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Summary of Safety and Effectiveness
K072629

AUG - 6 2008

Submitter:	Integrated Surgical Systems, Inc.
Address:	1433 N. Market Blvd., #1, Sacramento, CA 95834 USA
Phone Number:	916-285-9943
Fax Number:	916-575-7918
Contact Person:	Russ Hibbert
Date Submitted:	September 7, 2007
Trade Name:	DigiMatch™ ROBODOC® Surgical System
Common Name:	Stereotaxic Instrument
Device Classification;	Class II
Regulation Number:	21 CFR 882.4560

Substantial Equivalence Claim

The DigiMatch™ ROBODOC® Surgical System is substantially equivalent to the Voyager/Tactile Guidance System – CT (K052851), the Frameless Neuromate (K991081) and the da Vinci Surgical System (K043153).

Device Description

The DigiMatch™ ROBODOC® Surgical System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then ROBODOC component of the System, under direct control by the surgeon, will precisely implement the preoperative plan.

Indications for Use / Intended Use Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for Orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

Summary of Safety and Effectiveness
K072629

Comparison of Technological Characteristics and Principles of Operation

Table 1 provides a comparison of technological characteristics and principles of operation between the DigiMatch™ ROBODOC® Surgical System and its predicate devices, the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System.

Table 1 Comparison of Technological Characteristics and Principles of Operation

	Patient Image Data	Pre-Surgical Plan	Surgical Plan Data	Machine Instructions	Patient/Robot Registration Requirement	Robot Electromechanical Arm(s)
DigiMatch™ ROBODOC® Surgical System	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes point to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Voyager Tactile Guidance System – CT (K052851)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes surface to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Frameless Neuromate (K991081)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes fiducial marker registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
da Vinci® Surgical System (K043153)	No visual image	No intra-surgery	No control file developed in real time during surgery	Yes robotic arms driven by validated control software and hardware	Yes visual registration	Yes Robot with multiple electromechanical arms and end effector implement control file instructions

Summary of Safety and Effectiveness
K072629

Summary of Performance Testing

ISS has completed bench, animal, cadaver and clinical testing that assess the safety and efficacy of the ROBODOC System.

Nonclinical Studies

Nonclinical cadaver and animal studies provide an accurate means of determining cavity accuracy and placement. The value of such studies is that they allow a measurement of the gap between the bone and implant. They also permit histological examinations of the cavity/implant interface, which has value in determining whether the implant apposition within the cavity is sufficiently narrow.

Cadaver Study

The cadaver study compared the accuracy of cutting the femur with the ROBODOC versus manual broaching. The results showed that the ROBODOC was more accurate than manual broaching and led to significantly reduced gaps between the implant and bone.

Animal Study

The animal study, involving 20 male greyhounds, also supports the conclusion that the ROBODOC is more accurate than manual broaching in cutting the femur. Histological examination revealed many instances of fracture or osteotomy in the control group, compared to none in the ROBODOC group. In addition, histological examination revealed that the ROBODOC group had more consistent cortical bone continuity, better apposition of implants with cortical and cancellous bone, and appeared to have less cancellous bone hypertrophy.

Clinical Studies

The First U.S. Trial (G920035) was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. The primary endpoints of efficacy that demonstrated precise and reliable implantation of the preoperative plan were fit and alignment of the femoral implant. Primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

The Second U.S. Trial (IDE # G000071) was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical System. The DigiMatch™ technology modified the ROBODOC System so as not to require pre-operative placement of fiduciary pins. The data from this trial also confirmed the safety and efficacy of the ROBODOC System. As with the First IDE Trial, primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

Conclusion

The DigiMatch™ ROBODOC® Surgical System, which is substantially equivalent to the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System, has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2008

Intergrated Surgical Systems, Inc.
% Mr. Russ Hibbert
Director, Clinical & Regulatory Affairs
1433 N. Market Boulevard #1
Sacramento, California 95834

Re: K072629
Trade/Device Name: DigiMatch™ ROBODOC® Surgical System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OJP, HAW
Dated: March 31, 2008
Received: April 3, 2008

Dear Mr. Hibbert:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): Unknown at this time K072629

Device Name: DigiMatch™ ROBODOC® Surgical System

Indications for Use:

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for Orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Milhorn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072629

Document Cover Sheet:

Date of Submission:	07-SEP-2007
Description:	DIGIMATCH ROBODOC SURGICAL SYSTEM
Date of Scan:	21-MAY-2009
Document Prep:	DSF4 5/21/09
Scanner:	DSF4 5/21/09
Image Quality Reviewer:	

K072629-SPECIAL

FSR0701-000

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Total document pages: 2388				
Total separator pages: 156				
Total Scan pages: 2551				

QC Signature

QC Bar Code Sticker

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K072629/A1

ROBODOC®
INTEGRATED SURGICAL SYSTEMS

February 5, 2008

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

Attention: Michel D. Janda

Re: Amendment 1: K072629; Change of Contact Information

Dear Mr. Janda:

Integrated Surgical Systems, Inc. (ISS) respectfully requests that the facsimile number provided in the ISS contact information for K072629 be change. The fax number that is currently provided is 916-285-9104. The **new fax** number would be **916-575-7918**.

If you have any questions regarding this request, please contact me at the below number.

Sincerely,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
Cell: 801-455-0807
Office Phone: 916-285-9943 x 522
Office Fax: 916-575-7918
E-mail: rdhibbert@robodoc.com

cc: Dr. Ramesh Trivedi, President and CEO

FDA CDRH DMC
FEB - 6 2008
Received

K28

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K072629/A2

FDA CDRH DMC
AUG - 1 2008
Received

July 30, 2008

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

Attention: Michel D. Janda

Re: Supplement 3: DigiMatch™ ROBODOC® Surgical System; K072629

Dear Mr. Janda:

This submission provides the response to FDA's Request for Additional Information, dated July 30, 2008, regarding premarket notification number K072629. Supplement 3 contains the requested updated 510(k) Summary of Safety and Effectiveness, which is modified to reflect the previously revised indications for use.

Please contact me if you have any questions regarding the information submitted herein. Otherwise, please forward a copy of the substantial equivalence letter to me by facsimile at 916-575-7918. Thank you in advance for your cooperation.

Sincerely,

RD Hibbert
Director of Clinical, Regulatory and Quality Compliance
Integrated Surgical Systems
1433 N. Market Blvd., Suite 1
Sacramento, CA 95834
Cell: 801-455-0807
Office Phone: 916-285-9943 x 522
Office Fax: 916-575-7918
E-mail: rdhibbert@robodoc.com

K34

cc: Dr. Ramesh Trivedi, President and CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.

Attachment enclosed

DJA x00014

Section 5 - Summary of Safety and Effectiveness

A summary of this 510(k) submission is provided herein in accordance with 21 CFR 807.92.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DJA x00015

Summary of Safety and Effectiveness
K072629

Submitter:	Integrated Surgical Systems, Inc.
Address:	1433 N. Market Blvd., #1, Sacramento, CA 95834 USA
Phone Number:	916-285-9943
Fax Number:	916-575-7918
Contact Person:	Russ Hibbert
Date Submitted:	September 7, 2007
Trade Name:	DigiMatch™ ROBODOC® Surgical System
Common Name:	Stereotaxic Instrument
Device Classification;	Class II
Regulation Number:	21 CFR 882.4560

Substantial Equivalence Claim

The DigiMatch™ ROBODOC® Surgical System is substantially equivalent to the Voyager/Tactile Guidance System – CT (K052851), the Frameless Neuromate (K991081) and the da Vinci Surgical System (K043153).

Device Description

The DigiMatch™ ROBODOC® Surgical System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then ROBODOC component of the System, under direct control by the surgeon, will precisely implement the preoperative plan.

Indications for Use / Intended Use Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for Orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

DJA x00016

Summary of Safety and Effectiveness
K072629

Comparison of Technological Characteristics and Principles of Operation

Table 1 provides a comparison of technological characteristics and principles of operation between the DigiMatch™ ROBODOC® Surgical System and its predicate devices, the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System.

Table 1 Comparison of Technological Characteristics and Principles of Operation

	Patient Image Data	Pre-Surgical Plan	Surgical Plan Data	Machine Instructions	Patient/Robot Registration Requirement	Robot Electromechanical Arm(s)
DigiMatch™ ROBODOC® Surgical System	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes point to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Voyager Tactile Guidance System – CT (K052851)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes surface to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Frameless Neuromate (K991081)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes fiducial marker registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
da Vinci® Surgical System (K043153)	No visual image	No intra-surgery	No control file developed in real time during surgery	Yes robotic arms driven by validated control software and hardware	Yes visual registration	Yes Robot with multiple electromechanical arms and end effector implement control file instructions

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Summary of Safety and Effectiveness
K072629

Summary of Performance Testing

ISS has completed bench, animal, cadaver and clinical testing that assess the safety and efficacy of the ROBODOC System.

Nonclinical Studies

Nonclinical cadaver and animal studies provide an accurate means of determining cavity accuracy and placement. The value of such studies is that they allow a measurement of the gap between the bone and implant. They also permit histological examinations of the cavity/implant interface, which has value in determining whether the implant apposition within the cavity is sufficiently narrow.

Cadaver Study

The cadaver study compared the accuracy of cutting the femur with the ROBODOC versus manual broaching. The results showed that the ROBODOC was more accurate than manual broaching and led to significantly reduced gaps between the implant and bone.

Animal Study

The animal study, involving 20 male greyhounds, also supports the conclusion that the ROBODOC is more accurate than manual broaching in cutting the femur. Histological examination revealed many instances of fracture or osteotomy in the control group, compared to none in the ROBODOC group. In addition, histological examination revealed that the ROBODOC group had more consistent cortical bone continuity, better apposition of implants with cortical and cancellous bone, and appeared to have less cancellous bone hypertrophy.

Clinical Studies

The First U.S. Trial (G920035) was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. The primary endpoints of efficacy that demonstrated precise and reliable implantation of the preoperative plan were fit and alignment of the femoral implant. Primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

The Second U.S. Trial (IDE # G000071) was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical System. The DigiMatch™ technology modified the ROBODOC System so as not to require pre-operative placement of fiduciary pins. The data from this trial also confirmed the safety and efficacy of the ROBODOC System. As with the First IDE Trial, primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

Conclusion

The DigiMatch™ ROBODOC® Surgical System, which is substantially equivalent to the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System, has been shown to be safe and effective for its intended use.

DJA x00018

Russ Hibbert

From: Janda, Michel D [michel.janda@fda.hhs.gov]
Sent: Wednesday, July 30, 2008 8:44 AM
To: Russ Hibbert
Subject: DigiMatch Robodoc Surgical System, K072629

Mr. Hibbert,

In the previous request for additional information, revisions were requested in regards to the indications for use statement. Your response appropriately revised this statement. However, this revision must be reflected throughout the 510(k) submission. Specifically the 510(k) summary of safety and effectiveness must be modified to reflect the revised indications for use. Please provide a revised copy of this document. An electronic copy of this document is acceptable.

Sincerely,

Michel Janda

Biomedical Engineer

Phone #: (240) 276-3600

Fax #: (240) 276-3733

ODE/DGRND/GSDB

HIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

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Version: 8.0.138 / Virus Database: 270.4.5/1533 - Release Date: 7/3/2008 7:19 PM

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ROBODOC®
INTEGRATED SURGICAL SYSTEMS

FDA CDRH DMC

JAN 09 2008

Received

January 8, 2008

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Attention: Michel Janda

Re: Request for extension to January 31, 2008
DigiMatch™ ROBODOC® Surgical System Premarket Notification (K072629)

Dear Mr. Janda:

Integrated Surgical Systems, Inc. (ISS) received the FDA reviewer comments for the DigiMatch™ ROBODOC® Surgical System premarket notification (K072629) on December 5, 2007. As stated in our December 20, 2007 extension request ISS is currently addressing these comments. I am requesting an additional extension to complete our responses. ISS plans to submit the response documentation to FDA on or before January 31, 2008.

Please contact me if there are any questions.

Sincerely,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
Cell: 801-455-0807
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

cc: Dr. Ramesh C. Trivedi, President & CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.
Gerard J. Prud'homme, Esq., Hogan & Hartson L.L.P.

K13

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ROBODOC®
INTEGRATED SURGICAL SYSTEMS

SU

December 20, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Attention: Michel Janda

Re: DigiMatch™ ROBODOC® Surgical System Premarket Notification (K072629)

Dear Mr. Janda:

Integrated Surgical Systems, Inc. (ISS) received the FDA reviewer comments for the DigiMatch™ ROBODOC® Surgical System premarket notification (K072629) on December 5, 2007. ISS is currently addressing these comments and plans to submit our responses to FDA on or before January 15, 2008.

Please contact me if there are any questions.

Sincerely,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
Cell: 801-455-0807
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

cc: Dr. Ramesh C. Trivedi, President & CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.
Gerard J. Prud'homme, Esq., Hogan & Hartson L.L.P.

FDA CDRH DMC
Received
DEC 21 2007

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ROBODOC
INTEGRATED SURGICAL SYSTEMS

K072629

COPY

September 7, 2007

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

Attention: Neil R. Ogden

Re: 510(k) Premarket Notification for Integrated Surgical Systems, Inc.'s DigiMatch™ ROBODOC® Surgical System

Dear Mr. Ogden:

Integrated Surgical Systems, Inc. (ISS) hereby submits a premarket notification for the DigiMatch™ ROBODOC® Surgical System pursuant to 21 CFR PART 807 Subpart E. The following administrative information is provided in support of this notification:

Type of 510(k) Submission
Traditional – Based on recent discussions with the Food and Drug Administration (FDA), ISS requests an "interactive review" of this premarket notification.

Device Type/Common Name
Stereotaxic Instrument – This information is based on the premarket notification

510(k) Submitter
Integrated Surgical Systems, Inc.
1433 N. Market Boulevard, #1
Sacramento, CA 95834

K-15

Contact Person
Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: **rdhibbert@robodoc.com**

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2007 SEP 17 A 10: 31
FDA/CDRH/ODE/PMO

Confidentiality

ISS requests confidentiality of this notification in accordance with § 807.95(b)(1)(i-iv).

Volume I - 000036

1433 N. Market Boulevard, #1 · Sacramento, CA 95834
916.285.9943 phone · 916.285.9104 fax · www.robodoc.com

DJA x01097

Claimed Predicate Devices

1. 510(k) Number: K052851, Voyager/Tactile Guidance System – CT
2. 510(k) Number: K043153, da Vinci® Surgical System
3. 510(k) Number: K963256, NeuroMate Stereotactic System

*Recommended Classification Regulation

Class II

*Regulation Number

882.4560 – This information is based on the premarket notification submitted to FDA for the claimed predicate devices.

(a) *Identification.* A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.
(b) *Classification.* Class II (performance standards)

*Product Code

HAW – This information is based on the premarket notification submitted to FDA for the claimed predicate device.

*NOTE: The information regarding Recommended Classification Regulation, Regulation Number and Product Code is based on the premarket notification submitted to FDA for the claimed predicate device: Voyager/Tactile Guidance System – CT, K052851.

Demonstration of Substantial Equivalence

Section 12 of this submission contains discussions and comparisons that demonstrate substantial equivalence of the DigiMatch™ ROBODOC® Surgical System to the Voyager/Tactile Guidance System – CT and da Vinci® Surgical System.

Demonstration of ROBODOC® Surgical System Safety and Efficacy

Section 20 of this submission contains reports of two IDE clinical trials (IDE# G920035 and G000071) and two foreign trials, which are provided in support of this premarket notification.

The First IDE Clinical Trial (G920035), reported in Section 20.2 of this submission, was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. Upon review of the data from the First Trial in October, 2000, FDA identified four potential risk factors for the ROBODOC® system, namely:

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- The need for two surgical procedures (a separate surgical procedure to implant fiduciary pins prior to the primary THA procedure);
- Post-surgical ipsilateral knee pain (possibly associated with the pre-operative placement of fiduciary markers or pins);
- Longer surgical times during THA; and
- Significantly greater blood loss during THA*.

  * The greater blood loss was probably due to longer surgical times, as the blood loss per minute of surgery was equivalent between the two study groups.

Subsequently, the ROBODOC® Surgical System was modified to allow a less invasive technology that required 2, rather than 3, locator pins to be placed pre-operatively in order to register the location and orientation of robotic arm in relationship to the operative femur. Validation of the 2-pin registration technology was based, in part, on the results of a clinical study by Nishihara et al. (1). A copy of the published study is provided in Section 20.3 of this submission. This 140 patients (156 femora) randomized, controlled study showed a favorable comparison between the outcomes of hand-rasping and robotic milling with 3-dimensional preoperative planning using the ORTHODOC system.

Further development lead to an iteration of the device that uses pinless registration technology. This device is known as the DigiMatch™ ROBODOC® Surgical System. The pinless registration technology was validated in 31-patient subject German study in accordance ISS test protocol PV98-07-012. Results are reported in TR98-07-011, ROBODOC PINLESS SYSTEM Clinical Validation. A copy of the study, which was completed at Berufsgenossenschaftliche Unfallklinik (BGU) in Frankfurt, Germany, is provided in Section 20.4 of this submission.

The Second IDE Clinical Trial (IDE # G000071), reported in Section 20.5 of this submission, was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical Assistant System technology, modified so as not to require pre-operative placement of fiduciary pins, thereby eliminating the requirement for a separate surgical procedure and the potential association of ipsilateral knee pain. The issue of longer surgical times and greater blood loss was addressed by additional training of the participating surgeons and the improved DigiMatch™ technology of the device. The Second Trial was conducted in response to FDA's recommendation and was focused on demonstrating that the risk factors seen in the First Trial had been mitigated or eliminated.

In recent discussions, FDA has agreed that efficacy of the ROBODOC® Surgical Assistant System (pin-based system) was demonstrated in the First Clinical Trial. Subsequently, FDA requested that ISS demonstrate equivalence between the pin-based ROBODOC® system and the pinless DigiMatch™ system. Section 20 contains the data and documentation showing:

1. Equivalence in efficacy between the pin-based ROBODOC® system and the pinless DigiMatch™ system; and
2. The DigiMatch™ technology has mitigated or eliminated the risk factors observed in the First Clinical Trial.

FDA has stated that this premarket notification will undergo an "interactive review." Please contact me at any time with questions regarding this submission.

Sincerely,

Russ Hibbert
Director, Clinical & Regulatory Affairs

cc: Dr. Ramesh C. Trivedi, President & CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.
Gerard J. Prud'homme, Esq., Hogan & Hartson L.L.P.

Reference:

1. Nishihara S, Sugano N, Nishii T, Miki H, Nakamura N, and Yoshikawa H. Comparison Between Hand Rasping and Robotic Milling for Stem Implantation in Cementless Total Hip Arthroplasty. The Journal of Arthroplasty Vol. 21 No. 7 2006

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

DJA x01100

DigiMatch™ ROBODOC® Surgical System
Traditional 510(k) Premarket Notification
K _____ ORIGINAL

Integrated Surgical Systems, Inc. (ISS) hereby submits a premarket notification for the DigiMatch™ ROBODOC® Surgical System pursuant to 21 CRF PART 807 Subpart E. The format of this submission follows the recommendations contained in Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s, dated August 12, 2005.

K072629

1/2

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Section 5 – 510(k) Summary or 510(k) Statement
Section 6 – Truthful and Accuracy Statement
Section 7 – Class III Summary and Certification
Section 8 – Financial Certification or Disclosure Statement
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ISS requests confidentiality of this notification in accordance Sec. §807.95(b)(1)(i-iv).

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

Section 1 – Medical Device User Fee Cover Sheet (Form FDA 3601)

I. A copy of the Medical Device User Fee Cover Sheet is provided herein.

II. The Medical Device User Fee Cover Sheet process was completed electronically. The Payment Identification Number is [redacted]. A check in the amount of $[redacted], made out to Food and Drug Administration (FDA), was sent on 15 May 2007 via FedEx to US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. A non-negotiable copy of the check is provided herein.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6030883-956733** Write the Payment Identification number on your check.

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:

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.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
INTERGRATED SURGICAL SYSTEMS INC 1433 N. MARKET BLVD. NO. 1 Sacramento CA 95834 US	Russell Hibbert 2.1 E-MAIL ADDRESS rdhibbert@robodoc.com 2.2 TELEPHONE NUMBER (include Area code) 916-285-9943-522 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 916-285-9104
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) [redacted]	

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

Select an application type:	3.1 Select one of the types below
[X] Premarket notification(510(k)); except for third party	[X] Original Application
[ ] Biologics License Application (BLA)	Supplement Types:
[ ] Premarket Approval Application (PMA)	[ ] Efficacy (BLA)
[ ] Modular PMA	[ ] Panel Track (PMA, PMR, PDP)
[ ] Product Development Protocol (PDP)	[ ] Real-Time (PMA, PMR, PDP)
[ ] Premarket Report (PMR)	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

[redacted] 08-May-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Volume 1 - 000002

DJA x01103

(b) (4)

[redacted]

(b) (6)

[redacted]

Volume I - 000003

DJA x01104

ORIGINAL

Section 2 – CDRH Premarket Review Submission Cover Sheet

A copy of the CDRH Premarket Review Submission Cover Sheet is provided herein.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DJA x01105

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.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
September 7, 2007	[redacted]	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Integrated Surgical Systems, Inc.	2951340		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
n/a	(916) 285-9943		
Street Address	**FAX Number *(including area code)***		
1433 N. Market Blvd., #1	(916) 285-9104		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Sacramento	CA	95834	USA
Contact Name			
Russ Hibbert			
Contact Title	**Contact E-mail Address**		
Director, Clinical & Regulatory Affairs	rdhibbert@robodoc.com		

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

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

PSC Media Arts (301) 443-2454 EF

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

	Product codes unknown. A copy of each 510(k) summary is provided in Attachment 1.	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

X 510 (k) summary attached

☐ 510 (k) statement

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K052851	1	Voyager/Tactile Guidance System – CT	1	MAKO Surgical Corp.
2	K043153	2	da Vinci® Surgical System	2	Intuitive Surgical, Inc.
3	K960685	3	ORTHODOC Preoperative Planning Workstation	3	Integrated Surgical Systems, Inc.
4	K991081	4	Frameless Neuromate	4	Integrated Surgical Systems

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Stereotactic Instrument

	Trade or Proprietary or Model Name for This Device		Model Number
1	DigiMatch™ ROBODOC® Surgical System	1	TBD
2		2	

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

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

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HAW	21 CFR 882.4560	☐ Class I X Class II ☐ Class III ☐ Unclassified
Classification Panel: Neurology		

Indications *(from labeling)*

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary cementless total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

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

X Original ☐ Add ☐ Delete	FDA Establishment Registration Number: 2951340	X Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Integrated Surgical Systems, Inc.		Establishment Registration Number: 2951340	
Division Name *(if applicable)*: n/a		Phone Number *(including area code)*: (916) 285-9943	
Street Address: 1433 N. Market Blvd., #1		FAX Number *(including area code)*: (916) 285-9104	
City: Sacramento		State / Province: CA	ZIP/Postal Code: 95834 / Country: USA
Contact Name: Russ Hibbert	Contact Title: Director, Clinical & Regulatory Affairs	Contact E-mail Address: rdhibbert@robodoc.com	

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

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	

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

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	EN 60601-1	EN, European Standards	Medical electrical equipment Part 1: General requirements for safety		
	Standards No.	Standards Organization	Standards Title	Version	Date
2	EN 60601-1-1	EN, European Standards	Medical electrical equipment - part 1: general requirements for safety 1: collateral standard: safety requirements for medical electrical systems		
	Standards No.	Standards Organization	Standards Title	Version	Date
3	EN60601-1-2	EN, European Standards	Medical electrical equipment - part 1: general requirements for safety 2. Collateral standard: electromagnetic compatibility - requirements and tests		
	Standards No.	Standards Organization	Standards Title	Version	Date
4	IEC801-2	IEC, International Electrotechnical Commission	ESD		
	Standards No.	Standards Organization	Standards Title	Version	Date
5	IEC801-3	IEC, International Electrotechnical Commission	Radiated Electromagnetic Field Requirement		
	Standards No.	Standards Organization	Standards Title	Version	Date
6	IEC801-4	IEC, International Electrotechnical Commission	Electrical Fast Transient/Burst requirement		
	Standards No.	Standards Organization	Standards Title	Version	Date
7	IEC801-5	IEC, International Electrotechnical Commission	Surge Requirement		

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

[Please see attached page for complete copy standards/guidelines followed]

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

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Table of Standards and Device-Specific Guidance Documents

Standards No.	Standards Organization	Standards Title
EN 60601-1	EN, European Standards	Medical electrical equipment Part 1: General requirements for safety,
EN 60601-1-1	EN, European Standards	Medical electrical equipment - part 1: general requirements for safety 1: collateral standard: safety requirements for medical electrical systems
EN60601-1-2	EN, European Standards	Medical electrical equipment - part 1: general requirements for safety 2. Collateral standard: electromagnetic compatibility - requirements and tests
IEC801-2	IEC, International Electrotechnical Commission	ESD
IEC801-3	IEC, International Electrotechnical Commission	Radiated Electromagnetic Field Requirement
IEC801-4	IEC, International Electrotechnical Commission	Electrical Fast Transient/Burst requirement
IEC801-5	IEC, International Electrotechnical Commission	Surge Requirement
ISO 14971:2000	ANSI, American National Standards Institute AAMI, Advancement of Medical Instrumentation	Medical Devices – Application of Risk Management to Medical Devices
10993-1 Blue Book Memorandum G95-1	ISO, International Organization for Standardization US Food and Drug Administration	ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing "Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"
ANSI/AAMI/ISO 11137-1:2006	ANSI, American National Standards Institute AAMI, Advancement of Medical Instrumentation ISO, International Organization for Standardization	Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Table of Standards and Device-Specific Guidance Documents (continued)

Standards No.	Standards Organization	Standards Title
ANSI/AAMI/ISO 11137-2:2006	ANSI, American National Standards Institute AAMI, Advancement of Medical Instrumentation ISO, International Organization for Standardization	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
N/A	FDA Guidance Document	Guidance for Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005)
ANSI S20.20-1999	ANSI, American National Standards Institute	Standard for the development of an ESD control program
EN 980:1997	EN, European Standards	Graphical symbols for use in the labeling of medical devices
21 CFR 820		Quality Systems Regulation (QSR)

DJA x01...3

Attachment 1

Predicate Device 510(k) Premarket Notification Database and Summary

- Voyager/Tactile Guidance System – CT; K052851
- da Vinci® Surgical System; K043153
- ORTHODOC Preoperative Planning Workstation; K960685
- Frameless Neuromate; K991081

K050-2851

Page 1 of 1

NOV 1 8 2005

MAKO SURGICAL CORP.

2911 Simms Street Hollywood, Florida 33020 tel 954.927.2044 fax 954.927.0446

ATTACHMENT 12
510(K) SUMMARY

Submitter:	MAKO Surgical Corp.
Address:	2901 Simms Street, Hollywood, FL, 33020
Phone number:	954-927-2044
Fax number:	954-927-0446
Contact Person:	William F. Tapia
Date Prepared:	October 7, 2005
Cleared Device Trade Name:	Voyager Linux with the Tactile Guidance System (TGS)
Modified Device Trade Name:	Voyager/Tactile Guidance System - CT
Common Name:	Stereotaxic Instrument
Classification Name:	Class II
Classification #:	21 CFR 882.4560

Substantial Equivalence Claimed To: Voyager Linux with the Tactile Guidance System (TGS) as described in MAKO Surgical Corp.'s K050973. The modification to add CT capability is shown to be substantially equivalent to the previously cleared system. As required by risk analysis, all verification and validation activities performed to date by designated individuals and the results demonstrated substantial equivalence.

Description: The Voyager/Tactile Guidance System - CT is an image guided surgical device that includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, and the TGS. Voyager/Tactile Guidance System - CT uses patient CT data to assist the physician with presurgical planning and interpretive/intraoperative navigation. The TGS, which is an add-on to the Voyager platform, serves as an "intelligent" tool holder or tool guide used by a surgeon for stereotactic guidance during minimally invasive orthopedic surgical procedures. The TGS, an electromechanical arm, is passively constrained by software-defined spatial boundaries implemented through the use of the TGS and is designed to support a surgeon's preparation of an anatomical site for an orthopedic implant with standard surgical tools such as drills, awls, and 3rd party drill systems.

Summary of Technological Characteristics: The Voyager/Tactile Guidance System - CT consists of the following basic components:

- High Resolution color liquid crystal display (LCD) touch screen monitor
- Uninterruptible Power Supply (UPS)
- Central Processing Unit (CPU)
- Isolation Transformer
- Keyboard and Mouse
- Optical Detector
- Operating Room Cart
- Tool and accessories – surgical and TGS tools and accessories including instrumentation with reflective markers
- TGS – connected to the Voyager platform to enable stereotactic guidance of standard surgical tools.
- Software – application specific software provided as part of system or via standard media (e.g., CD-ROM)

Intended Use: The Voyager/Tactile Guidance System - CT is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.
The Voyager/Tactile Guidance System - CT is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made, such as:

- Intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous)
- Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms
- ENT Procedures
- Orthopedic surgical procedure

DJA x01:::5

510(k) Premarket Notification Database

Device Classification Name	Instrument, Stereotaxic
510(K) Number	K052851
Device Name	VOYAGER LINUX WITH TACTILE GUIDANCE SYSTEM (TGS)
Applicant	MAKO SURGICAL CORP. 2901 Simms Street Hollywood, FL 33020
Contact	William F Tapia
Regulation Number	882.4560
Classification Product Code	HAW
Date Received	10/11/2005
Decision Date	11/18/2005
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 8/07/2007

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K052851

MAKO
SURGICAL CORP.

2501 Stirling Street Hollywood, Florida [illegible] tel 954.927.2044 fax 954.927.2144

ATTACHMENT 10

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Voyager/Tactile Guidance System - CT

Indications for Use:
The Voyager/Tactile Guidance System - CT is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.
The Voyager/Tactile Guidance System - CT is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made, such as:

- Intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous)
- Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms
- ENT Procedures
- Orthopedic surgical procedures

Prescription Use ___X___ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052851

DJA x01119

510(k) Premarket Notification Database

Device Classification Name	System,Surgical,Computer Controlled Instrument
510(K) Number	K043153
Device Name	INTUITIVE SURGICAL DA VINCI SURGICAL SYSTEM AND E
Applicant	INTUITIVE SURGICAL, INC. 950 Kifer Rd. Sunnyvale, CA 94086 5206
Contact	Michael H Yramategui
Regulation Number	876.1500
Classification Product Code	NAY
Date Received	11/15/2004
Decision Date	12/15/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 8/07/2007

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DJA x01.20

1/3

DEC 15 2004

Section II

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K043153

Date	December 7, 2004
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Mike Yramategui Director, Regulatory Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 e-mail: mike.yramategui@intusurg.com
Subject Device	Name: Intuitive Surgical® da Vinci® Surgical System and Endoscopic Instruments Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR 876.1500) Common Name: Endoscopic Instrument Control System, Endoscopic Instruments and Accessories
Predicate Devices	Intuitive Surgical® da Vinci® Surgical System and Endoscopic Instruments (legally marketed under K990144 / K002489 / K011002 / K013416 / K021036 / K022574 / K040237); Guidant Microwave Ablation System and Flex 10 Accessory (legally marketed under K013946 / K041340)
Device Description	This special 510(k) is being submitted for a minor labeling change / clarification on the da Vinci® Surgical System. There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci Surgical System or the Guidant Flex 10 ablation probe and Microwave Ablation System. The only change is an updated indication statement and addendum user manual sheet for the da Vinci® Surgical System. The *da Vinci*® Surgical System consists of two integrated sub-systems as

DJA x011121

follows:

Device Description (continued)

Intuitive Surgical® Endoscopic Instrument Control System: This subsystem is comprised of the Surgeon Console and Patient Side Cart. While seated at the Surgeon Console, the surgeon controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within the operative field. Endoscopic instrument and camera movements are controlled by the surgeon through use of the Master Tool Manipulators (MTM), two hand operated mechanisms residing within the Surgeon Console. The endoscopic instruments are held in a fixed position (with respect to the patient) by either two (or optionally three) unique arms known as Patient Side Manipulators (PSM), which are located on the Patient Side Cart (PSC). The endoscope is also held in a fixed position (with respect to the patient) by another arm, similar to the PSM, known as the Endoscope Camera Manipulator (ECM) and also located on the PSC. Commands from the Surgeon Console are relayed to the PSC, which is located immediately adjacent to the patient, via cables. Instrument and endoscope changes are performed by another provider positioned adjacent to the PSC.

Intuitive Surgical® Stereo View Endoscopic System: The endoscopic vision system used with the *da Vinci*® Surgical System, also known as *Intuitive Surgical*® *Insite*™ Vision System, consists of a stereo endoscope, endoscopic camera, and various accessories, including a light source and light guides. The *Insite*™ Vision System provides two independent images that are relayed to the viewer located in the Surgeon Console, where they are fused to form a 3-D (or alternatively a 2-D image) image of the surgical field.

Intended Use

The *Intuitive Surgical*® Endoscopic Instrument Control System is intended to assist in the accurate control of *Intuitive Surgical*® Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave ablation probes and accessories during general laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed, with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. It is intended for use by trained physicians in an operating room environment in accordance with the representative specific procedures set forth in the Professional Instructions for Use.

DJA x01.22

Comparison to Predicate Device	There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci® Surgical System or the Guidant Flex 10 probe and Microwave Ablation System. The only difference is an updated indication statement that provides a clarification of tasks that can be performed with the da Vinci Surgical System; and an addendum instruction sheet that provides operational information for use of the da Vinci® Surgical System with the Guidant Flex 10 Probe and Microwave Ablation System. The use of the da Vinci® Surgical System to deliver and place the Flex 10 probe is equivalent to using conventional minimally invasive surgical instruments. This change does not impact the operational characteristics or change the intended use of either device.
Technological Characteristics	The technological characteristics of the subject devices are the same as for the predicate devices.
Performance Data	Design analysis and comparison, as well as bench testing, has been conducted to confirm that basic functional characteristics are substantially equivalent to the predicate devices cited, and that design output meets the design input requirements.
Conclusion	Based upon the technical information, intended use, and performance information provided in this pre-market notification, the da Vinci® Surgical System described herein has been shown to be substantially equivalent to current legally marketed predicate devices, and the results of the design control process confirm that the design output meets the design input requirements.

DJA x011125

Indications for Use

510(k) Number (if known): K043153

Device Name: *Intuitive Surgical*® Endoscopic Instrument Control System and Endoscopic Instruments

Indications For Use:

The *Intuitive Surgical*® Endoscopic Instrument Control System (hereinafter referred to as the " *da Vinci*® System") is intended to assist in the accurate control of *Intuitive Surgical*® Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave ablation probes and accessories during general laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K043153

DJA x01:26

510(k) Premarket Notification Database

Device Classification Name	Template
510(K) Number	K960685
Device Name	ORTHODOC PREOPERATIVE PLANNER MODEL 500
Applicant	INTEGRATED SURGICAL SYSTEMS, INC. 829 West Stadium Ln. Sacramento, CA 95834
Contact	Robert Van Osdel
Regulation Number	888.4800
Classification Product Code	HWT
Subsequent Product Code	JAK
Date Received	02/20/1996
Decision Date	01/17/1997
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary/Purged 510(K)
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 8/07/2007

Volume P- 000026

DJA x01127

JAN 17 1997

K960685

510(k) Summary

Submitter:	Integrated Surgical Systems, Inc. 829 W. Stadium Lane Sacramento, CA 95834 (916) 646-3487
Trade name:	ORTHODOCR Model 500 Preoperative Planning Software
Common name:	Templating System
Classification name:	Template for clinical use (21 CFR 888.4800)
Indications for use:	The ORTHODOC Preoperative Planner is a software device indicated for the planning of primary total hip arthroplasties on a personal computer. The software is intended to import computed tomography data, provide a constructed image of the data, and use computerized files, representing implant patterns of femoral components, to overlay the constructed image to aid surgeons in their selection and positioning of the femoral components.
Legally marketed predicate:	All femoral component templates supplied by femoral component manufacturers. For example, Depuy AML templates and Howmedica Osteolock HA templates.
Device description:	This software is designed to run on a PentiumR-based personal computer. The device is a software-only product and is not intended to operate any other medical device or act directly on a patient. The application stores scaled graphic images of femoral stem components and provides a means for surgeons to superimpose these patterns on a CT image of the patient's femur. The implant patterns can be moved over the femur images to select what in the surgeon's judgement is the best stem size, position, neck length, and head diameter to achieve the physician's surgical goal. The library of implant patterns, called surface model files, is developed from computer-aided-design (CAD) geometric data supplied by the implant's manufacturer. The implant surface model file used by ORTHODOC contains implant identification information as well as geometric data which defines the shape and dimensions of the implant surface.

Technological charactistics:	The implant patterns of the predicates are scaled computer-generated images that are plotted, photographed, and contact printed to maintain accurate scale. These are held over the x-ray and moved by hand to position them to assist the surgeon in planning the stem's placement. The ORTHODOC software contains a library of computer-generated femoral component images which can be called-up and superimposed over a CT image of the patients femur. The images are moved by hand, employing a mouse pointer, to position them to assist the surgeon in planning the stem's placement.
Performance data:	There has been no pre-clinical or clinical performance data generated upon which to make a decision of substantial equivalence.

DJA x01:29

510(k) Premarket Notification Database

Device Classification Name	Instrument, Stereotaxic
510(K) Number	K991081
Device Name	FRAMELESS NEUROMATE
Applicant	INTEGRATED SURGICAL SYSTEMS, INC. 1850 Research Park Dr. Davis, CA 95616
Contact	R.D. Hibbert
Regulation Number	882.4560
Classification Product Code	HAW
Date Received	03/31/1999
Decision Date	06/25/1999
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Summary/Purged 510(K)
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 8/07/2007

Volume I - 000029

JUN 25 1999

INTEGRATED
SURGICAL SYSTEMS

K991081

SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 DEVICE NAME (Trade, common, and classification): Frameless NeuroMate Stereotactic System.

2.0 PREDICATE DEVICE(s): K963256.

3.0 DESCRIPTION: A stereotactic system with an electromechanical, multijointed arm for spatial positioning and orientation of an instrument holder or tool guide. Guidance is based on a preoperative plan developed with three-dimensional imaging software and utilizes ultrasonic registration. The system is intended for use by neurosurgeons to guide standard neurosurgical instruments.

4.0 INTENDED USE: A computer-controlled image-guided electromechanical multijointed arm, intended to be used in a neurosurgical operating room for the stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by the surgeon to manually guide standard neurosurgical instruments, under a surgeon-developed, carefully prepared stereotactic treatment plan.

5.0 INDICATION FOR USE: Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.

6.0 BASIS OF REQUEST: The following factors are the basis of our request for a finding of substantial equivalency:

6.1 No substantive change in materials, basic components, or method of manufacture between this device and the predicate device; the system and its components have been used in the medical device industry for similar or identical products and for similar or identical uses with no record of any patient problems, adverse reactions;

6.2 No change in basic construction;

1850 Research Park Drive • Davis, California 95616-4884 • (530) 792-2600 • FAX (530) 792-2690

DJA x011131

6.3. The device and its components have been tested by independent labs for EMC and safety, EU standards compliance, and will be subjected to inspection and testing at IQA, and during/after manufacture and upon installation in the field; and

6.4. The function and use of this product will be no different than that of predicate devices and other similar devices currently in the marketplace.

7.0 SUBSTANTIVE DIFFERENCES: No substantive differences exist between the product defined in this 510(k) submission and the predicate device, except the registration system, which is similar to that currently used in other medical devices, and the incorporation of a commercially available imaging software for stereotactic planning, which has been developed, verified and validated to applicable standards, and guidance documents, cited herein.

Signed: _____ Dated: 3/29/99

RD Hibbert
Director of Clinical and Regulatory Affairs
Integrated Surgical Systems, Inc.
1850 Research Drive
Davis, CA 95616
Phone: 530-792-2621 Fax: 530-792-2690

DJA x01134

510(k) Number (if known):_____

Device Name: Frameless NeuroMate

Indications For Use:

Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991081

Prescription Use XX
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

DJA x01:35

Section 3 – 510(k) Cover Letter

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DJA x01:36

ROBODOC®
INTEGRATED SURGICAL SYSTEMS

September 7, 2007

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

Attention: Neil R. Ogden

Re: 510(k) Premarket Notification for Integrated Surgical Systems, Inc.'s DigiMatch™ ROBODOC® Surgical System

Dear Mr. Ogden:

Integrated Surgical Systems, Inc. (ISS) hereby submits a premarket notification for the DigiMatch™ ROBODOC® Surgical System pursuant to 21 CFR PART 807 Subpart E. The following administrative information is provided in support of this notification:

Type of 510(k) Submission
Traditional – Based on recent discussions with the Food and Drug Administration (FDA), ISS requests an "interactive review" of this premarket notification.

Device Type/Common Name
Stereotaxic Instrument – This information is based on the premarket notification

510(k) Submitter
Integrated Surgical Systems, Inc.
1433 N. Market Boulevard, #1
Sacramento, CA 95834

Contact Person
Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: **rdhibbert@robodoc.com**

Confidentiality

ISS requests confidentiality of this notification in accordance with § 807.95(b)(1)(i-iv).

1433 N. Market Boulevard, #1 · Sacramento, CA 95834
916.285.9943 phone · 916.285.9104 fax · www.robodoc.com

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Claimed Predicate Devices

1. 510(k) Number: K052851, Voyager/Tactile Guidance System – CT
2. 510(k) Number: K043153, da Vinci® Surgical System
3. 510(k) Number: K963256, NeuroMate Stereotactic System

*Recommended Classification Regulation

Class II

*Regulation Number

882.4560 – This information is based on the premarket notification submitted to FDA for the claimed predicate devices.

(a) *Identification.* A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.
(b) *Classification.* Class II (performance standards)

*Product Code

HAW – This information is based on the premarket notification submitted to FDA for the claimed predicate device.

*NOTE: The information regarding Recommended Classification Regulation, Regulation Number and Product Code is based on the premarket notification submitted to FDA for the claimed predicate device: Voyager/Tactile Guidance System – CT, K052851.

Demonstration of Substantial Equivalence

Section 12 of this submission contains discussions and comparisons that demonstrate substantial equivalence of the DigiMatch™ ROBODOC® Surgical System to the Voyager/Tactile Guidance System – CT and da Vinci® Surgical System.

Demonstration of ROBODOC® Surgical System Safety and Efficacy

Section 20 of this submission contains reports of two IDE clinical trials (IDE# G920035 and G000071) and two foreign trials, which are provided in support of this premarket notification.

The First IDE Clinical Trial (G920035), reported in Section 20.2 of this submission, was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. Upon review of the data from the First Trial in October, 2000, FDA identified four potential risk factors for the ROBODOC® system, namely:

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- The need for two surgical procedures (a separate surgical procedure to implant fiduciary pins prior to the primary THA procedure);
- Post-surgical ipsilateral knee pain (possibly associated with the pre-operative placement of fiduciary markers or pins);
- Longer surgical times during THA; and
- Significantly greater blood loss during THA*.

  * The greater blood loss was probably due to longer surgical times, as the blood loss per minute of surgery was equivalent between the two study groups.

Subsequently, the ROBODOC® Surgical System was modified to allow a less invasive technology that required 2, rather than 3, locator pins to be placed pre-operatively in order to register the location and orientation of robotic arm in relationship to the operative femur. Validation of the 2-pin registration technology was based, in part, on the results of a clinical study by Nishihara et al. (1). A copy of the published study is provided in Section 20.3 of this submission. This 140 patients (156 femora) randomized, controlled study showed a favorable comparison between the outcomes of hand-rasping and robotic milling with 3-dimensional preoperative planning using the ORTHODOC system.

Further development lead to an iteration of the device that uses pinless registration technology. This device is known as the DigiMatch™ ROBODOC® Surgical System. The pinless registration technology was validated in 31-patient subject German study in accordance ISS test protocol PV98-07-012. Results are reported in TR98-07-011, ROBODOC PINLESS SYSTEM Clinical Validation. A copy of the study, which was completed at Berufsgenossenschaftliche Unfallklinik (BGU) in Frankfurt, Germany, is provided in Section 20.4 of this submission.

The Second IDE Clinical Trial (IDE # G000071), reported in Section 20.5 of this submission, was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical Assistant System technology, modified so as not to require pre-operative placement of fiduciary pins, thereby eliminating the requirement for a separate surgical procedure and the potential association of ipsilateral knee pain. The issue of longer surgical times and greater blood loss was addressed by additional training of the participating surgeons and the improved DigiMatch™ technology of the device. The Second Trial was conducted in response to FDA's recommendation and was focused on demonstrating that the risk factors seen in the First Trial had been mitigated or eliminated.

In recent discussions, FDA has agreed that efficacy of the ROBODOC® Surgical Assistant System (pin-based system) was demonstrated in the First Clinical Trial. Subsequently, FDA requested that ISS demonstrate equivalence between the pin-based ROBODOC® system and the pinless DigiMatch™ system. Section 20 contains the data and documentation showing:

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1. Equivalence in efficacy between the pin-based ROBODOC® system and the pinless DigiMatch™ system; and
2. The DigiMatch™ technology has mitigated or eliminated the risk factors observed in the First Clinical Trial.

FDA has stated that this premarket notification will undergo an "interactive review." Please contact me at any time with questions regarding this submission.

Sincerely,

Russ Hibbert
Director, Clinical & Regulatory Affairs

cc: Dr. Ramesh C. Trivedi, President & CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.
Gerard J. Prud'homme, Esq., Hogan & Hartson L.L.P.

Reference:

1. Nishihara S, Sugano N, Nishii T, Miki H, Nakamura N, and Yoshikawa H. Comparison Between Hand Rasping and Robotic Milling for Stem Implantation in Cementless Total Hip Arthroplasty. The Journal of Arthroplasty Vol. 21 No. 7 2006

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

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Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Section 4 – Indications for Use Statement

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DJA x01142

Indications for Use

510(k) Number (if known): Unknown at this time K072629

Device Name: DigiMatch™ ROBODOC® Surgical System

Indications for Use:

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 5 – 510(k) SUMMARY

A summary of this 510(k) submission is provided herein in accordance with 21 CFR 807.92.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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K072629

Submitter:	Integrated Surgical Systems, Inc.
Address:	1433 N. Market Blvd., #1, Sacramento, CA 95834 USA
Phone Number:	916-285-9943
Fax Number:	916-285-9104
Contact Person:	Russ Hibbert
Date Submitted:	September 7, 2007
Trade Name:	DigiMatch™ ROBODOC® Surgical System
Common Name:	Stereotaxic Instrument
Device Classification;	Class II
Regulation Number:	21 CFR 882.4560

Substantial Equivalence Claim

The DigiMatch™ ROBODOC® Surgical System is substantially equivalent to the Voyager/Tactile Guidance System – CT (K052851), the Frameless Neuromate (K991081) and the da Vinci Surgical System (K043153).

Device Description

The DigiMatch™ ROBODOC® Surgical System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then ROBODOC component of the System, under direct control by the surgeon, will precisely implement the preoperative plan.

Indications for Use / Intended Use Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

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Section 5 – 510(k) SUMMARY

Comparison of Technological Characteristics and Principles of Operation

Table 1 provides a comparison of technological characteristics and principles of operation between the DigiMatch™ ROBODOC® Surgical System and its predicate devices, the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System.

Table 1 Comparison of Technological Characteristics and Principles of Operation

	Patient Image Data	Pre-Surgical Plan	Surgical Plan Data	Machine Instructions	Patient/Robot Registration Requirement	Robot Electromechanical Arm(s)
DigiMatch™ ROBODOC® Surgical System	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes point to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Voyager Tactile Guidance System – CT (K052851)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes surface to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Frameless Neuromate (K991081)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes fiducial marker registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
da Vinci® Surgical System (K043153)	No visual image	No intra-surgery	No control file developed in real time during surgery	Yes robotic arms driven by validated control software and hardware	Yes visual registration	Yes Robot with multiple electromechanical arms and end effector implement control file instructions

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Section 5 – 510(k) SUMMARY

Summary of Performance Testing

ISS has completed bench, animal, cadaver and clinical testing that assess the safety and efficacy of the ROBODOC System.

Nonclinical Studies

Nonclinical cadaver and animal studies provide an accurate means of determining cavity accuracy and placement. The value of such studies is that they allow a measurement of the gap between the bone and implant. They also permit histological examinations of the cavity/implant interface, which has value in determining whether the implant apposition within the cavity is sufficiently narrow.

Cadaver Study

The cadaver study compared the accuracy of cutting the femur with the ROBODOC versus manual broaching. The results showed that the ROBODOC was more accurate than manual broaching and led to significantly reduced gaps between the implant and bone.

Animal Study

The animal study, involving 20 male greyhounds, also supports the conclusion that the ROBODOC is more accurate than manual broaching in cutting the femur. Histological examination revealed many instances of fracture or osteotomy in the control group, compared to none in the ROBODOC group. In addition, histological examination revealed that the ROBODOC group had more consistent cortical bone continuity, better apposition of implants with cortical and cancellous bone, and appeared to have less cancellous bone hypertrophy.

Clinical Studies

The First U.S. Trial (G920035) was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. The primary endpoints of efficacy that demonstrated precise and reliable implantation of the preoperative plan were fit and alignment of the femoral implant. Primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

The Second U.S. Trial (IDE # G000071) was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical System. The DigiMatch™ technology modified the ROBODOC System so as not to require pre-operative placement of fiduciary pins. The data from this trial also confirmed the safety and efficacy of the ROBODOC System. As with the First IDE Trial, primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

Conclusion

The DigiMatch™ ROBODOC® Surgical System, which is substantially equivalent to the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System, has been shown to be safe and effective for its intended use.

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Section 6 – Truthful and Accuracy Statement

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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PREMARKET NOTIFICATION

K072629

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as (Director, Clinical & Regulatory Affairs) of (Integrated Surgical Systems, Inc.), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

RD Hibbert
(Typed Name)

Sept. 7, 2007
(Date)

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Section 7 – Class III Summary and Certification

This section is not applicable (N/A). The ROBODOC® Surgical Assistant is classified as a Class II device pursuant to §882.4560.

This classification is based on the 510(k) premarket notification submitted to FDA for the claimed predicate device – Voyager Linux with Tactile Guidance System (TGS), 510 (k) No: K050973.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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Section 8 – Financial Certification or Disclosure Statement

FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators is provided herein in accordance with 21 CFR Sec. 54.4 Certification and disclosure requirements.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2009

TO BE COMPLETED BY APPLICANT

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

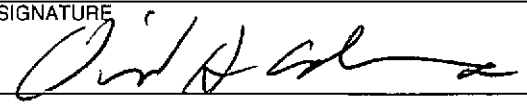
Please mark the applicable checkbox.

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

Clinical Investigators		
	See Attached	

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

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

NAME	TITLE
Dave Adams	CFO
FIRM/ORGANIZATION: Integrated Surgical Systems	
SIGNATURE: 	DATE: 9/7/07

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857

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DigiMatch™ ROBODOC® Surgical System
Clinical Trial Investigational Sites

001 – Sacramento Site

Dr. William Bargar
Dr. Thomas Blumenfeld
Join Surgeons of Sacramento
Sutter General Hospital
1020 29th Street, Suite 450
Sacramento, CA 95816

002 – Arkansas Site (Non-Active Site)

Dr. Carl Nelson (deceased)
Department of Orthopedic Surgery
University of Arkansas Medical Sciences
4301 West Markham, Slot 644
Little Rock, AK 72205

003 – New York Site (Non-Active Site)

Dr. Kenneth Krackow
Department of Orthopedics
Buffalo General Hospital
100 High Street
Buffalo, NY 14203

004 – Cincinnati Site

Dr. Michael Swank
Jewish Hospital
9825 Kenwood Road, #200
Cincinnati, OH 45242
Phone: 513-221-1914

005 – Japan Site

Dr. N Sugano
Dr. Nobuo Nakamura
Kyowakai Hospital
1-24-1, Kishibekita, Suita
Osaka 564-0001, Japan

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Section 9 – Declarations of Conformity and Summary Reports

Information regarding any declarations of conformity to a standard or a summary report recommended in any relevant device-specific guidance will be provided in accordance with Guidance for Industry and for FDA Staff Use of Standards in Substantial Equivalence Determinations, dated March 12, 2000.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

Section 9 – Declarations of Conformity and Summary Reports

A listing the applicable standards and/or device-specific guidance documents used in the design, development, testing and release of the DigiMatch™ ROBODOC® Surgical System is provided in the following table.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

Table of Standards and Device-Specific Guidance Documents

Standards No.	Standards Organization	Standards Title
EN 60601-1	EN, European Standards	Medical electrical equipment Part 1: General requirements for safety,
EN 60601-1-1	EN, European Standards	Medical electrical equipment - part 1: general requirements for safety 1: collateral standard: safety requirements for medical electrical systems
EN60601-1-2	EN, European Standards	Medical electrical equipment - part 1: general requirements for safety 2. Collateral standard: electromagnetic compatibility - requirements and tests
IEC801-2	IEC, International Electrotechnical Commission	ESD
IEC801-3	IEC, International Electrotechnical Commission	Radiated Electromagnetic Field Requirement
IEC801-4	IEC, International Electrotechnical Commission	Electrical Fast Transient/Burst requirement
IEC801-5	IEC, International Electrotechnical Commission	Surge Requirement
ISO 14971:2000	ANSI, American National Standards Institute AAMI, Advancement of Medical Instrumentation	Medical Devices – Application of Risk Management to Medical Devices
10993-1	ISO, International Organization for Standardization	ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
ANSI/AAMI/ISO 11137-1:2006	ANSI, American National Standards Institute AAMI, Advancement of Medical Instrumentation ISO, International Organization for Standardization	Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ANSI/AAMI/ISO 11137-2:2006	ANSI, American National Standards Institute AAMI, Advancement of Medical Instrumentation ISO, International Organization for Standardization	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

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Table of Standards and Device-Specific Guidance Documents (continued)

Standards No.	Standards Organization	Standards Title
ANSI/AAMI/ISO 11137-2:2006	ANSI, American National Standards Institute AAMI, Advancement of Medical Instrumentation ISO, International Organization for Standardization	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
N/A	FDA Guidance Document	Guidance for Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005)
ANSI S20.20-1999	ANSI, American National Standards Institute	Standard for the development of an ESD control program
EN 980:1997	EN, European Standards	Graphical symbols for use in the labeling of medical devices
21 CFR 820	U.S. Code of Federal Regulations	Quality Systems Regulation (QSR)

Section 10 – Executive Summary

The DigiMatch™ ROBODOC® Surgical System ("ROBODOC System" or the "System") is manufactured by Integrated Surgical Systems, Inc. ("ISS") for use in primary total hip replacement ("THR") surgery. The ROBODOC System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories, such as cutters, drapes, irrigation sets, probes and markers (ROBODOC). Together, the ORTHODOC and ROBODOC compose the DigiMatch™ ROBODOC® Surgical System, which is the subject of this submission.

In this submission, ISS demonstrates substantial equivalence (SE) of the ROBODOC® Surgical System to the relevant identified predicate devices (see Section 12). In addition, ISS believes that the substantial body of bench verification and validation testing discussed in Sections 16, 17 and 18, preclinical testing (Section 19) and clinical testing (Section 20) demonstrates the safety and effectiveness of the System for its intended use.

Integrated Surgical Systems
1433 N. Market Blvd., #I
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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10.1 Device Description and Intended Use/Indication for Use

10.1.1 ROBODOC System Device Description

The DigiMatch™ ROBODOC® Surgical System ("ROBODOC System" or the "System") is manufactured by Integrated Surgical Systems, Inc. ("ISS") for use in primary total hip replacement ("THR") surgery. The DigiMatch System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories, such as cutters, drapes, irrigation sets, probes and markers (ROBODOC).

ORTHODOC

The ORTHODOC is a 510(k) cleared (K960685) PC workstation with proprietary ISS software that enables the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur. Computed Tomography (CT) scan data of the patient's femur provide input to the system. The ORTHODOC stacks and interpolates between the individual scan slices to create three-dimensional images of the femur.

The ORTHODOC has a computerized directory of implant types and sizes, from which the surgeon may select an implant model. The system displays three-dimensional views of selected implant models for computerized templating with CT based femur images. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the image of the femur. The ORTHODOC also provides software tools allowing surgeons to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC with implant size, shape, and placement data. The output is saved on a transfer media and loaded into the electronics control cabinet of the ROBODOC prior to surgery.

ROBODOC

The operating room components of the ROBODOC system include a electromechanical arm, electronics control cabinet (which houses the computers and other electronic components and display monitor), a display monitor and miscellaneous accessories, such as cutters, drapes, irrigation sets, probes and markers. The transfer media containing the ORTHODOC preoperative plan provides input to the control cabinet computer.

A hospital technician prepares the robot for surgery by moving it into the operating room, connecting the cables, and turning the power on. Then, the display monitor provides instructions, which guides the technician step by step through loading the patient data transfer media and startup diagnostic procedures by displaying a series of

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display prompts. The purpose of the diagnostic procedures is to ensure proper functioning of the robot's electromechanical arm and accessories prior to surgery. The technician interfaces with the robot and responds to the prompts via a hand-held control device called a "pendant", which has five depressible buttons that enable the operator to select procedural alternatives, verify assumed conditions, and redirect the procedural flow, if necessary.

A sterile technician drapes the robot hardware with a customized sterile draping system that covers the robot arm, robot base, and attachments within the sterile field. The cutter drive, extension arm and the femoral fixator are then aseptically attached, and the technician performs a series of sterile diagnostic procedures.

When all diagnostics have been successfully completed, the monitor will display the patient verification data, which were loaded from the patient transfer media. The surgeon verifies the patient data (*i.e.*, name, operative side, type of implant, etc.), then the patient is anesthetized.

The surgeon begins the THA operation in the "normal" manner in accordance with the practice of medicine by exposing the femur. The surgeon may elect to perform a femoral neck osteotomy. If they do so, they would most likely perform the procedure according to the DigiMatch ROBODOC protocol for the selected implant and registration technique. However, this is optional; not required. The acetabulum will be prepared normally after the robot has milled the implant cavity because a femoral neck osteotomy or a high neck osteotomy will not provide adequate access for acetabulum preparation and installing the acetabular cup.

The surgeon clears soft tissue to facilitate registration procedures, secures the patient's leg in the femoral fixator and leg support fixture to prevent motion during surgery, and sets soft tissue retractors. Next, the surgeon performs registration procedures to provide orientation and reference information identifying where the bone is for the intra operative procedure (see Section 11.3).

When registration is complete, the robot's electromechanical arm will be manually oriented with respect to femur position. The femur must remain motionless to preserve the coordinate transformation and ensure accurate cavity placement. To prevent bone motion, the femoral fixator rigidly attaches to the robot base. The femoral fixator and a leg support fixture must be properly installed prior to registration procedures. Since bone motion could potentially change the registration, the robot is equipped with a bone motion monitoring system that detects unwanted motion of the femur. The system includes two bone motion monitors (BMMs), one for left legs and one for right legs (only one is used during a given surgery). The BMM is a small mechanical arm that has a sterile probe tip, which is attached to the bone and relays motion from the femur to enclosed position sensors. The probe makes direct contact with the bone and is held in place by an internal spring mechanism. If unwanted motion exceeding the predefined threshold during registration or cutting is detected, the ROBODOC's safety system will immediately disable motor power, stop the system and notify the surgeon

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by displaying an exception screen on the display monitor.

To expedite recovery in the event of unwanted bone motion, two bone motion recovery markers (also called "motion recovery posts") are installed and digitized during surface registration. One marker is installed in the proximal end of the femur and one is installed in the distal end. When the markers are digitized, the control cabinet computer records the positions of the marker and the initial registration obtained using the surface model. If unwanted bone motion occurs, this information facilitates recovery by enabling the surgeon to simply digitize a point on the top of each marker instead of re-digitizing the bone surface. Based on the location of the markers, the cabinet control computer performs the geometric computations to determine the new position of the femur.

The surgeon controls every phase of the surgical procedure by hand guiding the mechanical arm and using the control pendant. The control pendant has five buttons for initiating and aborting robotic assisted procedures, and for selecting options when prompted on the display monitor. The display monitor displays a series of menu screens that guide the surgeon in the use of the ROBODOC during surgery. The display monitor also provides visual feedback during the preparation of the femoral cavity.

10.1.2 Intended Use/Indication for Use

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary THA.

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

10.2 Comparison of Substantial Equivalence

Section 12 of this 510(k) submission contains tables and a discussion that demonstrates the ISS DigiMatch™ ROBODOC® Surgical System, MAKO Medical Voyager/Tactile Guidance System - CT, ISS Frameless Neuromate and Intuitive Surgical da Vinci® Surgical System are substantially equivalent or similar to one another in Intended Use, Indications for Use, technological characteristics and principles of operation.

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The ROBODOC and the above identified predicate devices are all intended for use as computer-aided robotic devices.

More specifically, the ROBODOC and the Voyager have the same Indications for Use. Each computer-aided robotic device is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

With few exceptions, there are no significant differences in the technological characteristics and principles of operation between the DigiMatch™ ROBODOC® Surgical System and one or more of its predicates. These few exceptions are explained below and discussed in more detail in Section 12:

1. The use of preoperative patient image data (CT scan data) to plan the surgery and produce a preoperative plan is the same for the ROBODOC and the predicate devices, the Voyager and the Neuromate. *Difference*: the da Vinci does not use preoperative patient image data (CT scan data) to plan the surgery and produce a preoperative plan. Rather, real time image data is gathered and surgery is planned in real time by the surgeon. However, this difference does not affect the intended use of the devices in that they all use robotic arms driven by control software and hardware to carry out the surgical intent.

2. The ROBODOC and the predicate devices, the Voyager and the Neuromate, require a High Level Operative Plan based upon a plan developed before surgery on a computer planning station. *Difference*: the da Vinci does not require this file to be generated before surgery. Instead, it is produced during the surgery. Although the plans are developed at different times, this does not affect the intended use of the devices in that they all use these instructions, once generated, to control one or more robotic arm.

3. The ROBODOC and the predicate devices, the Voyager and the Neuromate, use a single robotic arm. *Difference*: the da Vinci uses multiple robotic arms and end effectors. Although the number of arms and end effectors are different, all of the systems function in a similar manner and have the same intended use.

4. The difference in the type of registration and tracking technology are as follows:

   - The ROBODOC uses point to surface registration with mechanical tracking;
   - The Voyager uses surface to surface registration with optical tracking;
   - The Neuromate uses fiducial marker registration with ultrasonic tracking; and
   - The da Vinci uses visual registration and tracking.

These differences do not present any new issues of safety or effectiveness. The technologies and principles of operation are fundamentally the same in that they all use robotic arms driven by validated control software and hardware, and they have the same intended use and similar indications for use.

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Table 1 compares the Intended Use, Indications for Use, technological characteristics and principles of operation of the various devices.

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Table 1 Comparison of Substantial Equivalence

Substantial Equivalence Comparisons								
	Intended Use	**Indication for Use**	**Patient Image Data**	**Pre-Surgical Plan**	**Surgical Plan Data**	**Machine Instructions**	**Patient/Robot Registration Requirement**	**Robot Electromechanical Arm(s)**
DigiMatch™ ROBODOC® Surgical System	**Yes** computer aided robot	**Yes** orthopedic surgery	**Yes** CT Scan	**Yes** pre-surgery	**Yes** high level operative plan	**Yes** robotic arms driven by validated control software and hardware	**Yes** point to surface registration	**Yes** Robot with single electromechanical arm and end effector implement control file instructions
Voyager/Tactile Guidance System – CT (K052851)	**Yes** computer aided robot	**Yes** orthopedic surgery	**Yes** CT Scan	**Yes** pre-surgery	**Yes** high level operative plan	**Yes** robotic arms driven by validated control software and hardware	**Yes** surface to surface registration	**Yes** Robot with single electromechanical arm and end effector implement control file instructions
Frameless Neuromate (K991081)	**Yes** computer aided robot	**No** neurosurgery	**Yes** CT Scan	**Yes** pre-surgery	**Yes** high level operative plan	**Yes** robotic arms driven by validated control software and hardware	**Yes** fiducial marker registration	**Yes** Robot with single electromechanical arm and end effector implement control file instructions
da Vinci® Surgical System (K043153)	**Yes** computer aided robot	**No** endoscopic surgery	**No** visual image	**No** intra-surgery	**No** control file developed in real time during surgery	**Yes** robotic arms driven by validated control software and hardware	**Yes** visual registration	**Yes** Robot with multiple electromechanical arms and end effector implement control file instructions

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10.3 Summary of Performance Testing

The ROBODOC is designed as a tool to assist a surgeon in cutting the implant cavity. The use of computer technology permits surgeons to achieve precision and consistency when executing a surgical plan to a degree that they may not always attain with conventional tools and methods. The benefits of using a computer-directed tool is that it takes several variables out of the implant planning and implementation process. These variables include inconsistency and the potential for error, which is inherent in placement, manual broaching and cavity preparation. Another real, but less defined benefit is that by using the ROBODOC System the physician is required to create a preoperative plan. Rigorous preoperative planning is not always performed when traditional manual methods are employed.

Improved reliability in accurately placing and cutting the implant cavity does not alter the fundamentals of THR surgery itself. The surgeon continues to exercise traditional judgment as to implant size, shape and placement, which are the significant factors in determining the surgical outcome. These judgments are made in three dimensions using the preoperative planning phase with the aid of the 510(k) cleared ORTHODOC prior to surgery. The ROBODOC's role is not to aid in the formulation of the surgical plan, but rather as a tool to aid in achieving its precise execution.

ISS has completed bench, animal, cadaver and clinical testing that assess the safety and efficacy of the ROBODOC System. These are summarized below. Full reports of these tests are contained in Sections 14, 15, 16, 17, 18, 19 and 20.

10.3.1 Nonclinical Studies

Because the ROBODOC is intended primarily as an accurate and reliable surgeon controlled cutting tool, the principal question relating to the effectiveness of the device is whether the ROBODOC reliably and accurately cuts a cavity in the location specified by the surgeon.

Nonclinical cadaver and animal studies (see Section 19) provide an accurate means of determining cavity accuracy and placement. The value of such studies is that they allow a measurement of the gap between the bone and implant. They also permit histological examinations of the cavity/implant interface, which has value in determining whether the implant apposition within the cavity is sufficiently narrow. As is well documented in the literature, bone does not readily bridge gaps greater than 1 mm. A "White Paper" discussing this point was submitted to FDA on December 31, 1997. A copy of the paper entitled, *Relationship of Implant Fit and Alignment to Clinical Outcome in Cementless Hip Replacement – A Literature Review,* is provided in **Attachment 1** of Section 10.

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Cadaver Study

The cadaver study compared the accuracy of cutting the femur with the ROBODOC versus manual broaching. The results showed that the ROBODOC was more accurate than manual broaching and led to significantly reduced gaps between the implant and bone. A full report of this study is provided in Section 19.2 of this 510(k) submission.

Animal Study

The animal study, involving 20 male greyhounds, also supports the conclusion that the ROBODOC is more accurate than manual broaching in cutting the femur. Histological examination revealed many instances of fracture or osteotomy in the control group, compared to none in the ROBODOC group. In addition, histological examination revealed that the ROBODOC group had more consistent cortical bone continuity, better apposition of implants with cortical and cancellous bone, and appeared to have less cancellous bone hypertrophy. The full report and histological photos are included in Section 19.1 of this 510(k) submission.

10.3.2 Clinical Studies

Section 20 of this submission contains reports of two IDE clinical trials (IDE# G920035 and G000071) and two foreign trials, which are provided in support of this premarket notification.

The First IDE Clinical Trial (G920035), reported in Section 20.2, was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. Upon review of the data from the First Trial in October 2000, FDA identified four potential risk factors for the ROBODOC® Surgical System, namely:

- The need for two surgical procedures (a separate surgical procedure to implant fiduciary pins prior to the primary THA procedure);
- Post-surgical ipsilateral knee pain (possibly associated with the pre-operative placement of fiduciary markers or pins);
- Longer surgical times during THA; and
- Significantly greater blood loss during THA*.

* The greater blood loss was probably due to longer surgical times, as the blood loss per minute of surgery was equivalent between the two study groups.

A primary objective of the First IDE was to confirm that the ROBODOC® Surgical System safely and reliably implemented the preoperative plan developed by the surgeon on the ORTHODOC component of the system. The primary endpoints of efficacy that demonstrated precise and reliable implantation of the preoperative plan were fit and alignment of the femoral implant. This objective was accomplished and the results of the independent radiological review were reported to FDA in 1998. A copy of the paper that

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was presented, *Report of Radiographic Data from IDE Trial G920035* by Douglas Robertson, M.D., Ph.D., is provided in **Attachment 2**.

During a January 18, 2007 meeting, FDA indicated that the First IDE Trial, despite the potential risk factors, did demonstrate the overall safety and effectiveness of the ROBODOC System technology.

Because, in part, of the potential risk factors identified in the pin-based registration technology, the ROBODOC® Surgical System was modified to allow a less invasive technology that required 2, rather than 3, locator pins to be placed pre-operatively in order to register the location and orientation of robotic arm in relationship to the operative femur. Validation of the 2-pin registration technology was based, in part, on the results of a clinical study by Nishihara et al. (1). A copy of the published study is provided in Section 20.3 of this submission. This 140 patient, (156 femora) randomized, controlled study showed a favorable comparison between the outcomes of hand-rasping and robotic milling with 3-dimensional preoperative planning using the ORTHODOC system.

Further development lead to an iteration of the device that uses pinless registration technology. This device is known as the DigiMatch™ ROBODOC® Surgical System. The pinless registration technology was validated in 31-patient German study at Berufsgenossenschaftliche Unfallklinik (BGU) in Frankfurt, Germany. A report of this is provided in Section 16 and Section 20.4 of this submission.

The Second IDE Clinical Trial (IDE # G000071), reported in Section 20.5 of this submission, was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical Assistant System, which is the subject of this submission. This trial was conducted in response to FDA's recommendation and was focused on demonstrating that the risk factors seen in the First Trial had been mitigated or eliminated. The DigiMatch™ technology modified the ROBODOC System so as not to require pre-operative placement of fiduciary pins, thereby eliminating the requirement for a separate surgical procedure and the potential association of ipsilateral knee pain. The issue of longer surgical times and greater blood loss was addressed by additional training of the participating surgeons and the improved DigiMatch™ technology of the device. The data from this trial also confirmed the safety and efficacy of the ROBODOC System.

Although a complex new technology was introduced into the OR, integration of the System into daily routine was achieved without major problems. Preoperative planning on the ORTHODOC proved to be a benefit compared to traditional templating. The ROBODOC enabled the precise execution of the plan. No deviations from the preoperative plans have been detected in any of the more than 1400 surgeries in the overall European experience. No fractures occurred in this series of more than 750 consecutive patients and no other fractures have been reported at any of the other European centers. Short-term follow-up shows accurate positioning and adequate sizing. After two years, there has been no evidence of subsidence or tilting of the implants.

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Attachment 1

Relationship of Implant Fit and Alignment to Clinical Outcome in Cementless Hip Replacement – A Literature Review

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RELATIONSHIP OF IMPLANT FIT AND ALIGNMENT TO CLINICAL OUTCOME IN CEMENTLESS HIP REPLACEMENT: A LITERATURE REVIEW

I. Introduction

This document provides an overview of the scientific literature which describes the relationship between initial surgical fit and alignment to clinical outcome in cementless total hip replacement ("THR"), through the relationship between fit and alignment and the mediating factors of fixation, ingrowth, and stress transfer. The weight of the literature from both preclinical and clinical studies indicates that good initial fit and alignment increase bone-to-implant contact and reduce micromotion, thus facilitating bone ingrowth and long-term implant stability. Likewise, studies indicate a well-fit prosthesis with bone ingrowth along the length of the implant transfers axial and torsional strains as uniformly as possible. Uniform stress transfer minimizes harmful stress-related bone resorption, reducing the likelihood of implant loosening and associated thigh pain.

A fundamental tenet of cementless THR is that initial implant fit and alignment are critical to the ultimate clinical success of the procedure. [1]/ Although the exact relationship between surgical parameters and clinical outcome is still being investigated, the existence of a positive association between good fit and alignment and good clinical results is widely accepted. As has been observed, while "the biomechanical interactions between cementless femoral components and bone are not well described, . . . *(m)ost clinicians agree, however, that the quality of initial fixation is one of the most important factors in determining the success of the implant.*" [2]/

Accordingly, the orthopedic surgeon performing a THR undertakes to ream a femoral cavity that mirrors the dimensions of the hip implant as closely as possible. Implant manufacturers specify the optimal cavity dimensions for individual prostheses, and, within the

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[1]/ Otani and Whiteside observed: "The most important factor for initial success of cementless femoral components is to achieve rigid initial fixation so that micromotion between the implant and bone is low along the entire length of the implant" (p. 335).

[2]/ See Otani and Whiteside. (1992) at 335 (emphasis added).

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limitations of manual reaming techniques, surgeons reproduce these dimensions so as to maximize the surface contact between implant and bone. This practice conforms to the weight of orthopedic research and to the collective wisdom of clinical experience, which indicate that surgical fit and alignment directly affect the biological and biomechanical parameters that predict clinical success. These parameters include the quality of the initial surgical fixation, the extent of bone ingrowth, and the pattern of stress transfer from implant to bone.

II. Literature Review

A. Preclinical Studies

Converging lines of investigation -- from laboratory simulations of prosthesis implantation and computerized biomechanical models to animal and human cadaver studies -- provide clear evidence that fit and alignment bear a direct relationship to two major predictors of clinical outcome, namely implant stability and the quality of implant stress transfer.

It has been demonstrated that initial implant stability is maximized by optimal surgical fit. Exact fit reduces micromotion around the bone-implant interface, thus facilitating the bone ingrowth that is necessary for long-term stability and clinical success (Onsten et al., 1995; Won et al., 1995). Laboratory studies indicate that surgical fit is a critical determinant of initial stability (Kendrick, 1995, O'Toole, 1995) and that exact fit prostheses result in significantly less micromotion under laboratory conditions (Dujardin et. al., 1996; Harman et al., 1995; Schneider et al., 1989). Laboratory research has also demonstrated that metaphyseal alignment is significantly related to vertical and rotational implant stability (Pernell et al., 1995; Dujardin et al., 1996; Naidu et al., 1996).

A consistent finding in animal models of hip replacement is that initial fit determines the likelihood of successful biological fixation for cementless prostheses. *In vivo* animal studies of porous-coated implants indicate that long-term stability via bone ingrowth is largely determined by the initial degree of proximal and distal contact between implant and bone (Jasty et al., 1997). Furthermore, there is evidence from animal investigations of a critical gap width beyond which the space between implant and existing bone is unlikely to be bridged by

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new bone growth (Carlsson et al., 1988). [3]/ Where initial fit is poor, with little direct bone-to-implant contact, high fixation failure rates are seen among animals receiving cementless implants (Brujn et al., 1996). The failure to achieve adequate fixation through bone ingrowth may also be exacerbated by excessive motion at the bone-implant interface of a poorly-fitted prosthesis (Ducheyne, De Meester and Aernoudt, 1977).

Investigations with human cadavers have yielded evidence that surgical reaming technique (which largely determines initial fit and alignment) affects the quality of implant fixation and the resulting stability of cementless implants (Otani et al., 1995) [4]/. Furthermore, where a press fit can be obtained, destructive micromotion is reduced and implant stability is enhanced [5]/ (Won et al., 1995).

Fit and alignment also bear a direct relationship to the manner in which mechanical loads are distributed across the implant and the surrounding bone. Poorly-fitted implants with non-uniform bone ingrowth are associated with bone resorption. This stress-related pattern of bone loss results from abnormal load distribution. Without adequate biological fixation the shell of bone surrounding the implant does not carry stress uniformly, and stress shielding causes the bone to resorb, destabilizing the implant (Engh et al., 1987). Results from cadaver studies indicate that improving stem fit normalizes patterns of stress distribution, thus minimizing the potential for harmful bone resorption (Hua and Walker, 1995) [6]/.

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[3]/ Carlsson et al. (1988) examined the osteogenic response of rabbit tibia to titanium implants of varying diameters. Results indicated that after twelve weeks, biological fixation measured as direct bone-to-implant contact increased as implant diameter approached the diameter of the burr hole. When the width of the initial gap between implant and cavity exceeded one millimeter, no osteoblastic activity was detected.

[4]/ Otani et al. (1995) assessed average failure torque for cementless femoral stems implanted with each of several reaming techniques. In this human cadaver study, the reaming technique that produced contact both proximally and distally achieved the best surgical fixation.

[5]/ Some micromotion will always occur between two surfaces in contact but without compression when in the presence of a dynamic load. Bone resorption follows when this micromotion exceeds the tolerance of the surrounding tissues. As resorption increases, implant motion becomes more pronounced, further exacerbating resorption and producing a loose implant. See Schneider, et al., 1989.

[6]/ Even among optimally fitted implants, however, greater rigidity of implant materials and larger femoral stem size appear to increase stress-related bone loss (Engh, et al., 1987).

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B. Clinical Studies

1. Stability

The hypothesis that fit and alignment are directly related to stability and clinical outcome has received considerable support in the clinical literature. There is substantial evidence and investigator opinion that: (1) fit and alignment at the time of surgery is a strong predictor of implant stability, and (2) implant stability is a critical component in long-term clinical outcome.

Surgical fit and canal alignment is a chief component of initial fixation and biologic fixation which occurs over time, both of which are critical to successful fixation and stability (Engh & Massin, 1989b; Bertin et al., 1985). When prostheses are more accurately aligned within the bone canals, post-surgical movement of the device is less likely and a lower incidence of migration or subsidence is observed (Bands et al., 1991; Owen et al., 1994; Haddad et al., 1990). Correct positioning of the implant during surgery and the precision with which it is performed will improve initial fixation (Wagner & Wagner, 1996; Zweymuller, 1986). Improved sizing and improved surgical technique and instrumentation, which has occurred over time, contributes to this precision and to the resultant prosthesis stability (Engh et al., 1990a).

Implant loosening can be attributed to inaccurate fit due to undersizing of stems or to excessive reaming during implantation. Migration and subsidence are a common result of undersizing of cementless implants since there is a greater opportunity for implant movement if the implant is loose in the femoral canal (Sweetnam et al., 1995; Engh et al., 1990a; Bands et al., 1991; Kim & Kim, 1993; Kim & Kim, 1992). In addition, loosening and subsequent failure can result when the bone is reamed excessively during implantation (Wilson-MacDonald et al., 1990). Much of the literature supports the theory that lack of precision during surgery, with respect to inaccurate sizing and imperfect surgical technique, is a key component of implant stability (Engh & Massin, 1989b; Bertin et al., 1985; Amstutz et al., 1989; Wagner & Wagner, 1996; Zweymuller, 1986).

Biological fixation, like initial surgical fixation, is also a critical factor in the stability of an implant. "Immediate implant stability is an absolute requirement to cementless replacement" (Engh et., 1988), particularly since effective initial mechanical stability is required at the time of implantation to allow ingrowth fixation to occur (Rosenberg, 1989; Amstutz et al.,

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1989). Where press fit is not achieved during surgery, there is a greater likelihood of long-term prosthetic instability (Engh et al., 1988). In addition, cases with early fixation from bone ingrowth, compared with delayed stabilization by fibrous tissue, are more likely to remain stable over time (Engh & Massin, 1989b). There is evidence that fixation due to bone ingrowth is readily apparent within one year and will remain stable for a period of ten years (Engh & Massin, 1989a).

The clinical literature also supports the hypothesis that implant stability is positively correlated with clinical outcomes. Instable fixation, as evidenced by roentgenographic appearance, has been correlated with poor clinical outcome, such as high incidence of pain or limp (Engh et al., 1988; Engh et al., 1990a; Engh & Massin, 1989b;). While there is evidence that most patients with fixation at two years will maintain this stability (Engh & Massin, 1989b), there is a correlation between fit and loosening of the prosthesis in as little as three months time (Wilson-MacDonald et al., 1990). There are also studies in which a correlation between pain and insufficient fit or canal alignment have been observed directly without the interim assessment of stability (Kim & Kim, 1993; Callaghan et al., 1988; Haddad et al., 1990).

2. Stress Transfer

Biomechanical stresses on the human hip joint include compression, tension, and shearing forces (Engh & Bobyn, 1985, at 135). In a patient with a hip implant these biomechanical stresses are not transferred normally throughout the hip joint and femur; instead, stress is transferred preferentially through the rigid implant, causing the more flexible surrounding bone to bear a reduced load. In the absence of biological fixation, which creates the necessary bone-implant interface, normal implant-to-bone transfer of shear and tensile forces cannot occur (Id.).

This phenomenon, known as "stress shielding," can cause bone atrophy or resorption in understressed femoral areas (Bobyn et al., 1992; Engh & Bobyn, 1985). Clinical studies confirm that stress-related degenerative bone changes increase implant instability, micromotion, and rates of loosening (Kim & Kim, 1992), all of which are associated with thigh

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pain (Bands et al., 1991;) [7]. Thigh pain is perhaps the most troublesome of the clinical complications in THR; during the first two postoperative years the reported incidence of thigh pain ranges from 3% to 30% of patients (Petrou, et. al. 1994).

Stress-related resorption also increases fracture rates, either by weakening the entire femur, or by increasing the point stress in areas where concentrated loads are transferred back to bone (Engh & Bobyn, 1985, at 114). Additionally, concentrated load transfer can lead to bone hypertrophy, which is associated with end of stem pain (Id.).

The weight of the literature suggests that fit and alignment, as evaluated from postoperative radiographs, influence stress-related remodeling of cortical bone. Good initial fit and alignment are critical to biological fixation, without which stress-related canal enlargement and an unstable prosthesis are likely (Engh & Massin, 1989). Stress-related bone remodeling is in turn associated with clinical outcome, to the extent that "[t]he long-term success or failure of porous-coated, cementless joint replacements depends partially upon remodeling of surrounding bone" (p., et al., 1991). The quality of the initial fit and alignment achieved by the surgeon will inevitably influence the clinical success of THR (Engh et al., 1987).

Stress-related bone changes can be evaluated by comparing serial radiographs across the one to two-year postsurgical "adaptive" phase of transplant recovery (Engh & Bobyn; Rorabeck et al., 1995; Engh & Massin, 1989). Although the quantitative radiographic measurement techniques typical of THR studies often lack precision, researchers have found that radiographic measures of fit, alignment, and stability (e.g., measures of implant-cortical contact, migration, or radiolucent lines) are significantly correlated with intraoperative stability (based upon preoperative measurements made prior to revision surgery) (Vreslovic et al.; 1994; Glassman & Engh, 1992), and predict clinical outcomes such as loosening or the presence or absence of thigh pain (Engh et al., 1990). [8] Specifically, Engh et al.(1987) found a

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[7] While the goal of THR is to achieve "little or no changes in density or geometry" of the surrounding bone, a certain degree of stress-related resorption is inevitable. For a patient with a well-fixed cementless prosthesis, minor resorptive bone remodeling appears to have little clinical impact (Engh & Bobyn, 1985).

[8] Postmortem histological analysis has been used to successfully validate radiographic assessment of biological fixation and stress shielding (Engh et al., 1987).

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significantly decreased incidence of stress-related thigh pain among patients whose postoperative radiographs indicated good implant fit and the presence of bone ingrowth.

3. Absence of Demonstrable Relationship between Fit/Alignment and Outcome in Certain Studies

There is agreement among the vast majority of the world's experts in orthopedics that precise fit/alignment will result in positive clinical outcomes. This is and has been the primary basis for developing new prostheses and for improving precision in surgical technique. While some studies have failed to show such a correlation, despite the expectations of the investigators, there are clear explanations that may account for these results: (1) small numbers of patients with multiple confounding variables, (2) radiographic errors, and (3) type II error.

First, many of the studies in the literature comprised inadequate numbers of total hip replacements to show a statistically significant relationship between fit/alignment and clinical outcome. Typically, these studies did not use rigorous research methods to arrive at statistically significant outcomes and were often retrospective studies of radiographic data and outcomes (e.g., Wagner & Wagner, 1996; Bands et al., 1991; Nunn, 1988). In research regarding total hip replacements, multiple confounding variables must be accounted for in determining the necessary numbers of patients. These include patient age (Mok & Bryant, 1987), reason for the hip replacement (Brinker et al., 1996), overall health of the patient, type of procedure (primary total hip replacement or revision) (Cameron, 1994), design of the prosthesis (Onsten, 1995; Cameron, 1993), and the skill of the surgeon (Mok & Bryant, 1987; Zweymuller, 1986). Much of the literature suggests that these variables may have an impact on outcome, but frequently these differences were not accounted for nor controlled for in studies. Accordingly, few studies used statistical analysis to review the data and researchers have commented that additional research may be warranted (Wixson, 1991; Callahan, 1988; Jansson & Refior, 1992).

Second, radiographic errors are common and variations are expected. Errors or variations include rotation of the limb due to positioning, and magnification and density variations due to differing techniques. For instance, assessment of radiographic changes after hip replacement revision is "notoriously difficult" (Patterson, 1987). In addition, errors are inherent in radiographic testing due to the inadequacy of plain radiographs in assessing three dimensional fit (Barrak & Lebar, 1992). One study of the accuracy of migration measurements of total hip

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arthroplasties found that there was more than a 2mm error rate for radiographic measurements (Malchau et al., 1995); thus, radiolucencies which were detected may not provide accurate evidence of migration. Since studies have often used measurements greater than 2-3mm as evidence of migration, the accuracy of results may be in question and remeasurement could lead to the opposite result (Incavo et al., 1993; Wixson et al., 1991; Rorabeck et al., 1996). Moreover, acetabular radiolucencies may be manifestations of fibrous ingrowth in *well-fixed* components and may not be evidence of migration or be correlated with clinical outcome (Brinker et al. 1996). However, when radiolucencies are not found or are rare, as is the case with ROBODOC studies, there is a greater likelihood that this is a true reflection of good fit/alignment, if the measurements accounted for possible errors.

Third, simply because a study failed to find a correlation between fit/alignment and clinical outcome does not mean that there is no true correlation. Failure to show a difference between patients with precise fit/alignment and those without does not mean that a difference does not exist. For instance, technical faults such as "inadequate preparation of the medullary canal or excessive impaction of the stem" can lead to unrecognized femoral cracks and initial implant instability (Duparc & Massin, 1992). Studies which fail to show a direct correlation between fit/alignment and outcome do not disprove the relationship between fit/alignment an outcome, they are simply not adequately designed to support the proposition.

III. Conclusion

In carefully-conducted prospective studies, the quality of postoperative fit and the presence of biological ingrowth have been found to predict clinical outcome far better than age, underlying disease process, or type of implant (Engh et al. 1987; Engh et al., 1988). Similar observations are reported in numerous retrospective and clinical case studies (e.g., Amstutz et al., 1989; Kim & Kim, 1992; Sweetnam et al., 1995; Barrack & Newland, 1990). In contrast to these reports, one recent investigation by Robinson and Clarke (1996) failed to detect a relationship between fit and alignment and clinical ratings, a not-uncommon result in a clinical literature where measurement techniques are imprecise and where many studies are statistically underpowered. Despite their failure to detect a relationship between radiographic measures and clinical endpoints, it should be noted that Robinson and Clarke did find a significant correlation

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between canal alignment and stem migration, which is an important surrogate endpoint for clinical outcome.

Successful biological fixation requires a well-fit implant, and at present, initial implant fit is quite dependent upon the skill of the surgeon. Researchers who have undertaken THR studies acknowledge that good surgical technique is a necessary precursor to adequate initial fixation, and, ultimately, to good clinical results (Zweymuller, 1986).

Standard manual broaching techniques are at times overly aggressive, sometimes resulting in weakened femurs, intra-operative fractures (Otani et al., 1992; Duparc & Massin, 1993), or destruction of the weight-bearing cortex of the acetabulum (Wilson-MacDonald et al., 1990). Failures of early cementless implants can often be attributed to crude surgical techniques, poor instrumentation, or inaccurate reaming (Engh et al., 1990b). Conversely, surgeons who subsequently achieved good clinical outcomes attribute their success in part to the good fit obtained from accurately-reamed cavities (Kennedy, 1994). Thus, the accuracy of reaming can be shown to have a clear and predictable effect upon clinical outcomes: more precisely-reamed cavities result in better surgical fixation; better surgical fixation produces more extensive biological ingrowth, improved stability, and more uniform stress transfer; and patients with these stable, extensively ingrown prostheses have less pain and require fewer revisions.

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Attachment 2

Report of Radiographic Data from IDE Trial G920035

Douglas Robertson, M.D., Ph.D.
Independent Radiologist

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Abstract

Purpose: Computer-aided surgery has the potential to improve conventional surgery results for total hip replacement. The data which is the subject of this radiographic review is derived from a three-center IDE study of the ROBODOC device. The radiographic evaluation tested the hypothesis that computed-aided surgery improved the 3 month radiographic results of total hip replacement, as compared to conventional surgery.

Methods: Radiographic review of AP films was performed by an independent musculoskeletal radiologist, specializing in joint arthroplasty. 1/ Radiographs from the control and ROBODOC groups were reviewed at 3 months for fit, fill, seating, alignment, tip placement, radiolucent lines, loose porous coating, and fracture. Radiographs at 12 months were reviewed for radiolucent lines. Statistical analyses were performed comparing the control and ROBODOC group results.

Results: The ROBODOC group had better fit and fill at the proximal prosthesis regions, fulfilling the prosthesis manufacturers' goal of proximal interlocking fit. As expected, no difference was detected at the distal prosthesis regions. Seating and alignment was significantly improved in the ROBODOC group. As anticipated, no difference was detected in distal prosthesis tip centering. One fracture was radiographically detected on the series of follow-up radiographs and this fracture belonged to the control group. The ROBODOC group had less radiolucent lines in the distal stem zones. In the remaining zones there was no difference between the two groups. The ROBODOC group had fewer patients with 5 or more zones with radiolucent lines (which is an indicator of possible loosening of the implant).

Conclusion: The ROBODOC group had significantly better results for fit, fill, seating, alignment, and radiolucent line occurrence compared to the control group and was not surpassed in any of the studied radiographic parameters by the control group. These radiographic results demonstrate that the robotic-aided surgery improved the results of conventional hip replacement.

1/ The review was performed by Douglas Robertson, M.D., Ph.D., Assistant Professor of Radiology, Washington University Medical Center; curriculum vitae is appended to this report.

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Independent Radiographic Review

An independent Radiographic Review was performed by a board certified, fellowship trained, full-time musculoskeletal radiologist specializing in adult reconstructive surgery. Analyses were made of patient anteroposterior (AP) pelvis and AP ipsilateral hip radiographs taken at 3 and 12 months. The readings were made blinded to patient name, surgeon, or preparation process (manual or ROBODOC).

Methods

3 Month Evaluation

Radiographs from 129 study patients were available for analysis. ISS Independent Quantitative Radiographic Review (Form 14) and ISS Independent Qualitative Radiographic Review (Form 15) were used. 2/

ISS Independent Quantitative Radiographic Review, Form 14

Fit was measured in millimeters at the lines (see below) as the gap between the prosthesis and the cortical bone (see Form 14, pp. 2 &3 of 5, II. A & III. A). In the region of the lesser trochanter, medial and posterior measurements at Level 2, a smooth curve connected the cortex proximal and distal to the lesser trochanter and the distance between the implant and the fitted curve was measured.

Fit lines (p. 2 of 5) for the AP radiographs were drawn as lines perpendicular to the femoral long axis. The femoral long axis was defined by the line connecting midpoints of the width of the femoral canal from the lesser trochanter to the femoral isthmus. The femoral axis line was extended proximally to the level of the proximal femoral osteotomy. Based on the manufacturers' specifications, the following fit criteria were created for the AML and Osteolock prostheses. Fit Level 1 was drawn at the medial neck cut. Level 2 was at the midpoint of the lesser trochanter. Level 3 was drawn 1.5 cm distal to Line 2. Level 4 was at the top of the Osteolock prosthesis distal sleeve, the distal end of the porous coating for an AML prosthesis, or 3.0 cm proximal to Level 5 for an Osteolock prosthesis without a distal sleeve. Level 5 was drawn just proximal to the bottom of the Osteolock prosthesis with a distal sleeve, 1.5 cm

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2/ Copies of ISS Forms 14 and 15 are appended to this report.

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proximal to the AML prosthesis tip, or 1.5 cm proximal to tip of the Osteolock prosthesis without a distal sleeve. Lines for the lateral radiographs (p. 3 of 5) were drawn at equivalent locations as the AP radiographs described above.

Axial seating (p. 2 & 3 of 5, II. B & III. B) of the prosthesis collar (AML) or medial prosthesis body-prosthesis neck junction (Osteolock) was measured in millimeters as the distance from these points to the most medial point of the proximal femoral neck osteotomy. This vertical distance was in parallel with the femoral long axis. Prosthesis alignment (p. 2 & 3 of 5, II. C & III. C) was defined by the angle formed by the intersection of the femoral axis line and the prosthesis long axis line. Varus and valgus as well as anterior and posterior orientation were noted.

Radiographic technique (p. 2 & 3 of 5, II. D & III. D, Comments) was evaluated as adequate (no "film rotation" noted, no comment written) or less than adequate (estimate of "film rotation" made, comment written).

Evidence of a neocortex (radiolucency) in the Gruen zones (p. 4 of 5, IV. E 1 & 2) was counted as positive if the radiolucent line between the neocortex and the prosthesis was greater or equal to 1mm in thickness and if it occupied 50% or more of a Gruen zone (according to criteria specified by American College of Orthopedic Surgeons). Comments were written detailing if the neocortex was divergent, *i.e.* not paralleling the prosthesis surface. Additional comments included noting the presence of bony "spot welds", bony "streaming", periosteal hypertrophy, osteolysis, and calcar rounding. None of the findings described in this paragraph were present on the 3 month radiographs.

Distal tip displacement and direction (p. 4 of 5, IV. E & F) was measured according to Figure 5 (p. 4). The presence of loose porous coating (p. 4 of 5, IV. G) was also noted.

Independent Qualitative Radiographic Review, Form 15

Evidence of a neocortex (radiolucency) in the Gruen zones (p. 2 of 3, II. A & B) was counted identically to the method described above for Form 14. Gruen Zone Fit (p. 2 of 3, II. A & B) was defined as present for proximal zones 1, 2, 6, 7 and 8, 9, 13, 14 when the prosthesis-cortex distance was less than or equal to 2 mm at any point in the zones which have

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cancellous bone. For distal zones 3, 5 and 10, 12 a prosthesis-cortex distance of less than 1 mm (since these zones do not have cancellous bone), at any point, defined fit.

Distal tip presence and direction (p. 2 of 3, II. C) was measured according to Figure 3 (p. 2, Form 15). The presence of loose porous coating (p. 2 of 3, II. D) was also noted. The presence of femoral fracture (p. 3 of 3, II. A), stem tip placement (p. 3 of 3, II. B), implant sizing (p. 3 of 3, II. C. 1.), and implant positioning within the canal (p. 3 of 3, II. C. 2.) were also recorded.

The proximal medial fit score was recorded in the Comment Section (bottom of p. 3 of 3). This score described the fit of the proximal medial aspect of the prosthesis to the proximal medial (endosteal) cortex. The proximal medial cortex was defined as the medial (endosteal) cortex extending from the midpoint of the lesser trochanter up to the medial portion of the femoral neck osteotomy. Scores ranged from 1 to 5, where 5 denoted 50% or greater prosthesis-cortex contact, 4 denoted 25-49% contact, 3 denoted less than 25% but greater than 2 point contact, 2 denoted parallel stem and cortex edges with 1 point contact or no cortical contact and 1 denoted non-parallel edges with no cortical contact. An prosthesis-cortex distance of less than 1 mm defined contact.

12 Month Evaluation

Radiographs from 100 study patients were available for the 12 month and 24 month analyses. ISS Independent Quantitative Radiographic Review, Form 14 was used (a copy of Form 14 is included in this **Appendix 6**).

Evidence of a neocortex (radiolucency) in the Gruen zones (Form 14, p. 4 of 5, IV. E. 1&2) was counted as positive if the radiolucent line between the neocortex and the prosthesis was greater or equal to 1mm in thickness and if it occupied 50% or more of a Gruen zone. Comments were written detailing if the neocortex was divergent, *i.e.* not paralleling the prosthesis surface. Additional comments included noting the presence of bony "spot welds", bony "streaming", periosteal hypertrophy, osteolysis, and calcar rounding. These findings were made without comparison to earlier studies.

Statistical Analysis

All analyses were performed using The *SAS* System (*SAS* Institute, Inc., Cary NC). Means and standard deviations were used to describe continuous values. Proportions were

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used to describe discrete values. Differences between groups were determined by the Wilcoxon rank sum test for continuous variables and by the Chi-square test for categorical variables. For categorical tests with small expected cell counts, Fisher's Exact Test was employed.

Results

3 Month Results

Films from a total of 129 hips were evaluated at 3 months; 65 control and 64 ROBODOC cases. Thirty AML prostheses were inserted into 24 patients; 15 were in the control group and 15 in the ROBODOC group. One hundred and six Osteolock prostheses were inserted into 96 patients; 50 were in the control group and 56 in the ROBODOC group.

a. Fit (prosthesis to cortical bone distance)

The pooled fit data (AML and Osteolock) for the AP radiographs are presented in Table 1. (Data for Level 5 were not pooled because the AML prosthesis was not designed to contact at this level compared to the distal sleeve Osteolock prosthesis. Both prostheses were designed to contact in Levels 1-4; hence, the data for these levels was pooled.) At the proximal levels (Levels 1-3) the medial and lateral fit of the ROBODOC cavities was significantly closer than the control group cavities (unpaired t-test). There was no significant difference in the fit at the distal levels.

Analysis of the frequency of levels with $\leq$ 2mm fit demonstrated a statistically significant difference between the control and ROBODOC groups (chi-square, p=0.001). See Tables 2 and 3. It is generally believed that bone will not remodel and fill in >gaps 2mm, and 2mm is also beyond typical measurement error.

Analysis of the Osteolock prosthesis group, revealed similar differences as the pooled data. Analysis of the AML prosthesis group revealed no significant differences between the control group and the ROBODOC likely due to the small number of AML implants; nevertheless fit appeared to be generally better in ROBODOC cavities (unpaired t-test).

b. Fill

The pooled fill data (AML and Osteolock) for the AP radiographs are provided in Table 4. The proximal levels (Levels 1-3) had statistically larger fill in the ROBODOC group as compared to the control group (unpaired t-test). There was no significant difference in the fill at the distal levels.

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Analysis of the frequency of levels with ≥ 90 percent fill (Table 5) demonstrated a statistically significant difference between the control and ROBODOC groups (chi-square. p=0.01).

Analysis of the Osteolock prosthesis group, separate from the AML prosthesis group, revealed similar differences as the pooled data. Analysis of the AML prosthesis group revealed no significant differences between the control group and the ROBODOC at any level (unpaired t-test).

c. Axial seating-prosthesis distance from neck cut

The average axial seating distance for the pooled data (AML and Osteolock) for the ROBODOC group was significantly less than the control group's average (unpaired t-test). See Tables 6, 7 and 9.

d. Alignment

The average alignment (in absolute value) for the pooled data (AML and Osteolock) for the ROBODOC group was approximately 0.4 deg in the frontal plane and 0.8 deg in the lateral plane. These values were significantly less than the control group's average of approximately 0.8 and 1.1 deg, respectively (unpaired t-test). See Tables 6, 7 and 10.

e. Neocortex (radiolucency)

No evidence of a neocortex was present for any of the patients at the 3 month radiographic follow-up.

f. Distal tip displacement and direction

There was no statistical difference in the displacement of the distal tip of the prosthesis and the center of the canal, between the control and ROBODOC groups (unpaired t-test, chi-square). See Tables 6, 7 and 8.

g. Loose porous coating

Only one patient had evidence of bead shedding. Loose beads were noted adjacent to Gruen zones 6, 9, and 13 at the time of surgery; this finding is not unexpected due to the interference fit of the prosthesis. Bead shedding did not increase over time. This patient was in the ROBODOC group. There was no statistical difference, in loose porous coating, between the control and ROBODOC groups (unpaired t-test, chi-square).

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h. Femoral fracture

Only one femur fracture was detected in this 3 month radiographic review. This fracture occurred during the insertion of an AML prosthesis. The patient was in the control group. No statistical difference was detected between the control and ROBODOC groups (unpaired t-test, chi-square).

i. Proximal medial fit

The proximal medial fit of the ROBODOC group was statistically higher than the control group (unpaired t-test, chi-square). See Table 11. The average values of the control and ROBODOC groups were 3.9 mm and 2.5 mm, respectively. Note that 5 was best proximal medial fit and 1 was the worst.

12 Month Results

The radiolucency data (AML and Osteolock) for the AP are provided in Tables 12 and 13. There were significantly less radiolucencies (neocortices) in Gruen zones 3, 5, 6, 10, and 12 for the ROBODOC group than the control group (unpaired t-test). There was no statistical difference, in the number of radiolucencies in the other Gruen zones between the control and ROBODOC groups. Importantly, there were more patients in the control group with radiolucencies in five or more zones than similar patients in the ROBODOC group.

Discussion

3 Month Analysis

Overall, the 3 month radiographic results were better for ROBODOC patients than for those in the control group. It is important to note that were no instances where the ROBODOC group results were worse than the control group.

The ROBODOC group had better fit (closer cortical bone to prosthesis distance) and fill (canal filling of the prosthesis) in the proximal regions than did the control group. This was especially evident in the proximal medial zone. The proximal region corresponded to the region that in conventional surgery was prepared using a rasp. The precision machining of the ROBODOC system produced better fit and fill than the hand rasping of the control group. Improved fit, especially proximal medially, has been implicated to produce more normal stress

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environments in the proximal bone, less micromotion between the bone and prosthesis, and better clinical results.

No difference between the control and ROBODOC groups were detected in the fit or fill for the distal region. The distal region corresponded to the region that in conventional surgery is prepared using powered reamers. These cutting tools are fairly simple and their effectiveness is aided by being powered instruments. Thus, it was not surprising that ROBODOC did not improve the control group's distal reaming results, which had fit measurements averaging less than 0.3 mm and fill values of 98 percent.

The Osteolock prosthesis analysis followed the positive pooled prosthesis results. While analysis of the AML prostheses by themselves demonstrated no significant difference in fit or fill between the control and ROBODOC groups, this result is likely due to the small sample size (15 in each group).

The ROBODOC group prostheses were inserted in more optimal positions than their control counterparts. The ROBODOC group prostheses were seated significantly closer to the proximal femoral neck osteotomy than the controls, maximizing prosthesis-bone surface contact. The ROBODOC group also had better prosthesis alignment (varus-valgus, anterior-posterior). No difference was detected between the two groups in the location (centering) of the distal prosthesis tip.

In this radiographic review, there were no instances of radiographically detectable intraoperative fractures in the ROBODOC group. There was one intraoperative fracture detected in the control group 3 month films.

12 Month Analysis

Again, the ROBODOC group results were at least as good as and often better than the control group results. In the distal region, there were statistically-significantly less radiolucent lines medially, laterally, anteriorly, and posteriorly than in the ROBODOC group. For the remaining portions of the prosthesis there was no statistically significantly difference between the two groups. The ROBODOC group did have significantly fewer instances of prostheses with radiolucent lines in five or more Gruen zones than did the control group.

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Conclusion

The ROBODOC group had better results for fit, fill, seating, alignment, and radiolucent line occurrence than did the control group. Moreover, the ROBODOC group was not surpassed in any of the studied radiographic parameters by the control group. Good alignment and prosthesis fit are important conditions for successful hip replacement. These 3 and 12 month radiographic results demonstrate that the ROBODOC group fulfilled these conditions and improved the radiographic results of conventional total hip replacement surgery. We expect this radiographic improvement to translate into improved long-term clinical results.

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Table 1

3-Month Quantitative X-Ray Data

Fit and Fill by Level

All Implants	Control	ROBODOC	p-value
N	65	64	
AP Film Lateral Fit (mm)			
Level 1	16.79	13.75	0.002
Level 2	5.83	4.81	0.004
Level 3	3.09	2.28	0.006
Level 4	0.26	0.12	0.09
AP Film Medial Fit (mm)			
Level 1	3.06	1.14	0.0001
Level 2	3.66	1.44	0.0001
Level 3	2.68	1.48	0.0006
Level 4	0.12	0.14	0.78
AP Film - Fill (%)			
Level 1	66.3	77.8	0.0001
Level 2	73.1	82.9	0.0001
Level 3	80.0	86.9	0.0001
Level 4	97.9	98.5	0.34

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Table 2

3-Month Quantitative X-Ray Data

Percent Hips with ≤ 2mm Fit by Level

All Implants	Control	ROBODOC	p-value
N	65	64	
AP Film Lateral Fit			
Level 1	0.0	1.6	0.32
Level 2	3.1	14.1	0.03
Level 3	41.5	59.4	0.04
Level 4	100.0	100.0	1.00
Level 5	98.5	100.0	0.32
AP Film Medial Fit			
Level 1	43.1	87.5	0.001
Level 2	47.7	84.4	0.001
Level 3	53.9	82.8	0.001
Level 4	100.0	100.0	1.00
Level 5	98.5	98.4	0.99

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Table 3

3-Month Quantitative X-Ray Data

Number of Levels with ≤ 2mm Fit

All Implants	Control	ROBODOC
N	65	64
0	0	0
1	0	0
2	0	0
3	0	0
4	8	2
5	22	1
6	15	8
7	12	26
8	7	20
9	1	7
10	0	0
Chi-square p=0.001		

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Table 4

3-Month Quantitative X-Ray Data

Percent Fill by Level

All Implants	Control	ROBODOC	p-value
N	65	64	
AP Film - Fill			
Level 1	0.0	1.6	0.32
Level 2	0.0	15.6	0.001
Level 3	7.7	37.5	0.001
Level 4	93.8	95.3	0.71
Level 5	90.8	84.4	0.27

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Table 5

3-Month Quantitative X-Ray Data

Number of Levels with at Least 90% Fill

All Implants	Control	ROBODOC
N	65	64
0	3	3
1	4	2
2	53	38
3	5	13
4	0	7
5	0	1
Chi-square p=0.012		

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Table 6

3-Month Quantitative X-Ray Data

AML	Control	ROBODOC	p-value
N	15	15	
Displacement (mm)	0.37	0.07	0.12
Loose Porous Coating	0.00	0.007	0.33
AP Film - Axial Seat	1.53	0.17	0.20
AP Film - Alignment	1.13	0.40	0.11
Lat Film - Alignment	1.3	1.07	0.75

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Table 7

3-Month Quantitative X-Ray Data

Osteolock	Control	ROBODOC	p-value
N	50	49	
Displacement (mm)	0.13	0.24	0.22
Loose Porous Coating	0	0	----
AP Film - Axial Seat	2.26	0.94	0.01
AP Film - Alignment	0.72	0.43	0.02
Lat Film - Alignment	1.06	0.69	0.04

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Table 8

3-Month Quantitative X-Ray Data Displacement

All Implants	Control	ROBODOC
N	65	64
-2.0	1	0
-1.0	0	1
-0.5	1	0
0.0	49	46
0.5	1	6
1.0	11	11
1.5	2	0
Chi-square p = 0.194		

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Table 9

3-Month Quantitative X-Ray Data

AP Film - Axial Seating

All Implants	Control	ROBODOC
N	65	64
-4	0	1
-2	2	2
-1	3	1
-0.5	0	1
0	23	38
0.5	2	3
1	2	2
1.5	0	1
2	9	8
3	8	2
4	3	3
5	6	1
6	1	0
7	4	0
8	1	0
14	1	1
Chi-square p = 0.133		

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Table 10

3-Month Quantitative X-Ray Data

Alignment

	Control	ROBODOC
N	65	64
AP Film - Alignment		
0	25	39
1	33	23
2	4	2
3	2	0
4	0	0
5	0	0
6	1	0
Chi-square p = 0.075		
Lateral Film Alignment		
0	11	21
1	40	36
2	10	5
3	1	1
4	0	0
5	1	0
Chi-square p = 0.199		

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Table 11

3-Month Qualitative X-Ray Data

Proximal Medial Fit

All Implants	Control	ROBODOC
N	63	64
0	1	0
1	8	0
2	31	9
3	10	10
4	6	21
5	7	24
Chi-square p = 0.001		

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Table 12

12-Month Qualitative X-Ray Data

Hips by Number of Radiolucent Zones in Any Zone

All Implants	Control	ROBODOC
N	49	51
No. Radiolucent Zones		
0	12	12
1	9	18
2	10	11
3	5	4
4	3	1
5	2	2
6	4	0
7	1	1
8	2	1
9	1	1
Chi-square p = 0.489		

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Table 13

12-Month Qualitative X-Ray Data

Hips by Number of Radiolucent Zones in Key Zones

All Implants	Control	ROBODOC
N	48	51
No. Radiolucent Zones		
0	25	36
1	10	8
2	5	5
3	3	1
4	5	1
Chi-square p = 0.22		

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Section 11 – Device Description

11.1 Introduction
11.2 System Overview
- 11.2.1 Registration Procedures for Robot Orientation
- 11.2.2 Pin Based Registration
- 11.2.3 DigiMatch (Pinless) Anatomically-Based Registration
- 11.2.4 System Accuracy Requirements

11.3 Principles of Operation
- 11.3.1 Preoperative Planning (ORTHODOC)
- 11.3.2 Operating Room (ROBODOC®)
- 11.3.3 Safety Features

11.4 Major Components
- 11.4.1 ORTHODOC Hardware
- 11.4.2 ORTHODOC Software
- 11.4.3 ROBODOC® (Robot) Hardware
- 11.4.4 ROBODOC® (Robot) Software

Attachment 1 List of Patient Contacting Components and Materials
Attachment 2 Specification Summary Data Sheet

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

11.1 Introduction

The DigiMatch™ ROBODOC® Surgical System (the System) consists of Integrated Surgical System, Inc.'s (ISS) 510(k) cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a robot composed of an electromechanical arm, an electronics control cabinet, a display monitor and miscellaneous accessories, such as cutters, drapes, irrigation sets, probes and markers (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional, graphical, preoperative planner and implementation tool, and is intended as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. The ROBODOC component of the System supports implementation of the preoperative plan produced on the ORTHODOC.

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11.2 ROBODOC® System Overview

The ORTHODOC is a 510(k) cleared (K960685) PC workstation with proprietary ISS software that enables the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur. Computed Tomography (CT) scan data of the patient's femur provides input to the system. ORTHODOC stacks and interpolates between the individual scan slices to create three-dimensional images of the femur.

The ORTHODOC allows the surgeon to select an implant model from a computerized directory of implant types and sizes. The system displays three-dimensional views of selected implant models for computerized templating with CT based femur images. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the image of the femur. The ORTHODOC also provides software tools that allow surgeons to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC with the implant size, shape, and placement data. The output is saved on a transfer media and loaded into the electronics control cabinet of the ROBODOC prior to surgery.

The operating room components of the ROBODOC include an electromechanical arm, an electronics control cabinet (which houses the computers and other electronic components and display monitor), a display monitor and miscellaneous accessories, such as, cutters, drapes, irrigation sets, probes and markers. The transfer media containing the ORTHODOC preoperative plan provides input to the control cabinet computer of the ROBODOC.

A hospital certified and trained nurse or technician prepares the robot for surgery by moving it into the operating room, connecting the cables, and turning the power on. Then, the display monitor provides instructions that guide the technician step by step through loading the patient data transfer media and startup diagnostic procedures by displaying a series of display prompts. The purpose of the diagnostic procedures is to ensure proper functioning of the robot's electromechanical arm and accessories prior to surgery. The nurse or technician interfaces with the robot and responds to the prompts via a hand-held control device connected to the system called a "pendant." The control pendant has five buttons for initiating and aborting robotic actions, and for selecting options when prompted on the display monitor.

The nurse or technician drapes the robot hardware with a customized sterile draping system that covers the robot arm, robot base, and attachments within the sterile field. The cutter drive, extension arm and the femoral fixator are then aseptically attached, and the technician performs a series of sterile diagnostic procedures.

After all diagnostics have been successfully completed, the monitor will display the patient verification data, which were loaded from the patient transfer media. The surgeon verifies the patient data (*i.e.*, name, operative side, type of implant, etc.), then the patient is anesthetized.

The surgeon begins the THA operation in the "normal" manner in accordance with the practice of medicine by exposing the femur. (Note: The Robot does not assist with preparation of the acetabulum. The acetabulum will be prepared in the normal manner after completion of femoral cavity preparation.).

After normal exposure the surgeon, secures the patient's leg in the femoral fixator and leg support fixture to prevent motion during registration and femoral cavity preparation, and sets

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soft tissue retractors as required. Bone motion monitors Next, the surgeon performs registration procedures to provide orientation and reference information identifying where the bone is located for the intra operative femoral preparation. (see Section 11.3).

Upon registration completion, the robot's electromechanical arm will be manually guided and oriented with respect to femur position. The femur must remain motionless to preserve the coordinate transformation and ensure accurate cavity placement. To prevent bone motion, the femoral fixator rigidly attaches to the robot base. As stated above, the femoral fixator and leg support fixture must be properly installed prior to the registration procedures. Since bone motion could potentially change the registration, the robot is equipped with a bone motion monitoring system that detects unwanted motion of the femur. The system includes two bone motion monitors (BMMs), one for left legs and one for right legs; however, only one is used during a given surgery. The BMM is a small mechanical arm that has a sterile probe tip, which is attached to the bone and relays motion from the femur to enclosed position sensors. The probe makes direct contact with the bone and is held in place by an internal spring mechanism. If unwanted motion exceeding the predefined threshold during registration or cutting is detected, the ROBODOC's safety system will immediately disable motor power, stop the system and notify the surgeon by displaying an exception (Motion Detected) screen on the display monitor.

To expedite recovery in the event of unwanted bone motion, two bone motion recovery markers (also called "motion recovery posts") are installed and digitized during surface registration. One marker is installed in the proximal end of the femur and one is installed in the distal end. When the markers are digitized, the control cabinet computer records the positions of the marker and the initial registration obtained using the surface model. If unwanted bone motion occurs, this information facilitates recovery by enabling the surgeon to simply digitize each marker instead of re-digitizing the bone surface shorting the time of re registration. Based on the location of the markers, the cabinet control computer performs the geometric computations to determine the new position of the femur.

The surgeon controls every phase of the surgical procedure by hand guiding the mechanical arm and using the control pendant. The display monitor displays a series of menu screens that guide the surgeon in the use of the ROBODOC during surgery. The display monitor also provides visual feedback during the preparation of the femoral cavity.

11.2.1 Registration Procedures for Robot Orientation

The primary difference between the DigiMatch™ ROBODOC® System (Pinless) and its predecessor (Pin Based) is the manner in which the patient's femur is "registered" so that the System can locate the femur in space. Registration requires physical landmarks that appear in the CT data (input to the system), and which can be physically sensed by the System. As described in the following section, the first-generation system relied upon three titanium bone screws, called *locator pins,* for registration. The second-generation ROBODOC System reduced the number of locator pins to two. The current DigiMatch system that is the subject of this submission uses anatomical landmarks rather than locator pins. The differences in registration methods (Pin verses Pinless) between the various generations of the System do not alter the essential operating principles and technology of the ROBODOC System.

Regardless of method, registration is the process that establishes a mathematical relationship

between the CT coordinate system and the robot coordinate system. This process is responsible for ensuring accurate cavity placement. Registration does not affect cavity dimensions, which correspond to manufacturer specifications, nor any other performance characteristic of the robot. Registration is also independent of femur orientation; the mathematical computations that provide the link between CT data and robot space are the same regardless of how the bone is positioned.

11.2.2 Pin-Based Registration

The first-generation ROBODOC system, which was used in a US multi-center clinical trial, relied on fiducial-based registration. Three locator pins served as the fiducial points. Through percutaneous incisions, the locator pins were temporarily implanted in the femur. One locator pin was implanted in the greater trochanter and one was implanted in each femoral condyle. The locator pins appeared in the CT data and the ORTHODOC computed the distances and angles between the three pins. In surgery, the robot performed a tactile search on a divot located on the head of each locator pin. After determining the position of all three pins, the robot control computer calculated a coordinate transformation between the CT-measured locator pin positions and the robot-measured locator pin positions. The coordinate transformation based on the correspondence of these three points located the femur and the intended implant cavity with respect to the robot. The three-pin system provided accurate registration, but temporary implantation of the locator pins required an extra surgical procedure and some patients experienced transient postoperative ipsilateral knee pain. ISS initially addressed the post-operative knee pain by eliminating the need for one of the condyle pins.

The two-pin system required temporary implantation of one pin in the greater trochanter and one pin in one of the femoral condyles. Instead of a coordinate transformation utilizing three points, this system of registration utilized two points and the vector along a pin axis. In the operating room, the robot performed a tactile search in the same manner as the three-pin system except that the robot located multiple points on the head of the distal pin to compute the plane normal vector.

11.2.3 DigiMatch™ Anatomically-Based Registration

ISS has developed an anatomically-based registration method to eliminate the pin implantation surgical procedure. The objectives for developing this Pinless method included equivalent clinical placement accuracy, safety, and reliability to that of the pin-based method. The DigiMatch (pinless) system registers a bone surface rather than single points used in the pin based system..

During the ORTHODOC preoperative planning, a bone surface model is created by viewing individual CT slices and building a surface model in a small area of the femoral shaft, greater trochanter and neck we call the region of interest.. The ORTHODOC builds the surface model based on user input for each slice of CT data. The proximal part of the surface model includes the bone surface along the medial aspect of the greater trochanter, the femoral neck, and the anterior surface of the femur from the top of the femoral neck to the top of the lesser trochanter. The distal part of the surface model includes the anterior, medial, and lateral aspect of a portion of bone surface at the distal end of the femoral shaft. The process of defining and generating a

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surface model is completely independent from the procedures for implant selection and templating.

In the operating room, the surgeon guides a digitizing probe to specific locations on the bone surface within the area of the surface model defined using the ORTHODOC. This procedure is sometimes referred to as "point collection." The robot control computer compares the set of digitized points to the bone surface model transferred from the ORTHODOC, and finds the location of the point set that minimizes the distances from the points to the surface model. From this calculation, the location of the femur with respect to the robot can be determined.

11.2.4 System Accuracy Requirements

There are two separate accuracy requirements for the ROBODOC System: 1) cavity placement accuracy; and 2) dimensional accuracy of the cavity. Cavity placement accuracy is dependent upon accurate registration because the system must know where the bone is located in order to know where the cavity is to be placed.

Dimensional accuracy of the cavity is previously determined and validated by evaluating the difference between the actual cavity dimensions and the dimensions specified by the manufacturer of the implant. Milling a cavity with the correct shape and dimensions is dependent on robot's ability to precisely position the cutter as it follows pre-defined paths to cut a cavity corresponding to the selected implant. Dimensional accuracy of the cavity is not dependent on registration.

11.3 PRINCIPLES OF OPERATION

11.3.1 Preoperative Planning Component (ORTHODOC)

As previously stated, the ORTHODOC component of the ROBODOC System is a 510(k) cleared PC workstation with proprietary ISS software that enables the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur. This process is also known as templating. CT scan data of the patient's femur provides input to the system. The ORTHODOC stacks and interpolates between the individual scan slices to create three-dimensional images of the femur.

The ORTHODOC component has a computerized directory of implant types and sizes, from which the surgeon may select an implant model. The system displays three-dimensional views of selected implant models for computerized templating for THR procedures. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the image of the femur.

Before or after templating, the user invokes a program called (b) (4) [redacted] (b) (4) [redacted] which can be used for registration purposes. The created surface model file is transferred to the ORTHODOC, which provides this model, along with the implant data, to the robot. Please note that the surgeon will guide a digitizing probe to points on the bone surface and the points recorded by the digitizer (b) (4) [redacted]

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In addition to the tools for selecting an implant, templating, and creating a surface model, the ORTHODOC also provides software tools that allow surgeons to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC System with implant size, shape, and placement data. The preoperative plan is saved on a storage medium (*e.g.*, CD-R) and loaded into the electronic control computer prior to surgery.

11.3.2 Operating Room Components (ROBODOC)

The ROBODOC Surgical Assistant (ROBODOC) is the part of the ROBODOC System that is present in the operating room during THA surgery. The ROBODOC, which consists of an electromechanical arm, computer control cabinet and display, receives the input data from the ORTHODOC. Under direct control of the surgeon, the ROBODOC combines the ORTHODOC input data with data obtained during the surgical procedure, to aide in machining the implant envelope in the location specified by the surgeon.

The ROBODOC Surgical Assistant is present in the sterile field and contains all of the components that physically interact with the patient during the surgery. The computer control cabinet is a mobile cabinet that houses most of the electronic components of the ROBODOC. A color display monitor, is mounted on top of the computer control cabinet. The combined unit is positioned outside the sterile field, but within view of the surgical team.

The robot is a five-axis electromechanical arm with two revolute axes in the X-Y plane, a prismatic axis, and two wrist rotations (roll and pitch). This kinematic configuration allows the robot to be oriented in the desired directions for the THA application. (b) (4) [redacted]

As previously mentioned, the robot is equipped with a femoral fixator, which immobilizes the femur during robotic cavity preparation. A bone motion monitor (BMM) is attached to the femur during surgery to detect potential movement of the fixated femur. The robot is equipped with two BMMs; one for left leg cases and one for right leg cases. A digitizer, which is permanently mounted on the robot base, is used for spatial registration. (b) (4) [redacted] (b) (4) [redacted] The comparison registers (locates) the femur and identifies the intended placement of the cavity.

The monitor displays menu screens and informational messages during surgery. The menus and messages are designed to guide the surgeon through the use of the robot in the operation. The display monitor, which is controlled by the computer control cabinet during cavity preparation, shows CT slices of the femur overlaid with a model of the selected prosthesis and uses color to indicate the finished portion of the cavity.

The computer control cabinet houses the robot control computer (RCC), real-time monitor (RTM) computer, intelligent power module (IPM), and miscellaneous electronics, such as the data input/output drives, video switch, service keyboard, and isolation transformer. The Total

DJA x01210

Hip application and motion control software run on the RCC, and the RCC performs safety system processing. The RTM computer visually simulates the progress of the rotary cutting tool during cavity preparation. The IPM includes three joint controller boards (JCBs) and runs the servo control software.

The surgeon controls the robot at all times, hand guiding the electromechanical arm and using a hand-held, five-button pendant. Three of the buttons on the pendant enable the surgeon to select options from menus displayed on the display monitor and the other two are used to stop or pause the robot and initiate error recovery procedures.

11.3.3 Safety Features

Before the surgeon begins templating, the ORTHODOC validates the CT data by confirming the lack of bone motion during the scan, appropriate spacing of CT slices, and adequate field of view.

The robot has relatively [redacted] during initialization of robotic arm position sensors, diagnostic tests, drape installation, re-orientation for tool changes, and cutting. Most automatic motions cover relatively short distances. Significant repositioning or movements of the robotic arm must be accomplished by manual (force-assisted) hand guiding, in which the robot moves in response to forces applied to the robot end effector (cutter drive assembly) by the user. [redacted]

The robot is equipped with a force sensor that continuously monitors forces applied to the robot's tool tip. During cutting, the software monitors force sensor values and, if necessary, slows down the automated cutting motion to ensure that the maximum force is below a specified threshold. However, motion is never reduced below a specified minimum speed; if force is too great at the minimum speed, a "force freeze" condition results that halts any robot motion.

As stated above, the robot is equipped with [redacted]

A red latching button on the pendant and a manual twist-to-reset switch on the computer control cabinet provide two direct ways to remove power from the robot and deactivate the cutter [redacted] This hardware implementation uses [redacted] Reactivation requires all safety and control systems to be within tolerance and manual depression of the robot motor power switch. A yellow button on the pendant halts robot motion and deactivates the cutter drive [redacted] The display monitor presents recovery options, as well as an option to abort the procedure at any point.

As an additional safety feature in the event that the pendant is dropped, the buttons are designed to prevent depression upon impact with a flat surface. To prevent accidental selection of menu options, the SELECT button on the pendant must be held for a specified duration ([redacted] and then released before the choice is accepted. The selection bar around the current menu option on the display monitor becomes thicker, but remains white, when the SELECT button

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is pressed; however, the selection bar around the menu option turns green after the specified duration (b) (4)) to indicate that releasing the button will cause the option to be selected. The user can cancel the selection by pressing either the UP or DOWN button before releasing the SELECT button. This causes the selection bar to become white, indicating that the SELECT button can be released without causing an option to be selected.

The robot is equipped with a brake that engages when power is removed (b) (4)

ISS has designed a custom cutter accessory for optimal performance in creating a cavity for each type of ROBODOC compatible prosthesis. Prior to cutting, the display monitor prompts the surgeon to install the cutter associated with the selected prosthesis, identifying it by its ISS part number.

The ROBODOC system is designed so that no single point of failure can cause uncontrolled robot (b) (4)

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11.4 MAJOR COMPONENTS

11.4.1 ORTHODOC Hardware

The ORTHODOC Preoperative Planning Workstation has the following hardware components, which are illustrated in Figure 1:

11.4.1.1 Color graphics monitor

The monitor is used to display the following items:

- application screens
- menus and program buttons
- mouse pointer
- patient information
- graphic images
- graphic icons

11.4.1.2 Keyboard

A standard 101-key keyboard is used for login, data entry, and menu selection.

11.4.1.3 Mouse

A standard two-button mouse is used for menu selection, program button activation, graphic icon selection, and graphic image marking.

11.4.1.4 CT Data Drive

This drive (typically a magneto-optical or CD drive) is used for importing the CT data that serves as input for creating a preoperative plan.

11.4.1.5 ROBODOC Data Drive

This drive is used for saving a preoperative plan (also called "transfer file") on a storage medium (*e.g.*, tape or CD-R).

11.4.1.6 Personal Computer (PC)

The PC has a Pentium®-type central processing unit, a minimum of 64 MB of RAM and a hard drive with a capacity of at least 1.2 GB. The PC also has a 2 MB-capacity video card, CD-ROM drive, and an SVGA-type monitor with a minimum 17" diagonal screen.

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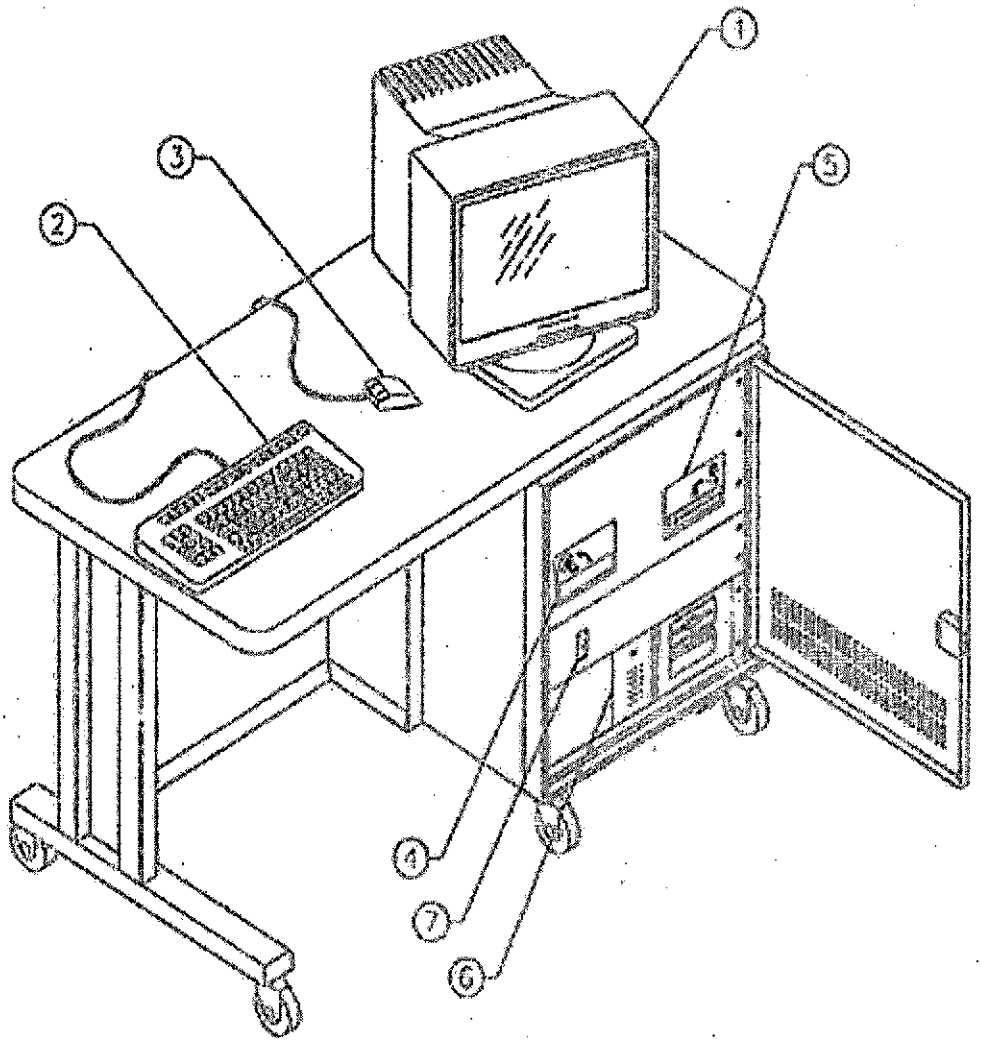

Figure 1. The ORTHODOC Workstation

① Color monitor
② Keyboard
③ Mouse
④ CT tape drive
⑤ ROBODOC tape drive
⑥ ORTHODOC computer
⑦ Power switch

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11.4.2 ORTHODOC Software

The operating system is LINUX, a PC form of UNIX. ORTHODOC software has self-contained modules, which require no user inputs and modules which rely on user inputs to perform some functions. The major software modules are described in the following subsections.

14.4.2.1 (b) (4)

(b) (4)

14.4.2.2

(b) (4)

14.4.2.3

(b) (4)

14.4.2.4 (b) (4)

(b) (4)

14.4.2.5 (b) (4)

(b) (4)

14.4.2.6 (b) (4)

(b) (4)

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11.4.3 ROBODOC Hardware

The ROBODOC component of the System is comprised of the robot and the computer control cabinet and display monitor. A photograph of the surgical robot is provided Figure 2 and the control cabinet and OR monitor is provided Figure 3.

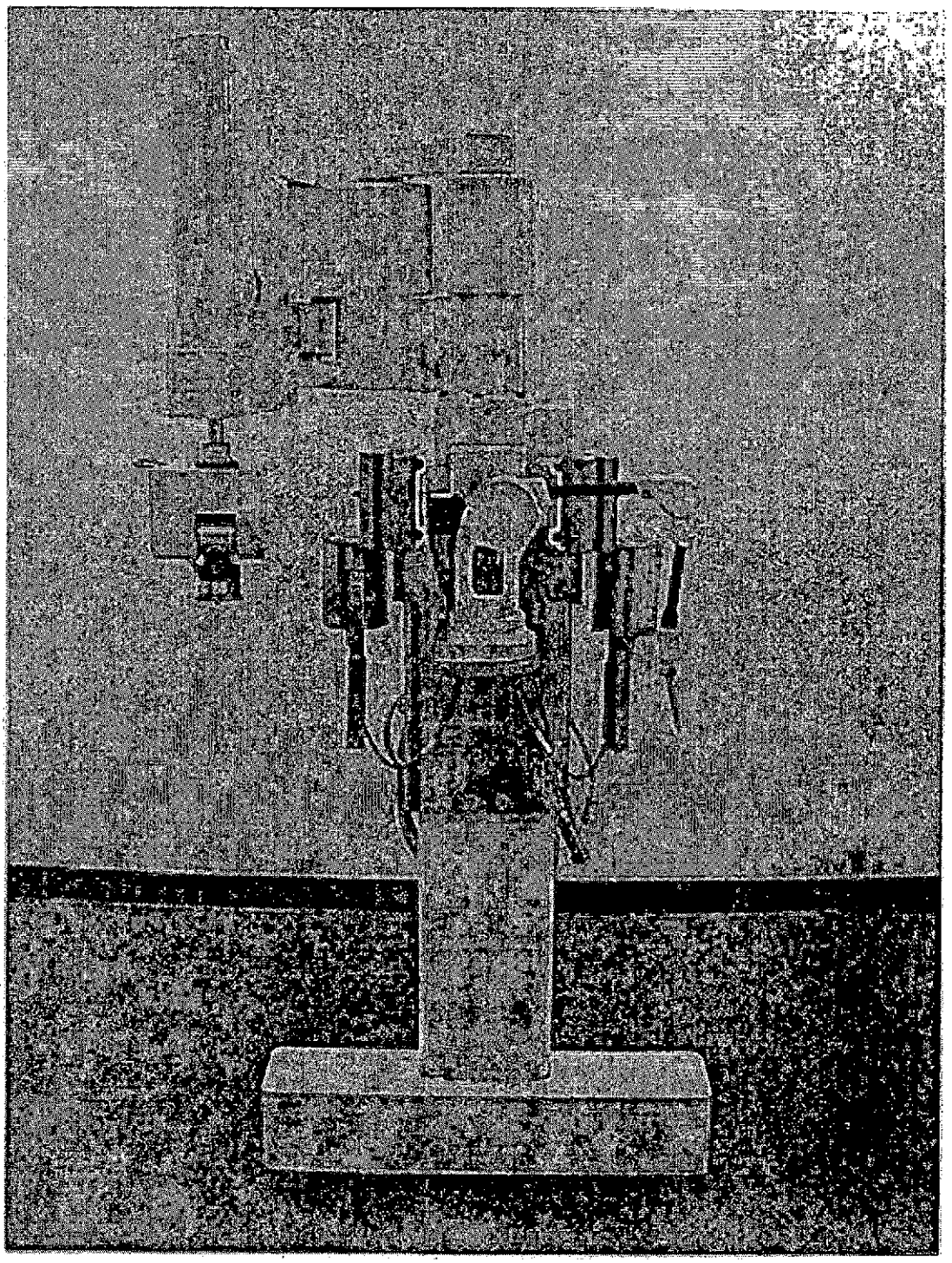

Figure 2. Robot

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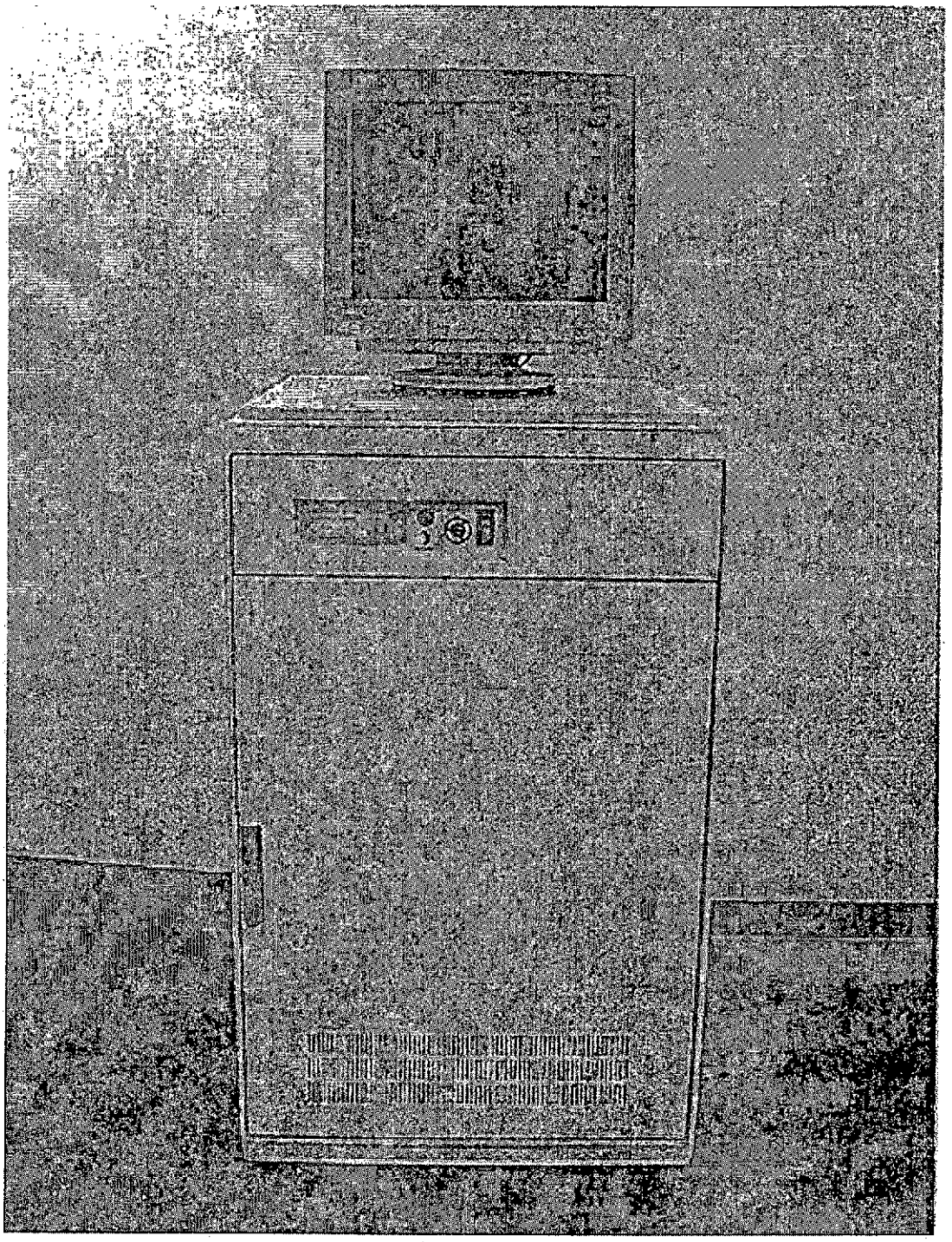

Figure 3. Control Cabinet and Display Monitor

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11.4.3.1 User Interface (Display Monitor, Pendant, Operator Controls, and Indicator Lights)

The User Interface consists of a display monitor, a hand-held pendant for controlling the robot, operator controls (switches/buttons), and indicator lights.

11.4.3.1.1 Display Monitor

The display monitor is a high-resolution, 21-inch or larger color VGA monitor that displays informative and interactive menu screens. Interactive screens contain a menu from which the user can select options by pressing buttons on the pendant. Each menu screen contains explanatory text followed by the available options, with one option per line. The default option line is indicated by a selection bar (*e.g.*, a box formed by thin white lines). The user can move the selection bar to the other option lines by pressing the UP or DOWN buttons on the pendant. When the selection bar is on the desired option, the user can press the SELECT button on the pendant to make the selection; however, the SELECT button needs to be depressed for approximately (b) (4) before the desired option will be selected and the SELECT button needs to be depressed for the selected action to occur. Some screens display only one option; single-option screens are typically used to receive confirmation from the user.

The display monitor provides informative screens (rather than menu screens) when the system is performing automated actions, such as homing the robot or cutting the femur. During the DigiMatch registration procedure, the display monitor provides information that assists the surgeon in digitizing the femur and in verifying that the registration is correct. During the cutting procedure, informative screens show the paths taken by the robot tool (*i.e.*, cutter) super-imposed on the patient's CT image (RTM function).

11.4.3.1.2 Pendant

The pendant is a hand-held control device that plugs into the robot base. The cable is long enough to avoid impeding operator movement and is easily attached and detached from the base. The pendant has five depressible buttons, which enable the surgeon and OR technicians to select procedural alternatives, verify assumed conditions, and redirect the procedural flow, if necessary. The user can hold the pendant in either hand and press the buttons with the holding hand. The buttons are designated as UP, DOWN, SELECT, PAUSE, and STOP. The STOP button mechanically latches when pressed, and must be manually unlatched. The other buttons do not latch.

The pause function is a safety feature that allows the user, at any time, to halt robot motion without removing robot motor power. (b) (4) (b) (4) This function is activated by pressing the yellow PAUSE button on the pendant. In addition to halting robot motion pressing the PAUSE button causes a pause menu screen to be displayed. The pause menu contains an option to resume the procedure, which re-displays the interrupted screen and, if safe, resumes the motion that was halted. In emergency situations, the user can turn off robot motor power completely by pressing the red STOP button on the pendant. The STOP button latches mechanically when pressed, thereby requiring the user to manually release it before power can be restored.

The pendant is initially used for non-sterile calibration and startup procedures. Prior to use by the

surgeon inside the sterile field, it is covered with a customized sterile drape that is provided with the ROBODOC drape.

11.4.3.1.3 Operator Controls and Indicator Lights

The ROBODOC System is equipped with the operator controls (buttons and switches) and indicator lights listed below:

Description	Location
Main Power toggle switch (circuit breaker) for AC power to the Control Cabinet	Control Cabinet
Main Power toggle switch (circuit breaker) for AC power to the Robot Base	Robot
AC Power switch for Display Monitor.	Display Monitor
Robot Motor Power button (green)	Control Cabinet
Robot Motor Power indicator light integrated with Robot Motor Power switch (green)	Control Cabinet
Emergency Power Off switch (red)	Control Cabinet
Pendant STOP button (red)	Pendant
Pendant PAUSE button (yellow)	Pendant
Pendant UP button (blue)	Pendant
Pendant DOWN button (blue)	Pendant
Pendant SELECT button (green)	Pendant
Base UP/DOWN switch	Robot Base
Irrigation Pump ON/OFF/AUTOMATIC	Robot Base
Irrigation Pump Speed Adjust Low to High	Robot Base

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11.4.3.2 Robot Arm

The robot arm (electromechanical arm) is an articulated manipulator capable of programmable motions with attachments for application-specific (end effectors) tools mounted on the final link. The types of programmable motions include (b) (4) (b) (4). For safety, a redundant (b) (4) on the manipulator to continuously monitor the position of the arm.

The robot arm has two possible configurations, called left elbow and right elbow, and each configuration has a different workspace. The total workspace of the robot is the union of these two configuration-specific workspaces. The workspace of the robot is large enough to mill an implant envelope for THA on right or left femurs. Within this workspace, the robot has sufficient accuracy to create an envelope within an acceptable tolerance of the surgeon's desired placement. In addition, the robot arm and attached tools have sufficient stiffness to ensure that dimensional accuracy of the implant envelope is within specified tolerances.

The manipulator motors are electrically powered (DC current), and (b) (4) (b) (4). The robot motors obtain power only after all safety checks have been passed, and the user responds to a screen indicating that the robot is to be powered on and manually presses the Motor Power On button on the computer control cabinet. The red STOP button on the hand-held pendant can be used to remove robot motor power, independent of software commands, because the STOP button consists only of hardware components.

Movement of the robot arm is accomplished manually, by (b) (4) after user confirmation. Automatic motions are enabled only when safe and necessary, and only after user confirmation and manual activation.

(b) (4)

11.4.3.3 Robot Base

The robot base is a mobile base that contains a column of adjustable height. The mobile base allows the user to roll the robot to the OR table, to lock it in place during surgery, and to move it away from the OR table when femoral canal preparation is complete. The locking mechanism on the robot base consists of manually actuated hydraulic brakes.

The femoral fixator attaches to a mounting bracket on the base that is located a fixed distance from the floor, and the robot is mounted on the adjustable-height column. This allows the vertical position of the robot arm to be adjusted so its workspace optimally accommodates the patient's femur (the optimal position of the workspace varies according to table height, patient anatomy and surgical approach). Other base attachments include the digitizer, two BMMs, and irrigation accessory.

(b) (4)

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module.

Internally, the base includes a CPU board, which controls the adjustable column, and the cutter and irrigation system relays. The adjustable column is powered by an AC motor. Base height is measured redundantly by a linear encoder and a magnetostrictive sensor. In the event of a discrepancy between base height as reported by the encoder and sensor, robot motor power is paused.

11.4.3.4 Computer Control Cabinet

The computer control cabinet houses the RCC, RTM, IPM, and video switchbox.

11.4.3.4.1 Robot Control Computer (RCC)

The RCC is a personal computer with a Pentium processor that contains hardware and software components that control the robot motors, runs the THA application, and monitors the inputs from the pendant and safety sensors. The RCC contains four adapter cards: CAN controller board, force sensor interface board, robot I/O board, and a video board.

11.4.3.4.2 Real Time Monitor (RTM) Computer

The RTM computer controls the display monitor during certain digitizer registration procedures and during cutting. It is a personal computer with a Pentium processor and at least 64 Megabytes of RAM. The RTM computer contains a SCSI controller board and a video board, and it connects to the RCC via a serial link.

11.4.3.4.3 Intelligent Power Module (IPM)

The IPM contains the motor power supplies, motor power amplifiers, and three joint controller boards (JCBs). The JCBs are embedded computer modules that monitor the position of the robot arm and performs the low-level servo control functions.

11.4.3.4.4 Video Switchbox

During cutting and digitization of points on the surface model, the display monitor presents graphical representations from the RTM computer; at all other times, it displays informative screens and screens that prompt the user to perform specific actions (from the RCC). The video switchbox receives output from the RCC and RTM computer and sends the appropriate signal to the monitor.

11.4.3.5 Bone Attachment System (BAS)

The BAS consists of the femoral fixator and two BMMs.

11.4.3.5.1 Femoral Fixator

The femoral fixator holds the femur at a fixed position relative to the robot during surgical procedures. The fixator is designed to accommodate left and right legs, and a significant range of leg sizes. The femoral fixator is steam sterilizable using a standard autoclave.

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11.4.3.5.2 Bone Motion Monitors (BMMs)

The robot base is equipped with two BMMs: one for left femurs and one for right femurs (only one is used during a surgery). BMMs are safety sensors that monitor motion of the bone relative to the robot. The surgeon attaches the BMM directly to the bone using a sterile pointed probe. BMM probes are detachable, reusable components. A procedure to re-establish registration must be performed if bone motion exceeds a predefined threshold (b) (4) [redacted]. The BMM probe is inserted after fixation, but prior to registration.

11.4.3.6 Digitizer

This component is a high-resolution digitizing system, manufactured by Immersion Corp. The digitizer generates computer models of physical objects by contacting their surfaces. The purpose of the digitizer is to collect data for CT/bone registration (orientation of the robot with respect to CT coordinates in the ORTHODOC preoperative plan and the physical position of the bone within its workspace). The digitizer is permanently mounted on the robot base between the two BMMs.

11.4.3.7 Robot Tooling

The primary robot tool is a cutter drive assembly, which connects to the tool attachment plate on the robot. It is the sterile interface between the robotic arm and the instruments that contact the patient.

11.4.3.7.1 Bearing Sleeves

A bearing sleeve containing a probe or cutter can be installed in the cutter drive assembly. Bearing sleeves are available in different sizes and correspond to implant models and sizes.

11.4.3.7.2 Robot Probes

These robot probes are used for diagnostic tests, *i.e.*, calibration.

11.4.3.7.3 Cutters

Cutters of various sizes depending upon the implant size are used to machine the implant envelope. Power to the cutter is controlled by ROBODOC software, but for safety reasons, a hardware relay immediately turns off the cutter when robot motor power is removed and prevents the cutter from being turned on while the Robot motor power is off. In addition, when robot motion is paused (*e.g.*, using the PAUSE button on pendant), the software turns off the cutter.

11.4.3.7.4 Digitizer Tools

The removable components and tools associated with the digitizer include: (1) a non-sterile digitizer probe, which is used for non-sterile diagnostics; (2) a sterile digitizer probe, which is the sterile interface between the digitizing arm and the surgical tool tips (*i.e.*, ball tip and pointed tip); (3) a ball tip, which is used for sterile diagnostics; and (4) a pointed tip, which is used for contacting the bone surface to collect data points on the femoral surface and for motion recovery.

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11.4.3.7.5 Diagnostic Tool and Fixture

A non-sterile diagnostic tool is used for robotic arm diagnostic and maintenance procedures. The diagnostic fixture consists of an attachment plate, which contains posts that can be found by the robot, as required for tool calibration and kinematic verification.

11.4.3.8 Irrigation System

The irrigation system is mounted on the base and consists of a pump, sterile tubing, and controls for on/off and flow velocity. Irrigation automatically starts when the cutter turns on and stops when it turns off. There is also a manual override switch. The CPU board inside the base controls irrigation system relays.

11.4.3.9 Sterile Drape Set

A sterile drape set contains five separate drapes for the following components: (1) the robotic arm; (2) the robot base; (3) the digitizer; (4) the pendant; and (5) the bonnet. The bonnet drape is provided for use in the event that the cutter drive must be reinstalled and part of the arm drape must be sacrificed.

11.4.4 ROBODOC Software

The ROBODOC has four major software modules: (1) (b) (4) (2) (3) (b) (4) and (4) (b) (4) (4)
(b) (4)
(b) (4)

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Attachment 1

Material Specs of Sterile Parts / Accessories Used with the DigiMatch™ System
DigiMatch™ ROBODOC® System Material Specs
Parts/Accessories

Part Number	Description	Material	Patient Contact
(b) (4)	Drape Set	(b) (4)	No
	Assy, Sleeve,		No
	Digitizer Sterile Interface		No
	Assy, Sleeve		No
	Extension Arm		No
	Proximal Post Tool		No
	Irrigation Tube Set	(b) (4)	Yes Indirect
	Assy, Cutter Drive,	(b) (4)	Yes Indirect
	Cutters	(b) (4)	Yes Direct
	Distal Recovery Posts		Yes Direct
	Proximal Recovery Post	(b) (4)	Yes Direct
	BMM Probe	(b) (4)	Yes Direct
	Probe, Pointed Digitizer	(b) (4)	Yes Direct
	Bone Clamp	(b) (4)	Yes Direct

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Attachment 2 **ROBODOC System Specification Summary Data Sheet**

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4.0 SPECIFICATION SUMMARY DATA SHEET

ROBODOC® Surgical Assistant System

The **ROBODOC® Surgical Assistant System, Model 2000**, consists of the following components:

- ***ORTHODOC PREOPERATIVE PLANNING WORKSTATION***
- ***ROBODOC® SURGICAL ASSISTANT***

THE ORTHODOC PREOPERATIVE PLANNING WORKSTATION INCLUDES:

- ORTHODOC Computer Workstation & Software
- Hi-Resolution Color Graphics Monitor
- CT Data Input Device
- ROBODOC Data Output Tape Drive
- Surgical Application Software

The ROBODOC® SURGICAL ASSISTANT includes:

- A Five-Axis Surgical Robot, mounted on a mobile base, with a force sensor and bone motion monitor.
- A Control Cabinet with Integrated VGA Display Monitor that contains the robot control computer, real time monitor computer, tape drive, and electronic componetry. The display monitor displays the screens that guide the technician and surgeon through all robotic procedures and provides visual feedback during the automated milling process.
- A Femoral Fixator for bone immobilization.
- A Hand-held Pendant for controlling the robot and selecting options displayed on the display monitor.
- A Cutter Drive Assembly with high-speed surgical cutting tools for femoral canal preparation.
- Diagnostic tools and fixtures for verification of system integrity.
- Robot Application & Control Software (b) (4) [redacted]

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TECHNICAL SPECIFICATIONS SUMMARY

ORTHODOC Workstation

PHYSICAL SPECIFICATIONS

WORKSTATION (DESK)

- Length 130cm (51in)
- Width 84cm (33 in)
- Height (with monitor) 127 cm (50in)
- Weight (with monitor) 141Kg (310lb)

Computer (Including Color Graphics Monitor, Mouse & Keyboard)

- Pentium III 933Mhz or better
- 384 MB Ram Minimum
- 7.6GB HDD Capacity minimum
- External 10/100 MPS Ethernet LAN – DICOM
- External 56K Internal Modem Port
- Parallel Printer Port
- Internal Service CD & Floppy Drives
- User Accessible Magneto-Optical & CDRW
- Linux OS & Orthodoc Planning Software
- Surgical Application Software Module

ELECTRICAL SPECIFICATIONS

- ~ 230/240 V, 2 A, 50/60 Hz
- ~ 100/115V, 4A, 50/60Hz
- Rated for continuous operation
- Internal Power Distribution System
- EMI/RFI Compliant Filters

ENVIRONMENTAL SPECIFICATIONS

- Temperature
  - Operating 10-35° C (50-95° F)
  - Storage -40-65° C (-40-149° F)
- Humidity (Non-condensing)
  - Operating 8-80% Relative Humidity
  - Storage 8-80% Relative Humidity

TECHNICAL SPECIFICATIONS SUMMARY

ROBODOC® Surgical Assistant

PHYSICAL SPECIFICATIONS

Robot Arm and Base

- Length (Base) 98 cm (38.5 in)
- Width (Base) 79 cm (31 in)
- Height
  - Minimum 191 cm (75 in)
  - Maximum 225 cm (88.5 in)
- Weight 359 Kg (790 lb)
- Radius (Robot Arm) Maximum 80 cm

Attachments

- Digitizer, Bone Motion Monitors
- Probes, Fixators and Markers.

Control Cabinet

- Length 91 cm (36 in)
- Width 74 cm (29 in)
- Height (with monitor) 189 cm (74 in)
- Weight (with monitor) 306 Kg (674 lb)
- RTM Control Computer
- RCC Control Computer
- IMP Power Control Modules
- Monitor, CDRW

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ELECTRICAL SPECIFICATIONS

- ~ 230/240 V, 5 A, 50/60 Hz
- ~ 110/115 V, 10A, 50/60 Hz
- Rated for continuous operation
- Integrated Isolation Transformer

ENVIRONMENTAL SPECIFICATIONS

- Temperature

Operating	15-30© C	(59-86© F)
Storage	15-35© C	(59-95© F)

- Humidity (Non-condensing)

Operating	45 to 80 % Relative Humidity
Storage	10 to 90 % Relative Humidity

PNEUMATIC SPECIFICATIONS (CUTTER MOTOR DRIVE)

- Input Supply Pressure 13.8 bar (200psi)
- Motor Speed Approx. 70,000 rpm

CLASSIFICATIONS

- Class I Device per IEC 601-1
- Type B Applied Parts per IEC 601-1

- TUV tested compliant with IEC 601-1
- CE Mark (EC 93/42 EEC).

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Section 12 – Substantial Equivalence Discussion

In this section, Integrated Surgical Systems (ISS) demonstrates substantial equivalence (SE) between the DigiMatch™ ROBODOC® Surgical System (DigiMatch System) and the below-identified predicate devices.

ISS followed the August 12, 2005, FDA guidance entitled, *Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s* (including the "Substantial Equivalence" Decision-Making Process flowchart), as the basis of the following SE discussion.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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12.1 Overview

The DigiMatch™ ROBODOC® Surgical System (the System) consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories, such as cutters, drapes, irrigation sets, probes and markers (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional, graphical, preoperative planner and implementation tool and is intended as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. The ROBODOC component of the System, under direction from the surgeon, precisely implements the preoperative plan.

The information presented in the following tables and discussion demonstrates that the ISS DigiMatch™ ROBODOC® Surgical System, the MAKO Medical Voyager /Tactile Guidance System – CT, the ISS Frameless Neuromate and the Intuitive Surgical da Vinci® Surgical System are substantially equivalent or similar to one another in Intended Use/Indications for Use, technological characteristics, and principles of operation.

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12.2 Predicate Devices

As explained in detail below, the DigiMatch™ ROBODOC® Surgical System is substantially equivalent to other legally marketed Class II, stereotaxic instruments. Specifically, the DigiMatch™ ROBODOC® Surgical System is substantially equivalent to the following devices:

- Voyager/Tactile Guidance System – CT (K052851), manufactured by MAKO Surgical Corp.
- Frameless Neuromate (K991081), manufactured by Integrated Surgical Systems, Inc.
- da Vinci® Surgical System (K043153), manufactured by Intuitive Surgical, Inc.

As explained in more detail below, DigiMatch™ ROBODOC® Surgical System has the same general intended use and similar indications, and technological characteristics as the previously cleared predicate devices. Substantial equivalence tables comparing the similarities and differences between the DigiMatch™ ROBODOC® Surgical System and its predicate devices are provided in the following pages. As also explained in more detail below, minor differences in the technological characteristics do not raise new questions of safety or efficacy. Bench, animal, cadaver and clinical testing demonstrates that the DigiMatch™ ROBODOC® Surgical System is as safe and effective as its predicate devices. Study reports related to these tests are provided in sections 18, 19, and 20 of this 510(k) submission.

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12.3 Regulatory Strategy

ISS is employing a similar strategy for the DigiMatch™ ROBODOC® Surgical System that MAKO Surgical Corporation (MAKO) used in bringing their VOYAGER/Tactile Guidance System - CT to market via the 510(k) premarket notification process in the US. Specifically, MAKO received 510(k) clearance (K052851) for their Voyager/Tactile Guidance System - CT by claiming substantial equivalence to a series of predicate devices, which are classified as Class II, stereotaxic instruments. The first device in the Voyager/Tactile Guidance System – CT historical linage was the Picker International ViewPoint ENT/Orthopedic Option (K991256). This is a software program intended for presurgical planning and providing orientation and reference information during operative procedures. The Voyager/Tactile Guidance System – CT ultimately received 510(k) clearance as a device that uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.

Similarly, ISS claims substantial equivalence to the ORTHODOC® Preoperative Planning Workstation (K960685) and Frameless Neuromate (K991081). The ORTHODOC® is a software program that is intended for presurgical planning and providing orientation and reference information that is used during operative procedures, while the Neuromate is cleared for use as a computer-controlled stereotactic system with an image-guided electromechanical multi-jointed arm.

Thus, similar to the Voyager Linux with the Tactile Guidance System – CT, the DigiMatch™ ROBODOC® Surgical System incorporates preoperative planning functions and intra-operative "stereotactic navigation" via an electromechanical arm.

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12.4 Intended Use

Table 1 compares the Intended Use claims between the DigiMatch™ ROBODOC® Surgical System and the predicate devices. The table shows that the DigiMatch™ ROBODOC® Surgical System and all three predicate devices are all are intended for use as computer-aided robotic devices to perform surgery.

The Frameless Neuromate, Voyager/Tactile Guidance System - CT and ROBODOC all provide the surgeon with software designed to preoperatively plan the surgical procedure and all provide the surgeon with an electromechanical arm [robotic] that, under direct surgeon control, implements the parameters of the preoperative plan. With the DigiMatch™ ROBODOC® Surgical System, Frameless Neuromate, and Voyager/Tactile Guidance System - CT systems, the surgeon must use preoperative image data to produce preoperative plans to produce preoperative control files for the robot (electromechanical arm). The primary difference between the DigiMatch™ ROBODOC® Surgical System, the Frameless Neuromate, the Voyager/Tactile Guidance System – CT, and the da Vinci® Endoscopic Instrument Control System is the preoperative planning function. The da Vinci® does not have a "preoperative" planning function. Rather, the surgeon makes immediate operative decisions based on visual and tactile feedback from the operative field. The da Vinci® system produces control files for the robot (electromechanical arms) based upon actions taken in the operating room during the surgery. Thus, the surgeon cannot preplan the various types of operations performed by the da Vinci® system in the same manner that the other systems produce preoperative plans via specially designed software.

Because the surgeon is performing "preoperative" planning in one way or another, either in real time based on visual and tactile feedback from the operative field, or by using preoperative patient image data based on software planning methods, the differences in Intended Use do not affect the device's diagnostic or therapeutic effects.

Since the DigiMatch™ ROBODOC® Surgical System and the identified predicate devices are all intended for use as computer-aided robotic devices, the DigiMatch™ ROBODOC® Surgical System satisfies the first criteria for a finding of substantial equivalence.

Table 1 Comparison of Manufacturer's Claimed Intended Use

Intended Use					
da Vinci® Surgical System (K043153)	**Frameless Neuromate (K991081)**	**Voyager/Tactile Guidance System – CT (K052851)**	**DigiMatch™ ROBODOC® Surgical System** (which includes the cleared ORTHODOC preoperative planning software)	**Differences in Intended Use**	**Similarities in Intended Use**
The da Vinci® Endoscopic Instrument Control System is intended to assist in the accurate control of *Intuitive Surgical®* Endoscopic Instruments.	The Frameless Neuromate is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning.	The Voyager/Tactile Guidance System - CT is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.	The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures.	The da Vinci® does not have a "preoperative" planning function. Rather, the surgeon makes immediate operative decisions based on visual and tactile feedback from the operative field. The da Vinci® provides the surgeon with electromechanical arms [robotic] that implement the surgeon's real time operative plan based on based on visual and tactile feedback from the operative field.	All four devices are intended for use as computer-aided robotic devices **to perform surgery**. The Neuromate, Voyager and ROBODOC all provide the surgeon with software designed to preoperatively plan the surgical procedure.
Instrument movements are [computer] controlled by the surgeon through use of the Master Tool Manipulators, two hand operated mechanisms. Commands from the Surgeon Console are relayed via cables.	The computer-controlled image-guided electromechanical arm is intended to be used in neurosurgical operating room for the stereotactic spatial positioning and orientation of an instrument holder or tool guide	The computer-controlled image-guided electromechanical arm is intended to be used for the stereotactic spatial positioning and orientation of a bone cutting device	The computer-controlled image-guided electromechanical arm is intended to be used for the stereotactic spatial positioning and orientation of a bone cutting device		The Neuromate, Voyager and ROBODOC all provide the surgeon with an electromechanical arm [robotic] device that, under direct surgeon control, implements the parameters of the preoperative plan.

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12.4 Indications for Use

Table 2 compares the Indications for Use between the DigiMatch™ ROBODOC® Surgical System and the identified predicate devices. The table shows that the DigiMatch™ ROBODOC® Surgical System and the Voyager/Tactile Guidance System – CT have the same Indications for Use. Specifically, both computer-aided robotic devices are indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.[1] Thus, the DigiMatch™ ROBODOC® Surgical System satisfies the second criteria for a finding of substantial equivalence.

[1] Please note that the Voyager/Tactile Guidance System – CT is also indicated for various other types of surgery, with orthopedic surgery being only one of its indications for use.

Table 2 Comparison of Manufacturer's Claimed Indications for Use

Indications for Use					
da Vinci® Surgical System (K043153)	**Frameless Neuromate (K991081)**	**Voyager/Tactile Guidance System – CT (K052851)**	**DigiMatch™ ROBODOC® Surgical System** (which includes the cleared ORTHODOC preoperative planning software)	**Differences in Indications for Use**	**Similarities in Indications for Use**
The da Vinci® Endoscopic Instrument Control System is indicated during general laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed, with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization.	The Frameless Neuromate is indicated for use by the surgeon to manually guide standard neurosurgical instruments, under a surgeon-developed, carefully prepared stereotactic treatment plan.	The Voyager/Tactile Guidance System - CT is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made, such as… orthopedic surgical procedure.	The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.	The da Vinci® Endoscopic Instrument Control System is designed to assist in the accurate control of endoscopic instruments during general laparoscopic, etc., procedures. The Frameless Neuromate is indicated as an instrument holder or tool guide for the stereotactic spatial positioning and orientation in neurosurgical procedures.	The DigiMatch™ ROBODOC® Surgical System and the Voyager/Tactile Guidance System – CT are indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

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12.6 Technological Characteristics/Principles of Operation

Tables 3a and 3b compare the technological characteristics/principles of operation between the DigiMatch™ ROBODOC® Surgical System and the three predicate devices: the Voyager/Tactile Guidance System–CT, the Frameless Neuromate, and the da Vinci Surgical System, which are all computer-aided robotic devices.

The table shows the technological differences and similarities between the DigiMatch™ ROBODOC® Surgical System and all three predicate devices.

The primary differences relate to the fact that the da Vinci System does not use preoperative patient image data (CT scan) to pre-surgically plan, rather it uses real time image data at the time of surgery to develop a set of control files to drive the robotic arms during surgery. This is different from the ROBODOC System, Voyager and Neuromate, which all contain preoperative planning software packages that use preoperative patient image data (CT scan images) to create a pre-surgical plan containing control files to drive the robotic arm.

Another difference is that the ROBODOC System, Voyager and Neuromate all have planning modules, which produce robot control instructions based upon pre-surgical plans that are sent to the robot before surgery begins. These systems all require the surgeon to be present and exercise direct control of the device. The da Vinci Surgical System uses robot control instructions developed in real time based upon a surgeon's actions produced remotely during the surgery.

Another difference relates to the fact that the ROBODOC System, Voyager and Neuromate all use a single robotic arm. The da Vinci System uses multiple robot arms.

The DigiMatch™ ROBODOC® Surgical System, Voyager/Tactile Guidance System–CT, Frameless Neuromate, and da Vinci Surgical System, all use some various type of registration and tracking technology; however, these differences are validated alternate ways of achieving the same end. The various methods are listed below:

- da Vinci uses Visual registration and tracking;
- Neuromate uses fiducial marker registration with ultrasonic tracking;
- Voyager uses surface to surface registration with optical tracking;
- ROBODOC uses point to surface registration with mechanical tracking.

The DigiMatch™ ROBODOC® Surgical System, Voyager/Tactile Guidance System–CT, Frameless Neuromate and da Vinci Surgical System are all computer-aided robotic devices. The differences in technological characteristics/principles of operation of the devices do not affect diagnostic or therapeutic effects. Since all four are computer-aided robotic devices with similar or substantially equivalent technological characteristics/principles of operation the DigiMatch™ ROBODOC® Surgical System satisfies the third and final criteria for a finding of substantial equivalence.

Table 3a Comparison of Technological Characteristics

Comparison of Technological Characteristics						
Characteristic	**da Vinci® Surgical System**	**Frameless Neuromate**	**Voyager/ Tactile Guidance System – CT**	**DigiMatch™ ROBODOC® Surgical System** (which includes the cleared ORTHODOC preoperative planning software)	**Differences in Technology**	**Similarities in Technology**
Patient Image Data	Endoscope Real Time Image	CT/MR	CT	CT	da Vinci uses real time endoscopic imagining and the Neuromate can also use MR data as well.	Neuromate, Voyager & ROBODOC all use CT scan images.
Pre-Surgical Plan	Real Time Surgeon Plan	Preoperative Planning Computer Neuromate Software	Preoperative Planning Computer Voyager Software	Preoperative Planning Computer ORTHODOC Software	da Vinci does not use pre-surgical planning technology. Plans made in the OR during surgery.	Neuromate, Voyager & ROBODOC all contain preoperative planning software.
Surgical Plan Data	No High Level Operative Plan Control File for the system is developed in real time during surgery.	High Level Operative Plan based upon preoperative plan. Predetermined Control File developed for use on the system	High Level Operative Plan based upon preoperative plan. Predetermined Control File developed for use on the system	High Level Operative Plan based upon preoperative plan. Predetermined Control File developed for use on the system	da Vinci does not require preoperative planning. Plans are developed in surgery using computer technology that is continuously changing based upon remote inputs from the surgeon.	Operative plans, created in the Neuromate, Voyager & ROBODOC software systems, are created preoperatively.
Machine Instructions	High Level l Machine Instructions generated based upon remote Operator actions and choices used to drive robotic arm control software & hardware.	Predetermined Control File Instructions used to drive robotic arm control software & hardware	Predetermined Control File Instructions used to drive robotic arm control software & hardware	Predetermined Control File Instructions used to drive robotic arm control software & hardware	Except for the source of the control files there are no differences in Technology. Robotic arms are controlled and driven by Validated Software & Hardware.	Similar Technology; Robotic arms are controlled and driven by Validated Software & Hardware.

Table 3b Comparison of Technological Characteristics (Continued)

Comparison of Technological Characteristics (Continued)						
Characteristic	**da Vinci® Surgical System**	**Frameless Neuromate**	**Voyager/ Tactile Guidance System – CT**	**DigiMatch™ ROBODOC® Surgical System (which includes the cleared ORTHODOC preoperative planning software)**	**Differences in Technology**	**Similarities in Technology**
Patient/Robot Registration Requirement	Visual registration and tracking	Fiducial marker registration Ultrasonic tracking	Surface to surface registration Optical tracking	Point to surface registration Mechanical tracking	da Vinci uses Visual (Optical) registration and tracking. Neuromate uses fiducial marker registration with ultrasonic tracking. Voyager uses surface to surface registration with optical tracking. ROBODOC uses point to surface registration with mechanical tracking.	da Vinci, Neuromate, Voyager, ROBODOC use registration to ensure the Robotic instructions can be accurately carried out in the right place. Tracking is required to ensure the instructions are carried out in the right place. The same functions are realized when you use optical, or electromechanical arm tracking technology.
Robot electromechanical arms	Robot with multiple electromechanical arms and end effectors implement Control File instructions	Robot with a single electromechanical arm and end effectors implements Control File instructions	Robot with a single electromechanical arm and end effectors implements Control File instructions	Robot with a single electromechanical arm and end effectors implements Control File instructions	da Vinci, employs technology that use two or more electromechanical arms to implement desired control file instructions.	Neuromate, Voyager & ROBODOC all employ technology that use of a single electromechanical arm to implement the control file instructions

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12.7 Conclusion

The DigiMatch™ ROBODOC® Surgical System and predicate devices (*i.e.*, da Vinci Surgical System, Frameless Neuromate, and Voyager/Tactile Guidance System – CT) have the same intended use, similar indications, technological characteristics and principles of operation. There are no significant differences in the technological approaches between the DigiMatch™ ROBODOC® Surgical System and its predicates.

1. The use of preoperative patient image data (CT scan data) to plan the surgery and produce a preoperative plan is the same for the ROBODOC System, and the predicate devices, Voyager and Neuromate. The da Vinci does not use preoperative patient image data (CT scan data) to plan the surgery and produce a preoperative plan. In contrast,, real time image data is gathered and surgery planned in real time. This difference does not affect the intended use of the devices in that they all use robotic arms driven by control software and hardware to carry out the surgical intent.

2. The ROBODOC System requires a High Level Operative Plan based upon a plan developed before surgery on a computer planning station as does the predicate devices, Voyager and Neuromate. The da Vinci does not require this file be generated before surgery. It is produced during the surgery. Although the plans are developed at different times this does not affect the intended use of the devices in that they all use these instructions once generated to control one or more robotic arms.

3. The ROBODOC System uses a single robotic arm as does the predicate devices, Voyager and Neuromate. The da Vinci uses multiple robotic arms and end effectors. Although the number of arms and end effectors are different, all of the systems function in a similar manner and have the same intended use.

These differences do not present any new issues of safety or effectiveness. The technologies are fundamentally the same in that they all use robotic arms driven by validated control software and hardware and all of the devices have the same intended use, and similar indications.

Thus, the DigiMatch™ ROBODOC® Surgical System is substantially equivalent to the Voyager/Tactile Guidance System – CT , the Frameless Neuromate and the da Vinci Surgical System.

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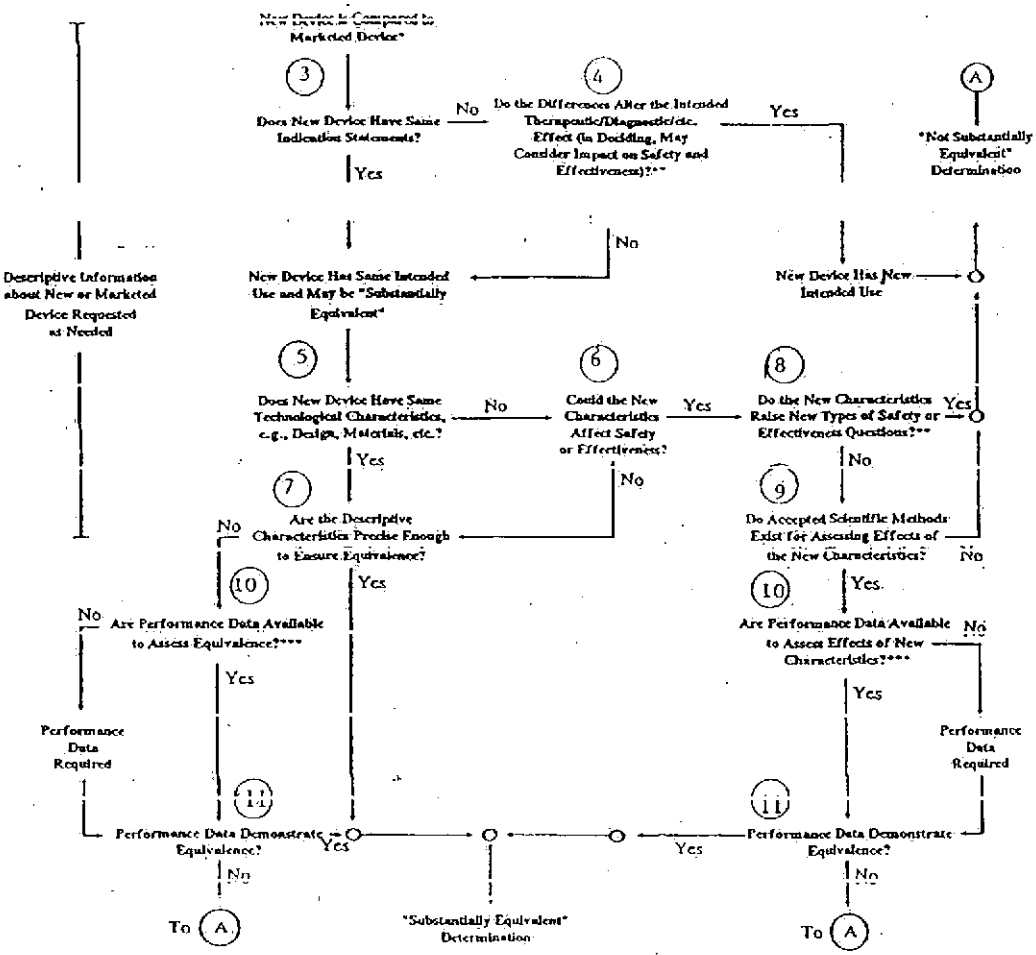
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 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.

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DigiMatch™ ROBODOC® Surgical System
Traditional 510(k) Premarket Notification

K _____ ORIGINAL

Integrated Surgical Systems, Inc. (ISS) hereby submits a premarket notification for the DigiMatch™ ROBODOC® Surgical System pursuant to 21 CRF PART 807 Subpart E. The format of this submission follows the recommendations contained in Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s, dated August 12, 2005.

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ISS requests confidentiality of this notification in accordance Sec. §807.95(b)(1)(i-iv).

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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Section 13 – Proposed Labeling

ROBODOC® Preoperative Protocols

ORTHODOC® User Guide

ROBODOC® User Manual

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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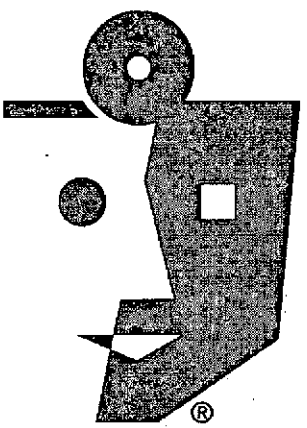
ROBODOC® Preoperative Protocols

U.S. Edition



ROBODOC®

INTEGRATED SURGICAL SYSTEMS

CE 0197

Preliminary procedures for primary cementless total hip arthroplasty with the ROBODOC® Surgical Assistant

Volume II - 000002

DJA x01245

WARNING

Read the entire manual before performing a computed tomography (CT) scan or implanting locator pins on patients who will undergo surgery using the ROBODOC Surgical Assistant System.

The ROBODOC Surgical Assistant is intended for use only by ISS-trained and ISS-certified surgeons and technicians.

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Manufactured by Integrated Surgical Systems, Inc.
1433 North Market Blvd. Unit #1
Sacramento, CA 95834

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Chapter 1

INTRODUCTION

General Information

This manual is intended for orthopedic surgeons who perform primary cementless total hip arthroplasty (THA) with the ROBODOC® Surgical Assistant System and for radiology technicians who perform computed tomography (CT) scans on ROBODOC patients. Chapter 2 contains CT protocols.

The procedures described in this documentation are interrelated because their combined purpose is to provide the ORTHODOC® Preoperative Planning Workstation (ORTHODOC) and the ROBODOC Surgical Assistant (ROBODOC) with spatial information, measurements, and graphical data about patient anatomy and prosthesis geometry.

DigiMatch™ SMG (DigiMatch) surface registration techniques will be used to provide ORTHODOC and ROBODOC with input regarding planned implant cavity position and orientation.

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Indications and Contraindications

The indications and contraindications listed below are for performing CT scans and implanting locator pins in ROBODOC patients.

Indications for Use

- Candidate for primary or revision THA with the ROBODOC Surgical Assistant System.
- For primary THA, a severely disabled hip joint due to primary or secondary degenerative osteo-, rheumatoid, or post-traumatic arthritis; avascular necrosis of the femoral head; or acute femoral neck fracture.
- For primary THA, patient anatomy is compatible with one of the hip implant designs validated for use with the ROBODOC Surgical Assistant.

Contraindications

- Skeletal immaturity.
- Any active infection.
- Neuromuscular disorders, which would create an unacceptable risk of prosthesis instability or fixation failure.
- A pathological skeletal condition, which would impair the ability of the bone to withstand the stress of femoral canal preparation and prosthesis placement (e.g., severe osteoporosis, Paget's disease, renal osteodystrophy).
- A systemic illness, which would render the patient unable to perform appropriate postoperative rehabilitation or preclude adequate assessment of pain and gait.
- Mental disorders, which could complicate preoperative and postoperative care.
- Obesity.
- Pregnancy.
- In DigiMatch cases, poor skin coverage or bone stock of the operative femur adjacent to the greater trochanter, or the lateral or medial epicondyle.

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- In DigiMatch cases, severe femoral deformity due to trauma or severe cases of degenerative osteoporosis of the operative femur, with significant deformation of the surfaces required for DigiMatch surface registration.

- In DigiMatch cases, any metallic objects in the operative or counter-operative leg which would cause unacceptable levels of artifact in the CT slices over the surfaces required for DigiMatch registration.

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Warnings, Adverse Effects, and Precautions

The warnings and adverse effects listed below are for performing CT scans and implanting locator pins on ROBODOC patients.

Warnings

- Using a CT scanner that has not been properly maintained and calibrated per the manufacturer's specifications could result in unsatisfactory implant fit or placement.

Adverse Effects

The following adverse effects are risks believed to be associated with locator pin implantation and CT scans for ROBODOC patients:

- Radiation during the CT scan may pose a slightly greater risk to the patient than radiation from conventional x-rays required for THA using traditional techniques.

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Procedural Overview

CT data provides ORTHODOC with input regarding patient anatomy and with the data required for building three-dimensional images of the bone for computerized templating. The data must be obtained by following the appropriate CT protocol provided in Chapter 2.

To properly position the implant cavity, ROBODOC needs information about the spatial orientation of the planned implant cavity. This information may be obtained by performing DigiMatch surface registration procedures.

The scan provides ORTHODOC with input to create three-dimensional images of the bone for computerized templating. Chapter 2 provides protocols to perform conventional and spiral scans. The integrity of the data sets produced by conventional and spiral scans result in a similar degree of placement accuracy.

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Chapter 2

CT PROTOCOLS

Introduction

This chapter is intended for use by the CT technicians who will scan ROBODOC patients.

This chapter provides general guidelines for scanning ROBODOC patients.

Preventing patient motion is critical for the production of CT data that will serve as input to ORTHODOC and ROBODOC. Carefully follow the instructions in the next section to immobilize the legs and advise the patient of the importance of remaining motionless during the scan.

Spacing of the scan intervals is another critical factor. Be sure to scan at appropriate spacing.

Scanner settings vary depending upon manufacturer and model. If your scanner does not have the specified setting for Scan Thickness, Table Motion, or any other parameter, select the closest setting that will result in a higher resolution than the specified setting. **(Do not increase the thickness, table motion, or reconstruction increment.)**

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DO NOT BEGIN SCANNING UNTIL:

- You have read this chapter.
- You are reasonably confident that the patient will be able to remain motionless for the entire scan and the patient fully understands the importance of a motionless scan.
- The ISS bone motion detection rod is available.
- All metal items, such as clips and pins, have been removed from the wrappings on the operative leg.
- With the surgeon's approval, radiopaque items have been removed from the operative leg (e.g., hemovac).
- The patient is positioned so that the scan can include the entire femur from the acetabular rim to the femoral condyles distally, including the bone motion rod and locator pins, if applicable.
- The scanner settings reflect the ISS protocol for your scanner and scan type (i.e., conventional or spiral).
- You have completed the scan header and ID fields according to the ISS protocol.
- You have established a field of view (FOV) that will include the entire femur and bone motion rod within the required 20 centimeters (cm) display FOV.
- You have verified that no slices will overlap in the scan range.

The CT images must be continuous and all under one exam number, with each scout view under a separate series number. Do not adjust table height or FOV during the scan. If patient motion or a mistake occurs at any time during the exam, cancel the exam and begin again with a new exam number.

The first slice in the exam should be approximately 1 cm superior to the proximal margin of the acetabulum so that the entire femoral head and acetabular rim will be scanned. Scanning at the proper spacing is critical for producing data that can be used by ORTHODOC and ROBODOC.

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Preventing Femoral Motion

This section describes a recommended procedure for attaching the bone motion detection rod and stabilizing the femur to prevent motion during the scan.

Patient comfort is essential for minimizing the likelihood of motion during the CT scan. Attempt to make the patient comfortable and calm, and explain the importance of remaining motionless during the scan.

The procedure described below is a recommended method for attaching the bone motion detection rod and stabilizing the femur.

⇨ To stabilize the femur:

1. Assemble the following items:
   - ISS bone motion detection rod (ISS P/N 100573 or 101530)
   - Short Velcro® straps or full-length leg hose (site provided)
   - Wide Velcro straps or full-length leg hose (site provided)
2. Lift the lower portion of the cradle pad from the CT table, exposing the cradle, as shown in Figure 2-1 (A).
3. Position the wide straps on the cradle in the approximate position where the upper thighs and lower legs will be, as shown in Figure 2-1 (A).
4. Replace the cradle pad, covering the middle of the wide straps.
5. Position the patient on the cradle pad for a feet-first scan, as shown in Figure 2-1 (B).
6. Place the bone motion detection rod on the operative leg and secure it with the straps, as shown in Figure 2-1 (B).
7. Pull the wide straps over both legs and tighten, as shown in Figure 2-1 (C).
8. Verify that the bone motion detection rod is secured to the leg with enough pressure to prevent it from slipping during the scan.
9. Ensure that the patient is comfortable and that the straps are securely fastened, but not painfully tight.

   Since the patient's comfort is the greatest factor affecting potential

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bone motion, every effort should be taken to ensure that the patient is comfortable.

10. Remind the patient to relax and remain motionless.

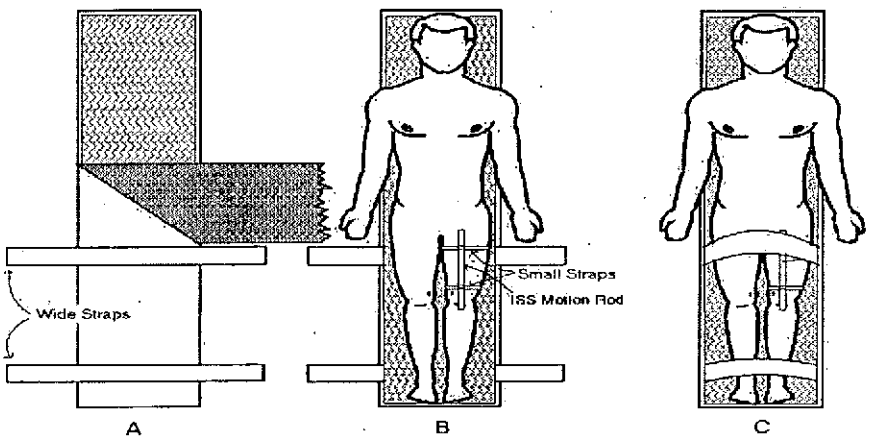

Figure 2-1. Femur Stabilization Procedure

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Preparing for the Scan

This section describes preliminary procedures that must be performed by the CT technician prior to beginning the scan.

Completing the Scan Header

Failure to enter an ID or name will cause ORTHODOC to reject the scan data.

⇨ **To enter scan header information:**

1. Enter the hospital identification number for the patient.
2. Enter the patient's full name (last, first, and middle initial).

   NOTE: The first character must be alphanumeric (a letter or number, not a space, hyphen, or special character).

Setting Scan Parameters

⇨ **To set up the scanner, select the following settings:**

1. **Type of Scan:** Axial or Spiral (depending upon selected protocol).
2. **Anatomical Feature of Study:** Acetabular cup, proximal femur, femoral condyles.
3. **Patient Positioning:** Feet first into gantry.
4. **Table Motion:** Out of gantry (top of femur toward knee).
5. **Scout View:** A/P to include entire femur.
6. **Scan Thickness:** Per appropriate scan interval diagram.
7. **Scan Intervals:** Per appropriate scan interval diagram.
8. **Calibration File:** Large body.
9. **Field of View:** 20 cm for all scan slices.
10. **Matrix Size:** 512 x 512.
11. **Algorithm:** Abdomen.

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12. **mA and Scan Time:** Set these parameters to provide an exposure of approximately 200 mAs per rotation.

13. **kV:** 120

14. **Gantry Tilt:** 0 degrees

15. **Raw Scan Data Save:** Temporarily retain raw data for recalculation; ORTHODOC cannot use raw data.

Preparing the Patient and Taking Scout Views

⇨ **To prepare the patient and take scout views:**

1. Position the patient and secure the bone motion detection rod as described in the "Preventing Femoral Motion" section.

2. Take an anteroposterior and mediolateral scout view when the patient is secure in the fixture and fully aware of the importance of remaining motionless.

   NOTE: Be sure to include the acetabulum, the entire femur distally to the femur-tibial junction, and the bone motion detection rod.

Verification of Number of Slices (THA Cases Only)

Users should verify prior to scanning the patient that the result will include no more than 200 slices. Refer to the "Scan Interval Diagrams" section.

⇨ **If it appears that the exam will result in more than 200 slices, perform the following strategies:**

1. The most proximal region of 1.0 mm slice density may stop at the midpoint of the lesser trochanter, rather than distal to the lesser trochanter.

2. The number of slices through the femoral condyles should be the minimum number necessary to measure anteversion in ORTHODOC (typically 5-10 slices).

   NOTE: The less than 200 number of slices requirement is only applicable for THA cases

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Scanning the Patient

⇨ **To scan the patient:**

1. Remind the patient to relax and remain motionless.
2. Do not adjust the FOV or table height during the exam.
3. During the scan, watch for patient movement.

NOTE: If the patient appears to move or a mistake occurs at any time during the exam, cancel the exam and begin again with a new exam number. The CT images must be continuous and under one exam number, with each scout view under a separate series number.

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Scan Interval Diagrams

The diagrams in this section show scan intervals and other settings for various scanners. Follow these guidelines as closely as possible.

This section includes two diagrams:

- Conventional Protocol for DigiMatch Patients
- Spiral Protocol for DigiMatch Patients

Specific scanner settings may vary slightly depending upon scanner defaults and technician preferences.

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Conventional Protocol for DigiMatch Patients

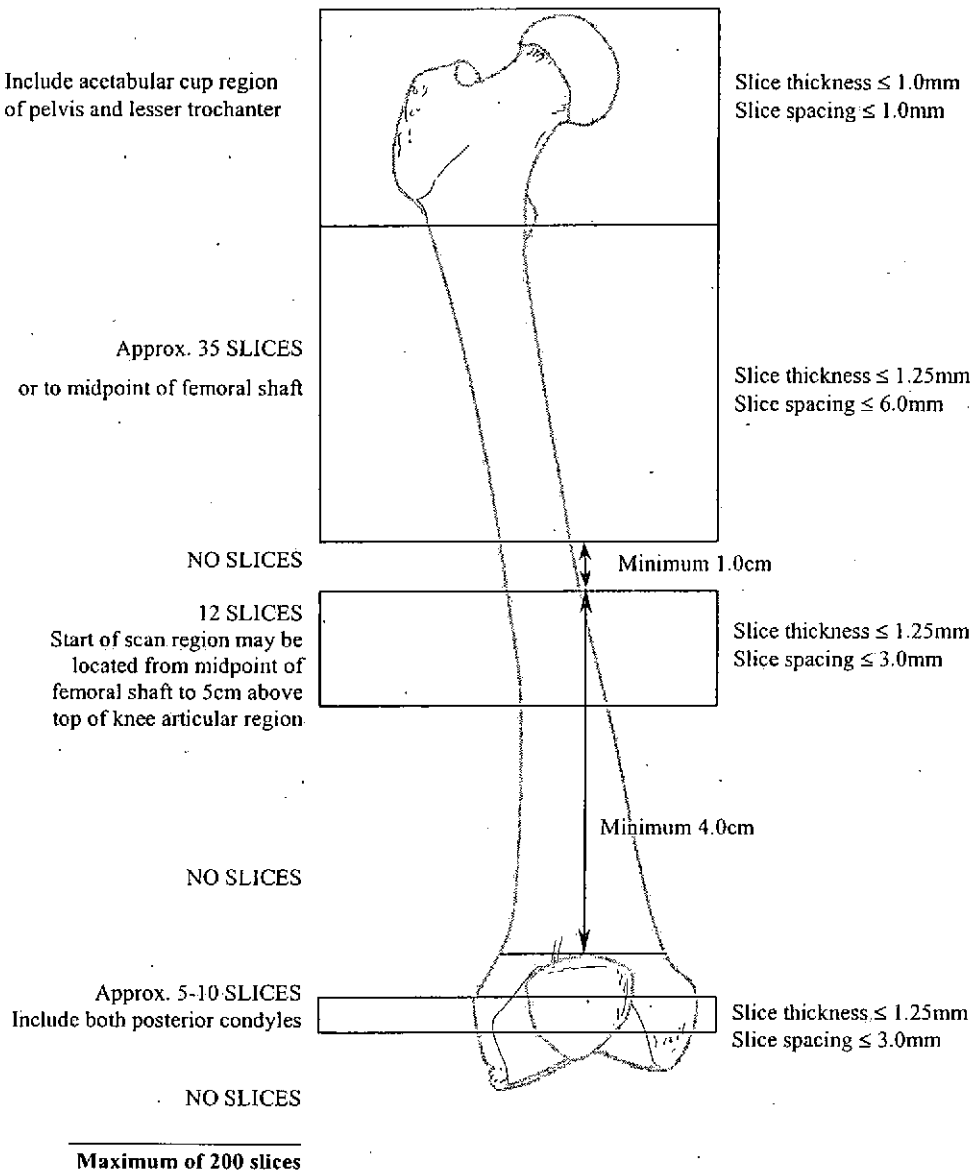

Figure 2-2. Conventional Protocol for DigiMatch Patients

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Spiral Protocol for DigiMatch Patients

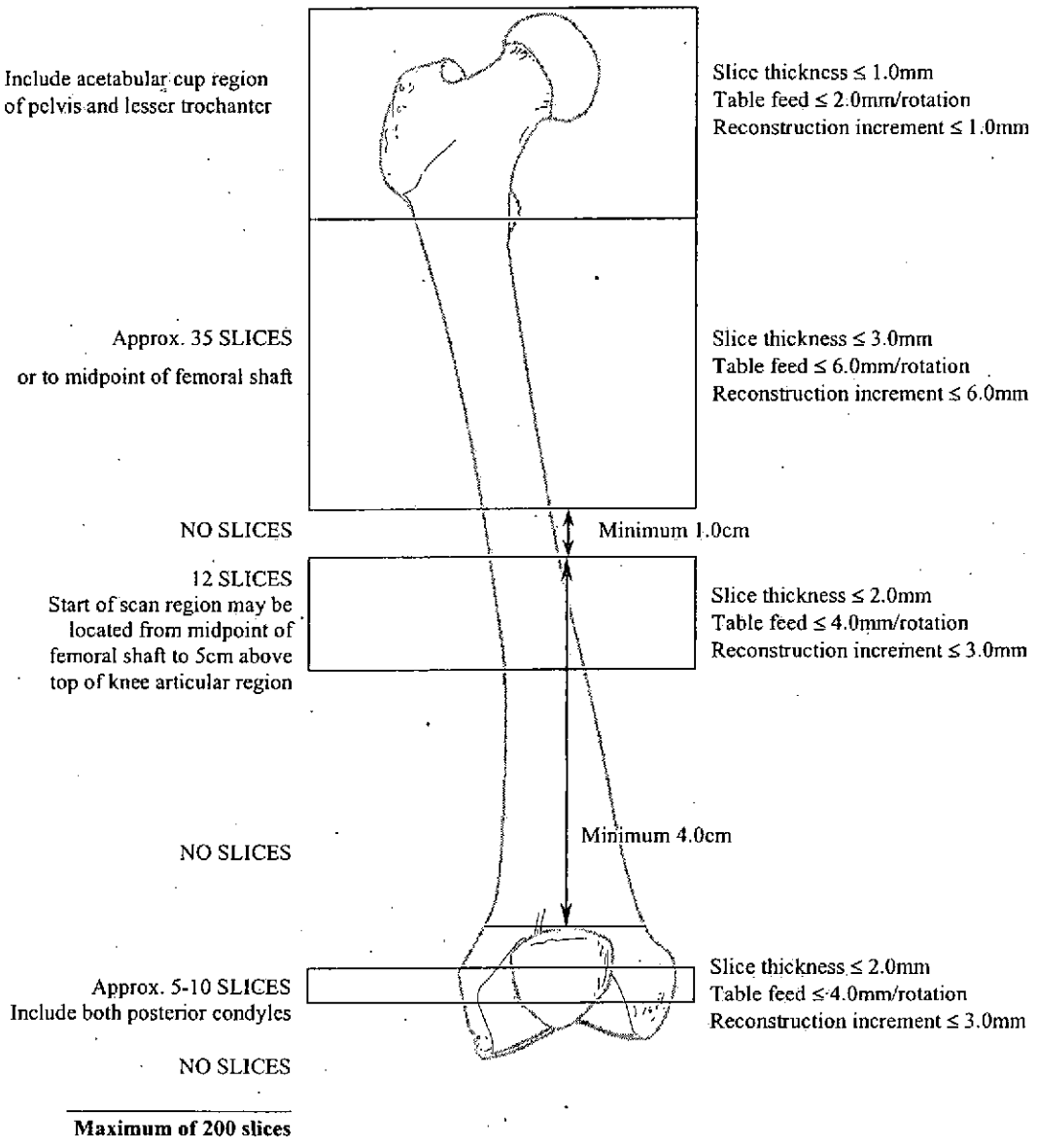

Figure 2-3. Spiral Protocol of DigiMatch Patients

Transferring Data to ORTHODOC

The section explains how to create an ORTHODOC tape or optical disk. The ORTHODOC also supports the transfer of DICOM data via an ethernet connection.

Follow the appropriate procedure depending upon the output device at your site.

Transfer CT Data via Ethernet

⇨ **To complete the exam:**

1. Send DICOM data from the CT Scanner to the ORTHODOC according to instructions appropriate for the scanner.

2. Do not release the patient until the ORTHODOC technician confirms that the scan data passed the motion test, pin finding test (locator pin cases), and test for protocol compliance. If any of these tests fail, the patient may need to be rescanned, as determined by the radiology staff.

Creating an ORTHODOC Tape

When archiving the exam to tape, do not attempt to mount it.

⇨ **To complete the exam:**

3. Insert a new magnetic tape into the drive.

4. Copy the exam onto the tape.

   NOTE: If multiple exams were taken of the same patient, archive only one exam number.

5. Label the tape with the following information:

   - Exam number
   - Patient's full name
   - Exam date
   - Exam time

6. Give the tape to the ORTHODOC technician.

7. Do not release the patient until the ORTHODOC technician confirms that the scan data passed the motion test, pin finding test (locator pin

cases), and test for protocol compliance. If any of these tests fail, the patient may need to be rescanned, as determined by the radiology staff.

Creating an ORTHODOC Optical Disk

⇨ **To create an ORTHODOC optical disk:**

1. Place an optical disk in the scanner drive.
2. Save the image data to the drive without compression.
3. Label the disk with the following information:
   - Exam number
   - Patient's full name
   - Exam date
   - Exam time
4. Give the disk to the ORTHODOC technician.
5. Do not release the patient until the ORTHODOC technician confirms that the scan data passed the motion test, pin finding test (locator pin cases), and test for protocol compliance. If any of these tests fail, the patient may need to be rescanned, as determined by the radiology staff.

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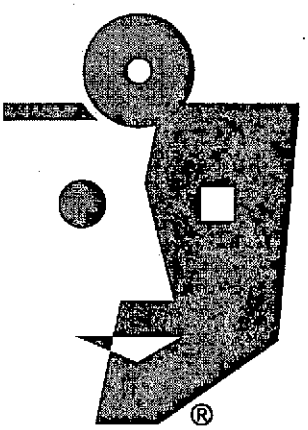
ORTHODOC® User Guide

U.S. Edition



ROBODOC®

INTEGRATED SURGICAL SYSTEMS

Preoperative Planning Workstation for use with
the ROBODOC® Surgical Assistant System

Volume II - 000025

DJA x01268

WARNING:
Read this entire manual before using the ORTHODOC Preoperative Planning Workstation

The ORTHODOC Preoperative Planning Workstation is intended for use only by ISS-trained and ISS-certified surgeons and technicians.

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Rev. 01

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Preface

About This Manual

This manual explains how to use the ORTHODOC® Preoperative Planning Workstation (ORTHODOC Workstation). It describes how to preprocess CT data, select an implant, and develop a computerized preoperative plan.

Audience

This manual is intended for ISS-certified orthopaedic surgeons, technicians, nurses, and administrative personnel who will use the ORTHODOC Workstation. ISS-certified surgeons have experience performing traditional total hip replacement surgeries and have attended a training program covering the use of the ORTHODOC Workstation and the ROBODOC® Surgical Assistant.

The technicians, nurses, and administrative personnel who assist ISS-certified surgeons may use the workstation to perform a variety of procedures such as preprocessing CT data and case management. However, only ISS-certified surgeons are authorized to create transfer files containing preoperative plans.

How To Use This Manual

To assist you in finding information, a table of contents is provided at the beginning of the manual

The glossary describes terms that are unique to the ORTHODOC Workstation and the ROBODOC Surgical Assistant System. Use the glossary whenever you encounter an unfamiliar word or when you need to refresh your memory about a particular feature or procedure.

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Other Manuals

The ***ORTHODOC ®User Guide*** has three companion volumes:

ROBODOC® Preoperative Protocols

This manual provides the protocol for implanting locator pins and the protocol for performing a CT scan that will provide input for the system.

ROBODOC® User Guide

This manual lists the supplies required for a ROBODOC surgery, explains how to set up the operating room, provides the surgical protocol, and describes postoperative maintenance procedures. The surgical protocol provided in this manual covers only the unique aspects of a ROBODOC surgery. It does not describe surgical hip replacement techniques that are identical to the traditional techniques employed in non-robotic surgeries.

ORTHODOC Step-by-Step Templating

This manual provides step-by-step instructions for templating a patient file that has been imported into the ORTHODOC system.

The ORTHODOC® Planning Session

This manual is seperated into four sections. The section and associated chapters are listed below.

Section	*Chapters*
Working with the computer	1, and 2
Preprocessing the Patients CT Data	3
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Chapter 1

INTRODUCTION

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ORTHODOC® User Manual

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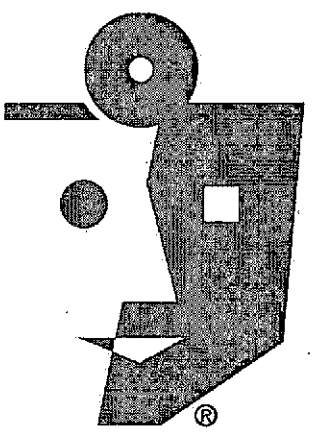

ROBODOC®

INTEGRATED SURGICAL SYSTEMS

CE 0197

Preoperative Planning Workstation for Use with the ROBODOC® Surgical Assistant System

Volume II - 000033

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Product Conformity

Medical Directive (93/42/EEC)

Product	Classification
Surgical Robot	IIB
Locator Pins	IIB
Cutters	IIA (sterile)
Drapes	I (sterile)
Irrigation Tubing	I (sterile)
ORTHODOC Workstation	I

Electro-Magnetic Compatibility (EMC) Directive (89/336/EEC)

This product complies with the EMC standards of EN55011 Class B. Under normal intended use, this device will not interfere with other electrical devices.

EN 60601-1 Classification

Class I Equipment; rated for continuous operation. Type B applied parts per EN 60601-1 include the femoral fixator, the bone motion monitor, and cutter accessories. The DigiMatch digitizing arm is a Type BF applied part.

WARNING

Read this entire manual before using the ORTHODOC Preoperative Planning Workstation.

The ORTHODOC Preoperative Planning Workstation is intended for use only by ISS-trained and ISS-certified surgeons and technicians.

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What is ORTHODOC?

The ORTHODOC® Preoperative Planning Workstation (ORTHODOC) is a computerized system for planning ROBODOC®-assisted total hip replacement surgeries. The software's graphical presentation of CT data gives surgeons the power and precision of computer-aided tools for selecting and templating femoral components.

Computerized tomography (CT) data from a scan of the patient's operative femur provides the input for preoperative planning on the ORTHODOC Workstation. ORTHODOC stacks and interpolates between the individual scan slices to create three-dimensional images of the femur.

ORTHODOC has a computerized directory of implant types and sizes, from which the surgeon may select. The system displays three-dimensional views of selected implant models for computerized templating with femur images.

The system also provides tools for surgeons to preoperatively determine implant head size, neck offset, version angle, and osteotomy level.

Output from an ORTHODOC planning session provides the ROBODOC Surgical Assistant with implant size, shape, and placement data. The output is saved on a CD/tape cartridge, and loaded into the robot control computer prior to surgery.

ORTHODOC also provides a case management system for archiving (storing), retrieving, and deleting old files.

This manual describes how to perform all ORTHODOC procedures.

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Indication for Use, Adverse Effects, and Precautions

The indication for use, adverse effects, and precautions listed below are for use of the ORTHODOC Preoperative Planning Workstation.

Indications for Use

- Candidate for primary cementless total hip replacement surgery using the ROBODOC Surgical Assistant System.

Adverse Effects

- If the implant model is not properly positioned prior to creating the transfer file, cavity placement problems may occur.
- An inaccurate measurement of the version angle of the implant may result in dislocation of the hip.
- Invalid CT data may cause cavity placement problems.
- Selecting an oversized implant may cause the robot to remove too much cortical bone and weaken the femur.
- Selecting an undersized implant may prevent bone ingrowth and mechanical stability.
- Selecting an inappropriate neck offset may adversely affect leg length.
- Failure to detect bone motion may cause cavity placement problems.
- If the femoral component of the prosthesis exceeds the manufacturer's stated tolerances, problems associated with undersizing or oversizing may occur.
- If the three-dimensional model is not properly generated, it could result in an incorrect angle for measuring the version and subsequently lead to dislocation of hip.
- Failure to correctly identify which side the operative leg is on (left or right) may lead to surgical complications during the THR procedure.

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Precautions

- Check the placement of the proximal pin to determine whether it will be in the path of the cutter. If so, the surgeon must remove the proximal pin prior to cutting.

Technical Specifications

Physical Specifications

Length	127.0 cm	(50 in)
Width	82.5 cm	(32.5 in)
Height	76.2 cm	(30 in)
Height (including monitor)	127.0cm	(50 in)
Weight (including monitor)	160 kg	(352 lb)

Electrical Specifications

Power Requirements	115 VAC at 4A	
or	230 VAC at 2A	
Frequency	50 or 60 Hz	

Environmental

Operating

Temperature	5 to 40° C	(40 to 104° F)
Humidity (Non-condensing)	30 to 80 % Relative Humidity	
Atmosphere	700 hPa to 1060 hPa	

Note: ***The workstation is not intended for use in the operating room.***

Transportation & Storage

Temperature	-5 to 65° C (13 to 150° F)
Humidity (Non-condensing)	10 to 90 % Relative Humidity
Atmosphere	700 hPa to 1060 hPa

Workstation Components

The ORTHODOC Preoperative Planning Workstation has the following components, which are illustrated in :

- ORTHODOC software
- UNIX workstation
- Color graphics monitor
- Mouse
- ROBODOC Output drive
- CT Input Device

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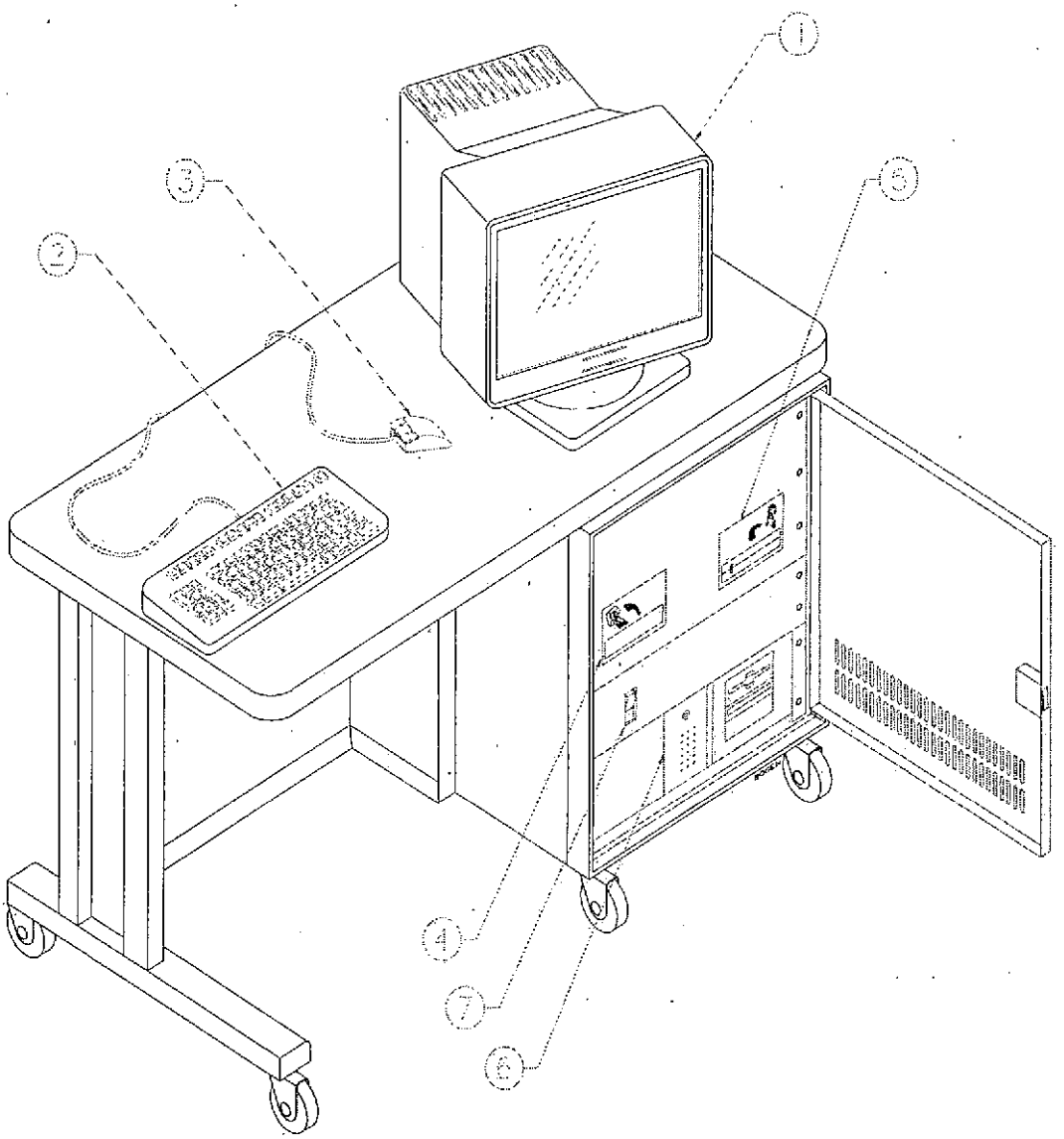

Figure 1-1. The ORTHODOC Workstation

1. Color monitor
2. Keyboard
3. Mouse
4. CT tape drive (site-specific configuration)
5. Cartridge tape drive
6. ORTHODOC Computer
7. Power switch

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Procedural Overview

This section summarizes a typical sequence of procedures in an ORTHODOC preoperative planning session. Many of these procedures may be performed by a nurse or technician, but the surgeon is responsible for templating, measuring version angle and osteotomy level, and creating the transfer file.

Preprocessing

Before preoperative planning can begin, the raw data from a CT scan of the patient's femur must be loaded into the workstation and processed into a file format that will generate three-dimensional images for templating. The preprocessing procedure involves importing the CT data into the ORTHODOC Workstation, finding the locator pins in the data, checking for protocol compliance and motion during the scan, and generating a three-dimensional model.

Selecting and Previewing a Patient File

The Patient Directory window lists all the patient files that have been preprocessed and are ready for templating. This window also provides buttons for previewing the CT images, pin data, motion detection data, and scan information. Previewing these items and checking the Process Log enables you to verify that the patient file contains valid data and is ready for templating.

Selecting and Previewing an Implant File

The Implant Directory window lists all the implant types and sizes that are available for use with the ROBODOC Surgical Assistant System. This window also provides buttons for previewing implant models and displaying manufacturing specifications. Checking these images and data can be helpful in selecting an appropriate implant.

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Templating

When patient and implant files are selected, three-dimensional images appear on the screen, with a different view of the femur and implant model in each quadrant. Using the mouse to move and rotate these images, the surgeon positions the implant model in the desired location in relation to the bone.

To facilitate templating, ORTHODOC enables the surgeon to enlarge the images and to view the femur and implant from an unlimited number of perspectives. ORTHODOC also provides the surgeon with tools for evaluating certain aspects of the surgery that will be performed manually. The surgeon must measure the angle of implant version. To select an appropriate head size and neck offset, the surgeon must display and evaluate models of the various head and neck options available with the selected implant.

The surgeon must also determine if the proximal pin will interfere with the robot's cutter by checking its position relative to the implant model. If the pin is close to the path of the cutter, it will need to be unscrewed a few turns prior to starting the cutter.

Creating a Transfer File

When the surgeon is satisfied that the implant model is properly positioned within the femur image, he or she selects the **Transfer File** button to create a tape cartridge. Prior to creating the tape, ORTHODOC requires the surgeon to confirm that the locator pin and bone motion data appear valid, and identify the leg (left or right). If the data is validated, the system then creates a transfer media containing data describing implant size, shape, and planned position within the femur. In the operating room, this cartridge will be loaded into the control computer for the robot.

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Performing Administrative Functions

ORTHODOC has other features, which are not used on a case-by-case basis. One of these features is the Case Manager, which provides the capability of archiving, restoring, and deleting old files. The surgeon or an assistant must periodically use the Case Manager to remove non-active files and free space on the ORTHODOC computer for new cases.

Assigning and changing passwords is another function that is performed on an as-needed basis. Since passwords ensure system security by restricting access to authorized users, some organizations may require that passwords are frequently changed.

Performing Routine Maintenance

Cleaning Instructions

Display Monitor

Clean the monitor screen with a soft cloth and any commercial product for cleaning cathode ray tube screens. Clean workstation surfaces with in the same manner as other office furniture. Clean the mouse *with the computer powered off* by following these steps:

1. Remove the ball cover from the underside of the mouse.
2. Turn the mouse right side up and catch the ball in your hand.
3. Use adhesive tape to remove dust or lint from the ball. Use a cloth to clean inside the mouse socket (or use a cotton swab dipped in isopropyl alcohol to loosen dirt or lint).
4. Return the ball to its socket and replace the ball cover.

CT Input Devices

Cleaning of the CT input device is dependent upon the type of device used by your system. Your ISS service representative can assist you in obtaining the cleaning protocol for your device.

ROBODOC Output Device

Cleaning the ROBODOC output device is dependent upon the type of device used by your system. Your ISS service representative can assist you in obtaining the cleaning protocol for your device.

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Chapter 2

WORKING WITH ORTHODOC

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Starting the Workstation

ORTHODOC® is a fully integrated workstation. It's ready to go when you first sit down in front of the computer. All you need to know before beginning the procedures described in this manual are the name and password assigned to you as an authorized user of the system.

Powering On

⇨ **To activate the system:**

1. Turn on the power switch located inside the cabinet door, to the right of the cartridge unit, as shown in Figure 1-1.
2. Check the monitor switch to verify that it has been left on.
3. The system takes several minutes to complete its internal checks. When these checks are complete, the screen displays copyright information and the console login prompt.

Entering the User Name and Password

ISS assigns user names and initial passwords to authorized ORTHODOC users. You must contact ISS to set up accounts for new users. However, authorized users may change their own passwords as often as desired. Appendix A provides instructions for changing a password. We recommend that new users perform this procedure before using the system for the first time to change preassigned passwords to personalized ones that may be easier to remember.

⇨ **To display the main menu:**

1. When the Console login prompt is displayed, enter your ISS user name and press Enter.

   The screen prompts you to enter your password.

   Note: ***Logins and passwords are case sensitive. If caps Lock is on, the login procedure will assume all capital letters. To recognize lower case letters, turn off (Press) the caps Lock key and then press ctrl-d to restart the login procedure.***

2. Type your password and press Enter.

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For security reasons, the screen does not display your password as you type. When you have successfully entered your name and password, the main menu shown in Figure 2-1 appears.

3. Select the button for the program you wish to use.

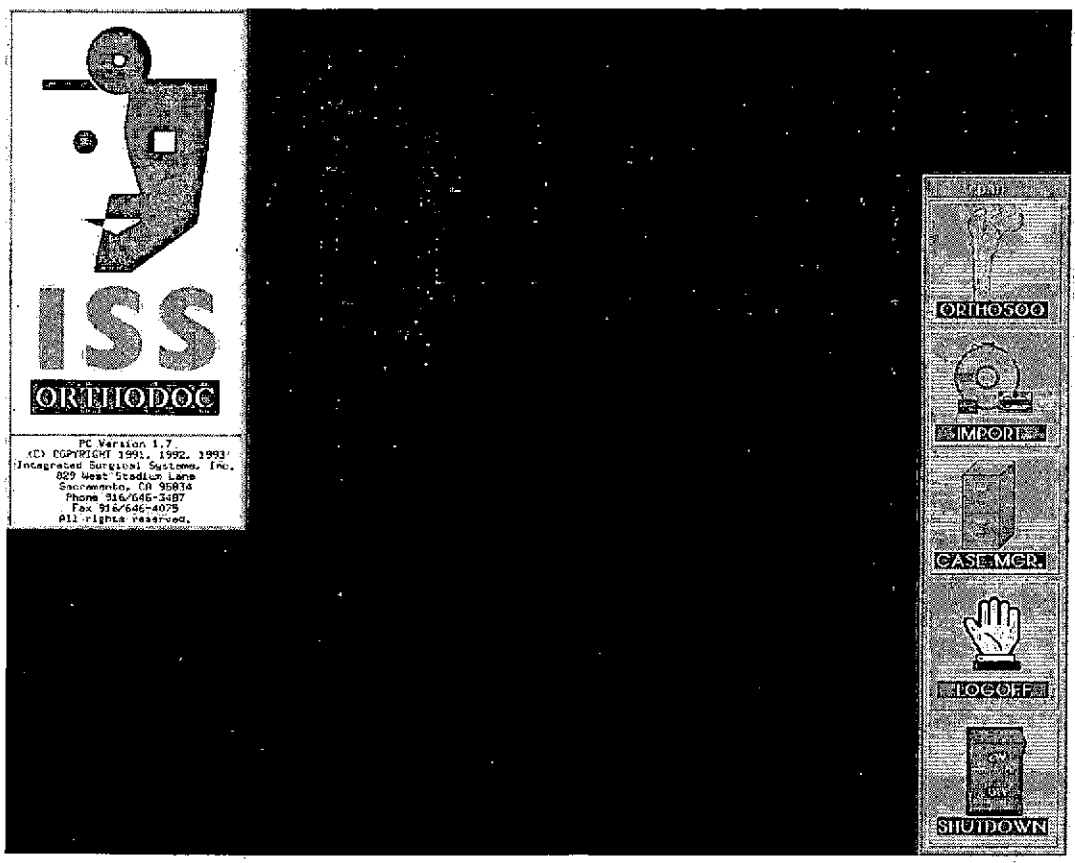

Figure 2-1. The Main Menu

The main menu displays the ISS logo and copyright information. It also displays the following five buttons:

ORTHODOC. This button starts an ORTHODOC preoperative planning session. Select this option when preprocessing is complete and you are ready to develop the plan.

IMPORT. This button starts the import program, which will load CT data into the ORTHODOC case database and enable you to perform preprocessing and data validation functions.

CASE MGR.. This button starts the Case Manager program, which provides functions for deleting files from the case database and restoring archived transfer files from tape.

LOGOFF. This button is used to end your planning session and changes the display to the login prompt. It is a good idea to log off from the computer when you are finished using it or need to leave the computer unattended for an extended period of time.

SHUTDOWN. This button is used to prepare the computer before turning off the power. The ORTHODOC computer should never be turned off before running the shutdown procedure. When this procedure is finished the screen prompt will display a message that it is ready for the power to be removed.

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Using the Mouse

The mouse is the small plastic device attached to your workstation by a cord. It fits into the palm of your hand and you can roll it in all directions on your desktop or mouse pad. As you roll the mouse, a pointer moves around the computer screen. The mouse also has "buttons." By rolling the mouse and clicking the left button, you can open menus and windows, select items, respond to prompts, and move objects.

Moving the Pointer

The movement of the mouse (not the position of the mouse on the desk or mouse pad) causes the pointer to move. You can lift the mouse off the desktop and set it down in a new location without moving the pointer on the screen. Roll the mouse in the direction that you want the pointer on the screen to move.

Dragging Objects

To drag (move) an object from one area on the screen to another, position the pointer on the object to be moved. Then depress the left mouse button while rolling the mouse in the direction that you want the object to move. When the object is properly positioned, release the mouse button.

Selecting Objects

To select an object on the screen such as a tool, button, pull-down menu, or an option in a window, move the pointer until it touches any part of the desired item and "click" (press and release) the left mouse button.

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Chapter 3

PREPROCESSING

DJA x01293

Introduction

This chapter describes how to generate an ORTHODOC® file from CT data. The procedure involves importing (loading and translating) the CT data and initiating several processes by selecting buttons. An orthopedic surgeon or a technician familiar with CT data and the ORTHODOC Workstation may perform preprocessing.

Allow approximately 15 minutes to process each patient file.

1. The first step in generating an ORTHODOC file is to import the source data from tape, disk, or directly from the CT scanner. The medium will depend upon the equipment at your site. Importing the data from a CT scan loads the data into the case database and translates it into a format ORTHODOC can use to produce images.

2. The second step is to initiate the following three processes:

   - Checking for bone motion during the CT scan
   - Building a three-dimensional model

   After each procedure, it is advisable to check the Process Log to determine whether the process was successfully completed.

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Importing Patient Files

The medium for importing patient files varies from site to site. Some options available include 4mm, 8mm, 1/4-inch, or Magnetic-Optical disks as the transfer medium.

Perform this procedure to convert the CT data into a file in the case database.

⇨ To import CT data:

1. From the main menu, select the **IMPORT** button.

   The Import screen shown in Figure 3-1 appears.

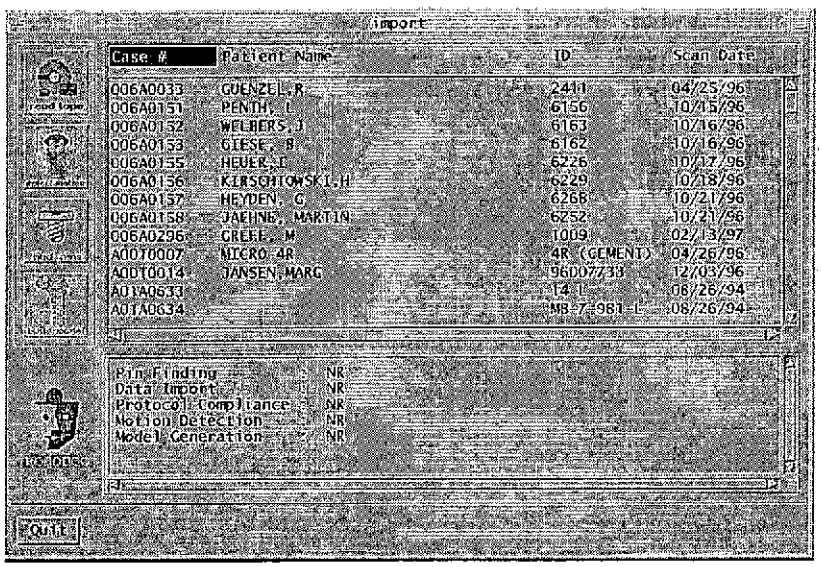

Figure 3-1. The Import Screen

2. Open the Import Sources menu by selecting the **Read Tape** button.

   The Read Tape menu displays all available sources of CT data. For example, if your site is equipped with a 9-track tape and GE HiLite cartridge, the menu lists these options.

3. Select the appropriate source. The tape will be read automatically once the source has been selected.

Selecting Patient Files

This section describes how to select a patient file for preprocessing.

After you import a file as described in the previous section, it will be listed in the read patient database. If you want to process a file that has not yet been imported, you must first perform the import procedure.

⇨ To select a patient file:

1. The screen displays a listing of patient files in the case database. The case database contains all patient files, including files that have not yet been preprocessed and files that have already been templated.

2. Select the desired file from the list of files, using the scroll bars to display entries if the listing is longer than the monitor can display.

3. The screen highlights the line containing the file description of the selected file.

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Processing Patient Files

This section describes the procedures for initiating the processes that validate the data and build a three-dimensional model for use during templating.

The following three processes may be performed in any order:

- Motion detection
- Building a 3D model

However, ISS recommends performing the motion detection processes before building a three-dimensional model because these processes validate the data in the patient file. If the file fails either of these processes, you will not waste time building a model with invalid data.

Detecting Motion

The CT Motion Detection procedure consists of three steps:

1. Selecting the Patient File (described in the previous section)
2. Starting the Pin Finding Program
3. Verifying the pins

Starting the Detection Program

1. Move the mouse pointer to the **Detect Motion** button.
2. Click once on the left mouse button.
3. The Motion Detection window appears.
4. Select the **Start** button.

   The system processes one CT slice at a time. Sections of the bone motion rod are visible in the slices. When all of the slices have been processed, the last slice stays on the screen and the **Done** button appears.

5. Verify that the Process Log displays a "PASS" for the Motion Detection process.

   - Do not proceed if the Process Log entry for Motion Detection is "FAIL" or "NR."

     FAIL. If the process log shows the message FAIL, the CT Scan must be repeated.

     NR. If the log show NR, restart the motion detection program.

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Building a 3D Model

Building a 3D model may take up to 15 minutes. This process enables ORTHODOC to display a three-dimensional model in the fourth quadrant and wire-frame models in all quadrants. A wire-frame model is necessary for determining implant version. When you select the **Build Model** button, the screen displays the Contour window, which contains tools for customizing the 3D model. These tools include a histogram, threshold scales, and a resolution (filter size) scale. Figure 3-5 shows the Contour window.

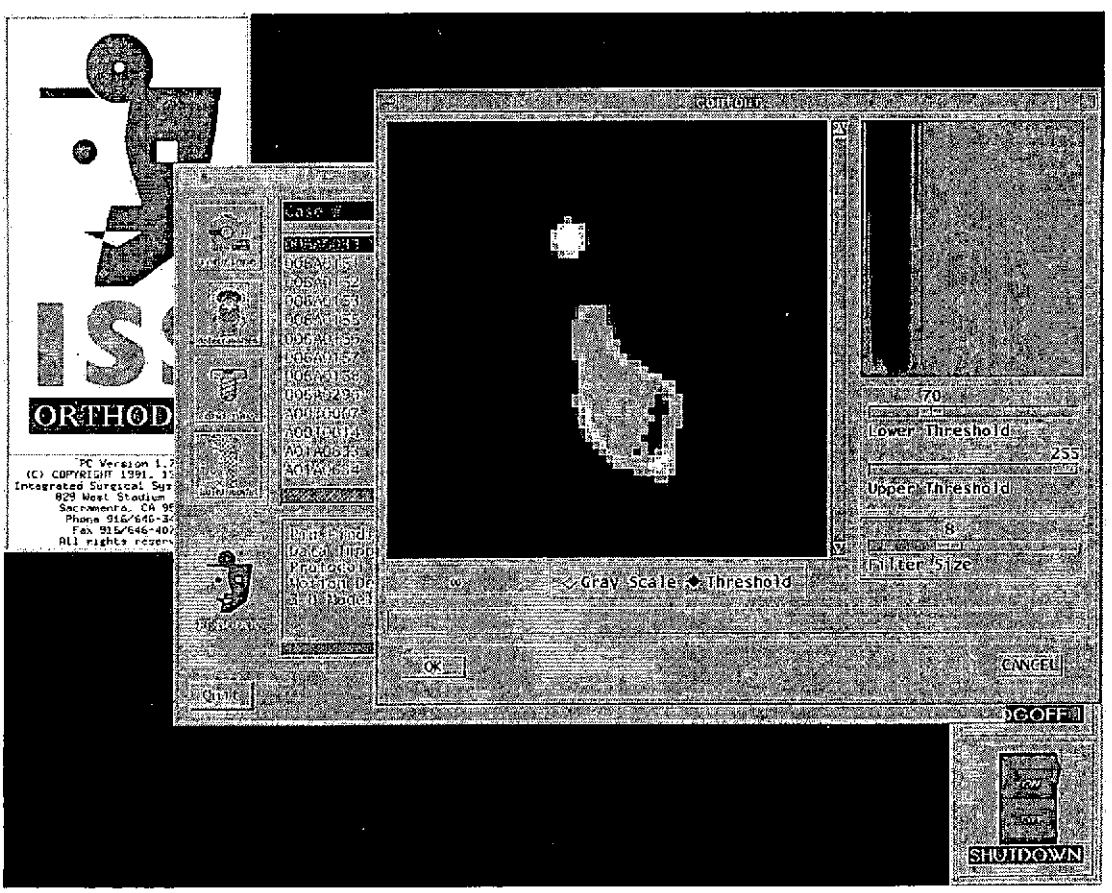

Figure 3-2. The Contour Window

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Histogram. The histogram is located to the right of the displayed CT image. It is a graph that indicates the distribution of intensity values in a file of CT images. The horizontal axis represents the range of intensity values and the vertical axis represents the number of pixels. A peak on the graph indicates a large number of pixels with similar intensities. A typical histogram has several peaks of varying sizes and shapes: the one on the left (with the lowest intensity value) corresponds to background areas on the CT data; tissue, bone motion rod, and locator pins are represented by peaks toward the higher end of the threshold.

Threshold scales. The threshold scale settings determine the range of intensities that will be displayed in the 3D model. For example, if you set the lower Threshold to 107 and the upper threshold to 179, only the pixels with intensities between 107 and 179 will comprise the 3D model. To create the sharpest image, the threshold scales should be set to include the histogram values that span the length of all peak areas (spikes), except the one on the leftmost side, which corresponds to background. If the background intensity values are included, there will be no contrast between bone and background. You can change threshold settings by dragging the sliders in each of the threshold scales to the desired value or zone in the histogram. The upper threshold must be set to 255 to activate the **Threshold** button.

Gray Scale radio button. Displays the 3D model in gray scale, rather than applying the threshold settings. This setting is useful for previewing the anatomical structures prior to selecting the threshold option.

Threshold radio button. Applies the threshold settings to the 3D model. This setting is useful for reducing the number of surfaces that will be generated in producing a 3D model. A 3D model with fewer surfaces will require less memory and increase system response time.

Filter Size scale. This scale screens out objects that are smaller than the specified number of pixels. Higher settings screen out a greater number of objects. Lower settings create more detailed 3D models, but degrade system response time for manipulating images during templating. The default setting of 8 is satisfactory for most users.

⇨ To build a 3D model:

1. Select the **Build Model** button.

   The Contour window appears and the system begins loading the CT data to build the model.

2. Move the threshold scales until they encompass the desired range of pixel intensities.

3. Align the vertical line on the lower threshold scale with the area on the histogram corresponding to the lowest intensity to be included and the vertical line on the upper threshold scale with the highest intensity. To preview the effect of the threshold settings, select the **Threshold** radio button located to the left of the Threshold scales.

4. To change the resolution of the 3D model, change the value on the **Filter Size** scale.

   Resolution values range from 1-20, with lower values corresponding to higher resolutions. Be aware that higher resolutions require more memory and longer processing times both for model building and for manipulation of the model during templating. The default setting of 8 produces an image that is adequate for measuring version on the 3D model.

5. Select **OK** to begin the processing for building a model.

   The status bar fills as the model is being built.

6. When processing is complete, the Contouring Results window appears. It displays the number of points and surfaces in the model.

7. Select **OK** to close the Contour window and return to the Import screen.

   The Process Log will indicate that the status of Model Generation is "PASS" if the procedure was successfully completed.

Closing the Import Program

This section explains how to exit from the import program and redisplay the main menu.

Close the Import screen and return to the main menu by selecting **Quit**.

You need not import and preprocess a file in a single session. After you import a file, it is saved in the case database. You may perform the Find Pins, Detect Motion, and Build Model processes in a subsequent session(s).

Conversely, you may import and process an unlimited number of files in a single session.

DJA x01302

Chapter 4

USING THE ORTHODOC PLANNING PROGRAM

DJA x01303

Introduction

Templating with ORTHODOC® is a very powerful means of quickly determining the fit and alignment of the femoral component for a THR procedure. The templating tools and procedures are demonstrated in this and subsequent chapters. A quick reference planning sequence is listed at the end of this chapter. Some implant lines (for example, S-ROM) require additional templating instructions. Additional information for those lines is contained in the appendix. This chapter provides general information useful in navigating through the ORTHODOC program.

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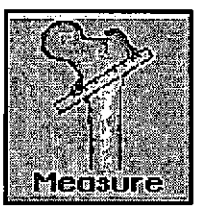
Using Screen Elements

The mouse-driven interface includes a combination of graphic elements that allow users to run the ORTHODOC program without much typing. This section describes these screen elements.

Buttons



Buttons can be pictorial representations of ORTHODOC functions, like the **Measure** button shown here. These buttons display tools and options to perform the functions. For example, the button shown here represents the function for taking measurements within the CT data. Selecting this button displays tools for taking measurements. When a button is "camouflaged" (the same color as the background), the function is temporarily unavailable.

Buttons can also be rectangles containing labels describing their functions (e.g., **Reset**, **Undo**, **Start**, and **Done**). These buttons implement functions that do not require tools. For example, selecting the **Undo** button reverses the most recent editing action.

Radio buttons are groups of diamond-shaped buttons, each of which has two states: on and off. Only one radio button in a group can be activated at any given time. A filled diamond indicates the on state; an empty diamond indicates the off state. **Change View Plane** and **Center Window** are examples of radio buttons.

Window Manager Buttons

There are three window manager buttons located on the line above the title bar (the top row on the screen). They perform the following functions:

Toaster button. This button located on the right side of the top line closes the ORTHODOC program and redisplays the main menu.

Minimize button. This button redisplays the main menu without closing the ORTHODOC program. The ORTHODOC program is represented by a rectangular icon located in the lower right corner of the main menu. To redisplay the ORTHODOC screen, you can move the pointer to the icon and double-click (click twice in rapid succession).

Maximize button. This button is not currently implemented.

Menus

A *menu* is a list of options that appears when you select the menu name on the title bar. You can open menus and select menu options in one of two ways:

- Move the pointer to the menu or option name and click; or
- Simultaneously press the ALT key and the underlined letter in the menu or option name.

You can close a menu by moving the pointer anywhere outside the menu and clicking the left mouse button.

Figure 4-1 shows an example of an ORTHODOC menu.

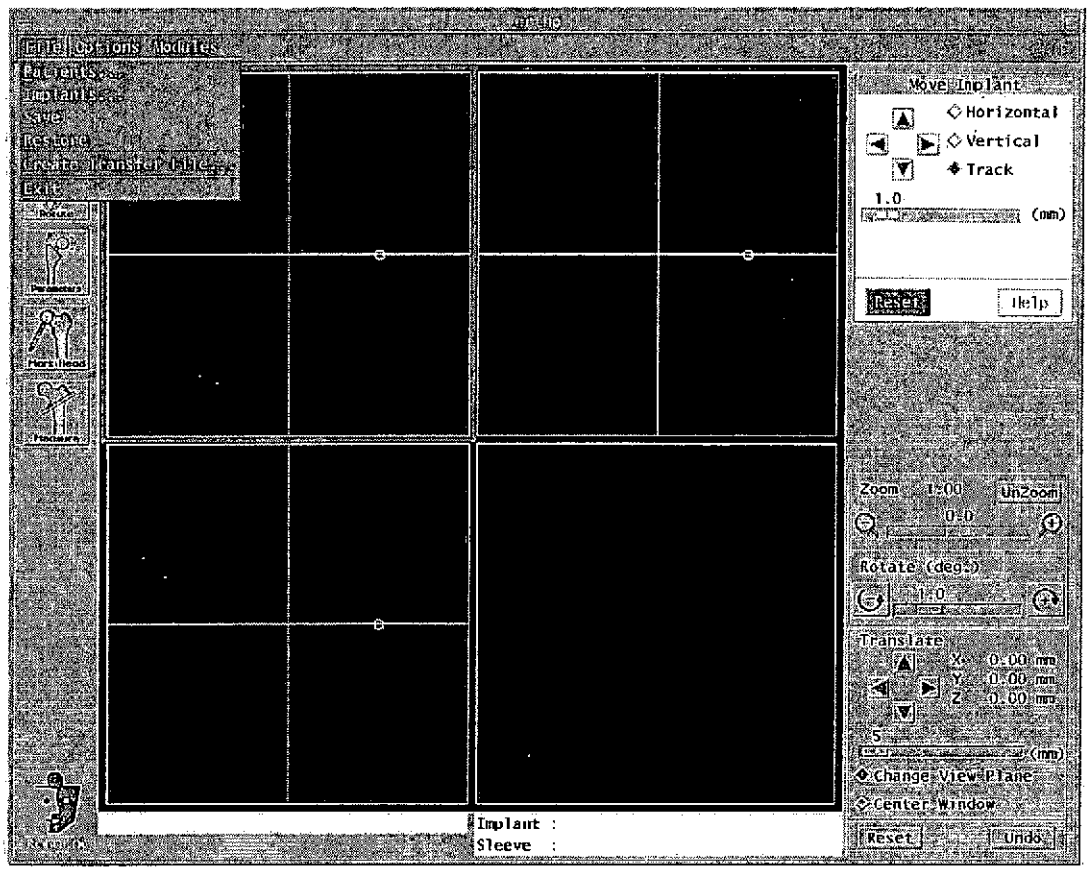


Figure 4-1. The File Menu

ORTHODOC has three menus, as indicated by the buttons on the title bar:

- File
- Options
- Modules

The options on these menus are listed on the pages that follow. More detail on these options is presented late in this manual.

DJA x01307

File Menu

Patients. Displays the Patient Directory window, which lists all of the patient files.

Implants. Displays the Implant Directory window, which lists all of the implant models and sizes that are available for use.

Save. Saves the preoperative plan in its current state.

Restore. Cancels any changes made to the preoperative plan since the last time it was saved.

Create Transfer File. Creates a file containing the preoperative plan, which will serve as input for the robot.

Exit. Closes the ORTHODOC application and redisplays the main menu.

Options Menu

Tissue Color. Determines whether the bone image is displayed in color or gray scale.

Bone Image. Determines whether the bone is displayed as a CT-slice or wire-frame model.

CT Reconstruction. Determines whether the bone models will be built by interpolation or replication of the individual CT slices.

Implant Image. Determines the display characteristics of the implant.

3D Model. Determines whether the fourth quadrant will display three-dimensional images.

Modules Menu

This menu is reserved for future use.

DJA x01308

Windows

A *window* is a rectangular area that appears on the screen to present information, buttons, or lists of items pertaining to the function being performed.

Figure 4-2 shows an example of an ORTHODOC window.

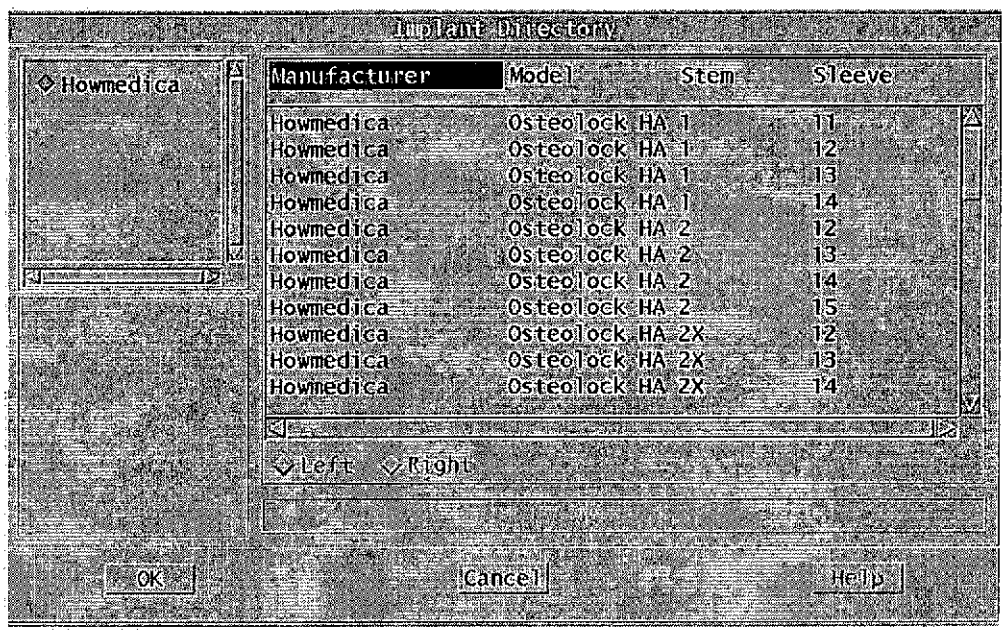


Figure 4-2. The Implant Window

You can reposition a window by moving the pointer to the title bar and dragging it to a new location on the screen.

Scroll Bars

Scroll bars are located next to lists. They provide the means to move up or down through lists that are too long to fit on a single screen. Scroll bars consist of a slider, scroll area, and scroll arrows. Dragging the slider, clicking a scroll area, or clicking a scroll arrow will move the display to parts of a list that are not currently on the screen.

In a long list of patient files, for example, clicking the down scroll arrow will advance the screen forward through the file, past the last line that is currently displayed.

DJA x01309

Clicking the up arrow will move backward toward the top of the list.

Left and right arrows allow you to scroll beyond the margins at the side of the screen. When scrolling, the bar between the arrows indicates your relative position in the list or display.

Crosshairs

Intersecting lines or *crosshairs* divide each of the templating quadrants. You can move and rotate bone and implant images, and change the viewing plane, by dragging the crosshairs.

The crosshairs are color coded to indicate which view will be affected by changing its position. The green crosshair located in quadrants 2 and 3 changes the view in quadrant 1. The red crosshair located in quadrants 1 and 3 changes the view in quadrant 2. The yellow crosshair located in quadrants 1 and 2 changes the view in quadrant 3.

Scales

A *scale* is a slider that sets or displays a value in a range. The position of the slider indicates the value of the current setting relative to the range. Dragging the slider changes the value.

To move a slider exactly one position at a time, press either the right or the left directional arrow on the keyboard. The right arrow increases the value and left arrow decreases the value.

DJA x01310

Suggested Steps for Templating

During a typical templating session, you will use some of the functions more than once, returning to fine tune a setting, slightly reposition an image, or check the effect of a templating action on a previous action. For example, after selecting an implant head and neck offset, you will probably want to move or rotate the implant again to achieve an optimal position. Throughout a templating session it will be necessary to change the view and display a new plane.

ISS recommends performing the basic templating functions in the following order:

1. Align the femur images.
2. Mark the femoral head.
3. Select and load an implant (see Chapter 6).
4. Tentatively position the implant in relation to the femur to verify implant selection (repeat step #3, if necessary).
5. Select the implant head size and neck offset.
6. Adjust implant position to accommodate the head size and neck offset.
7. Measure for osteotomy level.
8. Measure osteotomy angle.
9. Measure version angle.
10. Check proximal pin clearance.

When these functions are complete, the femur and implant images should appear in the relative positions illustrated in Figure 4-3.

DJA x01311

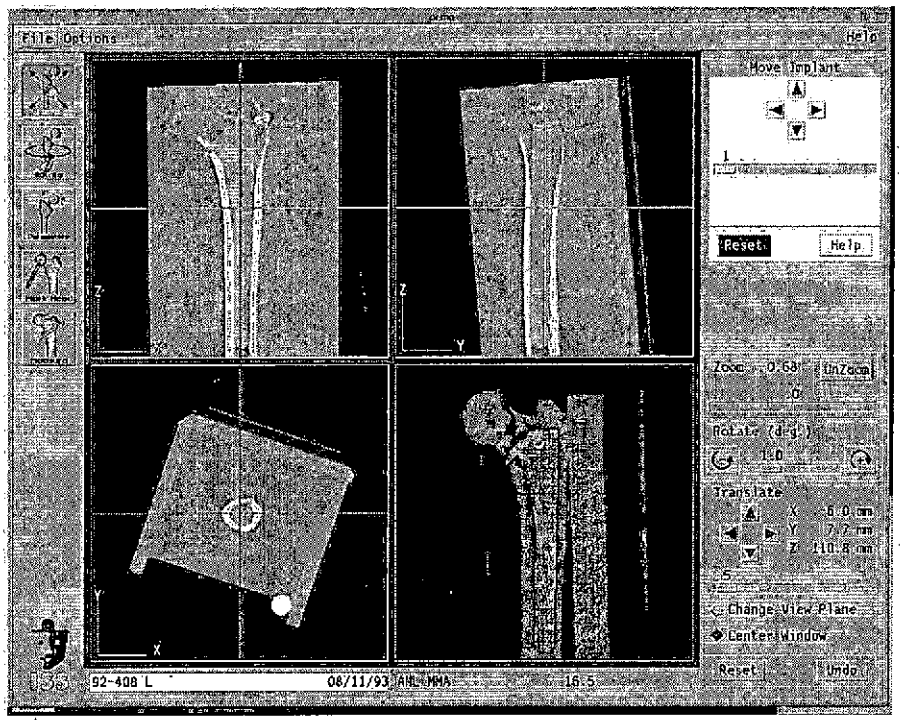


Figure 4-3. Femur and Implant Images After Templating

DJA x01312

Chapter 5

CUSTOMIZING IMAGE OPTIONS

DJA x01313

Using the Options Menu

You can customize the way ORTHODOC® displays femur and implant images by changing the settings in the Options menu.

The display options affect the way the images are displayed for templating. They are available on a cascading menu, which first lists the option names and then lists specific settings for a selected option in a secondary menu. The options include:

- Tissue Color (gray or color)
- Bone Image (CT slice or wire-frame)
- CT Reconstruction (interpolate or replicate)
- Implant Image (opaque, transparent, outline, or off)
- 3D View (wire-frame, transparent, shaded, or off)

⇨ **To change a display option:**

1. Select the Options menu from the title bar.

   The screen displays the first level of the cascading Options menu, which is shown in Figure 5-1.

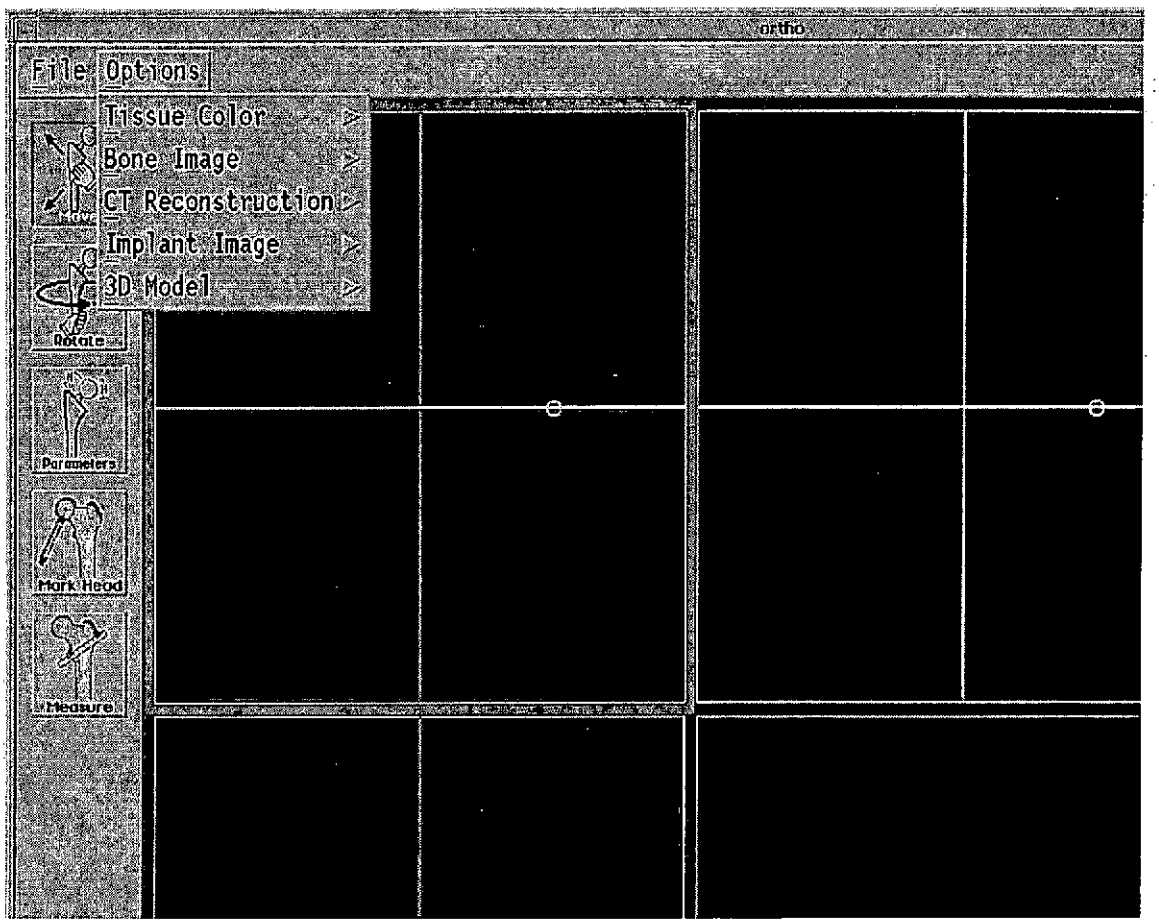


Figure 5-1. The Options Menu

2. Select the option that you wish to change.

   The menu cascades to reveal a secondary menu, which contains settings for the selected option.

3. Select the desired setting.

4. Close the Options menu by moving the pointer away from the menu and clicking the left mouse button.

   The image option settings will remain in effect until you change them again.

The rest of this chapter describes the individual display options.

DJA x01315

Setting the Tissue Color Option

This setting determines whether the femur image will be displayed in shades of gray or in color.

Default = Gray

When the Tissue Color option is selected, the cascading menu displays two options: Gray and Color.

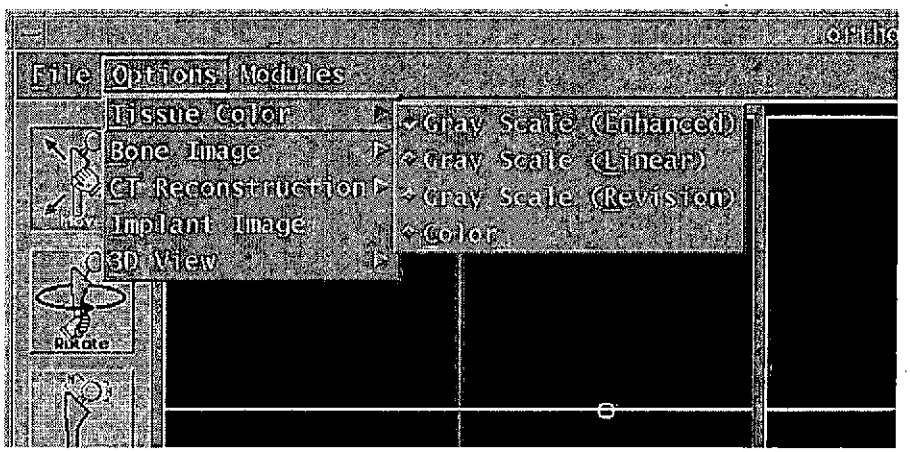


Figure 5-2. The Tissue Color Options

Gray. Displays the image in shades of gray, with the brightest (highest intensity) shades corresponding to the highest density bone.

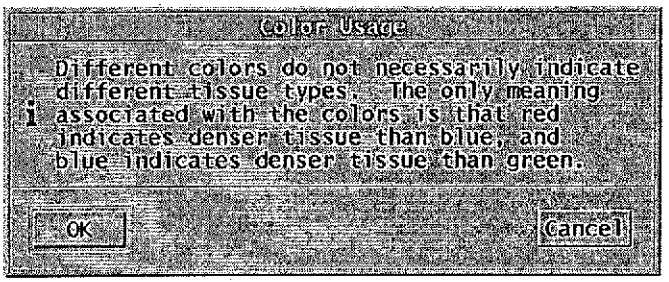
Color. Displays the image in the following colors:

Red. Highest density

Green. Medium density

Blue. Lowest density

If you select the Color option, the following warning appears:



The purpose of this warning is to advise the surgeon not to rely on colors to identify different tissue types. It appears only the first time that this option is selected during an ORTHODOC session.

Note: Color has no effect with wire-frame models.

DJA x01317

Setting the Bone Image Option

This setting determines whether the femur will be displayed as a solid or wire-frame image.

Default = CT Slice

When the Bone Image option is selected, the cascading menu displays two options: CT Slice and Wire-frame.

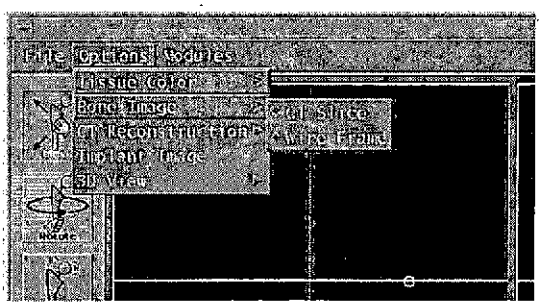


Figure 5-3. The Bone Image Options

CT Slice. Displays a complete image of the femur, which the system has created by stacking and interpolating between CT slices.

Wire-frame. Displays a monochrome wire-frame outline of the femur. The wire-frame option can simultaneously display the distal femoral condyles and the proximal femoral head, which is useful for measuring version angle. This procedure is described in Chapter 7.

Note: Color has no effect with wire-frame models.

DJA x01318

Setting the CT Reconstruction Option

This setting tells the system how to construct the image of the femur from individual CT images.

Default = Interpolate

When the CT Reconstruction option is selected, the cascading menu displays two options: Interpolate and Replicate.

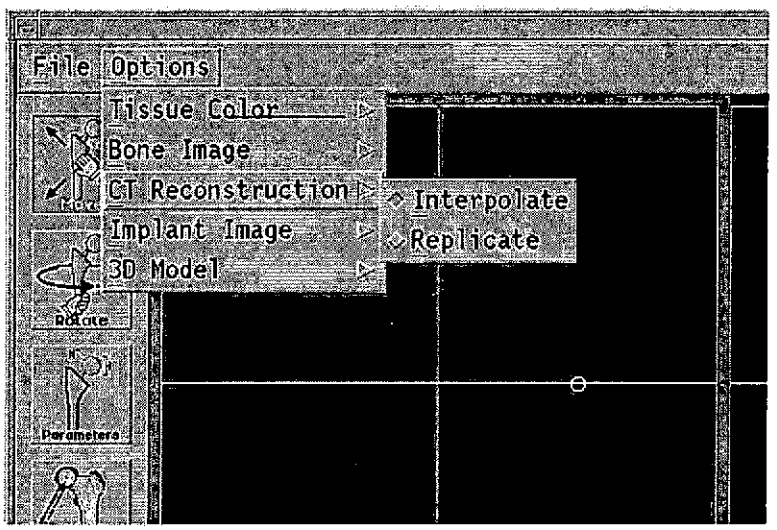


Figure 5-4. The CT Reconstruction Options

Interpolate. Constructs the image by interpolating between the individual CT images to create a smooth, x-ray-like image. This method of image reconstruction is sometimes referred to as "tri-linear interpolation."

Replicate. Constructs the image by stacking individual CT images, without interpolation. This method of image reconstruction is sometimes referred to as "nearest neighbor interpolation."

DJA x01319

Setting the Implant Image Option

This setting determines the characteristics of the implant image.

Default = Solid

When the Implant Image option is selected, the cascading menu displays four options: Opaque, Transparent, Outline and Off.

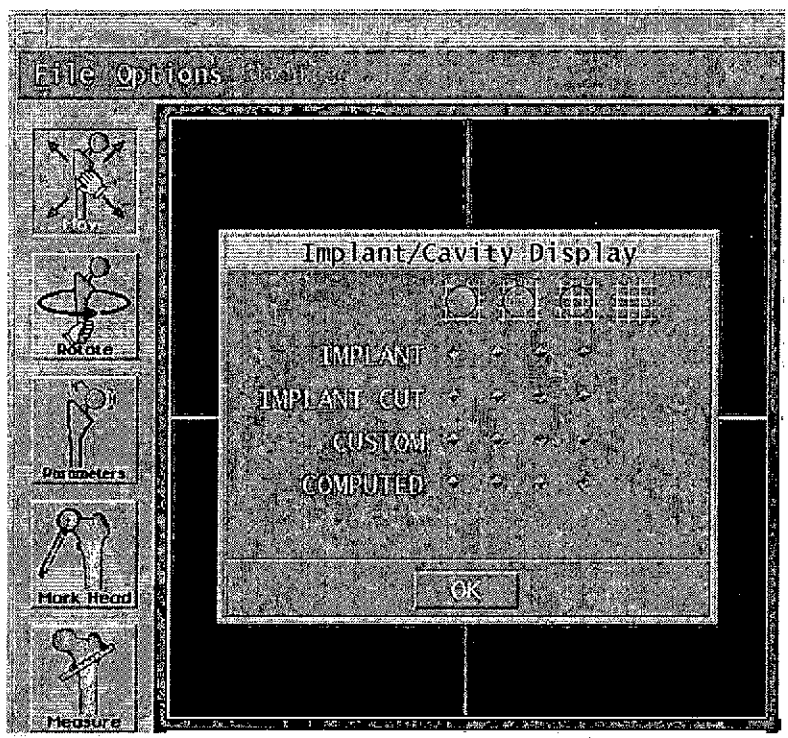


Figure 5-5. The Implant Image Options

Opaque. Displays the implant as a solid image. In areas where the implant overlaps the bone, the bone will not be visible.

Transparent. Superimposes the implant image on the image of the femur. In areas where the implant overlaps the bone, The bone will still be visible.

Outline. Displays only the outline of the implant.

Off. Removes the implant image from the templating quadrants.

DJA x01320

Setting the 3D View Option

This setting determines whether the three-dimensional images in the fourth quadrant will be wire-frame, transparent, shaded, or off (not displayed).

Default = Off

When the 3D View option is selected, the cascading menu displays four options: Wire-frame, Transparent, Shaded, and Off. The default for this option is Off.

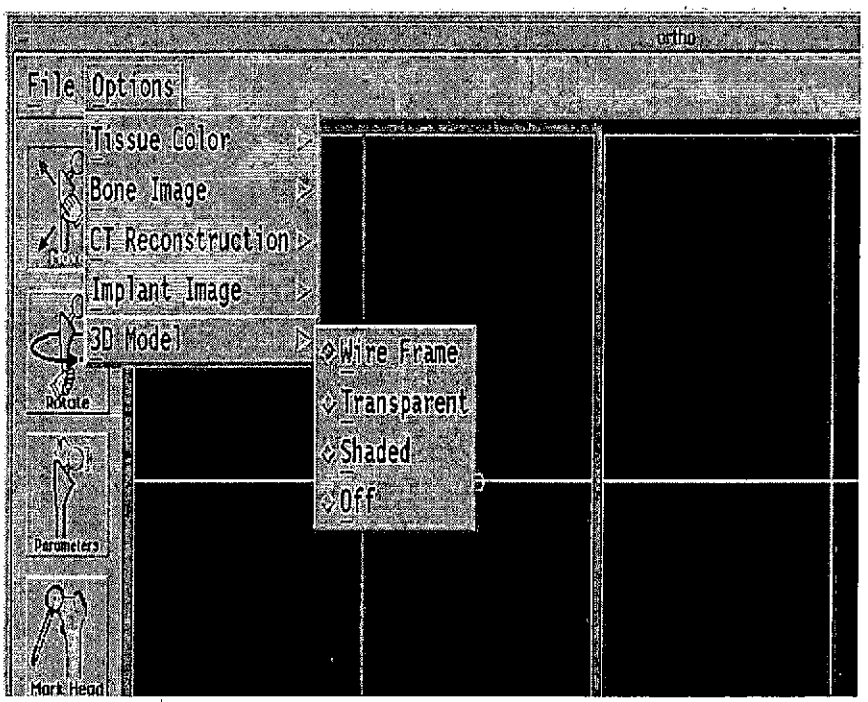


Figure 5-6. The 3D Model Options

Wire-frame. Displays the bone as a wire-like frame.

Transparent. Displays the implant in a transparent bone.

Shaded. Displays the implant in a shaded bone.

Off. Clears the fourth quadrant of images.

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Chapter 6

SELECTING A PATIENT FILE

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Introduction

This chapter describes how to select, preview, validate, and load a file containing patient CT data.

After setting the display options, the next step in a preoperative planning session is to select a patient file from the Patient Directory. The Patient Directory lists all the patient files that have been imported.

Prior to loading a file, it is advisable to check for potential problems with pin data and bone motion. Although these items must always be verified just prior to creating a transfer file, checking them before templating will immediately identify any problems and prevent you from wasting time working with invalid CT data.

Previewing CT images and scan data are also optional procedures, which may be performed at the surgeon's discretion.

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Displaying the Patient Directory Window

Begin this procedure when the ORTHODOC templating screen is displayed.

⇨ To display the Patient Directory window:

1. Select the File command on left side of the title bar or simultaneously press ALT-F.

   The pull-down menu, shown in Figure 6-1, appears.

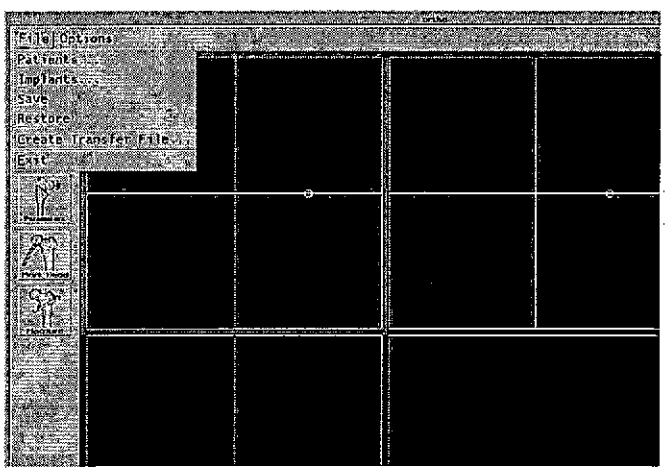

Figure 6-1. The File Menu

2. Select the **Patients** option.

   A Patient Directory window, similar to the one shown in Figure 6-2, appears.

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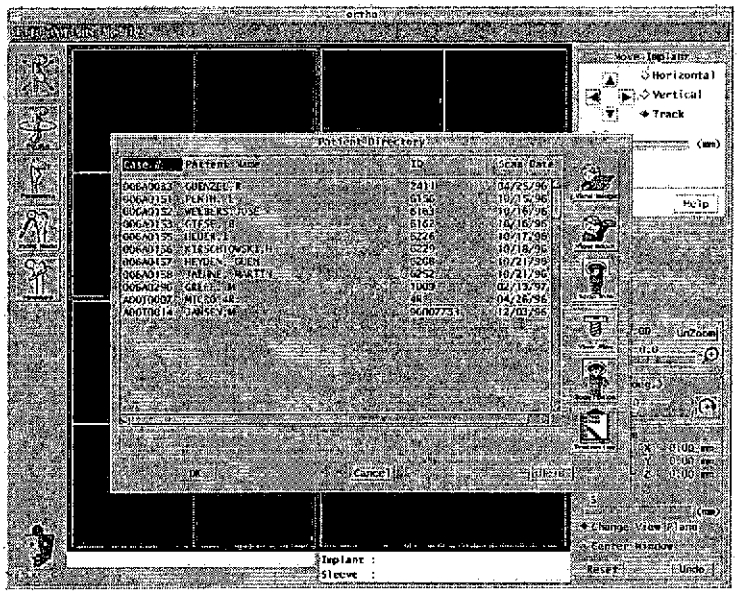

Figure 6-2. A Patient Directory Window

The Patient Directory window lists all of the patient files that have been imported. The window also contains buttons for previewing images and for detecting problems with bone motion and pin data.

Sorting the Files

Case number sort. By default, the directory sorts the files in increasing order by case number.

Patient Name, ID, or Scan Date sort. You can sort the patient files in the directory by any of the other items, including Patient Name, ID, or Scan Date. To do so, click on the title of the column.

For example, to list the files in the order of scan date, move the pointer to the words "Scan Date" and click the left mouse button. The Patient Directory will then list patient files by date, with the file containing the most recent scan at the top of the list.

It is important to select the most recent scan if the patient has been scanned more than once. To do so, you can check the scan date against the date on the patient's file or you can sort the directory by patient name to see if multiple scans exist.

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Previewing Scan Images and Data

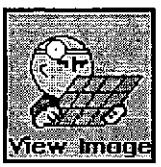
*The Patient Directory window has two buttons, **View Image** and **View Scout**, which display images from the CT data for a selected patient. **View Image** displays individual CT slices and **View Scout** displays a scout image of the entire femur. It also has a button, **Scan Info**, which displays data that was entered into the scan header by the CT technician.*

You can use the **View Image** and **View Scout** buttons to preview images before loading a patient file for templating, but you cannot move, measure, template, or manipulate these images in any way.

The **Scan Info** button displays data about the patient, doctor, and scan protocol.

These buttons are camouflaged (unavailable) until a patient file has been selected.

Viewing CT Slices



The **View Image** button displays a panel of CT slices similar to the one shown in Figure 6-3.

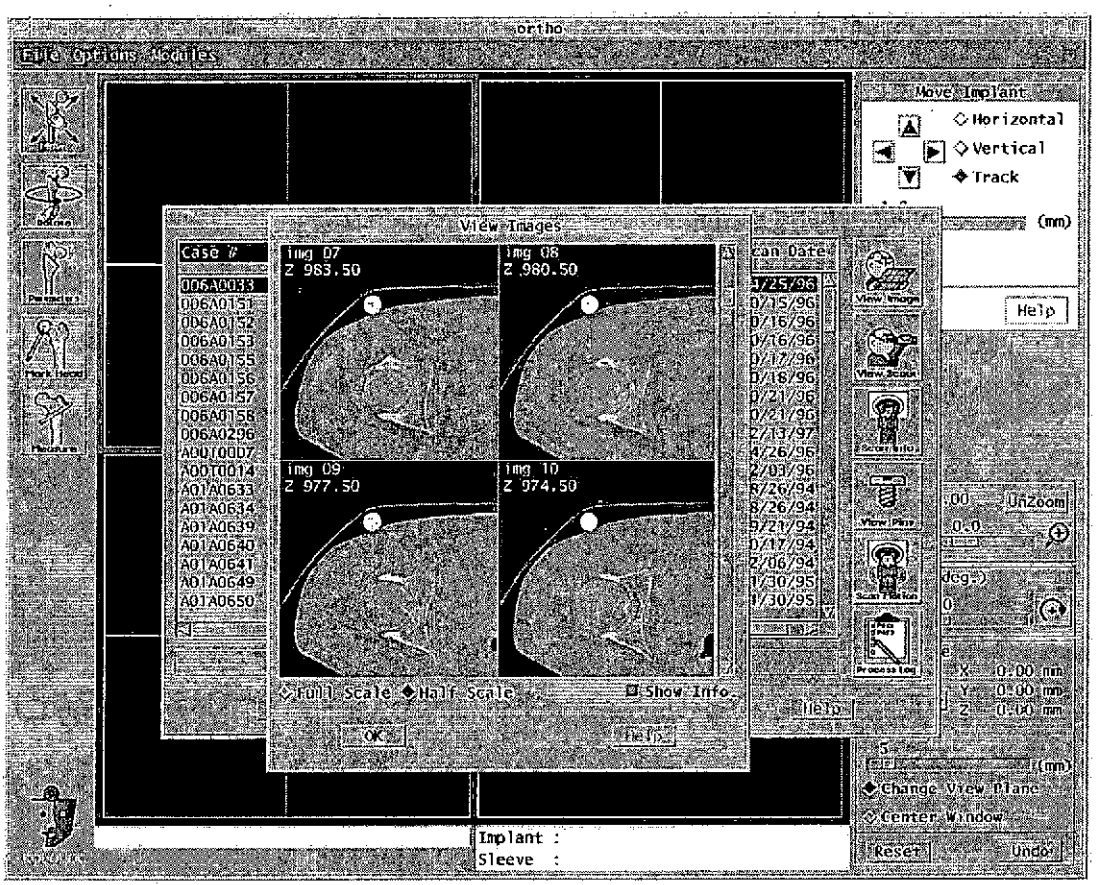


Figure 6-3. CT Slices in the Patient Directory Window

The View Images function is an easy way to preview individual CT images, before loading the file for templating. Use the scroll bar to display additional panels.

⊙ ***Full Scale*** The **Full Scale** radio button displays one CT slice at a time.

⊙ ***Half Scale*** The **Half Scale** radio button displays four slices at a time (as shown in Figure 6-3).

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Viewing a Scout Image

The **View Scout** button displays an x-ray-like image of the entire bone similar to the one shown in Figure 6-4.

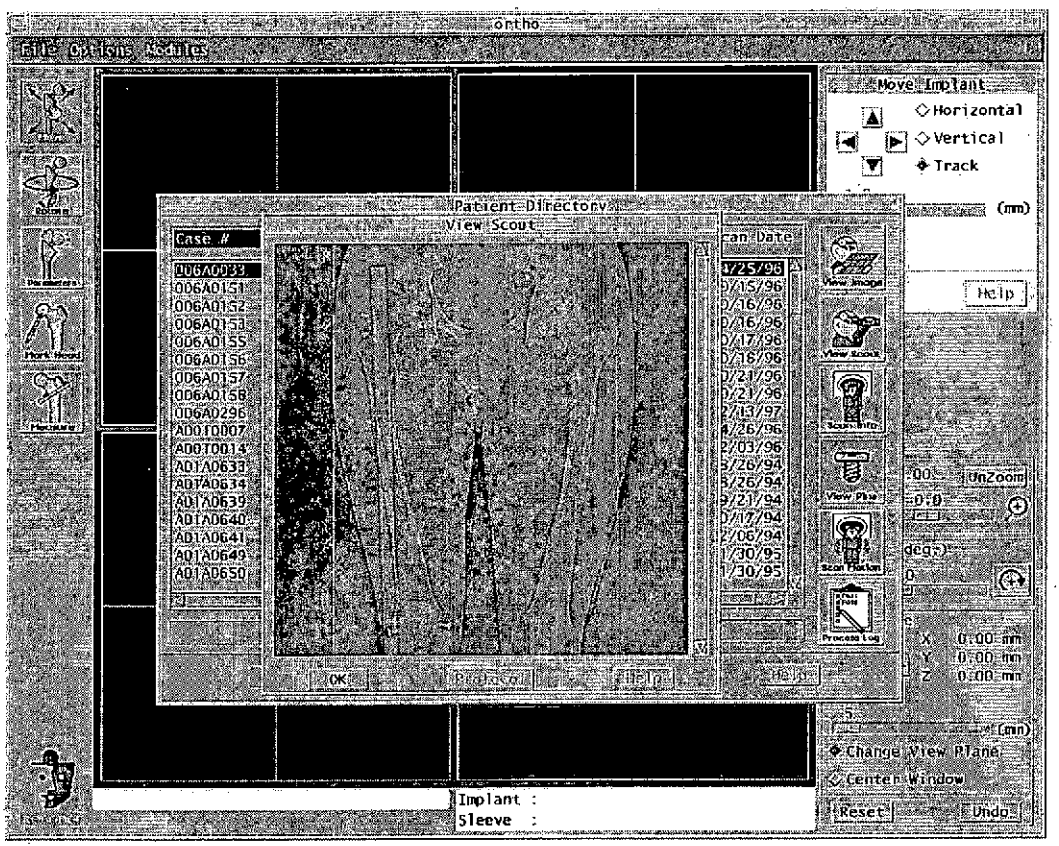

Figure 6-4. A Scout Image in the Patient Directory Window

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The **Protocol** button displays a series of horizontal lines on the scout image indicating where each CT scan was taken.

Viewing Scan Information

The **Scan Info** button displays information about the scan including the patient's name, radiologist, exam type, exam date and time, image modality, number of slices, etc. This information comes from the scan header, which was entered by the radiologist. It is displayed in the format shown in Figure 6-5.

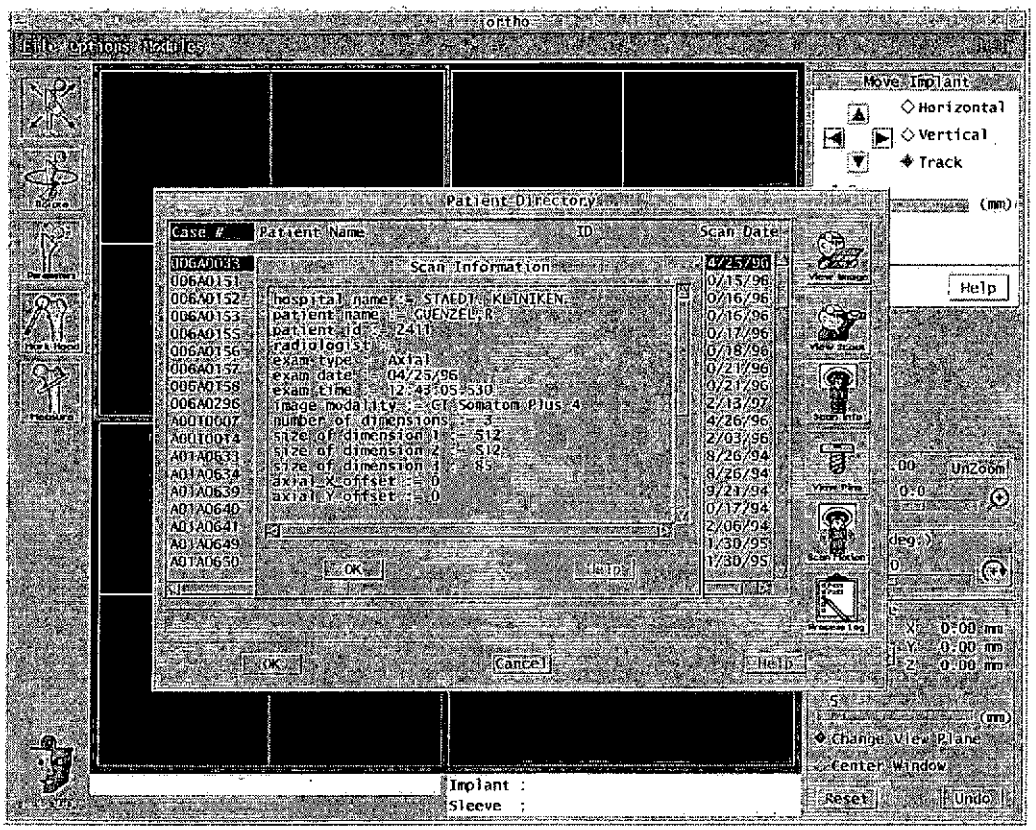

Figure 6-5. Scan Information in the Patient Directory Window

The scan information will not fit in a single panel. Use the scroll bars to view parts of the file that are not currently displayed.

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Validating CT Data

Although the system requires the surgeon to view and confirm locator pin and bone motion data just prior to creating a transfer file, we recommend that you perform the following procedure before selecting a file for templating. If problems are detected at this point, no time will be wasted developing a preoperative plan with invalid CT data.

The Process Log indicates the status of the preprocessing and data validation checks for a selected patient file. You should not proceed with templating until you have verified that the file has passed all of these checks. Then, you should use the View Pins and Scan Motion functions to visually confirm that the data is valid.

The **Process Log**, **View Pins**, and **Scan Motion** buttons are camouflaged (unavailable) until a patient file has been selected.

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Checking the Process Log

The **Process Log** button displays the status of various processes that are performed during preprocessing. These processes include importing the CT data, finding pins, detecting motion, and building a 3D model. PASS indicates that the process was successfully completed; FAIL indicates that errors were detected; and NR indicates that the process was not run. Before loading a file for templating, you should verify that all of the processes have a PASS status.

Figure 6-6 shows a Process Log that indicates successful completion of preprocessing.

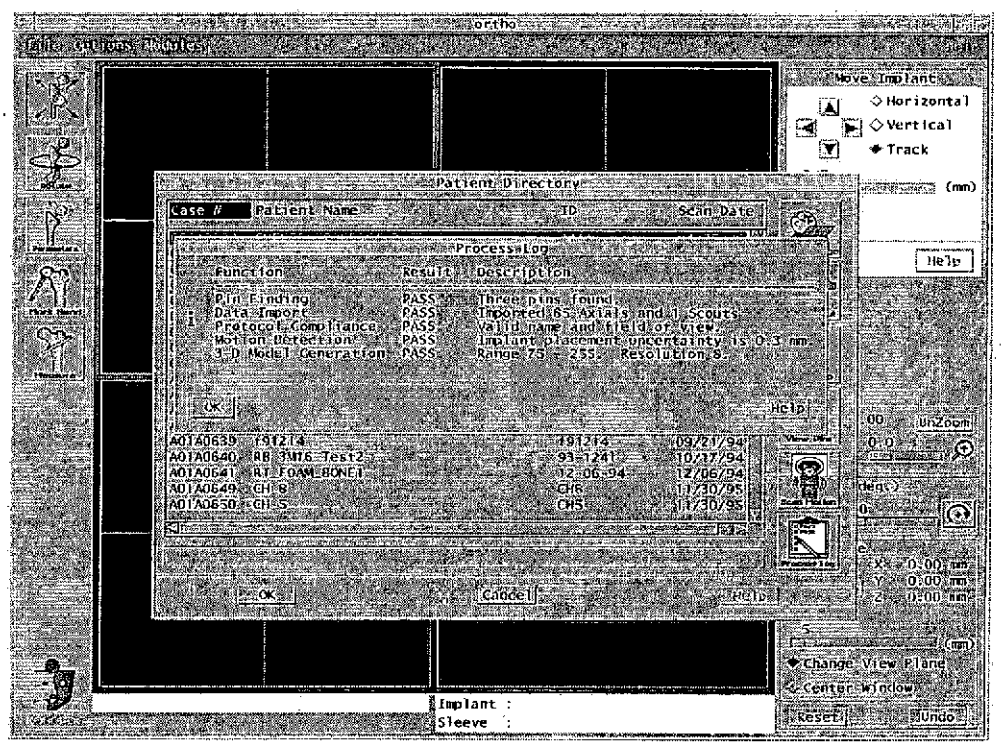

Figure 6-6. A Process Log

Checking for Motion During the Scan

During the CT scan, the patient has a straight metal rod strapped around the thigh. When the ORTHODOC file is generated, the system reconstructs the rod from individual CT slices. If no motion occurred during the scan, the reconstructed rod will be straight, without any bends or discontinuities in it. A crooked rod or a rod with a discontinuity is an indicator that the bone moved and the CT data is invalid.

The **Scan Motion** button displays data indicating how far the bone moved during the CT scan. The top line in the Scan Motion window indicates whether motion occurred during the scan. After this line and patient identification information, the data from the reconstructed rod is presented in a numeric table. This table is intended for use by ISS technical support in the event that a problem occurs.

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⇨ To confirm the lack of bone motion:

1. Select the **Scan Motion** button.

   The Patient Directory window displays a window similar to the one shown in Figure 6-7.

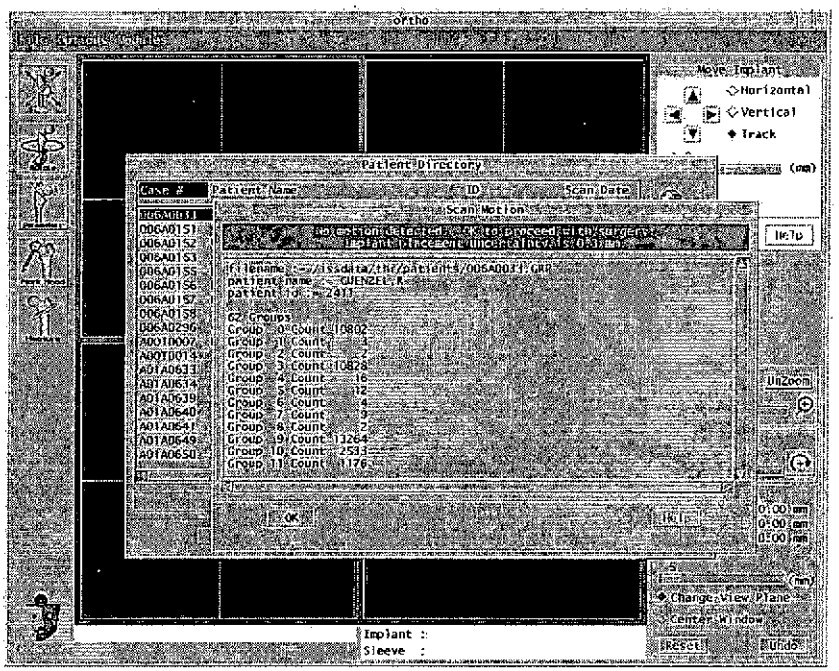

Figure 6-7. A Scan Motion Window

   The highlighted area at the top of the Scan Motion window indicates whether the data passed or failed the motion detection test.

3. Check the message on the top line to determine whether motion was detected.

   If motion was detected, do not continue. The patient needs to be re-scanned.

4. Select **OK** to close the window.

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Loading a File

This procedure loads a file for templating. When the file has been loaded, three views of the femur appear in the templating quadrants.

⇨ To load a patient file for templating:

1. If you have not already done so, select the desired file by placing the mouse pointer on the desired patient name and pressing the left mouse button.

2. Select **OK**.

   The patient file takes a few minutes to load. After loading the Patient Directory window closes and femur images appear in the templating quadrants.

   Note: When you first load a patient file, you cannot tell if the femoral image is from the left or right side of the patient.

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Chapter 7

SELECTING AN IMPLANT

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Introduction

This chapter describes how to select, preview, and load an implant in preparation for templating.

After loading a patient file, you need to select and load an appropriate implant. Implant selection should be guided by the manufacturer's recommendations regarding fit.

The Implant Directory window lists all of the available implant models and sizes. If you are not satisfied with your initial choice, you may return to the Implant Directory as many times as you wish to select other models and sizes.

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Displaying the Implant Directory Window

⇨ **To display the Implant Directory window:**

1. Select the File command on left side of the title bar or simultaneously press ALT-F.

   The pull-down menu, shown in Figure 7-1, appears.

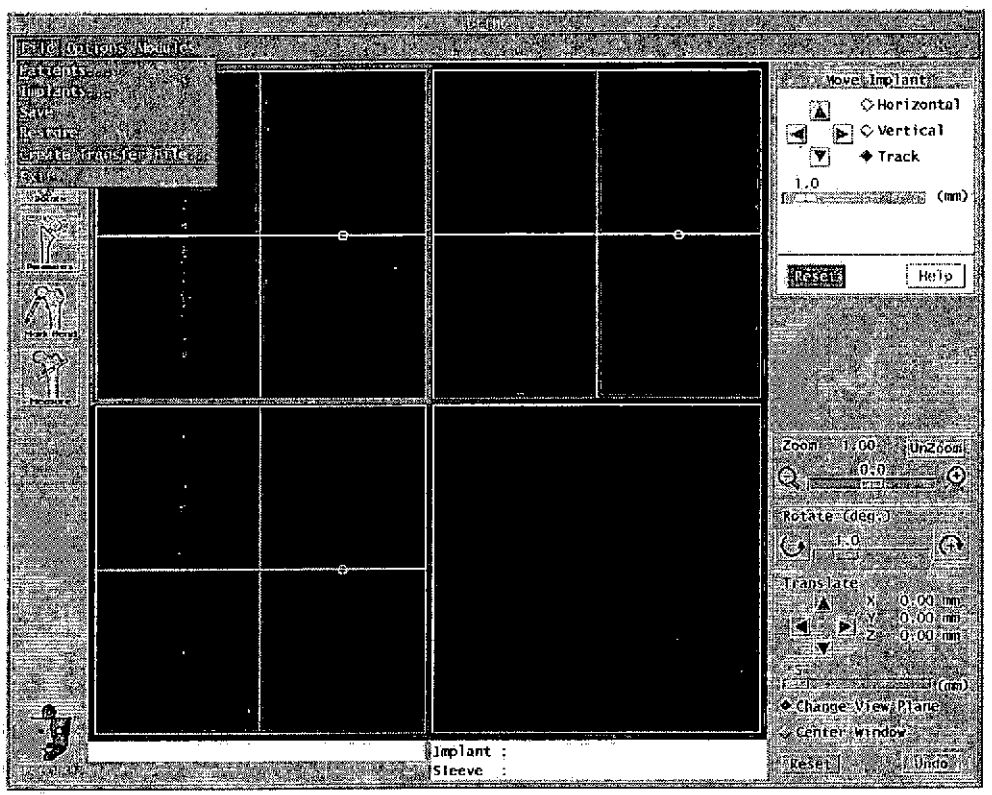

Figure 7-1. The File Menu

2. Select the **Implants** option.

   An Implant Directory window, similar to the one shown in Figure 7-2, appears.

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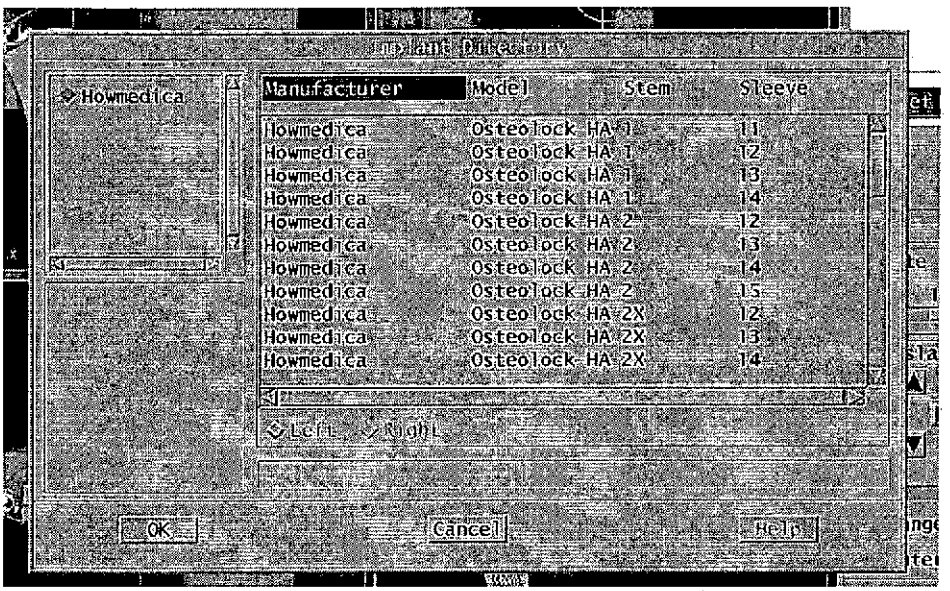

Figure 7-2. An Implant Directory Window

Selecting a Manufacturer

The Implant Directory window has one or more manufacturer radio buttons in the upper right corner, depending upon the number of implant lines used at your site. When you change the setting of these radio buttons, the window will list implants for the selected manufacturer.

Sorting the Implant List

By default, the directory sorts the implants in alphabetical order by model if the manufacturer has more than one model. You can also sort the implants by size. To do so, simply click the word "Size" where it appears as title of the column. The Implant Directory will then list the implants in ascending order by size.

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Loading an Implant

This procedure loads an implant for templating. When the file has been loaded, three views of the implant appear in the templating quadrants along with the femur image.

⇨ To load an implant for templating:

1. If you have not yet selected an implant, locate and select one now.
2. Select **OK**.

   The Implant Directory window closes and implant images appear in the templating quadrants.
3. If the implant image does not appear on the screen, select either the **Move Implant** or **Rotate Implant** button and then select the **Reset** button in the active toolbox that appears (upper right corner of the screen).

   This procedure will display the implant in "home" position.

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Chapter 8

TEMPLATING

Introduction

ORTHODOC displays three different cross sections of the femur and implant for use in templating. The tools for manipulating these images include buttons, crosshairs, and sliding scales. This chapter describes how to use these tools to position the femur and the implant stem, determine the appropriate head size and position, select the neck offset, take measurements, and check the position of the proximal pin to ensure adequate clearance for the cutter.

ORTHODOC creates the femur images that appear in the templating quadrants by stacking and interpolating between CT slices to create a complete view of the bone. Each quadrant shows a different cross-section of the femur. When planning begins the views must be arranged such that the first quadrant (X,Z) initially displays the A/P x-ray view; the second quadrant (Y,Z) initially displays the lateral x-ray view; and the third quadrant (X,Y) initially displays a view that corresponds to a plane through the AP and lateral views.

The system provides functions for orienting and reorienting the images and changing the views in an unlimited number of ways. When using a templating function, as you perform the procedure in one of the templating quadrants, the other quadrants will reflect the changes. A red border surrounds the active quadrant where the procedure is being performed.

To plan implant placement, the surgeon superimposes the implant on the femur, using the mouse to drag and rotate the implant image. The end result of a templating session is data that will guide the robot to mill a cavity in the shape of the selected implant, and position it as indicated by the respective locations of the femur and implant images.

The templating process also involves evaluating and determining other factors including:

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- Implant head size;
- Center of rotation;
- Neck offset;
- Osteotomy level and angle of cut;
- Version angle; and
- Proximal pin location in relation to the path of the cutter.

Proper positioning of the implant is dependent upon selecting an appropriate head size and neck offset, performing the osteotomy at the appropriate level and angle, and achieving the correct version angle.

The procedures described in this chapter may be performed in any order, however, ISS recommends using the Mark Head function to determine the patient's natural center of rotation before attempting to center the implant in the canal.

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Using the Templating Functions

This section describes the templating functions and tools.

Before you can perform the procedures described in this section, you must select and load a patient file. To use the functions that manipulate implant images, an implant file must also be loaded. Refer to Chapter 6 of this manual for instructions on Selecting An Implant.

Changing the View

Each templating quadrant displays a view of the femur and implant along a different plane. When you change the viewing plane, the modified image retains its orientation within the coordinate system while revealing a different plane. In other words, if you make changes on an AP view, the screen will display another AP view. Likewise, you can modify the lateral or transverse views to reveal different planes.

The crosshairs in the middle of the templating quadrants determine where the planes will intersect the image. Each crosshair is color-coded to indicate which view will be affected by changing its position. The green crosshair in the second and third quadrants changes the view in the first quadrant; the red crosshair in the first and third quadrants changes the view in the second quadrant; and the yellow crosshair in the first and second quadrants changes the view in the third quadrant.

As you drag the crosshairs across the image, the Translate box displays the changing X, Y, and Z coordinates. The coordinates are expressed in millimeters. When you change a view in one quadrant, the images in the other quadrants will be updated accordingly.

Change View Plane and Center Window are radio buttons that determine how the images will be affected when the viewing plane changes. When Change View Plane is selected, you move the crosshairs to designate a new viewing plane. When Center Window is selected, you move the crosshairs to recenter the image on the display, thus revealing a new plane. Figure 8-1 shows the tools for changing the view:

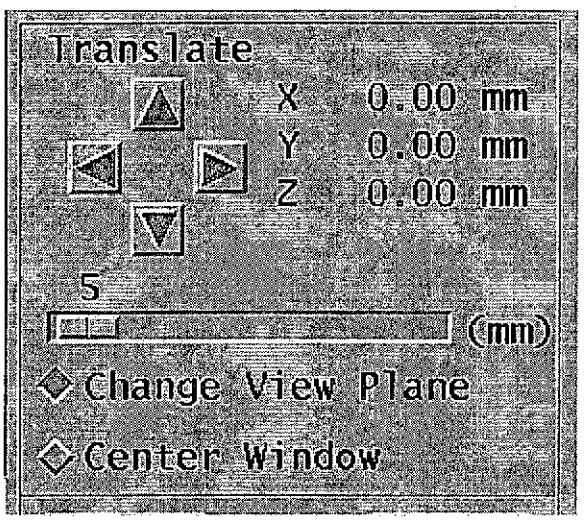

Figure 8-1. Translate Arrows, Slider, and Radio Buttons

⇨ To change the view in Change View Plane mode:

1. Select the **Change View Plane** radio button, if necessary.
2. The radio button will be filled if Change View Plane mode is already active.
3. Click in the templating quadrant where you want to work to activate the quadrant.
4. Change the viewing plane in one of the following ways:
   - Set the translate slider to the number of columns or rows from the current viewing plane to the new one; then click the appropriate Translate arrow to define the direction; or

- Click and drag the crosshairs to the desired viewing plane (you may drag the horizontal crosshair, the vertical crosshair, or both at once by dragging their intersection).

⇨ To change the view in Center Window mode:

1. Select the **Center Window** radio button, if necessary.

   The radio button will be filled if Center Window mode is already active.

2. Click in the templating quadrant where you want to work to activate the quadrant.

3. Change the viewing plane in one of the following ways:

   - Set the translate slider to the number of columns or rows from the current viewing plane to the new one; then click the appropriate Translate arrow to define the direction; or

   - Click and drag the intersection of the crosshairs to the position on the images where you want the center of the display to be.

⇨ To change the view by crosshair rotation:

1. Move the cursor into the quadrant where you want to work.

   Be aware that the image in the active quadrant will rotate, but the viewing plane will not change. The other two quadrants will display different viewing planes as the images rotate.

2. Click and drag the circle on the right side of the horizontal crosshair.

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Moving the Implant

There are two ways to move an implant: by dragging the image across one of the templating quadrants or by using the Move Implant tools. Dragging is the faster method, but the Move Implant tools are useful for small movements and precise placement.

When you select the **Move** button, the toolbox shown in Figure 8-2 appears in the upper right corner of the screen.

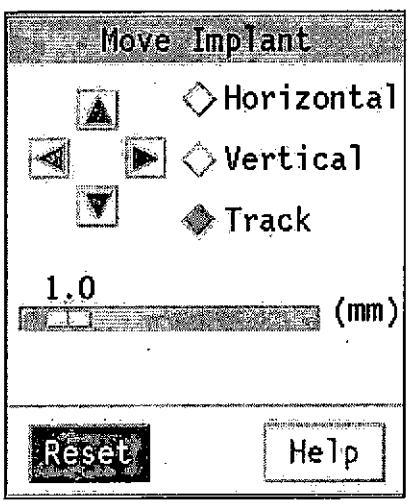

Figure 8-2. The Move Implant Toolbox

These tools will move the implant an exact number of millimeters along either axis. The slider sets the distance that each click of a directional arrow will move the implant. The distances on the slider range from 1 to 192 millimeters. To move the implant more than 192 millimeters, you can set the slider to a factor of the desired distance and click the directional arrow more than once.

The **Move** button also activates a mode where the cursor can drag the implant. The shape of the pointer changes from an arrow to a hand as you drag the implant across one of the templating quadrants. The radio buttons in the toolbox enable you to restrict the implant's movement to the horizontal or vertical axis, if desired. The default, **Track**, tracks the cursor in any direction.

The **Reset** button at the bottom of the Move Implant toolbox returns the implant to its original position.

⇨ To move the implant:

1. Select the **Move** button.

   The Move Implant toolbox appears in the upper right corner of the screen.

2. Move the implant in one of the following ways:

   - Set the slider in the toolbox to the desired distance and click one of the directional arrows; or

   - Position the pointer on the implant in the quadrant where you want to work, click, and drag (the pointer will change to a hand when you click the mouse button).

     Note: ***Avoid the intersection of the crosshairs and the crosshair rotation circle when moving the implant. A small region around these areas is reserved for the Change View Plane and Center Bone functions. The pointer will not change to a hand if you click in this region.***

   The Move Implant toolbox will continue to be displayed until you select another function.

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Rotating the Implant

There are two ways to rotate an implant: by clicking and dragging the implant around its center of rotation at the intersection of the crosshairs or by using the Rotate Implant tools.

Before rotating the implant, you may designate the center of rotation in the implant image by moving the intersection of the crosshairs to the desired position.

When you select the Rotate button, the toolbox shown in Figure 8-3 appears in the upper right corner of the screen.

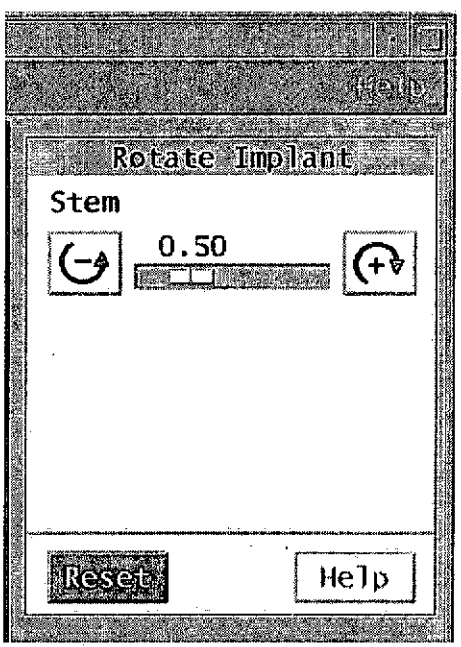

Figure 8-3. The Rotate Implant Toolbox

These tools will rotate the implant an exact number of degrees in either direction around its center of rotation at the intersection of the crosshairs. The slider sets the number of degrees of rotation that will occur for each click of the + or - button. The + button rotates the implant clockwise and the - button rotates the implant counterclockwise. The degrees on the slider range from .10 to 2.00. To rotate the implant more than 2.00 degrees, you can continue to click the + or - button until the implant reaches the desired amount of rotation.

At any time you may select the **Reset** button to return the implant to its default location in the center of the quadrant.

⇨ To rotate the implant:

1. Select the **Rotate** button.
2. The Rotate Implant toolbox appears in the upper right corner of the screen.
3. If desired, designate a new center of rotation by using the Change View and Center Window functions.
4. Rotate the implant in one of the following ways:
   - Set the slider in the Rotate Implant toolbox to the desired number of degrees and click the + or - button; or
   - Position the pointer on the implant in the quadrant where you want to work, click, and drag (turn) to the desired amount of rotation. (The pointer will change to a hand when you click the mouse button.)

     Note: ***Avoid the intersection of the crosshairs and the crosshair rotation circle when moving the implant. A small region around these areas is reserved for the Change View Plane and Center Bone functions. The pointer will not change to a hand if you click in this region.***

The Rotate Implant toolbox will continue to be displayed until you select another function.

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Magnifying Images

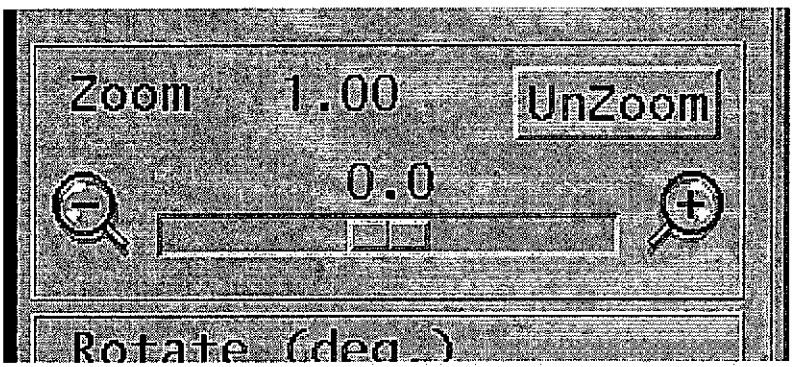

Figure 8-4. The Zoom Scale

The Zoom scale enlarges or reduces the size of a selected portion of an image. When you change the magnification factor in one templating quadrant, the images in the other quadrants will change by the same factor. You can select the **UnZoom** button to restore the images to their previous magnification.

The magnification factors on the Zoom scale range from -4.0 to 4.0. Negative factors divide the size of the image and positive factors multiply the size of the selected portion of the image by the number displayed on the scale. The number at the top of the scale shows the magnification factor of the currently displayed images in relation to the size of the original images.

This function allows close examination of selected portions of an image. It is useful for taking measurements, evaluating implant placement near the distal tip and medial arc, marking the femoral head, and checking the location of the proximal pin.

⇨ **To enlarge or reduce a portion of the display:**

1. Click and drag the crosshairs to the approximate center of the portion of the display that you want to enlarge or reduce.

   You may perform this procedure in any of the templating quadrants.

2. Click and drag the slider on the Zoom scale to the desired amount of magnification.

To "zoom in" or magnify the images, drag the slider to the right. To "zoom out" or reduce the images, drag the slider to the left. To restore the images to their previous magnification, select the **Unzoom** button.

A box in the templating quadrant indicates the portion of the image that will be displayed when the new setting is applied. The box decreases in size as the magnification factor increases.

A few seconds after releasing the mouse button, each of the templating quadrants will update the images to reflect the new Zoom scale setting. If you want to change the setting again, wait until the images in all of the templating quadrants have been updated before repeating this procedure.

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Undoing a Templating Action

The **Undo** button in the bottom right hand corner of the screen reverses the most recent editing action. Use this function when you are dissatisfied with the results of the last change that you made in one of the templating quadrants. For example, if you inadvertently rotated the implant the wrong way, you can return it to its previous position by selecting the **Undo** button before performing another task.

Be aware that you cannot undo a templating action if any intervening changes have been made.

⇨ To undo a templating action:

1. Select the **Undo** button.

   The images will revert to their previous state.

Aligning the Images

When a patient file is first loaded, the femur is not aligned and it is difficult to understand the perspective that is displayed in any of the templating quadrants.

The Change View Plane, Center Window, Zoom, and Translate functions enable you to align the images to simulate an AP x-ray in Quadrant #1, a lateral x-ray in Quadrant 2, and an axial cross-sectional view in Quadrant 3.

You must perform this procedure before marking the femoral head, selecting the neck offset, moving the implant into place, or taking measurements.

⇨ To align the images:

1. Activate the first quadrant by moving the pointer into the quadrant and clicking.

   A red border will outline the quadrant when it is active.

2. Select the **Change View Plane** radio button.

   It will be green when selected.

3. Click and drag the yellow crosshair in the first quadrant to the top of the quadrant.

4. Click and drag the yellow crosshair back down at ½" inch intervals until the image in the third quadrant resembles a donut.

5. Select the **Center Window** radio button.

   It will be green when selected.

6. Click and drag the intersection of the crosshairs in the third quadrant to the center of the donut-like image.

7. Click and drag the circle on the horizontal crosshair in the second quadrant to rotate the image until it is parallel with the vertical crosshair.

8. Click and drag the circle on the horizontal crosshair in the first quadrant to rotate the image until it is parallel with the vertical crosshair.

9. Click and drag the circle on the horizontal crosshair in the third quadrant to rotate the image until the first quadrant displays the femoral head, neck, and proximal third of the femoral shaft.

   If necessary, use the Zoom function to fit the image into the window.

10. Select the **Save** option on the File menu to save the file in this state.

Note: ***You cannot determine whether you are viewing a right or a left femur <u>even after aligning the images</u>. Unlike a regular AP hemipelvis x-ray, the femur may be rotated 180° on the ORTHODOC screen. However, you may align the femur in true anatomical position by adjusting the images so that the bone motion rod appears in the bottom half (anterior) of the third quadrant. The image in the first quadrant may face either way. The correct orientation of the femur can be visually verified by comparing the image in the first quadrant with the AP Scout Image for the patient.***

Selecting Head Size and Neck Offset

The Mark Head and Neck Offset functions enable you to determine the appropriate head size and neck offset for the implant.

