



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO 66 - 0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K141921

July 5, 2014

FDA CDRH DMC

JUL 16 2014

Received

510(k) Submission

Trade Name: HIVOX Spopad EMS SP-910, SP-920, SP-620

Document Control Clerk:

This 510k submission for HIVOX Spopad EMS SP-910, SP-920, SP-620. We are so regret that the previous 510k submission, K131741, missed the response deadline as the following page. Thus, we have revised the relevant deficiencies and paid the 510k review fee for (b)(4) (b)(4) for new submission; and we provide a hard copy and an eCopy by CD format.

- eCopy Statement: the eCopy is an exact duplicate of the paper copy.

Sincerely Yours,

JEN, KE-MIN, official correspondent

S



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“ eCopy Statement ”

- eCopy Statement: The eCopy is an exact duplicate of the paper copy.

FDA/CDRH/DCC

JUL 15 2014

RECEIVED

Sincerely Yours,

Jen, Ke-M n,
510K correspondent person



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Premarket Notification [510(K)] Submission

July 5, 2014

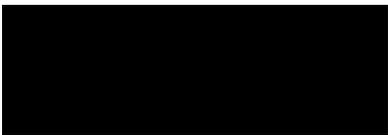
for

Spopad Electrical Muscle Stimulator

SP-620, SP-910, SP-920

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1. MDUFMA COVER SHEET

We place the FDA Form 3601 and the receipt from Bank for payment. Please refer to the following pages.

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: FDA User Fees

Pay.gov Tracking I (b)(4)

Agency Tracking I

Transaction Date and Time: 06/25/2014 06:29 EDT

Payment Summary

Address Information

Account Holder Name: HIVOX BIOTEK, INC.

5F., No.123, Shingde

Billing Address: Road, San-Chong District

Billing Address 2:

City: New Taipei City

State / Province:

Zip / Postal Code: 24158

Country: CHN

Account Information

Card Type: (b)(4)

Card Number: (b)(4)

Payment Information

Payment Amount: (b)(4)

Transaction Date and Time: 06/25/2014 06:29 EDT

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) HIVOX BIOTEK, INC. 5F.,No. 123, Shinde Rd., Sanhong Dist. New Taipei City 24158 TW 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME David Tuan 2.1 E-MAIL ADDRESS ceirs.jen@msa.hinet.net 2.2 TELEPHONE NUMBER (include Area code) 886-2-8511-2668 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 886-2-8511-2669		
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) Select an application type: <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice </td> <td style="width: 50%; vertical-align: top;"> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>		<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER <u>3.2 Select one of the types below</u> <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD145343			
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? <input checked="" type="checkbox"/> 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.) <input type="checkbox"/> 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. <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>		<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
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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 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, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [Redacted]

25-Jun-2014

Form FDA 3601 (01/2007)

["Close Window"](#) [Print Cover sheet](#)

2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

- This is a 5-page FDA Form 3514 of 510k review submission cover sheet.
- We also provide the FDA registration and the previous 510k records.
- We place the certifications of ISO 13485 and CE marketing for the subject devices.

Please refer to the following inlet pages.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 07/05/2014	User Fee Payment ID Number [REDACTED]	FDA Submission Document Number (if known)
----------------------------------	--	---

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name HIVOX	Establishment Registration Number (if known) 9611558		
Division Name (if applicable) N/A	Phone Number (including area code) +886-2-85112668		
Street Address 5F., No.123, Shinde Road, Sanchong Dist.	FAX Number (including area code) +886-2-85112669		
City New Taipei City,	State / Province	ZIP/Postal Code 24158	Country Taiwan, R.O.C.
Contact Name Dr. Jen, Ke-Min			
Contact Title official correspondent		Contact E-mail Address ceirs.jen@msa.hinet.net	

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

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

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

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		

Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
--	---	---

Other Reason (specify):

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	NGX	2		
3		4		
5		6		
7		8		

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K092476	1 Body Control System, model 4M Sport-Elec	1 SPORT-ELEC S.A.
2		2	2
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
Powered Muscle Stimulator

	Trade or Proprietary or Model Name for This Device	Model Number
1	HIVOX Spopad EMS	1 SP-910, SP-920, SP-620
2		2
3		3
4		4
5		5

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

1	K131741	2	K112392	3	K092448	4	K021952	5	K020471	6	
7		8		9		10		11		12	

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code NGX	C.F.R. Section (if applicable) 890.5850	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Physical Medicine		

Indications (from labeling)
 These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 9611558	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name HIVOX BIOTEK INC.		Establishment Registration Number 9611558		
Division Name (if applicable)		Phone Number (including area code) +886-2-85112668		
Street Address 5F, No.123, Shinde Road, Sanchong Dist.		FAX Number (including area code) +886-2-85112669		
City New Taipei City		State / Province	ZIP Code 24158	Country Taiwan, R.O.C.
Contact Name Dr. Jen, Ke-Min		Contact Title official correspondent		Contact E-mail Address ceirs.jen@msa.hinet.net

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

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

SECTION I

UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC/EN 60601-1	IEC / CEN	Medical electrical equipment Part 1. General requirements for safety	1990+A1:1993 +A2:1995	02/04/2013
2	IEC/EN 60601-1-2	IEC / CEN	Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests	2007+A1:2010	02/04/2013
3	IEC/EN 60601-2-10	IEC / CEN	Medical electrical equipment, Particular requirements for safety of nerve and muscle stimulators	1987+A1:2001	02/04/2013
4					
5					
6					
7					

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

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

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

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Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:

HIVOX BIOTEK, INC.
5 F., No. 123, Shingde Road
San-Chong District
New Taipei City, TAIWAN (CHINA) 24158
Registration Number: 9611558
Status: Active
Date Of Registration Status: 2013

Owner/Operator:

HIVOX BIOTEK, INC.
5 F., No. 123, Shingde Road
San-Chong District
New Taipei City, TW-TPQ TAIWAN (CHINA) 24158
Owner/Operator Number: 9044329

Official Correspondent:

Jen Ke-Min
ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY
No. 58, Fu Chiun St.
Hsin Chu City, TW-HSQ TAIWAN (CHINA) 30067
Phone: 886-3-5208829

US Agent:

SHU-CHEN CHENG
ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY
2064 Tamarin Dr
Columbus, OH 43235
Phone: 614 4511918 Ext
Email: TILYSC@HOTMAIL.COM

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3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>

Page Last Updated: 05/03/2013

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Silver Spring, MD 20993
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1 to 4 of 4 Results
Applicant: *HIVOX*

Results per Page: 10

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Device Name	Applicant	510(k) Number	Decision Date
Hivox Biotech Inc.	Hivox Biotech, Inc.	K112392	03/19/2012
Hivox Electric Stimulator Tens & Ems, Hd	Hivox Biotech, Inc.	K092448	03/30/2010
Hivox Dreamate Dm-800	Hivox Biotech, Inc.	K021952	05/02/2003
Hivox Ear Thermometer, Ts Series	Hivox Biotech, Inc.	K020471	05/02/2002

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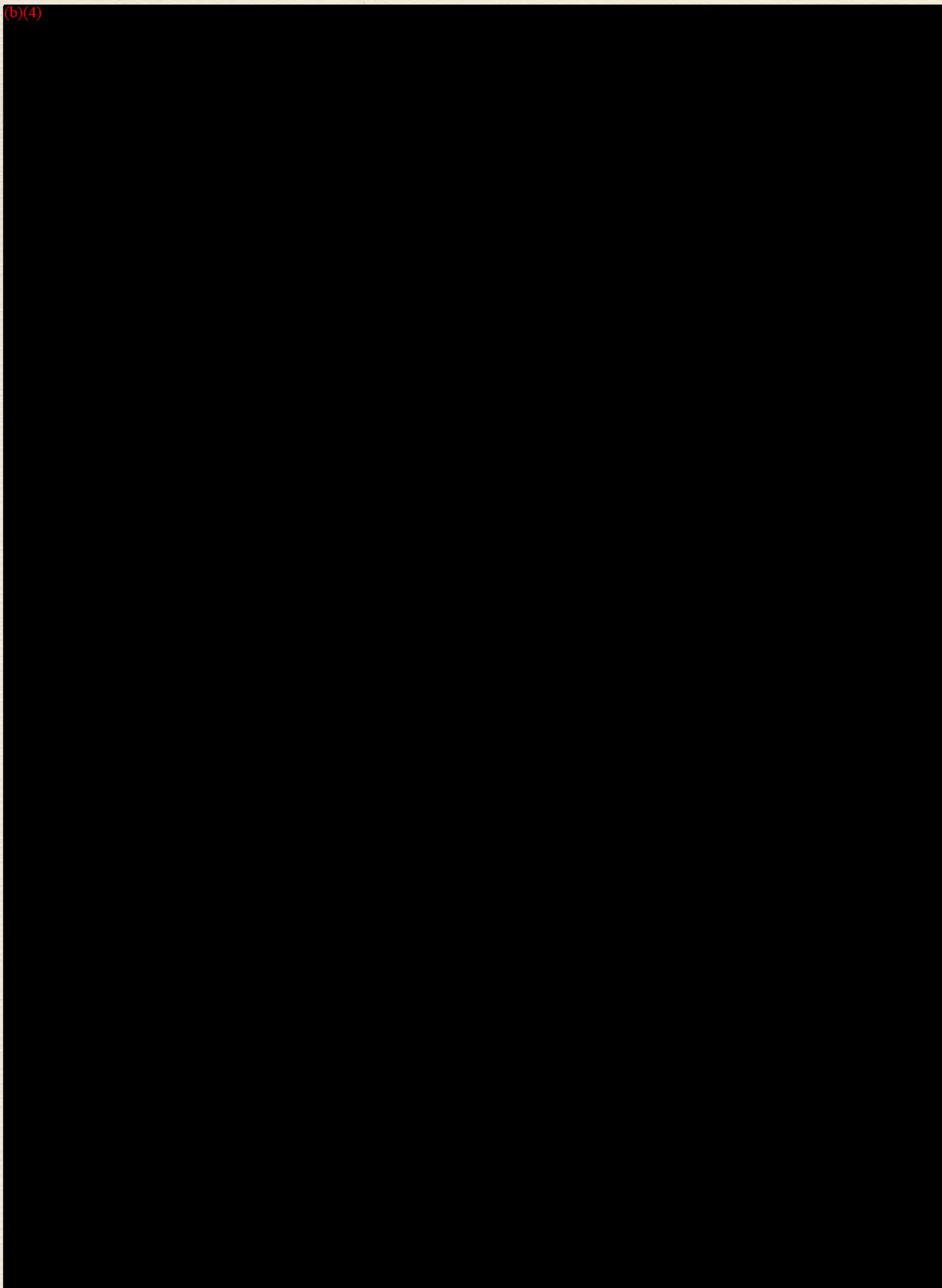
For Government | For Press

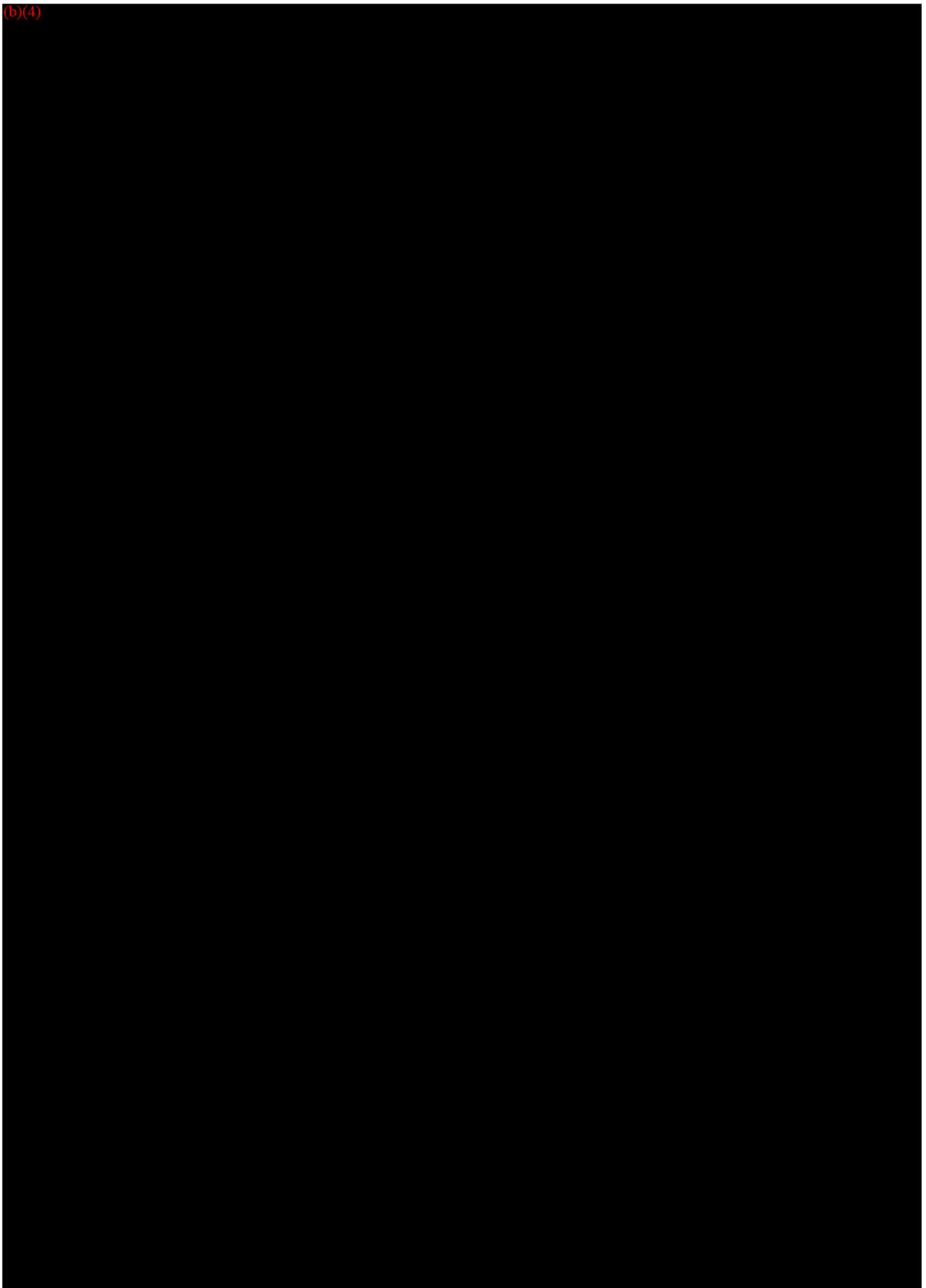
Combination Products
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Training and Continuing Education
Inspections/Compliance

U.S. Department of Health & Human Services

105%

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3. 510(K) COVER LETTER

Type Of 510(K) Submission	Traditional
Basis for the submission	A New Device
Common Name Of The Proposed Device	Powered muscle stimulator
510(K) Submitter	HIVOX BIOTEK INC. 5F, No.123, Shinde Road, Sanchong Dist., New Taipei City, 24158, TAIWAN, R.O.C. TEL: +886-2-85112668 FAX: +886-2-85112669 Contact Person Dr. JEN, KE-MIN TEL: 886-2-85112668 FAX:886-3-5209783 Email: ceirs.jen@msa.hinet.net
Preference For Continued Confidentiality (21 CFR 807.95)	510(k) Summary
Classification Regulation	Powered muscle stimulator for muscle conditioning (21 CFR 890.5850)
Class	II
Panel	Physical Medicine
Product Code	NGX

Design and Use of the Device

Is the device intended for prescription use (21 CFR 801 Subpart D)?	NO
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	YES
Does the device contain components derived from a tissue or other biologic source?	NO
Is the device provided sterile?	NO
Is the device intended for single use?	NO
Is the device a reprocessed single use device?	NO
If yes, does this device type require reprocessed validation data?	N/A
Does the device contain a drug?	NO
Does the device contain a biologic?	NO

Does the device use software?	YES
Does the submission include clinical information?	NO
Is the device implanted?	NO

eCOPY STATEMENT: The eCopy is an exact duplicate of the paper copy.



Dr. Jen, Ke-Min
Official Correspondent



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

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4. INDICATIONS FOR USE STATEMENT

See the next page.

Indications for Use

510(k) Number (if known)

Device Name

HIVOX Spopad EMS SP-910, SP-920, SP-620

Indications for Use (Describe)

These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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

FOR FDA USE ONLY

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

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

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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“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 number.”

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5. 510(k) SUMMARY (According to 21 CFR 807.92)

- 510(K) OWNER'S NAME
HIVOX BIOTEK INC.
5F, No.123, Shingde Road, Sanchong Dist.,
New Taipei City, 24158, TAIWAN, R.O.C.
TEL: +886-2-85112668 FAX:+886-2-85112669
- Name Of Contact Person
Dr. JEN, KE-MIN
TEL: 886-2-85112668 FAX:886-3-5209783
Email: ceirs.jen@msa.hinet.net
- Date Of Submission
July 5, 2014
- Trade Name
HIVOX Spopad EMS SP-910, SP-920, SP-620
- Common Name
Powered Muscle Stimulator
- Classification Name
Powered Muscle Stimulator
(21 CFR 890.5850, Product Code NGX)
- Panel
Physical Medicine
- Intended Use
These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.
Not intended for use in any therapy or for the treatment of any medical conditions or diseases.
- Device Design
EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relaxes stiff muscle through the skin. It is recognized as a clinically proven, effective, non-medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training.

HIVOX Spopad EMS SP series, SP-910 / SP-920 / SP-620 are the proposed subject devices for this 510(k) submission.

These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

SP-910 / SP-920 / SP-620 are 1-channel battery-operated user-friendly muscle stimulation systems specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-910/620 comprises 2 electrodes, which connects the signals from the stimulator to the skin. SP-920 comprises 4 electrodes, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors.

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Compare to Legally Marketed Predicate Devices

Comparison items	Predicate device 1 (PD)	Subject device (1)	Subject device (2)	Subject device (3)
Manufacturer Submitter	SPORT-ELEC S.A.	HIVOX-BIOTEK		
Device name	Body Control System	Spopad EMS, SP series		
Model number	4M	SP-910	SP-920	SP-620
510(k) number	K092476	TBA	TBA	TBA
Product code	NGX	NGX		
Classification name	Powered Muscle Stimulator	Powered Muscle Stimulator		
Regulation number	21 CFR 890.5850	21 CFR 890.5850		
Indications for use	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas. Contraindicated use on injured or otherwise impaired muscles Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.		
Technology	Electrical Muscle Stimulation	Electrical Muscle Stimulation		
Power Source	1.5V battery *3	3V Battery *1		
- Method of Line Current Isolation	Battery supply	Battery Supply		
- Patient Leakage Current Normal Condition (μA)	< 3	2.0		
Single Fault Condition(μA)	< 4	2.1		
Method of channel isolation	Software	1 channel		

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Average DC current through electrodes when device is on but no pulses are being applied	0 μ A	0 μ A		
Number of output modes	1	1		
Regulated current or regulated voltage?	Voltage	Voltage		
Software /firmware / Microprocessor control?	Yes	Yes		
Automatic overload trip?	No	No		
Automatic no-load trip?	No	No		
Automatic shut-off?	Yes	Yes		
User overrides control?	Yes	Yes		
Indicator display - On/Off Status	Yes	No		
Indicator display – Low battery?	Yes	No		
Indicator display – Voltage /Current	No	No		
Timer Range (minutes)	N/A	20		
Compliance with voluntary standards?	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2 IEC 60601-1-4	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2		
Compliance with 21 CFR 898?	Yes	Yes		
Housing material and construction	ABS	Silicone		
Output waveform	Monophasic	Symmetrical biphasic		
Shape	Rectangular	Rectangular		
Duration of primary (depolarizing) phase	0	0		
Pulse duration (μ Sec)	N/A	400		
Maximum output voltage (Voltage, +/-10%) at 500 ohms	N/A	52	58.4	60
Maximum output voltage (Voltage, +/-10%) at 2k ohms	N/A	98	106	109
Maximum output voltage (Voltage, +/-10%) at 10k ohms	N/A	150	146	140

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Maximum output current (mA +/-10%) at 500 ohms	N/A	104	117	120	
Maximum output current (mA +/-10%) at 2k ohms	N/A	49	53	54.5	
Maximum output current (mA +/-10%) at 10k ohms	N/A	15	14.6	14	
Frequency (Hz)	N/A	3/4/5	2/4/25	2/4/25	
Net charge per pulse at 500 ohms (μC)	N/A	0.416	0.468	0.960	
Maximum charge at 500 ohms (μC)	N/A	41.6	46.8	48	
Maximum current density at 500 ohms (mA/cm^2)	< 2	1.187	1.057	1.952	
Maximum average power density at 500 ohms (W/cm^2)	< 0.25	0.0617	0.0617	0.117	
Burst mode	A. Pulse per burst	N/A	N/A	25	25
	B. Burst per second	N/A	N/A	1	1
	C. Burst duration (sec)	N/A	N/A	20	20
	D. Duty cycle	N/A	N/A	20	20

Summary of comparison

Basically, the predicate device and Subject Devices are all Over-The-Counter muscle stimulators. Thus, the indications for use for the devices do not differ much.

PD and Subject Devices are all battery-powered, thus electric hazards or safety do not raise much concern, since maximum current / power densities for the devices are all less than 2 (mA/cm^2) / 0.25 (W/cm^2), which are the FDA recommended ratings. Since the electric output data for PD and Subject Devices only exist minor differences, the minor differences of the electric outputs do not raise any safety and effectiveness aspect. PD and Subject Devices all have the same safety and effectiveness, especially they all pass medical device electric safety standard, IEC 60601-1 and standard for Nerve and Muscle Stimulator, IEC 60601-2-10 and electromagnetic compatibility standard IEC 60601-1-2.



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We know that for effectiveness in achieving repeated muscle contractions, powered muscle stimulators typically are capable of stimulating muscle for at least one second per burst, and are capable of providing at least one second of muscle relaxation between successive pulse bursts. PD should meet these requirements. Subject Devices meet these requirements too. PD and Subject Devices are all validating-software processing, thus keeping regular processing parameters and safety functions normal. The Subject Devices have the same effectiveness as the predicate device.

In conclusion, the Subject Devices do not raise any new safety and effectiveness aspect with respect to the PD. Thus the Subject Devices are **substantially equivalent** to the predicate device.



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6. TRUTHFUL AND ACCURATE STATEMENTS

[As required by 21 CFR 807.87 (j)]

See the next page.



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TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87 (j)]

I certify that, in my capacity as official correspondent of HIVOX Biotek Inc., I believe to the best of my knowledge, that all data and information submitted in the Pre-market Notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Jen, Ke-Min

(Typed Name)

February 28, 2014

(Dated)

(Premarket Notification 510(k) Number)



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

7. CLASS III SUMMARY AND CERTIFICATION

N/A



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

8. FINANCIAL CERTIFICATION OF DISCLOSURE STATEMENT

N/A



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

9. DECLARATION OF CONFORMITY AND SUMMARY REPORTS

N/A

10. EXECUTIVE SUMMARY

- 510(K) OWNER'S NAME
HIVOX BIOTEK INC.
5F, No.123, Shingde Road, Sanchong Dist.,
New Taipei City, 24158, TAIWAN, R.O.C.
TEL: +886-2-85112668 FAX: +886-2-85112669
- Name Of Contact Person
Dr. JEN, KE-MIN
TEL: +886-2-85112668 FAX: +886-3-5209783
Email: ceirs.jen@msa.hinet.net
- Date Of Submission: May 28, 2013
- Trade Name - HIVOX Spopad EMS SP-910, SP-920, SP-620
- Common Name Powered muscle stimulator
- Classification Name Powered muscle stimulator
(21 CFR 890.5850, Product Code NGX)
- Panel Physical Medicine
- Intended Use
This Electrical Muscle Stimulation unit is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.
- Device Design
EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relaxes stiff muscle through the skin. It is recognized as a clinically proven, effective, non-medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training.
HIVOX Spopad EMS SP series, SP-910 / SP-920 / SP-620 are the proposed subject devices for this 510(k)

submission. These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

SP-910 / SP-920 / SP-620 are 1-channel battery-operated user-friendly muscle stimulation systems specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-910/620 comprises 2 electrodes, which connects the signals from the stimulator to the skin. SP-920 comprises 4 electrodes, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors.

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Compare to Legally Marketed Predicate Devices

Comparison items	Predicate device 1 (PD1)	Subject device (1)	Subject device (2)	Subject device (3)
Manufacturer Submitter	SPORT-ELEC S.A.	HIVOX-BIOTEK		
Device name	Body Control System	Spopad EMS, SP series		
Model number	4M	SP-910	SP-920	SP-620
510(k) number	K092476	TBA	TBA	TBA
Product code	NGX	NGX		
Classification name	Powered Muscle Stimulator	Powered Muscle Stimulator		
Regulation number	21 CFR 890.5850	21 CFR 890.5850		
Indications for use	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas. Contraindicated use on injured or otherwise impaired muscles Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.		
Technology	Electrical Muscle Stimulation	Electrical Muscle Stimulation		
Power Source	1.5V battery *3	3V Battery *1		
- Method of Line Current Isolation	Battery supply	Battery Supply		
- Patient Leakage Current Normal Condition (μ A)	< 3	2.0		
Single Fault Condition(μ A)	< 4	2.1		
Method of channel isolation	Software	1 channel		

HIVOX BIOTEK INC.

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Average DC current through electrodes when device is on but no pulses are being applied	0 μ A	0 μ A		
Number of output modes	1	1		
Regulated current or regulated voltage?	Voltage	Voltage		
Software /firmware / Microprocessor control?	Yes	Yes		
Automatic overload trip?	No	No		
Automatic no-load trip?	No	No		
Automatic shut-off?	Yes	Yes		
User overrides control?	Yes	Yes		
Indicator display - On/Off Status	Yes	No		
Indicator display – Low battery?	Yes	No		
Indicator display – Voltage /Current	No	No		
Timer Range (minutes)	N/A	20		
Compliance with voluntary standards?	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2 IEC 60601-1-4	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2		
Compliance with 21 CFR 898?	Yes	Yes		
Housing material and construction	ABS	Silicone		
Output waveform	Monophasic	Symmetrical biphasic		
Shape	Rectangular	Rectangular		
Duration of primary (depolarizing) phase	0	0		
Pulse duration (μ Sec)	N/A	400		
Maximum output voltage (Voltage, +/-10%) at 500 ohms	N/A	52	58.4	60
Maximum output voltage (Voltage, +/-10%) at 2k ohms	N/A	98	106	109
Maximum output voltage (Voltage, +/-10%) at 10k ohms	N/A	150	146	140

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Maximum output current (mA +/-10%) at 500 ohms	N/A	104	117	120	
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Maximum output current (mA +/-10%) at 10k ohms	N/A	15	14.6	14	
Frequency (Hz)	N/A	3/4/5	2/4/25	2/4/25	
Net charge per pulse at 500 ohms (μC)	N/A	0.416	0.468	0.960	
Maximum charge at 500 ohms (μC)	N/A	41.6	46.8	48	
Maximum current density at 500 ohms (mA/cm^2)	< 2	1.187	1.057	1.952	
Maximum average power density at 500 ohms (W/cm^2)	< 0.25	0.0617	0.0617	0.117	
Burst mode	A. Pulse per burst	N/A	N/A	25	25
	B. Burst per second	N/A	N/A	1	1
	C. Burst duration (sec)	N/A	N/A	20	20
	D. Duty cycle	N/A	N/A	20	20

Summary of comparison

Basically, the predicate device and Subject Devices are all Over-The-Counter muscle stimulators. Thus, the indications for use for the devices do not differ much. Basically the devices are to stimulate the muscle of the healthy body.

PD and Subject Devices are all battery-powered, thus electric hazards or safety do not raise much concern, since maximum current / power densities for three of the devices are all less than 2 (mA/cm^2) / 0.25 (W/cm^2), which are the FDA recommended ratings. Since the electric output data for PD and Subject Devices only exist minor differences, the minor differences of the electric outputs do not raise any safety or effectiveness aspect. PD and Subject Devices all have the same safety and effectiveness, especially they all pass medical device electric safety standard, IEC 60601-1 and standard for Nerve and Muscle Stimulator, IEC 60601-2-10 and electromagnetic compatibility standard IEC 60601-1-2.



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We know that for effectiveness in achieving repeated muscle contractions, powered muscle stimulators typically are capable of stimulating muscle for at least one second per burst, and are capable of providing at least one second of muscle relaxation between successive pulse bursts. PD1 should meet these requirements.. Subject Devices meet these requirements too. PD and Subject Devices are all validating-software processing, thus keeping regular processing parameters and safety functions normal. The Subject Devices have the same effectiveness as the predicate device.

In conclusion, the Subject Devices do not raise any new safety or effectiveness aspect with respect to the PD. Thus the Subject Devices are **substantially equivalent** to the predicate device.

11. DEVICE DESCRIPTION

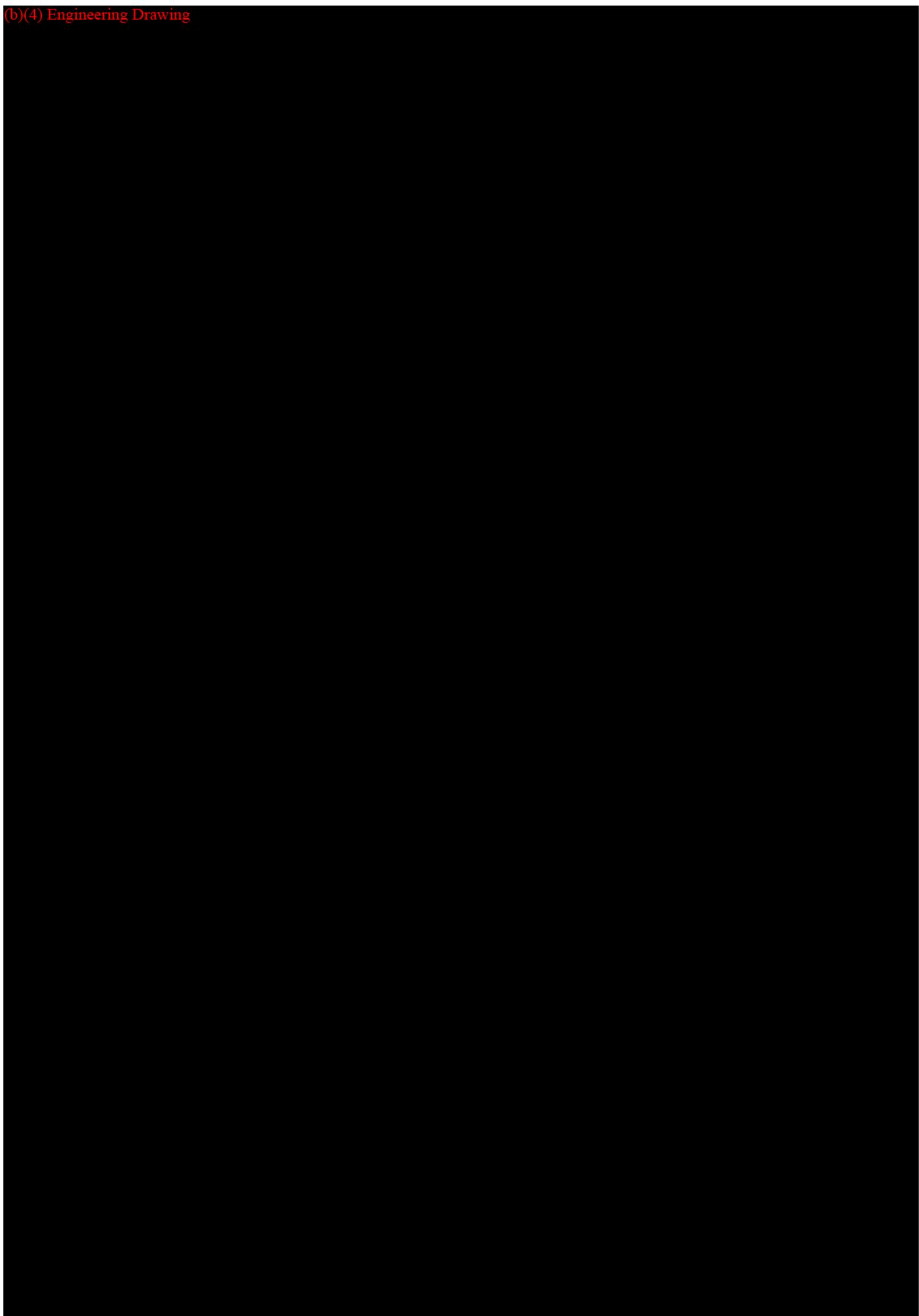
HIVOX Spopad EMS SP series, SP-910 / SP-920 / SP-620 are the proposed subject devices for this 510(k) submission. These Electrical Muscle Stimulation units are indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, back, and buttocks areas. Contraindicated use on injured or otherwise impaired muscles. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

SP-910 / SP-920 / SP-620 are 1-channel battery-operated user-friendly muscle stimulation systems specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-910/620 comprises 2 electrodes, which connects the signals from the stimulator to the skin. SP-920 comprises 4 electrodes, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors.

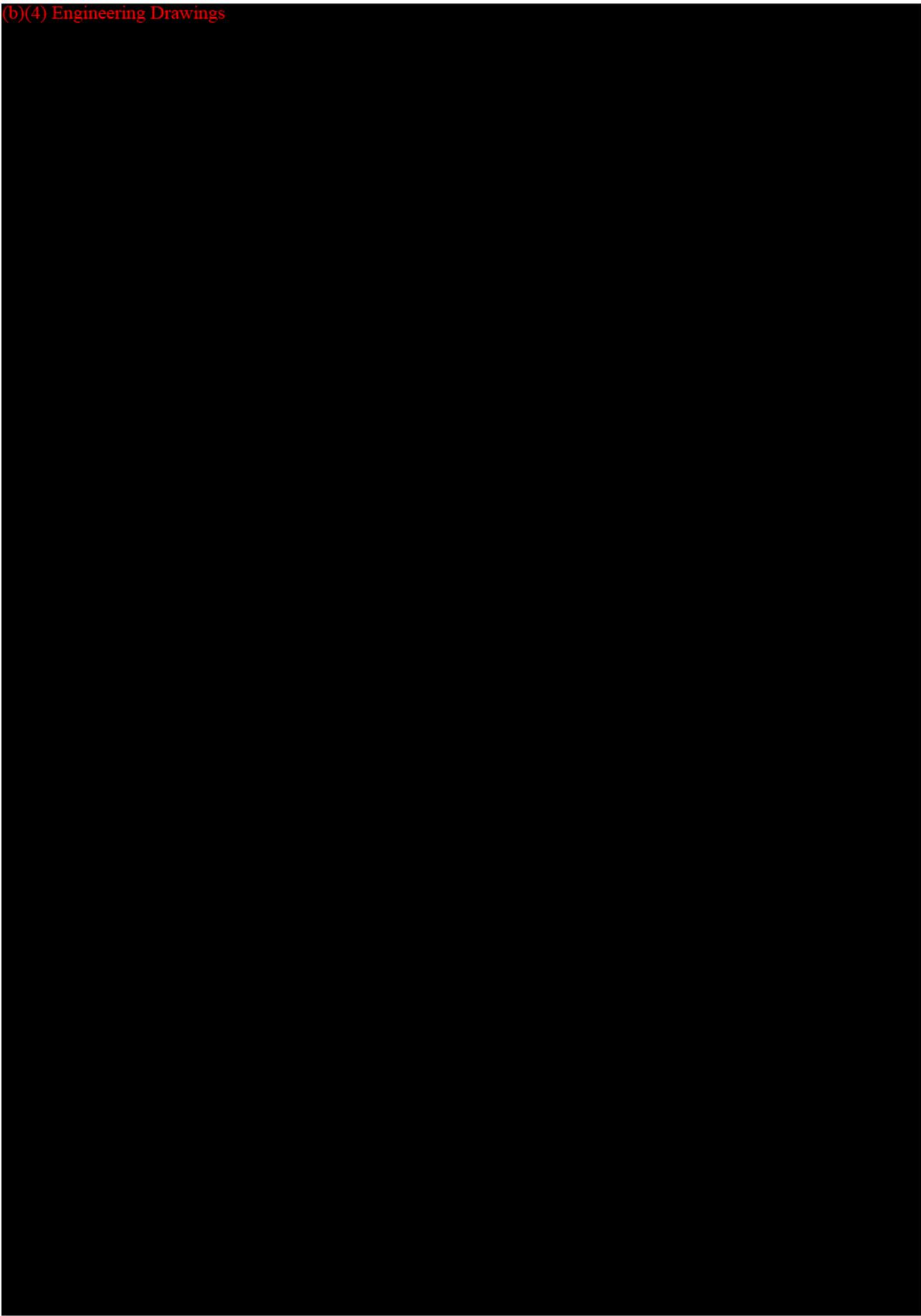
We place the device engineering diagrams, output waveforms, and device photos in the following sections, section 11.1 ~ section 11.3 for each device.

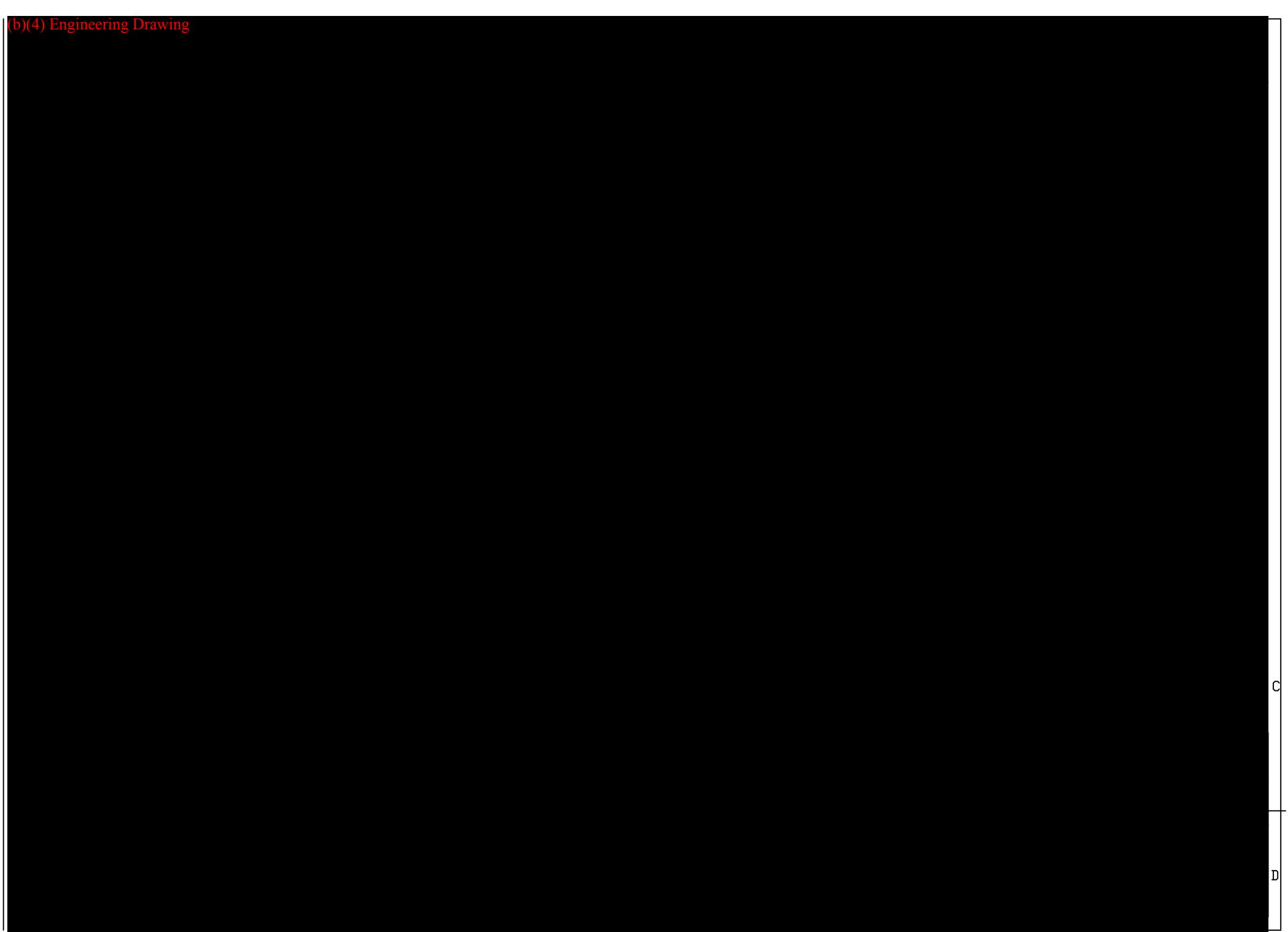
11.1 Device Engineering Diagrams





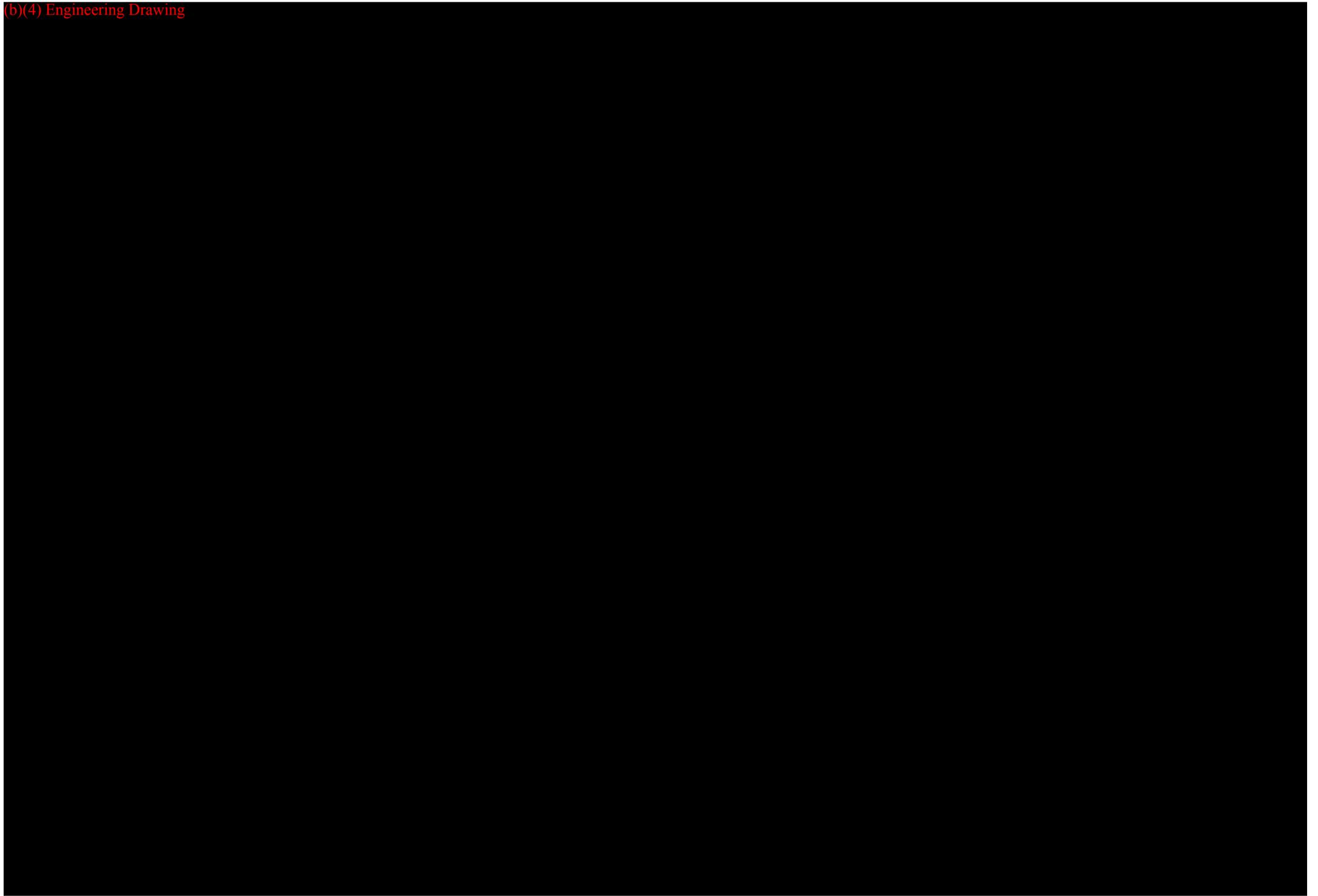
(b)(4) Engineering Drawings



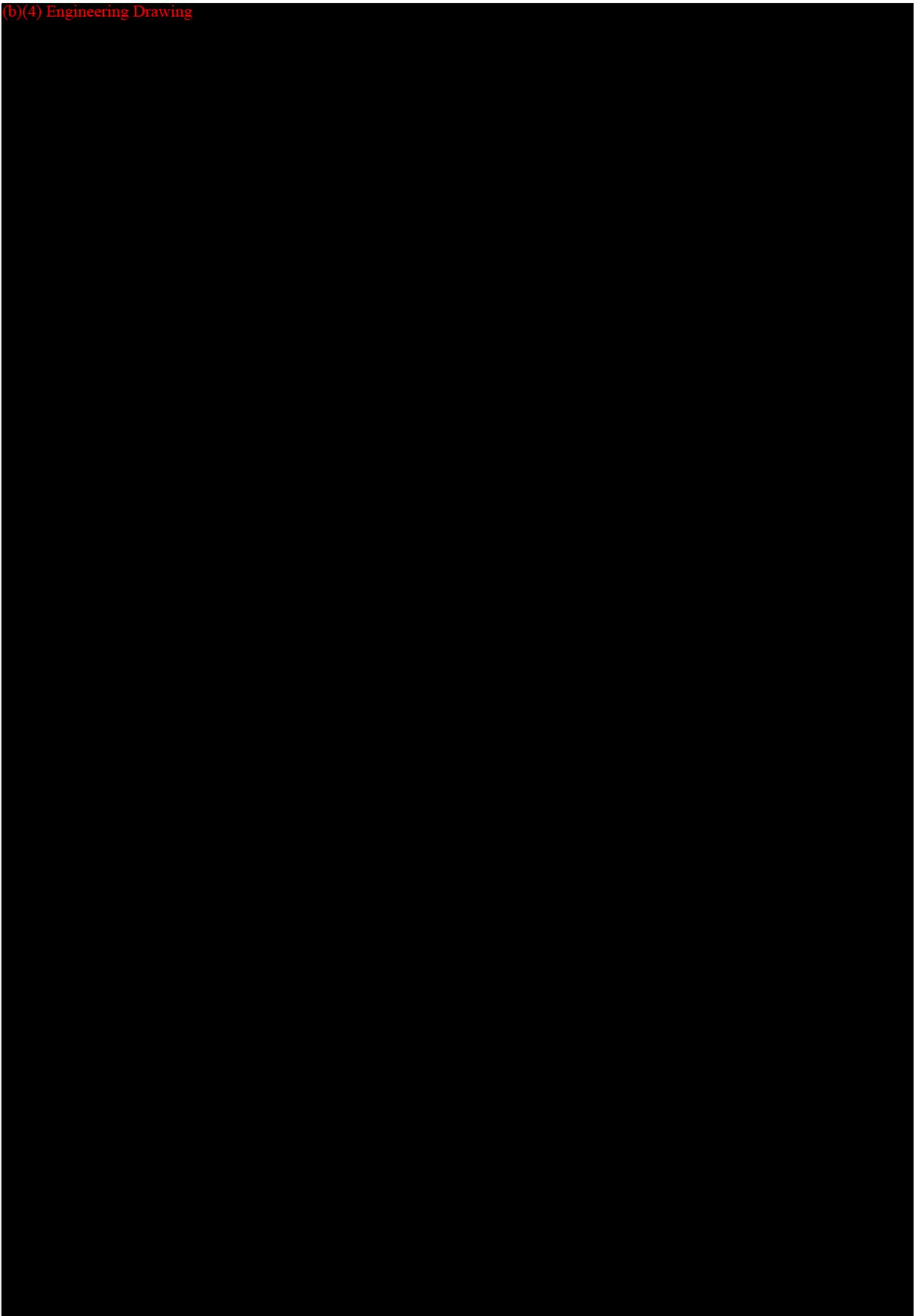


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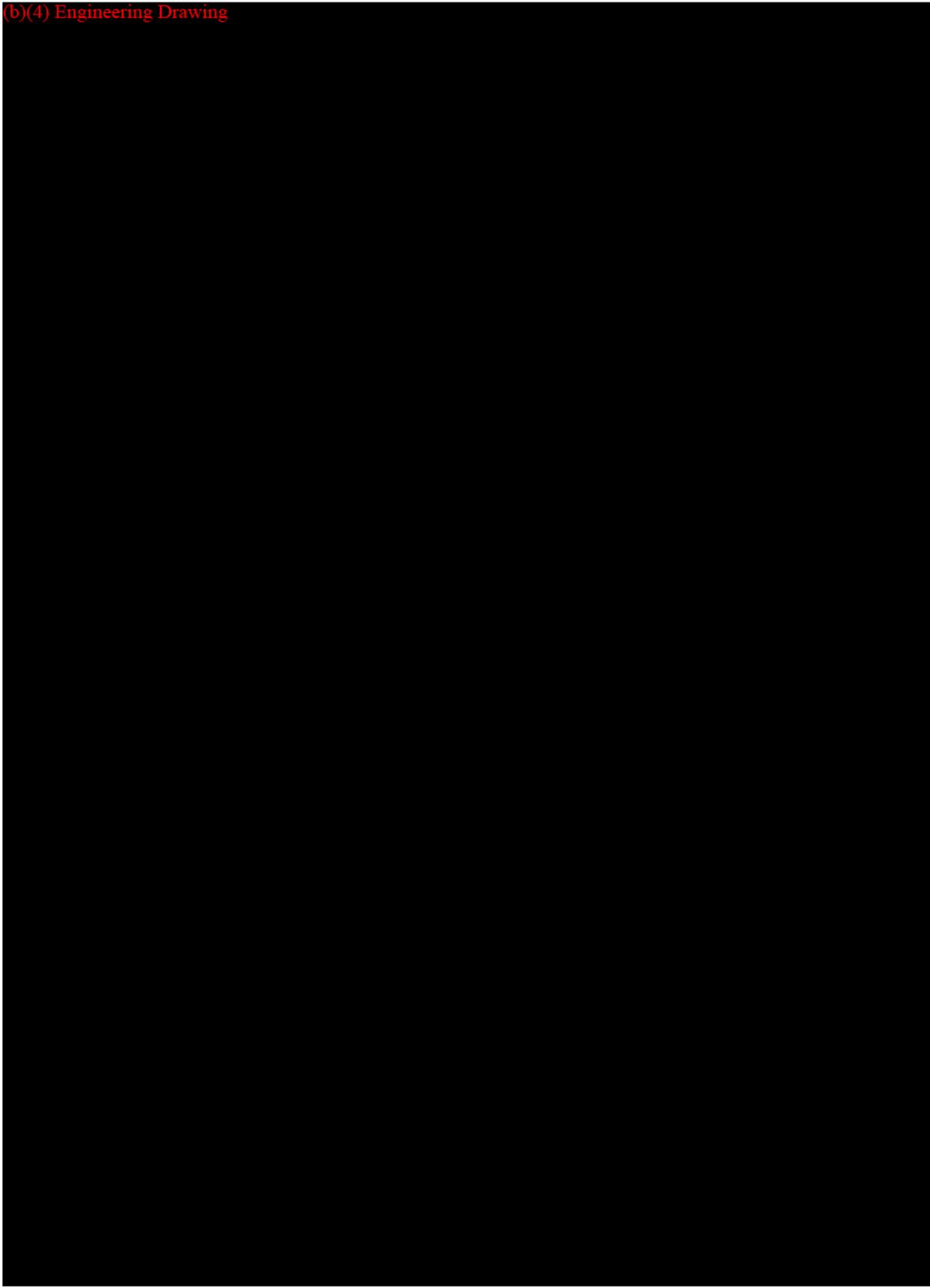
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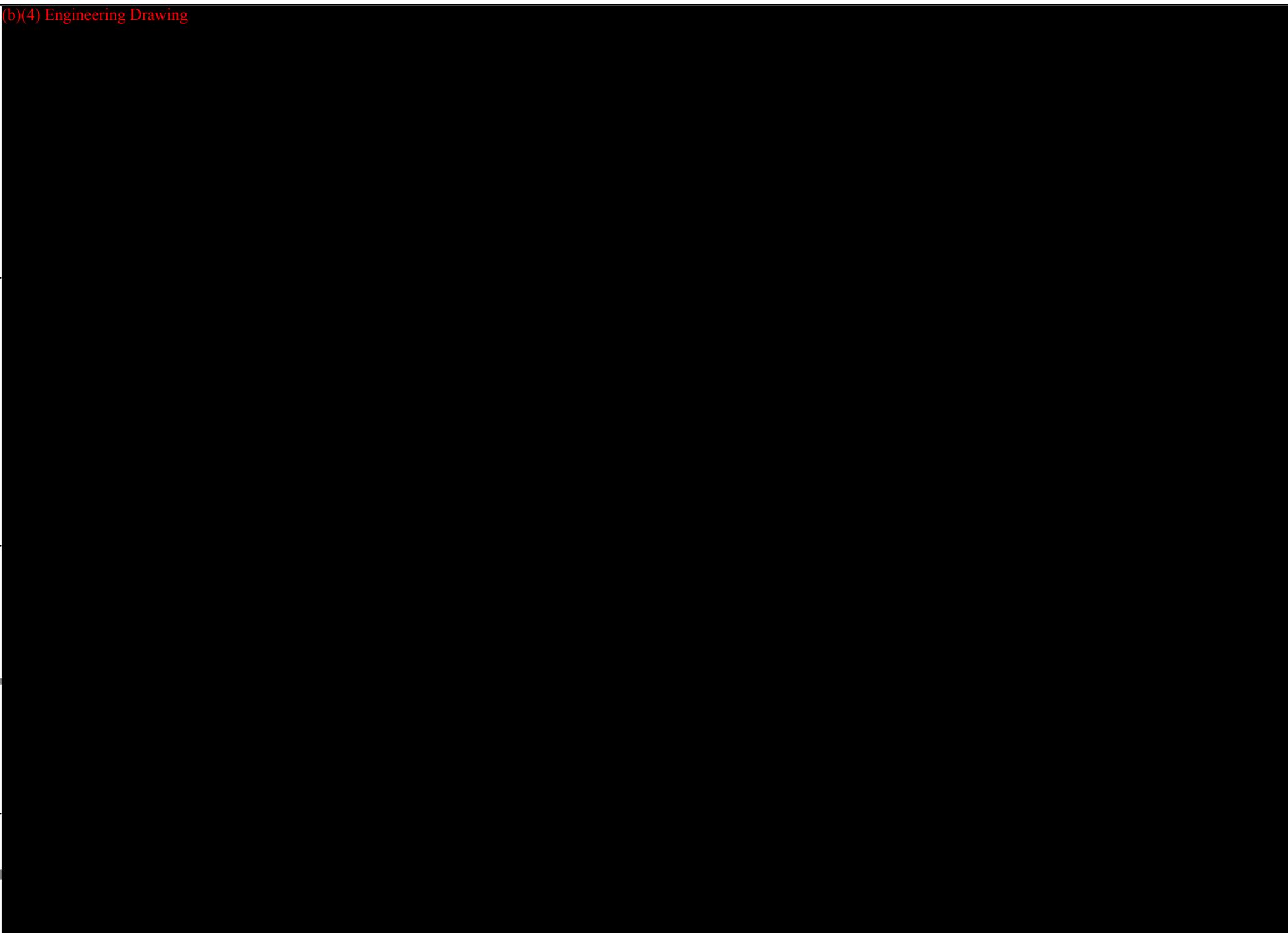


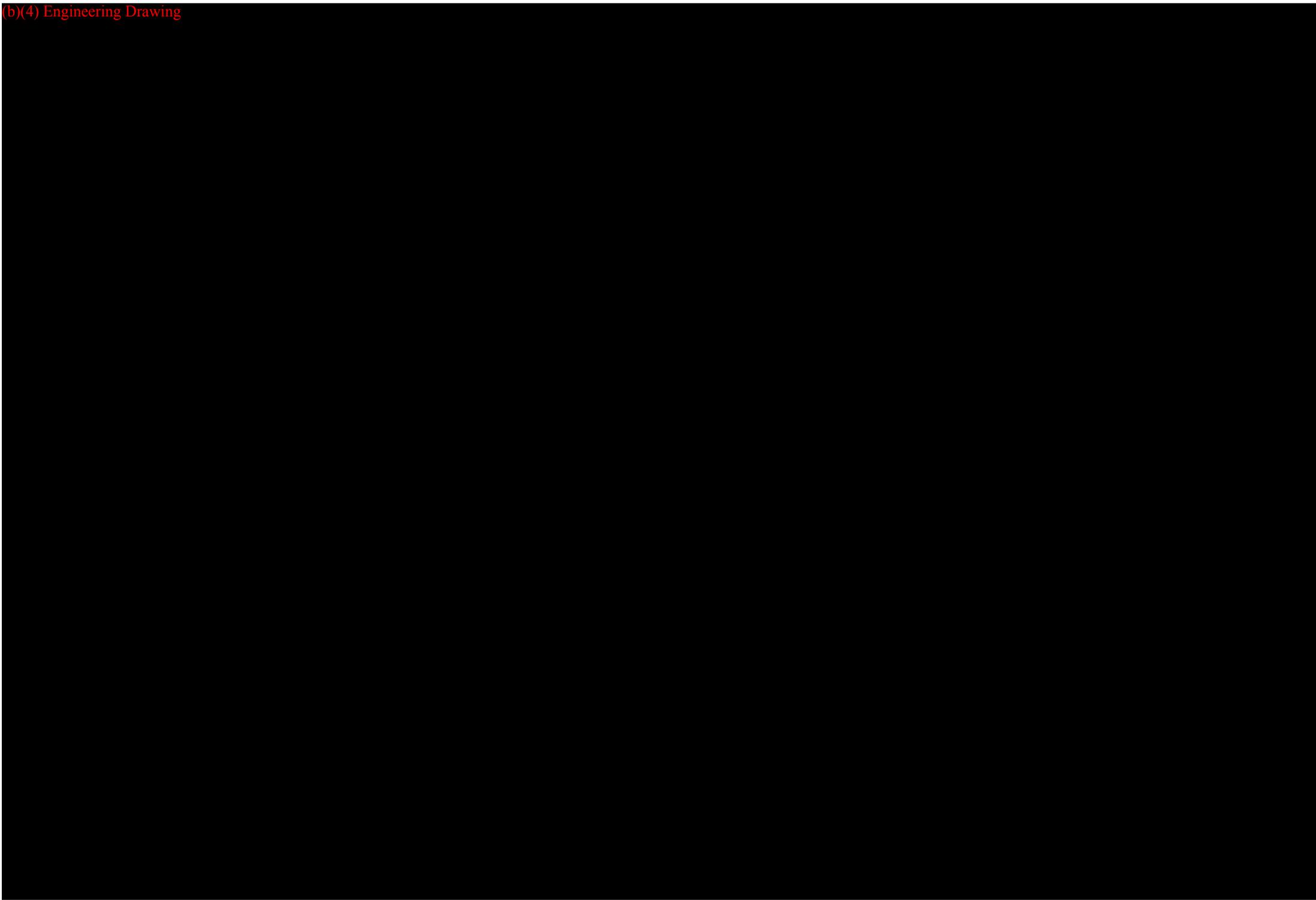




(b)(4) Engineering Drawing

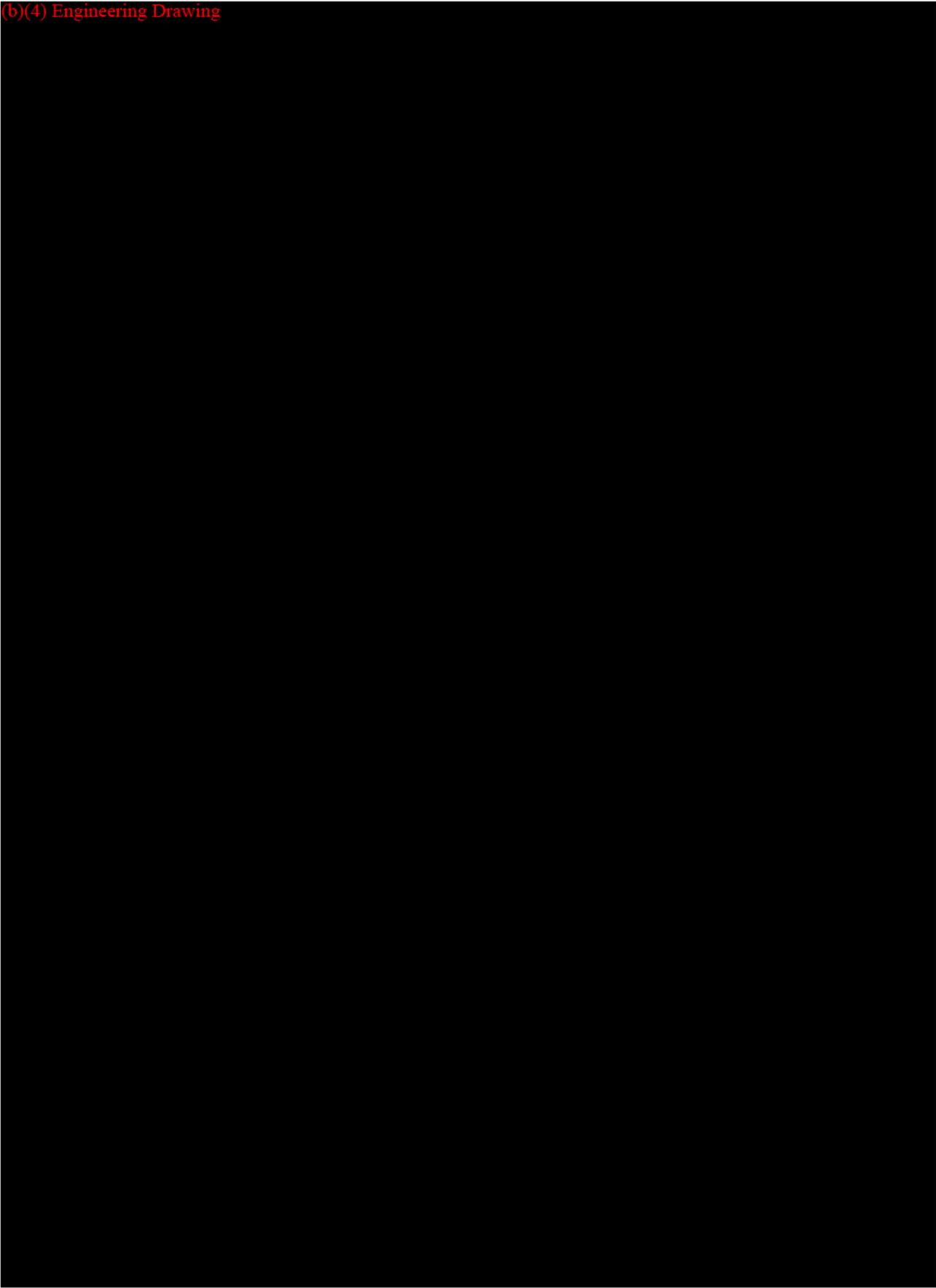








(b)(4) Engineering Drawing

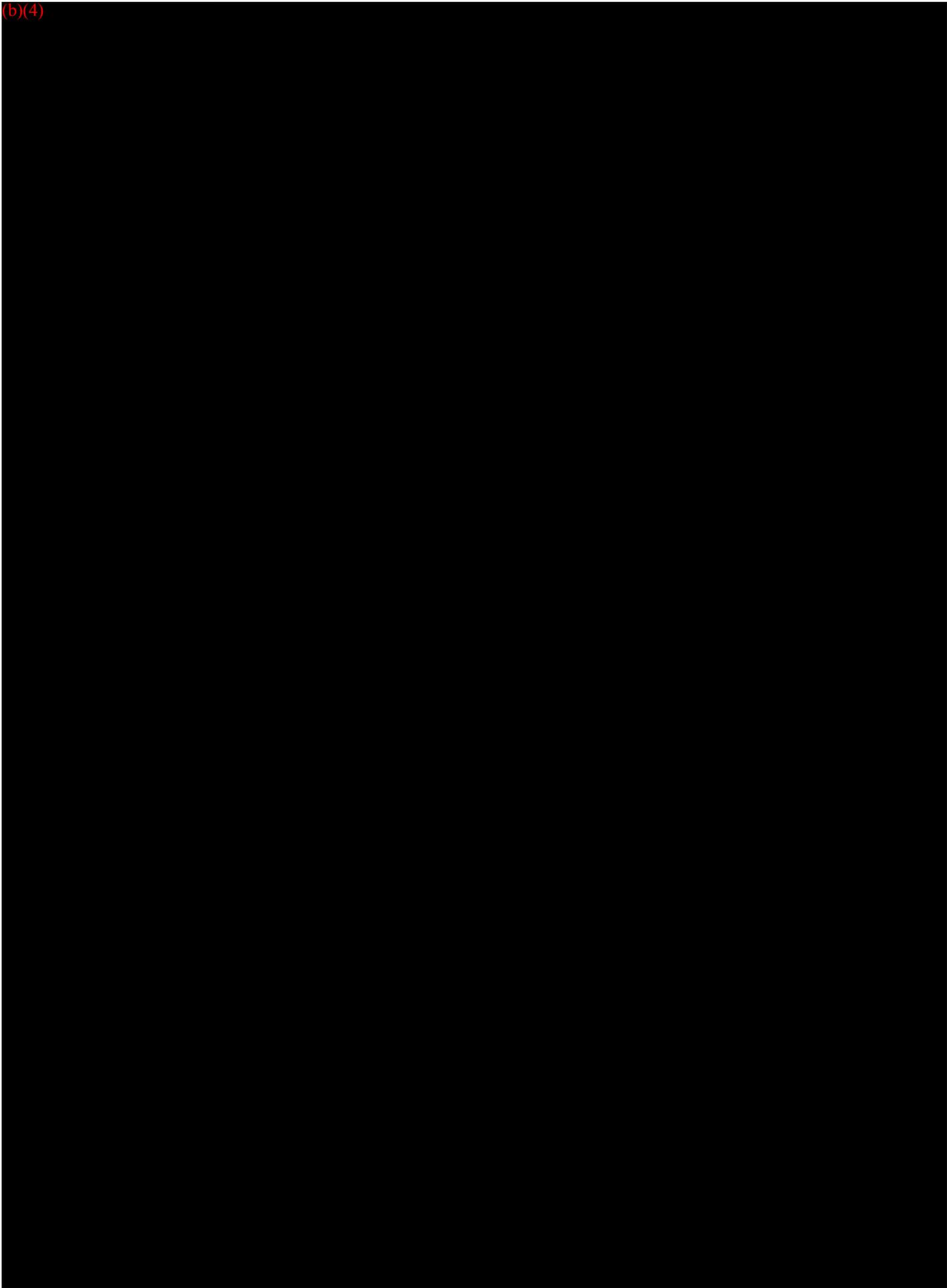


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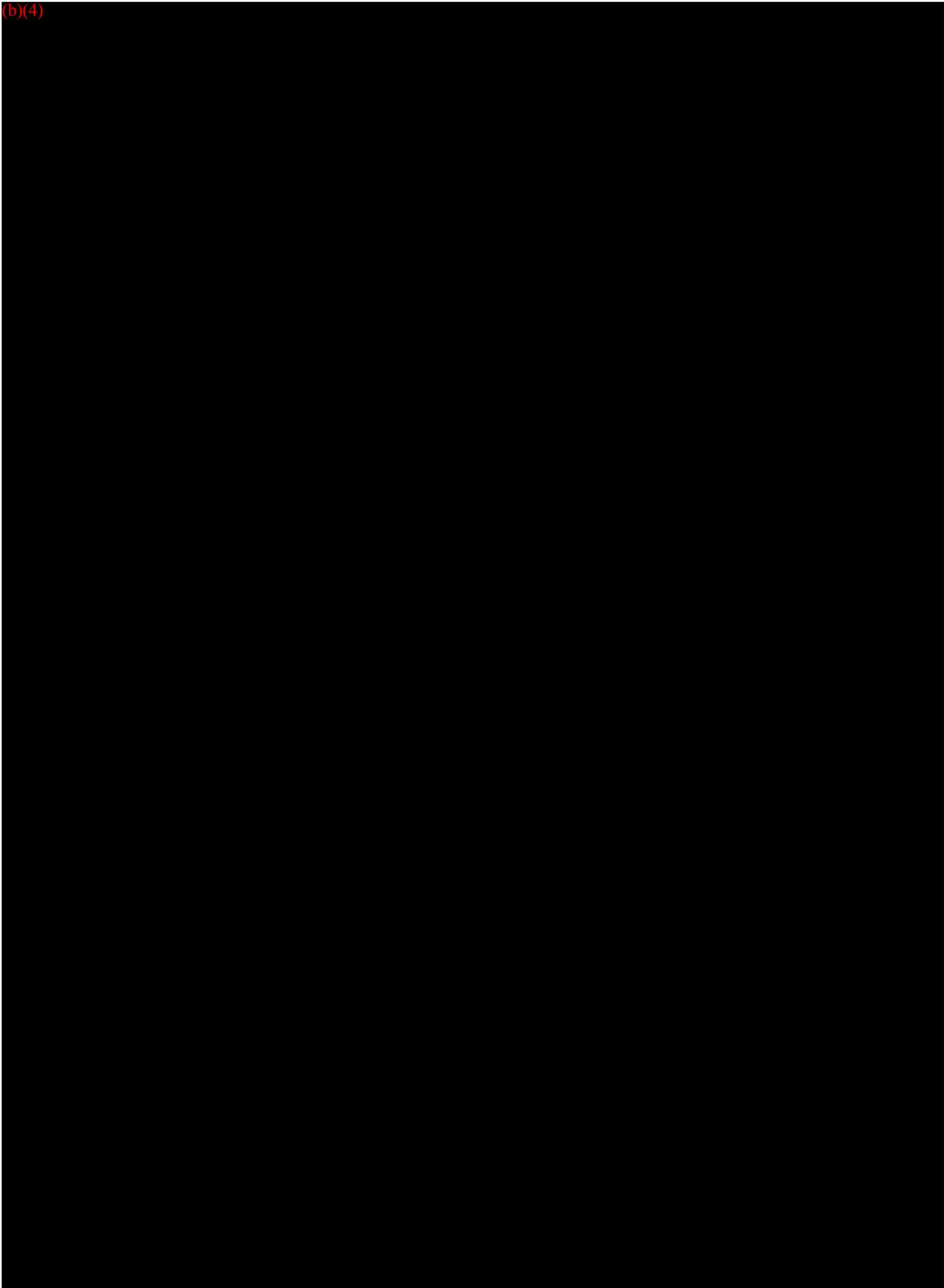
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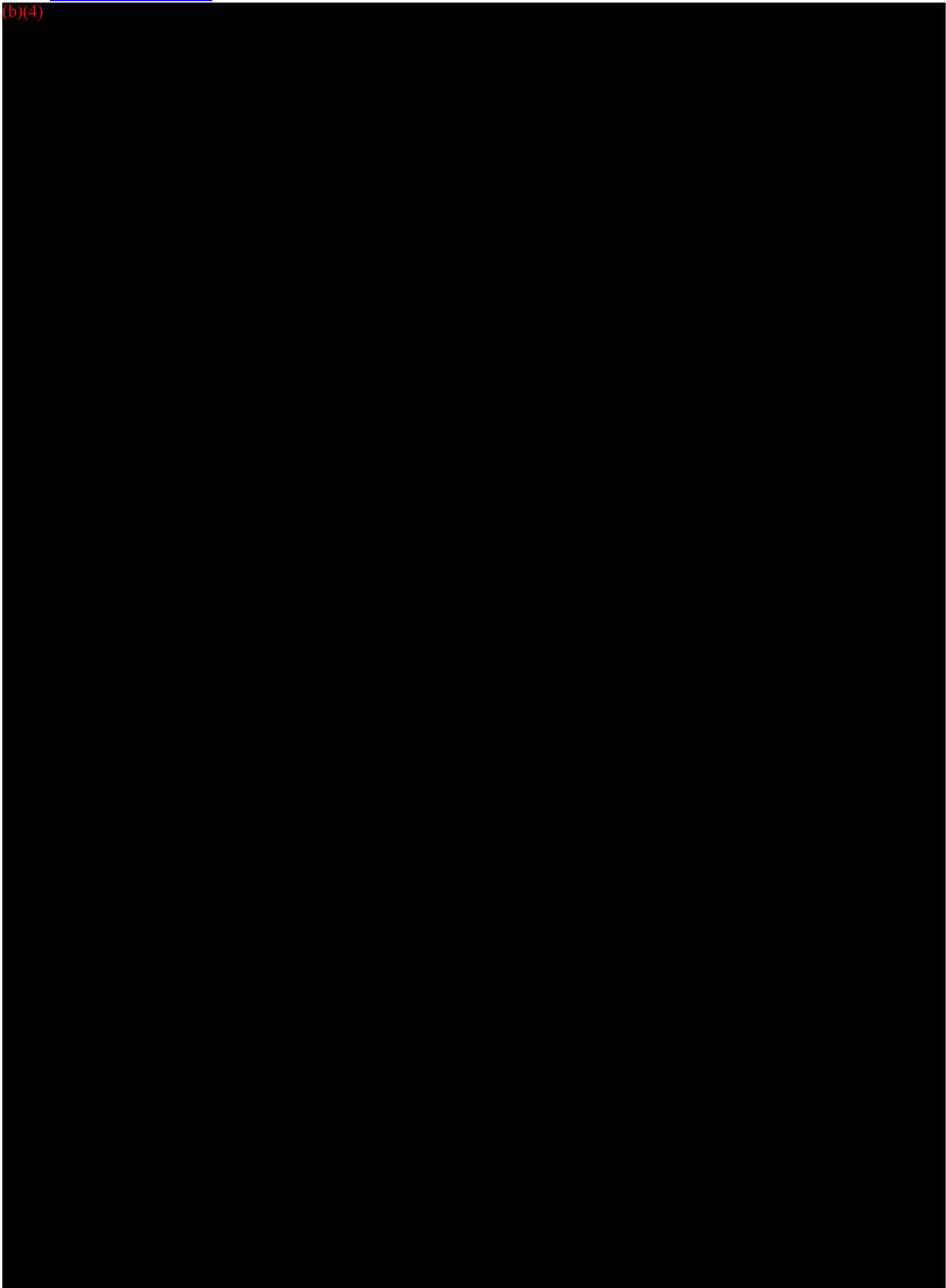
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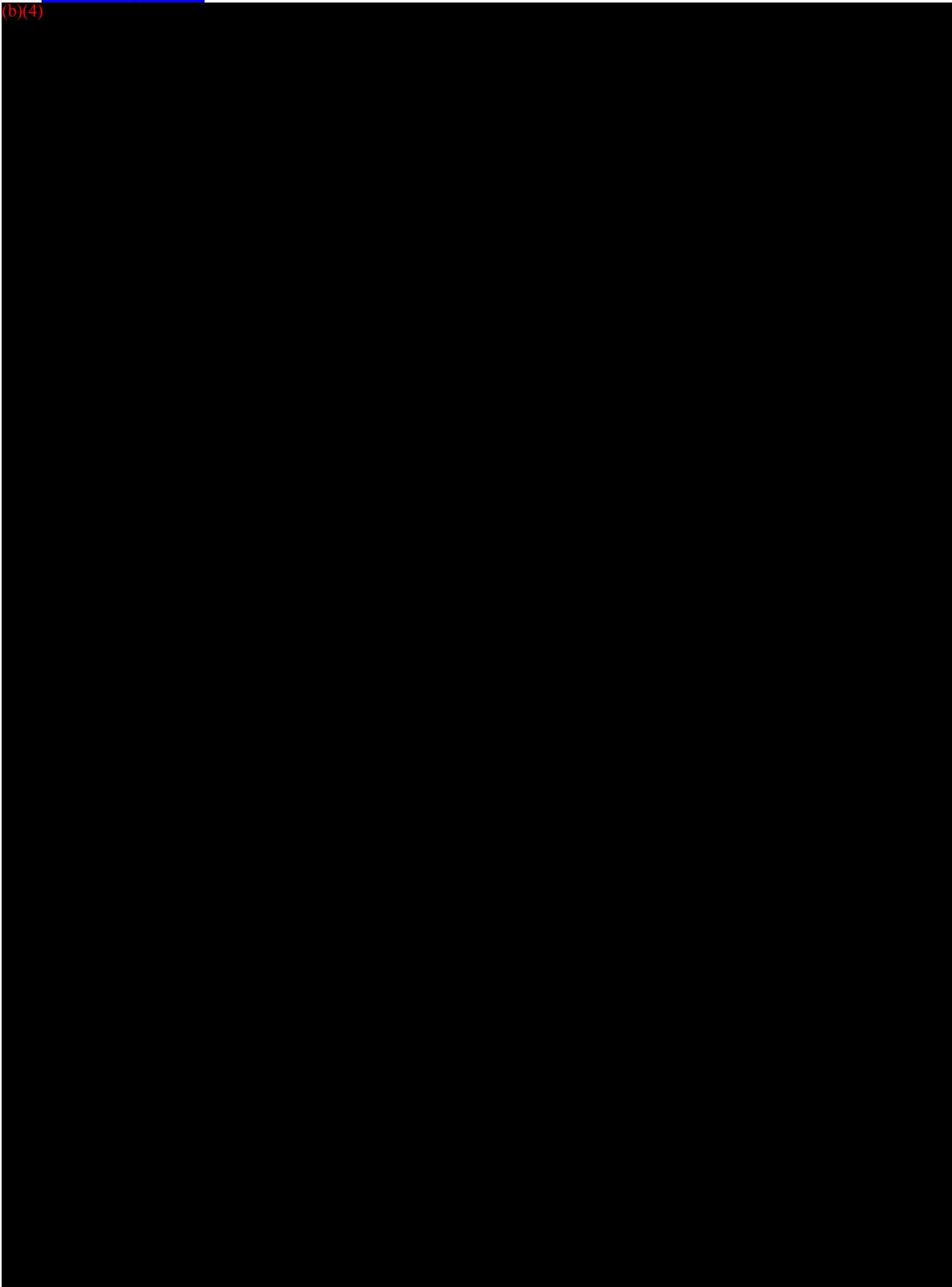
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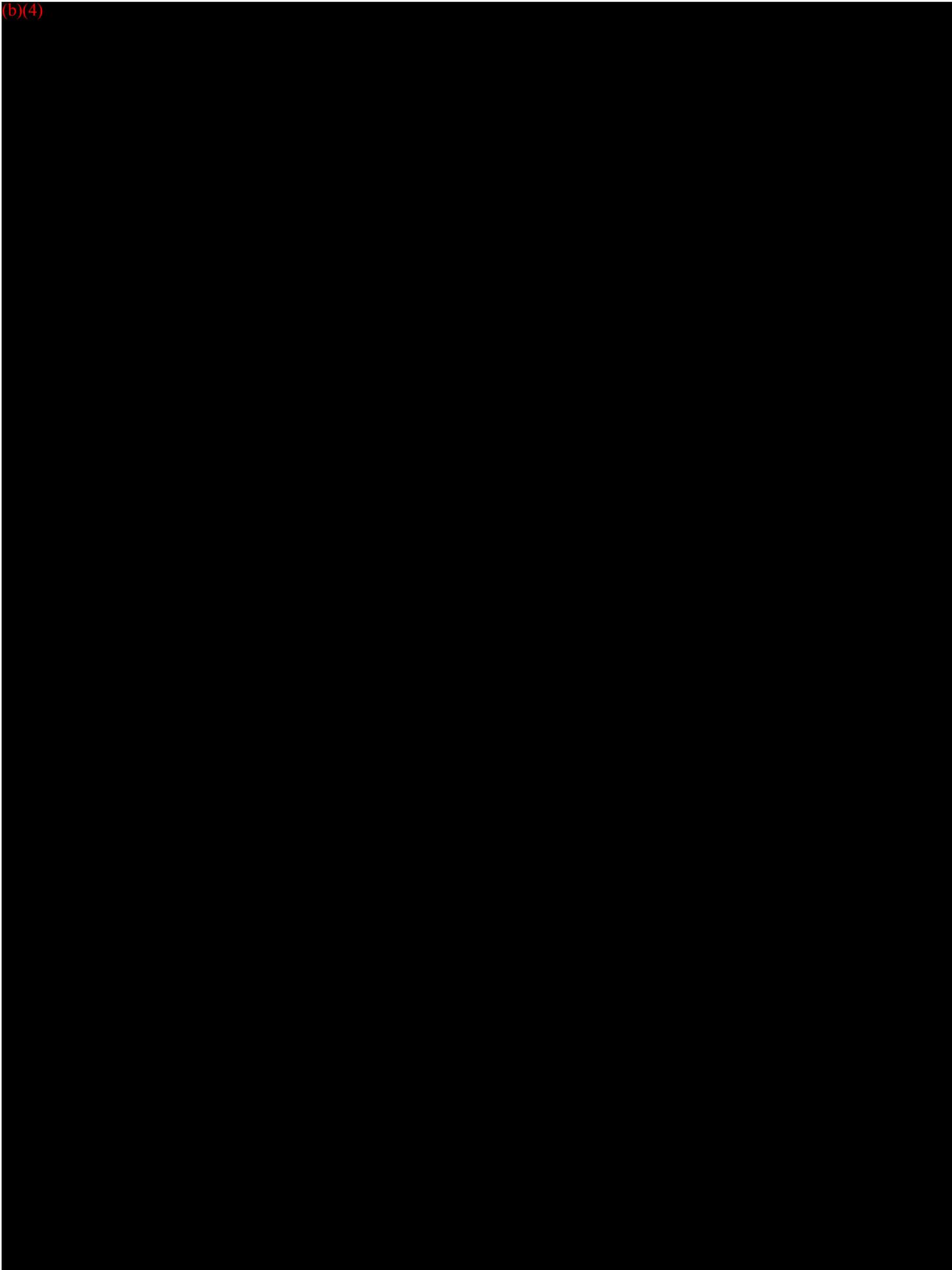
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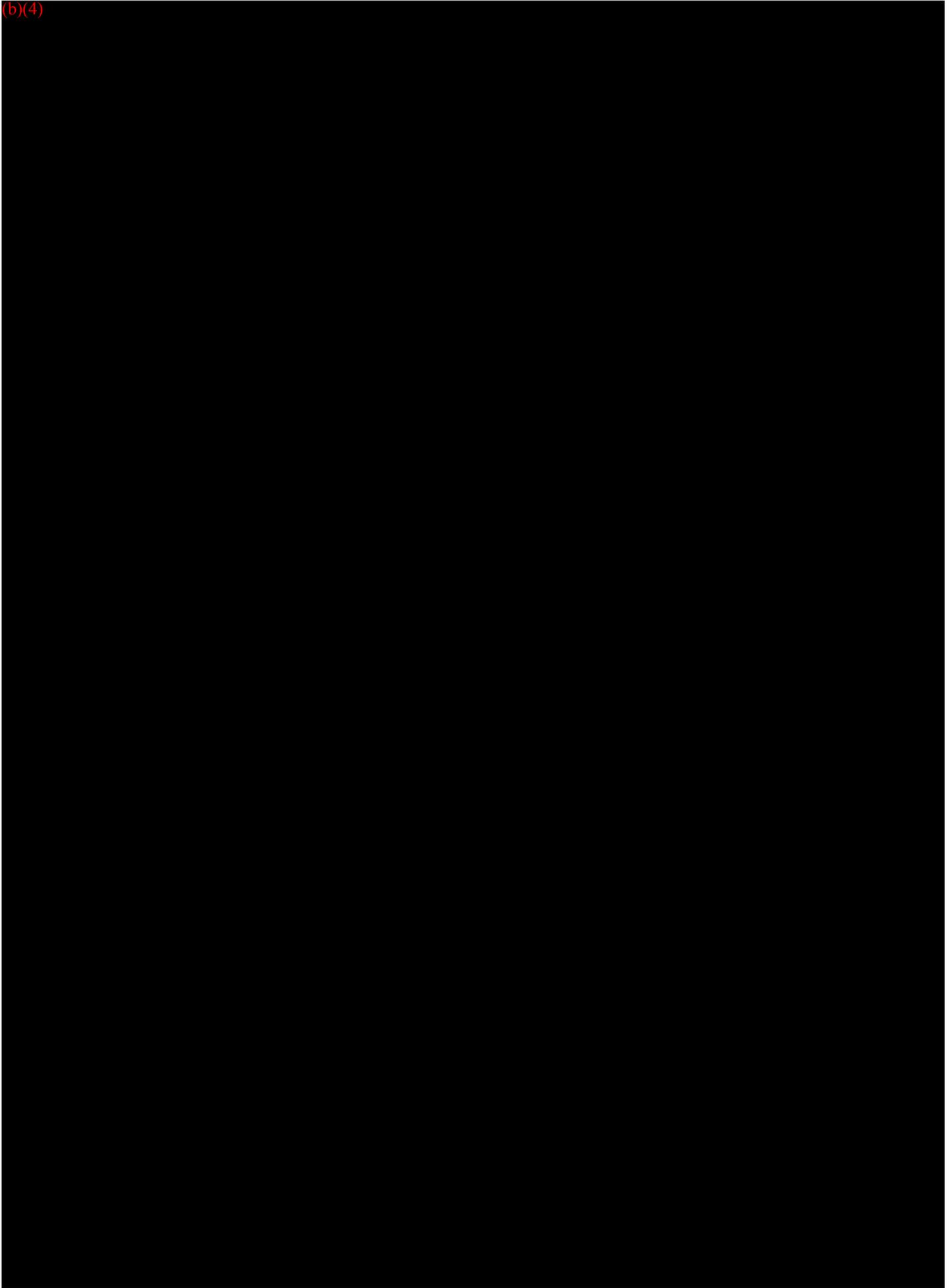
Test Report :

