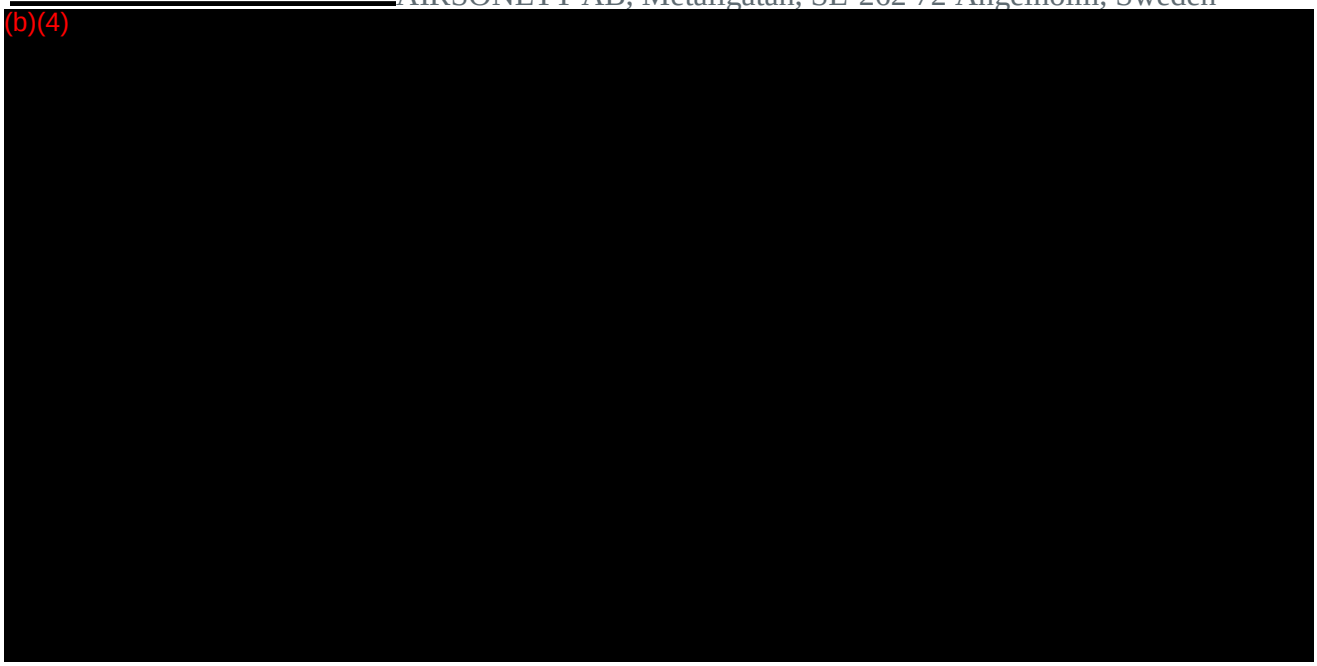

Device Hazard Analysis

For a detailed discussion of the software related device hazard analysis, see FMEA in Appendix 1.4. Hazards and risk control measures have been identified in the FMEA and have been considered in the Software/Hardware validation, see Appendix 1.3a-n. Identified risks have been reduced as much as possible and remaining risks are considered to be as low as reasonably practical. The benefits of the device exceed the remaining risks and therefore all remaining risks are considered acceptable.

Software Requirements Specification (SRS)

The specification of the electrical system in AIR-4 is found in Appendix 1.3b-c (Hardware Requirement Specification see Appendix 1.3j).

Traceability Analysis

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Verification and validation documentation

All tests performed, related to software and hardware functions, are specified in Software Test Specification (Appendix 1.3e) and Hardware Test Specification (Appendix 1.3l). All performed tests passed and fulfil the electrical requirements specifications. Performed tests are documented in Test protocols (see Appendix 1.3f1-f3 and 1.3m). Code reviews were performed according to Appendix 1.3g1-g4 and 1.3n.

Revision history

Version 1.000 [2009-01-23]
First release of firmware./Martin Voss, BRV AB.

Version 1.100 [2009-04-08]
Timer function added./Martin Voss, BRV AB.

Version 1.200 [2009-06-09]
Time between each display screen increased from 2 sec to 5 sec./Martin Voss, BRV AB.

Version 1.300 [2009-10-06]
Addition of heating function when room air is too cold at floor./Martin Voss, BRV AB.

Version 1.400 [2010-01-16]
Error message if target temperature not reached within 30 min.

Version 1.500 [2010-11-17]
Addition of function Delayed SetDayZero.

Version 1.502 [2010-07-06]
Logging of Total operating time saved every 15 min.

Version 1.600 [2013-02-26]
Text Protexo deleted in display screens.

EMC AND SAFETY TESTING

Listing of standards applied

- IEC 60601-1, Second edition, 1988 with Amendment 1, 1991 and Amendment 2, 1995, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2, Third edition, 2007, Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance; Electromagnetic Compatibility – Requirements and tests.

Test protocols that verify compliance to these standards can be found in Appendices 1.6-1.9.

PERFORMANCE TESTS – BENCH

Study endpoint	Description of Test	Acceptance criteria	Conclusion	Appendix

(b)(4)

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

APPENDIX 1.2 CONFIDENTIAL

PERFORMANCE OF AIRSONETT AIR-4 – FILTRATION EFFICIENCY

Objective

Airsonett AIR-4 have been tested with regard to treated air quality (particle cleanliness of clean zone) to confirm the efficiency of each device.

Test Method

(b)(4) [redacted]

Test Equipment

(b)(4) [redacted]

Test Articles

(b)(4) [redacted]

Acceptance criteria

(b)(4) [redacted]

Result

(b)(4)

[redacted]

Discussion

(b)(4)

[redacted]

Conclusion

(b)(4)

[redacted]

(b)(4) Third Party Test Data

System Requirements

Electrical Installation

AIR-4

	Title: System Requirements Electrical Installation AIR-4
	(b)(4) [redacted]

Page size	Page	Document number
A4	1 of 12	TBD (b)(4) [redacted]

Index

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Software Requirement Specification

AIR-4

	Title: Software Requirement Specification			
	(b)(4) [redacted]			
	Page size A4	Page 1 of 18	Document number TBD	[redacted]

Index

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(b)(4) Software Document

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Software Design Description

AIR-4

	Title: Software Design Description			
	(b)(4) [redacted]			
	Page size A4	Page 1 of 24	Document number TBD	Revision (b)(4) [redacted]

Index

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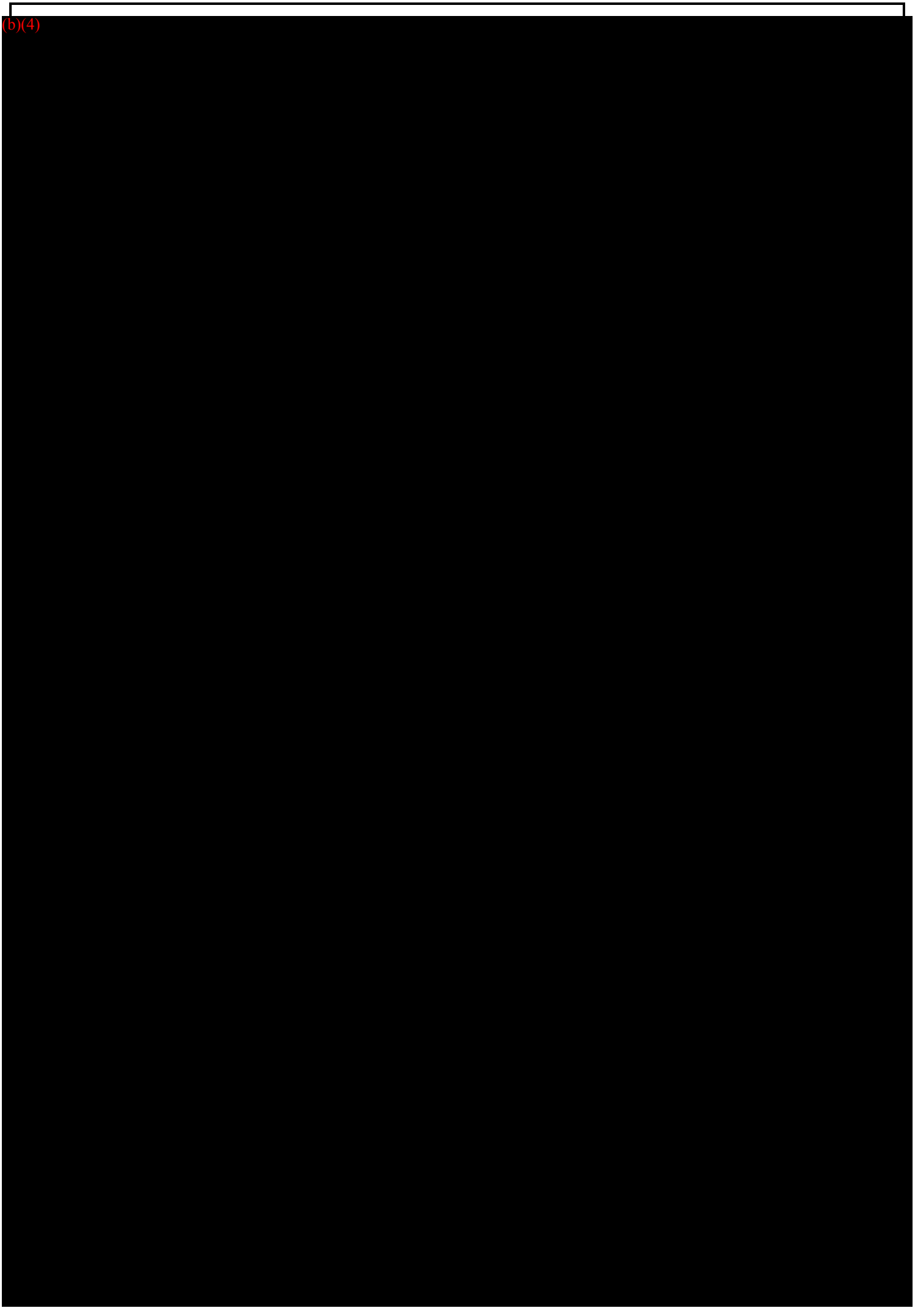

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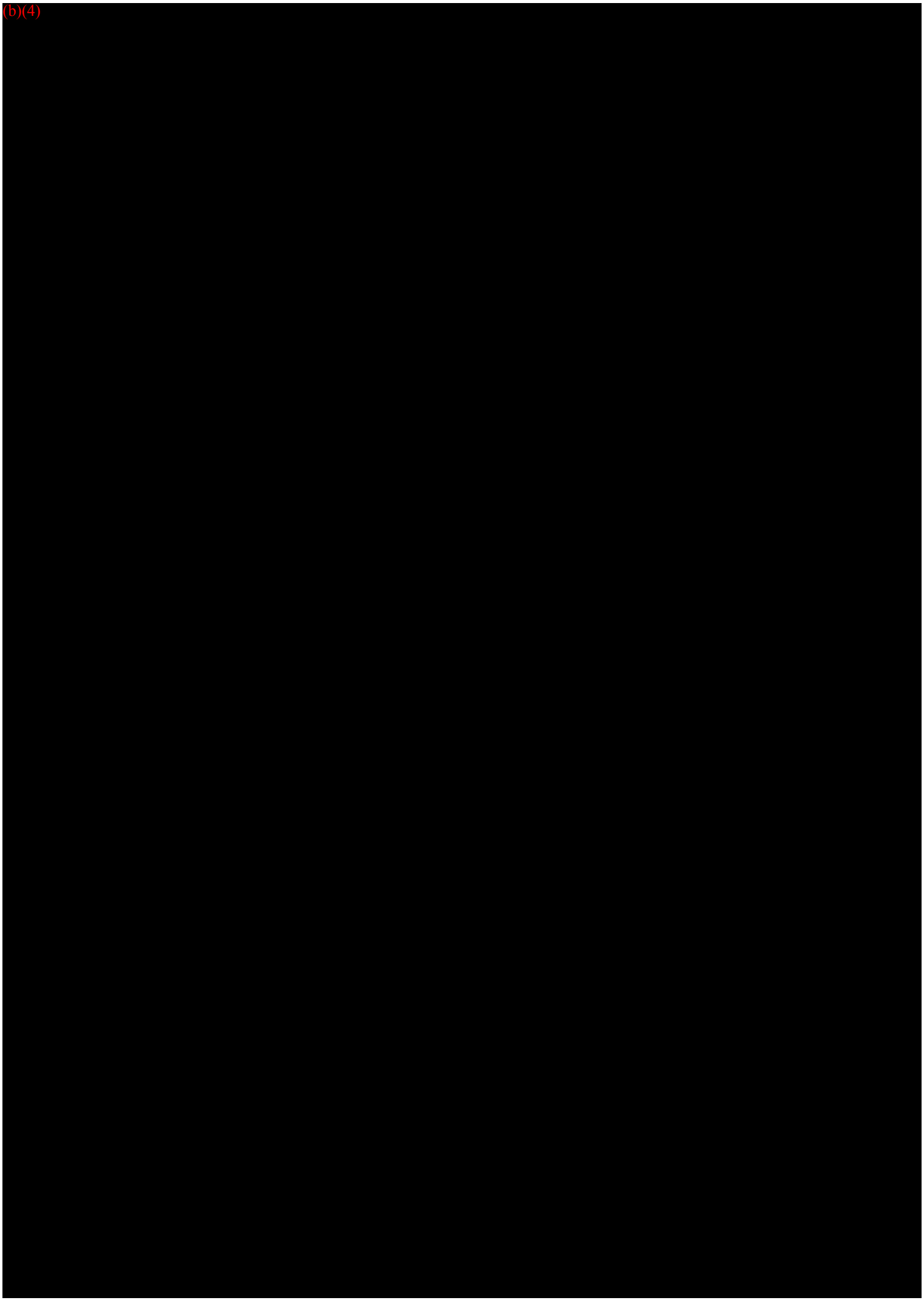
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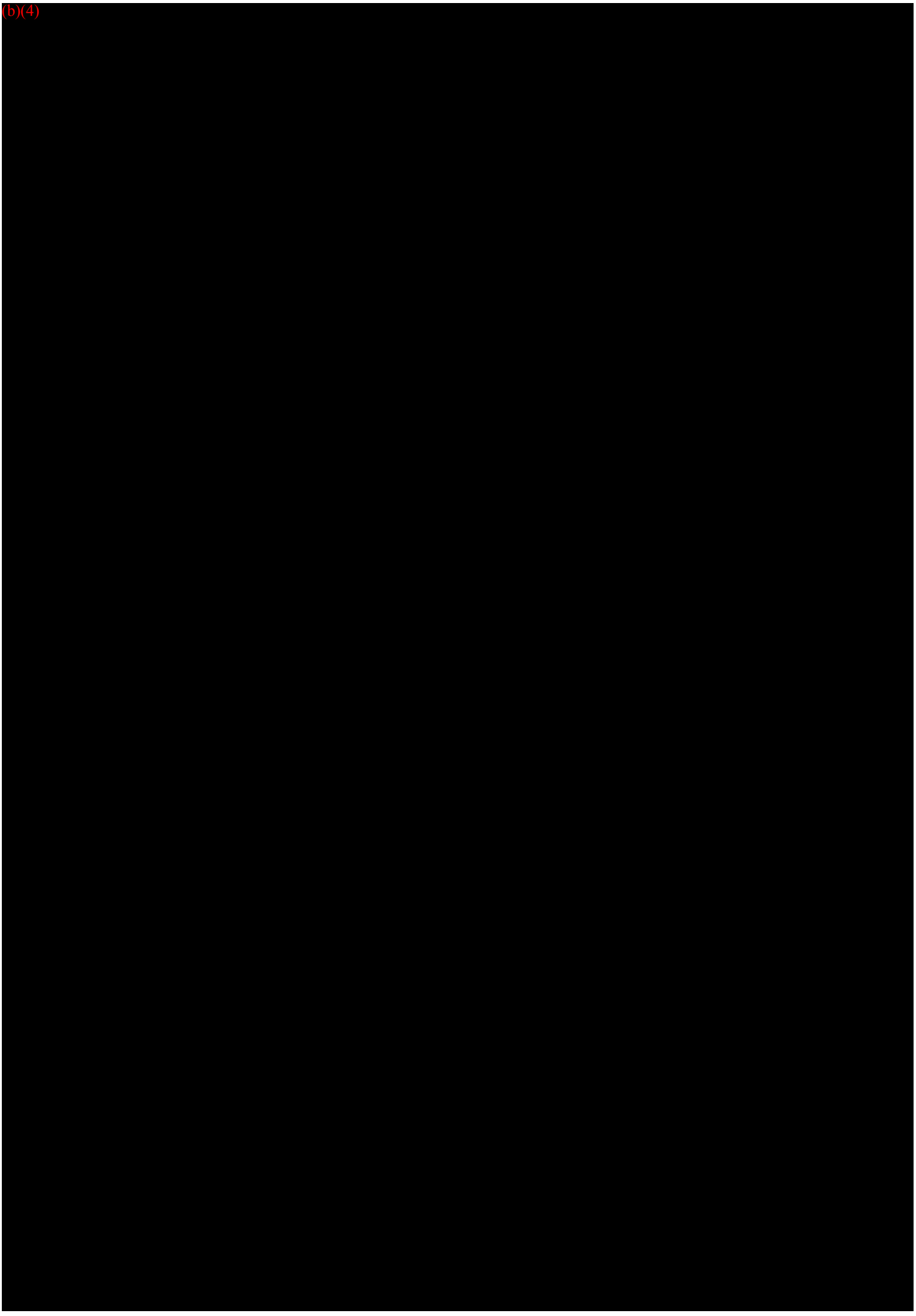
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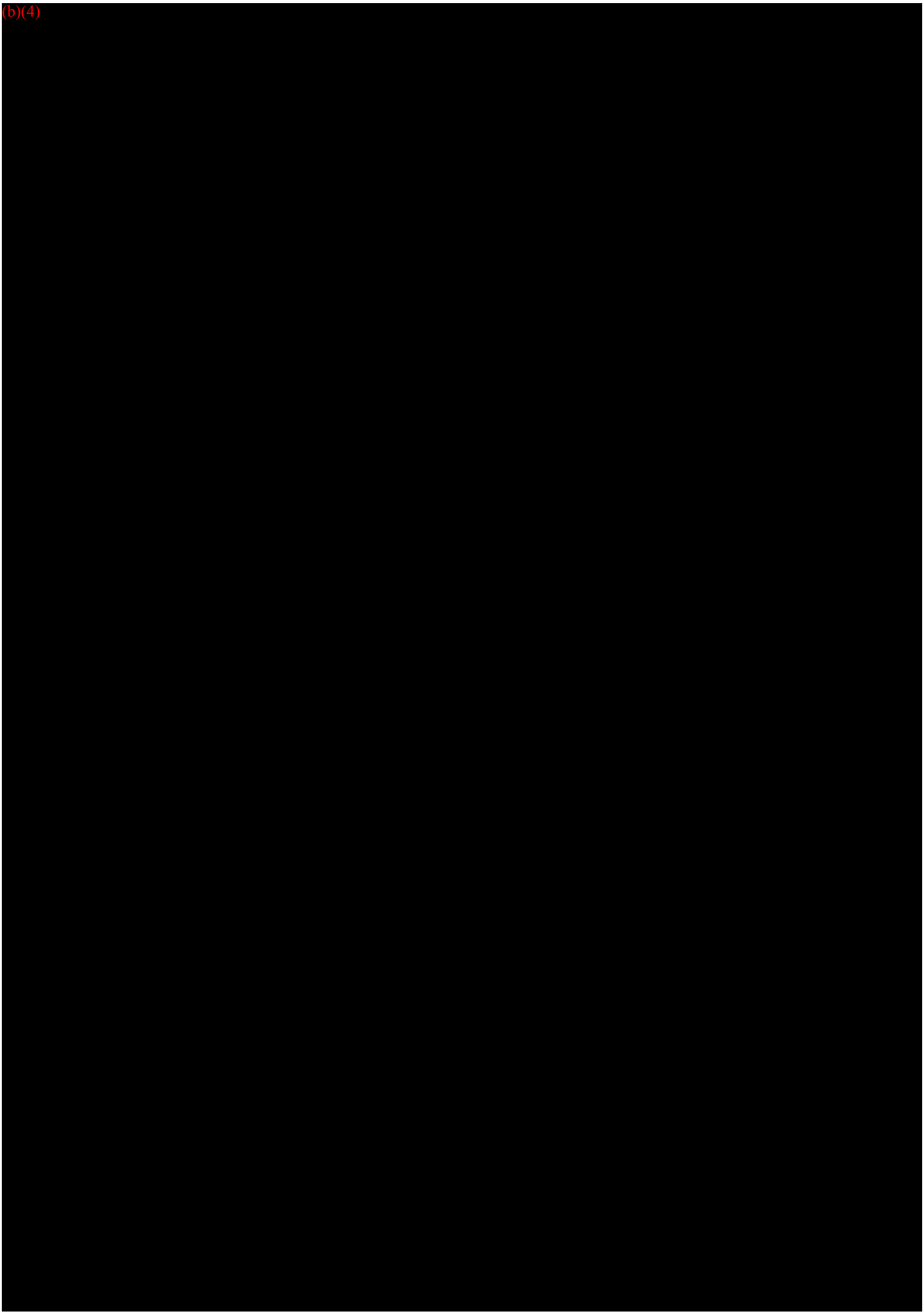
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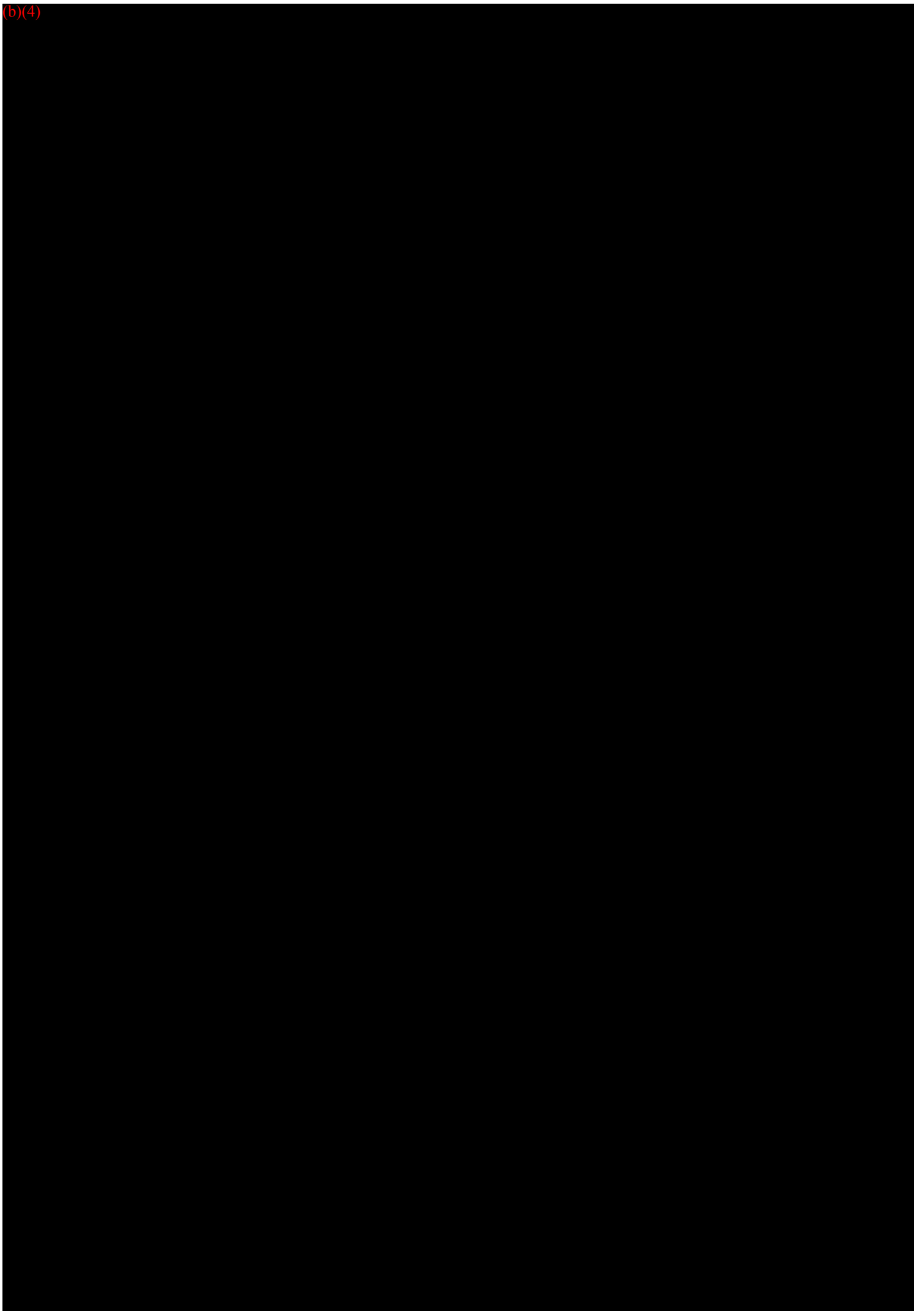