Selecting head size and neck offset is a two-step process. The first step is to mark the center and perimeter of the patient's femoral head. The second step is to select the size and neck offset of a prosthetic head and position it, using the femoral head markers as guidelines.

Perform the procedures described in this section after completing the templating process for the femoral stem.

Marking the Femoral Head

The **Mark Head** button displays tools for marking the perimeter and center of rotation of the femoral head in its pre-diseased state. In other words, if the femoral head is irregularly shaped or malpositioned due to disease or injury, you should mark the optimum position for the femoral head rather than its current location.

When you select the **Mark Head** button, a femoral head marker (circle) appears in each of the templating quadrants and the Mark Femur Head toolbox appears in the upper right corner of the screen as shown in Figure 8-5.

DJA x01357

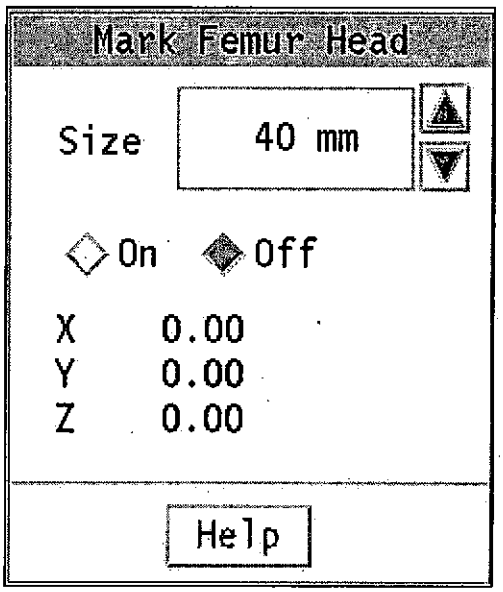

Figure 8-5. The Mark Femur Head Toolbox

These tools set the size of the femoral head marker, determine whether the femoral head marker will be displayed at all times, and display the coordinates of the center of rotation. When this toolbox is displayed, you can move the femoral head marker by clicking anywhere within the red circle and dragging.

⇨ To mark the femoral head:

1. Use the Center Window function to center the femoral head in the quadrants displaying the AP and lateral views.

2. Use the Zoom function to magnify the femoral head until it is approximately 1½ inches in diameter.

3. Select the **Mark Head** button.

   The Mark Femur Head toolbox appears in the upper right corner of the screen and circular markers appear in the center of each templating quadrant.

4. Position the pointer inside the red circle in the quadrant where you want to work.

5. Click and drag until the circle encompasses the femoral head and the red crosshairs mark the optimal center of rotation for the femoral head.

   The coordinates at the center of rotation are displayed in the Mark Femur Head toolbox.

6. Enlarge or reduce the size of the femoral head by clicking the arrows next to the Size box.

   Each click of an arrow increments or decrements the diameter of the femoral head marker by 2 mm.

7. When you are satisfied with the position and the size of the femoral head marker, check the **On** and **Off** radio buttons and change the setting, if necessary.

   - ***On.*** The On setting displays the femoral head markers at all times.

   - ***Off.*** The Off setting displays the femoral head markers only when the Mark Head function is active.

   The Mark Femur Head toolbox will continue to be displayed until you select another function.

Setting Head and Neck Parameters

The Implant Parameters function enables you to select the implant head size and neck offset. To perform this procedure, an implant must be loaded with the patient file and the femoral head must be marked as described in the previous section.

The available head sizes and neck offsets vary from one implant to another, and some implant models and sizes have more head and neck options than others. This function will enable you to view all of the options that are available for the selected implant.

The **Parameters** button displays the toolbox shown in Figure 8-6.

DJA x01359

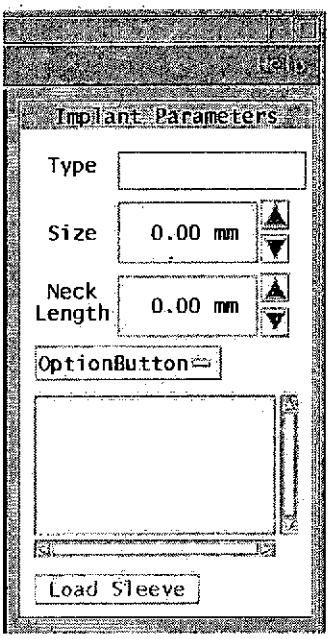

Figure 8-6. The Implant Parameters Toolbox

These tools determine the head type (e.g., cobalt chrome or ceramic), head size, and neck offset. The number and type of head and neck options vary depending upon the implant type. For example, some implants may be available with three different head sizes and some with only one.

These options should be selected with the goal of restoring pre-diseased kinematics (i.e., center of rotation) and adjusting leg length.

Before performing this procedure, you must mark the femoral head as described in the previous section.

⇨ To set the head and neck parameters:

1. Select the **Parameters** button.

   The Implant Parameters toolbox appears in the upper right corner of the screen.

2. Cycle through the available head sizes by clicking the up or down arrow next to the Size box and stop when the desired size is displayed.

As you increment or decrement the head size, the size of the head marker in the templating quadrants will change.

3. Cycle through the available neck offsets by clicking the up or down arrow next to the Offset box and stop when the desired neck offset is displayed.

   As you increment or decrement the Offset setting, the position of the head marker in the templating quadrants will move.

4. Move and rotate the implant as necessary to achieve implant and femoral head concentricity.

   The position of the head should reflect the patient's normal offset and desired leg length.

5. Repeat any combination of steps 2 through 5 until you are satisfied with head size, neck offset, and position of the head.

The Implant Parameters toolbox will continue to be displayed until you select another function.

DJA x01361

Measuring Distances and Angles

The Measure function lets you determine the distance in millimeters between two points on an image and the angle between a line and the horizontal axis.

The Measure function is necessary for measuring the osteotomy level and version angle, procedures, which are specifically described later in this section. You can also use this function for taking optional measurements (e.g., for measuring cortical thickness). For ease and accuracy in measuring, we recommend that you use the Zoom scale to enlarge the measurement area *before* selecting the **Measure** button.

The **Measure** button displays the toolbox shown in Figure 8-7.

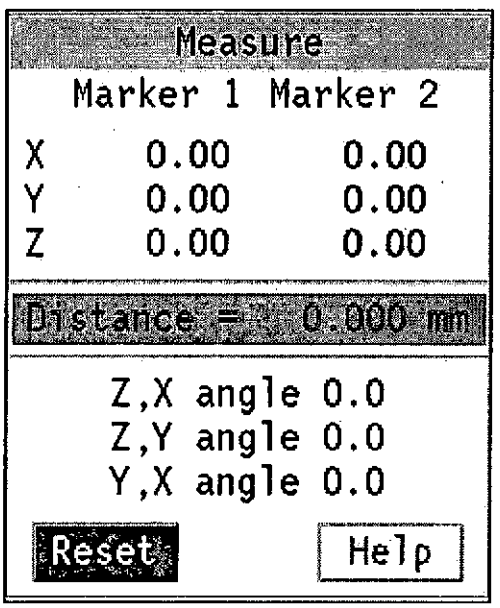

Figure 8-7. The Measure Toolbox

Before taking a measurement, the object must be properly positioned in the templating quadrant where the measurement will be taken. If the object is rotated so that the plane where the measurement should be taken is not fully visible, the measurement will be inaccurate.

The procedure for measuring a distance involves dragging two markers from the intersection of the crosshairs to the endpoints of the distance to be measured. The toolbox displays the coordinates of the endpoint markers and the distance between them.

The procedure for measuring an angle involves dragging the markers to create an angle based on the horizontal axis. Prior to measuring an angle, it is important to position the object properly with respect to the horizontal axis in the quadrant where you want to take the measurement. The Measure toolbox displays the angle of the line between the markers in all three dimensions. If you take a measurement in one of the templating quadrants and then change one of the markers in another quadrant, the angle in the first quadrant will also change.

⇨ To take a measurement:

1. Select the **Measure** button.

   Markers 1 and 2 appear at the intersection of the crosshairs in each templating quadrant and the Measure toolbox appears in the upper right corner of the screen.

2. Position the pointer on the markers in the quadrant where you want to work.

3. Click and drag Marker 1 (the square) to the first endpoint.

   A line extends from the origin to Marker 1 and the toolbox displays the coordinates of the marker, the distance, and the angles in all three planes.

4. Move the pointer back to the origin.

5. Click and drag Marker 2 (the circle) to the second endpoint.

   The toolbox displays the distance between the two endpoint markers and the angles in all three planes.

6. To take another measurement, select the **Reset** button.

The Measure toolbox will continue to be displayed until you select another function.

DJA x01363

Measuring for Osteotomy Level

This section describes the procedure for measuring the level at which a surgeon should perform a femoral neck osteotomy. Care must be taken not to overcut (cut too low on the bone). The reference point from which the osteotomy level will be measured is dependant up the approach used and the surgeon's preference. The procedure described below is the generally accepted method for the reference approach.

⇨ To measure for osteotomy level (Posterior Approach):

1. Reposition the implant to 0° of rotation by rotating the bone and the implant so that the axes in all three quadrants fall in the center of the implant images.

2. Turn on the Mark Femur Head function and mark the femoral head if you have not yet done so.

3. Working in Quadrant 1, measure the distance from the end of the femoral head marker to the top of the implant or to collar level for collared implants, as shown in Figure 8-8.

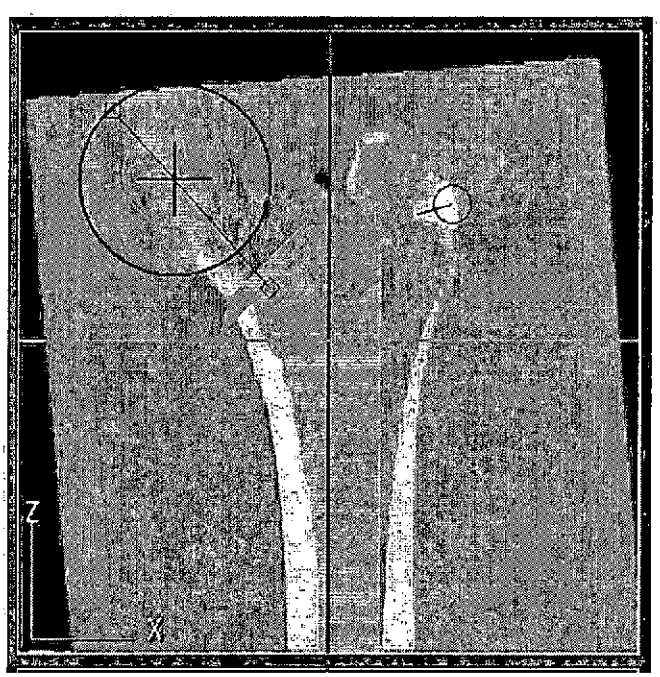

Figure 8-8. Measuring Osteotomy Level (Posterior Approach)

This figure shows how the images and the markers must be positioned in Quadrant 1 to measure for osteotomy level.

4. When the images and measurement markers are positioned as shown in Figure 8-8, subtract 5 mm from the distance shown in the Measure toolbox.

5. Record the measurement on the labels for the tape cartridge and cover of the tape cartridge.

⇨ To measure for osteotomy level (Anterior/Lateral or Lateral Approaches):

1. Reposition the implant to 0° of rotation by rotating the bone and the implant so that the axes in all three quadrants fall in the center of the implant images.

2. Working in Quadrant 1, change the view plane until the image in Quadrant 3 shows the most prominent aspect of the lesser trochanter.

3. Select the Measure button.

4. Working in Quadrant 1, measure the distance lesser trochanter (horizontal line) to the point where a line extending along the slope on the proximal end of the implant would exit from the bone, as shown in Figure 8-9.

5. When the images and measurement markers are positioned as shown in Figure 8-9, add 5 mm from the distance shown in the Measure toolbox.

6. Record the measurement on the labels for the tape cartridge and cover of the tape cartridge.

DJA x01365

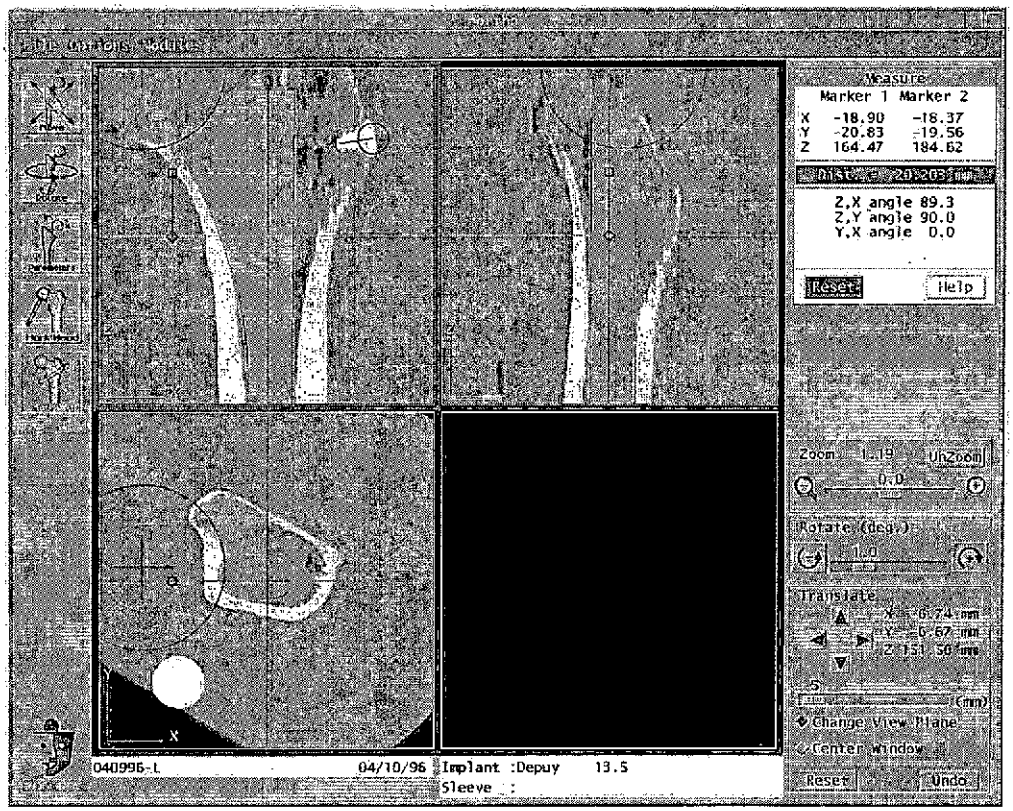

Figure 8-9. Measuring Osteotomy Level

DJA x01366

Measuring Version Angle

This procedure enables you to determine the version of the femoral stem in order to ensure stability of the femoral head in the acetabular component of the prosthesis. You must take this measurement on the wire-frame image in the third (Y,X) quadrant because this image includes both the condyles and the femoral head.

⇨ **To measure version:**

1. Display a wire-frame model by selecting the wire-frame setting for the Bone Image option on the Options menu.

2. Turn on the Mark Femur Head function and mark the femoral head if you have not yet done so.

3. Reposition the implant to 0° of rotation by rotating the bone and the implant so that the axes in all three quadrants fall in the center of the implant images.

   To match the patient's natural anteversion, align the prosthesis head in Quadrant 3 on the same plane as the femoral head.

4. In the Y,X quadrant measure the angle from the top of one condyle to the top of the other.

   Figure 8-10 shows how the measurement markers should be positioned.

DJA x01367

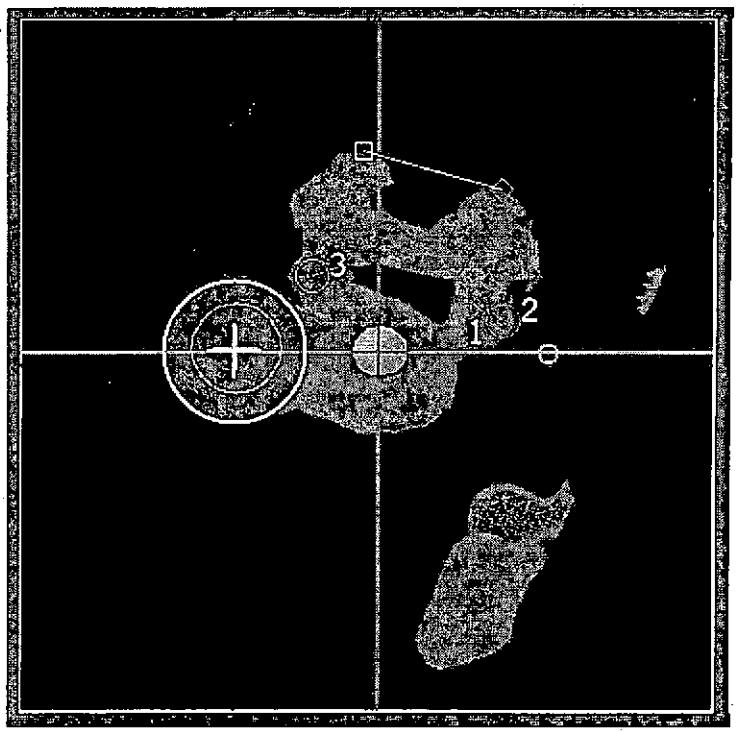

Figure 8-10. The Condyles With Measurement Markers

5. Record the angle from the Y,X view, as indicated in the Measure toolbox, on the labels for the tape cartridge and cover of the tape cartridge.

DJA x01368

Chapter 9

CREATING A TRANSFER FILE

DJA x01369

Introduction

The procedure described in this chapter creates a file that will guide the ROBODOC Surgical Assistant during THR. Only ISS-certified surgeons may perform this procedure.

A transfer file contains data describing patient anatomy, implant geometry, and planned placement data from the preoperative planning session.

Do not perform this procedure until you are satisfied with all the following items:

- You have selected and loaded the correct patient file.
- The selected implant is the appropriate model and size.
- The images of the implant within the femur accurately reflect where you want to place the implant during surgery.
- You have transfer Media and markers or labels for it.

If any of these items are incomplete or you are unsure of their status, do not create a transfer file now. You can select the **Save** option on the File menu to end the templating session and store the ORTHODOC file in its current state so it can be finished later.

If any of the import processes failed (i.e., the check for protocol compliance, or motion detection), the system will not allow you to create a transfer file.

Creating the File

⇨ To create a transfer file:

1. Select the File command on left side of the title bar or simultaneously press **ALT-F**.

   The pull-down menu shown in Figure 9-1 appears.

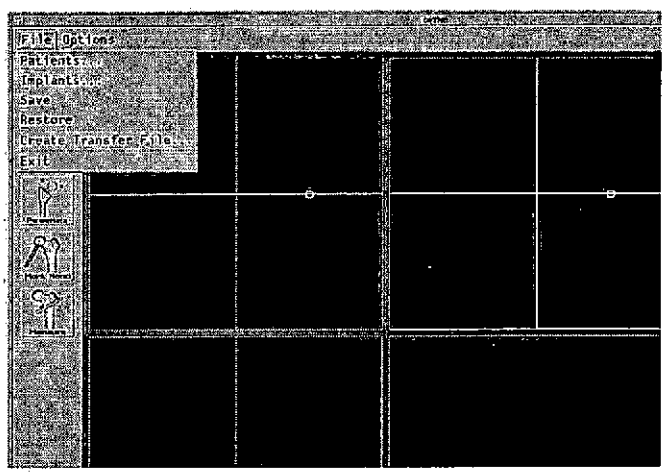

Figure 9-1. The File Menu

2. Select the Create Transfer File option.

   The pop-up window shown in Figure 9-2 appears.

DJA x01371

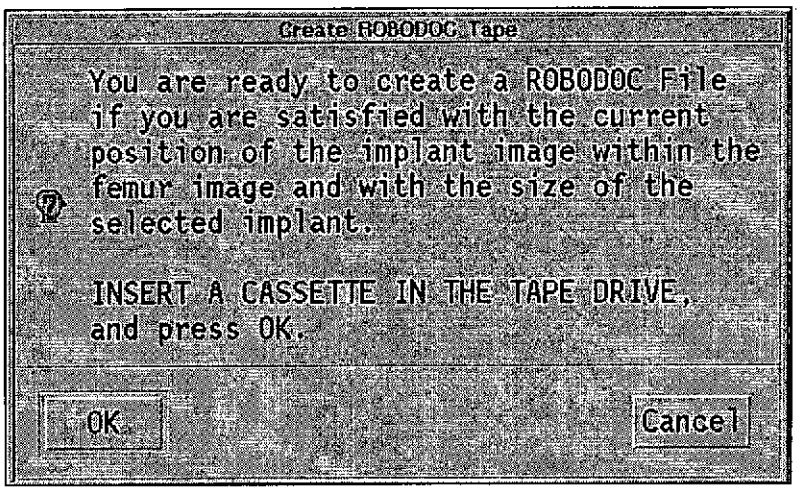

Figure 9-2. The Create ROBODOC Tape Window

3. Insert transfer media into the drive and select **OK**.

   A number of verification screens will appear that the user must respond to. These screens include the following:

   - Surgical Site (left or right)
   - Confirm that the pins were found correctly
   - Confirm that no motion was detected

Surgical Site

The pop-up window shown in Figure 9-3 appears.

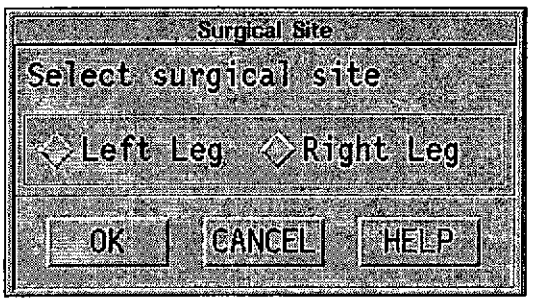

Figure 9-3. The Leg Orientation Window

1. Select the appropriate radio button (**Left Leg** or **Right Leg**).
2. Select **OK**.

Confirming the Absence of Bone Motion

The pop-up window shown in Figure 9-4 appears.

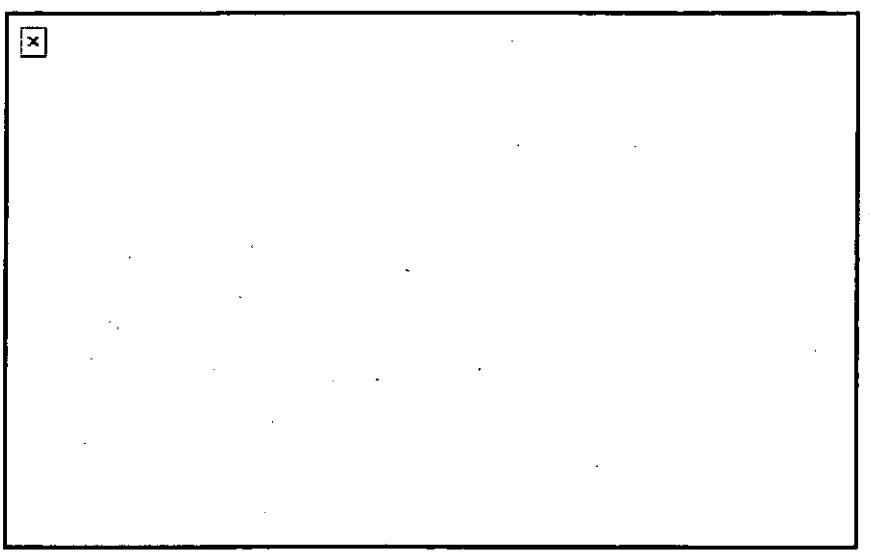

Figure 9-4. The Visual Motion Verification Window

⇨ **To confirm the absence of bone motion:**

1. When the Visual Motion Verification window is displayed, check the image for evidence that motion occurred during the CT scan by looking for steps or jogs in the bone.

2. To confirm the absence of bone motion, select **NO**.

Writing the ROBODOC® Transfer Media

The screen displays a message while the transfer file is being copied on the tape cartridge. Do not remove the transfer media until processing is complete. While the media is being written, take the time to fill out the labels for the transfer media. The label should contain the following information:

- Patient's name
- Surgeon's name
- Date
- Implant manufacturer, model, and size
- Osteotomy level and angle
- Version angle

When the media has been written, remove it from the drive. Mark or affix one label to the media and the other to the case, where it will be visible when inserted into the drive in the operating room.

DJA x01374

Chapter 10

SAVING, RESTORING, RESETTING, AND EXITING

DJA x01375

Saving an ORTHODOC File

This section explains how to save your work for use during a future templating session. If you have already created a transfer file, as described in the previous chapter, you do not need to perform this procedure.

Perform this procedure whenever you are unable to finish an entire preoperative plan in one session and you want to complete your work on the patient file later. You should also use this procedure periodically during a templating session to ensure that your work will not be lost in the event of a problem such as a power failure.

⇨ **To save your work:**

1. Select the File menu.
2. Select the **Save** option.

   The pop-up window shown in Figure 10-1 appears.

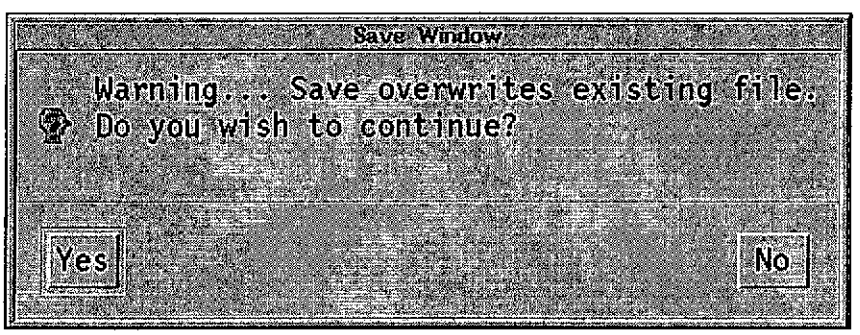

Figure 10-1. The Save Window

3. To save the ORTHODOC file in its current state, select **Yes.**

DJA x01376

Restoring a File

This section explains how to cancel all of the changes that have been made to a patient file since the last time the file was saved.

⇨ **To restore a file:**

1. Select the File menu.
2. Select the **Restore** option.

   The screen redisplays data in the templating quadrants as it appeared when it was last saved.

Resetting a File

This section explains how to cancel all of the changes that have been made to a patient file, returning the file to its original state prior to performing any templating procedures.

⇨ To reset a file:

1. Select the **Reset** button.

   The **Reset** button is located at the bottom of the screen, to the left of the **Undo** button.

   The screen redisplays the data in its original state.

DJA x01378

Exiting From ORTHODOC

Before allowing you to exit from ORTHODOC, the system prompts you to indicate whether modifications should be saved.

If you save modifications when exiting from ORTHODOC, the next time you load the file, it will reflect the results of this templating session. If you do not save your modifications, the system will discard any changes made since the last save.

⇨ To exit from ORTHODOC:

1. Select the File menu.
2. Select the Exit option.

   The Exit window shown in Figure 10-2 appears.

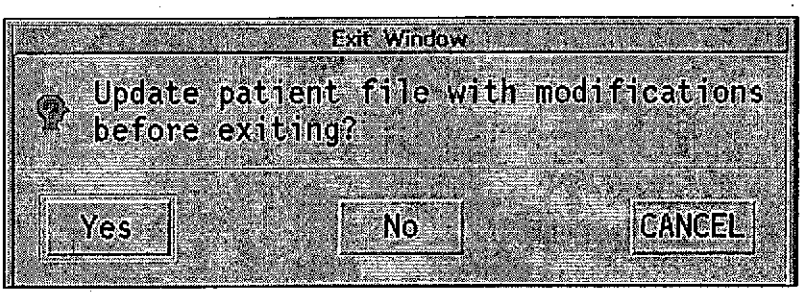

Figure 10-2. The Exit Window

3. To save changes made during the most recent templating session, select **Yes**.

   To exit without saving, select **No**.

DJA x01379

Chapter 11

CASE MANAGER

DJA x01380

Introduction

This chapter describes how to perform file management functions, including restoring and deleting patient files.

The case database has a limited amount of space to store patient files. When cases are complete, the non-active patient files may be deleted to free space for new cases. If an archived file is needed later, you can use the Restore function to load it back into the case database from a tape containing the transfer file.

Since the Case Manager and the Import program both perform file-management functions, they cannot run simultaneously. In other words, the Import program must be closed and not just minimized or iconized when you select the CASE MGR button.

⇨ To start the Case Manager program:

1. From the main menu, select the **CASE MGR** button.

   The Case List window shown in Figure 11-1 appears.

DJA x01381

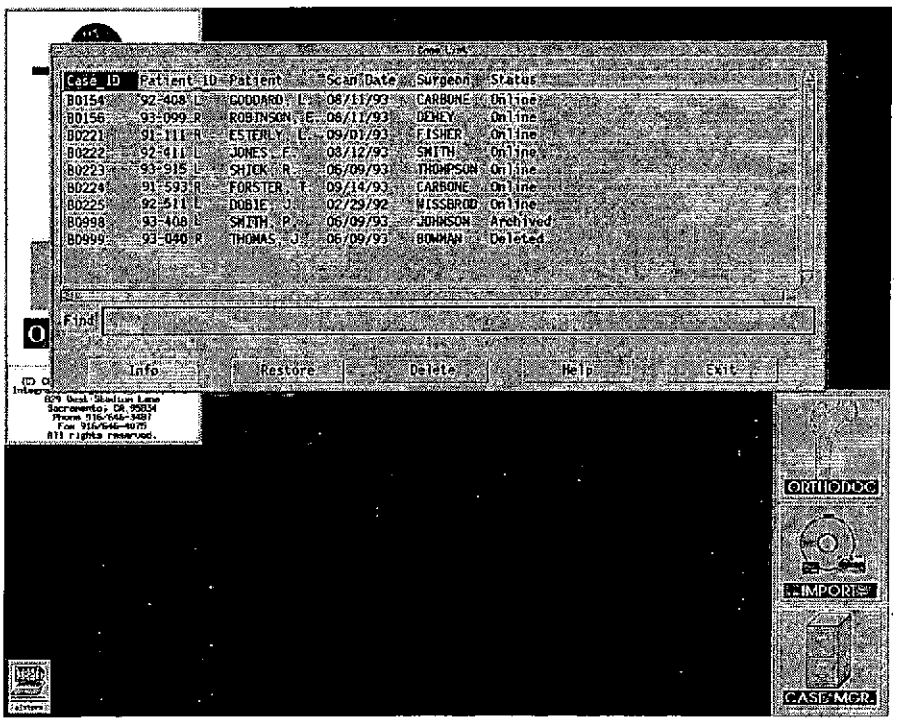

Figure 11-1. The Case List Window

The Case List window displays all of the patient files that have ever been in the case database, including files that have been archived to tape or deleted. The Status column displays the following entries:

- ***Online.*** Indicates files currently in the case database.
- ***Archived.*** Indicates ROBODOC transfer files that have been saved on tape and removed from the case database.
- ***Deleted.*** Indicates files that were removed from the case database before a ROBODOC transfer file was created.

Selecting Patient Files

This section describes how to select a patient file for use with Case Manager functions.

When the Case List window first appears, the files are sorted in ascending order by Case ID. You can click on any of the column titles to sort by other parameters:

Patient ID. Sorts in ascending order by Patient ID.

Patient. Sorts alphabetically by patient name.

Scan Date. Sorts by date of CT scan, with the most recent scan at the top of the list.

Surgeon. Sorts alphabetically by surgeon name.

Status. Sorts alphabetically by status (Archived, Deleted, Online).

⇨ To select a patient file:

1. Find the desired file using one or more of the following methods if the listing is long:

   - Sort the files by patient ID or name; scan date, surgeon, or status.
   - Select the **Find** button and then type data from any of the columns (e.g., patient id, name, or scan date) in the data entry area. The system will move the first file that meets the entered criteria to the top of the list and highlight it.
   - Use the scroll bars to move through the listing.

2. Select the file by moving the pointer to it and clicking the left mouse button.

   The screen highlights the line containing the file description of the selected file.

DJA x01383

Viewing and Entering Case Information

This section describes the function for viewing and entering information about a selected case.

Perform this procedure after selecting a patient from the Case List window.

⇨ To view and/or enter case information:

1. Select the **Info** button at the bottom of the Case List window.

   A window like the one shown in Figure 11-2 appears.

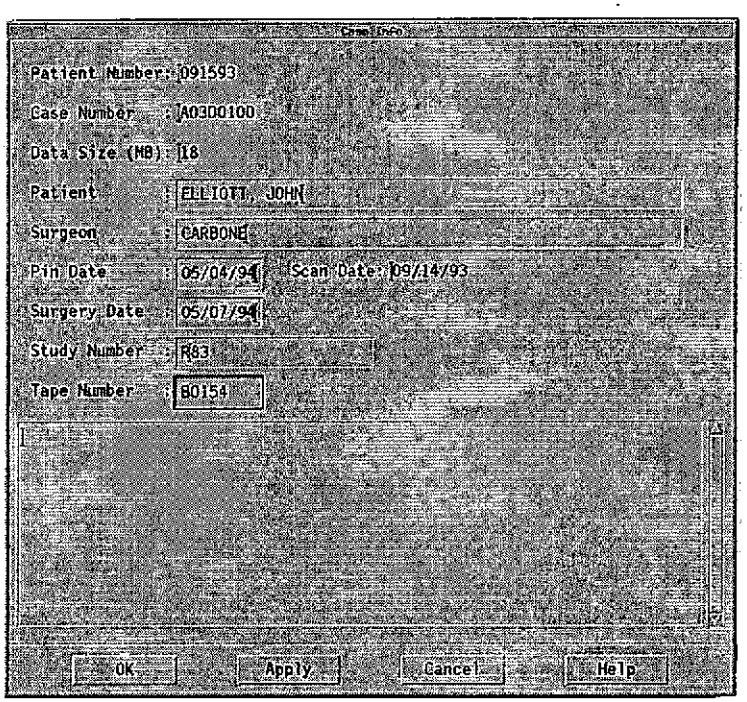

Figure 11-2. A Case Info Window

The first three fields and the Scan Date field in the Case Info window cannot be changed:

Patient Number. A number assigned to this patient by the CT scan technician.

Case Number. A number automatically assigned during the import process.

DJA x01384

Data Size. The number of megabytes in the patient file.

Scan Date. The date of the CT scan for this case.

The boxed fields may be changed:

Patient. The patient's name.

Surgeon. The surgeon's name.

Pin Date. The date the locator pins were implanted.

Surgery Date. The date of the THR surgery.

Study Number. A number assigned to this patient by ISS for tracking purposes during clinical trials.

Tape Number. Displays the Case Number by default, but some sites use this field to enter a new number associated with their tape archiving system.

2. View the information displayed in the window.

3. If you want to add or change information in any of the fields, move the pointer into the area, click, and type.

   You can save your work without exiting the window by selecting the **Apply** button.

   If the system cannot change the information in one of the boxed fields, a window appears with an explanatory message. Write it down and contact ISS for assistance.

4. When you are finished viewing and entering information, select **OK**.

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Restoring Files

This section describes the function for restoring archived files into the case database from tape.

Before beginning this procedure, you must obtain the tape containing the file that you want to restore to the case database and select the archived patient file from the Case List window.

⇨ To restore a file:

1. Select the **Restore** button at the bottom of the Case List window.

   The window shown in Figure 11-3 appears.

Figure 11-3. A Restore Image Data Window

2. Insert the tape and select **OK**.

   The screen displays a spinning symbol while the file is being restored from tape.

When the file has been restored, its status in the case list changes from "Archived" to "Online."

If the restore function fails, a window appears with a message describing the problem. Figure 11-4 is an example of restore failure window.

DJA X01386

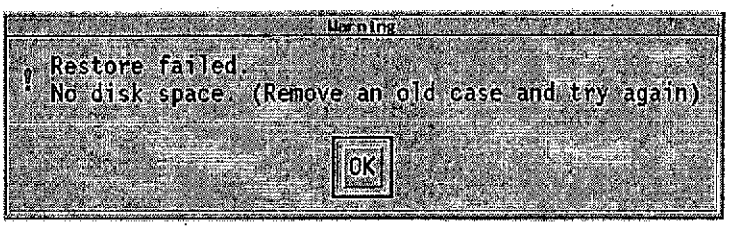

Figure 11-4. A Restore Failure Window

This restore failure window advises the user that there is not enough disk space to contain the restored file and suggests removing (deleting) an old case. If the window displays a message that you do not understand, write it down and contact ISS. To exit from a restore failure window, you must select OK.

Deleting Files

This section describes the function for deleting a file from the case database.

This procedure deletes files and frees space in the case database for new cases. Typically, you will use this function to delete an ORTHODOC file after a transfer file has been created from it. When you delete a file for which there is a transfer file, its status will change from "Online" to "Archived." Files that are archived on tape may be subsequently restored to the case database. When you delete a file for which there is no transfer file, its status will change from "Online" to "Deleted." There is no way of restoring or retrieving data from deleted files.

⇨ To delete a file:

1. Select the **Delete** button at the bottom of the Case List window.

   If a transfer file has been created from this data, a window like the one shown in Figure 11-5 appears.

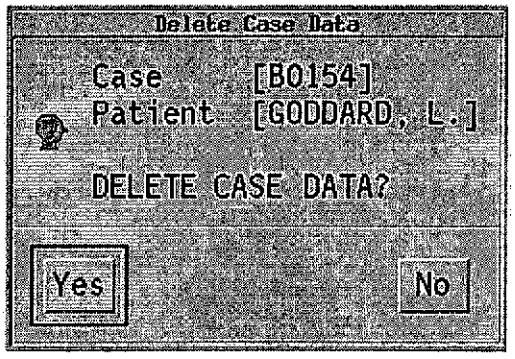

Figure 11-5. A Delete Case Data Window

If a transfer file has not yet been created, a window like the one shown in Figure 11-6 appears.

DJA x01388

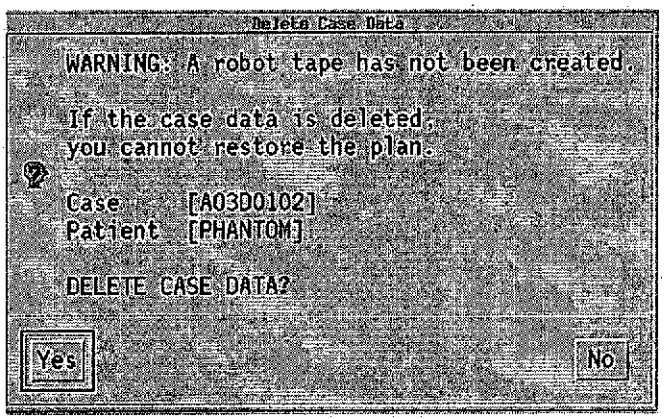

Figure 11-6. A Delete Case Data Window with Warning

This warning is intended to prevent you from inadvertently deleting case data before a transfer file is made.

2. If you want to delete the file, select **Yes**.

   If the delete function fails, a window like the one shown in Figure 11-7 appears.

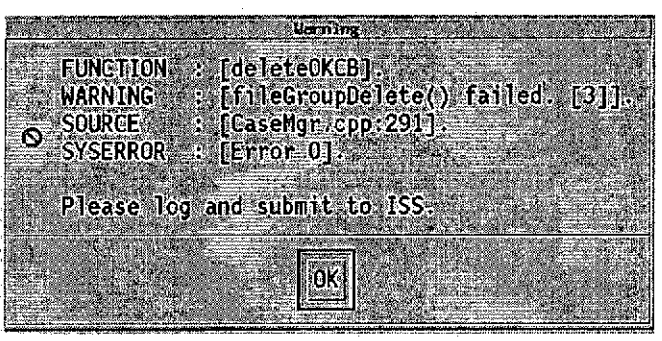

Figure 11-7. A Delete Failure Window

This window displays some codes that will enable ISS to diagnose the problem. Write them down and contact ISS. To exit from a delete failure window, you must select OK.

DJA x01389

Closing the Case Manager Program

This section describes how to close the Case Manager program.

⇨ **To close the Case Manager program:**

1. Select the **Exit** button at the bottom of the Case List window.

   The Case List window disappears and main menu is displayed.

DJA x01390

Appendix A

Glossary

DJA x01391

Glossary

Bone Image options. The display options that determine whether the femur will be displayed as a CT slice or a wire-frame image.

Button. A basic control for selecting an option, activating an operation, or displaying a window containing tools for performing a certain function.

Camouflaged. A button that blends into the background because its function is temporarily unavailable.

Cascading menu. A menu containing options that display secondary menus. The Options menu is a cascading menu.

Case database. The collection of patient files that exists on the ORTHODOC Workstation.

CASE MGR button. The button on the main menu used to restore transfer files and delete files from the case database.

Center Window button. The button that lets you display a different view of the bone by designating a new location on the bone to be centered on the display.

Click. To quickly press and release a button.

Crosshairs. Intersecting lines that divide each of the templating quadrants. They are used for moving, rotating and changing the viewing plane for images.

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Default. The initial setting for a menu option. ORTHODOC defaults are the most commonly used settings.

Double click. To select an icon or activate an operation by clicking the left mouse button twice in rapid succession.

Drag. To move an object across the screen by moving the pointer to the object, pressing the left mouse button, moving the mouse until the object is in the desired location, and then releasing the mouse button when the object is properly positioned.

File. A set of data containing items such as patient information and CT images or implant specifications.

File menu. The pull-down menu that displays the functions for loading, saving, and creating files.

Find Pins button. The button on the Import screen that scans each individual CT slice to find the locator pins, evaluate their placement, and determine their metal content for validation purposes.

Full Scale button. A radio button in the View Images window that causes just one full-size image of a CT slice to be displayed. The other radio button is **Half Scale**.

Half Scale button. A radio button in the Patient Directory window that causes four half-size CT slices to be displayed. The other radio button is **Full Scale**.

Highlighted. An object or text, which is displayed in color or reverse video, indicating that the item has been selected and will be affected by your next action.

Histogram. A graph indicating the distribution of intensity values in a file of CT images.

Icon. A rectangular symbol on the main menu that represents a program that has been minimized (i.e., its screen has been closed without closing the program).

Image options. The radio button settings that determine how bone and implant images will be displayed in the templating quadrants.

Implant Directory. The window that lists all of the available implant models and sizes and contains buttons for previewing implant images and manufacturing specifications.

Implant Image option. The option that determines if the implant image will be opaque, transparent, an outline, or not displayed.

IMPORT button. The button on the main menu that starts the program to load CT data, process it, and generate an ORTHODOC file.

Interpolate. To construct a bone image by projecting the probable geometry of areas between individual CT images to create a smooth, x-ray-like image.

Leg Orientation window. The window where you indicate which leg (left or right) will be implanted.

Main menu. The menu containing the **ORTHODOC, IMPORT, CASE MGR, LOGOFF,** and **SHUTDOWN** buttons.

Mark Head button. The button that displays the toolbox for marking the perimeter and center of rotation of the femoral head in its pre-diseased state.

Measure button. The button that displays the toolbox for measuring distances and angles in the CT data.

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Menu. A list of options or set of buttons.

Mouse. The small hand-held device that you use to move, select, and manipulate objects on ORTHODOC screens.

Move button. The button that activates a mode where you can move the implant.

Option. A choice in a window or on a menu. Options can initiate your next action or change the screen display.

Options menu. The pull-down, cascading menu that provides display options for customizing the way images are displayed in the templating quadrants.

ORTHODOC. ISS's Preoperative Planning Workstation.

ORTHODOC button. The button on the main menu that starts an ORTHODOC session.

Parameters button. The button that displays a toolbox for selecting implant head size and neck offset.

Password. The alphabetic and/or numeric code that enables you to use ORTHODOC files and prevents access by unauthorized users.

Patient Directory. The window that lists patient files and contains buttons for previewing CT images and data.

Pixel. The smallest element of an image that can be processed by a video display system.

Pointer. The arrow on the screen that indicates the current cursor position.

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Preprocessing. The steps of loading CT data into the case database, checking pin and bone motion data, and generating a 3D model for display during templating.

Process Log. A table that displays the status of five processes including importing the CT data, checking for protocol compliance during the scan, finding pins, detecting motion, and building a 3D model. PASS indicates that the process was successfully completed; FAIL indicates that errors were detected; and NR indicates that the process was not run.

Pull-down menu. A menu that drops down from the title bar when you move the pointer to the command identifying the menu and click the left mouse button.

Radio buttons. A group of buttons, each of which has two states: on and off. Only one radio button in a group can be activated at any given time. The graphic indicator for a radio button is a diamond, which is filled to indicate the on state or empty to indicate the off state.

Reconstruction methods. The display options that determine whether the system will construct the bone images by interpolation or replication for display in the templating quadrants.

Replicate. To construct a bone image by stacking individual CT images, without projecting the probable geometry of areas between the images.

Restore option. The option on the File menu that returns a file to its previous status, undoing all changes since the last save.

ROBODOC. The ISS surgical robot that uses ORTHODOC output files to ream the femoral cavity with dimensional accuracy.

Root menu. A utility menu containing window and screen manager functions. To display the Root menu, press and hold the left mouse button when the main menu is displayed.

Rotate button. The button that activates a mode where you can rotate the implant image.

Save option. The option on the File Menu that writes a file to disk and saves the current status of the file for future use.

Scale. A slider that sets or displays a value in a range. Dragging the slider changes the value.

Scan Info button. The button in the Patient Directory window that displays information about the scan including the patient's name, radiologist, exam type, exam date and time, image modality, number of slices, etc.

Scan Motion button. The button in the Patient Directory window that displays a numeric table of data with summary information that indicates whether patient motion during the CT scan was within acceptable limits.

Scroll. To move the cursor beyond the current boundaries on the screen and display new parts of the file.

Scroll bars. The bars that appear next to ORTHODOC lists and displays. When the information is too long to fit on a single screen, you can drag the scroll bar up or down to move through the list.

Templating quadrant. One of the four rectangular areas where bone and implant images are displayed for computerized templating.

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Threshold scale. The slider that sets the range of intensities in the CT data that will be displayed in the 3D model.

Tissue Color options. The radio button settings that determine whether the bone image will be displayed in shades of gray or in color.

Title bar. The second line on the screen, which contains the commands to open the File and Options menus, and the help index.

Toolbox. A set of buttons, sliders, directional arrows, and data fields that enable you to perform a specific function such as taking a measurement. Toolboxes appear in the upper right corner of the screen when you select certain buttons from the templating screen.

Tools menu. A utility menu containing the option to assign passwords.

Transfer file. A file containing data that describes patient anatomy, implant geometry, and planned placement data from the preoperative planning session.

Undo button. The button that cancels your last editing action and restores the images to their previous state.

Utility menu. A menu that can be displayed by pressing and holding a mouse button from the main menu. Utility menus provide a variety of tools and functions.

View Pins button. The button in the Patient Directory window that displays an image of the pins and pin data (e.g., metal content, distance, and absolute position) for the purpose of visually verifying that the system correctly located the pins.

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View Scout button. The button in the Patient Directory window that displays a preliminary image of the complete bone, similar to the ones displayed for templating.

Window. A message area that appears on an ORTHODOC screen to display buttons, menu options, or a prompt.

Wire-frame. The display option that causes the bone image to be displayed as a wire-like frame, rather than as a solid or transparent image.

Zoom scale. The scale that sets the degree of magnification.

3D Model option. The option that determines whether images in the fourth display quadrant will be opaque, wire-frame, shaded, or transparent.

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Appendix B

USING UTILITY MENUS

Introduction

The ORTHODOC Workstation has two utility menus: the Tools Menu and the Root Menu. The Tools Menu enables you to assign personalized passwords and the Root Menu enables you to perform window manager functions.

Both of the utility menus are accessed from the main menu, which contains the Orthodoc, Import, and Case Mgr buttons.

If you have already started a preoperative planning or import session, you can access the utility menus without exiting the program.

⇨ To access a utility menu without exiting to the main menu:

1. Press the minimize button to redisplay the main menu.

   The ORTHODOC screen disappears, but the program is not closed. It is represented by the rectangular icon located in the lower right corner of the main menu.

2. Move the pointer to the middle of the screen, away from the buttons and icons.

3. To display the Tools menu, depress and hold the right mouse button.

   or

   To display the Root menu, depress and hold the left mouse button.

4. To redisplay the ORTHODOC or Import screen, move the pointer to the icon and double-click the left mouse button (click twice in rapid succession).

Changing Passwords

Password protection is an ORTHODOC security feature that prevents unauthorized users from accessing the system. The system comes with pre-assigned passwords, but you should change them to unique, private passwords for individuals at your site.

Follow these guidelines in selecting a password:

- A password may include both letters and numbers and should be six to twelve characters in length.
- Select a password that is easy to remember, but one that a casual acquaintance could not guess. Some good choices might include your mother's maiden name, your social security number, a favorite celebrity, a food, or a city. Poor choices would be the word "password," your name, or the name of your spouse or child.

After you follow the procedure described in this section to assign yourself a password, be sure to remember it. It is your personal key to the system.

⇨ To change a password:

1. From the main menu containing the **ORTHODOC**, **IMPORT**, and **CASE MGR** buttons, move the pointer into the center of the screen, away from the buttons and logo area.

2. Depress and hold the right mouse button.

   The Tools menu shown in Figure B-1 appears. It contains only one option.

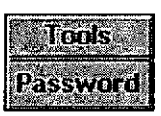

Figure B-1. The Tools Menu

3. When the Tools menu appears, move the pointer to the Password option while continuing to hold the right button.

4. Release the right mouse button when the pointer is on the Password option.

   A window with instructions appears.

5. Follow the instructions in the window.

   You will need to enter the current password before entering the new one. If you have never used the system before, enter your pre-assigned password. The system will require you to enter the new password twice for verification.

   For security reasons, the screen does not display passwords when they are typed.

Performing Window Manager Functions

The Root Menu contains several options that affect the way that the ORTHODOC Workstation displays screens and windows. This section explains how to use these options.

The window manager functions are located on the Root Menu.

⇨ To display the Root Menu:

1. From the main menu containing the **ORTHODOC, IMPORT**, and **CASE MGR** buttons, move the pointer into the center of the screen, away from the buttons and logo area.

2. Depress and hold the left mouse button.

   The Root Menu shown in Figure B-2 appears.

Figure B-2. The Root Menu

The options on the Root Menu perform the following functions:

Shuffle Up. When windows are layered one on top of another, Shuffle Up moves a window from the background to the foreground.

Shuffle Down. When windows are layered one on top of another, Shuffle Down moves a window from the foreground to the background.

Refresh. Redraws the screen. When something is wrong with the way an image or a menu is displayed, Refresh often solves the problem.

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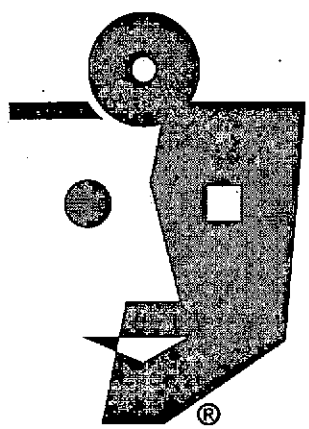

ROBODOC®

INTEGRATED SURGICAL SYSTEMS

CE 0197

ROBODOC® Surgical Assistant

Volume II - 000162

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Preface

ABOUT THIS MANUAL

This manual explains how to prepare and use the ROBODOC Surgical Assistant for femoral canal preparation, and perform postoperative maintenance procedures. The surgical protocol provided in this manual covers the unique aspects of surgery using the ROBODOC. It does not describe surgical hip replacement techniques that are identical to the traditional techniques employed in non-robotic assisted surgeries.

Audience

This manual is intended for Integrated Surgical Systems (ISS)-certified orthopaedic surgeons and operating room technicians who will use the ROBODOC Surgical Assistant. ISS-certified orthopaedic surgeons are experienced in performing total hip arthroplasty (THA) and have attended a training program covering the use of the ORTHODOC® Preoperative Planning Workstation (ORTHODOC) and the ROBODOC Surgical Assistant. At the beginning of each chapter, a box containing introductory information indicates whether the chapter is intended for surgeon, technician, or both.

How To Use This Manual

To assist you in finding information, a comprehensive table of contents for each chapter and appendix is included at the beginning of this manual. An index is located at the end of the manual.

A glossary describes terms that are unique to the ROBODOC Surgical Assistant System (Appendix A). Use the glossary whenever you encounter an unfamiliar word or when you need to refresh your memory about a particular component, feature, or procedure. A special label glossary explains the meaning of the labels affixed to ROBODOC equipment (Appendix C).

Other Manuals

The *ROBODOC User Manual, U.S. Edition,* has two companion volumes:

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ROBODOC Preoperative Protocols, U.S. Edition

This manual provides the protocol for performing a CT scan that will provide input for the system.

ORTHODOC User Manual, U.S. Edition

This manual explains how to use ORTHODOC for DigiMatch™ SMG (DigiMatch) surface model generation, prosthesis selection, computerized templating, and creating an input file for the ROBODOC Surgical Assistant.

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Chapter 1

INTRODUCTION

What Is the ROBODOC® Surgical Assistant?

The ROBODOC Surgical Assistant is a robotic system for preparation of the femur during primary or revision total hip arthroplasty (THA). Using the surgeon's input from an ORTHODOC planning session, the robotic device creates a femoral cavity accurately shaped and positioned for implantation of a selected prosthesis or removes bone cement for revision cases. This chapter provides information for surgeons and technicians.

The ROBODOC Surgical Assistant (ROBODOC) includes a Surgical Robot and a color computer screen called the *OR Monitor*. The OR Monitor is mounted on the Control Cabinet, which contains the robot control computer, real-time monitor computer, tape drive, and other electronic components.

The surgeon controls every phase of the surgical procedure using a hand-held device, called a "pendant." The pendant has five buttons for initiating and aborting robotic procedures, and for selecting options displayed on the OR Monitor. The OR Monitor displays a series of menu screens that guide the surgeon through the robotic phase of the surgery and provide visual feedback during the automated process of preparing the femoral cavity.

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Indications, Contraindications, Warnings/ Precautions, and Adverse Effects

The indications and contraindications listed below are for use of the ROBODOC Surgical Assistant System.

Indications for Use

- Severely disabled hip joint due to primary or secondary degenerative osteo-, rheumatoid, or post-traumatic arthritis; avascular necrosis of the femoral head; or acute femoral neck fracture.
- Patient anatomy is compatible with one of the hip implant designs validated for use with the ROBODOC Surgical Assistant.

Contraindications

- Skeletal immaturity.
- Any active infection.
- Neuromuscular disorders, which would create an unacceptable risk of prosthesis instability or fixation failure.
- Femoral bone stock that is of poor quality or inadequate to provide stability for the femoral fixator and/or locator pins, in cases where locator pins will be utilized for registration.
- Femoral bone stock that may be damaged by femoral fixation.
- A pathological skeletal condition, which would impair the ability of the bone to withstand the stress of femoral canal preparation and prosthesis placement (e.g., severe osteoporosis, Paget's disease, renal osteodystrophy).
- DigiMatch surface registration is contraindicated for use in cases with severe femoral deformity due to trauma or degenerative osteoporosis of the operative femur, or with significant deformation of the surfaces required for DigiMatch surface registration.

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- DigiMatch surface registration is contraindicated for use in cases where metallic objects present in the operative leg would cause unacceptable levels of artifact in the CT slices over the surfaces required for DigiMatch registration.

- DigiMatch surface registration is contraindicated for use in cases where non-titanium implants are present in the counter-operative leg.

- Poor skin coverage or bone stock of the operative femur adjacent to the greater trochanter, or the lateral or medial epicondyle.

Warnings/Precautions

- Read and follow all of the instructions for use provided in the user manuals, release notes, external labels on ROBODOC components, package inserts for consumable components, and OR Monitor screens.

- The operating room must be equipped with surgical instruments for manual broaching in the event that the surgeon must abort robotic cavity preparation.

- Do not anesthetize the patient until the robot has successfully completed all diagnostic procedures, the patient tape has been loaded, and the patient information has been confirmed by the surgeon.

- Do not adjust the position of the OR table or the position of the patient after starting the digitizing procedure in DigiMatch cases or pin finding procedure in locator pin cases.

- Continuously irrigate the femoral area. If the irrigation system fails, pause the robot while preparing a backup irrigation system.

- A preoperative planning error may result in a misplaced or improperly shaped cavity.

- During DigiMatch surface registration, points must be collected as displayed on the OR Monitor to ensure that the points are adequately spaced over the region of interest.

- During DigiMatch surface registration, the surgeon must use a light touch to avoid moving the bone, while ensuring that the probe tip makes contact with the bone.

- Surgeon verification of digitized points is a critical step in DigiMatch surface registration. When re-collecting verification points, the surgeon must ensure that points are collected at the

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locations indicated on the display. Subsequently, the surgeon must inspect each bone image to confirm that the identified probe position corresponds to the bone surface.

- Gross movement of the operative femur relative to the femoral fixator, resulting from improper fixator installation or physical contact by OR staff with the fixated leg, could cause soft-tissue damage, bone damage, or placement errors; take care to avoid bumping the lower leg or leg support device during the case.

- Unanticipated robot motion while the cutter is off could cause injury in the event of a collision between the robot arm and the patient.

- Unanticipated robot motion while the cutter is on could cause unnecessary soft-tissue and/or bone damage.

- If the PAUSE button fails to stop the robot, press the STOP button.

- Failure to operate the cutter at the recommended air pressure (8 bar ± 1) may increase the cutting force, increasing the frequency of force freezes.

- Abort the robot procedure and proceed with traditional tools if the ROBODOC Surgical Assistant System malfunctions.

- Do not press the red emergency **STOP** button on the pendant unless the **PAUSE** button fails to stop the robot. It is easier to resume the procedure after pausing.

- Do not install any of the removable components while they are still warm from the autoclave; all components must be cooled to room temperature before installation.

- Do not overtighten any of the removable components.

- During digitizing, ensure that the probe tip and sterile interface remain securely attached and do not loosen when reorienting the probe. A loose probe may cause errors in point collection.

- Handle the digitizing arm with care at all times; the arm is a delicate measurement instrument.

- Ensure that the distal recovery marker is stable and has bicortical contact or engagement.

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- Ensure that the proximal recovery marker is stable and positioned so that it will not interfere with the cutter.
- Ensure that the recovery markers are properly digitized.
- Before leaving the robot unattended, be sure to turn off power to the arm by pressing the red Stop button on the pendant or the Emergency Power Off button on the Control Cabinet.
- Do not use extension cords to plug in any of the ROBODOC components.
- Disconnect nitrogen gas supply cutter hose to robot base connection when changing cutters.
- For the anterolateral and posterolateral approaches, install the robot extension arm in the middle of the fixator mounting block to ensure a rigid connection during surgery.

Adverse Effects

- The same risks and adverse effects associated with standard THA are present with ROBODOC assisted surgeries, including pain, blood and bone loss, femoral fracture, infection, anesthetic reaction, soft-tissue damage, and possibly death.
- In a small percentage of DigiMatch cases, probing the distal region of interest (ROI) on the femur and installation/removal of the distal motion recovery post may cause unexpected blood loss, infection and delayed healing, soft-tissue damage, stress fracture, and/or pain.

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Hardware Components

The EN60601 classification for the system is Class I, Type B. All of the components, except the robot arm, are designed for continuous use.

- A five-axis Surgical Robot with force sensor, bone motion monitor, base, and digitizing arm.
- An OR Monitor, which displays the screens that guide the surgeon through all robotic procedures and provides visual feedback during the automated femoral preparation process.
- A Control Cabinet upon which the OR Monitor is mounted that contains the robot control computer, real time monitor computer, tape drive, power modules for robot motors, and other electronic components.
- A femoral fixator for bone immobilization.
- Hand-held pendant for controlling the robot and selecting options from the OR Monitor.
- Non-sterile diagnostic fixtures for start-up procedures that verify system integrity.
- Probes for performing diagnostics, digitizing points during DigiMatch surface registration, and finding locator pins during locator-pin surgeries.
- Cutter drive assembly with high-speed surgical cutting tools for femoral canal preparation.
- Specialized tools and gauges for procedures such as verifying cutter installation.

NOTE: See Appendix D for a complete list of accessories and detachable components with ISS part numbers.

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Physical Specifications

The ROBODOC Surgical Assistant consists of two main physical components - the Surgical Robot and the Control Cabinet.

Surgical Robot (Arm and Base)

Weight	352 kg	(774 lbs)
Length	98 cm	(38.5 in)
Width	79 cm	(31.0 in)
Minimum Height	194.5 cm ± 0.5	(76.5 in)
Maximum Height	228.5 cm ± 0.5	(90.0 in)

Control Cabinet

Length	91 cm	(36 in)
Width	74 cm	(29 in)
Height (including OR Monitor)	189 cm	(74.5 in)
Weight (including OR Monitor)	306 kg	(674 lbs)

Electrical Specifications

Power Requirements	115 VAC at 10A or 230 VAC at 5A
Frequency	50 or 60 Hz

Environmental Conditions

Operating	
Temperature	5 to 30° C (40 to 86° F)
Humidity (Non-condensing)	30 to 80 % Relative Humidity
Atmosphere	700 hPa to 1060 hPa
Transportation & Storage	
Temperature	-5 to 65° C (13 to 150° F)
Humidity (Non-condensing)	10 to 90 % Relative Humidity
Atmosphere	700 hPa to 1060 hPa

Electrical Power Requirements

Slow-acting 10A @ 230V Circuit Breaker

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Pneumatic Requirements

Nitrogen Pressure	8 ±1 Bar
Nitrogen Flow Rate	8 ±1 L/S

Robot Accuracy

Implant Placement Accuracy

±2.0 mm	Along the axis of the bone
±1.0 mm	In the plane perpendicular to the bone axis

Implant Cavity Accuracy

±0.4 mm	Accuracy of cross-sectional dimensions

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Procedural Overview

This section summarizes the process for performing THA with the ROBODOC Surgical Assistant.

CT Scan

The patient is CT scanned according to the ISS protocol for the specific scanner and registration technique (DigiMatch). The CT scan will provide input to ORTHODOC. Protocols for performing CT scans on ROBODOC patients are provided in the *U.S. Edition* of the *ROBODOC Preoperative Protocols* manual.

ORTHODOC Preoperative Planning

ORTHODOC transforms patient CT data into three-dimensional computerized images of the complete bone. The surgeon views and manipulates these images, along with implant images, to select an implant and graphically depict its placement within the femur. When the implant image is optimally positioned within the bone image on the computer screen, the surgeon saves the data on a transfer media device such as a CD.

The preoperative planning procedure also includes developing and generating a surface model using the DigiMatch module. This data will be used to guide and orient the robot in three-dimensional space during surgery.

The ORTHODOC system is described in the *U.S. Edition* of the *ORTHODOC User Manual.*

Preparing the Robot for Surgery

A technician prepares the robot for surgery by moving it into the operating room, connecting the cables, and turning the power on. Then, the OR Monitor guides the technician through loading the patient data tape and startup diagnostics by displaying a series of prompts. The technician interfaces with the robot and responds to the prompts via a hand-held control device called a *pendant*.

A sterile technician drapes the robot arm, robot base, digitizer, bone motion monitor, and pendant. He or she then attaches the cutter drive and the extension arm for the femoral fixator, and performs sterile diagnostics.

The surgeon verifies the patient data (name, operative side, type of implant, etc.), which were loaded from a tape cartridge. Then, the patient is anesthetized.

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Surgical Protocol for DigiMatch Cases

The surgeon begins the operation by exposing the femur in the normal manner. He or she then performs a femoral neck osteotomy according to an ISS protocol for the selected implant and DigiMatch registration technique.

The surgeon clears soft tissue to facilitate digitization of surface points, secures the patient's leg in the femoral fixator, sets soft-tissue retractors, and installs two motion recovery posts.

The surgeon orients the robot by guiding the digitizing probe to specific locations on the bone surface. The robot control computer compares the digitized points to the coordinate locations contained in the ORTHODOC file to determine the position of the femur and the intended cavity. When surface registration is complete, the surgeon digitizes the motion recovery posts to ensure that the procedure can be resumed in the event that bone motion occurs.

The surgeon replaces the digitizing probe with a cutter. A technician connects the gas and irrigation supply lines. The surgeon guides the cutter to a position near the top of the femur and initiates cavity preparation with the pendant. While the robot cuts the cavity, the surgeon watches the OR Monitor and monitors the procedure to ensure continuous irrigation of the area around the cutter. The OR Monitor shows the progress of the robot as it machines the cavity. The surgeon can pause or stop cavity preparation at any time by pressing a button on the pendant.

When cavity preparation is complete, the robot arm withdraws from the femoral canal, the surgeon removes the femoral fixator and bone motion monitor, and a technician moves the robot away from the OR table. The surgeon prepares the acetabulum and installs the acetabular cup. Then, the surgeon inserts the implant and finishes the procedure in the normal fashion.

Postoperative ROBODOC Maintenance

A technician powers off the ROBODOC equipment, removes and discards the sterile drapes, folds the robot arm into travel position, lowers the robot base, disconnects the cables, disassembles the removable parts for cleaning and sterilization, and changes the diffuser and the motor safety seal.

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Disposal of Waste

Follow hospital procedures, local regulations, and national laws when disposing of consumables and devices.

Some consumables may be soiled with biological hazards after use. Take appropriate measures to assure safe handling of these materials.

Do not reuse single-use items (e.g., drapes, irrigation sets, cutters and locator pins).

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Safety Features

The ROBODOC Surgical Assistant has many features to ensure patient safety and cavity preparation accuracy.

The robot arm is equipped with a force sensor that automatically pauses cutting and robot motion if the force applied by the cutter exceeds a certain limit. If the femur slips or moves during surgery, the bone motion monitor pauses cutting action and robot motion. Startup diagnostics verify the accuracy of the robot arm, wrist kinematics, force sensor, bone motion monitor, and digitizing arm.

Redundant position sensors continuously monitor the position of the arm and crosscheck one another. Internal mechanisms constantly monitor the position of the robot arm and pause cutting if the cutter strays outside a predefined "safety envelope" that is based on the geometry of the intended implant. Cutting tool control by the application software ensures that the cutter receives power only in the absence of error conditions.

If any of these safety systems detects error conditions, special screens on the OR Monitor notify the surgeon and OR team. The pendant provides push-button stop and pause functions in case of emergency, and the system requires the surgeon to initiate all robotic actions.

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Chapter 2

WORKING WITH THE ROBOT

Introduction

This chapter provides both surgeon and technician with information on interacting with the robot. It explains how to respond to prompts and select menu options from the OR Monitor, use the pendant, guide the robot arm and digitizing arm, move and adjust the robot base, install tools, use Pendant Pause menus, and operate the robot safely.

Before performing or assisting in a ROBODOC surgery, everyone who interacts with the robot should be familiar with the fundamental procedures described in this chapter.

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User Interface

The ROBODOC user interface includes menu screens, prompts, informational messages, and graphical images that appear on the OR Monitor. It also includes a hand-held control device, called a pendant. A sterile drape is provided that allows the surgeon to use the pendant during surgery.

This section explains how the system communicates with the user via the OR Monitor and how the user responds by performing required actions and by pressing buttons on the pendant.

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OR Monitor

The OR Monitor guides the surgeon and technician through each procedure by displaying a series of screens that prompt them to perform the next required action. Some screens provide other options such as reorienting the tool tip.

The surgeon and technician press pendant buttons to signal the system that actions have been performed. Figure 2-1 shows an example of an OR Monitor screen.

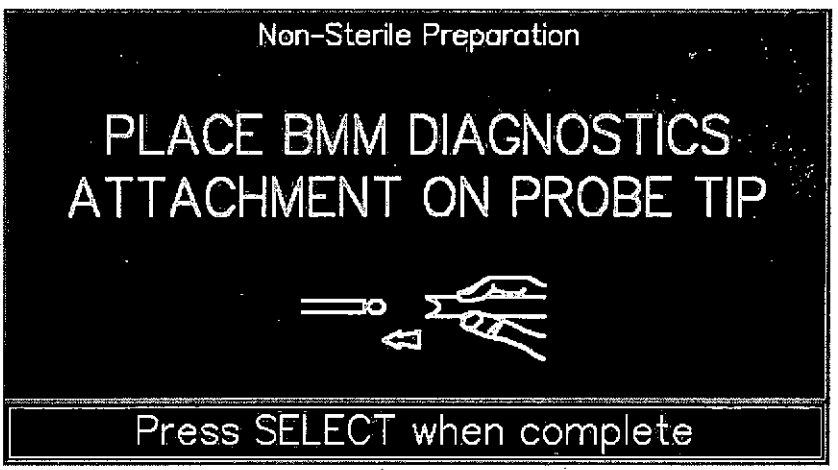

Figure 2-1. An OR Monitor Screen

During robotic cavity preparation, the OR Monitor displays a graphical representation of the cutting procedure. The real-time monitor (RTM) computer creates this image using CT data and computations based on planned implant placement and tool-tip movement. The graphical image enables the surgeon to visually monitor the femoral preparation process.

Pendant

*A pendant is a hand-held control device for operating the robot. It is held in the palm of the hand with the red **STOP** button near the user's wrist.*

A ROBODOC pendant has five buttons, labeled with their respective functions. The user responds to prompts and selects options from the OR Monitor by pressing the buttons. The pendant also enables the user to pause or power off the robot motors at any time, and to raise or lower the base when prompted to do so.

The technician performs non-sterile setup and diagnostic procedures. When the robot is moved to the OR table, the OR Monitor prompts the technician and surgeon to cover the pendant with a sterile surgical drape. The surgeon then assumes control of the robot via the pendant.

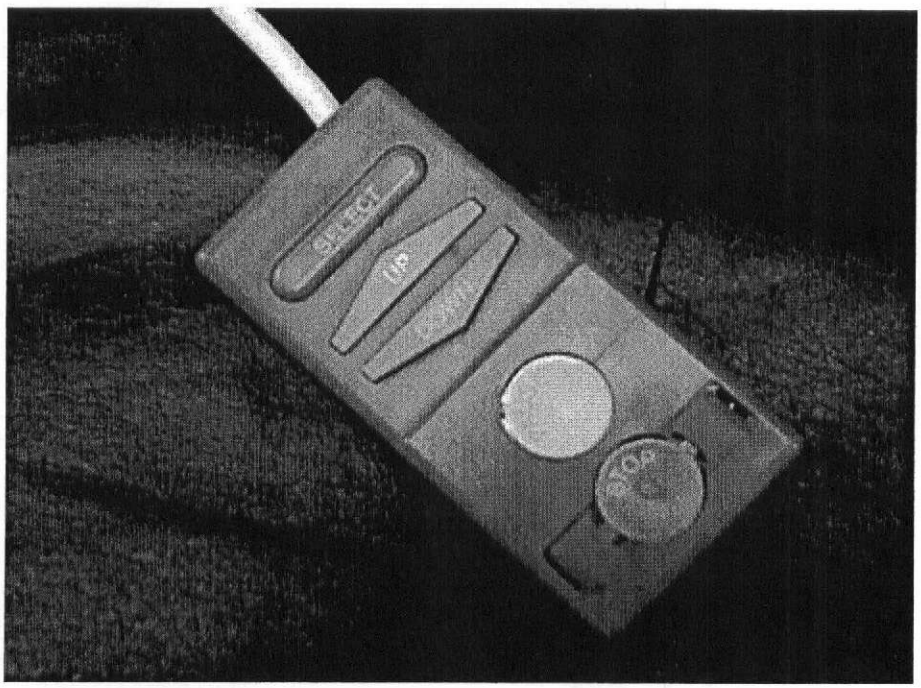

Figure 2-2. A ROBODOC Pendant

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Pendant Buttons

The ROBODOC pendant has the following five buttons:

- **SELECT.** The **SELECT** button is the green rectangle at the top of the pendant. Use it to select the currently highlighted option or to indicate that an action requested by an OR Monitor prompt is complete. After you press **SELECT**, the OR Monitor advances to the next screen.

  You must depress the **SELECT** button for 1-2 seconds until the white box surrounding the desired option changes color. The **SELECT** function cannot be implemented until the box becomes bright green and the button is released. If you release the button before the box brightens, it will have no effect. If you inadvertently press and hold **SELECT**, you can cancel the action by pressing **UP** or **DOWN** before releasing **SELECT**.

- **UP.** The **UP** button is the first blue button. Quickly press and release it to move the highlighted rectangle up to the previous option on a menu screen or hold it down to scroll up through the menu. When the OR Monitor displays a base height adjustment screen, press and hold the **UP** button to raise the base.

- **DOWN.** The **DOWN** button is the second blue button. Quickly press and release it to move the highlighted rectangle down to the next option on a menu screen or hold it down to scroll down through the menu. When the OR Monitor displays a base height adjustment screen, press and hold the **DOWN** button to lower the base.

- **PAUSE.** The **PAUSE** button is the round yellow button. Use it to pause the robot. When the robot is paused, the OR Monitor provides several options, which usually includes one for resuming the interrupted procedure. See the last section in this chapter for a detailed description of Pause options and reasons for pausing the robot.

- **STOP.** Press the round red **STOP** button in case of emergency, or if the **PAUSE** button fails. **STOP** powers off the robot motors.

Positioning the Robot Arm

This section explains how to guide the robot arm and reorient the tool tip, describes the standard arm positions from which the robot begins certain actions, and discusses automated arm movements.

Several times during a ROBODOC surgery, the OR Monitor prompts the user (surgeon or technician) to guide the robot arm to a specific position. At other times, the user may decide that the arm needs to be repositioned for clear and easy access to the starting point for a procedure or to avoid contact with an obstacle in its path.

Before the arm can be moved, the robot must be in Guide Mode. Whenever the OR Monitor prompts the user to guide the arm, the robot is already in Guide Mode. At other times, the user can activate Guide Mode from a Pause menu, as described later in this chapter.

The robot arm moves only in response to force applied *below* the force sensor, which is the blue circular component located immediately above the cutter drive or diagnostic assembly. To execute smaller, precise movements (e.g., during diagnostics or locator pin finding), the user should grasp the shaft of the tool as shown in Figure 2-3.

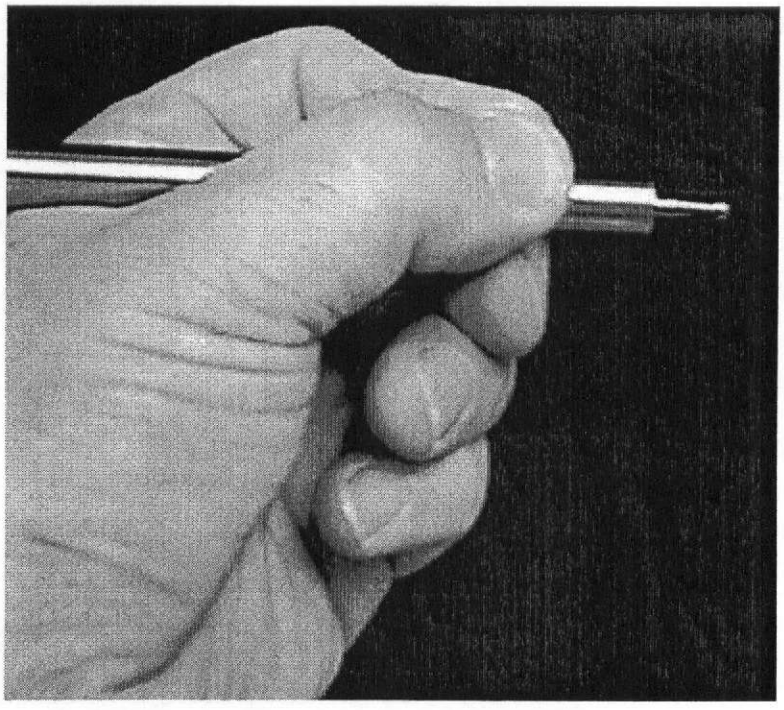

Figure 2-3. Hand Position for Small Precise Movements

For larger movements, it is more efficient to hold the cutter drive assembly while pushing or pulling. Figure 2-4 illustrates where to hold the robot when guiding the arm a long distance.

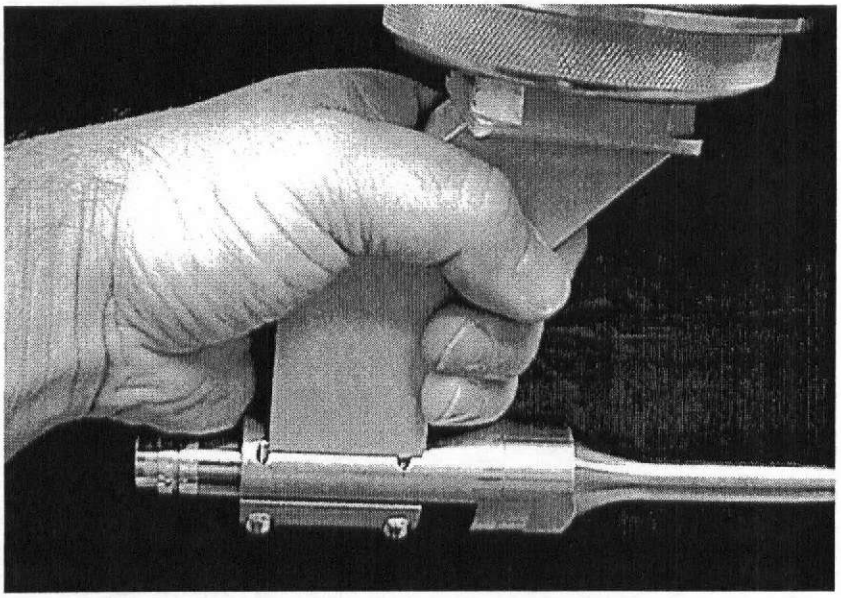

Figure 2-4. Hand Position for Long Movements

To guide the robot arm, gradually and evenly apply more force as you push or pull. The robot steadily gains momentum and provides less resistance as force is applied. Jerky movements or the sudden application of too much force may cause a *force freeze* or *force EPO* (Emergency Power Off). These conditions occur when the force sensor pauses or stops the robot.

Whenever the OR Monitor displays a prompt to guide the ball probe to a fixed object (e.g., a post on the diagnostics fixture or the center of a locator pin head), the probe does not need to actually contact the object. It is preferable to place the probe 1 to 2 millimeters above the object. The robot automatically moves in to sense the exact location of the object.

The robot has two modes for manual guidance: *Hand Guide* and *Guide Along Tool Axis*. The following sections describe these modes in detail.

Hand Guide

Hand Guide is the default mode for the robot arm. It enables a full range of motion, including tool tip reorientation. When Guide Mode is activated automatically by the system or by user selection of the *Hand Guide* option from a Pause menu, the user can move and reorient (rotate) the tool tip in any direction. Whenever the system is in Guide Mode, the OR Monitor provides the menu options ENABLE REORIENTING and DISABLE REORIENTING. During

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certain procedures (e.g, kinematic diagnostics or cutter drive installation verification), Guide Mode is activated, but reorientation is not allowed.

Guide Along Tool Axis

Guide Along Tool Axis mode restricts the arm to forward and backward movement along the current axis of the tool. It enables the tool tip to move forward or backward in a straight line. In this mode, the robot responds only to forces along the tool axis, ignoring forces in any other direction and preventing tool tip reorientation.

This mode is useful when removing the cutter from a prepared or partially prepared cavity. It enables the surgeon to pull the cutter straight out without contacting bone at the edge of the cavity.

Reorienting the Tool Tip

Occasionally, the surgeon must reposition or *reorient* the tool tip. To reorient the probe or cutting tool, grasp the tool tip and slowly rotate it to the desired angle.

For certain procedures, the robot automatically reorients the tool tip, as described in the "Automated Arm Movements" section in this chapter.

Clear Area

A *clear area* is an unobstructed space away from the patient, robot base, and fixtures, with adequate room to reorient the tool tip in any direction. Prior to certain procedures and automated movements of the tool tip and robot arm, the OR Monitor prompts the user to move the robot arm to a clear area.

Tool Change Position

Tool change position is a configuration of the robot arm where the tool tip is in a clear area with access for the surgeon or technician to install a tool. At appropriate times, the OR Monitor prompts the user to move the robot arm to tool change position. When the user signals that the robot is in tool change position by pressing the **SELECT** button on the pendant, the tool tip automatically tilts upwards to facilitate the tool change.

Home Position

For the robot to initialize its internal coordinate system, the robot arm must move to a configuration called *home position*, as shown in Figure 2-5.

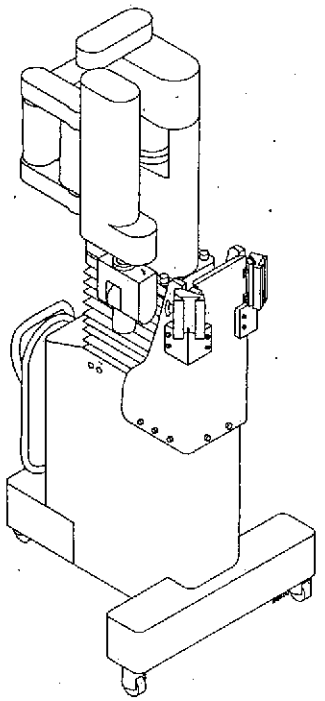

Figure 2-5. Home Position

In home position, the arm must be folded back toward the base in a "right elbow" configuration. The robot automatically moves to the exact home position after the elbow is manually oriented to an appropriate starting position or "approximate home position."

Before the arm moves to home position, the base must be homed by lowering or raising it in response to a prompt on the OR Monitor.

⇨ **To move the arm to approximate home position:**

1. Move the arm to a *right elbow* configuration.

   In a right elbow configuration, the arm is folded back toward the base like a right elbow bent with the forearm near the chest.

2. When prompted to do so, either raise or lower the base.

3. Twist the pitch axis casing, as described in the following section.

Twisting the Pitch Axis Casing

Before raising the robot base in preparation for homing and after most tool changes, the OR Monitor prompts you to twist the pitch axis casing.

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⇨ To twist the pitch axis casing:

1. While facing the robot, grasp the pitch axis casing with both hands.
2. Firmly twist the pitch axis casing by pushing with your right hand and pulling with your left as indicated by the graphic on the OR Monitor screen. (The "L" and "R" on the graphic indicate where to grip the casing, but the casing itself is not labeled.)
3. Press **SELECT**.

   If the screen is re-displayed, the pitch axis casing was not twisted properly and you must repeat this procedure.

NOTE: Twisting the pitch axis with too much force will cause an encoder EPO. If this occurs, select the option to continue and turn motor power back on. Use less force the next time.

Automated Arm Movements

For safety reasons, automated movements of the robot arm are relatively limited. When the robot arm must move a significant distance, the OR Monitor prompts the user to manually guide the robot arm. Then, if the arm needs to reach a specific destination such as the center point of a locator pin or the start position for cavity preparation, it automatically moves a short distance to the target location.

Before beginning an automated movement, the OR Monitor informs the user of the forthcoming action and requires the user to initiate the action by selecting the **CONTINUE** option. During the movement, the OR Monitor displays the "DO NOT TOUCH" warning. The user should watch automated motions and be ready to pause the robot if the arm moves toward an obstacle. Then, the user can either move the obstacle or guide the arm to a new clear position and restart the procedure.

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Positioning the Robot Base

This section explains how to raise and lower the robot base, safely move the robot, and position the robot base by the OR table.

The robot arm is mounted on an adjustable column on the robot base. When enabled by the application software, the **UP** button on the pendant raises the base and the **DOWN** button lowers it. **UP** and **DOWN** buttons on the back of the base will also raise and lower the base. The base is on wheels and has steering and transport handles in the rear for ease for transportation. Figure 2-6 shows the various mechanisms for positioning the base and locking it in place.

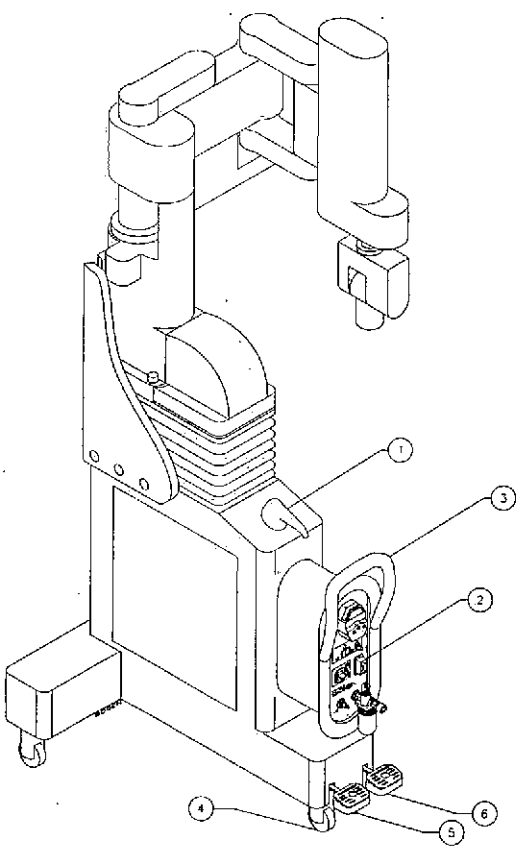

Figure 2-6. Base Transport and Adjustment Mechanisms

① Crank handle for steering wheels

② UP and DOWN buttons

③ Transport handle

④ Wheel

⑤ Brake locking pedal

⑥ Brake release pedal

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Adjusting Base Height

The adjustable column on the robot base can be raised or lowered to facilitate diagnostic procedures and positioning near the OR table. The system requires base height to be adjusted several times during startup procedures, and the height can sometimes be adjusted at the technician or surgeon's discretion. During cavity preparation, digitization of surface points, or locator pin finding, the software prevents the base from being adjusted.

The base has a toggle switch for height adjustment. Push **UP** or **DOWN** on the switch for the desired direction of travel. The **UP** and **DOWN** buttons on the pendant can also be used when a base height adjustment screen is displayed. To adjust the height of the base with the pendant, depress and hold the appropriate button until the base is in the desired position.

During postoperative maintenance procedures, transport, and storage, the base should be in the lowest position.

Moving the Robot Base

⇨ **To move the robot long distances:**

1. Put the robot in *transport position*:
   - Detach all removable fixtures.
   - Adjust base height to its lowest position.
   - Fold the arm inward into a compact configuration.
2. If the wheels are locked, release the brake by depressing the brake release pedal (Figure 2-7).
3. Push the robot using the transport handle on the back of the base.

Storing the Robot

⇨ **To store the robot after surgery:**

1. Leave the robot arm and base in *transport position* (base in the lowest position and arm folded in a reverse elbow).
2. Lock the base in place by pumping the brake locking pedal three times (Figure 2-7).

   Fully depress the pedal each time. The pedal will return to Up position when not depressed.

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NOTE: This brake was implemented on robots with serial numbers above 2028. To lock the brake on older models, depress the brake locking pedal only once; the pedal will remain depressed when the brake is engaged.

Positioning the Robot at the OR Table

⇨ To position the robot at the OR Table:

1. If the wheels are locked, release the brake by depressing the brake release pedal (Figure 2-7).

   Monitor the movement of the arm and cutter drive assembly to avoid contact with the patient and other equipment.

2. Push the robot using the rear transport handle.

3. Steer the robot using the steering handle.

4. Lock the base in place by pumping the brake locking pedal three times.

   Fully depress the pedal each time. The pedal will return to Up position when not depressed.

   NOTE: This brake was implemented on robots with serial numbers above 2028. To lock the brake on older models, depress the brake locking pedal only once; the pedal will remain depressed with the brake is engaged.

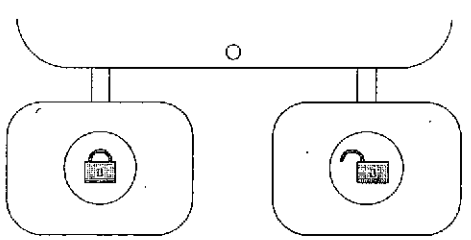

Figure 2-7. Brake Locking Pedal (left) and Brake Release Pedal (right)

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Verifying Motor Installation

The motor must be cleaned, sterilized, and installed as described in Chapter 9.

The installed motor must be compatible with the desired cutter. Air motors are compatible with all cutter sizes. Electric motors come in two sizes:

P/N 103333	1/8" diameter shaft	Natural metallic collet
P/N 103426	3/32" diameter shaft	Colored collet

To distinguish between the two electric motor sizes, check the color of the collet. The collet on a 1/8" motor is uncolored; the collet on a 3/32" motor is colored.

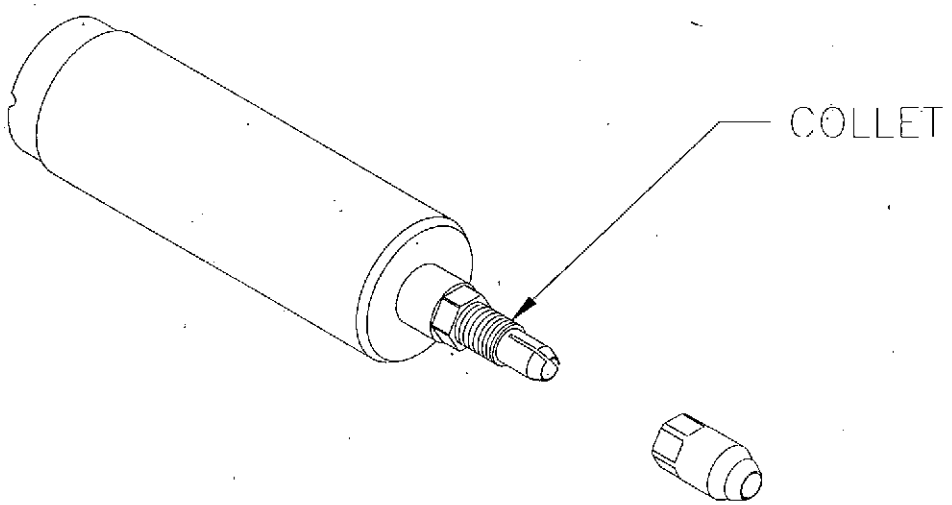

Figure 2-8. Motor Collet Color Indicates Motor Size

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Installing Probes and Cutters

A prompt on the OR Monitor indicates when a new tool needs to be installed. The tools include:

- **Cutters.** Used for cavity preparation.
- **Digitizing probes.** Used for digitizing surface points.
- **Ball probes.** Used for locator pin finding.
- **Sleeves.** A specific sleeve is used to hold each probe or cutter in the cutter drive assembly.

The OR Monitor uses part numbers to identify each probe or cutter to be installed. Make sure that the part number on the tool corresponds to the part number displayed on the OR Monitor.

Installing Tools

⇨ To install a tool in the tool tip on the robot arm:

The following instructions pertain to all tools. For small cutters (3/32" diameter), you must first install a spacer and collet nut as described in the next section.

1. Move the robot arm to an unobstructed clear area with room for the tool to reorient and within reach of the surgeon or sterile technician.

2. When prompted to do so, press **SELECT** to indicate that the arm is in the clear area.

   The robot automatically moves the tool tip upward as shown in Figure 2-9. Do not touch the robot arm while it is moving.

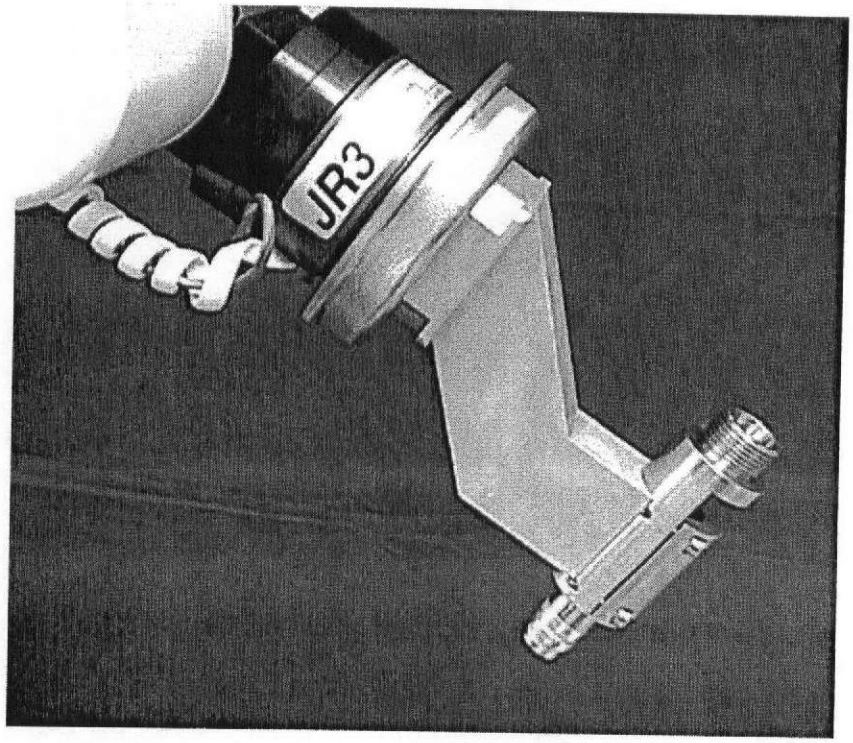

Figure 2-9. Tool Installation Position

3. Thread the bearing sleeve onto the threaded end of the cutter drive assembly.

4. Manually tighten the bearing sleeve.

5. Insert and fully seat the appropriate probe or cutter.

   Compare the etched part number to the part number displayed on the screen to ensure that you have the right tool.

6. For air motors, use the small rod and wrench set to secure the tool as shown in Figure 2-10:

- Insert the rod through the hole in the bottom of the collet attachment, positioning it perpendicular to the bearing sleeve and midway between the sides of the collet.
- Position the wrench to turn the motor collet nut, which is located immediately above the hole.
- Turn the wrench clockwise and the rod counterclockwise to tighten, but do not apply too much torque to the rod.

NOTE: Applying too much torque or tightening the collet nut with the wrench when the rod is against the side of the collet may break the rod. When the rod begins to bend, the collet nut is secure.

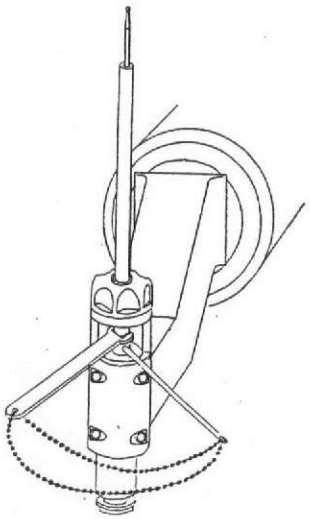

Figure 2-10. Securing the Tool With Rod & Wrench Set on Systems With Air Motors

6. For electric motors, use the small open-end wrenches to secure the tool as shown in Figure 2-11:

- Place the 9/32" wrench on the hex of the motor attachment, positioning it perpendicular to the bearing sleeve and midway between the sides of the collet.
- Position the 1/4" wrench to turn the motor collet nut, which is located immediately above the motor hex.
- Turn the upper 1/4" wrench clockwise and the lower 9/32" wrench counterclockwise to tighten, but do not apply too much force.

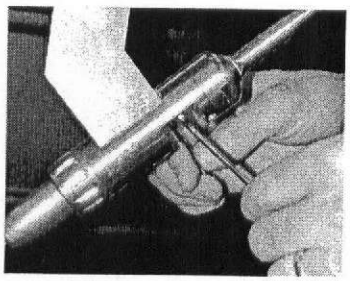

Figure 2-11. Securing the Tool With 1/4" and 9/32" Wrenches on Systems With Electric Motors

NOTE: Applying too much torque may damage the collet. Only a small amount of force (2 kg or 4 lb) is required to secure the nut.

7. Securely tighten the bearing sleeve with the large 1-1/8" wrench, as shown in Figure 2-12.

8. If prompted by the OR Monitor, twist the pitch axis casing as described earlier in this chapter.

9. Press **SELECT**.

   For all cutters and probes, the OR Monitor displays a screen requesting that tool installation be verified.

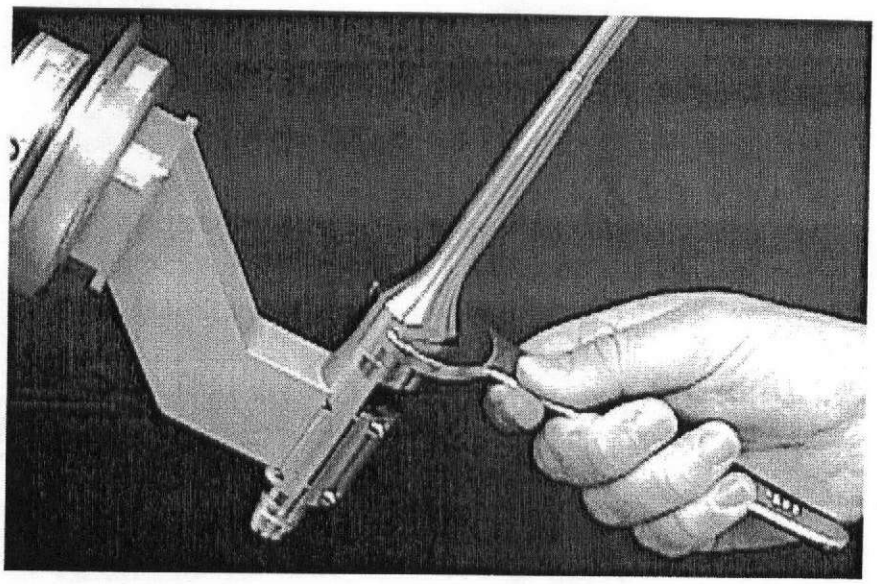

Figure 2-12. Tightening Sleeve with Wrench

Verifying Installation

Follow the instructions in this section to verify that the tool is fully seated. Be sure to use the appropriate installation verification gauge.

⇨ To verify cutter installation:

1. Slide the verification gauge between the cutter and the bearing sleeve so the bottom of the gauge rests on the bearing sleeve.

2. Slide until the gauge stops (as shown in Figure 2-13).

   If the gauge passes the first notch (as shown in Figure 2-14), the cutter is not fully seated and must be reinstalled.

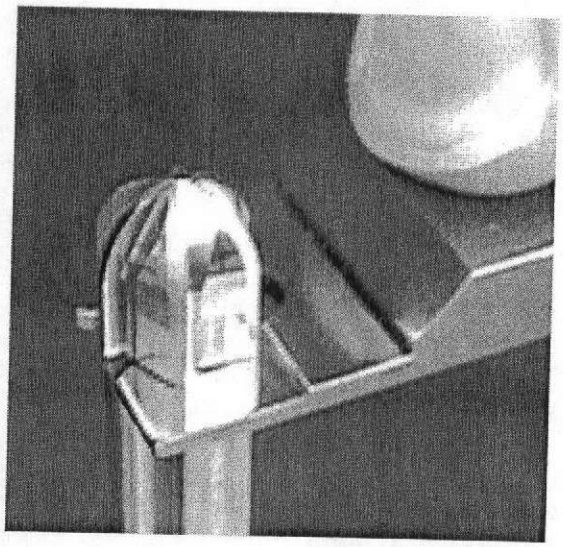

Figure 2-13. Verifying Correct Cutter Installation

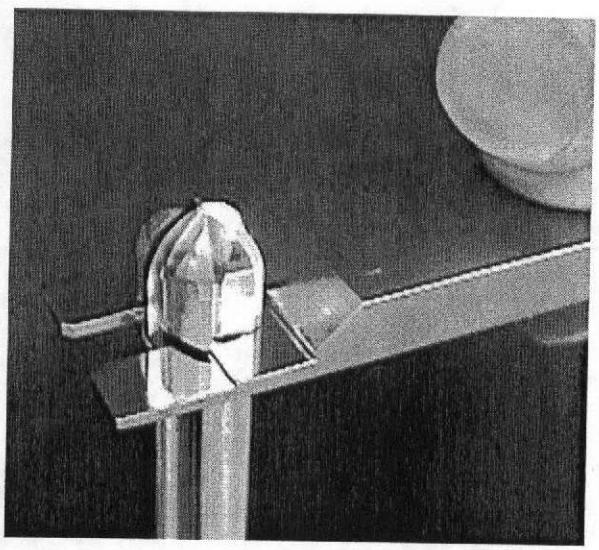

Figure 2-14. Incorrect Cutter Installation

⇨ To verify ball probe installation:

1. Slide the long gauge (labeled "L") over the probe so the bottom of the gauge rests on the sleeve (as shown in Figure 2-15).

2. If the gauge does not touch the sleeve (as shown in Figure 2-16), the probe is not fully seated and must be reinstalled.

3. Repeat this procedure with the short gauge (labeled "S").

   This gauge should bottom out on the probe ball without touching the sleeve (as shown in Figure 2-16).

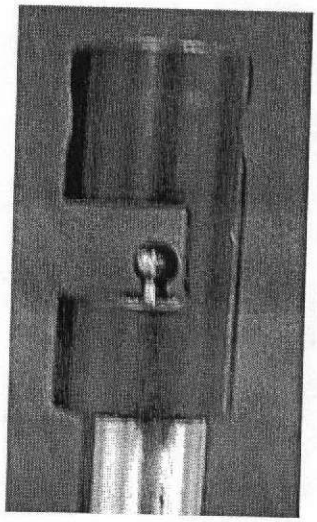

Figure 2-15. Correct for Short Gauge/Incorrect for Long Gauge

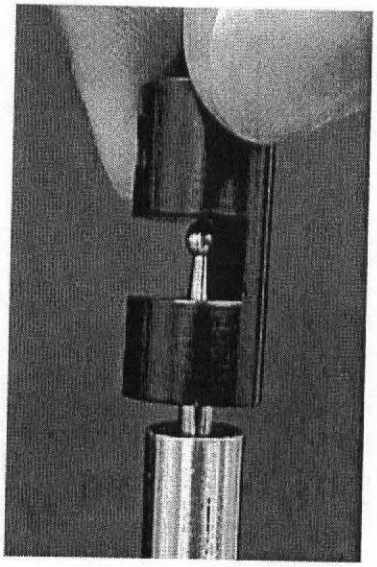

Figure 2-16. Incorrect for Short Gauge/Correct for Long Gauge

⇨ To install a digitizer probe:

1. Hold the end of the digitizing arm with one hand and the probe with the other, as shown in Figure 2-17.

2. Screw the probe onto the digitizing arm.

   Securely bottom out the probe; a loose probe may move, causing digitizer diagnostics to fail.

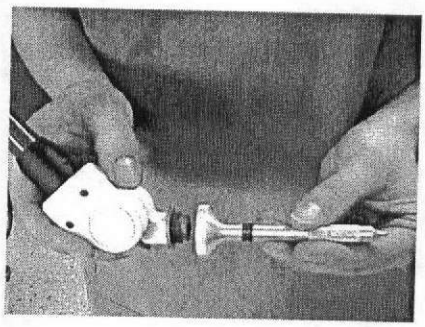

Figure 2-17. Installing the Non-Sterile Digitizer Probe

Installing a Spacer and Collect Adapter for Small Cutters

Perform this procedure before installing 3/32" diameter bearing sleeves and cutters.

⇨ To install the air motor and associated hardware:

1. Remove the four cap screws on the motor clamp with the 3 mm hex wrench, as shown in Figure 2-18:

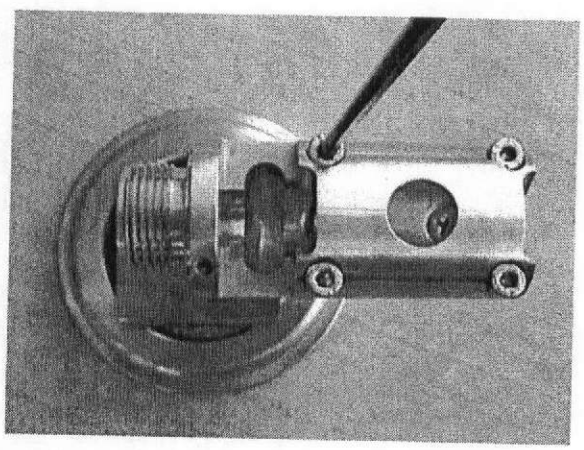

Figure 2-18. Removing Cap Screws From Motor Clamp

2. Remove the motor clamp.
3. Carefully pull the motor out of the motor holder.
4. Remove the collet nut by unscrewing it in a counterclockwise direction as shown in Figure 2-19:

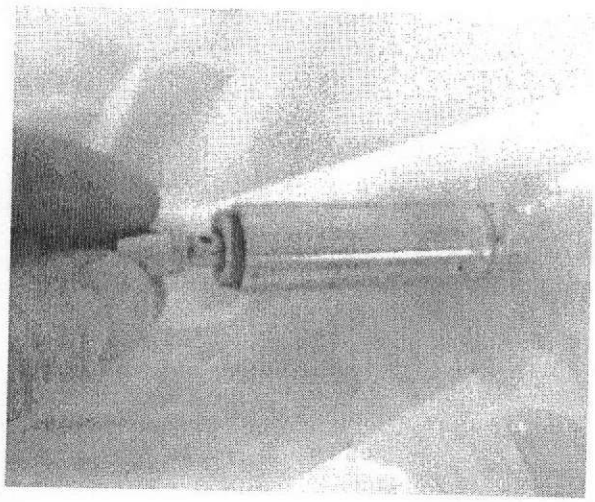

Figure 2-19. Removing the Collet Nut

5. Install the motor spacer as shown in Figure 2-20:

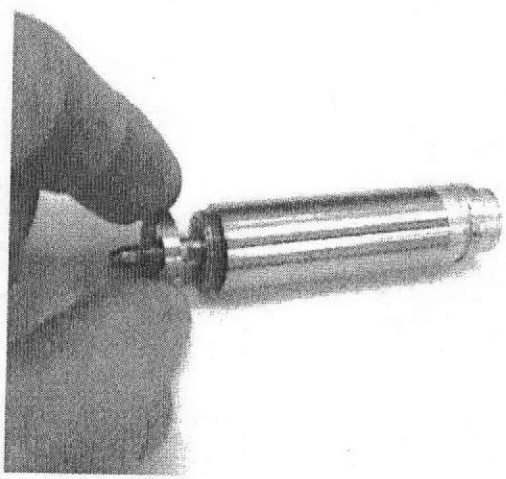

Figure 2-20. Installing the Motor Spacer

6. Insert the collet adapter into the motor as shown in Figure 2-21:

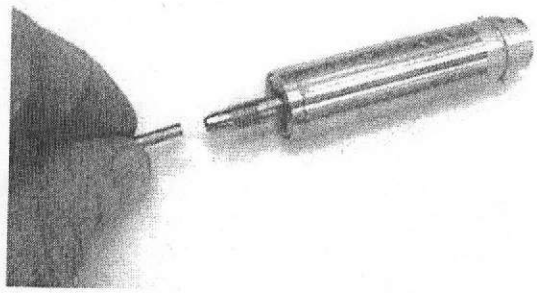

Figure 2-21. Inserting the Collet Adapter

7. Carefully install the collet nut, as shown in Figure 2-22.

   Do not over-tighten the collet nut before inserting a cutter into the bearing sleeve. Over-tightening without a cutter will damage the collet adapter and motor.

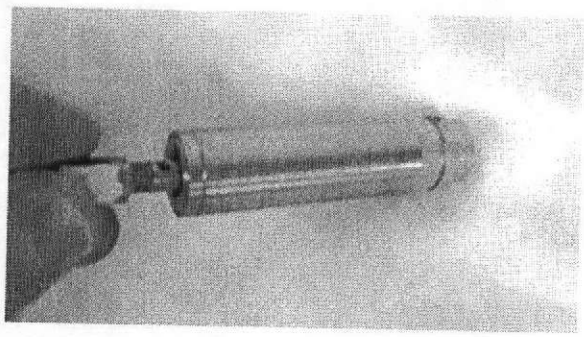

Figure 2-22. Installing the Collet Nut

8. Insert the motor into the motor holder.

   Be sure to fully insert the motor. If the motor is not fully inserted, probes and cutters cannot be properly seated.

9. While holding the motor in place with the motor clamp, evenly tighten the four cap screws on the motor clamp.

   Do not over-tighten the cap screws because over-tightening may damage the motor.

NOTE: After the surgical procedure, remove the collet and spacer before cleaning. Discard the single-use collet. Sterilize and store the spacer in a sterile tray.

DJA x01447

Coaxial Wall Air Supply System

Systems with air motors require a coaxial wall air supply system to power the cutting tool. This section provides instructions for connecting and disconnecting the system.

The filter element inside the filter box must be replaced after each use. Worn O-rings must also be replaced. For instructions on replacing these components, see Chapter 9.

Figure 2-23 illustrates the system:

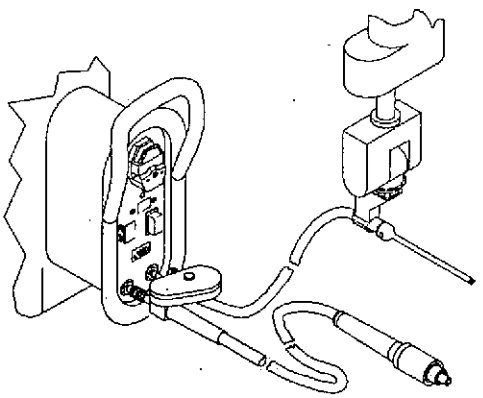

Figure 2-23. Coaxial Wall Air Supply System

⇨ To connect the air supply:

1. Connect the black coaxial supply hose (P/N 102471) to the robot base with the logo facing upward.

2. Connect the green Midas Rex hose to the robot base with the return air nipple facing upward.

3. Push the return air nipple on the green hose into the O-ring gland on the larger side of the filter box (P/N 102539).

   Use lubrication and a rocking motion to ease insertion.

4. Push the black supply hose into the wall air motor receptacle in the same manner.

⇨ To disconnect the air supply:

1. Remove the black supply hose from the wall air motor receptacle.
2. Remove the return air nipple on the green hose from the O-ring gland on the filter box.
3. Disconnect the green Midas Rex hose from the robot base.
4. Disconnect the black coaxial supply hose from the robot base.

Installing Electrical Cable

Systems with electric motors have cables that connect the motor to the back panel of the robot. This section provides instructions for connecting and disconnecting the cable. This procedure requires two persons: a sterile and a non-sterile technician.

The connector should be clean and dry when you perform this procedure.

⇨ To connect the cable:

1. Sterile Technician: Connect the cable to the electrical motor as shown in Figure 2-24.

   The cable connector may be rotated to fit into the motor in any of the three different orientations.

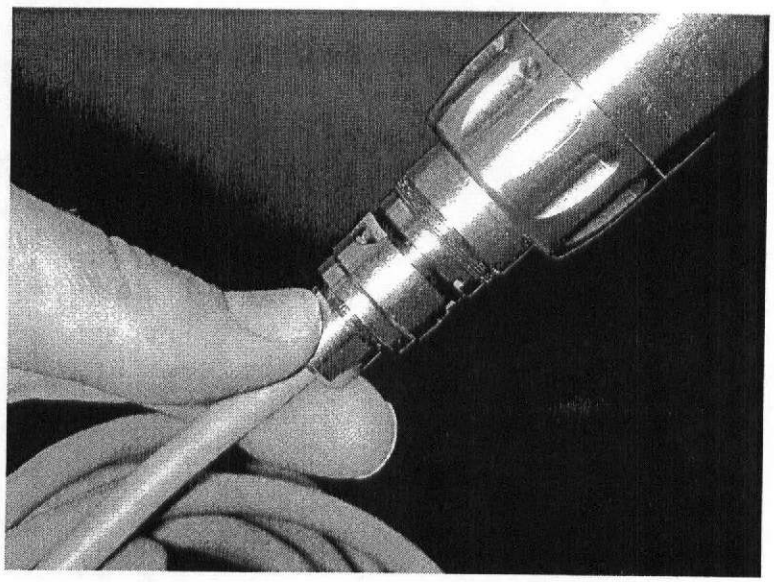

Figure 2-24. Connecting the cable to the motor

2. Sterile Technician: Tighten the collar over the connector on the motor as shown in Figure 2-25.

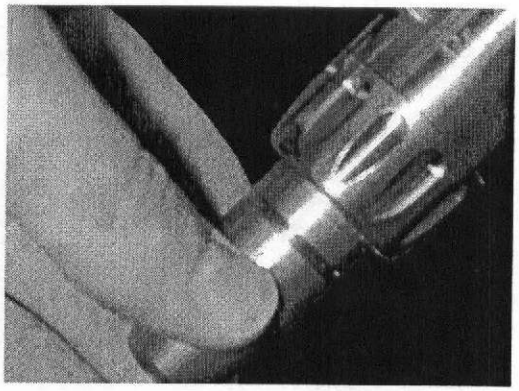

Figure 2-25. Tightening the collar

3. Sterile Technician: Hand the cable to the non-sterile technician.

4. Non-sterile Technician: Insert the other end of the cable into the electrical motor connection on the back of the robot until it latches. A fully inserted connector is shown in 2-26.

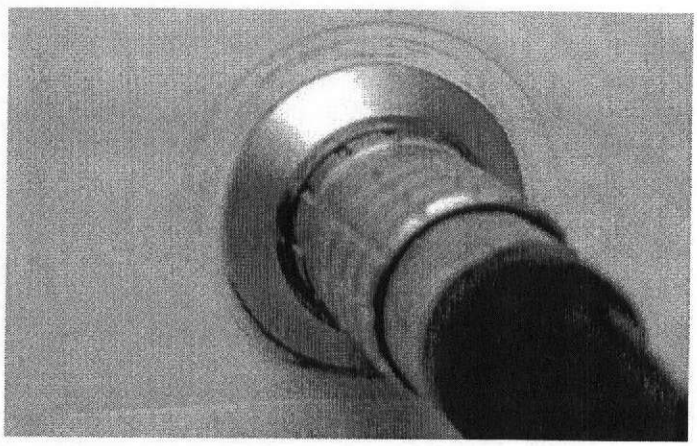

Figure 2-26. Cable Connected To Robot Base

⇨ To disconnect the cable:

1. To disconnect the cable from the robot, grasp the ribbed sleeve on the connector and pull the connector straight back out of the robot.

2. To disconnect the cable from the motor, loosen the threaded collar and pull the connector straight off of the motor.

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Pausing the Robot

Pressing the yellow **PAUSE** button on the pendant interrupts the current procedure and stops the robot.

When **PAUSE** is pressed, a Pendant Pause menu appears on the OR Monitor. The options on Pendant Pause menus vary depending upon the current status of the procedure. For example, the **Change Cutter** option only appears if a cutter is currently installed and the **Change Probe** option only appears if a probe is installed.

Pendant Pause menus provide an easy way to resume the procedure when ready. For this reason, it is almost always best to pause the robot, rather than using the red **STOP** button. If you then decide not to continue, an option on the Pendant Pause menu lets you abort the procedure.

Reasons for Pausing the Robot

There are three basic reasons for pressing the **PAUSE** button on the pendant:

1. To stop robot motion in order to perform one of the following procedures:
   - Prevent the robot arm from physically contacting an obstacle
   - Reset a retractor
   - Check or replenish irrigation fluid
   - Replenish the gas supply
   - Adjust base height
   - Remove tissue or clear debris from the femoral preparation site
   - Examine the femoral preparation site before continuing
2. To restart a procedure from the beginning.
3. To select one of the following options from a Pendant Pause menu:
   - Change Probe
   - Change Cutter
   - Adjust Base Height
   - Hand Guide Robot
   - Guide Robot Along Tool Axis
   - Abort Procedure

Pendant Pause Menus

Pressing the **PAUSE** button gives you access to a series of menu screens, each of which provides some of the options listed above. Figure 2-27 shows a sample Pendant Pause menu:

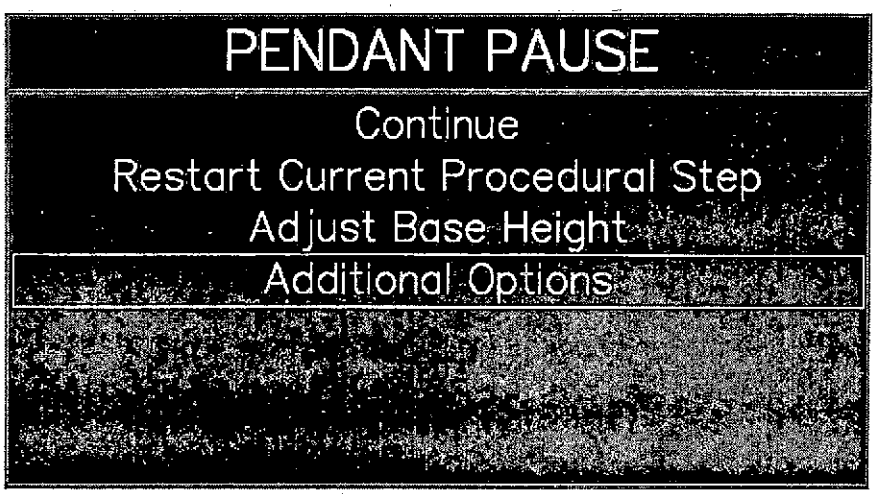

Figure 2-27. A Pendant Pause Menu

Pendant Pause menus vary depending upon the status of the procedure being performed when the menu appears. The menu shown in includes the following options:

- **Continue.** Resumes the interrupted procedure (the default option). When you select **Continue**, the screen from which the **PAUSE** button was pressed is redisplayed and, if robot motion was interrupted, it will be resumed.

- **Restart Current Procedural Step.** Restarts from the beginning of the current procedure. Select the **Restart Current Procedural Step** option if you paused the robot to restart at the beginning of a procedure, such as pin finding. The OR Monitor redisplays the appropriate screens.

- **Hand Guide Robot.** Initiates *Hand Guide* mode for manual guidance of the robot arm.

- **Adjust Base Height.** Provides options for raising or lowering the base.

- **Additional Options.** Displays a secondary pause menu. If you select **Additional Options**, the OR Monitor displays a new menu similar to the sample shown in :

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Figure 2-28. A Secondary Pendant Pause Menu

Pendant Pause Menu Options

Subsequent Pendant Pause menus vary depending upon the current status of the procedure, but each one includes some combination of the following options:

- **Abort Procedure.** Prepares the system to terminate an incomplete operation.
- **Additional Options.** Displays a secondary Pendant Pause menu similar to the example shown in .
- **Adjust Base Height.** Provides options for raising or lowering the base (displayed only when base height adjustment is allowed.)
- **Change Cutter.** Guides you through the process of changing the cutter (displayed only when a cutter is currently installed.)
- **Change Probe.** Guides you through the process of changing the ball probe (displayed only when a probe is currently installed.)
- **Continue.** Resumes the procedure and redisplays the screen that was on the OR Monitor when the procedure was paused.
- **Correct for Tool Drift.** Enables you to stop the arm if it moves without being touched while in Guide Mode.
- **Cutting Options.** Displays a menu containing options for selecting different cutting speeds based on percentages of the maximum cutting speed. The **Disable Adaptive Cutting Speed**, **Enable Adaptive Cutting Speed,** and **Go Back One Checkpoint** options are also on this menu.
- **Disable Adaptive Cutting Speed.** Causes the robot to prepare the cavity at a pre-programmed speed (displayed during cutting only).
- **Enable Adaptive Cutting Speed.** Allows the robot to accelerate or decelerate based on sensed force/hardness of bone (displayed during cutting only).
- **Go Back One Checkpoint.** Causes the robot to continue cutting from an earlier point in the cutting procedure.
- **Guide Robot Options.** Displays a menu containing four options: 1) Previous Options; 2) Hand Guide Robot; 3) Guide Robot Along Tool Axis; and 4) Correct for Tool Drift.

- **Guide Robot Along Tool Axis.** Enables you to guide the robot arm in a straight line along the tool axis.
- **Hand Guide Robot.** Enables you to guide the robot arm in any direction and reorient the tool tip.
- **Previous Options.** Redisplays the previous Pendant Pause menu. To resume the robotic procedure, you can redisplay previous Pendant Pause menus until the first one is displayed, and then select **Continue**.
- **Restart Current Cutting Step.** Restarts the cutting procedure at the last checkpoint (displayed only if the robot was paused while cutting).
- **Restart Current Procedural Step.** Resumes from the beginning of the current procedure (displayed only if the robot was paused while not cutting).
- **Restart Cutting Procedure.** Restarts the cutting procedure from the beginning (displayed only if the robot was paused while cutting).
- **Restart Kinematic Diagnostics.** Restarts the kinematic diagnostic phase (displayed only during kinematic diagnostics).

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Safety Considerations

- **Moving the robot.** Before transporting the robot to or from the operating room, lower the base and fold the arm inward. Then, push the robot by the transport handle.

- **Tool installation and verification.** Carefully install the diagnostic fixture, cutter drive assembly, and tools (probes and cutters). Use the installation verification gauges to verify that probes and cutters are properly installed.

- **Locking the base.** Lock the base in place at the OR table.

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Chapter 3

PRE-SURGICAL PREPARATION

Introduction

This chapter provides information about preparing for a ROBODOC surgery. It lists required supplies, explains how to set up equipment, and describes safety considerations. The OR staff and hospital technicians perform these procedures.

The patient must not be anesthetized until successful completion of the procedures described in this chapter and the diagnostic procedures described in Chapter 4.

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Assembling Supplies

This section describes the sterile packs and other special supplies that should be prepared for a ROBODOC surgery.

This section does not cover many of the items that are necessary for standard procedures, such as making the incision or suturing the patient. Nor does it include the instruments that may be necessary in the event that the robotic procedure must be aborted and finished manually. ISS recommends that all items necessary for a traditional surgery be readily available during ROBODOC surgeries.

The following surgical supplies (sterile and non-sterile) are suggested for use with ROBODOC:

ISS-Supplied Items

- Sterile Packs (see Appendix D for a list of sterile pack components):
  - Sterile Pack #1
  - Sterile Pack #2
  - Back-Up Pack
- Selected implant system
- Sterile, single-use ROBODOC supplies:
  - ROBODOC cutters (3)
  - ROBODOC sterile drape sets (2)
- Non-sterile ROBODOC supplies:
  - Transfer media with transfer file
  - Pendants (2)
  - ROBODOC diagnostic fixture case
  - OR table attachment for leg support fixture
  - *ROBODOC User Manual, International Edition*
  - Instrument oil

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Hospital-Supplied Items

- Sterile irrigation fluid and delivery system
- Soft-tissue retractors
- Standard surgical instruments for manual case

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Setting up the Equipment

This section describes how to set up ROBODOC equipment in the operating room.

Before setting up the equipment, determine which side the operative leg is on (left or right). Then, arrange the equipment so the robot can be easily positioned next to the appropriate side of the OR table and the OR Monitor will be visible from that side of the table.

⇨ **To set up the equipment:**

1. Position the Control Cabinet on the surgeon's side of the OR table in a location where the screen will be visible to the technician and surgeon throughout all diagnostic and surgical procedures.

2. Move the robot to the operating side of the table in an unobstructed area with adequate workspace for performing non-sterile diagnostic tests and sterile draping.

Connecting Cables and Power Cords

All of the cables and their respective receptacles are labeled. To prevent cabling problems, each connection is unique—a receptacle will not accept a connector for the wrong cable.

Before connecting cables, verify that the robot will have access to the OR table after the cables are connected and that the power switch on the Control Cabinet is off.

WARNING: Do not use extension cords because additional cords could pose a safety hazard.

⇨ **To make the cable connections:**

1. Connect the cables from the robot base to the receptacles on the back of the Control Cabinet.

2. If an auxiliary monitor will be used, plug it into the receptacle on the back of the Control Cabinet.

3. Plug the pendant into the robot base.

4. Check the force sensor cable to ensure that it is connected to the pitch axis casing.

5. Plug the power cord from the Control Cabinet into an electrical outlet.

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Powering On

⇨ **To power on the system:**

1. Turn on the main A/C power switch, located on the front of the Control Cabinet.
2. Verify that the circuit breaker on the rear of the robot base is on.
3. After a few minutes a screen will appear requesting the user to select one of two applications:
   - **Total Hip Surgery.** This option initiates the surgical procedure, from non-sterile diagnostics through femoral canal preparation.
   - **Robot Calibration.** This option initiates robot tool calibration, a routine maintenance procedure.

NOTE: If a screen does not appear, verify that the power switch on the OR Monitor is on by checking the indicator light on the OR Monitor.

Preparing the Operating Room

This section describes a variety of tasks that must be performed in preparation for a ROBODOC surgery.

⇨ To prepare the operating room:

1. Connect the coaxial air supply system to the cutter drive (see Chapter 2).
2. Set up the irrigation delivery system and verify the availability of irrigation fluid.
3. Prepare suction return containers.
4. Check the fluid level in the inline oiler on the regulator.
5. If the lubricant reservoir is less than 50% full, refill the inline oiler as described in the "Routine Maintenance" section of Chapter 9.

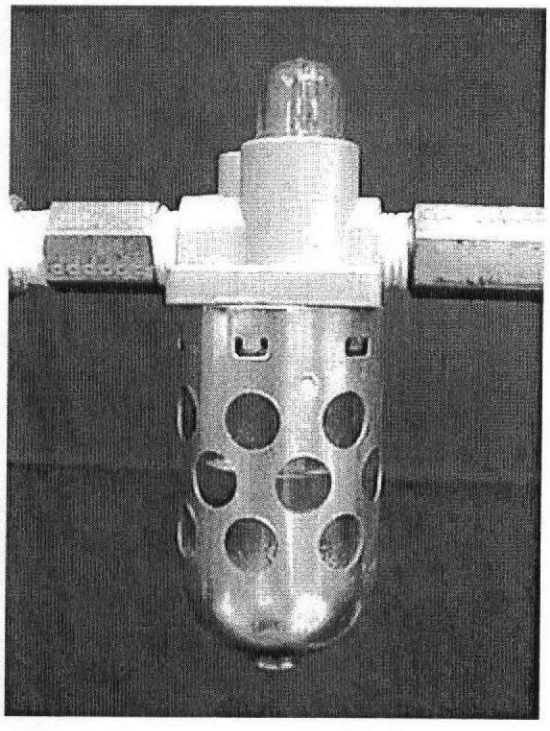

Figure 3-1. Refilling the Oiler

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Safety Considerations

- **Supplies.** Ensure the availability of all supplies listed in this chapter, including backup instrumentation for performing a manual surgery.
- **Sterilization.** Ensure that all items are properly sterilized.

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Chapter 4

NON-STERILE DIAGNOSTIC AND PATIENT VERIFICATION PROCEDURES

Introduction

This chapter explains how to perform the tests that verify that the robot and its safety systems are functioning properly and are ready for surgery. ISS recommends that a technician perform these procedures before the patient is brought to the operating room.

The patient should not be anesthetized until completion of the sterile tool verification procedure described later in this manual.

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Starting the ROBODOC System

This section explains how to install the fixture and tools used to perform non-sterile diagnostic tests.

To start the ROBODOC system, you must perform the following procedures in response to OR Monitor prompts and screens:

1. Select the **Total Hip Surgery** option from the startup screen.
2. Load the patient data (described in the next section).
3. Identify the operative side of the patient (left or right).
4. Verify selection of the operative side.
5. Press the green button on the OR Monitor cabinet to turn on motor power.
6. Complete the homing procedure for the robot base.
7. Home the robot arm (see *Home Position* in Chapter 2 for more information).
8. Clear a path to the tool changing area.
9. Complete the non-sterile diagnostics described in this chapter.

These procedures are described in detail in the following sections.

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Powering On and Selecting the Application

When powered on, the system requires a few minutes to load and validate files. Systems with the DigiMatch Module take slightly longer to start because extra graphic files must be loaded.

⇨ To start up the system:

1. Turn on the main A/C power switch, located on the front of the Control Cabinet and verify that the circuit breaker on the rear of the robot base is on.

   After a few minutes, the OR Monitor displays the **SELECT APPLICATION** menu. The menu options include:

   TOTAL HIP SURGERY: Starts the THA application. You will select this option to proceed with pre-surgical preparation.

   ROBOT CALIBRATION: Starts the application for calibrating the robot arm. This option is used during system maintenance.

   DIGITIZER CALIBRATION: Starts the application for calibrating the digitizer. This option is performed only in the unlikely event that the system fails to pass digitizer diagnostic tests. (This option does not appear on systems that do not have the DigiMatch Module.)

2. Select the **TOTAL HIP SURGERY** option.

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Loading the Transfer File

The transfer file provides the robot with information about implant geometry and intended cavity placement. For DigiMatch surgeries it contains surface model data. The transfer file is contained on transfer media, which should be labeled with the patient's name and other identification data.

Keep the plastic case for the transfer media available for reference purposes during the surgery. The label on the case contains information that the surgeon will need during surgery.

Perform the following procedure when the OR Monitor prompts you to insert the ORTHODOC data in the system.

⇨ To load the transfer file:

1. Insert the Patient data transfer media into the ROBODOC Control console as shown below.
2. Verify that the information on the transfer media label matches the information on the plastic cover.
3. Open the door to the media drive on the Control Cabinet.
4. Insert the media.

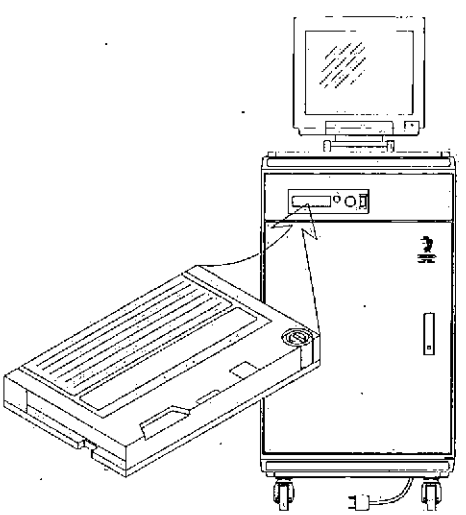

Figure 4-1. Loading the Transfer File

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5. Close the media drive door and wait a few seconds for the drive to initialize.

6. Press **SELECT**.

   The OR Monitor displays a series of messages indicating that the system is loading and processing the patient data on the transfer media. Then, the OR Monitor prompts you to identify the operative side of the patient (left or right).

7. Select the appropriate option to indicate the operative side.

   If your system has the DigiMatch Module, the OR Monitor displays the following screen:

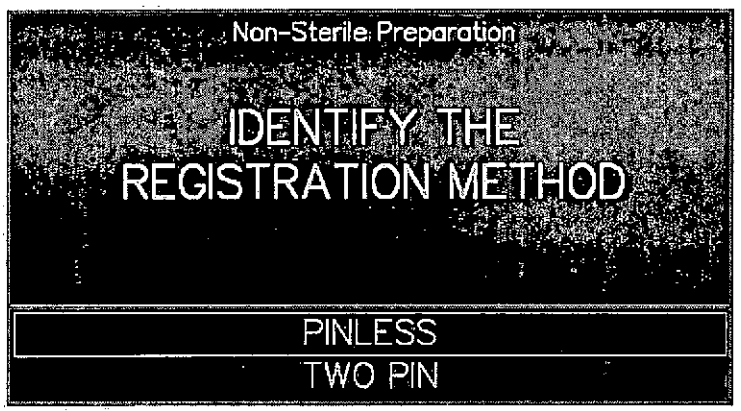

Figure 4-2. The Registration Method Screen

8. If this screen appears, select the **PINLESS** for a DigiMatch.

9. Press green button on Control Cabinet to turn on power to the robot motors.

10. Set the base to its highest position.

    The robot base and arm will be automatically homed; avoid contact with the arm.

11. Twist the pitch axis (if needed).

NOTE: Chapter 2 provides detailed instructions for performing steps 10 and 11.

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Non-Sterile Diagnostics

This section explains how to install the tools that will be used during the non-sterile diagnostic tests and initiate the tests. The purpose of non-sterile diagnostic tests is to confirm proper functioning of the digitizer and robot arm.

Most of the procedures for systems without the DigiMatch Module are the same, but the sequence is slightly different and the bone motion monitor (BMM) location is not the same. The procedures also vary slightly when a locator pin case is performed on a system with the DigiMatch Module. The sequence of instructions in this section is in the order for DigiMatch cases.

Diagnostic Probe Installation

The *diagnostic probe* is the instrument used to verify the kinematics and calibration of the robot arm during several diagnostic tests. The probe is on a mounting block with a threaded clamping ring, similar to the cutter drive assembly. The clamping ring attaches to the force sensor in the same manner as the cutter drive.

⇨ To install the diagnostic probe:

1. Push the diagnostic probe assembly flush against the force sensor, aligning the two holes on the probe assembly with the dowel pins on the force sensor.

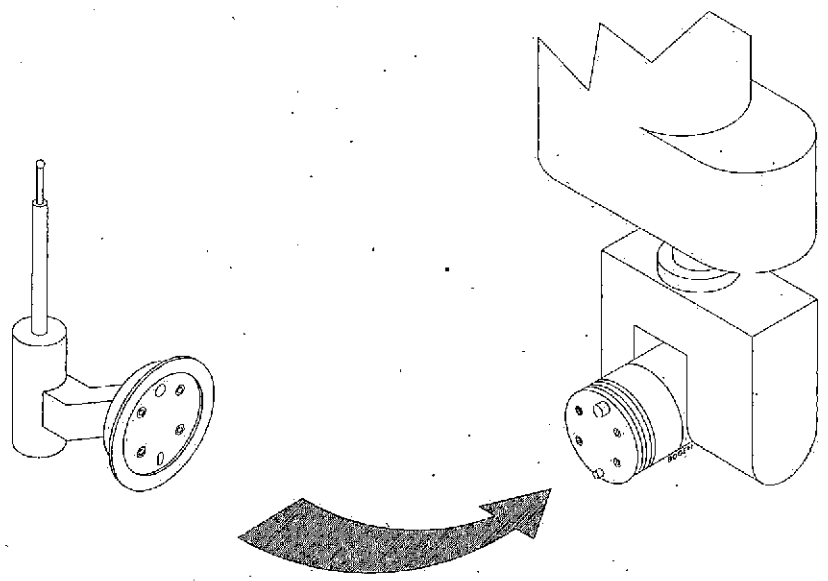

Figure 4-3. Diagnostic Probe Assembly and Force Sensor

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2. While holding the diagnostic probe assembly and the force sensor together, turn the threaded clamping ring until the assembly is secure.

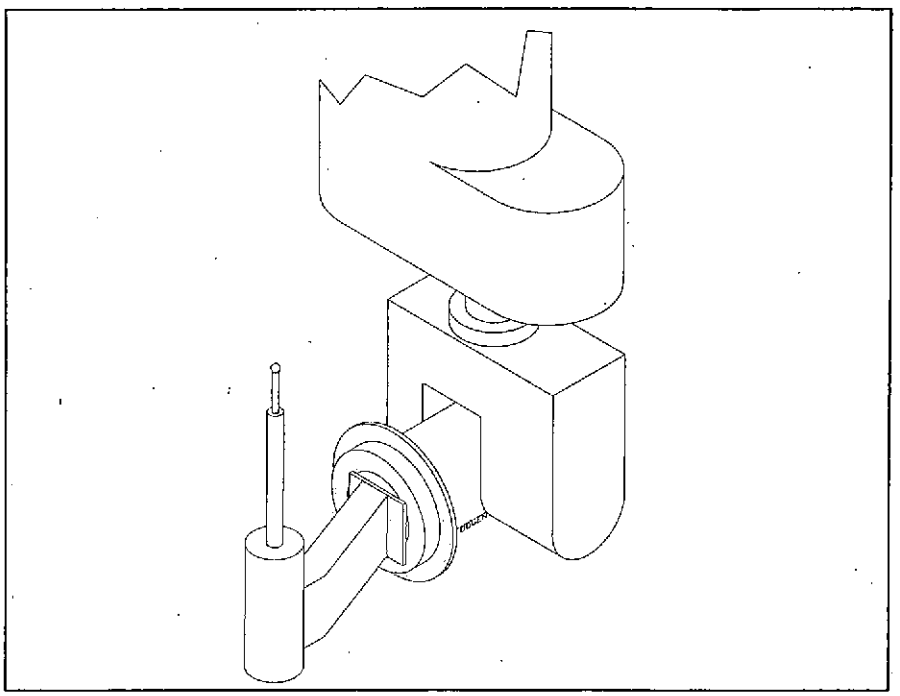

Figure 4-4. Installed Diagnostic Probe

BMM Diagnostics Attachment

The *BMM diagnostics attachment* is a cylindrical rod with a square end that connects to the BMM in the same manner as the BMM probe. The dimple on the other end of the BMM diagnostics attachment holds the ball on the diagnostic probe during the BMM test.

For non-DigiMatch systems, the BMM diagnostics attachment is installed after the diagnostic fixture (see the next set of instructions).

⇨ To install the BMM diagnostics attachment:

1. Insert the square end of the rod into the end of the BMM and fasten securely by tightening the thumbscrew.

2. If your DigiMatch system has a BMM switch, set the switch to the appropriate side (left or right) when prompted to do so.

   Newer systems do not have switches because software activates the appropriate BMM. On earlier systems, the switch is located on the robot base between the BMMs.

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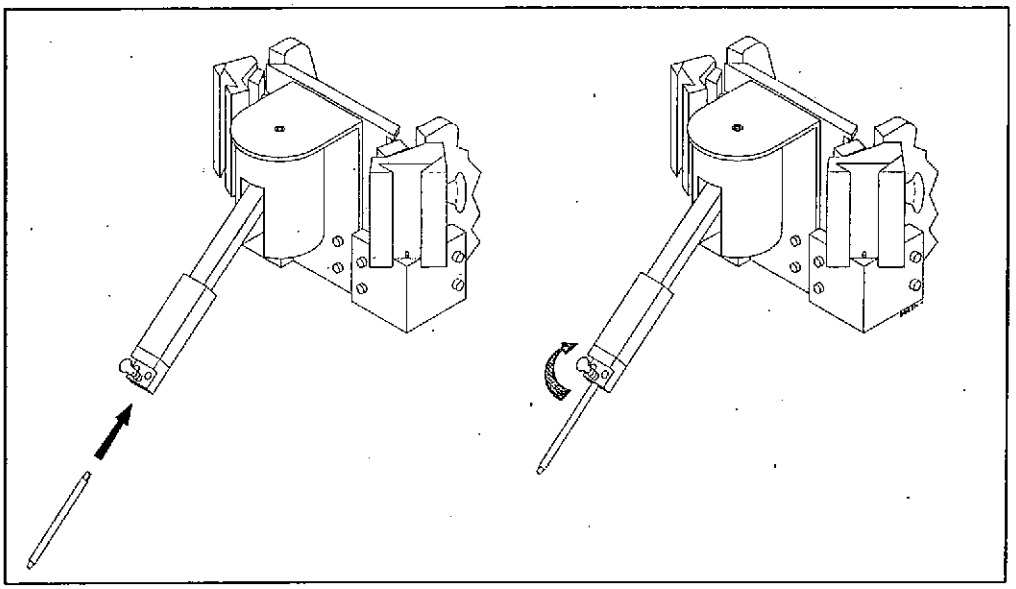

Figure 4-5. BMM Diagnostics Attachment Installation

3. Attach the BMM to the diagnostic probe

4. Couple the rod on the BMM and the diagnostic probe by retracting the spring-loaded BMM and placing the ball at the end of the probe in the divot on the rod.

5. Press **SELECT** when the parts are coupled.

Force Sensor Diagnostic Test

The force sensor test is completely automatic and requires no user interaction. During the test, the OR staff must be careful not to touch the robot or diagnostic fixtures. After installation of the diagnostic tools, the robot begins the force sensor test. After successful completion of the force sensor test, the robot automatically moves to start the BMM test.

The force sensor test ensures the proper functioning of the device that measures forces applied to the end of the tool tip. If the force sensor test fails, an error screen will be displayed. See Chapter 10, "Troubleshooting," for corrective action.

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BMM Diagnostic Test

The BMM test is completely automatic and requires no user interaction. During the test, the OR staff must be careful not to touch the robot or diagnostic fixtures. The OR Monitor will display a warning about not touching the robot while the BMM probe makes automated movements.

When the test is complete, the OR Monitor will display a prompt to uncouple the BMM diagnostic probe.

The BMM test ensures that the safety device for detecting femoral movement is functioning properly. If the BMM test fails, an error screen will be displayed. See Chapter 10, "Troubleshooting," for corrective action.

Diagnostic Fixture Installation

The *diagnostic fixture* is a non-sterile rectangular test plate with six vertical posts. The extension arm on the test plate connects to a dovetail mounting block on the base in the same manner as the femoral fixator. For the anterolateral and posterolateral approaches, the clamping mechanism is a knob located on the mounting block. For the direct lateral approach, a clamp screw in the extension arm connects the extension arm to the mounting block, and a sterile hex wrench is used to turn the screw.

The posts on the diagnostic fixture are *known points* (pre-determined coordinate locations) that the probe must contact to verify robot arm kinematics and calibration.

⇨ To install the diagnostic fixture:

1. Turn the knob on the clamping mechanism to loosen the dovetail opening.

   NOTE: Be sure to use the mounting block corresponding to the operative side.

2. Insert the end of the extension arm on the test plate into the dovetail opening and lower the fixture to level 5, if the blocks have level marks, or to a position within 2 cm from the bottom of the mounting block.

3. Turn the knob to lock the diagnostic fixture in place.

   NOTE: For the direct lateral approach, use the non-sterile hex wrench to tighten the clamp screw.

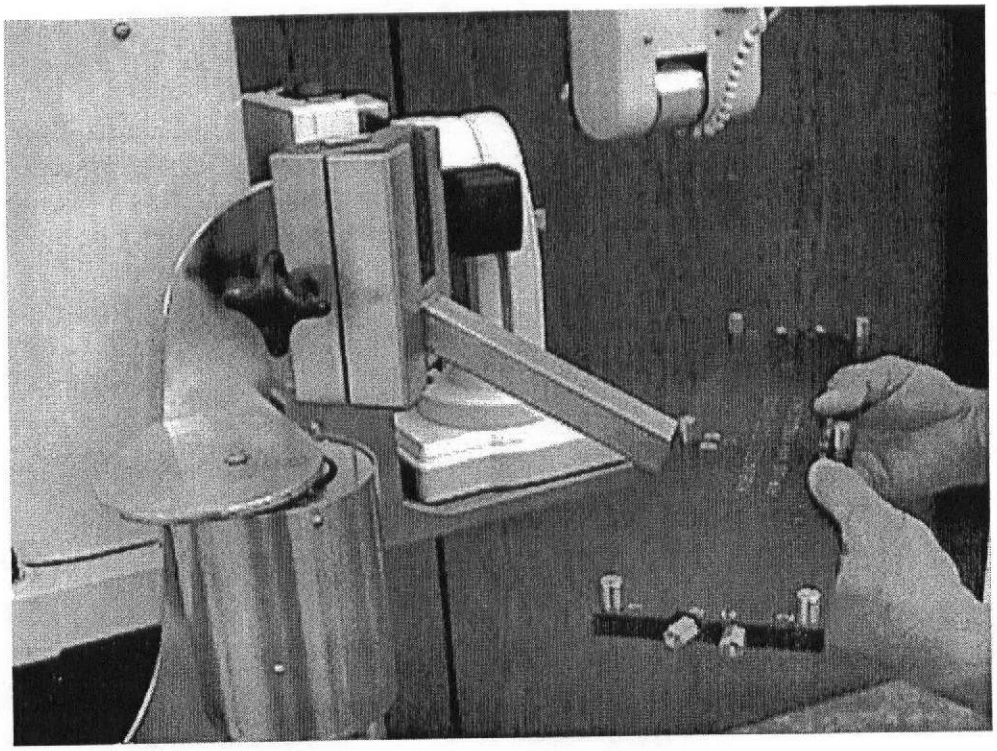

Figure 4-6. Diagnostic Fixture Installation

Figure 4-6 shows a system configured for the anterolateral or posterolateral approach. The knob for locking the fixture in place is located on the mounting block and the mounting block does not have a vertical ruler for positioning the extension arm.

Digitizer Ball Probe Installation

The *digitizer ball probe* is the instrument used to verify the kinematics and calibration of the digitizer during diagnostic tests. This procedure is performed for DigiMatch cases only.

⇨ **To install the non-sterile digitizer probe:**

1. Hold the end of the digitizer in one hand and probe in the other as shown in the following figure.

2. Securely bottom out the probe.

   A loose probe may cause digitizer diagnostics to fail.

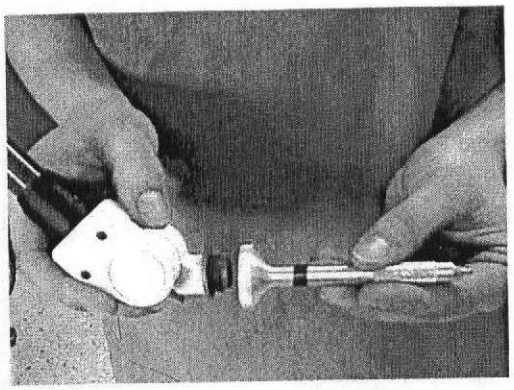

Figure 4-7. Installing the Non-Sterile Digitizer Ball Probe

Digitizer Diagnostic Test

The digitizer diagnostic test verifies the kinematics and calibration of the digitizer. This procedure is performed for DigiMatch cases only.

1. Place the digitizer in home position as shown in Figure 4-8:

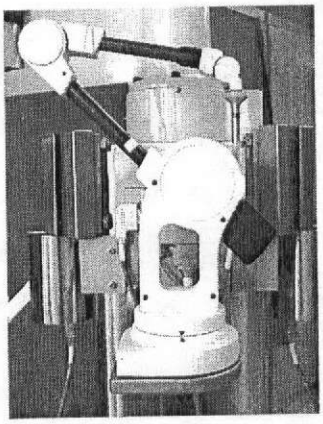

Figure 4-8. The Digitizer in Home Position

2. Verify that the ball probe is firmly seated and that all of the joint indicator arrows are aligned.

3. Guide the digitizing ball probe to Post 1 on the diagnostics fixture and securely place the probe in the divot on the post.

   To guide the probe, hold it in the same manner as a pencil.

4. Press **SELECT** when the probe is securely positioned in the divot.

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5. Keeping the tip of the probe securely positioned in the divot, change the joint angles of the digitizer, then press **SELECT**; repeat this procedure until you have collected 5 points on the post.

   To reduce the potential for a diagnostics error, you must ensure that the digitizer's angle and joint position varies each time you collect a point on the same post.

   If the tip of the probe loses contact with the divot during digitizing of any of the 5 points, the OR Monitor will display the error message **"VARIANCE OF DIGITIZED POINTS EXCEEDS LIMIT. RE-COLLECT POINTS."** (This message will also be displayed if the digitizer is out of calibration.)

6. Repeat steps 2 through 4 for additional posts, in response to prompts displayed on the OR Monitor.

   When the final point has been collected on Post R-2, the OR Monitor displays a prompt to guide the robot to clear position. The diagnostics fixture must not move between digitizer diagnostics and robot arm diagnostics because the digitizer and the arm must register to the same coordinate frame.

Kinematics Test

The kinematics test ensures that the robot is properly calibrated and capable of accurately measuring distances and angles. The technician or surgeon must guide the ball probe close to each post on the diagnostic fixture. Placing the probe a few millimeters above a post is more effective than bringing the probe into direct contact with the post.

The robot will detect the exact location of each post by performing a *tactile search.* Impact with solid objects, including the diagnostic posts, may result in a *force freeze* or *force EPO* (Emergency Power Off). If a force freeze occurs during the kinematics test, you may resume by pressing **SELECT**. For detailed instructions on robot guidance techniques, see the "Positioning the Robot Arm" section in Chapter 2. Avoid moving the diagnostics fixture until digitizer and robot arm diagnostics are both complete. Movement may cause discrepancies between digitizer and arm calibration.

Begin this procedure when the OR Monitor displays the following prompt:

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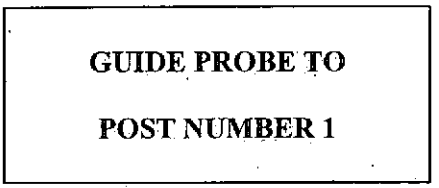

Figure 4-9. Prompt to Guide Probe

⇨ To perform the kinematics test:

1. Guide the probe to a location *slightly above* the divot on the post marked "1" and press **SELECT** when the probe is in the desired position.

   The probe makes small automated movements while performing a tactile search to determine the exact position of the post.

   The OR Monitor displays the message:

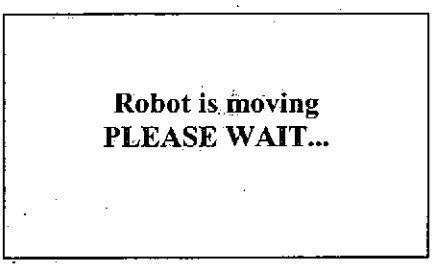

Figure 4-10. OR Monitor Message

When the tactile search on the first post is complete, the OR Monitor displays the following screen:

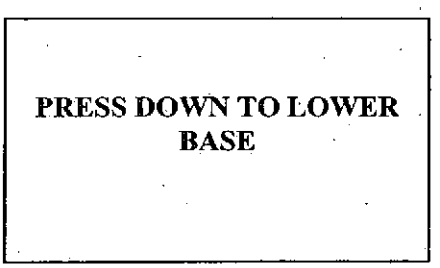

Figure 4-11. Prompt to Lower Base

When base height has been properly adjusted, the OR Monitor prompts you to guide the probe to post number 1 again.

2. Guide the probe to a position slightly above post 1 and press **SELECT**.

   The probe makes small automated movements while performing a tactile search to determine the exact position of the post. After a successful search, the probe automatically moves to a location above the next post.

3. Repeat Step 3 for additional posts in response to prompts on the OR Monitor.

   If the kinematics test fails, an error screen will be displayed. See Chapter 10, "Troubleshooting," for corrective action.

   When the kinematics test for a DigiMatch case is complete, the OR Monitor prompts you to re-digitize five points at Post 4.

4. Keeping the tip of the digitizer probe securely positioned in the divot on Post 4, change the joint angles of the digitizer, then press **SELECT**; repeat this procedure until you have collected 5 points on the post.

   This step enables the system to verify that the diagnostics fixture did not move between digitizer diagnostics and the kinematics test.

After completing the non-sterile diagnostics procedures described above, the OR Monitor will prompt the surgeon to guide the arm to clear position, remove the non-sterile diagnostic tools, and verify patient data and cutter/instrument availability.

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Non-Sterile Diagnostic Test Completion

When the diagnostic tests have been successfully completed, the OR Monitor prompts for removal of diagnostic fixture and tools.

When the diagnostics tests are complete, the OR Monitor displays a prompt to remove diagnostic tools and fixtures.

⇨ To remove diagnostic tools and fixtures:

1. Release the diagnostic probe assembly by turning the threaded clamping ring.
2. Remove the diagnostic fixture by turning the leverage knob or loosening the clamp screw.
3. Remove the BMM diagnostics attachment by loosening the thumbscrew.
4. For DigiMatch cases, remove the non-sterile digitizer probe.

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Safety Considerations

- **Automated movements.** Do not touch the robot during automated movements. Whenever the robot is about to move automatically, the OR Monitor will display a warning screen.

- **Anesthesia.** The patient should not be anesthetized during non-sterile diagnostics. If the robot fails diagnostics, the surgeon has the option to reschedule surgery after the problem has been corrected.

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Chapter 5

PATIENT VERIFICATION AND STERILE DIAGNOSTICS

Introduction

This chapter provides information for surgeons and technicians regarding verification of critical patient data, installation of sterile tools and drapes, and performing sterile diagnostics.

Patient verification must be performed by the surgeon.

Installation of some of the sterile items requires both a sterile and a non-Sterile person.

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Patient Verification

This procedure must be performed by the surgeon, rather than a nurse or OR technician.

The system prompts the surgeon to confirm the following information:

- Patient name
- Side of patient the operation will be performed on (left/right)
- Size and availability of the implant to be installed
- Availability of ROBODOC cutters for the selected implant type
- Availability of tools needed to perform a manual surgery if the ROBODOC surgical procedure must be aborted

If the prompts are not confirmed, the OR Monitor will prompt the surgeon to abort the ROBODOC procedure and perform a manual surgery.

Installing Sterile Tools and Drapes

This section explains how to install sterile tools and the sterile draping system. These procedures require two nurses or technicians, one sterile and one non-sterile.

WARNING: Do not install any of the items described in this chapter while they are still warm from the autoclave. All components must be cooled to room temperature before installation.

Installing the Sterile Digitizer Probe

This procedure is performed only for DigiMatch cases.

⇨ **To install the sterile digitizer probe:**

1. Non-sterile person: Lift the digitizer to facilitate probe installation.
2. Sterile person: Securely install the sterile probe.

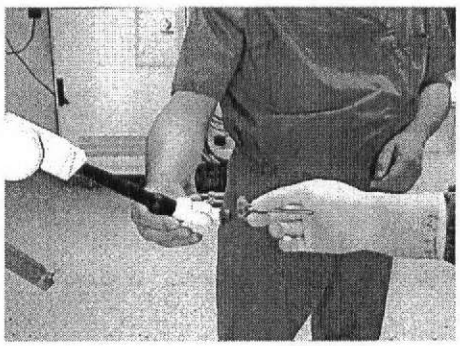

Figure 5-1. Sterile Probe Installation

Installing the Sterile Digitizer Drape

This procedure is performed only for DigiMatch cases.

⇨ **To install the sterile digitizer drape:**

1. Non-sterile person: Lift the digitizer to facilitate installation of the drape over the probe, avoiding contact with the sterile probe.
2. Sterile person: Pull the digitizer drape over the digitizer probe, avoiding contact with the non-sterile digitizer.

3. Sterile person: Position the elastic opening on the drape between the lip and the threaded attachment for the probe as shown in Figure 5-2:

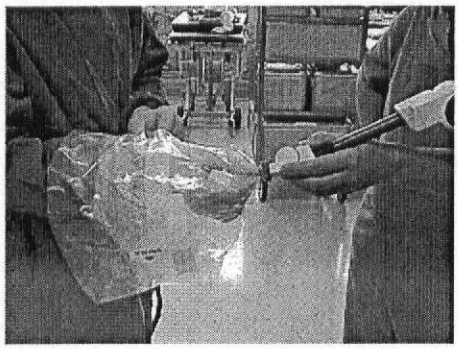

Figure 5-2. Digitizer Drape Installation

NOTE: During digitizer drape installation, take care to prevent contact between the sterile digitizer probe and non-sterile objects.

Installing the Cutter Drive Assembly

The cutter drive assembly must be at room temperature during installation (i.e., not warm from the autoclave). If the cutter drive assembly is warm when installed, it will contract when it cools and will be difficult to remove. Subsequent removal of the cutter drive may damage the force sensor.

Begin this procedure when the OR Monitor displays the following prompt:

Sterile Preparation
INSTALL **CUTTER DRIVE ASSEMBLY**
Press SELECT when complete

Figure 5-3. Cutter Drive Assembly Installation Prompt

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⇨ To install the cutter drive assembly:

1. Sterile person: Align the dowel pins and push the cutter drive assembly flush against the force sensor in the same manner as the diagnostic probe assembly (see Figure 4-3 in Chapter 4).

2. Sterile person: While holding the cutter drive assembly against the force sensor, turn the threaded clamping ring until the assembly is secure.

   NOTE: Do not touch the non-sterile force sensor.

Installing the Arm Drape

Arm drape installation is a two-person procedure. The sterile person unfolds the drape and passes it over the top of the arm to the non-sterile person, who secures it in back. For DigiMatch cases, non-sterile contact with the sterile digitizer probe must be avoided.

Begin this procedure when the OR Monitor displays the following prompt:

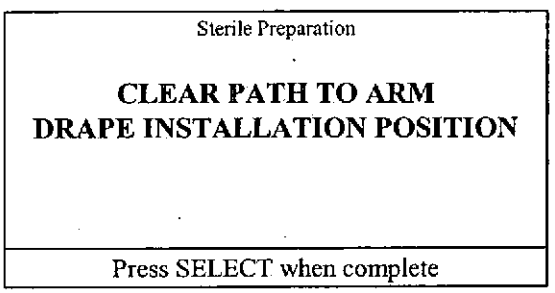

Figure 5-4. Clear Path Prompt

⇨ To install the arm drape:

1. Non-sterile person: Remove any obstacles that would prevent the arm from extending straight forward.

2. Non-sterile person: Press **SELECT** when the path is clear.

   The arm automatically moves into position for draping and the OR Monitor prompts you to install the arm drape.

3. Non-sterile person: If necessary, lower the base to facilitate pulling the drape over the top of the arm.

4. Sterile person: Unfold the sterile drape and pass it up and over the top of the arm to the non-sterile person.

5. Non-sterile person: Pull the drape over the top of the arm and down in back..

6. Non-sterile person: If necessary, raise the base to facilitate straightening the drape.

7. Sterile person: Form a sterile seal by fitting the drape fenestration over the lip on the cutter drive assembly.

8. Non-sterile person: Press **SELECT** when drape installation is complete.

Installing the Fixator Extension Arm

Fixator extension arm installation is a two-person procedure. A sterile person slides the extension arm into the dovetail mounting block on the base and a non-sterile person uses the knob on the mounting block to secure the connection.

NOTE: Systems configured for the direct lateral approach have clamp screws on the extension arm, instead of knobs, and a sterile hex wrench for turning the screws. A sterile person can install the extension arm without any assistance.

When the robot is draped for sterility, an opening in the drape will fit over the sterile extension arm to form a seal at the mounting block.

Before beginning this procedure, you must adjust (raise) the height of the base. After the arm drape has been installed and the base has been raised, the OR Monitor prompts you to install the fixator extension arm and the skirt drape.

⇨ To install the fixator extension arm:

1. Sterile person: Holding the cylindrical end of the extension arm, slide the dovetail into the non-sterile mounting block on the base. Then, move the fixator extension arm to the bottom of mounting block.

2. Non-sterile person: Turn the knob on the fixator attachment block to secure the extension arm. (On systems configured for the direct lateral approach, the sterile person uses the sterile hex wrench to tighten the clamp screw in the extension arm.)

Installing the Skirt Drape

This section contains two sets of instructions, one for DigiMatch systems and one for non-DigiMatch systems. DigiMatch skirt drapes contain an opening for the digitizing arm. DigiMatch drapes must be used for DigiMatch systems, regardless of whether the surgery will be pinless or pin-based.

Skirt drape installation is a two-person procedure. A sterile person unfolds the drape and feeds the openings over the digitizing and fixator extension arms, covers the BMM arm with a pocket in the drape, and passes the top ends of the drape to a

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non-sterile person. The non-sterile person wraps the drape around the bottom of the robot base and fastens it together in the back.

⇨ **To install a DigiMatch skirt drape:**

1. Non-sterile person: Hold the back of the drape to facilitate draping of the digitizing arm and fixator extension arm.
2. Sterile person: Pull the draped digitizing arm through the opening in the drape.
3. Sterile person: Feed the opening in the skirt drape over the fixator extension arm.
4. Non-sterile person: Position the BMM on the surgical side (left or right) to facilitate draping.
5. Sterile person: Place the BMM on the surgical side into its pocket.
6. Sterile person: Pass the rest of the drape to the non-sterile person.
7. Non-sterile person: Wrap the drape around the back of the robot and fasten the sides together with the adhesive on the drape. If necessary, use additional adhesive tape to secure the drape in back.
8. Non-sterile person: Press **SELECT** when drape installation is complete.

Sterile Probe Installation

The probe is an instrument used for verifying that the cutter drive assembly has been properly installed, and for pin finding in locator pin cases. It may be a single-piece probe or a probe/sleeve combination. If a probe/sleeve combination is used, the probe and sleeve must both be securely seated in the collet on the cutter drive assembly.

Probe installation requires the following items:

- Large collet wrench
- Small rod and wrench set (if the probe and sleeve are separate)

The "Installing Probes and Cutters" section in Chapter 2 provides illustrations of probe installation procedures.

Begin this procedure when the OR Monitor displays a prompt for installation of components appropriate for the selected implant type. For example:

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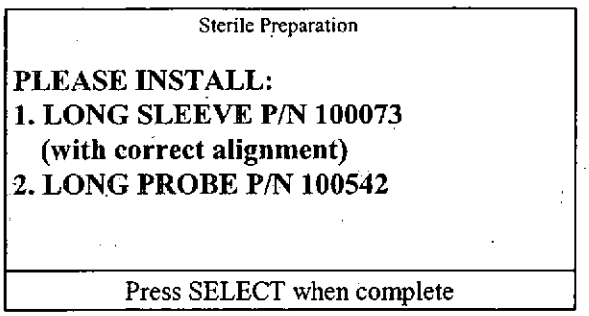

Figure 5-6. Sleeve and Probe Installation Prompt

⇨ To install a sterile probe:

1. Sterile person: Follow the procedure described in the "Installing Probes and Cutters" section of Chapter 2.

2. Non-sterile person: Use the pendant to respond to prompts displayed on the OR Monitor during probe installation.

Sterile Diagnostics

This section explains how to perform sterile diagnostic tests, which confirm proper installation and calibration of the sterile tools. These instructions are intended for surgeons and OR technicians.

Sterile diagnostics for DigiMatch cases consist of two procedures: 1) verifying cutter drive tool installation and calibration; and 2) verifying digitizer probe installation and calibration by digitizing sterile verification points. Sterile diagnostics for locator pin cases do not include the second procedure.

The sterile diagnostic point differs for non-DigiMatch systems. For these systems, the calibration point is one of two posts located on the top or bottom of the fixator extension arm. At the start of sterile calibration, the tool will be angled to indicate which post to use as the calibration point. If the tool is angled downward, guide the probe to a position 1 to 2 mm above the upper post; if the tool is angled upward, guide the probe to a position 1 to 2 mm below the lower post, but do not directly contact the post.

⇨ To verify cutter drive tool installation and calibration:

1. Sterile Person: When prompted to do so, gently guide the probe on the robot arm to the calibration point.

   For DigiMatch systems, the calibration point is located on the side of the fixator extension arm as shown in Figure 5-7:

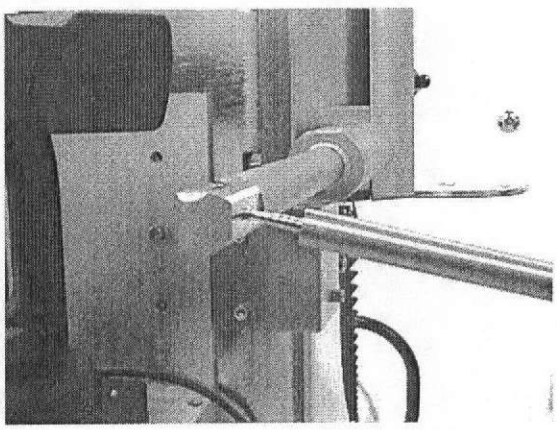

Figure 5-7. Probe Positioned at Calibration Point on Fixator Extension Arm

2. Non-sterile person: Press **SELECT** when the probe is in the desired position.

   The probe will make automated movements to change orientation when it performs a tactile search at the sterile verification point. Take care to prevent the arm and/or probe from contacting the digitizer during these

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movements. During the tactile search, the "Robot is Moving" warning will be displayed on the OR Monitor. Then, this prompt will appear:

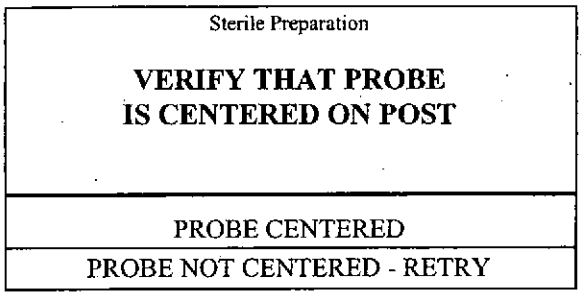

Figure 5-8. Center Probe Verification Prompt

3. Non-sterile person: Respond to this prompt in one of the following ways:

   - If the probe appears to be centered in the divot on the post, select the **PROBE CENTERED** option.

   - If the probe is not centered, select the **PROBE NOT CENTERED - RETRY** option, and repeat steps 1 and 2.

   The cutter drive assembly will reorient to several positions while collecting data for the calibration computation. If the calibration computation fails repeatedly, the procedure must be aborted, and the robot must be calibrated using the non-sterile robot calibration program before a surgery can be performed (see Chapter 9). After the post data collection is completed, the robot will measure the orientation (roll and pitch) offset of the probe sleeve by touching the sleeve to various locations on the fixator extension arm. If there are any problems reaching the required locations, the user will be prompted to guide the robot to the starting position for each of these procedures.

The starting positions for the pitch and roll offset measurements for DigiMatch systems are illustrated in Figure 5-9 and Figure 5-5, respectively:

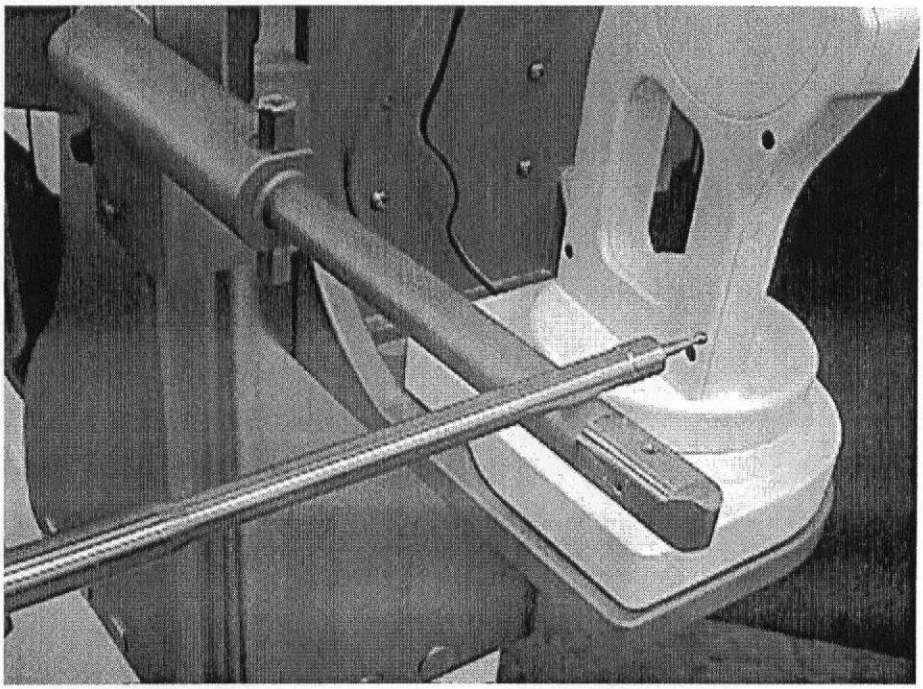

Figure 5-9. Starting Position for Pitch Offset Measurement

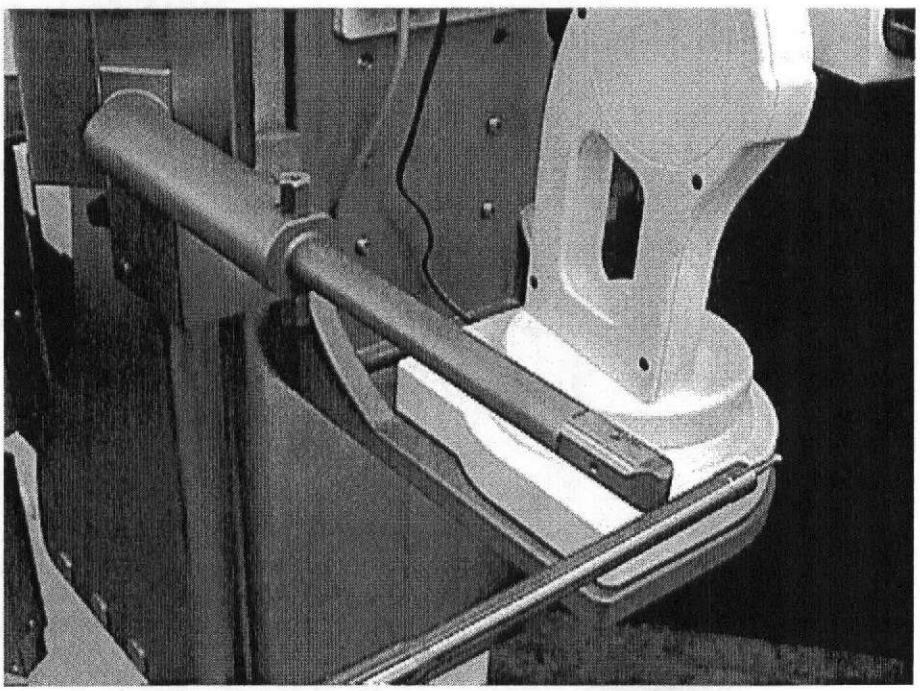

Figure 5-5. Starting Position for Roll Offset Measurement

The starting positions for the pitch and roll offset measurements for non-DigiMatch systems are illustrated in Figure 5-6 and Figure 5-7respectively.

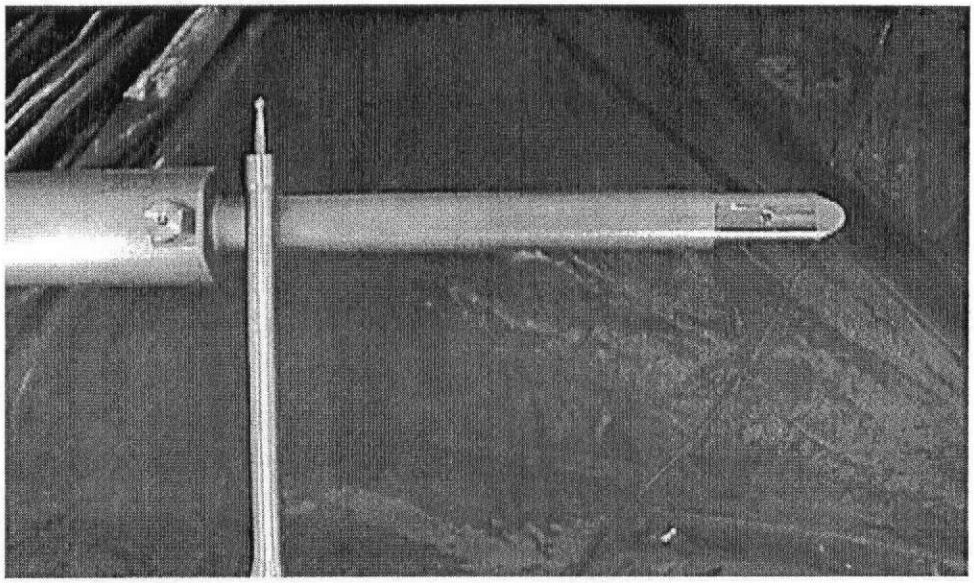

Figure 5-6. Starting Position for Pitch Offset Measurement

For the pitch offset measurement, the tool should also be horizontal and clear for travel. There should be sufficient clearance (approximately 2 mm) between the tool and the fixator arm so the robot can travel without hitting the arm.

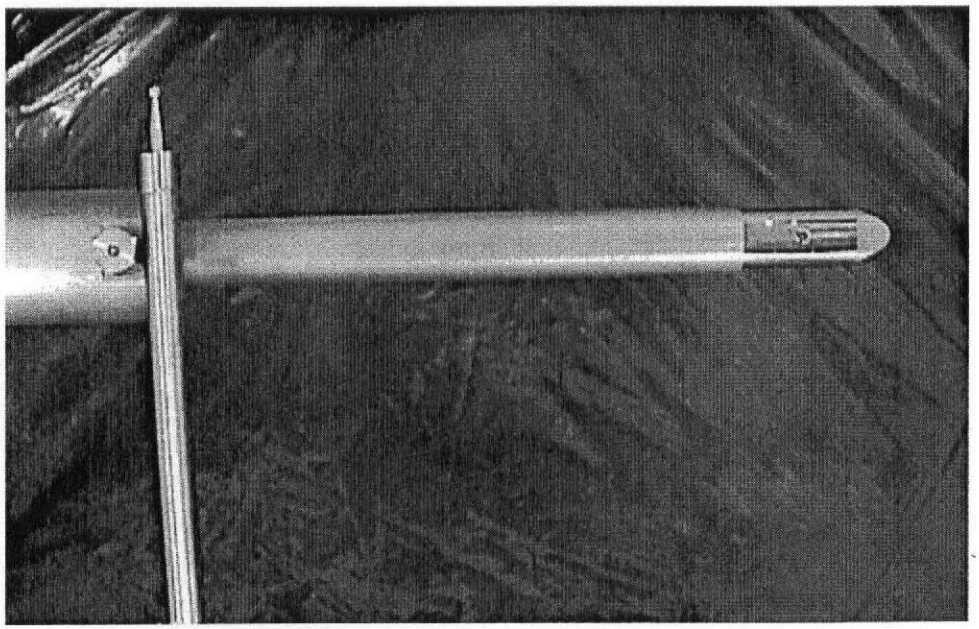

Figure 5-7. Starting Position for Roll Offset Measurement

For the roll offset measurement, the tool should be horizontal and oriented in a direction where the tool can travel without encountering any obstructions. The

tool should be vertically centered with respect to the post, with sufficient clearance (approximately 2 mm) to travel without hitting the post.

After the offset measurements have been completed, sterile calibration for the installed sleeve is complete. If a second sleeve will be used for the surgery, the user will be prompted to install and calibrate the additional sleeve. When the sterile calibrations are complete, the robot is ready for surgery.

After successful calibration, the sterile person will be prompted to guide the arm to travel location. Then, power to the robot arm will automatically shut off.

⇨ To verify digitizer probe installation and calibration:

Begin this procedure when the OR Monitor displays the prompt to digitize sterile verification point.

1. Guide the digitizer ball probe to the divot located on top of the fixator extension arm and securely place the probe in the divot.

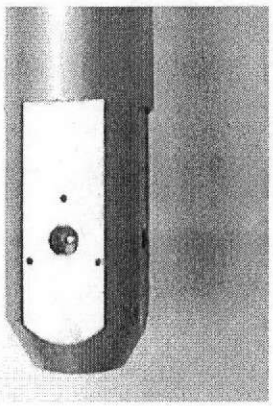

Figure 5-8. Divot and SterileVerification Points on Top of Fixator Extension Arm

2. Press **SELECT** when the digitizer probe is securely positioned in the divot.

3. Keeping the tip of the probe securely positioned in the divot, change the joint angles of the digitizer and press **SELECT**; repeat this procedure until you have collected 5 points.

   To reduce the potential for a diagnostics error, you must ensure that the digitizer's angle and joint position varies each time you collect a point on the same post. You must also ensure that the tip of the probe remains in contact with the divot.

4. Replace the ball tip on the digitizer probe with the pointed tip.

5. Guide the digitizer probe to the three small verification points on the fixator arm.

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These verification points are located at 12:00, 4:00, and 8:00 with respect to the larger divot as shown in Figure 5-13.

When these diagnostic tests are complete, the robot is ready and the surgeon, anesthetist, and OR team can begin preparing the patient for surgery.

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Safety Considerations

- **Sterility.** Be aware that maintaining sterility is the primary safety consideration during installation of sterile tools and drapes.
- **Installation verification gauges.** Use the installation verification gauges to confirm that the ball probe is properly seated in the cutter drive.
- **Anesthesia.** The patient should not be anesthetized until the system passes all non-sterile and sterile diagnostic tests.

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Chapter 6

FEMORAL FIXATION

Introduction

This chapter describes a variety of procedures that must be performed to prepare the robot and the patient for femoral canal preparation. This chapter provides information for the surgeon and technician.

Before beginning the procedures described in this chapter, the following procedures must be complete:

- Sterile tool installation
- Draping the robot for sterility
- Non-sterile and sterile diagnostics

WARNING: Do not administer anesthesia until the surgeon has confirmed the information on the patient verification screens and the robot has passed the diagnostic tests.

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Starting the Surgery

This section provides instructions for the surgeon and OR team regarding the initial procedures for THA using the ROBODOC System. This section explains how to start.

After the robot passes all diagnostic tests and the surgeon confirms the data on the surgeon verification screens, anesthesia can be administered. The surgery begins in the same fashion as a non-robotic assisted hip operation.

The osteotomy for DigiMatch surgeries must be at the approximate level illustrated in Figure 6-1 because some of the bone surfaces required for surface registration are located high on the femoral neck. The acetabulum will be prepared after the robot has milled the implant cavity because the high neck cut will not provide adequate access for acetabulum preparation and installing the acetabular cup.

⇨ To start a DigiMatch surgery:

1. Administer anesthesia.

2. Position the patient for an anterolateral (modified Watson-Jones), posterolateral, or direct lateral approach, whichever is supported by the configuration of your system.

   When prepping and draping, expose a slightly larger area posteriorly to ensure clearance for the cutter and soft-tissue retractors around the proximal femur.

3. Make the opening incision.

   Later it may be necessary to slightly extend the proximal end of the incision to ensure adequate clearance for the cutter.

4. Dislocate the hip.

5. Perform an initial femoral neck osteotomy at the approximate level shown in Figure 6-1.

   NOTE: The entire femoral neck must be intact for surface registration.

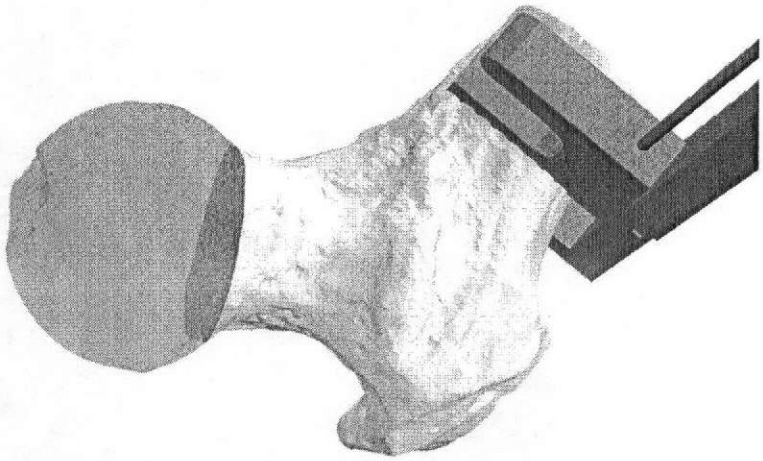

Figure 6-1. Osteotomy Level for DigiMatch Cases

6. Clear soft tissue from the region of interest (ROI).

   To facilitate surface registration, soft tissue should be cleared from the surface of the bone where data points will be collected. Clearing soft tissue will help to visually locate the required points on the bone surface. Figure 6-2 shows the ROI where soft tissue should be cleared:

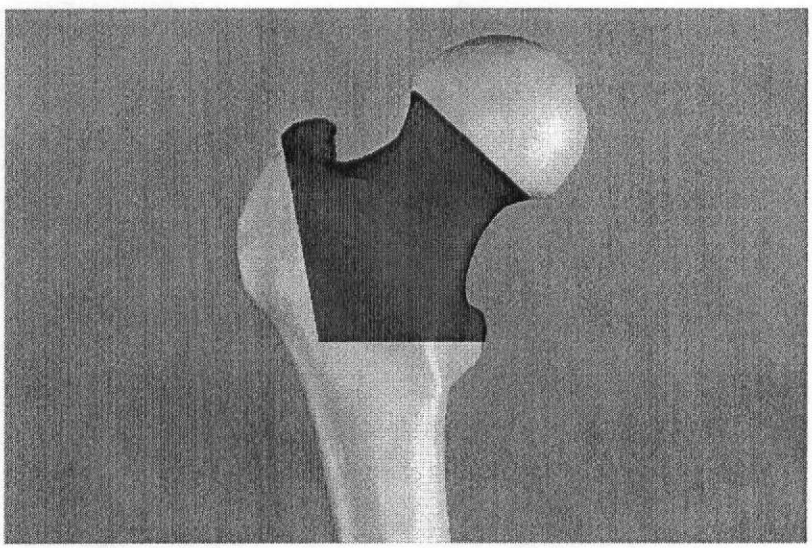

Figure 6-2. ROI Requiring Soft Tissue Removal

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Installing the Femoral Fixator

This section explains how to install the femoral fixator. These procedures will be performed by the surgeon and OR team.

The femoral fixator is a proximal bone clamp that attaches to the robot base. The femoral fixator must be properly installed prior to registration procedures (digitizing points on the bone or finding locator pins) to ensure that no motion occurs after the robot has located the femur and performed the necessary geometric computations to determine cavity placement.

To accommodate variations in patient anatomy and leg side, the fixator is designed to secure the proximal portion of the femur by means of a bone clamp. The distal portion of the femur must be stabilized by means of a hospital-supplied support device. Adequate distal fixation is critical for DigiMatch cases.

Although the fixator components must be securely assembled to prevent the femur from moving, do not overtighten. Overtightening may damage the bone and/or soft tissue, or freeze the joints and make it difficult to detach and disassemble the fixator after femoral preparation.

WARNING: Bone quality in the proximal femur must be good to achieve adequate fixation without damaging or fracturing the bone.

The fixator components are shown in the following figure:

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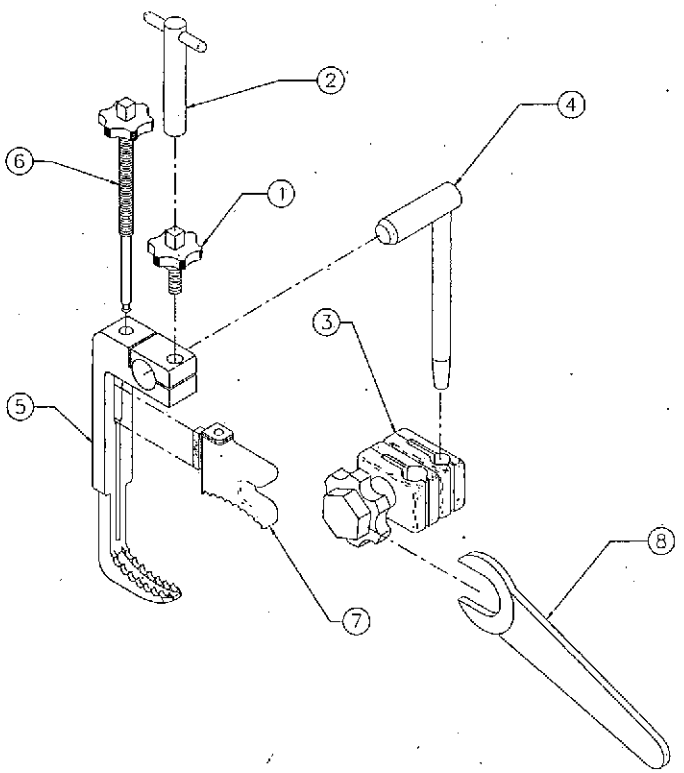

Figure 6-3. Fixator Components

①	Knob Bolt	⑤	Lower Jaw
②	T-Handle Wrench	⑥	Clamp Bolt
③	Swivel Block	⑦	Upper Jaw
④	Fixator attachment rod	⑧	Wrench

Proximal Fixation

⇨ **To assemble the proximal clamp:**

1. Place the upper jaw (7) into the slide channel on the lower jaw (5).
2. Place the clamp bolt (6) into the hole nearest the slide channel and join the upper and lower jaws by threading the clamp bolt through both jaws, leaving jaws fully open.
3. Thread the knob bolt (1) into the other hole provided in the lower jaw, but do not tighten.
4. Insert the fixator attachment rod (4) into the hole in the proximal end of the lower jaw.
5. Manually tighten the knob bolt (1).

⇨ To install the proximal clamp:

1. Holding the proximal assembly, slide the proximal hook into place under the femur.

   NOTE: To avoid interference with the cutter, the proximal hook must be positioned below the level of the osteotomy.

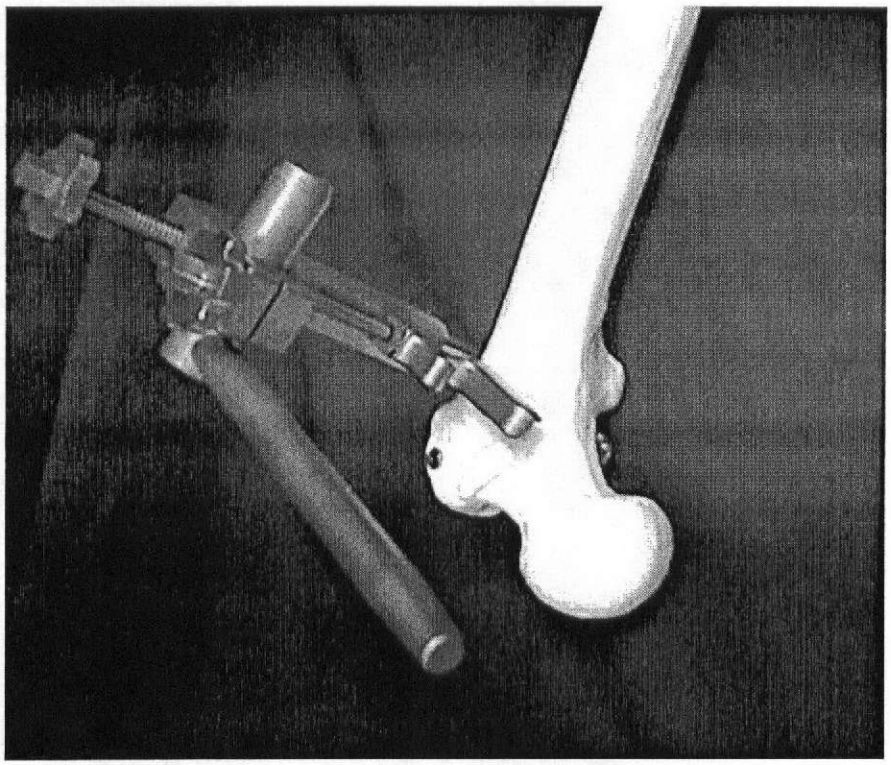

Figure 6-4. Proximal Clamp Position

2. Tighten the proximal clamp, using the T-handle to maintain a firm grip on the femur.

3. Ensure that the clamp holds the bone securely.

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Distal Fixation

Distal fixation requires an external means of stabilizing the femur. Adequate distal fixation is especially critical for DigiMatch cases because surface registration involves inserting the digitizer probe through soft tissue and contacting the distal femur. Bone motion may result if distal fixation is inadequate.

ISS does not provide a device for distal fixation. Most ROBODOC sites are equipped with a non-sterile, table-mounted patient positioning device that can be positioned so the lower leg can rest firmly on it. This device is covered with a sterile barrier and, during fixator installation, the leg is secured to the support fixture using sterile elastic wraps. Bending the knee slightly may help stabilize the rotational tendency of the femur, and applying fixation slightly above the knee will help stabilize translational motions near the condyles.

The exact best method of fixation will be determined by the surgeon.

WARNING: To avoid causing bone motion, the surgical team must not contact the lower leg during a ROBODOC procedure. Adequate distal fixation is necessary to prevent motion.

Attaching the Fixator to the Robot Base

⇨ **To attach the fixator to the robot base:**

1. Loosely place the swivel block on the fixator extension arm.
2. Move the robot to the OR table on the operative side of the patient and lock the base in place.

   For the direct lateral approach, the robot will be positioned at an angle to the OR table.
3. Make sure that the bolt on the swivel block is loose. If the bolt is too tight, the fixator attachment rod will not fit into the swivel block.
4. Insert the fixator attachment rod into the swivel block as shown in Figure 6-5.

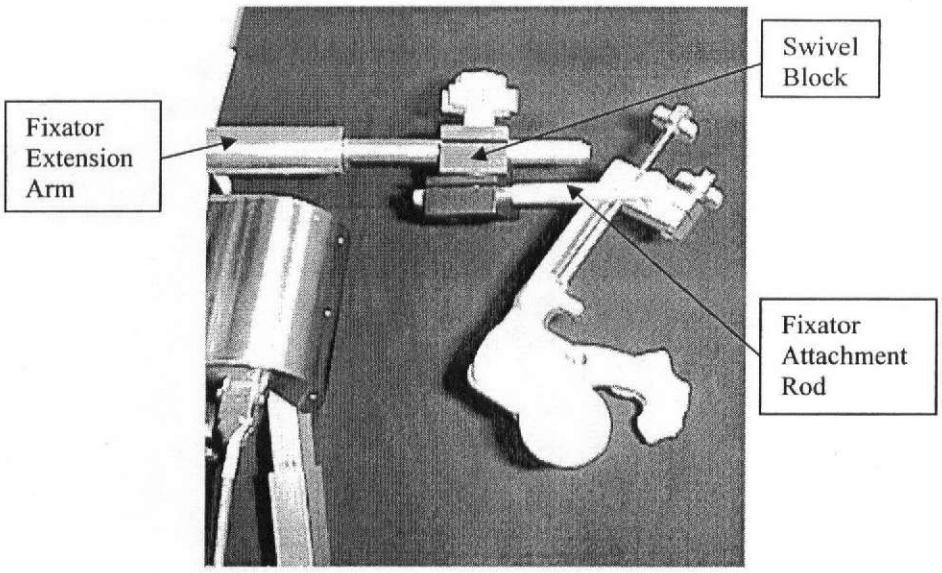

Figure 6-5. Attaching the Fixator to the Robot Base

5. Adjust the height of the OR table and/or the fixator extension arm as necessary to facilitate coupling.

   To adjust extension arm height, a non-sterile person can reach under the drape and loosen the knob on the fixator block. For all systems, except those configured for direct lateral DigiMatch surgeries, the extension arm should be positioned near the middle of the fixator mounting block to ensure that it is rigidly held during surgery.

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For the direct lateral DigiMatch systems, the height of the fixator extension arm can be adjusted by loosening the hex screw with the sterile hex wrench.

6. Verify fixator extension arm stability.

7. The femur should be positioned within 45 degrees of horizontal.

8. Tighten the swivel block bolt.

   Use the bearing sleeve wrench to ensure tightness, but do not overtighten because overtightening may freeze the joint and make it difficult to detach the frame after femoral canal preparation.

9. Check distal fixation.

10. Tighten the knob on the fixator mounting block or, for the direct lateral approach, tighten the clamp screw in the extension arm using the sterile hex wrench.

Checking Fixator Installation

This procedure involves checking all attachments and adjustment sites to verify that the femur is securely positioned in the fixator and the fixator is securely mounted on the base.

⇨ **To check fixator installation:**

1. Verify that there is no mechanical play between any of the mating components.

2. Verify that the femur is within 45 degrees of horizontal.

3. Check lower leg fixation.

4. Confirm that the swivel block is tight.

5. Ensure that the proximal clamp jaw is firmly tightened against the femur.

6. Ensure that the fixator extension arm is secure in the fixator mounting block.

7. Lock the robot base in place.

Setting Soft-Tissue Retractors

To prevent bone motion and minimize the need for manual retraction, it is important to set all self-retaining retractors, both proximally and distally, for pin-based registration before installing the BMM. After installing the fixator, apply as

much required retraction as possible to provide access for surface registration (digitizing surface points or finding locator pins) and femoral canal preparation. Manual retraction may cause bone motion and should be avoided, if possible.

Set the retractors in locations where they will not interfere with the probe or cutter. In DigiMatch cases, the digitizer probe must access the ROI for surface registration. The cutter needs to approach the proximal femur in alignment with the long axis of the femur. Adequate soft tissue retraction or other methods of protection should be applied so that critical soft tissue is not inside the robot cut path. It may be necessary to extend the incision to provide adequate exposure. To avoid damage to soft tissue, apply adequate retraction to provide the robot clear access for surface registration procedures and femoral preparation. **Do not proceed until you have sufficient exposure..**

Warning: Failure to provide adequate soft tissue retraction or other methods of protection for critical soft tissue could result in soft tissue damage.

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Installing the Sterile Pendant Drape

Draping the surgical pendant is a two-person procedure. The pendant drape is sterile and is for single use only.

Before installing the sterile pendant drape, the robot must be positioned at the OR table.

⇨ **To install the pendant drape:**

1. Non-sterile person: Hold the pendant cord approximately 30 centimeters from the control end of the pendant.

2. Surgeon or sterile person: Unwrap the sterile pendant drape and hold the opening in an upright position.

3. Non-sterile person: Lower the pendant into the sterile drape opening until the pendant is resting on the sealed end of the drape. While the surgeon or sterile person holds the draped pendant, pull the drape along the cord until it has completely unfolded and secure it with the tape provided in the drape kit.

4. Surgeon or sterile technician: Press **SELECT** when the pendant has been successfully draped.

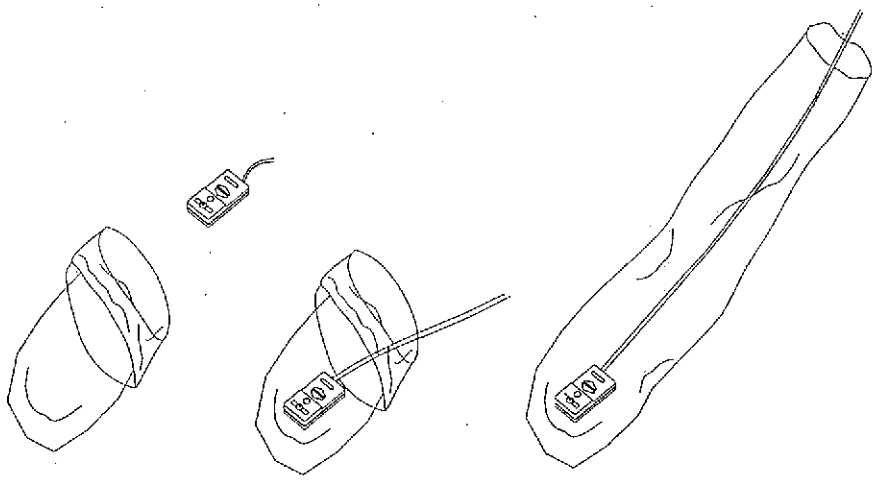

Figure 6-6. Pendant Drape Installation

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Installing the BMM

The BMM must be installed before performing registration procedures (digitizing surface points or finding locator pins). This procedure is performed by the surgeon.

The BMM is a safety feature that detects motion of the proximal femur relative to the robot base. The BMM has a sterile probe, which relays motion from the femur to its position sensors. The probe makes direct contact with the bone and is held in place by an internal spring mechanism. If movement exceeds a predefined threshold, the safety system will disable cutting action and notify the surgeon via the OR Monitor.

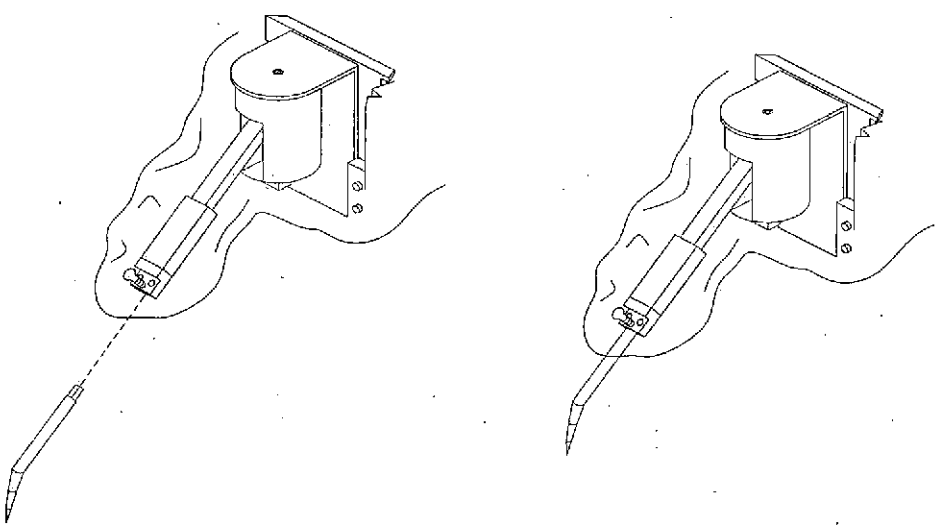

Figure 6-7. BMM Probe Installation

⇨ To install the BMM:

1. When the robot is in place in the sterile field, push the BMM probe through the drape and into the end of the adapter.
2. Tighten the thumb screw to hold it in place.
3. Locate an appropriate site in the open area of the proximal femur, where the BMM probe will not interfere with the digitizer probe, surface registration in proximal ROI for DigiMatch cases, or cutter during femoral canal preparation.
4. Press the sharp end of the probe firmly against the bone in the open area and release.

5. Apply slight pressure from side to side and top to bottom to confirm that the probe will not easily slip off the bone.

6. Verify that there is access for registration procedures and cutting, and that all components are securely tightened before activating the BMM.

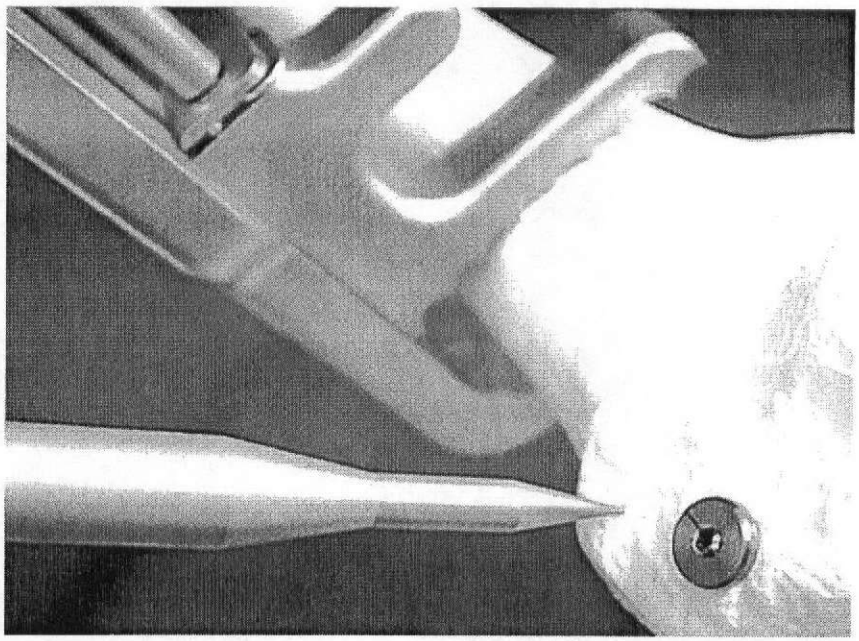

Figure 6-8. BMM Probe Installed in Femur

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Safety Considerations

- **Surgeon verification.** Only the surgeon may respond to the prompts requesting confirmation of patient data and implant description. Surgeon confirmation of patient and implant data ensure that the correct ORTHODOC tape has been loaded.

- **Distal fixation.** Ensure that fixation of the distal femur is adequate to prevent bone motion during surface registration and other procedures.

- **Proximal clamp.** Securely tighten the proximal clamp.

- **Fixator assembly.** Confirm that there is no mechanical play between any of the mating components after fixator assembly and installation.

- **Retractors.** Prior to registration, carefully set all soft-tissue retractors, positioning them to prevent interference with the probe during registration procedures or with the cutter during femoral canal preparation. Avoid applying additional retraction after installing the BMM in order to reduce the potential for bone motion.

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Chapter 7

REGISTRATION PROCEDURES

Introduction

This chapter provides the surgeon with information about performing registration procedures that spatially orient the robot in relation to the femur.

For DigiMatch cases, registration is obtained by digitizing specified points on the bone surface.

DigiMatch Surface Registration

This section provides the surgeon with information about digitizing surface points, verifying surface registration, and digitizing the recovery marker.

Digitizing Surface Points

When digitizing points on the bone, as described in the following set of instructions, gently contact the bone with the probe, but *do not* push on the bone. Pushing on the bone will cause bone motion. The probe tip must remain motionless while the data point is being captured. If the probe tip moves during data point capture, the OR Monitor will display an error message and you will have to re-digitize the point.

During DigiMatch surface registration, points must be collected as displayed on the OR Monitor to ensure that the points are adequately spaced over the region of interest. The surgeon must use a light touch to avoid moving the bone, while ensuring that the probe tip makes contact with the bone.

⇨ To digitize surface points:

1. When prompted to do so, contact the tip of the greater trochanter with the pointed digitizer probe and press **SELECT** when the probe is in the desired position.

   Gently contact the bone with the probe, but *do not* push on the bone.

2. Install the distal recovery marker using a standard surgical air drill.

   The distal recovery marker should be installed in a location that can be easily accessed by the digitizer probe, but not in an area where the post may interfere with collection of data points during surface registration. The distal marker is typically installed on the medial side of the bone.

3. Install the proximal recovery marker using the ISS-supplied installation tool (P/N 102750).

   The proximal recovery marker should be installed in a location that can be easily accessed by the digitizer probe, but not in an area where the post may interfere with collection of data points during surface registration or with the cutter during cavity preparation. Figure 7- illustrates an appropriate location for the proximal recovery marker:

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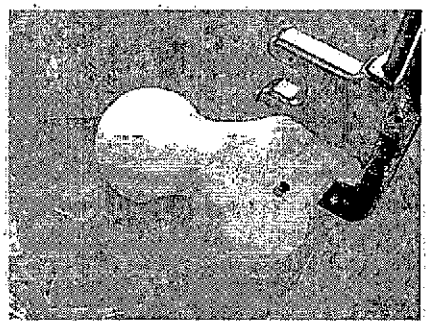

Figure 7-1. An Appropriate Location for the Proximal Recovery Marker

4. Whenever you are prompted to do so, digitize the distal recovery marker.

   While digitizing distal points on the bone surface, the OR Monitor will alternately prompt you to digitize the distal recovery marker. This procedure confirms that distal point collection has not caused bone motion.

5. When prompted to do so, digitize a lateral, anterior, and medial point on the distal femur through small percutaneous incisions made with a standard scalpel.

   The OR Monitor displays a distance bar indicator with a green band in the zone where the points lie. Digitize each point (lateral, anterior, and medial) by contacting the bone surface with the digitizer probe and pressing **SELECT** when the display indicates that the digitizer probe is approximately centered within the green band. Gently contact the bone with the probe, but *do not* push on the bone.

   WARNING: Be sure to space the points sufficiently apart. If the spacing between the points is insufficient, the OR Monitor will display the following error message:

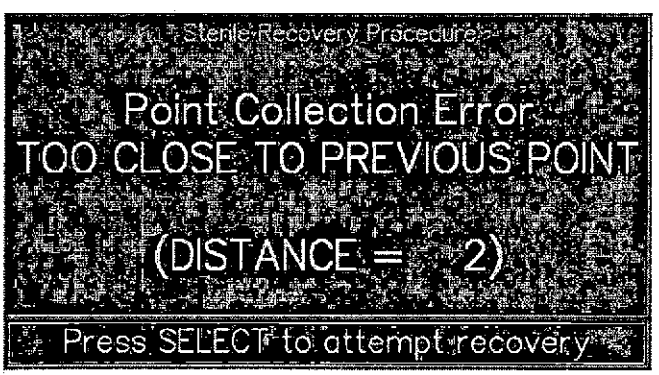

Figure 7-2. Error Message Indicating Insufficient Space Between Points

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After this error message appears, the OR Monitor will prompt you to recollect the last data point. Move the probe the distance specified away from the last collected point and recollect.

6. After digitizing the three distal points, digitize a total of 14 points in the proximal ROI as illustrated on the OR Monitor.

   The OR Monitor will display color-coded dots that identify the status of the points as follows:

   - **Red:** The red dot identifies the next point to be digitized.
   - **Green:** Green dots identify points that have already been digitized.
   - **Yellow:** Yellow dots identify points that need to be digitized.

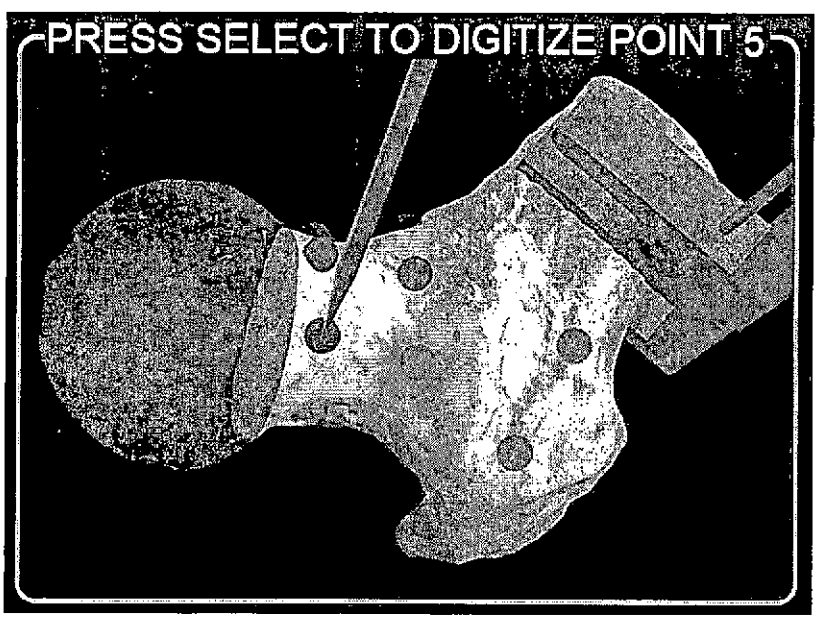

Figure 7-3. Surface Registration Points on the OR Monitor

After all 17 surface points have been collected and the recovery markers have been digitized, the OR Monitor displays the message, "**REGISTERING POINTS...PLEASE WAIT**," and a green progress bar. While this message is displayed, the system is computing point-to-surface registration.

Digitizing Recovery Markers

This procedure is extremely important because it confirms that the bone has not moved during point collection. In response to prompts on the OR Monitor

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during point collection, a single point on the distal recovery marker must be collected after each distal point. Additionally, multiple points must initially be collected, which include five points each on the distal recovery marker, extender sleeve on distal recovery marker, and proximal recovery marker. This procedure is described in the following set of instructions.

⇨ To digitize the recovery markers:

1. Gently position the probe in the divot on the distal recovery marker and press **SELECT** when the probe is in the desired position.

2. Without lifting the probe off the post, slightly change the angle and joint position of the digitizer and press **SELECT** when the probe is in the desired position.

   The angle of the pointed probe should not be changed as significantly as the ball probe during diagnostics. A few degrees is sufficient.

3. Collect a total of five points, slightly varying the angle and joint position of the digitizer between points.

4. Install the extender sleeve over the distal recovery marker as shown in Figure 7-4:

Figure 7-4. Extender Sleeve Installation

5. Gently position the probe in the divot on the extender sleeve and press **SELECT** when the probe is in the desired position.

6. Without lifting the probe off the post, change the angle and joint position of the digitizer and press **SELECT** when the probe is in the desired position.

7. Varying the angle and joint position of the digitizer, collect a total of five points.

8. Remove the extender sleeve.

9. Gently position the probe in the divot on the proximal recovery marker and press **SELECT** when the probe is in the desired position.

10. Without lifting the probe off the post, change the angle and joint position of the digitizer and press **SELECT** when the probe is in the desired position.

11. Varying the angle and joint position of the digitizer, collect a total of five points.

This procedure creates readily accessible landmarks that can be used to quickly reestablish registration in the event that bone motion occurs. If motion occurs, only the posts will need to be re-digitized, rather than the surface points on the bone. This procedure is critical because some of the surface points will no longer be present if motion occurs after some of the surfaces are cut away.

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Verifying Surface Registration

Verification of surface registration is critical, and the surgeon, not another member of the OR team, must perform this procedure. Registration is verified by re-digitizing three points in the distal ROI and six points in the proximal ROI (the "verification points"). When collecting verification points, the surgeon must ensure that points are collected at the locations indicated on the display. Subsequently, the surgeon must inspect each bone image to confirm that the identified probe position corresponds to the bone surface.

After each of the verification points is re-digitized, the OR Monitor displays an illustration of the digitized point superimposed on cross-sectional CT images:

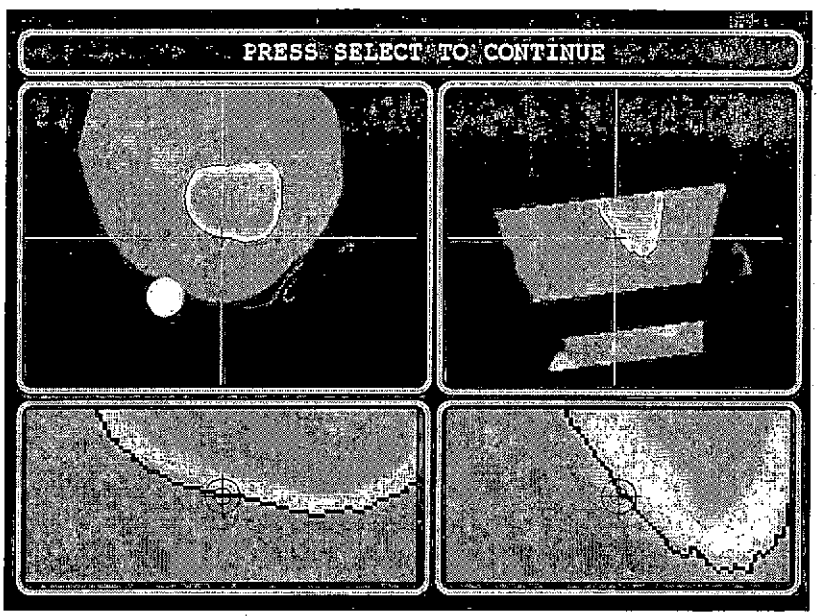

Figure 7-5. Verification Point Screen

The circular grids centered at each point indicate the physical distance from circle to point. The radius of the blue inner circle is 1 mm and the radius of the red outer circle is 2 mm. During registration verification, the surgeon must visually verify that the point is within 2 mm of the bone surface (inside the red circle).

⇨ To verify registration:

1. When prompted to do so, re-digitize three points on the distal femur and six points on the proximal femur by visually locating their positions and digitizing the verification points on the bone surface.

2. After digitizing each distal point, the OR Monitor will prompt you to digitize a single point on the distal recovery marker.

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This procedure ensures that the bone has not moved during collection of verification points.

3. After re-digitizing these points, the OR Monitor displays the following prompt:

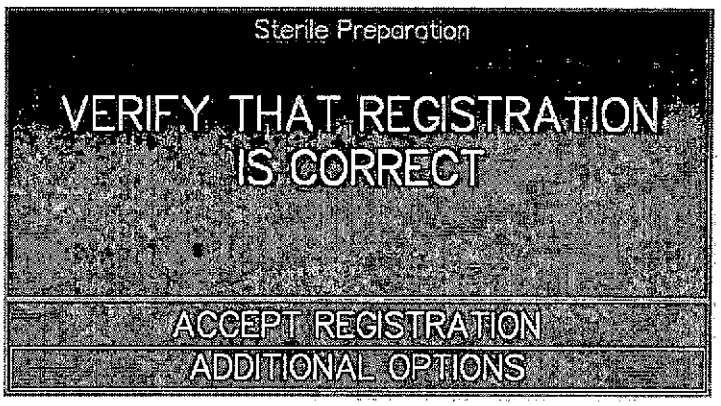

Figure 7-6. Prompt to Verify Registration

When this screen is displayed, the surgeon must decide if registration is satisfactory (i.e., that all the points are within 2 mm of the surface).

4. Select **ACCEPT REGISTRATION** to indicate that registration appears to be satisfactory or **ADDITIONAL OPTIONS** if there is uncertainty about any of the verification points.

   If **ACCEPT REGISTRATION** is selected, begin the procedure described in the following section.

   If **ADDITIONAL OPTIONS** is selected, the OR Monitor displays the following verification options:

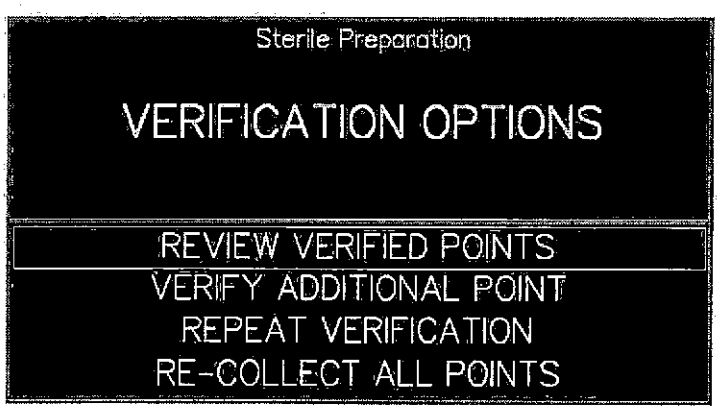

Figure 7-7. Verification Options

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⇨ **To use additional options:**

Select one of the following options from the Verification Options screen:

- **REVIEW VERIFIED POINTS**: This option enables visual review of verification points. If visual review indicates a potential placement problem with one or more points, select one of the other options to correct the problem. When this option is selected, the OR Monitor displays the first verification point. Use the pendant to display additional verification points: **UP** displays the next point; **DOWN** displays the previous point; and **SELECT** redisplays the **"VERIFY THAT REGISTRATION IS CORRECT"** prompt.

- **VERIFY ADDITIONAL POINT**: This option enables you to re-digitize additional points for verification purposes. Use this option when you are uncertain about the placement of verification points in a certain direction. For example, if the distal anterior verification point and the anterior neck verification point both appear to be approximately 2 mm from the edge of the bone (near the blue circle), select this option to collect an additional point on the anterior surface of the bone. After collecting the additional point, the OR Monitor will display the verification screen for that point, followed by the **"VERIFY THAT REGISTRATION IS CORRECT"** prompt. If repeated verification still indicates a problem with the location of verification points, repeat registration by recollecting all points.

- **REPEAT VERIFICATION**: This option enables you to re-digitize all verification points. Use this option when you are uncertain about the placement of multiple points and want to re-digitize all of the verification points (i.e., repeat the verification process described in the previous section). If repeated verification still indicates a problem with the location of verification points, repeat registration by recollecting all points.

- **RECOLLECT ALL POINTS**: This option enables you to repeat the entire surface registration and verification procedure. Use this option if one or more of the verification points is more than 2 mm from the edge of the bone (outside the blue circle). The system will re-compute surface registration.

Error Detection for DigiMatch Surgeries

The OR Monitor will display error message screens if problems occur during point collection or verification. If registration procedures cannot be successfully completed, the operation must be performed manually with the broach.

After registration, the BMM and safety system will automatically pause the robot if motion exceeding a predefined threshold occurs. The OR Monitor will then prompt the surgeon to digitize the motion recovery markers.

When registration is complete, the robot evaluates the position of the bone to verify that the entire implant cavity is within its workspace. If part of the cavity is

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outside the workspace, the OR Monitor displays an error message screen that prompts you to perform the appropriate recovery procedure. Recovery procedures include adjusting base height and then digitizing the motion recovery markers.

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Safety Considerations

- **Automated movements.** Do not touch the robot during automated movements. Whenever the robot is about to move automatically, the OR Monitor will display a warning screen.

- **Patient position.** Do not adjust the position of the OR table or the position of the patient after starting the digitizing procedure in DigiMatch cases or the pin-finding procedure in locator pin cases.

- **Surgeon verification of digitized points.** In DigiMatch cases, verification of digitized points by the surgeon is critical. When re-collecting verification points, the surgeon must ensure that points are collected at the locations indicated on the display and inspect each bone image to confirm that the identified probe position corresponds to the bone surface.

- **Bone motion.** Because the bone motion monitor is installed in the proximal femur, motion of the distal femur may not be detected and may result in sub-optimal cavity placement.

- **Visual verification of probe position.** When prompted to verify that the probe is centered on the locator pin head, confirm that the ball of the probe is seated in the hex socket.

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Chapter 8

FEMORAL PREPARATION

Introduction

This chapter provides the surgeon with information about starting and monitoring the femoral preparation process.

Prior to femoral preparation, the surgeon must set the soft-tissue retractors, replace the ball probe with a cutter, and guide the robot to the starting position.

Femoral preparation is completely automated and takes 10 to 30 minutes depending on the type and size of the implant cavity to be prepared. The surgeon must continuously monitor the process, irrigate the area being drilled, and aspirate the cavity. If the surgeon detects a problem or needs to replenish irrigation fluid, the yellow **PAUSE** button on the pendant will interrupt drilling.

Exception conditions such as force freezes or bone motion sometimes occur during femoral preparation and the surgeon may need to perform recovery procedures to restart drilling.

When femoral preparation is complete or a tool change is necessary, the cutter automatically stops and withdraws from the cavity.

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Installing a Cutter

This section provides instructions for surgeons on installing cutting burrs in the tool tip.

ROBODOC cutters are sterile, single-use femoral cutting burrs that are specially designed for compatibility with validated implant systems. If the cutter is damaged by contact with a locator pin, retractor, or any other object, the surgeon must install a new one.

The cutter is installed after successful surface registration using the digitizer or the ball probe and locator pins. Depending upon the implant system being used, the surgeon may be prompted to remove the original cutter and replace it with a finishing cutter.

The "Installing Probes and Cutters" section in Chapter 2 provides illustrations of the installation and verification procedures described in this section.

⇨ To install a cutter:

1. When prompted to do so, guide the robot arm to a clear tool change position.
2. Verify the part number of the cutter prior to installation.
3. The OR Monitor displays the part number (P/N) of the appropriate cutter.
4. Use the small rod and wrench set to loosen and remove the ball probe (or original cutter) as follows:
   - Insert the rod through the hole in the motor spindle and hold it stationary to prevent the spindle from moving.
   - Grip the collet nut with the small wrench.
   - Turn the wrench counterclockwise until the probe is loose.
   - When the probe is loose, pull it out of the bearing sleeve.
5. Insert the cutter as far as possible into the bearing sleeve.
6. Use the small rod and wrench set to install the cutter, turning the wrench clockwise and the rod counterclockwise.

   Tighten the collet nut using only the rod; tightening with the wrench may apply too much force and cause the rod to break.
7. Press **SELECT** when the cutter is installed.

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8. Verify installation of the cutter by sliding the cutter verification gauge into the gap between the cutter and the sleeve.

   The small step of the gauge should fit in the gap, but the large step should not fit. If the verification fails, repeat the steps 3 through 7. If cutter installation repeatedly fails, refer to the "Troubleshooting" chapter in this manual.

Connecting the Gas and Air Supply

This section explains how to connect the gas and air supply to the cutter drive assembly on systems with air motors.

This section does not apply to systems with electric motors.

⇨ **To connect the gas and air supply:**

1. Attach the black coaxial supply hose (P/N 102471) to the robot base with the logo facing upward.

2. When prompted to do so, attach one end of the green gas supply hose to the back of the cutter drive assembly as shown in Figure 8-1.

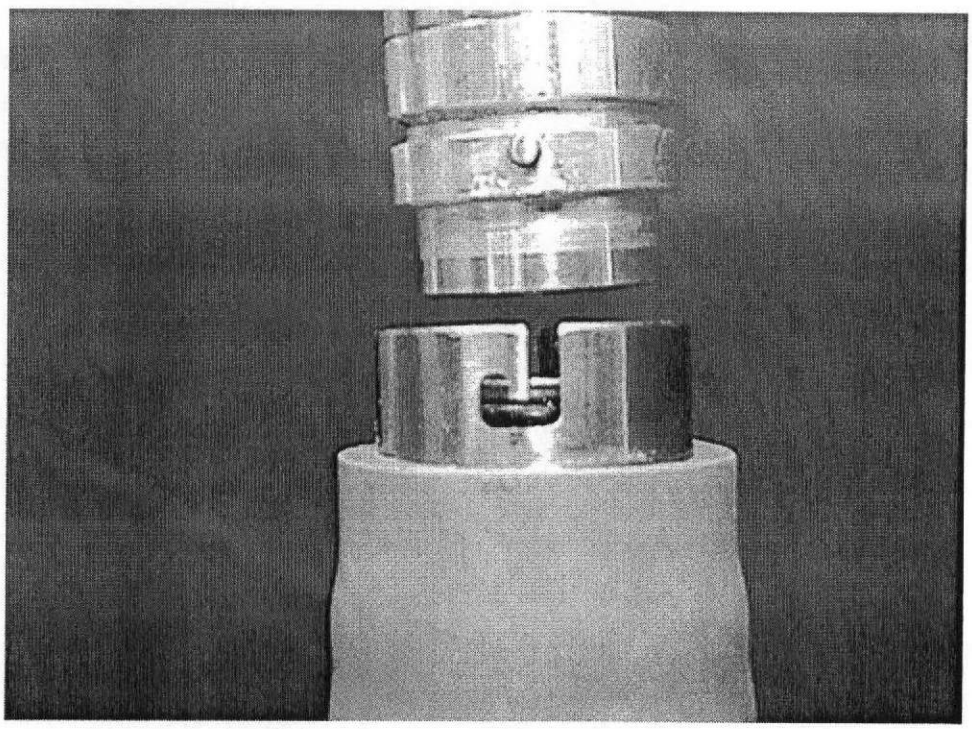

Figure 8-1. Sterile Gas Hose Attachment

NOTE: After attaching the hose, ISS does not recommend removing the hose from the cutter drive assembly until the cutting procedure is finished. At that time, the supply hose should be detached from the robot base end of the hose so that any gas that escapes will be vented away from the sterile field.

3. Connect the other end of the green gas supply hose to the robot base with the return air nipple facing upward.

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4. If your system is equipped with a filter box (P/N 102539), push the return air nipple on the green hose into the O-ring gland on the larger side of the filter box and push the filter box onto the return air nipple on the black supply hose.

   Use lubrication and a rocking motion to ease insertion of the nipples.

5. Push the other end of the black supply hose into the air motor receptacle on the wall.

NOTE: When disconnecting, separate the components in the reverse order of connection. Be prepared for hose recoil and air noise when disconnecting the hose from the wall receptacle.

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Operating the Irrigation System

This section explains how to connect the irrigation system before surgery, adjust the flow, and disconnect the system when the procedure is complete. Figure 8-2 and Figure 8-3 illustrate the components associated with the irrigation system:

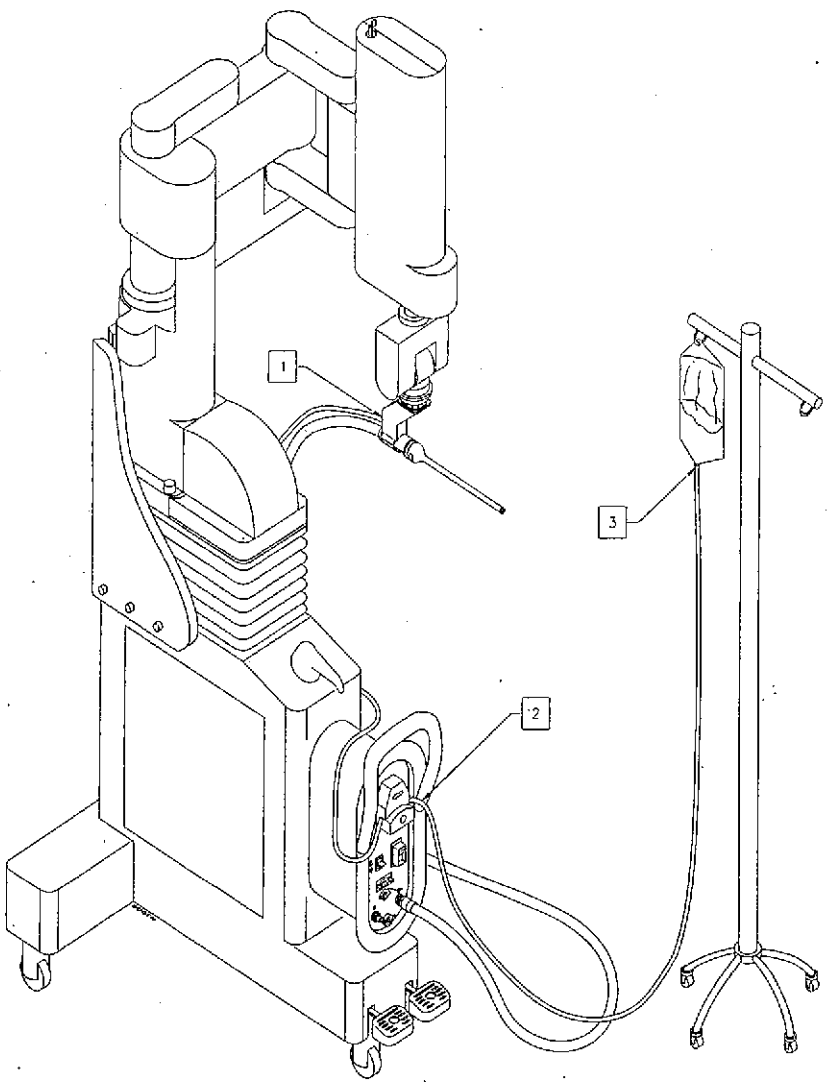

Figure 8-2. Irrigation System Components

[1] Luer Fitting [2] Irrigation Line [3] Supply Spike

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⇨ To connect the irrigation system:

1. Sterile Person: Connect the Luer fitting on the end of the disposable irrigation line to the rear of the cutter drive.

2. Non-sterile Person: Insert the disposable irrigation line through the pump head.

3. Non-sterile Person: Move the pump lever to the right to clamp the line on the rear panel of the robot.

   The arrow on the pump head decal indicates direction of flow to the cutter drive.

4. Non-sterile Person: Using a standard aseptic technique, connect spike end to a sterile saline supply.

   The elevation of the supply is not critical. The supply can be suspended from an IV stand or can reside in a solid container resting on the floor.

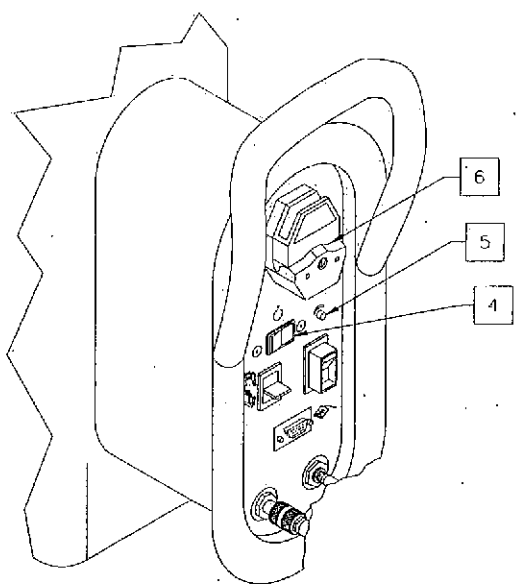

Figure 8-3. Irrigation System Components

[4] Irrigation Switch [5] Flow Adjustment Knob [6] Pump Head

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⇨ To adjust the flow:

1. Non-sterile Person: Prime the cutter drive by toggling the irrigation switch on the rear panel of the robot to the right (manual mode).

2. Non-sterile Person: When saline sprays from the cutter sleeve, toggle the irrigation switch to the left (automatic mode).

   The center switch position is the off position.

3. Non-sterile Person: Turn the adjustment knob to increase or decrease flow from the sleeve.

   Turning the knob to the right increases flow and turning to the left decreases flow.

⇨ To disconnect the irrigation system:

1. Turn the irrigation switch to the off position.

2. Disconnect the supply spike from the saline supply.

3. Unclamp the irrigation line on the rear panel

4. Disconnect the Luer fitting from the cutter drive.

5. Dispose of the irrigation line in accordance with hospital procedures and regulations for disposal of biohazardous waste.

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Resetting the Retractors

Retraction of the abductors is necessary to provide clear access for the cutter. The surgeon must be careful to avoid moving the bone whenever retraction is applied after surface registration.

The abductors should be dissected laterally and retracted as far as possible without detachment, prior to starting the cutter. However, it may not be possible to determine how much retraction is necessary until the cutter actually starts spinning and begins its approach. Then, if clearance appears to be inadequate, the surgeon should pause the robot, manually guide the cutter away from the bone, complete the dissection, and reset the retractors.

As the automatic drill cuts the cavity, additional retraction may be required to clear soft tissue from the path of the cutter. If necessary, the surgeon may pause the robot and back the cutter out of the cavity in Guide Along Tool Axis mode.

The surgeon must be careful to avoid bone motion when applying additional retraction. If bone motion occurs after surface registration, the appropriate recovery procedure must be performed (digitizing the recovery markers or re-finding the locator pins). Retractor adjustments can be made without the risk of bone motion by disabling the BMM from the Pause menu. Bone motion monitoring will resume when the procedure continues.

Milling the Femur

The surgeon guides the robot to an approximate starting position in front of the bone. The robot stops automatically in an appropriate location and then moves to the initial cutting position.

The surgeon initiates all automated movements and starts the cutter by responding to prompts on the OR Monitor. In DigiMatch cases, when the robot finishes the "precut" region (area proximal to the stem), the surgeon must re-digitize the proximal and distal recovery markers.

⇨ To start the cutter:

1. Surgeon: When prompted to guide the robot in front of the bone, guide the cutter to a position within a cone-shaped zone that extends outward from the proximal femur as shown in Figure 8-4:

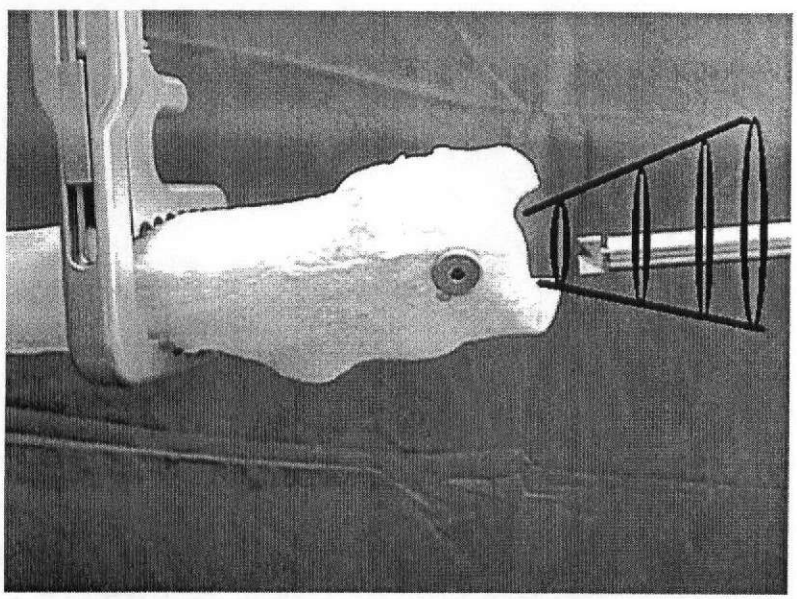

Figure 8-4. The Cutter Starting Position

When you guide the cutter into this cone-shaped zone, the robot will automatically stop in an appropriate location and the OR Monitor will display a message advising that the robot is ready to move to the initial cutting position. If you have difficulty finding this cone-shaped zone, pull the cutter back and try again (the cone becomes wider as you move away from the bone).

2. Surgeon: Press **SELECT** to initiate the automated movement to the initial cutting position.

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The OR Monitor will first display a warning not to touch the robot and then prompt for guidance to the top of the bone. The robot will allow guiding along the tool axis.

3. Surgeon: Guide the cutter tip just above the bone and press **SELECT**.

4. Surgeon: Press **SELECT** again to start femoral drilling.

   The cutter will briefly spin in air before it contacts the bone.

5. Non-sterile Person (for systems with air motors): As soon as the cutter starts spinning, confirm that the lubricant in the inline oiler is dripping at a rate of one drop every ten seconds.

   In DigiMatch cases, when the precut region (area proximal to the femoral stem) is complete, the OR Monitor prompts the surgeon to re-digitize the proximal and distal recovery markers.

6. Surgeon: When prompted to do so, re-digitize the distal marker center, distal marker sleeve, and proximal marker, being careful to avoid moving the marker or pressing too hard with the digitizer probe.

   If registration has changed by more than 1 mm proximally, 2 mm distally, or 2° of rotation about the proximal-distal axis, cutting must be re-started from the beginning. If the change in registration is negligible, the robot reorients to the new registration and cutting continues.

   For some implant systems, when the cavity is nearly complete, the tool tip will withdraw from the cavity and the OR Monitor will prompt the surgeon to install a finishing cutter.

7. Surgeon: Replace the cutter by following the instructions on the OR Monitor and in the "Installing Probes and Cutters" section in Chapter 2.

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Monitoring the Procedure

The surgeon and OR team must continuously irrigate, aspirate, and retract soft tissue while the robot prepares the femoral cavity. It is also important to visually monitor the drilling process, both directly and by viewing the OR Monitor. This section describes all of the tasks that must be performed during robotic femoral preparation.

Irrigation

The high-speed cutter generates heat. To prevent thermal damage to the bone and to clear debris, the area around the cutter must be continuously irrigated during drilling. Whenever the fluid needs to be replenished, the surgeon must immediately pause the robot.

Aspiration

Due to the amount of irrigation fluid used during drilling, the cavity should be periodically aspirated.

Visual Monitoring

The OR Monitor displays a simulation of the current status of the cavity. The displayed images are based on the distance the cutter has actually traveled and information in the transfer file about the planned dimensions of the cavity. These images are useful in determining where the robot should currently be cutting. The intended path of the cutter is displayed in green. When the cutter should have completed a particular path, it turns red.

The system has many built-in safety features to ensure accurate cutting, but surgeons can also detect cut path errors using visual and audible clues. The surgeon should watch the image on the screen to ensure that it corresponds to the sound of the cutter. If a problem is suspected, the surgeon should pause the robot, back the cutter out of the cavity in Guide Along Tool Axis mode, and examine the cavity.

Inline Oiler

For systems with air motors, monitor the oil level in the inline oiler to ensure that the lubricant continuously drips at a rate of one drop every 10 seconds.

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Common Exception Conditions

To ensure patient safety, the robot is equipped with sensors that automatically pause the robot if an out-of-threshold condition is detected. In most cases, the surgeon can restart the robot simply by selecting **Continue** from the menu of recovery options that appears on the OR Monitor. The most common exception conditions include:

- **Force Freezes:** The robot is equipped with a force sensor that continuously monitors the forces applied at the tool tip. When forces exceed a predefined limit, the force sensor pauses the robot. If forces exceed a higher threshold, the sensor initiates an emergency power off (EPO).

  Force freezes occasionally occur when the cutter first engages the proximal femur where the bone is dense. Direct contact between the tool and a solid object such as a retractor may also cause a force freeze.

  The force freeze is the exception condition that occurs most often during a typical surgery. When a force freeze occurs, the OR Monitor displays a menu similar to the one shown in. The Restart Cutting option does not appear if the robot is not cutting at the time of the force freeze.

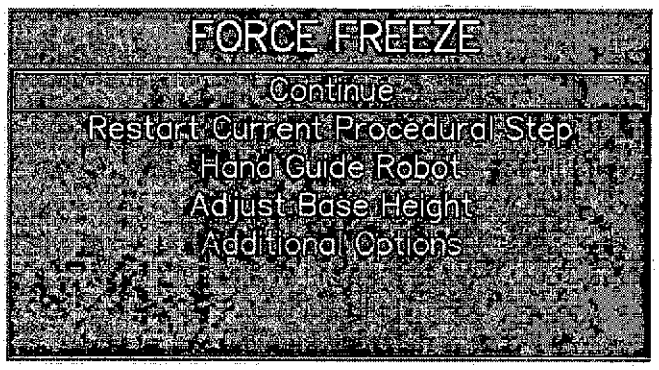

Figure 8-5. The Force Freeze Menu

  If the force freeze occurred when the robot was not touching anything or the cause of the force freeze is no longer present, you can immediately resume by selecting **Continue** (the default option). If you suspect that the force freeze was triggered by a problem such as contact with a retractor or other solid object, select the **Guide Along Tool Axis** option, move the tool slightly, and check the area before continuing.

- **Encoder Freezes:** The robot has two sets of encoders that constantly monitor joint positions and cross check each other to ensure accuracy. An encoder freeze results in the unusual event that cross checking reveals a discrepancy. When an encoder freeze occurs, the OR Monitor displays the menu shown in Figure 8-6.

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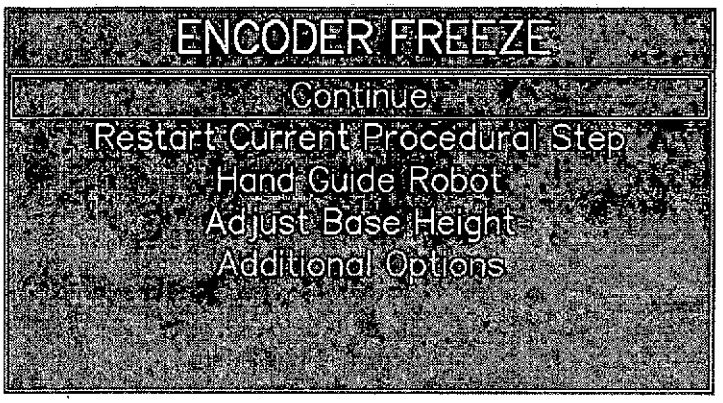

Figure 8-6. The Encoder Freeze Menu

To restart the robot after an encoder freeze, select **Continue** (the default option).

- **Bone Motion:** The BMM pauses the robot if the femur moves in relation to the robot base. If the femoral fixator is properly installed and the OR team is careful to avoid bumping the leg or the OR table, bone motion will rarely occur. Since the robot determines the location of the bone by surface registration, the appropriate recovery procedure must be performed if the bone moves (digitizing the recovery markers or re-finding the locator pins).

- **Oil Level:** If the motor starts to slow down, check the inline oiler to ensure that it contains enough lubricant to continuously drip at a rate of one drop every 10 seconds.

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Safety Considerations

- **Irrigation.** To cool the bone and prevent thermal damage, irrigation must be continuously delivered to the area being prepared.

- **Cutter installation verification.** Use the installation verification gauge to confirm that the cutter is properly installed.

- **Soft-tissue retraction.** To avoid damage to soft-tissue, apply adequate retraction to provide the robot with clear access for surface registration procedures and femoral preparation.

- **Visual monitoring.** While the robot prepares the cavity, watch the images on the OR Monitor and the actual progress of the cutter. If there seems to be a discrepancy, back the cutter out and examine the cavity.

- **Force freeze recovery during cutting or pin finding.** Before continuing with the procedure, check the area near the tool tip to ensure that the force freeze was not triggered by a problem such as contact with a retractor.

- **Cutter noise.** If the cutter sounds as if it may have contacted a retractor or clamp even in the absence of a force freeze, the cutter must be inspected for damage. Pause the robot, guide the arm out the cavity (guide along tool axis), inspect the cutter (burr) for damage, and replace it.

  NOTE: ISS recommends cutter replacement even if no damage is visible because the cutter may have been dulled even if damage is not apparent.

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Chapter 9

CLEANING, CALIBRATION, AND ROUTINE MAINTENANCE

Introduction

This chapter describes all of the routine maintenance procedures that must be performed by a hospital technician or OR staff for each ROBODOC surgery. It also provides instructions for cleaning and sterilizing removable components and for calibrating the robot.

ISS recommends that you perform these procedures in the following order:

⇨ **After surgery:**

1. Disassemble, disinfect, and clean the removable parts, and tools.
2. Change the diffuser on systems with air motors.

⇨ **Before surgery:**

1. Check the inline oiler on systems with air motors and refill it, if necessary.
2. Replace the motor safety seal on systems with air motors.
3. If using non-sterile cutters, clean and sterilize cutters.
4. Sterilize the cutter drive assembly, removable parts, and tools.

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Disassembling and Cleaning

This section provides instructions for cleaning and sterilizing the removable components and instrumentation associated with the ROBODOC Surgical Assistant System.

Disassembling Removable Parts

⇨ **To disassemble the system after surgery:**

1. Disconnect the cables.
2. Remove the cutter drive and all probes and tools.
3. Fully disassemble all of the removable parts and tools, as required.

   NOTE: When disassembling the **Fixator Assembly,** unscrew and remove the knob bolt from the bone clamp, remove the bone clamp from the extension arm, unscrew and remove the threaded bone clamp bolt from the bone clamp, and remove the upper jaw from the bone clamp. For the **Digitizer Sterile Interface** (Digimatch™ only), unscrew and remove the probe tip from the shaft.
4. Remove and discard the plastic drapes on the robot arm , base, and pendant.
5. Clean the robot and all removable parts.
6. Discard all single-use parts.

Cleaning Robot and Control Cabinet

⇨ **To clean the Robot and Control Cabinet:**

1. If necessary, wipe the robot base with a disinfectant such as a 2 percent solution of gluteraldehyde.
2. If necessary, wipe the OR Monitor and Control Cabinet with the same disinfectant used on the robot base.
3. Wipe the case and the cable on the pendant with isopropyl alcohol.

NOTE: Do not sterilize the pendant or immerse it in water.

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Cleaning Removable Parts

Do not immerse in water, machine wash, or use ultrasound equipment to clean the cutter air motor and green hose with quick connect or the electric motor and cable.

⇨ To clean removable parts and tools:

1. For systems with air motors, wipe off all oil residue from the green hose with quick connect checking to be sure that any trace of motor lubricating oil is removed from hose surfaces (oil may interfere with sterilization).

2. Wearing gloves and protective attire, run cool or warm tap water over each part to remove visible debris.

   NOTE: The cutter drive assembly (with motor attached) may be held upright under the cool or warm tap water to rinse the visible soil from all surfaces. Again be sure that the motor is not immersed. Dry the cutter drive assembly using a clean non-shedding wiper.

3. Remove the motor (air or electric) from the cutter drive assembly and clean the cutter drive assembly along with the other removable parts.

4. Prepare the following: a solution of 1% Alconox® per manufacturer's instructions (10 grams/liter distilled or deionized water), or an equivalent type of detergent in sufficient volume to completely cover the parts and tools. If parts are heavily soiled, use a 1% solution (10 grams/liter) of Terg-A-Zyme, or an equivalent detergent containing protease enzyme.

   NOTE: Refer to the manufacturer's instructions for information about dispensing, measuring, and storing the detergent, and for a description of potential health hazards associated with the use of the product. To prevent coagulation of protein material on the surface of parts, use only ambient (room-temperature) water.

5. When the detergent is completely dissolved, immerse the parts and tools in the solution and soak for 10 minutes.

6. Using soft non-metal bristle brushes, thoroughly clean all surfaces of parts. Small brushes should be used to clean threaded holes and parts. DO NOT USE cleansing or scouring aids (such as metal pads or bristles) that may scratch metal finishes.

7. For bearing sleeve assemblies, use a soft bristle brush (3 mm diameter) to clean the inner lumen of bearing sleeves.

8. Remove parts and tools from the detergent solution and rinse thoroughly (at least 1 minute) in tap water. Be sure to flush holes and lumens.

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9. Drain parts and tools.

10. Perform a final rinse in deionized or distilled water, soaking for at least two (2) minutes with periodic agitation.

11. To rinse the irrigation ports for the cutter drive assembly and bearing sleeve begin by attaching the bearing sleeve to the cutter drive assembly.

12. Obtain a clean luer lock syringe of at least 10 ml capacity and fill with deionized or distilled water.

13. Attach the syringe to the irrigation port located on the extension arm of the cutter drive assembly.

14. Use the syringe to flush the irrigation channel. Water should exit through the irrigation holes on the bearing sleeve hub. Flush the entire contents of the syringe.

15. If an irrigation hole appears to be plugged, a cleaning wire with a diameter no larger than 0.46 mm (0.018") may be passed through the bore.

16. Fill the syringe with air, attach to the inlet port, and blow out the water remaining in the irrigation channel. Repeat if needed.

17. Remove the bearing sleeve from the cutter drive assembly.

18. Use soft, non-shedding wipers to thoroughly dry all parts and let parts and tools air dry.

19. Examine the parts and tools to ensure that they are dry and clean.

20. On systems with air motors, replace the motor safety seal on the cutter drive assembly as describe in the next section.

WARNING: Failure to adequately clean tools may result in:

- Secondary infections
- Post-surgical complications
- Reduced tool longevity
- Increased number of field service calls and resultant costs

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Cleaning the Electric Motor

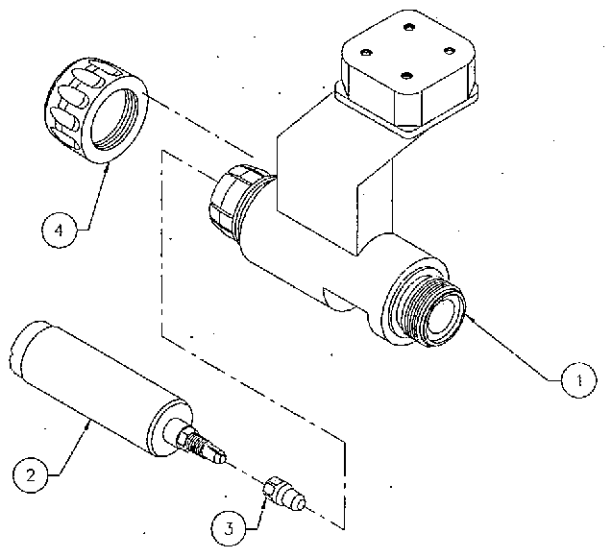

Figure 9-1. Electric Motor and Motor Holder Components

1. Motor holder (P/N 103376)
2. Electric motor (1/8" shaft [P/N 103333]or 3/32" shaft [P/N 103426])
3. Collet nut (P/N 103378)
4. Motor holder nut (P/N 103377)

NOTE: Do not clean these parts in an ultrasonic bath, washing machine, or dishwasher.

⇨ To clean the electric motor parts:

1. Rinse the motor, motor cable, and other components with water.
2. Disconnect the motor from the cable (see Chapter 2).
3. Clean the motor externally by wiping with a cloth soaked in a cleaning solution containing alcohol.
4. If desired, clean the motor internally by spraying an alcohol-based solution into the nose of the motor for 1 to 2 seconds.
5. Disinfect using a product with phenol-alcohol, glutaraldehyde (up to 3%), or alcohol; apply the disinfectant with a cloth or soak the motor for no more than one minute.

   Do not use products containing chlorine, acetone, or bleaching water in any concentration and do not soak for more than one minute.

6. If desired, spray a lubricant into the nose of the motor for 0.5 to 1 second.
7. Rinse the motor in running water.
8. Dry the motor at a temperature not to exceed 136°C.

Cleaning Non-Sterile Cutters

All ROBODOC cutters are single-use instruments. Those cutters that are supplied non-sterile (packaged in tube) must be cleaned and sterilized prior to clinical use. Wear protective gloves and other attire appropriate for cleaning. Handle cutters with care; sharp blade edges can cause injury if mishandled. Cutters can be damaged if dropped or placed in contact with other metal instruments during cleaning. Immediately dispose of damaged cutters to prevent unintended clinical use.

⇨ **To clean non-sterile cutters:**

1. Prepare a solution of 1% Alconox, Terg-A-Zyme, or equivalent type detergent per manufacturer's recommendations (10 grams/liter distilled or deionized water).
2. Soak the cutters in the solution for a minimum of five minutes.
3. Using soft brushes, thoroughly clean all surfaces of the cutters. DO NOT USE cleansing or scouring aids (such as metal pads or bristles) that may scratch metal finishes.
4. Remove the cutters from the detergent solution and rinse thoroughly (at least 1 minute) in tap water.
5. Drain cutters.
6. Perform a final rinse in deionized or distilled water, soaking for at least two minutes with periodic agitation.
7. Use soft, non-shedding wipers to thoroughly dry the cutters.

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Sterilizing All Removable Parts

⇨ **To sterilize the parts, tools, and non-sterile single use cutters:**

1. Place used parts, tools, and non-sterile cutters into trays.

   ISS recommends placing back-up components in a separate tray.

   Appendix D lists ROBODOC parts and tools.

2. Using a gravity displacement autoclave sterilization, wrap each item in cotton muslin, 2 ply or equivalent, and arrange the sterilizer load so that each item is exposed as follows:

   Sterilization of motors (air or electric)
   Temperature: **132°C (270°F)** Minimum Time: **25 minutes**
   CAUTION: Do not exceed 136°C (277°F) or 30 minutes

   Sterilization of all other removable parts (including non-sterile cutters)
   Temperature: **132°C (270°F)** Minimum Time: **15 minutes**

   The sterilizable components are designed to withstand resterilization.

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Routine Maintenance

The diagnostic tests are designed to identify the failure of ROBODOC components. When the system fails to pass a diagnostic test, notify ISS. The only ROBODOC components that must be routinely serviced by ISS are the cutter drive, bearing sleeves, and tape drive. The other routine maintenance procedures described in this section must be performed on a per-surgery basis by hospital technicians.

Servicing the Cutter Drive

Immediately notify ISS if problems such as vibrational loosening of components are observed. Return motor to ISS if a performance failure (e.g., unusual noise, loss of power, non-functionality) is observed.

Cleaning the Media Drive

The Media drives in the Control Cabinet and ORTHODOC workstation should be cleaned each time a field technician visits a ROBODOC installation.

Maintaining the Coaxial Wall Air Supply on Systems with Air Motors

The filter element inside the filter box for the air supply system must be replaced after every surgery. DO NOT steam or heat sterilize the filter box.

⇨ **To maintain the air supply filter:**

1. Disassemble and clean the filter box with soap and water.
2. Replace the filter element (P/N 102543).
3. If the O-rings are worn, replace them.

   Replacement O-rings are provided in the Coaxial Wall Air Module P/N 102527.

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Replacing the Safety Seal on the Air Motor

The safety seal on the air motor (ISS P/N 100496) must be replaced after every surgery.

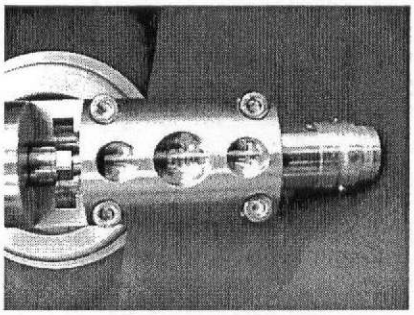
⇨ **To replace the safety seal:**

1. With a 3 mm hex wrench, loosen the four cap screws on the motor clamp one turn (see Figure 9-2A).
2. Pull the motor out of the motor cover (see Figure 9-2B).
3. Remove the collet nut (see Figue 9-2C).
4. Remove the used safety seal with a small pick (see Figure 9-2D).
5. Grasping the green portion of the safety seal installer, slide the green and yellow installer onto the rotor shaft until the green portion of the installer is flush against the motor.
6. Grasping the motor, depress the yellow portion of the installer as far as possible to insert the seal into the top nut.
7. Remove the plastic installer from the rotor shaft.

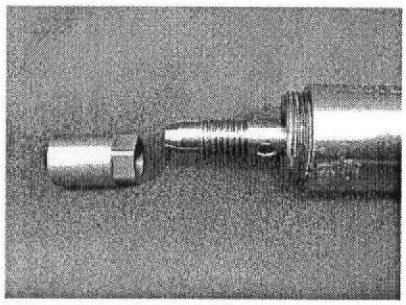
   If the clear internal sleeve is left on the shaft, remove it with a hemostat.
8. Replace the collet nut.
9. Insert the motor as far as possible.

   Probes and cutters will not seat properly if the motor is not inserted all the way.
10. While holding the motor in place, evenly tighten the four cap screws on the motor clamp.

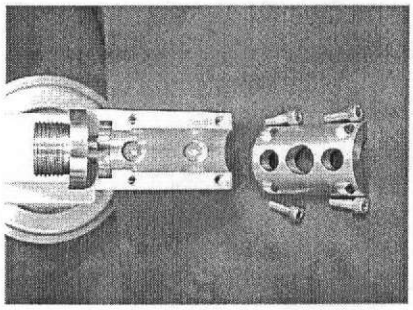
    Do not overtighten the screws because overtightening may damage the motor.



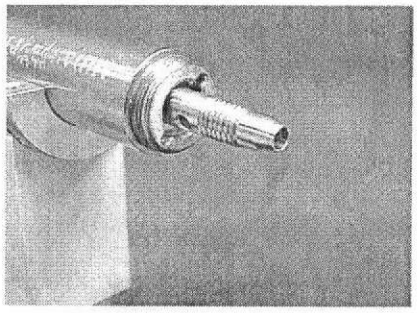
A. Remove Motor Retaining Bolts



C. Remove Collet Nut from Motor



B. Remove Motor



D. Remove Safety Seal

Figure 9-2. Replacing the Safety Seal on the Air Motor

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Installing the Air Motor for Small Cutters

Perform the procedure described in this section when small (3/32-inch shaft diameter) cutters will be used for the next surgery. The following instructions explain how to install the air motor and associated hardware in the cutter drive assembly to accommodate small sleeves and cutters. This procedure must be performed using sterile technique. The assembly drawing shown in Figure 9-3 identifies the individual components associated with air motor installation. All parts must be sterile. Be aware that the disposable collet adapter (3) is provided non-sterile and must be sterilized prior to assembly. After the surgical procedure, remove the collet adapter and spacer before cleaning. Discard the collet adapter and sterilize and store the spacer in the sterile tray.

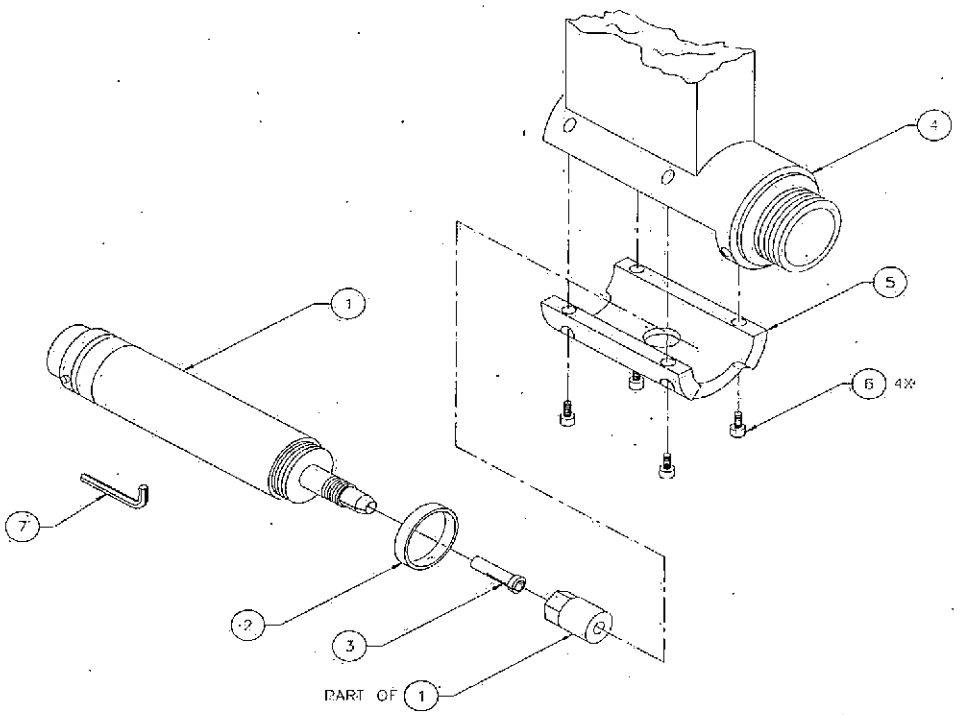


Figure 9-3. Air Motor and Motor Holder Components

1. Air motor with collet nut (P/N 102241)
2. Spacer (P/N 102719)
3. Collet adapter (P/N 102778)
4. Motor holder (P/N 102415)
5. Motor clamp (P/N 100049)
6. Screw (P/N 100233)
7. 3 mm hex wrench (P/N 102777)

⇨ To install the air motor and associated hardware:

1. Remove the four cap screws on the motor clamp with the 3 mm hex wrench, as shown in Figure 9-4:

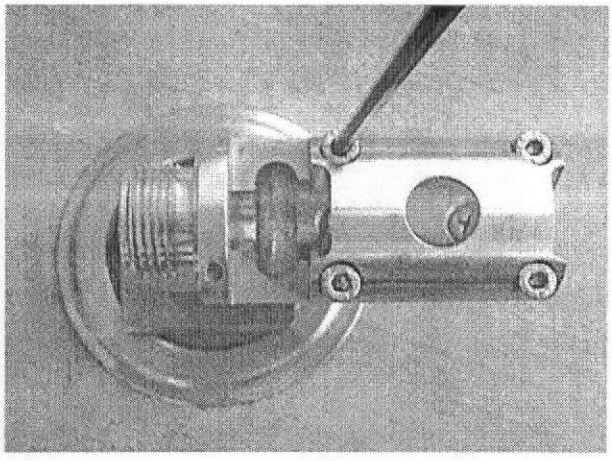


Figure 9-4. Removing Cap Screws From Motor Clamp

2. Remove the motor clamp.

3. Gently pull the motor out of the motor holder, as shown in Figure 9-5:

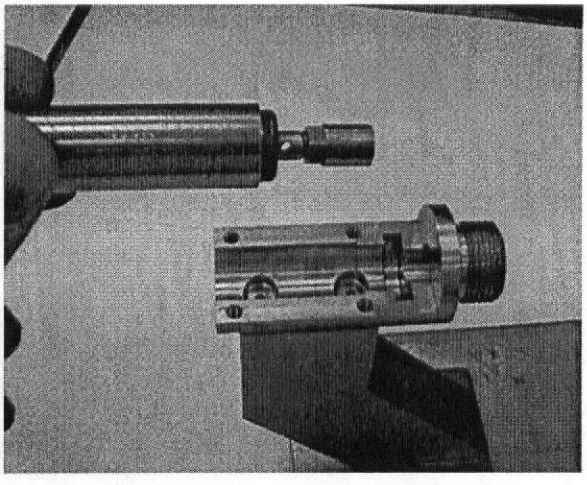


Figure 9-5. Removing Air Motor From Motor Holder

4. Remove the collet nut by unscrewing it in a counterclockwise direction, as shown in Figure 9-6:

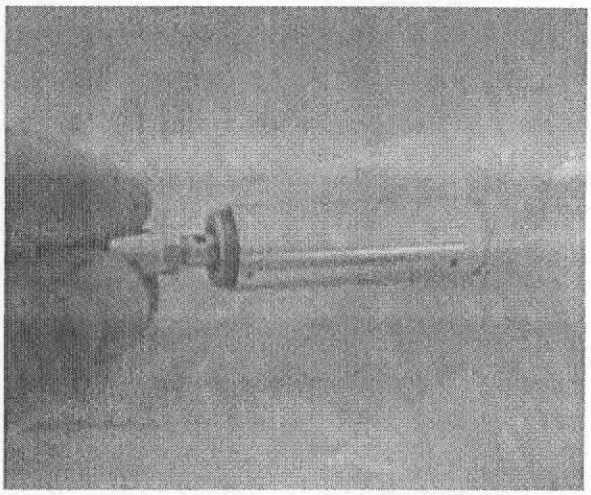


Figure 9-6. Removing the Collet Nut

5. Install the motor spacer as shown in Figure 9-7:

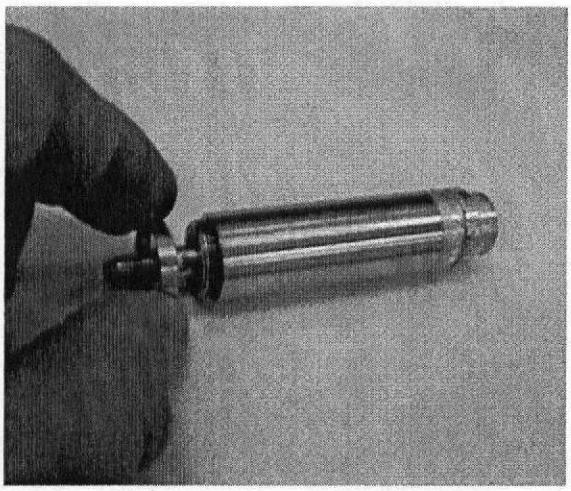


Figure 9-7. Installing the Motor Spacer

6. Insert the collet adapter into the motor, as shown in Figure 9-8:

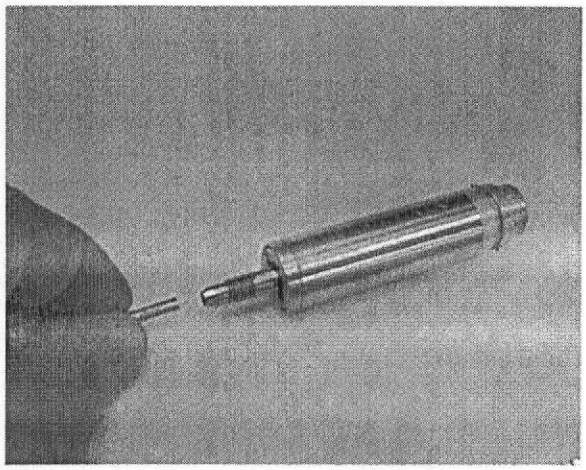


Figure 9-8. Inserting the Collet Adapter

7. Carefully install the collet nut, as shown in Figure 9-9.

   Do not over-tighten the collet nut before inserting a cutter into the cutter sleeve. Over-tightening without a cutter will damage the collet adapter and motor.

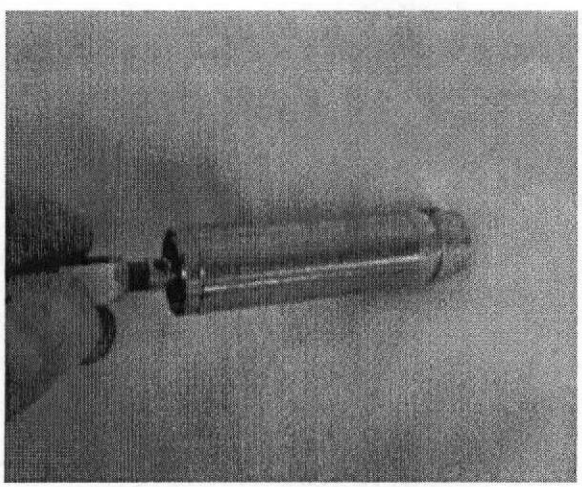


Figure 9-9. Installing the Collet Nut

8. Insert the motor into the motor holder as shown in Figure 9-10.

   Be sure to fully insert the motor. If the motor is not fully inserted, probes and cutters cannot be properly seated.

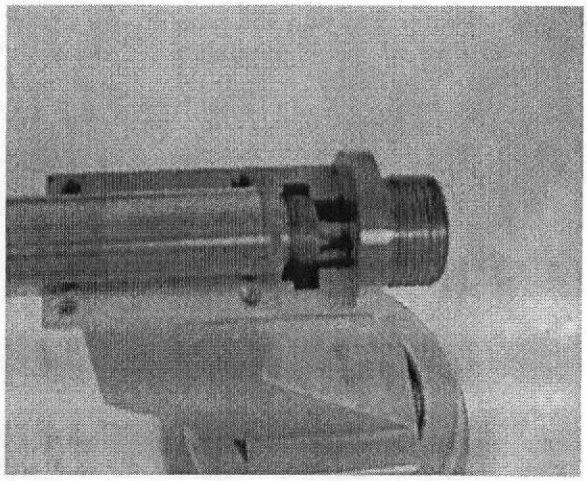


Figure 9-10. Inserting the Air Motor

9. While holding the motor in place with the motor clamp, evenly tighten the four cap screws on the motor clamp, as shown in Figure 9-11.

   Do not over-tighten the cap screws because over-tightening may damage the motor.

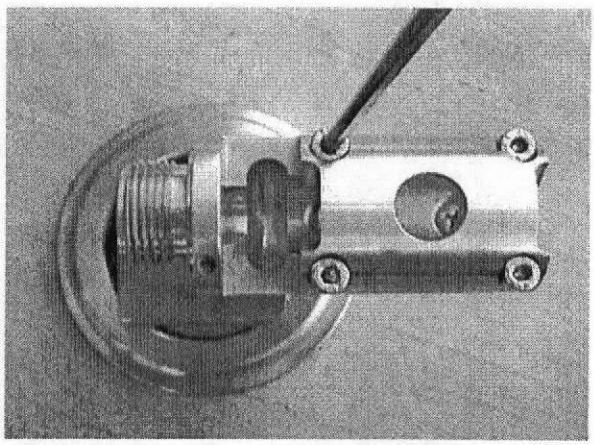


Figure 9-11. Tightening the Cap Screws

NOTE: Again, after the surgical procedure, remove the collet adapter and spacer before cleaning. Discard the collet adapter. Sterilize and store the spacer in the sterile tray.

DJA x01555

Changing the Diffuser on Systems With Air Motors

The diffuser (ISS P/N 100488) must be changed after every surgery.

⇨ **To change the diffuser:**

1. Unsnap the used diffuser from the green hose near the quick connect.
2. Snap on a new diffuser.

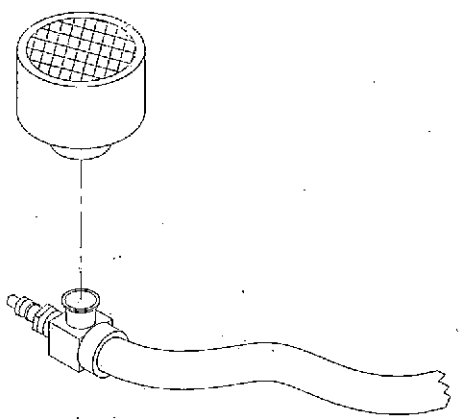


Figure 9-12. Changing the Diffuser

DJA x01556

Chapter 9

CLEANING, CALIBRATION, AND ROUTINE MAINTENANCE

Introduction

This chapter describes all of the routine maintenance procedures that must be performed by a hospital technician or OR staff for each ROBODOC surgery. It also provides instructions for cleaning and sterilizing removable components and for calibrating the robot.

ISS recommends that you perform these procedures in the following order:

⇨ **After surgery:**

1. Disassemble, disinfect, and clean the removable parts, and tools.
2. Change the diffuser on systems with air motors.

⇨ **Before surgery:**

1. Check the inline oiler on systems with air motors and refill it, if necessary.
2. Replace the motor safety seal on systems with air motors.
3. If using non-sterile cutters, clean and sterilize cutters.
4. Sterilize the cutter drive assembly, removable parts, and tools.

Duplicate Section 9 MDT

Disassembling and Cleaning

This section provides instructions for cleaning and sterilizing the removable components and instrumentation associated with the ROBODOC Surgical Assistant System.

Disassembling Removable Parts

⇨ **To disassemble the system after surgery:**

1. Disconnect the cables.
2. Remove the cutter drive and all probes and tools.
3. Fully disassemble all of the removable parts and tools, as required.

   NOTE: When disassembling the **Fixator Assembly,** unscrew and remove the knob bolt from the bone clamp, remove the bone clamp from the extension arm, unscrew and remove the threaded bone clamp bolt from the bone clamp, and remove the upper jaw from the bone clamp. For the **Digitizer Sterile Interface** (Digimatch™ only), unscrew and remove the probe tip from the shaft.

4. Remove and discard the plastic drapes on the robot arm , base, and pendant.
5. Clean the robot and all removable parts.
6. Discard all single-use parts.

Cleaning Robot and Control Cabinet

⇨ **To clean the Robot and Control Cabinet:**

1. If necessary, wipe the robot base with a disinfectant such as a 2 percent solution of gluteraldehyde.
2. If necessary, wipe the OR Monitor and Control Cabinet with the same disinfectant used on the robot base.
3. Wipe the case and the cable on the pendant with isopropyl alcohol.

NOTE: Do not sterilize the pendant or immerse it in water.

DJA x01558

Cleaning Removable Parts

Do not immerse in water, machine wash, or use ultrasound equipment to clean the cutter air motor and green hose with quick connect or the electric motor and cable.

⇨ To clean removable parts and tools:

1. For systems with air motors, wipe off all oil residue from the green hose with quick connect checking to be sure that any trace of motor lubricating oil is removed from hose surfaces (oil may interfere with sterilization).

2. Wearing gloves and protective attire, run cool or warm tap water over each part to remove visible debris.

   NOTE: The cutter drive assembly (with motor attached) may be held upright under the cool or warm tap water to rinse the visible soil from all surfaces. Again be sure that the motor is not immersed. Dry the cutter drive assembly using a clean non-shedding wiper.

3. Remove the motor (air or electric) from the cutter drive assembly and clean the cutter drive assembly along with the other removable parts.

4. Prepare the following: a solution of 1% Alconox® per manufacturer's instructions (10 grams/liter distilled or deionized water), or an equivalent type of detergent in sufficient volume to completely cover the parts and tools. If parts are heavily soiled, use a 1% solution (10 grams/liter) of Terg-A-Zyme, or an equivalent detergent containing protease enzyme.

   NOTE: Refer to the manufacturer's instructions for information about dispensing, measuring, and storing the detergent, and for a description of potential health hazards associated with the use of the product. To prevent coagulation of protein material on the surface of parts, use only ambient (room-temperature) water.

5. When the detergent is completely dissolved, immerse the parts and tools in the solution and soak for 10 minutes.

6. Using soft non-metal bristle brushes, thoroughly clean all surfaces of parts. Small brushes should be used to clean threaded holes and parts. DO NOT USE cleansing or scouring aids (such as metal pads or bristles) that may scratch metal finishes.

7. For bearing sleeve assemblies, use a soft bristle brush (3 mm diameter) to clean the inner lumen of bearing sleeves.

8. Remove parts and tools from the detergent solution and rinse thoroughly (at least 1 minute) in tap water. Be sure to flush holes and lumens.

9. Drain parts and tools.

10. Perform a final rinse in deionized or distilled water, soaking for at least two (2) minutes with periodic agitation.

11. To rinse the irrigation ports for the cutter drive assembly and bearing sleeve begin by attaching the bearing sleeve to the cutter drive assembly.

12. Obtain a clean luer lock syringe of at least 10 ml capacity and fill with deionized or distilled water.

13. Attach the syringe to the irrigation port located on the extension arm of the cutter drive assembly.

14. Use the syringe to flush the irrigation channel. Water should exit through the irrigation holes on the bearing sleeve hub. Flush the entire contents of the syringe.

15. If an irrigation hole appears to be plugged, a cleaning wire with a diameter no larger than 0.46 mm (0.018") may be passed through the bore.

16. Fill the syringe with air, attach to the inlet port, and blow out the water remaining in the irrigation channel. Repeat if needed.

17. Remove the bearing sleeve from the cutter drive assembly.

18. Use soft, non-shedding wipers to thoroughly dry all parts and let parts and tools air dry.

19. Examine the parts and tools to ensure that they are dry and clean.

20. On systems with air motors, replace the motor safety seal on the cutter drive assembly as describe in the next section.

WARNING: Failure to adequately clean tools may result in:

- Secondary infections
- Post-surgical complications
- Reduced tool longevity
- Increased number of field service calls and resultant costs

DJA x01560

Cleaning the Electric Motor

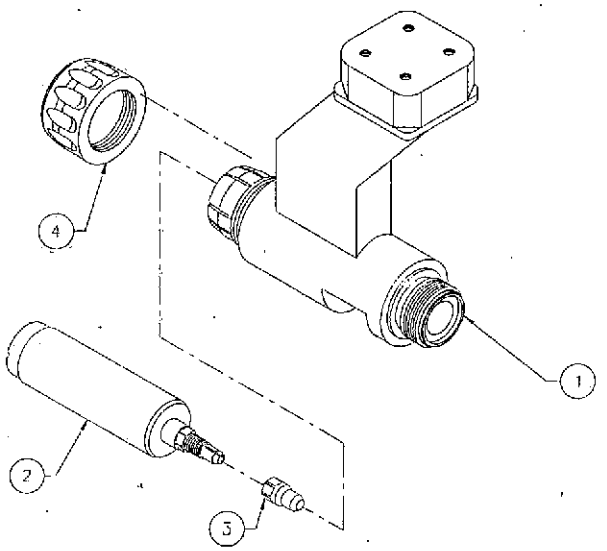


Figure 9-1. Electric Motor and Motor Holder Components

1. Motor holder (P/N 103376)
2. Electric motor (1/8" shaft [P/N 103333]or 3/32" shaft [P/N 103426])
3. Collet nut (P/N 103378)
4. Motor holder nut (P/N 103377)

NOTE: Do not clean these parts in an ultrasonic bath, washing machine, or dishwasher.

⇨ **To clean the electric motor parts:**

1. Rinse the motor, motor cable, and other components with water.

2. Disconnect the motor from the cable (see Chapter 2).

3. Clean the motor externally by wiping with a cloth soaked in a cleaning solution containing alcohol.

4. If desired, clean the motor internally by spraying an alcohol-based solution into the nose of the motor for 1 to 2 seconds.

5. Disinfect using a product with phenol-alcohol, glutaraldehyde (up to 3%), or alcohol; apply the disinfectant with a cloth or soak the motor for no more than one minute.

   Do not use products containing chlorine, acetone, or bleaching water in any concentration and do not soak for more than one minute.

DJA x01561

6. If desired, spray a lubricant into the nose of the motor for 0.5 to 1 second.
7. Rinse the motor in running water.
8. Dry the motor at a temperature not to exceed 136°C.

Cleaning Non-Sterile Cutters

All ROBODOC cutters are single-use instruments. Those cutters that are supplied non-sterile (packaged in tube) must be cleaned and sterilized prior to clinical use. Wear protective gloves and other attire appropriate for cleaning. Handle cutters with care; sharp blade edges can cause injury if mishandled. Cutters can be damaged if dropped or placed in contact with other metal instruments during cleaning. Immediately dispose of damaged cutters to prevent unintended clinical use.

⇨ **To clean non-sterile cutters:**

1. Prepare a solution of 1% Alconox, Terg-A-Zyme, or equivalent type detergent per manufacturer's recommendations (10 grams/liter distilled or deionized water).
2. Soak the cutters in the solution for a minimum of five minutes.
3. Using soft brushes, thoroughly clean all surfaces of the cutters. DO NOT USE cleansing or scouring aids (such as metal pads or bristles) that may scratch metal finishes.
4. Remove the cutters from the detergent solution and rinse thoroughly (at least 1 minute) in tap water.
5. Drain cutters.
6. Perform a final rinse in deionized or distilled water, soaking for at least two minutes with periodic agitation.
7. Use soft, non-shedding wipers to thoroughly dry the cutters.

DJA x01562

Sterilizing All Removable Parts

⇨ **To sterilize the parts, tools, and non-sterile single use cutters:**

1. Place used parts, tools, and non-sterile cutters into trays.

   ISS recommends placing back-up components in a separate tray.

   Appendix D lists ROBODOC parts and tools.

2. Using a gravity displacement autoclave sterilization, wrap each item in cotton muslin, 2 ply or equivalent, and arrange the sterilizer load so that each item is exposed as follows:

   Sterilization of motors (air or electric)
   Temperature: **132°C (270°F)** Minimum Time: **25 minutes**
   CAUTION: Do not exceed 136°C (277°F) or 30 minutes

   Sterilization of all other removable parts (including non-sterile cutters)
   Temperature: **132°C (270°F)** Minimum Time: **15 minutes**

   The sterilizable components are designed to withstand resterilization.

DJA x01563

Routine Maintenance

The diagnostic tests are designed to identify the failure of ROBODOC components. When the system fails to pass a diagnostic test, notify ISS. The only ROBODOC components that must be routinely serviced by ISS are the cutter drive, bearing sleeves, and tape drive. The other routine maintenance procedures described in this section must be performed on a per-surgery basis by hospital technicians.

Servicing the Cutter Drive

Immediately notify ISS if problems such as vibrational loosening of components are observed. Return motor to ISS if a performance failure (e.g., unusual noise, loss of power, non-functionality) is observed.

Cleaning the Media Drive

The Media drives in the Control Cabinet and ORTHODOC workstation should be cleaned each time a field technician visits a ROBODOC installation.

Maintaining the Coaxial Wall Air Supply on Systems with Air Motors

The filter element inside the filter box for the air supply system must be replaced after every surgery. DO NOT steam or heat sterilize the filter box.

⇨ **To maintain the air supply filter:**

1. Disassemble and clean the filter box with soap and water.
2. Replace the filter element (P/N 102543).
3. If the O-rings are worn, replace them.

   Replacement O-rings are provided in the Coaxial Wall Air Module P/N 102527.

DJA x01564

Replacing the Safety Seal on the Air Motor

The safety seal on the air motor (ISS P/N 100496) must be replaced after every surgery.

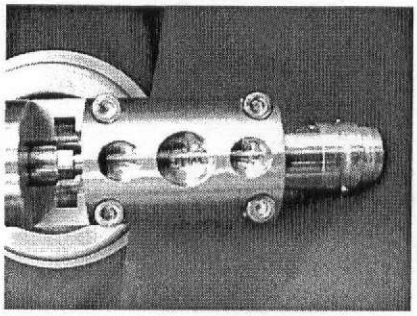
⇨ **To replace the safety seal:**

1. With a 3 mm hex wrench, loosen the four cap screws on the motor clamp one turn (see Figure 9-2A).
2. Pull the motor out of the motor cover (see Figure 9-2B).
3. Remove the collet nut (see Figue 9-2C).
4. Remove the used safety seal with a small pick (see Figure 9-2D).
5. Grasping the green portion of the safety seal installer, slide the green and yellow installer onto the rotor shaft until the green portion of the installer is flush against the motor.
6. Grasping the motor, depress the yellow portion of the installer as far as possible to insert the seal into the top nut.
7. Remove the plastic installer from the rotor shaft.

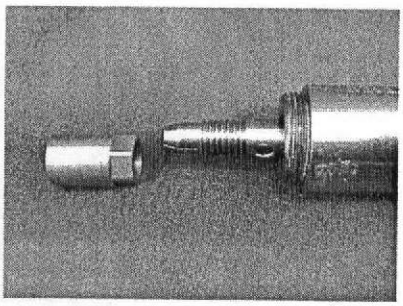
   If the clear internal sleeve is left on the shaft, remove it with a hemostat.
8. Replace the collet nut.
9. Insert the motor as far as possible.

   Probes and cutters will not seat properly if the motor is not inserted all the way.
10. While holding the motor in place, evenly tighten the four cap screws on the motor clamp.

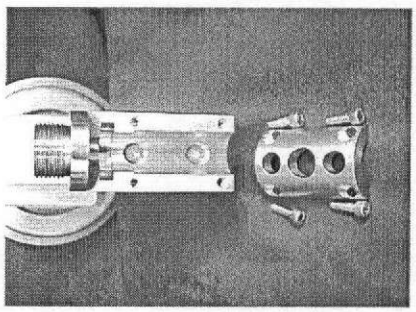
    Do not overtighten the screws because overtightening may damage the motor.



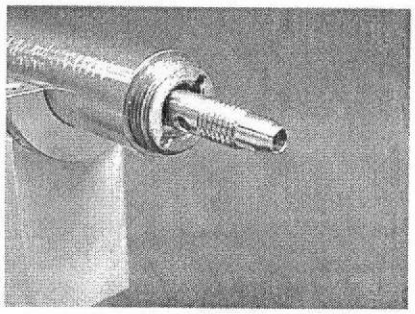
A. Remove Motor Retaining Bolts



C. Remove Collet Nut from Motor



B. Remove Motor



D. Remove Safety Seal

Figure 9-2. Replacing the Safety Seal on the Air Motor

DJA x01566

Installing the Air Motor for Small Cutters

Perform the procedure described in this section when small (3/32-inch shaft diameter) cutters will be used for the next surgery. The following instructions explain how to install the air motor and associated hardware in the cutter drive assembly to accommodate small sleeves and cutters. This procedure must be performed using sterile technique. The assembly drawing shown in Figure 9-3 identifies the individual components associated with air motor installation. All parts must be sterile. Be aware that the disposable collet adapter (3) is provided non-sterile and must be sterilized prior to assembly. After the surgical procedure, remove the collet adapter and spacer before cleaning. Discard the collet adapter and sterilize and store the spacer in the sterile tray.

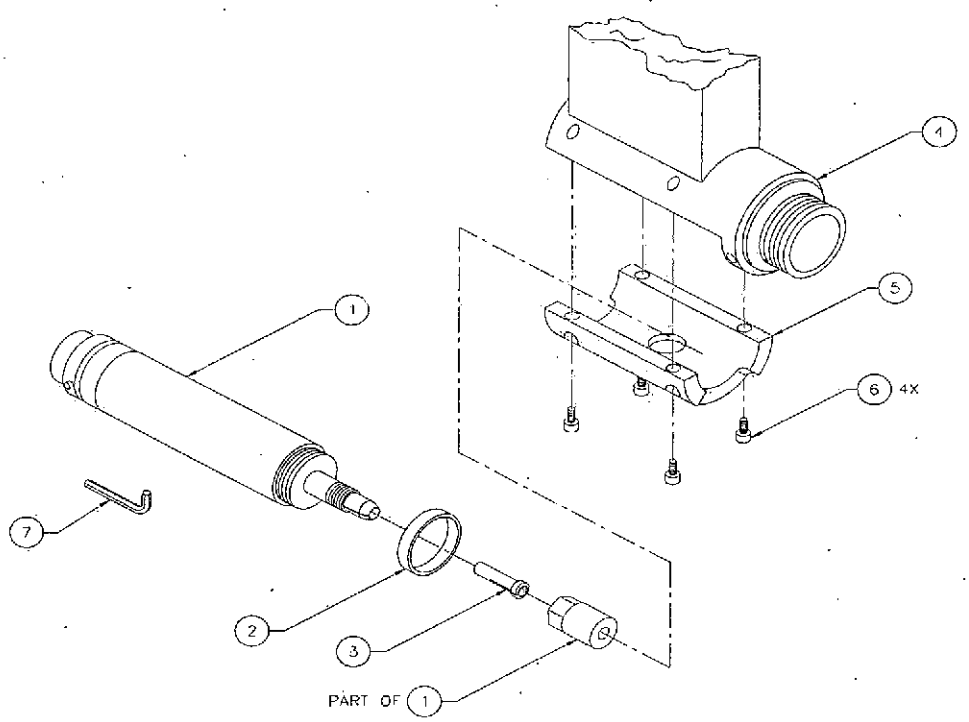


Figure 9-3. Air Motor and Motor Holder Components

1. Air motor with collet nut (P/N 102241)
2. Spacer (P/N 102719)
3. Collet adapter (P/N 102778)
4. Motor holder (P/N 102415)
5. Motor clamp (P/N 100049)
6. Screw (P/N 100233)
7. 3 mm hex wrench (P/N 102777)

⇨ To install the air motor and associated hardware:

1. Remove the four cap screws on the motor clamp with the 3 mm hex wrench, as shown in Figure 9-4:

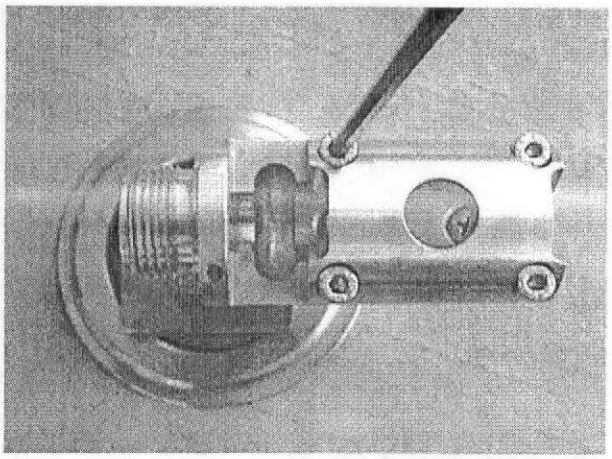


Figure 9-4. Removing Cap Screws From Motor Clamp

2. Remove the motor clamp.

3. Gently pull the motor out of the motor holder, as shown in Figure 9-5:

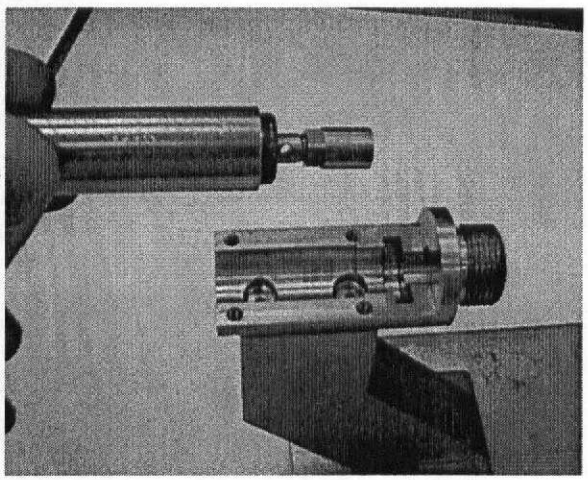


Figure 9-5. Removing Air Motor From Motor Holder

4. Remove the collet nut by unscrewing it in a counterclockwise direction, as shown in Figure 9-6:

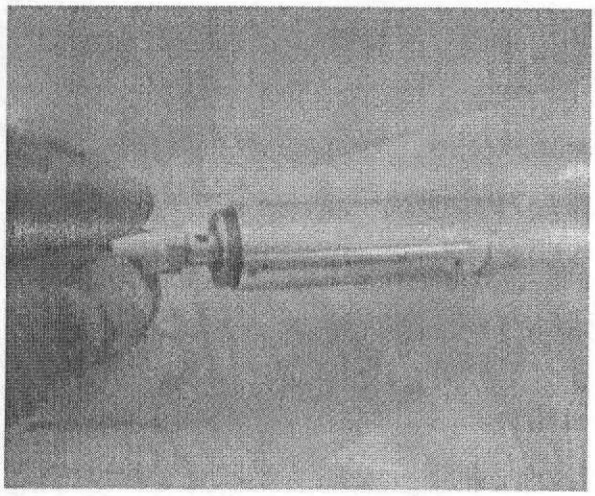


Figure 9-6. Removing the Collet Nut

5. Install the motor spacer as shown in Figure 9-7:

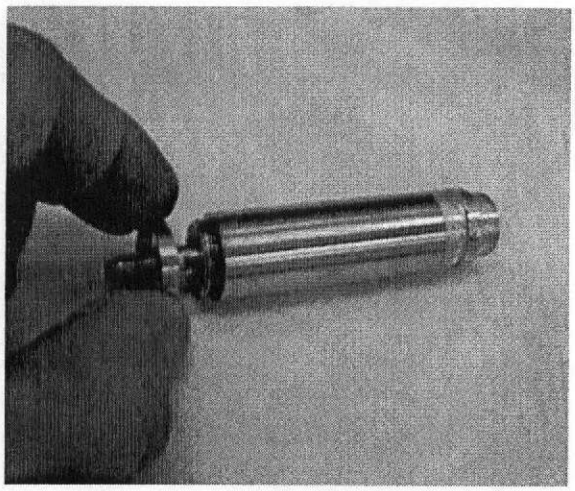


Figure 9-7. Installing the Motor Spacer

6. Insert the collet adapter into the motor, as shown in Figure 9-8:

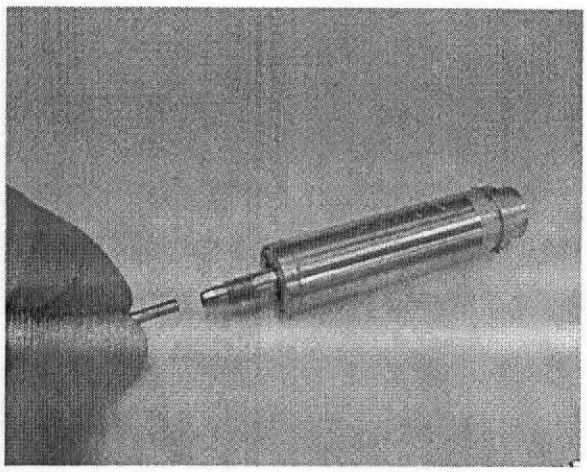


Figure 9-8. Inserting the Collet Adapter

7. Carefully install the collet nut, as shown in Figure 9-9.

   Do not over-tighten the collet nut before inserting a cutter into the cutter sleeve. Over-tightening without a cutter will damage the collet adapter and motor.

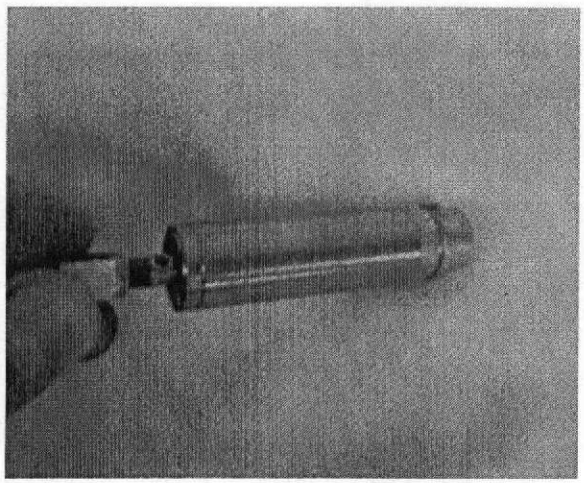


Figure 9-9. Installing the Collet Nut

8. Insert the motor into the motor holder as shown in Figure 9-10.

   Be sure to fully insert the motor. If the motor is not fully inserted, probes and cutters cannot be properly seated.

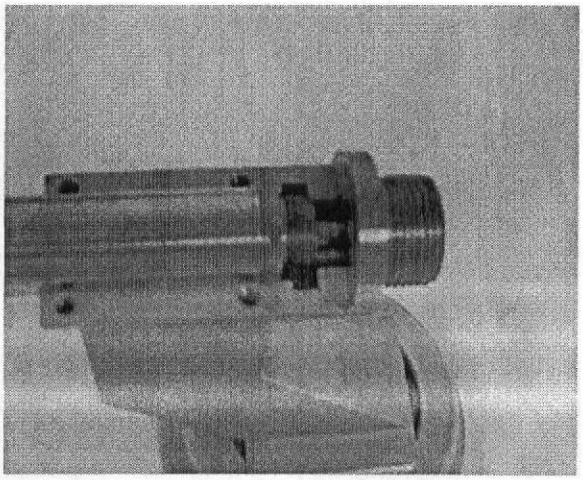


Figure 9-10. Inserting the Air Motor

9. While holding the motor in place with the motor clamp, evenly tighten the four cap screws on the motor clamp, as shown in Figure 9-11.

   Do not over-tighten the cap screws because over-tightening may damage the motor.

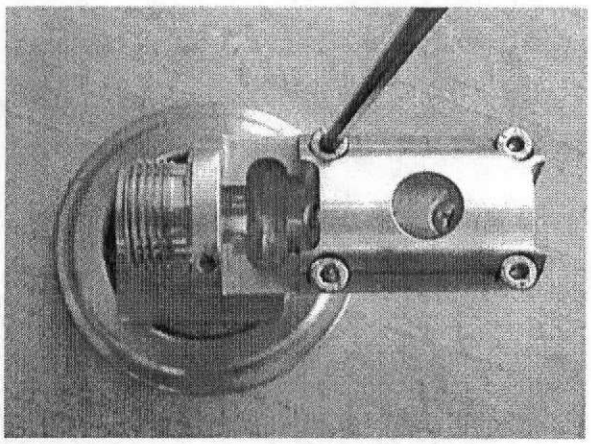


Figure 9-11. Tightening the Cap Screws

NOTE: Again, after the surgical procedure, remove the collet adapter and spacer before cleaning. Discard the collet adapter. Sterilize and store the spacer in the sterile tray.

DJA x01571

Changing the Diffuser on Systems With Air Motors

The diffuser (ISS P/N 100488) must be changed after every surgery.

⇨ To change the diffuser:

1. Unsnap the used diffuser from the green hose near the quick connect.
2. Snap on a new diffuser.

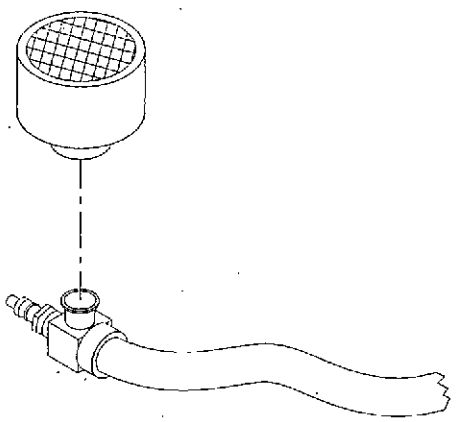


Figure 9-12. Changing the Diffuser

Refilling the Inline Oiler on Systems With Air Motors

The inline oiler on the regulator must be at least 50 percent full prior to surgery. You can visually check the fluid level by looking through the holes in the lubricant reservoir (see "Preparing the Operating Room" in Chapter 3).

⇨ **To refill the inline oiler:**

1. Turn the pressure off and release the pressure in the line.

   WARNING: Do not loosen the reservoir with the line under pressure.

2. Unscrew the lubricant reservoir.

3. Refill with Midas Rex® lubricant.

4. Screw the lubricant reservoir back on.

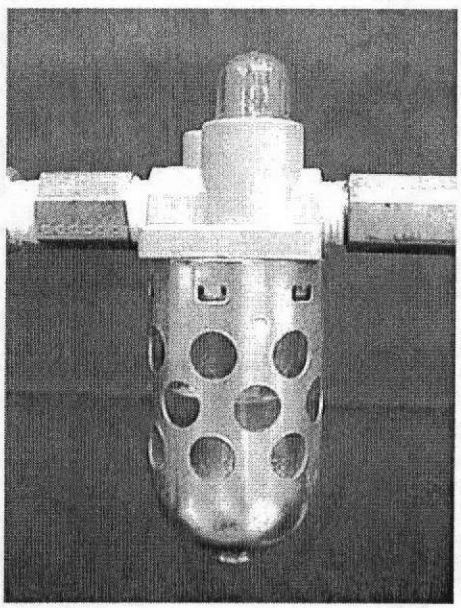


Figure 9-13. Refilling the Inline Oiler

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Chapter 10

TROUBLESHOOTING

Introduction

This chapter describes a variety of exception conditions and problems that may arise during a ROBODOC surgery. These problems range in severity from brief interruptions in the normal procedural flow to potentially significant issues that could require the operation to be completed manually.

The ROBODOC Surgical Assistant System has a comprehensive safety system that consists of sensors and software programs that continuously monitor a variety of conditions. If these sensors detect a potentially unsafe condition, the software is designed to automatically pause or stop the robot.

During a typical surgery the robot will generally pause several times due to detection of minor exception conditions. When this happens, the OR Monitor displays a message describing the problem, along with the available options. The surgeon resumes the procedure by selecting an appropriate option after ensuring that it is safe to proceed.

This chapter describes how to troubleshoot and respond to problems.

DJA x01574

Power/Cabling Problems at Startup

The cables and power cords must be connected as described in Chapter 3

Improper power and cable connections are generally evident by the time the user presses the green motor power button on the OR Monitor cabinet for the first time. If the system detects a problem, the OR Monitor displays a message indicating which connection is causing the problem. If the OR Monitor is not receiving power, the green light on the monitor will be off.

⇨ To resolve a power/cabling problem:

1. Identify the specific connection causing the problem by:
   - Checking any connection mentioned on the OR Monitor
   - Checking the power indicator lights on the OR Monitor cabinet
   - Checking power to the robot by trying to raise or lower the base using the **Adjust Height** option on the Pause menu
2. Connect the cable(s) as described in Chapter 3.

   NOTE: Do not connect cables with the power on. Make sure the system is powered off before connecting cables. The exception is the pendant cable, which may be connected when the power is on.

DJA x01575

Diagnostic Test Failure

The robot must pass all diagnostic procedures before the surgery can proceed.

The diagnostic tests verify that the hardware, software, and safety systems are properly functioning. The diagnostic tests include:

- Force sensor test
- Kinematics test
- BMM test
- Sterile diagnostics

After each of these tests, the OR Monitor indicates whether the test passed or failed.

Force Sensor Test

⇨ **To resolve a force sensor test failure:**

1. Verify that the diagnostic tool is properly installed and that the force sensor cable is securely connected.
2. Select the option to retry the test.

If the test fails again, the force sensor may require servicing.

Kinematics Test

⇨ **To resolve a kinematics test failure:**

1. Verify that the diagnostic tool is properly installed and that the diagnostic fixture is firmly attached to the mounting block.
2. Select the option to retry the test.

If the test fails again, the robot may require servicing.

DJA x01576

BMM Test

⇨ **To resolve a BMM test failure:**

1. Verify that the BMM cable is firmly attached to the BMM and the robot base.
2. Select the option to retry the test.
3. If the test fails again, pause the robot and re-install the BMM probe.
4. Select the option to retry the test.

If the test fails again, the BMM may require servicing.

Sterile Diagnostics

⇨ **To resolve a sterile diagnostics test failure:**

1. Select the option to retry the test.
2. If the test fails again, pause the robot and re-install the probe.
3. Retry the test.
4. If the test fails again, pause the robot and select the option to re-install the cutter drive assembly.
5. Use the bonnet drape to form a sterile seal over the section of the arm drape that was sacrificed.
6. Retry the test.
7. If the test fails again, re-calibrate the probe.

DJA x01577

Encoder Freeze

The robot is equipped with two sets of encoders that continuously monitor the position of each joint on the robot arm and cross check each other. When cross-checking reveals a discrepancy between the positions reported by the two sets, the safety system pauses or stops the robot.

Two thresholds are defined for comparison of encoder positions. Exceeding the first threshold causes the safety system to pause the robot. Exceeding the second threshold causes the safety system to stop the robot by shutting off power to the robot motors. In either case, the OR Monitor displays a screen that identifies the problem and provides an option to continue.

⇨ To resume the procedure after an encoder freeze:

1. Select the option to continue.
2. If motor power was shut off, press the green motor power button on the Control Cabinet when prompted to do so.
3. If encoder freezes repeatedly occur, power off the robot by pressing the red **STOP** button on the pendant.
4. Manually move the robot to ensure that none of the joints are in contact with an obstacle.
5. Resume the procedure by pressing **SELECT**.

NOTE: Multiple encoder freezes in the absence of rapid robot arm movements may indicate a hardware problem. If this happens, abort the robot procedure and complete the operation manually. After surgery, contact ISS Technical Support.

DJA x01578

Force Freeze

The robot is equipped with a force sensor that measures the forces applied at the tool tip. If forces exceed a predefined threshold, the safety system pauses the robot.

Force freezes may occur under the following circumstances:

- The arm is moved with a rapid, jerky movement.
- The tool encounters a solid object such as a retractor or locator pin.
- The robot is cutting in dense bone (this condition occasionally occurs when the cutter first engages the cavity).

The force sensor uses two thresholds. Exceeding the first threshold causes the safety system to pause the robot. Exceeding the second threshold causes the safety system to stop the robot by shutting off power to the robot motors. In either case, the OR Monitor displays a screen that identifies the problem and provides an option to continue.

⇨ To resume the procedure after a force freeze:

1. Check the area around the tool to ensure that it is not touching a solid object such as a retractor.

   If necessary, back the robot out of the cavity to check.

2. Select the option to continue.

3. If motor power was shut off, press the green motor power button on the Control Cabinet when prompted to do so.

DJA x01579

Bone Motion

The robot is equipped with a BMM that senses femur movement. Since the robot computes the location of the bone from data obtained during surface registration, the bone must not move after digitizing surface points.

After surface registration, avoid contact with the leg and BMM. Do not lean against the OR table.

The primary causes of bone motion include:

- Improper installation of the bone in the femoral fixator
- Physical contact with the leg
- Physical contact with the BMM
- Moving the OR table or adjusting table height
- Applying manual retraction or repositioning self-retaining retractors

⇨ To resume the procedure after bone motion is detected:

1. Select the option to resume the procedure.
2. When prompted to do so, check fixator installation and reinstall the BMM.
3. For DigiMatch surgeries, digitize the distal recovery marker and then the proximal recovery marker.

DJA x01580

Workspace Limitations

The robot's workspace is limited to the area that can be accessed by the tool tip. When workspace limitations become a problem, the OR Monitor prompts you to adjust one of the robot joints.

The workspace is the area accessible to the robot's tool. The position of the robot base and the configuration of the joints in the robot arm determine this area. When one of the joints in the robot arm is tightly folded, it may restrict the range of motion.

The robot has five joints, as illustrated in Figure 10-1:

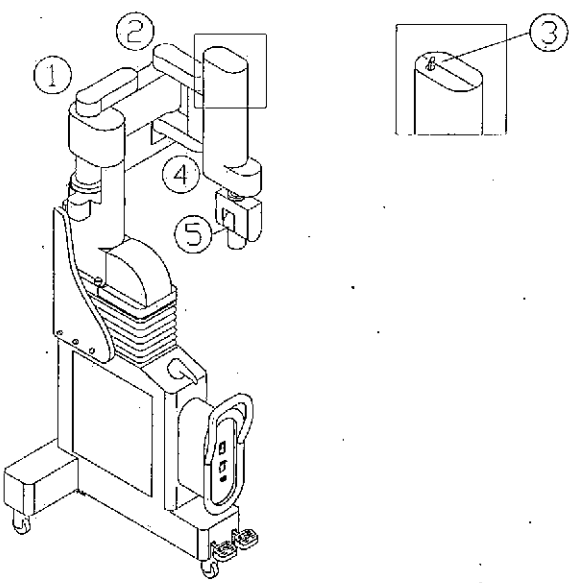

Figure 10-1. Robot Joints and Brake Release Ring

1. **Shoulder joint.** The shoulder joint is located directly above the robot base. It can be adjusted by pushing on the arm near the elbow joint.