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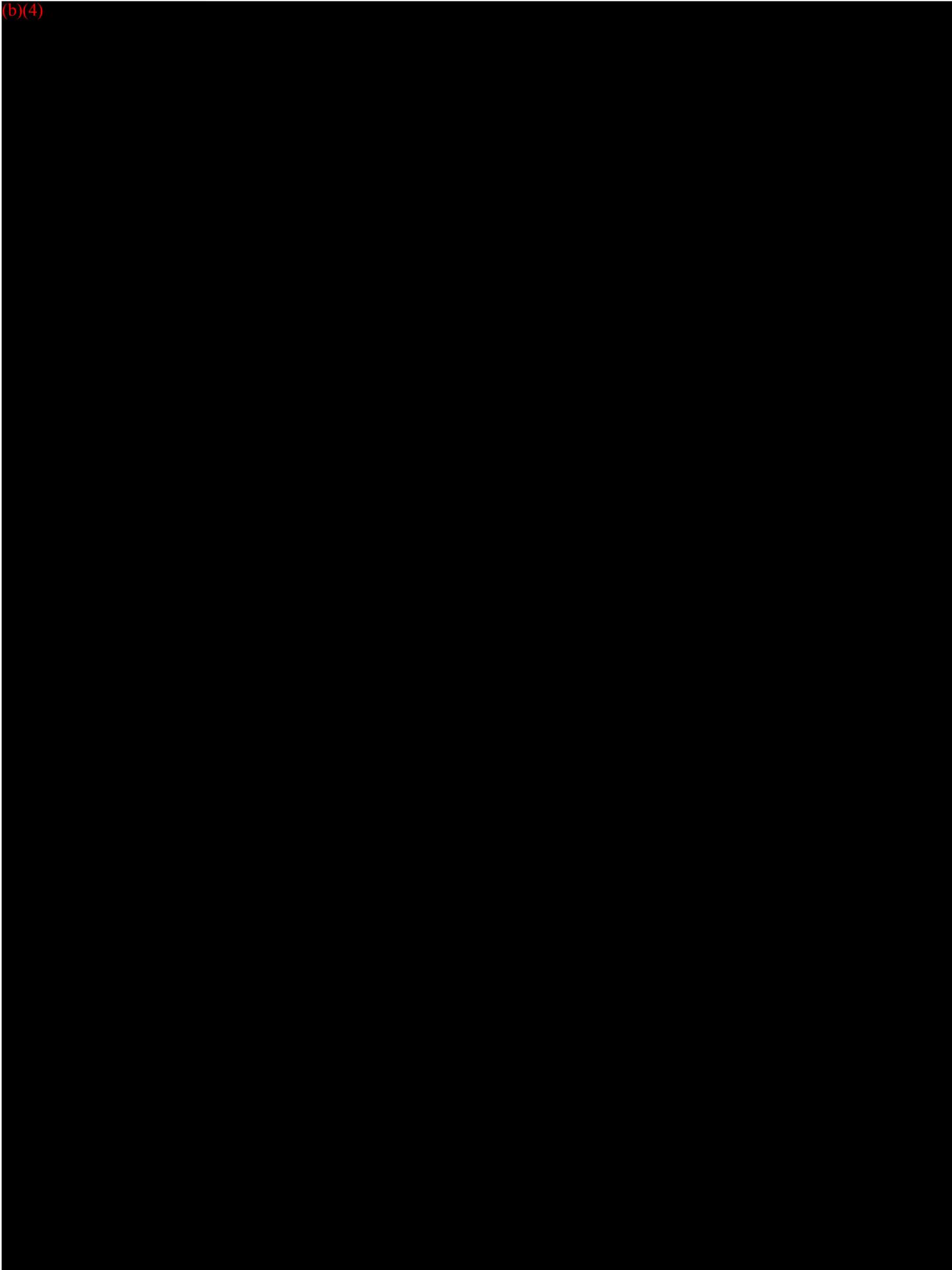
Test Report :

(b)(4)



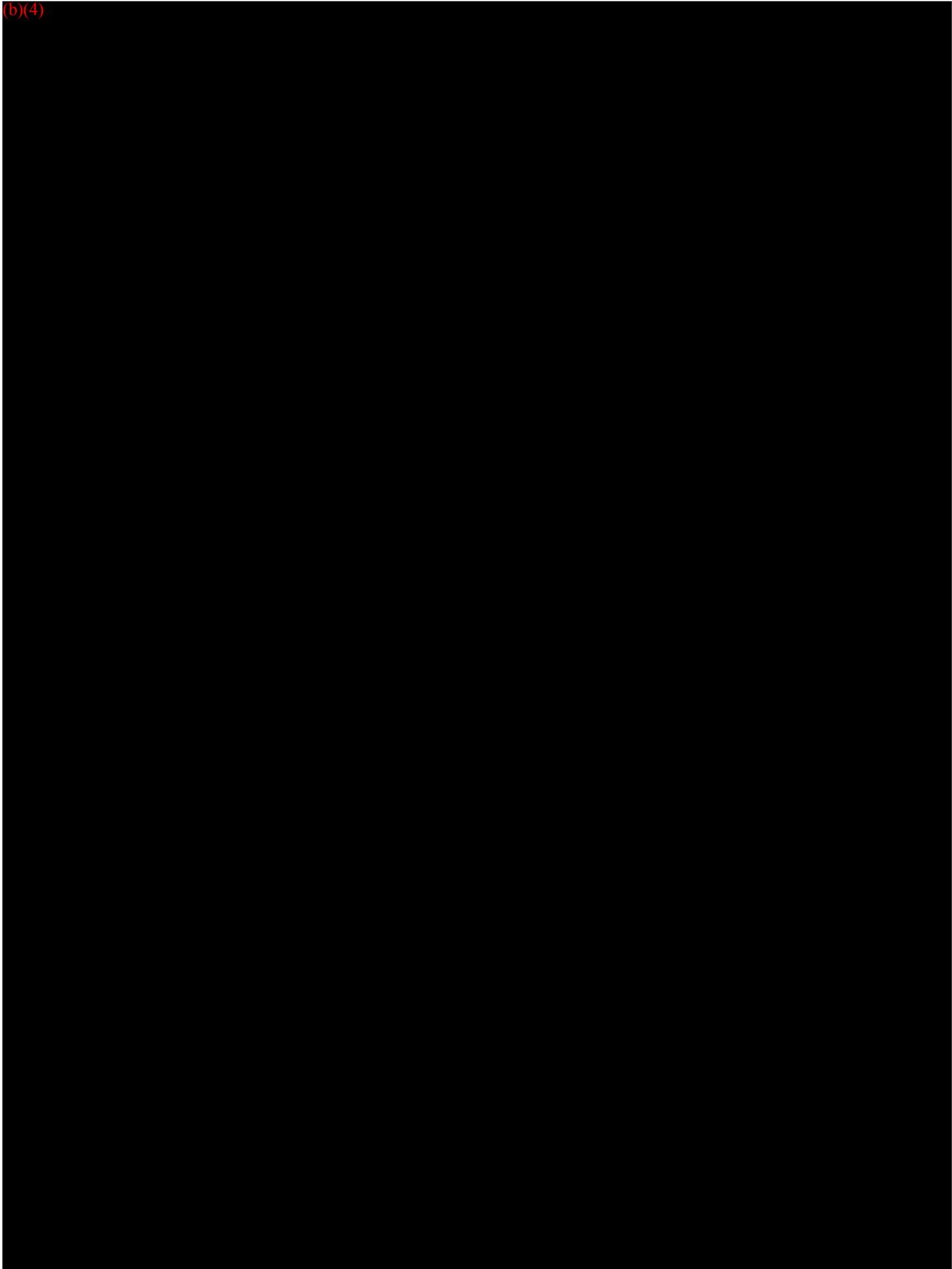
Test Report :

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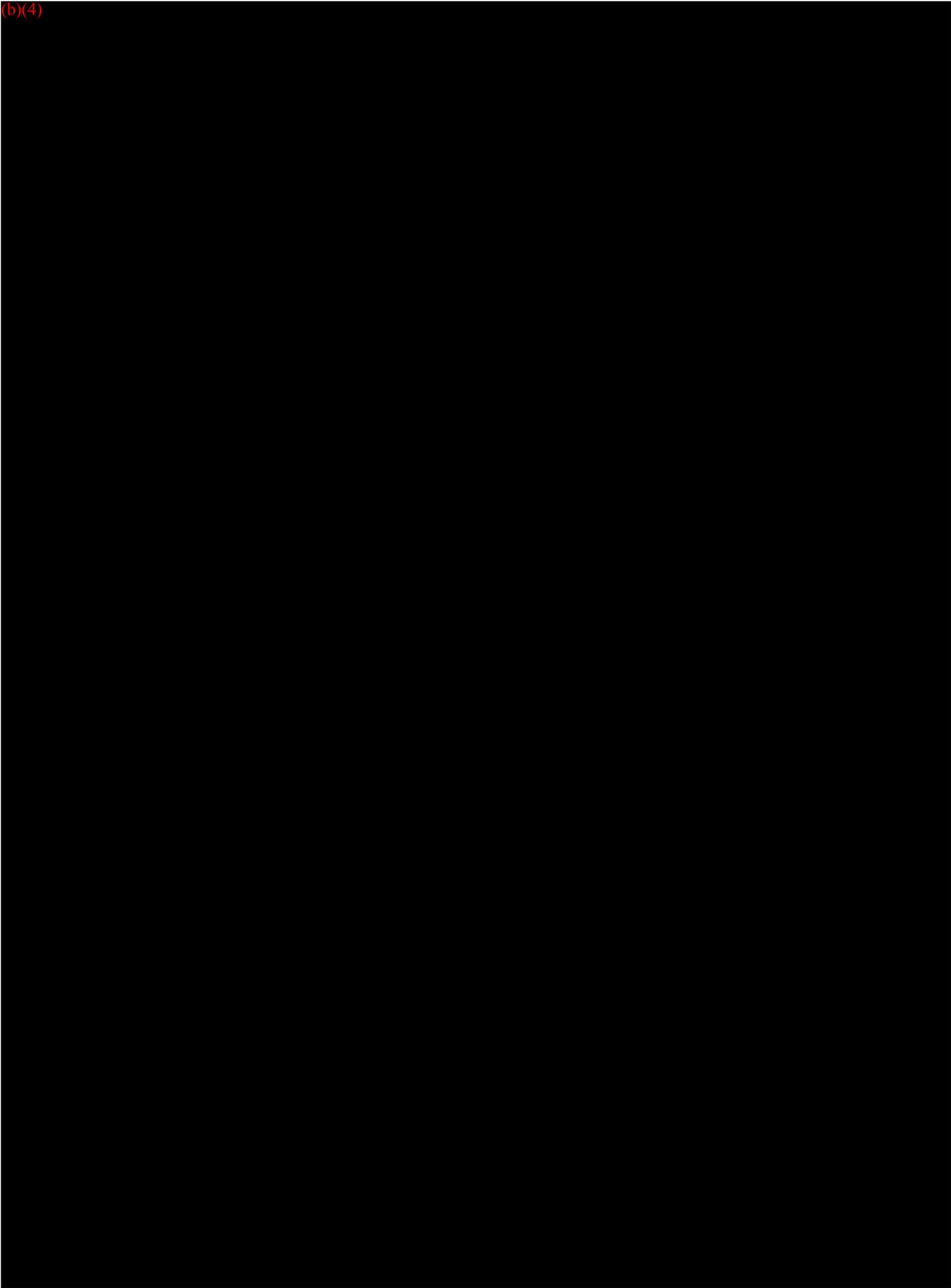
Test Report :

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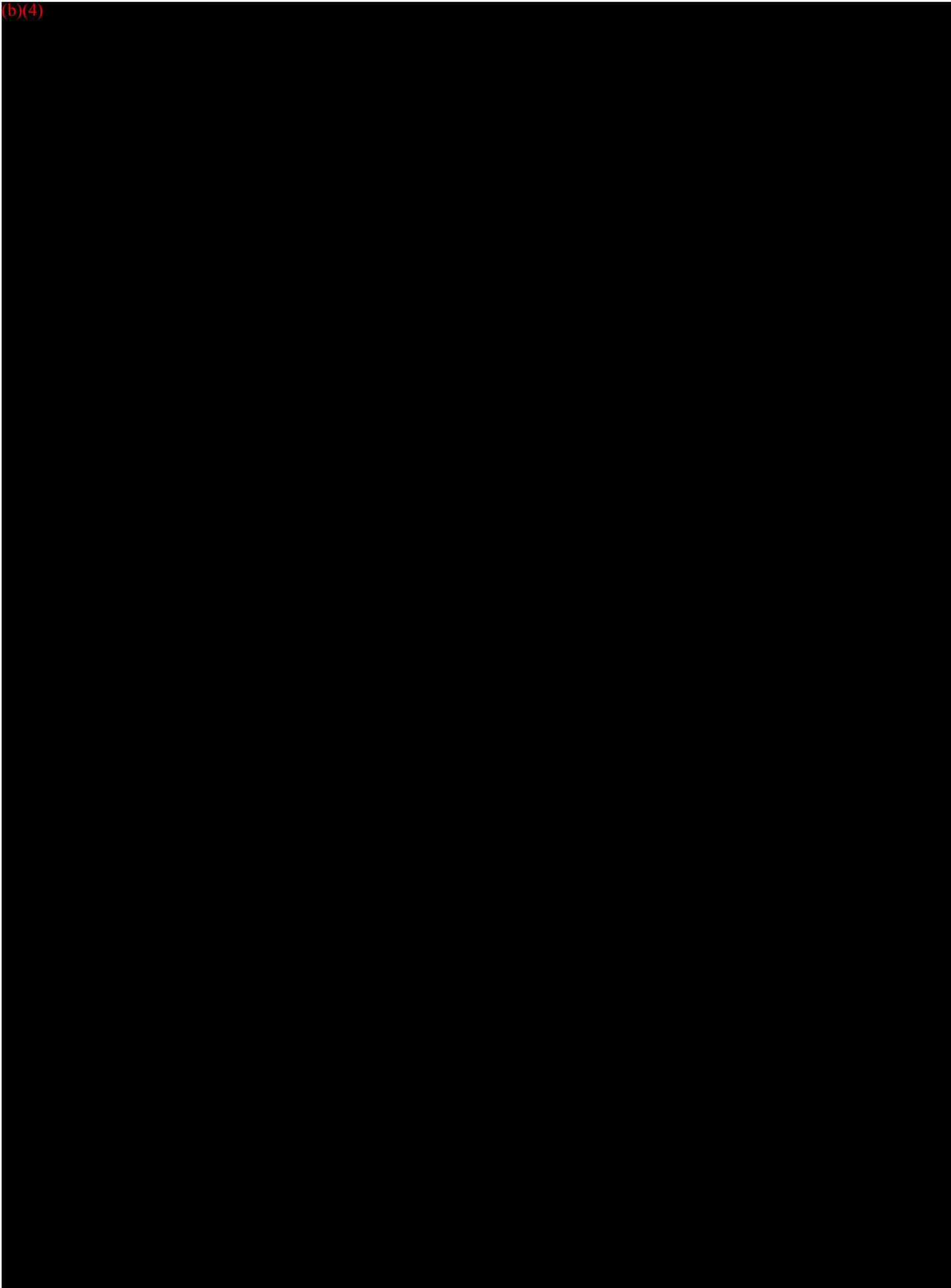
Test Report :

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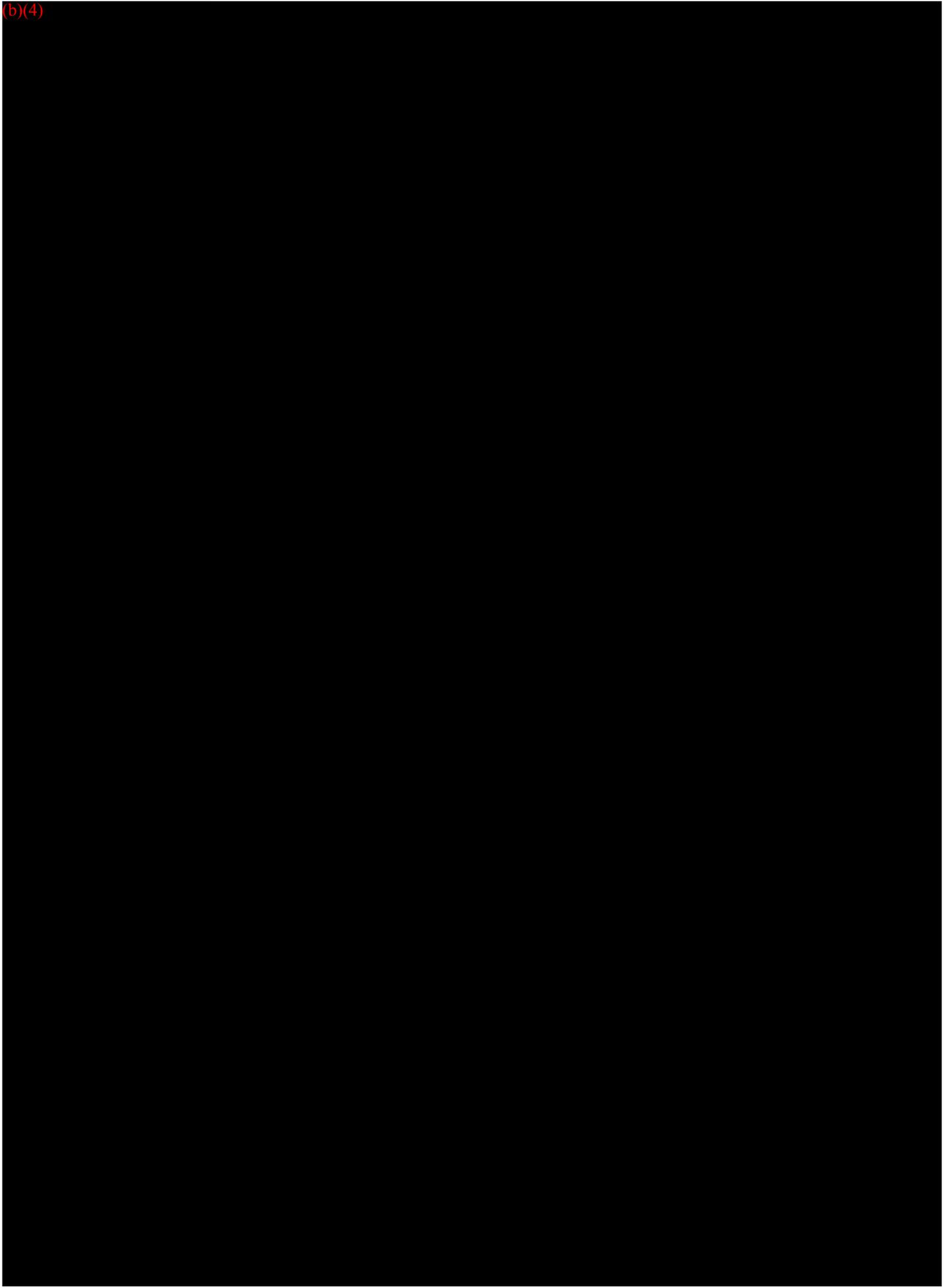
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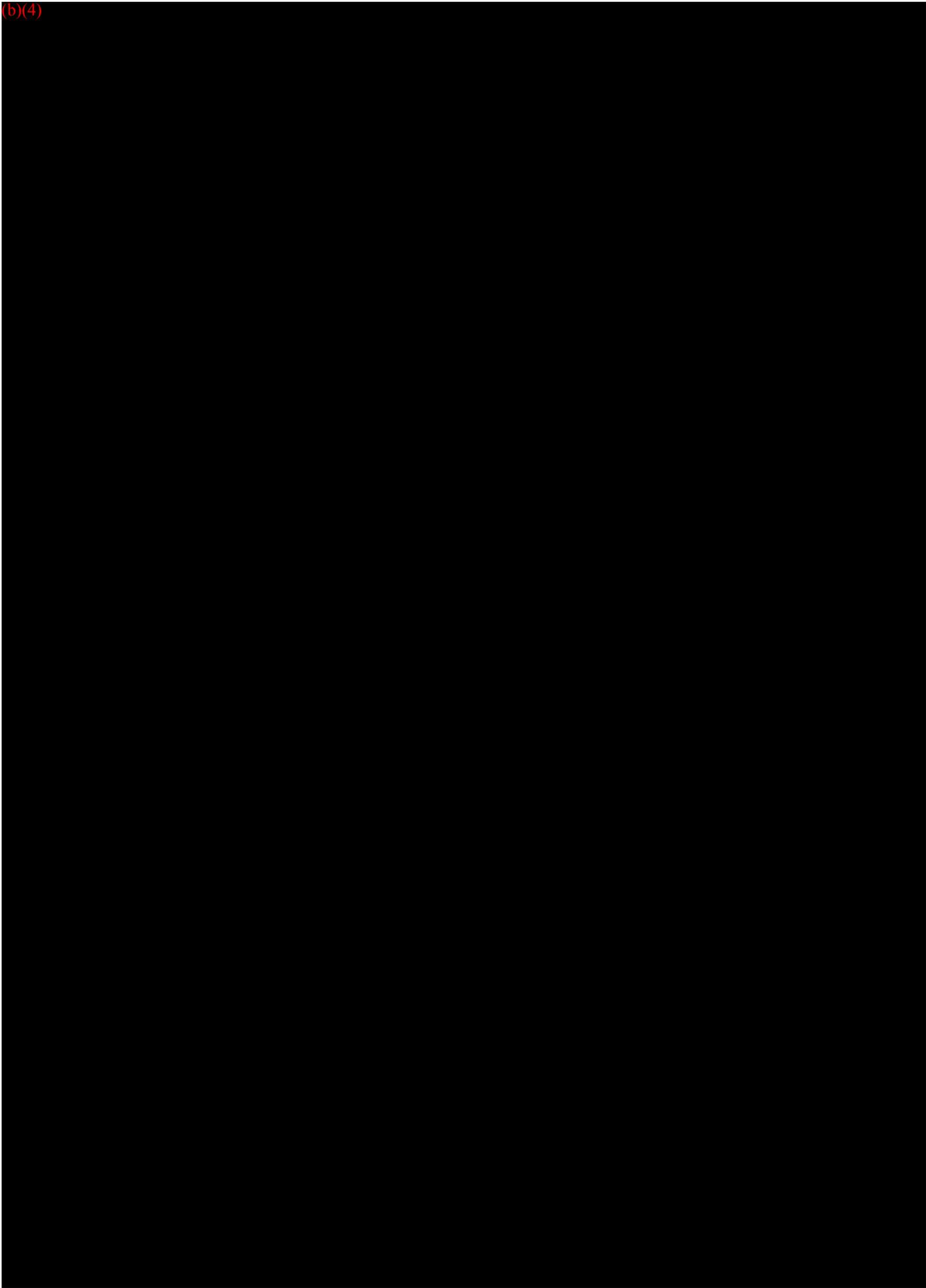
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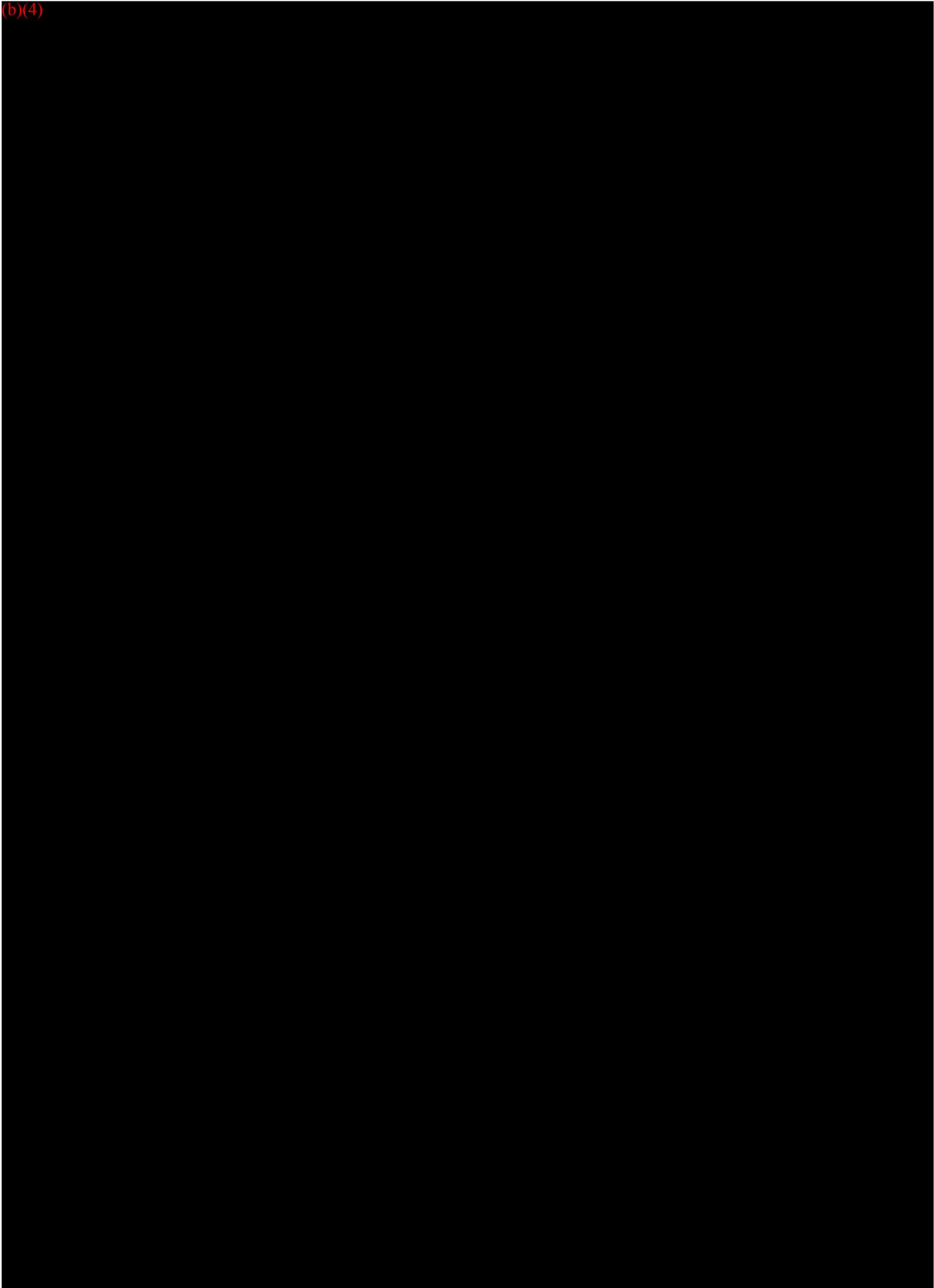
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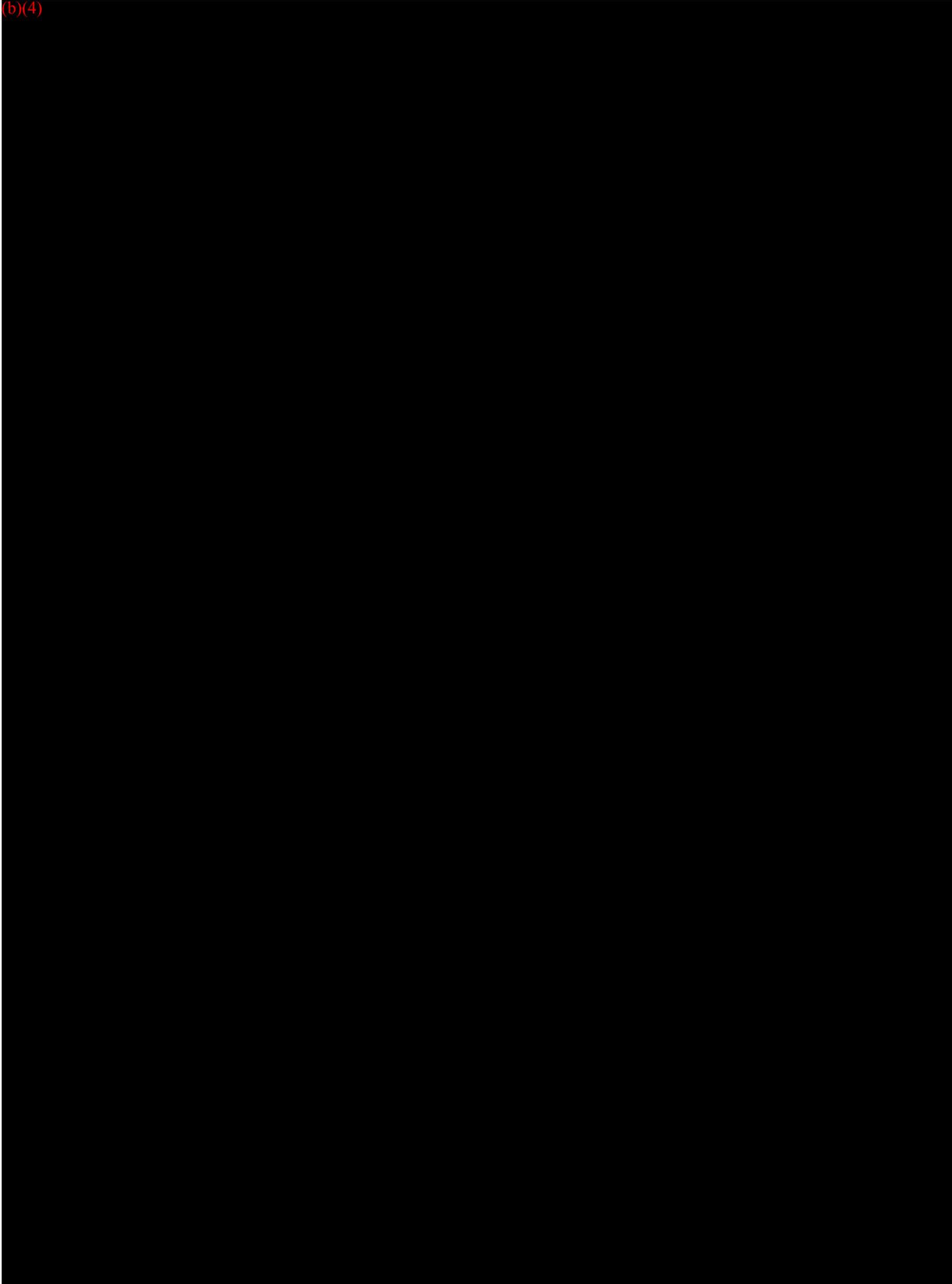
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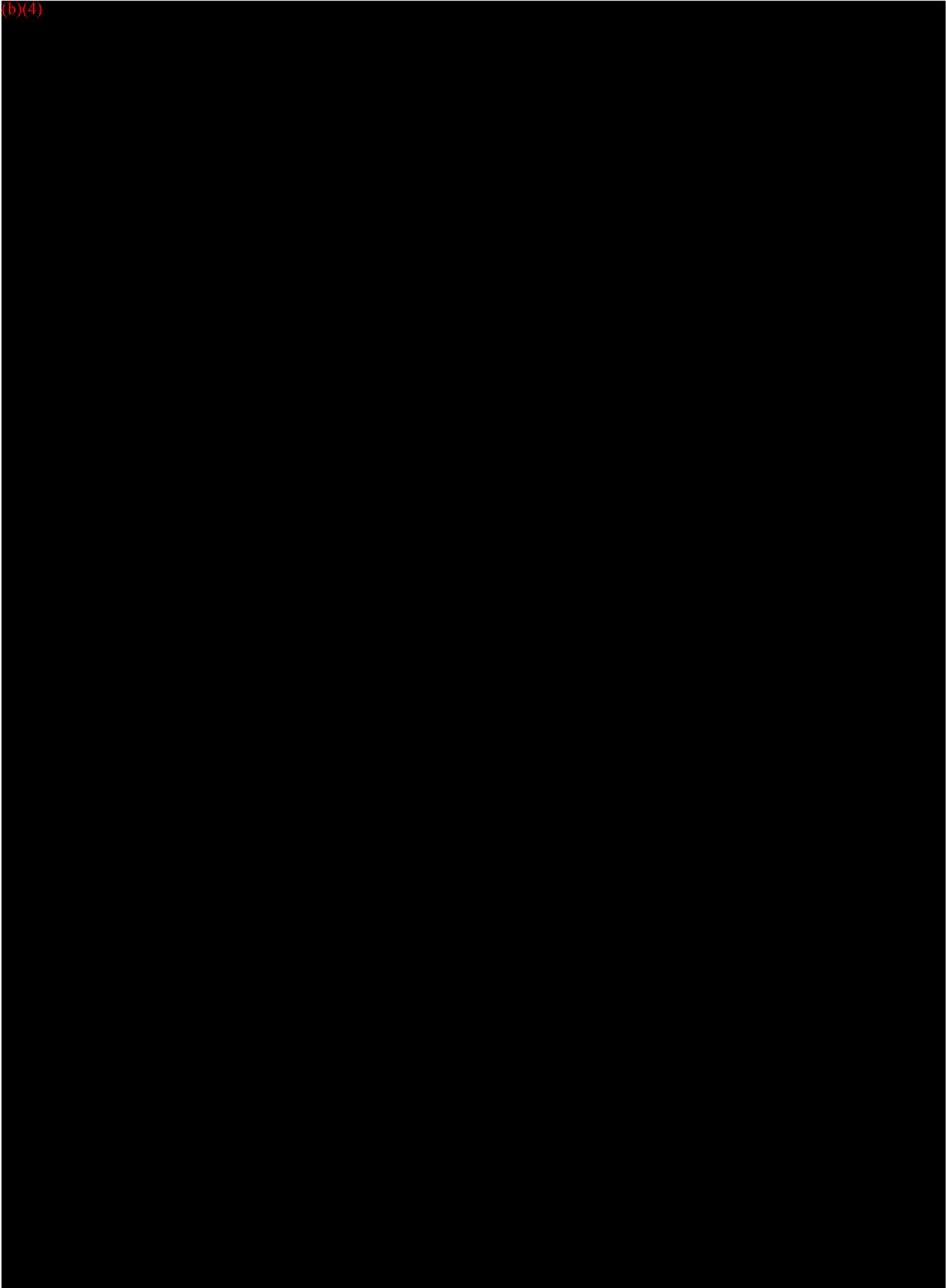
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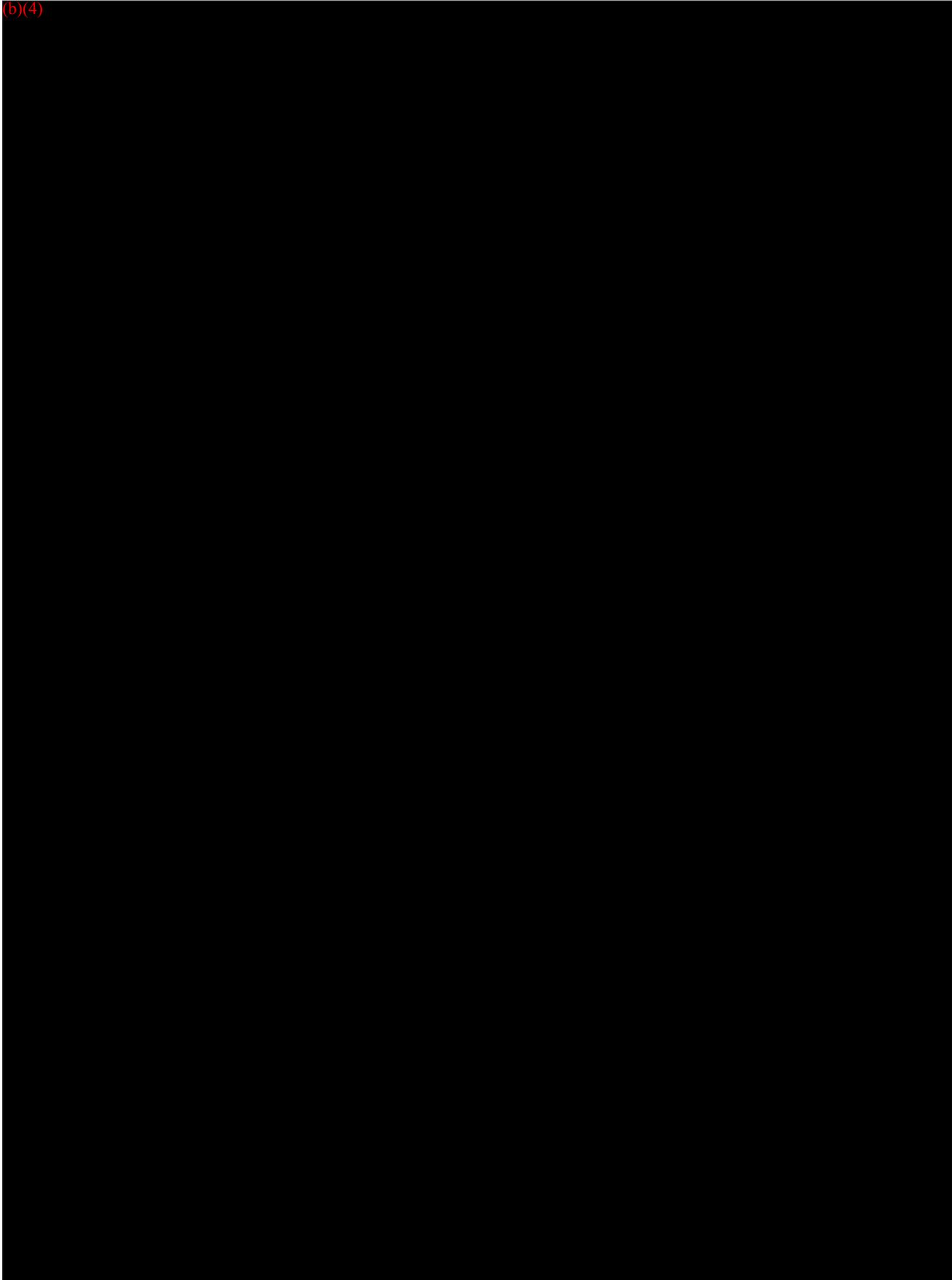
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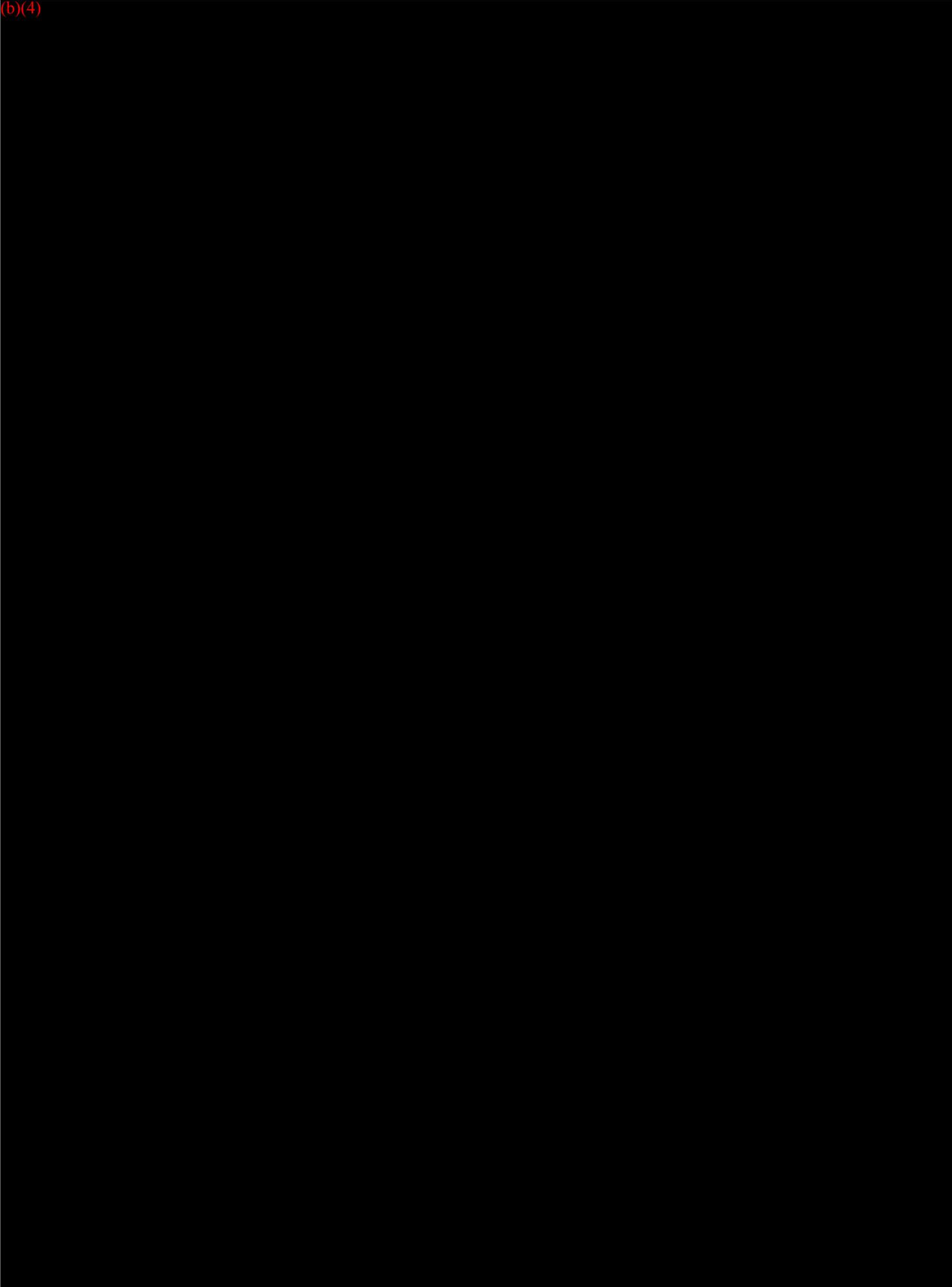
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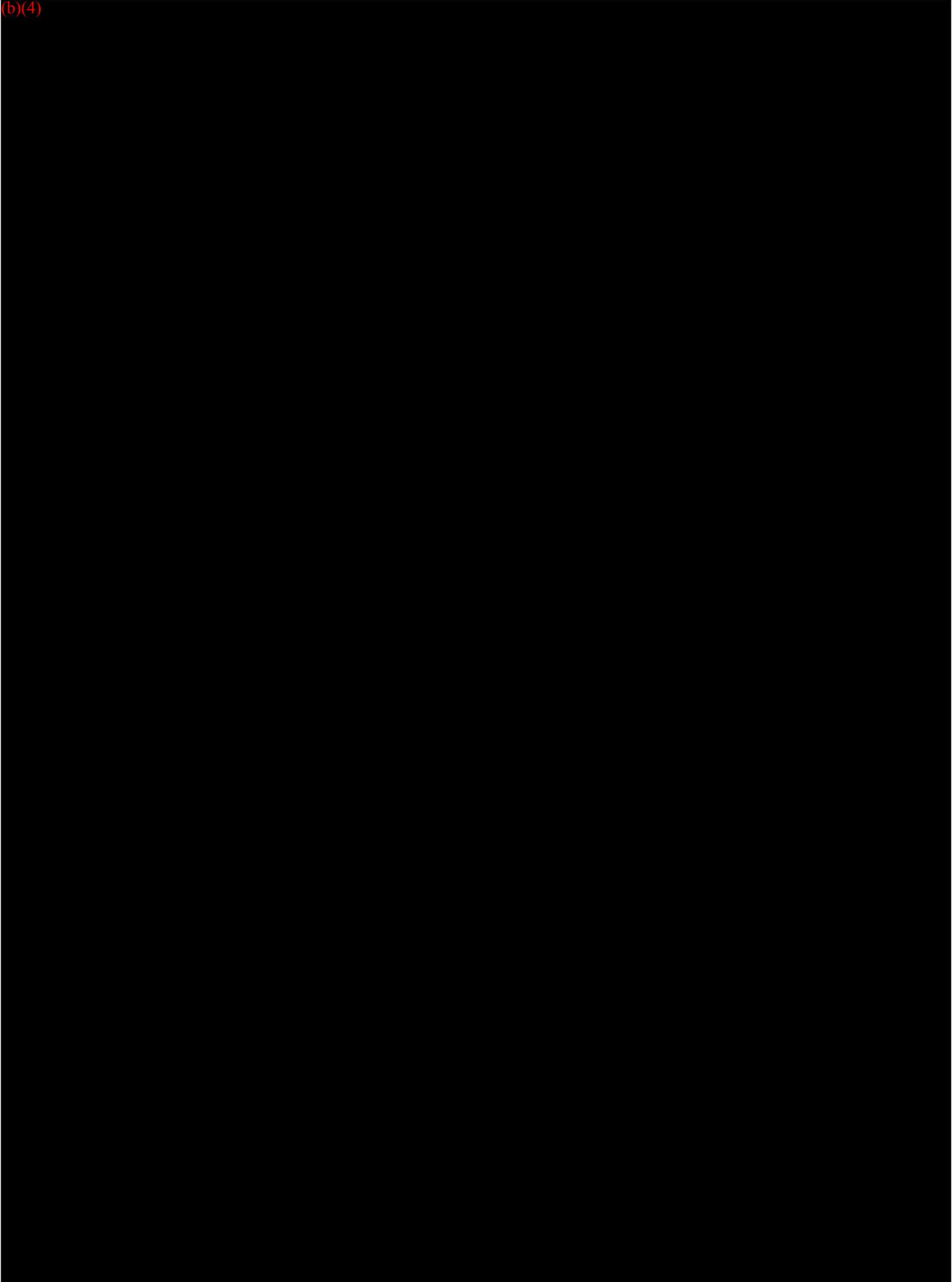
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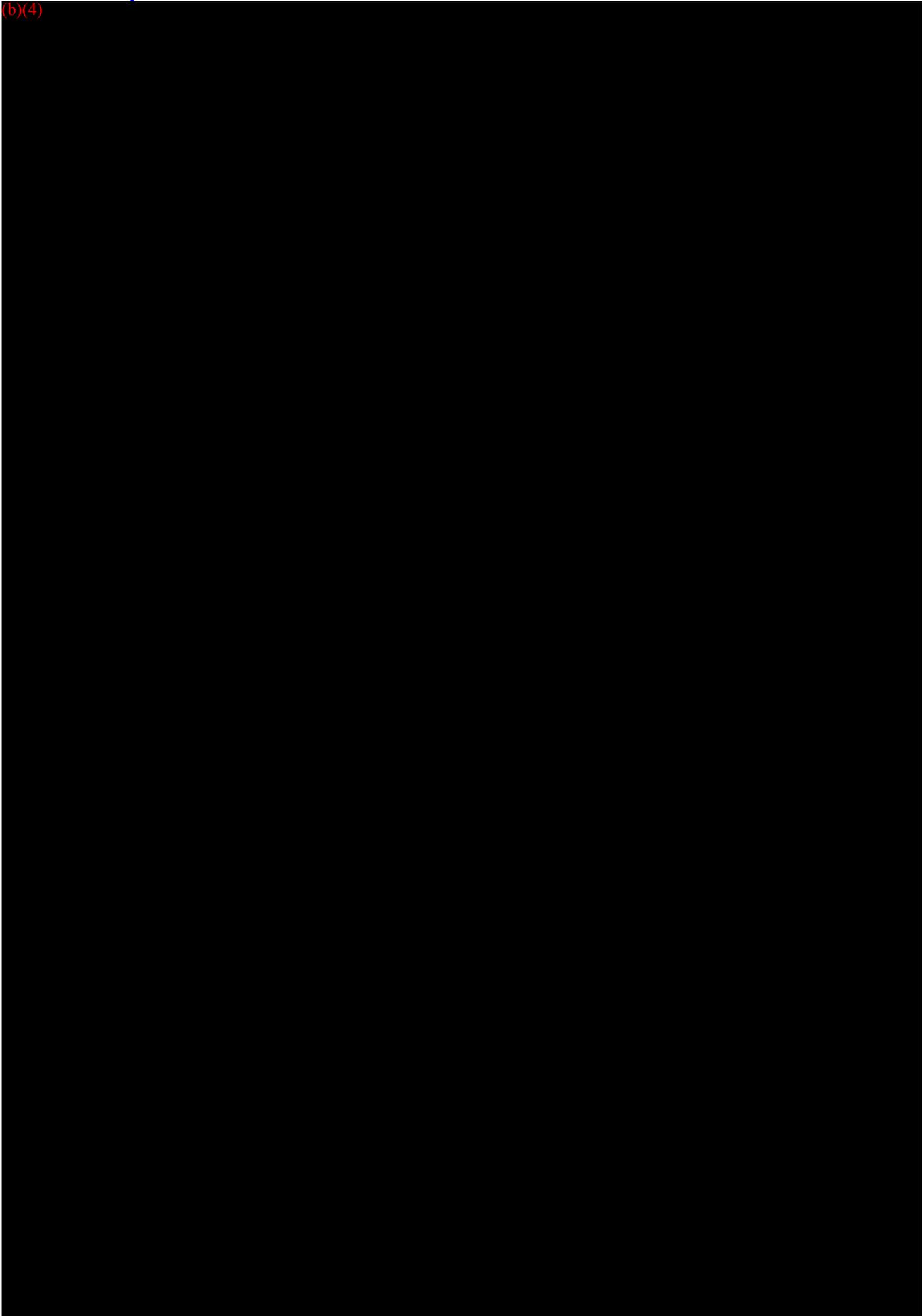
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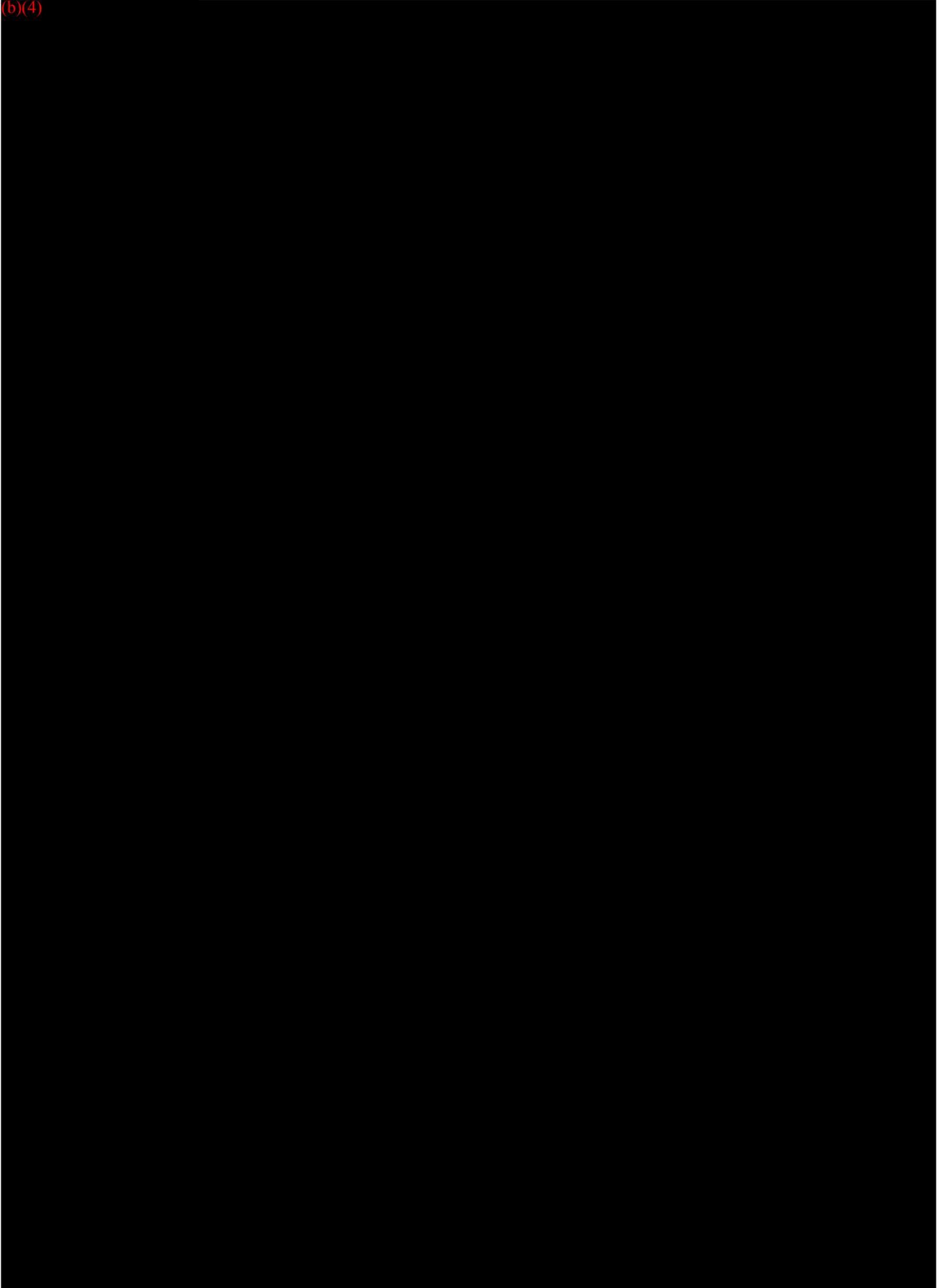
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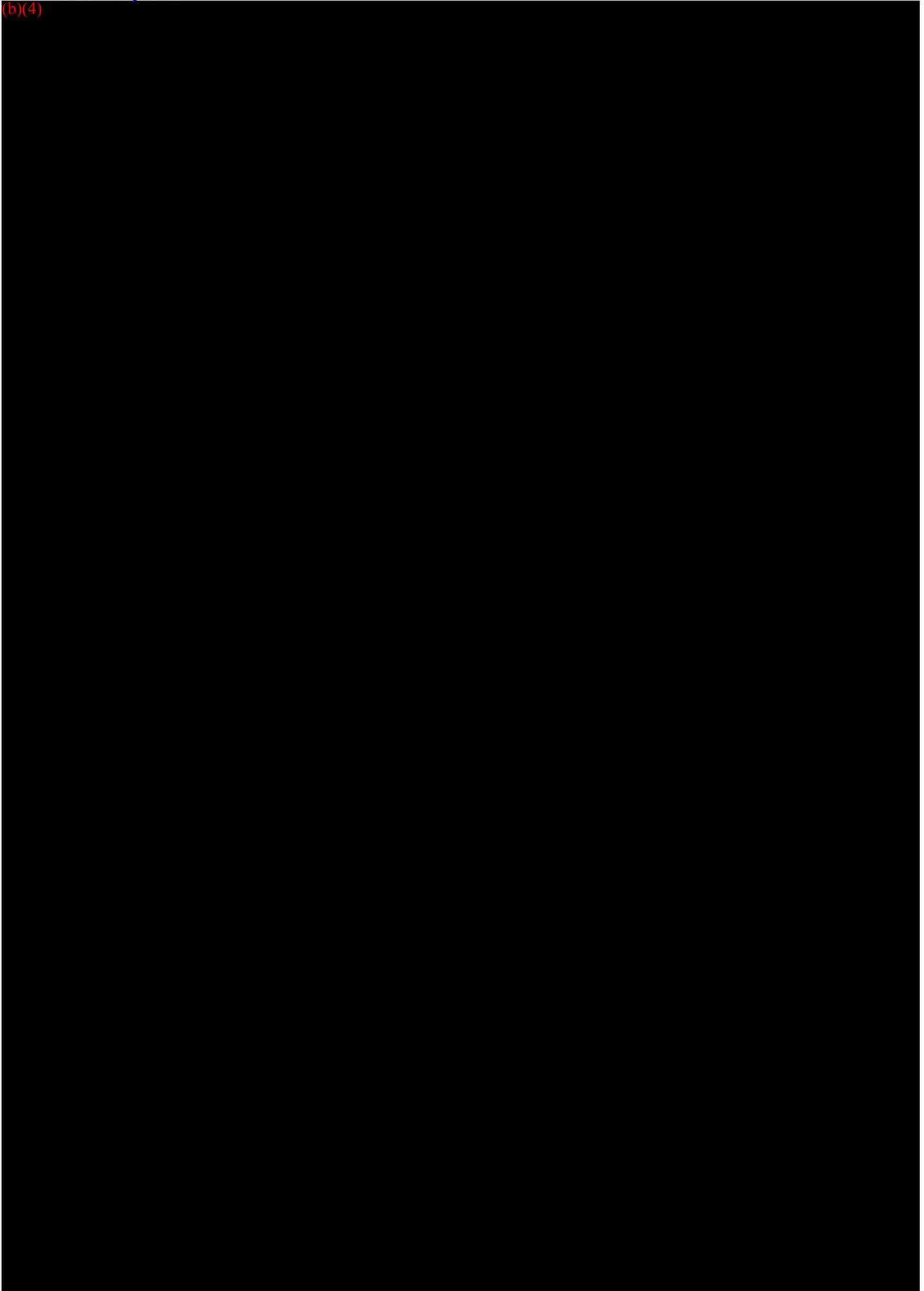
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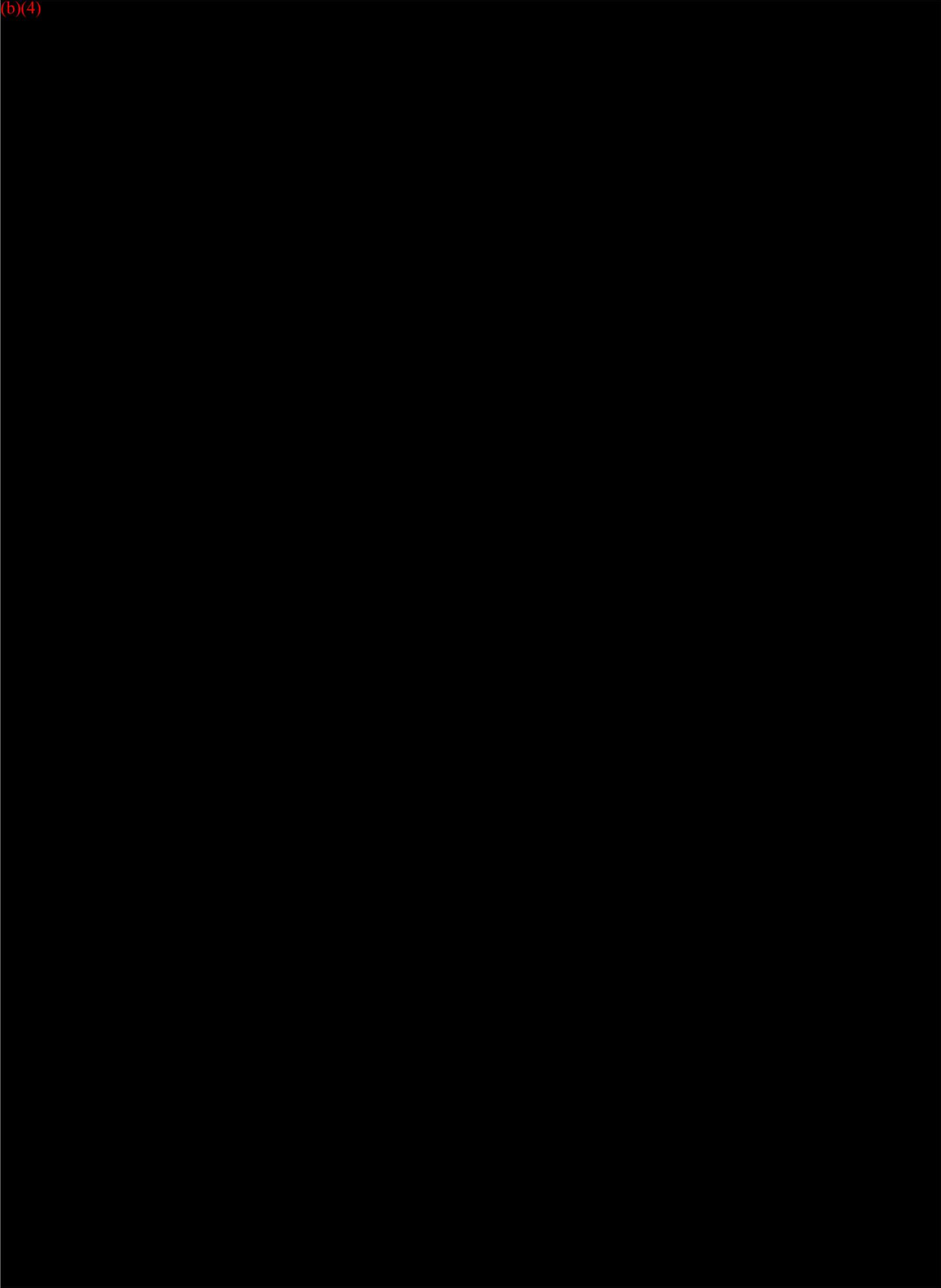
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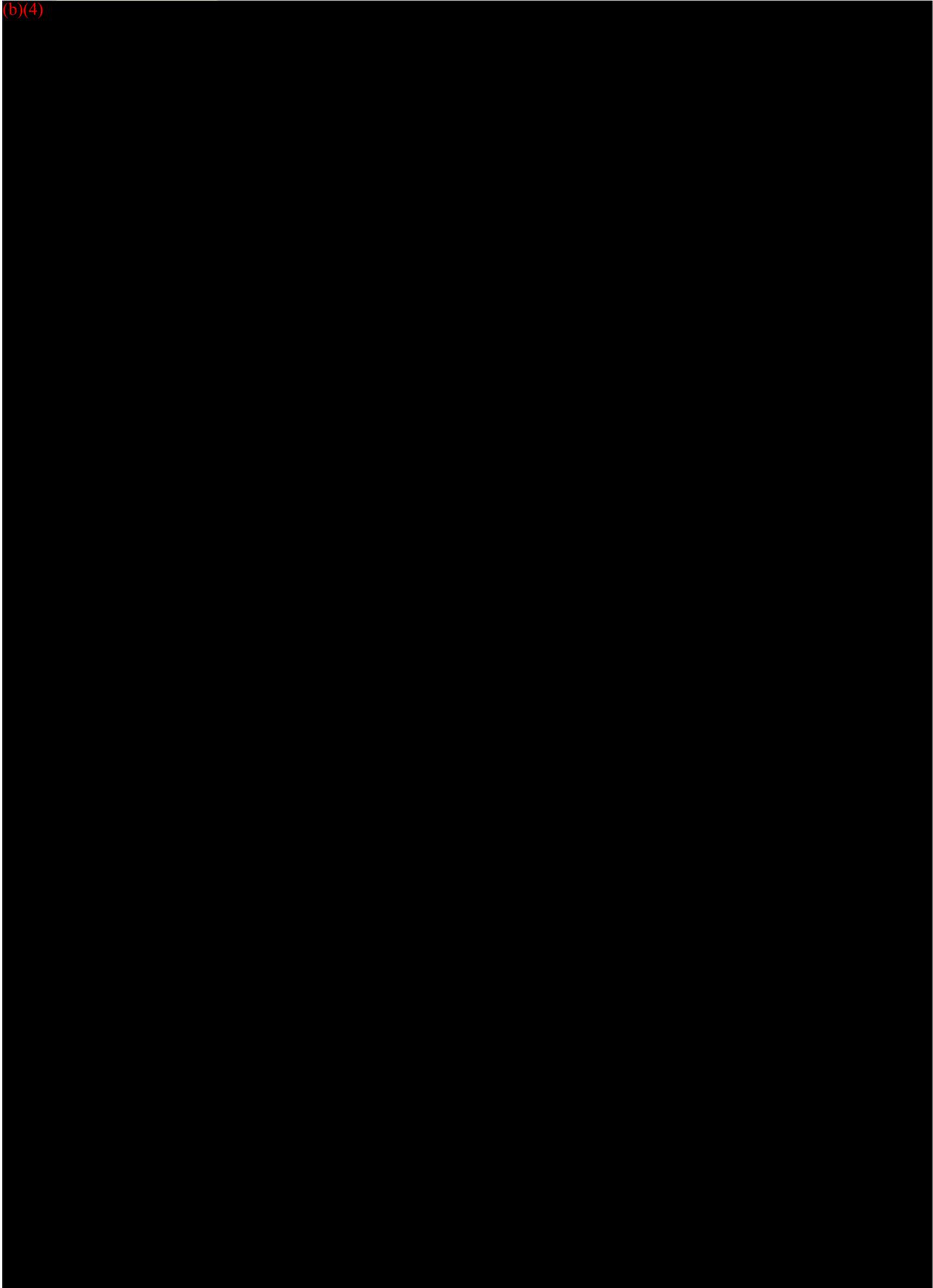
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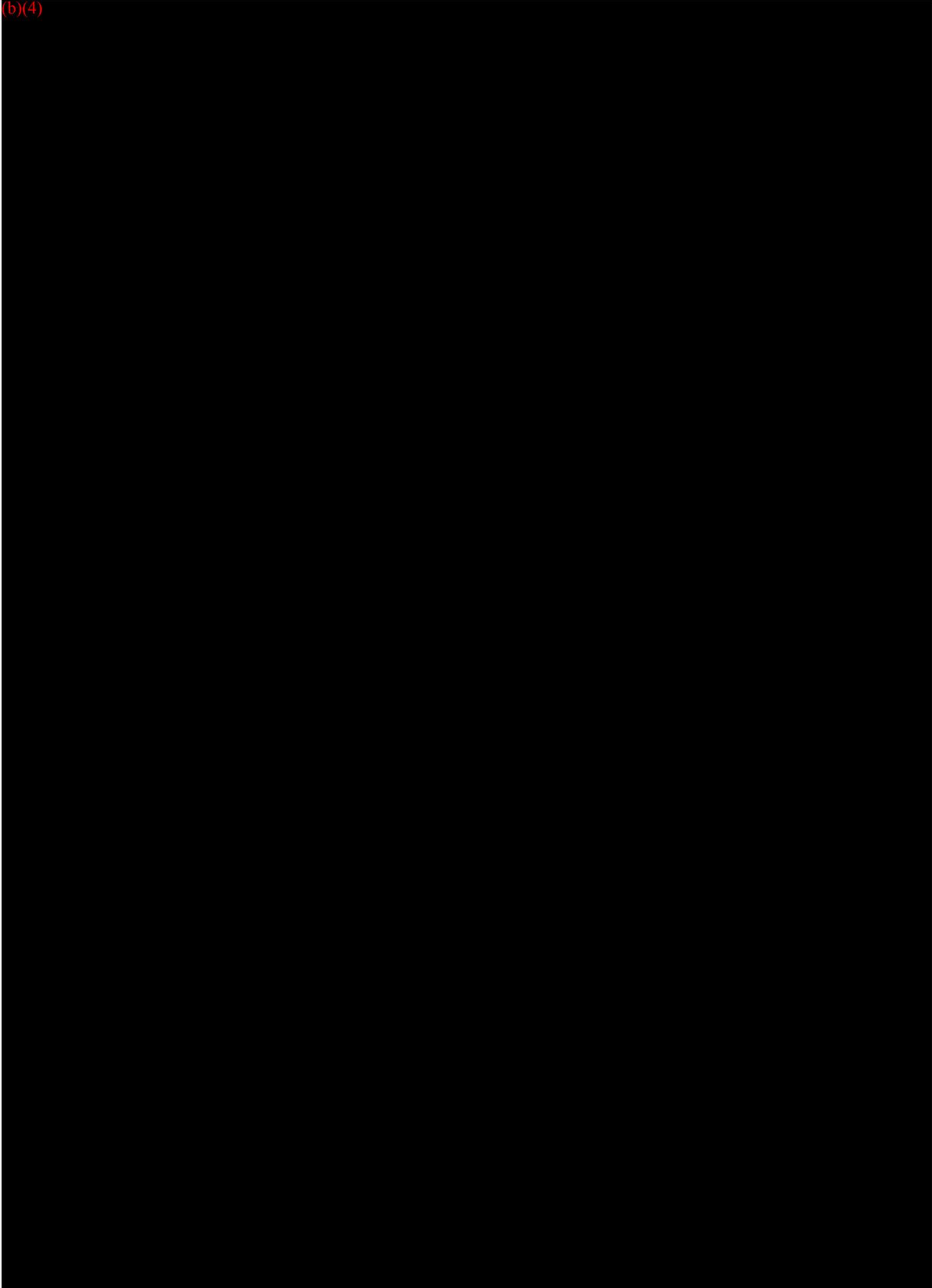
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Test Report :

