



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (smw)
FOLDER: K062481 - 228 pages
COMPANY: PISHON HIGH TECH CO., LTD. (PISHHIGHTECH)
PRODUCT: STETHOSCOPE, ELECTRONIC (DQD)
SUMMARY: Product: SERENO ELECTRONIC STETHOSCOPE

DATE REQUESTED: Oct 21, 2015

DATE PRINTED: Oct 21, 2015

Note: Printed



OCT 16 2006

EXHIBIT 2
510(k) Summary

Pishon High Tech Co., Ltd
2nd Floor, Moeller building 403-1, Daebang-dong, Dongjak-gu,
Seoul, 156-020, Korea
Phone: 82-2-826-1750
Fax: 82-2-826-1724

July 12, 2006

Contact: Y.Y. Park, Managing Director

1. Identification of the Device:

Proprietary-Trade Name: SERENO Electronic Stethoscope

Classification Name: Electronic Stethoscope, Product code DQD

Common/Usual Name: Electronic Stethoscope

2. Equivalent legally marketed devices 3M™ Littmann™ Electronic Stethoscope (K003723), JABES Electronic stethoscope (k031446)

3. Indications for Use (intended use) The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

4. Description of the Device: The SERENO electronic stethoscope is intended for use as a diagnostic aid in patient diagnosis and monitoring. The SERENO electronic stethoscope amplifies sounds up to 20 times bigger than ordinary acoustic stethoscope in a broad frequency range including a range higher than the traditional diaphragm mode. It looks similar to the traditional stethoscope including parts like a probe head, binaural pipes and ear tips. It has four (4) buttons on the top of the chest set (opposite to the probe). Each of the buttons has a function of controlling the modes, volume up/down and power on/off. As an electronic stethoscope, it needs two (2) batteries (AAA type, 1.5V) to operate. The stethoscope has automatic power off function for longer battery life and has a LCD display to show volume level, frequency mode and low battery indicator. With the enclosed audio cable, utilizing a personal computer, the user can store sound signals in the PC and transmit diagnosis data via e-mail. This stethoscope is a stand-alone unit, has no software and operates using an analog audio system with a digital timer for power saving and a digital control for the volume and the filter mode selection. It can be connected to audio input of a sound card in a computer to use the PC software functions. However, the software does not operate nor control the stethoscope in any manner. In fact, the stethoscope's audio output can be connected to any ordinary audio equipment such as a cassette recorder, a hi-fi audio component and portable audio..

5. Safety and Effectiveness, comparison to predicate device. The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

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~~Page 8 of 168~~

6. Substantial Equivalence Chart

Device name	Predicate Devices		New Device
	3M Littmann Electronic stethoscope, Model 4000(K003723)	JABES electronic stethoscope (K031446)	SERENO electronic stethoscope
Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Applicant	3M	GS Technology Co., Ltd	Pishon High Tech Co., Ltd
Frequency Response Mode	Bell(20-200Hz), Diaphragm(100-500Hz) Extended range: (20-1,000Hz)	Bell(20-500Hz), Diaphragm(200-800Hz) Extended range: (20-1,000Hz)	Bell(20-450Hz), Diaphragm(200-1,200Hz) Extended range: (20-1,500Hz)
Amplification	Up to 18times amplification	Up to 18times amplification	Up to 20 times amplification
Display heart rate	Yes	No	No
Permits data transfer of stored digital signal to IBM-Compatible PC	Yes	No	No
Volume control	8 Steps Volume control	12 Steps Volume control	12 Steps Volume control
Energy source	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries
Manual On/Off button Automatic shut-off by electronics	Yes	Yes	Yes
Low Battery Indicator	Yes	Yes	Yes

7. Conclusion

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Pishon High Tech Co., Ltd., that the SERENO Electronic is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Pishon High Tech Co., LTD
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
PO Box 7007
Deerfield, IL 60015

Re: K062481

Trade Name: Sereno Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 22, 2006
Received: August 24, 2006

Dear Mr. Kamm:

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.

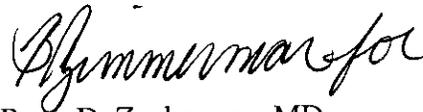
Page 2 – Mr. Daniel Kamm

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 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,



Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062481

Device Name: Electronic stethoscope (Model: SERENO)

Indications for Use: The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1


(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062481



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Pishon High Tech Co., LTD
c/o Mr. Daniel Kamm, P.E.
Regulatory Engineer
PO Box 7007
Deerfield, IL 60015

Re: K062481

Trade Name: Sereno Electronic Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 22, 2006
Received: August 24, 2006

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Page 2 – Mr. Daniel Kamm

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Sincerely yours,



Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062481

Device Name: Electronic stethoscope (Model: SERENO)

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

B. Himmelman
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062481

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 30, 2006

PISHON HIGH TECH CO., LTD.
C/O KAMM & ASSOCIATES
P.O. BOX 7007
DEERFIELD, IL 60015
ATTN: DANIEL KAMM

510(k) Number: K062481
Received: 29-AUG-2006
Product: SERENO ELECTRONIC
STETHOSCOPE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review:
1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsb.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 25, 2006

PISHON HIGH TECH CO., LTD.
C/O KAMM & ASSOCIATES
P.O. BOX 7007
DEERFIELD, IL 60015
ATTN: DANIEL KAMM

510(k) Number: K062481
Received: 24-AUG-2006
Product: SERENO ELECTRONIC
User Fee ID Number: 6027040

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier (e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsb.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

K062481

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement

<p>DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET</p>	<p>PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.</p>
<p>A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:</p> <ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 	
<p>--></p> <p>1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)</p> <p>PISHON HIGH TECH CO LTD PO Box 7007 Deerfield IL 60015 US</p> <p>1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) NO DATA</p>	<p>2. CONTACT NAME Daniel Kamm</p> <p>2.1 E-MAIL ADDRESS dkamm@icee.org</p> <p>2.2 TELEPHONE NUMBER (include Area code) 847-374-1727</p> <p>2.3 FACSIMILE (FAX) NUMBER (Include Area code) NO DATA</p>
<p>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/dc/mdufma)</p> <p>Select an application type: 3.1 Select one of the types below</p> <p><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input checked="" type="checkbox"/> Original Application</p>	

CV #

<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)	<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 type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <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	
6. 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).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) (b)(4)	
11-Aug-2006	

Form FDA 3601 (05/2003)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET	Form Approval OMB No. 9010-0120 Expiration Date: May 31, 2007. See OMB Statement on page 5.
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Date of Submission 8/22/2006	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)
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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 Pishon High Tech Co., Ltd	Establishment Registration Number (if known) Will register		
Division Name (if applicable)	Phone Number (including area code) 82-2-826-1750		
Street Address 2nd Floor, Moeller Building 403-1, Daebang-dong, Dongjak-gu,	FAX Number (including area code) 82-2-826-1724		
City Seoul	State / Province	ZIP/Postal Code 156-020	Country Korea
Contact Name Y.Y. Park			
Contact Title Managing Director	Contact E-mail Address		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Kamm & Associates	Phone Number (including area code) 847-374-8854 / CELL 847-374-1727		
Division Name (if applicable)	FAX Number (including area code) 206-260-4162		
Street Address PO Box 7007	FAX Number (including area code)		
City Deerfield	State / Province IL	ZIP/Postal Code 60015	Country USA
Contact Name Daniel Kamm			
Contact Title Principal Consultant	Contact E-mail Address d.kamm@sbcglobal.net		

SECTION D1			REASON FOR APPLICATION - PMA, PDP, OR HDE		
<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"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <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			
<input type="checkbox"/> 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"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose 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"/> 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			
<input type="checkbox"/> Other Reason (specify):					

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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 DQD	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 K003723	1 3M™ Littmann™	1 3M
2 K031446	2 Jabes	2 Jabes
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

Trade or Proprietary or Model Name for This Device	Model Number
1 SERENO	1
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code DQD	C.F.R. Section (if applicable) 870.1875	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Cardiovascular		

Indications (from labeling)
 The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

<i>Note:</i> 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	FDA Establishment Registration Number Will register	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Pishon High Tech Co., Ltd		Establishment Registration Number Will register	
Division Name (if applicable)		Phone Number (including area code) 82-2-826-1750	
Street Address 2nd Floor, Moeller Building 403-1, Daebang-dong, Dongjak-gu.		FAX Number (including area code) 82-2-826-1724	
City Seoul	State / Province	ZIP/Postal Code 156-020	Country Korea
Contact Name Y.Y. Park	Contact Title Managing Director	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <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/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <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/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

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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 60601-1	IEC	Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety	Current	
2	IEC 60601-1-2	IEC	Standard for Electromagnetic Compatibility.	Current	
3					
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:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

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

Pishon High Tech Co., Ltd
2nd Floor, Moeller Building 403-1, Daebang-dong, Dongjak-gu,
Seoul, 156-020, Korea
Phone: 82-2-826-1750
Fax: 82-2-826-1724

This submission was prepared by:

Daniel Kamm, P.E.
Kamm & Associates
PO Box 7007
Deerfield IL 60015 USA
Phone 1-847-374-8854
Fax 1-206-260-4162
email dkamm@fda-consultant.com

**Please fax or email questions or requests for additional information to
Mr. Kamm, who will expedite a reply.**

August 22, 2006

Document Mail Center
Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Blvd. (HFZ-401)
Rockville, Maryland 20850

Attention: Document Mail Clerk

Re: Traditional 510(k) Notification: SERENO Electronic Stethoscope.

Purpose of submission: This is to notify you of the intention by Pishon High Tech Co., Ltd. to market a new but substantially equivalent to a legally marketed device: SERENO Electronic Stethoscope. There have been no changes to the indications for use and many other essential characteristics as compared to the predicate device.

Confidentiality: Pishon High Tech Co., Ltd. considers the information contained in this submission to be confidential in nature (except for Exhibit 2 as required by the SMDA)

Fax and Email communications specifically authorized: Requests for additional information are hereby authorized and may be emailed to dkamm@fda-consultant.com or faxed to 847-384-1728.

510(k) Summary In response to the requirements addressed by the SMDA of 1990, I am enclosing a summary of the safety and effectiveness information upon which the substantial equivalence determination is based. (Exhibit 2)

RECEIVED
AUG 22 2006
FBI/DOJ

K24
Page 1 of 168

Sincerely yours,



Y.Y. Park, Managing Director



Daniel Kamm
(Regulatory Engineer)

Enclosures

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EXHIBIT 1

General Information

a) Trade name /Proprietary Name: SERENO Electronic Stethoscope

b) Common name /Usual Name: Electronic Stethoscope

c) Establishment registration number and address:

Pishon High Tech Co., Ltd
2nd Floor, Moeller building 403-1, Daebang-dong, Dongjak-gu,
Seoul, 156-020, Korea
Phone: 82-2-826-1750
Fax: 82-2-826-1724

Firm will register upon receipt of 510(k) clearance.

d) Device class: Class II per regulation 870.1875

e) Classification Name/Product Code: DQD

f) New or Modification: This notification is for a new device for the US market.

g) Predicate Device (Substantial Equivalence): 3M™ Littmann™ Electronic Stethoscope (K003723), JABES Electronic stethoscope (K031446)

h) 513/514 Compliance (Performance Standard): None established. Complies with voluntary standards:

1. IEC 60601-1, Safety of Medical Electrical Equipment, Part 1, General Requirements for Safety, including Amendment 1 and 2.
2. IEC 60601-1-2 first edition, Standard for Electromagnetic Compatibility.

i) Truth and Accuracy Certification

I certify that, in my capacity as Managing Director of Pishon High Tech Co., Ltd., I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

Handwritten signature in black ink, consisting of three characters: 朴, 榮, 輝.

Y.Y. Park, Managing Director
July 12, 2006

Indications for Use

510(k) Number (if known): *K062481*

Device Name: Electronic stethoscope (Model: SERENO)

Indications for Use: The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

K062481

EXHIBIT 2
510(k) Summary

Pishon High Tech Co., Ltd
2nd Floor, Moeller building 403-1, Daebang-dong, Dongjak-gu,
Seoul, 156-020, Korea
Phone: 82-2-826-1750
Fax: 82-2-826-1724

July 12, 2006

Contact: Y.Y. Park, Managing Director

1. **Identification of the Device:**
Proprietary-Trade Name: SERENO Electronic Stethoscope
Classification Name: Electronic Stethoscope, Product code DQD
Common/Usual Name: Electronic Stethoscope
2. **Equivalent legally marketed devices** 3M™ Littmann™ Electronic Stethoscope (K003723), JABES Electronic stethoscope (k031446)
3. **Indications for Use (intended use)** The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.
4. **Description of the Device:** The SERENO electronic stethoscope is intended for use as a diagnostic aid in patient diagnosis and monitoring. The SERENO electronic stethoscope amplifies sounds up to 20 times bigger than ordinary acoustic stethoscope in a broad frequency range including a range higher than the traditional diaphragm mode. It looks similar to the traditional stethoscope including parts like a probe head, binaural pipes and ear tips. It has four (4) buttons on the top of the chest set (opposite to the probe). Each of the buttons has a function of controlling the modes, volume up/down and power on/off. As an electronic stethoscope, it needs two (2) batteries (AAA type, 1.5V) to operate. The stethoscope has automatic power off function for longer battery life and has a LCD display to show volume level, frequency mode and low battery indicator. With the enclosed audio cable, utilizing a personal computer, the user can store sound signals in the PC and transmit diagnosis data via e-mail. This stethoscope is a stand-alone unit, has no software and operates using an analog audio system with a digital timer for power saving and a digital control for the volume and the filter mode selection. It can be connected to audio input of a sound card in a computer to use the PC software functions. However, the software does not operate nor control the stethoscope in any manner. In fact, the stethoscope's audio output can be connected to any ordinary audio equipment such as a cassette recorder, a hi-fi audio component and portable audio..
5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart

Device name	Predicate Devices		New Device
	3M Littmann Electronic stethoscope, Model 4000(K003723)	JABES electronic stethoscope (K031446)	SERENO electronic stethoscope
Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Applicant	3M	GS Technology Co., Ltd	Pishon High Tech Co., Ltd
Frequency Response Mode	Bell(20-200Hz), Diaphragm(100-500Hz) Extended range: (20-1,000Hz)	Bell(20-500Hz), Diaphragm(200-800Hz) Extended range: (20-1,000Hz)	Bell(20-450Hz), Diaphragm(200-1,200Hz) Extended range: (20-1,500Hz)
Amplification	Up to 18times amplification	Up to 18times amplification	Up to 20 times amplification
Display heart rate	Yes	No	No
Permits data transfer of stored digital signal to IBM-Compatible PC	Yes	No	No
Volume control	8 Steps Volume control	12 Steps Volume control	12 Steps Volume control
Energy source	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries
Manual On/Off button Automatic shut-off by electronics	Yes	Yes	Yes
Low Battery Indicator	Yes	Yes	Yes

7. Conclusion

After analyzing bench, electrical safety, EMC, and user testing data, it is the conclusion of Pishon High Tech Co., Ltd., that the SERENO Electronic is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

EXHIBIT 3: Labeling

Predicate Device Brochure, JABES electronic stethoscope (K031446)

Electronic Stethoscope

the SOUND!

Application

- Do you want better and clearer sound?
JABES amplifies up to 18 times greater than conventional stethoscopes. With the frequency mode selector, you can hear clearer body sound.

Do you want the upgraded practice environment?

JABES help you listen and visualize the sound. With 50 standardized normal and abnormal body sound data samples, you can easily compare the your patient's sound with it. Also, you can save the patient's record and the sounds into a data base for upgraded patients management with JABES ANALYZER.

The future for every home

JABES not only monitor the body sound but also counts the heart rate. It support the future tele-medicine environments. You can record and save the own body sound into the database. JABES will help the patients at home with difficulties to travel to a hospital or doctor's office.



JABES
Electronic Stethoscope

Specifications

Functions	Specifications
Power	DC 3.0V
Length	29 inch
Weight	170g
Battery	1.5V AAA x 2
Battery life	Over 100 hours
Frequency Mode	Bell mode Diaphragm mode Wide mode

Accessory
Spare Ear Tips (2)
Batteries (AAA * 2)
Cable (1m, 3m)
JABES ANALYZER installation CD (1)
User's Manual

Manufacturer
GST Technology
R-307, SBI CENTER 617-26
Daejeon-Dong, Kangsan-Gu, Seoul, Korea
TEL: +82-2-2659-0810
FAX: +82-2-2659-0752
<http://www.gp-tec.co.kr>

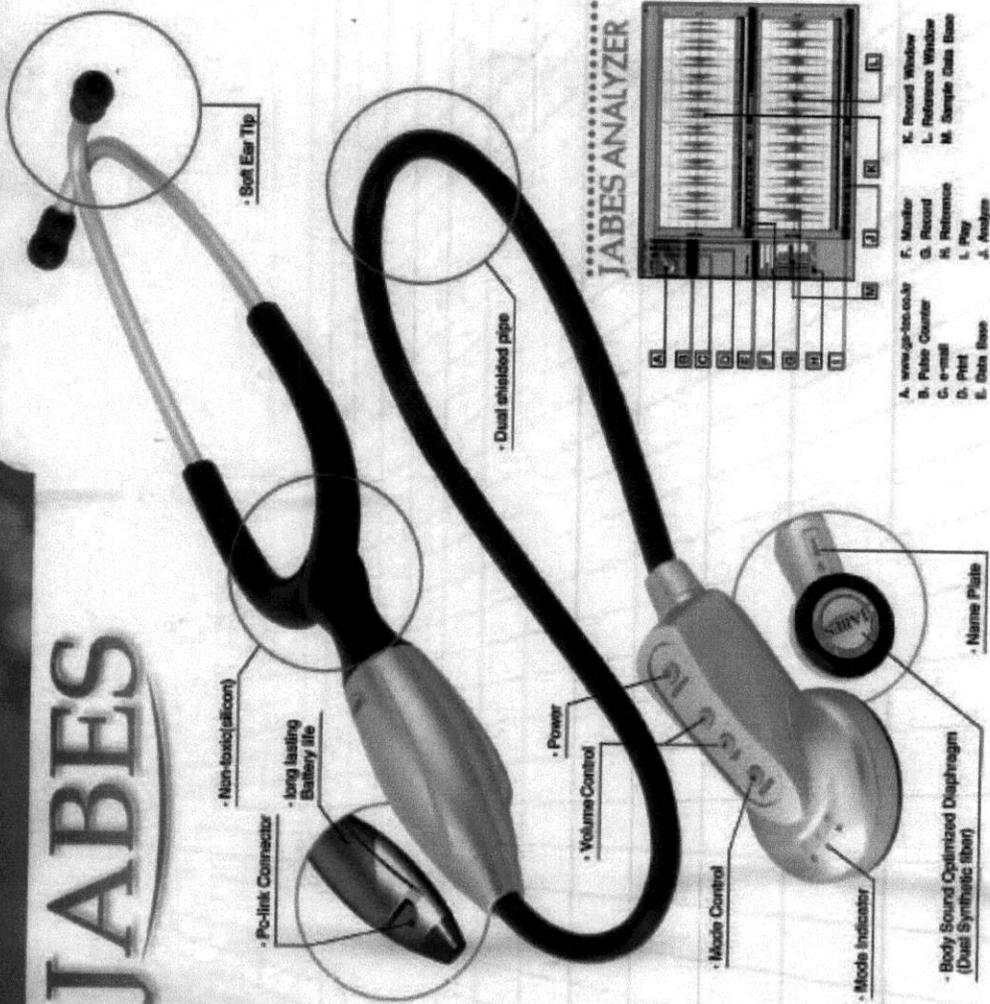
Distributor
CHOONGWAE PHARM CORPORATION

J. Advanced Biomedical Electronic Stethoscope

view

Features

- **You can monitor the actual body sound**
JABES-ANALYZER displays and visualizes the body sound on real-time basis. You can zoom, record, save, analyze, compare and build a data base with it for the easy data management.
- **Clearer and Better Sound**
JABES amplifies up to 18 times greater than a conventional stethoscope.
- **Pulse counting**
JABES-ANALYZER automatically counts the heart rate while recording the visual body sound.
- **Simple button type mode changer**
You are no longer need to turn your stethoscope to change the frequency mode. The integrated electronic filter help you change the desired frequency mode at your fingertip.
- **Print the sound**
JABES-ANALYZER can print the body sound data for better patient management.
- **Ordinary sound equipment connectivity**
When you are not in office, you can record the patient's body sound into a walkman, voice recorder, etc. You can analyze it later with JABES-ANALYZER.
- **Internet Tele-Medical capability**
You can sender received the body sound data to (or from) the sender parties using the internet.
- **Compare the body sounds in visual waveforms**
JABES-ANALYZER has 50 specific sound samples in the sample database. Compare it with the patient's body sound. The recorded patient's body sound may be stored in the sample database if necessary.



JABES ANALYZER

- A. www.ja-bio.com
- B. Pulse Counter
- C. e-mail
- D. Print
- E. Data Base
- F. Monitor
- G. Record
- H. Reference
- I. Play
- J. Analyze
- K. Record Window
- L. Reference Window
- M. Sample Data Base

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SERENO Brochure

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SEREND
ELECTRONIC STETHOSCOPE



PISHON HIGH TECH



Caution: US Federal Law restricts this device to sale by or on the order of a physician.



PISHON HIGH TECH



SERENO
ELECTRONIC STETHOSCOPE
PISHON HIGH TECH

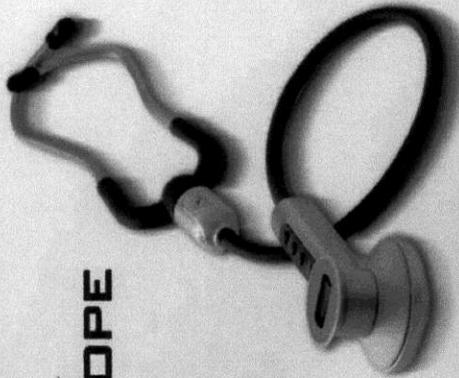


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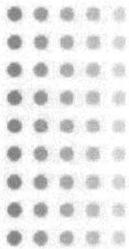


SERENO ELECTRONIC STETHOSCOPE

PISHON HIGH TECH



- Full Performance of Basic Functions
- Patented Sound Processing Application
- Improved User Convenience



Full performance of Basic Functions

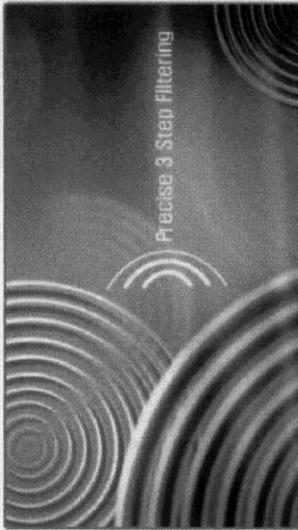
PISHON HIGH TECH

SERENO ELECTRONIC STETHOSCOPE



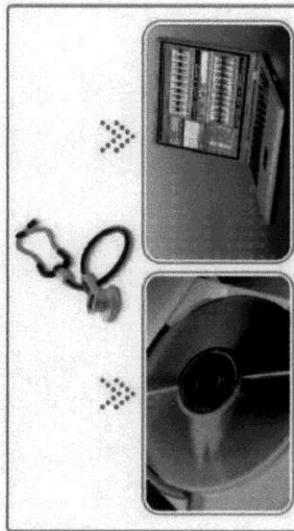
Extended Auscultation Range

With ideal sound amplification and extended frequency range (20Hz - 1,500Hz), SERENO Electronic Stethoscope enables for you to detect hidden or faint sounds you might miss with other stethoscopes.



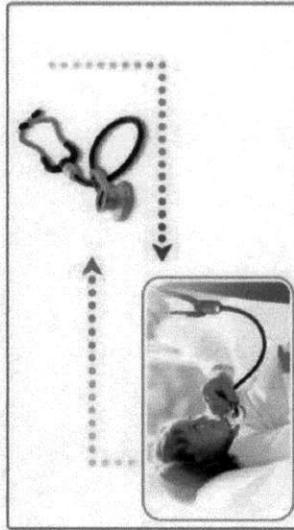
Precise 3 Step Filtering

SERENO Electronic Stethoscope has a 3 step filtering circuitry, Bell (Low) - Diaphragm (High) - Wide, which was devised in order to fine tune frequencies to the optimal range for your precise auscultation by filtering noises and detecting sounds from the target.



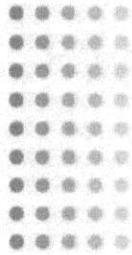
Convenient Data Share and Transfer

The stethoscoped body sounds can easily be downloaded into PC, transferred and shared for further analysis and study, medical education and etc. as well as diagnosis data.



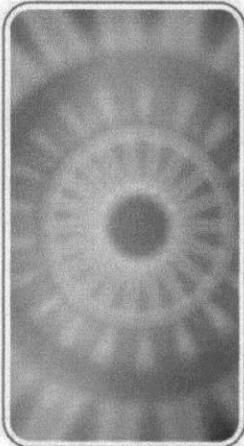
Auscultation through Indirect Contact

Since SERENO Electronic Stethoscope works very sensitively, though not recommended, you may listen through a patient's clothing. It can contribute toward creating more comfortable consultation atmosphere for patients.



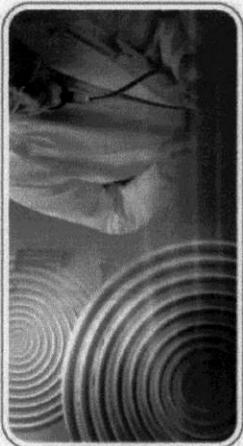
PISHON HIGH TECH

State-of-the-art technology



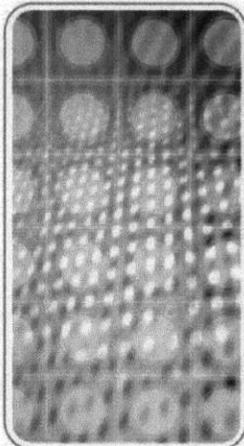
With Pishon's sound processing application, SERENO Electronic Stethoscope reproduces the sounds closer to the original body sounds by solving sound distortion caused by an internal resonance of the traditional acoustic stethoscope.