2. **Elbow joint.** The elbow joint is located between the shoulder joint and the vertical joint of the robot arm. It can be adjusted by pushing on the arm near the vertical joint.

3. **Vertical joint.** The vertical joint is located on the end of the robot arm and workspace limitations occur when the arm is fully extended either up or down. To prevent the arm from dropping, the vertical joint locks when the vertical limit is reached. A brake release ring, located on top of the robot

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arm, will unlock the vertical joint and enable you to move it back into the workspace. In Figure 10-1 a dashed line surrounds the brake release ring.

4. **Roll joint.** The roll joint is located above the pitch joint and it rotates the end effector around the pitch axis. It can be adjusted by grasping the pitch axis casing and manually rotating it.

5. **Pitch joint.** The pitch joint is located above the force sensor. It reorients the tool in a vertical arc, without raising or lowering the vertical axis of the arm. The pitch joint can be adjusted by grasping the pitch axis casing and manually reorienting the tool.

When the system detects a potential workspace problem because one of the joints is tightly folded, the OR Monitor prompts you to adjust the appropriate joint.

⇨ To adjust a joint in response to a prompt on the OR Monitor:

1. Push the robot arm to change the configuration of the affected joint.

   To adjust the vertical joint, you must first pull the brake release ring on the top of the robot arm.

2. Press **SELECT**.

3. When prompted to do so, press the green motor power button on the Cabinet.

   If you have not properly adjusted the joint so that the arm can move freely within the workspace, the OR Monitor will redisplay the prompt to adjust the joint.

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Safety Volume Exception

The safety volume is a predefined area, slightly larger than the intended implant, within which the cutter must stay while cutting. If the cutter strays outside of this area, the safety system will pause the robot.

Hardware failure is the probable cause for this problem. The surgeon may attempt to resume, but if the problem continues, he or she should abort the robot procedure and complete the operation manually. After surgery, contact ISS Technical Support.

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Probe Installation Problems

When the short installation verification gauge indicates that a probe is improperly installed, the most likely cause is improper installation of the motor.

If the motor has not been properly installed, the short gauge will touch the sleeve, rather than bottoming out on the probe ball as illustrated in Figure 2-13 in Chapter 2. This problem occurs when the motor has not been inserted completely.

⇨ To resolve a probe installation problem:

1. Loosen the motor retaining screws.
2. Push the motor all the way forward.
3. Retighten the motor retaining screws.
4. Recalibrate all of the tools.

Bearing Sleeve Failure

Bearing sleeves must be periodically returned to ISS for refurbishing. This section describes how to replace a bearing sleeve intraoperatively in the event of failure during femoral preparation.

The symptoms of a worn bearing sleeve include a high-pitched whine during cutter operation and the sleeve feeling hot to the touch. If these problems occur during surgery, you must decide whether to replace the sleeve intraoperatively. If the symptoms are minor, ISS recommends finishing the femoral preparation operation, due to the time required to replace the sleeve. Immediately return the sleeve to ISS for routine maintenance.

If the symptoms are severe, you must interrupt the femoral preparation operation to replace the bearing sleeve. The following instructions explain how to do so. The "Installing Probes and Cutters" section in Chapter 2 contains illustrations of sleeve/cutter installation and verification.

⇨ To replace a bearing sleeve during cutting:

1. Press the **PAUSE** button and select the **Change Cutter** option from the Pause menu.

2. Move the robot arm to an unobstructed "clear" area with room for the tool to reorient and within reach of the surgeon or sterile technician and press **SELECT.**

   The robot automatically moves the tool tip upward. Do not touch the robot arm while it is moving.

3. Remove the worn-out bearing sleeve and cutter.

   NOTE: Keep the cutter handy for reinstallation.

4. Find a replacement bearing sleeve in the sterile back-up pack and verify that the part number matches the part number on the sleeve being replaced.

5. Follow the sleeve installation instructions provided in the "Installing Probes and Cutters" section of Chapter 2.

6. Insert and fully seat the cutter.

7. Use the small rod and wrench set to secure the tool:

   - Insert the rod through the hole in the bottom of the collet attachment.

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- Position the wrench to turn the motor collet nut, which is located immediately above the hole.
- Turn the wrench clockwise and the rod counterclockwise to begin fastening, but do not tighten.
- Tighten the collet nut using only the rod.

Using the wrench to tighten the collet nut may apply too much torque and cause the rod to break.

8. Fully tighten the collet surrounding the sleeve with the large 1-1/8" wrench without moving the alignment marker.

9. Verify that the tool is fully seated by sliding the unmarked gauge over the cutter so the bottom of the gauge rests on the bearing sleeve.

   If the gauge does not touch the sleeve, the cutter is not fully seated and must be reinstalled.

   Replacing the sleeve without recalibrating may cause slight cavity displacement (0.5 mm or less). However, ISS does not recommend intraoperative calibration because of the extra time it requires.

   After surgery, decontaminate and sterilize the worn-out sleeve and contact ISS. ISS will refurbish the bearing sleeve.

10. Recalibrate a new sleeve and place it in the sterile tray.

Cutter Drive Problems

A failure of the pneumatic system may cause problems with the cutter drive.

The symptoms of pneumatic system failure include inability to completely shut off the cutter drive and inability to turn the cutter drive on.

Cutter Drive Won't Stop

When the cutter is paused or stopped, the tool should not rotate in the cutter drive. If the tool continues to rotate, the pneumatic system is malfunctioning. Abort the procedure and call ISS Technical Support.

Cutter Drive Won't Start

When the robot control computer actuates the solenoid, you should hear a click inside the robot base and the cutter drive should start. If the cutter drive does not start, the pneumatic system is not functioning properly.

⇨ **To start the cutter drive:**

1. Check the connections to the cutter drive.
2. Check the wall air pressure to verify that the pressure is at least 8 bar, if possible.
3. Check the hose for leaks.
4. Check the cables from the robot to the Control Cabinet to verify that they are securely connected.

WARNING: If the cutter drive won't start and power to the base appears to be on, do not continue the robot procedure. Remove the robot from service and call ISS Technical Support.

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Appendix A

GLOSSARY

adaptive cut speed. The ability of the robot to continuously change the bone cutting speed based on the hardness of the bone being cut.

arm drape. The sterile drape that covers the robot arm and forms a sterile seal over the lip on the cutter drive.

ball probe. The tool-tip instrument for finding locator pins.

ball tip. The DigiMatch surgical tool tip used for sterile diagnostics.

bar. A unit of pressure equal to one million dynes per square centimeter.

bearing sleeve. A reusable, autoclavable instrument that provides support for a ball probe or cutter.

BMM. See bone motion monitor.

BMM probe. The sterile BMM probe that attaches to an exposed area on the bone.

BMM switch. The switch on the robot base that must be set for the surgical side (left/right) in DigiMatch surgeries.

bone motion monitor (BMM). A sensing device that detects motion of the femur in relation to the robot base.

bonnet drape. A custom sterile drape that can be used to cover the cutter drive if a portion of the arm drape must be sacrificed to reinstall the cutter drive.

calibration. The process that ensures that the robot can compute the exact position of the tool tip.

checkpoint. A progress reference mark within the bone cutting procedure.

clear area. An unobstructed space away from the patient and robot base, with room to reorient or change the tool.

CT. Computed tomography.

cutter. A high-speed cutting burr for cutting the cavity.

cutter drive. The sterile assembly that attaches the cutting tool motor to the robot.

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default. An option on the OR Monitor that is automatically highlighted when the menu first appears. To select a default option, the technician or surgeon simply presses the **SELECT** button on the pendant.

diagnostic fixture. A rectangular fixture with six vertical posts and an extension arm that connects to the dovetail on the base.

diagnostic probe. The tool for performing startup diagnostics, which is on an assembly that connects to the force sensor with a threaded clamping ring.

diagnostics. The tests that must be performed prior to surgery to ensure that the robot and its safety systems are functioning properly.

digitize. To contact a point on the bone, diagnostic post, or divot with the digitizer probe tip and record its position by pressing the pendant **SELECT** button.

digitizer. The DigiMatch digitizing arm, which is permanently mounted on the robot base.

digitizer probe (non-sterile). The probe used for non-sterile diagnostics.

digitizer probe (sterile). The sterile interface between the digitizing arm and the surgical tool tips (ball tip and pointed tip).

distal recovery marker. An 11.5-centimeter-long post that screws into the distal end of the femur. This DigiMatch tool is sterile and intended for single use.

distal recovery marker cap. A sleeve that attaches to the distal recovery marker to provide an additional data point for surface registration in the event of bone motion. This DigiMatch tool is sterile and reusable.

elbow. The second joint on the robot arm.

Emergency Power Off (EPO). A condition where the robot is powered off, either automatically by the safety system or manually by pressing the red STOP button on the pendant or OR Monitor cabinet.

encoder. A sensor that monitors the current position of the robot arm; the robot is equipped with two sets of five encoders.

encoder freeze. A condition that occurs when a discrepancy is detected between the two sets of encoders that monitor the position of the robot arm.

end effector. The cutter drive assembly and the currently installed tool-tip instruments (e.g., bearing sleeve and cutter or probe).

EPO. See Emergency Power Off.

exception condition. An interruption to the normal procedural flow caused by an event such as a force freeze, encoder freeze, or bone motion.

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femoral fixator. An external fixation device that secures the femur to the robot base to prevent motion during surgery.

fixator extension arm. A cylindrical attachment to the robot base that connects the femoral fixator to the dovetail mounting blocks on the base.

fixator swivel. The fixator component that attaches the proximal assembly to the fixator extension arm.

force freeze. A condition that occurs when forces applied to the tool tip exceed a predefined threshold and the safety system pauses the robot. Causes include contact with a solid object, rapid or jerky movements while hand guiding the arm, and cutting cortical bone.

force sensor. A safety feature that monitors the forces being applied to the tool tip.

force sensor test. A procedure performed during non-sterile diagnostics to verify that the force sensor is functioning properly.

Guide Mode. A condition that enables the robot arm to be manually moved. Guide Mode is activated automatically when required by the current procedure or manually by selecting an option from a Pendant Pause menu.

home position. A configuration of the robot arm or Digimatch digitizer where the arm is folded back toward the base.

installation verification gauges. Devices for verifying that ball probes and cutters have been properly installed.

kinematics test. A procedure performed during non-sterile diagnostics to verify the mechanical accuracy of the robot joints and wrist.

kinematics test plate. See diagnostic fixture.

leg support fixture. A device that attaches to the OR table and cradles the patient's leg.

locator pins. Titanium pins implanted in a preliminary surgical procedure to serve as landmarks for spatial orientation of the ROBODOC Surgical Assistant.

menu. An OR Display screen that provides several options.

motor safety seal. The sterile component that prevents the motor from leaking lubricating oil. This component must be replaced after every surgery.

option. A choice on a menu screen that initiates an action when selected by the pendant.

OR Monitor. A large color monitor that displays prompts and menus to guide the surgeon and technician through every task involving the robot. During femoral cutting, the monitor shows a graphic depiction of the robot's progress.

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ORTHODOC. ISS's pre-operative planning system for hip replacement surgery.

pause. To press the yellow pendant button, interrupting the robot procedure and displaying a Pause menu.

pendant. A hand-held device for controlling the robot, performing startup diagnostics, and responding to prompts on the OR Monitor. The pendant has five buttons, including buttons for pausing and stopping the robot.

Pendant Pause menu. A menu that appears when the PAUSE button is pressed. It offers a variety of options such as Hand Guide Robot, Change Probe, etc.

pin extender. A small rod that fits into the head of locator pins. The surgeon guides the ball probe to the tip of the pin extender to orient the robot with respect to the angle of the pin shaft.

pin normal. The direction perpendicular to the head of a locator pin (the direction in line with the pin shaft).

point collection error. The error condition that occurs when the most recently collected point is too close to the previously collected point.

pointed tip. The DigiMatch surgical tool tip used for contacting the bone surface to collect data points on the femoral surface.

proximal assembly. A component of the femoral fixator to which the proximal hook, proximal swivel clamp, fixator mounting attachment can be attached.

proximal hook. A component of the femoral fixator that holds the proximal femur in place.

proximal recovery marker. A one-centimeter-long post that screws into the proximal end of the femur. This DigiMatch tool is sterile and intended for single use.

psi. Pounds per square inch.

real-time monitor (RTM) computer. The computer that creates a graphical representation of the cutting procedure for display on the OR Monitor.

recovery markers. Two ISS-supplied disposable components that are inserted into the femur when DigiMatch surface registration is complete. These markers eliminate the need to repeat the entire digitizing procedure in the event that bone motion occurs.

reorient. To change the direction of a tool.

reorient position. A configuration where the robot arm is in a clear, unobstructed area for safe automatic reorientation.

ROBODOC Surgical Assistant. Integrated Surgical System's Surgical Robot, and OR Monitor cabinet.

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robot control computer (RCC). The computer that runs the application and safety-system software.

ROI. Region of interest.

RTM computer. See Real-Time Monitor Computer.

safety volume. A predefined area, slightly larger than the intended implant, within which the cutter must stay while cutting.

short probe. An ISS-supplied instrument that may be used for verifying proper installation of the cutter drive and finding the distal pins.

skirt drape. The sterile drape that covers the robot base and forms a sterile seal over the fixator extension arm and BMM probe.

surface registration. The procedure that spatially orients the robot with respect to the femur. For DigiMatch cases, surface registration is obtained by digitizing specified points on the bone surface. For locator pin cases, registration is obtained by using a ball probe to perform a tactile search on the divot on each locator pin.

threaded clamping ring. The mechanism that connects tool-tip attachments to the robot arm.

tool axis. The direction in which the tool is pointing.

tool change position. A configuration where the tool tip is pitched upward to facilitate installation of a probe or cutter.

transfer file. The input dataset containing patient data, prosthesis information, and femoral cutting specifications.

transport position. A configuration where the robot arm is folded back toward the base and the base is in its lowest position. This configuration protects the robot arm when the robot is being moved.

verification points. Two points in the distal ROI and six points in the proximal ROI that must be re-digitized to verify the accuracy of surface registration.

workspace. Any configuration of the arm within which the robot is operational. The robot cannot be powered on when the arm extends too far backward, the Z axis is all the way up or down, or the pitch axis is greater than 90 degrees.

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Appendix B

OR MONITOR SCREENS

Introduction

This appendix lists the screens that appear on the OR Monitor and explains the information they contain. The screens are organized in the sections described below, and presented in alphabetical order within each section.

This appendix is divided into the following three sections:

- **Diagnostics and Surgery Screens.** This section provides a listing of the messages and options that appear during the normal sequence of procedures.
- **Pendant Pause Menu Screens.** This section provides a listing of the messages and options that may appear on the Pendant Pause menu.
- **Error Message Screens.** This section provides a listing of the messages and recovery options that appear when the system detects an exception condition and interrupts the normal sequence of procedures.

The entries in each of these sections are organized in the following groups:

- **Screen titles.** These entries appear at the top of the screen and identify the type of procedure being performed when the screen is displayed.
- **Selection options.** These entries appear at the bottom of the screen and offer a choice of one or more actions.
- **Prompts and messages.** These entries appear in the center of the screen and either prompt the user to take further action or provide information about the current process.

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Diagnostics and Surgery Screens

This section explains the meaning of the screens (screen titles, selection options, prompts and messages) that appear during normal diagnostics and surgery. The entries are presented in alphabetical order.

A screen title identifies the type of procedure being performed when the screen is displayed. Selection options appear at the bottom of screen. Some screens display only one option, for example, "**Press SELECT to continue.**" Other screens provide multiple selection options. Status message screens do not offer selections because the next screen appears automatically. Prompts and messages are displayed in the center of the OR Monitor screen.

Screen Titles

Final Procedures

Meaning: The procedures that the OR Monitor is prompting you to perform are the last procedures in preparation for closing the patient..

Non-Sterile Preparation

Meaning: The action described on the OR Monitor must be performed by a non-sterile member of the OR team in order to prepare the robot for surgery.

Non-Sterile Procedure

Meaning: The action described on the OR Monitor must be performed by a non-sterile member of the OR team.

Preparation For ROBODOC Surgery

Meaning: The action described on the OR Monitor is a final step in preparation for robotic cutting.

ROBODOC Procedure Complete

Meaning: The part of the procedure performed by the robot has been completed.

ROBODOC Surgery

Meaning: The robot is currently cutting the femur.

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Sterile Preparation

Meaning: The action described on the OR Monitor must be performed by a sterile member of the OR team to prepare the robot for surgery.

Sterile Procedure

Meaning: The action described on the OR Monitor must be performed by a sterile member of the OR team.

Verification By SURGEON

Meaning: The surgeon must verify the patient or implant data displayed on the OR Monitor.

Selection Options

ANTEROLATERAL

DIRECT LATERAL

POSTERIOR

Meaning: Indicates which surgical approach will be used for THA.

AVAILABLE

Meaning: Indicates that the specific item(s) described on the screen (e.g., specific implant types or cutters) ors available.

CONTINUE

Meaning: Indicates that the system can proceed to the next action.

CORRECT

INCORRECT

Meaning: Indicates that the displayed patient or implant information is valid or invalid.

Disable Reorienting

Enable Reorienting

Meaning: Toggle the system into or out of the mode where the tool can be reoriented during guiding.

Press SELECT to continue

Meaning: Press the **SELECT** button on the pendant to display the next OR Monitor screen and perform the next procedure.

Press SELECT When Complete

Meaning: Press the **SELECT** button on the pendant to notify the system that the action prompted for on this screen has been performed.

PROBE CENTERED

PROBE NOT CENTERED – RETRY

Meaning: Indicates that the ball probe is either centered or not centered above the locator pin head.

YES

YES/MAYBE

NO

Meaning: Indicates whether the answer to the prompted question is "Yes," "Maybe," or "No."

Prompts and Messages

BONE MAY BE

BLOCKING CUTTER APPROACH

CLEAR AREA __ mm

IN FRONT OF CUTTER

Meaning: The femur appears to extend beyond the top of the cut cavity. Remove the specified amount of bone to clear the top of the cut cavity.

CHECKING WORKSPACE

PLEASE WAIT...

Meaning: The robot control computer is verifying that the bone and intended cavity are within its workspace given the current arm, base height, and patient positions.

CLEAR PATH TO ARM

DRAPE INSTALLATION POSITION

Meaning: Move any obstructions between the current arm position and the position where you will install the arm drape.

CLEAR PATH TO

CUTTER DRIVE ASSEMBLY

INSTALLATION POSITION

Meaning: Move any obstructions between the current arm position and the position where you will install the cutter drive assembly.

CLEAR PATH TO

DIAGNOSTIC TOOL

CHANGING POSITION

Meaning: Move any obstructions between the current arm position and the position where you will change the diagnostic tool.

CLEAR PATH TO STARTING

POSITION FOR BONE

MOTION MONITOR TEST

Meaning: Move any obstructions between the current arm position and the position where the BMM test will start.

COMPUTING NEW CALIBRATION

Meaning: The new calibration parameters for the currently installed tool are being calculated..

COMPUTING REGISTRATION

Meaning: The robot is calculating the implant cavity placement.

CONFIRM AVAILABILITY OF INSTRUMENTS TO PERFORM

A MANUAL PROCEDURE

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Meaning: Verify that all of the traditional instruments for manual femoral canal preparation are in the operating room.

CONFIRM CUTTER AVAILABILITY

P/N _____

P/N _____

Meaning: Verify that the specified ROBODOC cutters are in the operating room.

CONFIRM IMPLANT SELECTION

AND AVAILABILITY

Meaning: Verify that the displayed implant model and size are in the operating room.

CONNECT GAS

AND IRRIGATION

Meaning: Connect air power (from wall air or nitrogen) and set up irrigation.

CUTTING COMPLETE

PLEASE REMOVE:

1. **CUTTER P/N _____**
2. **LONG SLEEVE P/N _____**
3. **GAS AND IRRIGATION _____**

Meaning: The robot has finished cutting the cavity.

CUTTING PROCEDURE COMPLETE

GUIDE ROBOT ARM INTO TRAVEL POSITION

Meaning: The robot has finished cutting the cavity. (See "GUIDE ROBOT ARM INTO TRAVEL POSITION.")

DIAGNOSTICS COMPLETE

PLEASE REMOVE:

1. DIAGNOSTIC TOOL

2. DIAGNOSTIC FIXTURE ON BASE

3. BMM DIAGNOSTICS ATTACHMENT

Meaning: The diagnostic tests are complete. Please remove the diagnostic tool (probe), diagnostic fixture on base (kinematics test plate), and BMM diagnostics attachment (the cylindrical rod on the BMM).

1. **DISCONNECT FIXATOR AND BMM**
2. **MOVE ROBOT AWAY FROM TABLE**
4. **REMOVE LOCATOR PINS**
5. **IMPLANT: _____**
6. **SLEEVE: _____, ROT: _____**
7. **HEAD: _____, NECK: _____**

Meaning: Remove the fixator and BMM from the patient's leg, move the robot away from the OR table, remove the locator pins. The screen also displays the information for the implant to be inserted (note that some fields may not be present for certain implants).

DISCONNECT GAS

FOR TOOL CHANGE

Meaning: Disconnect the hose from the robot base.

DO NOT TOUCH

ROBOT OR FIXTURES

Performing Bone Motion Monitor Test

PLEASE WAIT...

Meaning: Do not touch the robot or test fixtures while this message is displayed. The robot is performing a diagnostic test on the BMM.

DO NOT TOUCH ROBOT

OR PATIENT

Finding Pin Normal

Meaning: Do not touch the robot while it is finding the pin direction.

DO NOT TOUCH ROBOT OR PATIENT

Pin Search in Progress

PLEASE WAIT...

Meaning: Do not touch the robot or the bone while this message is displayed. The robot is performing a tactile search on a locator pin.

DO NOT TOUCH ROBOT

Performing Force Sensor test

PLEASE WAIT...

Meaning: Do not touch the robot while this message is displayed. The robot is performing a diagnostic test on the force sensor.

DO NOT TOUCH ROBOT

Robot is preparing to cut

PLEASE WAIT...

Meaning: Do not touch the robot while this message is displayed. The robot is about to start cutting.

DO NOT TOUCH ROBOT

Robot is cutting

PLEASE WAIT...

Meaning: The robot is about to start cutting. Normally, the RTM screen is displayed instead of this message.

GUIDE ARM TO CLEAR

REORIENTING POSITION

Meaning: Manually position the arm in a location where the tool can be reoriented without encountering any obstructions.

GUIDE ARM TO CLEAR

TOOL CHANGE POSITION

Meaning: Manually position the arm in a location where the tool can be changed without encountering any obstructions.

GUIDE PROBE TO

CALIBRATION POST ON

FIXATOR EXTENSION ARM

Meaning: Manually move the probe to a location just above (or just below) the dimple on the post at the end of the fixator extension arm.

GUIDE PROBE TO

INSTALLATION VERIFICATION

POINT ON

FIXATOR EXTENSION ARM

Meaning: Manually move the probe to a location just above the dimple on the fixator extension arm.

GUIDE PROBE TO

PIN CENTER

(Remove pin extender)

Meaning: Manually guide the probe to the indentation in the center of the pin after removing the pin extender.

GUIDE PROBE TO

POST NUMBER [1-6]

Meaning: Move the diagnostic probe to a location above the appropriate post and gently set the bottom of the ball just above the dimple.

GUIDE PROBE TO

START POSITION FOR

PITCH OFFSET TEST

Meaning: The tool is in the wrong position to start the pitch offset test. Figure 5-16 in Chapter 5 shows the proper start position.

GUIDE PROBE TO

START POSITION FOR

ROLL OFFSET TEST

Meaning: The tool is in the wrong position to start the roll offset test. Figure 5-15 in Chapter 5 shows the proper start position.

GUIDE ROBOT

ALONG TOOL AXIS

Meaning: Manually guide the robot arm in either direction along the axis of the tool.

GUIDE ROBOT

IN FRONT OF BONE

(Robot will stop automatically)

Meaning: Manually guide the robot arm so that the cutter is in the cone-shaped starting zone in front of the bone. (When the robot is properly positioned within this zone, it will stop.)

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GUIDE ROBOT ARM

INTO TRAVEL POSITION

Meaning: Fold the robot arm inward toward the base for safety while moving the robot.

GUIDE ROBOT TO

TOP OF BONE

Meaning: Manually guide the robot along the tool axis so that the cutter is near the most proximal part of the femur.

IDENTIFY PATIENT

The Patient's Name is _____

Meaning: Indicate whether the displayed name is the name of this patient.

IDENTIFY THE OPERATIVE HIP

LEFT

RIGHT

Meaning: Which side (right or left) will be operated on?

IDENTIFY THE

SURGICAL APPROACH

Meaning: Indicate whether the surgeon will use an anterolateral, direct lateral, or posterior approach for THA.

INCORRECT ELBOW

MANUALLY MOVE ARM TO

CORRECT CONFIGURATION

Meaning: Manually move the robot arm and fold it into the opposite elbow.

INSERT PATIENT DATA

CARTRIDGE IN

TAPE DRIVE

Meaning: Put the tape cartridge for this patient in the tape drive on the Control Cabinet.

INSTALL _____

Meaning: Install the specified probe or cutter.

INSTALL

CUTTER DRIVE ASSEMBLY

Meaning: Install the cutter drive assembly.

INSTALL

PENDANT DRAPE

Meaning: Install the sterile drape on the pendant.

INSTALL

PIN EXTENDER AND

GUIDE PROBE TO OUTER END

Meaning: Guide the probe to the end of the pin extender (away from the patient).

INSTALL

ROBOT ARM DRAPE

(Change base height if needed)

Meaning: Install the sterile drape on the robot arm. (Raise or lower the base, if necessary to facilitate installation.)

LOADING PATIENT DATA

Meaning: The system is reading patient data from the tape cartridge.

LOWER BASE

FOR TRANSPORT

Meaning: Adjust base height to its lowest position to facilitate moving through doorways.

LOWER FIXATOR

EXTENSION ARM

AND RESTART PROCEDURE

Meaning: The fixator extension arm is outside the robot's workspace during the calibration procedure. Lower the fixator extension arm and restart the procedure. (The ideal location for the fixator extension arm is at the bottom of the base attachment. The arm can be raised after the sterile calibration procedure is complete.)

MANUALLY MOVE ARM

NEAR HOME POSITION

Meaning: Move the arm into a right elbow configuration.

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MANUALLY MOVE ROBOT

SO THAT END EFFECTOR

ISN'T TOUCHING ANYTHING

Meaning: Move the robot arm so that the tool is not in contact with a solid object.

MOVE BONE WITHIN ROBOT WORKSPACE

Meaning: The fixator must be repositioned to bring the bone into the robot's workspace. (Adjusting base height will not suffice because the bone is outside of the X-Y workspace.)

MOVE ROBOT AWAY

FROM O.R. TABLE

Meaning: Move the robot away from the OR table because the robotic part of the procedure is complete.

PERFORMING BONE MOTION MONITOR TEST

Meaning: The robot is performing the automated diagnostic procedure to confirm that the BMM is functioning properly.

PERFORMING FORCE SENSOR TEST

Meaning: The robot is performing the automated diagnostic procedure to confirm that the force sensor is functioning properly.

PLACE BMM DIAGNOSTICS

ATTACHMENT ON PROBE TIP

Meaning: Couple the diagnostic probe and the rod on the BMM by retracting the spring-loaded BMM and placing the ball on the probe into the dimple on the rod.

PLEASE INSTALL

CUTTER P/N _____

Meaning: Install the specified cutter.

PLEASE INSTALL:

1. DIAGNOSTIC TOOL

2. DIAGNOSTIC FIXTURE ON BASE

3. BMM DIAGNOSTICS ATTACHMENT

Meaning: Install the diagnostic probe assembly, the diagnostics plate, and the BMM diagnostics attachment.

PLEASE INSTALL:

1. FIXATOR EXTENSION ARM

(with installation verification point up)

2. SKIRT DRAPE

Meaning: Install the cylindrical extension arm for the fixator (with the dimple on the top side) and the skirt drape.

PLEASE INSTALL

1. LONG SLEEVE P/N _____

2. LONG PROBE P/N _____

Meaning: Install the specified long sleeve in the appropriate position and the specified long probe.

PLEASE INSTALL

1. SHORT SLEEVE P/N _____

2. SHORT PROBE P/N _____

Meaning: Install the specified short sleeve in the appropriate position and the specified short probe.

PLEASE WAIT...

Meaning: Wait until the system has finished this automated procedure before touching the robot or pressing a pendant button.

POSITION ROBOT AND LEG:

1. INSTALL KNEE SUPPORT FIXTURE

2. INSTALL FEMORAL FIXATOR

3. MOVE ROBOT TO TABLE

4. LOCK ROBOT BASE

Meaning: Change base height if needed. Install the knee support fixture on the table, secure the leg in the knee support fixture, secure the leg in the femoral fixator, move the robot into position for the operation, attach the fixator to the robot base, and lock the base.

POWER OFF SYSTEM

Meaning: Turn the robot and control cabinet power off.

POWER OFF SYSTEM WHEN COMPLETE

Meaning: Power off system when all actions specified on screen have been performed.

PREPARE LEG:

1. INSTALL SOFT TISSUE RETRACTORS

2. VERIFY BONE STABILITY IN FIXATOR

Meaning: Get the leg ready for surgery. Make incisions to obtain access to the locator pins. Set the soft tissue retractors. Confirm that the bone is stable in the fixator.

PRESS DOWN

TO LOWER BASE

(BASE WILL STOP AUTOMATICALLY)

Meaning: Press the pendant DOWN button so that the base moves down. The base will automatically stop at the correct height.

PRESS UP

TO RAISE BASE

(BASE WILL STOP AUTOMATICALLY)

Meaning: Press the pendant UP button so that the base moves up. The base will automatically stop at the correct height.

READY TO

RESUME CUTTING AT

LAST CHECKPOINT

Meaning: The robot is ready to begin cutting from a location that was recently cut.

RECEIVING PATIENT DATA

PLEASE WAIT...

Meaning: The system is transferring patient data from the real-time monitor computer to the robot control computer.

RECONNECT GAS

Meaning: Re-attach the gas hose to the robot base.

REINSERT PROBE INTO BONE

Meaning: After recovering from a bone motion exception, insert the BMM probe into the femur again.

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Meaning: Release (version number), copyright date, company name, copyright.

REMOVE AND RE-INSTALL

CUTTER DRIVE ASSEMBLY

Meaning: Remove the cutter drive assembly, then re-install taking care to ensure that it is fully seated.

REMOVE BMM DIAGNOSTICS

ATTACHMENT FROM PROBE TIP

Meaning: Separate the diagnostic probe and the rod on the BMM by retracting the spring-loaded BMM.

REMOVE GAS AND IRRIGATION

Meaning: Disconnect the gas hose and irrigation system.

ROBOT IS CUTTING

Meaning: The robot is cutting the cavity.

ROBOT IS HOMING

PLEASE WAIT...

Meaning: The robot arm is automatically moving to home position. Do not touch the robot or press a pendant button while this message is displayed.

DJA x01608

ROBOT IS MOVING

PLEASE WAIT...

Meaning: The robot arm is moving. Do not touch the robot or press a pendant button while this message is displayed.

ROBOT IS PREPARING TO CUT

Meaning: The robot will begin cutting shortly.

ROBOT IS READY TO CUT

DO NOT TOUCH ROBOT

Meaning: The robot is in the initial cutting position and ready to prepare the cavity.

ROBOT MOVING TO

TOP OF BONE

Meaning: The robot is automatically moving to the top of the femur.

ROBOT MOVING TO

TOP OF IMPLANT

Meaning: The robot is automatically moving to the top of the implant.

ROBOT READY TO MOVE TO

INITIAL CUTTING POSITION

Meaning: The robot tool is ready to move to the location where it will begin the cutting motion.

SET BASE HEIGHT FOR

DIAGNOSTICS

Meaning: Raise or lower the base to an appropriate height for performing diagnostics.

SET BASE HEIGHT FOR

HOMING

Meaning: Raise or lower the base to an appropriate height for homing the robot.

SET BASE HEIGHT FOR

STERILE SETUP

Meaning: Raise or lower the base to an appropriate height for performing sterile set up procedures.

SET ROBOT BASE

TO HIGHEST POSITION

Meaning: Raise the base as far as possible.

SET ROBOT BASE

TO LOWEST POSITION

Meaning: Lower the base as far as possible.

SET UP BMM:

1. **INSTALL BMM PROBE** (*probe number*)
2. **REMOVE TIP PROTECTOR**
3. **INSERT PROBE INTO BONE**

Meaning: Install the BMM. Push the BMM probe into the end of the adapter and tighten the thumb screw to hold it in place. Remove the cover on the tip. Press the sharp end of the probe against the bone in the open area of the greater trochanter and release. If more than one BMM probe is available, the screen includes the probe part number.

SUGGEST LOWERING BASE

BASE HEIGHT OK

SUGGEST RAISING BASE

Meaning: If "Suggest Lowering Base" or "Suggest Raising Base" is highlighted, base height should be adjusted accordingly, if possible, to facilitate the next procedure.

DJA x01610

TEST PENDANT BUTTONS

Press SELECT

Press UP

Press DOWN

Press PAUSE

Meaning: Verify that the pendant buttons are functioning properly. Press the green SELECT button. Press the blue UP button. Press the blue DOWN button. Press the yellow PAUSE button. The system will continue to the next screen after all buttons have been pressed.

TURN ON GREEN

MOTOR POWER SWITCH

ON CONTROL CABINET

Meaning: Press the green button on the Control Cabinet to turn the motor power on.

TWIST PITCH AXIS CASING

(PUSH ON 'R' AND PULL ON 'L')

Meaning: Grasp the pitch axis casing with both hands and twist it as indicated by the graphic on the screen.

UNSCREW PROXIMAL PIN

(1 Turn = 2.5 mm)

Meaning: Unscrew the proximal locator pin the appropriate number of turns to avoid interference with the cutter (as indicated on the tape cartridge label), but do not remove it completely.

UPDATING NEW CALIBRATION

Meaning: The new calibration parameters for the currently installed tool are being updated.

VERIFY AREA CLEAR

FOR PIN SEARCH

Meaning: Confirm that the pin head is accessible by the ball probe and free of soft tissue and other debris.

VERIFYING PATIENT DATA

PLEASE WAIT...

Meaning: The system is checking the patient data in the Transfer File.

VERIFY INSTALLATION

USING GAUGE SET

Meaning: Ensure that the tool is properly installed using the installation gauges.

VERIFY PATIENT DATA

The implant is intended for the _____ femur.

Meaning: Confirm that this patient needs the implant on the specified femur (left or right).

VERIFY SELECTION OF

LEFT HIP

RIGHT HIP

Meaning: Confirm the selection of the left hip/right hip.

VERIFY THAT PROBE

IS CENTERED ON FIXATOR

INSTALLATION VERIFICATION POINT

Meaning: Confirm that the ball probe is centered above the installation verification point (dimple) on the fixator extension arm.

VERIFY THAT PROBE

IS CENTERED ON POST

Meaning: Confirm that the ball probe is centered above the post on the diagnostic fixture.

VERIFY THAT PROBE TIP

IS CENTERED ON PIN

Meaning: Confirm that the tip of the ball probe is centered above the indentation in the top center of the locator pin.

WAIT: ARCHIVING DATA TO TAPE...

Meaning: Wait while the data is being saved to tape.

DJA x01612

Pendant Pause Menu Screens

This section explains the meaning of the selection options that appear on the Pendant Pause menu and the prompts and messages that appear when an option is selected.

Pendant Pause menus are displayed when the PAUSE button on the pendant is pressed. See the "Pendant Pause Menus" section in Chapter 2 for a detailed description of these menus and their options.

Screen Titles

ENCODER FREEZE

Meaning: The robot has paused because cross-checking encoders reported discrepant joint positions.

FORCE FREEZE

Meaning: The robot has paused because the force sensor detected excessive forces at the tool tip.

PENDANT PAUSE

Meaning: The robot has paused because the yellow PAUSE button on the pendant was pressed.

Selection Options

ABORT PROCEDURE

Meaning: Stop the robot and finish the surgery manually.

ADDITIONAL OPTIONS

Meaning: Display another Pendant Pause menu.

ADJUST BASE HEIGHT

Meaning: Raise or lower the robot base.

CHANGE CUTTER

Meaning: Install a different cutter.

DJA x01613

CHANGE PROBE

Meaning: Install a different probe.

CORRECT FOR TOOL DRIFT

Meaning: If the robot moves when no force is being applied in guide mode, selecting this option will re-zero the force sensor to stop the motion.

CONTINUE

Meaning: Continue the surgery from the point at which it was interrupted.

CUTTING OPTIONS

Meaning: Display menu options for cutting performance changes.

DISABLE ADAPTIVE CUT SPEED

Meaning: Turn off the adaptive cut speed feature to cut at preprogrammed speeds.

DISABLE CHECKING

Meaning: Temporarily turn off bone motion monitoring.

ENABLE ADAPTIVE CUT SPEED

Meaning: Turn on the adaptive cut speed feature to automatically adjust cutting speed to the sensed bone hardness.

ENABLE CHECKING

Meaning: Resume bone motion monitoring, allowing the procedure to continue.

GO BACK ONE CHECKPOINT

Meaning: Restart cutting at the checkpoint prior to the current checkpoint.

GUIDE ROBOT ALONG TOOL AXIS

Meaning: Enable the mode for manually moving the robot arm in a straight line along the axis of the tool.

GUIDE ROBOT OPTIONS

Meaning: Menu choices for manual guidance modes (i.e., Hand Guide Robot, Guide Robot Along Tool Axis, Correct for Tool Drift).

DJA x01614

HAND GUIDE ROBOT

Meaning: Enable the mode for manually moving the robot arm.

PREVIOUS OPTIONS

Meaning: Return to the previous Pendant Pause menu.

RESET BMM

Meaning: Re-initialize the BMM insertion position to the current position. This option is only available if no pins have yet been found.

RESTART CURRENT CUTTING STEP

Meaning: Continue cutting from the beginning of the current checkpoint, rather than from where the cutting was interrupted.

RESTART CURRENT PROCEDURAL STEP

Meaning: Continue the surgery from the beginning of the current step of the procedure, rather than from the point at which the procedure was interrupted.

RESTART CUTTING PROCEDURE

Meaning: Repeat the entire cutting procedure from the beginning.

RESTART KINEMATIC DIAGNOSTICS

Meaning: Repeat the entire kinematic diagnostics procedure from the beginning.

RETURN TO PREVIOUS MENU

Meaning: Display the previous set of options.

USE MAXIMUM CUTTING SPEED

Meaning: Continue cutting using the maximum (normal) cutting speed as the highest allowed cutting speed.

USE 75% CUTTING SPEED

Meaning: Continue cutting using 75 percent of the maximum (normal) cutting speed as the highest allowed cutting speed.

USE 50% CUTTING SPEED

Meaning: Continue cutting using 50 percent of the maximum (normal) cutting speed as the highest allowed cutting speed.

USE 25% CUTTING SPEED

Meaning: Continue cutting using 25 percent of the maximum (normal) cutting speed as the highest allowed cutting speed.

VIEW BONE MOTION

Meaning: Display a screen that displays the distance the femur has moved since the BMM probe was inserted.

DJA x01616

Prompts and Messages

READY TO

ABORT PROCEDURE

Meaning: The robot is prepared abort the ROBODOC surgery.

READY TO

RESTART CUTTING

PROCEDURE

Meaning: The robot is ready to restart cutting the implant cavity from the beginning.

RETURN TO

PREVIOUS POSITION

BEFORE CONTINUING?

Meaning: Should the tool return to the position where the robot was paused and the Guide Along Tool Axis option was selected?

DJA x01617

Exception and Error Message Screens

This section explains the meaning of the screens that appear when the normal sequence of procedures is interrupted by an exception or error condition.

Screen Titles

ABORTING ROBOT PROCEDURE

Meaning: The system is preparing to end robotic activity so that the robot can be moved away from the OR table and the operation can be completed manually.

NON-STERILE RECOVERY PROCEDURE

Meaning: The non-sterile procedure that the OR Monitor is prompting you to perform is necessary to resume the normal sequence of procedures.

ROBOT POWERED OFF

Meaning: The robot motors have lost power.

STERILE RECOVERY PROCEDURE

Meaning: The sterile procedure that the OR Monitor is prompting you to perform is necessary to resume the normal sequence of procedures.

SYSTEM ERROR

Meaning: A hardware, software, or user error has interrupted the normal sequence of procedures.

Selection Options

ABORT ROBOT SURGERY

Meaning: Stop the robot and finish the surgery manually.

CONTINUE WITHOUT REAL TIME MONITOR

Meaning: Start robotic cutting even though the OR Monitor will not be able to display images indicating the progress of the cutter during femoral canal preparation.

PRESS SELECT TO ATTEMPT RECOVERY

Meaning: Press the **SELECT** button on the pendant to try to restart the procedure.

PRESS SELECT TO CONTINUE

Meaning: Press the **SELECT** button on the pendant to resume the procedure or attempt recovery.

PRESS SELECT TO RECALIBRATE

Meaning: Press the **SELECT** button on the pendant to retry the calibration procedure.

RE-HOME WITHOUT ORIENT CHECK

Meaning: Repeat the homing procedure without finding roll home orientation.

RELOAD FILES FROM TAPE

Meaning: Repeat the automatic procedure to reload all of the files on the tape cartridge.

RELOAD TAPE

Meaning: Reload the tape cartridge because the system could not find some of the required files.

RESTART SEARCH

Meaning: Retry search or pin finding.

RETRY COMMUNICATION

Meaning: Try again to establish the communication link between the real-time monitor computer and the robot control computer.

RETRY CONNECTING

Meaning: Try again to re-establish the failed communication link between the real-time monitor computer and the robot control computer.

RETRY INITIALIZATION

Meaning: Repeat the automatic procedure to initialize the CT graphics data so that the OR Monitor can display images indicating the progress of the cutter during femoral canal preparation.

RETRY ORIENT CHECK

Meaning: Repeat the automated procedure to find roll home orientation.

RETRY RECEIVING FILE

Meaning: Repeat the automatic procedure to read data from the real-time monitor computer.

RETRY TAPE LOADING

Meaning: Repeat the automatic procedure to read the tape cartridge containing the Transfer File.

RETRY TEST

Meaning: Repeat the test procedure that has failed.

Prompts and Messages

BONE MOTION MONITOR

DIAGNOSTIC ERROR

Meaning: The system failed the BMM test.

BONE MOTION

WAS DETECTED

Meaning: The BMM detected femur movement.

CABINET STOP BUTTON PRESSED

Meaning: The large red button on the front of the Control Cabinet has been pressed.

CANNOT RESUME MOVE

Meaning: The interrupted motion cannot be restarted.

CAN'T REORIENT

WHILE ROBOT IS

INSIDE BONE

Meaning: The tool can't be reoriented until it is moved out of the implant cavity and into clear reorient position.

DJA x01620

CHECK CABLE CONNECTIONS

Meaning: Check to see that all cables are properly connected.

COMMANDED MOTION WAS TOO FAST

Meaning: A robot joint was moving too fast. If no problems were observed, such as a jerking arm motion, try again.

CONFLICT WITH

PREOPERATIVE PLAN

If selection error was made, retry

Meaning: The surgeon rejected the displayed patient or implant information, which indicates a conflict with the preoperative plan. If the wrong option was selected, retry and select the correct option.

CONNECT CABLE TO

BASE ABSOLUTE ENCODER

Meaning: Verify that the base absolute encoder cable (inside the robot base) is connected.

CONNECT CABLE TO

BASE INCREMENTAL ENCODER

Meaning: Verify that the base incremental encoder cable (inside the robot base) is connected.

CONNECT CABLE TO

BASE PANEL SWITCHES

Meaning: Verify that the base panel switch cable (inside the robot base) is connected.

CONNECT CABLE TO

BONE MOTION MONITOR

Meaning: Verify that the BMM cable is connected.

CONNECT CABLE TO

FORCE SENSOR

Meaning: Verify that the force sensor cable is connected.

CONNECT CABLE TO HIGH

POWER BOARD

Meaning: Verify that the high power board cable (inside the robot base) is connected.

CONNECT CABLE TO

ROBOT BASE

Meaning: Verify that the robot base cable is connected.

CONNECT CABLE TO

ROBOT REDUNDANT ENCODERS

Meaning: Verify that the robot redundant encoder cable is connected.

CUT PATHS NOT ENTIRELY

WITHIN ROBOT WORKSPACE

Decrease bone angle

Meaning: The robot will not be able to access all of the areas that need to be cut. Readjust the bone within the fixator to make it more parallel with the fixator frame and then repeat the surface registration procedure.

CUT PATHS NOT ENTIRELY

WITHIN ROBOT WORKSPACE

Lower bone or change bone angle

Meaning: The robot will not be able to access all of the areas that need to be cut. Readjust the bone within the fixator to make it more parallel with the fixator frame or lower the fixator and then repeat the surface registration procedure.

CUT PATHS NOT ENTIRELY

WITHIN ROBOT WORKSPACE

Raise bone or change bone angle

Meaning: The robot will not be able to access all of the areas that need to be cut. Readjust the bone within the fixator to make it more parallel with the fixator frame or raise the fixator and then repeat the surface registration procedure.

CUT PATHS NOT ENTIRELY

WITHIN ROBOT WORKSPACE

Move bone within robot workspace

Meaning: The robot will not be able to access all of the areas that need to be cut. Re-position the bone so that lies within the robot workspace and repeat the surface registration procedure.

CUTTER DRIVE

INSTALLATION ERROR

Meaning: The cutter drive assembly is not properly installed. Remove and re-install it.

CUTTER ERROR

Meaning: A software error occurred.

Diagnostics must be finished

before beginning surgery

Meaning: Remove the cutter drive assembly and diagnostic tools, if present.

DIAGNOSTICS PERFORMED

FOR INCORRECT SIDE

Meaning: The side where the diagnostics were performed differs from the patient's operative side.

ENCODER EPO

Meaning: The cross-checking encoders reported discrepant joint positions and shut off power to the robot motors.

ENCODER FREEZE

Meaning: The cross-checking encoders reported discrepant joint positions and paused the robot.

ERROR ACCESSING

ARCHIVE FILE

Meaning: The robot control computer failed to access the archive file.

ERROR DETECTED COMPUTING

IMPLANT TRANSFORMATION

Meaning: The robot control computer found an error in the transfer file while converting ORTHODOC implant geometry to robot implant geometry.

ERROR FINDING

ROLL HOME ORIENTATION

Meaning: A hardware or software error occurred during homing.

ERROR HOMING BASE

Meaning: The base was not properly homed.

ERROR HOMING ROBOT

Meaning: The robot failed to home.

ERROR INITIALIZING

CT GRAPHICS

Meaning: The system failed to prepare the CT graphics data that will be used for displaying the progress of the cutter during femoral canal preparation.

ERROR LOADING SAFETY VOLUME FILE

Meaning: The CT data on the transfer media may be corrupt.

ERROR OPENING FILE

Meaning: A software error occurred.

ERROR RECEIVING

CHECK VOLUME FILE

Meaning: The robot control computer could not read the check volume data from the real-time monitor computer.

ERROR RECEIVING

IMPLANT FILE

Meaning: The robot control computer could not read the implant data from the real-time monitor computer.

ERROR RECEIVING

PATIENT FILE

Meaning: The robot control computer could not read the patient data from the real-time monitor computer.

ERROR SETTING

BASE HEIGHT

Meaning: The height of the base was not properly adjusted.

DJA x01624

EXPANSION SERVO POWER MODULE IS OFF

Meaning: The expansion servo power module is not functioning and the procedure cannot continue without it.

FLOATING POINT ERROR

Meaning: A software error occurred.

FORCE EPO

Meaning: The force sensor detected excessive forces at the tool tip and shut off power to the robot motors.

FORCE FREEZE

Meaning: The force sensor detected excessive forces at the tool tip and paused the robot.

FORCE HW EPO

Meaning: The system detected a hardware problem with the force sensor and shut off power to the robot motors.

FORCE SENSOR
DIAGNOSTIC ERROR

Meaning: The force sensor test failed.

GOAL OUTSIDE SAFETY VOLUME

Meaning: The cutter cannot move because the next destination is outside of the predefined boundaries for the cavity.

GOAL OUTSIDE WORKSPACE

Meaning: The arm cannot move because the next destination of the robot arm is outside of the workspace.

IMPLANT CUT FILE
INVALID OR CORRUPTED

Meaning: The file on transfer media provides the robot with implant geometry that is unusable.

INDICATE IF THE TOOL

IS TOUCHING ANYTHING

Meaning: Select the appropriate option to confirm whether the tool is in contact with a solid object.

INCORRECT ELBOW

Meaning: The robot arm is folded in the wrong direction.

INSTALL

BONNET DRAPE

Meaning: Install the sterile bonnet drape over the cutter drive assembly.

INVALID CALIBRATION FILE

Meaning: A software or disk drive error occurred.

INVALID DIAGNOSTICS FILE

Meaning: A software error occurred.

KINEMATIC

DIAGNOSTIC ERROR

Meaning: The system failed the kinematics test.

LOWER DIAGNOSTIC FIXTURE

AND RESTART PROCEDURE

Meaning: Lower the diagnostic fixture (diagnostics plate) in the dovetail mounting mechanism and restart the diagnostic procedure.

MANIP POWER DROP

Meaning: The robot arm is not receiving power, probably because the STOP button on the pendant has been pressed.

DJA x01626

MANUALLY MOVE

ROBOT ARM TO

TRAVEL POSITION

Meaning: Fold the arm inward to prevent damage when the robot is moved.

MAXIMUM RESIDUAL = __

AVERAGE RESIDUAL = __

POSITION DIFFERENCE = __

ANGLE DIFFERENCE = __

CALIBRATION UNSUCCESSFUL

Meaning: The currently installed tool was not calibrated to an accuracy that is acceptable for surgery.

MCS FLOATING POINT ERROR

Meaning: A software error occurred.

MCS MATH ERROR

Meaning: A software error occurred.

PENDANT STOP BUTTON PRESSED

Meaning: The red STOP button on the pendant has been pressed.

PRESURGICAL PLAN

DATA FILE CORRUPTED

Meaning: The file on transfer media is unusable.

PROCEDURE WAS INTERRUPTED

FOR PATIENT

CONTINUE PROCEDURE FOR PATIENT

START NEW PROCEDURE

Meaning: The procedure in progress for the named patient was neither completed nor aborted. Selecting "CONTINUE" will resume the procedure for the named patient, while selecting "START NEW PROCEDURE" will begin the ROBODOC surgery from the beginning.

RAISE DIAGNOSTIC FIXTURE

AND RESTART PROCEDURE

Meaning: Raise the diagnostic fixture in the dovetail mounting mechanism and resume the diagnostic procedure.

REAL TIME ERROR

Meaning: A hardware or software error occurred. This error may be caused by contact between the robot arm and an obstacle.

REAL TIME MONITOR

COMMUNICATION ERROR

Meaning: The OR Monitor will not be able to display images indicating the progress of the cutter during femoral canal preparation.

REAL TIME MONITOR ERROR

Meaning: The OR Monitor cannot display images indicating the progress of the cutter during femoral canal preparation.

REAL TIME MONITOR

NOT RESPONDING

Meaning: The real-time monitor is malfunctioning.

RECOVERY DATA CORRUPTED

Meaning: The data required to continue an interrupted procedure is unusable..

RELEASE CABINET STOP BUTTON

OR PENDANT STOP BUTTON

Meaning: Unlatch the red STOP button on the pendant and/or the large red button on the front of the Control Cabinet.

RELEASE PENDANT STOP BUTTON

Meaning: Unlatch the red STOP button on the pendant.

REMOVE GAS AND IRRIGATION

Meaning: Disconnect the air supply and irrigation system in preparation for error recovery and repeating surface registration procedures after bone motion.

DJA x01628

REQUIRED FILES MISSING OR INVALID

Meaning: The tape cartridge does not contain all of the necessary files.

ROBOT NOT HOMED

Meaning: The robot has not successfully completed the homing procedure or has lost its home orientation.

ROBOT POWER HAS DROPPED

Meaning: The robot motors have lost power.

ROBOT POWER IS OFF

Meaning: There is no power to the robot motors.

RT FLOATING POINT ERROR

Meaning: A software error occurred.

RT MATH ERROR

Meaning: A software error occurred.

SAFETY PROCESSOR STOP

Meaning: An internal safety error has occurred. The safety processor has powered off the robot motors.

SAFETY VOLUME MCS EXCEPTION

Meaning: The robot tried to cut outside of the safety volume.

STOP BUTTON PRESSED

Meaning: One of the Emergency Power Off buttons has been pressed.

SYSTEM ERROR (_)

Meaning: A system error occurred.

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DJA x01629

TAPE ERROR!! - Power off system

Meaning: There is a problem with the transfer media. Turn the robot and Control Cabinet power off.

TOO LONG TO WAIT FOR MOVE

Meaning: The system tried to start a move before another motion function (such as guiding) was complete.

UNABLE TO READ

TRANSFER TAPE

Meaning: The real time monitor computer cannot read the data on the transfer media.

UNEXPECTED BASE MOTION DETECTED

Meaning: The base unexpectedly moved.

UNRECOVERABLE

DATA CORRUPTION

DETECTED

Meaning: A software error occurred.

USER INTERFACE ERROR

Meaning: A software error occurred.

WORKSPACE LIMIT EXCEEDED

ADJUST ELBOW JOINT

Meaning: The elbow joint, which is located between the shoulder joint and the end of the robot arm, has moved outside the robot's workspace. To bring it back into the workspace, reposition the elbow joint by pushing on the arm near the vertical joint.

WORKSPACE LIMIT EXCEEDED

ADJUST PITCH JOINT

Meaning: The pitch joint, which is located above the force sensor, has moved outside the robot's workspace. Adjust it by grasping the currently installed tool and reorienting it.

DJA x01630

WORKSPACE LIMIT EXCEEDED

ADJUST ROLL JOINT

Meaning: The roll joint, which is located above the pitch joint and rotates the end effector around the pitch axis, has moved outside the robot's workspace. Adjust it by grasping the pitch axis casing and manually rotating it.

WORKSPACE LIMIT EXCEEDED

ADJUST SHOULDER JOINT

Meaning: The shoulder joint, which is located directly above the robot base, has moved outside the robot's workspace. Adjust it by pushing on the arm near the vertical joint.

WORKSPACE LIMIT EXCEEDED

ADJUST VERTICAL JOINT

(Pull brake release ring)

Meaning: The vertical joint, which is located directly above the robot base, has moved outside the robot's workspace. Unlock the vertical joint by pulling on the brake release ring (located on top of the robot arm) and then move it back into the workspace.

DJA x01631

Appendix C

LABEL GLOSSARY

Introduction

This glossary lists the labels on the ROBODOC Surgical Assistant (Surgical Robot and Control Cabinet), and describes the meaning and location of each label. Several labels appear in more than one location.

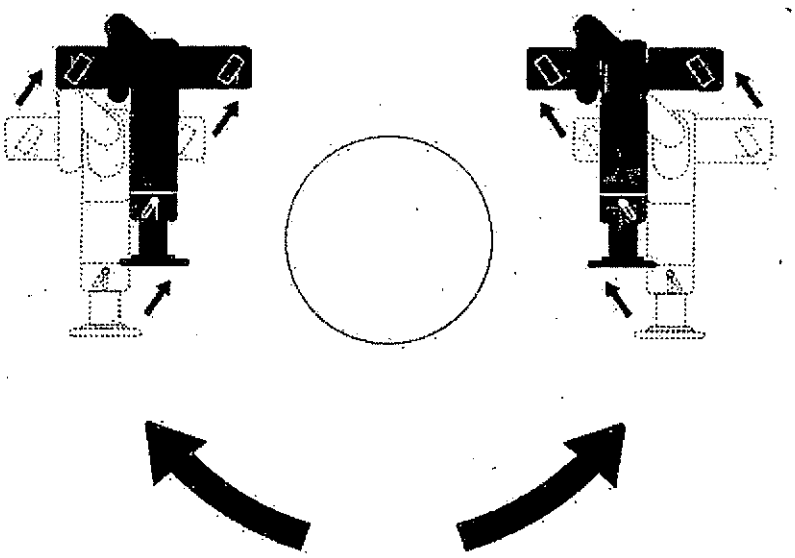
DJA x01632

External Labels

These labels are affixed to the exterior surfaces of ROBODOC equipment.

CAUTION
LOWER ROBOT AND FOLD ARM PRIOR TO TRANSPORT

Warns the user to lower the robot and fold the arm before moving the robot (located on the robot arm).

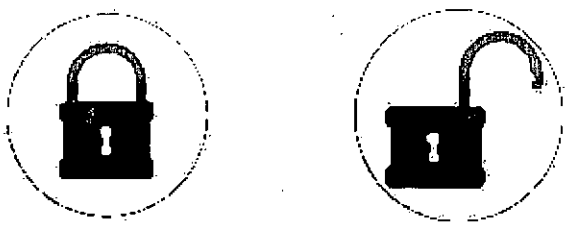


Located on the steering panel, this decal indicates the direction that the base will move when the lever is turned clockwise or counterclockwise.

Integrated Surgical Systems, Inc.
Sacramento, CA 95834
part # nnnnnn Serial # nnnn
VAC: nnn Amps: n Hz: nn

Identifies manufacturer, part number, serial number, and power requirements (located near the power cord on the Control Cabinet and on the robot base).

Identifies the quick connect for nitrogen into the solenoid (located on the overlay on the robot base).



Identifies the pedals that lock and unlock the robot base. The symbol on the left is located on the locking pedal; the symbol on the right is located on the unlocking pedal.

Identifies the quick connect for nitrogen out from the solenoid (located on the robot base).

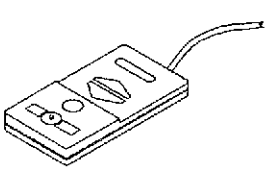
Identifies the automatic setting for the irrigation system switch on the rear panel of the robot base.

DJA x01634

Identifies the manual setting for the irrigation system switch on the rear panel of the robot base.

Identifies the off setting for the irrigation system switch on the rear panel of the robot base.

Indicates the flow control direction for the irrigation system adjustment knob (i.e., turning the knob clockwise increases flow and turning the knob counterclockwise decreases flow).



Identifies the receptacle for the pendant cable (located on the robot base).

RIGHT LEFT

Identifies the respective fixator blocks.

CAUTION KEEP FINGERS AWAY FROM ROTOR WHILE PUMP IS IN OPERATION

BETRIEBNAHME DIE FINGER NICHT IN DIE UMDREHUNGSMACHINE BRINGEN!

Cautions the user not to contact the blade during operation of the irrigation system.

WARNING
OPERATING CONDITIONS
DEPRESSURIZE UNIT
BEFORE REMOVING BOWL
MAX. PRESSURE 200 PSIG (14 BARg)
MAX. TEMP. 175°F (79°C)

Cautions the user not to unscrew the pressure vessel while it is pressurized or hot.

FULL

ADD
LUBRICANT

Indicates the level of lubricant in the oiler.

R1

Identifies a cable and the receptacle for it on the Control Cabinet (located on the Control Cabinet and on the cable).

R2

Identifies a cable and the receptacle for it on the Control Cabinet. (located on the Control Cabinet and on the cable).

R3

Identifies a cable and the receptacle for it on the Control Cabinet (located on the Control Cabinet and on the cable).

R4

Identifies a cable and the receptacle for it on the Control Cabinet (located on the Control Cabinet and on the cable).

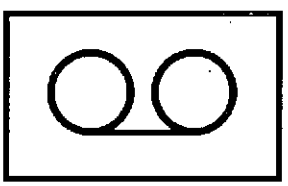
DJA x01636

ROBODOC
PENDANT
P/N 102027
Lot No. xxx

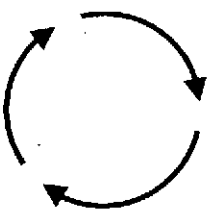
Identifies the control pendant (located on the back of the pendant case).

SELECT
UP
DOWN
PAUSE
STOP

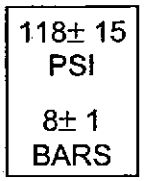
Identifies the functions of the pendant buttons. The **SELECT** button selects options from OR Monitor screens, the **UP** button moves up to the previous option on an OR Monitor menu, the **DOWN** button moves down to the next option on an OR Monitor menu, the **PAUSE** button pauses the robot and displays a Pendant Pause menu, and the **STOP** button turns off power to the robot motors (each word is located on one of the five pendant buttons).



Identifies the door to the input device (located on the overlay on the Control Cabinet).



Indicates that turning the Stop button clockwise will reset it (located on the Control Cabinet).



Advises the user that the maximum pressure for nitrogen is 118 pounds per square inch or 8 bars (located on the robot base, between the nitrogen hoses).

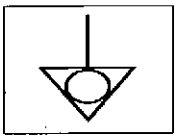
Identifies the main power switch for the Control Cabinet (located on the outside of the Control Cabinet).

Identifies the power off setting (located on the control panel on the robot base).

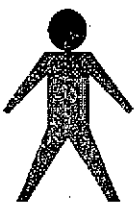
Identifies the power on setting (located on the control panel on the robot base).

Warns the user to read the manual before using the equipment (located near the power cord on the Control Cabinet).

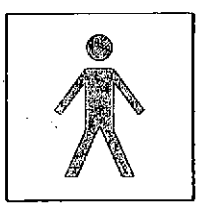
DJA x01638



Identifies the equipotential grounding lug (earth ground) located on the Control Cabinet.



Indicates that the Applied Parts are Type B, (i.e., parts that contact the patient are not electrically isolated from all other parts of the equipment). Located near the power cord on the Control Cabinet.



Indicates that the Applied Parts are Type BF (i.e., parts that contact the patient are fully insulated). Located on the digitizer.

Identifies the switch that adjusts the height of the robot base (located on the robot base).

Identifies pinch points, i.e., areas that users should not touch to avoid injury (located near the joints on the robot arm).

DJA x01639

CE 0197

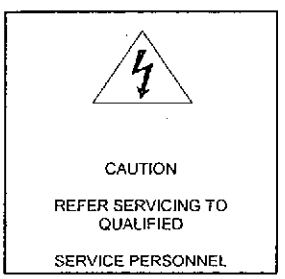
Indicates that the product complies with the requirements of EC Directive 93/42/EEC for medical devices as certified by TÜV Rheinland. This product also complies with the EC Directive 89/336/EEC (located near the power cord on the Control Cabinet).

DJA x01640

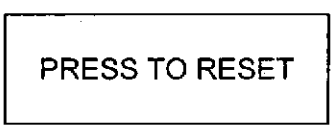
Internal Labels

These labels are affixed to surfaces inside the Control Cabinet and robot base.

Identifies the switch positions that determine whether control of the OR Monitor will be assigned to the RTM or the RCC automatically or manually. The manual setting works in conjunction with the RTM-RCC MANUAL SELECT switch. AUTO is the normal setting (located inside the Control Cabinet).

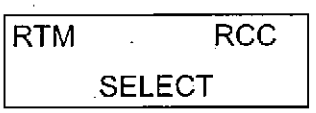


Warns the user not to attempt repair or maintenance procedures (located inside the robot base and Control Cabinet).

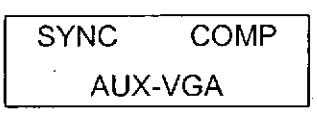


Identifies the circuit breaker and informs the user how to reset it (located inside the Control Cabinet on the power strips).

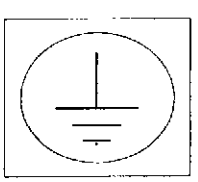
Identifies the switch positions that activate and deactivate power (located inside the Control Cabinet).



Identifies the switch positions that assign control of the OR Monitor to the RTM or the RCC when the DISPLAY SWITCHING switch is set to MANUAL (located inside the Control Cabinet).



Identifies the switch positions that determine whether the auxiliary monitor receives the same signal (SYNC) or a different signal (COMP) than the OR Monitor receives. This switch is for use only by qualified service personnel (located on the video switchbox).



Identifies the protective earth ground (located inside the Control Cabinet).

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DJA x01643

Appendix D

ACCESSORIES, COMPONENTS, AND TOOLS

Only ISS-approved accessories, components, and tools should be used with the ROBODOC system.

Accessories

Cutters

Recovery marker, distal

Recovery marker, proximal

Irrigation Tube Set, sterile

Drape set, sterile, DigiMatch

ORTHODOC workstation

Detachable Components

Bearing sleeves

Cutter drive assembly

Extension arm, anterolateral

Extension arm, direct lateral

Femoral fixator

Hose, cutter drive

Hose, nitrogen supply

Probe, BMM

Probe, digitizer, non-sterile

Probes, digitizer, sterile (pointed and ball)

Recovery marker cap

DJA X01644

Tools

CT motion detection rod

Diagnostic kit

Distal recovery marker removal tool

Installation verification gauge

Proximal recovery marker installation tool

Rod and wrench tool set

Wrench, cutter drive collet

T-handle wrench

Hex wrench for extension arm clamp screw (configuration for direct lateral approach only)

Consumable Components

Coaxial hose diffuser

Diffuser

Irrigation set, sterile

Motor safety seal

Oil, motor lubrication

Sterile Components

ISS recommends sterilizing the components listed below using the process described in Chapter 9:

Cutters

Bearing sleeves

Cutter drive assembly

Distal recovery marker removal tool*

Femoral fixator components

Green hose with quick connect

Installation verification gauge

Probe, BMM

Probes, digitizer, sterile (pointed and ball)*

Recovery marker cap*

Proximal recovery marker installation tool*

DJA x01645

Rod and wrench tool set

Wrench, cutter drive collet

T-handle wrench

*DigiMatch cases only

CJTA XO1646

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DJA X01647

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DJA x01650

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DJA x01651

Cutter Labels

DJA x01652

REF: 103277

ROBODOC®

12.5mm X 269mm

Flat Cutter	EN
Kopffraese	DE
Fraise à bout plat	FR
Planos Fresa	SP
Taglierina Piana	IT

LOT : NNNN

CE 0197

See ROBODOC® manual for cleaning and sterilization instructions.
Sehen Sie ROBODOC Handbuch für Reinigung und Serilisationanweisungen
Voir le manuel de ROBODOC pour les instrucions de nettoyage et de sterilization
Vea el manual de ROBODOC para las instrucciones de la limpieza y de la esterilizacion

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

For use on the ROBODOC system by ISS-Trained and ISS-certified surgeons and technicians only

MFG / DIST By: Integrated Surgical Systems, Inc.
1433 North Market Blvd. Suite #1
Sacramento, CA 95834 USA

DJA x01653

REF: 102862

ROBODOC®

8.5mm X 269mm

Flat Cutter	EN
Kopffraese	DE
Fraise à bout plat	FR
Planos Fresa	SP
Taglierina Piana	IT

LOT : NNNN

CE 0197

See ROBODOC® manual for cleaning and sterilization instructions.
Sehen Sie ROBODOC Handbuch für Reinigung und Serilisationanweisungen
Voir le manuel de ROBODOC pour les instrucions de nettoyage et de sterilization
Vea el manual de ROBODOC para las instrucciones de la limpieza y de la esterilizacion

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MFG / DIST By: Integrated Surgical Systems, Inc.
1433 North Market Blvd. Suite #1
Sacramento, CA 95834 USA

REF: 102231

ROBODOC®

12.5mm X 286mm

Flat Cutter	EN
Kopffraese	DE
Fraise à bout plat	FR
Planos Fresa	SP
Taglierina Piana	IT

LOT : NNNN

CE 0197

See ROBODOC® manual for cleaning and sterilization instructions.
Sehen Sie ROBODOC Handbuch für Reinigung und Serilisationanweisungen
Voir le manuel de ROBODOC pour les instrucions de nettoyage et de sterilization
Vea el manual de ROBODOC para las instrucciones de la limpieza y de la esterilizacion

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1433 North Market Blvd. Suite #1
Sacramento, CA 95834 USA

DJA x01655

REF: 103238

ROBODOC®

9.5mm X 269mm

Flat Cutter	EN
Kopffraese	DE
Fraise à bout plat	FR
Planos Fresa	SP
Taglierina Piana	IT

LOT : NNNN

CE 0197

See ROBODOC® manual for cleaning and sterilization instructions.
Sehen Sie ROBODOC Handbuch für Reinigung und Serilisationanweisungen
Voir le manuel de ROBODOC pour les instrucions de nettoyage et de sterilization
Vea el manual de ROBODOC para las instrucciones de la limpieza y de la esterilizacion

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

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Sacramento, CA 95834 USA

DJA x01656

REF: 103186

ROBODOC®

10.5mm X 269mm

Flat Cutter	EN
Kopffraese	DE
Fraise à bout plat	FR
Planos Fresa	SP
Taglierina Piana	IT

LOT : NNNN

CE 0197

See ROBODOC® manual for cleaning and sterilization instructions.
Sehen Sie ROBODOC Handbuch für Reinigung und Serilisationanweisungen
Voir le manuel de ROBODOC pour les instrucions de nettoyage et de sterilization
Vea el manual de ROBODOC para las instrucciones de la limpieza y de la esterilizacion

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Sacramento, CA 95834 USA

DJA x01657

Marker Labels

DJA x01658

REF: 103306

ROBODOC®

Distal Marker	EN
Distaler Marker	DE
Marqueur Distal	FR
Fijaciòn Distal	SP

LOT : NNNN

CE 0197

See ROBODOC® manual for cleaning and sterilization instructions.
Sehen Sie ROBODOC Handbuch für Reinigung und Serilisationanweisungen
Voir le manuel de ROBODOC pour les instrucions de nettoyage et de sterilization
Vea el manual de ROBODOC para las instrucciones de la limpieza y de la esterilizacion

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1433 North Market Blvd. Suite #1
Sacramento, CA 95834 USA

DJA x01659

REF: 102794

ROBODOC®

Proximal Marker	EN
Proximaler Marker	DE
Marqueur Proximal	FR
Fijaciòn Proximal	SP

LOT : NNNN

CE 0197

See ROBODOC® manual for cleaning and sterilization instructions.
Sehen Sie ROBODOC Handbuch für Reinigung und Serilisationanweisungen
Voir le manuel de ROBODOC pour les instrucions de nettoyage et de sterilization
Vea el manual de ROBODOC para las instrucciones de la limpieza y de la esterilizacion

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

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1433 North Market Blvd. Suite #1
Sacramento, CA 95834 USA

DJA x01660

Sterile Single Use Disposables Label

DJA x01661

REF: 102390

ROBODOC®

IRRIGATION TUBE SET	EN
SPULSCHLAUCH-SET	DE
TUBE D'IRRIGATION	FR
TUBO DE IRRIGATION	SP

LOT : NNNN
MFG. DATE: YYYY-MM
EXPIRATION DATE: YYYY-MM
STERILE EO

CE 0197

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

For use on the ROBODOC system by ISS-Trained and ISS-certified surgeons and technicians only

MFG: HEMODIA, Inc.
Rue du Chene Vert, B.P. 148
Labege, Cedex (France) F-31676

DIST By: Integrated Surgical Systems, Inc.
1433 North Market Blvd. Suite #1
Sacramento, CA 95834 USA

DJA x01662

REF: 102592

ROBODOC® DIGIMATCH

DISPOSABLE DRAPE EN
EINWEGABDECKUNG DE
JETABLE HOUSSE FR
DESECHABLE TAPA ES
GETTARE COPERTURA IT

STERILE EO

LOT NNNN

YYYY-MM

CE 0473

Manufactured By: BDF. Ltd.
Girvan, Ayrshire, Scotland KA26 9PL.

Distributed By: Integrated Surgical Systems, Inc.
1433 North Market Blvd. Suite #1
Sacramento, Ca. 95834

DJA x01:693

Section 14 – Sterilization and Shelf Life

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DJA x01664

CLEANING and STERILIZATION

Cleaning Validation

Single Use Cutters and Reusable Tools

The ROBODOC single use cutters and reusable tools are provided non-sterile to be steam sterilized by the hospital. Recommended cleaning procedures, validated by ISS, are provided for the user in the ROBODOC Manual.

For the cleaning validation representative devices were contaminated with *Geobacillus stearothermophilis* in an organic soil. Bioburden extracts were performed to determine the number of viable organisms on the positive control. Each device was contaminated and then cleaned individually using the recommended manual cleaning procedure. A total of five replicates was done for each device. After cleaning another bioburden assay was performed to determine the bioload reduction.

The percent reduction in bacterial counts were calculated using the following formula:

Percent Reduction = 100 – ((Final Population)/(Initial Population) X 100)

The log reduction was calculated using the following formula:

Log reduction = log (Positive control titer) – Log (Avg # organisms after cleaning)

A summary of the results are as follows:

Device	Avg. Percent Reduction	Avg. Log Reduction
Wrenches	99.99	5.6
Bearing Sleeve	99.96	3.4
Fixator/Bone Clamp	99.99	4.0
Cutter Drive	99.99	4.0
Probe	99.99	4.9
Extension Arm	99.99	4.5

The acceptance criteria was a minimum of a two log reduction. In addition samples were tested for cytotoxicity post cleaning via the MEM elution method. All results were acceptable.

The results demonstrate that the recommended cleaning methods are effective in reducing the population of inoculated bioburden by at least two logs and are acceptable for processing by the ISS recommended sterilization parameters.

DJA x01665

Sterilization

The ROBODOC System uses various tools, posts probes and cutters which are provided non-sterile and have a validated recommended sterilization cycle. A tabulated listing of the components/accessories is shown in table 14.1.

Table 14.1

Component/Accessory	Provided to the User	Sterilization Method	Standard(s) used	Sterility Assurance Level
Reusable Tools	Non-sterile	Steam	AAMI TIR 12 ANSI/AAMI/ISO 11134	10^{-6}
Single Use Cutters	Non-sterile	Steam	AAMI TIR 12 ANSI/AAMI/ISO 11134	10^{-6}
Probes/Recovery markers	Non-sterile	Steam	AAMI TIR 12 ANSI/AAMI/ISO 11134	10^{-6}

Surgical drapes and tubing sets are also included with the ROBODOC System. These accessories are purchased finished devices, provided sterile by the original manufacturers.

A description of the sterility process and validation methods for each of the applicable components/accessories is found below:

ROBODOC Reusable Tools

The ROBODOC reusable tools are provided non-sterile to be steam sterilized by the hospital. Recommended sterilization parameters are provided for one method of steam sterilization.

The reusable tools consist of the bearing sleeve, bone clamp fixator, cutter drive assembly, extension arm, wrenches, gauge set, probes, recovery markers, and air motor.

The tools are reusable instruments and the user is instructed to follow ISS recommendations for any cleaning prior to sterilization.

The ISS recommended steam sterilization parameters are:

Gravity Displacement:

Temperature 132°C to 135°C Minimum Time: 15 minutes

DJA x01666

Validation of the above recommended parameters was done per the requirements of AAMI TIR 12 and ANSI/AAMI/ISO 11134 at Nelson Laboratories, 6280 South Redwood Rd, Salt Lake City, UT 94123; FDA Reg. # 1721109.

A SAL of 10^{-6} was validated using the overkill method. The devices were inoculated with BI's of *Geobacillus stearothermophilis*. The inoculated devices were wrapped in two layers of 2 ply, 140 count cotton muslin and placed in the "cold" spot of the steam sterilizer. Five half cycles each were run in total. Within one hour after sterilization the inoculated devices were placed into soybean casein digest broth for sterility testing. Positive and negative controls were used. The test media was tested for growth promotion by inoculation with the test organism.

No growth was observed in any of the five half cycles. Positive and negative control results were also acceptable. The results support that the recommended steam sterilization cycle parameters can provide a SAL of 10^{-6}.

ROBODOC Single Use Cutters

ISS may provide single use cutters non-sterile to be steam sterilized by the hospital. Recommended sterilization parameters are provided for two methods of steam sterilization.

The cutter products consist of various sizes that have been grouped into one family. There are no lumens, or other barriers to steam penetration. All cutters share the following common characteristics with respect to sterilization parameters: raw material, overall dimensions, similar flute design, manufacturing processes and equipment, and final cleaning process.

The cutters are single use devices that are cleaned and packaged in a controlled environment. They are intended to be user sterilized following a cleaning preparation step.

The ISS recommended steam sterilization parameters are:

Gravity Displacement:

Temperature 132°C to 135°C Minimum Time: 15 minutes

Validation of the above recommended parameters was done per the requirements of AAMI TIR 12 and ANSI/AAMI/ISO 11134 at Nelson Laboratories, 6280 South Redwood Rd, Salt Lake City, UT 94123, FDA Reg. # 1721109.

A SAL of 10^{-6} was validated using the overkill method. The devices were inoculated with BI's of *Geobacillus stearothermophilis*. The inoculated devices were wrapped in two layers of 2 ply, 140 count cotton muslin and placed in the

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"cold" spot of the steam sterilizer. Five half cycles each were run in total. Within one hour after sterilization the inoculated devices were placed into soybean casein digest broth for sterility testing. Positive and negative controls were used. The test media was tested for growth promotion by inoculation with the test organism.

No growth was observed in any of the five half cycles. Positive and negative control results were also acceptable. The results support that the recommended steam sterilization cycle parameters can provide a SAL of 10^{-6}.

PACKAGING and SHELF LIFE

Packaging

ROBODOC tools and accessories are provided non-sterile. The packaging is designed to provide stabilization of the components during storage and transportation.

The ROBODOC labeling includes the Instructions for Use and the packaging labeling.

The surgical drapes and irrigation tubing set accessories are provided in standard medical device sterile barrier packaging by the original manufacturers.

Shelf Life

ROBODOC single use cutters and reusable tools are provided non sterile and do not have a labeled shelf life. The sterile surgical drapes and sterile irrigation tube set are both labeled by the original manufactured with their respective established shelf lives.

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Section 15 – Biocompatibility of DigiMatch™ ROBODOC® Surgical Assistant Components

INTEGRATED SURGICAL SYSTEMS
1433 N. Market Blvd., #1
SACRAMENTO, CA 95834

CONTACT: RUSS HIBBERT
Director, Clinical & Regulatory Affairs
PHONE: 916-285-9943, EXT. 522
FAX: 916-285-9104
E-MAIL: RDHIBBERT@ROBODOC.COM

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APPLIED STANDARD

ISO 10993 was used as a standard for biocompatibility compliance. ISO 10993-1 was used to determine the appropriate categorization of the device based on the nature and duration of contact with the body. The Blue Book Memorandum G95-1 entitled "Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and Table 1 of ISO 10993-1 were used as tools for the initial evaluation of tests for consideration.

CATEGORIZATION OF DEVICES

Intended Use

The ROBODOC® Surgical accessories are intended for use with the DigiMatch™ ROBODOC® Surgical Assistant.

Nature And Duration Of Body Contact

The ROBODOC surgical accessories consist of reusable instrument accessories, cutter drive assembly, bearing sleeves, posts, probes, bone clamp, wrenches, gages and single use equipment cutters, drapes and an irrigation set.

Reusable Instrument Accessories

The reusable instrument accessories consist of the cutter drive assembly, bearing sleeve, extension arm assembly, t-handle, Allen, C and motor wrenches, sleeve assembly, and post tool. The reusable instrument accessories are components of the robotic surgical instrument and have no patient contact.

Cutter Drive Assembly

The Cutter Drive Assembly is used to secure the bearing sleeves and cutters to the ROBODOC surgical instrument. Irrigation is provided to the cutters during use through ports in the cutter drive assembly and the bearing sleeves. As the Cutter Device Assembly and bearing sleeves indirectly contacts the surgical site by way of the fluid path, it is considered to be externally communicating devices with tissue/bone contact for a limited (< 24 hr) time.

Pinless Recovery Posts

The ROBODOC Pinless Recovery Posts provide a means of re-registration of the robot surgical plan to the operative bone in the event of bone movement during a pinless surgical procedure. The ROBODOC Recovery Posts are anchored in bone tissue. The recovery posts remain in place during the surgical procedure and are removed thereafter. As such the ROBODOC Recovery Posts are considered to be externally communicating devices with tissue/bone contact for a limited (< 24 hr) time.

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ROBODOC Cutters

The ROBODOC Cutters provide the means with which to perform incisions and other such surgical cutting techniques. As such the ROBODOC Cutters are considered to be externally communicating devices with tissue/bone contact for a limited (< 24 hr) time.

Probes

The probes used with the ROBODOC system are externally communicating devices with tissue/bone contact for a limited (< 24 hr) time.

Bone Clamp

The bone clamp used with the ROBODOC system is externally communicating devices with tissue/bone contact for a limited (< 24 hr) time.

Surgical Drape Sets

The surgical drape provided with the ROBODOC. System is purchased from BDF Healthcare Ltd.. The drape is CE Marked and commercially distributed within the European economic community. The application of the surgical drape is merely to cover the ROBODOC instrumentation during use. There is no anticipated patient contact. The surgical drapes are purchased from BDF as a finished device, packaged sterile by the manufacturer, therefore additional biocompatibility testing was deemed unnecessary in support of the ROBODOC premarket notification submission.

Irrigation Tubing Set

The irrigation tubing set provided with the ROBODOC System is purchased from Hemodia, located in Labege, France. The irrigation tubing set is commercially distributed within the US and has an active device listing. The irrigation set are purchased from Hemodia as a finished device, packaged sterile by the manufacturer, therefore additional biocompatibility testing was deemed unnecessary in support of the ROBODOC premarket notification submission.

TESTING RATIONALE

Using ISO 10993-1, in conjunction with Blue Book Memorandum G-95, the following analysis was performed for the ROBODOC accessories. The patient contact characterization for the applicable materials is found in **Table 1**.

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Table 1 Material and Nature of Contact

Material	Nature of the Contact	Component
Stainless Steel, 440C, ASTM A 276; passivated per ASTM A967	Direct Contact Externally communicating with tissue/bone contact for a limited (<24 hr) time	Cutters
Stainless Steel 303, ASTM A582; passivated to ASTM A967	Direct and Indirect Contact Externally communicating with tissue/bone contact for a limited (<24 hr) time	Bone Clamp Cutter Drive Assembly
Stainless Steel, 316LM, ASTM F138; passivated to ASTM A967	Direct Contact Externally communicating with tissue/bone contact for a limited (<24 hr) time	Recovery posts
630 (17-4) Stainless Steel	Externally communicating with tissue/bone contact for a limited (<24 hr) time	Probes

Stainless Steel 316L- Test Requirements Analysis

The toxicological risks of Stainless Steel 316L, as an externally communicating device for limited contact (< 24hr), is incredibly low. Stainless Steel, specifically 316 is used in a wide variety of medical devices including long-term implants.

The stainless steel material used for the ROBODOC accessories is implant grade surgical Stainless Steel 316L that meets the requirements of ASTM F138. The passivation process, per ASTM A967 is common industry practice and does not increase the toxicological profile of the material. As the 316L stainless steel meets the referenced ASTM standards and has a long, proven history of use throughout the medical device industry as a biocompatible material, it is accepted that the biocompatibility requirements of the material per ISO 10993-1 and FDA's Blue Book memorandum G-95 have been demonstrated.

Stainless Steel 440C-Test Requirements Analysis

The toxicological risks of Stainless Steel 440C, as an externally communicating device for limited contact (< 24hr), is incredibly low. Stainless Steel 440C has a long history of use in medical devices used as cutting instruments in surgical applications, including orthopedic procedures. Stainless steel 440C is commonly used in chisels, surgical knives, osteotomes, and scalpels[1,2]. The passivation process, per ASTM A967 is common industry practice and does not increase the toxicological profile of the material

As Stainless Steel 440C is a well characterized material with an established use identical to the ROBODOC device, it is accepted that the biocompatibility requirements of the material per ISO 10993-1 and FDA's Blue Book memorandum G-95 have been demonstrated.

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Stainless Steel 303- Test Requirements Analysis

The toxicological risks of 303 stainless steel, as an externally communicating device for limited contact (< 24hr), is incredibly low. Stainless Steel 303 is widely used in a broad range of medical devices, including those characterized as externally communicating devices with tissue/bone contact for < 24 hours. Examples of medical device include cutting knives, cannulaes, rectractors, forceps, specula, spreaders, clamps, drills, and punches.[1,2]. The passivation process, per ASTM A967 is common industry practice and does not increase the toxicological profile of the material

As the material has a long history of use medical applications exceeding the patient contact of the ROBODOC device, it is accepted that the biocompatibility requirements of the material per ISO 10993-1 and FDA's Blue Book memorandum G-95 have been demonstrated.

Stainless Steel 630 (17-4)- Test Requirements Analysis

The toxicological risks of 630 (17-4) stainless steel, as an externally communicating device for limited contact (< 24hr), is incredibly low. Stainless Steel 630, more commonly known as 17-4 Stainless Steel, is a common stainless steel used in a variety of medical devices, including bone/tissue contacting permanent implant devices. Devices include metallic bone fixation appliances and allograft delivery systems (reference K022246, K030198, K032705, K043289). The passivation process, per ASTM A967 is common industry practice and does not increase the toxicological profile of the material.

As the material has an established history of use in medical applications exceeding the patient contact of the ROBODOC device, it is accepted that the biocompatibility requirements of the material per ISO 10993-1 and FDA's Blue Book memorandum G-95 have been demonstrated.

CONCLUSION

The results of the biocompatibility analysis indicate that the patient contacting materials of the ROBODOC accessories are biocompatible for its intended use.

[1] http://www.devicelink.com/mddi/archive/02/11/002.html

[2] *Annual Book of ASTM Standards*, vol. 13.01 (West Conshohocken, PA: American Society for Testing and Materials, 2001).

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DigiMatch™ ROBODOC® Surgical System
Traditional 510(k) Premarket Notification

K _____ **ORIGINAL**

Integrated Surgical Systems, Inc. (ISS) hereby submits a premarket notification for the DigiMatch™ ROBODOC® Surgical System pursuant to 21 CRF PART 807 Subpart E. The format of this submission follows the recommendations contained in Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s, dated August 12, 2005.

K072629
Vol. III

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RECEIVED

ISS requests confidentiality of this notification in accordance Sec. §807.95(b)(1)(i-iv).

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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Section 16 – Software

Section 16 of this premarket notification provides information concerning verification and validation (V&V) of software used in the DigiMatch™ ROBODOC® Surgical System (ROBODOC System). The FDA guidance document, Guidance for Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005), has been followed in preparation and presentation of the software V&V documentation. Integrated Surgical Systems, Inc. (ISS) has determined, based on this guidance, the software used in the ROBODOC System presents a moderate level of concern. The following information is discussed:

16.1 Device and Software Description
16.2 Device Hazard Analysis
16.3 Software Requirements Specification (SRS)
16.4 Architecture Design Chart
16.5 Software Design Specification (SDS)
16.6 Traceability Matrix
16.7 Software Development Environment Description
16.8 Verification and Validation Documentation
16.9 Revision Level History
16.10 Unresolved Anomalies (Bugs or Defects)

Appendix 16A - SRS for the ORTHODOC® Preoperative Planning Workstation
Appendix 16B - SRS for the ROBODOC® Surgical Assistant
Appendix 16C - SDS for the ORTHODOC® Preoperative Planning Workstation
Appendix 16D - SDS for the ROBODOC® Surgical Assistant
Appendix 16E - Software Development Procedure
Appendix 16F - Validation of "Pinless" DigiMatch™ ROBODOC® Technology at BGU
Appendix 16G - DigiMatch ROBODOC® Risk Analysis - DC reviewed
Appendix 16H - ROBODOC® DigiMatch Validation Protocol and Report
Appendix 16I - ORTHODOC® Validation Protocol and Report

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16.1 Device and Software Description

The DigiMatch™ ROBODOC® Surgical System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The ORTHODOC software included in the DigiMatch™ ROBODOC® Surgical System is identical to the cleared software with the exception of an additional software module [redacted] that allows the output of data in the format required by the ROBODOC®. The three major components in the System, ORTHODOC, electromechanical arm, electronics control cabinet, operate or are controlled by software that has been developed or modified by Integrated Surgical Systems, Inc. (ISS). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then the ROBODOC component of the System will precisely implement the preoperative plan.

16.1.1 Definitions, acronyms, and abbreviations

16.1.1.1 3D – Three-dimensional
16.1.1.2 A/P - Anterior Posterior
16.1.1.3 CD – Compact Disk
16.1.1.4 CT - Computed tomography
16.1.1.5 [redacted]
16.1.1.6
16.1.1.7 LINUX – The Linux Operating System
16.1.1.8 M/L - Medial Lateral
16.1.1.9 [redacted]
16.1.1.10 MSDOS – Microsoft Disk Operating System
16.1.1.11 OR – Operating Room
16.1.1.12 ORTHODOC - ORTHODOC® Preoperative Planning Workstation
16.1.1.13 PC – Personal Computer
16.1.1.14 [redacted]
16.1.1.15
16.1.1.16 ROI – Region of Interest
16.1.1.17 [redacted]

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16.1.1.18 ROBODOC – Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories
16.1.1.19 (b) (4)
16.1.1.20 SRS – Software Requirements Specification
16.1.1.21 SDS – Software Design Specification
16.1.1.22 THR – Total Hip Replacement
16.1.1.23 UNIX – The UNIX Operating System

16.1.2 DigiMatch ROBODOC Surgical System Description

The DigiMatch ROBODOC Surgical System consists of the ORTHODOC® Preoperative Planning Workstation (ORTHODOC) and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC).

16.1.2.1 ORTHODOC® Component Description

The ORTHODOC is a PC workstation with proprietary ISS software that enables the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur. This device has previous FDA clearance (K960685). Computed tomography (CT) scan data of the patient's femur provide input to the system. ORTHODOC (b) (4) create three-dimensional images of the femur.

The ORTHODOC software contains a computerized directory of implant types and sizes, from which the surgeon selects an implant model. The system displays three-dimensional (3-D) views of selected implant models for computerized templating with femur images obtained from, the CT scan. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the image of the femur. The ORTHODOC also provides software tools, which allow the surgeon to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC with information relating to implant size, shape, and placement data. The output, which reflects the ORTHODOC preoperative plan, is saved on a media and loaded into the ROBODOC computer prior to surgery.

The DigiMatch additions to the ORTHODOC are not changes to the original software, but rather an additional module that allows the CT data to be manipulated and outputted in a format that the ROBODOC can use for "pinless" registration.

16.1.2.2 ROBODOC Component Description

The operating room components of the System include the surgical electromechanical system, electronics control cabinet, and a display (computer) monitor. The electromechanical system, which contains the electromechanical arm, and the electronics

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control cabinet, with a mounted display monitor, are standalone units. Together, these components are referred to as the ROBODOC. The media containing the ORTHODOC preoperative plan provides input to the Robot Control Computer.

Proprietary ISS software allows the technician and/or surgeon to control all aspects of the ROBODOC's activities. The primary function of the ROBODOC is to precisely implement the preoperative plan that was developed by the surgeon. Redundant safety features and controls are built into the ROBODOC's software and hardware functions. The patient data media, which contains the pre-op plan, is loaded into the Control Cabinet. The technician and/or surgeon are able to interface with the ROBODOC and respond to any prompt via a hand-held control device called a "pendant." The Pendant is also used to control every phase of the robotic procedure. The Pendant has five buttons for initiating and aborting procedures, and for selecting options displayed on the OR Monitor. The OR Monitor displays a series of menu screens that guide the surgeon through the automated phase of the surgery and provide visual feedback during the automated process of preparing the femoral cavity.

16.1.3 Analysis for Level of Concern

As discussed in greater detail below, the software for the DigiMatch ROBODOC Surgical System (DigiMatch) presents a "moderate" level of concern as defined in FDA's Guidance Document: *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005)*. According to the Guidance Document, software for a device has a "moderate" level of concern if a failure or latent design flaw could directly result in minor injury to the patient or operator. The level of concern is also Moderate if a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Using FDA's "Approach to Deciding Level of Concern" as detailed in the Guidance Document, ISS has assessed the Level of Concern within the context of the worst possible, reasonably foreseeable, clinical consequences of failure of the device. The questions presented in the FDA guidance are answered as follows:

Major Level of Concern Questions:

1. Does the Software Device qualify as Blood Establishment Computer Software?

   Answer: No. The DigiMatch ROBODOC Surgical System is not a Blood Establishment Computer Software

2. Is the Software Device intended to be used in combination with a drug or biologic?

   Answer: No. The DigiMatch ROBODOC Surgical System is not intended to be used in combination with a drug or biologic.

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3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?

   Answer: No. The DigiMatch ROBODOC Surgical System software is not an accessory to a device of Major Level of Concern, or any other medical device.

4. Does the Software Device control a life supporting or life sustaining function?

   Answer: No. The DigiMatch ROBODOC Surgical System does not provide life supporting or sustaining functions.

5. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?

   Answer: No. The DigiMatch ROBODOC Surgical System does not control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury. All treatment is limited to the hard bone area of the hip while the surgeon maintains full control of the surgical procedure.

6. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

   Answer: No. The DigiMatch ROBODOC Surgical System software does not control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury. When used in accordance with operating instructions the system cannot exert sufficient force or supply sufficient energy to cause serious injury. Additionally all treatment using the system is limited to the hard bone areas of the hip with the surgeon maintaining full control of the system at all times.

7. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

   Answer: No. The DigiMatch ROBODOC Surgical System does not provide any patient diagnostic information during its use.

8. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

   Answer: No. The DigiMatch ROBODOC Surgical System does not provide monitoring of vital signs.

Based on the above analysis, the DigiMatch does not represent a Major level of Concern since there is no hardware or software component, operating in a properly configured

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environment, whose failure or latent design defect could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Moderate Level of Concern Questions:

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

   Answer: No. The DigiMatch ROBODOC Surgical System software is not an accessory to a device of Moderate Level of Concern, or any other medical device.

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

   Answer: Yes. Prior to mitigation of hazards a failure of the software that controls the DigiMatch ROBODOC Surgical System could result in minor patient injury.

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

   Answer: Yes. A failure of the software that controls the DigiMatch ROBODOC Surgical System could result in minor patient injury.

Based on the above analysis, the device represents a Moderate level of Concern since the answers to two questions are affirmative. The potential hazards and the ability of the customer to avoid these hazards are detailed in the company's hazards analysis and confirm this summary.

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16.2 Device Hazard Analysis

A risk analysis for each of the system components and accessories was conducted, and the complete document is in Appendix H. The risk analysis includes use and misuse conditions and identifies known and foreseeable hazards for each system component. For each hazard, risk evaluation was completed and severity, probability and detectability numbers assigned. The numbers assigned are the final numbers that include the risk control measures, where applicable. The number of hazards for the different system components is tabulated below using risks remaining after risk control measures:

	Component/Accessory	Minor (<12)	Moderate (12-21)	Major (>21)
1	ORTHODOC Preoperative Planning Station	14	4	0
2	DigiMatch™ ROBODOC® Surgical Assistant	60	26	0
3	Cutters	3	2	0
4	Drapes	0	2	0
5	Tube Sets	0	3	0
6	Markers	1	1	0

16.2.1 Risk Control and Implementation

Risk control measures for the DigiMatch™ ROBODOC® product are implemented prior to the commercial release. Effectiveness of design elements are checked through validation of the design elements during the product release process. Effectiveness of manufacturing processes is checked through validation of those processes.

16.2.2 Risk Evaluation

The risks from all identified hazards, after appropriate risk control measures have been implemented, have been evaluated. The computed RPN for all mitigated risks is less then 21, therefore any residual risk associated with each hazard is judged acceptable (minor or moderate level of risk).

Based upon the evaluation of published and unpublished reports, from worldwide clinical experience, ISS concludes that the DigiMatch™ ROBODOC® Surgical System performs safely and effectively for its intended use. The evaluation included consideration of all reported product complaints and clinical adverse events.

Section 20 of the DigiMatch™ ROBODOC® Surgical System 510(k) Premarket Notification submission contains a summary of U.S., German and Japanese clinical experience.

16.2.3 Overall Residual Risk Evaluation

Since the residual risks, following risk control measures, are acceptable (**minor or moderate level of risk),** and the review of the clinical data shows acceptable complication rates, the overall residual risk posed by the DigiMatch™ ROBODOC® Surgical Assistant system is considered acceptable. The overall level of risk is considered to be Moderate.

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16.3 Software Requirements Specification (SRS)

The Software Requirement Specifications for the DigiMatch™ ROBODOC® Surgical System is divided into two section; 1) ORTHODOC® Preoperative Planning Workstation requirements; and 2) ROBODOC® Surgical Assistant requirements.

16.3.1 ORTHODOC® Preoperative Planning Workstation

The ORTHODOC Preoperative Planning system is intended to facilitate the process of planning for orthopedic arthroplasty. Currently, the preoperative planning is accomplished by use of planar X-rays and clear implant overlays. The ORTHODOC utilizes digitized Computed Tomography (CT) scans of the patient to provide three dimensional representations of the bone. These displays can be easily zoomed and rotated to improve representations of the bone. The objectives of utilizing CT image data for planning are to reduce the time to plan and to increase the accuracy of the measurements taken to achieve the plan. The ORTHODOC software included in the DigiMatch™ ROBODOC® Surgical System is identical to the 510(k)-cleared (K960685 software with the exception of an additional software module (b) (4) that allows the output of data in the format required by the ROBODOC®. A complete Software Requirements Specification for the ORTHODOC is in Appendix 16A.

16.3.2 DigiMatch™ ROBODOC® Surgical Assistant

The ROBODOC Surgical Assistant will consist of a 5-DOF (degree-of-freedom) robot controlled by a computer system. The robot will be able to translate its end-effector in 3 dimensions due to its first three robot joints, and rotate its end-effector in 2 dimensions (roll and pitch) due to its wrist which will contain its fourth and fifth robot joints. A cutting motor will be connected to the wrist which will turn about an axis that is perpendicular to the two wrist axes. The user is guided through the surgical procedure by the software, which in turns controls the motions of the robot controlled arm. The complete Software Requirements Specification for the DigiMatch™ ROBODOC® Surgical Assistant is in Appendix 16B.

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16.4 Architecture Design Chart

The high-level system architecture for DigiMatch™ ROBODOC® Surgical System is described below. Detail architecture of each software component can be found in section 5.0 in the ROBODOC SRS in Appendix 16B and in section 3.0 in the ORTHODOC® Preoperative Planning Workstation SDS in Appendix 16C.

16.4.1 Overall Architecture

The DigiMatch™ ROBODOC® Surgical System consists of two main software components. These two main components operate independently. The only dependence between the two is on the data transferred from the ORTHODOC software to the ROBODOC software via the transfer media. The relationship between the software components of the DigiMatch™ ROBODOC® Surgical System is shown in Figure 16.4.1.

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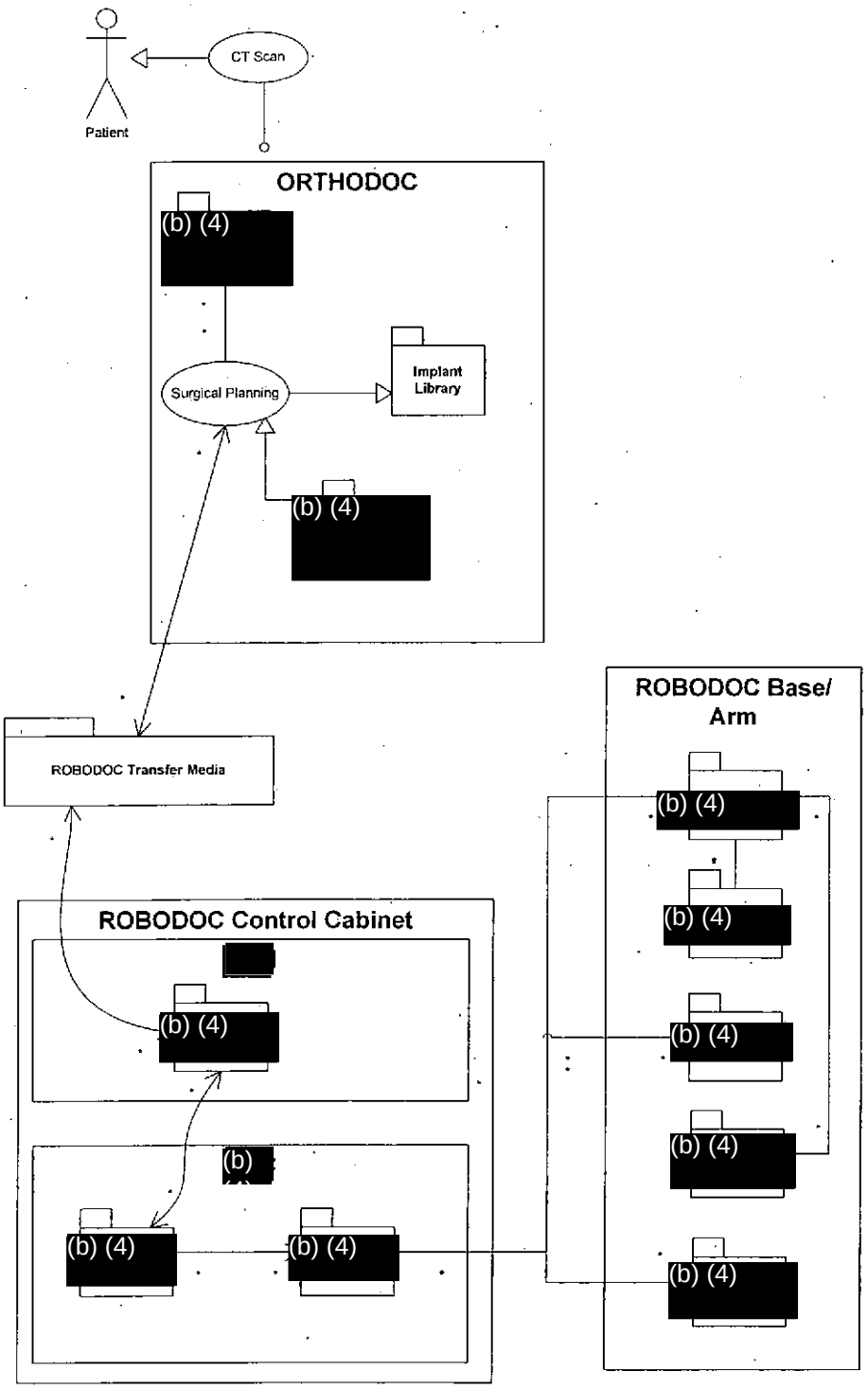

Figure 16.4.1. Overall System Architecture

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16.5 Software Design Specification (SDS)

This section describes the design of the DigiMatch™ ROBODOC® Surgical System.

16.5.1 ORTHODOC® Preoperative Planning Workstation

The software design specification is included in Appendix 16C. It describes the design of the (b) (4) module in addition to the complete ORTHODOC® Preoperative Planning Workstation.

16.3.3 DigiMatch™ ROBODOC® Surgical Assistant

The complete software design specification for the DigiMatch™ ROBODOC® Surgical Assistant is included in Appendix 16D.

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16.6 Traceability Matrix

(b) (4)

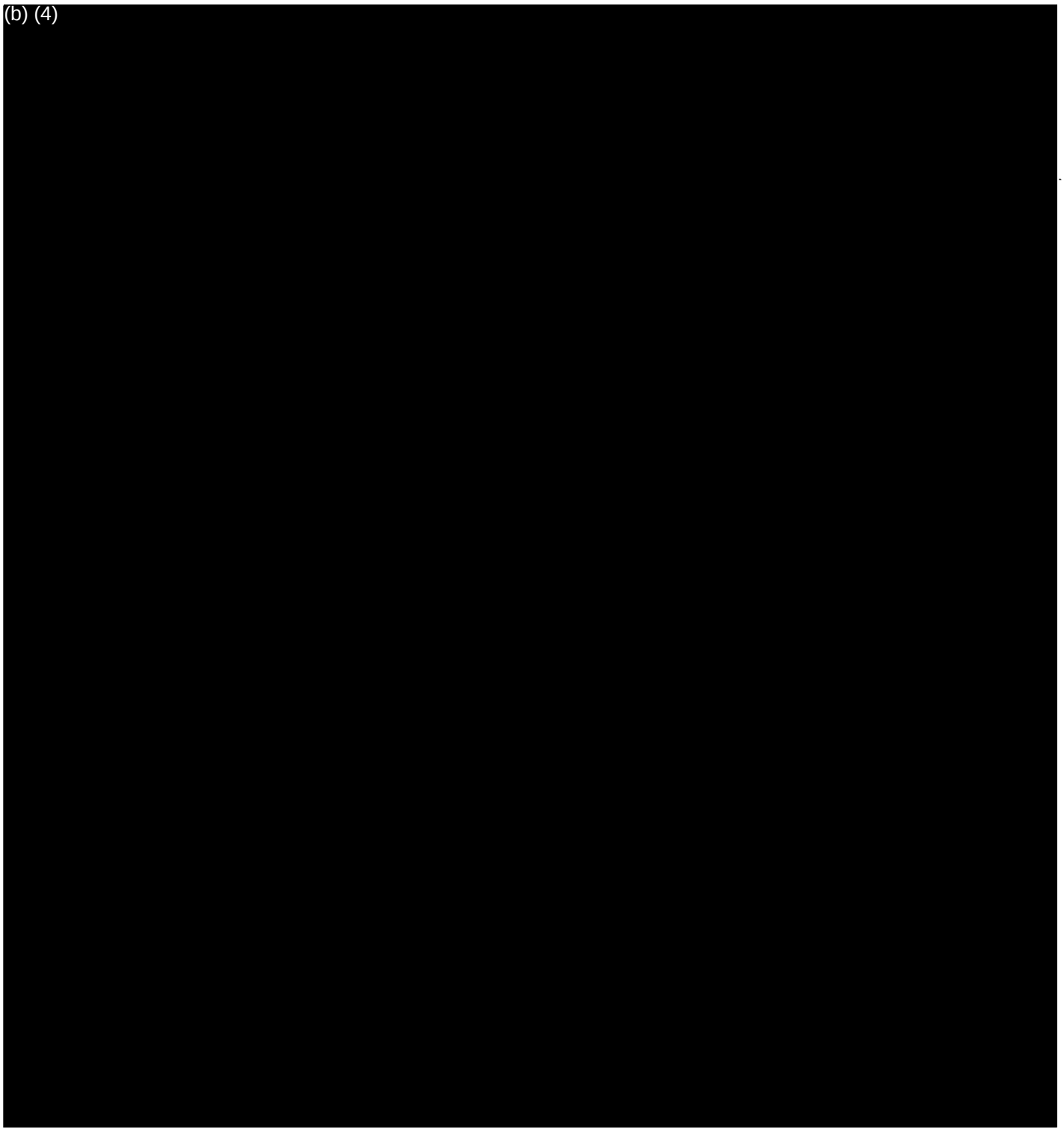

Table 16.6.2. Hazard Traceability Matrix Specific to the DigiMatch™ ROBODOC® Surgical Assistant

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Hazard ID	SRS ID	SDS ID	Verification Test	Results of Verification Test
(b) (4)				

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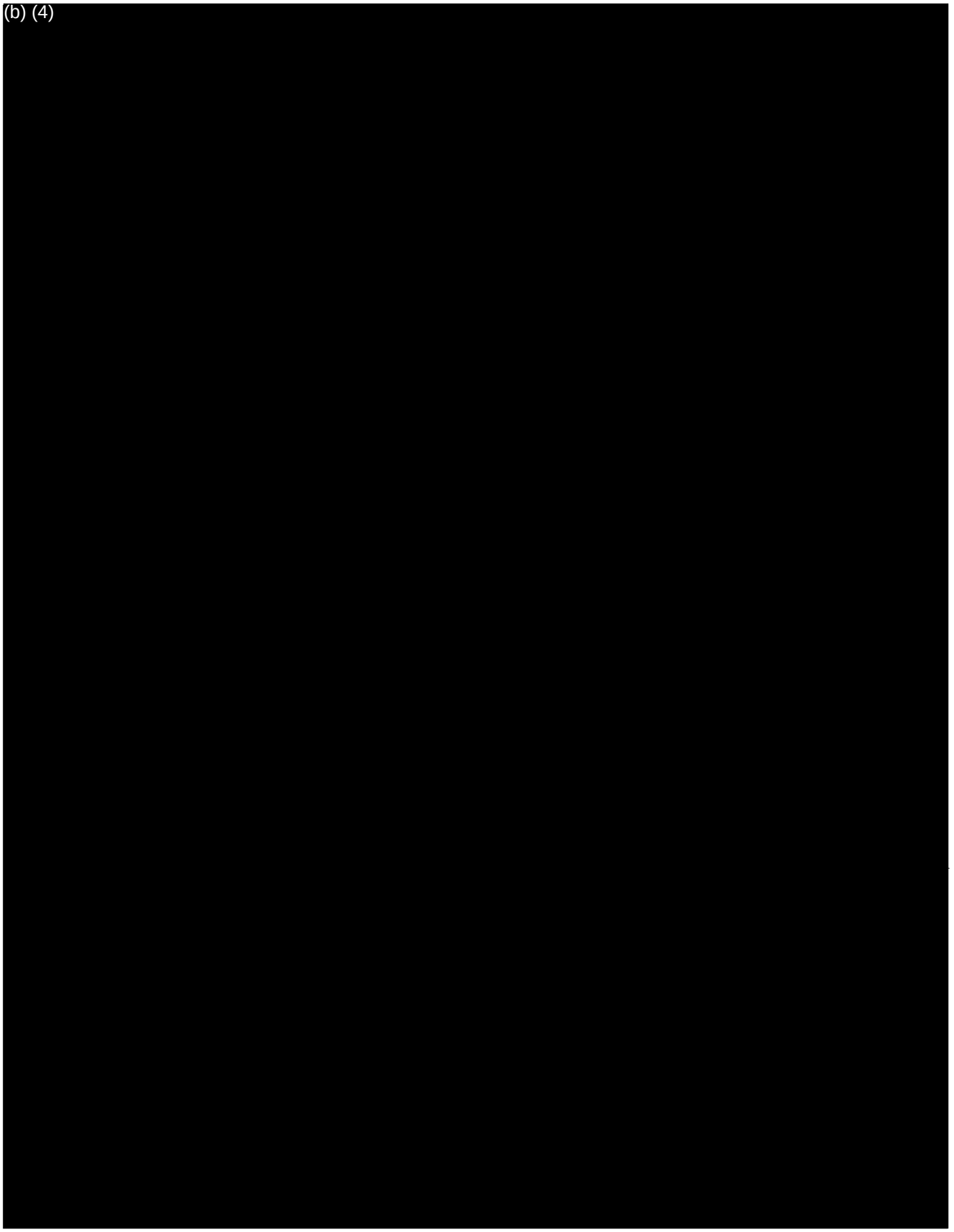

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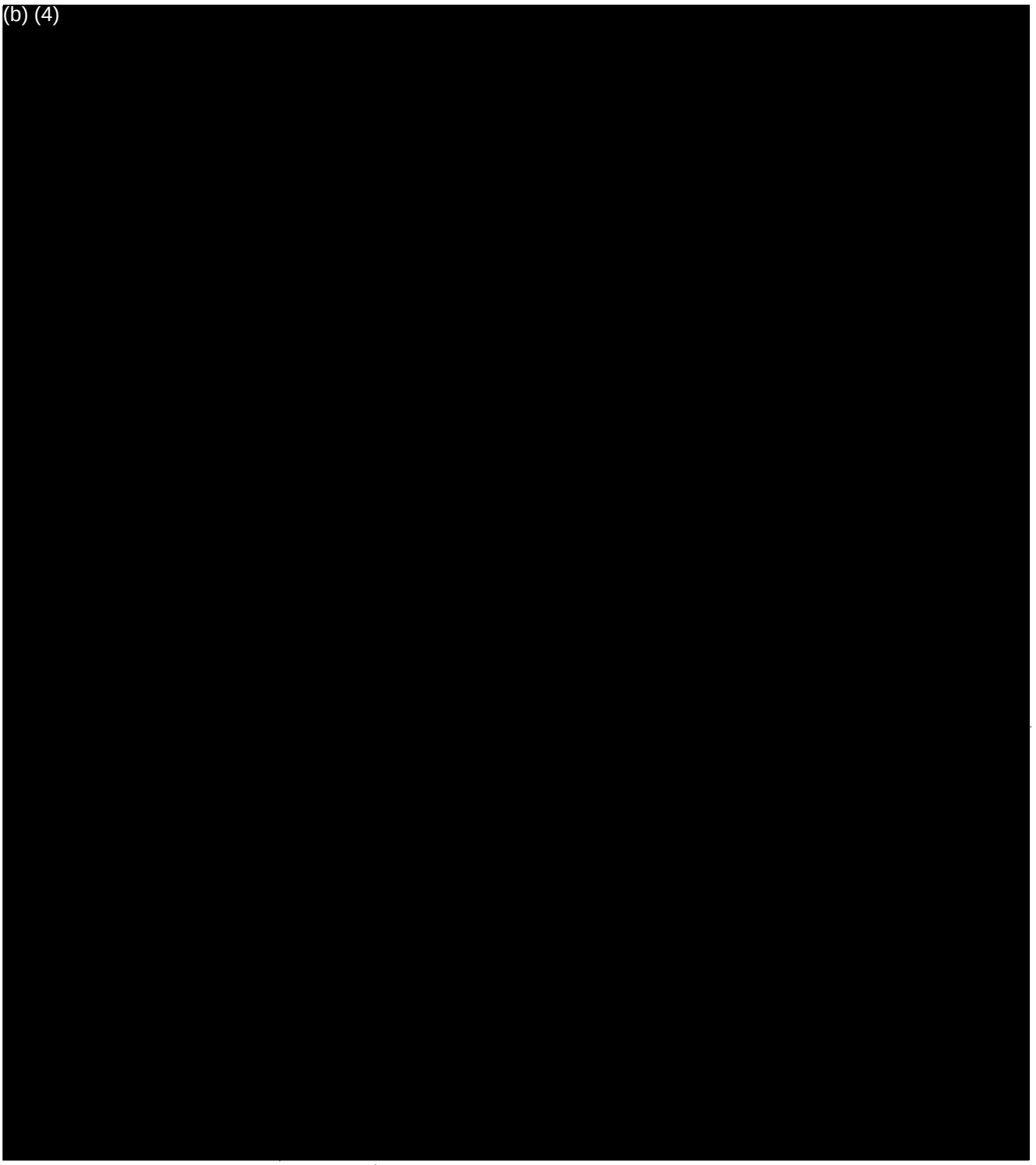
(b) (4)



DJA x01690

16.7 Software Development Environment Description

The software environment was developed following procedures outlined in ISS (b) (4) . The software life cycle provided information for (b) (4) (b) (4) . Activities in the software life cycle included the following phases:

(b) (4)

Below is a summary of the development process. The entire procedure is included in Appendix E.

16.7.1 Requirements Phase.

16.7.2 Design Phase

16.7.3 Implementation Phase

DJA x01691

16.7.4 Integration and Testing

[redacted]

16.7.5 Installation Testing

[redacted]

16.7.6 Maintenance Phase

[redacted]

DJA x01692

16.8 Verification and Validation Documentation

16.8.1 Overview

The verification and validation process for the software of the DigiMatch™ ROBODOC® Surgical System consists of various actives to insure the software meets its intended use. Each test plan was developed in parallel with the software design and implementation phase.

16.8.2 Firmware Verification Testing

Firmware verification testing functionally verified that each firmware requirement for the DigiMatch™ ROBODOC® Surgical System was met. The verification test plan was developed in parallel with the firmware design and the firmware implantation phase. Table 16.8.2A provides a summary of the completed firmware verification testing.

Table 16.8.2A Summary of Firmware Verification Testing

Summary of Firmware Verification Testing	Sample Tested	Results
[redacted]	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed

DJA x01693

Summary of Firmware Verification Testing	Sample Tested	Results
[redacted]	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed
	[redacted]	Passed

DJA x01694

Summary of Firmware Verification Testing	Sample Tested Firmware	Results
[redacted]	[redacted]	Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed

DJA x01695

16.8.3 Software Verification Testing

Software verification testing was performed on the DigiMatch™ ROBODOC® Surgical System application and supporting software. This includes software for the ORTHODOC® Preoperative Planning Station and the ROBODOC® Surgical Assistant. Table 16.8.3A provides a summary of the completed software verification testing.

Table 16.8.3A Summary of Software Verification Testing

Summary of Software Verification Testing	Sample Tested	Results
[redacted]		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed
		Passed

DJA x01696

[redacted]	
	Passed
	Passed
	Passed
	Passed
	Passed
	Passed
	Passed

16.8.4 System Testing

System testing of the DigiMatch™ ROBODOC® Surgical System was performed to ensure that all system components work together appropriate under simulate and real clinical situations. This was completed on each system component (ORTHODOC and ROBODOC) and then on the completely integrated system (DigiMatch™ ROBODOC® Surgical System). Table 16.8.4A contains a summary of System Testing that has been performed.

Table 16.8.4A Summary of System Testing

Summary of [redacted] Verification Testing	Sample Tested	Report and Protocol Location	Results
[redacted]		Appendix F	Passed
		Appendix I	Passed
		Appendix H	Passed

DJA x01697

16.9 Revision Level History

The following table outlines the revision history for the DigiMatch™ ROBODOC® Surgical System. The software is released as two items, one for the ORTHODOC® Preoperative Planning Station, and the other for the DigiMatch™ ROBODOC® Surgical Assistant.

16.9.1 The following table tracks the revision history for the ORTHODOC® Preoperative Planning Workstation software:

Revision	Date	Summary of change
01	12/04/00	Initial Release
02	02/27/01	[redacted]

16.9.2 The following table tracks the revision history for the DigiMatch™ ROBODOC® Surgical System

Revision	Date	Summary of change
06	11/12/99	[redacted]
07	3/31/00	
08	9/26/00	
09	10/19/00	
10	11/06/00	
11	12/13/00	

DJA x01698

16.10 Unresolved Anomalies (Bugs or Defects)

16.10.1 A review of the complaint data was conducted. At this time, no unresolved anomalies were found.

DJA x01699

Appendix 16A

Software Requirement Specification for the ORTHODOC® Preoperative Planning Workstation

DJA x01700

Approval & Change Control Page

[redacted]

INITIAL RELEASE APPROVALS	DATE
[redacted]	

TITLE
Software Requirements Spec. for the Orthodoc Model 500 Preoperative Planning Station
Part No : **300154**
Page 1 of 20 [redacted]

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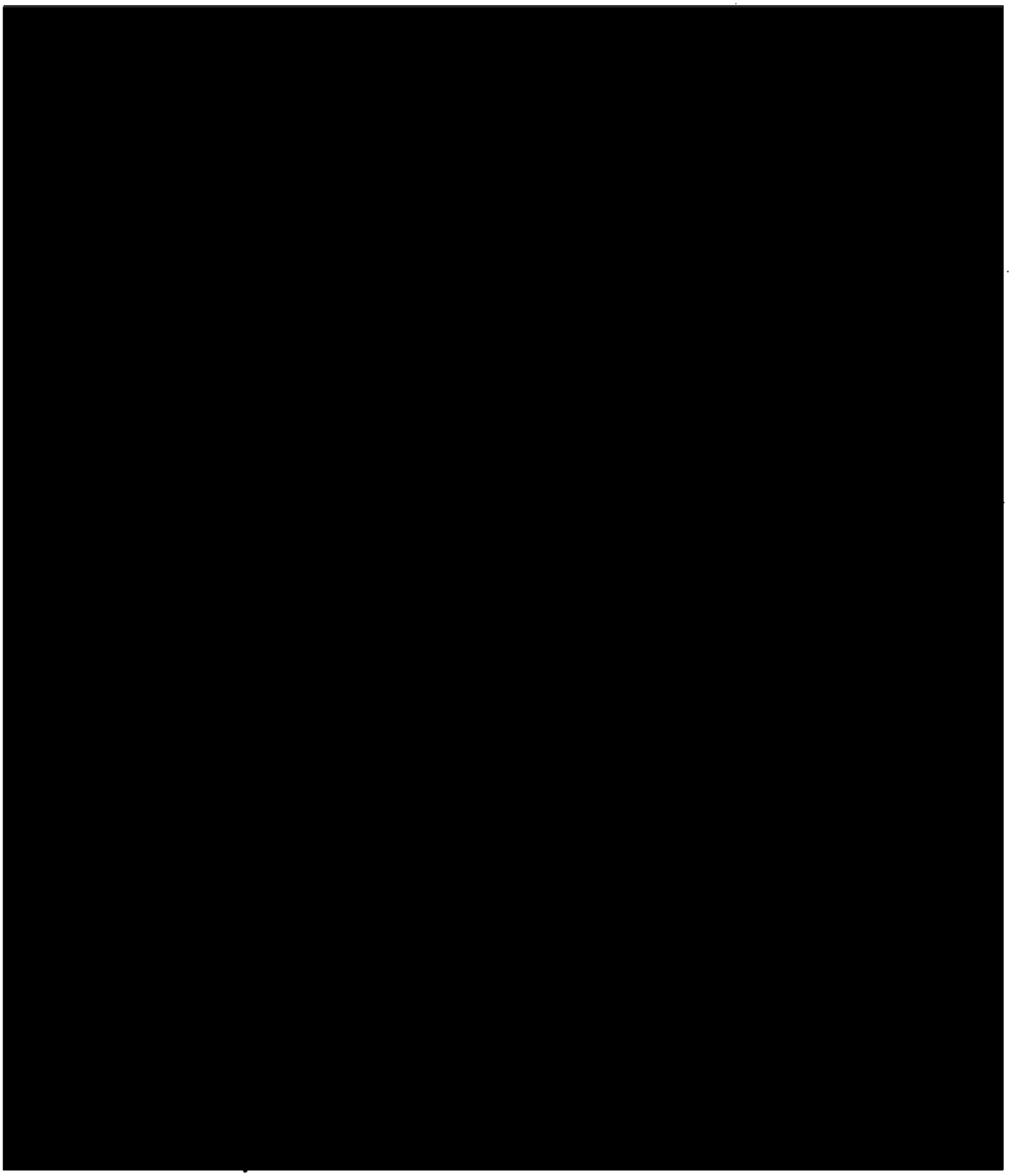

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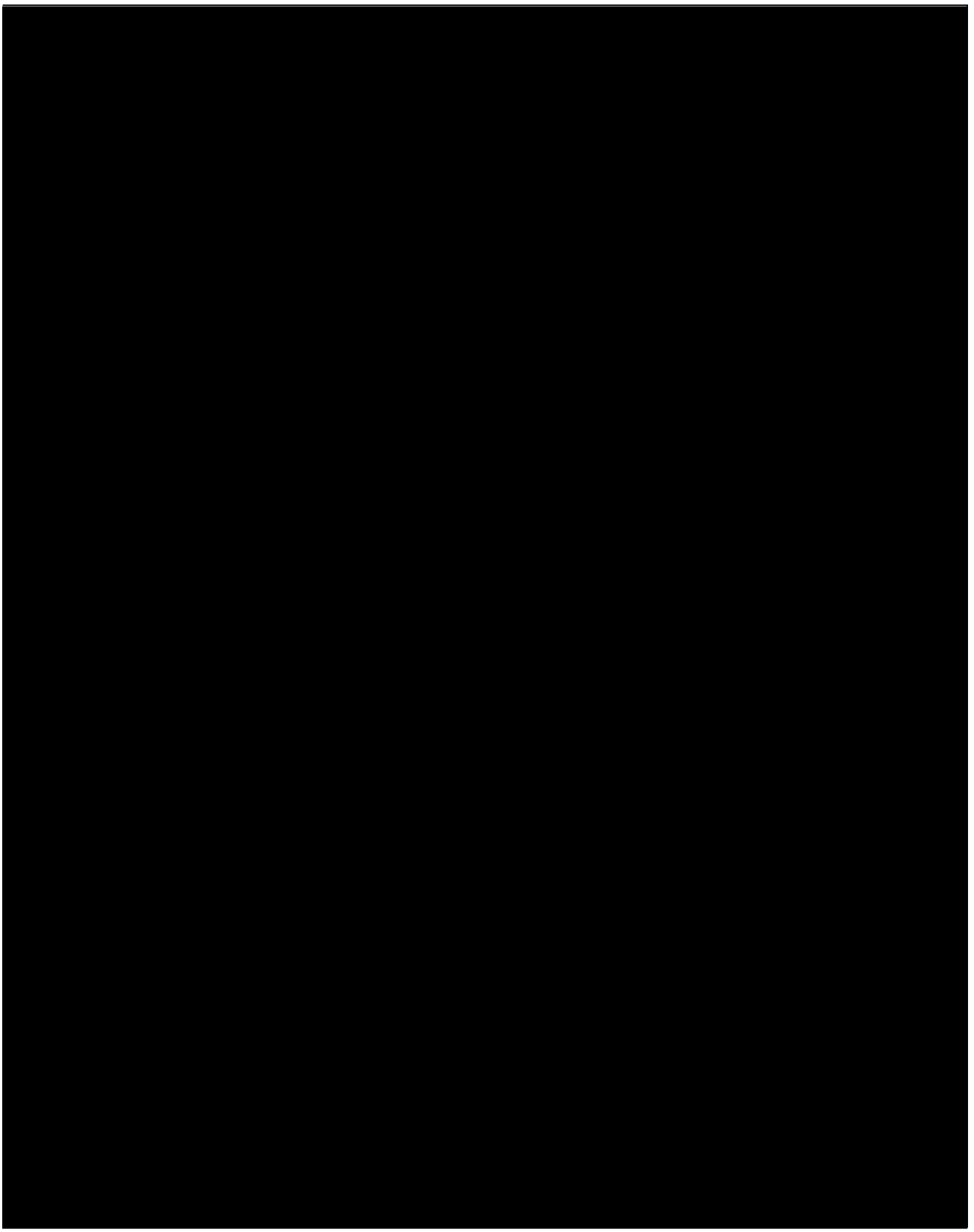

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[redacted]

DJA x01704

[redacted]

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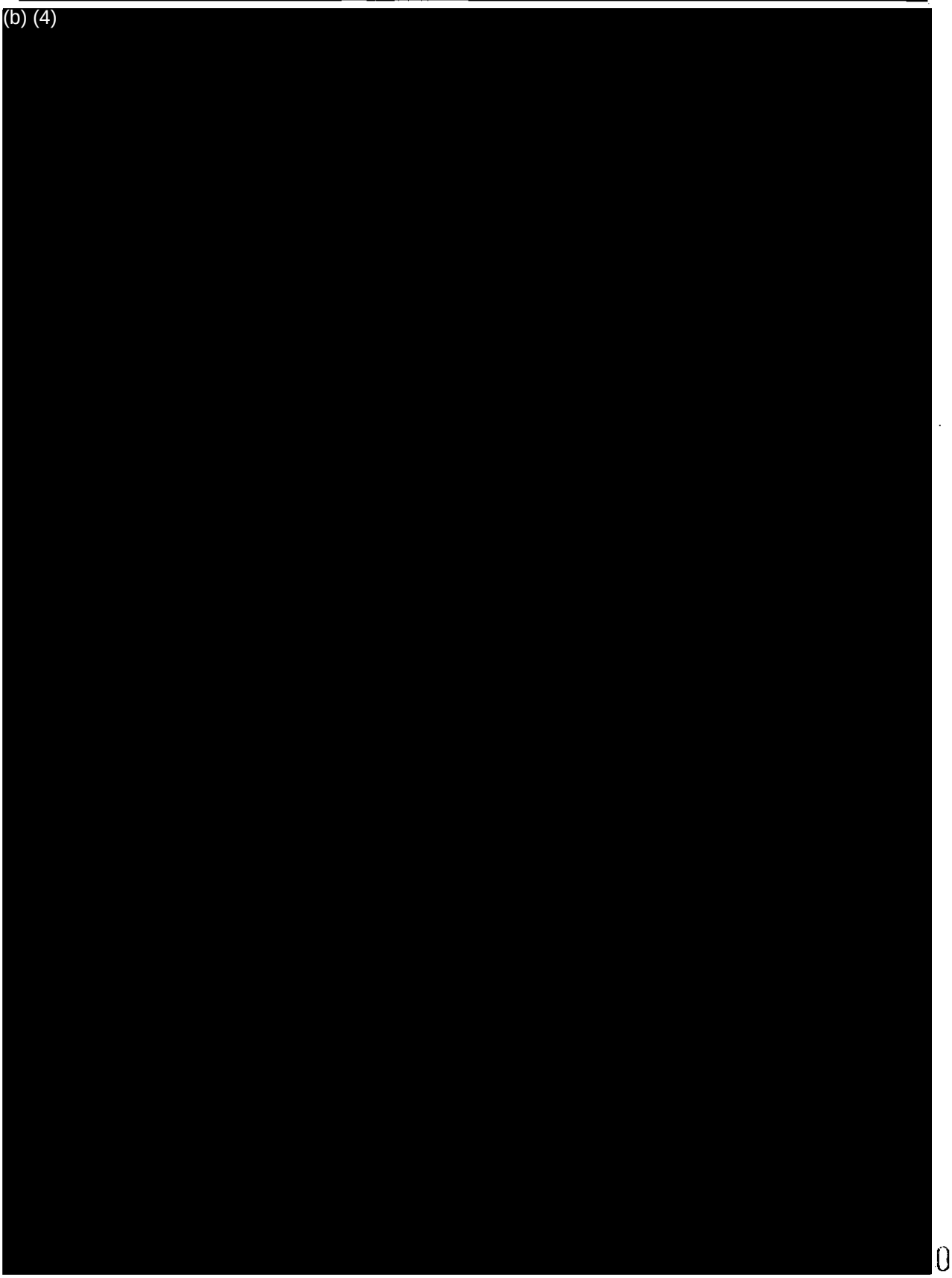

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[redacted]

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Appendix 16B

Software Requirement Specification for the ROBODOC Surgical Assistant

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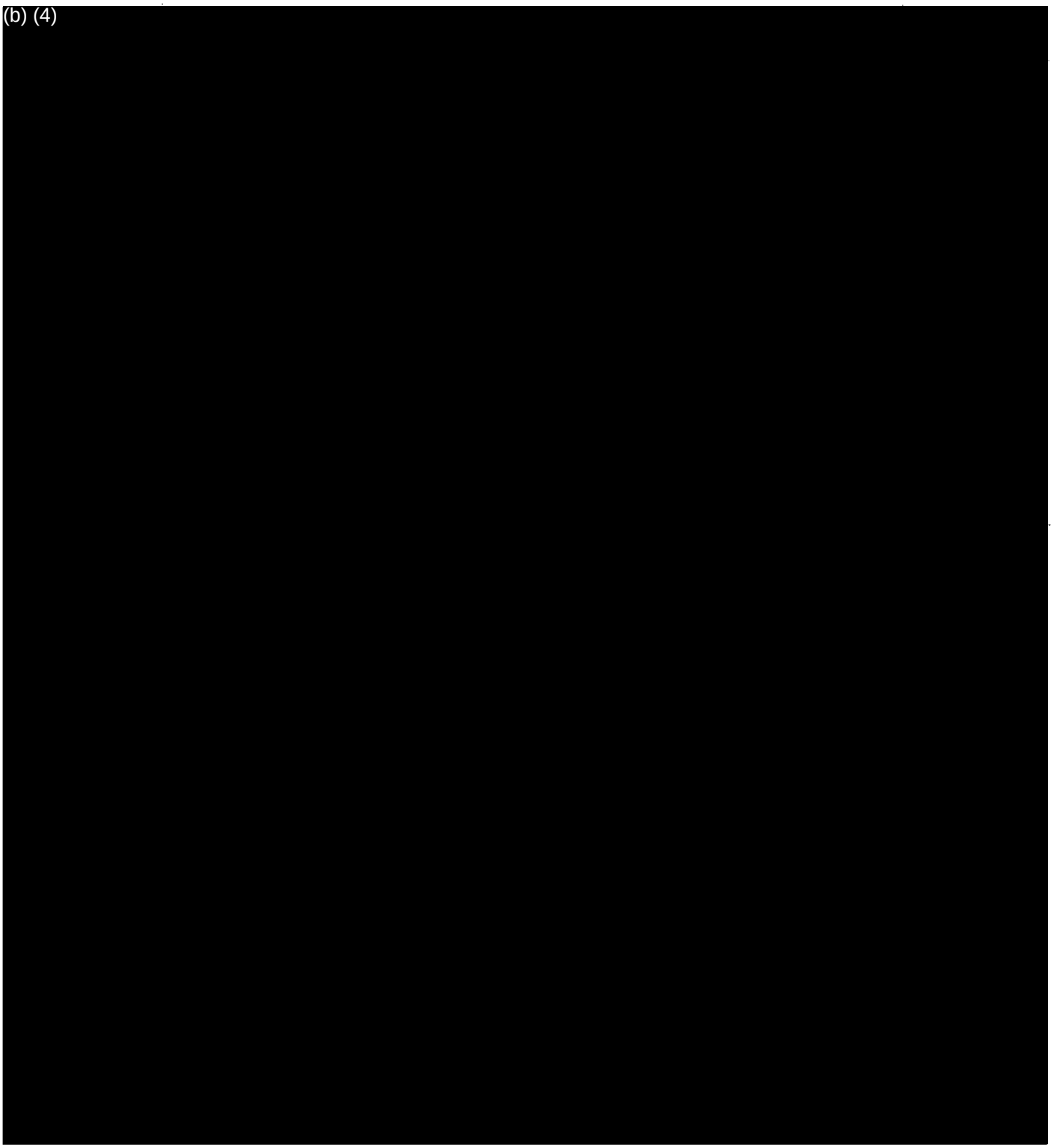

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1. Introduction

1.1 This document defines the Software Requirements Specification (SRS) for the ROBODOC Surgical Assistant.

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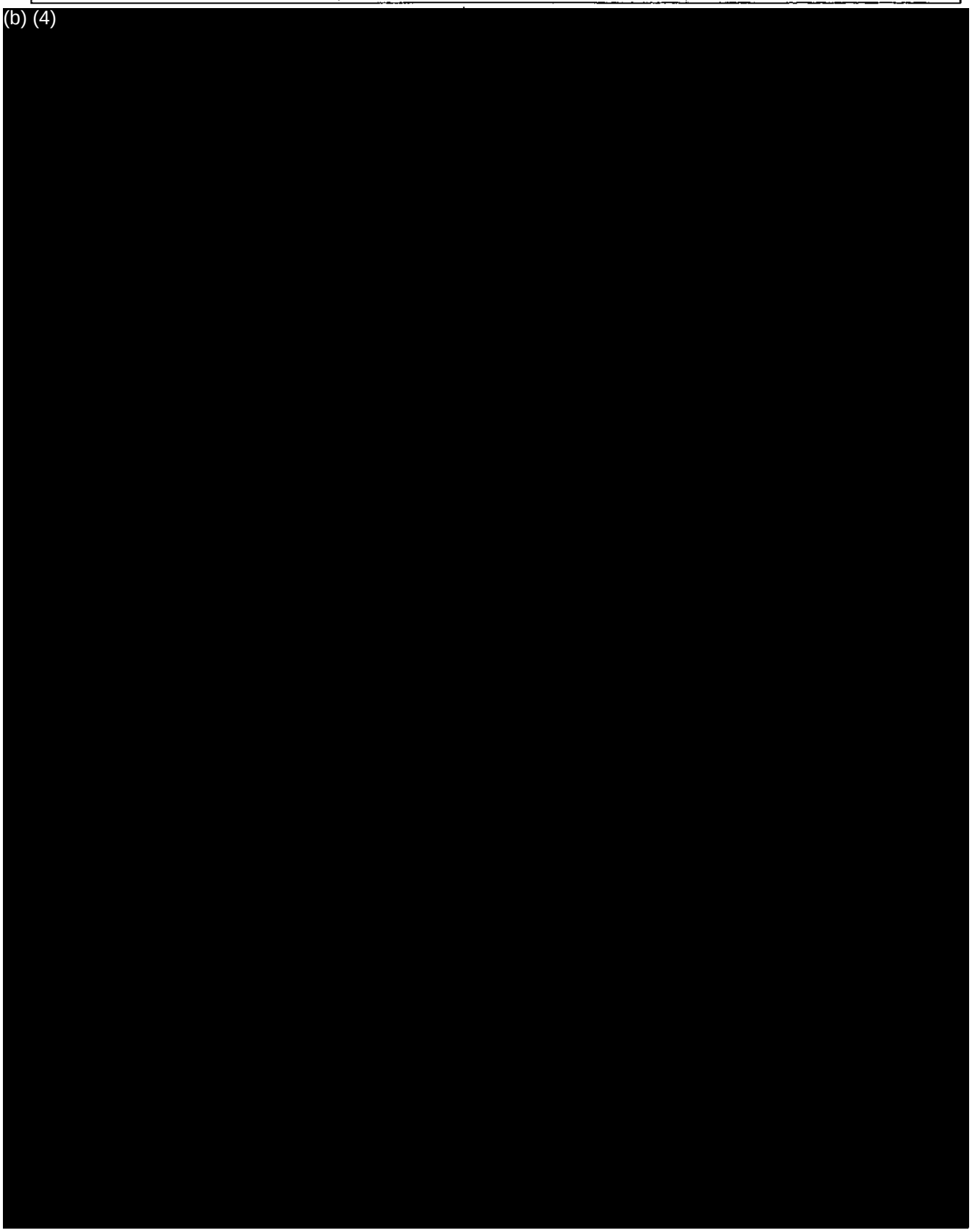

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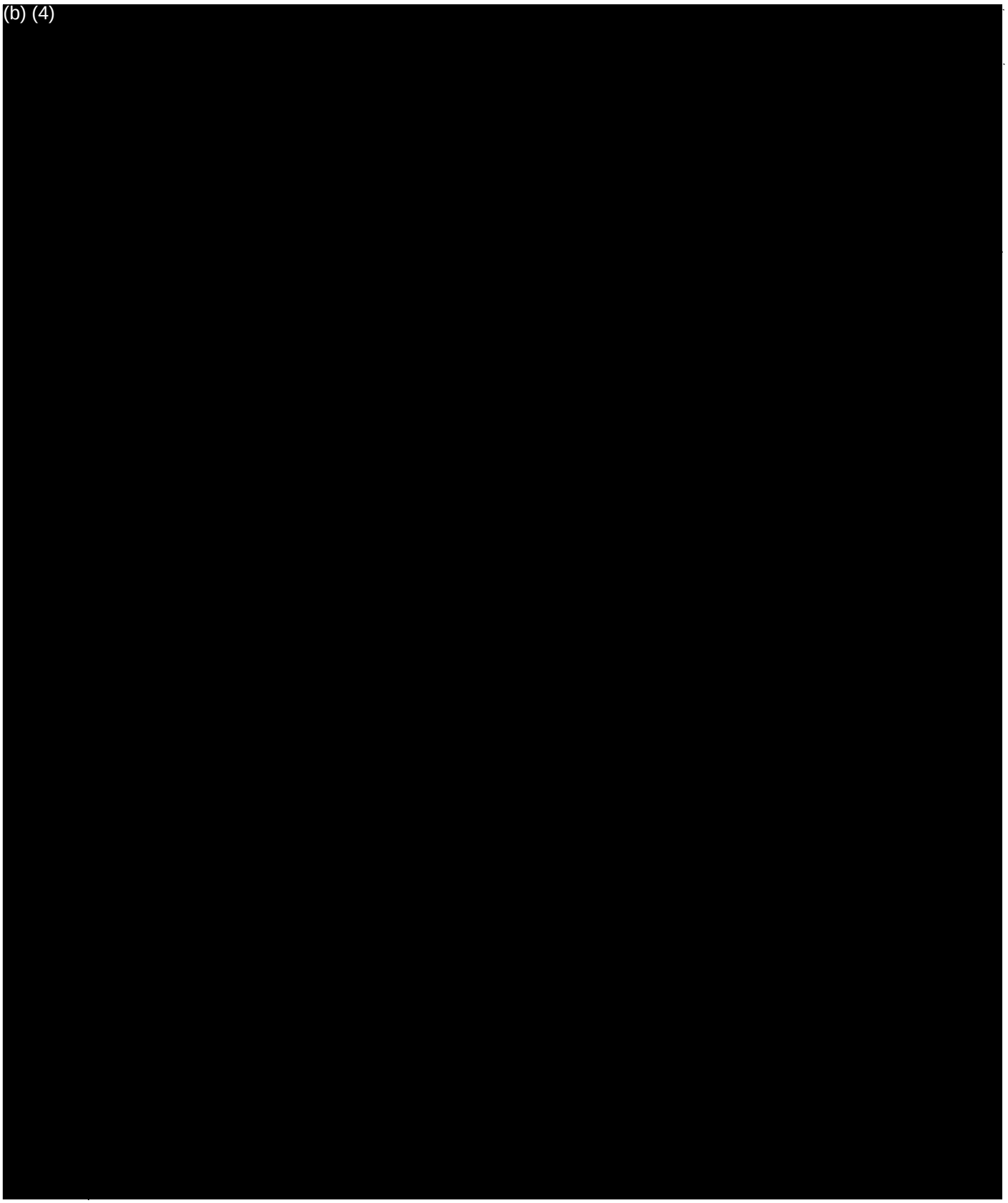

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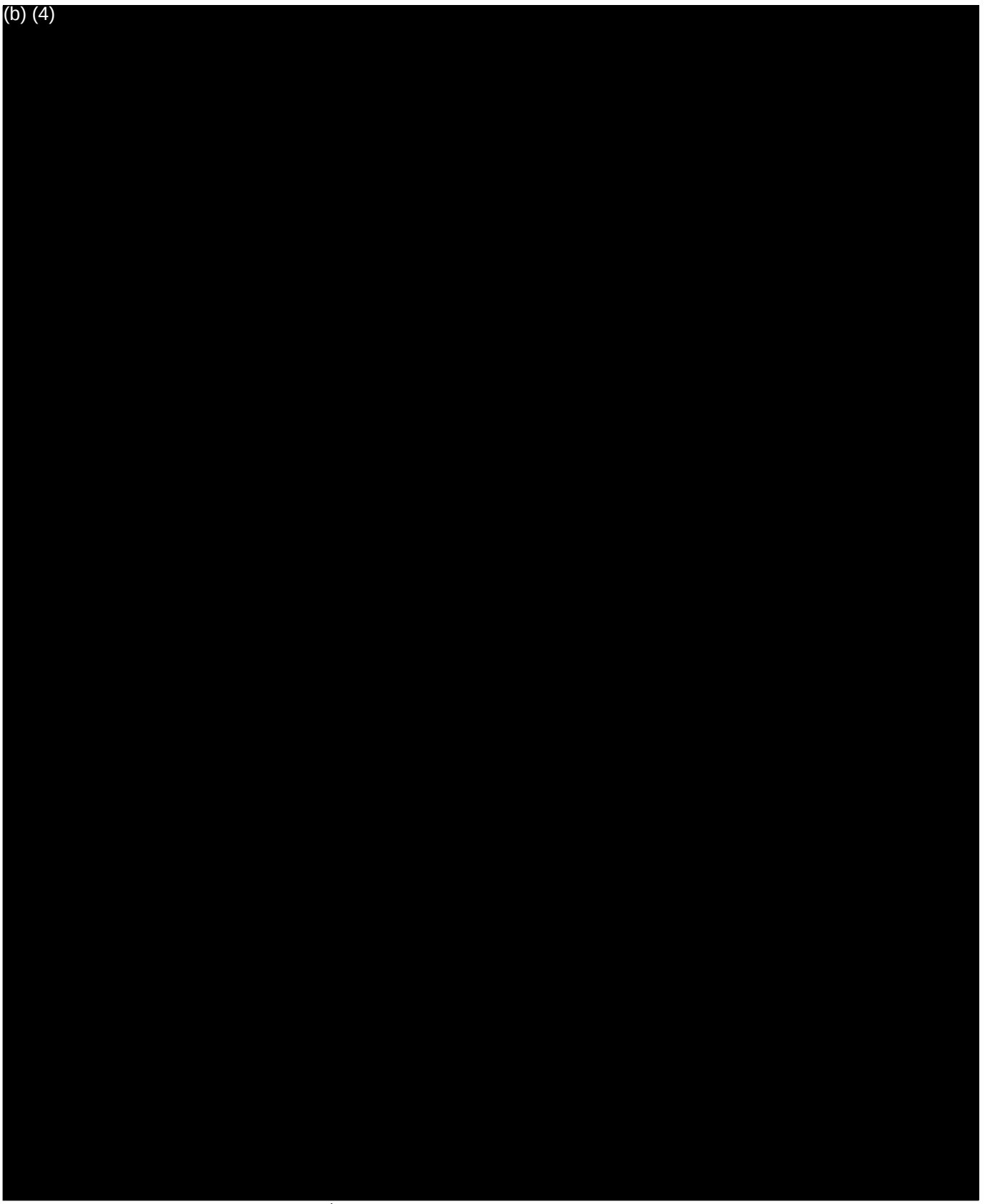

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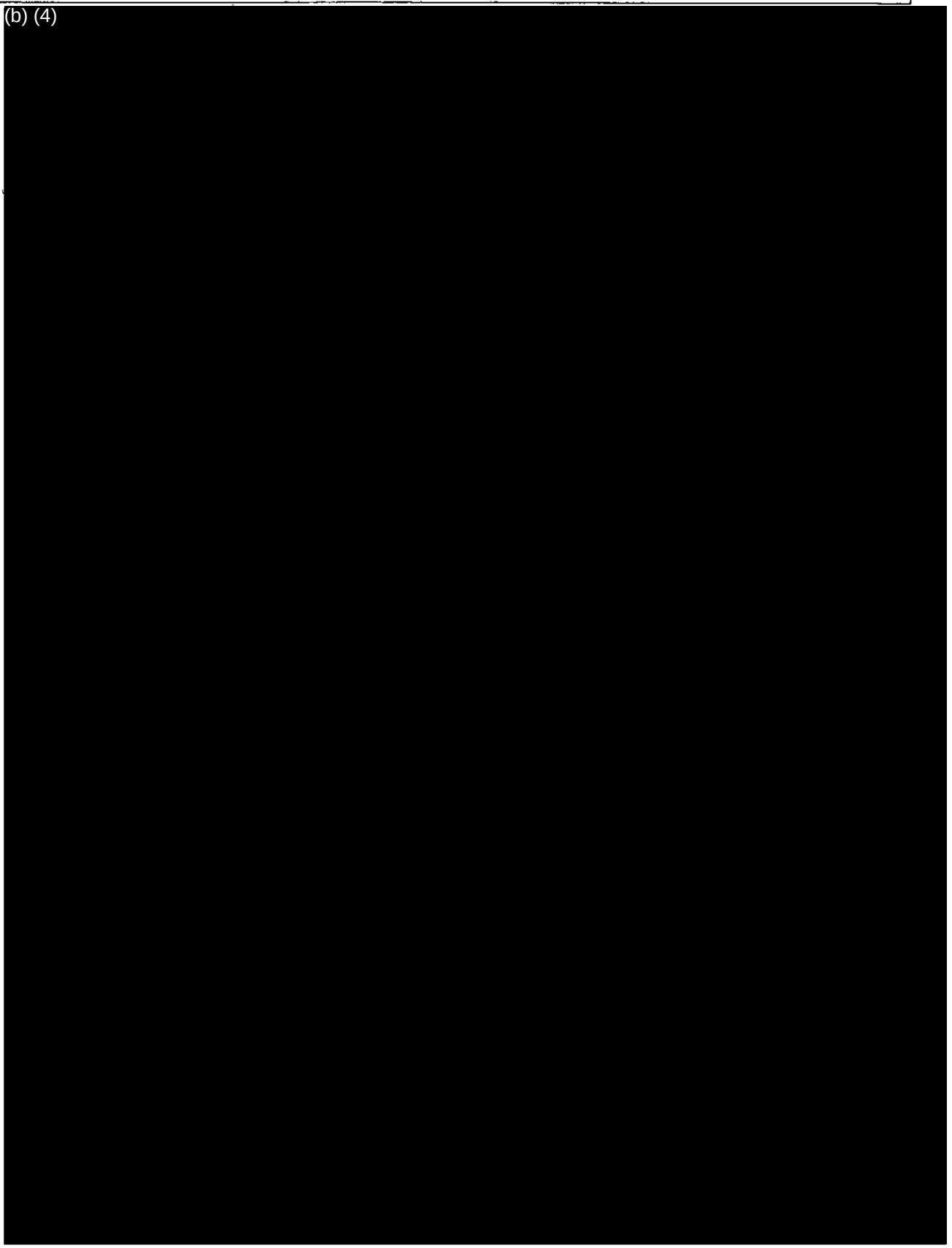

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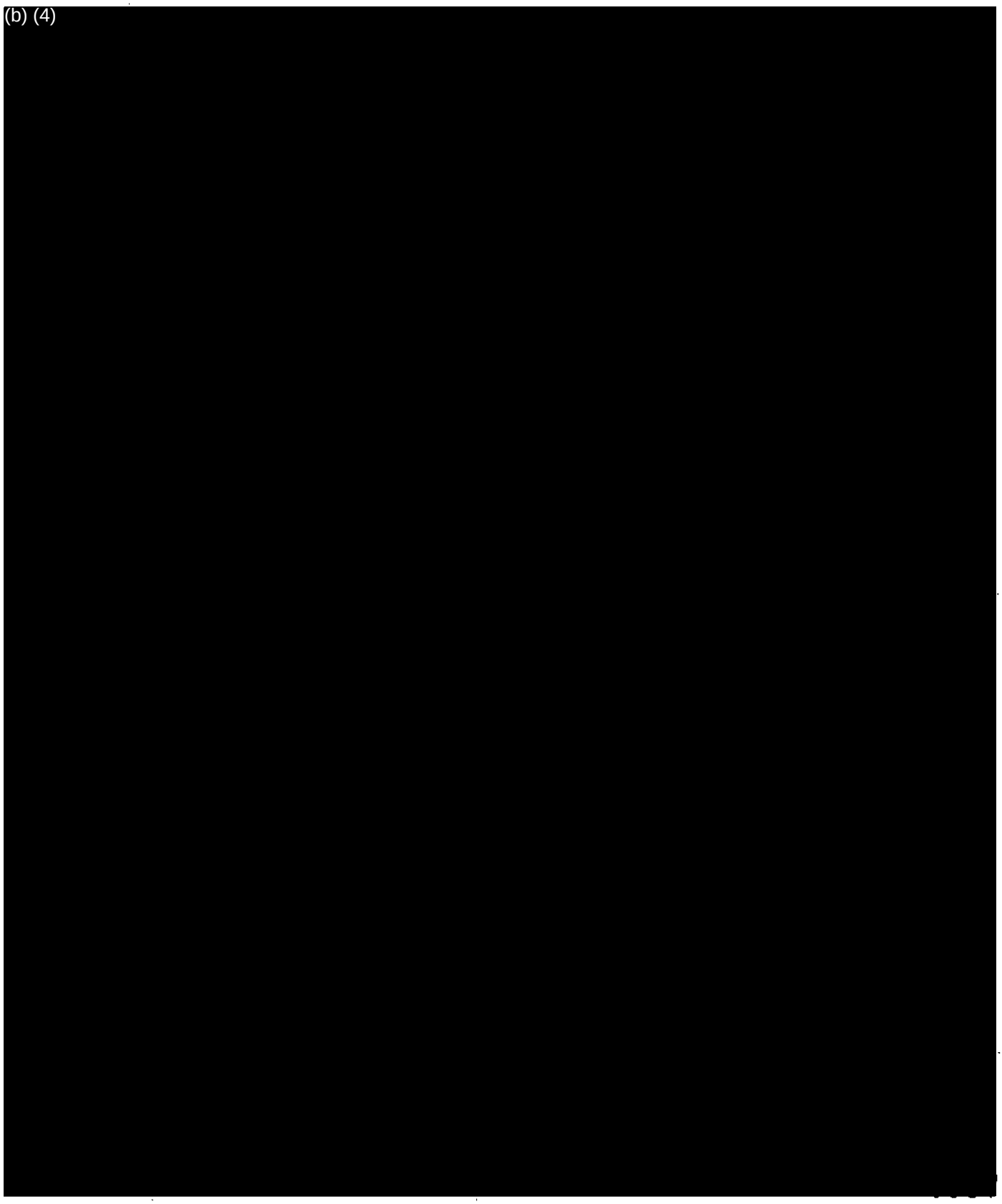

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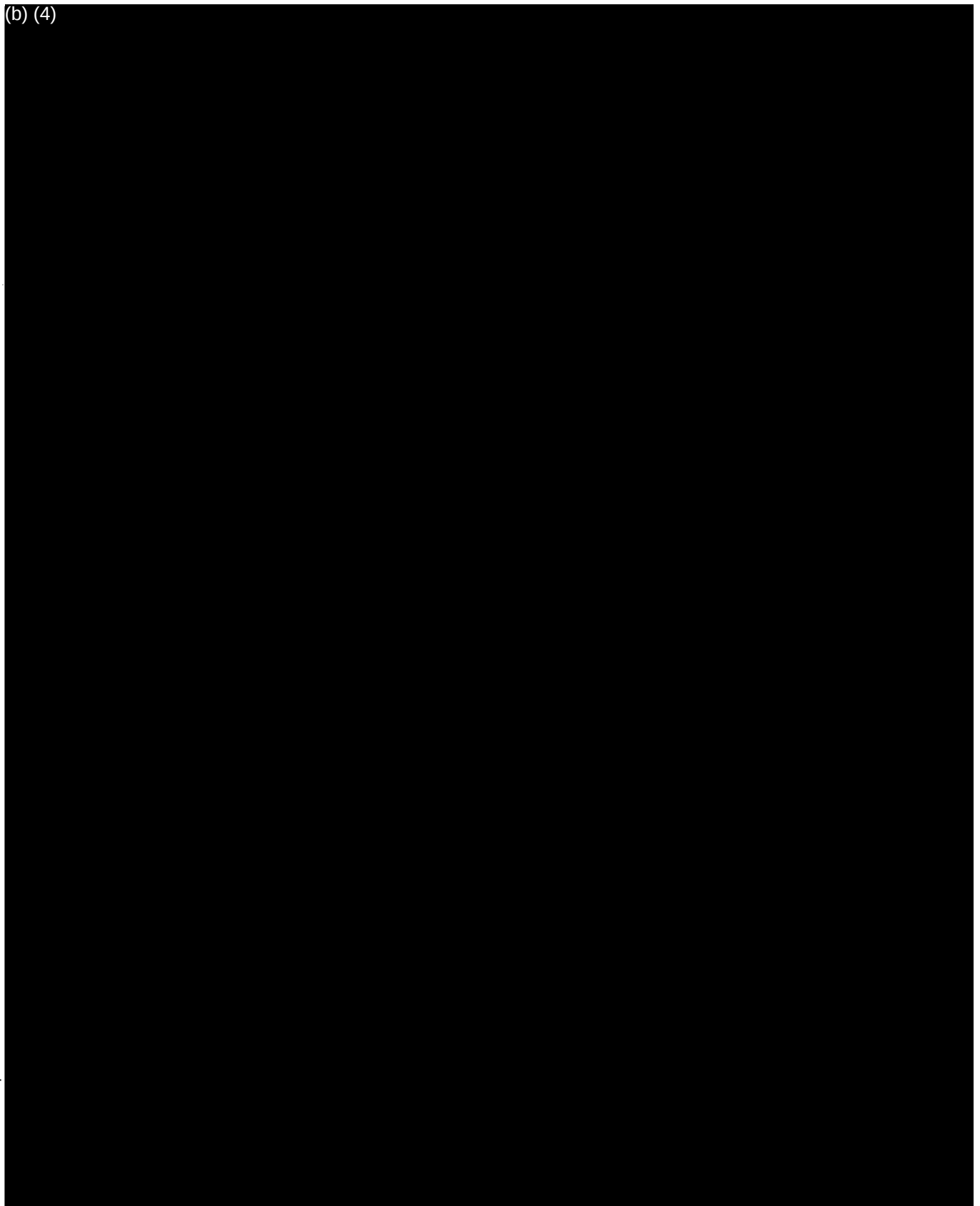

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Appendix 16C

Software Design Specification for the ORTHODOC® Preoperative Planning Workstation

DJA x01754

Approval & Change Control Page

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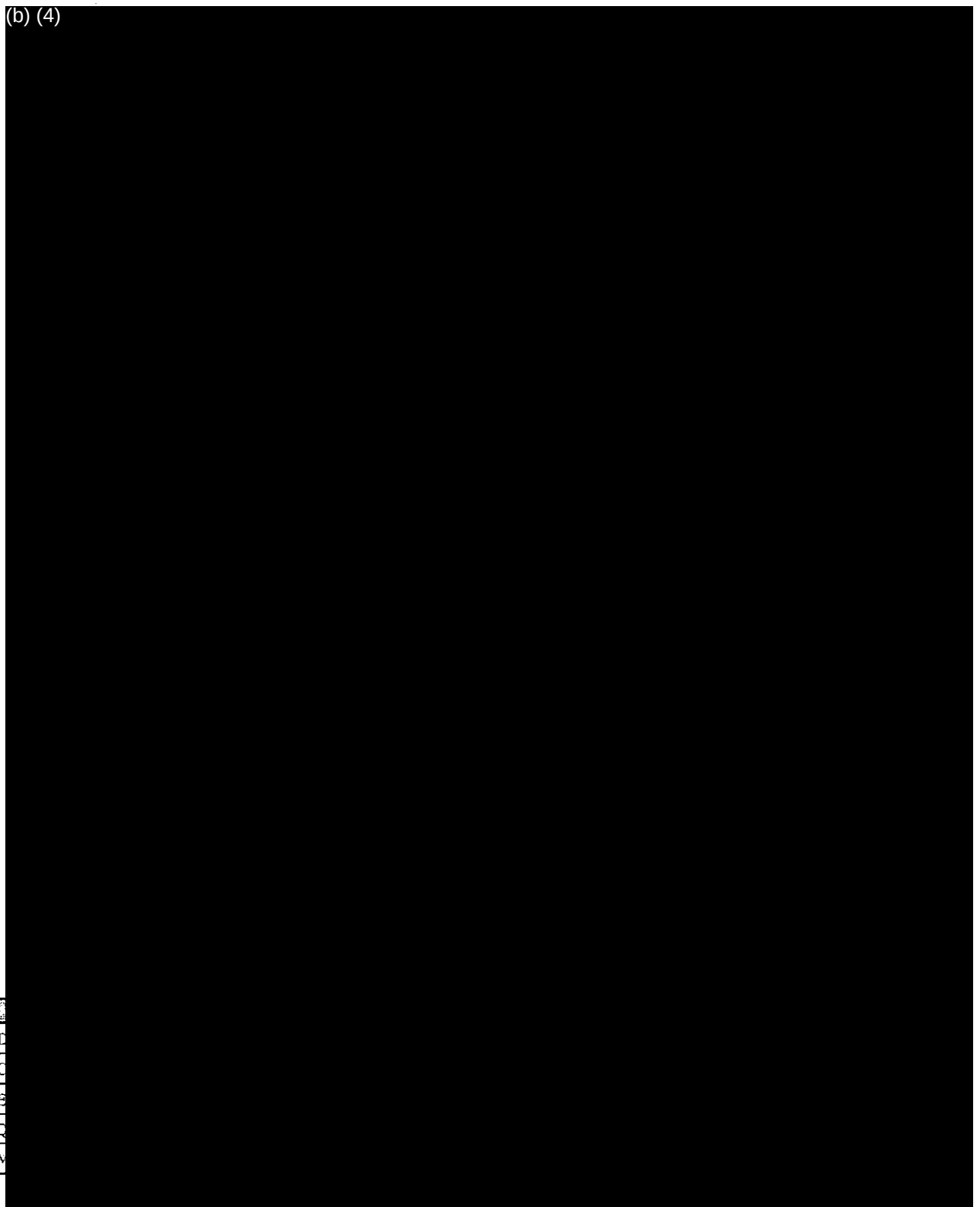

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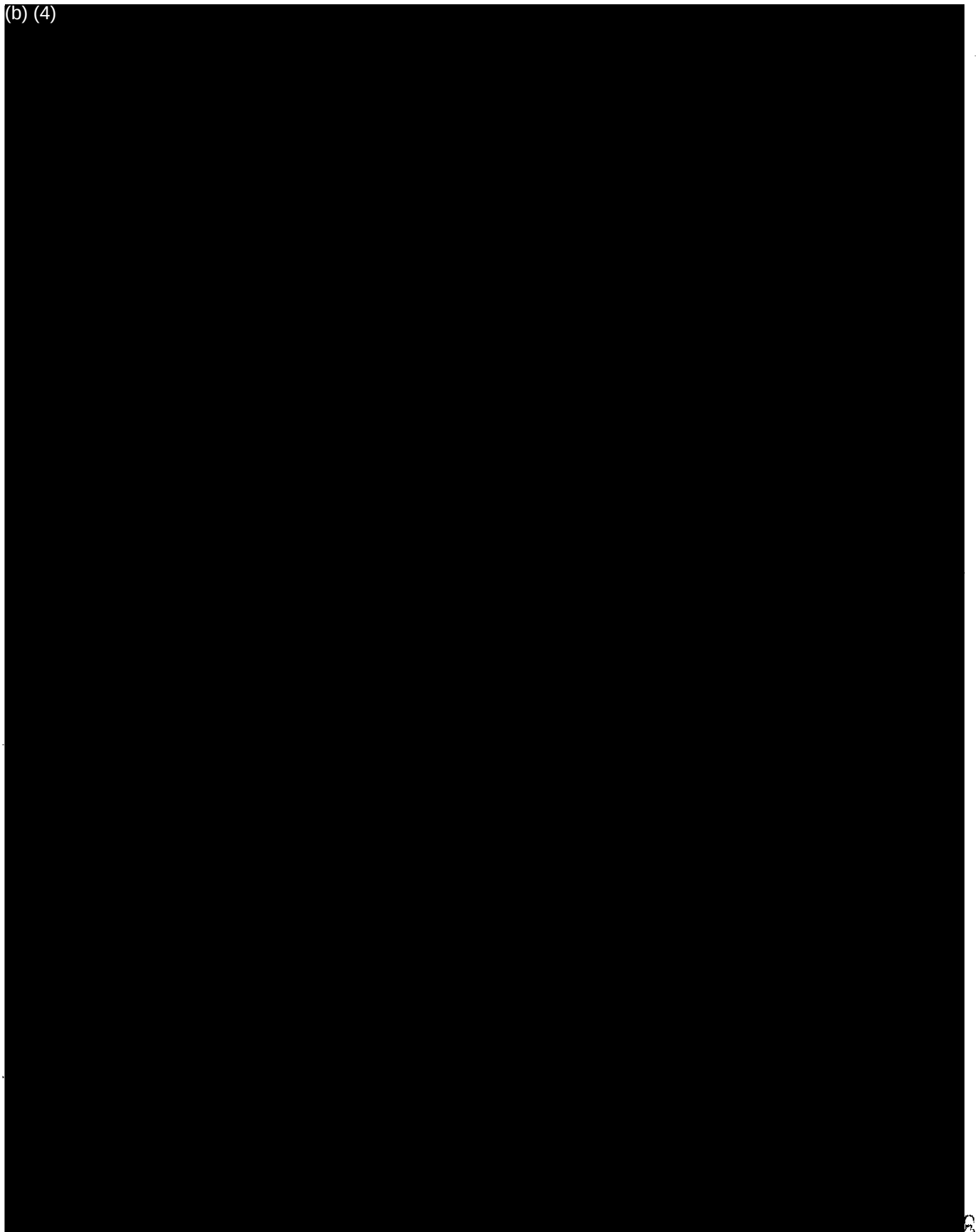

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SOFTWARE DESIGN DESCRIPTION

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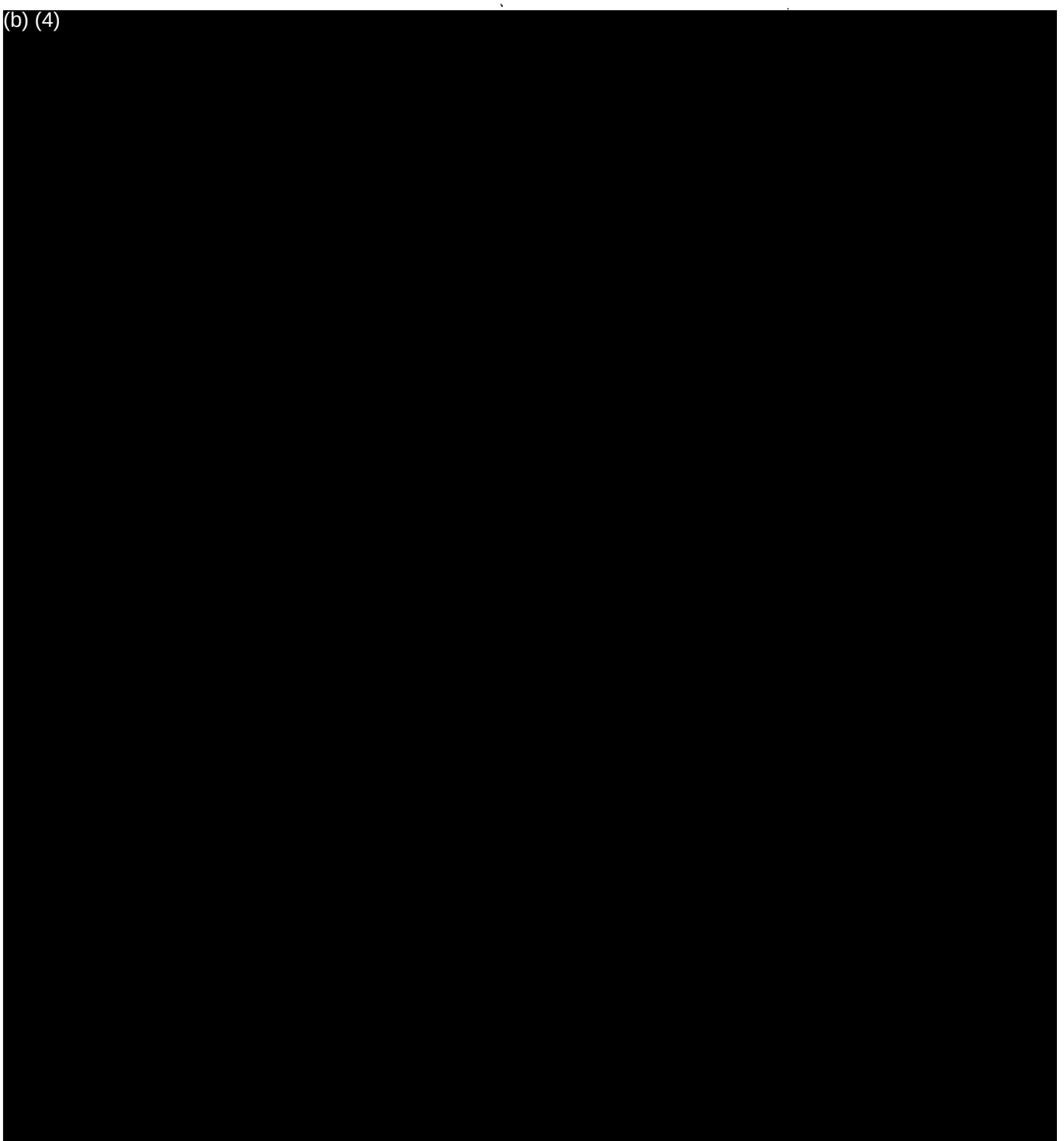

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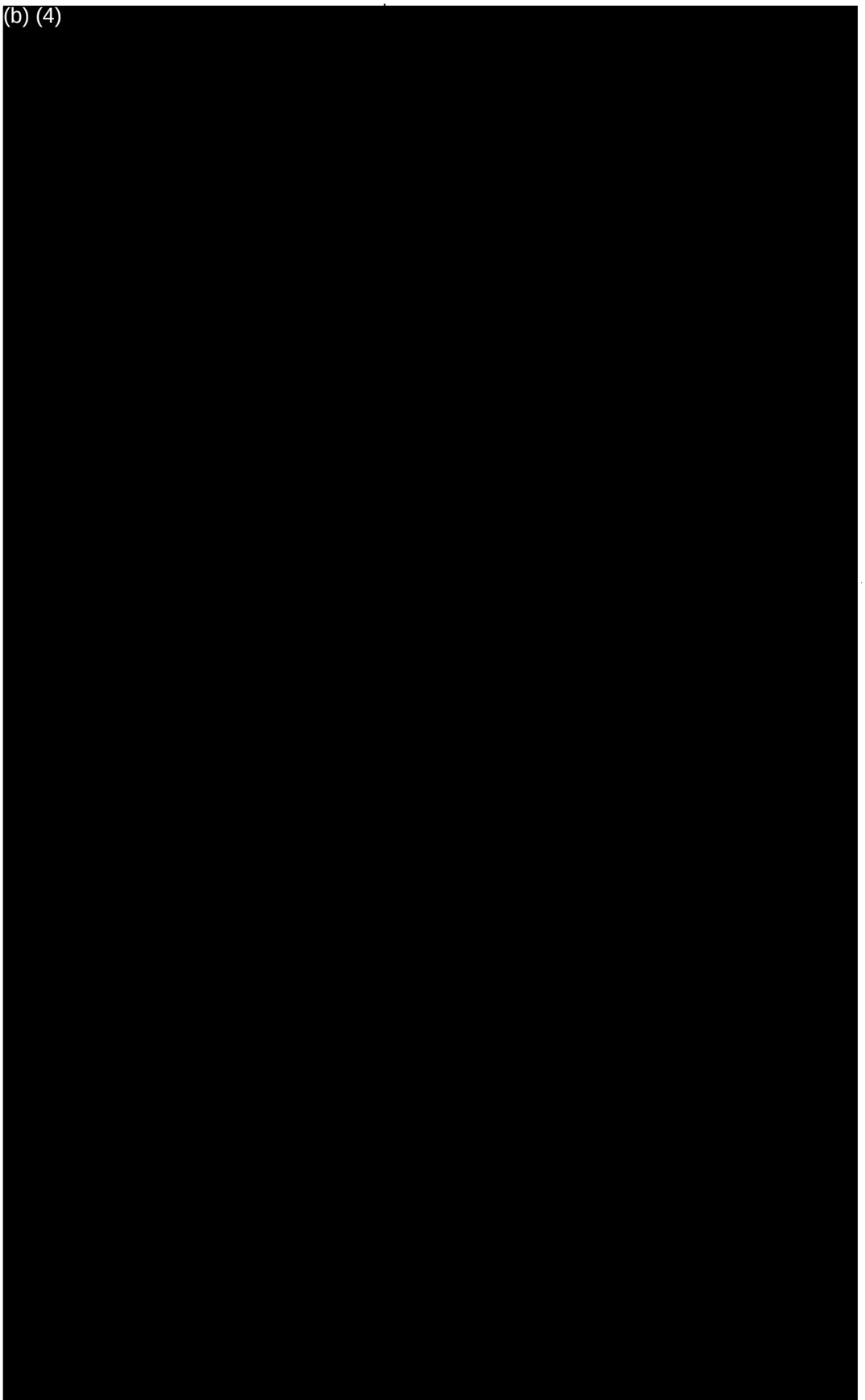

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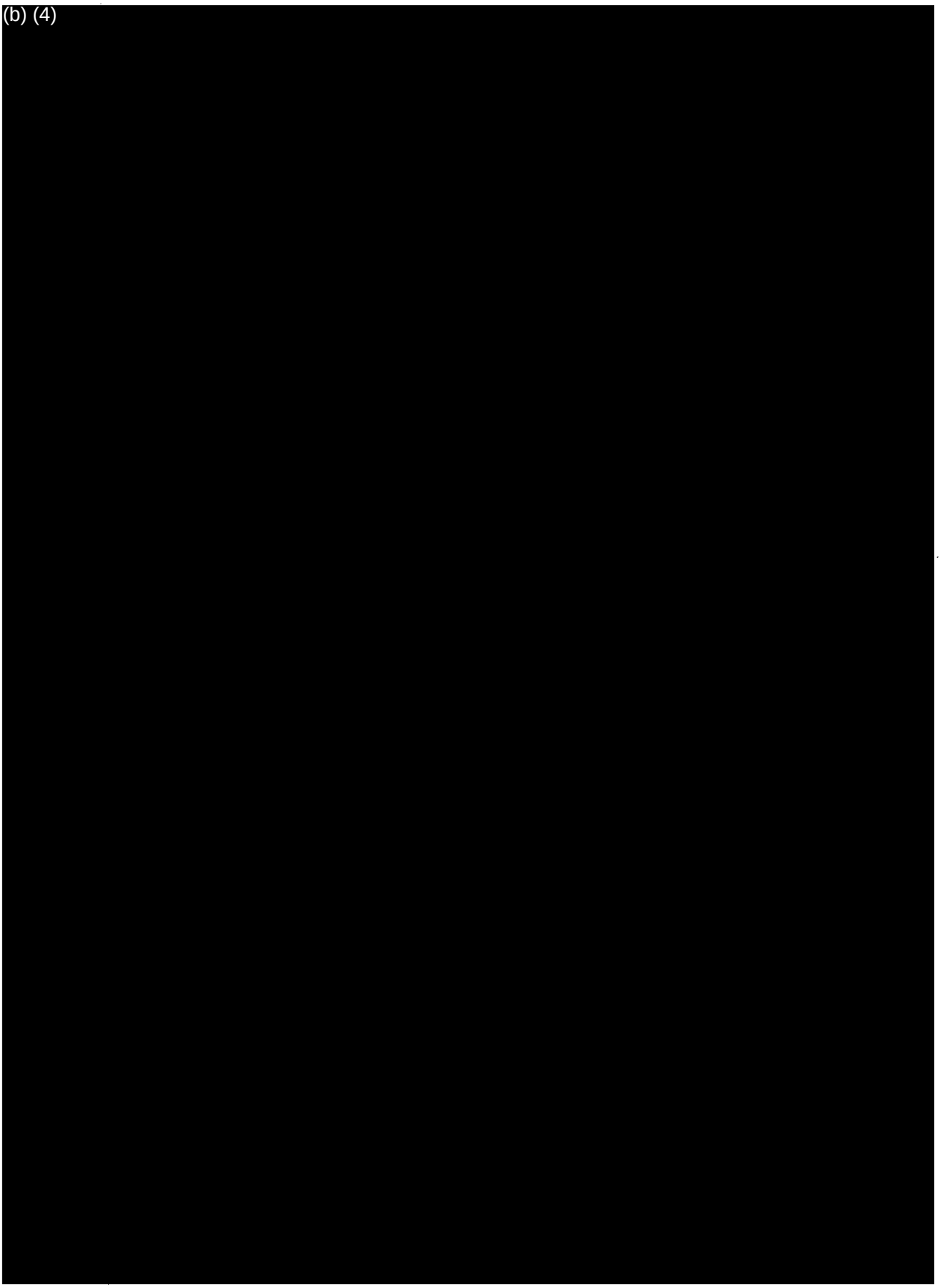

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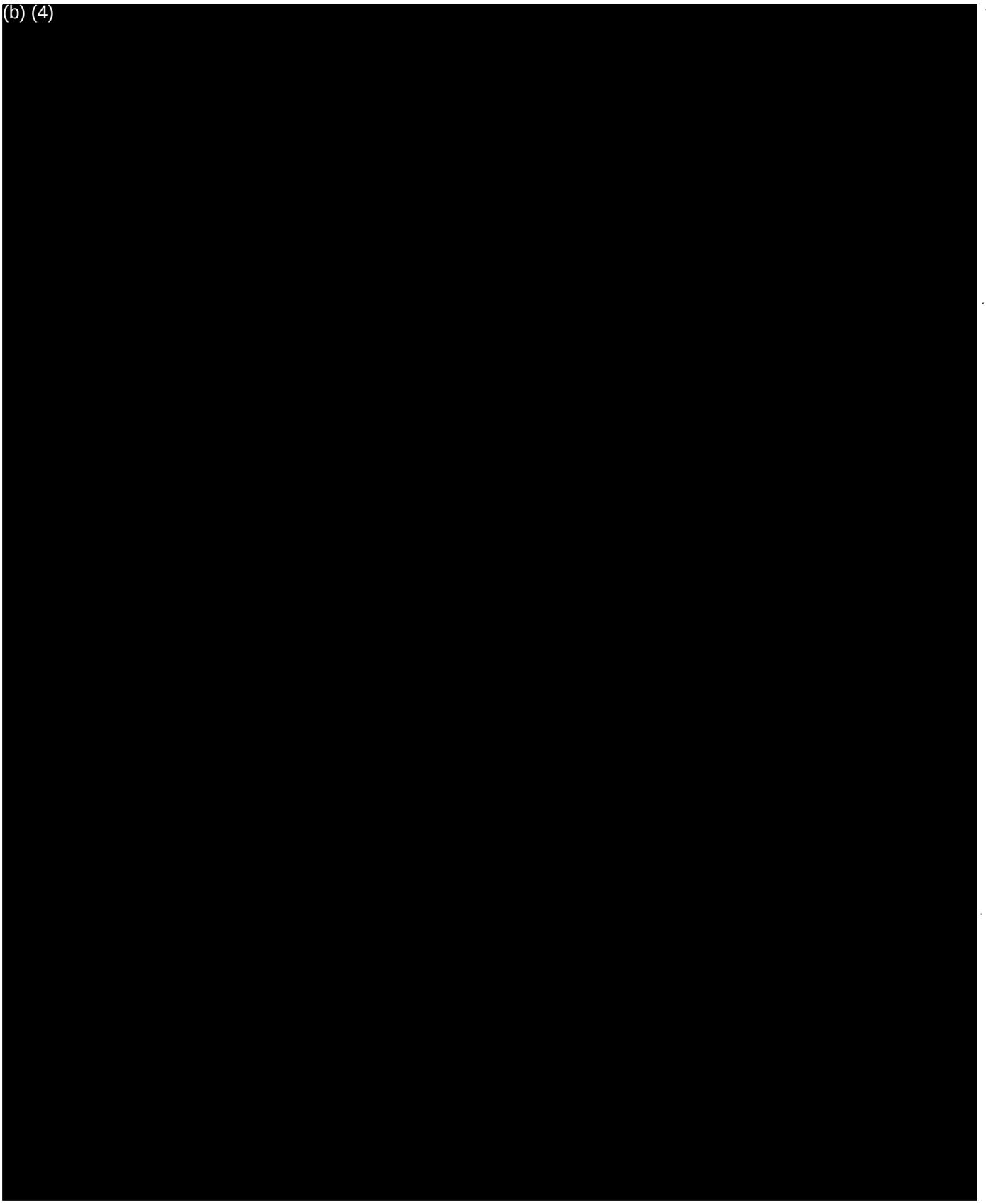

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3. FUNCTIONAL ARCHITECTURAL DESIGN

The ORTHODOC system operational software is depicted by the following structure:

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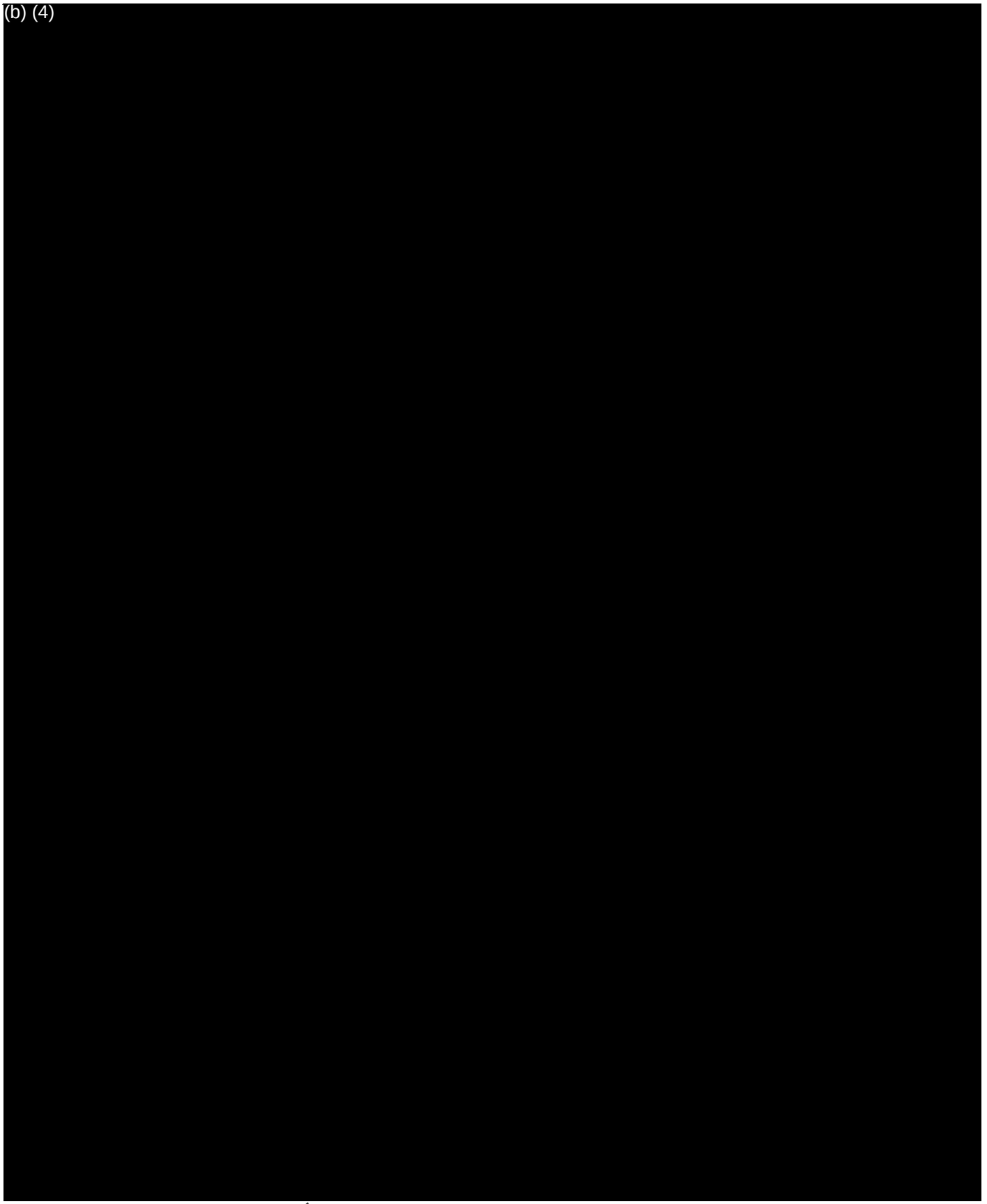

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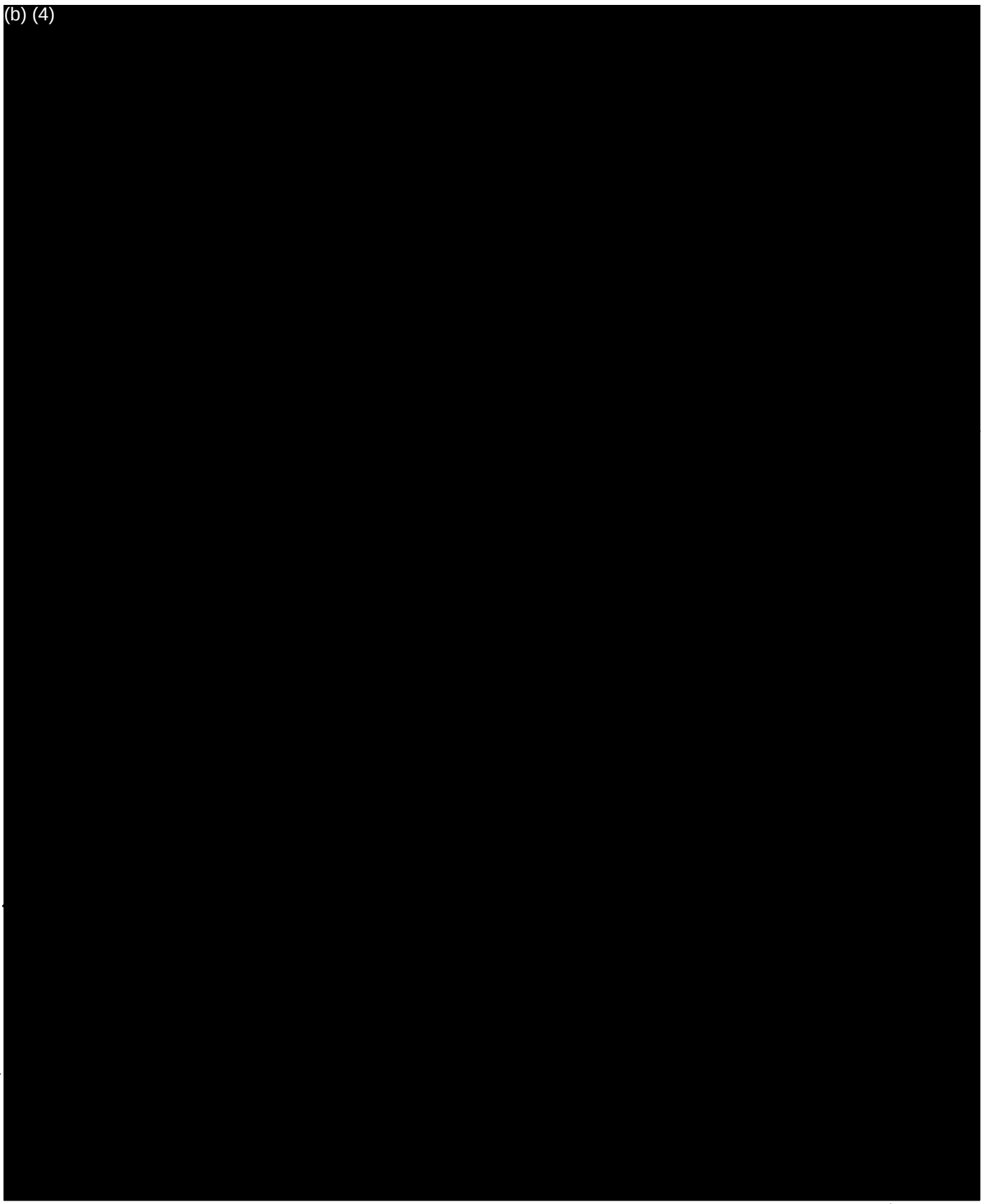

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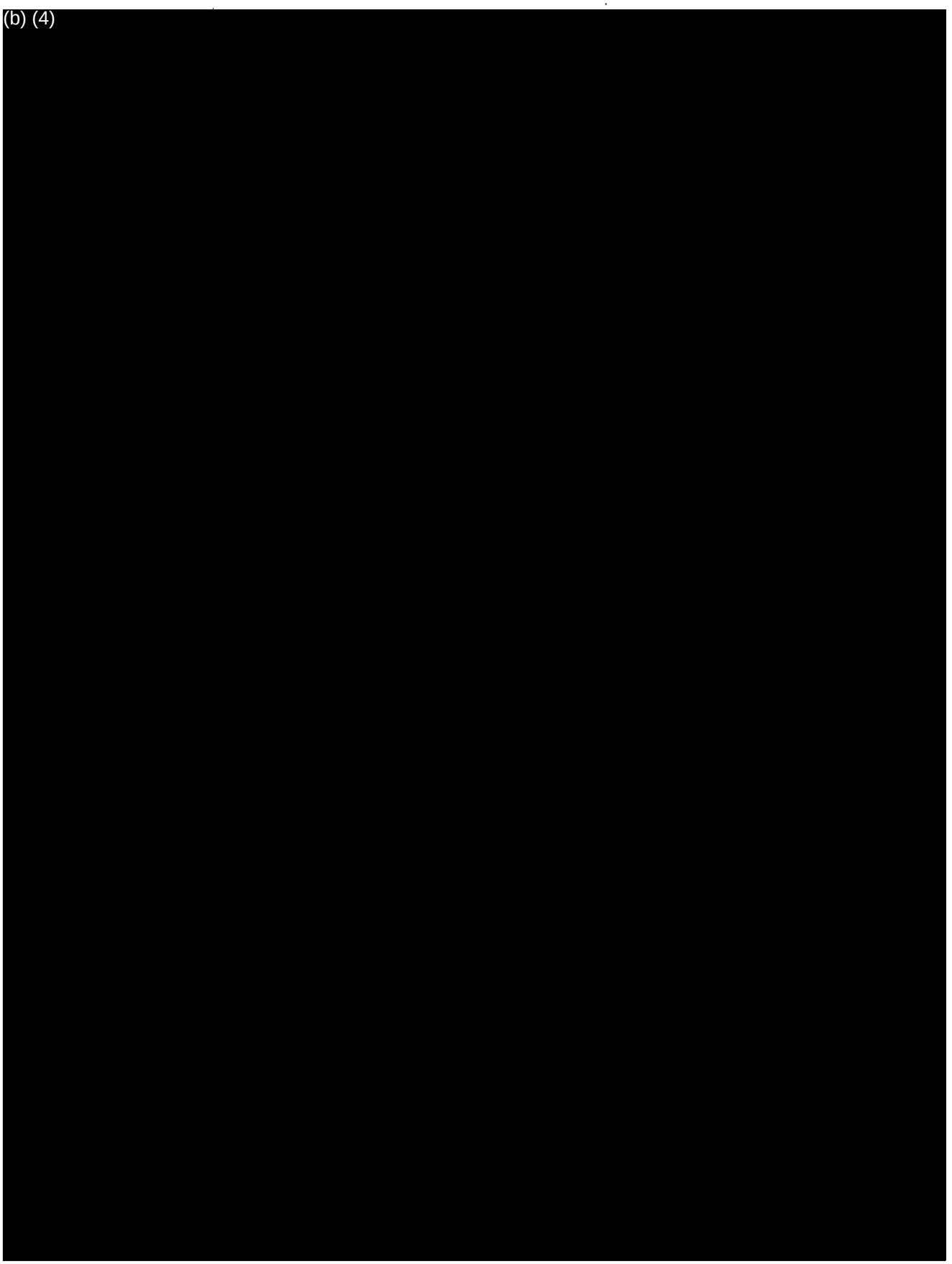

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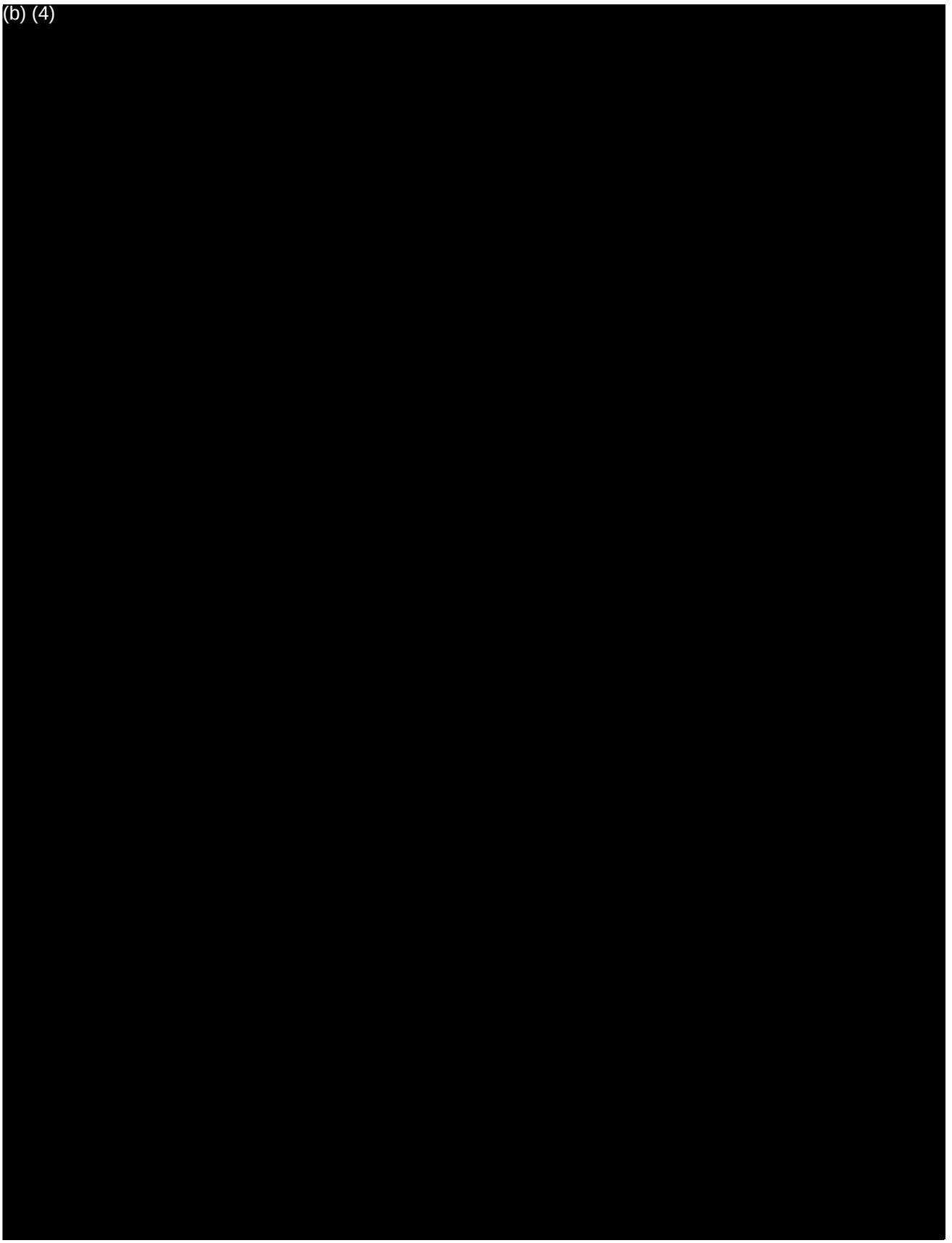

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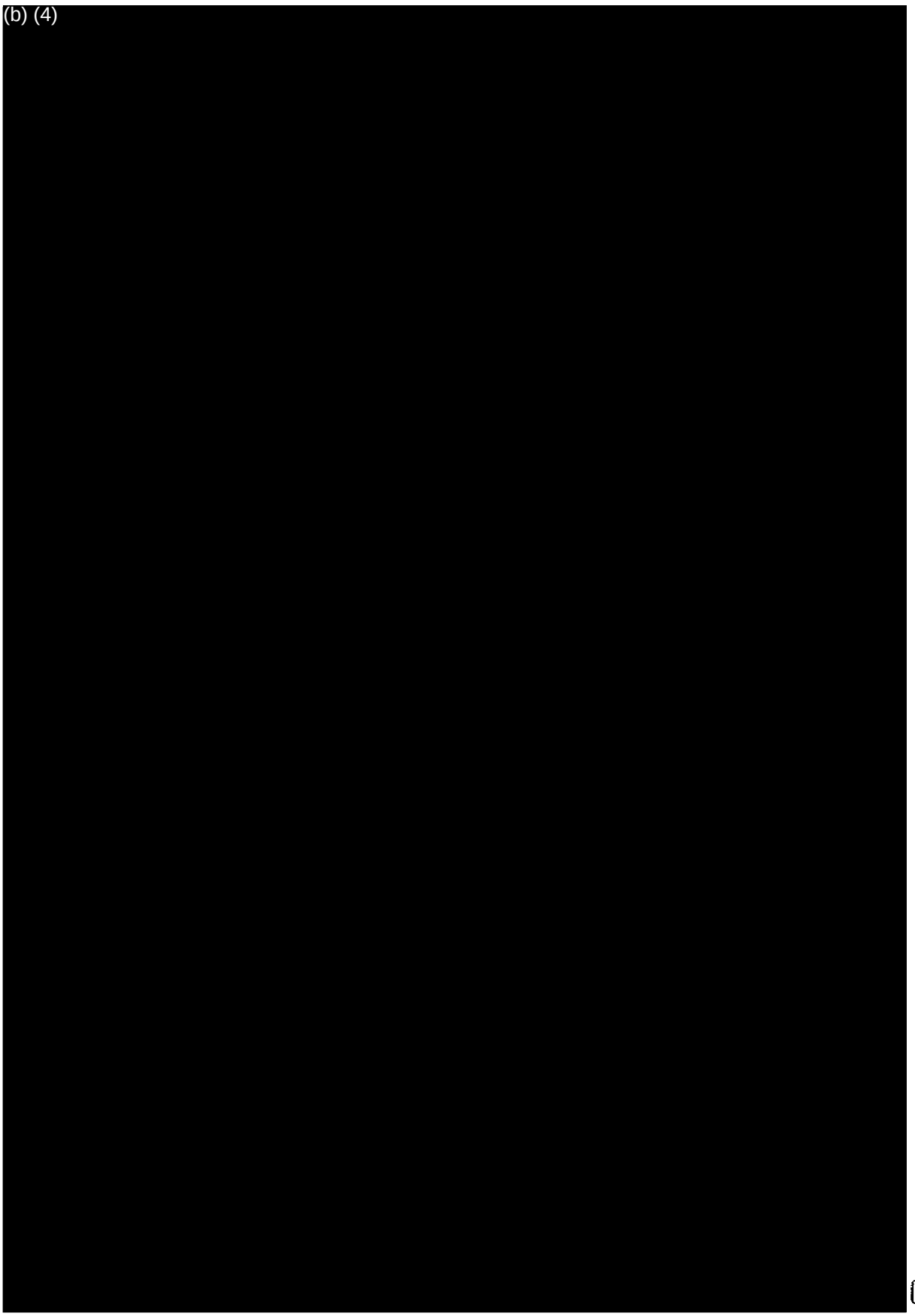

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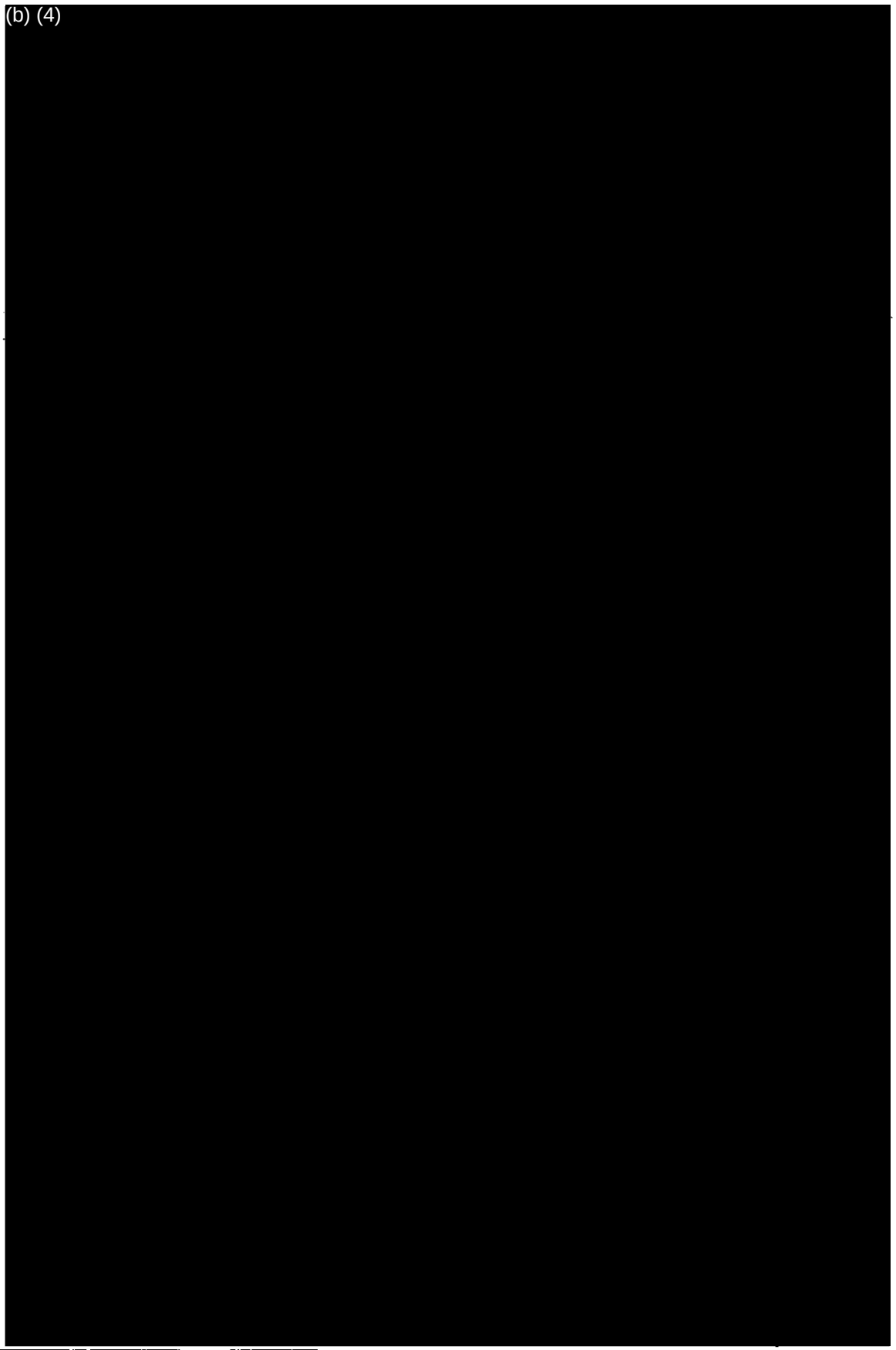

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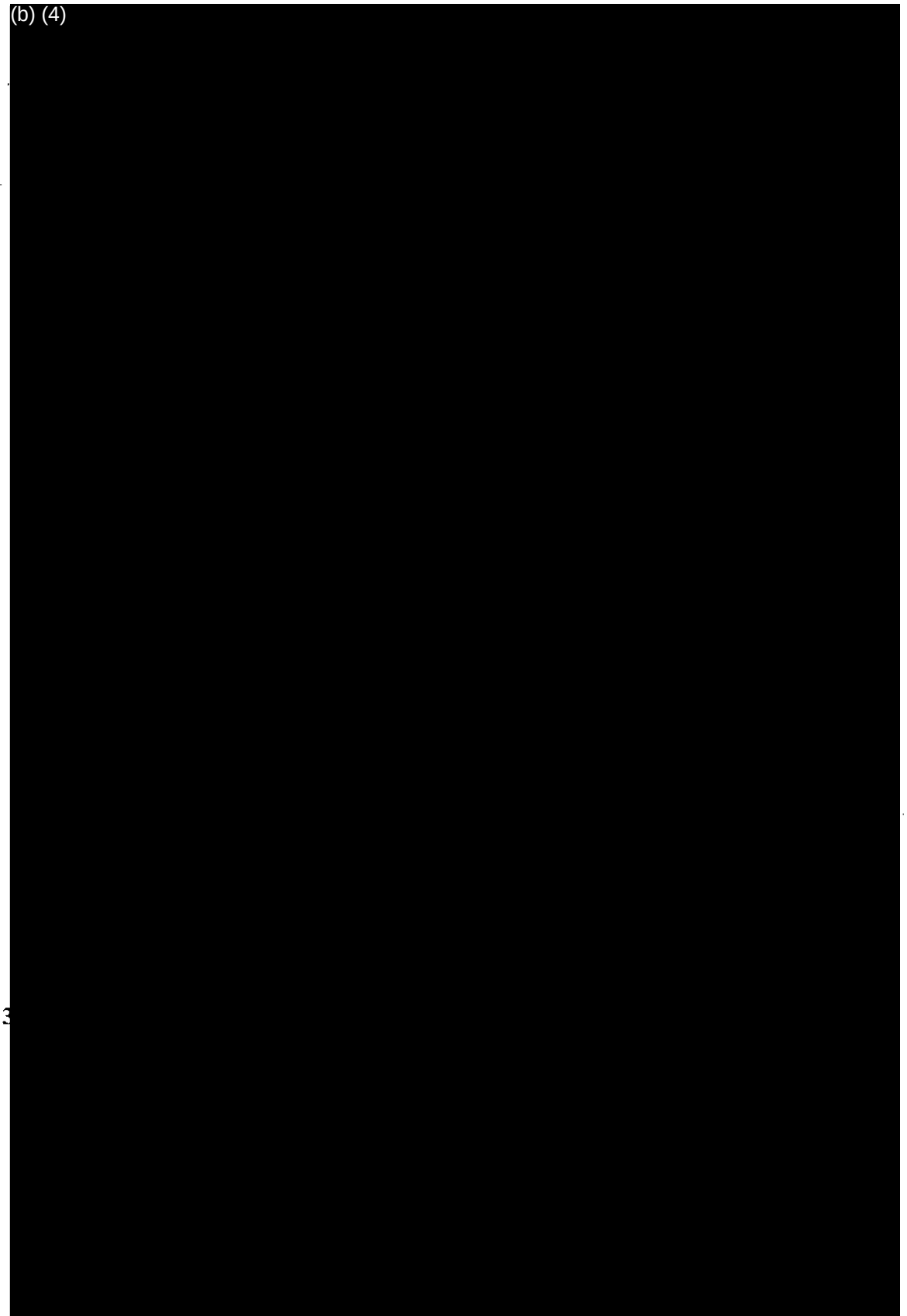

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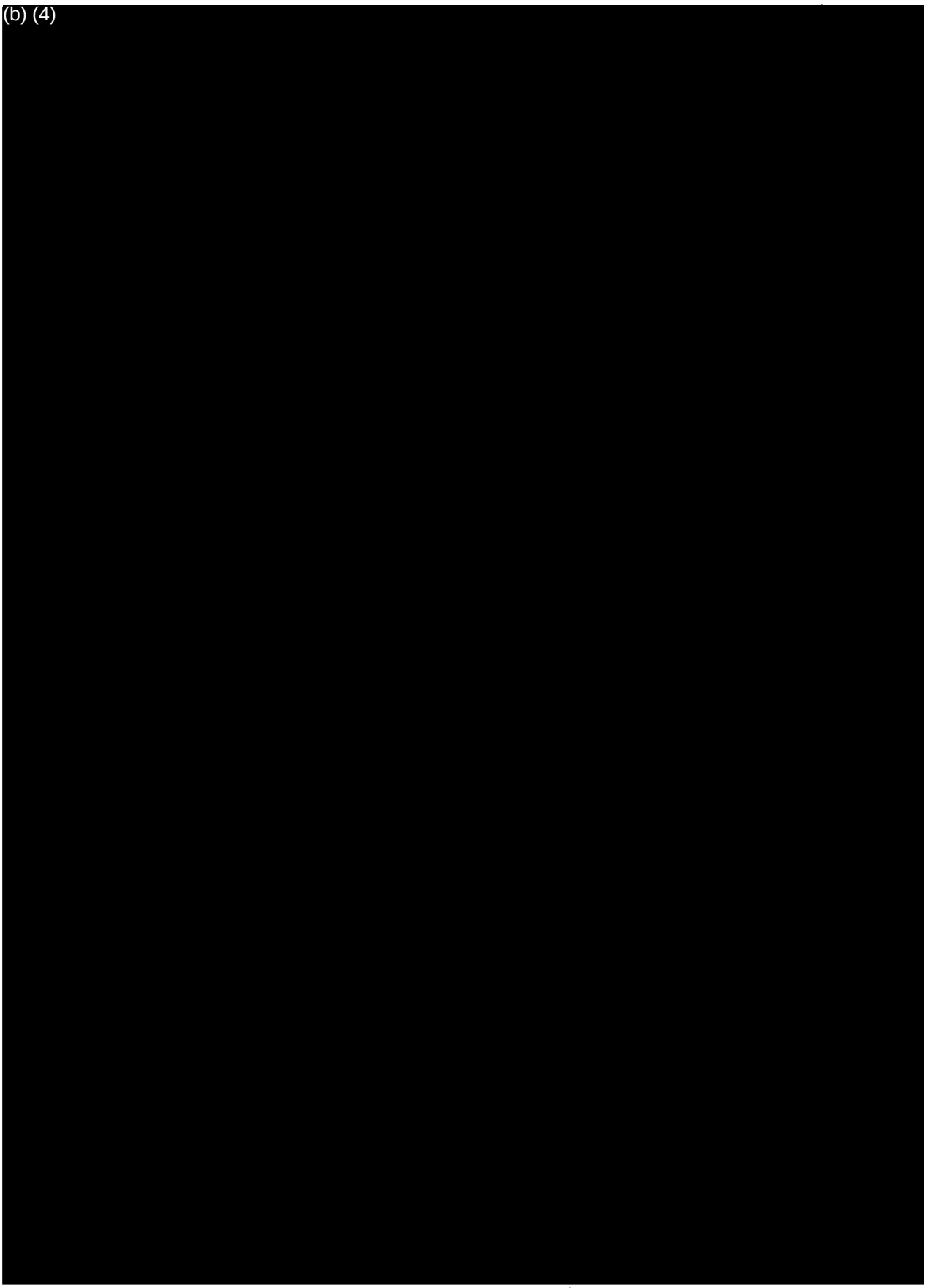

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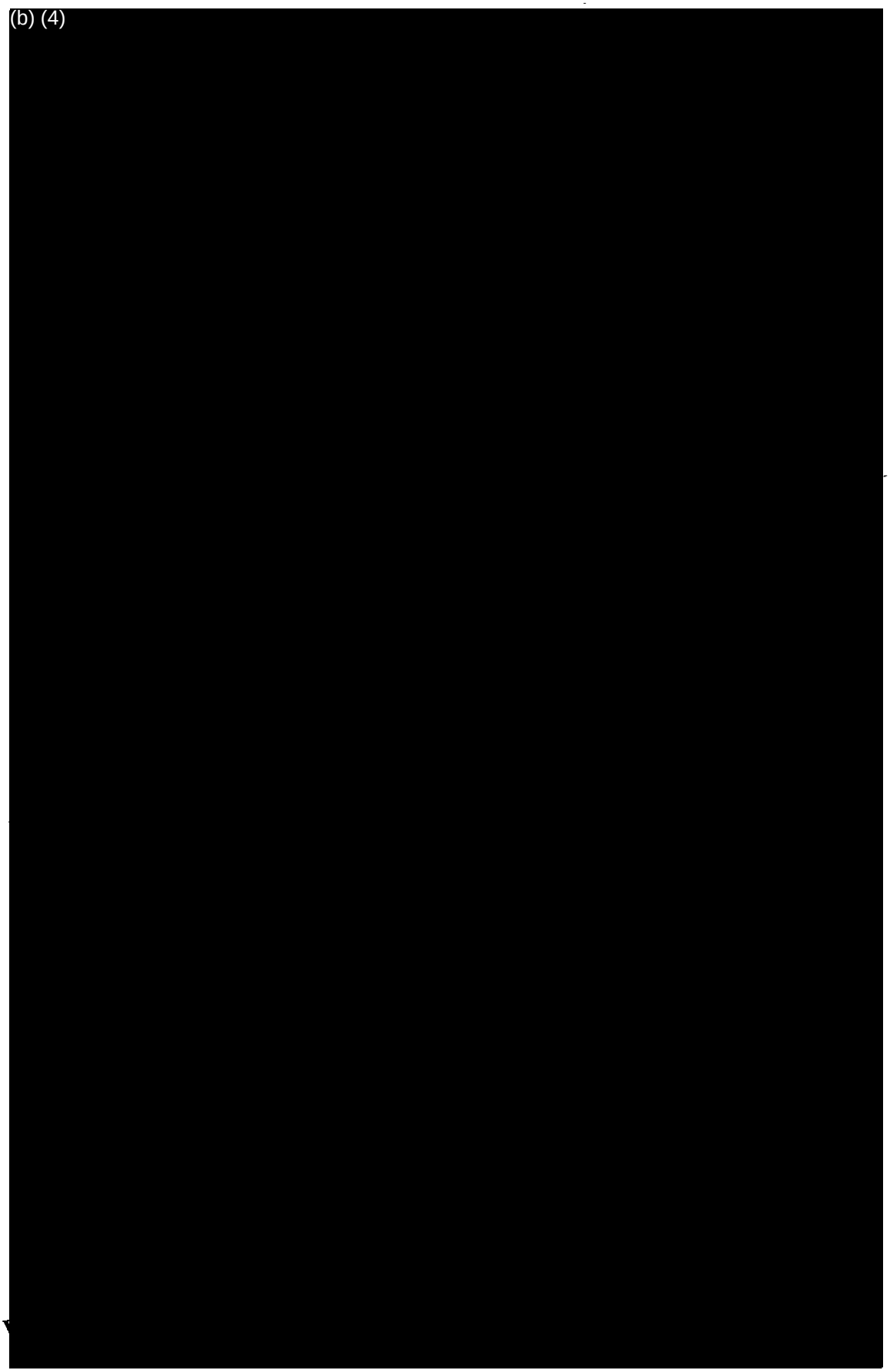

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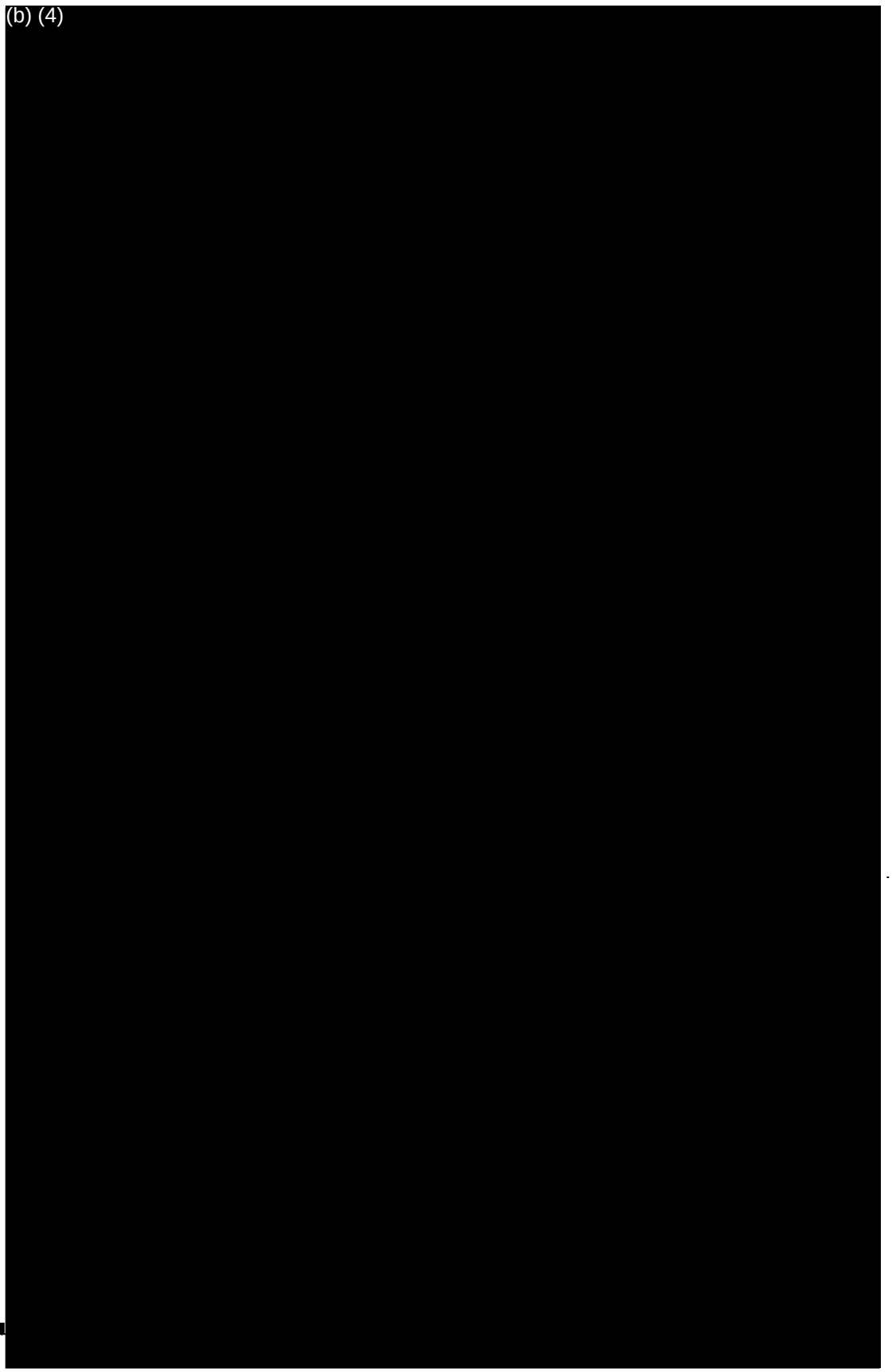

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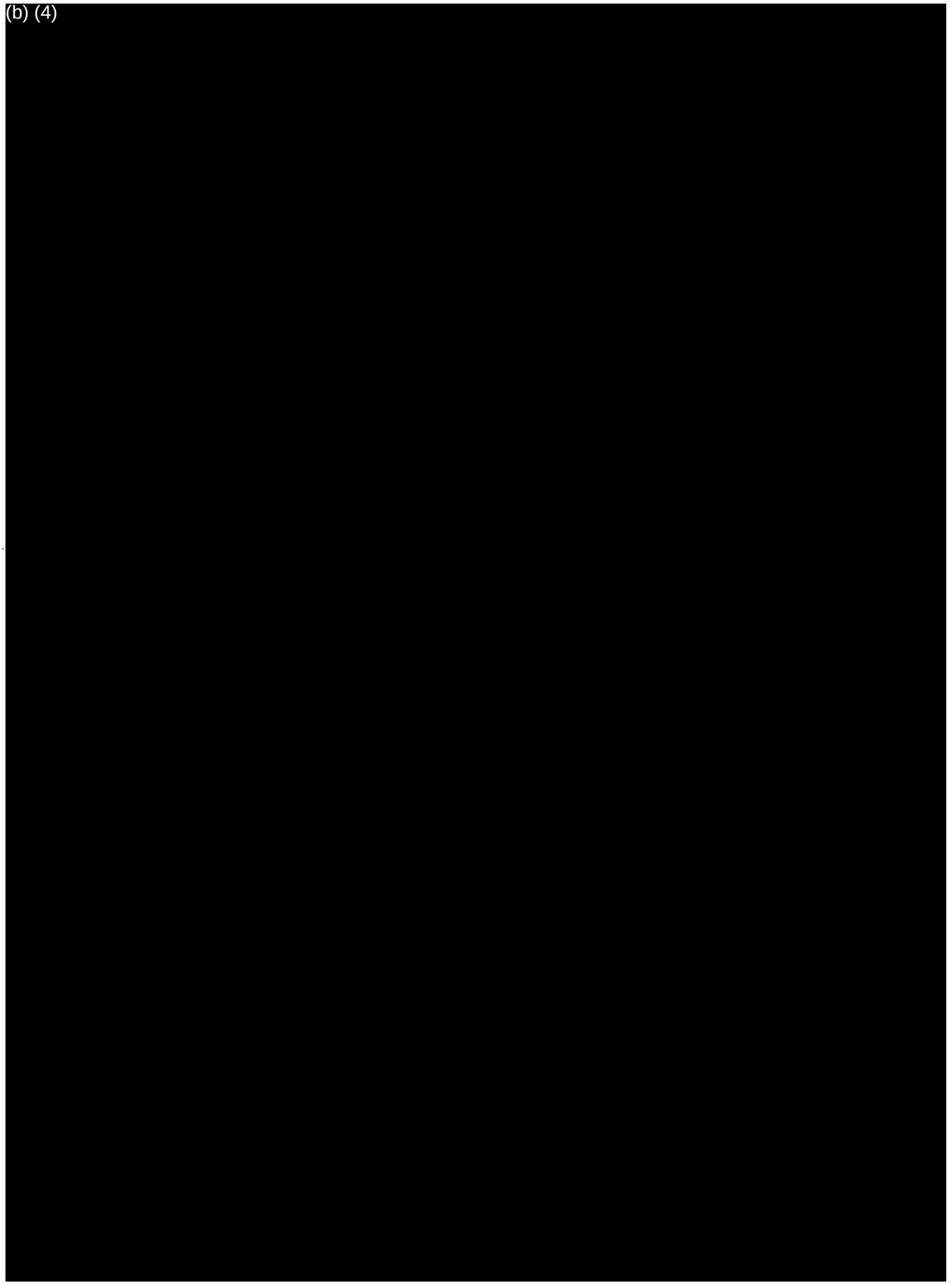

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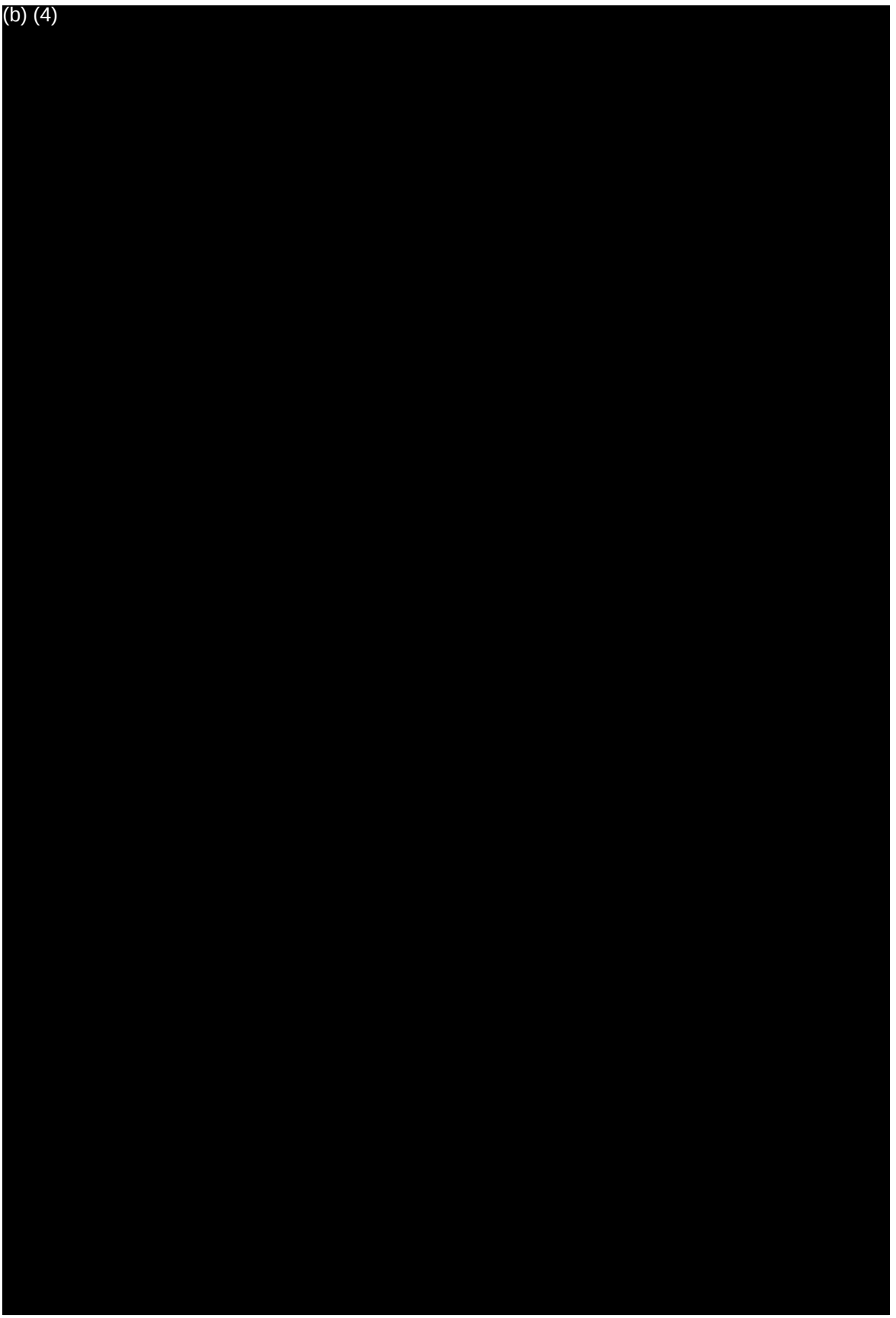

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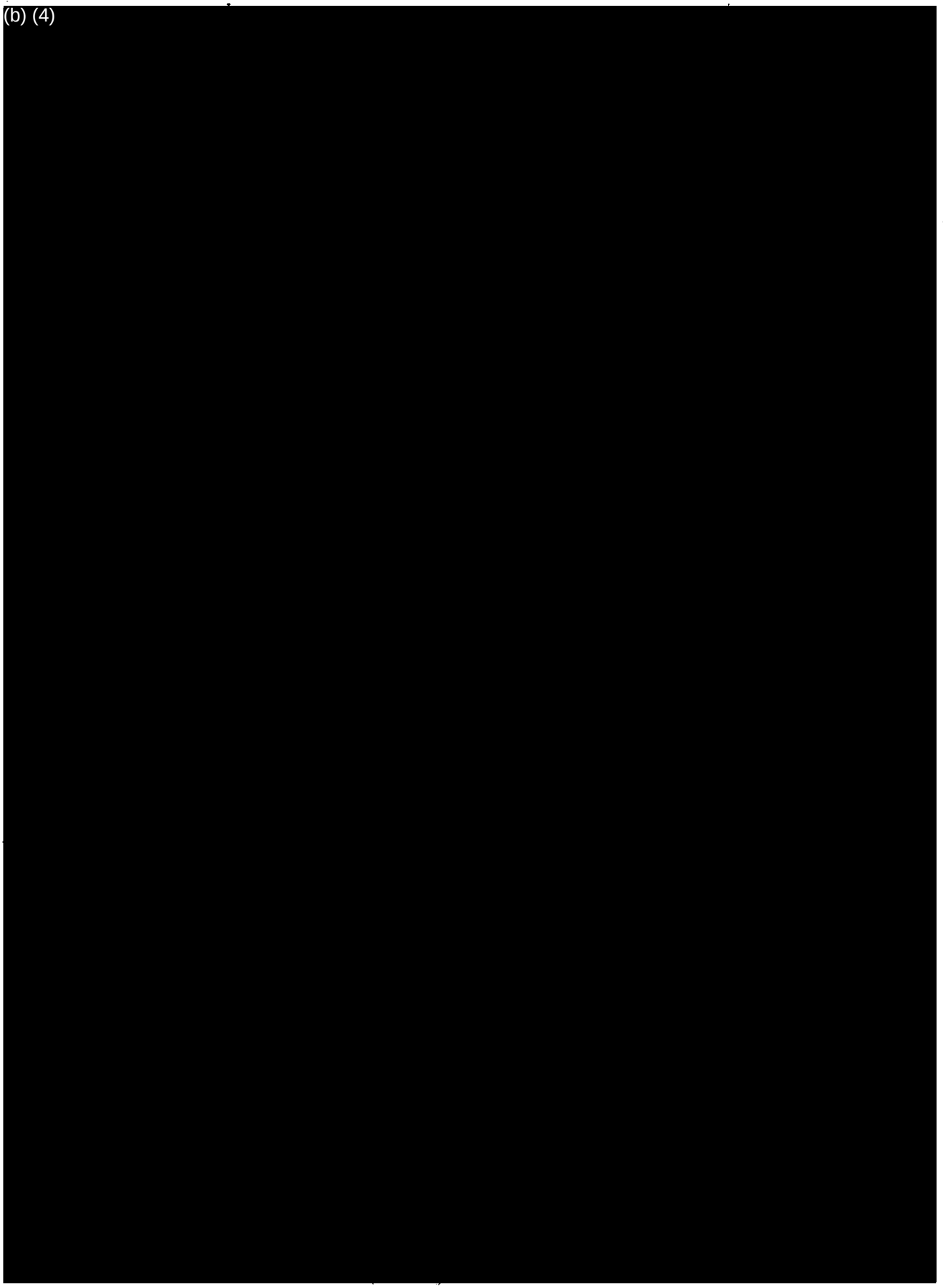

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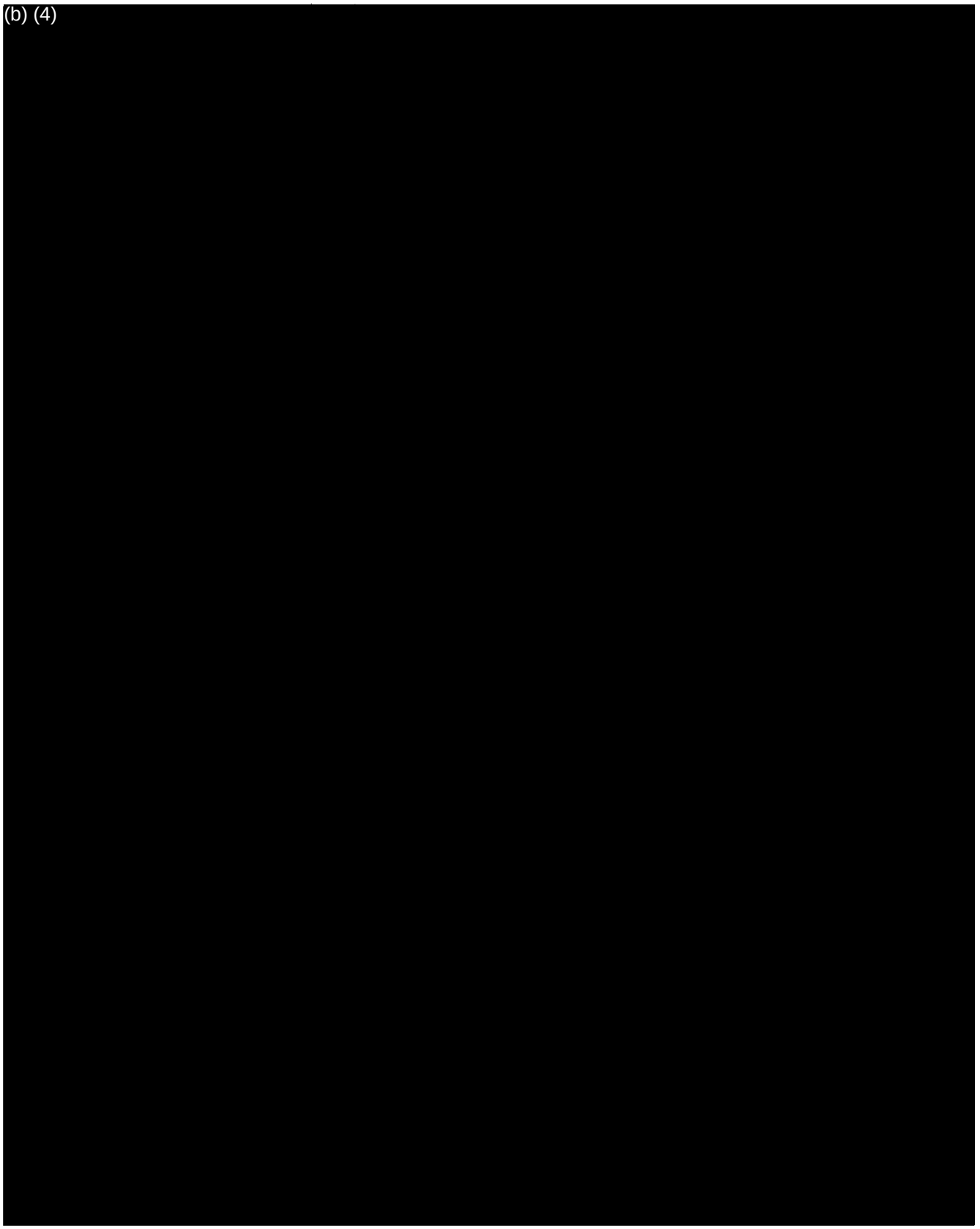

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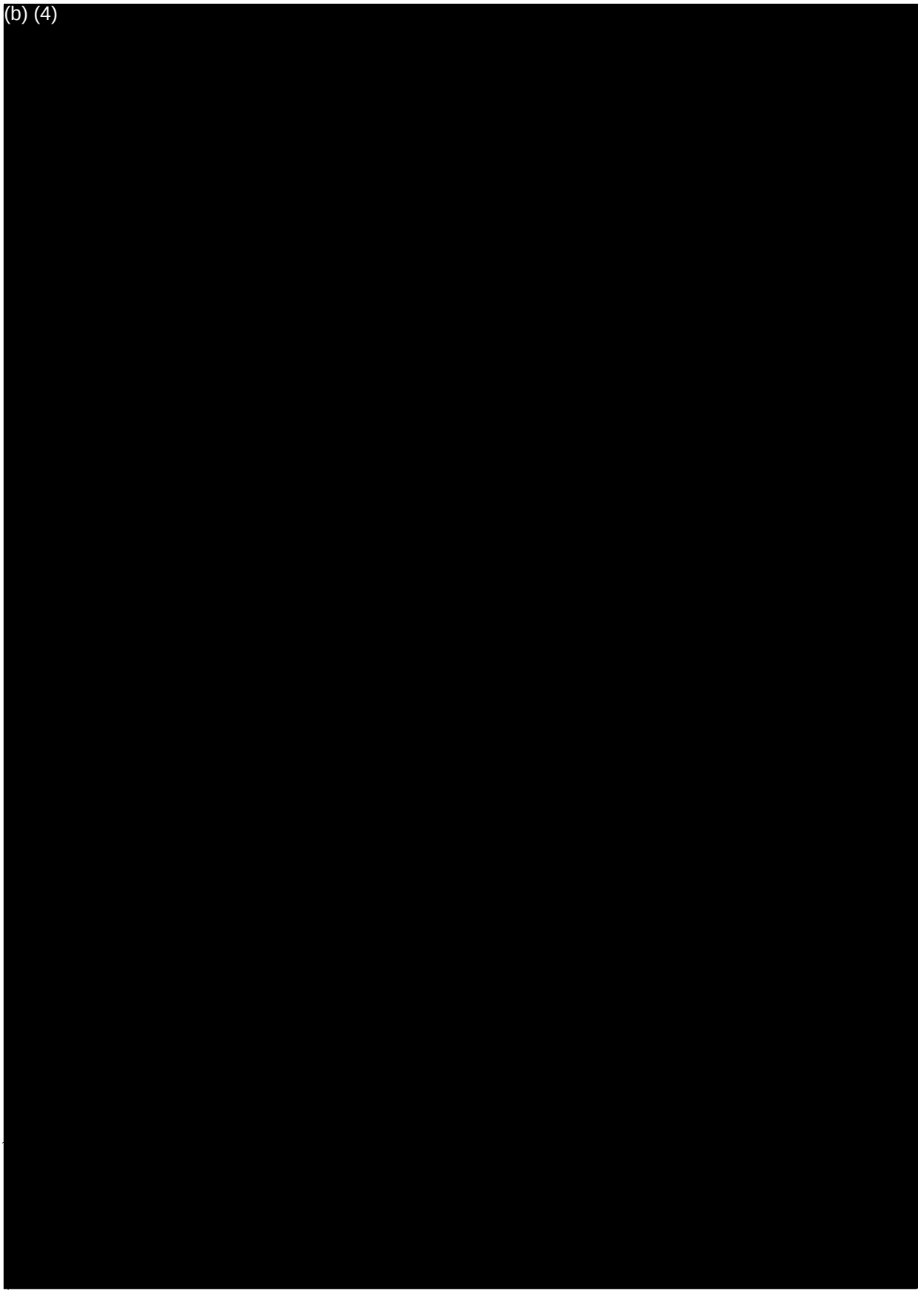

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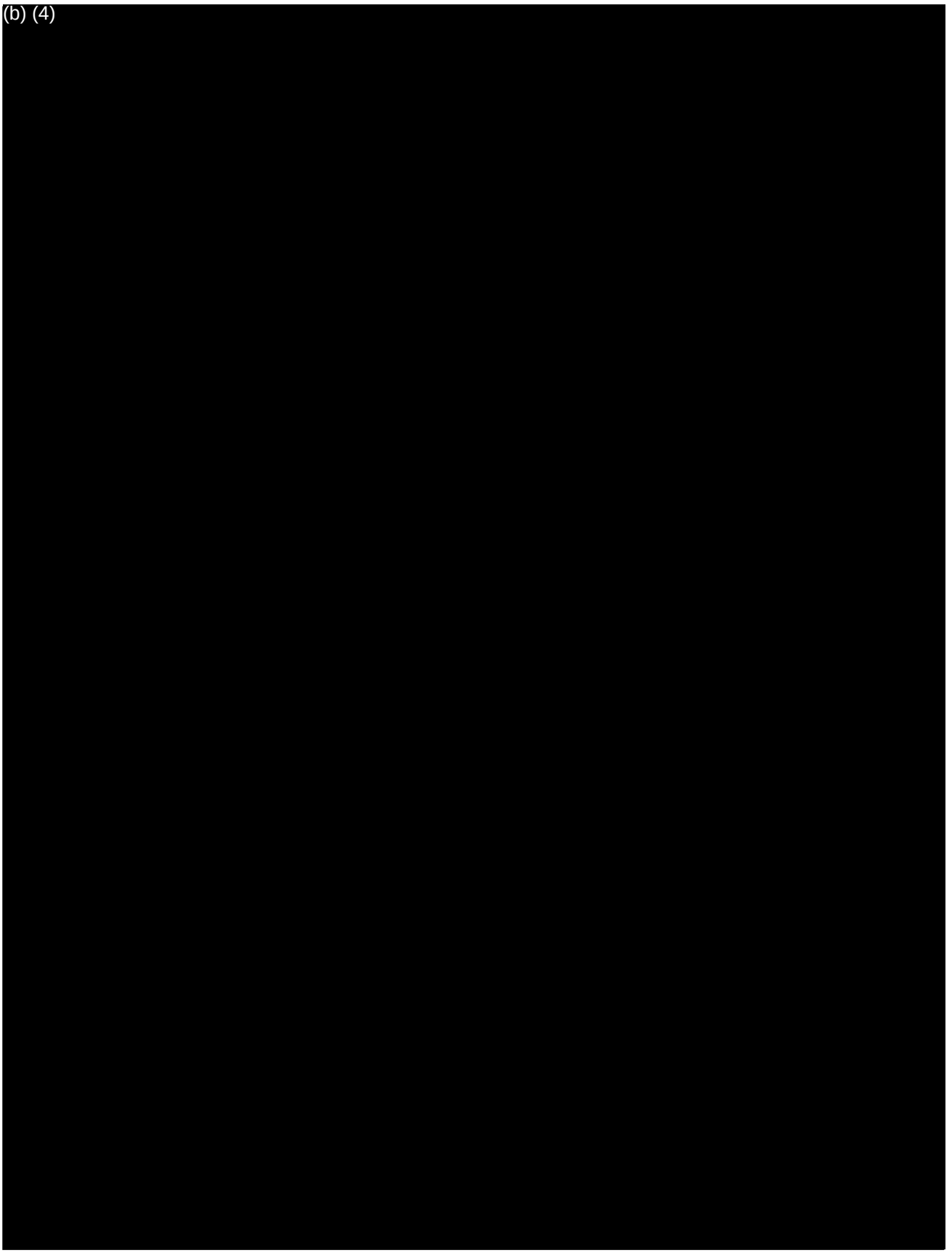

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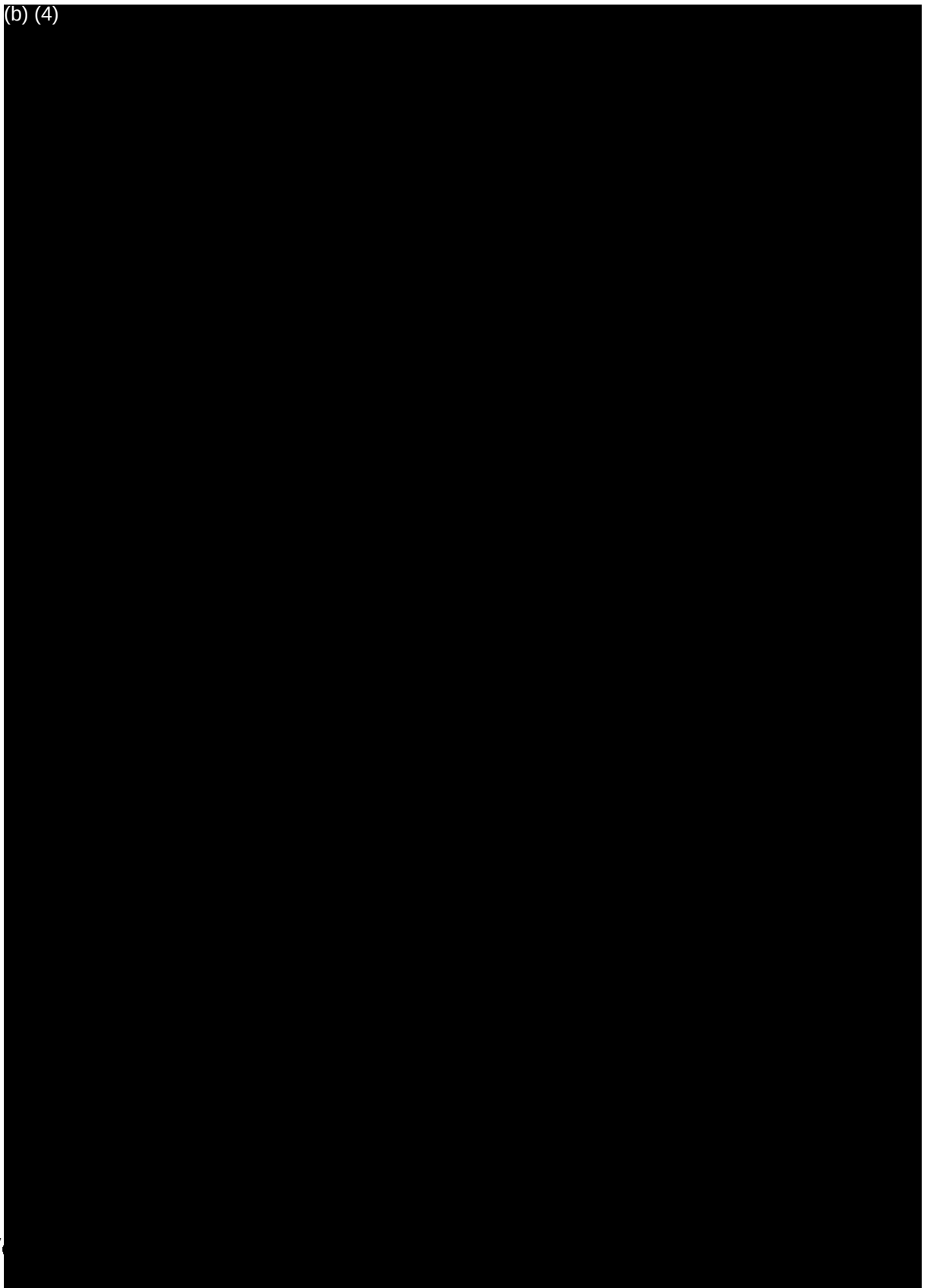

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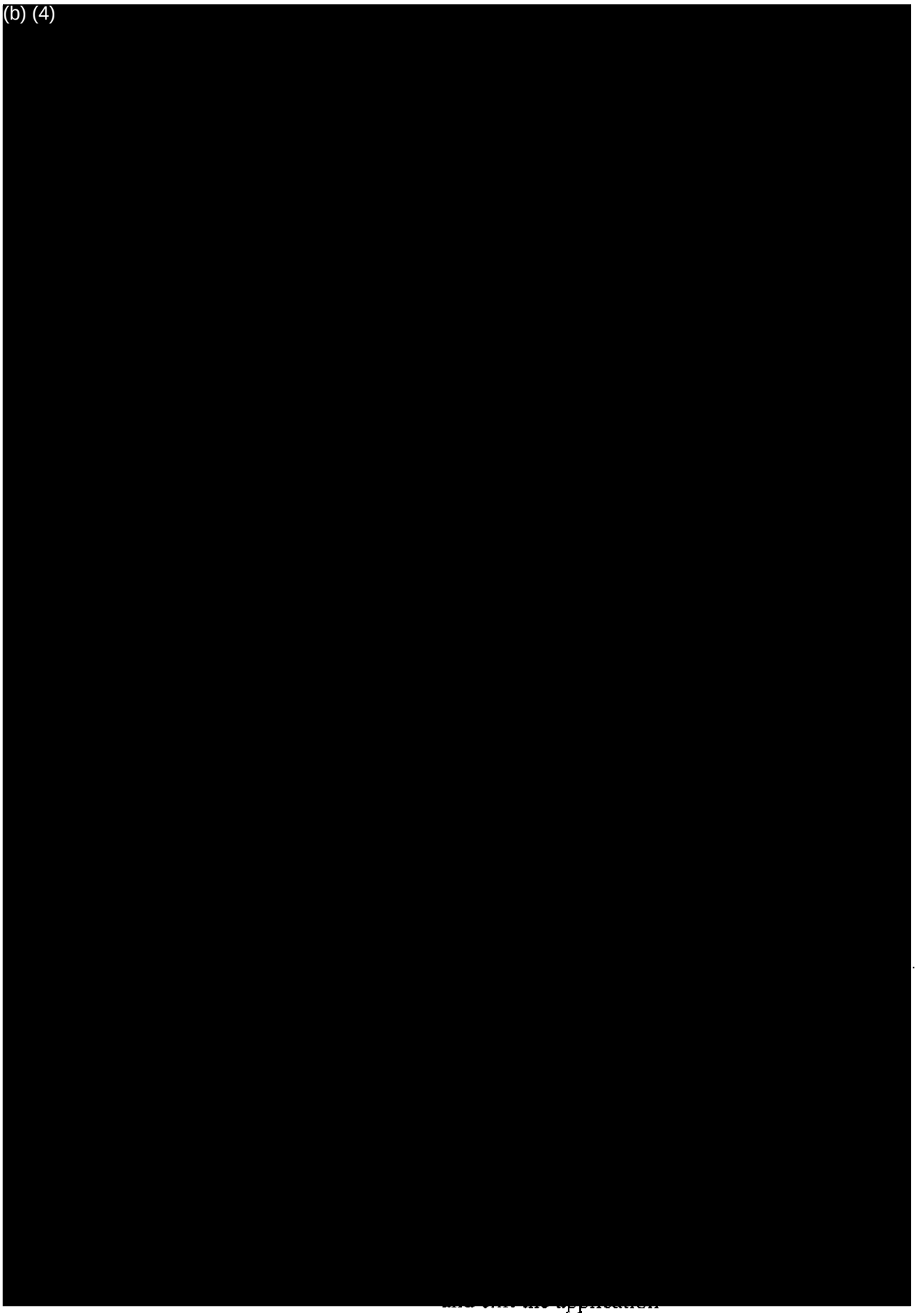

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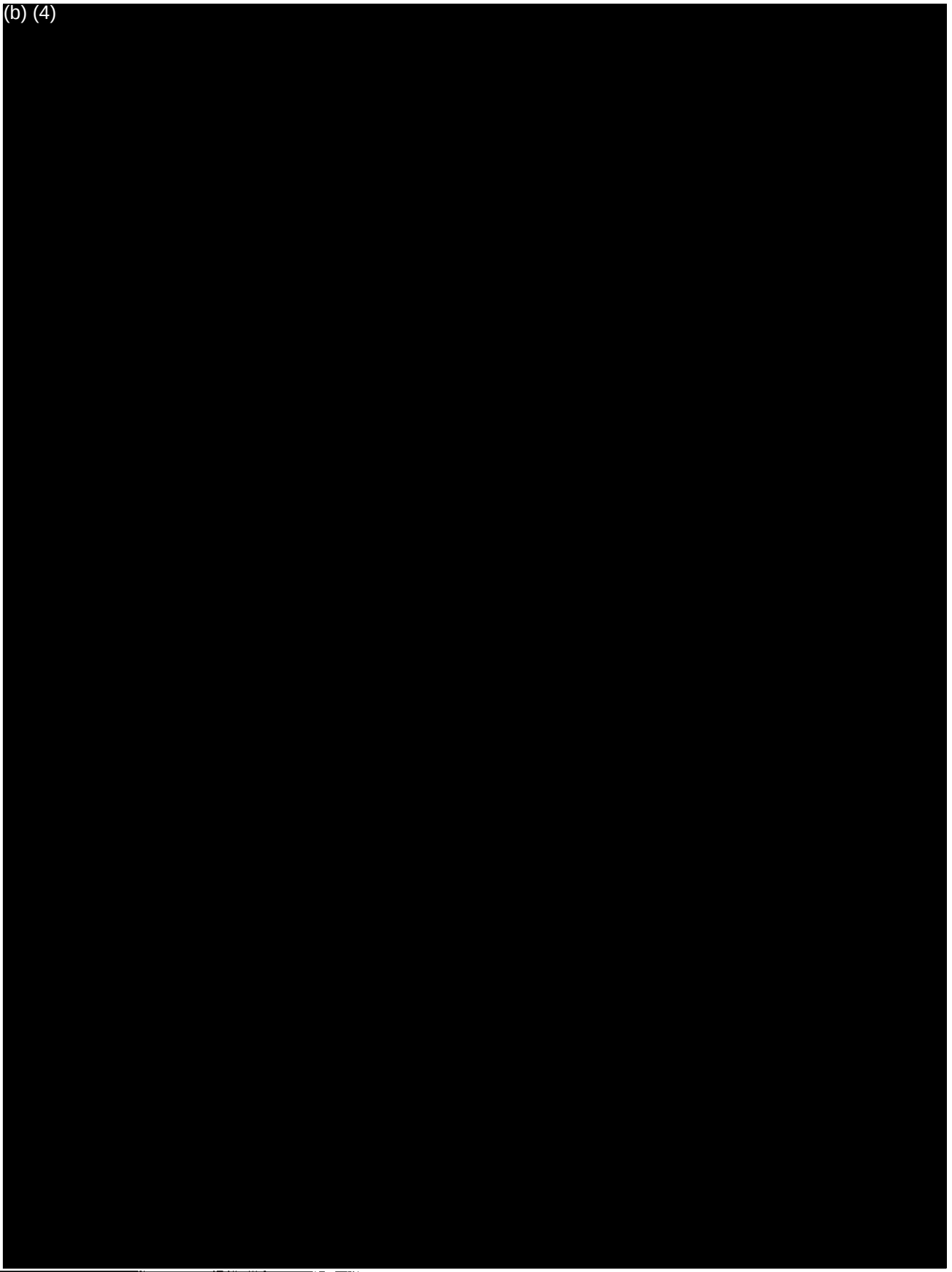

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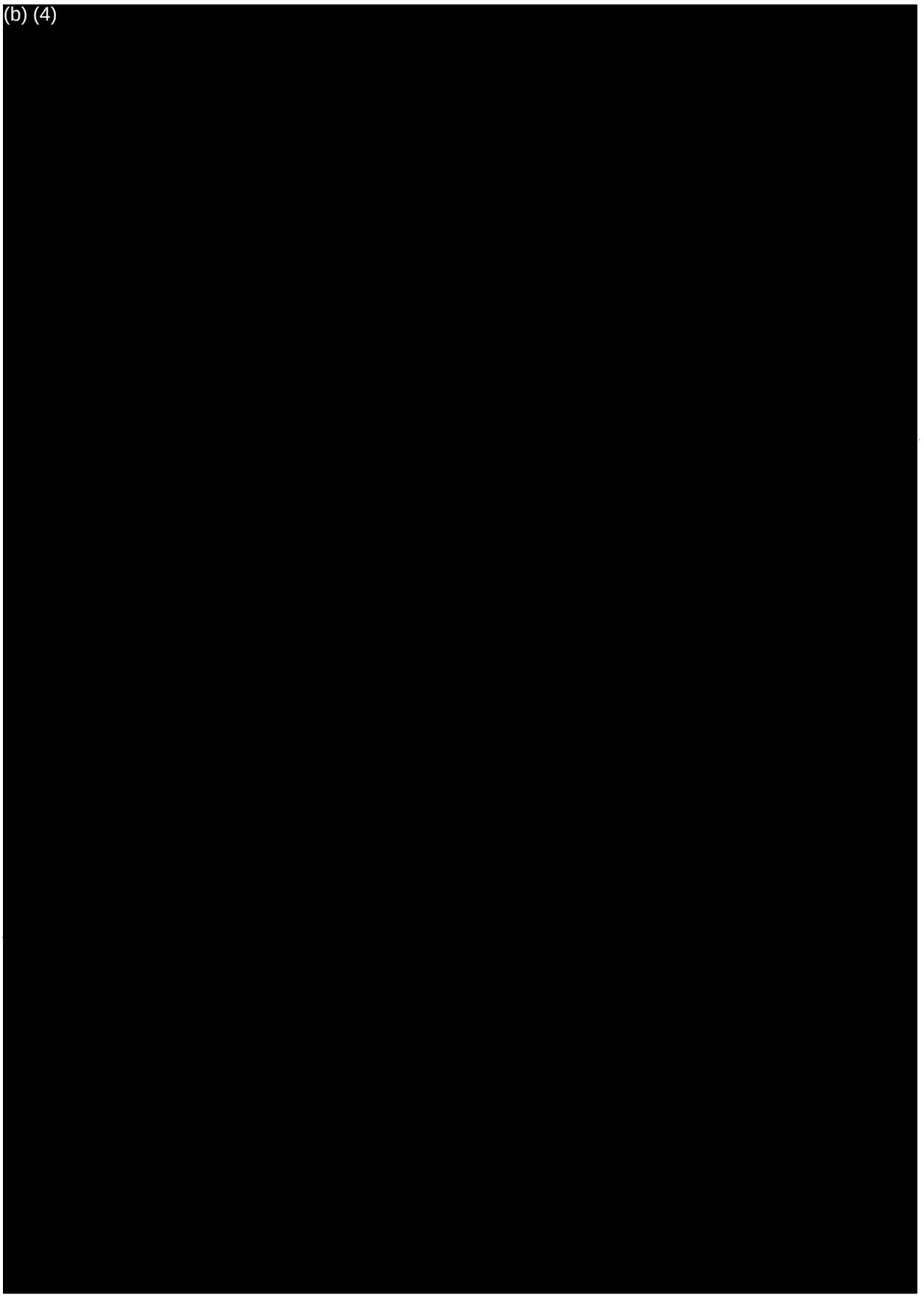

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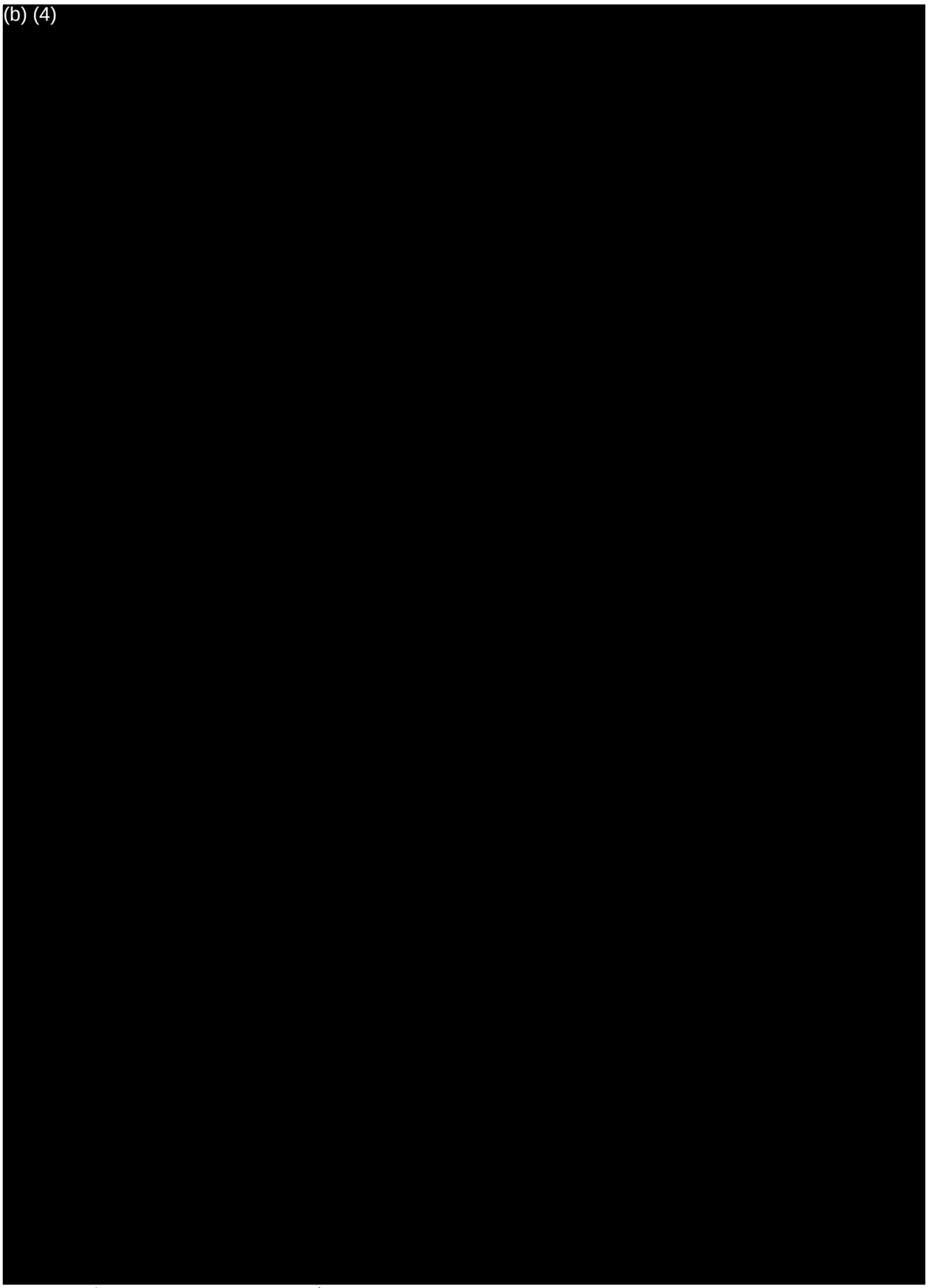

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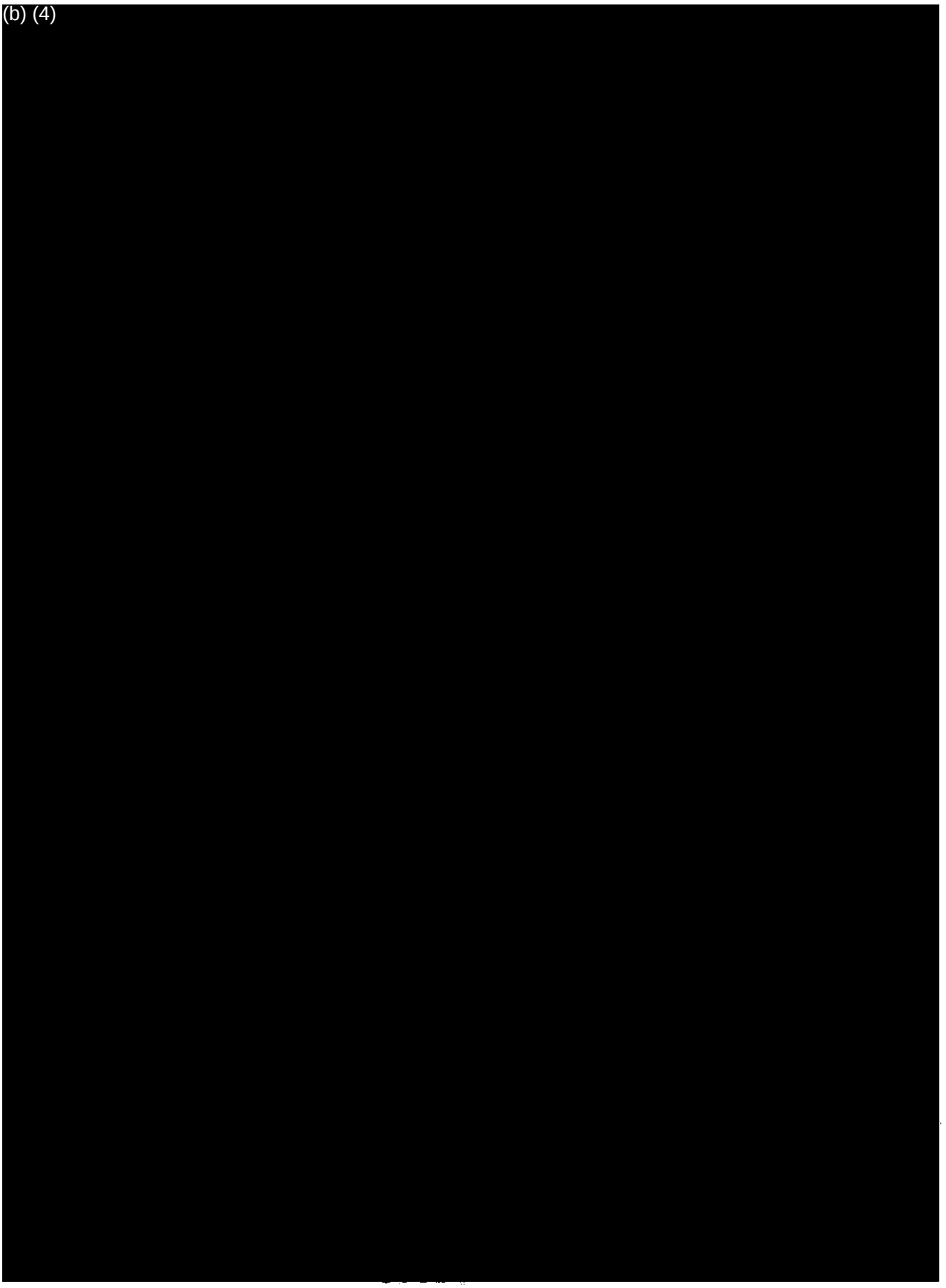

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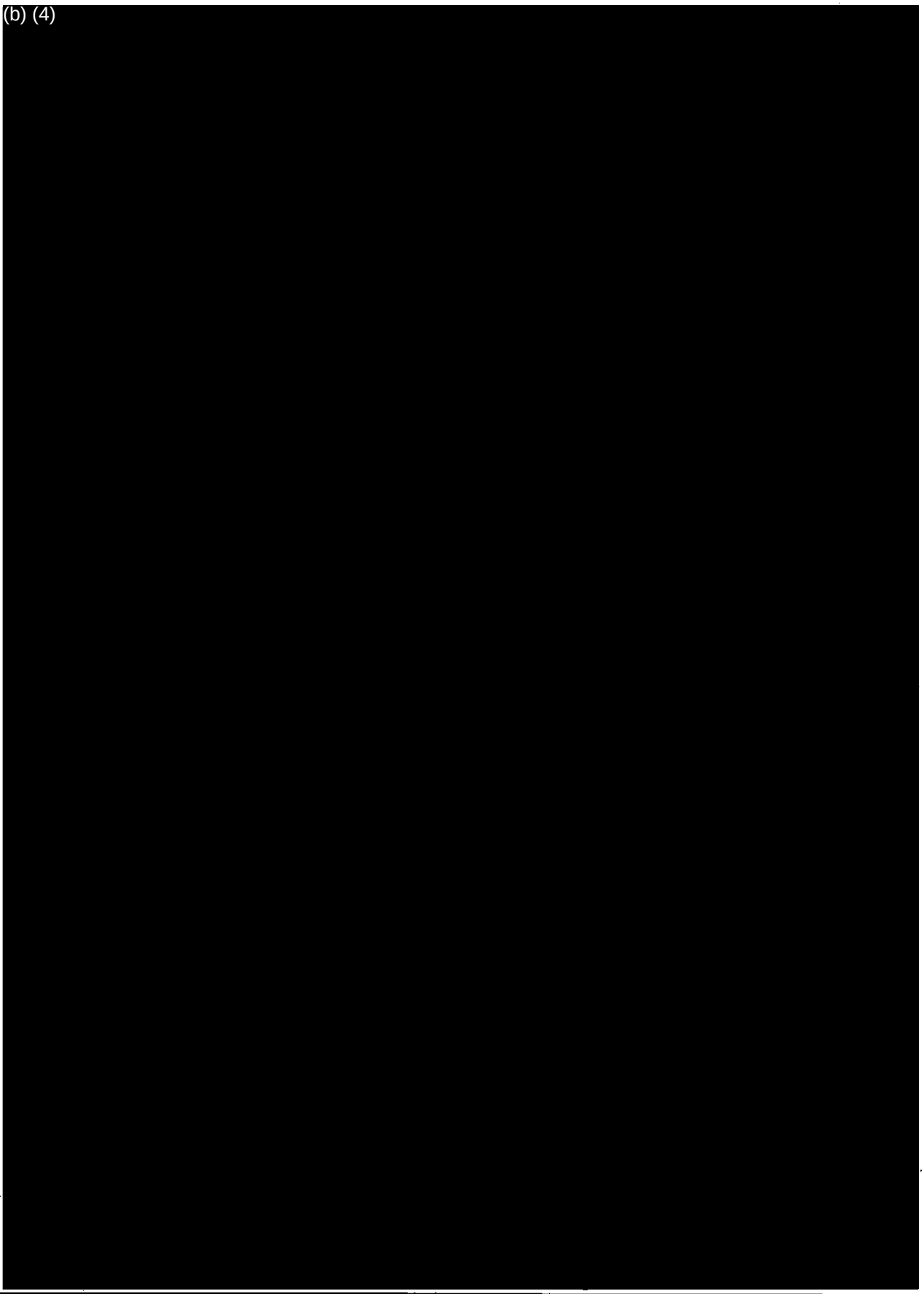

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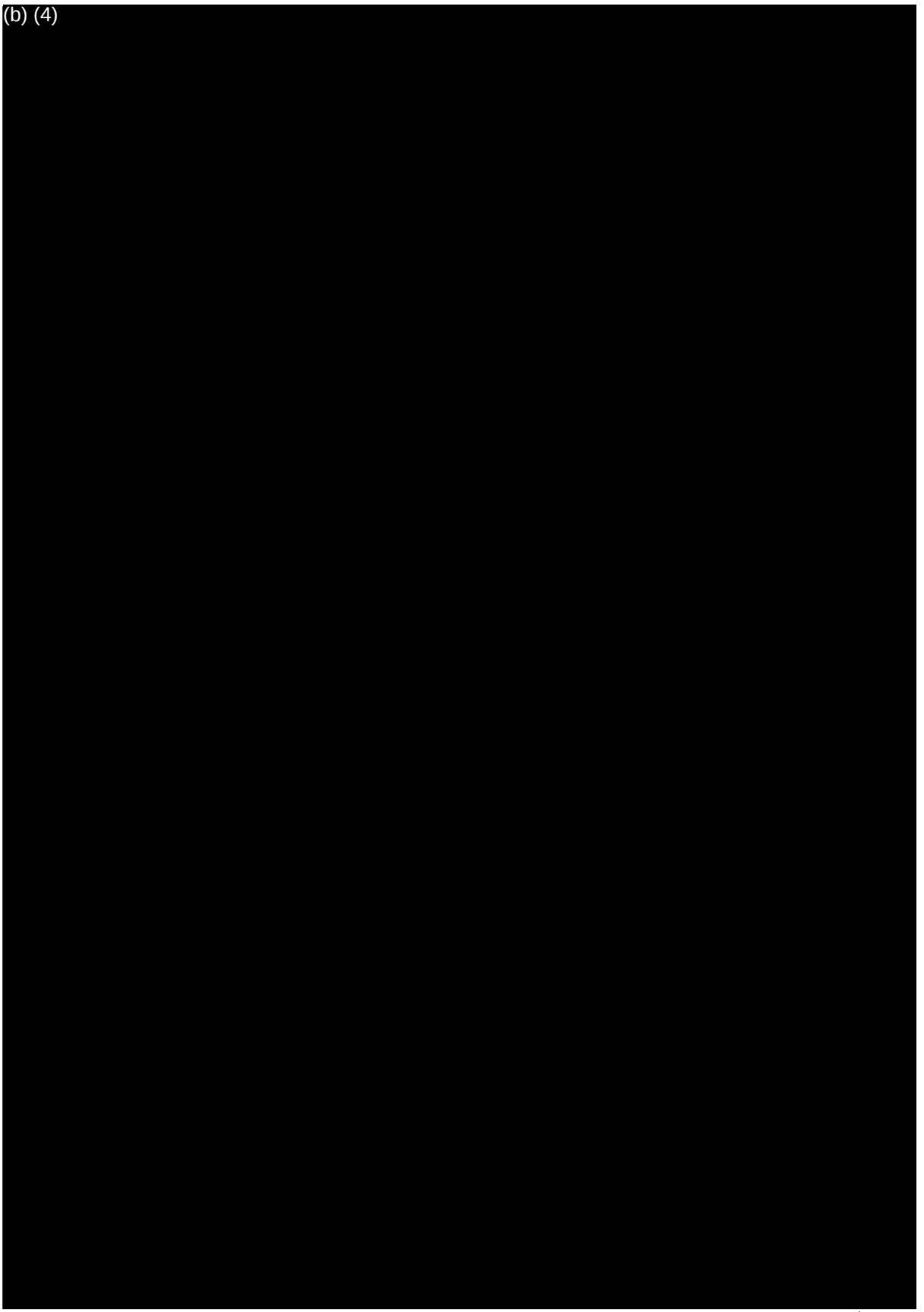

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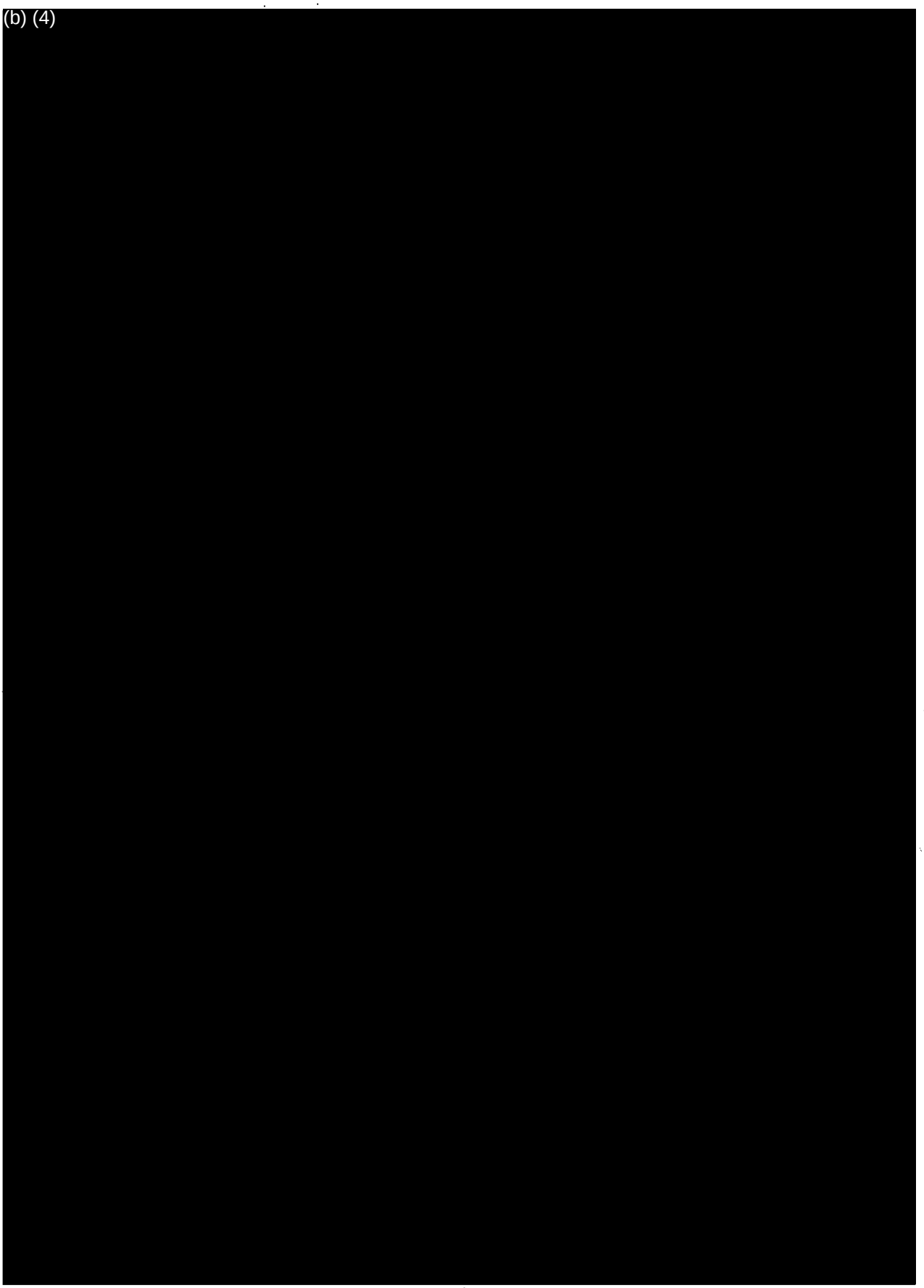

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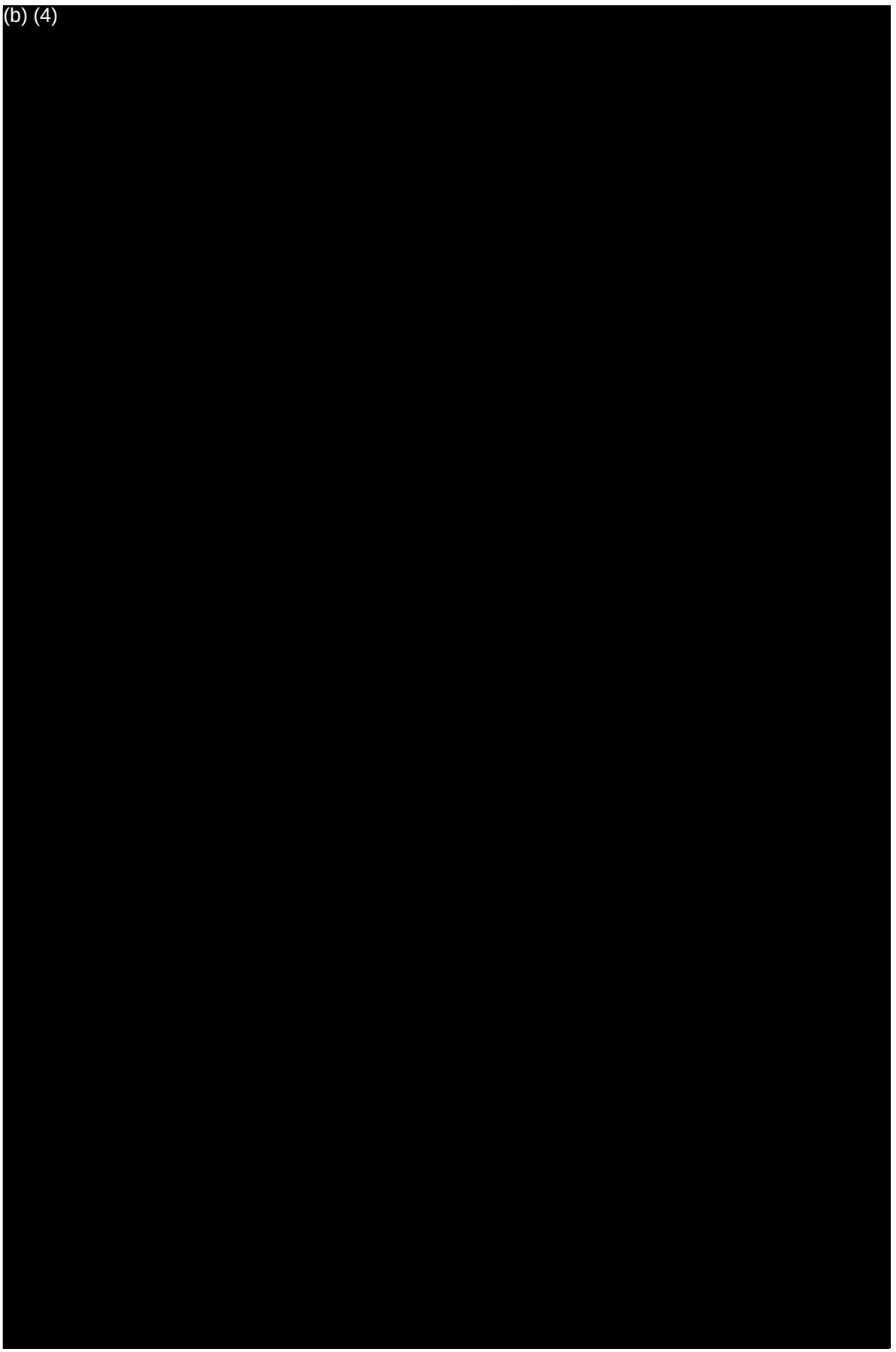

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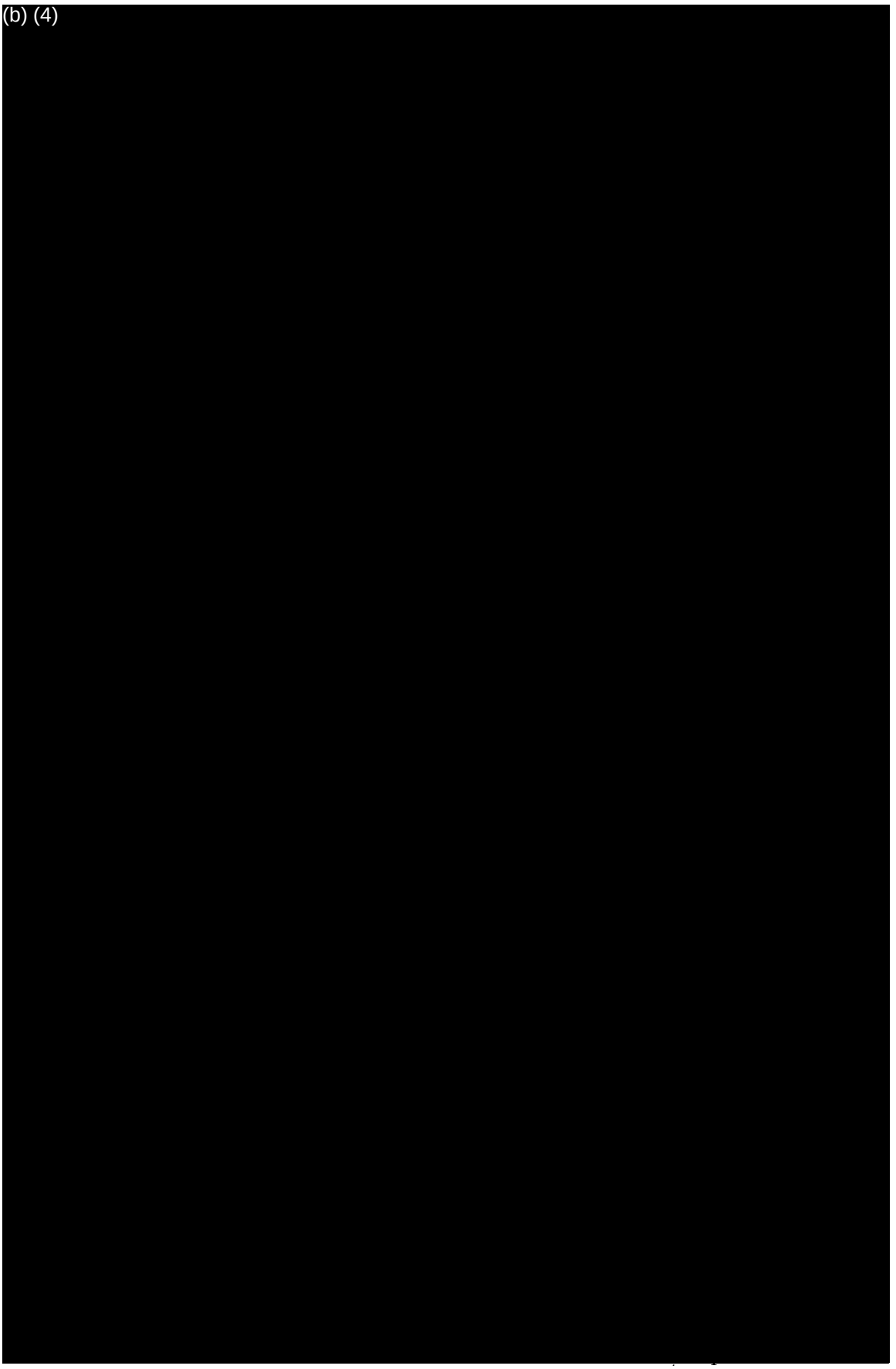

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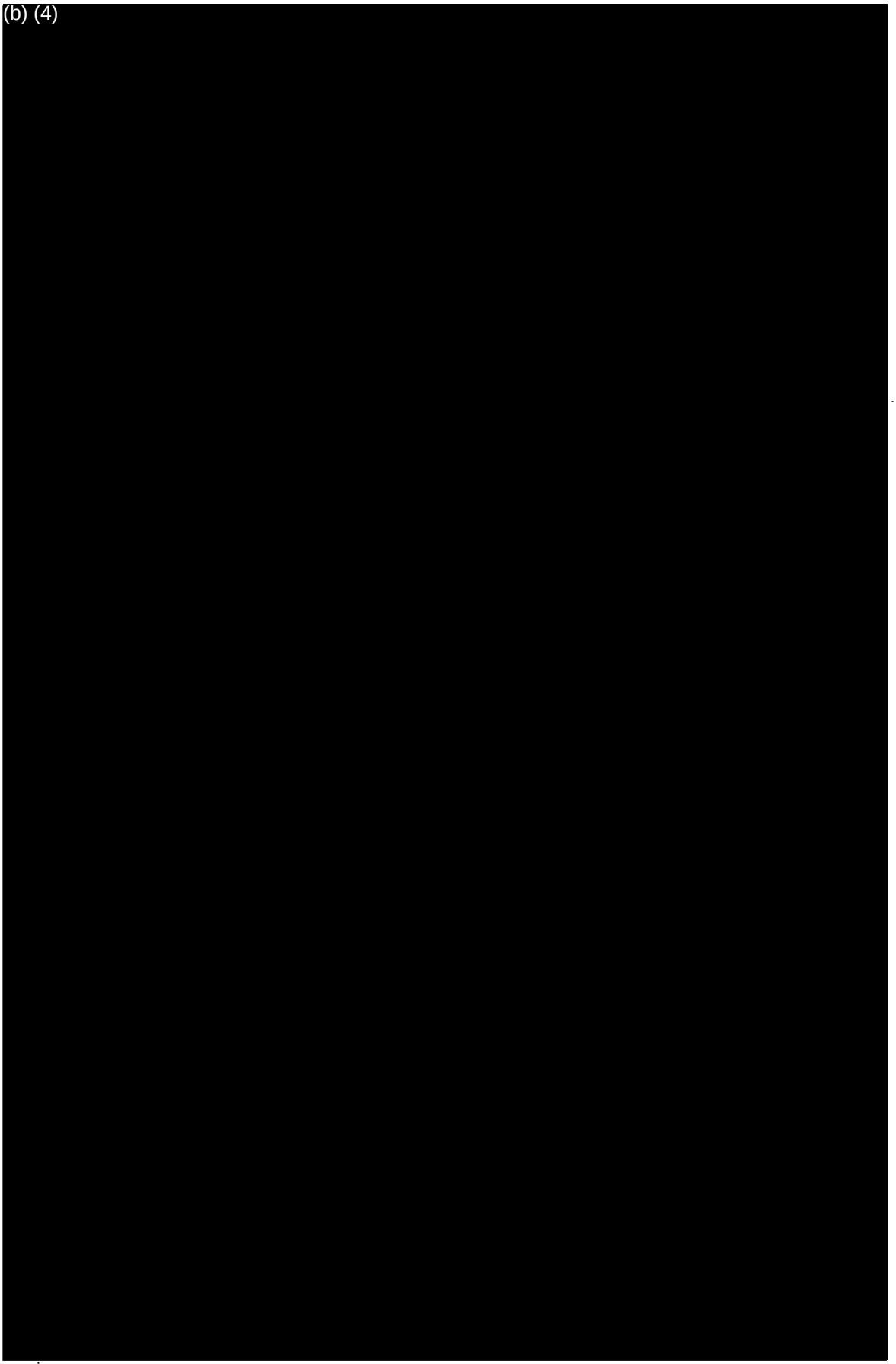

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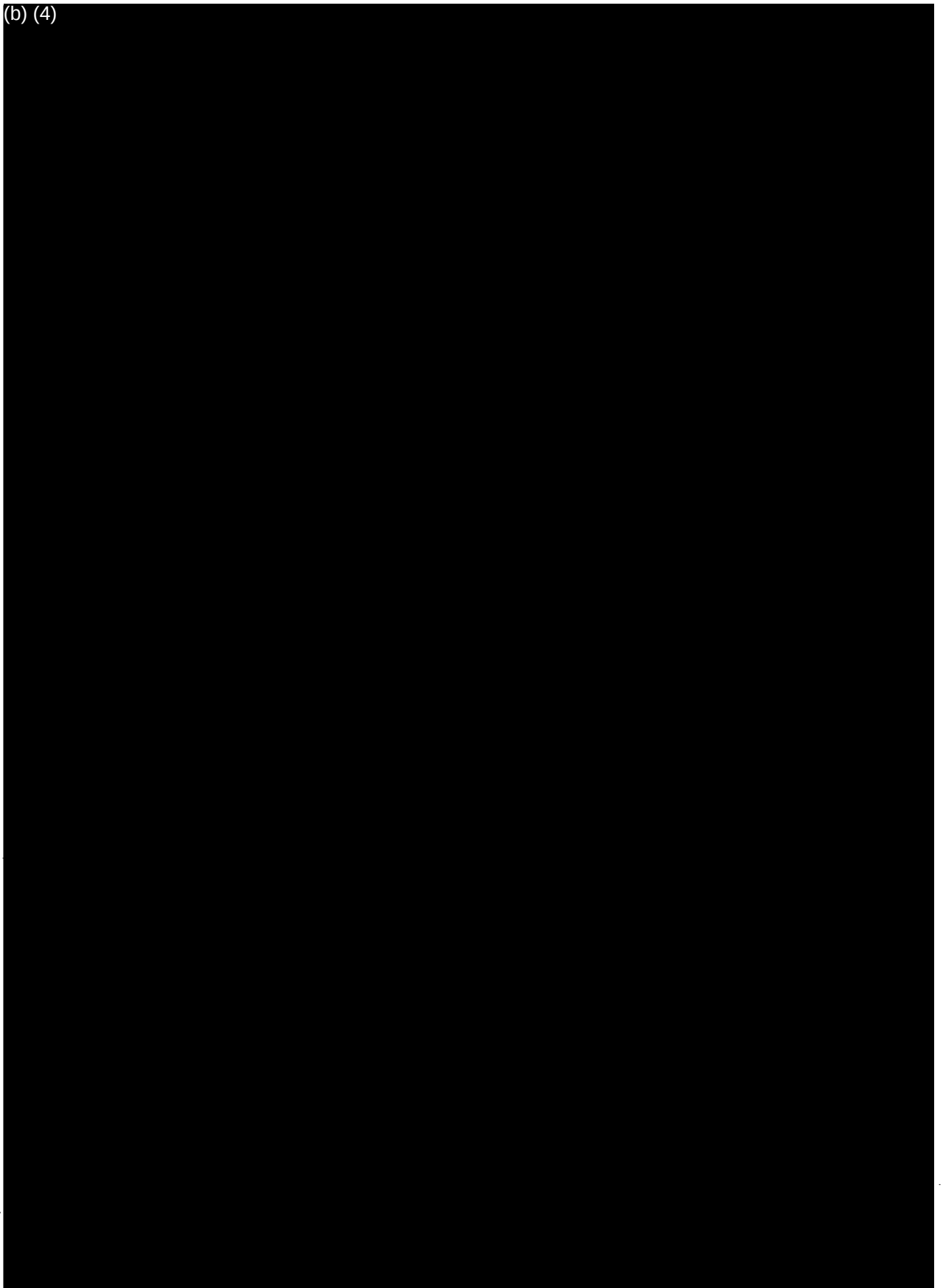

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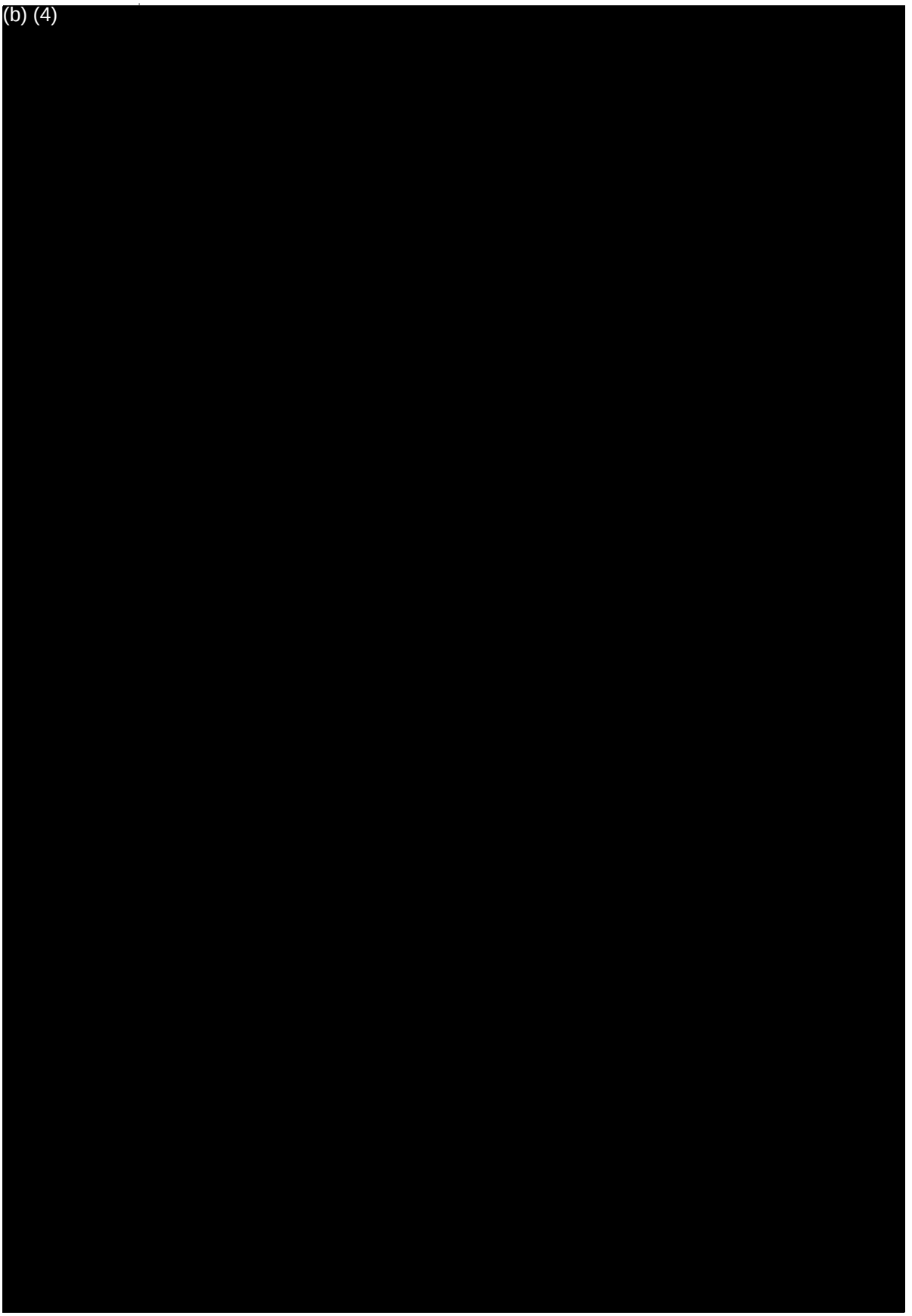

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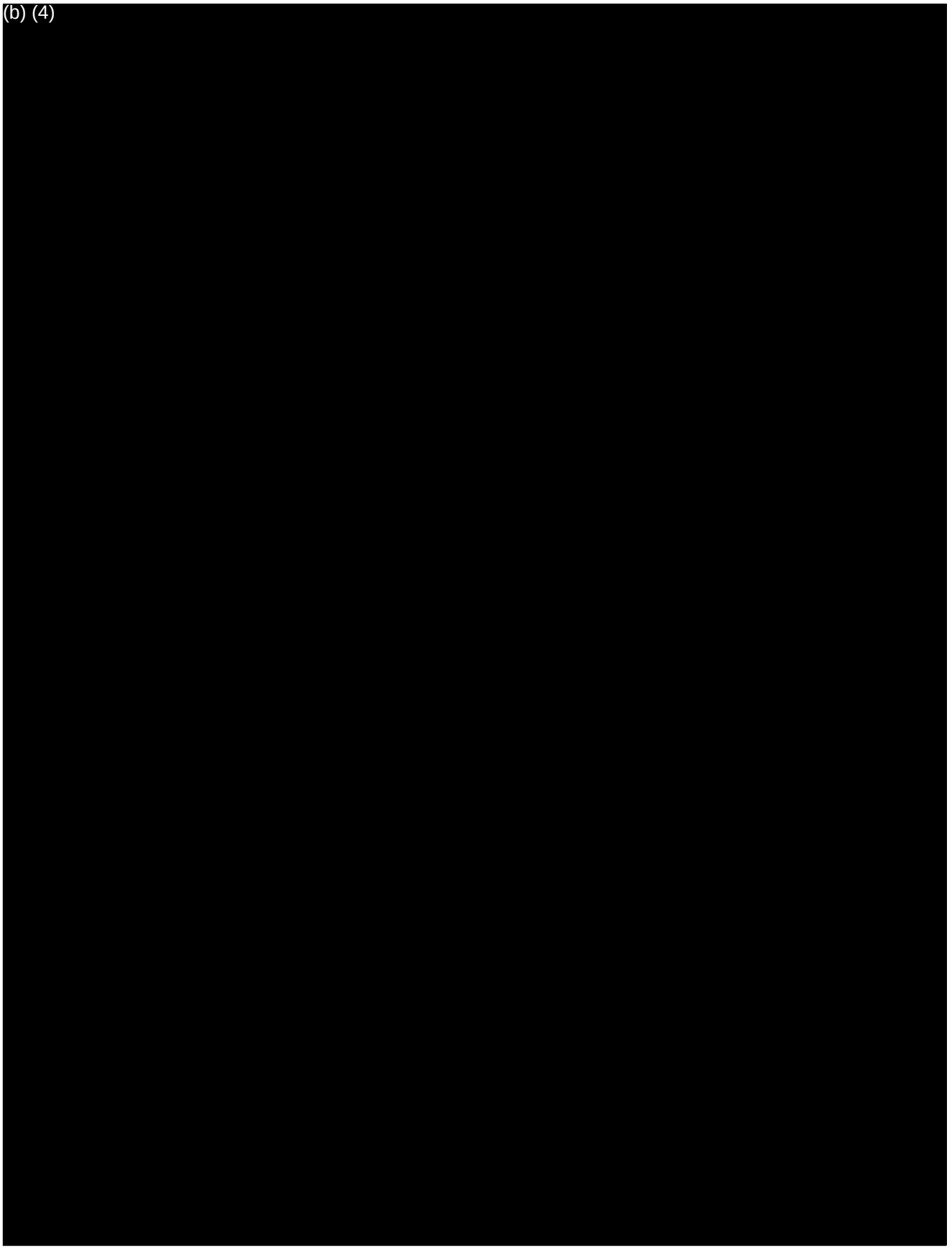

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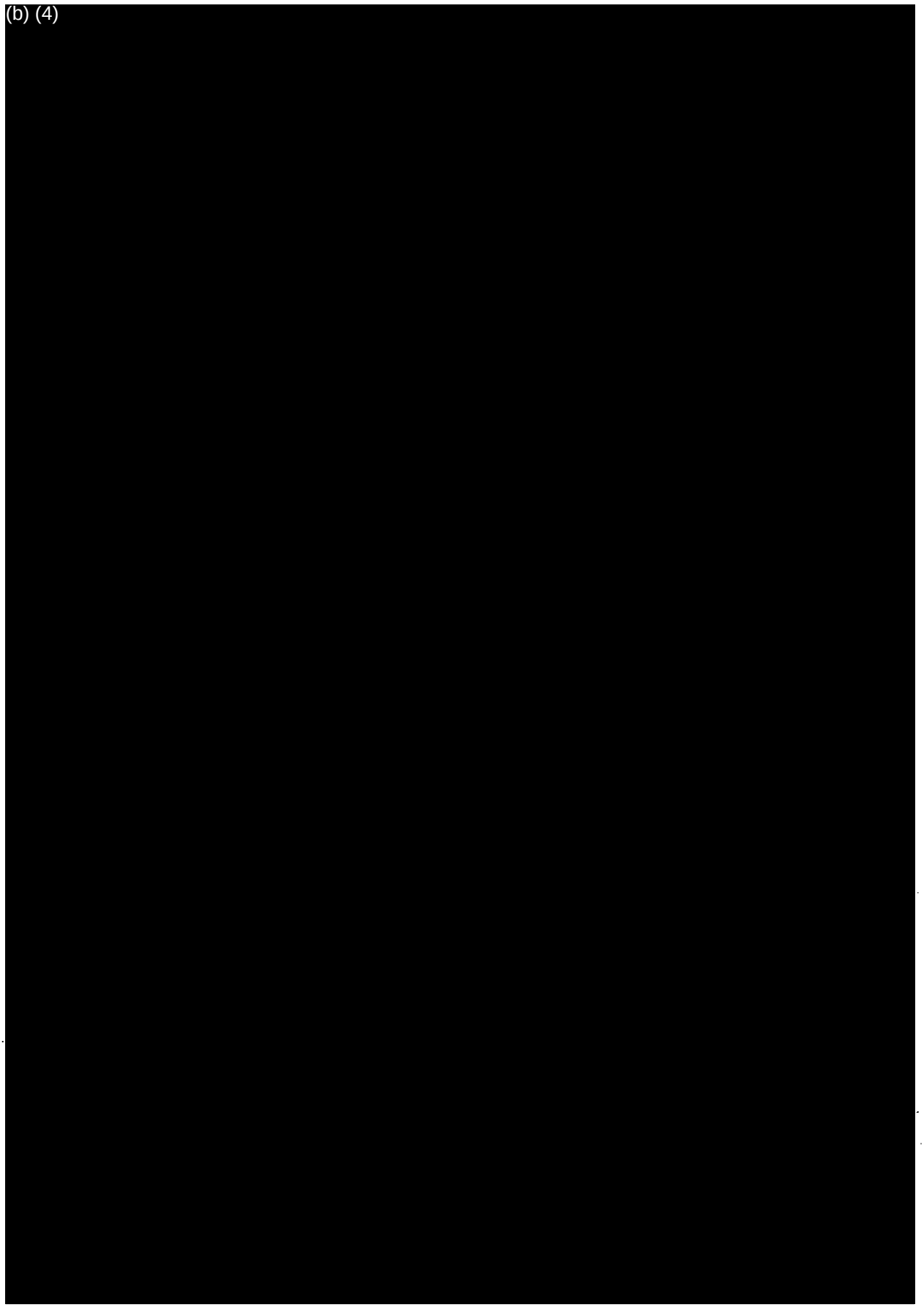