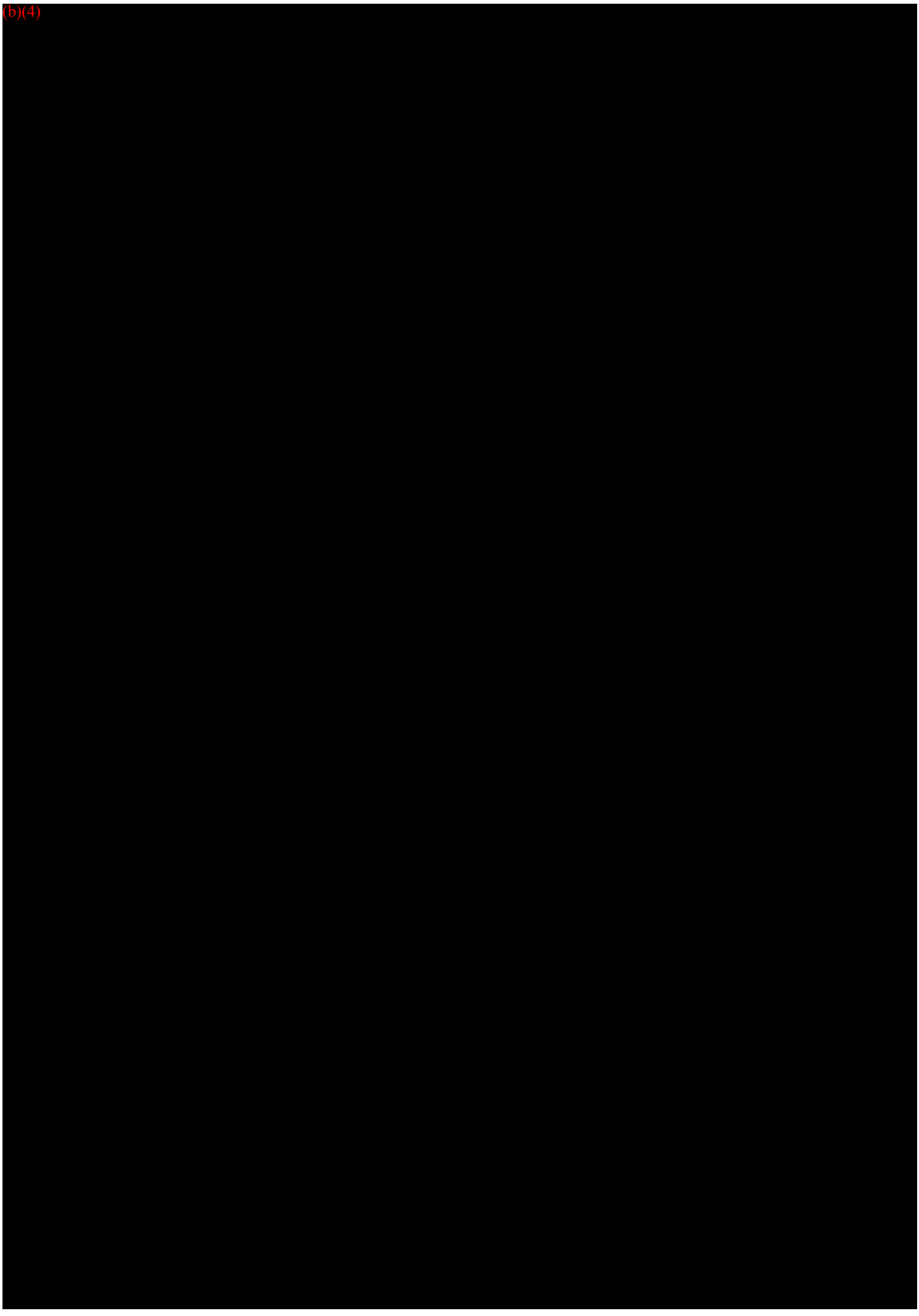
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Software Test Specification

AIR-4

	Title: Software Test Specification AIR-4
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Page size	Page	Document number	Revision
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Software Test Protocol

AIR-4

	Title: Software Test Protocol AIR-4
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Software Test Protocol

AIR-4

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	(b)(4) [redacted]			
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Software Test Protocol

AIR-4

	Title: Software Test Protocol AIR-4
	(b)(4) [redacted]

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Software Design Review Protocol

AIR-4

	Title: Software Design Review Protocol AIR-4
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Software Design Review Protocol

AIR-4

	Title: Software Design Review Protocol AIR-4			
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Software Design Review Protocol

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Configuration Management

for

AIR-4 Software

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	(b)(4) [redacted]			
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Hardware Requirement Specification

Electrical Installation

AIR-4

	Title: Hardware Requirement Specification Electrical Installation AIR-4			
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Hardware Design Description

AIR-4

	Title: Hardware Design Description			
	(b)(4) [redacted]			
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Hardware Test Specification

Electrical Installation

AIR-4

	Title: Hardware Test Specification Electrical Installation AIR-4			
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Hardware Test Protocol

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Hardware Design Review Protocol

Electrical Installation

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INSTRUCTIONS FOR USE
AIRSONETT AIR-4

Please read this document before operating the device

Airsonett

IMPORTANT INSTRUCTIONS

Airsonett® is an electrical device. Please read these instructions before use.

1. Read instructions carefully and keep for future reference.

2. Pay attention to all warnings; follow the instructions.

3. Limited Warranty applies only if the Airsonett is used according to these instructions.

4. Check the product carefully upon delivery and contact Airsonett, or local service provider, immediately if something seems to be damaged.

5. Do not use this apparatus near water or in any moist environment. This apparatus should not be exposed to any item that drips or splashes. No object filled with liquids should be placed on the apparatus. Always remove the power cord from the outlet and contact Airsonett if your Airsonett has been exposed to rain or moisture.

6. Airsonett may not be used in the presence of Flammable Anaesthetic Mixture with Air or Oxygen or Nitrous Oxide.

7. Do not block any ventilation openings (see Product Description page 6).

8. The power cord must not in any way be modified.

9. To avoid electric shock and fire hazards, plug the Airsonett directly into an appropriate electrical outlet according to the label on the Airsonett.

10. Protect the power cord from being walked on, pinched or in any other way damaged.

11. This apparatus has been equipped with an all-pole mains power switch. This switch is located on the rear panel close to the power inlet and should remain readily accessible to the user.

12. Always turn off the mains power switch before removing the power cord.

13. Unplug this apparatus during a lightning storm or when unused for long periods of time.

14. Only use original Airsonett filters and other accessories specified by Airsonett.

15. Refer all service concerns to qualified Airsonett service personnel. Servicing is required when the apparatus has been damaged in any way. If you suspect any form of malfunction, immediately turn off the apparatus, disconnect the power cord from the outlet and contact Airsonett. Don't use the apparatus until inspected by Airsonett.

16. Airsonett is Class II equipment (IEC/EN 60601-1) in terms of type and degree of protection against electrical shock.

17. This equipment has been tested and found to comply with the limits for the electromagnetic compatibility standard IEC/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a residential/medical environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the Instructions for Use, may cause harmful interference to radio communications, in which case the user will be required to correct the interference at his/her own expense. Please contact Airsonett for more information about EMC (Electro Magnetic Compatibility).

18. Operating ambient conditions:

    Temperature range:
    59°F to 86°F (+15°C to +30°C)

19. Electrical equipment. Please do NOT dispose of your Airsonett in the household trash. Please take the equipment to an electronics recycling centre; OR, contact your local representative or Airsonett AB for proper disposal.

20. USB The Airsonett is equipped with an USB port.

    This is solely for use by service personnel. Do not use this port to connect to other USB equipment or devices.

TABLE OF CONTENTS

INTRODUCTION

Intended use
The Airsonett is a mobile air cleaner intended to be used to remove particles from the air for medical purposes. The device is intended for home use only.

Airsonett is developed based on the discovery of high allergen exposure in the breathing zone when lying in bed
During night the concentration of indoor airborne allergens in the breathing zone is primarily generated from bed reservoirs (e.g. house dust mite and pet allergens) and is higher than the concentration of allergens in the ambient bedroom air[1]. The reason for the difference in concentration of allergens in the breathing zone and the room in general is the body convection; the air warmed by the body in the bed creates an airflow that rises due to the lower density of the warm air. The warm air transports the allergens present in the bedding towards the opening in the duvet where it rises and passes by the breathing zone. Airsonett effectively displaces the allergen rich body convection and dramatically reduces the level of inhalant allergens during sleep.

Technology
Airsonett is based on the Temperature controlled Laminar Airflow (TLA) technology. The air from the room enters the Airsonett and passes a filter that captures allergens and other particles. The filtered air is cooled to slightly below the ambient room temperature and is supplied with a low velocity from the air supply nozzle. Since the filtered air is slightly cooler, and therefore heavier than the surrounding air, the filtered air will descend slowly from the air supply nozzle by means of gravity in a laminar manner (non-turbulent). This descending colder air counteracts the body convection, displaces the allergen load in the breathing zone and thus dramatically reduces the level of inhalant allergens for the patient all through the night.

Precaution
Always consult your doctor before changing or reducing your medication. At any uncertainty, contact your doctor. Airsonett is not recommended for individuals with Multiple Chemical Sensitivity (Odour sensitivity).

Pregnancy, breast-feeding and small children
Experience from using Airsonett during pregnancy, breast-feeding and in small children is limited. However, Airsonett does not supply any substances that can affect the pregnancy, breast-feeding or small children.

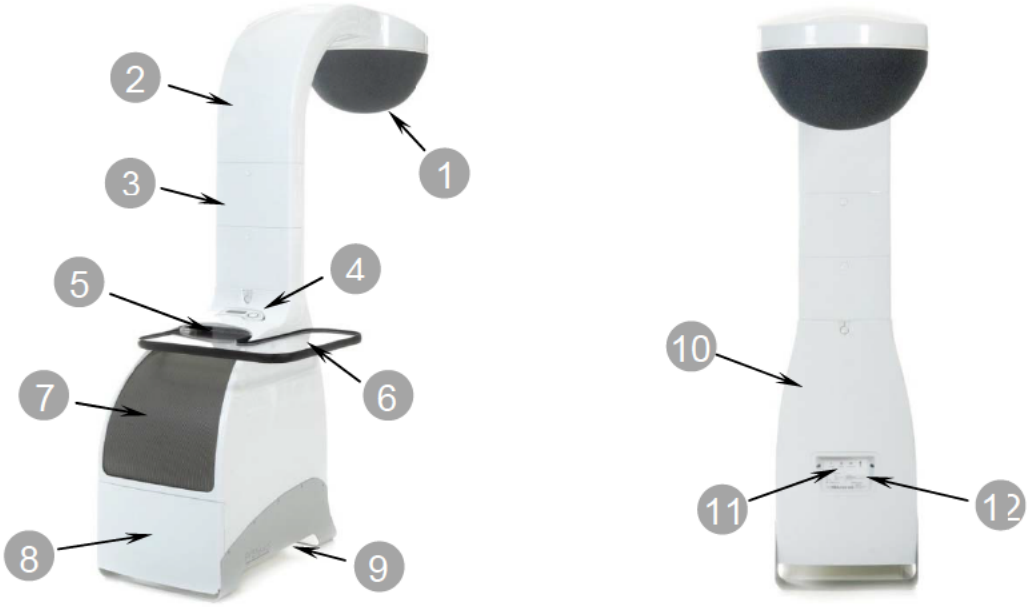
Side effects
Airsonett has an excellent safety profile.

Usage
Airsonett is installed next to the bed and is easy to use. Effectiveness is dependent on following these Instructions for Use.

REFERENCES

1. J.Y. Lau, J.K. Sercombe, E.R. Tovey. Characterisation of personal Der p 1 exposure from upper bedding, when placed in a clean environment Journal of Allergy and Clinical Immunology Vol. 115, Issue 2, Supplement, Page S94

PRODUCT DESCRIP 'ION



Fi jure 1

1	Air supply nozzle (Airshower) for slightly cooled air
2	Bent neck
3	Neck
4	Control panel (details see Fig 2)
5	Built-in handle
6	Table (removable)
7	Warm air outlet
8	Filter door
9	Air intake
10	Base unit
11	- Mains input socket (con ects to grounded or ungrounded outlet) - Mains power switch (O =Off, I=On) - Fuse box - USB connection (only used by service personnel)
12	Label Alternating curr nt ON/OFF Fuse USB Serial Number Read instructions for use Manufacturer Class II equipment according to I EC 60601-1 Do not dispose of your Airsonett in the household trash. Pl ease take the equipment to an electroni cs recycling centre. Airsonett is CE-marked according to Medical Device Directive 93/42/EEC.

CONTROL PANEL

The menu system consists of a couple of screens, dedicated to specific functions, see Menu screens on next page.

It is possible to change screens by using Me .u button. Wherever there is a value that can be changed, the Value button is used to alter the value.

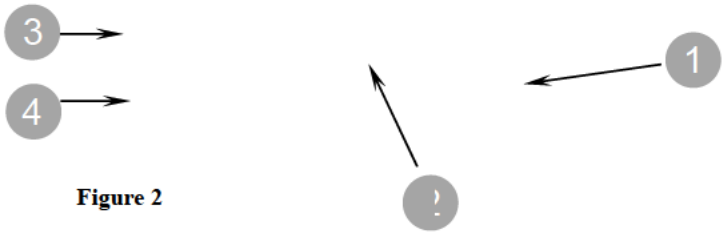
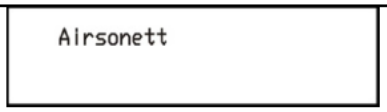
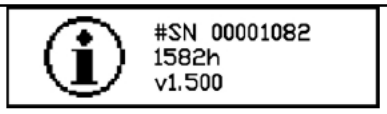
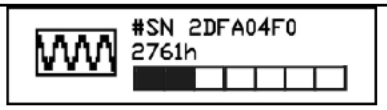
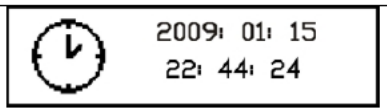
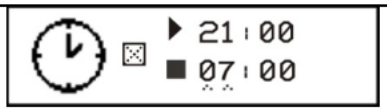
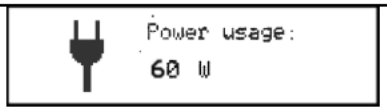
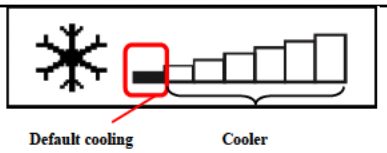


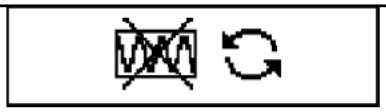
Figure 2

1	Start/Stop
2	Display
3	Menu button
4	Value button

MENU SCREENS

SCREEN	
	**Screen saver** Indicates that the Airsonett is energized but not in operation.
	**Welcome screen** Displays the product name
	**Information screen** Serial number of Airsonett Total operating time of Airsonett. Firm Ware Version
	**Filter status screen** The serial number of the filter in use Time left until filter change Graphical: Used time / Time left until change
	**Time and date screen** Date: YYYY-MM-DD Time: HH:MM:SS (24h format), adjustable by the user.
	**Timer screen** Timer function ON ☒ or OFF ☐. Time for automatic START every 24h-period. Time for automatic STOP every 24h-period.
	**Power consumption screen** Momentary power consumption. The unit is Watt [W]. The picture shows an example of power consumption.
	**Temperature screen** Temperature setting of the cooled air coming from the air supply nozzle. Alternations by the user are an option for the individual comfort. This is the screen that every other screen returns to after a few seconds of user inactivity.

FAILURE MODE SCREENS

SCREEN	
	**Filter warning** Th s screen indicates that • the filter has expired • a ıd/or that the filter is missing • a ıd/or that the filter is not in a correct position. Please see section *Filter Change*.
# 1	**General failure** Failure code. Please contact your local support provider. Please refer to thi ; code when contacting the support.
 	**Cooling failure** Th :se screens appear when the cooling is out of its limits. This ıay for ins :ance occur under extremely draughty conditions. Please check that Airsonett is not positioned near any heat sourc :s such as radiators, or close to an inlet air vent, ventilator, air-conditioning unit or draught. Please contact your local support provider if the failure ıode remains.

ASSEMBLY AND POSITIONING

1

Check the packaging for any outer damage. Open the packaging (ar ows in upward direction). Carefully take out the necks, bent neck, air su ply nozzle, pow r cord, base unit, table (including 2 screws, locking plate, hex key) an Instructions For Use.

2

Place the ba e unit close to the bed. Measure the height, H, from the floor to the top of the pillow in the bed.

3

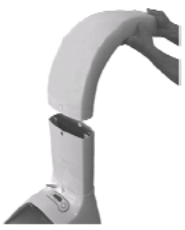
Depending on the height from floor to the pillow in the bed, please follow the t ble which tells you how many necks you should ad.