**Excellent Sound
Reproduction**



With Noise Cancellation Technology (Patent Pending # PCT/KR2005/003011), SERENO Electronic Stethoscope mutes ambient noise inputs and minimizes noise amplifications so that listeners may auscultate in noisy surroundings.

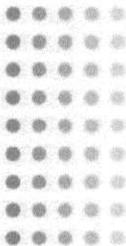
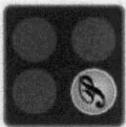
Ambient Noise Muting



Pishon's Sound Processing application (Patent Pending # PCT/KR2005/002809) catches and reduces white noise and various noises caused by hand tremor and contact to the least possible level.

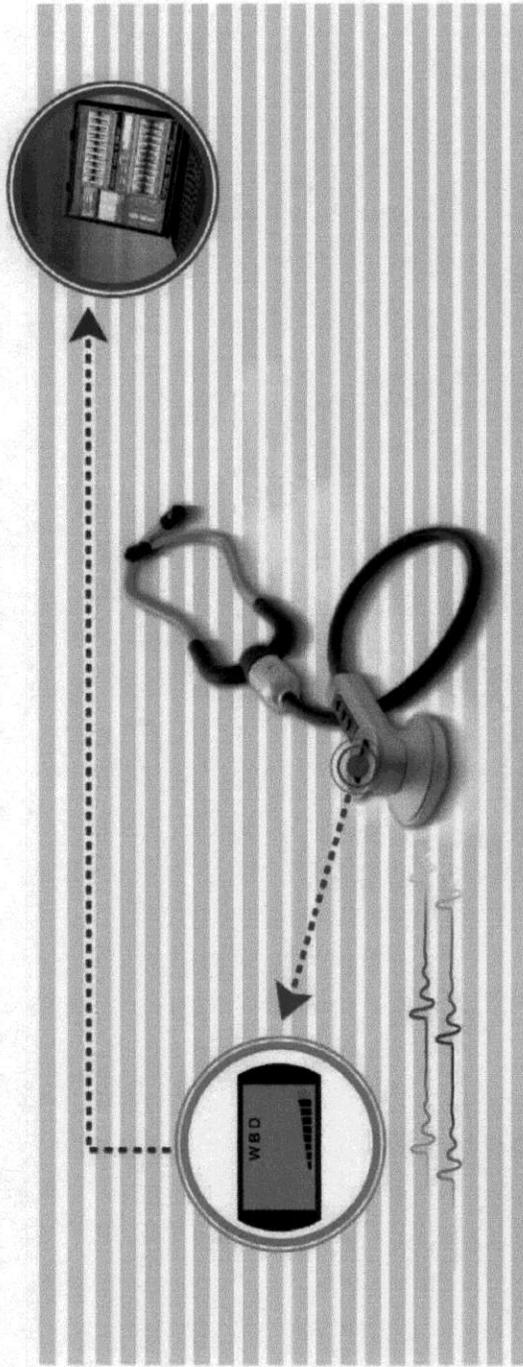
Noise Cancellation

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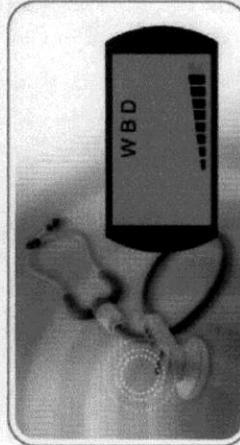


Improved Convenience

PISHON HIGH TECH

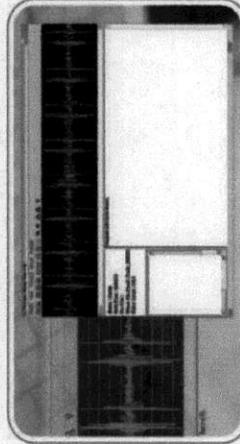


SERENO ELECTRONIC STETHOSCOPE



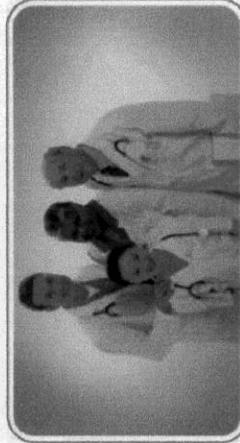
LCD Display

Located on the top of the chest piece, LCD display shows the frequency mode, volume and battery replacement timing with graphic icons in order that users can see informative data at a glance.



Phonocardiogram

Using PC-based analysis software, PishonWave, you can analyze the body sounds into phonocardiogram, and organize the diagnosis data. (PishonWave can be downloaded at www.e-pishon.com)



Comfortable Fit

Combined with excellent performance and smooth binaural set, SERENO Electronic Stethoscope provides comfortable fit for your ears without giving such pressure as experienced with the traditional acoustic stethoscope.



PISHON
HIGHTECH

PISHON

SEREND ELECTRONIC STETHOSCOPE

Specification



Length	74cm
Weight	174gr (battery excluded)
Power	DC 3V
Batteries	AAA(1.5V) x 2
Battery Life	30 hours for continuous use
PC Connecting Cable	3m

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SERENO ELECTRONIC STETHOSCOPE



Pishon High Tech Co., Ltd.
2nd Fl., Moeller Bldg., 403-1, DaeBang-Dong, DongJak-Gu, Seoul, Korea
Ph. + 82 2 826 1750 Fax + 82 2 826 1724

www.e-pishon.com
E-Mail : sales@e-pishon.com

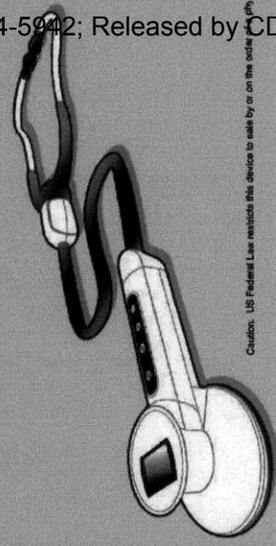
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Operating Manual



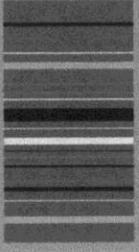
SERENO ELECTRONIC STETHOSCOPE

PISHON HIGH TECH



Caution: US Federal Law restricts this device to sale by or on the order of a physician.

USER MANUAL



- SHARP-CUT SOUND REPRODUCTION
- AMBIENT NOISE MUTING
- NOISE FILTERING
- LCD DISPLAY
- COMFORTABLE FIT
- PC-BASED SOFTWARE



Explanation of Symbols

SYMBOL	DESCRIPTION
==	DIRECT CURRENT
⚠	ATTENTION. SEE INSTRUCTIONS FOR USE
⚡	TYPE BF APPLIED PART

Function Test

When you turn on SERENO, the display panel will show the current listening mode and volume level. This verifies that the device is working properly.

This pack contains:

- Stethoscope
- AAA battery 2 pieces
- PC Connecting Cable
- Earrip 2 pieces
- and this manual

Classification

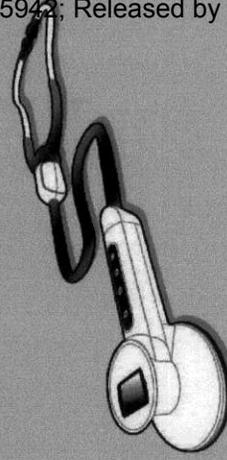
- This product is classified as follows:
 - Shock Protection: Internally powered equipment
 - Degree of Protection Against Electric Shock: Type BF Applied Part.
 - Degree of Protection Against Harmful Ingress of Water: Ordinary equipment (IPX0).
 - Degree of Safety in the Presence of Flammable Anaesthetic Mixture with Air or With Oxygen or Nitrous Oxide: Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
 - Mode of Operation: Continuous operation.

Warning

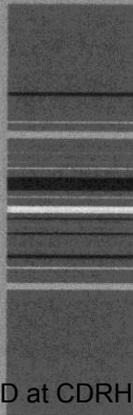
- Potential electromagnetic or other interference between medical equipments and other devices being operated together in the same environmental may exert an adverse influence on functioning of the medical equipment. Non-medical equipments not in compliance with the requirements of EN 60601-1 and EN 60601-1-2 should not be used together in the same environmental as the medical equipments.
- This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.
- External equipment intended for connection to signal input, signal output, or other connectors, must comply with the relevant IEC/EN standard IEC/EN 60601-1 series for medical electrical equipment). In addition, all such connections (system) must comply with the standard IEC/EN 60601-1. Safety requirements for medical electrical systems.
- Any person who connects external equipment to signal input, signal output, or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC/EN 60601-1-1. If in doubt, speak with a qualified technician.
- Do not touch signal input, signal output or other connectors, and the patient simultaneously.
- Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

CONTENTS

- Explanation of Symbols/Classification
- Warning
- Warning / Cautions
- Parts
- Specification
- Operating Instructions
- Software
- Service and Warranty



**SERENO ELECTRONIC
STETHOSCOPE
PISHON HIGH TECH**



Warning
 Fishon electronic stethoscope is a medical device. This product is not intended for use other than listening to biological sounds, and is not designed for use by unlicensed, unapproved or untrained persons. Read the following carefully, and use for the purpose in the right directions.

Use



• Electronic stethoscope is a sensitive instrument, and do not use, too big sounds such as tapping on chest piece may cause hearing damage.



• Do not let it vent or shocked harsh.



• Do not disassemble the device or do not attempt to repair it yourself.

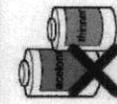
Cleaning



• Remove the batteries from the device, and wipe the stethoscope clean with alcohol cloth



• Do not apply organic solvent such as gasoline, thinner or acetone.



Battery



AAA 1.5V batteries

• Use two AAA 1.5V batteries, and do not mix different types or different life batteries (old and new etc.)



• Make sure of the right + - direction for insert.



• Whenever the stethoscope will not be used for a long time, remove the batteries from the device.

Maintenance



• Avoid places of high humidity. Be careful not to immerse the stethoscope in water or any liquid. In case the device is wet, do not use until it is completely dried. It may cause irreparable damage to the device.

Storage/Use Condition
 -4°F to 140°F (-20°C to 60°C)
 30% to 90% relative humidity
 Normal atmospheric pressure

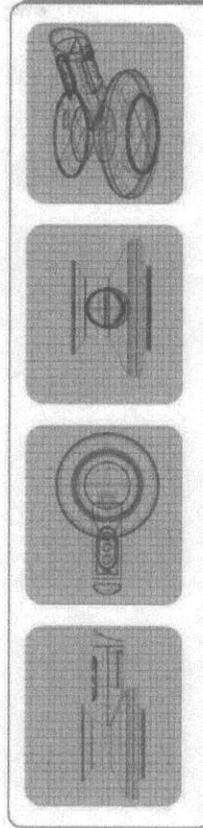


• Avoid direct exposure to sunlight, extreme heat or cold, solvents and oil. Storage conditions are from -4°F (-20°C to 60°C), 30% to 90% relative humidity.

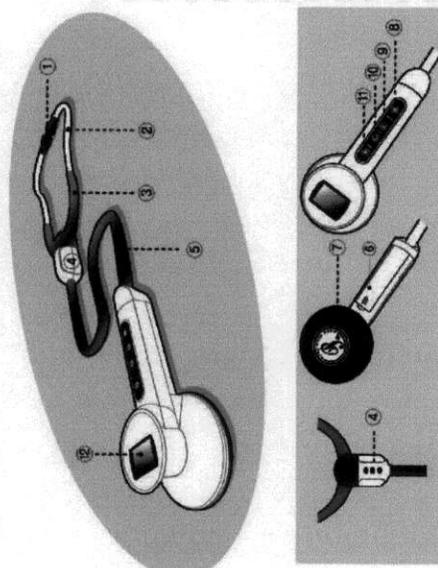
Although SERENO electronic stethoscope does not require maintenance on general use, you may wipe the device clean with an alcohol pad after each use so as to reduce the risk of contamination.

Specification

Length	74cm
Weight	174g (battery excluded)
Power	DC 3V
Battery	AAA(1.5V) x 2
Battery Life	30 hours for continuous use
PC cable	3m



- ① Ear Tips
- ② Binaural
- ③ Joint Hose
- ④ Phone Jack
- ⑤ Hose
- ⑥ Battery Case
- ⑦ Sensor
- ⑧ Power
- ⑨ Volume Decrease
- ⑩ Volume Increase
- ⑪ Mode Selection
- ⑫ LCD Display

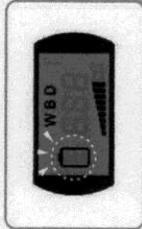


Parts

Battery
Slide the battery cover on the back of the chest piece and insert two AAA type 1.5V batteries. Be sure of the right polarity direction and slide the battery cover back until it clicks into place.



Battery
When the batteries are low, the battery indicator on the LCD display will blink. Then, replace the batteries with new ones as soon as possible.



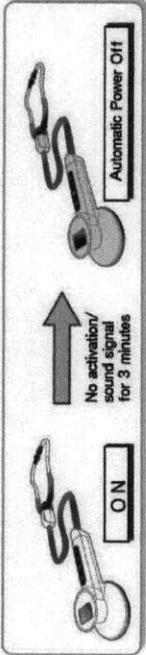
Power On/Off
Press Power Button on top of the chest piece to turn on the electronic stethoscope. To turn off, press Power Button and hold for two seconds.



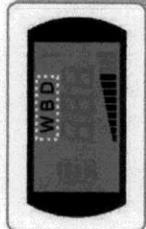
Volume Control
Press the volume buttons (▲▼) on the top of chest piece to increase or decrease the volume to the desired level. New set level will not change even at power-off, and will resume at setting by battery removal.



Automatic Power Off
The stethoscope automatically turns off three minutes after the last button or sound signal is inputted.



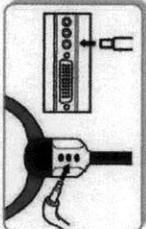
Mode Selection
Press mode button to select the proper frequency range for your target auscultation. LCD display will show the charge B(Belt), W(Wide), D(Diaphragm), W(Wide).



Personalized Setup
Power-Off does not change the volume level and the mode you adjusted on use. The device will function with the last volume and mode on startup. For reset, remove batteries out of the case.



PC Connection
PC connecting cable is enclosed in the stethoscope package. Insert the rectangular plug into stethoscope phone jack and the straight plug into line-in or audio-in terminal of your PC.



Ear Tip Replacement
To replace the ear tips, hold a pipe with one hand and twist out the ear tips, and then twist in the new ear tips.



How to get the software

- 1. Download PishonWave at www.e-pishon.com
- 2. Learn how to use the program at www.e-pishon.com

Recommended PC Spec.

- CPU: Pentium 2 or higher
- OS: Window 98, Window Me, Window 2000, Window XP
- RAM 64MB or more
- Hard Disk available with 4MB or more
- Sound Card and Speaker



Service and Warranty



Pishon SERENO Electronic Stethoscope is warranted against defects in material or workmanship for a period of one year. If a material or manufacturing defect is discovered during the warranty period, repair or replace will be made, at its option, without charge upon return of the product to its authorized service representative.

Exceptions: The foregoing warranty shall not apply in the following cases.

1. Defects or damages resulting from misuse or improper maintenance.
2. Defects or damages related to unauthorized disassembly, repair or modification.
3. Defects or damages caused by fire or convulsion of nature.

For inquiry, please contact our EU representative:

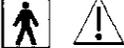
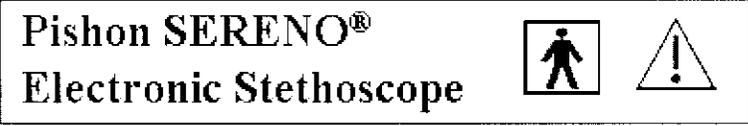
Amigos de Pishon SA c/o Corea C/Gonzalez Arnigo 15, 28003, Madrid, Spain
Ph. (34) 91-353-2000 Fax (34) 91-353-2001

Pishon High Tech Co., Ltd.

2nd Fl., Moeller Bldg., 403-1, DaeBang-Dong,
Dongjak-Gu, Seoul, Korea
Phone: + 82 2 826 1750 Fax + 82 2 826 1724
E-Mail: service@e-pishon.com

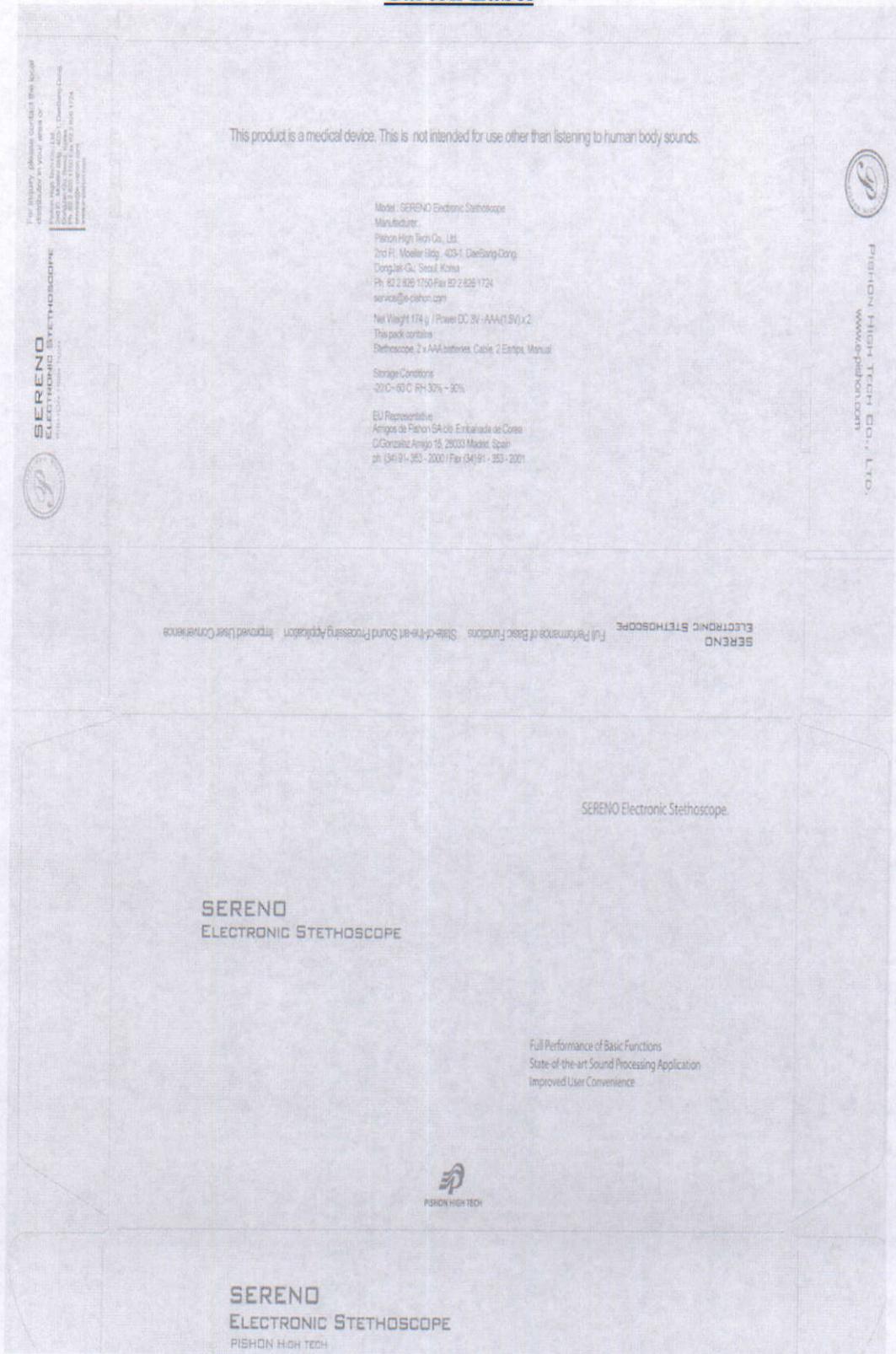
www.e-pishon.com

Device Labels

Control Panel	
Battery Case Cover	
Side of Handle	
Head Top	
Probe	
Speaker Part	

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Carton Label



For inquiry, please contact the local distributor in your area or:
SERENO, Inc., 10011, Chesham Lane,
San Diego, CA 92126, USA
Tel: 619 451-1100 / Fax: 619 451-1124
www.pishon.com

SERENO
ELECTRONIC STETHOSCOPE



This product is a medical device. This is not intended for use other than listening to human body sounds.

Model: SERENO Electronic Stethoscope
Manufacturer:
Pishon High Tech Co., Ltd.
2nd Fl., Mosier Bldg., 403-1, Daesung-Dong,
Dongjak-Gu, Seoul, Korea
Ph: 82 2 826 1700 Fax: 82 2 826 1724
service@pishon.com
Net Weight: 174 g / Power: DC 3V - AAA(1.5V) x 2
This pack contains:
Stethoscope, 2 x AAA-batteries, Case, 2 Earps, Manual
Storage Conditions:
-20°C - 60°C RH: 30% - 90%
EU Representative:
Amigos de Pishon SA de CV, Embarcadero de Costa
C/Gonzalez Arango 15, 28033 Madrid, Spain
ph: (34)91-363-2000 / Fax: (34)91-363-2001



PISHON HIGH TECH CO., LTD.
www.pishon.com

SERENO ELECTRONIC STETHOSCOPE
Full Performance of Basic Functions
State-of-the-art Sound Processing Application
Improved User Convenience

SERENO Electronic Stethoscope.

SERENO
ELECTRONIC STETHOSCOPE

Full Performance of Basic Functions
State-of-the-art Sound Processing Application
Improved User Convenience



SERENO
ELECTRONIC STETHOSCOPE
PISHON HIGH TECH

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EXHIBIT 4
Description of Device

Description
Photo
Engineering Drawing
Bill of Materials
Inspection: Receiving
Inspection: In Process
Inspection: Final

Description

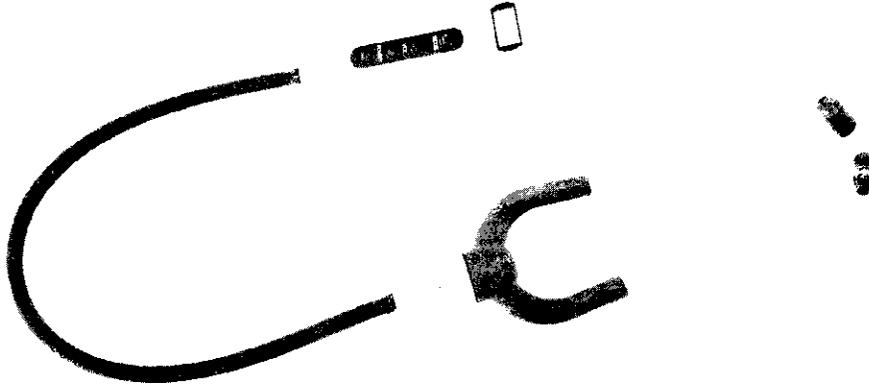
The SERENO electronic stethoscope is intended for use as a diagnostic aid in patient diagnosis and monitoring. The SERENO electronic stethoscope amplifies sounds up to 20 times bigger than ordinary acoustic stethoscope in a broad frequency range including a range higher than the traditional diaphragm mode. It looks similar to the traditional stethoscope including parts like a probe head, binaural pipes and ear tips. It has four (4) buttons on the top of the chest set (opposite to the probe). Each of the buttons has a function of controlling the modes, volume up/down and power on/off.

As an electronic stethoscope, it needs two (2) batteries (AAA type, 1.5V) to operate. The stethoscope has automatic power off function for longer battery life and has a LCD display to show volume level, frequency mode and low battery indicator. With the enclosed audio cable, utilizing a personal computer, the user can store sound signals in the PC and transmit diagnosis data via e-mail.

This stethoscope is a stand-alone unit, has no software and operates using an analog audio system with a digital timer for power saving and a digital control for the volume and the filter mode selection. It can be connected to audio input of a sound card in a computer to use the PC software functions. However, the software does not operate nor control the stethoscope in any manner. In fact, the stethoscope's audio output can be connected to any ordinary audio equipment such as a cassette recorder, a hi-fi audio component and portable audio.