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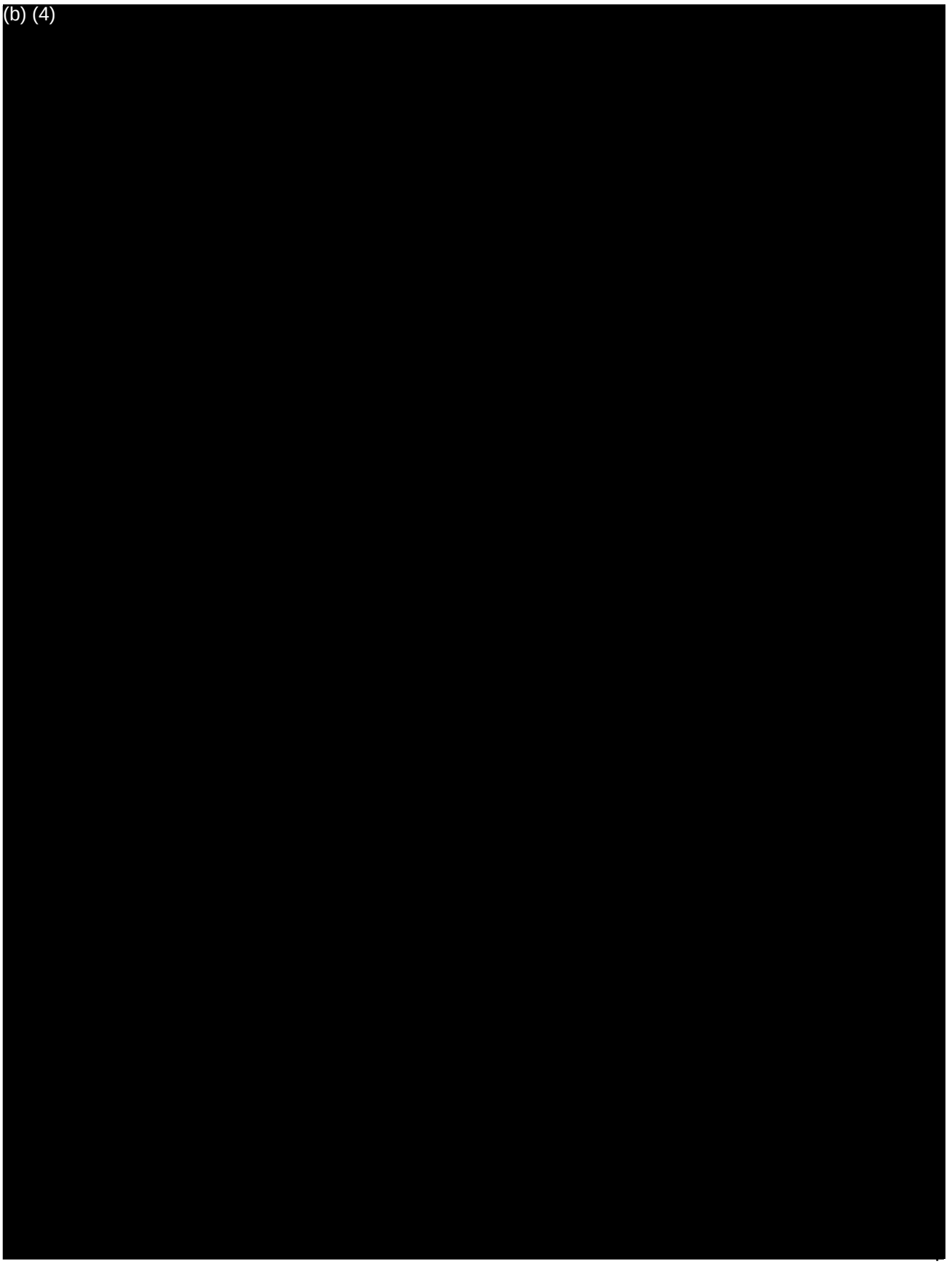

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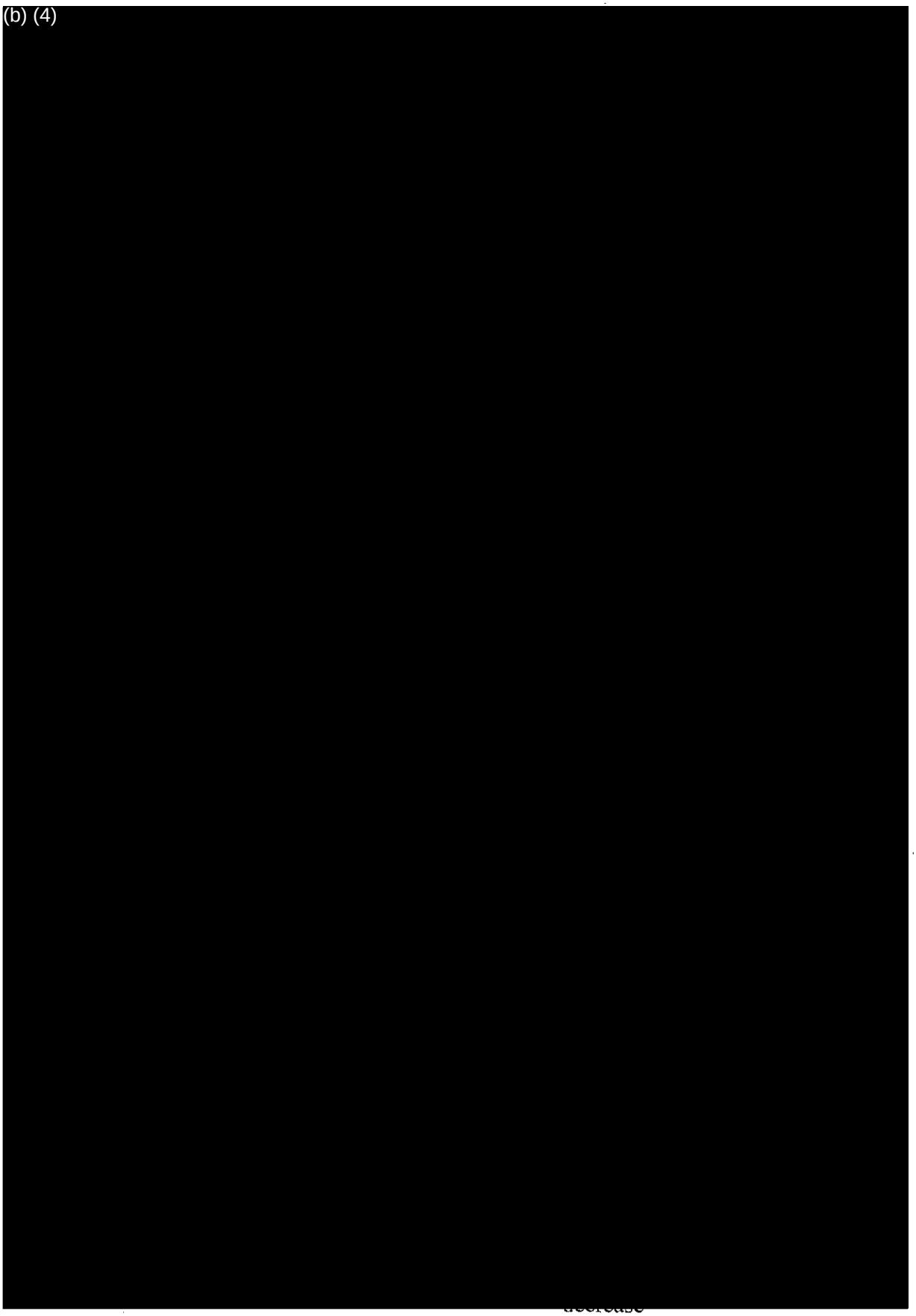

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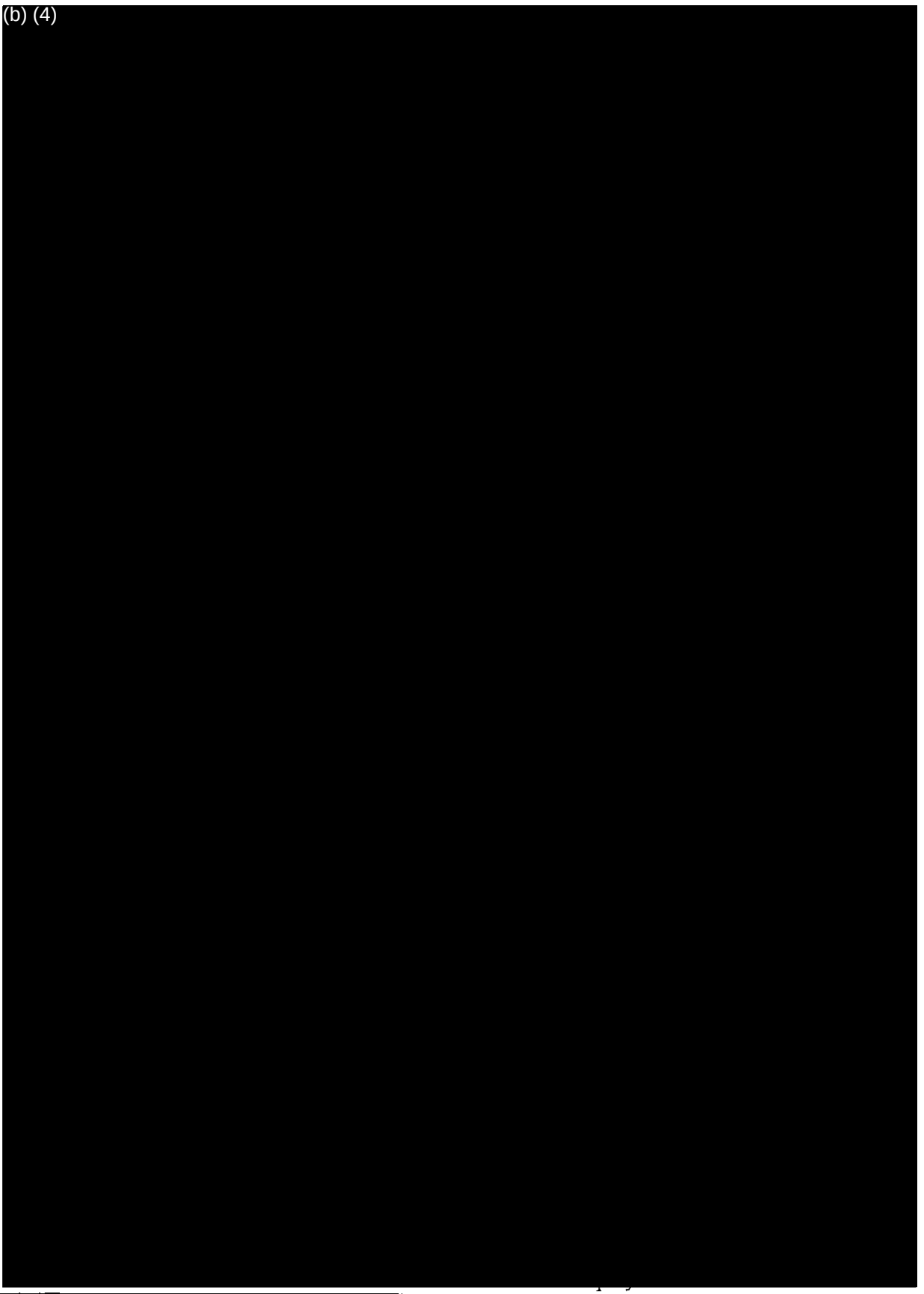

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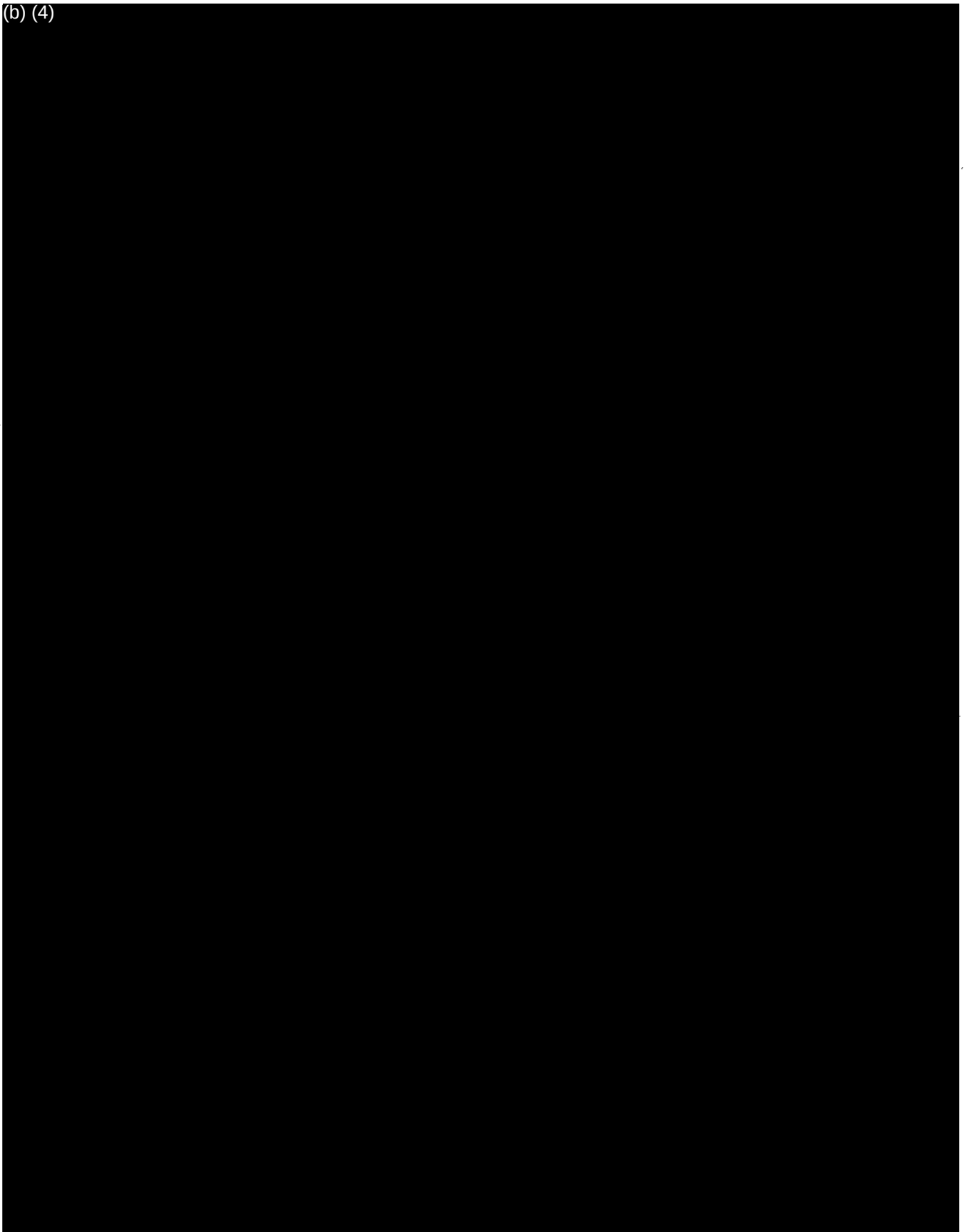

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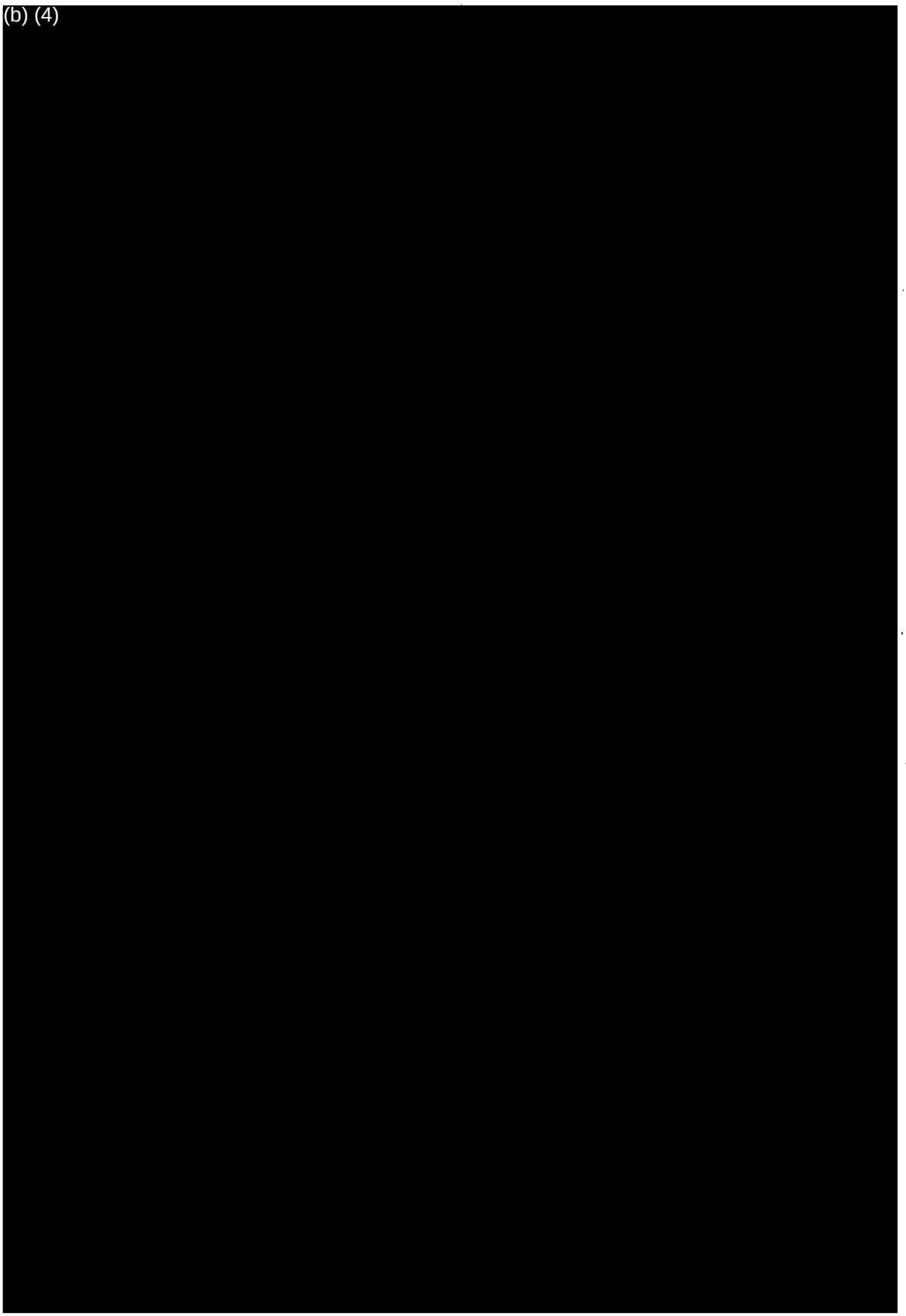

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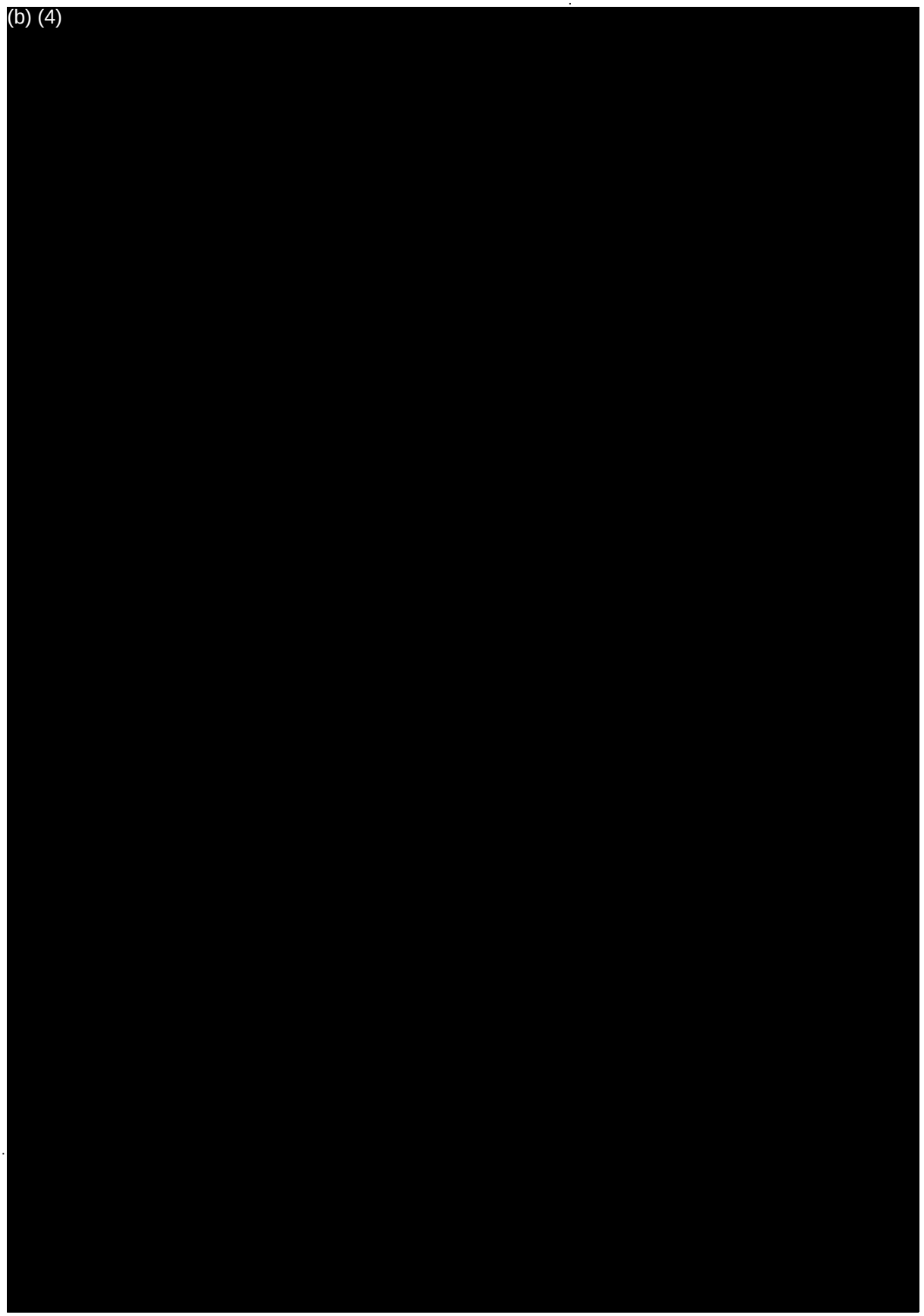

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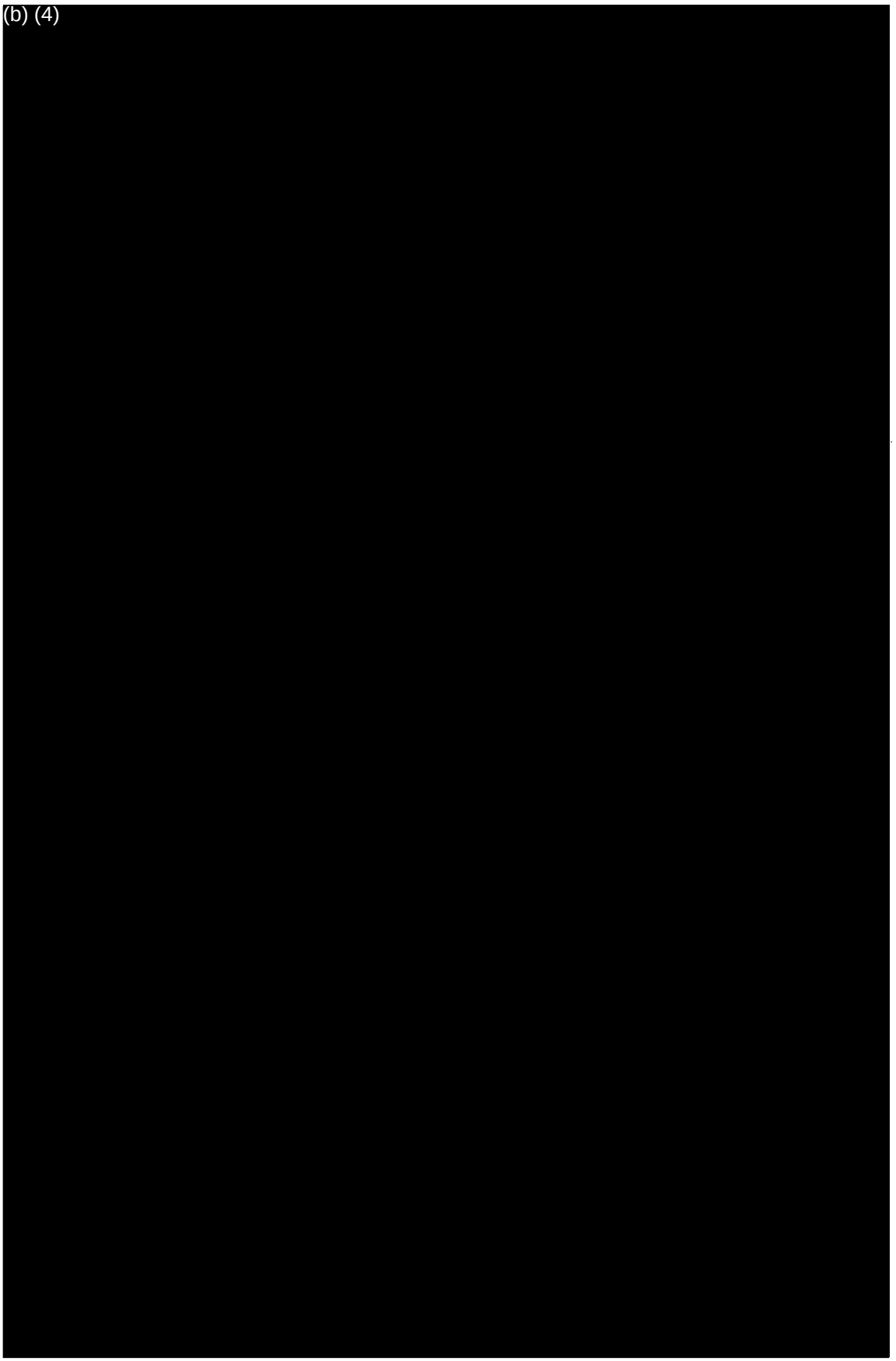

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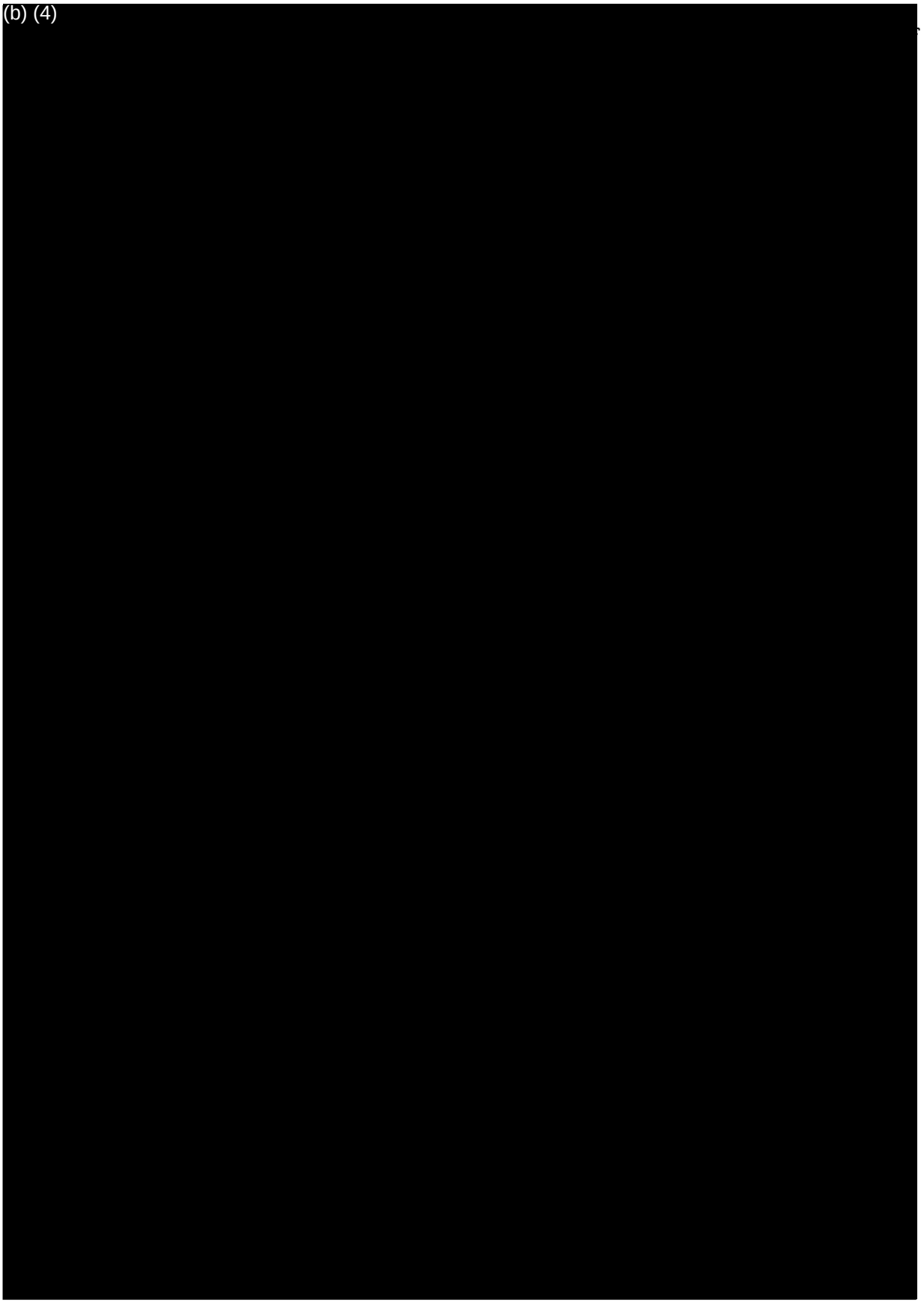

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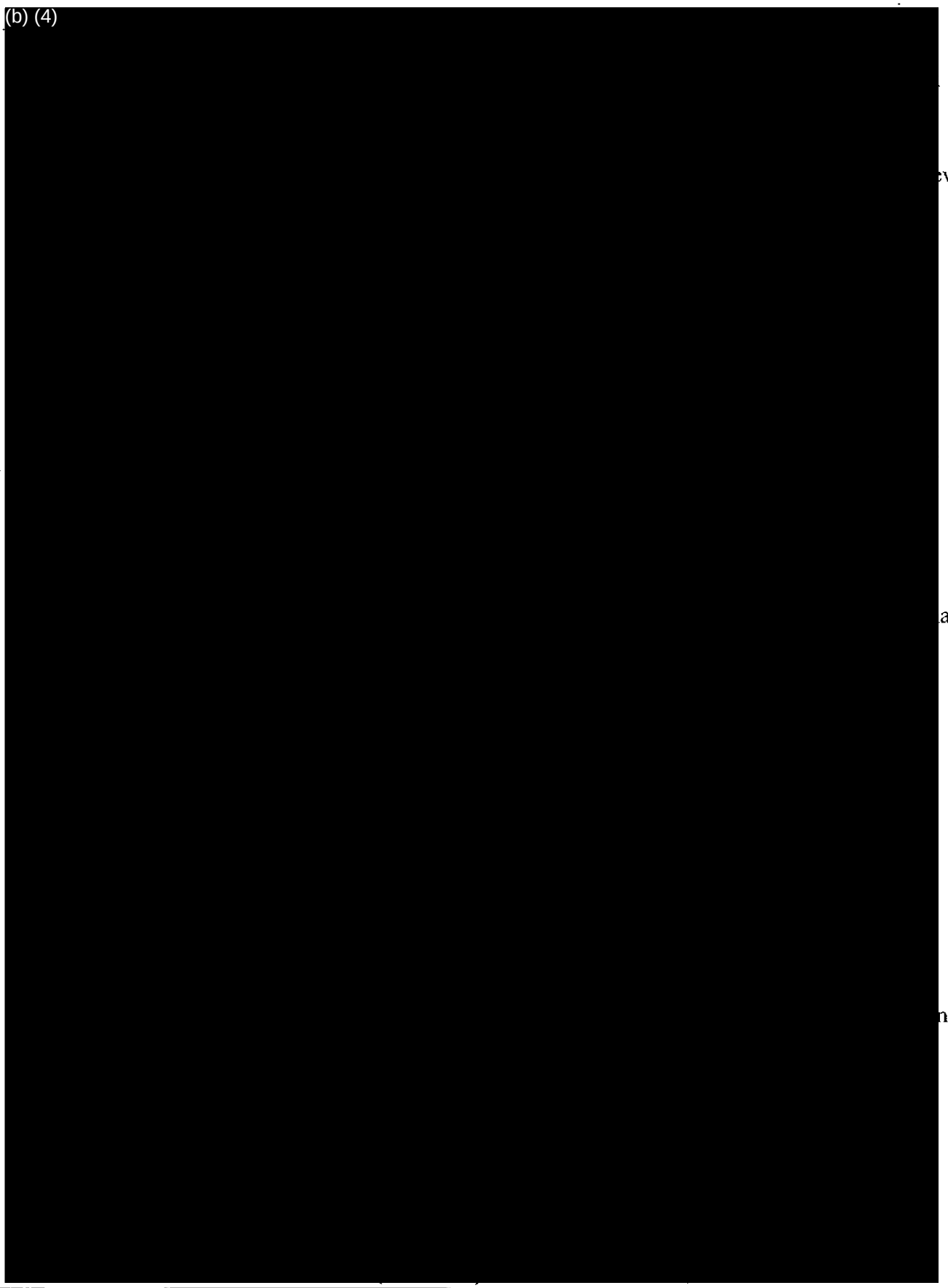

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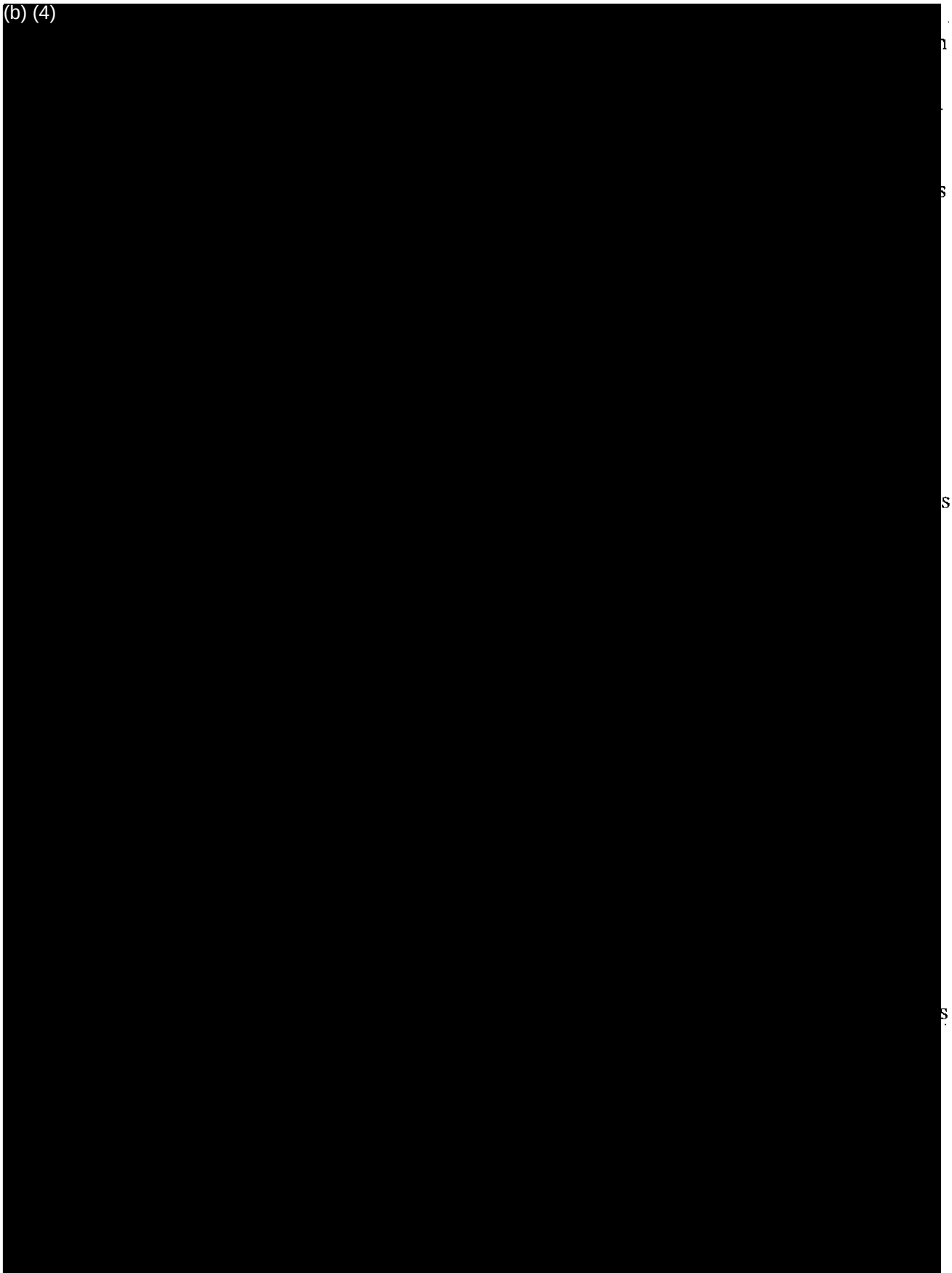

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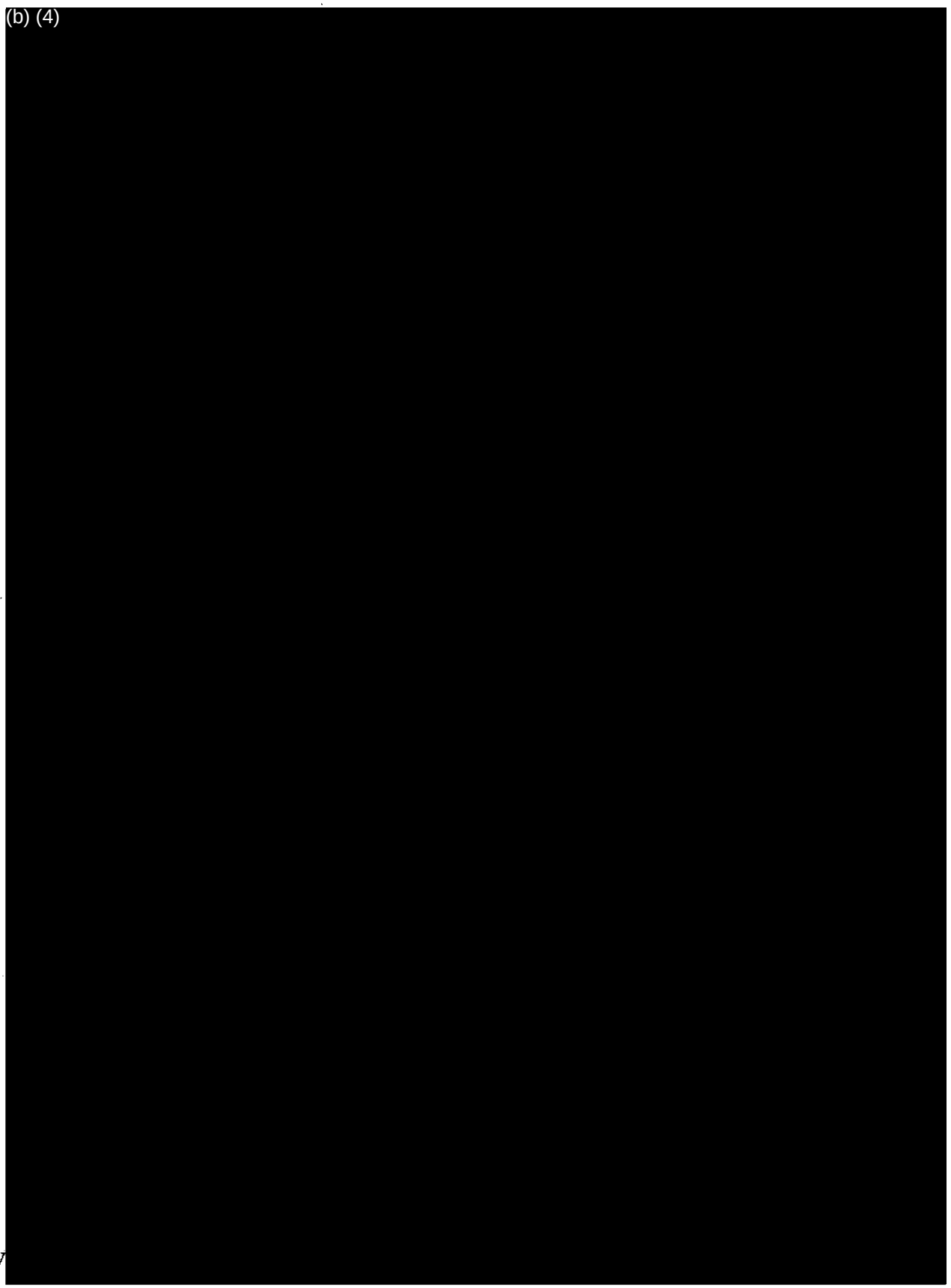

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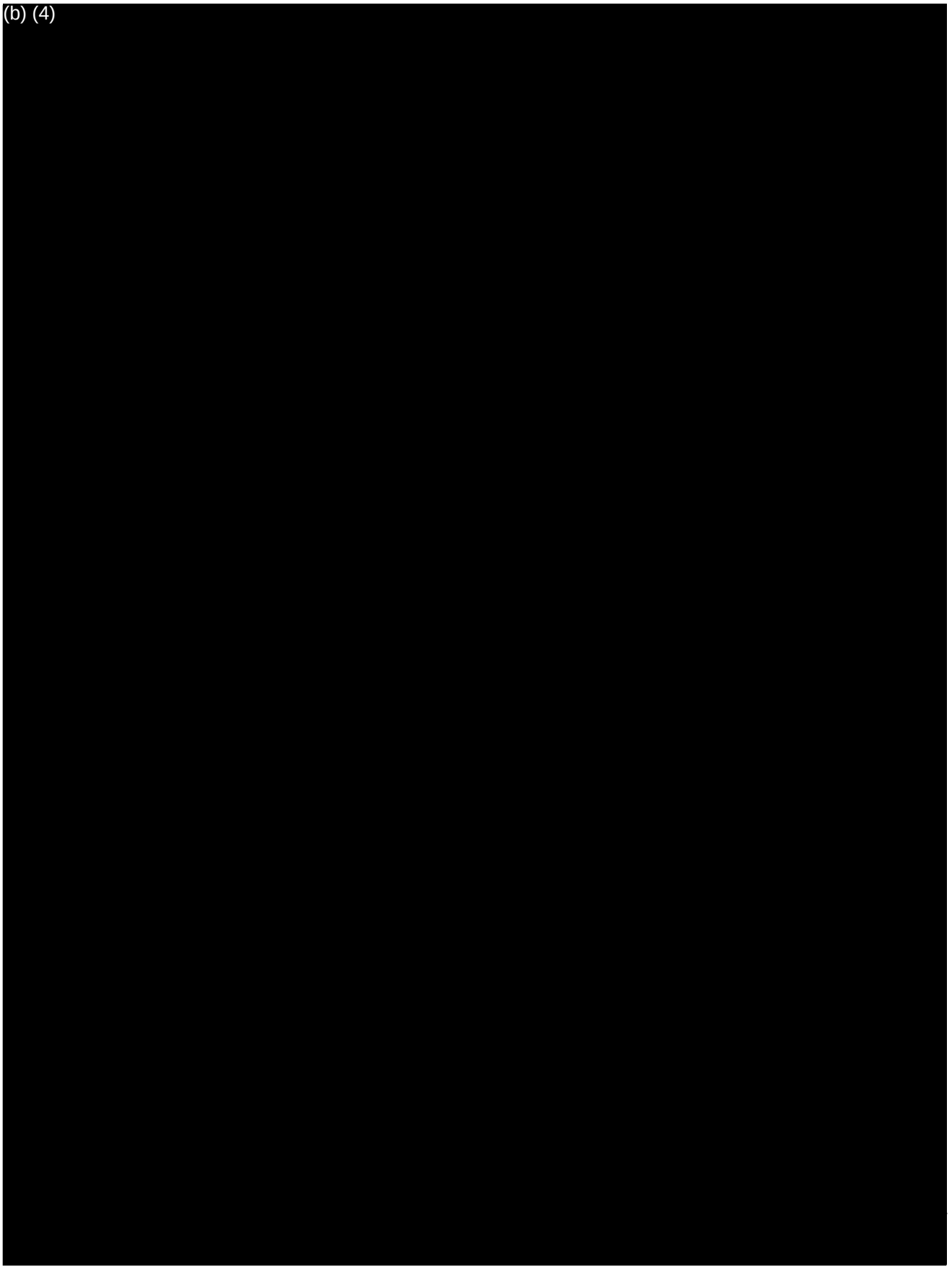

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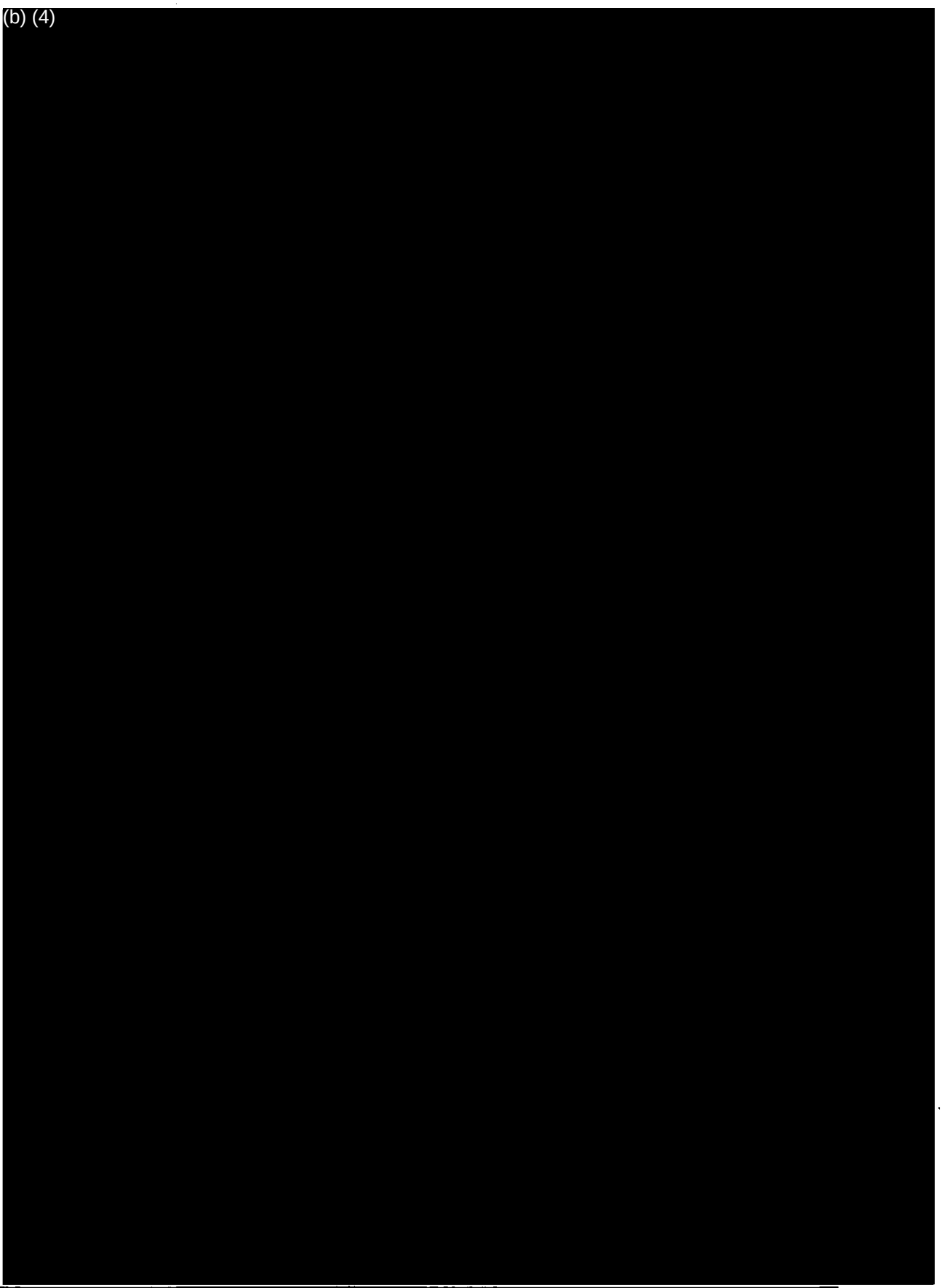

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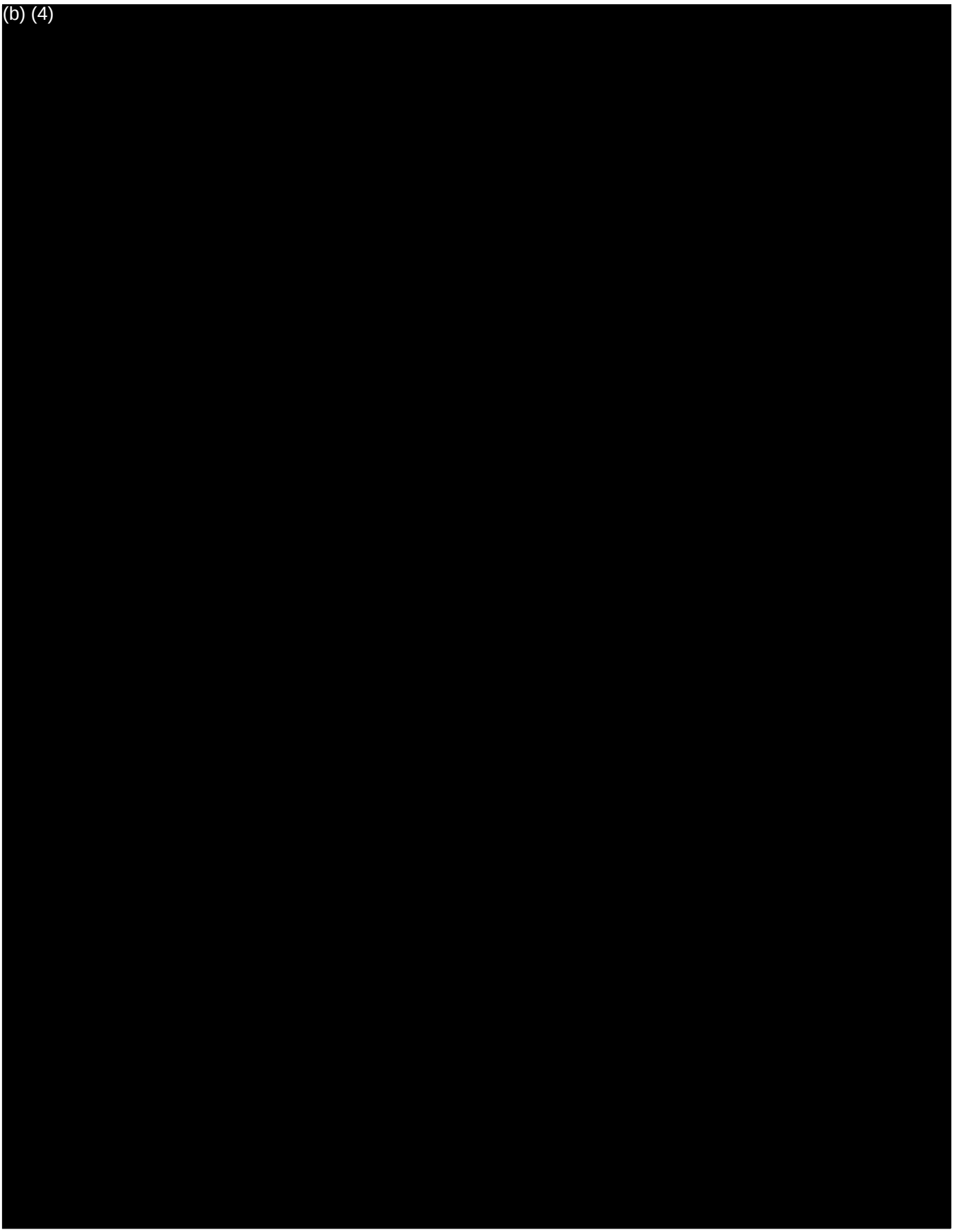

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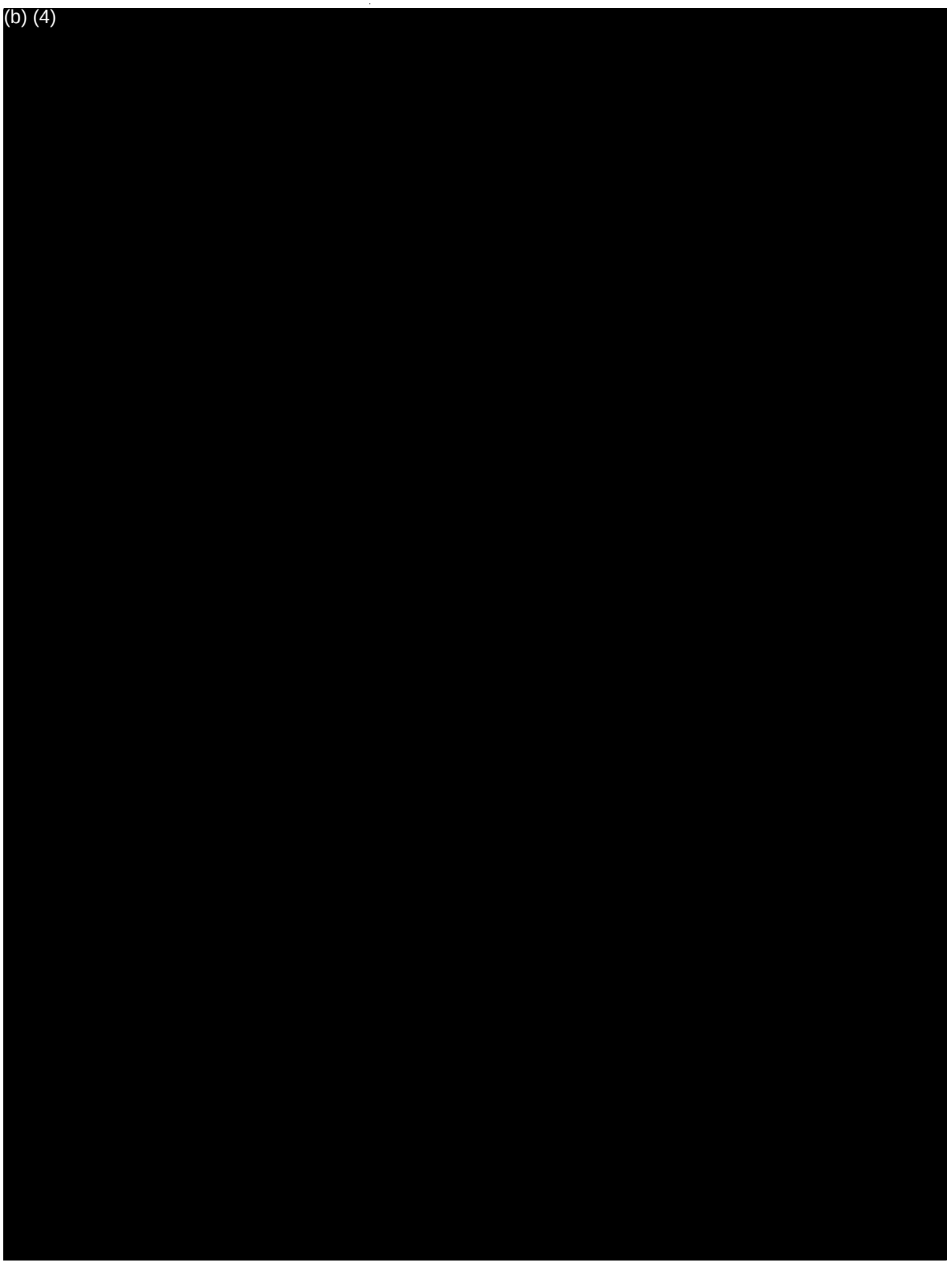

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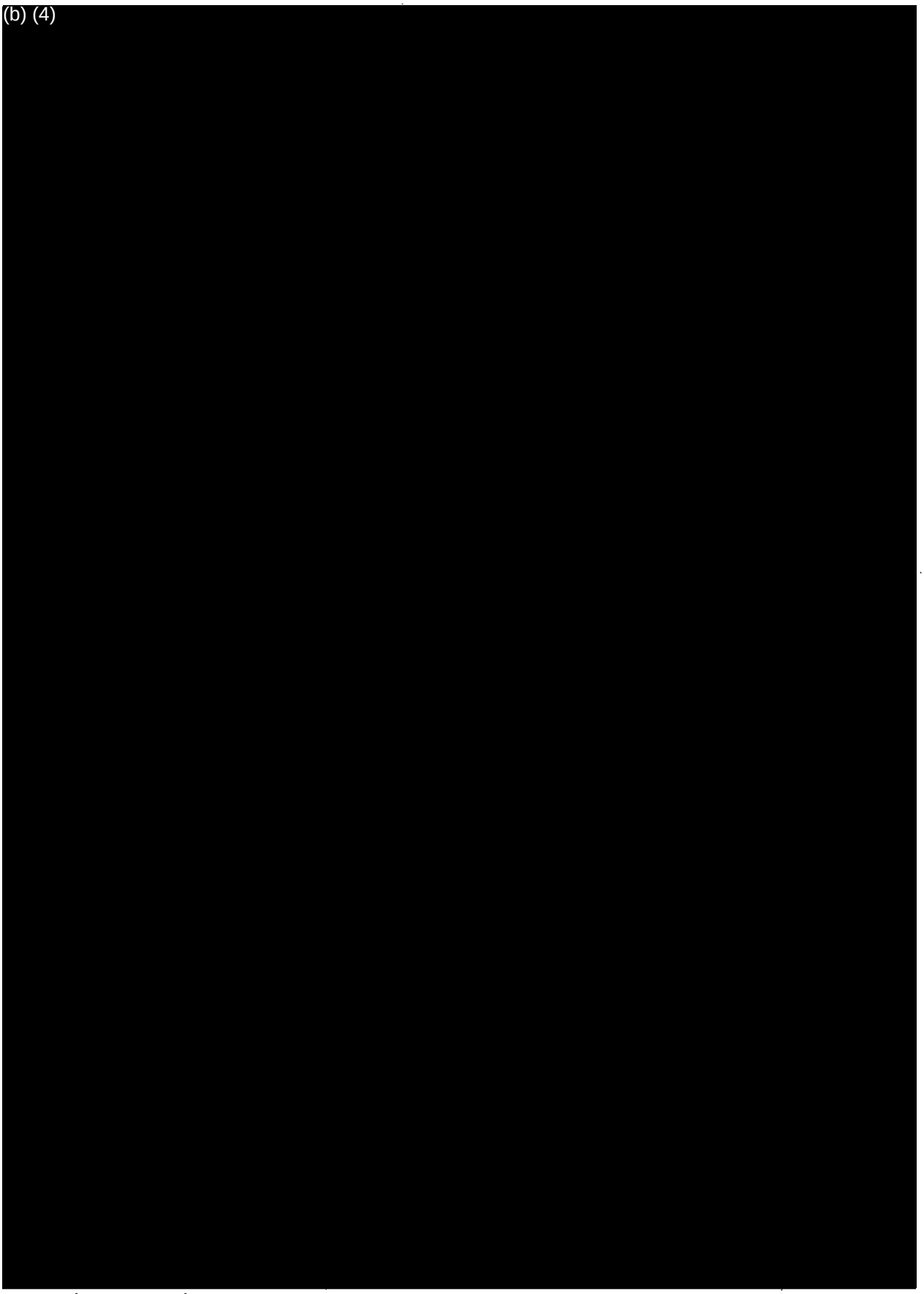

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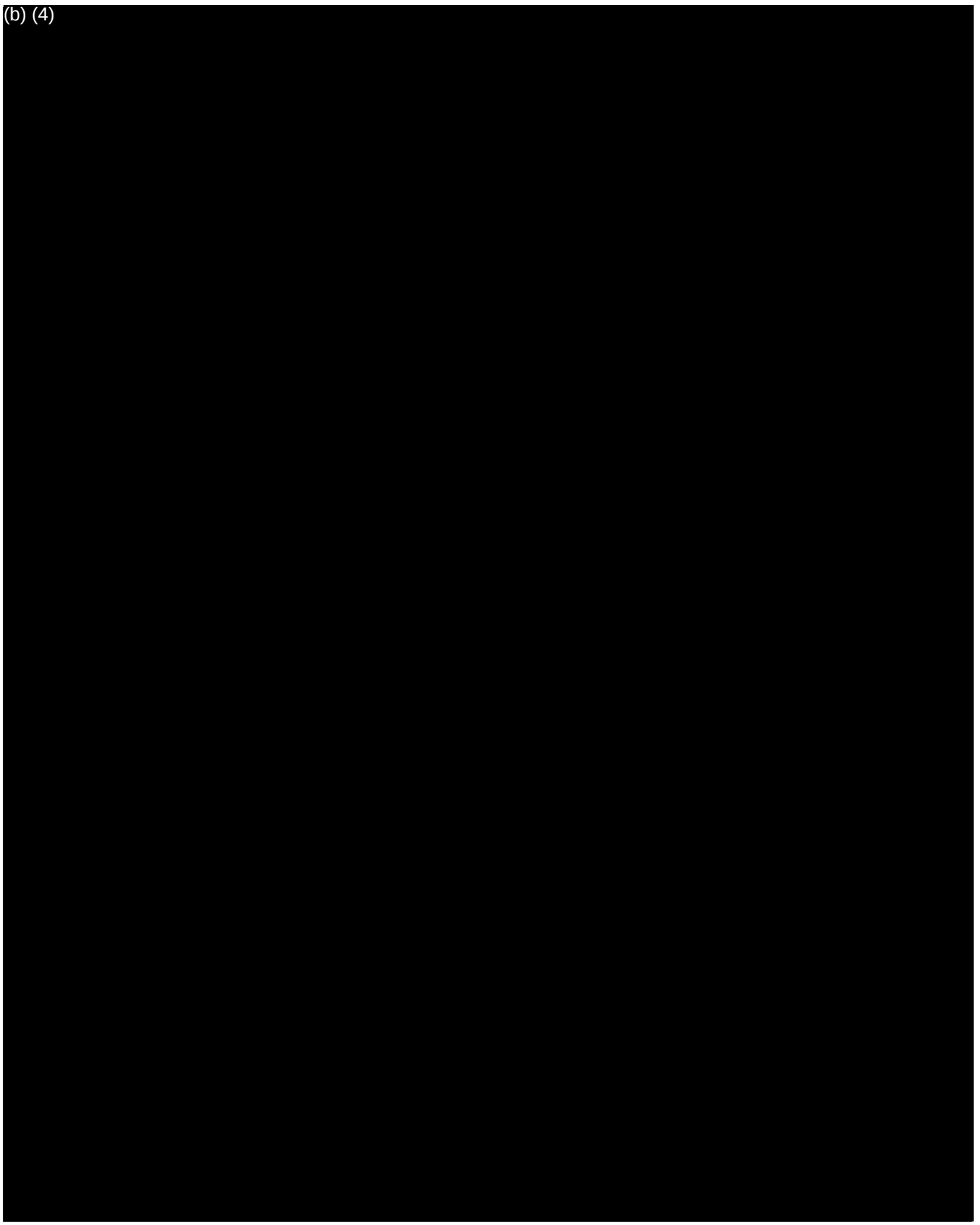

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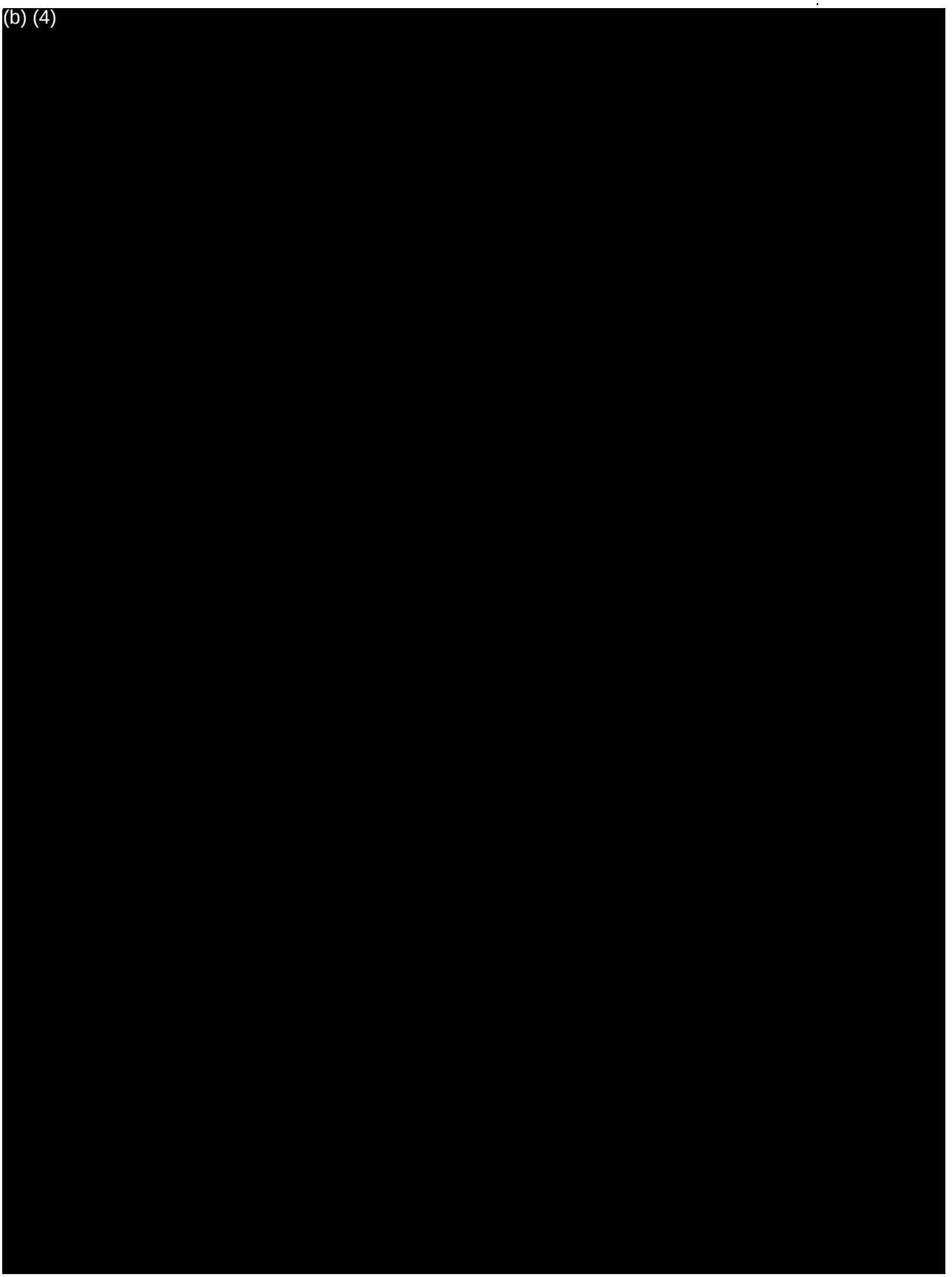

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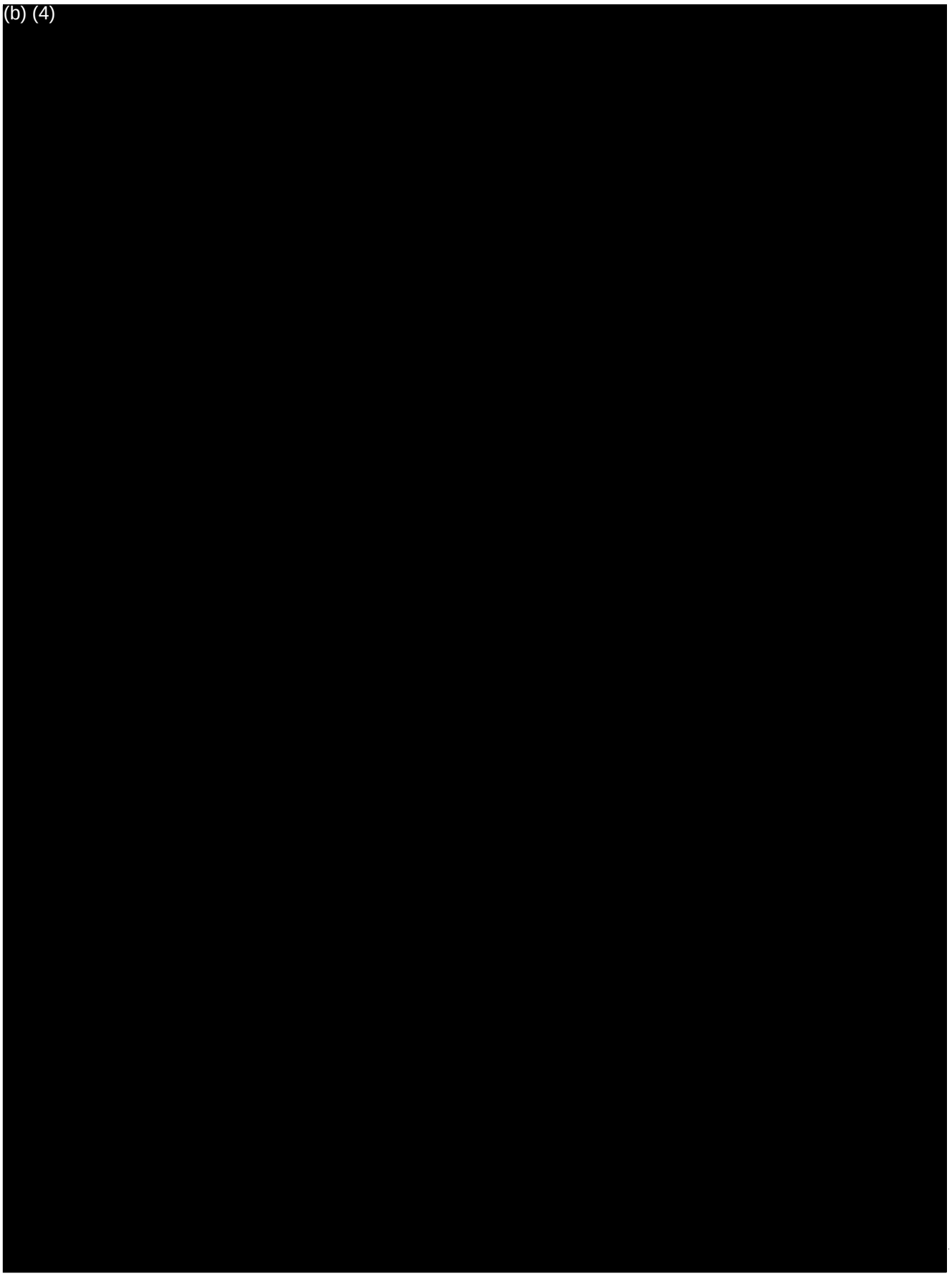

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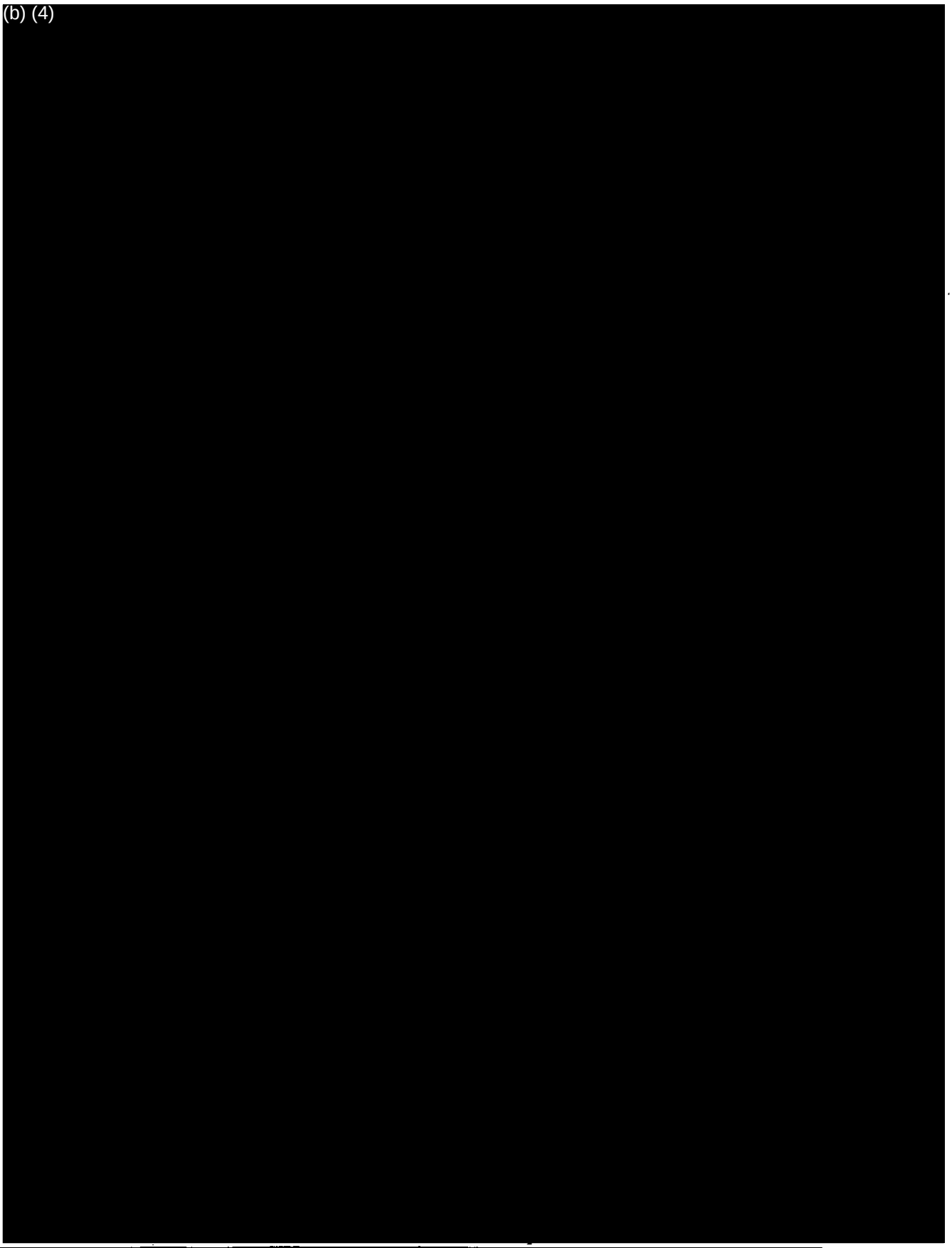

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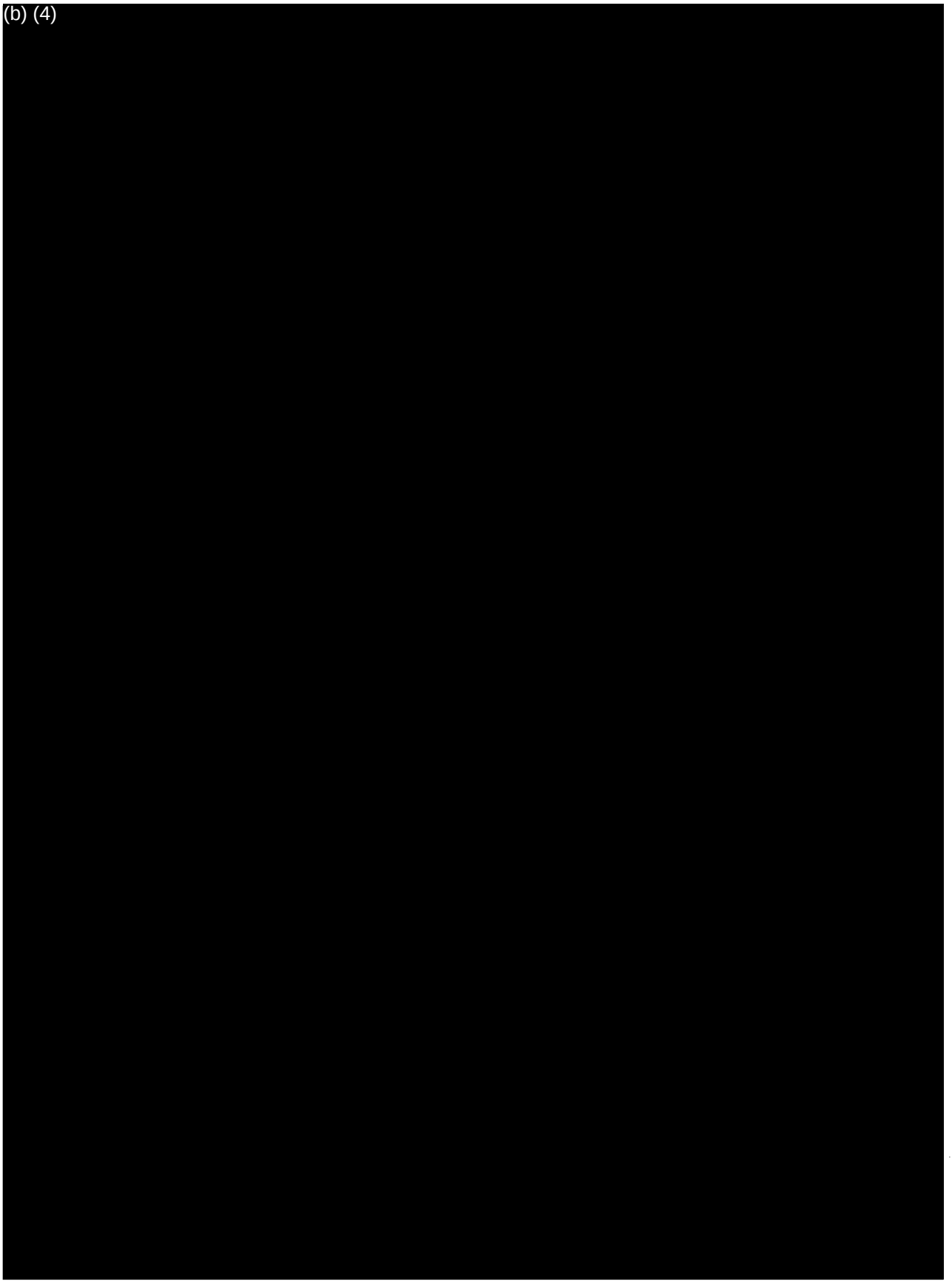

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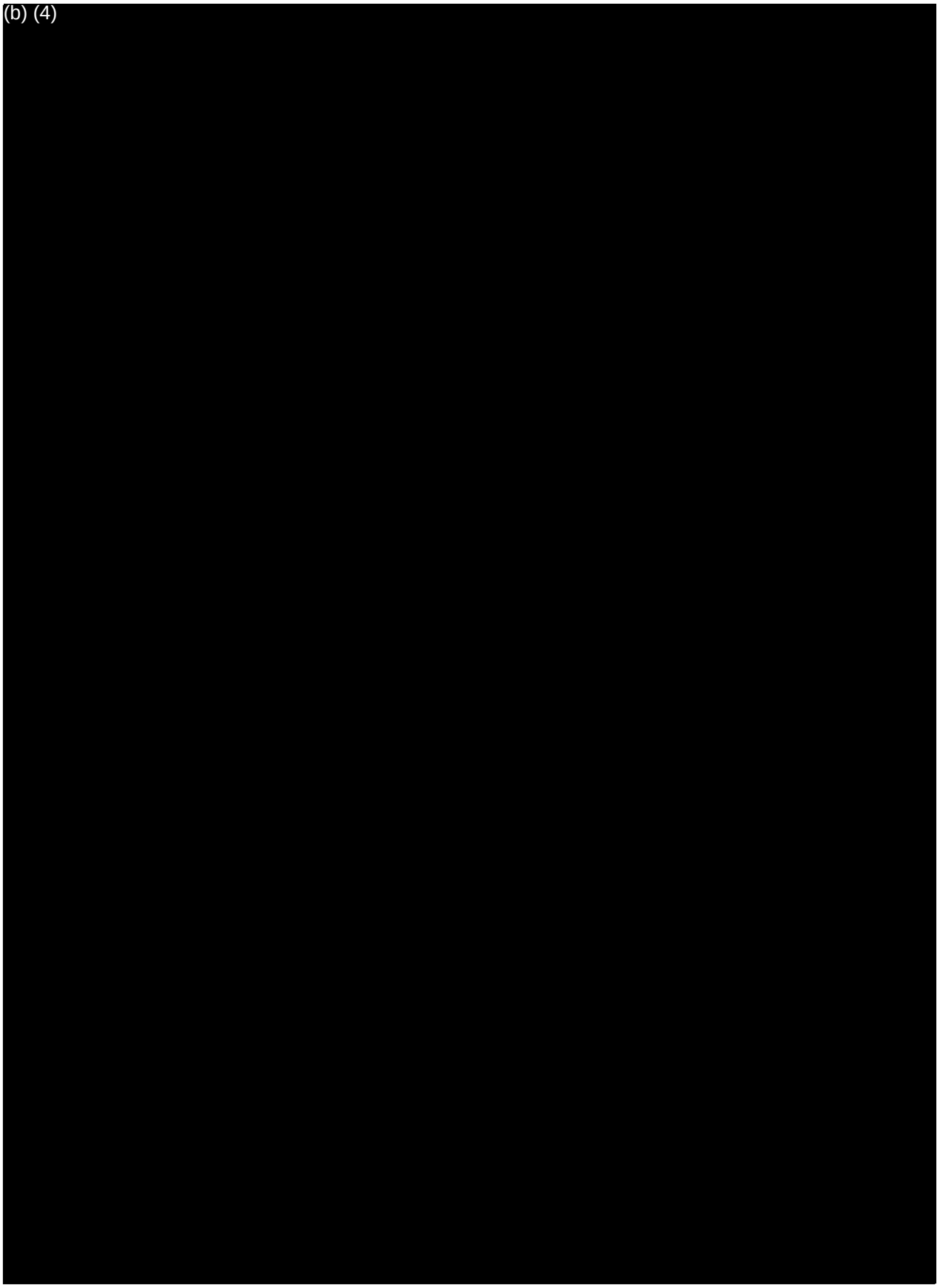

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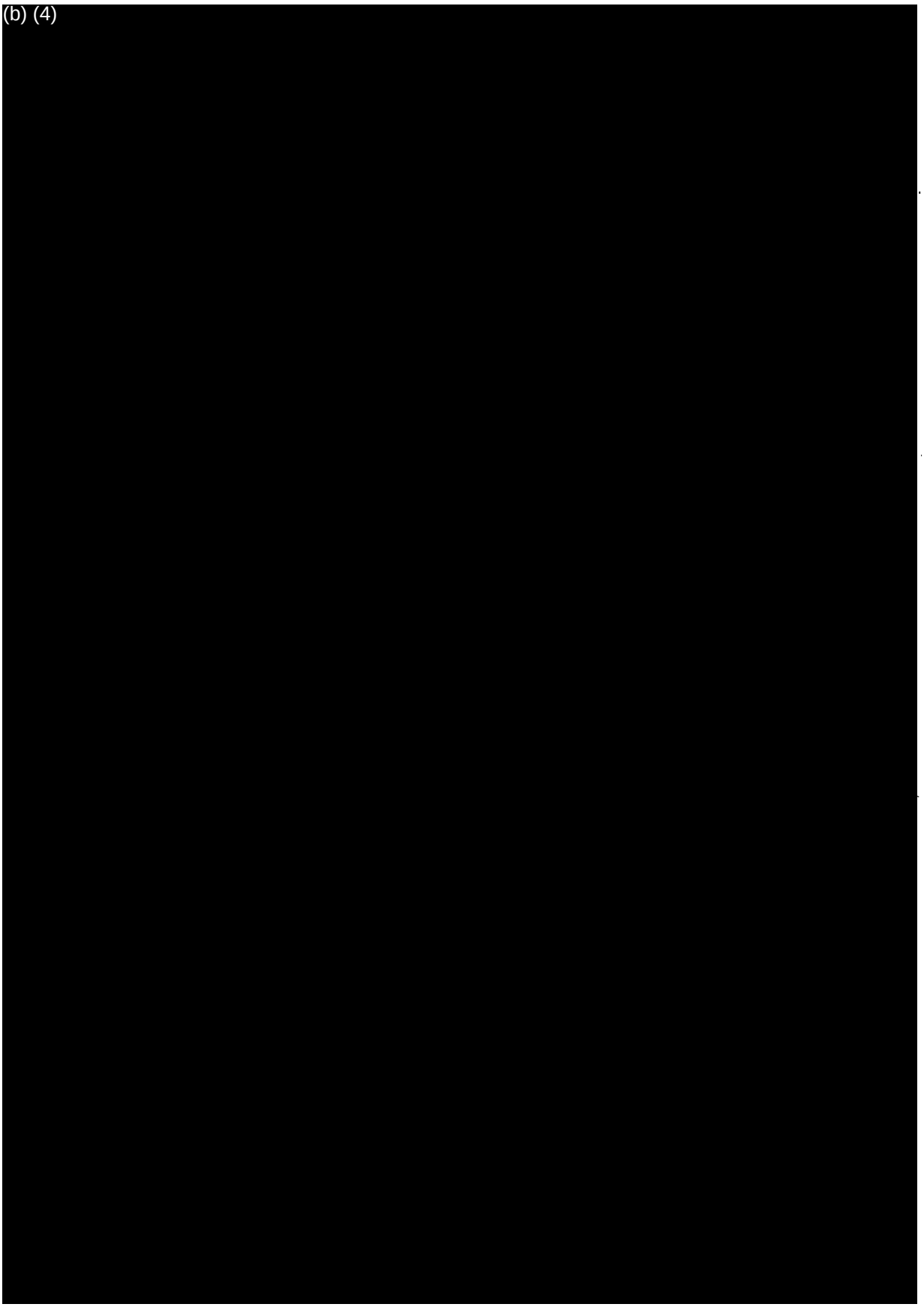

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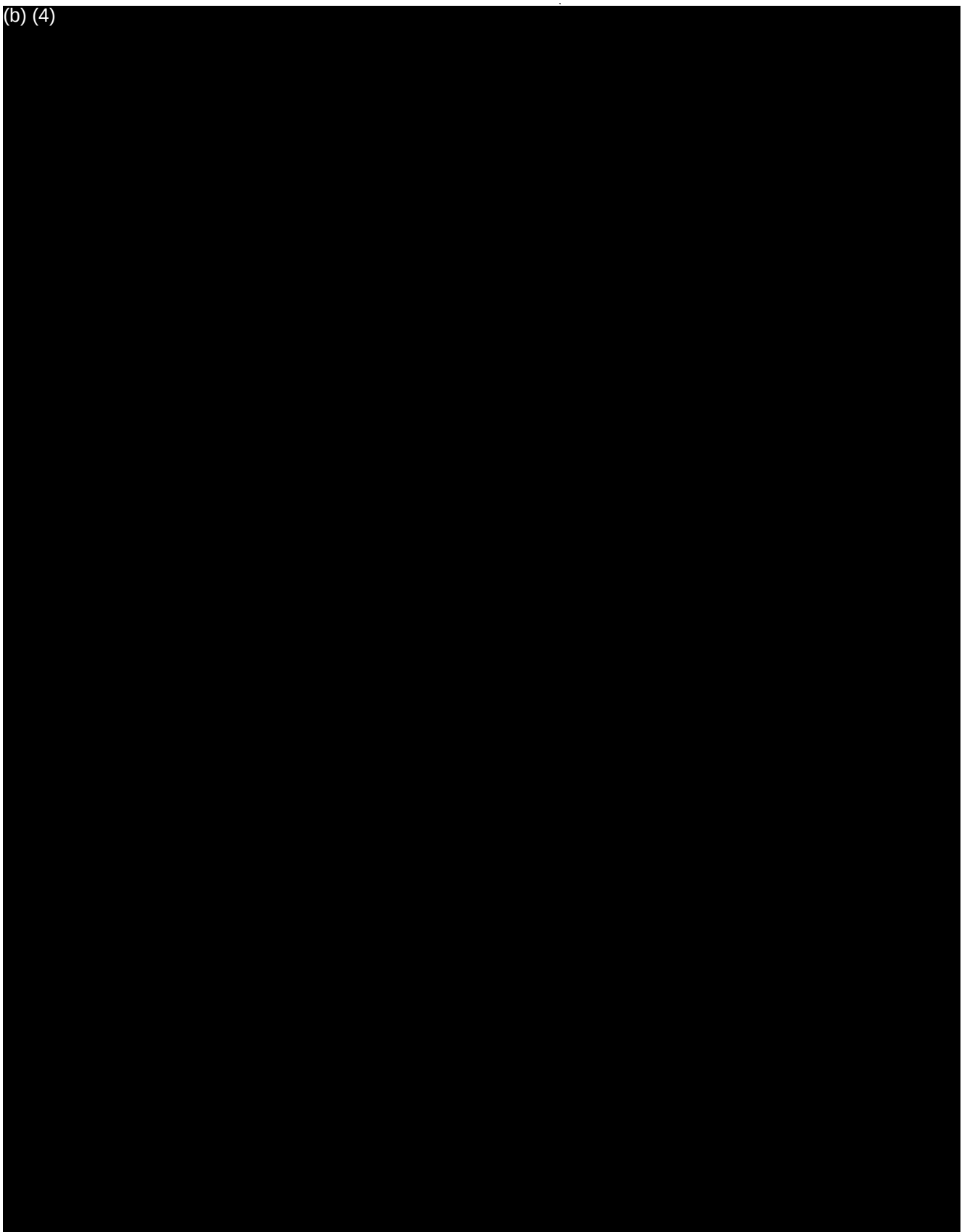

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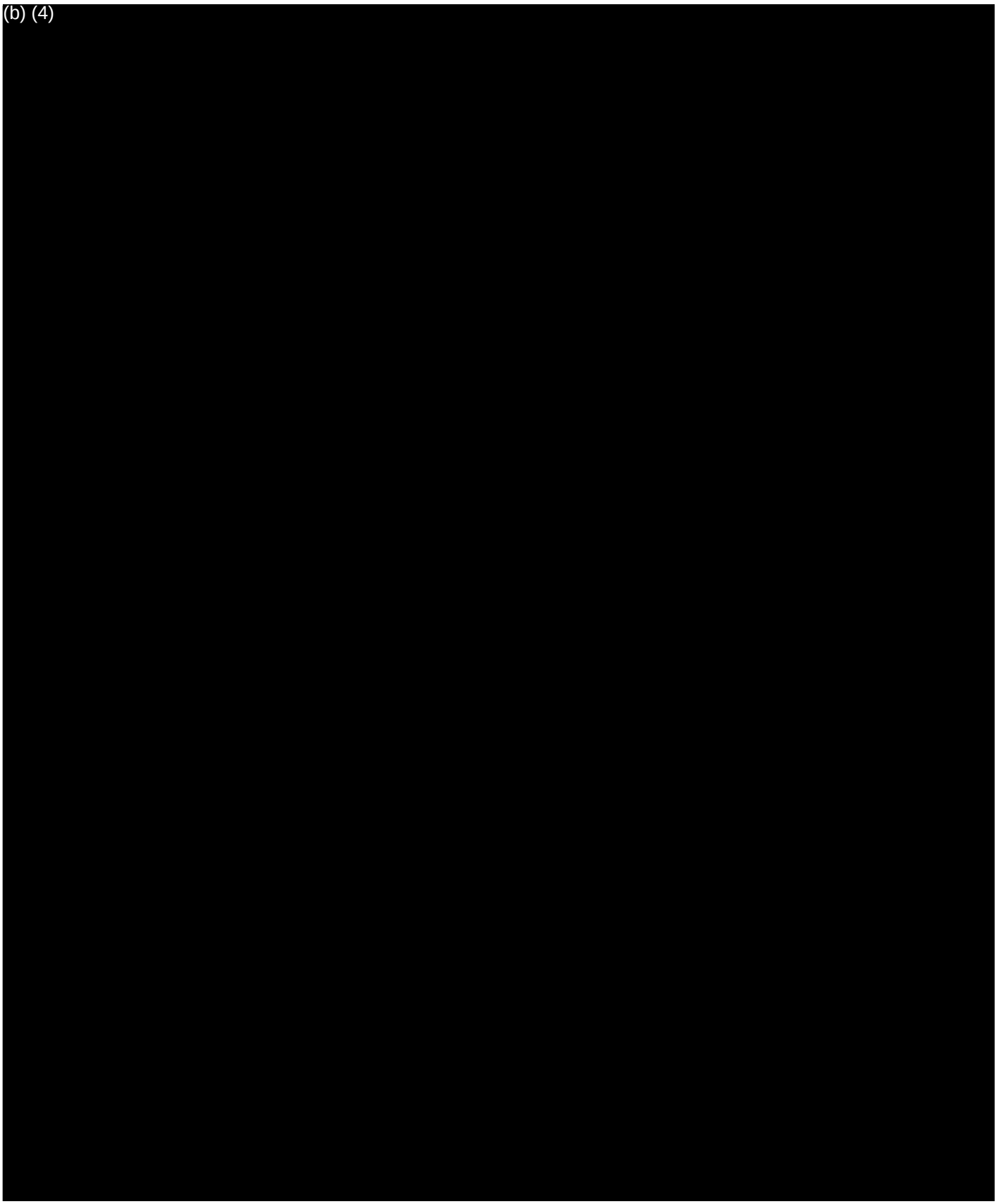

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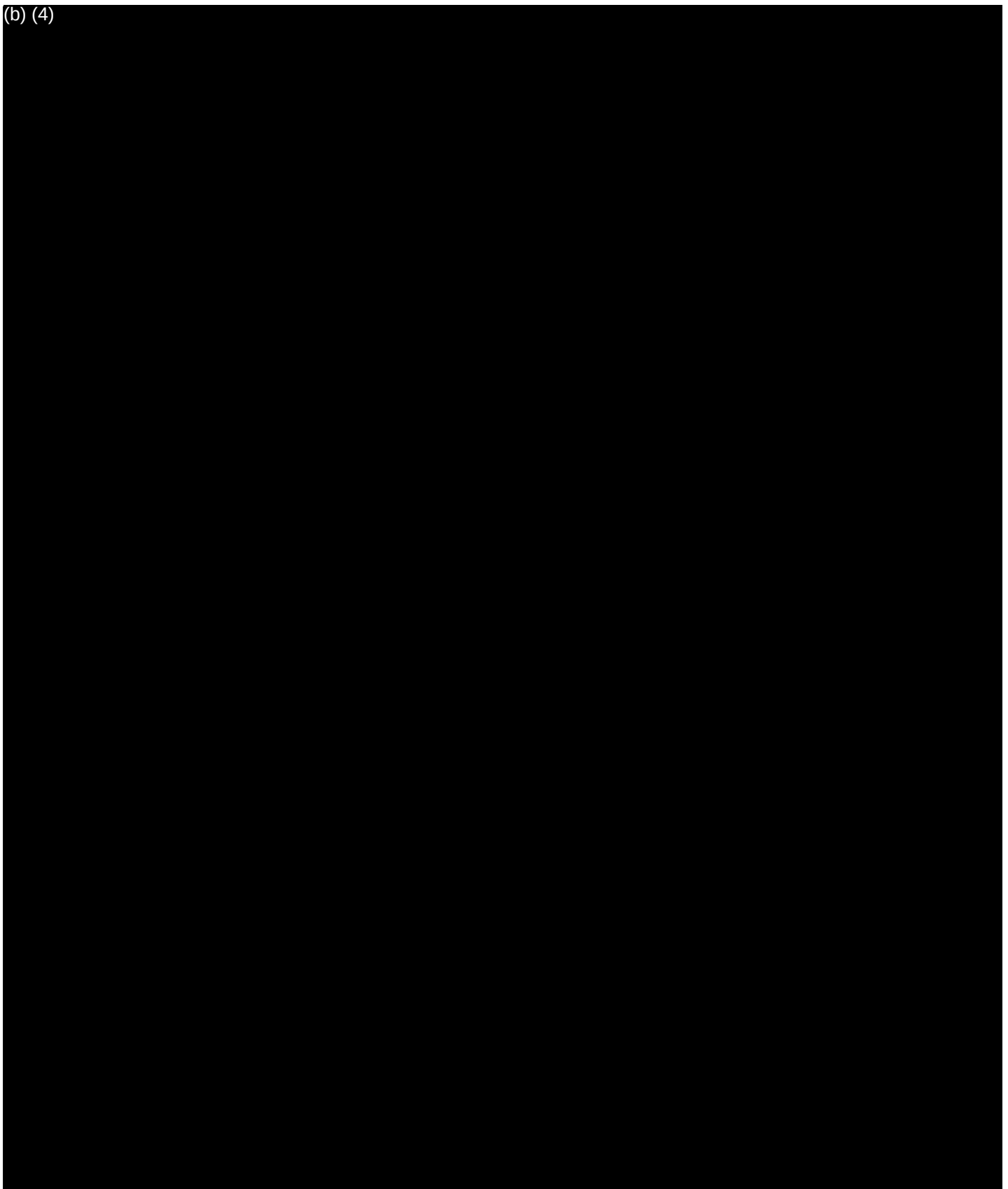

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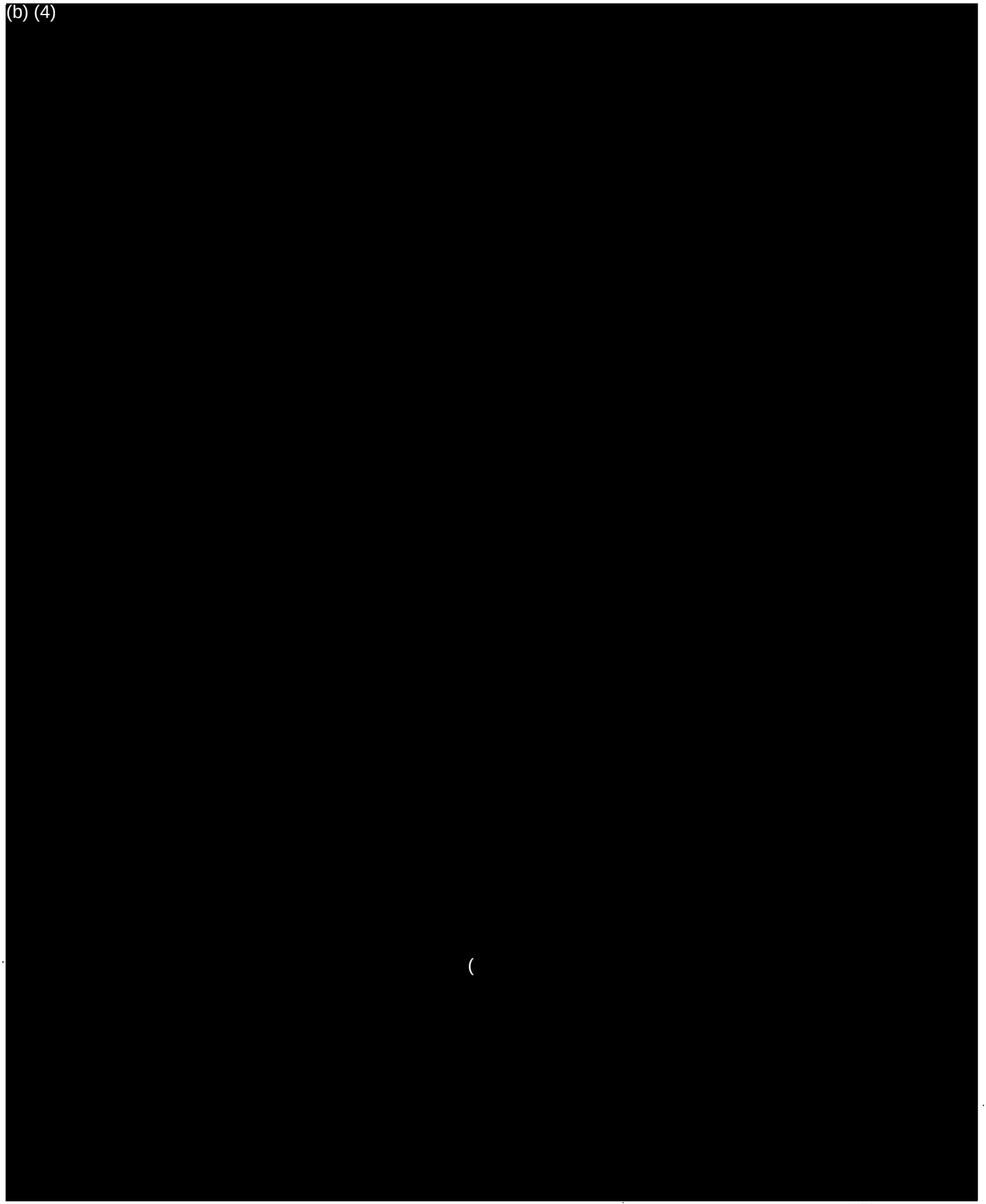

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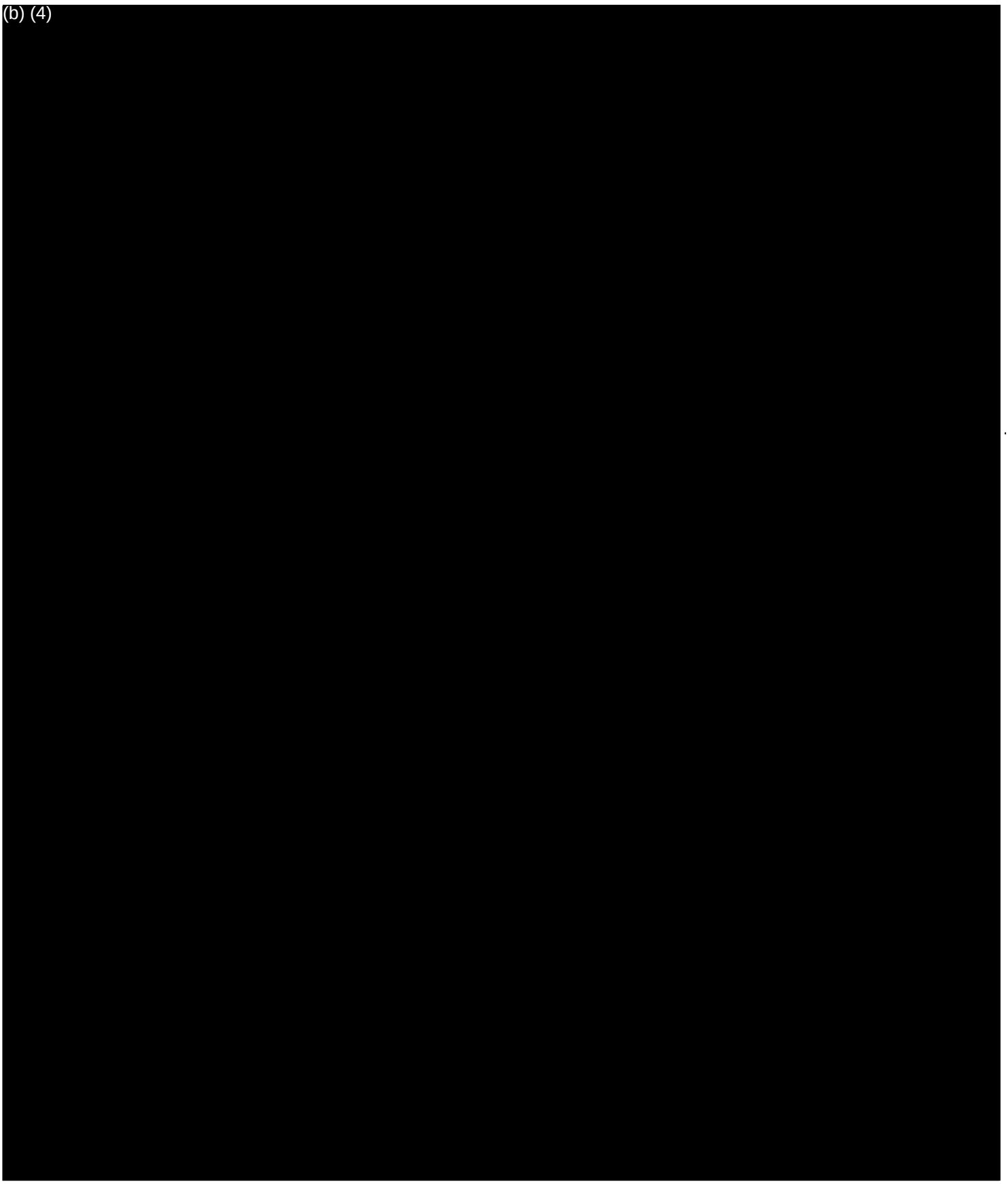

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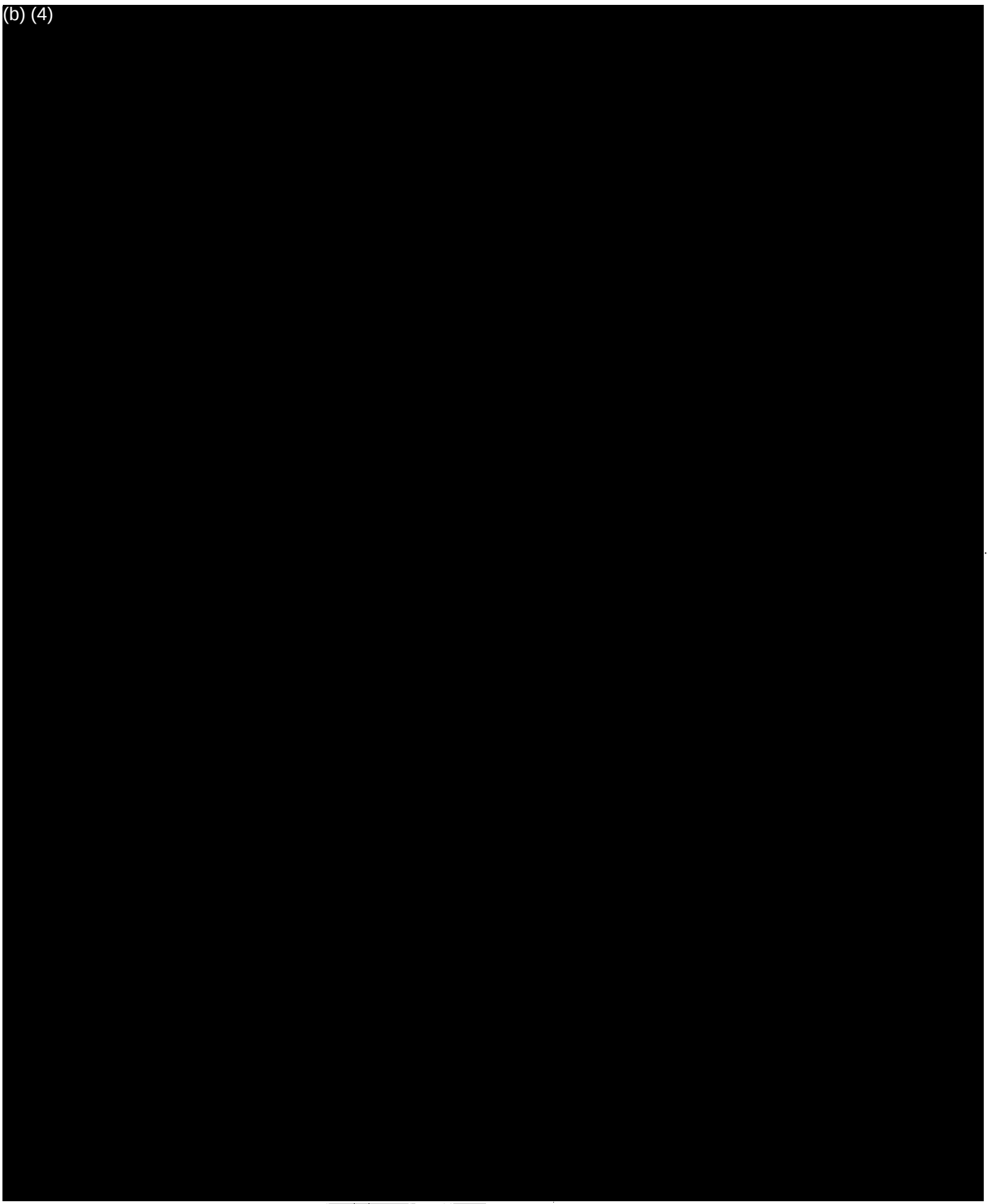

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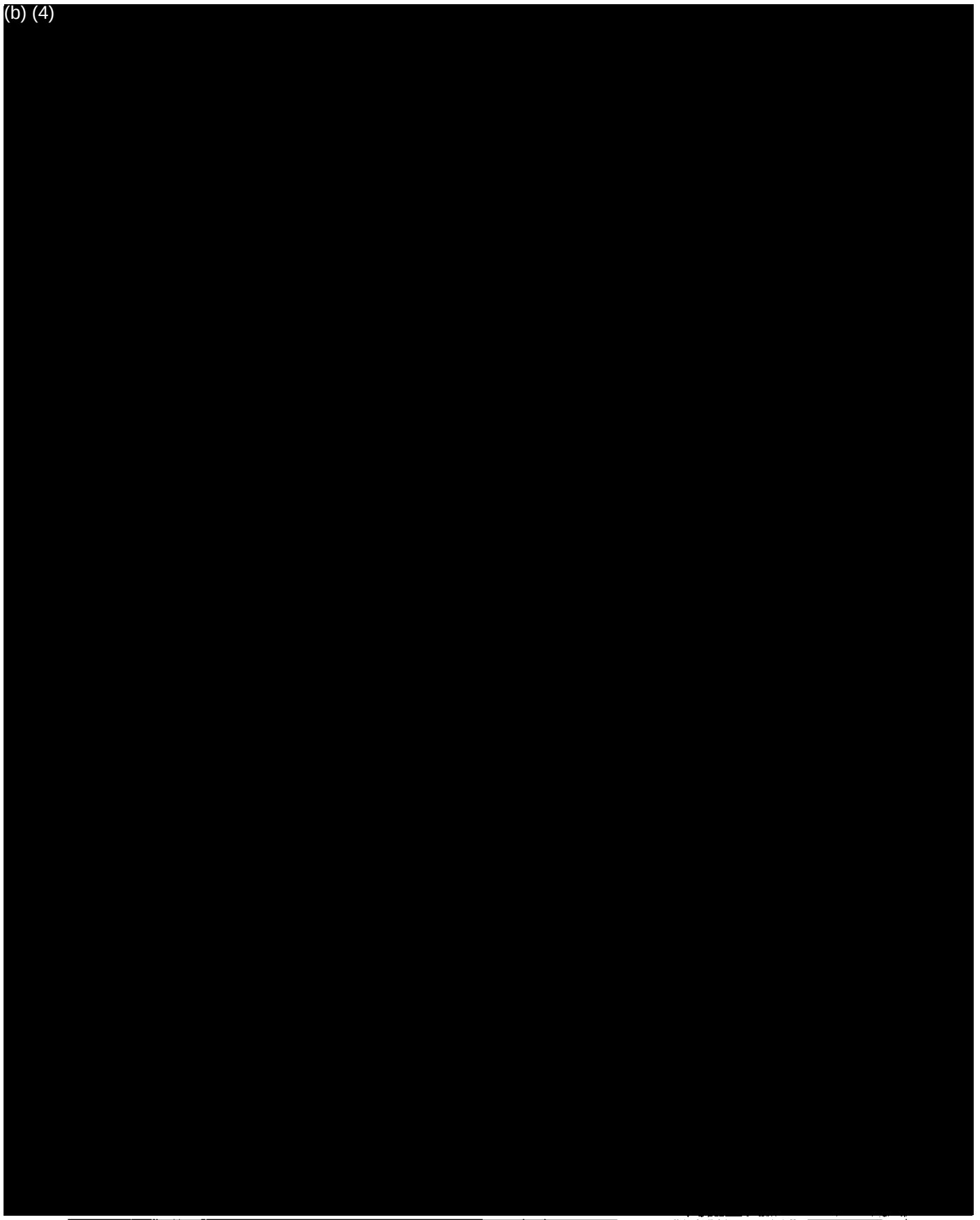

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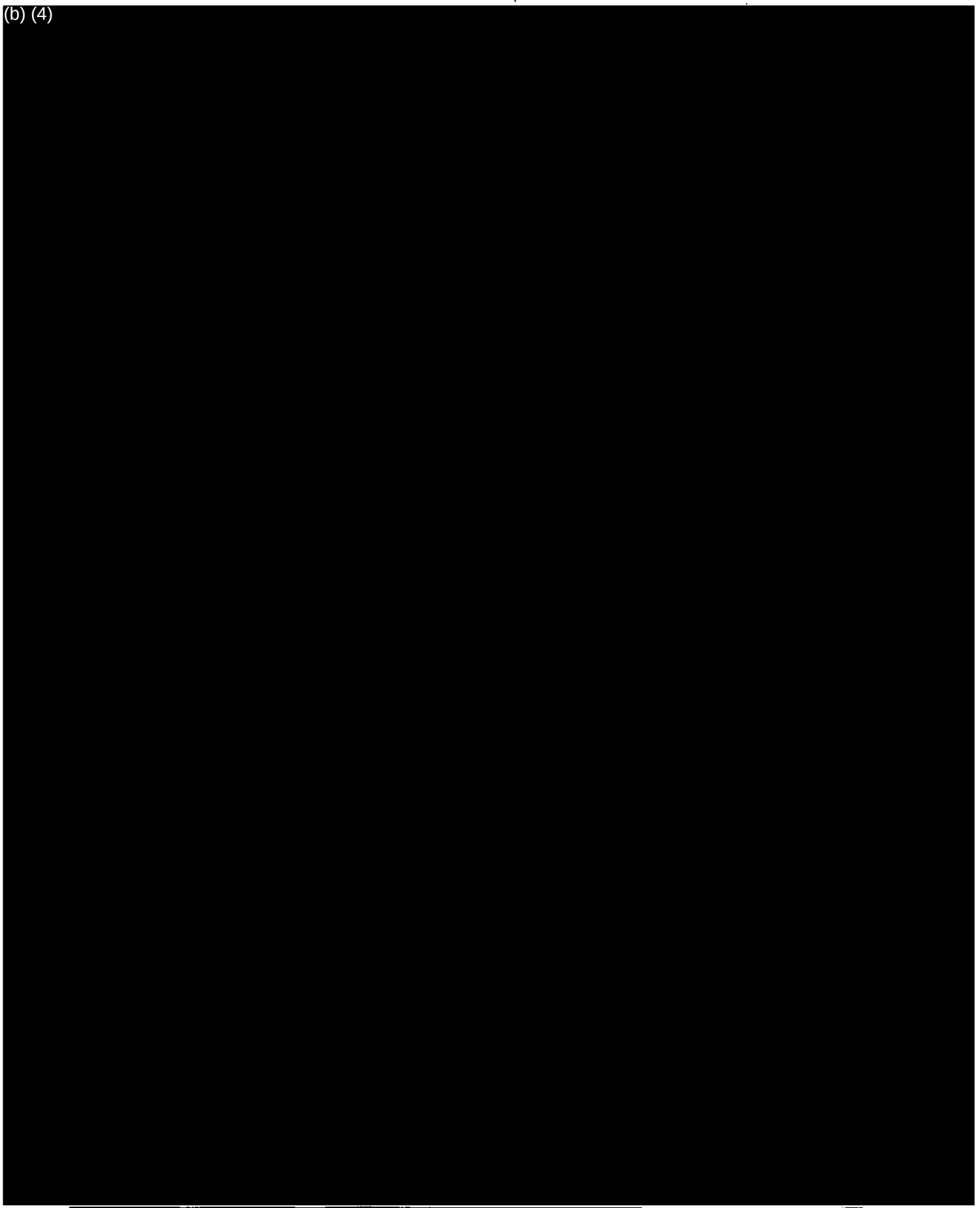

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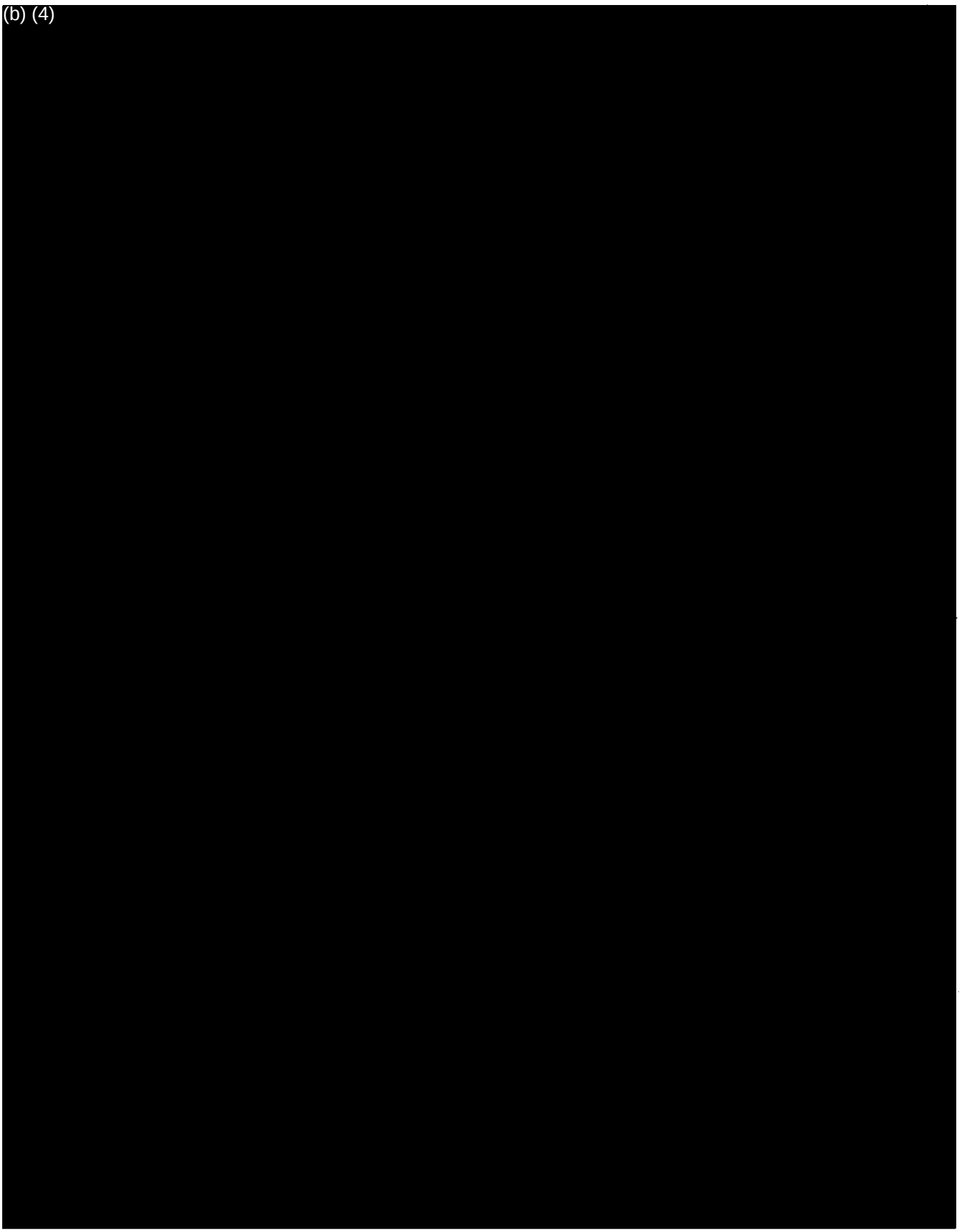

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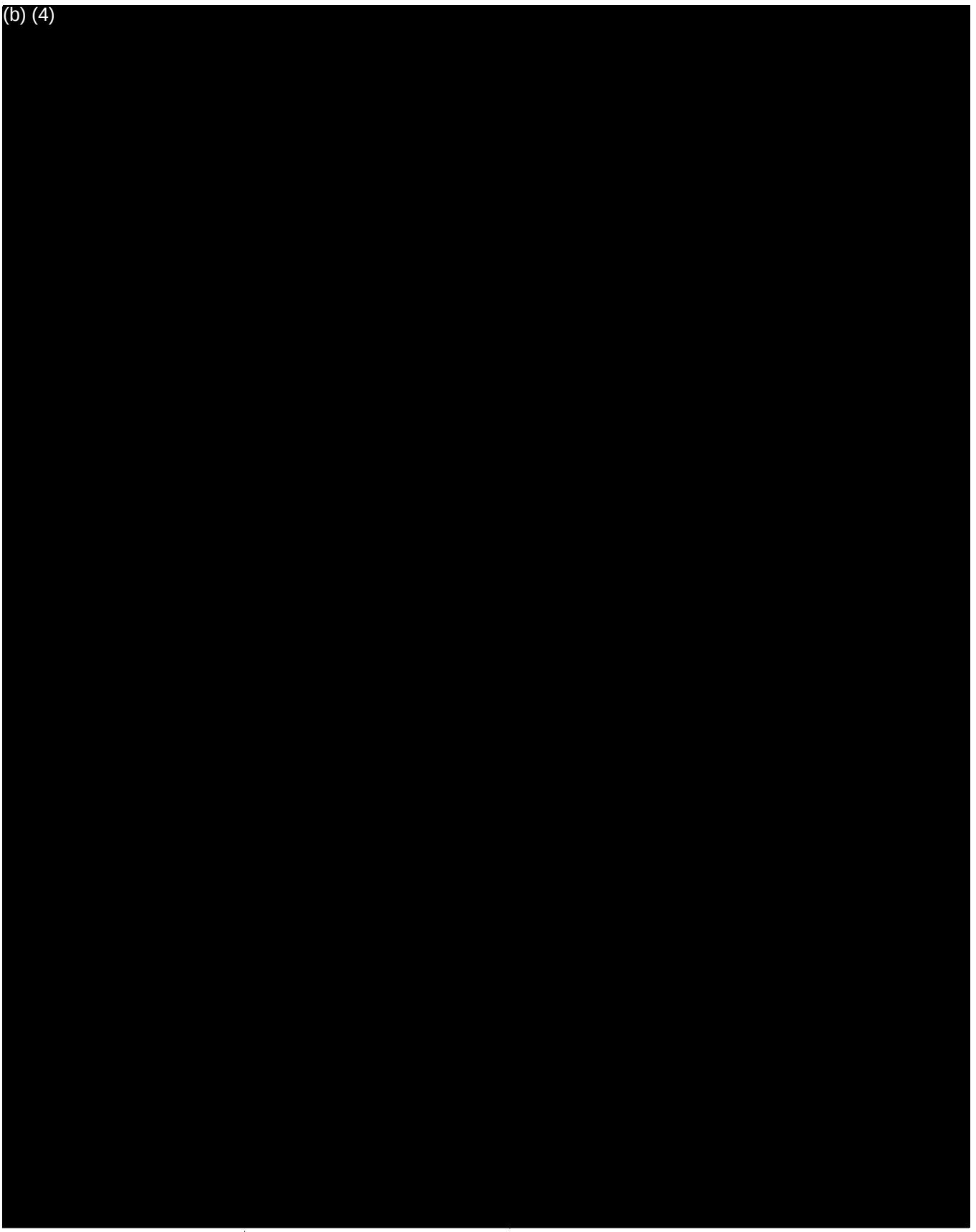

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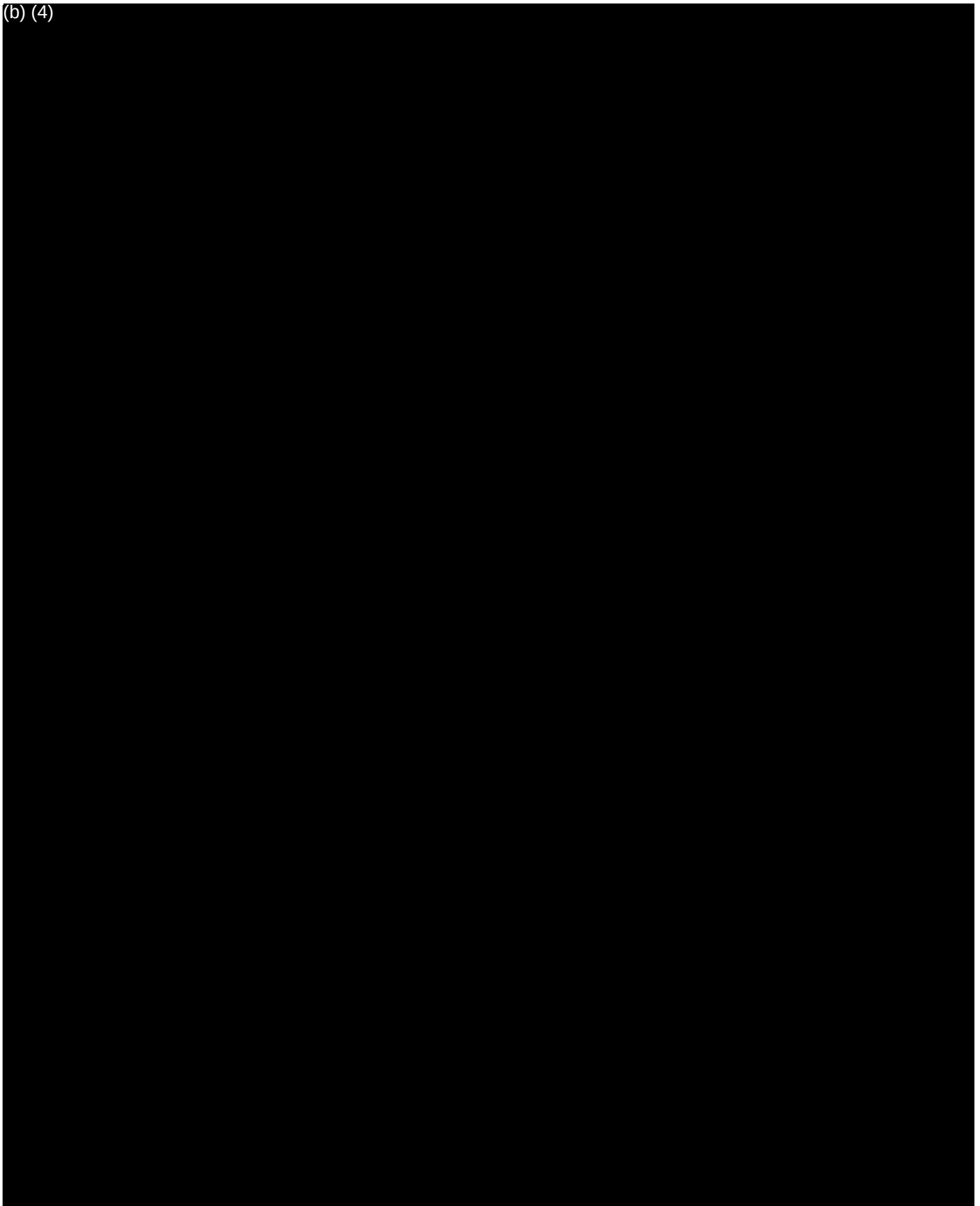

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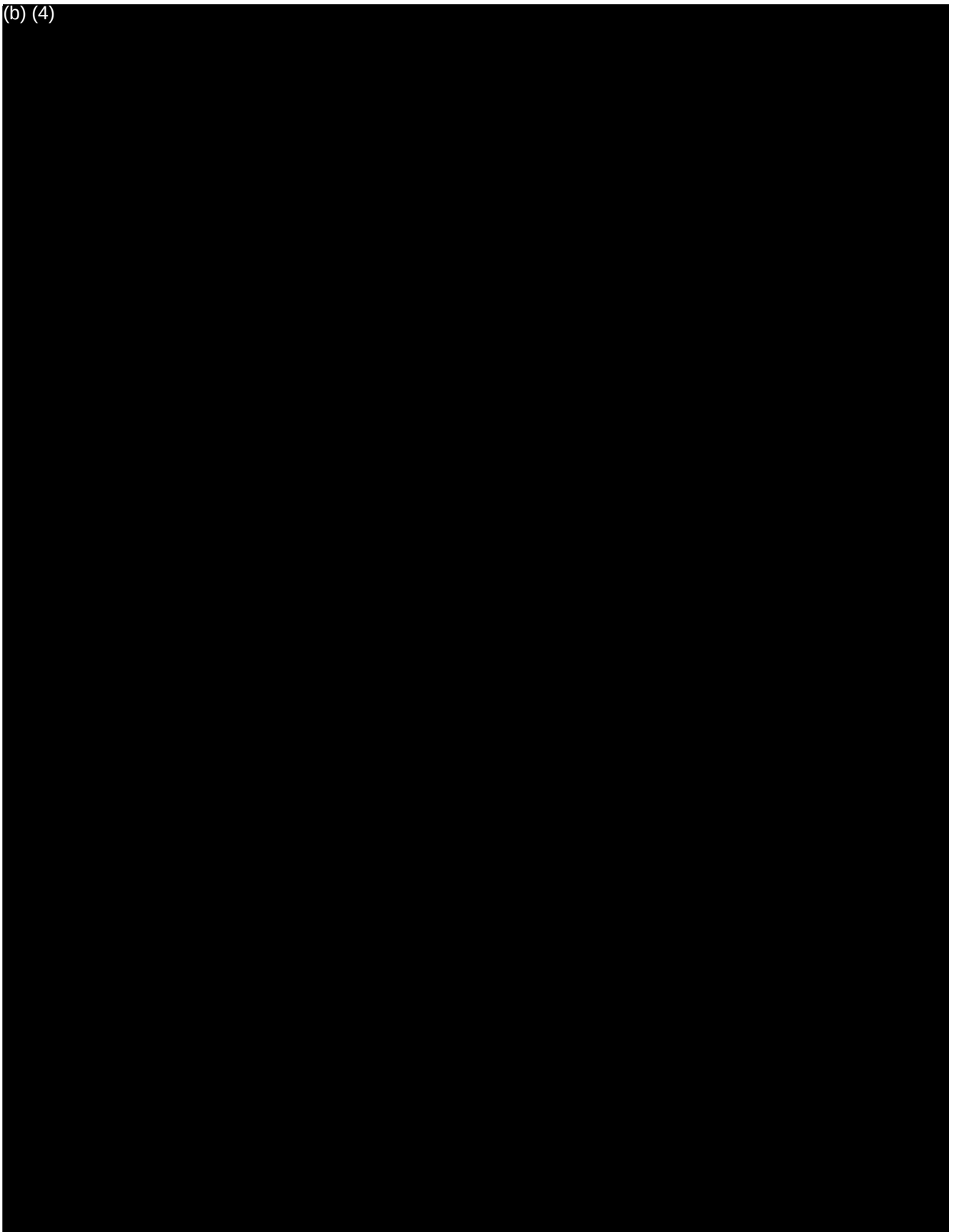

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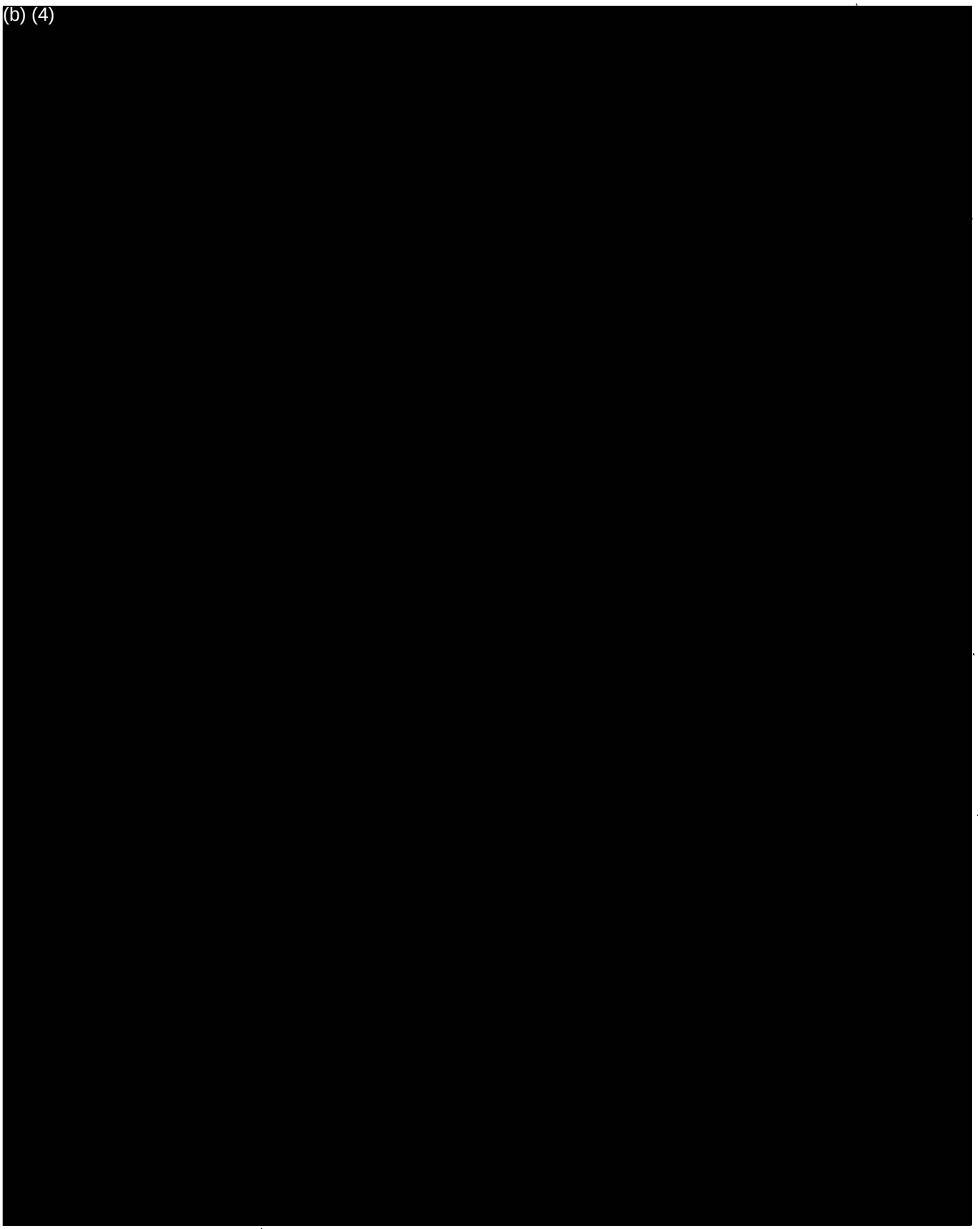

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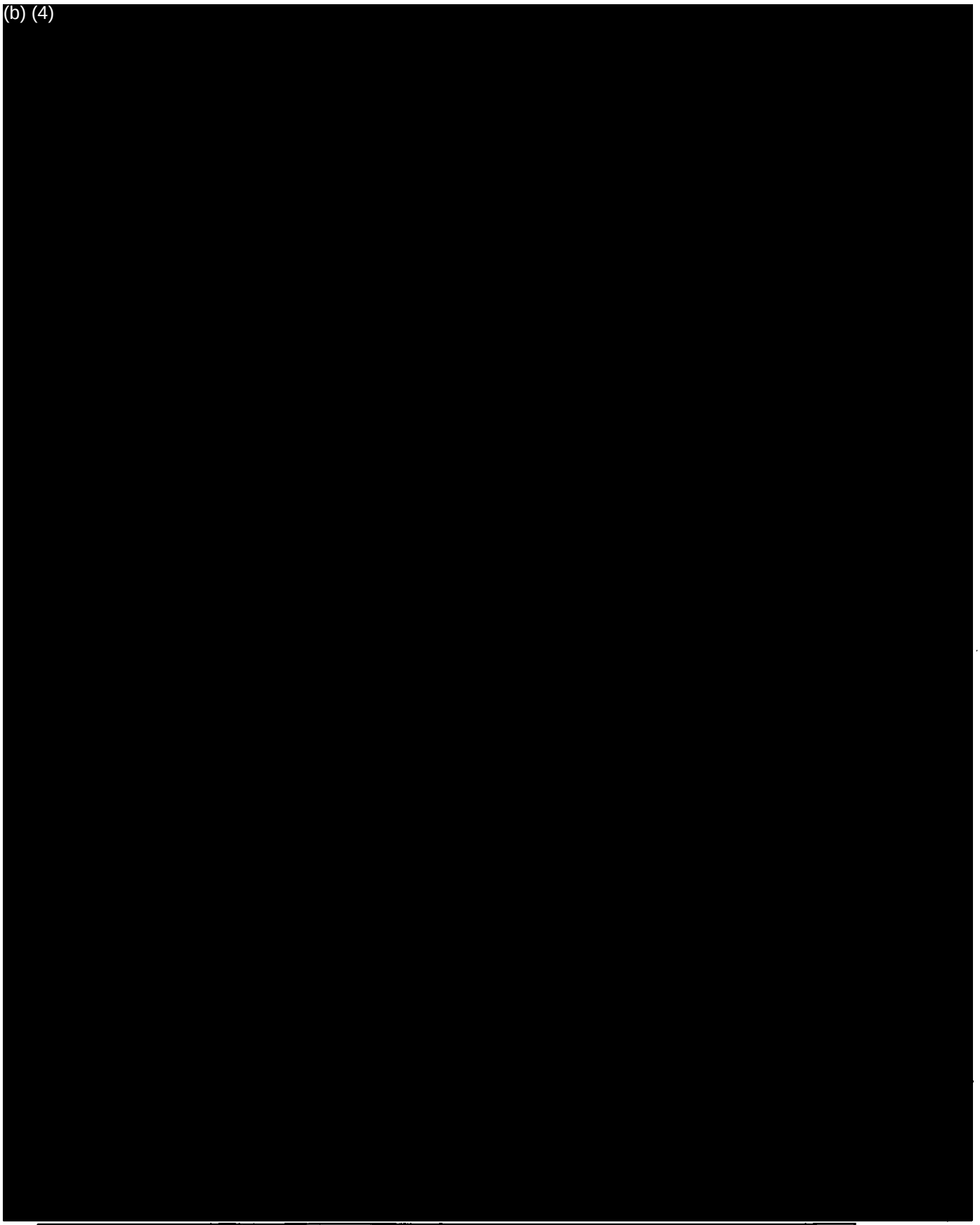

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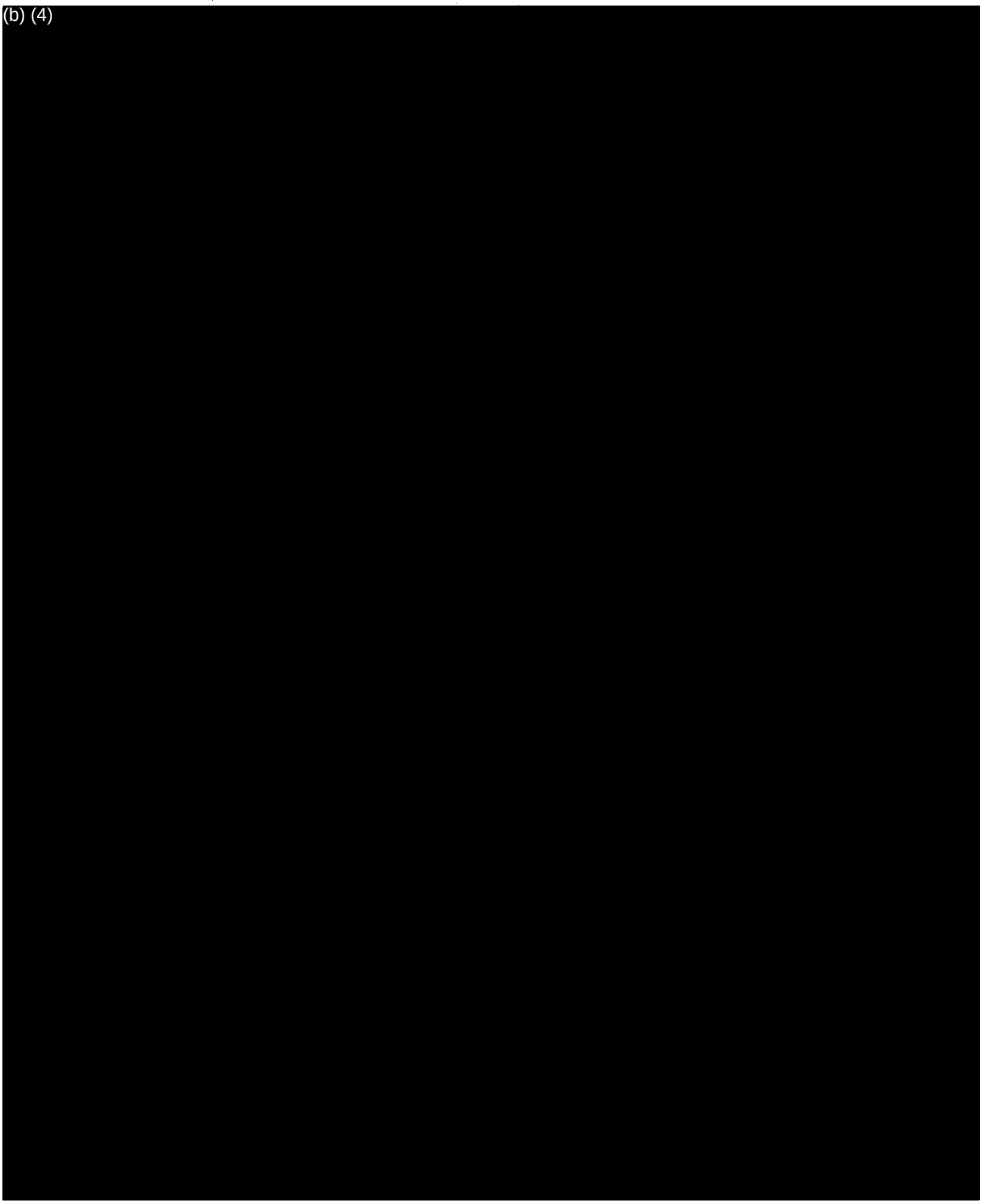

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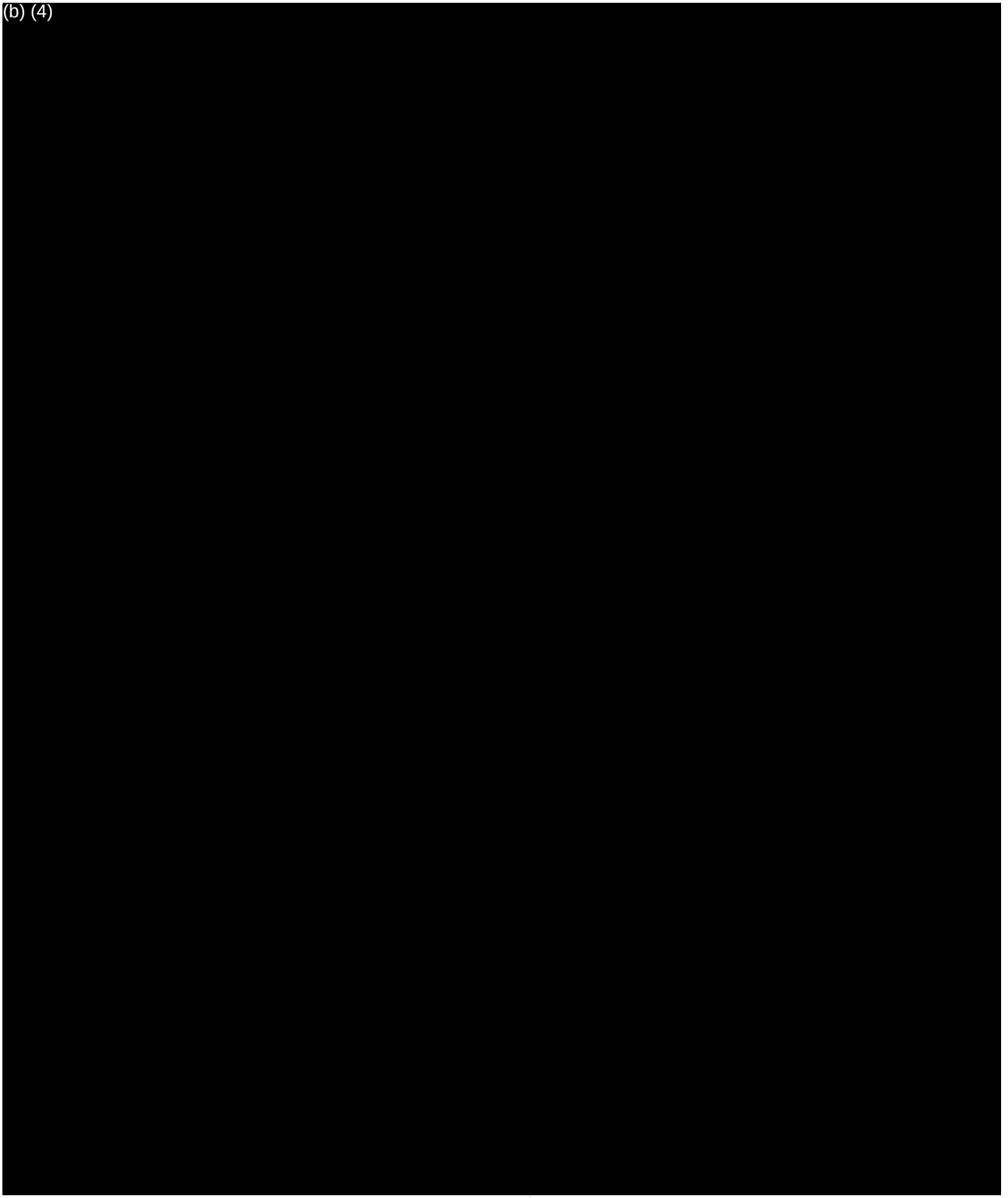

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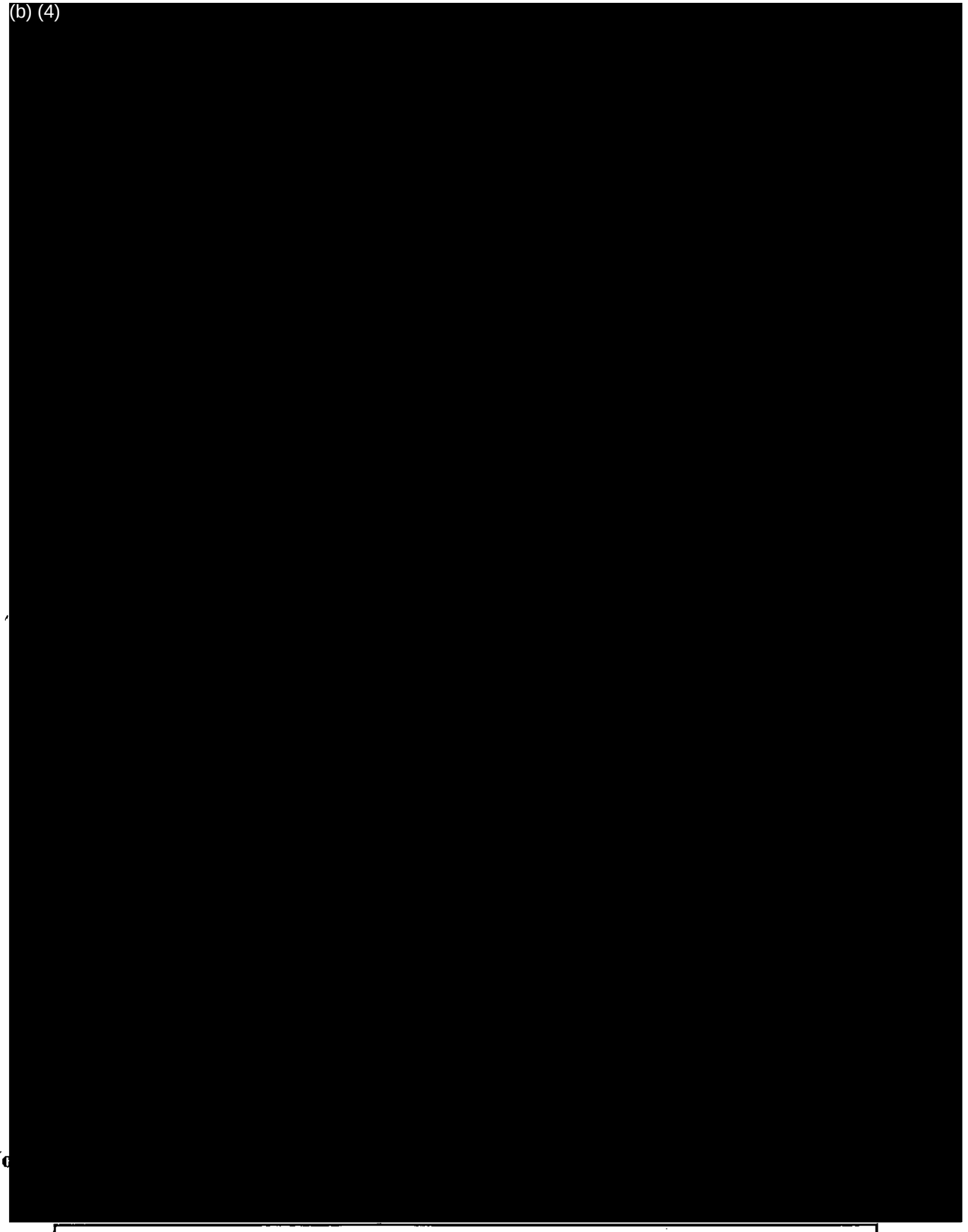

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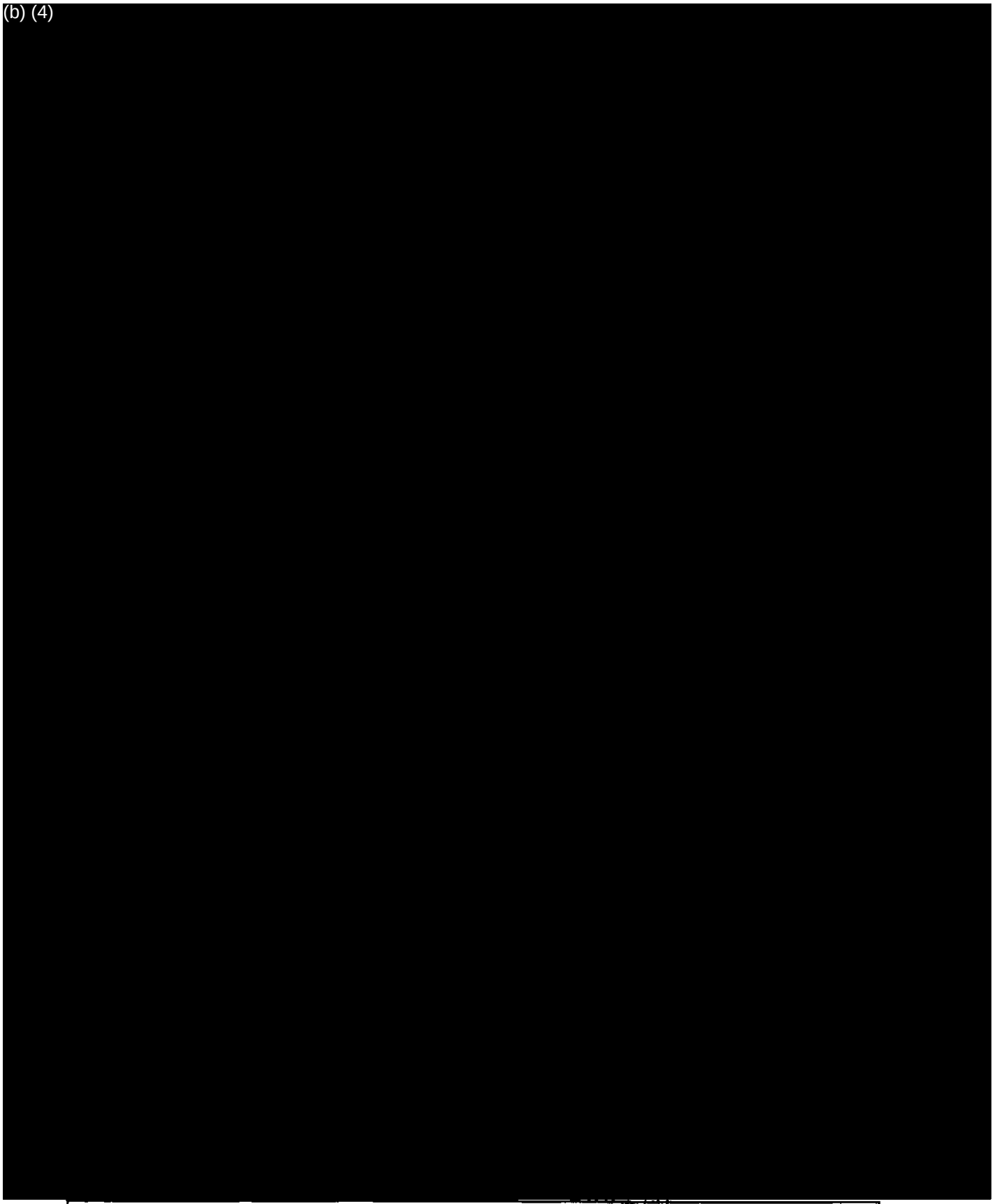

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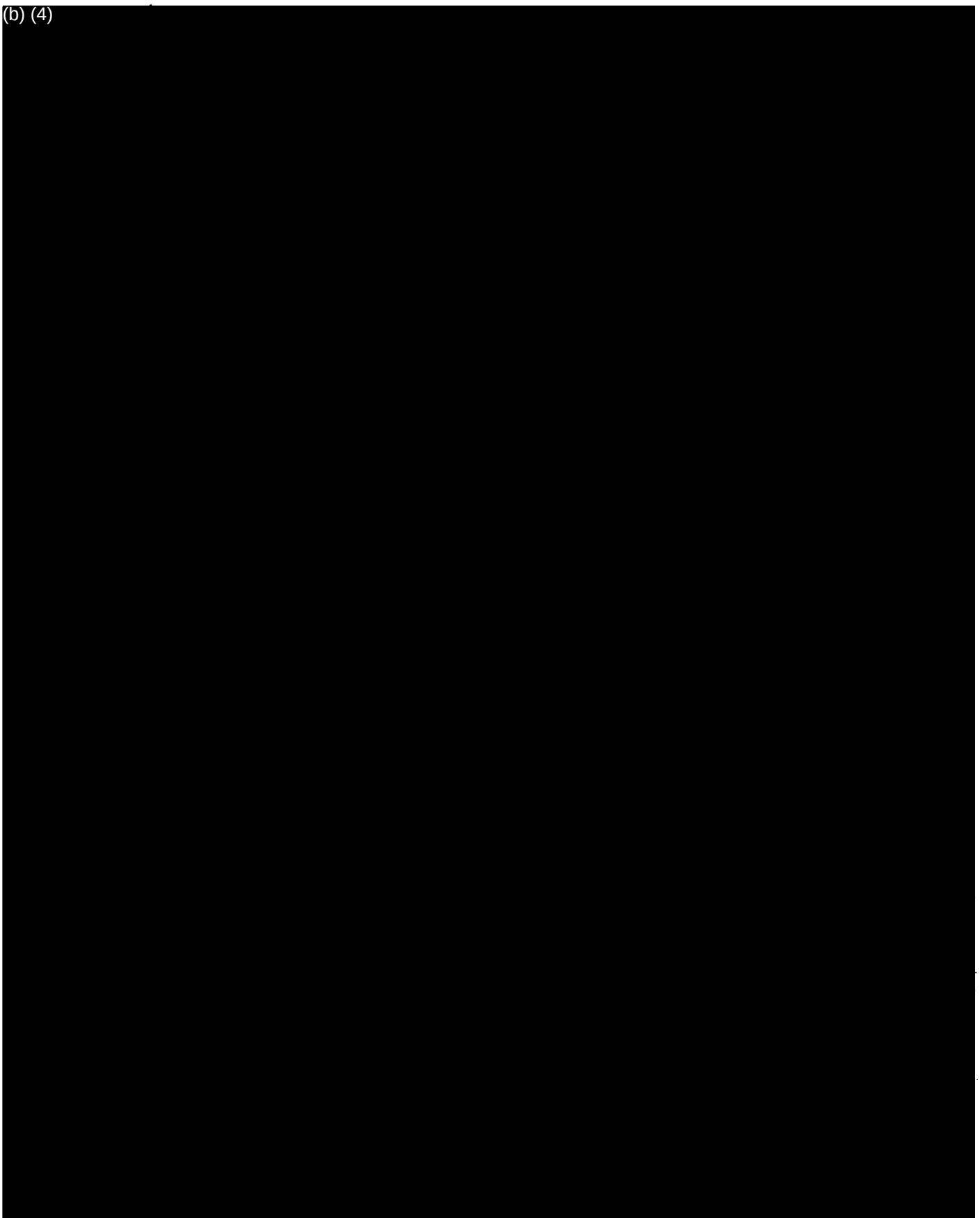

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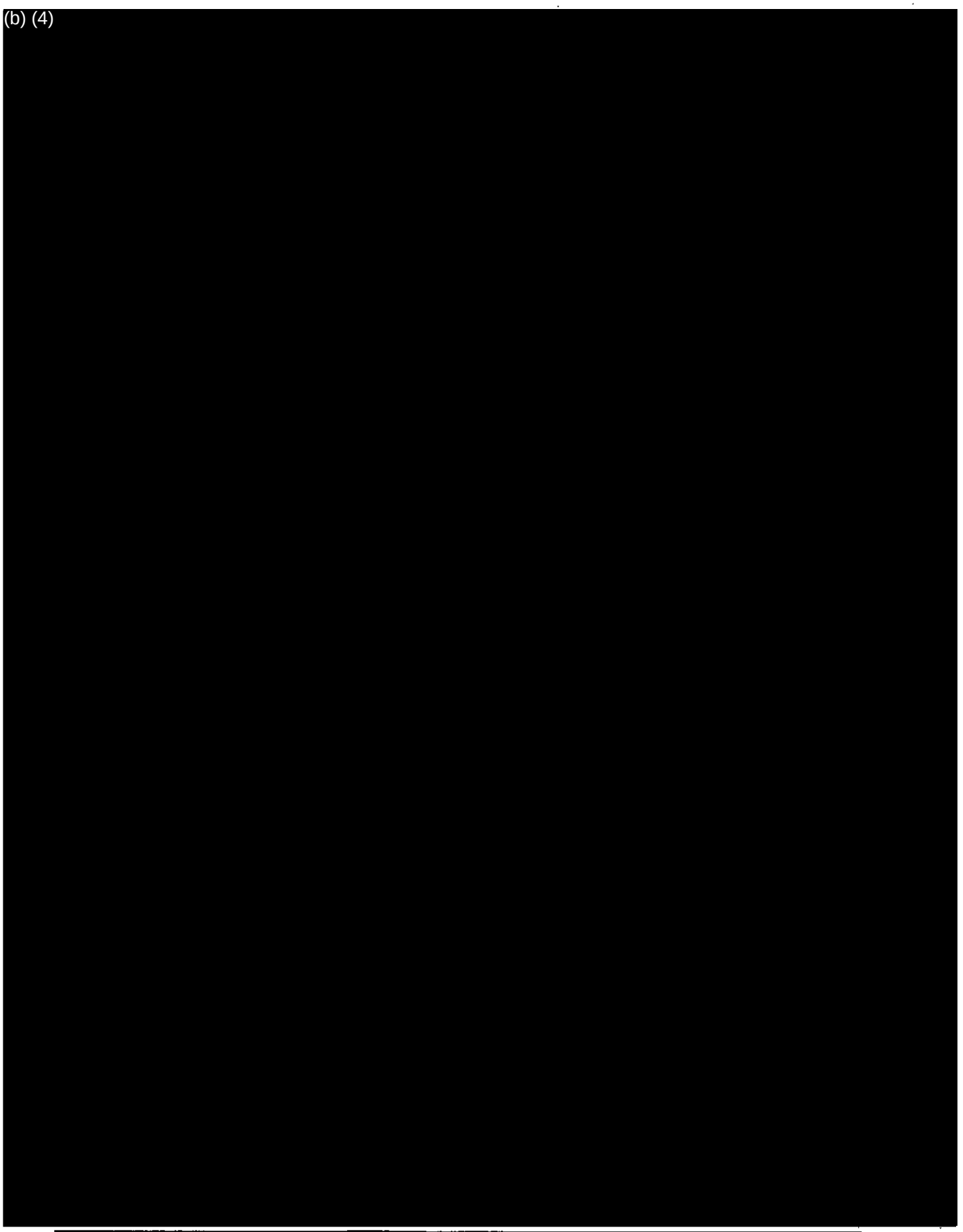

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Appendix 16D

Software Design Specification for the ROBODOC Surgical Assistant

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Approval & Change Control Page

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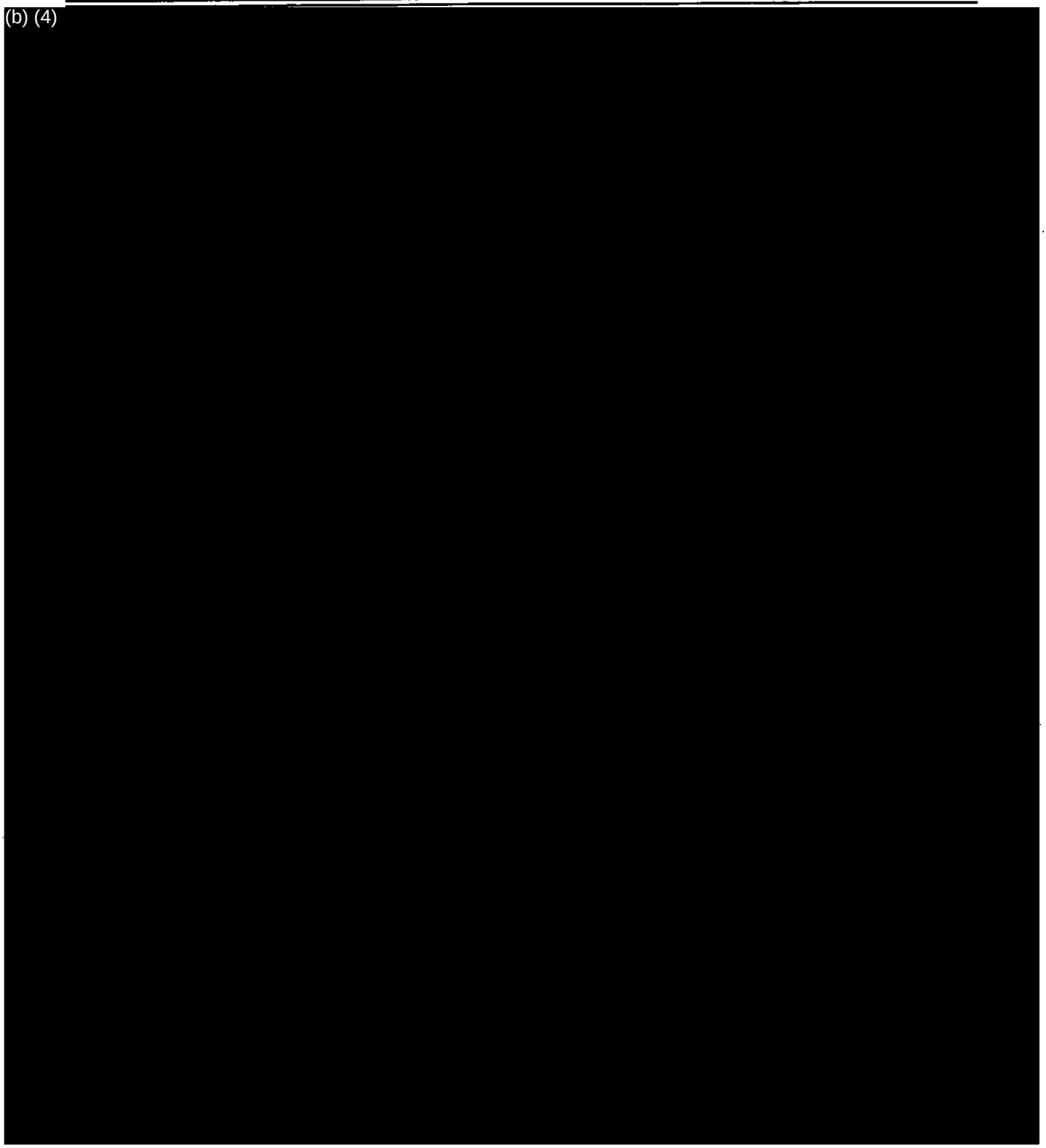

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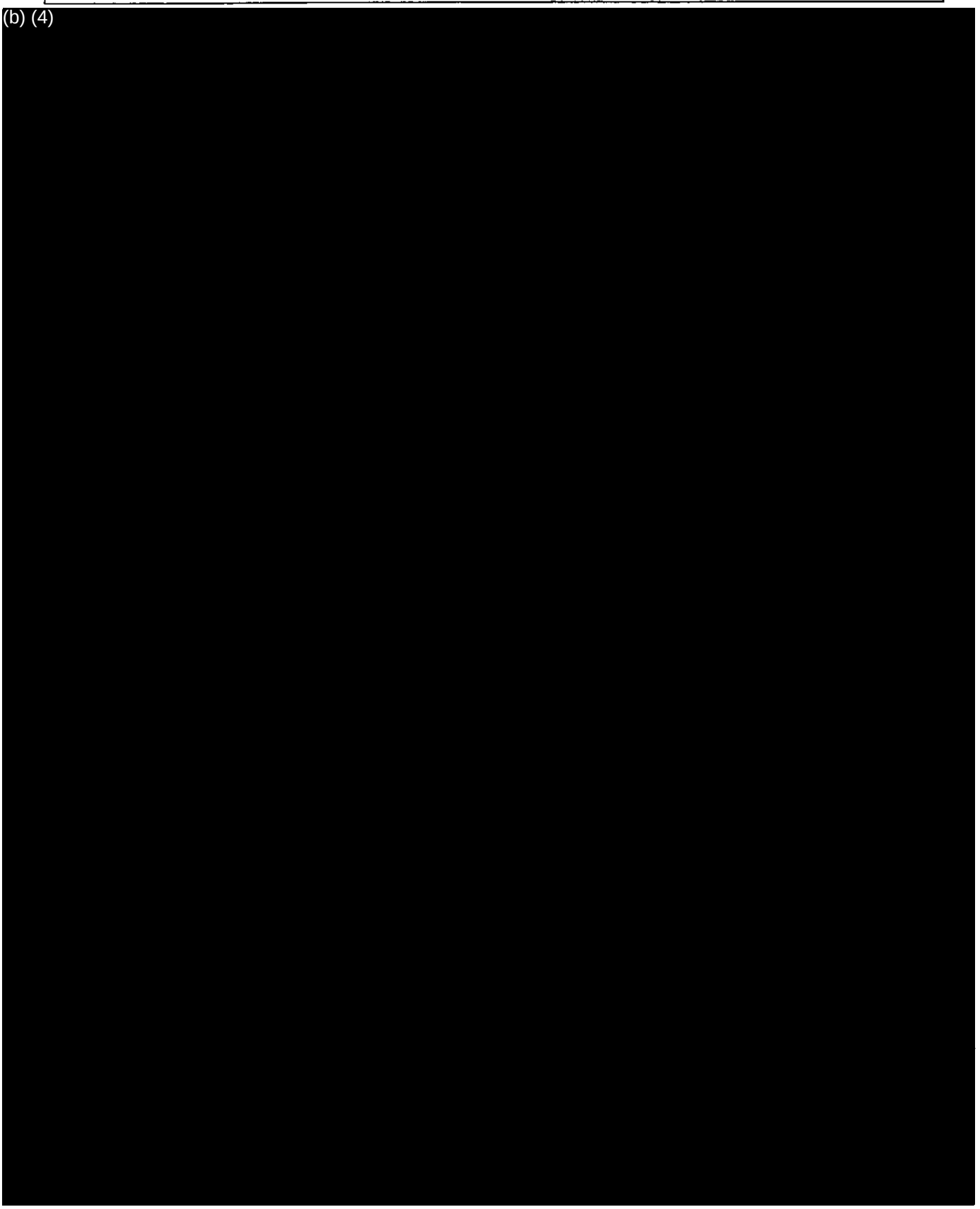

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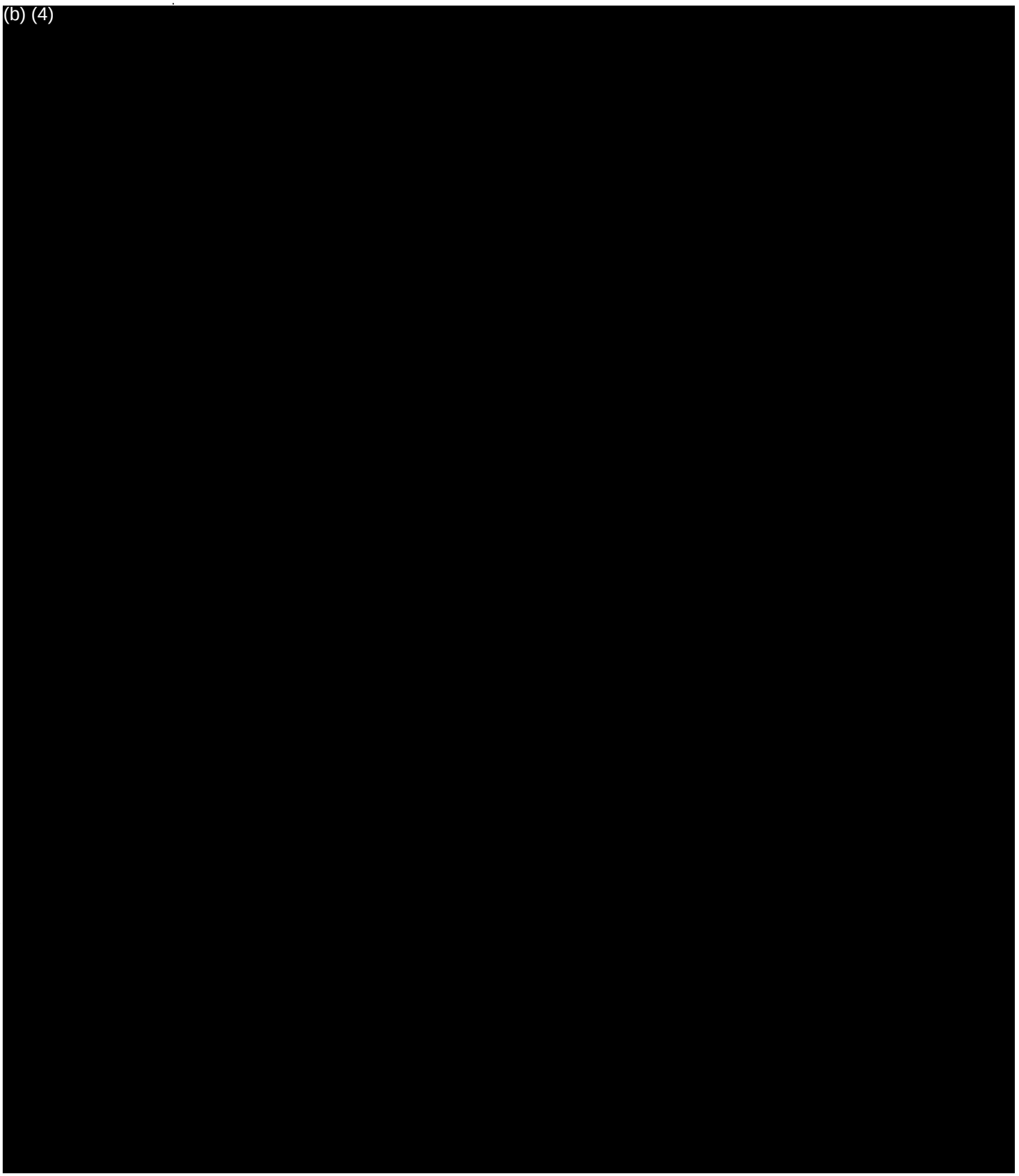

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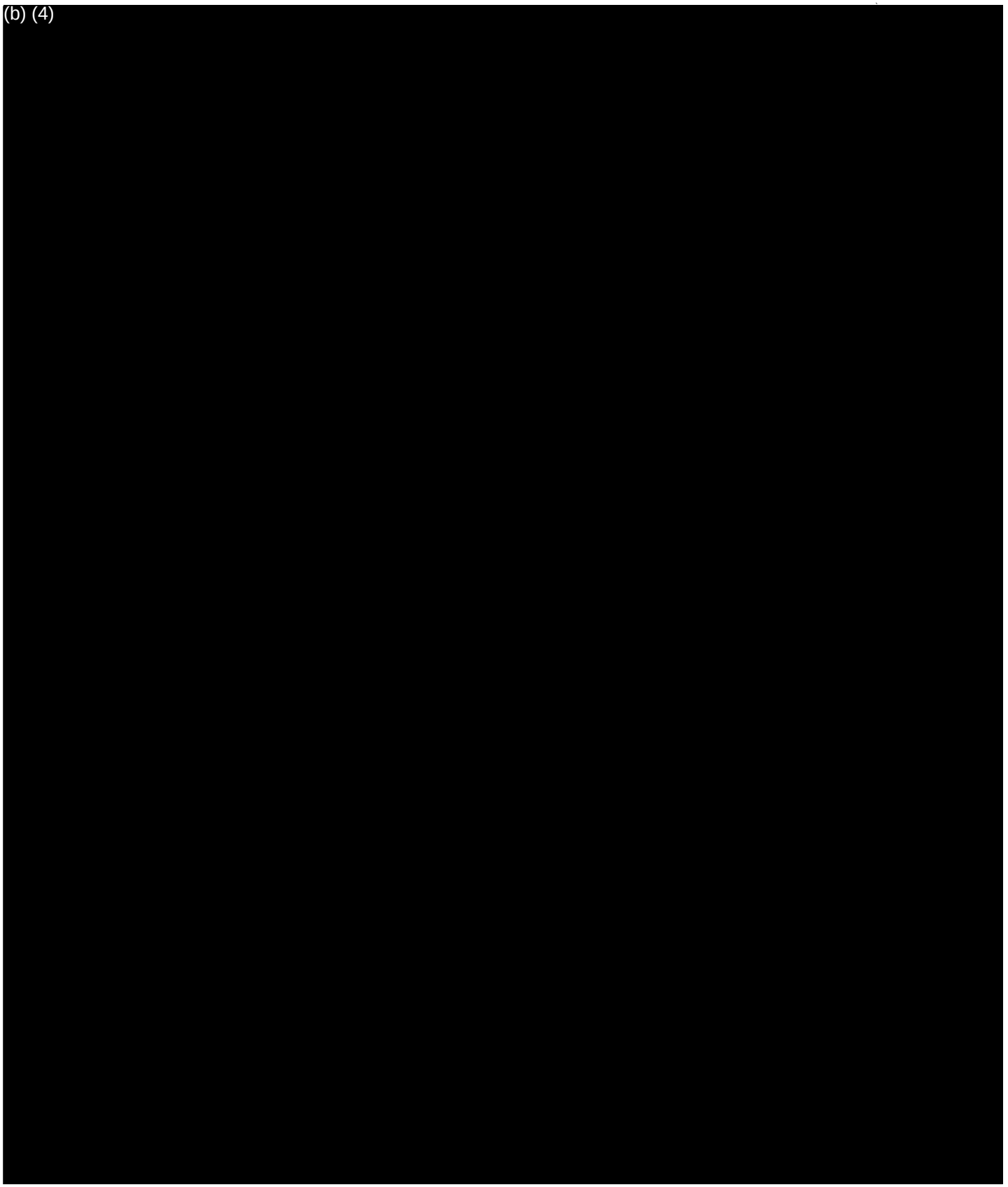

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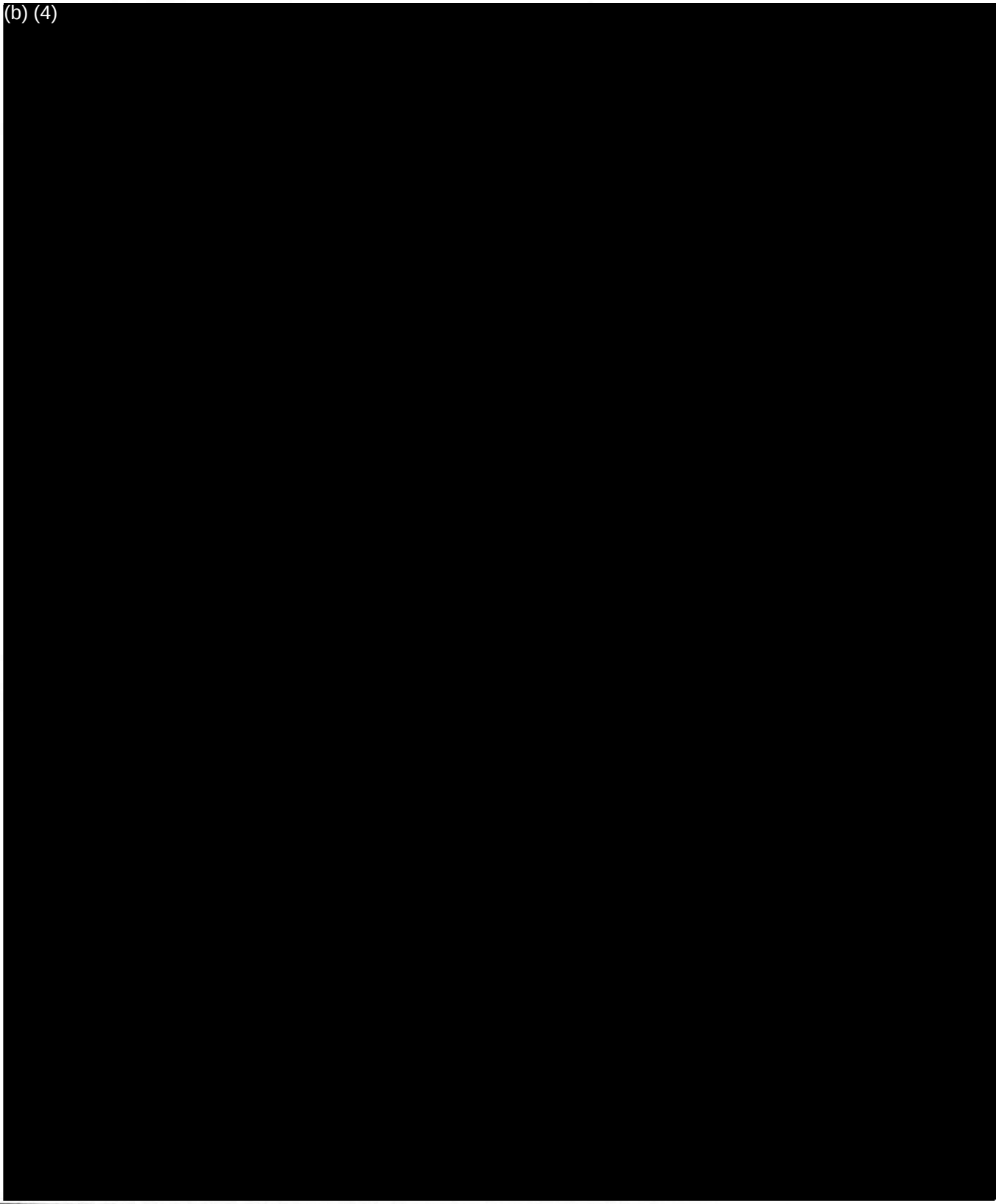

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6. Architectural Design

6.1 The software associated with the ROBODOC Surgical Assistant consists of the following software components which interact as shown in Figure 6.1.

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Figure 6.1. ROBODOC Application Software Modules

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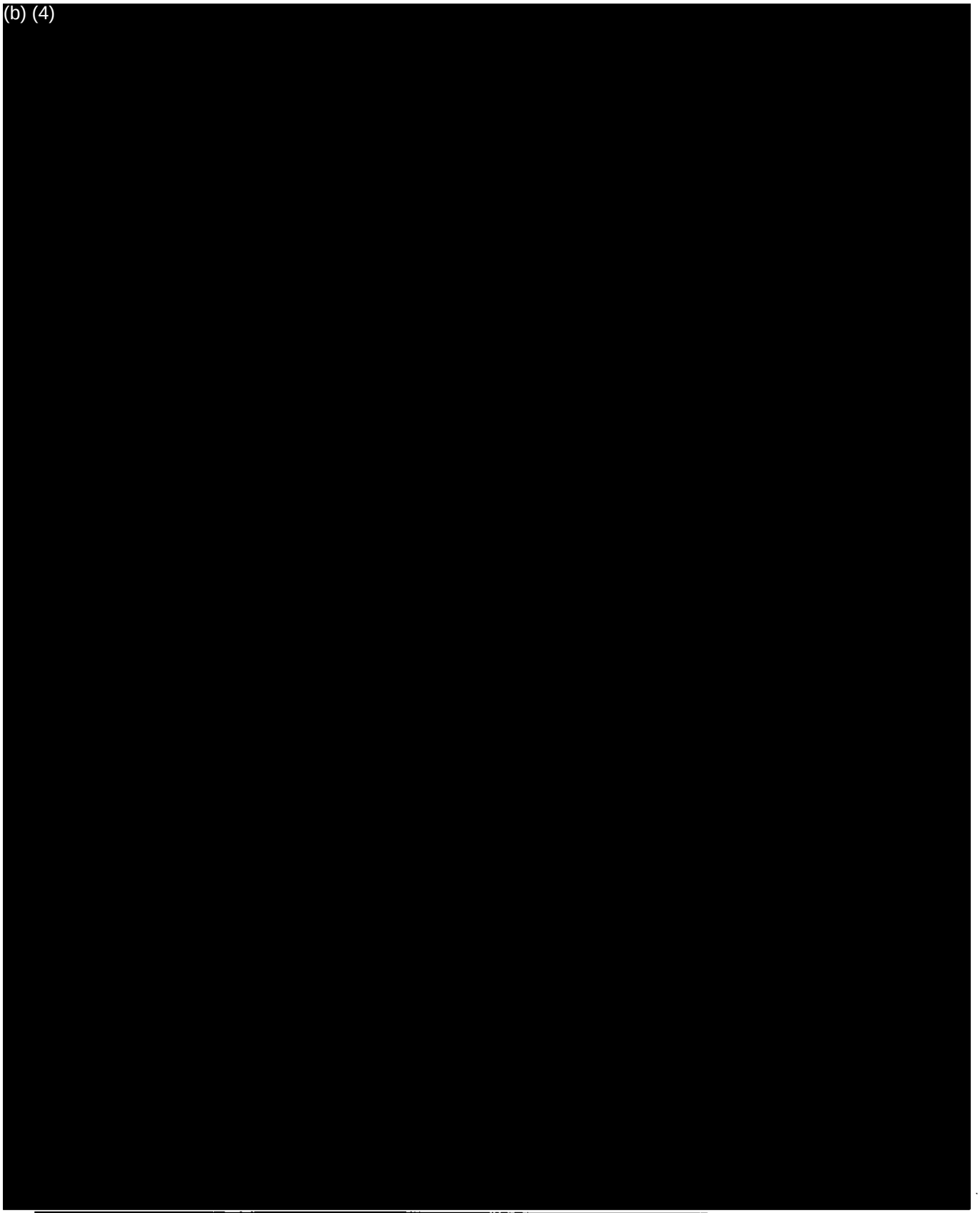

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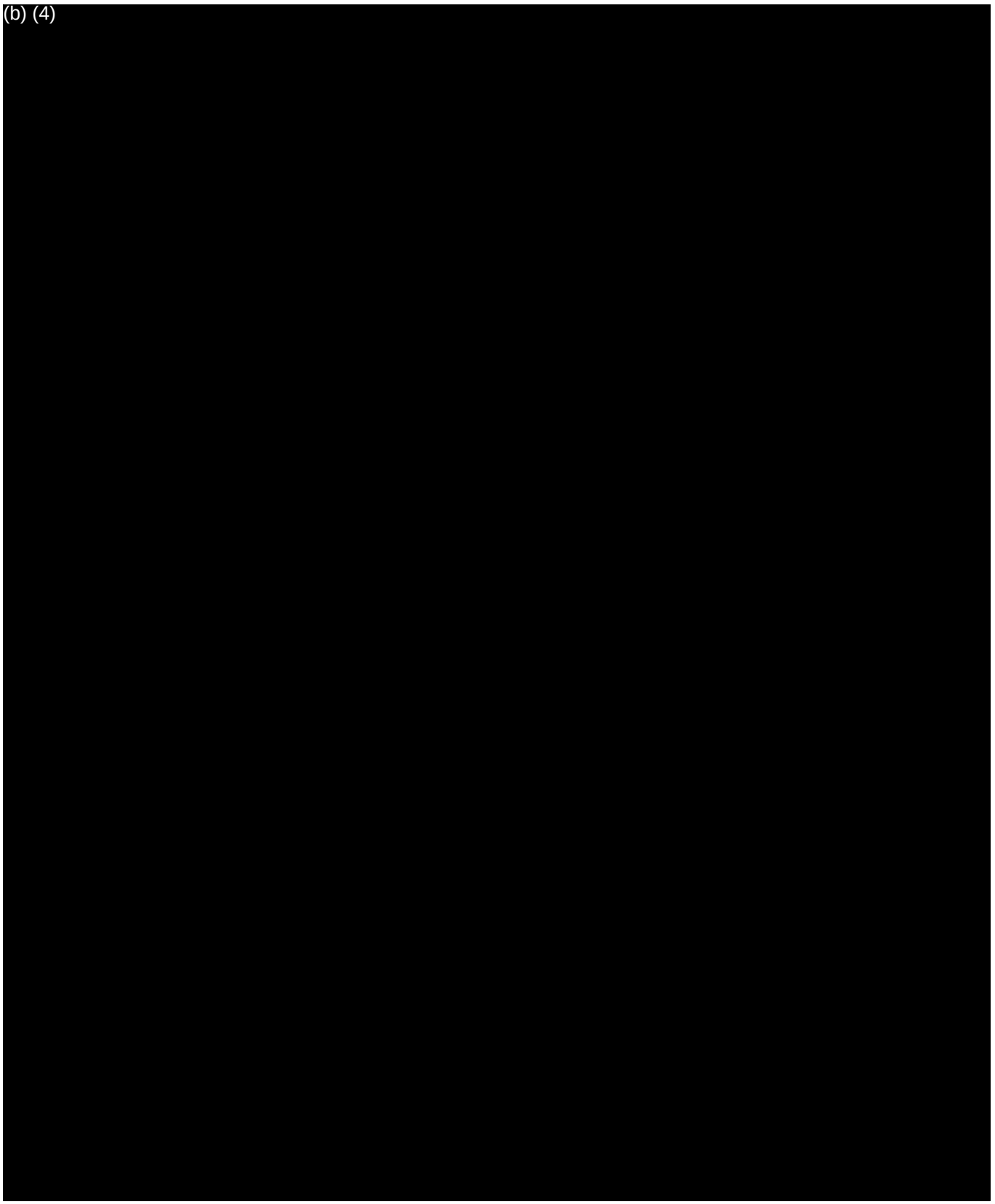

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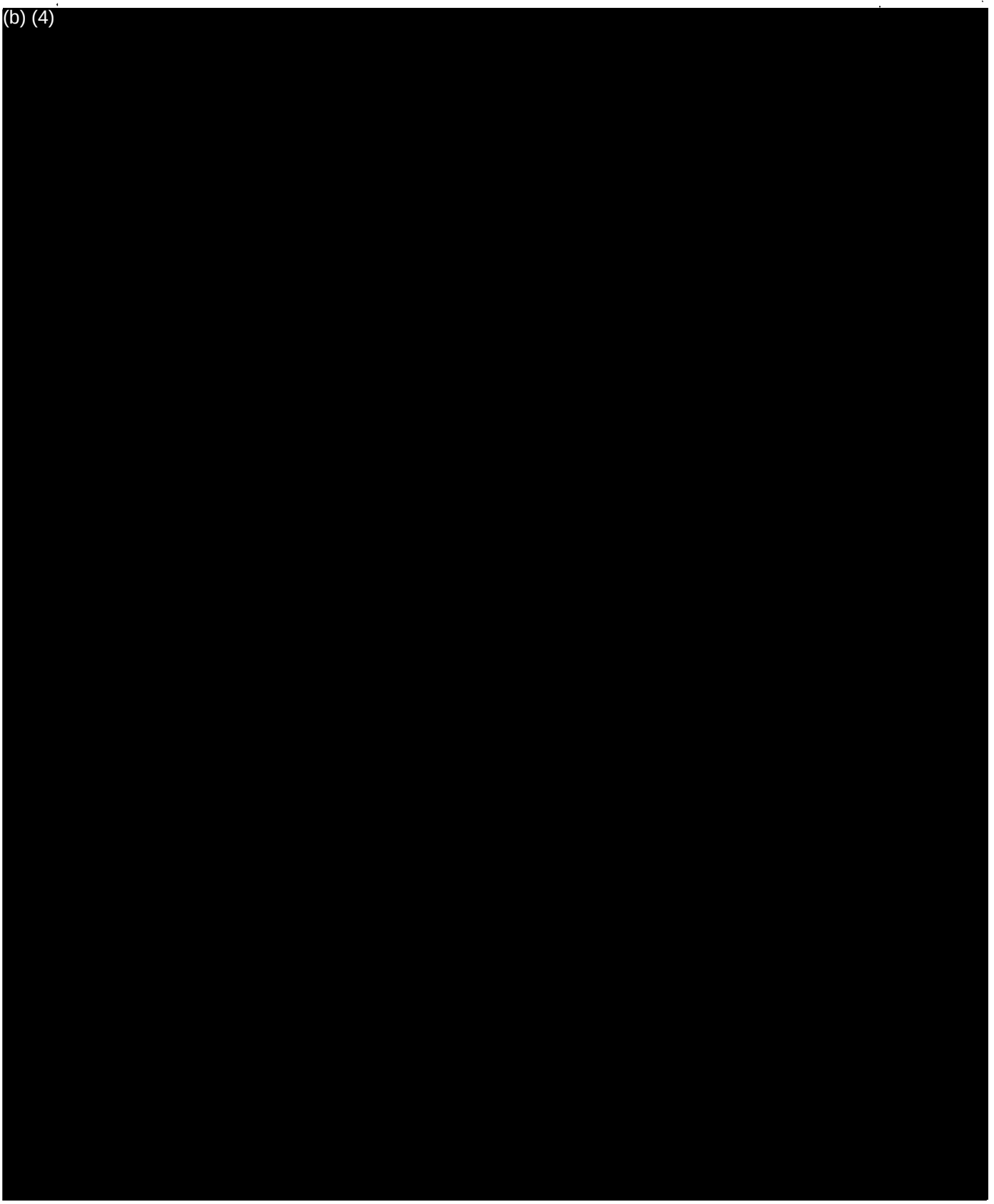

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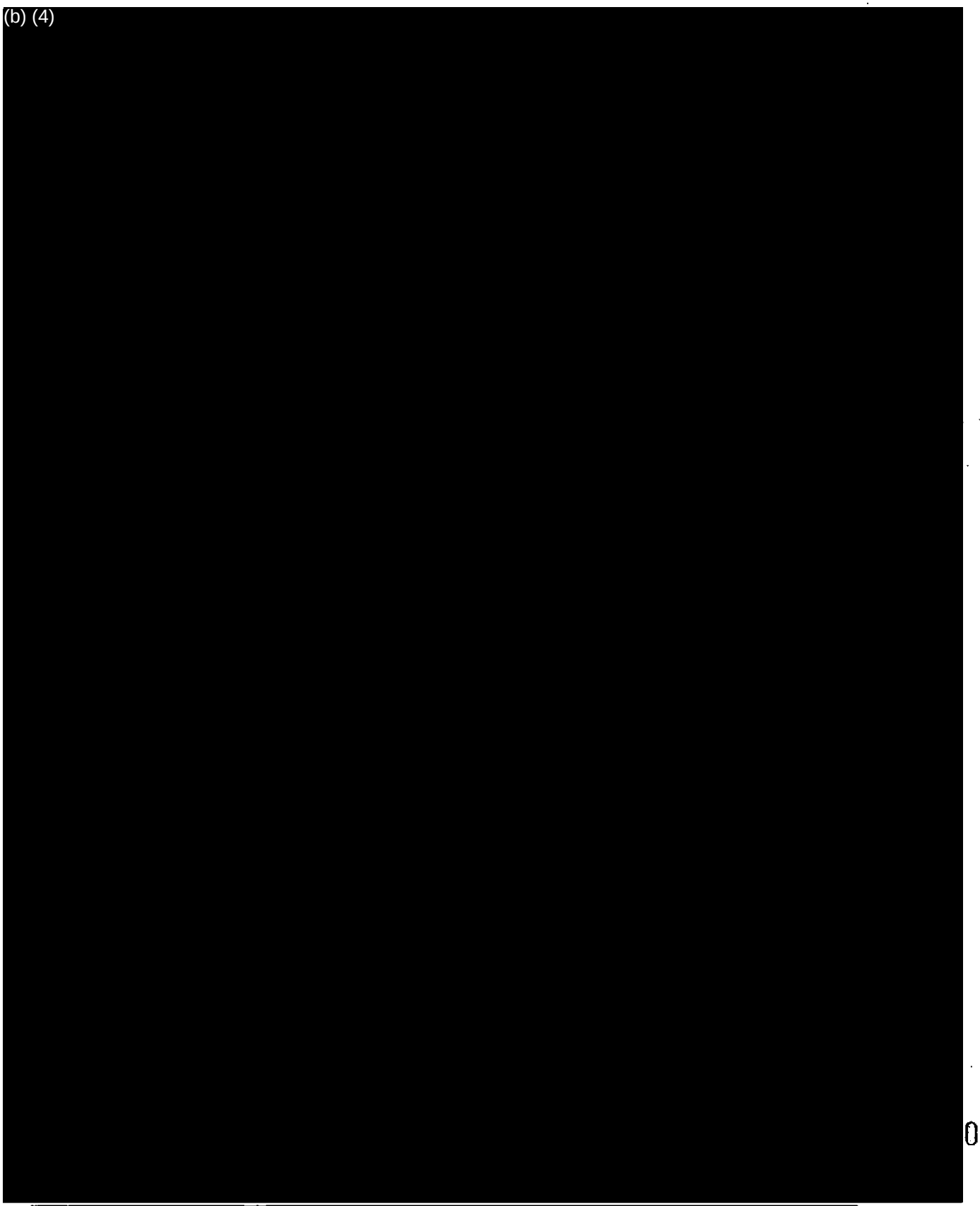

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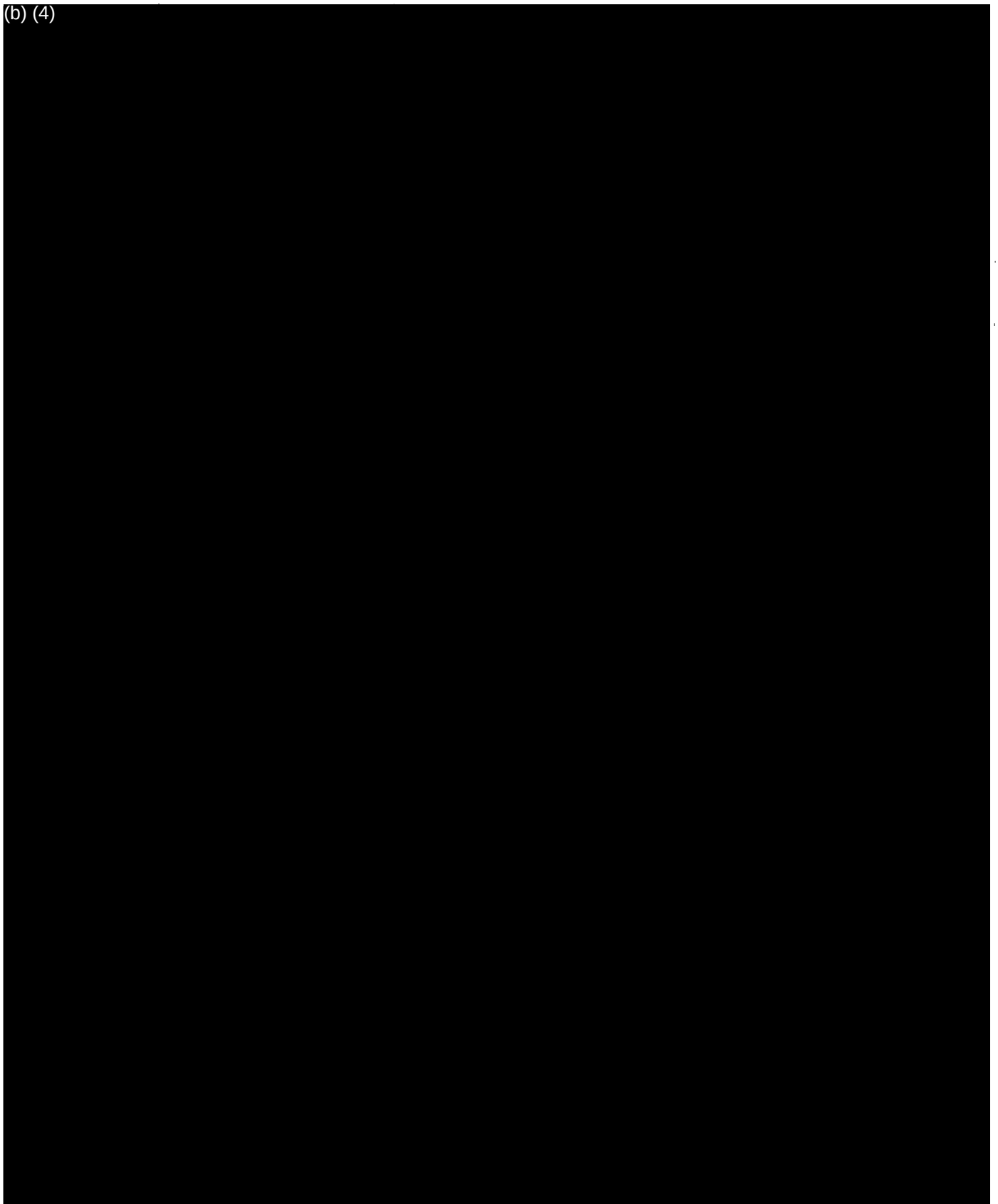

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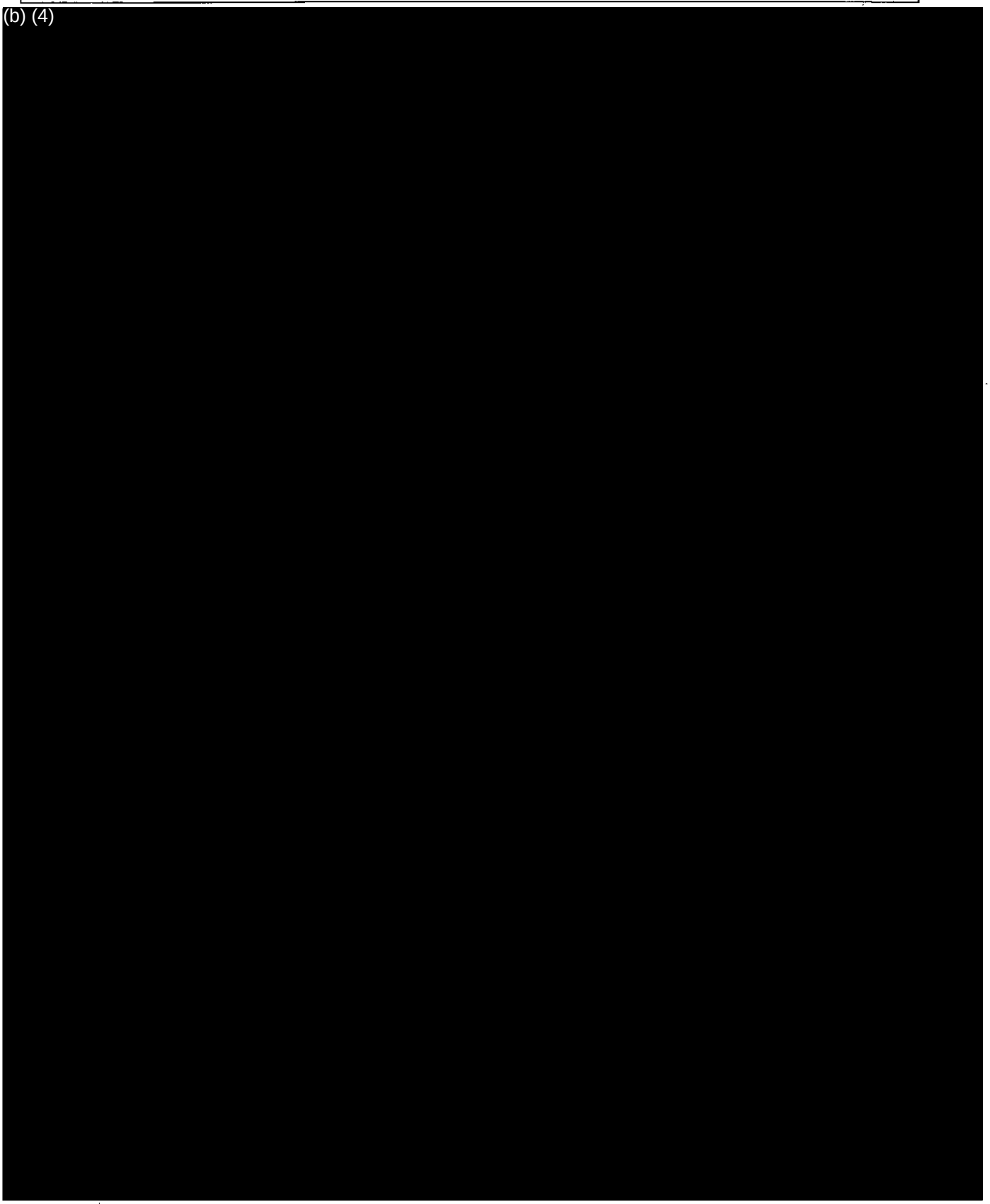

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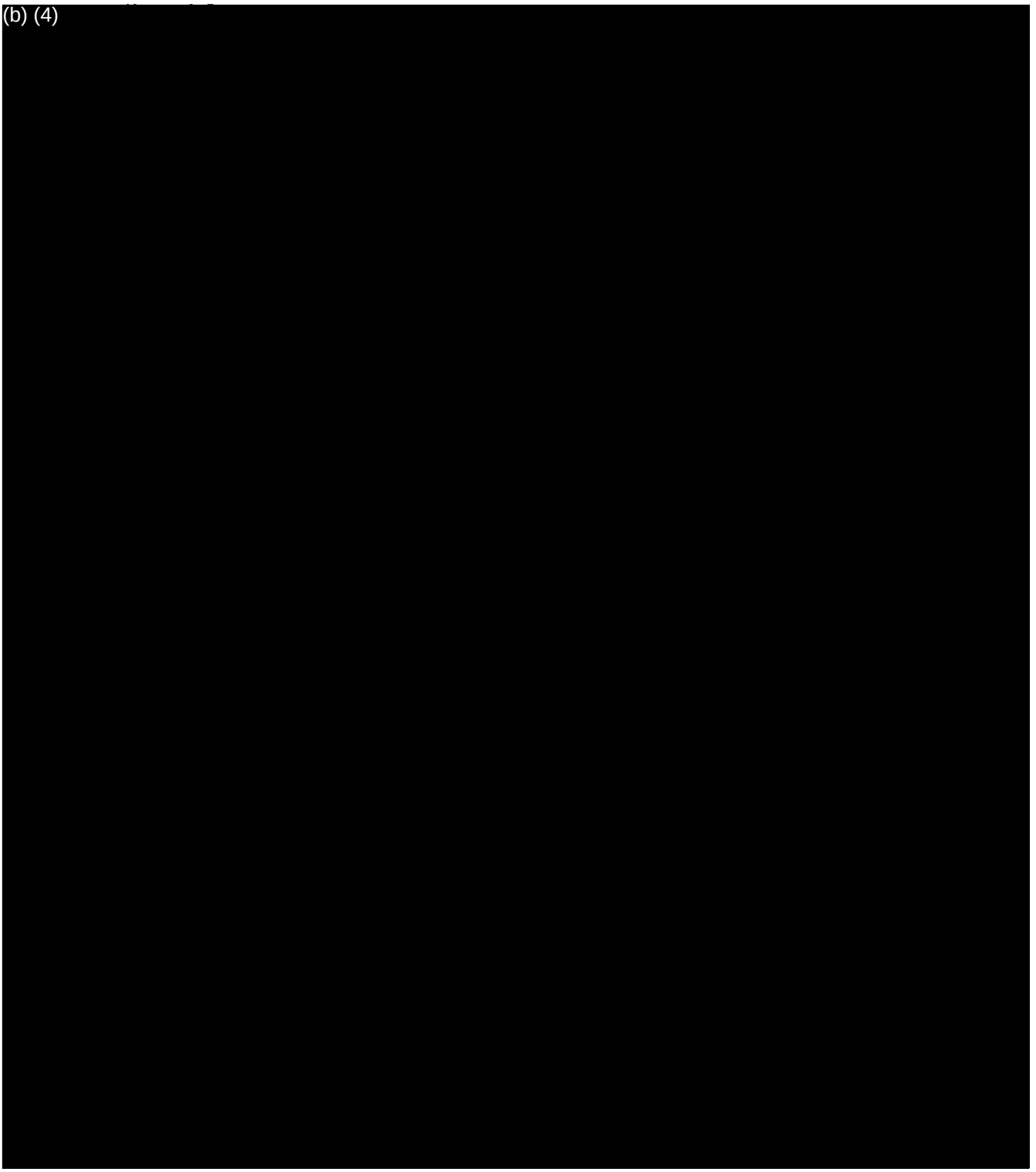

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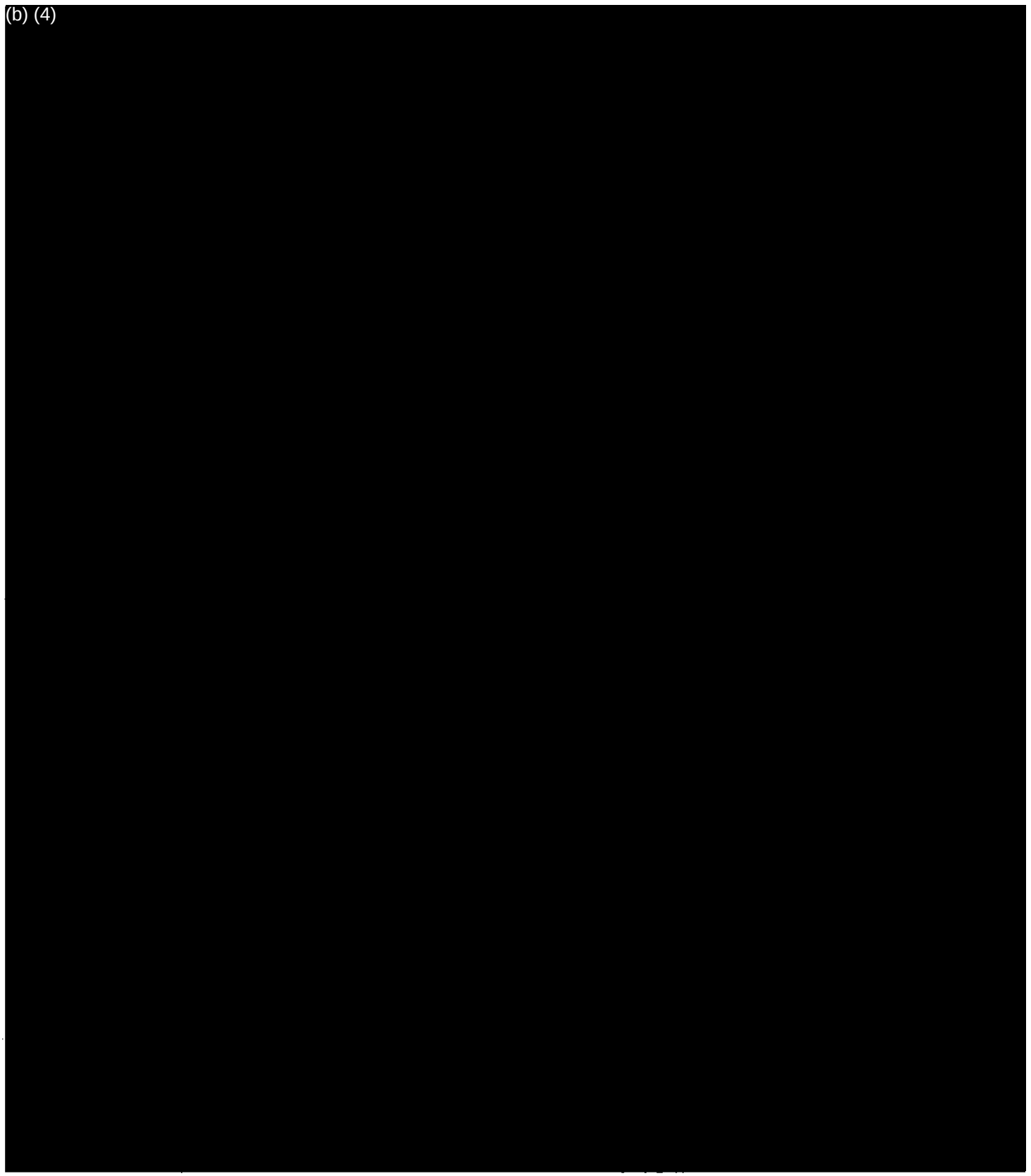

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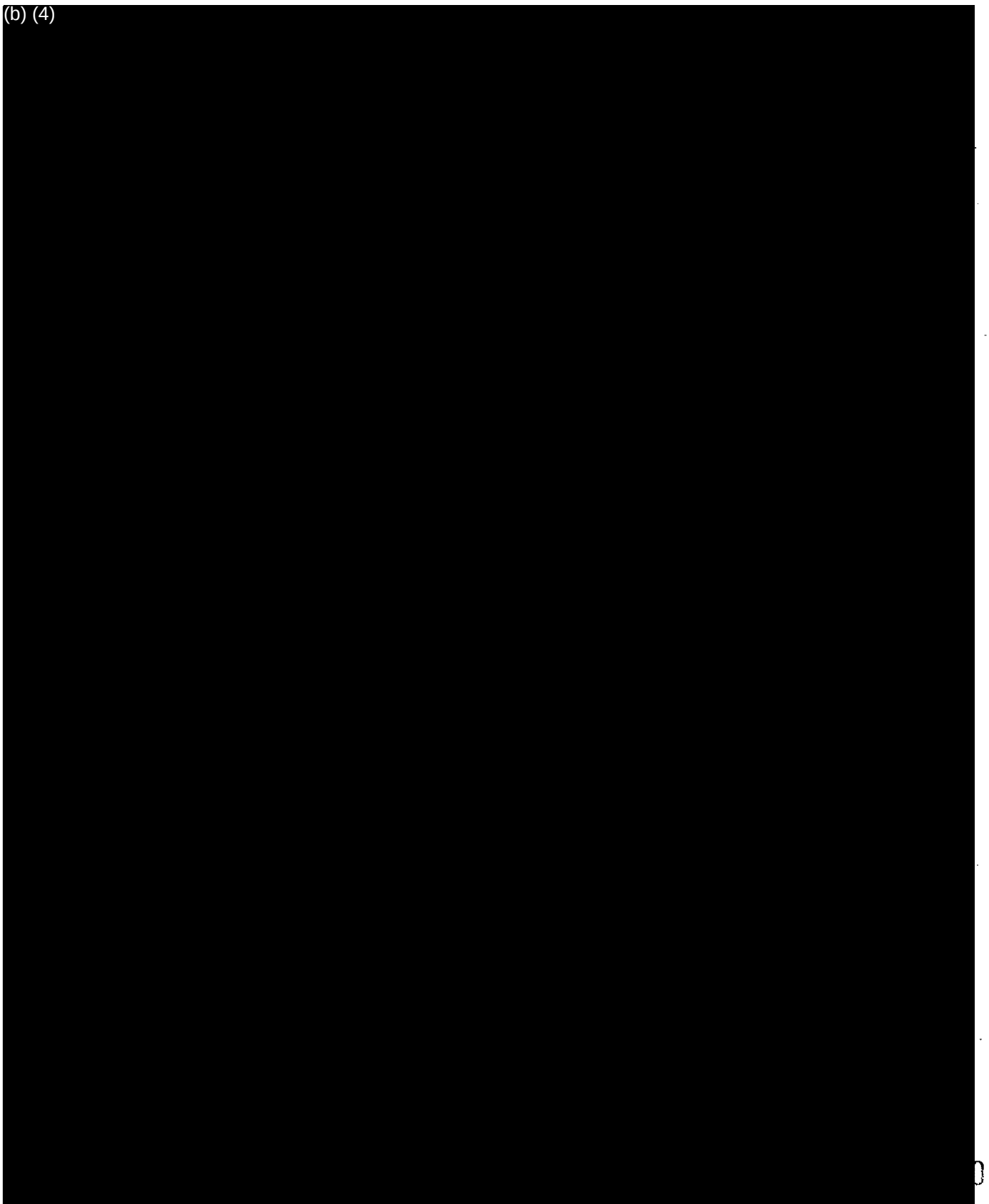

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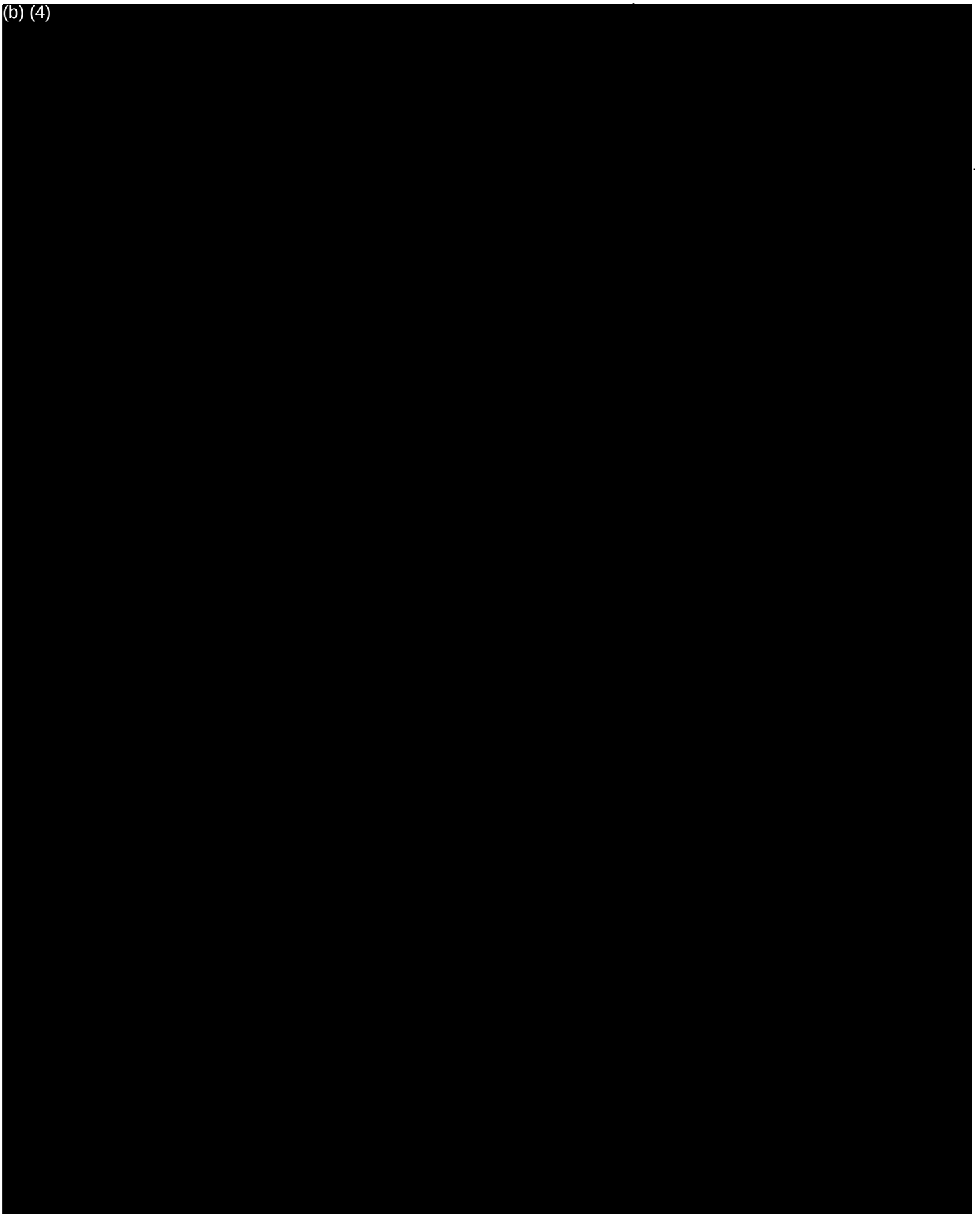

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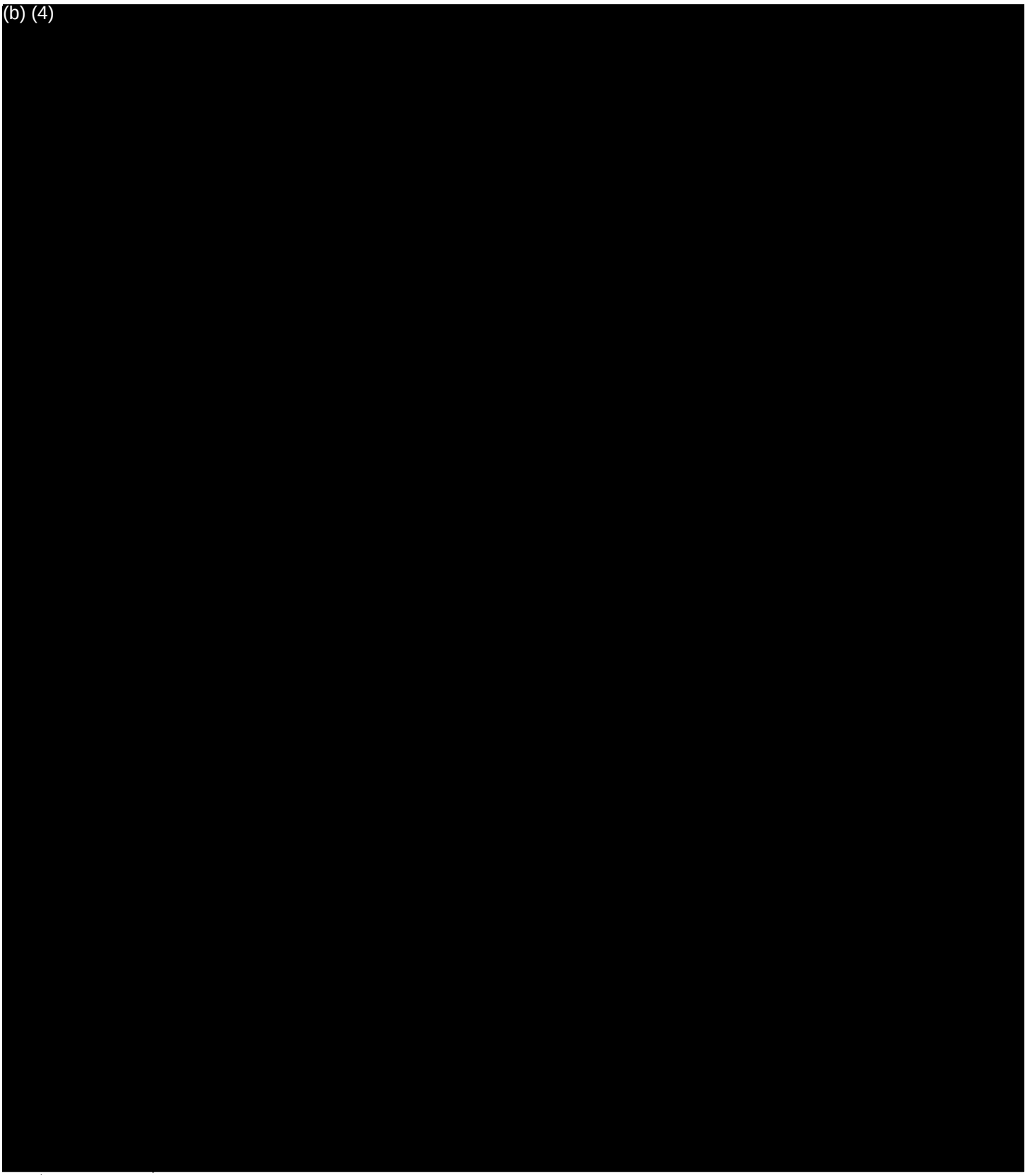

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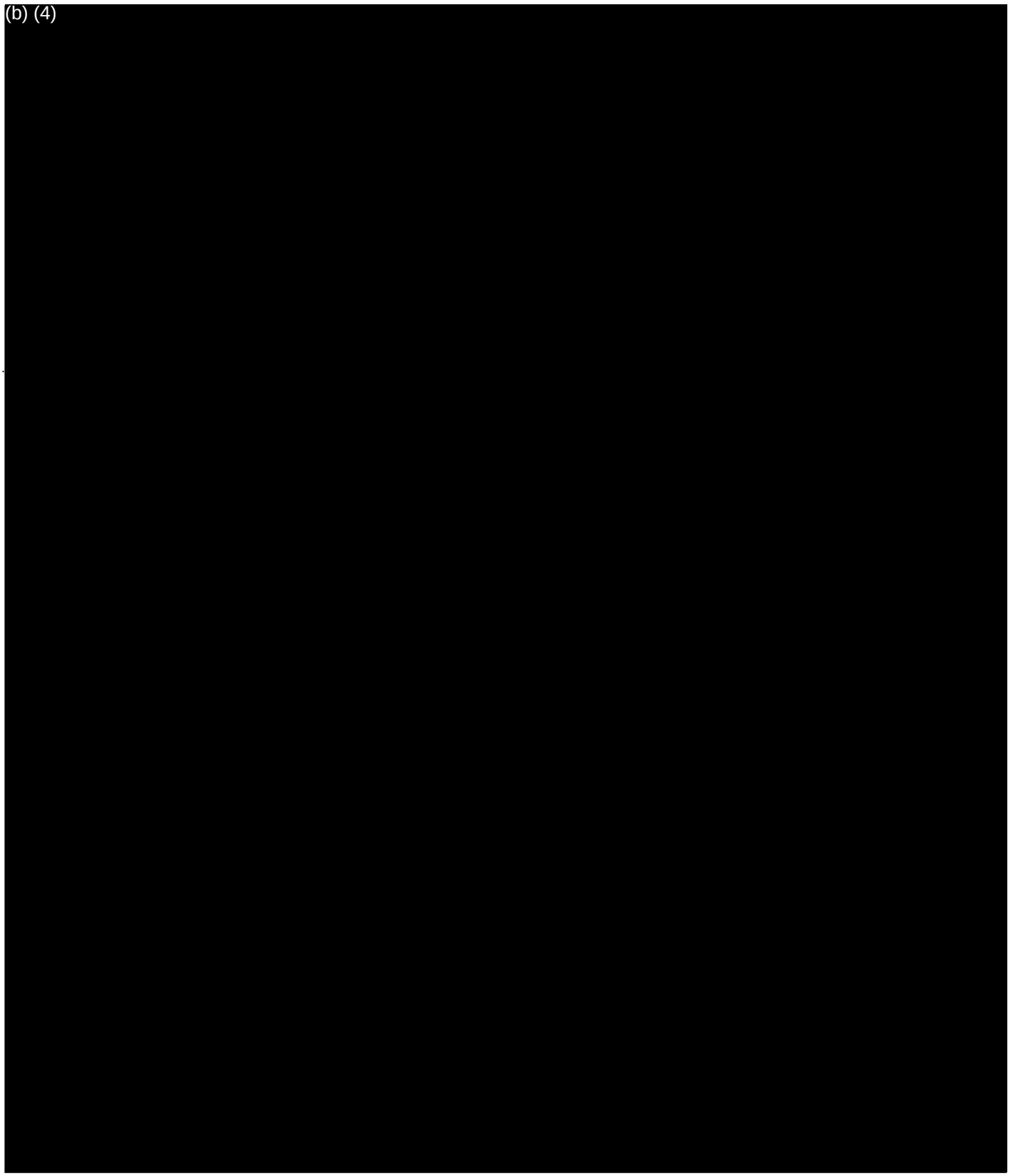

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DJA x01916

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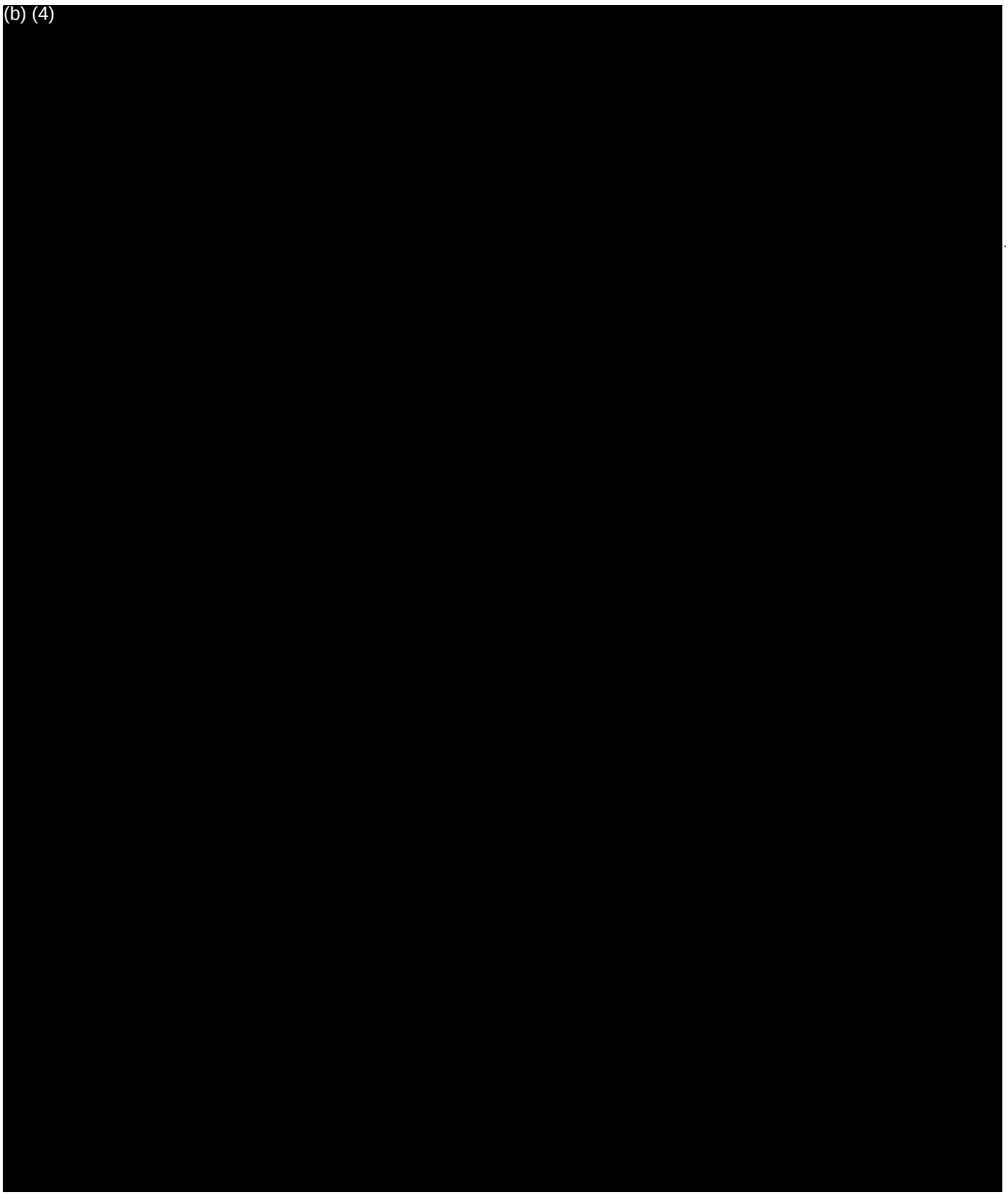

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DJA x01.920

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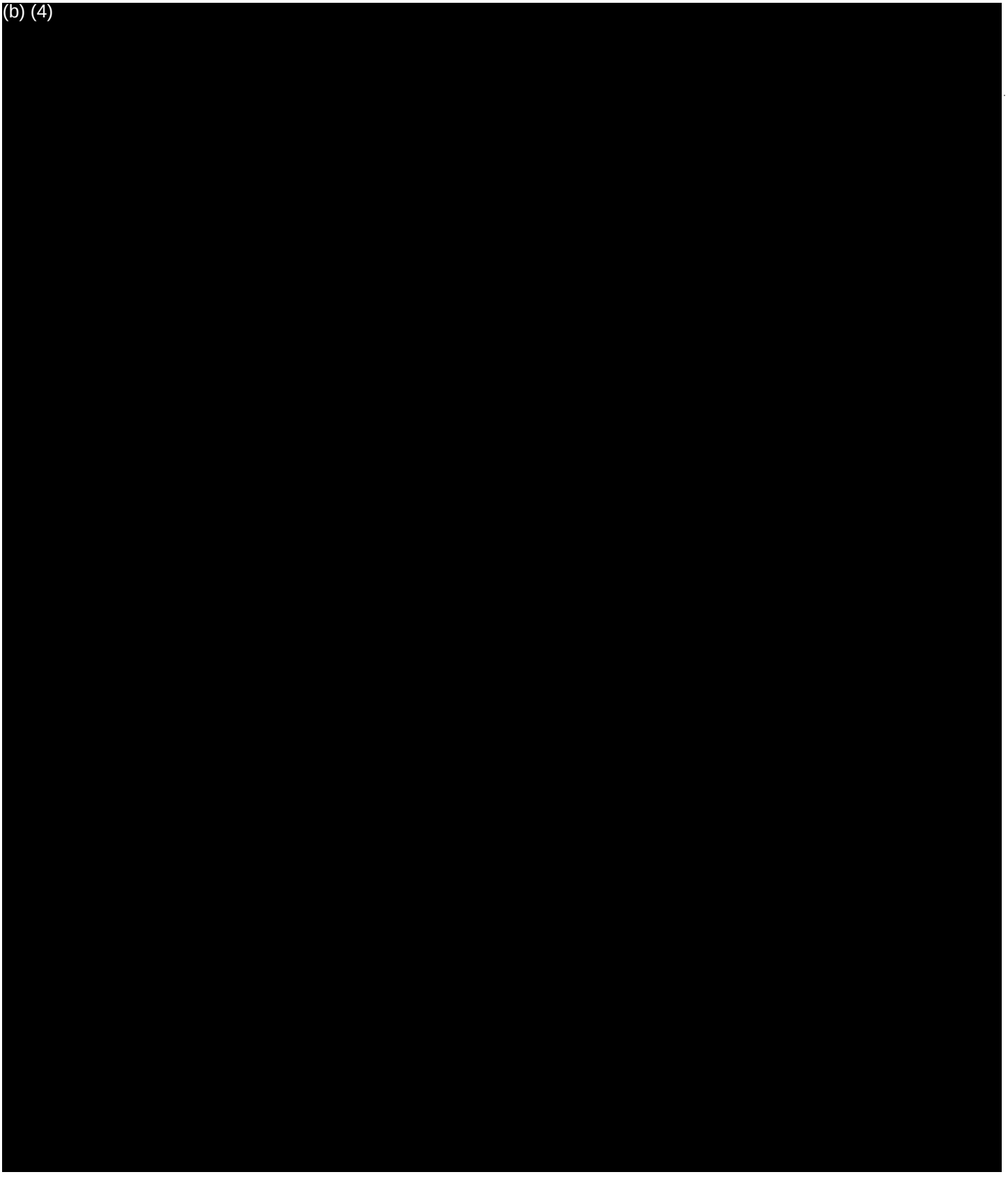

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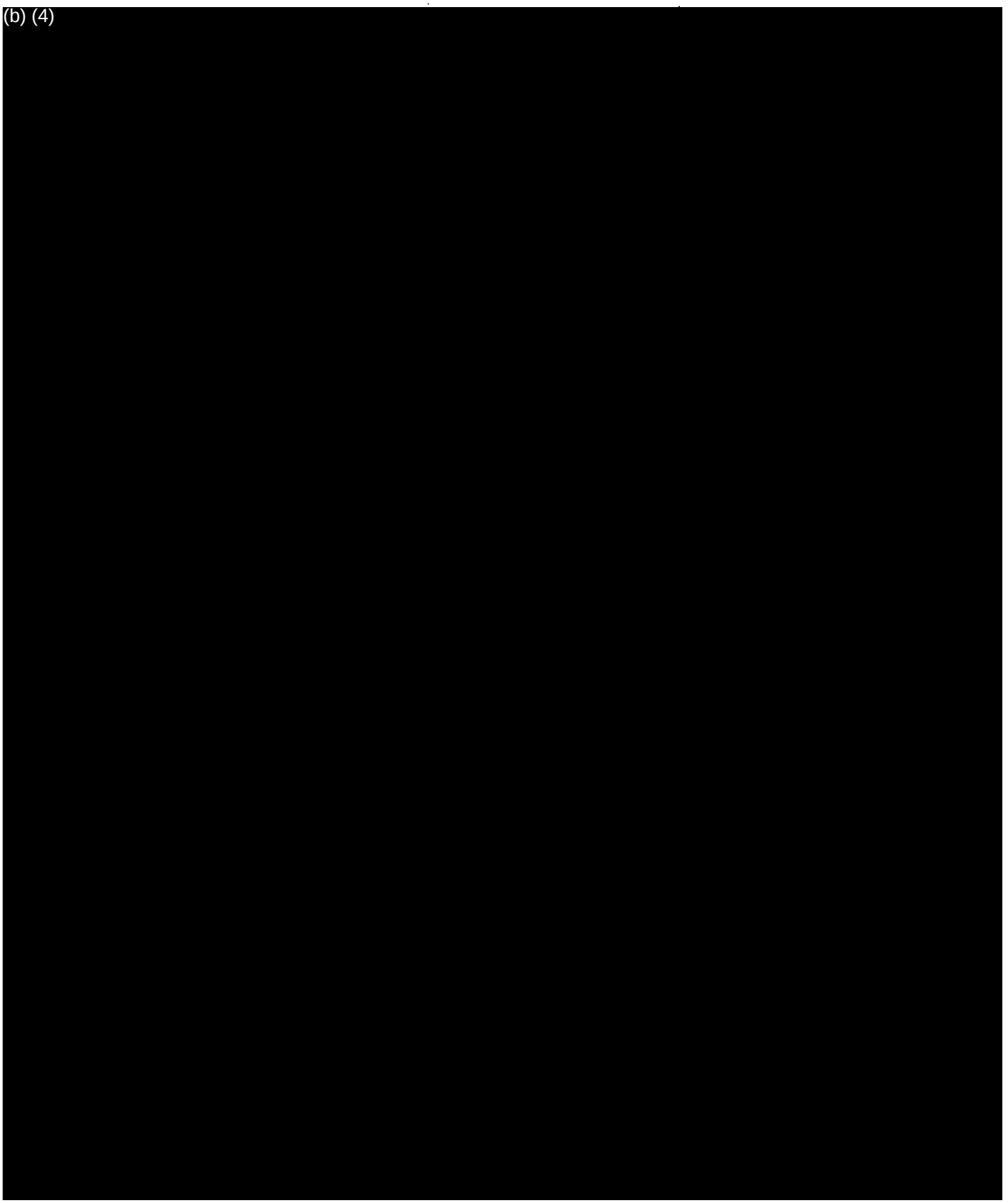

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DJA x01924

Appendix 16E

Software Development Procedure

DJA x01925

Software Development

(b) (4)

[redacted]

DJA x01926

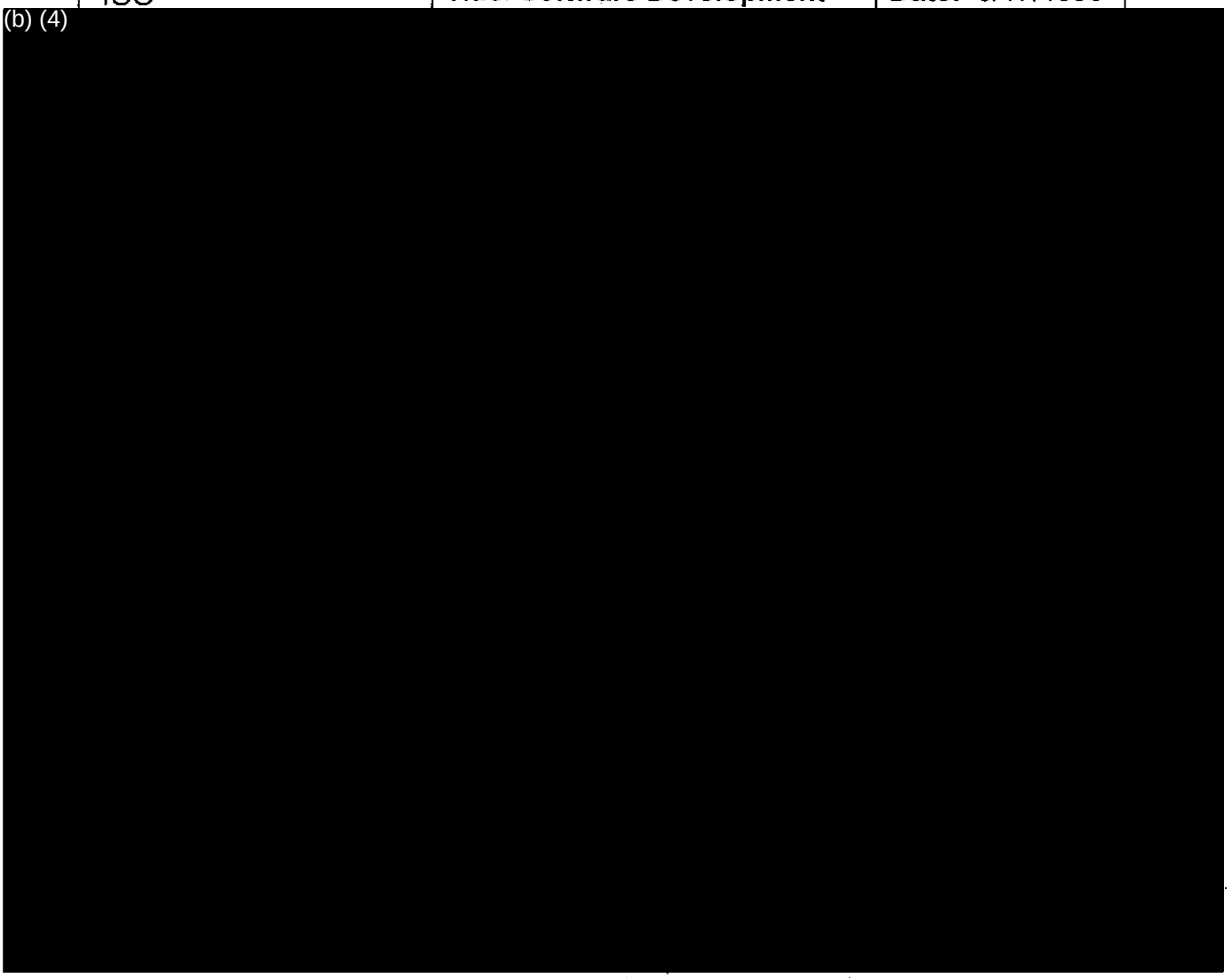
ISS	Title: Software Development	Date: 3/17/1998

(b) (4)

[redacted]

DJA x01927

(b) (4)



DJA x01928

(b) (4)

[redacted]

DJA x01929

(b) (4)

[redacted]

DJA x01930

(b) (4)

[redacted]

DJA x01931

(b) (4)

[redacted]

DJA x01932

(b) (4)

[redacted]

DJA x01933

(b) (4)

[redacted]

DJA x01934

(b) (4)

[redacted]

DJA x01935

APPENDIX 1

Software Design Specification Requirements

1. Software Design Specifications may include the following:

(b) (4) [redacted]

DJA x01936

QUALITY POLICY AND PROCEDURE APPROVAL AND REVISION RECORD

(b) (4) [redacted]

DJA x01937

Appendix 16F

Validation of "Pinless" DigiMatch™ ROBODOC® Technology at
(b) (4)

DJA x01938

ROBODOC PROTOCOL and TEST REPORT APPROVAL SHEET

(b) (4)

[redacted]

Integrated Surgical Systems, Inc.
1433 N. Market Blvd, Sacramento, CA 95834

(b) (4)

DJA x01939

(b) (4)

1 Objectives

(b) (4)

2 Deviations from Protocol

(b) (4)

3 Background

(b) (4)

4 Description of Study Device

(b) (4)

DJA x01940

5 Data Analysis

(b) (4)

[redacted]

6 Acceptance Criteria

(b) (4)

[redacted]

7 Results

(b) (4)

[redacted]

DJA x01941

Table 1 Summary of Implant Placement

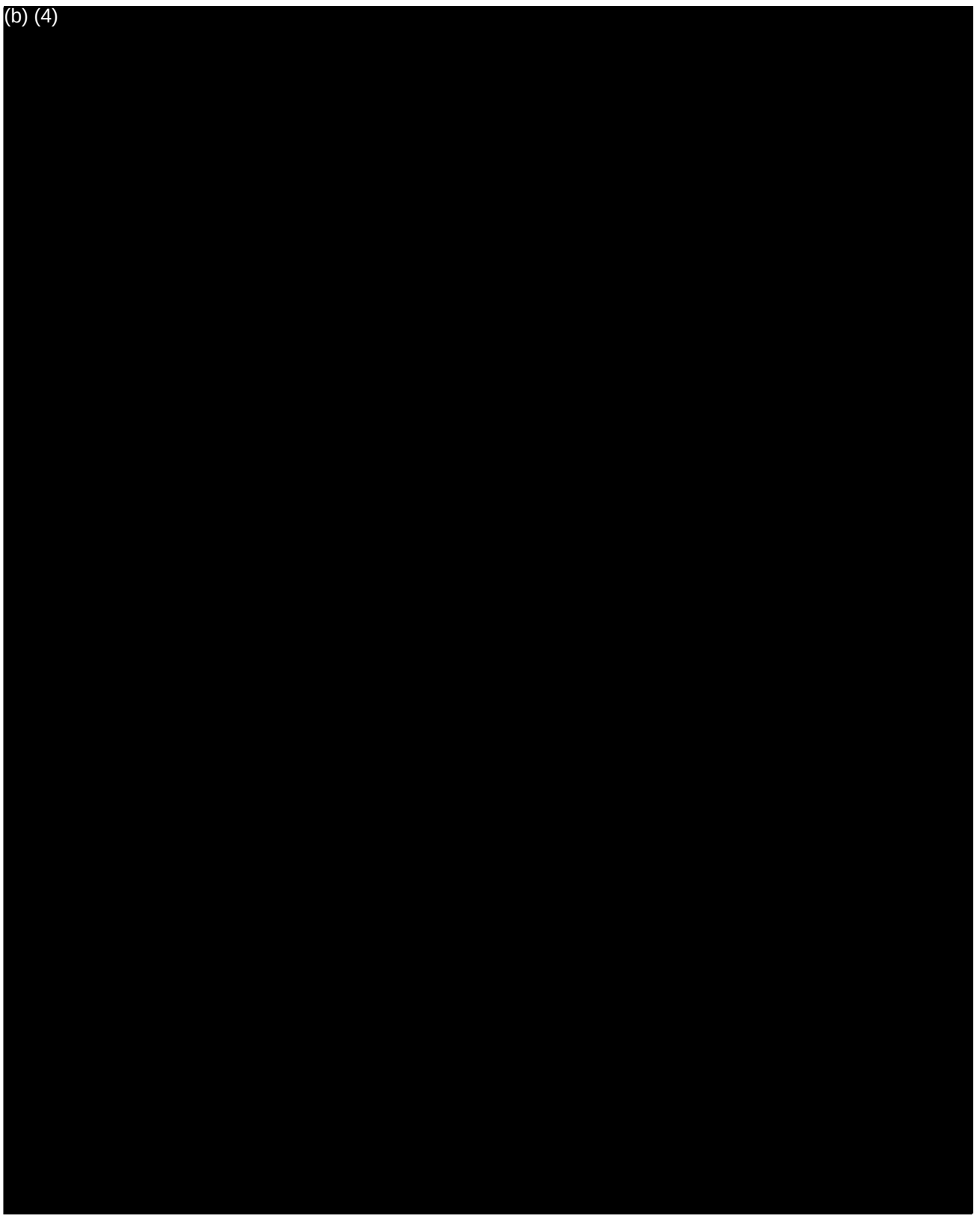
(b) (4)

[redacted]

DJA x01942

Table 1 Summary of Implant Placement (continued)

(b) (4)



DJA x01943

(b) (4)

[redacted]

DJA x01944

Table 2 Registration Performance Metrics (continued)

(b) (4)

Table 2a Statistics for Registration Performance

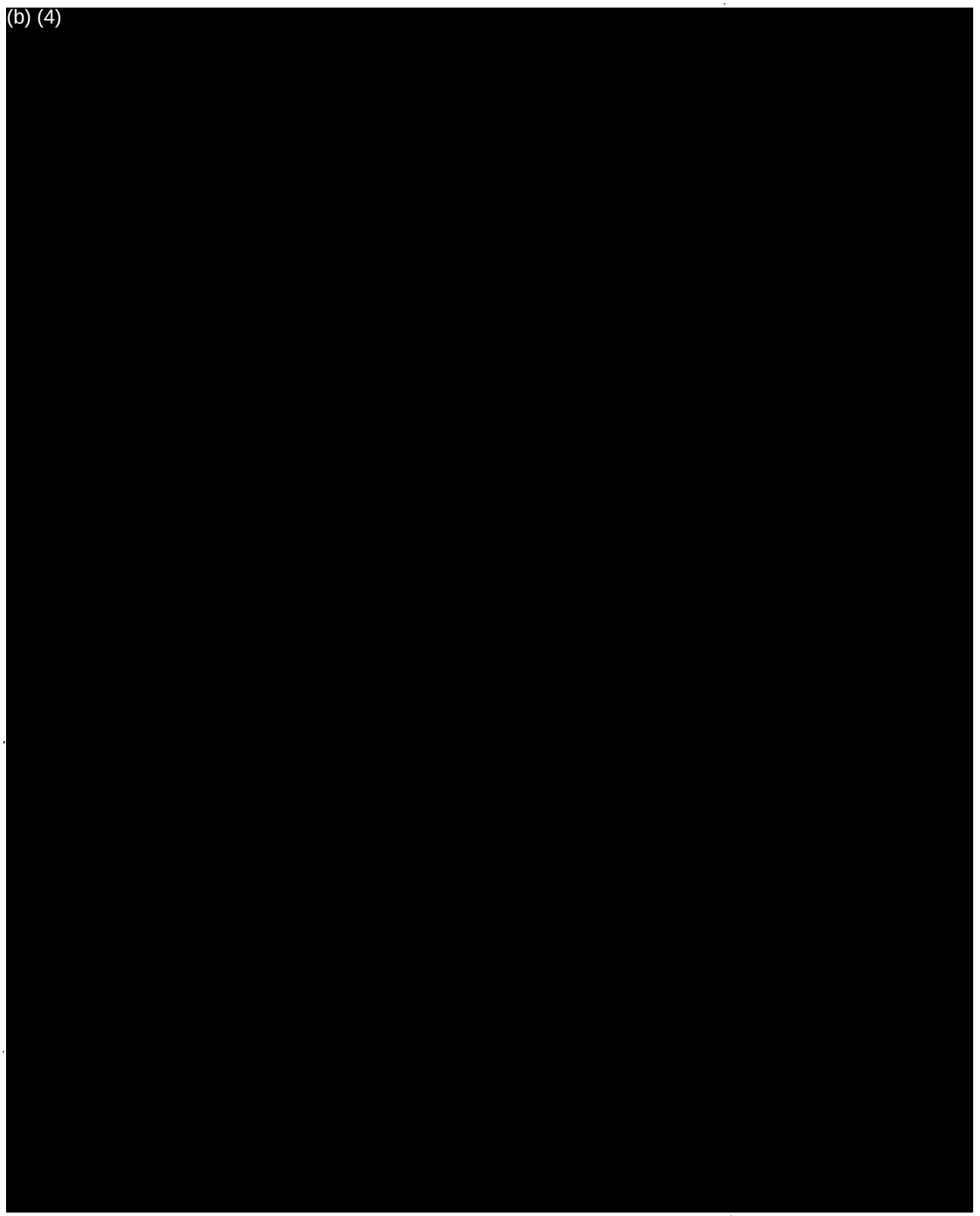
(b) (4)

8 Discussion

(b) (4)

DJA x01945

(b) (4)



(b) (4)

DJA x01946

(b) (4)

[redacted]

9 Conclusions

The following conclusions were drawn from this validation study:

(b) (4)

[redacted]

DJA x01947

10 Attachments

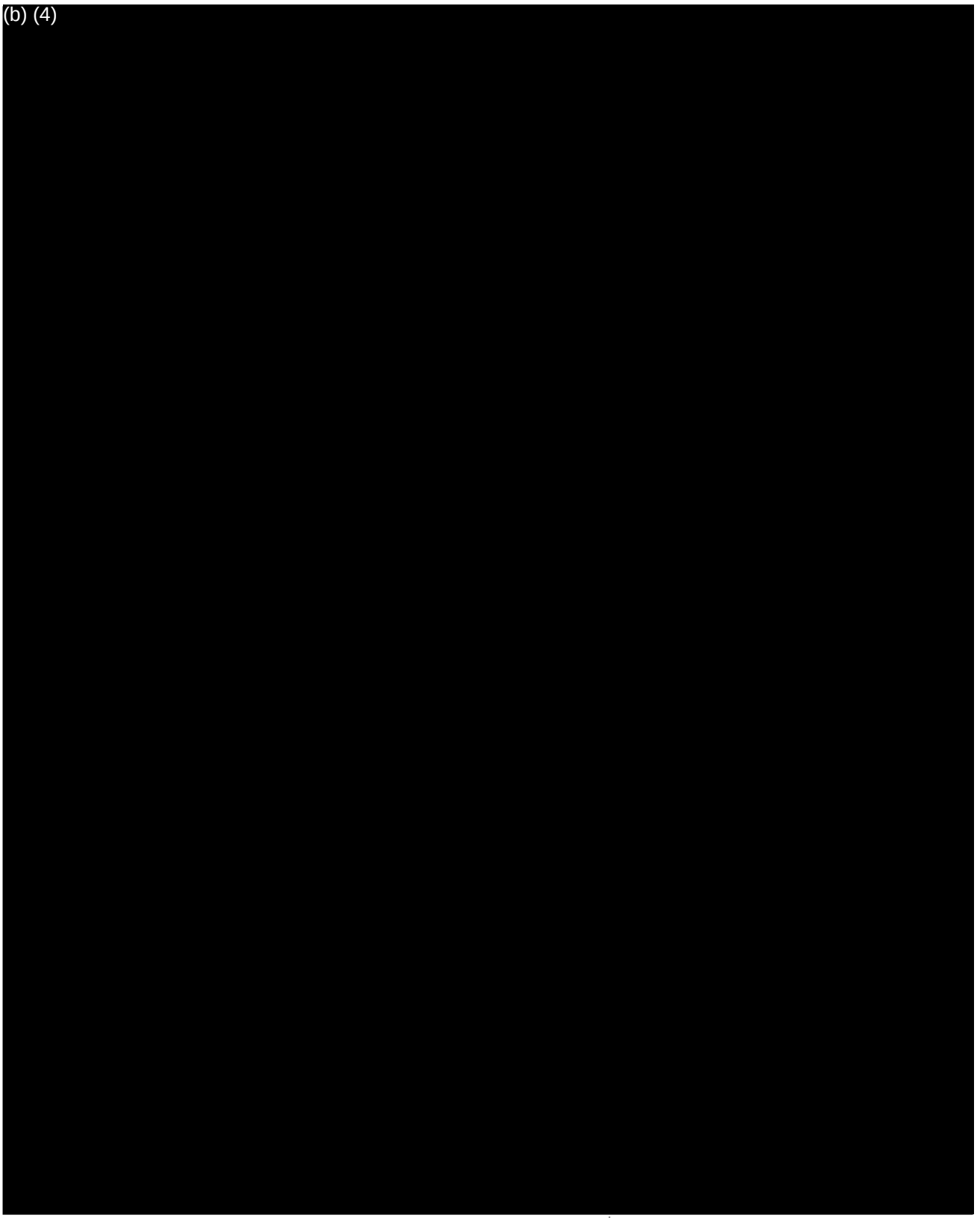
(b) (4)

[redacted]

DJA x01948

Attachment 1 **Statistics from Pinless ROBODOC Clinical Validation**

(b) (4)



DJA x01949

Attachment 2 **Data Collection Form Summary Information**

(b) (4)

DJA x01950

Appendix 16G

Risk Analysis for the ROBODOC and ORTHODOC Systems

DJA x01951

Approval & Change Control Page

(b) (4)

[redacted]

DJA x01952

1. INTENDED USE OF THE DEVICE

The DigiMatch™ ROBODOC® Surgical System is intended for use as a stereotactic device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to conventional manual templating and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

2. PURPOSE

(b) (4)

[redacted]

3. SCOPE

(b) (4)

[redacted]

4. REFERENCES

(b) (4)

[redacted]

Volume III- 000279

DJA x01953

5. METHODOLOGY

(b) (4)

[redacted]

DJA x01954

(b) (4)

6. RISK ANALYSIS

(b) (4)

7. RISK CONTROL AND IMPLEMENTATION.

Risk control measures for the DigiMatch™ ROBODOC® product are implemented prior to the commercial release. Effectiveness of design elements are checked through validation of the design elements during the product release process. Effectiveness of manufacturing processes is checked through validation of those processes.

DJA x01955

8. RISK EVALUATION

(b) (4)

[redacted]

9. OVERALL RESIDUAL RISK EVALUATION

(b) (4)

[redacted]

DIRECTOR, REGULATORY AFFAIRS

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazards Without Controls	RPN			Applicable Controls	Response After Controls	RPN		
							S	P	D			S	P	D
(b) (4)														

(b) (4)

DIGIMATCH ROBODOC

(b) (4)

DJA x01958

(b) (4)

(b) (4)

(b) (4)

(b) (4)

[redacted]

(b) (4)

[redacted]

(b) (4)

(b) (4)

CUTTERS

(b) (4)

DRAPES

(b) (4)

TUBE SET

(b) (4)

MARKERS

(b) (4)

[redacted]

DJA x01966

Appendix 16H

Validation of "Pinless" DigiMatch™ ROBODOC® Software Protocol and Report

DJA x01967

ROBODOC PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 4
KEY WORDS: ROBODOC Software Validation Report	PROTOCOL REF. NO. (If applicable) (b) (4)	PROJECT NO.: (If applicable) 7

(b) (4)

[redacted]

Volume III - 000294

DJA x01968

1 Test Objectives

(b) (4)

[redacted]

DJA x01969

(b) (4)

8 Discussion

All the tests were passed. The ROBODOC successfully operated correctly in normal and error conditions.

(b) (4)

9 Conclusions

No anomalies were observed. All the test cases were passed and reported. The acceptance criteria are satisfied. The validation tests passed.

DJA x01970

ROBODOC
INTEGRATED SURGICAL SYSTEMS

ROBODOC PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 8
KEY WORDS: ROBODOC Software Validation Protocol	PROTOCOL REF. NO. (If applicable) N/A	PROJECT NO.: (If applicable) 7

(b) (4)

[redacted]

Volume III.- 000297

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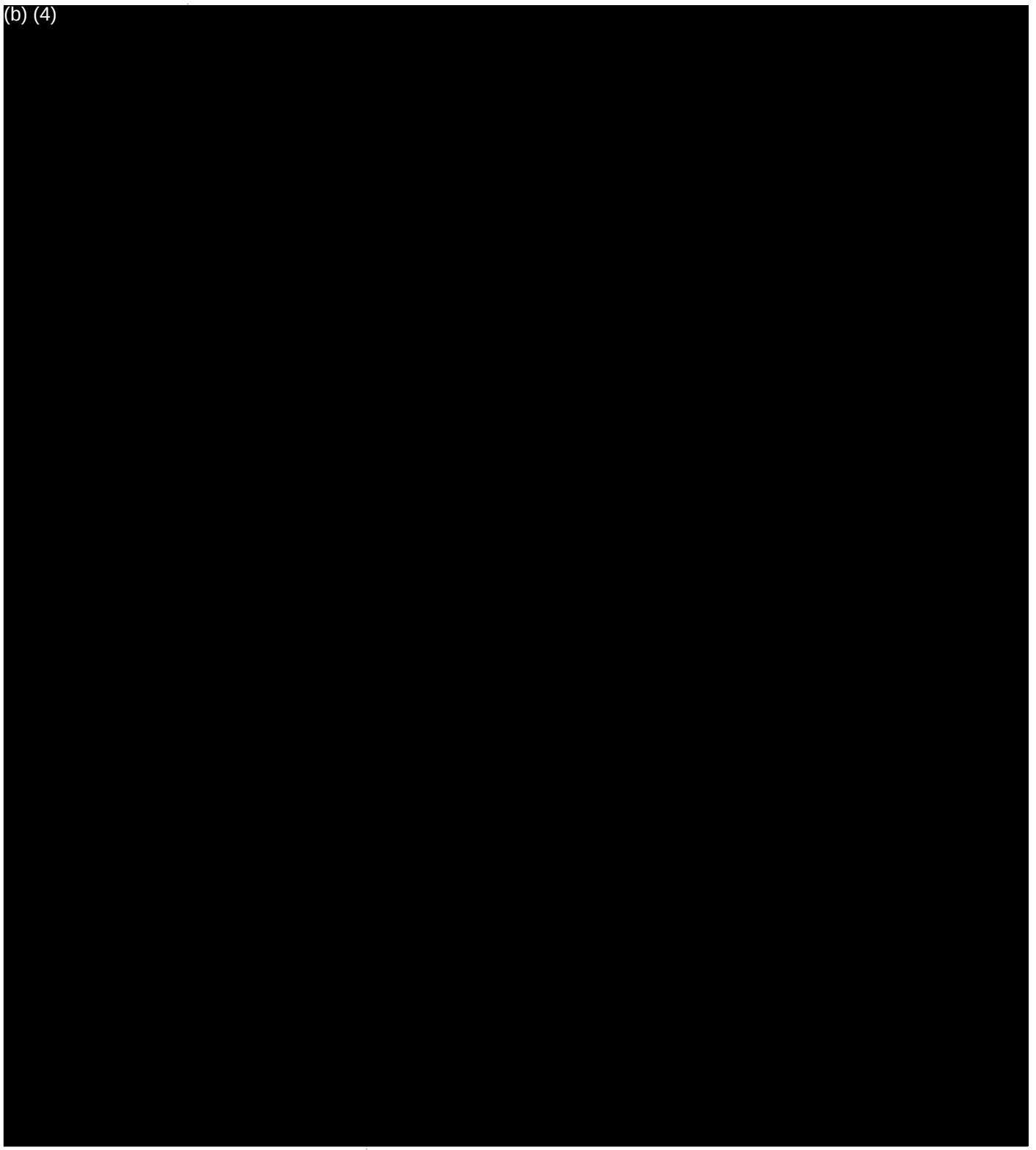
DJA x01971

I. Test Objective

(b) (4)



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DJA x01972

VIII. Test Methods / Procedure

(b) (4)

[redacted]

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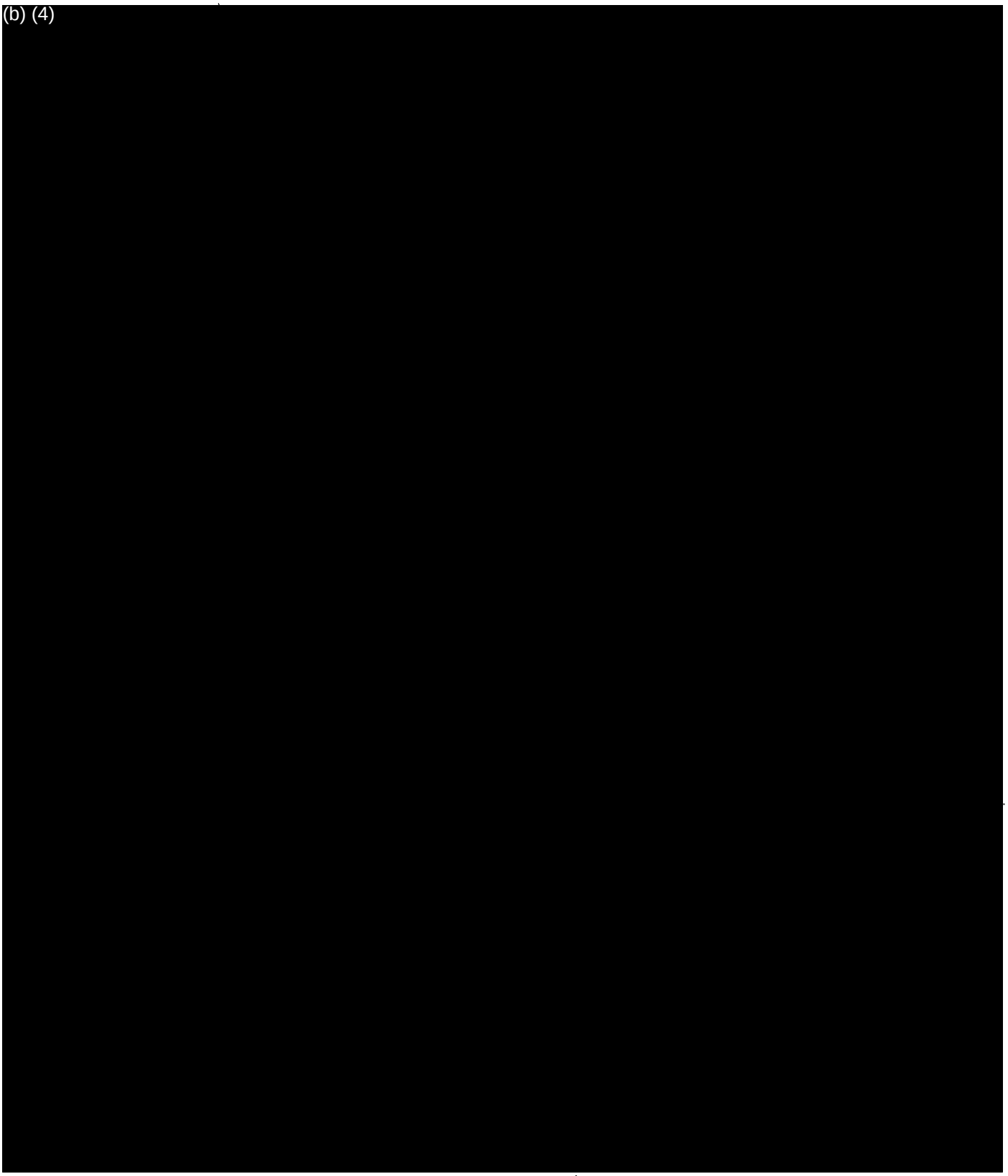
DJA x01973

(b) (4)



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DJA x01974

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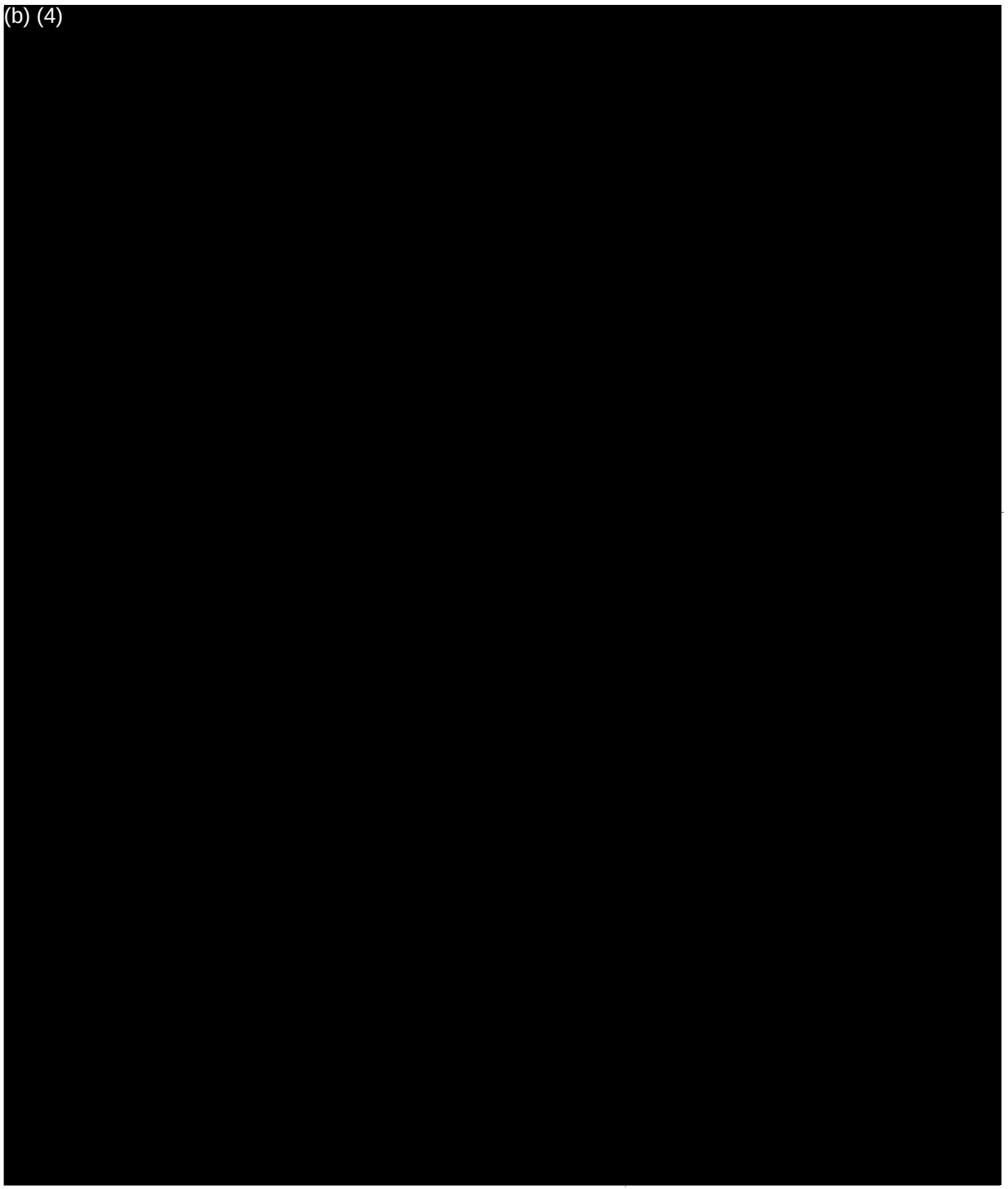

SYSTEM INITIALIZATION AND DIAGNOSTICS

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DJA x01975

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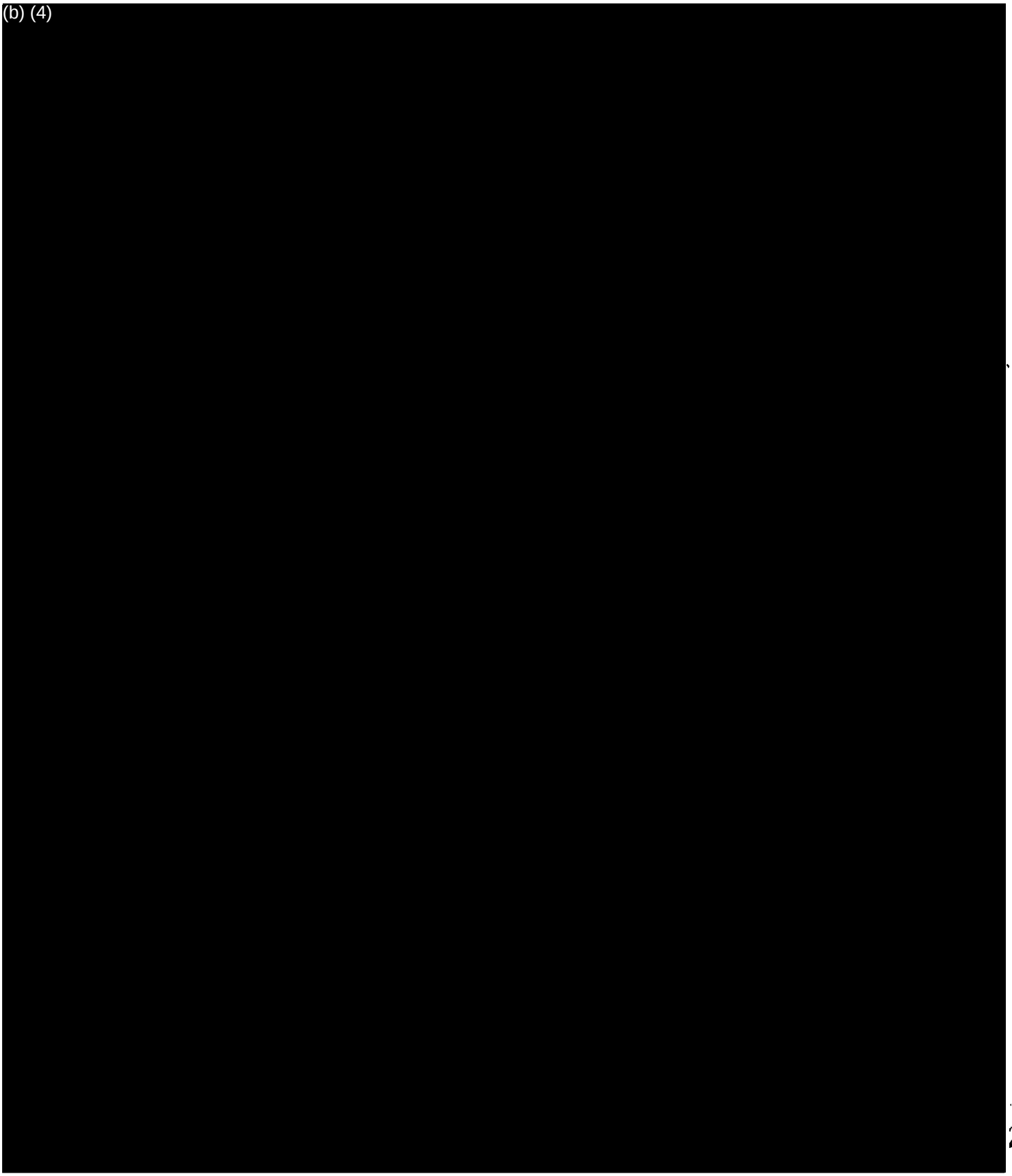

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DJA x01976

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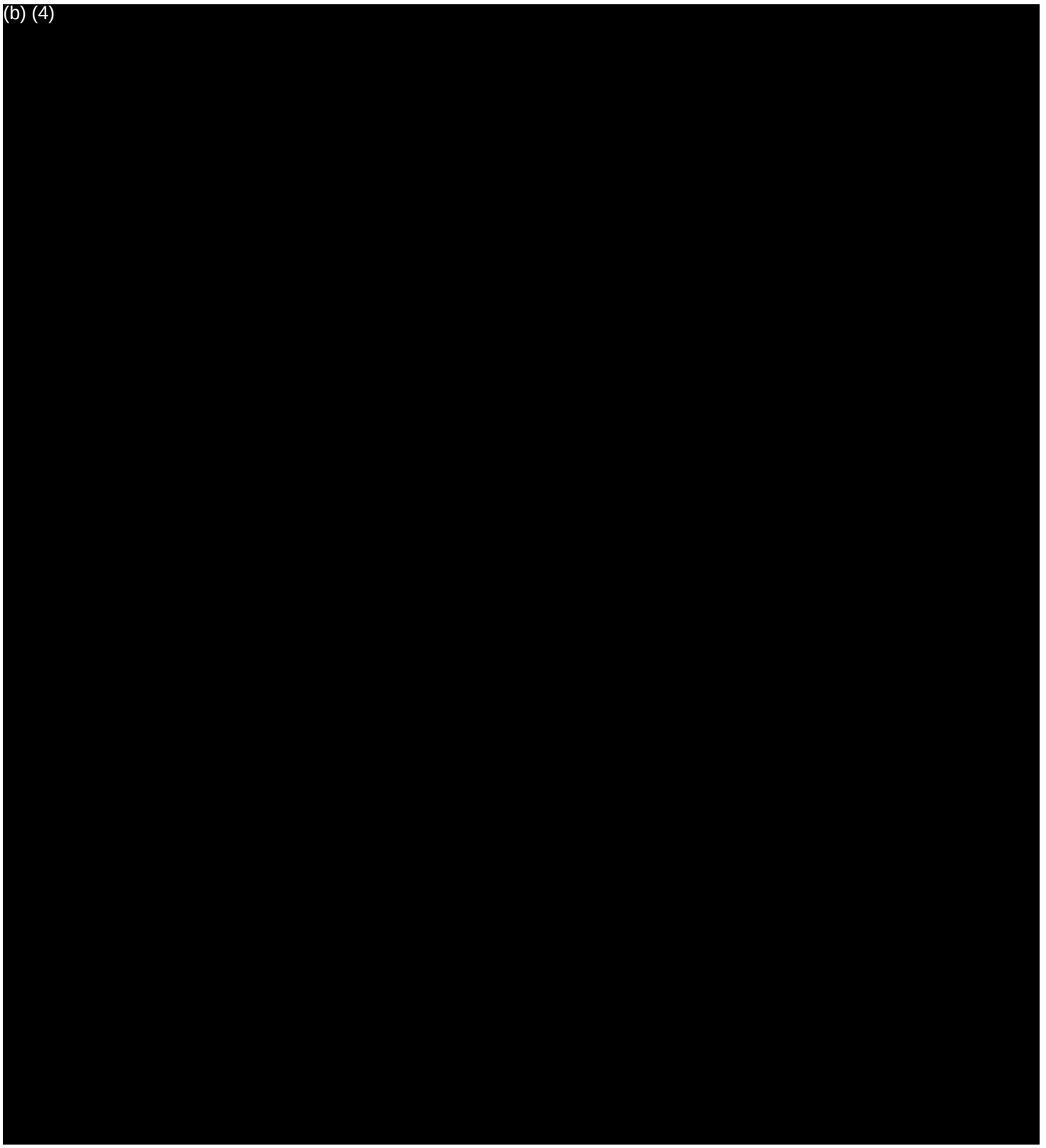

N/A

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DJA x01977

X. Acceptance Criteria

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DJA x01978

(b) (4)

(b) (4)

Invoice

INVOICE #
1484

BILL TO
Integrated Surgical Systems 1433 N. Market Blvd., #1 Sacramento, CA 95834 Attn: RD Hibbert

DATE
8/31/2007
P.O. NUMBER
DUE DATE
9/30/2007

ITEM	Description	Hours/Qty	Rate ($)	AMOUNT
(b) (4)				

	Total	1,755.00

DJA x01979

Appendix 16I

ORTHODOC® Software Validation Protocol and Report

DJA x01980

ORTHODOC PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER (b) (4)		PAGE 1 OF 3
KEY WORDS: ORTHODOCC Software Validation Report	PROTOCOL REF. NO. (If applicable) (b) (4) 1	PROJECT NO.: (If applicable) 42

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[redacted]

Integrated Surgical Systems, Inc.
1433 N. Market Blvd, Sacramento, CA 95834

DJA x01981

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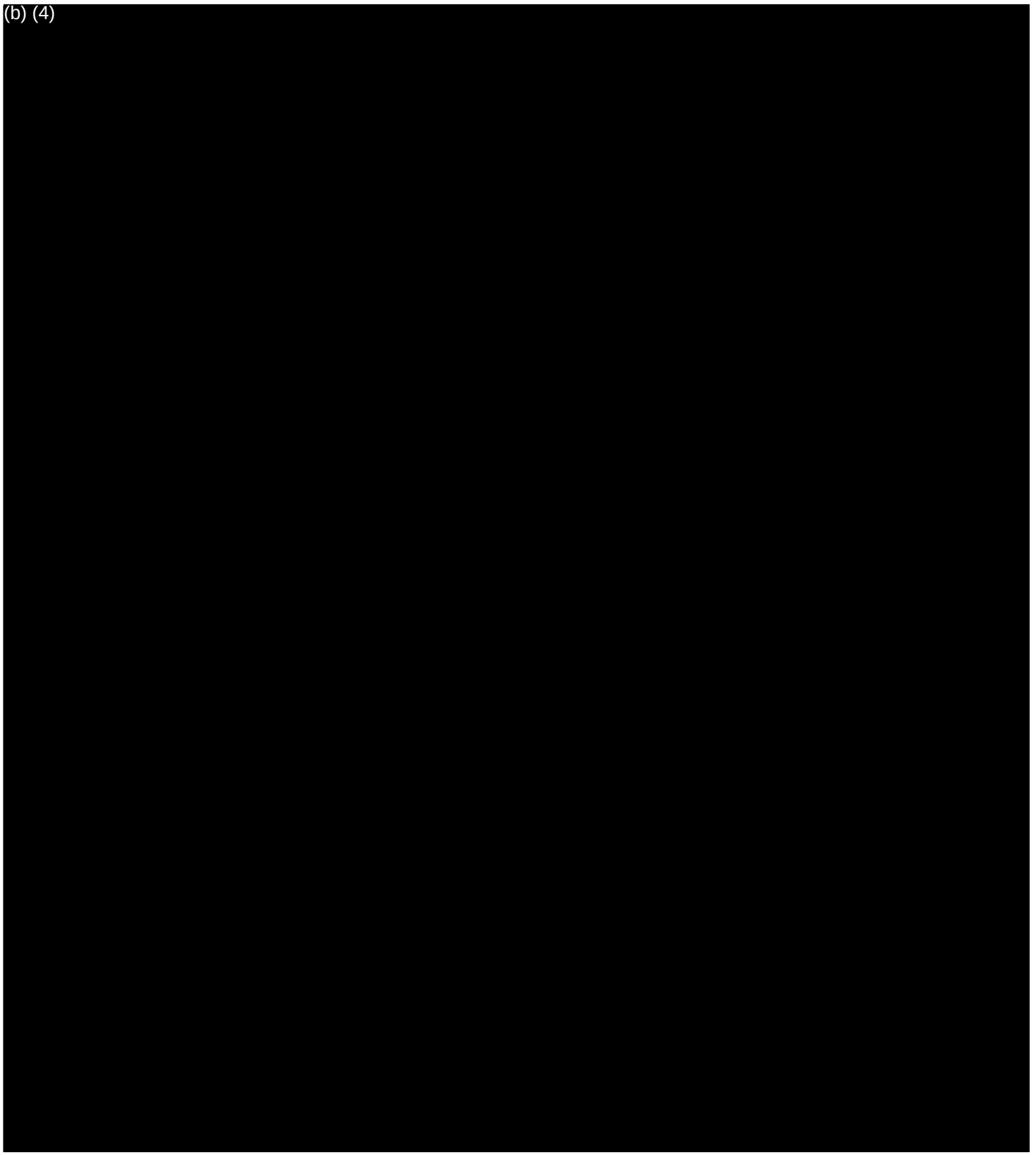

DJA x01982

- (b) (4)
-
-

5.3 (b) (4)

5.4

5.5

5.6

5.7

5.8

6 Discussion

All the tests were passed . The ORTHODOC successfully imported the data, managed the case data, displayed images, loaded and navigated the implants, created the transfer media to use with ROBODOC® Surgical Assistant.

7 Conclusion

No anomalies were observed. All the test cases were passed and reported. The acceptance criteria is satisfied. The validation tests passed.