H (in.)	H (cm)	Recommended combinations
<12	<30	
12-18	30-45	
18-24	45-60	
24-30	60-75	
30-35	75-90	

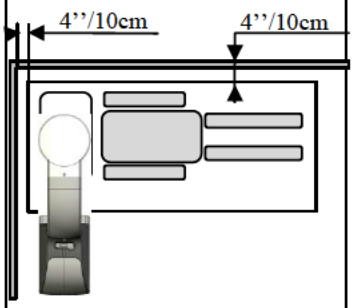
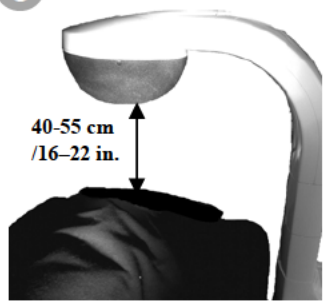
4

Assemble correct quantity of necks to the base unit. The buttons snap when correc tly assembled.

5

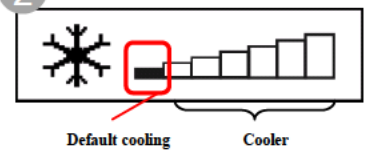
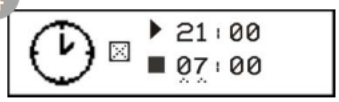


Assemble b nt neck (short side down). The buttons snap when corr ctly assembled. If no necks are needed, the bent neck is assembled directly onto the bas e unit.

6	Assemble air supply nozzle onto the bent neck. The buttons snap when correctly assembled. Be extra careful with the air supply nozzle (Airshower).
7 	**a)** If possible, do not place the bed directly against a wall; leave at least 5–10 cm/2–4 in. space between the wall and the bed for optimal function. **b)** Position Airsonett to get the air supply nozzle (Airshower) positioned right above the pillow. **c)** Be careful not to block the air intake, located at floor level, or the warm air outlet. d) Do not position the Airsonett near any heat sources such as radiators, or close to air inlet air vent, ventilator, air-conditioning unit or draught.
8 	Measure the distance between the air supply nozzle (Airshower) and pillow to ensure it is 40-55cm/16–22in. When measuring, the pillow should be slightly pressed down equivalent to normal use. If distance is not correct, adjust the height by adding or removing neck pipes. The effectiveness of Airsonett is dependent on distance being ≤55 cm/22in.
9 	The table is optional. The table can be positioned on either the right or the left side of Airsonett.
10 	Mount locking plate turned to the upper side of the table, using the two screws. Tighten screws using the hex key.

11	Push the table gently into the slot of Airsonett. The locking plate snaps when correctly assembled. Confirm fixatio . by trying gentl · pulling the table away from the Airsonett.
12 	Connect po ver cord to mains input socket and to the wall socket. Press mains powe · switch (next to Mains input socket) and then start the Airsonett, see section Airsonett In Operation. **Airsonett should be operated fo r 24 hours prior first use, to assure that scents that ıight have occurred during transport disappear.**

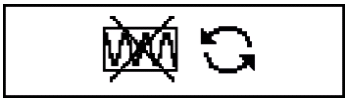
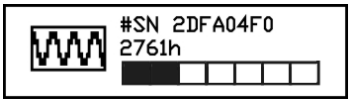
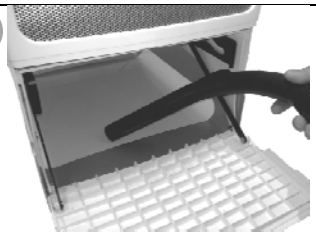
AIRSONETT IN OPERATION

1 	St rt the Airsonett by pressing button Start/Stop on Contr l Panel. The display will show screens with a short interval ending up at the default screen; Temperature screen.
2 	Te mperature setting of the cooled air coming from the Air Supply Nozzle (Airshower) may be modified. Alternations by the user are an option for the individual comfort, for people wanting a cooler se sation.
3	W ıen not in use, Airsonett may be stopped by pressing St urt/Stop bu ton on Control Panel. Airsonett will quickly restore the air qu ality when started again.
4 	There is an automatic Start/Stop function that can be activ ated via the Timer Screen (please see the *Menu Screen* section).

CLEANING AND MAI NTENANCE

1 	The outside plastic surfaces can be wiped off with a soft lint free cloth lightly moistened with water as part of normal household clea ning. Be careful not to expose the filter to fluids and/or to any physical damage.
2	Check at least weekly that the air supply nozzle (Airshower) is undam aged.

FILTER CHANGE

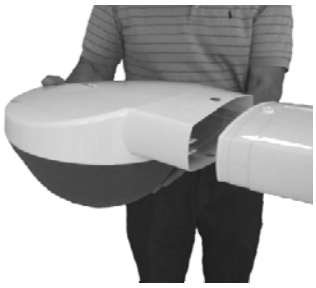
1 **a)**  **b)** 	**To maintain the intended effect of Airsonett it is very important that the filter is changed every 6th month.** Airsonett indicates when it is time to change filters (see Fig. a). Filters are distributed on a regular basis to the user. If the filter is not changed when indicated, the Airsonett will stop after a while and cannot be started until a new filter is installed. The remaining time before the filter must be changed is shown in the Filter Screen (hours and graphical) see Fig. b).
2	Airborne particles in the environment are concentrated in the filter; thus, persons suffering from allergy or asthma should avoid changing the filters by themselves due to the risk of allergen and particle exposure.
3	Disconnect the power cord. Open the filter door by using the small grips at the sides.
4	Grasp the old filter at the grip and pull it straight out. Be careful not to shake or jerk the used filter since that will allow contaminants into the room. Put the filter gently in a plastic waste bag, and preferably into the packaging of the new filter, and dispose of it properly with household trash.
5 	Vacuum dry debris in the filter compartment, including all crevices.
6 	Vacuum the floor area in, and around, the filter compartment.

7	Vacuum the filter door.
8 	Han le the new filter with care, not to expose it to fluids, contamination or physical damage. Be very careful not to to ıch the pleat ɜd filter on the top and bottom. Grasp the new filter on he sides of th ɜ plastic frame. Insert the filter all the way in. Make sur ɜ the filter grip is pointing outwards.
9	Clos ɜ the filter door and assure that it is properly closed. If not, the filter might not be correctly installed.
10 	Reconnect the power cord. The Airsonett should be operated for at least 10 minutes prior use. Your Airsonett is now ready to use!

Airsonett

Airsonett AB
Metallgatan 2E, 262 72 Ängelholm,
SWEDEN
Tel: +46 431-40 25 30
E-mail: info@airsonett.ɜe
Internet: www.airsonett.com

DISASSEMBLY

1 	Do not disassembly the Airsonett unless absolutely needed, e.g. for shipment or moving to another location. Disconnect the power cord and begin with disassembling the air supply nozzle (Airshower).
2	Then disassemble the rest of the neck (as a whole or in parts). Don't let any necks remain on the base unit during transportation.
3 	When the Airsonett is in its new location, reassemble it according to section *Assembly and Positioning*. The Airsonett should be operated for 24 hours after reassembly prior use, to assure that scents that might have occurred during transport disappear.

TROUBLESHOOTING, REPAIR AND SUPPORT

Is the power cord properly connected to the wall socket and to the mains input socket of the Airsonett?

Is the power supply to the wall socket working properly?

Is the mains power switch (located next to the power cord) switched on?

Does the display show anything?

Is the Start/Stop button activated?

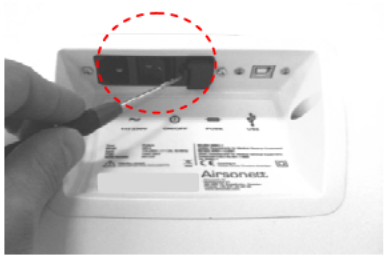
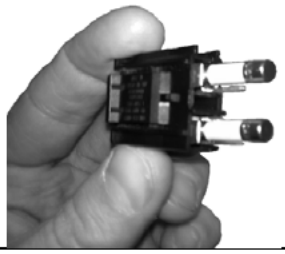
Is the fuses of the Airsonett intact? (See section *Changing fuses*)

Is any failure mode screen shown in the display?

If problems remain despite the foregoing checks, contact your local support provider or Airsonett.

All repairs should be carried out by Airsonett authorized service provider.

CHANGING FUSES

1	Disconnect the power cord. Locate the fuse bo .
2 	Open the fuse box with a flat screw driver and pull out the fuse holder cartridge.
3 	Check if the fuses are intact. If broken, change :o new fuses type 250V 4 A ceramic with slow time la ɜ (T4AH 250V, 5x20 mm).
4	Reinstall the fuse holder cartridge to its origina position and ensure that it is properly locked. Reconnect the power cord and start the Airsonett.

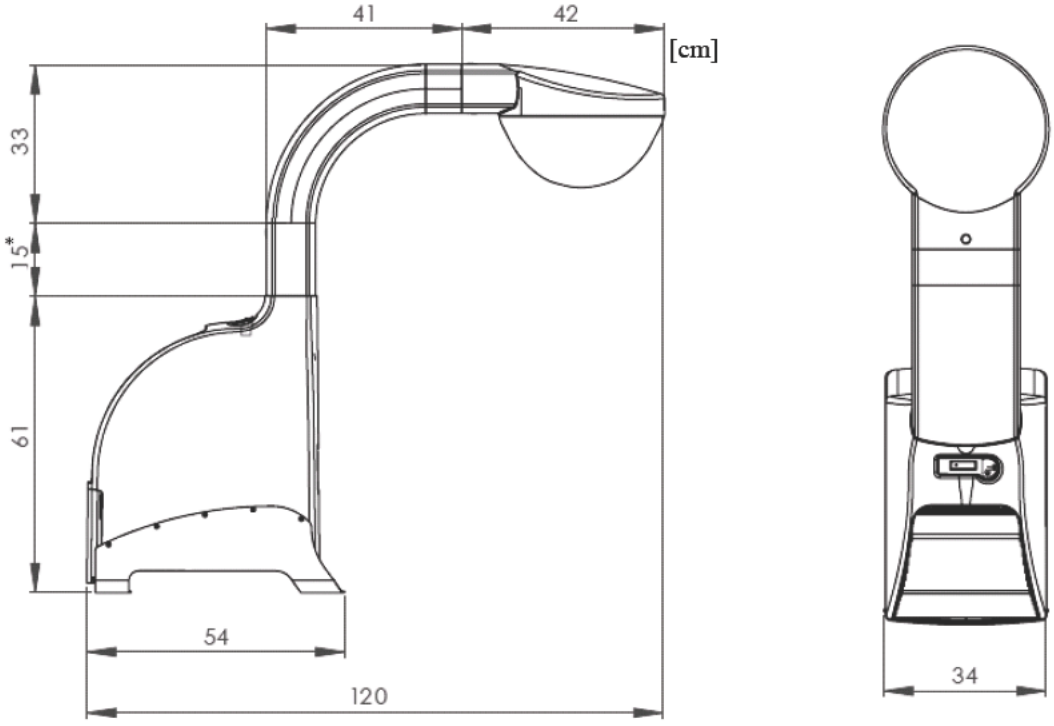
TECHNICAL DATA

DIRECTIVE
Airsonett® is CE-marked according to Medical Device Directive 93/42/EEC. CE

EQUIPMENT CLASSIFICATIONS
Airsonett is Class II equipment according to IEC/EN 60601-1.

STANDARDS
Airsonett complies with: IEC/EN 60601-1; CAN/CSA-C22.2 No.601.1-M90 and UL 60601-1.
Airsonett complies with the electromagnetic compatibility standard IEC/EN 60601-1-2.

TECHNICAL DATA
Filter type: HEPA. Filtration efficiency ≥99.5% of particles with size Ø≥0.5µm.
Input: 115-230V~, 1.7-1.0A, 60-50Hz
Fuse: T4AH 250V, 5x20 mm
Casing: ABS plastics
Sound level: ≤38 dB(A)
Weight: 25 kg (55 lbs)
Dimensions: see below. *Total height depends on multiples of necks.



Airsonett

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Metallgatan 2E, 262 72 Ängelholm, SWEDEN
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E-mail: info@airsonett.se
Internet: www.airsonett.com

A-1007/01/2013-02

(b)(4) Third Party Test Data

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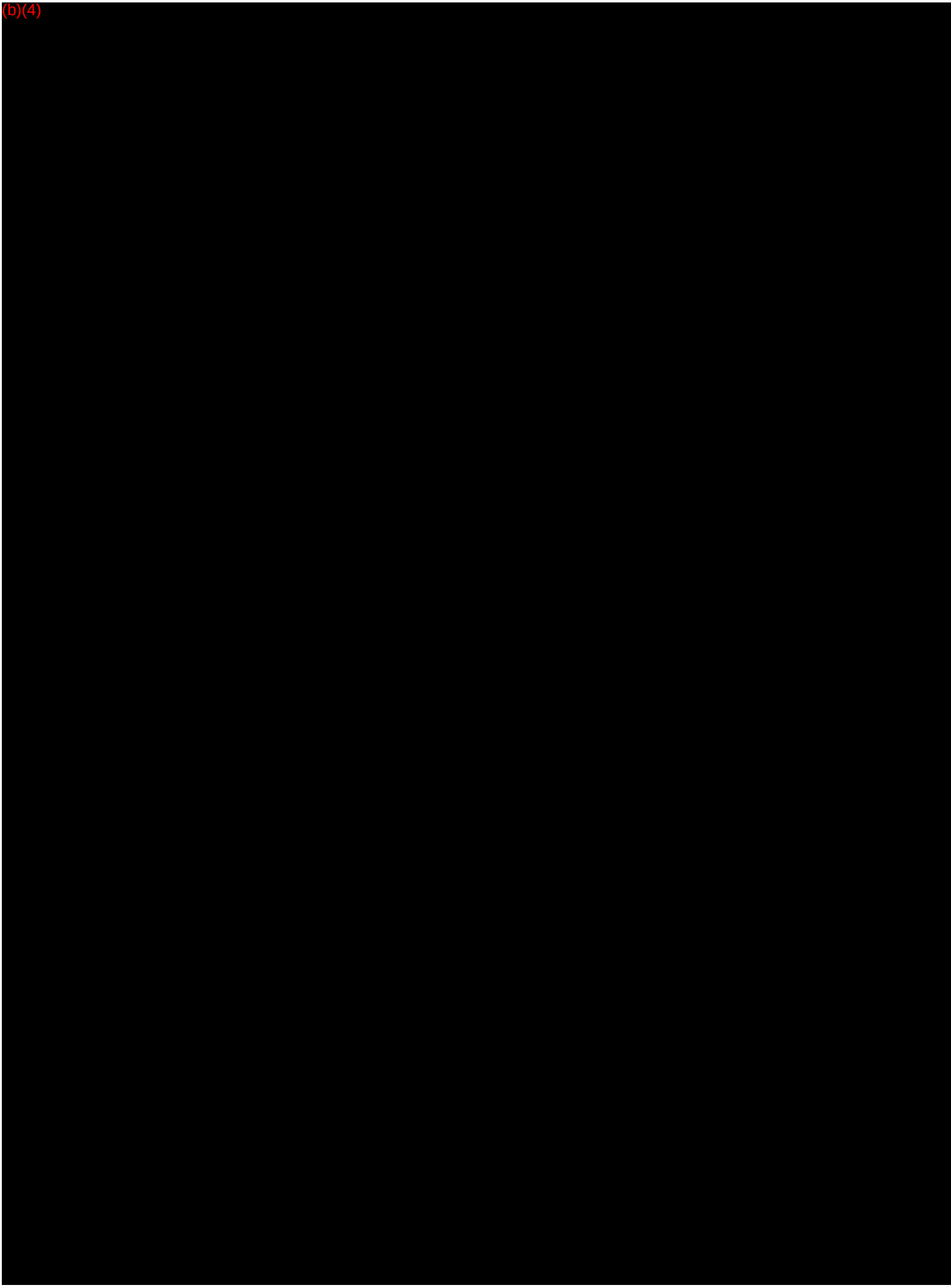
(b)(4)

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

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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]

IEC60601-1-2, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-60	
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], www.fda.gov/cdrh/stdsprog.html

[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 descr bed; 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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖
Identification, marking and documents have not been evaluated by Intertek.

DESCRIPTION

JUSTIFICATION
No hazards, related to Identification, marking and documents, that would affect electromagnetic compatibility, have been identified.

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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, 1988

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-4	
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], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.1v	Protective packaging requirement - Marking for unpacking safety hazard	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Packaging not evaluated by Intertek.

DESCRIPTION

JUSTIFICATION
No safety hazards, related to unpacking the device, that would affect electrical safety and/or performance, have been identified.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10.1	Equipment is capable while packed for transport or storage of being exposed...	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ❖
Packaging not evaluated by Intertek.

DESCRIPTION
Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer.

JUSTIFICATION
There are no specific requirements for conditions during transport or storage.

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.

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Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Mawii, Lal Pek *

From: Mawii, Lal Pek *
Sent: Wednesday, July 24, 2013 1:21 PM
To: 'cgbundy@live.com'
Cc: DCCLetters
Subject: K130702 - Correspondence
Attachments: 2013_07_24_13_20_01.pdf

S

COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Shani Smith

Subject: 510(k) Number K130702

To: The Record

Please list CTS decision code: SE

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
oes firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number: 21 CFR 880.5045

Class: II

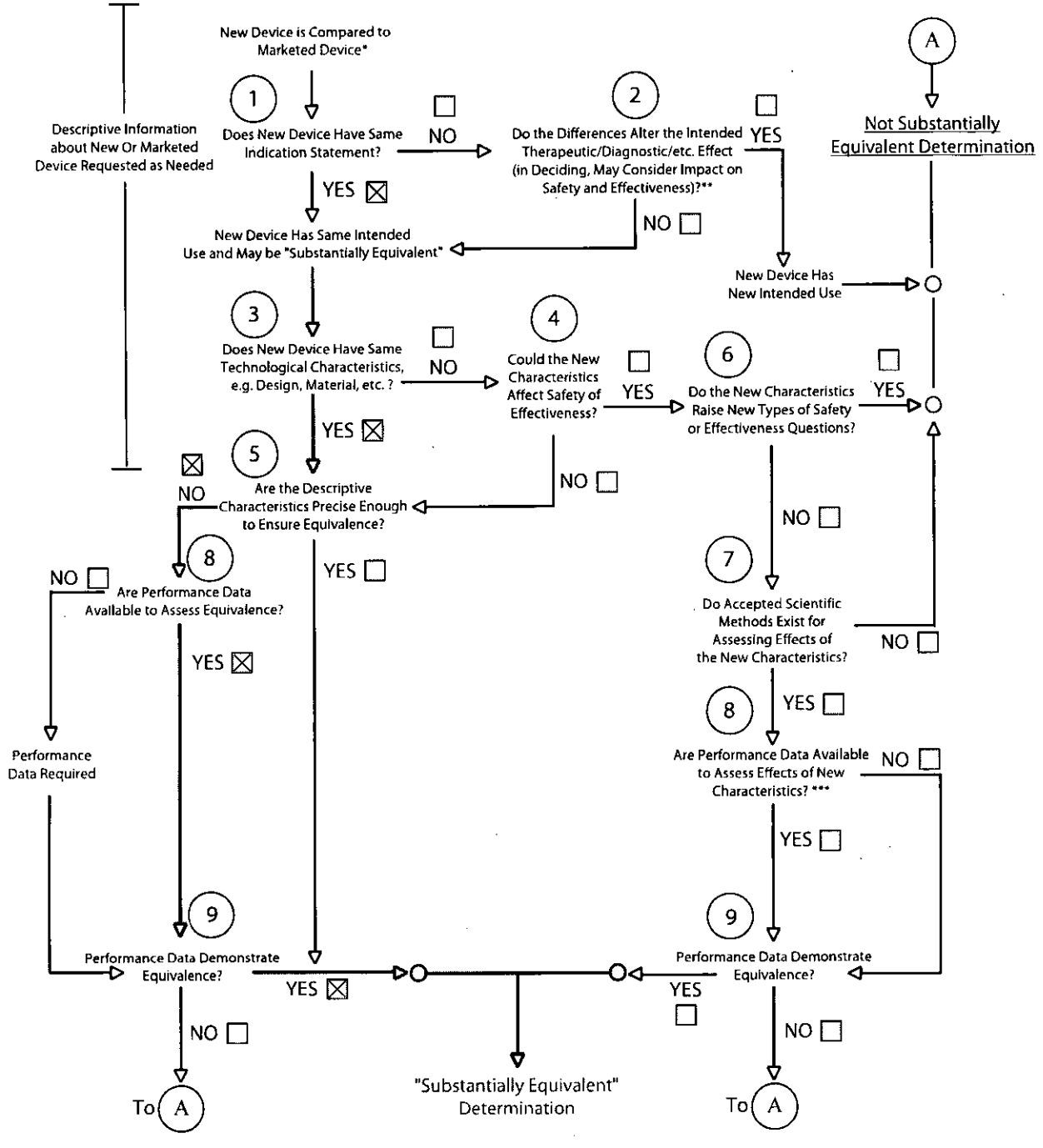
Product Code: FRF

Additional Product Codes:

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Elizabeth F. Claverie 2013.07.19 17:53:33 -04'00'
Division Sign-Off	Tejashri S. Purohitsheth -S 2013.07.23 14:30:40 -04'00' Tejashri Purohit-Sheth, M.D. Clinical Deputy Director DAGRID

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



SE

* 510(k) Submissions compare new device to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear .

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k) , other 510(k)s, the Center's classification files, or literature.