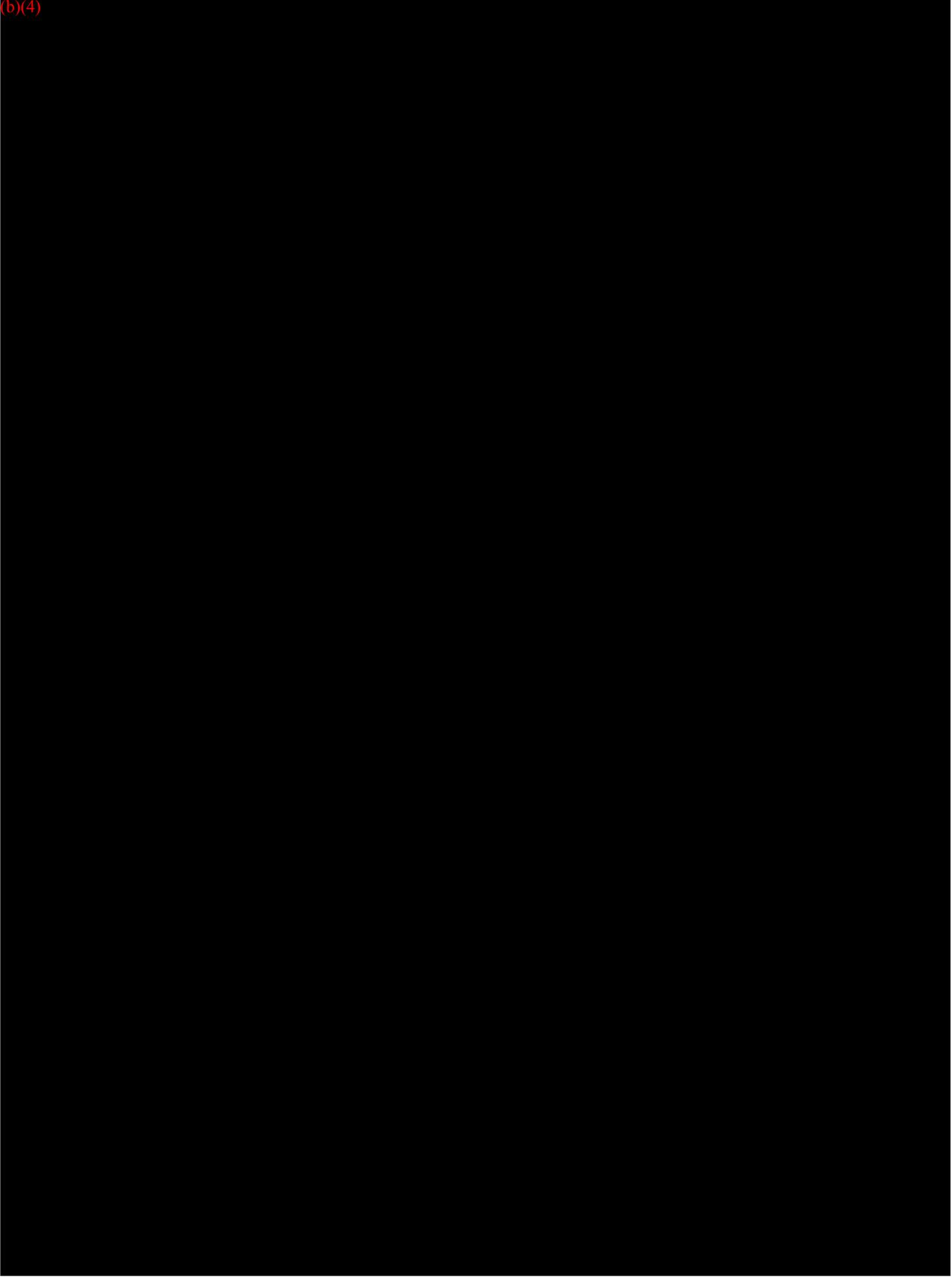
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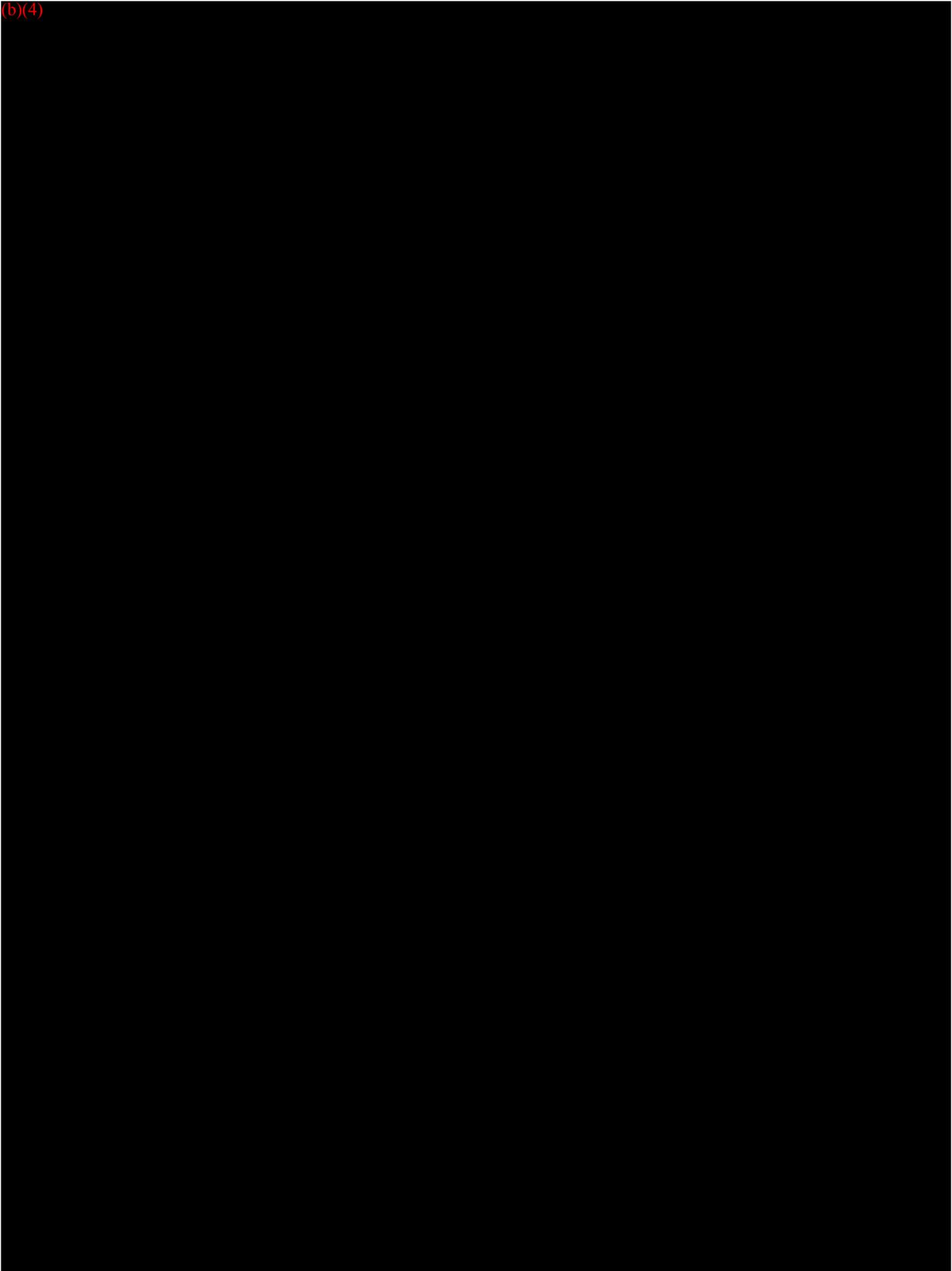
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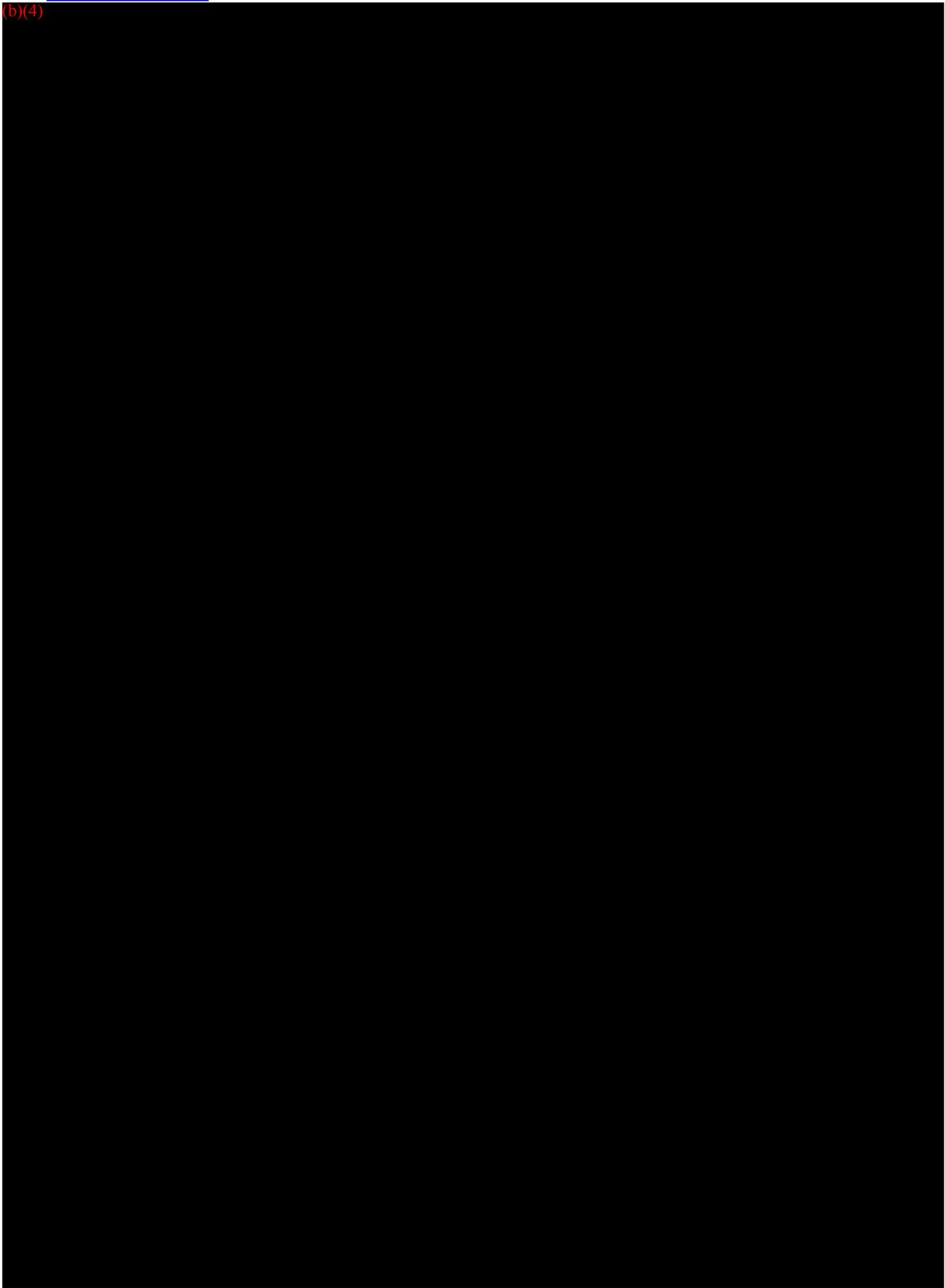
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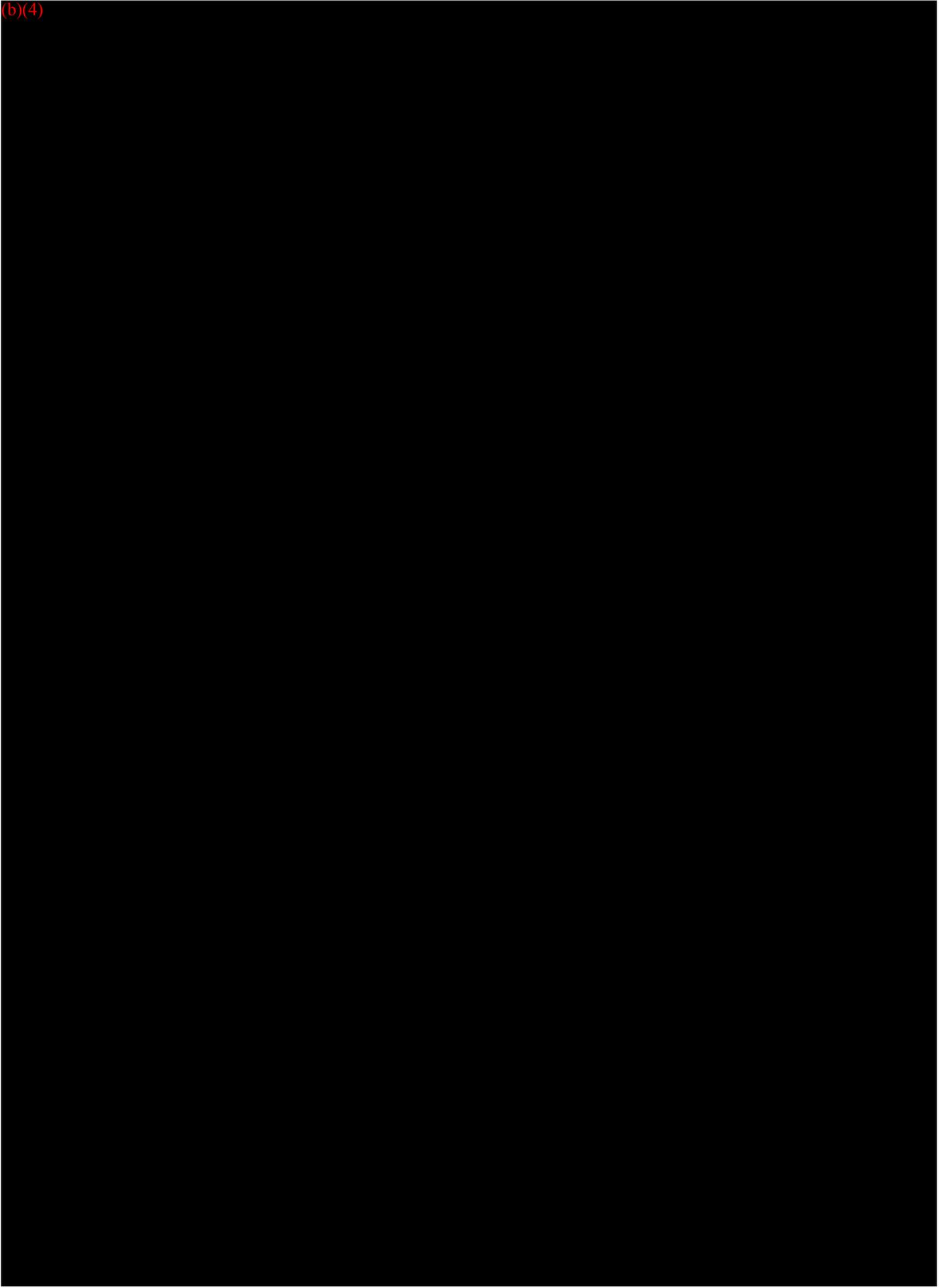
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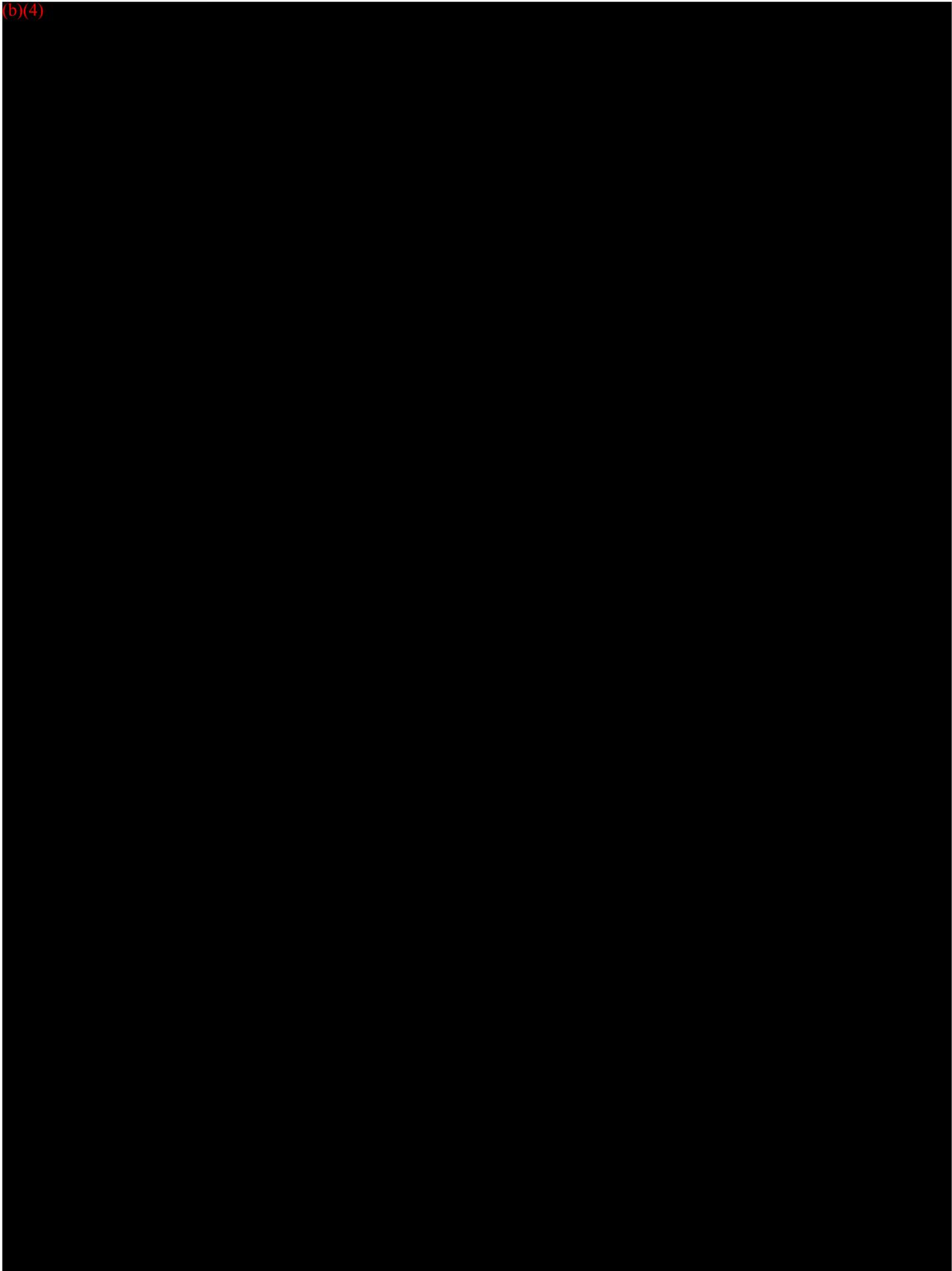
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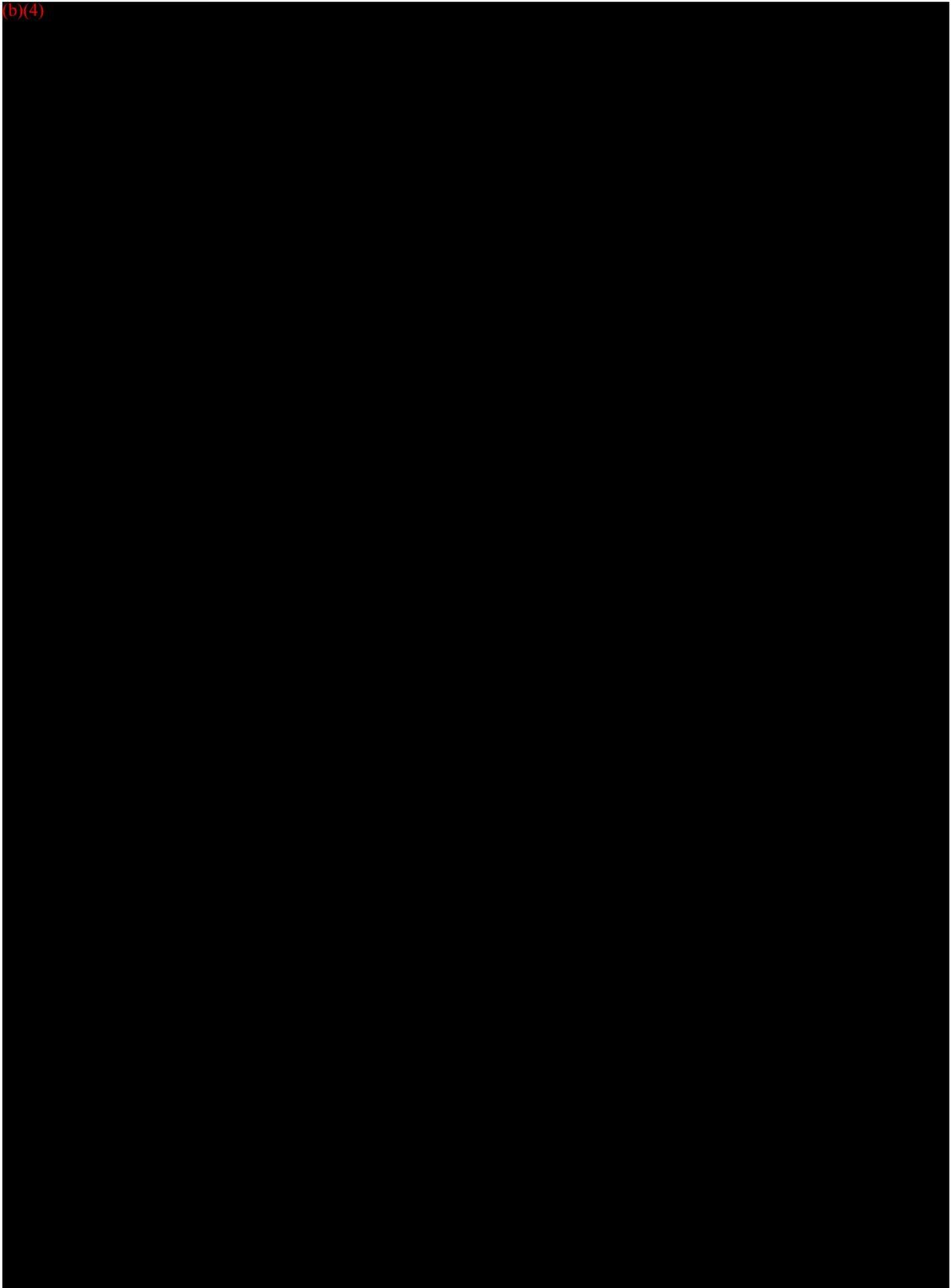
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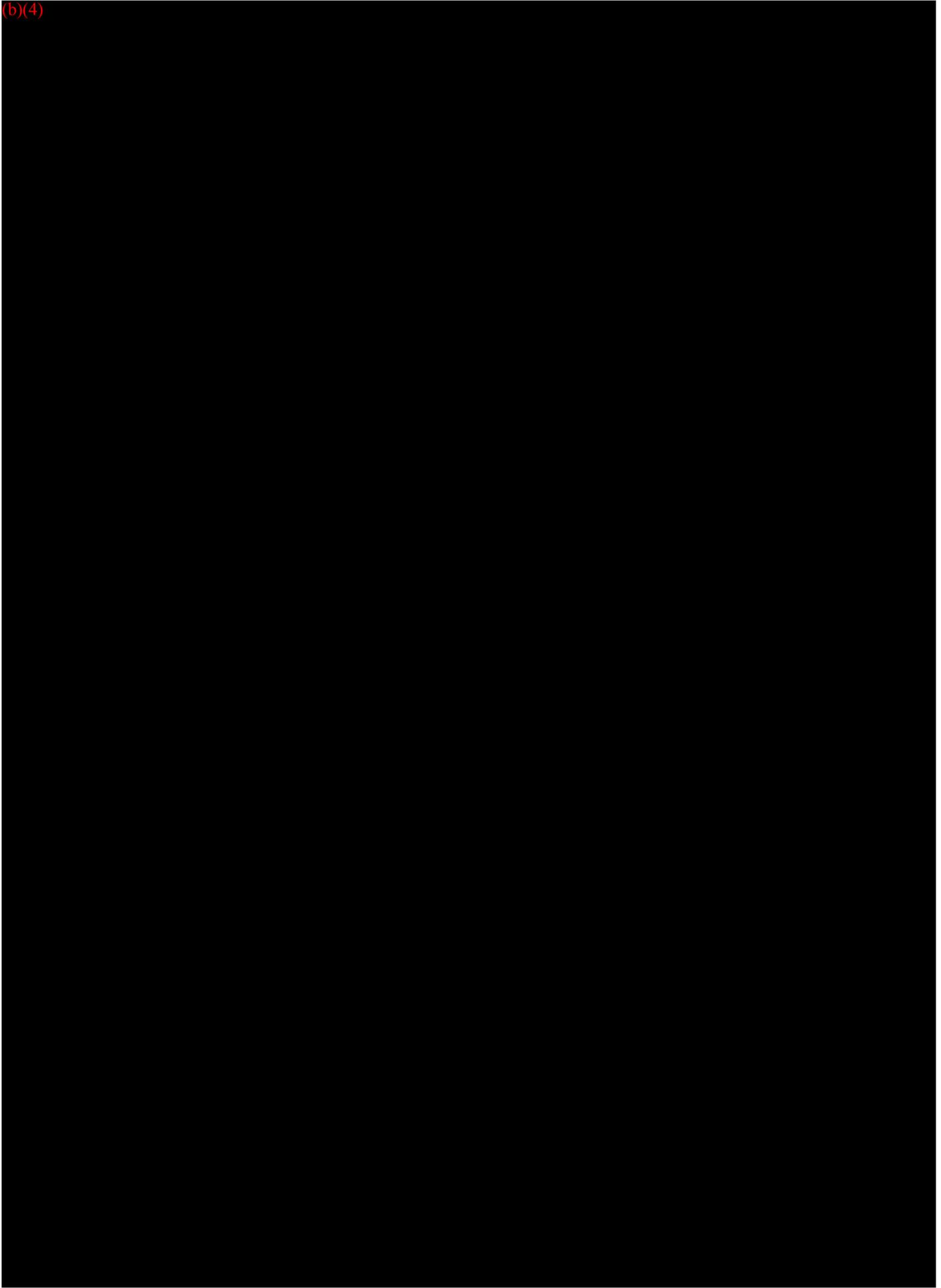
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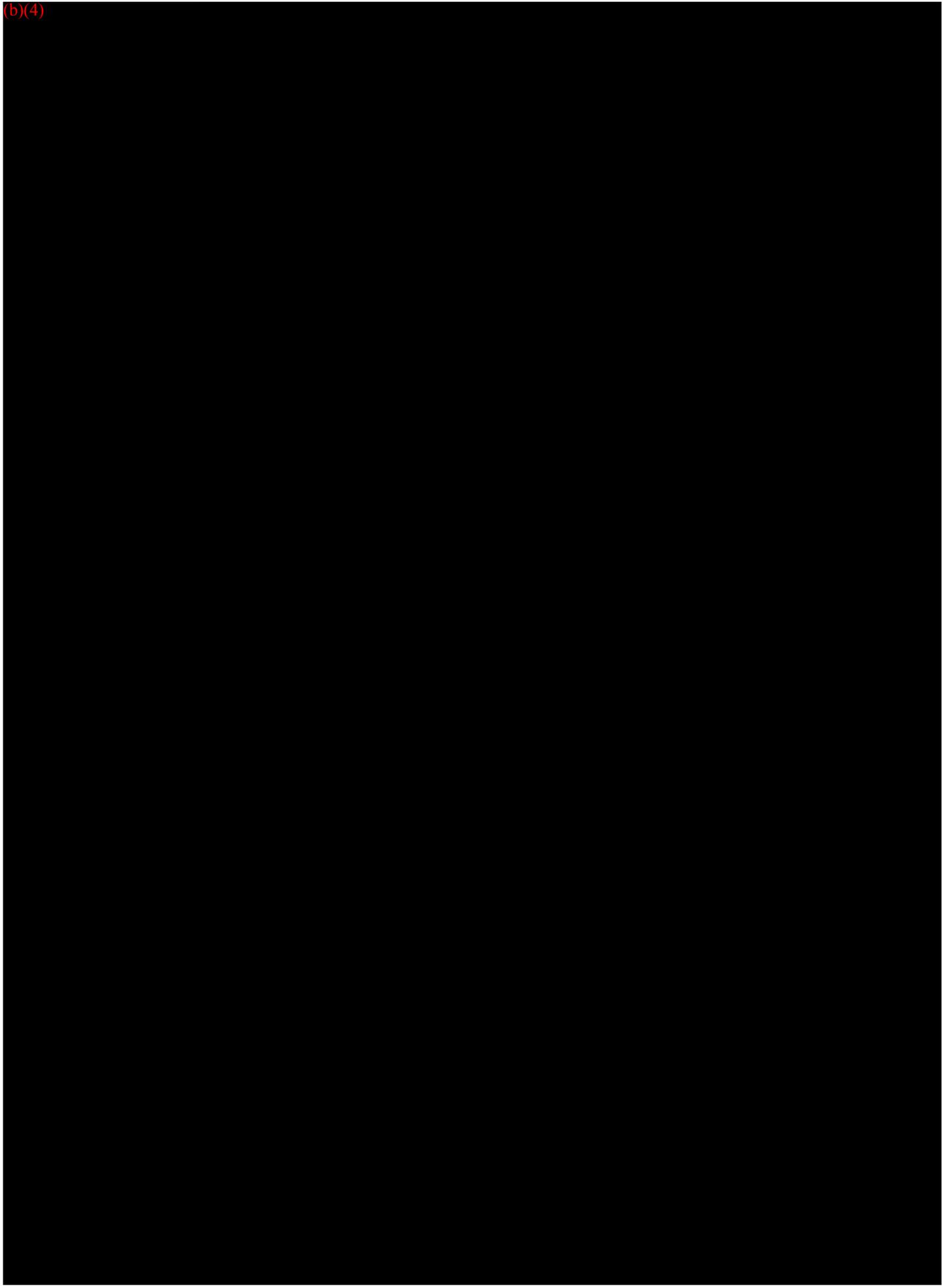
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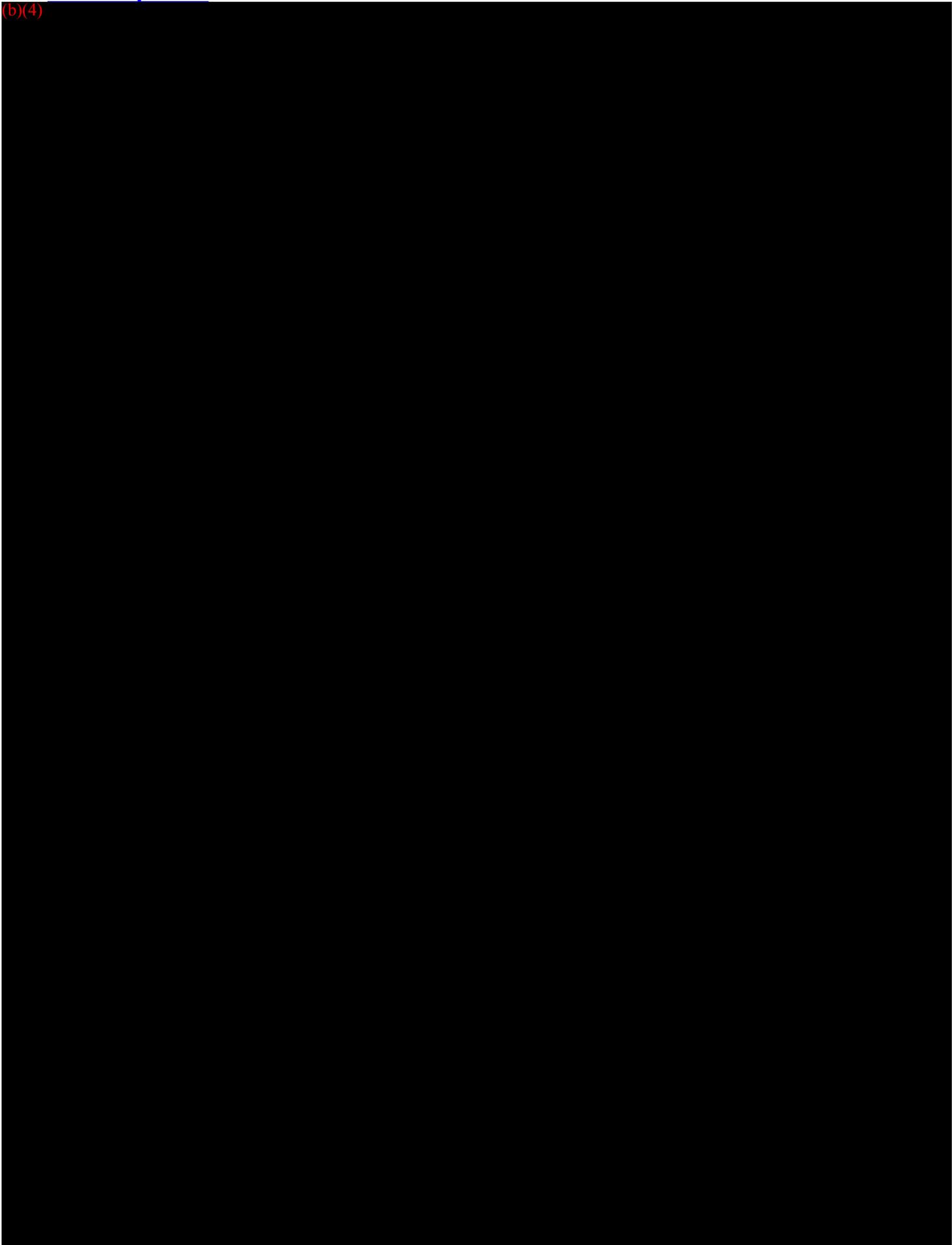
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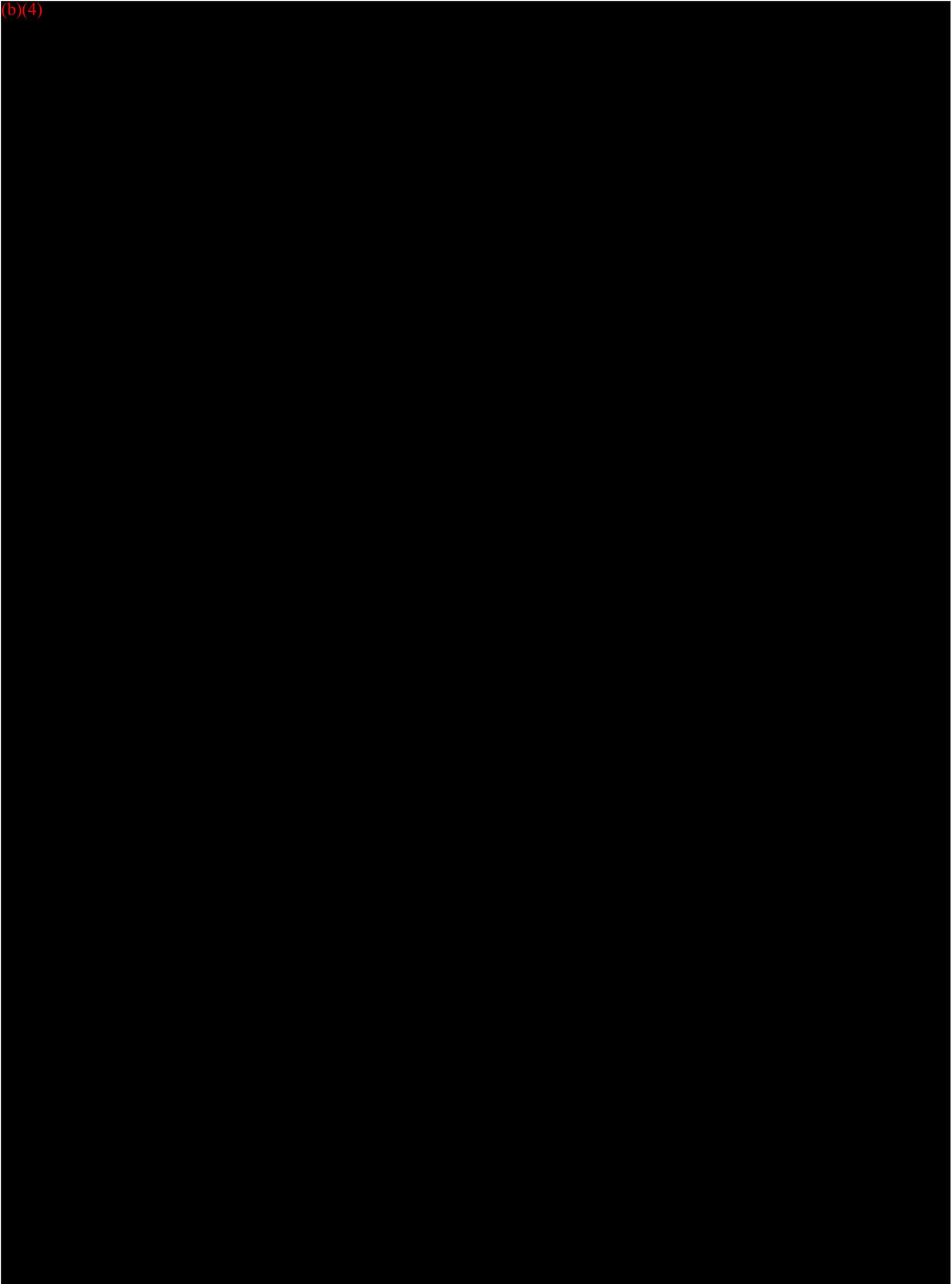
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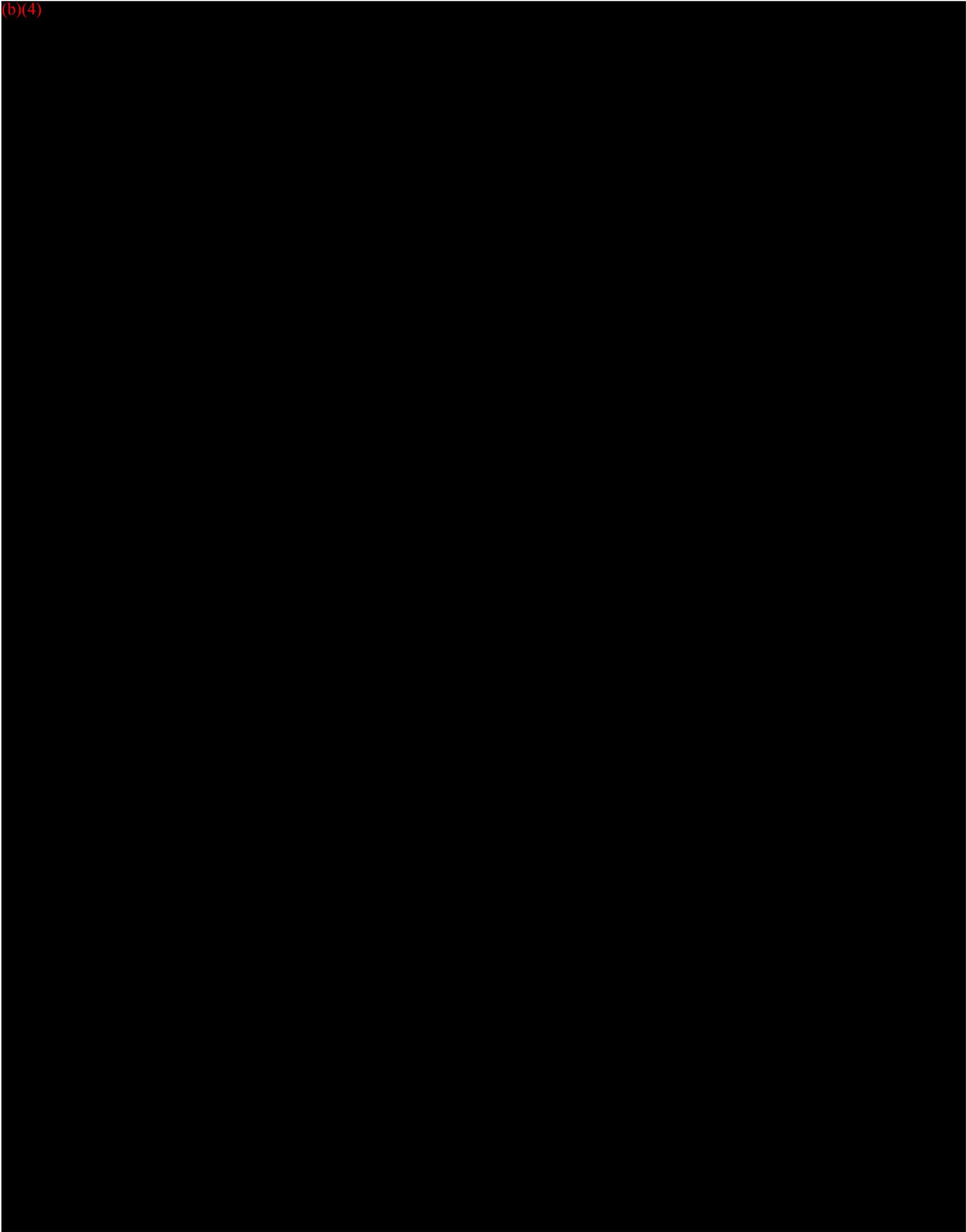
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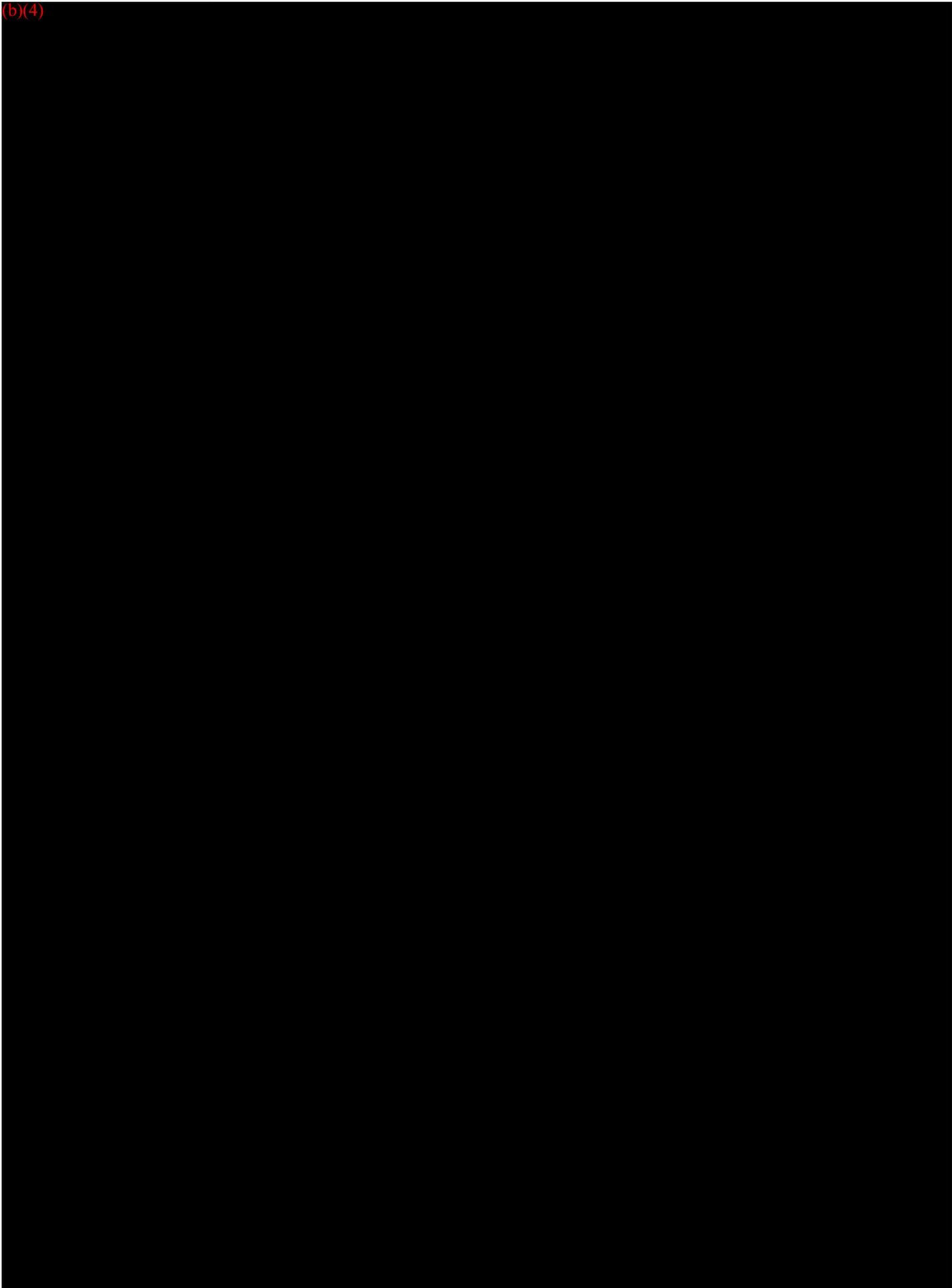
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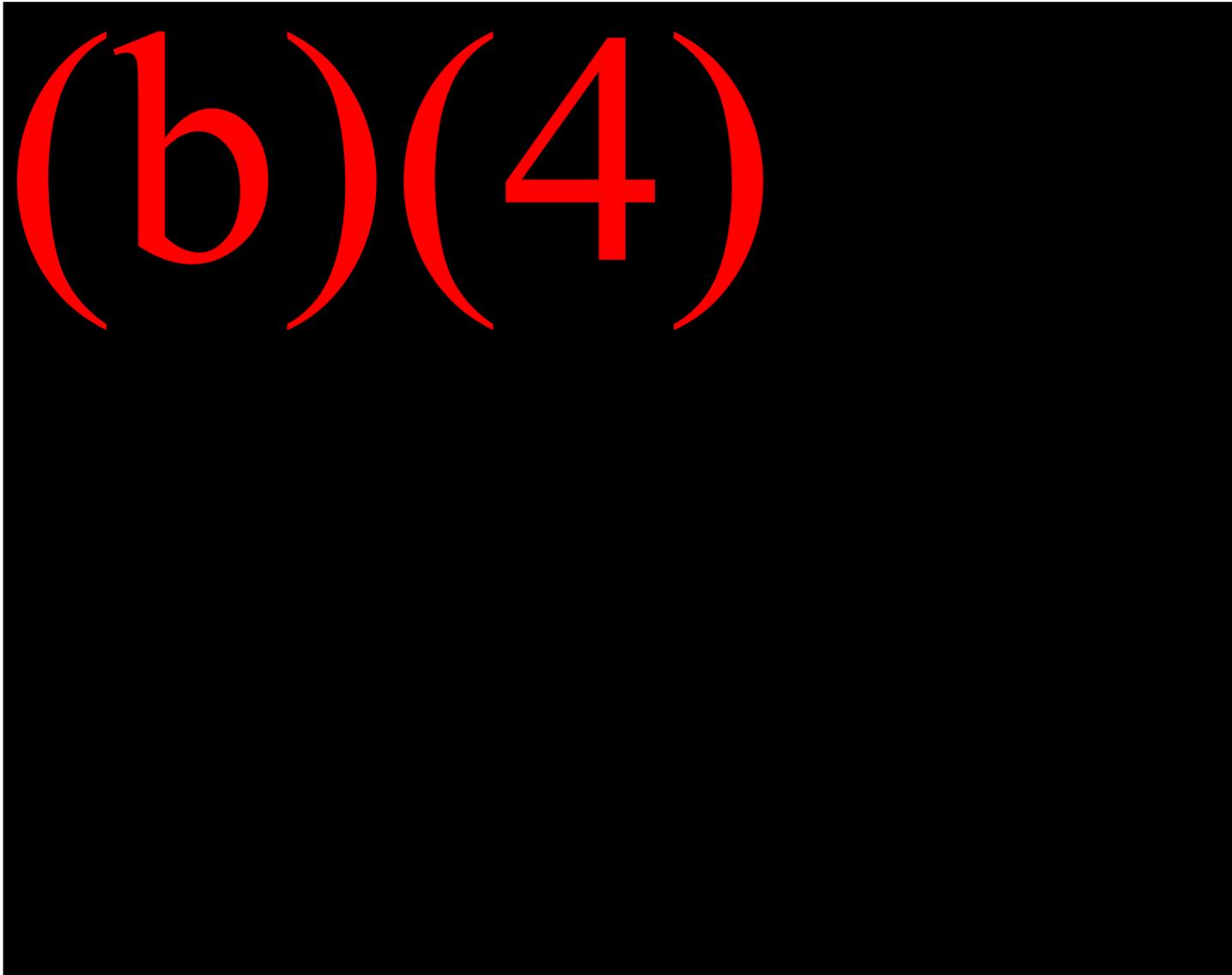
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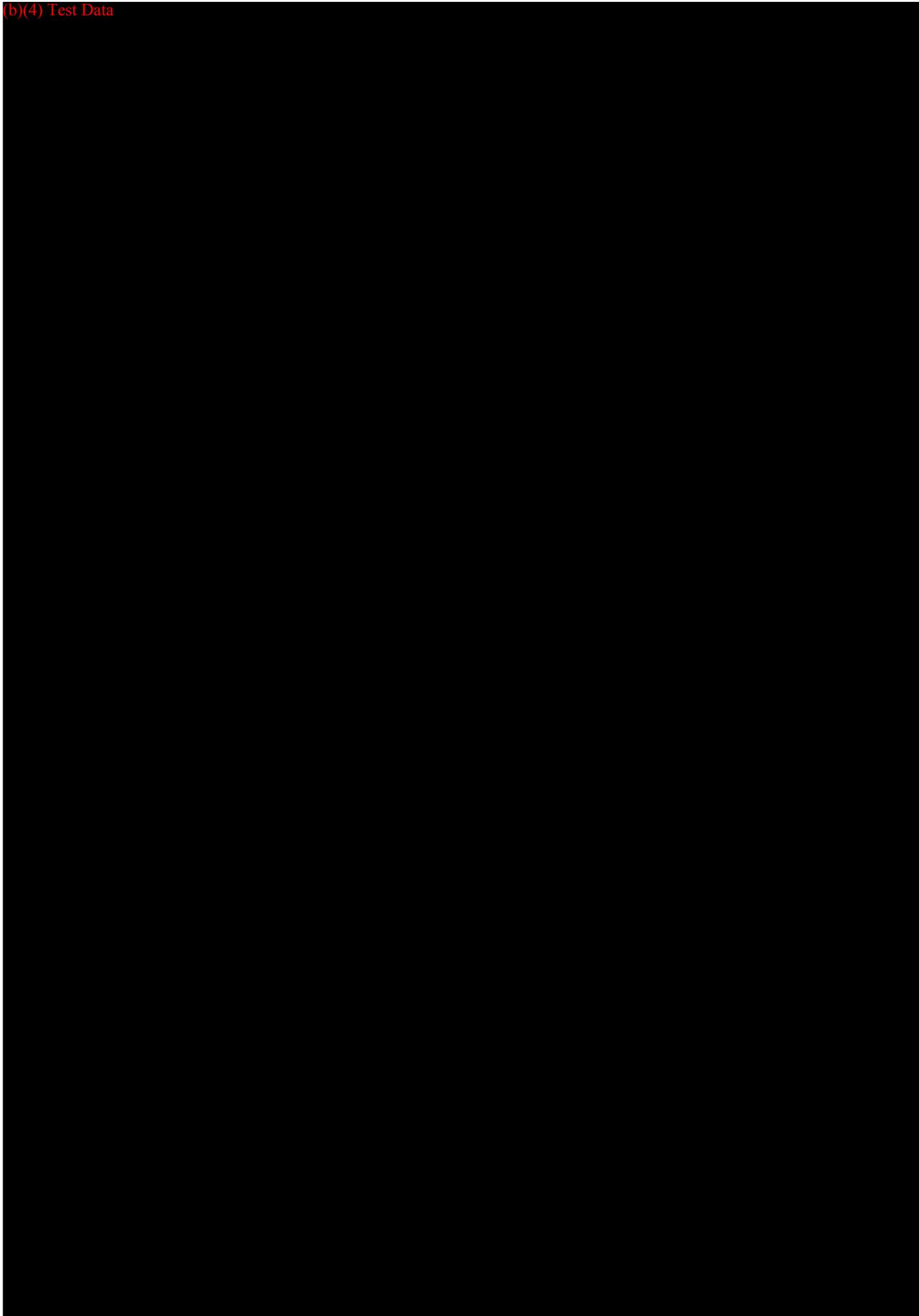
Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

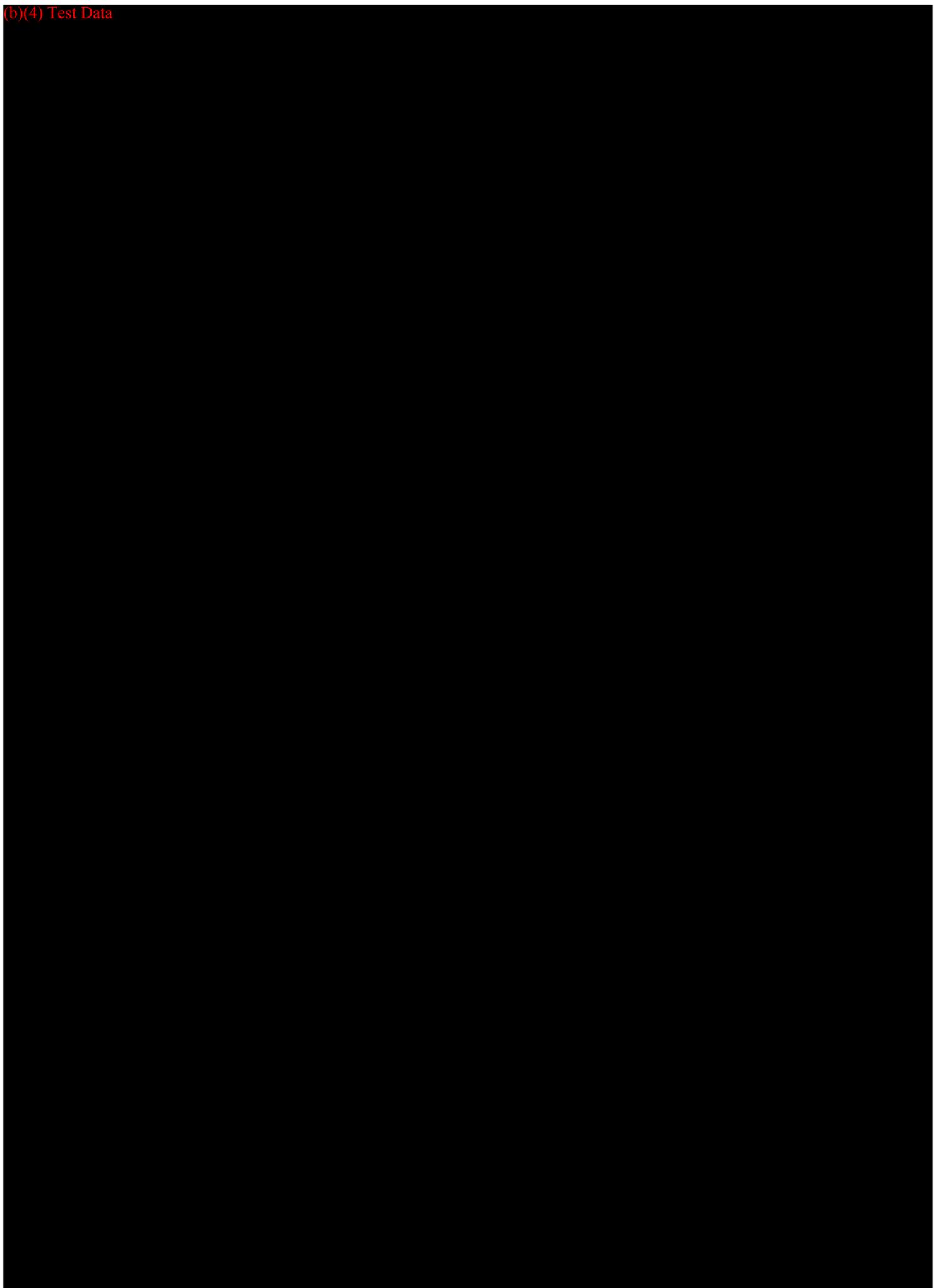


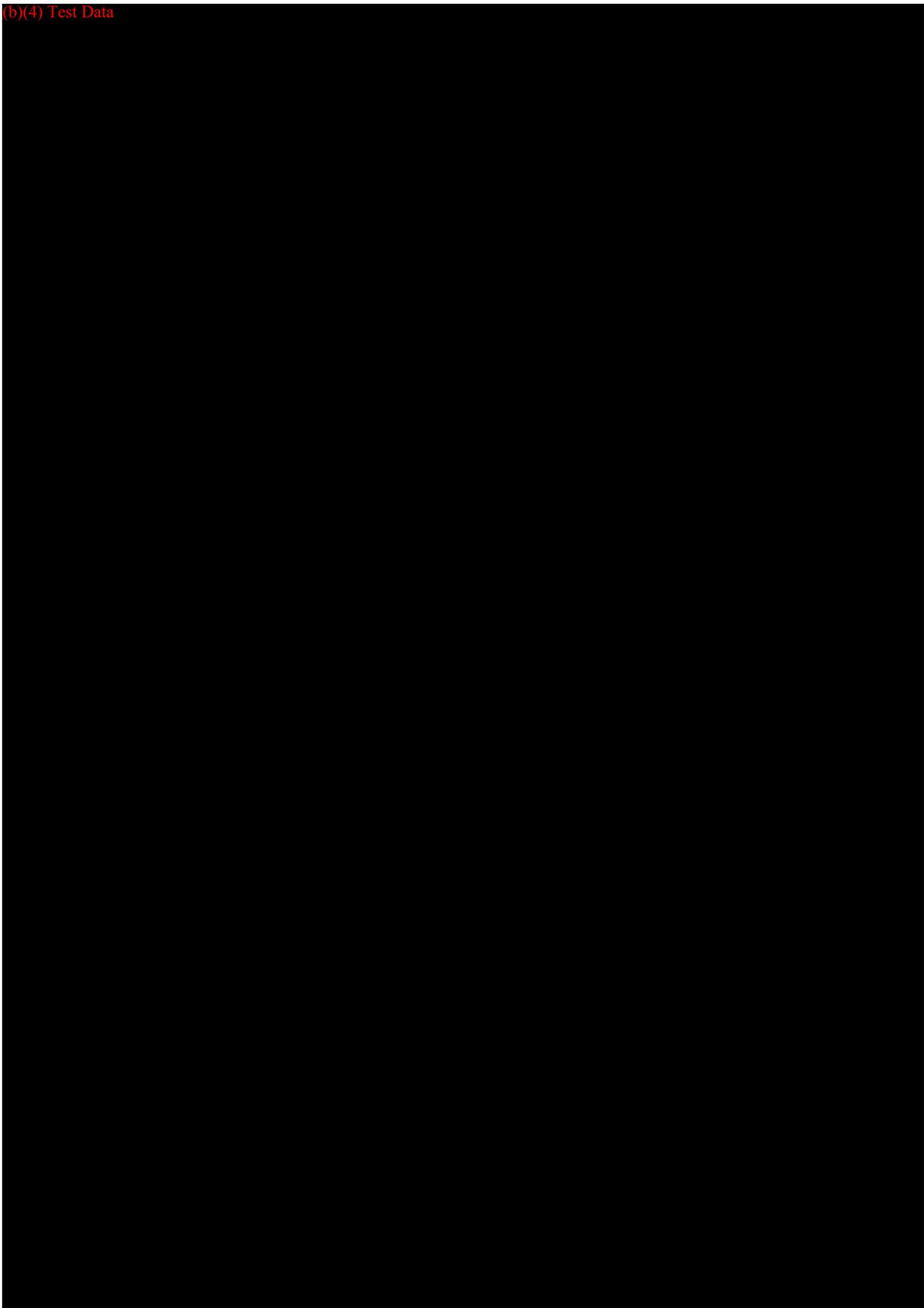
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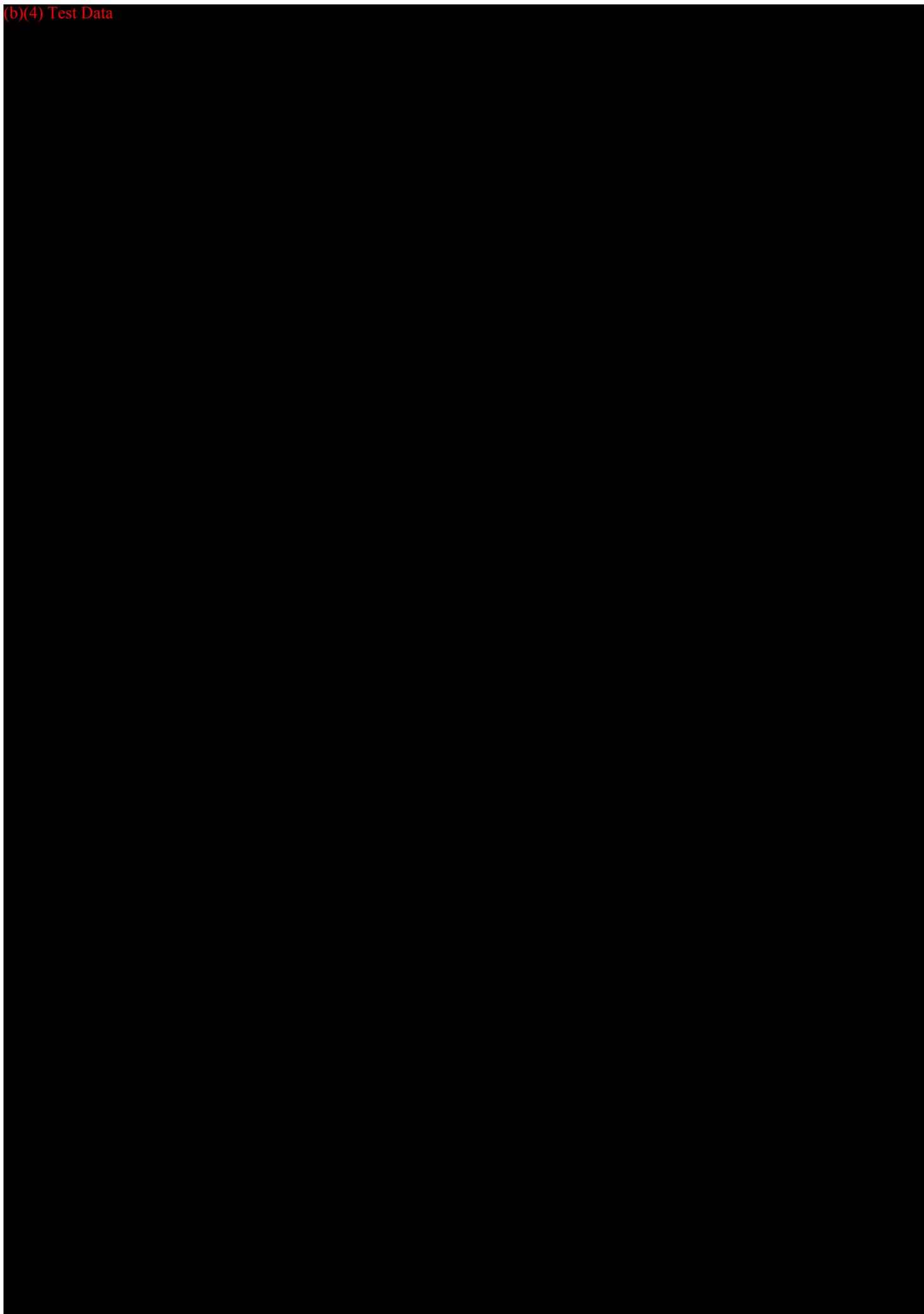
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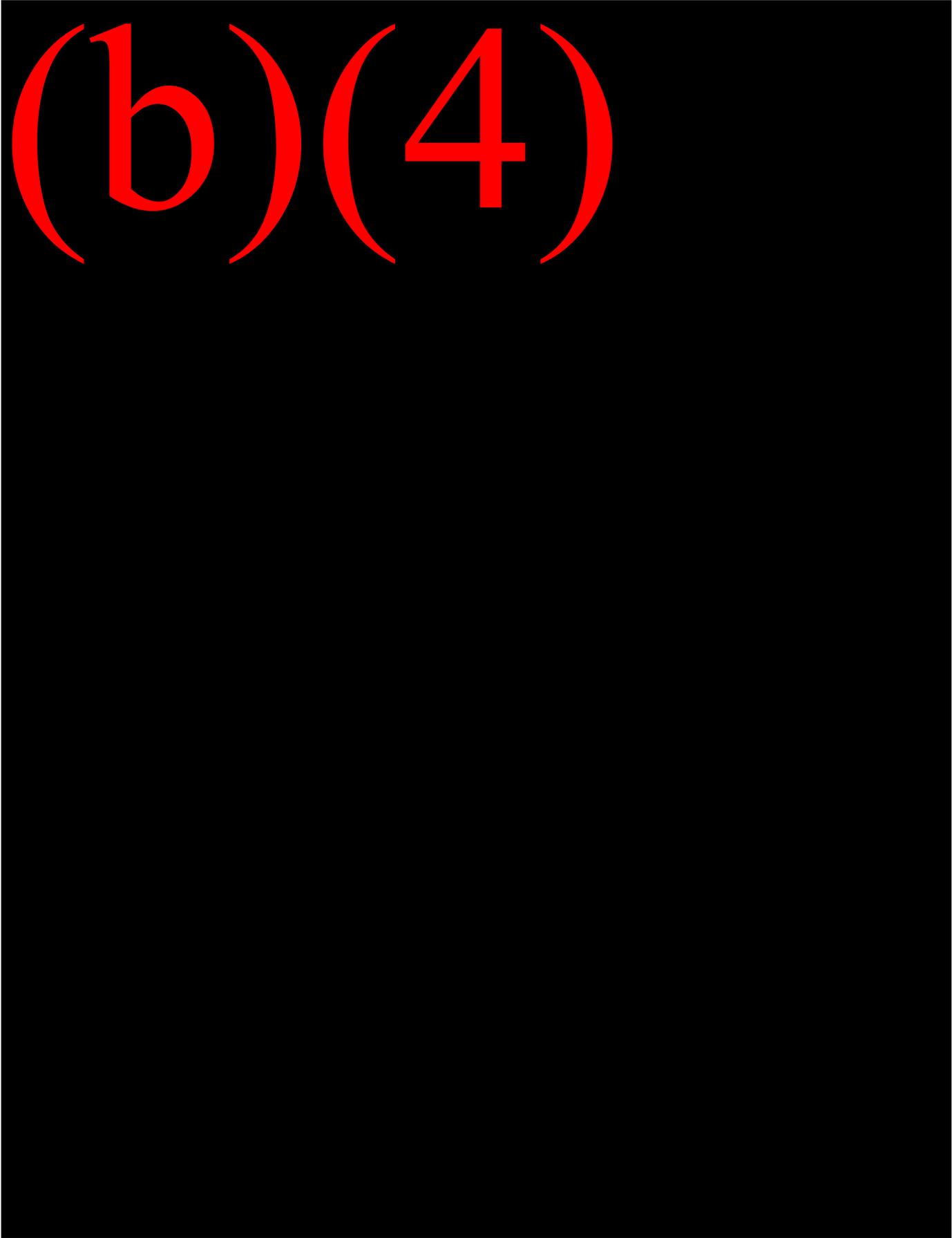
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12. SUBSTANTIAL EQUIVALENCE DISCUSSION

Comparison items	Predicate device 1 (PD1)	Subject device (1)	Subject device (2)	Subject device (3)
Manufacturer Submitter	SPORT-ELEC S.A.	HIVOX-BIOTEK		
Device name	Body Control System	Spopad EMS, SP series		
Model number	4M	SP-910	SP-920	SP-620
510(k) number	K092476	TBA	TBA	TBA
Product code	NGX	NGX		
Classification name	Powered Muscle Stimulator	Powered Muscle Stimulator		
Regulation number	21 CFR 890.5850	21 CFR 890.5850		
Indications for use	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas. Contraindicated use on injured or otherwise impaired muscles Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.		
Technology	Electrical Muscle Stimulation	Electrical Muscle Stimulation		
Power Source	1.5V battery *3	3V Battery *1		
- Method of Line Current Isolation	Battery supply	Battery Supply		
- Patient Leakage Current Normal Condition (μA)	< 3	2.0		
Single Fault Condition(μA)	< 4	2.1		
Method of channel isolation	Software	1 channel		

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Average DC current through electrodes when device is on but no pulses are being applied	0 μ A	0 μ A		
Number of output modes	1	1		
Regulated current or regulated voltage?	Voltage	Voltage		
Software /firmware / Microprocessor control?	Yes	Yes		
Automatic overload trip?	No	No		
Automatic no-load trip?	No	No		
Automatic shut-off?	Yes	Yes		
User overrides control?	Yes	Yes		
Indicator display - On/Off Status	Yes	No		
Indicator display – Low battery?	Yes	No		
Indicator display – Voltage /Current	No	No		
Timer Range (minutes)	N/A	20		
Compliance with voluntary standards?	IEC 60601-1 IEC 60601-2-10 IEC 60601-1-2 IEC 60601-1-4	EN/IEC 60601-1 EN/IEC 60601-2-10 EN/IEC 60601-1-2		
Compliance with 21 CFR 898?	Yes	Yes		
Housing material and construction	ABS	Silicone		
Output waveform	Monophasic	Symmetrical biphasic		
Shape	Rectangular	Rectangular		
Duration of primary (depolarizing) phase	0	0		
Pulse duration (μ Sec)	N/A	400		
Maximum output voltage (Voltage, +/-10%) at 500 ohms	N/A	52	58.4	60
Maximum output voltage (Voltage, +/-10%) at 2k ohms	N/A	98	106	109
Maximum output voltage (Voltage, +/-10%) at 10k ohms	N/A	150	146	140

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Maximum output current (mA +/-10%) at 500 ohms	N/A	104	117	120	
Maximum output current (mA +/-10%) at 2k ohms	N/A	49	53	54.5	
Maximum output current (mA +/-10%) at 10k ohms	N/A	15	14.6	14	
Frequency (Hz)	N/A	3/4/5	2/4/25	2/4/25	
Net charge per pulse at 500 ohms (μC)	N/A	0.416	0.468	0.960	
Maximum charge at 500 ohms (μC)	N/A	41.6	46.8	48	
Maximum current density at 500 ohms (mA/cm^2)	< 2	1.187	1.057	1.952	
Maximum average power density at 500 ohms (W/cm^2)	< 0.25	0.0617	0.0617	0.117	
Burst mode	A. Pulse per burst	N/A	N/A	25	25
	B. Burst per second	N/A	N/A	1	1
	C. Burst duration (sec)	N/A	N/A	20	20
	D. Duty cycle	N/A	N/A	20	20

Summary of comparison

Basically, the predicate device (PD1 and PD2) and Subject Devices are all Over-The-Counter muscle stimulators. Thus, the indications for use for the devices do not differ much. Basically the devices are to stimulate the muscle of the healthy body.

PD and Subject Devices are all battery-powered, thus electric hazards or safety do not raise much concern, since maximum current / power densities for the devices are all less than 2 (mA/cm^2) / 0.25 (W/cm^2), which are the FDA recommended ratings. Since the electric output data for PD and Subject Devices only exist minor differences, the minor differences of the electric outputs do not raise any safety or effectiveness aspect. PD and Subject Devices all have the same safety and effectiveness, especially they all pass medical device electric safety standard, IEC 60601-1 and standard for Nerve and Muscle Stimulator, IEC 60601-2-10 and electromagnetic compatibility standard IEC 60601-1-2.



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We know that for effectiveness in achieving repeated muscle contractions, powered muscle stimulators typically are capable of stimulating muscle for at least one second per burst, and are capable of providing at least one second of muscle relaxation between successive pulse bursts. PD should meet these requirements. Subject Devices meet these requirements too. PD and Subject Devices are all validating-software processing, thus keeping regular processing parameters and safety functions normal. The Subject Devices have the same effectiveness as the predicate device.

In conclusion, the Subject Devices do not raise any new safety or effectiveness aspect with respect to the PD. Thus the Subject Devices are **substantially equivalent** to the predicate device.



FDA Home³ Medical Devices⁴ Databases⁵

510(k) Premarket Notification



510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³
CFR Title 21¹⁴|Radiation-Emitting Products¹⁵|X-Ray Assembler¹⁶|Medsun Reports¹⁷|CLIA¹⁸|TPLC¹⁹

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Device Classification Name	<u>Stimulator, Muscle, Powered, For Muscle Conditioning</u> ²⁰
510(K) Number	K092476
Model	4M
Device Name	SPORT-ELEC BODY CONTROL SYSTEM, MODEL 4M
Applicant	SPORT-ELEC 141 Research Drive Compliance Dept. Hampton, VA 23666
Contact	Kimberly Ross
Regulation Number	<u>890.5850</u> ²¹
Classification Product Code	<u>NGX</u> ²²
Date Received	08/12/2009
Decision Date	05/07/2010
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	Neurology
Summary	<u>Summary</u> ²³
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No

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19. [../cfTPLC/tplc.cfm](..cfTPLC/tplc.cfm)

K092476

5. 510(K) SUMMARY

[As Required by 21 CFR 807.92]
Summary of Safety and Effectiveness

1	Submitter	SPORT-ELEC S.A. Route de Rouen BP 35 27520 Bourgtheroulde France	MAY - 7 2010
	Contact Person	Karine Coral / Sylviane Lardeur Phone number : (+33) 2 32 96 50 50 Fax number : (+33) 2 32 96 50 59	
	Preparation date	Jan 20 th 2009	
2	Device name	Body Control System "4M"	
	Trade Name	SPORT-ELEC®	
	Common Name	Muscle stimulator	
	Code product and classification name	Stimulator, muscle, powered for muscle conditioning (NGX) 21 CFR Section 890.5850 Powered Muscle Stimulator	
3	Predicate devices	SPORT-ELEC Body Control System, manufactured by Sport-Elec REF BCS K 081026 Cleared Nov 5 th 2008 Sport-Elec REF BCS AT K 091865 Cleared Nov 13 th 2009 Sport-Elec REF BCS BS K 092142 Cleared Feb 5 th 2010	
4	Description	Body Control System "4M" is a 2 channel battery operated muscle stimulation system specifically designed to exercise the muscles. It comprises namely an electronic stimulator module which generates the required stimulation signals. Body Control System "4M" comprises 4 electrodes, which connects the signals from the stimulator to the skin. (EXHIBIT C) The product is supplied with a User's Guide and a carry case.	
	Explanation of how the device operates	Power is supplied from 3 batteries located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors.	
	Intended use	The Body Control "4M" is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes -improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas	

- 5 Performance data Testing was carried out to assure compliance with recognized electrical safety standards:
IEC 60601-1 and -2-10 standards for electrical safety
IEC 60601-1-2 standard for electromagnetic compatibility
IEC 60601-1-4 standard for the software (ISO 14971).
Performance data were also verified versus the requirements of the FDA Guidance for Pre Market Submissions and for Software contained in Medical Devices.
- 6 Substantial equivalence summary The technological characteristics, features, specifications, materials, mode of operation, and intended use of the Body Control System "4M" device are substantially equivalent to the predicate devices quoted above.
The differences that exist between the devices do not raise new issues of safety or effectiveness regarding the Body Control System Device.
The Body Control System "4M" use the same as the BCS system in its delivery of the stimulation signal and has similar parameter setting. There are similar restrictions between the two devices in that electrode positioning is governed by the user manual.



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

Sport-Elec S.A.
% Ms. Camille D. Thornton, M.S.
Regulatory Specialist
144 Research Drive
Hampton, Virginia 23666

MAY - 7 2010

Re: K092476
Trade/Device Name: Body Control System "4M"
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: April 27, 2010
Received: April 28, 2010

Dear Ms. Thornton:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFICES/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Body Control System "4M"

Indications for Use: Body Control System 4M is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.

Contraindicated use on injured or otherwise impaired muscles

Not intended for use in any therapy or for the treatment of any medical conditions or diseases

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X____
(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)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092476



HIVOX BIOTEK INC.

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13. PROPOSED LABELING

First we place three User Manuals in the section 13.1, and the other labeling in the sections 13.2.

13.1 User Manuals

Refer to 3 user manuals for the proposed devices of SP-910 / SP-920 / SP-620.

ELECTRICAL MUSCLE STIMULATOR



SpopadTM

Instruction Manual

For

SP-910

WELCOME

Dear user, thank you for choosing HIVOX Spopad SP-910. Please read the manual carefully to learn the correct operation of this equipment. Understanding the operation will enable you to discover and enjoy the benefits of the device for a long time.

Manufacturer: HIVOX BIOTEK INC
5/F, #123 Shingde Road. Sanchong City, 24158,
Taipei Taiwan R.O.C.
Tel:886-2-85112668 Email: vt@hivox-biotek.com
Ver. 1.0, July 2014.



Important information is highlighted by these terms:

Contraindications – Symptoms or diseases the device not applied to

Warnings – Danger for patient or operating staff.

Precautions – Information for preventing damage to the product.

Adverse Reactions – Important operating instructions.

Product Description

EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relax stiff muscle through the skin. It is recognized as a clinically proven, effective, non- medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training.

SP-910 is a 1-channel battery-operated user-friendly muscle stimulation systems specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-910 comprises 2 electrodes, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors. The shelf life of the device is 30 months. For more information about HIVOX Spopad SP-910, please visit our website at <http://www.hivox-biotek.com> or contact our customer service for further assistance.

Indications for Use

The Electrical Muscle Stimulation unit is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.

Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Contraindication

- Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

- If you are in the care of a physician, consult with your physician before using this device;
- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;

- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal;
- Do not apply stimulation over painful areas. If you have painful areas, you should consult with your physician before using this device;
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
- Do not apply stimulation over, or in proximity to, cancerous lesions;
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
- Do not apply stimulation when in the bath or shower;
- Do not apply stimulation while sleeping;
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury; and
- Do not use the device on children. The device has not been evaluated for pediatric use.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals; and
- Apply stimulation only to normal, intact, clean, healthy skin.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.

Precautions

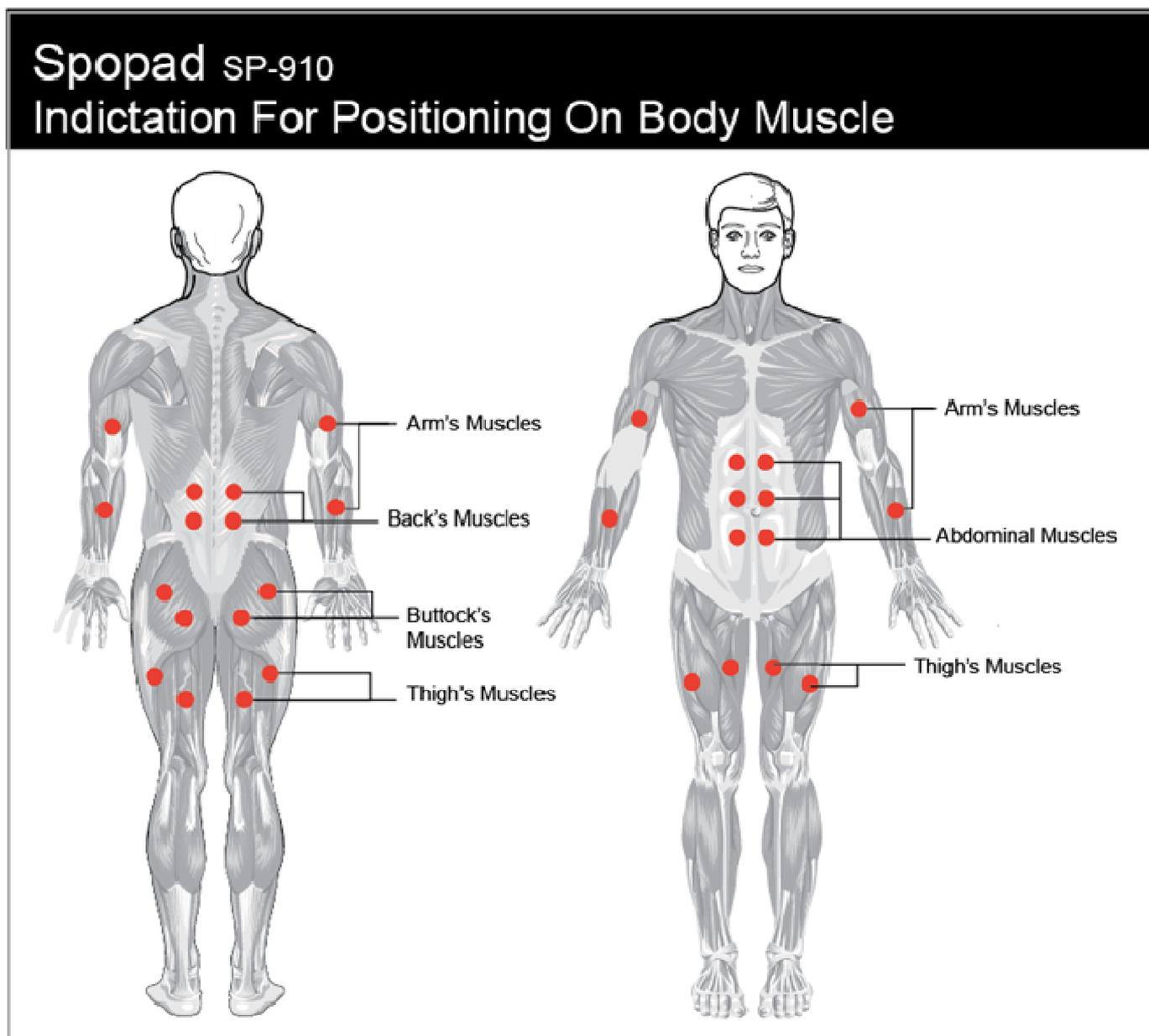
- The long-term effects of electrical stimulation are unknown;
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head;
- The safety of electrical stimulation during pregnancy has not been established;
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- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician; and
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture;
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;
- Use caution if stimulation is applied over the menstruating or pregnant uterus; and
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

Adverse Reactions

- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;
- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face; and
- You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

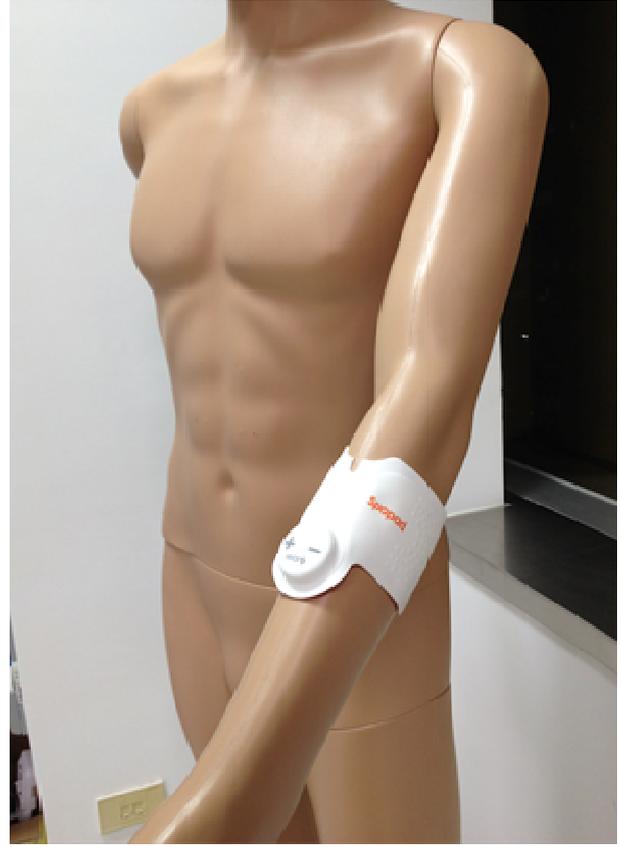
Indications for positioning the unit on body (*Back's muscles are not included in the indications for use, and it is only for reference.*)

1. Body muscle map



2. Positioning photos

2.1 Arm's muscles



2.2 Abdominal muscles



2.3 Buttock's muscle



2.4 Thigh's muscles



Spopad SP-910 Program Mode:

SP-910 has one program mode with 3 cycles which are changing cycle by cycle automatically. Please see the table as below:

Spopad SP-910 Program Mode			
Cycle	Pulse Width	Frequency	On-Time
1	400µs	3 Hz	30 Sec.
2	400µs	4 Hz	30 Sec.
3	400µs	5 Hz	30 Sec.