DJA x01983

PROTOCOL and TEST REPORT APPROVAL SHEET

DCO # 1579

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 49
KEY WORDS: ORTHODOC TEST REPORT	PROTOCOL REF. NO. (If applicable) (b) (4)	PROJECT NO.: (If applicable) 42

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DJA x01984

(b) (4)

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DJA x01985

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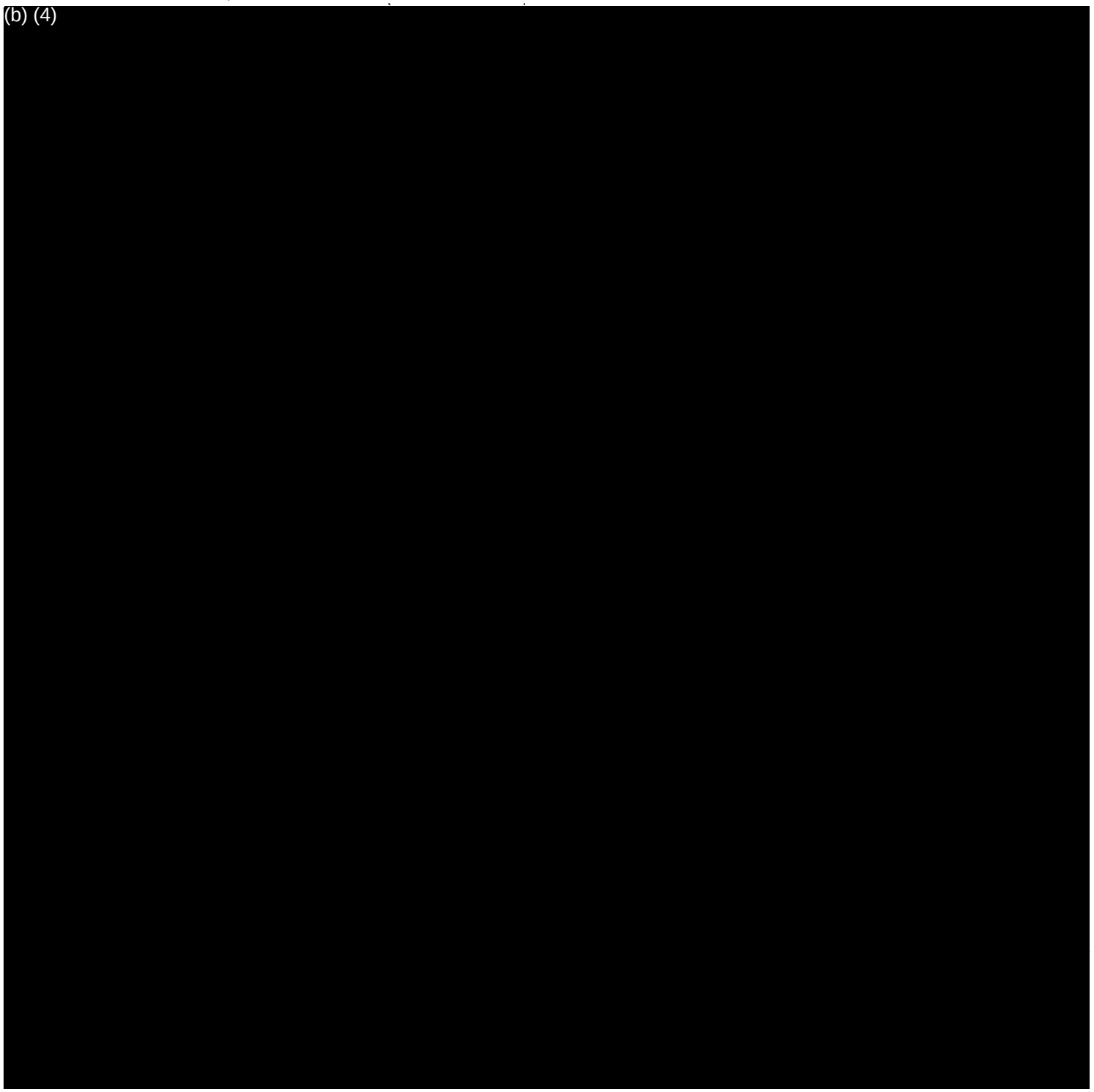

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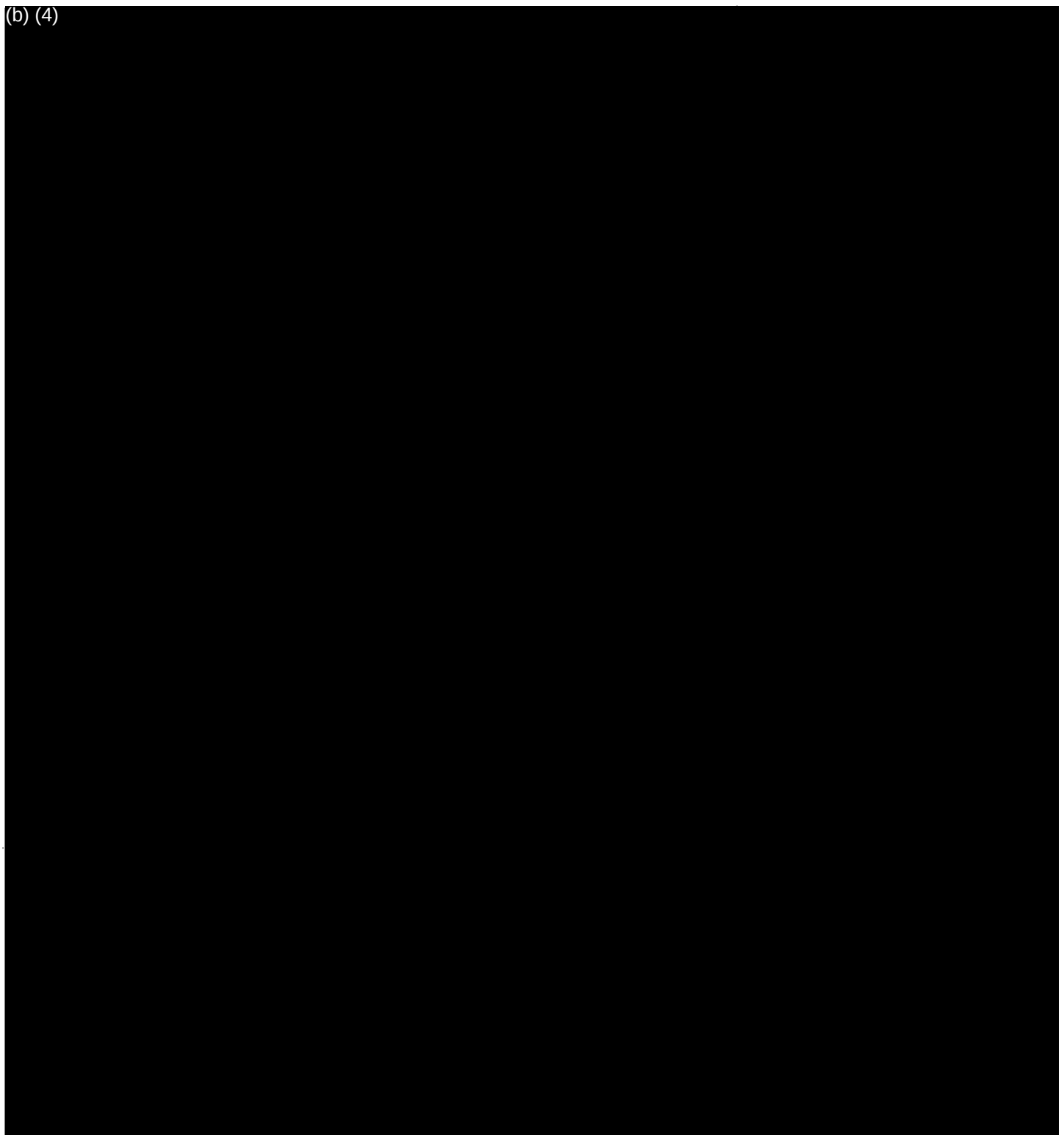

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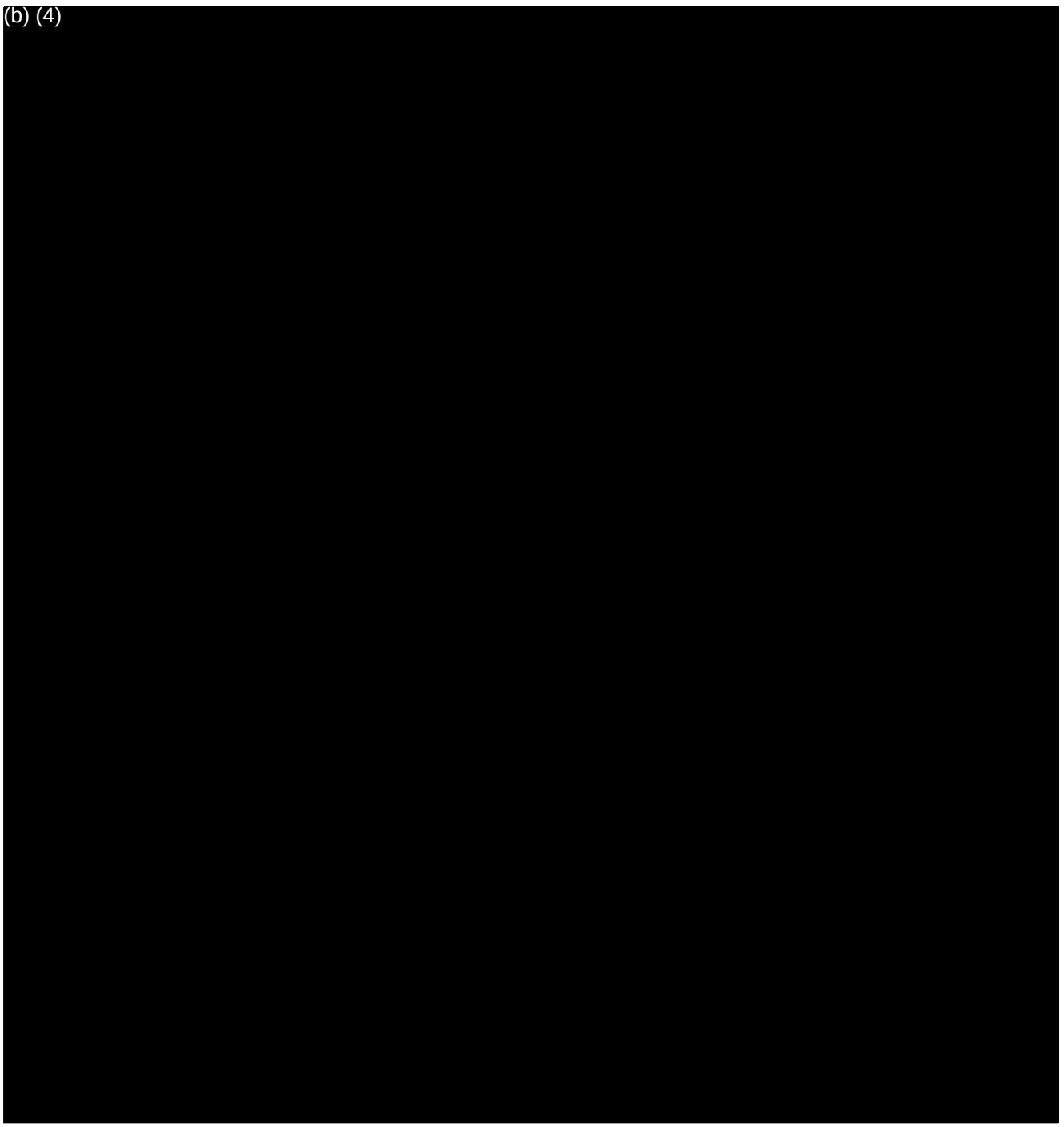

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DJA x01989

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storage

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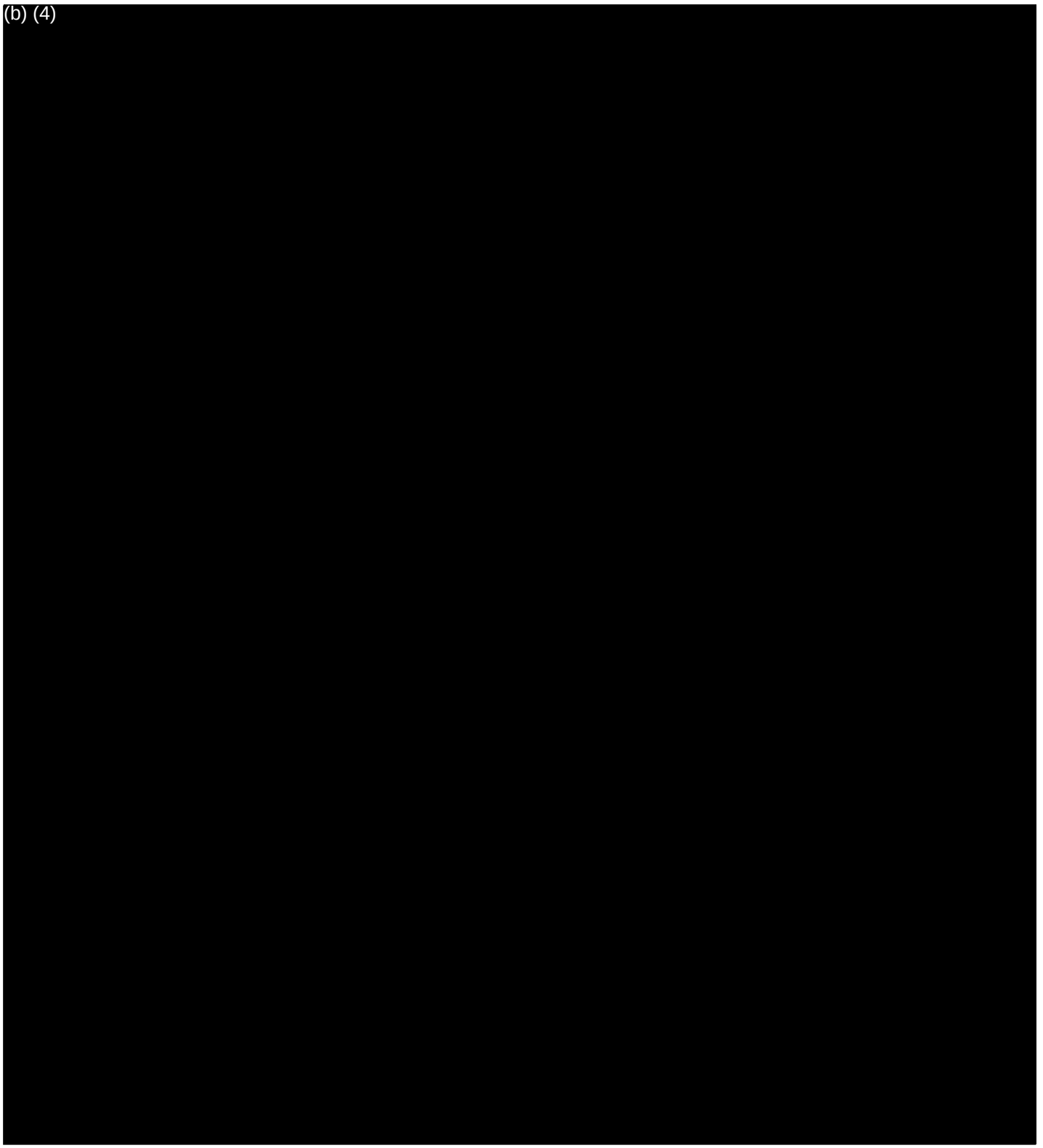

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DJA x01991

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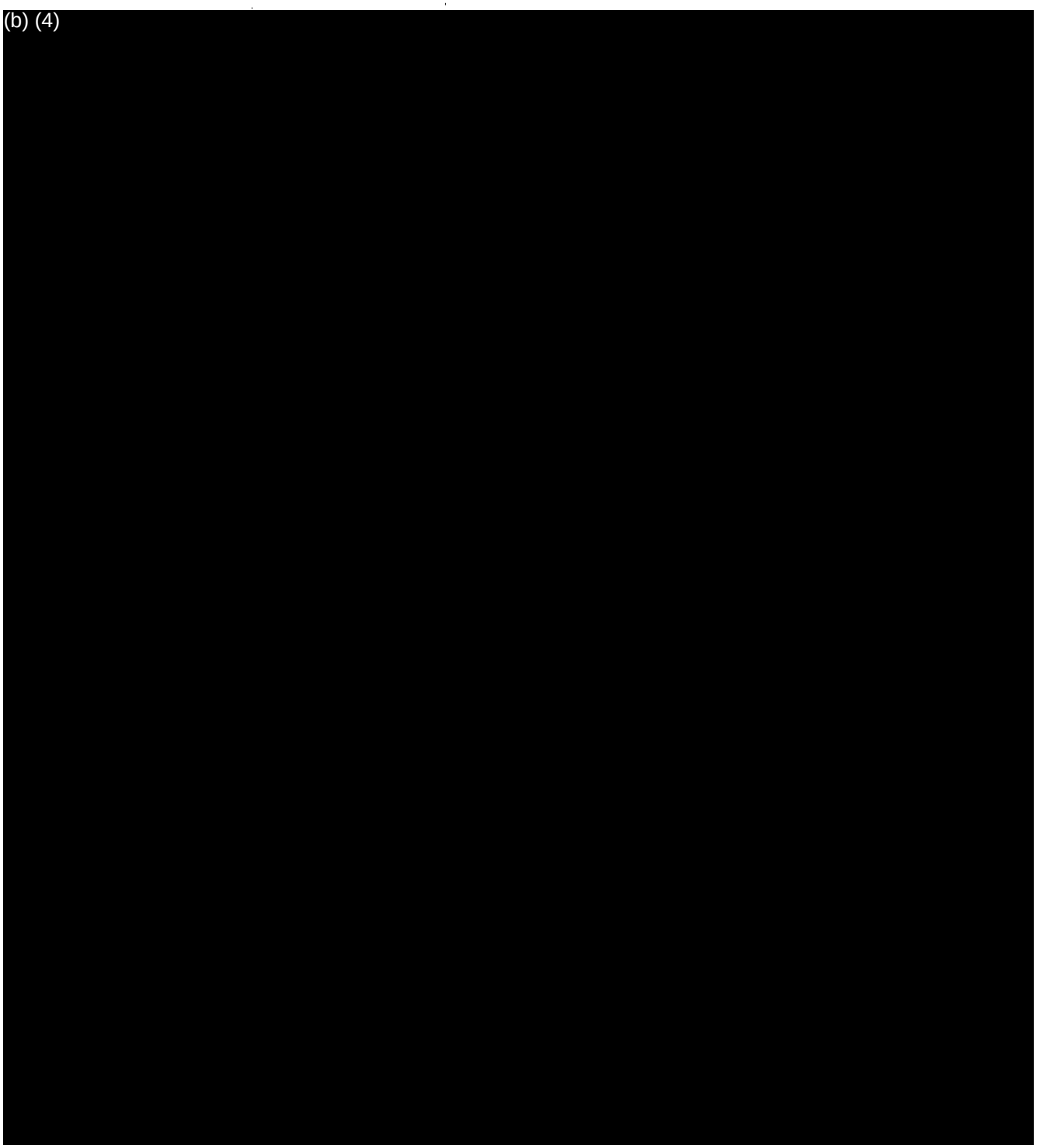

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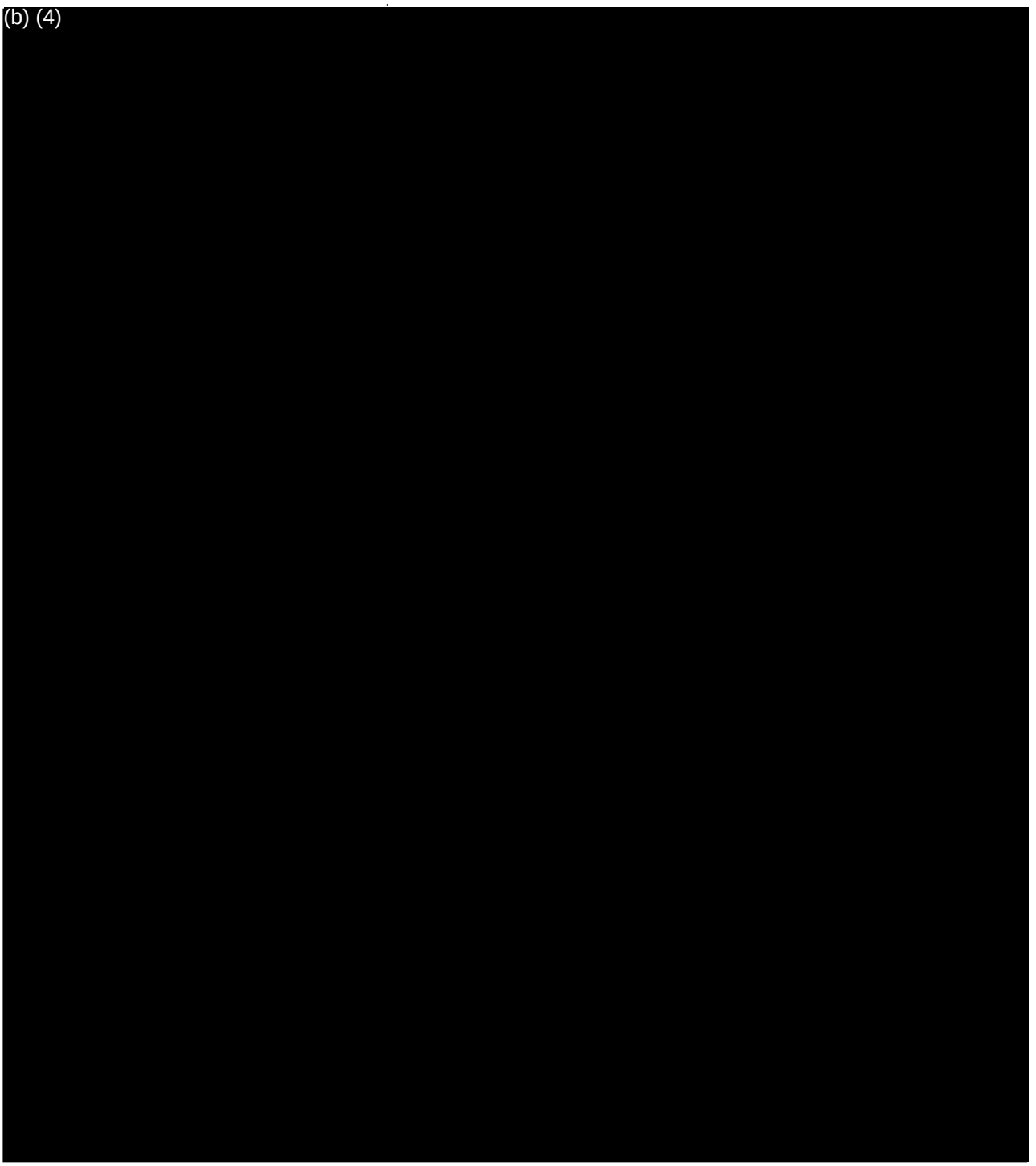

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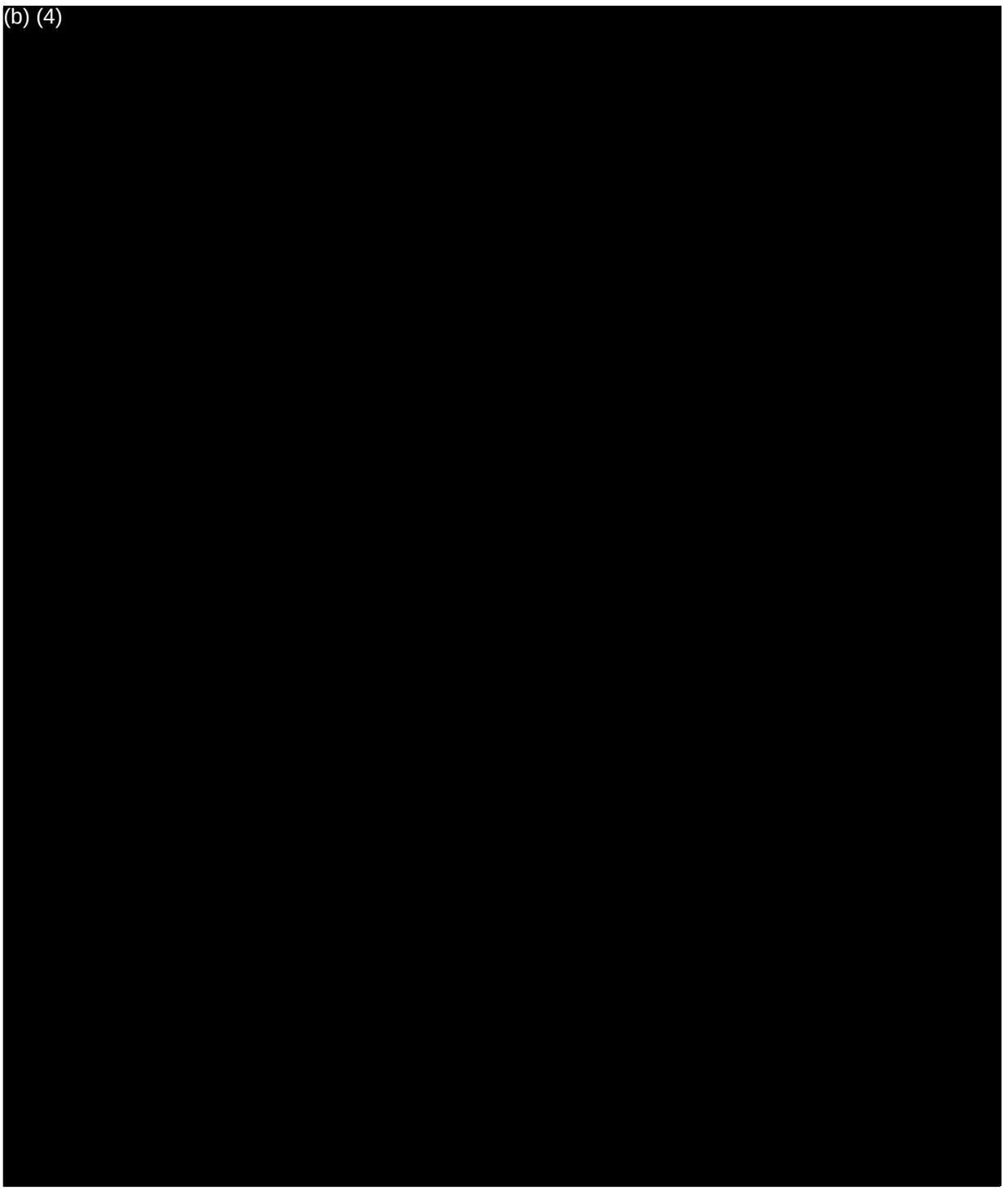

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DJA x01996

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DJA x01997

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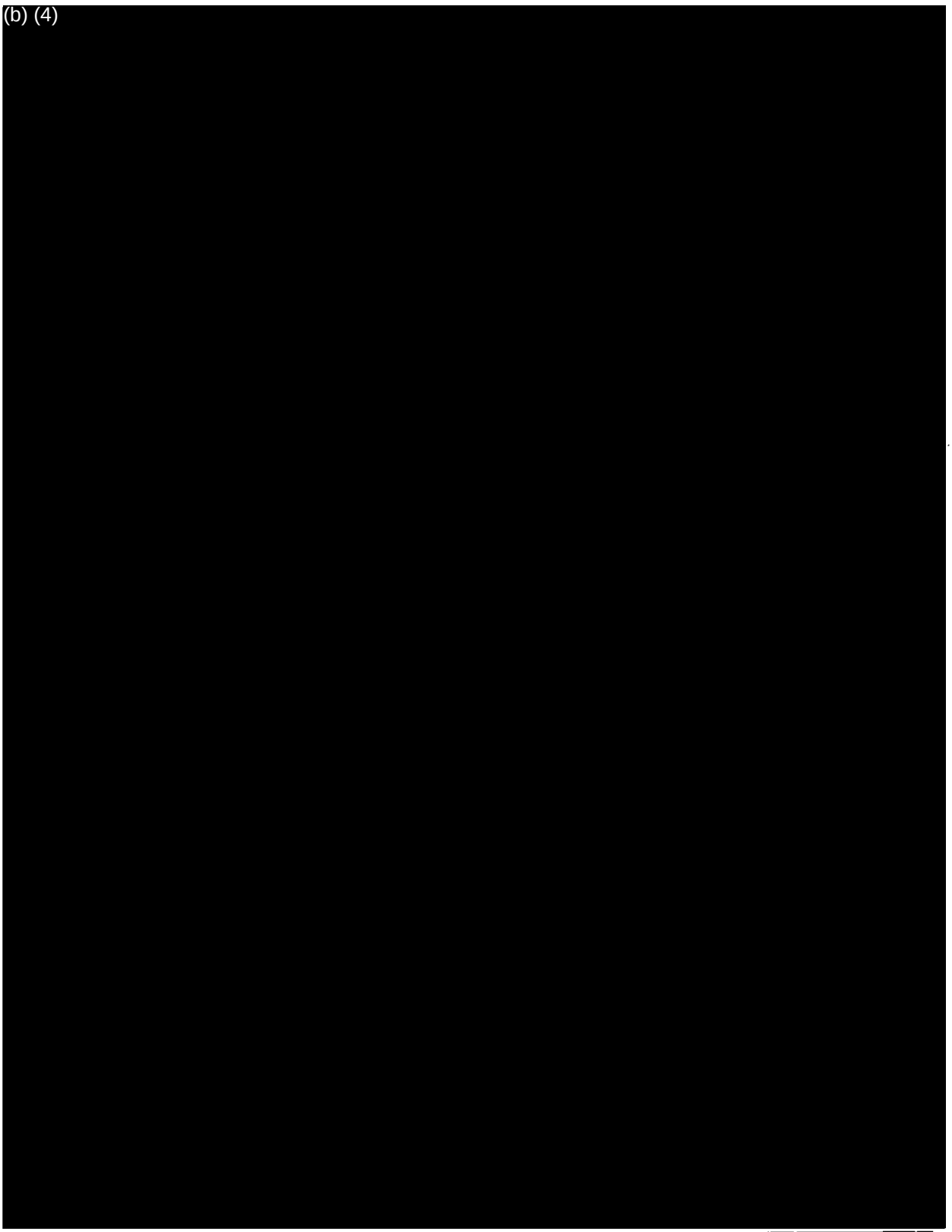
DJA x01998

(b) (4)

DJA x01999

(b) (4)



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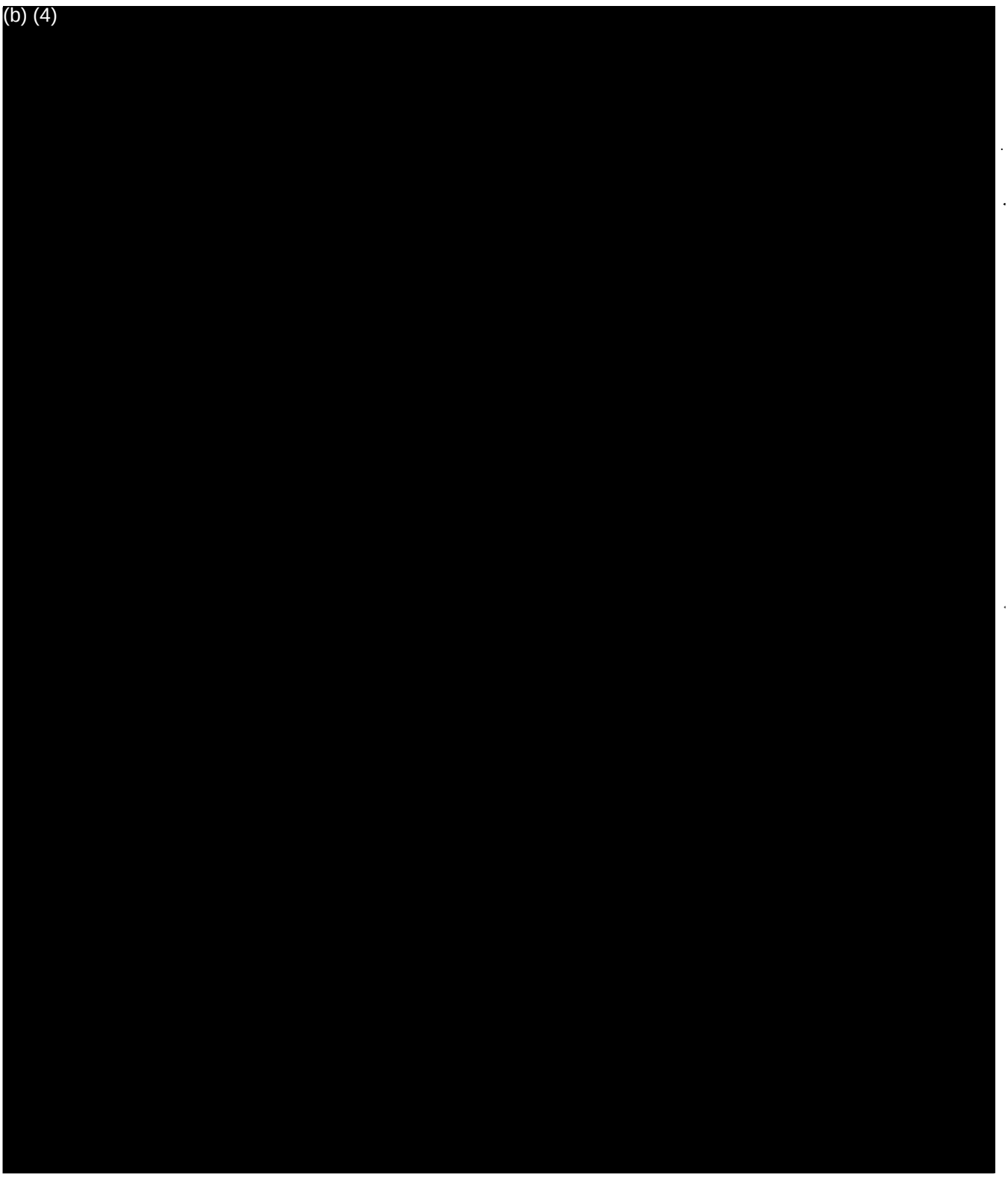

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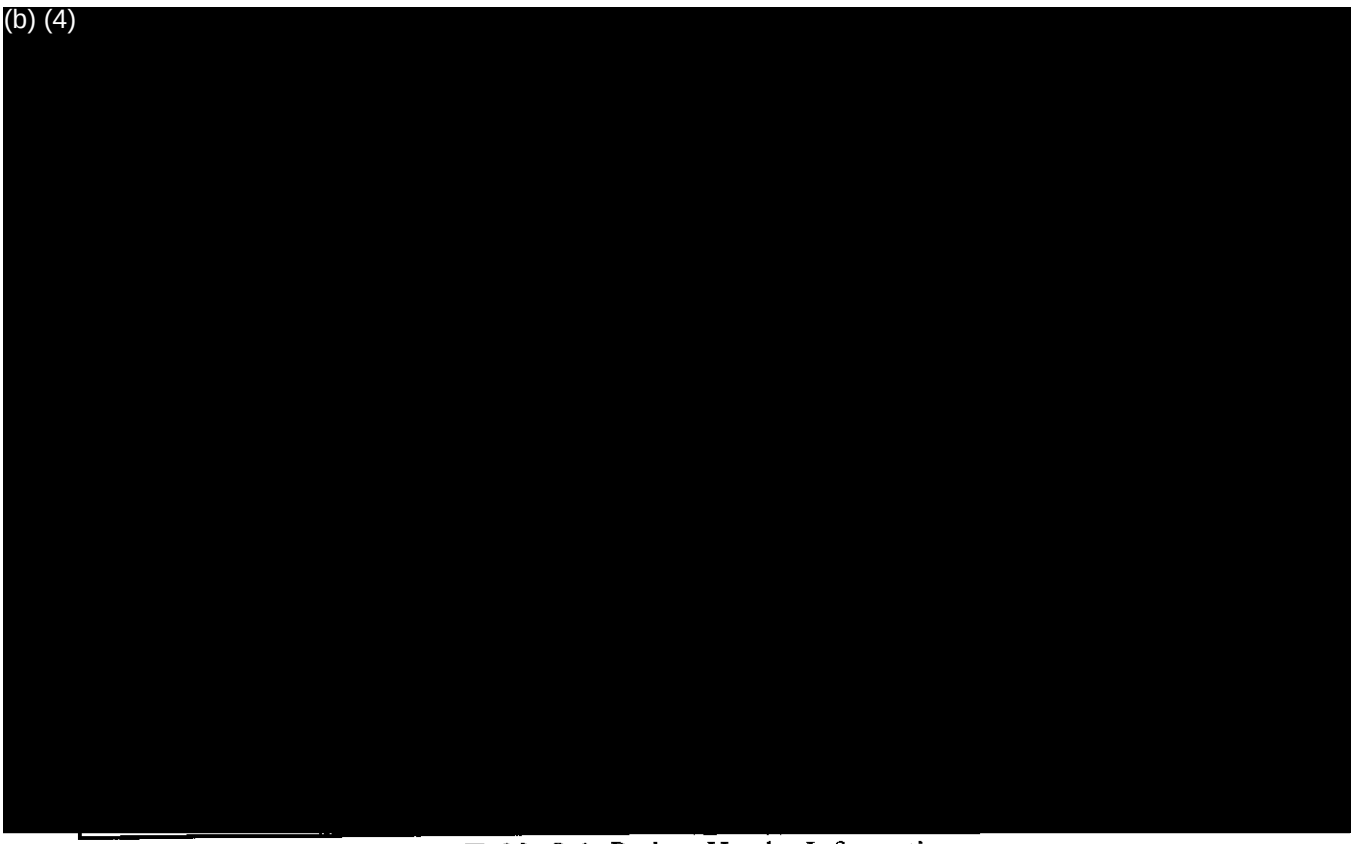

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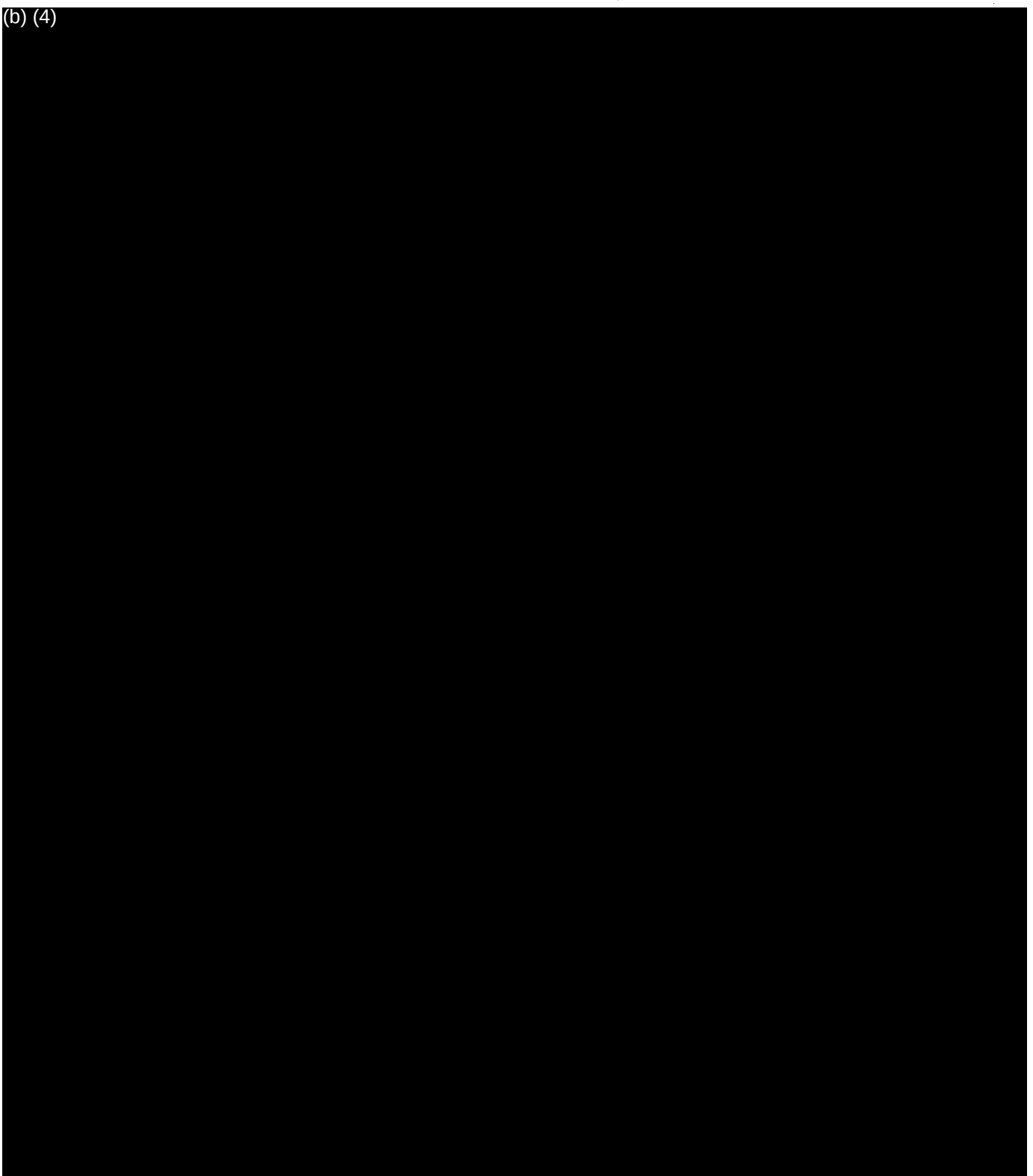

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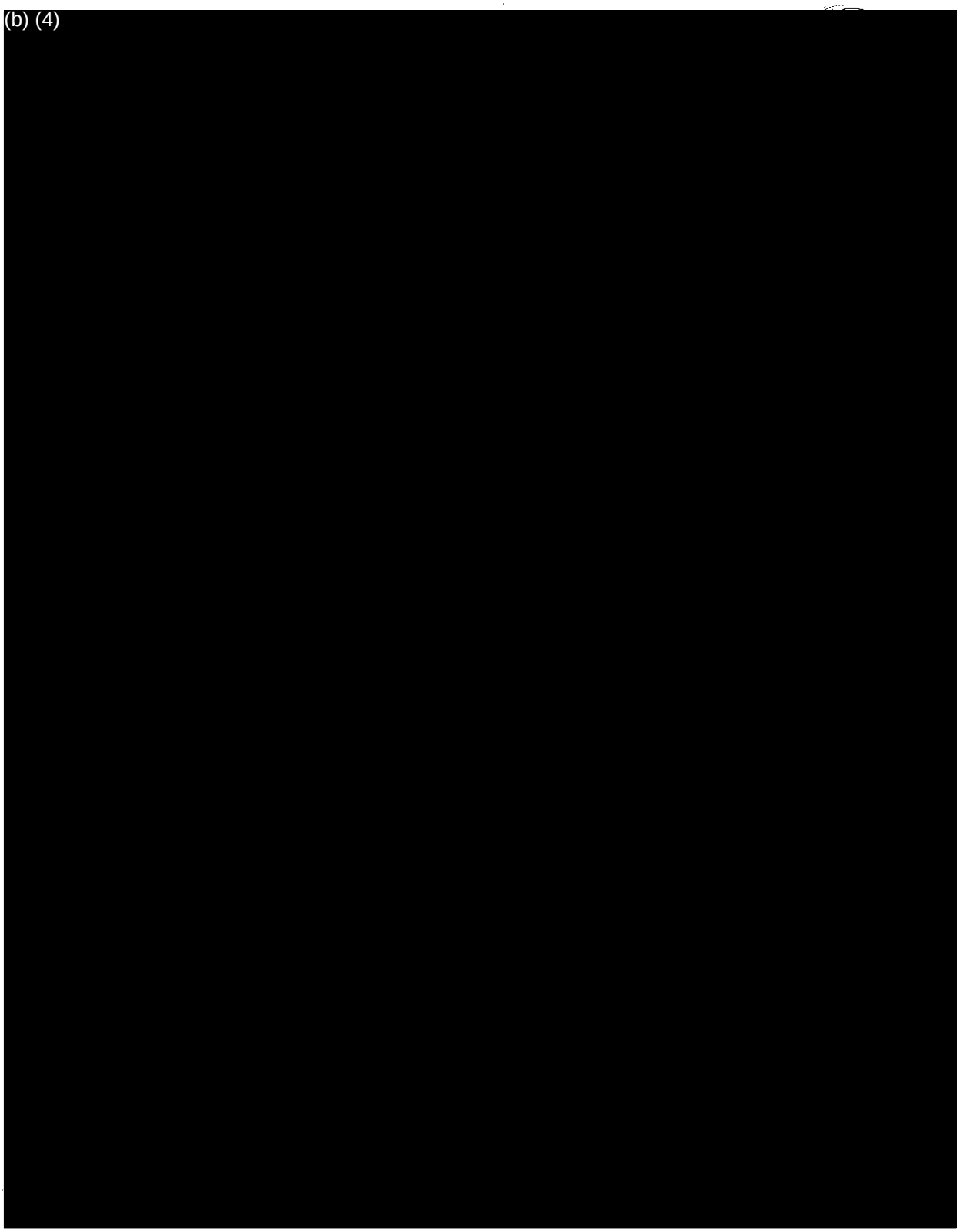

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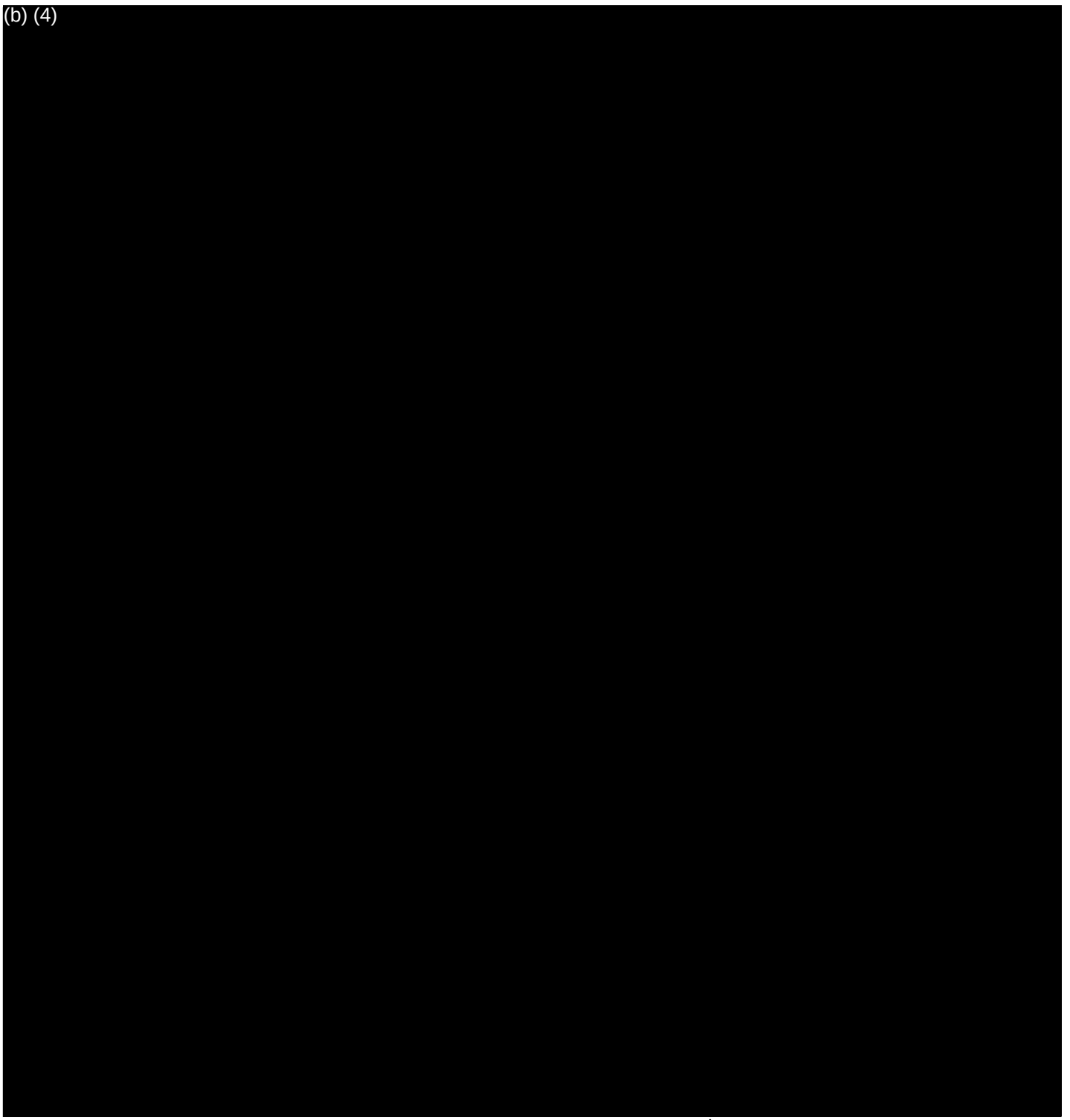

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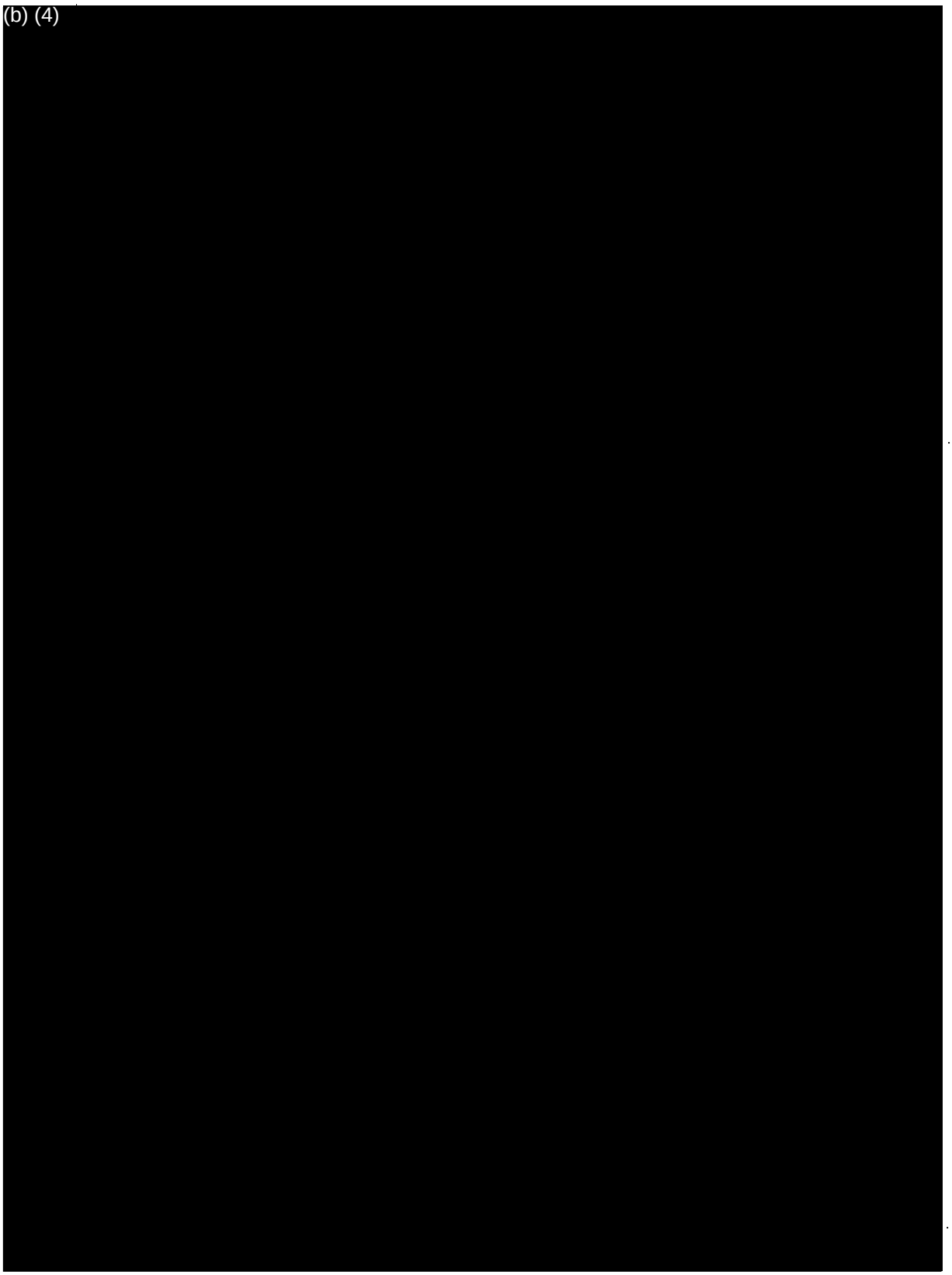

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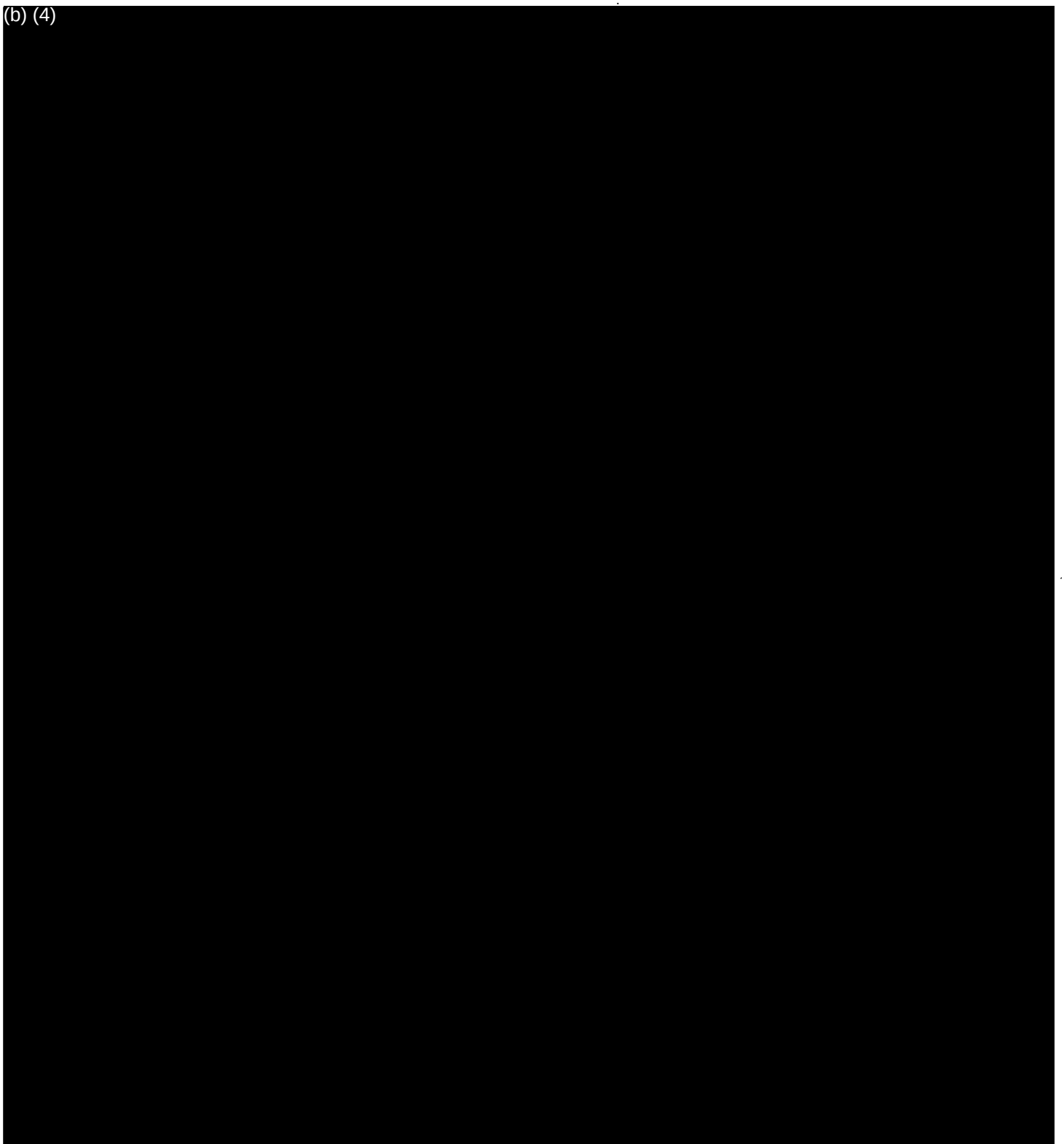

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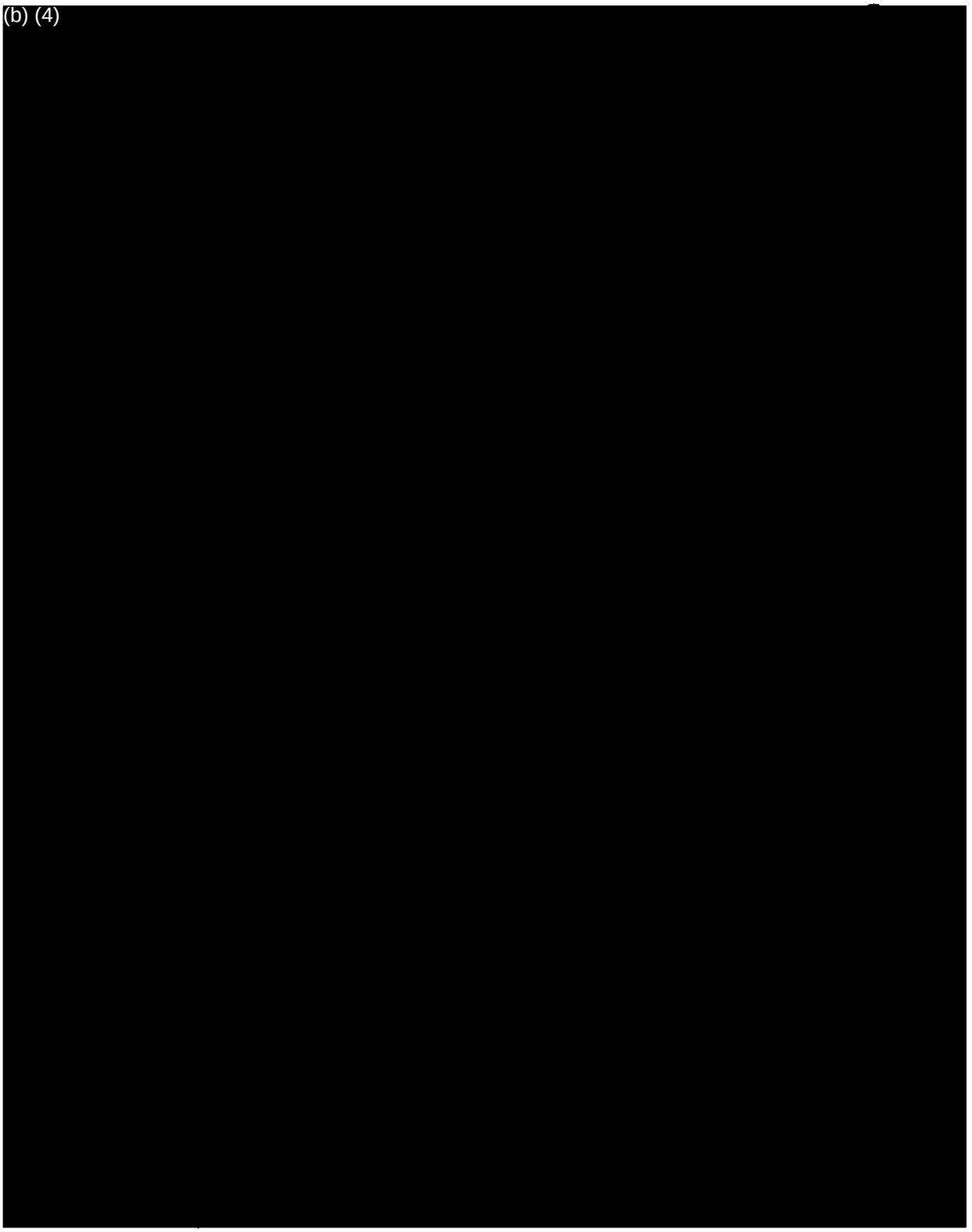

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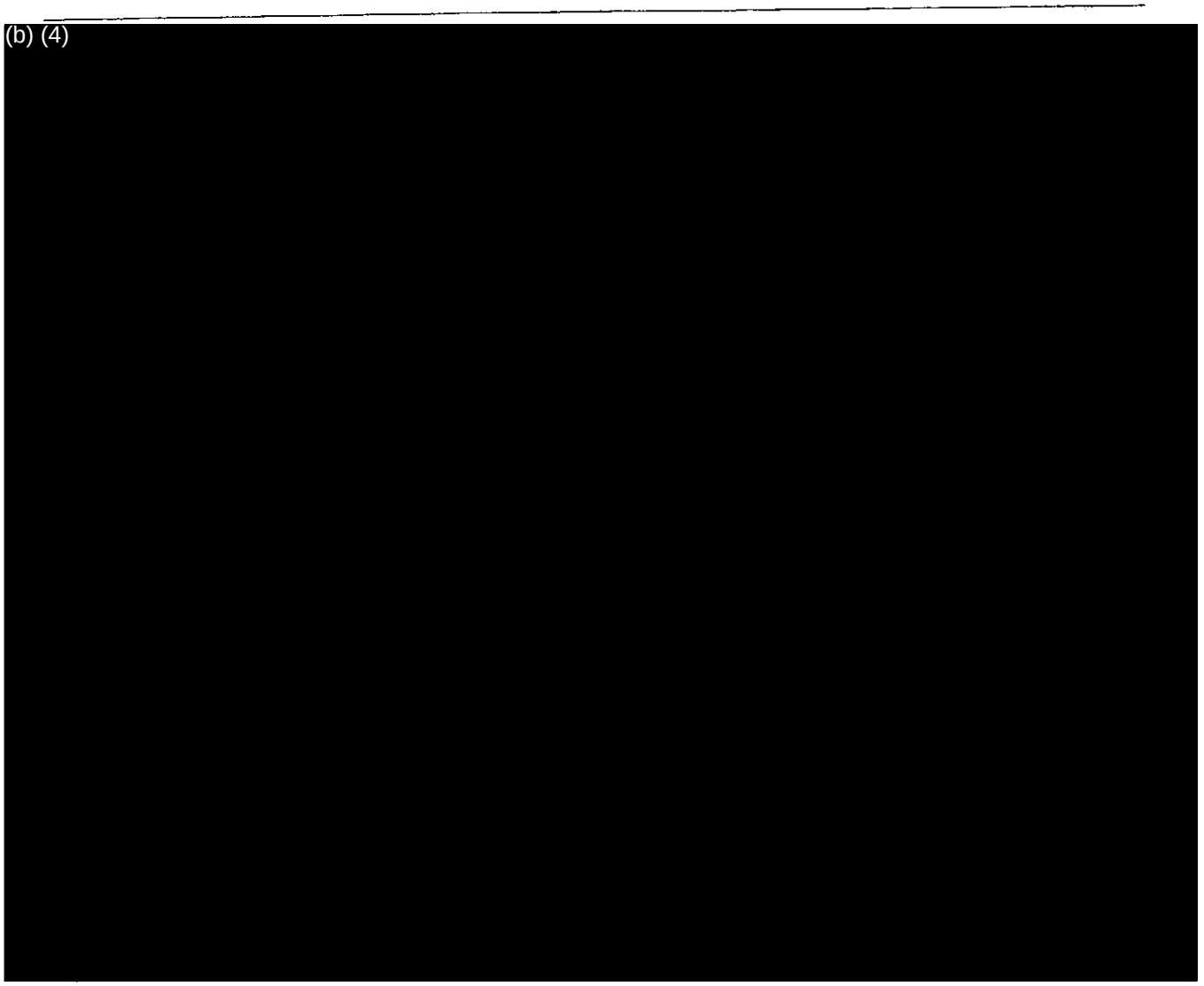

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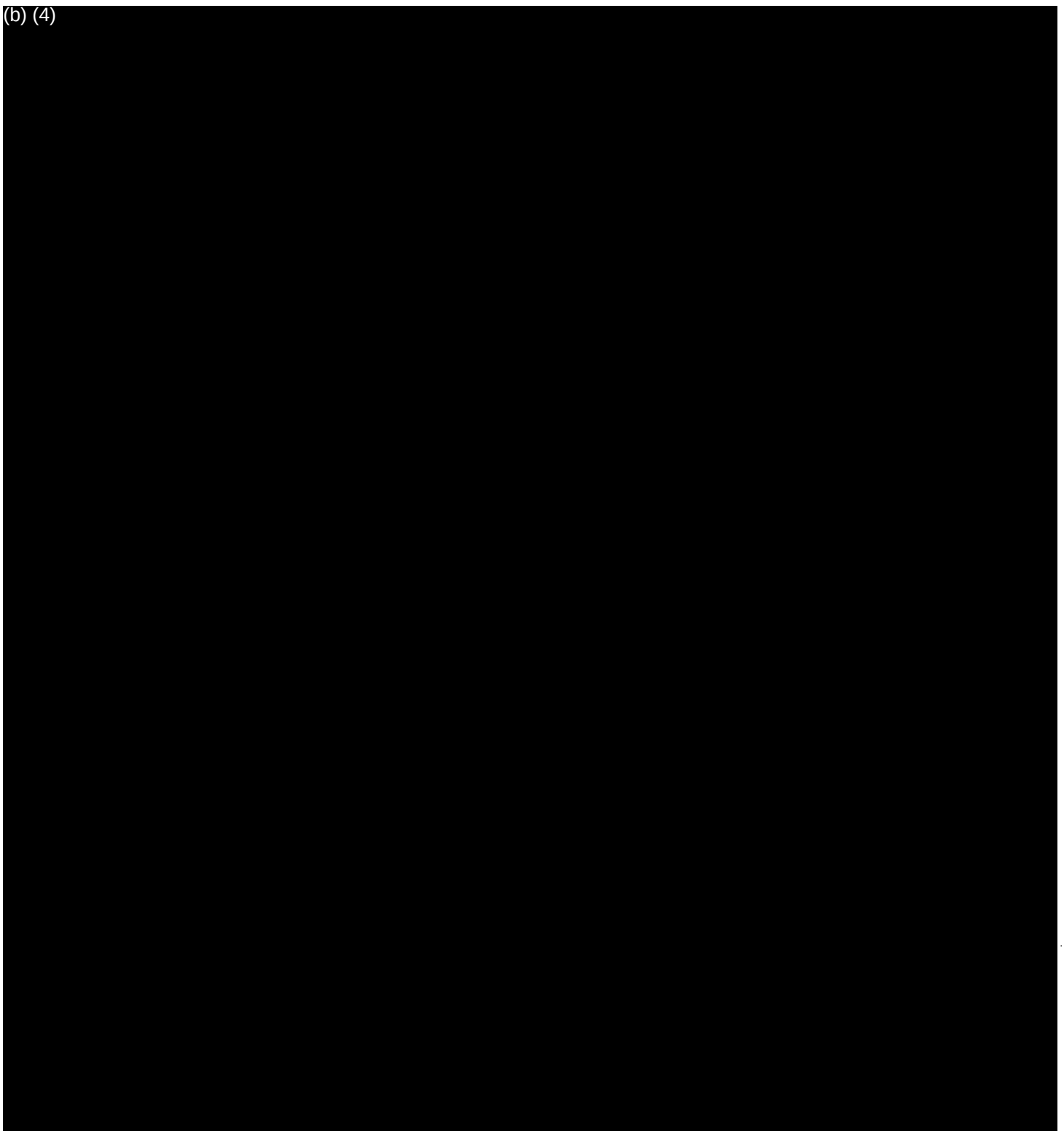

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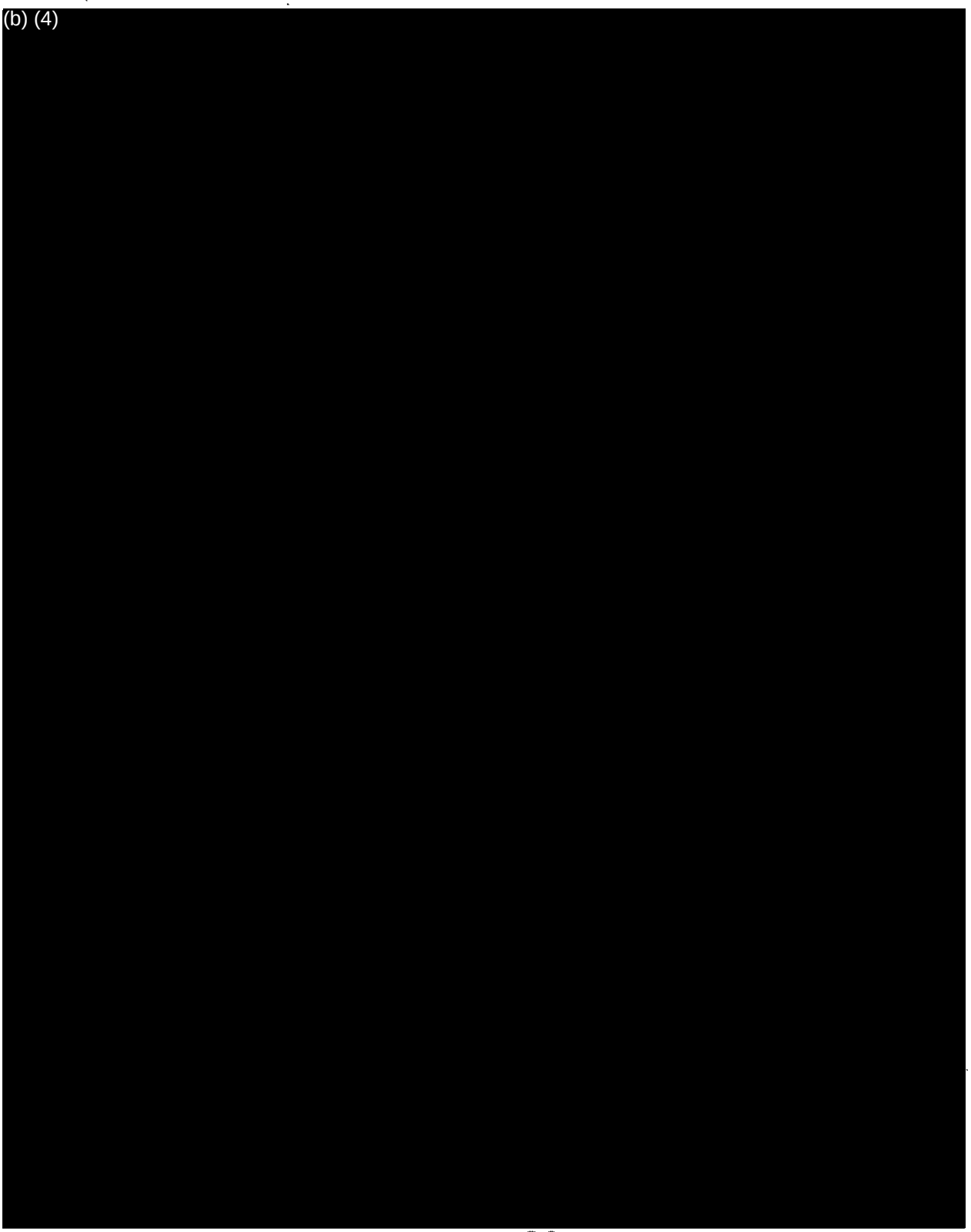

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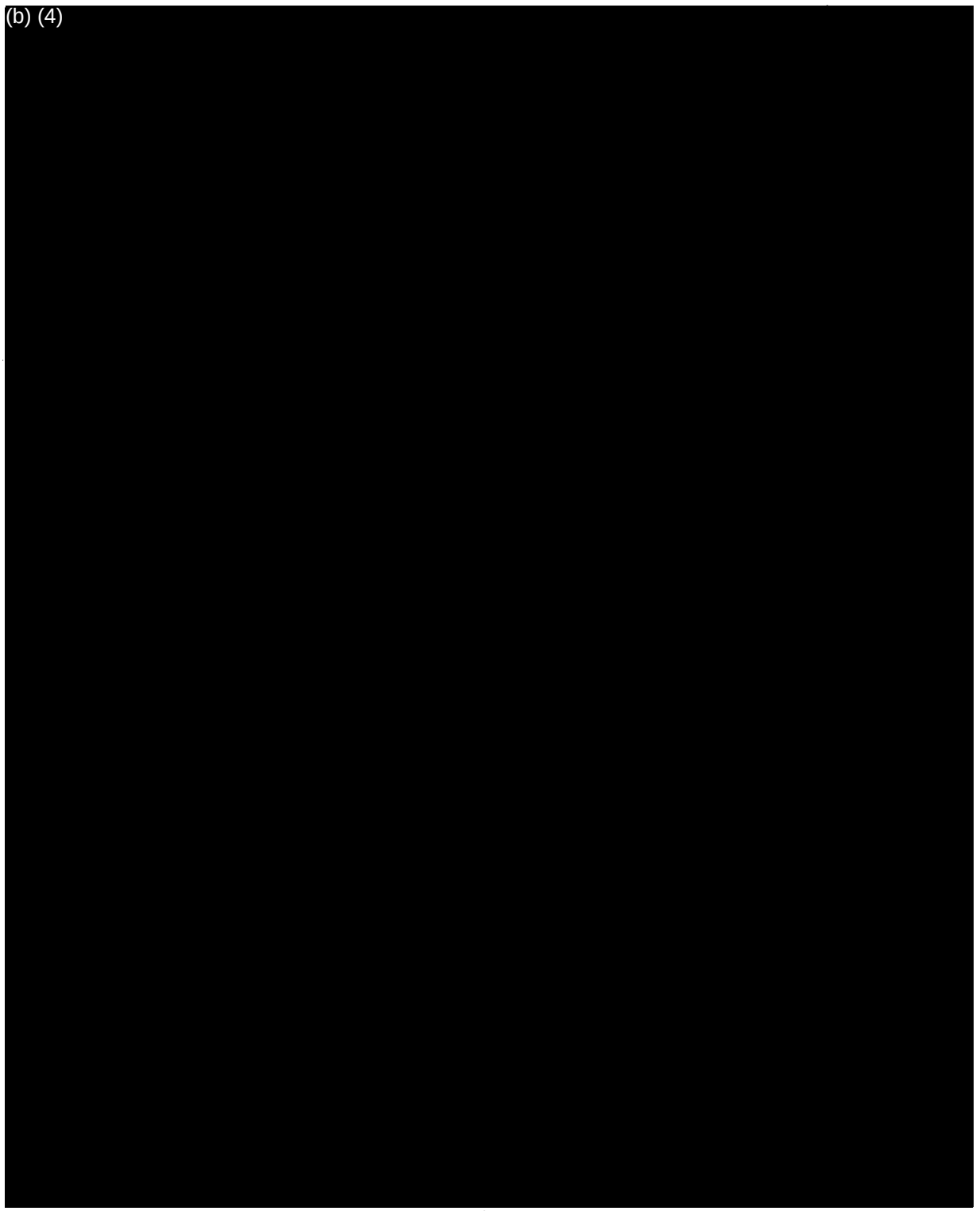

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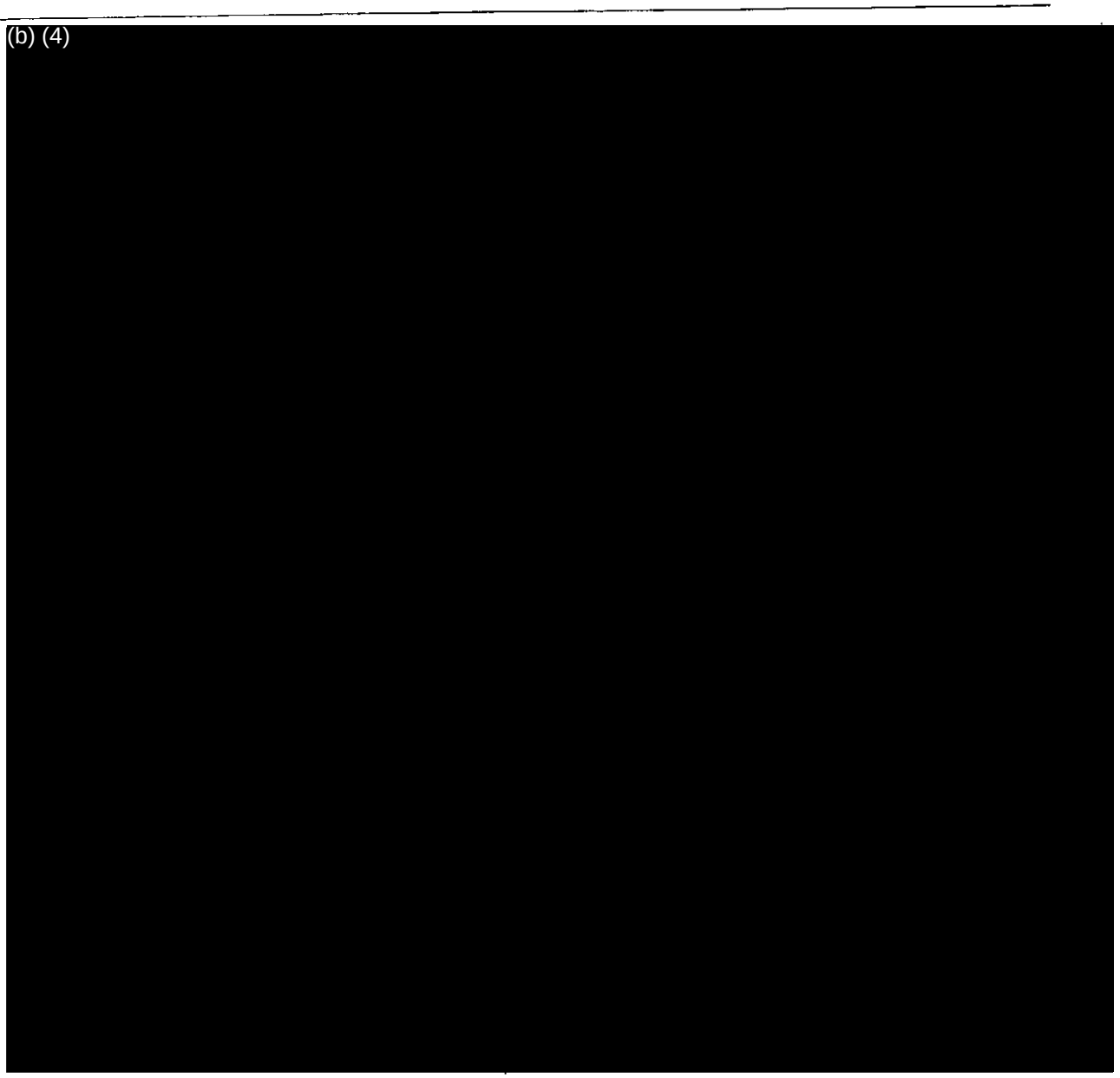

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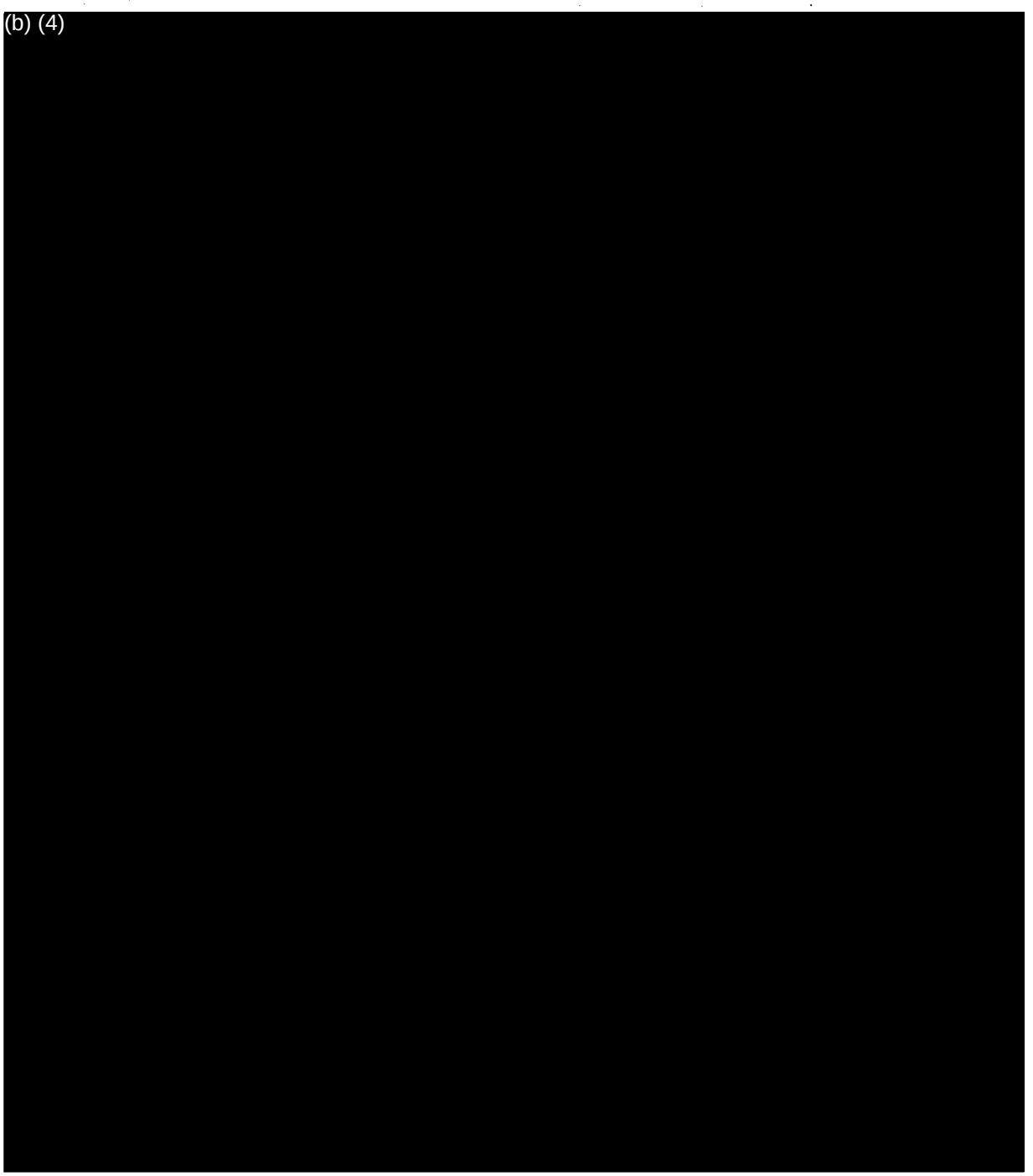

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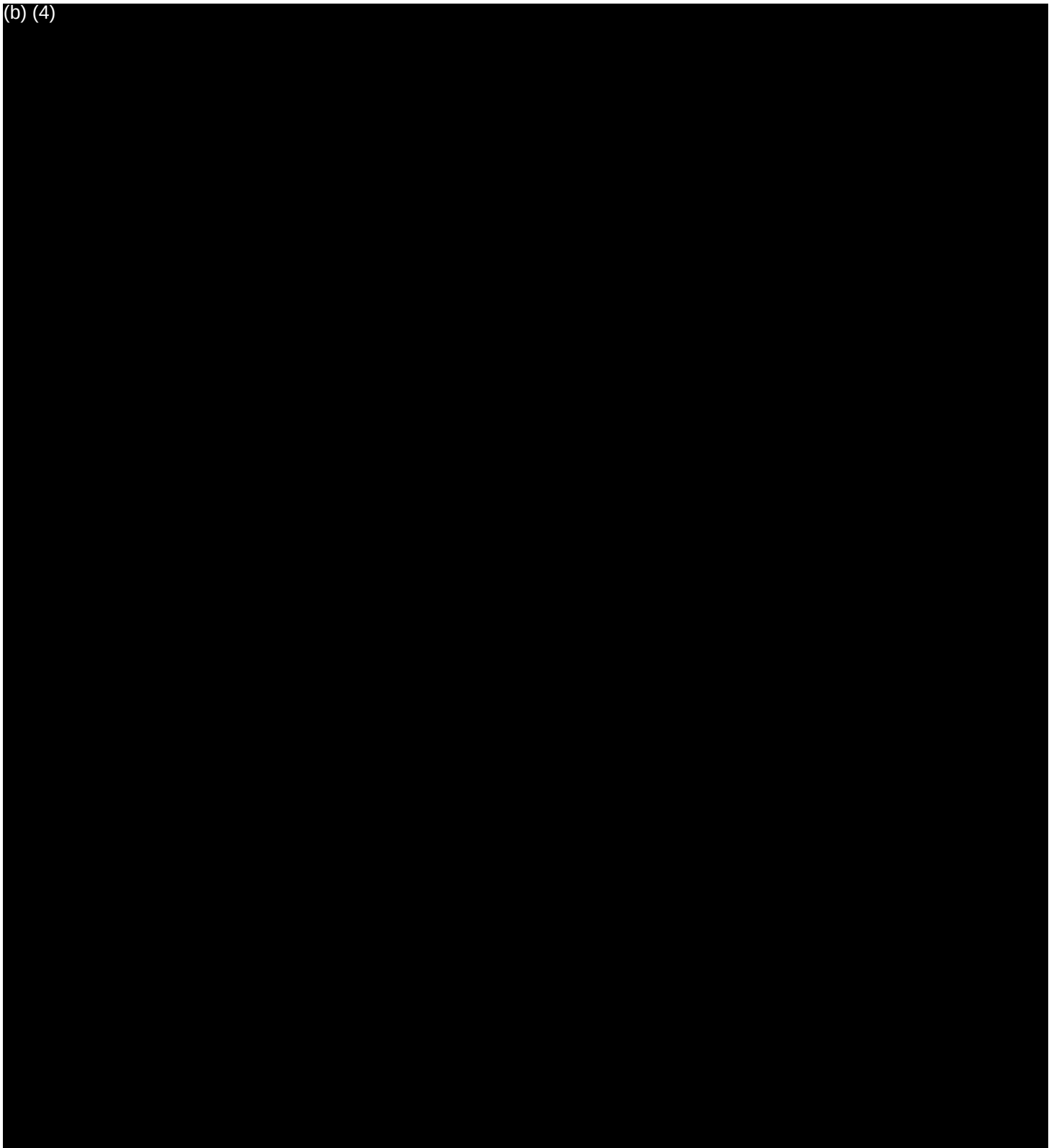

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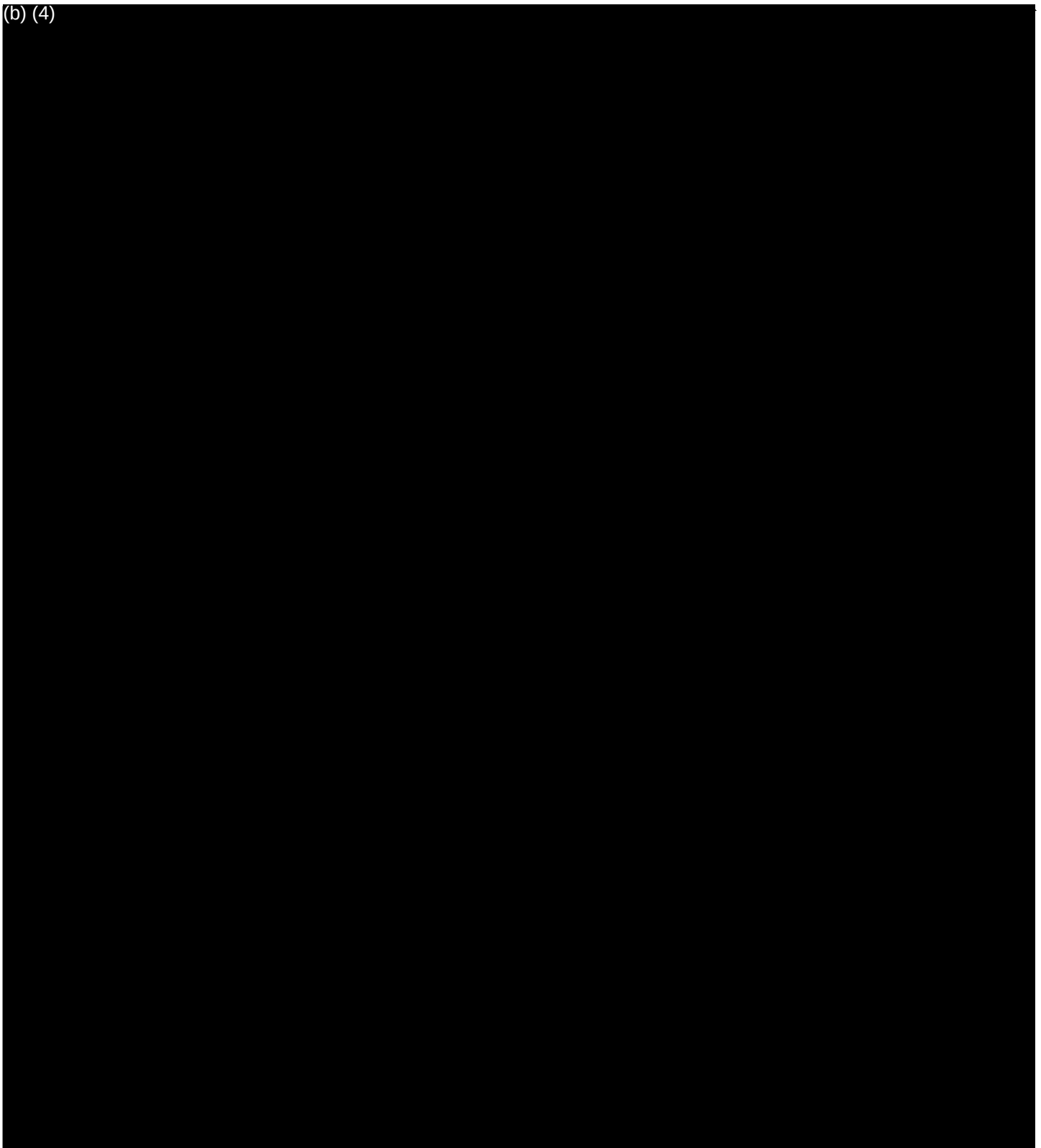

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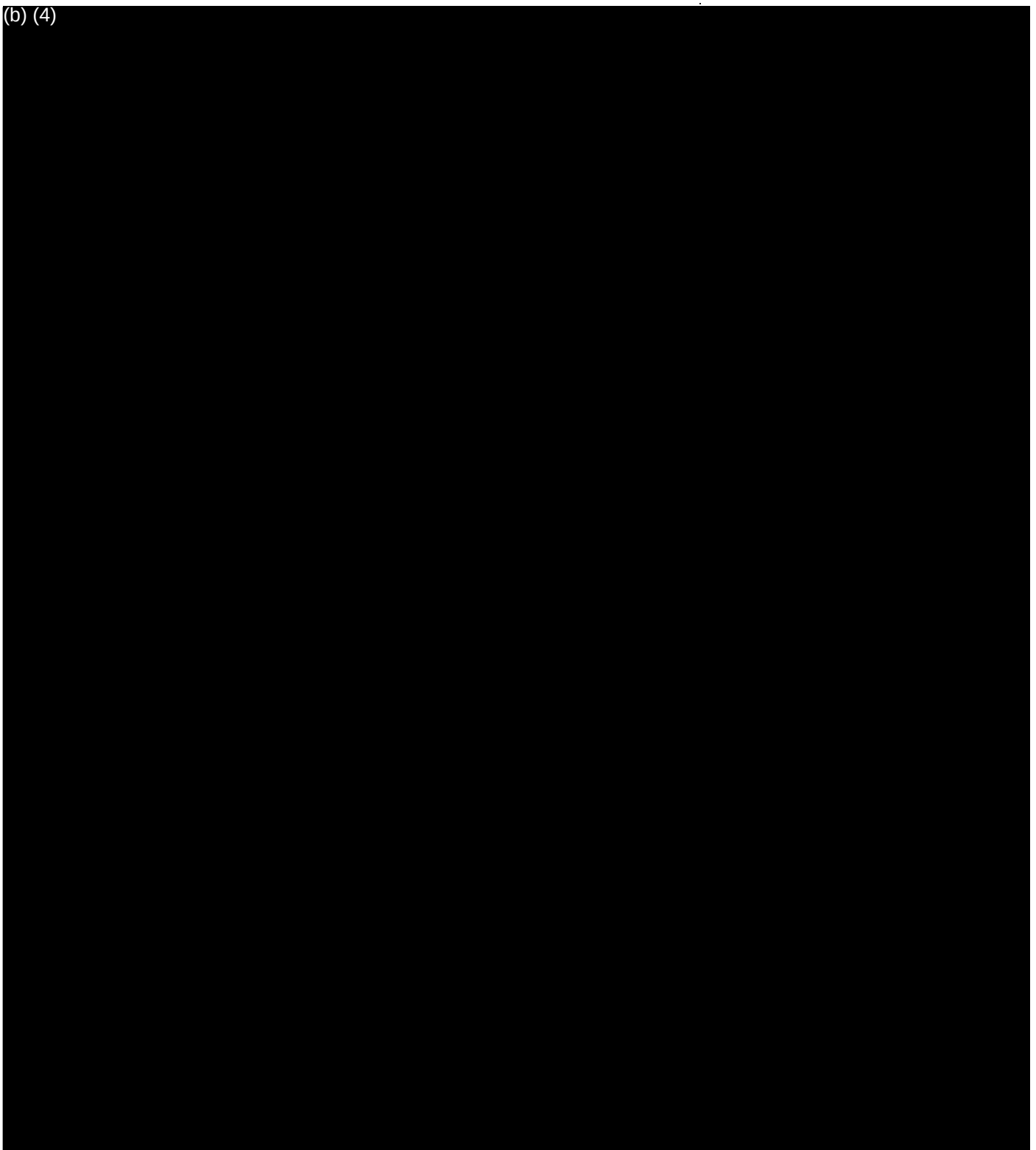

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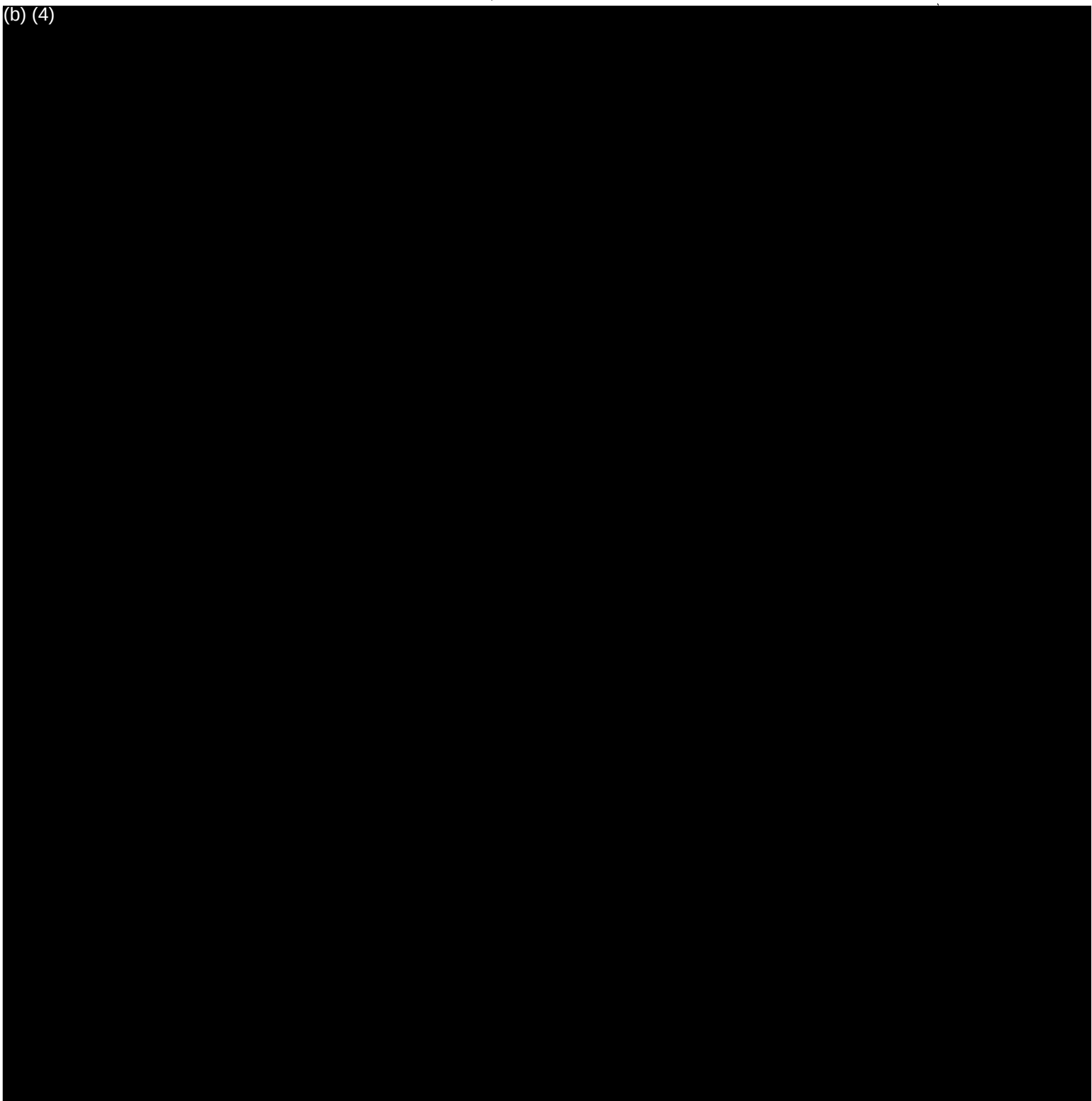

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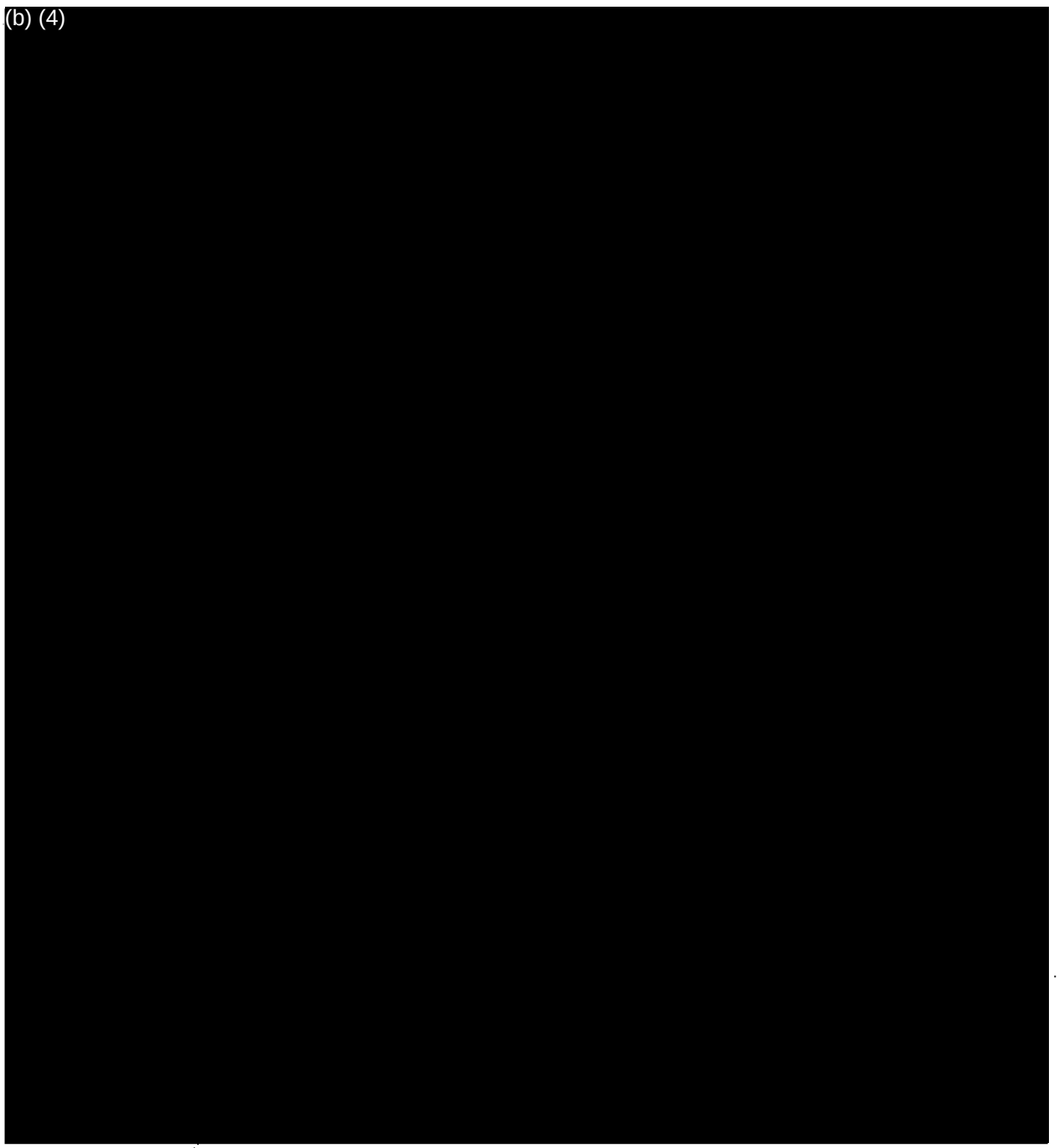

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DigiMatch™ ROBODOC® Surgical System
Traditional 510(k) Premarket Notification
K _____ ORIGINAL

Integrated Surgical Systems, Inc. (ISS) hereby submits a premarket notification for the DigiMatch™ ROBODOC® Surgical System pursuant to 21 CRF PART 807 Subpart E. The format of this submission follows the recommendations contained in Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s, dated August 12, 2005.

K072629
Vol. IV

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ISS requests confidentiality of this notification in accordance Sec. §807.95(b)(1)(i-iv).

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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Section 17 – Electromagnetic Compatibility and Electrical Safety

17.1 Electromagnetic Compatibility and Electrical Safety
17.2 Electrical Safety Testing Summary
17.3 Electromagnetic Compatibility Testing Summary

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DJA x02033

17.1 Electromagnetic Compatibility and Electrical Safety

The ROBODOC Surgical System can be classified as a device in contact with the patient. Therefore, ISS has tested the device to ensure conformance with EN60601 and its applicable Collateral Standards.

17.2 Electrical Safety Testing Summary

A series of tests were performed to demonstrate that the DigiMatch™ ROBODOC© Surgical System meets all applicable acceptance criteria for EN60601-1. The test results are reported in the test report: TR98-07-016, Medical Electrical Safety and Type Tests for the Project Frontier ROBODOC©.

17.3 Electromagnetic Compatibility Testing Summary

A series of tests were performed to demonstrate that the DigiMatch™ ROBODOC© Surgical System meets all applicable acceptance criteria for EN60601-1-2. The test results are reported in the test report: Verification Test Report for the ROBODOC ROBOT, EN60601-1-2 (1993).

The testing of the DigiMatch™ ROBODOC© Surgical System was conducted using the following test methods.

1. IEC801-2 - Electrostatic Discharge Requirements.
2. IEC801-3 - Radiated Electromagnetic Field Requirements
3. IEC801-4 - Electrical Fast Transient/Burst Requirements
4. IEC801-5 - Surge Requirements
5. EN55011 - Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment

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Section 18 Performance Testing – Bench

18.1 DigiMatch™ ROBODOC® Surgical System Description
18.2 DigiMatch Registration Verification
- 18.2.1 Digitizer accuracy with respect to a known object
- 18.2.2 Digitizer accuracy with respect to the 2-pin design using patient data
- 18.2.3 Verification of digitizer accuracy with respect to the Electro-Mechanical arm
- 18.2.4 Verification of DigiMatch Registration Verification performed by the surgeon
- 18.2.5 Verification that the ROBODOC system can recover from bone movement

18.3 Summation

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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18 Bench Testing

In Vitro bench verification testing focused on the steps to verify the DigiMatch registration process, software flow, and device safety. All verification associated with software can be found in Section 16, Software.

Definitions and Acronyms

- **Bone Motion Monitor (BMM)** – a passive electro-mechanical sensor arm which is used to detect bone motion during a surgical procedure.
- **Pendant** – a five-button keyboard which acts as the user input device during a surgical procedure.
- **Digitizer Arm** – a passive electro-mechanical sensor arm which is used to record locations in 3-D space. The digitizer is controlled using off-the-shelf software and interface components.

18.1 DigiMatch ROBODOC Surgical System Description

The DigiMatch™ ROBODOC® Surgical System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then ROBODOC component of the System will precisely implement the preoperative plan.

18.1.1 ORTHODOC® Component Description

The ORTHODOC is a PC workstation with proprietary ISS software that enables the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur. Computed tomography (CT) scan data of the patient's femur provide input to the system. ORTHODOC stacks and interpolates between the individual scan slices to create three-dimensional images of the femur.

The cleared ORTHODOC software contains a computerized directory of implant types and sizes, from which the surgeon selects an implant model. The system displays three-dimensional views of selected implant models for computerized templating with femur images. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the image of the femur. The ORTHODOC also provides software tools, which allow the surgeon to preoperatively determine implant head size, neck offset,

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version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC with information relating to implant size, shape, and placement data. The output, which reflects the ORTHODOC preoperative plan, is saved on a media and loaded into the ROBODOC computer prior to surgery.

18.1.2 ROBODOC® (Electromechanical Arm, Electronics Control Cabinet, Display Monitor, Miscellaneous Accessories)

The operating room components of the system, known as the ROBODOC System, include a robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (Digitizer Arm, Pendant, Probes, Markers, Wrenches, Gauge Sets and disposable items such as Cutters, Drapes and Irrigation tube sets). The media containing the ORTHODOC preoperative plan provides input to the Robot Control Computer.

Proprietary ISS software allows the technician and/or surgeon to control all aspects of the ROBODOC's activities. The primary function of the ROBODOC is to precisely implement the preoperative plan that was developed by the surgeon. Redundant safety features and controls are built into the ROBODOC's software and hardware functions. The patient data media, which contains the pre-operative plan, is loaded into the Control Cabinet. The technician and/or surgeon are able to interface with the ROBODOC and respond to any prompt via a hand-held control device called a "Pendant." The Pendant is used to control every phase of the robot-related surgical procedure. The Pendant has five buttons for initiating and aborting procedures, and for selecting options displayed on the OR Monitor. The OR Monitor displays a series of menu screens that guide the surgeon in the use of the tool through the setup, registration and bone cutting phases (preparing the femoral cavity) of the surgery.

18.2 DigiMatch Registration Verification

During primary cementless THA using the DigiMatch procedure, the Digitizer Arm is used to record three-dimensional coordinates for points on the surface of the femur. These points are used to compute the registration between the electro-mechanical arm and the CT-based ORTHODOC physician generated plan; *i.e.*, to determine the correspondence between electro-mechanical arm coordinates and CT coordinates in the preoperative plan. To verify the DigiMatch registration, the following verification process was executed:

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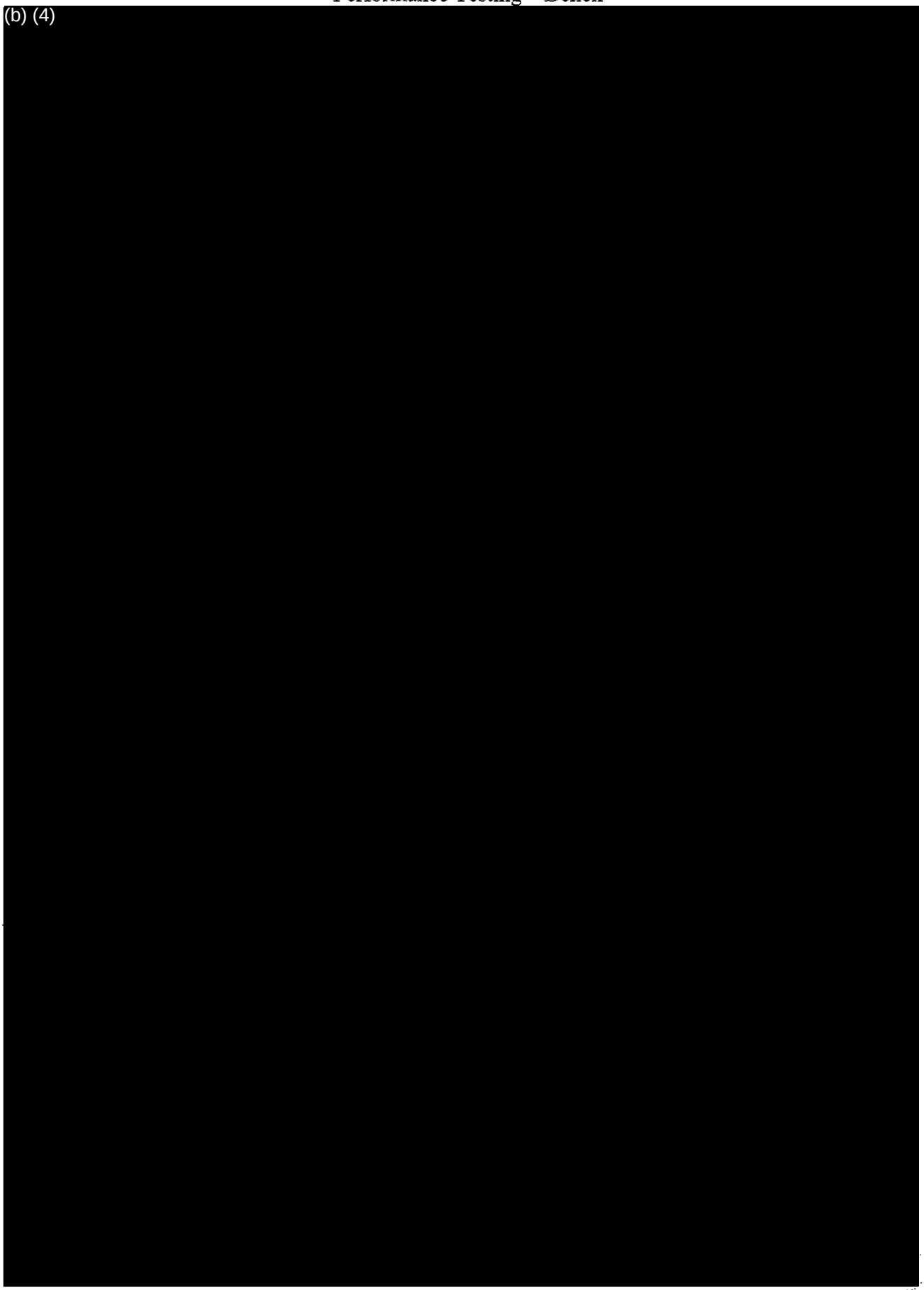

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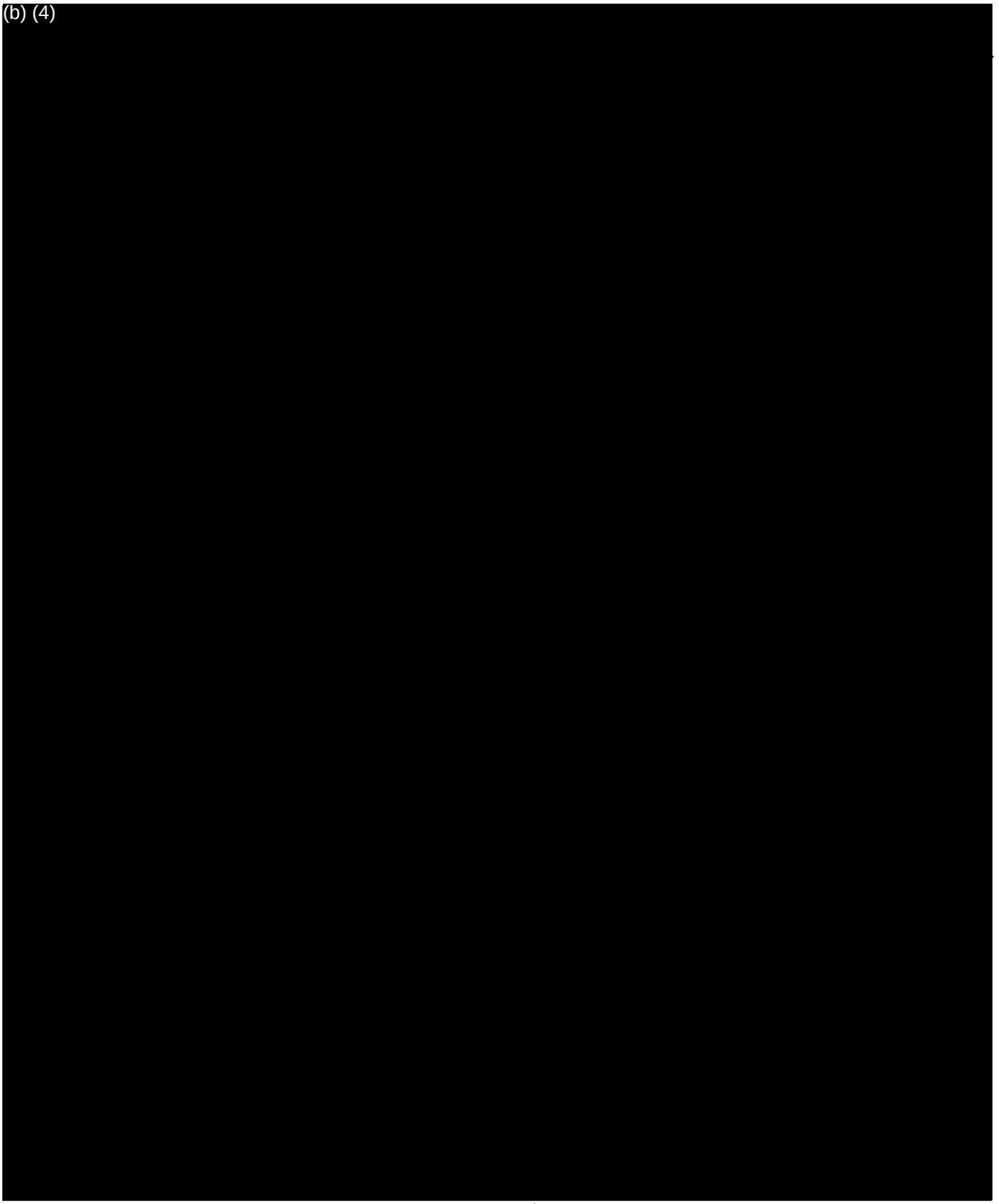

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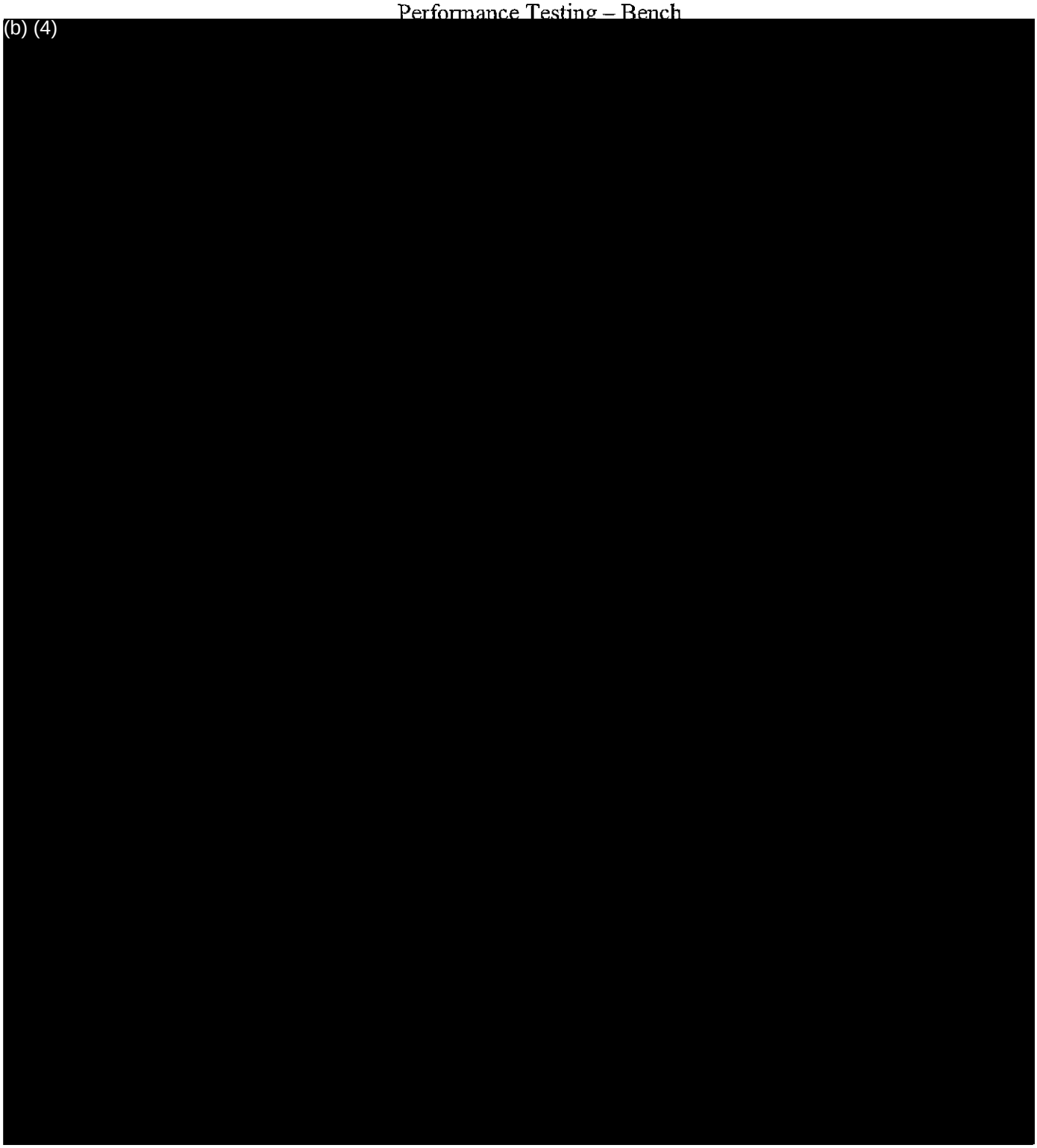

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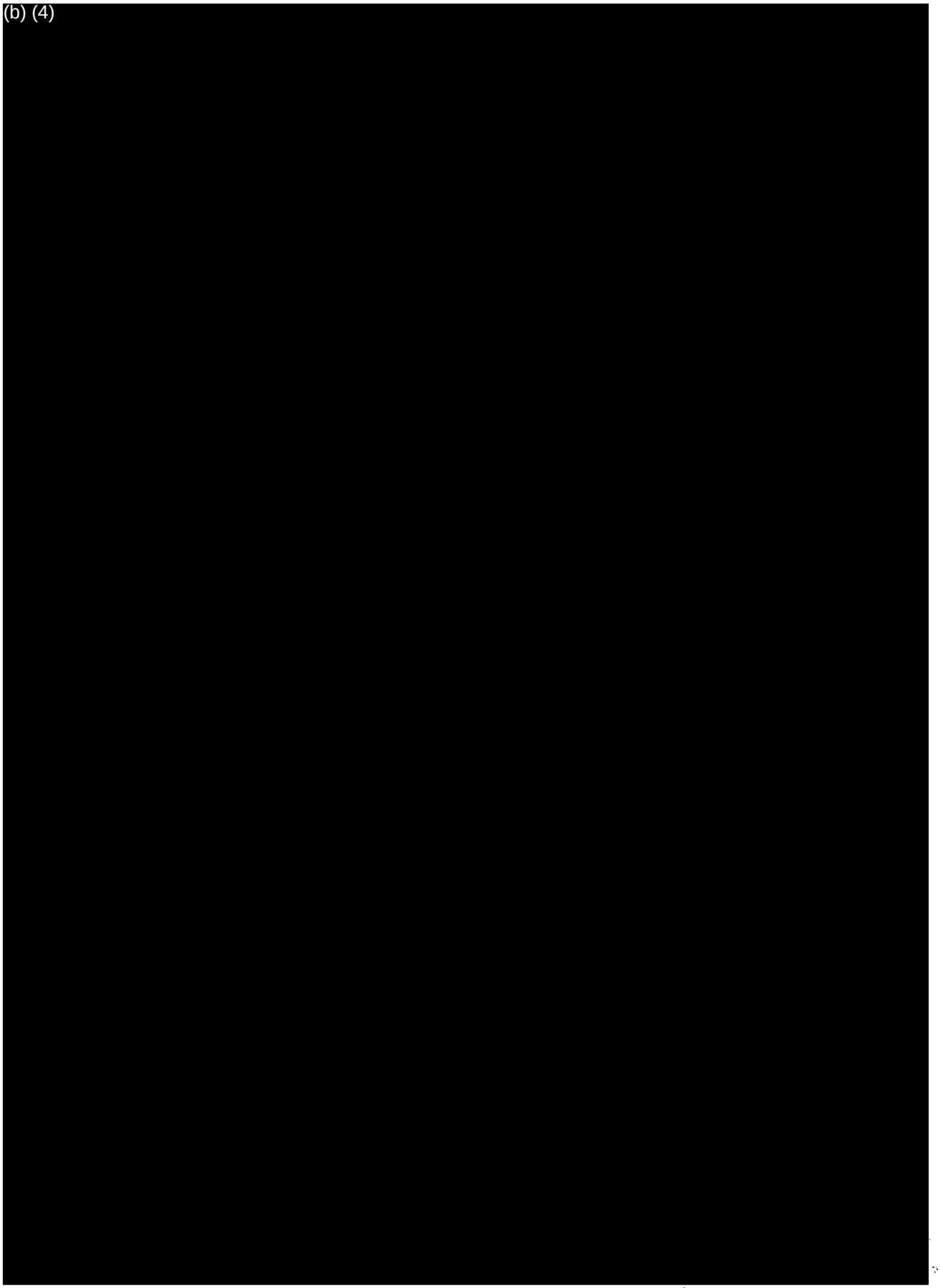

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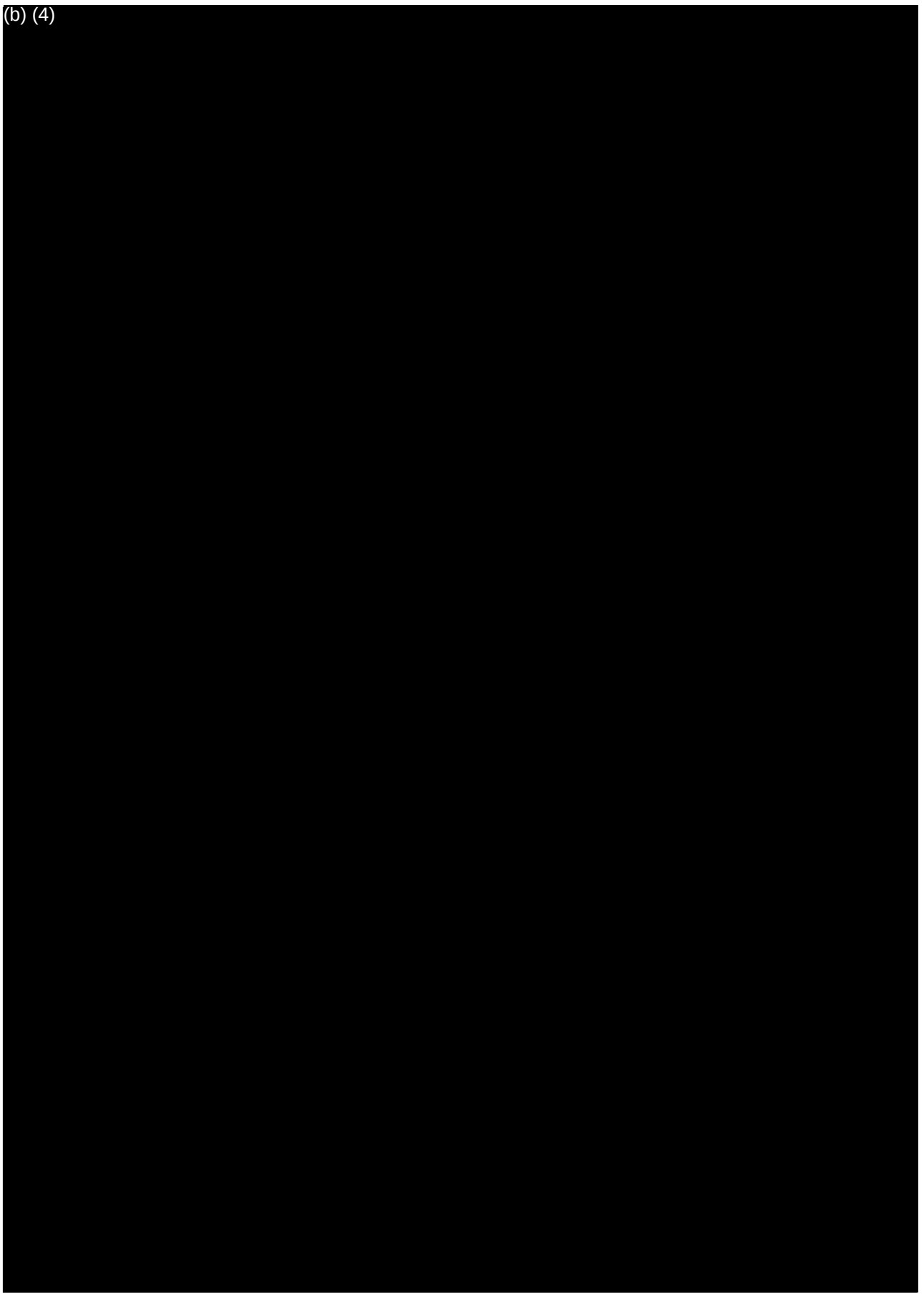

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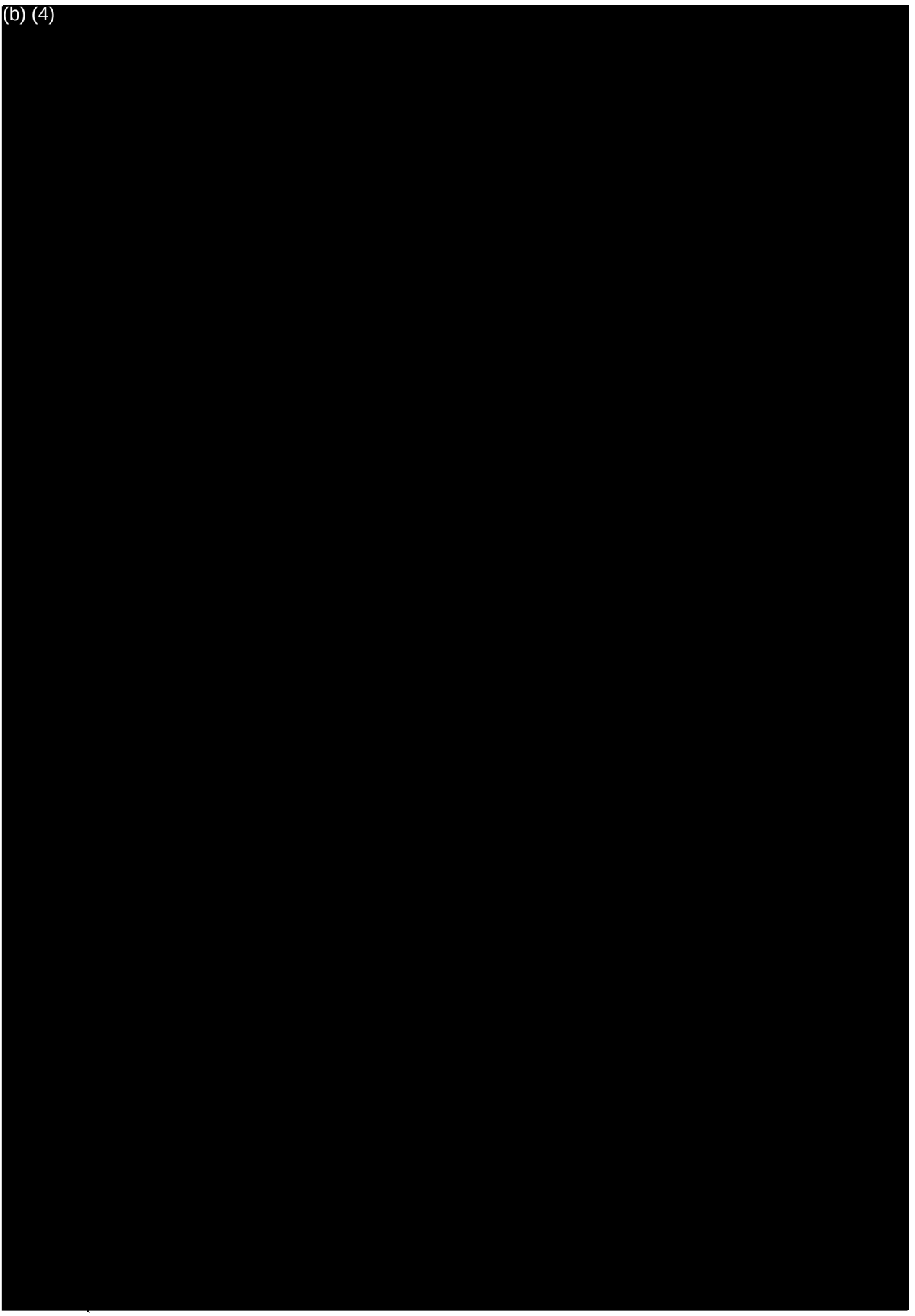

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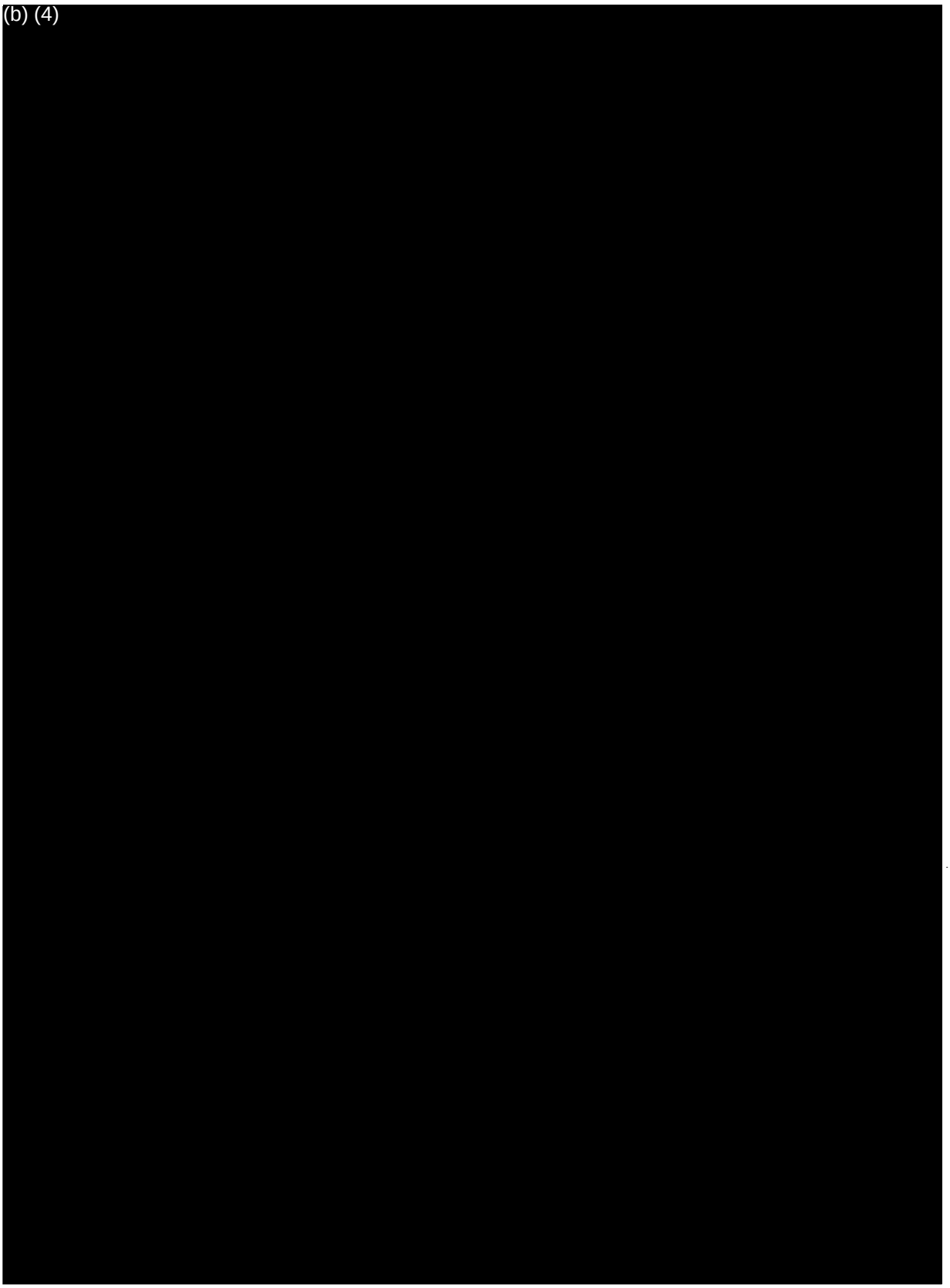

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18.3 Summation

The verification testing performed on the DigiMatch System verify that the device meets the required registration process, software flow, and device safety requirements established in the design specification for the device.

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Section 19 – Performance Testing – Animal *In Vivo* and Cadaver *Ex Vivo*

Section 19.1 Animal *In Vivo* Testing

Section 19.2 Cadaver *Ex Vivo* Study to Evaluate Pin-Based Registration

Section 19.3 Cadaver *Ex Vivo* Study to Evaluate Pinless Registration

Section 19.4 Conclusion from Cadaver and Animal Testing

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

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Section 19.1 Animal *In Vivo* Testing

Animal testing that was performed using the ROBODOC® Surgical System is reported in the "Lecture Notes in Computer Science", CVR-Med MRCAS '97. The report discusses results of parallel testing between a clinical study conducted at Berufsgenossenschaftliche Unfallklinik (BGU) in Frankfurt Am Main, Germany and a prospective two arm animal experiment that was conducted at the Small Animal Clinic, Auburn University, in Auburn, Alabama. A summary of the animal experiment is provided in this subsection. A complete copy of the report is provided in **Attachment** 1 of Section 19.

The parallel testing was conducted by the authors to evaluate performance and possible benefits of the ROBODOC Surgical System.

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From: "Lecture Notes in Computer Science"
CVR-Med MRCAS '97

Summary

ROBODOC Surgical System - Animal Experiment

André Bauer, Martin Börner, Armin Lahmer
Berufsgenossenschaftliche Unfallklinik (BGU)
Frankfurt Am Main, Germany

1. Introduction

In cementless total hip replacement (THR), primary fixation between bone and the femoral component is a critical phase in the procedure. In cemented procedures, any gaps between the implant and bone are filled in with cement, and primary stability is achieved through the bonding of the cement; whereas, cementless procedures require an exact fit of the implant into the cavity, initial stability avoiding any micro motion or rotational instability and precise positioning of the implant. Missing any of these goals in the cementless procedure might result in early micro motion, leading to possible interposition of fibrous tissue between bone and implant and eventually aseptic loosening. As handheld broaches used in the preparation of the femoral cavity are prone to tear out pieces of bone and are often deflected by hard bone, machine milling of the cavity is likely to enhance surgical precision. ROBODOC is an orthopedic operational system that allows accurate planning of the cementless THR procedure and the execution of the plan by a computer guided robot. Parallel to clinical testing, a prospective two arm animal experiment was conducted to evaluate performance and possible benefits of the ROBODOC Surgical System.

2. Materials and Methods

In a canine animal model experiment, 20 male greyhounds were randomized to either hand broached or robot assisted hemiarthroplasty. The study was performed by Dr. André Bauer and Dr. Montgomery of the Small Animal Clinic, Auburn University, in Auburn, Alabama, between December 1995 and December 1996. The study was approved by the Ethical Committee of Auburn University and, in part, supported by Integrated Surgical Systems, Inc.

All dogs received preoperative vaccinations, standard hip x-rays and an orthopedic examination. For dogs randomized to the hand broached group, planning was performed with acetate templates over x-rays and the femoral cavity was prepared with handheld broaches. In the robot group, 3 locator pin placement and CT scans were performed under general anesthesia. Planning was performed via the ORTHODOC system, and the femoral cavity was milled by the robot after intraoperative registration. Aside from registration, fixation of the bone to the robot and milling by the robot, the procedures in both groups were identical.

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The postoperative regimen was also identical in both groups. Partial weight bearing on the first postoperative day was followed by full weight bearing after day 2. Beginning on day 5, all dogs received a polychrome sequence labeling with yellow, red, blue and green markers. Each label was applied for 5 days. A postoperative gait analysis was carried out after 1, 3, 6, 9 and 12 months. Necropsy dates were at 35 days for 8 dogs (4 each group), 84 days (6 dogs), and 365 days (6 dogs). Histological evaluation was carried out by Dr. Draenert in Munich.

3. Results

In the robot group, all dogs were successfully operated on. No procedure had to be aborted, and in all cases, the preoperative plan regarding size and position of the implant was accomplished. In the hand broached group, 2 dogs suffered a fracture of the femur. One (1) dog had to be sacrificed intraoperatively because the femur cracked and the implant could not be positioned deep enough to allow reduction of the joint. In another dog, the fracture became evident in the x-rays before necropsy, when a large callus formation developed as result of a long spiral fracture. Operating time in the robot group was a mean of 29 minutes longer than in the hand broached group.

Gait analysis one month after surgery showed a significantly better performance of the robot group. PFz (peak vertical force) and IFz (impulse of vertical force) were 93.1% and 94.5%, respectively, of the preoperative value in the robot group, while the hand broached dogs reached 80.6% and 77.1%, respectively. Similar differences were found in the 6-month and 12-month gait analyses.

The histological evaluations revealed a closer alignment of the implants to strong cortical bone in the robot group. Signs of major repair and remodeling were visible in the slides of the hand broached group; whereas, the robot group showed all signs (*i.e.*, [insert examples of signs]) of primary healing between the implant and bone.

4. Discussion

According to the authors, this animal experiment, when evaluated with the results of a concurrently run clinical study, demonstrated that the use of a robot in orthopedic surgery is feasible and is not connected with any risk to the patient.

In this experiment, early concerns during the development of the robotic system regarding the possibility of uncontrolled action by the robot, potentially causing harm to patients or staff within the workspace, were found to be unsubstantiated. In no case did the robot deviate from the plan and no unplanned action of the robot was encountered. In contrast, all safety features worked as intended. The procedure was halted immediately when inaccurate data were detected by the robot intraoperatively due to a failure in the motion of the CT table.

Registration using pins , which require a second surgery, is a disadvantage of the pin-based registration system used in this animal experiment, although no complications due to pin placement were encountered in this study. Yet, a pinless registration is already in

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use in the lab and has been successfully used in the OR at the BGU institution, comparing pin data with pinless data on the same subject.

Another major concern with the use of the ROBODOC concerns operating time. At the time of this experiment, robotic surgery was prone to take longer than the hand broached procedure, and early experiences in the US with the ROBODOC supported these concerns. This animal study, when evaluated with the results of the concurrently run clinical study, showed a consistent prolongation of surgery of approximately 30 minutes due to the use of the robot (see Table 1). This additional time is due to the fixation of the bone to the robot, installation of the bone motion monitor, registration (pin finding), and finally, the milling, which takes about 15 minutes. This longer operating time potentially exposes the patient to a higher risk (*i.e.*, infection, thrombosis, etc.). Evaluation of this animal study and the concurrently run clinical study, showed no such correlation. No infection or higher rate of thrombosis was seen in these subjects as compared to the rates seen in a comparable series. In addition, we saw no fracture or no fissures in the robotic group, which are common complications in cementless THR and likely to support an early failure.

Despite immediate weight bearing, no subsidence of an implant was seen in the follow-up x-rays. Based on gait analyses, postoperative pain in this animal experiment appeared to be less in the robot group. Finally, the precise execution of the thorough preoperative plan on ORTHODOC allows the close alignment of the implant to supporting bone and promotes primary healing between the implant and bone, which was proven by the histological evaluation in this animal experiment. Thus, good performance of the implants is expected because any malpositioning can most likely be avoided.

The authors of this study conclude that both studies (*i.e.*, the animal study described above and the concurrent clinical study) prove the feasibility of robot-assisted surgery in THR. Disadvantages of the system, *i.e.*, longer operating time and pin registration, are outweighed by proven and expected benefits. These results further support the clinical use of the ROBODOC in THR and intensified research for further applications.

5. Conclusion

The results of this canine study showed no system-related complications, a tolerable longer oeprating time and benefits regarding position and healing of the implant in the robot group. No fractures or malposition were seen in the robot group.

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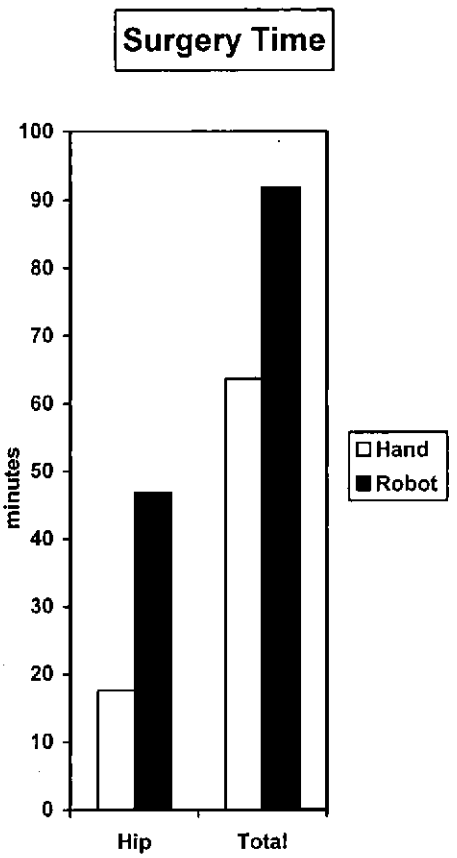
Table 1 Surgical Time in Animal Experiment

	HIP OUT TO HIP IN	TOTAL SX TIME
HAND	{minutes}	{minutes}
H-1	14	51
H-2	9	43
H-3	13	61
H-5	22	72
H-6	10	51
H-7	11	64
H-8	22	65
H-9	21	90
H-10	37	76
Mean	14	64
Average	17.67	63.67
ROBOT	51	87
R-2	35	86
R-3	81	120
R-4	37	82
R-8	38	95
R-1	42	91
R-5	37	90
R-6	65	110
R-7	43	78
R-9	39	79
R-10	46.8	91.8
Mean	42	90
Average	46.8	91.8
Avg. Diff	29.13	28.13



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Section 19.2 Cadaver *Ex Vivo* Study to Evaluate Pin-Based Registration

A study of ten fresh cadaveric femora (5 pairs), entitled THE FIT OF CEMENTLESS STEMS IN THE FEMUR: ROBOT VS SURGEON was conducted by the INSTITUTE OF ORTHOPEDIC RESEARCH AND EDUCATION, 6565 Fannin, Suite F115, Houston TX. The study was performed to measure the accuracy of a surgical robot in preparing the femur for implantation of a cementless femoral prosthesis in comparison with conventional manual broaching. One femur of each pair was prepared by the ROBODOC preparation technique and according to the preoperative plan determined by 3D computer-assisted templating. The contralateral femur was prepared by conventional manual broaching. A surgeon with extensive experience in both techniques prepared all specimens. Using customized software (Pv Wave, Visual Numerics), the distances between the bone and implant surfaces (gaps) were calculated at 1 degree circumferential increments. A bilinear interpolation method was then used to generate a surface map of gaps at 1mm vertical intervals and 1 degree circumferential increments.

Results: The width of the gaps surrounding the implant varied significantly between the preparation methods. The average gap width within the manually prepared cavities was 0.63±0.39mm (range 0.11-1.43mm), compared to 0.422±0.21mm (range 0.07-1.11mm) ($p<0.00001$) for the ROBODOC method; on the average the gap width for manually prepared cavities was 50% larger than that for ROBODOC.

The difference in gap width varied with anatomic location within the femur. Over the most proximal 20% of the implant, where potential for cancellous ingrowth is greatest, the manually prepared gaps were considerably larger on average (manual 0.31±0.19mm vs. ROBODOC 0.23±0.12mm, $p=0.023$). This size difference increased when comparing the average width of the largest gap produced by the preparation methods within each zone (0.81 vs 0.57mm, $p=0.023$).

This trend continued in the mid-stem region, defined as the zone extending from 20% to 50% of the length of the implant. In this area, the average gap width was 0.81±0.34mm in the manually prepared bones (range: 0.25-1.43mm) compared to 0.53mm±0.15mm in the ROBODOC cases (range 0.29-1.11mm), a difference of 53% ($p<0.001$). As anticipated, both preparation methods produced wider gaps in the moral distal section, in order to accommodate initial placement of the prosthesis.

The differences between preparation methods also varied around the circumference of the implant. In the anterior-lateral, lateral and posterior lateral zones, there was only a slight increase in gap width from the proximal surface to the mid-stem level between the robot and manually prepared specimens. The greater differences were seen in the medial region where the width of the gaps in the manually prepared bones increased rapidly in the zone between 25% to 50% of the implant length. In the anterior, anterior medial, posterior and posterior medial regions, the gaps were consistently smaller in the ROBODOC prepared femora.

When the gap data are expressed in terms of the four quadrants of the implant, the medial quadrant had the largest difference of 85% between the preparation methods. Conversely,

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in the lateral quadrant, the difference in width between the ROBODOC and manually created gaps was only 9%.

Preparation method also had a significant effect on the area of the surface that was close enough to support bony ingrowth. In the ROBODOC prepared bones, the separation of the implant and the bony cavity was less than 0.5mm over 69% of its surface, compared to 50% for the manually prepared bones ($p=0.14$). Gaps larger than 1mm, typically considered the upper bound for bony ingrowth, covered only 7% on the ROBODOC specimens while the manually prepared bones had such gaps over 23% of the surfaces.

The differences were even more significant when the proximal area was divided into two parts. In the top 20% of the implant surface, the trabeculae were within 0.5mm over 92% of the surface in the ROBODOC prepared bones as compared to 81% for the manually prepared bones ($p=0.216$). In the mid-stem region, 57% of the surface was within 0.5mm for ROBODOC prepared bones compared to 36% for the manual cases ($p=0.073$). Perhaps most important, gaps larger than 1mm were found over only 10% of the mid-stem region in the ROBODOC prepared cases while in the manual cases, these gaps were found over 31% of the surface ($p=0.025$).

Conclusion. This experiment demonstrated that preparation of the femur to receive an implant was typically more accurate with the ROBODOC than with manual broaching. Manual broaching generated gaps larger than 1mm over 23% of the implant surface compared to 7% with ROBODOC preparation. Use of a robotically prepared canal led to a 34% reduction in gap width, and a 19% increase in the area of the implant surface located within 0.5mm of the bony cavity. The ROBODOC cases had 15% more surface area in close proximity to the bony surface (<0.2mm), even with implants designed with a proximal interference fit. This closer approximation can be expected to reduce micromotion and increase bony ingrowth in femoral prosthesis.

This study was used to support V&V activities during development of the ROBODOC® Surgical System.

A copy of the research report is provided in **Attachment 2** of Section 19.

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Section 19.3 Cadaver *Ex Vivo* Study to Evaluate Pinless Registration

Integrated Surgical Systems (ISS) conducted a study of 10 fresh cadaveric femora (5 pairs). This section provides a summary of the test report, TR-07-010, entitled *Laboratory Accuracy Validation Using Cadaver Femora with Pinless Prototype ROBODOC® System.* The data was generated to evaluate a point to surface approach for solving the pinless registration problem. The protocol and test report are summarized below.

I. Test Objective

The protocol was designed for laboratory tests with cadaver bone to evaluate a point to surface approach for solving the pinless registration problem. The high level goals for the testing were:

1. To quantify the accuracy of the pinless registration method as compared to the pin-based method using actual cadaver femora. The data was used for comparison to corresponding data collected clinically.

2. To quantify the repeatability of the pinless registration procedure for individual bones where the data are collected multiple times.

The testing involved the use of a preproduction ROBODOC® system containing the digitizer, which is a precision measurement device. The digitizer was used to measure surface points for point to surface registration for comparison to the pin-based registration method. Using the traditional pin-based registration method, pins were found using the robot. This comprised one set of data. Additional data was collected from the experimental pinless registration method. For each bone data set, differences between pin-based registration and the pinless approach were computed and compared with specified limits. These results are discussed below.

II. Deviations from Protocol

None

III. Materials and Equipment

1. Current Pin-Based System (for comparison purposes – See Test Objective Summary) –]Please confirm.]
2. Complete preproduction Pinless ROBODOC® System (ref. ISS P/N)
3. Matlab Software for analyzing the results
4. View3d Software for analyzing the results
5. Preproduction version of the Pinless ORTHODOC® software (ref. ISS P/N) module

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IV. Process / Product Description

The product is a ROBODOC Surgical Assistant that was modified to accept a pinless upgrade package (*i.e.*, Project Frontier prototype). The pinless upgrade package allowed the ROBODOC unit to perform a THR procedure using either the current two-pin registration procedure or the pinless registration procedure to determine the location of the bone.

V. Test Methods / Procedure

Cadaver Bone Preparation

1. Five (5) fresh/frozen human femoral specimens were selected that were: a) free of obvious defects, b) covered a range of adult sizes and d) included both right and lefts. Both left and right femoral specimens were selected.
   The femoral specimens were numbered: 1. Pinless
   2. Pinless
   3. Pinless
   4. Pinless
   5. Pinless

   A left and a right foam femoral specimens were also selected:.
   The foam specimens were numbered: 1. Pinless-Z (caseid: DEMC0001)
   2. Pinless-YR (caseid: DEMC0004

2. The bones were labeled appropriately with a durable tag.

3. Three [Company: Were 2 or 3 pins used in this study? Please confirm.] locator pins were placed in accordance with the bone preparation and CT scan procedure.

4. A CT scan of all seven femora (fresh/frozen and foam) was performed in accordance with the CT scan procedure. This produced a total of 7 CT scan exams. Each CT scan was labeled with the appropriate bone identification and scan trial description. The test results were documented and recorded.

5. Steps 6 – 11 below were repeated for each scan of the 7 femora.

6. The femoral CT scans were imported into the ORTHODOC®. The motion checks and pin finding was performed using the standard procedure [Company: Please define 'standard procedure'.].

7. The CT modeling software (DCS Contour) created a detailed surface model for the regions of interest. This step was accomplished by following the "CT model creation and inspection" procedure. The output of this program was a data file: "CASEID.PTL".

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8. The ORTHODOC® recorded the CT coordinates for a point at the tip of the greater trochanter.

9. The case was planned in ORTHODOC® in the normal fashion and created a ROBODOC® transfer tape.

10. A pinless .ROB file was created by running the XPIG and editing the pinless contents of the DCS file into the ROB file generated by ORTHODOC®.

11. The Microscribe Calibration Procedure was performed for each of the following microscribe/probe combinations.
    - Digitizer (5 DOF) MicroScribe with Wakeup Probe (P/N).
    - Digitizer (5 DOF) MicroScribe with Sterile Interface (P/N) and 4 inch Pointed (sterile) Probe (P/N).

12. The calibration files were copied to the preproduction pinless "DigiMatch" ROBODOC® in the c:\probes directory. The calibration file for the Wakeup Probe was called NONSTER.CAL and the calibration file for the Sterile Pointed Probe was called STERILE.CAL.

Bone Data Collection Procedure

13. Steps 13 – 30 below were repeated 3 times for each of the 7 femora, yielding a total of 35 data sets.

14. The preproduction pinless DigiMatch ROBODOC® system was setup for the procedure by installing the Wakeup Probe on the MicroScribe (making sure that the number on the probe matched the serial number for the MicroScribe).

15. The MicroScribe power and serial cables were connected and the MicroScribe was powered up. The ROBODOC® system was then powered up.

16. The MCS program was started by typing MCS at the c:\mcs directory, in the RCC computer.

17. The pinless ROB file and the .PTL file were manually copied into the c:\rtm\data directory. The RTM program was started by typing RTM32 at the c:\rtm\bin, in the RTM computer.

18. At the DOS prompt in the RCC computer, the directories were changed to c:\thrpless. The THR application was run by typing THR. This started up the pinless THR software that guides the operator through the complete data collection procedure. The software then ran in the pinless THR procedure.

Note: The following procedural steps were all completed by following the ROBODOC® screen prompts.

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19. Prior to beginning data collection, the series of start up procedures were completed, which include robot and microscribe initialization, non-sterile diagnostics and sterile diagnostics.
20. The fixator clamp was attached to the fixator extension arm.
21. The proximal bone clamp was installed with the cadaver bone and the distal femur was stabilized by securing it on to the ROBODOC® system. Efforts were made to ensure that the femur did not move during the entire procedure.
22. The Pointed Probe (straight 4" probe P/N) was installed on the digitizer and the tip of the greater trochanter was located. This data was used to compute the initial estimate of the transformation.
23. The approximate location on the femur, which corresponds to the band of distal CT surfaces, was identified. This was done by using the digitizer to measure down from the tip of the greater trochanter. Screen prompts indicated when the probe was at the correct level.
24. Using the digitizer, distal surface points were located.
25. Using the digitizer, the proximal surface points were located in the order specified by the anatomic sites pictured on the screen images.
26. During the "find recovery pins" procedure, the THR program was reset to do a pinless ROBODOC® procedure. This was done by invoking the interpreter and typing "goto_twopin" and then typing "resume".
27. The distal and proximal pin finding procedure was then completed with the robot.
28. After the robot calculated the workspace, the procedure was exited prior to cutting by invoking the interpreter and typing "exit".
29. The bone clamp was disconnected from the fixator extension arm.
30. Copies of the following data files were made following completion of data collection.
    - All normal ORTHODOC® files (CASEID.ROB).
    - Point data file and surgical record file from RCC computer (CASEID.RGI, THR.SCR and RECOVER.RBT).

VI. Data Analysis

1. For each patient data set, the RECOVER.RBT file was evaluated to determine the pin distances and normals.

2. For each patient data set, the registration results were computed by following the registration analysis procedure. This resulted in registration accuracy reported relative to the pin-based registration technique.

3. The data obtained in steps one and two were input into a spreadsheet or database program.

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4. The following statistics were computed for all of the numerical records (mean, standard deviation, maximum and minimum values).

VII. Acceptance Criteria

1. Accuracy results for the pinless approach will be described relative to the current pin-based method. The accuracy will be dependent on anatomic directions and will be within the following limits.

(b) (4)

[redacted]

2. For all cases, access to the required surfaces must be sufficient to allow for successful completion of the data collection procedure.

VIII. Results

Results of the study demonstrate that the Acceptance Criteria specified in Section IX were met. Specifically:

1. Accuracy results for the pinless approach were described relative to the current pin-based method. The accuracy for all trials was within the set limits of the acceptance criteria.

2. For all cases, access to the required surfaces was sufficient to allow successful completion of the data collection procedure.

IX. References

None

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Section 19.4 Conclusion from Cadaver and Animal Testing

These experiments demonstrate on a measurement, functional, and histometric level that the cavity generated using ROBODOC Surgical Assistant more closely approximates the "ideal" cavity needed for implant placement than conventional broach methods. The cadaver testing demonstrates that ROBODOC created cavities produce less "gaps" than cavities produced by hand broaching. The "ideal" cavity being defined in terms of 1) shape – pursuant to the manufacturer's specifications for the implant and 2) position – pursuant to the surgeon's pre-operative plan. The gait analysis demonstrates improved function and the histological results confirm that a smaller gap produces better bone apposition. The histological study also confirmed more consistent placement of prostheses, fewer fractures and no untoward effects on long-term repair in the ROBODOC group.

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Attachment 1

Lecture Notes in Computer Science, CVR-Med MRCAS '97: ROBODOC Surgical System - Animal Experiment; André Bauer, Martin Börner, Armin Lahmer; Berufsgenossenschaftliche Unfallklinik, Frankfurt Am Main, Germany

From: "Lecture Notes in Computer Science
CVR-Med MRCAS '97

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Robodoc- Animal Experiment and Clinical Evaluation

André Bauer, Martin Börner, Armin Lahmer
Berufsgenossenschaftliche Unfallklinik
(ÄRZTL.DIR.PD.DR.M.Börner)
Frankfurt Am Main, Germany

Abstract: Robot-assisted surgery in Total Hip Replacement, was evaluated using the Robodoc system. 490 patients were operated with Robodoc since November 1994, and a two arm trial was conducted on twenty greyhounds. Results in both studies showed no system-related complications, a tolerable longer OR-time and benefits regarding position and healing of the implant in the robot group. No fractures or malposition were seen in the robot-operated people and dogs. Study results support further clinical use and applications.

1 Introduction

In cementless total hip replacement, primary fixation between bone and femoral component is a critical phase in the procedure. While in cemented procedures any gaps between implant and bone are filled by cement, and primary stabiltiy is achieved through the bonding of the cement (2), cementless procedure requires exact fit of the implant into the cavity, initial stability avoiding any micro motion or rotational instabilty and precise positioning of the implant. Missing any of these goals might result in early micro motion, leading to possible interposition of fibrous tissue between bone and implant and eventually aseptic loosening (3,4,6). As handheld broaches used in the preparation of the femoral cavity are prone to tear out pieces of bone and are often deflected by hard bone, machine milling of the cavity is likely to enhance surgical precision. Robodoc is the first operational system in orthopedics that allows accurate planning of the cementless THR procedure and the execution of the plan by a computer guided robot (1,5) . Parallel to clinical testing a prospective two arm animal experiment was conducted to evualate performance and possible benefits of the system.

2 Materials and Methods

In the clinical trial, 490 patients have been operated with the Robodoc system between November 1994 and November 1996. All patients received a cementless THR using the Osteolock implant by Howmedica. All patients were informed on the experimental status of the system and gave their informed consent. Included in the study were patients between the age of 18 and 72 years. Elderly patients were excluded when preop x-rays revealed osteoporotic bone not likely to support cementless implants. Prior to the actual procedure, patients underwent a minimal invasive procedure to implant three small metal pins into the femoral condyles and greater trochanter. These serve registration purposes. After pin placement a CT scan of the femur is taken and CT data are loaded into Orthodoc, a workstation that displays the image of the femur and allows, after choosing an implant from an implant library,

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the virtual placement of the prosthesis into the bone. The surgeon can check size and fit of the implant, as well as position, offset, bone density and anteversion. The finally created plan is transferred via tape to the computer guiding Robodoc. During surgery, a probe attached to the robots arm touches the three pins and correlates the bone to the preop plan. After successful registration, the preop plan is executed by the robot with the highest accuracy regarding position and size of the implant.

To prevent heterotopic bone formation, all patients were on an indomethacin regimen. They all received a standard antithrombosis prophylaxis with heparin. Postoperativly, from patient No. 31 on, they all were encouraged to immediate full weight bearing the day after surgery. Postop x-rays were performed in the OR and at 10 days, 3, 6, 12 and 24 months, orthopedic examen in the same intervalls.

In the animal experiment, 20 male greyhounds were randomized to either handbroached or robot assisted hemiarthroplasty. The study was performed by the first author and Dr. Montgomery of the Small Animal Clinic, Auburn University, in Auburn, Alabama, between December 1995 and December 1996. The study was approved by the Ethical Commitee of Auburn University and in part supported by Intergrated Surgical Systems, Sacramento, California.

All dogs received preop vaccinations, standard hip x-rays and orthopedic examen. For dogs randomized to the handbroached group, planning was performed with acetate templates over x-rays and the femoral cavity was prepared with handheld broaches. In the robot group, pin placement and CT scan were performed in general anaesthesia. Planning was performed on Orthodoc, and the femoral cavity was milled by the robot after intraoperative registration. Aside from registration, fixation of the bone to the robot and milling by the robot, the procedures in both groups were carried out identicly.

Postoperative regimen was identical in both groups. Partial weight bearing on the first postop day was followed by full weight bearing after day 2. Beginning on day 5, all dogs received a polychrome sequence labeling with yellow, red, blue and green markers. Each label was applied for 5 days. A postoperative gait analysis was carried out after 1, 3, 6, 9 and 12 month. Necropsy dates were at 35 days for 8 dogs (4 each group), 84 days (6 dogs) and 365 days (6 dogs). Histological evaluation was carried out by Drs. Draenert in Munich.

3 Results

A. Clinical trial

Between November 1994 and November 1996 the Robodoc procedure was performed on 490 patients. In all cases, the preoperative plan was executed with the highest precision. No femur fractures or fissurs occurred. Postoperative x-rays revealed not one case of varus- or valgus malposition. Although immediate full weight bearing was encouraged, no subsidence of implants, even on the 2 year follow up rays, was seen. OR time in the beginning averaged 200 minutes in the first 5 cases (compared to appr. 85 minutes in handbroached THR), but the learning curve showed a steady decline. From case 20 on, OR time came down to 120 minutes, and is now steadily between 90 and 100 minutes. Faster OR time was due to better training of surgeons as well to improvements in software guiding the procedure and cutting files.

In overall 15 cases, the robot procedure could not be performed although pin placement and Orthodoc planning was completed. Reasons for these were CT-failures (inaccurate table motion), software problems, user errors and loose pins due to

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osteoporosis or poor placement. In none of these cases the preop plan regarding size of the implant could be accomplished, but smaller prosthesis had to be implanted.
As complications we saw some transient nerve palsies (1,9%), pulmonary embolism (1,8%), deep vein thrombosis (2,1%), and 2,7% postoperative dislocations that were not connected to the robot procedure but to problems with the acetabular component.
In 14 patients, Robodoc procedure was performed bilaterally, with a mean intervall between procedures of appr. 6 months. In these cases we were able to evaluate the perfomance of the robot regarding accuracy by comparing the Orthodoc images created for the second procedure with those for the first hip: in all 14 cases we found a perfect correlation between preop plan and postop images.
Two cases were actually revision cases, as both patients already had - loose - implants, one cemented and one cementless stem. Despite some metal artefacts in CT Orthodoc planning was feasible and the image of the implant could be layed over the loose stem, thus creating a cutting file that would remove all cement resp. fibrous membrane. Both cases could be performed without complication, especially avoiding any fracture and saving a lot of time during cement removal.

B. Animal Experiment

In the robot group, all dogs could be operated successfully, no procedure had to be aborted and in all cases the preoperative plan regarding size and position of the implant could be accomplished. In the handbroached group, two dogs suffered a fracture of the femur. One dog had to be sacrifzed intraoperativly, when the femur cracked, and the implant could not be positioned deep enough to allow reduction of the joint. In another dog the fracture became evident in the x-rays before necropsy, when a large callus formation developed as result of a long spiral fracture. OR time in the robot group was a mean of 29 minutes longer than in the handbroached group.
Gait analysis one month after surgery showed a significant better performance of the robot group. PFz (peak vertical force) and IFz (impulse of vertical force) were 93,1% and 94,5% of the preoperative value in the robot group, while the handbroached dogs reached 80,6% and 77,1% respectivly. Similar difference were found in the 6 months and 12 months gait analysis.
The histological evaluation revealed a closer alignment of the implants to strong cortical bone in the robot group. Signs of major repair and remodeling were visible in the slides of the handbroached group, while in the robot group all signs of primary healing between implant and bone werde present.

4 Discussion

Both animal experiment and clinical study proved for the first time that the use of a robot in orthopedic surgery is feasible and is not connected with any risk to the patient. Early concerns during the development of the robotic system about the possibility of uncontrolled action by the robot, potentially causing harm to patients or staff within the workspace (5) , could be refuted. Not in one case the robot moved away from the plan, and no weird action of the robot was encountered. Quite in contrast, all safety features worked perfectly. When, due to a failure in the motion of the CT table, inaccurate data were detected by the robot intraoperativly, the procedure was halted immediatly.

DJA x02064

Registration using pins that require a second surgery is a disadvantage of the current system, although no complications due to pin placement were encountered. Yet a pinless registration is already in use in the lab and has been successfully used in the OR at our institution, comparing pin data with pinless data on the same patient. We expect to commence routine use of the pinless procedure early in 1997.
Another major concern in robot surgery regarded OR time. Obviously robotic surgery was prone to take longer than the handbroached procedure, and early experiences in the US with Robodoc supported these concerns. Our clinical study, as well as the animal experiment, showed a consistent prolongation of surgery due to the use of the robot of appr. 30 minutes. This time is consumed by the fixation of the bone to the robot, installation of the bone-motion monitor, registration (pin finding) and finally the milling, which takes about 15 minutes. This longer OR- time potentially exposes the patient to a higher risk (i.e. infection, thrombosis etc.). Both studies showed no such correlation, especially no infection or a higher rate of thrombosis than in comparable series. On the benefit side, we saw no fracture or no fissur, which are common complications in cementless THR and likely to support an early failure (7). Despite immediate weight bearing, no subsidence of an implant was seen in the follow-up x-rays. Postoperative pain was less in the robot group, which was noted in the human patients and proven by gait analysis in the dog study. Finally, the precise execution of the thorough preop plan on Orthodoc allows the close alignement of the implant to supporting bone and promotes primary healing between implant and bone, which was proven by the histological evaluation in the animal experiment. We expect a good performance of the implants, because any malpositioning could be avoided.
In conclusion, both studies proved the feasibility of robot-assisted surgery in THR. Disadvantages of the system, i.e. longer OR- time and pin registration, are outweight by proven and expected benefits. The results support further clincal use in THR and intensified research for further applications.

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DJA x02065

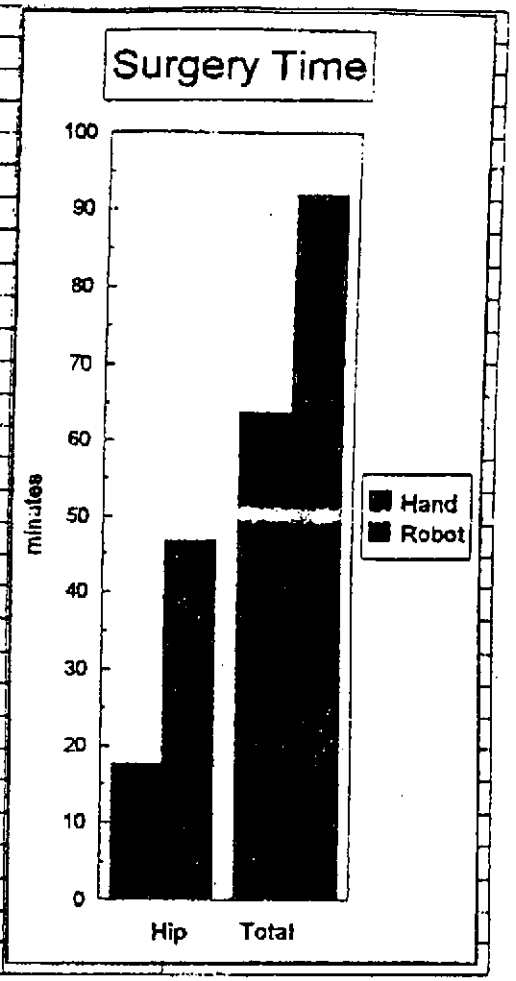
PFz	Preop	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
Hand	80.533	64.98125	69.87	77.43333	75.48333	71.44
Robot	83.398	71.018	78.9	85.91667	83.72333	91.52
IFz	Preop	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
Hand	11.008	8.335	9.67	10.42	9.873333	9.1
Robot	10.954	10.39889	10.11	10.98333	10.16	10.7

DJA x02066

	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
PFz % Hand	80.66	91.95	99.59	97.02	91.82
PFz % Robot	92.99	95.69	99.73	96.95	106.22
	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
IFz % Hand	77.16	89.2	96.84	91.41	84.17
IFz % Robot	94.63	89.85	94.03	86.63	91.39

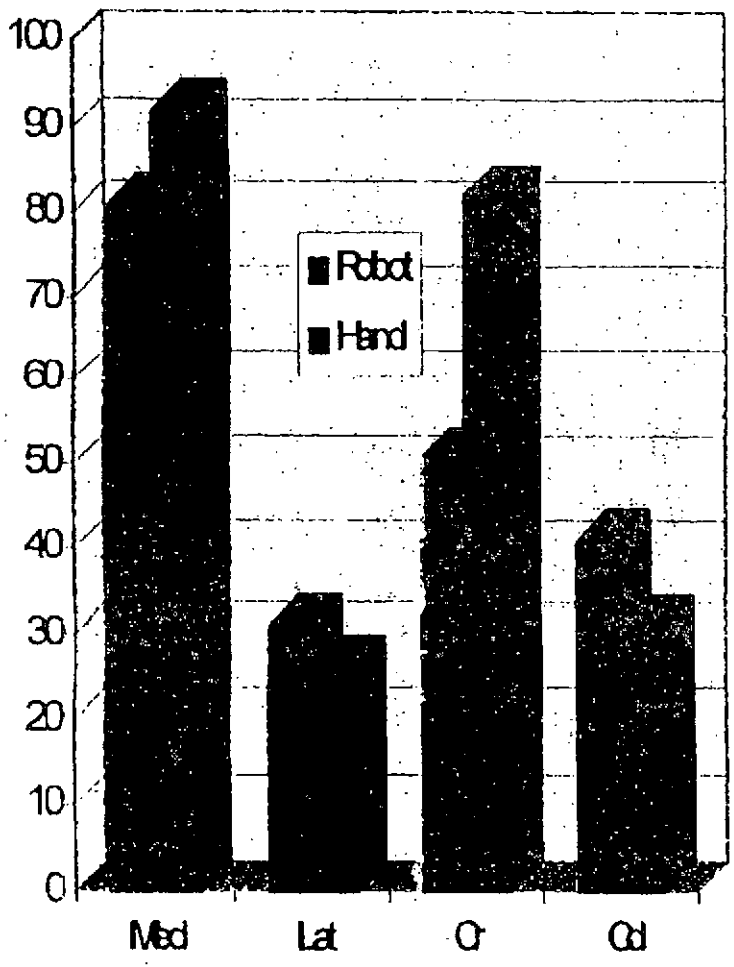
DJA x02067

HAND	HIP OUT TO HIP IN (minutes)	TOTAL SX TIME (minutes)
H-1	14	51
H-2	9	43
H-3	13	61
H-5	22	72
H-6	10	51
H-7	11	64
H-8	22	65
H-9	21	90
H-10	37	76
Mean	14	64
Average	17.67	63.67
ROBOT	51	87
R-2	35	86
R-3	81	120
R-4	37	82
R-8	38	95
R-1	42	91
R-5	37	90
R-6	65	110
R-7	43	78
R-9	39	79
R-10	46.8	91.8
Mean	42	90
Average	46.8	91.8
Avg. Diff.	29.13	28.13



DJA x02068

Robot v. Hand Mean % Fit



- Robot group had better mean fit caudal and lateral
- Hand group had better mean fit cranial and medial
- Overall (sum) fit, Robot was 49% Hand was 50%

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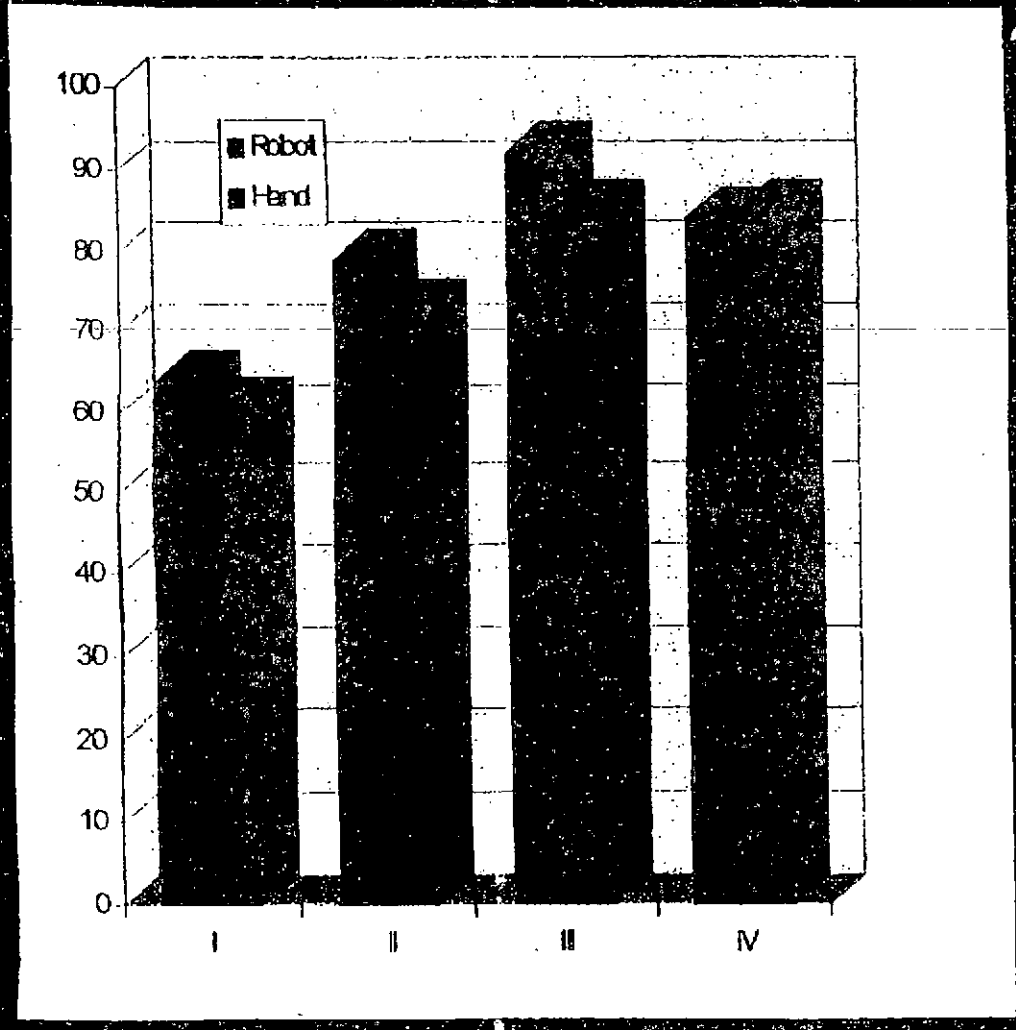
DJA x02069

Robot v. Hand % Fill



- Mean % fill was better with the Robot group than the Hand group at all sites, except at site IV.
- Subsidence was 0 with the Hand group and a mean of 2 mm with the Robot group

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DJA x02070

Mrs
Mary J. Edwards
Director Regulatory Affairs
Robodoc
829 West Stadium Lane
USA 95834 Sacramento California

FAX **Munich** , September 24, 1997

Dear Mrs. Edwards:

Thank you for your fax . Enclosed find the list of our code related to your animal code . To explain our code :

i.e. E 278.02 BF 04 AA FE RE
E= experimental
278 = Robodoc
BF = Börner Frankfurt (Head of the Institute)
04 = dog
AA =Individuum AA=first stage A-series = Robodoc ; B = conventional
FE = Femur (organ)
RE = Rechts (right side)
* = Picture not included in set.
For any reproduction , please refer to the negative-number .

AA FE RE 37 D(ays) 80869 (minor trochanter level) CX05
(the minor trochanter indicates the posterior and medial side) . The stem is nicely positioned in slight ante-version . The circumference is in fibrous tissue free contact with the cancellous bone trabeculae . No defect . The scaffolding of cancellous bone of the cross section is uninterrupted ; there is no bony atrophy apparent .

*80865 CX04 one level above : same findings .

80889 EX01 Fibrous and bony encapsulation of the distal part of the stem .

Explanation: relative motion between metal and tissue induces tangentially oriented fibrous tissue which anchors in a bony baseplate ...fibrous and bony(outer shell) capsule .

BA FE RE 34 D 80973 (minor trochanter) CX07

DJA x02071

The stem is in correct position . The circumference is medially and dorsally in contact to the bony trabeculae ; **ventrally and antero-medially a defect is pronounced which is filled in by fibrous tissue tangentially oriented to the stems surface .** ***Also laterally a small gap is revealed .***
The unstained section clearly shows restricted areas with tremendous activities of new bone formation i.e.: medially , posterolaterally and antero-laterally .

82155 CX06 stained with basic fuchsine : the fibrous tissue filling the defects is more clearly revealed .

80980 DX02 level of the femur's rectangular shape (below the minor trochanter) : fibrous and bony encapsulation is already apparent .

82157 EX02 fibrous and bony encapsulation of the distal stem .

AB FE RE 40D 82159 CX04 (minor tr.level) .Stem in correct position . Uninterrupted trabecular integration . Stem in contact with the cortex : anteromedially . Along the postero-medial circumference the calcar femoris (= posterior wall of the femoral neck) is preserved providing rotational stability . No defect no bony atrophy over the cross sectional structure .

82161 EX02 fibrous and partly bony encapsulation .

BB FE LI 35 (LI=left) D(ays) 82151 CX02 (minor tr.level) More pronounced anteversion of the stem . Bony contacts only in selected areas : dorso-laterally and antero-laterally . Wide defects medially , anteriorly and postero-medially . The gaps are filled in by fibrous tissue . Response in terms of bone healing : medially and ventrally and even a periosteal reaction along the medial circumference . Severe bony atrophy outside the contact areas , i.e.: lateral aspect of the cross section .

82153 EX02 Essentially fibrous encapsulation (early stage) .

AC FE LI 40 D 82167 (minor tr.level) The stem is in pronounced anteversion . The trabecular contact around the surface is evenly formed . No bony atrophy and no defect is revealed . A bone healing reaction is missed . As in AA , AB a slight periosteal reaction formed during the last week (green of Calcein green) corresponds to the shape of the stem.

Explanation : load transfer metal-bone is deforming the medial circumference of the femur and thus inducing a periosteal reaction stiffening the cortex .

82165 EX02 essentially fibrous and partly bony encapsulation . Encapsulation means : there is always fibrous tissue in the interface oriented tangentially to the implant.

BC FE RE 35 D 82147 (minor tr.level) CX03 The stem is placed medially , the cortex has broken . The fracture gap is filled with dense fibrous tissue . Periosteal callus formation has already formed . The dorsal , lateral , and anterior circumference reveals nice bony contact with tremendous new bone formation (bone healing stage) and reinforcement of the scaffolding of cancellous bone (conversion to partly compact bone) .

DJA x02072

BC FE RE Explanation of the compactisation of the cancellous bone : The femur has lost it's stiffest structure , the Adam's arc ; therefore the deformation at the stiff implant is more pronounced and the bony response is the reinforcement of the cancellous scaffolding surrounding the implant = strain adapted bone remodelling .

82149 EX02End of the racture - healed cortex .Severe periosteal reaction (callus formation) fibrous encapsulation of the stem .

AD FE LI 41 D 82170 CX04 (minor tr.level) Correct position of the stem . Minimal defect in the middle of the anterior surface (slight traumatization) . Nice trabecular support of the rest of the circumference . No bony atrophy . Bone ingrowth along the medial cortex of Adam's arc as revealed in all other Robodoc cases earlier .

82174 EX02 Fibrous and partly bony encapsulation .

BD FE RE 36 D 82142 CX02 (minor tr. level) . Posteversio of the stem . Posteromedial contact with the cortex . Bone ingrowth and tremendous reinforcement of the cancellous bone in this circumscript area (load transfer) . Wide gap filled with fibrous tissue anteromedially . Bone healing response around the circumference . Severe atrophy of the mineralized scaffolding in the lateral part of the cross section .

82143 FX01 fibrous and bony encapsulation . **End of the bone healing phase .**

Remodelling phase .

AE FE RE 80D 80952 CX03 (minor tr. level) Correct anteverted position . Deep osteotomie (healed ring of Adam's arc) . Trabecular contact around the surface , no bony atrophy .

80956 CX06 (end of minor tr.level) Nice trabecular support without any defect . Reinforcement of the trabeculae only pronounced along the medial circumference .

80963 DX02 (rectangular shape of the femur below the min.trochanter) . Fibrous and bony encapsulation .

82175 EX02 fibrous and bony encapsulation .

BE FE LI 78D 82138 CX03 (minor troch.level) The stem is in pronounced anteverted position . The cortex has healed (oblique osteotomiy) . A nice trabecular contact is pronounced around the stem . Anteriorly a wide gap filled with fibrous tissue is revealed . Laterally the trabeculae have atrophied .

DJA x02073

82139 FX01 fibrous and bony encapsulation .

AF FE LI 83 D * 81698 BX07 (minor troch.level) Exact position of the stem (slight anteversion) ; nice trabecular support , reinforced along the medial circumference ; no bony atrophy in the cross section .

81608

* 81609 BX07 Reinforcement of the medial trabecular support . Partly compacted columns . Yellow = first , green = last week of labeling .

81629 EX02 Fibrous and bony encapsulation .

BF FE LI 84D * 82168 CX02 The stem is in neutral 0 position . The cortex has closed the Adam's arc (very oblique osteotomy) . Small persisting gap anteromedially . Nice and uninterrupted trabecular support around the implant . No fibrous tissue in the interface .

* 81735 CX04 Conversion to compact bone during the bone healing of Adam's arc due to the oblique osteotomy . Yellow= first week ; green = last week of labeling .

81725

81750 EX01 Fibrous and bony encapsulation .

AG FE LI 85 D 82177 CX03 (minor tr.level) .Correct anteversion of the stem . Thinned Adam's arc and fibrous tissue in the medial interface . Trabecular contact from the posterolateral edge to the middle of the anterior circumference . Unequal reinforcement of cancellous bone ventrally and posterolaterally . Explanation : Medial defect by milling - pre-operative planning ?

82179 EX01 fibrous and bony encapsulation .

BG FE LI 81D * 82129 CX03 (minor trochanter level) Oblique osteotomy . Healed Adam's arc with periosteal reactive bone formation . Correct position of the stem . Three-point support on a cross sectional level . Huge defects anteriorly and laterally - filled with fibrous tissue , no bony reaction .

* 80990 CX01 Open Adam's arc . Three-point support with compacted trabecular structures . Atrophied restricted areas in between .

80991 CX04 Three-point-support . Closed arc . Defects anteriorly and laterally .

* 80994 DX02 fibrous and bony encapsulation around the distal half of the stem .

82134 EX03 fibrous and bony encapsulation .

End of the remodelling phase .

DJA x02074

Modelling Phase (1Y) .

AII FE LI 362D ✱ 82104 CX05 (minor trochanter level , Adam´s arc still open) . Rarefication of the cancellated structures . Multipoint support by reinforced partly compacted structures of bone . Marrow fibrosis is revealed at this level .

82159 CX07 Deep minor trochanter level . Nearly complete compact structure around the stem . Rarefication of the trabecular pattern in the cross section ; reinforced single trabeculae and pronounced reinforced columns antero- and postero-laterally . Fully mineralization of the compact sheath . 82160 Select area of CX07 : lateral support .

✱ 82107 CX08 End of the minor trochanter . Stable compact bony sheath around the implant .

82165 FX01 Fibrous and bony encapsulation around the implant .

BH FE LI 355D ✱ 82130 CX01 (minor tr.level) Neutral 0 position of the stem . Trabecular contact medially and laterally . Along the posterior and anterior surface fibrous and bony encapsulation .

82168 CX02 Reinforced bony support and bone ingrowth medially , nice trabecular support laterally . Along the anterior wall tangential orientation of fibrous tissue and newly formed bone..Along the posterior wall atrophied bony trabeculae in contact with the implant´s surface .

✱ 82123 CX03 Trabecular pattern around the implant . Compacted structures medially . Tangentially oriented fibrous tissue along the anterior wall .

82170 FX03 Fibrous and bony encapsulation of the distal part of the stem .

AI FE RE 363 D 82114 CX02 (minor troch.level) Correct position in slight anteversion of the stem . Milling defect at Adam´s arc (medially) . Fibrous tissue and bony capsule there . Bony trabecular support around the stem . Rarefication of the trabeculae but no atrophy . Pronounced periosteal reaction in correspondance of the medial pole of the stem .

82117 FX01 Fibrous and bony encapsulation of the distal part of the stem .

BI FE RE 355D 82208 CX05 (minor trochanter level ; Adam´s arc still open) Very oblique osteotomy . Trabecular support around the implant except it´s anterior wall . There, a tangentially oriented fibrous tissue is pronounced . Correct slight anteversion of the stem .

✱ 82210 CX05 (view from below) Compact medial support . The stem is too far medially placed .

DJA x02075

82215 EX02 Fibrous and bony encapsulation of the stem . Well pronounced reinforcement of the sidestanding cancellous bone .

AK FE RE 363 D 82203 CX03 (minor trochanter level) Correct enteverted position of the stem . Nice trabecular support around the stem . Regular architecture of the pattern . No gap , no atrophy .

82205 EX02 Fibrous and bony encapsulation . No reation of the sidestanding cancellous bone .

BK FE RE 355D 82192 CX03 (Transition to the minor trochanter level) Slight retroverted position . Gap around the medial pole of the stem with fibrous tissue in the interface and tangential bone formation . Trabecular support along the posterior and anterior wall , fibrous tissue medially and severe atrophy in the lateral cross section .

82200 EX02 Fibrous and bony encapsulation . The bony frame reveals reinforced support towards the cortex .

End of the series .

I wish to you a safe trip and a succesful presentation

With kind regards

Professor Dr med Klaus Draenert

DJA x02076

80869 – CXO4

AA FE RE 37 D

DJA x02077

80889 – EX01

AA FE RE 37 D

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DJA x02078

80973 – CX07

BA FE RE 34 D

DJA x02079

82157 – EX02

BA FE RE 34 D

DJA x02080

82159 – CX04 AB FE RE 40 D

DJA x02081

82161 – EX02 AB FE RE 40 D

DJA x02082

82151 – CX02 BB FE LI 35

DJA x02083

82153 – EX02 BB FE LI 35 D

DJA x02084

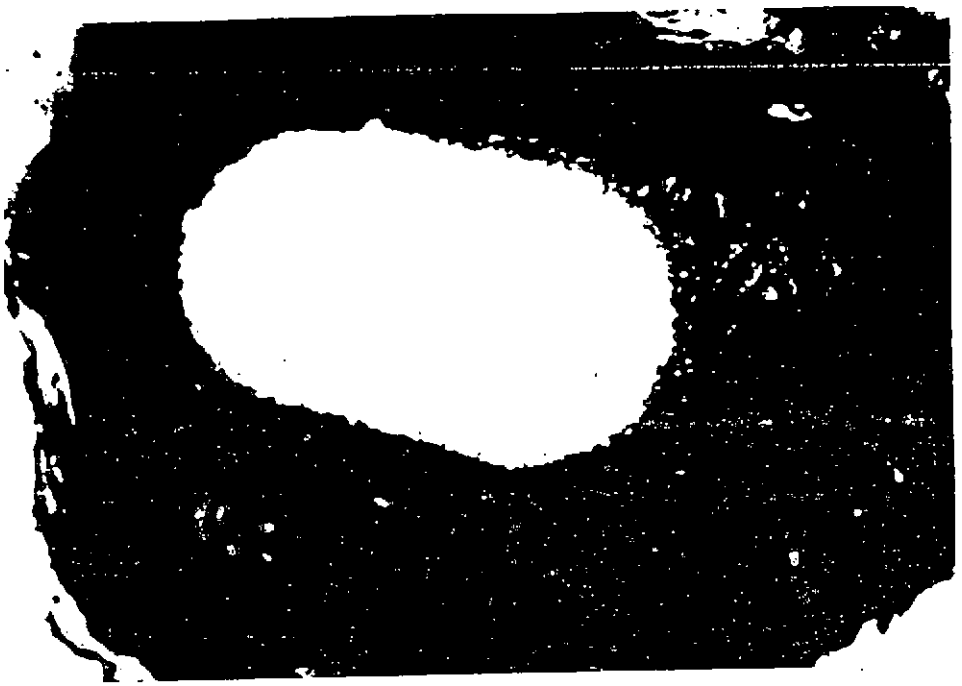
82167 – CX03

AC FE LI 40 D

DJA x02085

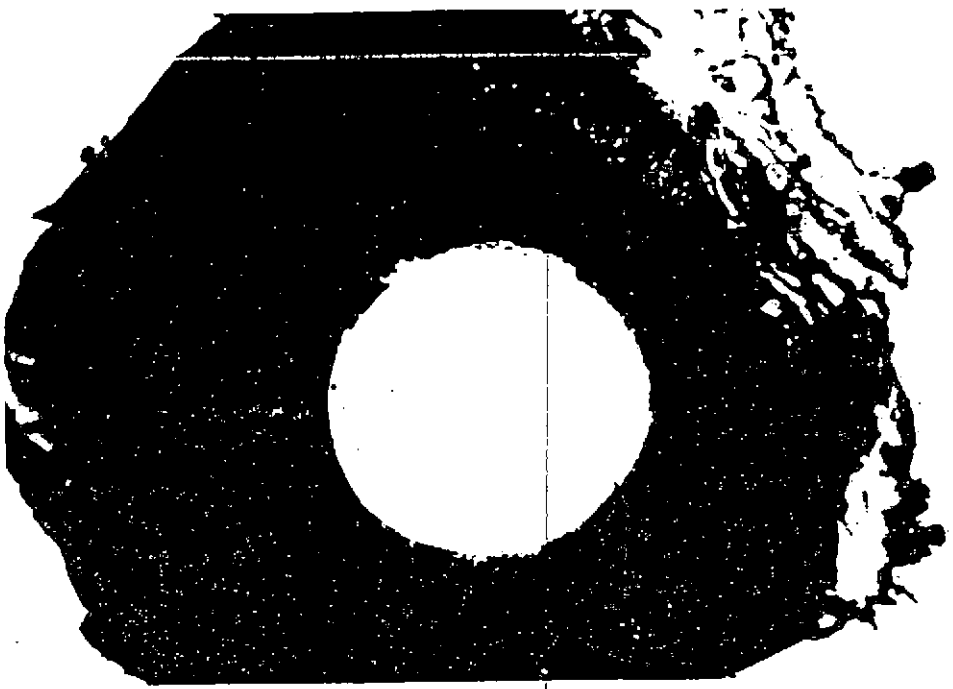
82165 – EX02 AC FE LI 40 D

DJA x02086



82147 – CX03 BC FE RE 35 D

DJA x02087



82149 – EX02

BC FE RE 35 D

DJA x02088

82170 – CX04

AD FE LI 41 D

DJA x02089

82174 – EX02

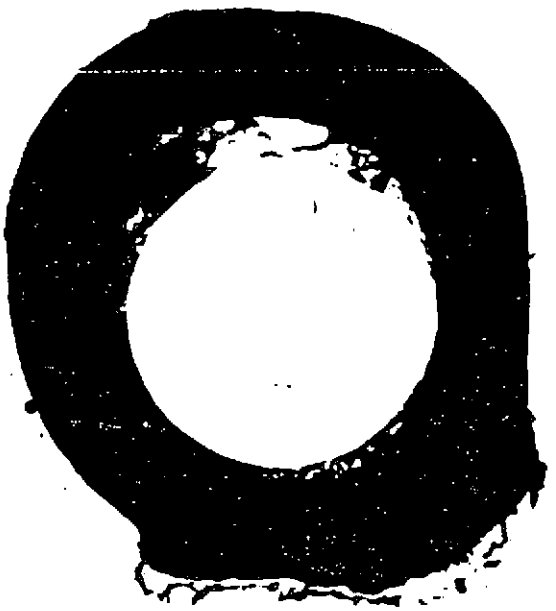
AD FE LI 41 D

DJA x02090

82142 – CX02

BD FE RE 36 D

DJA x02091



82143 – FX01

BD FE RE 36 D

DJA x02092

80952 – CX03

AE FE RE 80 D

DJA x02093

82175 – EX02 AE FE RE 80 D

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DJA x02094

82138 – CXO3 BE FE LI 78 D

DJA x02095

82139 – FX01

BE FE LI 78 D

Volume IV - 000064

DJA x02096

81608 – BX07

AF FE LI 84 D

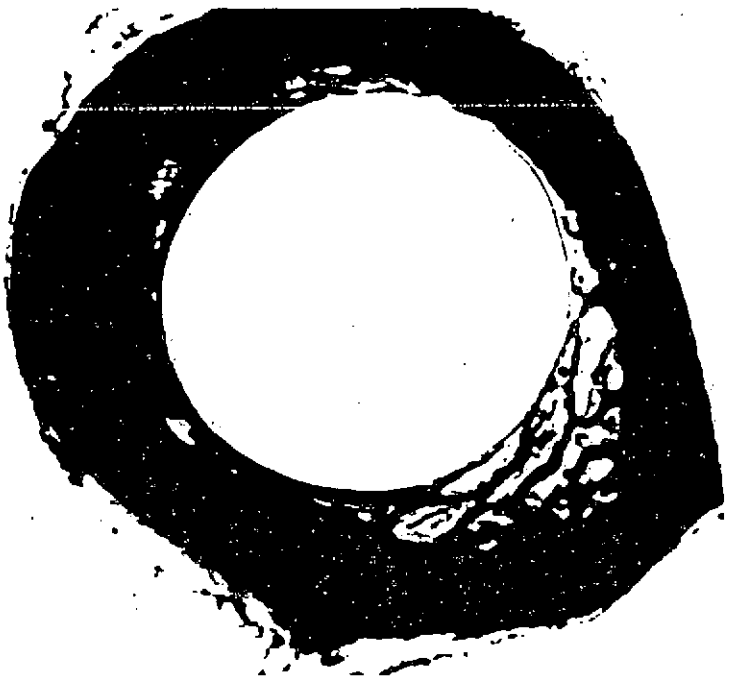
DJA x02097

81629 – EX02 AF FE LI 83 D

DJA x02098

81725 – CX03 BF FE LI 84 D

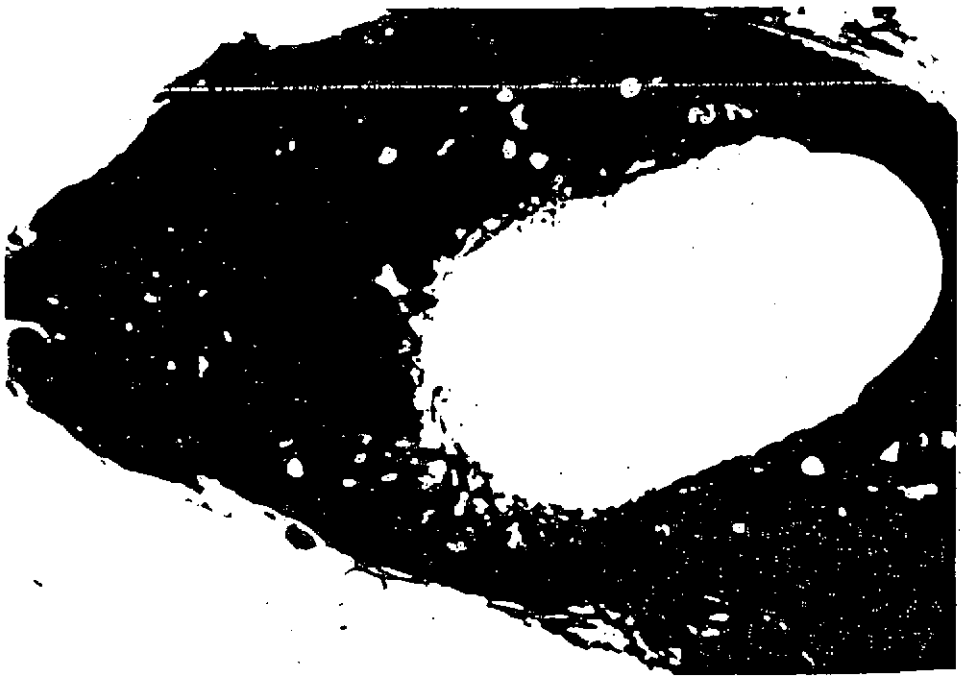
DJA x02099



81750 – EX01

BF FE LI 84 D

DJA x02100

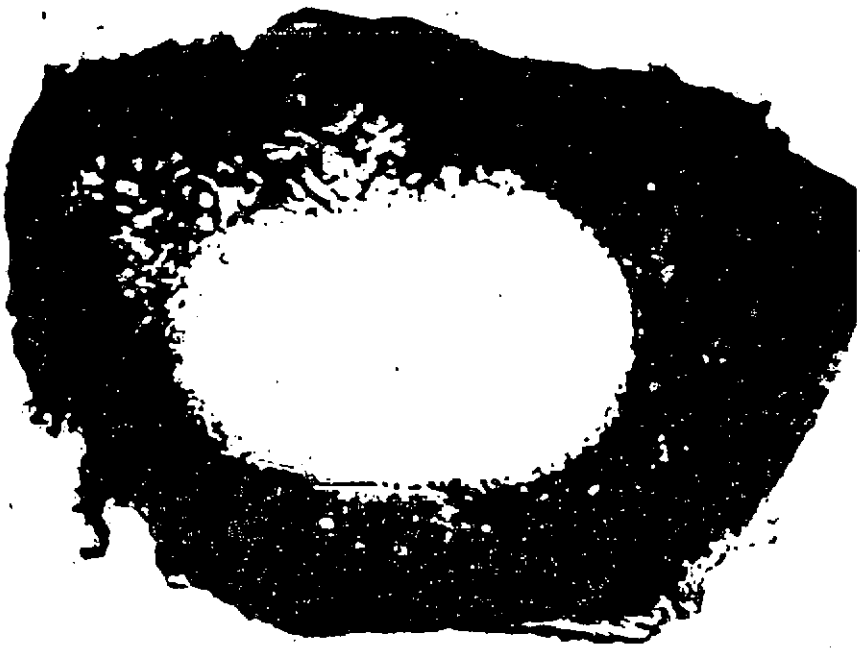


82177 – CX03 AG FE LI 85 D

DJA x02101

82179 – EX01 AG FE LI 85 D

DJA x02102



80991 - CX04 BG FE LI 81 D

DJA x02103

82134 - EX03 BG FE LI 81 D

DJA x02104

82159 – CX09 AH FE LI 362 D

DJA x02105

82165 – FX01 AH FE LI 362 D

Volume IV: 000074

DJA x02106

82168 – CX02 BH FE LI 355 D

DJA x02107

82170 – FXO3 BH FE LI 355 D

DJA x02108

82114 – CX02 AI FE RE 363 D

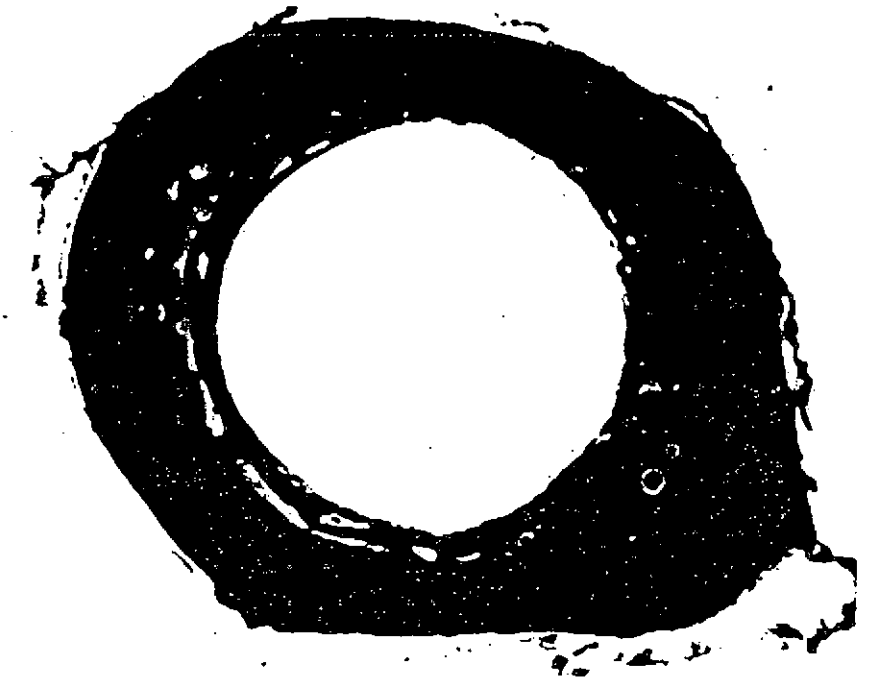
DJA x02109

82117 – CX02 AI FE RE 363 D

DJA x02110

82208 – CX05 BI FE RE 355 D

DJA x02111



82215 – EX02 BI FE RE 355 D

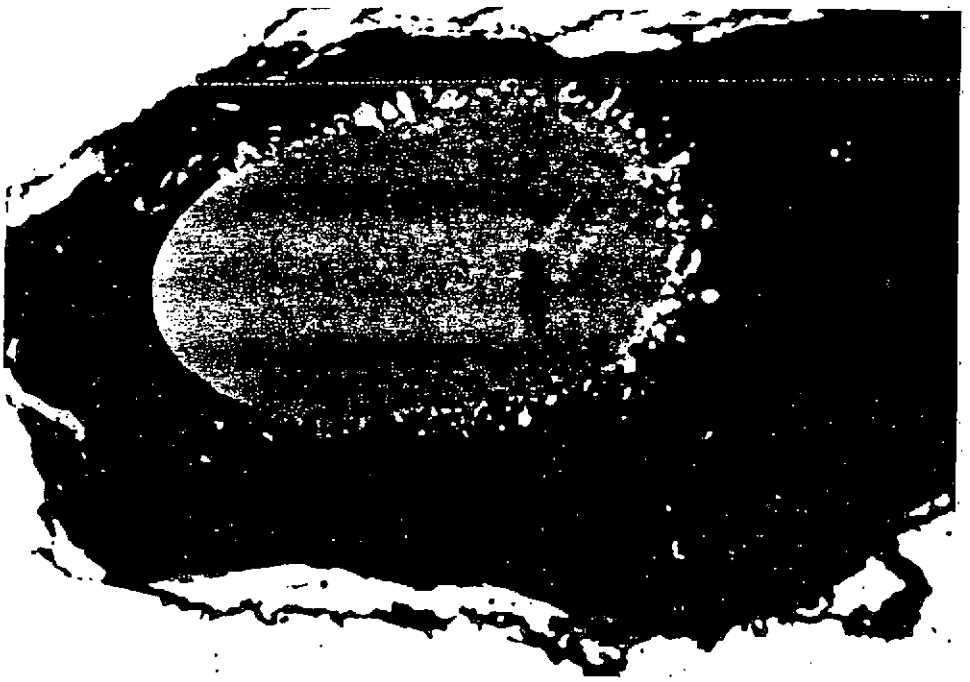
DJA x02112

82203 – CX03 AK FE RE 363 D

DJA x02113

82205 – EX02 AK FE RE 363 D

DJA x02114



82192 – CX03

BK FE RE 355 D

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DJA x02115

82200 – EX02

BK FE RE 355 D

DJA x02116

Attachment 2

The Fit of Cementless Stems in the Femur: Robot versus Surgeon; Institute of Orthopedic Research and Education, 6565 Fannin, Suite F115, Houston TX

DJA x02117

INSTITUTE OF ORTHOPEDIC RESEARCH AND EDUCATION

THE FIT OF CEMENTLESS STEMS IN THE FEMUR: ROBOT VS SURGEON

6565 FANNIN
SUITE F115
HOUSTON TX 77030
713-790-4273

Volume IV - 000086

DJA x02118

THE FIT OF CEMENTLESS STEMS IN THE FEMUR: ROBOT VS SURGEON

INTRODUCTION

One of the factors influencing the clinical success of cementless hip replacement is the fit of the implant in the femur. Previous studies have shown that conventional hand broaching causes large gaps between the implant and bone thereby decreasing the ability of the implant to achieve a "press-fit". Lack of a good fit in critical areas of the implant/bone interface increases relative motion between the implant and the bone during weight bearing. This is thought to increase the incidence of aseptic loosening and bone loss secondary to osteolysis.

This observation has led to the development of new methods to prepare the femur for cementless fixation, including robotic machining. This study was performed to measure the accuracy of a surgical robot in preparing the femur for implantation of a cementless femoral prosthesis in comparison with conventional manual broaching.

MATERIALS AND METHODS

Ten fresh cadaveric femora (5 pairs) were prepared for implantation of a standard straight-stemmed cementless femoral prosthesis (Osteolock, Howmedica Inc.). Based on random selection, one femur from each pair was prepared manually, while a surgical robot prepared the other. Pre-operative planning and broaching for the manually prepared cases was performed according to the guidelines specified by the implant manufacturer (Osteolock, Howmedica NJ). The robotic machining path was determined and executed according to a pre-operative plan developed through 3D computer-assisted templating (ROBODOC® and ORTHODOC®, ISS Inc). Both plans were implemented by a surgeon with extensive experience using both methods.

Following preparation, each bone was stained with Toluene Blue (0.9%) and allowed to dry for 24 hours. The femora were then implanted with an accurate replica of the corresponding femoral prosthesis. To ease analysis, the ABS replicas were manufactured with a 0.25" square hole centered over the longitudinal axis of the implant. Low viscosity cement (Surgical Simplex) was used to secure the replicas to the bones during sectioning. Once the acrylic cement had polymerized, each femur was embedded in a block of rigid polyurethane foam. A system of precision markers was aligned with the prosthetic replica and attached to the foam block to allow the level of subsequent sections to be accurately determined. Each block was cut into approximately 15 sections of 4-5 mm in thickness, extending distally from the proximal surface of the femoral stem. All sections were ground and polished for later analysis.

DJA x02119

To allow measurement of the width of gaps present between the irregular cancellous surface and the implant, each slice was photographed using a digital camera (Kodak DCS 420). On the image of each section, coordinates defining the surface of the implant and the tips of the bony trabeculae were recorded at regular intervals around the circumference of the prosthetic replica. Each surface was described in polar coordinates using the longitudinal axis of the replica as the origin. The 0° angular position was defined as the line joining the implant axis and the apex of the medial edge of the implant. Positive angles were measured from the 0° position anteriorly.

Using customized software (PvWave, Visual Numerics), the coordinates of the implant replica and the trabeculae were used to generate spline curves approximating the implant and bony boundaries. Using these curves, distances between the bone and implant surfaces (gaps) on each of the slices were calculated at 1° circumferential increments. The gaps calculated on the individual slices were then used to develop a surface map of gaps for the entire implant. At locations between sections, gap widths were estimated at increments of 1°. circumferentially and 0.1 mm along the longitudinal axis using a bi-linear interpolation. To facilitate comparison of data derived from implants of different size (2-12 through 3x-15), the surface maps were normalized to the Osteolock 3x implant, using the implant lengths as the scaling factor.

The surface maps were trimmed to ensure that gap dimensionse were only calculated at points located on the surface of the prosthesis. To simplify further analysis, representative transverse sections were extracted from the surface maps at 5mm intervals (every 3.4% on the 3x implant) along the longitudinal axis. Each section was then divided into 8 zones located in the following partitions around the medullary axis: Medial (-22.5°-22.5°), Anterior-Medial (22.5°-67.5°), Anterior (67.5°-112.5°), Anterior-Lateral (112.5°- 157.5°), Lateral (157.5°- 202.5°), Posterior-Lateral (202.5°- 247.5°), Posterior (247.5°- 292.5°), and Posterior-Medial (292.5°- 337.5°). The average gap width within each of these sections was calculated using measurements that were extracted from the surface gap map in 1° increments, for a 40° arc around the center angle of each zone.

Gap distributions were extracted from the proximal 50% of the length of the implant and sorted into 5 bins: 0-0.2mm, 0.2-0.5mm, 0.5-1.0mm, 1.5-2.0mm, and 2.0-5.0mm. The proximal surface was further divided into two regions: from 0-20%, and from 20%-50% of the implant surface.

RESULTS

The width of the gaps surrounding the implant varied significantly between the preparation methods. The average gap width within the manually prepared cavities was 0.63±0.39mm (range: 0.11-1.43mm), compared to 0.42±0.21mm (range: 0.07-1.11mm) ($p<0.001$) for the robotically prepared cases (Table 1), an average difference of 50%.

The differences in gap width varied significantly with anatomic location within the femur. Over the most proximal 20% of the implant, where potential for cancellous ingrowth is greatest, the manually prepared gaps were 35% larger on average (manual: 0.31±0.19mm

DJA x02120

vs. robot 0.23±0.12mm, p=0.023). This size difference increased to 42% when comparing the average width of the largest gap produced by the preparation methods within each zone(0.81 vs 0.57mm, p=0.023).

This trend continued in the mid-stem region, defined as the zone extending from 20% to 50% of the length of the implant. In this area, the average gap width was 0.81±0.34mm in the manually prepared bones (range: 0.25–1.43mm) compared to 0.53±0.15mm in the robotic cases (range: 0.29–1.11mm), a difference of 53% (p<0.001). Both preparation methods produced wider gaps in the more distal sections (Figure 1 and Figure 2). The average gap width increased by 161% for the manually prepared cases and 130% for the robotically prepared femora between the proximal 20% of the implant and the mid stem region.

The differences between preparation methods also varied around the circumference of the implant. In the Anterior-Lateral, Lateral and Posterior Lateral zones, there was only a slight increase in gap width from the proximal surface to the mid-stem level (Figure 6 through Figure 8) between the robotic and manually prepared specimens. The greatest differences were seen in the Medial region where the width of the gaps in the manually prepared bones increased rapidly in the zone between 25% to 50% of the implant length (Figure 3). In the Anterior, Anterior Medial, Posterior, and Posterior Medial regions the robotic gaps were consistently smaller in the robotically prepared femora.

When the gap data are expressed in terms of the four quadrants of the implant (Medial (PM,M,AM), Anterior (AM, A, AL), Lateral (AL, L, PL) and Posterior (PL,P,PM)), the medial quadrant had the largest difference of 85% between the preparation methods (0.85±0.37mm vs. 0.46±0.20mm) (p<0.001). Conversely, in the Lateral quadrant, the difference in width between the robotic and manually created gaps was only 9% (p = 0.49)(Table 1, Figure 11).

Preparation method also had a significant effect the area of the surface of the implant that was close enough to support bony ingrowth. In the robotically prepared bones, the separation of the implant and the bony cavity was less than 0.5mm over 69% of its surface, compared to 50% for the manually prepared bones (p=0.14). Gaps larger than 1mm, the upper bound for bony ingrowth, covered only 7% of the robotic specimens while the manually prepared bones had 23% coverage in the same range (p=0.005) (Figure 12).

The differences were even more significant when the proximal area was divided into two parts. In the top 20% of the implant surface, the trabeculae were within 0.5 mm over 92% of the surface for the robot compared to 81% for the manually prepared bones (p=0.216)(Table 2). In the mid-stem region, 57% of the robot implant surface was within 0.5mm of the bone compared to 36% for the manual bones (p=0.073). Perhaps more importantly, gaps larger than 1 mm were found over only 10% of the mid-stem region in the robotic bones while in the manual bones these gaps were found over 31% of the surface (p=0.025) (Table 2).

DJA x02121

CONCLUSIONS

1. This experiment demonstrates that conventional broaching is a relatively inaccurate method of machining the femur. This method generated gaps larger than 1mm over 23% of the surface compared to 7% for robotic preparation.

2. Use of a surgical robot led to a 34% reduction in gap width, and a 19% increase in the area of the implant surface located within 0.5mm of the bony cavity.

3. Even with implants designed with an proximal interference fit, the robotic cases had 15% more surface area in close proximity (<0.2mm) to the bony surface.

4. Due to the enhanced fit of the prosthesis, robotic preparation of the implantation site is expected to lead to reduced micromotion and increased bony ingrowth into cementless femoral prostheses.

DJA x02122

Implant from Proximal	Surgeon Gaps [mm]			Robot Gaps [mm]			% Increase	p
	Avg ± SD	Min	Max	Avg ± SD	Min	Max		
0%-50%	0.63 ± 0.39	0.11	1.43	0.42 ± 0.21	0.07	1.11	50%	<0.001
0%-20%	0.31 ± 0.19	0.11	0.81	0.23 ± 0.12	0.07	0.57	35%	0.023
20%-50%	0.81 ± 0.34	0.25	1.43	0.53 ± 0.15	0.29	1.11	53%	<0.001
Location	**Avg ± SD**	**Min**	**Max**	**Avg ± SD**	**Min**	**Max**		
Medial	0.85 ± 0.37	0.15	1.43	0.46 ± 0.20	0.07	1.11	85%	<0.001
Anterior	0.63 ± 0.39	0.11	1.42	0.42 ± 0.27	0.07	1.11	50%	0.007
Lateral	0.38 ± 0.23	0.11	0.85	0.35 ± 0.16	0.07	0.65	9%	0.488
Posterior	0.66 ± 0.38	0.11	1.38	0.39 ± 0.15	0.09	0.65	69%	<0.001

Table 1 Gap Averages.

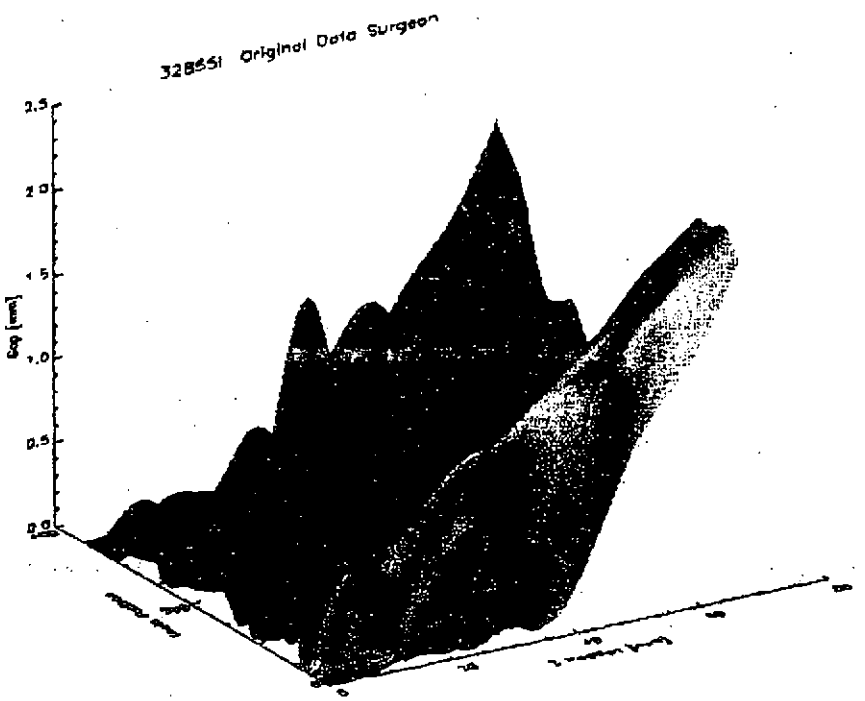

Figure 1 Sample Surface Map of Gaps: Surgeon .

DJA x02123

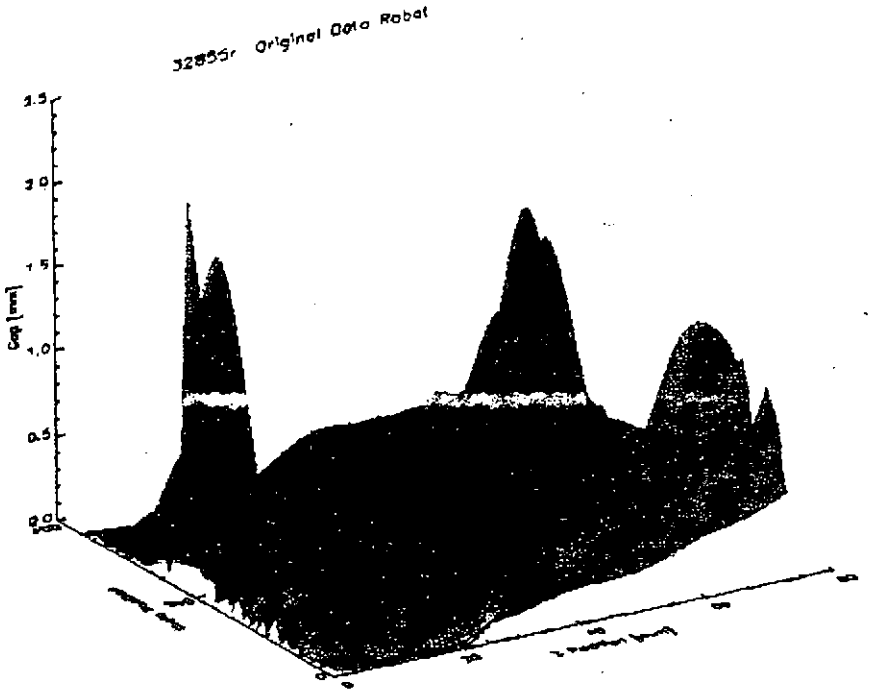

Figure 2 Sample Surface Map of Gaps: Robot.

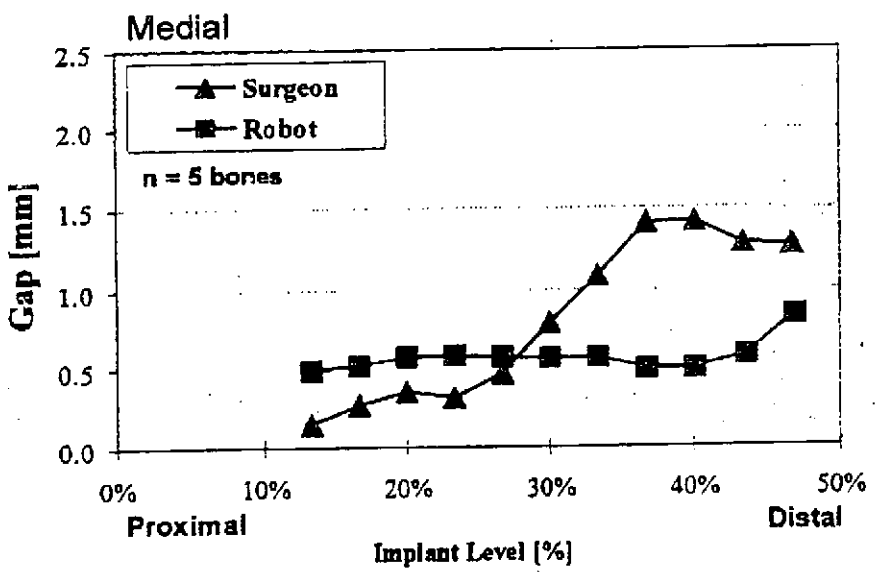

Figure 3 Average Gaps in the Medial Area.

DJA x02124

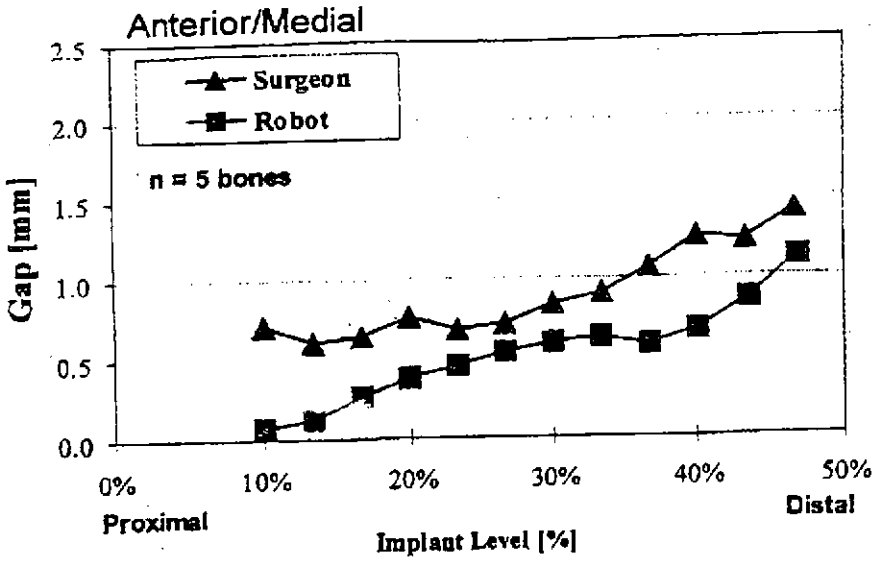

Figure 4 Average Gaps in the Anterior Medial Area.

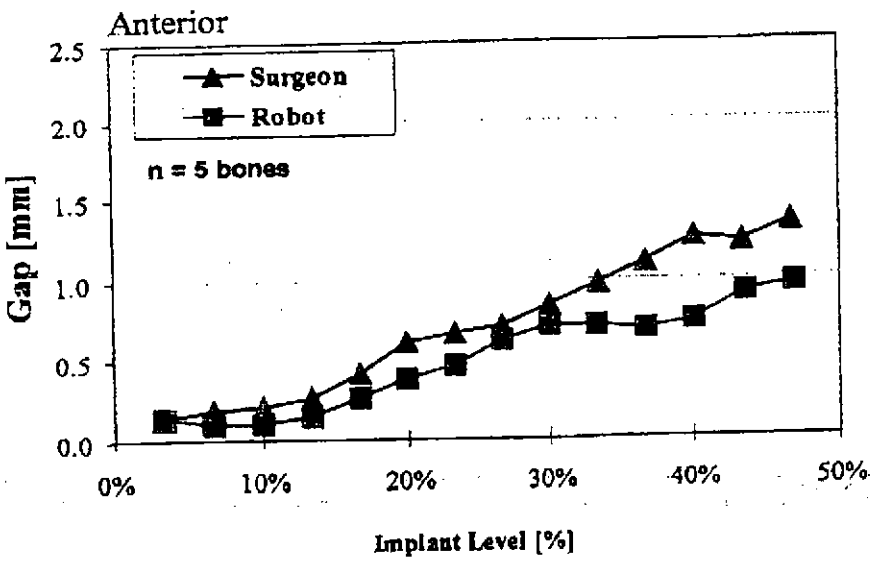

Figure 5 Average Gaps in the Anterior Area.

DJA x02125

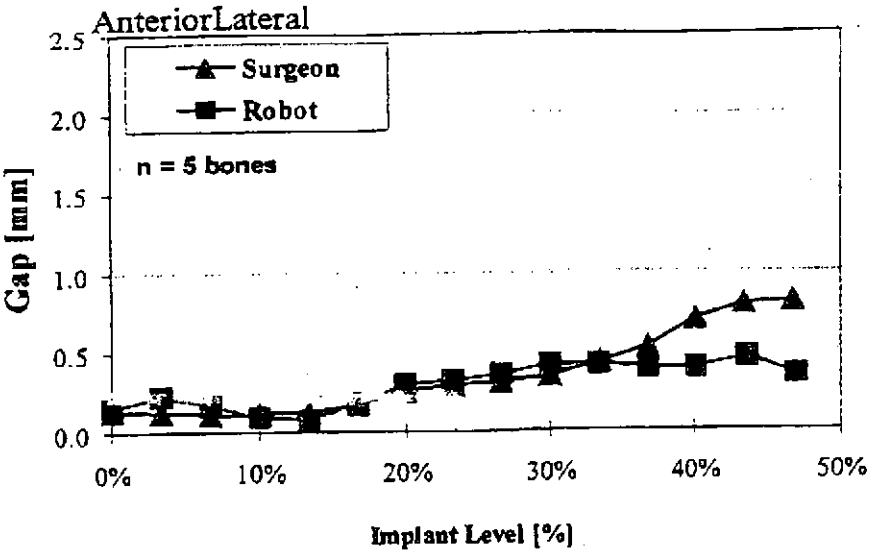

Figure 6 Average GAps in the Anterior Lateral Area.

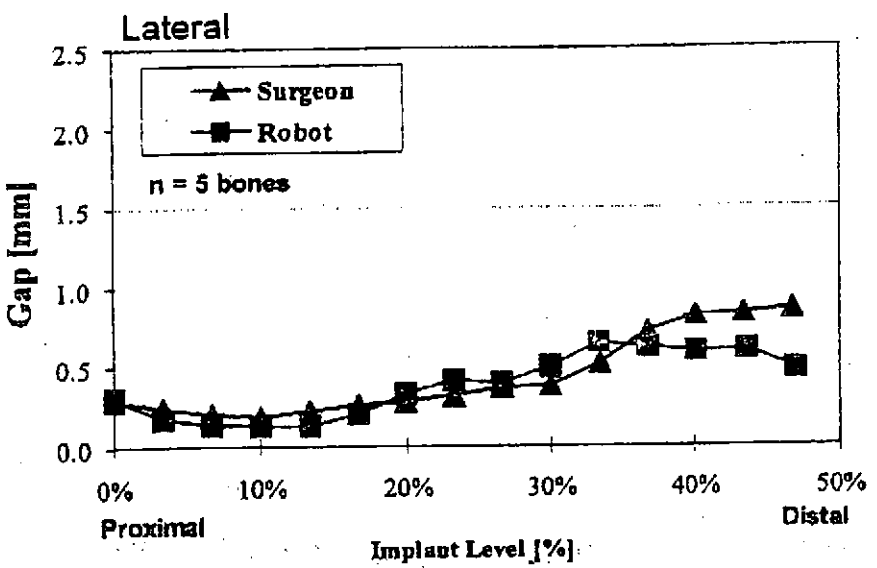

Figure 7 Average Gaps in the Lateral Area.

DJA x02126

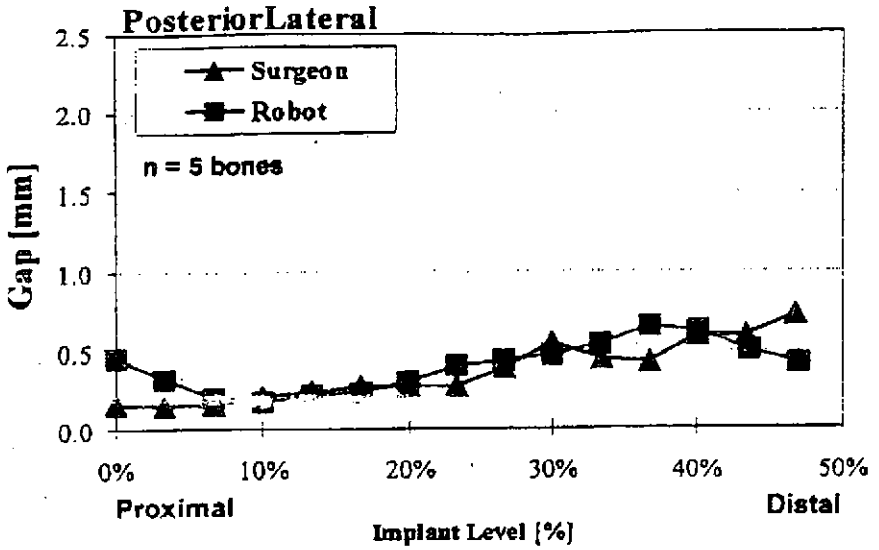

Figure 8Average Gaps in the Posterior Lateral Area.

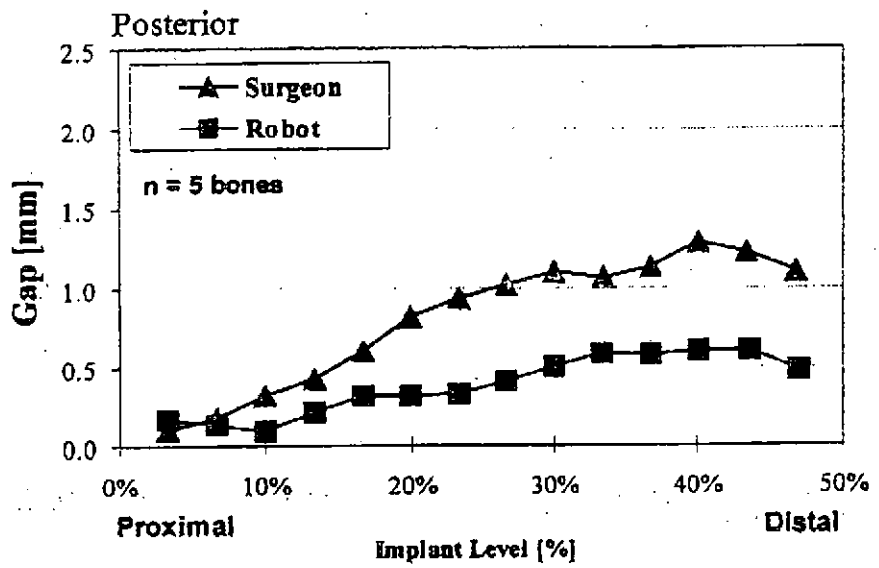

Figure 9Average Gaps in the Posterior Area.

DJA x02127

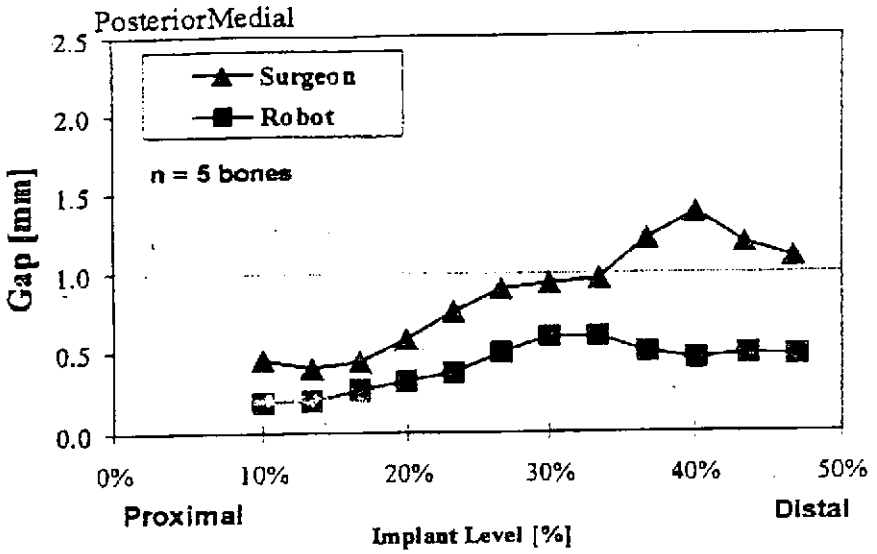

Figure 10 Average Gaps in the Posterior Medial Area.

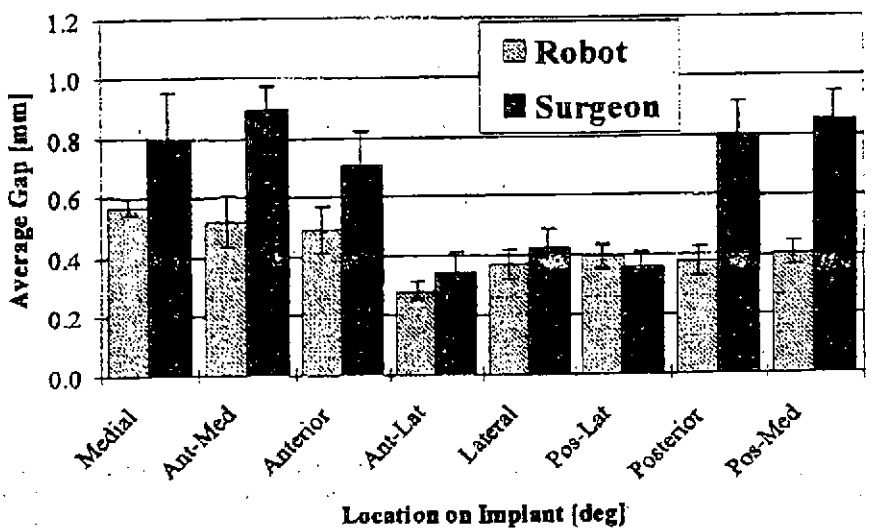

Figure 11 Average Gaps vs Position on Proximal Half.

DJA x02128

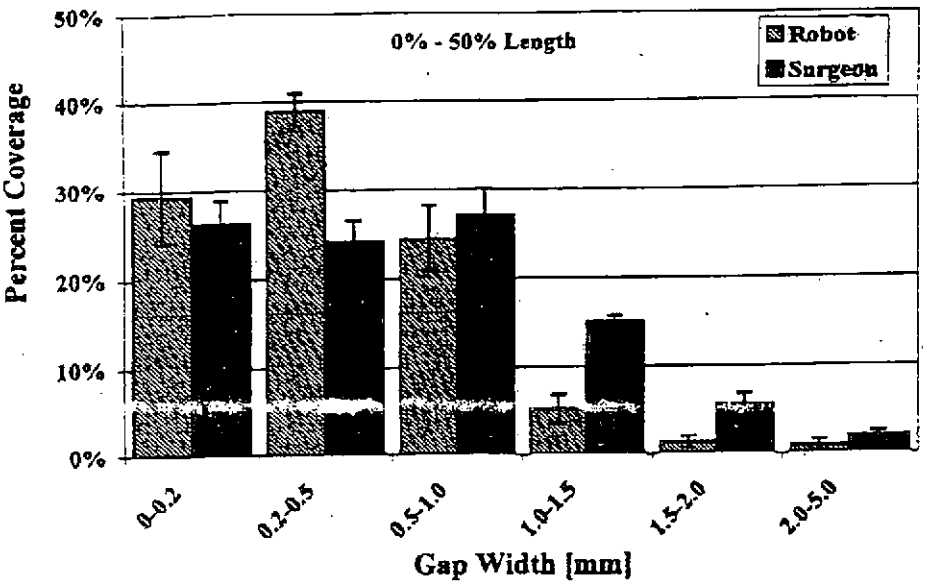

Figure 12 Distribution of Gaps for the Proximal Surface.

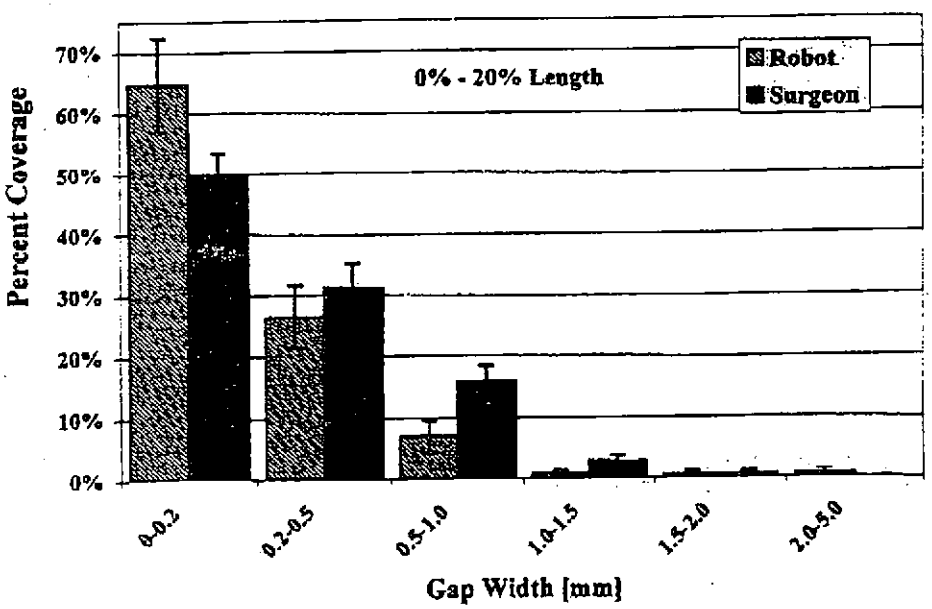

Figure 13 Distribution of Gaps for the 0%-20% of the Proximal Surface

DJA x02129

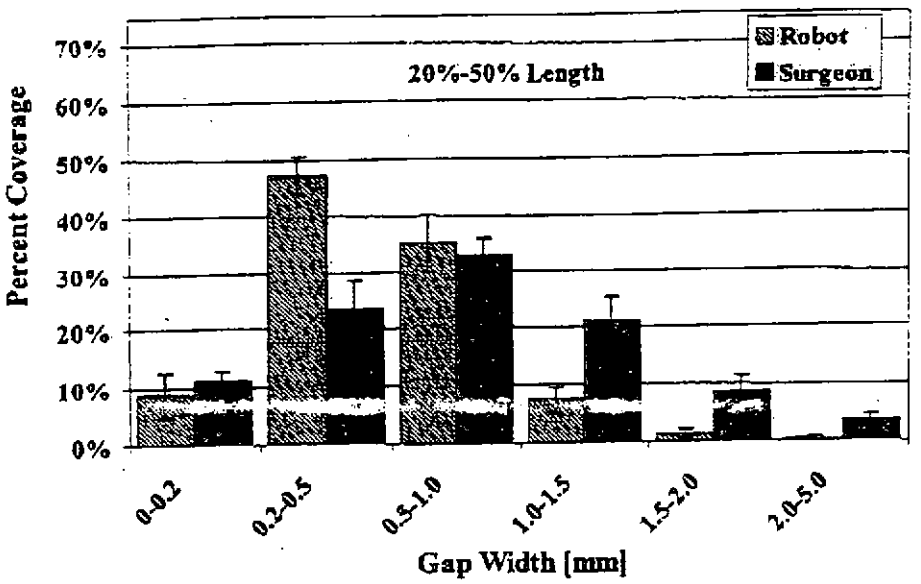

Figure 14 Distribution of Gaps for the 20%-50% of the Proximal Surface.

Gap Range [mm]	0-50% Surface		0-20% Surface		20%-50% Surface	
	Surgeon	*Robot*	*Surgeon*	*Robot*	*Surgeon*	*Robot*
0-0.2	26.4%	29.6%	50.0%	64.8%	11.5%	9.1%
0.2-0.5	24.0%	39.1%	31.0%	26.7%	24.7%	47.8%
0.5-1.0	27.0%	24.4%	15.8%	6.7%	33.3%	33.6%
1.0-1.5	15.1%	4.9%	2.6%	0.7%	19.4%	7.5%
1.5-2.0	5.7%	1.1%	0.6%	0.5%	8.1%	1.6%
2.0-5.0	1.9%	0.8%	0.0%	0.6%	3.0%	0.4%

Table 2 Coverage of Impplant Surface.

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Section 20 – Performance Testing – Clinical

FDA has agreed that efficacy of the ROBODOC® Surgical System (pin-based registration system) has been demonstrated in the First U.S. Clinical Trial. FDA has requested that equivalence between the pin-based and pinless ROBODOC® systems be demonstrated to show that there has been no degradation in technological characteristics or clinical outcome.

Section 18 of this premarket notification discusses the bench (*in vitro*) testing performed to demonstrate equivalence between the system technologies. Section 20 will present clinical trial results and validation studies that will address FDA comments regarding clinical safety and efficacy. This section provides the following information:

20.1 Background and Overview

20.2 First Clinical Trial (IDE #G920035): "3-pin" ROBODOC® Technology

20.3 Summary: BGU Clinical Evaluation of ROBODOC Surgical System

20.4 SUMMARY - Published Japanese Study: Evaluation of "2-pin" ROBODOC® Technology

20.5 Summary: TR98-07-011, Validation of "Pinless" ROBODOC® Technology at BGU

20.6 Second Clinical Trial (IDE # G000071): DigiMatch™ ROBODOC® Technology

20.7 Comparison of Clinical Outcomes using 3-Pin, 2-Pin and Pinless Registration Technologies

20.8 Mitigation of Pin-Based Risk Factors with Pinless DigiMatch™ Technology

20.9 Conclusions

20.1 Background and Overview

The ROBODOC® Surgical System is a CE Marked pre-operative planning workstation and stereotaxic (robotic) surgical instrument intended for qualified patients undergoing primary Total Hip Arthroplasty (THA) procedures. It was developed as an alternative to the conventional manual tools to accurately and reliably implement a preoperative plan developed by the surgeon on the FDA 510(k) cleared ORTHODOC® Pre-Surgical Planning Workstation (K960685). The device enables precise milling of a femoral cavity in the location specified in the pre-operative plan by the surgeon, thereby enabling optimal execution of the restorative surgical procedure.

Integrated Surgical Systems (ISS) conducted its First randomized Clinical Trial in the U.S. under IDE # G920035 using the "1st Generation" of the ROBODOC® Surgical System. The 1st generation system was based on 3 locator (fiducial) pin registration. Safety and efficacy data were gathered and analyzed on 119 patients (136 hips). Section 20.2 provides a summary of the First IDE Trial. The information contained therein is based on the Final Report for IDE G920035, which was submitted to FDA in October 2000. This information was also provided to FDA in the March 15, 2007 submission.

The data from the First U.S. Clinical Trial demonstrated to FDA that the ROBODOC® System was effective and showed superiority for some parameters over the conventional surgical procedure. During a January 18, 2007, meeting FDA stated that it was their position that the First Clinical Trial adequately documented the efficacy of the ROBODOC® System. However, based on the Final Report for IDE # G920035 submitted on October 20, 2000, FDA identified four risk factors associated with the use of the 1st generation device and suggested that ISS conduct a Second Clinical Trial to demonstrate that these risk factors have been eliminated or mitigated.

Following FDA's recommendation, ISS began a Second, randomized Clinical Trial (IDE # G000071) in 2000 with the "3rd Generation" of the Device. The 3rd generation system is based on the "pinless" registration (DigiMatch™) technology for the same patient population. The focus of this trial was to demonstrate that the four identified potential risk factors had been eliminated or mitigated. Efficacy of the DigiMatch™ ROBODOC® System was measured using endpoints similar to those used in the First Clinical Trial. Section 20.5 provides a summary of the Second IDE Trial. Since FDA agreed that a formal statistical analysis was not required, data obtained in this trial was compared with the data from the First Clinical Trial. Section 20.7 contains a discussion that demonstrates the comparable clinical outcomes between the ROBODOC® Surgical System registration technologies.

At the beginning of the Second Clinical Trial, FDA had not yet revised its classification of this device, so the protocol was designed to support a PMA submission. The sample size for the trial was established based on the statistical requirements to document efficacy for a PMA submission. Subsequently, FDA determined that the ROBODOC® System would be a 510(k) device and FDA agreed with ISS that the focus of the Second Clinical Trial would be to demonstrate that the potential risks factors identified in the First Clinical Trial have been eliminated or mitigated.

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Two separate studies, one performed by a group of Japanese investigators and the second performed by German investigators, were used as validation of the 2-pin and pinless systems respectively.

A report of the two IDE clinical trials and two validation studies is provided in the following subsections.

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20.2 First U.S. Clinical Trial (IDE #G920035): "3-pin" ROBODOC® Technology

Information presented in this section is based on the Final Report for IDE G920035, which was submitted to FDA in October 2000. This information was also provided to FDA in the March 15, 2007 submission.

20.2.1 Summary of Protocol

This multi-center clinical trial began in 1993 and ended in February 1996. It was performed with the 1st generation ROBODOC® Surgical System, which used 3 locator (fiduciary) pins. The 3 pins were placed in the patient's operative hip and knee during a separate surgery prior to the total hip arthroplasty (THA) surgery for spatial registration of the robot to the patient for subsequent bone cavity milling.

20.2.1.1 Objectives

The objectives of this clinical trial were to demonstrate that the ROBODOC® System safely and effectively performs its intended use as an alternative to conventional manual surgical broaching techniques for femoral canal preparation in patients receiving cementless prostheses for primary THA. Occurrence of adverse events, measurements of radiographic parameters (i.e., fit, fill, position, precision and consistency) and clinical outcomes data were to be evaluated in all enrolled subjects to demonstrate clinical efficacy and safety of the surgical robot.

20.2.1.2 Study Design

This study was a randomized, controlled trial conducted at three U.S. medical centers: Sutter General Hospital (Sacramento, CA), New England Baptist Hospital (Boston, MA), and Shadyside Hospital (Pittsburgh, PA). The trial consisted of 119 patients (136 hips) randomly assigned to either the ROBODOC® study group (n=71) or the manual broaching control group (n=65) for femoral canal preparation. Subjects were monitored for two years following surgery.

20.2.1.3 Patient Selection

Candidates for primary THA were screened for eligibility with specific inclusion and exclusion criteria. During patient screening, the investigators evaluated the patients' interest and ability to participate in the study; the nature of their hip injuries; pathologies; previous surgical interventions; their current health status; and the type of femoral prostheses required. All subjects selected were candidates for primary, cementless THA. Patients were randomly assigned to either the ROBODOC® test group or manual broaching control group. The randomization assignment was disclosed after a patient was deemed eligible as a subject and gave informed consent.

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Table 1: Overview of Patients (Units in Hips) Entered in Study

	ROBODOC® Group				Control Group				Total Hips			
Clinical Site	01	02	03	**Total**	01	02	03	Total	01	02	03	**Total**
Enrolled	21	40	10	**71**	20	36	9	65	41	76	19	**136**

Site Name: 01 = Sutter Hospital / 02 = New England Baptist Hospital / 03 = Shadyside Hospital
(There were 119 patients. However, some patients had bilateral procedures for a total 136 procedures.)

20.2.1.4 Data Collection

All patients underwent a baseline medical and physical examination that included a complete medical and orthopedic history; a complete physical examination, including adjunct laboratory tests; a functional evaluation based on the Harris Hip score, Hip Society evaluations (Johnson) and SF-36 scoring systems; and a review of historical x-rays of the affected femur, based on availability. Clinical data were collected at baseline, intra-operatively, postoperatively, at hospital discharge, and at 3, 6, 12, and 24 months. Baseline, intra-operative, 3-month, 1-year and 2-year radiographs underwent a "blinded," independent review by a qualified skeletal radiologist, who evaluated a series of radiographic measurements for each study subject.

20.2.1.5 Safety and Effectiveness Endpoints

The safety endpoints included the rate of intra-operative fractures, intra-operative and postoperative complications, and adverse events. The primary endpoints intended to demonstrate system effectiveness were fit, fill, and alignment of the femoral stem implant. These parameters were chosen as the best practical means of assessing the consistency and accuracy of femoral stem canal preparation. These endpoints were evaluated by radiographic assessment. Other radiographic assessments included parameters that are widely recognized as indicators of a good clinical outcome for a cementless THA implant, including incidence and location of radiolucent lines, bone ingrowth, sclerotic lines, osteolysis, subsidence, hypertrophy, and stress shielding. This also included functionality and pain as measured by Harris Hip score, Hip Society evaluations (Johnson) and the SF-36 scores for quality of life measures, which provide a measure of the clinical outcome.

20.2.2 Safety Results

Although there were four potential surgical risks identified with the use of the ROBODOC® System in the First Clinical Trial, the study demonstrated that the investigational device was generally safe for its intended use. There were no serious ROBODOC® related complications. While there were no intra-operative fractures in the study group, there were 3 intra-operative fractures reported in the control group. The four potential surgical risks associated with the ROBODOC procedure included:

1. Need to perform a separate preoperative procedure to implant the locator pins for registration of the affected femur;
2. Longer surgical time;
3. Increased intraoperative blood loss; and

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4. Post-surgical ipsilateral knee pain.

NOTE: There were no significant adverse events or sequelae attributed to the identified risks.

The safety results, including these potential risks, are discussed in the following subsections.

20.2.2.1 Locator Pin Implantation

Patients in the ROBODOC® group were required to undergo a preoperative procedure to implant the locator pins for registration of the affected femur. This procedure was usually performed under local anesthesia in an outpatient surgical setting within 24 hours of the THA. There were no reported adverse events attributed to this additional procedure. To address this issue, ISS is developing a "pinless" registration technology that will eliminate this potential risk.

20.2.2.2 Longer Surgical Time and Increased Estimated Blood Loss

Data collected on the clinical systems showed mean length of primary THA surgery to be 258 minutes for the ROBODOC® group and 134 minutes for the manually broached group, as shown in Table 2. The increased surgical time associated with the ROBODOC® can be primarily attributed to lack of adequate training of the surgeons, inadequate emphasis on controlling the surgical time and the "intrigue" with the innovative robotic technology. However, there were no complications or adverse events associated with the increased surgical time in this Clinical Trial.

The data show a direct correlation between surgical time and blood loss. The mean estimated rate of blood loss for ROBODOC® was 4.5 ml/min (1189.4 ml total) compared to 4.8 ml/min (644 ml total) for the control group which indicates that the rate of blood loss is similar for both methods. The greater amount of total estimated blood loss in the ROBODOC group is directly related to the longer surgical time. There were no complications or adverse events associated with blood loss in this Clinical Trial.

Table 2: Peri- and Post-Operative Findings

	ROBODOC® N=71 hips		**Control N=65 hips**	
	Mean	STD	Mean	STD
Estimated Blood Loss During Operation (ml/min)	4.5	1.92	4.8	2.1
Estimated Blood Loss During Operation (ml)	1189.4	581.1	644	316.5
Length of Surgery (min.)	258	54.5	134	27.1

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20.2.2.3 Postoperative Ipsilateral Knee Pain

Ipsilateral knee pain has been reported for patients requiring THA. Some knee pain reported in this Clinical Trial may also be associated with pin implantation. The following Table 3 shows the incidence of ipsilateral knee pain.

Table 3: Ipsilateral Knee Pain

	6 wks.	3 mos.	6 mos.	12 mos.	24 mos.
ROBODOC®	40 (57%)	31 (46%)	16 (28%)	14 (28%)	15 (22%)
Control Group	7 (12%)	14 (22%)	11 (20%)	9 (16%)	10 (17%)
Difference	33 (45%)	17 (24%)	5 (8%)	5 (12%)	5 (5%)

20.2.2.4 Complications and Adverse Events

Intra-operative and postoperative complications and adverse events were reported and are summarized in the following table:

Table 4: Surgery-Related Events Resulting in Complications and Adverse Effects

Complication	ROBODOC®	Control Group
Intra-operative fractures	0 (0%)	3 (5%)
Postoperative hip dislocation	3 (4%)	5 (10%)
Infection	2 (3%)	1 (2%)
Deep vein thrombosis (DVT)	1 (2%)	1 (2%)
Pulmonary embolism	0 (0%)	1 (2%)
Over-reaming*	1 (1%)	0 (0%)
Detachment of implant coating†	1 (1%)	0 (0%)

* In the case where over-reaming was reported, the medical monitor's investigation suggests that the surgeon's plan may have called for an implant that was too large for a small canal. The plan instructed the robot to remove more cortical bone than was desirable, but there was no device malfunction..

†*Not device related as failure of implant coating was not caused by or due to the ROBODOC® device*

A variety of other common surgical complications occurred in both groups: nausea/vomiting; irregular heartbeat/afibrile; painful urination and inability to void; urethral stricture; fever; atelectasis; cellulitis; hematoma; numbness in various parts of the body; T-wave inversion; sciatic nerve palsy; muscle spasm, and hyperesthesia. None of the above complications were considered ROBODOC® related. Two patients (one in the ROBODOC® group and one in the control group) died during the follow-up period. Both deaths were due to cardiac problems unrelated to their surgeries.

Two of the ROBODOC® surgeries were completed manually because of device malfunctions: a tool cone/pin extender error occurred in one case and a pin-finding problem occurred in the other case. Since the current system does not use pins, these malfunctions are now irrelevant. Several other minor device malfunctions occurred, but the surgeries were not aborted. These problems included: 1) the proximal locator pin required re-insertion preoperatively; 2) the proximal pin was relocated; 3) vein laceration occurred during "halo pin" installation; 4) the proximal pin stripped out of the bone; 5)

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the pin driver became stuck in the locator pin head and had to be forcefully separated; 6) computer problems occurred during pin finding; 7) the robot required recalibration during surgery; and 8) a possible step off near the stem tip was observed in postoperative x-rays. The two-year follow-up data showed that there was no statistical difference in operative complications or outcome parameters between the study and the control groups.

20.2.3 Effectiveness Results

The effectiveness of the ROBODOC® system was measured using the endpoints outlined in Section 20.2.1.4-5.

20.2.3.1 Radiographic Review

Qualitative radiographic assessments (primarily to detect radiolucencies) and non-radiographic clinical data (Harris Hip scores, Hip Society evaluations, and SF-36 quality of life scores) were collected at 3, 6, 12, and 24 months.

Quantitative radiographic assessment revealed significantly better fit and fill for the ROBODOC® group (see Table 5). The ROBODOC® group prostheses were seated significantly closer to the proximal femoral neck osteotomy than prostheses for the control group. The ROBODOC® group also had better alignment (varus-valgus, anterior-posterior). No difference was detected between the two groups in the location (centering) of the distal prosthesis tip. Quantitatively, there was significantly less radiolucency for the ROBODOC® group in five of the Gruen Zones. The quantitative and qualitative assessments were performed by an independent radiologist. The results of the independent radiological review were reported to FDA in 1998. A copy of the paper that was presented, *Report of Radiographic Data from IDE Trial G920035* by Douglas Robertson, M.D., Ph.D., is provided in **Attachment 1**.

The proximal-medial fit score described the fit of the proximal medial aspect of the prosthesis to the proximal medial (endosteal) cortex. Fit in this region is considered important for initial implant stability and subsequent bone remodeling. The proximal medial cortex was defined as the medial (endosteal) cortex extending from the midpoint of the lesser trochanter up to the medial portion of the femoral neck osteotomy. Scores were assigned ranging from 1 to 5, where 5 denoted 50% or greater prosthesis-cortex contact, 4 denoted 25-49% contact, 3 denoted less than 25% but greater than 2 point contact, 2 denoted parallel stem and cortex edges with one point contact or no cortical contact and 1 denoted non-parallel edges with no cortical contact. A prosthesis-cortex distance of less than 1 mm was defined as contact.

This Clinical Trial demonstrated that the ROBODOC® Surgical System provides a significant improvement in implant fit, fill and position in the femoral canal. This improvement is clinically relevant because it helps surgeons achieve better fit and position, more reliably and consistently. Currently, surgeons strive to achieve these objectives with manual broaching techniques as well. Additionally, the data demonstrate that the robot can precisely and reliably implement the preoperative plan.

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Table 5: 3-Month Quantitative Radiographic Fit and Fill Data

	ROBODOC®	Control
N	64	65
AP Film Lateral Fit (mm)		
Level 1	13.75	16.79
Level 2	4.81	5.83
Level 3	2.28	3.09
Level 4	0.12	0.26
AP Film Medial Fit (mm)		
Level 1	1.14	3.06
Level 2	1.44	3.66
Level 3	1.48	2.68
Level 4	0.14	0.12
AP Film - Fill (%)		
Level 1	77.8	66.3
Level 2	82.9	73.1
Level 3	86.9	80.0
Level 4	98.5	97.9

20.2.3.2 Harris Hip Scores

The mean Harris Hip score at 3 months averaged 79.9 for the ROBODOC® group and 80.3 for the control group. At 6 and 12 months the average score was 85.3 and 89.4 for the ROBODOC® group and 85.5 and 86.5 for the control group. The average improvement from baseline at 6 and 12 months was 35.5 and 39.1 for the ROBODOC® group and 33.6 and 34.8 for the control group. Similar improvements from baseline at 2 years were observed in both groups. The ROBODOC® group had slightly better overall improvement than was seen in the control group; however, none of these differences are statistically significant (see Tables 6A and 6B).

Table 6A: Harris Hip Scores

HARRIS HIP TOTAL SCORE SUMMARY STATISTICS						
	ROBODOC®			Control		
	N	Mean	STD	N	Mean	STD
Baseline	70	49.1	9.5	64	51.4	10.3
3 Month	67	79.9	9.7	64	80.3	13.1
6 Month	58	85.3	12.2	56	85.5	12.4
12 Month	60	89.4	10.6	56	86.5	12.2
24 Month	54	88.4	10.3	52	91.1	5.9

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Table 6B: Harris Hip Scores

HARRIS HIP TOTAL SCORE CHANGES FROM BASELINE						
	ROBODOC®			**Control**		
	N	Mean	STD	N	Mean	STD
3 Month	66	30.0	12.5	63	28.9	16.1
6 Month	57	35.5	13.0	55	33.6	13.6
12 Month	59	39.1	12.5	55	34.8	14.5
24 Month	53	38.9	11.6	52	38.6	12.2

20.2.3.3 Hip Society (Johnson) Hip Scores

Comparable results were demonstrated in the Hip Society Scores between the ROBODOC® and control group (see Table 7). The data show that 94% (44/47) of the ROBODOC® group and 88% (38/43) of the control group patients rated their pain index lower (as reported in the Mild to None Categories) than from the Severe and Moderate categories, at 12 months after the surgery. The ROBODOC® System shows slightly better results but there was no significant difference in the change in pain index at 12 months between the two groups.

Table 7: Hip Society (Johnson) Hip Scores

*HIP SOCIETY SUBJECTIVE RATINGS (PAIN DEGREE BY VISIT)**										
	ROBODOC®					**Control**				
	Baseline	3-m	6-m	12-m	24-m	Baseline	3-m	6-m	12-m	24-m
Severe	19	0	1	1	1	12	1	2	1	0
Moderate	37	2	4	2	6	36	3	1	4	2
Mild	1	26	12	13	11	2	13	13	13	11
None	0	25	27	31	24		32	26	25	28
N	57	53	44	47	42	50	49	42	43	41

20.2.3.4 SF-36 Quality of Life Scores

SF-36 data were collected at 3, 6, 12, and 24 months showing overall scores in both groups (see Table 8). While the ROBODOC® group showed slightly better results than the control group, there was no statistically significant difference detected. Most patients experienced significant overall improvement in SF-36 scores in both groups.

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Table 8: SF-36 Total Scores

*SF-36 Overall Scaled Score**										
	ROBODOC®					**Control**				
	Baseline N=57	3-m N=53	6-m N=45	12-m N=46	24-m N=41	Baseline N=50	3-m N=50	6-m N=41	12-m N=44	24-m N=41
Mean	54.7	65.7	72.8	78.6	78.1	51.1	68.2	76.1	76.3	76.7
Std	16.6	19.1	21.9	15.6	20.0	14.1	18.5	17.1	18.4	18.9

** Unit of observation is patient. Individual patients with both ROBODOC® & control hips are excluded.*

20.2.3.5 Reduction in Intra-operative Fracture Rate

Intra-operative fracture is a potential complication of THA surgery. The medical literature reports fracture rates ranging from 3% to 28%, but clinical outcome results are likely to be worse for low-volume surgeons. (Refs. 1-13). In the First Clinical Trial, the ROBODOC® group had a fracture rate of 0% (0/71), compared to 5% (3/65) for the manually broached group. This difference was not statistically significant.

20.2.4 Discussion

Results of the First U.S. Clinical Trial demonstrate that the ROBODOC® system accurately, precisely, reliably and consistently implements the preoperative surgical plan. The ROBODOC® group showed significantly better fit, fill and alignment of the femoral stem implant compared to the control group. Radiographic assessment showed significantly improved results for the ROBODOC® group compared to the control group. These assessments are widely recognized as indicators of a good clinical outcome for a cementless THA implant, including incidence and location of radiolucent lines, bone in-growth, sclerotic lines, osteolysis, subsidence, hypertrophy, and stress shielding. Achieving precise femoral canal preparation is clinically relevant because most surgeons strive for optimal fit and alignment as an objective of manual broaching.

Functionality and pain as measured by Harris Hip score, Hip Society evaluations, and SF-36 quality of life scores showed that there were no statistically significant differences between the ROBODOC® and control group. This also demonstrates that the ROBODOC® is not associated with long-term unanticipated adverse effects or sequelae.

20.2.5 Conclusions

1. Results of the First U.S. Clinical Trial demonstrate that the ROBODOC® System performed safely and effectively during its intended use.

2. There were no significant adverse events or sequelae reported; however, certain potential risks associated with the 1st generation ROBODOC® system were identified.

3. Clinical outcomes using the ROBODOC® technology compare favorably to manual broaching.

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Attachment 1

Report of Radiographic Data from IDE Trial G920035
by Douglas Robertson, M.D., Ph.D.

DJA x02143

Abstract

Purpose: Computer-aided surgery has the potential to improve conventional surgery results for total hip replacement. The data which is the subject of this radiographic review is derived from a three-center IDE study of the ROBODOC device. The radiographic evaluation tested the hypothesis that computed-aided surgery improved the 3 month radiographic results of total hip replacement, as compared to conventional surgery.

Methods: Radiographic review of AP films was performed by an independent musculoskeletal radiologist, specializing in joint arthroplasty. 1/ Radiographs from the control and ROBODOC groups were reviewed at 3 months for fit, fill, seating, alignment, tip placement, radiolucent lines, loose porous coating, and fracture. Radiographs at 12 months were reviewed for radiolucent lines. Statistical analyses were performed comparing the control and ROBODOC group results.

Results: The ROBODOC group had better fit and fill at the proximal prosthesis regions, fulfilling the prosthesis manufacturers' goal of proximal interlocking fit. As expected, no difference was detected at the distal prosthesis regions. Seating and alignment was significantly improved in the ROBODOC group. As anticipated, no difference was detected in distal prosthesis tip centering. One fracture was radiographically detected on the series of follow-up radiographs and this fracture belonged to the control group. The ROBODOC group had less radiolucent lines in the distal stem zones. In the remaining zones there was no difference between the two groups. The ROBODOC group had fewer patients with 5 or more zones with radiolucent lines (which is an indicator of possible loosening of the implant).

Conclusion: The ROBODOC group had significantly better results for fit, fill, seating, alignment, and radiolucent line occurrence compared to the control group and was not surpassed in any of the studied radiographic parameters by the control group. These radiographic results demonstrate that the robotic-aided surgery improved the results of conventional hip replacement.

1/ The review was performed by Douglas Robertson, M.D., Ph.D., Assistant Professor of Radiology, Washington University Medical Center; curriculum vitae is appended to this report.

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Independent Radiographic Review

An independent Radiographic Review was performed by a board certified, fellowship trained, full-time musculoskeletal radiologist specializing in adult reconstructive surgery. Analyses were made of patient anteroposterior (AP) pelvis and AP ipsilateral hip radiographs taken at 3 and 12 months. The readings were made blinded to patient name, surgeon, or preparation process (manual or ROBODOC).

Methods

3 Month Evaluation

Radiographs from 129 study patients were available for analysis. ISS Independent Quantitative Radiographic Review (Form 14) and ISS Independent Qualitative Radiographic Review (Form 15) were used. 2/

ISS Independent Quantitative Radiographic Review, Form 14

Fit was measured in millimeters at the lines (see below) as the gap between the prosthesis and the cortical bone (see Form 14, pp. 2 &3 of 5, II. A & III. A). In the region of the lesser trochanter, medial and posterior measurements at Level 2, a smooth curve connected the cortex proximal and distal to the lesser trochanter and the distance between the implant and the fitted curve was measured.

Fit lines (p. 2 of 5) for the AP radiographs were drawn as lines perpendicular to the femoral long axis. The femoral long axis was defined by the line connecting midpoints of the width of the femoral canal from the lesser trochanter to the femoral isthmus. The femoral axis line was extended proximally to the level of the proximal femoral osteotomy. Based on the manufacturers' specifications, the following fit criteria were created for the AML and Osteolock prostheses. Fit Level 1 was drawn at the medial neck cut. Level 2 was at the midpoint of the lesser trochanter. Level 3 was drawn 1.5 cm distal to Line 2. Level 4 was at the top of the Osteolock prosthesis distal sleeve, the distal end of the porous coating for an AML prosthesis, or 3.0 cm proximal to Level 5 for an Osteolock prosthesis without a distal sleeve. Level 5 was drawn just proximal to the bottom of the Osteolock prosthesis with a distal sleeve, 1.5 cm

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2/ Copies of ISS Forms 14 and 15 are appended to this report.

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proximal to the AML prosthesis tip, or 1.5 cm proximal to tip of the Osteolock prosthesis without a distal sleeve. Lines for the lateral radiographs (p. 3 of 5) were drawn at equivalent locations as the AP radiographs described above.

Axial seating (p. 2 & 3 of 5, II. B & III. B) of the prosthesis collar (AML) or medial prosthesis body-prosthesis neck junction (Osteolock) was measured in millimeters as the distance from these points to the most medial point of the proximal femoral neck osteotomy. This vertical distance was in parallel with the femoral long axis. Prosthesis alignment (p. 2 & 3 of 5, II. C & III. C) was defined by the angle formed by the intersection of the femoral axis line and the prosthesis long axis line. Varus and valgus as well as anterior and posterior orientation were noted.

Radiographic technique (p. 2 & 3 of 5, II. D & III. D, Comments) was evaluated as adequate (no "film rotation" noted, no comment written) or less than adequate (estimate of "film rotation" made, comment written).

Evidence of a neocortex (radiolucency) in the Gruen zones (p. 4 of 5, IV. E 1 & 2) was counted as positive if the radiolucent line between the neocortex and the prosthesis was greater or equal to 1mm in thickness and if it occupied 50% or more of a Gruen zone (according to criteria specified by American College of Orthopedic Surgeons). Comments were written detailing if the neocortex was divergent, *i.e.* not paralleling the prosthesis surface. Additional comments included noting the presence of bony "spot welds", bony "streaming", periosteal hypertrophy, osteolysis, and calcar rounding. None of the findings described in this paragraph were present on the 3 month radiographs.

Distal tip displacement and direction (p. 4 of 5, IV. E & F) was measured according to Figure 5 (p. 4). The presence of loose porous coating (p. 4 of 5, IV. G) was also noted.

Independent Qualitative Radiographic Review, Form 15

Evidence of a neocortex (radiolucency) in the Gruen zones (p. 2 of 3, II. A & B) was counted identically to the method described above for Form 14. Gruen Zone Fit (p. 2 of 3, II. A & B) was defined as present for proximal zones 1, 2, 6, 7 and 8, 9, 13, 14 when the prosthesis-cortex distance was less than or equal to 2 mm at any point in the zones which have

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cancellous bone. For distal zones 3, 5 and 10, 12 a prosthesis-cortex distance of less than 1 mm (since these zones do not have cancellous bone), at any point, defined fit.

Distal tip presence and direction (p. 2 of 3, II. C) was measured according to Figure 3 (p. 2, Form 15). The presence of loose porous coating (p. 2 of 3, II. D) was also noted. The presence of femoral fracture (p. 3 of 3, II. A), stem tip placement (p. 3 of 3, II. B), implant sizing (p. 3 of 3, II. C. 1.), and implant positioning within the canal (p. 3 of 3, II. C. 2.) were also recorded.

The proximal medial fit score was recorded in the Comment Section (bottom of p. 3 of 3). This score described the fit of the proximal medial aspect of the prosthesis to the proximal medial (endosteal) cortex. The proximal medial cortex was defined as the medial (endosteal) cortex extending from the midpoint of the lesser trochanter up to the medial portion of the femoral neck osteotomy. Scores ranged from 1 to 5, where 5 denoted 50% or greater prosthesis-cortex contact, 4 denoted 25-49% contact, 3 denoted less than 25% but greater than 2 point contact, 2 denoted parallel stem and cortex edges with 1 point contact or no cortical contact and 1 denoted non-parallel edges with no cortical contact. An prosthesis-cortex distance of less than 1 mm defined contact.

12 Month Evaluation

Radiographs from 100 study patients were available for the 12 month and 24 month analyses. ISS Independent Quantitative Radiographic Review, Form 14 was used (a copy of Form 14 is included in this **Appendix 6**).

Evidence of a neocortex (radiolucency) in the Gruen zones (Form 14, p. 4 of 5, IV. E. 1&2) was counted as positive if the radiolucent line between the neocortex and the prosthesis was greater or equal to 1mm in thickness and if it occupied 50% or more of a Gruen zone. Comments were written detailing if the neocortex was divergent, *i.e.* not paralleling the prosthesis surface. Additional comments included noting the presence of bony "spot welds", bony "streaming", periosteal hypertrophy, osteolysis, and calcar rounding. These findings were made without comparison to earlier studies.

Statistical Analysis

All analyses were performed using The *SAS* System (*SAS* Institute, Inc., Cary NC). Means and standard deviations were used to describe continuous values. Proportions were

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used to describe discrete values. Differences between groups were determined by the Wilcoxon rank sum test for continuous variables and by the Chi-square test for categorical variables. For categorical tests with small expected cell counts, Fisher's Exact Test was employed.

Results

3 Month Results

Films from a total of 129 hips were evaluated at 3 months; 65 control and 64 ROBODOC cases. Thirty AML prostheses were inserted into 24 patients; 15 were in the control group and 15 in the ROBODOC group. One hundred and six Osteolock prostheses were inserted into 96 patients; 50 were in the control group and 56 in the ROBODOC group.

a. Fit (prosthesis to cortical bone distance)

The pooled fit data (AML and Osteolock) for the AP radiographs are presented in Table 1. (Data for Level 5 were not pooled because the AML prosthesis was not designed to contact at this level compared to the distal sleeve Osteolock prosthesis. Both prostheses were designed to contact in Levels 1-4; hence, the data for these levels was pooled.) At the proximal levels (Levels 1-3) the medial and lateral fit of the ROBODOC cavities was significantly closer than the control group cavities (unpaired t-test). There was no significant difference in the fit at the distal levels.

Analysis of the frequency of levels with $\leq$ 2mm fit demonstrated a statistically significant difference between the control and ROBODOC groups (chi-square, p=0.001). See Tables 2 and 3. It is generally believed that bone will not remodel and fill in >gaps 2mm, and 2mm is also beyond typical measurement error.

Analysis of the Osteolock prosthesis group, revealed similar differences as the pooled data. Analysis of the AML prosthesis group revealed no significant differences between the control group and the ROBODOC likely due to the small number of AML implants; nevertheless fit appeared to be generally better in ROBODOC cavities (unpaired t-test).

b. Fill

The pooled fill data (AML and Osteolock) for the AP radiographs are provided in Table 4. The proximal levels (Levels 1-3) had statistically larger fill in the ROBODOC group as compared to the control group (unpaired t-test). There was no significant difference in the fill at the distal levels.

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Analysis of the frequency of levels with ≥ 90 percent fill (Table 5) demonstrated a statistically significant difference between the control and ROBODOC groups (chi-square, p=0.01).

Analysis of the Osteolock prosthesis group, separate from the AML prosthesis group, revealed similar differences as the pooled data. Analysis of the AML prosthesis group revealed no significant differences between the control group and the ROBODOC at any level (unpaired t-test).

c. Axial seating-prosthesis distance from neck cut

The average axial seating distance for the pooled data (AML and Osteolock) for the ROBODOC group was significantly less than the control group's average (unpaired t-test). See Tables 6, 7 and 9.

d. Alignment

The average alignment (in absolute value) for the pooled data (AML and Osteolock) for the ROBODOC group was approximately 0.4 deg in the frontal plane and 0.8 deg in the lateral plane. These values were significantly less than the control group's average of approximately 0.8 and 1.1 deg, respectively (unpaired t-test). See Tables 6, 7 and 10.

e. Neocortex (radiolucency)

No evidence of a neocortex was present for any of the patients at the 3 month radiographic follow-up.

f. Distal tip displacement and direction

There was no statistical difference in the displacement of the distal tip of the prosthesis and the center of the canal, between the control and ROBODOC groups (unpaired t-test, chi-square). See Tables 6, 7 and 8.

g. Loose porous coating

Only one patient had evidence of bead shedding. Loose beads were noted adjacent to Gruen zones 6, 9, and 13 at the time of surgery; this finding is not unexpected due to the interference fit of the prosthesis. Bead shedding did not increase over time. This patient was in the ROBODOC group. There was no statistical difference, in loose porous coating, between the control and ROBODOC groups (unpaired t-test, chi-square).

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h. Femoral fracture

Only one femur fracture was detected in this 3 month radiographic review. This fracture occurred during the insertion of an AML prosthesis. The patient was in the control group. No statistical difference was detected between the control and ROBODOC groups (unpaired t-test, chi-square).

i. Proximal medial fit

The proximal medial fit of the ROBODOC group was statistically higher than the control group (unpaired t-test, chi-square). See Table 11. The average values of the control and ROBODOC groups were 3.9 mm and 2.5 mm, respectively. Note that 5 was best proximal medial fit and 1 was the worst.

12 Month Results

The radiolucency data (AML and Osteolock) for the AP are provided in Tables 12 and 13. There were significantly less radiolucencies (neocortices) in Gruen zones 3, 5, 6, 10, and 12 for the ROBODOC group than the control group (unpaired t-test). There was no statistical difference, in the number of radiolucencies in the other Gruen zones between the control and ROBODOC groups. Importantly, there were more patients in the control group with radiolucencies in five or more zones than similar patients in the ROBODOC group.

Discussion

3 Month Analysis

Overall, the 3 month radiographic results were better for ROBODOC patients than for those in the control group. It is important to note that were no instances where the ROBODOC group results were worse than the control group.

The ROBODOC group had better fit (closer cortical bone to prosthesis distance) and fill (canal filling of the prosthesis) in the proximal regions than did the control group. This was especially evident in the proximal medial zone. The proximal region corresponded to the region that in conventional surgery was prepared using a rasp. The precision machining of the ROBODOC system produced better fit and fill than the hand rasping of the control group. Improved fit, especially proximal medially, has been implicated to produce more normal stress

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environments in the proximal bone, less micromotion between the bone and prosthesis, and better clinical results.

No difference between the control and ROBODOC groups were detected in the fit or fill for the distal region. The distal region corresponded to the region that in conventional surgery is prepared using powered reamers. These cutting tools are fairly simple and their effectiveness is aided by being powered instruments. Thus, it was not surprising that ROBODOC did not improve the control group's distal reaming results, which had fit measurements averaging less than 0.3 mm and fill values of 98 percent.

The Osteolock prosthesis analysis followed the positive pooled prosthesis results. While analysis of the AML prostheses by themselves demonstrated no significant difference in fit or fill between the control and ROBODOC groups, this result is likely due to the small sample size (15 in each group).

The ROBODOC group prostheses were inserted in more optimal positions than their control counterparts. The ROBODOC group prostheses were seated significantly closer to the proximal femoral neck osteotomy than the controls, maximizing prosthesis-bone surface contact. The ROBODOC group also had better prosthesis alignment (varus-valgus, anterior-posterior). No difference was detected between the two groups in the location (centering) of the distal prosthesis tip.

In this radiographic review, there were no instances of radiographically detectable intraoperative fractures in the ROBODOC group. There was one intraoperative fracture detected in the control group 3 month films.

12 Month Analysis

Again, the ROBODOC group results were at least as good as and often better than the control group results. In the distal region, there were statistically-significantly less radiolucent lines medially, laterally, anteriorly, and posteriorly than in the ROBODOC group. For the remaining portions of the prosthesis there was no statistically significantly difference between the two groups. The ROBODOC group did have significantly fewer instances of prostheses with radiolucent lines in five or more Gruen zones than did the control group.

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Conclusion

The ROBODOC group had better results for fit, fill, seating, alignment, and radiolucent line occurrence than did the control group. Moreover, the ROBODOC group was not surpassed in any of the studied radiographic parameters by the control group. Good alignment and prosthesis fit are important conditions for successful hip replacement. These 3 and 12 month radiographic results demonstrate that the ROBODOC group fulfilled these conditions and improved the radiographic results of conventional total hip replacement surgery. We expect this radiographic improvement to translate into improved long-term clinical results.

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Table 1

3-Month Quantitative X-Ray Data

Fit and Fill by Level

All Implants	Control	ROBODOC	p-value
N	65	64	
AP Film Lateral Fit (mm)			
Level 1	16.79	13.75	0.002
Level 2	5.83	4.81	0.004
Level 3	3.09	2.28	0.006
Level 4	0.26	0.12	0.09
AP Film Medial Fit (mm)			
Level 1	3.06	1.14	0.0001
Level 2	3.66	1.44	0.0001
Level 3	2.68	1.48	0.0006
Level 4	0.12	0.14	0.78
AP Film - Fill (%)			
Level 1	66.3	77.8	0.0001
Level 2	73.1	82.9	0.0001
Level 3	80.0	86.9	0.0001
Level 4	97.9	98.5	0.34

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Table 2

3-Month Quantitative X-Ray Data

Percent Hips with ≤ 2mm Fit by Level

All Implants	Control	ROBODOC	p-value
N	65	64	
AP Film Lateral Fit			
Level 1	0.0	1.6	0.32
Level 2	3.1	14.1	0.03
Level 3	41.5	59.4	0.04
Level 4	100.0	100.0	1.00
Level 5	98.5	100.0	0.32
AP Film Medial Fit			
Level 1	43.1	87.5	0.001
Level 2	47.7	84.4	0.001
Level 3	53.9	82.8	0.001
Level 4	100.0	100.0	1.00
Level 5	98.5	98.4	0.99

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Table 3

3-Month Quantitative X-Ray Data

Number of Levels with ≤ 2mm Fit

All Implants	Control	ROBODOC
N	65	64
0	0	0
1	0	0
2	0	0
3	0	0
4	8	2
5	22	1
6	15	8
7	12	26
8	7	20
9	1	7
10	0	0
Chi-square p=0.001		

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Table 4

3-Month Quantitative X-Ray Data

Percent Fill by Level

All Implants	Control	ROBODOC	p-value
N	65	64	
AP Film - Fill			
Level 1	0.0	1.6	0.32
Level 2	0.0	15.6	0.001
Level 3	7.7	37.5	0.001
Level 4	93.8	95.3	0.71
Level 5	90.8	84.4	0.27

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Table 5

3-Month Quantitative X-Ray Data

Number of Levels with at Least 90% Fill

All Implants	Control	ROBODOC
N	65	64
0	3	3
1	4	2
2	53	38
3	5	13
4	0	7
5	0	1
Chi-square p=0.012		

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Table 6

3-Month Quantitative X-Ray Data

AML	Control	ROBODOC	p-value
N	15	15	
Displacement (mm)	0.37	0.07	0.12
Loose Porous Coating	0.00	0.007	0.33
AP Film - Axial Seat	1.53	0.17	0.20
AP Film - Alignment	1.13	0.40	0.11
Lat Film - Alignment	1.3	1.07	0.75

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Table 7

3-Month Quantitative X-Ray Data

Osteolock	Control	ROBODOC	p-value
N	50	49	
Displacement (mm)	0.13	0.24	0.22
Loose Porous Coating	0	0	----
AP Film - Axial Seat	2.26	0.94	0.01
AP Film - Alignment	0.72	0.43	0.02
Lat Film - Alignment	1.06	0.69	0.04

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Table 8

3-Month Quantitative X-Ray Data Displacement

All Implants	Control	ROBODOC
N	65	64
-2.0	1	0
-1.0	0	1
-0.5	1	0
0.0	49	46
0.5	1	6
1.0	11	11
1.5	2	0
Chi-square p = 0.194		

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Table 9

3-Month Quantitative X-Ray Data

AP Film - Axial Seating

All Implants	Control	ROBODOC
N	65	64
-4	0	1
-2	2	2
-1	3	1
-0.5	0	1
0	23	38
0.5	2	3
1	2	2
1.5	0	1
2	9	8
3	8	2
4	3	3
5	6	1
6	1	0
7	4	0
8	1	0
14	1	1
Chi-square p = 0.133		

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Table 10

3-Month Quantitative X-Ray Data

Alignment

	Control	ROBODOC
N	65	64
AP Film - Alignment		
0	25	39
1	33	23
2	4	2
3	2	0
4	0	0
5	0	0
6	1	0
Chi-square p = 0.075		
Lateral Film Alignment		
0	11	21
1	40	36
2	10	5
3	1	1
4	0	0
5	1	0
Chi-square p = 0.199		

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Table 11

3-Month Qualitative X-Ray Data

Proximal Medial Fit

All Implants	Control	ROBODOC
N	63	64
0	1	0
1	8	0
2	31	9
3	10	10
4	6	21
5	7	24
Chi-square p = 0.001		

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Table 12

12-Month Qualitative X-Ray Data

Hips by Number of Radiolucent Zones in Any Zone

All Implants	Control	ROBODOC
N	49	51
No. Radiolucent Zones		
0	12	12
1	9	18
2	10	11
3	5	4
4	3	1
5	2	2
6	4	0
7	1	1
8	2	1
9	1	1
Chi-square p = 0.489		

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Table 13

12-Month Qualitative X-Ray Data

Hips by Number of Radiolucent Zones in Key Zones

All Implants	Control	ROBODOC
N	48	51
No. Radiolucent Zones		
0	25	36
1	10	8
2	5	5
3	3	1
4	5	1
Chi-square p = 0.22		

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Section 20.3 Summary: BGU Clinical Evaluation of ROBODOC Surgical System

Four hundred ninety (490) patients undergoing cementless THR were operated on using the ROBODOC System between November 1994 and November 1996. The results of the clinical study are reported in the "Lecture Notes in Computer Science", CVR-Med MRCAS '97. The authors report no system-related complications, a tolerable longer OR-time and benefits regarding position and healing of the implant in the robot group. No fractures or malposition reported for the ROBODOC treated subjects. This study confirms the ROBODOC® Surgical System performs safely and effectively for its intended use. A summary of the clinical study is provided in this subsection. A complete copy of the report is provided in **Attachment 2**.

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From: "Lecture Notes in Computer Science"
CVR-Med MRCAS '97

Summary

ROBODOC® Surgical System - Clinical Evaluation

André Bauer, Martin Börner, Armin Lahmer
Berufsgenossenschaftliche Unfallklinik
(ÄRZTL.DIR.PD.DR.M.Börner)
Frankfurt Am Main, Germany

20.3.1 Overview

Robot-assisted surgery in Total Hip Replacement (THR) was evaluated at Berufsgenossenschaftliche Unfallklinik (BGU) using the ROBODOC Surgical System. Four hundred ninety (490) patients undergoing cementless THR were operated on using the ROBODOC System between November 1994 and November 1996. Concurrently, a second study was conducted on twenty greyhounds. Section 19.1 of this 510(k) Premarket Notification contains a summary of the canine study. Results in both studies showed no system-related complications, a tolerable longer OR-time and benefits regarding position and healing of the implant in the robot group. No fractures or malposition were seen in the robot-operated people and dogs. Study results support further clinical use and applications.

20.3.2 Introduction

In cementless total hip replacement, primary fixation between bone and femoral component is a critical phase in the procedure. While in cemented procedures any gaps between implant and bone are filled by cement, and primary stability is achieved through the bonding of the cement, cementless procedures require exact fit of the implant into the cavity, initial stability avoiding any micro motion or rotational instability and precise positioning of the implant. Missing any of these goals might result in early micro motion, leading to possible interposition of fibrous tissue between bone and implant and eventually aseptic loosening. As handheld broaches used in the preparation of the femoral cavity are prone to tear out pieces of bone and are often deflected by hard bone, machine milling of the cavity is likely to enhance surgical precision. The ROBODOC® Surgical System is the first operational system in orthopedics that allows accurate planning of the cementless THR procedures and the execution of the plan by a computer guided robot. Parallel to clinical testing a prospective two arm animal experiment was conducted to evaluate performance and possible benefits of the system. This section summarizes the human clinical results reported in "Lecture Notes in Computer Science" CVR-Med MRCAS '97. Section 19.1 summarizes results of the experimental animal arm of the study.

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20.3.3 Materials and Methods

Between November 1994 and November 1996 four hundred ninety subjects underwent THR surgery at BGU using the ROBODOC® Surgical System. All patients received a cementless THR using the Osteolock implant by Howmedica. All patients were informed on the experimental status of the system and gave their informed consent. The study included patients between the age of 18 and 72 years. Elderly patients were excluded when preoperative x-rays revealed osteoporotic bone not likely to support cementless implants.

Prior to the actual THR procedure, patients underwent a minimally invasive procedure to implant three small metal locator (fiducial) pins into the femoral condyles and greater trochanter. These allow registration of the operative hip to the robotic arm component of the System. After pin placement a computed tomography (CT) scan of the femur is taken. The CT data are loaded into ORTHODOC component of the ROBODOC® Surgical System. The ORTHODOC is the workstation that displays the image of the femur and allows, after choosing an implant from an implant library, the virtual placement of the prosthesis into the bone. The surgeon can check size and fit of the implant, as well as position, offset, bone density and anteversion. The preoperative plan is transferred via tape to the computer guiding ROBODOC. During surgery, a probe attached to the robots arm touches the three pins and correlates the bone to the preoperative plan. After successful registration, the preoperative plan is executed by the robot with the highest accuracy regarding position and size of the implant.

To prevent heterotopic bone formation, all patients were on an indomethacin regimen. They all received a standard antithrombosis prophylaxis with heparin. Postoperatively, from patient No. 31 on, they all were encouraged to immediate full weight bearing the day after surgery. Postoperative x-rays were performed in the OR and at 10 days, 3, 6, 12 and 24 months. Orthopedic examinations were performed at the same intervals.

20.3.4 Results

In the 490 cases completed, the preoperative plan was executed with the highest precision. No intraoperative femoral fractures or fissures occurred. Postoperative x-rays revealed no cases with varus or valgus malposition. Although immediate full weight bearing was encouraged, no subsidence of implants was seen on x-rays during the 2 year follow-up period.

Surgical time in the 1st five cases averaged 200 minutes, compared to approx. 85 minutes, which is historically seen in hand-broached THR procedures. From the 6th patient on the learning curve showed a steady decline. From case 20 on, surgical time came down to 120 minutes, and is now steadily between 90 and 100 minutes. The drop in overall surgical time was due to better training of surgeons as well as to improvements in software guiding the procedure and cutting files.

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There were 15 cases in which the robotic procedure could not be performed, although pin placement and ORTHODOC planning was completed. Reasons for these incomplete procedures were CT-failures, due to table motion, software problems, user errors and loose pins due to osteoporosis or poor placement.

Reported complications included transient nerve palsies (1.9%), pulmonary embolism (1.8%), deep vein thrombosis (2.1%), and postoperative dislocations (2.7%). The postoperative dislocations were attributed to problems with the acetabular component and were not robot procedure related.

In 14 patients, the ROBODOC procedure was performed bilaterally, with a mean interval between procedures of approx. 6 months. In these cases the authors were able to evaluate the performance of the robot regarding accuracy by comparing the ORTHODOC images created for the second procedure with those for the first hip. In all 14 cases a perfect correlation between preoperative plan and postoperative images was found.

Two cases became revision THR cases because the patients had – loose – implants; one cemented and one cementless stem. Despite some metal artifacts in CT data ORTHODOC planning was feasible and the image of the implant could be layered over the loose stem, thus creating a cutting file that would remove all cement. Both cases were performed without complications and there were no fractures reported. Although not quantified, the authors report "saving a lot of time during cement removal."

20.3.5 Discussion

According to the authors, this clinical study proved for the first time that the use of a robot in orthopedic surgery is feasible and is not connected with any risk to the patient. Early concerns during the development of the robotic system about the possibility of uncontrolled action by the robot, potentially causing harm to patients or staff within the workspace, could be refuted. In no case did the robot move away from the plan, and no weird action of the robot was encountered. Quite in contrast, all safety features worked perfectly. When, due to a failure in the motion of the CT table, inaccurate data were detected by the robot intraoperatively, the procedure was halted immediately.

Registration using pins that require a second surgery is a disadvantage of the current system, although no complications due to pin placement were encountered. Yet a pinless registration is already in use in the lab and has been successfully used in the OR at our institution, comparing pin data with pinless data on the same patient. [See Section 20.5, BGU Pinless Validation Study, TR98-07-011] We expect to commence routine use of the pinless procedure early in 1997.

Another major concern related to robot surgery OR (surgical) time. Obviously robotic surgery was prone to take longer than the hand-broached procedure, and early experiences in the US with ROBODOC supported these concerns. This clinical study, as well as the animal experiment, showed a consistent prolongation (approx. 30 minutes) of surgery due to the use of the robot. This time is consumed by the fixation of the bone to

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the robot, installation of the bone-motion monitor, registration (pin finding) and finally the milling, which takes about 15 minutes. This longer surgical time potentially exposes the patient to a higher risk (i.e. infection, thrombosis, etc.), however, no such correlation was seen.

The authors report that on the benefit side, there were no fractures or fissures, which are common complications in cementless THR and likely to support an early failure. Additionally, despite immediate weight bearing, no subsidence of an implant was seen in the follow-up x-rays. Postoperative pain was less in the robot group, which was noted in the human patients and proven by gait analysis in the dog study. Finally, the precise execution of the preoperative plan on ORTHODOC allowed close alignment of the implant to supporting bone. As proven by the histological evaluation in the animal experiment this promotes primary healing between implant and bone. The authors also report that they expect good [long-term] performance of the implants, because malposition of the femoral implant could be avoided.

20.3.6 Conclusion

The authors concluded that both the 490 patient BGU study and the 20 greyhound animal study proved the feasibility of robot-assisted surgery in THR. Disadvantages of the system, i.e. longer OR-time and pin registration, were outweighed by proven and expected benefits.

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Attachment 2

"Lecture Notes in Computer Science", CVR-Med MRCAS '97

From: "Lecture Notes in Computer Science"
CVR-Med MRCAS '97

DJA x02171

Robodoc- Animal Experiment and Clinical Evaluation

André Bauer, Martin Börner, Armin Lahmer
Berufsgenossenschaftliche Unfallklinik
(ÄRZTL.DIR.PD.DR.M.Börner)
Frankfurt Am Main, Germany

Abstract: Robot-assisted surgery in Total Hip Replacement, was evaluated using the Robodoc system. 490 patients were operated with Robodoc since November 1994, and a two arm trial was conducted on twenty greyhounds. Results in both studies showed no system-related complications, a tolerable longer OR-time and benefits regarding position and healing of the implant in the robot group. No fractures or malposition were seen in the robot-operated people and dogs. Study results support further clinical use and applications.

1 Introduction

In cementless total hip replacement, primary fixation between bone and femoral component is a critical phase in the procedure. While in cemented procedures any gaps between implant and bone are filled by cement, and primary stabiltiy is achieved through the bonding of the cement (2), cementless procedure requires exact fit of the implant into the cavity, initial stability avoiding any micro motion or rotational instabilty and precise positioning of the implant. Missing any of these goals might result in early micro motion, leading to possible interposition of fibrous tissue between bone and implant and eventually aseptic loosening (3,4,6). As handheld broaches used in the preparation of the femoral cavity are prone to tear out pieces of bone and are often deflected by hard bone, machine milling of the cavity is likely to enhance surgical precision. Robodoc is the first operational system in orthopedics that allows accurate planning of the cementless THR procedure and the execution of the plan by a computer guided robot (1,5) . Parallel to clinical testing a prospective two arm animal experiment was conducted to evualate performance and possible benefits of the system.

2 Materials and Methods

In the clinical trial, 490 patients have been operated with the Robodoc system between November 1994 and November 1996. All patients received a cementless THR using the Osteolock implant by Howmedica. All patients were informed on the experimental status of the system and gave their informed consent. Included in the study were patients between the age of 18 and 72 years. Elderly patients were excluded when preop x-rays revealed osteoporotic bone not likely to support cementless implants. Prior to the actual procedure, patients underwent a minimal invasive procedure to implant three small metal pins into the femoral condyles and greater trochanter. These serve registration purposes. After pin placement a CT scan of the femur is taken and CT data are loaded into Orthodoc, a workstation that displays the image of the femur and allows, after choosing an implant from an implant library,

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the virtual placement of the prosthesis into the bone. The surgeon can check size and fit of the implant, as well as position, offset, bone density and anteversion. The finally created plan is transferred via tape to the computer guiding Robodoc. During surgery, a probe attached to the robots arm touches the three pins and correlates the bone to the preop plan. After successful registration, the preop plan is executed by the robot with the highest accuracy regarding position and size of the implant.

To prevent heterotopic bone formation, all patients were on an indomethacin regimen. They all received a standard antithrombosis prophylaxis with heparin. Postoperativly, from patient No. 31 on, they all were encouraged to immediate full weight bearing the day after surgery. Postop x-rays were performed in the OR and at 10 days, 3, 6, 12 and 24 months, orthopedic examen in the same intervalls.

In the animal experiment, 20 male greyhounds were randomized to either handbroached or robot assisted hemiarthroplasty. The study was performed by the first author and Dr. Montgomery of the Small Animal Clinic, Auburn University, in Auburn, Alabama, between December 1995 and December 1996. The study was approved by the Ethical Commitee of Auburn University and in part supported by Intergrated Surgical Systems, Sacramento, California.

All dogs received preop vaccinations, standard hip x-rays and orthopedic examen. For dogs randomized to the handbroached group, planning was performed with acetate templates over x-rays and the femoral cavity was prepared with handheld broaches. In the robot group, pin placement and CT scan were performed in general anaesthesia. Planning was performed on Orthodoc, and the femoral cavity was milled by the robot after intraoperative registration. Aside from registration, fixation of the bone to the robot and milling by the robot, the procedures in both groups were carried out identicly.

Postoperative regimen was identical in both groups. Partial weight bearing on the first postop day was followed by full weight bearing after day 2. Beginning on day 5, all dogs received a polychrome sequence labeling with yellow, red, blue and green markers. Each label was applied for 5 days. A postoperative gait analysis was carried out after 1, 3, 6, 9 and 12 month. Necropsy dates were at 35 days for 8 dogs (4 each group), 84 days (6 dogs) and 365 days (6 dogs). Histological evaluation was carried out by Drs. Draenert in Munich.

3 Results

A. Clinical trial

Between November 1994 and November 1996 the Robodoc procedure was performed on 490 patients. In all cases, the preoperative plan was executed with the highest precision. No femur fractures or fissurs occurred. Postoperative x-rays revealed not one case of varus- or valgus malposition. Although immediate full weight bearing was encouraged, no subsidence of implants, even on the 2 year follow up rays, was seen. OR time in the beginning averaged 200 minutes in the first 5 cases (compared to appr. 85 minutes in handbroached THR), but the learning curve showed a steady decline. From case 20 on, OR time came down to 120 minutes, and is now steadily between 90 and 100 minutes. Faster OR time was due to better training of surgeons as well to improvements in software guiding the procedure and cutting files.

In overall 15 cases, the robot procedure could not be performed although pin placement and Orthodoc planning was completed. Reasons for these were CT-failures (inaccurate table motion), software problems, user errors and loose pins due to

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osteoporosis or poor placement. In none of these cases the preop plan regarding size of the implant could be accomplished, but smaller prosthesis had to be implanted.
As complications we saw some transient nerve palsies (1,9%), pulmonary embolism (1,8%), deep vein thrombosis (2,1%), and 2,7% postoperative dislocations that were not connected to the robot procedure but to problems with the acetabular component.
In 14 patients, Robodoc procedure was performed bilaterally, with a mean intervall between procedures of appr. 6 months. In these cases we were able to evaluate the perfomance of the robot regarding accuracy by comparing the Orthodoc images created for the second procedure with those for the first hip: in all 14 cases we found a perfect correlation between preop plan and postop images.
Two cases were actually revision cases, as both patients already had - loose - implants, one cemented and one cementless stem. Despite some metal artefacts in CT Orthodoc planning was feasible and the image of the implant could be layed over the loose stem, thus creating a cutting file that would remove all cement resp. fibrous membrane. Both cases could be performed without complication, especially avoiding any fracture and saving a lot of time during cement removal.

B. Animal Experiment

In the robot group, all dogs could be operated successfully, no procedure had to be aborted and in all cases the preoperative plan regarding size and position of the implant could be accomplished. In the handbroached group, two dogs suffered a fracture of the femur. One dog had to be sacrifzed intraoperativly, when the femur cracked, and the implant could not be positioned deep enough to allow reduction of the joint. In another dog the fracture became evident in the x-rays before necropsy, when a large callus formation developed as result of a long spiral fracture. OR time in the robot group was a mean of 29 minutes longer than in the handbroached group.
Gait analysis one month after surgery showed a significant better performance of the robot group. PFz (peak vertical force) and IFz (impulse of vertical force) were 93,1% and 94,5% of the preoperative value in the robot group, while the handbroached dogs reached 80,6% and 77,1% respectivly. Similar difference were found in the 6 months and 12 months gait analysis.
The histological evaluation revealed a closer alignment of the implants to strong cortical bone in the robot group. Signs of major repair and remodeling were visible in the slides of the handbroached group, while in the robot group all signs of primary healing between implant and bone werde present.

4 Discussion

Both animal experiment and clinical study proved for the first time that the use of a robot in orthopedic surgery is feasible and is not connected with any risk to the patient. Early concerns during the development of the robotic system about the possibility of uncontrolled action by the robot, potentially causing harm to patients or staff within the workspace (5) , could be refuted. Not in one case the robot moved away from the plan, and no weird action of the robot was encountered. Quite in contrast, all safety features worked perfectly. When, due to a failure in the motion of the CT table, inaccurate data were detected by the robot intraoperativly, the procedure was halted immediatly.

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Registration using pins that require a second surgery is a disadvantage of the current system, although no complications due to pin placement were encountered. Yet a pinless registration is already in use in the lab and has been successfully used in the OR at our institution, comparing pin data with pinless data on the same patient. We expect to commence routine use of the pinless procedure early in 1997.
Another major concern in robot surgery regarded OR time. Obviously robotic surgery was prone to take longer than the handbroached procedure, and early experiences in the US with Robodoc supported these concerns. Our clinical study, as well as the animal experiment, showed a consistent prolongation of surgery due to the use of the robot of appr. 30 minutes. This time is consumed by the fixation of the bone to the robot, installation of the bone-motion monitor, registration (pin finding) and finally the milling, which takes about 15 minutes. This longer OR- time potentially exposes the patient to a higher risk (i.e. infection, thrombosis etc.). Both studies showed no such correlation, especially no infection or a higher rate of thrombosis than in comparable series. On the benefit side, we saw no fracture or no fissur, which are common complications in cementless THR and likely to support an early failure (7). Despite immediate weight bearing, no subsidence of an implant was seen in the follow-up x-rays. Postoperative pain was less in the robot group, which was noted in the human patients and proven by gait analysis in the dog study. Finally, the precise execution of the thorough preop plan on Orthodoc allows the close alignement of the implant to supporting bone and promotes primary healing between implant and bone, which was proven by the histological evaluation in the animal experiment. We expect a good performance of the implants, because any malpositioning could be avoided.
In conclusion, both studies proved the feasibility of robot-assisted surgery in THR. Disadvantages of the system, i.e. longer OR- time and pin registration, are outweight by proven and expected benefits. The results support further clincal use in THR and intensified research for further applications.

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PFz	Preop	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
Hand	80.533	64.98125	69.87	77.43333	75.48333	71.44
Robot	83.398	71.018	78.9	85.91667	83.72333	91.52
IFz	Preop	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
Hand	11.008	8.335	9.67	10.42	9.873333	9.1
Robot	10.954	10.39889	10.11	10.98333	10.16	10.7

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	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
PFz % Hand	80.66	91.95	99.59	97.02	91.82
PFz % Robot	92.99	95.69	99.73	96.95	106.22
	1 mo.	3 mo.	6 mo.	9 mo.	12 mo.
IFz % Hand	77.16	89.2	96.84	91.41	84.17
IFz % Robot	94.63	89.85	94.03	86.63	91.39

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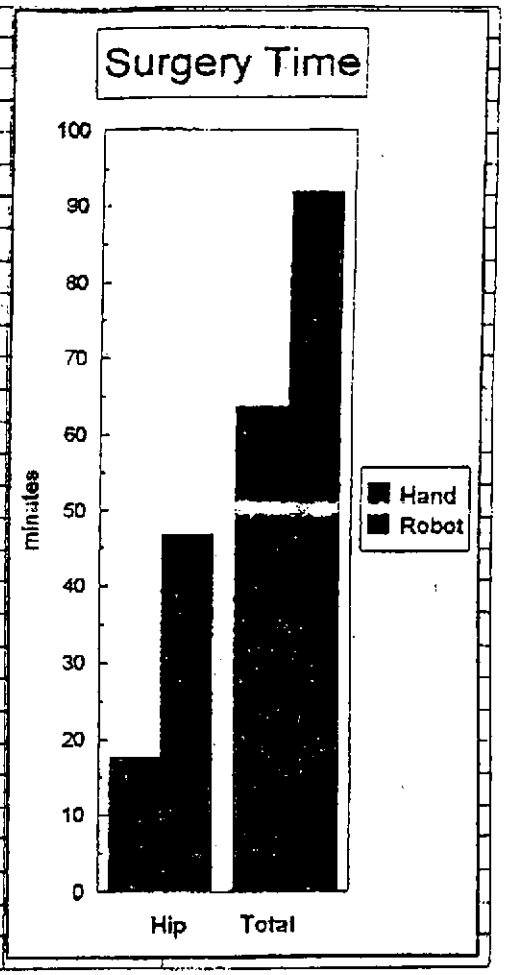
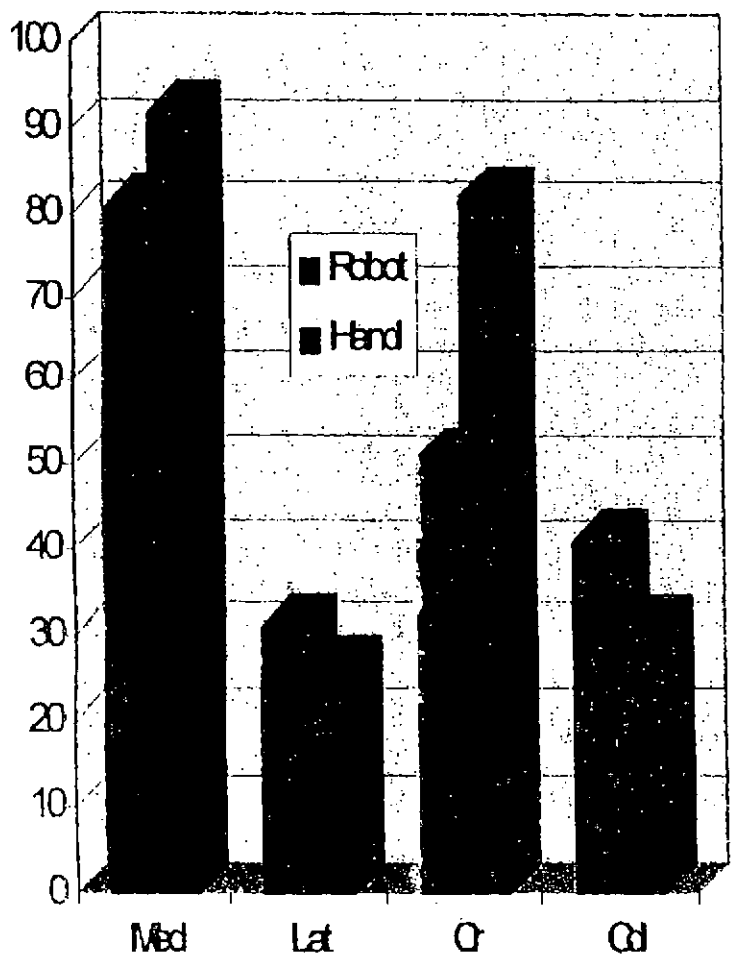
	HIP OUT TO HIP IN	TOTAL SX TIME
HAND	(minutes)	(minutes)
H-1	14	51
H-2	9	43
H-3	13	61
H-5	22	72
H-6	10	51
H-7	11	64
H-8	22	65
H-9	21	90
H-10	37	76
Mean	14	64
Average	17.67	63.67
ROBOT	51	87
R-2	35	86
R-3	81	120
R-4	37	82
R-8	38	95
R-1	42	91
R-5	37	90
R-6	65	110
R-7	43	78
R-9	39	79
R-10	46.8	91.8
Mean	42	90
Average	46.8	91.8
Avg. Diff.	29.13	28.13



Robot v. Hand Mean % Fit



- Robot group had better mean fit caudal and lateral
- Hand group had better mean fit cranial and medial
- Overall (sum) fit, Robot was 49% Hand was 50%

3-20-1995 2:56AM FROM CR. R.D. MONTGOMERY 3344844163

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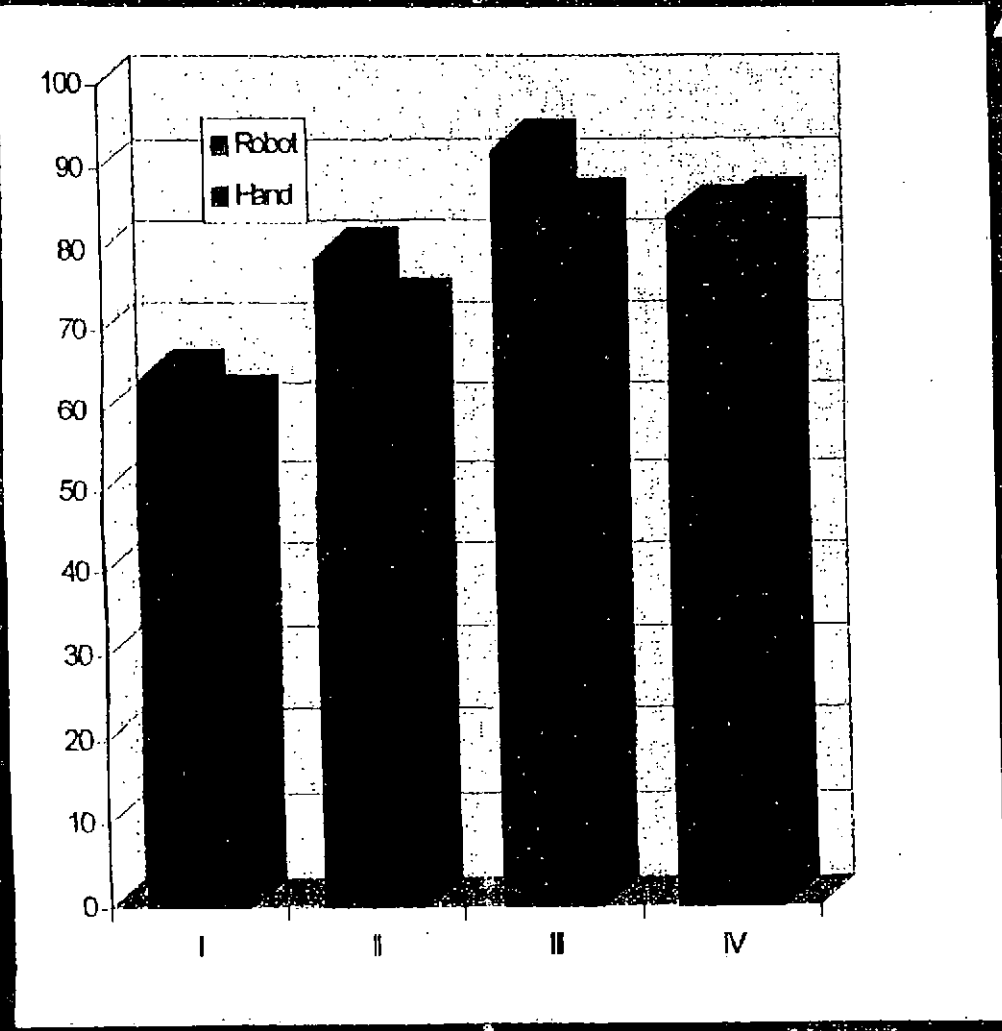
Robot v. Hand % Fill



- Mean % fill was better with the Robot group than the Hand group at all sites, except at site IV.
- Subsidence was 0 with the Hand group and a mean of 2 mm with the Robot group

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20.4 SUMMARY - Published Japanese Study: Evaluation of "2-pin" ROBODOC® Technology

The ROBODOC® Surgical System was initially developed using technology that required 3 locator or fiduciary pins to "register" the patient's operative femur to the robotic arm and cutting tool during primary cementless total hip arthroplasty (THA) procedures. Subsequently, a less invasive technology was developed that required 2, rather than 3, locators pins to be placed pre-operatively in order to register the location and orientation of robotic arm in relationship to the operative femur. The resulting "2-pin" ROBODOC® Surgical System was later CE marked.

An independent clinical trial that studied the 2-pin registration technology was published in the following journal:

> Nishihara S, Sugano N, Nishii T, Miki H, Nakamura N, and Yoshikawa H. Comparison Between Hand Rasping and Robotic Milling for Stem Implantation in Cementless Total Hip Arthroplasty. The Journal of Arthroplasty Vol. 21 No. 7, 2006; pp 957-966.

Section 20.3 is a summary of the Nishihara paper. A copy of the peer reviewed paper is provided in **Attachment 3**.

20.4.1 Purpose

The purpose of the study was to compare clinical and radiographic results of cementless THA performed by hand rasping or robotic milling procedures.

20.4.2 Study Design

This study was a multicenter, randomized, controlled trial conducted at Osaka University Medical School (Osaka, Japan) and Kyowakai Hospital (Osaka, Japan). The trial consisted of 140 patients (156 femora), randomly assigned to either the robotic milling (ROBODOC®) study group (n=73) or the hand rasping (manual) control group (n=67) for femoral canal preparation. Subjects were monitored for two years following surgery. Results were based on assessment of preoperative baseline data compared to three-month and two-year postoperative data.

20.4.3 Patient Selection

Candidates for primary cementless THA were screened for eligibility with defined selection criteria. Inclusion criteria included good bone quality (Dorr type A or B) and Crowe class I, II, or III (0%-100% subluxation of the hip). Patients with poor bone quality (Dorr type C) were excluded because of the need for use of cement. Patients with Crowe class IV (>100% subluxation of the hip) were excluded because of the need for subtrochanteric osteotomy to be included in the surgery. The randomization assignment was disclosed after a patient was deemed eligible as a subject and gave informed consent.

The study was approved by the Institutional Internal Clinical Research Committees of the two institutions.

20.4.4 Demographics

A total of 156 cementless THA procedures were performed on 140 patients at two institutions. The ROBODOC® group comprised 73 patients who underwent 78 primary THAs using the 2-pin-based procedure of the ROBODOC® System. The manual group comprised 67 patients who underwent 78 primary THAs. There was no significant difference in age (Mann-Whitney *U* test) or gender ratio (χ^2 test) between the two groups. Patient demographics are given in **Table 1**.

Table 1. Demographics of Patients Used for Comparison

Randomized Group	No. of Patients (Femora)	Gender (Male/Female)	Age (years)
Robotic milling ROBODOC® group	73 (78)	14: 64	58 (27-81)
Hand-rasping manual group	67 (78)	14: 64	58 (29-77)

20.4.5 Preoperative Planning and Surgical Procedures

All THAs were performed via the posterolateral approach, with the patient in the lateral decubitus position. VerSys fiber metal taper hydroxypatite-coated femoral stems (Zimmer, Warsaw, Ind) were used in all THAs. Intraoperatively, the two groups had the same length of skin incision for the hip (12-15 cm). In ROBODOC® treated patients, an extra skin incision was created over the lateral condyle of the affected femur to accommodate placement of 1 locator pin.

20.4.5.1 Preoperative Planning

Three-dimensional preoperative planning, using the ORTHODOC® Preoperative Planning Workstation, was performed in both the ROBODOC® and manually treated study groups. Because three arbitrarily selected orthogonal planning reconstructed images of the computed tomography (CT) data could be displayed on ORTHODOC®, the center of the femoral head was at first located using a circle drawing tool to encompass the femoral head contour. The femur was reoriented on the workstation to obtain the coronal plane that passed through the head center and the proximal femoral medullary axis. Then, the sagittal plane through the medullary axis was obtained. A femoral stem of the maximum size that would not over-ream the endosteal cortical bone was selected from the software's implant library and virtually implanted into the femoral canal. The type of proximal metaphysis (standard or large metaphysis) was chosen, which would achieve the required limb length. Each preoperative plan was discussed by two of the senior authors until a consensus was obtained.

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20.4.5.2 ROBODOC® Treated Patients

For this study, ROBODOC® treated patients had CT images of the femur taken after 1 locator pin was inserted into the greater trochanter of the affected femur and the other locator pin was inserted into the lateral condyle. Three-dimensional preoperative planning was performed on the ORTHODOC® Preoperative Planning Workstation using CT data. The preoperative plan, containing the robot milling path, was transferred to the robot controller.

After the leg was secured in the leg holder and the femur was rigidly attached to the robot base with the femoral external fixator, intraoperative pin-based registration using the 2 locator pins was performed. The robot then milled the inside of the femoral canal according to the preoperative plan. Surgeons inserted and impacted the femoral stem manually.

20.4.5.3 Manual Treated Patients

In the hand-rasping group, preoperative CT images of the affected femur were transferred to the ORTHODOC® Workstation for 3-dimensional preoperative planning of the THA procedure. The preoperative plan was used to select the size of the femoral stem and the proposed stem location. During surgery, the femoral canal was prepared using a handheld rasp. Surgeons inserted and impacted the femoral stem manually.

20.4.6 Evaluation Parameters

20.4.6.1 Clinical Measurements

The clinical results for each patient were assessed according to the Merle D'Aubigne hip score, in which up to 6 points each are given for pain, motion, and gait. These scores were obtained preoperatively, 3 months postoperatively, and 2 years postoperatively.

Operative time, femoral canal preparation time, estimated blood loss, donation of allogeneic blood, intraoperative femoral fractures, and other complications were monitored. Intraoperative femoral fractures were classified according to the Vancouver classification. Allogeneic blood units were transfused based on a variety of criteria, including clinical symptoms, hemodynamic stability, and whether the hematocrit fell below 24%. The decision whether to perform a transfusion was made by the operating surgeon.

In the hand-rasping group, the femoral canal preparation time was defined as the duration of the hand rasping. In the robotic milling group, the femoral canal preparation time was defined as the combined duration of positioning of the robot, registration, and milling.

Physical therapy with full-weight bearing, as tolerated, was initiated on the third postoperative day. The duration of rehabilitation required to gain the ability to walk

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more than 6 blocks, corresponding to 500 m, without a cane was recorded. Clinical measurements were compared between the two groups.

20.4.6.2 Radiographic Measurements

Radiographic evaluation using reconstructed CT images was performed preoperatively and at one month after THA.

Synthetic anteroposterior radiographs of the proximal femur parallel to the symmetry plane of the femoral stem, lateral synthetic radiographs of the proximal femur perpendicular to the symmetry plane of the femoral stem, and axial images of the femur perpendicular to the femoral stem axis, were reconstructed using the ORTHODOC® and the CT data. These reconstructed CT images were created using both preoperative and postoperative CT data.

Radiographic measurements were taken at the following 5 predefined levels:

- Level 1 – lower corner of the femoral neck cut;
- Level 2 – center of the lesser trochanter;
- Level 3 – 1.5 cm distal from the center of the lesser trochanter;
- Level 4 – 4.5 cm proximal from the femoral component tip; and
- Level 5 – 1.5 proximal from the femoral component tip.

Synthetic anteroposterior radiographs were used to evaluate the mediolateral alignment of the femoral stem (angle between the femoral stem axis and the proximal femoral canal axis), the medial gap between the medial endocortical bone and the femoral stem, the lateral gap between the femoral stem and the lateral cortical bone, and the mediolateral canal filling ratio of the femoral stem (percentage of canal occupied by the femoral stem).

Synthetic lateral radiographs were used to evaluate anteroposterior alignment of the femoral stem (angle between the femoral stem axis and proximal femoral canal axis). Axial images of the femur were used to evaluate the vertical seating (vertical distance from the femoral stem shoulder to the center of the lesser trochanter) and canal fill ratio of the femoral stem (ratio of femoral stem area to the total medullary cavity area) at all 5 levels. Femoral anteversion was defined as the angle between the stem neck axis and the table plane including the posterior condyles and the most prominent posterior point of the greater trochanter. The observers who performed the radiographic analysis were blinded to which group each patient belonged.

The type and size of each implanted femoral stem was compared with those chosen in the preoperative plans. Differences in the radiographic measurements between values from preoperative planning and measurements from postoperative CT images were compared between the two groups. Pearson's correlation coefficient for the difference in vertical seating and the absolute value of the difference in femoral anteversion between the preoperative plan and the postoperative CT images to evaluate the effect of larger differences in femoral anteversion on unexpectedly higher vertical seating were calculated. Next, the mediolateral canal filling ratio, the canal fill ratio, and the

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alignment of the femoral stem from preoperative planning or postoperative CT images between the two groups were compared. Finally, the clinical results and the differences in radiographic measurements between values from preoperative planning and measurements from postoperative CT images were compared between the two groups, after excluding the two patients with intraoperative femoral fracture and those for whom there was a difference in the type and size of the femoral stem between the preoperative plans and the postoperative results.

Radiographic evaluation included measurement of implant-bone interface. The implant-bone interface was estimated on the two-year postoperative radiograph as stable bony ingrowth, stable fibrous ingrowth, or unstable, using the criteria of Engh et al [Clin Orthop 1990;261-63].

The unpaired *t* test, the Mann-Whitney *U* test, the χ^2, and the Pearson's correlation coefficient were used for statistical analysis. Differences were considered significant when the *P* value was less than .05.

20.4.7 Patient Accounting

One patient in the ROBODOC® group was lost at the final follow-up. Four patients in the hand-rasping group were lost at the final follow-up. One patient (2 hips) in the hand-rasping group died with lung cancer during follow-up period. Complete clinical follow-up including evaluation on the two-year postoperative radiograph was available for 77 hips in the robotic milling group and 72 hips in the hand-rasping group. Radiographic evaluation using reconstructed CT images obtained preoperatively and at one month after THA was available for all the hips. The mean follow-up was 2.3 years (range, 2-3.6 years).

20.4.8 Results

20.4.8.1 Merle D'Aubigne Hip Scores

There were no significant differences in Merle D'Aubigne hip scores preoperatively or three months postoperatively between the two groups (Mann-Whitney *U* test) (see **Table 2**). There was significant difference in Merle D'Aubigne hip score two years postoperatively between the two groups (Mann-Whitney *U* test) (**Table 2**).

Table 2. Clinical Results

	Robotic Milling Group		Hand-Rasping Group		*P*
Clinical Results	**Mean**	**Range**	**Mean**	**Range**	
Merle D'Aubigne hip score					
Preoperative	10.1	6-14	9.8	5-16	.4828
3 mo	15.8	13-18	15.3	11-18	.0556
2 yr	17.4	14-18	17.1	14-18	<.05

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20.4.8.2 Serious Complications and Operative Risks

The authors report no serious complications such as sciatic nerve palsy, deep vein thrombosis, and infection in either group. No revisions were performed at the final follow-up in either group.

As shown in **Table 3**, there were significant differences in operative time (unpaired *t* test, $P < .0001$), femoral canal preparation time (unpaired *t* test, $P < .001$), and estimated blood loss (unpaired *t* test, $P < .01$) between groups. However, no patient received transfusion of allogeneic blood.

There were five intraoperative femoral fractures in the hand-rasping group (see **Table 3**); the difference in intraoperative femoral fracture between the two groups was significant (χ^2 test, $P < .05$). All the patients who had an intraoperative femoral fracture were females. All fractures occurred during the final insertion of the femoral stem. All fractures were undisplaced linear cracks (type A_2 in the Vancouver classification); that is, there were no severe fractures such as types A_3, B, and C in the Vancouver classification. All five patients with fractures were treated by cable cerclage, which consisted of removing the femoral stem, applying cerclage, and reinserting the femoral stem. Postoperatively, the five patients with fractures underwent conditioning consisting of six weeks of graduated weight bearing.

Table 3. Operative Risks

	Robotic Milling Group		Hand-Rasping Group		*P*
Operative Risks	**Mean**	**Range**	**Mean**	**Range**	
Operative time (min)	122	70-205	102	50-193	<.0001
Femoral canal prep time (min)	42	27-80	23	15-45	<.001
Estimated blood loss (mL)	527	150-1400	694	230-2665	<.01
Intraoperative femoral fracture	**Number Reported**				
Positive	0		5		
Negative	78		73		< .05

20.4.8.3 Post-Operative Ambulation and Thigh Pain

There were no significant differences in the time required to gain the ability to walk more than six blocks without a cane (Mann-Whitney *U* test) between groups (see **Table 4**).

The number of patients who gained the ability to walk more than six blocks without a cane within 13 days was significantly greater in the robotic milling group than in the hand-rasping group (χ^2 test, $P < .05$) (see **Table 4**).

Results of reported post-op thigh pain are shown in **Table 4**. There were no significant differences in thigh pain at one and three months between the two groups (χ^2 test).

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Table 4. Post-Operative Ambulation and Thigh Pain

	Robotic Milling Group		Hand-Rasping Group		
Post-Operative Ambulation					
	Mean	**Range**	**Mean**	**Range**	***P***
Time required to walk > 6 blocks without a cane (days)	14	7-31	16	7-46	.0552
Number pts to walk > 6 blocks without a cane (days)	**No. Pts.**		**No. Pts.**		
≤ 13	41		28		
≥ 14	37		50		< .05
Post-Operative Thigh Pain					
Thigh pain at 1 month					
Positive	4		11		
Negative	74		67		.0573
Thigh pain at 3 months					
Positive	2		3		
Negative	76		75		.6494

20.4.8.4 Agreement of the Type and Size of the Femoral Stem

In the hand-rasping group, there was significant disagreement between the type and size of stems that were implanted and those that were chosen in the preoperative plans (χ^2 test, $P < .01$) (see **Table 5**).

Table 5. Comparison in Agreement

	Robotic milling group	Hand-rasping group	*P*
Agreement of the type and size of the stem			
Agreement	78	71	
Disagreement	0	7	< .01

20.4.8.5 Differences in Radiographic Measurements between Preoperative Planning and Postoperative CT Images

Measurements for all hips are shown in Table 6. There were significant differences in the following measurements between preoperative planning and postoperative CT images: the medial gap at levels 1 to 3 (unpaired *t* test, $P < .0001$); the mediolateral canal filling ratio at levels 1 to 3 (unpaired *t* test, $P < .0001$), level 4 (unpaired *t* test, $P < .01$), and level 5 (unpaired *t* test, $P < .05$); the canal fill ratio at level 1 (unpaired *t* test, $P < .001$); anteroposterior alignment (unpaired *t* test, $P < .001$); femoral anteversion (unpaired *t* test, $P < .001$); and vertical seating (unpaired *t* test, $P < .0001$). The difference in vertical seating between the preoperative planning and postoperative CT images weakly correlated with the absolute value of the difference in femoral anteversion ($r = 0.37$).