K130702-S1

Airsonett AB
Angelholm, Sweden

April 1, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: 510(k) K130702, Airsonett version AIR-4
Response to Refuse to Accept Notification (received by email April 1, 2013)

As required, Airsonett is submitting two copies of this response. One copy is paper and one copy is an eCopy. The eCopy is an exact duplicate of the paper copy.

The response includes:
Corrected 510(k) Summary to include Common Name of device, and
Corrected page 22 regarding misprint.

Any questions regarding this response should be directed to Constance Bundy, Consultant to Airsonett AB.

Regards,

Constance G. Bundy

Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432 USA
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

29

Airsonett AB
Angelholm, Sweden

April 1, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: 510(k) K130702, Airsonett version AIR-4
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Corrected 510(k) Summary to include Common Name of device, and
Corrected page 22 regarding misprint.

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Regards,

Constance G. Bundy

Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432 USA
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

510(k) SUMMARY

Submitter: Airsonett AB
Metallgatan
SE-262 72 Angelholm
Sweden
+46 431 402470

Contact Information: Constance G. Bundy
C. G. Bundy Associates, Inc.
435 Rice Creek Terrace NE
Fridley, MN 55432 USA
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

Submission Date: March 15, 2013
Common Name: Medical recirculating air cleaner
Device Name and Classification: Airsonett, version AIR-4, Class II
21 CFR 880.5045
Product Code: FRF

Equivalent Device Identification: Airsonett Airshower Air-3, K081062, BREATHE EASY (Models AD and CD) by RespirAid Ltd (K981841)

Device Description:

Airsonett is based on the Temperature controlled Laminar Airflow (TLA) technology. The air from the room enters the Airsonett and passes a filter that captures allergens and other particles. The filtered air is cooled to slightly below the ambient room temperature and is supplied with a low velocity from the air supply nozzle. Since the filtered air is slightly cooler, and therefore heavier than the surrounding air, the filtered air will descend slowly from the air supply nozzle by means of gravity in a laminar manner (non-turbulent). This descending colder air counteracts the body convection, displaces the allergen load in the breathing zone and thus dramatically reduces the level of inhalant allergens for the patient all through the night.

Air is drawn in through the air intake at the floor level and through the **HEPA filter**. A silent **Blower** (fan) brings airflow through the filter. The air is directed through the **Cooler/Heater** and divided into a cool respectively warm air flow. The cool air flow is directed through the **Air guidance arm** (neck) and out through the **Airshower** (Air Supply Nozzle). The Airshower can be altered in height, by adding/removing and combining the neck parts, to adapt to different types of environments. The warm air flow is directed to the **Warm air outlet**. On its way to the outlet the air flow passes the electronics and transports away the extra heat produced by the electronics.

Element of Comparison	Subject Device	Claimed SE Device
Air Quality in treated air envelope (referred as clean zone in Appendix 1.2)	Filtration efficiency 99.5% of particles Ø ≥0.5µm which is equivalent to -Class 1000 according to FED STD 209E and -Class 6 according to ISO 14644-1 in environments of ≤200 000particles/ft^3	Class 100-1000 according to FED STD 209E
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour
Sound Level	≤38 dB(A)	~38 dB(A)

The Airsonett is substantially equivalent to Airsonett Airshower Air-3 regarding technology, intended use and performance.
The Airsonett is also substantially equivalent to the claimed SE device in the 510(k) for Airsonett Airshower Air 3: Breathe Easy (510(k) number: K981841)

Element of Comparison	Subject Device	Claimed SE Device	Previous 510(k) SE Device for Airsonett Airshower Air-3
Manufacturer	Airsonett AB	Airsonett AB	RespirAid Ltd.
Air Flow	Airflow in clean air zone (cool side): At least 120 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 200 m^3/h	Airflow in clean air zone (cool side): Approx. 150 m^3/h Airflow warm side: Approx. 80 m^3/h Total airflow: Approx. 230 m^3/h	20-40 m^3/h
Rate of Air Changed	At least 435 changes per hour	~1500 changes per hour	400-600 changes per hour

Discussion

Airsonett AIR-4 and the Airsonett Airshower Air-3 are substantially equivalent in Intended Use, technology and performance. Both devices are designed to remove particles from the air for medical purposes.
The Airsonett AIR-4 differs from the predicate device, AIR-3, in that

- the filter has been improved. The filter area of AIR-4 is larger than for AIR-3, enabling a larger filtration efficiency. The filtration efficiency of AIR-4 has been verified to be equivalent or better than the filtration efficiency of AIR-3, giving an equivalent Air Quality in treated air envelope.
- the software and hardware have been improved. AIR-4 has additional functions for improved usability, such as filter exchange control; the AIR-4 indicates in a display when filter shall be exchanged. The software of AIR-4 has been validated.

K130702/S2

Airsonett AB
Angelholm, Sweden

July 1, 2013

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re: **K130702, Airsonett AIR-4**
Response to Deficiencies received by email May 30, June 17 and 24, 2013

As required, Airsonett is submitting two copies of this Response to Deficiencies. One copy is paper and one copy is an eCopy. The eCopy is an exact duplicate of the paper copy.

Any questions regarding this submission should be directed to Constance Bundy, Consultant to Airsonett AB.

Regards,

Constance G. Bundy

Constance G. Bundy
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763-574-1976
Fax: 763-571-2437
cgbundy@live.com

1/2

Airsonett AB
Angelholm, Sweden

July 1, 2013

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Regards,

Constance G. Bundy

Constance G. Bundy
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Regards,

Constance G. Bundy

Constance G. Bundy
C. G. Bundy Associates, Inc.
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Fridley, MN 55432 USA
763-574-1976
Fax: 763-571-2437
cgbundy@live.com

FINAL RESPONSE TO QUESTIONS RECEICED BY EMAIL MAY 30, JUNE 17 AND JUNE 24, 2013 REGARDING K130702.

510(k) Holder:	Airsonett AB
Device Name:	Airsonett AIR-4
Address:	Metallgatan SE-262 72 Angelholm Sweden +46 431 402470
Contact:	Constance G. Bundy
Phone:	(763) 574-1976
Fax:	(763) 571-2437
Email	cgbundy@live.com

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APPENDICES

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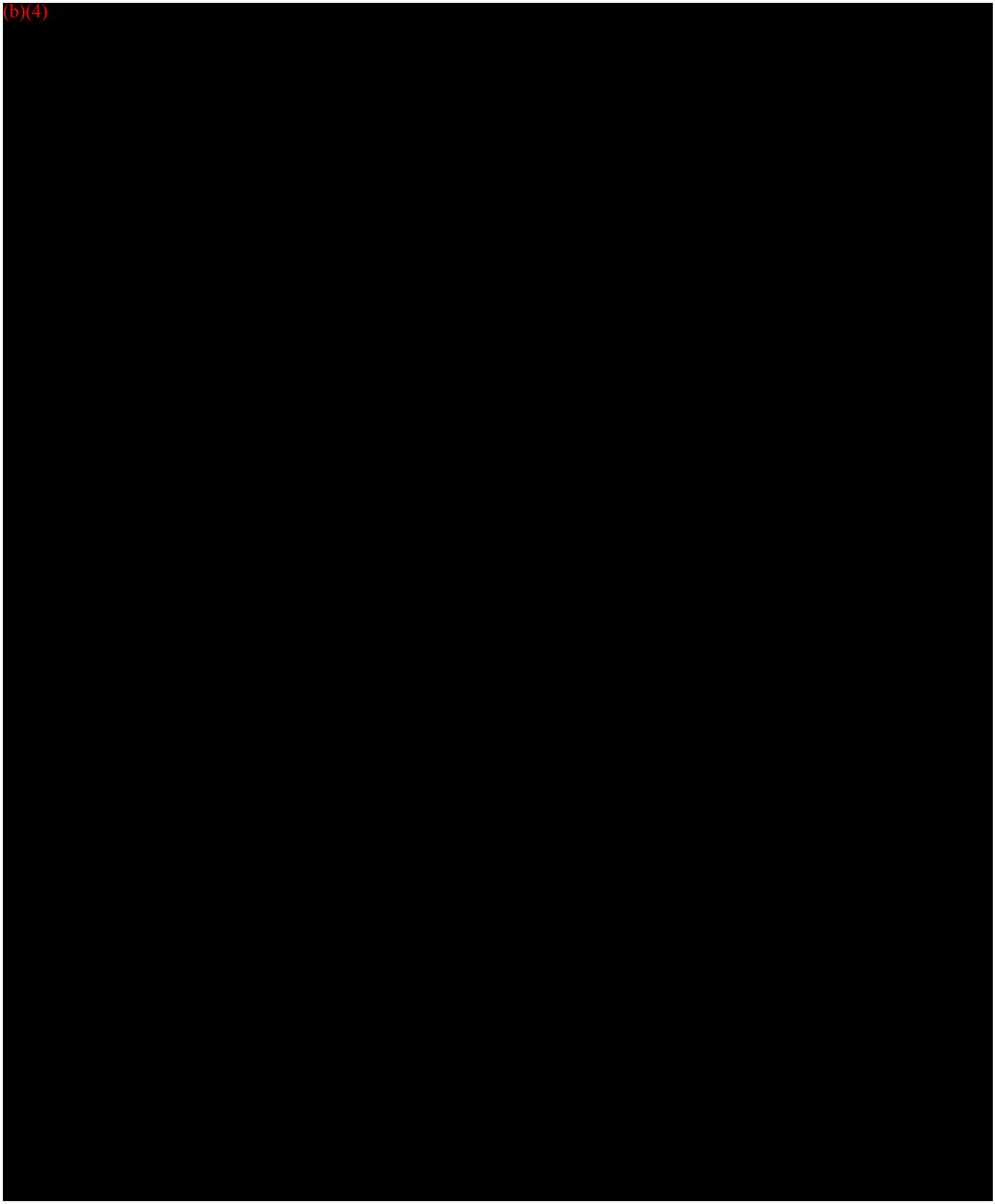

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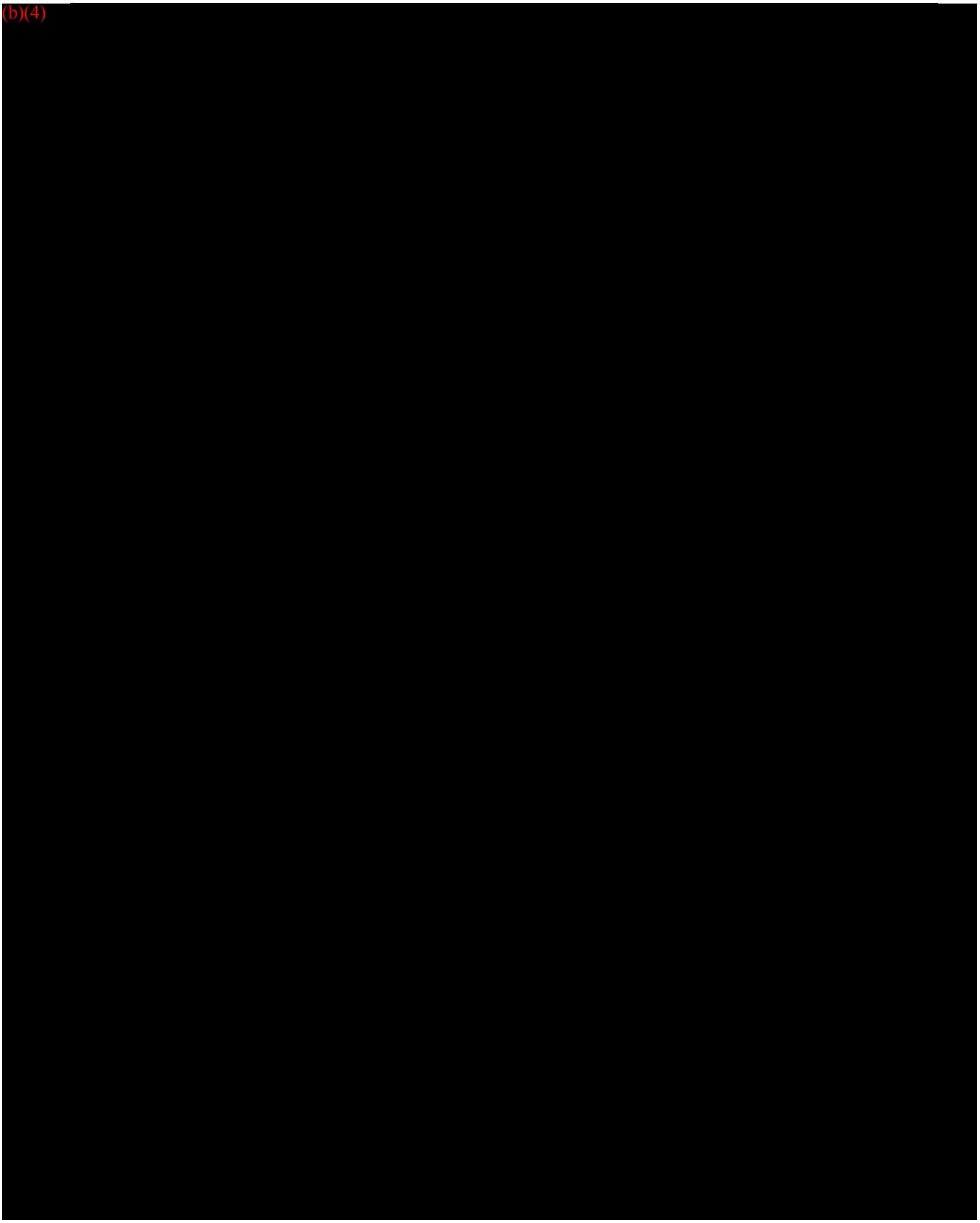

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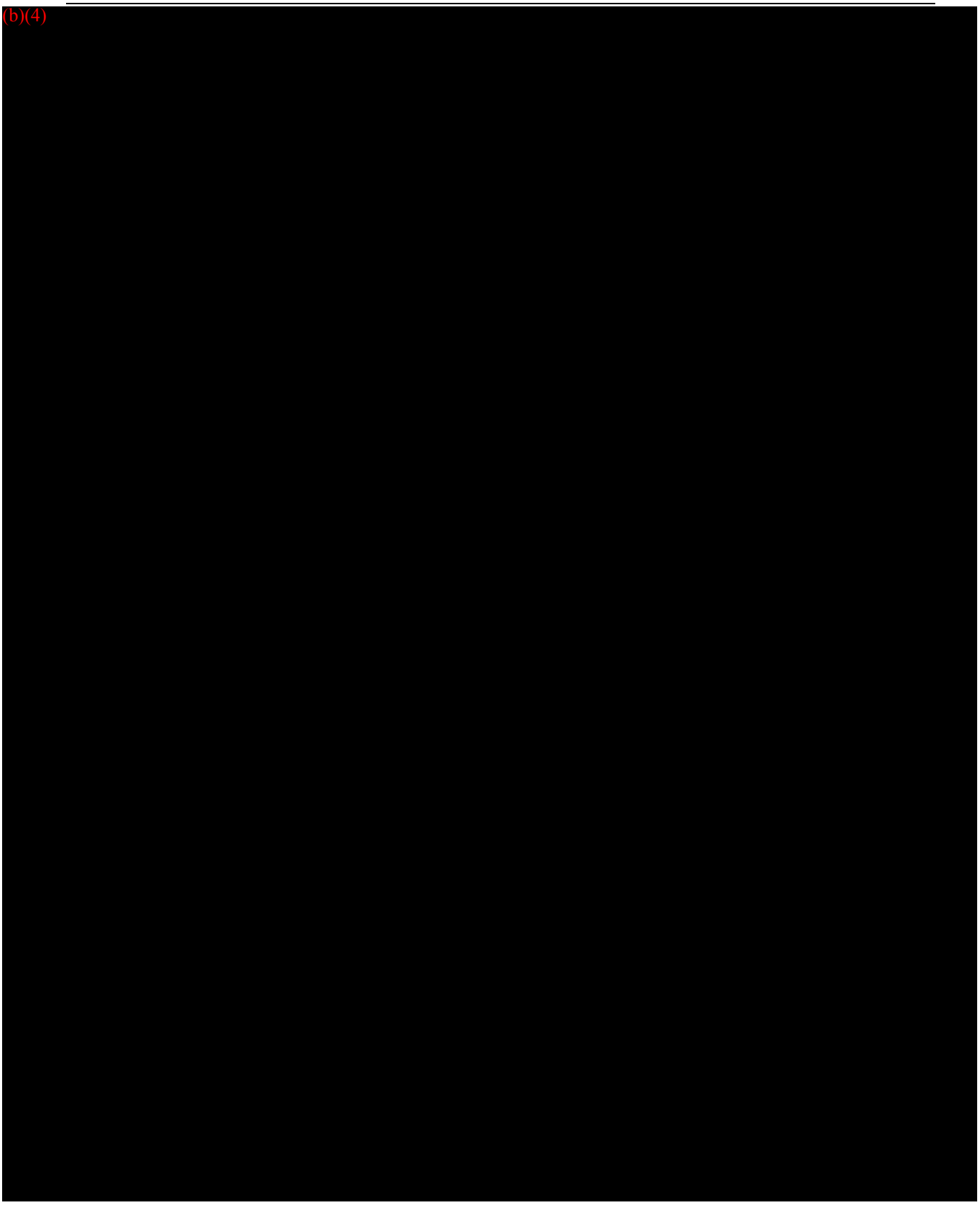

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APPENDIX 1.11

VERIFICATION AND VALIDATION OF USB-FUNCTION AND SD-CARD FUNCTION

1. BACKGROUND

Airsonett AIR-4 has a USB communication port for connection to a PC via HyperTerminal and a micro SD-card socket for data logging and firmware upgrade (none of these functions are intended to be used by the user).

2. OBJECTIVE

This report describes how safety and effectiveness related to USB and SD-card functions have been verified through black box tests and code reviews, and validated by performance tests of Airsonett.

3. TEST ITEM

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4. DESIGN INPUT

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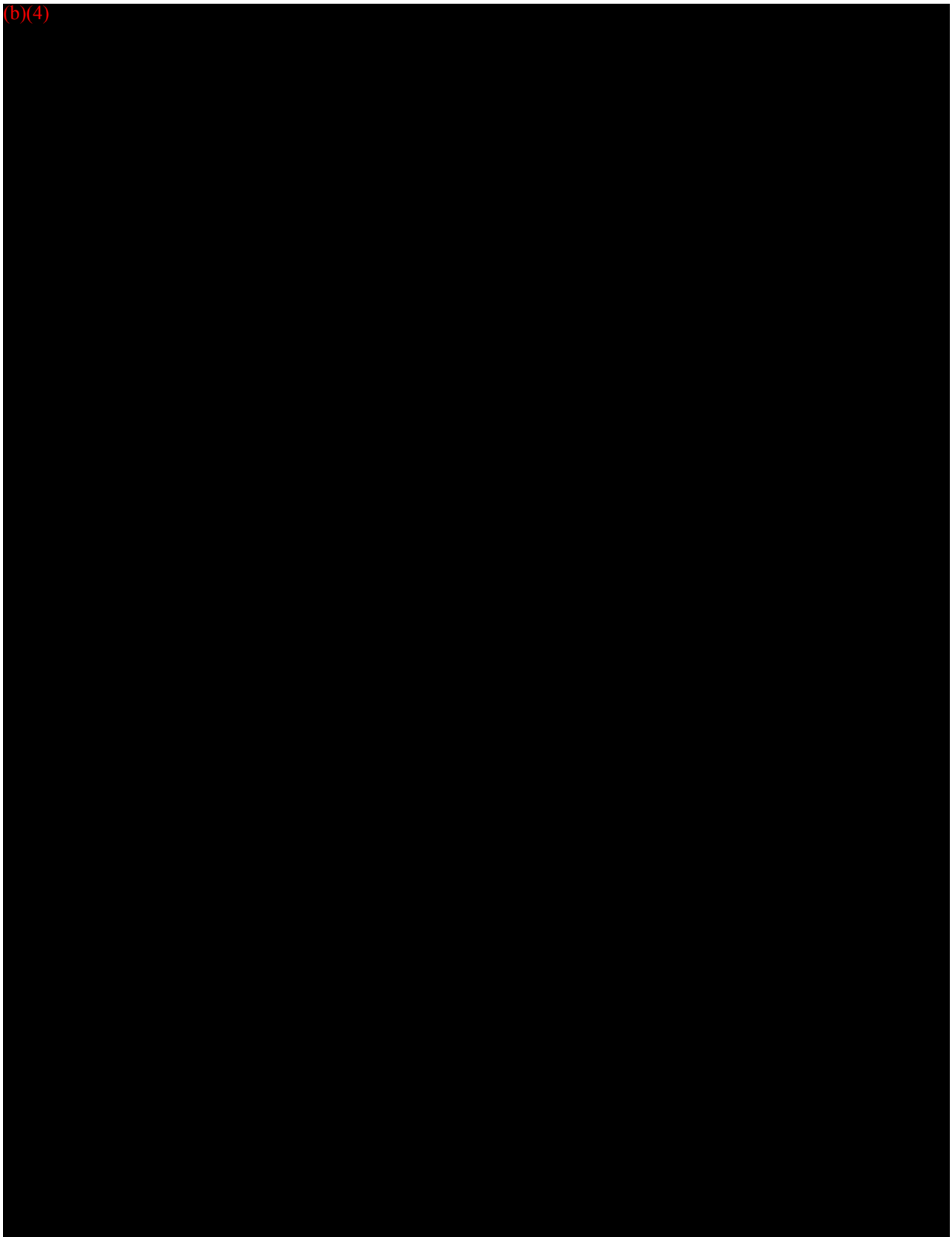