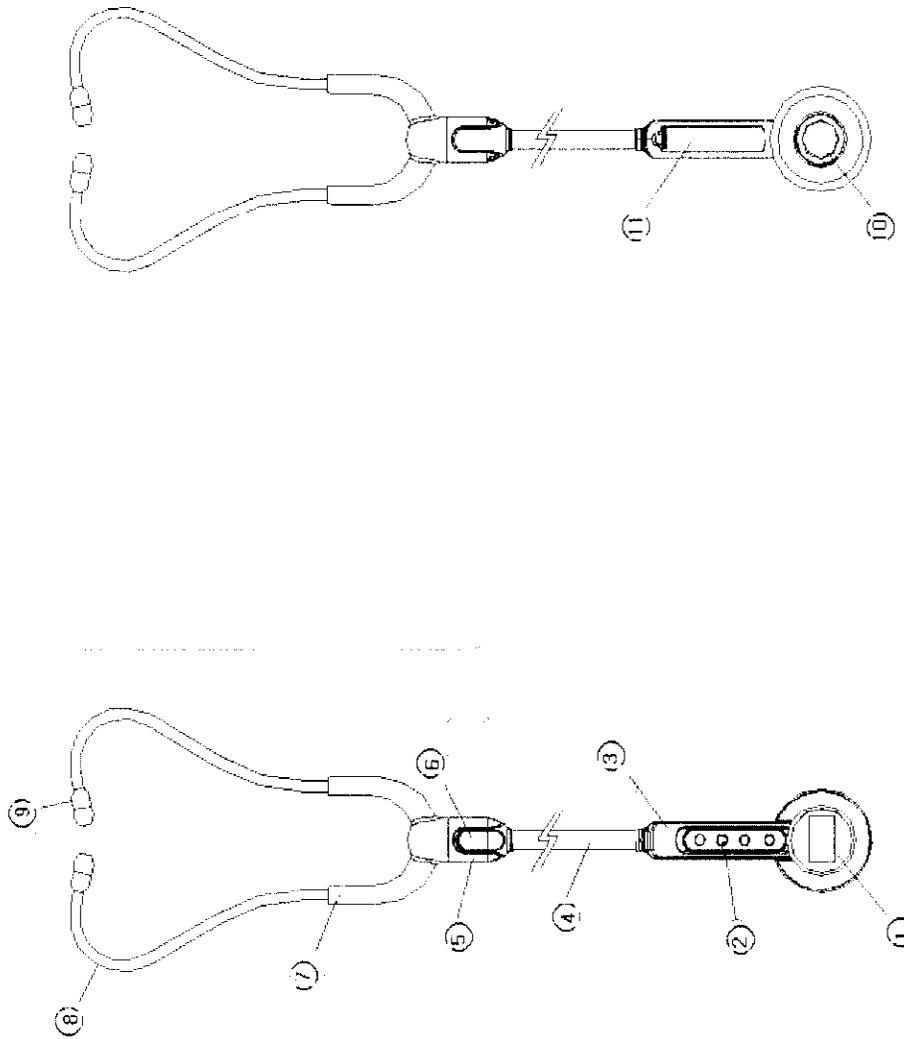
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Device Photo



Confidential and Proprietary

Engineering Drawing



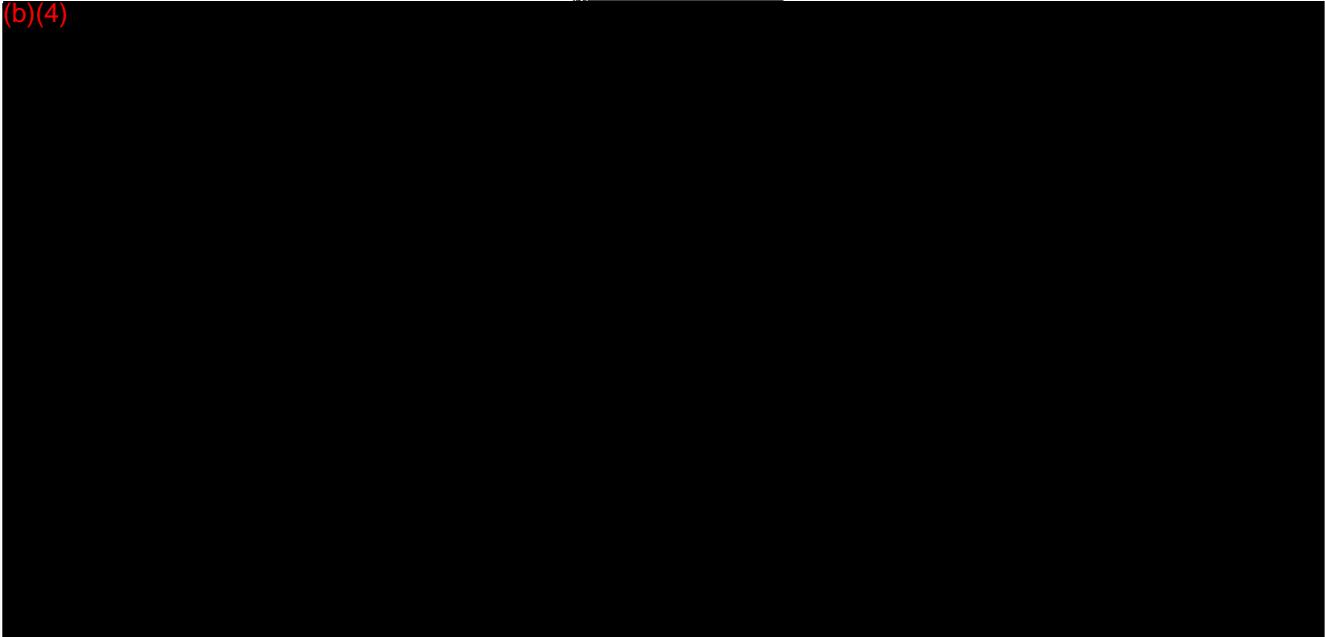
Drawing #	PSR-C
Product	SERENO Electronic Stethoscope
Date	01-Jun-05
Revised	25-Nov-05

No	Desc	Qty
1	LCD Display Panel	1
2	Operation Buttons	4
3	Probe Handle	1
4	Hose	1
5	Speaker Part	1
6	Phone Jack Cover	1
7	Joist Y Hook	1
8	Binaural	1
9	Ear Tip	2
10	Probe Sensor	1
11	Battery Case	1

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Bill of Materials

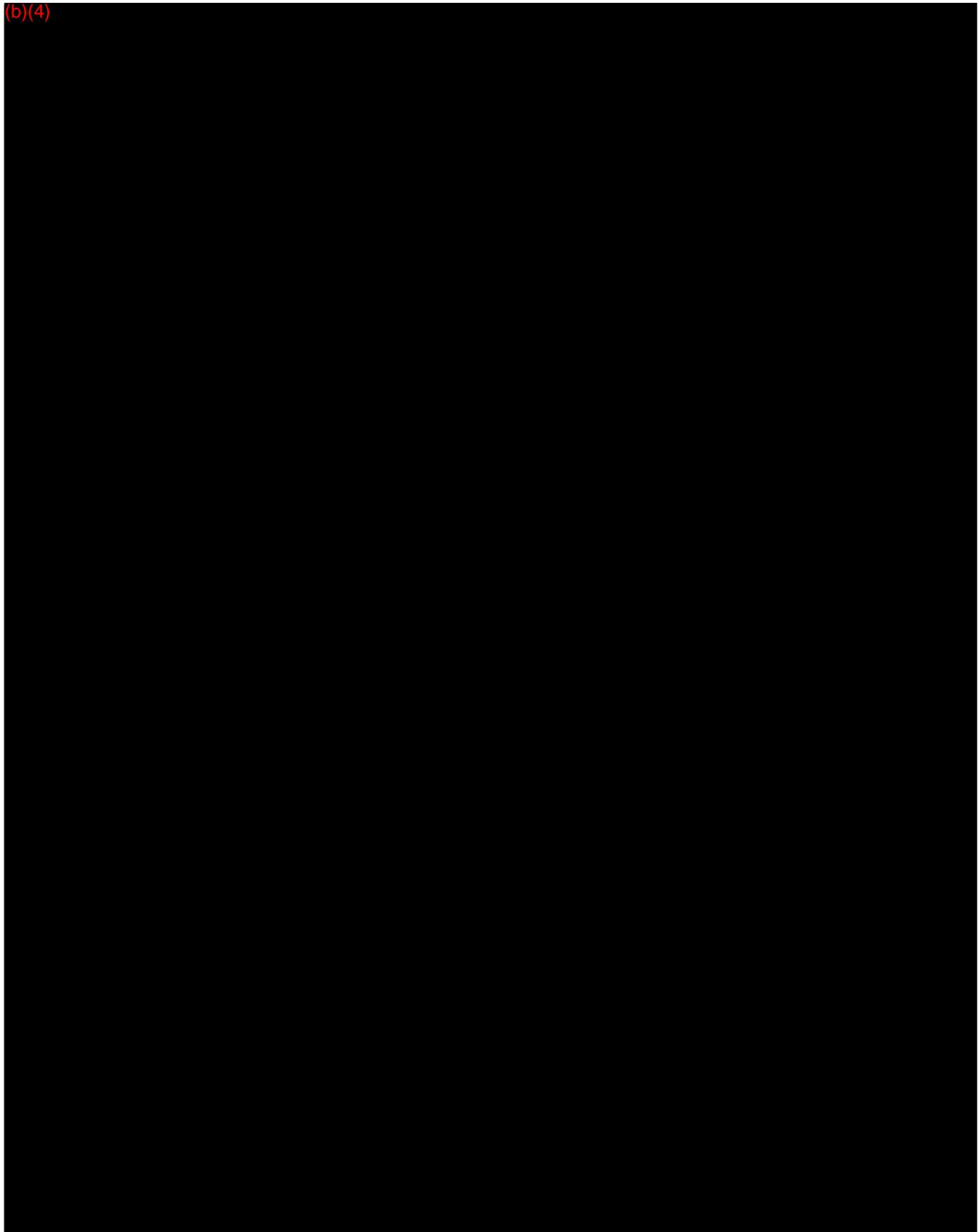
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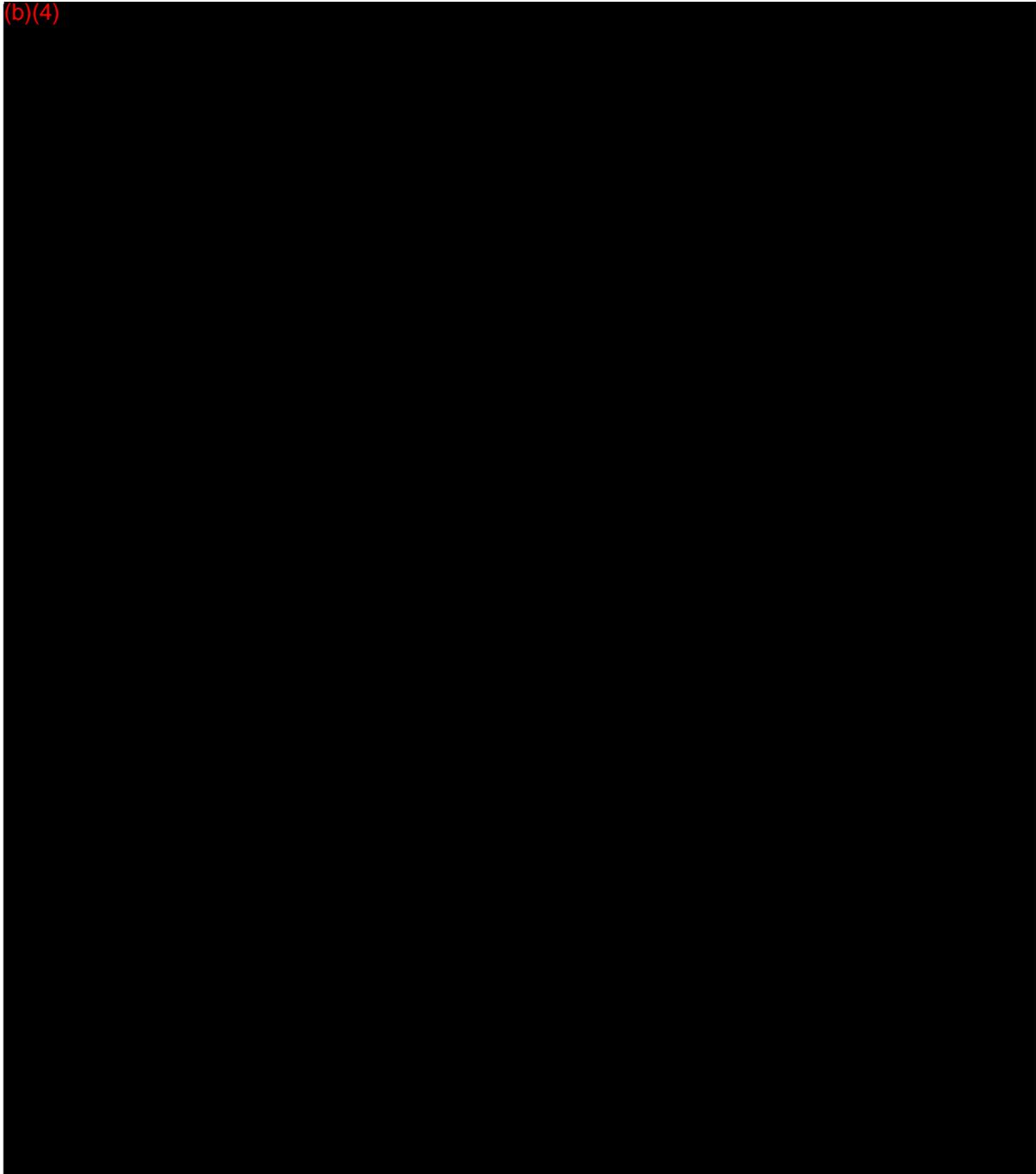
Inspection: Receiving

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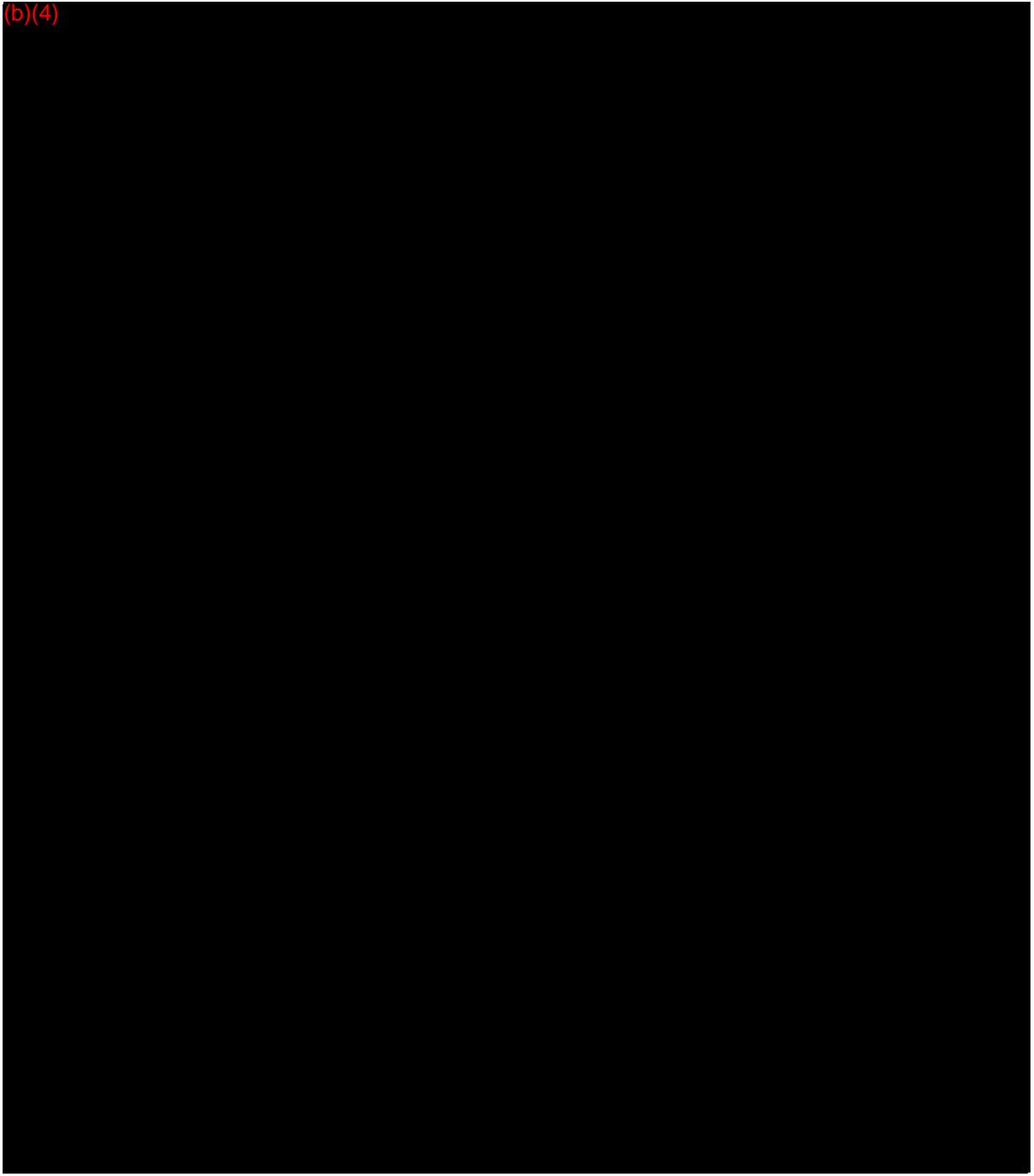
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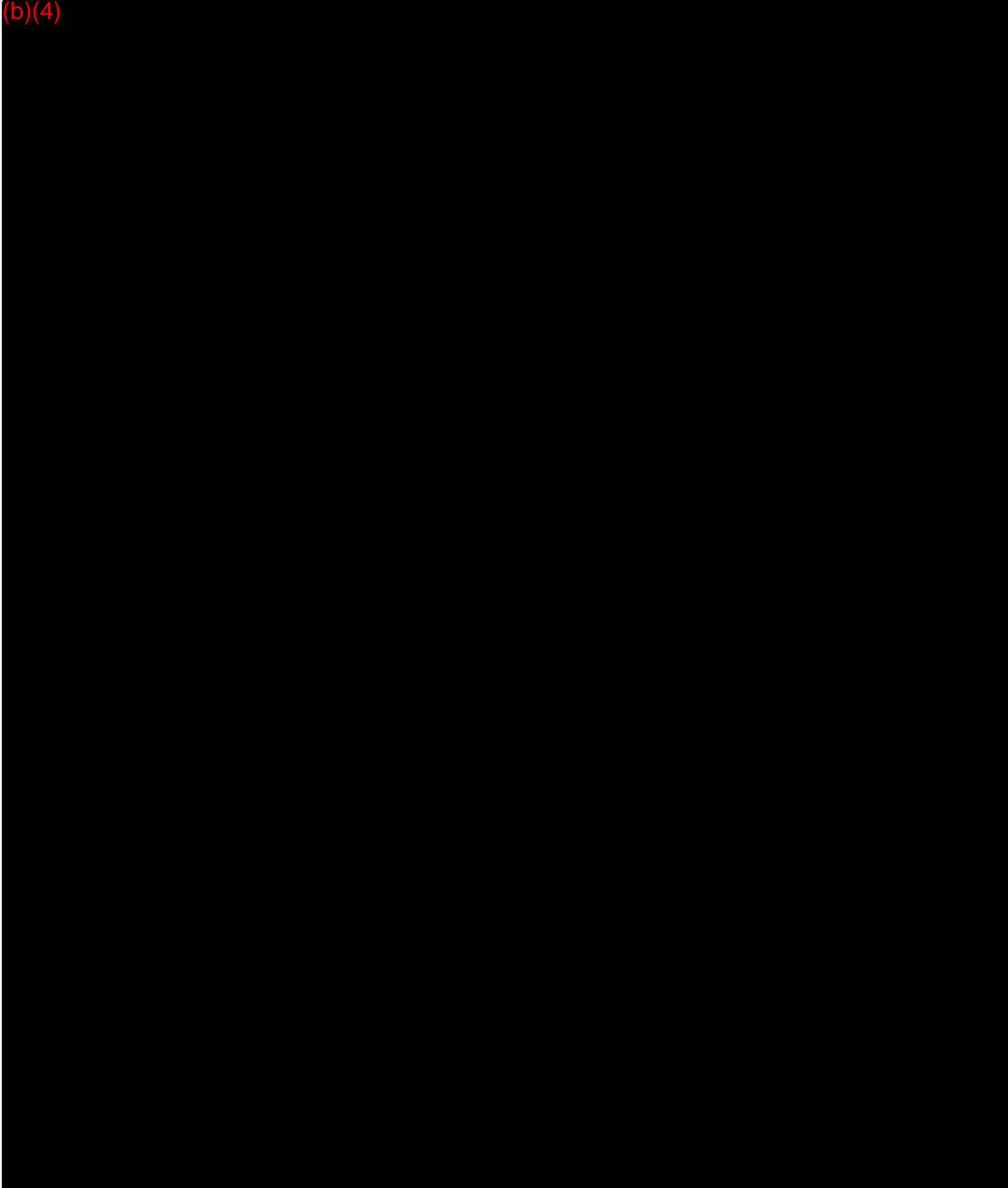
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Confidential and Proprietary

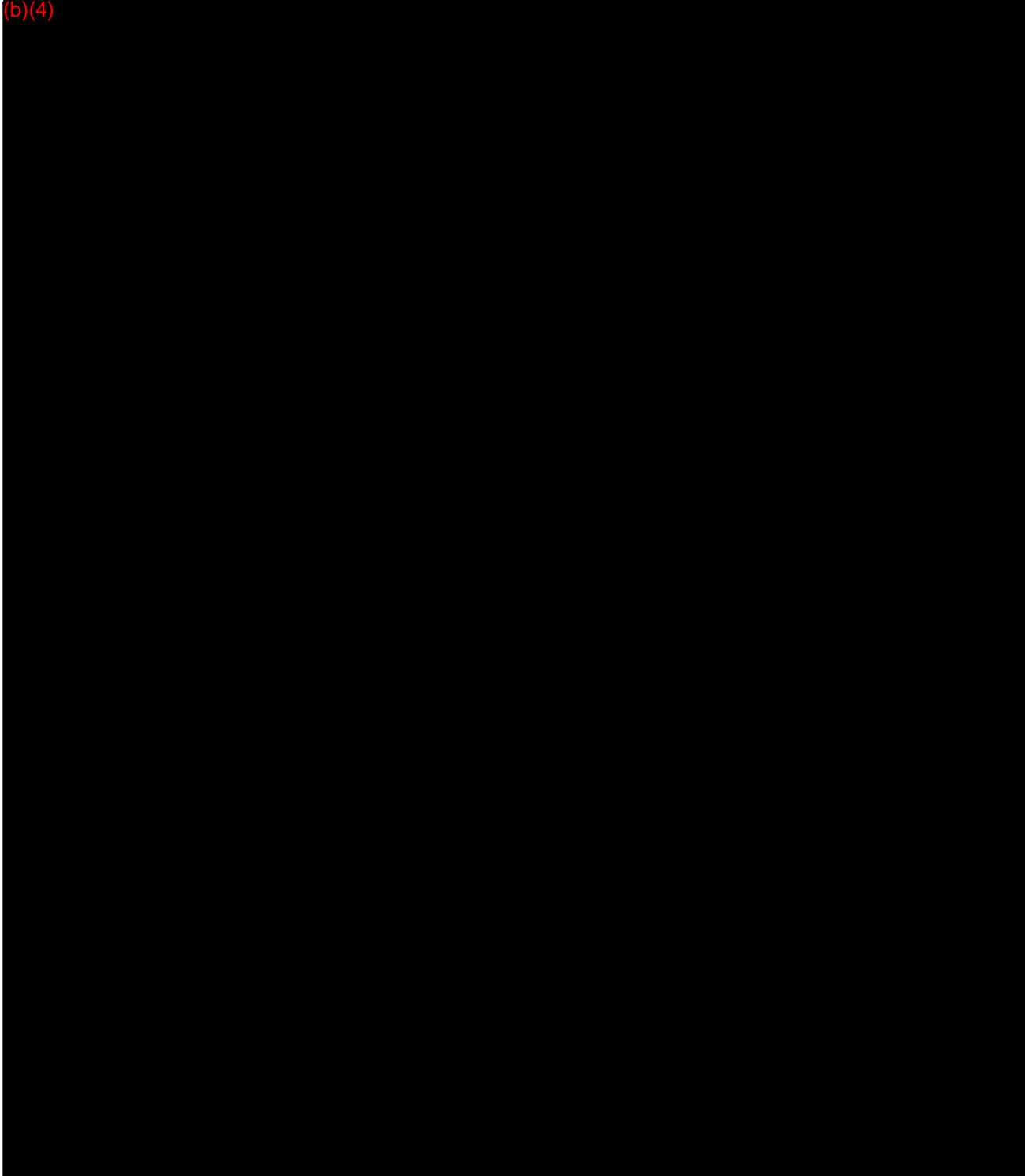
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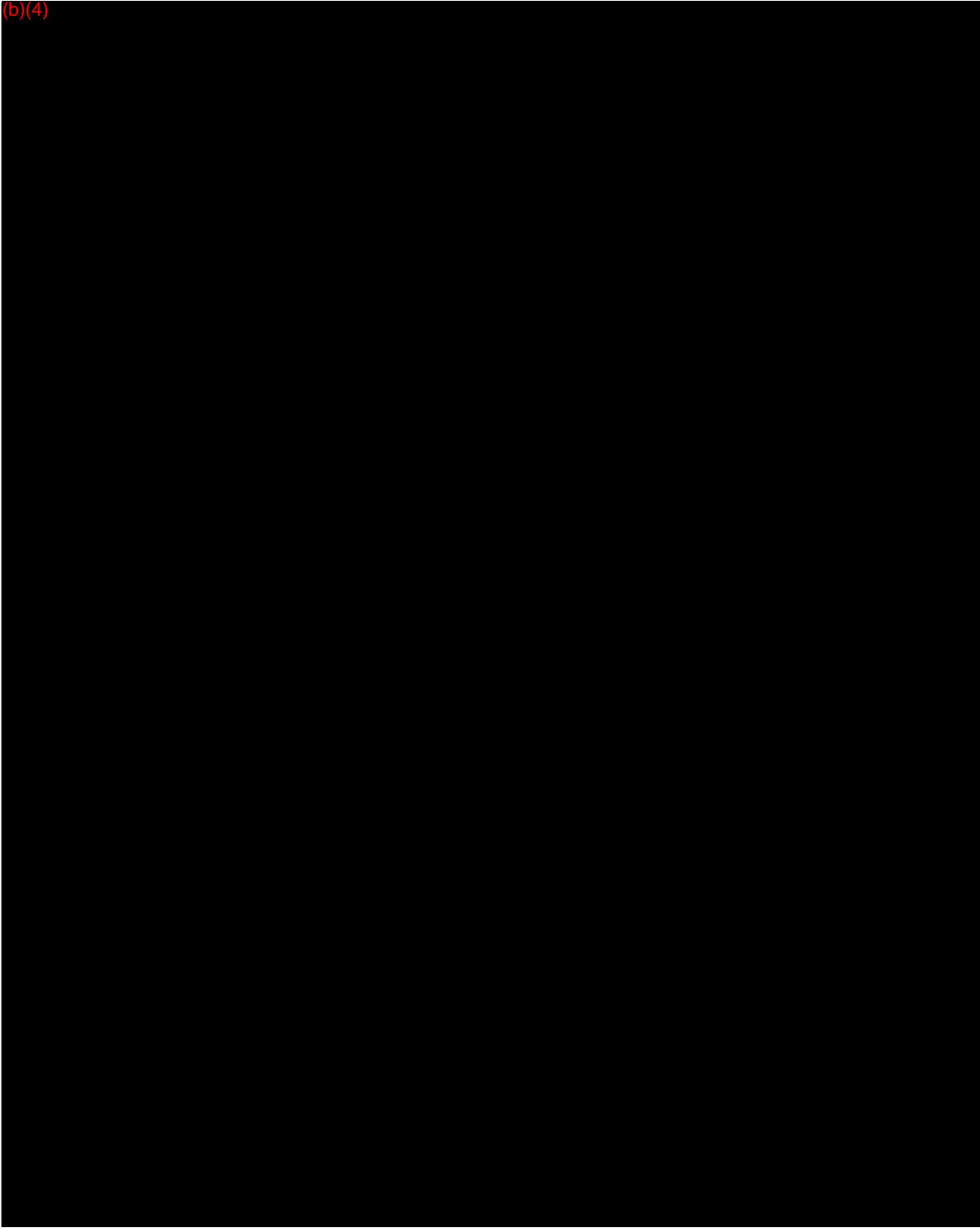