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Table 6. Comparison in Differences Between Preoperative Planning and Postoperative CT Images

	Robotic milling group		Hand-rasping group		
	Mean	SD	Mean	SD	*P*
Medial gap (mm)					
Level 1	0.03	0.17	0.84	1.09	< .0001
Level 2	0.03	0.27	0.52	0.52	< .0001
Level 3	0	0.29	0.35	0.45	< .0001
Level 4	-0.02	0.19	0.03	0.21	.1471
Level 5	0.09	0.32	0.14	0.37	.3329
Lateral gap (mm)					
Level 1	-0.3	1.37	0.03	2.73	.353
Level 2	-0.24	1.26	0.28	2.26	.0797
Level 3	-0.23	0.81	0.17	1.62	.055
Level 4	-0.09	0.21	-0.04	0.2	.1718
Level 5	0	0.34	0.1	0.33	.0836
Mediolateral canal filling ratio (%)					
Level 1	0.7	2.8	-1.8	5.3	< .001
Level 2	1.3	4.0	-2.0	6.9	< .001
Level 3	1.7	3.4	-1.4	6.9	< .001
Level 4	1.4	1.7	0.3	2.6	< .01
Level 5	0.1	3.0	-1.0	3.0	< .05
Canal fill ratio (%)					
Level 1	4.4	3.3	2.2	4.5	< .001
Level 2	0.6	4.1	-0.7	5.6	.0903
Level 3	1.9	4.5	0.9	5.5	.205
Level 4	1.5	3.8	1.1	5.1	.5645
Level 5	0.6	4.5	1.1	5.9	.529
Mediolateral alignment (°)	0.2	1.1	0.1	1.4	.5994
Anteroposterior alignment (°)	0.1	1.4	0.9	1.4	< .001
Femoral anteversion (°)	-0.3	2.5	-3.9	8.5	< .001
Vertical seating (mm)	0.9	1.7	3.9	3.4	< .0001

20.4.8.6 Comparison of the Mediolateral Canal Filling Ratio, the Canal Fill Ratio, and the Alignment of the Femoral Stem from Preoperative Planning or Postoperative CT Images

Measurements for all hips are shown in Table 7. There was no significant difference in the mediolateral canal filling ratio, canal fill ratio, and alignment of the femoral stem from preoperative planning, except for the mediolateral canal filling ratio at level 5 (unpaired *t* test). However, the robotic milling group had a significantly better mediolateral canal filling ratio from postoperative CT images at levels 2, 3 (unpaired *t* test, $P < .05$), and 5 (unpaired *t* test, $P < .0001$). The robotic milling group also had a significantly better canal fill ratio from postoperative CT images at levels 1 and 3 (unpaired *t* test, $P < .05$). There was a significant difference in anteroposterior alignment from postoperative CT images (unpaired *t* test, $P < .0001$).

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Table 7. Comparison in Preoperative Planning or Postoperative CT Images

	Robotic milling group		Hand-rasping group		
	Mean	SD	Mean	SD	*P*
Preoperative planning					
Mediolateral canal					
filling ratio (%)					
Level 1	73	6.0	74	5.9	.5585
Level 2	80	7.5	80	6.8	.9231
Level 3	85	6.5	85	5.1	.9033
Level 4	91	3.2	92	2.5	.4783
Level 5	88	3.4	87	3.0	< .05
Canal fill ratio (%)					
Level 1	46	6.4	46	5.1	.8794
Level 2	58	8.2	57	7.5	.42
Level 3	67	9.0	65	8.2	.1053
Level 4	76	8.1	76	9.5	.9917
Level 5	61	9.1	61	11	.9325
Mediolateral alignment (°)	0.3	1.1	0.1	0.7	.1608
Anteroposterior alignment (°)	0.4	1.3	0.6	1.1	.2191
Postoperative CT images					
Mediolateral canal					
filling ratio (%)					
Level 1	74	6.0	72	6.1	.0536
Level 2	81	7.2	78	7.4	< .01
Level 3	86	6.2	83	6.9	< .01
Level 4	93	2.9	92	2.3	.4534
Level 5	88	2.8	86	2.9	<.0001
Canal fill ratio (%)					
Level 1	51	6.8	49	6.1	< .05
Level 2	59	8.3	56	7.6	.0655
Level 3	69	8.4	66	7.9	< .05
Level 4	78	7.8	77	8.5	.741
Level 5	61	7.6	62	9.4	.7726
Mediolateral alignment (°)	0.3	1.2	0.2	1.4	.4116
Anteroposterior alignment (°)	0.5	1.2	1.5	1.5	< .0001

20.4.8.7 Comparison after Excluding Patients with Femoral Fracture and Patients with Disagreement in the Type and Size of the Femoral Stem

In seven patients in the hand-rasping group, the implanted femoral stem was of a smaller size and type than the stem selected in the preoperative planning. After excluding these seven patients and the five patients with intraoperative femoral fracture, only one clinical result changed and showed no significant difference in the time required to gain the ability to walk more than six blocks without a cane. However, the robotic milling group still had significantly better radiographic results than the hand-rasping group in the medial gap at levels 1 to 3, mediolateral canal filling ratio at levels 1 to 5, canal fill ratio at level 1, anteroposterior alignment, femoral anteversion, and vertical seating.

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20.4.8.8 Radiographic Results on the Two-Year Postoperative Radiograph

All the hips of both groups demonstrated stable bony ingrowth according to the criteria of Engh et al [Clin Orthop 1990;261-63].

20.4.8.9 Discussion

In this study, the investigators compared the clinical effectiveness of robotic milling and hand-rasping. There was no significant difference in the Merle D'Aubigne hip score between the two groups at three months. These findings are consistent with the reports of Bargar et al and Honl et al. [**References available in published paper*, **Attachment 1**]. There were no significant differences in thigh pain or the time required to gain the ability to walk more than six blocks without a cane. However, the number of patients who gained the ability to walk more than six blocks without a cane within 13 days was significantly greater in the robotic milling group than in the hand-rasping group. Moreover, there was a significant difference in the Merle D'Aubigne hip score two years postoperatively between the two groups. This difference may be due to inferior radiographic accuracy of femoral canal preparation using a handheld rasp.

The operative time and femoral canal preparation time were significantly greater for the robotic milling group. The mean difference in both the operative time and femoral canal preparation time was 19 minutes. Thus, the increased surgical time of the robotic milling group was due to the increased femoral canal preparation time. This increased surgical time is consistent with the report of Bargar et al [*]. The estimated blood loss was significantly smaller for the robotic milling group. However, no patient in either group received a transfusion of allogeneic blood. Therefore, there appears to have been no significant difference in blood loss.

The radiographic evaluation in the robotic milling group was clearly superior to that of the hand-rasping group. At levels 1 to 3, differences in the medial gaps between the preoperative plan and postoperative CT images were significantly smaller in the robotic milling group than in the hand-rasping group (***Fig. available in published paper,* **Attachment 1**). In the robotic milling group, there were no significant differences in the lateral gaps between the preoperative plan and postoperative CT images. This may be due to the limitations of the rasping device. The rasp can cut the endocortical bone parallel to the orientation of the rasp. In fact, the lateral endocortical bone and the medial endocortical bone in the diaphysis can be cut, but the medial endocortical bone in Adams' arch cannot be completely cut and may have caused the significantly greater differences in vertical seating in the hand-rasping group. Moreover, the greater differences in femoral anteversion may be one of the causes of the higher vertical seating. The absolute value of the difference in femoral anteversion weakly correlated with the unexpectedly higher vertical seating. This suggests that a greater difference in femoral anteversion can cause impingement of the femoral stem on the medial endocortical bone, resulting in unexpectedly higher vertical seating of the femoral stem. Consistent with the present findings, Gossé et al. [*] found unexpectedly higher seating of the femoral stem in their hand-rasping group. Higher seating of the tapered stem in patients who undergo

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hand rasping can result in poorer fit and fill. In fact, at levels 1 to 5, the mediolateral canal filling ratios of the robotic milling group were significantly better than those of the hand-rasping group. At level 1, the canal fill ratios of the robotic milling group were significantly better than those of the hand-rasping group. Inferior proximal fit and fill can affect the magnitude of stress shielding and long-term clinical results. In contrast, robotic milling of the medial endocortical bone in the Adams' arch can achieve as accurate a fit, fill, and vertical seating as in the preoperative planning.

A large difference between the preoperative plan and postoperative CT images may not always cause worse fit, fill, and alignment. There is a need for further studies of the value of preoperative planning in THA. In the present study, except for the mediolateral canal filling ratio at level 5, there was no significant difference in fit, fill, or alignment of the femoral stem on the preoperative plan between the two groups. However, the robotic milling group had significantly better fit, fill, and alignment on postoperative CT images than the hand-rasping group. The hand-rasping group had a significantly greater difference between preoperative planning and postoperative CT images than the robotic milling group, and such differences appear to have caused the worse fit, fill, and alignment. Preoperative planning using ORTHODOC appears to be optimal.

Differences in anteroposterior alignment and femoral anteversion were significantly smaller in the robotic milling group than in the hand-rasping group. The femoral stem tended to be inserted less antevertedly in the hand-rasping group. There is a complex interaction among acetabular anteversion, acetabular abduction, and femoral anteversion in determining the safe range of motion of the hip from prosthetic impingement. An unexpected change in the femoral anteversion can cause instability of the hip, resulting in dislocation.

An advantage of robotic milling is its prevention of intraoperative femoral fractures. This finding is consistent with a report by Bargar et al [*]. With cementless femoral stems, the frequency of intraoperative femoral fracture reportedly ranges from 2% to 20% of cases [*]. In the present series, intraoperative femoral fractures occurred in the hand-rasping group at a rate of 6%. In contrast, there were no intraoperative femoral fractures in the robotic milling group. All present fractures were undisplaced linear cracks (type A_2 in the Vancouver classification); that is, no severe fractures were observed. Cementless tapered designs that depend on tight proximal fit appear to be associated with a higher incidence of proximal fractures [*]. Insertion of the final stem can result in a fracture caused by the wedging effect proximally as the surgeon attempts to achieve a press fit [*]. Rasping may cause canellous bone to become tight, as in impaction bone grafting, reducing resistance to fractures during insertion of the final stem. Larger differences in femoral anteversion may also cause impingement of the femoral stem on the medial endocortical bone at an unexpected high level, resulting in femoral fractures in some cases [*]. The authors report that in the present series, the surgeon tried to achieve a tight fit with the femoral stem according to the CT-based planning. In 9% of the hand-rasping group, undersized stems were selected because the surgeons felt it was better to have a too tight fit than to further enlarge the femoral canal. The fracture rate associated with rasping performed according to CT-based planning may be a factor for fractures.

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Of the patients in the hand-rasping group, 15% had either undersized implantation or intraoperative femoral fracture. After exclusion of those patients, the robotic milling group still had better radiographic results than the hand-raping group. Even if the size and type of femoral stem chosen in the preoperative plan could be inserted by a handheld rasp without intraoperative femoral fracture, the accuracy of the stem implantation according to the preoperative plan could be inferior to that obtained by robotic milling. These differences in radiographic findings may affect the long-term outcome.

20.4.9 Validation of 2-pin Registration Technology

The ROBODOC® Surgical System was modified to allow a less invasive technology that required 2, rather than 3, locator pins to be placed pre-operatively in order to register the location and orientation of robotic arm in relationship to the operative femur. Validation of the 2-pin registration technology was based, in part, on the results of this study, which compared the outcomes of hand-rasping and robotic milling with three-dimensional preoperative planning using the ORTHODOC system.

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Attachment 3

Nishihara S, Sugano N, Nishii T, Miki H, Nakamura N, and Yoshikawa H.
Comparison Between Hand Rasping and Robotic Milling for Stem Implantation in Cementless Total Hip Arthroplasty
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Comparison Between Hand Rasping and Robotic Milling for Stem Implantation in Cementless Total Hip Arthroplasty

Shunsaku Nishihara, MD,* Nobuhiko Sugano, MD,† Takashi Nishii, MD,* Hidenobu Miki, MD,* Nobuo Nakamura, MD,† and Hideki Yoshikawa, MD*

Abstract: We evaluated the effects of conventional hand rasping and robotic milling on the clinical and radiographic results of cementless total hip arthroplasty, with the same computed tomography (CT)–based 3-dimensional preoperative planning using a ROBODOC workstation (Integrated Surgical Systems, Davis, Calif). The robotic milling group consisted of 78 hips, and the hand-rasping group 78 hips. The radiographic findings from the preoperative planning and postoperative CT data were evaluated using the most accurate CT images reconstructed by the ROBODOC workstation. The robotic milling group showed significant superior Merle D'Aubigne hip score at 2 years. In the robotic milling group, there were no intraoperative femoral fractures, and a radiographically superior implant fit was obtained. Hand rasping had the potential to cause intraoperative femoral fractures, undersizing of the stem, unexpectedly higher vertical seating, and unexpected femoral anteversion causing inferior implant fit. **Key words:** ROBODOC, ORTHODOC, femoral canal preparation, comparison between hand rasping and robotic milling, cementless total hip arthroplasty.
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Fit and fill of cementless femoral stems in the femoral canal are important factors for stable fixation and good clinical results in many types of cementless total hip arthroplasty (THA) [1-6]. As one of the options to obtain optimal fit and fill of cementless femoral stems, the ROBODOC system (Integrated Surgical Systems, Davis, Calif) was developed [7,8]. This system consists of a preoperative planning computer workstation (ORTHODOC, Integrated Surgical Systems, Davis, Calif) and a robotic arm equipped with a high-speed milling device to prepare the femoral canal. This system is an active robot that moves a milling device automatically, independent of an operator, according to preoperative planning [7]. ORTHODOC provides precise 3-dimensional information on fit and fill of the femoral stem in the femoral canal using computed tomography (CT) images and helps the surgeon to decide the optimal position and size of a femoral stem. Computed tomography–based planning is more accurate than conventional x-ray template preoperative planning because magnification and shape of the femoral canal on x-rays are highly variable depending on the x-ray technique [9-11]. Based on CT-based planning, the milling path for preparation of the femoral canal can be visualized using ORTHODOC, so that the surgeon can ensure that the path avoids interference with important structures such as the greater trochanter. After approval of the plan by the surgeon, ROBODOC precisely executes femoral canal milling according to the plan, using robotic machining intraoperatively [7,8].

*From the *Department of Orthopaedic Surgery, Osaka University Medical School, Suita, Osaka, Japan; and †Center of Arthroplasty, Kyowakai Hospital, Suita, Osaka, Japan.*
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Reprint requests: Shunsaku Nishihara, MD, Department of Orthopaedic Surgery, Osaka University Medical School, 2-2 Yamadaoka, Suita, Osaka 565-0871, Japan.
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In previous studies comparing robotic implantation of a femoral stem with conventional manual implantation [7,12], differences in outcome could be attributed to 2 factors. The first factor is the difference in preoperative planning between the conventional x-ray template method and the CT-based 3-dimensional preoperative planning. The second factor is the difference in surgical procedure between conventional hand rasping and robotic milling. There have been no previous reports of a pure comparison between conventional hand rasping and robotic milling using the same CT-based 3-dimensional preoperative planning.

The purpose of the present study was to compare clinical and radiographic results between hand rasping and robotic milling, based on the same 3-dimensional preoperative planning using ORTHODOC.

Materials and Methods

From September 2000 to September 2002, a total of 156 primary cementless THAs were performed on 140 patients at our 2 institutions. The indications were good bone quality (Dorr type A or B) [13] and Crowe class I, II, or III (0%-100% subluxation of the hip) [14]. Patients with poor bone quality (Dorr type C) were excluded because of the need for use of cement. Patients with Crowe class IV (>100% subluxation of the hip) were excluded because of the need for subtrochanteric osteotomy to be included in the surgery. Each patient was randomly assigned into the hand-rasping or robotic milling group. The patients' demographics are given in Table 1. The robotic milling group comprised 73 patients who underwent 78 primary THAs using the 2-pin–based procedure of the ROBODOC system. The diagnoses of the robotic milling group were as follows: degenerative arthritis secondary to hip dysplasia in 74 hips, osteonecrosis in 3 hips, and rheumatoid arthritis in 1 hip. The hand-rasping group comprised 67 patients who underwent 78 primary THAs. The diagnoses of the hand-rasping group were as follows: degenerative arthritis secondary to hip dysplasia in 73 hips, osteonecrosis in 4 hips, and rheumatoid arthritis in 2 hips. There was no significant difference in age (Mann-Whitney *U* test) or sex ratio (χ^2 test) between the 2 groups. This study was approved by the Institutional Internal Clinical Research Committees of our 2 institutions. Informed consent was obtained from all patients after the nature of the procedure had been fully explained.

Table 1. Demographics of Patients Used for Comparison

	No. of Patients (Femora)	Sex (Male/Female)	Age (y)*
Robotic milling group	73 (78)	14: 64†	58 (27-81)‡
Hand-rasping group	67 (78)	14: 64†	58 (29-77)‡

*Values represent average (range).
†Difference was not statistically significant (χ^2 test).
‡Difference was not statistically significant (Mann-Whitney *U* test).

All THAs were performed via the posterolateral approach, with the patient in the lateral decubitus position. VerSys fiber metal taper hydroxyapatite-coated femoral stems (Zimmer, Warsaw, Ind) were used in all THAs. The VerSys fiber metal taper femoral stem is a straight stem, with a symmetry plane that contains the femoral stem axis and the neck axis. The femoral stem has 2 variations in the proximal metaphysis: standard and large metaphysis.

In the robotic milling group, CT images of the femur were taken after 1 locator pin was inserted into the greater trochanter of the affected femur and the other locator pin was inserted into the lateral condyle. Three-dimensional preoperative planning (described hereinafter) was performed based on the CT data on the ORTHODOC, and the milling path was transferred to the robot controller. Intraoperatively, the 2 groups had the same length of skin incision for the hip (12-15 cm), except for the extra skin incision for the knee pin. After the leg was secured in the leg holder and the femur was rigidly attached to the robot base with the femoral external fixator, intraoperative pin-based registration using the 2 locator pins was performed. The robot milled the inside of the femoral canal according to the preoperative plan. Surgeons inserted and impacted the femoral stem manually.

In the hand-rasping group, CT images of the femur were taken preoperatively. The CT data were transferred to the ORTHODOC, which was used for the 3-dimensional preoperative planning described below. After surgeons obtained information about the position and size of the femoral stem, the femur was prepared using a handheld rasp. Surgeons inserted and impacted the femoral stem manually.

Three-dimensional preoperative planning in the 2 groups was performed as follows [15,16]. Because 3 arbitrarily selected orthogonal planner reconstructed images of the CT data could be displayed on ORTHODOC, the center of the femoral head was at first located using a circle drawing tool to encompass the femoral head contour. The femur was reoriented on the workstation to obtain the

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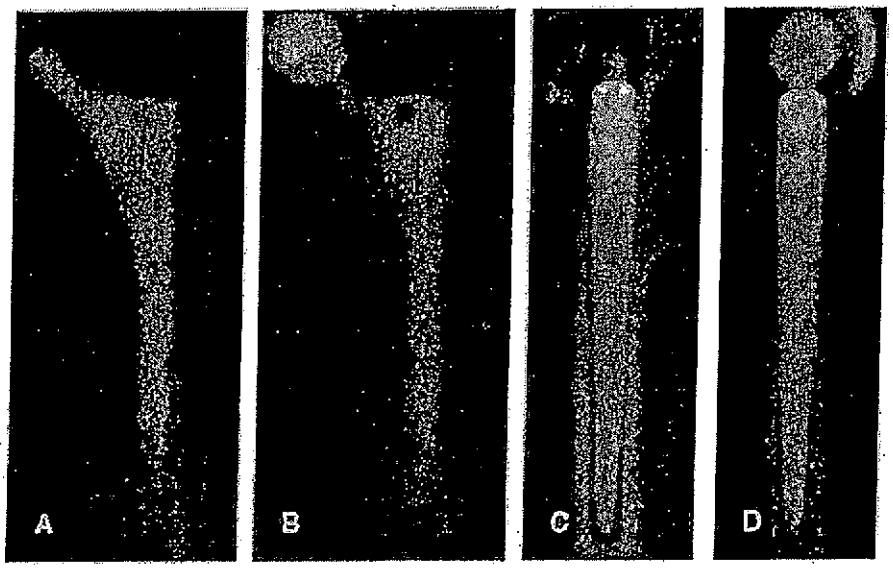

Fig. 1. A 47-year-old woman with degenerative arthritis underwent THA using the ROBODOC system. A, Anteroposterior synthetic radiograph from preoperative planning. B, Anteroposterior synthetic radiograph reconstructed from postoperative CT data. C, Lateral synthetic radiograph from preoperative planning. D, Lateral synthetic radiograph reconstructed from postoperative CT data.

coronal plane that passed through the head center and the proximal femoral medullary axis. Then, the sagittal plane through the medullary axis was obtained. A femoral stem of the maximum size that would not overream the endosteal cortical bone was selected and virtually implanted into the femoral canal. The type of proximal metaphysis (standard or large metaphysis) was chosen, which would achieve the required limb length. Each preoperative plan was discussed by 2 of the senior authors until a consensus was obtained.

The clinical results for each patient were assessed according to the Merle D'Aubigne hip score [17], in which up to 6 points each are given for pain, motion, and gait. These scores were obtained preoperatively, 3 months postoperatively, and 2 years postoperatively. We monitored the operative time, femoral canal preparation time, estimated blood loss, donation of allogeneic blood, intraoperative femoral fractures, and complication. Intraoperative femoral fractures were classified according to the Vancouver classification [18]. Allogeneic blood units were transfused based on a variety of criteria, including clinical symptoms, hemodynamic stability, and whether the hematocrit fell below 24%. The decision whether to perform a transfusion was made by the operating surgeon. In the hand-rasping group, the femoral canal preparation time was defined as the duration of the hand rasping. In the robotic milling group, the femoral canal preparation time was defined as the combined duration of positioning of the robot, registration, and milling. Physical therapy with full-weight bearing, as tolerated, was initiated on the third postoperative day. We recorded the duration of rehabilitation required to gain the ability to walk

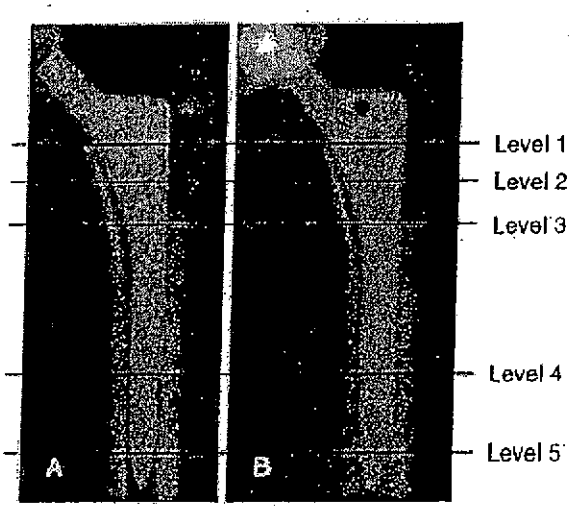

Fig. 2. The 5 lines indicate levels 1 to 5. A, Anteroposterior synthetic radiograph from preoperative planning. B, Anteroposterior synthetic radiograph reconstructed from postoperative CT data.

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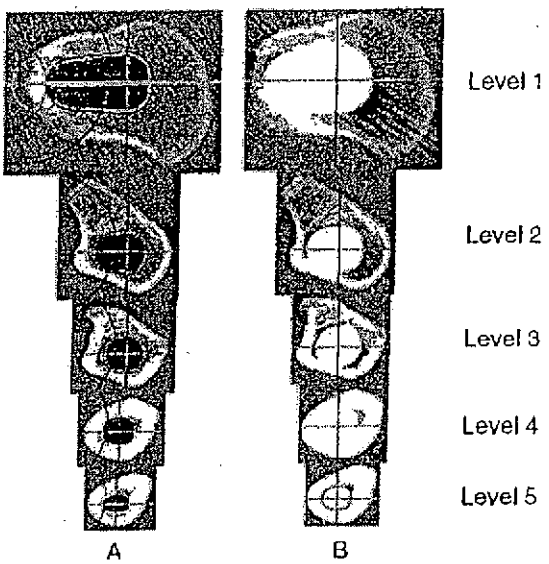

Fig. 3. Axial cross-sectional images of the proximal femur perpendicular to the symmetry plane of the femoral stem were reconstructed at levels 1 to 5. A, Axial images from preoperative planning. The line around the cross-sectional image of the femoral stem shows the milling path of the ROBODOC. The milling path in the metaphyseal stem is undersized by 0.5 mm, and the milling path in the diaphyseal stem is oversized by 0.5 mm, to achieve proximal tight fixation. B, Axial images reconstructed from postoperative CT data.

more than 6 blocks, corresponding to 500 m, without a cane [19]. Clinical measurements were compared between the 2 groups.

Radiographic evaluation using reconstructed CT images was performed preoperatively and at 1 month after THA. We reconstructed anteroposterior synthetic radiographs of the proximal femur parallel to the symmetry plane of the femoral stem (Figs. 1 and 2), lateral synthetic radiographs of the proximal femur perpendicular to the symmetry plane of the femoral stem (Fig. 1), and axial images of the femur perpendicular to the femoral stem axis (Fig. 3), using the ORTHODOC and the CT data. These reconstructed CT images were created using both preoperative and postoperative CT data. The synthetic anteroposterior radiographs were used to evaluate the mediolateral alignment of the femoral stem (angle between the femoral stem axis and the proximal femoral canal axis), the medial gap between the medial endocortical bone and the femoral stem, the lateral gap between the femoral stem and the lateral cortical bone, and the mediolateral canal filling ratio of the femoral stem (percentage of canal occupied by the femoral stem) at the following 5 levels (Fig. 2): the lower corner of the femoral neck cut (level 1), the center of the lesser trochanter (level 2), 1.5 cm distal from the center of the lesser trochanter (level 3), 4.5 cm proximal from the femoral component tip (level 4), and 1.5 cm proximal from the femoral component tip (level 5). Synthetic lateral radiographs were used to evaluate anteroposterior alignment of the femoral stem (angle between the femoral stem axis and the proximal femoral canal axis). Axial images of the femur were used to evaluate the vertical seating (vertical distance from the femoral stem shoulder to the center of the lesser trochanter) and canal fill ratio of the femoral stem (ratio of femoral stem area to the total medullary cavity area) at all 5 levels (Fig. 3). Femoral anteversion was defined as the angle between the stem neck axis and the table plane including the posterior condyles and the most prominent posterior point of the greater trochanter [20,21]. The observers who performed the radiographic analysis were blinded to which group each patient belonged.

The type and size of each implanted femoral stem was compared with those chosen in the preoperative plans. Differences in the radiographic measurements between values from preoperative

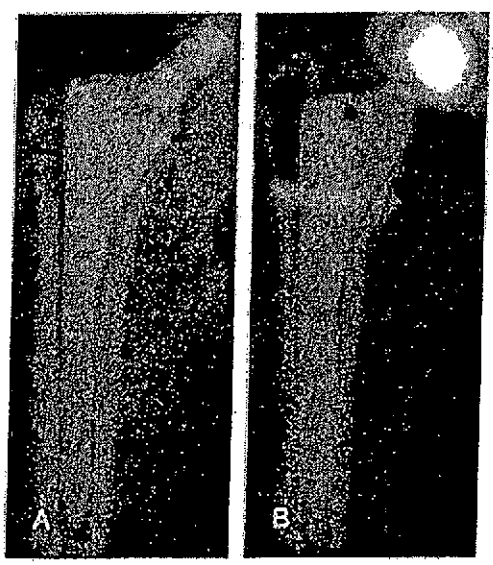

Fig. 4. A 77-year-old woman with degenerative arthritis underwent THA using a handheld rasp and had an intraoperative femoral fracture. A, Anteroposterior synthetic radiograph of the proximal femur from preoperative planning. B, Anteroposterior synthetic radiograph reconstructed from CT data obtained 1 month postoperatively.

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Fig. 5. A 53-year-old man with degenerative arthritis underwent THA using a handheld rasp. A, Anteroposterior synthetic radiograph of the proximal femur from preoperative planning. B, Anteroposterior synthetic radiograph reconstructed from CT data obtained 1 month postoperatively.

planning and measurements from postoperative CT images were compared between the 2 groups. We calculated Pearson's correlation coefficient for the difference in vertical seating and the absolute value of the difference in femoral anteversion between the preoperative plan and the postoperative CT images to evaluate the effect of larger differences in femoral anteversion on unexpectedly higher vertical seating. Next, we compared the mediolateral canal filling ratio, the canal fill ratio, and the alignment of the femoral stem from preoperative planning or postoperative CT images between the 2 groups. Finally, the clinical results and the differences in radiographic measurements between values from preoperative planning and measurements from postoperative CT images were compared between the 2 groups, after excluding the 2 patients with intraoperative femoral fracture and those for whom there was a difference in the type and size of the femoral stem between the preoperative plans and the postoperative results.

Radiographic evaluation included measurement of implant-bone interface. The implant-bone interface was estimated on the 2-year postoperative radiograph as stable bony ingrowth, stable fibrous ingrowth, or unstable, using the criteria of Engh et al [4].

For statistical analysis, we used the unpaired t test, the Mann-Whitney U test, the χ^2 test, and the Pearson's correlation coefficient. Differences were considered significant when the P value was less than .05.

Results

One patient of the robotic milling group was lost at the final follow-up. Four patients of the hand-rasping group were lost at the final follow-up. One patient (2 hips) of the hand-rasping group died with lung cancer during follow-up period. Complete clinical follow-up including evaluation on the 2-year postoperative radiograph was available for 77 hips in the robotic milling group and 72 hips in the hand-rasping group. Radiographic evaluation using reconstructed CT images obtained preoperatively and at 1 month after THA was available for all the hips. The mean follow-up was 2.3 years (range, 2-3.6 years).

Clinical Results

There were no significant differences in Merle D'Aubigne hip scores preoperatively or 3 months postoperatively between the 2 groups (Mann-Whitney U test) (Table 2). There was significant difference in Merle D'Aubigne hip score 2 years postoperatively between the 2 groups (Mann-Whitney U test) (Table 2). There were significant

Table 2. Comparison in the Clinical Results

	Robotic milling group		Hand-rasping group		
	Mean	Range	Mean	Range	P
Merle D'Aubigne hip score					
Preoperative	10.1	6-14	9.8	5-16	.4828
3 mo	15.8	13-18	15.3	11-18	.0556
2 y	17.4	14-18	17.1	14-18	<.05
Operative time (min)	122	70-205	102	50-193	<.0001
Femoral canal preparation time (min)	42	27-80	23	15-45	<.001
Estimated blood loss (mL)	527	150-1400	694	230-2665	<.01
Duration of gaining walking ability (d)	14	7-31	16	7-46	.0552

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Table 3. Comparison in the Duration of Gaining Walking Ability, Thigh Pain, Fracture, and Agreement

	Robotic milling group	Hand-rasping group	*P*
Duration of gaining walking ability (d)			
≦13	41	28	
≧14	37	50	<.05
Thigh pain at 1 mo			
Positive	4	11	
Negative	74	67	.0573
Thigh pain at 3 mo			
Positive	2	3	
Negative	76	75	.6494
Intraoperative femoral fracture			
Positive	0	5	
Negative	78	73	<.05
Agreement of the type and size of the stem			
Agreement	78	71	
Disagreement	0	7	<.01

differences in operative time (unpaired *t* test, $P < .0001$), femoral canal preparation time (unpaired *t* test, $P < .001$); and estimated blood loss (unpaired *t* test, $P < .01$) (Table 2). However, no patient received a transfusion of allogeneic blood. There were no significant differences in the time required to gain the ability to walk more than 6 blocks without a cane (Mann-Whitney *U* test) (Table 2).

The number of patients who gained the ability to walk more than 6 blocks without a cane within 13 days was significantly greater in the robotic milling group than in the hand-rasping group (χ^2 test, $P < .05$) (Table 3). There were no significant differences in thigh pain at 1 and 3 months between the 2 groups (χ^2 test) (Table 3).

There were 5 intraoperative femoral fractures in the hand-rasping group (Fig. 4) and none in the robotic milling group (Table 3); the difference in intraoperative femoral fracture between the 2 groups was significant (χ^2 test, $P < .05$). All the patients who had an intraoperative femoral fracture were females. All fractures occurred during the final insertion of the femoral stem. All fractures were undisplaced linear cracks (type A_2 in the Vancouver classification) [18]; that is, there were no severe fractures such as types A_3, B, and C in the Vancouver classification. All 5 patients with fractures were treated by cable cerclage, which consisted of removing the femoral stem, applying cerclage, and reinserting the femoral stem. Postoperatively, the 5 patients with fractures underwent

Table 4. Comparison in Differences Between Preoperative Planning and Postoperative CT Images

	Robotic milling group		Hand-rasping group		
	Mean	SD	Mean	SD	*P*
Medial gap (mm)					
Level 1	0.03	0.17	0.84	1.09	<.0001
Level 2	0.03	0.27	0.52	0.52	<.0001
Level 3	0	0.29	0.35	0.45	<.0001
Level 4	−0.02	0.19	0.03	0.21	.1471
Level 5	0.09	0.32	0.14	0.37	.3329
Lateral gap (mm)					
Level 1	−0.3	1.37	0.03	2.73	.353
Level 2	−0.24	1.26	0.28	2.26	.0797
Level 3	−0.23	0.81	0.17	1.62	.055
Level 4	−0.09	0.21	−0.04	0.2	.1718
Level 5	0	0.34	0.1	0.33	.0836
Mediolateral canal filling ratio (%)					
Level 1	0.7	2.8	−1.8	5.3	<.001
Level 2	1.3	4.0	−2.0	6.9	<.001
Level 3	1.7	3.4	−1.4	6.9	<.001
Level 4	1.4	1.7	0.3	2.6	<.01
Level 5	0.1	3.0	−1.0	3.0	<.05
Canal fill ratio (%)					
Level 1	4.4	3.3	2.2	4.5	<.001
Level 2	0.6	4.1	−0.7	5.6	.0903
Level 3	1.9	4.5	0.9	5.5	.205
Level 4	1.5	3.8	1.1	5.1	.5645
Level 5	0.6	4.5	1.1	5.9	.529
Mediolateral alignment (°)	0.2	1.1	0.1	1.4	.5994
Anteroposterior alignment (°)	0.1	1.4	0.9	1.4	<.001
Femoral anteversion (°)	−0.3	2.5	−3.9	8.5	<.001
Vertical seating (mm)	0.9	1.7	3.9	3.4	<.0001

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Table 5. Comparison in Preoperative Planning or Postoperative CT Images

	Robotic milling group		Hand-rasping group		
	Mean	SD	Mean	SD	*P*
Preoperative planning					
Mediolateral canal filling ratio (%)					
Level 1	73	6.0	74	5.9	.5585
Level 2	80	7.5	80	6.8	.9231
Level 3	85	6.5	85	5.1	.9033
Level 4	91	3.2	92	2.5	.4783
Level 5	88	3.4	87	3.0	<.05
Canal fill ratio (%)					
Level 1	46	6.4	46	5.1	.8794
Level 2	58	8.2	57	7.5	.42
Level 3	67	9.0	65	8.2	.1053
Level 4	76	8.1	76	9.5	.9917
Level 5	61	9.1	61	11	.9335
Mediolateral alignment (°)	0.3	1.1	0.1	0.7	.1608
Anteroposterior alignment (°)	0.4	1.3	0.6	1.1	.2191
Postoperative CT Images					
Mediolateral canal filling ratio (%)					
Level 1	74	6.0	72	6.1	.0536
Level 2	81	7.2	78	7.4	<.01
Level 3	86	6.2	83	6.9	<.01
Level 4	93	2.9	92	2.3	.4534
Level 5	88	2.8	86	2.9	<.0001
Canal fill ratio (%)					
Level 1	51	6.8	49	6.1	<.05
Level 2	59	8.3	56	7.6	.0655
Level 3	69	8.4	66	7.9	<.05
Level 4	78	7.8	77	8.5	.741
Level 5	61	7.6	62	9.4	.7726
Mediolateral alignment (°)	0.3	1.2	0.2	1.4	.4116
Anteroposterior alignment (°)	0.5	1.2	1.5	1.5	<.0001

conditioning consisting of 6 weeks of graduated weight bearing.

We had no serious complications such as sciatic nerve palsy, deep vein thrombosis, and infection. No revisions were performed at the final follow-up.

Agreement of the Type and Size of the Femoral Stem

In the hand-rasping group, there was significant disagreement between the type and size of stems that were implanted and those that were chosen in the preoperative plans (χ^2 test, $P < .01$) (Table 3).

Differences in Radiographic Measurements Between Preoperative Planning and Postoperative CT Images

Measurements for all hips are shown in Table 4. There were significant differences in the following measurements between preoperative planning and postoperative CT images: the medial gap at levels 1 to 3 (unpaired t test, $P < .0001$); the mediolateral canal filling ratio at levels 1 to 3 (unpaired t test, $P < .0001$), level 4 (unpaired t test, $P < .01$), and level 5 (unpaired t test, $P < .05$); the canal fill ratio at level 1 (unpaired t test, $P < .001$); anteroposterior alignment (unpaired t test, $P < .001$); femoral anteversion (unpaired t test, $P < .001$); and vertical seating (unpaired t test, $P < .0001$). The difference in vertical seating between the preoperative planning and postoperative CT images weakly correlated with the absolute value of the difference in femoral anteversion ($r = 0.37$).

Comparison of the Mediolateral Canal Filling Ratio, the Canal Fill Ratio, and the Alignment of the Femoral Stem from Preoperative Planning or Postoperative CT Images

Measurements for all hips are shown in Table 5. There was no significant difference in the mediolateral canal filling ratio, canal fill ratio, and alignment of the femoral stem from preoperative planning, except for the mediolateral canal filling ratio at level 5 (unpaired t test). However, the robotic milling group had a significantly better mediolateral canal filling ratio from postoperative CT images at levels 2, 3 (unpaired t test, $P < .05$), and 5 (unpaired t test, $P < .0001$). The robotic milling group also had a significantly better canal fill ratio from postoperative CT images at levels 1 and 3 (unpaired t test, $P < .05$). There was a significant difference in anteroposterior alignment from postoperative CT images (unpaired t test, $P < .0001$).

Comparison After Excluding Patients with Femoral Fracture and Patients with Disagreement in the Type and Size of the Femoral Stem

In 7 patients in the hand-rasping group, the implanted femoral stem was of a smaller size and type than the stem selected in the preoperative planning. After excluding these 7 patients and the 5 patients with intraoperative femoral fracture, only 1 clinical result changed and showed no significant difference in the time required to gain the ability to walk more than 6 blocks without a cane. However, the robotic milling group still had significantly better radiographic results than the hand-rasping group in the medial gap at levels 1 to 3, mediolateral canal filling ratio at levels 1 to 5, canal fill ratio at level 1, anteroposterior alignment, femoral anteversion, and vertical seating.

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Radiographic Results on the 2-Year Postoperative Radiograph

All the hips of both groups demonstrated stable bony ingrowth according to the criteria of Engh et al [4].

Discussion

In the present study, we compared the clinical effectiveness of robotic milling and hand rasping. There was no significant difference in the Merle D'Aubigne hip score between the 2 groups at 3 months. These findings are consistent with the reports of Bargar et al [7] and Honl et al [12]. There were no significant differences in thigh pain or the time required to gain the ability to walk more than 6 blocks without a cane. However, the number of patients who gained the ability to walk more than 6 blocks without a cane within 13 days was significantly greater in the robotic milling group than in the hand-rasping group. Moreover, there was a significant difference in the Merle D'Aubigne hip score 2 years postoperatively between the 2 groups. These may be due to inferior radiographic accuracy of femoral canal preparation using a handheld rasp.

The operative time and femoral canal preparation time were significantly greater for the robotic milling group. The mean difference in both the operative time and femoral canal preparation time was 19 minutes. Thus, the increased surgical time of the robotic milling group was due to the increased femoral canal preparation time. This increased surgical time is consistent with the report of Bargar et al [7]. The estimated blood loss was significantly smaller for the robotic milling group. However, no patient in either group received a transfusion of allogeneic blood. Therefore, there appears to have been no significant difference in blood loss.

The radiographic evaluation in the robotic milling group was clearly superior to that of the hand-rasping group. At levels 1 to 3, differences in the medial gaps between the preoperative plan and postoperative CT images were significantly smaller in the robotic milling group than in the hand-rasping group (Fig. 5). In the robotic milling group, there were no significant differences in the lateral gaps between the preoperative plan and postoperative CT images. This may be due to the limitations of the rasping device. The rasp can cut the endocortical bone parallel to the orientation of the rasp. In fact, the lateral endocortical bone and the medial endocortical bone in the diaphysis can be cut, but the medial endocortical bone in Adams' arch cannot be completely cut and may have caused the significantly greater differences in vertical seating in the hand-rasping group. Moreover, the greater difference in femoral anteversion may be one of the causes of the higher vertical seating. The absolute value of the difference in femoral anteversion weakly correlated with the unexpectedly higher vertical seating. This suggests that a greater difference in femoral anteversion can cause impingement of the femoral stem on the medial endocortical bone, resulting in unexpectedly higher vertical seating of the femoral stem. Consistent with the present findings, Gossé et al [22] found unexpectedly higher seating of the femoral stem in their hand-rasping group. Higher seating of the tapered stem in patients who undergo hand rasping can result in poorer fit and fill. In fact, at levels 1 to 5, the mediolateral canal filling ratios of the robotic milling group were significantly better than those of the hand-rasping group. At level 1, the canal fill ratios of the robotic milling group were significantly better than those of the hand-rasping group. Inferior proximal fit and fill can affect the magnitude of stress shielding and long-term clinical results. In contrast, robotic milling of the medial endocortical bone in Adams' arch can achieve as accurate a fit, fill, and vertical seating as in the preoperative planning.

A large difference between the preoperative plan and postoperative CT images may not always cause worse fit, fill, and alignment. There is a need for further studies of the value of preoperative planning in THA. In the present study, except for the mediolateral canal filling ratio at level 5, there was no significant difference in fit, fill, or alignment of the femoral stem on the preoperative plan between the 2 groups. However, the robotic milling group had significantly better fit, fill, and alignment on postoperative CT images than the hand-rasping group. The hand-rasping group had a significantly greater difference between preoperative planning and postoperative CT images than the robotic milling group, and such differences appear to have caused the worse fit, fill, and alignment. Preoperative planning using ORTHODOC appears to be optimal.

Differences in anteroposterior alignment and femoral anteversion were significantly smaller in the robotic milling group than in the hand-rasping group. The femoral stem tended to be inserted less antevertedly in the hand-rasping group. There is a complex interaction among acetabular anteversion, acetabular abduction, and femoral anteversion in determining the safe range of motion of the hip from prosthetic impingement [23,24]. An

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unexpected change in the femoral anteversion can cause instability of the hip, resulting in dislocation.

An advantage of robotic milling is its prevention of intraoperative femoral fractures. This finding is consistent with a report by Bargar et al [7]. With cementless femoral stems, the frequency of intraoperative femoral fracture reportedly ranges from 2% to 20% of cases [7,25-27]. In the present series, intraoperative femoral fractures occurred in the hand-rasping group at a rate of 6%. In contrast, there were no intraoperative femoral fractures in the robotic milling group. All present fractures were undisplaced linear cracks (type A_2 in the Vancouver classification) [18]; that is, no severe fractures were observed. Cementless tapered designs that depend on tight proximal fit appear to be associated with a higher incidence of proximal fractures [26]. Insertion of the final stem can result in a fracture caused by the wedging effect proximally as the surgeon attempts to achieve a press fit [25-27]. Rasping may cause cancellous bone to become tight, as in impaction bone grafting, reducing resistance to fractures during insertion of the final stem. Larger differences in femoral anteversion may also cause impingement of the femoral stem on the medial endocortical bone at an unexpected high level, resulting in femoral fractures in some cases [27]. In the present series, the surgeon tried to achieve a tight fit with the femoral stem according to the CT-based planning. In 9% of the hand-rasping group, undersized stems were selected because the surgeons felt too tight to go further enlargement of the femoral canal. The fracture rate associated with rasping performed according to CT-based planning may be a factor for fractures.

Of the patients in the hand-rasping group, 15% had either undersized implantation or intraoperative femoral fracture. After exclusion of those patients, the robotic milling group still had better radiographic results than the hand-rasping group. Even if the size and type of femoral stem chosen in the preoperative plan could be inserted by a handheld rasp without intraoperative femoral fracture, the accuracy of stem implantation according to the preoperative plan could be inferior to that obtained by robotic milling. These differences in radiographic findings may affect the long-term outcome.

New technology should also be evaluated in terms of cost-effectiveness. The cost of a complete ROBODOC system is approximately US$600 000 [7]. In contrast, the cost of a hand-rasping implant system is much lower. The present study showed no significant difference in the near-term clinical results between hand rasping and robotic milling. However, the robotic milling group had no intraoperative femoral fractures and had better fit, fill, and alignment in the radiographic findings. These advantages can help delay or eliminate costly repeat surgery in the longer term [28]. Moreover, the volume of intraoperative pulmonary embolisms can be reduced by robotic milling in the near term [29]. Therefore, a complete cost-benefit evaluation of robotic surgery requires consideration of longer-term outcomes.

The present study had 1 limitation: the short duration of follow-up. The robotic milling group showed superior radiographic findings according to the reconstructed CT images and significant superior Merle D'Aubigne hip score at 2 years. However, all the stems in the 2 groups achieved stable bony ingrowth at 2 years. It may be difficult to draw some conclusions about the advantages and disadvantages of the robotic milling or hand-rasping systems with a 2-year follow-up. In future studies, we will use longer-term follow-up periods to clarify whether the better radiographic results and elimination of fractures achieved by robotic milling will lead to significant long-term improvement.

The present study compared the outcomes of hand-rasping and robotic milling with 3-dimensional preoperative planning using the ORTHODOC system. The radiographic findings in the preoperative planning and postoperative results were evaluated using the most accurate reconstructed CT images. The robotic milling group showed significant superior Merle D'Aubigne hip score at 2 years. The results also showed that robotic milling had the advantages of no intraoperative femoral fractures and showed radiographically superior implant fit to delay or eliminate costly repeat surgery in the longer term. Hand rasping has the potential of intraoperative femoral fractures, undersizing of the femoral stem, unexpectedly higher vertical seating, and unexpected femoral anteversion to cause inferior implant fit and instability.

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20.5 Summary: TR98-07-011, Validation of "Pinless" ROBODOC®

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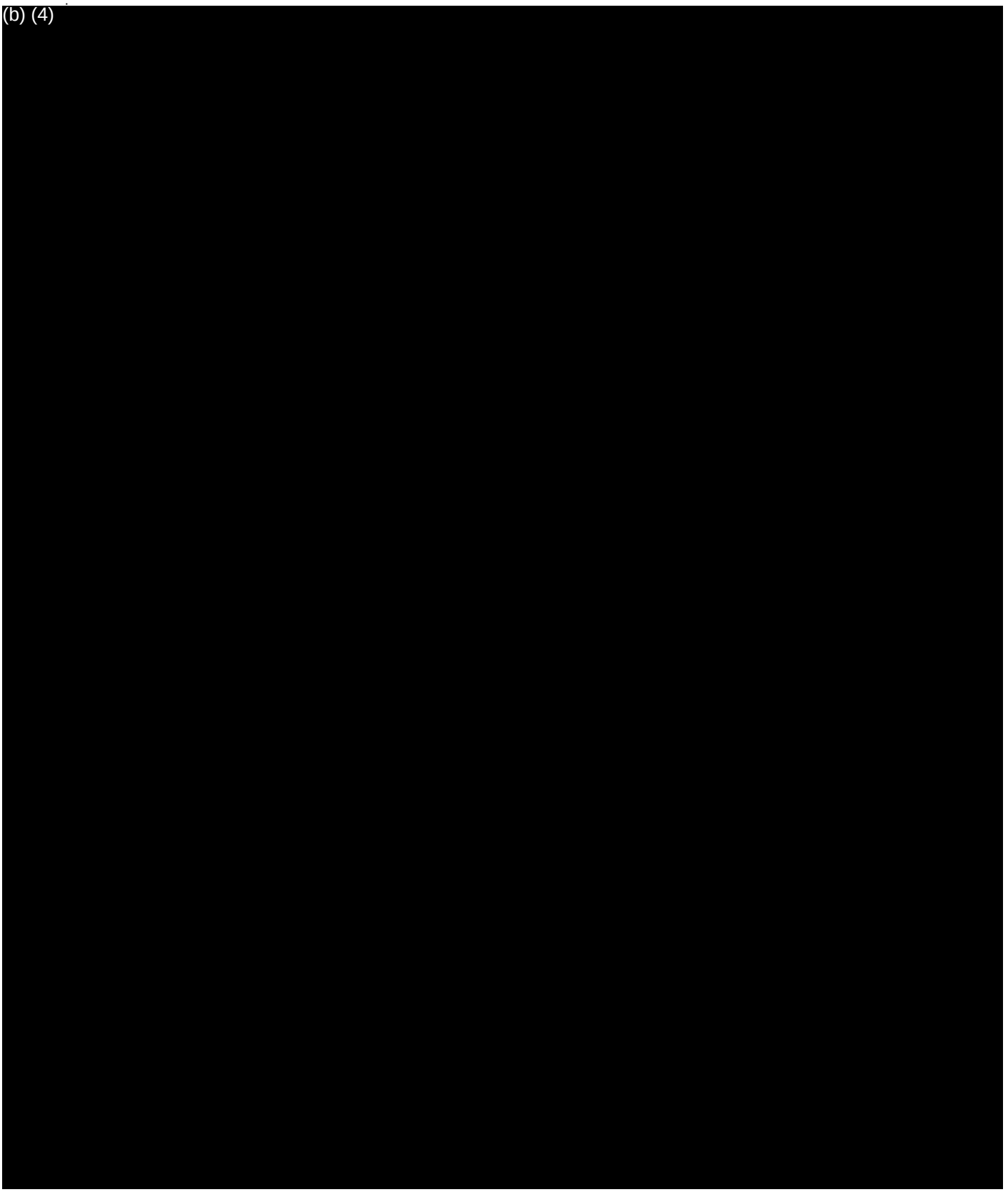

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Table 1 Summary of Implant Placement (Summary)

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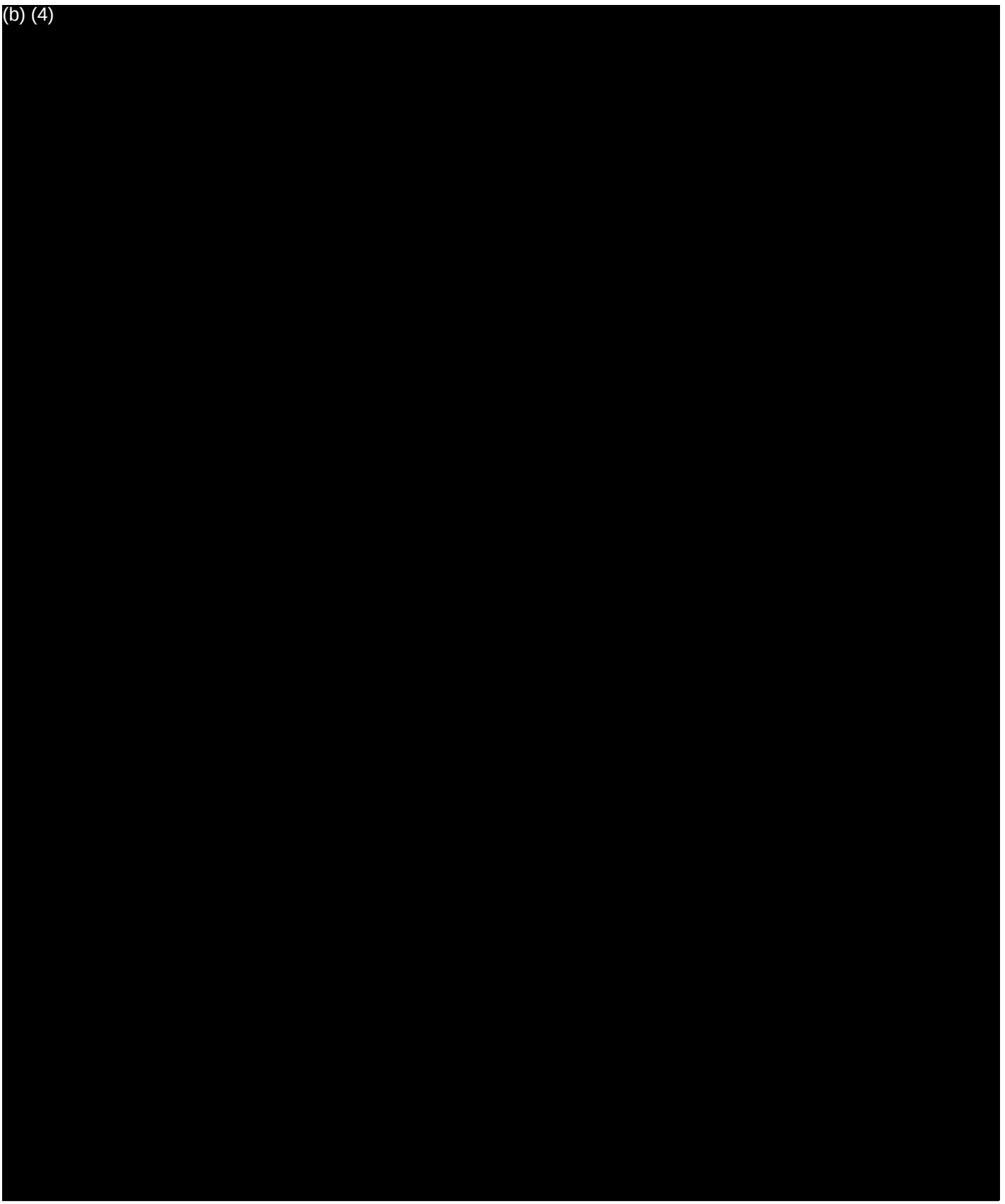

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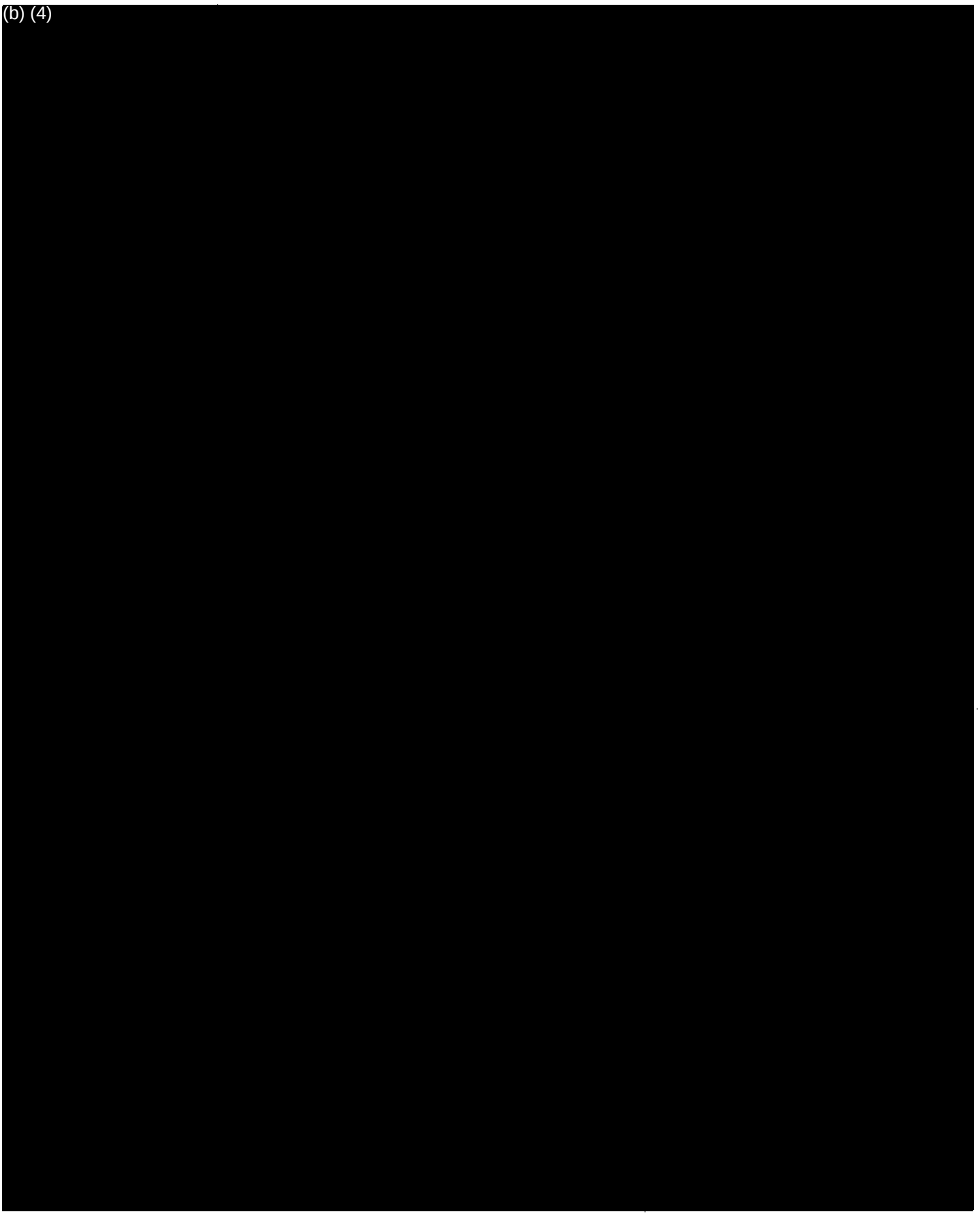

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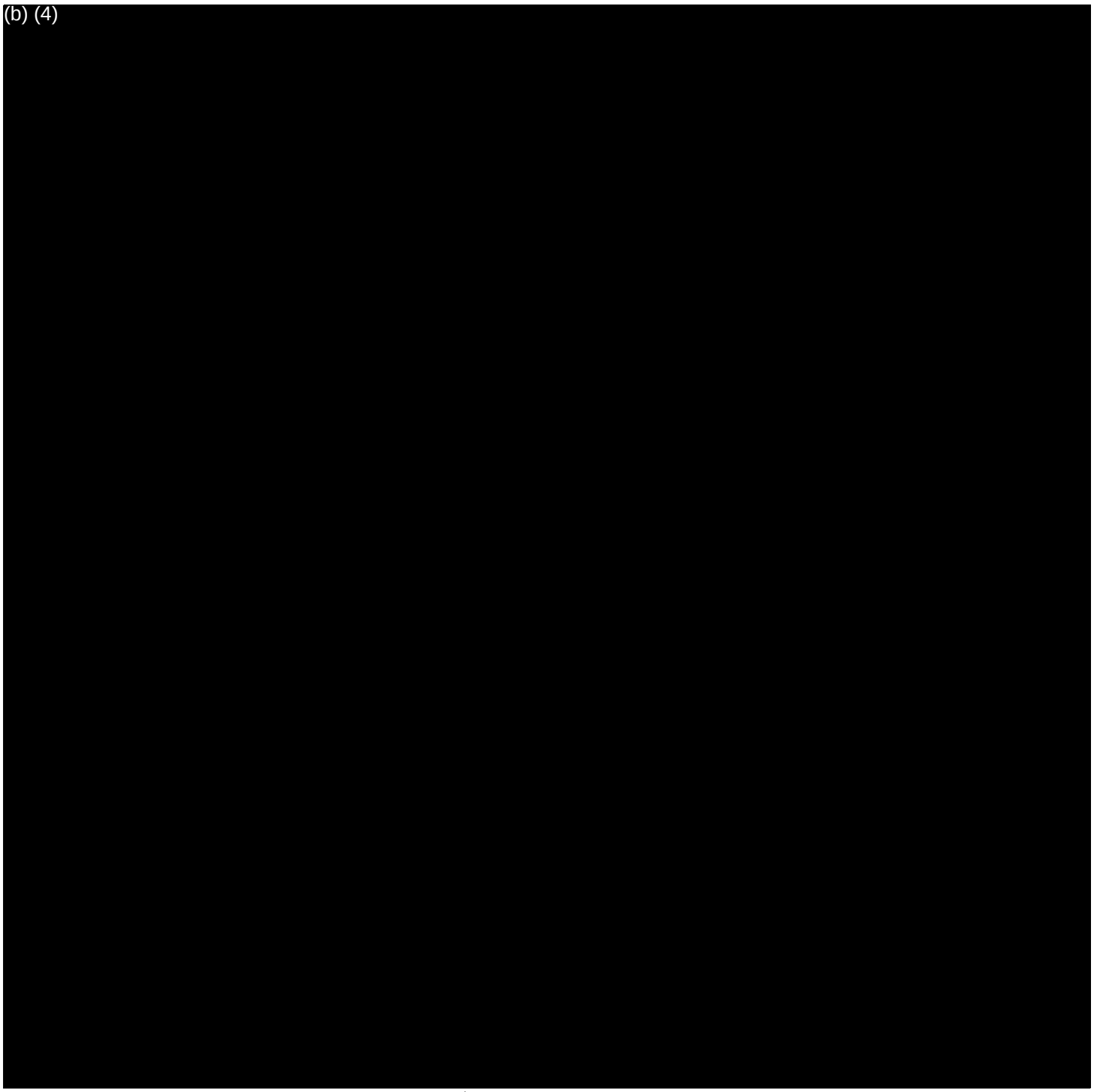

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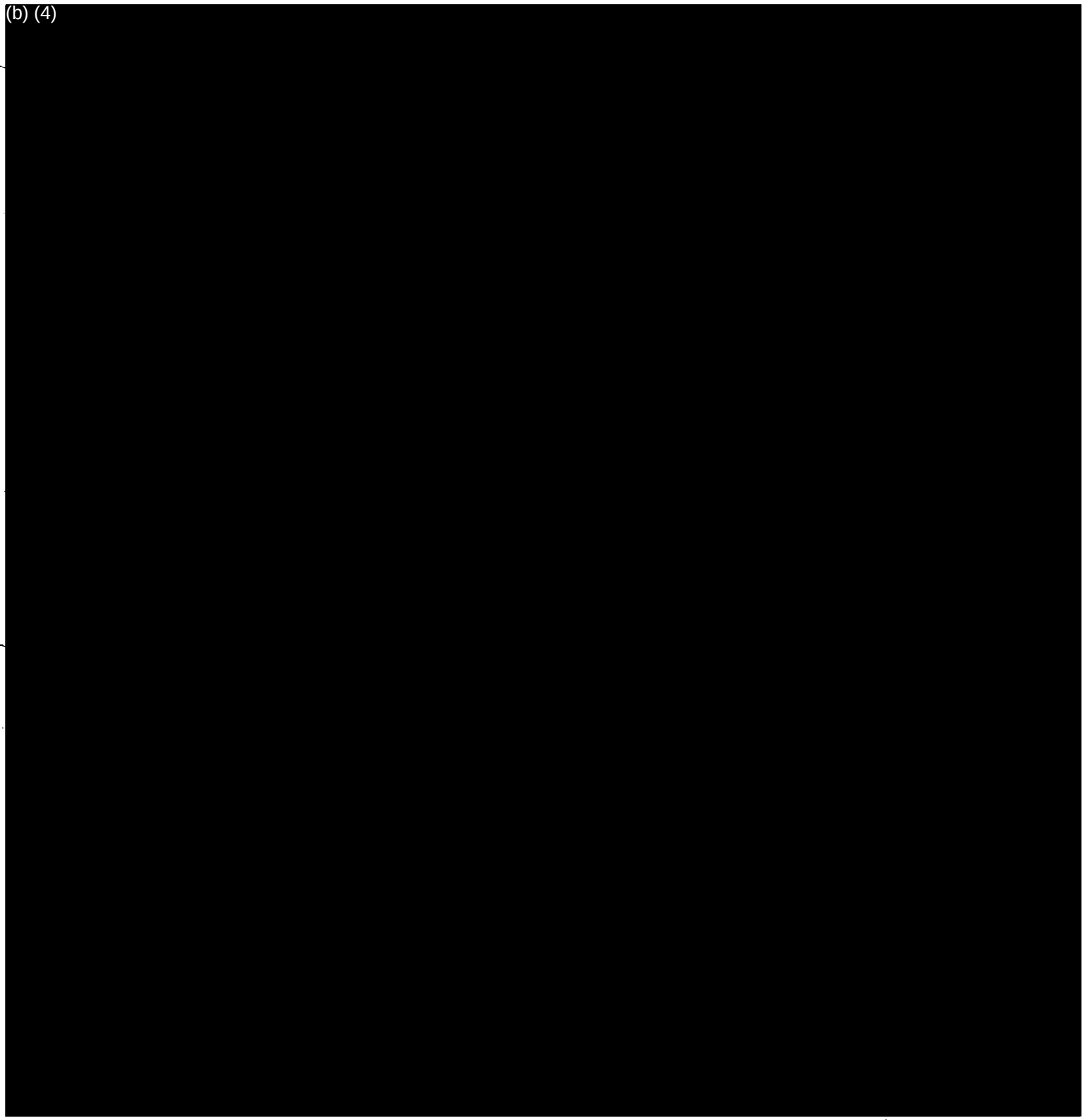

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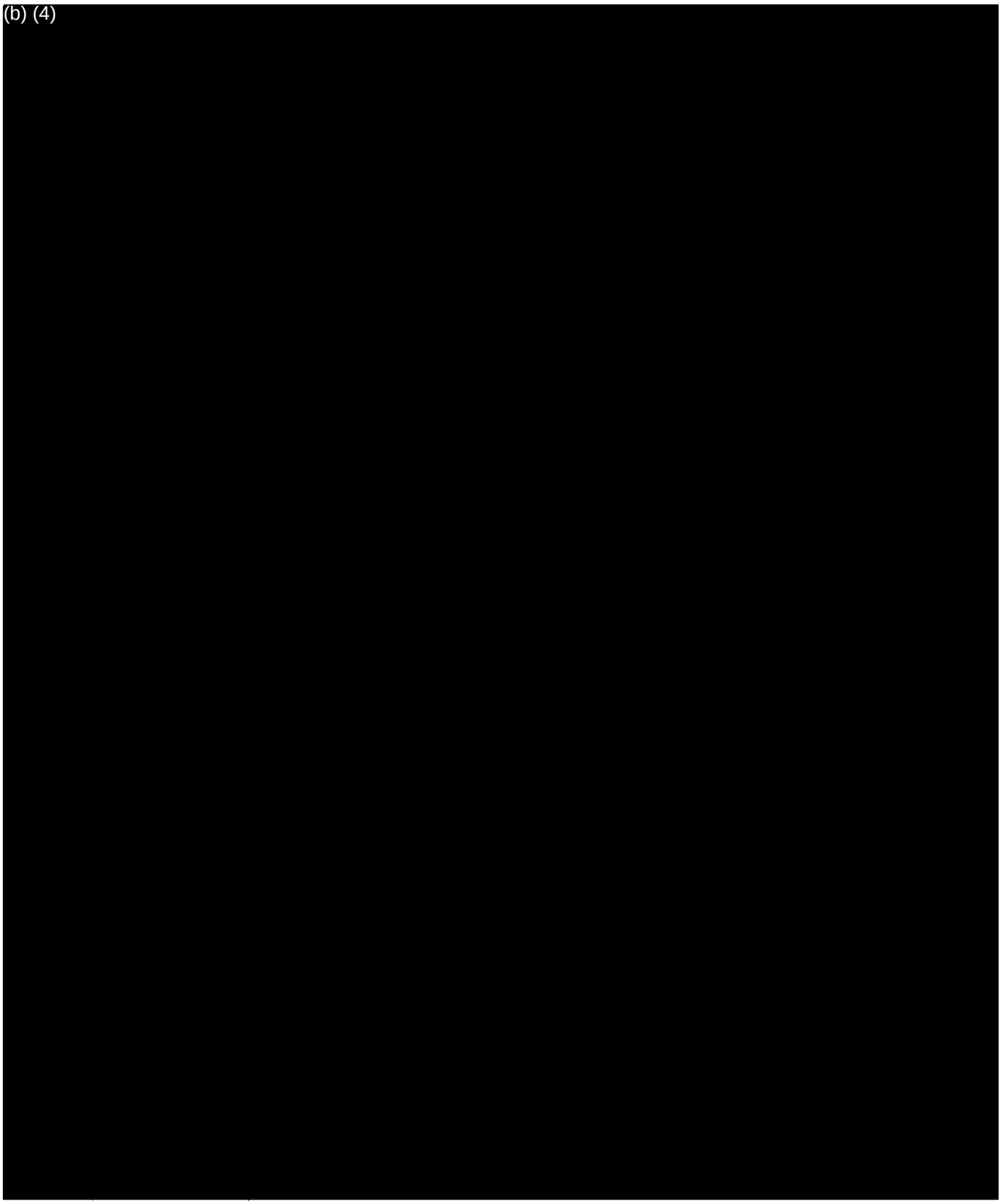

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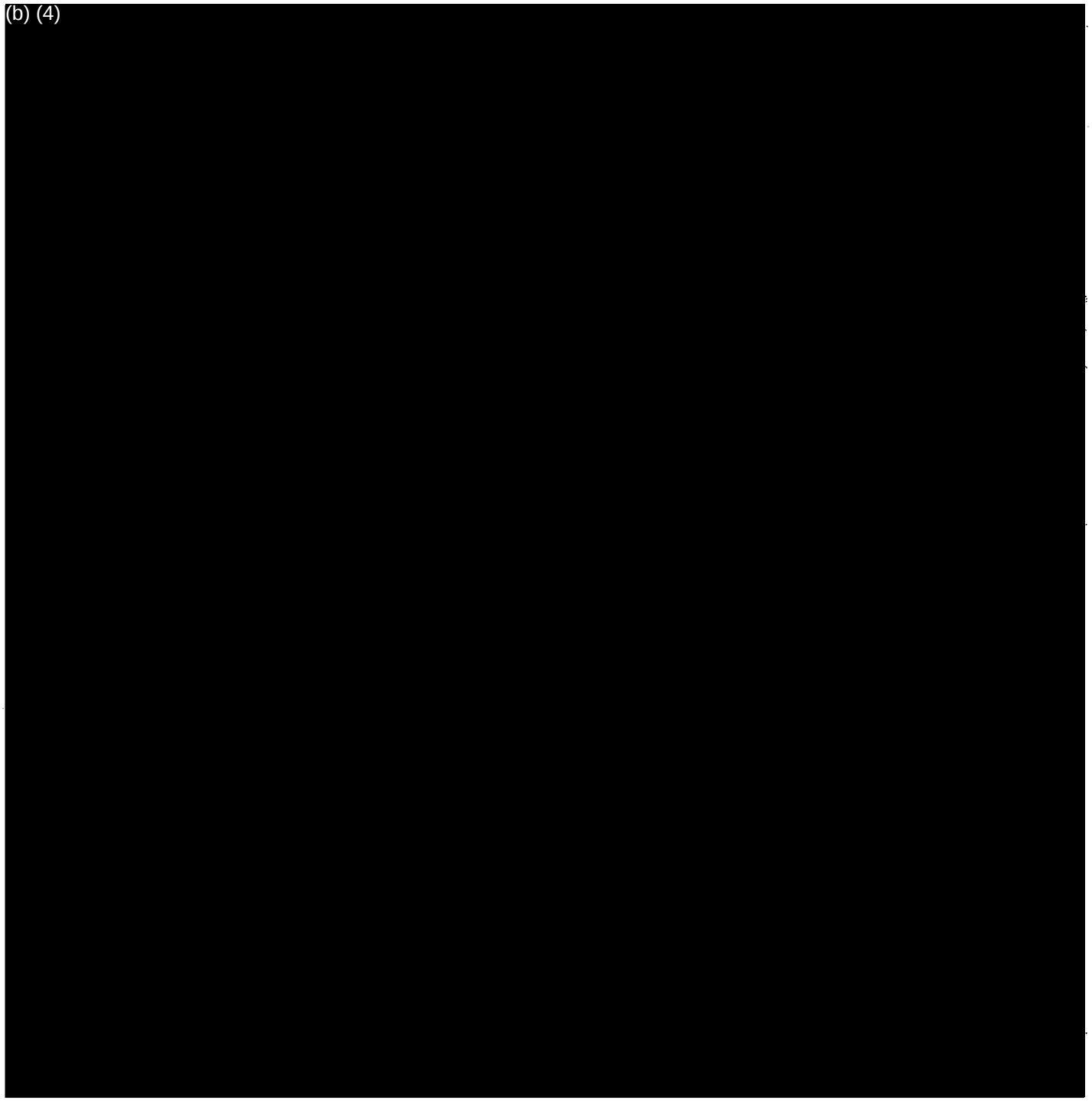

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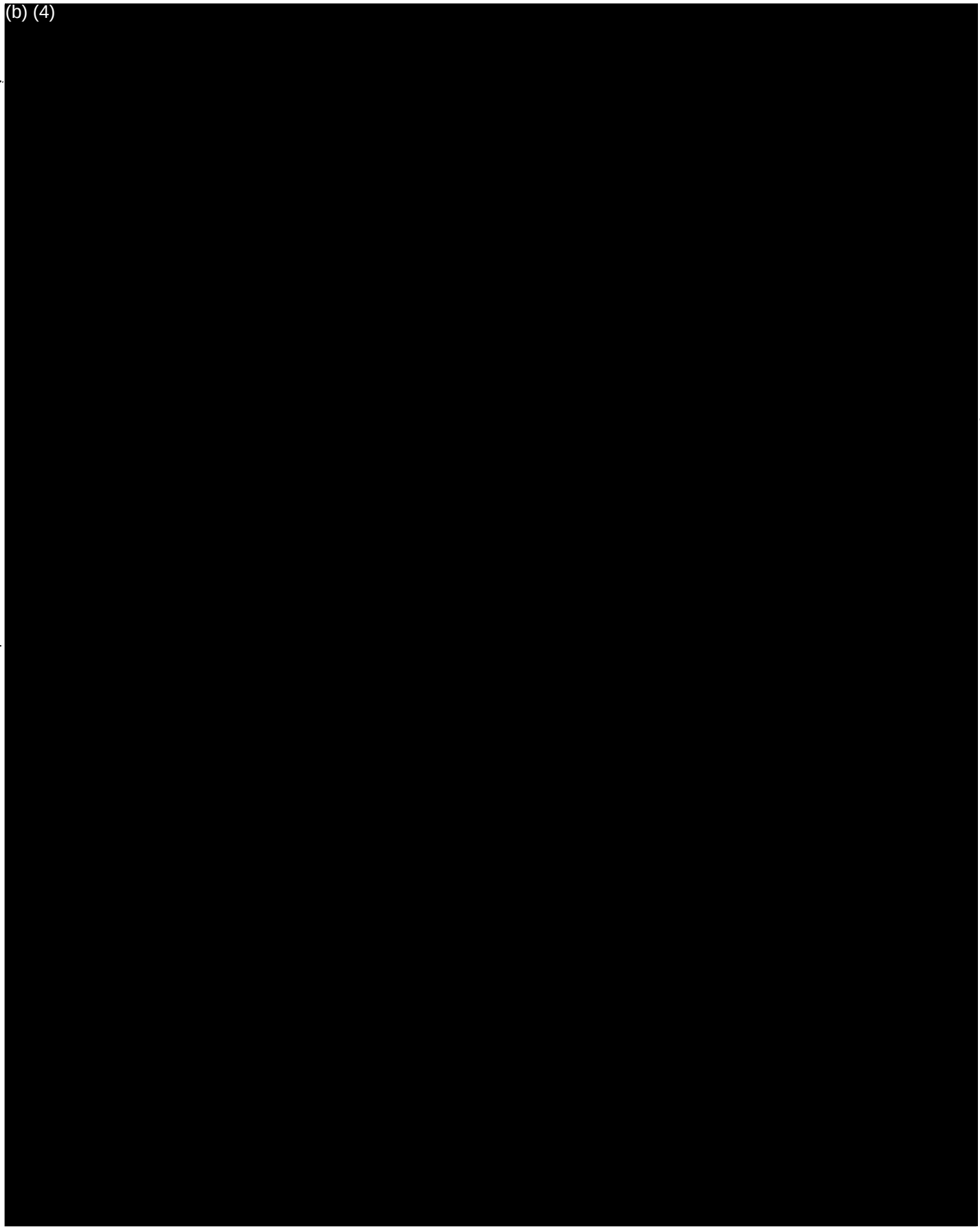

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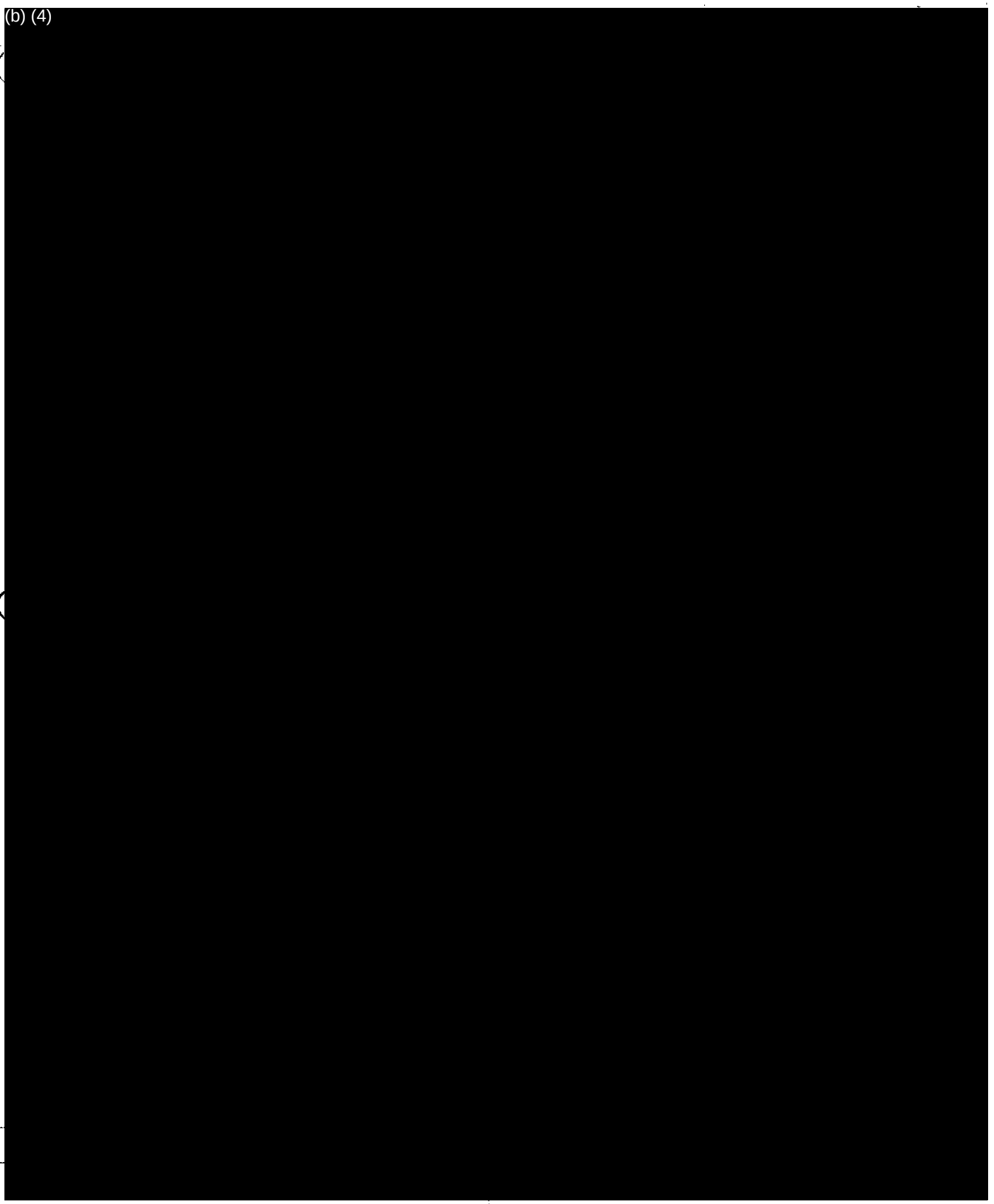

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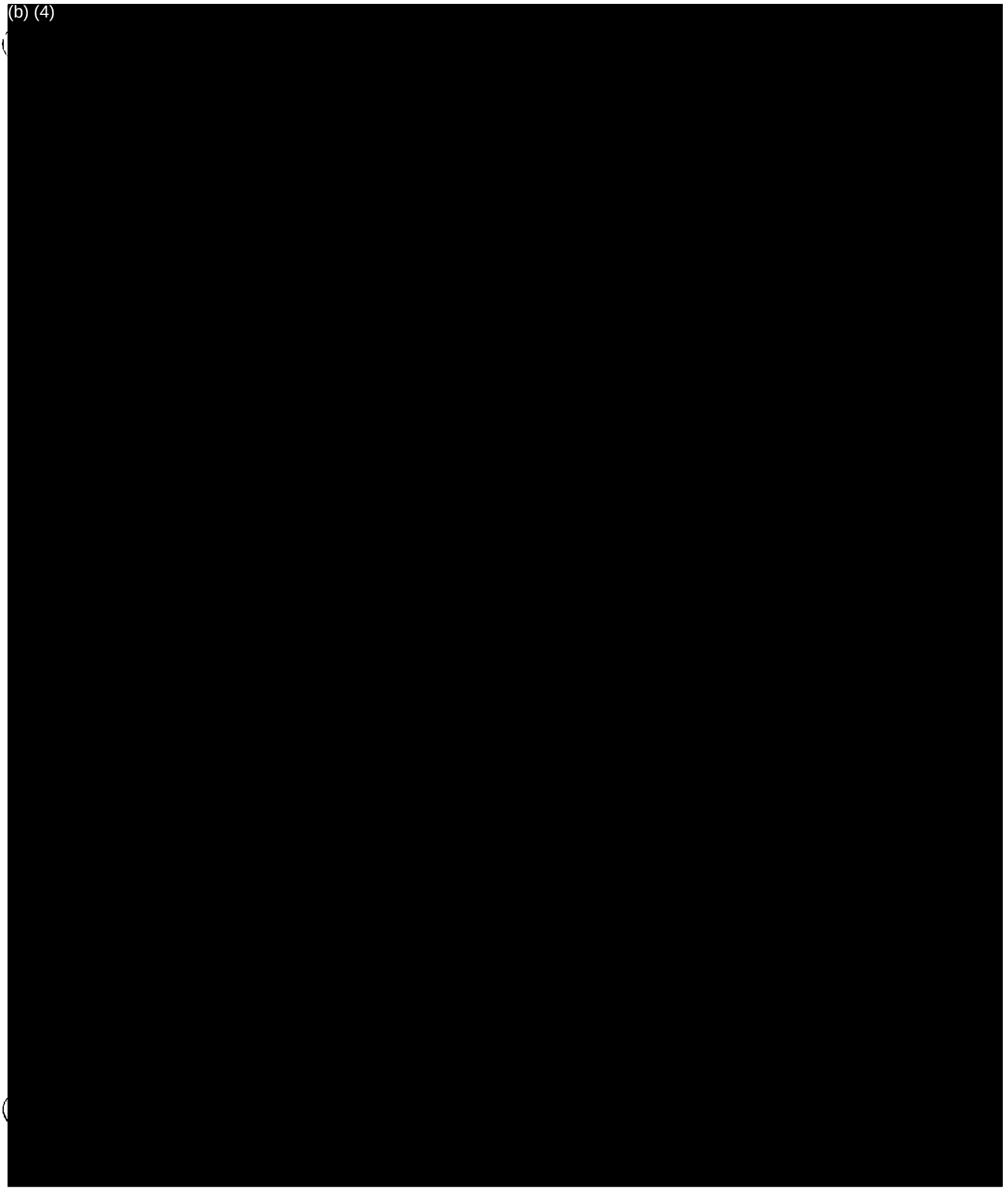

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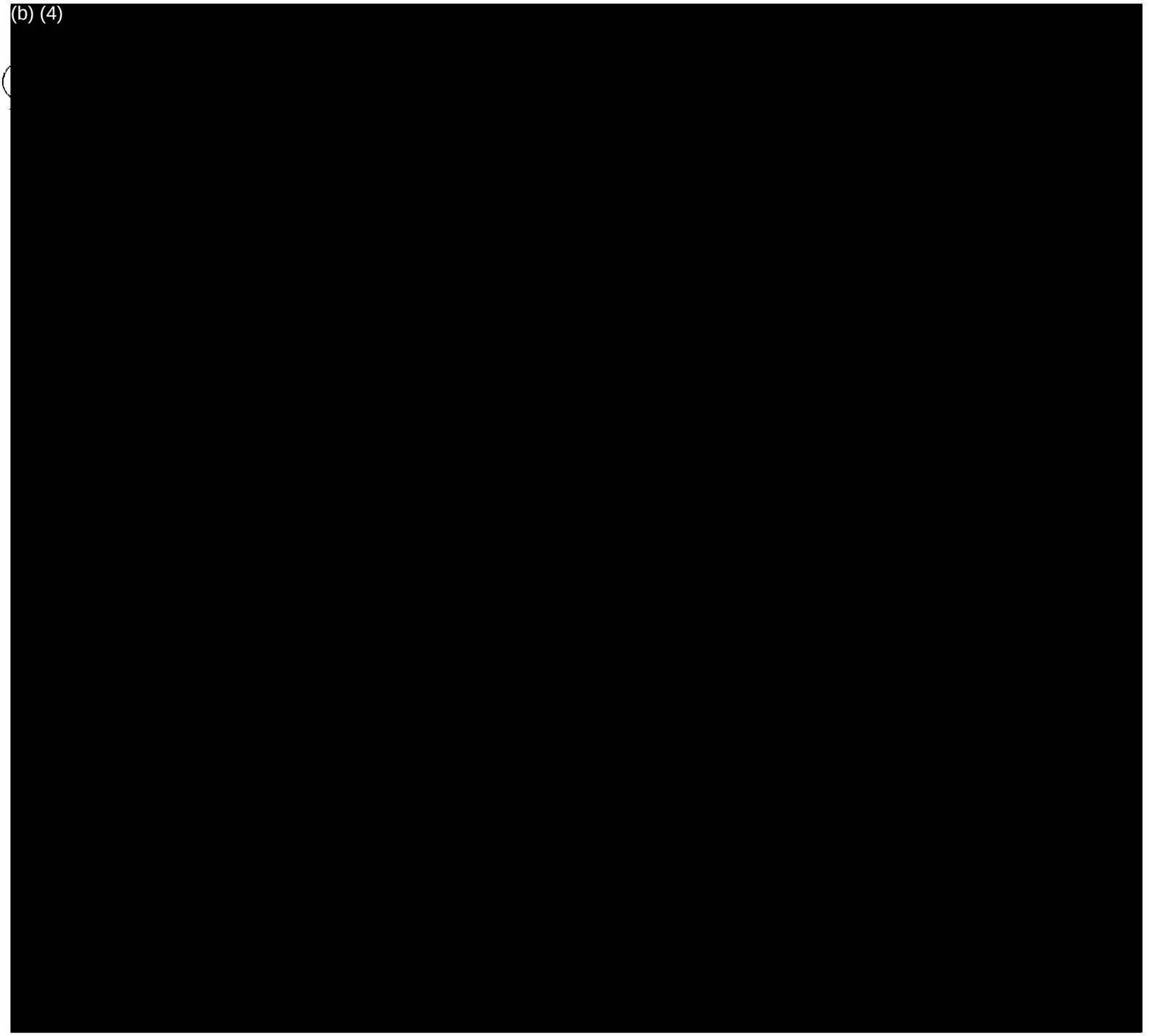

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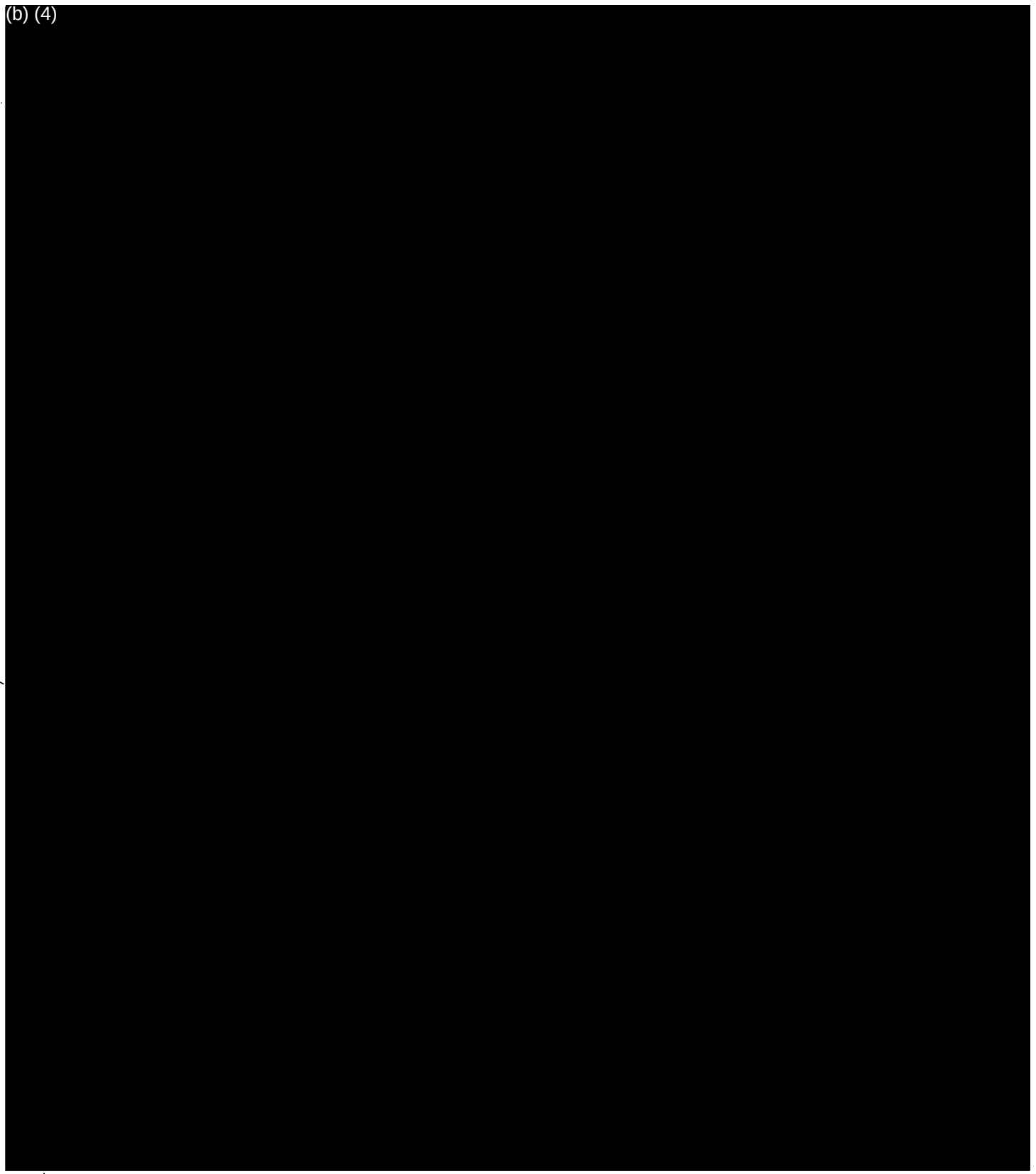

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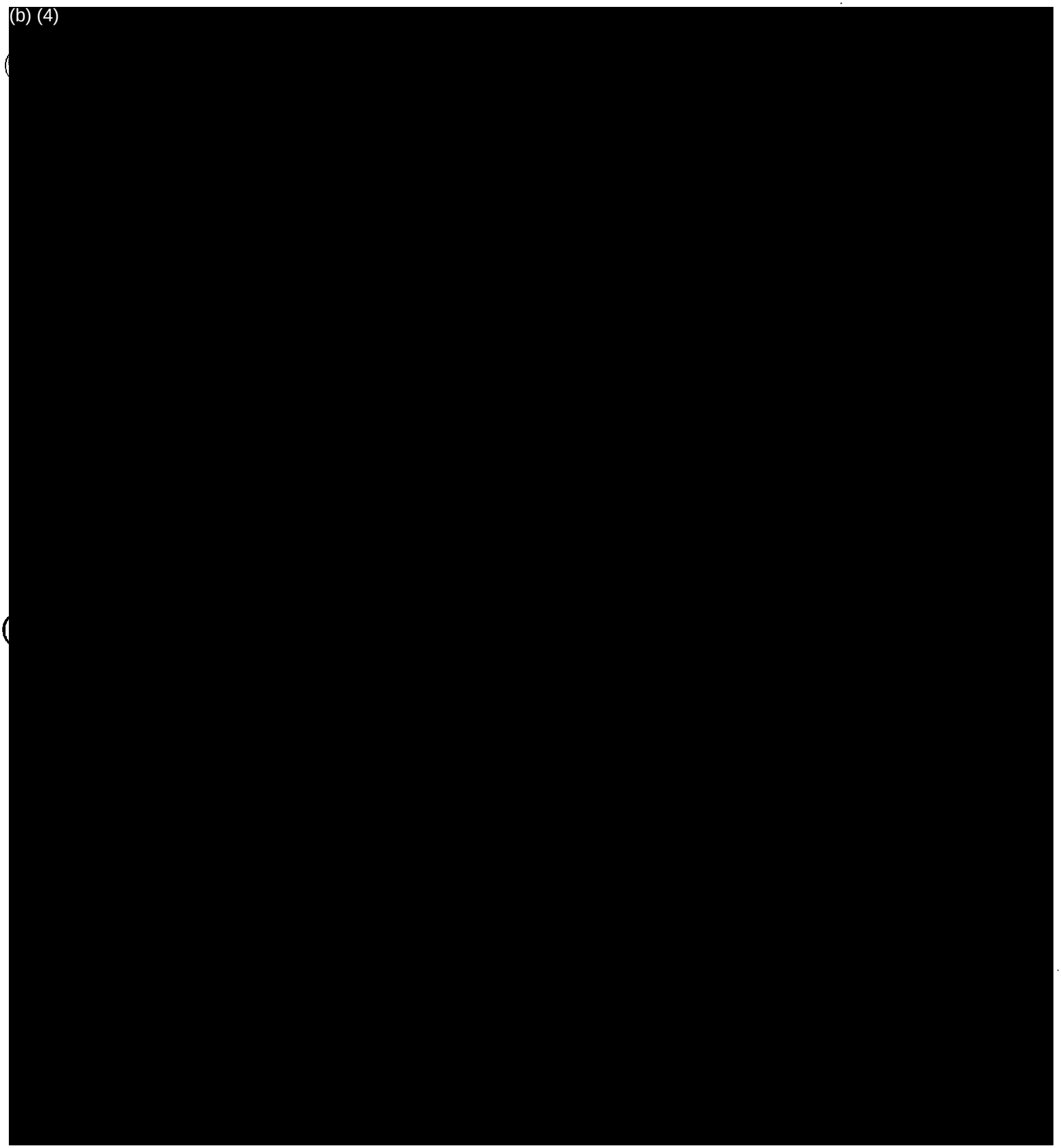

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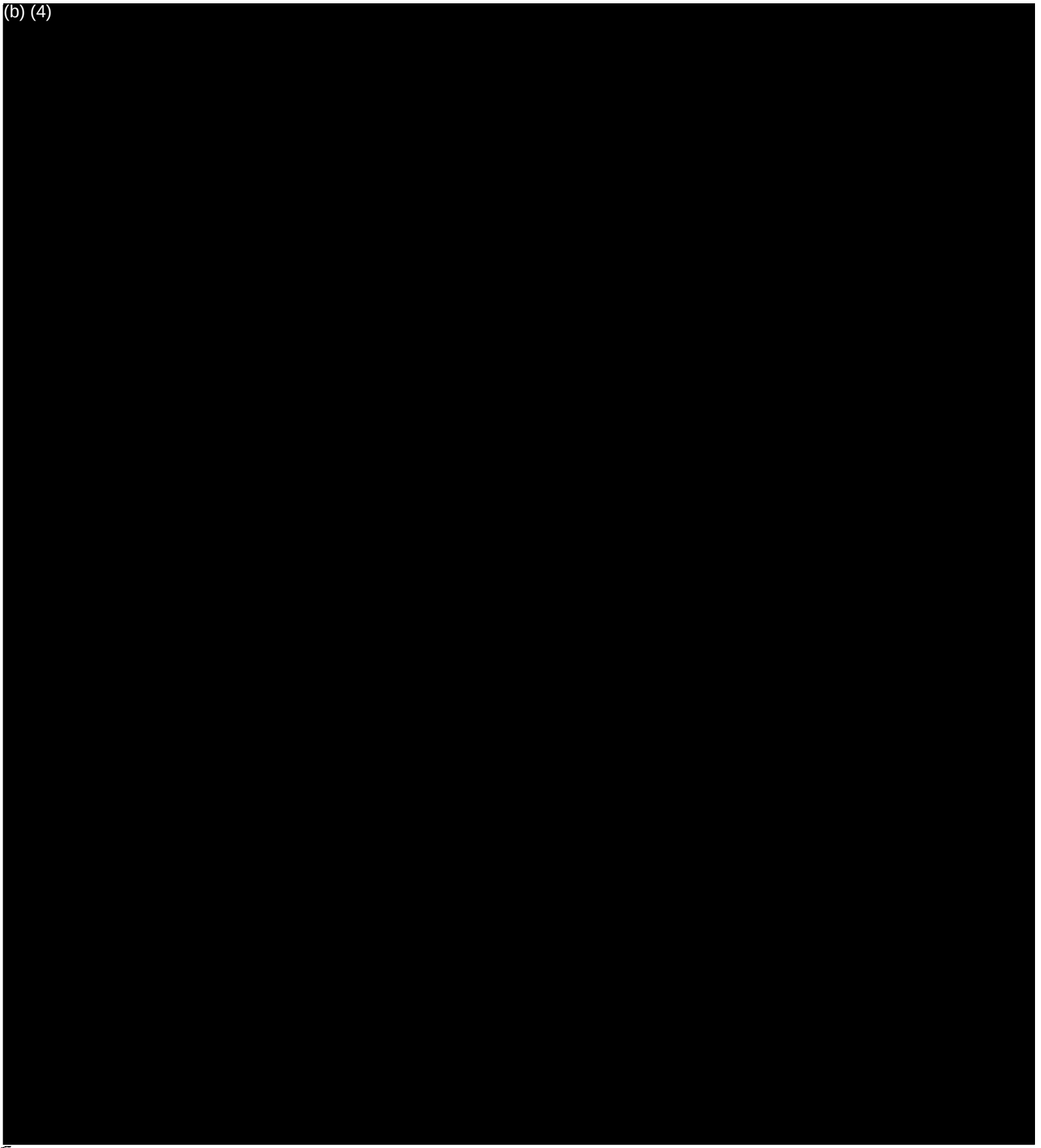

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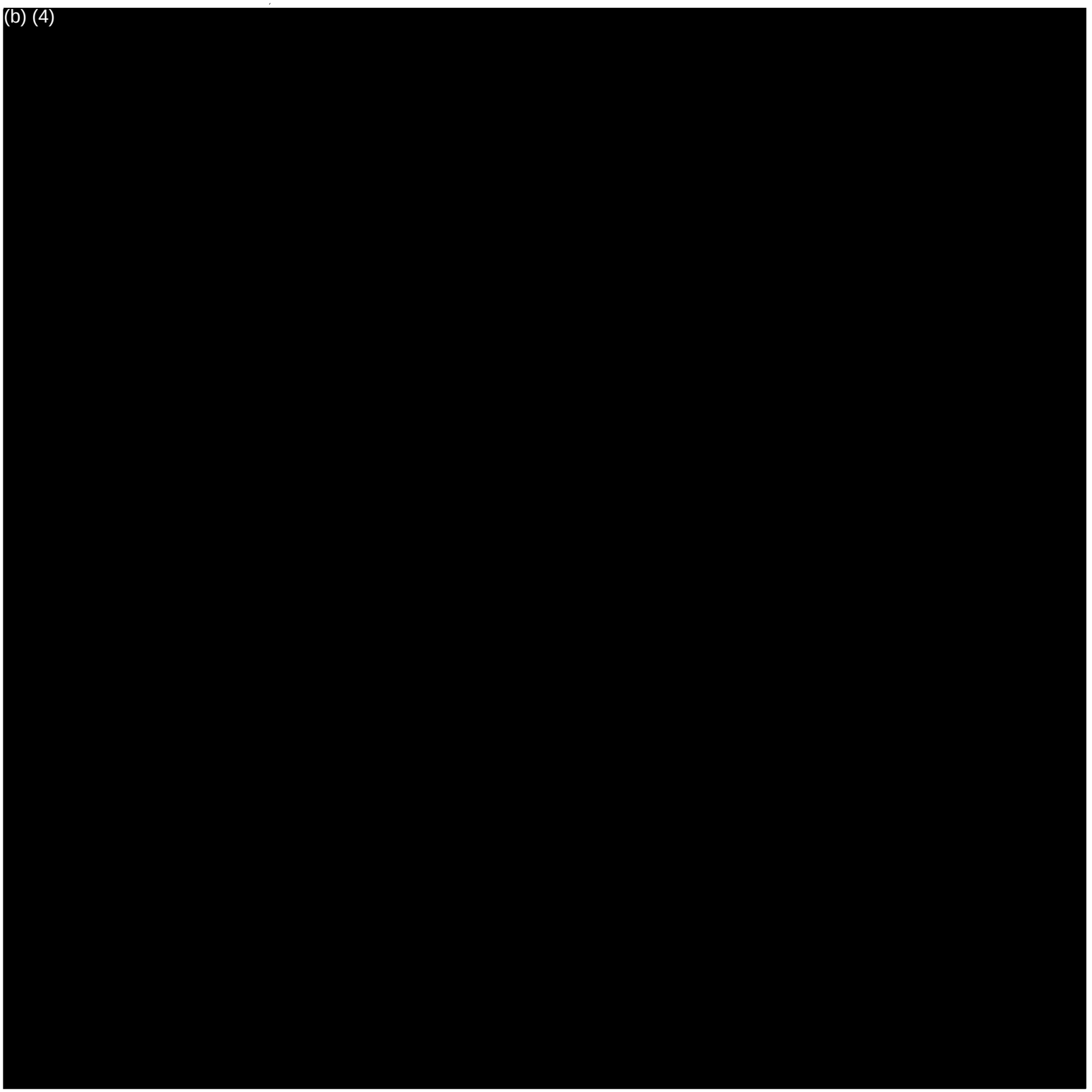

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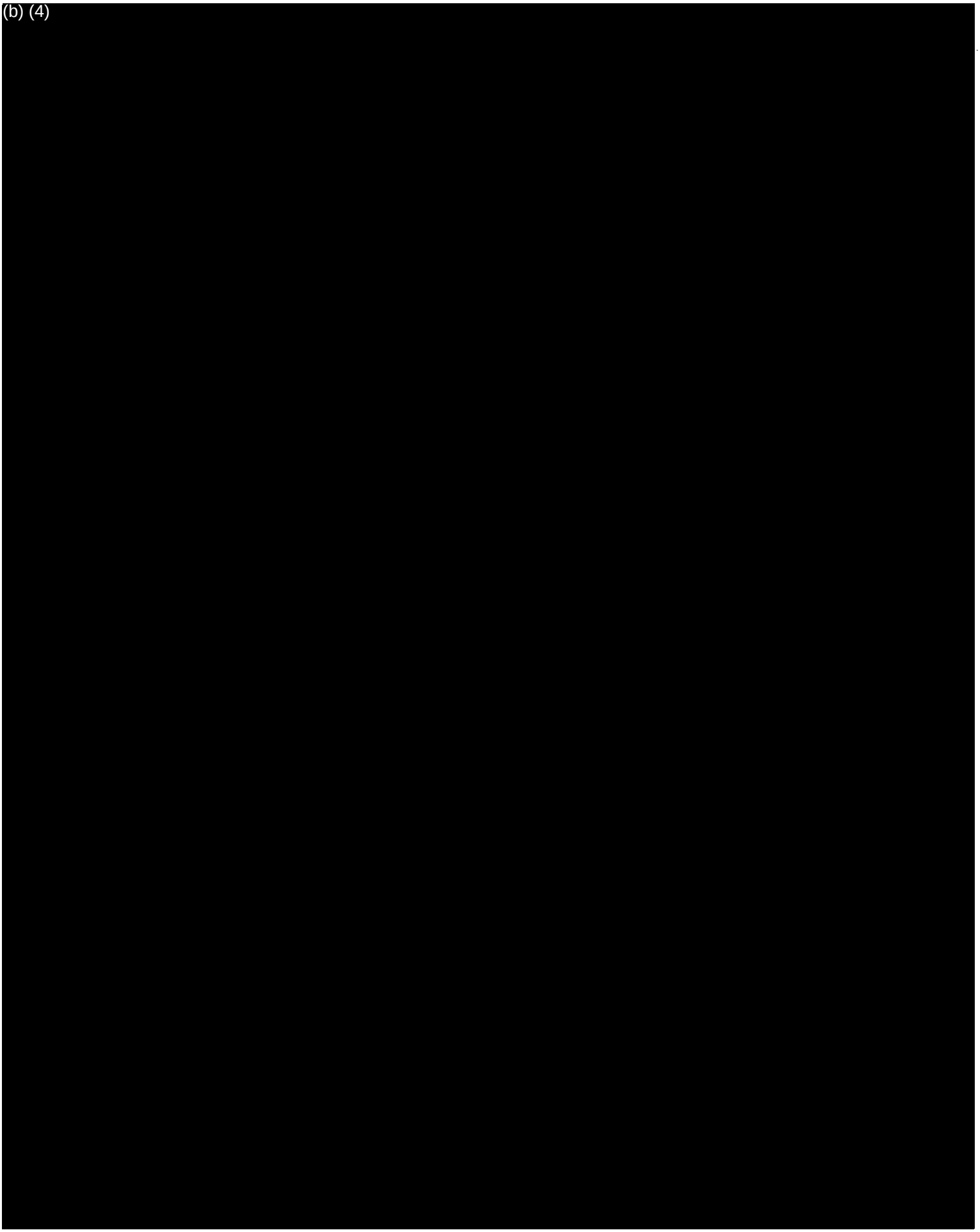

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DJA x02248

DJA x02249

(b) (4)

DJA x02250

(b) (4)

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DJA x02256

DJA x022S7

DJA x02258

DJA x02259

(b) (4)

(b) (4)

(b) (4)

DJA x02263

(b) (4)

(b) (4)

DJA x02266

DJA x02267

DJA x02268

(b) (4)

(b) (4)

DJA x022?1

(b) (4)

(b) (4)

DJA x022742

DJA x02275

(b) (4)

DJA x022776

DJA x02277

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DJA x022?8

DJA x022179

DJA x02280

DJA x02281

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DJA x02283

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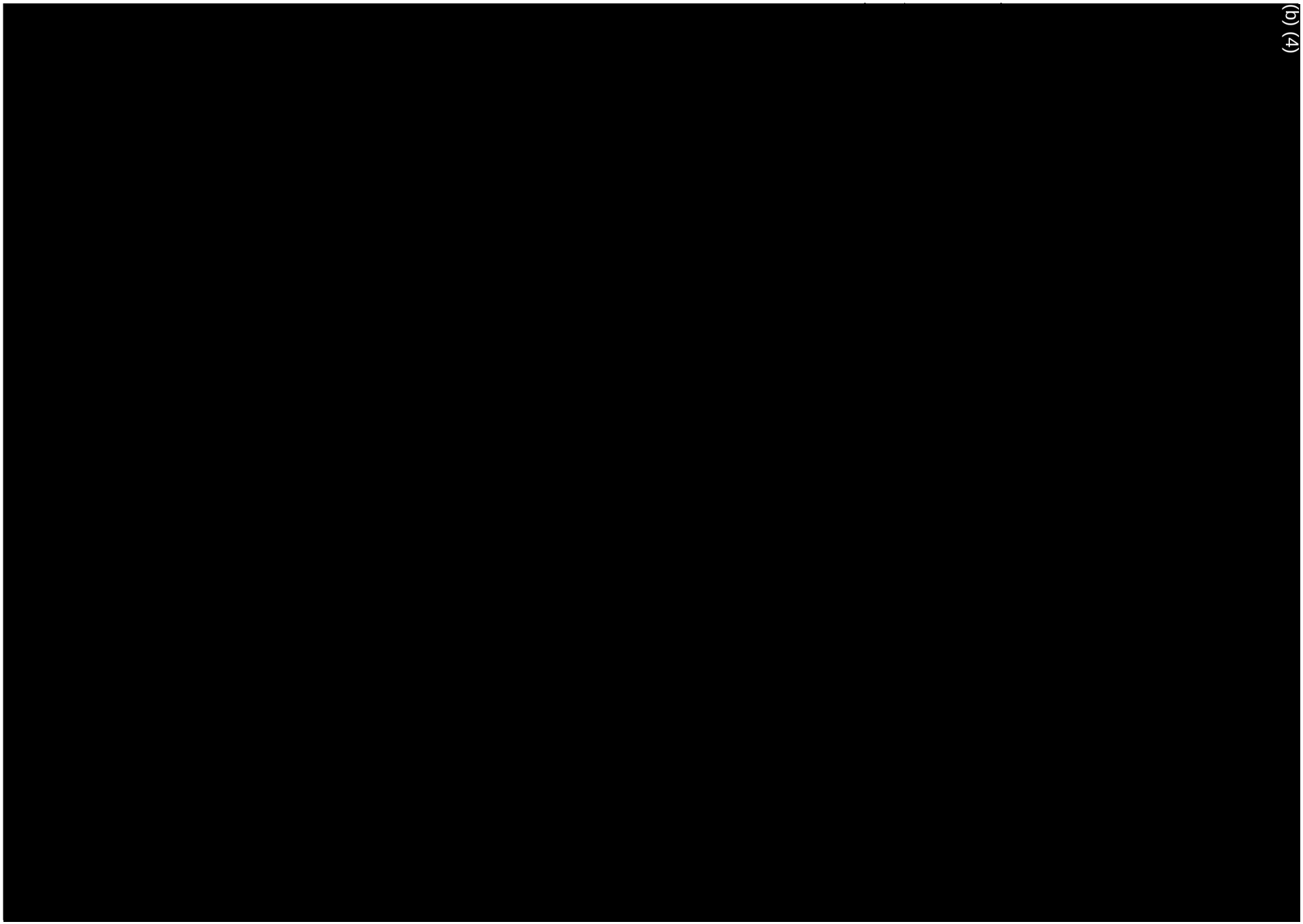
DJA x02293



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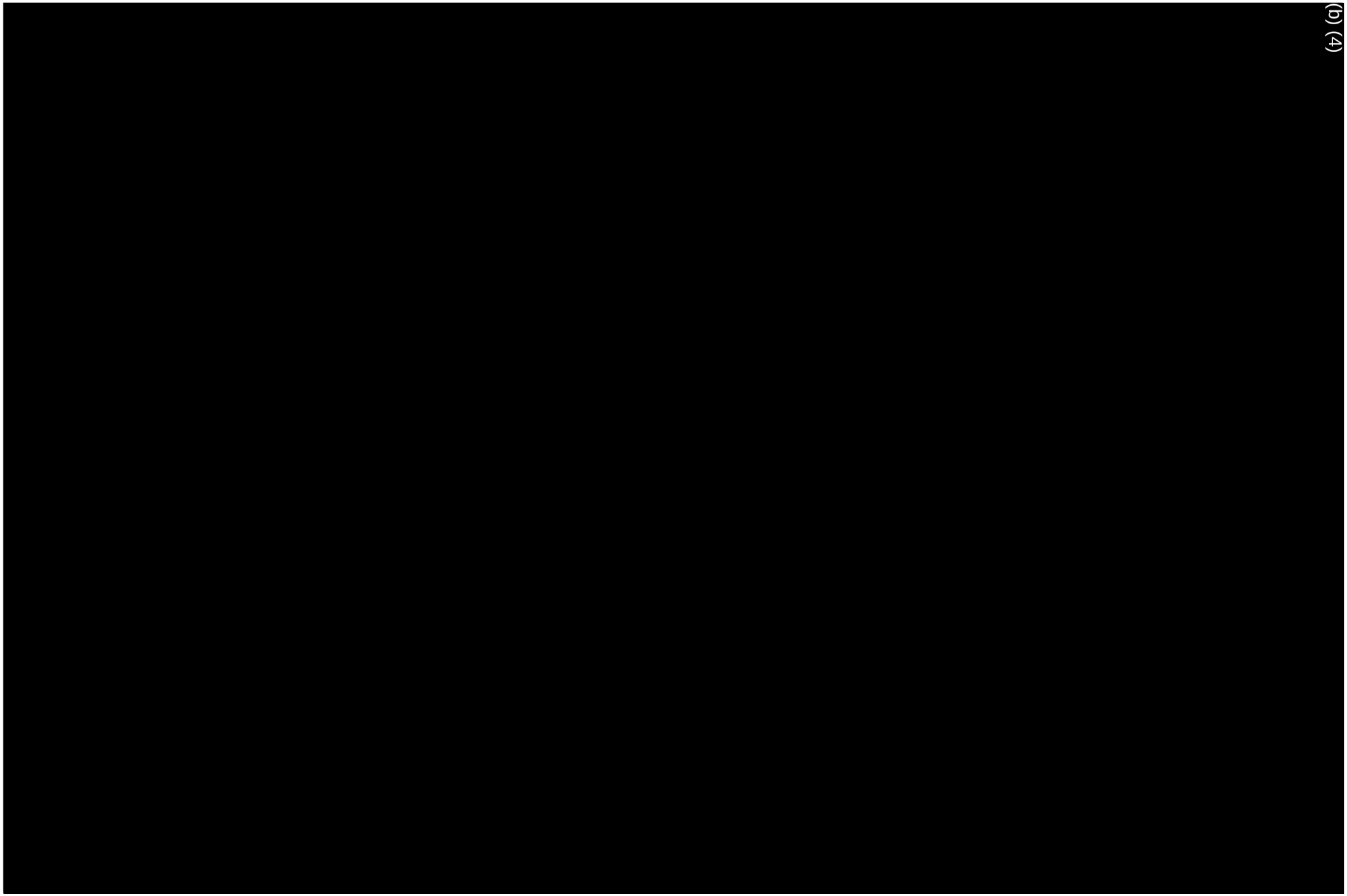
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DJA x02308

DJA x02309

DJA x02310

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DJA x023:3

(b) (4)

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DJA x02314

(b) (4)

(b) (4)

DJA x02317

(b) (4)

DJA x02319

DJA x02320

DJA x02321

DJA x02322

DJA x02323

(b) (4)

DJA x02325

(b) (4)

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DJA x02328

(b) (4)

DJA x02330

DJA x02331

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DJA x02332

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DJA x02335

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DJA x02346

(b) (4)

DJA x02347

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DJA x02348

(b) (4)

(b) (4)

DJA x02351

(b) (4)

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DJA x02353

DJA x02354

20.7 Comparison of Clinical Outcomes between Pin-Based and Pinless Registration Technologies

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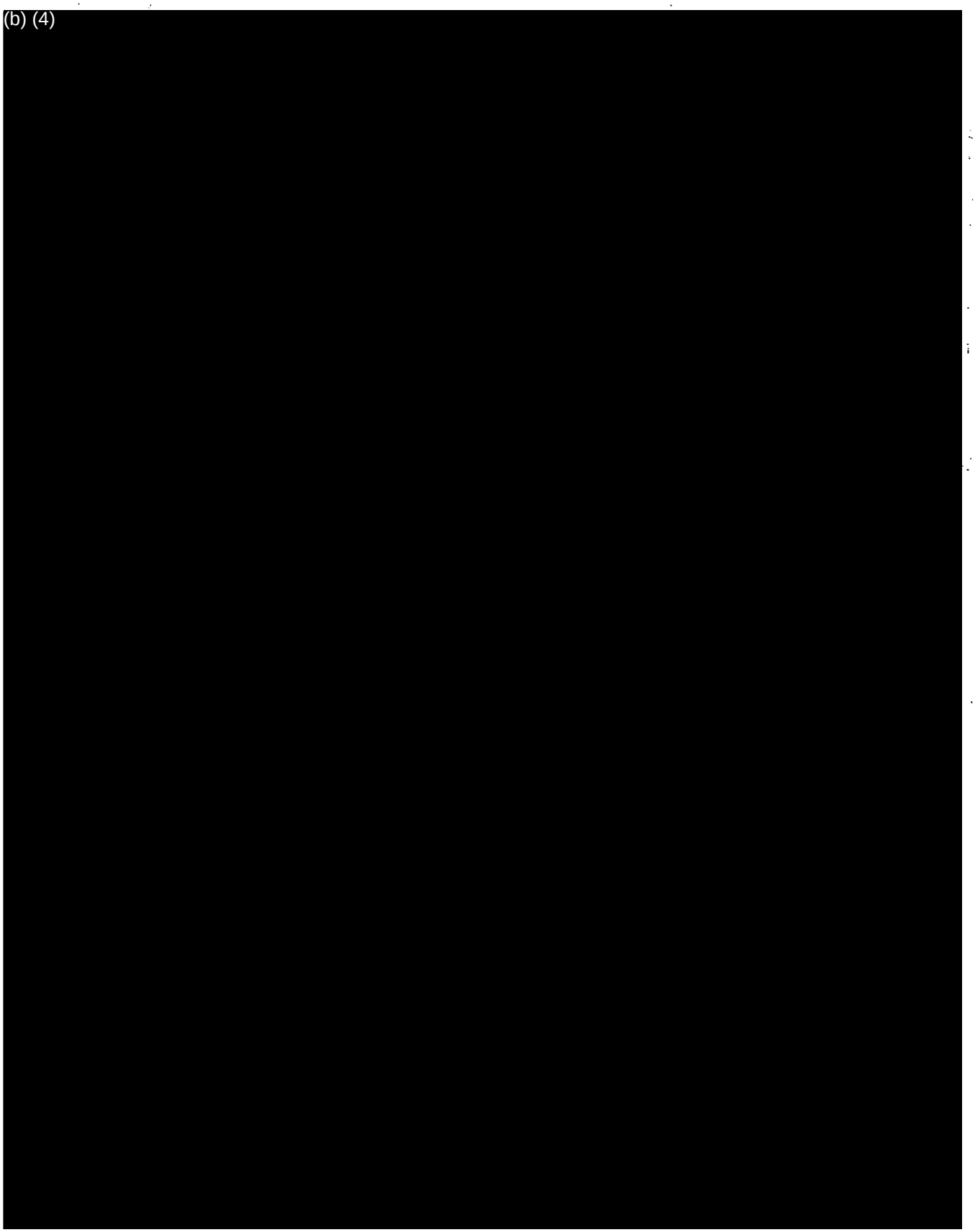

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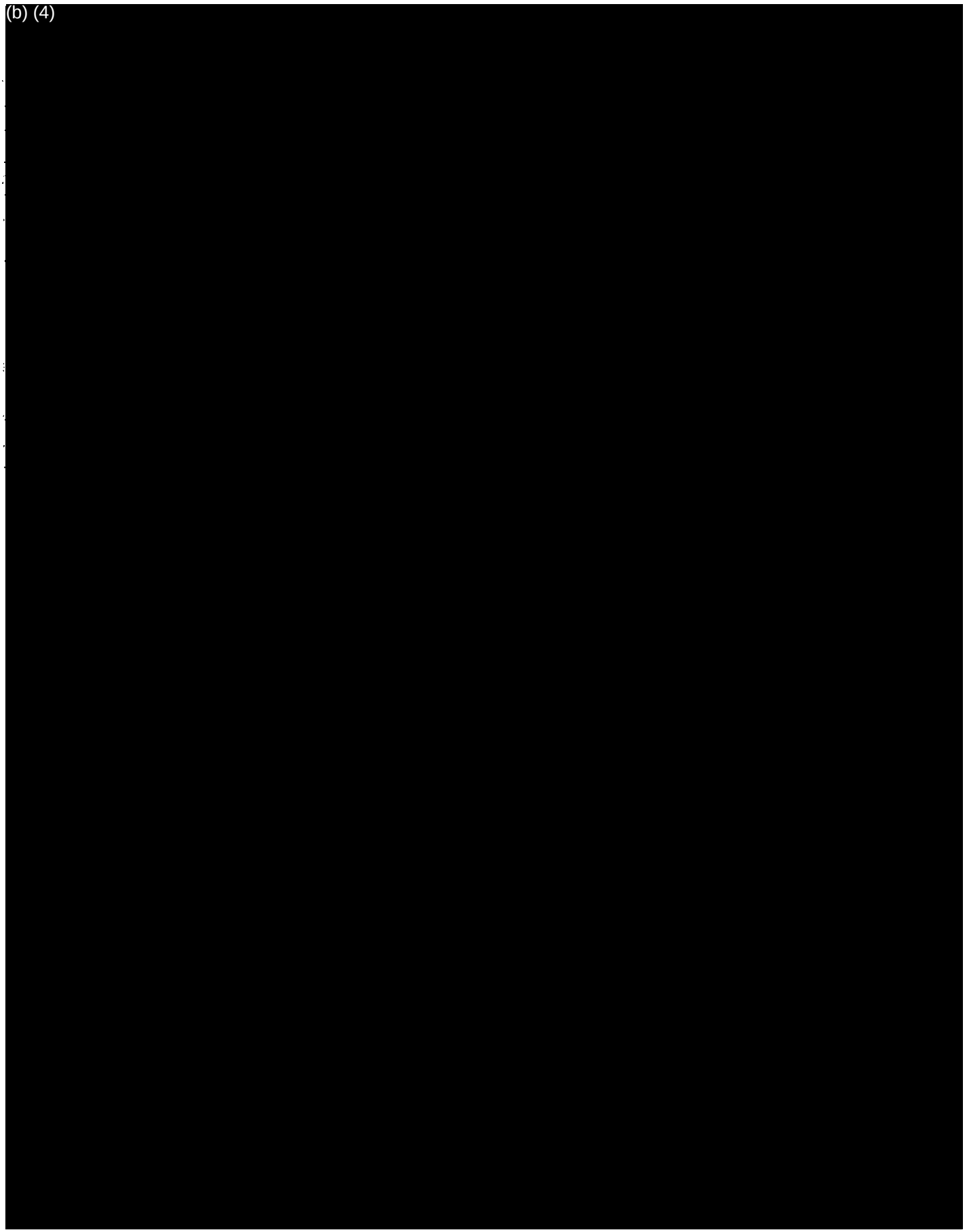

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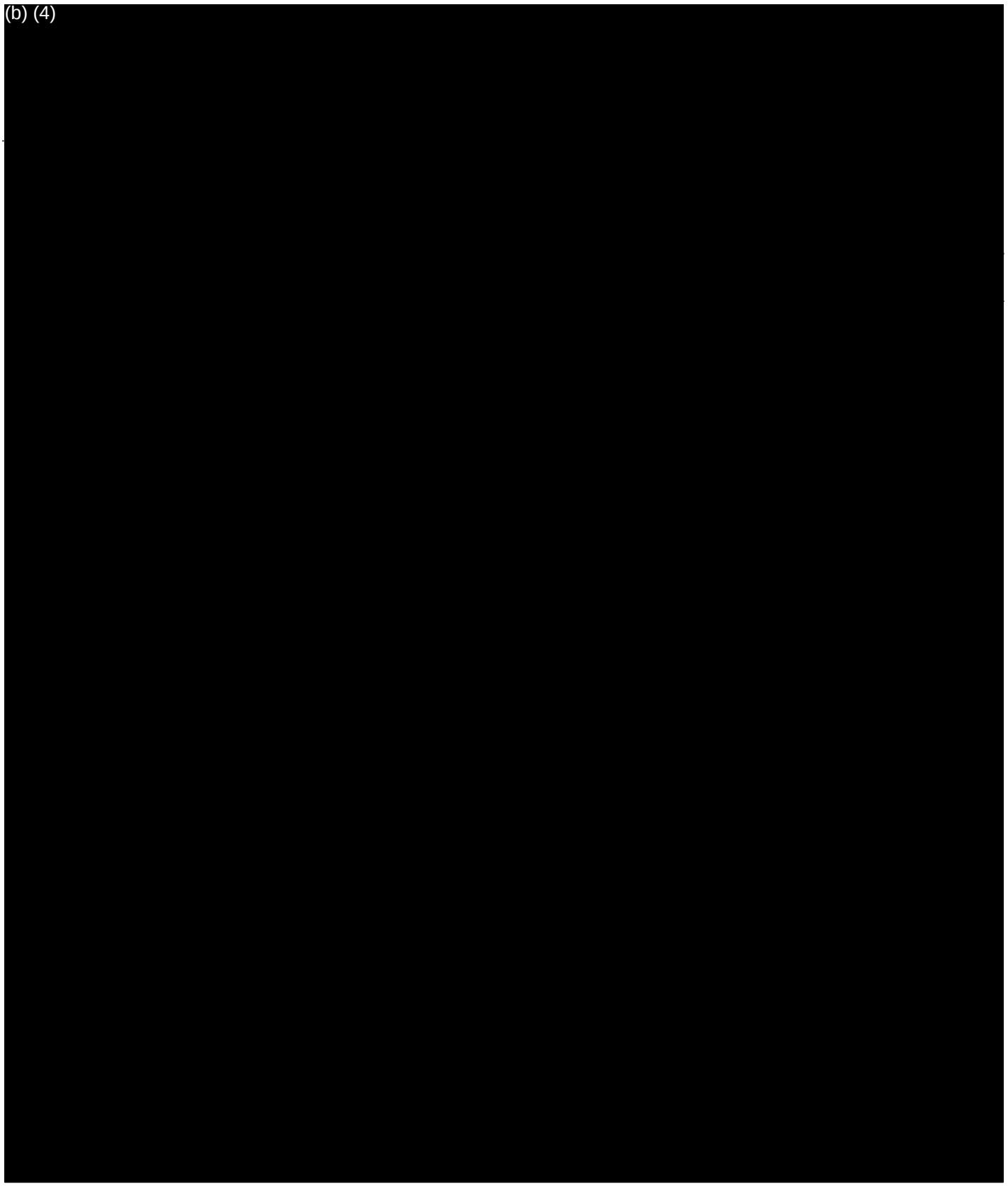

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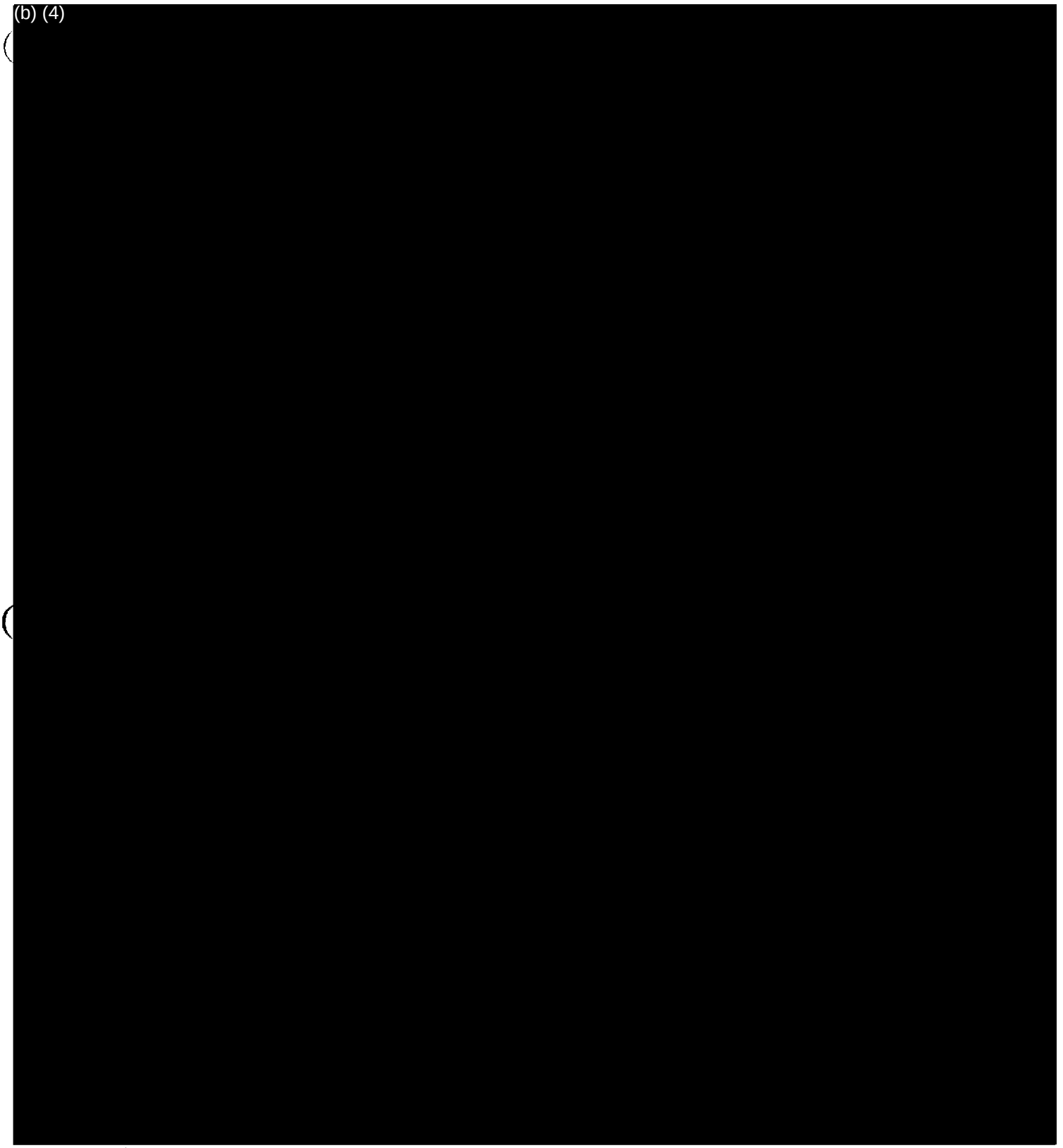

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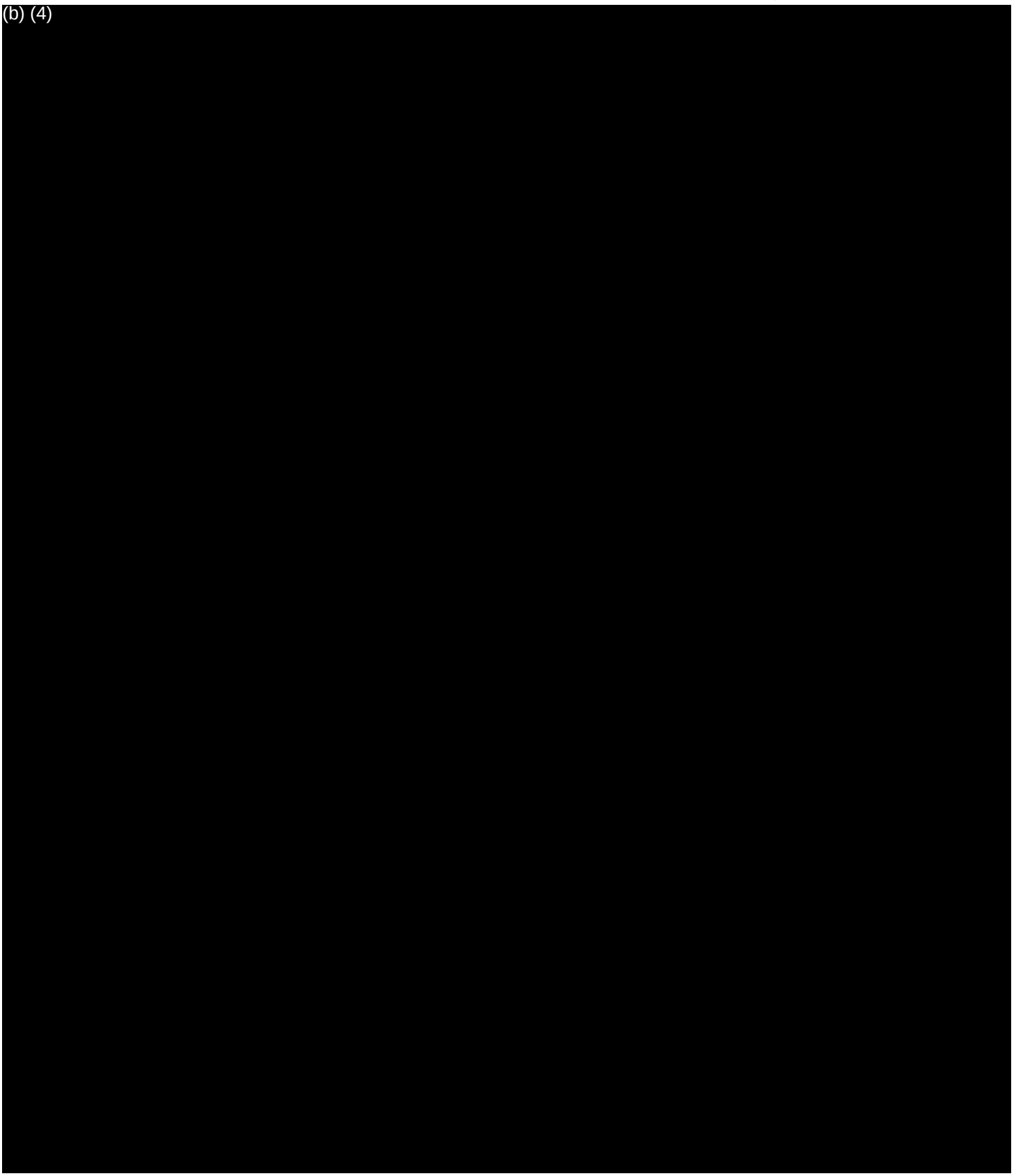

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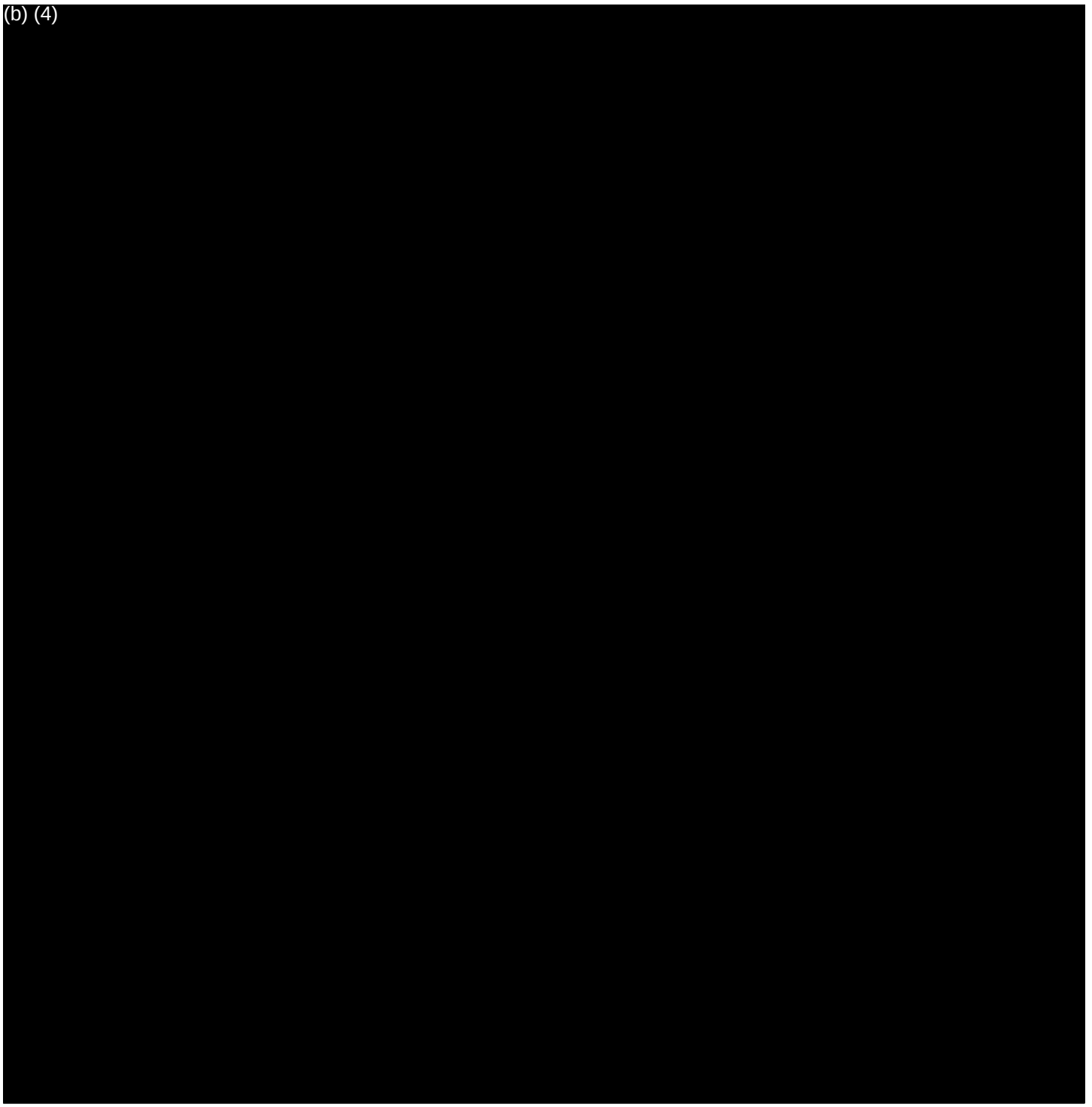

DJA x02361

20.8 Mitigation of Pin-Based Risk Factors by Pinless DigiMatch™ Technology

20.8.1 Introduction

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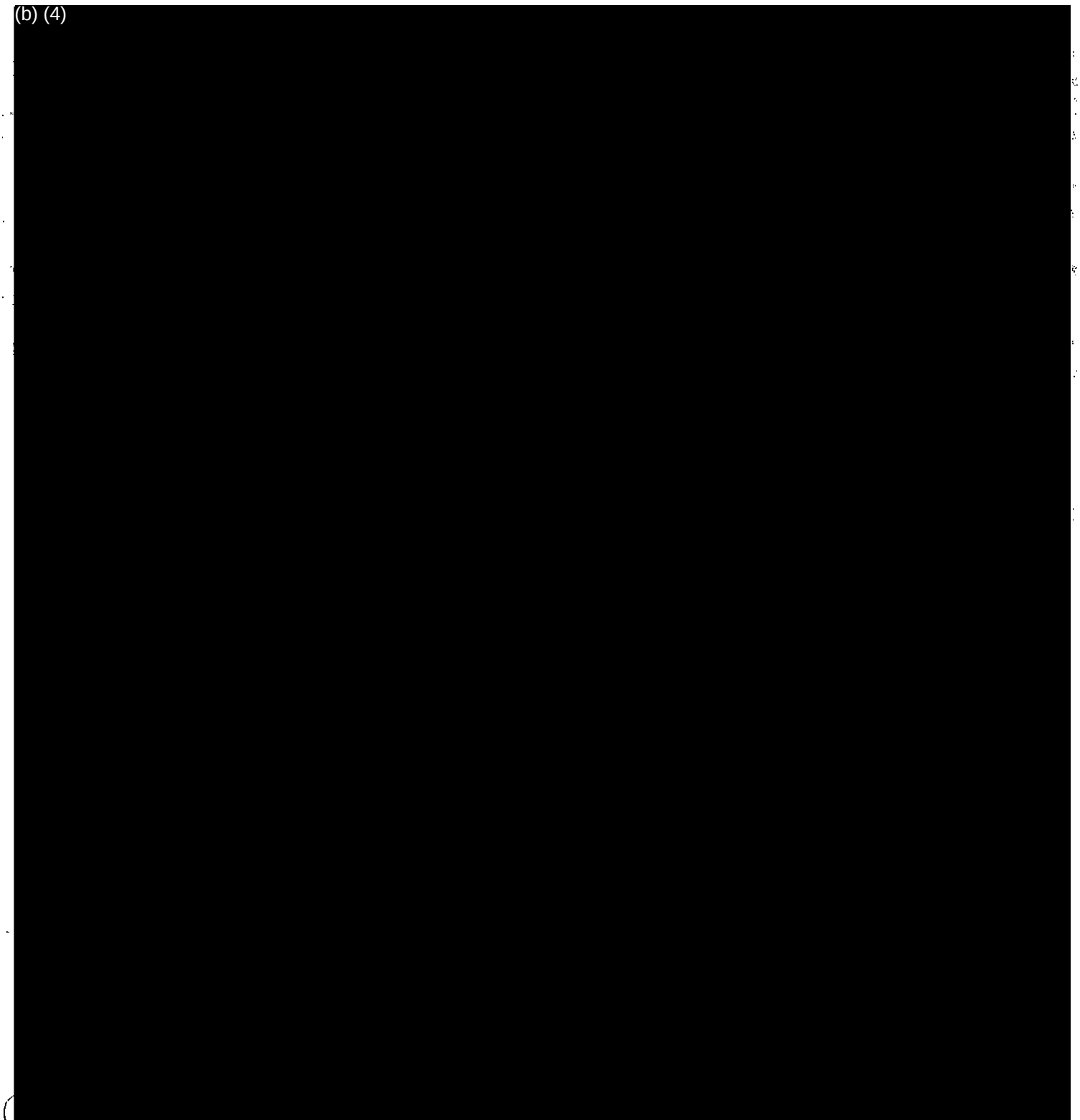
DJA x02362

20.8.2 ROBODOC® Surgical System Overview

20.8.2.1 ORTHODOC® Preoperative Planning Workstation

(b) (4)



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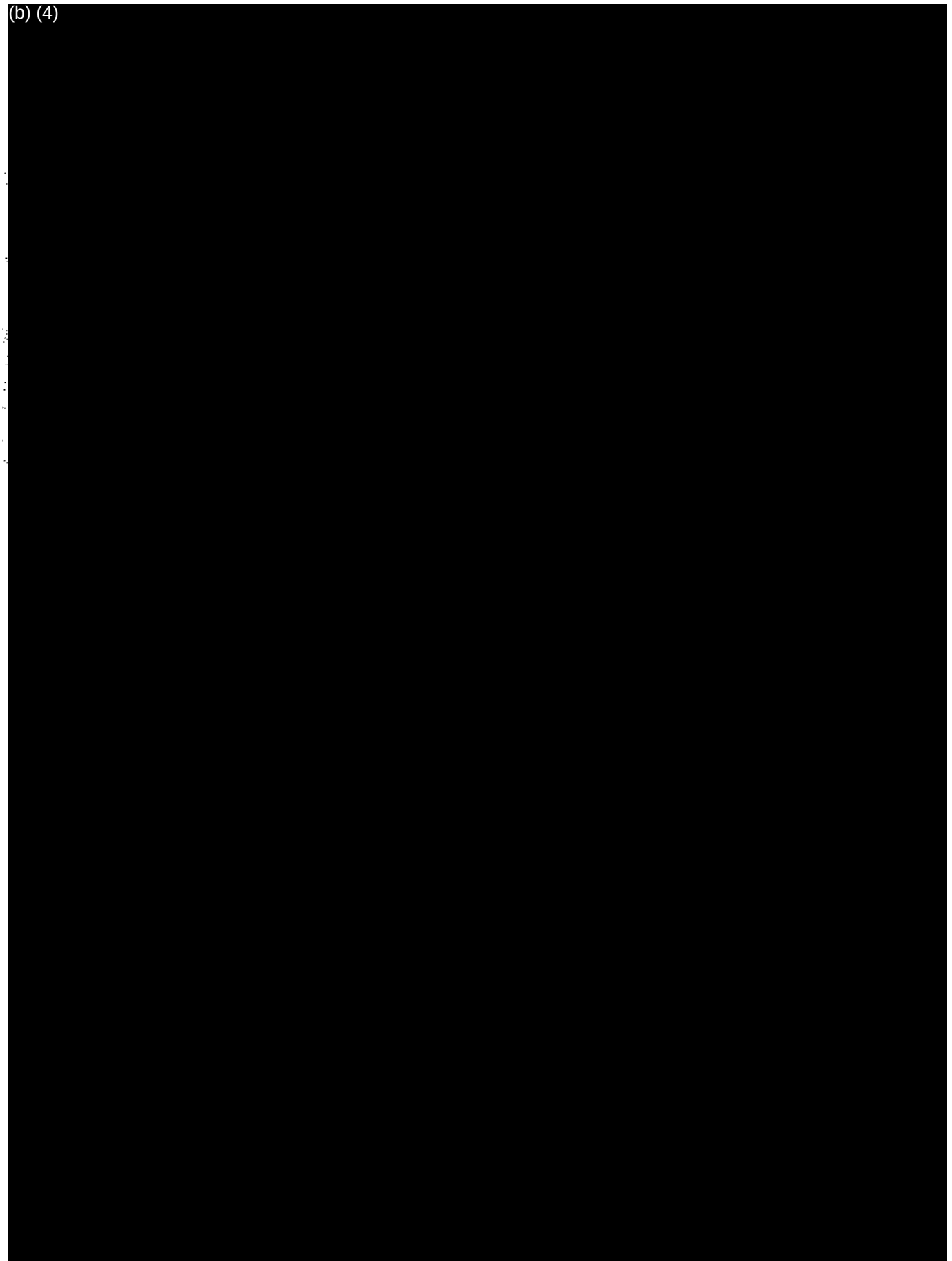

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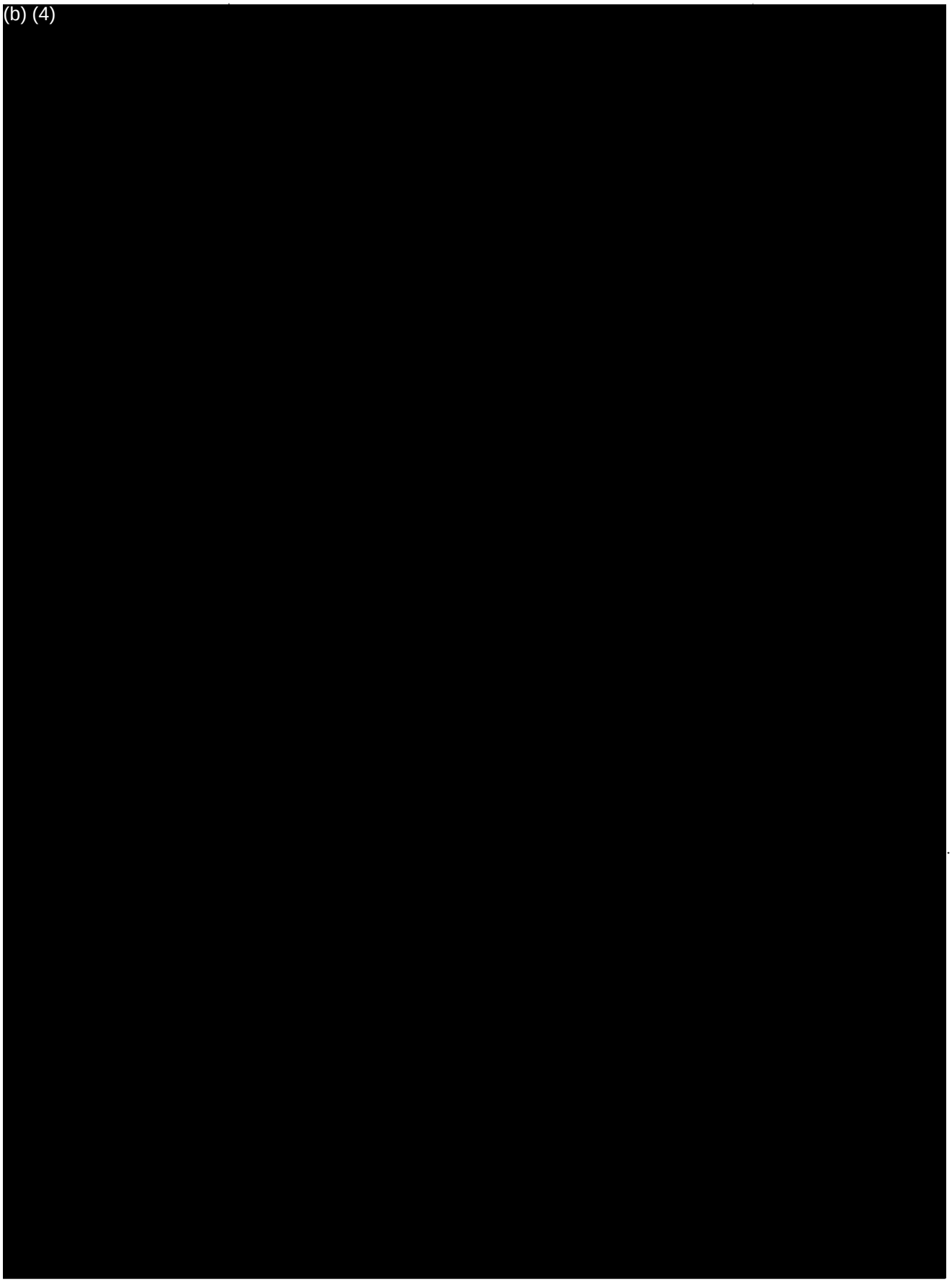

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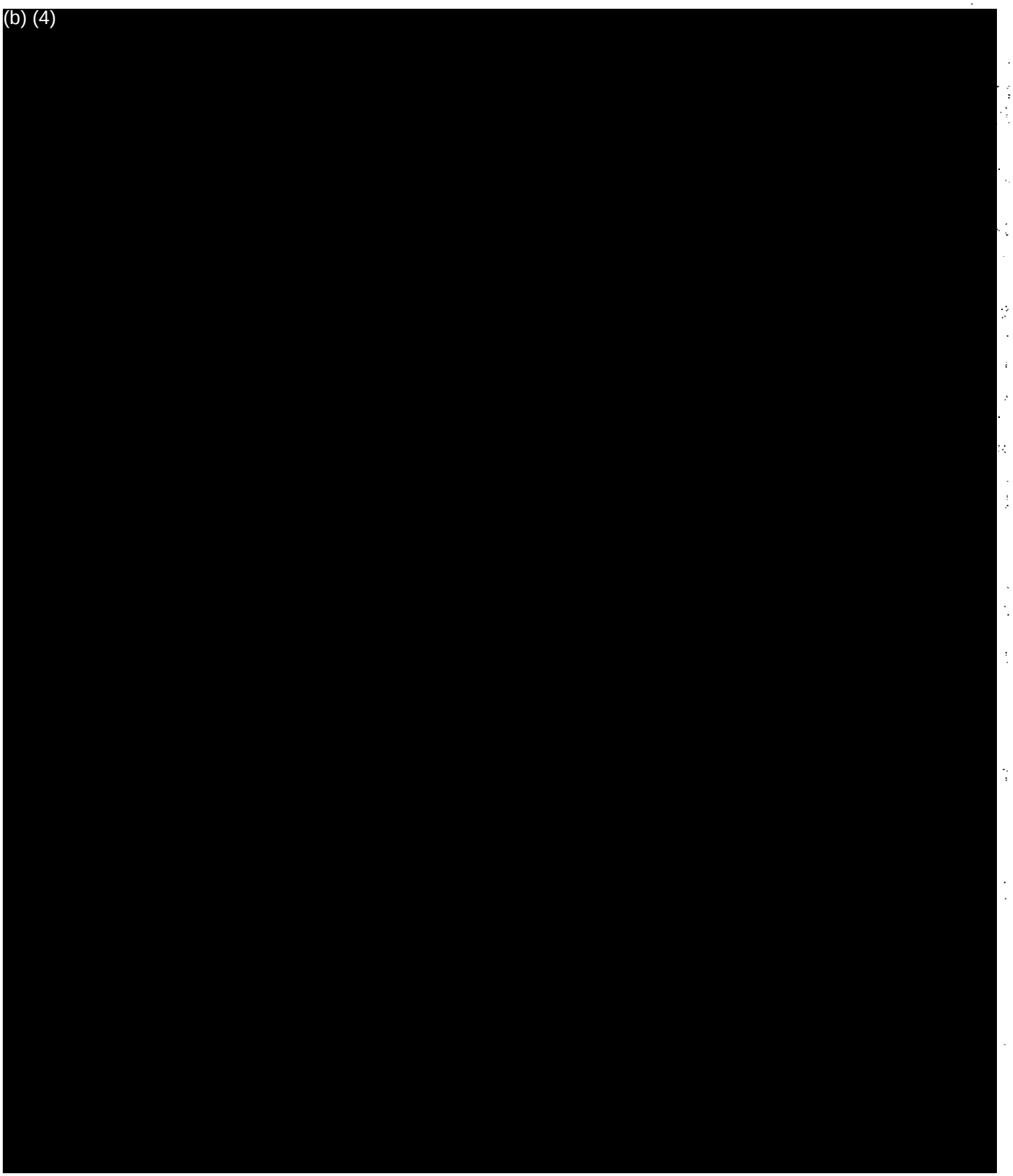

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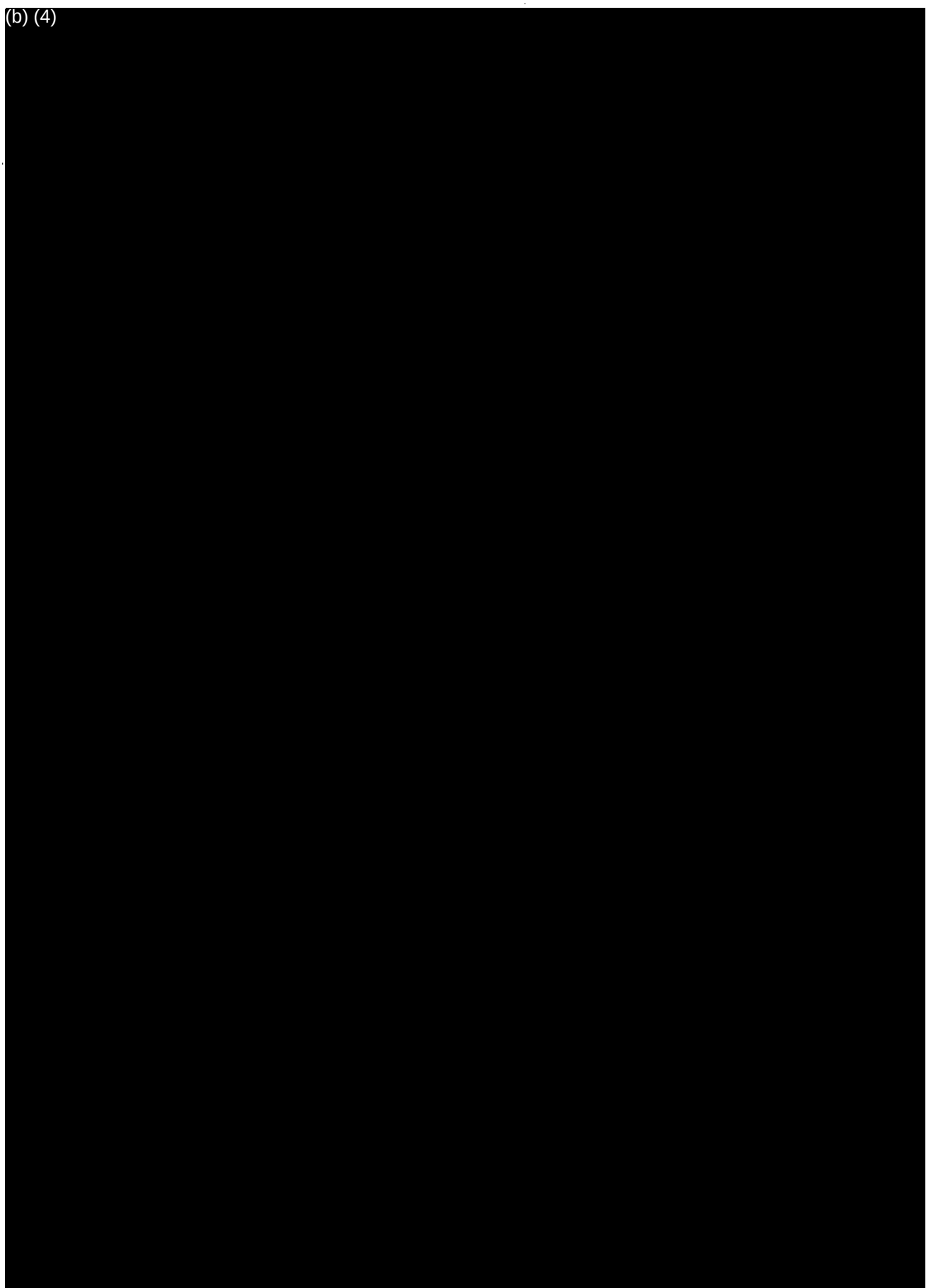

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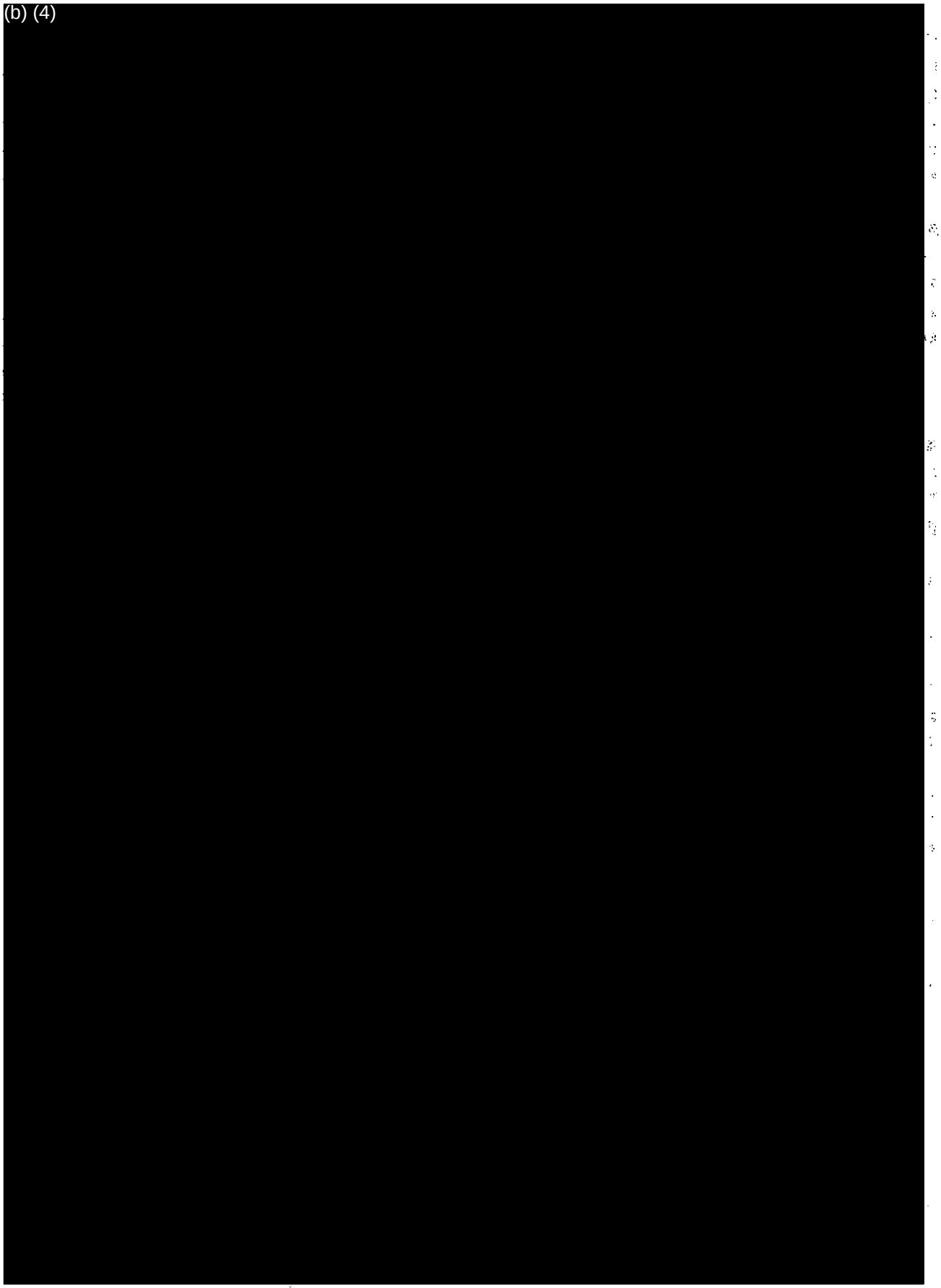

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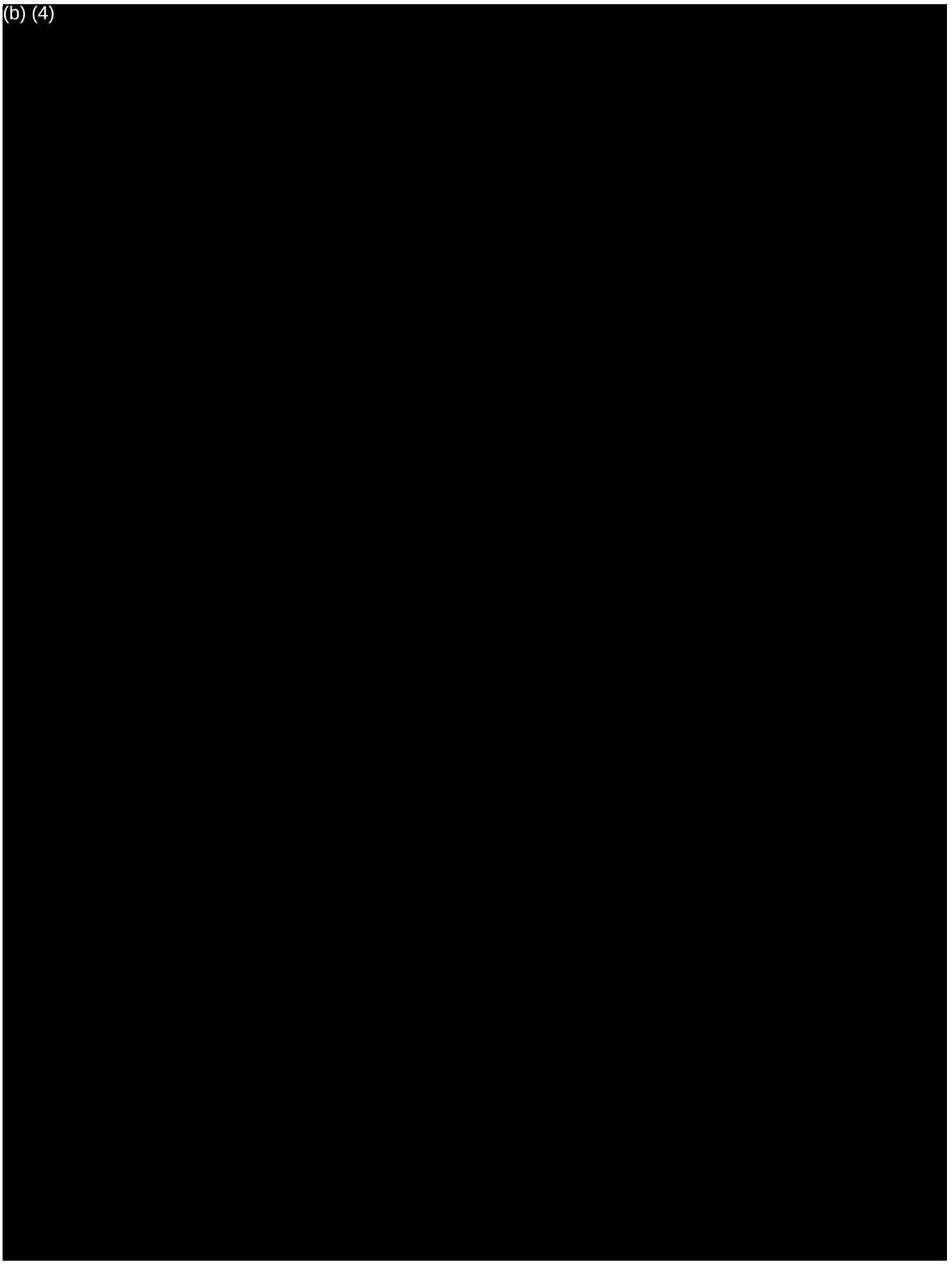

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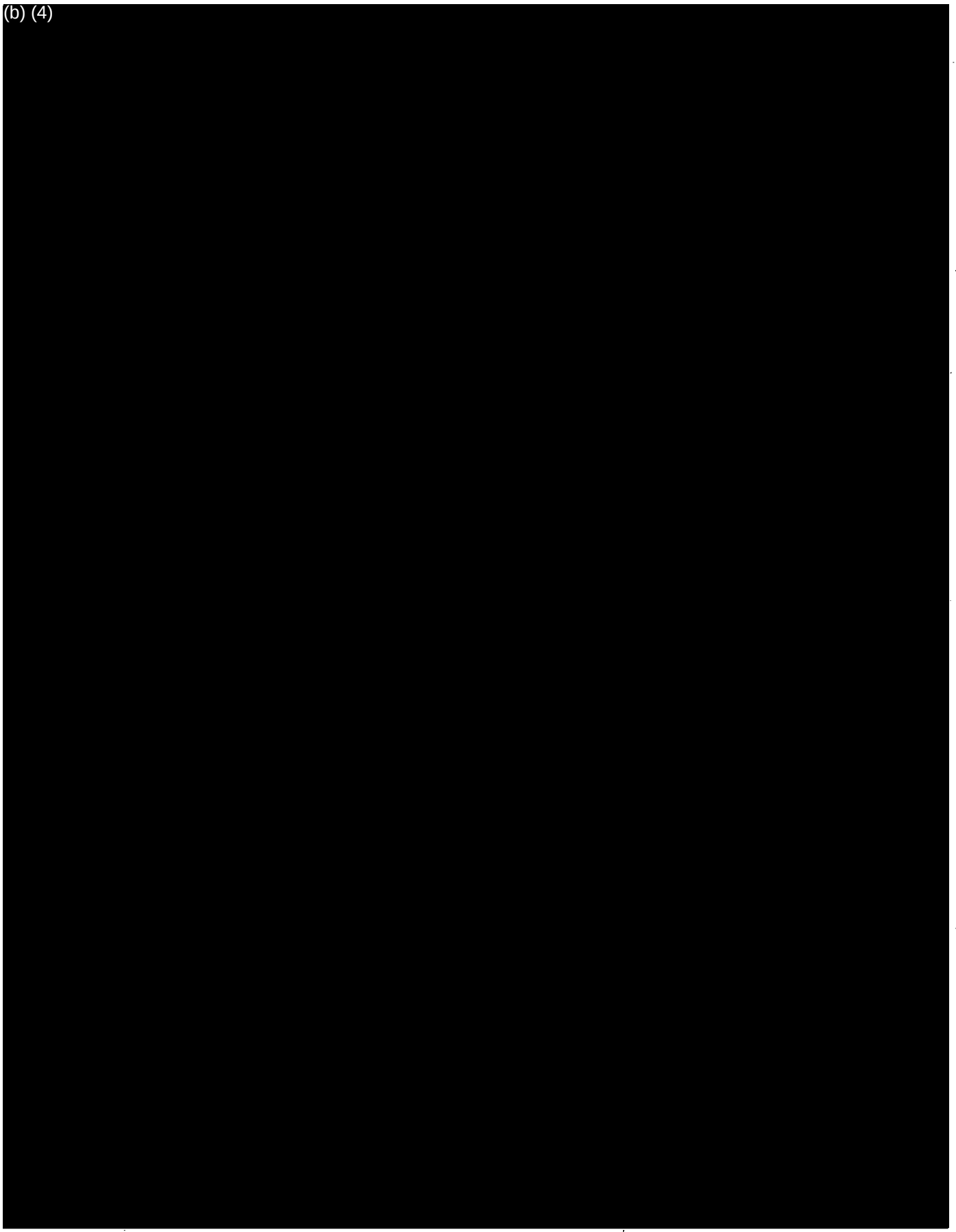

DJA x02370

(b) (4)

DJA x02371

Attachment 4

ISS Procedure 3000152, Customer Training Specifications for DigiMatch THR

DJA x02372

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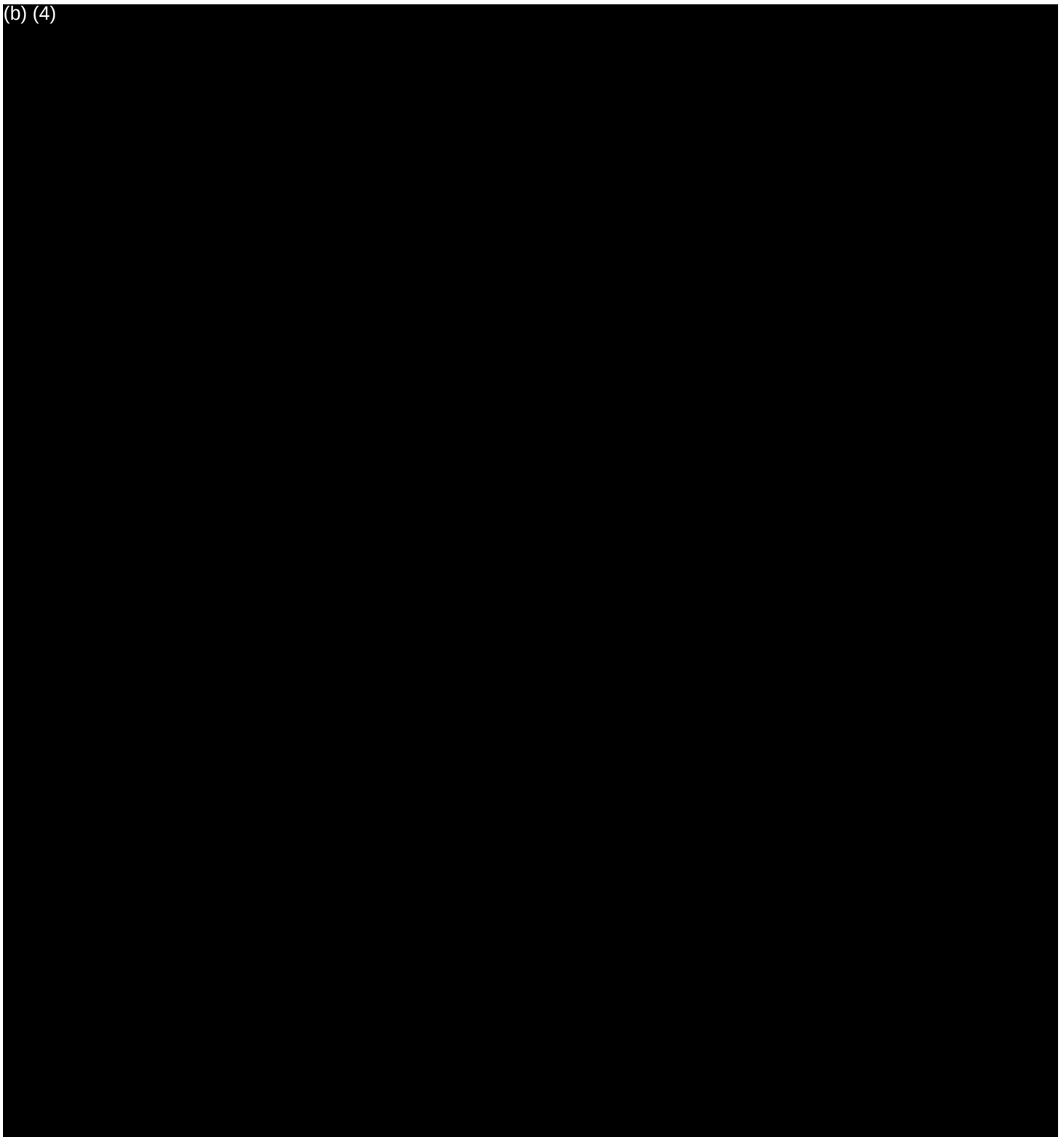

DJA x02373

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4. Minimum Suggested Staff Requirements

4.1. (b) (4)

4.2.

4.3.

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DJA x02374

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5. (b) (4)

[redacted]

DJA x02375

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(b) (4)

DJA x02376

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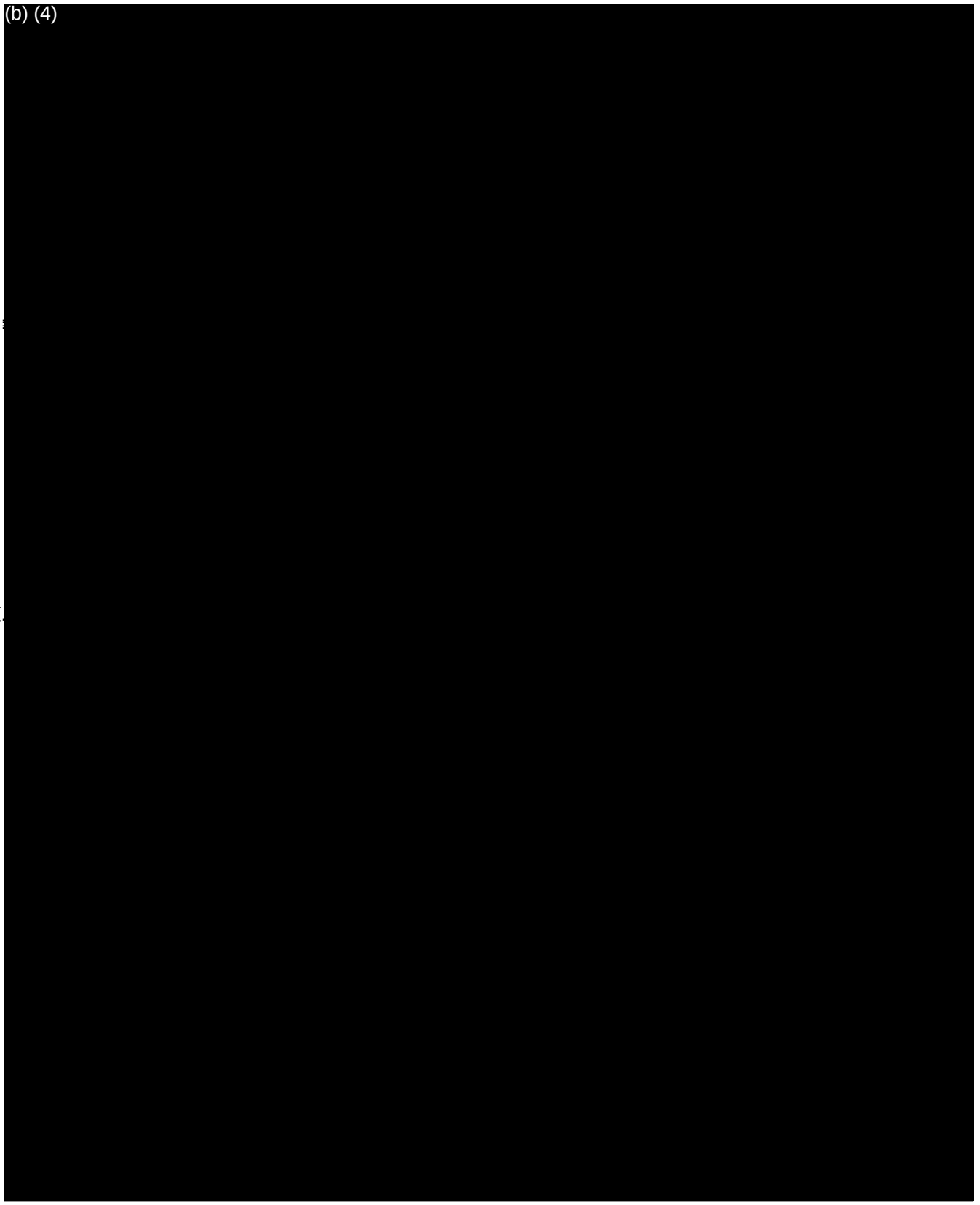

DJA X02377

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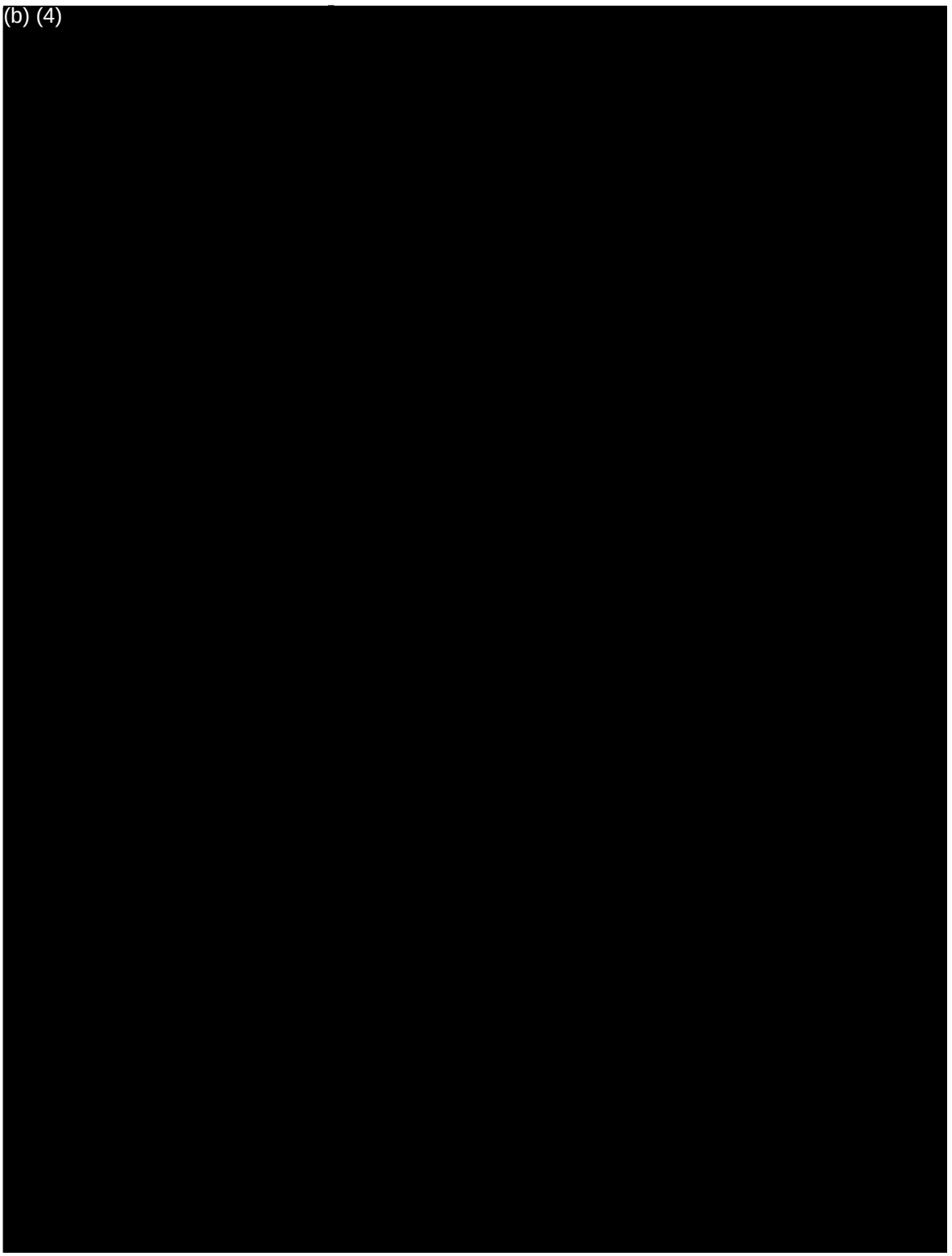

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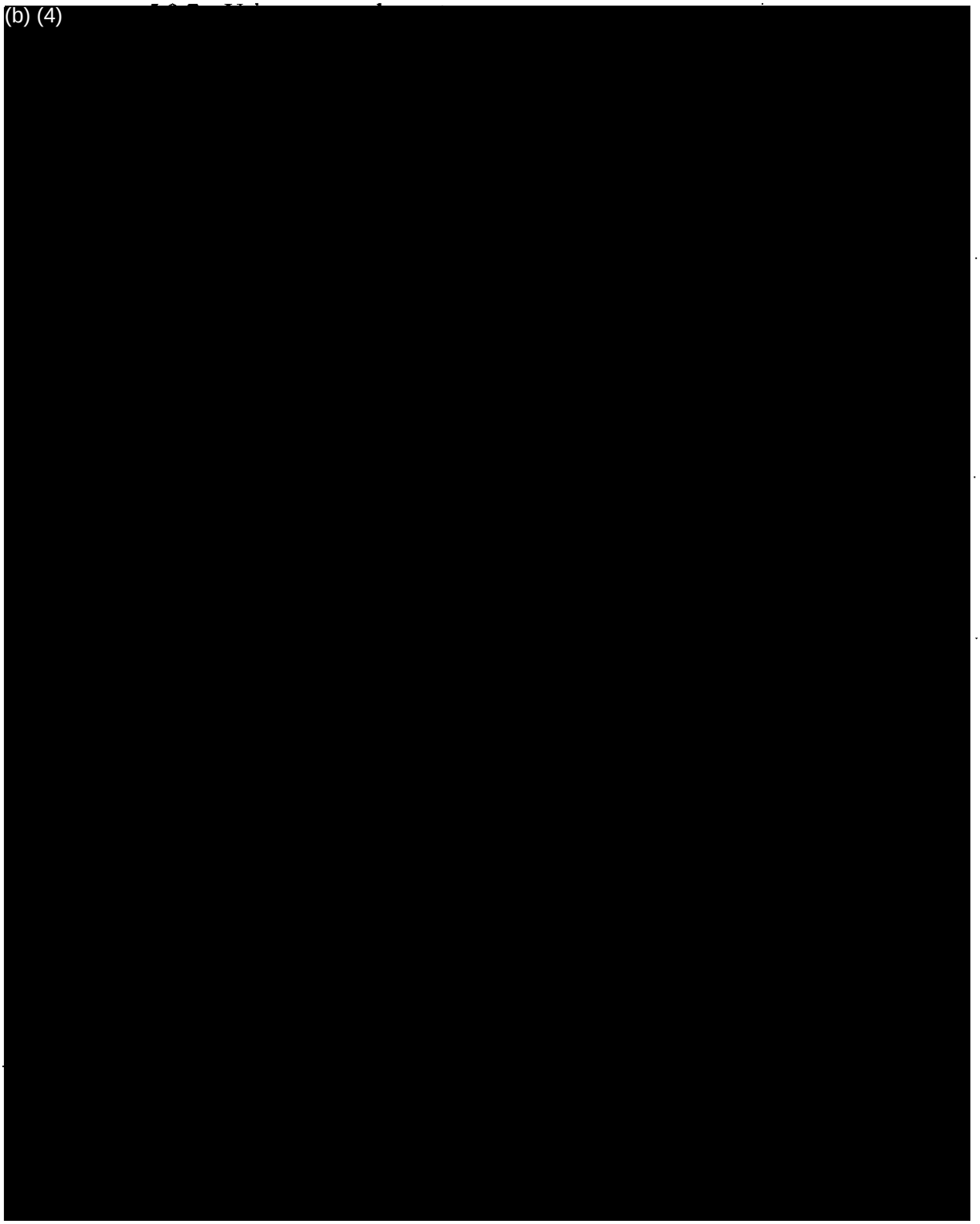

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(b) (4)

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DJA x02380

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(b) (4)

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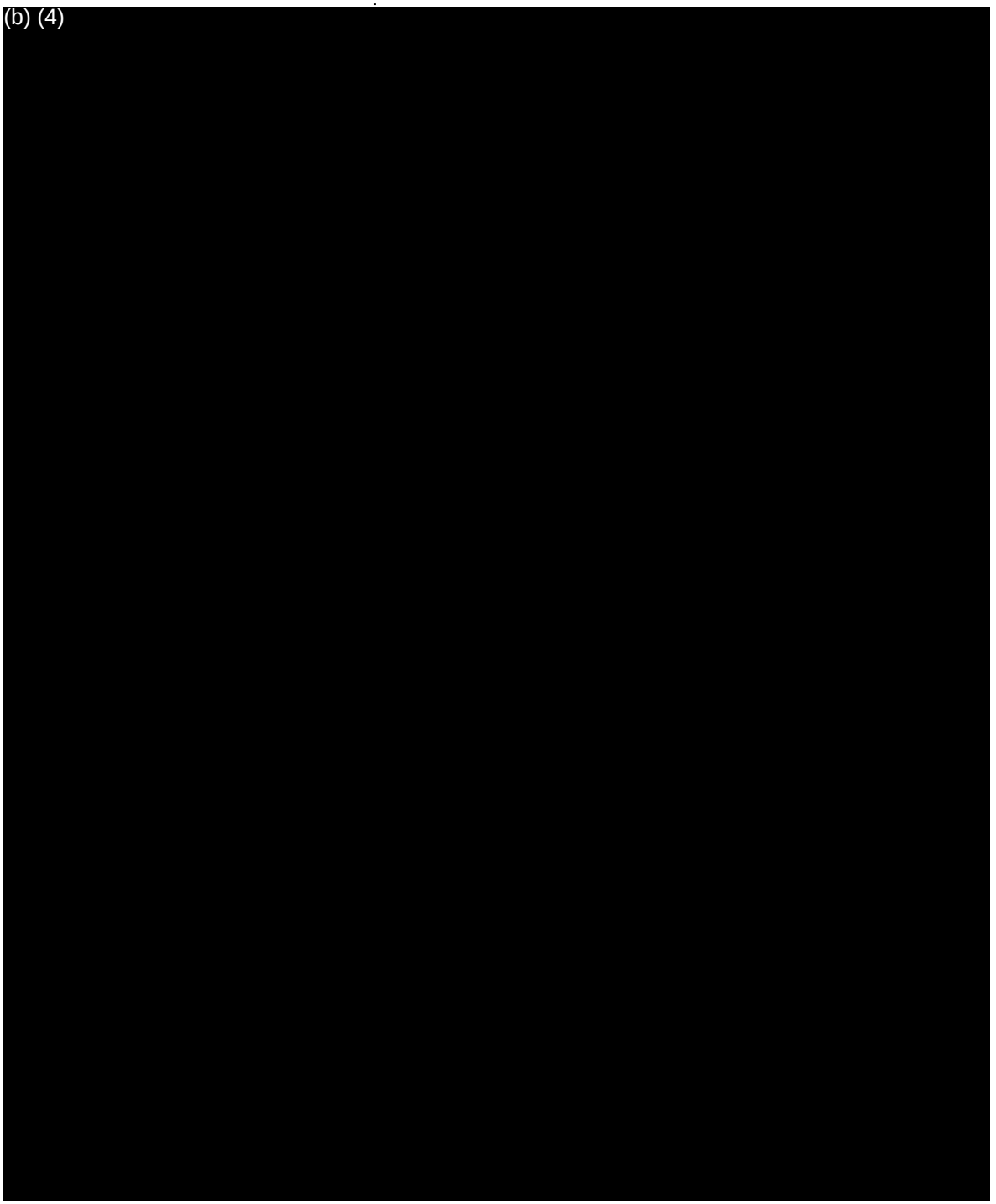

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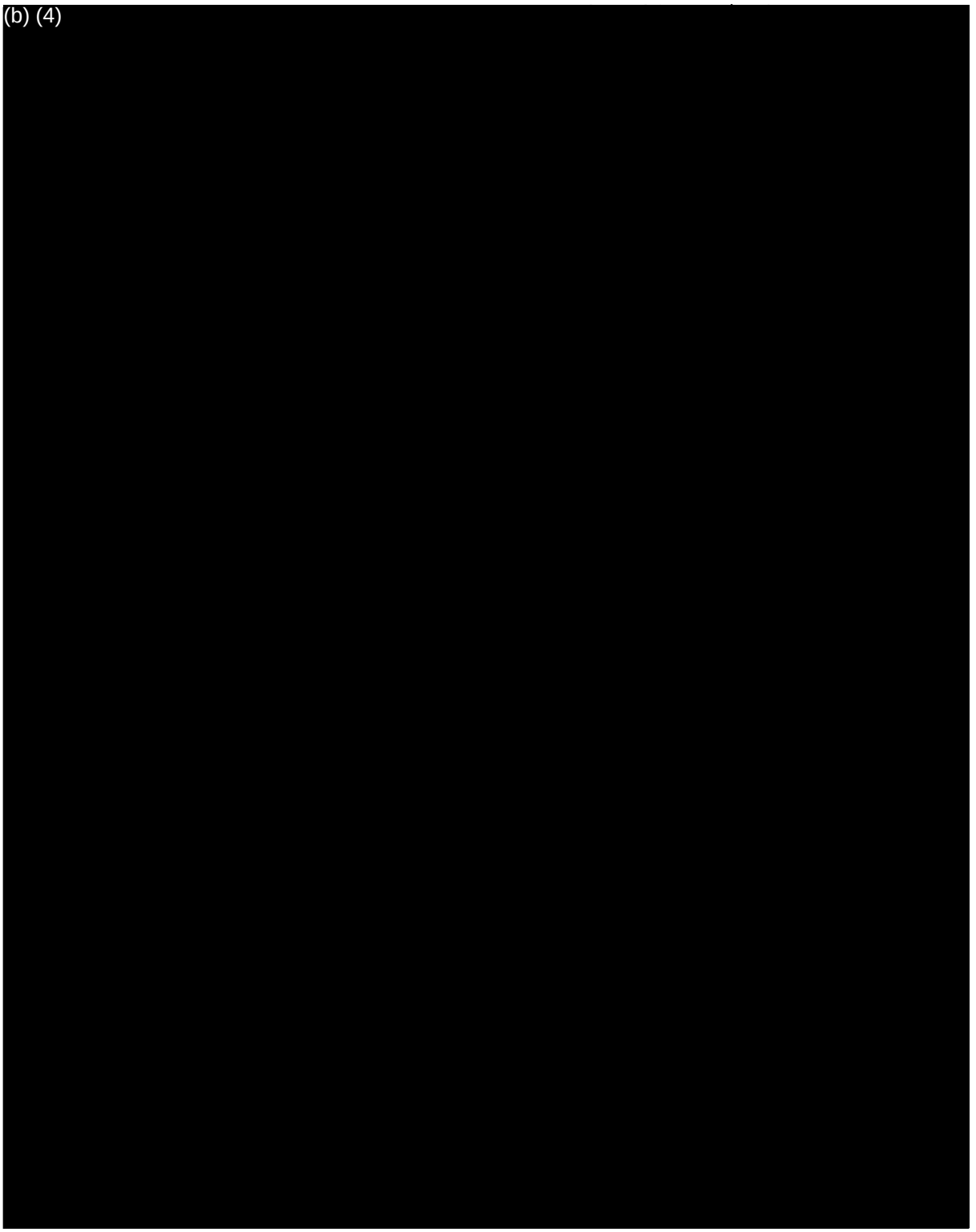

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(b) (4)

DJA x02384

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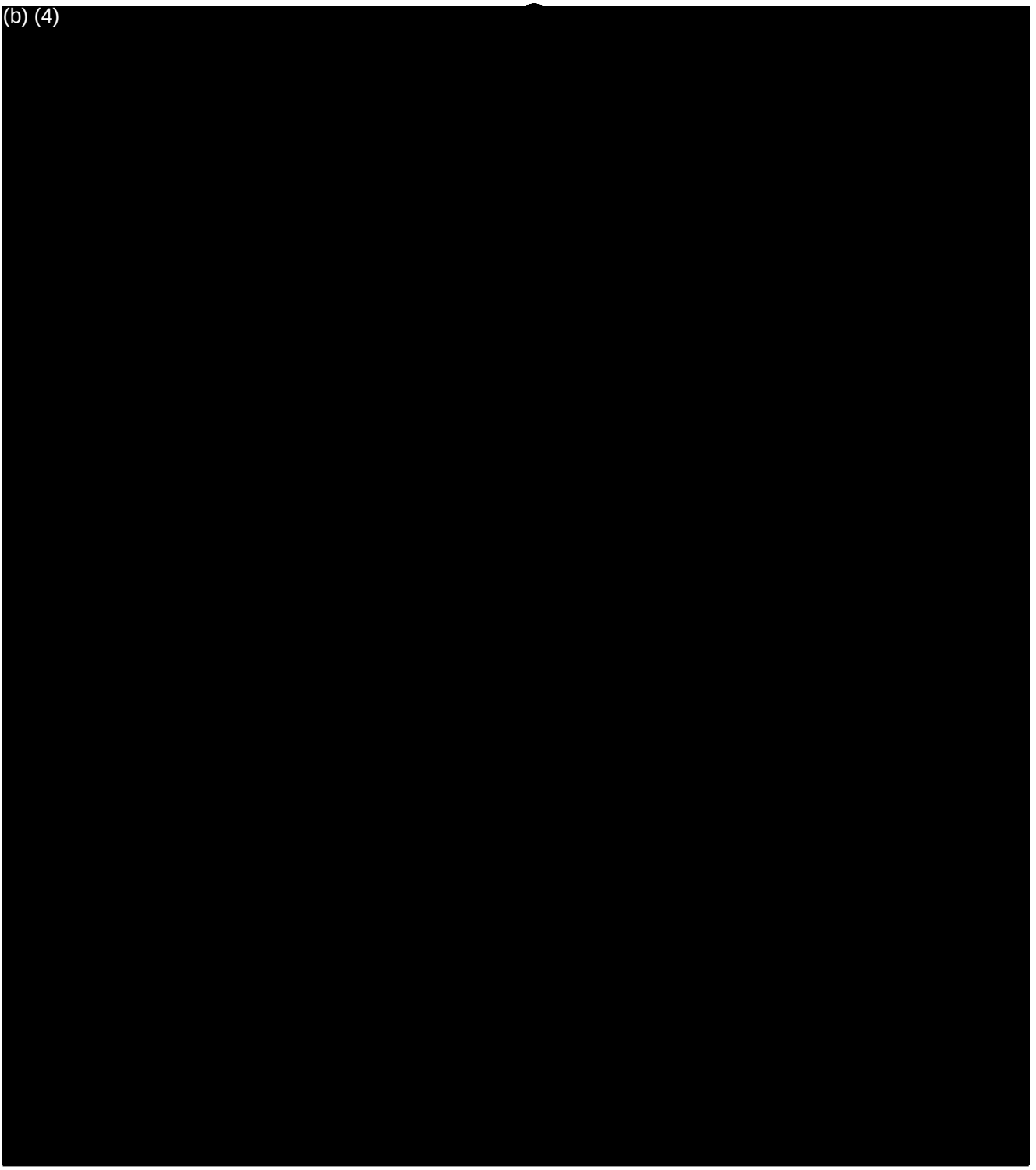

DJA x02385

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(b) (4)

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DJA x02386

20.9 Conclusions

(b) (4)

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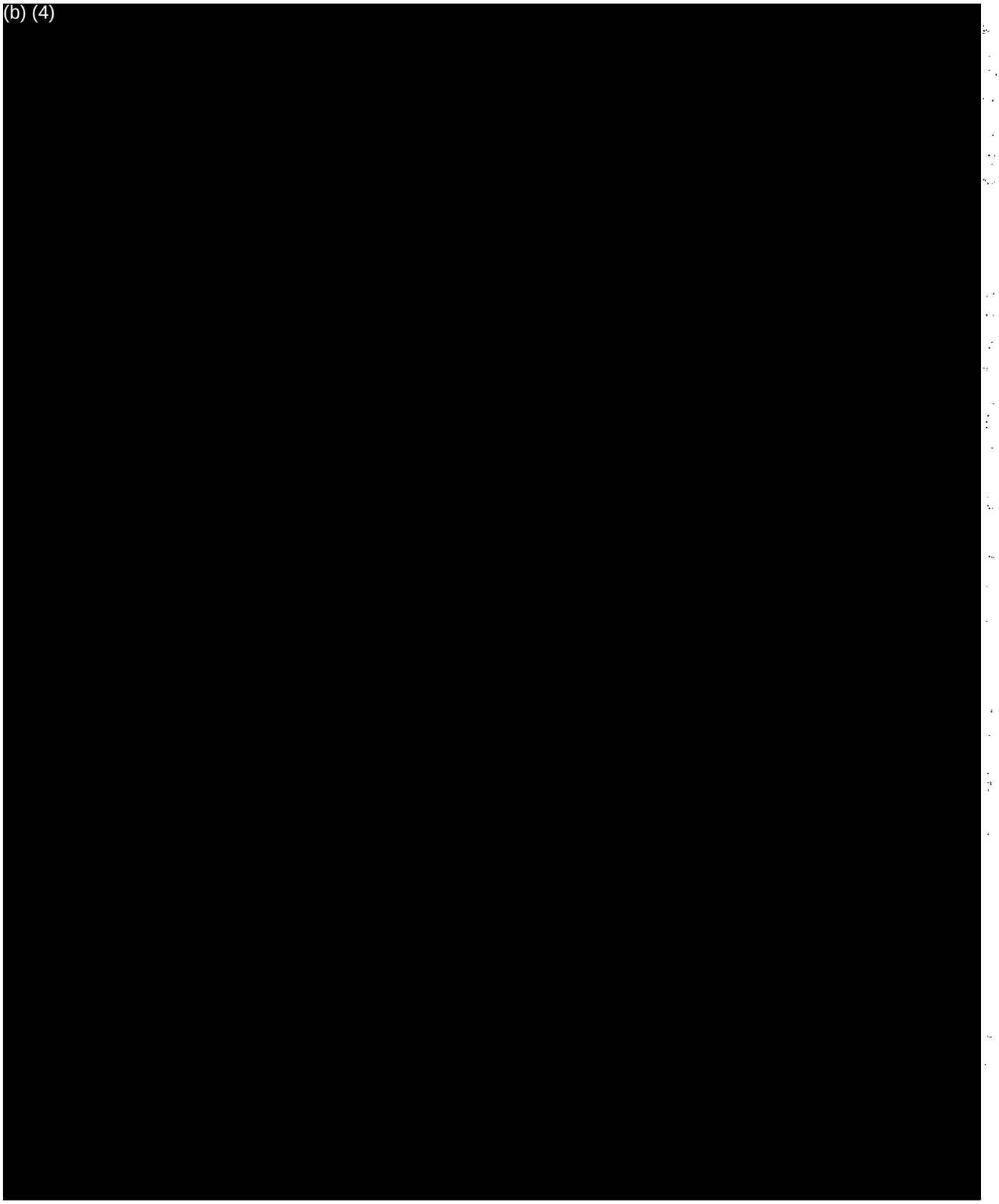
DJA x02387

(b) (4)



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(b) (4)

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DJA x02389

(b) (4)

[redacted]

DJA x00004

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

COVER SHEET MEMORANDUM

From: Reviewer Name Michel Jawda

Subject: 510(k) Number K072629/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)		X N.A.	
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

DJA x00005

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC:*		X

Regulation Number 882.4560 **Class*** II **Product Code** ~~OJE~~ OJP

(*If unclassified, see 510(k) Staff)

Additional Product Codes: HAW

Review: _____ (Branch Chief) GSDB (Branch Code) 8/4/08 (Date)

Final Review: _____ (Division Director) 8/6/08 (Date)

DJA x00006

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

COVER SHEET MEMORANDUM

From: Michel Janda, Biomedical Engineer
Subject: K072629
To: The Record

CTS decision code: **SE**

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☐ Hold (Additional Information or Telephone Hold).

X Final Decision (**SE**, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://croom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			X
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?		X	
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number: 882.4560 **Class: II** **Product Code: OJP**

Additional Product Codes: HAW

Review: _____
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

DJA x00007

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional - K072629/S002

Date: July 30, 2008
To: The Record
From: Michel Janda, Biomedical Engineer

Office: ODE
Division: DGRND

510(k) Holder: Integrated Surgical Systems, Inc.
1433 N. Market Boulevard, #1
Sacramento, CA 95834

Device Name: **DigiMatch Robodoc Surgical System**

Contact: Russ Hibbert, Director Clinical & Regulatory Affairs
Phone: (916) 285-9943 x522
Fax: (916) 575-7918
Email: rdhibbert@robodoc.com

Device Description

The DigiMatch System consists of the 510(k) cleared (K960685) ORTHODOC Preoperative Planning Workstation, a robotic electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (such as cutters, drapes, irrigation sets, probes and markers).

- **ORTHODOC** - The PC workstation enables the surgeon to select prosthesis and determine its desired position within the patient's femur. The system displays three-dimensional views of selected implant models for computerized templating with CT based femur images. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the interpolated CT image of the femur. Before or after templating, the user invokes a program calle[redacted](b) (4) which can be used for registration purposes. The ORTHODOC also provides software tools allowing surgeons to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC system with implant size, shape, and placement data. The output is saved on a transfer media and loaded into the electronics control cabinet of the ROBODOC prior to surgery.

- **ROBODOC** - The ROBODOC Surgical Assistant is present in the sterile field and contains all of the components that physically interact with the patient during the surgery. The operating room components of the ROBODOC system includes an electromechanical arm, electronics control cabinet, a display monitor, and miscellaneous accessories (such as cutters, drapes, irrigation sets, probes and markers). The User Interface consists of a display monitor, a hand-held pendant for controlling the robot, operator controls (switches/buttons), and indicator lights.

Indications for Use

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

DJA x00008

The DigiMatch ROBODOC Surgical System is indicated for orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

Deficiencies and Responses:

1. *The purpose of the second IDE clinical trial (G000071) was to validate the new pinless technology and demonstrate that the risk factors seen in the prior clinical trial had been mitigated or eliminated. These risk factors included longer surgical times and greater blood loss. During a January 18, 2007 meeting, FDA indicated that the data collected within the second IDE clinical trial would be reviewed to determine if the risk factors were properly mitigated and for validation of the new pinless technology. As such FDA requested that summary statistical analysis be performed on the available data. After reviewing the submitted analysis it appears that the risks of longer surgical times and greater blood loss were not fully mitigated. Therefore, FDA will be seeking the assistance of our expert panel members to judge the acceptability of these risks in relation to the potential benefit of your system. FDA believes that the recommendation of our expert panel is necessary in order to judge the risk/benefit profile of the subject device as compared to manual broaching and reaming as well as computer assisted surgery.*

   In order to enable this comparison, FDA is requesting that you provide additional formal statistical analysis of the study results. Possible analysis could include a comparison to data generated from the first clinical trial or a comparison to standard of care. Please provide additional information to demonstrate that the known risks of longer surgical times and greater blood loss have been fully mitigated or are acceptable given the device's potential benefit.

Response: A Benefit/Risk Analysis is provided in S002, Attachment 1. The Benefit/Risk Analysis concludes that the potential risks identified in the first clinical trial, namely, of two surgical procedures, ipsilateral knee pain, longer surgical time and increased blood loss have been substantially mitigated or eliminated with the pinless registration (DigiMatch™) ROBODOC® technology.

Reviewer's Comments: The sponsor's response was reformatted to provide an objective presentation of the benefit / risk analysis. This reformatted response and specific questions were forwarded as an orthopedic panel homework assignment. The sponsor was made aware that the division concluded that panel consultation was necessary to reach a determination regarding their file. The panel homework assignment was completed by Dr. Mabrey (homework assignment and memo attached). Dr. Mabrey's response indicated that he believed that the existing risks identified in the first IDE trial had been shown per the second IDE trial to be fully or substantially mitigated. As such, Dr. Mabrey recommended that the risk / benefit profile for the Robodoc system was appropriate. All comments received from Dr. Mabrey were positive with exception to a concern regarding the possibly steep learning curve associated with this technology. This concern is shared by the reviewer. However, the reviewer notes that the sponsor has provided an unsolicited training schedule which appears to be both intensive and robust and addresses all users (physicians, surgical staff, maintenance/engineering, etc.). This training document was not provided to the consulting panel member.

The recommendations of Dr. Mabrey were presented to Mr. Neil Ogden and Mr. Mark Melkerson for further review. Both concurred with Dr. Mabrey's concern regarding user training and acknowledged that the sponsor had initiated a user training program. They also concurred that while this device is clearly a technological step forward in computer assisted navigation systems it does not represent a new intended use and is appropriate for 510(k) review. It was recommended that a new product code be established under the stereotactic instrument regulation (21 CFR 882.4560). The reviewer concurs with the recommendations provided by Dr. Mabrey, Mr. Ogden, and Mr. Melkerson. The reviewer further suggests that future 510(k) submissions seeking to establish substantial equivalence to this robotic system should include clinical data and substantial validation testing.

2. *As previously indicated, assessment of the device risk/benefit profile remains as the primary concern. In order to allow this assessment, the FDA believes that additional information is needed regarding longer-term outcomes. Possible sources of long term data could include the first IDE clinical trial and Outside of the United States (OUS) studies. As the pooling of this data is likely to be problematic, summary*

DJA x00009

information and analysis is appropriate. Please provide additional long term data (2 year and beyond) to support the potential benefit of the subject device.

Response: There has been one controlled, FDA-reviewed IDE study and two controlled, peer-reviewed, published studies that follow the ROBODOC patients and manual hand-rasping control subjects out to two years. To date there have been no controlled, published studies reporting results of ROBODOC patients followed for more than two years.

Study One

The first study to report two-year follow-up data was the First IDE Trial (G920035). This trial included two-year follow-up using Harris Hip Score, Hip Society evaluations (Johnson) and the SF-36 scores for quality of life measures. The results showed no statistical difference between the ROBODOC and control groups at two-year follow-up for these self-assessment measures. The results of the functionality and pain assessment, and the radiographic assessment are provided in Section 3 of the Benefit/Risk Analysis (S002, Attachment 1).

Study Two

The second study to report two-year follow-up data was conducted by Nishihara, et al., and was published on the Journal of Arthroplasty, Vol. 21, No. 7, 2006. This study reports that Merle D'Aubigne hip scores at two-year follow-up were statistically better for the ROBODOC group compared to the hand-rasping group (Mann-Whitney *U* test, $p < 0.05$).

Study Three

The third study to report two-year follow-up data was conducted by Hananouchi a, et al., and was published on the Journal of Orthopaedic Research, Vol. 25, 2007. The authors evaluated the effects of robotic milling in cementless total hip arthroplasty (THA) in a longitudinal 24-month follow-up study using dual energy X-ray absorptiometry (DEXA) and plain radiographs of 29 patients (31 hips) after ROBODOC THA and 24 patients (27 hips) after manual THA with the same stem design. This study reports that the better fit and fill of the femoral stem and less destruction of the bony architecture as compared to manual broaching may have a beneficial affect on femoral periprosthetic bone remodeling. Significantly less bone loss occurred at the proximal periprosthetic areas in the ROBODOC group. In zone 1, the decrease was 15.5% versus 29.9% using conventional rasping; in zone 7, the loss was 17.0% with ROBODOC compared to 30.5% with conventional rasping ($p < 0.05$). On radiographs, endosteal spot welds in the proximal medial portion were more pronounced in the ROBODOC group (48% vs. 11% in the conventional group, $p < 0.05$).

Reviewer's Comments: The sponsor has provided all available information regarding long-term followup. This information only consists of two year data from three separate sources. The provided information does not appear to suggest a clear benefit of robotic rasping as compared to the manual group. However, the information also does not appear to suggest any clear disadvantage with the robotic rasping method. It is unclear if there is any long-term difference between the groups as more data may be required to detect a statistically significant difference. The reviewer defaults to the clinical opinion of the consulting orthopedic panel member in judging the long-term benefit of the robotic rasping method. As stated previously the robotic rasping method is only required to demonstrate equivalent safety and effectiveness to the manual rasping method.

3. *The submission includes an indication for use statement which appears to differ from that studied within first and secondary IDE studies. Specifically, the indication for use statement includes a paragraph which makes safety and effectiveness claims regarding other orthopedic procedures (Paragraph #3). Please revise the indications for use statement and device labeling where appropriate to remove this reference or provide additional clinical data to support this claim.*

Response: The Indication for Used Statement has been revised to address this comment. The revised statement is provided below (S002, Attachment 2):

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and

DJA x00010

reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

Reviewer's Comments: This revision addresses the concerns regarding other orthopedic procedures. The indications for use clearly indicate that the subject device is to be used only for femoral broaching/reaming during THA. This response is acceptable.

II. Recommendation

In the reviewer's opinion, the sponsor has provided adequate verification / validation documentation in the form of bench and clinical data to establish substantial equivalence to existing computer assisted navigation systems and manual broaching instruments. This device represents the first robotic device cleared within the stercotactic regulation.

Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotactic Instrument
Regulatory Class: Class II
Product Code: **New Product Code** – OJP - Orthopedic computer controlled surgical system

Reviewer — Date: 7/30/08

Branch Chief — Date

DJA x00011

U.S. FOOD AND DRUG ADMINISTRATION

New Device Clearance

DigiMatch™ ROBODOC® Surgical System

Product Name: DigiMatch™ ROBODOC® Surgical System
510(k) Sponsor: Integrated Surgical Systems, Inc.
Address: 1433 N. Market Boulevard, #1
Sacramento, CA 95834

What is it? The Robodoc Surgical Assistant is a robotic system for preparation of the femur during primary or revision total hip arthoplasty (THA). Following the surgeon's surgical plan and choice of implant dimensions using the 510(k) cleared (K960685) ORTHODOC Preoperative Planning Workstation, the robotic device creates a femoral cavity accurately shaped and positioned for implantation of a selected hip prosthesis.

How does it work? The surgeon begins the THA operation in accordance with the practice of medicine by exposing the femur and removing the femoral head. The surgeon performs registration procedures to provide orientation and reference information to the Robodoc system via proximal and distal markers on the patient's femur. The surgeon then attaches the appropriate end effecter and positions the robotic arm in the vicinity of the femur. The surgeon then activates the Robodoc milling arm. Robodoc begins to mill the femur as defined by the preoperative plan. Robodoc will terminate milling when a safety condition is detected, the surgeon activates the emergency stop button, or a different end effecter is required.

When is it used? The DigiMatch ROBODOC Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with pre-surgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the pre-surgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

What will it accomplish? The system will create a femoral cavity during primary or revision THA.

When should it not be used? The system does not assist with preparation of the acetabulum. The following contraindications also apply to the Robodoc Surgical System:

- Skeletal immaturity
- Any active infection.
- Neuromuscular disorders, which would create an unacceptable risk of prosthesis instability or fixation failure
- A pathological skeletal condition, which would impair the ability of the bone to withstand the stress of femoral canal preparation and prosthesis placement (e.g., severe osteoporosis, Paget's disease, renal osteodystrophy).
- A systemic illness, which would render the patient unable to perform appropriate postoperative rehabilitation or preclude adequate assessment of pain and gait.
- Mental disorders, which could complicate preoperative and postoperative care.
- Obesity.
- Pregnancy.
- Poor skin coverage or bone stock of the operative femur adjacent to the greater trochanter, or the lateral or medial epicondyle.

DJA x00012

- Severe femoral deformity due to trauma or severe cases of degenerative osteoporosis of the operative femur, with significant deformation of the surfaces required for DigiMatch surface registration.
- Any metallic objects in the operative or counteroperative leg which would cause unacceptable levels of artifact in the CT slices over the surfaces required for DigiMatch registration.

Concurrence:

510(k) Number: K072629

DJA x00019

Janda, Michel D

From: Russ Hibbert [rdhibbert@robodoc.com]
Sent: Wednesday, July 30, 2008 4:40 PM
To: Janda, Michel D
Subject: RE: DigiMatch Robodoc Surgical System, K072629
Attachments: Supplement 3_Revised K072629 Summary-Statement_rev-07.30.08.doc

Dear Mr. Janda,

Attached is Supplement 3 to K072629, which provides the requested revised 510(k) Summary of Safety and Effectiveness. Please let me know if you have any questions. I anticipate that with the submission of this supplement, FDA can finalize the clearance to market letter for the DigiMatch™ ROBODOC® Surgical System with Total Hip Arthroplasty (THA) Module. Please fax (916-575-7918) the clearance letter to may attention at your earliest opportunity.

Kind regards,

RD Hibbert
Director of Clinical, Regulatory & Quality Compliance
Integrated Surgical Systems
1433 N. Market Blvd, Suite 1
Sacramento, CA 95834
(b) (6)
Office Phone: 916-285-9943 ext. 522
Fax Number: 916-575-7918
E-mail: rdhibbert@robodoc.com

-----Original Message-----
From: Janda, Michel D [mailto:michel.janda@fda.hhs.gov]
Sent: Wednesday, July 30, 2008 8:44 AM
To: Russ Hibbert
Subject: DigiMatch Robodoc Surgical System, K072629

Mr. Hibbert,

In the previous request for additional information, revisions were requested in regards to the indications for use statement. Your response appropriately revised this statement. However, this revision must be reflected throughout the 510(k) submission. Specifically the 510(k) summary of safety and effectiveness must be modified to reflect the revised indications for use. Please provide a revised copy of this document. An electronic copy of this document is acceptable.

Sincerely,

Michel Janda

Biomedical Engineer

Phone #: (240) 276-3600

Fax #: (240) 276-3733

DJA x00020

ODE/DGRND/GSDB

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

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Version: 8.0.138 / Virus Database: 270.4.5/1533 - Release Date: 7/3/2008 7:19 PM

DJA x00021

ROBODOC®
INTEGRATED
SURGICAL SYSTEMS

July 30, 2008

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

Attention: Michel D. Janda

Re: Supplement 3: DigiMatch™ ROBODOC® Surgical System; K072629

Dear Mr. Janda:

This submission provides the response to FDA's Request for Additional Information, dated July 30, 2008, regarding premarket notification number K072629. Supplement 3 contains the requested updated 510(k) Summary of Safety and Effectiveness, which is modified to reflect the previously revised indications for use.

Please contact me if you have any questions regarding the information submitted herein. Otherwise, please forward a copy of the substantial equivalence letter to me by facsimile at 916-575-7918. Thank you in advance for your cooperation.

Sincerely,

RD Hibbert
Director of Clinical, Regulatory and Quality Compliance
Integrated Surgical Systems
1433 N. Market Blvd., Suite 1
Sacramento, CA 95834
(b) (6)
Office Phone: 916-285-9943 x 522
Office Fax: 916-575-7918
E-mail: rdhibbert@robodoc.com

cc: Dr. Ramesh Trivedi, President and CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.

Attachment enclosed

DJA x00022

Section 5 - Summary of Safety and Effectiveness

A summary of this 510(k) submission is provided herein in accordance with 21 CFR 807.92.

Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834

Contact: Russ Hibbert
Director, Clinical & Regulatory Affairs
Phone: 916-285-9943, ext. 522
Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

DJA x00023

Summary of Safety and Effectiveness
K072629

Submitter:	Integrated Surgical Systems, Inc.
Address:	1433 N. Market Blvd., #1, Sacramento, CA 95834 USA
Phone Number:	916-285-9943
Fax Number:	916-575-7918
Contact Person:	Russ Hibbert
Date Submitted:	September 7, 2007
Trade Name:	DigiMatch™ ROBODOC® Surgical System
Common Name:	Stereotaxic Instrument
Device Classification;	Class II
Regulation Number:	21 CFR 882.4560

Substantial Equivalence Claim

The DigiMatch™ ROBODOC® Surgical System is substantially equivalent to the Voyager/Tactile Guidance System – CT (K052851), the Frameless Neuromate (K991081) and the da Vinci Surgical System (K043153).

Device Description

The DigiMatch™ ROBODOC® Surgical System consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then ROBODOC component of the System, under direct control by the surgeon, will precisely implement the preoperative plan.

Indications for Use / Intended Use Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for Orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

DJA x00024

Summary of Safety and Effectiveness
K072629

Comparison of Technological Characteristics and Principles of Operation

Table 1 provides a comparison of technological characteristics and principles of operation between the DigiMatch™ ROBODOC® Surgical System and its predicate devices, the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System.

Table 1 Comparison of Technological Characteristics and Principles of Operation

	Patient Image Data	Pre-Surgical Plan	Surgical Plan Data	Machine Instructions	Patient/Robot Registration Requirement	Robot Electromechanical Arm(s)
DigiMatch™ ROBODOC® Surgical System	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes point to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Voyager Tactile Guidance System – CT (K052851)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes surface to surface registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
Frameless Neuromate (K991081)	Yes CT Scan	Yes pre-surgery	Yes high level operative plan	Yes robotic arms driven by validated control software and hardware	Yes fiducial marker registration	Yes Robot with single electromechanical arm and end effector implement control file instructions
da Vinci® Surgical System (K043153)	No visual image	No intra-surgery	No control file developed in real time during surgery	Yes robotic arms driven by validated control software and hardware	Yes visual registration	Yes Robot with multiple electromechanical arms and end effector implement control file instructions

DJA x00025

Summary of Safety and Effectiveness
K072629

Summary of Performance Testing

ISS has completed bench, animal, cadaver and clinical testing that assess the safety and efficacy of the ROBODOC System.

Nonclinical Studies

Nonclinical cadaver and animal studies provide an accurate means of determining cavity accuracy and placement. The value of such studies is that they allow a measurement of the gap between the bone and implant. They also permit histological examinations of the cavity/implant interface, which has value in determining whether the implant apposition within the cavity is sufficiently narrow.

Cadaver Study

The cadaver study compared the accuracy of cutting the femur with the ROBODOC versus manual broaching. The results showed that the ROBODOC was more accurate than manual broaching and led to significantly reduced gaps between the implant and bone.

Animal Study

The animal study, involving 20 male greyhounds, also supports the conclusion that the ROBODOC is more accurate than manual broaching in cutting the femur. Histological examination revealed many instances of fracture or osteotomy in the control group, compared to none in the ROBODOC group. In addition, histological examination revealed that the ROBODOC group had more consistent cortical bone continuity, better apposition of implants with cortical and cancellous bone, and appeared to have less cancellous bone hypertrophy.

Clinical Studies

The First U.S. Trial (G920035) was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. The primary endpoints of efficacy that demonstrated precise and reliable implantation of the preoperative plan were fit and alignment of the femoral implant. Primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

The Second U.S. Trial (IDE # G000071) was undertaken with the "pinless" DigiMatch™ ROBODOC® Surgical System. The DigiMatch™ technology modified the ROBODOC System so as not to require pre-operative placement of fiduciary pins. The data from this trial also confirmed the safety and efficacy of the ROBODOC System. As with the First IDE Trial, primary clinical efficacy was demonstrated showing equivalence in Harris Hip Scores between the ROBODOC group and the manual control group.

Conclusion

The DigiMatch™ ROBODOC® Surgical System, which is substantially equivalent to the Voyager/Tactile Guidance System – CT, the Frameless Neuromate and the da Vinci Surgical System, has been shown to be safe and effective for its intended use.

DJA x00026

Janda, Michel D

From: Mabrey, Jay D. [JayM@BaylorHealth.edu]
Sent: Sunday, June 22, 2008 2:26 PM
To: Melkerson, Mark N.; Janda, Michel D; Jean, Ronald P
Cc: Gilleland, Lee
Subject: ROBODOC
Follow Up Flag: Follow up
Flag Status: Red

Digimatch ROBODOC Surgical System (K072629)

Panel Homework Assignment
Jay D. Mabrey, MD
Chairman, FDA Device Panel
22 June, 2008

I have reviewed all materials sent by the FDA in conjunction with K072629 as well as reviewing additional materials off-line. I am a board-certified orthopaedic surgeon specializing in total hip and total knee replacement. I have extensive experience with surgical navigation for total knees and I follow closely any developments with respect to total hip navigation and planning.

A. Do you believe that the DigiMatch Robodoc Surgical System is safe and effective as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA)?
   a. During both the first and second IDE trials, the ROBODOC system demonstrated 0% intraoperative fractures compared to 5% for the conventional technique in trial 1.
   b. Leg length discrepancies were also significantly less in the ROBODOC group.
   c. Fit and fill of the component in navigated hips was noted to be superior to that of manually prepared hips. This may have long term benefits to the survival for navigated hips.
   d. The answer then is "yes" the ROBODOC Surgical System is safe and effective as an alternative to manual planning and broaching for THA.

B. Please compare and contrast the DigiMatch Robodoc Surgical System's risk/benefit profile to that of manual broaching/reaming techniques for femoral canal preparation in primary THA. Please comment on any differences which you believe may have significant impact upon clinical outcome.
   a. There is no longer a need for a second surgical procedure to implant the fiduciary pins.
   b. Post-surgical ipsilateral knee pain has been shown to be equivalent to or even less than the standard technique in the second IDE trial.
   c. Surgical times have improved adding at most 45 minutes to the navigated procedure. Data cited from the Kurtz article that longer surgical times equated with worse outcomes did not take into account the co-morbidities of the longer cases such as obesity, intra-operative fracture requiring additional time for fixation, heterotopic ossification, or the experience of the operating surgeon. Less experience equates with longer times as well.
   d. Blood loss has been shown to be equivalent or even less than standard technique with the second IDE. The clinical implications are that milling the bone rather than broaching is less likely to disturb the intramedullary canal and thus will lead to less bleeding.
   e. Fit and fill, as noted above, are significantly improved with the navigated technique. The

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clinical implications are that better fit and fill may equate with better bone ingrowth and stress transfer, thus providing better overall performance of the implant in the long run, particularly for younger more active patients.

f. Leg length discrepancy is less with the navigated system than the manual system. Leg length discrepancy is the number one cause of malpractice suits against total hip surgeons.

C. Based upon the previous risk/benefit comparison, what additional information/actions, if any, do you believe are necessary to improve the device's risk/benefit profile?

a. As outlined above, it is my professional opinion, and with a reasonable degree of medical certainty, that the sponsor has answered all of the questions posed by the FDA with reference to the first IDE. There is no second surgery, time difference is minimal, blood loss is similar, and ipsilateral knee pain is similar if not less.

b. There is obviously a learning curve associated with the use of the device. Based upon my review of the literature and information supplied by the FDA, there appears to be a training program in place at various institutions. I would ask that the Sponsor document the nature of the training program for the FDA's benefit.

Respectfully,

Jay D. Mabrey, MD
Chief, Department of Orthopaedics
Baylor University Medical Center
214-820-3434

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Panel Homework Assignment
DigiMatch™ ROBODOC® Surgical System (K072629)

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1. General Information

Device Name:	DigiMatch™ ROBODOC® Surgical System
Applicant:	Integrated Surgical Systems, Inc. 1433 N. Market Boulevard, #1 Sacramento, CA 95834

2. Background

The sponsor has submitted K072629 to notify the FDA of their intent to introduce the DigiMatch Robodoc Surgical System into interstate commerce. This device represents a first of its kind in that it employs robotic technology to perform femoral reaming during primary total hip arthroplasty (THA) surgery.

The sponsor has submitted this 510(k) notification after prematurely terminating enrollment of their second clinical study, G000071. The purpose of this clinical trial was to evaluate technical enhancements of the device, which were intended to eliminate or significantly mitigate the potential risks of longer surgical time, greater blood loss, and post-operative ipsilateral knee pain identified in an earlier trial of the first generation of the ROBODOC system, IDE G920035.

The first IDE Clinical Trial (G920035) was conducted using pin-based technology, which required three locator (fiduciary) pins to register the robotic device to the patient. A primary objective of the first IDE trial was to confirm that the ROBODOC Surgical System safely and reliably implemented the preoperative plan developed by the surgeon on the ORTHODOC component of the system. The primary endpoints of efficacy were fit and alignment of the femoral implant. Upon review of the data from the first trial in October 2000, FDA identified four potential risk factors for the ROBODOC Surgical System, namely:

- The need for two surgical procedures (a separate surgical procedure to implant fiduciary pins prior to the primary THA procedure);
- Post-surgical ipsilateral knee pain (possibly associated with the preoperative placement of fiduciary markers or pins);
- Longer surgical times during THA; and
- Significantly greater blood loss during THA.

Because of the potential risk factors identified in the pin-based registration technology, the system was modified to allow a less invasive technology that required 2 locator pins. Validation of the 2-pin registration technology was based on the results of a clinical study by Nishihara et al. This 140 patient, (156 femora) randomized, controlled study compared the outcomes of hand-rasping and robotic milling.

Further design developments lead to pinless registration technology. This development version is the subject device and is referred to as the DigiMatch ROBODOC Surgical System. The pinless registration technology was initially validated in a 31-patient study in Frankfurt, Germany.

The second IDE Clinical Trial (G000071) was conducted with the pinless DigiMatch ROBODOC Surgical Assistant System. The purpose of this trial was to validate the new pinless technology and demonstrate that the risk factors seen in the first Trial had been mitigated or eliminated. The issue of longer surgical times and greater blood loss was addressed by additional training of the participating surgeons and the improvement of cutting technology.

During a January 18, 2007 meeting, FDA concurred that the first IDE trial, despite the potential risk factors, did demonstrate the overall effectiveness (fit and fill) of the ROBODOC System technology. FDA agreed that the data collected within the second IDE clinical trial would be reviewed primarily to determine if the risk factors were properly mitigated and for validation of the new pinless technology.

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3. Device Description

The DigiMatch System consists of the 510(k) cleared (K960685) ORTHODOC Preoperative Planning Workstation, a robotic electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (such as cutters, drapes, irrigation sets, probes and markers).

- **ORTHODOC** - The PC workstation enables the surgeon to select prosthesis and determine its desired position within the patient's femur. The system displays three-dimensional views of selected implant models for computerized templating with CT based femur images. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the interpolated CT image of the femur. Before or after templating, the user invokes a program called (b) (4) (b) (4) (b) (4) (b) (4) (b) (4) can be used for registration purposes. The ORTHODOC also provides software tools allowing surgeons to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC system with implant size, shape, and placement data. The output is saved on a transfer media and loaded into the electronics control cabinet of the ROBODOC prior to surgery.

- **ROBODOC** - The ROBODOC Surgical Assistant is present in the sterile field and contains all of the components that physically interact with the patient during the surgery. The operating room components of the ROBODOC system includes an electromechanical arm, electronics control cabinet, a display monitor, and miscellaneous accessories (such as cutters, drapes, irrigation sets, probes and markers). The User Interface consists of a display monitor, a hand-held pendant for controlling the robot, operator controls (switches/buttons), and indicator lights.

4. Indications for Use Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopaedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

5. THA Procedure using the DigiMatch™ ROBODOC® System.

When using the DigiMatch™ ROBODOC® System in primary THA the surgeon follows the same major procedural steps. However, use of the system, as with other FDA cleared computer-assisted, image-guided systems, does add extra steps. The major THA procedural steps using the DigiMatch™ ROBODOC® System are as follows:

1. Planning – The user plans the surgical procedure using 3D patient specific images and 3D implant templates.

2. Patient Set Up - The surgical staff prepares the OR by setting up the equipment to be used during surgery.

Setting the robot up for surgery is an additional step that consists of a verification of robot operation directly before use. This is done both in the non-sterile and sterile system state. The non-sterile steps must always be completed prior to the start of surgery. The patient is brought to the operating room, prepared, anesthetized and positioned for surgery.

3. Surgical Exposure - The surgeon makes the appropriate incisions exposing the patient's femur.

4. Fixation - Dislocating the femoral head from the Acetabulum the surgeon brings the ROBODOC system to the patient on the operating table. The position of the Robot and the patient are stabilized. Safety devices are attached and verified.

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5. Registration - This step can be sub-divided into two parts: 1- Finding where the patient (femur) is, then 2- Verifying the system has correctly found the patient (femur). These two parts are called registration and registration verification.

Registration is achieved by gathering a series of points on the operative femur. Then using those points the software determines the exact position of the patient (femur) on the operating table.

Registration Verification is determined by asking the surgeon to find points on the femur, having the system display where it has calculated those points are and then having the surgeon verify if the system calculation is correct. If the surgeon verifies that the system has calculated correctly registration is verified and complete. The surgeon can now proceed to cavity preparation.

6. Stem Cavity Preparation - Instead of using manual tools to create the implant cavity the surgeon guides the Robot to the top of femur. Then the robot mills the cavity as planned to accept the chosen implant. When cavity preparation is completed the robot is removed from the surgical field and the femoral head is removed in the conventional manner.

7. Cup Preparation - After completing the stem cavity preparation the surgeon prepares the acetabulum. The acetabular cavity is created using powered cutting tools.

8. Surgical Verification - Trial components are removed and the new femoral and acetabular prostheses are fixed into position. With the replacement implants in place the surgeon revaluates the hip prostheses for size, fit, placement, and revaluates the hip for range of motion, overall alignment, and leg length.

9. Implantation - Trial components are removed and the new femoral and acetabular prostheses are fixed into position.

10. Exposure Close - The surgeon closes the incision.

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6. Summary of the first IDE Trial (G920035) - Pin-Based ROBODOC System

This multi-center clinical trial began in 1993 and ended in February 1996. It was performed with the 1st generation ROBODOC® Surgical System, which used 3 locator (fiduciary) pins. The 3 pins were placed in the patient's operative hip and knee during a separate surgery prior to the total hip arthroplasty (THA) surgery. These pins were used for spatial registration of the robot to the patient for subsequent bone cavity milling.

6.1 Objectives

The objectives of this clinical trial were to demonstrate that the ROBODOC® System was safe and effective for its intended use as an alternative to conventional manual surgical broaching techniques for femoral canal preparation in patients receiving cementless prostheses for primary THA. Occurrence of adverse events, measurements of radiographic parameters (i.e., fit; fill, position, precision and consistency) and clinical outcomes data were to be evaluated in all enrolled subjects to demonstrate clinical efficacy and safety of the surgical robot.

6.2 Study Design

(b) (4)

[redacted]

6.3 Effectiveness and Safety Endpoints

(b) (4)

[redacted]

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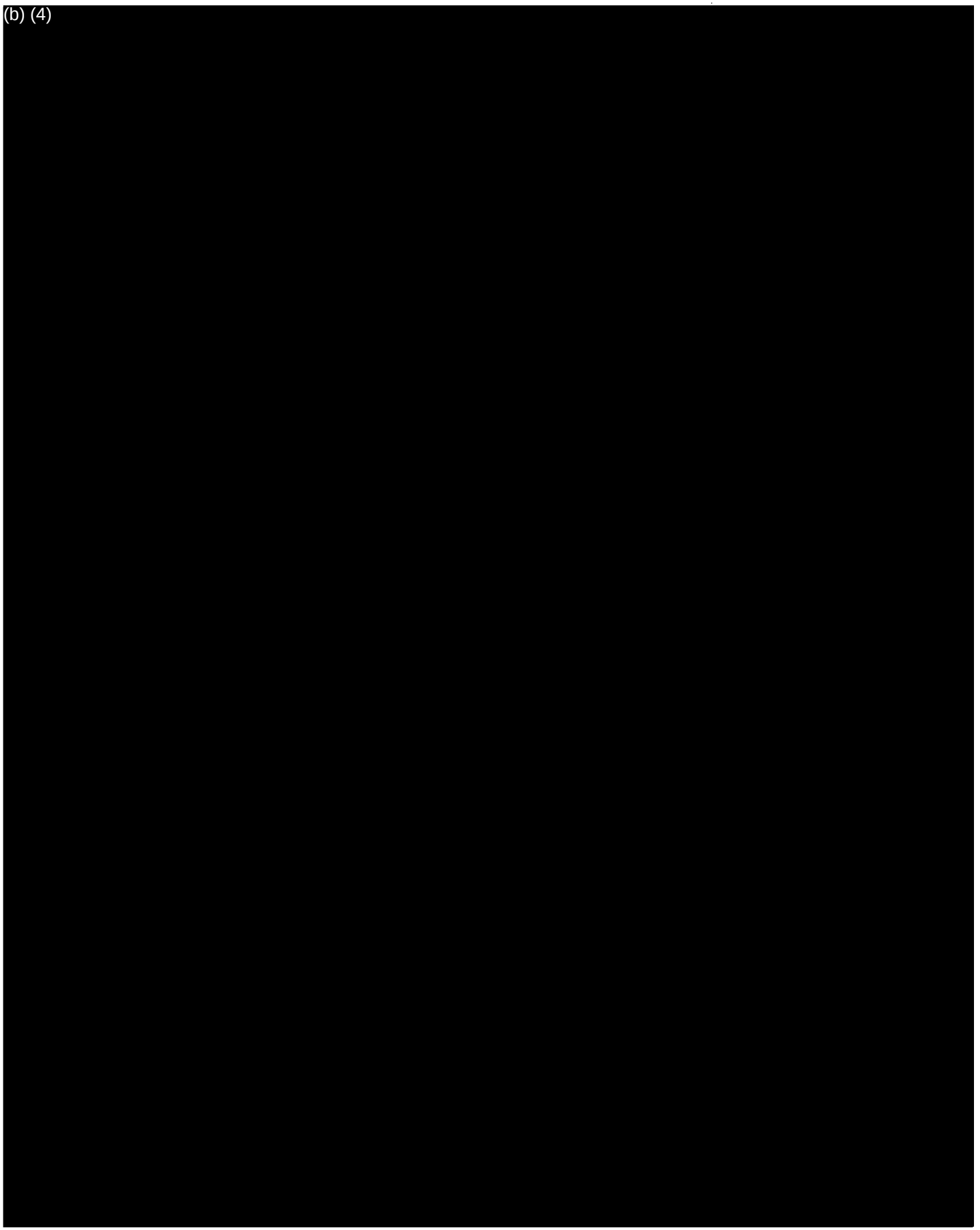
(b) (4)



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(b) (4)

[redacted]

7 Summary and Statistical Analysis of Second IDE Trial (G000071); Pinless ROBODOC® System

Results from the ROBODOC® System's First IDE Clinical Trial identified four potential risks associated with the use of the pin-based registration technology. After discussions with FDA, ISS designed and conducted the Second IDE Trial (G000071) to demonstrate that the pinless registration technology, called DigiMatch™, had substantially mitigated or eliminated the potential risks identified in the First IDE Trial. During subsequent discussions with FDA, ISS was informed that results from the First IDE Trial were considered sufficient to demonstrate the ROBODOC® System performed effectively during its intended use.

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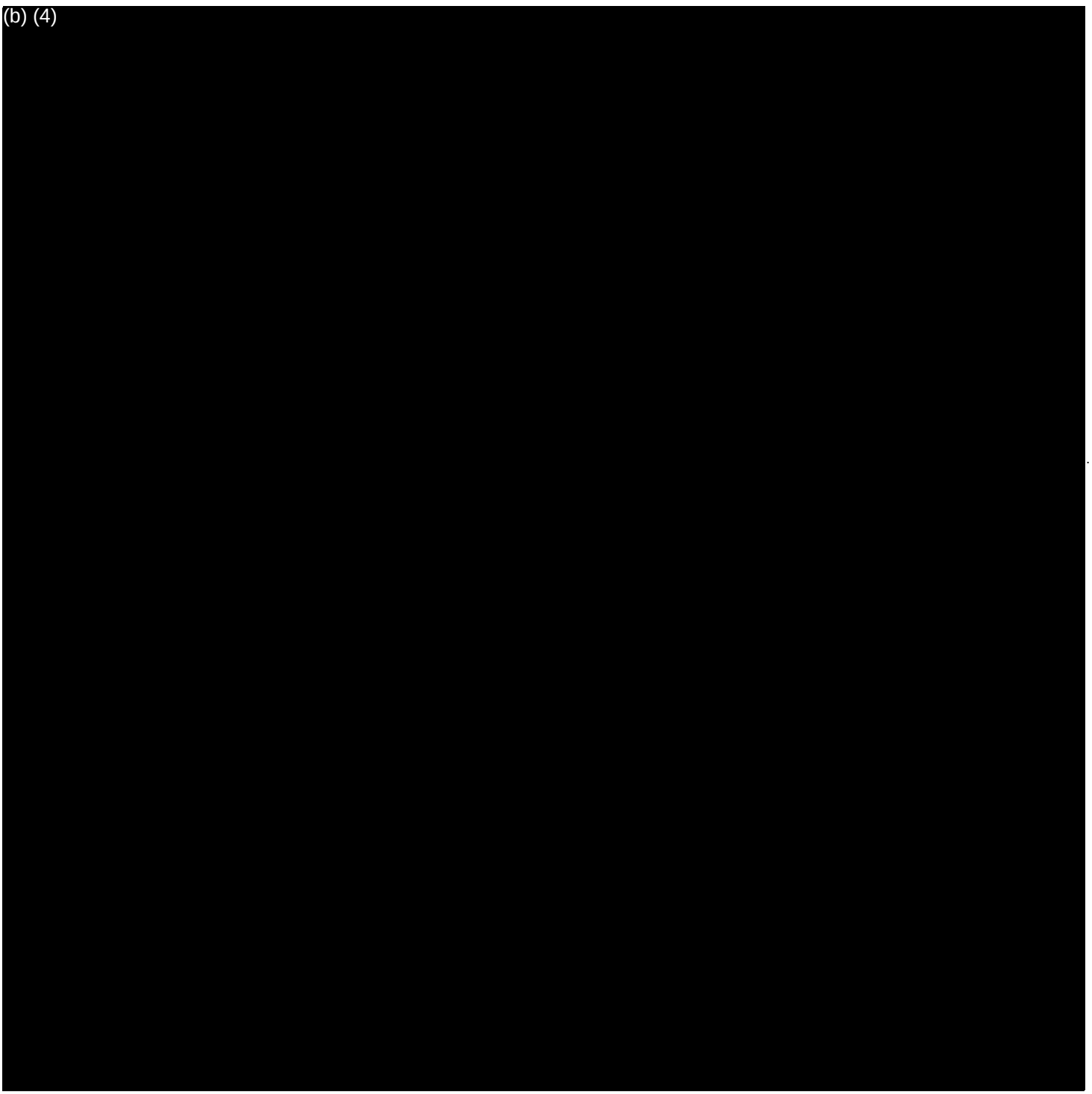
7.1 Objective

The primary objective of the Second IDE Clinical Trial was to show that the pinless registration DigiMatch™ ROBODOC® Surgical System is safe for its intended use as a surgical tool indicated for preoperative planning and femoral canal preparation in primary THA. The secondary objective was to demonstrate that potential risks identified in the First IDE Trial had been eliminated or mitigated. The third objective was to confirm efficacy of the ROBODOC® technology by comparing results of Harris Hip Score outcomes.

7.2 Study Design

(b) (4)



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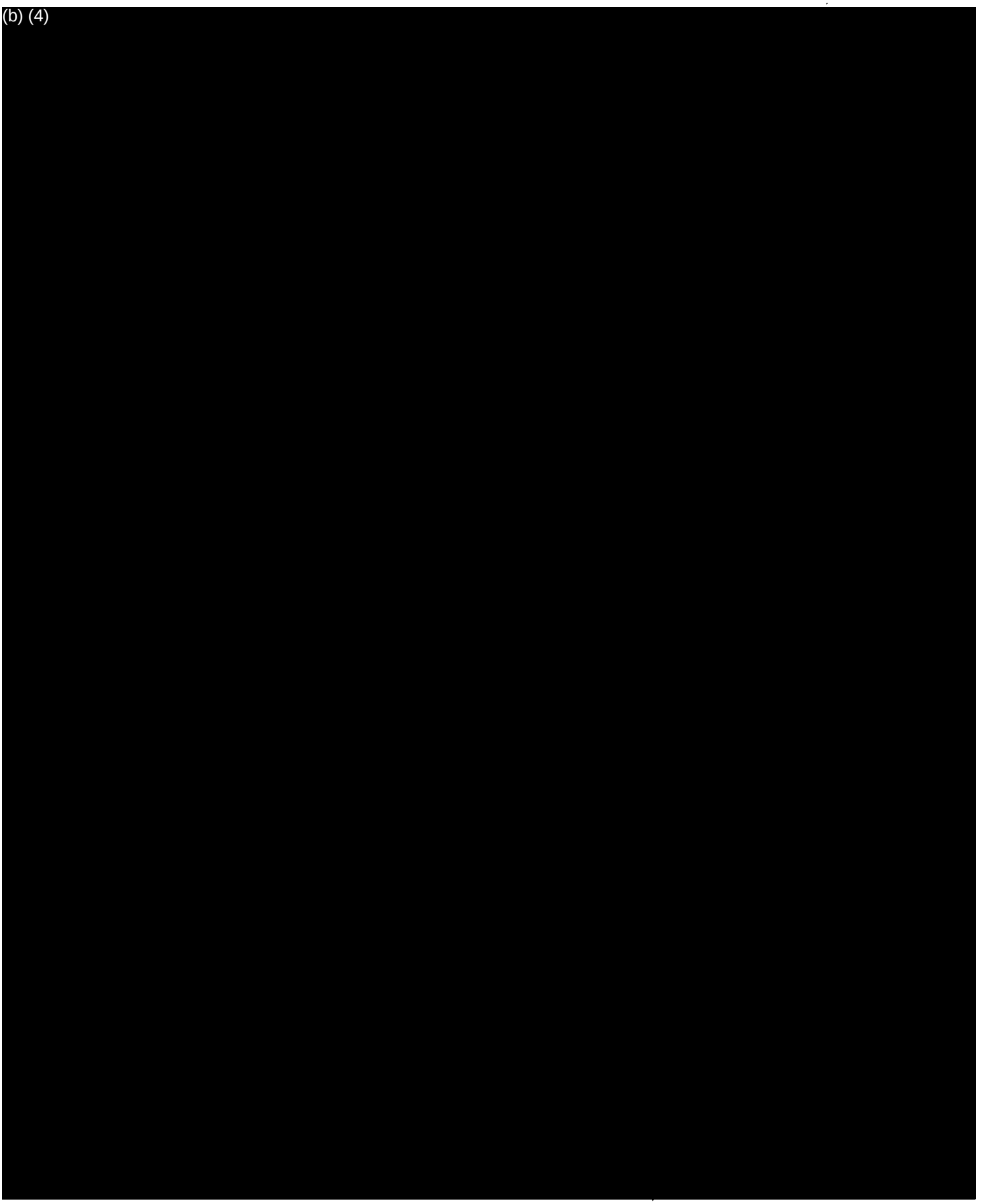

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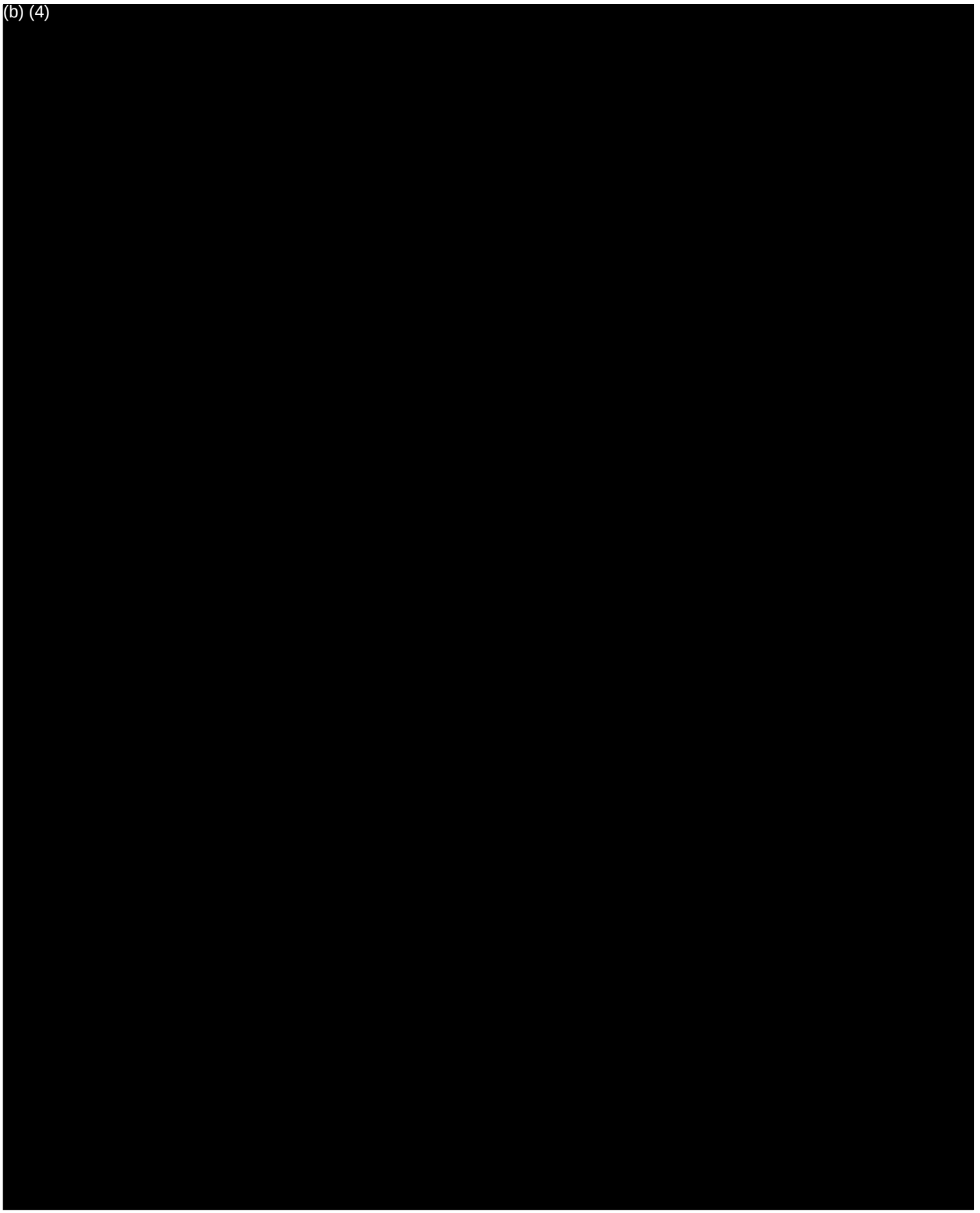

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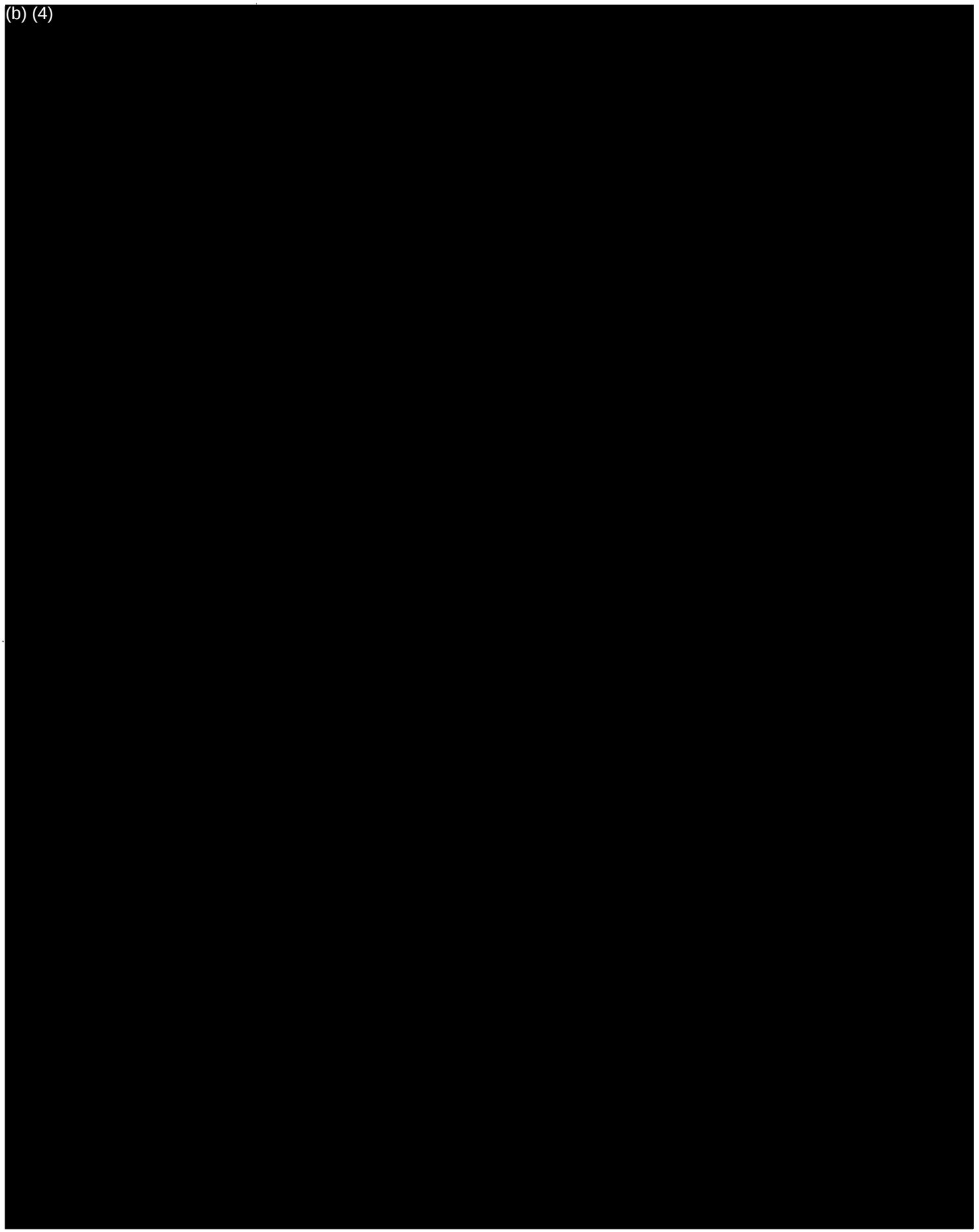

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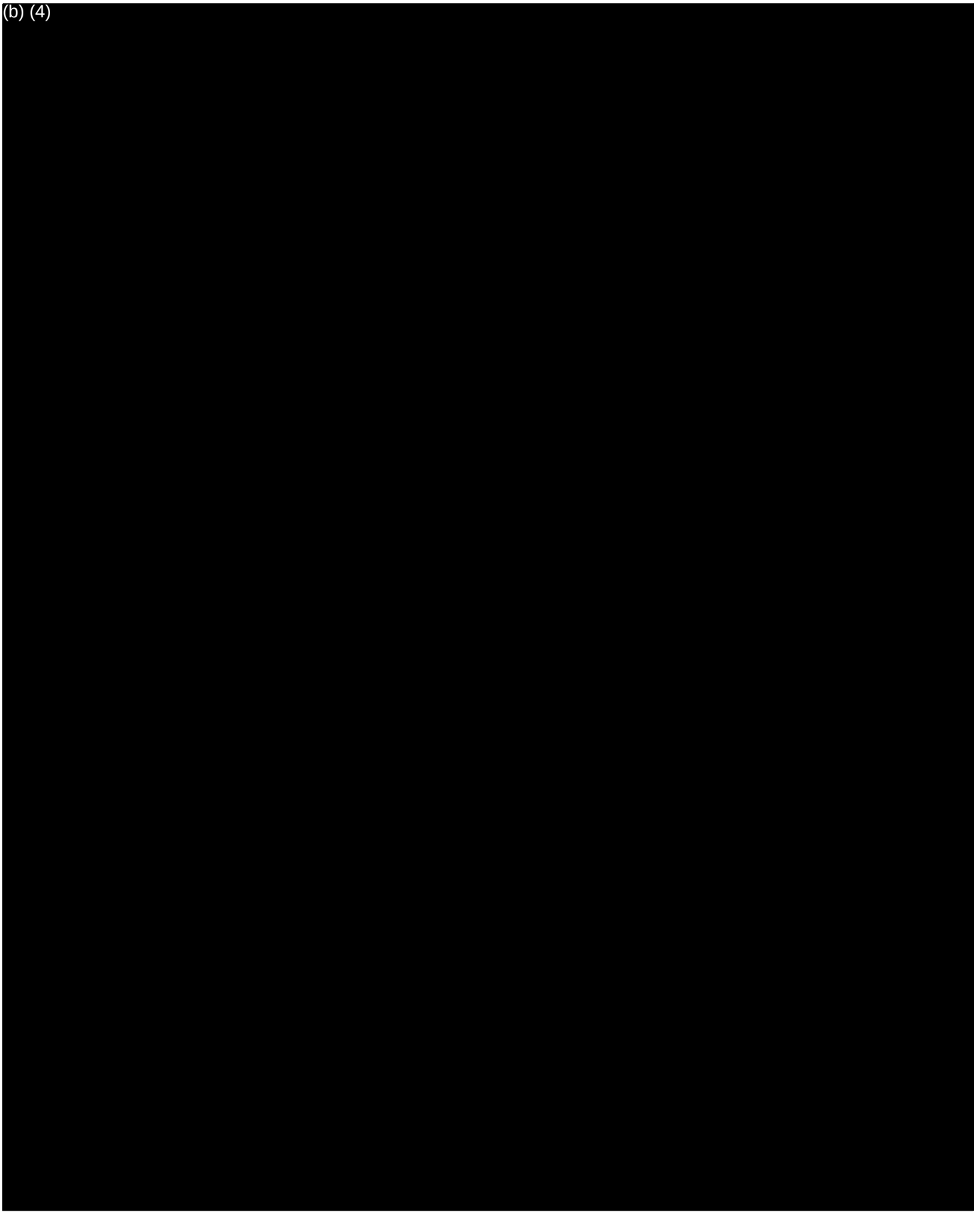

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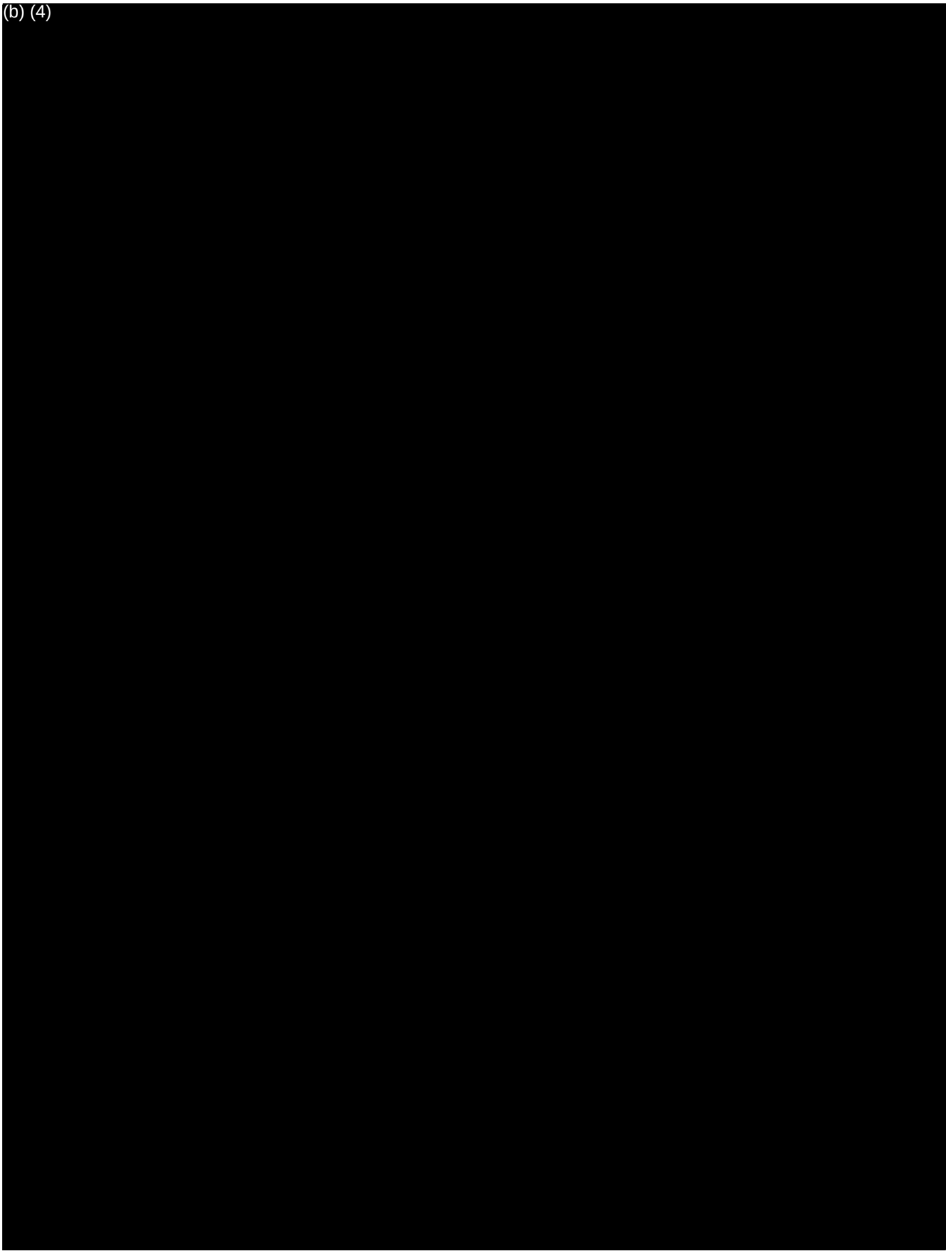

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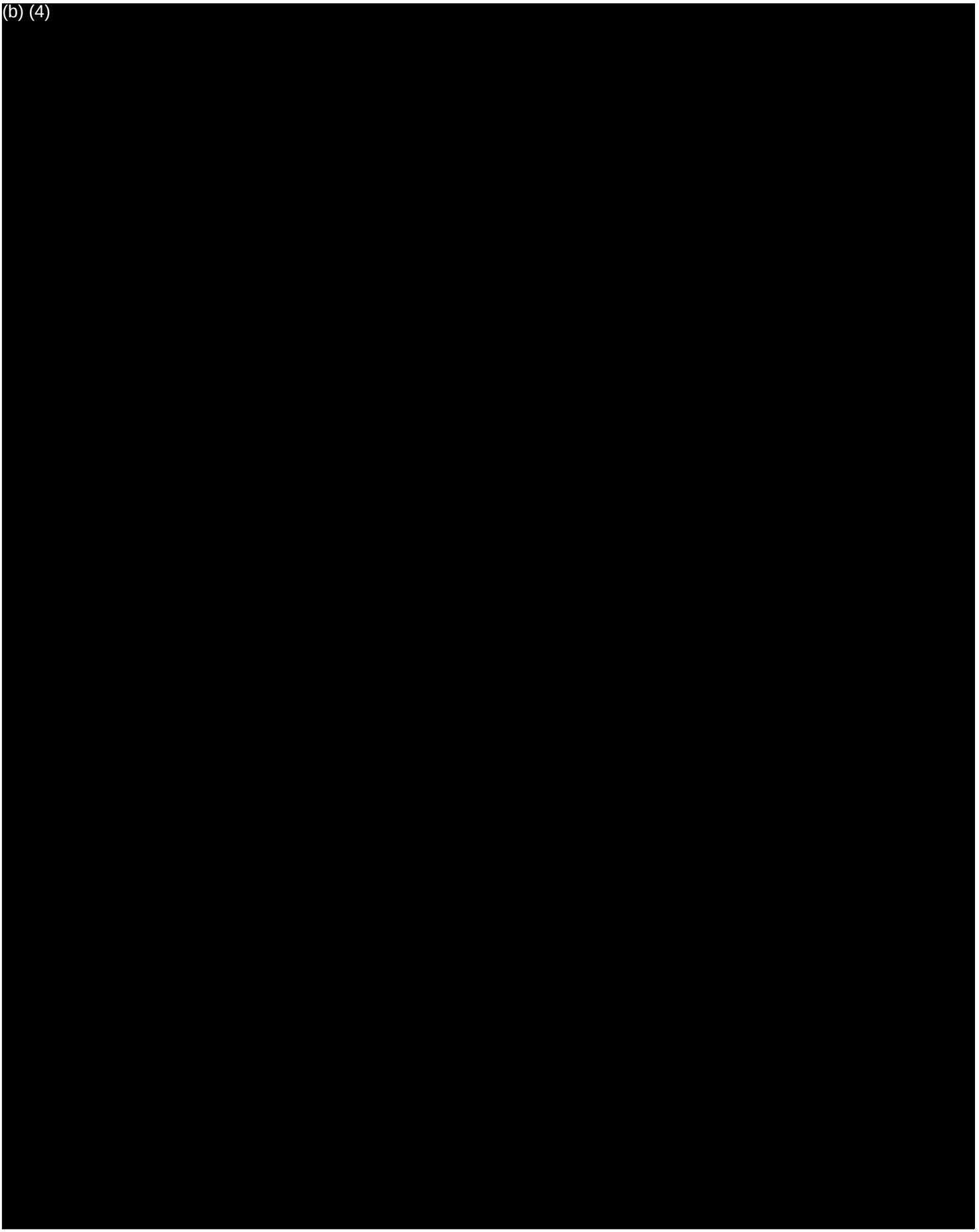

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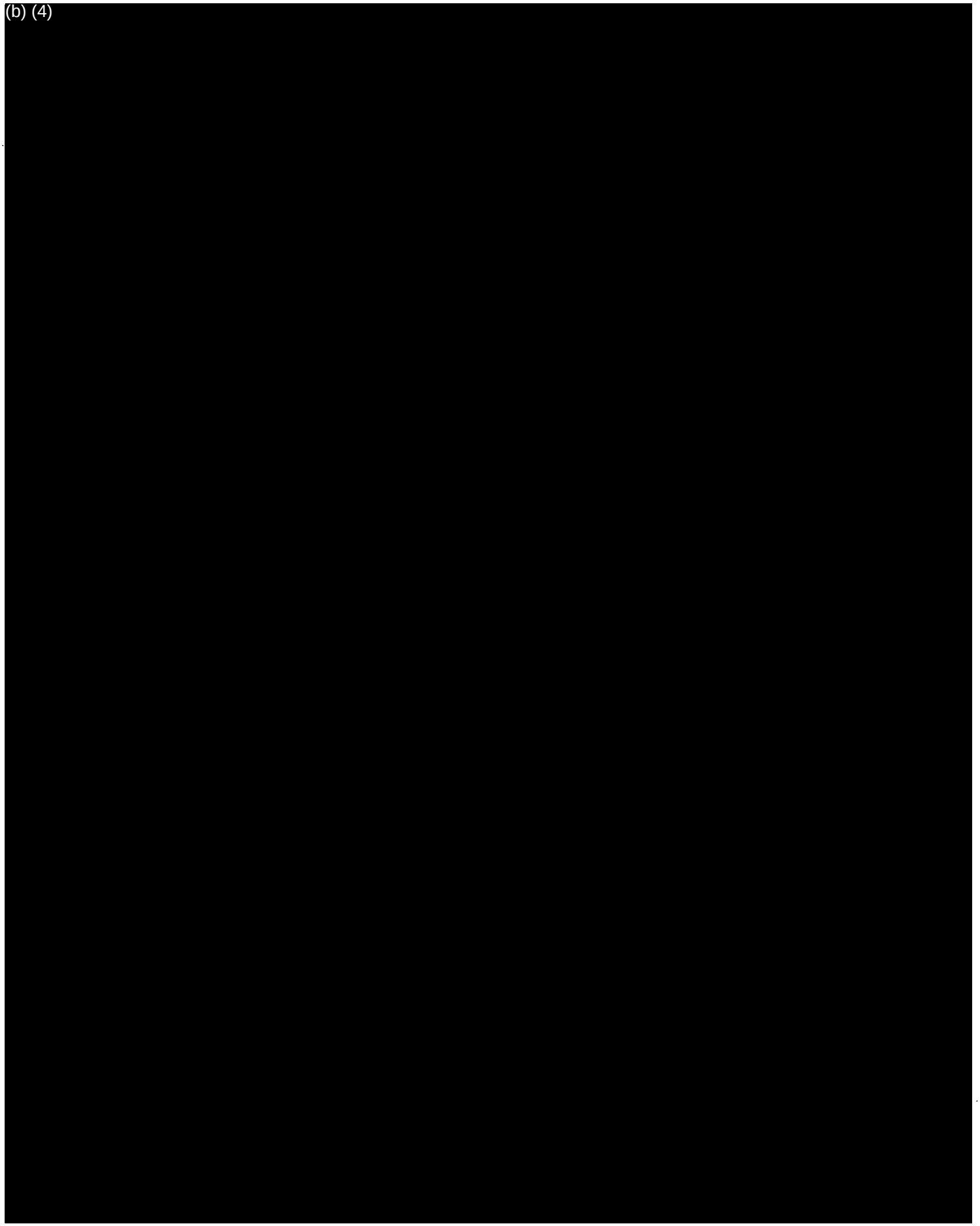

DJA x00098

Janda, Michel D

From: Janda, Michel D
ent: Friday, February 29, 2008 9:38 AM
To: 'rdhibbert@robodoc.com'
Cc: Ogden, Neil
Subject: DigiMatch Robodoc Surgical System, K072629.

Russ Hibbert
Director Clinical & Regulatory Affairs

Integrated Surgical Systems, Inc.
1433 N. Market Boulevard, #1
Sacramento, CA 95834

Re: DigiMatch Robodoc Surgical System, K072629.

Dear Mr. Hibbert,

After reviewing the 510(k) submission for the DigiMatch Robodoc Surgical System it appears that addition information is still required. The following information is necessary to continue the review of your 510(k).

1. The purpose of the second IDE clinical trial (G000071) was to validate the new pinless technology and demonstrate that the risk factors seen in the prior clinical trial had been mitigated or eliminated. These risk factors included longer surgical times and greater blood loss. During a January 18, 2007 meeting, FDA indicated that the data collected within the second IDE clinical trial would be reviewed to determine if the risk factors were properly mitigated and for validation of the new pinless technology. As such FDA requested that summary statistical analysis be performed on the available data. After reviewing the submitted analysis it appears that the risks of longer surgical times and greater blood loss were not fully mitigated. Therefore, FDA will be seeking the assistance of our expert panel members to judge the acceptability of these risks in relation to the potential benefit of your system. FDA believes that the recommendation of our expert panel is necessary in order to judge the risk/benefit profile of the subject device as compared to manual broaching and reaming as well as computer assisted surgery.

   In order to enable this comparison, FDA is requesting that you provide additional formal statistical analysis of the study results. Possible analysis could include a comparison to data generated from the first clinical trial or a comparison to standard of care. Please provide additional information to demonstrate that the known risks of longer surgical times and greater blood loss have been fully mitigated or are acceptable given the device's potential benefit.

2. As previously indicated, assessment of the device risk/benefit profile remains as the primary concern. In order to allow this assessment, the FDA believes that additional information is needed regarding longer-term outcomes. Possible sources of long term data could include the first IDE clinical trial and Outside of the United States (OUS) studies. As the pooling of this data is likely to be problematic, summary information and analysis is appropriate. Please provide additional long term data (2 year and beyond) to support the potential benefit of the subject device.

3. The submission includes an indication for use statement which appears to differ from that studied within first and secondary IDE studies. Specifically, the indication for use statement includes a paragraph which makes safety and effectiveness claims regarding other orthopedic procedures (Paragraph #3). Please revise the indications for use statement and device labeling where appropriate to remove this reference

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or provide additional clinical data to support this claim.

As per this email, K072629 has been placed on hold until further correspondence is received.

Please feel free to contact me if you would like to discuss any of these deficiencies. Hard copies of your response are required and can be directed to the FDA document center. Thank you.

Sincerely,

I concur with AE.
2/29/08

Michel Janda
Biomedical Engineer
Phone #: (240) 276-3600
Fax #: (240) 276-3733
ODE/DGRND/GSDB

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Janda, Michel D

From: Melkerson, Mark N.
Sent: Monday, February 18, 2008 2:38 PM
To: Ogden, Neil; Janda, Michel D
Cc: Buch, Barbara D; Rumm, Peter; Melkerson, Mark N.
Subject: K072629 DigiMatch Robodoc Surgical System, Integrated Surgical Systems, Inc.

Neil and Michel,

(b) (5)

[redacted]

Mark N. Melkerson
Director, Division of General, Restorative, and Neurological Devices
FDA/CDRH/ODE/DGRND
9200 Corporate Blvd., HFZ-410, 350C
Rockville, MD 20850
NEW -- 240-276-3737
NEW -- 240-276-3602
email mark.melkerson@fda.hhs.gov

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DJA x00101

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

COVER SHEET MEMORANDUM

From: Michel Janda, Biomedical Engineer
Subject: K072629
To: The Record

CTS decision code: **SE**

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☐ Hold (Additional Information or Telephone Hold)

X Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			X
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?		X	
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number: 882.4560 **Class: II** **Product Code:**

Additional Product Codes: HAW

Review: _____ GSDO 2/11/08
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

DJA x00102

PRE-REVIEW FORM:
COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1.	Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		X
2.	Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		X
3.	Does this device type require a PMA by regulation? (Please see management.)		X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4.	Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRH PremarketNotification 510kProgram/ Screening Checklist)		X
5.	a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)		X
6.	To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here: SEE REVIEW MEMO – "DEVISE HISTORY"	X	
7.	To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8.	Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

DJA x00103

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions
based on
Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s
http://www.fda.gov/cdrh/ode/guidance/1567.html

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	Y		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	Y		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Y		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	Y		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	Y		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	Y		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			N/A
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html.	Y		
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html. FDA Standards program www.fda.gov/cdrh/stdsprog.html. Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/reqrecstand.html			N/A
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Y		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Y		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html	Y		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10	Y		

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Title	Related Information	Present	Inadequate	N/A
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html	Y		
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html	Y		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html	Y		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)	Y		
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Y		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	Y		
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf	Y		
Kit Certification	See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance			N/A

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DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional - K072629

Date: February 11, 2008
To: The Record
From: Michel Janda, Biomedical Engineer

Office: ODE
Division: DGRND

510(k) Holder: Integrated Surgical Systems, Inc.
1433 N. Market Boulevard, #1
Sacramento, CA 95834

Device Name: **DigiMatch Robodoc Surgical System**

Contact: Russ Hibbert, Director Clinical & Regulatory Affairs
Phone: (916) 285-9943 x522
Fax: (916) 575-7918
Email: rdhibbert@robodoc.com

I. Device History:

The First IDE Clinical Trial (G920035) was conducted using the "pin-based" technology, which required three locator (fiduciary) pins to register the robotic device to the patient. A primary objective of the First IDE was to confirm that the ROBODOC Surgical System safely and reliably implemented the preoperative plan developed by the surgeon on the ORTHODOC component of the system. The primary endpoints of efficacy were fit and alignment of the femoral implant. Upon review of the data from the First Trial in October 2000, FDA identified four potential risk factors for the ROBODOC Surgical System, namely:

- The need for two surgical procedures (a separate surgical procedure to implant fiduciary pins prior to the primary THA procedure);
- Post-surgical ipsilateral knee pain (possibly associated with the preoperative placement of fiduciary markers or pins);
- Longer surgical times during THA; and
- Significantly greater blood loss during THA.

Because of the potential risk factors identified in the pin-based registration technology, the system was modified to allow a less invasive technology that required 2 locator pins. Validation of the 2-pin registration technology was based on the results of a clinical study by Nishihara et al. (Japan based trial – Section 20.3). This 140 patient, (156 femora) randomized, controlled study compared the outcomes of hand-rasping and robotic milling.

Further design developments lead to pinless registration technology. This development version is the subject device and is referred to as the DigiMatch ROBODOC Surgical System. The pinless registration technology was initially validated in a 31-patient study in Frankfurt, Germany (Section 20.4).

The Second IDE Clinical Trial (G000071, Section 20.5) was conducted with the "pinless" DigiMatch ROBODOC Surgical Assistant System. The purpose of this trial was to validate the new pinless technology and demonstrate that the risk factors seen in the First Trial had been mitigated or eliminated. The issue of longer surgical times and greater blood loss was addressed by additional training of the participating surgeons and the improvement of cutting technology.

During a January 18, 2007 meeting (Pre-IDE memo attached), FDA concurred that the first IDE Trial, despite the potential risk factors, did demonstrate the overall effectiveness (fit and fill) of the ROBODOC System technology. FDA agreed that the data collected within the second IDE clinical trial would be reviewed primarily to determine if the risk factors were properly mitigated and for validation of the new pinless technology.

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II. Purpose and Submission Summary:

The sponsor has submitted K072629 to notify the FDA of their intent to introduce the **DigiMatch Robodoc Surgical System** into interstate commerce.

(b) (4)

[redacted]

The results of this clinical study as well as supporting documentation collected as part of prior IDE, outside of the US, cadaver, animal, and bench top studies are presented in this 510(k). This device represents a first of its kind in that it employs robotic technology to perform femoral reaming during primary total hip replacement surgery. The device further represents a system / user relationship which is characterized as "autonomic." This means that the system relies upon a predetermined surgical plan to perform clinically relevant actions rather than realtime input from the user. While the user always has the option to override the actions of the robotic system, the risk profile of this system / user control relationship is heightened as compared to the predicate devices as intervention is always reactionary.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: **Prescription** or OTC)	Y		
Truthful and Accuracy Statement	Y		
510(k) Summary or 510(k) Statement	Y		
Standards Form			N/A

III. Device Description

The DigiMatch System consists of the 510(k) cleared (K960685) ORTHODOC Preoperative Planning Workstation, a robotic electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (such as cutters, drapes, irrigation sets, probes and markers).

- **ORTHODOC** - The PC workstation enables the surgeon to select prosthesis and determine its desired position within the patient's femur. The system displays three-dimensional views of selected implant models for computerized templating with CT based femur images. The surgeon uses a mouse to move the image of the implant into the desired position with respect to the interpolated CT image of the femur. Before or after templating, the user invokes a program called (b) (4) [redacted] s (b) (4) [redacted] (b) (4) [redacted]. The ORTHODOC also provides software tools allowing surgeons to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. Output from an ORTHODOC planning session provides the ROBODOC system with implant size, shape, and placement data. The output is saved on a transfer media and loaded into the electronics control cabinet of the ROBODOC prior to surgery.

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- **ROBODOC** - The ROBODOC Surgical Assistant is present in the sterile field and contains all of the components that physically interact with the patient during the surgery. The operating room components of the ROBODOC system includes an electromechanical arm, electronics control cabinet, a display monitor, and miscellaneous accessories (such as cutters, drapes, irrigation sets, probes and markers). The User Interface consists of a display monitor, a hand-held pendant for controlling the robot, operator controls (switches/buttons), and indicator lights.

    - *Display Monitor* - The display monitor displays informative and interactive menu screens. Interactive screens contain a menu from which the user can select options by pressing buttons on the pendant. Each menu screen contains explanatory text followed by the available options, with one option per line. The display monitor provides informative screens (rather than menu screens) when the system is performing automated actions, such as homing the robot or cutting the femur. During the DigiMatch registration procedure, the display monitor provides information that assists the surgeon in digitizing the femur and in verifying that the registration is correct. During the cutting procedure, informative screens show the paths taken by the robot tool (i.e., cutter) super-imposed on the patient's CT image (RTM function).
    - *Pendant* - The pendant is a hand-held control device that attaches to robot base via cable. The pendant has five depressible buttons. The buttons are designated as UP, DOWN, SELECT, PAUSE, and STOP. The pause function is a safety feature that allows the user to halt robot motion without removing robot motor power. When the robot is cutting, the pause function turns off the cutter and servo locks the motors in position. The pause menu contains an option to resume the procedure. The user can turn off robot motor power completely by pressing the red STOP button on the pendant. The STOP button latches mechanically when pressed and must be manually unlatched.
    - *Robotic Arm* - The electromechanical arm is an articulated manipulator capable of programmable motions with attachments for application-specific tools. The types of programmable motions include straight-line, circular (complete circles or arcs of circles), and helical. For safety, a redundant set of encoders are mounted at each link on the manipulator to continuously monitor the position of the arm. The robot arm has two possible configurations, called left elbow and right elbow, and each configuration has a different workspace. The total workspace of the robot is the union of these two configuration-specific work spaces. The manipulator motors are electrically powered (DC current). A force sensor is located on the robotic arm just above the end effector. The force sensor is a safety feature that continuously monitors forces applied at the robot's tool tip and pauses or stops the robot if forces exceed pre-defined thresholds. Additionally, the motor currents in all joints are monitored and the system is halted when these currents exceed a pre-defined limit indicating excessive forces.
    - *Robotic Base* - The robot base is a mobile base that contains a column of adjustable height. The mobile base allows the user to roll the robot to the OR table, to lock it in place during surgery (manually actuated hydraulic brakes), and to move it away from the OR table when femoral canal preparation is complete. The I/0 Expander (I0X) is a device that multiplexes communications between the RCC and the BMMs and digitizer, which plug into the IOX. The IOX is an embedded computer module. Internally, the base includes a CPU board, which controls the adjustable column, and the cutter and irrigation system relays. The adjustable column is powered by an AC motor. Base height is measured redundantly by a linear encoder and a magnetostrictive sensor. In the event of a discrepancy between base height as reported by the encoder and sensor, robot motor power is paused.
    - *Computer Control Cabinet* - The computer control cabinet houses the RCC, RTM, IPM, and video switchbox.
        - Robot Control Computer (RCC) - The RCC is a personal computer that controls the robot motors, runs the THA application, and monitors the inputs from the pendant and safety sensors.
        - Real Time Monitor (RTM) Computer - The RTM computer controls the display monitor during certain digitizer registration procedures and during cutting.
        - Intelligent Power Module (IPM) - The IPM contains the motor power supplies, motor power amplifiers, and three joint controller boards (JCBs). The JCBs are embedded computer modules that monitor the position of the robot arm and perform the low-level servo control functions.
        - Video Switchbox - During cutting and digitization of points on the surface model, the display monitor presents graphical representations from the RTM computer; at all other times, it displays informative screens and screens that prompt the user to perform specific actions (from the RCC).
    - *Bone Attachment System (BAS)* - The BAS consists of the femoral fixator and two BMMs.
        - Femoral Fixator - The femoral fixator holds the femur at a fixed position relative to the robot during surgical procedures.

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- Bone Motion Monitors (BMMs) - BMMs are safety sensors that monitor motion of the bone relative to the robot. The surgeon attaches the BMM directly to the bone using a sterile pointed probe. A procedure to re-establish registration must be performed if bone motion exceeds a predefined threshold (2 mm displacement for 1 second).

- *Digitizer* - The purpose of the digitizer is to collect data for CT/bone registration (orientation of the robot with respect to CT coordinates in the ORTHODOC preoperative plan and the physical position of the bone within its workspace). The digitizer is permanently mounted on the robot base.
- *Robot Tooling* - The primary robot tool is a cutter drive assembly, which connects to the tool attachment plate on the robot. It is the sterile interface between the robotic arm and the instruments that contact the patient.
- *Bearing Sleeves* - A bearing sleeve containing a probe or cutter can be installed in the cutter drive assembly. Bearing sleeves are available in different sizes and correspond to implant models and sizes.
- *Robot Probes* - These robot probes are used for diagnostic tests, i.e., calibration.
- *Cutters* - Cutters of various sizes depending upon the implant size are used to machine the implant envelope.
- *Digitizer Tools* - The removable components and tools associated with the digitizer include: (1) a non-sterile digitizer probe, which is used for non-sterile diagnostics; (2) a sterile digitizer probe, which is the sterile interface between the digitizing arm and the surgical tool tips (i.e., ball tip and pointed tip); (3) a ball tip, which is used for sterile diagnostics; and (4) a pointed tip, which is used for contacting the bone surface to collect data points on the femoral surface and for motion recovery.
- *Diagnostic Tool and Fixture* - A non-sterile diagnostic tool is used for robotic arm diagnostic and maintenance procedures. The diagnostic fixture consists of an attachment plate, which contains posts that can be found by the robot, as required for tool calibration and kinematic verification.
- *Irrigation System* - The irrigation system is mounted on the base and consists of a pump, sterile tubing, and controls for on/off and flow velocity. Irrigation automatically starts when the cutter turns on and stops when it turns off.
- *Sterile Drape Set* - A sterile drape set contains five separate drapes for the following components: (1) the robotic arm; (2) the robot base; (3) the digitizer; (4) the pendant; and (5) the bonnet. The bonnet drape is provided for use in the event that the cutter drive must be reinstalled and part of the arm drape must be sacrificed.

Surgical Workflow: The surgeon begins the THA operation in accordance with the practice of medicine by exposing the femur. The surgeon clears soft tissue to facilitate registration procedures, secures the patient's leg in the femoral fixator and leg support fixture to prevent motion during surgery, and sets soft tissue retractors. Next, the surgeon performs registration procedures to provide orientation and reference information identifying where the bone is for the intra operative procedure. The femur must remain motionless to preserve the coordinate transformation and ensure accurate cavity placement. If unwanted motion exceeding the predefined threshold during registration or cutting is detected, the ROBODOC's safety system will immediately disable motor power, stop the system and notify the surgeon. To expedite recovery in the event of unwanted bone motion, two bone motion recovery markers (also called "motion recovery posts") are installed and digitized during surface registration. One marker is installed in the proximal end of the femur and one is installed in the distal end. When the markers are digitized, the control cabinet computer records the positions of the marker and the initial registration obtained using the surface model. (Note: The Robot does not assist with preparation of the acetabulum. The acetabulum will be prepared in the normal manner after completion of femoral cavity preparation.).

Anatomical Registration Methodology: The second-generation ROBODOC System reduced the number of locator pins to two. The current DigiMatch system uses anatomical landmarks rather than locator pins. A digitizer, which is permanently mounted on the robot base, is used for spatial registration. By physically contacting points on the bone surface, the system registers a bone surface rather than single points used in the pin based system.

During the ORTHODOC preoperative planning, a bone surface model is created in a small area of the femoral shaft, greater trochanter and neck (regions of interest). The proximal part of the surface model includes the bone surface along the medial aspect of the greater trochanter, the femoral neck, and the anterior surface of the femur from the top of the femoral neck to the top of the lesser trochanter. The distal part of the surface model includes the anterior, medial, and lateral aspect of a portion of bone surface at the distal end of the femoral shaft.

In the operating room, the surgeon guides the digitizing probe to specific locations on the bone surface within the area of the surface model defined using the ORTHODOC. The robot control computer compares the set of digitized

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points to the bone surface model transferred from the ORTHODOC and finds the location of the point set that minimizes the distances from the points to the surface model. From this calculation, the location of the femur with respect to the robot can be determined.

Safety Features –

1. Before the surgeon begins templating, the ORTHODOC validates the CT data by confirming the lack of bone motion during the scan, appropriate spacing of CT slices, and adequate field of view.
2. The robot has relatively small motors, high gear ratios, and software-imposed velocity limitations that limit its speed and torque. Limited automatic motions are enabled only when necessary both during initialization of robotic arm position sensors, diagnostic tests, drape installation, reorientation for tool changes, and cutting. Significant repositioning or movements of the robotic arm must be accomplished by manual (force-assisted) hand guiding, in which the robot moves in response to forces applied to the robot end effector (cutter drive assembly) by the user.
3. The robot is equipped with a force sensor that continuously monitors forces applied to the robot's tool tip. During cutting, the software monitors force sensor values and, if necessary, slows down the automated cutting motion to ensure that the maximum force is below a specified threshold. A minimum speed is also set beyond which results in a "force freeze" condition.
4. The BMM is designed to detect unwanted motion of the femur after immobilization in the fixator. After the BMM probe is installed in the femur, the BMM measures spherical displacements from the probe's initial insertion point and halts any motion if femur motion exceeds pre-defined thresholds.
5. A red latching button on the pendant and a manual twist-to-reset switch on the computer control cabinet provide two direct ways to remove power from the robot and deactivate the cutter solenoid. Reactivation requires all safety and control systems to be within tolerance and manual depression of the robot motor power switch.
6. The pendent buttons are designed to prevent depression upon impact with a flat surface. To prevent accidental selection of menu options, the SELECT button on the pendant must be held for a specified duration (b) (4) and then released before the choice is accepted.
7. The robot is equipped with a brake that engages when power is removed from any motor having a significant load affected by gravity (i.e., any axis that supports a weight greater than approximately 5 pounds). This brake is designed to prevent the load from dropping more than 6 mm.
8. Custom cutter accessories are available for compatible prosthesis. Prior to cutting, the display monitor prompts the surgeon to install the cutter associated with the selected prosthesis.
9. The ROBODOC system is designed so that no single point of failure can cause uncontrolled robot motion. In addition, the system can detect collisions with objects in the environment and halt motion if the collision force exceeds a predefined threshold. When the robot is in the cutting phase, an additional check confirms that commanded robot positions fall within the implant safety envelope. The implant safety envelope is slightly larger than the implant envelope (up to 3.0 mm larger in each longitudinal cross-section).

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	
Is the device an implant (implanted longer than 30 days)?		N	
Does the device design use software?	Y		
Is the device sterile?	Y	N	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	Y		

IV. Indications for Use

The DigiMatch ROBODOC Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intraoperative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

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The DigiMatch ROBODOC Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

V. Predicate Device Comparison

da Vinci Surgical System (K043153) - The *Intuitive Surgical* Endoscopic Instrument Control System (hereinafter referred to as the " *da Vinci* System") is intended to assist in the accurate control of *Intuitive Surgical*® Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave ablation probes and accessories during general laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Frameless Neuromate (K991081) – Stereotactic spatial positioning and orientation of an instrument holder or tool guide to be used by a surgeon to manually guide standard neurosurgical instruments.

Voyager/Tactile Guidance System (K052851) - The Voyager/Tactile Guidance System - CT is intended for use as a device which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The Voyager/Tactile Guidance System - CT is indicated for any medical condition in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made, such as: Intra-cranial surgical procedures involving space occupying lesions or malformations (including soft tissue, vascular and osseous), Spinal surgical procedures involving spinal stabilization, neural decompression, or resection of spinal neoplasms, ENT Procedures, and Orthopedic surgical procedures

Characteristic	**Subject Device**	**da Vinci Surgical System, K043153**	**Frameless Neuromate, K991081**	**Voyager/Tactile Guidance System, K052851**
Patient Image Data	CT	Endoscope realtime image	CT/MR	CT
Pre-Surgical Plan	Preoperative planning software	No preoperative planning	Preoperative planning software	Preoperative planning software
Surgical Plan Data	High level operative plan based upon preoperative plan.	No High level operative plan. Control file for the system is developed in real time.	High level operative plan based upon preoperative plan.	High level operative plan based upon preoperative plan.
Control Type	**Autonomic.** System actions are independently performed as based upon a predetermined plan. **Risk** - Gross system failure could result in non-user intended clinical actions. **Risk Impact**- Clinical actions are controlled by the system at all times. User judgement can be used to stop	**Slave/master.** All clinical actions are initiated and controlled by the user. The system's actions are directly correlated to the user's actions. **Risk** - Gross system failure could adversely affect the user's intended clinical actions. **Risk Impact**- Clinical actions are correlated to the	**User controlled** - All clinical actions are directly controlled by the user. **Risk** - Gross system failure could adversely affect the user's clinical decision. **Risk Impact**- Clinical actions are controlled by the user at all times. User judgement can be used to prevent	**Cooperative Control** - System actions are simultaneously controlled by both the user and the computer. The system may alter or enhance the user's clinical actions. **Risk** - Gross system failure could adversely affect the user's intended clinical actions. **Risk Impact**-

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	system actions.	system's measurement of user actions. User judgement can be used to stop or adjust system actions.	patient injury.	Clinical actions are correlated to the system's interpretation of user intent. User judgement can be used User judgement can be used to stop system actions.
Patient / System Registration	Point to surface registration and mechanical tracking	Visual registration and tracking	Fiducial marker registration and ultrasonic tracking	Surface to surface registration and optical tracking
Robotic Technology	Single robotic arm with end effectors.	Multiple robotic arms with end effectors.	Single robotic arm with end effectors.	Single robotic arm with end effectors.

VI. Labeling

Labeling has been provided which includes instructions for use and an appropriate prescription statement as required by CFR 21.807.87 (e).

VII. Sterilization/Shelf Life/Reuse

The subject device includes both reusable and disposable patient contacting components. These components are supplied non-sterile and are intended for sterile processing by the user. The submission includes cleaning and sterilization instructions within "Cleaning, Disinfection, and Sterilization" - Section 13 - ROBODOC User Manual, Chapter 9.

The ROBODOC single use cutters and reusable tools are provided non-sterile to be steam sterilized by the hospital. Recommended sterilization parameters are provided for one method of steam sterilization. The reusable tools consist of the bearing sleeve, bone clamp fixator, cutter drive assembly, extension arm, wrenches, gauge set, probes, recovery markers, and air motor. The recommended steam sterilization parameters are: Gravity Displacement, Temperature 132°C to 135°C, and Minimum Time: 15 minutes. Validation of the recommended parameters was done per the requirements of [redacted](b) (4), [redacted](b) (4) [redacted]

	Yes	No
1. Sterilization method description (Steam)	Y	
2. Validation Method for the sterilization cycle: AAMI TIR 12 and ANSI/AAMI/ISO 11134	Y	
3. Sterility assurance level (SAL): (10^{-6})	Y	
4. Pyrogenicity claim:		N
5. A description of the packaging:	Y	

VIII. Biocompatibility

Patient Contacting Component	Material	Nature of Contact
Reusable Instrument Accessories - The reusable instrument accessories consist of the cutter drive assembly, bearing sleeve, extension arm assembly, t-handle, Allen, C and motor wrenches, sleeve assembly, and post tool.	Various Materials.	The reusable instrument accessories are components of the robotic surgical instrument and have no patient contact.
Irrigation Tubing Set - The irrigation tubing set is commercially distributed within the US and has an active device listing. The irrigation set is purchased as a finished device, packaged sterile by the manufacturer.	Tygon Tubing, PVC	Indirect Contact. Externally communicating with tissue/bone contact for a limited (<24 hr) time.

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Surgical Drape Sets - The surgical drape set is purchased as a finished sterile product and is not anticipated for patient contact.	Low Density Polythene Film	Not intended for patient contact. Intended as a sterilization barrier.
Cutters - The Cutters provide the means with which to perform incisions and other such surgical cutting techniques.	Stainless Steel, 440C, ASTM A 276; passivated per ASTM A967	Direct Contact. Externally communicating with tissue/bone contact for a limited (<24 hr) time.
Bone Clamp - The bone clamp is used to interface the system with the patient's femur. *Cutter Drive Assembly* - The Cutter Drive Assembly is used to secure the bearing sleeves and cutters to the ROBODOC surgical instrument. Irrigation is provided to the cutters during use through ports in the cutter drive assembly and the bearing sleeves.	Stainless Steel 303, ASTM A582; passivated to ASTM A967	Direct and Indirect Contact. Externally communicating with tissue/bone contact for a limited (<24 hr) time.
Pinless Recovery Posts - The Recovery Posts provide a means of re-registration of the robot surgical plan to the operative bone in the event of bone movement during a pinless surgical procedure. The ROBODOC Recovery Posts are anchored in bone tissue.	Stainless Steel, 316LM, ASTM F138; passivated to ASTM A967	Direct Contact Externally communicating with tissue/bone contact for a limited (<24 hr) time.
Probes - The probes are used for gross palpation of the patient's anatomy.	630 (17-4) Stainless Steel	Externally communicating with tissue/bone contact for a limited (<24 hr) time.

The sponsor identified patient contacting components of the ROBODOC system use known biocompatible materials for the stated intended use. The sponsor has provided acceptable scientific information and rationale to support the biocompatibility of the subject device.

VIII. Software (Formal Review Attached)

(b) (4)

[redacted]

DJA x00113

(b) (4)

[redacted]

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The sponsor claimed conformity to IEC 60601-1, IEC 60601-1-1, and IEC 60601-1-2 (additional standards conformance is described below), however the sponsor was asked to provide the test reports verifying conformity to these standards in order to demonstrate that no protocol deviations were needed to yield a "pass" result. The sponsor provided these reports which did not use protocol deviations. This response is acceptable. Thermal safety in regards to the milling process is discussed in detail within the deficiency and response section.

X. Voluntary Standards

The sponsor claims conformity to the following standards:

STANDARD NUMBER	DATE	STANDARD TITLE
IEC 60601-1	1988	Medical Electrical Equipment. Part 1: General Requirements for Safety
IEC 60601-1-1	2000	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	2001	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 801-2		IEC ESD
IEC 801-3		IEC Radiated Electromagnetic Field Requirement
IEC 801-4		IEC Electrical Fast Transient / Burst Requirement
IEC 801-5		IEC Surge Requirement
ISO 14971	2000	Medical Devices — Application of Risk Management to Medical Devices
10993-1		ISO 10993-1, Biological Evaluation of Medical Devices Part 1; Evaluation and Testing

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FDA Blue Book Memorandum G95-1		"Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"
ANSI/AAMI/ISO11137-1	2006	Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ANSI/AAMI/ISO 11137-2	2006	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
FDA Guidance		Guidance for Content of Premarket Submission for Software Contained in Medical Devices May 11, 2005
ANSI S20.20	1999	Standard for the development of an ESD control program
EN 980	1997	Graphical symbols for use in the labeling of medical devices
21 CFR 820		Quality Systems Regulation QSR

XI. Performance Testing – Bench

System Accuracy – With respect to system accuracy, the total accuracy is the sum of 1) cavity placement accuracy and 2) dimensional accuracy of the cavity. Cavity placement accuracy is dependent upon accurate registration. Dimensional accuracy of the cavity is previously determined and validated by evaluating the difference between the actual cavity dimensions and the dimensions specified by the manufacturer of the implant. The primary goal of bench testing is to validate these accuracy components.

Digitizer Accuracy with Respect to a Known Object

Objective	(b) (4)
Methods/ Materials	
Acceptance Criteria	
Results	

Digitizer Accuracy with Respect to the 2-Pin Design Using Patient Data

Objective	(b) (4)
Methods/ Materials	
Acceptance Criteria	
Deviations	

DJA x00115

Results	(b) (4) [redacted]

Verify Digitizer Accuracy with Respect to the Electro-Mechanical Arm.

Objective	(b) (4) [redacted]
Methods/ Materials	
Acceptance Criteria	
Results	

Verify DigiMatch Registration Verification performed by the surgeon.

Objective	(b) (4) [redacted]
Methods/ Materials	
Acceptance Criteria	
Results	

Verify that the ROBODOC system can recover from bone movement.

Methods/ Materials	(b) (4) [redacted]

DJA x00116

	(b) (4)
Acceptance Criteria	
Results	

Cadaver Ex Vivo Study to Evaluate Pin-Based Registration

Objective	(b) (4)
Methods/ Materials	
Results	

Cadaver Ex Vivo Study to Evaluate Pinless Registration

Objective	(b) (4)
Methods/ Materials	
Acceptance Criteria	

DJA x00117

	(b) (4) [redacted]
Results	[redacted]

XII. Performance Testing – Animal

In a canine animal model experiment, 20 male greyhounds were randomized to either hand broached or robot assisted hemiarthroplasty. For dogs randomized to the hand broached group, planning was performed with acetate templates over x-rays and the femoral cavity was prepared with handheld broaches. In the robot group, 3 locator pin placement and CT scans were performed under general anesthesia. Planning was performed via the ORTHODOC system, and the femoral cavity was milled by the robot after intraoperative registration. Partial weight bearing on the first postoperative day was followed by full weight bearing after day 2. Beginning on day 5, all dogs received a polychrome sequence labeling with yellow, red, blue and green markers. Each label was applied for 5 days. A postoperative gait analysis was carried out after 1, 3, 6, 9 and 12 months. Necropsy dates were at 35 days for 8 dogs (4 each group), 84 days (6 dogs), and 365 days (6 dogs).

In the robot group, all dogs were successfully operated on. No procedure had to be aborted, and in all cases, the preoperative plan regarding size and position of the implant was accomplished. In the hand broached group, 2 dogs suffered a fracture of the femur. One (1) dog had to be sacrificed intraoperatively because the femur cracked and the implant could not be positioned deep enough to allow reduction of the joint. In another dog, the fracture became evident in the x-rays before necropsy, when a large callus formation developed as result of a long spiral fracture. Operating time in the robot group was a mean of 29 minutes longer than in the hand broached group.

Gait analysis one month after surgery showed a significantly better performance of the robot group. PFz (peak vertical force) and IFz (impulse of vertical force) were 93.1% and 94.5%, respectively, of the preoperative value in the robot group, while the hand broached dogs reached 80.6% and 77.1%, respectively. Similar differences were found in the 6-month and 12-month gait analyses.

The histological evaluations revealed a closer alignment of the implants to strong cortical bone in the robot group. Signs of major repair and remodeling were visible in the slides of the hand broached group; whereas, the robot group showed all signs of primary healing between the implant and bone.

XIII. Performance Testing – Clinical (Formal Clinical Review attached)

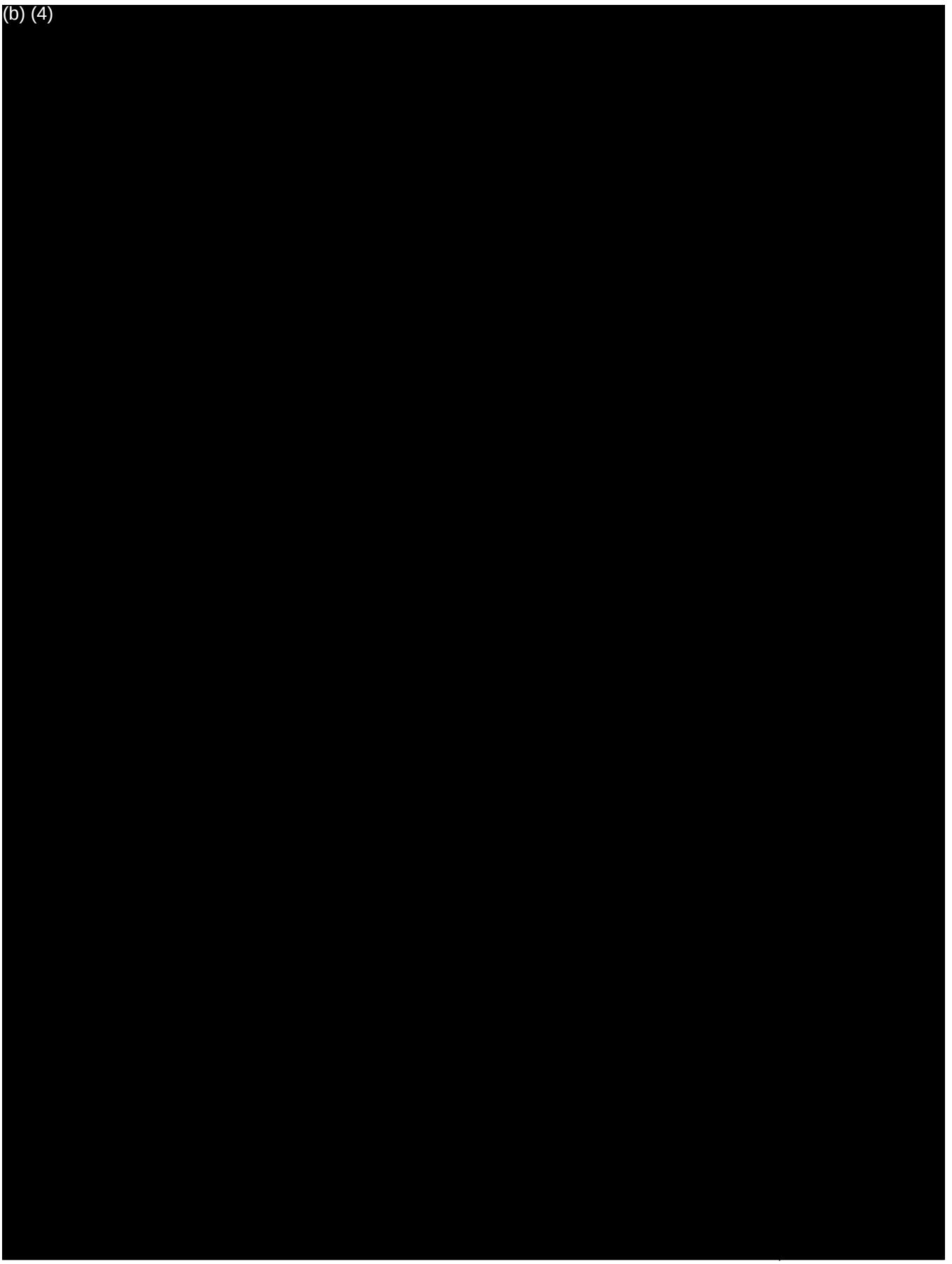
Section 20 of this submission contains reports of two IDE clinical trials (IDE# G920035 and G000071) and two foreign trials, which are provided in support of this premarket notification. The second clinical trial is summarized as follows:

Second IDE Clinical Trial (IDE # G000071): DigiMatch ROBODOC Technologies

Objectives - The primary objective of this trial was to show that the DigiMatch ROBODOC Surgical System is safe for its intended use as a surgical tool indicated for preoperative planning and femoral canal preparation in primary THA. The secondary objective was to demonstrate that potential risks identified in the First IDE Trial have been eliminated or mitigated. The third objective was to confirm efficacy of the ROBODOC technology, as demonstrated in the First IDE Trial, by comparing results of Harris Hip Score outcomes.