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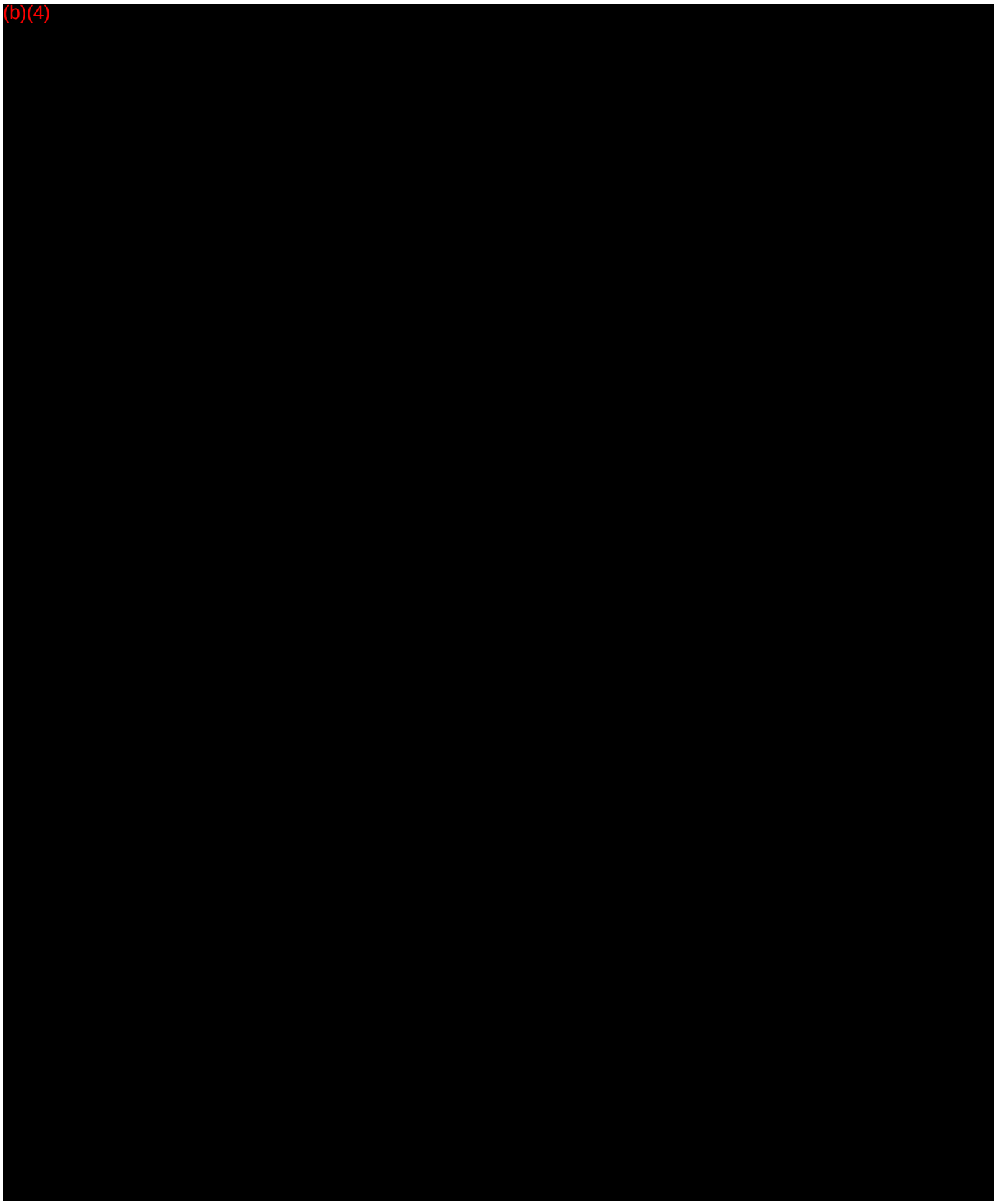

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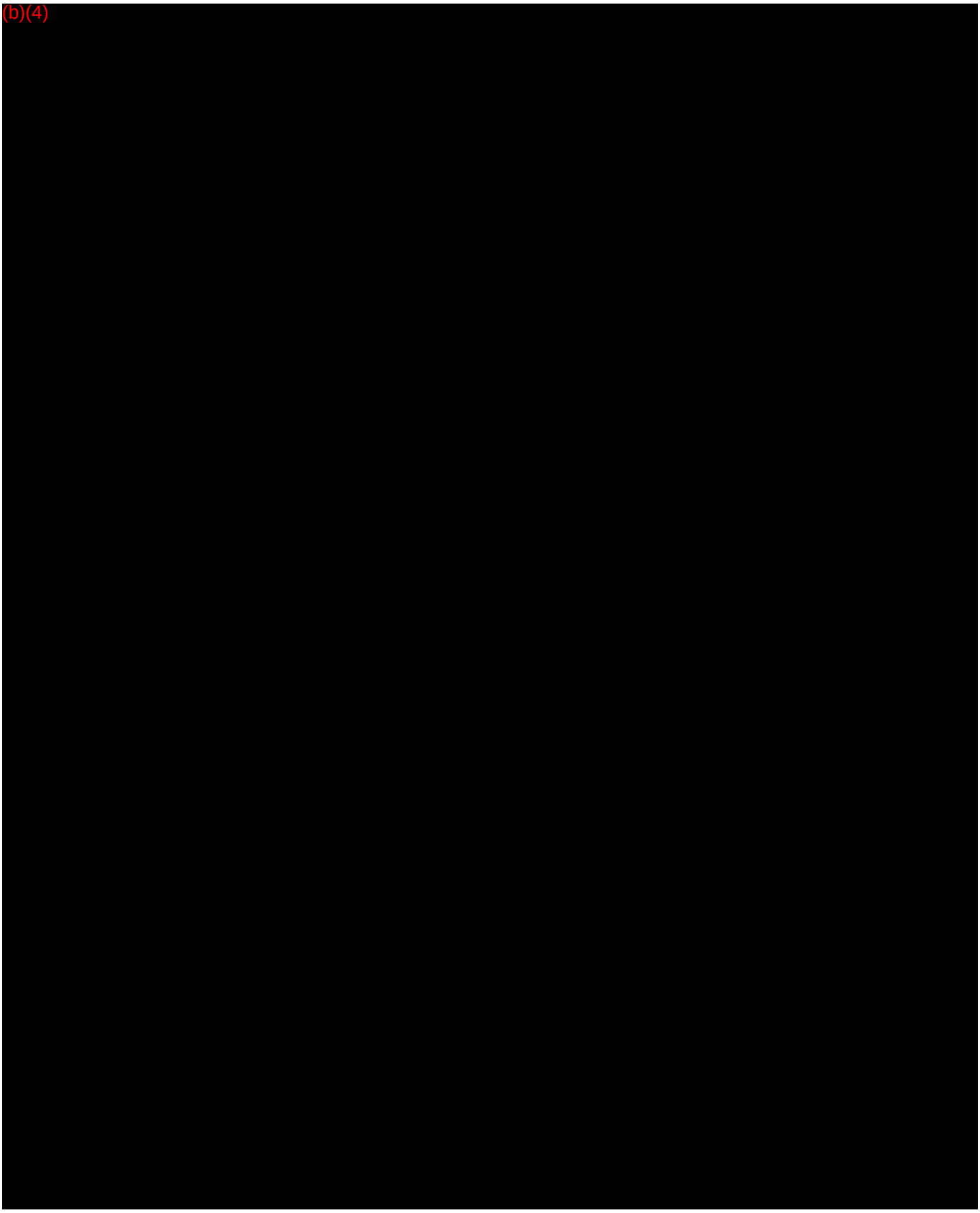

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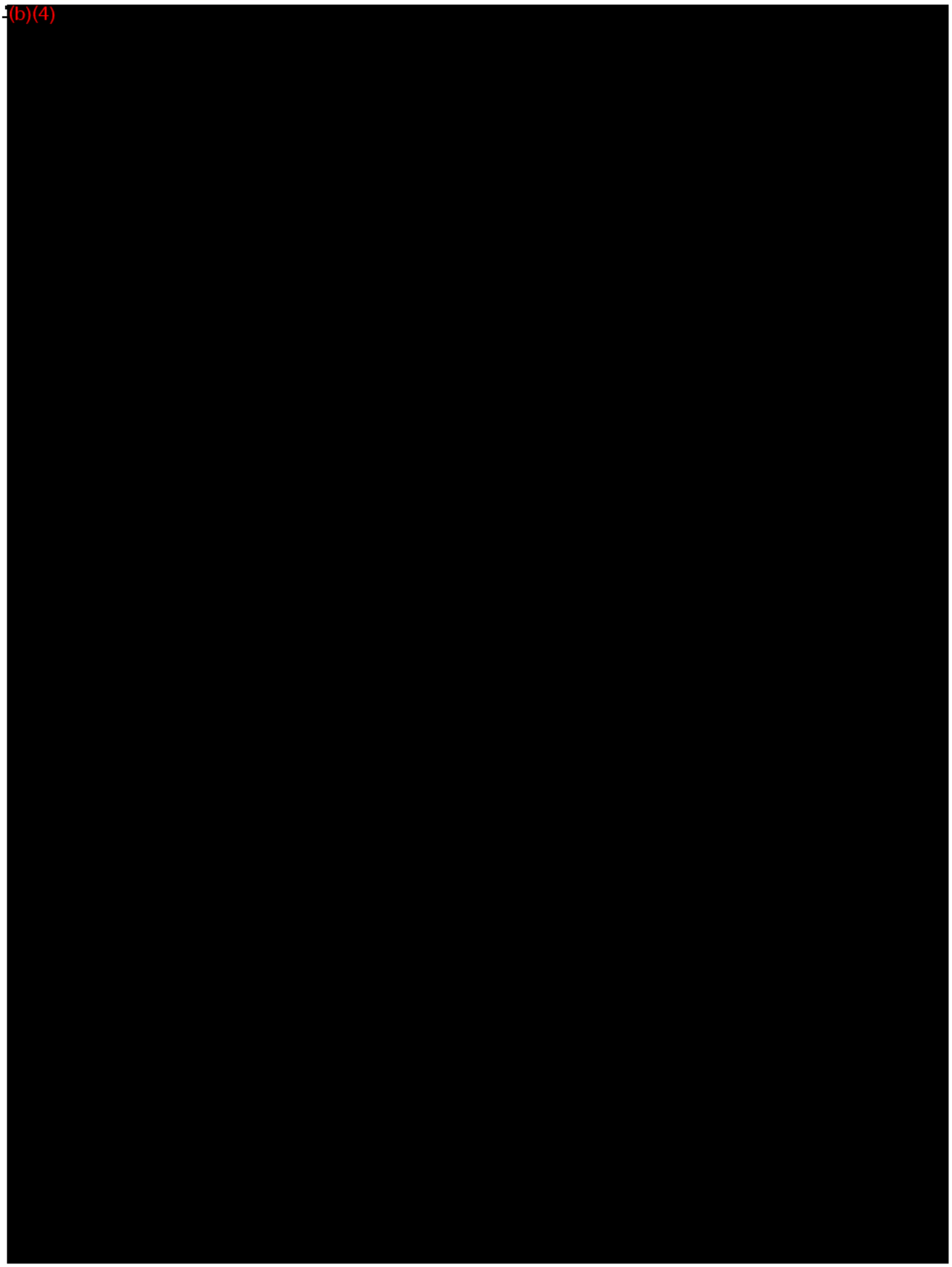

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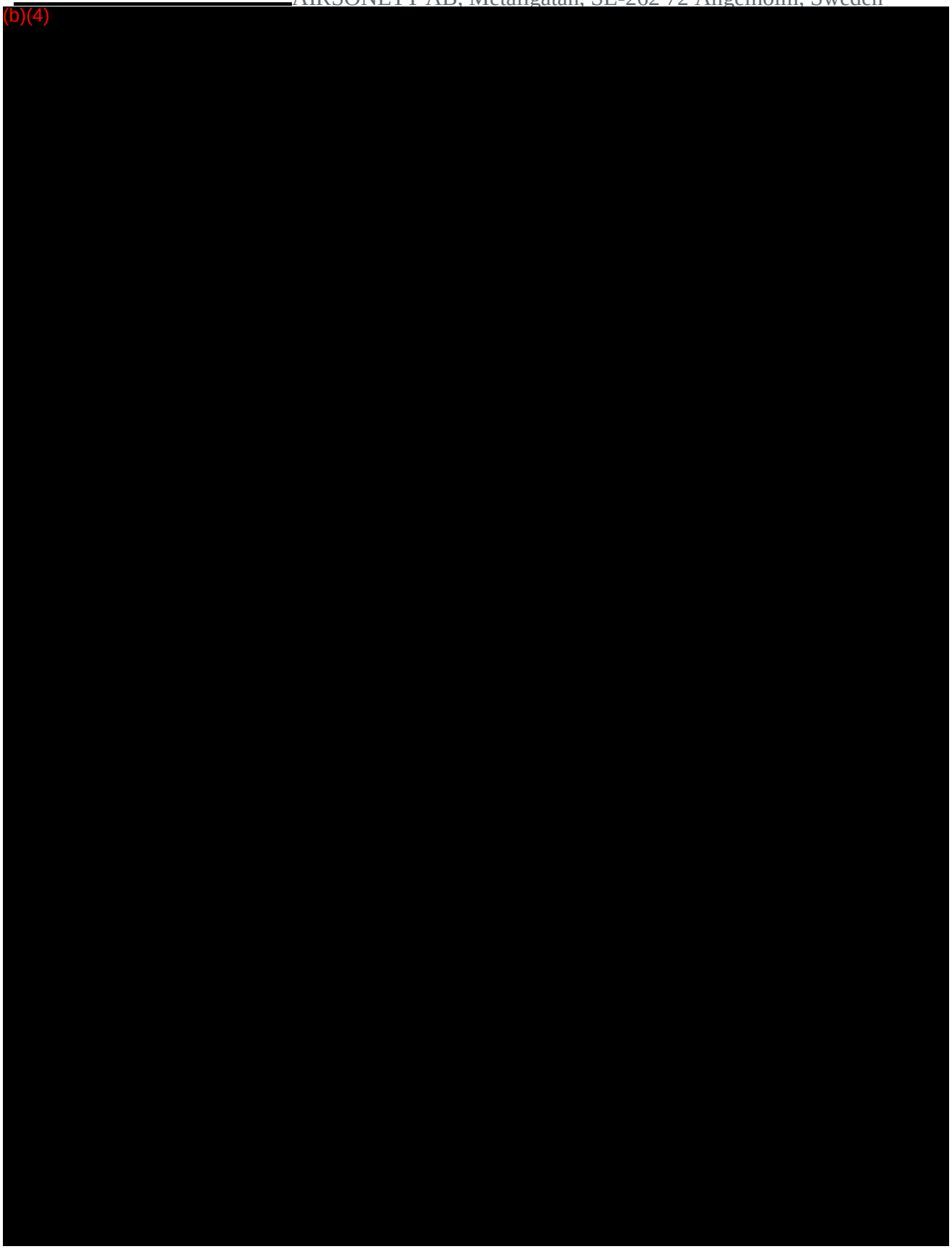

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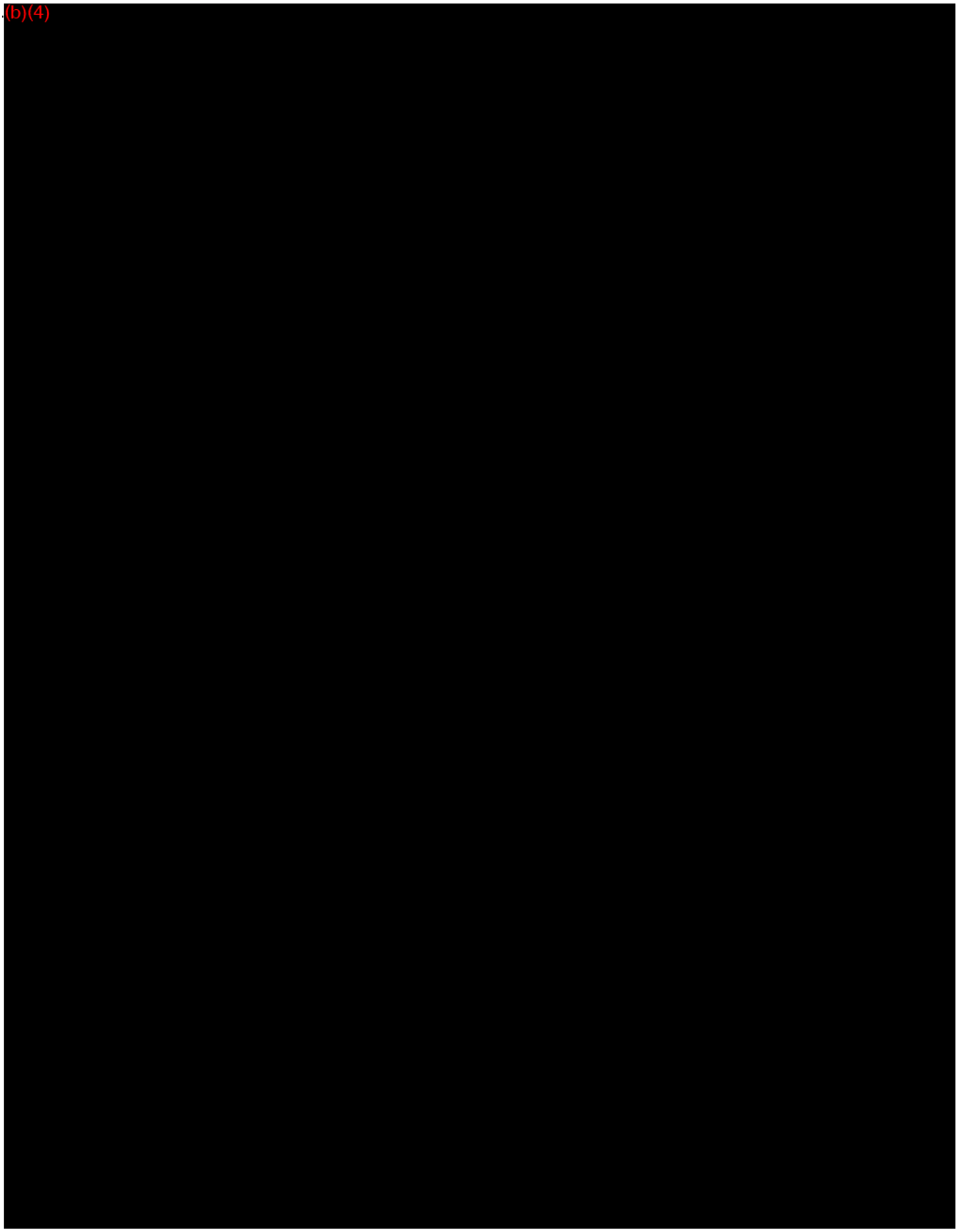