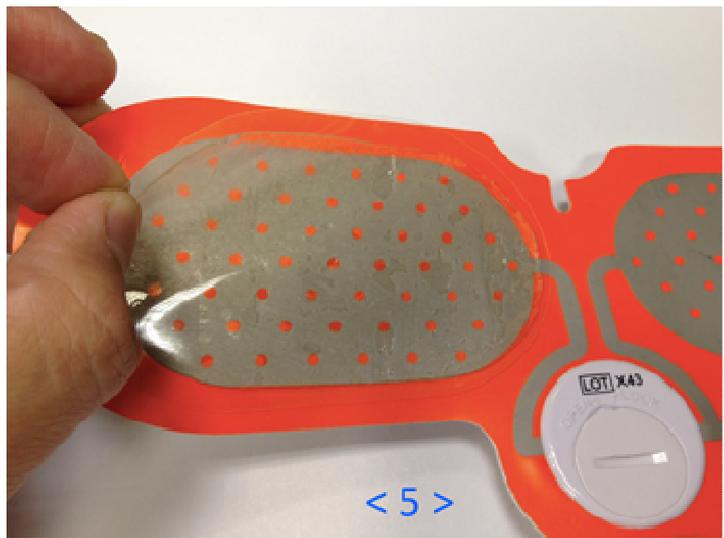
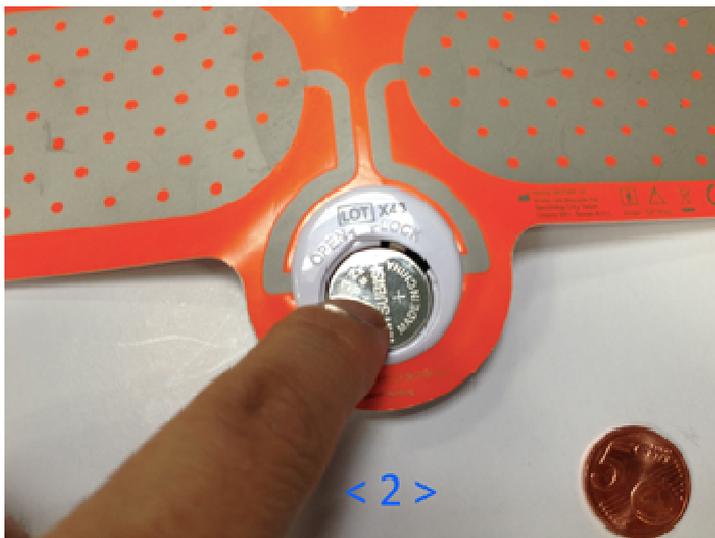
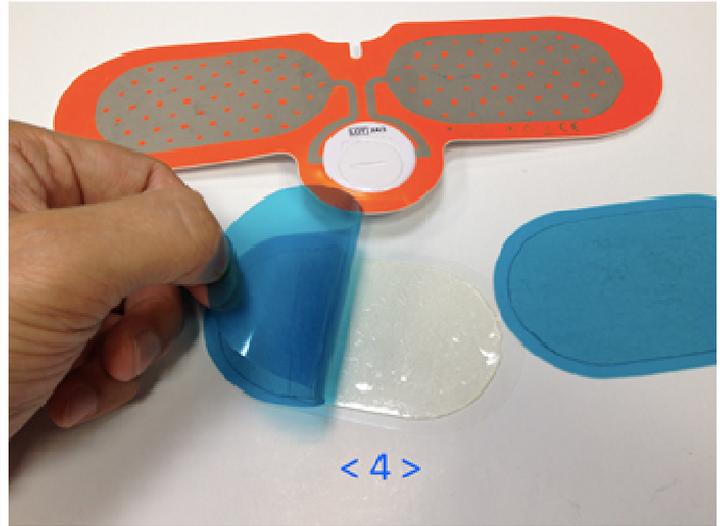
Spopad SP-910 is designed for one program mode with 3 cycles, and this mode with 3 cycles are not able to adjust. It uses external electrical impulses that act through the skin to stimulate the specific muscle group to improve, tone, firm & strengthen the muscles of Arm, Thigh, Abdomen, and Buttock. The muscle reacts in different ways depending on the strength of current and duration and frequency of the electrical impulse.

Those 3 cycles of one mode run automatically without changing by manual setting, all you have to do is to apply the unit to the muscle group and runs a treatment period in 20 minutes. Please note the cycle, pulse, frequency and timer are all not adjustable but only the intensity of impulse is adjustable with 15 levels. You can test the intensity of comfort based on the lowest level (level 1) to the greatest level (level 15) by manual adjustment.

For safety use for Spopad SP-910, the unit is preset by 20 minutes for a treatment then auto-off after every 20-minute treatment. Please place the unit where you want to stimulate the muscle group as shown in the above body map. For optimum outcome, move the unit to other muscle position indicated on the above body map after 20-minute cycle. **Please don't use over twice treatments a day on the same muscle group. Stop using the device if you experience a tingling or numbing sensation or other discomfort on the skin.**

Battery & Gel Pad Assembly

- < 1 > Use a coin to turn the battery cover to the OPEN position, and open it.
- < 2 > Insert battery with + mark facing up
- < 3 > Use a coin to lock the battery cover by turning the cover clockwise.
- < 4 > Remove the blue protective film from the gel pad.
- < 5 > Apply the Electrode gel pad on the device's electrode area. (same as the other electrode side)
- < 6 > Remove the transparent film from the gel pad and ready to put on body for stimulation



How to Operate

1. Press and hold + button for 2 seconds to power the unit on and listen for the beep.
2. Press + button again to activate stimulation.
3. Use +/- button to adjust stimulation level.
4. Automatic power off after 20 minutes.

Note:

- Battery needs to be replaced if the unit no longer makes a beep sound or send any electric impulses.
- Device only works when in contact with the skin. When the device is not in contact with the skin, the device will not send out stimulation.
- After use, always place the protective film back to gel pad.

Specifications

Power	3V CR2032 Battery X1
Number Of Output Modes	1
Number Of Output Channels	1
Mode of output channels	1
Regulated Current Or Regulated Voltage?	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip	No
Automatic No-Load Trip	No
Automatic Shut-Off	Yes
User Override Control	Yes
Indicator Display	No
On/Off Status	Beeper
Low Battery	Beeper
Current/Voltage Level	No
Timer Range (Minutes)	20
Compliance With Voluntary Standard	IEC60601-1 IEC 60601-1-2 IEC 60601-2-10
Compliance With 21 CFR 898?	Yes
Housing Materials and Construction	Silicone
Pulse Strength	0 ~ 15 Stages Adjustable
Operation Environment	10° ~ 40°C, 30% ~ 85% RH
Storage Environment	-10° ~ 50°C, 10 %~ 95% RH
Transport Environment	-10° ~ 50°C, 35 %~ 85% RH
Dimension (LxWxH, inch)	9.41 x 2.76 x 0.447
Weight (g)	35.8
Accessory	Instruction manual
Patient-contacting material	Top-Rank electrode pad

Parameter		Response
Mode or Program Name		Regular
Waveform (e.g., pulsed monophasic, biphasic)		Symmetrical
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular
Maximum Output Voltage (volts) (+/- <u>10</u> %)		<u>52</u> @500 Ω
		<u>98</u> @2 k Ω
		<u>150</u> @10 k Ω
Maximum Output Current (mA) (+/- <u>10</u> %)		<u>104</u> @500 Ω
		<u>49</u> @2 k Ω
		<u>15</u> @10 k Ω
Duration of primary (depolarizing) phase (μ sec)		0
Pulse Duration (μ sec)		400
Frequency (Hz)		3-4-5
For interferential modes only: Beat Frequency [†] (Hz)		N/A
For multiphasic waveforms only:	Symmetrical phases?	Yes
	Phase Duration(μ sec)	400
Net Charge (μ C)		<u>0.416</u> @500 Ω
Maximum Phase Charge, (μ C)		<u>41.6</u> @500 Ω
Maximum Current Density (mA/cm ²)		<u>1.187</u> @500 Ω
Maximum Average Current (average absolute value), mA		<u>104</u> @500 Ω
Maximum Average Power Density (W/cm ²)		<u>0.0617</u> @500 Ω
Burst Mode	(a) Pulses per burst	N/A
	(b) Bursts per second	N/A
	(c) Burst duration (seconds)	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A
Additional Features (specify, if applicable)		N/A

Beep Signal Description Chart

Power Mode	Operation	Types of Beep Signal	Signal Description
Unit is turned off	hold the + button 3 seconds	Single long beep	The unit has turned on.
Unit is turned on but cannot feel impulses	Short press of the + or - buttons	Two short beeps	The intensity adjustment feature is disabled because the gel pad is not in full contact with the skin. Reapply the gel pad and try again.
	No Action	Slow consecutive, intermittent beeps	The gel pad is not in contact with the skin, reapply the gel pad and try again.
	No Action	Fast consecutive, intermittent beeps	The battery power is low, replace the battery.
	No Action	Single long beep	The auto-off program is engaged and the unit is powering off.

Beep Signal Description Chart cont'd

Power Mode	Operation	Types of Beep Signal	Signal Description
In Use	Short press of the + button	Single short beep	The adjustable intensity feature has increased 1 level.
	Short press of the - button	Single short beep	The adjustable intensity feature has decreased 1 level.
	Multiple presses of the + button	Two short beeps	The adjustable intensity feature has reached 15, the maximum level.
	Multiple presses of the - button	Two short beeps	The adjustable intensity feature has reached 0, the minimum level.
	hold the - button 3 seconds	Single long beep	The unit has been turned off manually.
	No Action	Single long beep	The auto-off program is engaged and the unit is powering off.
	No Action	Fast consecutive, intermittent beeps	The battery power is low, replace the battery.

Maintenance & Disposal

1. Storage

- (1) Keep the unit away from children.
- (2) Remove the batteries if the unit will not be used for more than 10 days.
- (3) Reapply the protective film back to the electrode pad after each use.
- (4) Do not store the unit under high temperature, high humidity, and direct sunlight exposed environment or where there are a lot of dusts or corrosive gas.

2. Care for the electrode pads

- (1) If the adhesive gel pads get dirty or less sticky, you can prolong the lifetime for additional uses by cleaning it. With a drop of water on your finger, rub the water over the surface of the gel and allow it to dry.
- (2) Always store the electrode pads in a cool, airy area away from direct sunlight.
- (3) Be sure the skin is clean before the electrode pads are placed.
- (4) Always store the electrode pads with the protective film after use.

3. Disposal

Batteries and this unit must NOT be disposed in household waste. Return them to public collection points or shops selling batteries or devices of the same kind according to local regulations. In case of any confusion, consult with your local environmental protection agency.

Troubleshooting

1. The units fail to turn on.

- (1) Press the + button again and hold it down for 2 seconds.
- (2) Check if the batteries are properly in place with good connection.
- (3) Replace batteries if (1) and (2) both fail.

2. The electrode pads are not sticky as before.

With a drop of water on your finger, rub the water over the surface of the gel and allow it dry.

3. The unit beeps abnormally during treatment.

- (1) Check if the device is connected securely with the skin.
- (2) If the beeping persists, replace the batteries with new ones.

4. The stimulation is not felt.

- (1) Make sure electrode pads are not overlapped.
- (2) Increase the pulse intensity gradually.
- (3) Make sure the device is connected securely with the skin.

5. The skin of treated area turns red.

Stop treating that area immediately; wait until the skin restores to its healthy state. If irritation persists, consult with a dermatologist.

6. The intensity begins to drop:

Replace battery immediately

7. The stimulation is uncomfortable.

(1) Press – button to decrease intensity if the stimulation is too strong.

(2) If not improving, check if the device is connected securely with the skin.

(3) If (2) does not help, check if the electrode pads are worn out. Worn pads can not distribute current evenly across the skin, which may lead to irritating stimulation. In such a case, replace the electrode pads.

Guidance and manufacturer's declaration-electromagnetic emissions		
<p>The <u>SP-910</u> is intended for use in the electromagnetic environment specified below.</p> <p>The customer or the user of the <u>SP-910</u> should assure that it is used in such an environment.</p>		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>SP-910</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>SP-910</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-910 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-910 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <u>SP-910</u> requires continued operation during power mains interruptions, it is recommended that the <u>SP-910</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The <u>SP-910</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic immunity			
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the <u>SP-910</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <u>SP-910</u> is used exceeds the applicable RF compliance level above, the <u>SP-910</u> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the <u>SP-910</u> . b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the SP-910

The SP-910 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP-910 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP-910 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

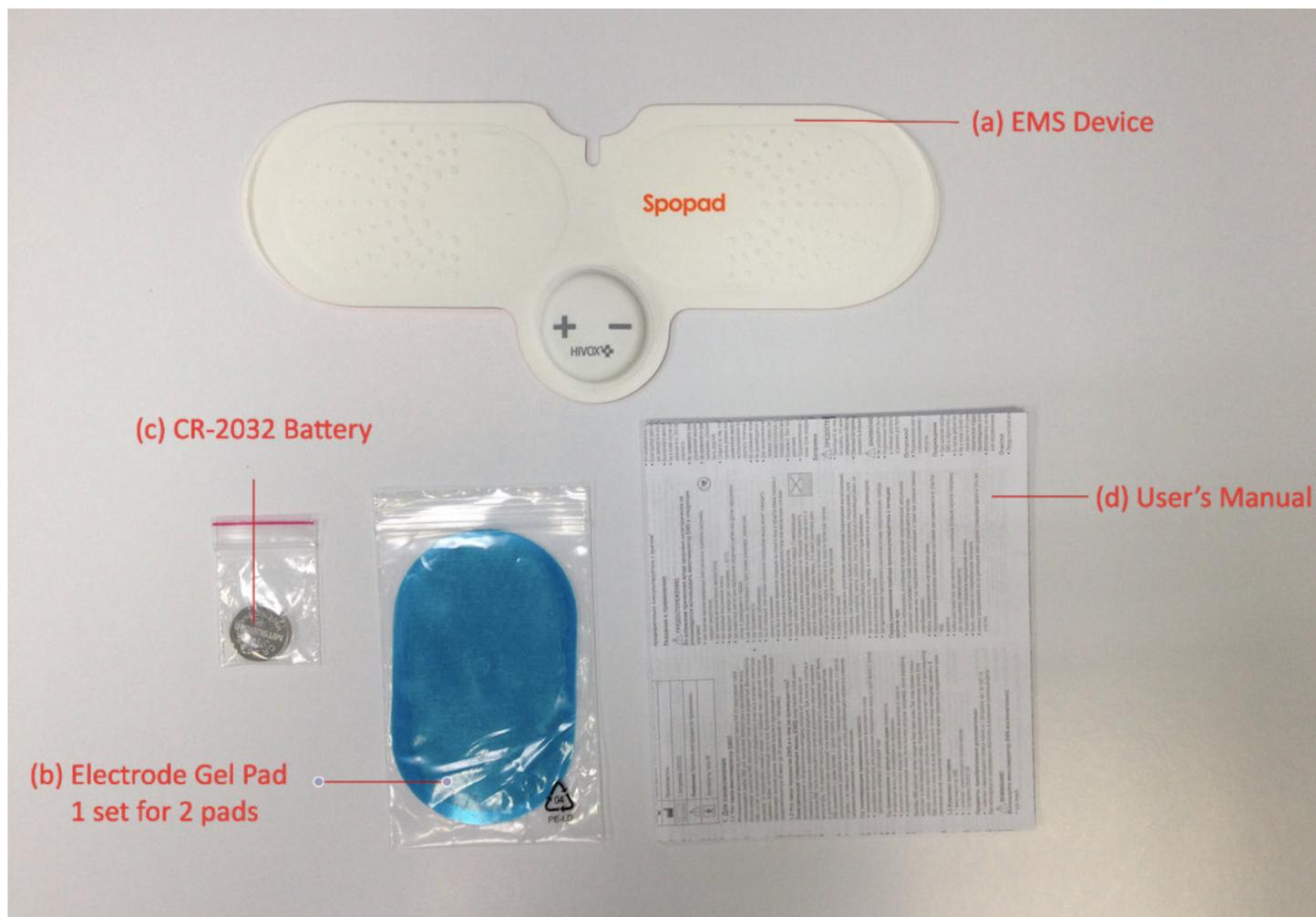
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Package list and photo

1. Photo



2. List

Item	Name	Quantity
a	EMS device –SP-910	1
b	Electrode Gel Pad (239.05 mm x 70.00 mm) (conducting area of 109.53 mm x 60 mm)	1 set of 2 pads
c	CR-2032 battery	1
d	User's Manual	1

ELECTRICAL MUSCLE STIMULATOR



SpopadTM

Instruction Manual

For

SP-920

WELCOME

Dear user, thank you for choosing HIVOX Spopad SP-920. Please read the manual carefully to learn the correct operation of this equipment. Understanding the operation will enable you to discover and enjoy the benefits of the device for a long time.

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Ver. 1.0, July 2014.

HIVOX

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Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Contraindication

- Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

- If you are in the care of a physician, consult with your physician before using this device;
- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;

- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal;
- Do not apply stimulation over painful areas. If you have painful areas, you should consult with your physician before using this device;
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
- Do not apply stimulation over, or in proximity to, cancerous lesions;
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
- Do not apply stimulation when in the bath or shower;
- Do not apply stimulation while sleeping;
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury; and
- Do not use the device on children. The device has not been evaluated for pediatric use.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals; and
- Apply stimulation only to normal, intact, clean, healthy skin.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.

Precautions

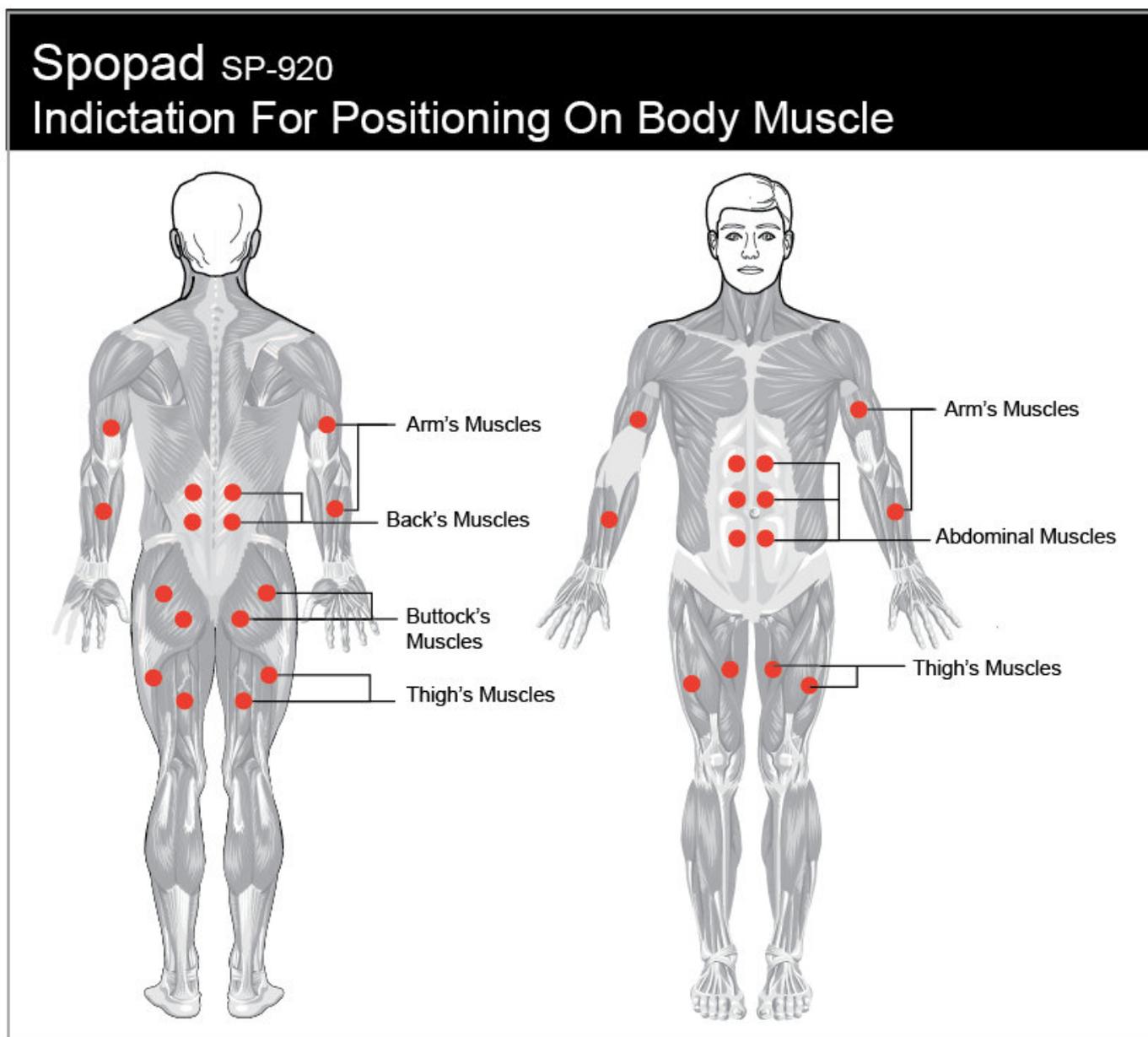
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- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head;
- The safety of electrical stimulation during pregnancy has not been established;
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician; and
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture;
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;
- Use caution if stimulation is applied over the menstruating or pregnant uterus; and
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

Adverse Reactions

- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;
- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face; and
- You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

Indications for positioning the unit on body

1. **Body muscles map** (*Back's muscles are not included in the indications for use, and it is only for reference*)



2. Positioning photos

2.1 Arm's muscle



2.2 Abdominal muscles



2.3 Buttock's muscles



2.4 Thigh's muscles



Spopad SP-920 Program Mode:

SP-920 has one program mode with 5 cycles which are changing cycle by cycle automatically. Please see the table as below:

Spopad SP-920 Program Mode			
Cycle	Pulse Width	Frequency	On-Time
1	400μs	2 Hz	60 Sec.
2	400μs	4 Hz	60 Sec.
3	400μs	25 Hz	20 Sec.
4	400μs	25 Hz	20 Sec.
5	400μs	25 Hz	20 Sec.

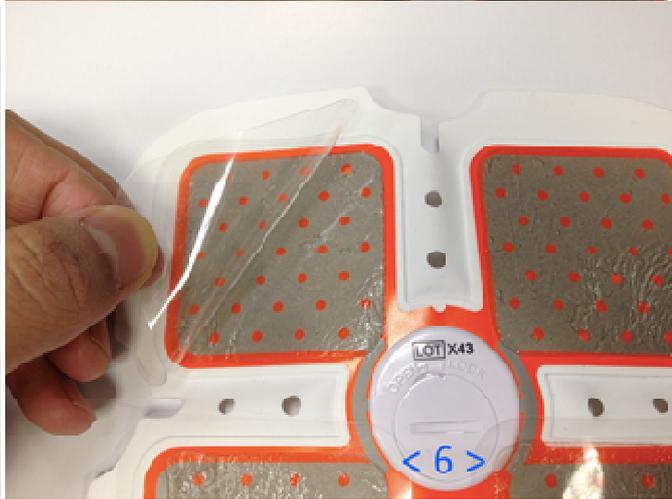
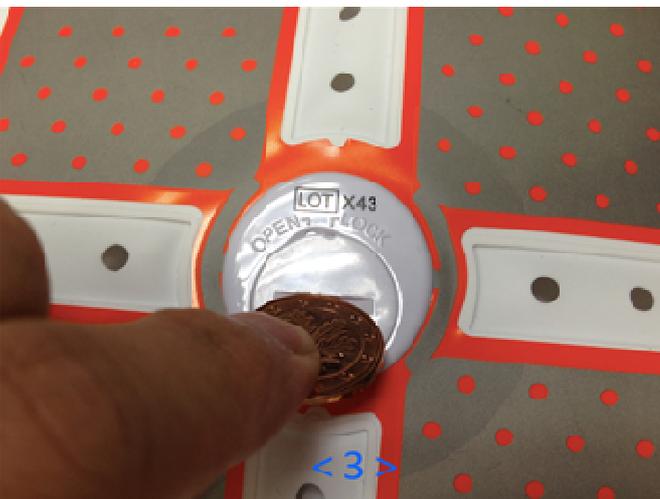
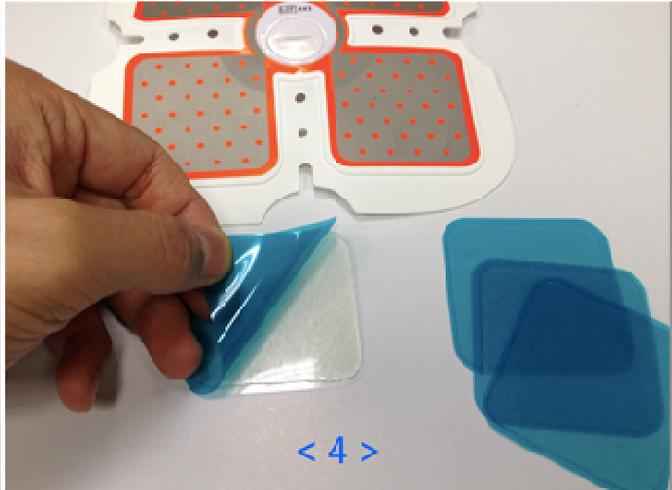
Spopad SP-920 is designed for one program mode with 5 cycles, and this mode with 5 cycles are not able to adjust. It uses external electrical impulses that act through the skin to stimulate the specific muscle group to improve, tone, firm & strengthen the muscles of Arm, Thigh, Abdomen, and Buttock. The muscle reacts in different ways depending on the strength of current and duration and frequency of the electrical impulse.

Those 5 cycles of one mode run automatically without changing by manual setting, all you have to do is to apply the unit to the muscle group and runs a treatment period in 20 minutes. Please note the cycle, pulse, frequency and timer are all not adjustable but only the intensity of impulse is adjustable with 15 levels. You can test the intensity of comfort based on the lowest level (level 1) to the greatest level (level 15) by manual adjustment.

For safety use for Spopad SP-920, the unit is preset by 20 minutes for a treatment then auto-off after every 20-minute treatment. Please place the unit where you want to stimulate the muscle group as shown in the above body map. For optimum outcome, move the unit to other muscle position indicated on the above body map after 20-minute cycle. **Please don't use over twice treatments a day on the same muscle group. Stop using the device if you experience a tingling or numbing sensation or other discomfort on the skin.**

Battery & Electrode Gel ad Assembly

- < 1 > Use a coin to turn the battery cover to the OPEN position, and open it.
- < 2 > Insert battery with + mark facing up
- < 3 > Use a coin to lock the battery cover by turning the cover clockwise.
- < 4 > Remove the blue protective film from the gel pad.
- < 5 > Apply the Electrode gel pad on the device's electrode area. (same as the other electrode side)
- < 6 > Remove the transparent film from the gel pad and ready to put on body for stimulation.



How to Operate

1. Press and hold + button for 2 seconds to power the unit on and listen for the beep.
2. Press + button again to activate stimulation.
3. Use +/- button to adjust stimulation level.
4. Automatic power off after 20 minutes.

Note:

- Battery needs to be replaced if the unit no longer makes a beep sound or send any electric impulses.
- Device only works when in contact with the skin. When the device is not in contact with the skin, the device will not send out stimulation.
- After use, always place the protective film back to gel pad.

Specifications

Power	3V CR2032 Battery X1
Number Of Output Modes	1
Number Of Output Channels	1
Mode of output channels	1
Regulated Current Or Regulated Voltage?	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip	No
Automatic No-Load Trip	No
Automatic Shut-Off	Yes
User Override Control	Yes
Indicator Display	No
On/Off Status	Beeper
Low Battery	Beeper
Current/Voltage Level	No
Timer Range (Minutes)	20
Compliance With Voluntary Standard	IEC60601-1 IEC 60601-1-2 IEC 60601-2-10
Compliance With 21 CFR 898?	Yes
Housing Materials And Construction	Silicone
Pulse Strength	0 ~ 15 Stages Adjustable
Operation Environment	10° ~ 40°C, 30 %~ 85% RH
Storage Environment	-10° ~ 50°C, 10 %~ 95% RH
Transport Environment	-10 °~ 50°C, 35 %~ 85% RH
Dimension (LxWxH, inch)	6.69 x 6.69 x 0.512
Weight (g)	52.6
Accessory	Instruction manual
Patient-contacting material	Top-Rank electrode pad

Parameter		Response
Mode or Program Name		Regular
Waveform (e.g., pulsed monophasic, biphasic)		Symmetrical
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular
Maximum Output Voltage (volts) (+/- <u>10</u> %)		<u>58.4</u> @500 Ω
		<u>106</u> @2 k Ω
		<u>146</u> @10 k Ω
Maximum Output Current (mA) (+/- <u>10</u> %)		<u>117</u> @500 Ω
		<u>53</u> @2 k Ω
		<u>14.6</u> @10 k Ω
Duration of primary (depolarizing) phase (μ sec)		0
Pulse Duration (μ sec)		400
Frequency (Hz)		2-4-25
For interferential modes only: Beat Frequency [†] (Hz)		N/A
For multiphasic waveforms only:	Symmetrical phases?	Yes
	Phase Duration(μ sec)	400
Net Charge (μ C)		<u>0.468</u> @500 Ω
Maximum Phase Charge, (μ C)		<u>46.8</u> @500 Ω
Maximum Current Density (mA/cm ²)		<u>1.057</u> @500 Ω
Maximum Average Current (average absolute value), mA		<u>117</u> @500 Ω
Maximum Average Power Density (W/cm ²)		<u>0.0617</u> @500 Ω
Burst Mode	(a) Pulses per burst	25
	(b) Bursts per second	1
	(c) Burst duration (seconds)	20
	(d) Duty Cycle [Line (b) x Line (c)]	20
Additional Features (specify, if applicable)		N/A

Beep Signal Description Chart			
Power Mode	Operation	Types of Beep Signal	Signal Description
Unit is turned off	hold the + button 3 seconds	Single long beep	The unit has turned on.
Unit is turned on but cannot feel impulses	Short press of the + or - buttons	Two short beeps	The intensity adjustment feature is disable because the gel pad is not in full contact with the skin. Reapply the gel pad and try again.
	No Action	Slow consecutive, intermittent beeps	The gel pad is not in contact with the skin, reapply the gel pad and try again.
	No Action	Fast consecutive, intermittent beeps	The battery power is low, replace the battery.
	No Action	Single long beep	The auto-off program is engaged and the unit is powering off.

Beep Signal Description Chart cont'd

Power Mode	Operation	Types of Beep Signal	Signal Description
In Use	Short press of the + button	Single short beep	The adjustable intensity feature has increased 1 level.
	Short press of the - button	Single short beep	The adjustable intensity feature has decreased 1 level.
	Multiple presses of the + button	Two short beeps	The adjustable intensity feature has reached 15, the maximum level.
	Multiple presses of the - button	Two short beeps	The adjustable intensity feature has reached 0, the minimum level.
	hold the - button 3 seconds	Single long beep	The unit has been turned off manually.
	No Action	Single long beep	The auto-off program is engaged and the unit is powering off.
	No Action	Fast consecutive, intermittent beeps	The battery power is low, replace the battery.

Maintenance & Disposal

1. Storage

- (1) Keep the unit away from children.
- (2) Remove the batteries if the unit will not be used for more than 10 days.
- (3) Reapply the protective film back to the electrode pad after each use.
- (4) Do not store the unit under high temperature, high humidity, and direct sunlight exposed environment or where there are a lot of dusts or corrosive gas.

2. Care for the electrode pads

- (1) If the adhesive gel pads get dirty or less sticky, you can prolong the lifetime for additional uses by cleaning it. With a drop of water on your finger, rub the water over the surface of the gel and allow it to dry.
- (2) Always store the electrode pads in a cool, airy area away from direct sunlight.
- (3) Be sure the skin is clean before the electrode pads are placed.
- (4) Always store the electrode pads with the protective film after use.

3. Disposal

Batteries and this unit must NOT be disposed in household waste. Return them to public collection points or shops selling batteries or devices of the same kind according to local regulations. In case of any confusion, consult with your local environmental protection agency.

Troubleshooting

1. The units fail to turn on.

- (1) Press the + button again and hold it down for 2 seconds.
- (2) Check if the batteries are properly in place with good connection.
- (3) Replace batteries if (1) and (2) both fail.

2. The electrode pads are not sticky as before.

With a drop of water on your finger, rub the water over the surface of the gel and allow it to dry.

3. The unit beeps abnormally during treatment.

- (1) Check if the device is connected securely with the skin.
- (2) If the beeping persists, replace the batteries with new ones.

4. The stimulation is not felt.

- (1) Make sure electrode pads are not overlapped.
- (2) Increase the pulse intensity gradually.
- (3) Make sure the device is connected securely with the skin.

5. The skin of treated area turns red.

Stop treating that area immediately; wait until the skin restores to its healthy state. If irritation persists, consult with a dermatologist.

6. The intensity begins to drop:

Replace battery immediately

7. The stimulation is uncomfortable.

(1) Press – button to decrease intensity if the stimulation is too strong.

(2) If not improving, check if the device is connected securely with the skin.

(3) If step (2) does not help, check if the electrode pads are worn out. Worn pads can not distribute current evenly across the skin, which may lead to irritating stimulation. In such a case, replace the electrode pads.

Guidance and manufacturer's declaration-electromagnetic emissions

The SP-920 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-920 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>SP-920</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>SP-920</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-920 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-920 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <u>SP-920</u> requires continued operation during power mains interruptions, it is recommended that the <u>SP-920</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The <u>SP-920</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-920 is intended for use in the electromagnetic environment specified below.
 The customer or the user of the SP-920 should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	Not applicable	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <u>SP-920</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p>
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	<p>Recommended separation distance:</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80MHz to 800 MHz</p> <p>$d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SP-920 is used exceeds the applicable RF compliance level above, the SP-920 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SP-920.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the SP-920

The SP-920 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP-920 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP-920 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

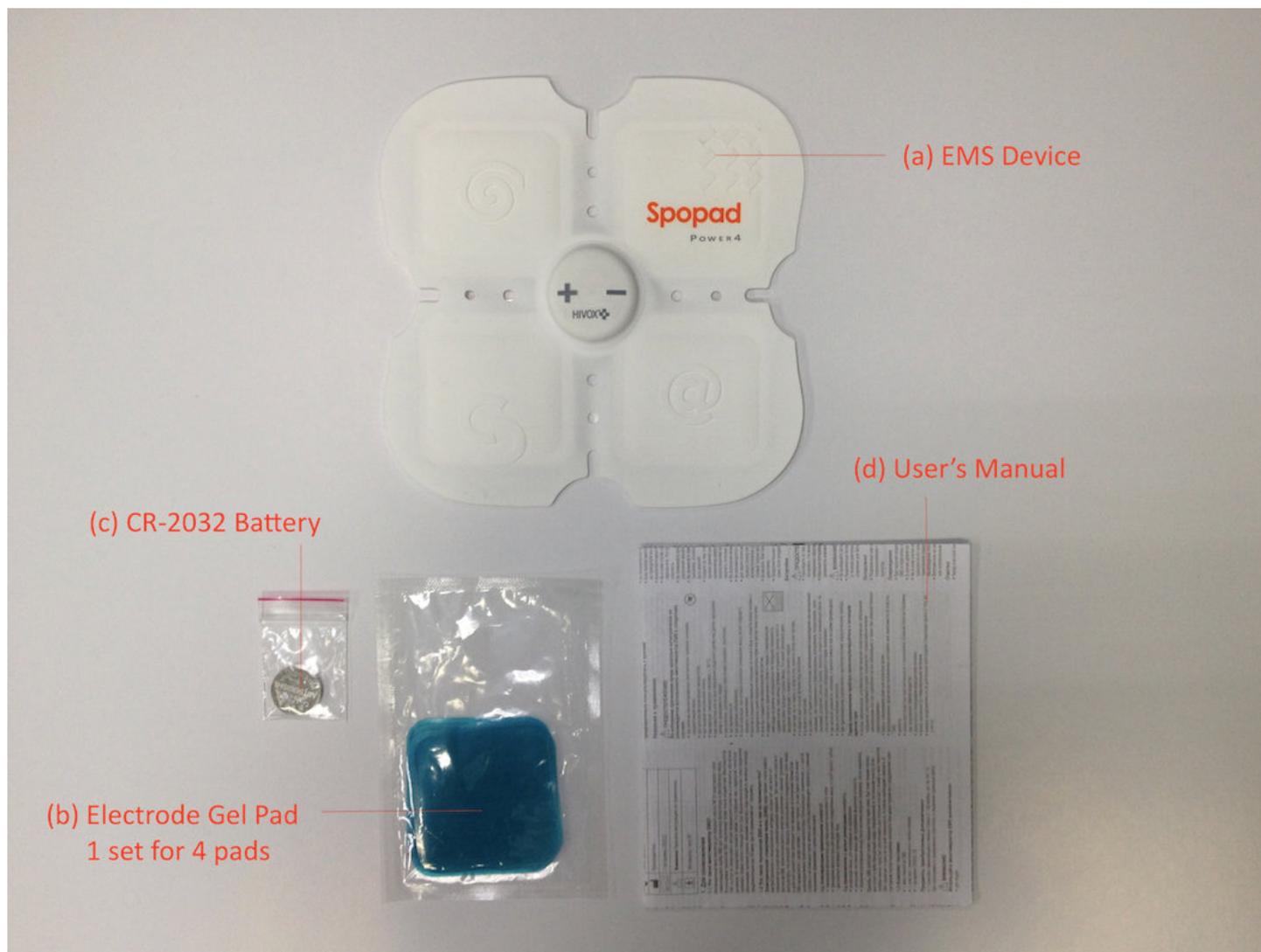
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Package list and photos

1. Photos



2. List

Item	Name	Quantity
a	EMS device –SP-920	1
b	Electrode Gel Pad (166.13 mm x 169.15 mm) (conducting areas of 52.95 mm x 48.53 mm)	1 set of 4 pads
c	CR-2032 battery	1
d	User's Manual	1

ELECTRICAL MUSCLE STIMULATOR



SpopadTM

Instruction Manual

For

SP-620

WELCOME

Dear user, thank you for choosing HIVOX Spopad SP-620. Please read the manual carefully to learn the correct operation of this equipment. Understanding the operation will enable you to discover and enjoy the benefits of the device for a long time.

Manufacturer: HIVOX BIOTEK INC
5/F, #123 Shingde Road. Sanchong City, 24158,
Taipei Taiwan R.O.C.
Tel:886-2-85112668 Email: vt@hivox-biotek.com
Ver. 1.0, July 2014.



Important information is highlighted by these terms:

Contraindications – Symptoms or diseases the device not applied to

Warnings – Danger for patient or operating staff.

Precautions – Information for preventing damage to the product.

Adverse Reactions – Important operating instructions.

Product Description

EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relax stiff muscle through the skin. It is recognized as a clinically proven, effective, non- medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training.

SP-620 is a 1-channel battery-operated user-friendly muscle stimulation system specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-620 comprises 2 electrodes, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors. The shelf life of the device is 30 months. For more information about HIVOX Spopad SP-620, please visit our website at <http://www.hivox-biotek.com> or contact our customer service for further assistance.

Indications for Use

The Electrical Muscle Stimulation unit is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.

Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Contraindication

- Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

- If you are in the care of a physician, consult with your physician before using this device;
- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure;
- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal;
- Do not apply stimulation over painful areas. If you have painful areas, you should consult with your physician before using this device;

- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins);
- Do not apply stimulation over, or in proximity to, cancerous lesions;
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use;
- Do not apply stimulation when in the bath or shower;
- Do not apply stimulation while sleeping;
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury; and
- Do not use the device on children. The device has not been evaluated for pediatric use.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals; and
- Apply stimulation only to normal, intact, clean, healthy skin.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy ME EQUIPMENT may produce instability in the STIMULATOR output.

Precautions

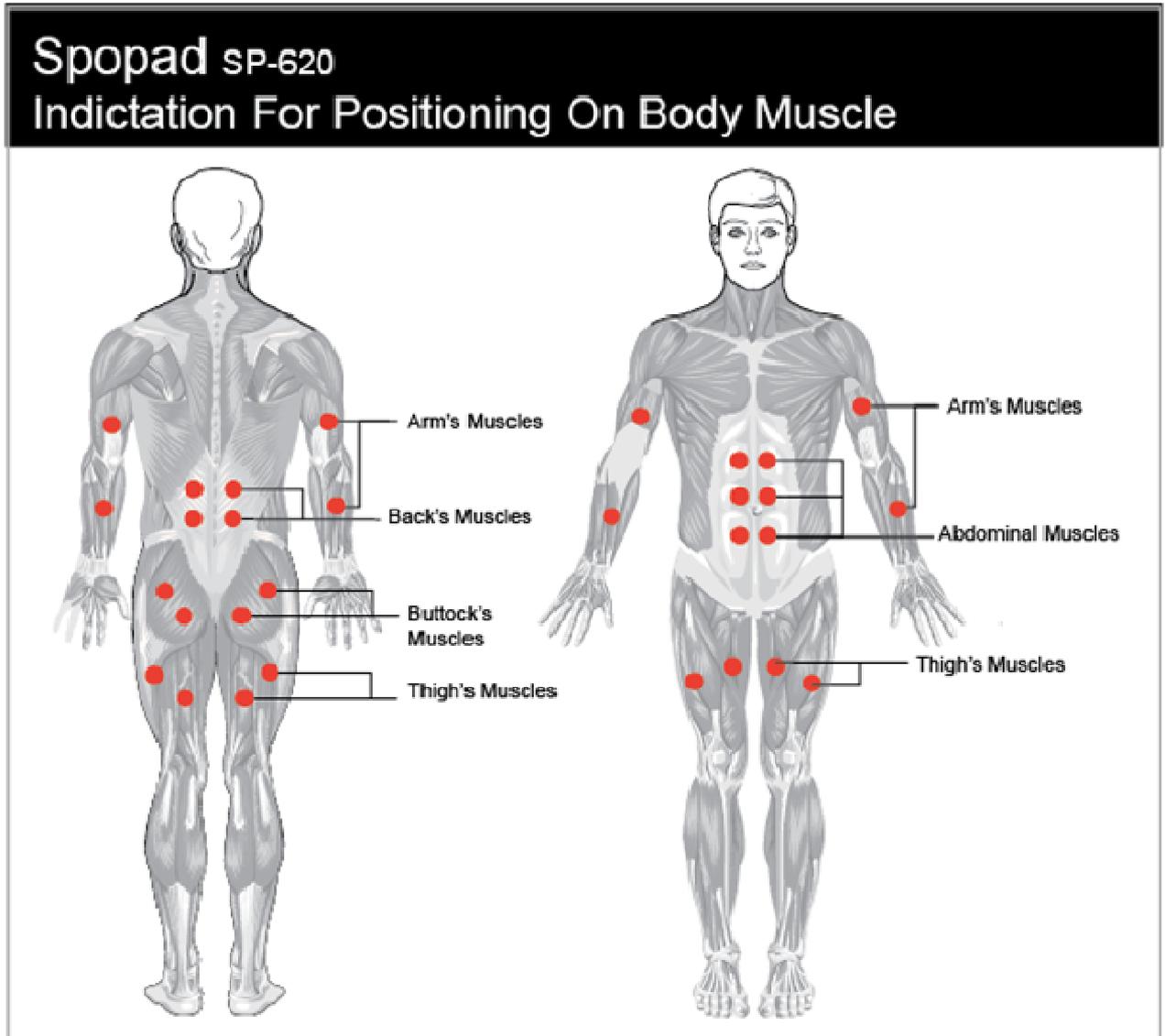
- The long-term effects of electrical stimulation are unknown;
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head;
- The safety of electrical stimulation during pregnancy has not been established;
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel);
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician; and
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture;
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process;
- Use caution if stimulation is applied over the menstruating or pregnant uterus; and
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

Adverse Reactions

- You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin;
- You may experience headache and other painful sensations during or following the application of electrical stimulation near your eyes and to your head and face; and
- You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

Indications for positioning the unit on body

1. **Body muscles map** (*Back's muscles are not included in the indications for use, and it is only for reference*)



2. Positioning photos

2.1 Arm's muscle



2.2 Abdominal muscles



2.3 Buttock's muscles



2.4 Thigh's muscles



Spopad SP-620 Program Mode:

SP-620 has one program mode with 5 cycles which are changing cycle by cycle automatically. Please see the table as below:

Spopad SP-620 Program Mode			
Cycle	Pulse Width	Frequency	On-Time
1	400µs	2 Hz	60 Sec.
2	400µs	4 Hz	60 Sec.
3	400µs	25 Hz	20 Sec.
4	400µs	25 Hz	20 Sec.
5	400µs	25 Hz	20 Sec.

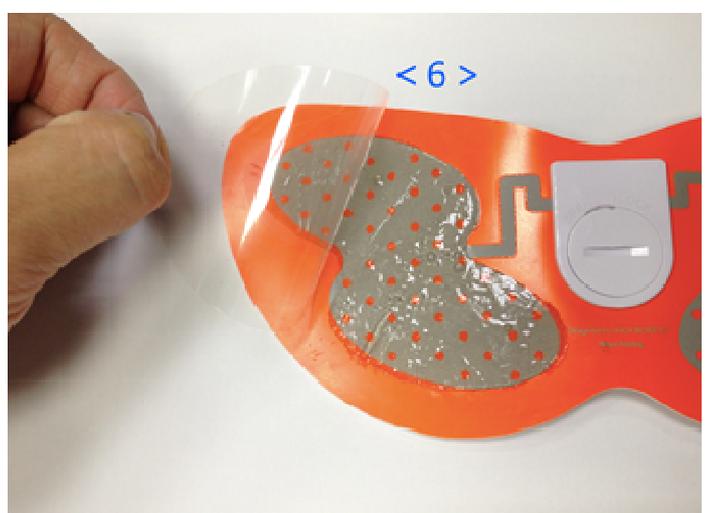
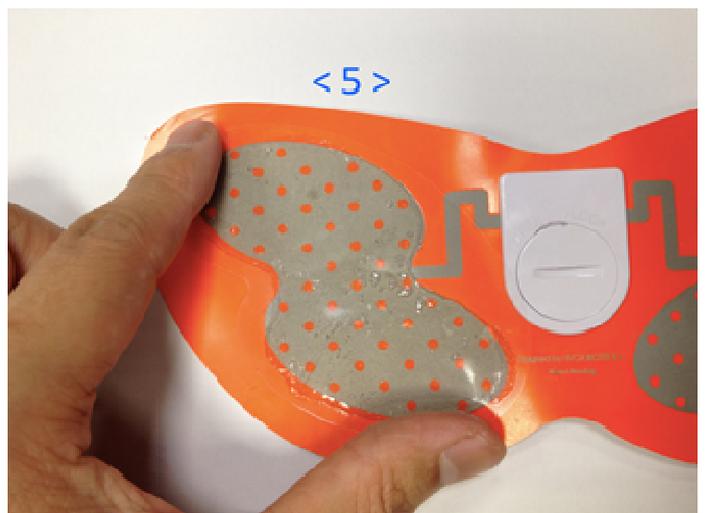
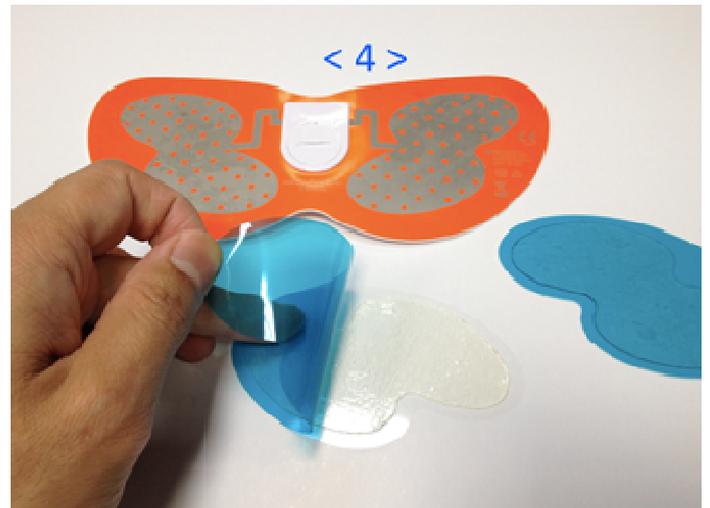
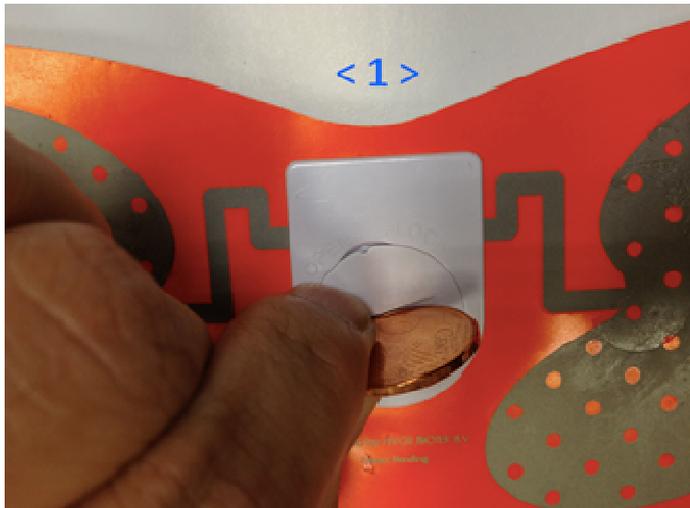
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Those 5 cycles of one mode run automatically without changing by manual setting, all you have to do is to apply the unit to the muscle group and runs a treatment period in 20 minutes. Please note the cycle, pulse, frequency and timer are all not adjustable but only the intensity of impulse is adjustable with 15 levels. You can test the intensity of comfort based on the lowest level (level 1) to the greatest level (level 15) by manual adjustment.

For safety use for Spopad SP-620, the unit is preset by 20 minutes for a treatment then auto-off after every 20-minute treatment. Please place the unit where you want to stimulate the muscle group as shown in the above body map. For optimum outcome, move the unit to other muscle position indicated on the above body map after 20-minute cycle. **Please don't use over twice treatments a day on the same muscle group. Stop using the device if you experience a tingling or numbing sensation or other discomfort on the skin.**

Battery & Gel Pad Assembly

- < 1 > Use a coin to turn the battery cover to the OPEN position, and open it.
- < 2 > Insert battery with + mark facing up
- < 3 > Use a coin to lock the battery cover by turning the cover clockwise.
- < 4 > Remove the blue protective film from the gel pad.
- < 5 > Apply the Electrode gel pad on the device's electrode area. (same as the other electrode side)
- < 6 > Remove the transparent film from the gel pad and ready to put on body for stimulation.



How to Operate

1. Press and hold + button for 2 seconds to power the unit on and listen for the beep.
2. Press + button again to activate stimulation.
3. Use +/- button to adjust stimulation level.
4. Automatic power off after 20 minutes.

Note:

- Battery will need to be replaced if the unit no longer makes a beep sound or send any electric impulses.
- Device only works when in contact with the skin. When the device is not in contact with the skin, the device will not send out stimulation.
- After use, always place the protective film back to gel pad.

Specifications

Power	3V CR2032 Battery X1
Number Of Output Modes	1
Number Of Output Channels	1
Mode of output channels	1
Regulated Current Or Regulated Voltage?	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip	No
Automatic No-Load Trip	No
Automatic Shut-Off	Yes
User Override Control	Yes
Indicator Display	No
On/Off Status	beeper
Low Battery	beeper
Current/Voltage Level	No
Timer Range (Minutes)	20
Compliance With Voluntary Standard	IEC60601-1 IEC 60601-1-2 IEC 60601-2-10
Compliance With 21 CFR 898?	Yes
Housing Materials And Construction	Silicone
Pulse Strength	0 ~ 15 Stages Adjustable
Operation Environment	10° ~ 40°C, 30% ~ 85% RH
Storage Environment	-10° ~ 50°C, 10% ~ 95% RH
Transport Environment	-10° ~ 50°C, 35% ~ 85% RH
Dimension (LxWxH, inch)	7.87 x 3.74 x 0.512
Weight (g)	26.0
Accessory	Instruction manual
Patient-contacting material	Top-Rank electrode pad

Parameter		Response
Mode or Program Name		Regular
Waveform (e.g., pulsed monophasic, biphasic)		Symmetrical
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular
Maximum Output Voltage (volts) (+/- <u>10</u> %)		<u>60</u> @500 Ω
		<u>109</u> @2 k Ω
		<u>140</u> @10 k Ω
Maximum Output Current (mA) (+/- <u>10</u> %)		<u>120</u> @500 Ω
		<u>54.5</u> @2 k Ω
		<u>14</u> @10 k Ω
Duration of primary (depolarizing) phase (μ sec)		0
Pulse Duration (μ sec)		400
Frequency (Hz)		2-4-25
For interferential modes only: Beat Frequency [†] (Hz)		N/A
For multiphasic waveforms only:	Symmetrical phases?	Yes
	Phase Duration(μ sec)	400
Net Charge (μ C)		<u>0.960</u> @500 Ω
Maximum Phase Charge, (μ C)		<u>48</u> @500 Ω
Maximum Current Density (mA/cm ²)		<u>1.952</u> @500 Ω
Maximum Average Current (average absolute value), mA		<u>120</u> @500 Ω
Maximum Average Power Density (W/cm ²)		<u>0.117</u> @500 Ω
Burst Mode	(a) Pulses per burst	25
	(b) Bursts per second	1
	(c) Burst duration (seconds)	20
	(d) Duty Cycle [Line (b) x Line (c)]	20
Additional Features (specify, if applicable)		N/A

Beep Signal Description Chart

Power Mode	Operation	Types of Beep Signal	Signal Description
Unit is turned off	hold the + button 3 seconds	Single long beep	The unit has turned on.
Unit is turned on but cannot feel impulses	Short press of the + or - buttons	Two short beeps	The intensity adjustment feature is disable because the gel pad is not in full contact with the skin. Reapply the gel pad and try again.
	No Action	Slow consecutive, intermittent beeps	The gel pad is not in contact with the skin, reapply the gel pad and try again.
	No Action	Fast consecutive, intermittent beeps	The battery power is low, replace the battery.
	No Action	Single long beep	The auto-off program is engaged and the unit is powering off.

Beep Signal Description Chart cont'd

Power Mode	Operation	Types of Beep Signal	Signal Description
In Use	Short press of the + button	Single short beep	The adjustable intensity feature has increased 1 level.
	Short press of the - button	Single short beep	The adjustable intensity feature has decreased 1 level.
	Multiple presses of the + button	Two short beeps	The adjustable intensity feature has reached 15, the maximum level.
	Multiple presses of the - button	Two short beeps	The adjustable intensity feature has reached 0, the minimum level.
	hold the - button 3 seconds	Single long beep	The unit has been turned off manually.
	No Action	Single long beep	The auto-off program is engaged and the unit is powering off.
	No Action	Fast consecutive, intermittent beeps	The battery power is low, replace the battery.

Maintenance & Disposal

1. Storage

- (1) Keep the unit away from children.
- (2) Remove the batteries if the unit will not be used for more than 10 days.
- (3) Reapply the protective film back to the electrode pad after each use.
- (4) Do not store the unit under high temperature, high humidity, and direct sunlight exposed environment or where there are a lot of dusts or corrosive gas.

2. Care for the electrode pads

- (1) If the adhesive gel pads get dirty or less sticky, you can prolong the lifetime for additional uses by cleaning it. With a drop of water on your finger, rub the water over the surface of the gel and allow it to dry.
- (2) Always store the electrode pads in a cool, airy area away from direct sunlight.
- (3) Be sure the skin is clean before the electrode pads are placed.
- (4) Always store the electrode pads with the protective film after use.

3. Disposal

Batteries and this unit must NOT be disposed in household waste. Return them to public collection points or shops selling batteries or devices of the same kind according to local regulations. In case of any confusion, consult with your local environmental protection agency.

Troubleshooting

1. The units fail to turn on.

- (1) Press the + button again and hold it down for 2 seconds.
- (2) Check if the batteries are properly in place with good connection.
- (3) Replace batteries if (1) and (2) both fail.

2. The electrode pads are not sticky as before.

With a drop of water on your finger, rub the water over the surface of the gel and allow it to dry.

3. The unit beeps abnormally during treatment.

- (1) Check if the device is connected securely with the skin.
- (2) If the beeping persists, replace the batteries with new ones.

4. The stimulation is not felt.

- (1) Make sure electrode pads are not overlapped.
- (2) Increase the pulse intensity gradually.
- (3) Make sure the device is connected securely with the skin.

5. The skin of treated area turns red.

Stop treating that area immediately; wait until the skin restores to its healthy state. If irritation persists, consult with a dermatologist.

6. The intensity begins to drop:

Replace battery immediately

7. The stimulation is uncomfortable.

(1) Press – button to decrease intensity if the stimulation is too strong.

(2) If not improving, check if the device is connected securely with the skin.

(3) If step (2) does not help, check if the electrode pads are worn out. Worn pads can not distribute current evenly across the skin, which may lead to irritating stimulation. In such a case, replace the electrode pads.

Guidance and manufacturer's declaration-electromagnetic emissions

The SP-620 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-620 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>SP-620</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>SP-620</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-620 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-620 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <u>SP-620</u> requires continued operation during power mains interruptions, it is recommended that the <u>SP-620</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The <u>SP-620</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-620 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-620 should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	Not applicable	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <u>SP-620</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P} \quad 80\text{MHz to } 800 \text{ MHz}$ $d = 2,3 \sqrt{P} \quad 800\text{MHz to } 2,5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SP-620 is used exceeds the applicable RF compliance level above, the SP-620 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SP-620.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distance between
portable and mobile RF communications equipment and the SP-620**

The SP-620 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP-620 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP-620 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

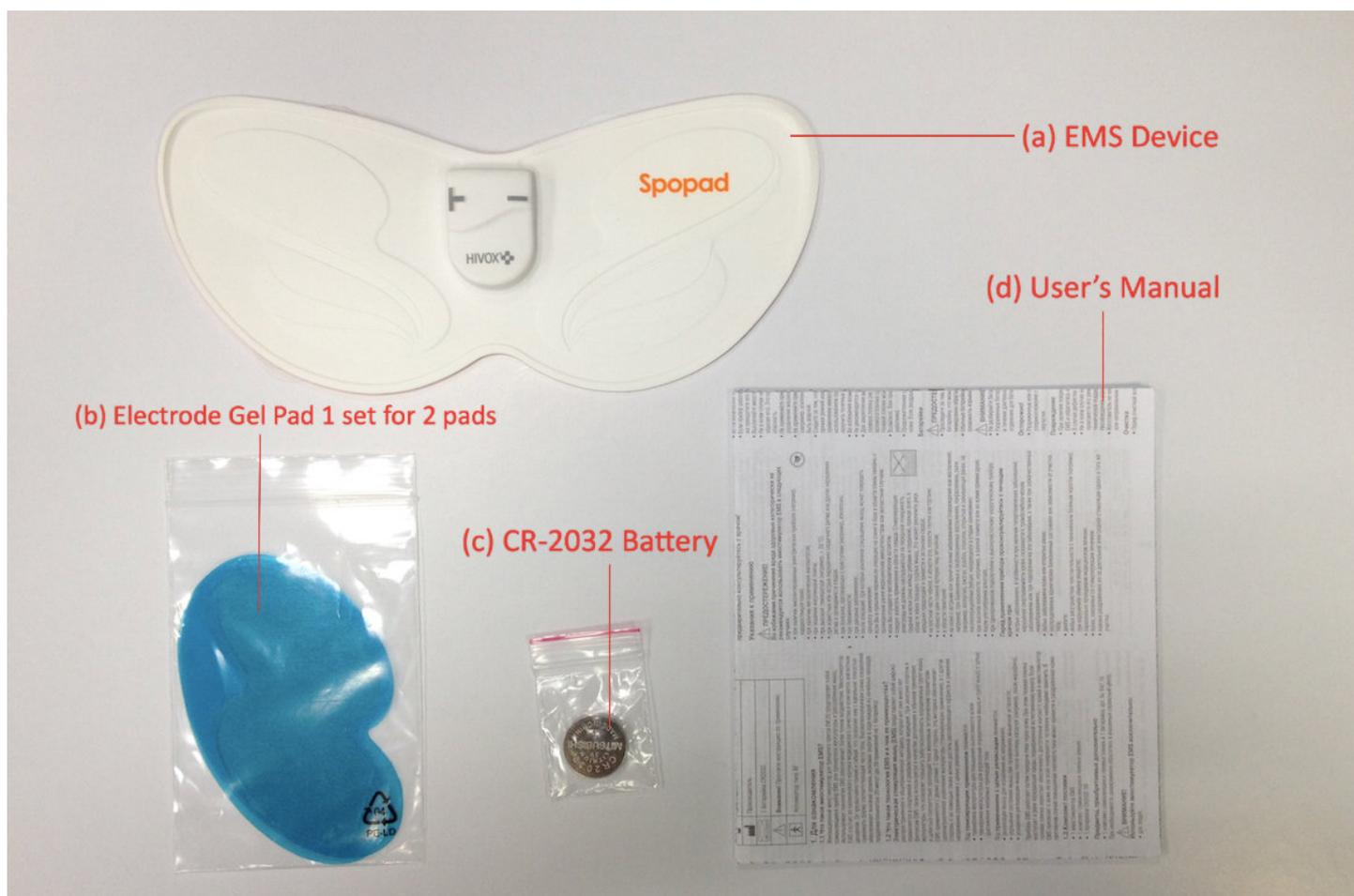
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Package list and photo

1. Photo



2. List

Item	Name	Quantity
a	EMS device –SP-620	1
b	Electrode Gel Pad (202.84 mm x 92.02 mm) (conducting area of 88.27 mm x 91.02 mm)	1 set of 2 pads
c	CR-2032 battery	1
d	User's Manual	1

13.2 Other labeling

We place the package labels for SP-910 / SP-920 / SP-620 here.

Spopad™

- Leadwires, Soft Unibody
- 3-Cycle Mode Training
- Storage
- Adhesive Electrodes



- Unibody Device 1x
- 3-Cycle Mode Gol Pad 4x
- 2032 Li-on Battery 1x
- User's Manual 1x

HIVOX BIOTEK INC.
 5F, No.123, Shingde Rd.,
 Sanchong District 241,
 New Taipei City, Taiwan R.O.C.
 Tel: (886) 2 8511-2668
 E-mail: info@hivox-biotek.com
 http://www.hivox-biotek.com



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NEW
 Silicon Unibody

EMS Stimulator

Spopad™

popadTM

P O W E R 4

- le Training
- es, Soft Unibody
- cle Mode Training
- e Type (No Belt Required)
- Adhesive Electrodes
- e Go

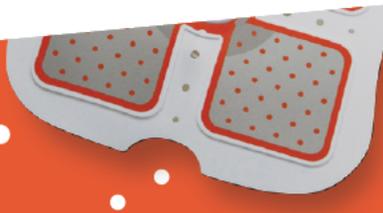


- Silicon Unibody Device 1x
- Electrode Gel Pad 4x
- CR2032 Li-on Battery 1x
- User's Manual 1x

HIVOX BIOTEK INC.
 5F, No.123, Shingde Rd.,
 Sanhong District 241,
 New Taipei City, Taiwan R.O.C.
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 E-mail: info@hivox-biotek.com
 http://www.hivox-biotek.com



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 Patent Pending
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NEW
 Silicon Unibody

EMS Stimulator

POWER4TM
 Spopad

SpopadTM

No Leadwires, Self Adhesive
Soft Unibody, Light & Invisible
Power 2 Self Adhesive Electrodes



- Silicon Unibody Device 1x
- Electrode Gel Pad 4x
- CR2032 Li-on Battery 1x
- User's Manual 1x



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NEW
 Silicon Unibody

Stimulator
 EMS
TM
Spopad

14. STERILIZATION / SHELF LIFE

(b) (4)

Shelf-life Time Test Report

(b)(4) Test Data

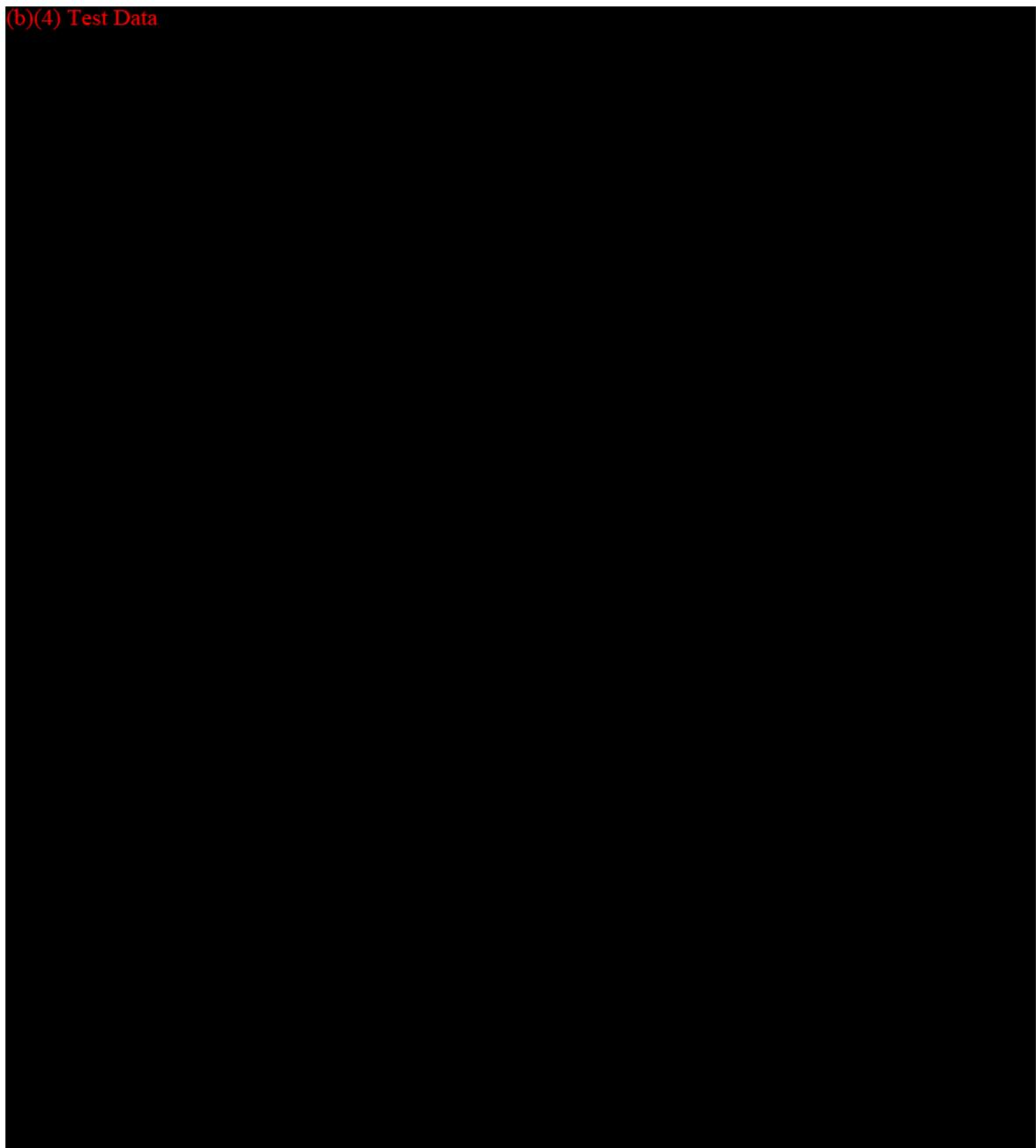
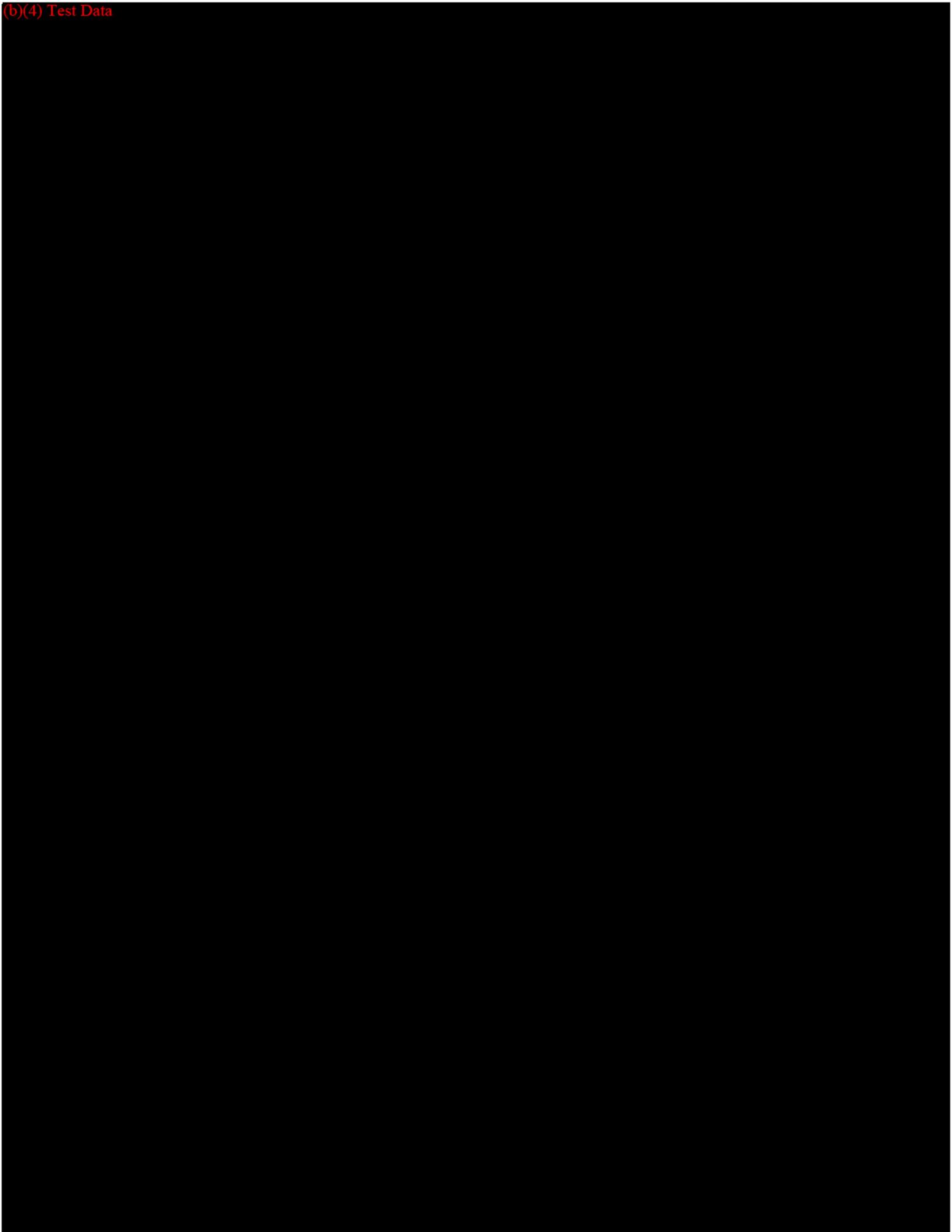


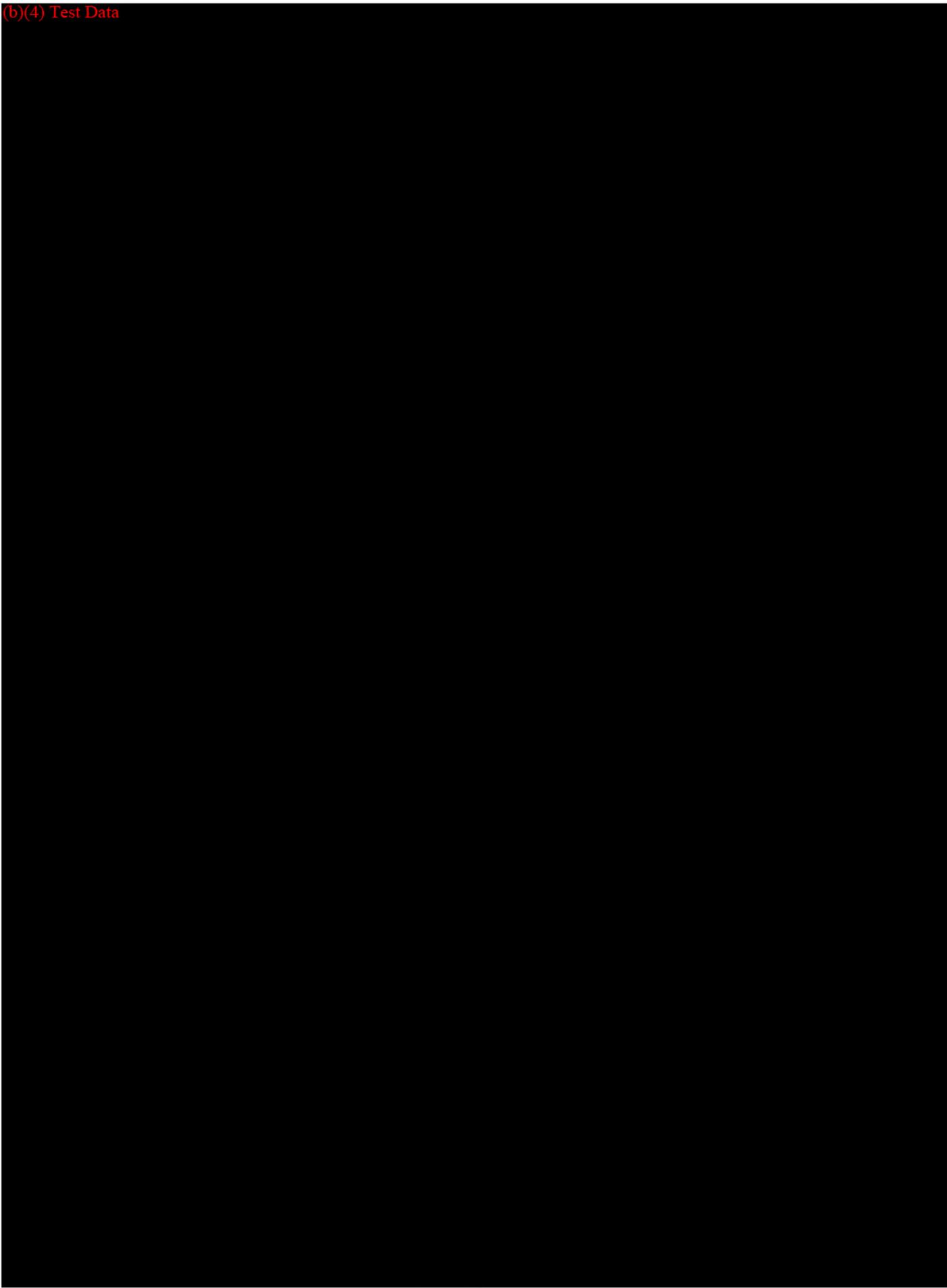
Table of Content

1. Objective
2. Personnel
3. Testing Equipment
4. Test Models
5. The Test Procedures
6. The Verification Result
7. Summary