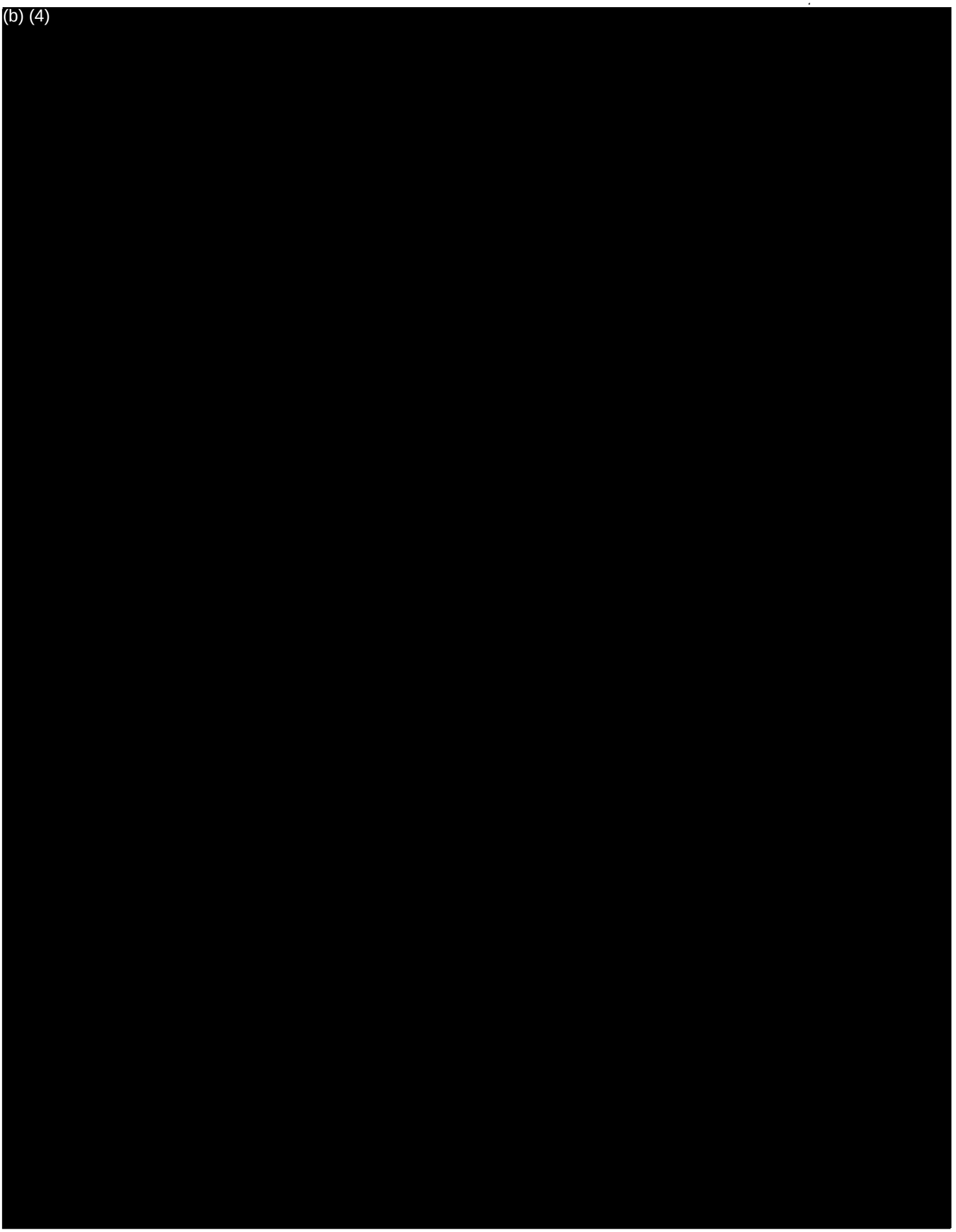
Summary of Protocol - This was a multi-center, randomized (3:1, ROBODOC to control) trial. For both groups, procedure surgical time and blood loss are recorded, and units of blood transfused are recorded at discharge from the hospital. Prior to randomization and surgery, baseline data were collected on all subjects. The principal efficacy outcome of interest was the Harris Hip Score which was collected for comparison to results from the First IDE Trial. Additional self-assessed scores, WOMAC osteoarthritis index and SF-12 scores were also collected. Follow-up visits were at 6 weeks, 3 months, and 6 months post-THA. Hip and knee pain and quality of life measures were recorded at all follow-up periods. All adverse events were recorded from the time of the procedure and throughout the follow-up period.

DJA x00118



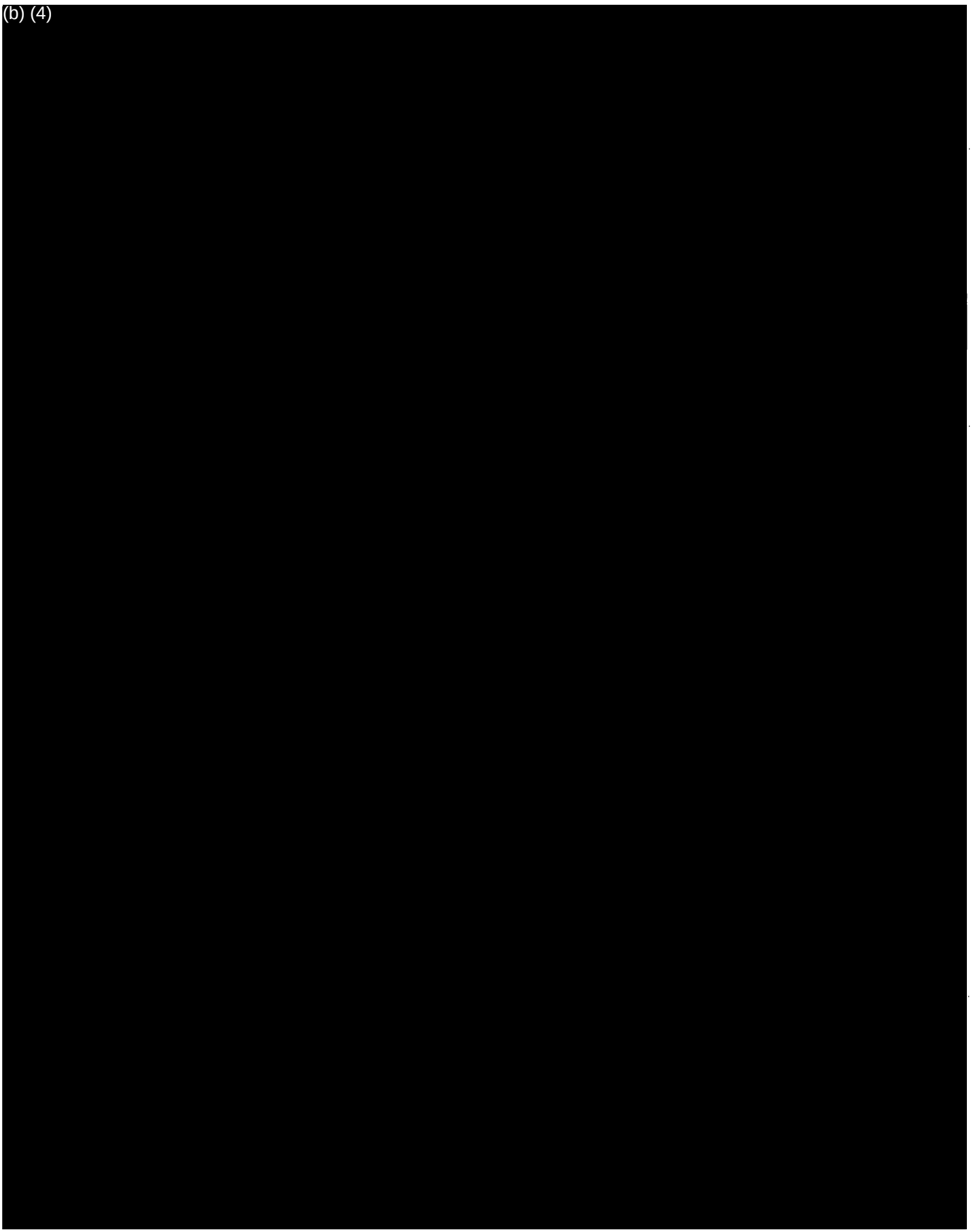
DJA x00119

(b) (4)



DJA x00120

(b) (4)



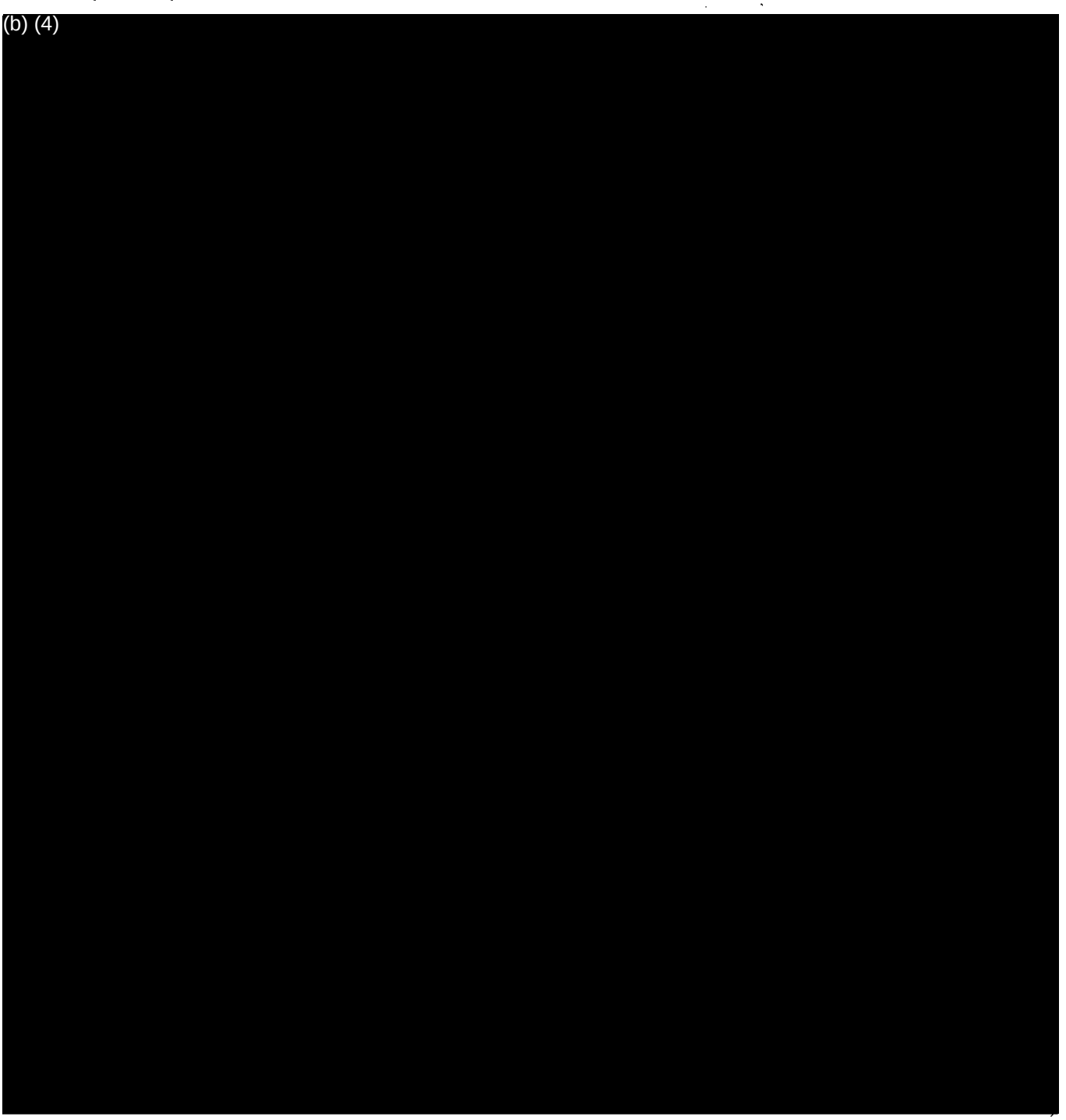
DJA x00121

Reviewer Comments:

In recent discussions, FDA has agreed that the efficacy of the ROBODOC Surgical Assistant System (pin-based system) was demonstrated in the First IDE Trial. Subsequently, FDA requested that similar efficacy between the pin-based ROBODOC system and the pinless DigiMatch system be established. As a result the sponsor believes that the full 188 subjects are not necessary as the primary purpose of the second trial was to confirm the mitigation of the risks identified in the first clinical trial. The sponsor further believes that data collected as part of a randomized clinical trial in Japan can be pooled with the data collected as part of the second IDE trial. To support the conclusion of continued device efficacy the sponsor has compared the data from the first and second IDE trials as follows:

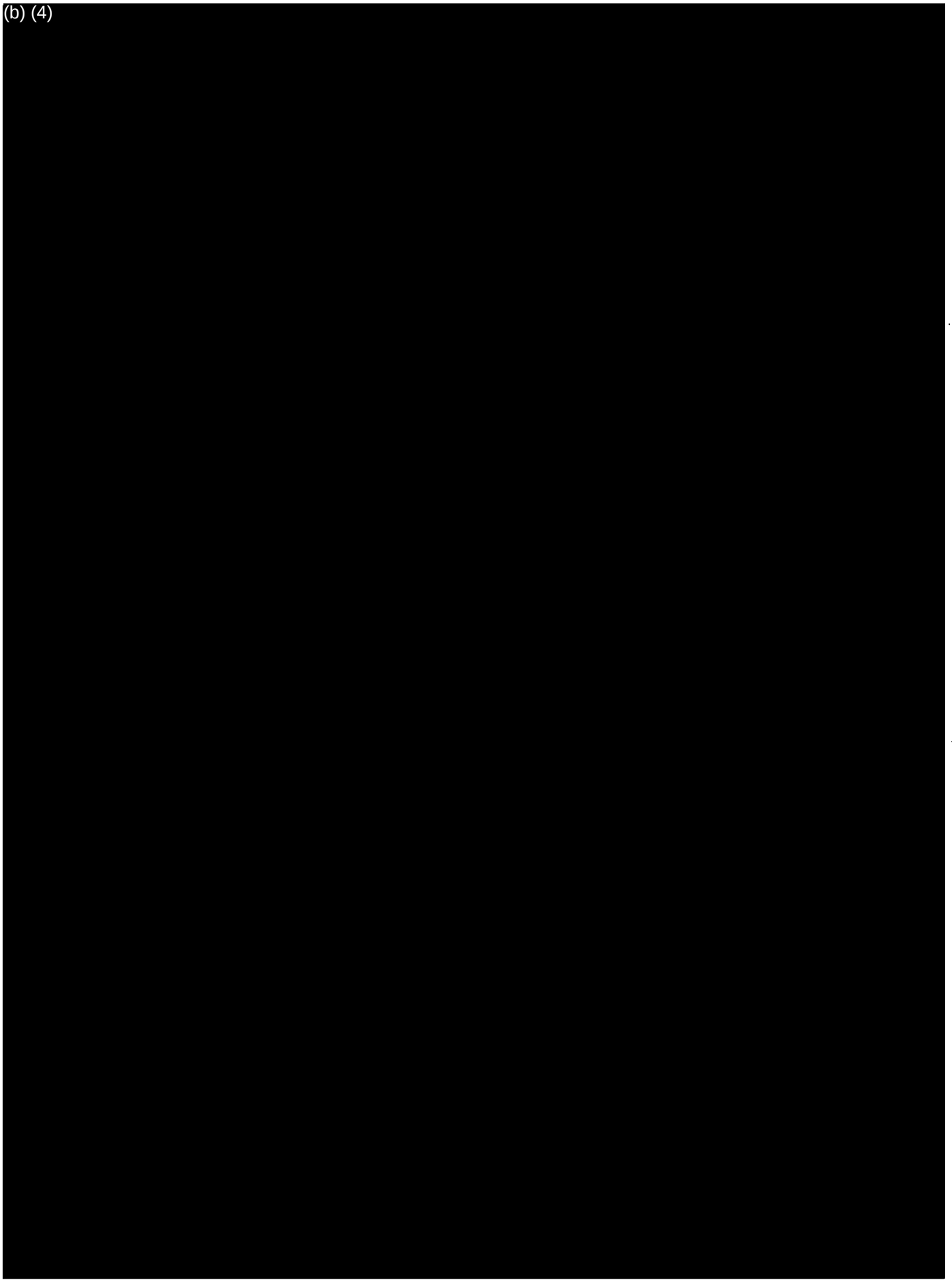
Comparison of Clinical Outcomes between Pin-Based and Pinless Registration Technologies

(b) (4)



DJA x00122

(b) (4)



DJA x00123

(b) (4)

[redacted]

XV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		N	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		N	If **YES** = Stop **NSE**
3. Same Technological Characteristics?		N	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	Y		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		N	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	Y		If **NO** = Stop **NSE**
8. Performance Data Available?	Y		If **NO** = Request Data
9. Data Demonstrate Equivalence?	Y		Final Decision: **SE**

1. Explain how the new indication differs from the predicate device's indication:
The DigiMatch ROBODOC Surgical System is indicated as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA). The predicate device systems are indicated for varying surgical applications including THA. The stereotactic predicate devices support the passive navigation of femoral broaching/reaming, but do not actively guide femoral broaching/reaming.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
While the cited predicate devices are similar in technology (electromagnetic articulated arms), they differ in clinical application (general surgical applications). Several stereotactic passive navigation systems are indicated for the same clinical application (i.e. THA and passive femoral reaming navigation). The combination of the two types of predicate devices (technology predicates and passive navigation predicates) demonstrates that the differences in the subject device's indications for use do not raise a new type of safety or effectiveness issue. The subject device and the predicate devices are subject to the same types of safety and effectiveness issues which include accuracy and usability issues.

3. Describe the new technological characteristics:
The primary technological difference is the control method of the subject device. The subject device is a computer controlled system. A computer controlled system automatically executes a predefined surgical plan. In contrast, the predicate devices mimic user actions (fly-by-wire) or provide navigational feedback which can be used by the user to adjust their own actions. It is important to distinguish that the control of the predicate devices directly involves the user. The control of the subject device is indirectly controlled by the user in that the user is responsible for pre-operatively defining the software plan and is responsible for supervising the behavior of the system. It is also worth noting that the user has the ability to override the computer control at all times.

In regards to the other technical characteristics, such as the hardware (electromagnetic arm, computer workstation, drill bits, sheaths, and etc.) and software (registration methodology, workflow, navigational functions, etc.), the subject device is similar to the predicate devices.

4. Explain how new characteristics could or could not affect safety or effectiveness:
The new technological characteristic (computer control) could adversely affect the safety and effectiveness profile that has been established for the predicate fly-by-wire and passive navigational systems. Namely, the user no longer initiates a clinical action which is based upon system feedback or mimicked by the system. Instead the computer initiates a clinical action which is based upon a pre-operative plan. In regards to safety, this difference results in the user reacting to a potentially inappropriate clinical action rather than judging the clinical action prospectively before initialization. Computer control could also result in decreased efficacy if the system is not robust enough to respond to variable clinical conditions (ex: differences in bone density, patient movement, atypical patient anatomy, etc.).

DJA x00124

5. Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
The introduction of computer controlled technology does not raise new questions of safety or effectiveness. The same questions apply to both the predicate devices as well as the subject device. The safety related question is whether the user can appropriately dictate the performance of the system. That is does the actions of the system reflect the user's actions. Further, does the system possess appropriate safe guards to compensate for variable clinical conditions? The effectiveness question is whether the system can perform as intended by the user. That is does the output of the system enable to make valid clinical judgements. They questions are not new and are assessed in the review of the predicate devices.

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:
The sponsor must demonstrate that the safety and effectiveness of the system is technologically substantially equivalent to computer assisted technology and is clinically substantially equivalent to traditional milling methods. Therefore, the sponsor must provide adequate bench/engineering performance testing (software and hardware V&V) and clinical performance testing (fit and fill clinical data).

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The sponsor has conducted the necessary verification and validation testing to establish substantial equivalence. The activities included usability testing, bench-top testing, software testing, an animal investigation, and two clinical investigations. Please refer to the respective sections within the previous reviewer memo for specifics regarding these activities.

XVI. Deficiencies

1. The submission includes a general description of various safety features. The description frequently references predefined minimum and maximum threshold values. These values are not defined in the general description. As the values dictate the efficacy of the safety features additional information is necessary. Please provide additional information regarding these safety features including the threshold values and a description of testing used to verify the appropriateness of these threshold values. In addition, please provide specifics on any additional threshold values such as the temperature limits, velocity limits, force limits, etc. that are used to dictate the behavior of the system.

   Response: *The general description of various safety features of the ROBODOC System has been updated to include additional information regarding the safety features. Threshold values, where applicable, were added in parentheses and a description of testing used to verify the appropriateness of these threshold values was provided.*

   Review: *The updated summary of the Robodoc safety features was provided on pages 9-16. This updated summary is sufficient to characterize the device's safety features. This response is acceptable.*

2. The submission does not appear to address the risk of system recovery resulting in inappropriate robotic arm movement. That is following a system crash and subsequent recovery the robotic arm could initiate movement to a "default" position. Please describe how the system will recover from a system crash and what mitigation exists to prevent unintended movement following a system crash.

   Response: *There is no defined default position that the robot arm moves to in the event of a system crash. If at any time during the set up or procedural use of the system any single or combination of computer system crashes, power to the arm is removed from the robot arm and the system stops. Unintended movement of the system in the event of a system crash is mitigated by removing all power to the robot.*

   The ROBODOC System is designed such that a system crash would force the surgeon to disconnect the patient from the system and manually move the robot to a safe position. The surgeon then must assess his/her options to restart the procedure using the robot or abort to manual. If the surgeon decides to restart using the ROBODOC, he/she must start from the very beginning. You cannot restart from the point of the system crash.

DJA x00:25

If the surgeon decides to complete the case manually, he/she can do so using the approved manual tools and methods. Chapter 10 of the ROBODOC User Manual has been revised to include a discussion of the steps to be taken in the event of a system crash. A copy of the added discussion is provided in Attachment 1 of this document.

Review: *The sponsor has adequately described the default status of the system. In the event of any software or hardware error the system removes power from the robot. In addition, the robotic arm is designed with a brake to allow minimal movement due to an applied load (<6mm) after the removal of power. The sponsor has further clarified that the system cannot be restarted at the point of the crash. The user is required to remove the robot from the patient's vicinity before restarting the procedure. This prevents the system from moving unintentionally following a restart. The sponsor has also revised the device labeling to provide explicit instructions for recovering the system after a crash. This response is acceptable.*

3. The device labeling reports an implant placement accuracy of ±2.0mm along the axis of the bone and ±1.0mm in the plane perpendicular to the bone axis. The implant cavity preparation accuracy is stated as ±0.4mm in the cross-sectional dimensions. It is unclear what validation data exists to support these values. Please provide a reference to the validation testing which supports this performance statement.

Response: *The validation of placement accuracy and cavity preparation accuracy are demonstrated in separate procedures. Validation placement accuracy is demonstrated in TR 98-07-009 and validation of cavity accuracy is demonstrated in TR 99-030-05-07. A copy of TR 98-07-009 and TR 99-030-05-07 is provided in Volume II of this document.*

Review: *The sponsor has provided performance testing to support the accuracy claims made in the device labeling. This response is acceptable.*

4. The clinical data provided to support the safety and efficacy of the pinless registration technology represents pooled data from both United States and Japanese study sites. The submission states that the same study protocol was followed for all site locations, however, a discussion is not provided regarding the equivalency of the patient populations. Please provide a discussion indicating why it is appropriate to pool this data.

Response: *Justification for pooling data from United States and Japanese study sites is based on the following principles:*

1. *All investigational sites followed the same IDE protocol with the same eligibility criteria.*
2. *All investigational sites used the same data collection procedures, the same patient case report forms (CRFs), and were monitored the same way to ensure proper conduct of the study.*
3. *The DigiMatch™ ROBODOC® Surgical System was used in the same way at each investigational site. All investigators and support staff received the same ROBODOC System training, including both didactic training and laboratory practicum training. Additionally, all investigators and support staff used the ROBODOC® Preoperative Protocols, ORTHODOC® User Guide and ROBODOC® User Manual as part of the training and reference materials.*
4. *The conventional preoperative template planning and manual broaching/reaming THA procedures were similar at each investigational site.*

Review: *Although there does appear to be some differences between the enrolled patient populations as suggested in the sponsor provided summary tables, the clinical data collected from the OUS site was minimal (6 patients) and was not used for efficacy analysis. Further, the clinical data collected as part of the second IDE focuses on demonstrating the improved performance of the pinless technology. The reviewer does not believe that the differences between the patient populations prevent the use of the OUS clinical data. The sponsor's response is acceptable.*

5. The submission describes a robotic device which is indicated for use with multiple implant systems. Please note that it is the sponsor's responsibility to verify that all supported implant systems are legally marketed within the United States. Please provide a list of the implant systems currently included within the implant database. In addition, please describe the process for integrating these implants into the database. This description should include a discussion of the relevant data needed and the activities performed to verify implant compatibility.

DJA x00126

Response: *As requested, ISS provided a statement that it understands its responsibility to verify that all implant systems used on the ROBODOC System are legally marketed within the United States. A list of the implants that will be included in the 510(k) cleared ROBODOC System is provided. Additionally, an overview of the implant development process and a discussion of the implant development process steps are presented.*

Implant Name	*Manufacturer*	*510K Number*	*ISS Validation*
Meridian Titanium Femoral Stems	*Howmedica*	*K972228*	*TR99-046-01*
Versys Hip System	*Zimmer Inc.*	*K964769*	*TR00-044-01*

Review: *As clarified in previous discussions, the sponsor states their understanding that all supported implant systems must be legally marketed in the United States. The sponsor has provided a list of all currently supported implant systems and has provided a description of the process that is used to validate the support of an implant system. This response is acceptable.*

6. The submission includes several user manuals within Section 13. This labeling does not appear to include the intended use / indications for use as presented in the 510(k) Indications for Use statement. Please revise the labeling to include the intended use / indications for use.

   Response: *As requested, ISS has revised the ORTHODOC and ROBODOC User Manual labeling to include the intended use / indications for use. A copy of the revised pages of the manuals is provided in Attachment 2 of this document.*

   Review: *This response is acceptable.*

7. The Robodoc user manual contains instructions regarding the importance of distal fixation (Chapter 6-7). This section indicates that distal fixation is the responsibility of the user. However, the section does not provide adequate discussion regarding the adverse affect of motion. Please revise this section to include a discussion of the limitations of the bone motion detection function (threshold value) and the corresponding decrease in system accuracy that could be expected if motion occurs.

   Response: *Chapter 7, REGISTRATION PROCEDURES, of the ROBODOC User Manual has been revised to include a replica of the bone motion indicator and a discussion of its intended use. Attachment 3 of this submission provides a copy of the revised pages.*

   Review: *This response is acceptable.*

8. The Robodoc user manual contains a troubleshooting section (Chapter 10). Within this section instructions are provided for replacing the bearing sleeve after part failure. The section also indicates that the part should be routinely maintained to prevent failure, however, adequate servicing instructions are not provided. Please provide a reference to part maintenance instruction or include additional detailed maintenance instructions for the bearing sleeve part and any other part which requires user maintenance.

   Response: *ISS has revised Chapter 9 of the ROBODOC® User Manual to clarify the servicing and routine maintenance requirements for the bearing sleeve part of device. Attachment 4 provides a copy of the revised User Manual page, which clarifies the servicing and routine maintenance requirements.*

   Review: *The purpose of this deficiency was to identify components which required user maintenance and evaluate the corresponding maintenance instructions. The prior version of the user manual failed to include adequate instruction and criteria for when the bearing sleeve should be serviced. The revised labeling includes a description of the conditions which warrant part servicing and instructions for maintenance. This response is acceptable.*

9. The Robodoc user manual refers to an "Adaptive Cut Speed" feature. This feature is described as be able to adjust bone cutting speed based upon bone hardness. It is unclear how this feature functions. Please provide additional information regarding this feature. In addition, please provide a discussion regarding the risk of thermal injury during robotic reaming. This discussion should include a definition of a worst case thermal scenario and describe all mitigating activities that are employed to address this risk.

DJA x00127

Response: *The adaptive cut speed feature uses force feedback to alter the feed rate of the cutting tool. This allows the robot to move in response to the type of material it is cutting when it encounters materials of different density (e.g., air, soft tissue or transitional material such as soft to hard bone), slowing down when hard bone is encountered. The adaptive cut speed is based on four parameters that are specified within the cutfile: a minimum speed, a maximum speed, a nominal speed, and a maximum force. In addition, the computations use the stiffness of the current cutting tool (sleeve and cutter), which is obtained from the tool database for the particular implant. The nominal speed is used if the adaptive cut speed feature is disabled by the surgeon (e.g., via an option on the pendant pause menu). Otherwise, the robot moves at the maximum speed if no force is measured, and slows down based on a nonlinear function of the sensed force. The robot will never cut at a feed rate lower than the minimum speed. If the minimum movement is not detected or the measured force is higher than allowed at that minimum speed, the robot is stopped and the cutter is turned off and an error condition is set.*

The worse case cutting scenario exists when irrigation fluid is not used and cutting is done with a dull (reused) cutter. In this case, it is possible to have cutting temperatures that may lead to thermal injury. This risk is mitigated by directives in the user manual (ROBODOC User Manual, Chapter 8), Cutter and irrigation tube set package labeling and system prompts requiring user confirmation during use. The combination of cutter design, cutter use, irrigation and adaptive cutting controls further mitigates the risks of thermal injury.

Review: *The sponsor has adequately described the adaptive cut speed feature. The sponsor has also identified a worst case scenario (reuse of cutter with no irrigation) and conducted a risk analysis in regards to thermal injury. The sponsor has mitigated the worst case scenario by prescribing single use only for the cutting accessories, continued use of irrigation during cutting, and an adaptive cutting feature which limits the robot cutting speed. While it would be preferred that a direct temperature sensing mechanism be employed at the cutting tip, these measures are reasonable for preventing thermal damage to the patient. Further, there were no reported adverse events related to excessive heat during use of the system. The response is acceptable.*

10. The submission has identified the level of concern for the DigiMatch Robodoc Surgical System software to be Moderate. However, we believe that the malfunction of the Robodoc Surgical System could pose a serious risk to the user. For example; software incorrect calculation of the position within the patient's femur could lead to a serious injury. Hence, the Agency believes that the system software has a "Major" Level of Concern associated with it. Please provide us with the DigiMatch Robodoc Surgical System software documentation that is based on "Major" Level of Concern as specified in FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Please also update your current software documentation to reflect Major level of concern.

    Response: *ISS has assessed the Level of Concern within the context of the worst possible, reasonably foreseeable, clinical consequences of failure of the device. This reassessment has again led the company to the conclusion that the ROBODOC® Surgical System software meets the definition of a "Moderate Level of Concern" in that the software for the device does not have a failure or latent design flaw that could directly or indirectly result in death or serious injury to the patient or operator. ISS interprets "a failure or latent design flaw" to mean a single failure or single latent design flaw. However, based on our December 14, 2007, discussion with Mr. Michel Janda, ISS is submitting the additional documentation that is required to support "Major" Level of Concern software.*

    Review: *The reviewer maintains that the software is of Major Level of Concern. The sponsor interprets the guidance document to include the probability of occurrence of a latent design flaw or system failure. The reviewer maintains that the level of concern is determined regardless of probability of an event occurring and regardless of the software safety feature redundancy. The level of concern should be determined under the assumption that a rare, worst case scenario can occur and that no software controlled safe guards exist. While the sponsor does not concur with this determination, the appropriate documentation for Major Level of Concern software has been provided. Thus, the response is acceptable. The review of the submitted software documentation is attached.*

11. The submission includes a description of the user training that is suggested for all new users. It is known that complicated systems such as the Robodoc system have an associated learning curve. While user training is an appropriate mitigating action to minimize the user's learning curve, it is unclear if additional human factors studies were undertaken in an attempt to simplify the use of the Robodoc system. Please clarify if any human

DJA x00128

factors studies were preformed to verify human performance and the risks associated with user error. If so, please provide us with the results of the study. For more information regarding Human Factors, please refer to http://www.fda.gov/cdrh/humanfactors/.

Response: *Human factors testing were performed in two tests (TR98-07-011 and TR99-007-01) at* [redacted] *The studies were designed to validate ease of use and performance of the DigiMatch System using a point to surface approach for addressing the pinless registration issue. The report of the study, TR98-07-011, is summarized in Section 20.5 of the original 510(k) submission (K072629). Copies of TR98-07-011 and TR99-007-01 are provided in Volume II of this document.*

Review: *This response is acceptable. Formal review of these test reports was provided within the software consultation memo.*

12. The submission includes a description of the testing conducted to establish electromagnetic compatibility and electrical safety (Section 17). While this section indicates that the system complies with the referenced standards, it is unclear if any testing deviations were needed to establish compliance. Please provide a copy of the electromagnetic compatibility and electrical safety test reports.

Response: *A completed copy of the electromagnetic compatibility and electrical safety test reports is provided in Attachment 5.*

Review: *The sponsor has provided the test reports which did not use any protocol deviations to yield a "pass" result. This response is acceptable.*

13. As the Robodoc system has undergone several technical enhancements throughout its development, it is unclear which device version is intended to be cleared within this 510(k). Please clarify if the described device is identical to that used in the second IDE clinical study. If any device modifications are intended to be included within this 510(k), please describe them.

Response: *ISS confirms that DigiMatch™ ROBODOC® Surgical System described in 510(k) Number K072629 is identical to the system used in the second IDE clinical trial (IDE #G000071). No device modifications are included within this 510(k).*

Review: *As no modifications were made to the IDE study system, the clinical results generated from this study can be extrapolated to the 510(k) device. This response is acceptable.*

14. In Device Hazard Analysis section you have provided a table that associates a risk severity number with the components. The Agency believes that a complete and detailed hazard analysis should consists of a description of the hazard presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. Hence, please revise your Device Hazard Analysis and provide us with an updated Device Hazard Analysis to reflect the points mentioned above. In addition, please update the device hazard analysis to include an analysis of the pendant.

Response: *The DigiMatch™ ROBODOC® Surgical System Device Hazard Analysis has been revised as requested. A column has been added that identifies the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. The pendant is covered in line items 56, 57 and 58. A copy of the updated Risk Management Report, DIGIMATCH™ ROBODOC® System, is provided in Attachment 6. A copy of the updated Device Hazard Analysis is provided in Attachment 7.*

Review: *This response is acceptable.*

15. In Revision Level History section you have provided a summary of your changes. We believe a revision history should also include the final finished versions released for the production units of the system, any configuration management software (i.e. Perforce, MS Visual Source safe) used to manage, control changes in the software

DJA x00129

classes and any bug tracking software used in your software development process. Hence, please provide us with the information stated above.

Response: *The sponsor has provided the requested information. In addition, tables that track the revision history for the ORTHODOC Preoperative Planning Workstation software and the DigiMatch ROBODOC Surgical Assistant are also provided.*

Review: *This response is acceptable. Additional review is provided in the attached software consultation memo.*

16. During a phone conversation with the sponsor, the reviewer requested that additional information be provided in regards to the bone fixation system and the mitigation methods that are implemented to avoid soft tissue damage. This request was made in response to comments received about soft tissue damage incurred from excessive force applied by the femoral clamp. These comments were communicated to the reviewer by Neil Ogden after attending a stereotactic working group and discussing the use of the Robodoc system in the European marketplace. The reviewer noted that this type of event may not have been detected and reported in the IDE study results as the endpoints did not specifically seek out this information.

Response: *ISS has provided the requested information explaining the use of the bone fixation system and any mitigation implemented to avoid soft tissue damage. Attachment 8 contains copies of revised pages from ROBODOC User Manual, Chapter 6, Femoral Fixation. These revisions were made in response to this FDA comment and are used to mitigate soft tissue damage caused by the user with improper use of the fixator.*

Review: *Although the IDE results did not report this specific adverse event, it is plausible that soft tissue damage could occur through misuse of the femoral fixation system. The sponsor has made acceptable changes to the device labeling in order to mitigate against this potential risk. This response is acceptable.*

XVII. Contact History

Frequent interactive review correspondence occurred during the review of this submission. The major discussions regarding this submission were documented within CTS.

XVIII. Recommendation

Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotactic Instrument
Regulatory Class: Class II
Product Code: **New Product Code** -

Reviewer — Date: 2/11/08

Branch Chief — Date: 2/14/08

DJA x001130

OFFICE OF DEVICE EVALUATION
CLINICAL CONSULT

From: J. C. Lyons, MD
Clinical Reviewer

To: Michael Janda
General Surgery Devices Branch

CC: Jonette Foy, Ph.D.
Chief, Orthopaedic Joint Devices Branch (OJDB)
Division of General, Restorative & Neurological Devices
FDA/CDRH/ODE

Subject: **K072629**
DigiMatch ROBODOC Surgical System

Date: 2.8.08

RECOMMENDATION:

Given the disadvantages of extended surgical times and increased blood loss, and without long-term result data confirming that the proposed improved surgical precision results in improved outcome, the clinical value of the device in its present form is uncertain.

SUMMARY

Robodoc Surgical System is a "3-D graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty."[1] (p000004) The ORTHODOC component is offered to enable "the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur" (p000004), and to enable preoperatively templating. The ROBODOC component is the electromechanical arm and accessories which enable the actual preparation of the proximal femur.

The system is offered "As handheld broaches used in the preparation of the femoral cavity are prone to tear out pieces of bone and are often deflected by hard bone, [whereas] machine milling of the cavity is likely to enhance surgical precision." (p000017)

The First IDE Clinical Trial (G920035) was performed using the "pin-based" technology. The Second IDE Clinical Trial (G000071) was performed using the "pinless" DigiMatch ROBODOC Surgical Assistant System.

[1] DigiMatch ROBODOC Surgical System. 510(k) Premarket Notification. Volume IV

DJA x00131

K072629, the DigiMatch Robodoc Surgical System is proposed for marketing.

Reviewer's Comment's:
The Sponsor's documents refer, variably, to broaching and milling operations by ROBODOC. Typically in clinical practice, the surgeon prepares the femoral canal using a box chisel to open the canal, a reamer (flexible or rigid) to ream the medullary canal for the prosthetic stem, then a broach to shape the proximal femoral canal for the proximal prosthetic contours. The term "milling" conjures the impression for reaming, whereas "broaching" clinically relates to the proximal box preparation for the femoral component. Since this reviewer has only Volume IV of the documents, and no pictures of the device, this point is raised only to be sure there is no terminology confusion, given how these terms are used clinically. It is presumed that the terms broaching and milling, as used in this submission, are used interchangeable to refer to surgical "broaching" of the proximal femur.
The preoperative templating continues to rely upon a surgeon's impression as opposed to a CAD/CAM assessment.

BACKGROUND INFORMATION

Study Design:
The First IDE Clinical Trial (G920035) was performed using the "pin-based" technology. The Second IDE Clinical Trial (G000071) was performed using the "pinless" DigiMatch ROBODOC Surgical Assistant System.
K072629, the DigiMatch Robodoc Surgical System, is proposed for marketing.

Duration:
The sponsor has completed two clinical trials, G920035 &G000071.

Control:
The results of ROBODOC G000071 were to compare to the results of manual femoral preparation, and also to the results of G920035.

Device Description (and History):
See above.

Intended Use:
The DigiMatch™ ROBODOC is a robotic surgical tool intended as an alternative to manual planing and broaching/reaming technique for femoral canal preparation in primary cementless total hip arthroplasty (THA).

Proposed Indications for Use:
The system is proposed for the proximal femoral preparation in total hip arthroplasty.

Brief Clinical Background:
The purpose of the G000071 clinical trial was to evaluate the effect of a pinless system on:

1. Surgical time

DJA x00132

2. Blood loss
3. Post-operative ipsilateral knee pain

The clinical trial was approved and patients that were followed for six months postop. The safety endpoints included surgical time, estimated blood loss, transfusions, post-operative ipsilateral knee pain, and any complications or adverse effects. The primary effectiveness endpoints included the precision of femoral canal preparation and the Harris Hip Score. Secondary effectiveness endpoints included the SF-12 Patient Self-Assessed Health Survey and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

The purpose of this trial was to validate the pinless technology and demonstrate that the risk factors seen in the First Trial had been mitigated or eliminated. The issue of longer surgical times and greater blood loss was addressed by additional training of the participating surgeons and the improvement of cutting technology

Reviewer's comments:

The second trial demonstrated improvement over the first, but although the results of the second trial demonstrate improvement, the clinical usefulness of the system at this time appears limited.

PRIOR INVESTIGATIONS

Pre-clinical Evaluations

The pre-clinical compatibility, cadaver, animal, safety and performance testings are referenced in Sections 17, 18 and 19.

Clinical Evaluations

The clinical performance testing for the pin and pinless systems is referenced in Section 20. (p000099)

According to the Section 20.2.5: Conclusions, the "Results of the First Clinical Trial demonstrate that the ROBODOC System performed safely and effectively during its intended use." (000109)

Comparison of clinical outcomes between pin-based and pinless technologies was discussed in Section 20.7, (page 000322)

Reviewer's comments:

Section 20.2.2 indicates that 4 potential surgical risks were identified in the First Clinical Trial. (p000103) These included 1.) the locator pin procedure, 2.) longer surgical time, 3.) increased intraoperative blood loss, and 4.) post-surgical ipsilateral knee pain. With the new locator mechanism, the first point is no longer of concern. The results of the second trial are discussed below.

SUMMARY AND REVIEW OF IDE CLINICAL PROTOCOL

Purpose/ Objective of Study

The primary objective of the second trial was to demonstrate that the DigiMatch ROBODOC Surgical System is safe as a surgical tool, and in preoperative planning for primary THA. The secondary objective was to demonstrate that potential risks identified

DJA x001133

in the First IDE Trial had been eliminated or mitigated. The third objective was to confirm efficacy of the ROBODOC technology, as demonstrated in the First IDE Trial, by comparing results of Harris Hip Score outcomes.

Intended Use
The DigiMatch ROBODOC Surgical System is intended for use as a device to assist the physician with presurgical planning, and to provide orientation and reference information during robotic preparation of the proximal femoral canal.

Sample Size Justification
Only 104 subjects were included in the Second IDE study with only 25 manual controls.

Protocol Synopsis
This was a multi-center, randomized trial. The procedure surgical time and blood loss were recorded, as well as the number of units of blood transfused.
The principal efficacy marker was the Harris Hip Score, which was collected for comparison to results from the First IDE Trial. In addition, self-assessed scores, WOMAC osteoarthritis index and SF-12 scores were also collected.
Follow-up visits were at 6 weeks, 3 months, and 6 months post-THA.

Controls
104 randomized subjects were treated in the Second IDE Trial. 79 were ROBODOC patients and 25 were manual control patients. 69 (87%) of the ROBODOC and 21 (84%) of the Control subjects have completed the 6-month follow-up visit.

Reviewer's comments:
The parameters of assessment of this second trial appear reasonable, given the purpose of the second trial. To know if the improved broaching has any affect on late loosening or revision will require long-term follow-up.
The sample size of this study appears small, given that proximal femoral anatomy can vary widely in terms of geometric contours, bone density, and the disease processes that may necessitate the need for THA.

Clinical Evaluations

Outcomes in the Second Trial:

(b) (4)

[redacted]

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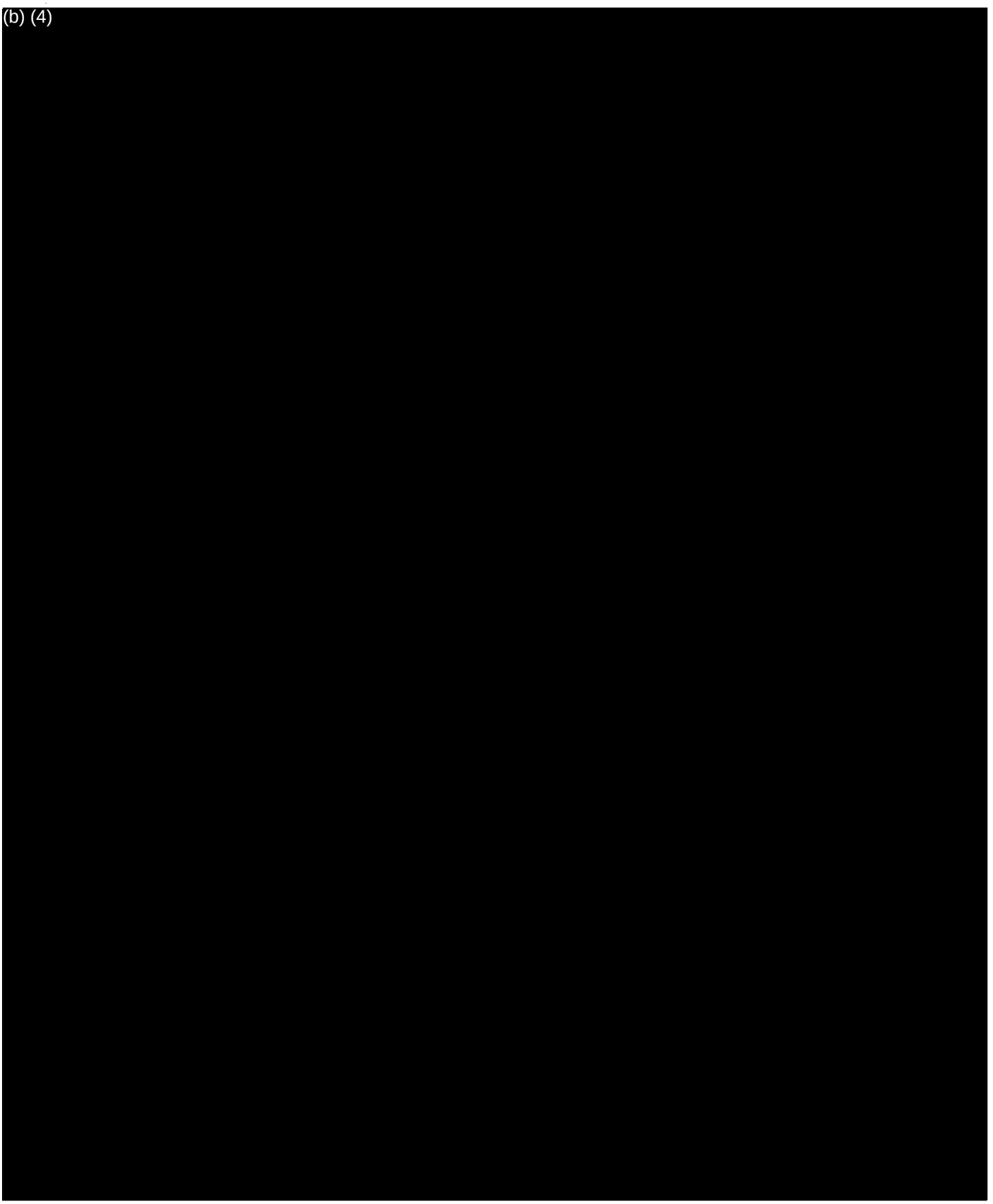
(b) (4)



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(b) (4)

[redacted]

Reviewer's Comments:
The outcomes in the pinless system trial compare favorably to the controls. The results are improved over the first clinical trial. In particular, the surgical times and blood loss were significantly improved.

EVALUATING DEVICE EFFECTIVENESS

STUDY ENDPOINTS

Primary Effectiveness/Safety:
The primary efficacy endpoint for the Second IDE Trial was the Harris Hip Score. The six month outcome revealed similar scores between the ROBODOC and control groups.

Reviewer's Comments:
This outcome is not unexpected when considering the first trial data.

Secondary Effectiveness/Safety
The secondary efficacy endpoints included the SF-12 Health Survey and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) self-assessment scores.
The SF-12® Health Survey measures both the "physical" and "mental" components of a subject's health. The six month outcome of the physical component revealed superiority of the ROBODOC in comparison to the control groups.
The six month outcome of the mental component revealed equivalence of the ROBODOC in comparison to the control groups
The six month outcome of the WOMAC scale revealed superiority of the ROBODOC in comparison to controls.

Reviewer's comments:
The statistical strength of the superiority findings are deferred to statistics.

Success/Failure Criteria
Study success was defined with regards to operative time, blood loss and ipsilateral knee pain.

Reviewer's comments:
The second trial demonstrates operative time, blood loss, and ipsilateral knee pain comparable to manual broaching. The difference in the femoral component selection, using ROBODOC vs. manual selection, the essential benefit of the Orthodoc system, is uncertain.

DJA x00136

Evaluating Device Safety

Evaluation of the mechanical safeguards of the system is deferred to engineering.

SUMMARY OF STATISITCAL PLAN

Please see the formal statistical review.

REVIEW CONCLUSIONS/DISCUSSION

With regard to operative time, blood loss and ipsilateral knee pain, the second clinical trial indicates that the ROBODOC system appears nearly comparable to manual preparation of the proximal femur. As long as the mechanical and software safeguards are in place, the system appears safe. The system appears effective in canal preparation but whether this "dimensional improvement" has a long-term benefit is uncertain, given the bony remodeling that routinely occurs after manual broaching. Still, the dimensional precision is an attractive surgical benefit.

A surgeon may find greater benefit in the system with anticipated evolutions. Evolutions of benefit would include innovations enabling the use of the system in complex pathologies, revision surgeries, acetabular and other joint applications, among other utilizations.

Increased operative time is a disadvantage to the patient, operating room personnel, and health care facility. The improvement in this parameter from the first trial is impressive. Without the improvement, it is doubtful many surgeons would opt for the system for primary reconstructions. If the system works equally well or perhaps more efficiently with more complex pathologies, again there may be practical utility and greater surgical appeal.

The decrease in blood loss in the second trial is also impressive. The blood loss in the first trial, from this reviewer's perspective, was excessive for the perceived benefit, but the blood loss in the second trial appears acceptable.

Ipsilateral knee pain may be multifactorial in nature, a function of stem size, stem contour, intramedullary fit, etc. There may be a benefit, however, to the combined templating and CAM broaching approach, as the six month results appear encouraging. The long-term significance of the 6 month findings (over controls) in this small population is uncertain.

From the data provided for review, there does not appear to be any proven long term benefit to the system. The short term outcomes appear safe, but provide only a limited theoretical advantage over hand broaching.

RECOMMENDATION

Given the disadvantages of extended surgical times and increased blood loss, and without long-term result data confirming that the proposed improved surgical precision results in improved outcome, the clinical value of the device in its present form is uncertain. The data does not suggest the device is unsafe.

DJA x001.37

Janda, Michel D

From: Lyons, John C *
Sent: Monday, February 11, 2008 1:23 PM
To: Janda, Michel D
Cc: Foy, Jonette
Subject: ROBODOC

Attachments: DigiMatch ROBODOC Surgical System.DOC

Dear Mike,

(b) (5)

[redacted]

DigiMatch
BODOC Surgical Sy
JCL

DJA x001:39

MEMO OF SOFTWARE REVIEW

510(K): K072629/S001

FROM: Sajjad H Syed, Electrical Engineer (CDRH General Hospital Devices Branch), 240-276-1374, sajjad.syed@fda.hhs.gov

TO: Michel Janda (DGRND - GSDB)

DATE: Friday February 1st, 2008

SUBJECT: Software Review of DigiMatch Robodoc Surgical System Response

Software description of the Device:

The DigiMatch Robodoc Surgical System consists of the Orthodoc Preoperative Planning Workstation (Orthodoc) and Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (Robodoc).

The Orthodoc is a PC workstation with proprietary ISS software that enables the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur. The Orthodoc software contains a computerized directory of implant types and sizes, from which the surgeon selects an implant model. Orthodoc also provides software tools, which allow the surgeon to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. The operating room components of the System include the surgical electromechanical system; electronics control cabinet, and a display (computer) monitor. The electromechanical system, which contains the electromechanical arm, and the electronics control cabinet, with a mounted display monitor, are stand-alone units. Together, these components are referred to as the Robodoc. The media containing the Orthodoc preoperative plan provides input to the Robodoc Control Computer.

Proprietary ISS software allows the technician/surgeon to control all aspects of the Robodoc activities. The primary function of the Robodoc is to precisely implement the preoperative plan that was developed by the surgeon.

Software Consultation (including Description, Comments, Deficiencies):

I think the sponsor has done a sufficient job of answering all our questions. They have updated their level of concern, revised their Device Hazard Analysis, and provided proof that they did conduct a Human Factors during the development stages of the device.

To meet FDA requirements, the sponsor should provide documentation listed in "Guidance for the Content of Premarket Submissions for Software Contained in Medical

DJA x00140

Devices" Guidance document. I have listed the sections below that are required information for a MAJOR level of concern.

1. **Level of Concern**
   The firm revised their level of concern and the supporting rationale to **Major**, as requested by the Agency. --- *Acceptable.*

2. **Software Description**
   The firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment. --- *Acceptable.*

3. **Device (including software) Hazard Analysis**
   The firm provided an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. --- *Acceptable.*

4. **Design Specification**
   The firm provided an acceptable design specification document, which describes what the program does and how it does it. --- *Acceptable.*

5. **Software Requirements Specifications (SRS)**
   The firm provided a copy of their software requirements specification document, which documented their functional, performance, interface, design and development requirements. --- *Acceptable.*

6. **Traceability**
   The firm provided their traceability matrix, which provided the links between the hazards, requirements, validation and testing. --- *Acceptable.*

7. **Validation (including verification and testing)**
   The firm did provide an acceptable description of their systematic process of life cycle activities, including analysis, evaluation, assurance and testing of the software, and supporting documentation. --- *Acceptable.*

8. **Architecture Design**
   The firm provided an acceptable description the software system partitioned into its functional subsystems. --- *Acceptable.*

9. **Development**
   The firm submitted a summary of their software development life cycle plan. The firm described the processes that have been put into place to manage the various software development life cycle activities, including a summary of the configuration management and maintenance activities. --- *Acceptable.*

DJA x00141

10. Revision Level History
The firm provided the revision history log, documenting all major changes to the software during its development cycle. --- *Acceptable.*

11. Unresolved Anomalies (bugs)
The firm stated that no unresolved anomalies or bugs were found. --- *Acceptable.*

12. Release Version Number
The firm provided an acceptable description of the version numbers and dates. The release versions for all the softwares / firmwares are identified. --- *Acceptable.*

Analysis of the sponsor's response to each of the deficiencies is described below.

Software Deficiencies that the Sponsor responded to:

1. You have identified the level of concern for the DigiMatch Robodoc Surgical System software to be Moderate. However, we believe that the malfunction of the Robodoc Surgical System could pose a serious risk to the user. For example; software incorrect calculation of the position within the patient's femur could lead to a serious injury. Hence, the Agency believes that the system software has a "Major" Level of Concern associated with it. Please provide us with the DigiMatch Robodoc Surgical System software documentation that is based on "Major" Level of Concern as specified in FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Please also update your current software documentation to reflect Major level of concern.

   Sponsor's Response (January 30th, 2008): The sponsor submitted all the documentation pertaining to a Major level of concern. The sponsor revised their level of concern to a major as well. The updated documentation included integrated, application and unit level testing and results. ***--- Acceptable.***

2. In Device and Software Description section, you have listed number of components, subsystems such as Orthodoc, Robodoc accessories that the DigiMatch Robodoc Surgical System comprises of. We believe that a user of this system can make an operational mistake since the system has number of features, components that may overwhelm the user. Please confirm if Integrated Surgical Systems, Inc. has performed any Human Factors study to verify human performance and the risks associated with user error. If so, please provide us with the results of the study. For more information regarding Human Factors, please visit http://www.fda.gov/cdrh/humanfactors/.

   Sponsor's Response (January 30th, 2008): According to the sponsor, they conducted two human factors tests at (b) (4) *to validate the DigiMatch™ ROBODOC® System design requirements of using a point-to-surface approach for pinless registration. The report of human factors test (TR98-07-011) was summarized*

DJA x00142

in Section 20.5 of the subject 510(k) submission (K072629). A copy of the test protocol PV98-07-002 and test report, TR98-07-011, is contained in Volume II of the supplemental submission and a brief summary is provided below. A copy of the test Protocol PV99-007-01 and test report, TR99-007-01, is contained in Volume II of this supplemental submission. Sponsor states that all 31 cases were completed successfully in accordance with the test protocol. In most cases the implant placement was as planned and in a few cases acceptable according to the defined criteria. There were no cases where the implant placement was unacceptable. In addition, other 10 cases were completed successfully in accordance with the test protocol. There were no aborts or system failures due to the new hardware from the direct lateral approach.

Reviewer's Comments: The sponsor has provided Human Factors protocols, procedures and results to support that their development process included user feedback and usability aspects. According to the sponsor, the users were able to successfully operate the device with minimal error. ***--- Acceptable.***

3. In Device and Software Description section on page 4, you have stated that *"the technician and/or surgeon are able to interface with the Robodoc and respond to any prompt via a hand-held control device called a pendant."* We believe this device is an integral part of your system since it facilitates control of every phase of the robotic procedure. Please provide us with a detailed description of the Pendant. For example; description could include wireless technology used, any customized firmware developed, any testing performed to ensure the safe operations of this subsystem. Please also verify if this Pendant conforms to any standards such as IEC 60601-1-2.

   Sponsor's Response (January 30th, 2008): The sponsor included a hazard analysis of the pendant and residual risks associated with it. The sponsor included all the tests and results of the IEC/EN 60601-1-2 (EMC) testing. This testing was performed at a third party independent lab which concluded that the subject device complied with the IEC 60601-1-2 standard. ***--- Acceptable.***

4. In Device and Software Description section on page 4, you have stated that *"redundant safety features and controls are built into the Robodoc's software and hardware functions."* We are unclear if you listed all these features and controls in your software documentation. Please provide us with a list of all the safety features, controls and their testing results.

   Sponsor's Response (January 30th, 2008): The sponsor submitted both general safety features and software safety requirements. The sponsor described the safety checks such as feedback failure, amplifier failure and processor failure that prevent uncontrolled robot motion. In addition, the sponsor listed the tests that verify the safety features and provided the results of the tests. ***--- Acceptable.***

DJA x00143

5. In Device Hazard Analysis section you have provided a table that associates a risk severity number with the components. The Agency believes that a complete and detailed hazard analysis should consists of a description of the hazard presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. Hence, please revise your Device Hazard Analysis and provide us with an updated Device Hazard Analysis to reflect the points mentioned above.

   Sponsor's Response (January 30th, 2008): *The sponsor revised the Device Hazard Analysis as requested. A column was added that identified the method of control of the hazards and the testing done to verify the correct implementation of that control and any residual hazards. A copy of the updated Risk Managment Report was also included.* --- ***Acceptable.***

6. In Revision Level History section you have provided a summary of your changes. We believe a revision history should also include the final finished versions released for the production units of the system, any configuration management software (i.e. Perforce, MS Visual Sourcesafe) used to manage, control changes in the software classes and any bug tracking software used in your software development process. Hence, please provide us with the information stated above.

   Sponsor's Response (January 30th, 2008): (b) (4)

   [redacted]

   response titled "Revision History" in the submission.

   Reviewer's Comments: *The sponsor has identified the final finished version of the software on the device. Plus they have provided the configuration management software, bug tracking method, and their version release description.* --- ***Acceptable.***

DJA x00144

Janda, Michel D

From: Syed, Sajjad H
Sent: Friday, February 08, 2008 3:58 PM
To: Janda, Michel D
Subject: RE: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.
Attachments: K072629_RobodocSurgicalSystem_Response1Analysis.doc

Hey Michel,

I have attached my review memo. I think the sponsor has sufficiently answered all the software related questions. If you have any comments please let me know.

Regards,

Sajjad

From: Janda, Michel D
Sent: Friday, February 01, 2008 10:44 AM
To: Syed, Sajjad H
Subject: RE: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.

Thanks. As soon as I get the document I will log in the consult so that you get credit for your work.

Michel

From: Syed, Sajjad H
Sent: Friday, February 01, 2008 10:43 AM
To: Janda, Michel D
Subject: RE: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.

Great, I will try to complete this consult by today. I will basically right down their responses to my deficiencies and review if they are acceptable or not.

Regards,

Sajjad

From: Janda, Michel D
Sent: Friday, February 01, 2008 10:41 AM
To: Syed, Sajjad H
Subject: RE: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.

Sajjad,

Yes, that is correct. I asked to send their response electronically so that we could get a head start. The hardcopy should be in house today.

DJA x00145

Michel

From: Syed, Sajjad H
Sent: Friday, February 01, 2008 10:39 AM
To: Janda, Michel D
Subject: RE: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.

Hey Michel,

The documents you sent me as attachments, I am assuming they are the sponsor's response to our deficiencies, right?

Regards,

Sajjad

From: Janda, Michel D
Sent: Wednesday, January 30, 2008 8:42 AM
To: Syed, Sajjad H
Subject: FW: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.

Hi Sajjad,

(b) (5)

[redacted]

Michel

From: Russ Hibbert [mailto:rdhibbert@robodoc.com]
Sent: Tuesday, January 29, 2008 8:17 PM
To: Janda, Michel D
Subject: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.

Dear Mr. Janda:

Attached are the electronic copies [19 total attachments] that contain the narrative response to the FDA reviewer comments for the DigiMatch ROBODOC Surgical System, K072629. As we discussed this morning a complete hardcopy of the submission will be delivered to the FDA Document Mail Center on or before January 31, 2008. The hardcopy submission will comprise three volumes and will contain the attachments, protocols, test reports and test studies that are references in the narrative responses.

We trust that the information contained in this response will be sufficient to support a finding of substantial equivalence. If you have any questions regarding this submission, please contact me at the below number. Otherwise, please forward a copy of the substantial equivalence letter to me by facsimile. Thank you in advance for your cooperation.

Sincerely,

DJA x00146

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
Cell: (b) (6)
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
Clinical Fax: 916-575-7918
E-mail: rdhibbert@robodoc.com

No virus found in this incoming message.
Checked by AVG Free Edition.
Version: 7.5.503 / Virus Database: 269.16.14/1172 - Release Date: 12/5/2007 8:41 AM

No virus found in this outgoing message.
Checked by AVG Free Edition.
Version: 7.5.516 / Virus Database: 269.19.15/1248 - Release Date: 1/28/2008 9:32 PM

DJA x00147

Janda, Michel D

From: Russ Hibbert [rdhibbert@robodoc.com]

Sent: Tuesday, January 29, 2008 8:17 PM

To: Janda, Michel D

Subject: 510(k) Review Reponses: DigiMatch ROBODOC Surgical System, K072629.

Attachments: CoverLtrHead_K072629 Response_01.29.08.doc; Executive Summary_K072629 Response_01.29.08.doc; Item1_Safety Features_K072629 Response_01.29.08.doc; Item2_SystCrashRecovery_K072629 Response_01.29.08.doc; Item3_CavityPrepAccuracy_K072629 Response_01.29.08.doc; Item4_Data Pooling_K072629 Response_01.29.08.doc; Item5_Implant List_K072629 Response_01.29.08.doc; Item6_IFU Statements_K072629 Response_01.29.08.doc; Item7_Distal Fixation_K072629 Response_01.29.08.doc; Item8_Bearing Sleeve_K072629 Response_01.29.08.doc; Item9_AdaptiveCutSpeed_K072629 Response_01.29.08.doc; Item10_MajorLevelSoftware_K072629_Response_01.29.08.doc; Item11_Human Factors_K072629 Response_01.29.08.doc; Item12_EMC Test Reports_K072629 Response_01.29.08.doc; Item13_Device Version_K072629 Response_01.29.08.doc; Item14_Device Hazard Analysis_K072629 Response_01.29.08.doc; Item15_Revison History_K072629 Response_01.29.08.doc; Item16_Device Version_K072629 Response_01.29.08.doc; Volume II-III Index_K072629 Response_01.29.08.doc

Dear Mr. Janda:

Attached are the electronic copies [19 total attachments] that contain the narrative response to the FDA reviewer comments for the DigiMatch ROBODOC Surgical System, K072629. As we discussed this morning a complete hardcopy of the submission will be delivered to the FDA Document Mail Center on or before January 31, 2008. The hardcopy submission will comprise three volumes and will contain the attachments, protocols, test reports and test studies that are references in the narrative responses.

We trust that the information contained in this response will be sufficient to support a finding of substantial equivalence. If you have any questions regarding this submission, please contact me at the below number. Otherwise, please forward a copy of the substantial equivalence letter to me by facsimile. Thank you in advance for your cooperation.

Sincerely,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
(b) (6)
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
Clinical Fax: 916-575-7918
E-mail: rdhibbert@robodoc.com

No virus found in this incoming message.
Checked by AVG Free Edition.
Version: 7.5.503 / Virus Database: 269.16.14/1172 - Release Date: 12/5/2007 8:41 AM

No virus found in this outgoing message.
Checked by AVG Free Edition.

DJA x00148

Version: 7.5.516 / Virus Database: 269.19.15/1248 - Release Date: 1/28/2008 9:32 PM

DJA x00149

Janda, Michel D

From: Russ Hibbert [rdhibbert@robodoc.com]
Sent: Monday, January 28, 2008 10:07 PM
To: Janda, Michel D
Subject: DigiMatch ROBODOC, K072629

Dear Mr. Janda,

I would like to inform you that by the close of our work day tomorrow I will be e-mailing you an electronic copy of our responses to FDA's review comments pertaining to the DigiMatch ROBODOC, K072629. This initial submission of documents will be in WORD format. The formal hardcopy submission will be delivered to the FDA mail center on or before January 31.

ISS greatly appreciates your willingness to fast track our responses and begin the review process as soon as possible. We also appreciate your offer to conduct a real-time interactive review of the submitted responses. We trust that the information provided will fully address FDA's comments and we look forward to receiving a SE determination letter for the DigiMatch ROBODOC Surgical System.

Kind regards,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
(b) (6)
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
Clinical Fax: 916-575-7918
E-mail: rdhibbert@robodoc.com

From: Janda, Michel D [mailto:michel.janda@fda.hhs.gov]
Sent: Thursday, January 24, 2008 12:16 PM
To: Russ Hibbert
Subject: RE: Thank you

Mr. Hibbert,

An electronic copy would be appreciated. I look forward to your response.

Michel

From: Russ Hibbert [mailto:rdhibbert@robodoc.com]
Sent: Thursday, January 24, 2008 3:09 PM
To: Janda, Michel D
Subject: RE: Thank you

Thank you for that request and your desire to fast track the review process. I can provide you with an electronic copy of our responses prior to submitting the formal hardcopy responses. Will that meet your needs? If so, I expect to have the electronic copies ready next Monday or Tuesday. I will give you a definitive date as soon as I have it.

DJA x00150

Thank you once again for all of your help.

Kind regards...RDH

From: Janda, Michel D [mailto:michel.janda@fda.hhs.gov]
Sent: Thursday, January 24, 2008 11:35 AM
To: Russ Hibbert
Subject: RE: Thank you

Mr. Hibbert,

Your welcome. As we previously discussed, once we receive your response we will try to make a final determination in a relatively short time frame. Therefore, I am requesting that you send me an update prior to sending in your formal response. This will allow me to fast track the receipt of your response and begin the review process as soon as possible. Thank you in advance.

Sincerely,

Michel

From: Russ Hibbert [mailto:rdhibbert@robodoc.com]
Sent: Thursday, January 24, 2008 2:26 PM
To: Janda, Michel D
Subject: Thank you

Dear Mr. Janda,

I want to thank you for the time you spent addressing my questions and providing additional helpful information. On behalf of ISS I thank you for your assurance regarding a real time interactive review and a timely wrap-up of this review. We look forward to completing the 510(k) review process and receiving clearance to market the ROBODOC System.

Sincerely,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
(b) (6)
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
Clinical Fax: 916-575-7918
E-mail: rdhibbert@robodoc.com

No virus found in this outgoing message.
Checked by AVG Free Edition.
Version: 7.5.516 / Virus Database: 269.19.10/1240 - Release Date: 1/23/2008 5:47 PM

DJA x00151

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Version: 7.5.516 / Virus Database: 269.19.13/1246 - Release Date: 1/27/2008 6:39 PM

DJA x01069

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

COVER SHEET MEMORANDUM

From: Reviewer Name Michael Janda

Subject: 510(k) Number K072629

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☒ Hold (Additional Information or Telephone Hold)

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			X
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)?		X	
Does this device include an Animal Tissue Source?			X
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		X

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) GSDB (Branch Code) 12/5/07 (Date)

Final Review: _____ (Division Director) (Date)

Rev. 5/30/07

DJA x01070

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			X
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			X
3. Does this device type require a PMA by regulation? (Please see management.)			X
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			X
5. a. Did the firm request expedited review? (See management.)			X
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here: See MeMO	X	
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		X
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			X

DJA x01071

Janda, Michel D

From: Janda, Michel D
ent: Wednesday, December 05, 2007 3:15 PM
To: 'rdhibbert@robodoc.com'
Cc: Ogden, Neil; Janda, Michel D
Subject: DigiMatch Robodoc Surgical System, K072629.

Russ Hibbert
Director Clinical & Regulatory Affairs

Integrated Surgical Systems, Inc.
1433 N. Market Boulevard, #1
Sacramento, CA 95834

Re: DigiMatch Robodoc Surgical System, K072629.

Dear Mr. Hibbert,

After reviewing the 510(k) submission for the DigiMatch Robodoc Surgical System it appears that addition information is required. The following information is necessary to continue the review of your 510(k).

1. The submission includes a general description of various safety features. The description frequently references predefined minimum and maximum threshold values. These values are not defined in the general description. As the values dictate the efficacy of the safety features additional information is necessary. Please provide additional information regarding these safety features including the threshold values and a description of testing used to verify the appropriateness of these threshold values. In addition, please provide specifics on any additional threshold values such as the temperature limits, velocity limits, force limits, etc. that are used to dictate the behavior of the system.

2. The submission does not appear to address the risk of system recovery resulting in inappropriate robotic arm movement. That is following a system crash and subsequent recovery the robotic arm could initiate movement to a "default" position. Please describe how the system will recover from a system crash and what mitigation exists to prevent unintended movement following a system crash.

3. The device labeling reports an implant placement accuracy of ±2.0mm along the axis of the bone and ± 1.0mm in the plane perpendicular to the bone axis. The implant cavity preparation accuracy is stated as ± 0.4mm in the cross-sectional dimensions. It is unclear what validation data exists to support these values. Please provide a reference to the validation testing which supports this performance statement.

4. The clinical data provided to support the safety and efficacy of the pinless registration technology represents pooled data from both United States and Japanese study sites. The submission states that the same study protocol was followed for all site locations, however, a discussion is not provided regarding the equivalency of the patient populations. Please provide a discussion indicating why it is appropriate to pool this data.

5. The submission describes a robotic device which is indicated for use with multiple implant systems. Please note that it is the sponsor's responsibility to verify that all supported implant systems are legally marketed within the United States. Please provide a list of the implant systems currently included within the implant database. In addition, please describe the process for integrating these implants into the database. This description should include a discussion of the relevant data needed and the activities performed to verify implant compatibility.

DJA x01072

6. The submission includes several user manuals within Section 13. This labeling does not appear to include the intended use / indications for use as presented in the 510(k) Indications for Use statement. Please revise the labeling to include the intended use / indications for use.

7. The Robodoc user manual contains instructions regarding the importance of distal fixation (Chapter 6-7). This section indicates that distal fixation is the responsibility of the user. However, the section does not provide adequate discussion regarding the adverse affect of motion. Please revise this section to include a discussion of the limitations of the bone motion detection function (threshold value) and the corresponding decrease in system accuracy that could be expected if motion occurs.

8. The Robodoc user manual contains a troubleshooting section (Chapter 10). Within this section instructions are provided for replacing the bearing sleeve after part failure. The section also indicates that the part should be routinely maintained to prevent failure, however, adequate servicing instructions are not provided. Please provide a reference to part maintenance instruction or include additional detailed maintenance instructions for the bearing sleeve part and any other part which requires user maintenance.

9. The Robodoc user manual refers to an "Adaptive Cut Speed" feature. This feature is described as be able to adjust bone cutting speed based upon bone hardness. It is unclear how this feature functions. Please provide additional information regarding this feature. In addition, please provide a discussion regarding the risk of thermal injury during robotic reaming. This discussion should include a definition of a worst case thermal scenario and describe all mitigating activities that are employed to address this risk.

10. The submission has identified the level of concern for the DigiMatch Robodoc Surgical System software to be Moderate. However, we believe that the malfunction of the Robodoc Surgical System could pose a serious risk to the user. For example; software incorrect calculation of the position within the patient's femur could lead to a serious injury. Hence, the Agency believes that the system software has a "Major" Level of Concern associated with it. Please provide us with the DigiMatch Robodoc Surgical System software documentation that is based on "Major" Level of Concern as specified in FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Please also update your current software documentation to reflect Major level of concern.

11. The submission includes a description of the user training that is suggested for all new users. It is known that complicated systems such as the Robodoc system have an associated learning curve. While user training is an appropriate mitigating action to minimize the user's learning curve, it is unclear if additional human factors studies were undertaken in an attempt to simplify the use of the Robodoc system. Please clarify if any human factors studies were preformed to verify human performance and the risks associated with user error. If so, please provide us with the results of the study. For more information regarding Human Factors, please refer to http://www.fda.gov/cdrh/humanfactors/.

12. The submission includes a description of the testing conducted to establish electromagnetic compatibility and electrical safety (Section 17). While this section indicates that the system complies with the referenced standards, it is unclear if any testing deviations were needed to establish compliance. Please provide a copy of the electromagnetic compatibility and electrical safety test reports.

13. As the Robodoc system has undergone several technical enhancements throughout its development, it is unclear which device version is intended to be cleared within this 510(k). Please clarify if the described device is identical to that used in the second IDE clinical study. If any device modifications are intended to be included within this 510(k), please describe them.

14. In Device Hazard Analysis section you have provided a table that associates a risk severity number with the

DJA x01073

components. The Agency believes that a complete and detailed hazard analysis should consists of a description of the hazard presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. Hence, please revise your Device Hazard Analysis and provide us with an updated Device Hazard Analysis to reflect the points mentioned above. In addition, please update the device hazard analysis to include an analysis of the pendant.

15. In Revision Level History section you have provided a summary of your changes. We believe a revision history should also include the final finished versions released for the production units of the system, any configuration management software (i.e. Perforce, MS Visual Source safe) used to manage, control changes in the software classes and any bug tracking software used in your software development process. Hence, please provide us with the information stated above.

As per this email, K072629 has been placed on hold until further correspondence is received.

Please feel free to contact me if you would like to discuss any of these deficiencies. Hard copies of your response are required and can be directed to the FDA document center. Thank you.

Sincerely,

Michel Janda
Biomedical Engineer
Phone #: (240) 276-3600
Fax #: (240) 276-3733
)DE/DGRND/GSDB

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

DJA x01074

Janda, Michel D

From: Syed, Sajjad H
Sent: Thursday, November 29, 2007 11:07 AM
To: Janda, Michel D
Subject: RE: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

Hi Michel,

I think the information pertaining to the handheld pendant is adequate. However in their risk analysis they should state the risks associated with the pendant and how the main system mitigates these risks. So basically for question 3, instead of asking for a description, we can ask for any risk analysis performed on this device (pendant). As for question 4, they have listed general safety features but they have not provided specific details such as "halt motion if the collision force exceeds a predefined threshold". What is the predefined threshold?. Anyways the safety cases are there. They need to provide more information about them including testing on these features.

The training schedule looks fine. I just want to know when they were designing the system, did they consult any end user to assure that system would be easy to interact with. They can train the user (surgeons, physicians) but point is that if suppose yellow button is right beside a light yellow button, what are the chances that even a trained individual would accidently press the wrong button. Therefore they should perform some human factors to ensure that the system is logically placed.

Regards,

Sajjad

From: Janda, Michel D
Sent: Wednesday, November 28, 2007 1:41 PM
To: Syed, Sajjad H
Subject: RE: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

Sounds great.

From: Syed, Sajjad H
Sent: Wednesday, November 28, 2007 1:05 PM
To: Janda, Michel D
Subject: RE: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

Hi Michel,

I will take a look at the info you have sent later today. Can I let you know by tomorrow.

Regards,

Sajjad

From: Janda, Michel D
Sent: Wednesday, November 28, 2007 11:38 AM
To: Syed, Sajjad H
Subject: RE: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

I also found the sponsor's training schedule for new users. The general outline follows:

Overview of User Training
ISS has developed a formal training program for surgeons and operating room technicians and nurses. The training is administered in accordance with ISS Procedure 3000152, Customer Training Specifications for DigiMatch THR. A copy of the procedure is provided in Attachment 3.

DJA x01075

Customer Training Schedule

(b) (4)

From: Janda, Michel D
Sent: Monday, November 26, 2007 4:10 PM
To: Syed, Sajjad H
Subject: RE: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

Sajjad,

I'm drafting an AI letter for this file and I noticed that some of your deficiencies (#3 and #4) may have been addressed in a section of the 510(k) that was not provided to you as part of your review. Please find the relevant sections below. Does this information address your concerns? As noted by the red font, I have some concerns regarding the safety features. In addition, I was wondering if the software documentation addressed the hazard of a system crash and reboot or restoration resulting in the robotic arm moving to a default position (possibly through the patient)? I heard that this was a risk in different robotic system. Thanks again for your help.

Michel

Pendant - The pendant is a hand-held control device that plugs into the robot base. The cable is long enough to avoid impeding operator movement and is easily attached and detached from the base. The pendant has five depressible buttons,

DJA x01076

which enable the surgeon and OR technicians to select procedural alternatives, verify assumed conditions, and redirect the procedural flow, if necessary. The user can-hold the pendant in either hand and press the buttons with the holding hand. The buttons are designated as UP, DOWN, SELECT, PAUSE, and STOP. The STOP button mechanically latches when pressed, and must be manually unlatched. The other buttons do not latch. The pause function is a safety feature that allows the user, at any time, to halt robot motion without removing robot motor power. When the robot is cutting, the pause function turns off the cutter and servo locks the motors in position. This function is activated by pressing the yellow PAUSE button on the pendant. In addition to halting robot motion pressing the PAUSE button causes a pause menu screen to be displayed. The pause menu contains an option to resume the procedure, which re-displays the interrupted screen and, if safe, resumes the motion that was halted. In emergency situations, the user can turn off robot motor power completely by pressing the red STOP button on the pendant. The STOP button latches mechanically when pressed, thereby requiring the user to manually release it before power can be restored.

Safety Features – **What are all the predefined thresholds and can they be modified by the user?????**

1. Before the surgeon begins templating, the ORTHODOC validates the CT data by confirming the lack of bone motion during the scan, appropriate spacing of CT slices, and adequate field of view.
2. The robot has relatively small motors, high gear ratios, and software-imposed velocity limitations that limit its speed and torque. Limited automatic motions are enabled only when necessary both during initialization of robotic arm position sensors, diagnostic tests, drape installation, reorientation for tool changes, and cutting. Most automatic motions cover relatively short distances. Significant repositioning or movements of the robotic arm must be accomplished by manual (force-assisted) hand guiding, in which the robot moves in response to forces applied to the robot end effector (cutter drive assembly) by the user. The velocity of motion is proportional to the applied force (i.e., small applied forces enable slow, fine motions and large forces result in fast, coarse motions). **At every point in time what is the "default position" of the arm after system crash and reboot???????**
3. The robot is equipped with a force sensor that continuously monitors forces applied to the robot's tool tip. During cutting, the software monitors force sensor values and, if necessary, slows down the automated cutting motion to ensure that the maximum force is below a specified threshold. A minimum speed is also set beyond which results in a "force freeze" condition.
4. The BMM is designed to detect unwanted motion of the femur after immobilization in the fixator. After the BMM probe is installed in the femur, the BMM measures spherical displacements from the probe's initial insertion point and halts any motion if femur motion exceeds pre-defined thresholds.
5. A red latching button on the pendant and a manual twist-to-reset switch on the computer control cabinet provide two direct ways to remove power from the robot and deactivate the cutter solenoid. This hardware implementation uses direct in-line relays. Reactivation requires all safety and control systems to be within tolerance and manual depression of the robot motor power switch. A yellow button on the pendant halts robot motion and deactivates the cutter drive solenoid. The display monitor presents recovery options, as well as an option to abort the procedure at any point. **What is the recovery condition?????**
6. As an additional safety feature in the event that the pendant is dropped, the buttons are designed to prevent depression upon impact with a flat surface. To prevent accidental selection of menu options, the SELECT button on the pendant must be held for a specified duration (approximately one second) and then released before the choice is accepted.
7. The robot is equipped with a brake that engages when power is removed from any motor having a significant load affected by gravity (i. e., any axis that supports a weight greater than approximately 5 pounds). This brake is designed to prevent the load from dropping more than 6 millimeters (mm) before the brake halts it.
8. ISS has designed a custom cutter accessory for optimal performance in creating a cavity for each type of ROBODOC compatible prosthesis. Prior to cutting, the display monitor prompts the surgeon to install the cutter associated with the selected prosthesis, identifying it by its ISS part number.
9. The ROBODOC system is designed so that no single point of failure can cause uncontrolled robot motion. For example, the robot contains a redundant means of sensing the tool tip position. The primary and redundant position sensors are not affected in the same way by failure of a single component (e.g. , transmission slippage or broken drive belt). In addition, the system can detect collisions with objects in the environment and halt motion if the collision force exceeds a predefined threshold. When the robot is in the cutting phase, an additional check confirms that commanded robot positions fall within the implant safety envelope. The implant safety envelope is slightly larger than the implant envelope (up to 3.0 mm larger in each longitudinal cross-section), and is defined independently of the robot motion.

From: Syed, Sajjad H
Sent: Monday, November 05, 2007 2:53 PM
To: Janda, Michel D
Subject: RE: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

Hi,

DJA x01077

I have added another deficiency regarding major level of concern

Sajjad

<< File: CON077595_K072629_RobodocSurgicalSystem_Revised.doc >>

From: Janda, Michel D
Sent: Monday, November 05, 2007 2:05 PM
To: Syed, Sajjad H
Subject: RE: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

Thanks!

From: Syed, Sajjad H
Sent: Monday, November 05, 2007 2:04 PM
To: Janda, Michel D
Subject: Software Review (CON077595) of DigiMatch Robodoc Surgical System (K072629)

Hi Michel,

I have finished my review of this system. Sorry for the delay. I have attached my memo below.

Regards,

Sajjad

<< File: CON077595_K072629_RobodocSurgicalSystem.doc >>

DJA x01078

MEMO OF SOFTWARE REVIEW

510(K): K072629

FROM: Sajjad H Syed, Electrical Engineer (CDRH General Hospital Devices Branch), 240-276-1374, sajjad.syed@fda.hhs.gov

TO: Michel Janda (DGRND - GSDB)

DATE: Friday November 2nd, 2007

SUBJECT: Software Review (CON077595) of DigiMatch Robodoc Surgical System

Software description of the Device:

The DigiMatch Robodoc Surgical System consists of the Orthodoc Preoperative Planning Workstation (Orthodoc) and Robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (Robodoc).

The Orthodoc is a PC workstation with proprietary ISS software that enables the surgeon to select an appropriate prosthesis and determine its desired position within the patient's femur. The Orthodoc software contains a computerized directory of implant types and sizes, from which the surgeon selects an implant model. Orthodoc also provides software tools, which allow the surgeon to preoperatively determine implant head size, neck offset, version angle, and osteotomy level. The operating room components of the System include the surgical electromechanical system; electronics control cabinet, and a display (computer) monitor. The electromechanical system, which contains the electromechanical arm, and the electronics control cabinet, with a mounted display monitor, are stand-alone units. Together, these components are referred to as the Robodoc. The media containing the Orthodoc preoperative plan provides input to the Robodoc Control Computer.

Proprietary ISS software allows the technician/surgeon to control all aspects of the Robodoc activities. The primary function of the Robodoc is to precisely implement the preoperative plan that was developed by the surgeon.

Software Consultation (including Description, Comments, Deficiencies):

First, the sponsor has done a sufficient job in providing the documentation specified in our software guidance document for the moderate level of concern. Having said that, there are few issues I have stated in my deficiencies that the sponsor should address. One of them is the issue of user interaction with this device. This system has a lot of options, features that in my opinion can even overwhelm a surgeon. The sponsor needs to show that relevant human factors study was conducted to prove that the controls, features are

DJA x01079

easily understandable. Also, we do not believe that this system has a Moderate level of concern. We think this system can cause a serious injury if the software calculates incorrect position within the patient's femur.

To meet FDA requirements, the sponsor should provide documentation listed in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" Guidance document. I have listed the sections below that are required information for a MODERATE level of concern.

1. **Level of Concern**
   The firm provided their level of concern and the supporting rationale as: **MODERATE.** We believe the level of concern should be Major. --- *Additional Information Required.*

2. **Software Description**
   The firm provided an acceptable overview of the device features that are controlled by software, and a description of the intended operational environment. --- *Acceptable.*

3. **Device (including software) Hazard Analysis**
   The firm DID NOT provide an acceptable description of the hazards presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. --- *Additional Information Required.*

4. **Design Specification**
   The firm provided an acceptable design specification document, which describes what the program does and how it does it. --- *Acceptable.*

5. **Software Requirements Specifications (SRS)**
   The firm provided a copy of their software requirements specification document, which documented their functional, performance, interface, design and development requirements. --- *Acceptable.*

6. **Traceability**
   The firm provided their traceability matrix, which provided the links between the hazards, requirements, validation and testing. --- *Acceptable.*

7. **Validation (including verification and testing)**
   The firm did provide an acceptable description of their systematic process of life cycle activities, including analysis, evaluation, assurance and testing of the software, and supporting documentation. --- *Acceptable.*

8. **Architecture Design**
   The firm provided an acceptable description the software system partitioned into its functional subsystems. --- *Acceptable.*

DJA x01080

9. Development

The firm submitted a summary of their software development life cycle plan. However, the firm did not completely describe the processes that have been put into place to manage the various software development life cycle activities, including a summary of the configuration management and maintenance activities. --- *Additional Information Required.*

10. Revision Level History

The firm provided the revision history log, documenting all major changes to the software during its development cycle. --- *Acceptable.*

11. Unresolved Anomalies (bugs)

The firm stated that no unresolved anomalies or bugs were found. --- *Acceptable.*

12. Release Version Number

The firm did not provide an acceptable description of the version numbers and dates. The release versions for all the softwares / firmwares are not identified. --- *Additional Information Required.*

Software deficiencies are listed on the next page. Reviewer is encouraged to include them in his/her additional information letter. Also, it is recommended that Reviewer includes the software sections listed above in his/her memo.

Software Deficiencies that require additional Information from the Sponsor:

1. You have identified the level of concern for the DigiMatch Robodoc Surgical System software to be Moderate. However, we believe that the malfunction of the Robodoc Surgical System could pose a serious risk to the user. For example; software incorrect calculation of the position within the patient's femur could lead to a serious injury. Hence, the Agency believes that the system software has a "Major" Level of Concern associated with it. Please provide us with the DigiMatch Robodoc Surgical System software documentation that is based on "Major" Level of Concern as specified in FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Please also update your current software documentation to reflect Major level of concern.

2. In Device and Software Description section, you have listed number of components, subsystems such as Orthodoc, Robodoc accessories that the DigiMatch Robodoc Surgical System comprises of. We believe that a user of this system can make an operational mistake since the system has number of features, components that may overwhelm the user. Please confirm if Integrated Surgical Systems, Inc. has performed any Human Factors study to verify human performance and the risks associated with user error. If so, please provide us with the results of the study. For more information regarding Human Factors, please visit http://www.fda.gov/cdrh/humanfactors/.

DJA x01081

3. In Device and Software Description section on page 4, you have stated that *"the technician and/or surgeon are able to interface with the Robodoc and respond to any prompt via a hand-held control device called a pendant."* We believe this device is an integral part of your system since it facilitates control of every phase of the robotic procedure. Please provide us with a detailed description of the Pendant. For example; description could include wireless technology used, any customized firmware developed, any testing performed to ensure the safe operations of this subsystem. Please also verify if this Pendant conforms to any standards such as IEC 60601-1-2.

4. In Device and Software Description section on page 4, you have stated that *"redundant safety features and controls are built into the Robodoc's software and hardware functions."* We are unclear if you listed all these features and controls in your software documentation. Please provide us with a list of all the safety features, controls and their testing results.

5. In Device Hazard Analysis section you have provided a table that associates a risk severity number with the components. The Agency believes that a complete and detailed hazard analysis should consists of a description of the hazard presented by this device, the causes and severity of the hazards, the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. Hence, please revise your Device Hazard Analysis and provide us with an updated Device Hazard Analysis to reflect the points mentioned above.

6. In Revision Level History section you have provided a summary of your changes. We believe a revision history should also include the final finished versions released for the production units of the system, any configuration management software (i.e. Perforce, MS Visual Sourcesafe) used to manage, control changes in the software classes and any bug tracking software used in your software development process. Hence, please provide us with the information stated above.

DJA x01082

Robodoc pre-IDE meeting memo

Date of pre-meeting:	January 18, 2007
Time of pre-meeting:	10:00 AM to 11:00 AM; Conference Room 330V 9200 Corporate Blvd.
Subject:	Digimatch Robodoc Surgical Assistant System (G000071)
Meeting type:	Face-to-face meeting

FDA attendees:

Neil Ogden, Branch Chief, General Surgery Devices Branch (DGRND/GSDB)
Michel Janda, Biomedical Engineer, (DGRND/GSDB)
Dr. Neven Popovic, Medical Officer (DGRND/OJDB)
John Dawson, Statistician (OSB/DBS) (via telephone)

Integrated Surgical System, Inc.'s attendees:

Howard Holstein – Hogan & Hartson
Ramesh Trivedi – ISS
Leland Witherspoon – ISS
Cheryl Hayden – Consultant

Submission Background: The primary purpose of this pre-IDE submission is to update the FDA regarding the status of an ongoing confirmatory clinical study and to solicit feedback regarding plans for completion of the study.

Regulatory History: The first-generation Robodoc system was studied in a U.S. multi-center clinical trial (G920035). The IDE trial demonstrated certain potential risks associated with the pin-based registration technology including longer surgical time, greater blood loss, and ipsilateral postoperative knee pain. Following the IDE trial, several hardware and software features were added to the system.

A confirmatory study (G000071 - topic of this pre-IDE submission) was conditionally approved on April 14, 2000 and an unconditionally approved on May 26, 2000. An Agreement Letter dated September 12, 2000 was also issued in regards to this study. In addition, a response to a 513(g) request was issued on January 24, 2001 requesting the submission of a 510(k).

The confirmatory study began on December 13, 2000. On September 15, 2005, the study was suspended due to financial difficulties. The study was resumed on October 20, 2006 after FDA review of the proposed plan for completion involving enrollment at the following sites: Sutter Medical Center, Freiberg Orthopaedics & Sports Medicine in Cincinnati, Ohio, and the Cleveland Center for Joint Reconstruction.

DJA x01083

Intended Use: The DigiMatch™ ROBODOC is a robotic surgical tool intended as an alternative to manual planning and broaching/reaming technique for femoral canal preparation in primary cementless total hip arthroplasty (THA).

IDE Summary: The purpose of the clinical trial is to evaluate technical enhancements of the device, which are intended to eliminate or significantly mitigate the potential risks of longer surgical time, greater blood loss, and post-operative, temporary, occasional ipsilateral knee pain identified in an earlier trial of the first generation of the ROBODOC system, IDE G920035. The clinical trial was approved for one hundred eighty eight (188) enrolled patients distributed among four (4) institutions. The study groups are assigned in a random 3:1 scheme, [study (n=141): control (n=47)]. The subjects will be followed for six months after the THA surgery.

Safety Endpoints:

a. Length of surgical time
b. Estimated blood loss
c. Blood transfustions
d. Post-operative ipsilateral knee pain
e. Complications and Adverse effects

Primary Effectiveness Endpoints:

a. Precision of femoral canal preparation
b. Harris Hip Score values

Secondary Effectiveness Endpoints:

a. SF-12 Patient Self-Assessed Health Survey
b. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Meeting Request Date: weeks of December 4th, 11th, and 18th.

Objectives: To gain FDA comments regarding the company's proposed study completion plans.

Current Study State: The confirmatory study has enrolled 112 subjects: 93 patients were enrolled at Site 1 in Sacramento, California with 68 subjects randomized to the ROBODOC study group, 22 subjects randomized to the control group, 1 subject was randomized twice with one ROBODOC hip and one control hip, and 2 training patients; 17 patients were enrolled at Site 2 in Arkansas with 12 subjects randomized to the ROBODOC study group and 5 subjects randomized to the control group; and 2 training patients at the Buffalo, New York site. Eleven (11) patients withdrew prior to surgery.

Completion Plan: The company plans to enroll approximately 6 additional subjects at the Sutter Medical Center, 14 subjects at the Freiberg Orthopaedics & Sports Medicine Site, 10 subjects at the Cleveland Center and 50 subjects at a Japan based site.

DJA x01084

The company intends to include subjects with both unilateral and bilateral hip disease in the efficacy analyses. The company intends to perform three separate analyses of the Harris hip score, WOMAC, and SF-12 outcomes for the following subsets of subjects:

- subjects with bilateral hip disease who have undergone THA for one hip under the protocol and whose contralateral hip is still impaired,
- subjects who have had both hips replaced under the protocol,
- and subjects with unilateral hip disease who have undergone THA per the protocol.

Patients defined as having bilateral hip disease in this document include both subjects with bilateral hip disease who have undergone THA for one hip under the protocol and whose contralateral hip is still impaired, and subjects who have had both hips replaced under the protocol.

Meeting Discussion:

The questions posed in the sponsor's background package and amended questions are provided, followed by the FDA response.

Sponsor Question

1. Does FDA concur with the company's plan to pool the data from Japan with the data collected in the US to support FDA clearance of the ROBODOC Surgical Assistant System?

- The pooling of this data may be acceptable. Poolability should be evaluated in the clinical trial data with logistic regression analysis, in which patient success is the dependent variable, and predictor variables are study arm (device/control), and sub-group. It is crucial that the study protocol not have undergone material change since the study outset.
- There is some concern regarding the difference between robotic training in the US as compared to Japan. The proposed Japanese site is known to be highly experienced in robotic procedures of this type. Adequate training must be addressed in the subsequent pre-market application.

2. Does FDA concur that additional surgeries can be performed at Sutter by the co-investigator and a new investigator even though the total number of subjects from the site will exceed its maximum allocated number?

- Yes, there is no maximum site number. Co-investigator is also okay.

DJA x01085

3. Does FDA concur that all 98 randomized subjects on whom surgery was performed can be considered for inclusion toward the company's goal of 168 evaluable subjects?

- The sponsor provided information regarding 3 cases which were inter-operatively converted from robot to manual, 7 cases of incomplete 6 month follow-up, and 6 bilateral hip cases. The agency noted that without further information and analysis the acceptability of including these patients is unknown. The agency stated that inclusion of these patients may weaken the study results. Analysis should be performed for the inclusion and exclusion of these patients.
- It is crucial that the study protocol not have undergone material change since the study outset.

4. Dr. Krackow (Buffalo) and Japanese surgeons wish to use implants offered by Stryker Corp for primary cementless THA. These implants are not a part of the identified group. Will FDA accept data collected if we use these different implants?

- The inclusion of a new implant system may be acceptable. The sponsor must justify why the new implant system will not bias the results. The sponsor should also conduct the implant integration validation activities (bench testing / compatibility testing) as discussed in the agreement letter. This should be submitted as an IDE supplement. The agency believes that limiting implant systems also limits the potential for confounding factors related to system differences.

5. Does FDA concur with the company's proposed plans to complete the study?

- The agency essentially concurs. The agency notes from previous conversations that pooling of bilateral/unilateral hip patients is known to introduce confounding factors and may not be appropriate. The agency would like to emphasize the following points in regards to described study completion:
- Poolability should be justified after the study by looking at performance across the sub-groups to be pooled (unilateral and bilateral cases). This should apply to effectiveness endpoints as well as safety endpoints. Effectiveness endpoints may be restricted to unilateral patients if favorable effectiveness results for the bilateral cases would not be believable (e.g. a Type I error).
- Poolability should be evaluated in the clinical trial data with logistic regression analysis, in which patient success is the dependent variable, and predictor variables are study arm (device/control), and sub-group. If study arm is statistically significant but so is sub-group, that means performance is different in the sub-groups, and pooling is not appropriate. There is no indication that this study was powered for sub-group analysis. The agency has concerns that the sample size is probably not large enough to allow non-significance to be interpreted as proof of a lack of confounding. Lacking sample size power, the agency could accept pooling only if device success rate is consistently numerically higher in the device arm versus control arm, across subgroups.

DJA x01086

- The pre-IDE discussion appears to indicate that the study will statistically evaluated using a non-inferiority hypotheses. The possible performance decrement or "non-inferiority delta" should be specified with accompanying clinical rationale for why this delta is acceptable.
- The agency believes that statistical analysis of safety endpoints is important. As noted in your future discussion suggestions, discussion may be necessary to agree on a method for analyzing the safety data.
- The agency believes that absolute surgical time is an issue that must be examined in the premarket application. The sponsor notes that cup preparation has been known to add significant time to the surgical procedure.
- The agency agrees that the effectiveness of the device in cavity preparation has been established in the first IDE study. The primary concern for the ongoing confirmatory study is in regards to safety analysis.
- The agency agrees that the 510(k) premarket notification process is the most appropriate, however, identifying a predicate device may be problematic. The Da Vinci system has been suggested as a possible candidate but features different fundamental technology. A de novo submission is also a possibility.

Future Actions: Additional discussion is needed regarding the analyses of study safety endpoints. The sponsor also wishes to discuss the possibility of utilizing clinical data from the first IDE study to support the findings of the ongoing confirmatory IDE. In the meantime the sponsor will continue enrolling patients in the confirmatory IDE.

_____
Michel Janda
Reviewer

Attachments: Sponsor's presentation (Attachment A)

Drafted: mdj 01/19/07
Reviewed:
Revised:
Final:

DJA x01087

Integrated Surgical Systems, Inc.

ROBODOC®
Surgical Assistant System

Pre-IDE Meeting
January 18, 2007

Meeting Participants

- Ramesh Trivedi, Ph.D.
  President and Chief Executive Officer, ISS
- Leland Witherspoon, Ph.D.
  Vice President and Chief Technology Officer, ISS
- Cheryl L. Hayden, Ph.D.
  Consultant, Clinical & Regulatory Affairs
- Howard M. Holstein, Hogan & Hartson, L.L.P.

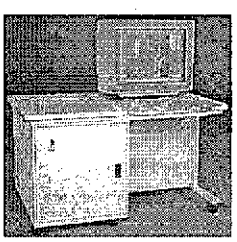
Agenda

I. Background
II. Current Study Status
III. Plan for Study Completion
IV. Discussion and Feedback from FDA

I. Background

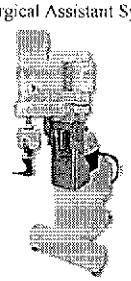
I. Device Description

- 510(k)-cleared ORTHODOC® Preoperative Planning Workstation



I. Device Description

- The ROBODOC® Surgical Assistant System.



DJA x01088

I. Device Description

Intended Use

The DigiMatch™ ROBODOC® Surgical Assistant System is an alternative tool to conventional techniques for femoral canal preparation in primary cementless Total Hip Arthroplasty (THA).

I. Regulatory History

1st trial (IDE # G920035)

- Demonstrated the ROBODOC System is an effective surgical tool for femoral canal preparation in primary cementless THA. It also identified three (3) related risks.

2nd trial (IDE # G000071 - the current study)

- Intended to demonstrate that the identified risks are eliminated/mitigated while preserving the safety and effectiveness of the device.

I. Regulatory History

1st U.S. Clinical Trial - Summary of Results

- 3 Sites, 119 subjects (136 hips)
- ROBODOC (71 hips) : Control (65 hips)
- Preoperative placement of pins required additional surgical procedure
- Statistically significant lower fracture rate in Study Group (Study 0%, Control 5%)
- ROBODOC group had significantly better proximal fit, fill & alignment (As determined by radiographic analysis)
- Harris Hip Scores (24 months): [ROBODOC 88.4(10.3), control 91.5(5.9) No significant difference]

I. Regulatory History

1st U.S. Clinical Trial - Summary of Results

- **Ipsilateral knee pain higher for ROBODOC Group (22% vs. 17%)**
- **Blood loss greater for ROBODOC group (1189ml vs 644ml)**
- **Surgery time longer with ROBODOC group (258min vs 134min)**

I. Regulatory History

- Following the 1st trial, the Company added features to eliminate / mitigate risks identified in the first trial.
- The company's DigiMatch™ technology eliminates the use of pre-operative knee pins, mitigating significantly the risks of post-operative ipsilateral knee pain, longer surgery times and associated greater blood loss.

II. Current Study (2nd trial) Status

II. Current Study Status

This study is a prospective, controlled, multi-center, randomized 3:1 (ROBODOC : Control) clinical trial.

This 2nd trial is intended to demonstrate that the enhancements to the ROBODOC® have eliminated or substantially mitigated the potential risks identified in the 1st IDE trial.

II. Current Study Status

Safety Endpoints

- **Length of surgical time**
- **Estimated blood loss & transfusions**
- **Ipsilateral post operative knee pain**
- **Adverse events & complications**

II. Current Study Status

Primary Efficacy Endpoints

- Precise Femoral Canal Preparation
- Harris Hip Scores at 6 weeks and 6 months

Sample Size

- 188 Randomized Subjects (168 evaluable subjects)
  - 141 ROBODOC
  - 47 Control

II. Current Study Status

2nd trial (IDE # G000071)

- ISS received IDE approval on May 26, 2000
- Company requested classification under section 513(g) July 19, 2000
- Agreement letter September 12, 2000
  (established study requirements)
- Response to 513(g) received January 24, 2001 noting appropriateness of 510(k) pathway

II. Current Study Status

- Started on December 13, 2000

  Investigators:
  - Dr. William Bargar / Dr. Tom Blumenfeld
    - Sutter General Hospital, Sacramento, California
  - Dr. Carl Nelson *(now deceased)*
    - University of Arkansas for Medical Sciences, Little Rock, Arkansas
  - Dr. Kenneth Krackeow
    - Buffalo General Hospital, Buffalo, New York

II. Current Study Status

- Trial suspended due to financial difficulties; FDA notified on September 15, 2005
- Informed FDA of intention to restart trial September 19, 2006
- Concurrence received from FDA October 20, 2006

DJA x01090

II. Current Study Status

- Trial Restarted on November 20, 2006
  - Dr. William Bargar / Dr. Tom Blumenfeld
    - Sutter General Hospital, Sacramento, California
  - Dr. Kenneth Krackeow
    - Buffalo General Hospital, Buffalo, New York
  - Dr. Michael Swank
    - Jewish Hospital, Cincinnati, Ohio
  - Dr. Bernie Stulberg *(not yet started)*
    - Lutheran Hospital, Cleveland, Ohio

II. Summary Table: Enrollment Status

		-------- Randomized----------		
Clinical Site	Training	Control	Robodoc	Total
Sacramento	2	22	69	91
Arkansas	0	5	12	17
Buffalo	2	0	0	0
Cincinnati	2	1	0	1
Total	6	28	81	109

II. Randomized Subjects

Subjects Withdrawn Prior to Surgery

Clinical site	Control	Study	Total
Sacramento	3	4	7
Arkansas	0	4	4
Total	3	8	11

Subjects who had surgery

Sacramento	84
Arkansas	13
Buffalo	0
Cincinnati	1
Total	98

II. Current Evaluable Patients

- 98 Randomized subjects had surgery
  - 3 Robodoc cases converted to manual
  - 6 Robodoc cases had both hips replaced under protocol
  - 7 (5/2) cases with incomplete follow-up
- Sponsor believes all 98 cases are evaluable

II. Analysis of Efficacy Data

	Robodoc	Control
Harris Hip Scores	(b) (4)	
Baseline		
6 weeks		
3 months		
6 months		

II. Analysis of Safety Data

	1st Study		2nd Study		
Group:	-------Robodoc------		----Robodoc-----		----Control------
	N	Results	N	Results	N Results
blood loss (m (Mean, SE)	(b) (4)				
knee pain (Number, %)					
Surgery time (#, % > 180 mi (Mean, SE)					

No unanticipated device-related adverse events

III. Plan for Study Completion

III. Proposed Study Completion Plan

- Enrollment of Remaining Subjects
  - 60 Study
  - 20 Control
- Complete study with six (7) Surgeons at four (5) sites
  - Dr. W. Bargar, Sutter General Hospital, Sacramento, California
  - Dr. T. Blumenfeld, Sutter General Hospital, Sacramento, California
  - Dr. Kenneth Krackow, Buffalo General Hospital, Buffalo, New York
  - Dr. M. Swank, Jewish Hospital, Cincinnati, Ohio
  - Dr. N. Sugano, Osaka University, Osaka Japan
  - Dr. M. Nakamura, Kyowakai Hospital, Kyowakai, Japan
  - Dr. B. Stulberg, Lutheran Hospital, Cleveland, Ohio

III. Poolability of Data from U.S. and Japan

- The practice of medicine in Japan, with respect to hip replacements, is similar to that in the US
- Demographic differences in patient populations will not affect the study results as the disease etiology and its treatment are similar
- The surgical procedures used for THA are the same in Japan and the US, for both the ROBODOC and control groups

III. Poolability of Data from U.S. and Japan

- The exact same protocol is used
- Same surgical approach & tools
- Recognized, competent clinical investigators
- The endpoints measured or assessed and the evaluation of the principal outcome variables (radiographic endpoints, Harris Hip Score, blood loss, surgical time) are the same in Japan and the US.
- The data with respect to this study are poolable.

Discussion and Feedback from FDA

IV. Feedback from FDA

- Does FDA concur with the company's plan to pool the data from Japan with the data collected in the US to support FDA clearance of the ROBODOC Surgical Assistant System?

DJA x01092

IV. Feedback from FDA

- Does FDA concur that additional surgeries can be performed at Sutter by the co-investigator and a new investigator even though the total number of subjects from the site will exceed its maximum allocated number?

IV. Feedback from FDA

- Does FDA concur that all 98 randomized subjects on whom surgery was performed can be considered for inclusion toward the company's goal of 168 evaluable subjects?

IV. Feedback from FDA

- Dr. Krackow (Buffalo) and Japanese surgeons wish to use implants offered by Stryker Corp for primary cementless THA
- These implants are not a part of the identified group
- Will FDA accept data collected if we use these different implants?

IV. Feedback from FDA

- Does FDA concur with the company's proposed plans to complete the study?

Future Discussion Topics

IV. Future Discussion Topics

- Proposal for Analyzing Patients with Bilateral Hip Disease
- Radiographic Review Criteria
- Sample Size

DJA x01093

IV. Proposal for Analyzing Patients with Bilateral Hip Disease

- Types of bilateral hip disease
  - 1st hip replaced prior to entry into study
  - More severely diseased hip replaced under protocol; contralateral hip still diseased
  - Both hips replaced under protocol
    - Follow-up after 1st THA, censored at time of 2nd THA
- Subject-specific items will be analyzed using the subject as the analyzable unit
  - Charnley classification included as covariate
- Hip- or procedure-specific items will be analyzed using the hip or procedure as the analyzable unit

IV. Radiographic Review

- Company proposes clarification of radiographic review criteria
- Femoral canal preparation evaluated 6 weeks post THA
- Fit: measurements taken at 3 specified points on the prosthesis; distance between prosthesis and cortical bone measured in mm
- Fill: outer diameter of prosthesis and inner diameter of cortical bone measured distally; difference recorded in mm
- Alignment: angle of the prosthesis compared to angle specified by ORTHODOC plan; difference recorded in degrees

IV. Sample Size

Evaluable subjects enrolled to date are sufficient to support 510(k) clearance

End

DJA x00152

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

February 01, 2008

INTEGRATED SURGICAL SYSTEMS, INC.
1433 N. MARKET BLVD., #1
SACREMENTO, CA 95834
ATTN: RUSS HIBBERT

510(k) Number: K072629
Product: DIGIMATCH
ROBODOC SURGICAL
SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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 premarket notification submission. Also, please note the new 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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://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).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

DJA x00153

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

DJA x00154

K072629/S1

ROBODOC®
INTEGRATED SURGICAL SYSTEMS

FDA CDRH DMC

JAN 31 2008

Received

January 29, 2008

FDA CDRH DMC

JAN 31 2008

Received

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

Attention: Michel D. Janda

Re: Supplement 1: Response to FDA Review Comments regarding DigiMatch™ ROBODOC® Surgical System 510(k) Premarket Notification (K072629)

Dear Mr. Janda:

This submission provides the responses to the Food and Drug Administration's ("FDA" or "the agency") December 5, 2007, review comments regarding the DigiMatch™ ROBODOC® Surgical System 510(k) Premarket Notification (K072629). In addition, as we discussed in our January 23, 2008, telephone conversation, ISS has addressed the additional review comment regarding the hip fixator. This response is provided in Item 16 of this supplement. For convenience of review, each of the questions raised in the agency's letter and in our recent discussion is repeated in italics below, followed by the company's response. We also have provided an overview of our response in an Executive Summary.

We trust that the information contained in this response will be sufficient to support a finding of substantial equivalence. If you have any questions regarding this letter, please contact me at the below number. Otherwise, please forward a copy of the substantial equivalence letter to me by facsimile. Thank you in advance for your cooperation.

Sincerely,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
Cell: 801-455-0807
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

KLH

cc: Dr. Ramesh Trivedi, President and CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.

Attachments enclosed

DJA x001155

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Volume II

Protocols, Test Reports, Test Studies Supporting Response to FDA Comment No. 10

Volume III

Protocols, Test Reports, Test Studies Supporting Response to FDA Comment No. 10

DJA x00156

Executive Summary

Supplement 1 for the pending K072629 submission provides Integrated Surgical System, Inc.'s (ISS) responses to FDA's December 5, 2007, review comments regarding the DigiMatch™ ROBODOC® Surgical System 510(k) Premarket Notification. This Executive Summary provides an overview of the responses, which ISS believes fully address each of FDA's comments. For the convenience of the reviewer, a brief description of the ROBODOC System and a summary comparison of the manual and ROBODOC total hip arthroplasty (THA) procedures are provided.

Overview of DigiMatch™ ROBODOC® Surgical System

The DigiMatch™ ROBODOC® Surgical System (the System) consists of ISS's 510(k) cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a robot composed of an electromechanical arm, an electronics control cabinet, a display monitor and miscellaneous accessories, such as cutters, drapes, irrigation sets, probes and markers (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional, graphical, preoperative planner and implementation tool, and is intended as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. The ROBODOC component of the System supports implementation of the preoperative plan produced on the ORTHODOC.

Comparison of Manual THA Procedure and ROBODOC THA Procedure

Summary of Major Steps in Manual THA Procedure

The surgeon completes the traditional "manual" THA procedure by performing the following procedural steps:

1. Positioning the patient on the OR table
2. Making the appropriate surgical incision and exposing the femur
3. Dislocating the femoral head from the acetabulum
4. Removing the femoral head
5. Manually creating the femoral canal by reaming and broaching methods
   a. Reaming is the process of "drilling" the intramedulary canal within the proximal femur
   b. Broaching is the process of hammering a rasp-like device (broach), which is shaped like the selected femoral prosthesis, into the proximal femur. The broach is directed along the pathway created by the reaming process.
6. A "trial" prosthesis is inserted into the broached femoral canal to test for size and fit
   a. If necessary, the reaming and broaching process is repeated until the desired femoral canal is created

DJA x00157

7. The acetabular cavity is created using reamers and a broached design to complete the acetabular prosthesis component of the THA procedure
8. The femoral and acetabular prostheses are fixed into position
9. The dislocated hip is relocated
10. The surgeon evaluates the hip prostheses for fit, range of motion, alignment, and leg length
11. The surgeon makes and required adjustments
12. The surgeon closes and dresses the surgical wound

Summary of THA Procedure Steps using ROBODOC System

The ROBODOC component of the System is designed to complete Step 5 above. Because the exact femoral implant size and femoral implant location is selected and determined preoperatively, using the ORTHODOC component, Step 6 is not required. The ROBODOC component of the System precisely creates the femoral cavity with minimal trauma as planned in the ORTHODOC preoperative plan. (Note: The Robot does not assist with preparation of the acetabulum. The acetabulum is prepared in the "normal" manner after completion of femoral cavity preparation.)

Intended Use/Indication for Use Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary THA.

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

ISS Responses to FDA Reviewer Comments

Item 1

Review comment 1 concerns the general description of various safety features that was provided in the 510(k) submission. The reviewer requested that additional information regarding these safety features, including the threshold values and a description of testing used to verify the appropriateness of these threshold values, be provided. Additionally, the reviewer requested that specifics on any additional threshold values, such as the temperature limits, velocity limits, force limit, etc. that are used to dictate the behavior of the system be provided.

DJA x001158

ISS Response

The general description of various safety features of the ROBODOC System has been updated to include additional information regarding the safety features. Threshold values, where applicable, were added in parentheses and a description of testing used to verify the appropriateness of these threshold values was provided.

Item 2

Review comment 2 concerns the risk of a system crash and subsequent recovery of the robotic arm to a "default" position. ISS was asked to describe how the system will recover from a system crash and what mitigation exists to prevent unintended movement following a system crash.

ISS Response

(b) (4)

Item 3

Review comment 3 concerns implant placement accuracy and implant cavity preparation accuracy. The reviewer requested that ISS provide a reference to the validation testing, which supports this performance statement.

ISS Response

The validation of placement accuracy and cavity preparation accuracy are demonstrated in separate procedures. Validation placement accuracy is demonstrated in (b) (4) and validation of cavity accuracy is demonstrated in (b) (4). A copy of TR (b) (4) provided in Volume II of this document.

DJA x00159

Item 4

Review comment 4 requested a justification for pooling data from United States and Japanese study sites.

ISS Response

A discussion and supportive tables are presented to establish why the data may be pooled.

Item 5

In review comment 5, ISS was asked to provide a list of the implant systems currently included within the ROBODOC System implant database. ISS was also asked to describe the process for integrating these implants into the database.

ISS Response

As requested, ISS provides a statement that it understands its responsibility to verify that all implant systems used on the ROBODOC System are legally marketed within the United States. A list of the implants that will be included in the 510(k) cleared ROBODOC System is provided. Additionally, an overview of the implant development process and a discussion of the implant development process steps is presented.

Item 6

Review comment 6 requests that ISS revise the ORTHODOC and ROBODOC User Manual labeling to include the intended use / indications for use.

ISS Response

As requested, ISS has revised the ORTHODOC and ROBODOC User Manual labeling to include the intended use / indications for use. A copy of the revised pages of the manuals is provided in **Attachment 2** of this document.

Item 7

Review comment 7 concerns the importance of distal fixation, which is discussed in Chapters 6 and 7 of the ROBODOC User Manual. FDA asked that the applicable sections be revised to include a discussion of the limitations of the bone motion detection function (threshold value) and the corresponding decrease in system accuracy that could be expected if motion occurs.

DJA x001-60

ISS Response

Chapter 7, REGISTRATION PROCEDURES, of the ROBODOC User Manual has been revised to include a replica of the bone motion indicator and a discussion of its intended use. **Attachment 3** of this submission provides a copy of the revised pages.

Item 8

Review comment 8 concerns Chapter 10 of the ROBODOC User Manual, which contains a troubleshooting section that provides instructions for replacing the bearing sleeve after part failure. ISS was asked to provide a reference to part maintenance instructions or include additional detailed maintenance instructions for the bearing sleeve part and any other part which requires user maintenance.

ISS Response

ISS has revised Chapter 9 of the ROBODOC® User Manual to clarify the servicing and routine maintenance requirements for the bearing sleeve part of device. **Attachment 4** provides a copy of the revised User Manual page, which clarifies the servicing and routine maintenance requirements.

Item 9

Review comment 9 concerns the "Adaptive Cut Speed" feature that is discussed in the ROBODOC User Manual. ISS was asked to provide additional information regarding this feature and to provide a discussion regarding the risk of thermal injury during robotic reaming.

ISS Response

This response contains a description of the adaptive cut speed feature and the risk of thermal injury during robotic reaming. The combination of cutter design, cutter use, irrigation and adaptive cutting controls mitigates the risks of thermal injury during cavity preparation using the ROBODOC system. The worse case cutting scenario exists when irrigation fluid is not used and cutting is done with a dull (reused) cutter. In this case, it is possible to have cutting temperatures that may lead to thermal injury. This risk is mitigated by directives in the user manual (ROBODOC User Manual, Chapter 8), Cutter and irrigation tube set package labeling and system prompts requiring user confirmation during use.

Item 10

Review comment 10 relates to the ROBODOC System software level of concern.

ISS Response

In the response to this FDA review comment, ISS has referenced the *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005).* Using FDA's "Approach to Deciding Level of Concern" as detailed in the Guidance Document, ISS has assessed the Level of Concern within the context of the worst possible, reasonably foreseeable, clinical consequences of failure of the device. The questions presented in the FDA guidance were reassessed and answered.

This reassessment has again led the company to the conclusion that the ROBODOC® Surgical System software meets the definition of a "Moderate Level of Concern." However, based on our December 14, 2007, discussion with Mr. Michel Janda, ISS is submitting the additional documentation that is required to support "Major" Level of Concern software.

Item 11

Review comment 11 states that it is unclear if additional human factors studies were undertaken in an attempt to simplify the use of the ROBODOC System. FDA asked that if any human factors studies were preformed to verify human performance and the risks associated with user error, the results of the study be provided.

ISS Response

Human factors testing were performed in two tests (b) (4) at Berufsgenossenschaftliche Unfallklinik (BGU) in Frankfurt, Germany. The studies were designed to validate ease of use and performance of the DigiMatch System using a point to surface approach for addressing the pinless registration issue. The report of the study, (b) (4) is summarized in Section 20.5 of the original 510(k) submission (K072629). Copies of (b) (4) are provided in Volume II of this document.

Item 12

Review comment 12 asked that ISS provide a copy of the electromagnetic compatibility and electrical safety test reports performed on the ROBODOC System.

ISS Response

A completed copy of the electromagnetic compatibility and electrical safety test reports is provided in **Attachment 5** to this submission.

DJA x001.62

Item 13

Review comment 13 asked that ISS clarify if the device described in the 510(k) submission is identical to that used in the second IDE clinical study. If any device modifications are intended to be included within this 510(k), ISS was asked to describe them.

ISS Response

ISS confirms that DigiMatch™ ROBODOC® Surgical System described in 510(k) Number K072629 is identical to the system used in the second IDE clinical trial (IDE #G000071). No device modifications are included within this 510(k).

Item 14

Review comment 14 asked that ISS provide an updated Device Hazard Analysis to reflect certain points that were that were made. Additionally, FDA asked that the device hazard analysis be updated to include an analysis of the pendant.

ISS Response

The DigiMatch™ ROBODOC® Surgical System Device Hazard Analysis has been revised as requested. A column has been added that identifies the method of control of the hazards and the testing done to verify the correct implementation of that method of control, and any residual hazards. The pendant is covered in line items 56, 57 and 58.

A copy of the updated Risk Management Report, DIGIMATCH™ ROBODOC® System, is provided in **Attachment 6**.

A copy of the updated Device Hazard Analysis is provided in **Attachment 7**.

Item 15

Review comment 15 asked that ISS provide additional information regarding the DIGIMATCH™ ROBODOC® System revision history and any configuration management software (*i.e.*, Perforce, MS Visual Source safe) used to manage or control changes in the software classes and any bug tracking software used in the software development process.

ISS Response

ISS has provided the requested information. In addition, tables that track the revision history for the ORTHODOC® Preoperative Planning Workstation software and the DigiMatch™ ROBODOC® Surgical Assistant are also provided.

DJA x00163

Item 16

Review comment 16 asked that ISS explain the use of the bone fixation system and any mitigations implemented to avoid soft tissue damage.

ISS Response

ISS has provided the requested information explaining the use of the bone fixation system and any mitigation implemented to avoid soft tissue damage. **Attachment 8** contains copies of revised pages from ROBODOC User Manual, Chapter 6, Femoral Fixation. These revisions were made in response to this FDA comment and are used to mitigate soft tissue damage caused by the user with improper use of the fixator.

DJA x00164

FDA Comment

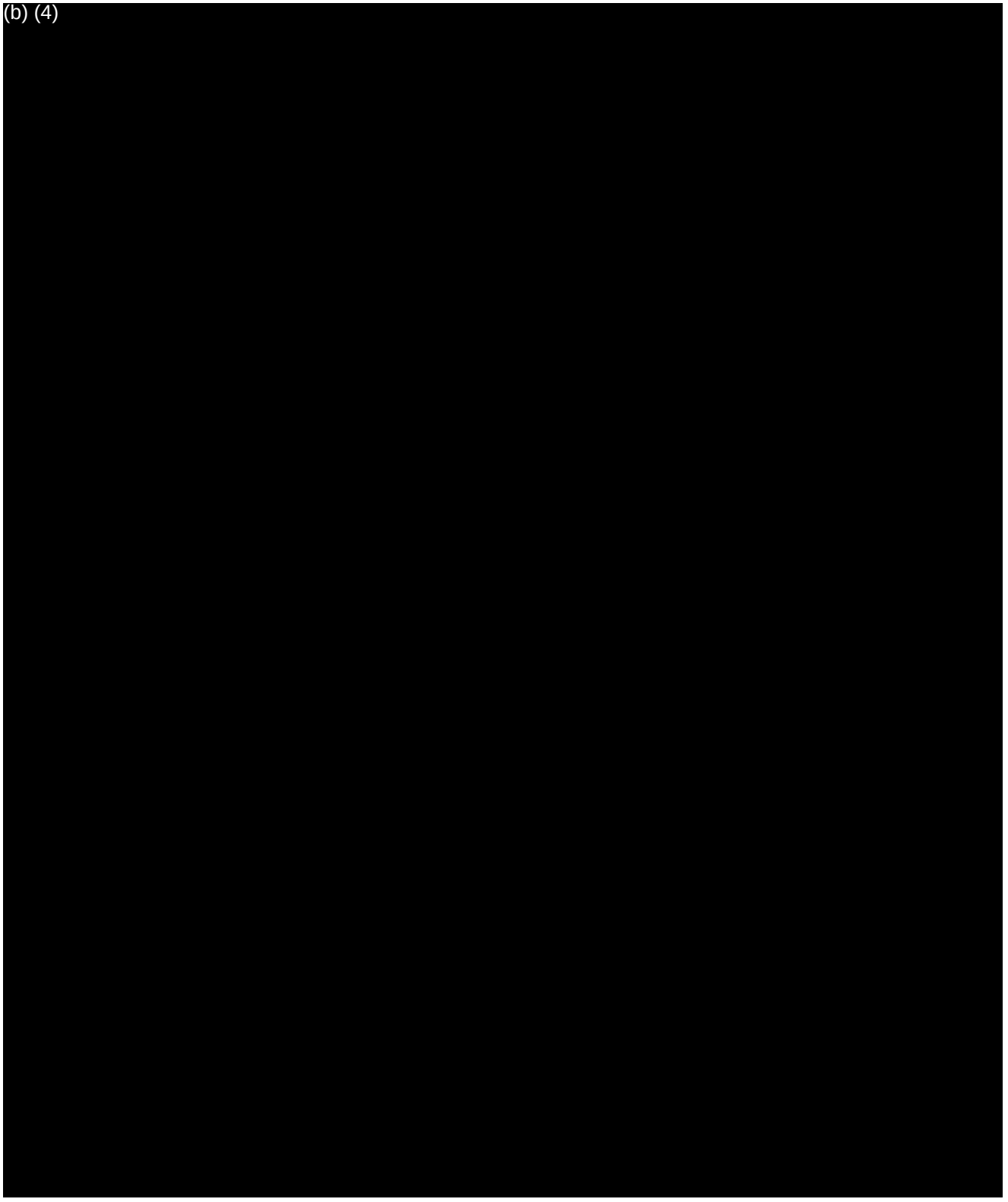
1. *The submission includes a general description of various safety features. The description frequently references predefined minimum and maximum threshold values. These values are not defined in the general description. As the values dictate the efficacy of the safety features additional information is necessary. Please provide additional information regarding these safety features including the threshold values and a description of testing used to verify the appropriateness of these threshold values. In addition, please provide specifics on any additional threshold values such as the temperature limits, velocity limits, force limits, etc. that are used to dictate the behavior of the system.*

ISS Response

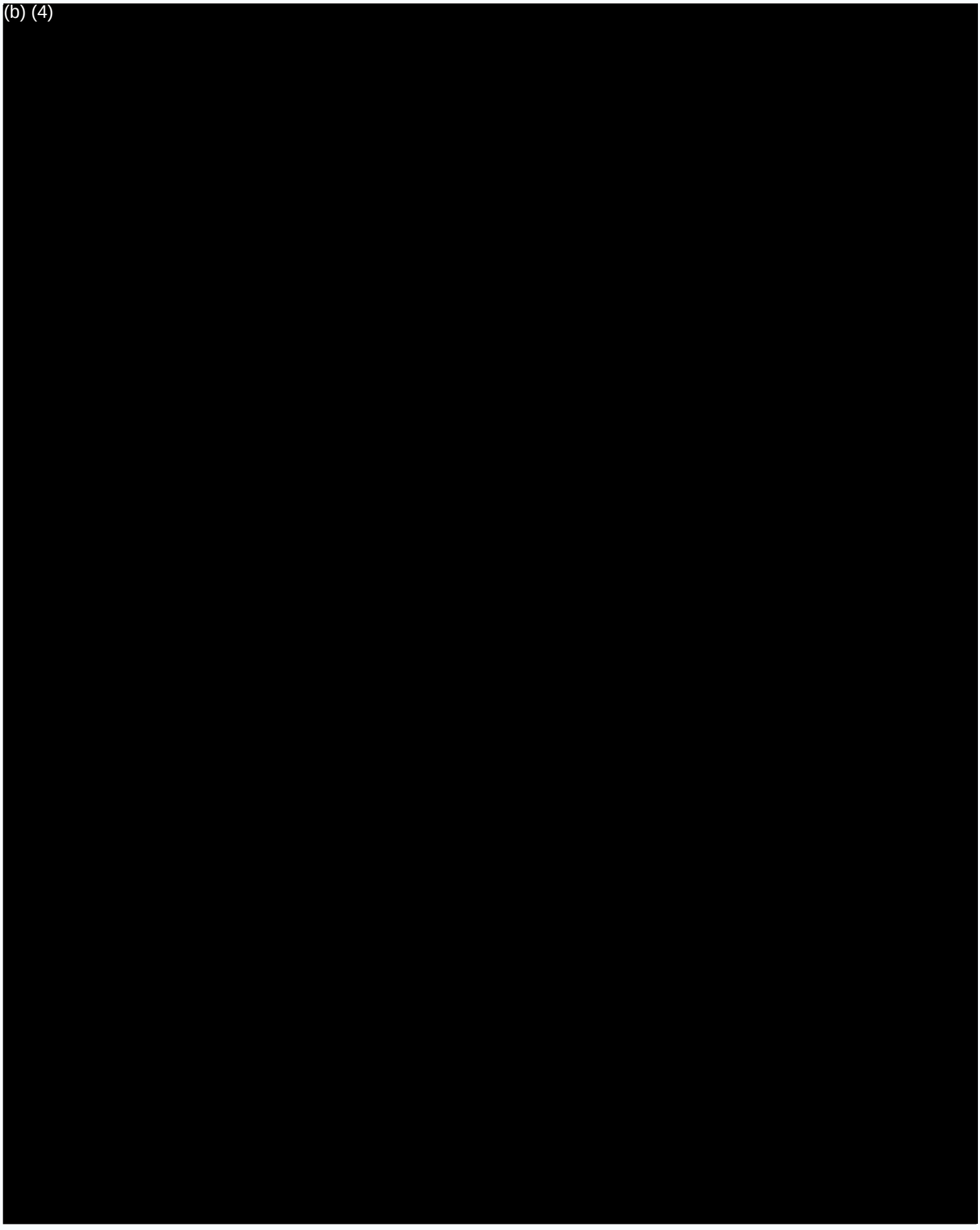
(b) (4)

DJA x00165

(b) (4)



DJA x00166



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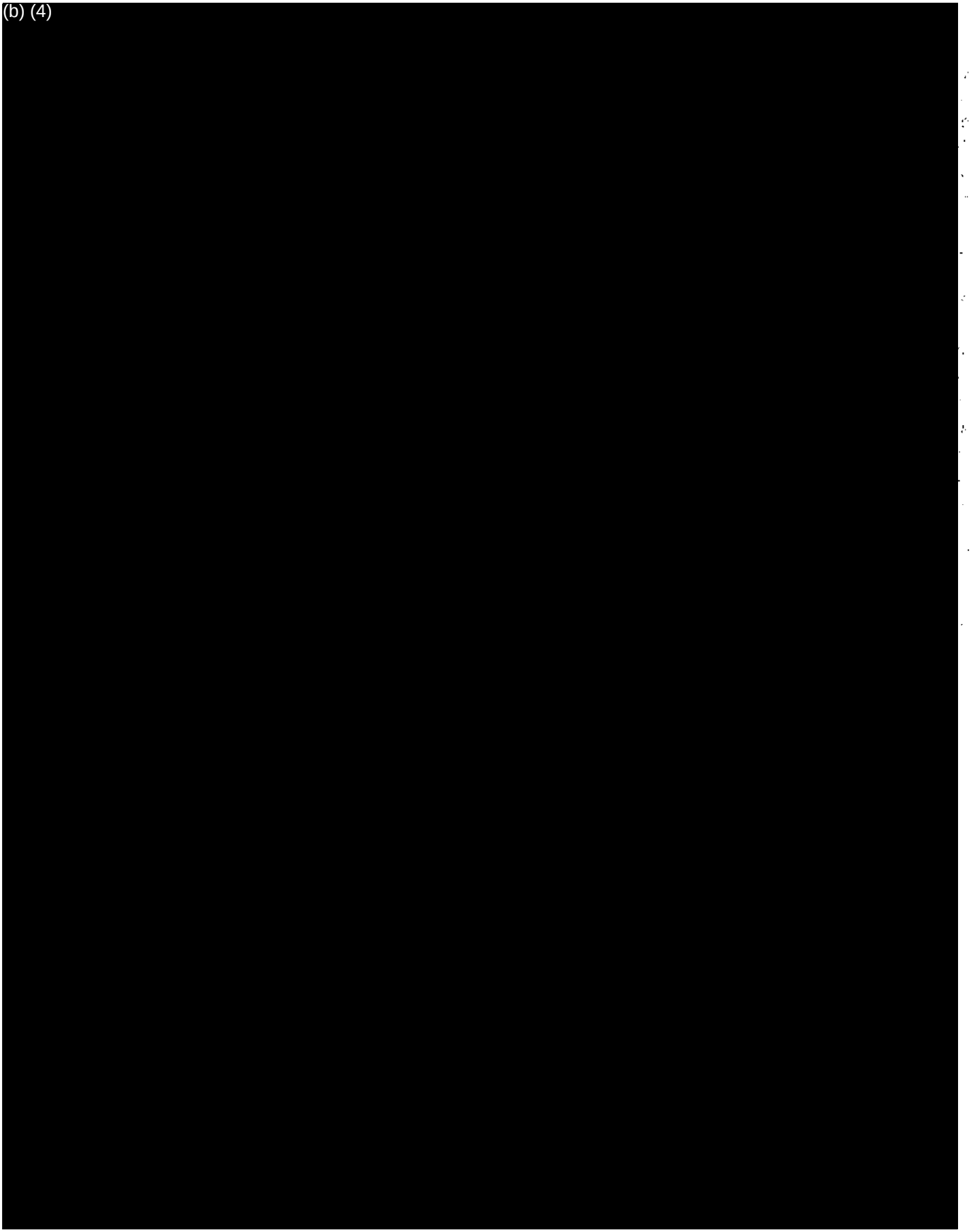

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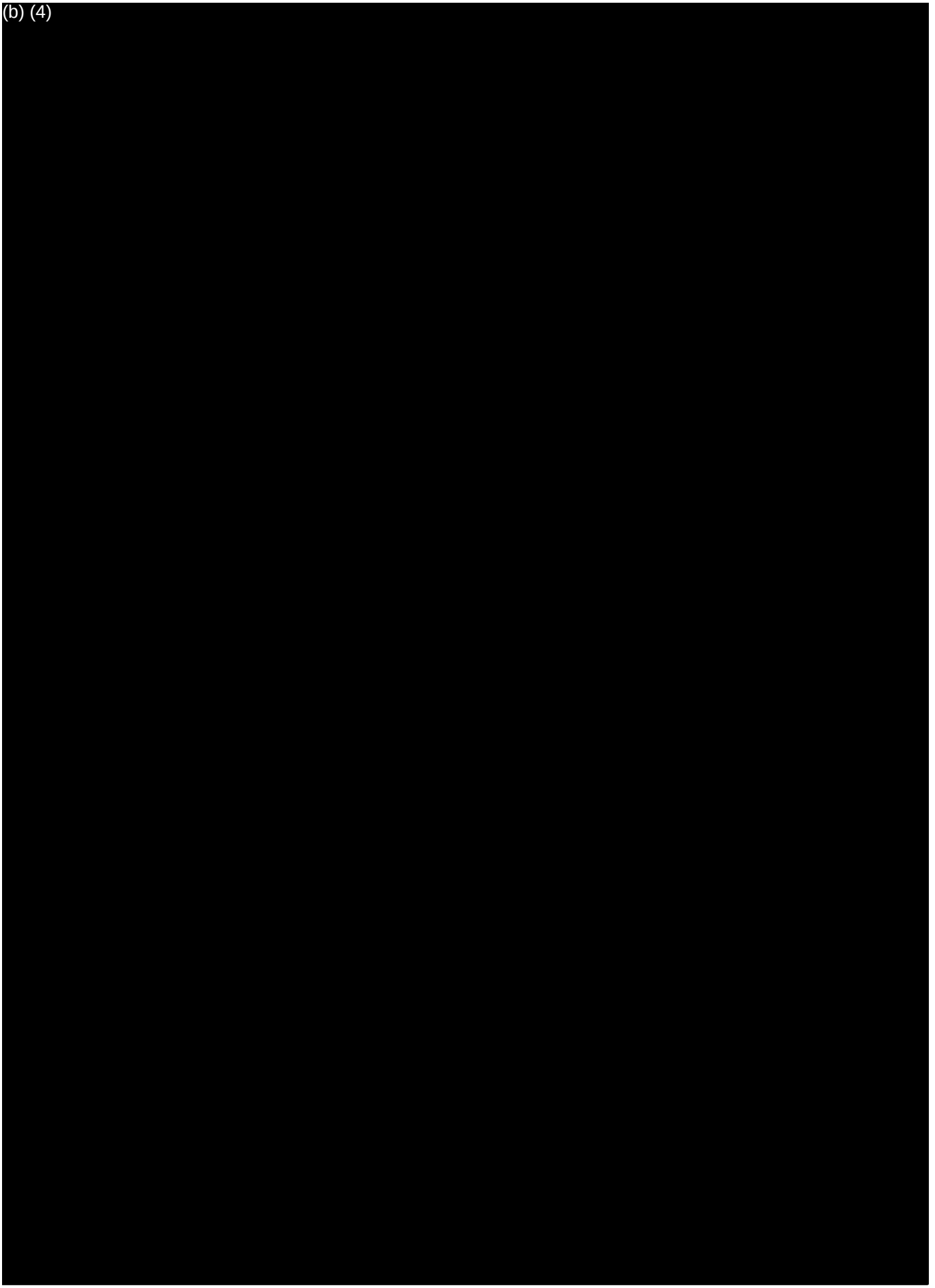

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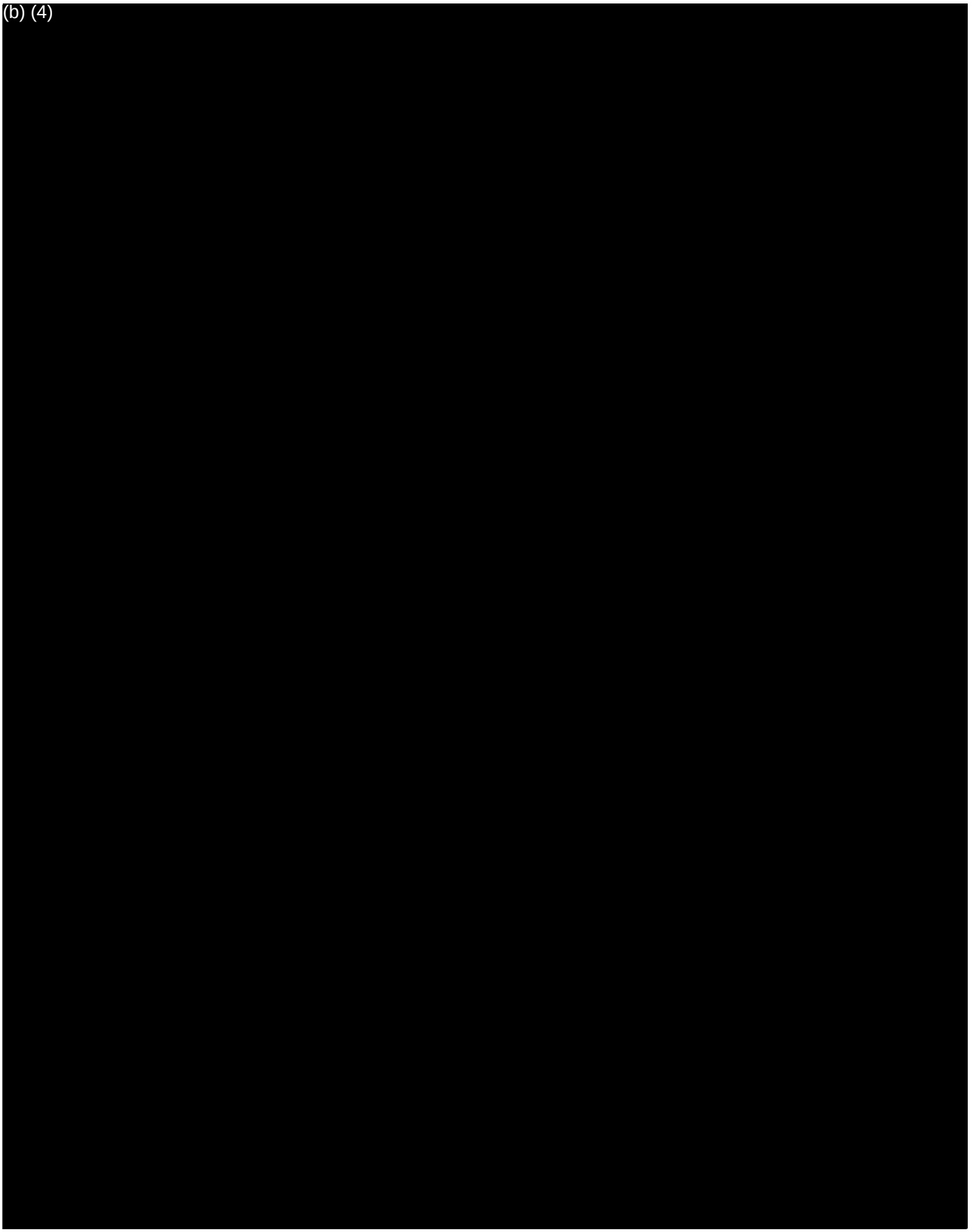

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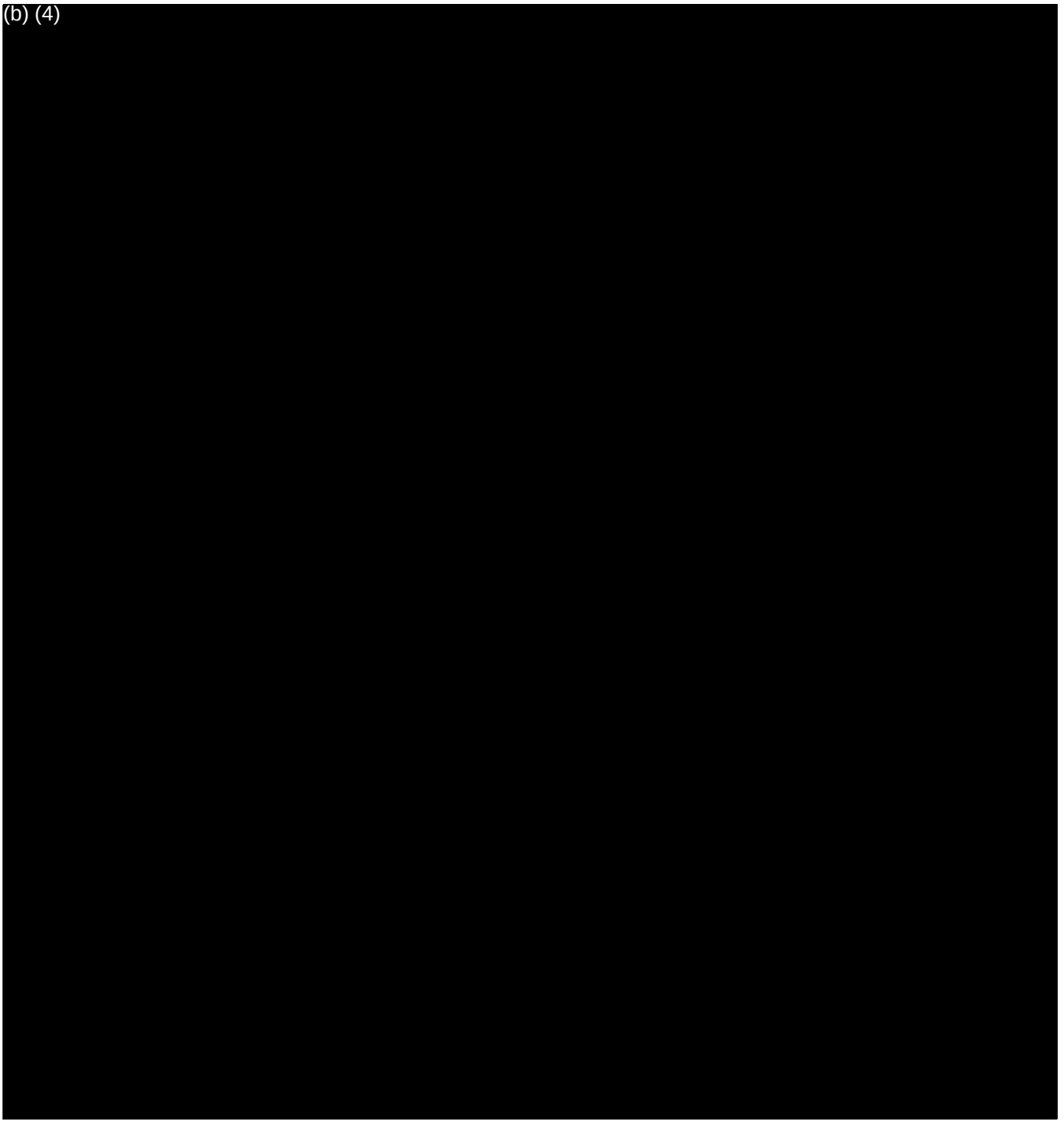

DJA x00171

List of Safety Requirement Tests

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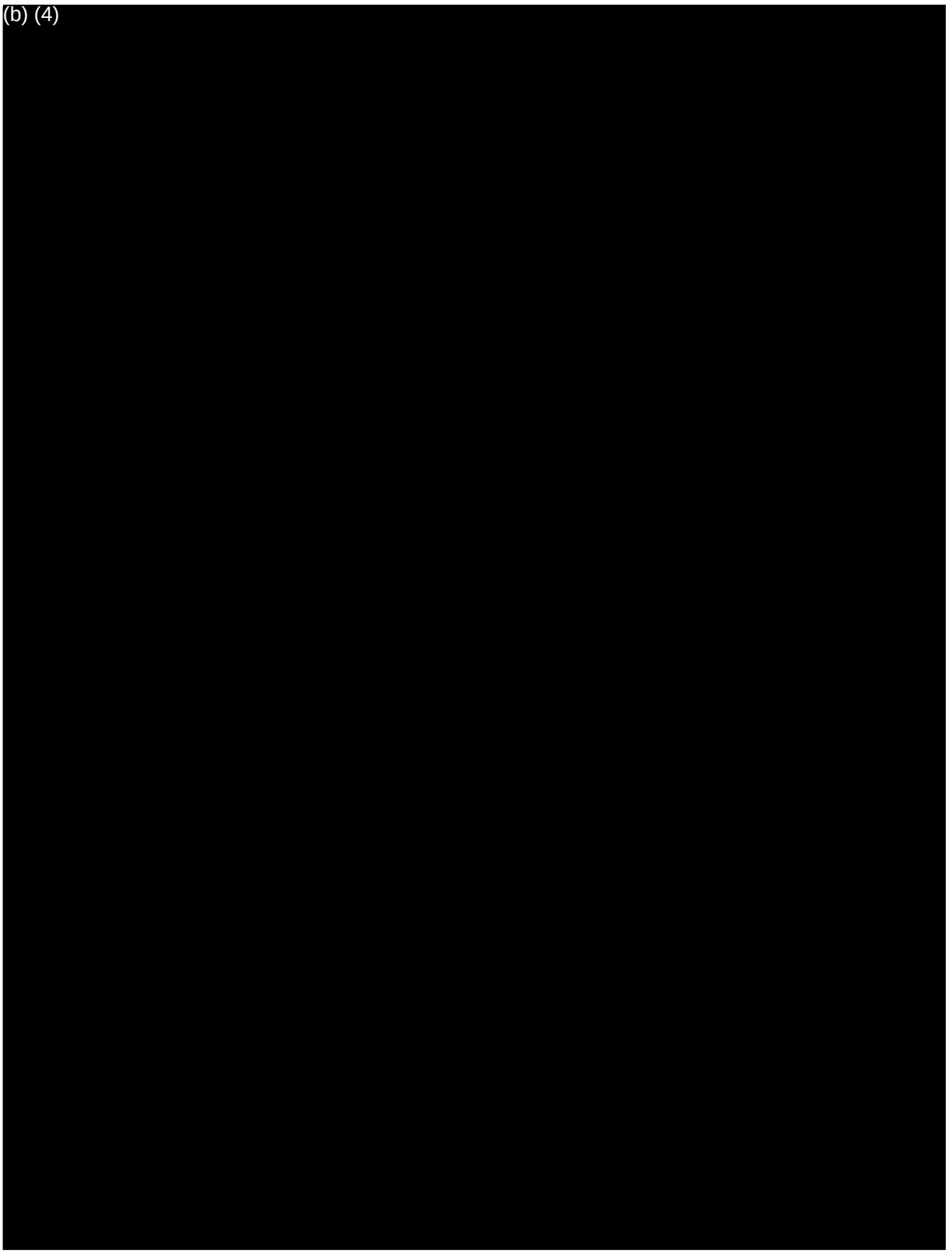

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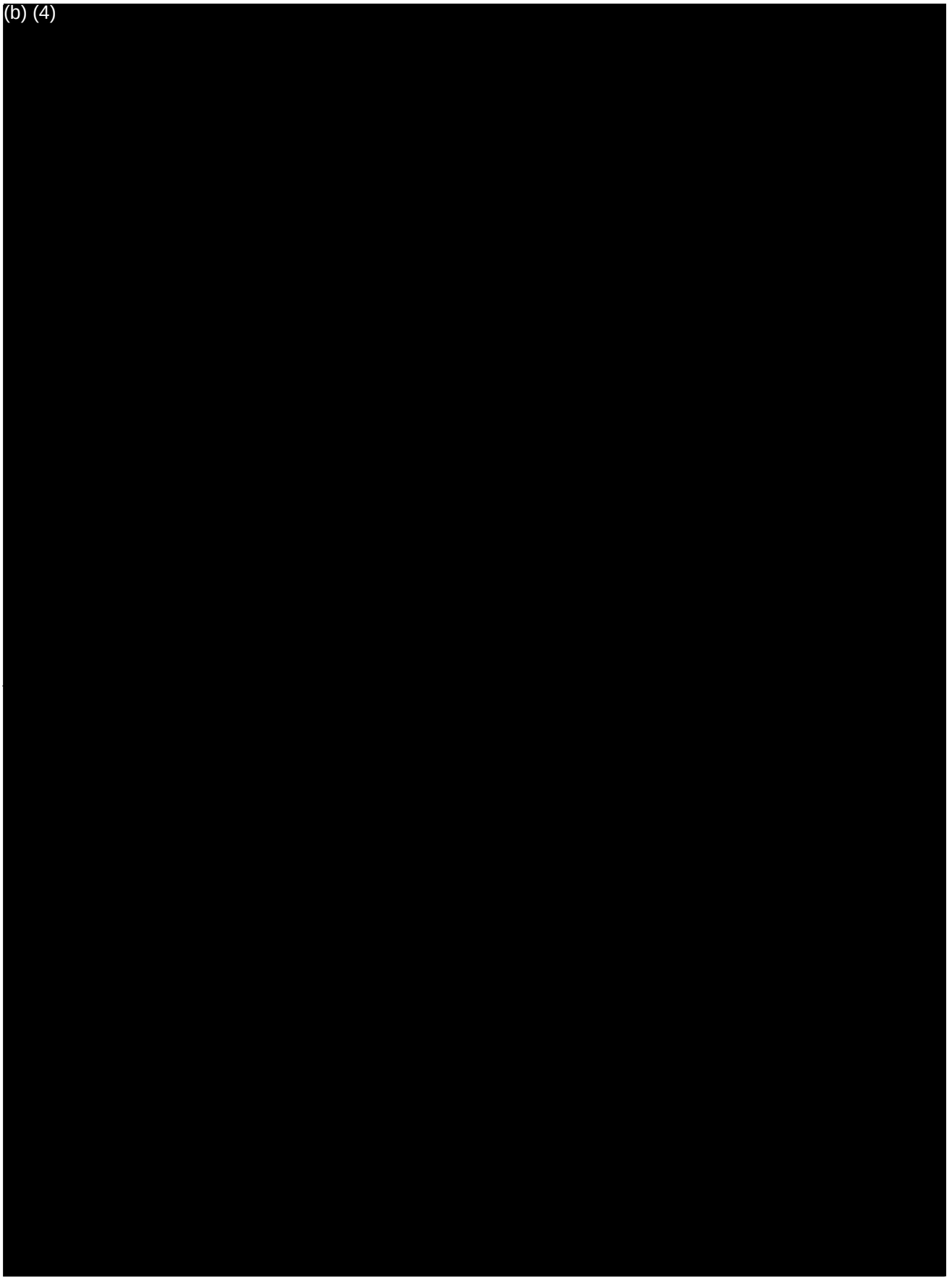

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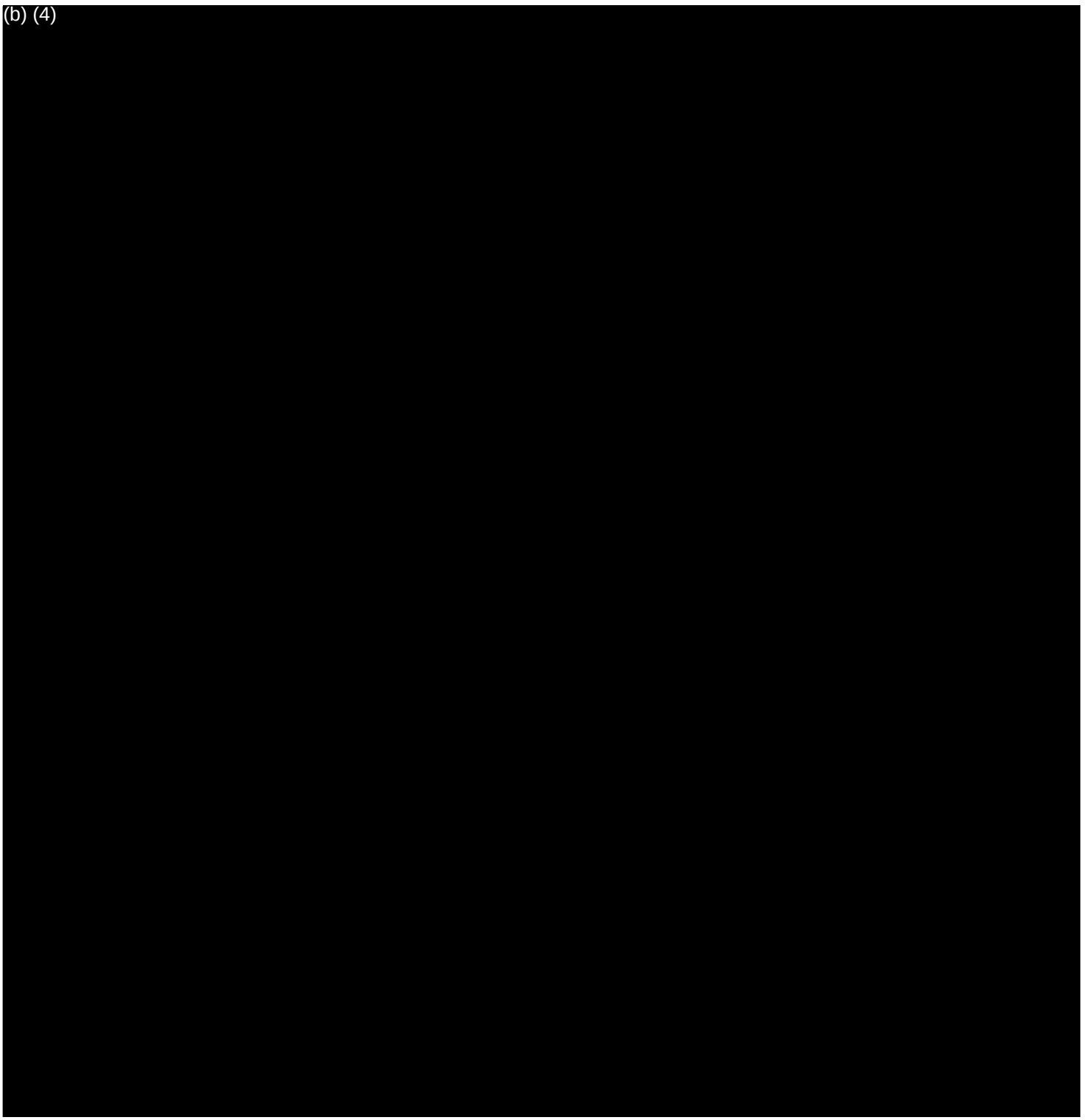
[redacted]

DJA x00174

(b) (4)



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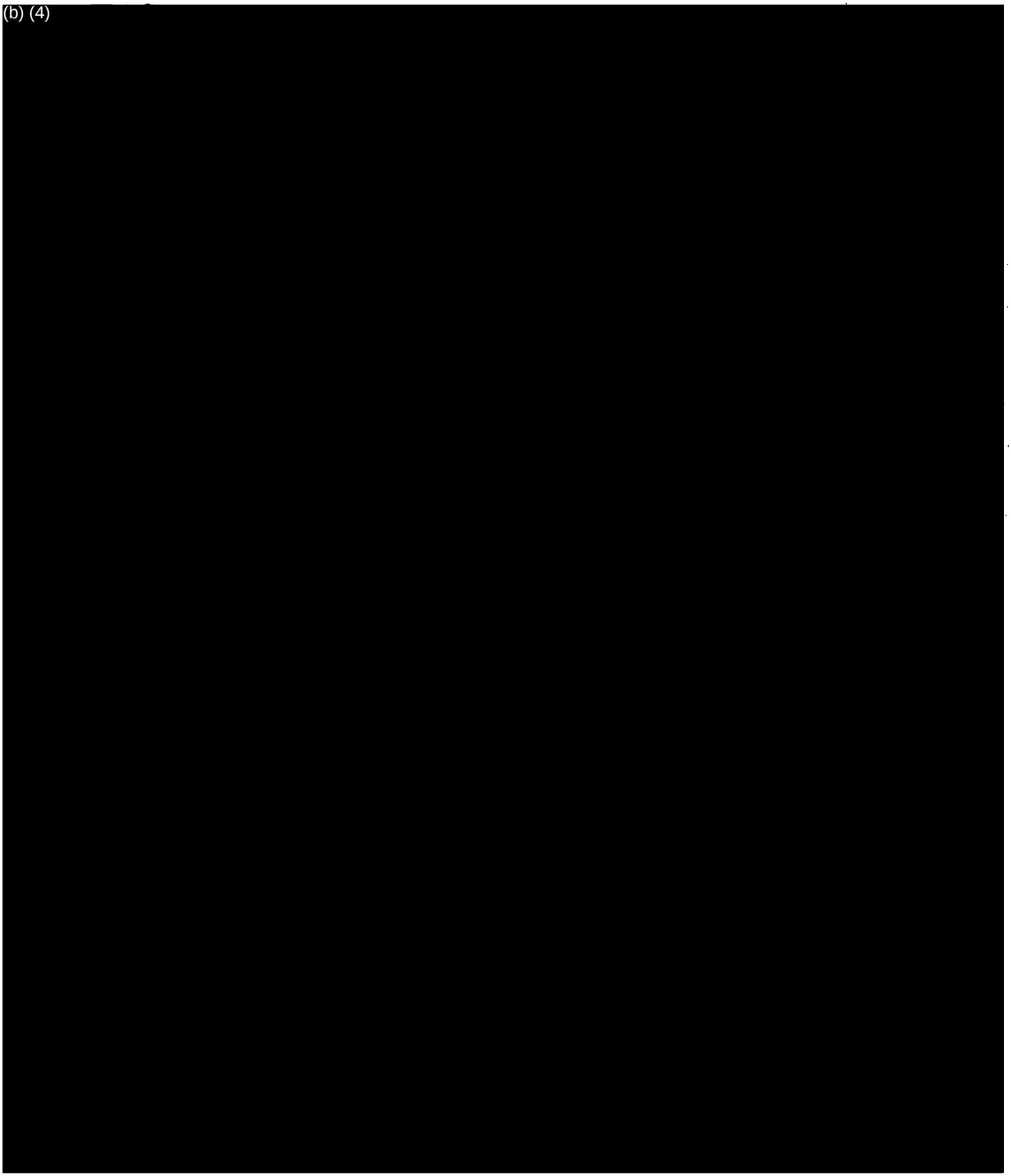
DJA x00176

(b) (4)



DJA x00177

(b) (4)

DJA x00178

DJA x001179

Safety Outcome Evaluation

(b) (4)

DJA x001B0

(b) (4)

DJA x00181

(b) (4)

DJA x001B2

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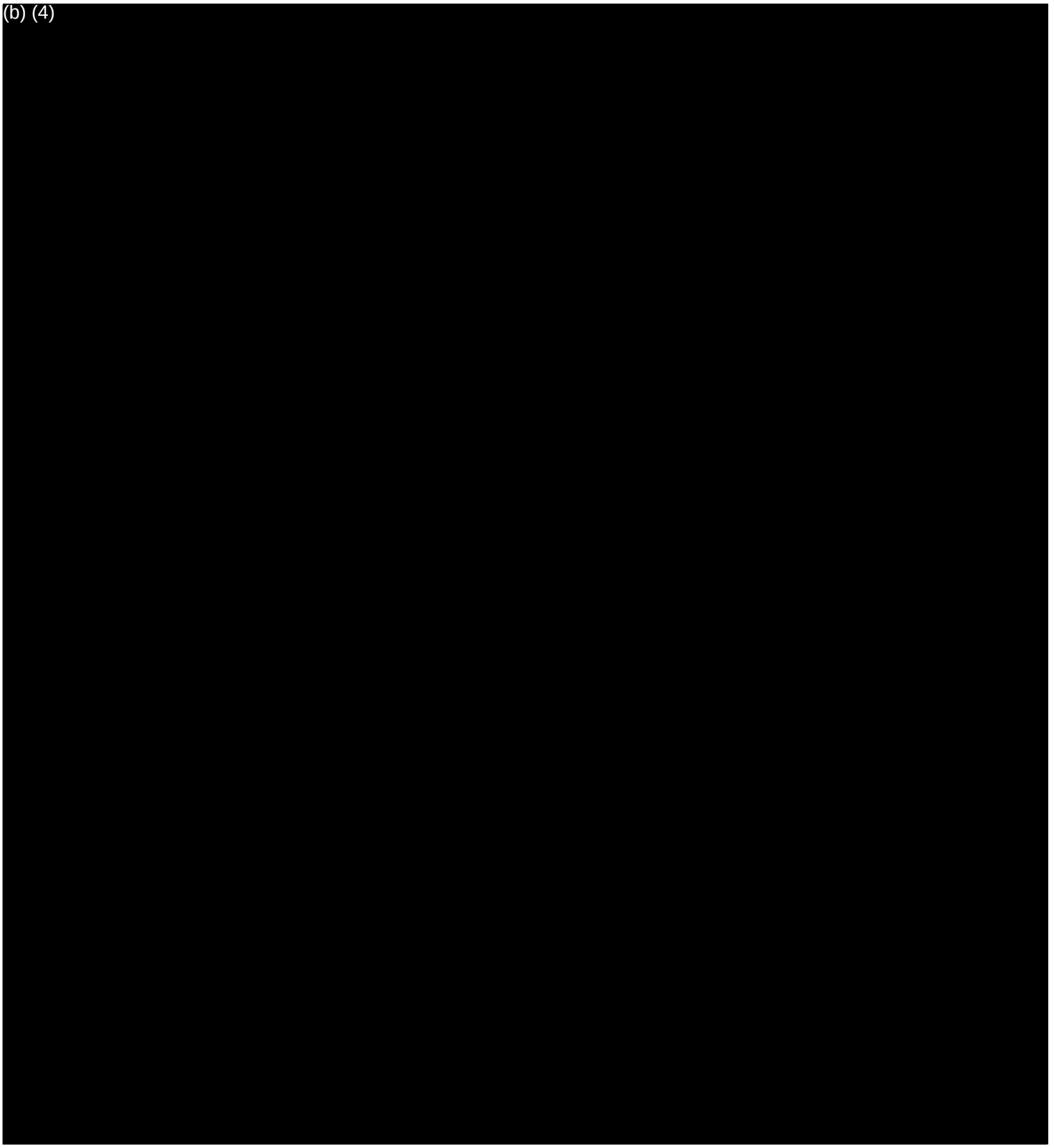

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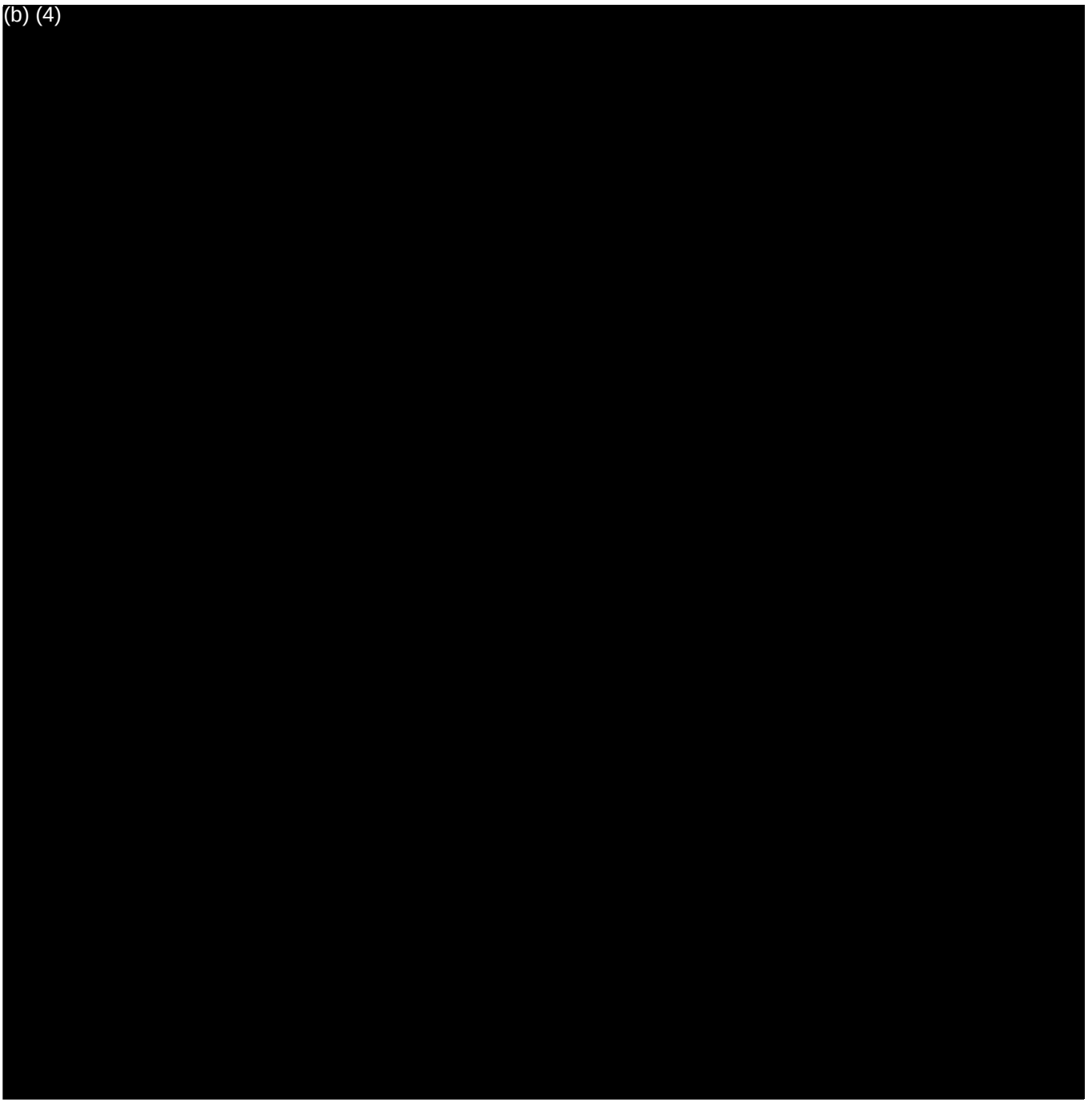

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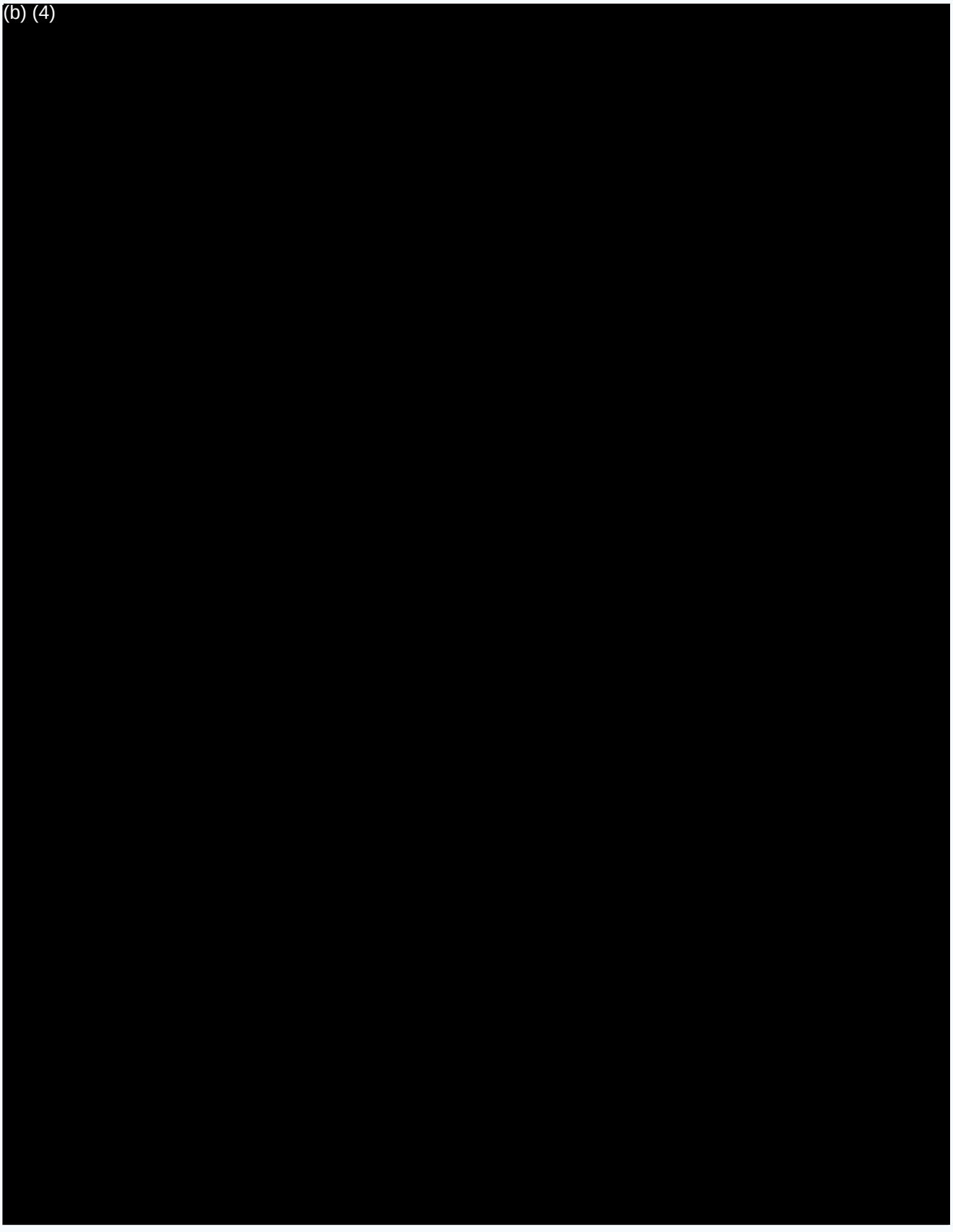

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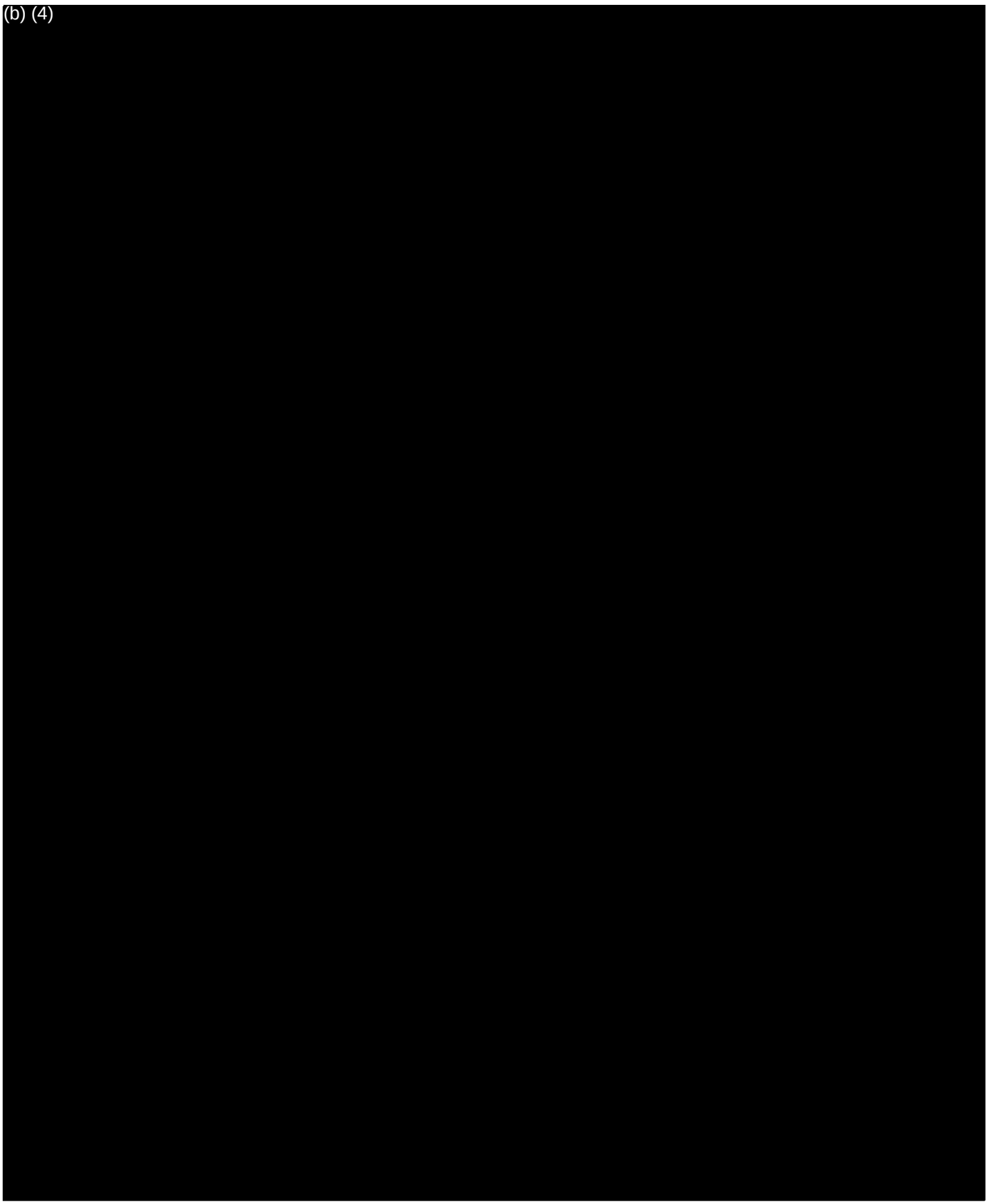

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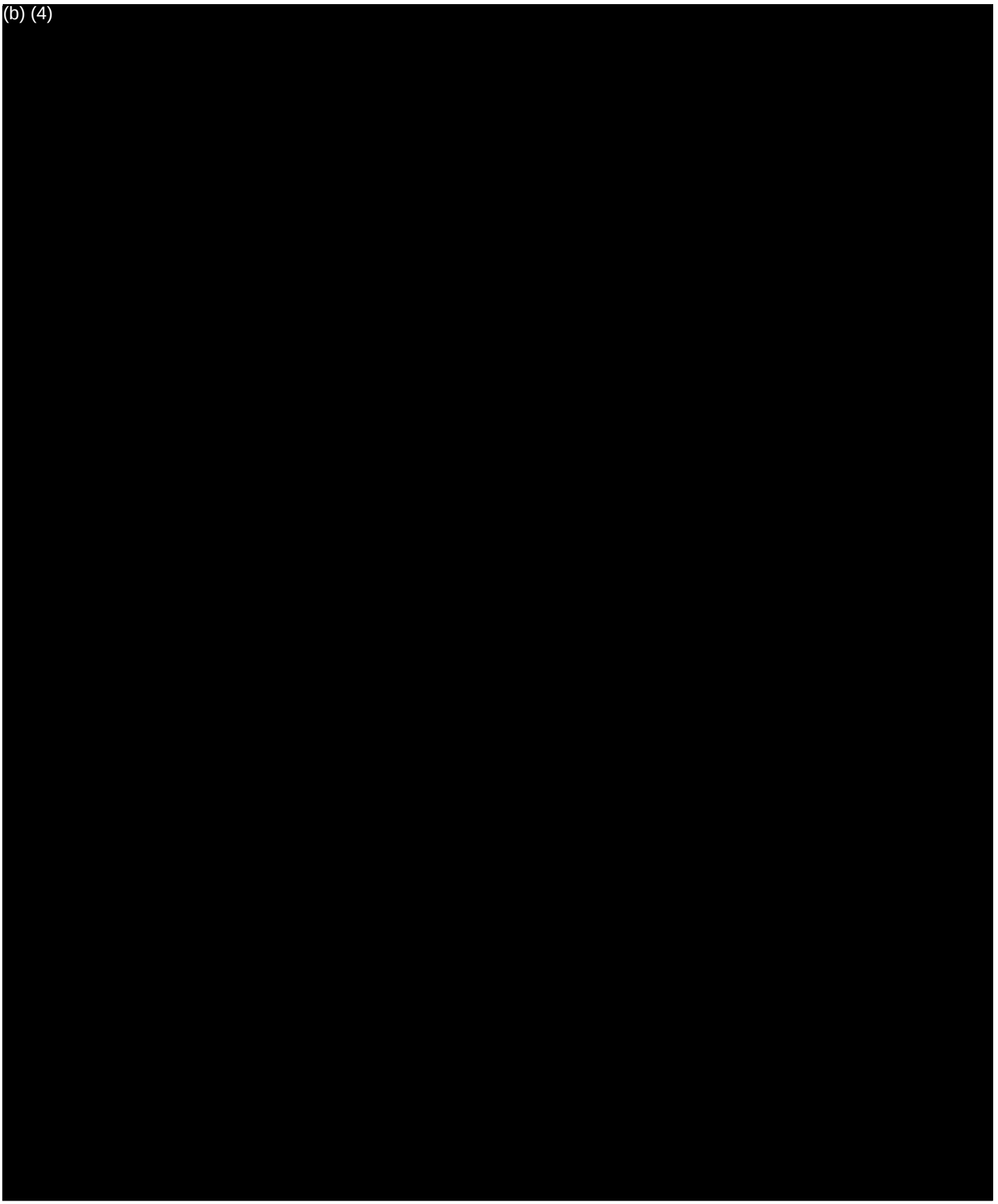
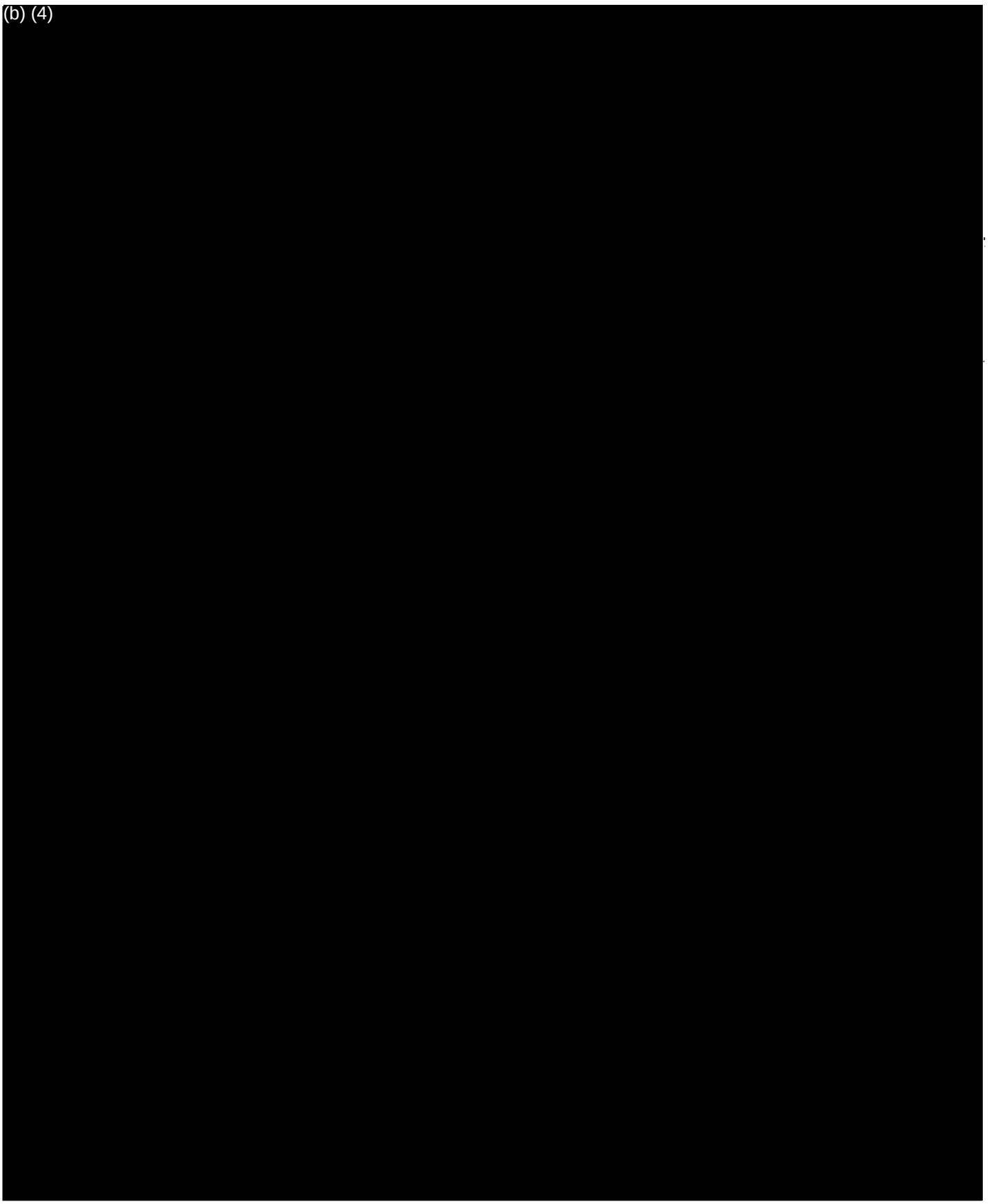


DJA x00187

Design Process

(b) (4)



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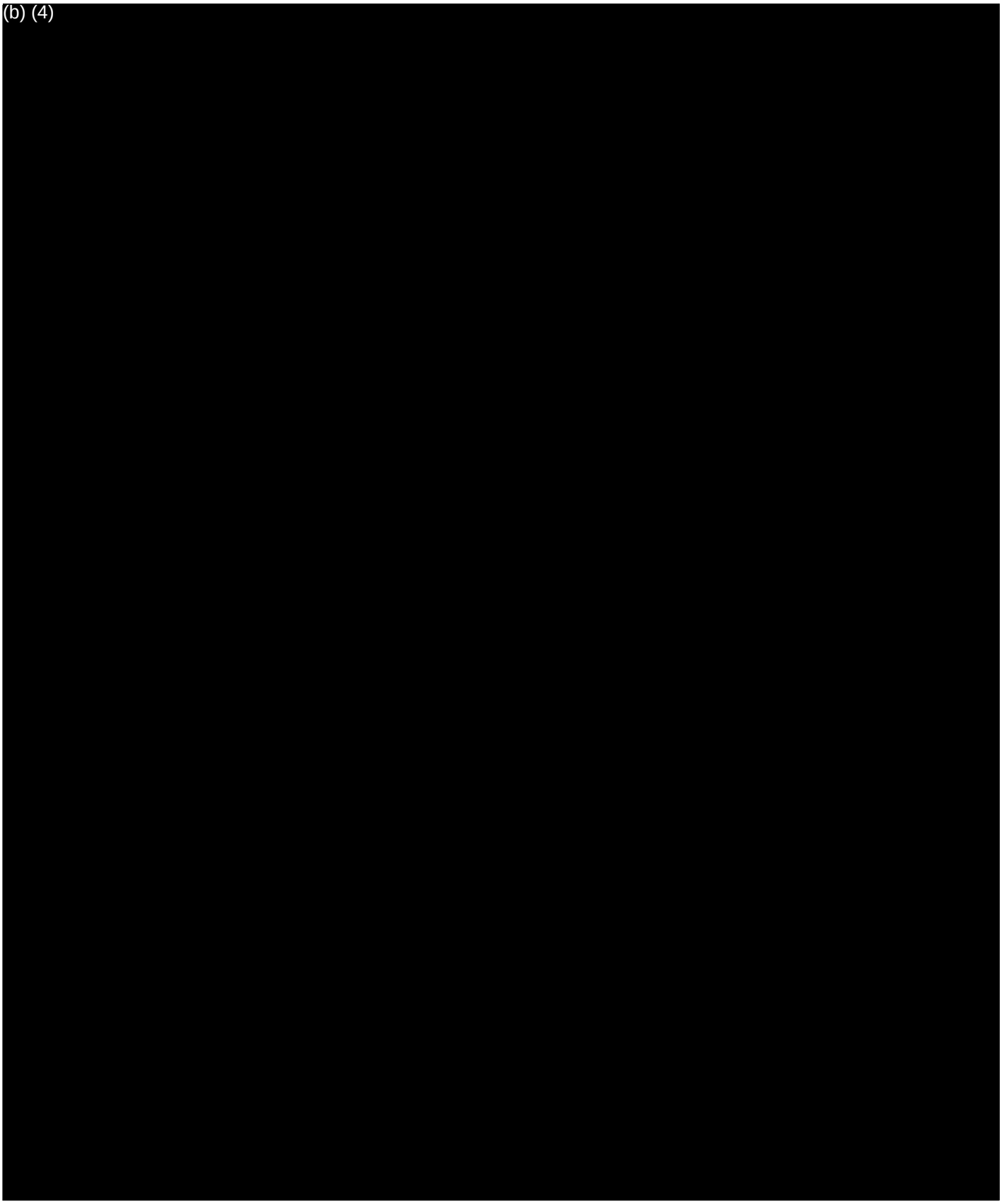

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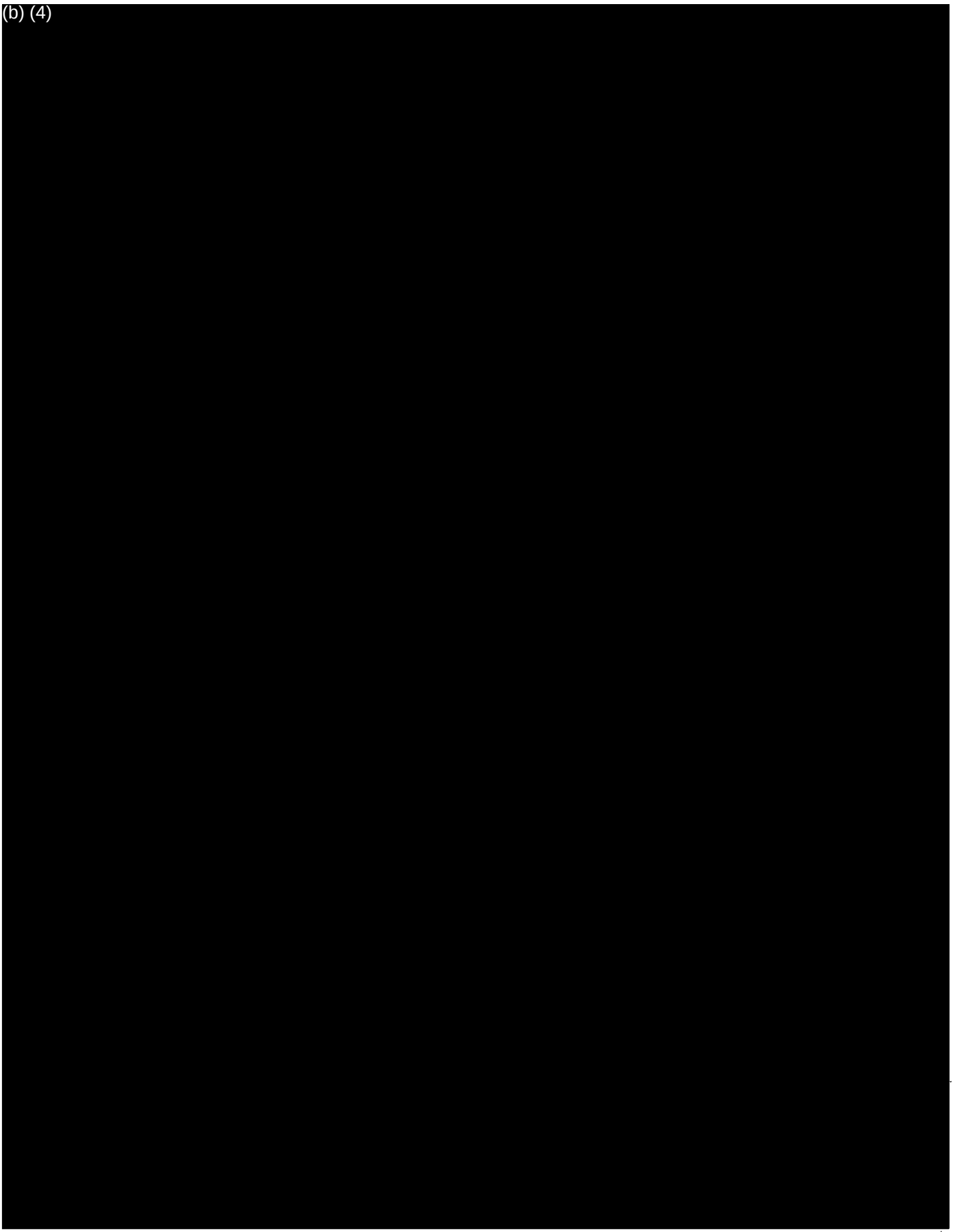

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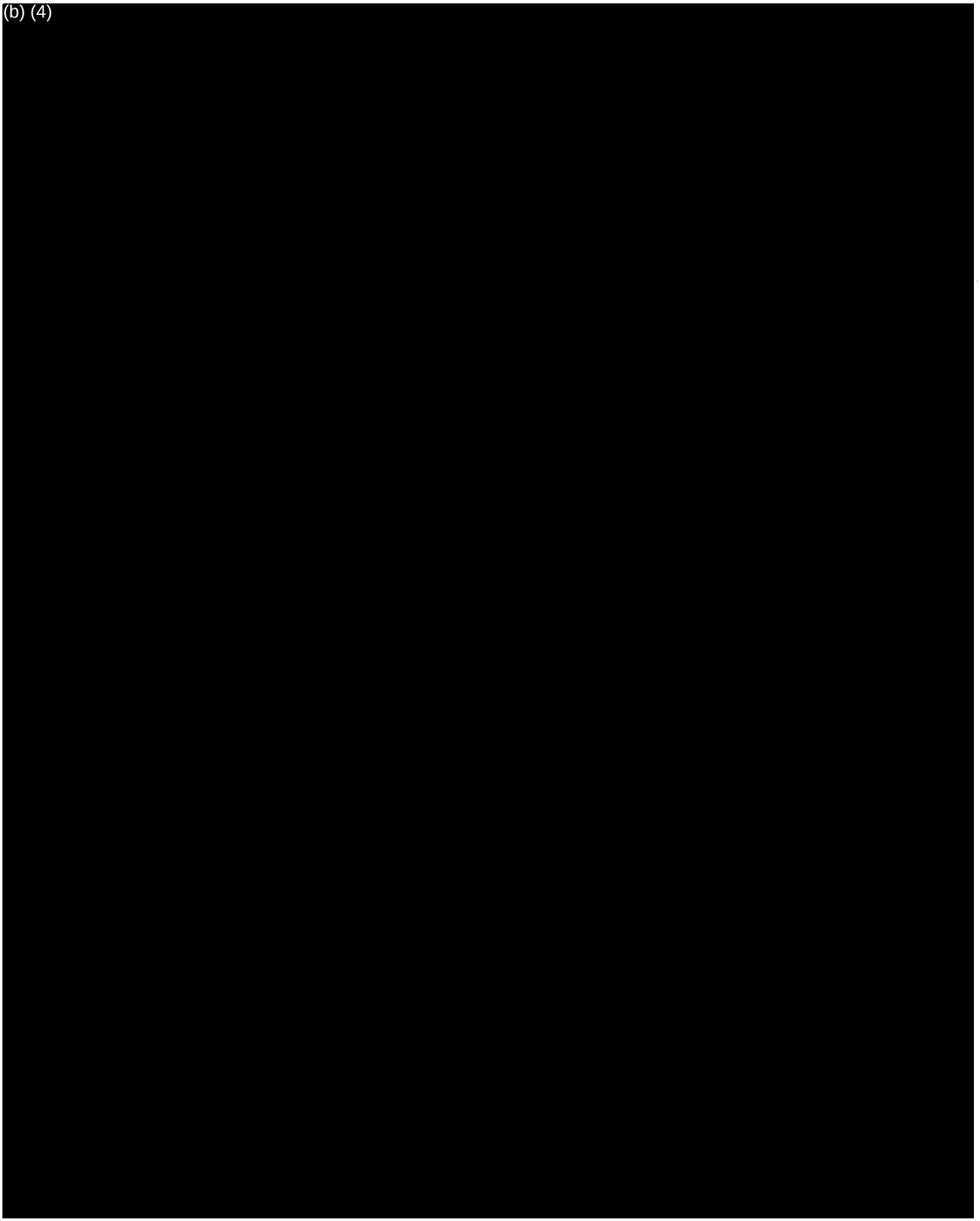

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DJA x00192

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DJA x00193

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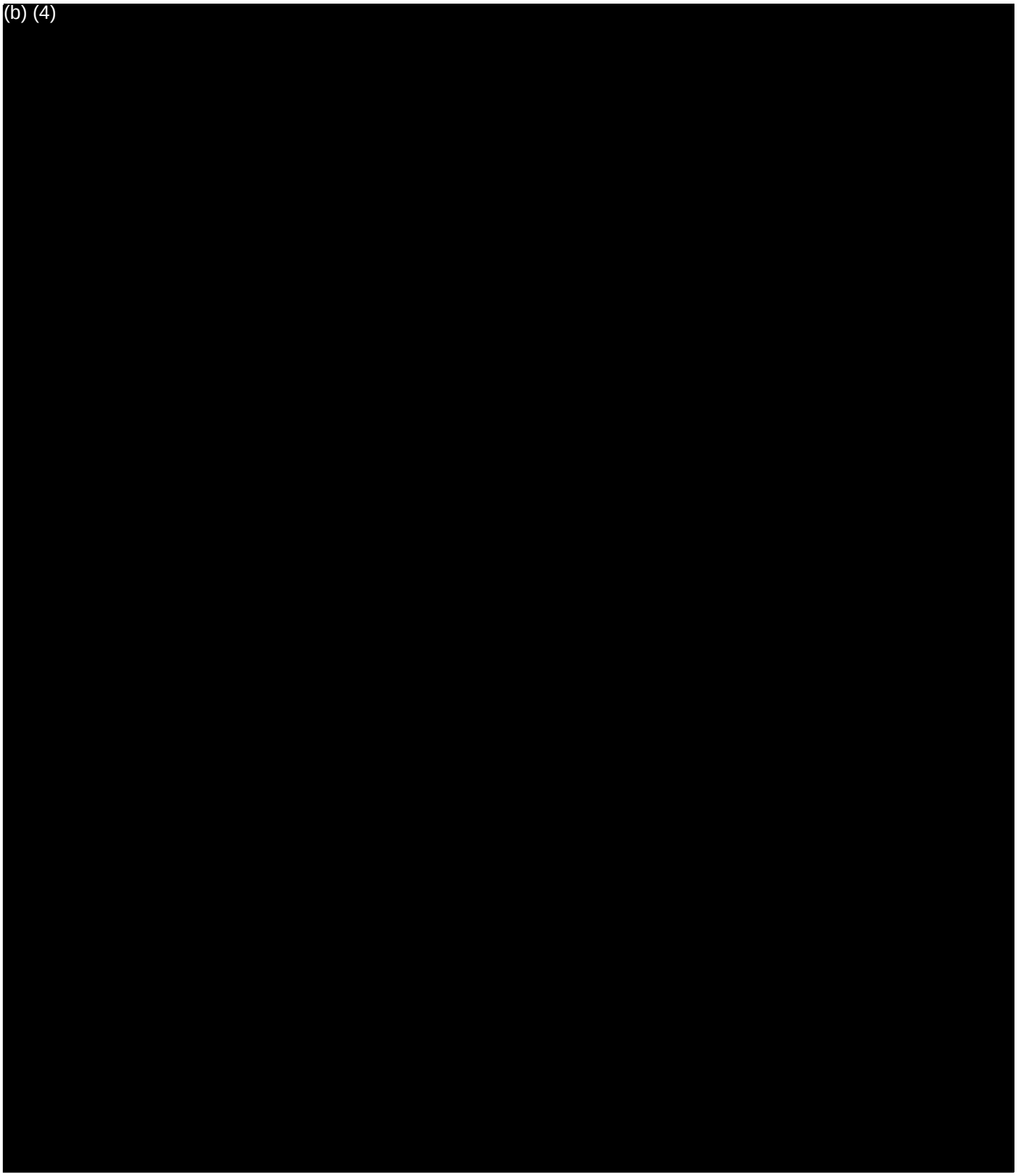

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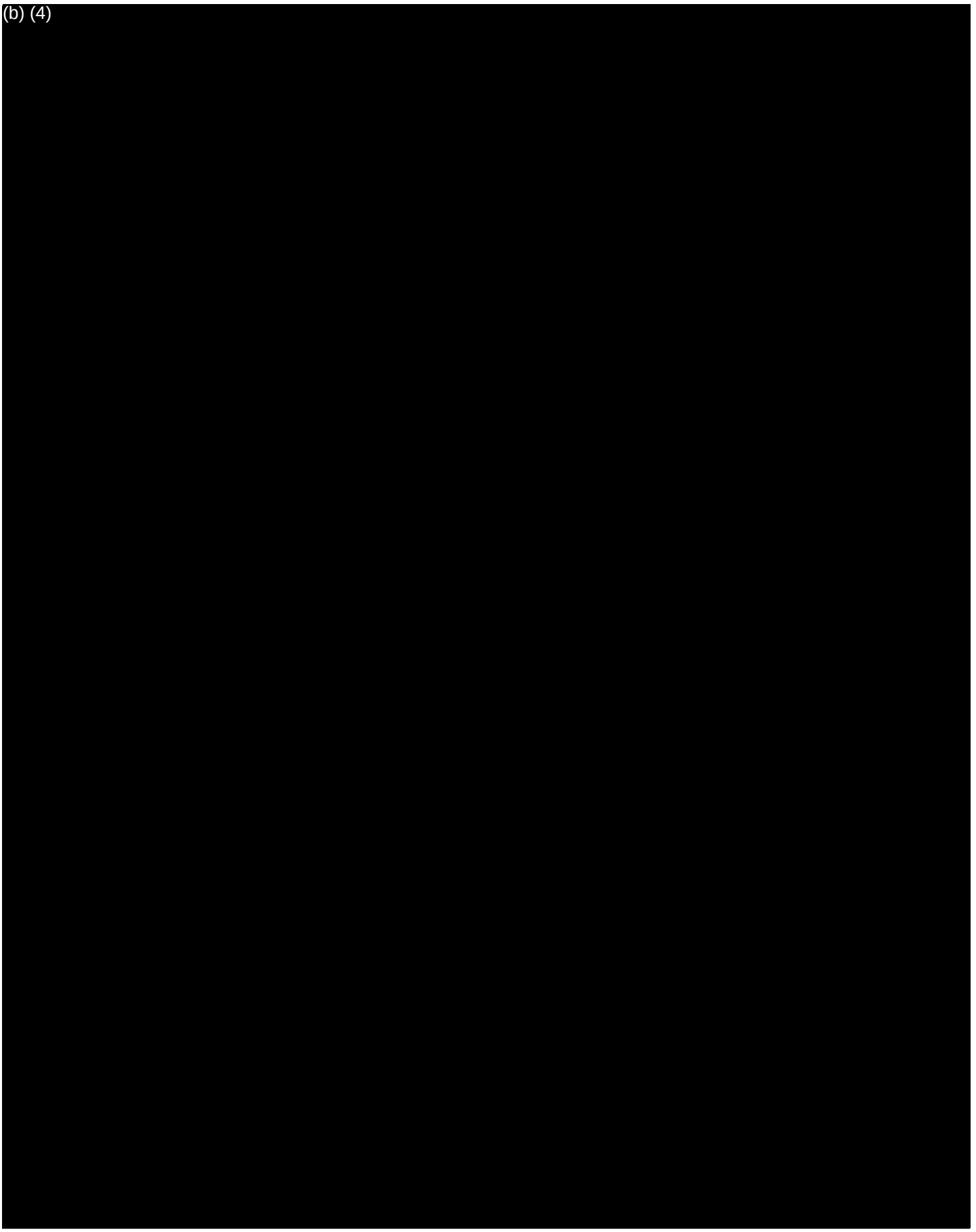

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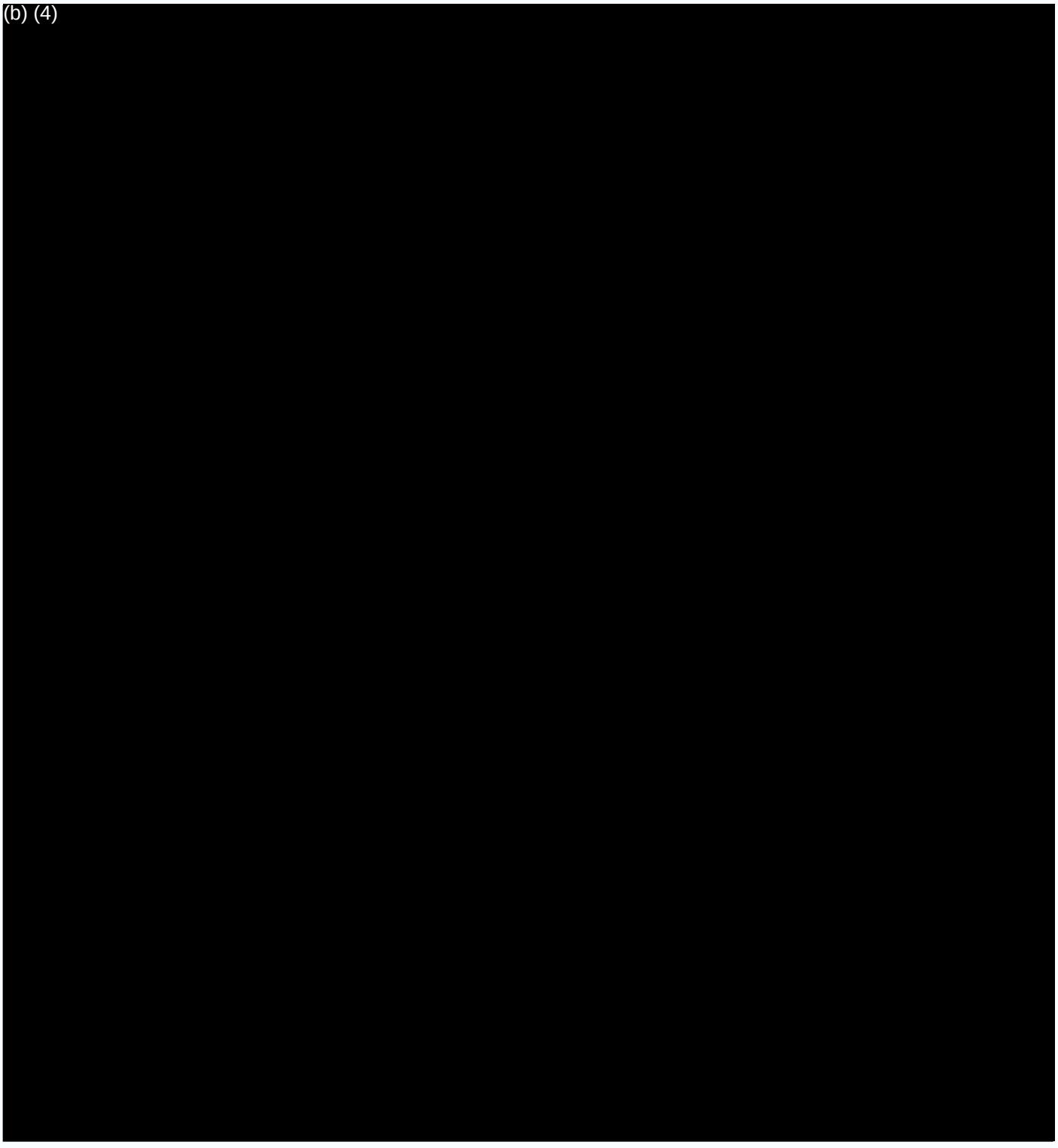

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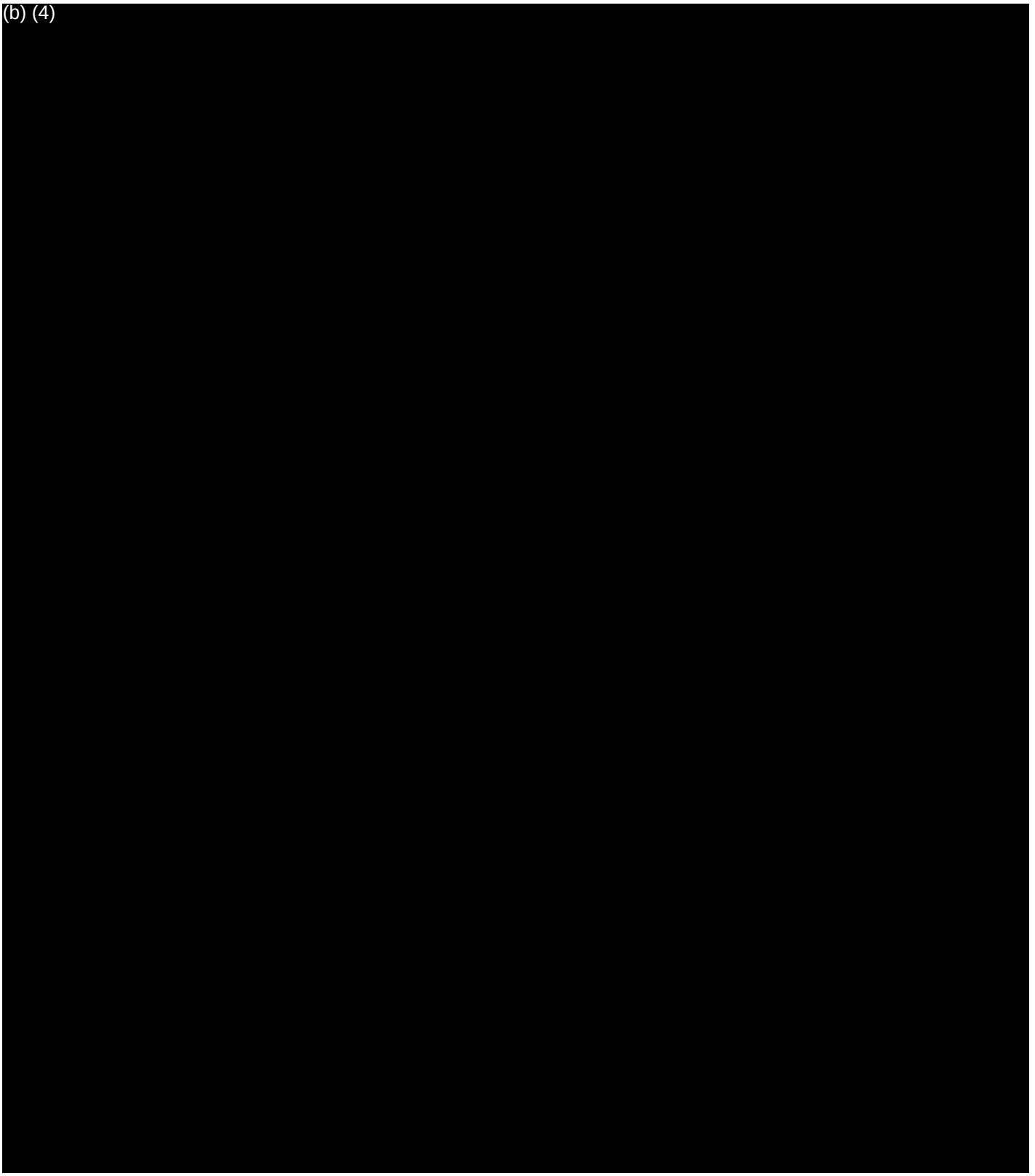

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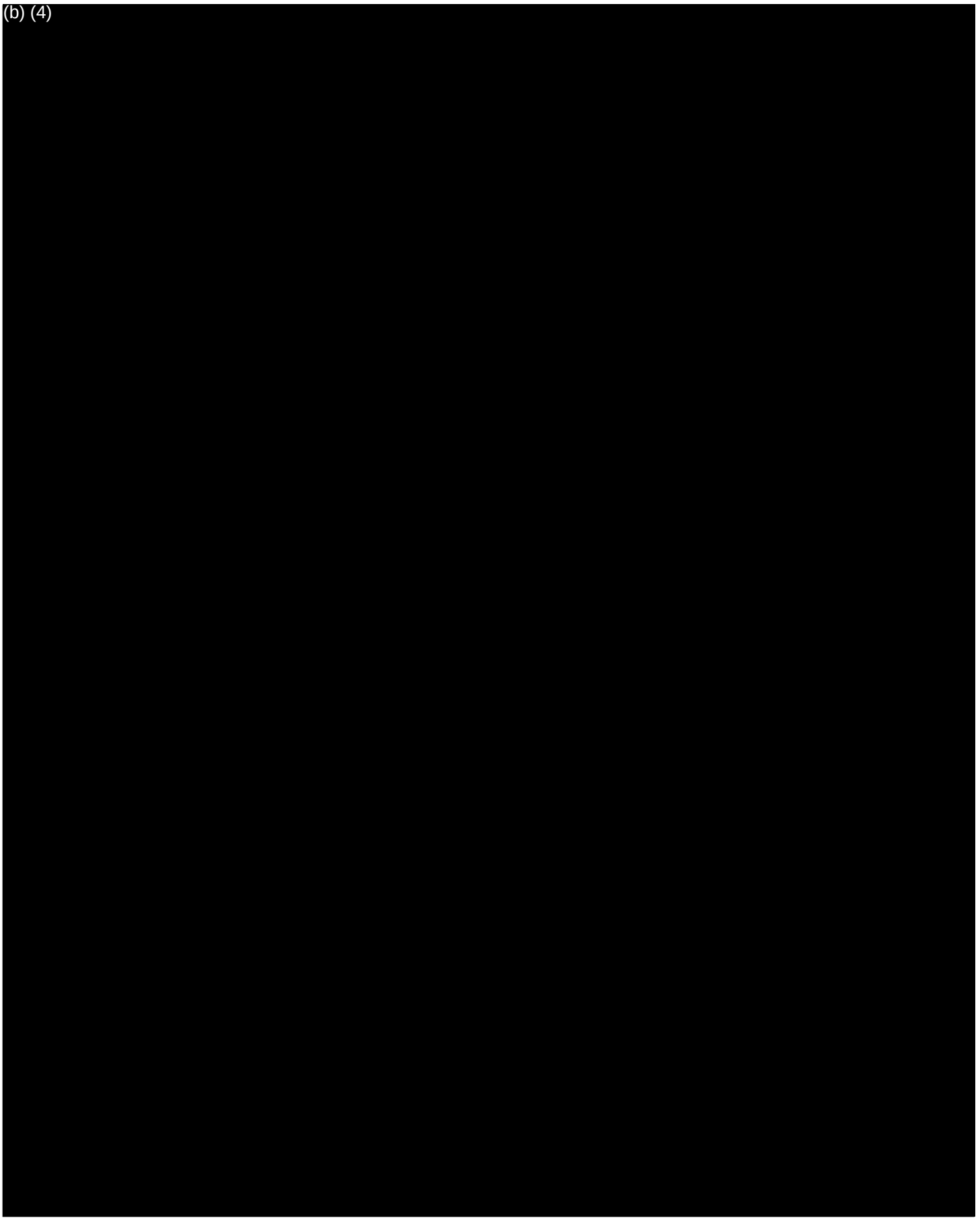

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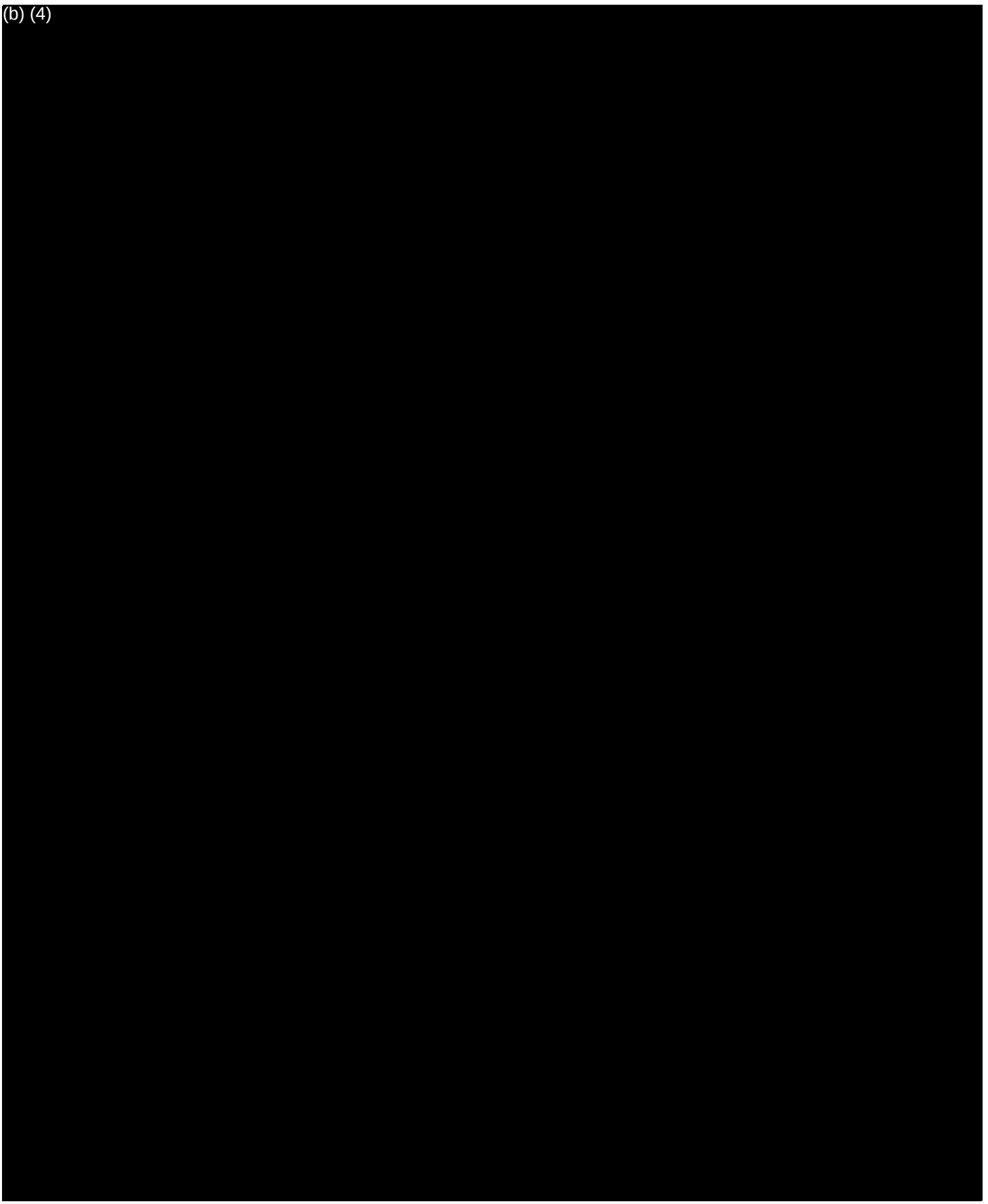

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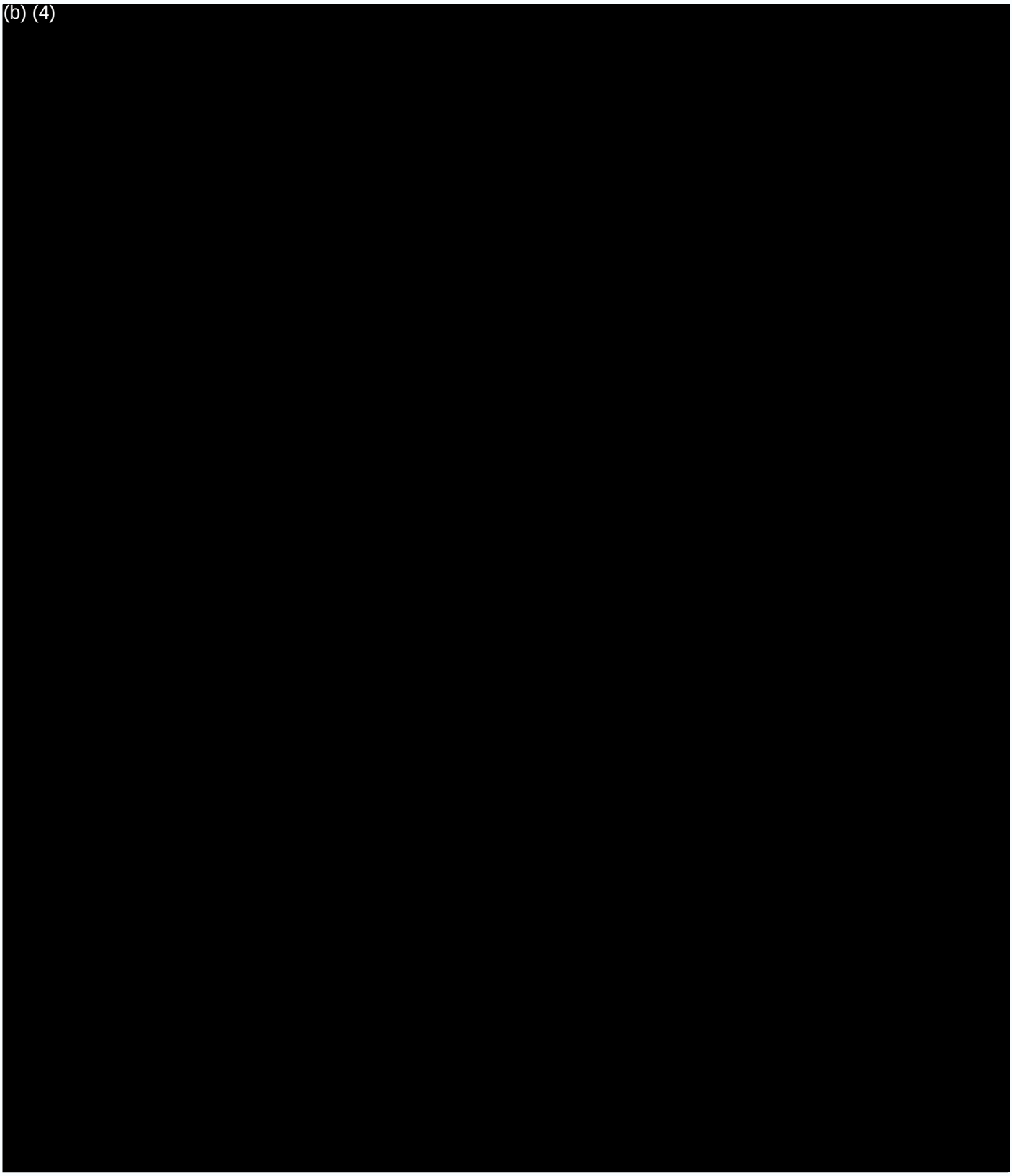

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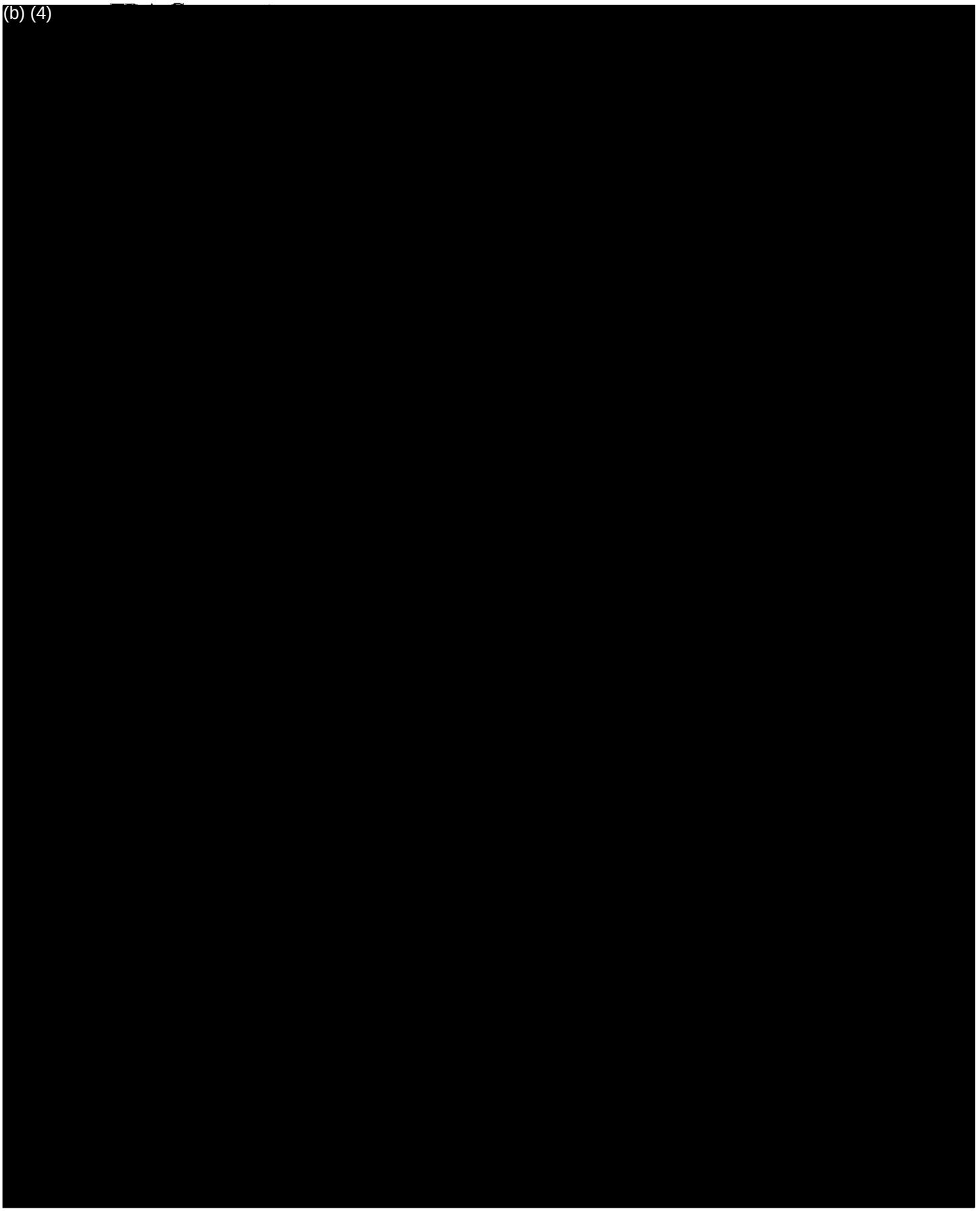

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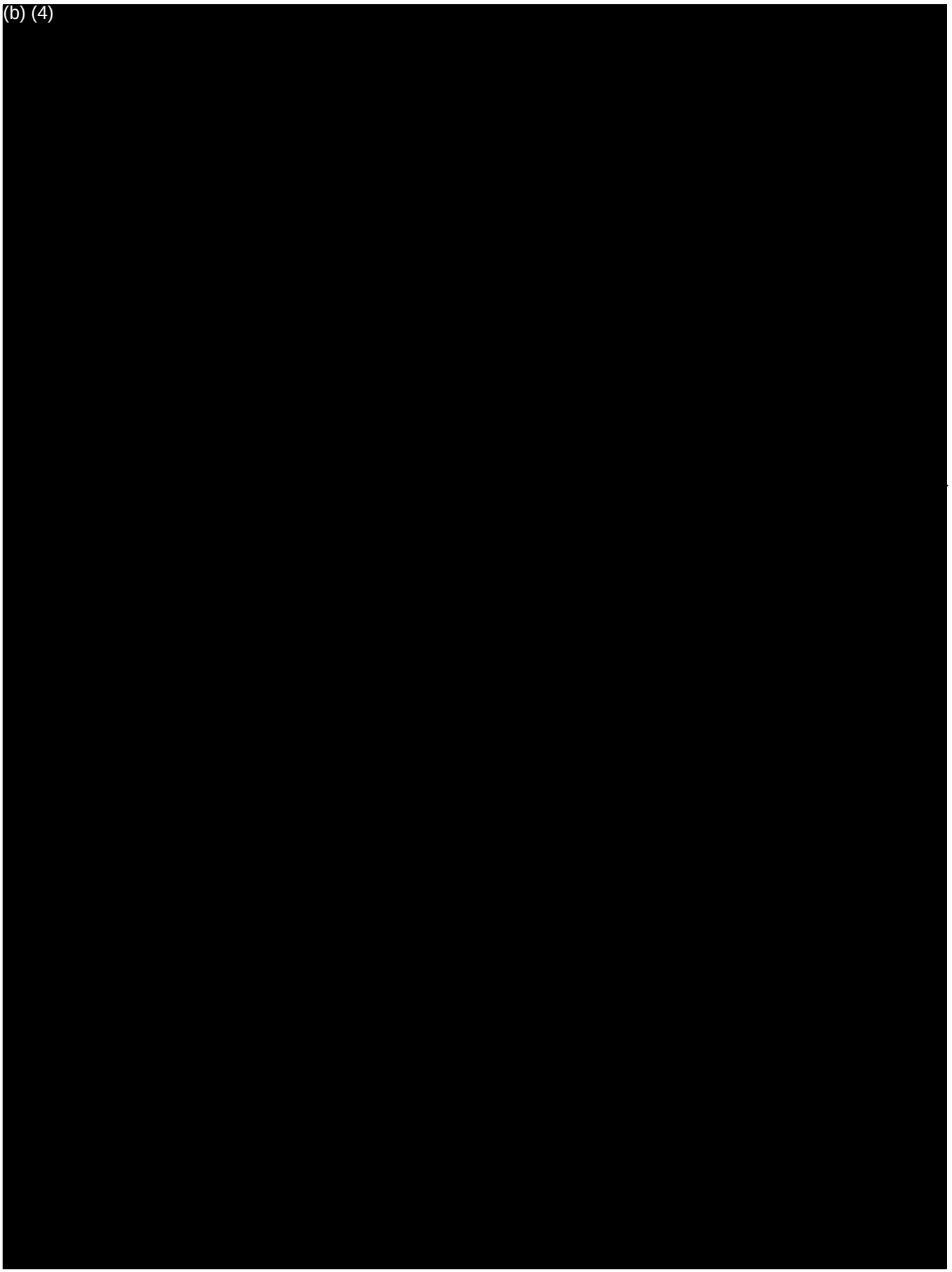

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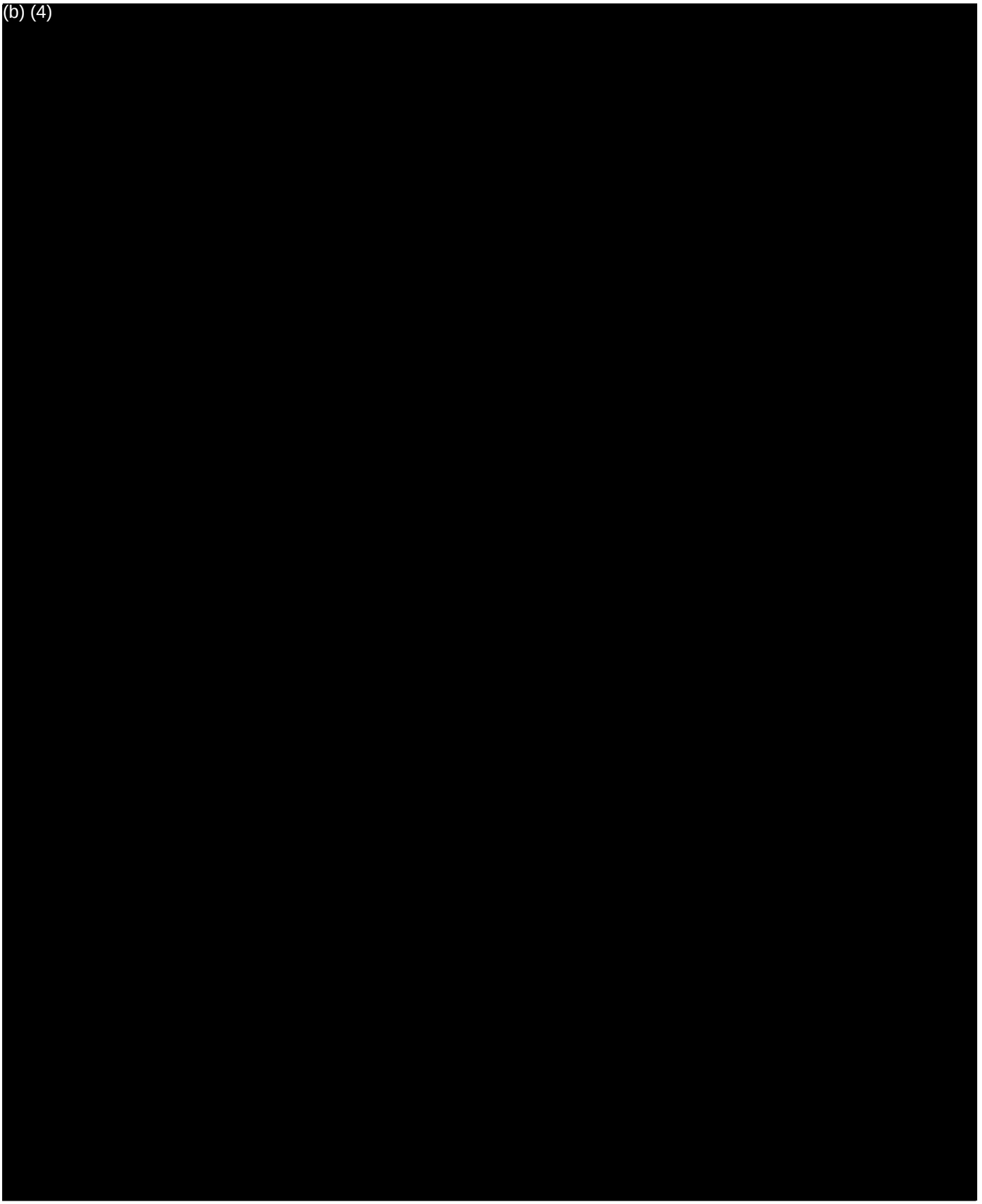

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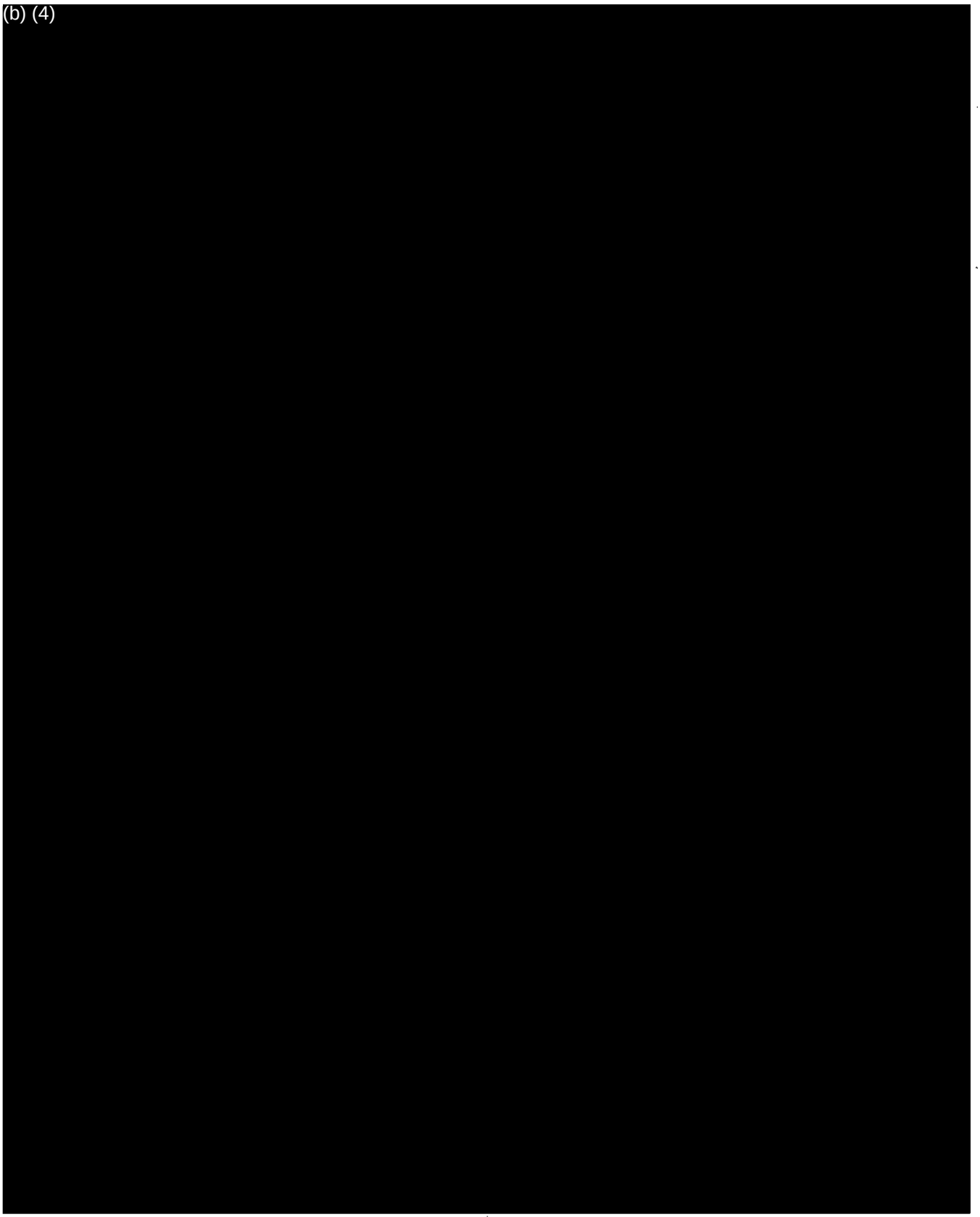

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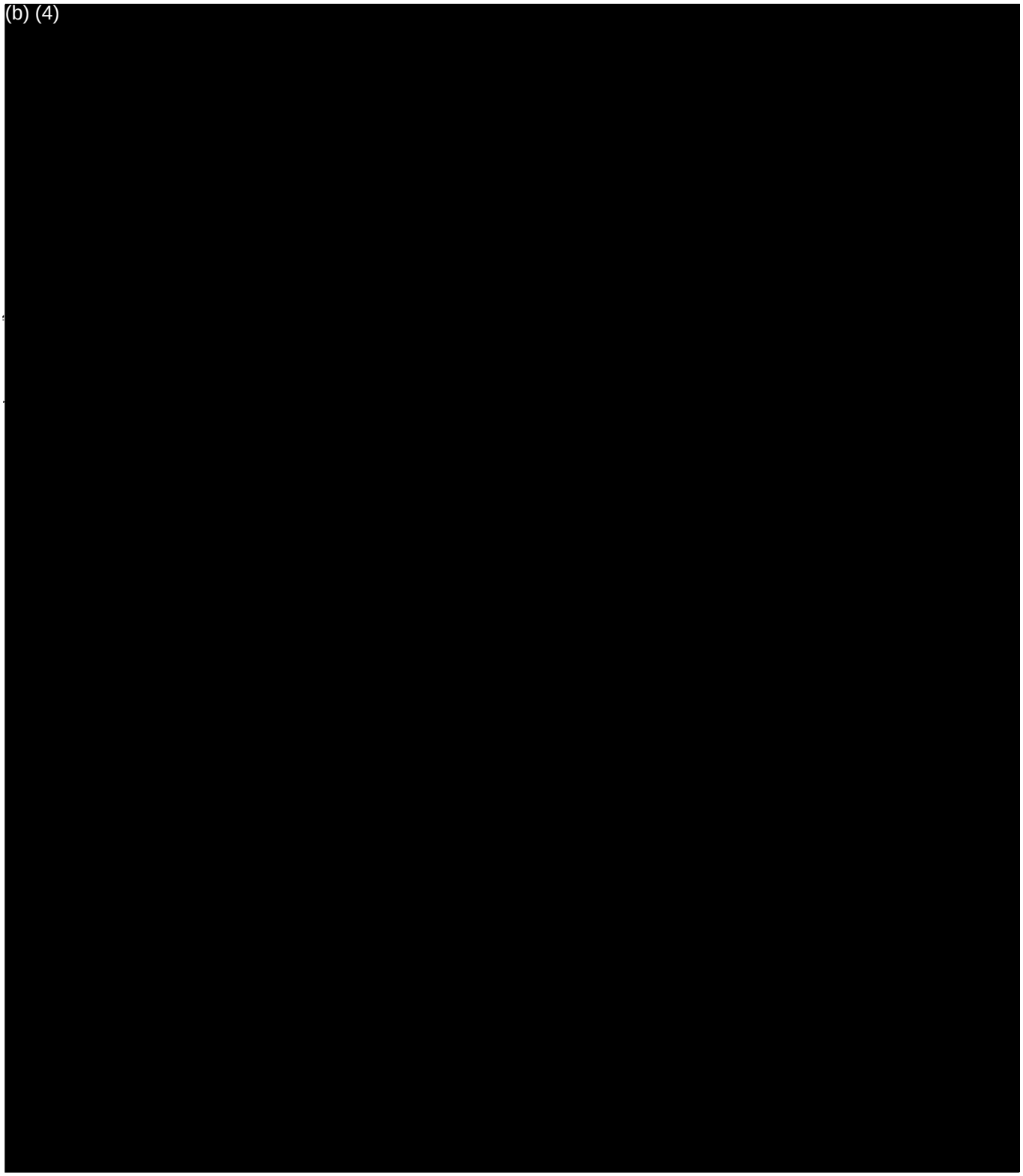

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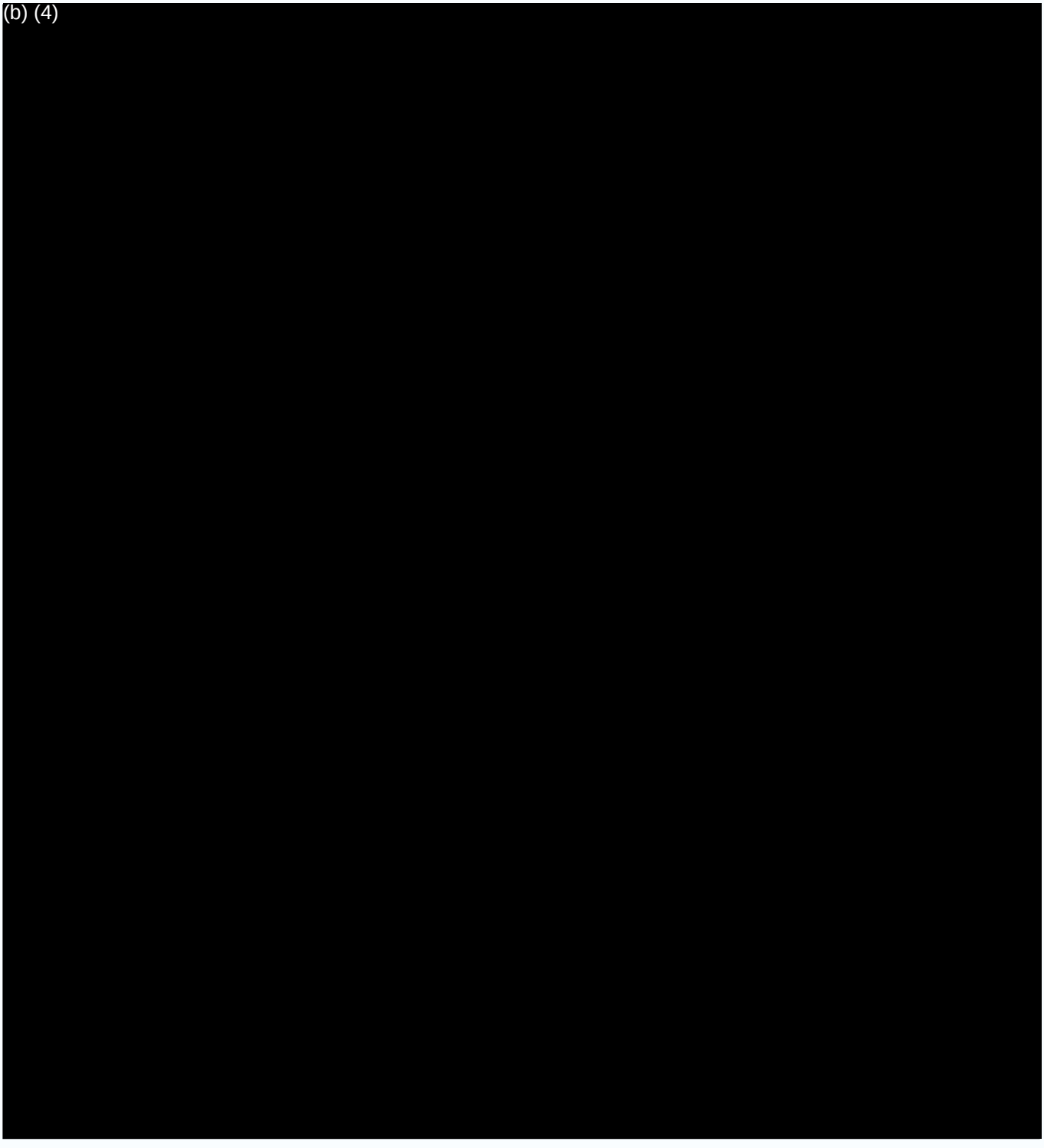

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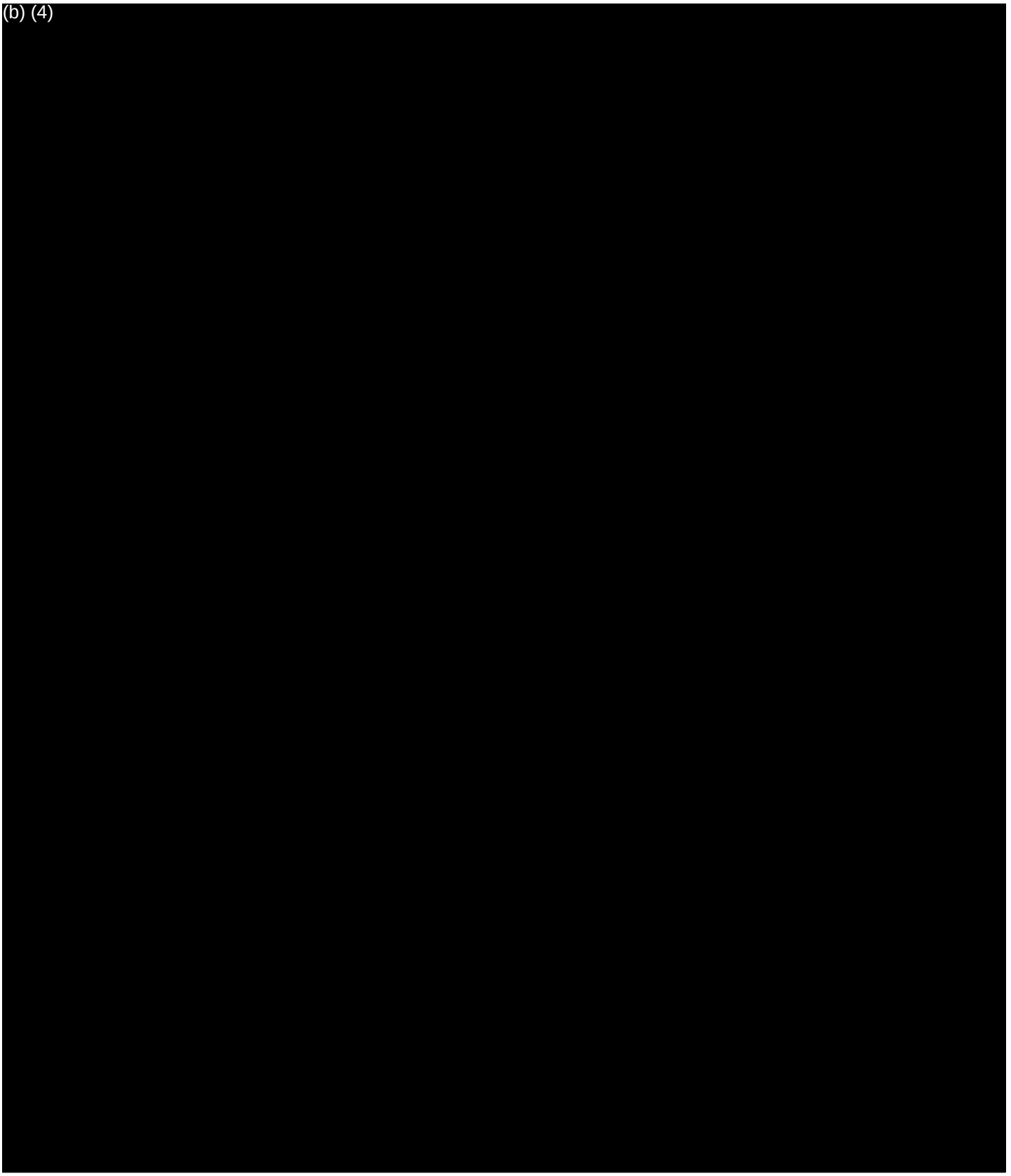

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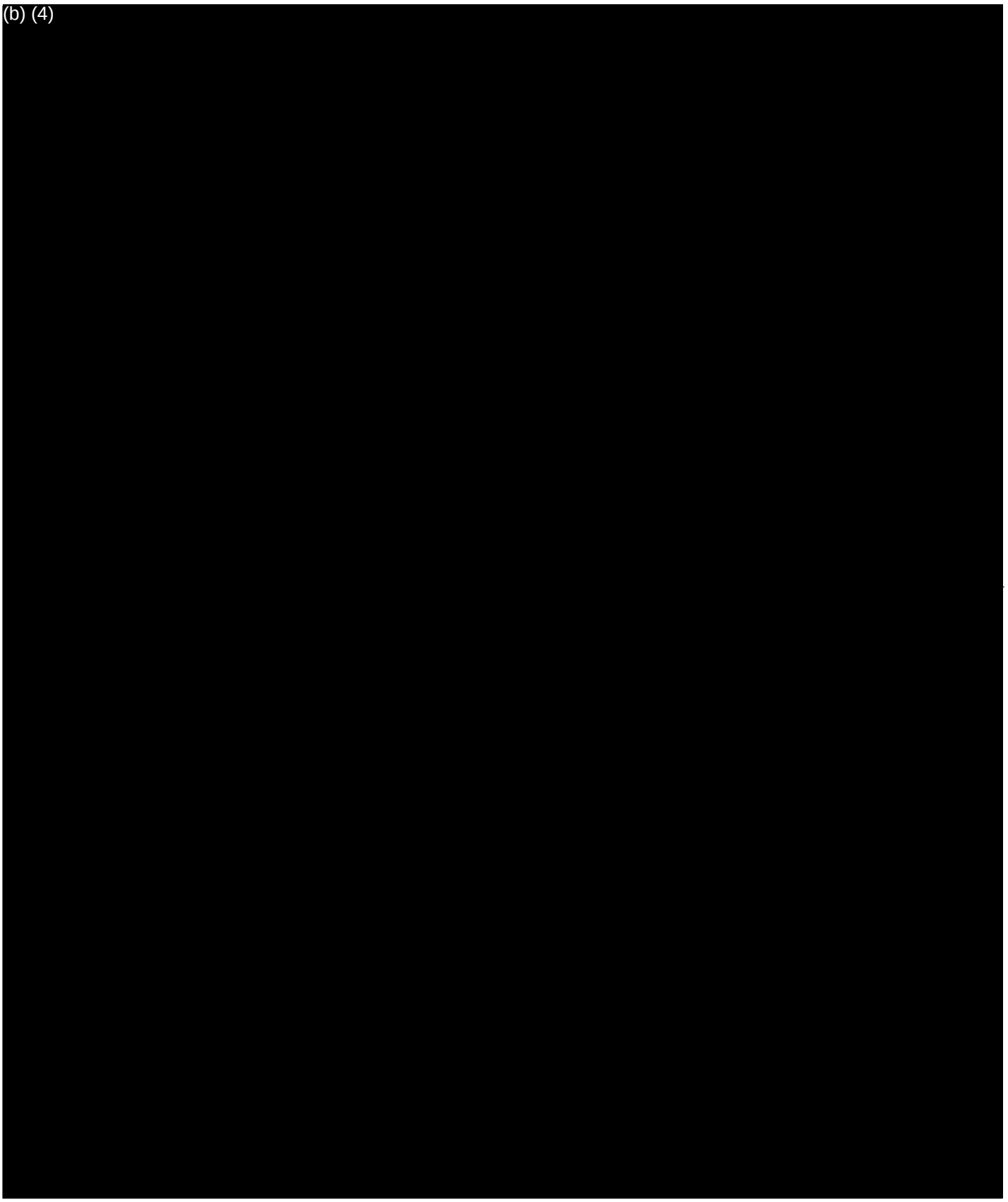

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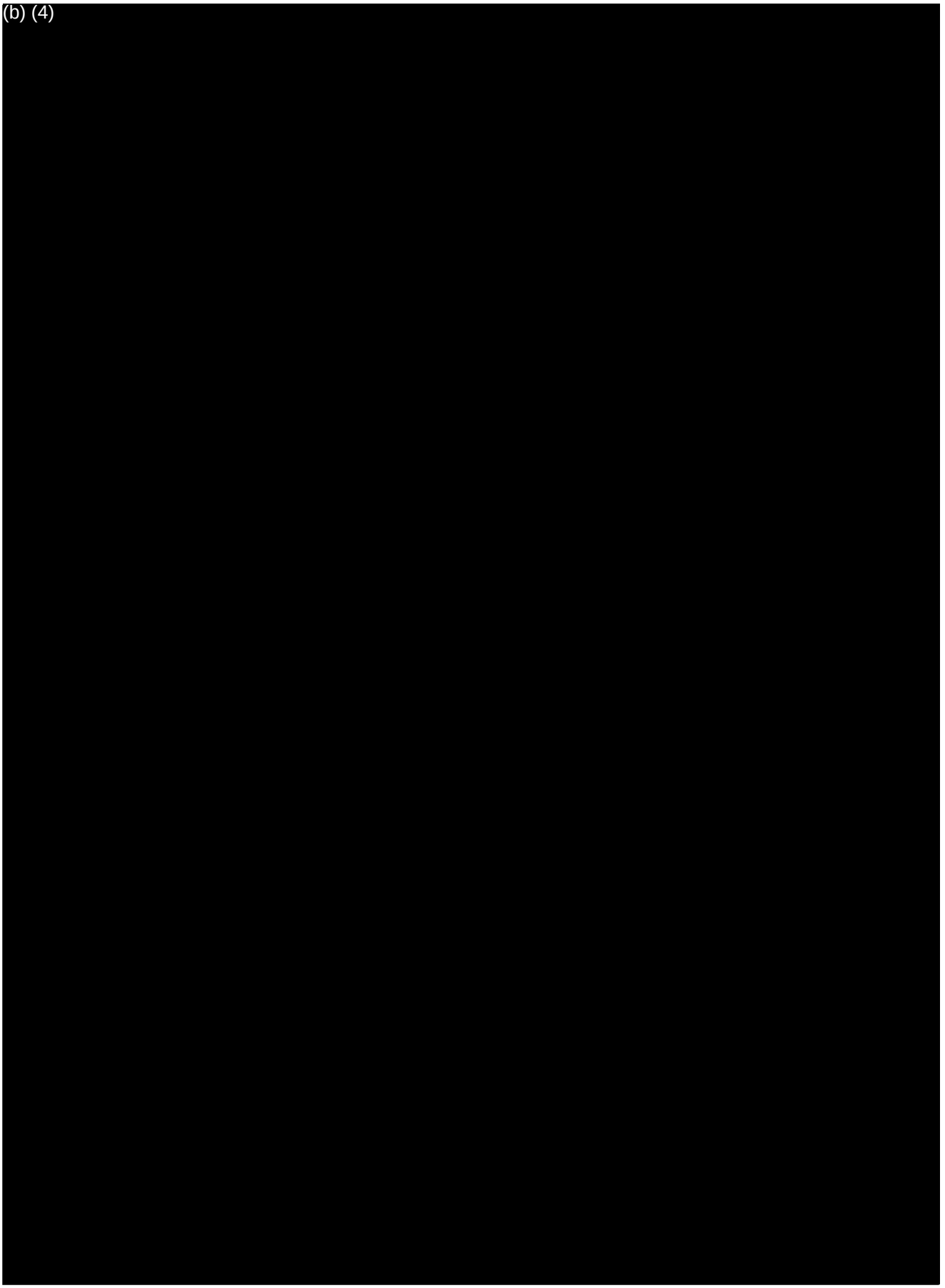

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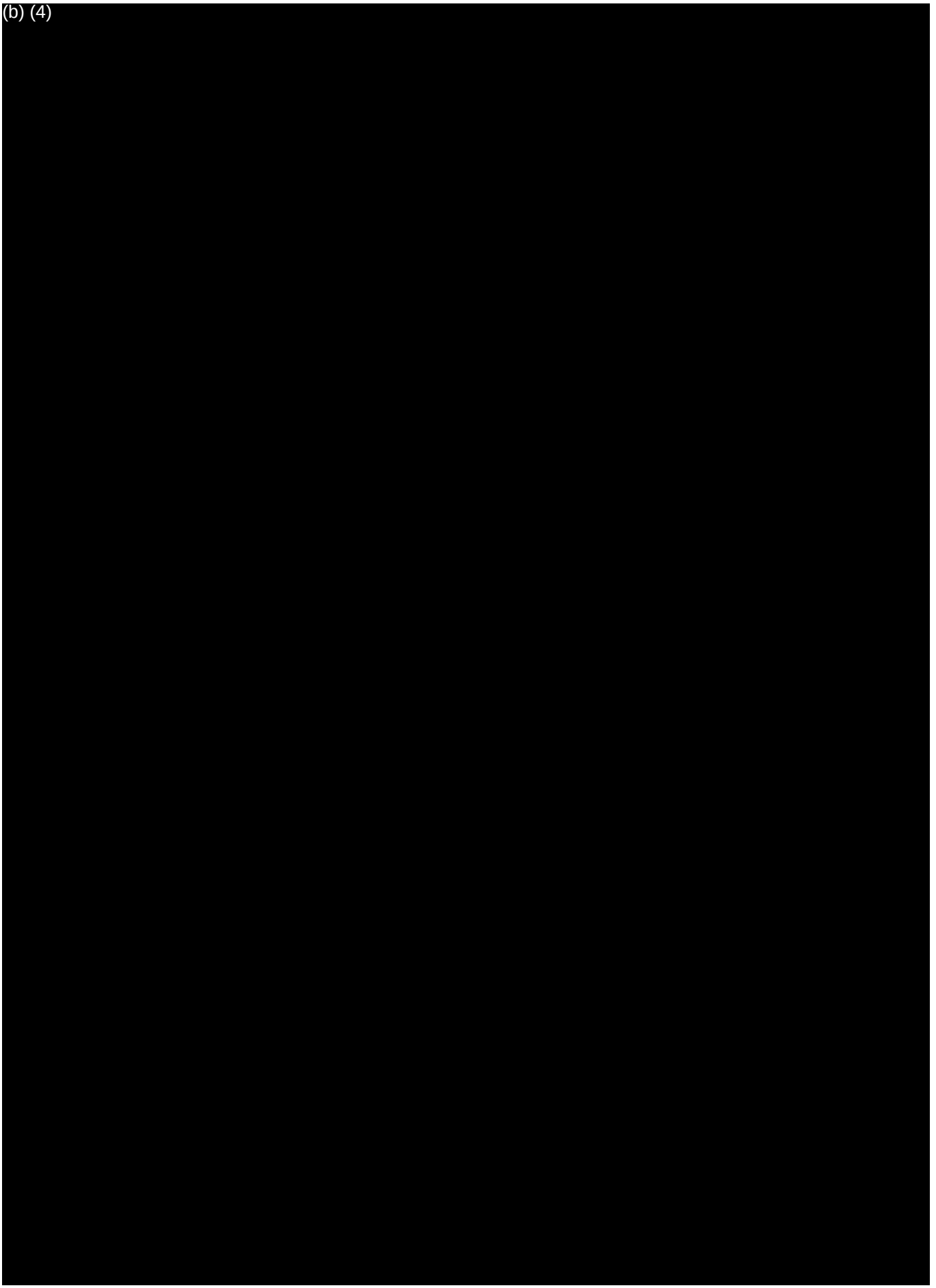

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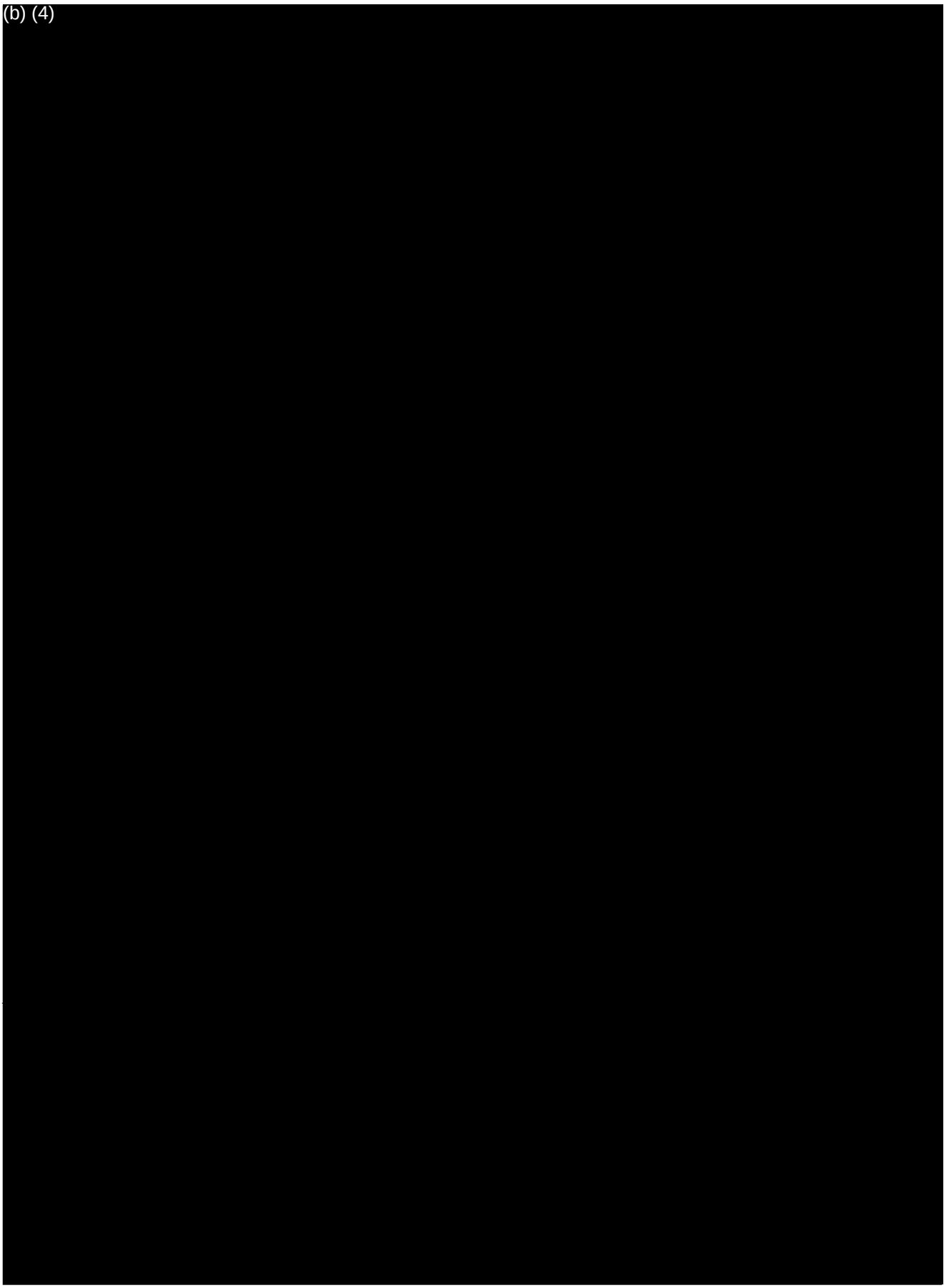

DJA x00212

(b) (4)

DJA x00213

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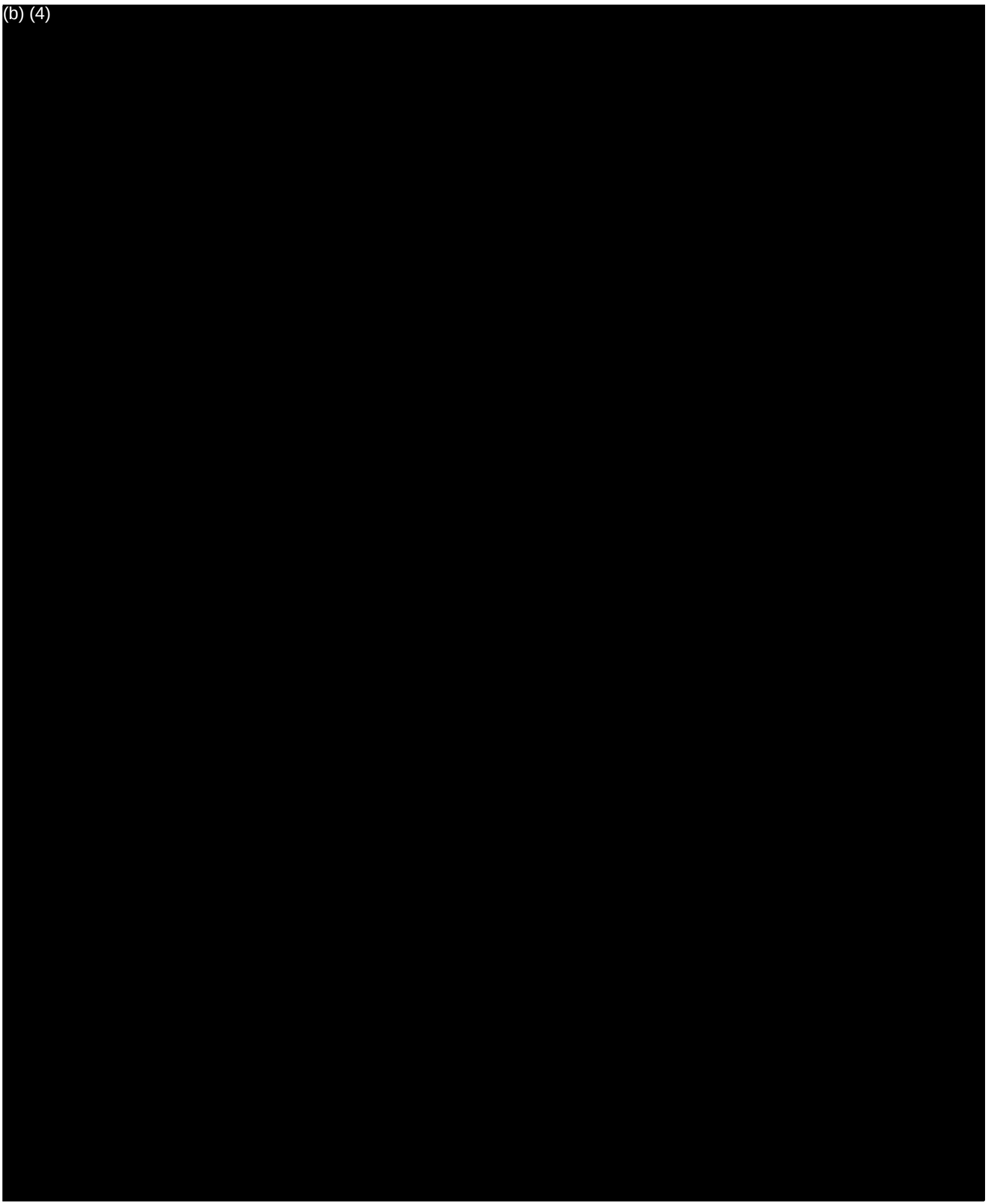

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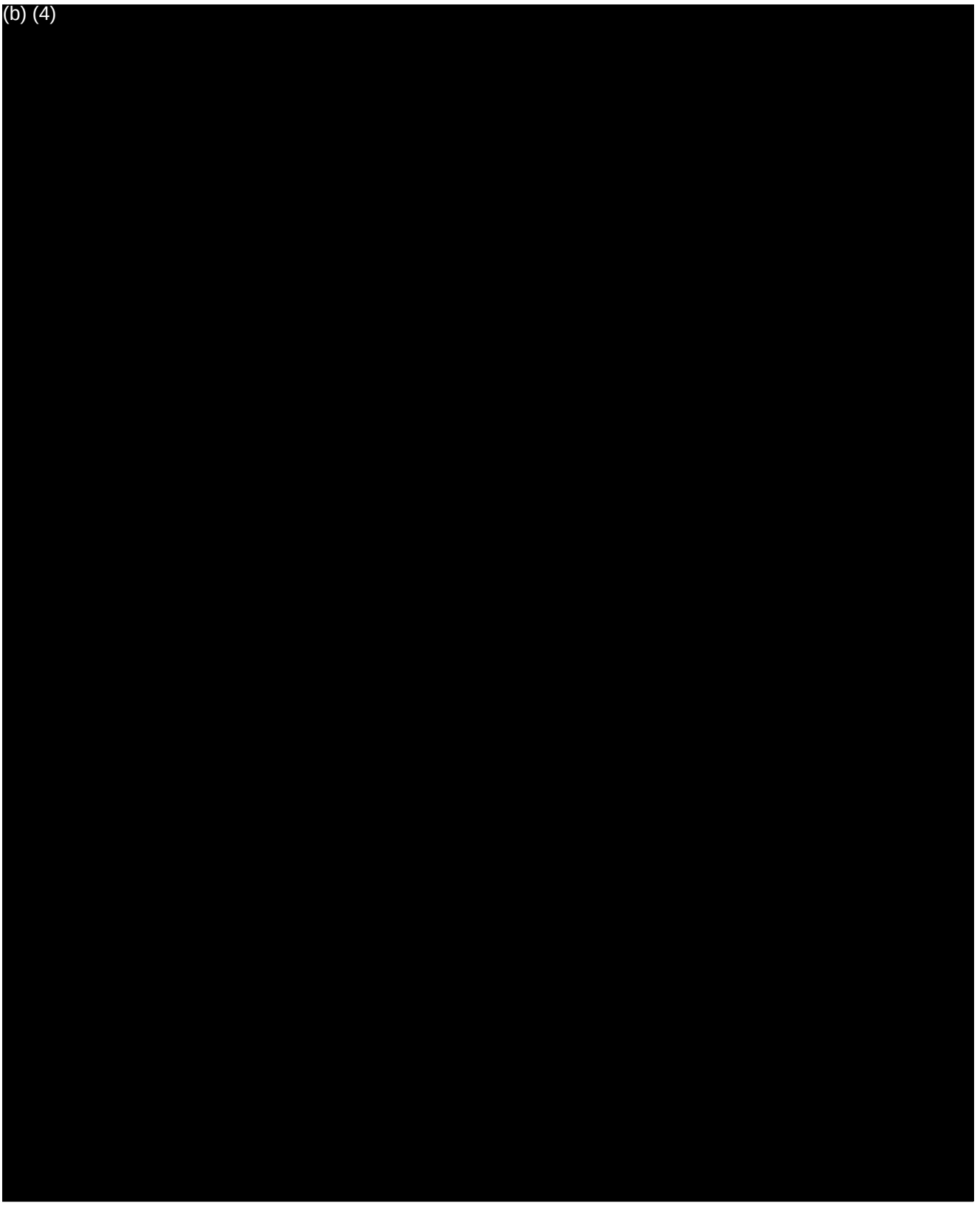

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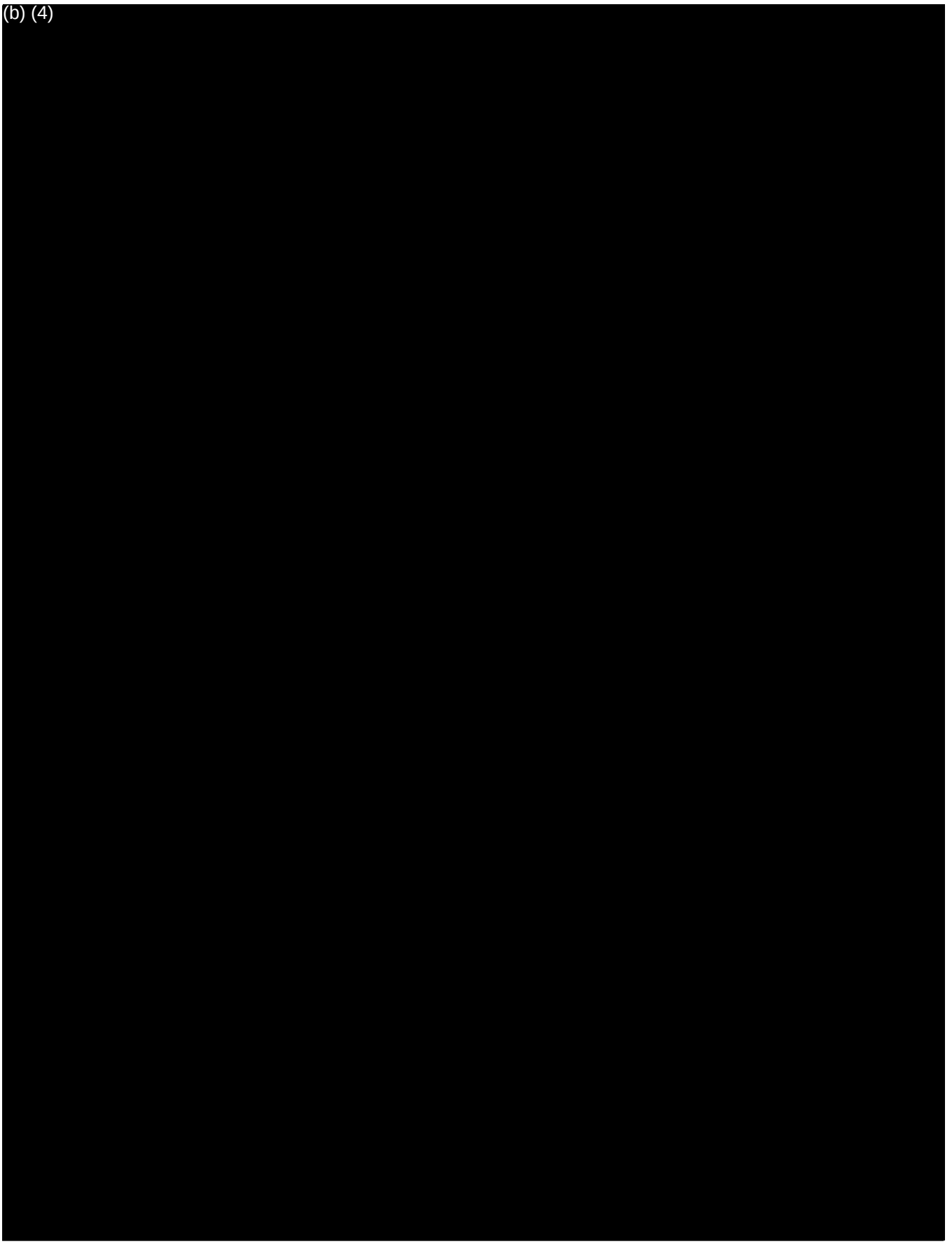

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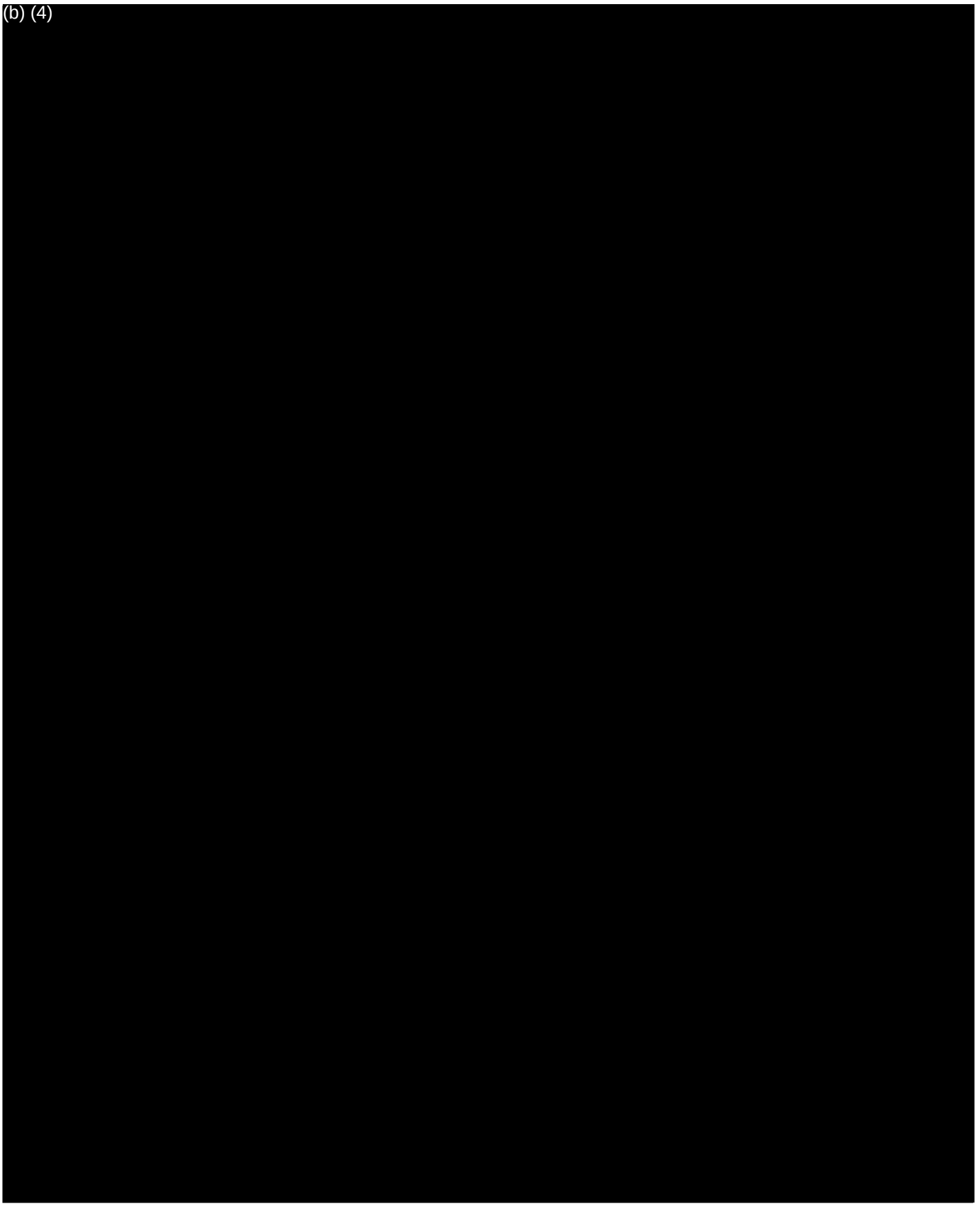

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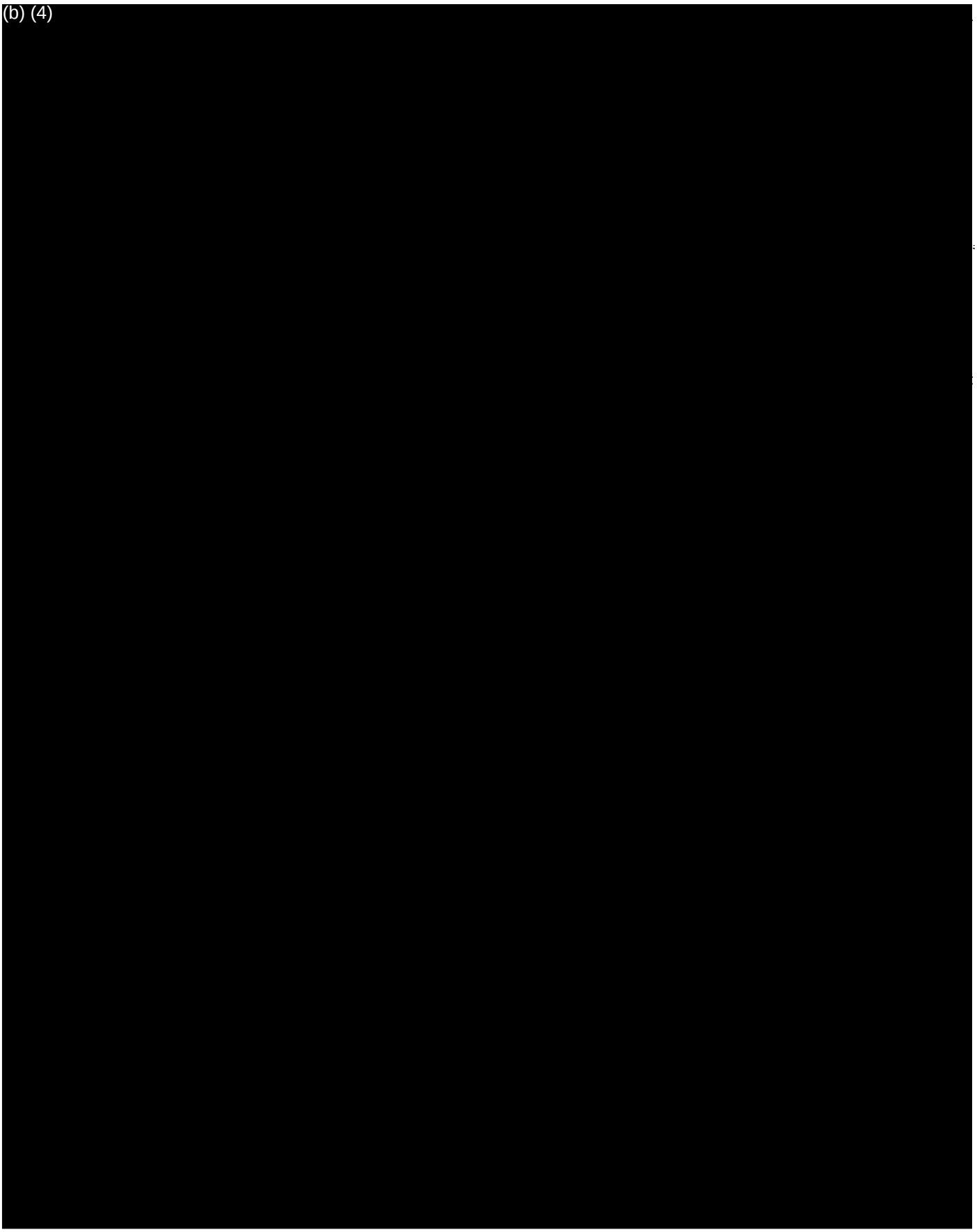

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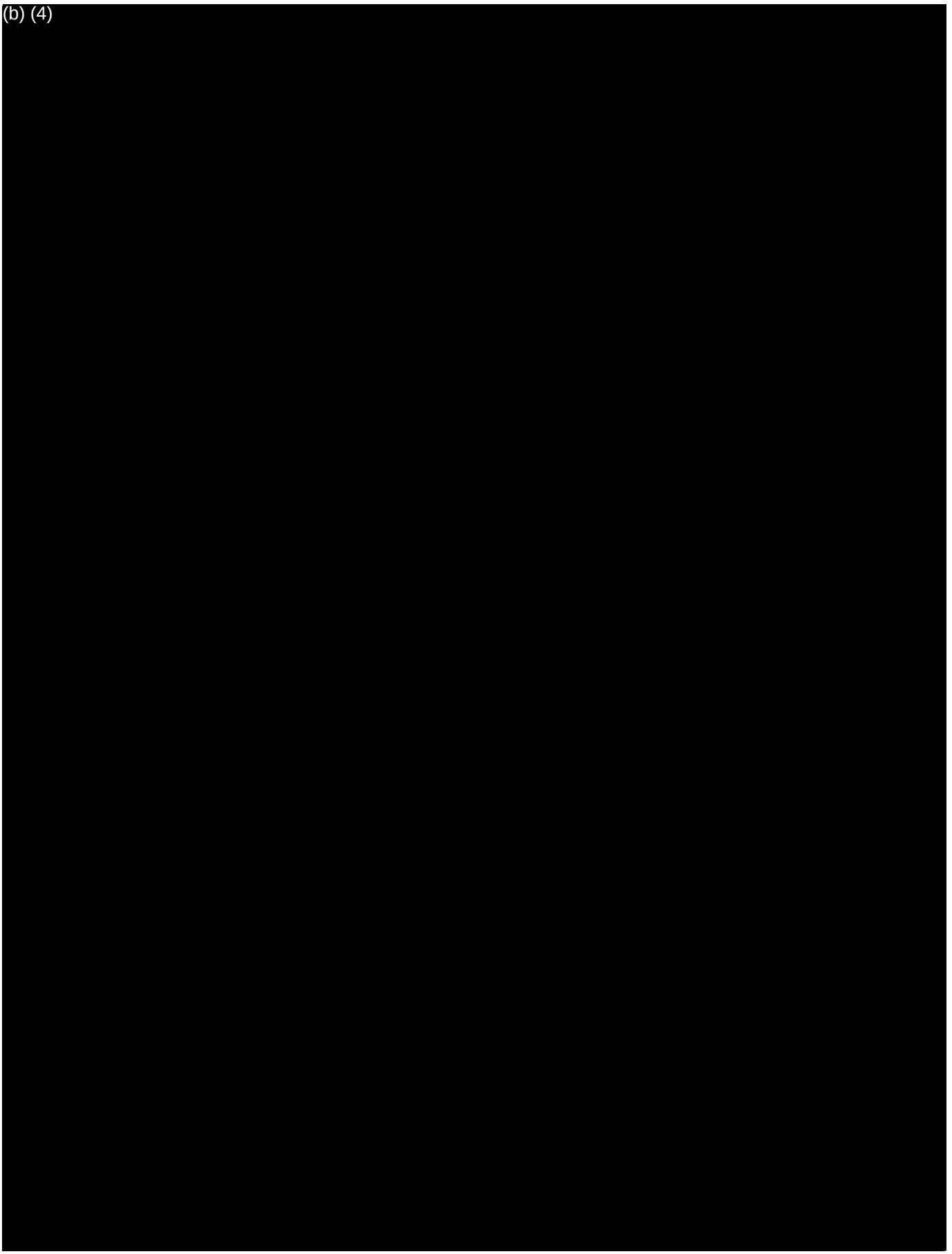

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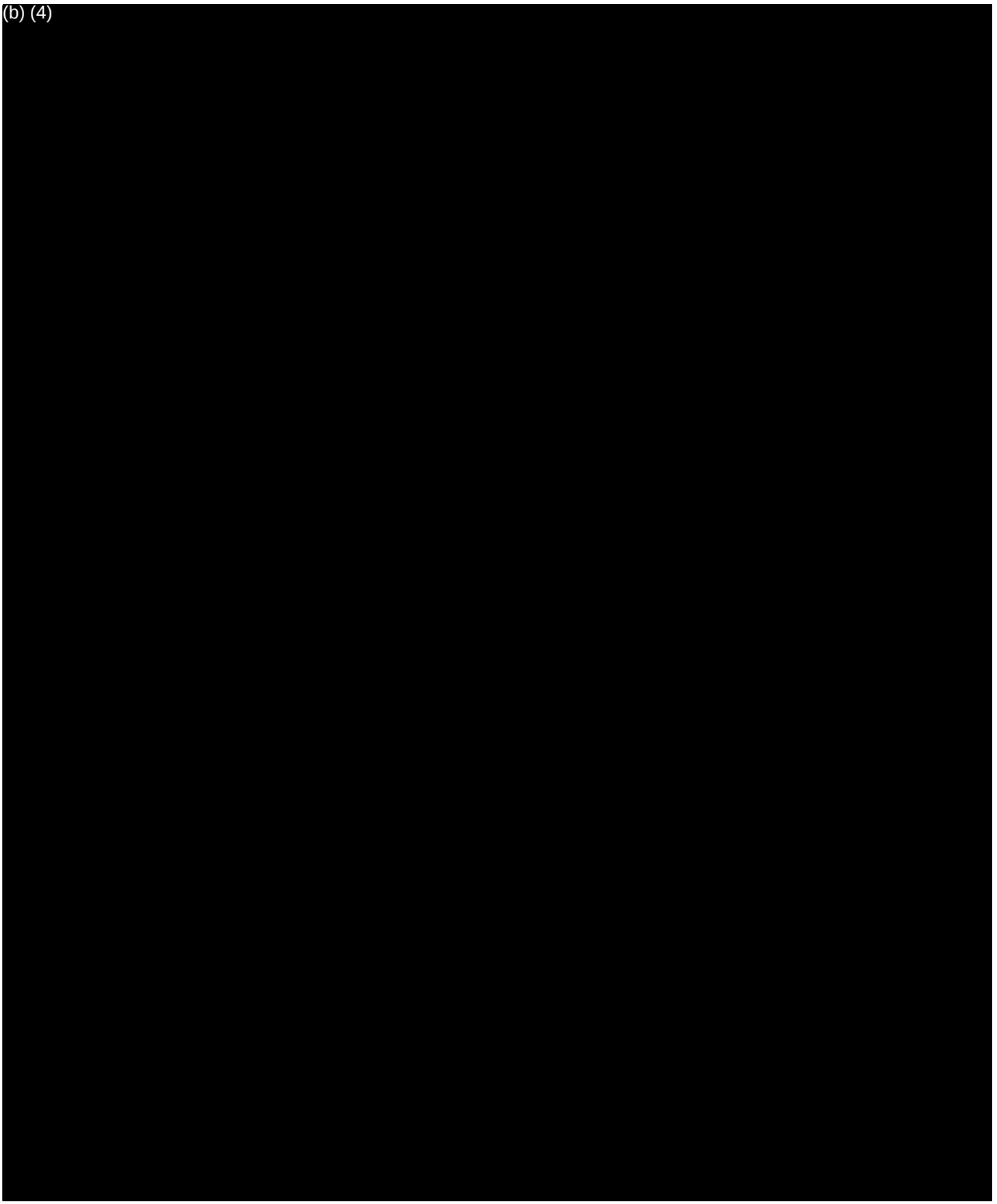

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DJA x00221

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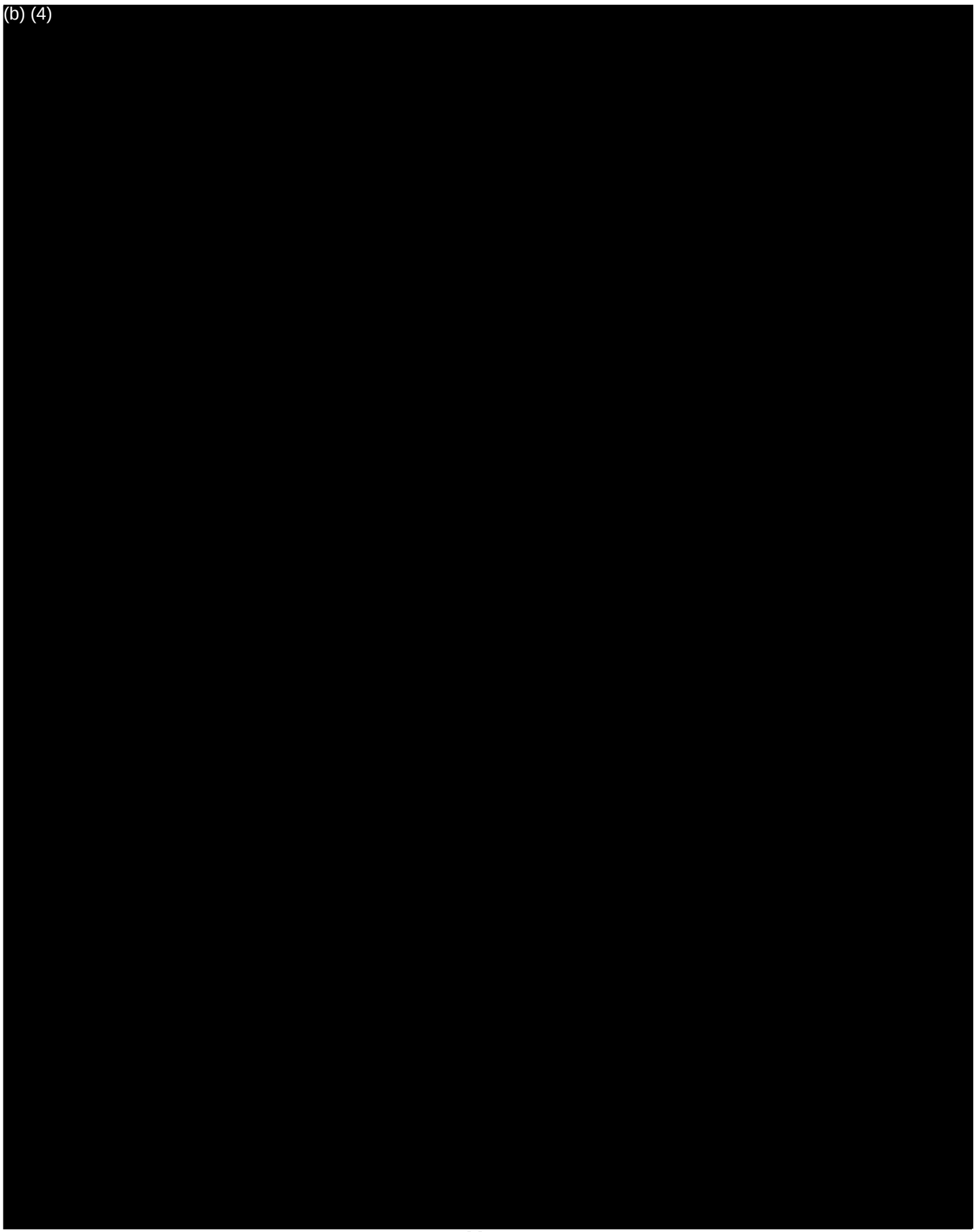

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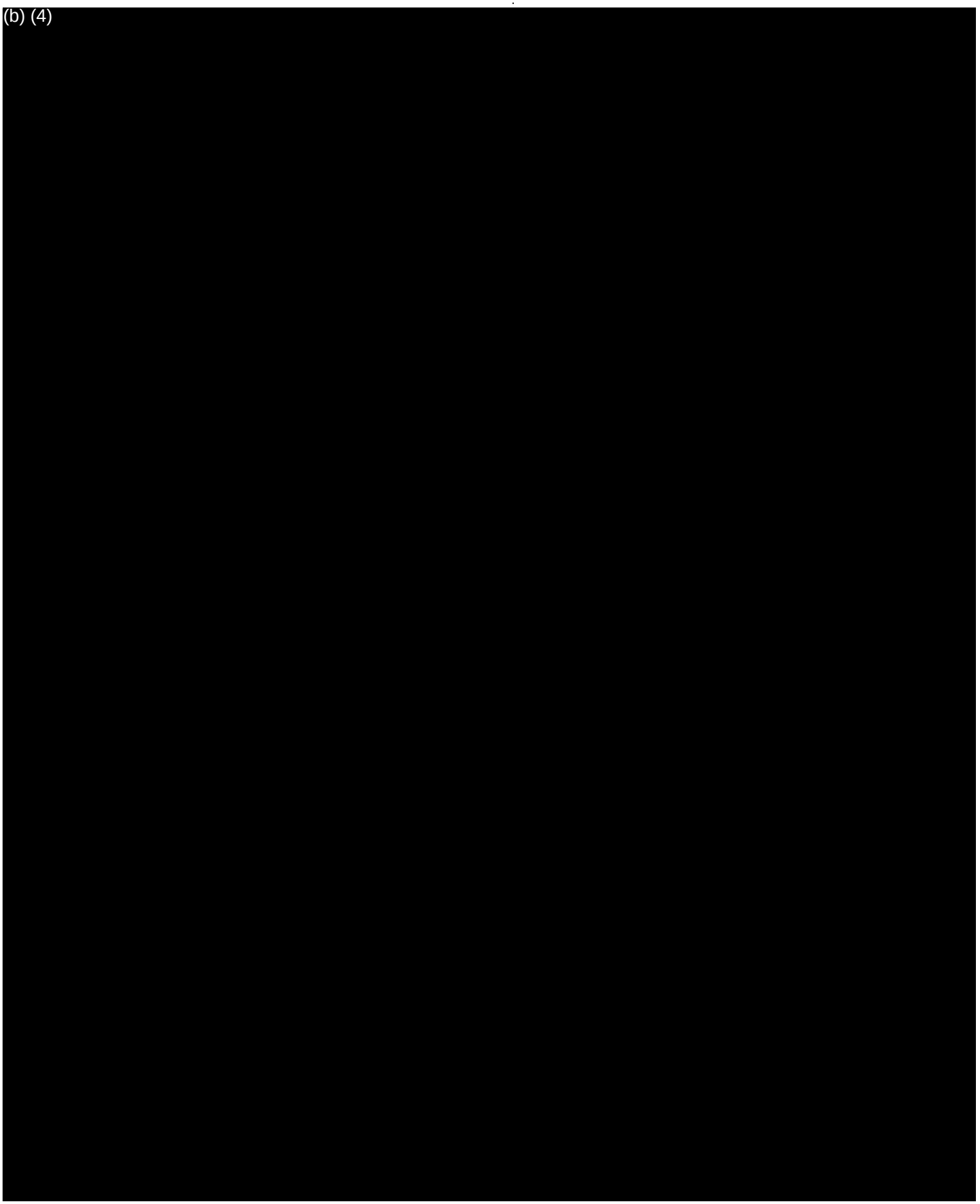

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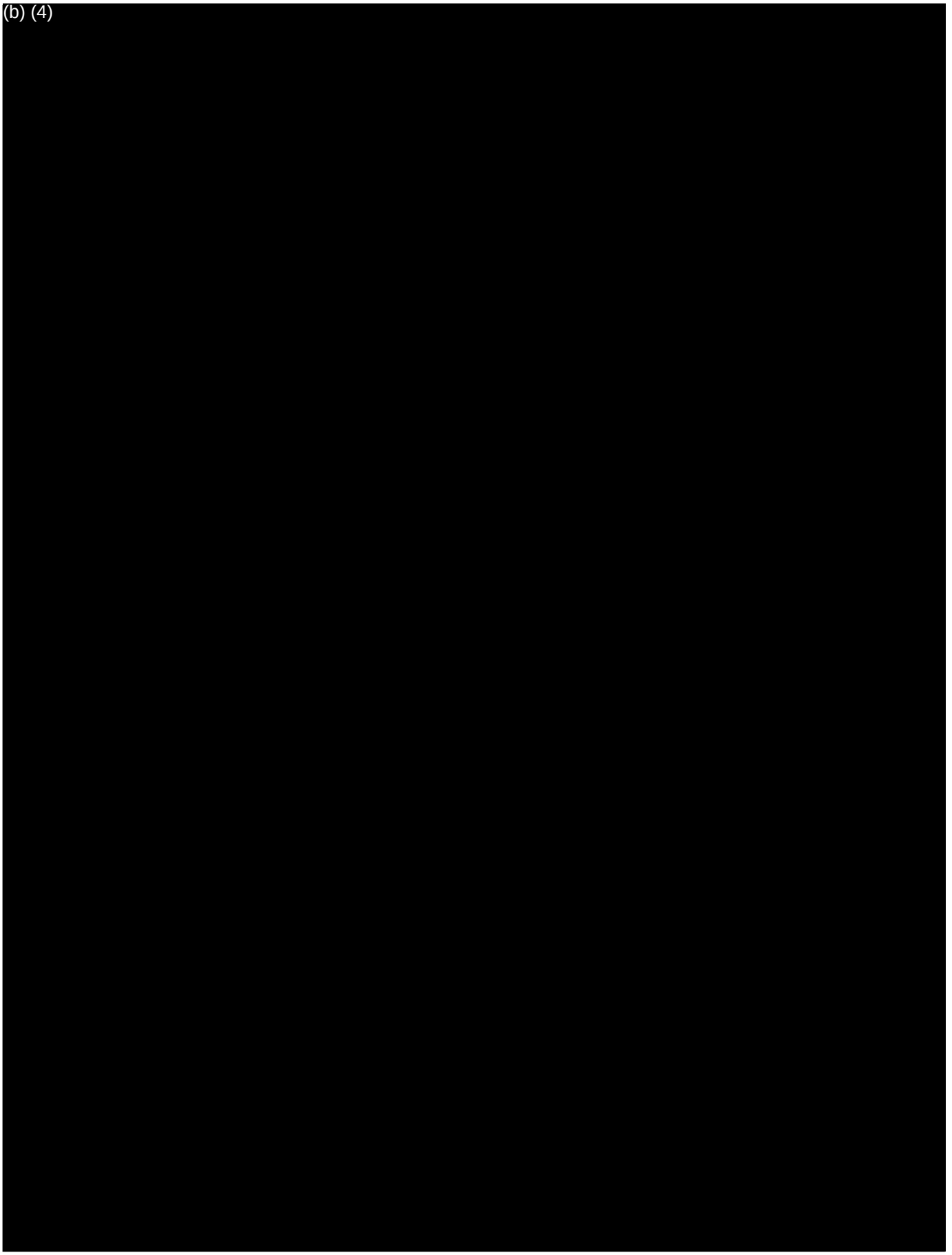

DJA x00224

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DJA x00225

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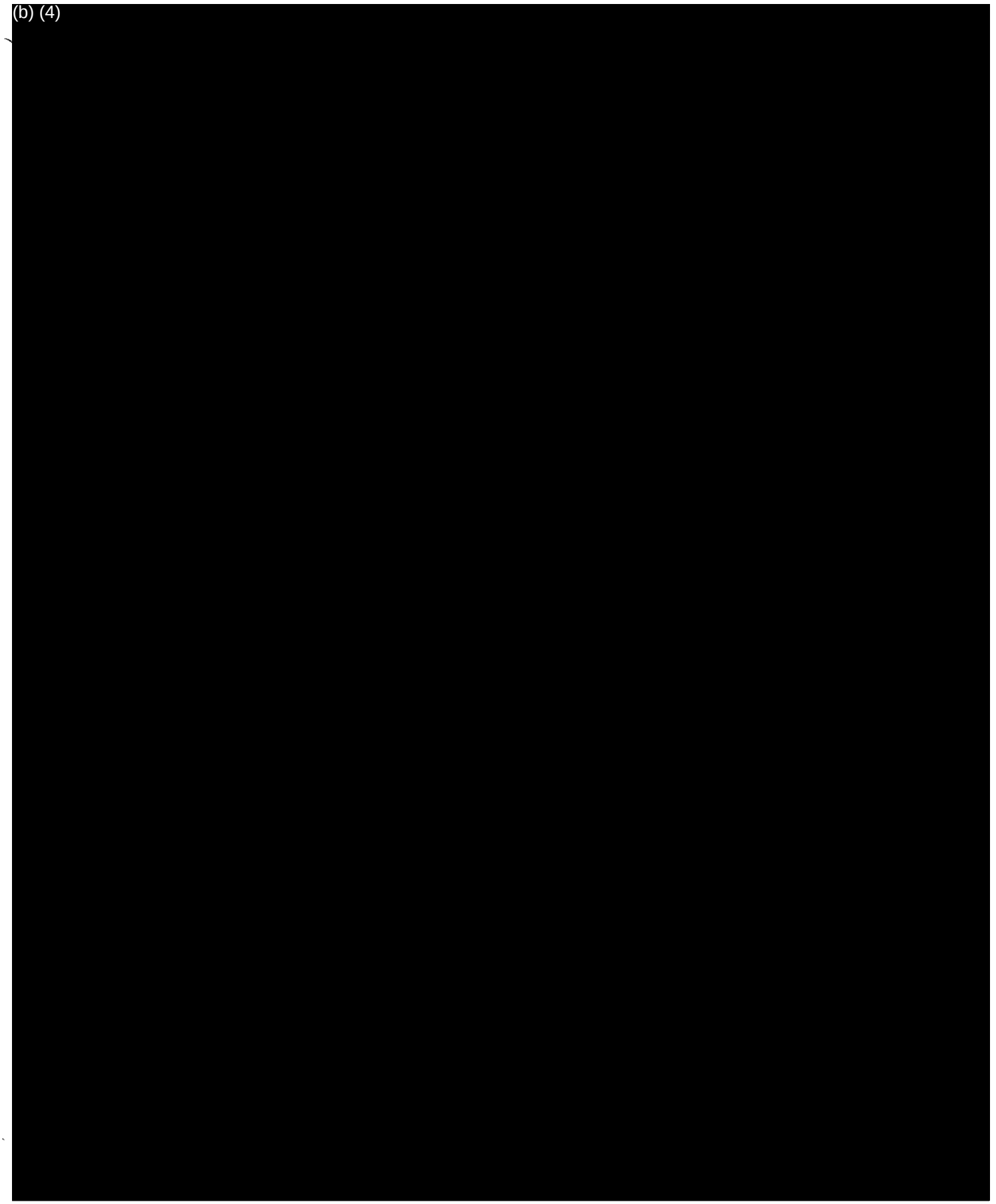

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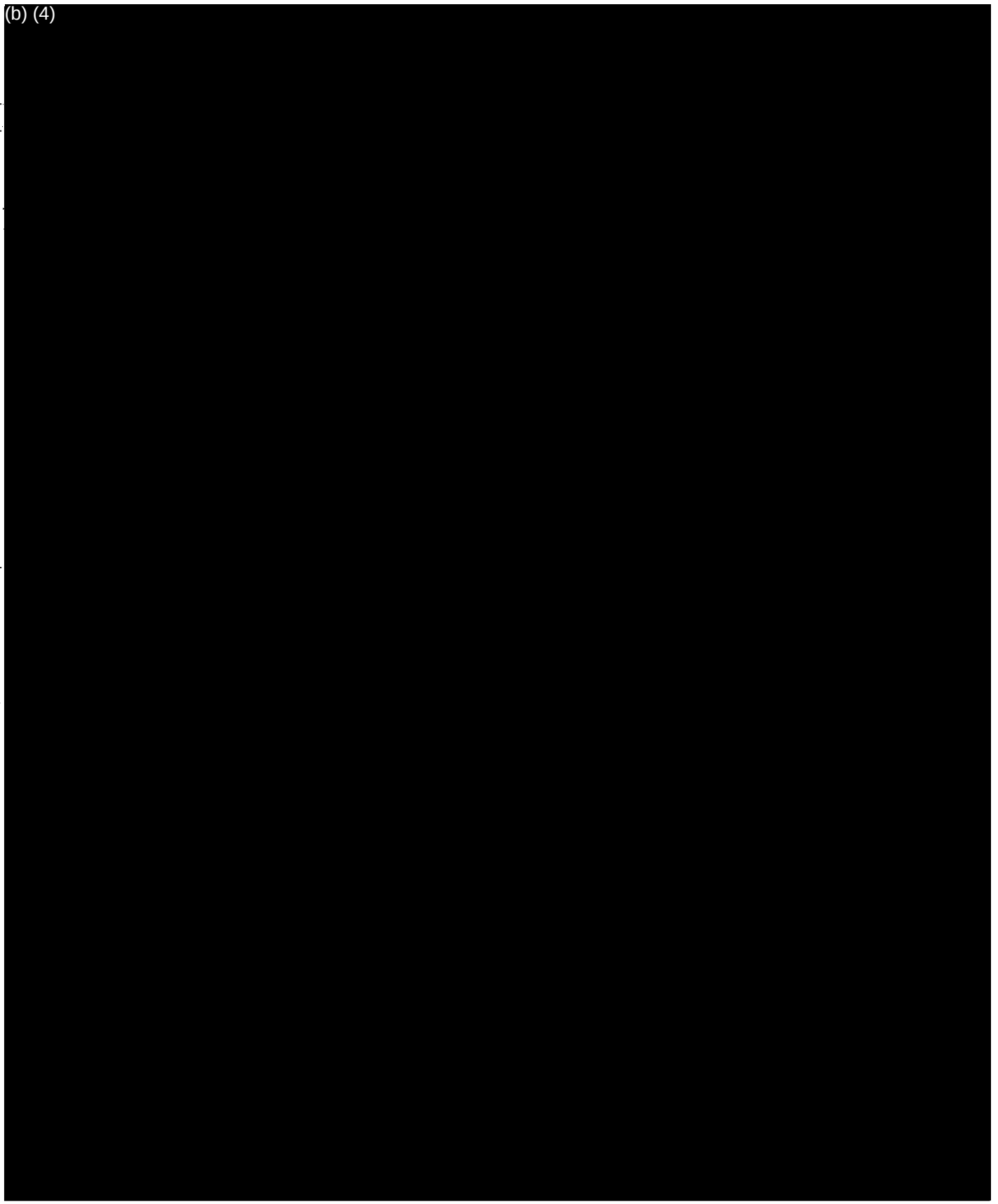

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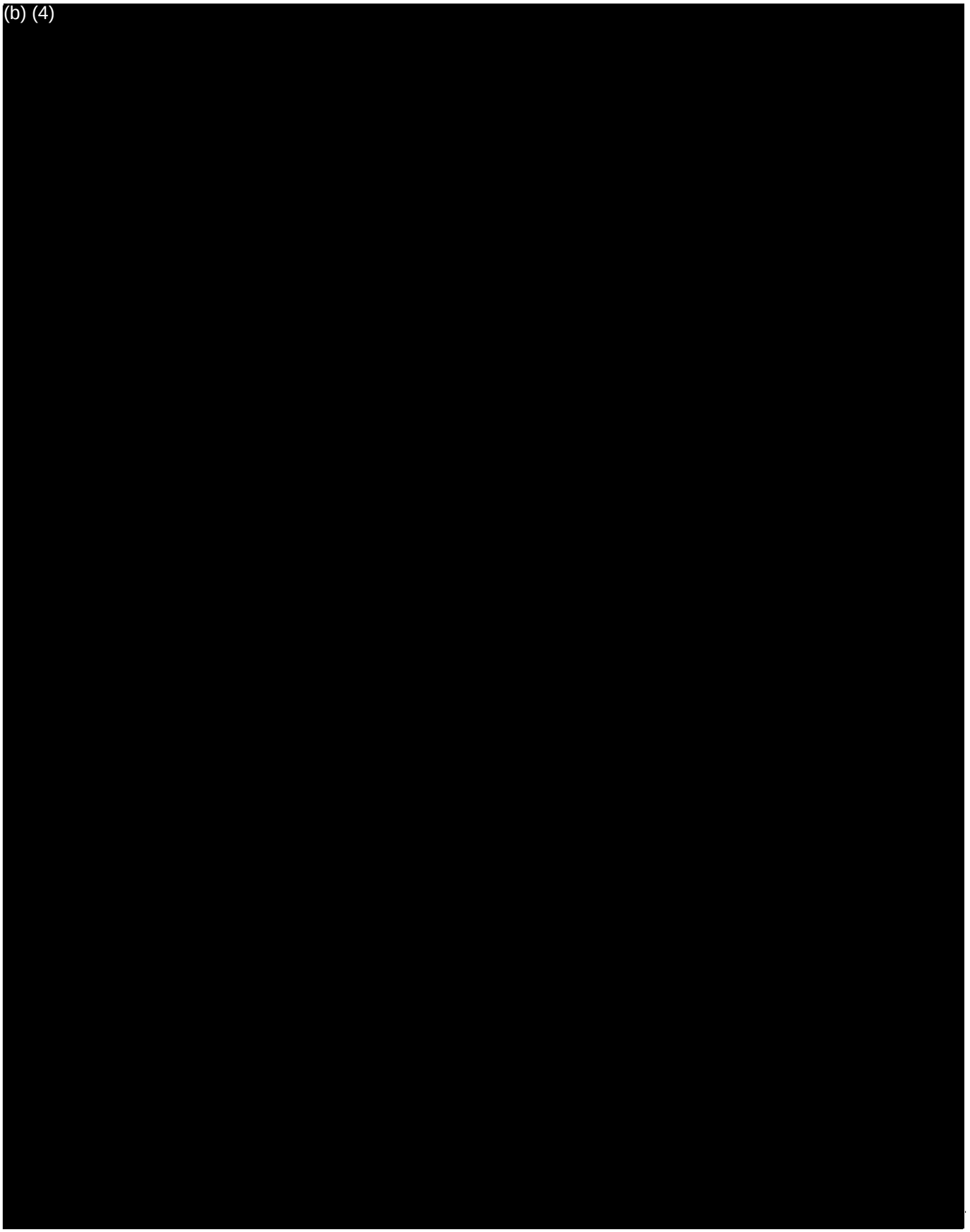


DJA x00228

Summation

ISS conducted two human factors tests at BGU in Frankfurt, Germany to validate the DigiMatch™ ROBODOC® System design requirements of using a point-to-surface approach for pinless registration.