6. DESIGN VALIDATION

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7. DISCUSSION

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8. CONCLUSION

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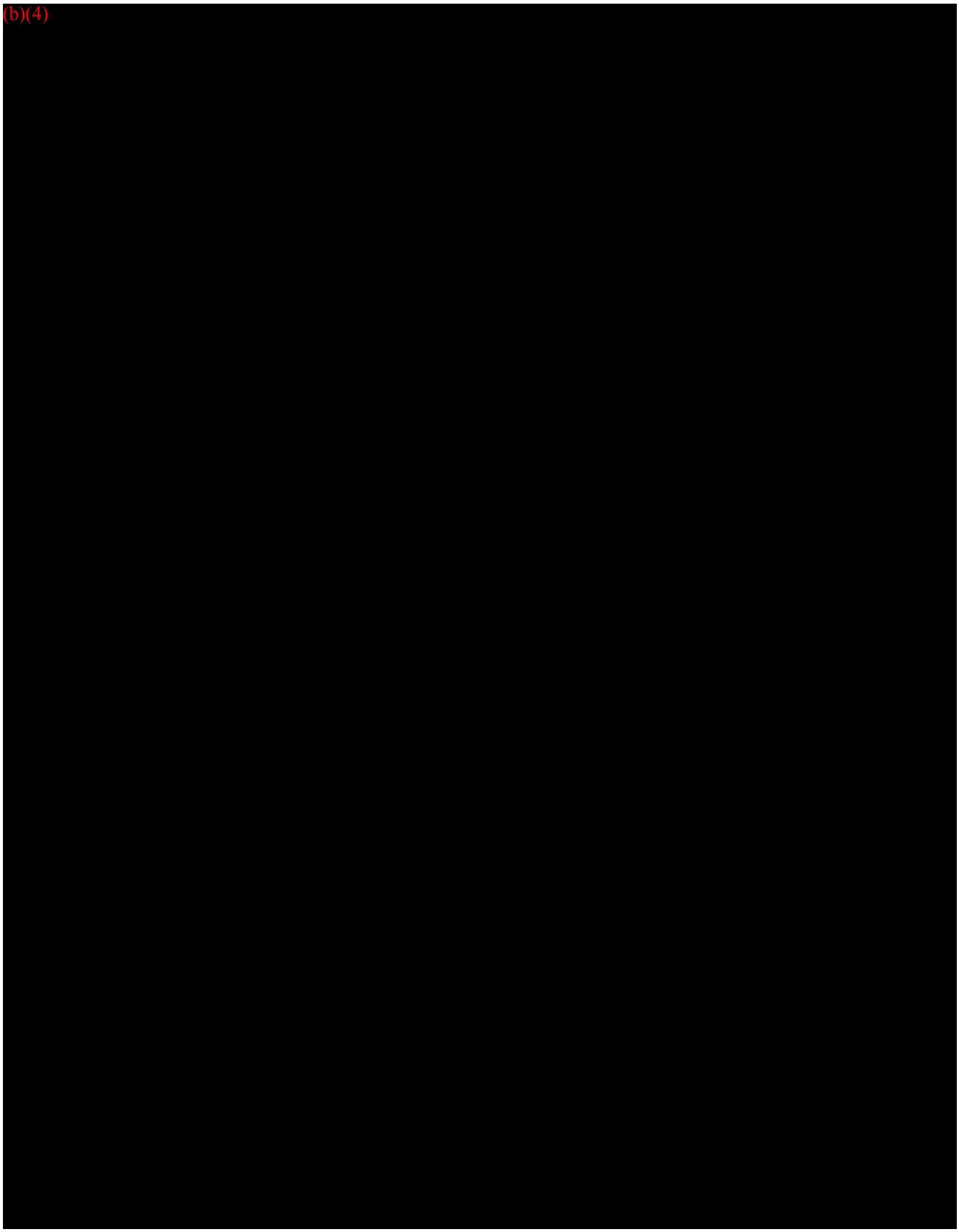

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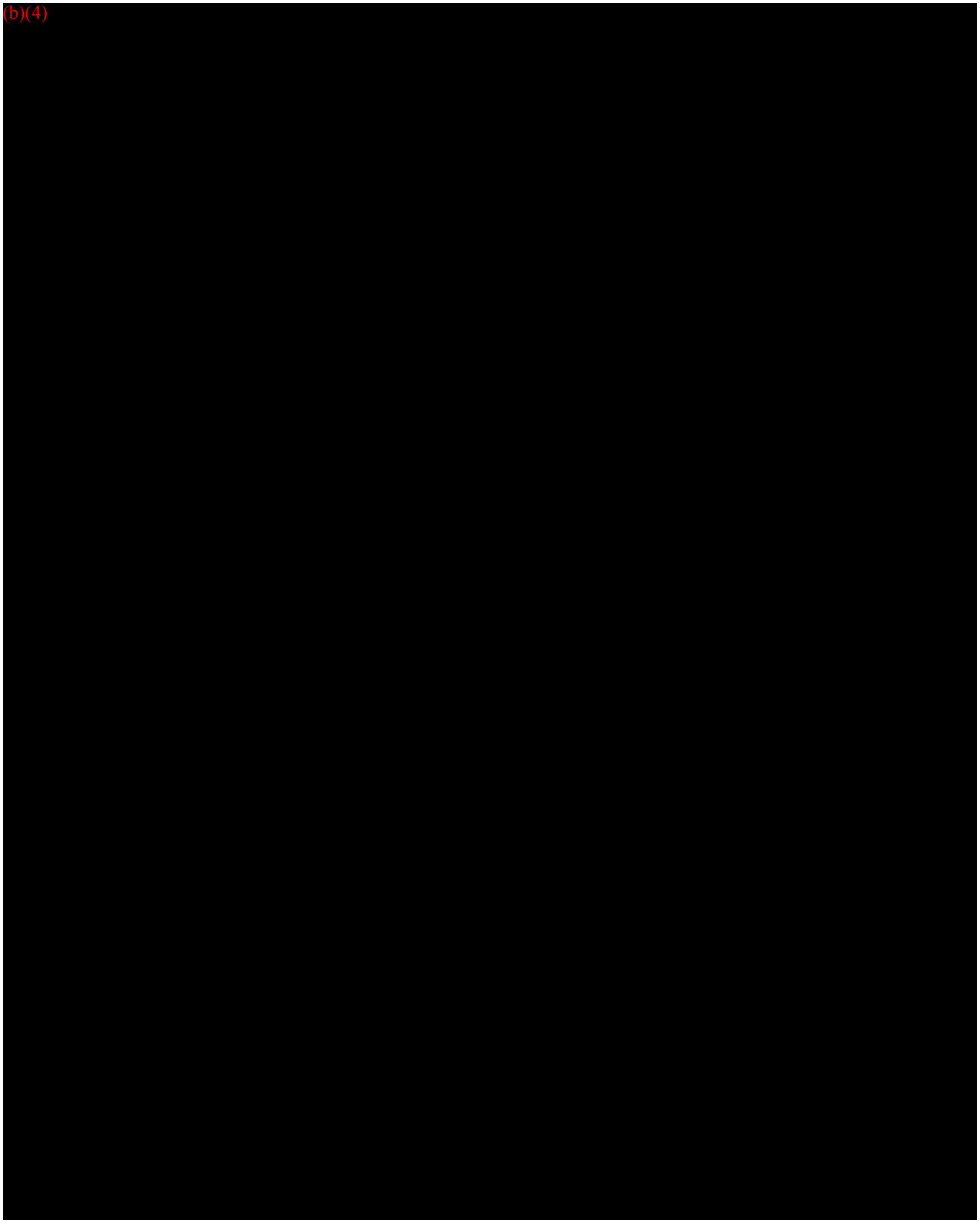

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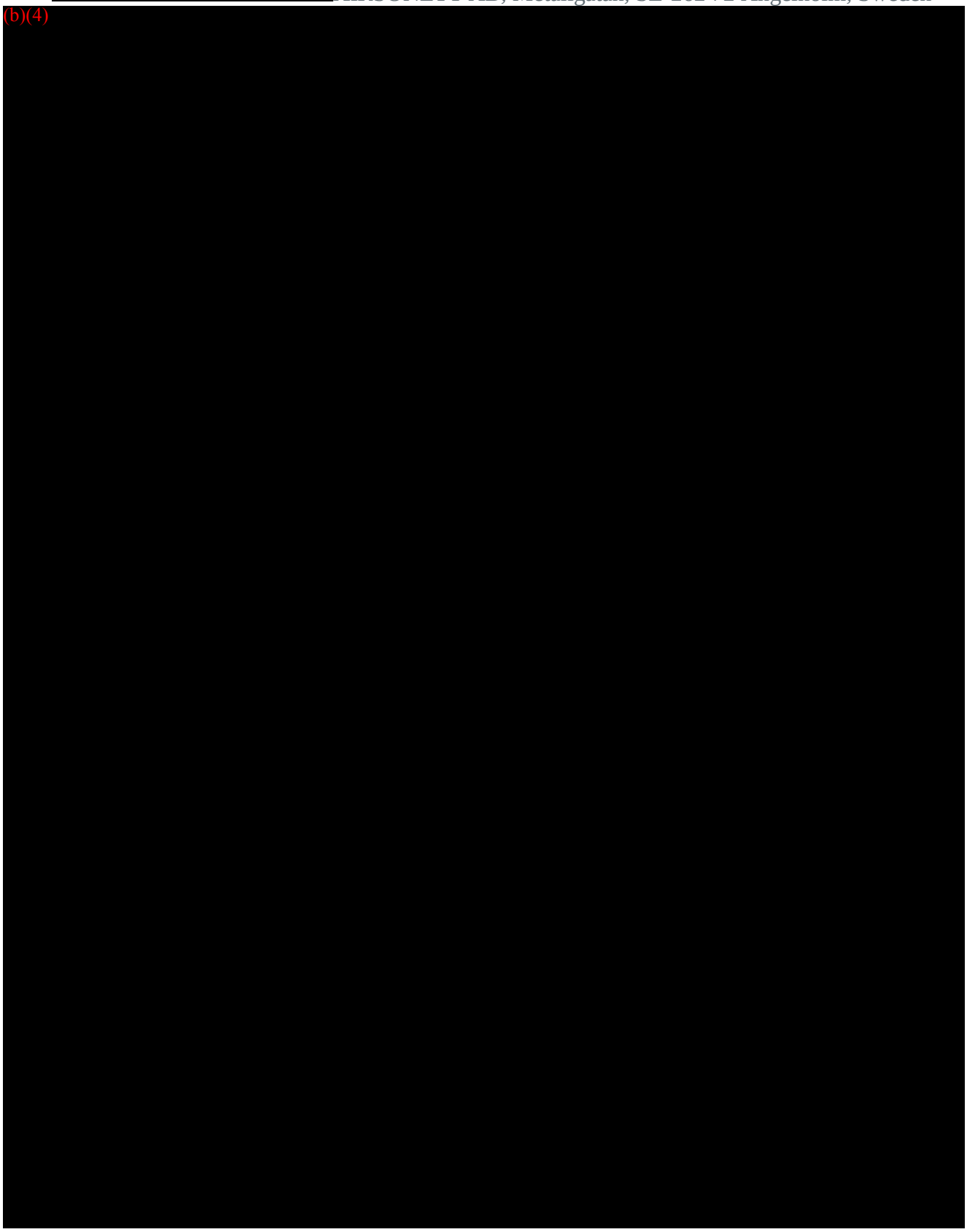

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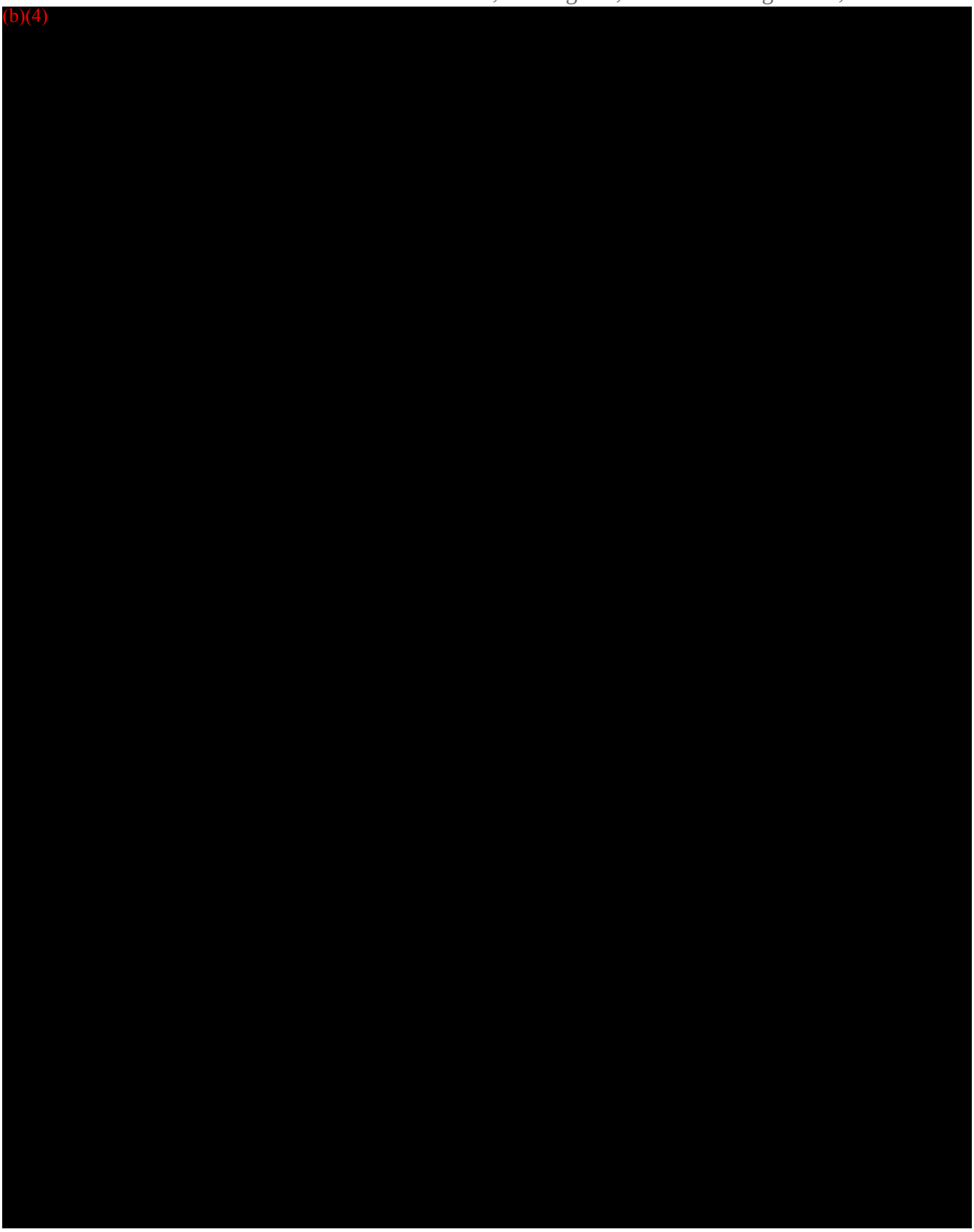

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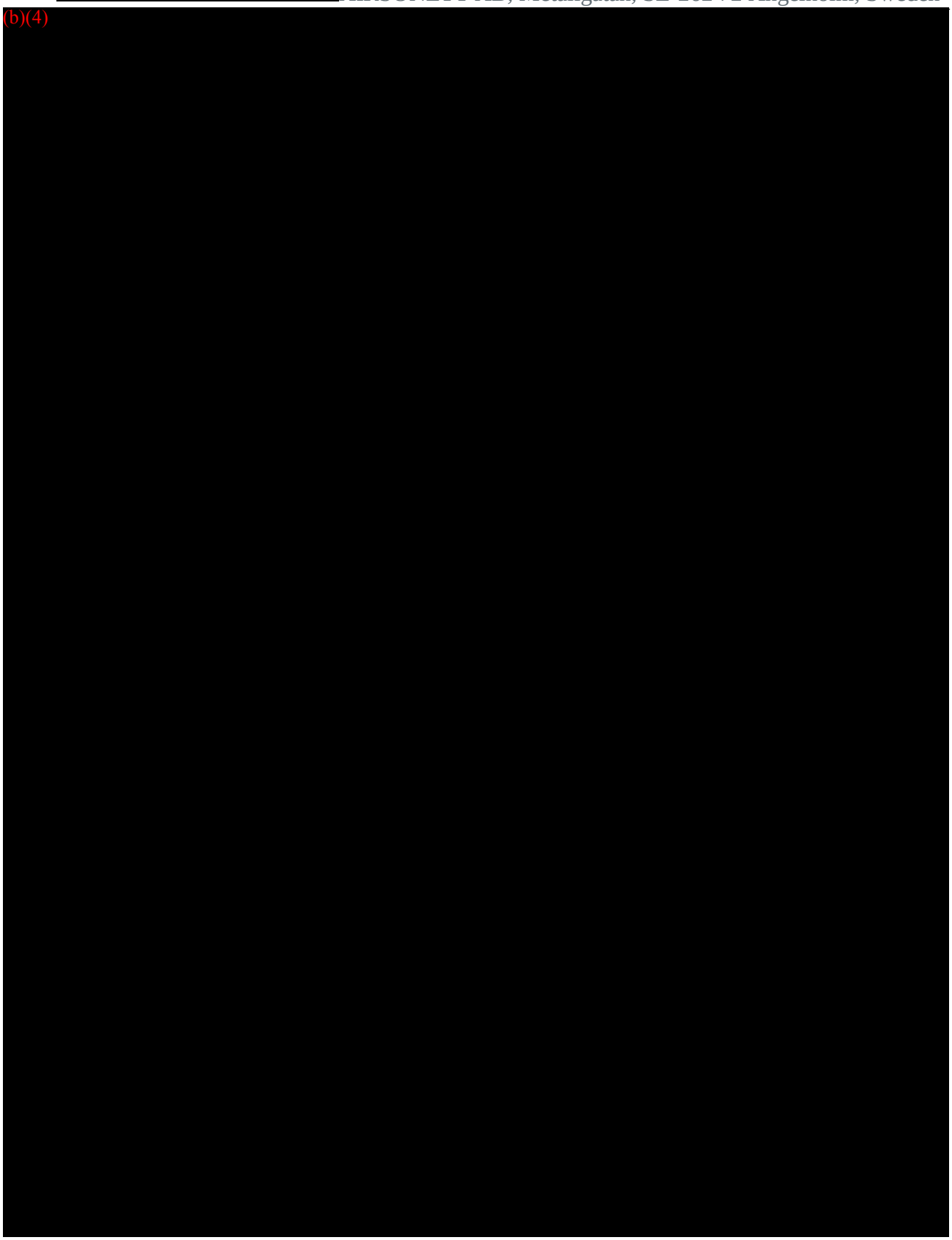

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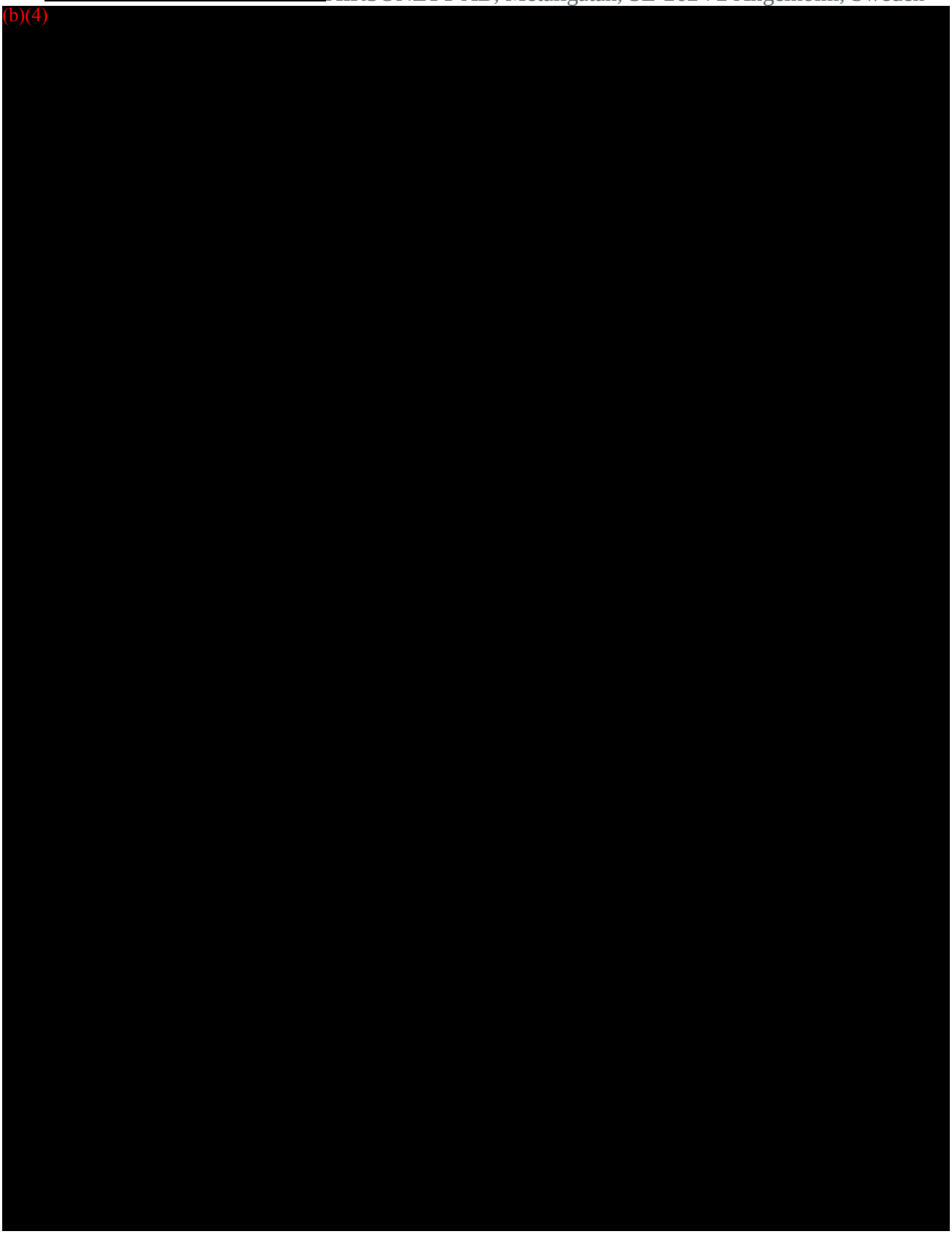