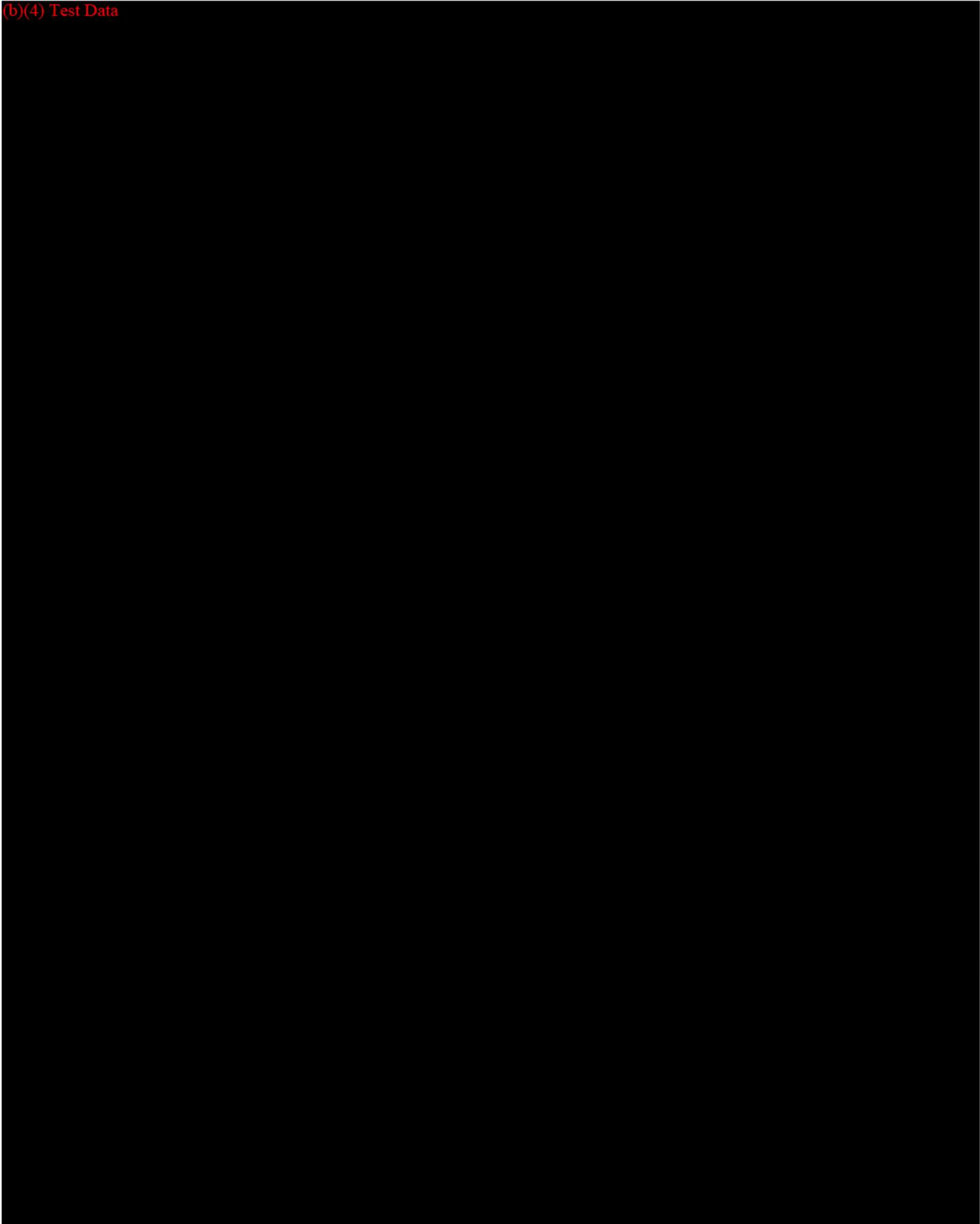
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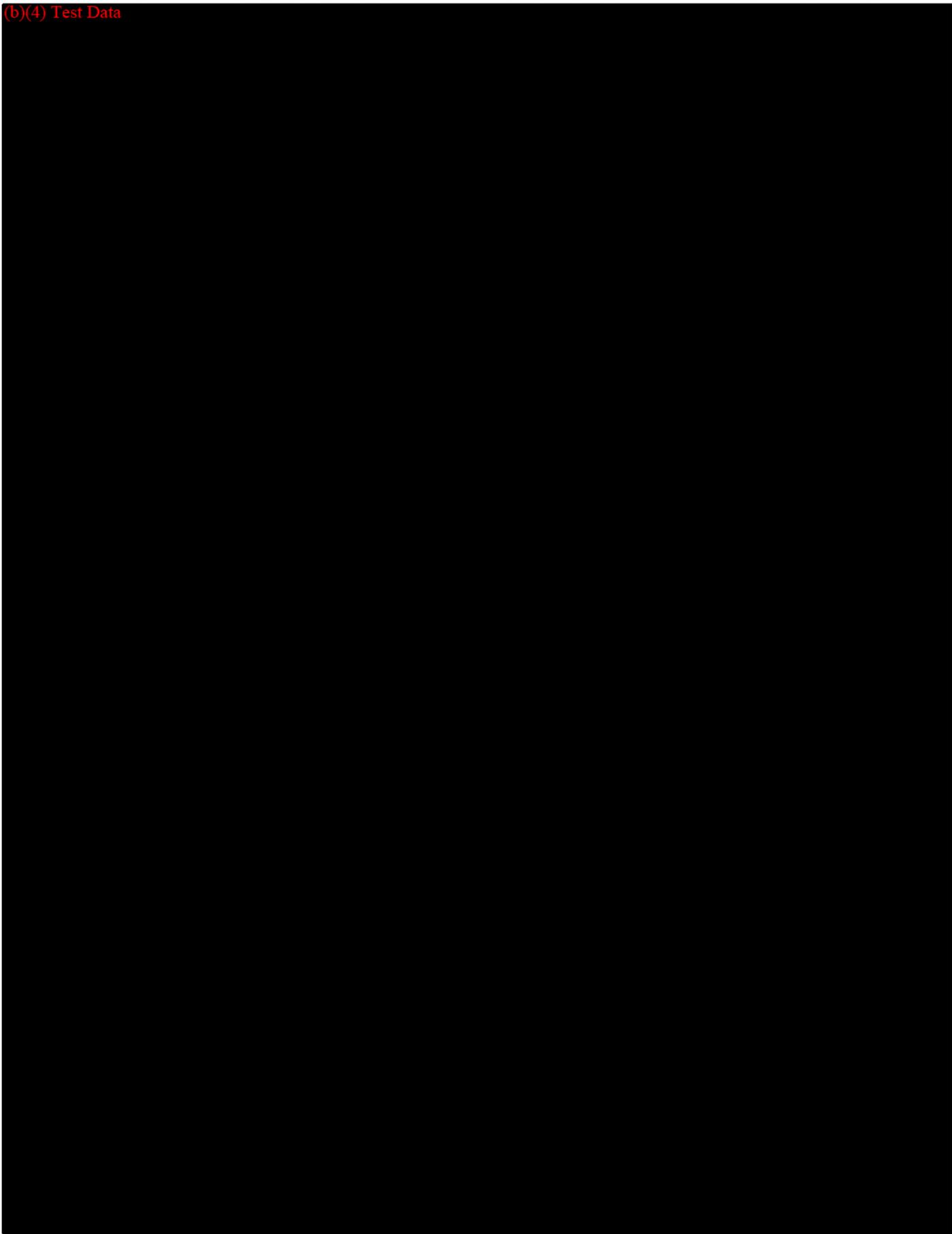
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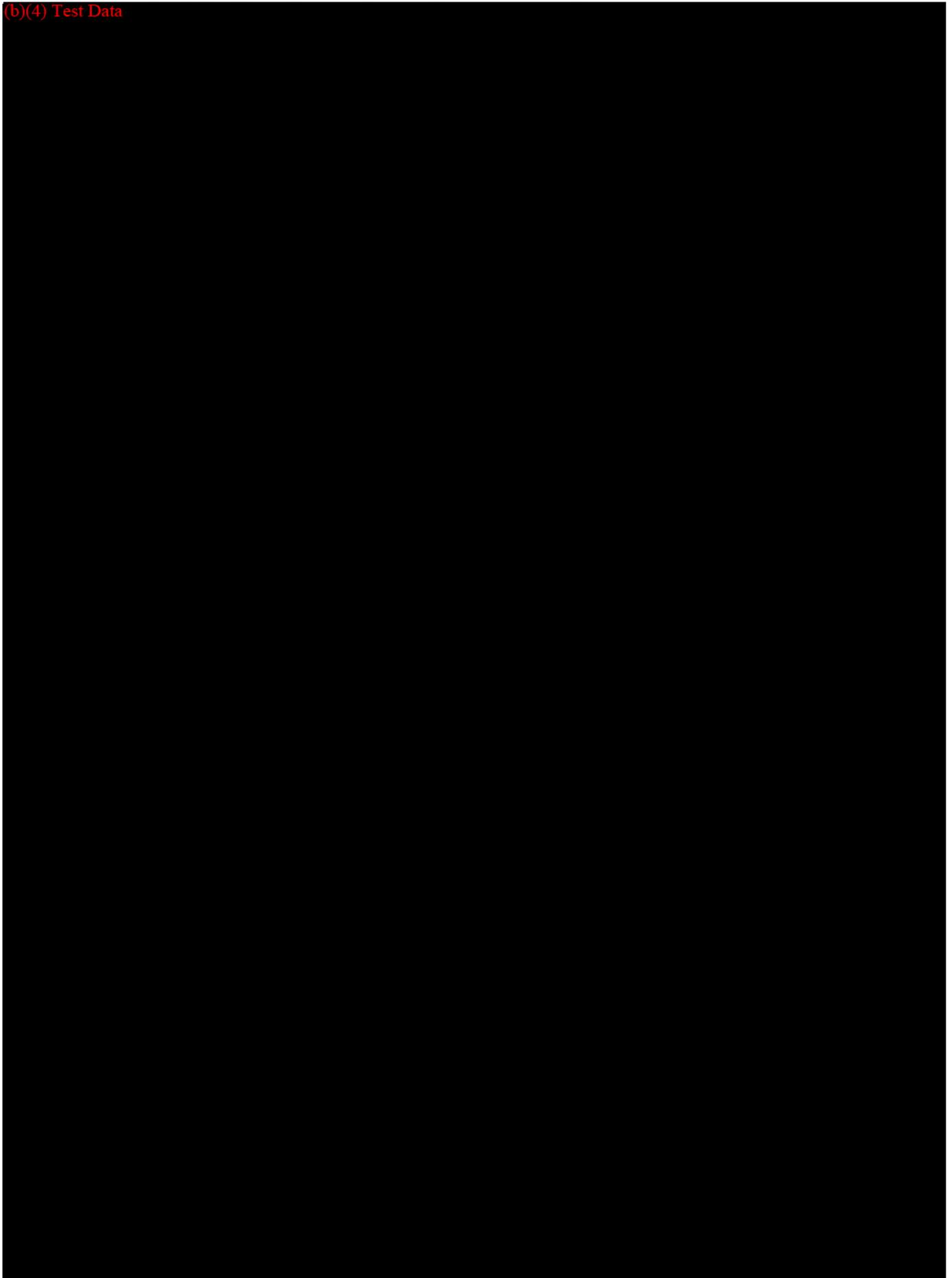
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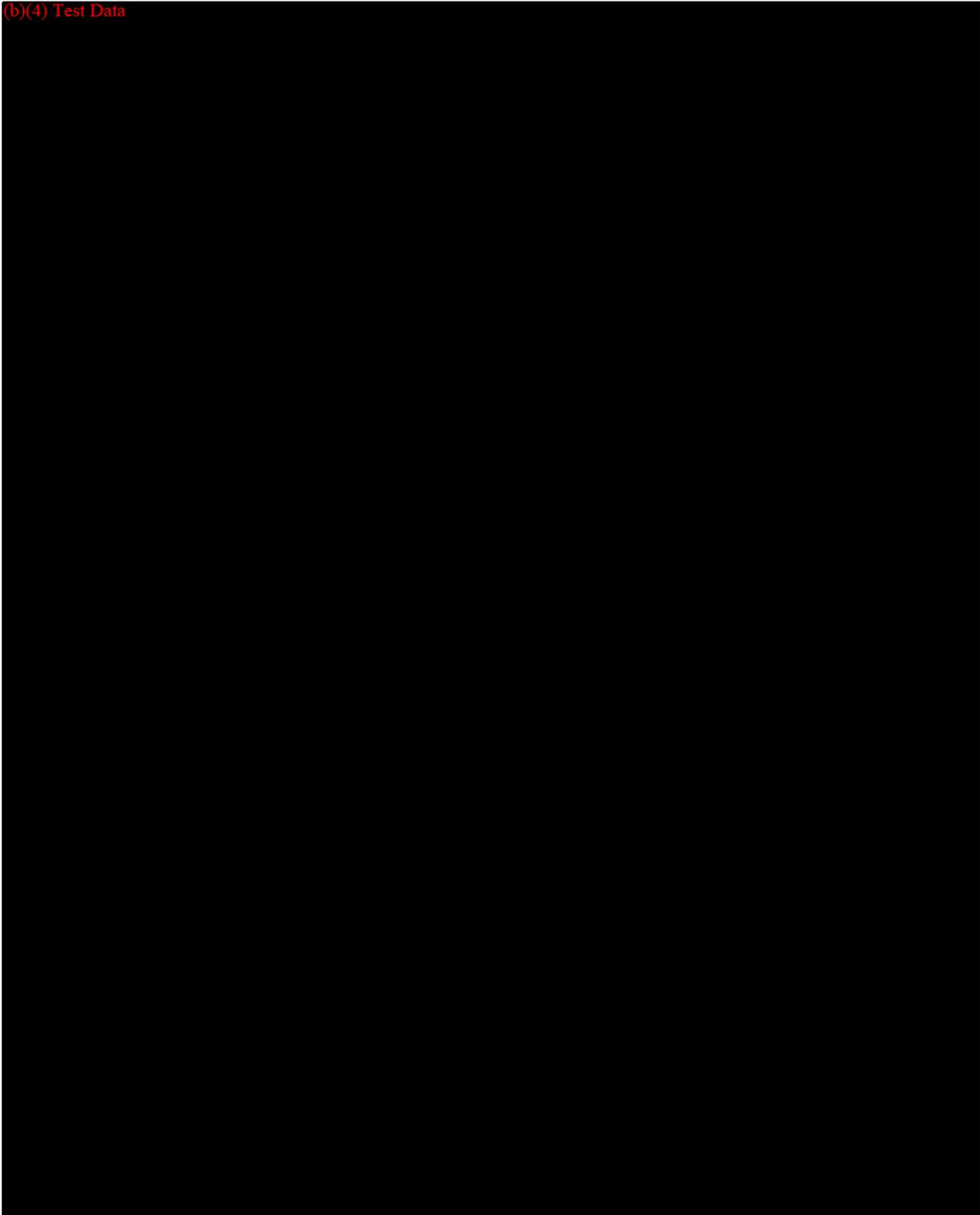
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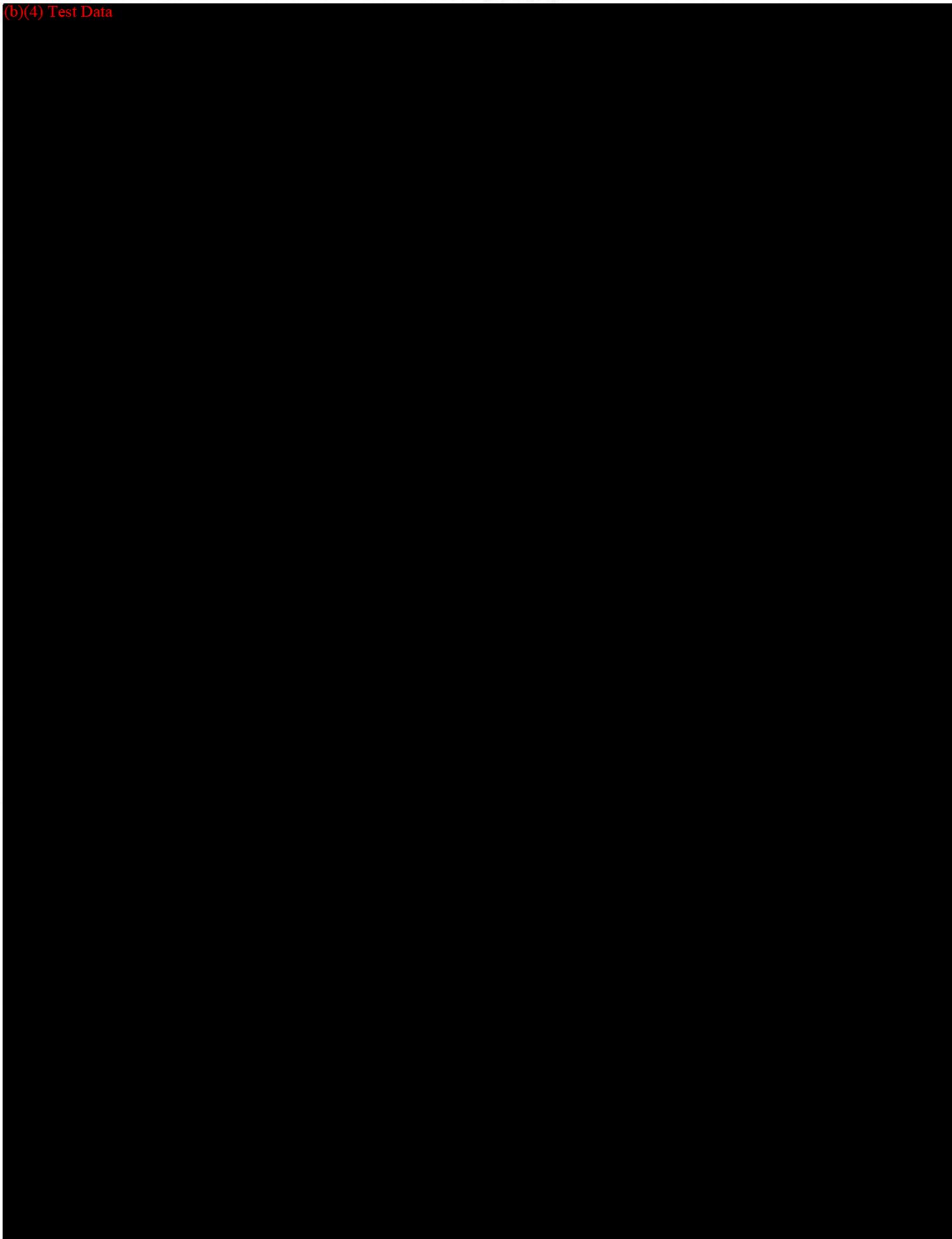


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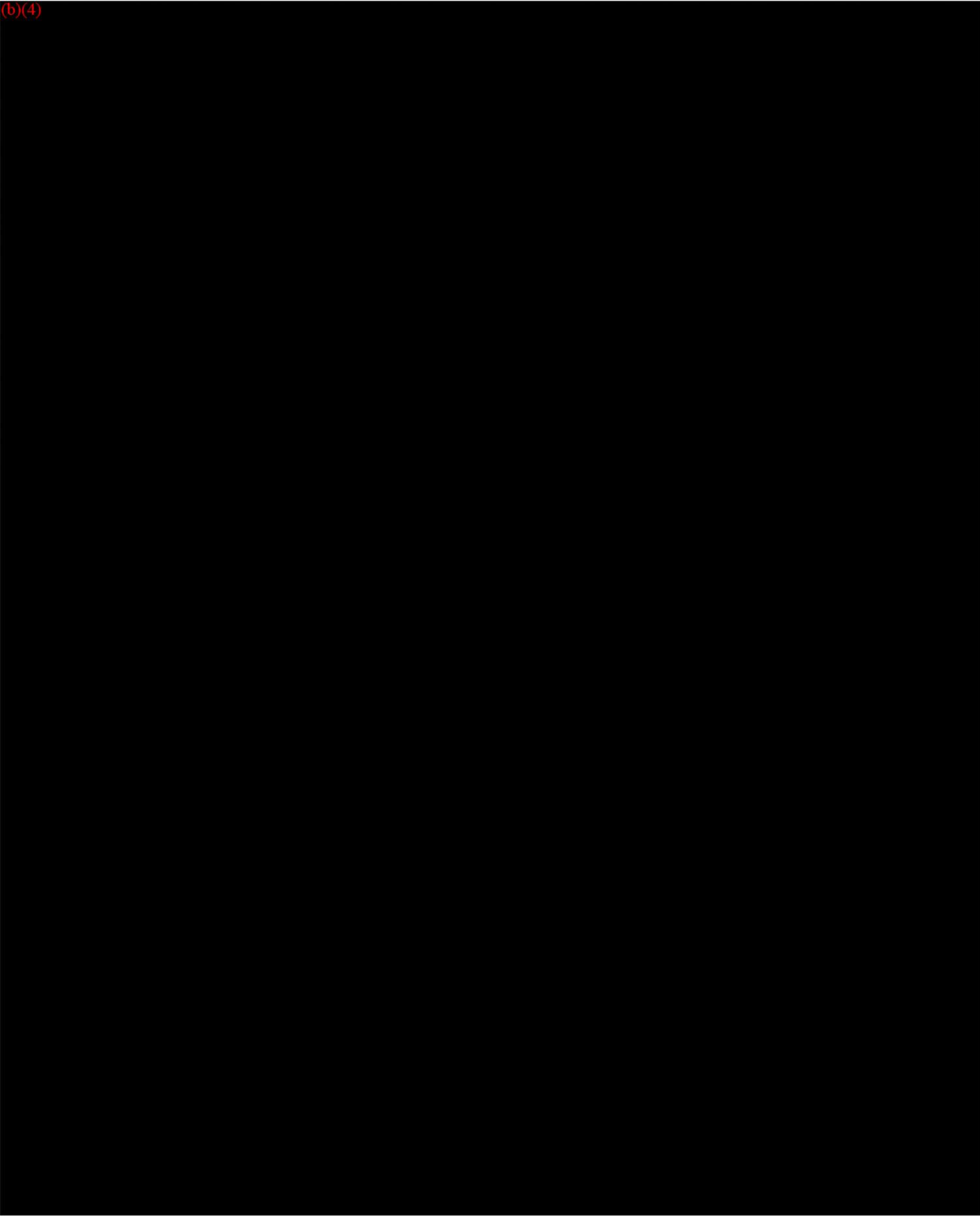


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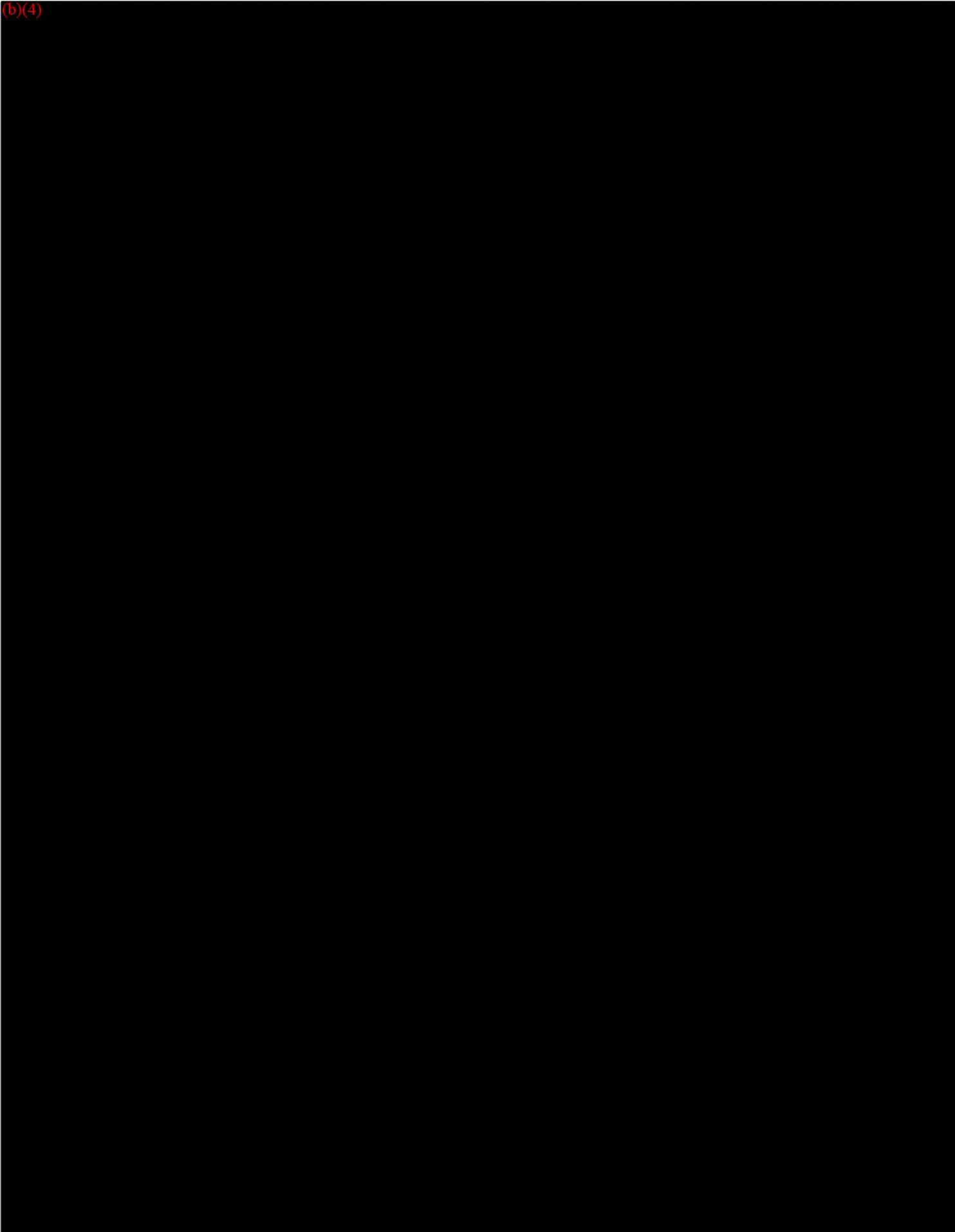




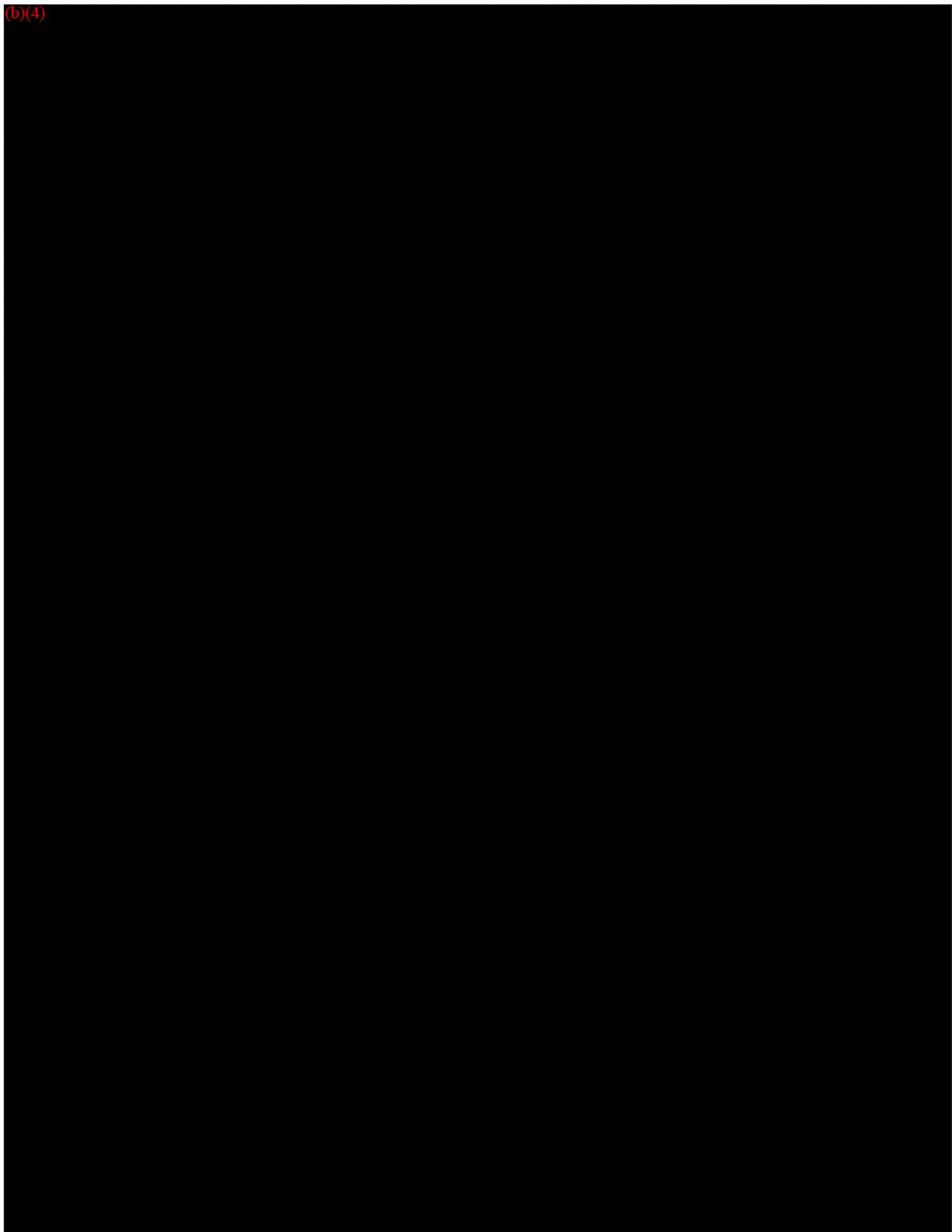
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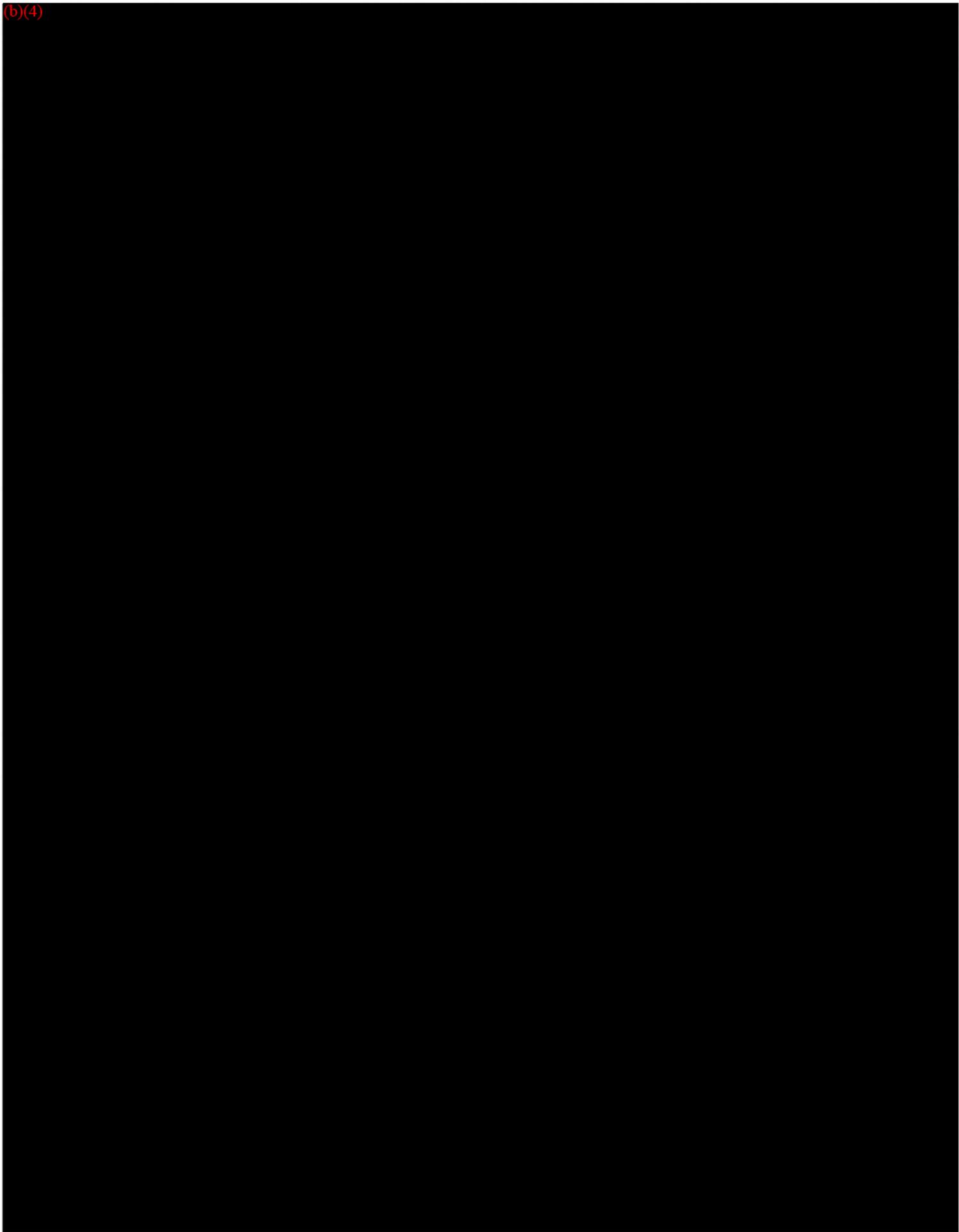
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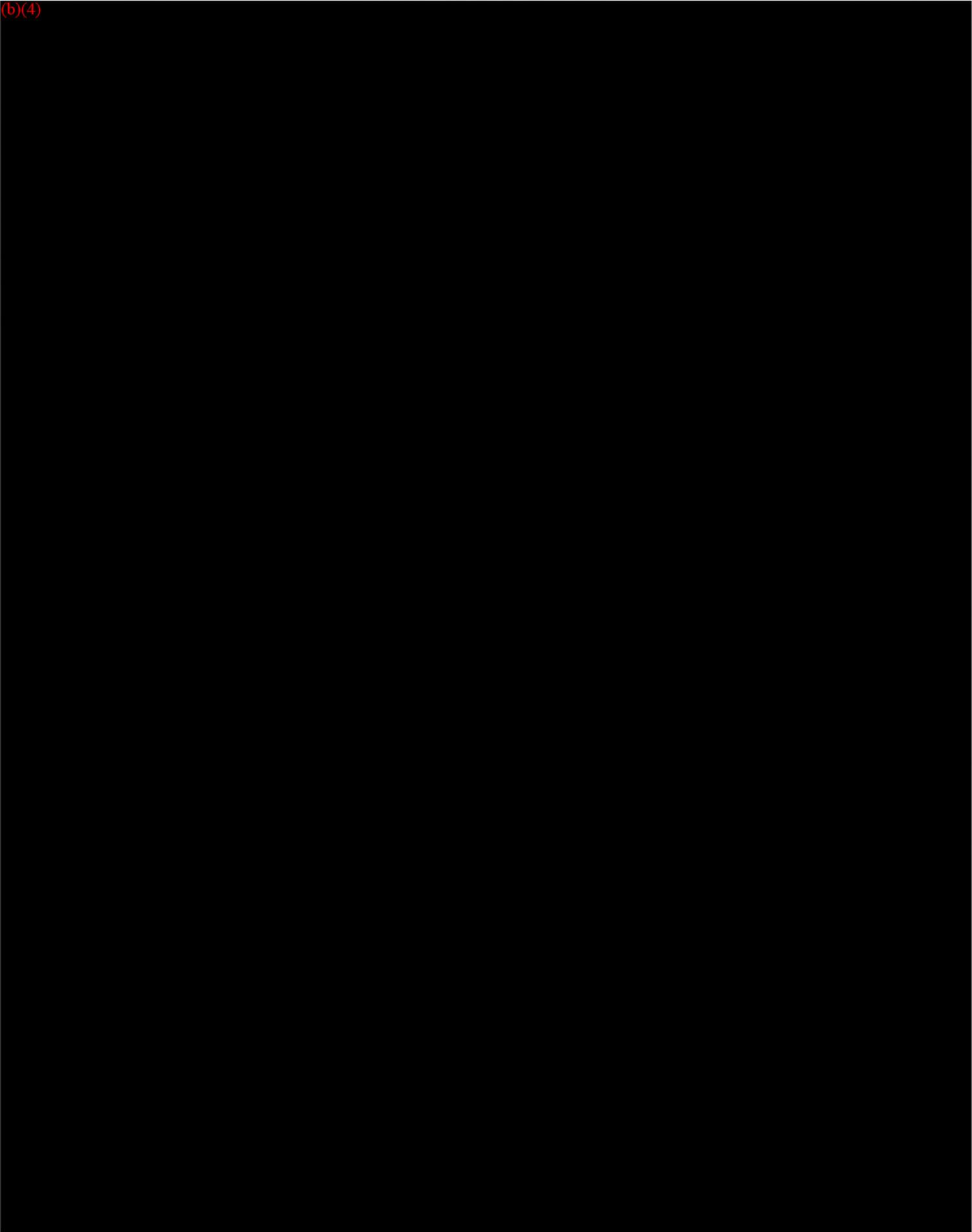
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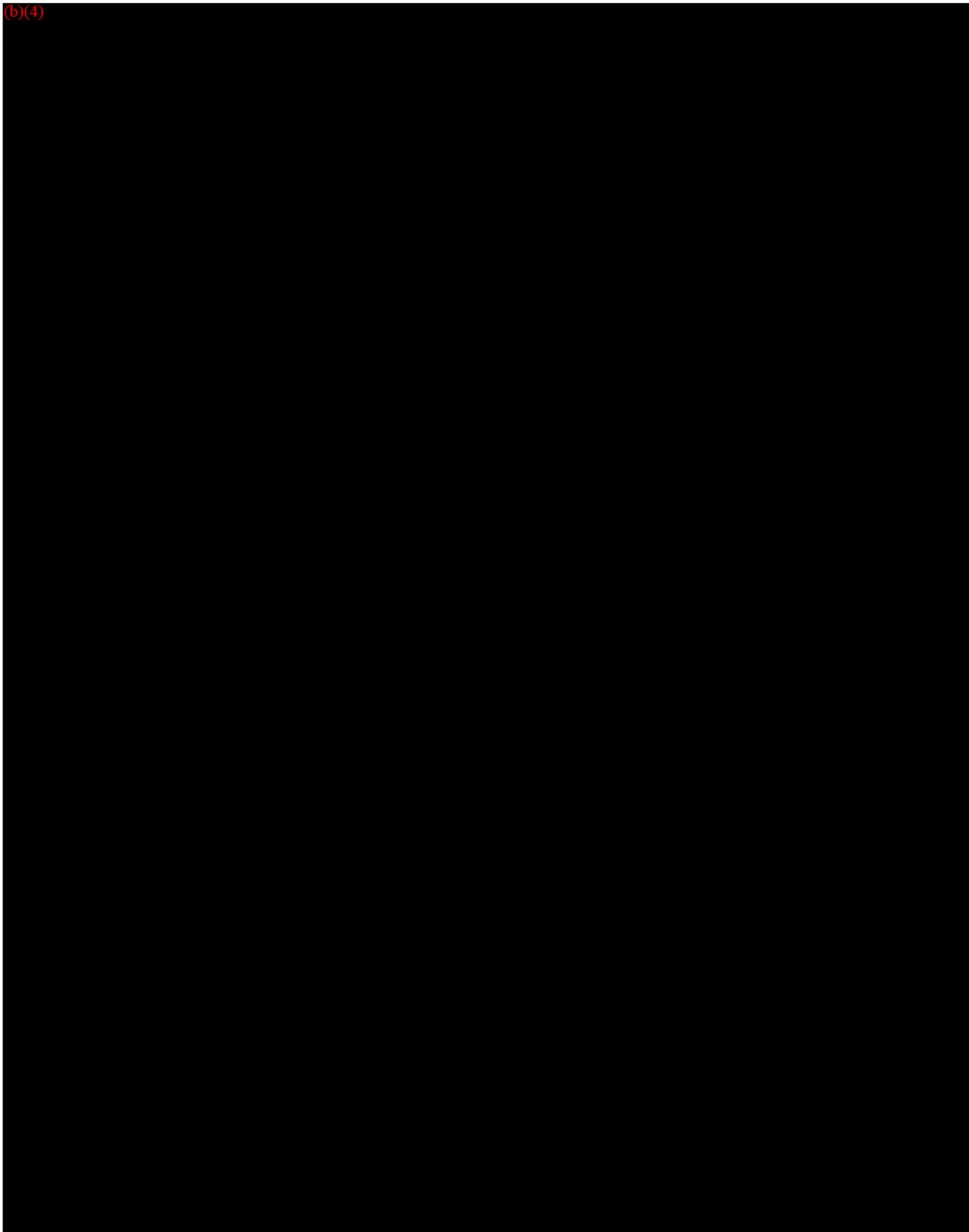
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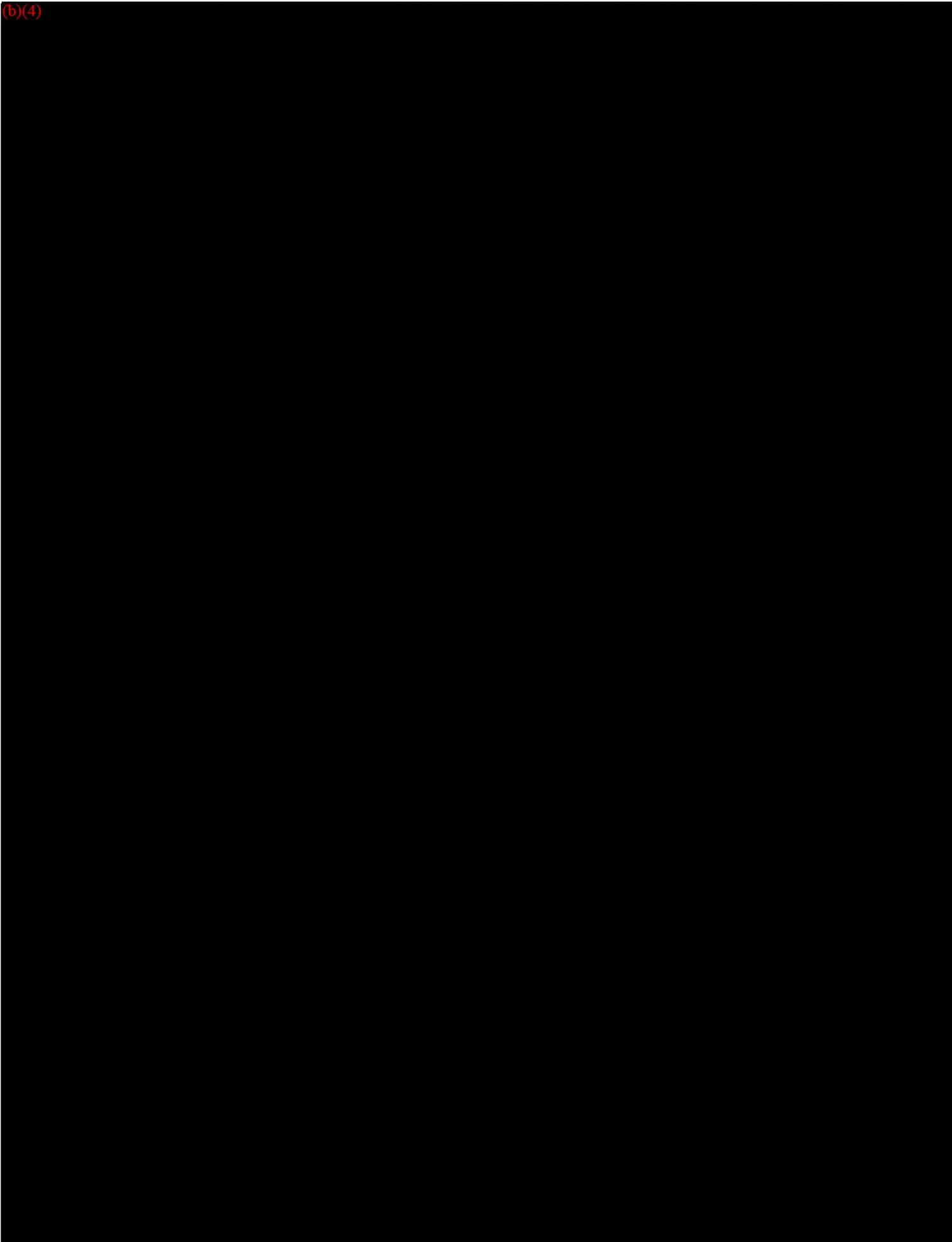


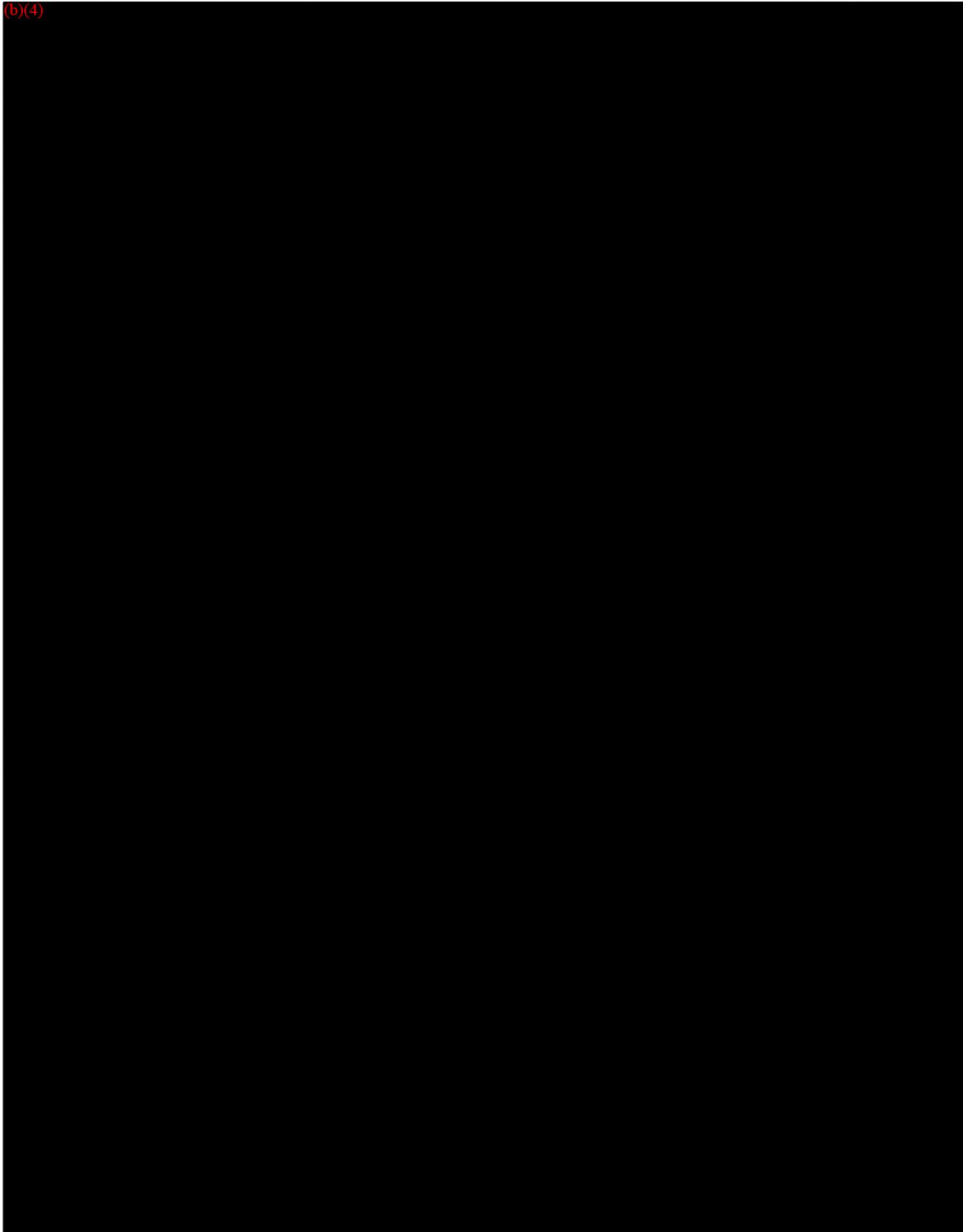
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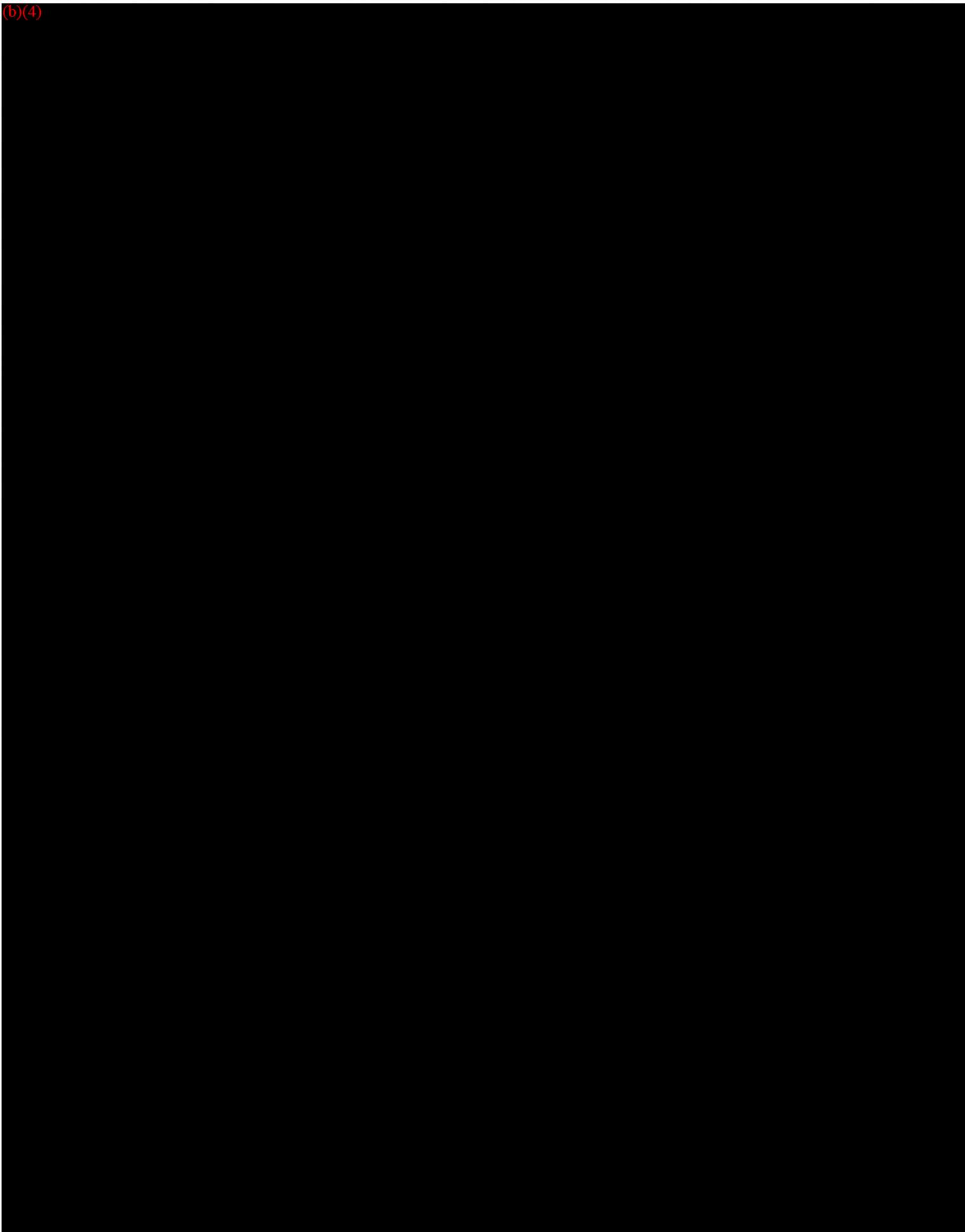
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(b)(4)









15. BIOCOMPATIBILITY

(b) (4)

HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

Top-Rank electrode pad 510k clearance information

Device Classification Name [Electrode, Cutaneous](#)²⁰

510(K) Number K070612

Device Name TOP-RANK ADHESIVE ELECTRODE

Applicant TOP-RANK HEALTH CARE EQUIPMENT CO., LTD.
Dongguan St. Shangyu City

Contact Uwe Degenhardt

Regulation Number [882.1320](#)²¹

Classification Product Code [GXY](#)²²

Date Received 03/05/2007

Decision Date 05/07/2007

Decision substantially equivalent (SE)

Classification Advisory Committee Neurology

Review Advisory Committee Neurology
statement [statement](#)²³

Type Traditional

Reviewed by Third Party Yes

Expedited Review No

Combination Product No

HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

Home Care electro conductive media 510k clearance information

Device Classification Name [media, electroconductive](#)²⁰

510(K) Number	K022494
Device Name	HOME CARE JELLY
Applicant	ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY 2064 tamarin dr. columbus, OH 43235
Contact	shu-chen cheng
Regulation Number	882.1275 ²¹
Classification Product Code	GYB ²²
Date Received	07/29/2002
Decision Date	12/02/2002
Decision	substantially equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee statement	Neurology statement ²³
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No
Combination Product	No

[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

510(k) Premarket Notification



510(k)⁷|[Registration & Listing](#)⁸|[Adverse Events](#)⁹|[Recalls](#)¹⁰|[PMA](#)¹¹|[Classification](#)¹²|[Standards](#)¹³
[CFR Title 21](#)¹⁴|[Radiation-Emitting Products](#)¹⁵|[X-Ray Assembler](#)¹⁶|[Medsun Reports](#)¹⁷|[CLIA](#)¹⁸|[TPLC](#)¹⁹

[New Search](#)

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Device Classification Name	Electrode, Cutaneous ²⁰
510(K) Number	K070612
Device Name	TOP-RANK ADHESIVE ELECTRODE
Applicant	TOP-RANK HEALTH CARE EQUIPMENT CO., LTD. Dongguan St. Shangyu City,
Contact	Uwe Degenhardt
Regulation Number	882.1320 ²¹
Classification Product Code	GXY ²²
Date Received	03/05/2007
Decision Date	05/07/2007
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement	Statement ²³
Type	Traditional
Reviewed By Third Party	Yes
Expedited Review	No
Combination Product	No

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20. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=GXY
21. </scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.1320>



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Top-Rank Health Care Equipment Co., Ltd.
% Ms. Laura Danielson
TPR Project Manager
TÜV SUD America Inc.
1775 Old Highway 8 NW
New Brighton, Minnesota 55112

MAY - 7 2007

Re: K070612

Trade/Device Name: Top-Rank Adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: April 20, 2007
Received: April 23, 2007

Dear Ms. Danielson:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set

Page 2 – Ms. Laura Danielson

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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is written in a cursive style with a large initial "M".

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

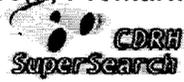
Radiological Health

Enclosure

510(k) Premarket Notification

FDA Home³ Medical Devices⁴ Databases⁵

510(k) Premarket Notification



510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³
CFR Title 21¹⁴|Radiation-Emitting Products¹⁵|X-Ray Assembler¹⁶|Medsun Reports¹⁷|CLIA¹⁸|TPLC¹⁹

[New Search](#)

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Device Classification Name	Media, Electroconductive ²⁰
510(K) Number	K022494
Device Name	HOME CARE JELLY
Applicant	ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY 2064 Tamarin Dr. Columbus, OH 43235
Contact	Shu-Chen Cheng
Regulation Number	882.1275 ²¹
Classification Product Code	GYB ²²
Date Received	07/29/2002
Decision Date	12/02/2002
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement	Statement ²³
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No
Combination Product	No

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18. [../cfClia/Search.cfm](..cfClia/Search.cfm)
19. [../cfTPLC/tplc.cfm](..cfTPLC/tplc.cfm)
20. /scripts/cdrh/cfdocs/cfpcd/classification.cfm?start_search=1&productcode=GYB



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 02 2002

Dr. Jen, Ken-Min
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, Taiwan, ROC

Re: K022494

Trade/Device Name: Home Care Jelly
Regulation Number: 21 CFR 882.1275
Regulation Name: Electroconductive media
Regulatory Class: Class II
Product Code: GYB
Dated: September 27, 2002
Received: November 1, 2002

Dear Dr. Jen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic

Page 2 - Dr. Jen

product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

Applicant : HOME CARE TECHNOLOGY CO., LTD.

510(k) Number : TO BE ASSIGNED K022494

Device Name : HOME CARE JELLY

Indications for Use :

Intended to be used with external electrodes to reduce the impedance of the contact between the electrode surface and the skin.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____
Per 21 CFR 801.109

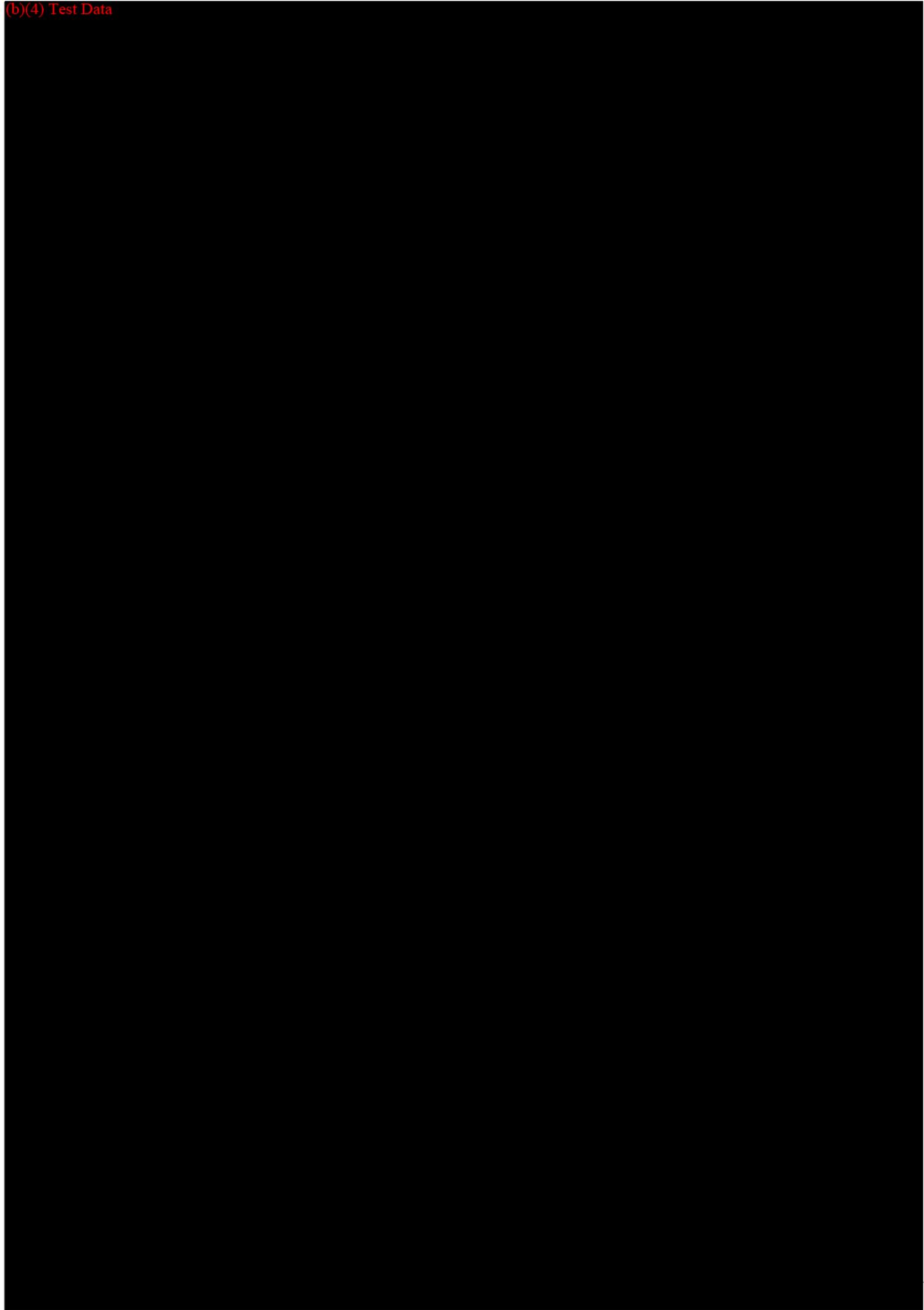
OR

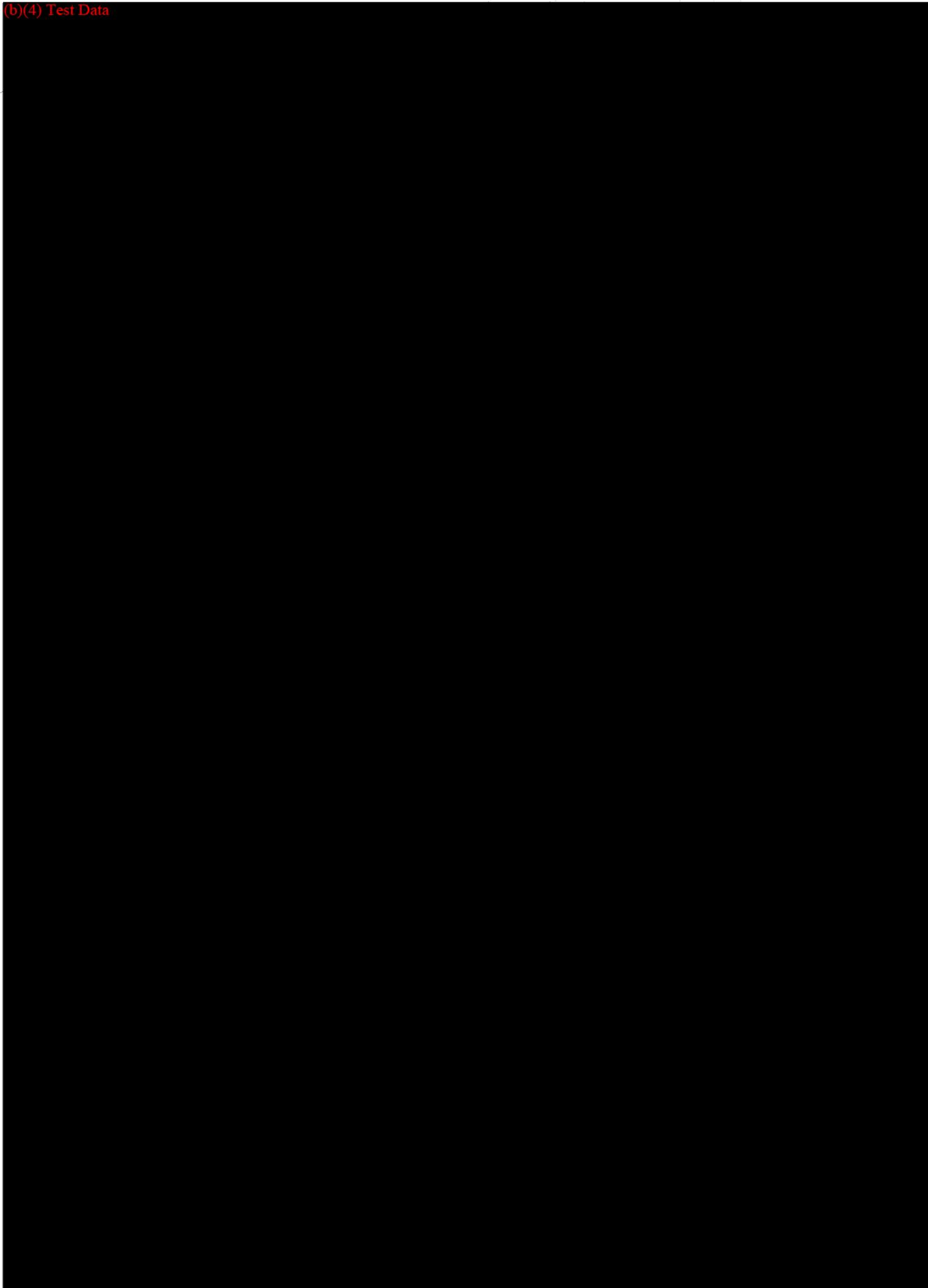
Over-The-Counter _____
(Optional Format 1-2-96)

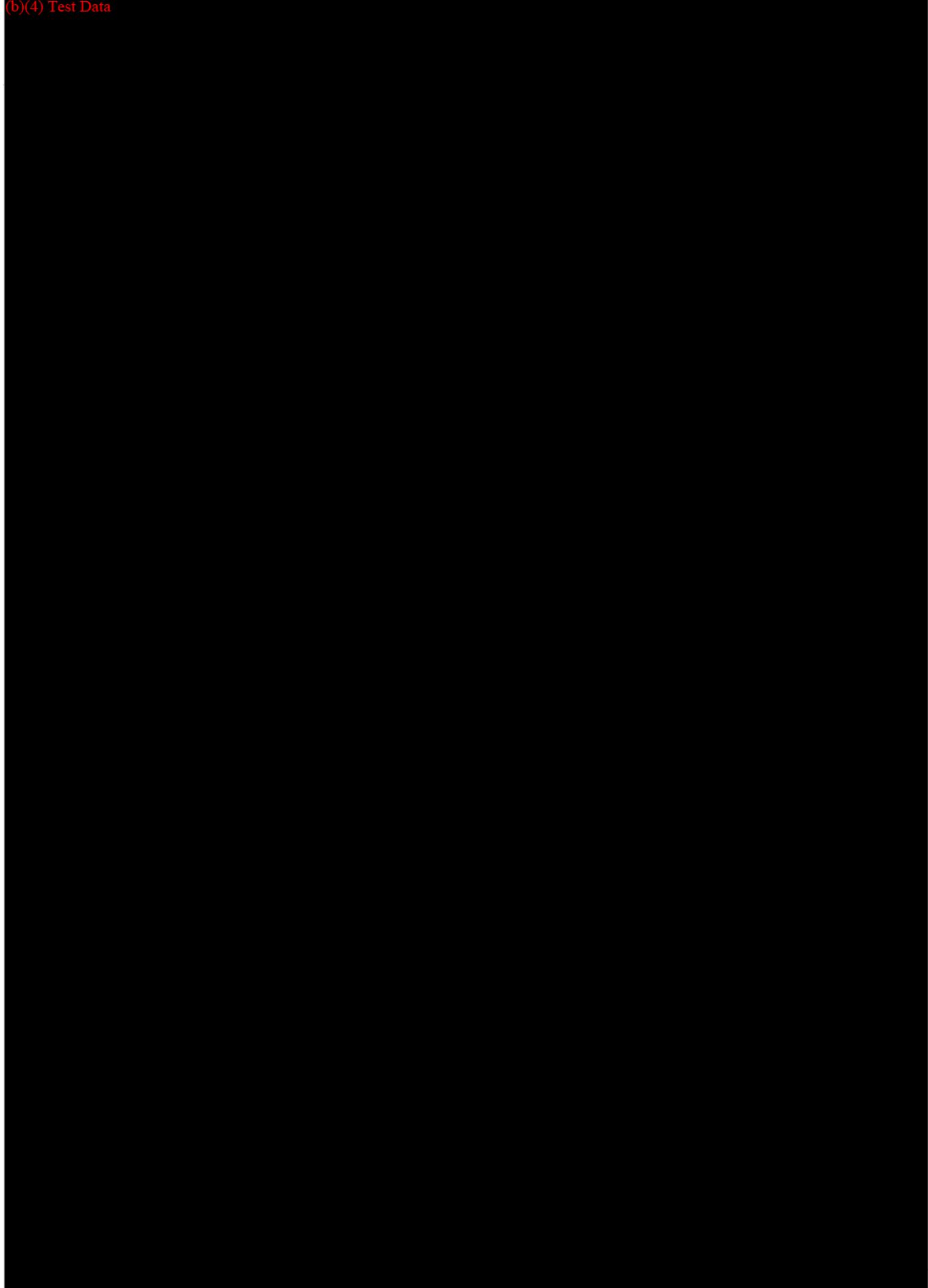
Miriam C. Provost

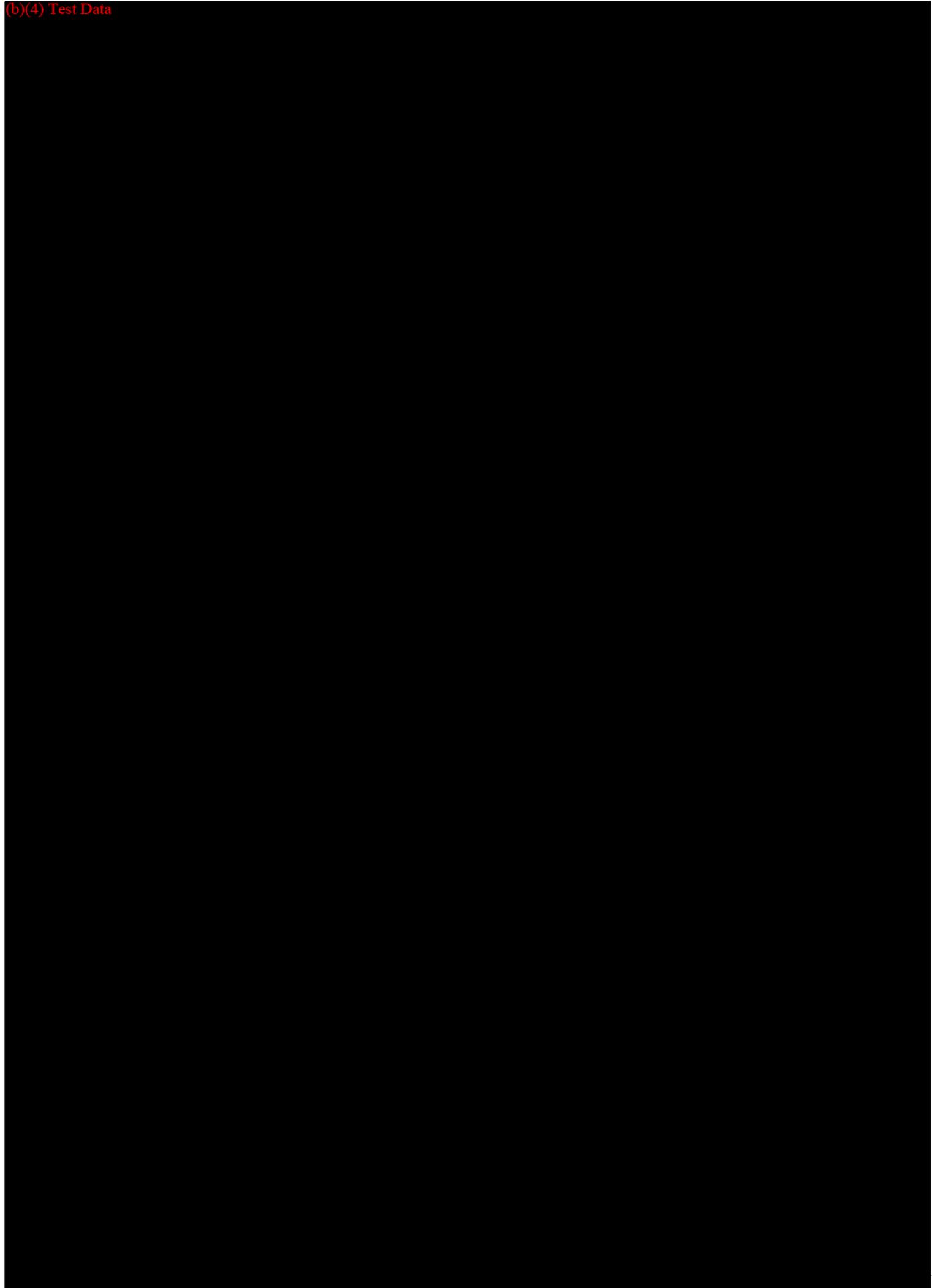
Division Sign-Off
Division of General Restorative
and Neurological Devices

K022494

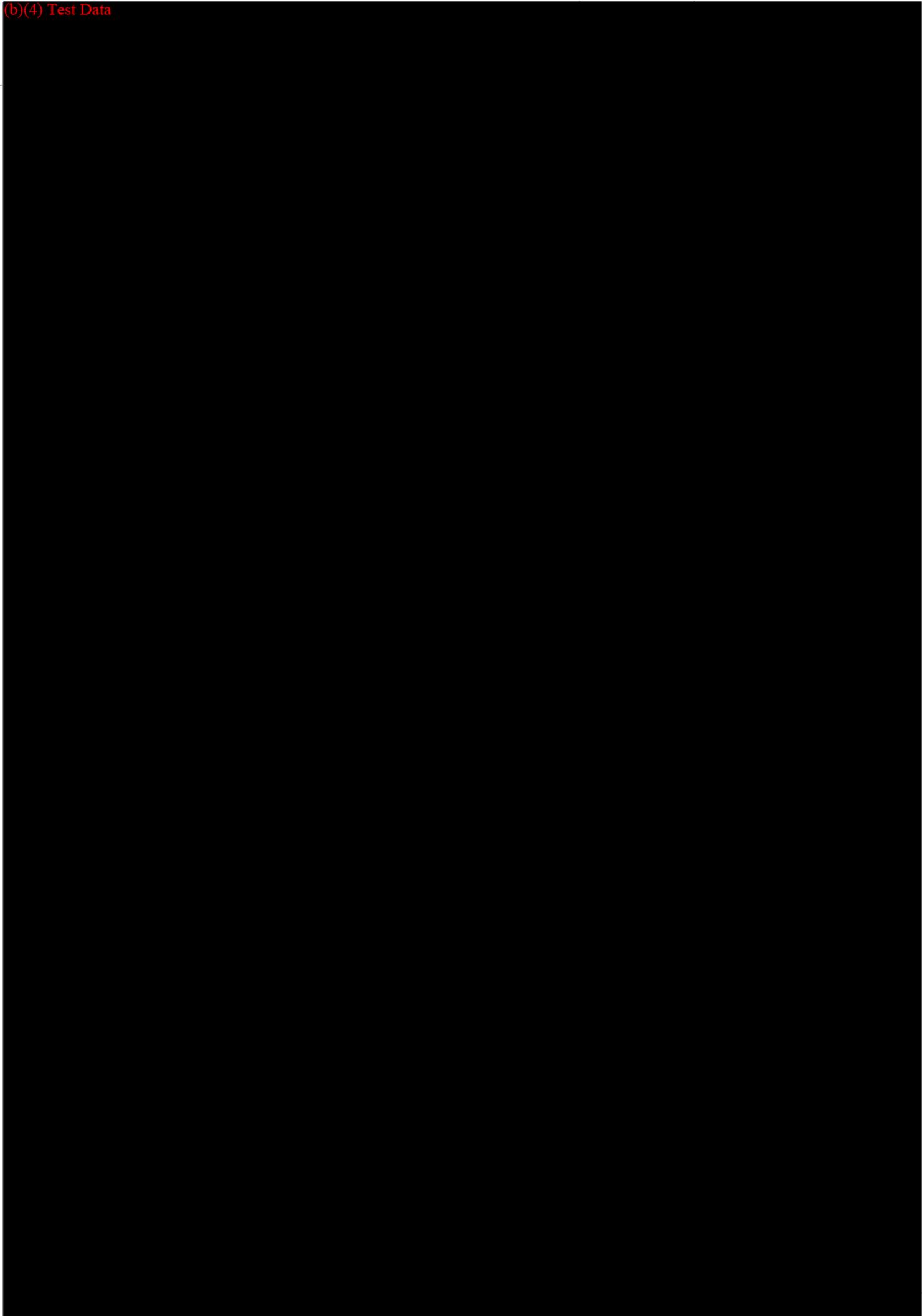


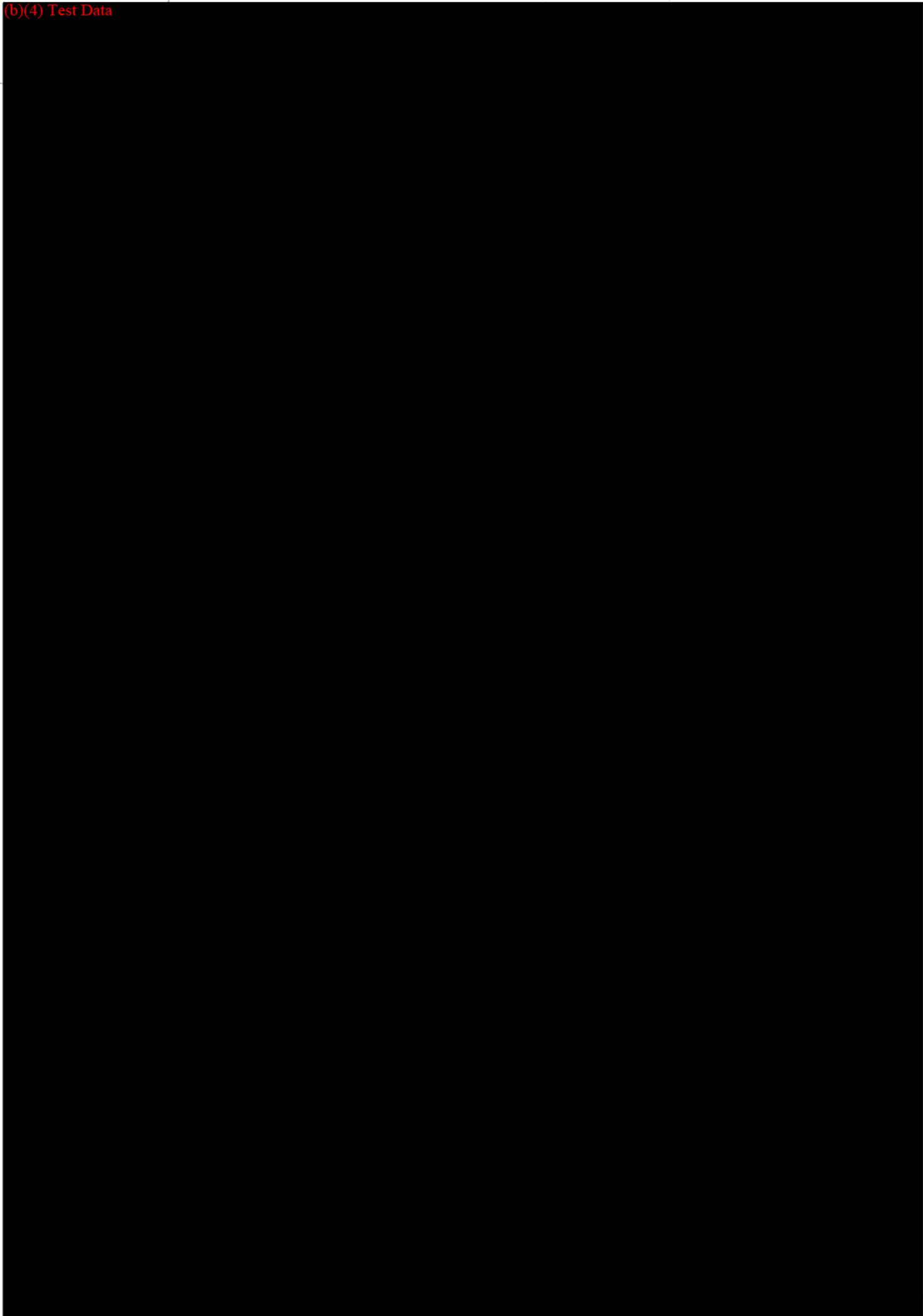


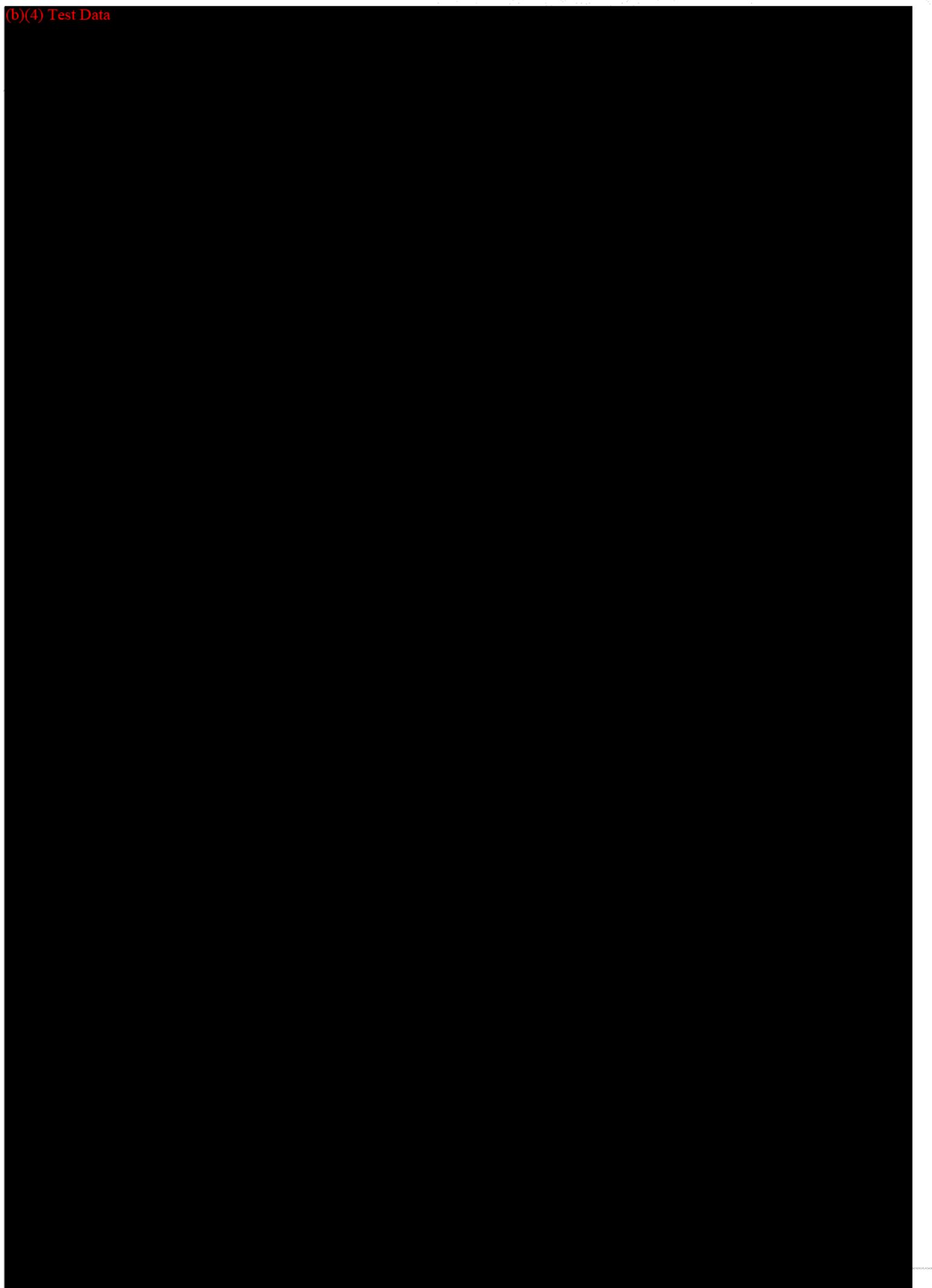












16. SOFTWARE

There are 5 Software-Control functions for the SP-910 / SP-920 / SP-620 :

1. **+/- Key Function:** Device turns on and output level control
2. **Power:** Turn on device with pushing down + key for 2-second long.
3. **Contact Detection:** If the pad is not contacted properly, the device cuts stimulation down to 0 level with audible alarm for warning.
4. **Low Battery Detection:** Audible alarm for warning when battery power is detected in low voltage.
5. **Stimulation Output:** Electrical pulse generated for stimulation.

We place two Software Validation Reports for SP-910 and for SP-920 / SP-620 in the following pages. The Software of HIVOX Spopad EMS SP-910 / SP-920 / SP-620 meet the requirements of FDA 510(K) guidance document “Guidance for the Content of Pre-market Submission for Software Contained in Medical Devices”.