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Inspection: In Process

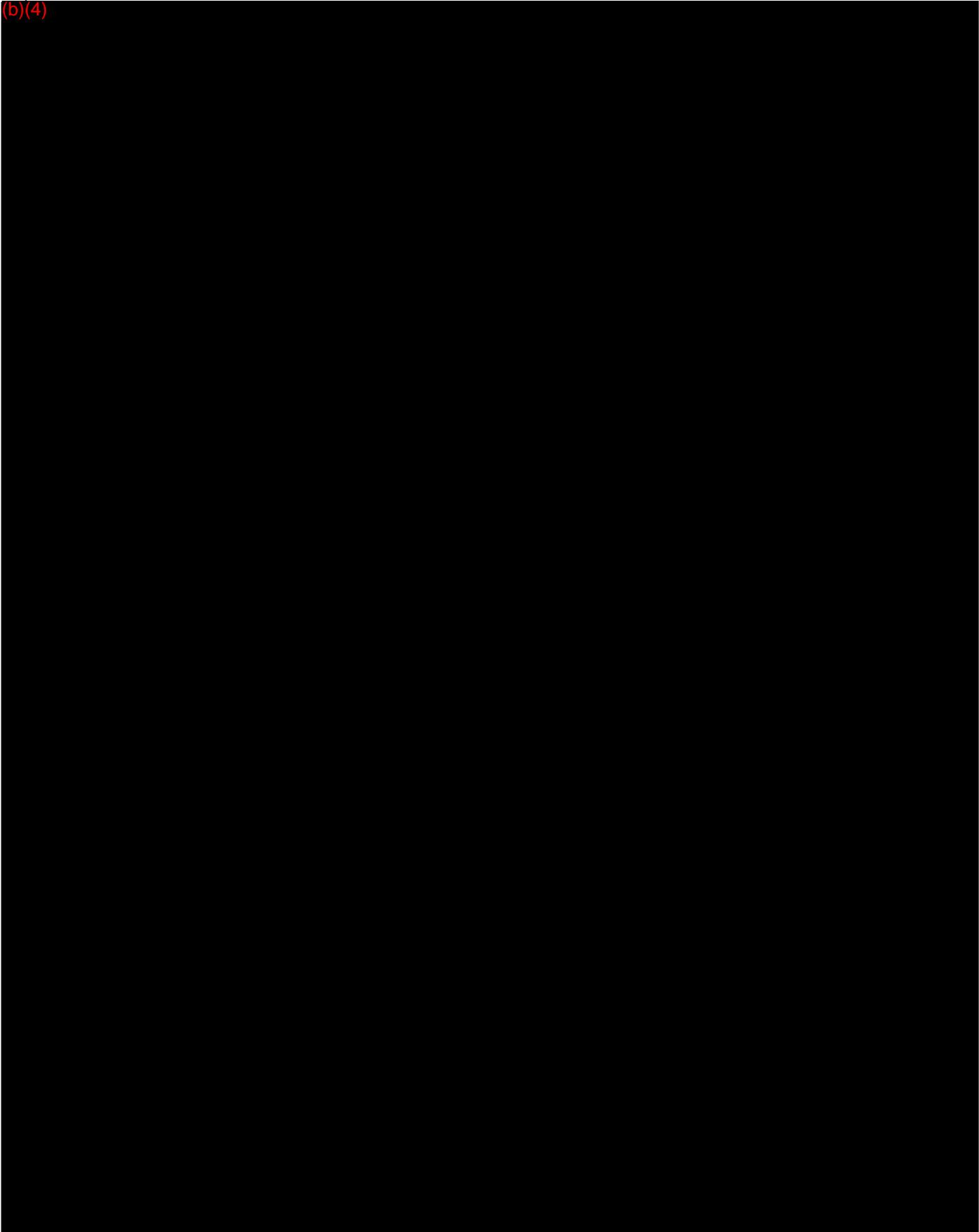
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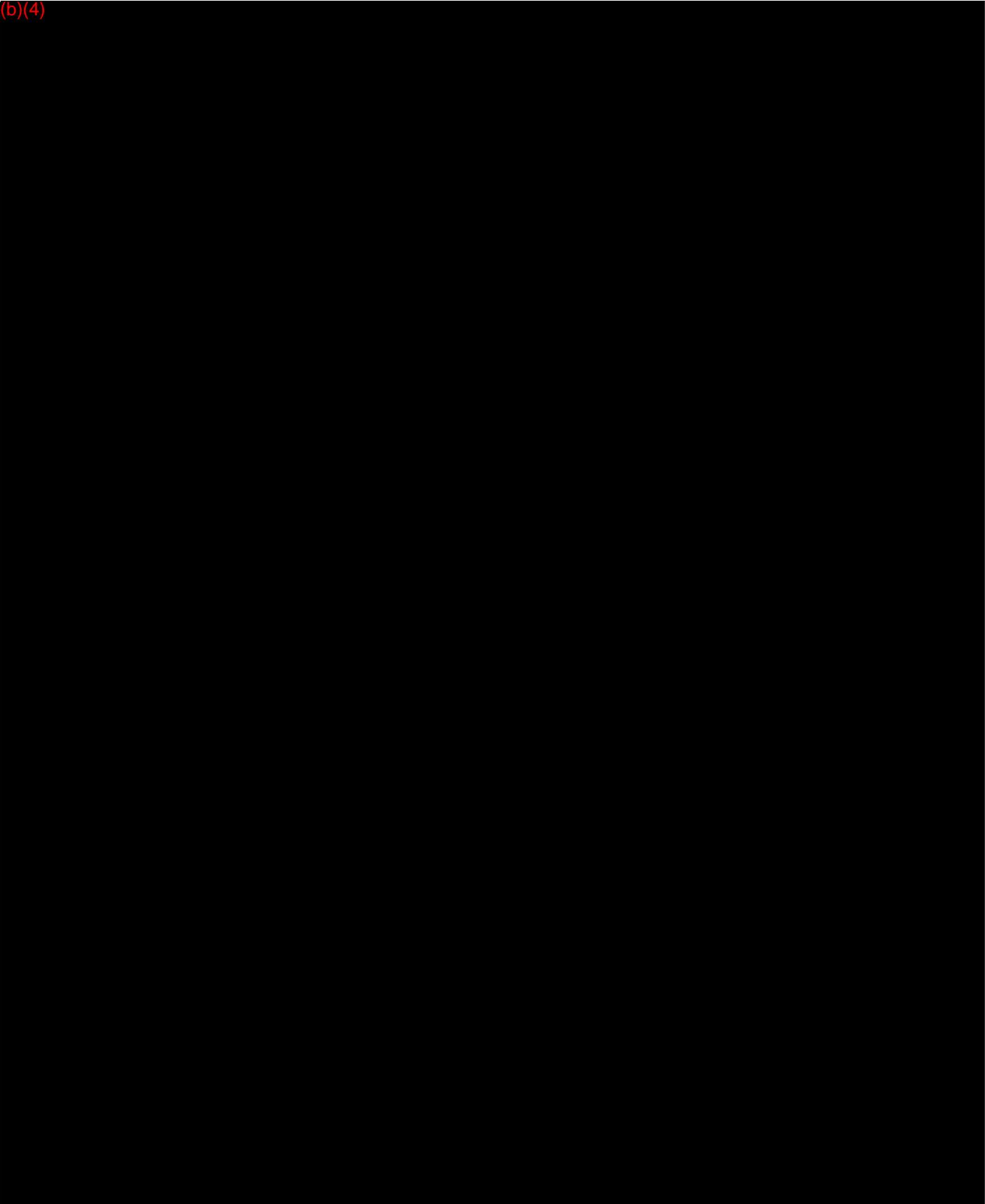
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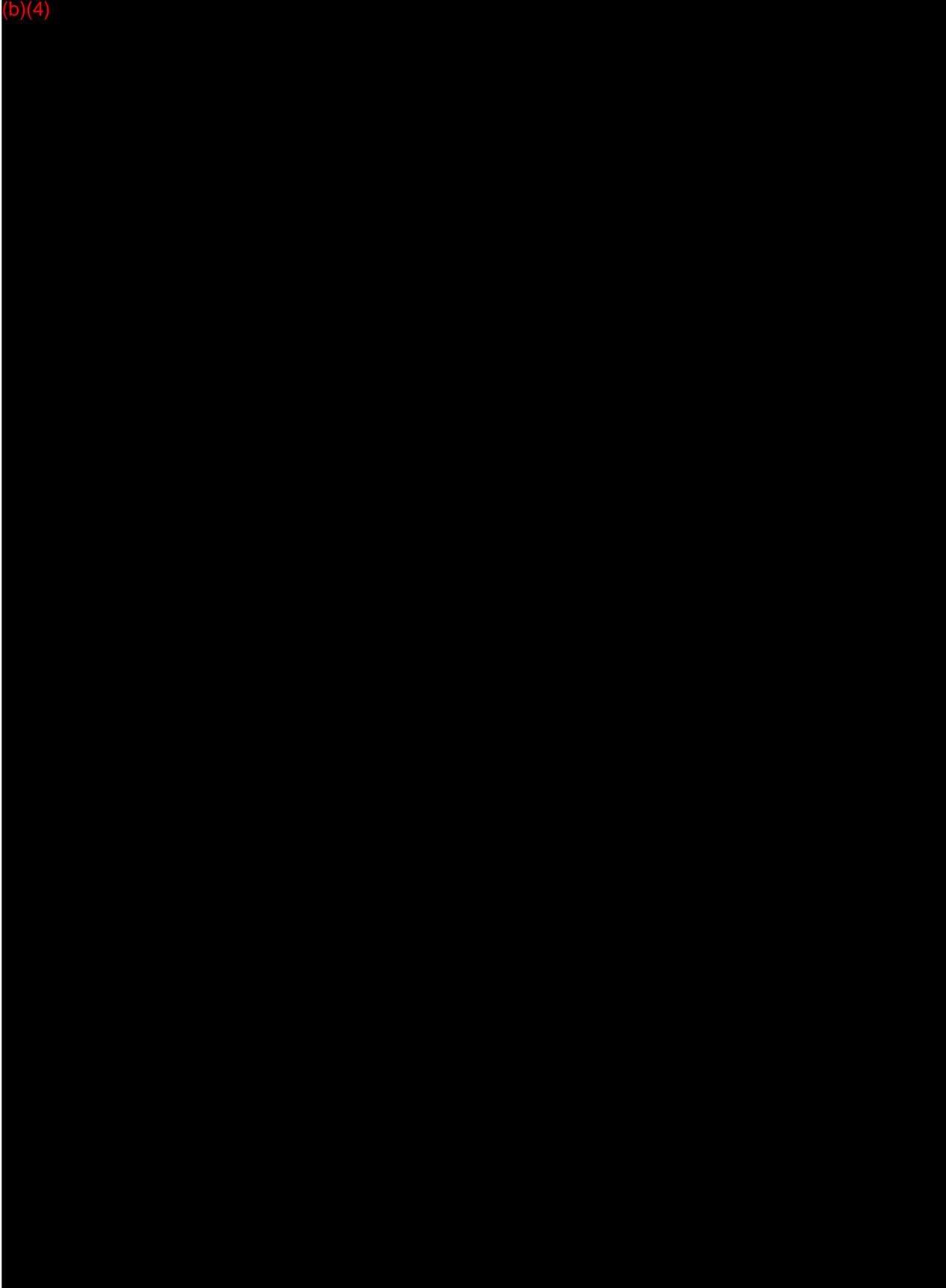


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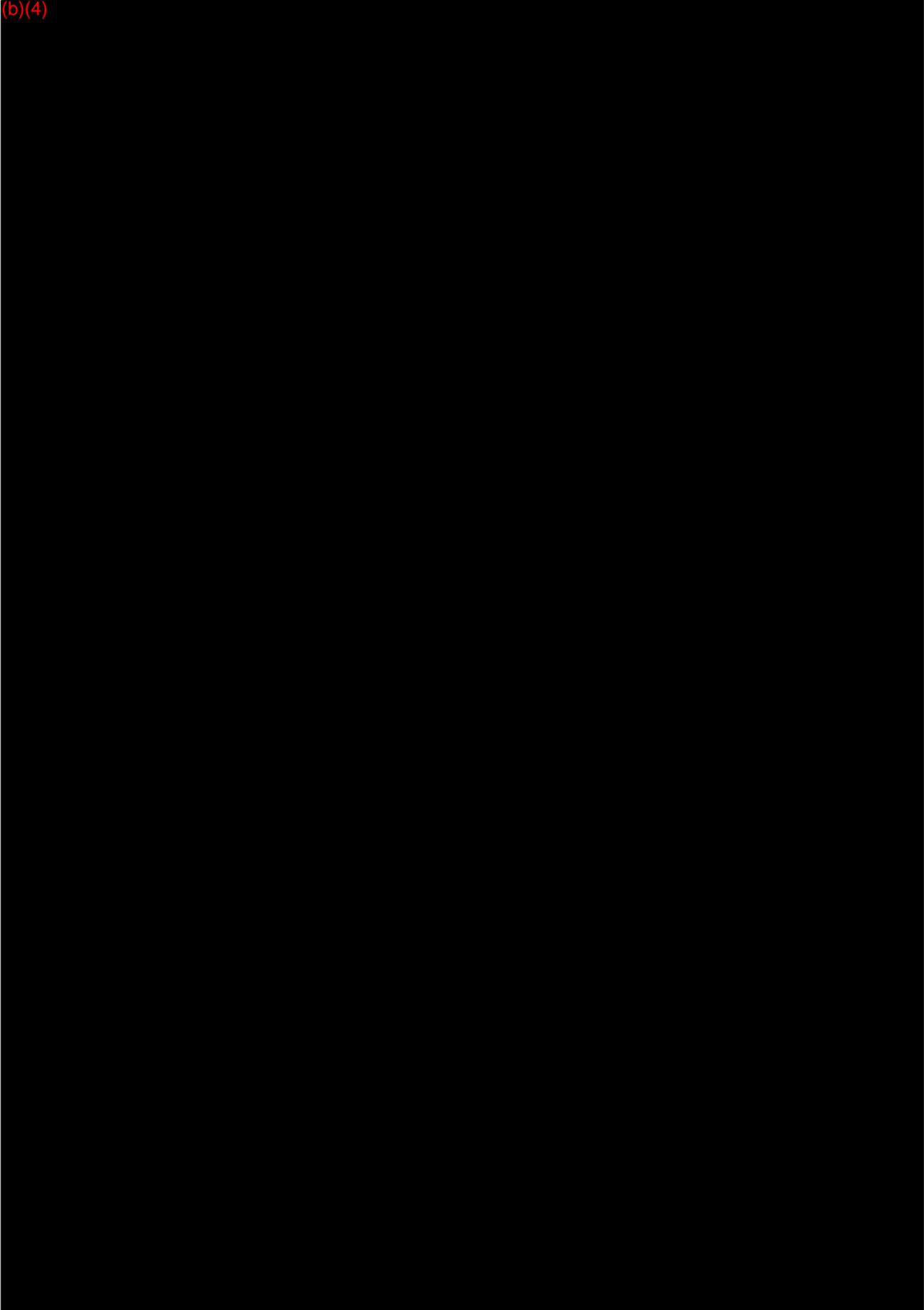
Confidential and Proprietary