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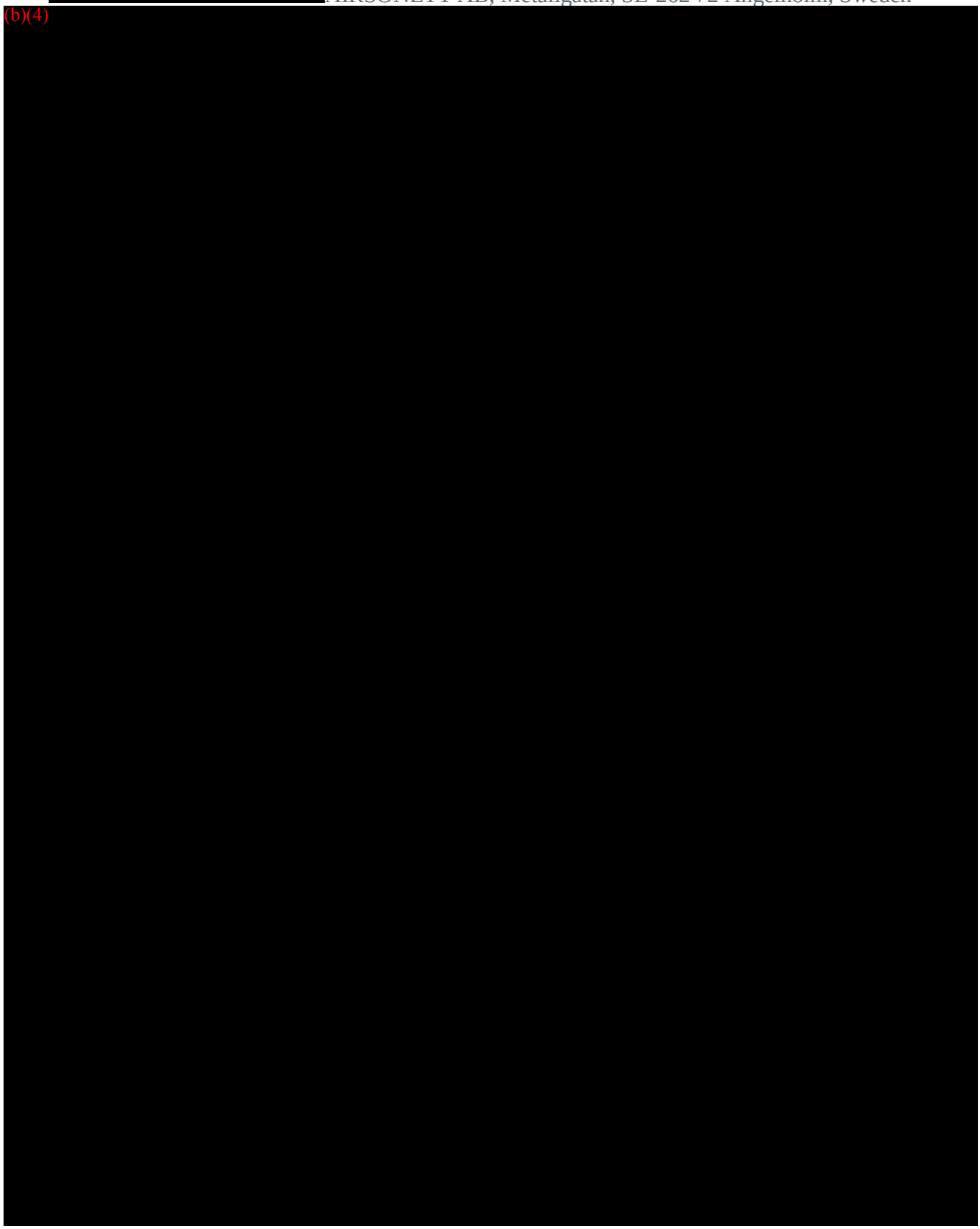

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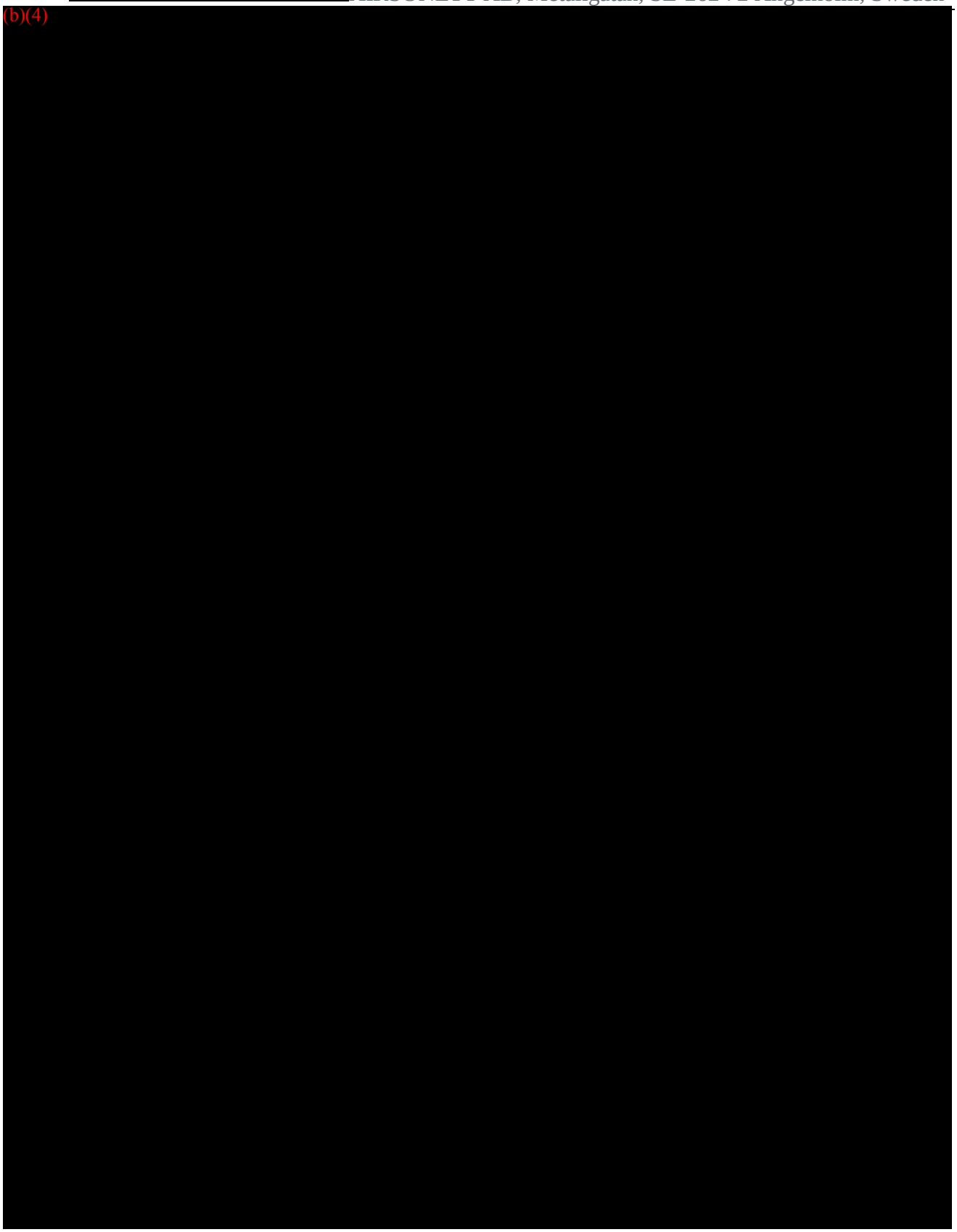

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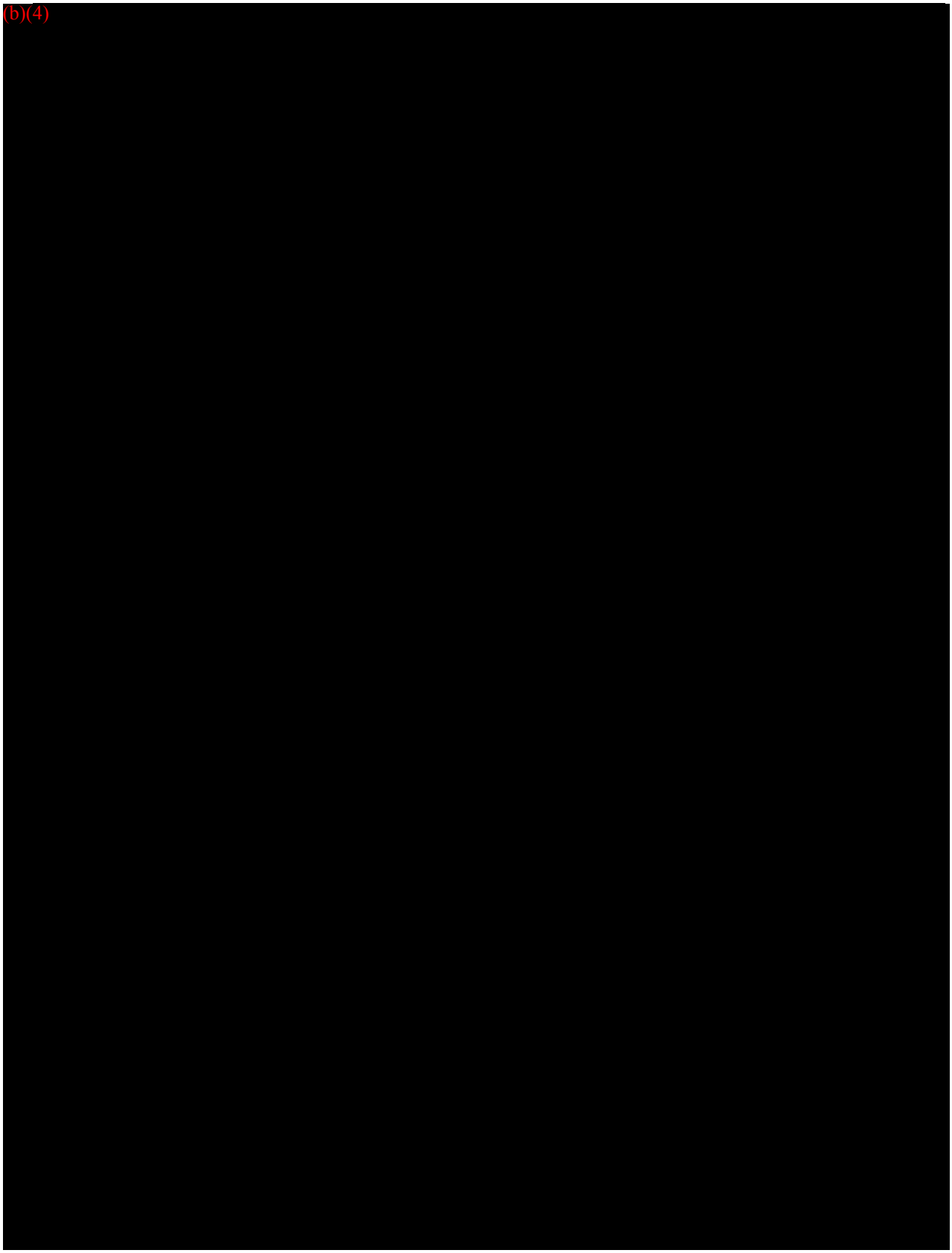

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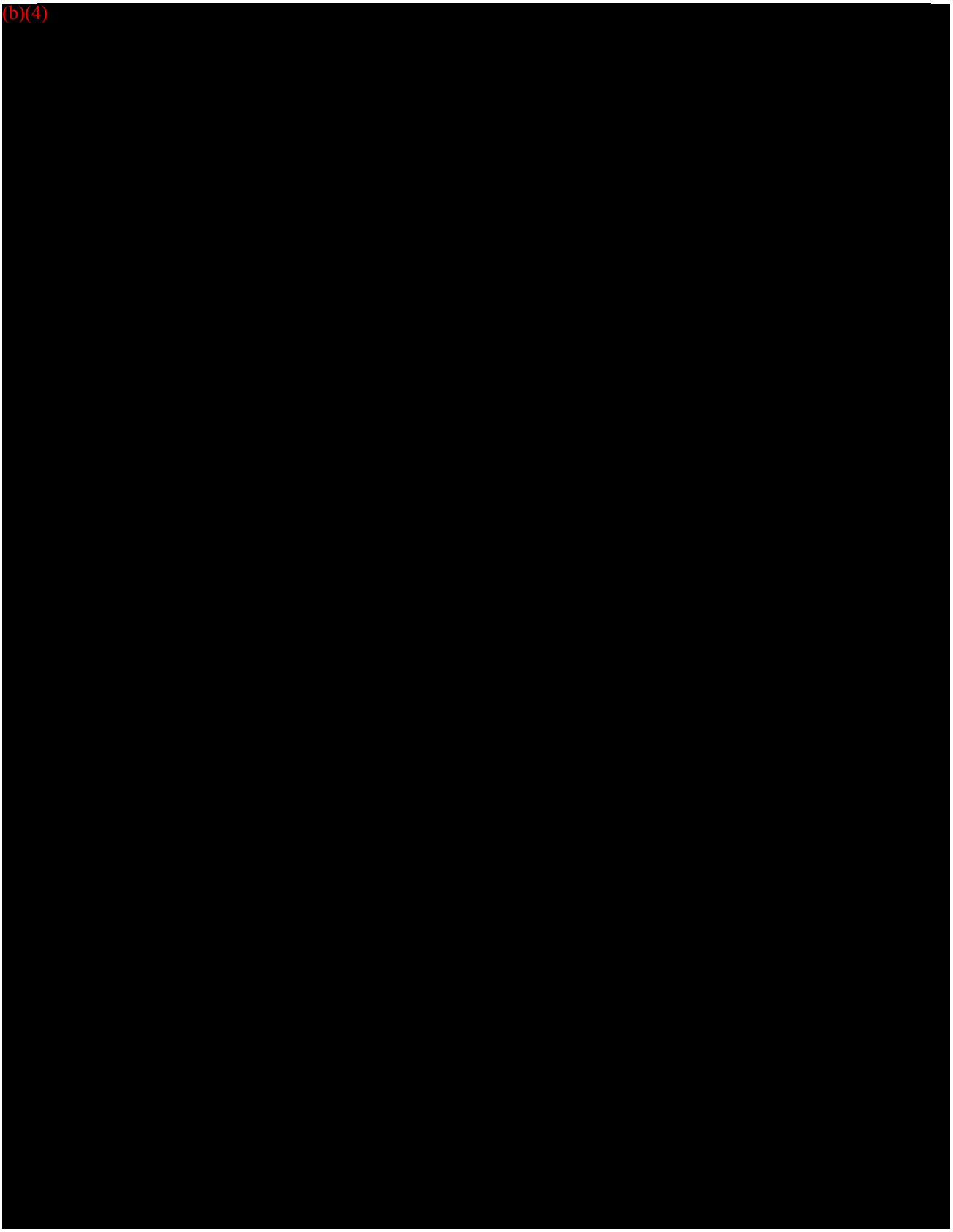

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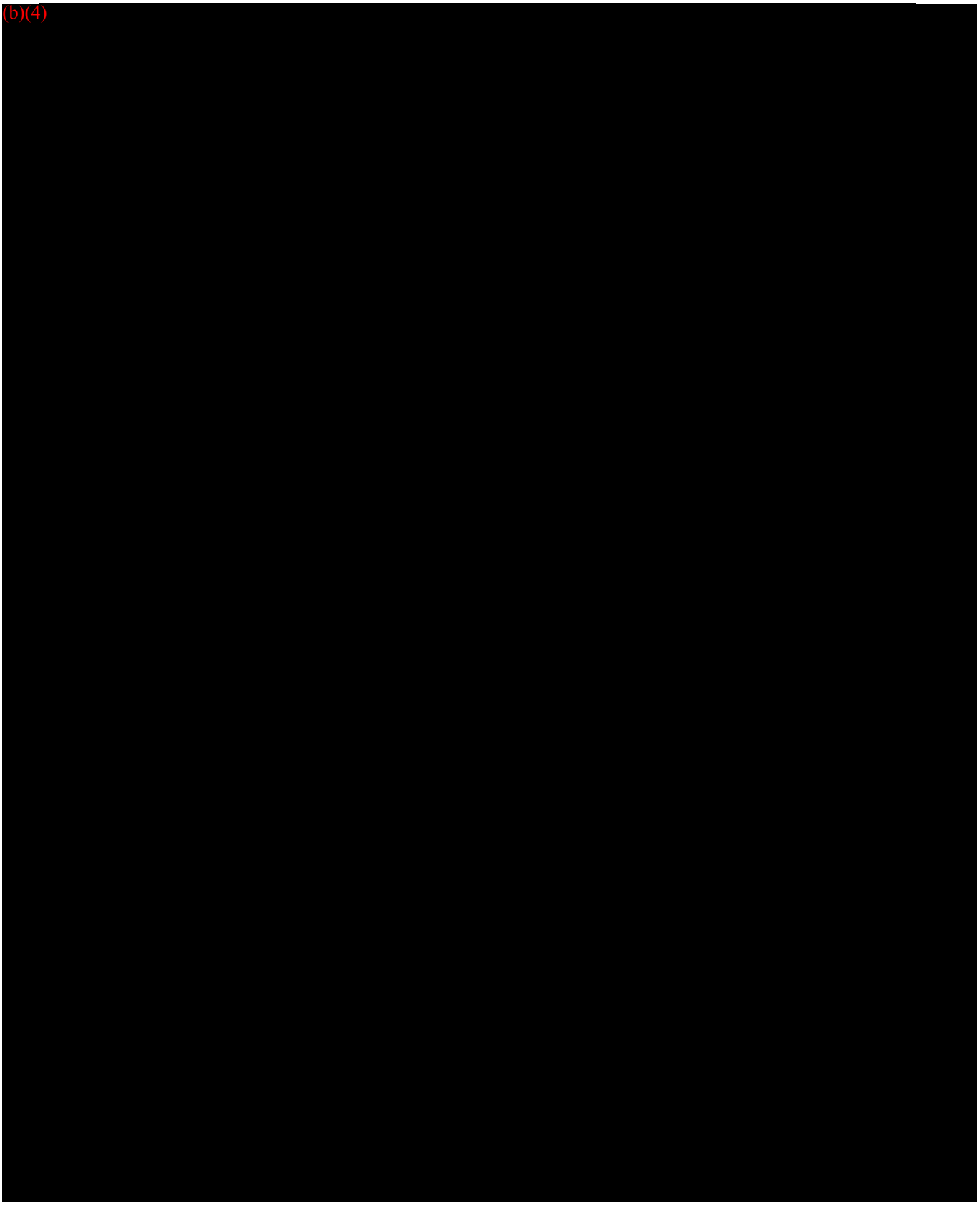

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APPENDIX 1.12

SOFTWARE TESTS PERFORMED ON THE FINAL FINISHED PRODUCTION READY DEVICE

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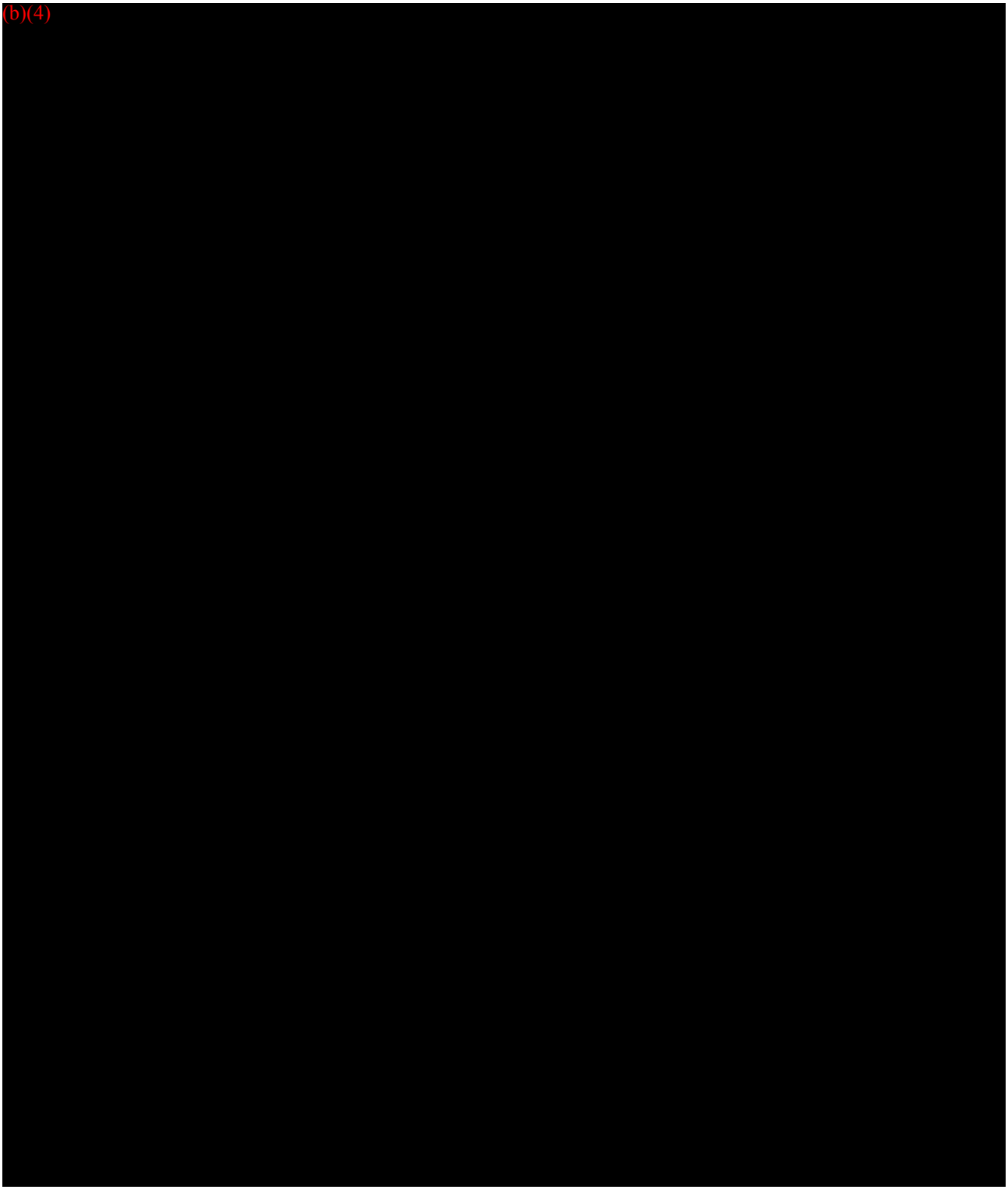

APPENDIX 1.13 ver 1.