Software Validation of HIVOX Spopad EMS SP-910

HIVOX BIOTEK INC.

version (b)(4)

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Write by :

(b) (6)

Review by

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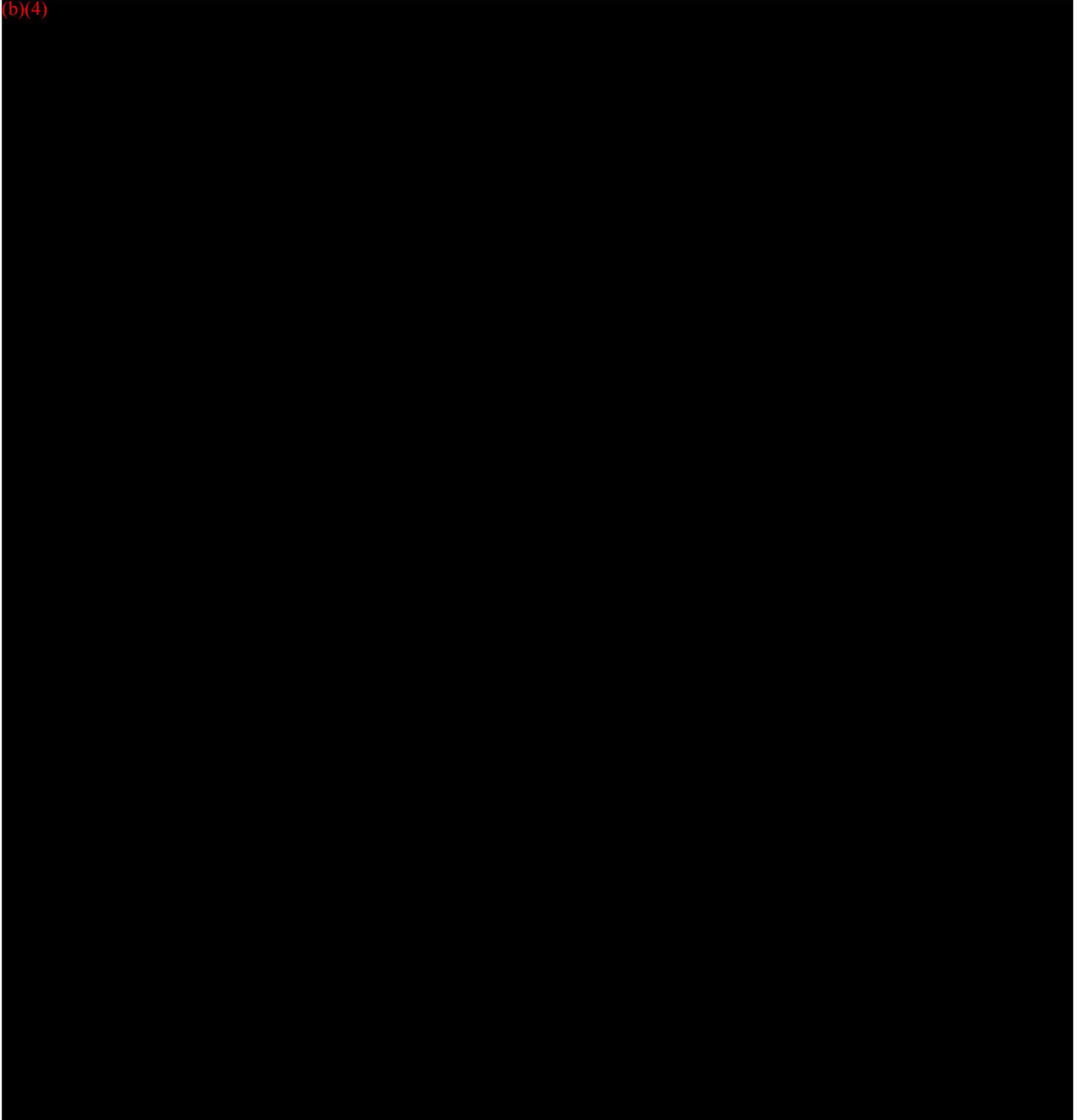
10. Software Revision History

11. Unresolved Anomalies

12. Conclusion

1. Level of Concern

(b)(4)

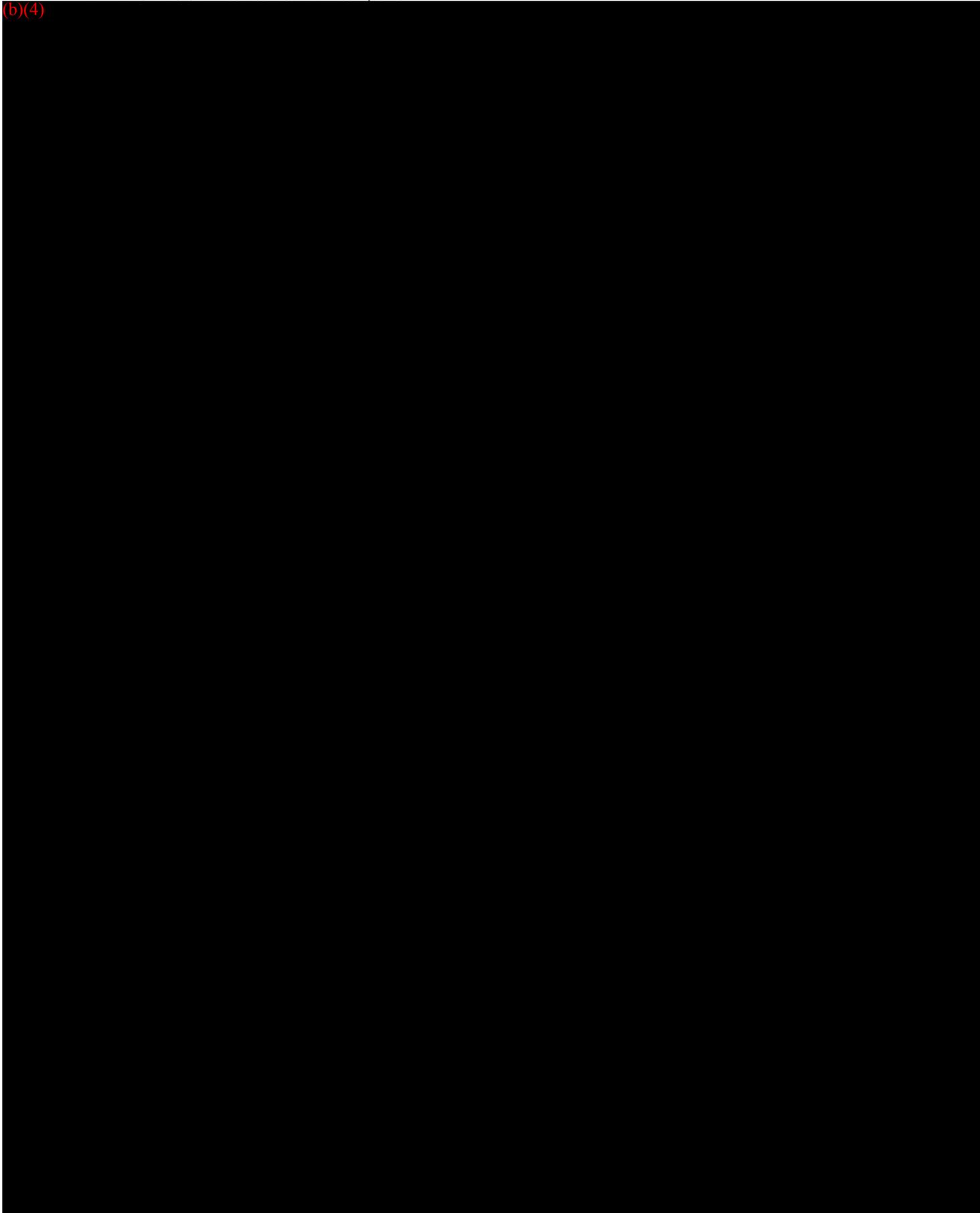


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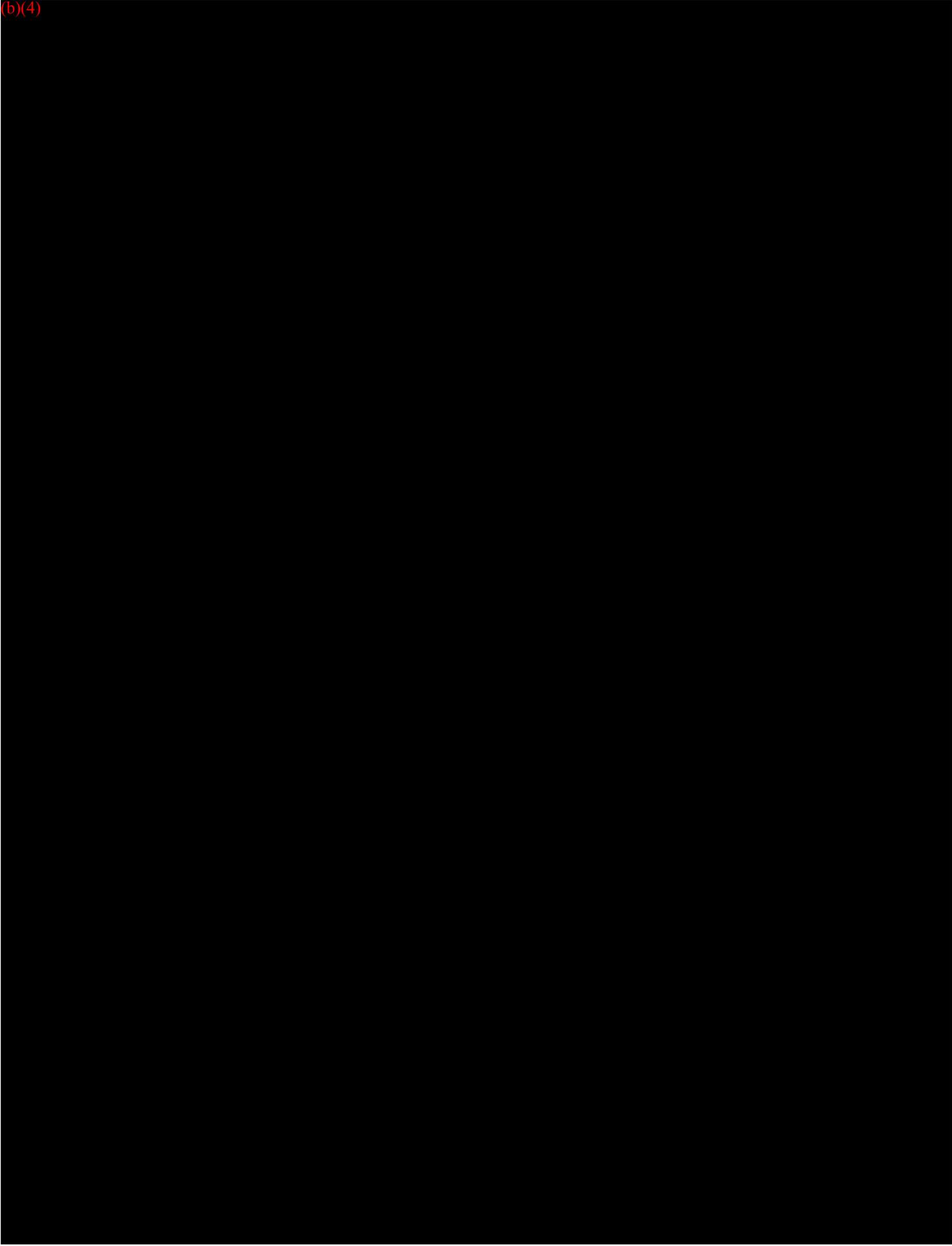


2. Device Hazard Analysis

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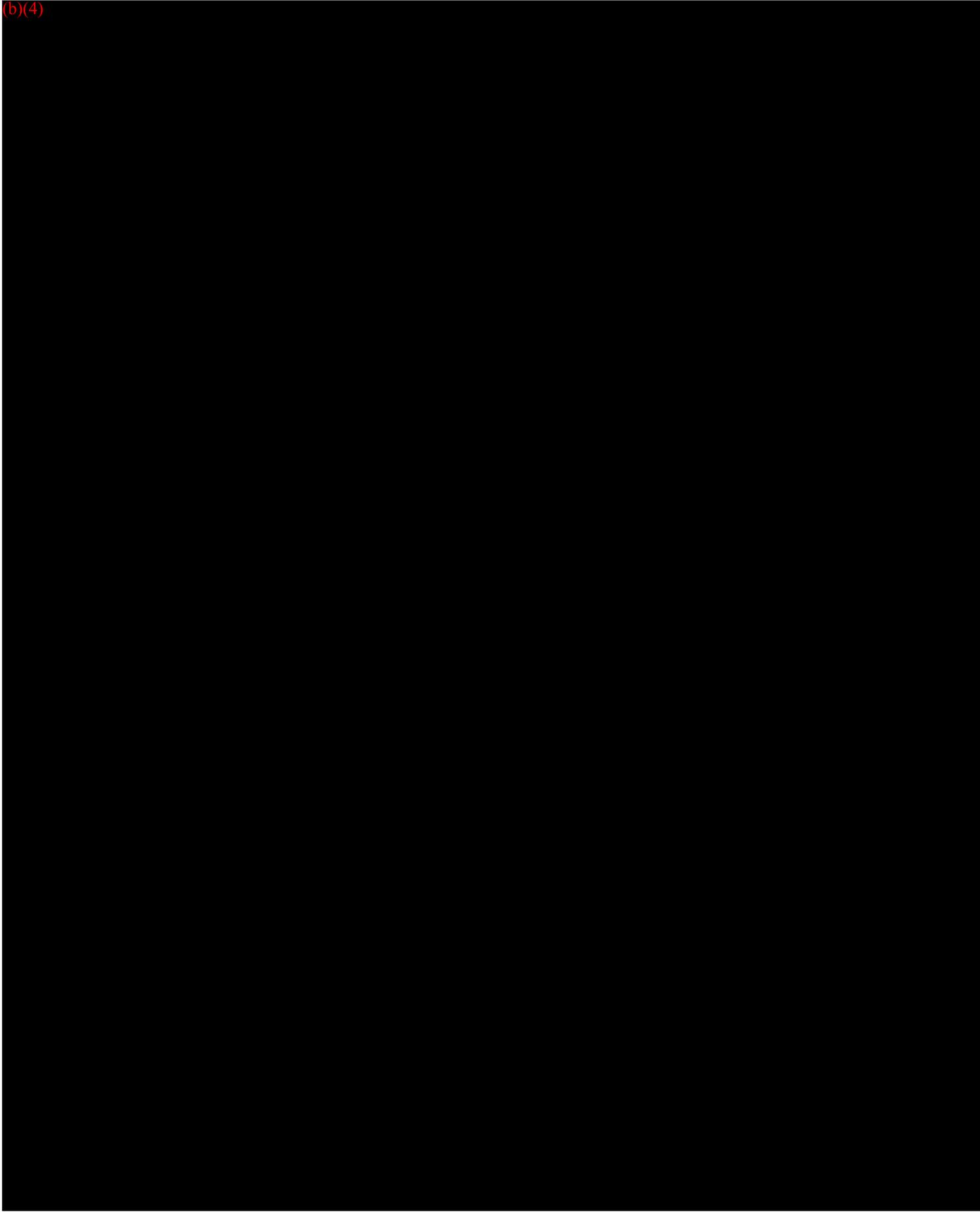


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3 Software Description:

(b)(4)



(b)(4)



(b)(4)

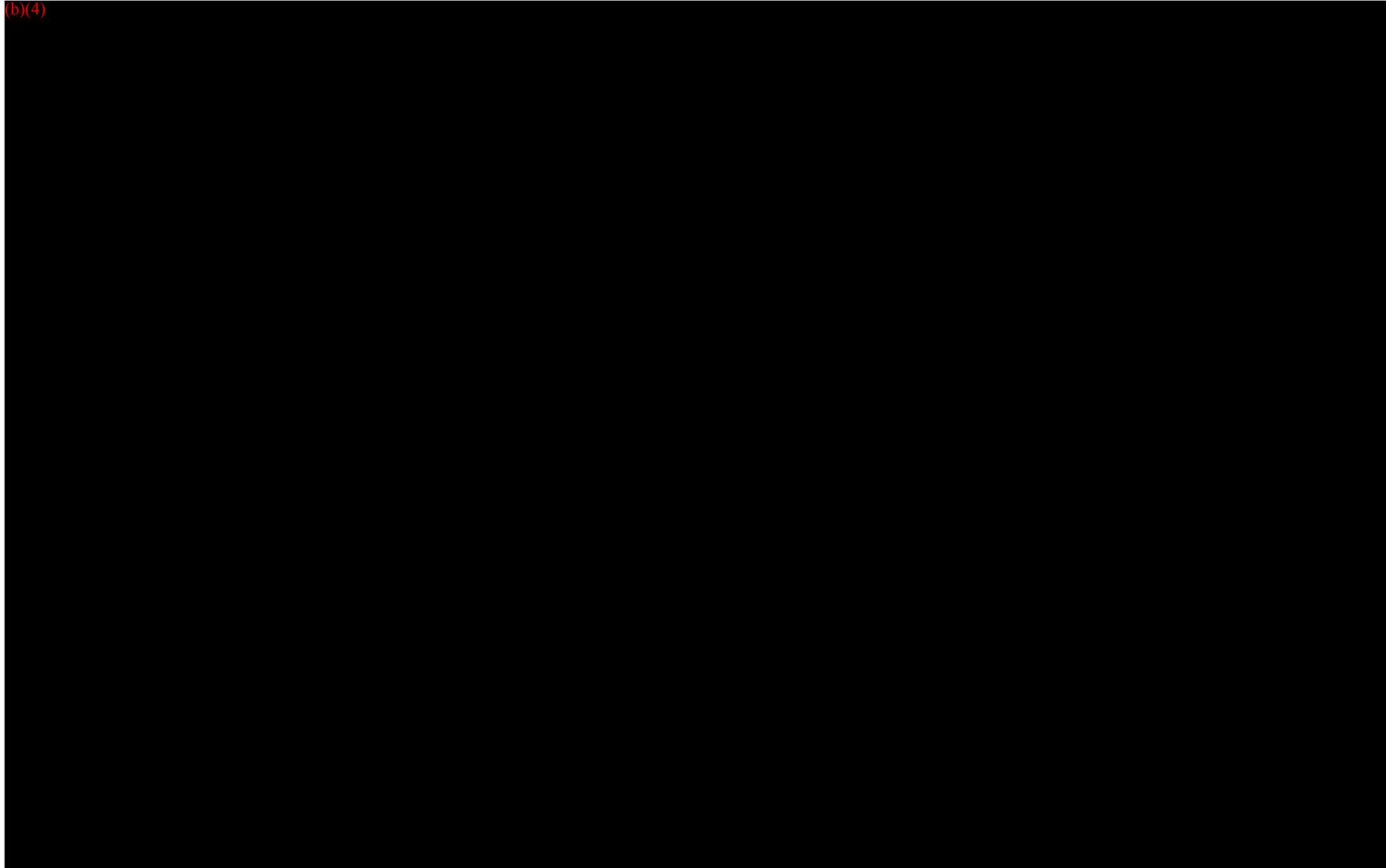


(b)(4)



4. Software Device Hazard Analysis :

(b)(4)



(b)(4)

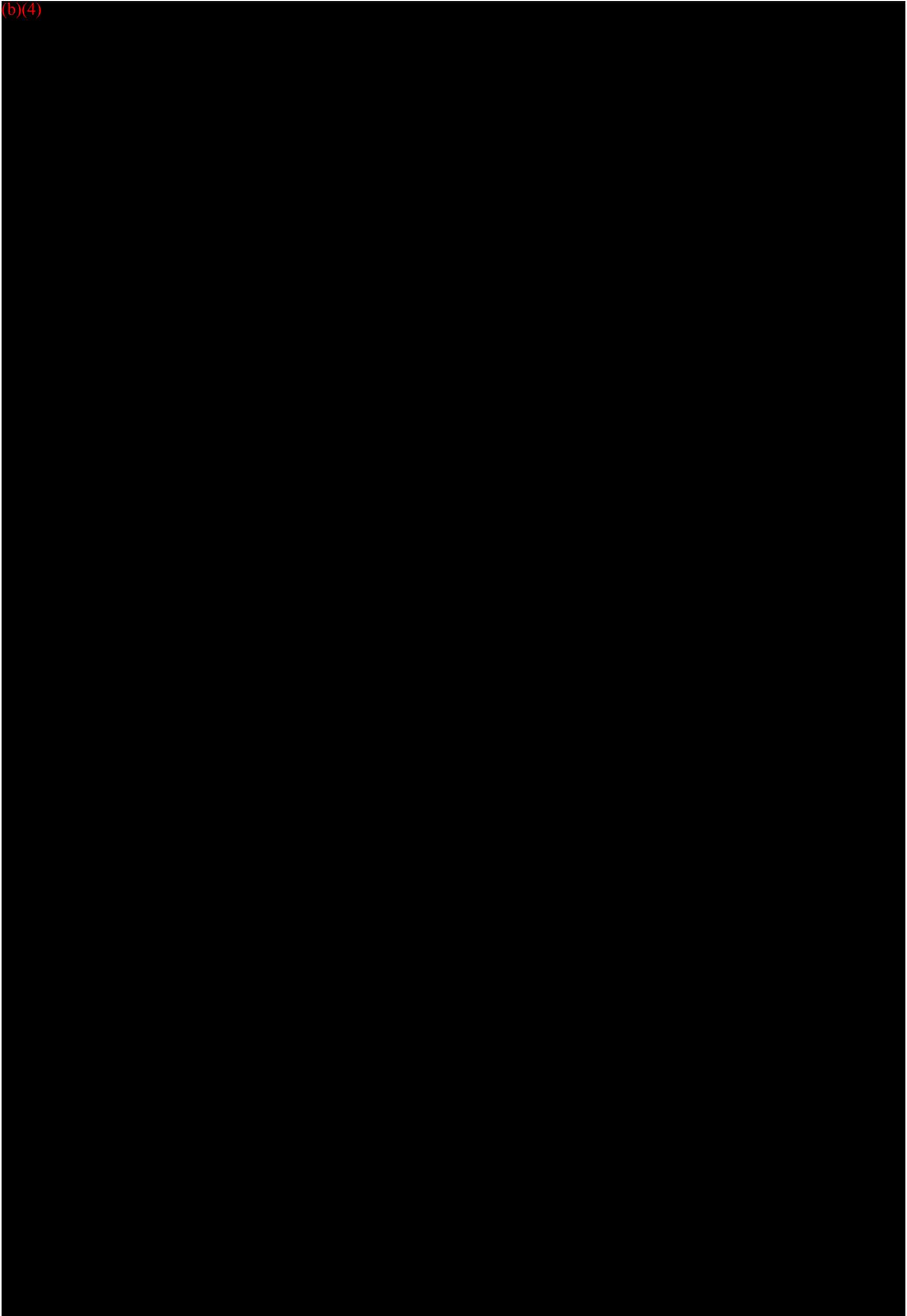


5 Software Requirements Specification



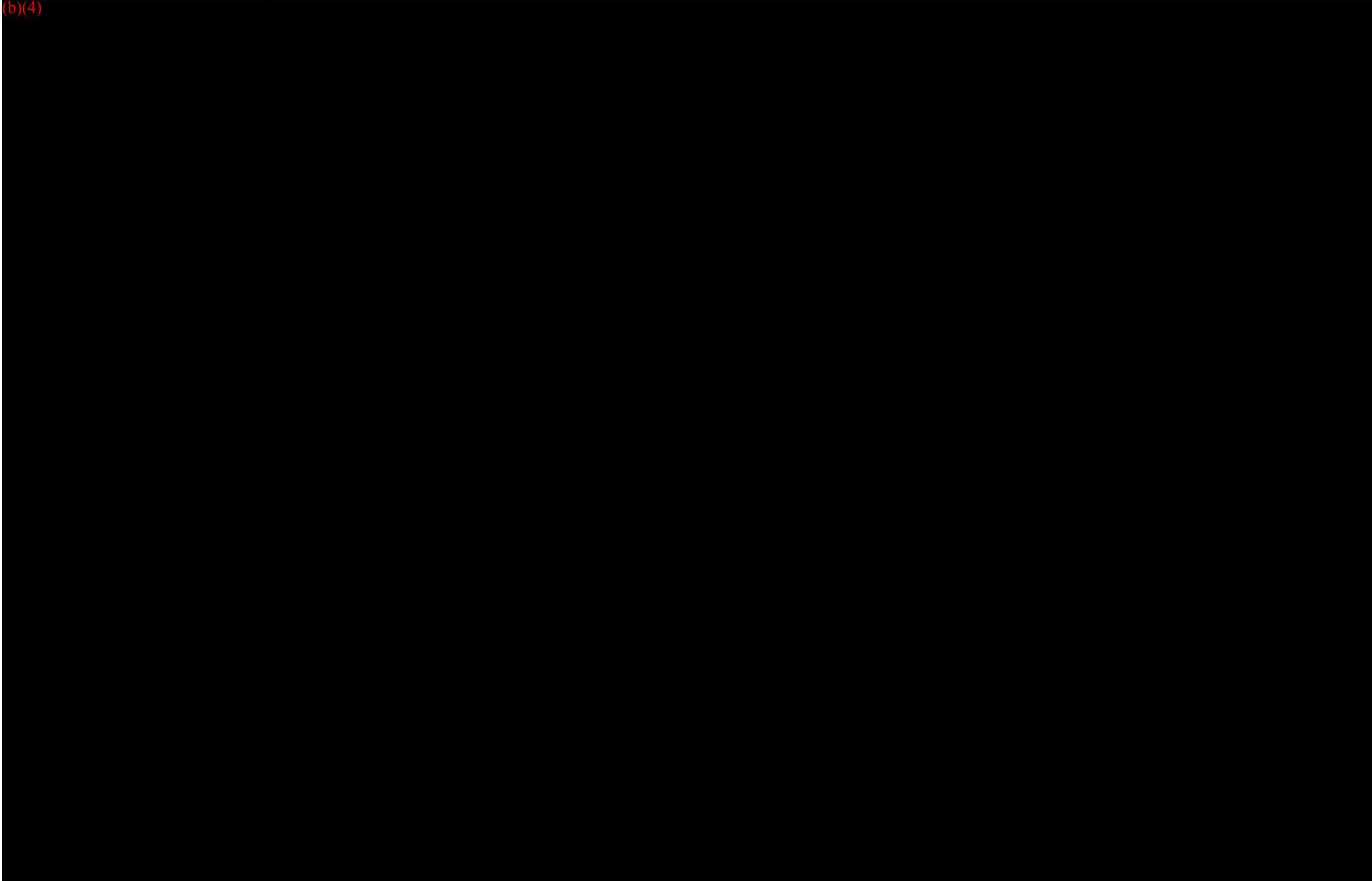
(b)(4)

(b)(4)

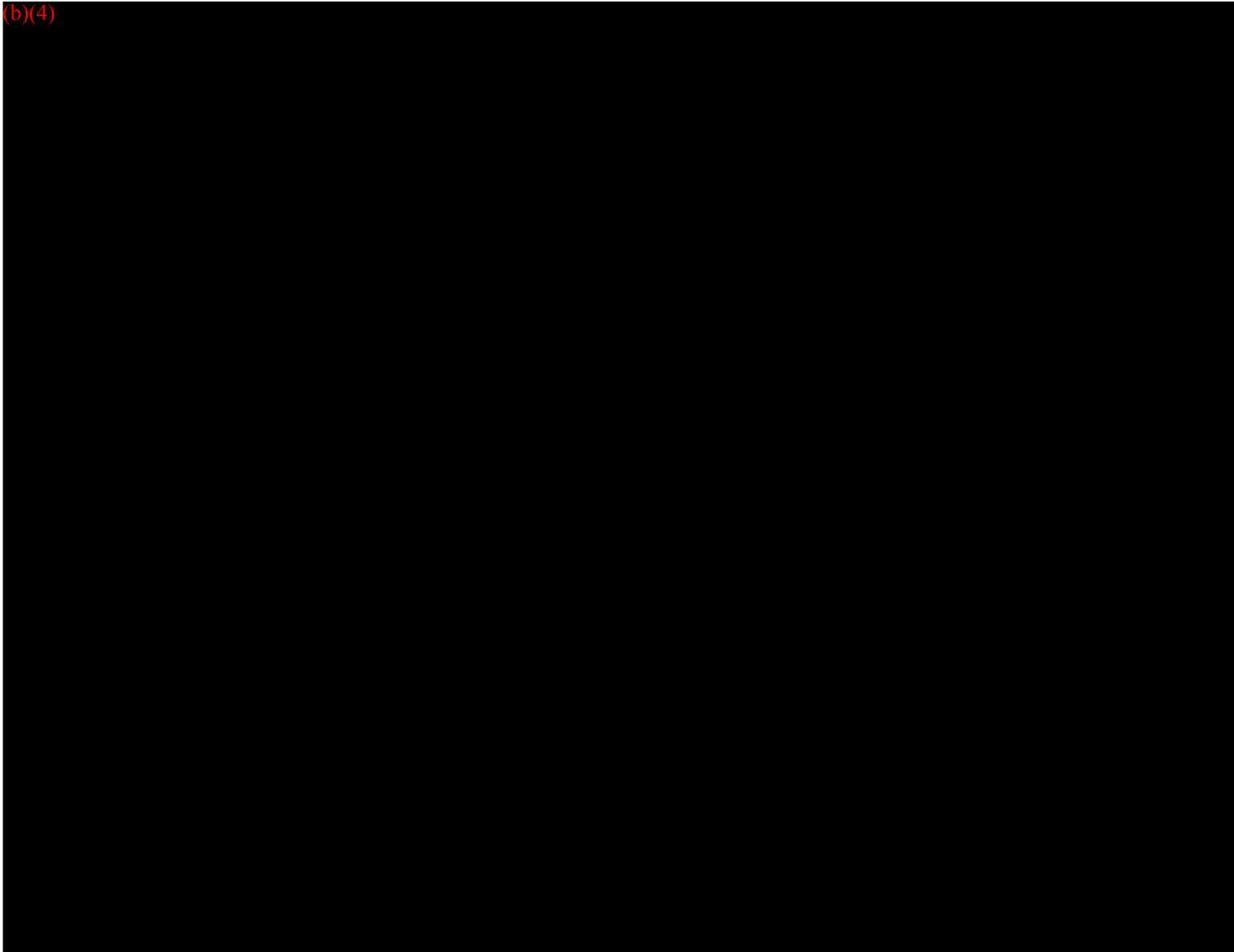


6 Architecture Design Chart:

(b)(4)



(b)(4)

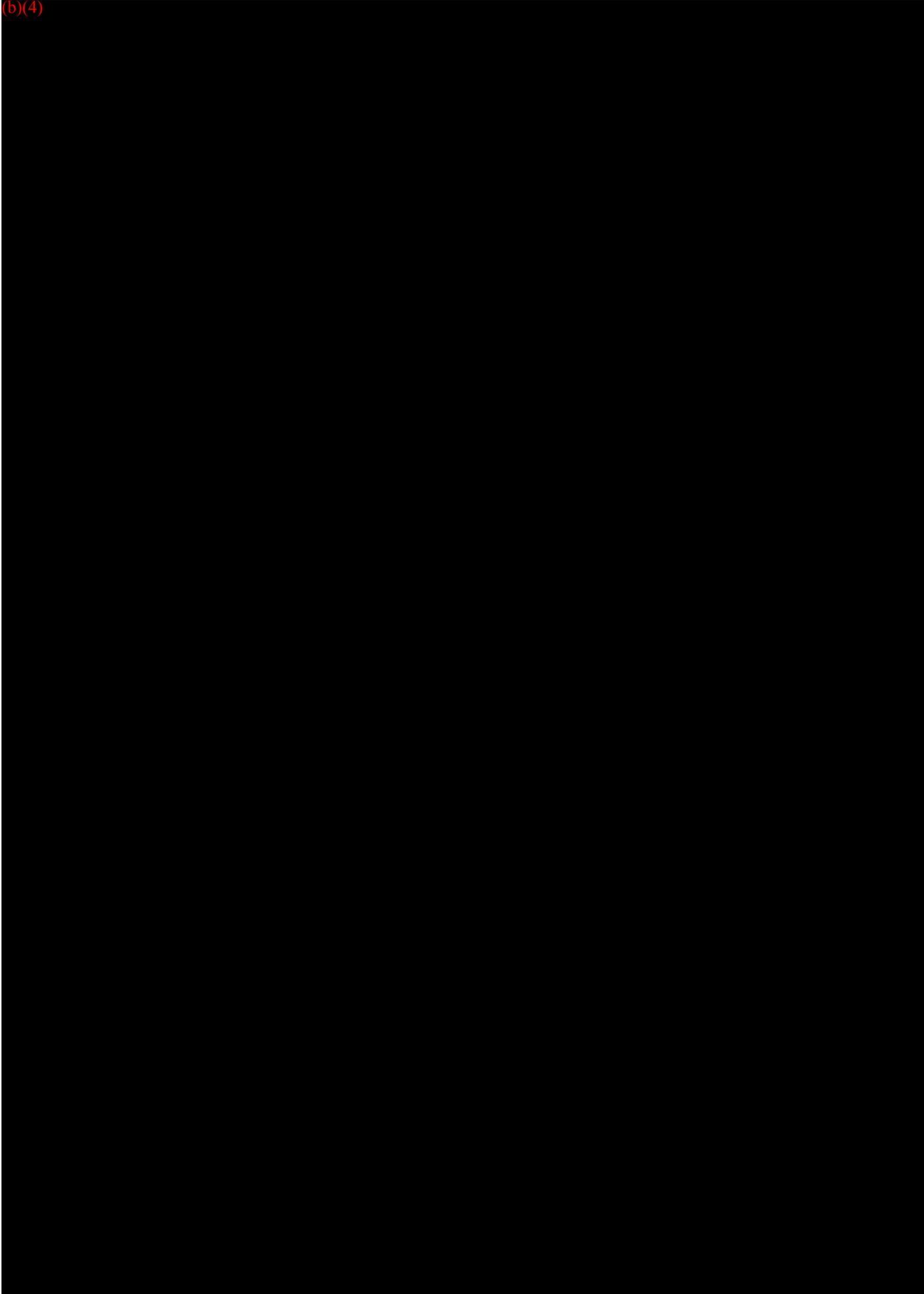


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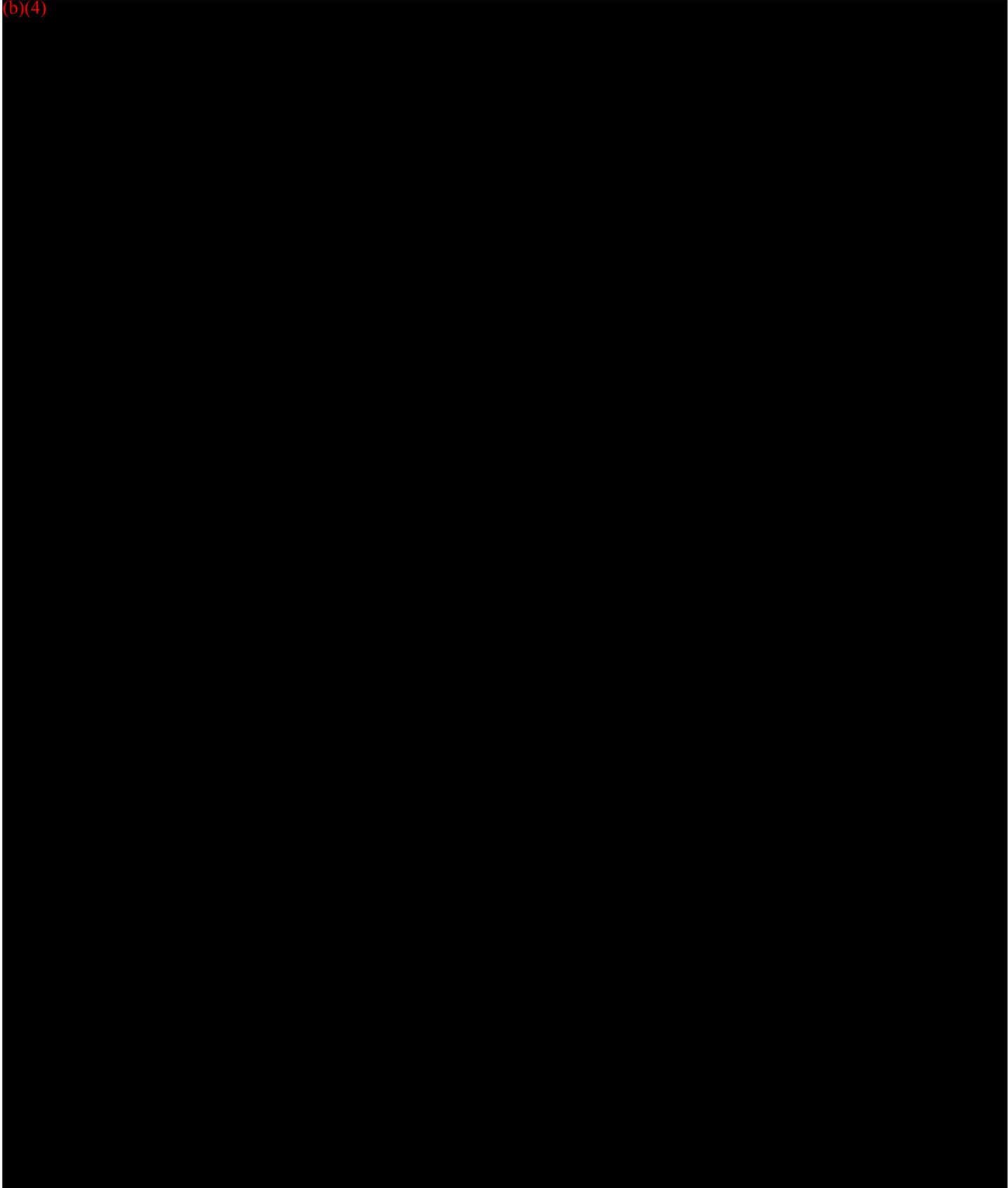
7 Software Design Specification

(b)(4)



8 Development & Traceability

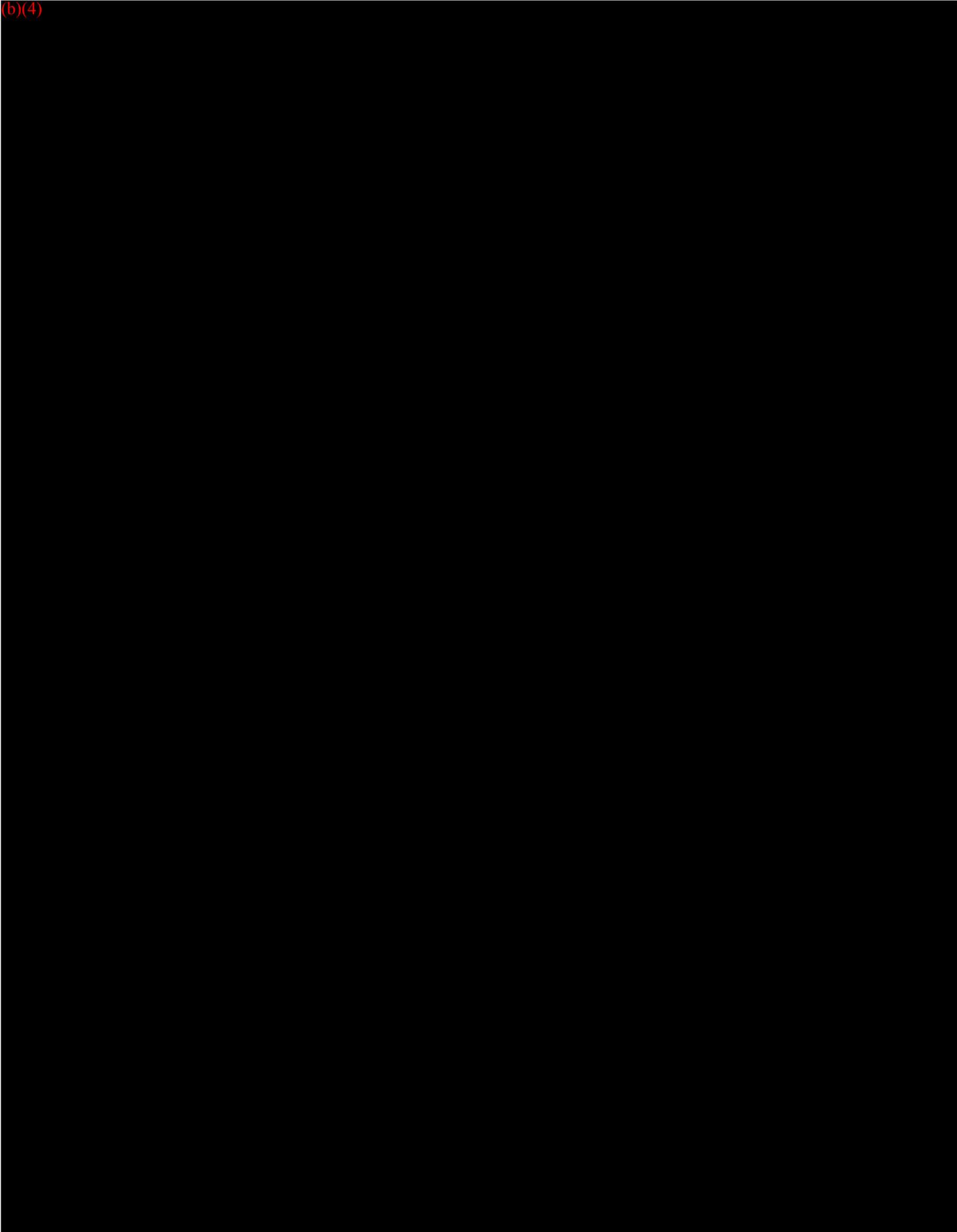
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(b)(4)



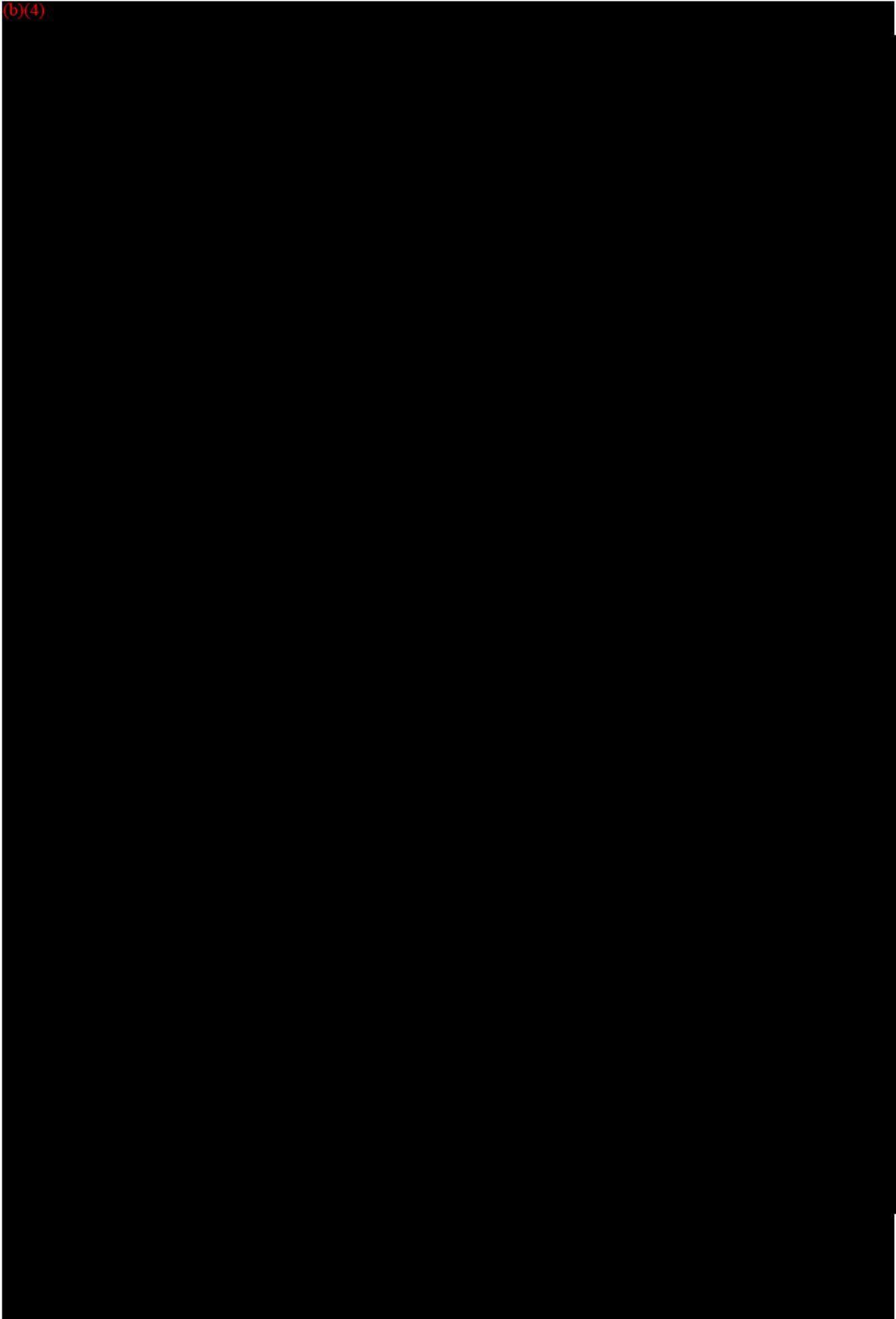
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(b)(4)



(b)(4)

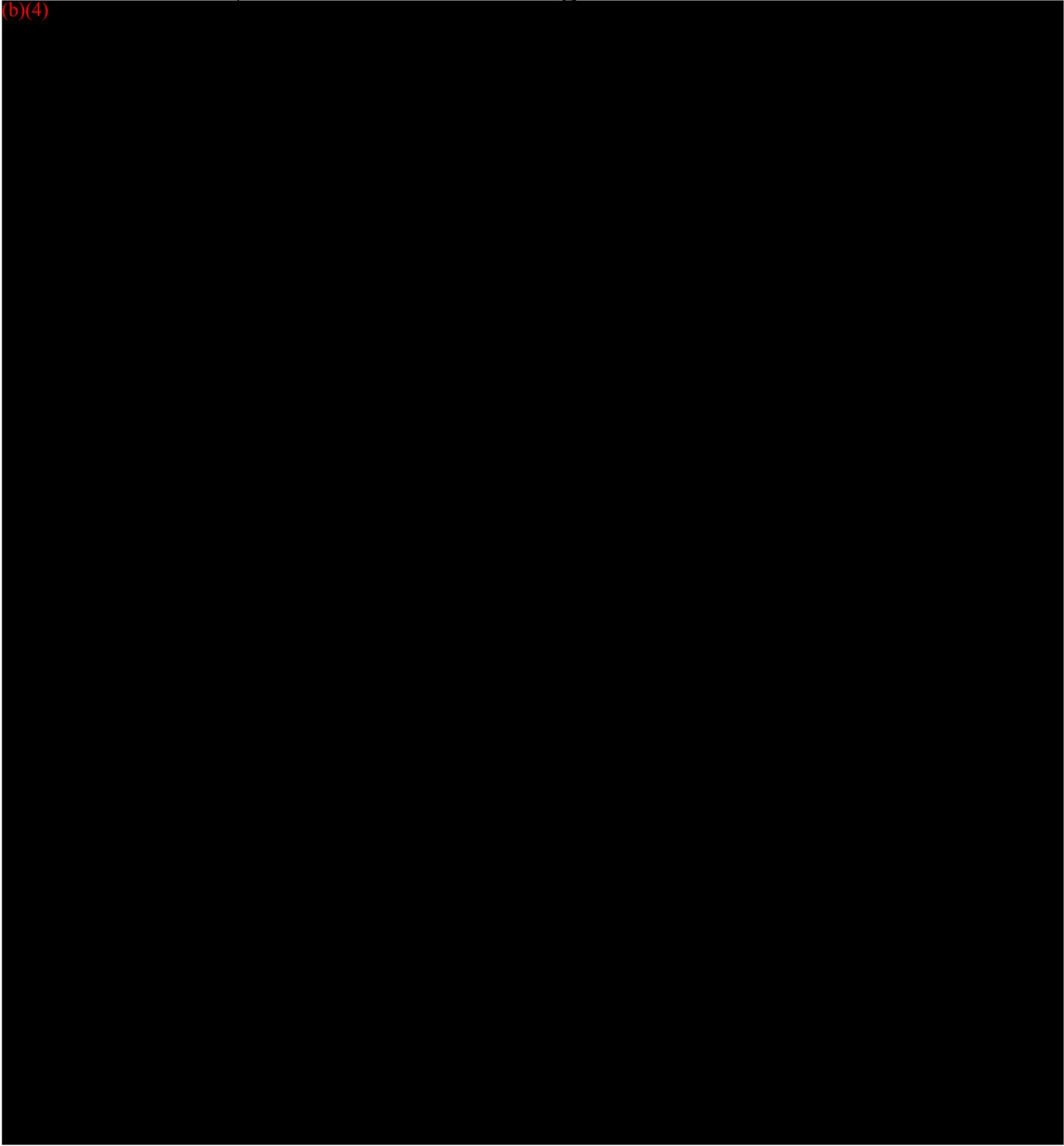


(b)(4)



9 Validation, Verification and Testing

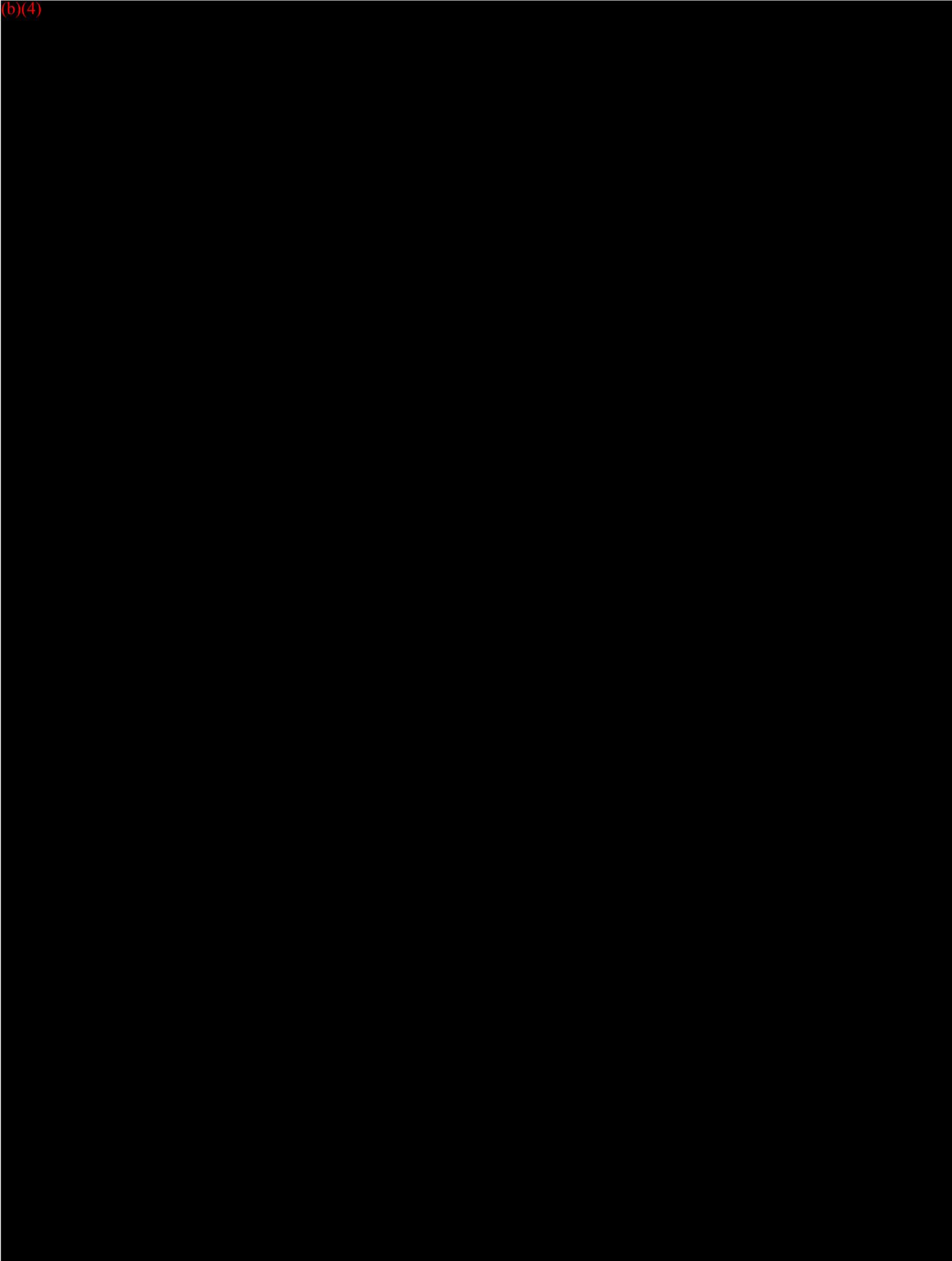
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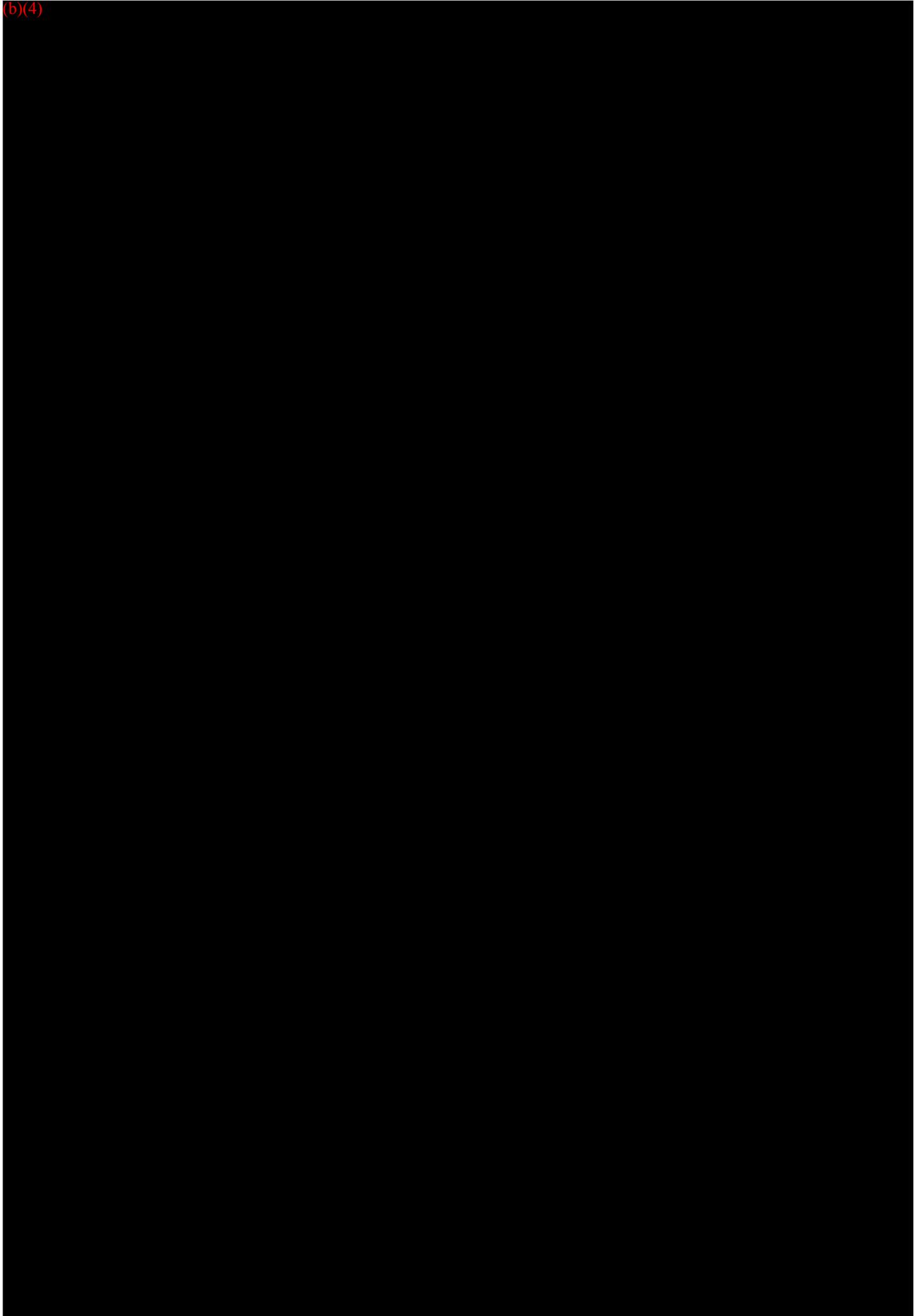
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(b)(4)



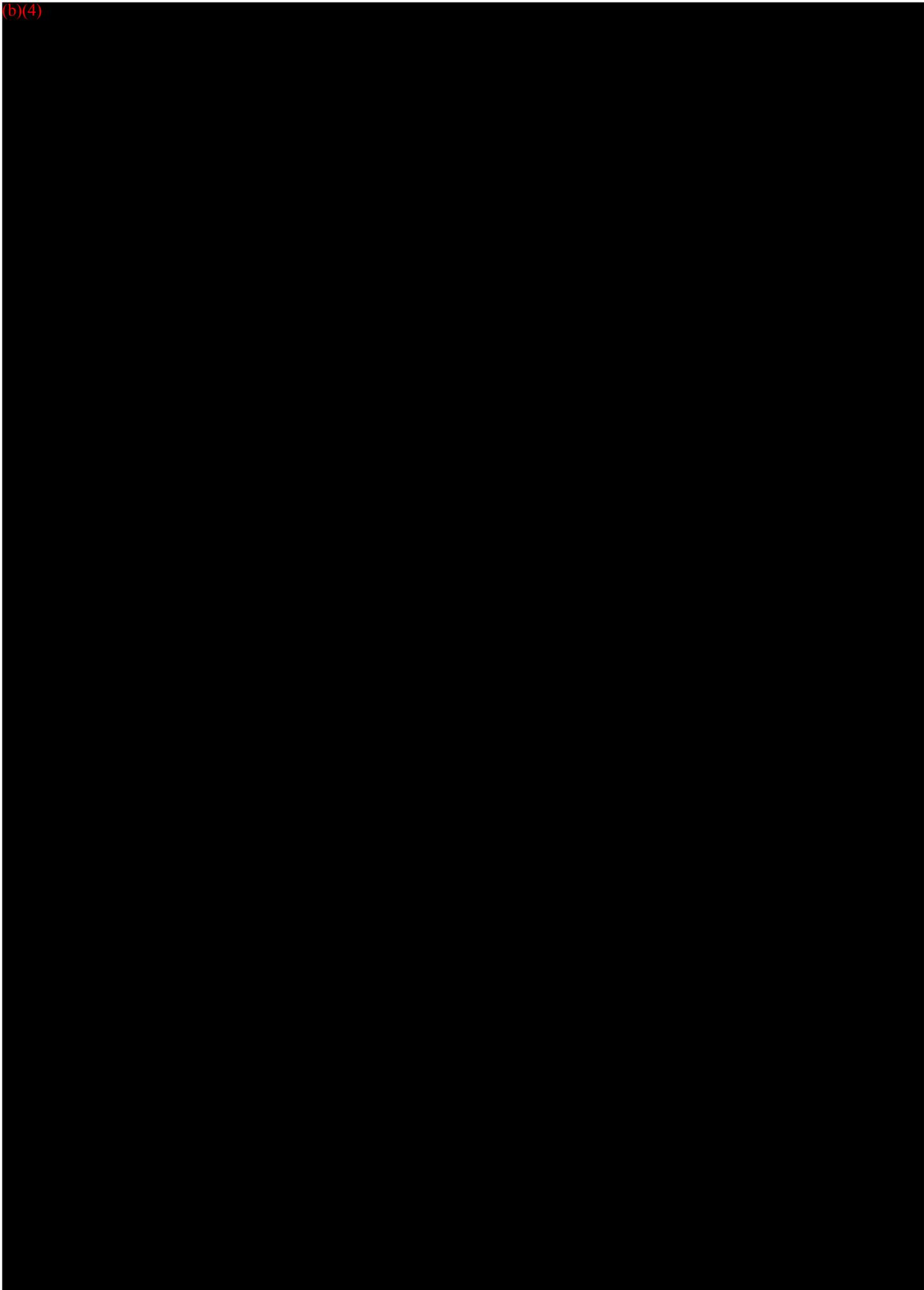
(b)(4)



(b)(4)

Test Report 002 – part 3

(b)(4)



10 Software Revision History

(b)(4)



11 Unresolved Anomalies

(b)(4)



12 Conclusions

(b)(4)



Software Validation of HIVOX Spopad EMS SP-920 / SP-620

HIVOX BIOTEK INC.

version (b)(4)

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Write by :

(b) (6)

Review by

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10. Software Revision History

11. Unresolved Anomalies

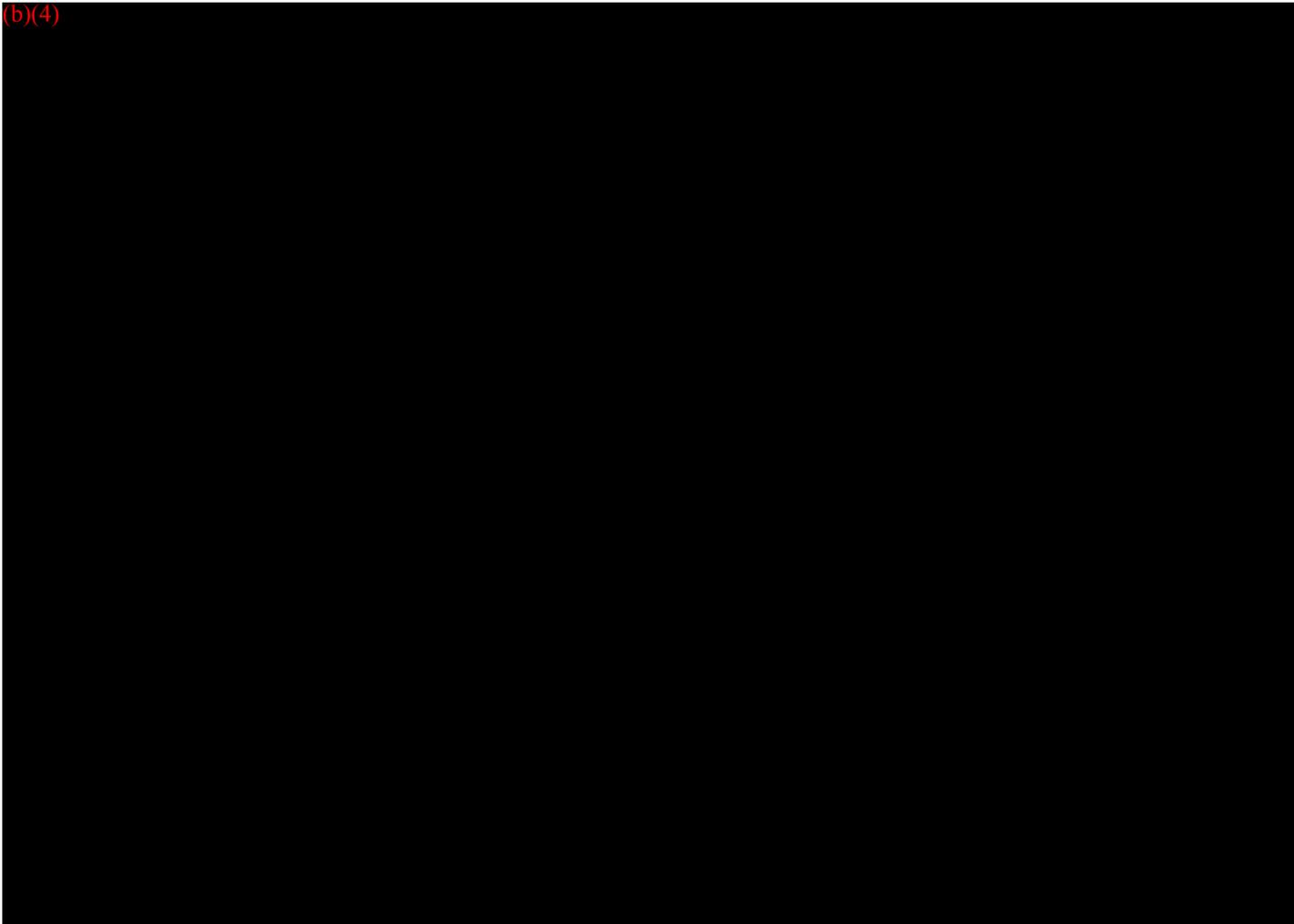
12. Conclusion

1. Level of Concern

(b)(4)

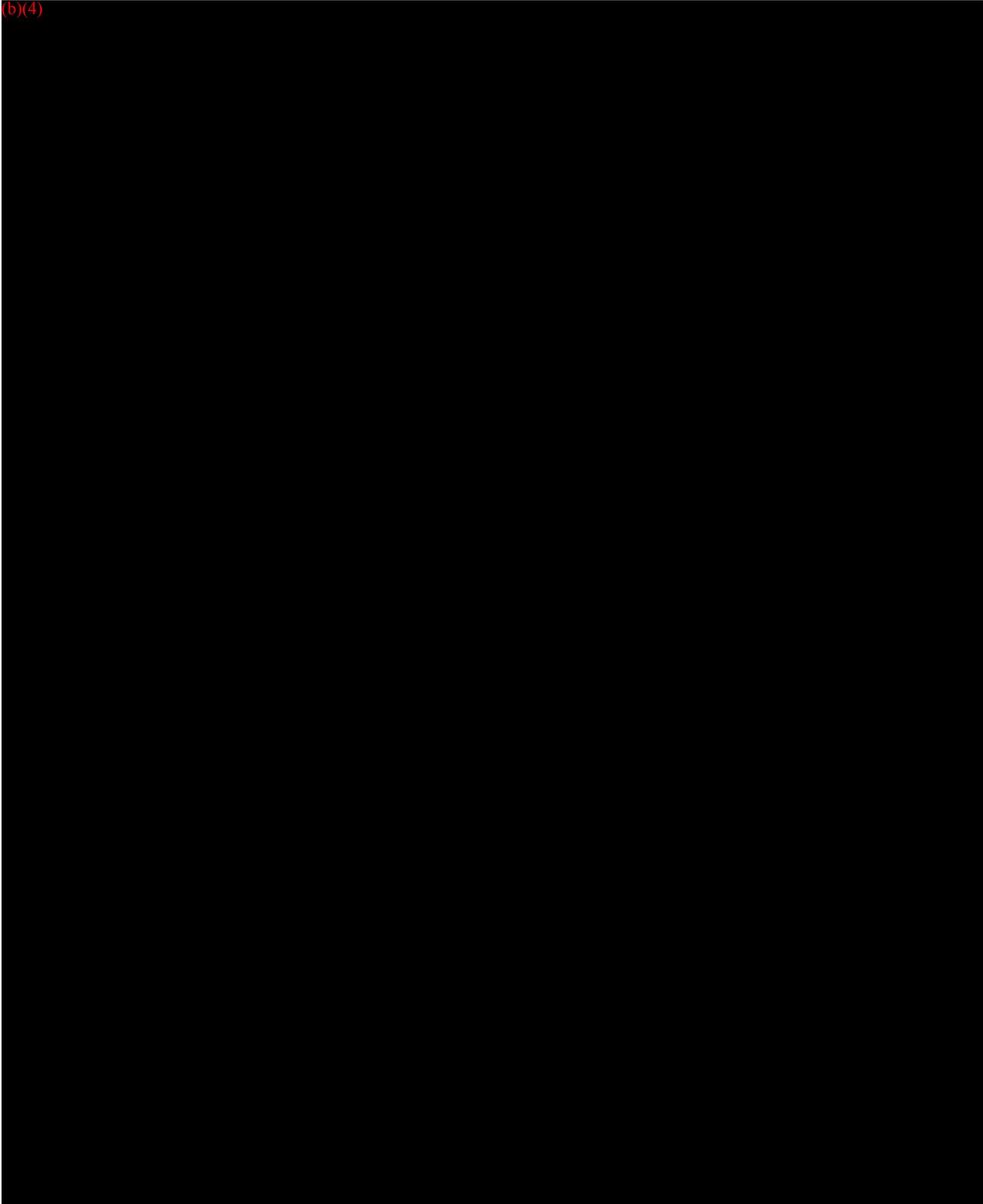


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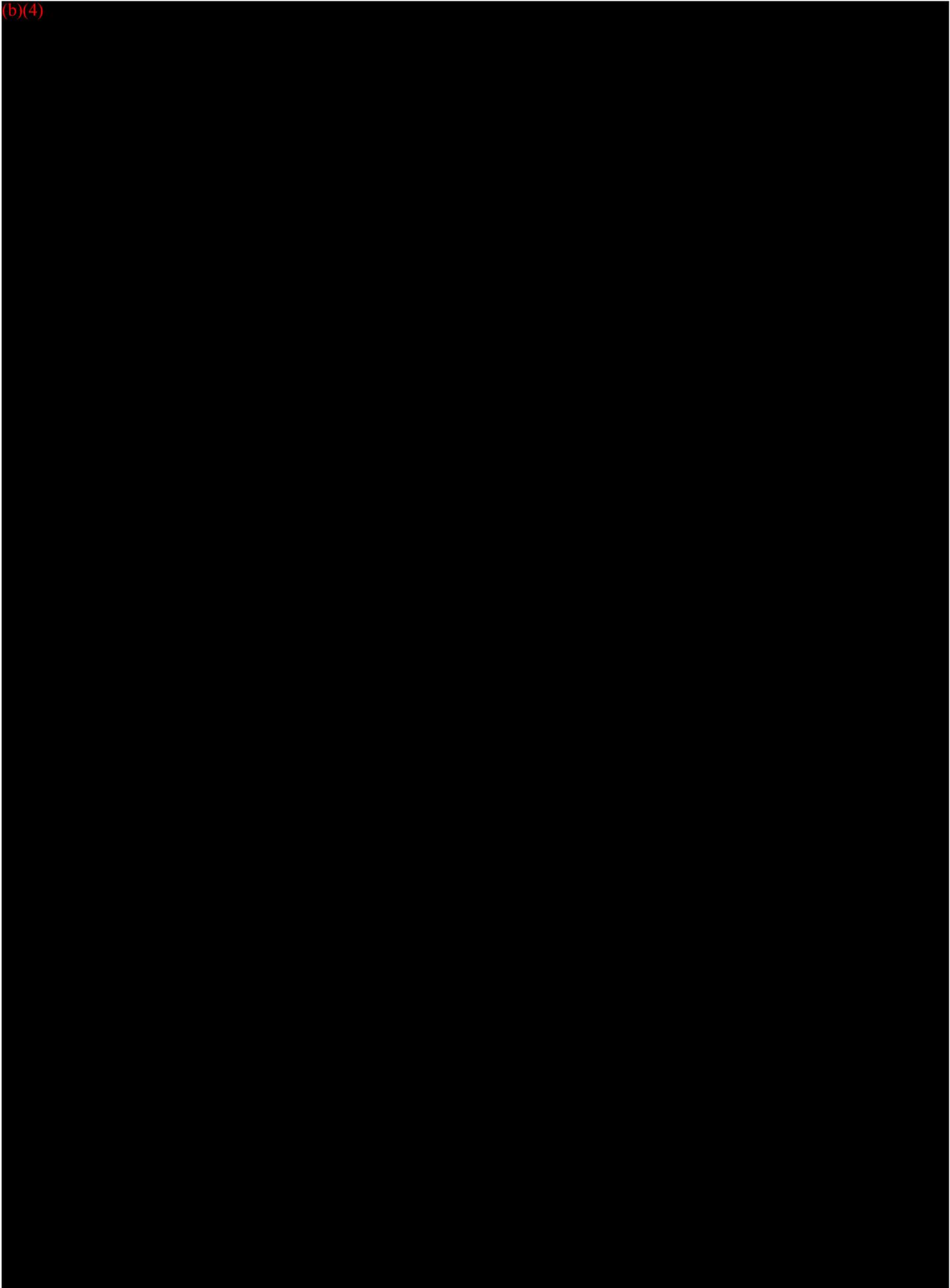


2. Device Hazard Analysis

(b)(4)

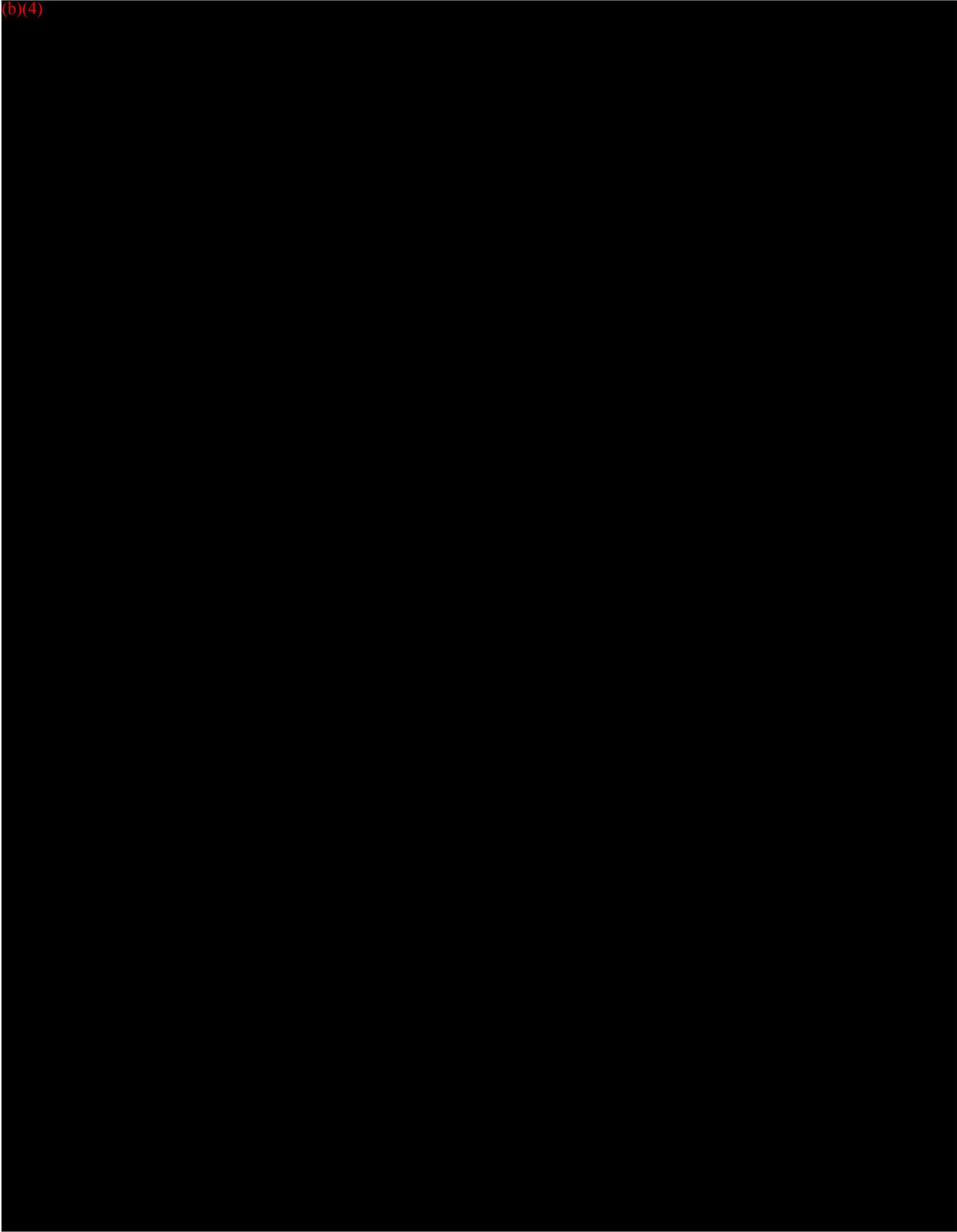


(b)(4)



3 Software Description

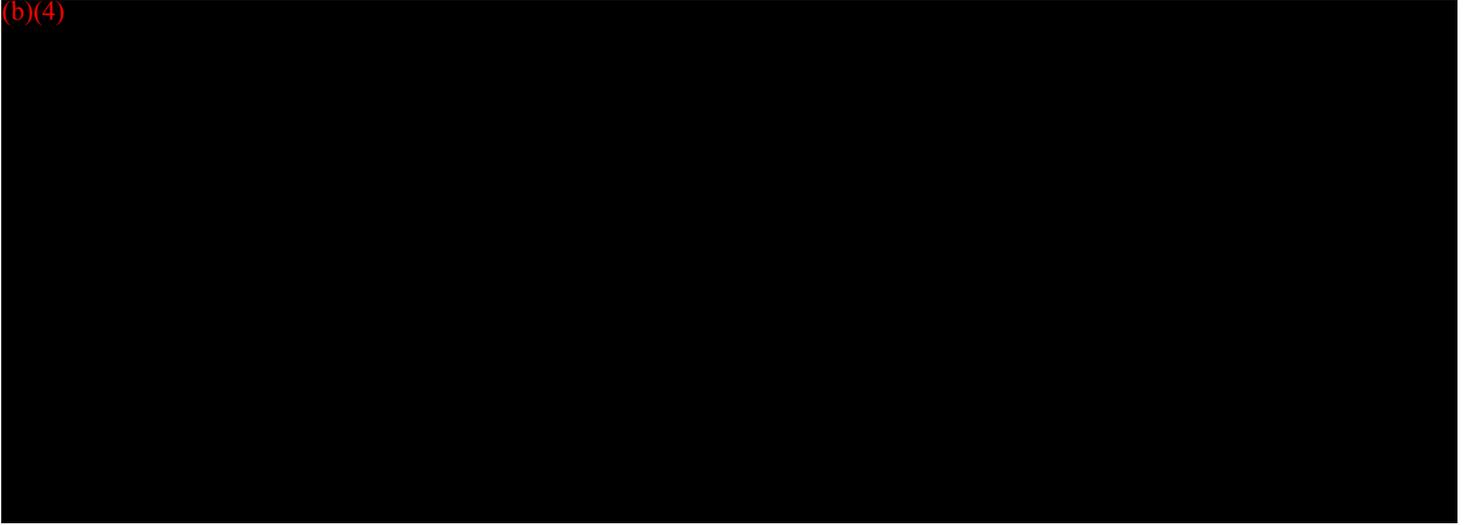
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(b)(4)



(b)(4)



(b)(4)