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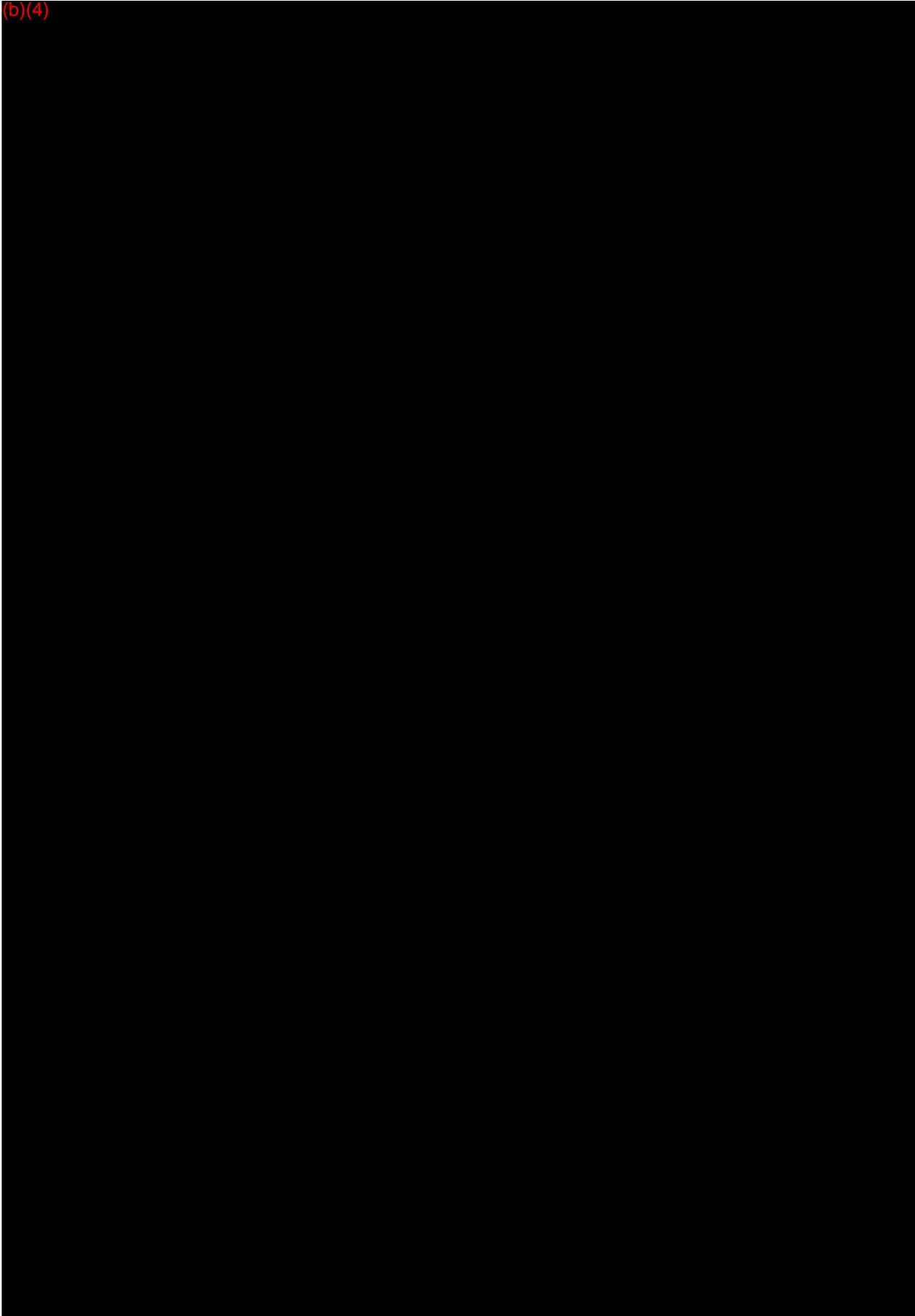
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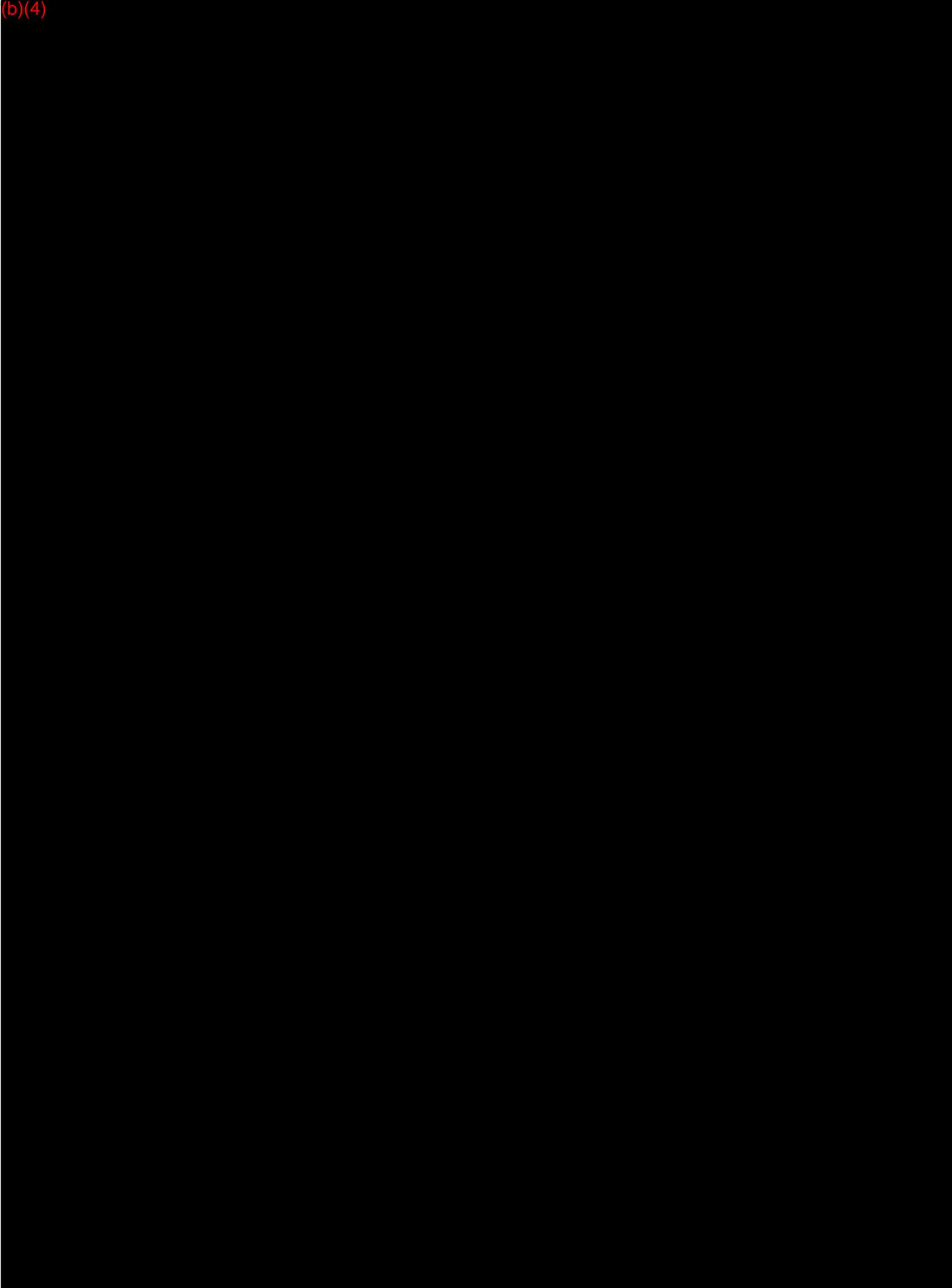
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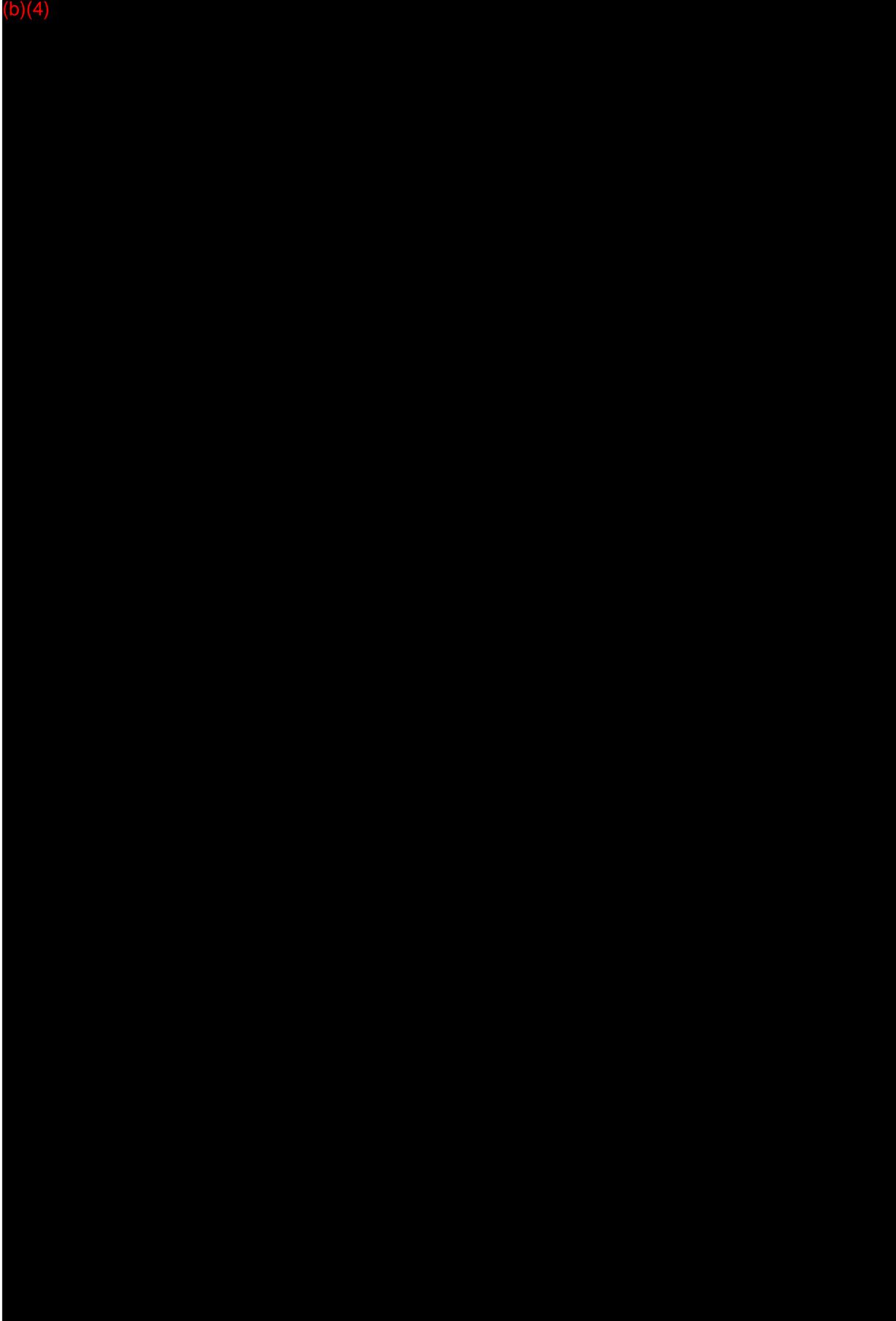
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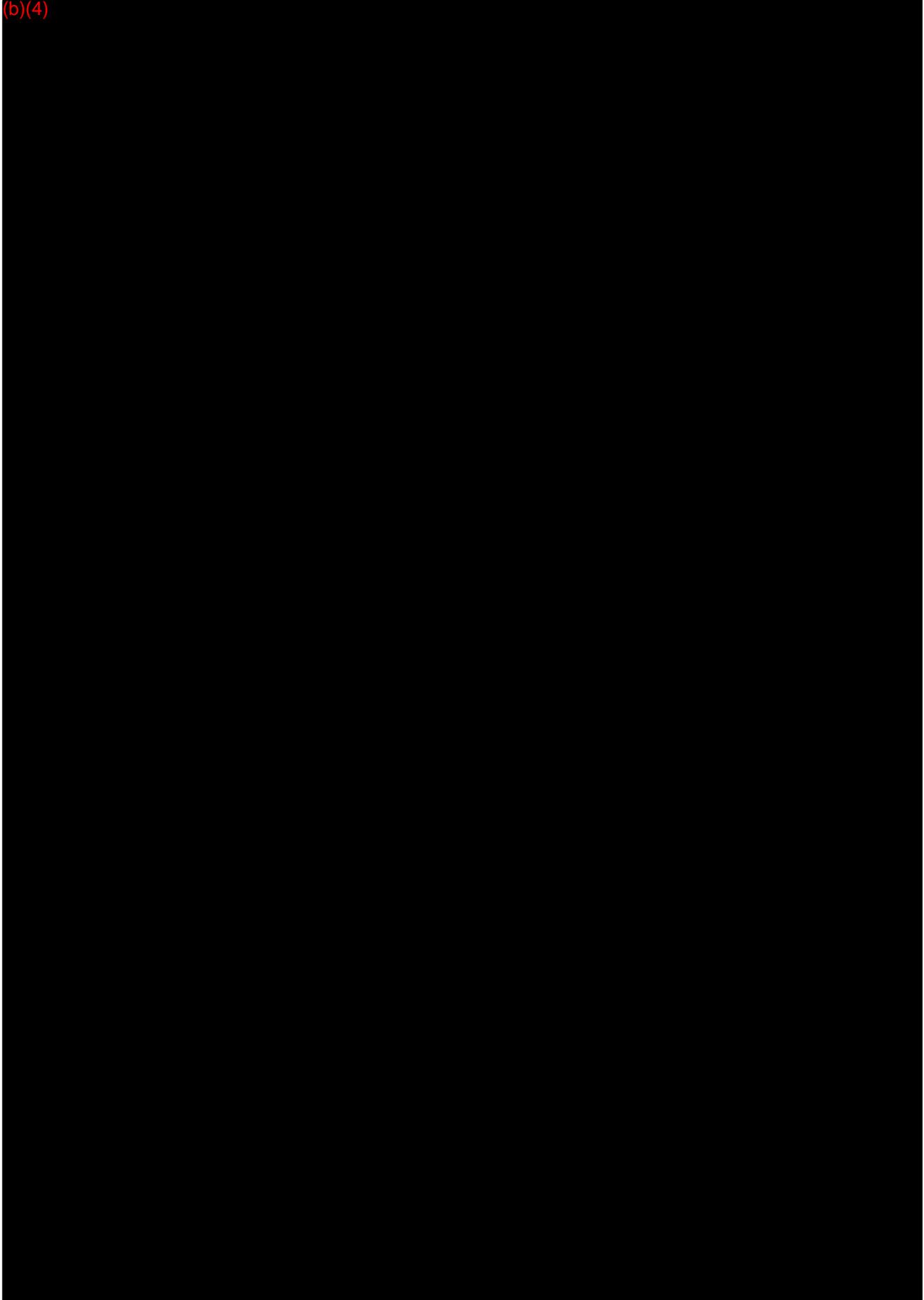
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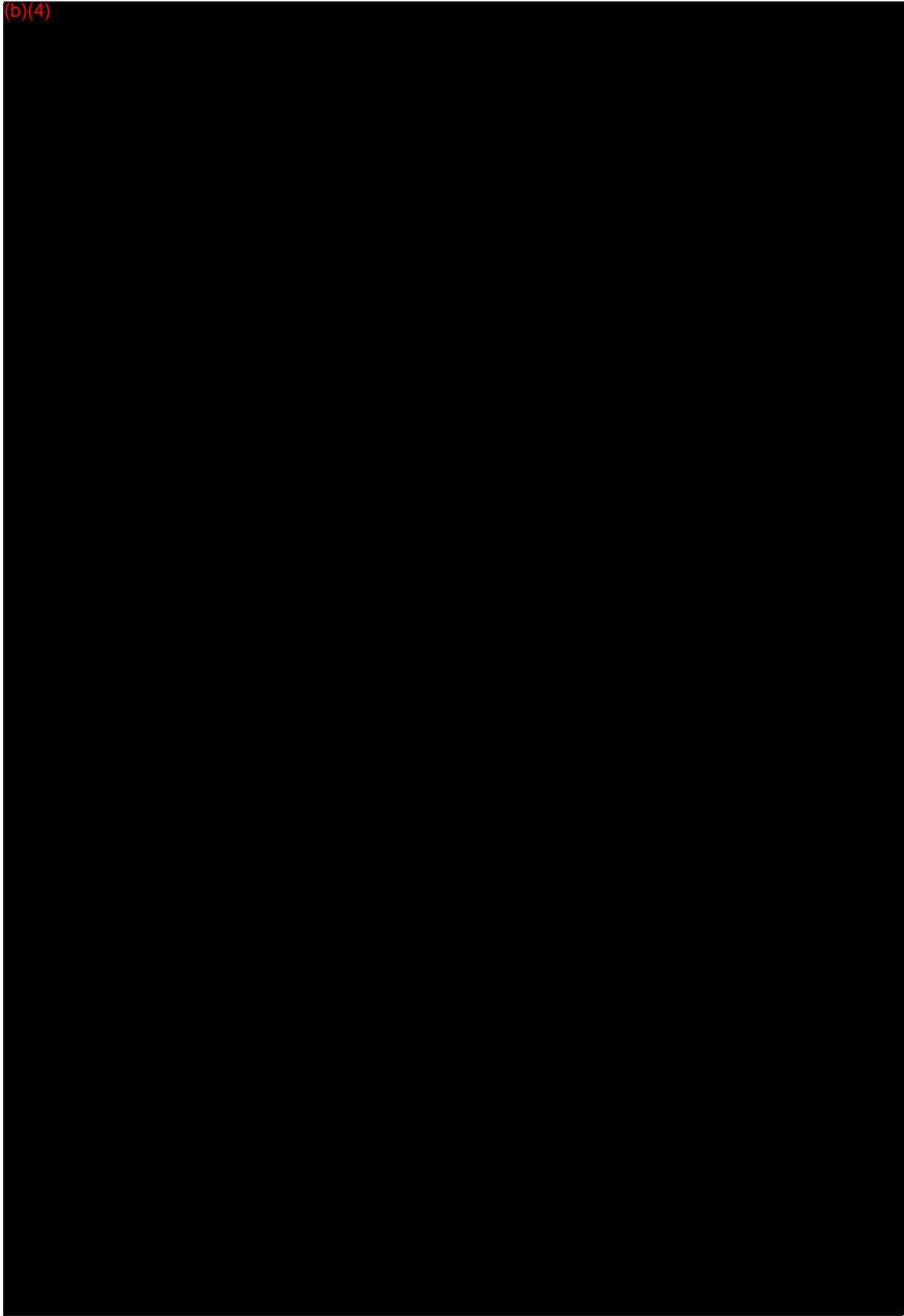
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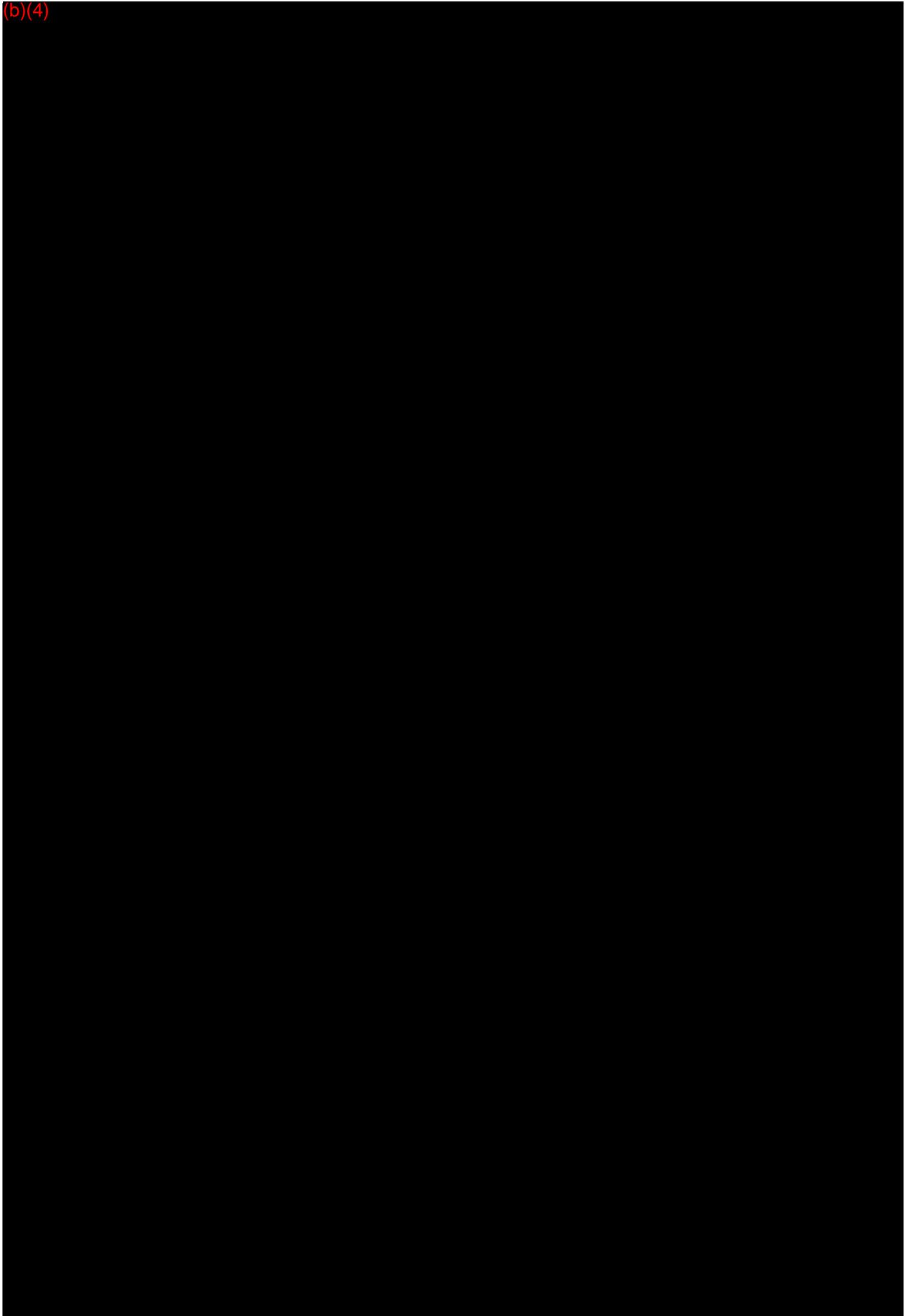
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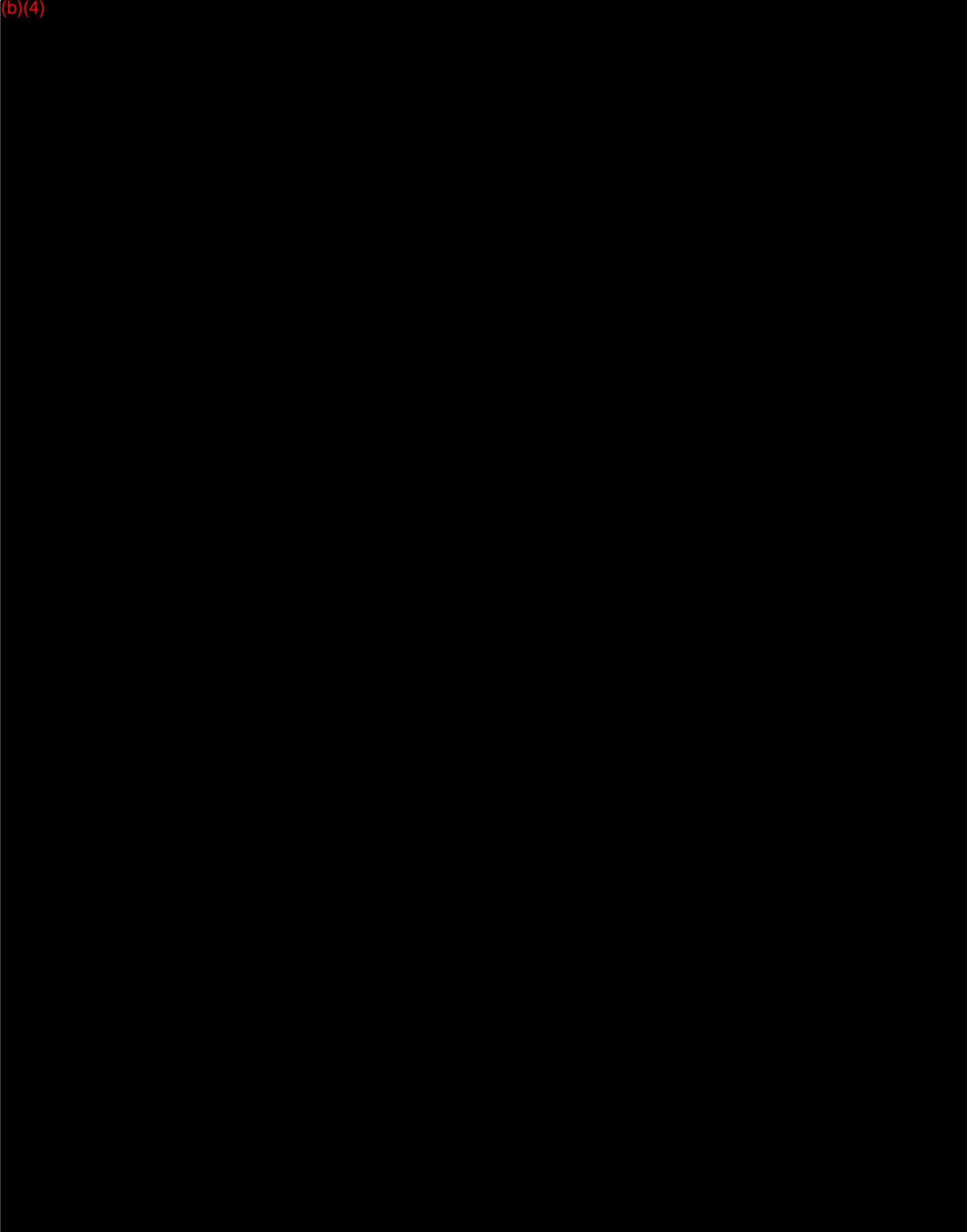
Confidential and Proprietary

Inspection: Final

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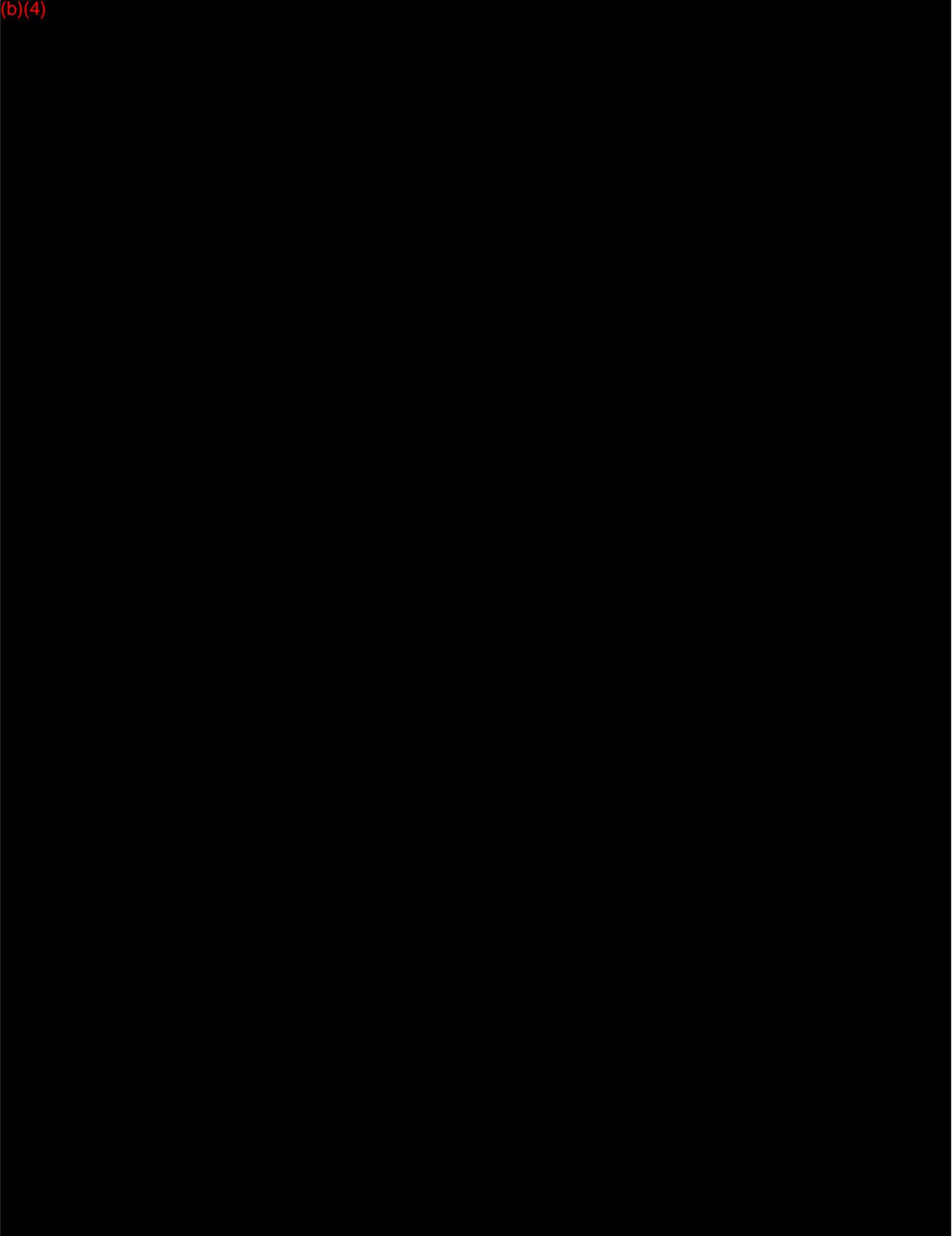
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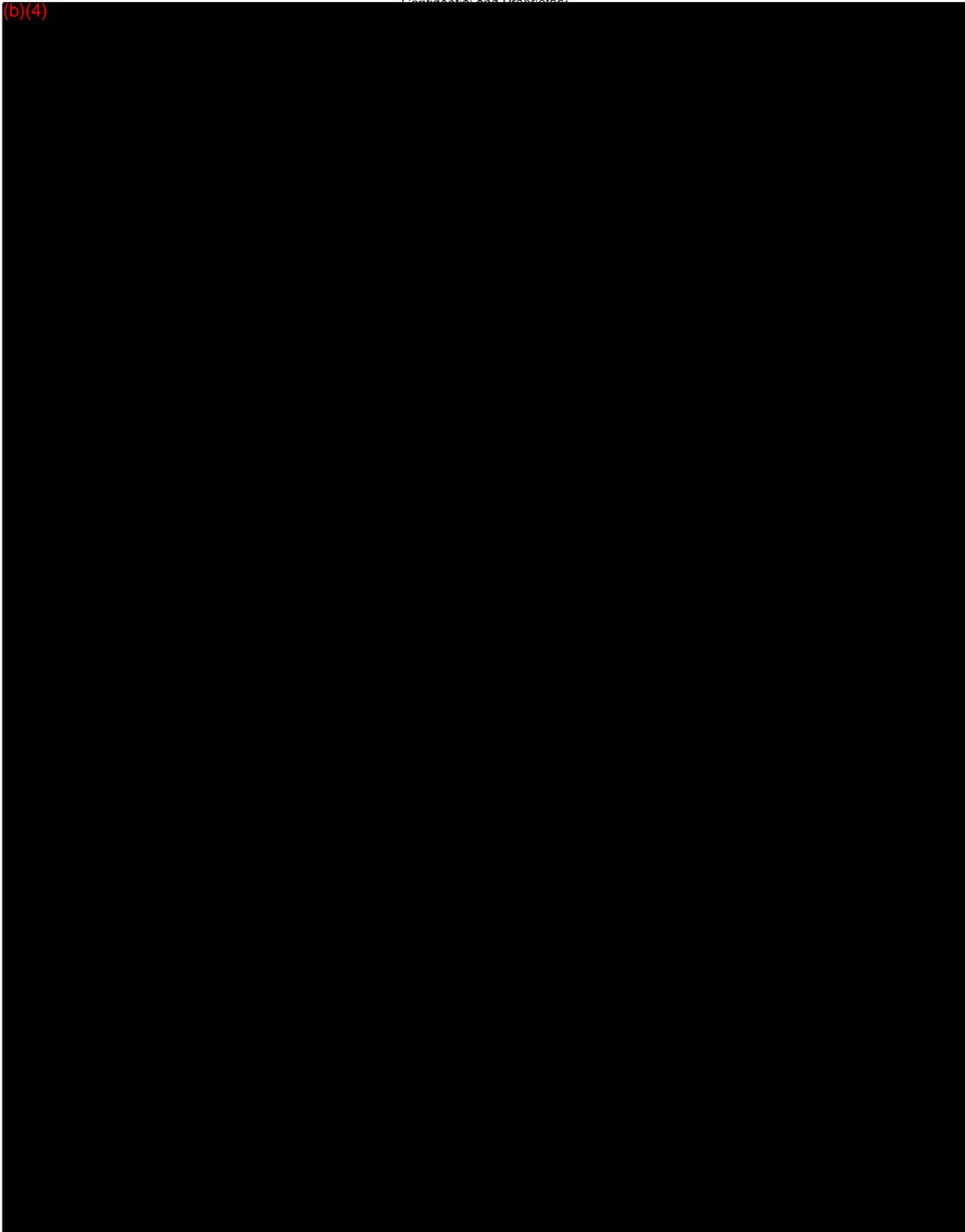