DETERMINATION OF CLEAN ZONE AND BREATHING ZONE AND DISCUSSION ON ROOMS OF VARYING DIMENSIONS AND AIR FLOWS

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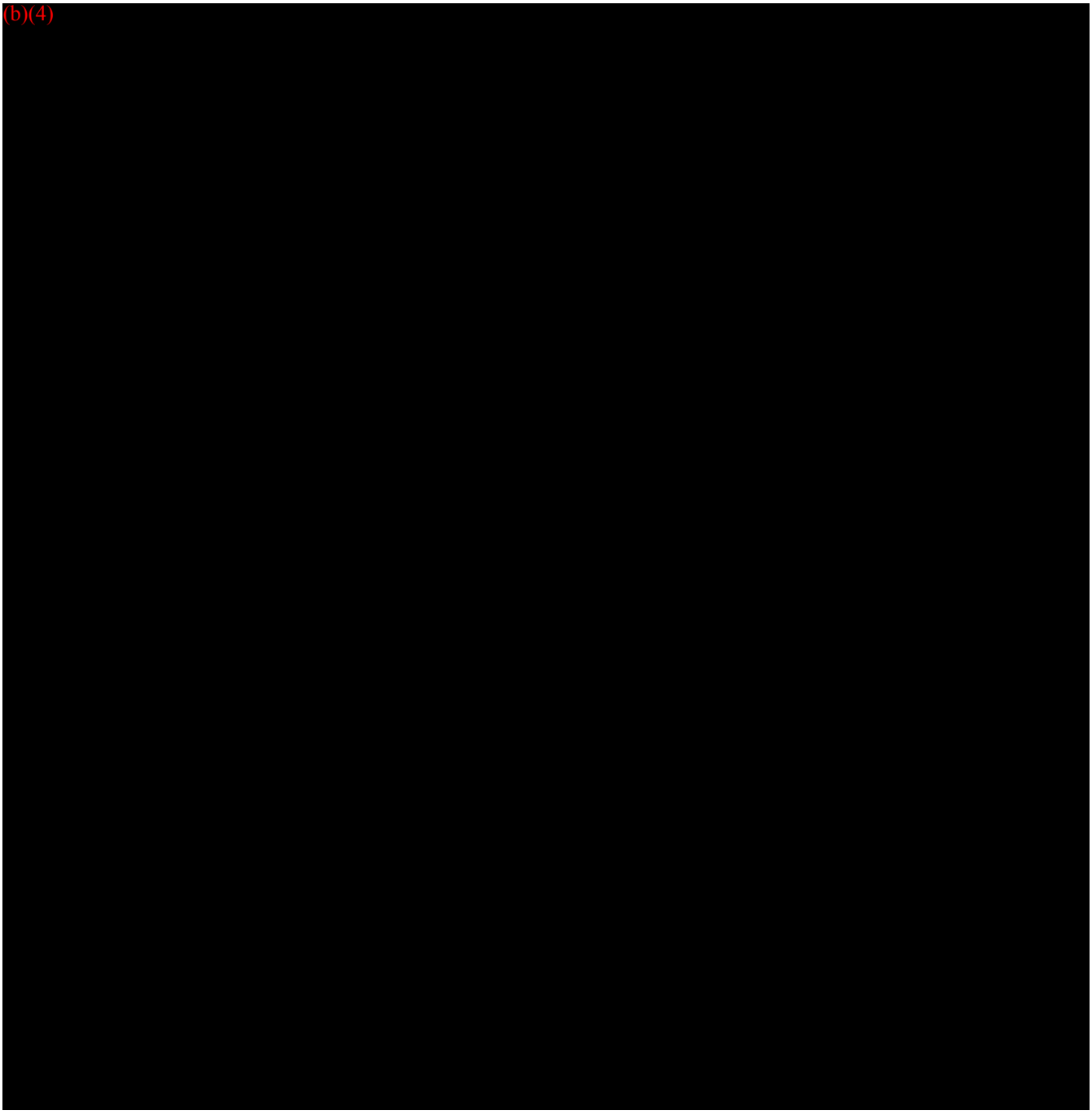

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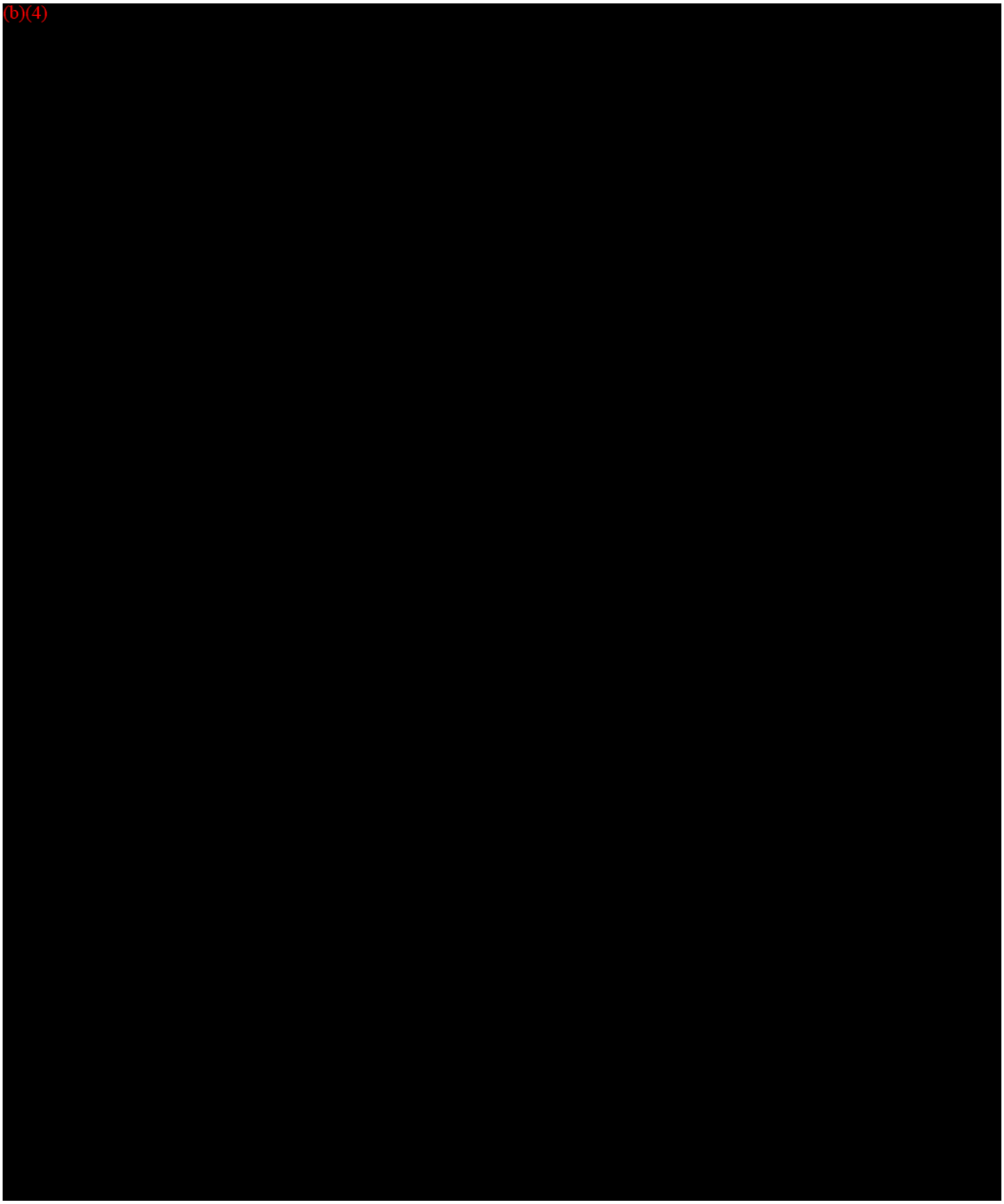

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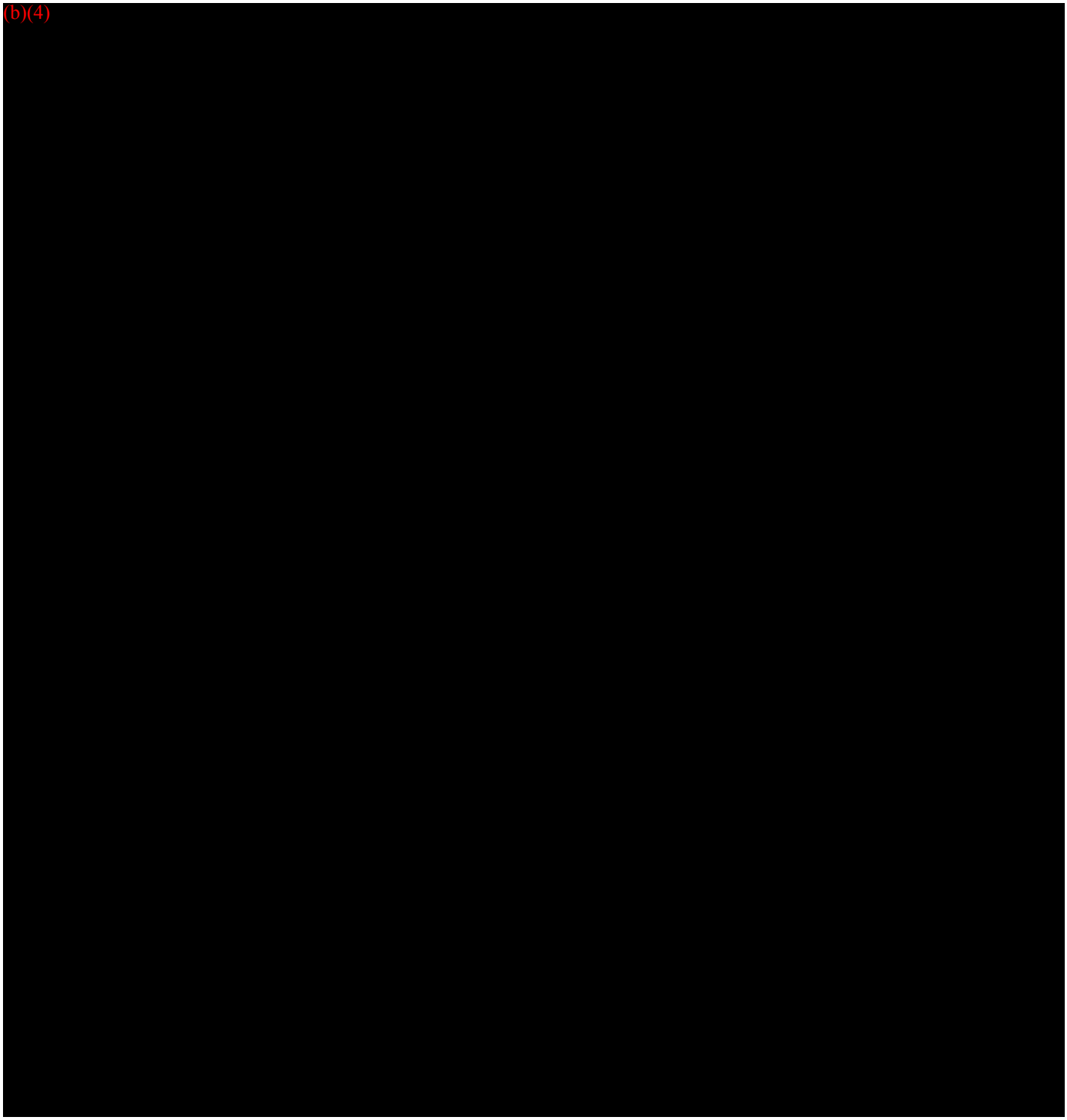

APPENDIX 1.14

FILTER – STABILITY OVER A NORMAL WORKING LIFE

1. BACKGROUND

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[redacted]

2. METHOD

(b)(4)

[redacted]

3. ACCEPTANCE CRITERIA

(b)(4)

[redacted]

4. RESULTS

(b)(4)

[redacted]

5. CONCLUSION

(b)(4)

[redacted]

APPENDIX 1.15 ver 2

PERFORMANCE TESTING SUPPORTING CLAIMS OF REDUCTION OF ALLERGENS AND PARTICLES

1. PURPOSE

(b)(4) [redacted]

2. BACKGROUND

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3. METHODS

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4. RESULTS

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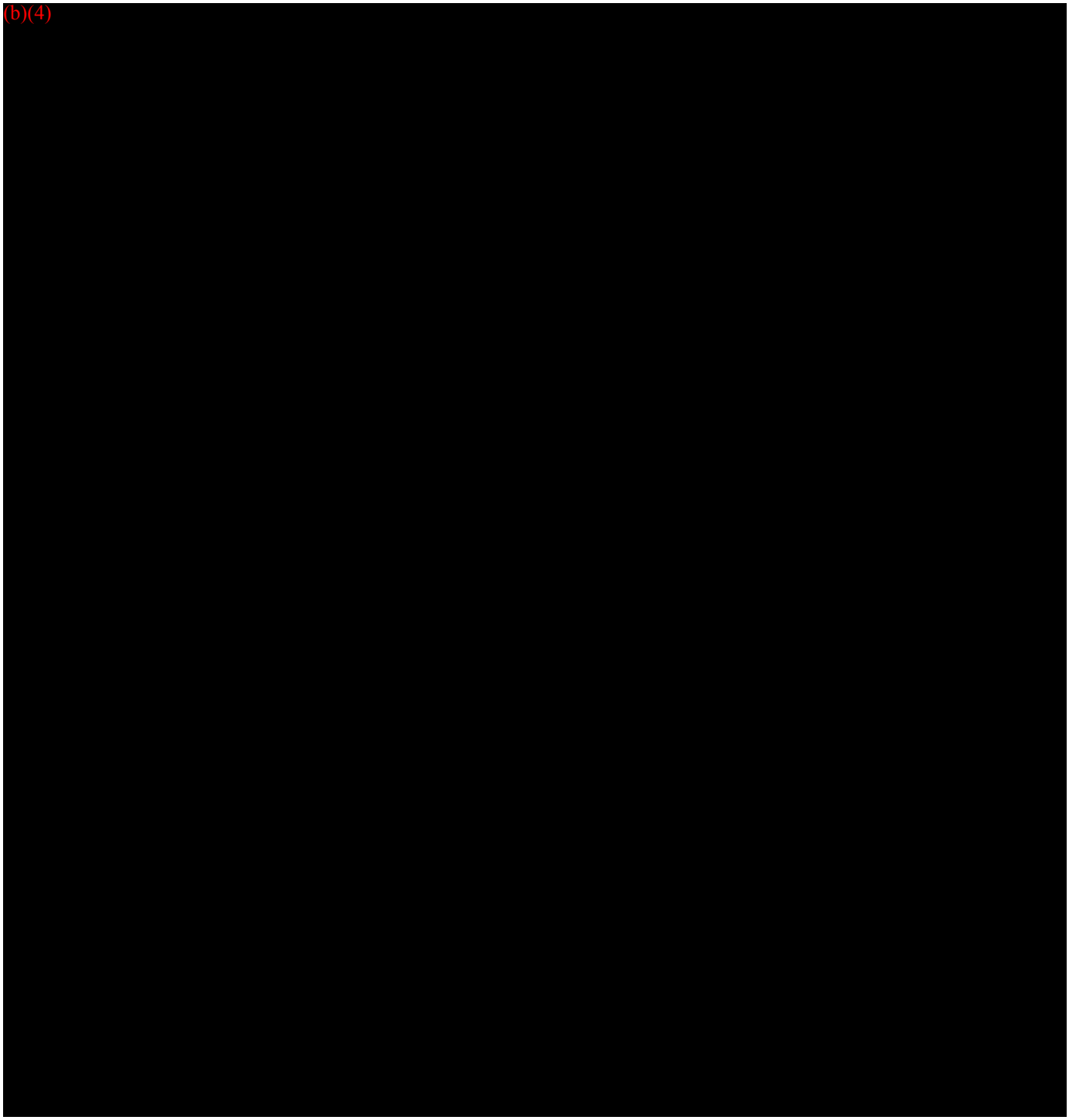

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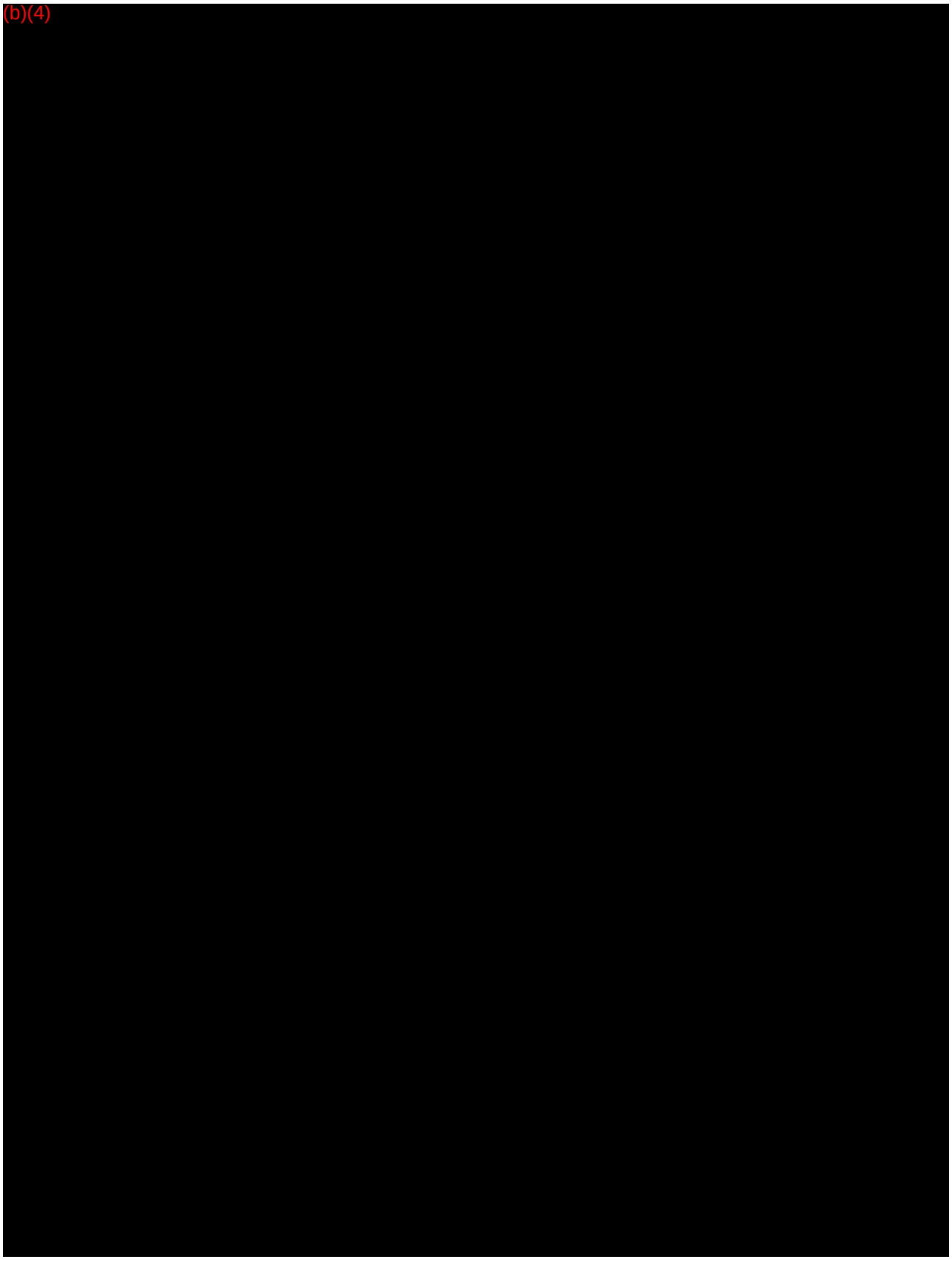

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5. CONCLUSION

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APPENDIX 1.16 ver 1

PERFORMANCE OF AIRSONETT AIR-4 – FILTRATION EFFICIENCY AT

a) OPTIONAL TEMPERATURE SETTINGS AND
b) ADJUSTMENT OF NECK OF THE DEVICE TO VARIOUS HEIGHTS

(b)(4)

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