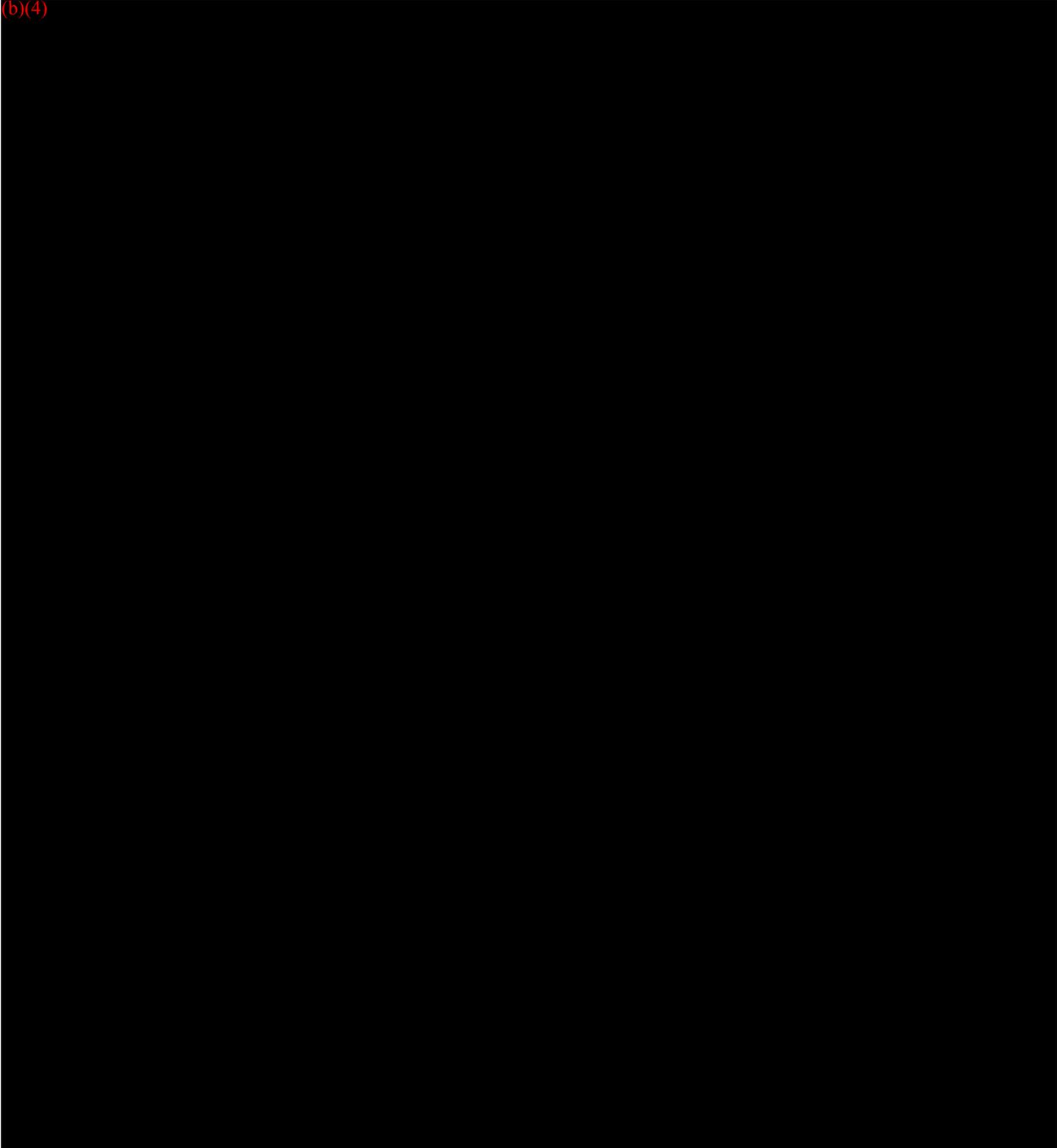
4. Software Device Hazard Analysis

(b)(4)

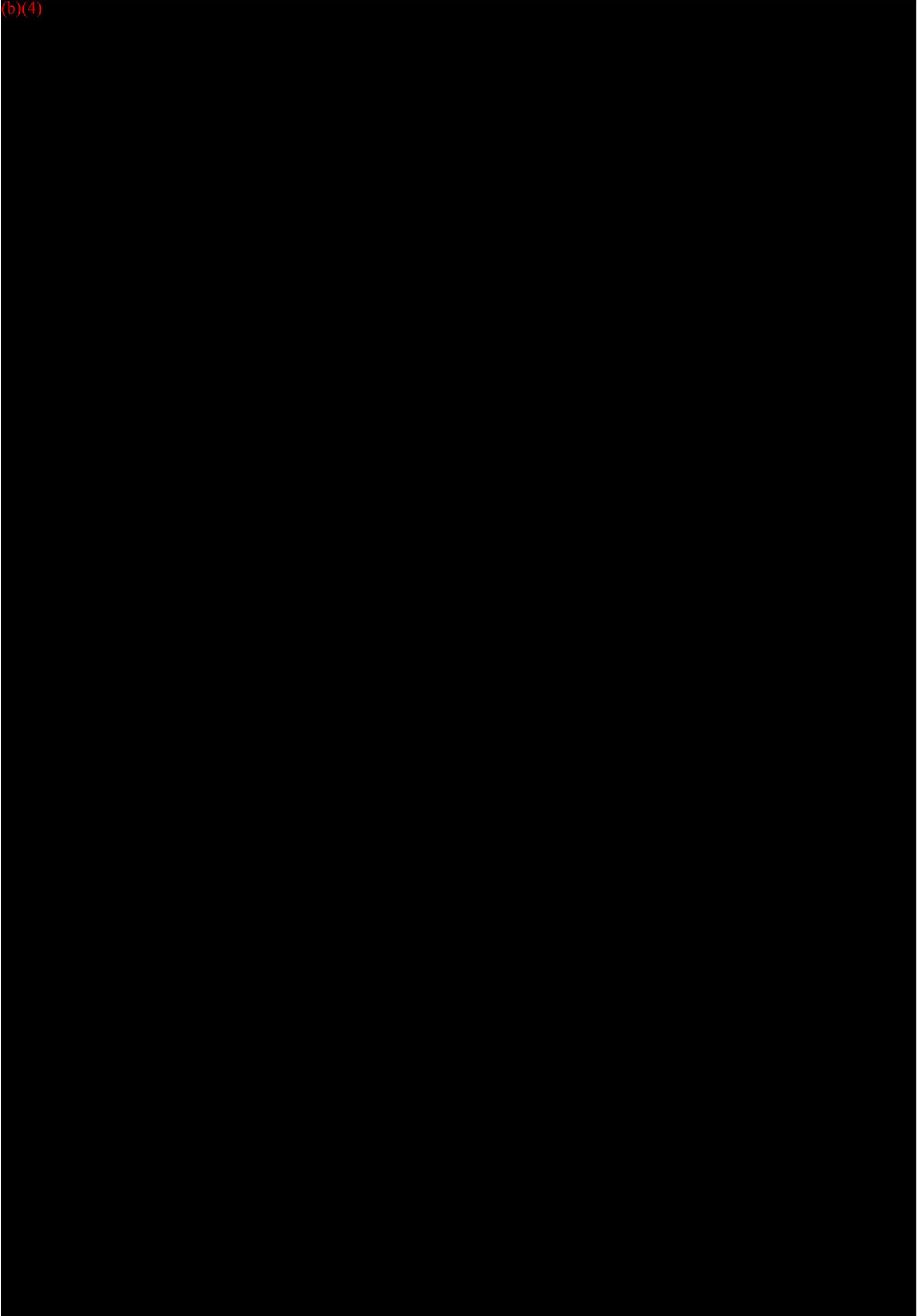


5 Software Requirements Specification:

(b)(4)

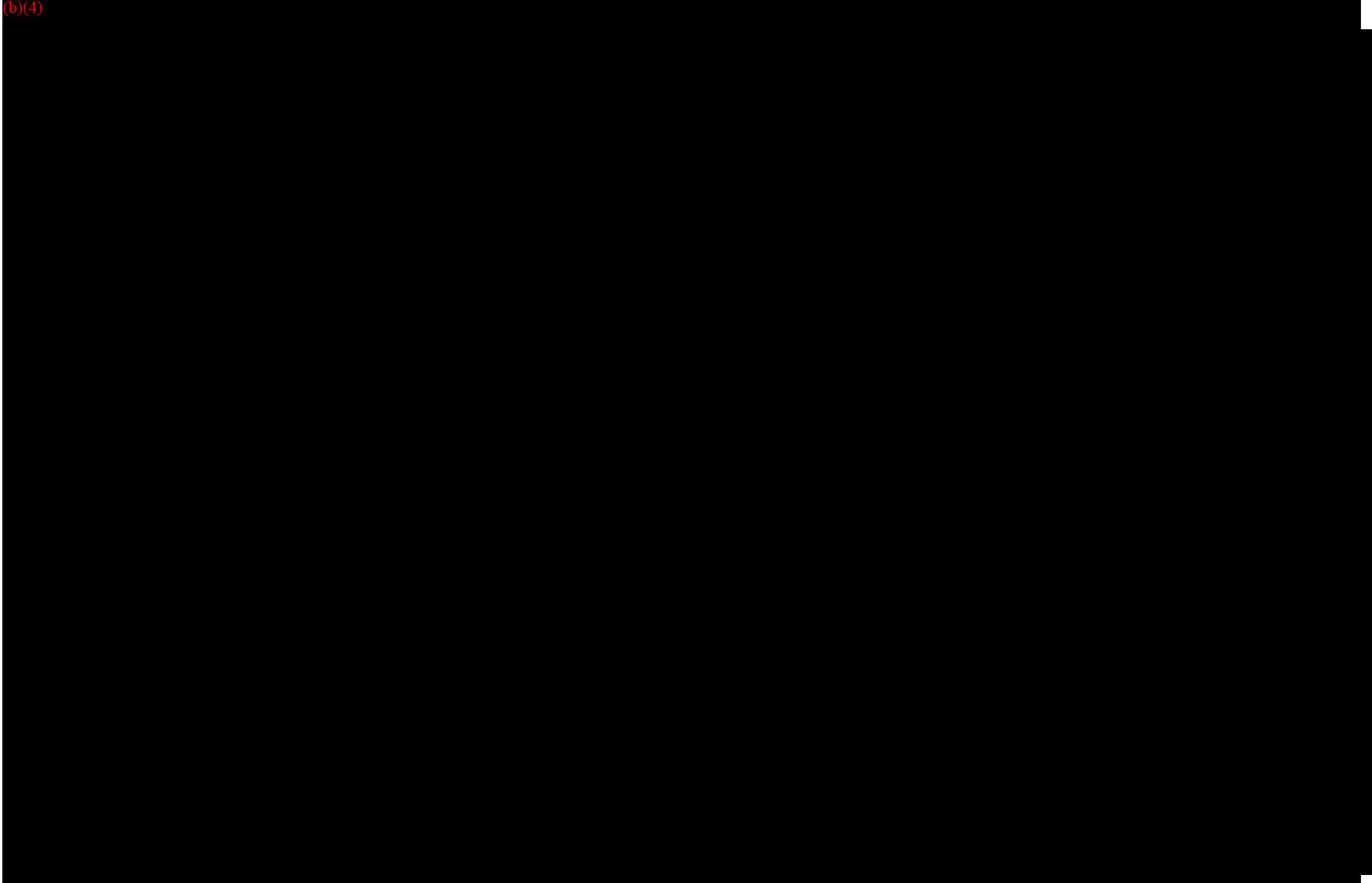


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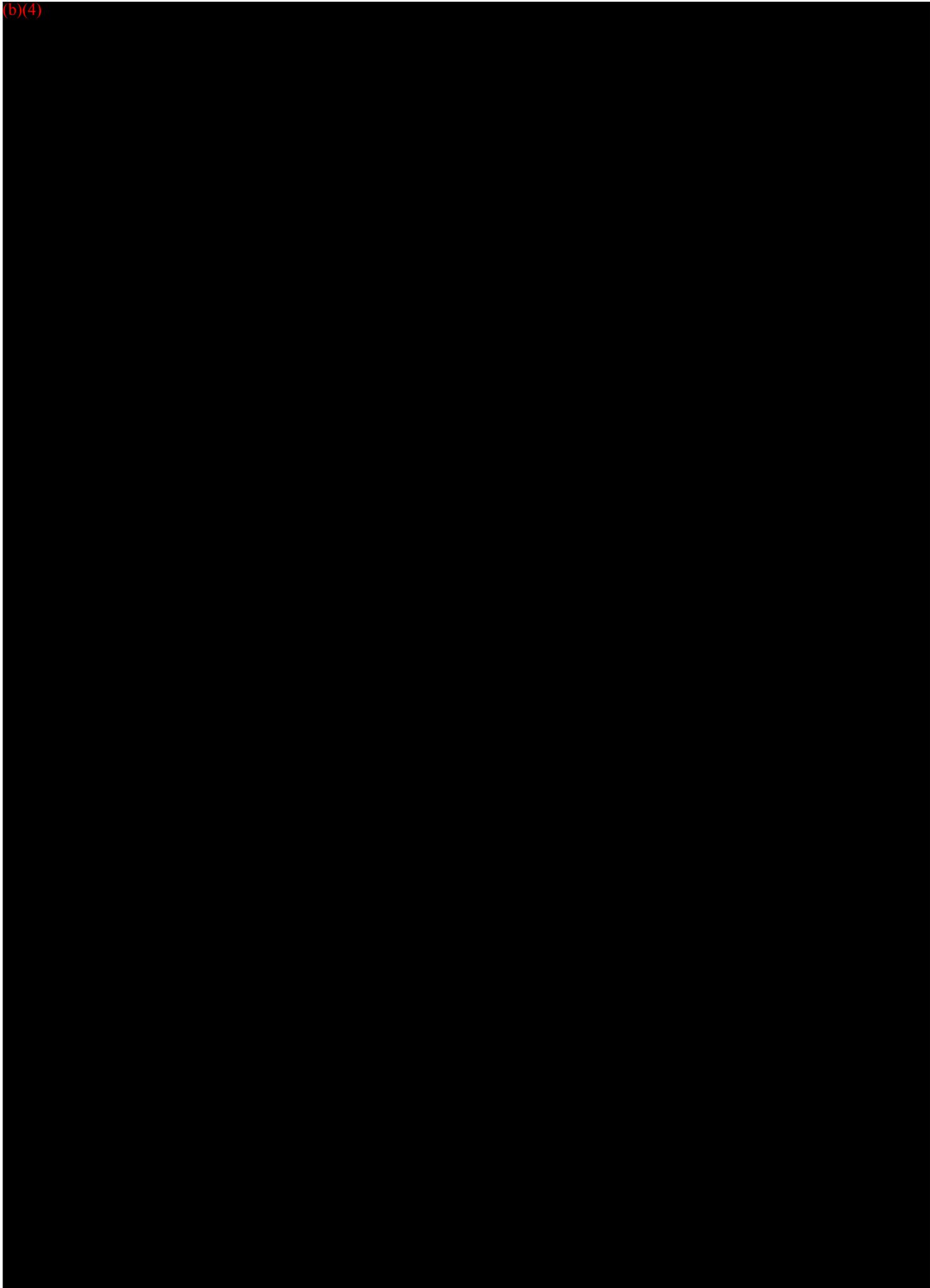


6 Architecture Design Chart:

(b)(4)

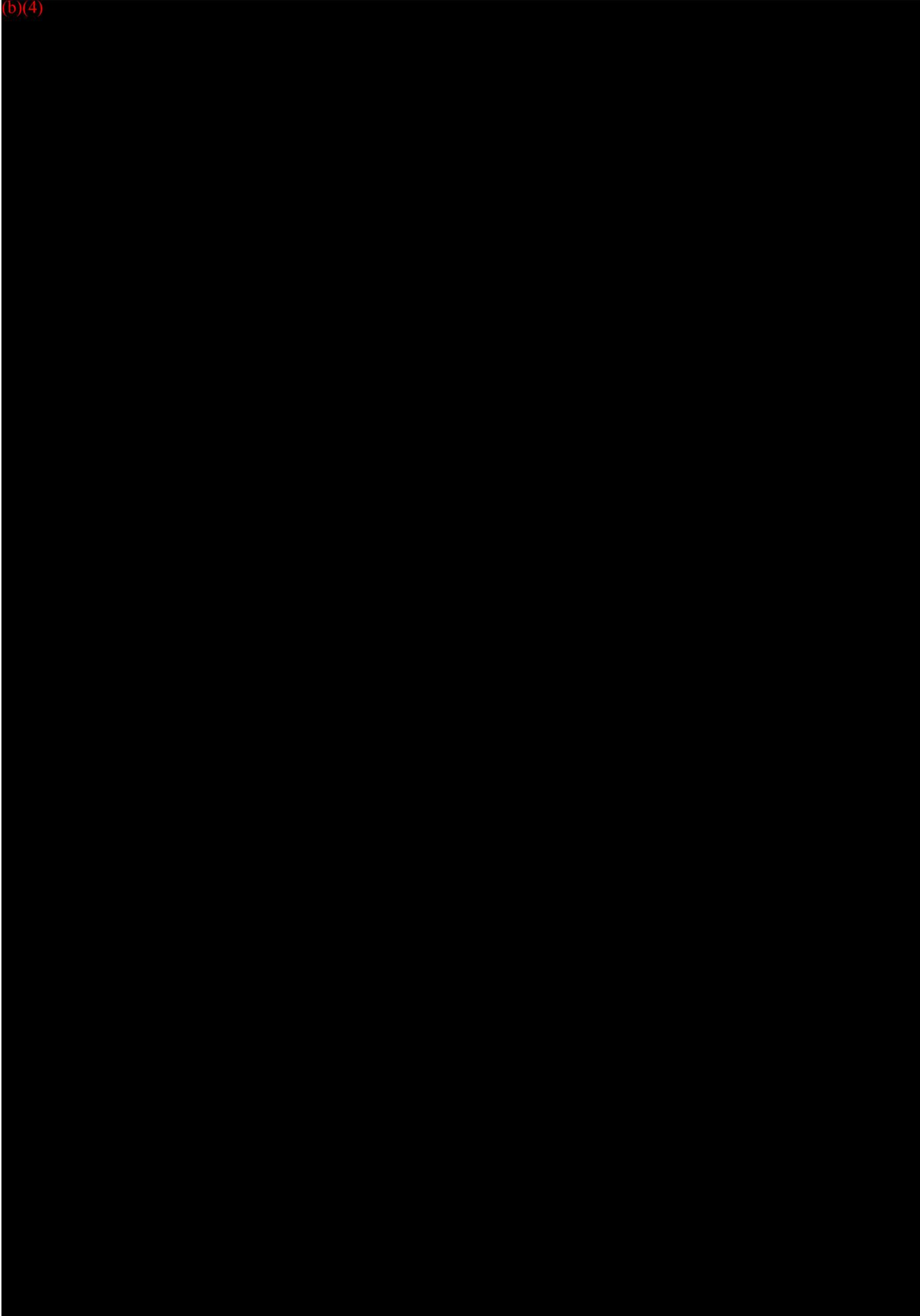


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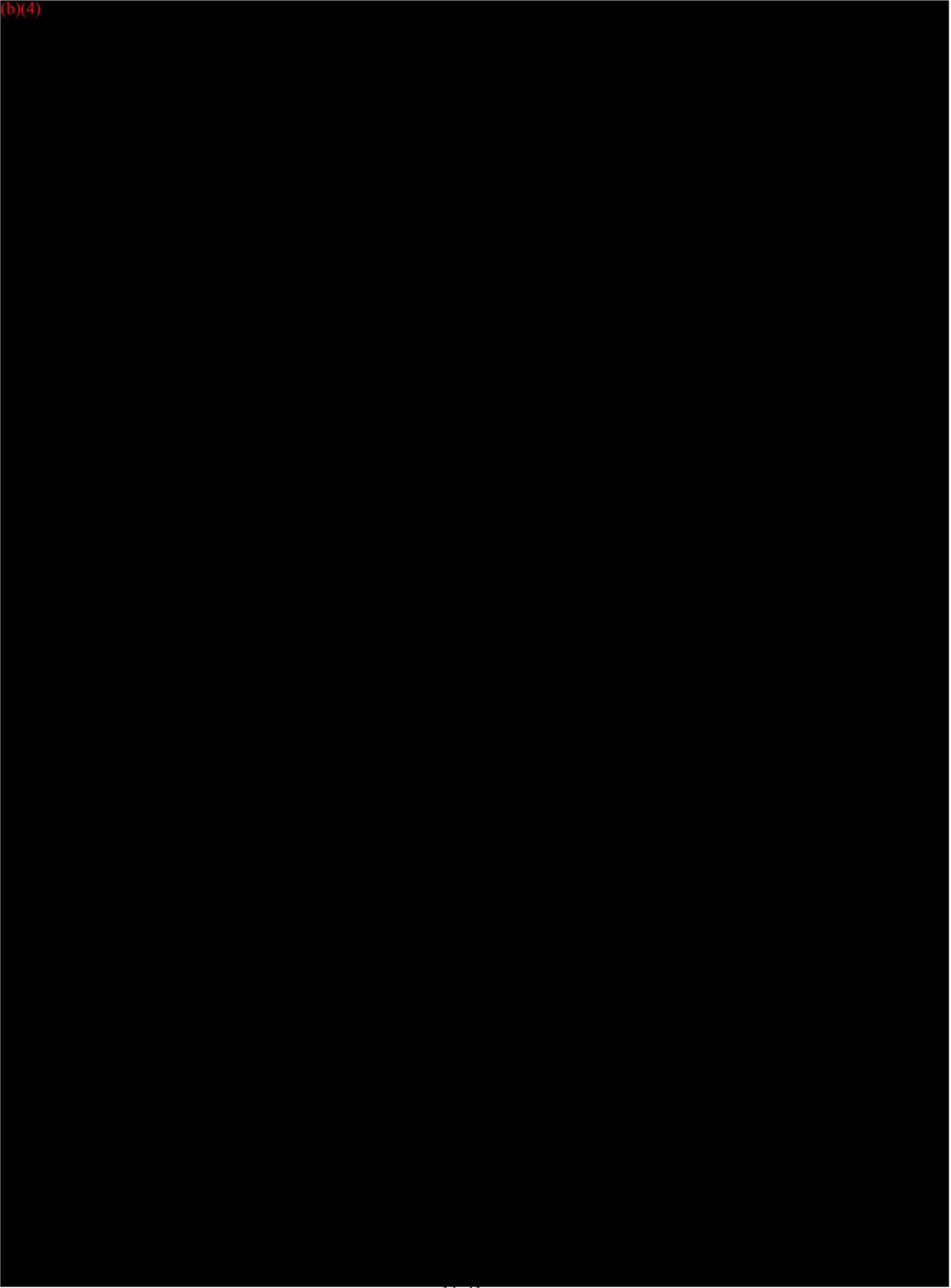
7 Software Design Specification

(b)(4)

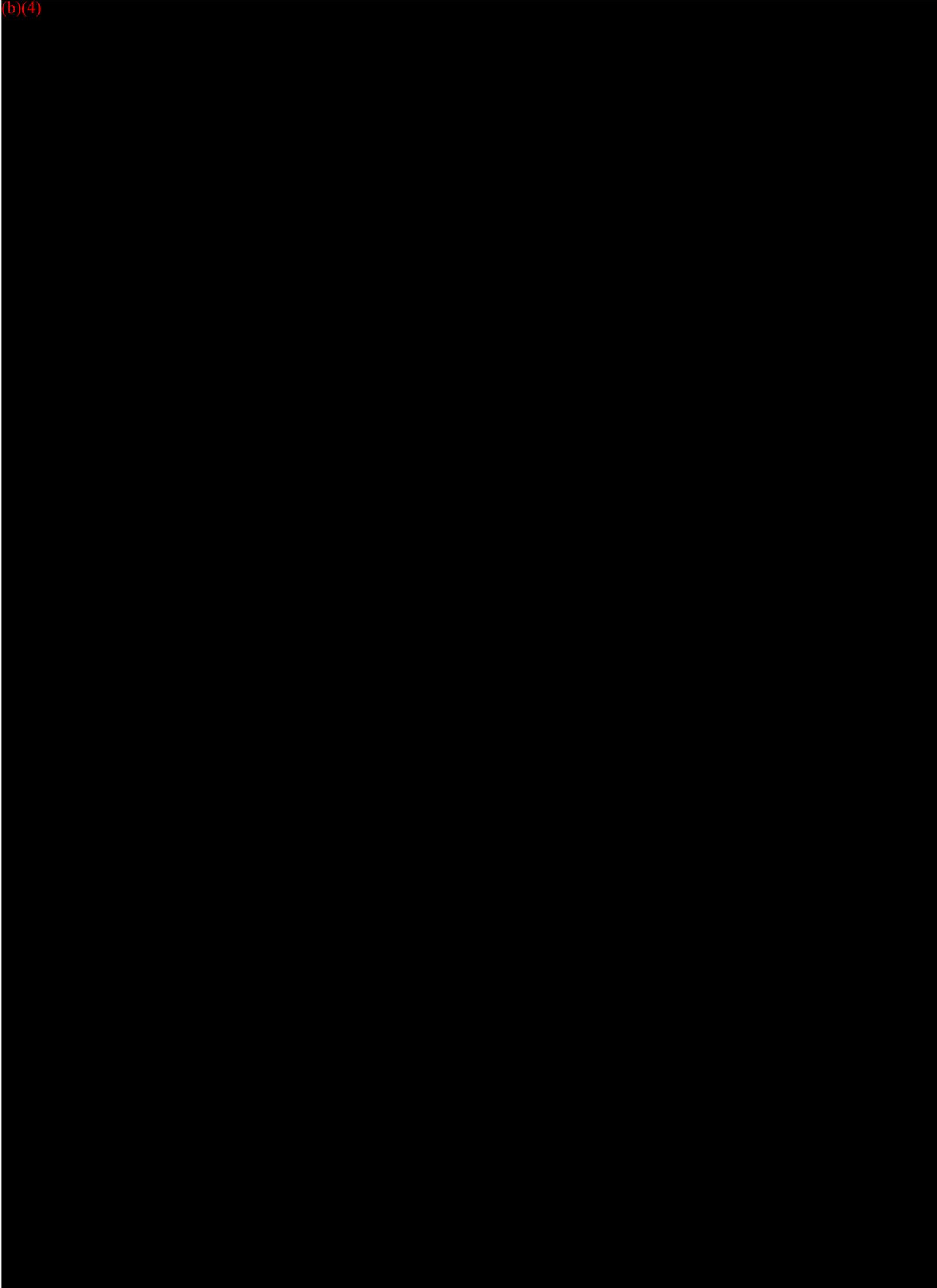


8 Development & Traceability

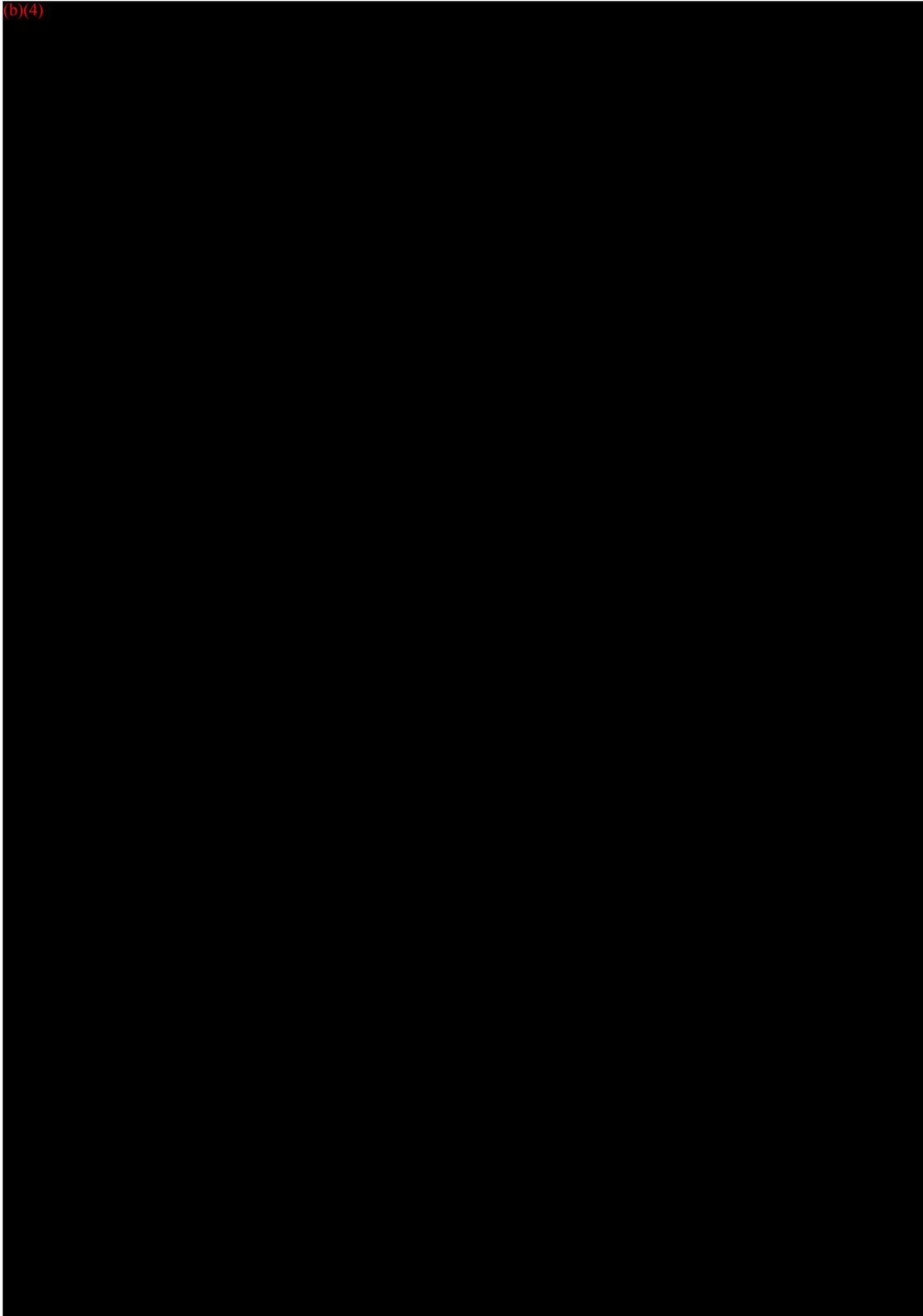
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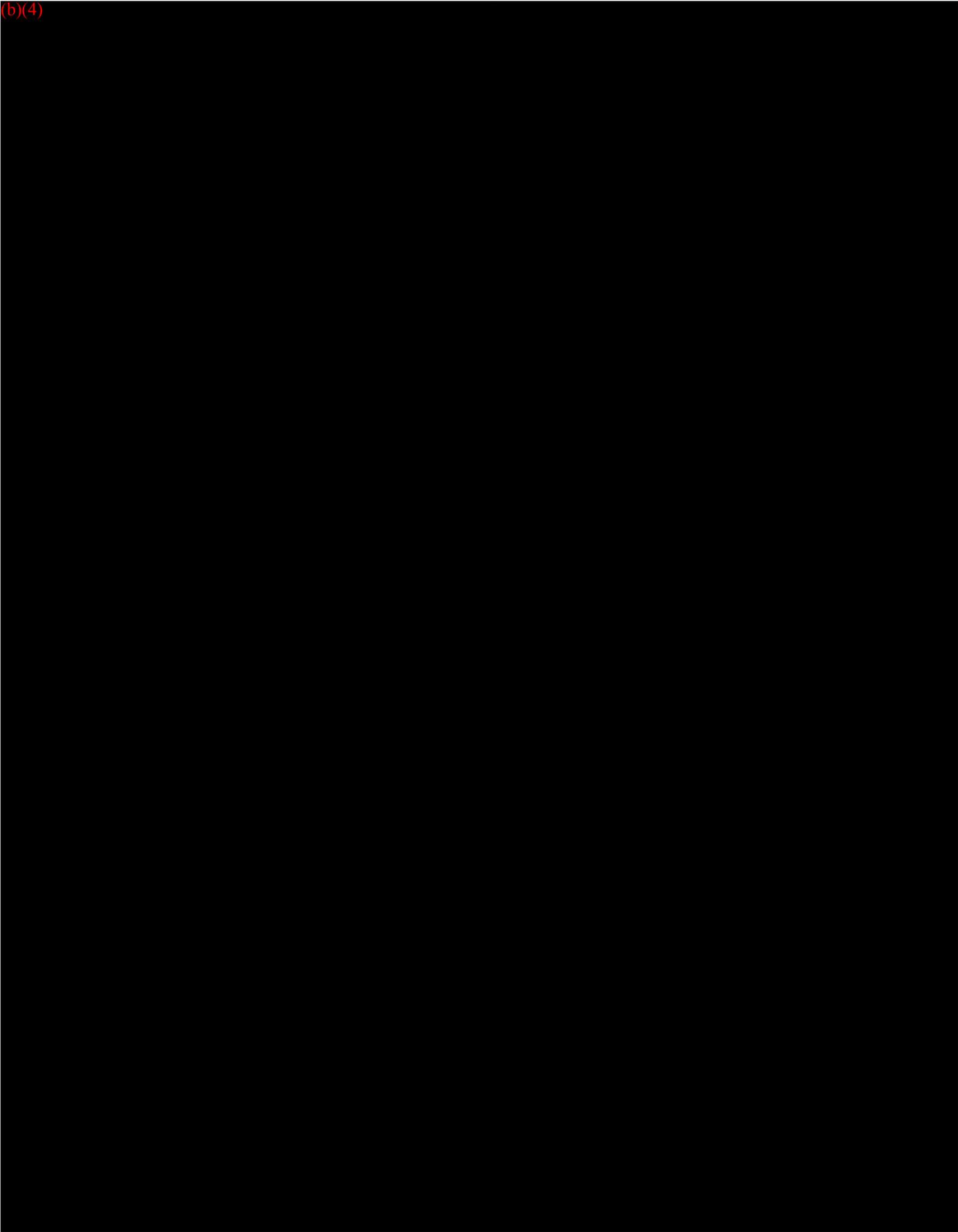


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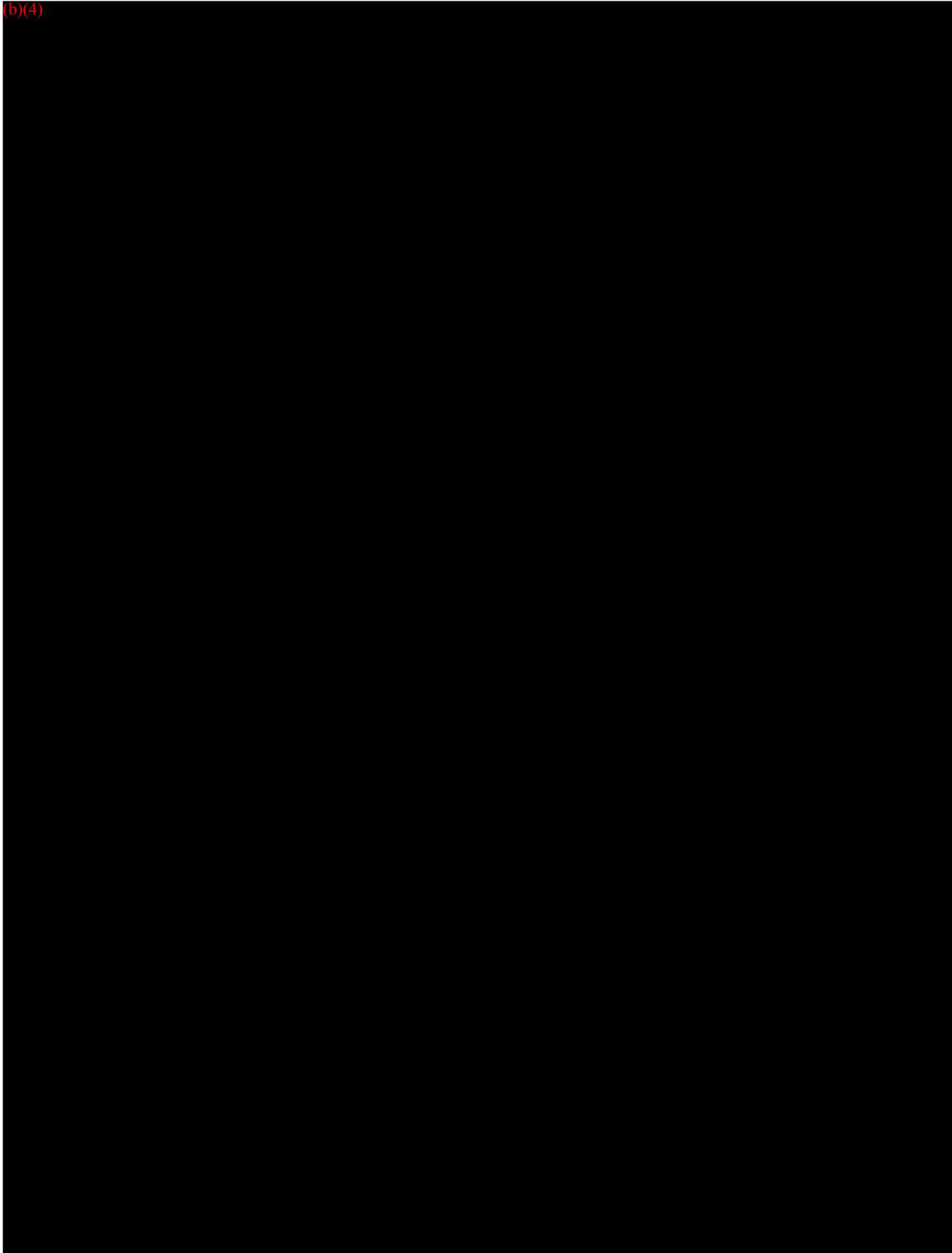
9 Validation, Verification and Testing

(b)(4)



(b)(4)

(b)(4)



(b)(4)

(b)(4)

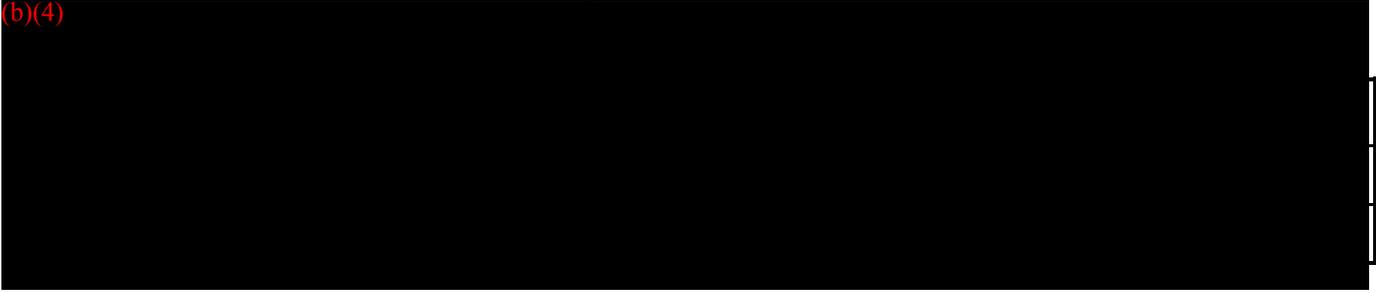


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(b) (4)

10 Software Revision History

(b)(4)



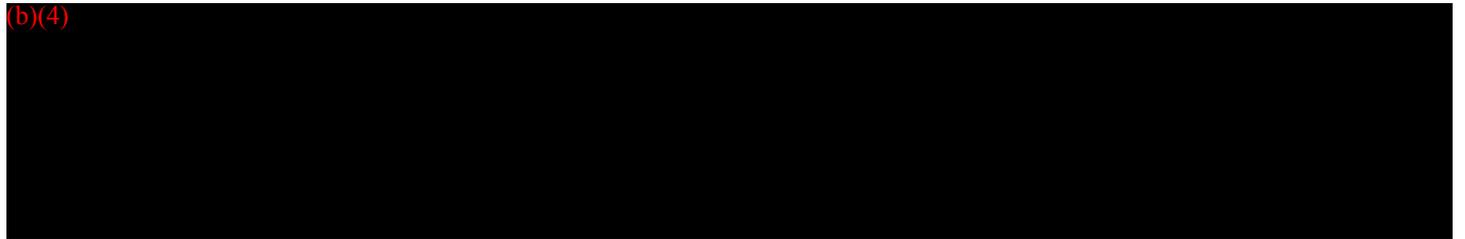
11 Unresolved Anomalies

(b)(4)



12 Conclusions

(b)(4)



(b)(4)



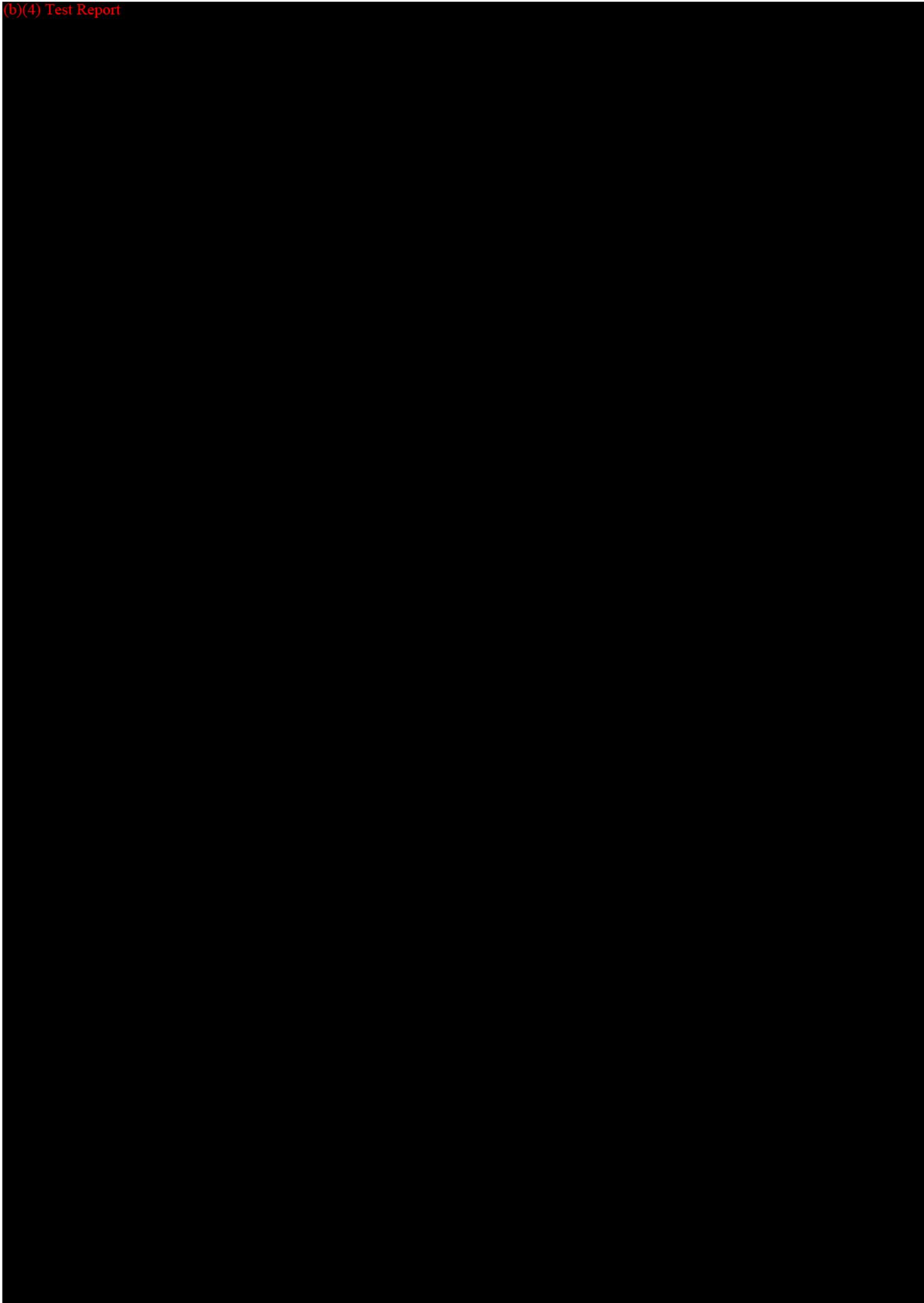
17. ELECTROMAGNETIC COMPATIBILITY / ELECTRICAL SAFETY

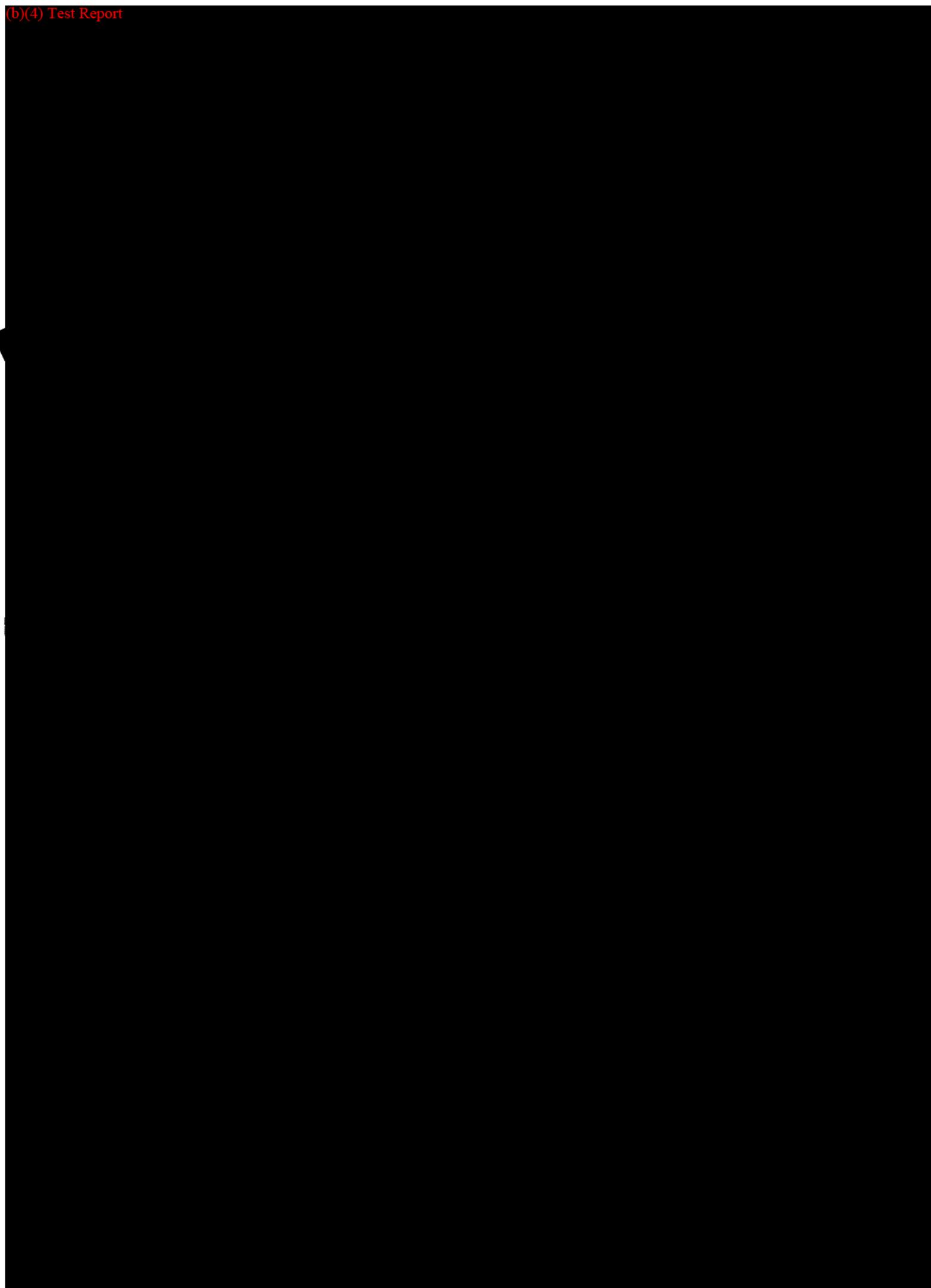
Hivox Spopad SP-910 / SP-920 / SP-620 pass the EMC the Safety test reports, which comply with the following standards:

- EMC Test Report:
EN60601-1-2: 2007 Electromagnetic Compatibility - Requirements and Tests
 - 1) SP-910 / SP-920: SGS Electromagnetic Compatibility testing;
 - 2) SP-620: ETC, Electronics Testing Center, Taiwan.

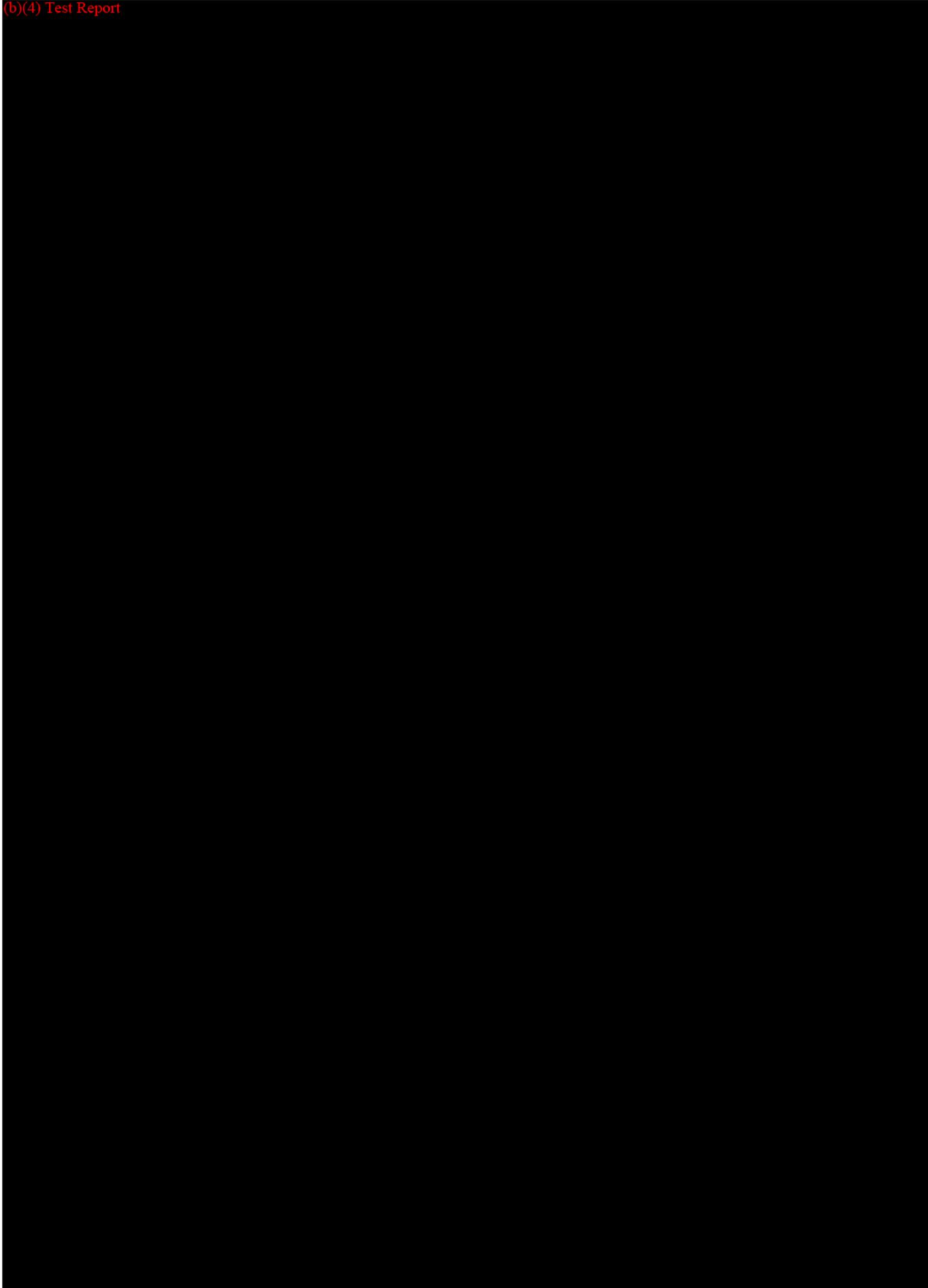
- Safety Test Report for SP-910 / SP-920 / SP-620 by Universal Testing Inc.:
 - 1) EN / IEC 60601-1 :1990 Medical Electrical Equipment, Part 1. General requirements for safety;
 - 2) EN / IEC 60601-2-10:2000 Particular requirements for the safety of nerve and muscle stimulators

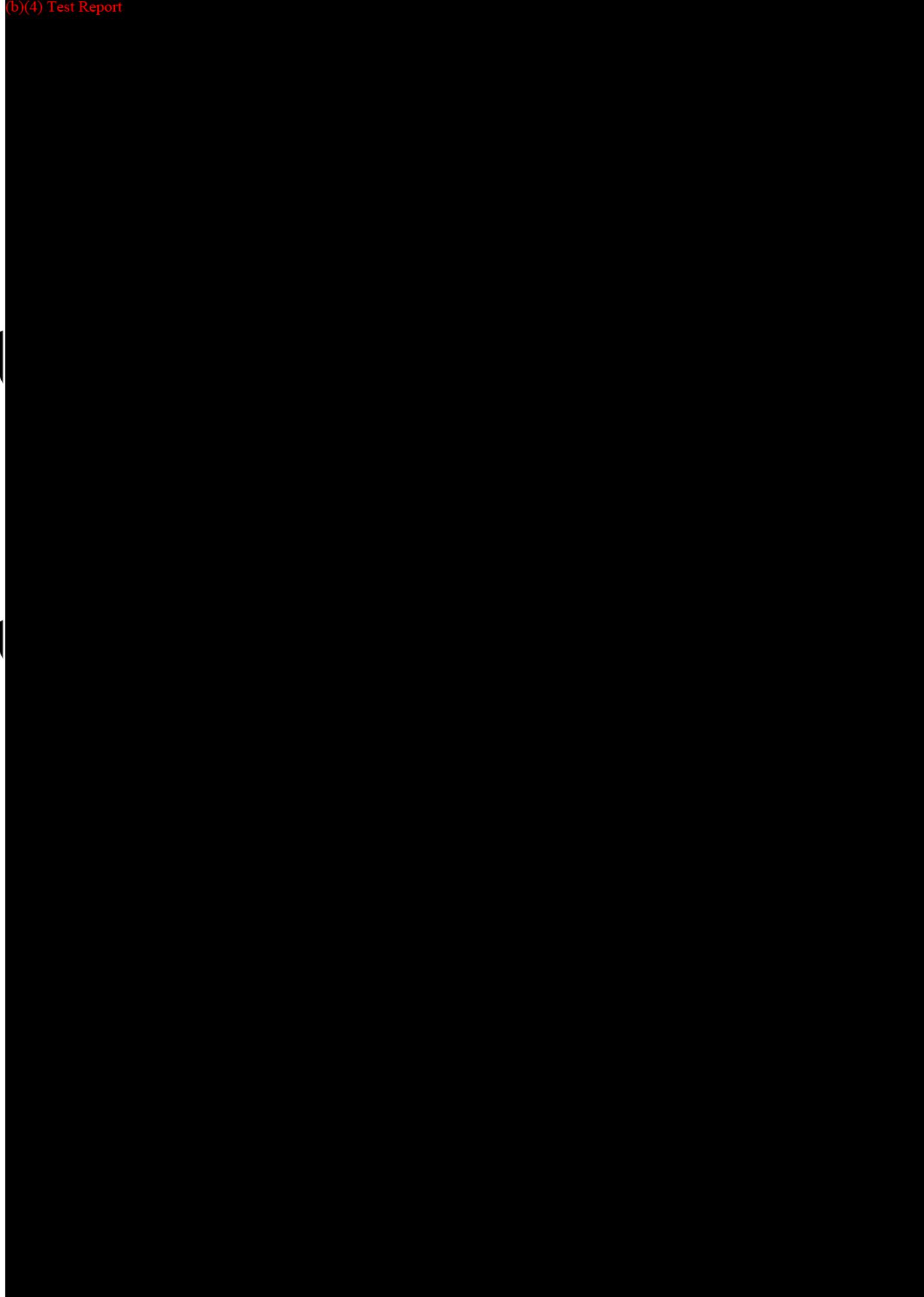
We place the relevant testing reports as follows.

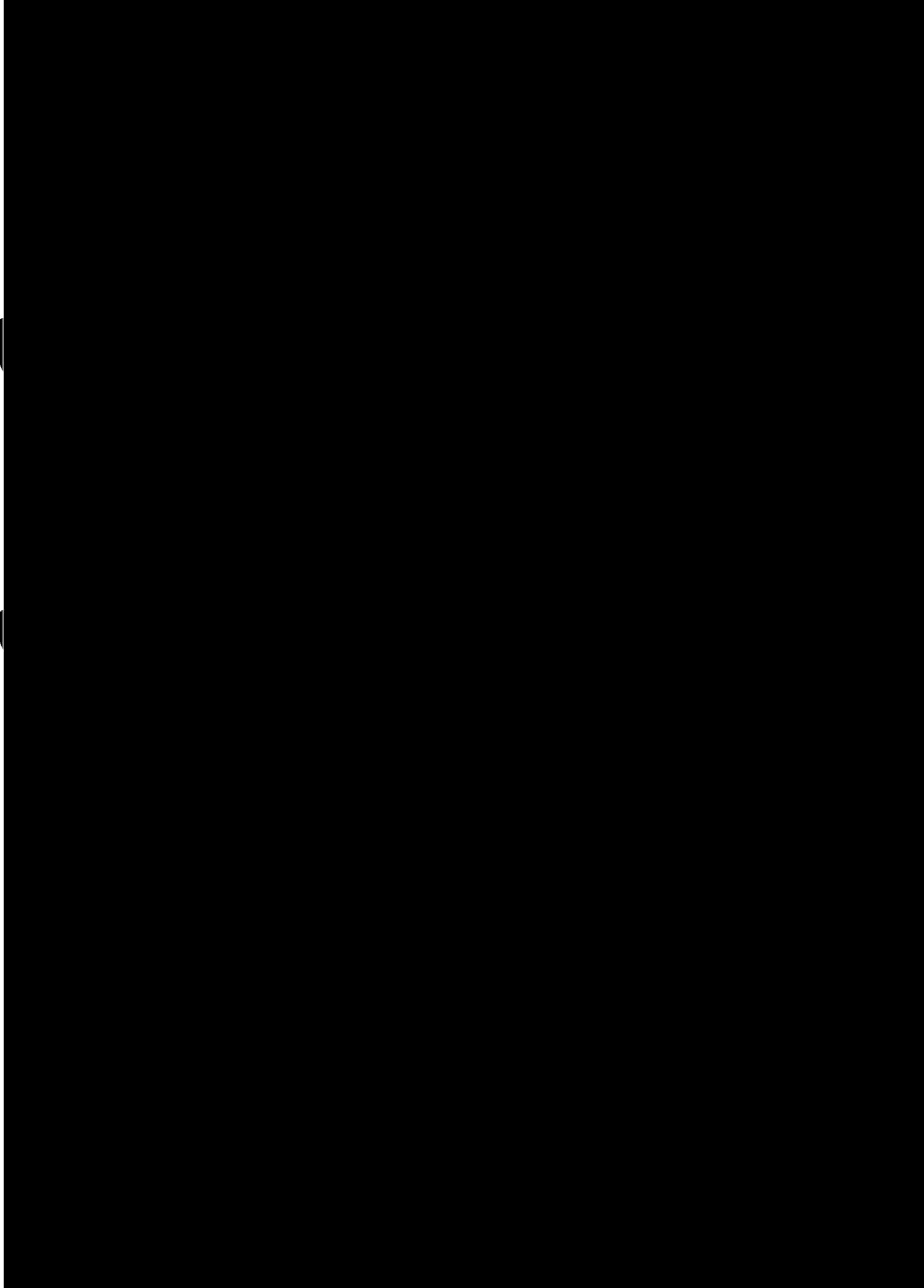














18. PERFORMANCE TESTING – BENCH

Please refer to the “Section 11.2 Device Output Waveforms” above for the performance testing.

- In addition, we provide the impedance performance test report here.
- And we also provide the duration of the stimulation as shown in the oscilloscope tracings. When turn on the SP-910/SP-920/SP-620 devices to the primary phase, and the oscilloscope tracings show no output.
- SP-920 & SP-620 are all with the burst mode on the cycle 3. Please see the attached file. We provide the oscilloscope tracings for SP-920/SP-620 to indicate the burst occurrence.

IMPEDANCE PERFORMANCE

STUDY REPORT

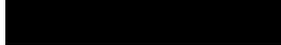
for

TOP RANK ELECTRODE GEL PADS

on

HIVOX SPOPAD EMS SP-620/SP-910/SP-920

Written by: (b) (6) 

Reviewed 

Issue date: 2014/04/20

Version: (b)(4) 

HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

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19. PERFORMANCE TESTING – ANIMAL

N/A



HIVOX BIOTEK INC.

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20. PERFORMANCE TESTING – CLINICAL

N/A



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

21. FORM FDA 3654 STANDARDS DATA REPORT FOR 510(K)S

The Hivox Spopad EMS SP-910 / SP-920 / SP-620 are in compliance with the electric safety standard and the electromagnetic compatibility standard. We fill in the FDA Forms 3654 and present them as follows.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1 – Medical electrical equipment Part 1. General requirements for safety, 1990+A1:1993+A2:1995.

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-1 – Medical electrical equipment Part 1. General requirements for safety, 1990+A1:1993+A2:1995.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3.	General requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7.3aa	Power input measurement conducted with a load resistance with the range	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

Exclusion of a section 7.3 aa in the standard

DESCRIPTION

The subject device is not a mains operated device.

JUSTIFICATION

The device uses one battery of DC 3V, and it is not a mains operated device, thus the content of the 7.3aa section is excluded from the standard. +

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
19	Continuous leakage current and patient auxiliary currents	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

* 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:

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Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2 – Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, (3rd ed.)2007.

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], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

IEC 60601-1-2 – Medical electrical equipment, Part 2. Electromagnetic compatibility – Requirements and tests, (3rd ed.)2007.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Identification, Marking and documents	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.1	Emission	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2	Immunity	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-2-10 Medical electrical equipment, Particular requirements for safety of nerve and muscle stimulators, 1987+A1:2001.

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 17-5

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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

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

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
IEC 60601-2-10 Medical electrical equipment, Particular requirements for safety of nerve and muscle stimulators, 1987+A1:2001.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	General requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Environmental conditions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
51	Protection against hazardous output	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* 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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HIVOX BIOTEK INC.

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Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

22. KIT CERTIFICATION

N/A



HIVOX BIOTEK INC.

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

August 25, 2014

FDA CDRH DMC

SEP 08 2014

Received

Re: K141921

Trade Name: HIVOX Spopad EMS SP-910, SP-920, SP-620

Dear Madam/Sir:

This letter is to respond the FDA request letter, signed-off date August 1, 2014. As shown in the table is the respective response detail.

Item	Request content	HIVOX response content	Attached files
A. Administrative			
A.9)a)	The sponsor did not identify where in the current submission they addressed the outstanding issues from the previous submission, K131741. Specifically, the sponsor should identify where in the submission they addressed the items in the last Request for Additional Information dated November 1, 2013.	We identify where in the attached file we addressed the items in the last Request for Additional Information dated November 1, 2013.	*Vol_001_Administrative 001_Identifying Items.pdf
D. Proposed Labeling			
D.19) b)	The package labels do not include the device common or usual name.	We include the device common or usual name in the package labels.	*Vol_002_Proposed Labeling 001_Hivox spopad SP box labels.pdf
D.20) b)	The user manual does not include all appropriate warnings and precautions recommended for powered muscle stimulators. The	We include all appropriate warnings and precautions recommended for	*Vol_002_Proposed Labeling 002_Hivox SP 620 user manual.pdf

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100



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<p>sponsor should refer to the Guidance Document for Powered Muscle Stimulators for a complete list of warnings and precautions or provide a justification for why the recommended warning or precautions are not applicable for this device. The guidance document can be found at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073783.pdf)</p>	<p>powered muscle stimulators per FDA PMS guidance in the user manuals.</p>	<p>003_Hivox SP 910 user manual.pdf 004_Hivox SP 920 user manual.pdf</p>
---	---	--

Sincerely yours,

Dr. Jen, Ke-min

Official Correspondent

K141921 152



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Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

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

FDA CDRH DDG December 7, 2014

DEC 11 2014

Received

Re: K141921.S001

Trade Name: HIVOX Spopad EMS SP-910, SP-920, SP-620

Dear Madam/Sir:

This letter is to respond the FDA request email letter, dated on October 29, 2014. As shown in the table is the respective response detail.

Item	Request content	HIVOX response content	Attached files
(b)(4)			

127 kcd



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan

Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

(b)(4)

A large, solid black rectangular redaction box covers the majority of the page's content, starting below the header and extending nearly to the bottom of the page.



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(b)(4)

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(b)(4)

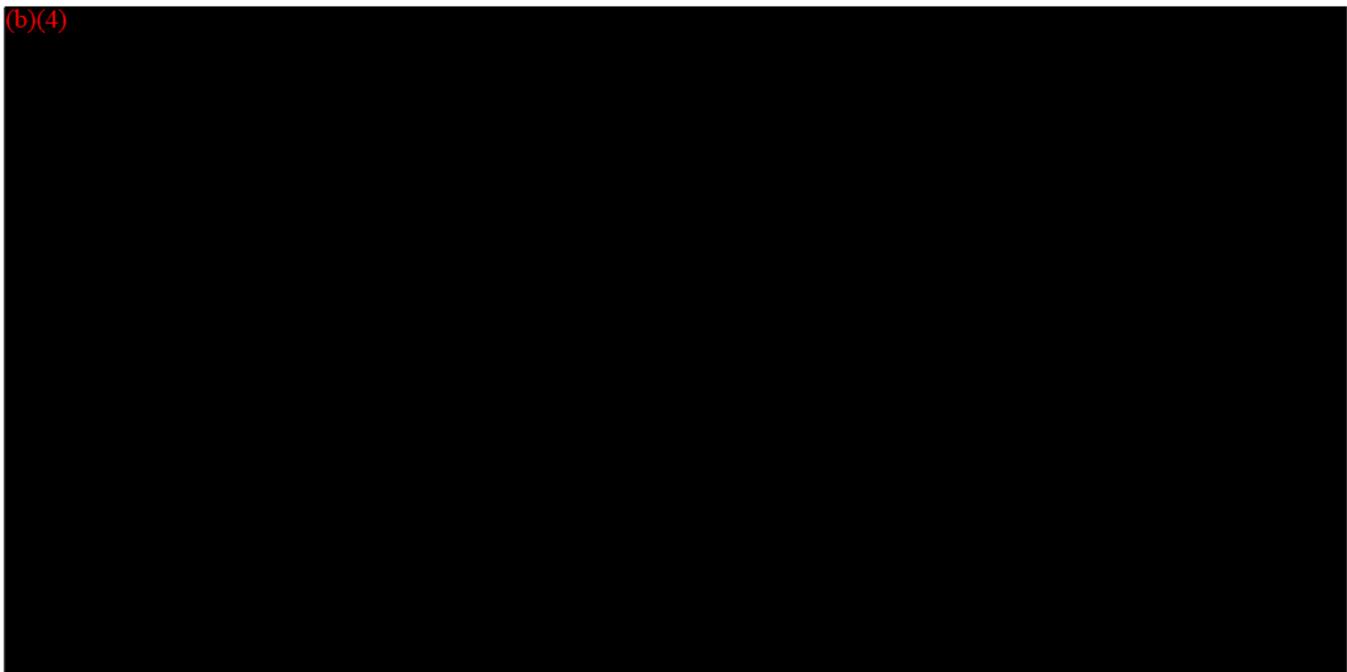
A large, solid black rectangular redaction box covers the majority of the page's content, starting below the header and extending nearly to the bottom of the page.



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(b)(4)

A large, solid black rectangular redaction box covers the majority of the page's content, starting below the header and ending above the signature.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ke-min Jen", written over a horizontal line.

Dr. Jen, Ke-min

Official Correspondent



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan
Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

“ eCopy Statement ”

- **eCopy Statement: The eCopy is an exact duplicate of the paper copy.**

Sincerely Yours,

JEN, KE-MIN, official correspondent

ELECTRICAL MUSCLE STIMULATOR



Spopad™

Instruction Manual

For

SP-910

WELCOME

Dear user, thank you for choosing HIVOX Spopad SP-910. Please read the manual carefully to learn the correct operation of this equipment. Understanding the operation will enable you to discover and enjoy the benefits of the device for a long time.

HIVOX BIOTEK INC.

5F, No.123, Shingde Road, Sanchong Dist.,

New Taipei City, 24158, TAIWAN, R.O.C.

TEL: +886-2-85112668 FAX: +886-2-85112669

HIVOX® 

Important information is highlighted by these terms:

Contraindications – Symptoms or diseases the device not applied to

Warnings – Danger for patient or operating staff.

Precautions – Information for preventing damage to the product.

Adverse Reactions – Important operating instructions.

Product Description

EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relax stiff muscle through the skin. It is recognized as a clinically proven, effective, non- medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training. SP-910 is a 1-channel battery-operated user-friendly muscle stimulation system specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-910 comprises 2 electrode gel pads, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors. The shelf life of the device is 30 months. For more information about HIVOX Spopad SP-910, please visit our website at <http://www.hivox-biotek.com> or contact our customer service for further assistance.

Indications for Use

The Electrical Muscle Stimulation unit is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.

Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Contraindication

Electrical muscle stimulators should not be used on patients with cardiac demand pacemakers. implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions

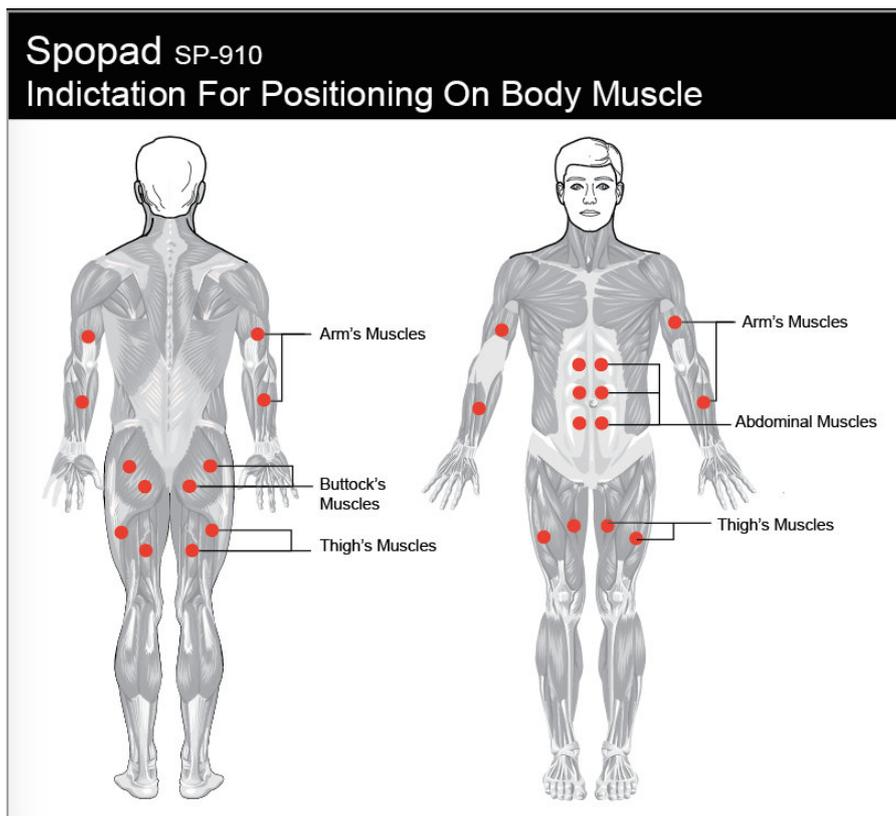
1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;
 - b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus; and
 - d. Over areas of the skin which lack normal sensation.
5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the electrode gel pads recommended for use by the manufacturer.
9. [FOR PORTABLE DEVICES ONLY]: Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Indications for positioning the unit on body

1. Body muscles map



2. Positioning photos

2.1 Arm's muscle



2.2 Abdominal muscles



2.3 Buttock's muscles



2.4 Thigh's muscles



Spopad SP-910 Program Mode:

SP-910 has one program mode with 3 cycles which are changing cycle by cycle automatically. Please see the table as below:

Spopad SP-910 Program Mode			
Cycle	Pulse Width	Frequency	On-Time
1	400µs	3 Hz	30 Sec.
2	400µs	4 Hz	30 Sec.
3	400µs	5 Hz	30 Sec.

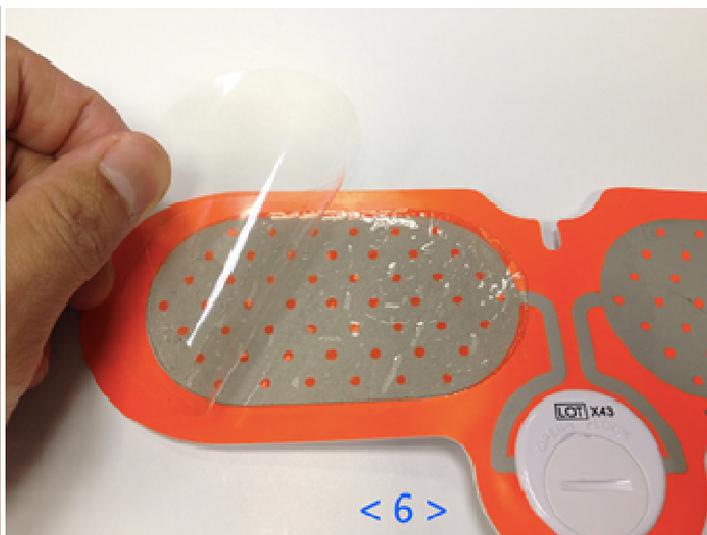
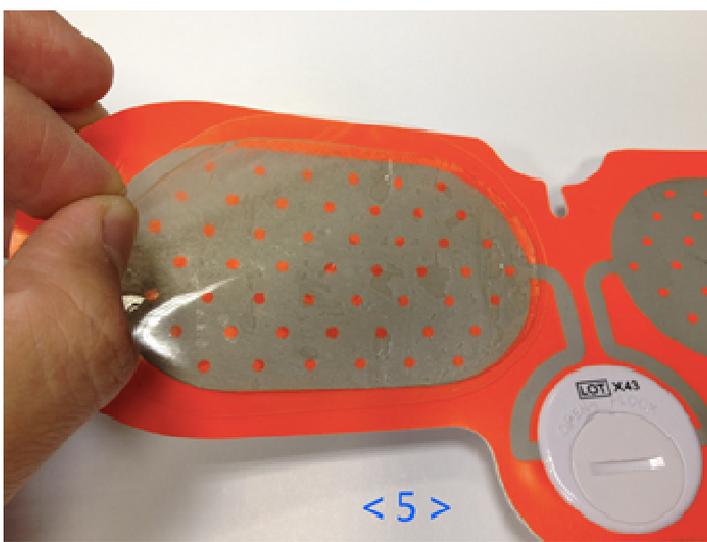
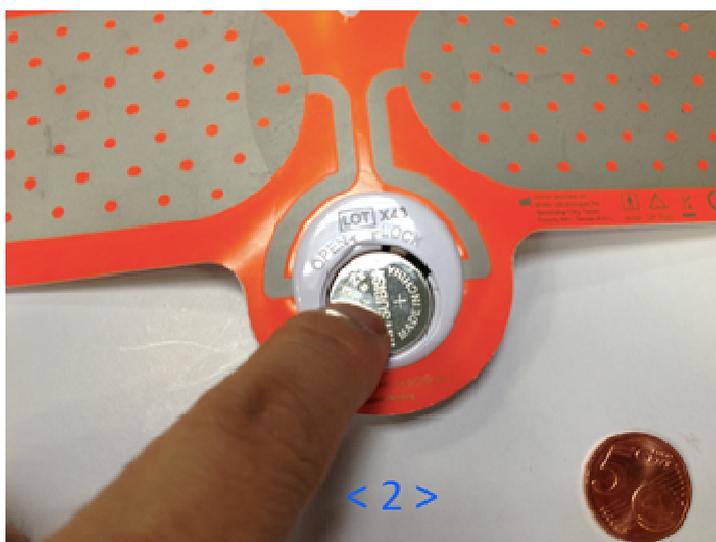
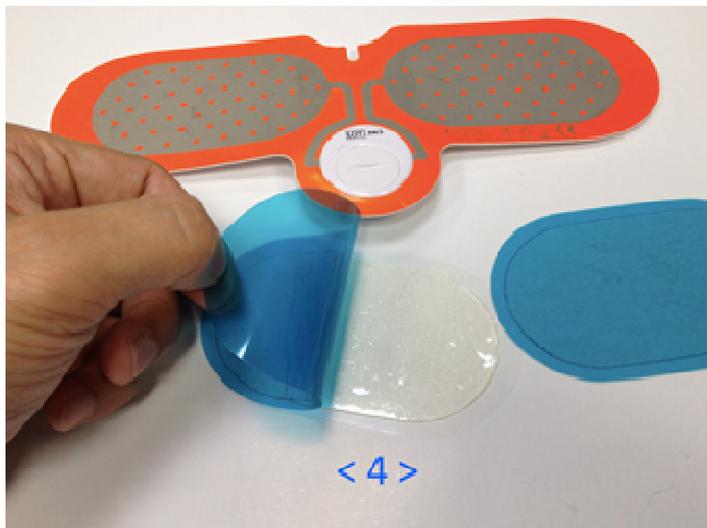
Spopad SP-910 is designed for one program mode with 3 cycles, and this mode with 3 cycles are not able to adjust. It uses external electrical impulses that act through the skin to stimulate the specific muscle group to improve, tone, firm & strengthen the muscles of Arm, Thigh, Abdomen, and Buttock. The muscle reacts in different ways depending on the strength of current and duration and frequency of the electrical impulse.

Those 3 cycles of one mode run automatically without changing by manual setting, all you have to do is to apply the unit to the muscle group and runs a treatment period in 20 minutes. Please note the cycle, pulse, frequency and timer are all not adjustable but only the intensity of impulse is adjustable with 15 levels. You can test the intensity of comfort based on the lowest level (level 1) to the greatest level (level 15) by manual adjustment.

For safety use for Spopad SP-910, the unit is preset by 20 minutes for a treatment then auto-off after every 20- minute treatment. Please place the unit where you want to stimulate the muscle group as shown in the above body map. For optimum outcome, move the unit to other muscle position indicated on the above body map after 20-minute cycle. **Please don't use over twice treatments a day on the same muscle group. Stop using the device if you experience a tingling or numbing sensation or other discomfort on the skin.**

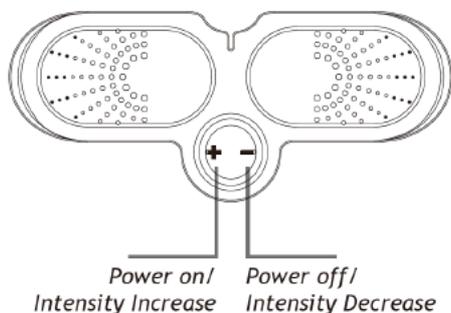
Battery & Gel Pad Assembly

1. Use a coin to turn the battery cover to the OPEN position, and open it.
2. Insert battery with + mark facing up
3. Use a coin to lock the battery cover by turning the cover clockwise.
4. Remove the blue protective film from the gel pad.
5. Apply the gel pad on the device's electrode area. (same as the other electrode side)
6. Remove the transparent film from the gel pad and ready to put on body for stimulation.



How to Operate

1. Press and hold + button for 3 seconds to turn the unit on and listen for the beep.
2. Use +/- button to adjust stimulation level. *
3. Press and hold - button for 3 seconds to turn the unit off, or it will automatically power off after 20 minutes.



* This device contains 15 intensity levels which is adjustable by manual. For your safety, please read charts below to understand the beep signal of stimulus intensity level indication before using the unit.