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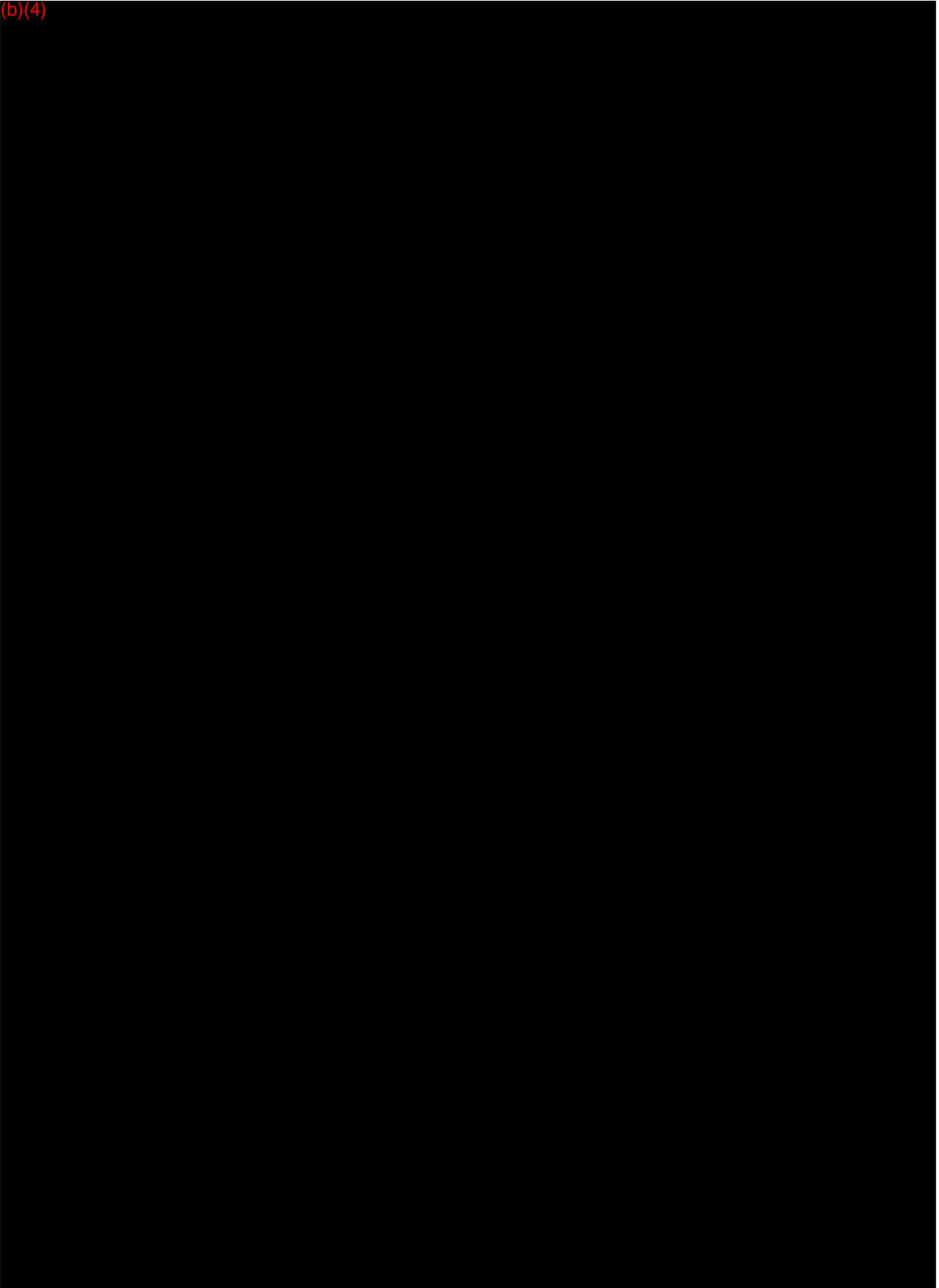
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Confidential and Proprietary

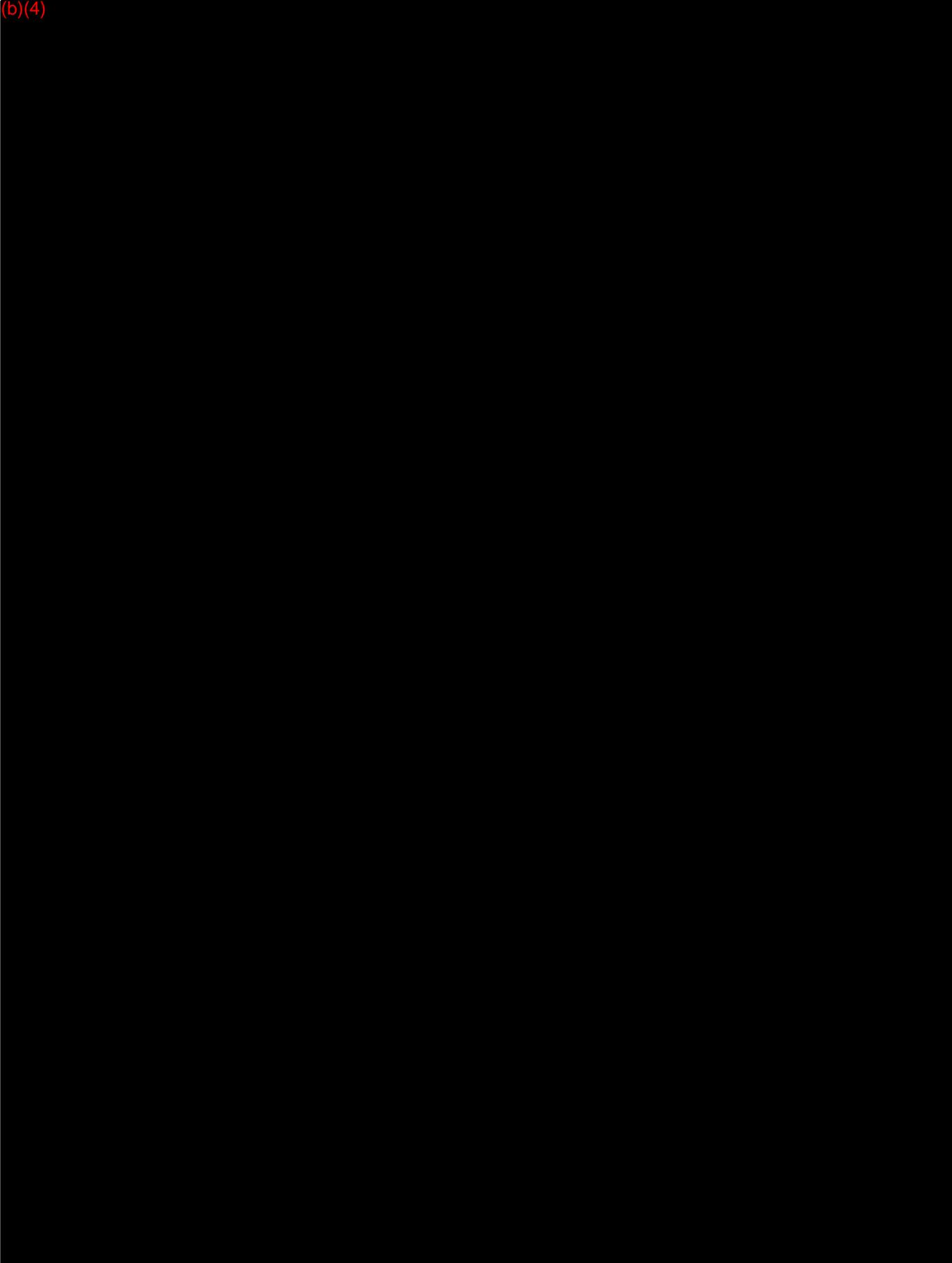
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EXHIBIT 5
Detailed Comparison Information

The SERENO electronic stethoscope is comparable in its intended use to other electronic stethoscopes currently on the market in the U.S. The SERENO electronic stethoscope is identical in use and product claims to 3M Littmann electronic stethoscope(K003723) of 3M and JABES electronic stethoscope (K031446 as shown on the table below.

Device name	Predicate Device		New Device
	3M Littmann Electronic stethoscope, Model 4000(K003723)	JABES electronic stethoscope (K031446)	SERENO electronic stethoscope
Classification Name	Electronic Stethoscope	Electronic Stethoscope	Electronic Stethoscope
Applicant	3M	GS Technology Co., Ltd	Pishon High Tech Co., Ltd
Frequency Response Mode	Bell(20-200Hz), Diaphragm(100-500Hz) Extended range: (20-1,000Hz)	Bell(20-500Hz), Diaphragm(200-800Hz) Extended range: (20-1,000Hz)	Bell(20-450Hz), Diaphragm(200-1,200Hz) Extended range: (20-1,500Hz)
Amplification	Up to 18times amplification	Up to 18times amplification	Up to 20 times amplification
Display heart rate	Yes	No	No
Permits data transfer of stored digital signal to IBM-Compatible PC	Yes	No	No
Volume control	8 Steps Volume control	12 Steps Volume control	12 Steps Volume control
Energy source	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries	Two(2) AAA alkaline batteries
Manual On/Off button Automatic shut-off by electronics	Yes	Yes	Yes
Low Battery Indicator	Yes	Yes	Yes

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EXHIBIT 6

Patient and doctor contact materials

The sensor of the stethoscope is the only patient contacting material, and the contact time is brief, typically less than a minute. (b)(4)

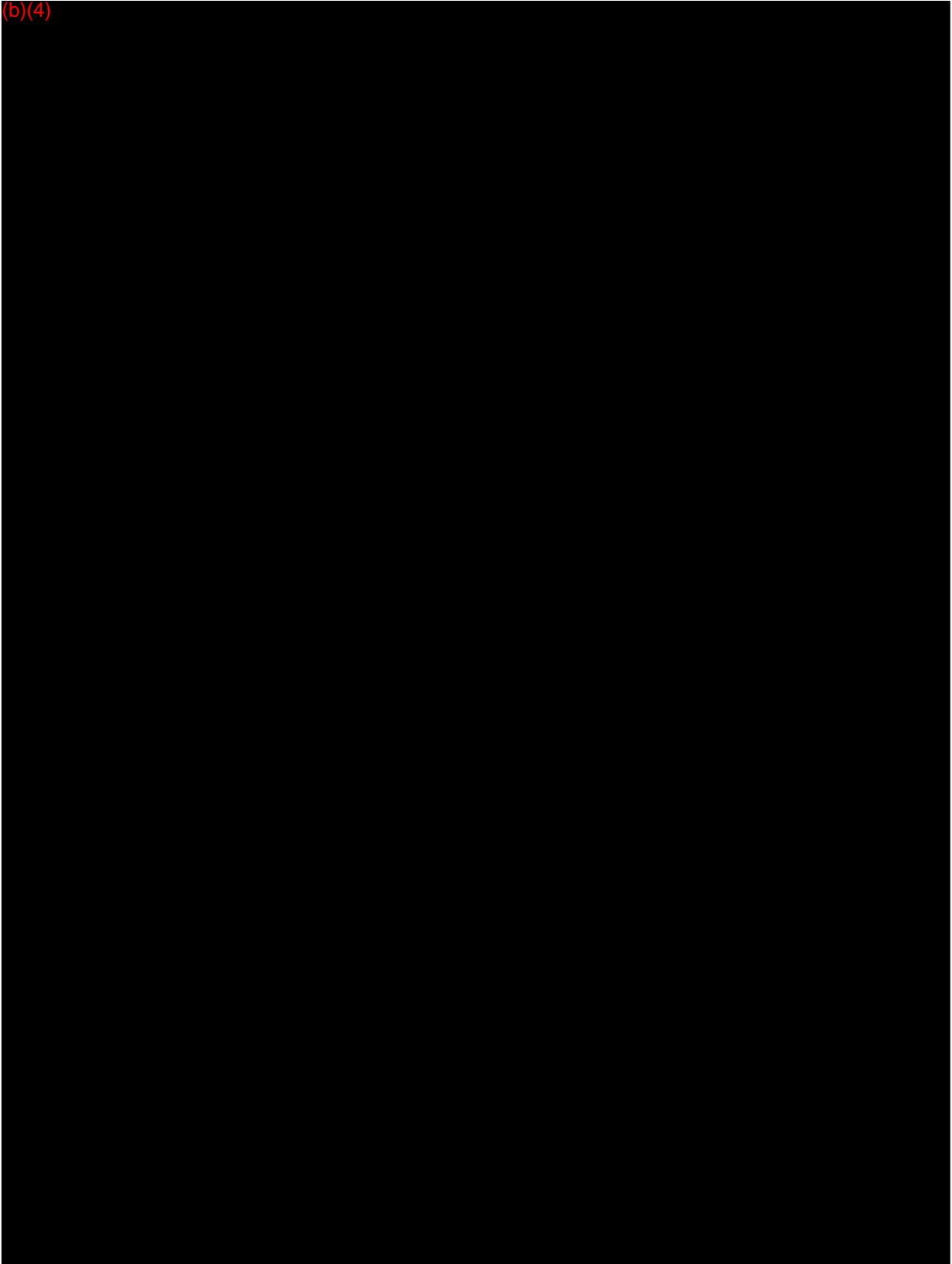
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MSDS: Enclosure and sensor head Material

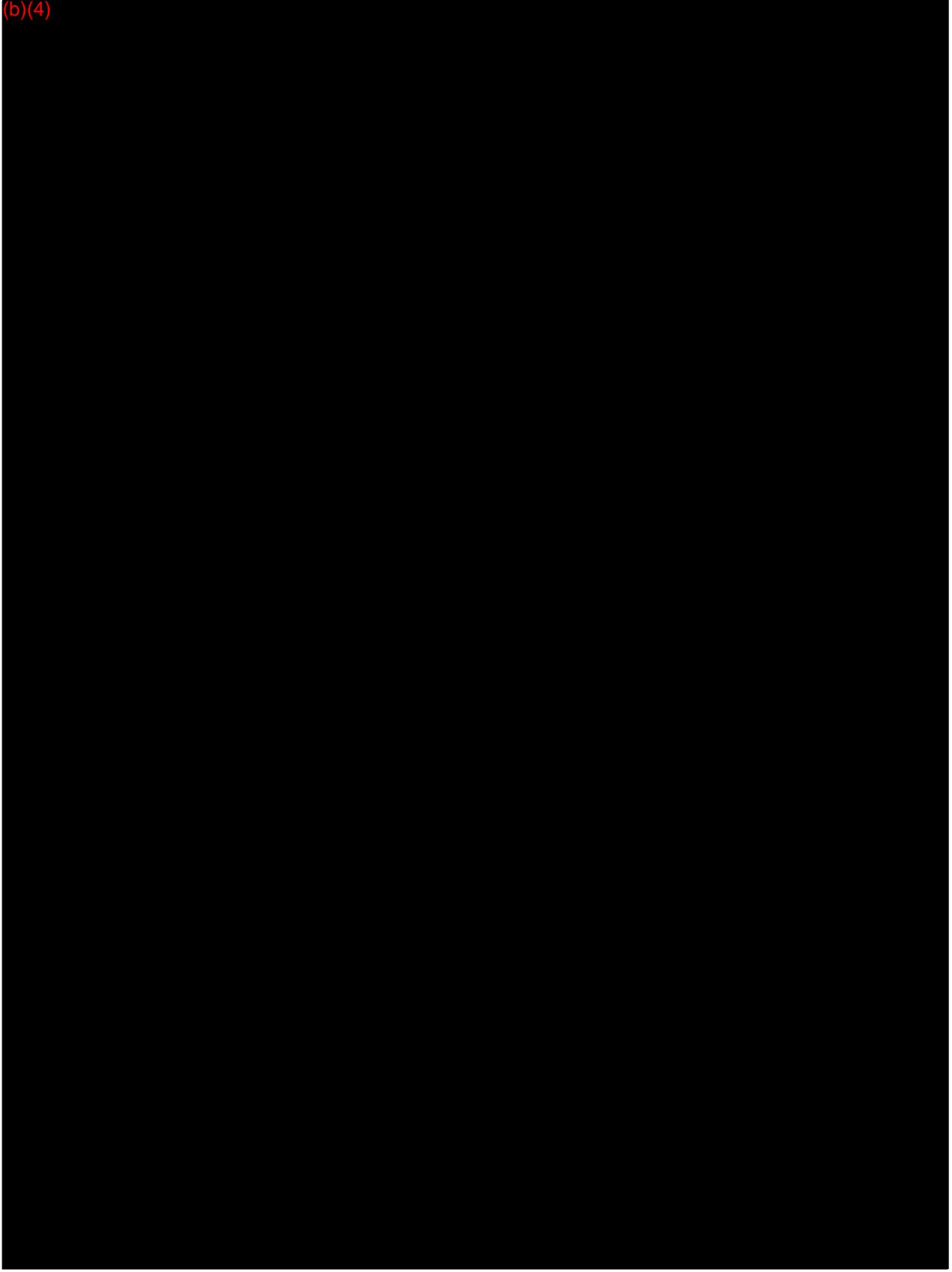
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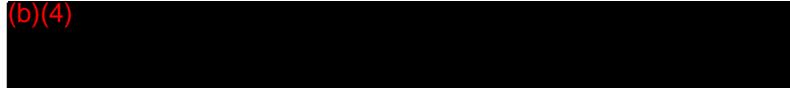
Confidential and Proprietary

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EXHIBIT 7
Software Development Information

1. Level of Concern
2. Software Description
3. Computer and Software Requirements Specification
4. Functional Software Requirements Specification
5. Architecture Design Chart
6. Device Risk Analysis
7. Software validation and verification: summary result
8. Software validation report
9. Software functional test report
10. Release Version Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) SKLAPPALAINEN
Subject: 510(k) Number (062481)
To: The Record - It is my recommendation that the subject 510(k)-Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this device subject to the Tracking Regulation?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Was clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Is this a prescription device?	<input checked="" type="checkbox"/> YES	<input type="checkbox"/> NO
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Special 510(k)?	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	<input type="checkbox"/> YES	<input checked="" type="checkbox"/> NO

Truthful and Accurate Statement Requested Enclosed
 A 510(k) summary OR A 510(k) statement
 The required certification and summary for class III devices
 The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 da.

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

74/DQD/II/21 CFR 870.1875

Review: [Signature] CEMB 10/12/06
(Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 10/13/06
(Division Director) (Date)



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

Memorandum

Date: October 10, 2006

From: Sharon K. Lappalainen, MT (ASCP), Scientific Reviewer, Cardiac Electrophysiology & Monitoring Branch, DCD (HFZ-450)

Subject: Substantial Equivalence (SE) Decision-Making Documentation

To: The Record of K062481

Device: SERENO Electronic Stethoscope

Sponsor: Pishon High Tech Co., Ltd.
2nd Floor Building 403-1
Daebang-dong, Dongjak-gu,
Seoul, 156-020, Korea

Contact: Daniel Kamm, PE
Kamm & Associates.

Review History/Background

Pishon High Tech, Co., Ltd presents a Traditional 510(k) for the SERENO Electronic Stethoscope. Electronic stethoscopes are Class II devices, regulated under Stethoscope (21 CFR § 870.1875) with a product code of 74 DQD.

Intended Use (From the Indications for Use Form)

The SERENO Electronic Stethoscope is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung, and other body sounds with the use of selective frequency and can be used on any patient undergoing a physical assessment.

	Yes	No
• Is the device life supporting or life sustaining?		✓
• Is the device implanted (short-term or long-term)?		✓
• Does the device design use software?	✓	
• Is the device sterile?		✓
• Is the device single-use?		✓
• Is the device for home use?		✓
• Or for prescription use?	✓	
• Does the device contain drug or biological product as a component?		✓
• Is this device a kit?		✓

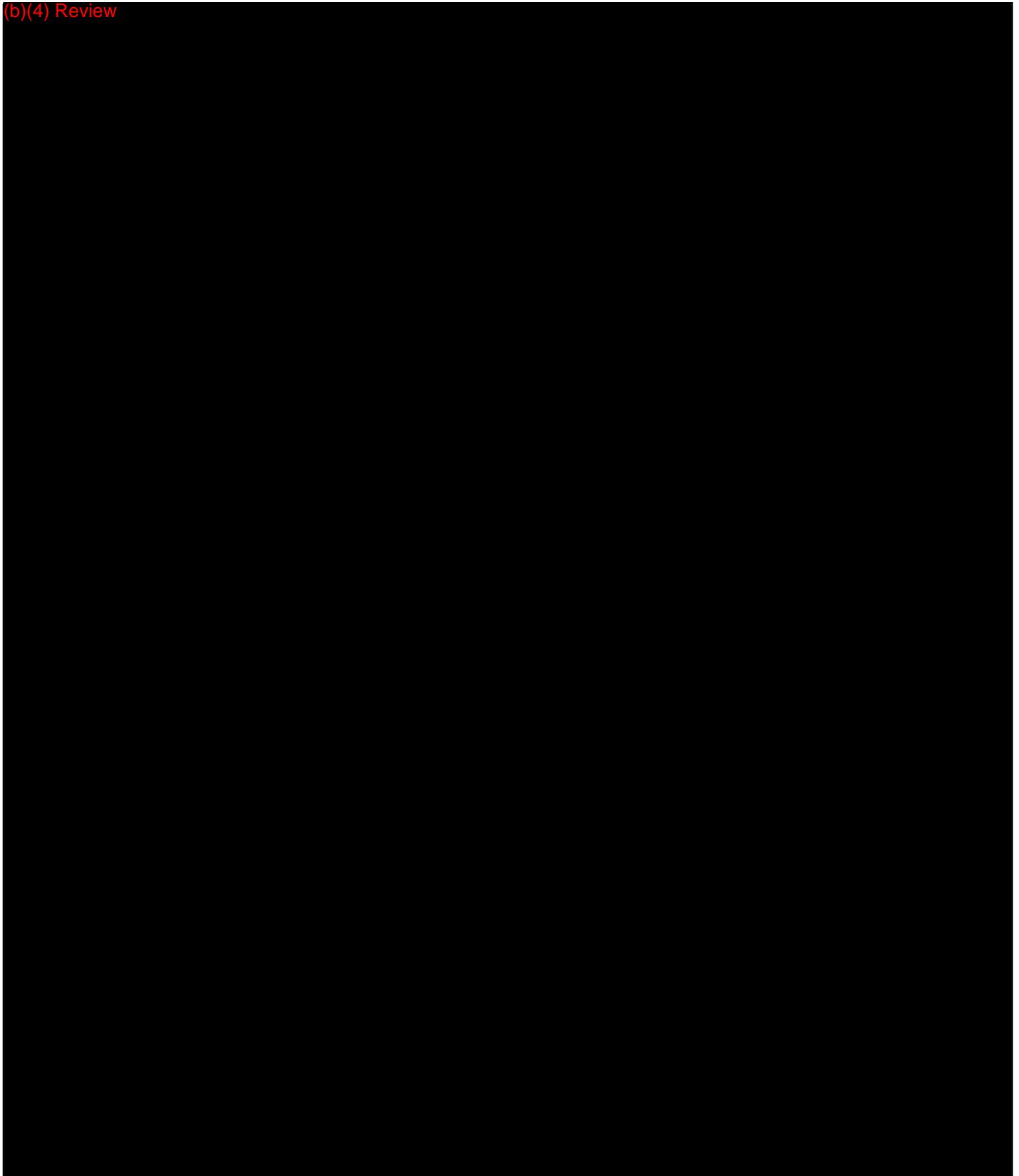
Device Description

The proposed device is a compact, portable, electronic stethoscope that amplifies sounds up to 20 times in a broad frequency range. The device is composed of a probe head, binaural pipes and ear tips. It incorporates 4 buttons on the top of the chest set which control/select mode, volume (up/down), and power (on/off). Sound amplification and frequency ranges for this device are

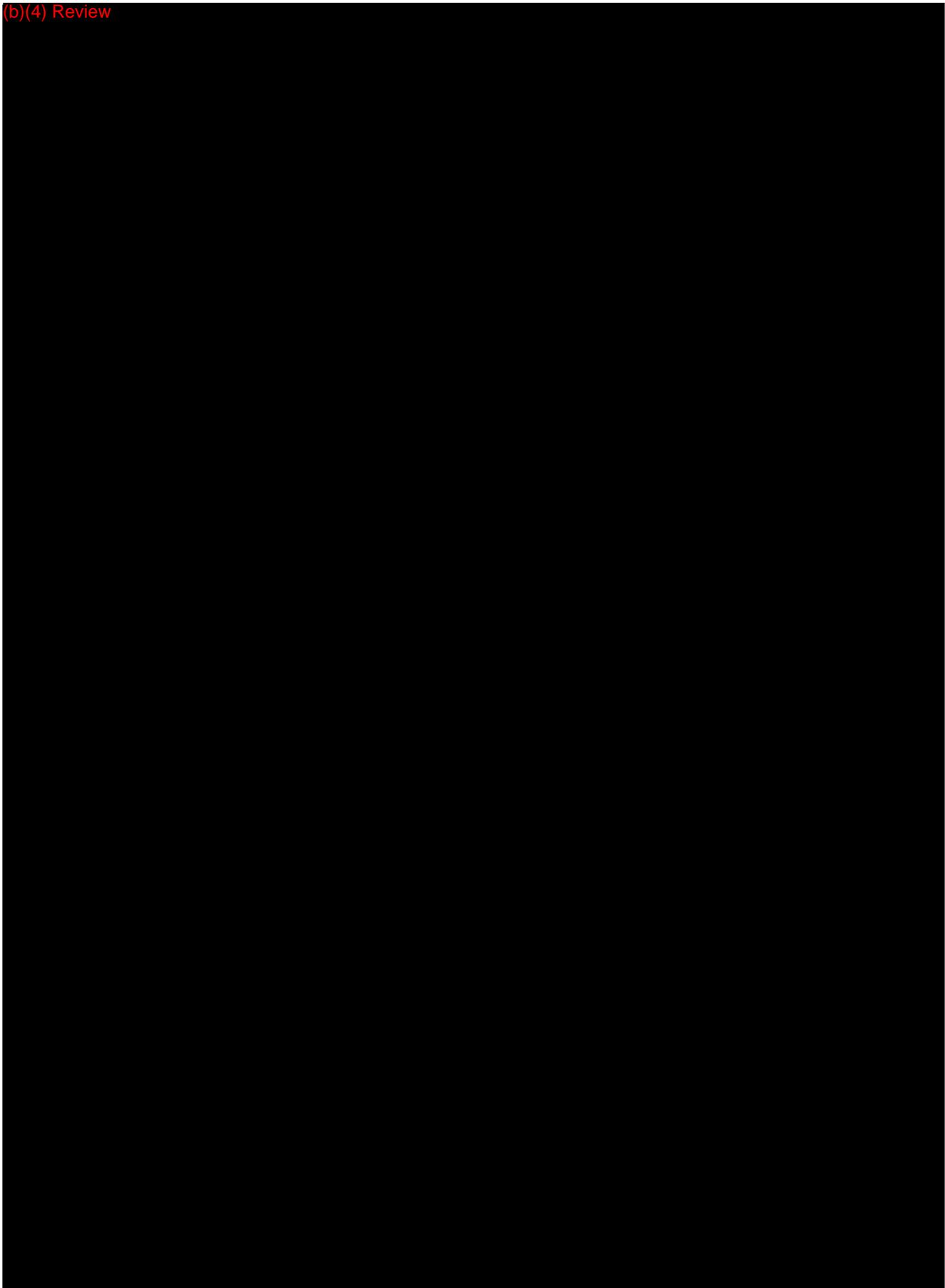
6

from 20 – 1,500 Hz. The device incorporates 3-step filtering circuitry in 3 modes: bell (low), diaphragm (high), and wide. The device also includes an LCD that displays volume level, frequency mode, and low battery indicator. The device supports connection for data share and transfer of audio sounds to audio equipment (cassette recorder, hi-fi audio component, or PC with sound card).

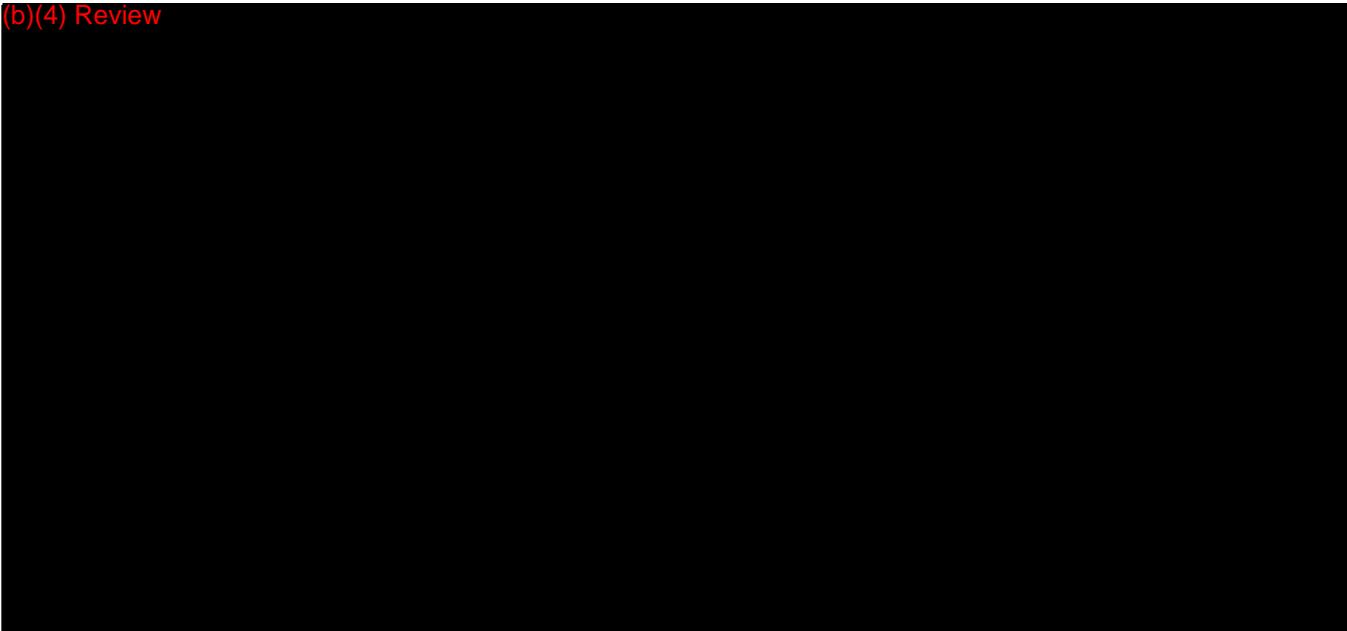
(b)(4) Review



(b)(4) Review



(b)(4) Review



The differences between the devices do not raise new issues of safety or effectiveness; therefore, I recommend the device be found substantially equivalent

Substantial Equivalence (SE) Decision Making Documentation

		YES	NO	
1.	Is Product A Device	4		If No = Stop
2.	Is Device Subject To 510(k)?	4		If NO = Stop
3.	Same Indication Statement?	4		If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5.	Same Technological Characteristics?	4		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		4	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?	4		If NO = Request Data
11.	Data Demonstrate Equivalence?	4		Final Decision: SE

7. Descriptive Characteristics are not sufficient. Explain.

Performance characteristics including information about biocompatibility, electrical safety, software, and performance information are needed to determine substantial equivalence.

9

10. Performance Characteristics demonstrate SE. Explain.

Data provided by the sponsor (e.g., biocompatibility, software documentation, and conformance to IEC/EN standards) indicate that the device will adequately perform to its intended use and indication for use.

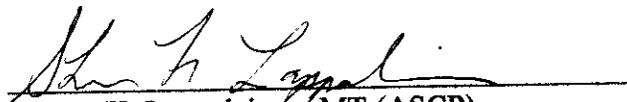
Administrative Requirements

The sponsor has provided the Truthful and Accurate Statement, 510(k) Summary, and Indication for Use Statement. **Administrative requirements are met.**

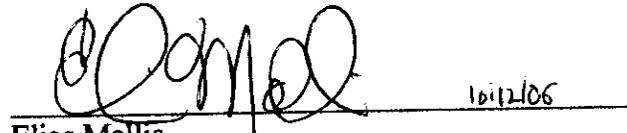
Recommendation

Substantially Equivalent to devices regulated under:

CFR Section: 21 CFR § 870.1875
Panel: 74
Product code: DQD,
Class: Class II


Sharon K. Lappalainen, MT (ASCP)

Scientific Reviewer, Cardiac Electrophysiology & Monitoring Branch, DCD


Elias Mallis,
Chief, Cardiac Electrophysiology & Monitoring Branch, DCD

Concur
 Do Not Concur

Comments:

Attachments (2):

- Attachment A: PishonWave Ver. 1.1 Instruction Manual
- Attachment B: 3M Littman Model 4000 Package Insert

INSTRUCTION

**How to use
PishonWave ver.1.1**

PISHON HK

BASIC INFORMATION

What is the PishonWave?

PishonWave is a PC-based analysis software to save and analyze diagnosis records from the Pishon Sereno Electronic Stethoscope.

This program supports below functions:

- Record & Visualize the sound signals into the wave data
- Playback the recorded data
- Save & Read the wave data and diagnosis records
- Calculate the pulse rate and Display its spectrum
- Send mail and Print wave or text

You may easily manage a patient's diagnosis records with this software.

Where can you find the PishonWave?

You may get access to Pishon High Tech's website www.pishon.com to download the software.

How to install the PishonWave?

- Get access to www.pishon.com and download the [PishonWave.exe] file to your PC.
- Double-click on the downloaded [PishonWave.exe] file, and the installation will start automatically.
- After the installation finishes, Activate the [PishonWave] on desktop.
- select [Directory] in the [Option] menu or click on  of the toolbar.
- Set a directory for the diagnosis and wave data.

PISHON 

BASIC INFORMATION

How to connect the stethoscope to your PC?

PC connecting cable is enclosed in the Sereno Electronic Stethoscope package.

- Insert the [⌋] plug of the cable into the phone jack and [—] plug into mic-in terminal of your PC.

⌋ plug into the phone jack



— plug into mic-in terminal



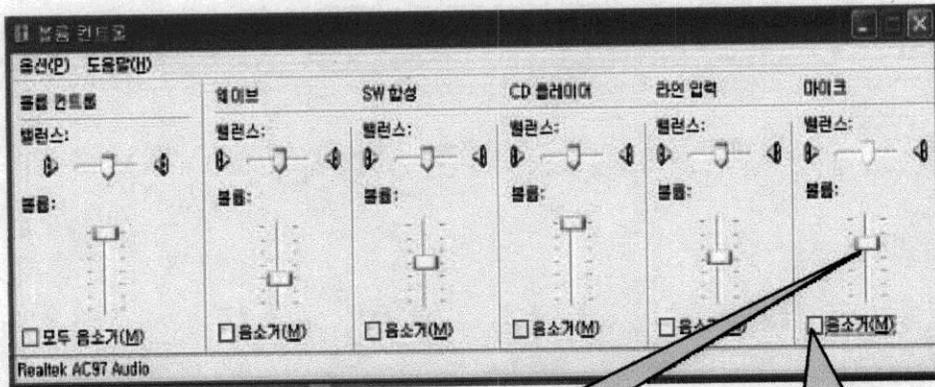
BASIC INFORMATION

Volume Control

Enter the Start -> Program -> Sub-Program -> Entertainment -> Volume Control menu of your Windows and adjust the Mic Volume properly.

NOTE

You must not set the Mute mode in order to enter the sound signals into your PC through the mic input.



Adjust the Mic Volume properly

You must not set the Mute mode.

Recommended PC specification

OS : Windows 98 or higher

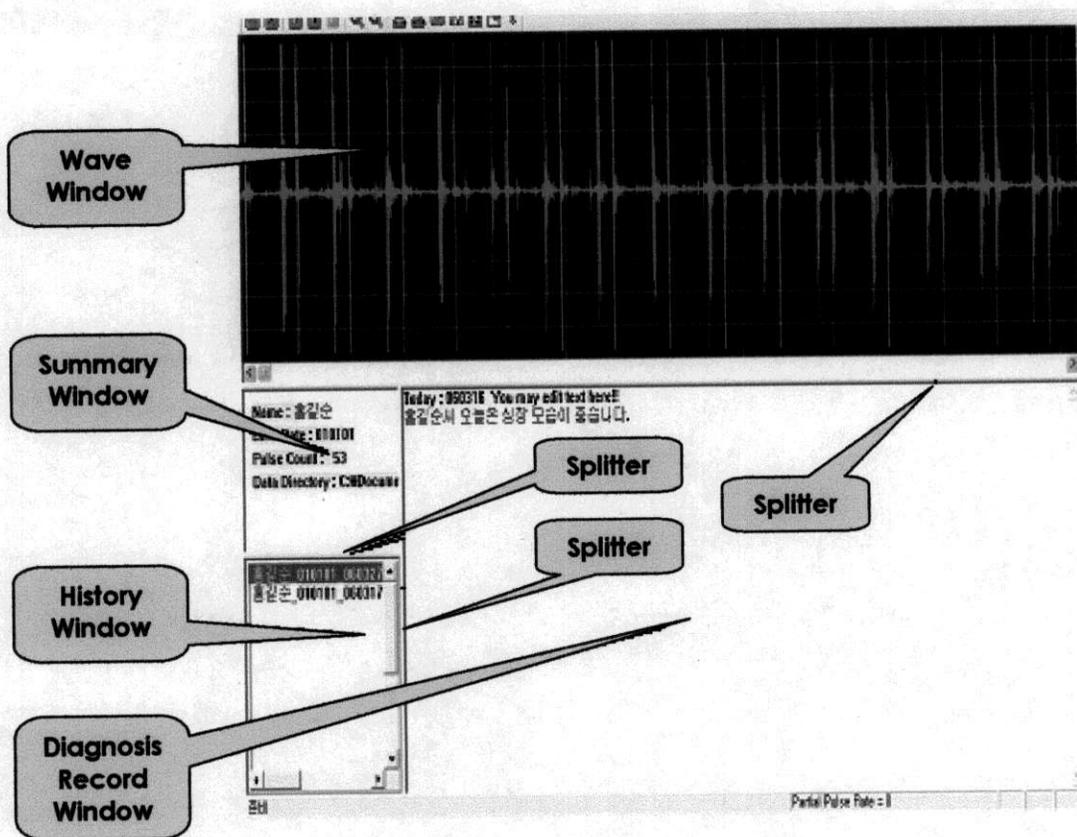
HOW TO USE THE PISHONWAVE

Window Composition

PishonWave is composed of 4 data windows;

- Upper window – **Wave Window**, Visualizes the sound signals into the wave data.
- Right lower sided window – **Diagnosis Record Window**, Write the diagnosis records.
- Left mid sided window – **Summary Window**, Shows the summarized information of the recorded file, patient' name/ birth date / pulse rate per min. & data directory. .
- Left lower sided window – **History Window**, Shows patient's diagnosis history as a list of the wave file.

You can adjust the window size by adjusting splitters.



HOW TO USE THE PISHONWAVE

Toolbar

There are 14 icons on the toolbar for the direct access to the menu.

-  **New** : Enters the patient's name and birth date.
-  **Save** : Saves the wave data and diagnosis records on the current window.
-  **Record** : Records the sound signals into the wave data.
-  **Play** : Playbacks the recorded sound signals.
-  **Stop** : Stops recording or playing back.
-  **Zoom In** : Zooms in the wave data.
-  **Zoom Out** : Zooms out the wave data.
-  **Print Wave** : Prints the wave data.
-  **Print Text** : Prints the diagnosis records text (*.pis) file.
-  **Send Mail** : Sends the diagnosis records or the wave data by e-mail.
-  **Mail Option** : Sets the SMTP server and your mail address.
-  **Directory Setting** : Sets a directory for the diagnosis and wave data.
-  **Partial Pulse** : Calculates a partial pulse rate for only one pulse cycle.
-  **Spectrum** : Displays a spectrum of the wave data.

MAIN MENU

New



New Client Window

You can enter a patient's name and birth date or search for the recorded data of other patients.

Click on  or Select [New Client] in the [File] menu, and the New Client window will appear.

This menu is composed as below;

- **Data Location** – shows the directory to enter the patient's information or to search for the recorded data.

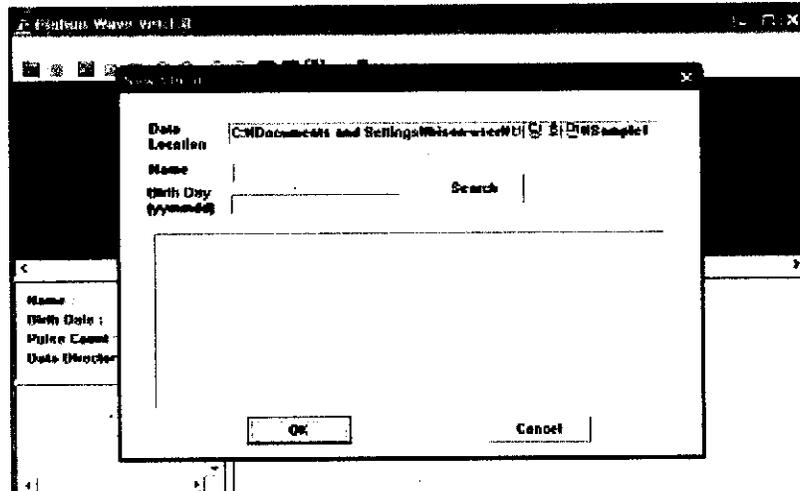
NOTE

You can just see the directory but, can not modify the directory. If you want to modify the directory setting, go to [Directory] in the [Option] menu or click on  of the toolbar.

- **Name** – Enter the patient's name.
- **Birth Date** – Enter the patient's birth date. You should enter the birth date in the integrated format, yymmdd (6 digits, Year-Month-Date).

Ex) If the birth date is March 9, 2001, you should enter 010309.

- **Lower blank window** – Shows the searched data for the patient you entered.



PISHON HA

MAIN MENU

How to use the New Client menu?

You can search for the patient's data by 4 ways below:

- **Name : Blank / Birth date : Blank** – Shows all patient's list in the current directory
- **Name : John / Birth date : Blank** – Shows all patient's list whose name starts with John in the current directory.
- **Name : Blank / Birth date : 010203** – Shows all patient's list whose birth date is February 3, 2001 in the current directory.
- **Name : John Smith / Birth date : 010203** – Shows all patient's list whose name is John Smith and his birth date is February 3, 2001 in the current directory.

How to select the patient's list?

If you select a patient in the searched patient's list, the selected patient's name and birth date will be displayed on the window.

You may enter the patient's name and birth date by manual without selecting the patient in the searched list.

Click on [OK] after selecting the patient, and the Summary Window will show the selected patient's name, birth date and pulse rate.

- If the selected patient has previous diagnosis histories, the Basic Window shows a list of the wave data file.
- If you double-click on the wave data file which you want to see, the wave data will be displayed on the Wave Window.

Click on  to record a new diagnosis data, and the current diagnosis data will be recorded.

PISHON 

MAIN MENU

Save

Save Window

You can save the wave data and diagnosis records on the current window.

Click on  or select [Save Wave Text] in the [File] menu, and the Save window will appear.

This menu is composed as below;

- **Data Location** – shows the directory to save the current diagnosis data.

NOTE

You can just see the directory but, can not modify the directory. If you want to modify the directory setting, go to [Directory] in the [Option] menu or click on  of the toolbar.

- **Client Name / Birth Date / Today / Sequence** – Enter the patient's name, his birth date, Today's date and Sequential No.

- **File Name** – shows the file name to save. The file name is automatically formed according to the of the patient's name, his birth date, Today's date and Sequential No.

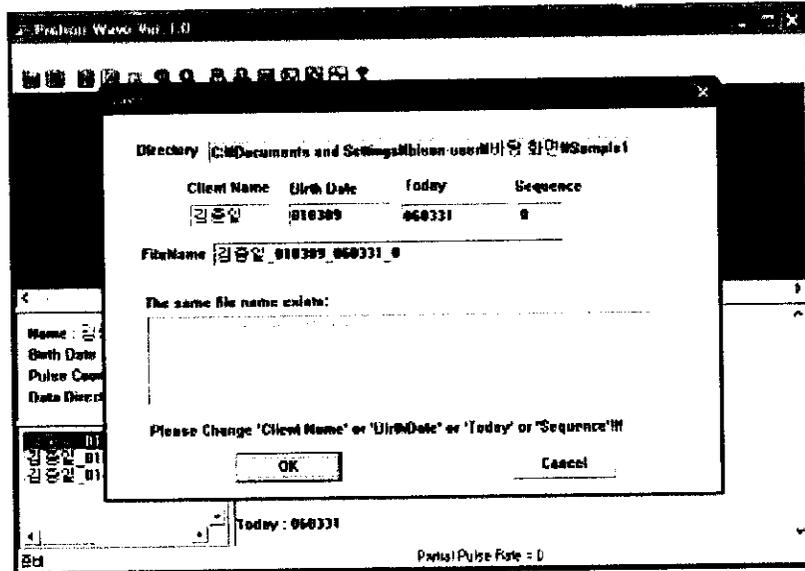
In order to edit the file name, you should modify one among Client Name / Birth Date / Today / Sequence.

- **The same file name exists** – This window shows whether the same file with the current file name to save exists in the fixed directory.

If the same file exists in the directory, you should modify the sequential no. among Client Name / Birth Date / Today / Sequence.

PISHON H

MAIN MENU



Record



You can record the sound signals into the wave data.

Click on  or select [Record] in the [Sound] menu, and the recording will start.

You can record the sound signals up to 20 sec.

If you want to stop recording, click on  or select [Stop] in the [Sound] menu.

During the recording, the sound signals will be transformed into the wave data on the Wave Window. When the recording time exceeds 20 sec. or you stop recording, the pulse rate per min. will be automatically calculated based upon the recorded wave data and it will be displayed on the Summary Window.

NOTE

In case of low quality of the recording or lack of the recording time (less than 6 seconds), it may not calculate the pulse rate.

PISHON H

MAIN MENU

Play

You can playback the recorded sound signals of the current wave data.
Click on  or select [Play] in the [Sound] menu, and the playback will start.

If you want to stop playing back, click on  or select [Stop] in the [Sound] menu.

Stop

You can stop recording or playing back the sound signals.
Click on  or select [Stop] in the [Sound] menu, and the recording or playback will stop.

Zoom In

You can zoom in the wave data on the current Wave Window.
Click on  or select [Zoom In] in the [View] menu.

Zoom Out

You can zoom out the wave data on the current Wave Window.
Click on  or select [Zoom Out] in the [View] menu.

MAIN MENU

Print Wave

You can print the wave data on the current Wave Window.
Click on  or select [Print Wave] in the [File] menu.

NOTE

As the PishonWave supports the horizontal print of the wave data, it is desirable to set the paper direction as Horizontal in the printer setup menu.

Print Text

You can print the text data on the Diagnosis Record Window.
Click on  or select [Print Text] in the [File] menu.

Send Mail

You can send the diagnosis records or the wave data by e-mail.
Click on  or select [Send Mail] in the [Options] menu.

Enter the e-mail addresses, subject, text and attach data files then, Click on [Send].
You may add the attachment files up to 5 and remove a selected file from the attachment file list.

MAIN MENU

Mail Option

You can set the SMTP server and your e-mail address.

Click on  or select [Mail Option] in the [Options] menu.

SMTP server is a sort of stopover.

Once you sent an e-mail, the mail will collect to the SMTP sever and it will be sent to a recipient again through the SMPT server.

- As almost ISPs (Internet Service Provider) provide the use of the SMTP server to their account users, the users can use the SMTP server from their mail account.
- In case you don't use the ISP server and have your own internet server, you can use the SMTP server from your own internet server.
- If you use neither the ISP server nor your own internet server, contact your leased line provider and you can get information of the SMTP server.

Directory Setting

You can set a directory for the diagnosis text file and the wave data file to be recorded.

Click on  or select [Directory] in the [Options] menu.

Select a disk volume and set the directory for data. You may input the directory by manual or select the directory among the folder tree of the selected disk by pressing the

 icon.

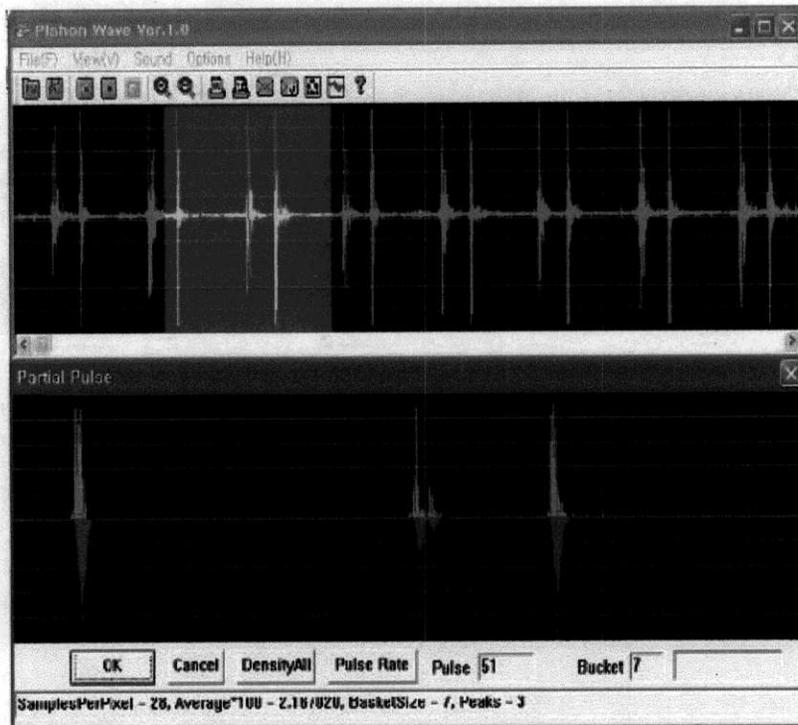
MAIN MENU

Partial Pulse

You can calculate a partial pulse rate for only one pulse cycle.

In general, a pulse rate is automatically calculated when the recording is finished or you select a wave data file. But in case there are a lot of noises or there is no consistency in the recorded file, it may not calculate the pulse rate. In this case, you can calculate the partial pulse rate for only one pulse cycle with this menu.

Drag an area for only one pulse cycle and click on  or select [Partial Pulse] in the [Sound] menu. Then, a new window for the partial pulse will appear and the pulse rate per min. will be automatically calculated.



MAIN MENU

Spectrum

You can analyze a frequency of the wave data.

Click on  or Select [Spectrum] in the [Sound] menu in order to see the spectrum of the wave data.



History of the PishonWave Ver.1.1

PishonWave Ver.1.1 released in Mar. 31, 2006 is a revised version of the PishonWave Ver.1.0 released in Nov., 2005.

The amendments from the Ver.1.0 are as below;

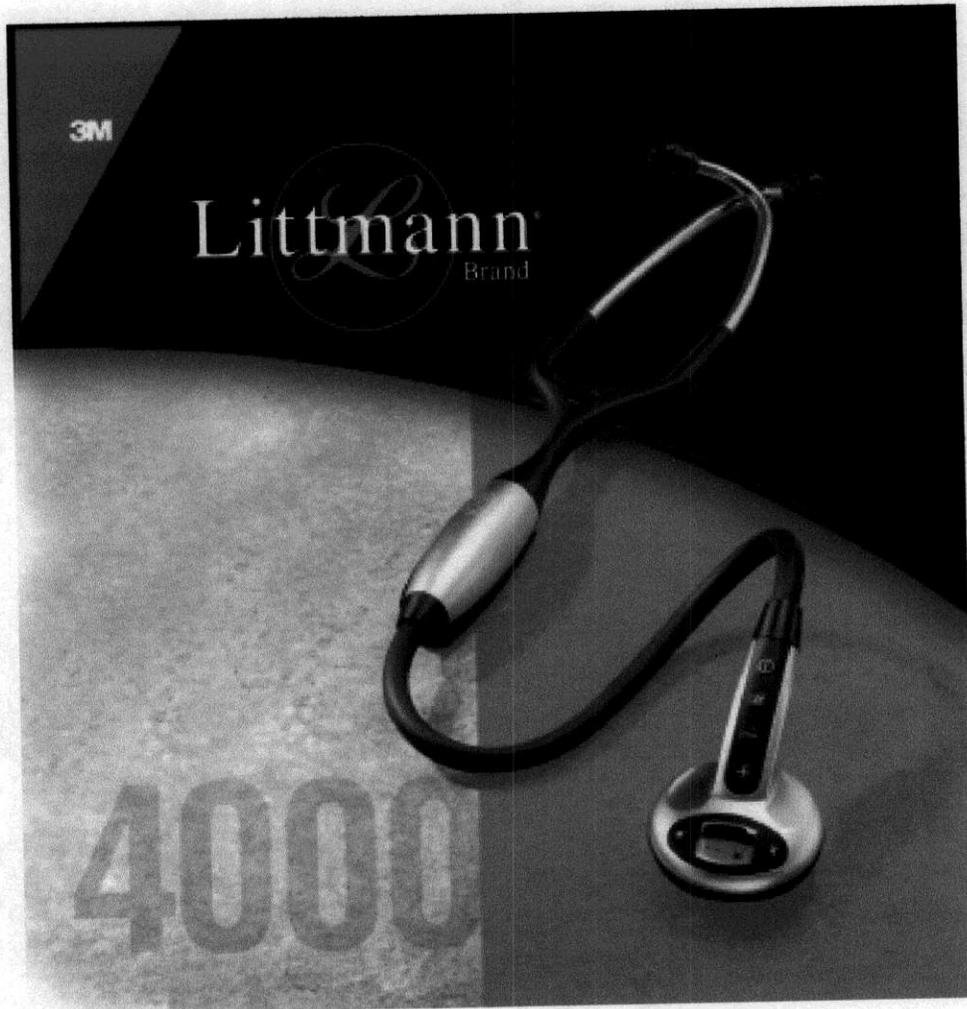
- The file I/O structure was modified.
- The partial pulse function and the Spectrum analysis function were added.