Beep signal of intensity level indication				
Power Mode	Operation	Type of Beep Signal	Signal Description	If the intensity cause you discomfort
Unit is turned off	Hold the + button 3 seconds	Single long beep	The unit has been turned on	NA
	One short press of + button	Single short beep	Increase the unit's intensity to the minimum 1st level	If any level of intensity makes your discomfort, please press the - button to decrease the intensity level by level until the intensity is comfortable to you. Or hold the - button 3 seconds to turn the unit off and consult your physician further.
Unit is turned on	Two short presses of + button	Two times of short beeps	Increase the unit's intensity to 2nd level	
	Three short presses of + button	Three times of short beeps	Increase the unit's intensity to 3rd level	
	Four short presses of + button	Four times of short beeps	Increase the unit's intensity to 4th level	
	Five short presses of + button	Five times of short beeps	Increase the unit's intensity to 5th level	
	Six short presses of + button	Six times of short beeps	Increase the unit's intensity to 6th level	
Seven short presses of + button	Seven times of short beeps	Increase the unit's intensity to 7th level		

Beep signal of intensity level indication

	Eight short presses of + button	Eight times of short beeps	Increase the unit's intensity to 8th level	If any level of intensity makes your discomfort, please press the - button to decrease the intensity level by level until the intensity is comfortable to you. Or hold the - button 3 seconds to turn the unit off and consult your physician further.
	Nine short presses of + button	Nine times of short beeps	Increase the unit's intensity to 9th level	
	Ten short presses of + button	Ten times of short beeps	Increase the unit's intensity to 10th level	
	Eleven short presses of + button	Eleven times of short beeps	Increase the unit's intensity to 11th level	
	Twelve short presses of + button	Twelve times of short beeps	Increase the unit's intensity to 12th level	
	Thirteen short presses of + button	Thirteen times of short beeps	Increase the unit's intensity to 13th level	
	Fourteen short presses of + button	Fourteen times of short beeps	Increase the unit's intensity to 14th level	
	Fifteen short presses of + button	Fifteen times of short beeps	Increase the unit's intensity to the maximum 15th level	
	Hold the - button 3 seconds	Single long beep	The unit has been turned off	NA

Other Beep signal of Description Chart

Power Mode	Operation	Type of Beep Signal	Signal Description
	Short press of the + or - button	Two short beeps	The intensity adjustment feature is disabled because the gel pad is not in full contact with the skin. Reapply the gel pad and try again.
Unit is turned on but cannot feel impulses	No Action	Slow consecutive intermittent beeps	The gel pad is not in contact with the skin, and reapply the gel pad and try again.
	No Action	Fast consecutive intermittent beeps	The battery power is low, and replace the battery.
	No Action	Single long beep	The auto-off program is engaged and the unit is off.
Unit is turned on and in use	Short press of the + button	Single short beep	The adjustable intensity feature has increased 1 level.

Other Beep signal of Description Chart			
	Short press of the - button	Single short beep	The adjustable intensity feature has decreased 1 level.
	Multiple presses of the + button	Two short beeps	The adjustable intensity feature has reached 15, the maximum level.
	Multiple presses of the - button	Two short beeps	The adjustable intensity feature has reached 0, the minimum level.
	Hold the - button 3 seconds	Single long beep	The unit has been turned off manually.
	No Action	Single long beep	The auto-off program is engaged and the unit is off.
	No Action	Fast consecutive intermittent beeps	The battery power is low, and replace the battery.

NOTE

- Battery needs to be replaced if the unit no longer makes a beep sound or send any electric impulses.
- Device only works when in contact with the skin. When the device is not in contact with the skin, the device will not send out stimulation.
- After use, always place the protective film back to gel pad.

The Function of Touches Mistake for Electrode Gel Pad Lost

This function is meant to detect if the electrode gel pad loses contact on your skin. When you follow the procedures of "Battery & Gel Pad Assembly" on page 7 and apply the device on your body for stimulation, during the stimulus process, if one gel pad or several gel pads cannot contact well and lose contact with your body skin, the beeper will start "slow consecutive intermittent beeps" for your notice. This situation is called "the function of touches mistake for electrode pad lost", reminding you of resetting the device.

How to Reset the Device If "the function of touches mistake for electrode pad lost" occurs.

1. When you hear "slow consecutive intermittent beeps" during using the device, please check if all of the gel pads are contacted on your skin without losing contact.
2. If one or several gel pads is/are not fully contacted on your skin, please remove the device from your body and reapply the device to the skin.
3. After reapplying the device, if one or several electrode pads still cannot be contacted with your body smoothly and keep sending "slow consecutive intermittent beeps", it means the gel pad gets dirty and becomes less sticky to contact your skin well.
4. Then, follow the procedures of **Care for the Gel pads & Replacing the Gel Pads** on page 13 to deal with this situation.
5. If above steps still do not work, please contact our local dealer to resolve this issue.

Specifications

Power	3V CR2032 Battery X1
Number Of Output Modes	1
Number Of Output Channels	1
Mode Of Output Channels	1
Regulated Current Or Regulated Voltage?	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip	No
Automatic No-Load Trip	No
Automatic Shut-Off	Yes
User Override Control	Yes
Indicator Display	No
On/Off Status	Beeper
Low Battery	Beeper
Current/Voltage Level	No
Timer Range (Minutes)	20
Compliance With Voluntary Standard	IEC60601-1 IEC 60601-1-2 IEC 60601-2-10
Compliance With 21 CFR 898?	Yes
Housing Materials And Construction	Silicone
Pulse Strength	0 ~ 15 Stages Adjustable
Operation Environment	10 ^o ~ 40°C, 30% ~ 85% RH
Storage Environment	-10 ^o ~ 50°C, 10% ~ 95% RH
Transport Environment	-10 ^o ~ 50°C, 35% ~ 85% RH
Dimension (LxWxH, inch)	9.41 x 2.76 x 0.447
Weight (g)	35.8
Accessory	Instruction manual
Patient-contacting material	HIVOX electrode gel pad, K131720

Parameter		Response
Mode or Program Name		Regular
Waveform (e.g., pulsed monophasic, biphasic)		Symmetrical
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular
Maximum Output Voltage (volts) (+/- <u>10</u> %)		<u>52</u> @500 Ω
		<u>102</u> @2 k Ω
		<u>150</u> @10 k Ω
Maximum Output Current (mA) (+/- <u>10</u> %)		<u>104</u> @500 Ω
		<u>51</u> @2 k Ω
		<u>15</u> @10 k Ω
Duration of primary (depolarizing) phase (μ sec)		0
Pulse Duration (μ sec)		400
Frequency (Hz)		3-4-5
For interferential modes only: Beat Frequency [†] (Hz)		N/A
For multiphasic waveforms only:	Symmetrical phases?	Yes
	Phase Duration (μ sec)	400
Net Charge (μ C)		<u>0.416</u> @500 Ω
Maximum Phase Charge, (μ C)		<u>41.6</u> @500 Ω
Maximum Current Density (mA/cm ²)		<u>1.187</u> @500 Ω
Maximum Average Current (average absolute value), mA		<u>104</u> @500 Ω
Maximum Average Power Density (W/cm ²)		<u>0.0617</u> @500 Ω
Burst Mode	(a) Pulses per burst	N/A
	(b) Bursts per second	N/A
	(c) Burst duration (seconds)	N/A
	(d) Duty Cycle [Line (b) x Line (c)]	N/A
Additional Features (specify, if applicable)		N/A

Maintenance & Disposal

1. Storage

- (1) Keep the unit away from children.
- (2) Remove the battery if the unit will not be used for more than 10 days.
- (3) Reapply the protective film back to the gel pads after each use.
- (4) Do not store the unit under high temperature, high humidity, and direct sunlight exposed environment or where there are a lot of dusts or corrosive gas.

2. Care for the Gel Pads

- (1) If the gel pads get dirty or less sticky, you can prolong the lifetime for additional uses by cleaning it with a drop of water on your finger, rub the water over the surface of the gel pads and allow it to dry.
- (2) Always store the gel pads in a cool, airy area away from direct sunlight.
- (3) Be sure the skin is clean before the gel pads are placed.
- (4) Always store the gel pads with the protective film after use.

3. Replacing the Gel Pads

When following the above procedures of Care for the Gel Pads to treat the gel pads, generally the gel pad can last 50 times of use to adhere to the skin smoothly. However, the number of times for reusing gel pad depends on the individual skin condition. Therefore sometimes it might not be able to last 50 times. **If the electrodes fail to adhere to the skin smoothly, then new electrodes should be used** by following the following 4 steps.

- (1) Remove the gel pad carefully and roll the gel upwards with your fingers until the entire pad has been lifted off.
- (2) Repeat step (1) on the other pad.
- (3) Clean the device with a drop of water on your finger to remove left over residue. Allow to dry.
- (4) Place new gel pads onto the unit by following steps 4-6 of Battery & Gel Pad Assembly section on page 7.

4. Disposal

Battery and this unit must NOT be disposed in household waste. Return them to public collection points or shops selling battery or devices of the same kind according to local regulations. In case of any confusion, consult with your local environmental protection agency.

Troubleshooting

1. The units fail to turn on.

- (1) Press the + button again and hold it down for 2 seconds.
- (2) Check if the battery is properly in place with good connection.
- (3) Replace battery if (1) and (2) both fail.

2. The gel pads are not sticky as before.

With a drop of water on your finger, rub the water over the surface of the gel and allow it dry.

3. The unit beeps abnormally during treatment.

- (1) Check if the device is connected securely with the skin.
- (2) If the beeping persists, replace the battery with new one.

4. The stimulation is not felt.

- (1) Make sure the gel pads are not overlapped.
- (2) Increase the pulse intensity gradually.
- (3) Makes sure the device is connected securely with the skin.

5. The skin of treated area turns red.

Stop treating that area immediately; wait until the skin restores to its healthy state. If irritation persists, consult with a dermatologist.

6. The intensity begins to drop:

Replace battery immediately

7. The stimulation is uncomfortable.

- (1) Press – button to decrease intensity if the stimulation is too strong.
- (2) If not improving, check if the device is connected securely with the skin.
- (3) If step (2) does not help, check if the gel pads are worn out. Worn pads cannot distribute current evenly across the skin, which may lead to irritating stimulation. In such a case, replace the gel pads.

Guidance and manufacturer's declaration-electromagnetic emissions

The SP-910 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-910 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>SP-910</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>SP-910</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-910 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-910 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <u>SP-910</u> requires continued operation during power mains interruptions, it is recommended that the <u>SP-910</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The <u>SP-910</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic immunity			
The <u>SP-910</u> is intended for use in the electromagnetic environment specified below.			
The customer or the user of the <u>SP-910</u> should assure that is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the <u>SP-910</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <u>SP-910</u> is used exceeds the applicable RF compliance level above, the <u>SP-910</u> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the <u>SP-910</u>.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distance between portable and mobile RF communications equipment and the SP-910

The SP-910 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP-910 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP-910 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

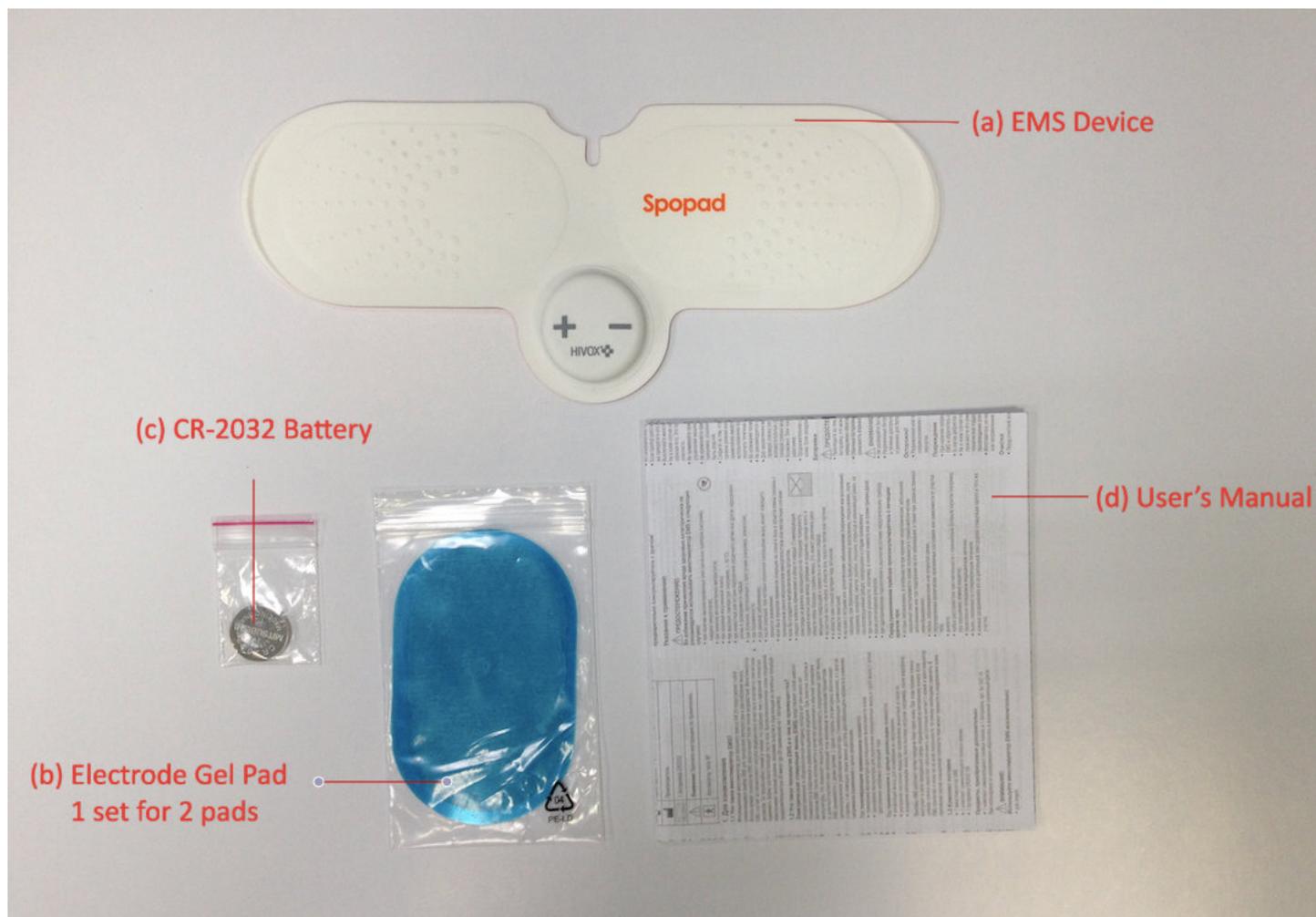
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Package list and photo

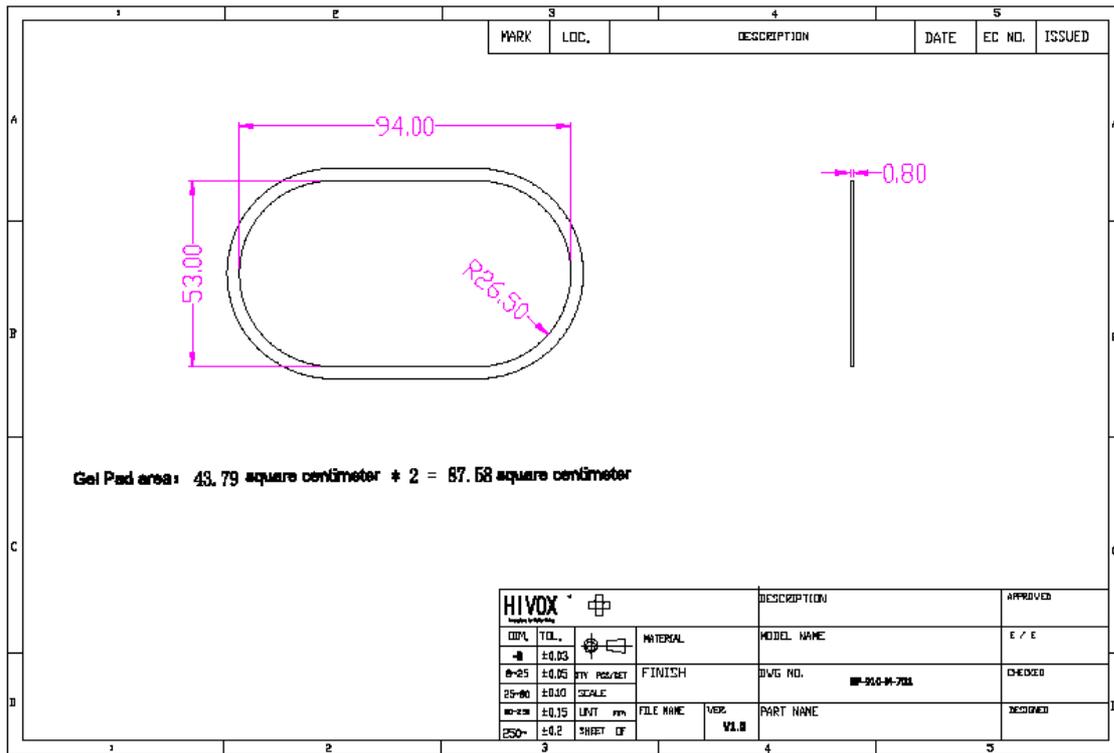
1. Photo



2. List

Item	Name	Quantity
a	EMS device –SP-910	1
b	Electrode Gel Pad* Conducting area: 87.68 cm ²	1 set of 2 pads
c	CR-2032 battery	1
d	User's Manual	1

* Electrode Gel Pad's area is equal to conducting area shown below.



ELECTRICAL MUSCLE STIMULATOR



Spopad™

Instruction Manual

For

SP-920

WELCOME

Dear user, thank you for choosing HIVOX Spopad SP-920. Please read the manual carefully to learn the correct operation of this equipment. Understanding the operation will enable you to discover and enjoy the benefits of the device for a long time



HIVOXBIOTEK INC.

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Important information is highlighted by these terms:

Contraindications – Symptoms or diseases the device not applied to

Warnings – Danger for patient or operating staff.

Precautions – Information for preventing damage to the product.

Adverse Reactions – Important operating instructions.

Product Description

EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relax stiff muscle through the skin. It is recognized as a clinically proven, effective, non- medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training. SP-920 is a 1-channel battery-operated user-friendly muscle stimulation system specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-920 comprises 2 electrode gel pads, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors. The shelf life of the device is 30 months. For more information about HIVOX Spopad SP-920, please visit our website at <http://www.hivox-biotek.com> or contact our customer service for further assistance.

Indications for Use

The Electrical Muscle Stimulation unit is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.

Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Contraindication

Electrical muscle stimulators should not be used on patients with cardiac demand pacemakers. implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions

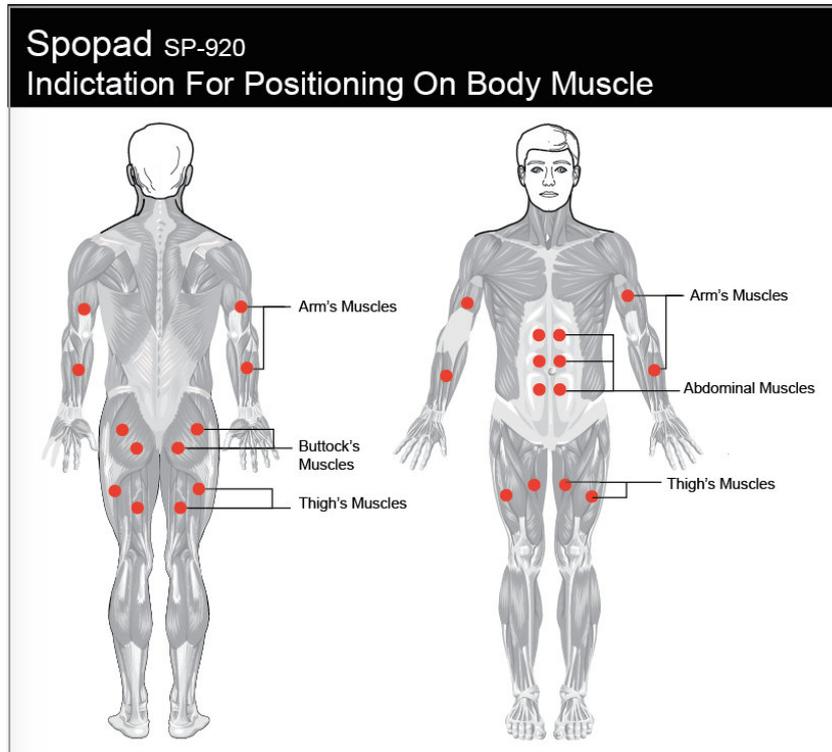
1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;
 - b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus; and
 - d. Over areas of the skin which lack normal sensation.
5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the electrode gel pads recommended for use by the manufacturer.
9. [FOR PORTABLE DEVICES ONLY]: Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators

Indications for positioning the unit on body

1. Body muscles map



2. Positioning photos

2.1 Arm's muscle



2.2 Abdominal muscles



2.3 Buttock's muscles



2.4 Thigh's muscles



Spopad SP-920 Program Mode:

SP-920 has one program mode with 5 cycles which are changing cycle by cycle automatically. Please see the table as below:

Spopad SP-920 Program Mode			
Cycle	Pulse Width	Frequency	On-Time
1	400µs	2 Hz	60 Sec.
2	400µs	4 Hz	60 Sec.
3	400µs	25 Hz	20 Sec.
4	400µs	25 Hz	20 Sec.
5	400µs	25 Hz	20 Sec.

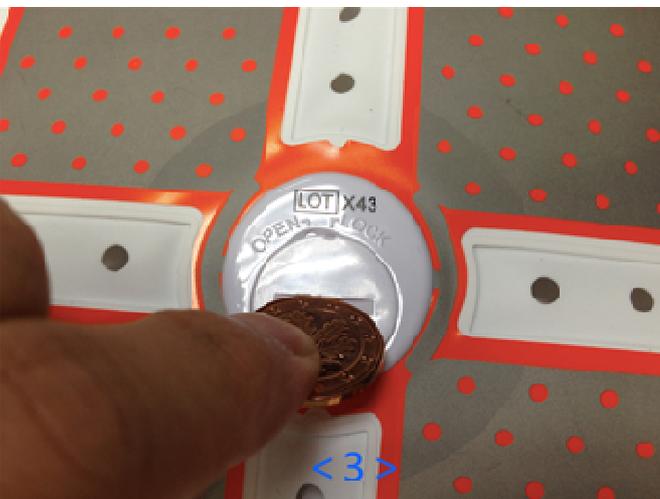
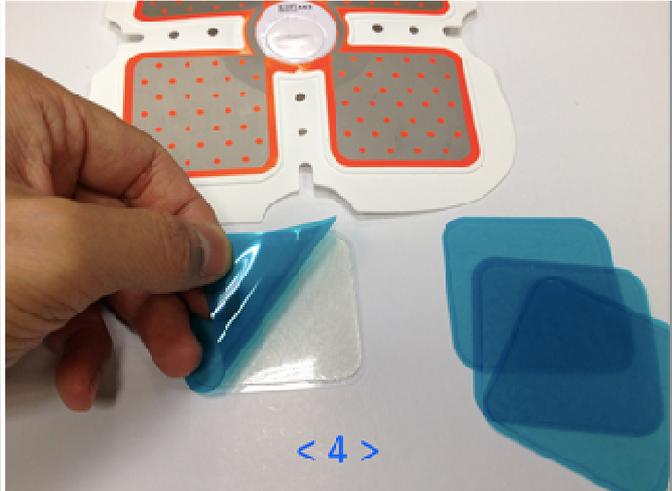
Spopad SP-920 is designed for one program mode with 5 cycles, and this mode with 5 cycles are not able to adjust. It uses external electrical impulses that act through the skin to stimulate the specific muscle group to improve, tone, firm & strengthen the muscles of Arm, Thigh, Abdomen, and Buttock. The muscle reacts in different ways depending on the strength of current and duration and frequency of the electrical impulse.

Those 5 cycles of one mode run automatically without changing by manual setting, all you have to do is to apply the unit to the muscle group and runs a treatment period in 20 minutes. Please note the cycle, pulse, frequency and timer are all not adjustable but only the intensity of impulse is adjustable with 15 levels. You can test the intensity of comfort based on the lowest level (level 1) to the greatest level (level 15) by manual adjustment.

For safety use for Spopad SP-920, the unit is preset by 20 minutes for a treatment then auto-off after every 20- minute treatment. Please place the unit where you want to stimulate the muscle group as shown in the above body map. For optimum outcome, move the unit to other muscle position indicated on the above body map after 20-minute cycle. **Please don't use over twice treatments a day on the same muscle group. Stop using the device if you experience a tingling or numbing sensation or other discomfort on the skin.**

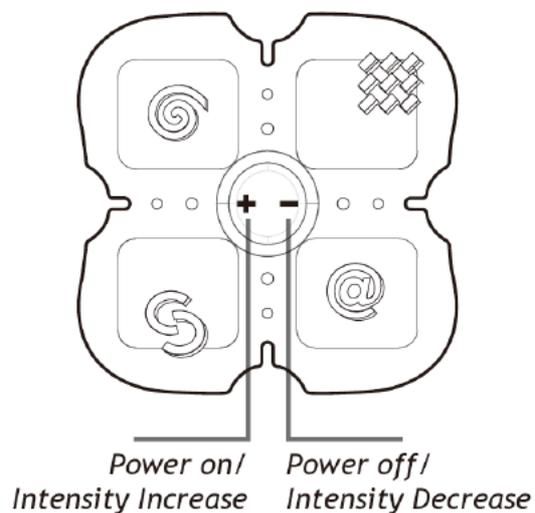
Battery & Gel Pad Assembly

1. Use a coin to turn the battery cover to the OPEN position, and open it.
2. Insert battery with + mark facing up
3. Use a coin to lock the battery cover by turning the cover clockwise.
4. Remove the blue protective film from the gel pad.
5. Apply the gel pad on the device's electrode area. (same as the other electrode side)
6. Remove the transparent film from the gel pad and ready to put on body for stimulation.



How to Operate

1. Press and hold + button for 3 seconds to turn the unit on and listen for the beep.
2. Use +/- button to adjust stimulation level. *
3. Press and hold - button for 3 seconds to turn the unit off, or it will automatically power off after 20 minutes.



* This device contains 15 intensity levels which is adjustable by manual. For your safety, please read charts below to understand the beep signal of stimulus intensity level indication before using the unit.

Beep signal of intensity level indication				
Power Mode	Operation	Type of Beep Signal	Function Description	If the intensity causes your discomfort, then
Unit is turned off	Hold the + button 3 seconds	Single long beep	The unit has been turned on	NA
	One short press of + button	Single short beep	Increase the unit's intensity to the minimum 1st level	If any level of intensity makes your discomfort, please press the - button to decrease the intensity level by level until the intensity is comfortable to you. Or hold the - button 3 seconds to turn the unit off and consult your physician further.
Unit is turned on	Two short presses of + button	Two times of short beeps	Increase the unit's intensity to 2nd level	
	Three short presses of + button	Three times of short beeps	Increase the unit's intensity to 3rd level	
	Four short presses of + button	Four times of short beeps	Increase the unit's intensity to 4th level	
	Five short presses of + button	Five times of short beeps	Increase the unit's intensity to 5th level	

Beep signal of intensity level indication				
	Six short presses of + button	Six times of short beeps	Increase the unit's intensity to 6th level	If any level of intensity makes your discomfort, please decrease the intensity by pressing the - button to decrease the intensity level by level until the intensity is comfortable to you. Or hold the - button 3 seconds to turn the unit off and consult your doctor further.
	Seven short presses of + button	Seven times of short beeps	Increase the unit's intensity to 7th level	
	Eight short presses of + button	Eight times of short beeps	Increase the unit's intensity to 8th level	
	Nine short presses of + button	Nine times of short beeps	Increase the unit's intensity to 9th level	
	Ten short presses of + button	Ten times of short beeps	Increase the unit's intensity to 10th level	
	Eleven short presses of + button	Eleven times of short beeps	Increase the unit's intensity to 11th level	
	Twelve short presses of + button	Twelve times of short beeps	Increase the unit's intensity to 12th level	
	Thirteen short presses of + button	Thirteen times of short beeps	Increase the unit's intensity to 13th level	
	Fourteen short presses of + button	Fourteen times of short beeps	Increase the unit's intensity to 14th level	
	Fifteen short presses of + button	Fifteen times of short beeps	Increase the unit's intensity to the maximum 15th level	
	Hold the - button 3 seconds	Single long beep	The unit has been turned off	NA

Description Chart of Other Beep Signal			
Power Mode	Operation	Type of Beep Signal	Signal Description
Unit is turned on but cannot feel stimulus.	Short press of the + or - button	Two short beeps	The intensity adjustment feature is disable because the gel pad is not in full contact with the skin. Reapply the gel pad and try again.
	No Action	Slow consecutive intermittent beeps	The gel pad is not in contact with the skin, reapply the gel pad and try again.
	No Action	Fast consecutive intermittent beeps	The battery power is low, and replace the battery.

Description Chart of Other Beep Signal			
	No Action	Single long beep	The auto-off program is engaged and the unit is off.
Unit is turned on and in use	Short press of the + button	Single short beep	The adjustable intensity feature has increased 1 level.
	Short press of the - button	Single short beep	The adjustable intensity feature has decreased 1 level.
	Multiple presses of the + button	Two short beeps	The adjustable intensity feature has reached 15, the maximum level.
	Multiple presses of the - button	Two short beeps	The adjustable intensity feature has reached 0, the minimum level.
	Hold the - button 3 seconds	Single long beep	The unit has turned off manually.
	No Action	Single long beep	The auto-off program is engaged and the unit is off.
	No Action	Fast consecutive intermittent beeps	The battery power is low, and replace the battery.

NOTE

- Battery needs to be replaced if the unit no longer makes a beep sound or send any electric impulses.
- Device only works when in contact with the skin. When the device is not in contact with the skin, the device will not send out stimulation.
- After use, always place the protective film back to gel pad.

The Function of Touches Mistake for Electrode Gel Pad Lost

This function is meant to detect if the electrode gel pad loses contact on your skin. When you follow the procedures of "Battery & Gel Pad Assembly" on page 7 and apply the device on your body for stimulation, during the stimulus process, if one gel pad or several gel pads cannot contact well and lose contact with your body skin, the beeper will start "slow consecutive intermittent beeps" for your notice. This situation is called "the function of touches mistake for electrode pad lost", reminding you of resetting the device.

How to Reset the Device If "the function of touches mistake for electrode pad lost" occurs.

1. When you hear "slow consecutive intermittent beeps" during using the device, please check if all of the gel pads are contacted on your skin without losing contact.
2. If one or several gel pads is/are not fully contacted on your skin, please remove the device from your body and reapply the device to the skin.
3. After reapplying the device, if one or several electrode pads still cannot be contacted with your body smoothly and keep sending "slow consecutive intermittent beeps", it means the gel pad gets dirty and becomes less sticky to contact your skin well.
4. Then, follow the procedures of **Care for the Gel pads & Replacing the Gel Pads** on page 13 to deal with this situation.
5. If above steps still do not work, please contact our local dealer to resolve this issue.

Specifications

Power	3V CR2032 Battery X1
Number Of Output Modes	1
Number Of Output Channels	1
Mode Of Output Channels	1
Regulated Current Or Regulated Voltage?	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip	No
Automatic No-Load Trip	No
Automatic Shut-Off	Yes
User Override Control	Yes
Indicator Display	No
On/Off Status	Beeper
Low Battery	Beeper
Current/Voltage Level	No
Timer Range (Minutes)	20
Compliance With Voluntary Standard	IEC60601-1 IEC 60601-1-2 IEC 60601-2-10
Compliance With 21 CFR 898?	Yes
Housing Materials And Construction	Silicone
Pulse Strength	0 ~ 15 Stages Adjustable
Operation Environment	10° ~ 40°C, 30% ~ 85% RH
Storage Environment	-10° ~ 50°C, 10% ~ 95% RH
Transport Environment	-10° ~ 50°C, 35% ~ 85% RH
Dimension (LxWxH, inch)	6.69 x 6.69 x 0.512
Weight (g)	52.6
Accessory	Instruction manual
Patient-contacting material	HIVOX electrode gel pad, K131720

Parameter		Response
Mode or Program Name		Regular
Waveform (e.g., pulsed monophasic, biphasic)		Symmetrical
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular
Maximum Output Voltage (volts) (+/- <u>10</u> %)		<u>58.4</u> @500 Ω
		<u>106</u> @2 k Ω
		<u>154</u> @10 k Ω
Maximum Output Current (mA) (+/- <u>10</u> %)		<u>117</u> @500 Ω
		<u>53</u> @2 k Ω
		<u>15.4</u> @10 k Ω
Duration of primary (depolarizing) phase (μ sec)		0
Pulse Duration (μ sec)		400
Frequency (Hz)		2-4-25
C		N/A
For multiphasic waveforms only:	Symmetrical phases?	Yes
	Phase Duration (μ sec)	400
Net Charge (μ C)		<u>0.468</u> @500 Ω
Maximum Phase Charge, (μ c)		<u>46.8</u> @500 Ω
Maximum Current Density (mA/cm ²)		<u>1.057</u> @500 Ω
Maximum Average Current (average absolute value), mA		<u>117</u> @500
Maximum Average Power Density (W/cm ²)		<u>0.0617</u> @500 Ω
Burst Mode	(a) Pulses per burst	25
	(b) Bursts per second	1
	(c) Burst duration (seconds)	20
	(d) Duty Cycle [Line (b) x Line (c)]	20
Additional Features (specify, if applicable)		N/A

Maintenance & Disposal

1. Storage

- (1) Keep the unit away from children.
- (2) Remove the battery if the unit will not be used for more than 10 days.
- (3) Reapply the protective film back to the gel pads after each use.
- (4) Do not store the unit under high temperature, high humidity, and direct sunlight exposed environment or where there are a lot of dusts or corrosive gas.

2. Care for the Gel Pads

- (1) If the gel pads get dirty or less sticky, you can prolong the lifetime for additional uses by cleaning it. With a drop of water on your finger, rub the water over the surface of the gel pads and allow it to dry.
- (2) Always store the gel pads in a cool, airy area away from direct sunlight.
- (3) Be sure the skin is clean before the gel pads are placed.
- (4) Always store the gel pads with the protective film after use.

3. Replacing the Gel Pads

When following the above procedures of Care for the Gel Pads to treat the gel pads, generally the gel pad can last 50 times of use to adhere to the skin smoothly. However, the number of times for reusing gel pad depends on the individual skin condition. Therefore sometimes it might not be able to last 50 times. **If the electrodes fail to adhere to the skin smoothly, then new electrodes should be used** by following the following 4 steps.

- (1) Remove the gel pad carefully and roll the gel upwards with your fingers until the entire pad has been lifted off.
- (2) Repeat step (1) on the other pad.
- (3) Clean the device with a drop of water on your finger to remove left over residue. Allow to dry.
- (4) Place new gel pads onto the unit by following steps 4-6 of Battery & Gel Pad Assembly section on page 7.

4. Disposal

Batteries and this unit must NOT be disposed in household waste. Return them to public collection points or shops selling batteries or devices of the same kind according to local regulations. In case of any confusion, consult with your local environmental protection agency.

Troubleshooting

1. The units fail to turn on.

- (1) Press the + button again and hold it down for 2 seconds.
- (2) Check if the batteries are properly in place with good connection.
- (3) Replace batteries if (1) and (2) both fail.

2. The gel pads are not sticky as before.

With a drop of water on your finger, rub the water over the surface of the gel and allow it dry.

3. The unit beeps abnormally during treatment.

- (1) Check if the device is connected securely with the skin.
- (2) If the beeping persists, replace the battery with new one.

4. The stimulation is not felt.

- (1) Make sure the gel pads are not overlapped.
- (2) Increase the pulse intensity gradually.
- (3) Makes sure the device is connected securely with the skin.

5. The skin of treated area turns red.

Stop treating that area immediately; wait until the skin restores to its healthy state. If irritation persists, consult with a dermatologist.

6. The intensity begins to drop:

Replace battery immediately

7. The stimulation is uncomfortable.

- (1) Press – button to decrease intensity if the stimulation is too strong.
- (2) If not improving, check if the device is connected securely with the skin.
- (3) If step (2) does not help, check if the gel pads are worn out. Worn pads cannot distribute current evenly across the skin, which may lead to irritating stimulation. In such a case, replace the gel pads.

Guidance and manufacturer's declaration-electromagnetic emissions

The SP-920 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-920 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>SP-920</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>SP-920</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-920 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-920 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <u>SP-920</u> requires continued operation during power mains interruptions, it is recommended that the <u>SP-920</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The <u>SP-920</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic immunity			
The <u>SP-920</u> is intended for use in the electromagnetic environment specified below.			
The customer or the user of the <u>SP-920</u> should assure that is used in such and environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	Not applicable	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <u>SP-920</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> <p>$d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <u>SP-920</u> is used exceeds the applicable RF compliance level above, the <u>SP-920</u> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the <u>SP-920</u>.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distance between portable and mobile RF communications equipment and the SP-920

The SP-920 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP-920 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP-920 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2 \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3 \sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

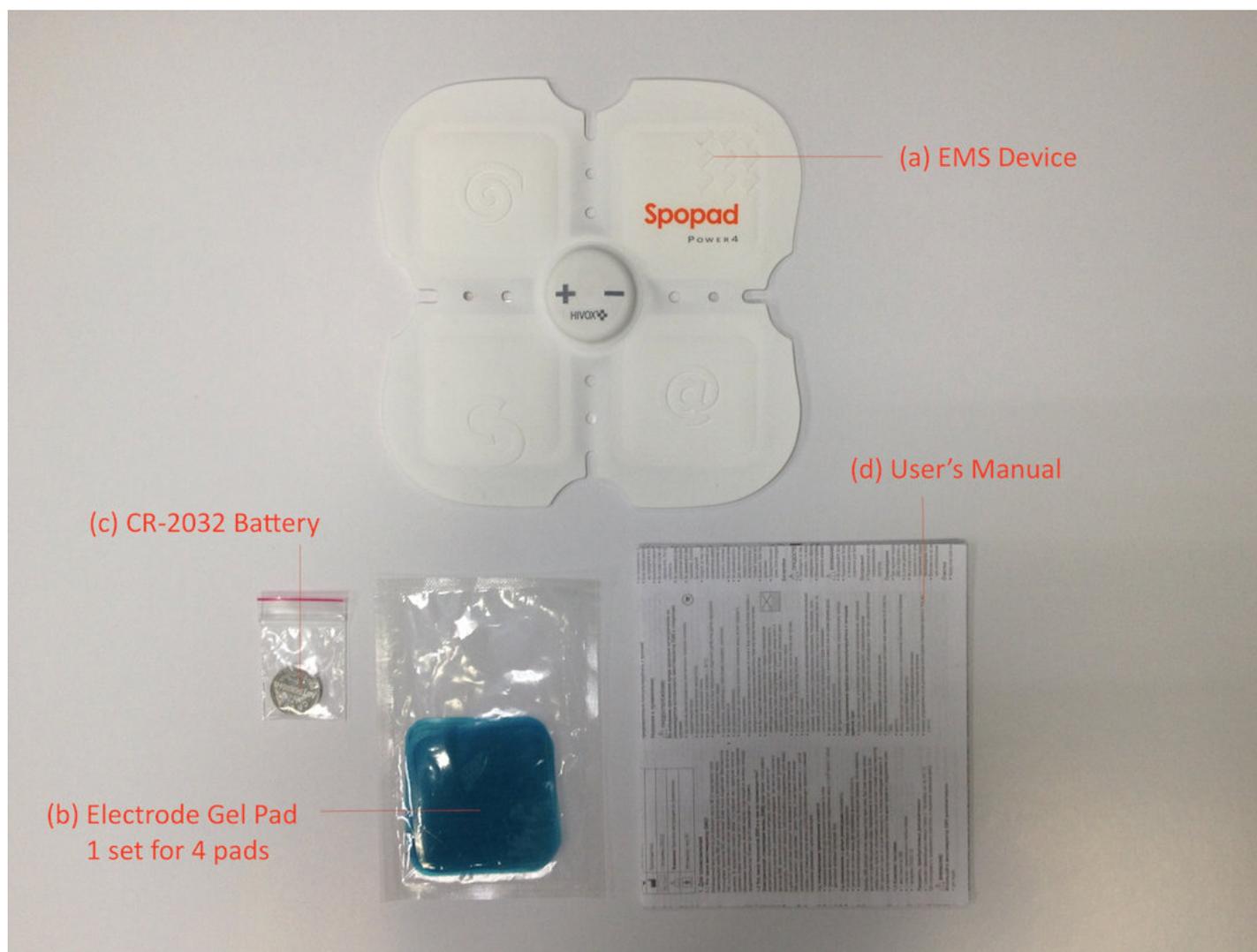
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Package list and photo

1. Photo

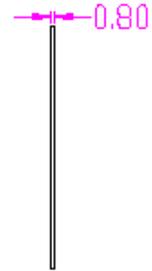
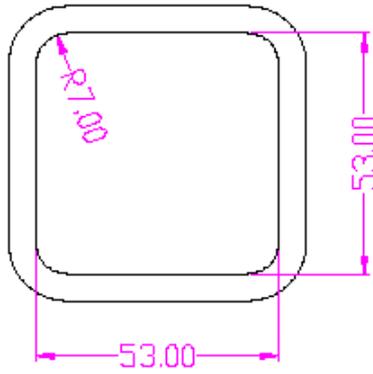


2. List

Item	Name	Quantity
a	EMS device –SP-920	1
b	Electrode Gel Pad* Conducting area: 110.68 cm ²	1 set of 4 pads
c	CR-2032 battery	1
d	User's Manual	1

* Electrode Gel Pad's area is equal to conducting area shown below.

MARK	LOC.	DESCRIPTION	DATE	EC NO.	ISSUED
------	------	-------------	------	--------	--------



Gel Pad area: 27.67 square centimeter * 4 = 110.68 square centimeter

HIVOX				DESCRIPTION	APPROVED
COMP.	TOL.		MATERIAL	MODEL NAME	E / E
0-25	±0.03				
25-50	±0.05	ITY	FINISH	DWG NO. 01-200-01-201	CHECKED
50-75	±0.10	SCALE			
75-100	±0.15	UNIT	FILE NAME	PART NAME	DESIGNED
100-250	±0.2	SHEET OF	VER. V1.0		

ELECTRICAL MUSCLE STIMULATOR



Spopad™

Instruction Manual

For

SP-620

WELCOME

Dear user, thank you for choosing HIVOX Spopad SP-620. Please read the manual carefully to learn the correct operation of this equipment. Understanding the operation will enable you to discover and enjoy the benefits of the device for a long time.

HIVOX® 

HIVOX BIOTEK INC.

5F, No.123, Shingde Road, Sanchong Dist.,

New Taipei City, 24158, TAIWAN, R.O.C.

TEL: +886-2-85112668 FAX: +886-2-85112669

Important information is highlighted by these terms:

Contraindications – Symptoms or diseases the device not applied to

Warnings – Danger for patient or operating staff.

Precautions – Information for preventing damage to the product.

Adverse Reactions – Important operating instructions.

Product Description

EMS, Electrical Muscle Stimulation, which improves, tones, firms & strengthens muscle and relax stiff muscle through the skin. It is recognized as a clinically proven, effective, non- medication method of training muscle from certain causes. It manages muscle strengthen, toning and firming. It is also free from side effects when used properly, and can also be used as a simple means of self-training. SP-620 is a 1-channel battery-operated user-friendly muscle stimulation system specifically designed to exercise the muscles. Each device comprises namely an electronic stimulator module which generates the required stimulation signals. SP-620 comprises 2 electrode gel pads, which connects the signals from the stimulator to the skin. Power is supplied from one battery, CR2032, located in a compartment protected by a removable battery cover. The user cannot access the wiring or connectors. The shelf life of the device is 30 months. For more information about HIVOX Spopad SP-620, please visit our website at <http://www.hivox-biotek.com> or contact our customer service for further assistance.

Indications for Use

The Electrical Muscle Stimulation unit is indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas.

Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

Contraindication

Electrical muscle stimulators should not be used on patients with cardiac demand pacemakers. implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Warnings

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

Precautions

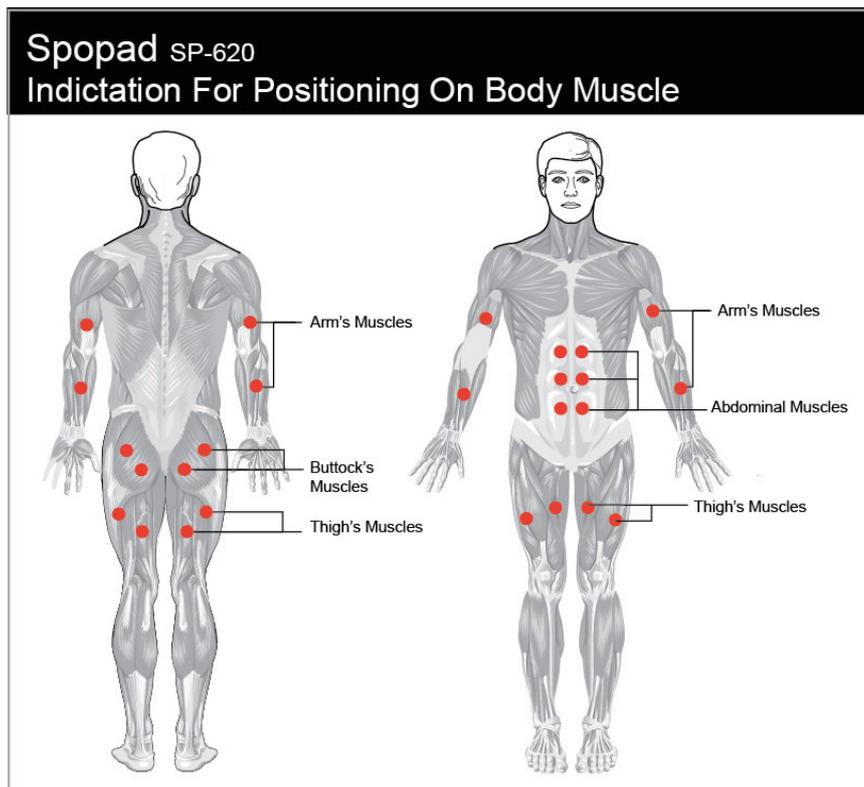
1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;
 - b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus; and
 - d. Over areas of the skin which lack normal sensation.
5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the electrode gel pad recommended for use by the manufacturer.
9. [FOR PORTABLE DEVICES ONLY]: Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

Indications for positioning the unit on body

1. Body muscles map



2. Positioning photos

2.1 Arm's muscle



2.2 Abdominal muscles



2.4 Thigh's muscles



Spopad SP-620 Program Mode:

SP-620 has one program mode with 5 cycles which are changing cycle by cycle automatically. Please see the table as below:

Spopad SP-620 Program Mode			
Cycle	Pulse Width	Frequency	On-Time
1	400 μ s	2 Hz	60 Sec.
2	400 μ s	4 Hz	60 Sec.
3	400 μ s	25 Hz	20 Sec.
4	400 μ s	25 Hz	20 Sec.
5	400 μ s	25 Hz	20 Sec.

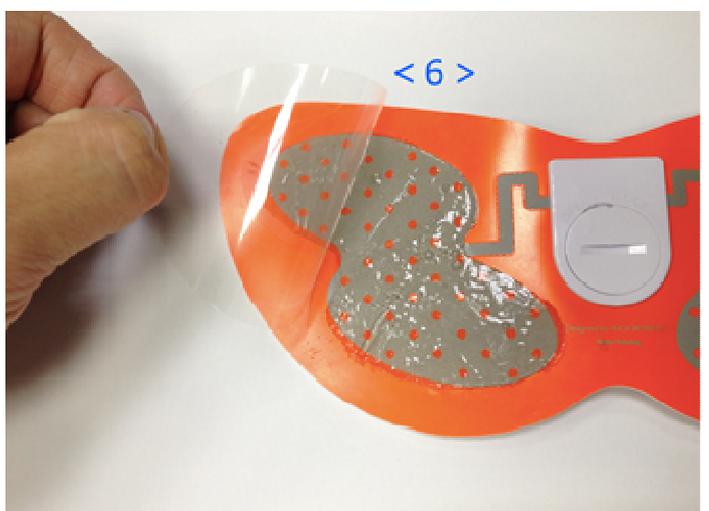
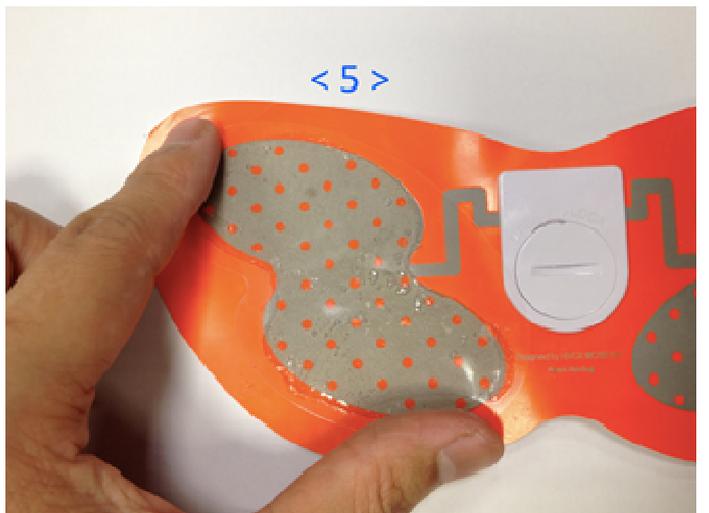
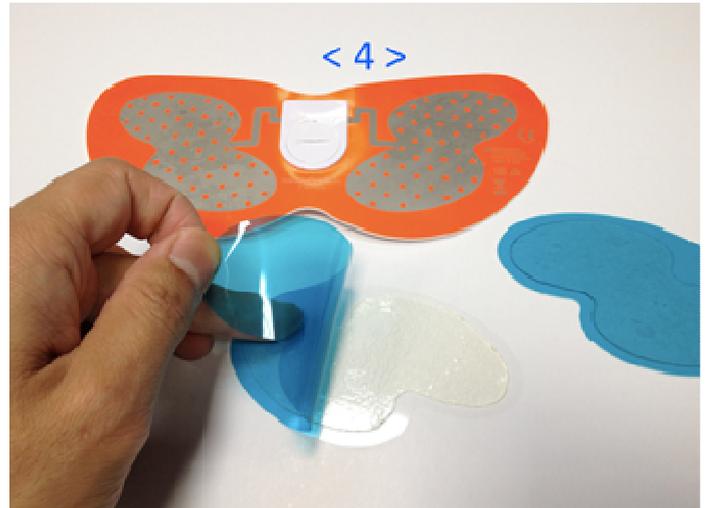
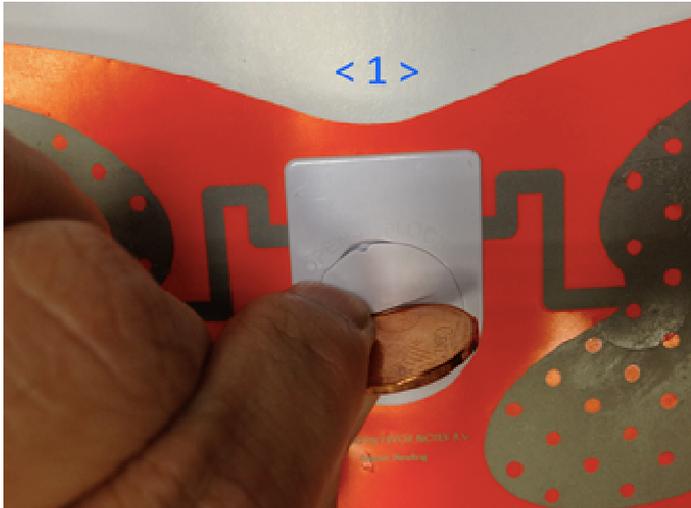
Spopad SP-620 is designed for one program mode with 5 cycles, and this mode with 5 cycles are not able to adjust. It uses external electrical impulses that act through the skin to stimulate the specific muscle group to improve, tone, firm & strengthen the muscles of Arm, Thigh, Abdomen, and Buttock. The muscle reacts in different ways depending on the strength of current and duration and frequency of the electrical impulse.

Those 5 cycles of one mode run automatically without changing by manual setting, all you have to do is to apply the unit to the muscle group and runs a treatment period in 20 minutes. Please note the cycle, pulse, frequency and timer are all not adjustable but only the intensity of impulse is adjustable with 15 levels. You can test the intensity of comfort based on the lowest level (level 1) to the greatest level (level 15) by manual adjustment.

For safety use for Spopad SP-620, the unit is preset by 20 minutes for a treatment then auto-off after every 20-minute treatment. Please place the unit where you want to stimulate the muscle group as shown in the above body map. For optimum outcome, move the unit to other muscle position indicated on the above body map after 20-minute cycle. **Please don't use over twice treatments a day on the same muscle group. Stop using the device if you experience a tingling or numbing sensation or other discomfort on the skin.**

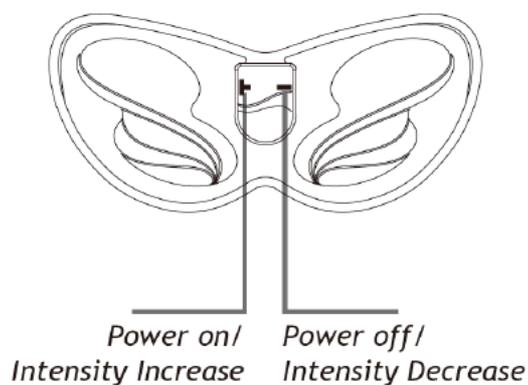
Battery & Gel Pad Assembly

1. Use a coin to turn the battery cover to the OPEN position, and open it.
2. Insert battery with + mark facing up
3. Use a coin to lock the battery cover by turning the cover clockwise.
4. Remove the blue protective film from the gel pad.
5. Apply the gel pad on the device's electrode area. (same as the other electrode side)
6. Remove the transparent film from the gel pad and ready to put on body for stimulation.



How to Operate

1. Press and hold + button for 3 seconds to turn the unit on and listen for the beep.
2. Use +/- button to adjust stimulation level. *
3. Press and hold - button for 3 seconds to turn the unit off, or it will automatically power off after 20 minutes.



* This device contains 15 intensity levels which is adjustable by manual operation. For your safety, please read charts below to understand the beep signal of stimulus intensity level indication before using the unit.

Beep signal of intensity level indication				
Power Mode	Operation	Type of Beep Signal	Signal Description	If the intensity causes your discomfort, then
Unit is turned off	Hold the + button 3 seconds	Single long beep	The unit has been turned on	NA
Unit is turned on	One short press of + button	Single short beep	Increase the unit's intensity to the minimum 1st level	If any level of intensity makes your discomfort, please press the - button to decrease the intensity level by level until the intensity is comfortable to you. Or hold the – button 3 seconds to turn the unit off and consult your physician further.
	Two short presses of + button	Two times of short beeps	Increase the unit's intensity to 2nd level	
	Three short presses of + button	Three times of short beeps	Increase the unit's intensity to 3rd level	
	Four short presses of + button	Four times of short beeps	Increase the unit's intensity to 4th level	
	Five short presses of + button	Five times of short beeps	Increase the unit's intensity to 5th level	
	Six short presses of + button	Six times of short beeps	Increase the unit's intensity to 6th level	
	Seven short presses of + button	Seven times of short beeps	Increase the unit's intensity to 7th level	

Beep signal of intensity level indication				
	Eight short presses of + button	Eight times of short beeps	Increase the unit's intensity to 8th level	If any level of intensity makes your discomfort, please press the - button to decrease the intensity level by level until the intensity is comfortable to you. Or hold the - button 3 seconds to turn the unit off and consult your physician further.
	Nine short presses of + button	Nine times of short beeps	Increase the unit's intensity to 9th level	
	Ten short presses of + button	Ten times of short beeps	Increase the unit's intensity to 10th level	
	Eleven short presses of + button	Eleven times of short beeps	Increase the unit's intensity to 11th level	
	Twelve short presses of + button	Twelve times of short beeps	Increase the unit's intensity to 12th level	
	Thirteen short presses of + button	Thirteen times of short beeps	Increase the unit's intensity to 13th level	
	Fourteen short presses of + button	Fourteen times of short beeps	Increase the unit's intensity to 14th level	
	Fifteen short presses of + button	Fifteen times of short beeps	Increase the unit's intensity to the maximum 15th level	
	Hold the - button 3 seconds	Single long beep	The unit has been turned off	NA

Description Chart of Other Beep Signal			
Power Mode	Operation	Type of Beep Signal	Signal Description
	Short press of the + or - button	Two short beeps	The intensity adjustment feature is disabled because the gel pad is not in full contact with the skin. Reapply the gel pad and try again.
Unit is turned on but cannot feel stimulus	No Action	Slow consecutive intermittent beeps	The gel pad is not in contact with the skin, reapply the gel pad and try again.
	No Action	Fast consecutive intermittent beeps	The battery power is low, and replace the battery.
	No Action	Single long beep	The auto-off program is engaged and the unit is off.
Unit is turned on and in use	Short press of the + button	Single short beep	The adjustable intensity feature has increased 1 level.

Description Chart of Other Beep Signal			
	Short press of the - button	Single short beep	The adjustable intensity feature has decreased 1 level.
	Multiple presses of the + button	Two short beeps	The adjustable intensity feature has reached 15, the maximum level.
	Multiple presses of the - button	Two short beeps	The adjustable intensity feature has reached 0, the minimum level.
	Hold the - button 3 seconds	Single long beep	The unit has been turned off manually.
	No Action	Single long beep	The auto-off program is engaged and the unit is off.
	No Action	Fast consecutive intermittent beeps	The battery power is low, and replace the battery.

NOTE

- Battery needs to be replaced if the unit no longer makes a beep sound or send any electric impulses.
- Device only works when in contact with the skin. When the device is not in contact with the skin, the device will not send out stimulation.
- After use, always place the protective film back to gel pad.

The Function of Touches Mistake for Electrode Gel Pad Lost

This function is meant to detect if the electrode gel pad loses contact on your skin. When you follow the procedures of "Battery & Gel Pad Assembly" on page 7 and apply the device on your body for stimulation, during the stimulus process, if one gel pad or several gel pads cannot contact well and lose contact with your body skin, the beeper will start "slow consecutive intermittent beeps" for your notice. This situation is called "the function of touches mistake for electrode pad lost", reminding you of resetting the device.

How to Reset the Device If "the function of touches mistake for electrode pad lost" occurs.

1. When you hear "slow consecutive intermittent beeps" during using the device, please check if all of the gel pads are contacted on your skin without losing contact.
2. If one or several gel pads is/are not fully contacted on your skin, please remove the device from your body and reapply the device to the skin.
3. After reapplying the device, if one or several electrode pads still cannot be contacted with your body smoothly and keep sending "slow consecutive intermittent beeps", it means the gel pad gets dirty and becomes less sticky to contact your skin well.
4. Then, follow the procedures of **Care for the Gel pads & Replacing the Gel Pads**" on page 13 to deal with this situation.
5. If above steps still do not work, please contact our local dealer to resolve this issue.

Specifications

Power	3V CR2032 Battery X1
Number Of Output Modes	1
Number Of Output Channels	1
Mode Of Output Channels	1
Regulated Current Or Regulated Voltage?	Regulated Voltage
Software/Firmware/Microprocessor Control?	Yes
Automatic Overload Trip	No
Automatic No-Load Trip	No
Automatic Shut-Off	Yes
User Override Control	Yes
Indicator Display	No
On/Off Status	Beeper
Low Battery	Beeper
Current/Voltage Level	No
Timer Range (Minutes)	20
Compliance With Voluntary Standard	IEC60601-1 IEC 60601-1-2 IEC 60601-2-10
Compliance With 21 CFR 898?	Yes
Housing Materials And Construction	Silicone
Pulse Strength	0 ~ 15 Stages Adjustable
Operation Environment	10 ⁰ ~ 40°C, 30% ~ 85% RH
Storage Environment	-10 ⁰ ~ 50°C, 10% ~ 95% RH
Transport Environment	-10 ⁰ ~ 50°C, 35% ~ 85% RH
Dimension (LxWxH, inch)	7.87 x 3.74 x 0.512
Weight (g)	26.0 g
Accessory	Instruction manual
Patient-contacting material	HIVOX electrode gel pad, K131720

Parameter		Response
Mode or Program Name		Regular
Waveform (e.g., pulsed monophasic, biphasic)		Symmetrical
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular
Maximum Output Voltage (volts) (+/- <u>10</u> %)		<u>60</u> @500 Ω
		<u>115</u> @2 k Ω
		<u>151</u> @10 k Ω
Maximum Output Current (mA) (+/- <u>10</u> %)		<u>120</u> @500 Ω
		<u>57.5</u> @2 k Ω
		<u>15.1</u> @10 k Ω
Duration of primary (depolarizing) phase (μ sec)		0
Pulse Duration (μ sec)		400
Frequency (Hz)		2-4-25
For interferential modes only: Beat Frequency [†] (Hz)		N/A
For multiphasic waveforms only:	Symmetrical phases?	Yes
	Phase Duration (μ sec)	400
Net Charge (μ C)		<u>0.960</u> @500 Ω
Maximum Phase Charge, (μ C)		<u>48</u> @500 Ω
Maximum Current Density (mA/cm ²)		<u>1.952</u> @500 Ω
Maximum Average Current (average absolute value), mA		<u>120</u> @500 Ω
Maximum Average Power Density (W/cm ²)		<u>0.117</u> @500 Ω
Burst Mode	(a) Pulses per burst	25
	(b) Bursts per second	1
	(c) Burst duration (seconds)	20
	(d) Duty Cycle [Line (b) x Line (c)]	20
Additional Features (specify, if applicable)		N/A

Maintenance & Disposal

1. Storage

- (1) Keep the unit away from children.
- (2) Remove the battery if the unit will not be used for more than 10 days.
- (3) Reapply the protective film back to the gel pads after each use.
- (4) Do not store the unit under high temperature, high humidity, and direct sunlight exposed environment or where there are a lot of dusts or corrosive gas.

2. Care for the Gel Pads

- (1) If the gel pads get dirty or less sticky, you can prolong the lifetime for additional uses by cleaning it. With a drop of water on your finger, rub the water over the surface of the gel pads and allow it to dry.
- (2) Always store the gel pads in a cool, airy area away from direct sunlight.
- (3) Be sure the skin is clean before the gel pads are placed.
- (4) Always store the gel pads with the protective film after use.

3. Replacing the Gel Pads

When following the above procedures of Care for the Gel Pads to treat the gel pads, generally the gel pad can last 50 times of use to adhere to the skin smoothly. However, the number of times for reusing gel pad depends on the individual skin condition. Therefore sometimes it might not be able to last 50 times. **If the electrodes fail to adhere to the skin smoothly, then new electrodes should be used** by following the following 4 steps.

- (1) Remove the gel pad carefully and roll the gel upwards with your fingers until the entire pad has been lifted off.
- (2) Repeat step (1) on the other pad.
- (3) Clean the device with a drop of water on your finger to remove left over residue. Allow to dry.
- (4) Place new gel pads onto the unit by following steps 4-6 of Battery & Gel Pad Assembly section on page 7.

4. Disposal

Battery and this unit must NOT be disposed in household waste. Return them to public collection points or shops selling battery or devices of the same kind according to local regulations. In case of any confusion, consult with your local environmental protection agency.

Troubleshooting

1. The units fail to turn on.

- (1) Press the + button again and hold it down for 2 seconds.
- (2) Check if the battery is properly in place with good connection.
- (3) Replace battery if (1) and (2) both fail.

2. The gel pads are not sticky as before.

With a drop of water on your finger, rub the water over the surface of the gel and allow it dry.

3. The unit beeps abnormally during treatment.

- (1) Check if the device is connected securely with the skin.
- (2) If the beeping persists, replace the battery with new one.

4. The stimulation is not felt.

- (1) Make sure the gel pads are not overlapped.
- (2) Increase the pulse intensity gradually.
- (3) Makes sure the device is connected securely with the skin.

5. The skin of treated area turns red.

Stop treating that area immediately; wait until the skin restores to its healthy state. If irritation persists, consult with a dermatologist.

6. The intensity begins to drop:

Replace battery immediately

7. The stimulation is uncomfortable.

- (1) Press – button to decrease intensity if the stimulation is too strong.
- (2) If not improving, check if the device is connected securely with the skin.
- (3) If step (2) does not help, check if the gel pads are worn out. Worn pads cannot distribute current evenly across the skin, which may lead to irritating stimulation. In such a case, replace the gel pads.

Guidance and manufacturer's declaration-electromagnetic emissions

The SP-620 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-620 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <u>SP-620</u> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The <u>SP-620</u> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-620 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-620 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Not applicable Not applicable Not applicable Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the <u>SP-620</u> requires continued operation during power mains interruptions, it is recommended that the <u>SP-620</u> be powered from an uninterruptible power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The <u>SP-620</u> power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity

The SP-620 is intended for use in the electromagnetic environment specified below.

The customer or the user of the SP-620 should assure that is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the <u>SP-620</u> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	<p>Recommended separation distance:</p> <p>$d = 1,2 \sqrt{P}$</p> <p>$d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SP-620 is used exceeds the applicable RF compliance level above, the SP-620 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SP-620.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the SP-620

The SP-620 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SP-620 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SP-620 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	12	23

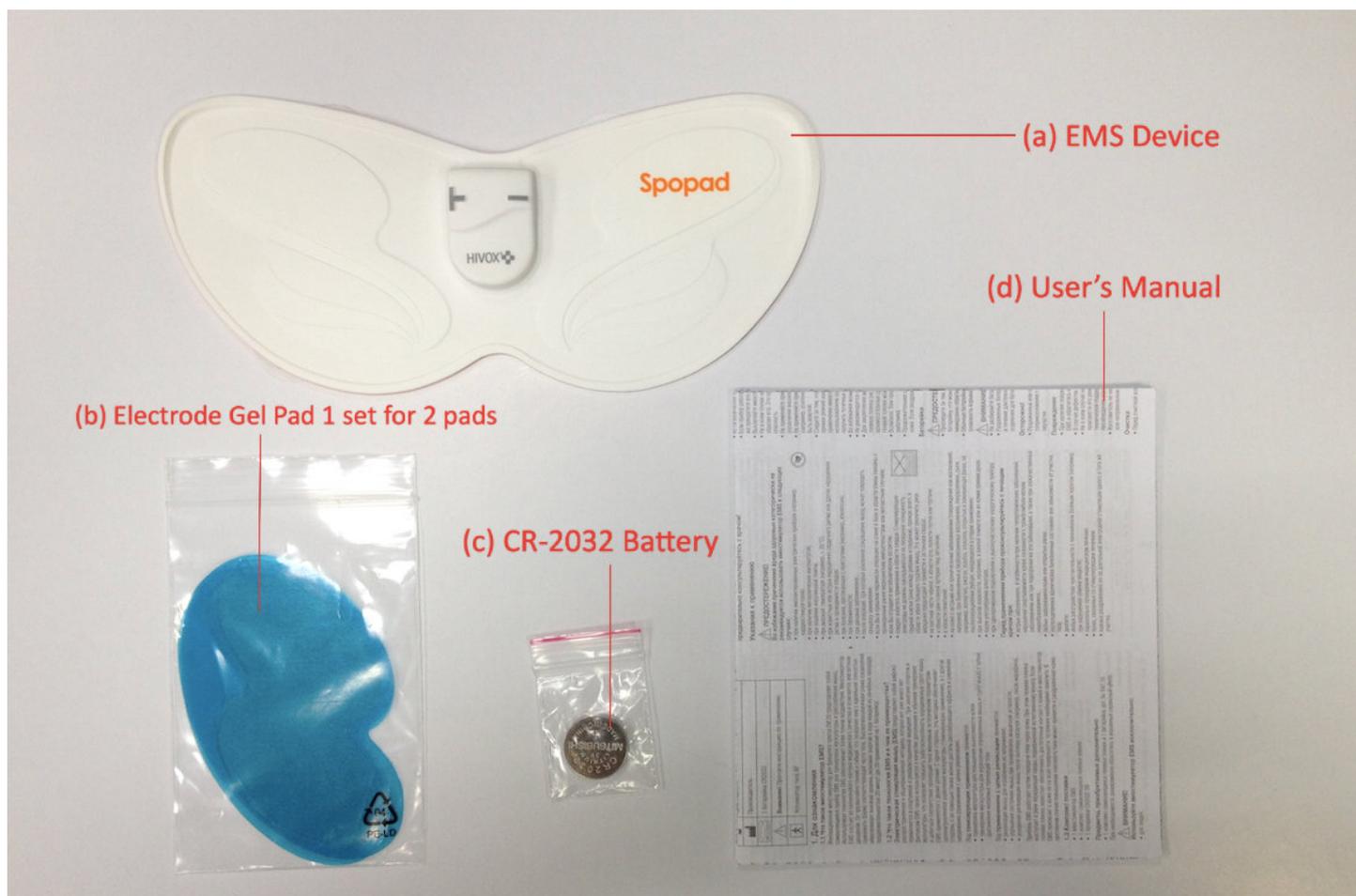
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Package list and photo

1. Photo

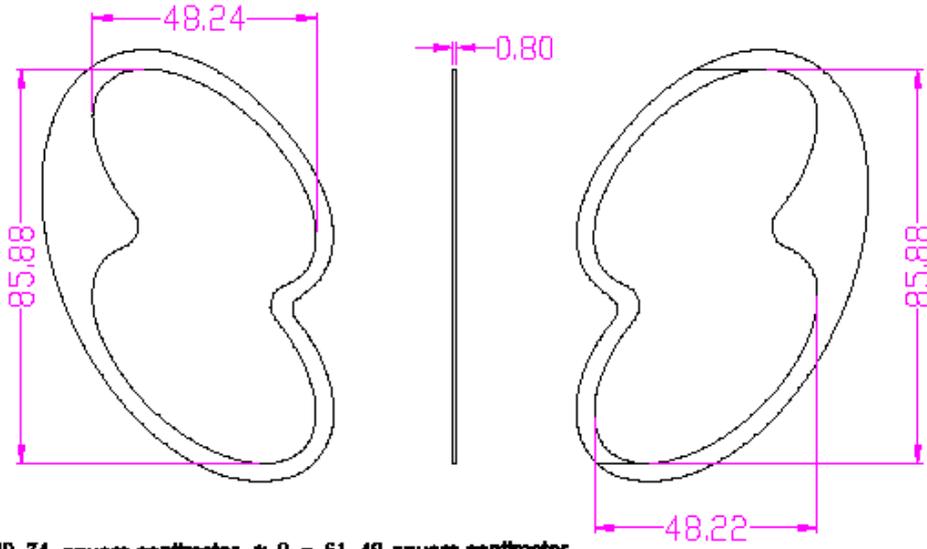


2. List

Item	Name	Quantity
a	EMS device –SP-620	1
b	Electrode Gel Pad* Conducting area: 61.48 cm ²	1 set of 2 pads
c	CR-2032 battery	1
d	User's Manual	1

* Electrode Gel Pad's area is equal to conducting area shown below.

MARK	LOC.	DESCRIPTION	DATE	EC NO.	ISSUED
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Gel Pad area: 30.74 square centimeter * 2 = 61.48 square centimeter

HIVOX		DESCRIPTION		APPROVED
QTY	TOL.		MATERIAL	MODEL NAME
25	±0.03	±0.05	PCB/NET	E / E
25-80	±0.10	SCALE	FINISH	DWG NO. 09-130-04-701
10-25	±0.15	UNIT mm	FILE NAME	PART NAME
250	±0.2	SHEET OF	VER. V1.0	DESIGNED



HIVOX BIOTEK INC.

5F., No. 123, Shingde Road, Sanchong District, New Taipei City, Taiwan
Phone: +886 2 8511 2668 Fax: +886 2 8511 2669

JUL 25 2014

K131720

510(K) SUMMARY
(Per 21 CFR 807.92.)

Submission Date: July 22, 2014

Submitter: HIVOX BIOTEK INC.
5F, No.123, Shingde Road, Sanchong Dist.,
New Taipei City, 24158, TAIWAN, R.O.C.
Tel: +886-2-85112668 Fax:+886-2-85112669

**Establishment
Registration No.:** 9611558

Official Contact: Dr. Jen, Ke-Min
Tel: 886-2-85112668 Fax:886-3-5209783
Email: ceirs.jen@msa.hinet.net

**Common /
Usual Name:** Electrode, Cutaneous

Trade Name: HIVOX self-adhesive electrode gel pads.

510(k) Number: K131720

**Classification
Code:** GXY, Class II, 882.1320

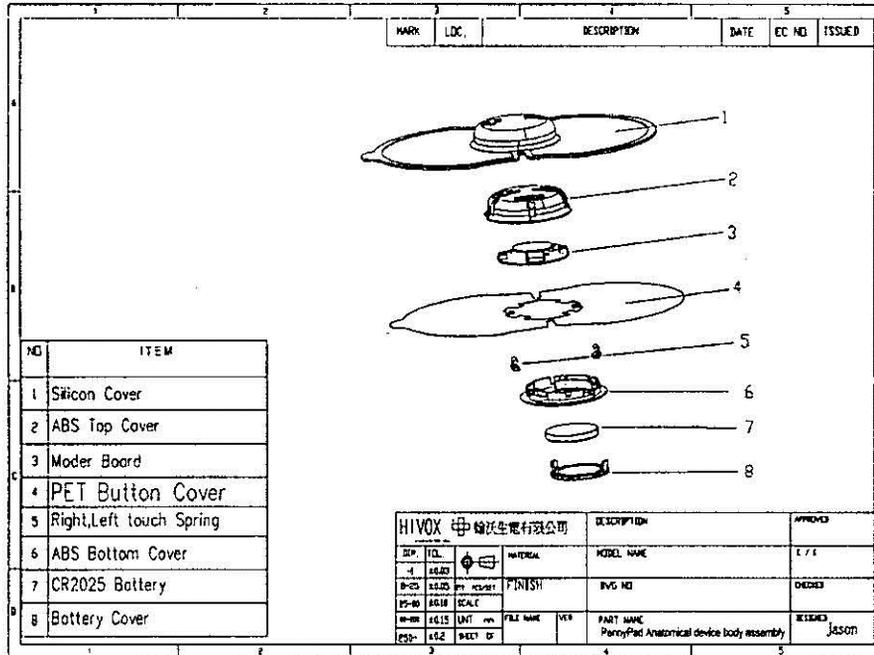
Intended Use: HIVOX self-adhesive electrode gel pads are intended for use as disposable, conductive adhesive interface between the patient's skin and the electrical stimulator. The device is a gel pad for use with an electrode and not an electrode itself. .

**Predicated
Devices:** 1) K070612, Top-Rank Adhesive Electrodes
Top-Rank Health Care Equipment Co., Ltd.
2) K132588, Top-Rank Adhesive Electrodes
Top-Rank Health Care Equipment Co., Ltd.
3) K000947, Ultrastim Electrode
Axelgaard Mfg. Co., Ltd.

Device Description: HIVOX self-adhesive electrode gel pads are series of cutaneous electrodes with various shapes and sizes, which use the same materials from the predicate suppliers, i.e. K070612 (Top-Rank Health Care Equipment Co., Ltd.) and K000947 (Axelgaard Mfg. Co., Ltd.). HIVOX self-adhesive electrode gel pads are non-sterile, self-adhesive, for single patient use only, and to be disposable.

Specifications:

HIVOX self-adhesive electrode gel pads have the following possible dimensions and shapes.



Scientific Concept:

When we put the battery into the stimulator device, and the device will enable to transmit the electric pulse to the device's electrode area. The self-adhesive electrode gel pads should be placed onto the bottom of PET cover to enable to stick on the user's skin and conduct the electric pulse fully around the self-adhesive electrode gel pads.

Function and Characteristics:

- HIVOX self-adhesive electrode gel pads are non-sterile, self-adhesive, for single patient use only, and to be disposable.
- The subject device is designed for Hivox device use only.
- HIVOX self-adhesive electrode gel pads are series of cutaneous electrodes with various shapes and sizes, which use the same material as K070612 (Top-Rank Health Care Equipment Co., Ltd.) and K000947 (Axelgaard Mfg. Co., Ltd.).

Performance Tests:

Biocompatibility Tests:

- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for in irritation and skin sensitization.

Clinical Tests:

NONE



HIVOX BIOTEK INC.

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Comparison table

Items	Predicate device	Predicate device	Predicate device	Subject Device
Trade Name	Top-Rank Adhesive Electrode	Top-Rank Adhesive Electrode	ULTRASTIM ELECTRODE, MODEL US4040	HIVOX self-adhesive electrode gel pads.
Manufacturer	Top Rank	Top Rank	Axelgaard	Top Rank, Axelgaard
510(k) Number	K070612	K132588	K000947	K131720
Intended Use	<p>Top-Rank Adhesive Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator.</p> <p>Top-Rank Adhesive Electrodes are intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).</p> <p>These electrodes will include the precaution statement: Federal Law restricts the device to sale by or on the order of a licensed practitioner or therapist.</p>	<p>Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator.</p> <p>Top-Rank Adhesive Electrodes are intended to be used with marketed, Electrical Stimulators i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).</p>	<p>UltraStim Electrodes are intended for use with a garment/wrap designed with a snap connection for distributing electrical impulses from transcutaneous neurostimulation devices to UltraStim electrodes placed on the skin.</p> <p>Transcutaneous neurostimulation electrodes are passive devices serving as an interface between a patient's skin and a neurostimulation device.</p>	<p>HIVOX Self Adhesive Electrodes are intended for use as disposable, conductive adhesive interface between the patient's skin and the electrical stimulator. The device is a gel pad for use with an electrode and not an electrode itself. .</p>
Prescription Use	Prescription use	OTC	Prescription use	Prescription use & OTC
Classification Name	Cutaneous Electrode	Cutaneous Electrode	Cutaneous Electrode	Cutaneous Electrode



Product Code	GXY 882.1320	GXY 882.1320	GXY 882.1320	GXY 882.1320
Single-Patient Use	Yes	Yes	Yes	Yes
Multiple Applications	Yes	Yes	Yes	Yes
Sterility Status	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Biocompatibility Test	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10	Meets Triparties Biocompatibility Guidance for Medical Devices & ISO 10993-5, ISO 10993-10
Conductive Surface Shapes	Various shapes (rectangular, circle, oval)			

Predicated Technological Characteristics Comparison:

The subject device, HIVOX self-adhesive electrode gel pads, uses the same materials from the suppliers, predicate devices' manufacturers. And the suppliers, Top Rank and Axelgaard will provide all components materials of the HIVOX self-adhesive electrode gel pads.

The differences between the subject device and K000947 are prescription use and OTC use. The subject device has OTC use but K000947 hasn't OTC use. But we have added a predicate device K132588 with OTC use, the OTC use of the safety and effectiveness of our device are ensured.

The subject device and predicate device (K000947) have the minor different intended use and use the same gel ingredients and the conductive films; thus the effects of impedance levels for the intended situations are the same for both of the devices. We notice there are different wording of the intended uses between the subject device and the predicate device K000947. But the key sentences for K000947 : serving as an interface between a patient's skin and a neurostimulation device, and the key sentences for the subject device : interface between the patient's skin and the electrical stimulator are similar. Thus they have similar intended use. Both of them have the same safety and effectiveness.

And all of four devices had passed the Tripartite Biocompatibility Guidance for Medical Devices and the ISO 10993 relevant requirements for skin contact. Thus the subject device and predicate devices have the same safety and effectiveness.

The subject device and the predicate devices have the same physical and technological characteristics, which are intended to be used with marketed Electrical Stimulators, including: TENS(Transcutaneous Electrical Nerve Stimulator), EMS (Electrical Muscular Stimulator), and IF (Interferential Stimulator). And all of the devices are for gel pads use with an electrode and not an electrode itself.

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed devices identified in the submission. Thus the subject device is substantially equivalent to the predicate devices.



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

July 25, 2014

HIVOX BIOTEK, Inc.
Dr. Jen, Ke-Min
5 F No. 123 Shinde Road
Sanchong District
New Taipei City 24158
TAIWAN, ROC

Re: K131720

Trade/Device Name: HIVOX Self-Adhesive Electrode Gel Pads
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrodes
Regulatory Class: Class II
Product Code: GXY, GYB
Dated: June 18, 2014
Received: June 25, 2014

Dear Dr. Jen, Ke-Min,

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Felipe Aguel -S

for Carlos Pena, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K131720

Device Name
HIVOX Self-Adhesive Electrode Gel Pads

Indications for Use (Describe)

HIVOX self-adhesive electrode gel pads are intended for use as disposable, conductive adhesive interface between the patient's skin and the electrical stimulator. The device is a gel pad for use with an electrode and not an electrode itself.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

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

FOR FDA USE ONLY

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

Felipe Aguel -S Date: 2014.07.25 17:34:13
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