PISHON HIGHTECH

If you have any inquiry about PishonWave Ver.1.1,
please contact us by using Call Center (82-2-826-1750)
or Q/A board on our web site www.e-pishon.com.

PISHON HHS

ATTACHMENT B



3M™ Littmann® Electronic Stethoscope Model 4000

Congratulations on the purchase of your new Littmann Electronic Stethoscope Model 4000, the next generation electronic stethoscope that offers the very latest in advanced auscultation technology.

This powerful, state-of-the-art electronic stethoscope provides superior acoustics. With amplification up to 18 times greater than the best conventional stethoscopes, the Model 4000 is specially designed to pick up difficult-to-hear heart and other body sounds. Three frequency modes are available for optimal heart and lung auscultation: Bell, Diaphragm and Extended Range.

The Littmann Electronic Stethoscope Model 4000 offers recording, storage and playback capabilities on six different soundtracks. Instant playback is available at normal and half speed.

Additionally, the Model 4000 provides infrared data transmission of recorded sounds to either another Model 4000 or an IBM-compatible PC, giving you the option of sharing or storing the sounds.

Other features include digital signal processing over the entire acoustic range, built-in display for easy viewing of the heart rate, patient-friendly nonchill rim, and patented 3M™ Littmann® Snap Tight Soft-Sealing Eartips for excellent acoustic seal and comfortable fit. Plus, the Model 4000 operates on just two AAA alkaline batteries.

Most of all, know that the Model 4000 carries the Littmann brand name, the name known worldwide for unsurpassed quality. As a trusted leader in auscultation technology, the Littmann brand of stethoscopes is your assurance of acoustic superiority, innovative design and exceptional performance.

The following symbols are applicable to this device:



• Attention, see instructions for use.



• Indicates Type B Equipment: The equipment provides protection against electrical shock and electrical current leakage.

IPX4

• Avoid penetration of fluids into the eartip openings. The remainder of stethoscope is protected against splashing liquid.



• This product and package do not contain natural rubber latex.

Each Littmann Electronic Stethoscope Model 4000 has a serial number beginning with "SN P".

Indications

The Littmann Electronic Stethoscope Model 4000 is intended for medical diagnostic purposes only. It can be used for the amplification of heart, lung and other body sounds with selective frequency filtering. The Model 4000 can also be used for recording, playback and transmitting/receiving of heart, lung, and other body sounds. This product is not designed, sold, or intended for use except as indicated.

⚠ Caution

- Failure to follow directions, general use, and maintenance recommendations could result in damage to the device or possible injury to the user. Damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.
- Half speed playback is for reference and should not be the only basis for diagnosis.
- It is the responsibility of the clinician to assure that all recordings and data transmissions correspond to the appropriate patient data.
- Transmissions of soundtracks to a computer are for storage purposes only. Soundtracks should not be listened to from a computer for diagnostic purposes.

- The Littmann Electronic Stethoscope Model 4000 has been tested to be resistant to both electromagnetic fields (EMI) and electrostatic discharge (ESD). However, it may be susceptible to very strong radio frequency signals. When using the stethoscope, if sudden or unexpected sounds are heard, the Model 4000 may be in close proximity to a strong radio transmitter. If this should occur, move away from the radio's transmitting antenna.
- Use only AAA alkaline batteries.
- The Model 4000 will not function if the batteries are depleted.
- Do not immerse the stethoscope in any liquid or subject it to any sterilization processes. The entire Model 4000 can be wiped clean with alcohol.
- At the end of this device's useful life, dispose or recycle in accordance with your local, state, and governmental regulations.
- If you have any problems with the Model 4000, do not attempt to repair it yourself. Refer to the Service and Warranty section of this manual.

Instructions For Use

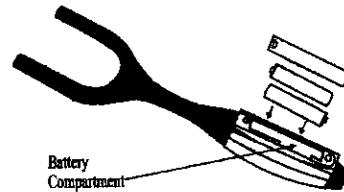
Battery

When used in a typical setting, the Littmann Electronic Stethoscope Model 4000 will operate for about one month on two AAA alkaline batteries. Using the recording options or infrared data transfer will reduce the average battery life.

When the batteries are close to depletion, the LOW BATTERY indicator, located on the display, will blink. When this occurs, the batteries should be replaced within two hours of continuous use.

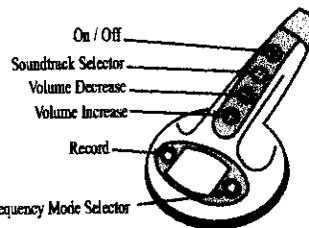
When the batteries are no longer able to power the Model 4000 stethoscope, the stethoscope will automatically turn off. All recorded sounds and settings are saved. The Model 4000 will not function if the batteries are depleted.

Insert batteries as shown

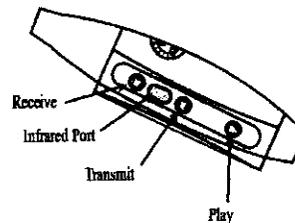


Electronic Controls

The chestpiece of the Littmann Electronic Stethoscope Model 4000 contains six buttons:



The battery compartment of the Model 4000 contains three buttons and the infrared port:



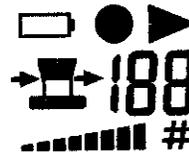
Electronic Control Quick Reference

(Refer to Operation section for complete instructions)

- On/Off** Press the ON/OFF button to turn the stethoscope on.
Press the ON/OFF button for approximately two seconds to turn the stethoscope off.
Pressing the ON/OFF button cancels the current action, for example, to stop a playback, transmission, or reception of a soundtrack.
- Soundtrack Selector** There are six soundtracks available on the Model 4000. Press the SOUNDTRACK SELECTOR button once to display soundtrack one, press again to advance to the next sound track.
- Volume Decrease** Press the VOLUME DECREASE button to decrease the sound level.
- Volume Increase** Press the VOLUME INCREASE button to increase the sound level.
- Record** Press the RECORD button for one second to record sound onto the selected soundtrack. Press again to stop recording.
- Frequency Mode Selector** Press the FREQUENCY MODE SELECTOR button to select Bell, Diaphragm or Extended Range.
- Receive** Press the RECEIVE button to receive a soundtrack from another Model 4000 or computer.

- Transmit** Press the TRANSMIT button to transmit the displayed soundtrack to another Model 4000 or computer.
- Play** Press the PLAY button to hear the selected soundtrack. The display panel will indicate that the playback is at normal speed. Press and hold the PLAY button for two seconds to play back in half speed. The display panel will indicate that the playback is at half speed. To return to normal speed, press the PLAY button again. Stop playback by pressing the ON/OFF button.

Display Panel



The above picture demonstrates the graphics that are used on the Model 4000 display panel. As a functional test, when the Model 4000 is turned on, all the graphic indicators as shown above will be briefly displayed. After this brief test, the display will then indicate the current listening mode and the volume setting. The factory setting for listening mode is Bell mode and a volume setting of level three.

If *Er* is shown on the display, refer to the Error Message section.

When the display panel shows:



It means:

Blinking means the two batteries are almost depleted.



The sound volume has eight levels. The bar shows the current sound level, increasing from the left. The more bars visible, the higher the sound level. When one element is displayed, the sound level is similar to a typical acoustic stethoscope. This is also used to indicate soundtrack reception or transmission progress during data transmission.



Bell mode.



Diaphragm mode.



Extended range mode. The extended range amplifies sound from a broader range of frequencies than the bell or diaphragm mode.



Playing a recorded sound at normal speed.



Playing a recorded sound at half speed.



Recording a sound.



Transmitting a recording. The arrow will blink until the infrared connection is made. After connection is made, the arrow will no longer blink.



Receiving a recording. The arrow will blink until the infrared connection is made. After connection is made, the arrow will no longer blink.



The number displayed indicates the soundtrack currently selected.



The symbol indicates that the soundtrack is occupied by a previous recording. If is not displayed, the soundtrack is vacant. When the is rotating, a sound transmission is in progress.

is located below the number of the soundtrack you have selected.



A number displayed is the heart rate. If two dashed lines are displayed, refer to the heart rate section.



If the display is blinking , the heart rate is above bpm and cannot be displayed.



Error Message. See Error Message section of this manual

**Operation
Power On**

Press the ON/OFF button on the Littmann Electronic Stethoscope Model 4000. The factory or personalized setting will be in operation.

Automatic Power Off	<p>The Model 4000 automatically turns off three minutes after the last actuation of any button. Press the ON/OFF button within 10 seconds of automatic power off and the same settings will be restored. If longer than 10 seconds have transpired, the Model 4000 will power up at your personalized setting or factory setting.</p> <p>Note, the stethoscope will not power off automatically during a data transmission.</p>	<p>rate is not displayed during recording or playback.</p> <p>The acoustic-based heart rate display functions best when the Model 4000 is placed near the apex of the patient's heart. If the heart rate changes from consistent to inconsistent or if there is excessive ambient noise, patient movement or lung sounds during auscultation, the heart rate display number will flash or display two dashes (-). The flashing heart rate will change to two dashes (-) after 10 seconds of inconsistent sounds or no heart rate detection.</p>
Change Sound Volume Level	<p>Press the VOLUME INCREASE or VOLUME DECREASE button. The sound volume bar displays the change.</p>	Select Soundtrack
Change Frequency Mode	<p>Press the FREQUENCY MODE SELECTOR button to select one of the frequency ranges (Bell, Diaphragm or Extended). The selection is indicated on the display panel.</p>	<p>Select any one of the six soundtracks by pressing the SOUNDTRACK SELECTOR button one or more times. The selected soundtrack is displayed. A number shown by itself indicates an empty track. A number shown with the  indicates a recorded soundtrack. Recording on a soundtrack that displays the  will erase the currently stored sound.</p>
Personalized Setup	<p>The Model 4000 is factory set in bell mode and sound level 3. To personalize setup, select the desired frequency mode and volume level, and then press and hold the FREQUENCY MODE SELECTOR button for two seconds. The Model 4000 will now function with these settings on startup.</p>	Recording
Heart Rate	<p>The Model 4000 detects and displays an acoustic-based heart rate. It takes five seconds to compute the initial heart rate and is updated every two seconds. For heart rates below 30 bpm or before the initial reading, the display shows two dashes (-). Heart rates above 199 bpm will flash the number 199. Heart</p>	<p>Press the ON/OFF button to return to the heart rate display.</p> <p>Press and hold the RECORD button for one second. The record symbol will flash in the display. Press the record button again to stop recording. Wait for approximately two - three seconds after an auscultation event before pressing the RECORD button to stop recording. Each soundtrack has a recording duration of eight seconds. Each recording must be at least two seconds in duration.</p>

	<p>The recording process captures the full frequency range and stores it on the soundtrack. This allows the ability to change the frequency mode from bell, diaphragm or extended range during playback. To ensure that clear auscultation sounds are captured, do not adjust volume or frequency mode during recording.</p>	
Playback	<p>To play back a recording, select the desired soundtrack and press the PLAY button. When the entire soundtrack has been played, there is a one second delay before the soundtrack will play again. To end playback, press the ON/OFF button.</p>	
Half Speed Playback	<p>Press and hold the PLAY button for two seconds. To stop the continuous half speed and return to normal playback, press the PLAY button. To end playback, press the ON/OFF button.</p>	
Erase Single Soundtracks	<p>Erase soundtracks by recording new sounds onto them. Erased soundtracks cannot be recovered.</p>	
Erase All Sound Tracks (use with caution)	<p>Press and hold the SOUNDTRACK SELECTOR button for two seconds. This will erase all soundtracks. Erased soundtracks cannot be recovered.</p>	
Data transmission to another Littmann Electronic Stethoscope Model 4000	<p>1. Select the soundtrack to be transmitted and the soundtrack to receive the transmission. 2. Position the two IR ports within two feet.</p>	<p>3. Press the RECEIVE button on the receiving Model 4000 then press the TRANSMIT button on the transmitting Model 4000. The arrow will blink until the infrared connection is made. 4. Transmission is indicated on the Model 4000 display by a rotating . 5. Progress of the transmission is shown on the Model 4000 display with the  symbol. To stop the transmission, press the ON/OFF button on either stethoscope.</p> <p>1. Select the soundtrack to be transmitted. 2. Position the two IR ports within two feet 3. Press the Model 4000 TRANSMIT button. The arrow will blink until the infrared connection is made. 4. Transmission is indicated on the Model 4000 display by a rotating . The computer status bar will display two red lights flashing towards one another. 5. Progress of the transmission is shown on the Model 4000 display with the  symbol. 6. WINDOWS 95/98 - Downloaded soundtracks are stored in: C:\My Received Files.</p>

Sending a copy of a soundtrack to a computer using Microsoft® Windows® 95/98/2000® with an infrared (IR) port

1. Prompts may vary between versions of Windows and are the responsibility of the Microsoft. References to Windows in it pertain to use of the Littmann Electronic Stethoscope Model 4000 are for clarification only. Please consult your Microsoft users manual for specific instructions. Microsoft® and Windows® are trademarks of Microsoft Corporation.

WINDOWS 2000 - Downloaded soundtracks are stored in: C:\Documents and Settings\username\Desktop and appear on the desktop.
7. The soundtrack filename format is: 'Trk*.e4k' (* is the soundtrack number on the stethoscope)
Example: soundtrack 2 = 'Trk2.e4k'
If the default soundtrack filename already exists, a new name, 'Copy of Trk*.e4k' or 'Copy # of Trk*.e4k' is given, example: soundtrack 2 = 'Copy of Trk2.e4k' (# is the number of duplicates from the same soundtrack)
It is advisable to rename the soundtrack files once they are transmitted to avoid confusion. It is not necessary to maintain the file extension *.e4k.

If Er appears in the display of the stethoscope, refer to the Error Messages section of this manual to determine a possible cause.

Receiving a copy of a soundtrack from a computer using Microsoft® Windows® 95/98/2000® with an infrared (IR) port

WINDOWS 95/98 - From the Start menu select 'Start - Programs - Windows Explorer'. Open the folder "My Received Files" and locate the soundtrack file to be transmitted.
WINDOWS 2000 - From the desktop (or within the folder that contains the soundtrack file to be transmitted) locate the soundtrack file to be transmitted.
1. Select the Model 4000 soundtrack to receive the transmitted file
Caution: If the selected soundtrack contains a recording, the transmitted

file will replace it. Erased soundtracks cannot be recovered.

2. Position the two IR ports within two feet.
3. Press the Model 4000 RECEIVE button. The arrow will blink until the infrared connection is made.
4. Immediately right click on the soundtrack file to be transmitted and select 'Send To - Infrared Recipient'
5. Transmission is indicated on the Model 4000 display by a rotating symbol. The computer status bar will display two red lights flashing towards one another.
6. Progress of the transmission is shown on the Model 4000 display with the symbol.

Note: The soundtrack filename is not transmitted to the stethoscope. If Er appears in the display of the stethoscope, refer to the Error Messages section of this manual to determine a possible cause.

Error Messages

If Er shows while transmitting data to another Model 4000 or a computer:

- The path of infrared light may be blocked. Position the infrared ports at each other and retry the operation.
- The infrared port may be dirty. Clean both infrared ports.
- The Model 4000 was removed before the soundtrack was

2. Products may vary between versions of Windows and are the responsibility of the Microsoft. References to Windows as it pertains to use of the Littmann Electronic Stethoscope Model 4000 are for clarification only. Please consult your Microsoft users manual for specific instructions. Microsoft® and Windows® are trademarks of Microsoft Corporation

completely transferred. Do not move the stethoscopes until the  is finished rotating.

- The Model 4000 may be exposed to excessive EMI/RFI, electromagnetic noise. Remove the source of noise.

If none of these is the cause, refer to the Littmann Stethoscope Service and Warranty section.

Headset Positioning

The Littmann Electronic Stethoscope Model 4000 is designed to provide a comfortable, acoustically sealed ear fit. Notice that the eartubes are permanently set at an angle to accommodate the typical anatomy of the ear canal. The eartips should point in a forward direction when inserted into the ear canals.

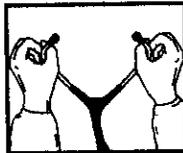


Correct

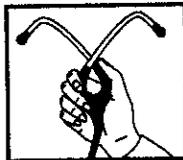


Incorrect

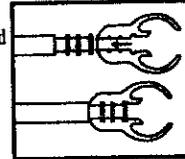
To reduce spring tension in the headset, hold each eartube at the bend near the eartip and gradually pull apart until fully extended.



To increase spring tension, grasp the headset with one hand where the eartubes enter the plastic tubing and squeeze until the plastic tubing on one eartube touches the other. Repeat as necessary.



For maximum acoustic performance, comfortable patented 3M™ Littmann® Soft-Sealing Eartips are provided with the stethoscope. The stethoscope utilizes a unique design for attaching the eartip to the eartube.



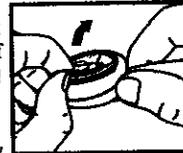
The eartips are pushed onto the end of the eartube and snapped in place. To remove, pull firmly on the eartip.

Diaphragm Removal and Replacement

Under normal conditions, it is unnecessary to remove the rim and diaphragm for cleaning. The diaphragm can easily be cleaned with an alcohol wipe. If, however, it is necessary to remove the rim and diaphragm, carefully follow instructions:

Rim Removal:

- With diaphragm side up, using a thumbnail, pry the rim out of its designated groove, and pull towards you. If the diaphragm does not come off along with the rim, remove this separately.



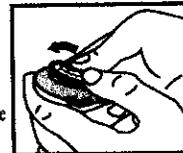
Do not disturb the components located under the diaphragm once it is removed.

Cleaning of the Rim and Diaphragm:

- Separate the diaphragm from the rim, and clean with mild soapy water and/or alcohol. The surface of the chestpiece can also be wiped with alcohol. Take care not to saturate the chestpiece. Excess liquid used in the cleaning process can result in moisture getting into the internal components.

Diaphragm and Rim Reassembly:

- Once the rim and diaphragm are completely dry, place the rim on a firm surface. Insert the diaphragm into the inside



groove of the rim, starting at one point, and running your finger around the inside of the rim. This technique will position the diaphragm properly in the designated groove.

- Place the rim and diaphragm assembly on the chestpiece surface. Totally engage the assembly in the groove on chestpiece at one point and hold in place with thumb. Slowly roll the rim around the chestpiece edge using both thumbs moving in opposite directions.

General Use and Maintenance

- The entire stethoscope can be wiped clean with alcohol.
- Do not immerse the stethoscope in any liquid or subject it to any sterilization process.
- Eartips can be removed for a thorough cleaning.
- Remove the battery whenever the stethoscope is stored or will not be used for several months.
- Avoid extreme heat, cold, solvents and oils. Recommended storage conditions are from -4°F to 140°F (-20°C to 60°C), 15 to 95% relative humidity.

Failure to follow care and maintenance recommendations could result in damage to the internal components of the Model 4000. Internal damage could cause malfunction of the product, ranging from a slight decrease in auditory response to complete failure of the product.

If you experience any problems with the Model 4000 do not attempt to repair it yourself. Please notify the 3M Health Care Service Center for directions on shipping and receiving.

Littmann Stethoscope Service and Warranty Program

The Littmann Electronic Stethoscope Model 4000 is warranted against any defects in material and manufacture for a period of one year. If a material or manufacturing defect is discovered during the warranty period, repairs will be made

without charge upon the return of the instrument to 3M, except in cases of obvious abuse or accidental damage.

For technical questions, call the 3M Health Care Tech Line at 1-800-441-1922.

For maintenance or repair services in the United States, send your stethoscope directly to:

3M Health Care Service Center

3M Building 502-1W-01
3350 Granada Ave N
Suite 200
Oakdale, MN 55128
1-800-292-6298

Enclose your name, address, phone number and reason for repair with your stethoscope.

In Canada:

3M Health Care Service Center
3M Canada Inc.
80 Enterprise Drive South
London, Ontario
Canada N6N1C2
1-519-668-3663

Outside of the United States and Canada, contact your local 3M subsidiary for maintenance and repair information.

Littmann
Brand



Made in Denmark for **3M Health Care**, St. Paul, MN 55114
(U.S.A.) 1-800-228-3957 • Fax 612-736-2803
Visit our web site: <http://www.3M.com/Littmann>

 Attention, see instructions for use.
0086 **3M Health Care** D-46325 Borken, Germany

3M is a trademark of 3M.
Littmann is a registered trademark of 3M.
34-7051-7198-0

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	N/A	CLASS II
4. If, not, has POS been notified?		
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?	✓	✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	—	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	—	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.	✓	

**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: K062481

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	—	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	—	
510(k) Kit Certification ***	—	

* - May not be applicable for Special 510(k)s.
 ** - Required for Class III devices, only.
 *** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	✓	
b) Sterilization and expiration dating information:	N/A ↓ REUSABLE ↓ ✓	
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:	✓	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No
 Reviewer: [Signature]
 Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

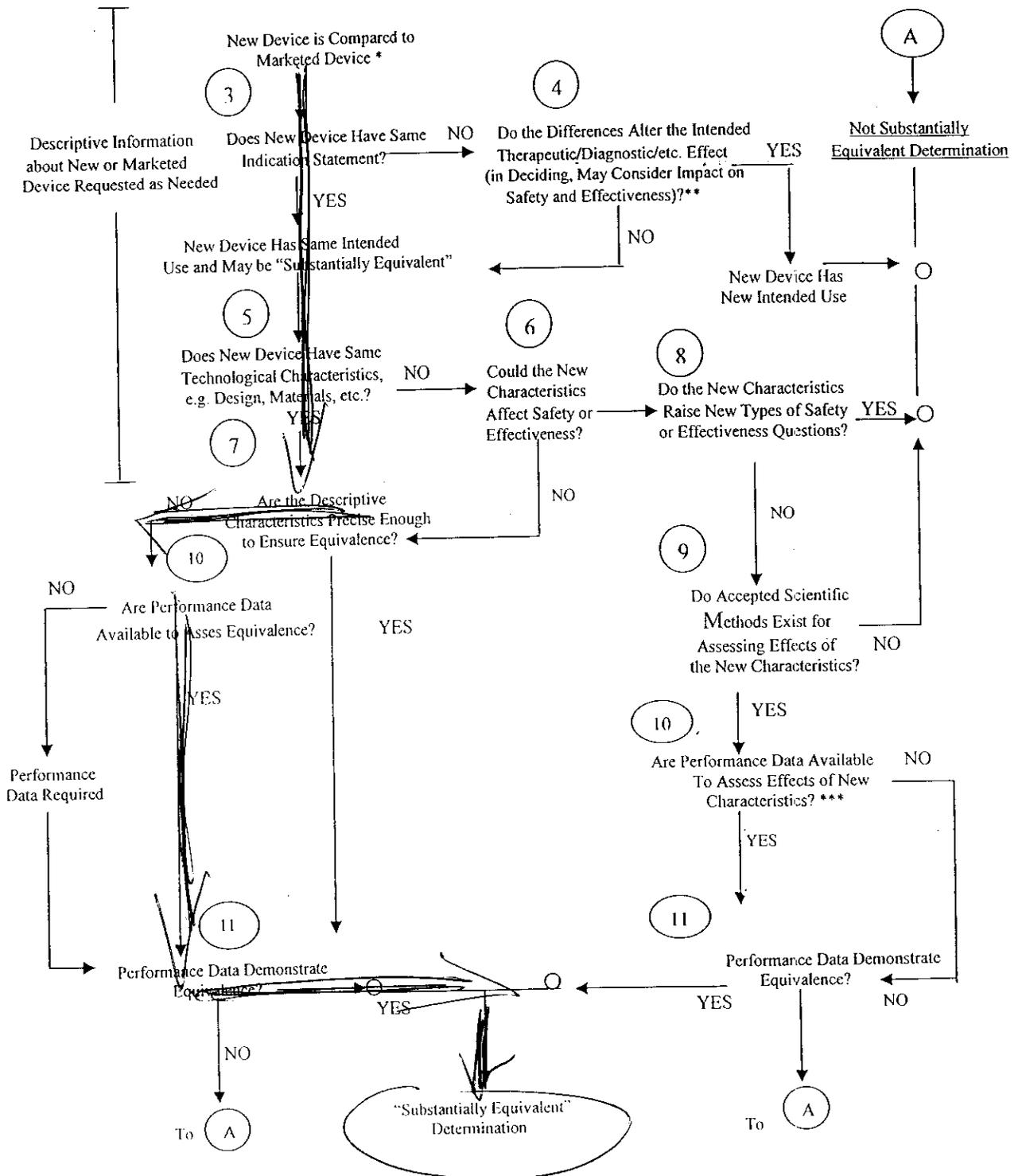
1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

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



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

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

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