DJA x00229

FDA Comment

12. *The submission includes a description of the testing conducted to establish electromagnetic compatibility and electrical safety (Section 17). While this section indicates that the system complies with the referenced standards, it is unclear if any testing deviations were needed to establish compliance. Please provide a copy of the electromagnetic compatibility and electrical safety test reports.*

ISS Response

A completed copy of the electromagnetic compatibility and electrical safety test reports is provided in **Attachment 5**.

DJA x00230

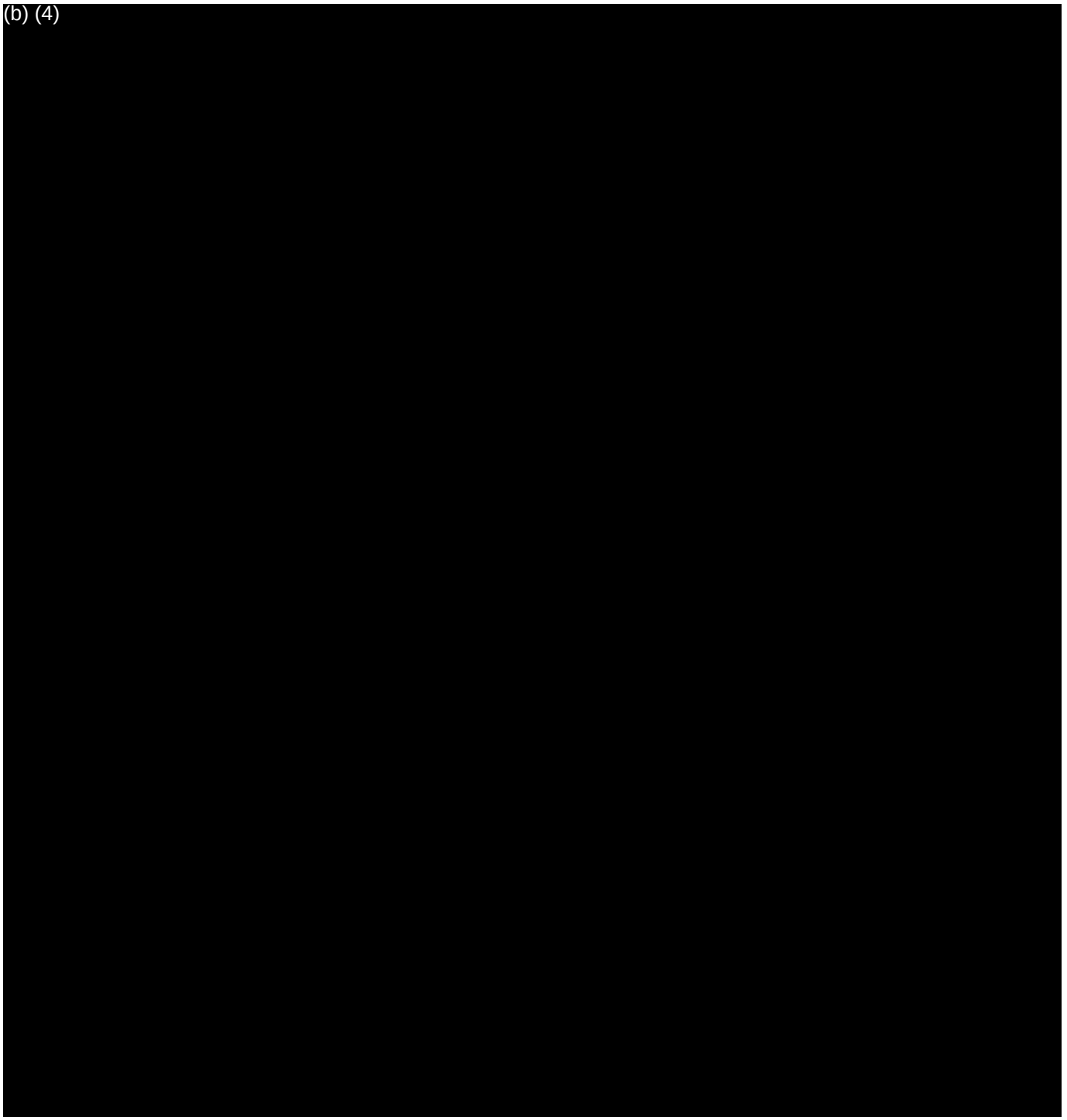
(b) (4)

DJA x00231

(b) (4)

DJA x00232

(b) (4)



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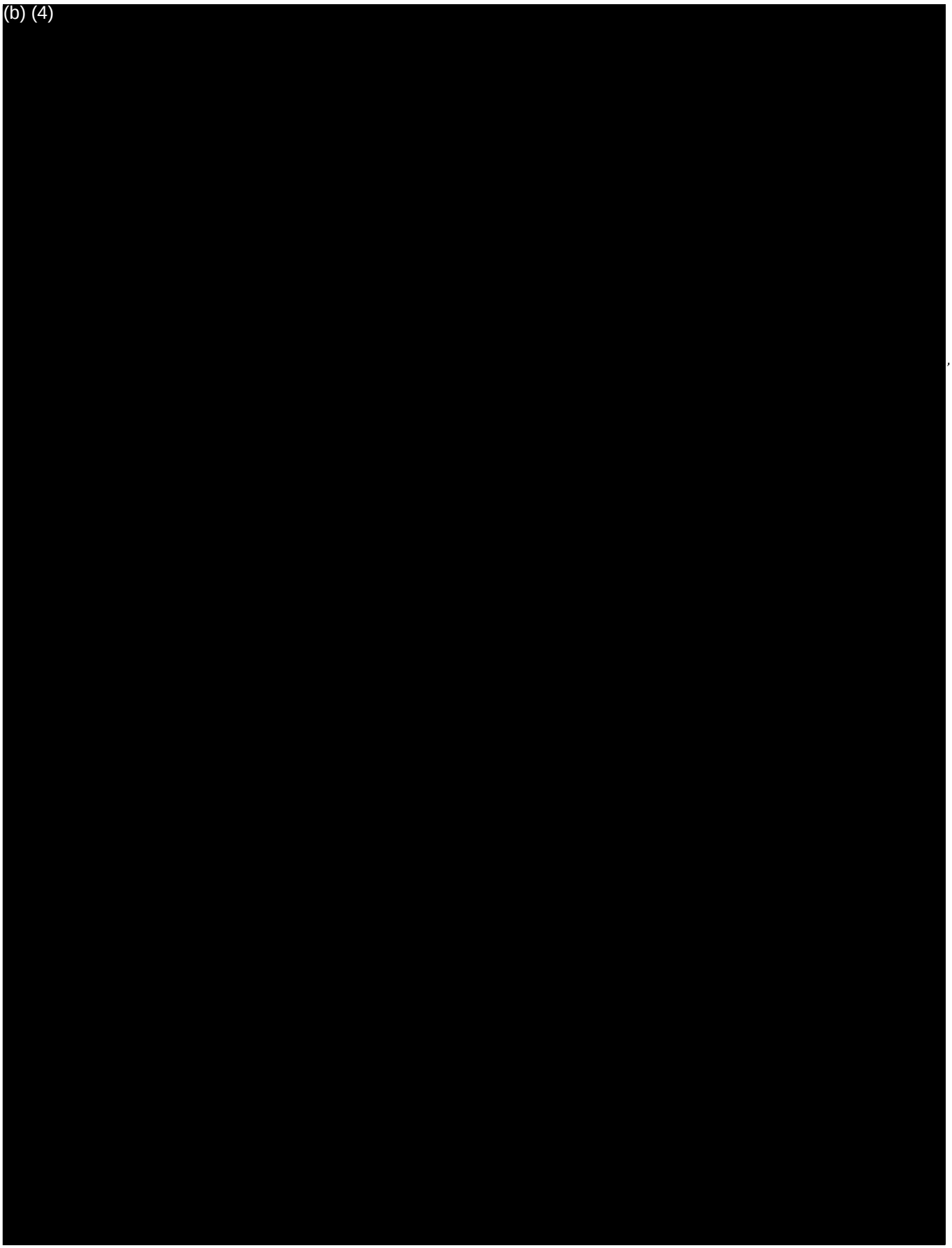

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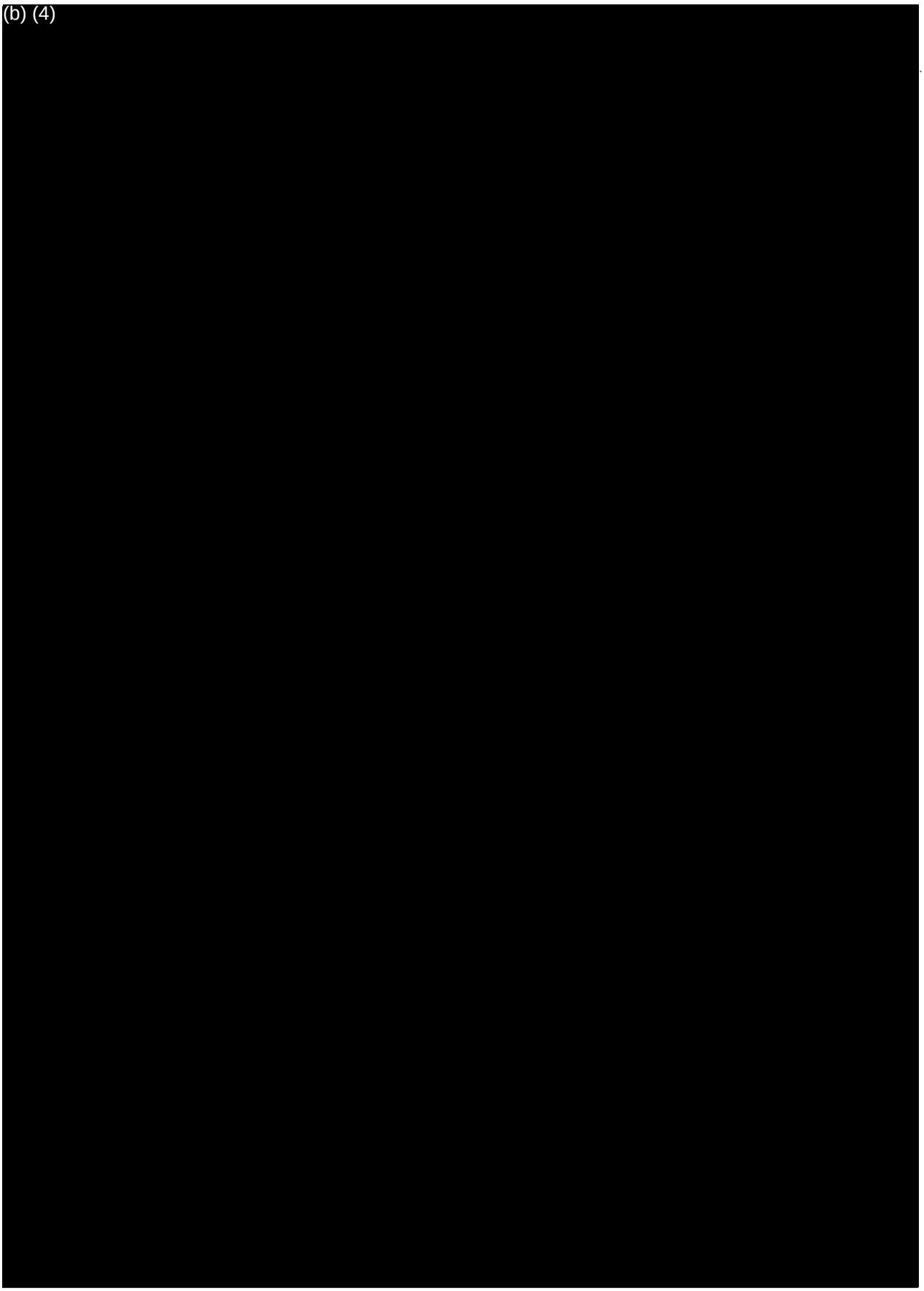

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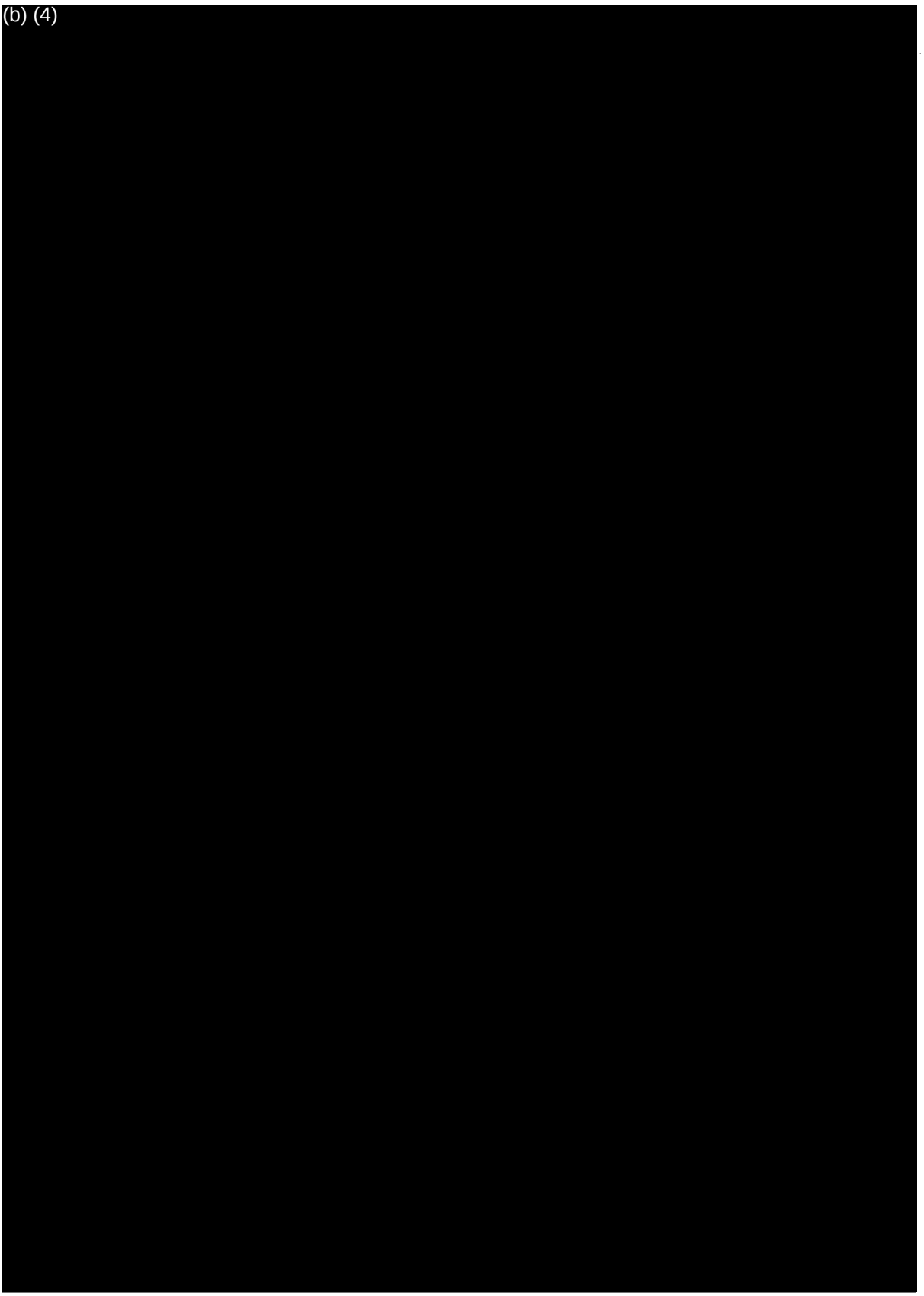


DJA x00236

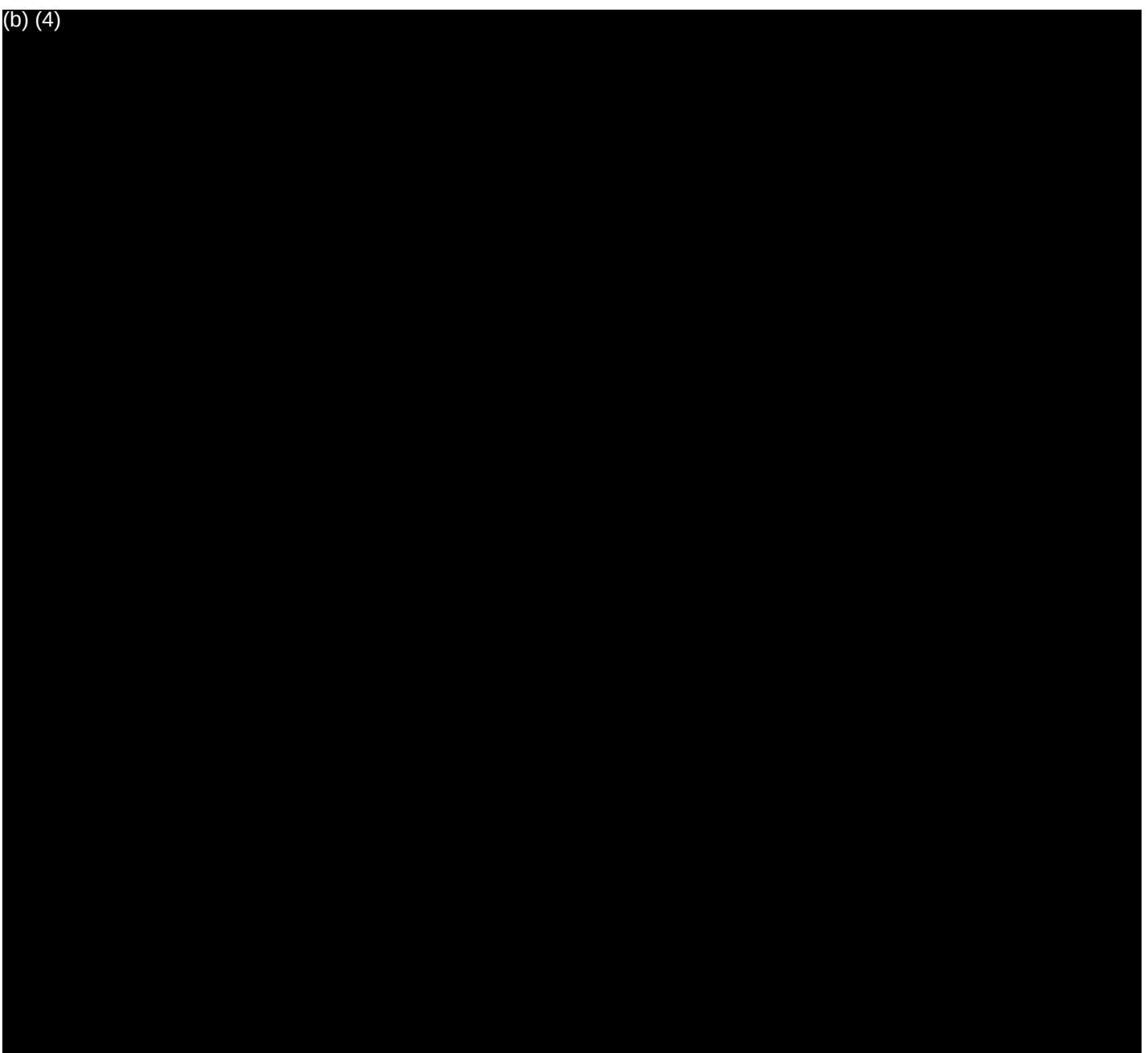
APPENDIX A

Software Configuration Management Plan

DJA x00237

Software Configuration Management Plan

(b) (4)



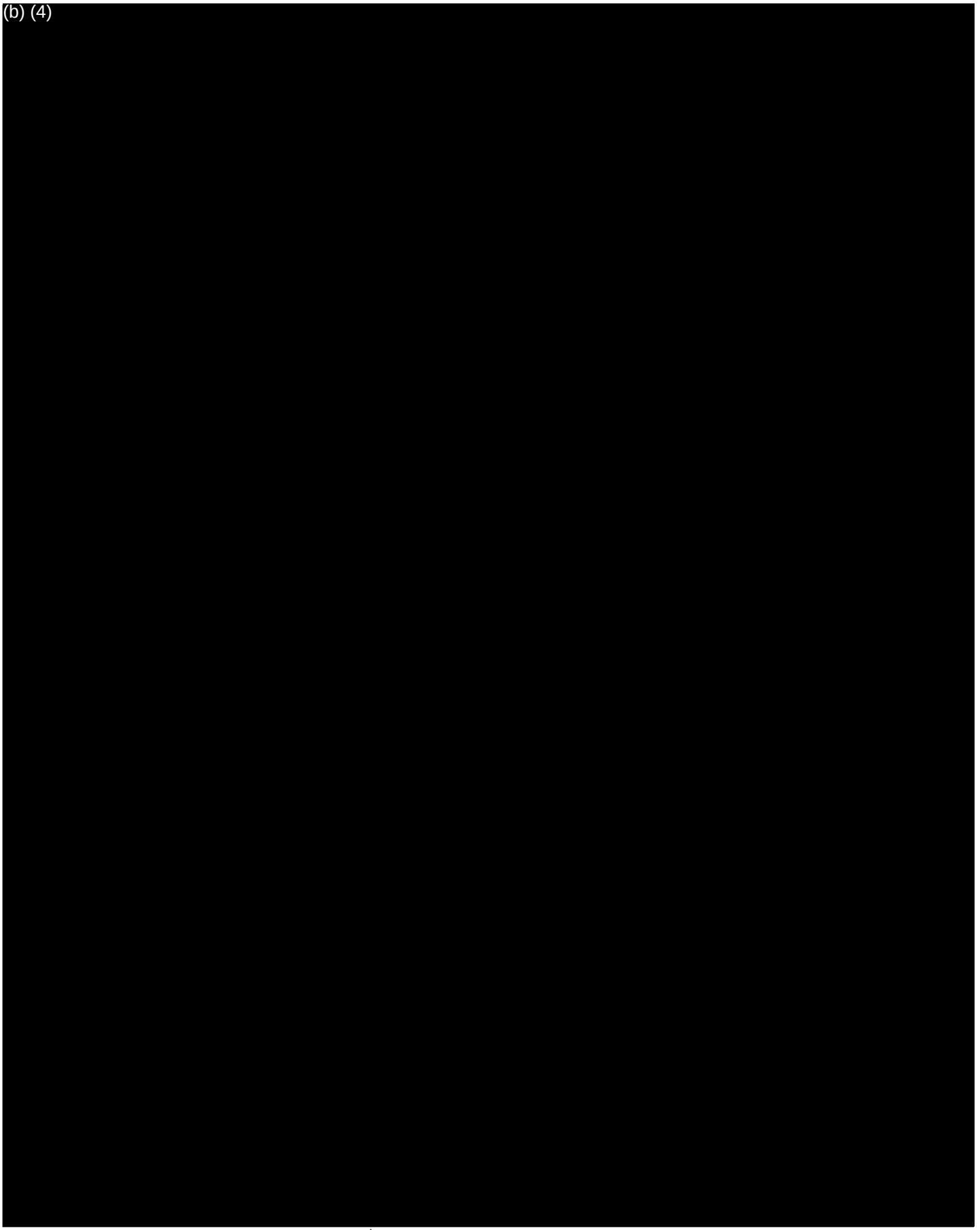
DJA x00238

(b) (4)

[redacted]

DJA x00239

(b) (4)



DJA x00240

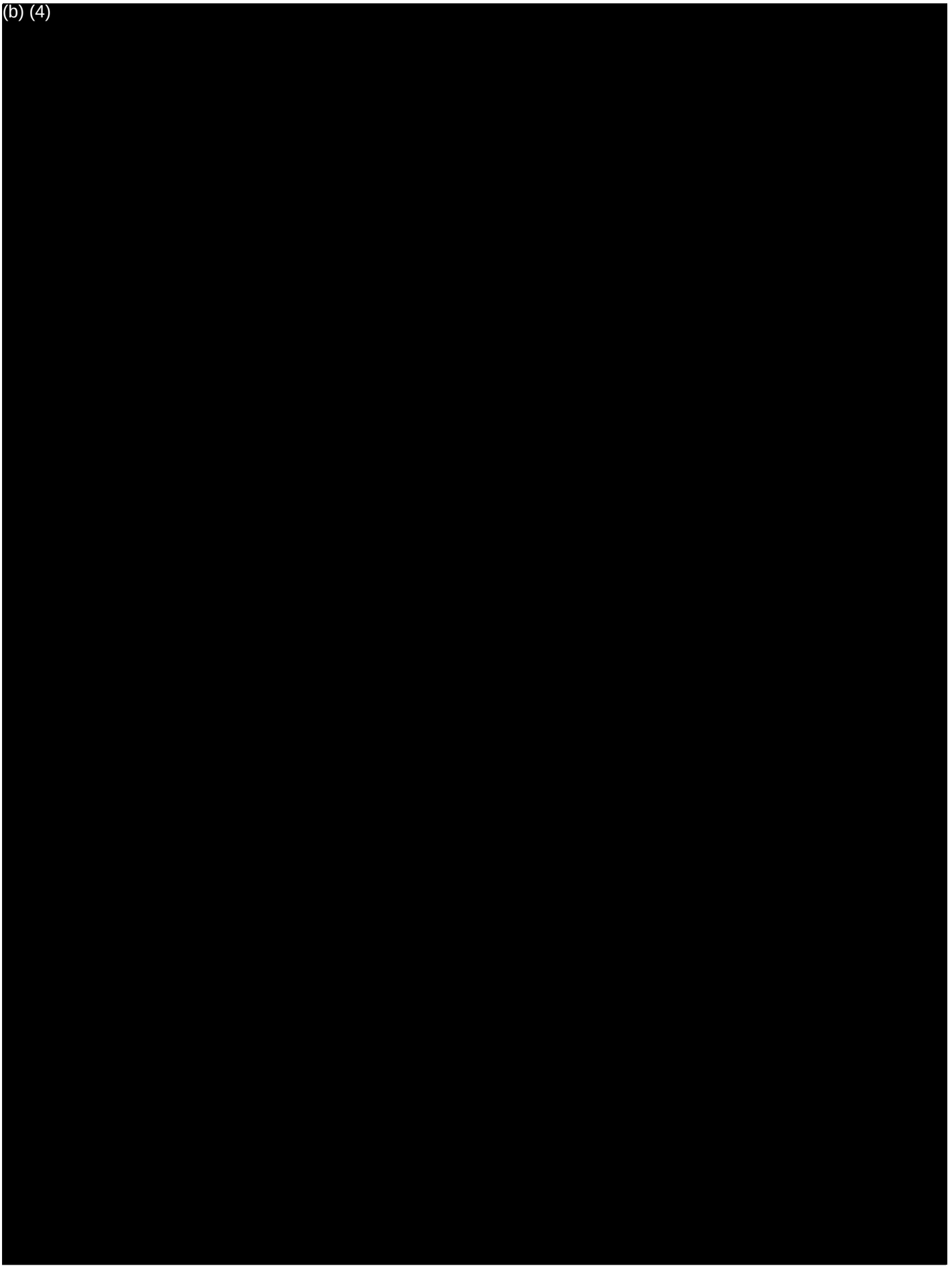
DJA x00241

APPENDIX B

Bug Report Form

DJA x00242

(b) (4)



DJA x00243

FDA Comment

16. *Explain the use of the bone fixation system and any mitigations implemented to avoid soft tissue damage.*

ISS Response

ISS provides a proximal fixation system for securing the bone to the robot prior to system preparation of the implant cavity. As shown in figure 1 the fixator clamp consists of an upper and lower jaw mechanism that is used to constrain its motion.

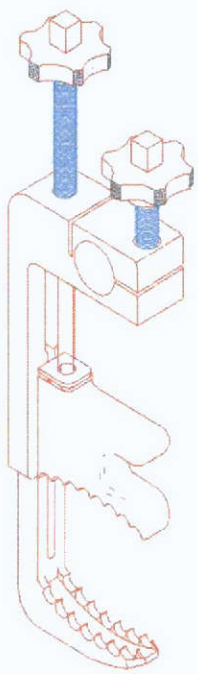


Figure 1

In routine manual total hip replacement surgery the surgeon is charged with protecting and minimizing any soft tissue damage during the surgical procedure. As is done in this routine hip surgery the surgeon exposes the operative area and places the proximal femoral fixator clamp onto the properly exposed bone (Figure 2). The surgeon is trained and instructed in the assembly and use of the fixator clamp in Chapter 6 of the ROBODOC User Manual. Adequate cautions and warnings are provided in this chapter, which direct the surgeon to use their surgical skill placing the fixator clamp to mitigate soft tissue damage that may result from improper placement or use of the fixator. The following caution and warnings are provided in Chapter 6:

DJA x00244

CAUTION:

- To facilitate safe placement of the proximal clamp on the proximal femoral, use standard surgical technique to clear the area of muscle and tissue from the femur where the clamp is to be placed.

- Take appropriate care to protect the sciatic nerve.

WARNING:

- Over tightening may damage the bone and/or soft tissue, or freeze the joints and make it difficult to detach and disassemble the fixator after femoral preparation.

- Bone quality in the proximal femur must be good to achieve adequate fixation without damaging or fracturing the bone.

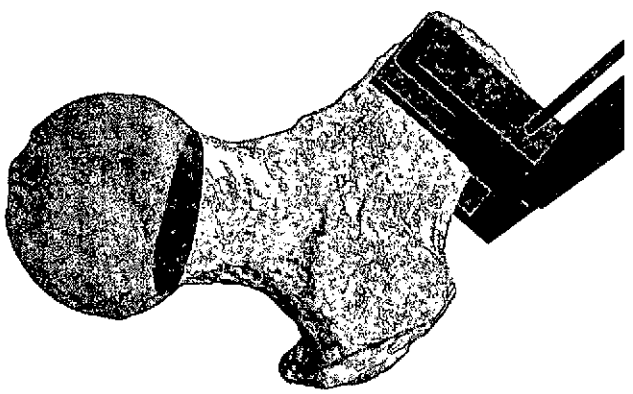


Figure 2

Once the fixator clamp is secured to the proximal femur, the fixator is attached to the robot. This is completed prior to registration and the fixator is not removed until the cavity milling process is complete. **Attachment 8** contains copies of revised pages from ROBODOC User Manual, Chapter 6, Femoral Fixation. These revisions were made in response to this FDA comment and are used to mitigate soft tissue damage that may be caused by improper use of the fixator.

DJA x00245

Attachment 1

Description – Cutter Drive Assembly Removal Process

DJA x00246

Total System Shutdown

Complete loss of electrical power, resulting in an inability to manually manipulate the Robot arm during femoral cutting (when cutter and sleeve has progressed deep/distally within the femoral canal.

⇨ To Remove THA Cutter Assembly Drive

1. Unthread the cutter drive assembly off of the force sensor until the cutter drive assembly is free, as illustrated in Figure 10-2

2. Withdraw/Manipulate the cutter sleeve and cutter drive assemble out of the Proximal femoral canal and proximal femur area with care, as illustrated in Figure 10-3

3. Abort the use of the robot and complete procedure manually

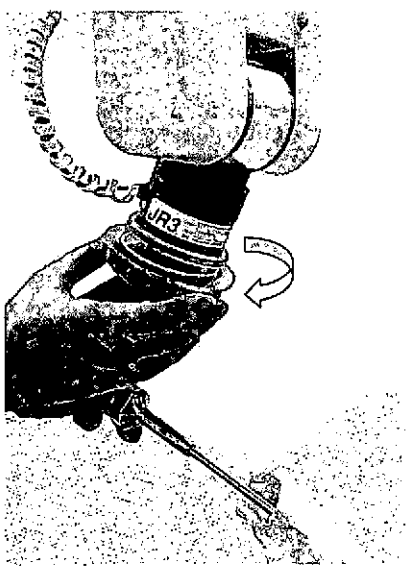


Figure 10-2. Unthread the the
cutter drive assembly

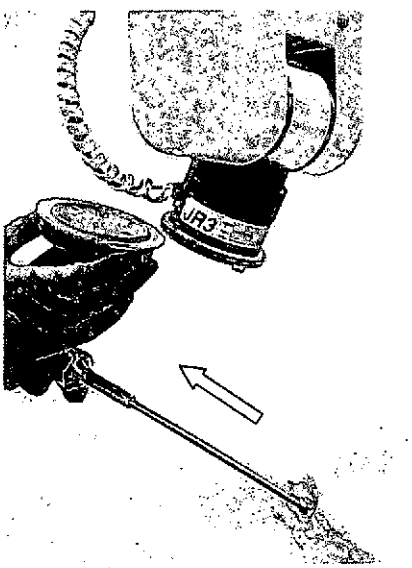


Figure 10-3. Withdraw/Manipulate

cutter drive assembly

DJA x00247

Attachment 2

Revised ORTHODOC User Manual and ROBODOC User Manual
Pages that Reflect
Intended Use/Indications for Use Statement

DJA x00248

Indication for Use, Warnings/Precautions, and Adverse Effects

Indication for Use

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

Contraindications

- Metallic objects in the operative leg which would cause unacceptable levels of artifact in the CT slices over the surfaces required for DigiMatch registration (DigiMatch THA cases only) or for delineating bone cement in revision cases.

Warnings/Precautions

- If the implant model is not properly positioned prior to creating the transfer file, problems may occur with placement of cavities or cut planes.
- Failure to generate a three-dimensional model could result in an incorrect angle for measuring the version and subsequently lead to dislocation of the hip (THA cases only).
- An inaccurate measurement of the version angle of the implant may result in dislocation of the hip (THA cases only).
- Invalid CT data may cause problems with placement of cavities or cut planes.
- Selecting an oversized implant may cause the robot to remove too much cortical bone and weaken the femur (THA cases only).

DJA x00249

Indications, Contraindications, Warnings/ Precautions, and Adverse Effects

The indications and contraindications listed below are for use of the ROBODOC Surgical Assistant System.

Indications for Use

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopedic procedures in which the use of stereotactic surgery may be considered to be safe and effective, and where a reference to a rigid anatomical structure may be made.

Contraindications

- Skeletal immaturity.
- Any active infection.
- Neuromuscular disorders, which would create an unacceptable risk of prosthesis instability or fixation failure.
- Femoral bone stock that is of poor quality or inadequate to provide stability for the femoral fixator and/or locator pins, in cases where locator pins will be utilized for registration.
- Femoral bone stock that may be damaged by femoral fixation.
- A pathological skeletal condition, which would impair the ability of the bone to withstand the stress of femoral canal preparation and prosthesis placement (e.g., severe osteoporosis, Paget's disease, renal osteodystrophy).

DJA x00250

Attachment 3

Revised pages – ROBODOC User Manual, Chapter 7
REGISTRATION PROCEDURES

⇨ To use additional options:

Select one of the following options from the Verification Options screen:

- **REVIEW VERIFIED POINTS**: This option enables visual review of verification points. If visual review indicates a potential placement problem with one or more points, select one of the other options to correct the problem. When this option is selected, the OR Monitor displays the first verification point. Use the pendant to display additional verification points: **UP** displays the next point; **DOWN** displays the previous point; and **SELECT** redisplays the **"VERIFY THAT REGISTRATION IS CORRECT"** prompt.

- **VERIFY ADDITIONAL POINT**: This option enables you to re-digitize additional points for verification purposes. Use this option when you are uncertain about the placement of verification points in a certain direction. For example, if the distal anterior verification point and the anterior neck verification point both appear to be approximately 2 mm from the edge of the bone (near the blue circle), select this option to collect an additional point on the anterior surface of the bone. After collecting the additional point, the OR Monitor will display the verification screen for that point, followed by the **"VERIFY THAT REGISTRATION IS CORRECT"** prompt. If repeated verification still indicates a problem with the location of verification points, repeat registration by recollecting all points.

- **REPEAT VERIFICATION**: This option enables you to re-digitize all verification points. Use this option when you are uncertain about the placement of multiple points and want to re-digitize all of the verification points (i.e., repeat the verification process described in the previous section). If repeated verification still indicates a problem with the location of verification points, repeat registration by recollecting all points.

- **RECOLLECT ALL POINTS**: This option enables you to repeat the entire surface registration and verification procedure. Use this option if one or more of the verification points is more than 2 mm from the edge of the bone (outside the blue circle). The system will re-compute surface registration.

Error Detection for DigiMatch Surgeries

The OR Monitor will display error message screens if problems occur during point collection or verification. If registration procedures cannot be successfully completed, the operation must be performed manually with the broach.

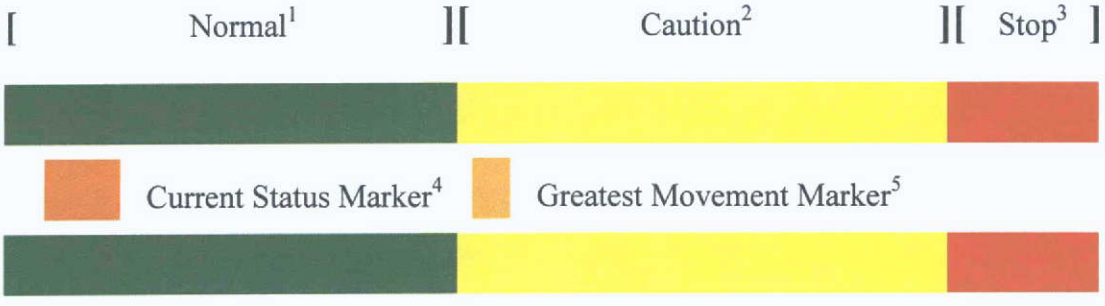
When registration is complete, the robot evaluates the position of the bone to verify that the entire implant cavity is within its workspace. If part of the cavity is outside the workspace, the OR Monitor displays an error message screen that prompts you to perform the appropriate recovery procedure. Recovery procedures include adjusting base height and then digitizing the motion recovery markers.

DJA x00252

After registration, the BMM and safety system will automatically pause the robot if motion exceeding a predefined threshold (2mm for 1 second) occurs. The OR Monitor will then prompt the surgeon to digitize the motion recovery markers. Figure 7-8 is a replica of the bone motion indicator, which is displayed on these screens. It gives the surgeon a visual indication of bone motion throughout the milling procedure. The green zone indicates bone motion that is within specification range (1mm). The yellow zone indicates a caution; the bone motion is approaching outer limits of specification range. The red zone indicates bone motion that is out of specification range (2mm for 1 second).

The bone motion indicator also gives visual information regarding bone motion during the ROBODOC milling procedure. The dark orange maker shows current status of bone motion and the light orange maker marks the greatest amount of bone motion that occurs during the course of the milling procedure.

Figure 7-8. Replica of Bone Motion Indicator



Legion:
[1]Green zone indicates bone motion is within specification range
[2]Yellow zone indicates bone motion is approaching outer limits of specification range
[3]Red zone indicates bone motion is out of specification range
[4]Dark orange maker shows current status of bone motion
[5]Light orange maker marks the greatest amount of bone motion

DJA x00253

Attachment 4

Revised Page – ROBODOC User Manual
Chapter 9, page 9-8

Servicing and Routine Maintenance

The diagnostic tests are designed to identify the failure of ROBODOC components. When the system fails to pass a diagnostic test, notify ISS. The only ROBODOC components that must be routinely serviced by ISS are the cutter drive, bearing sleeves, and tape drive. The other routine maintenance procedures described in this section must be performed on a per-surgery basis by hospital technicians.

Servicing the Cutter Drive

Immediately notify ISS if problems such as vibrational loosening of components are observed. Return motor to ISS if a performance failure (e.g., unusual noise, loss of power, non-functionality) is observed.

Servicing the Bearing Sleeve

Bearing sleeves must be periodically returned to ISS for refurbishing. The symptoms of a worn bearing sleeve include a high-pitched whine during cutter operation and the sleeve feeling hot to the touch. If these problems occur during surgery, you must decide whether to replace the sleeve intraoperatively.

If the symptoms are minor, ISS recommends finishing the femoral preparation operation, due to the time required to replace the sleeve. After surgery, decontaminate and sterilize the worn-out sleeve and contact ISS. ISS will refurbish the bearing sleeve

If the symptoms are severe, you must interrupt the femoral preparation operation to replace the bearing sleeve. Instructions in Chapter 10, page 10-12, explain how to do so.

Cleaning the Media Drive

The Media drives in the Control Cabinet and ORTHODOC workstation should be cleaned each time a field technician visits a ROBODOC installation.

Maintaining the Coaxial Wall Air Supply on Systems with Air Motors

The filter element inside the filter box for the air supply system must be replaced after every surgery. DO NOT steam or heat sterilize the filter box.

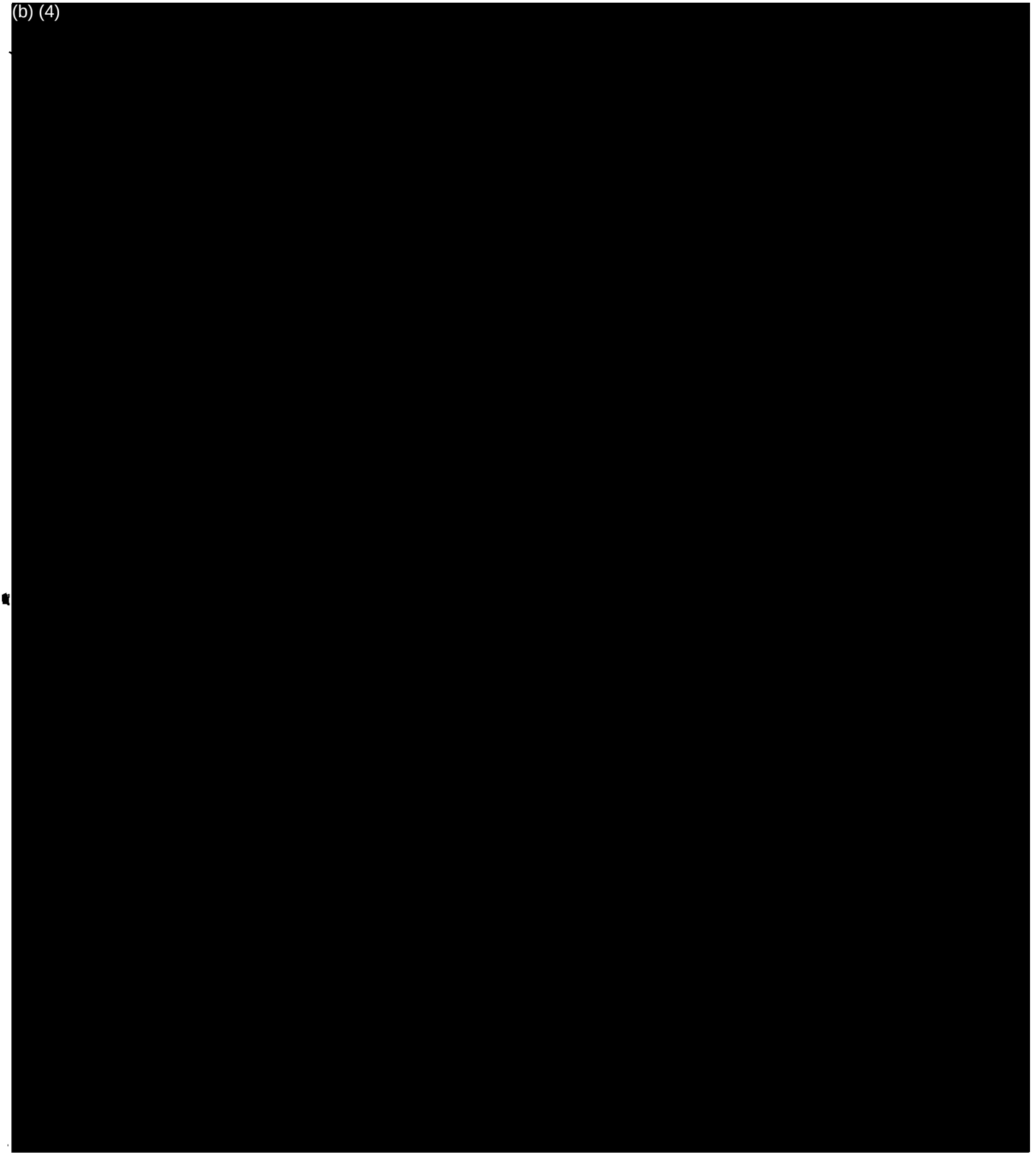
DJA x00255

Attachment 5

Test Reports
Electromagnetic Compatibility and Electrical Safety Test

DJA x00256

(b) (4)



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DJA x00257

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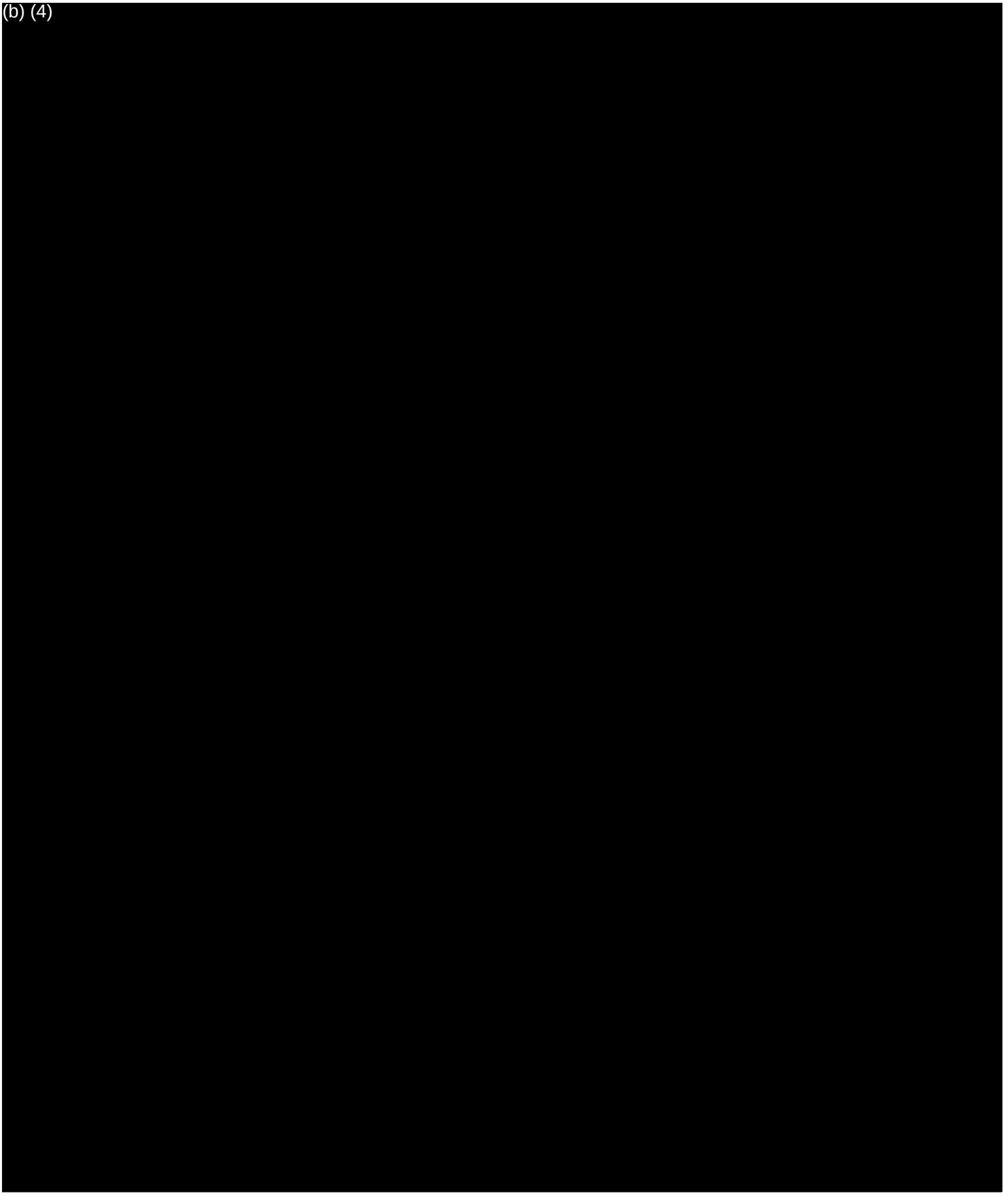

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DJA x00259

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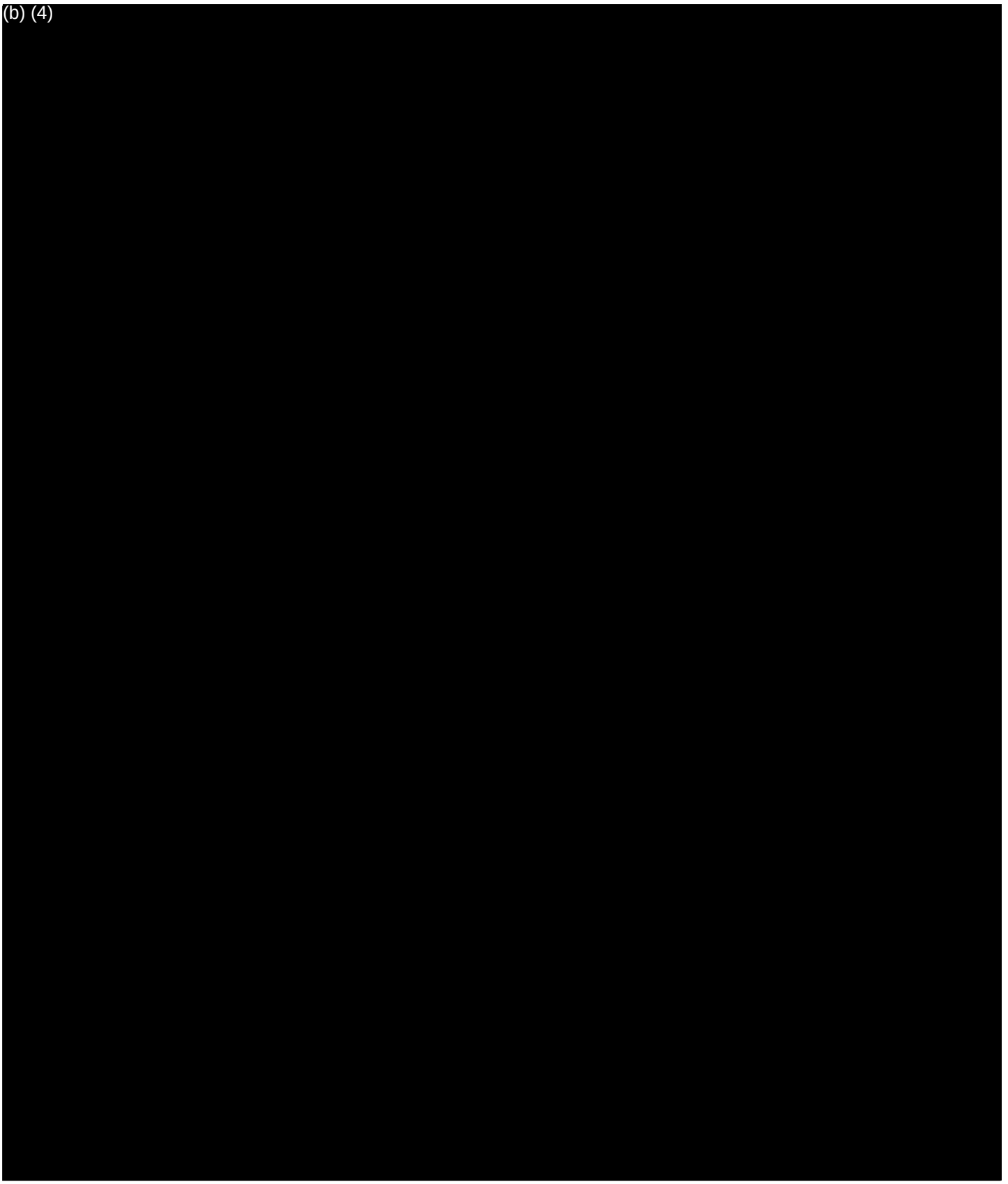

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DJA x00260

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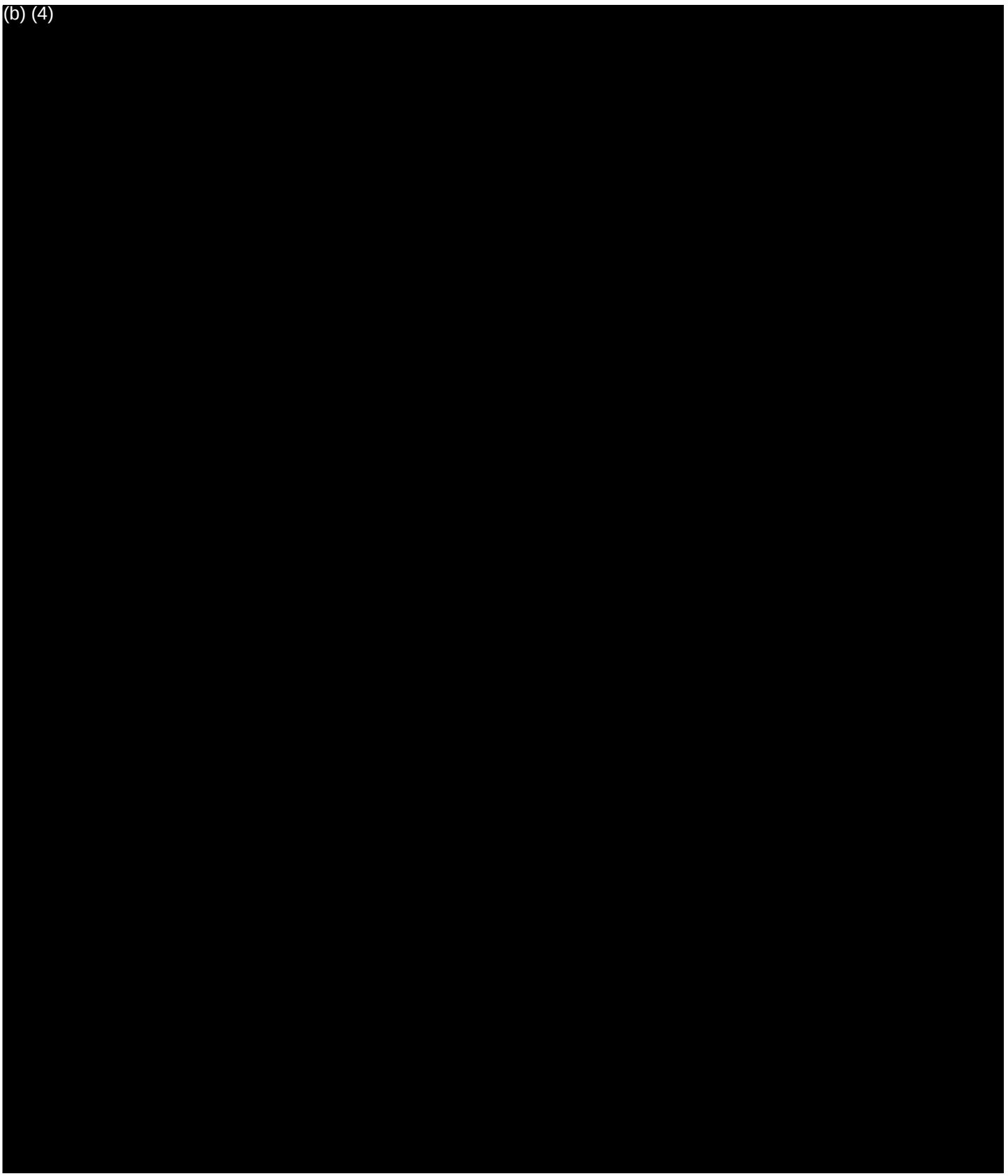

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EN60601
ELECTRICAL SAFETY TESTING

The Section numbers that are underlined indicate those sections that are changed from revision A.

Test	Description	Comments		Test	Description	Comments
(b) (4)						

Test	Description	Comments		Test	Description	Comments
(b) (4)						

DJA x00263

Test	Description	Comments		Test	Description	Comments

(b) (4)

DJA x00264

Test	Description	Comments		Test	Description	Comments
(b) (4)						

DJA x00265

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TEST: C03

SUBJECT: Markings on the PINLESS ROBODOC® Surgical system

(b) (4)

[redacted]

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00266

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(b) (4)

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TESTS: C05

SUBJECT: Classification of the PINLESS ROBODOC* Surgical system

(b) (4)

[redacted]

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00268

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TEST: C10

SUBJECT: Mechanical Strength of the PINLESS ROBODOC® Surgical System

(b) (4)

[redacted]

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829 West Stadium Lane, Sacramento, California 95834

DJA x00269

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(b) (4)

DJA x00270

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TEST: C12

SUBJECT: Surfaces, Corners, and Edges of the PINLESS ROBODOC® Surgical system

(b) (4)

[redacted]

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00271

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TEST: C13

SUBJECT: Stability in Normal Use for the PINLESS ROBODOC® Surgical system

(b) (4)

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00272

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(b) (4)

[redacted]

DJA x00273

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TEST: C17

SUBJECT: Electromagnetic compatibility for PINLESS ROBODOC® Surgical system

(b) (4)

INTEGRATED SURGICAL SYSTEMS, Inc.
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DJA x00274

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TEST: C23

SUBJECT: Abnormal Operation

(b) (4)

[redacted]

(b) (6) [redacted]
Quality Assurance

3/17/98
date

(b) (6) [redacted]
Test Operator

03/17/98
date

DJA x00275

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TEST: C31

SUBJECT: Components and General Assembly of the PINLESS ROBODOC® Surgical system

1. Description

(b) (4)

[redacted]

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00276

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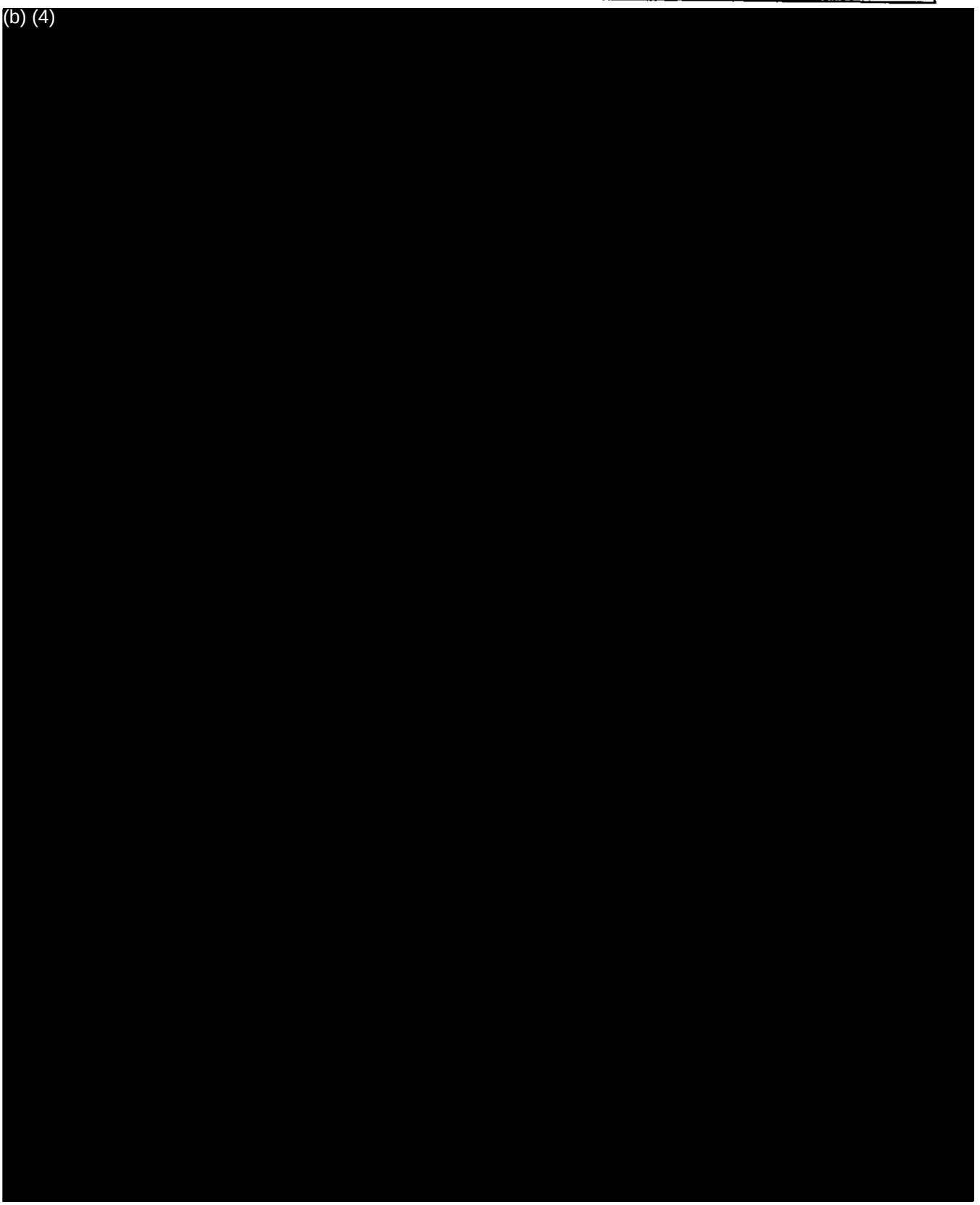
(b) (4)



DJA x00277

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(b) (4) [redacted]

(b) (6) [redacted]	[illegible]	(b) (6) [redacted]	03/17/98
Quality Assurance	date	Test Operator	date

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

Sheet 3 of 3

DJA x00278

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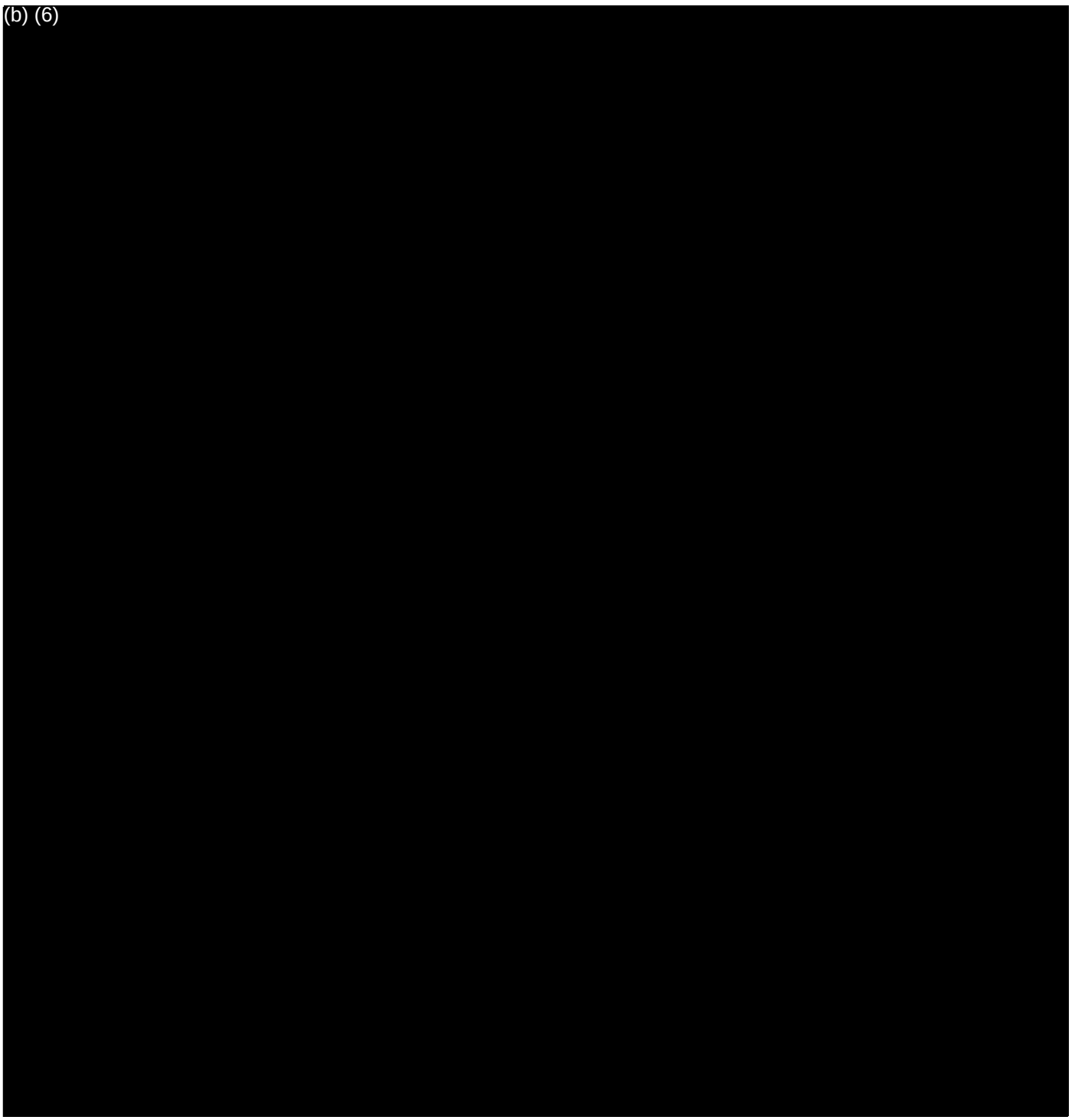
TEST: C32

SUBJECT: Mains Parts, components and layout of the PINLESS ROBODOC® Surgical system

(b) (6)



INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00279

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(b) (6)

[redacted]

DJA x00280

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(b) (6) [redacted]

(b) (6) [redacted]	[illegible]	(b) (6) [redacted]	03/17/98
Quality Assurance	date	Test Operator	date

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00281

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TEST: C34

SUBJECT: Construction and Layout of the PINLESS ROBODOC® Surgical system

1. Description

(b) (4)

[redacted]

INTEGRATED SURGICAL SYSTEMS, Inc.
829 West Stadium Lane, Sacramento, California 95834

DJA x00282

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(b) (4)

[redacted]

(b) (6) [redacted]

Quality Assurance

date

(b) (6) [redacted]

Test Operator

03/17/98

date

DJA x00283

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TEST: C36

SUBJECT: Verification of Markings on the PINLESS ROBODOC® Surgical system

1. **Purpose**

1.1. To assure that the PINLESS ROBODOC® Surgical system's markings are durable under Normal Use. This test is based upon clause 6.1 of the EN60601-1 Standard.

(b) (6) [redacted]

(b) (6) [redacted]
Quality Assurance

Date

(b) (6) [redacted]
Test Operator

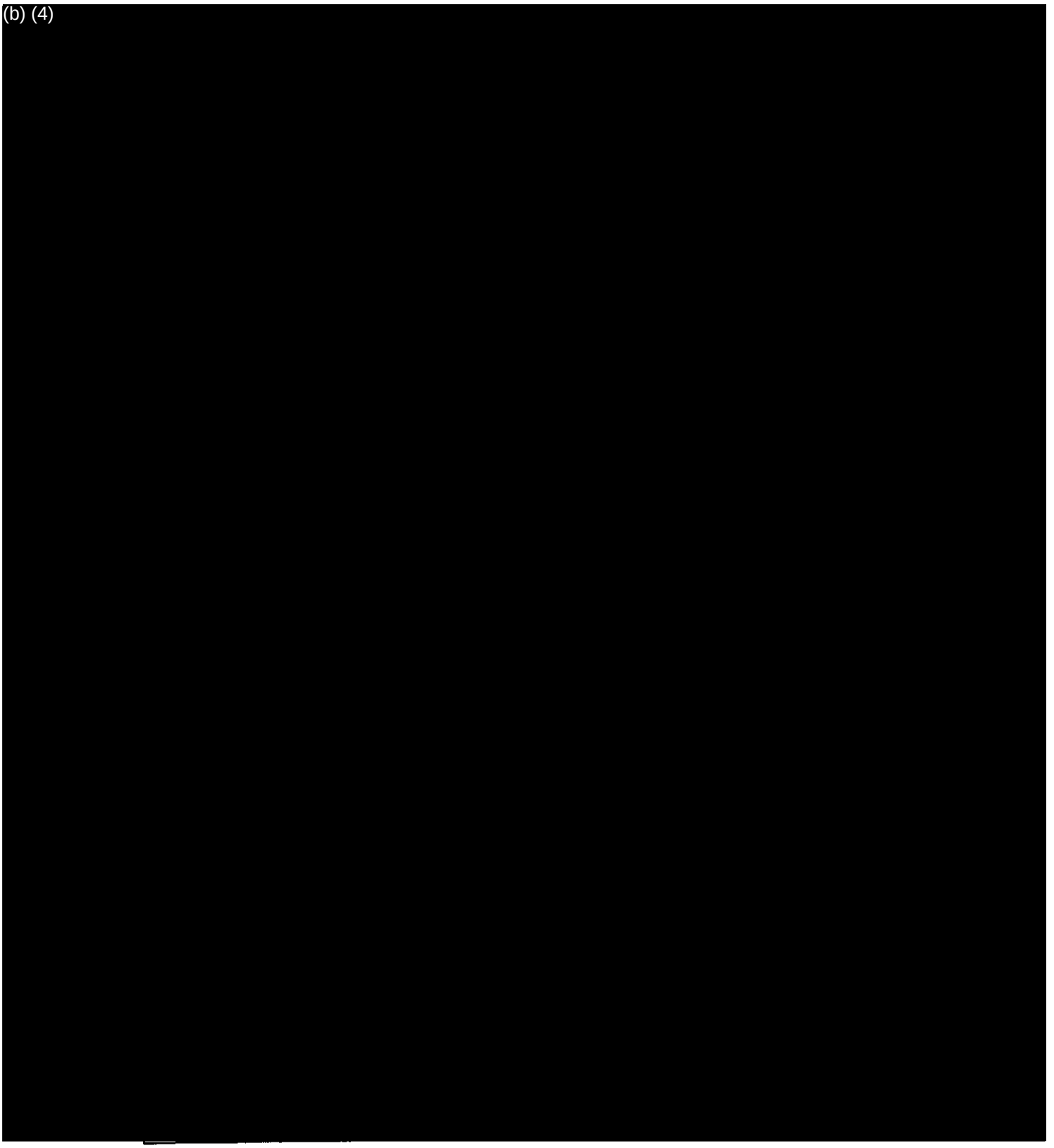
03/17/98
Date

DJA x00284

Approval & Change Control Page

205

(b) (4)



DJA x00285

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PART NUMBER: 500049

SUBJECT: **Procedure, Test, Electrical Safety**

(b) (4)

[redacted]

DJA x00286

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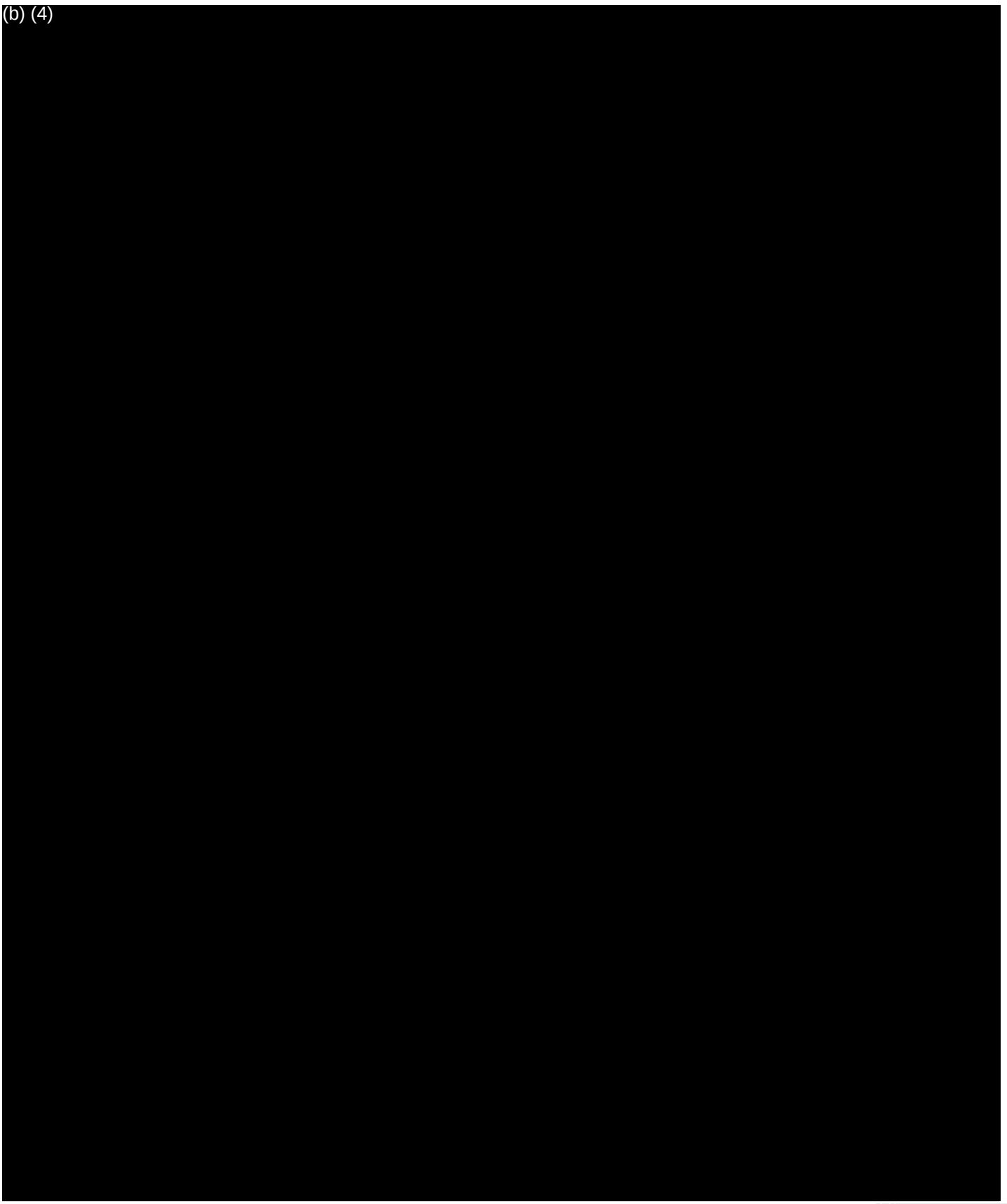
(b) (4)



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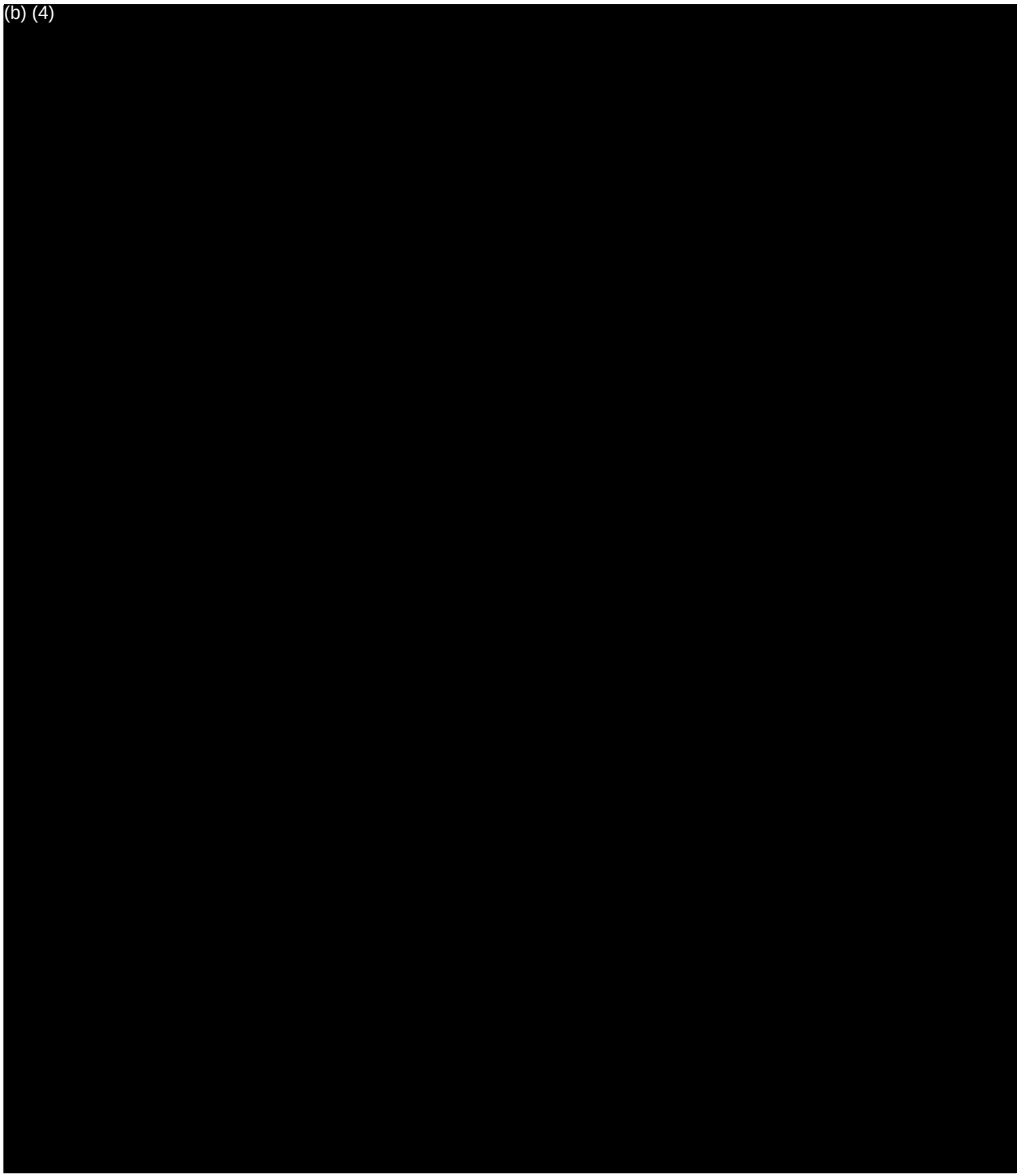
(b) (4)



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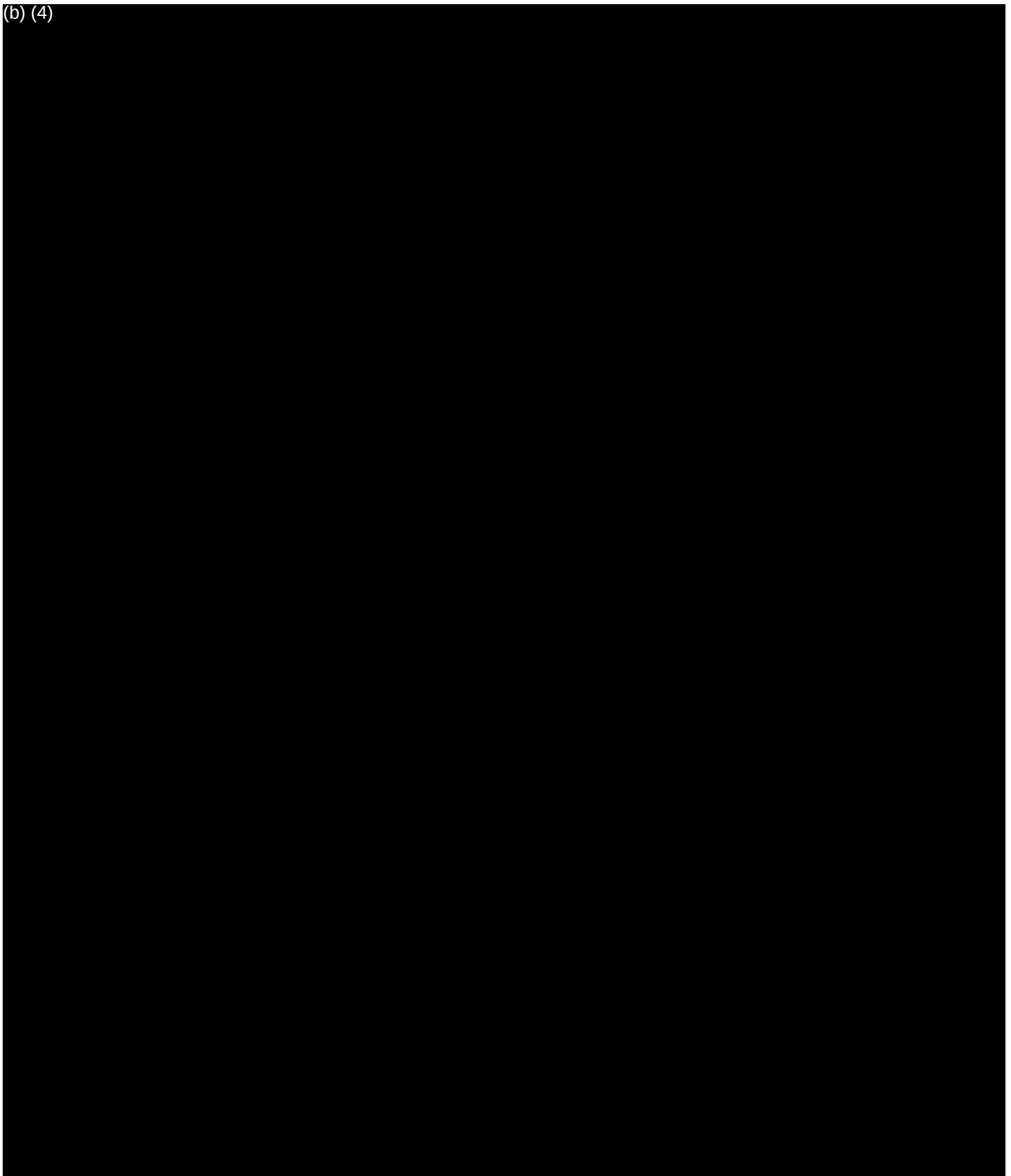

DJA x00289

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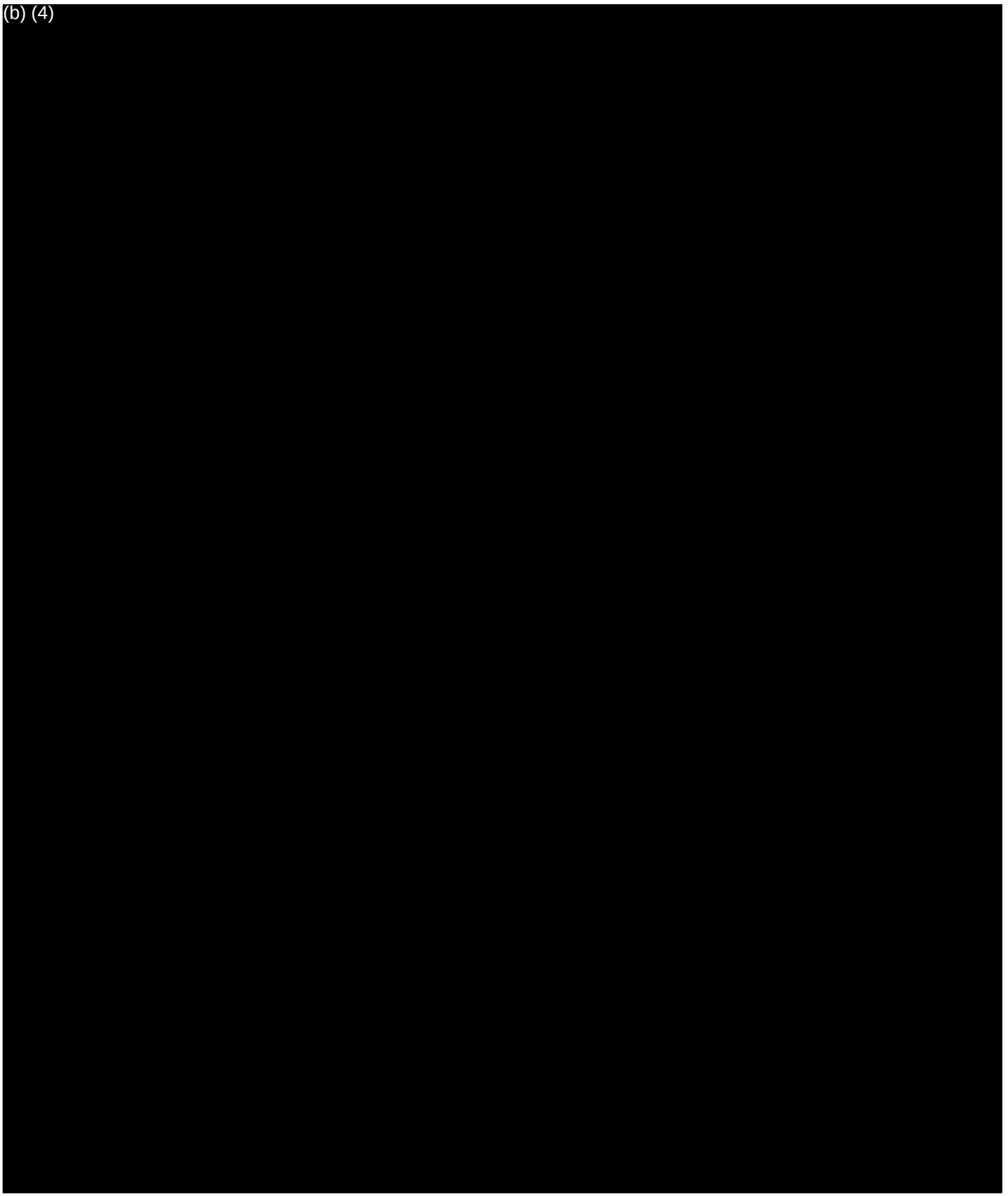
(b) (4)



DJA x00290

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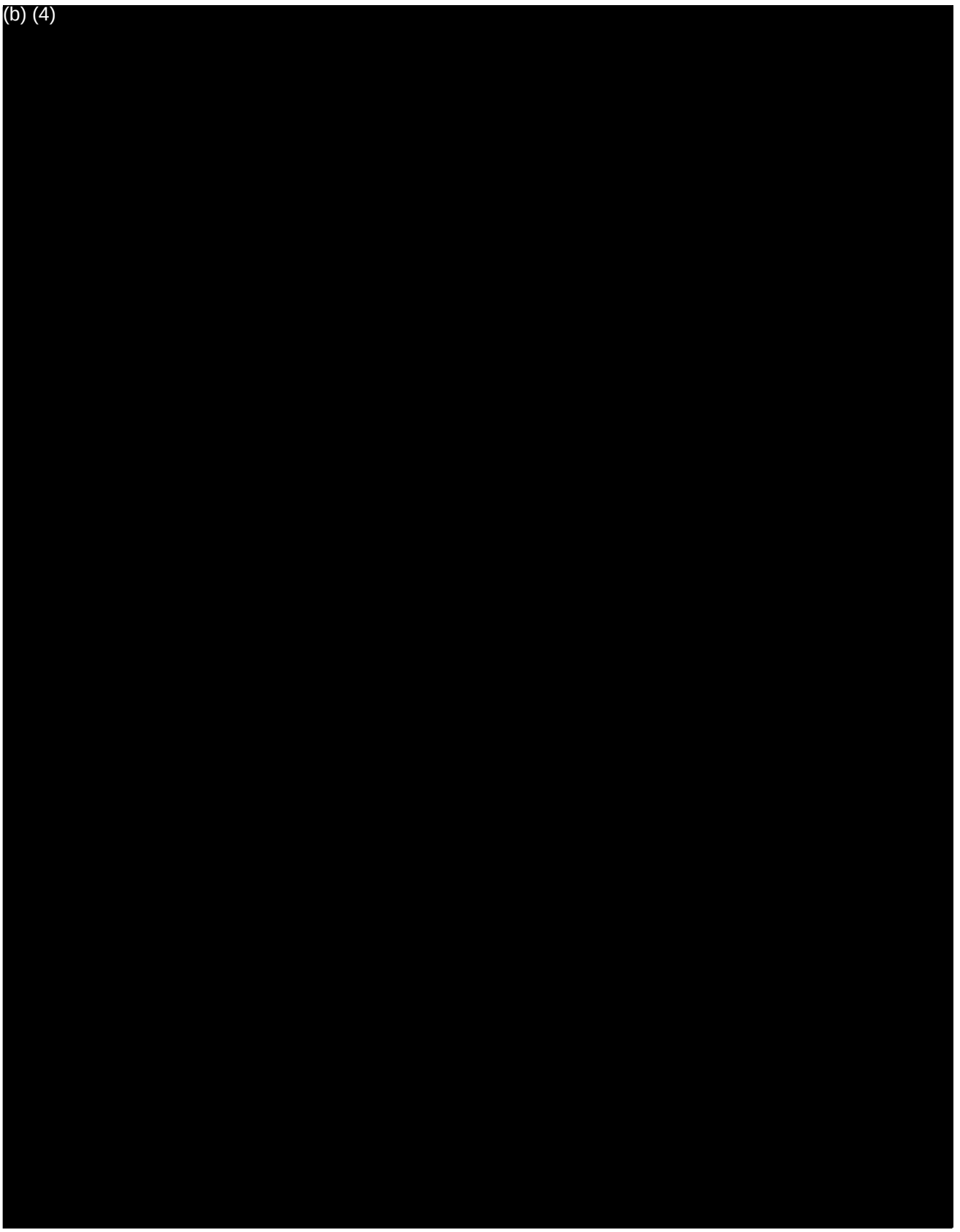
(b) (4)



DJA x00291

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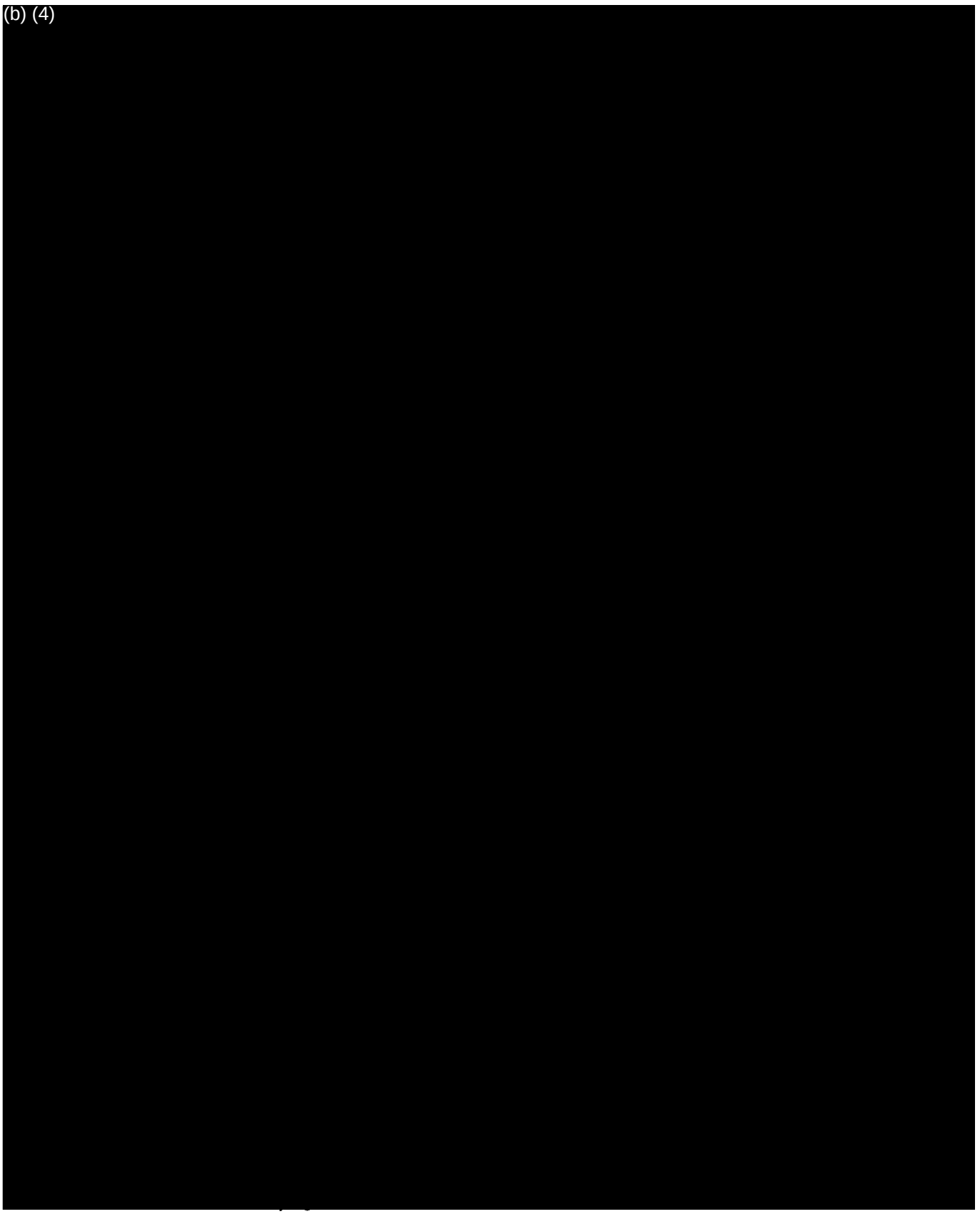
(b) (4)



DJA x00292

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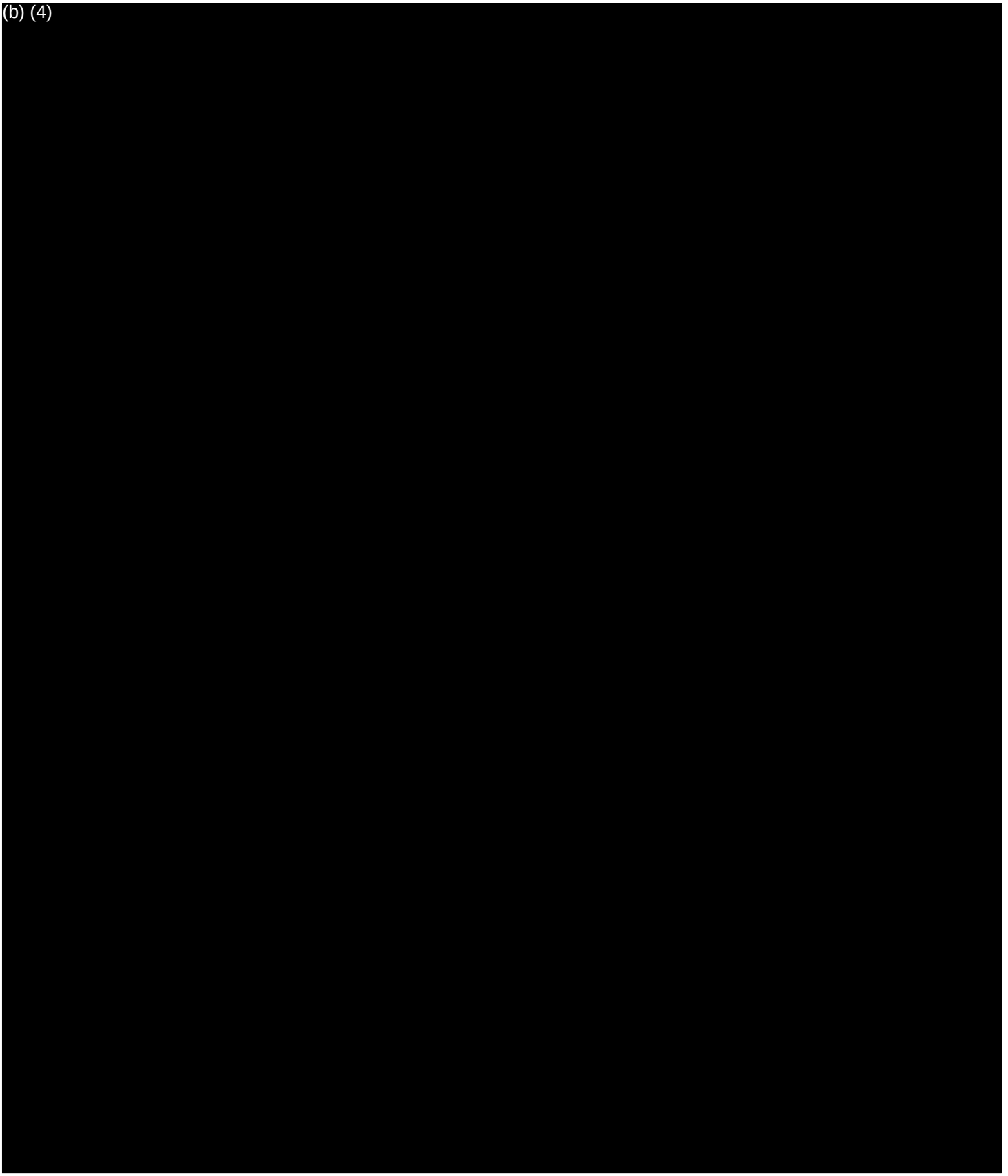
(b) (4)



DJA x00293

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(b) (4)

[redacted]

DJA x00294

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(b) (4)

[redacted]

DJA x00295

(b) (4) [redacted]

Integrated Surgical Systems Inc.

Frontier RoboDoc

Test Report

March 2, 1998

Report Prepared By:

(b) (4) [redacted]

(b) (4) [redacted]

Report No. (b) [redacted]

Test Report

DJA x00296

Integrated Surgical Systems, Inc.

Frontier RoboDoc

Test Report

Report Prepared By:

(b) (4) [redacted]

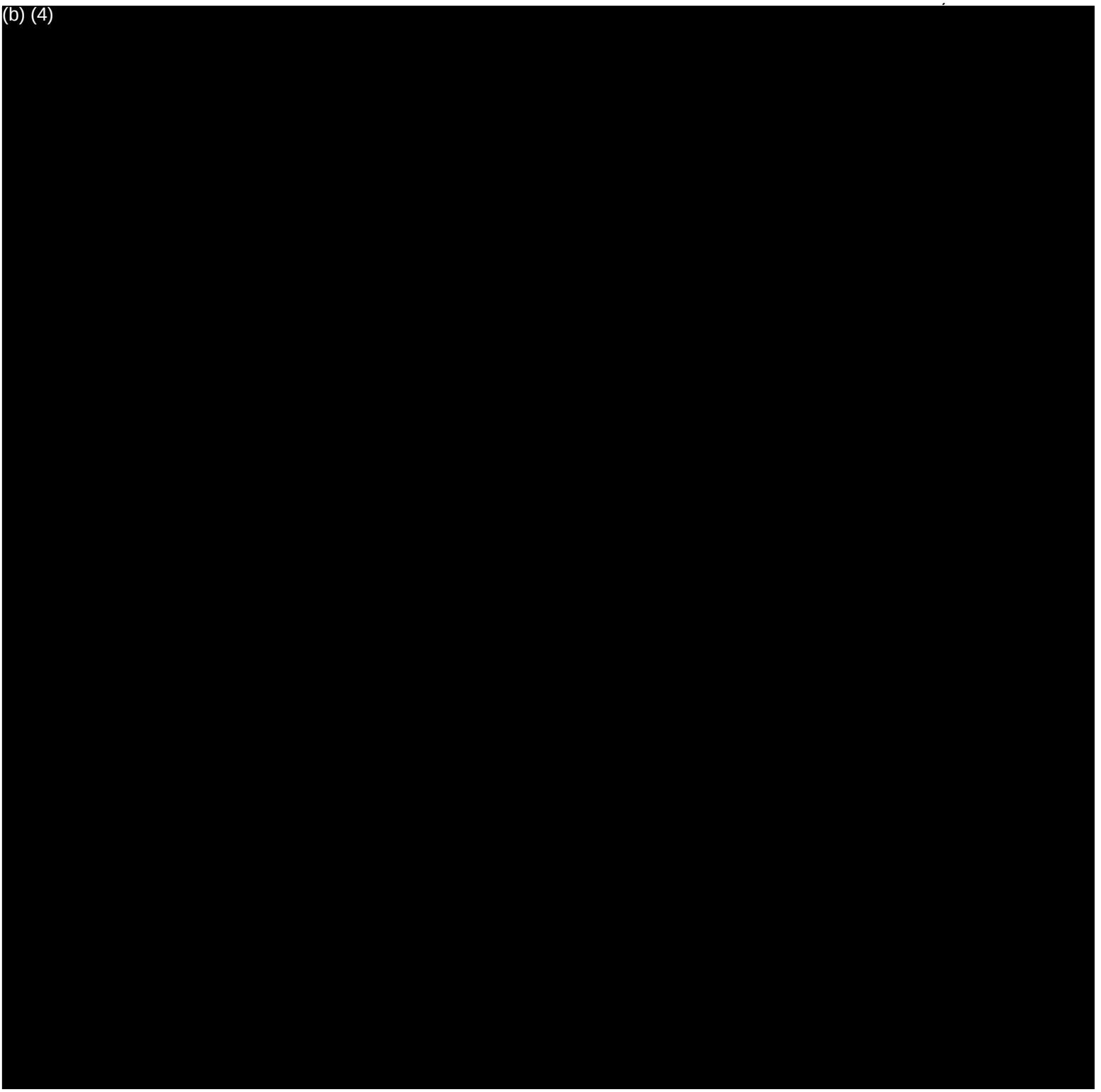
March 2, 1998

Report No. (b) (4) [redacted]

(b) (4)

[redacted]

(b) (4)



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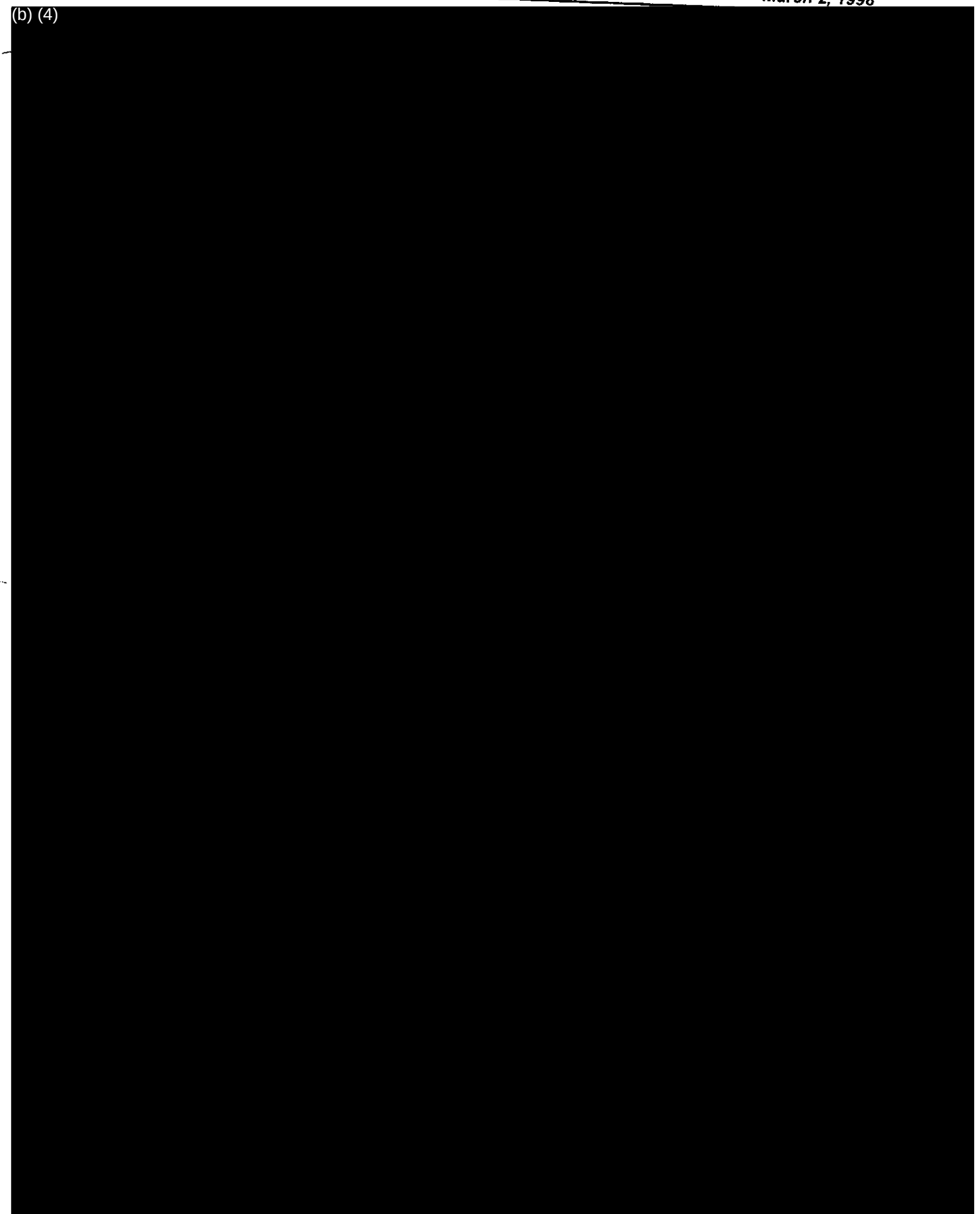


DJA x00299

Figure 1.6 Configuration of Tested System (Block Diagram)

DJA x00301

1.7 Test Methodology

(b) (4)

[redacted]

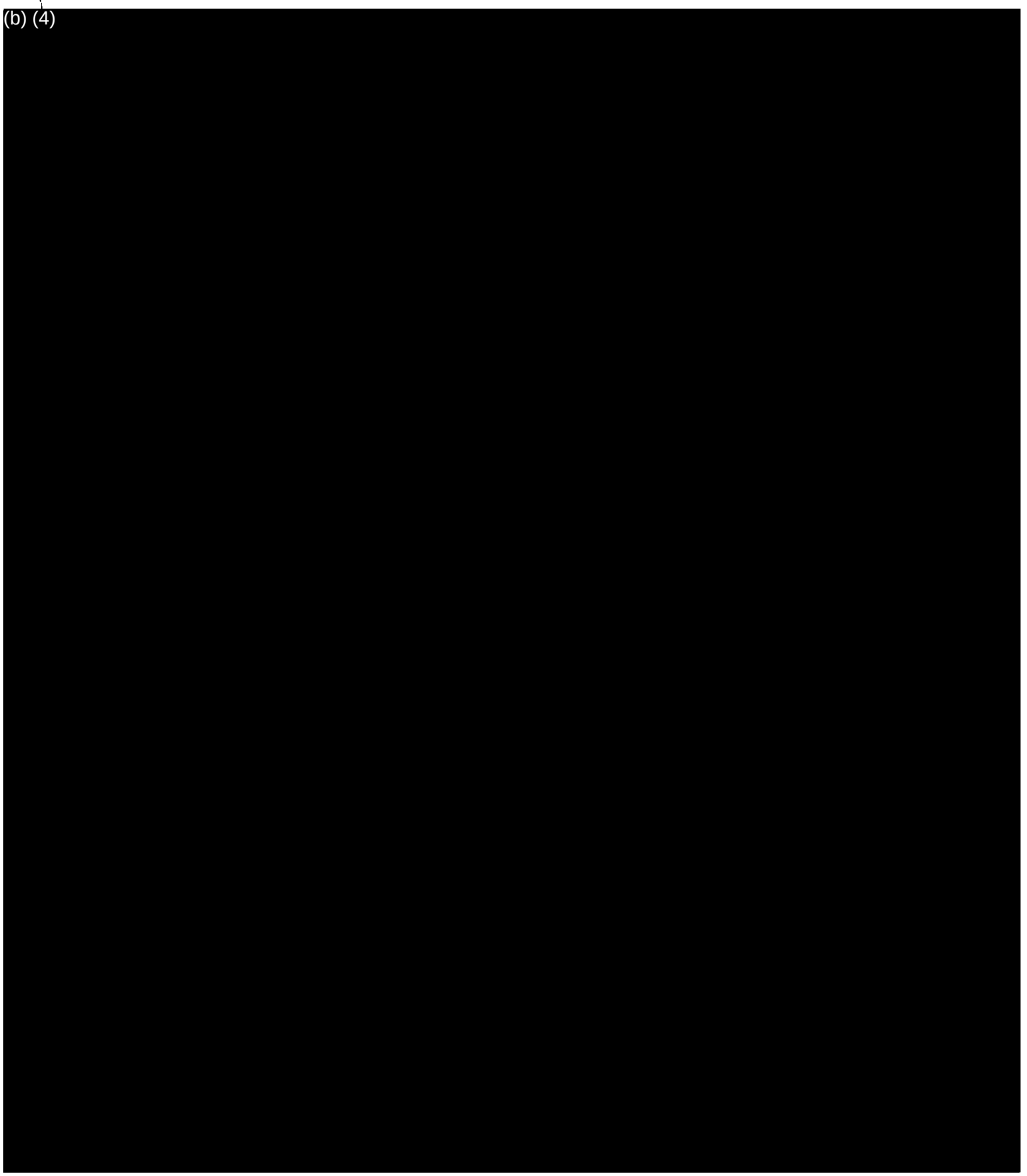
1.8 Test Location

Integrated Surgical Systems, Inc.
829 West Stadium Lane
Sacramento, CA 95834
(916) 920-5009

DJA x00302

1.9 Accreditations and Authorizations

(b) (4)



DJA x00303

2.0 System Test Configuration

(b) (4)

DJA x00304

3.0 Electrostatic Discharge (ESD)

3.1 Test Description

(b) (4)

DJA x00305

3.4 Performance Criteria

(b) (4)

[redacted]

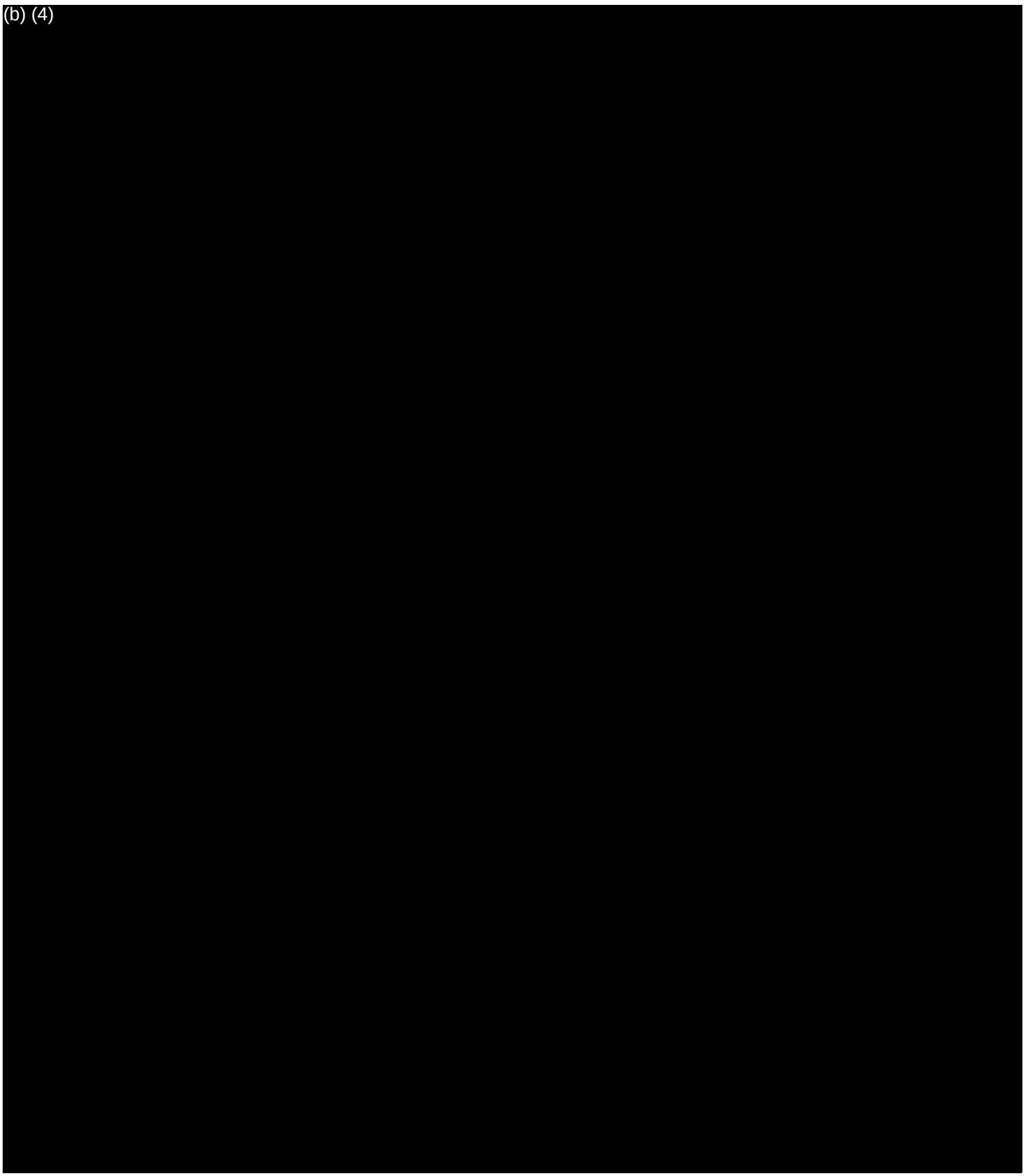
3.5 Test Results

(b) (4)

[redacted]

DJA x00306

(b) (4)



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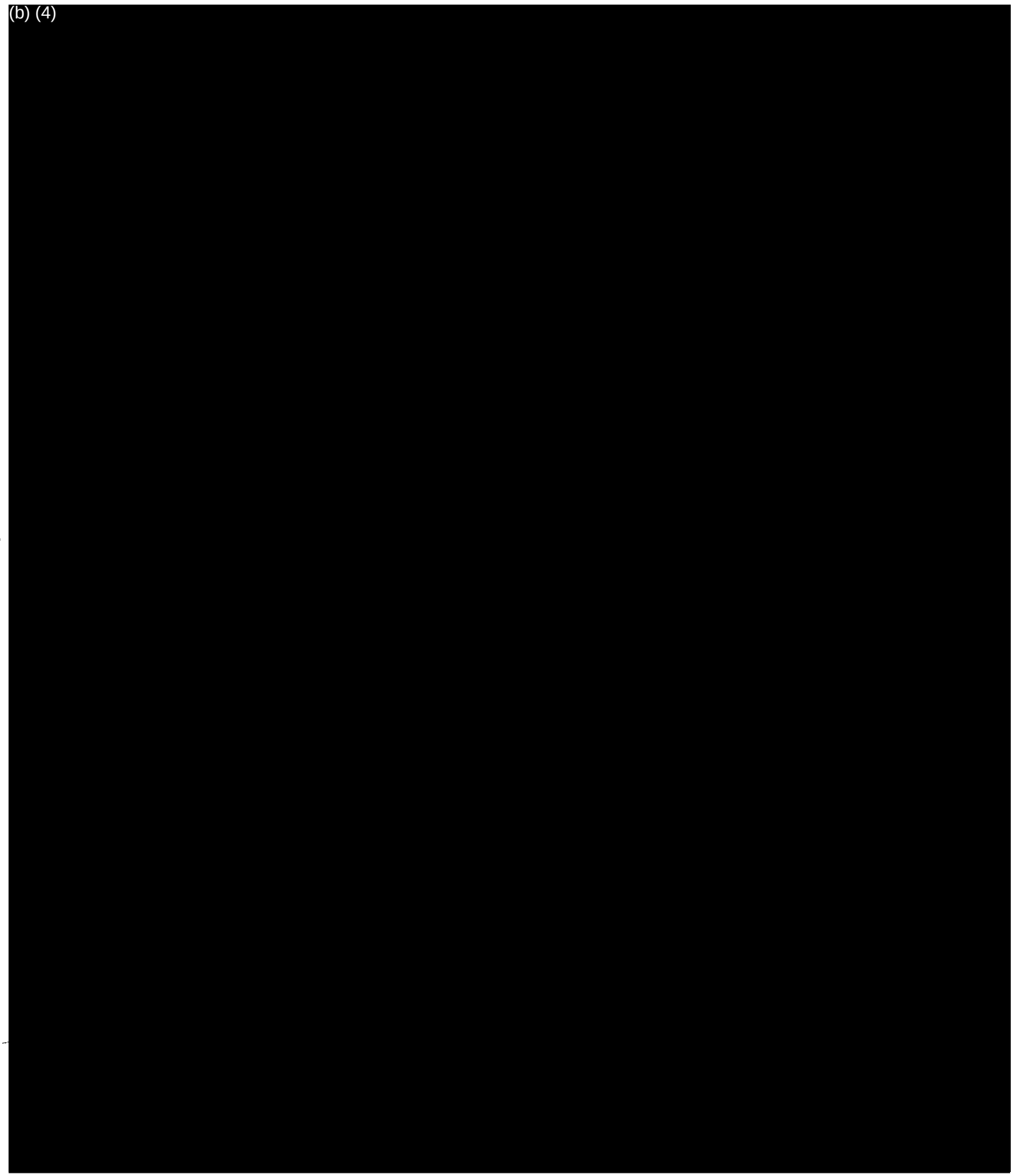

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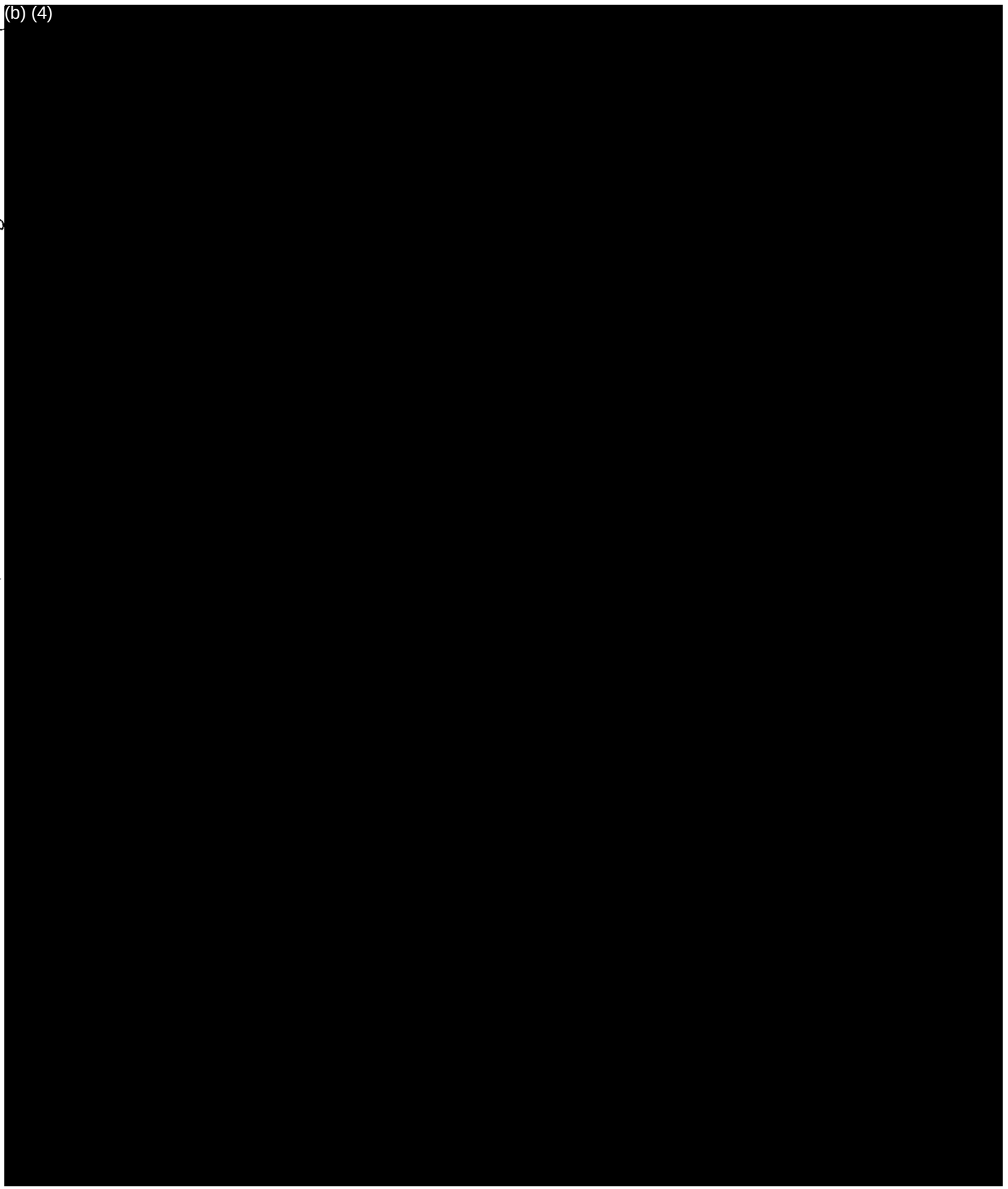

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DJA x00309

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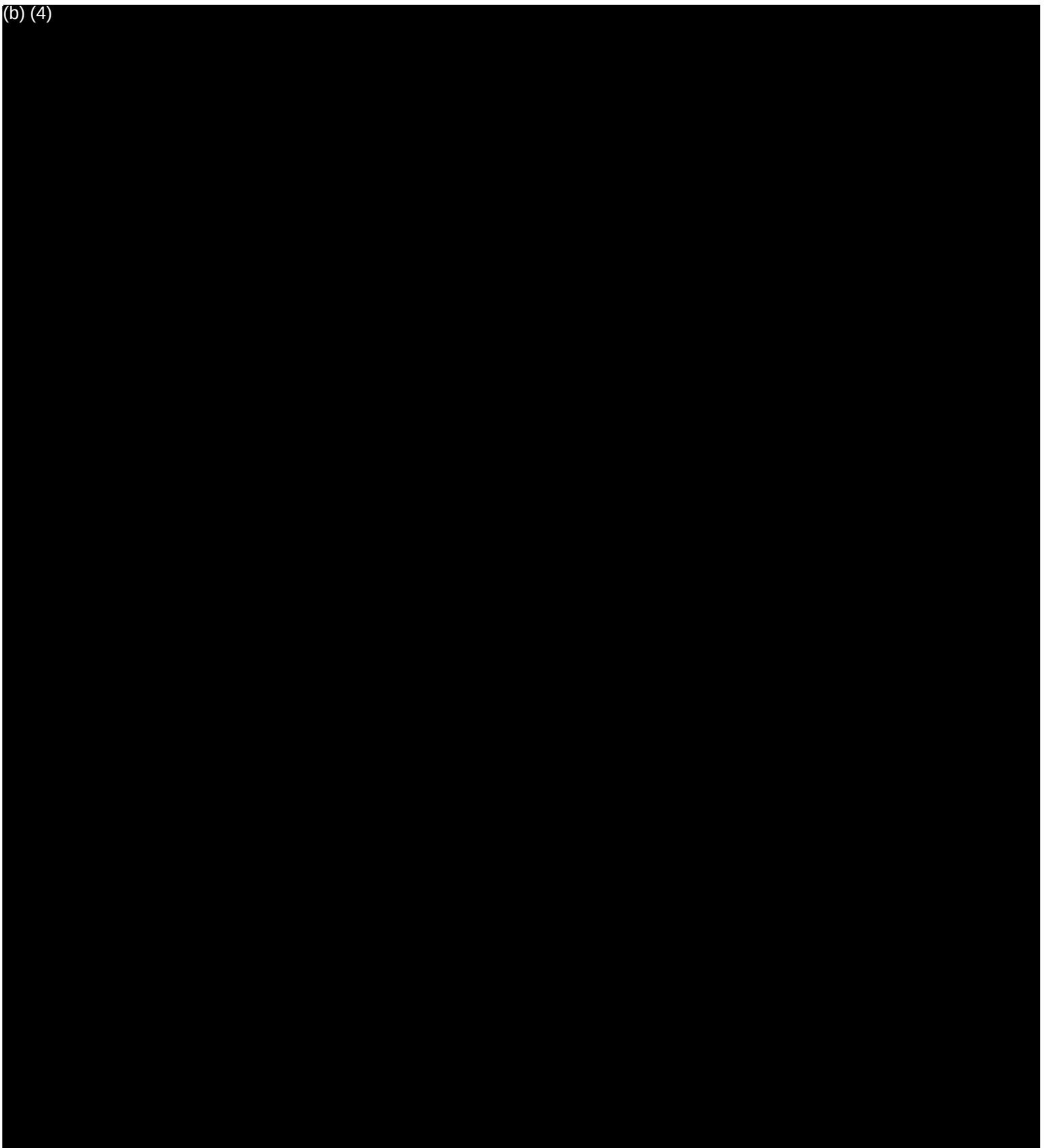

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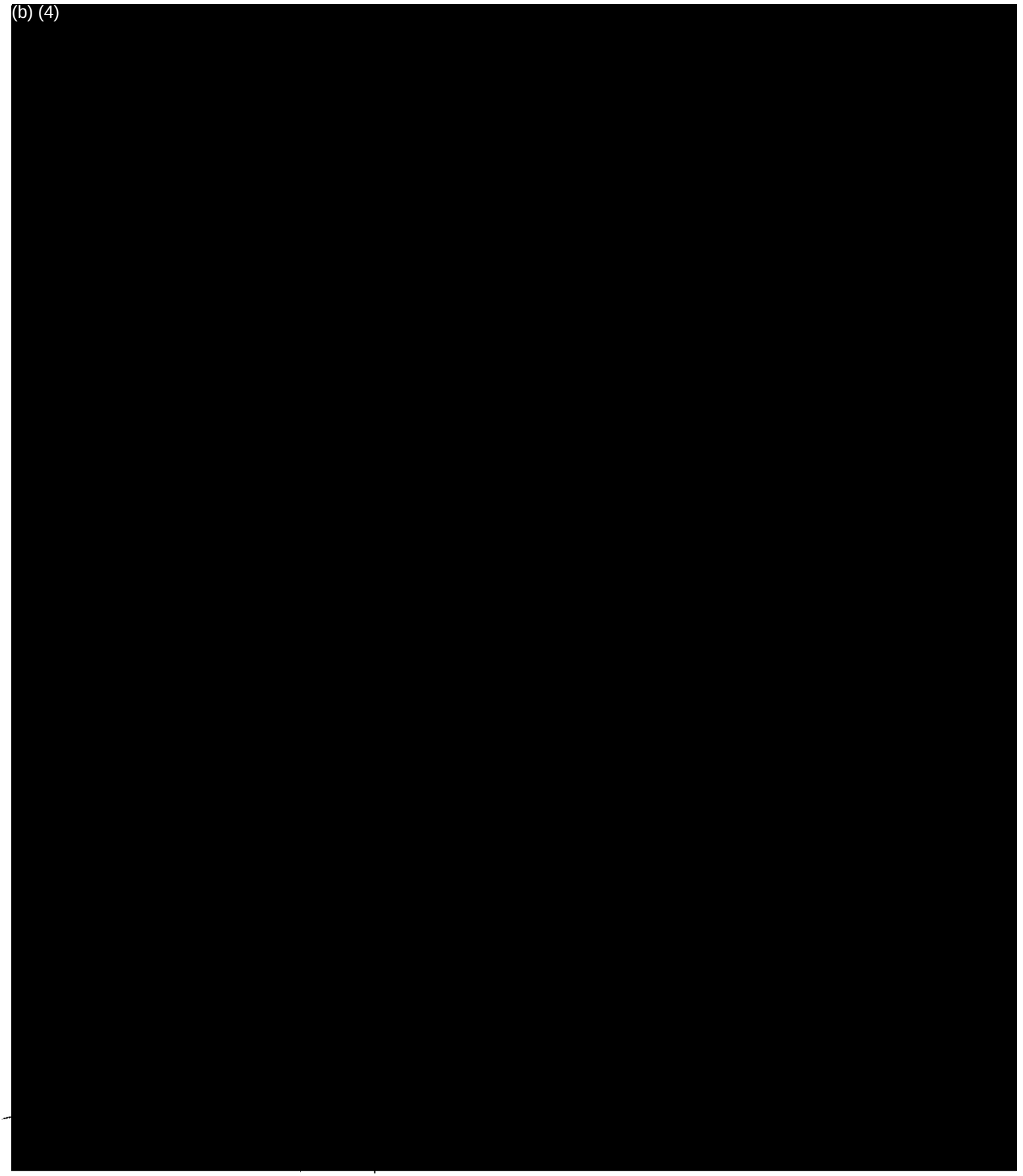

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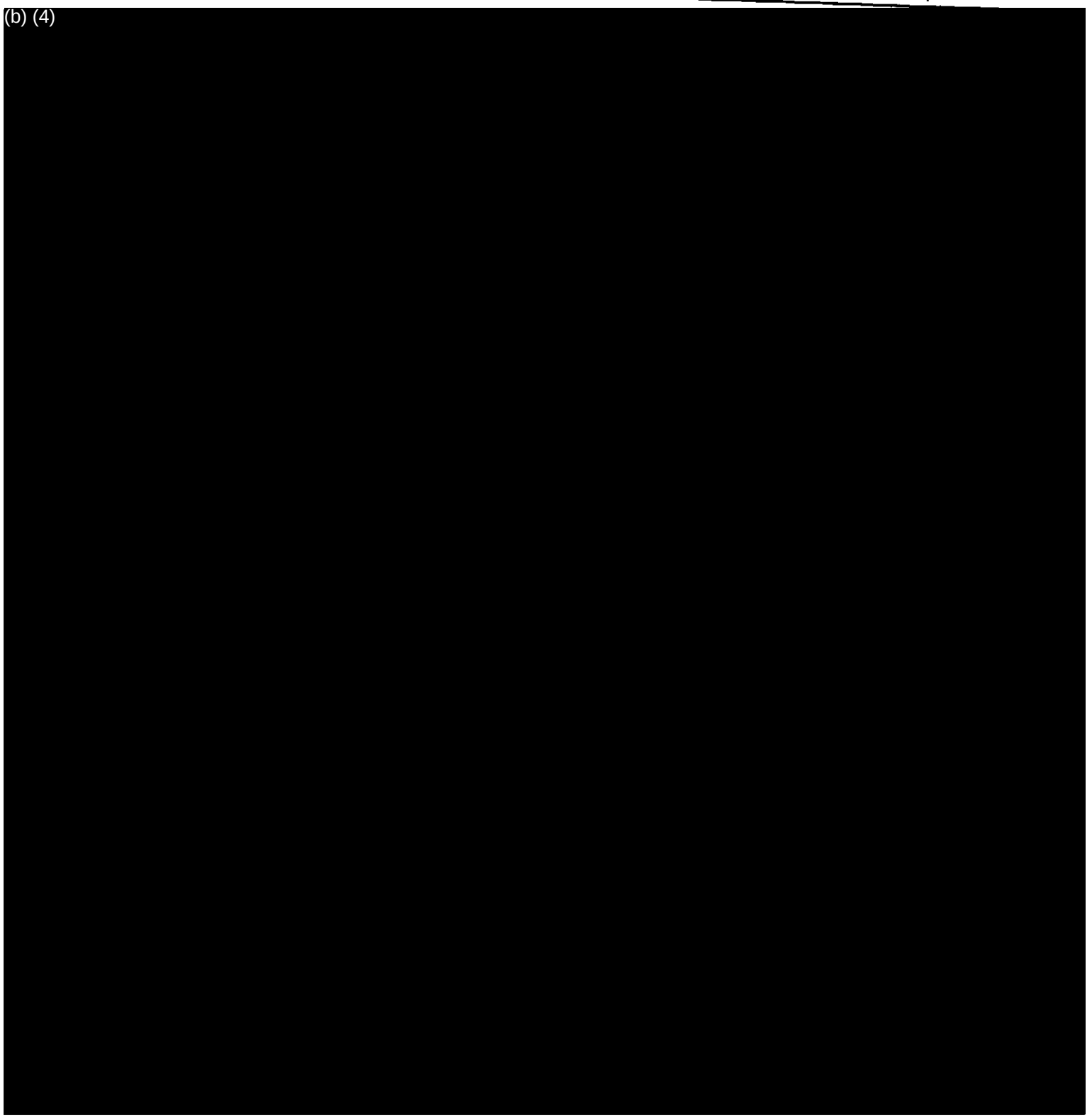

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DJA x00313

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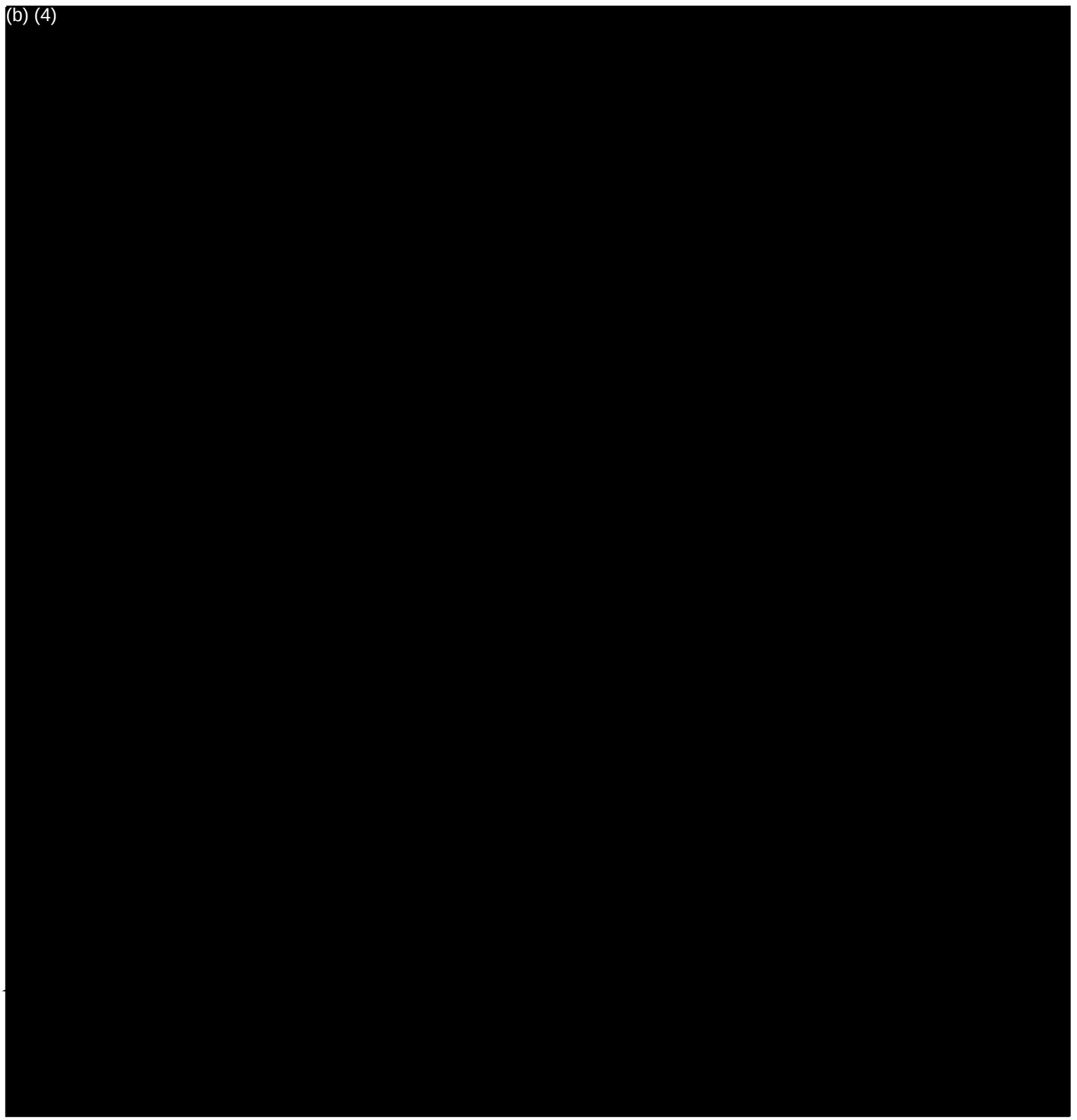

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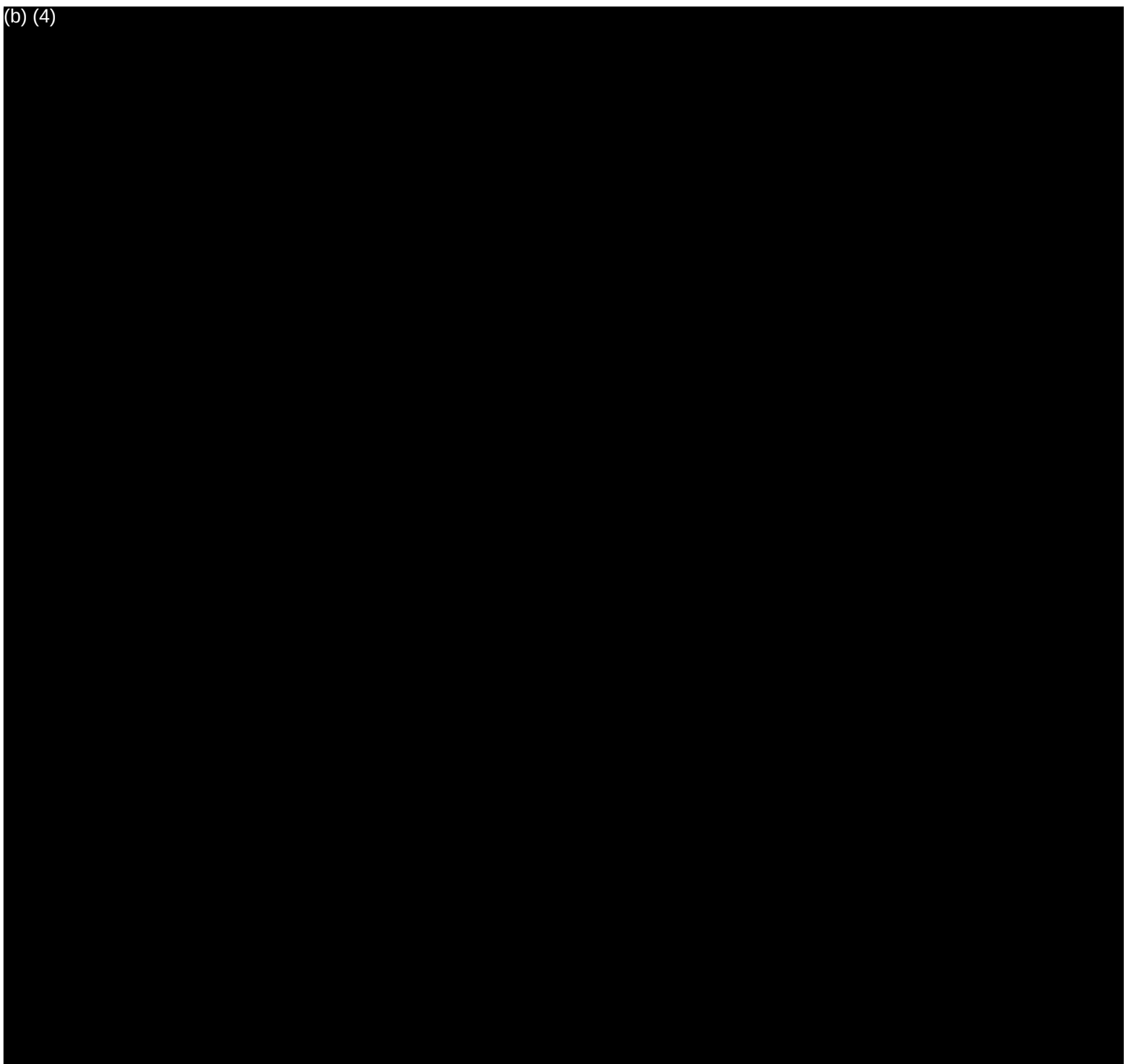

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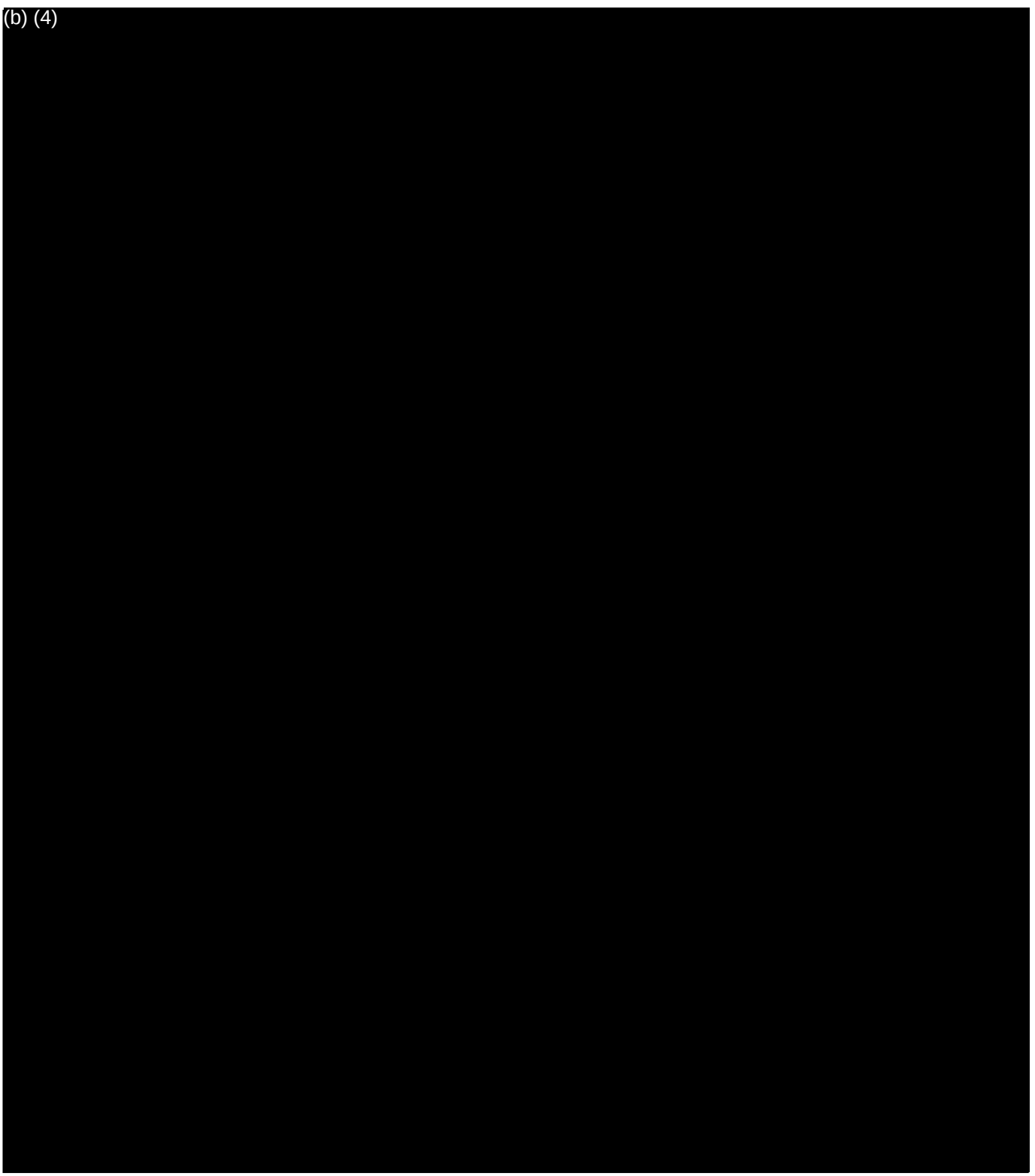

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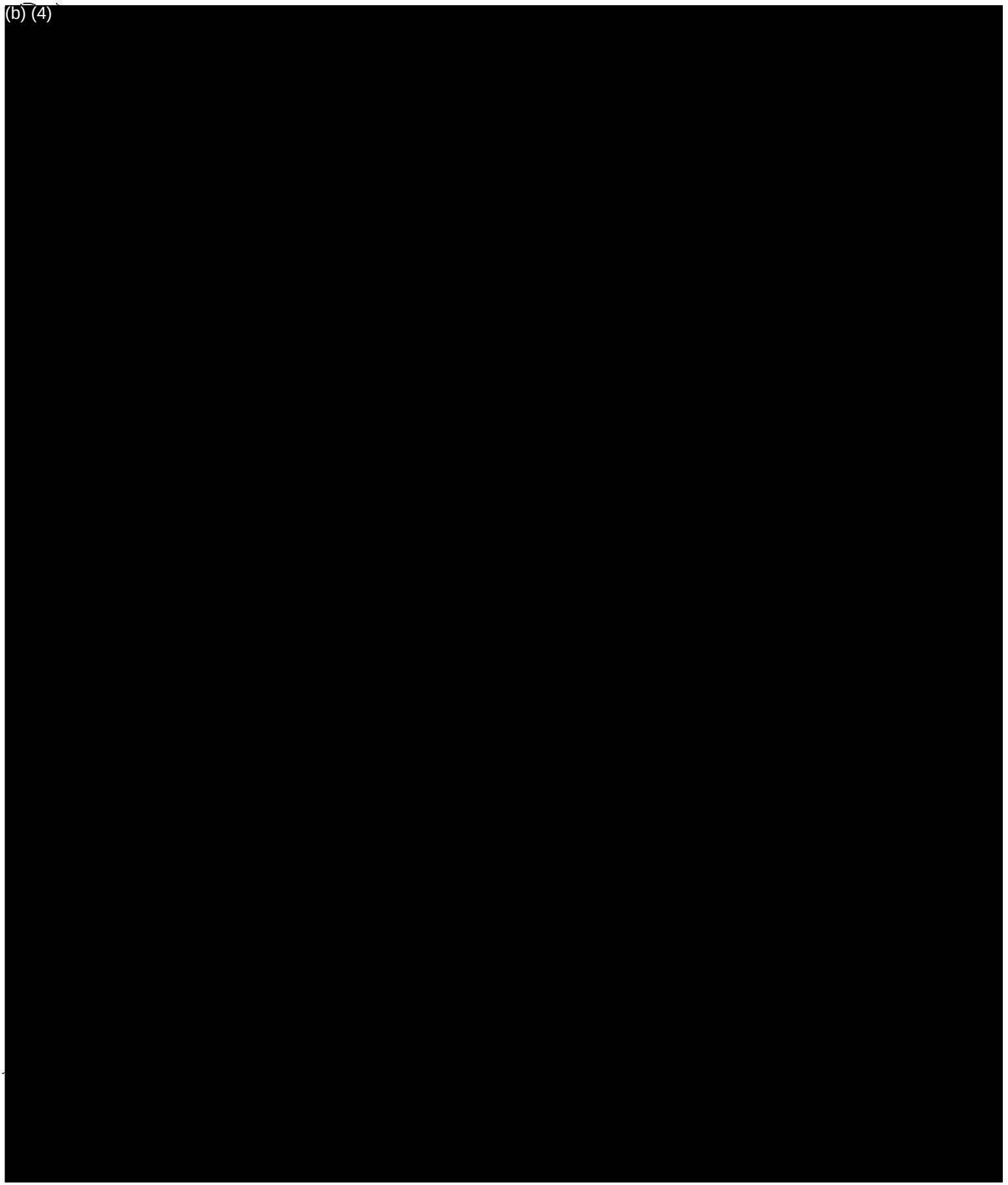

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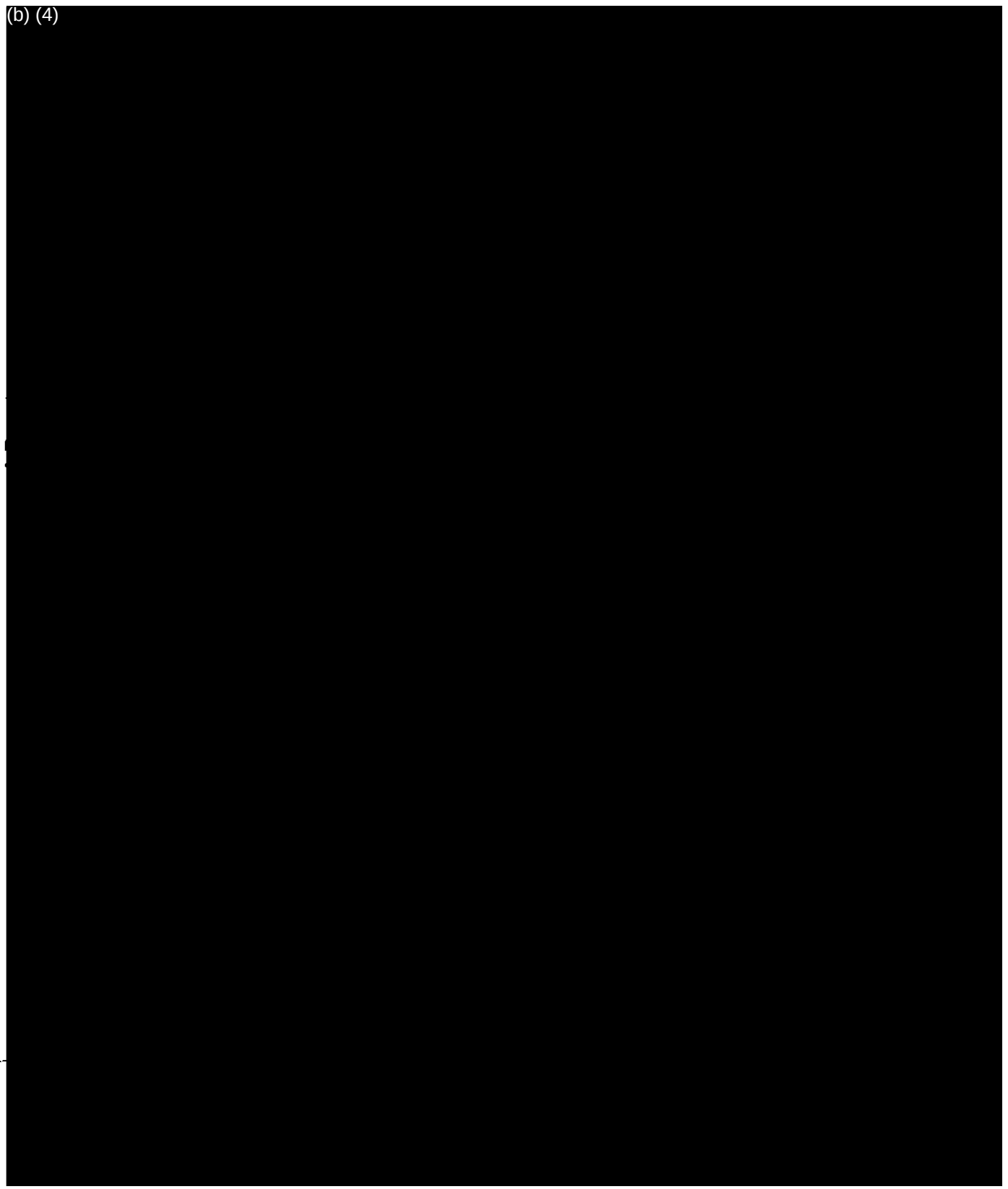

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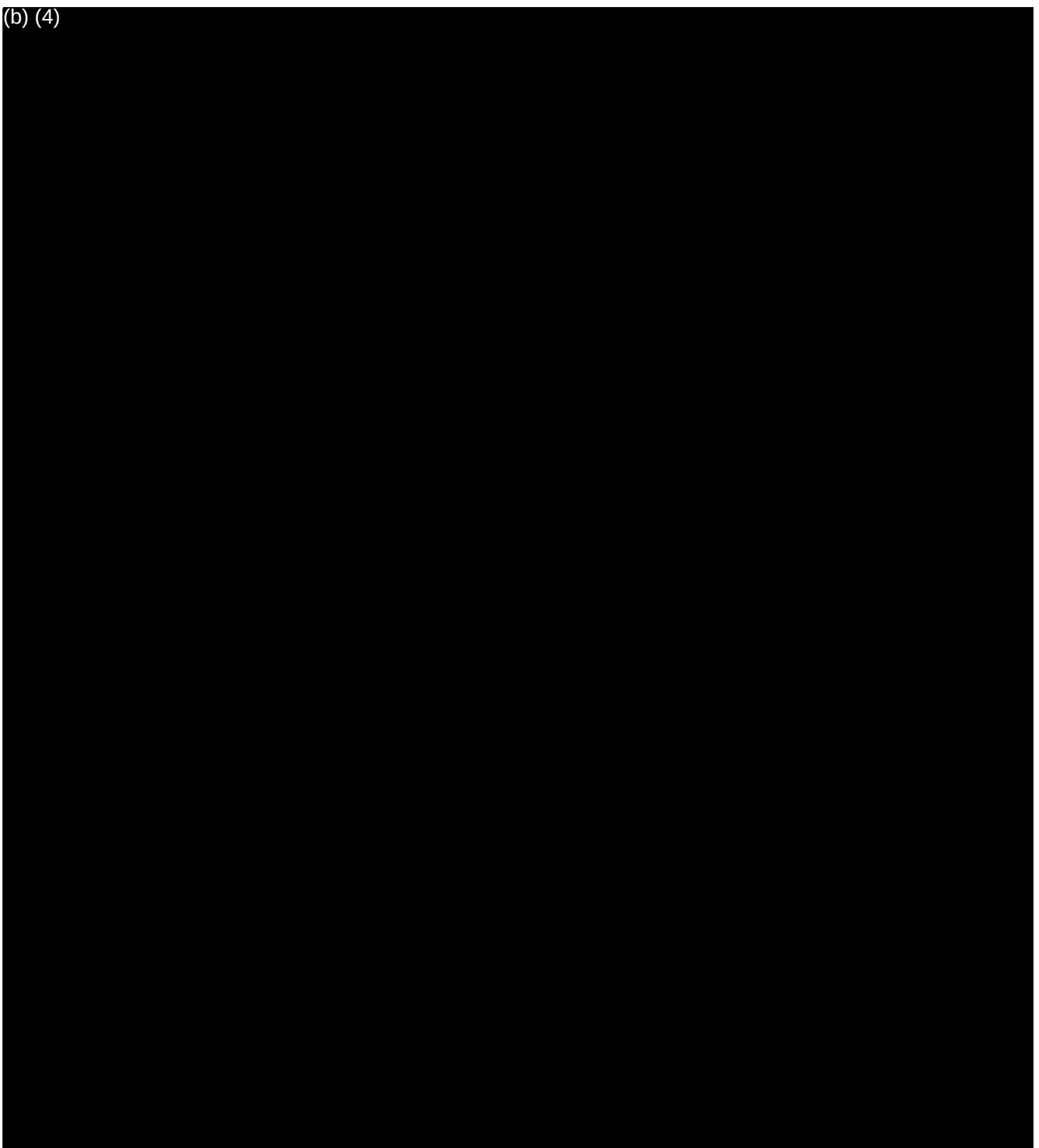


(b) (4)

DJA x00320

Appendix I Test Data

DJA x00321

ESD TEST FORM

(b) (4)

[redacted]

ESD TEST FORM

(b) (4)

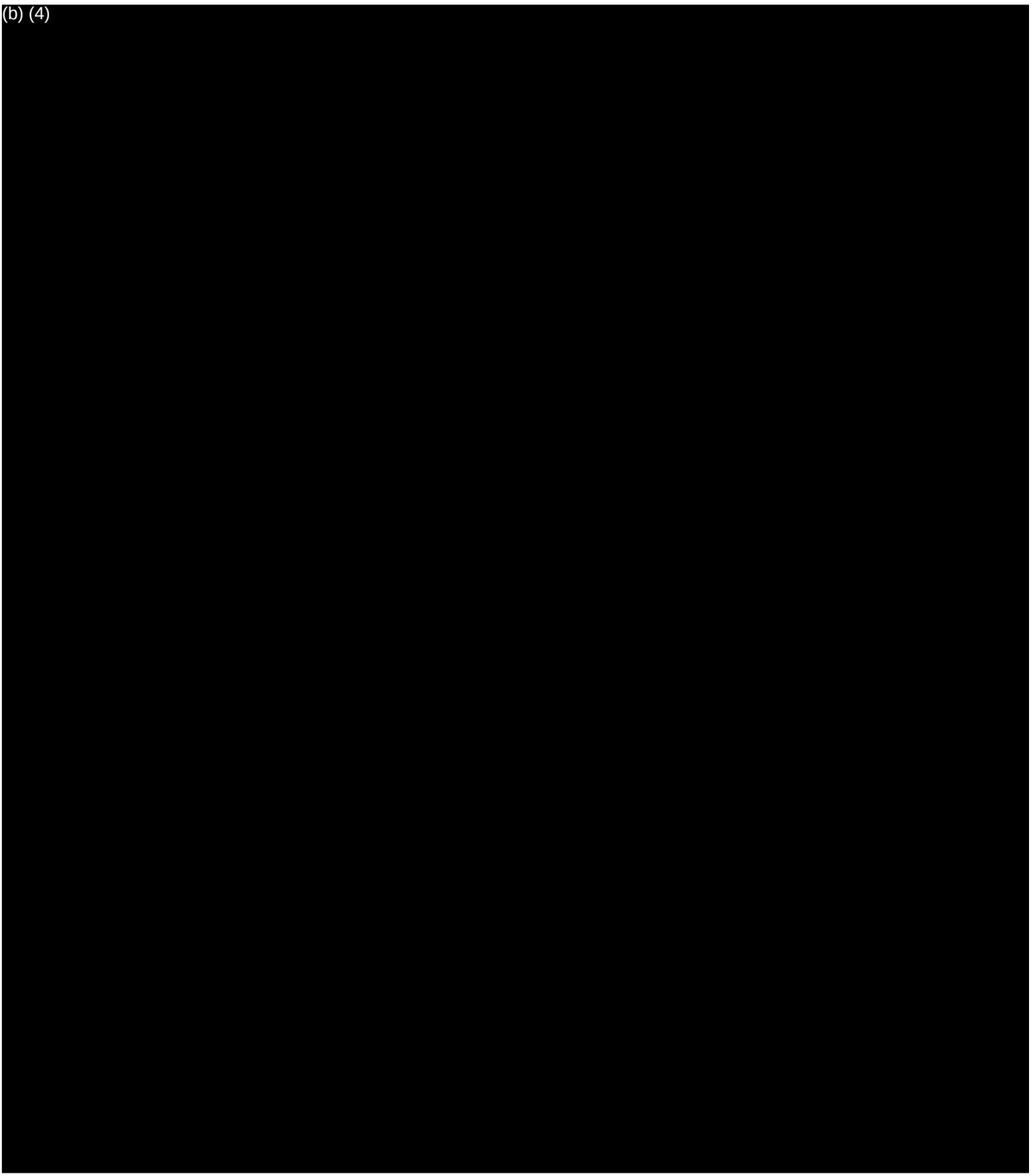
[redacted]

Tested By: (b) (6) [redacted]

Date: 2/27/98

DJA x00323

(b) (4)



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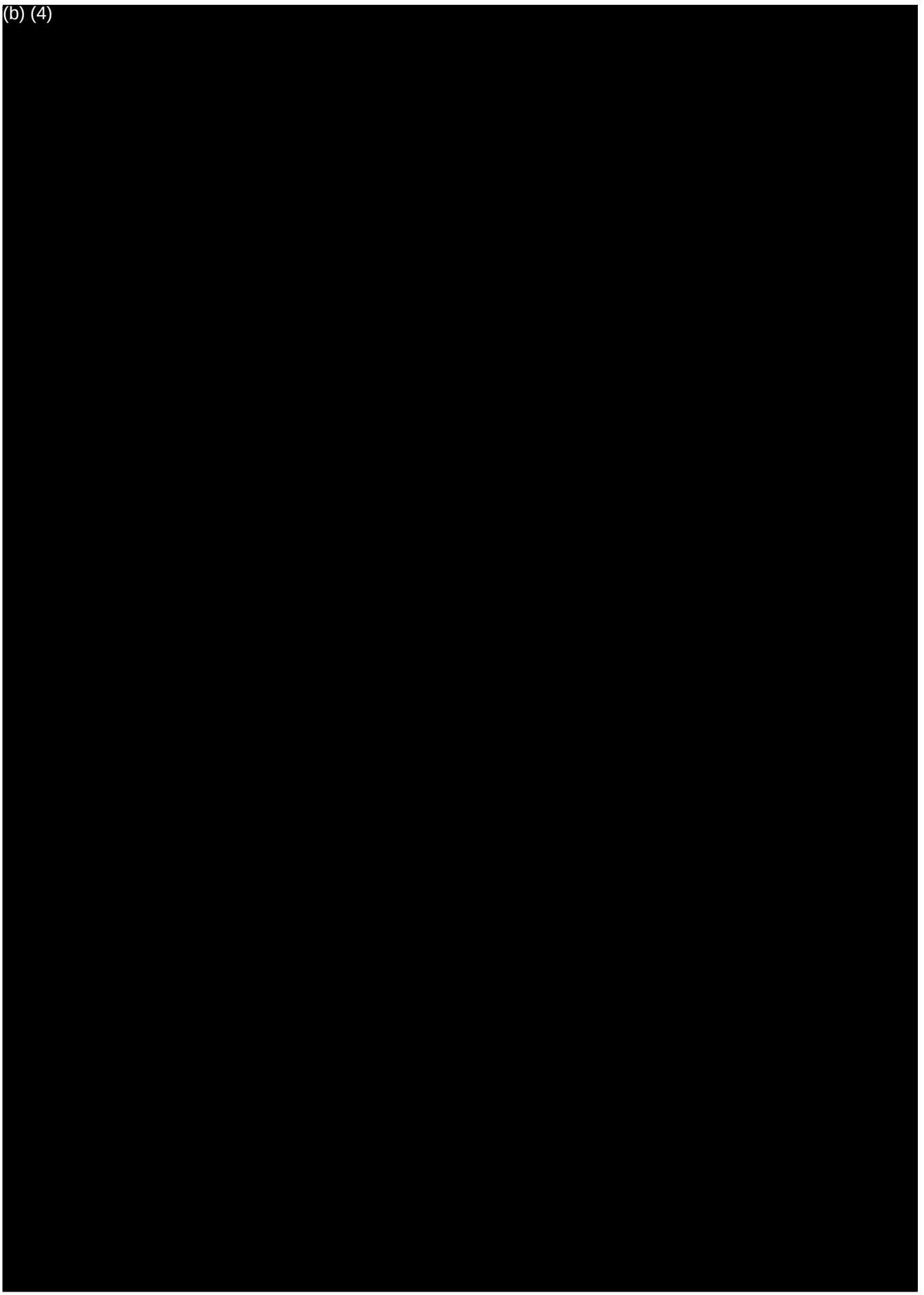

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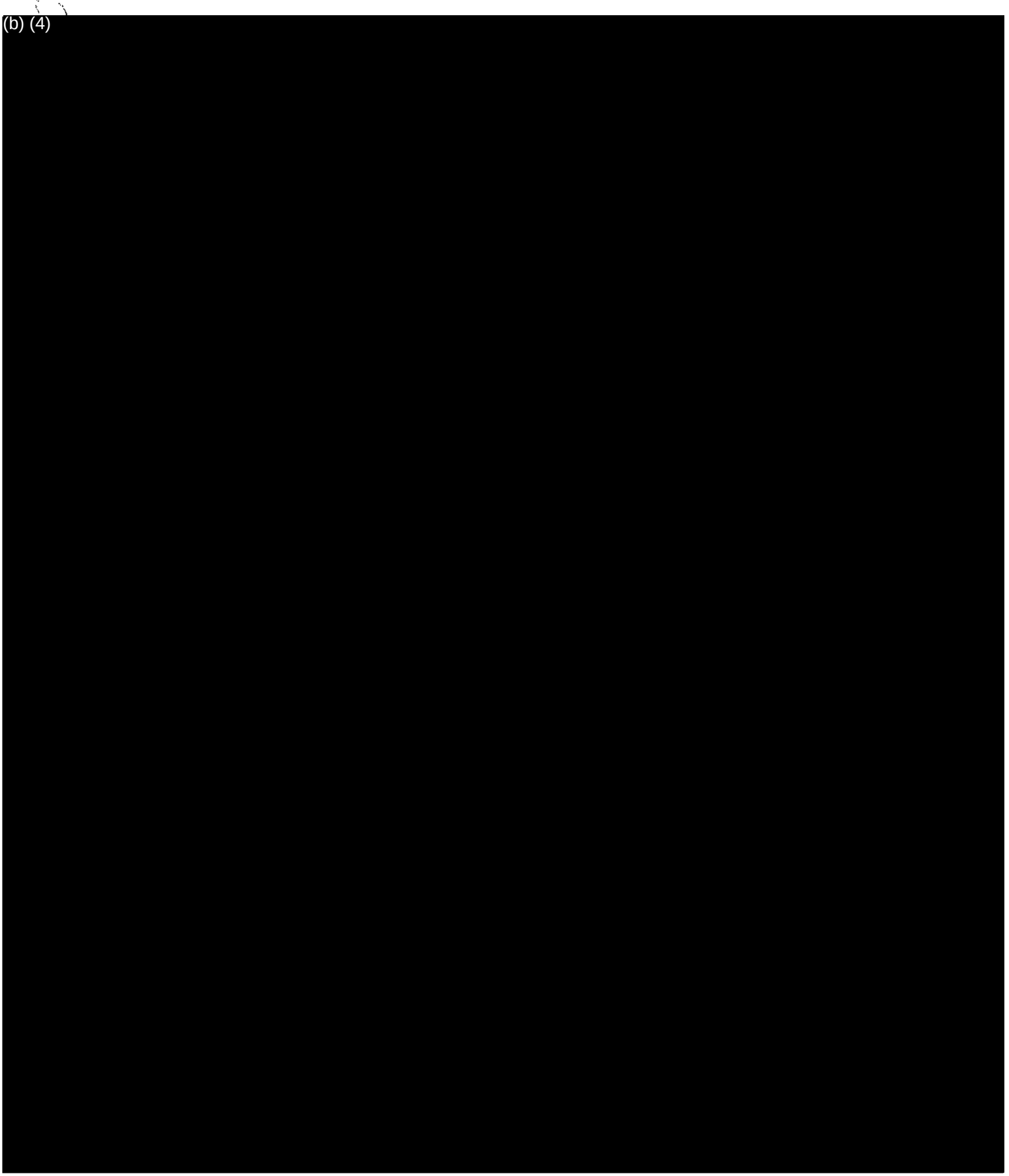

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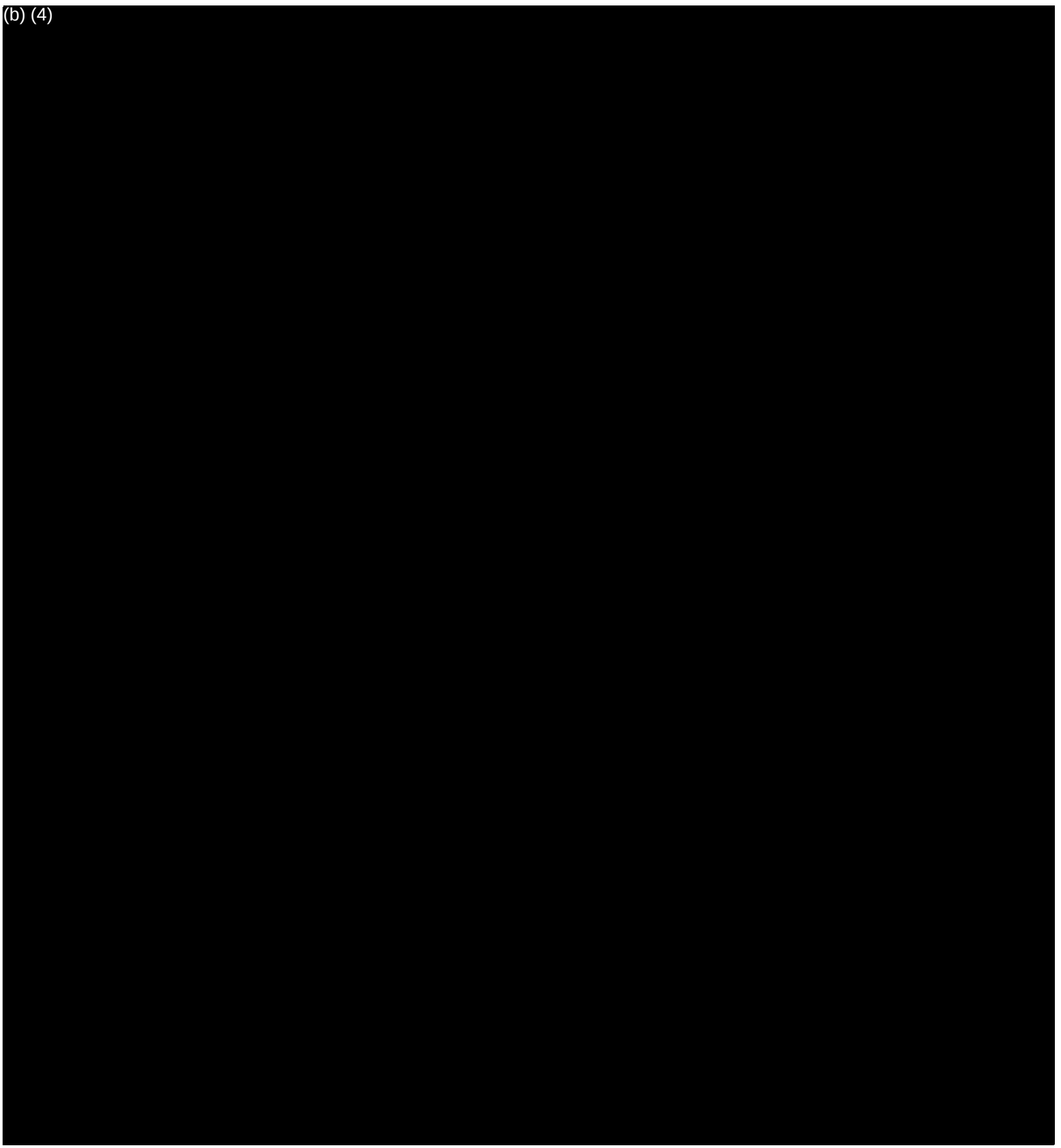
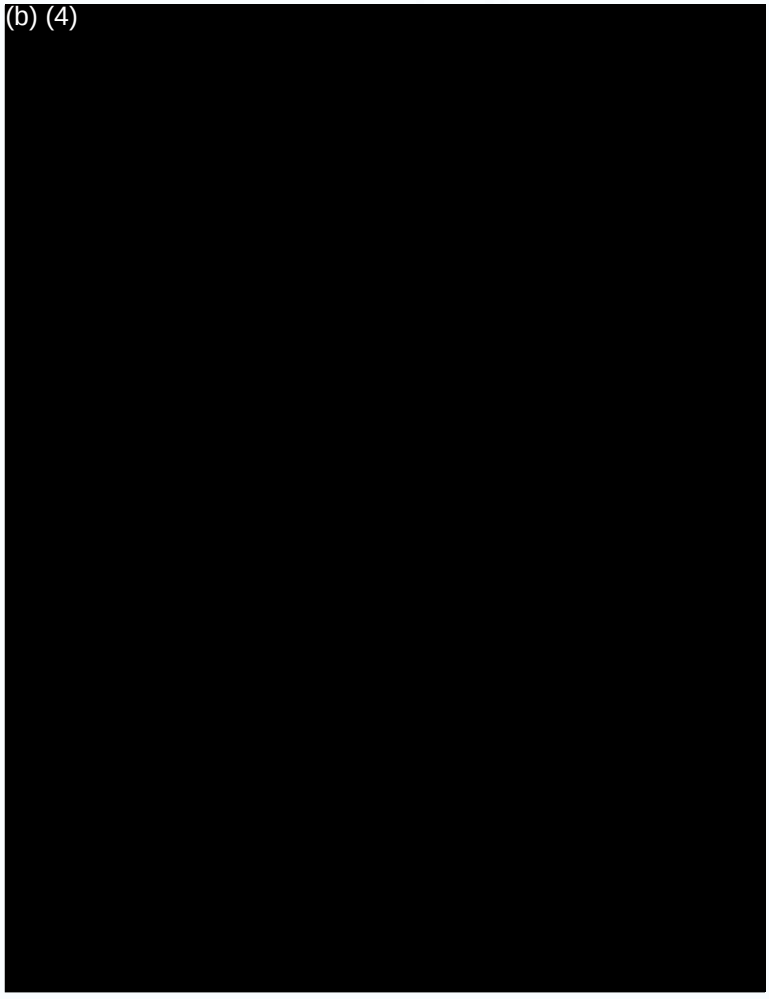


DJA x00327

6.0 Photographs

ESD, Test Setup



DJA x00328

6.0 Photographs

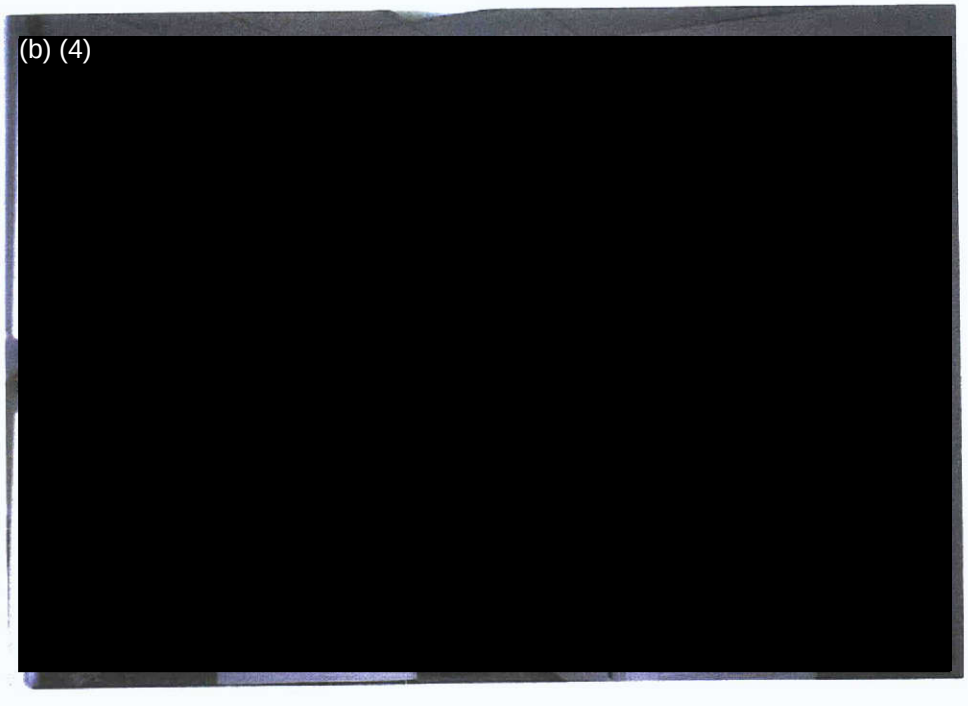
Conducted Emissions, Test Setup

DJA x00329

6.0 Photographs

Radiated Emissions, Test Setup

Radiated Emissions, Test Setup



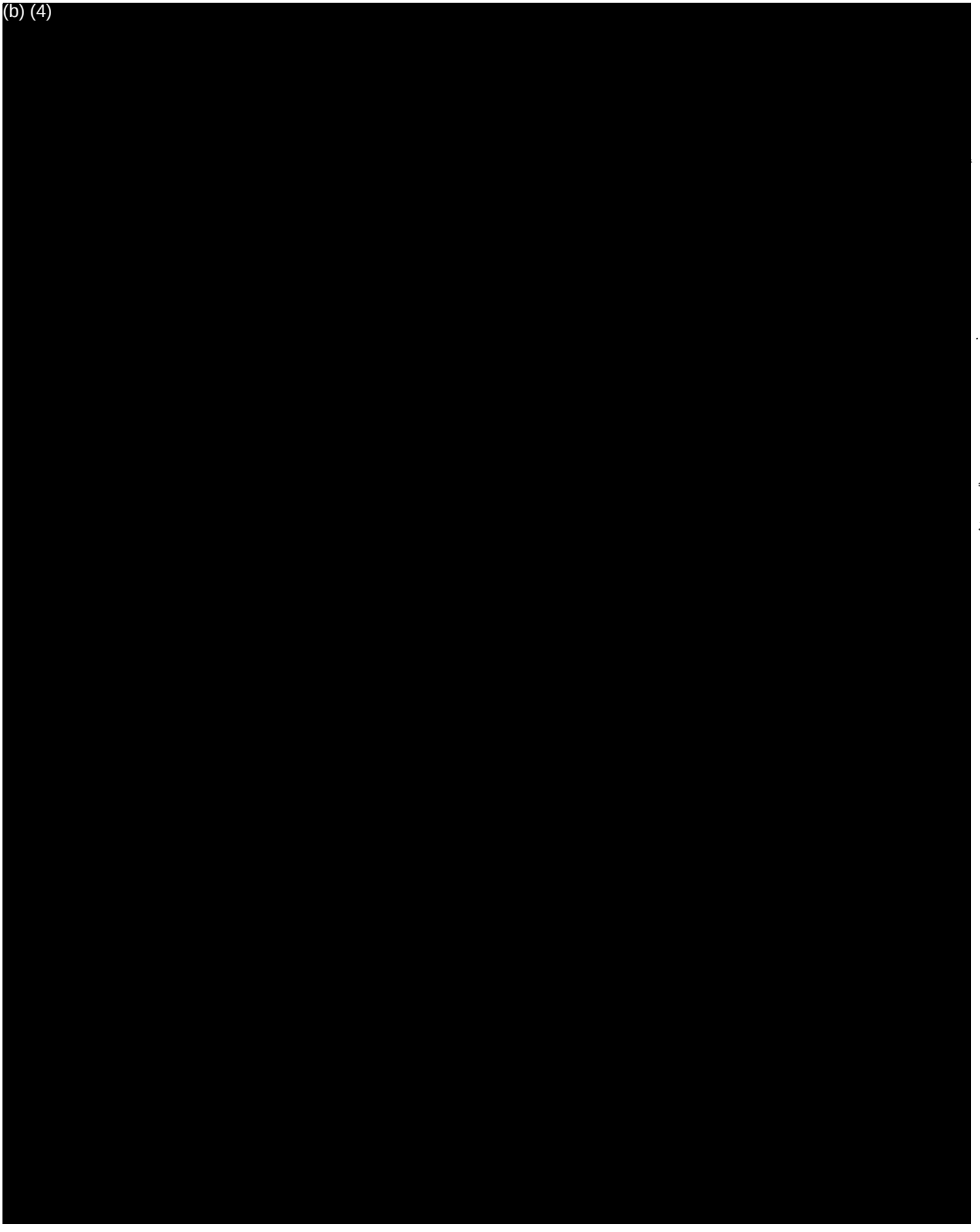
DJA x00330

Attachment 6

Updated Risk Management Report
DIGIMATCH™ ROBODOC® System

DJA x00331

(b) (4)



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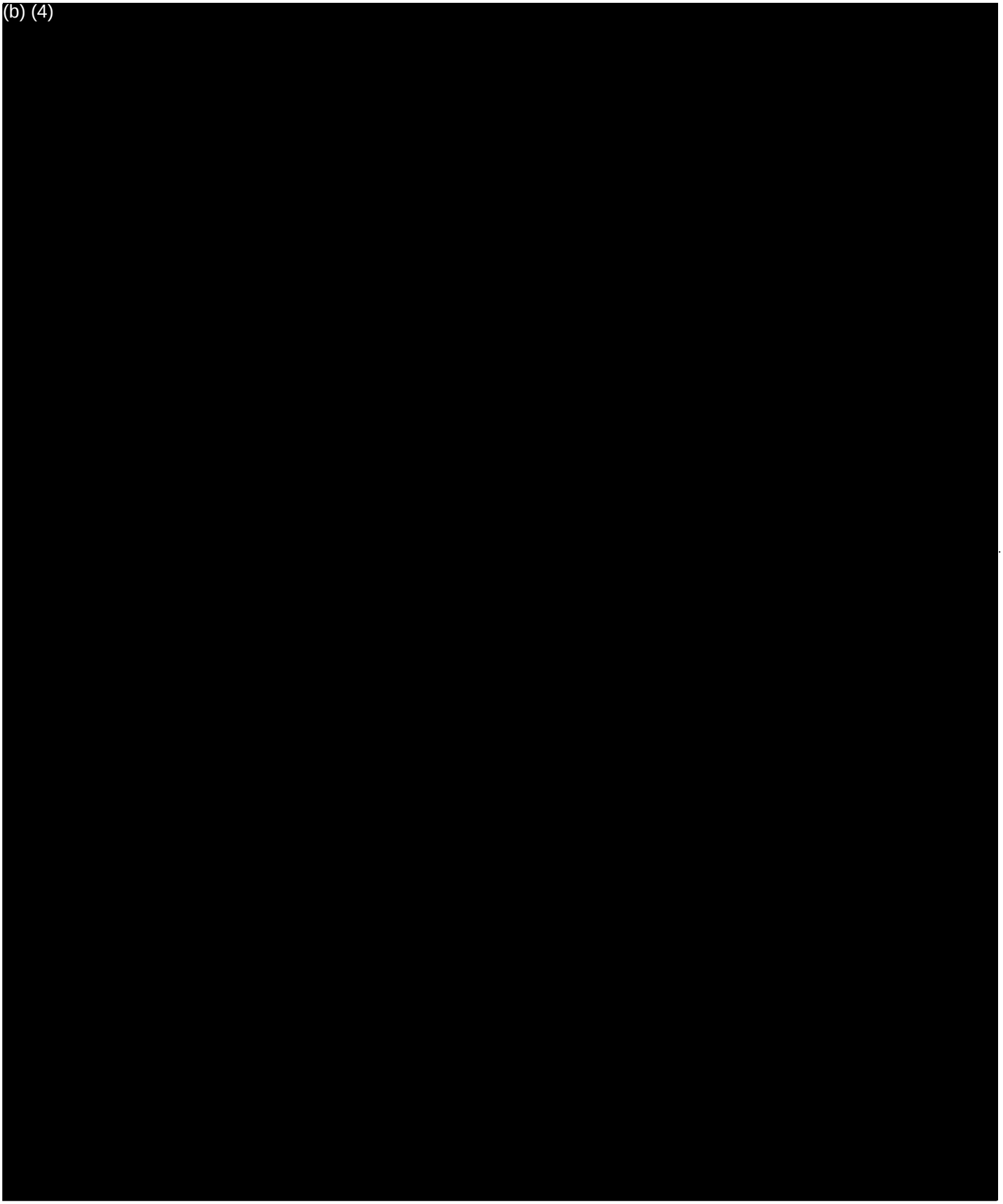

DJA x00333

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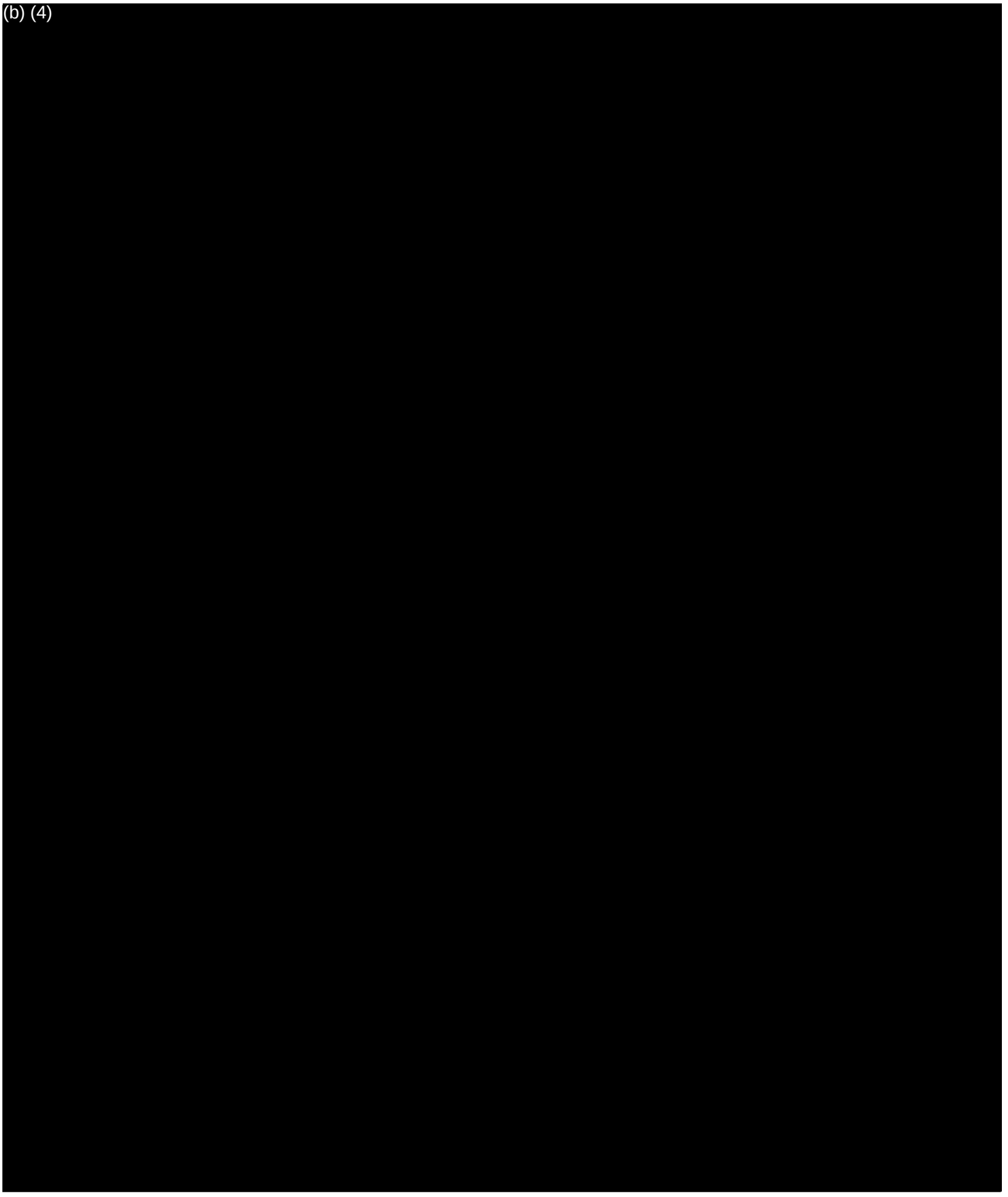

DJA x00334

(b) (4)

DJA x00335

Attachment 7

Updated Device Hazard Analysis

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazards Without Controls	RPN SPD	Applicable Controls	Response After Controls	RPN SPD	Referenced Document
ORTHODOC											

(b) (4)

[redacted]

[redacted]

(b) (4)

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazards Without Controls	RPN SPD	Applicable Controls	Response After Controls	RPN SPD	Referenced Document

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazards Without Controls	RPN SPD	Applicable Controls	Response After Controls	RPN SPD	Referenced Document
(b) (4)											

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazards Without Controls	RPN / SPD	Applicable Controls	Response After Controls	RPN / SPD	Referenced Document
								BMM diagnostics			TS99-022-38

(b) (4)

[redacted]

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazards Without Controls	RPN Sev	Applicable Controls	Response After Controls	RPN Sev	Referenced Document

(b) (4)

[redacted]

(b) (4)

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazard Without Controls	RPN SPD	Applicable Controls	RPN SPD	Response After Controls	RPN SPD	Referenced Document

DJA x00342

ID	Item	Function	Failure Mode	Cause	Effect On System	Possible Hazards Without Controls	RPN / SPD	Applicable Controls	Response After Controls	RPN / SPD	Referenced Document
(b) (4)											

DJA x00343

Attachment 8

Excerpts – ROBODOC User Manual, Chapter 6
Femoral Fixation

DRAFT 300344

Chapter 6

FEMORAL FIXATION

Introduction

This chapter describes a variety of procedures that must be performed to prepare the robot and the patient for femoral canal preparation. This chapter provides information for the surgeon and technician.

Before beginning the procedures described in this chapter, the following procedures must be complete:

- Sterile tool installation
- Draping the robot for sterility
- Non-sterile and sterile diagnostics

WARNING: Do not administer anesthesia until the surgeon has confirmed the information on the patient verification screens and the robot has passed the diagnostic tests.

Starting the Surgery

This section provides instructions for the surgeon and OR team regarding the initial procedures for THA using the ROBODOC System. This section explains how to start.

After the robot passes all diagnostic tests and the surgeon confirms the data on the surgeon verification screens, anesthesia can be administered. The surgery begins in the same fashion as a non-robotic assisted hip operation.

The osteotomy for DigiMatch surgeries must be at the approximate level illustrated in Figure 6-1 because some of the bone surfaces required for surface registration are located high on the femoral neck. The acetabulum will be prepared after the robot has milled the implant cavity because the high neck cut will not provide adequate access for acetabulum preparation and installing the acetabular cup.

⇨ **To start a DigiMatch surgery:**

1. Administer anesthesia.

2. Position the patient for an anterolateral (modified Watson-Jones), posterolateral, or direct lateral approach, whichever is supported by the configuration of your system.

   When prepping and draping the operative hip, expose a slightly larger area posteriorly to ensure clearance for the cutter and soft-tissue retractors around the proximal femur.

3. Make the opening incision.

   Later it may be necessary to slightly extend the proximal end of the incision to ensure adequate clearance for the cutter.

4. Dislocate the hip.

5. Perform an initial femoral neck osteotomy at the approximate level shown in Figure 6-1.

   NOTE: The entire femoral neck must be intact for surface registration.

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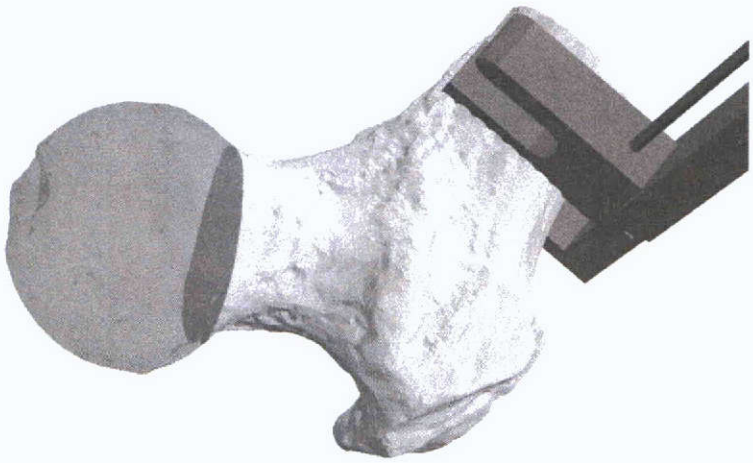

Figure 6-1. Osteotomy Level for DigiMatch Cases

6. Clear soft tissue from the region of interest (ROI).

   To facilitate surface registration, soft tissue should be cleared from the surface of the bone where data points will be collected. Clearing soft tissue will help to visually locate the required points on the bone surface.

Figure 6-2 shows the ROI where soft tissue should be cleared:

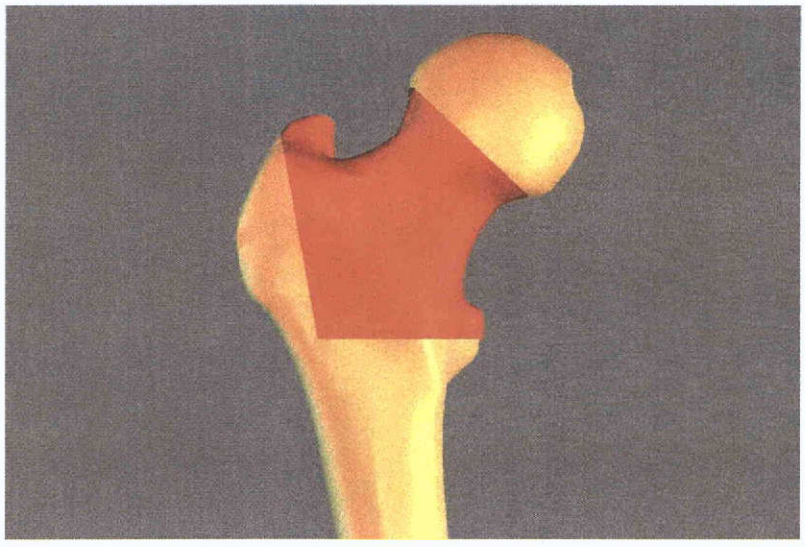

Figure 6-2. ROI Requiring Soft Tissue Removal

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Installing the Femoral Fixator

This section explains how to install the femoral fixator. These procedures will be performed by the surgeon and OR team.

The femoral fixator is a proximal bone clamp that attaches to the robot base. The femoral fixator must be properly installed prior to registration procedures (digitizing points on the bone or finding locator pins) to ensure that no motion occurs after the robot has located the femur and performed the necessary geometric computations to determine cavity placement.

To accommodate variations in patient anatomy and leg side, the fixator is designed to secure the proximal portion of the femur by means of a bone clamp. The distal portion of the femur must be stabilized by means of a hospital-supplied support device. Adequate distal fixation is critical for DigiMatch cases.

Although the fixator components must be securely assembled to prevent the femur from moving, do not overtighten.

CAUTION:

- To facilitate safe placement of the proximal clamp on the proximal femoral, use standard surgical technique to clear the area of muscle and tissue from the femur where the clamp is to be placed.
- Take appropriate care to protect the sciatic nerve.

WARNING:

- Overtightening may damage the bone and/or soft tissue, or freeze the joints and make it difficult to detach and disassemble the fixator after femoral preparation.
- Bone quality in the proximal femur must be good to achieve adequate fixation without damaging or fracturing the bone.

The fixator components are shown in the following figure:

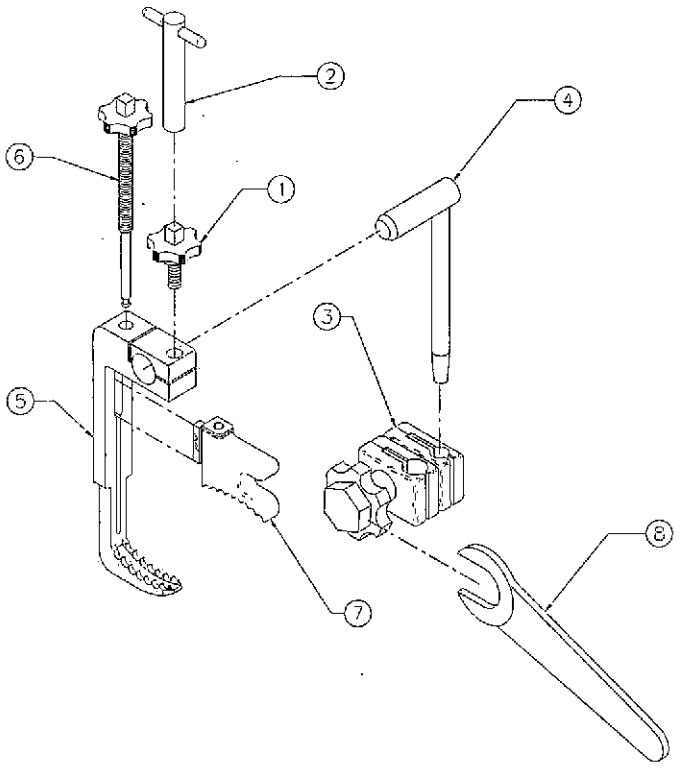

Figure 6-3. Fixator Components

① Knob Bolt	⑤ Lower Jaw
② T-Handle Wrench	⑥ Clamp Bolt
③ Swivel Block	⑦ Upper Jaw
④ Fixator attachment rod	⑧ Wrench

Proximal Fixation

⇨ To assemble the proximal clamp:

1. Place the upper jaw (7) into the slide channel on the lower jaw (5).
2. Place the clamp bolt (6) into the hole nearest the slide channel and join the upper and lower jaws by threading the clamp bolt through both jaws, leaving jaws fully open.
3. Thread the knob bolt (1) into the other hole provided in the lower jaw, but do not tighten.
4. Insert the fixator attachment rod (4) into the hole in the proximal end of the lower jaw.
5. Manually tighten the knob bolt (1).

DJA x00349

⇨ To install the proximal clamp:

1. Holding the proximal assembly, slide the proximal hook into place under the femur.

CAUTION:

- To facilitate safe placement of the proximal clamp on the proximal femoral, use standard surgical technique to clear the area of muscle and tissue from the femur where the clamp is to be placed.
- Take appropriate care to protect the sciatic nerve.

NOTE: To avoid interference with the cutter, the proximal hook must be positioned below the level of the osteotomy.

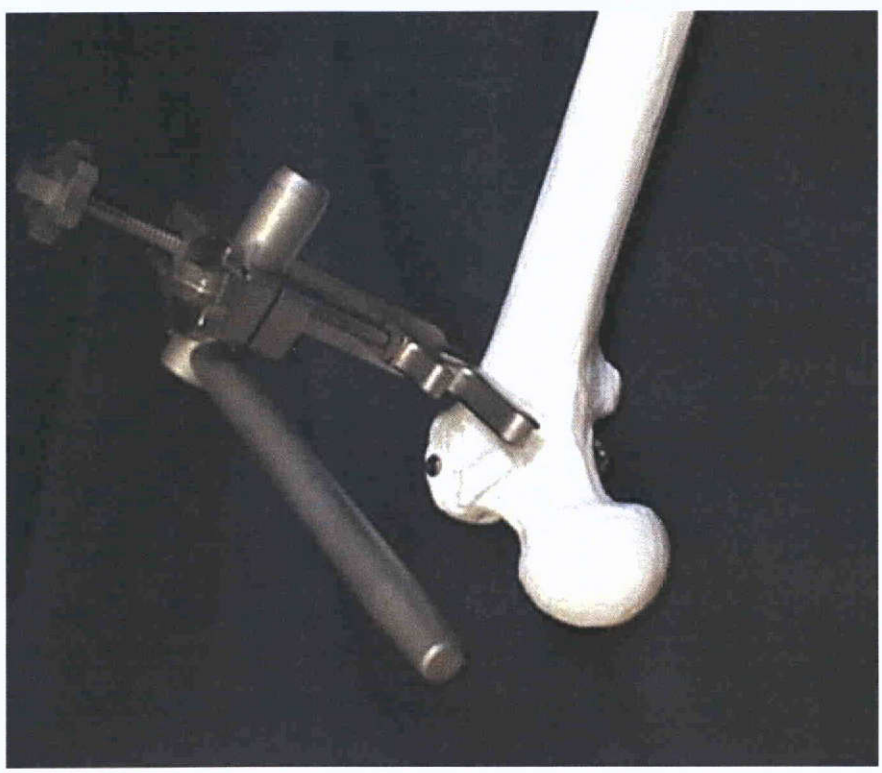

Figure 6-4. Proximal Clamp Position

2. Tighten the proximal clamp, using the T-handle to maintain a firm grip on the femur.
3. Ensure that the clamp holds the bone securely.

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VOL II

Index for Test Reports

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ROBODOC
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SURGICAL SYSTEMS

Pinless Prototype ROBODOC Software Procedural Test

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PRE-TEST PREPARTION

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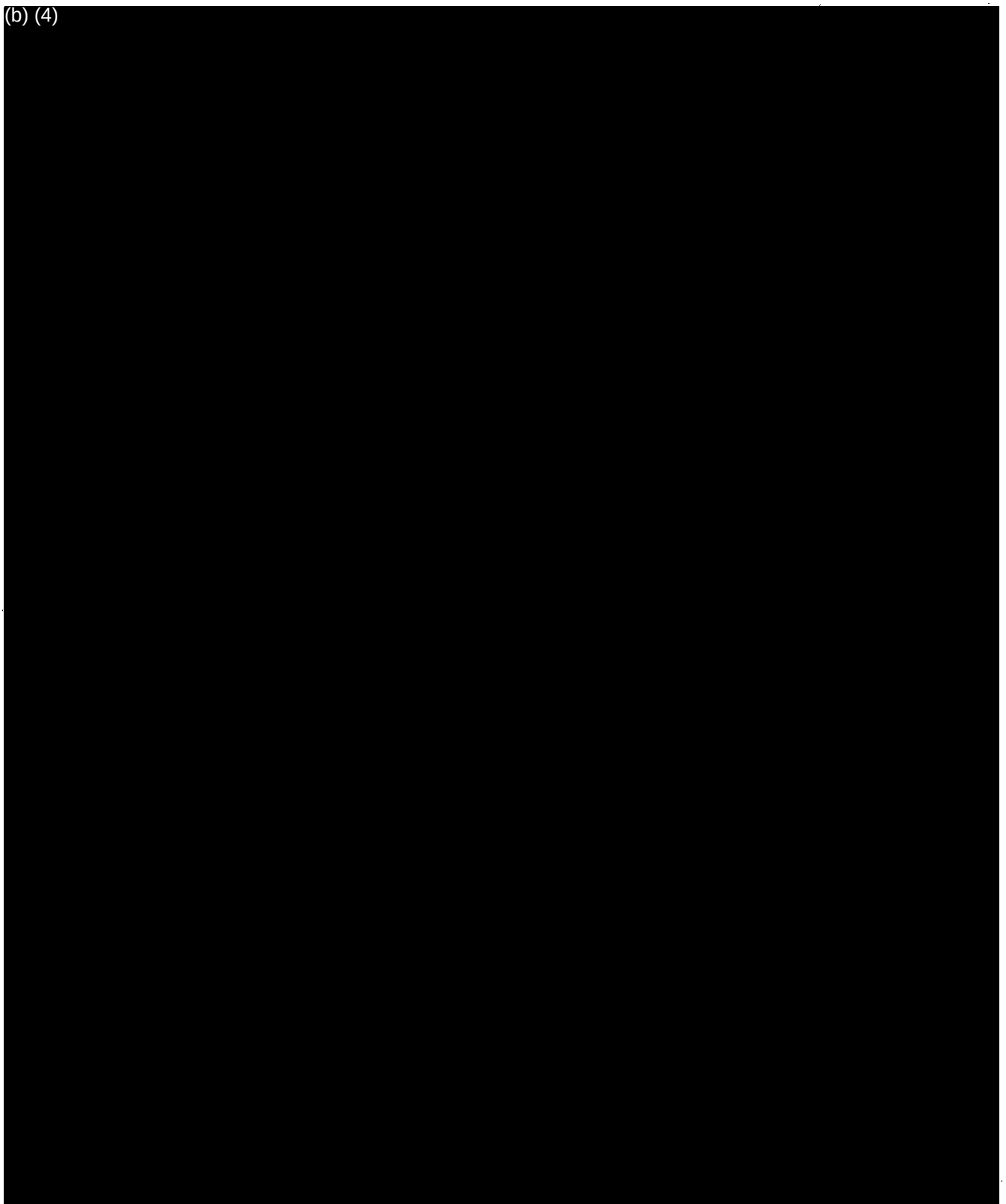

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PROCEDURAL TESTING

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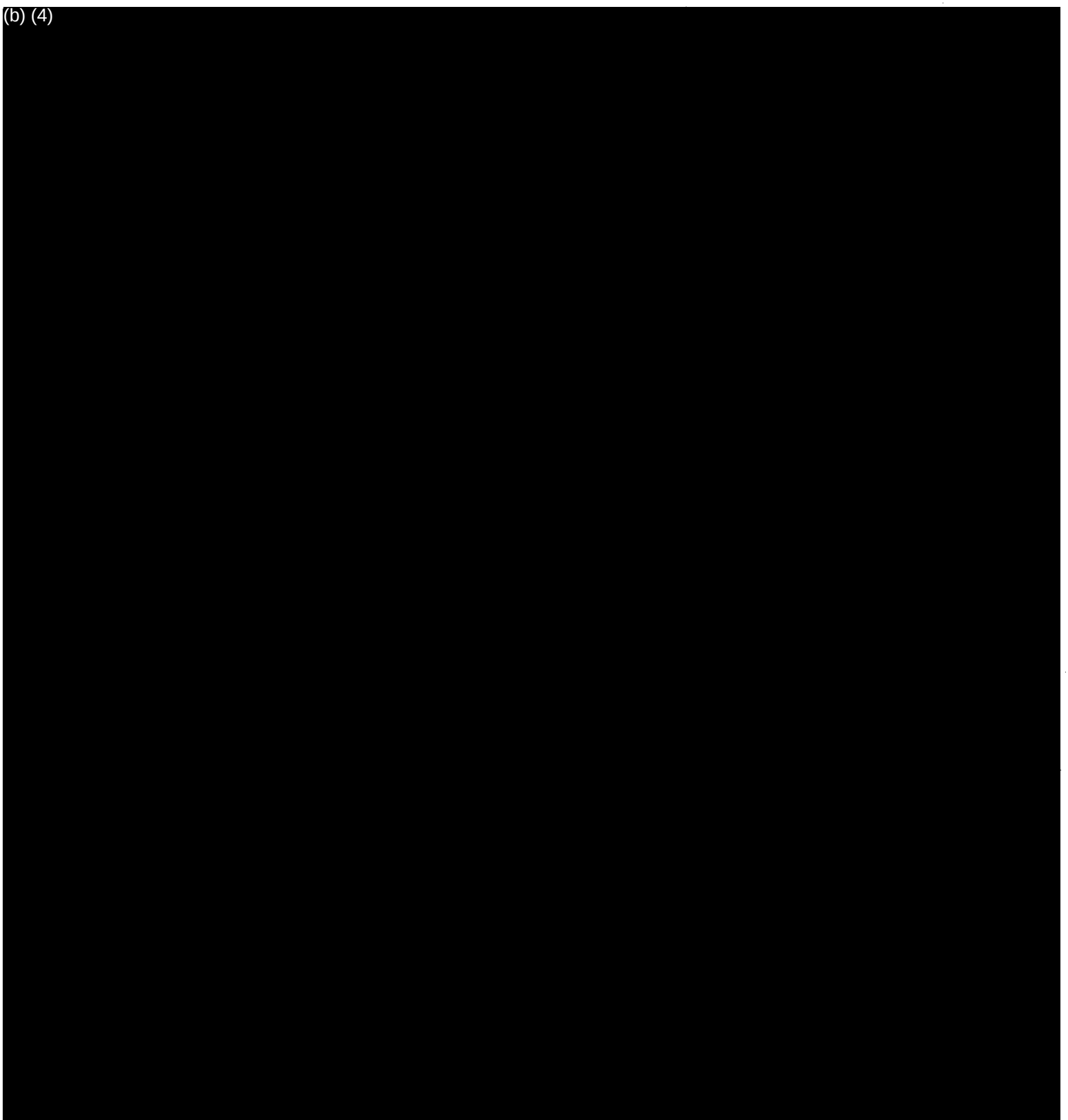

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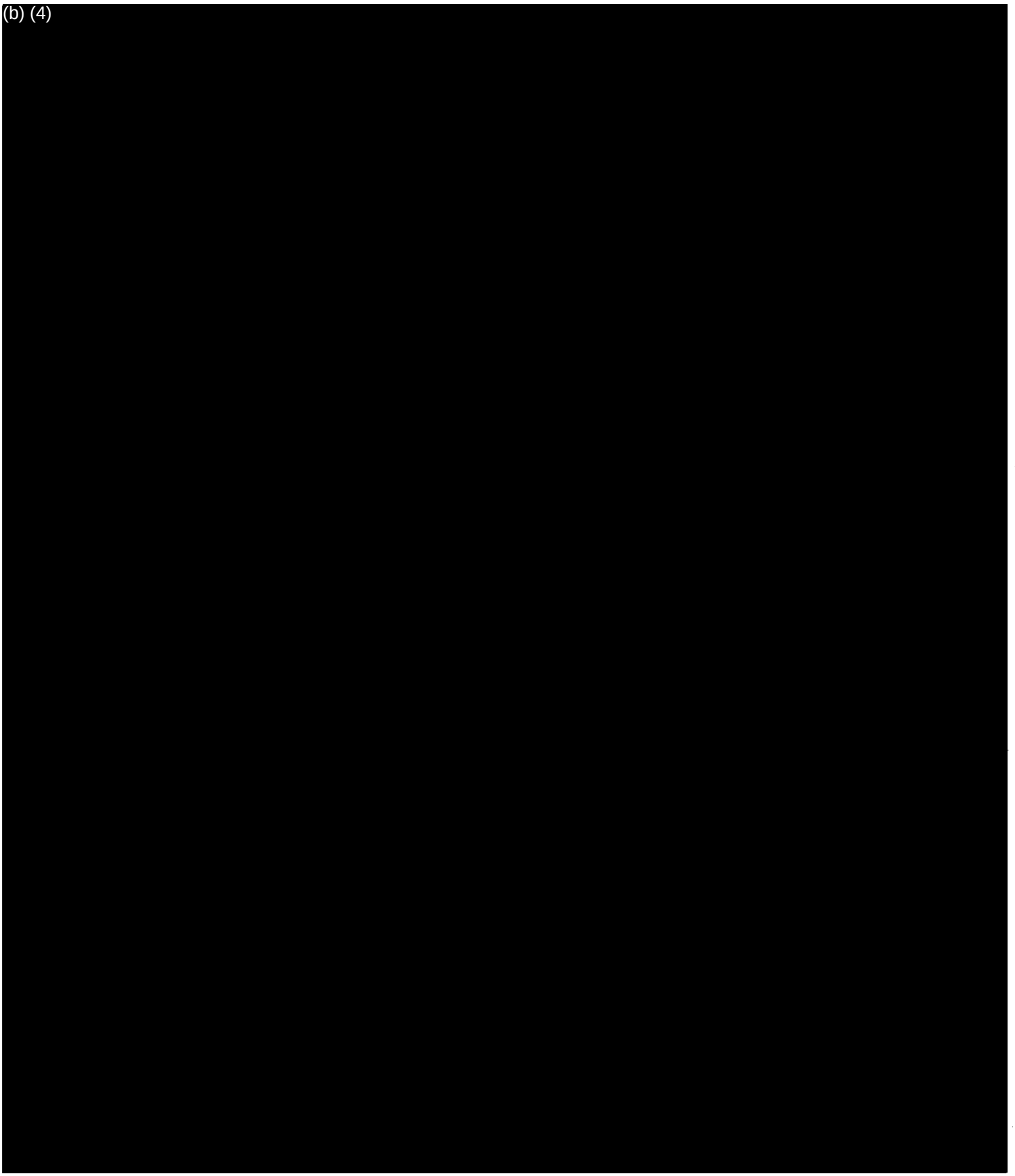

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IX. Data Analysis

N/A

X. Acceptance Criteria

The test passes if:

a) (b) (4)

[redacted]

b)

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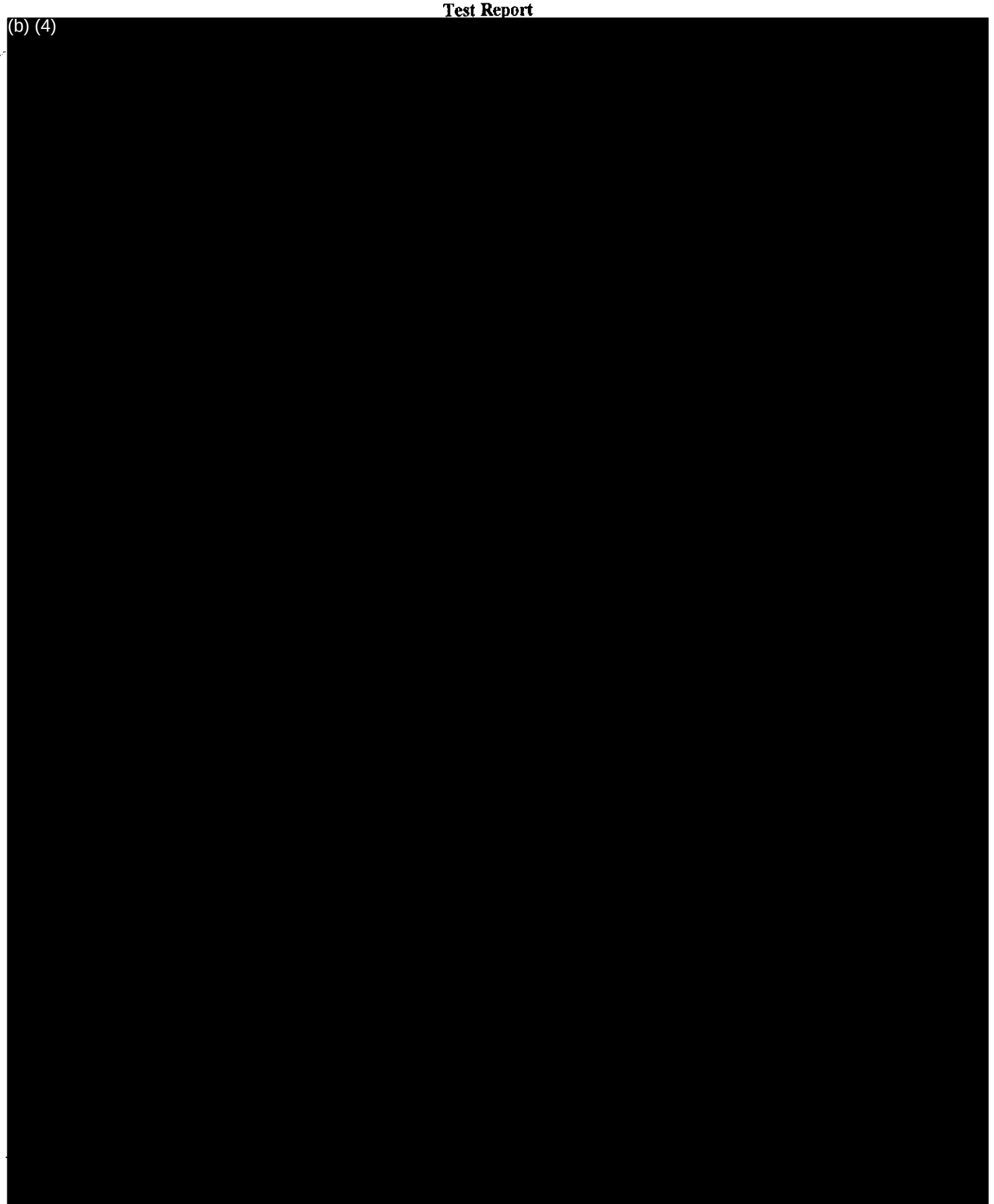

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ROBODOC
INTEGRATED SURGICAL SYSTEMS

Validation of Registration Verification with Pinless RTM System (Software Testing)

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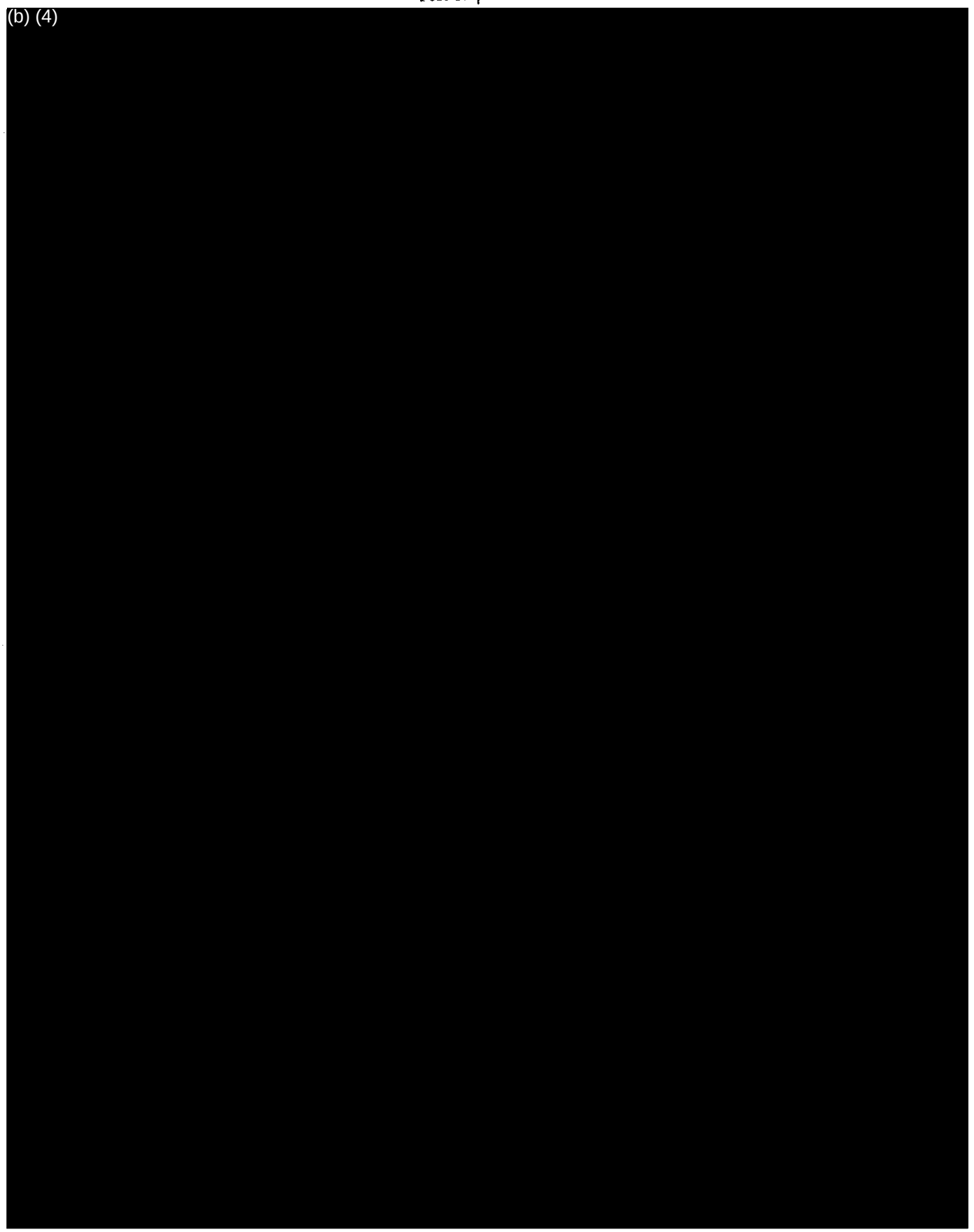

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Verification Software Validation

DJA x00366

(b) (4)

[redacted]

DJA x00367

" Raw Data

(b) (4)

Passive Point and Plane Verification

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DJA x00368

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[redacted]

DJA x00369

Verification Software Validation

(b) (4)

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DJA x00371

Active Point and Plane Verification

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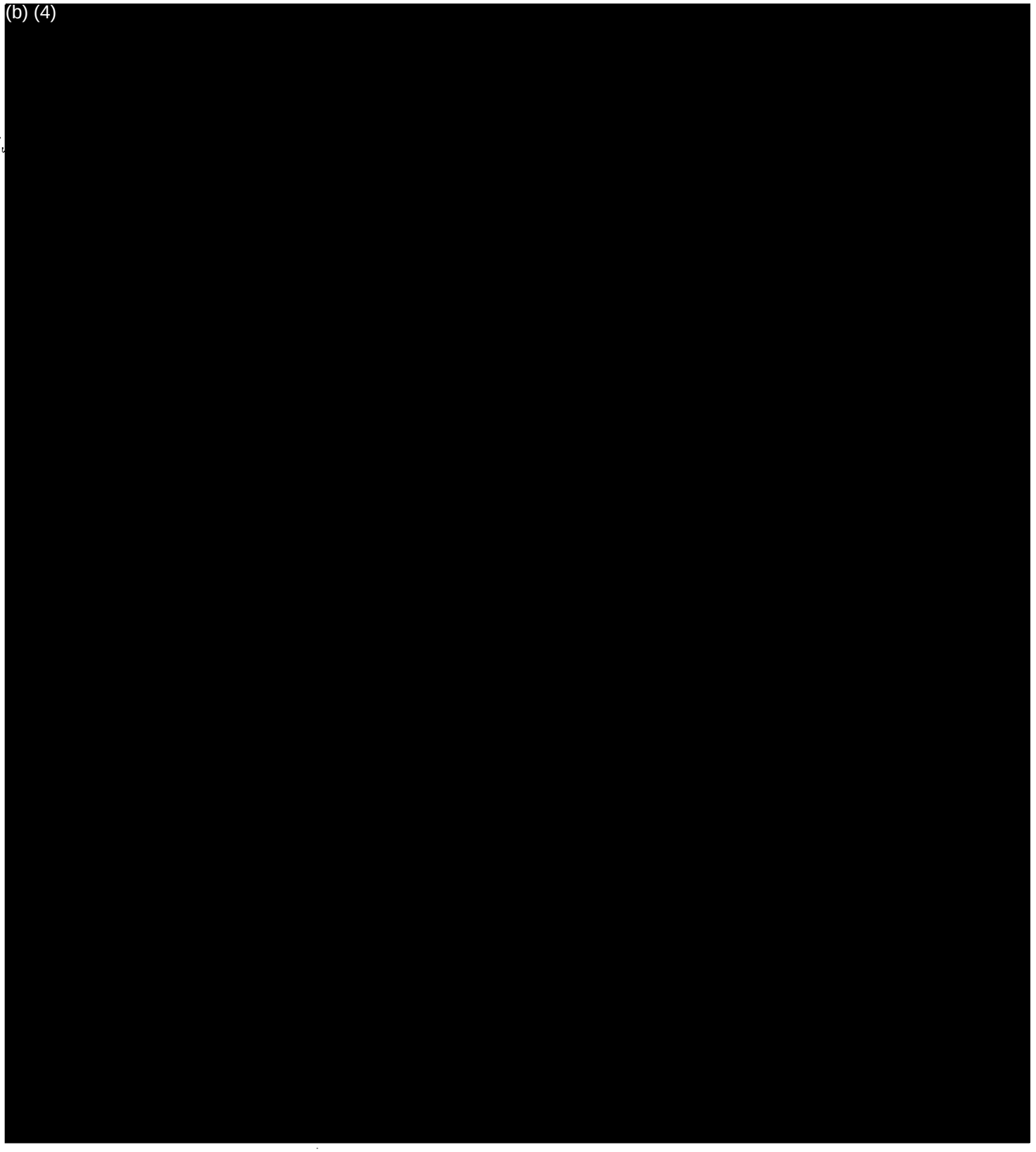

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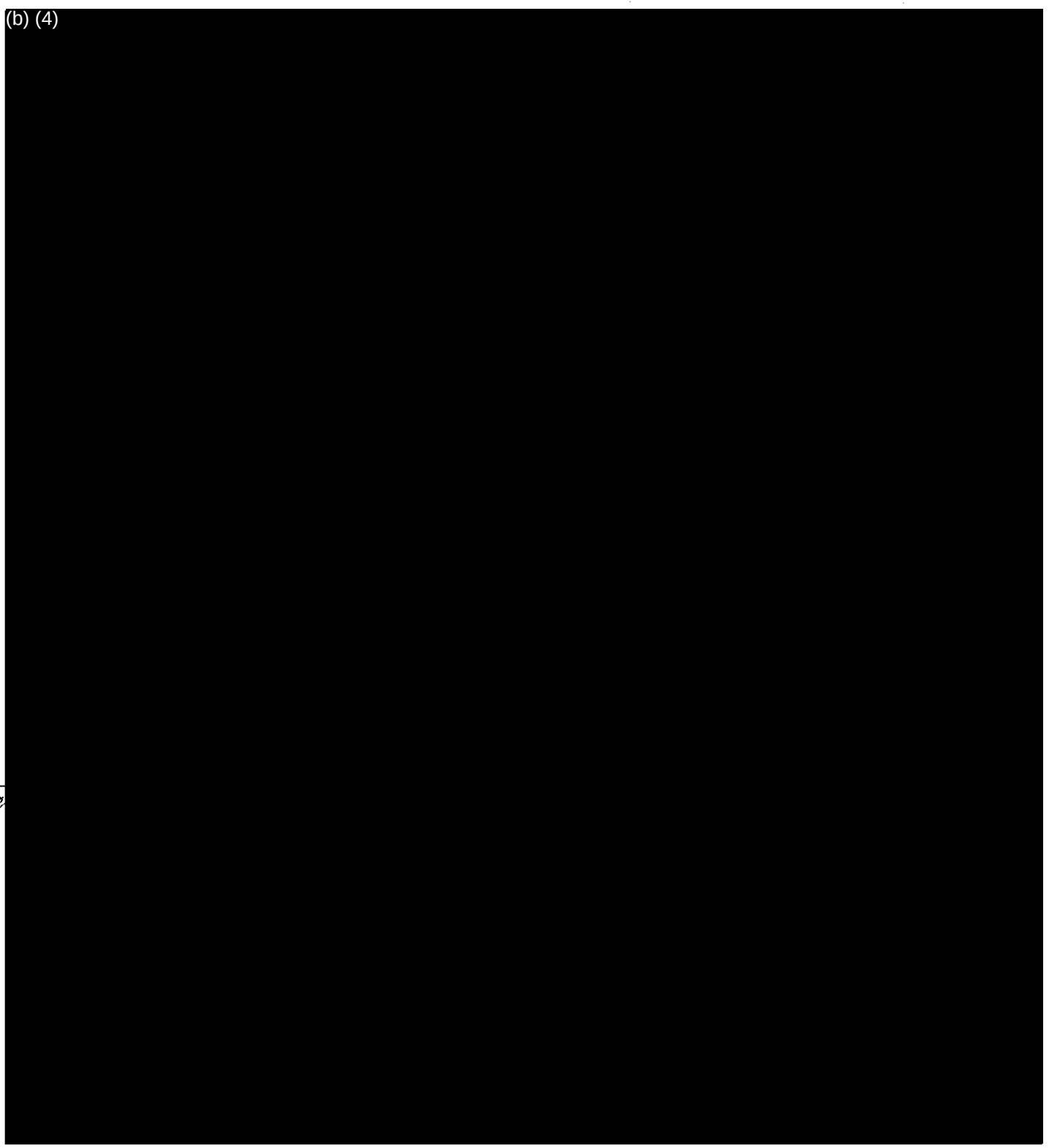

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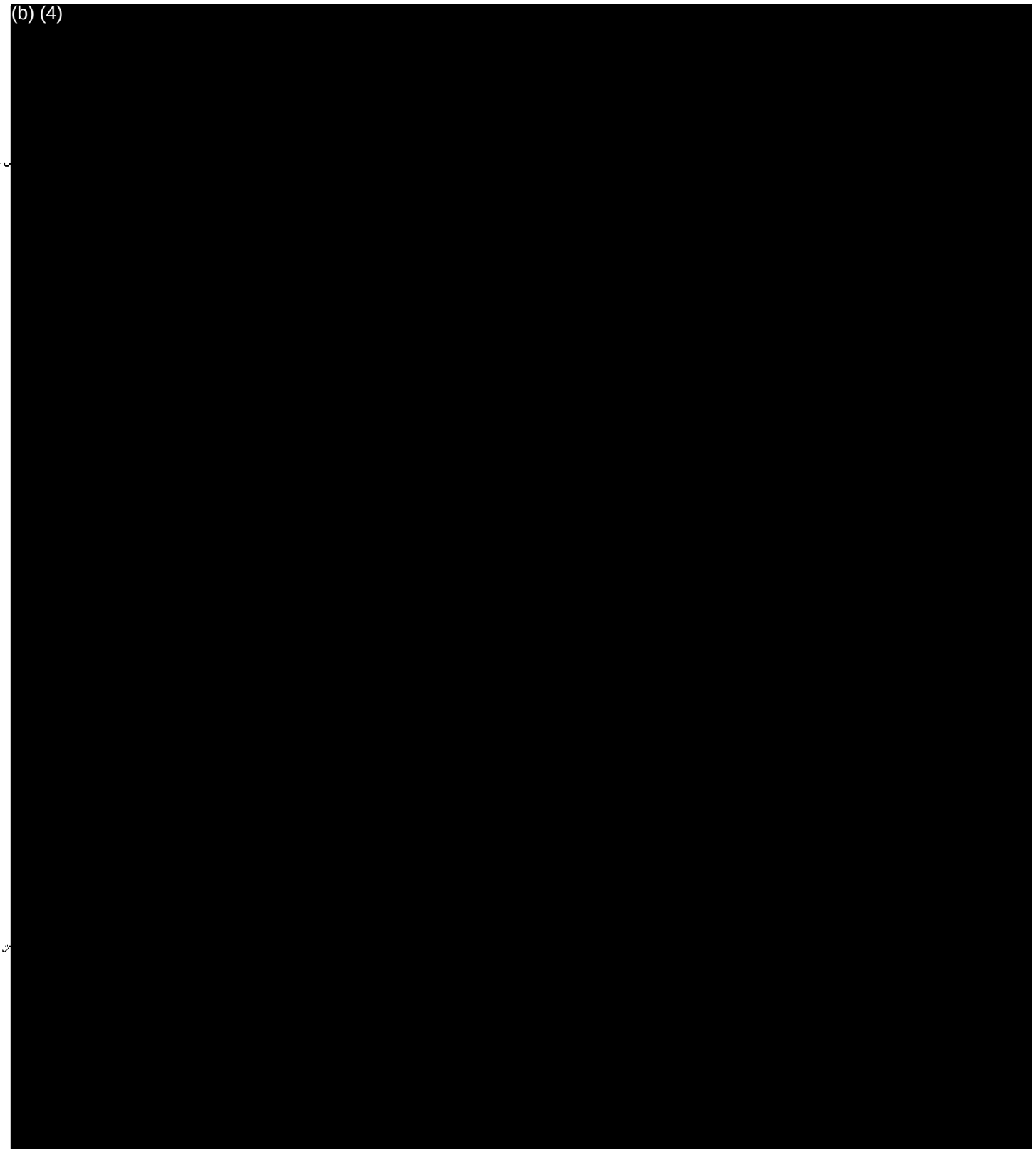

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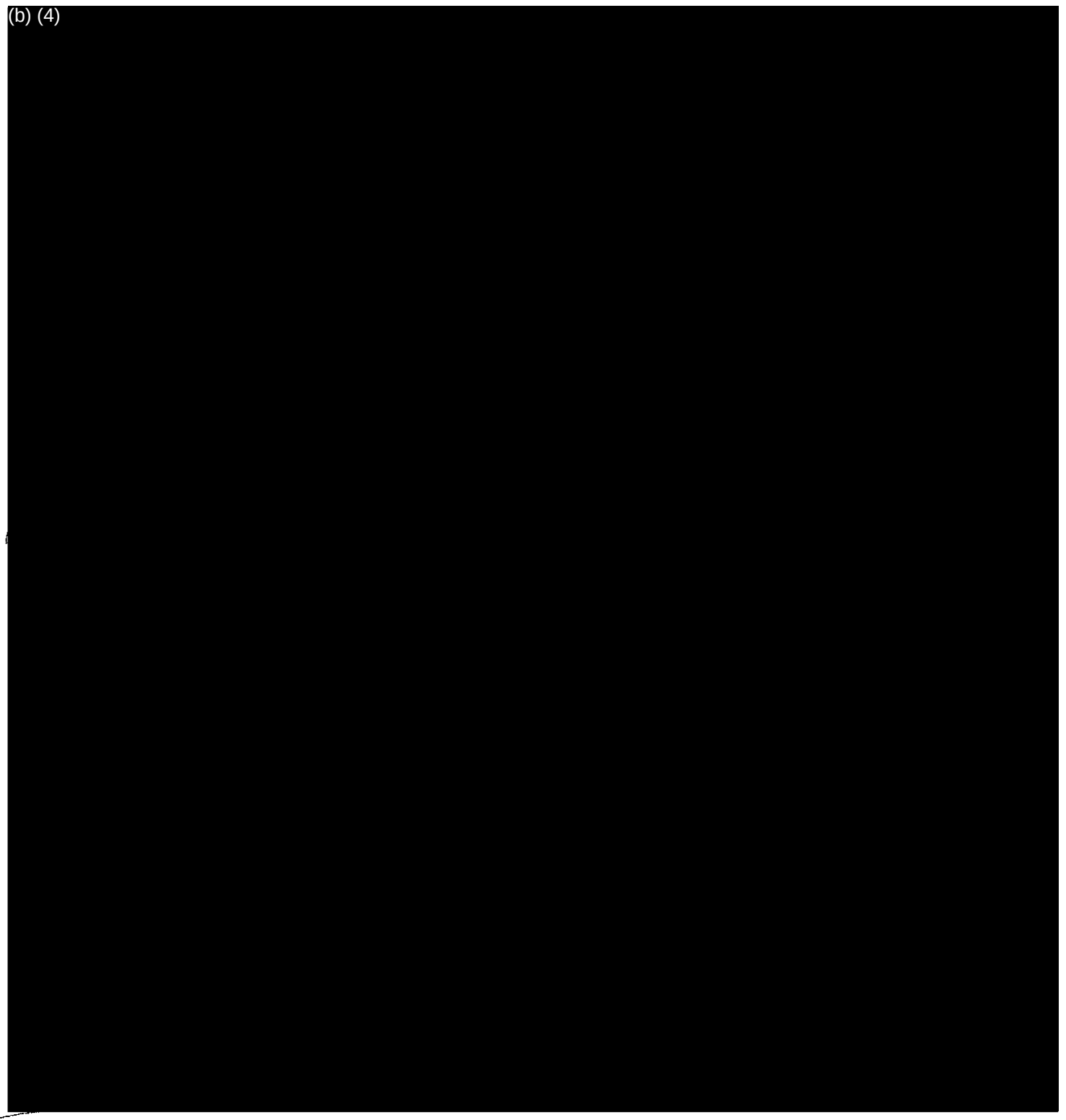

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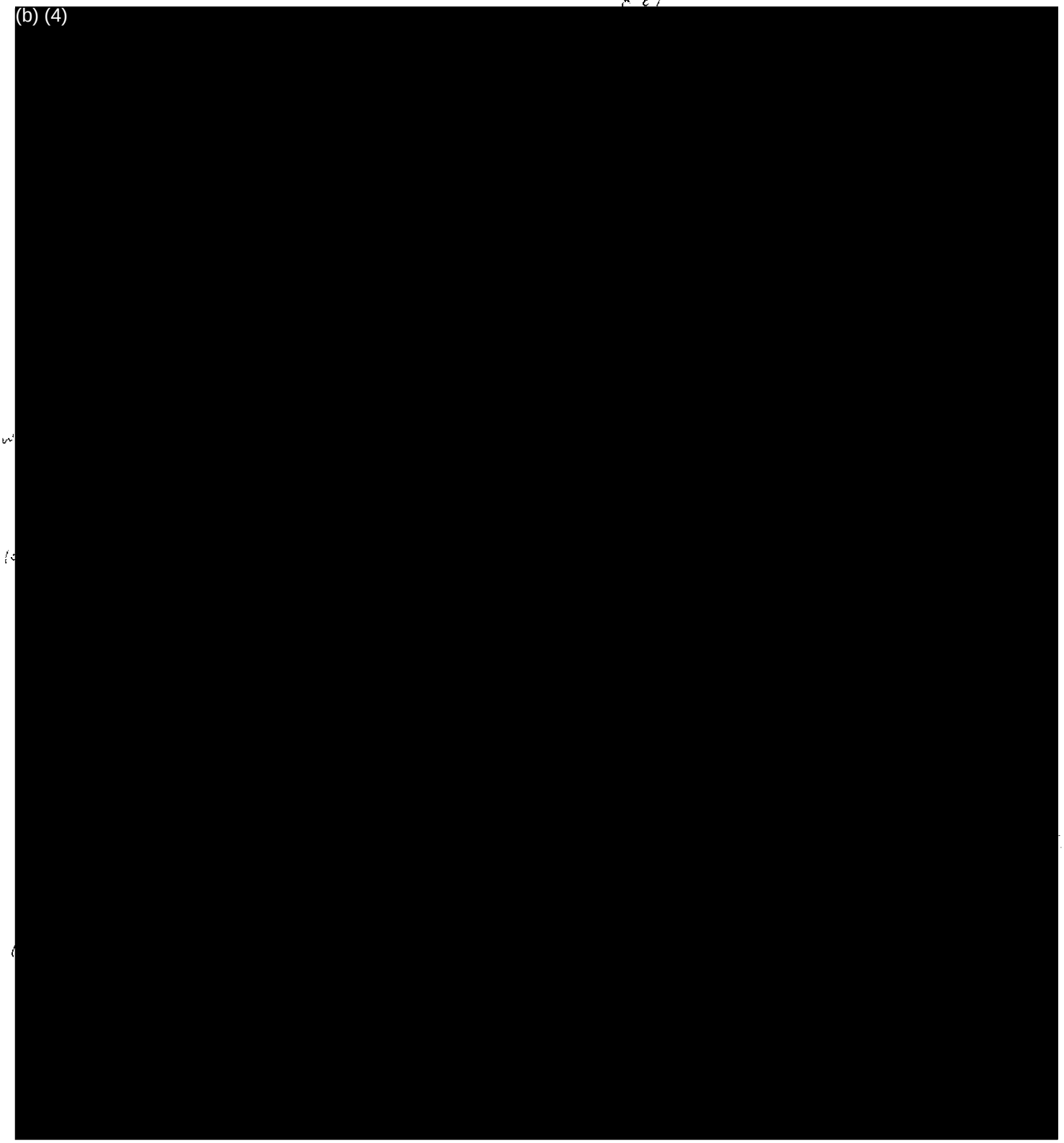

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(b) (4)

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Conclusion:

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ROBODOC
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Validation of Registration Verification with Pinless Prototype ROBODOC® System (Software Test)

(b) (4)

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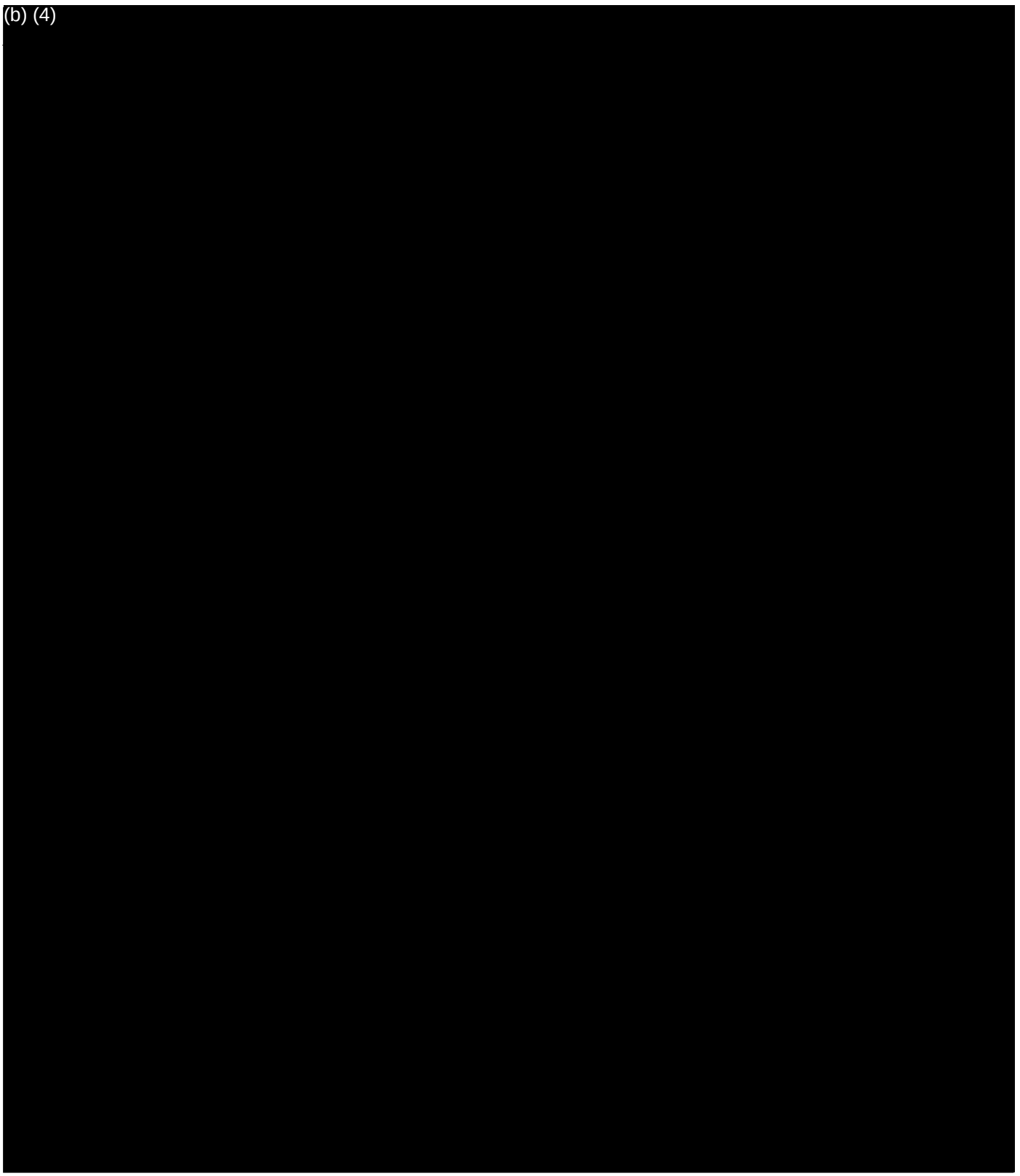

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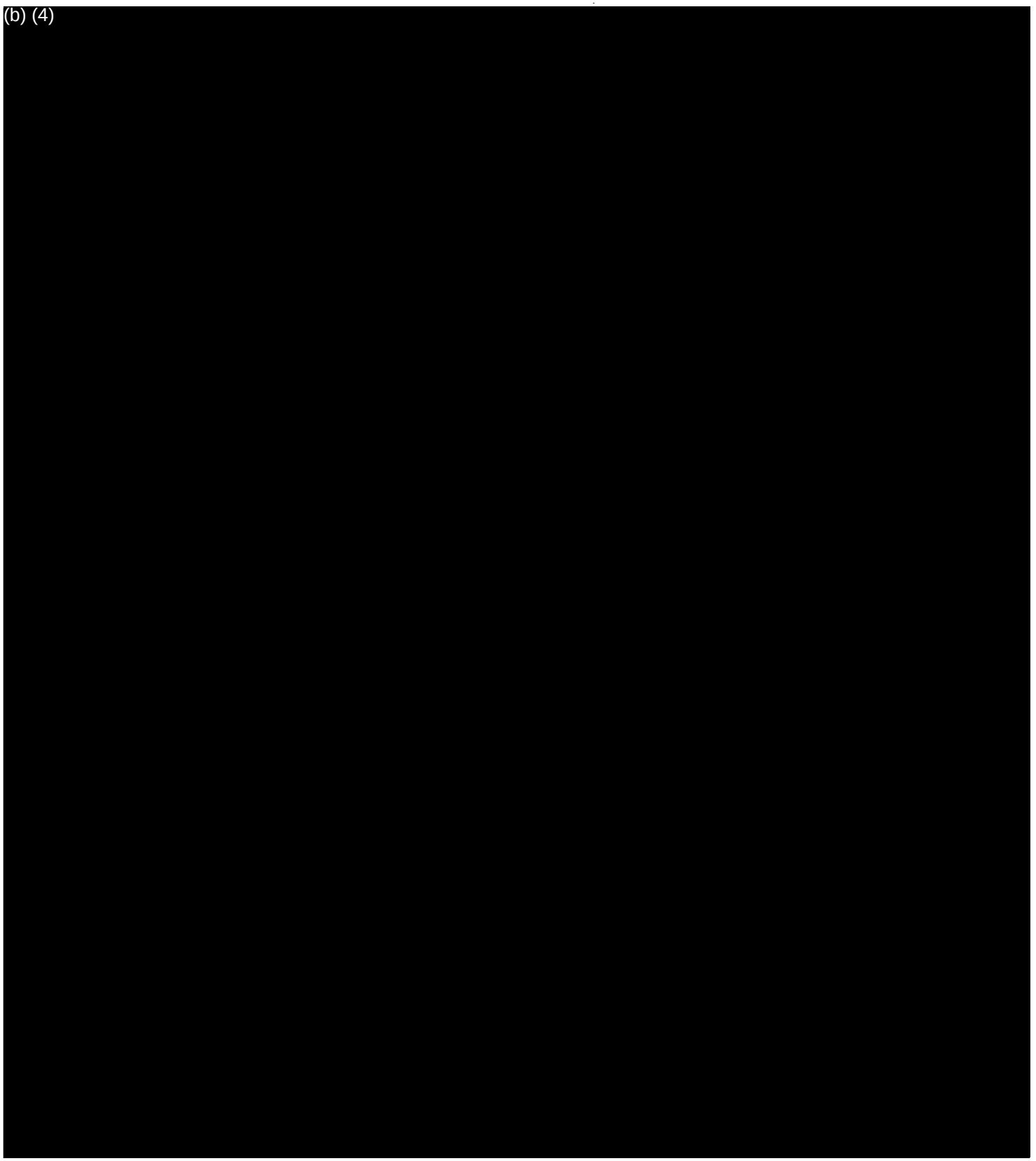

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Definition:

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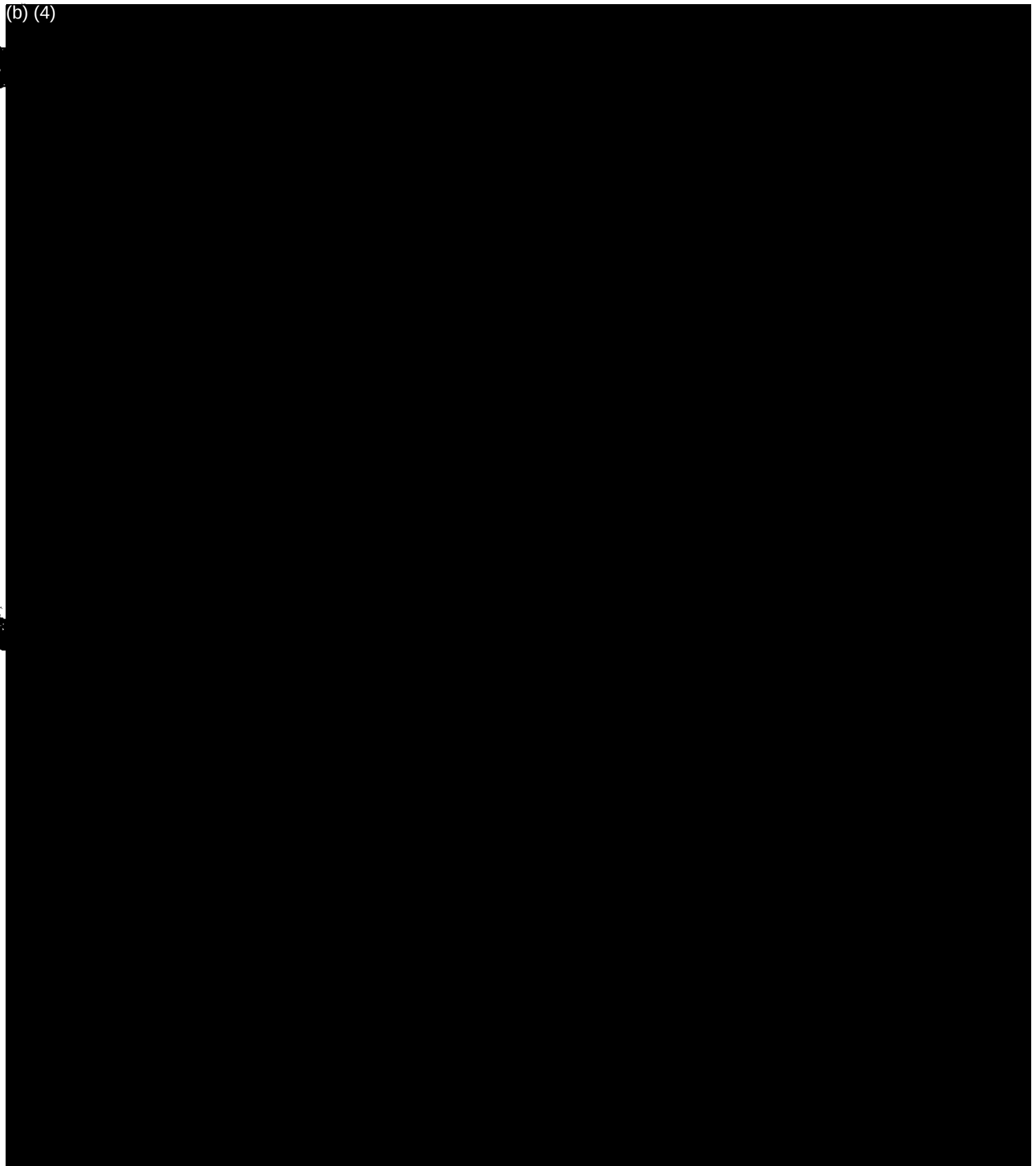

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XIV. Conclusion

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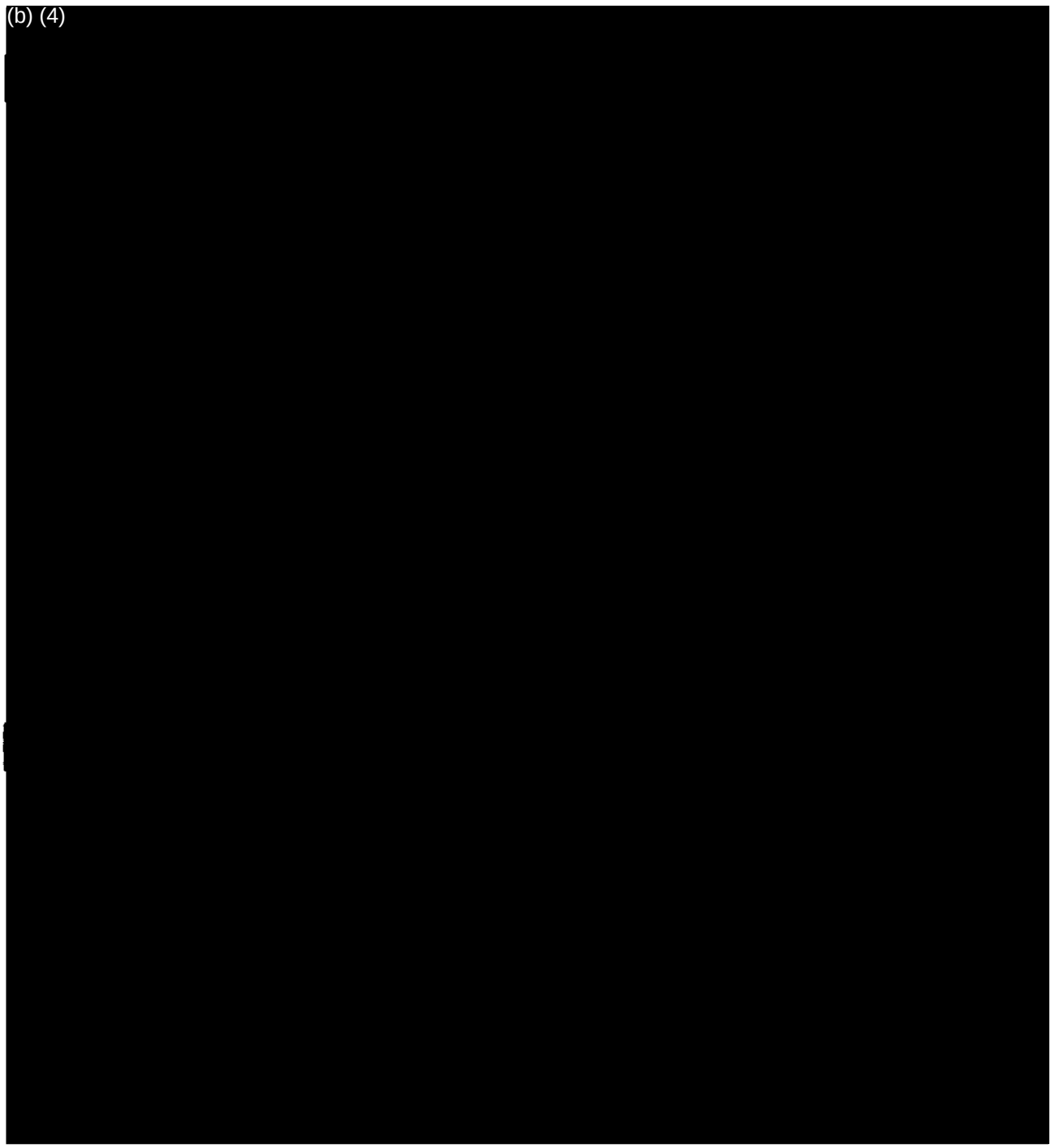

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Verification of Motion Recovery with Pinless Prototype ROBODOC® system.

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VII. Test Method/Procedure

8.1. Femur Model Preparation

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8.2. Data collection Procedure

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VIII. Data Collection/Analysis Method

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(b) (4) [redacted]

IX. Acceptance Criteria

The registration differences depend on anatomic directions and must be within the following limits.

(b) (4) [redacted]

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DJA x00396

Pinless ROBODOC® System
CT Scan Protocol
(Appendix A)

(b) (4)

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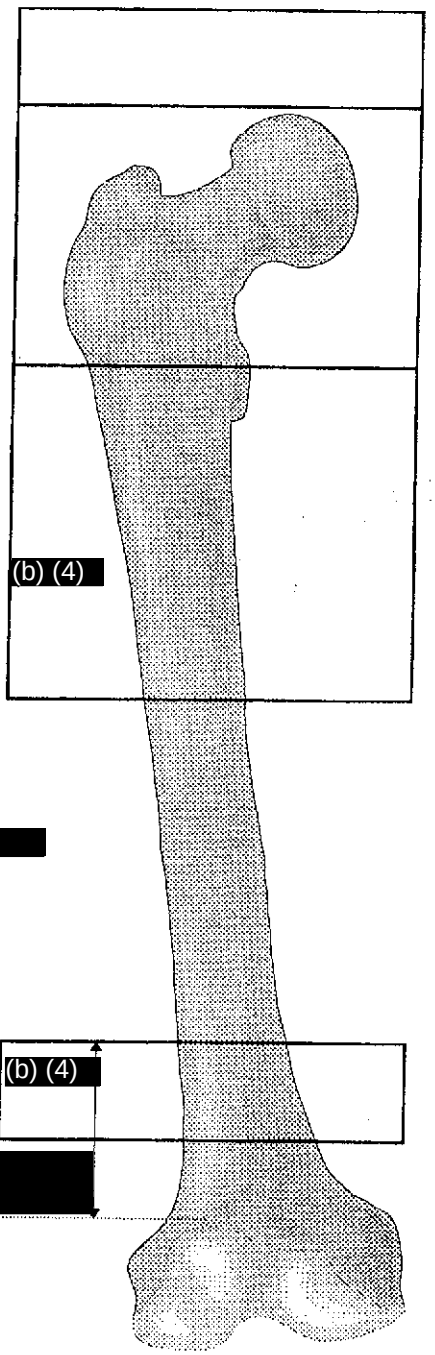

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(b) (4)

ROBODOC®
INTEGRATED
SURGICAL SYSTEMS

Pinless ROBODOC® CT Protocol
Anterolateral Approach

APPENDIX B

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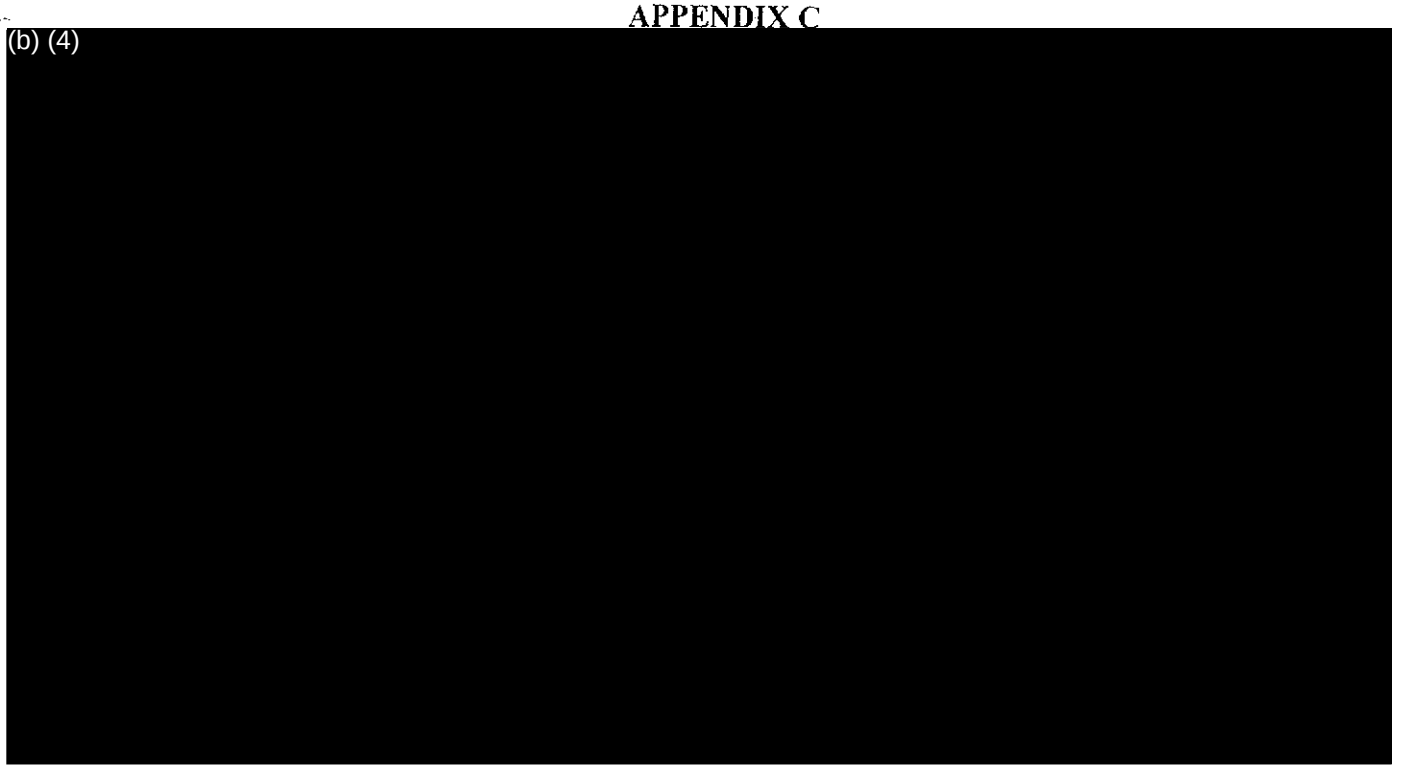
(b) (4)

APPENDIX C

(b) (4)



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Test Report

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Test Report

Page 2 of 3

(b) (4)

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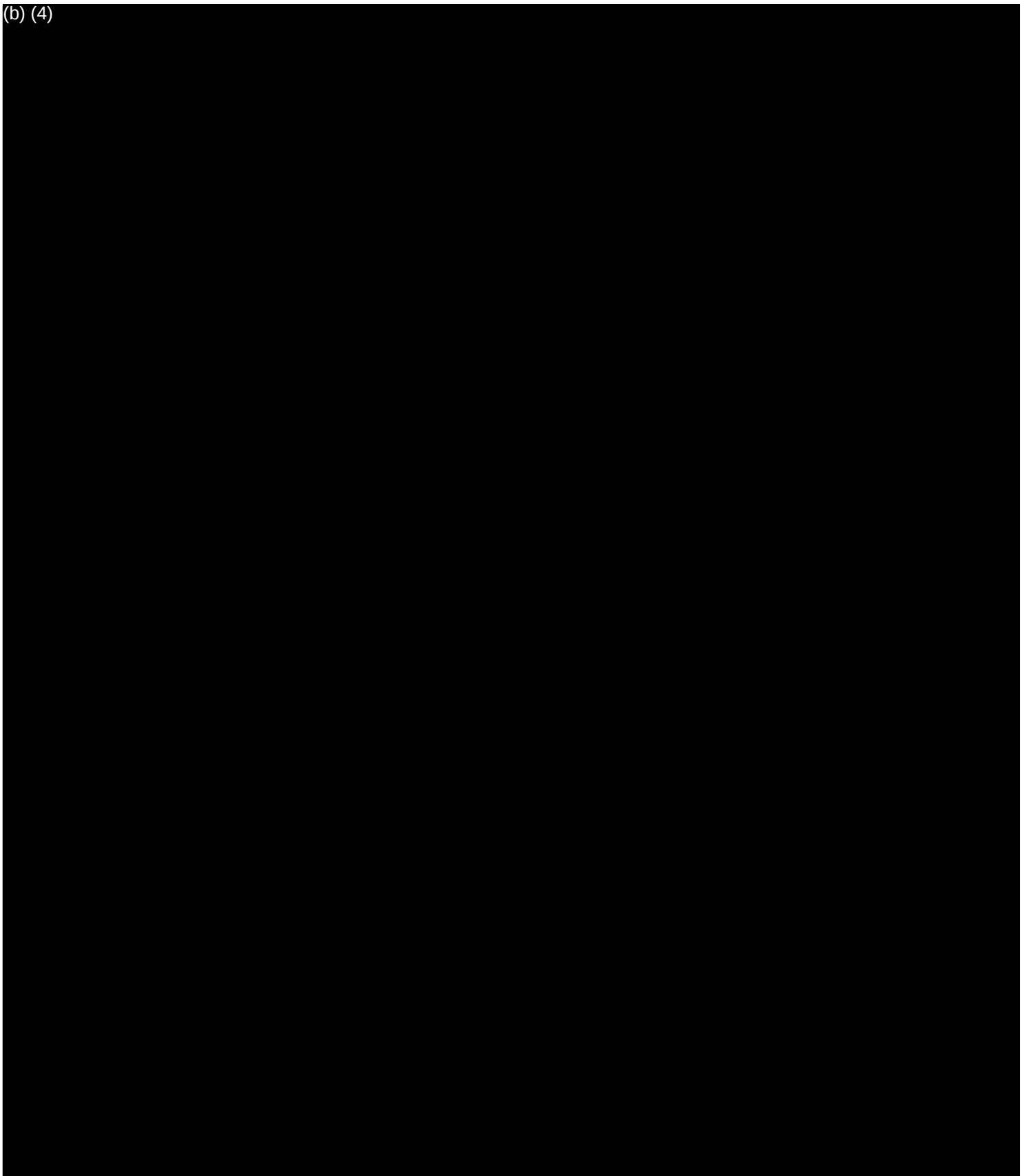

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XIII. Discussion

None

XIV. Conclusion

The accuracy results of the 2-Pin Registration Matrices (THR 2.11 & THRPLESS 3.1) are less than or equal to the set limits of the acceptance criteria.

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DJA x00405

2-pin Integrity Test Results

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[redacted]

DJA x00406

Pin Distance and Normal data

	Normals	distances
(b) (4)		

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ROBODOC
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2-Pin Integrity Test with Pinless Prototype ROBODOC® System

(b) (4)

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DJA x00410

- (b) (4)
- [redacted]

IX. Data Analysis

(b) (4)

[redacted]

X. Acceptance Criteria

The registration difference depends on anatomic directions and must be within the following limits.

(b) (4)

[redacted]

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DJA x004

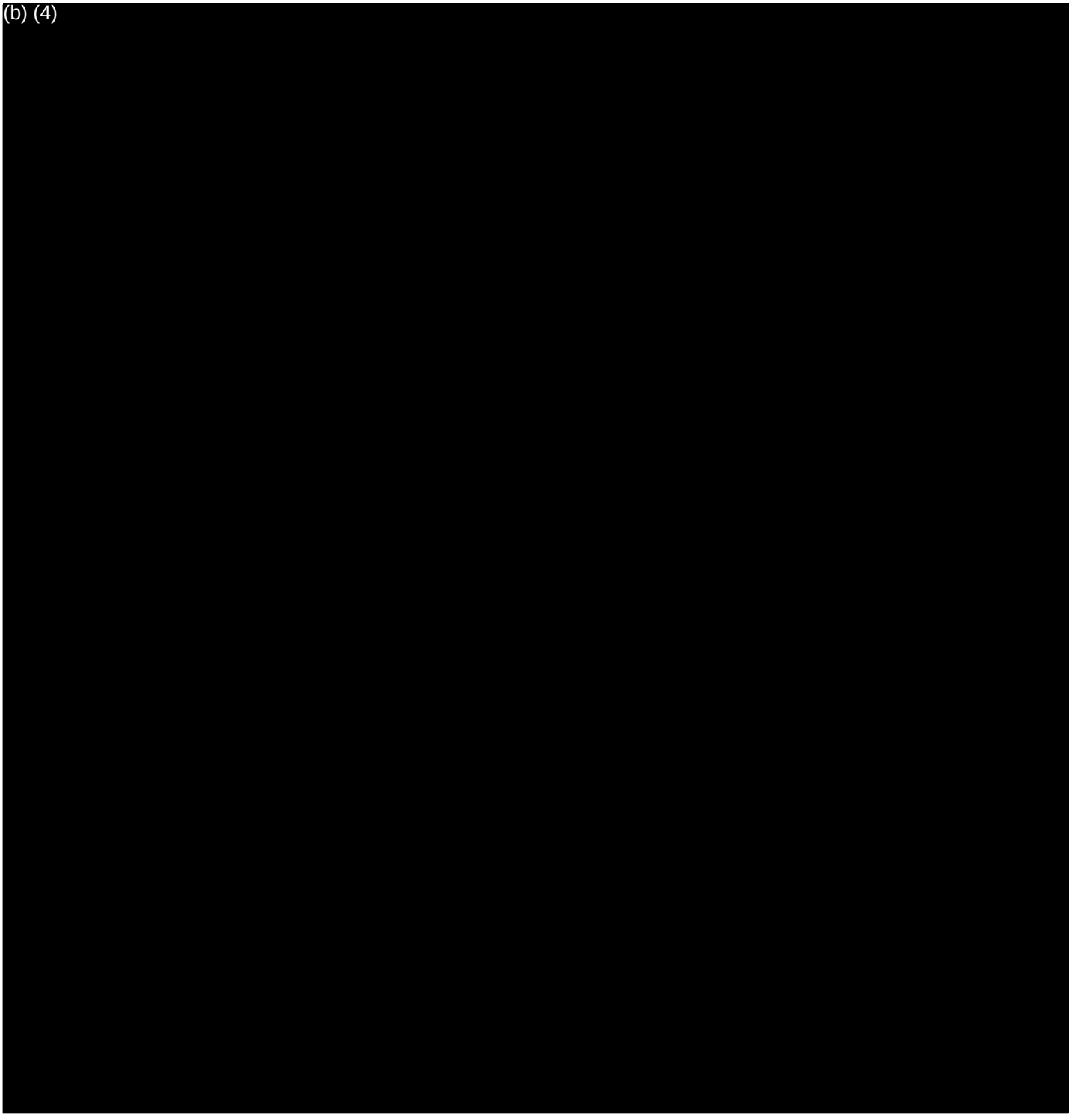
PROTOCOL and TEST REPORT APPROVAL SHEET

(b) (4)

[redacted]

DJA x00412

(b) (4)



DJA x00413

ROBODOC PINLESS SYSTEM
Clinical Validation

(b) (4)

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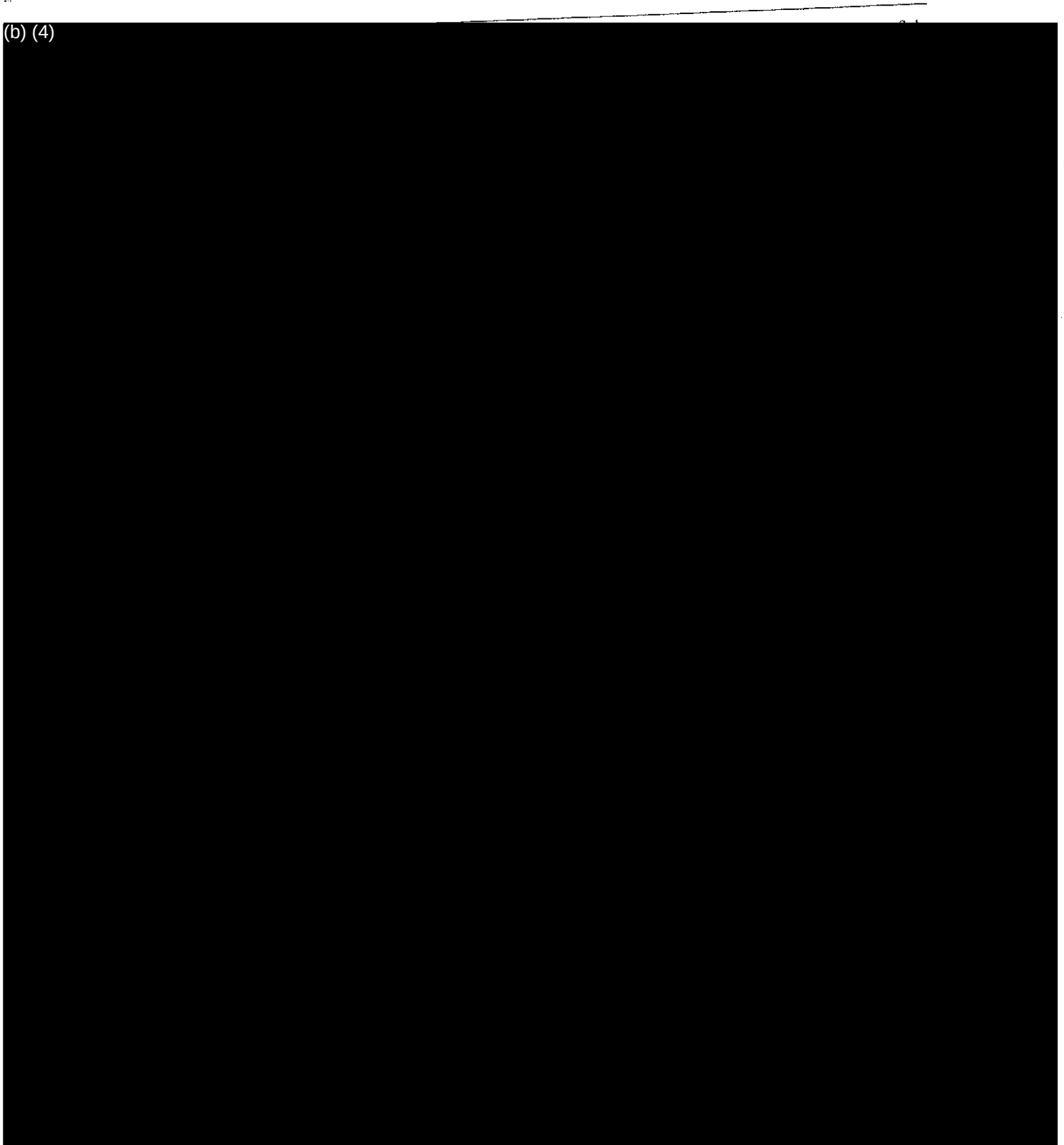
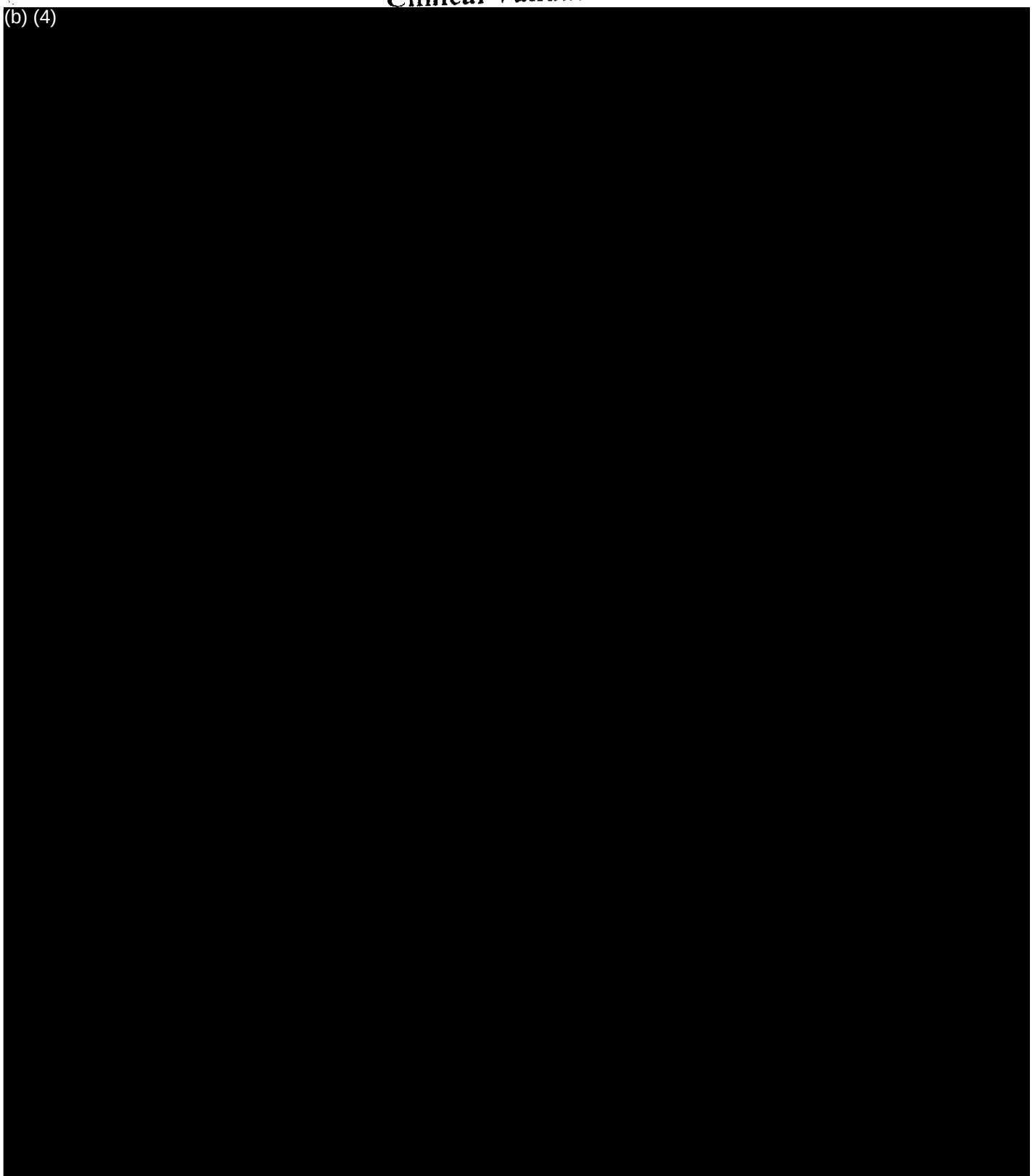
DJA x00414

(b) (4)



ROBODOC PINLESS SYSTEM
Clinical Validation

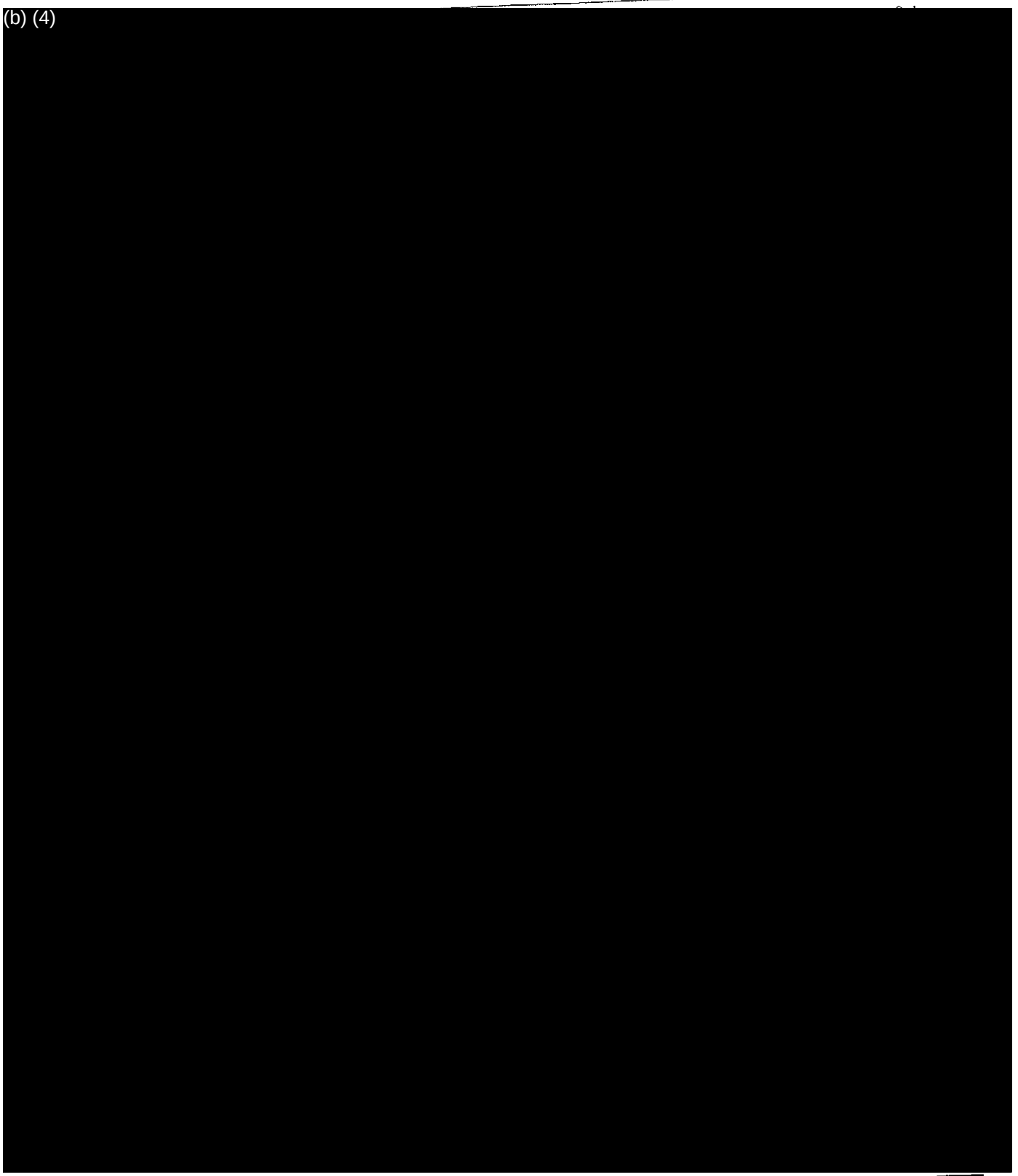
(b) (4)



proximal neck points for a pinless surgery. Point

DJA x00416

(b) (4)



DJA x00417

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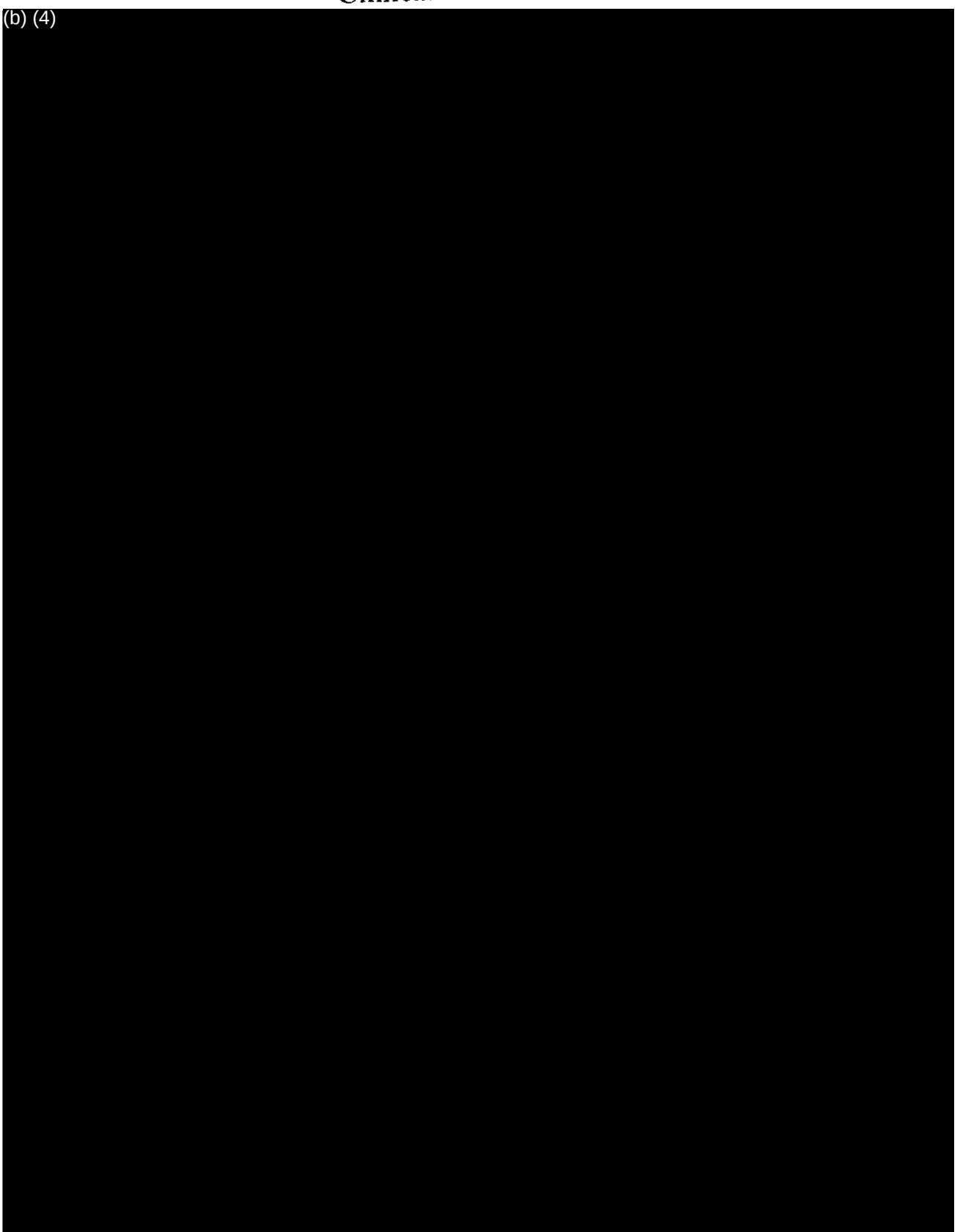

DJA x00418

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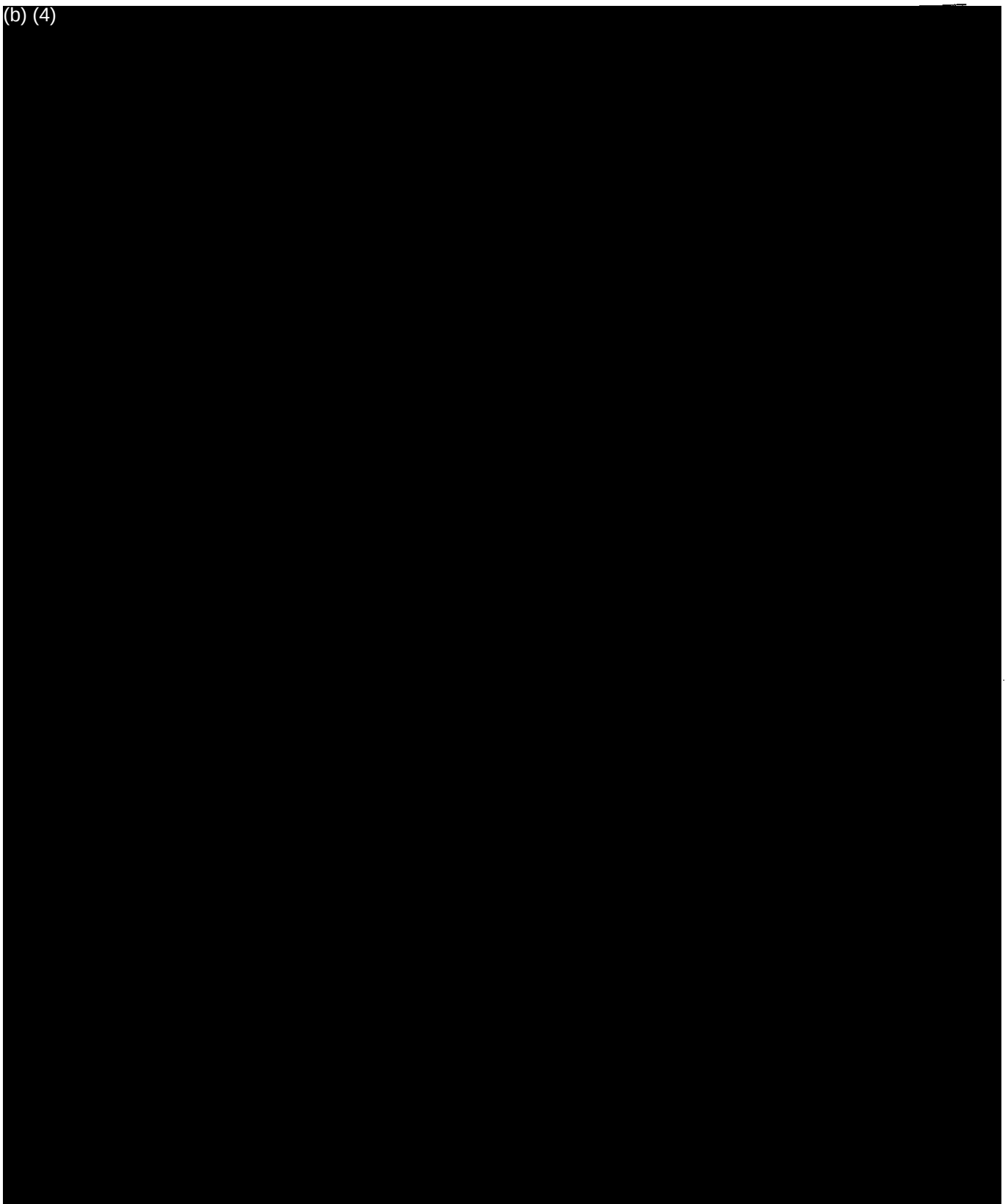

DJA x00419

Additional Statistics from Pinless ROBODOC Clinical Validation:

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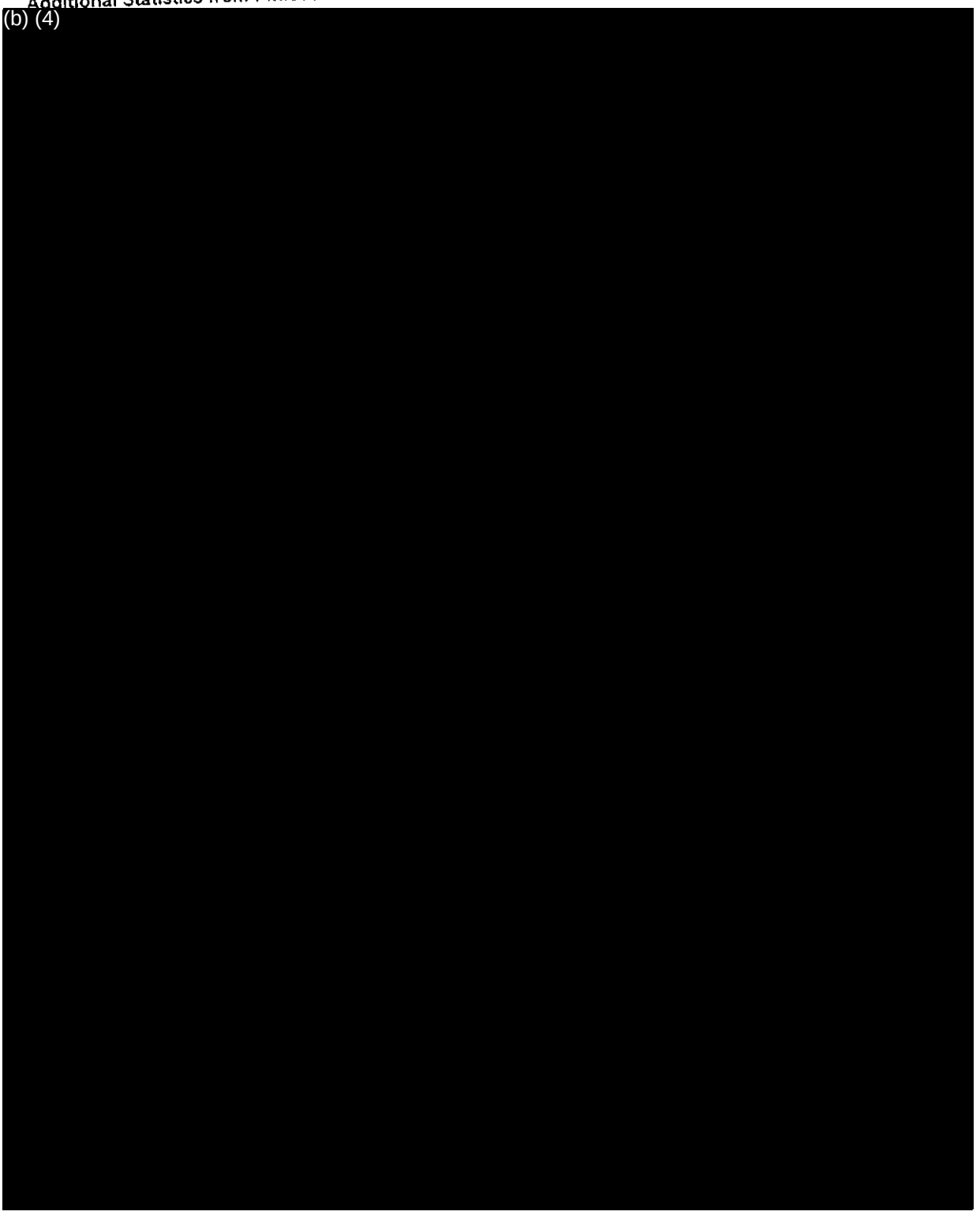

DJA x00420

Data Collection Form Summary Information:

DJA x00421

INTEGRATED
SURGICAL SYSTEMS

Clinical Prototype Pinless ROBODOC®
Clinical Validation Protocol

(b) (4)

[redacted]

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DJA x00422

(b) (4)

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DJA x00423

(b) (4)

[redacted]

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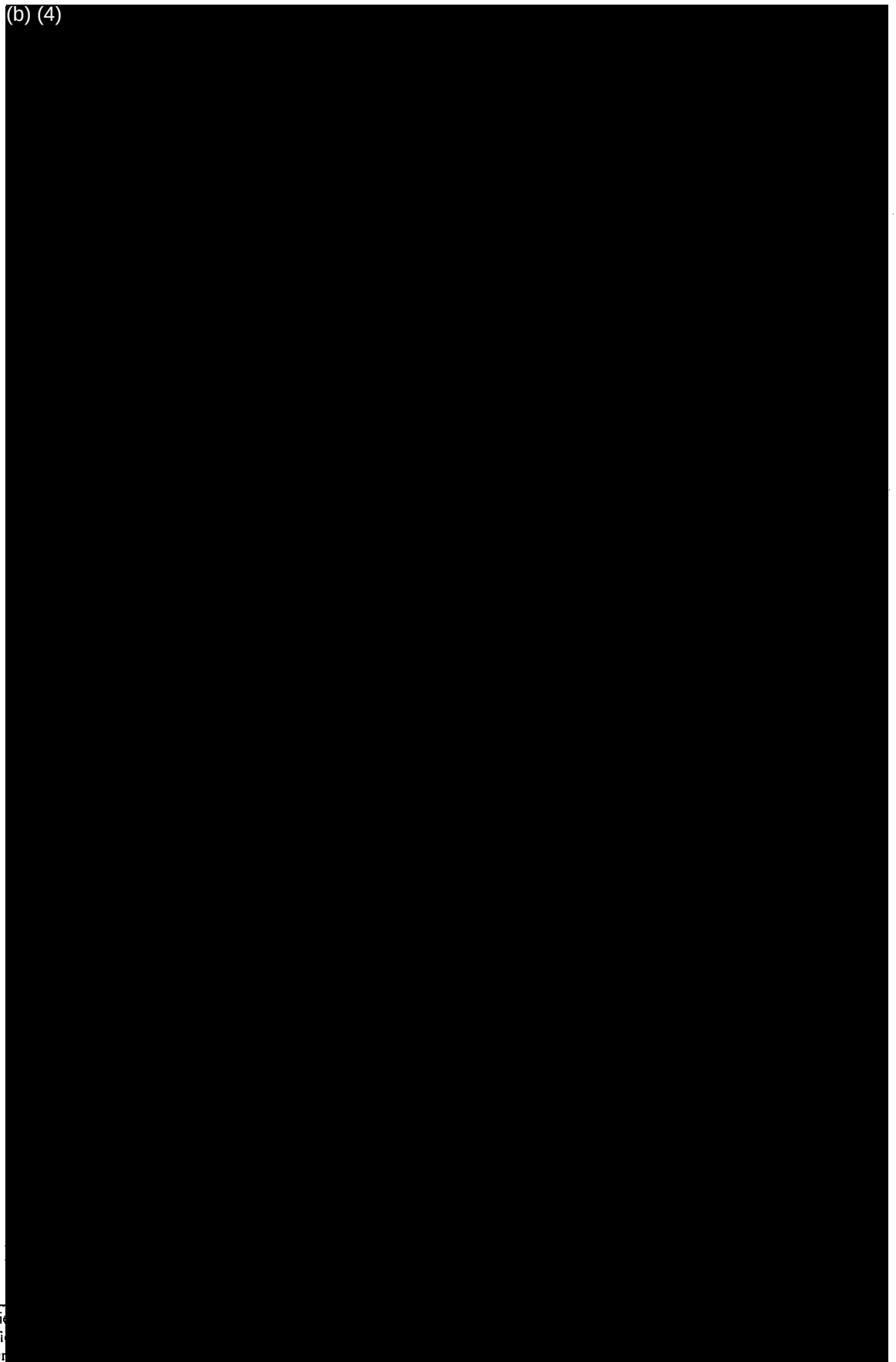
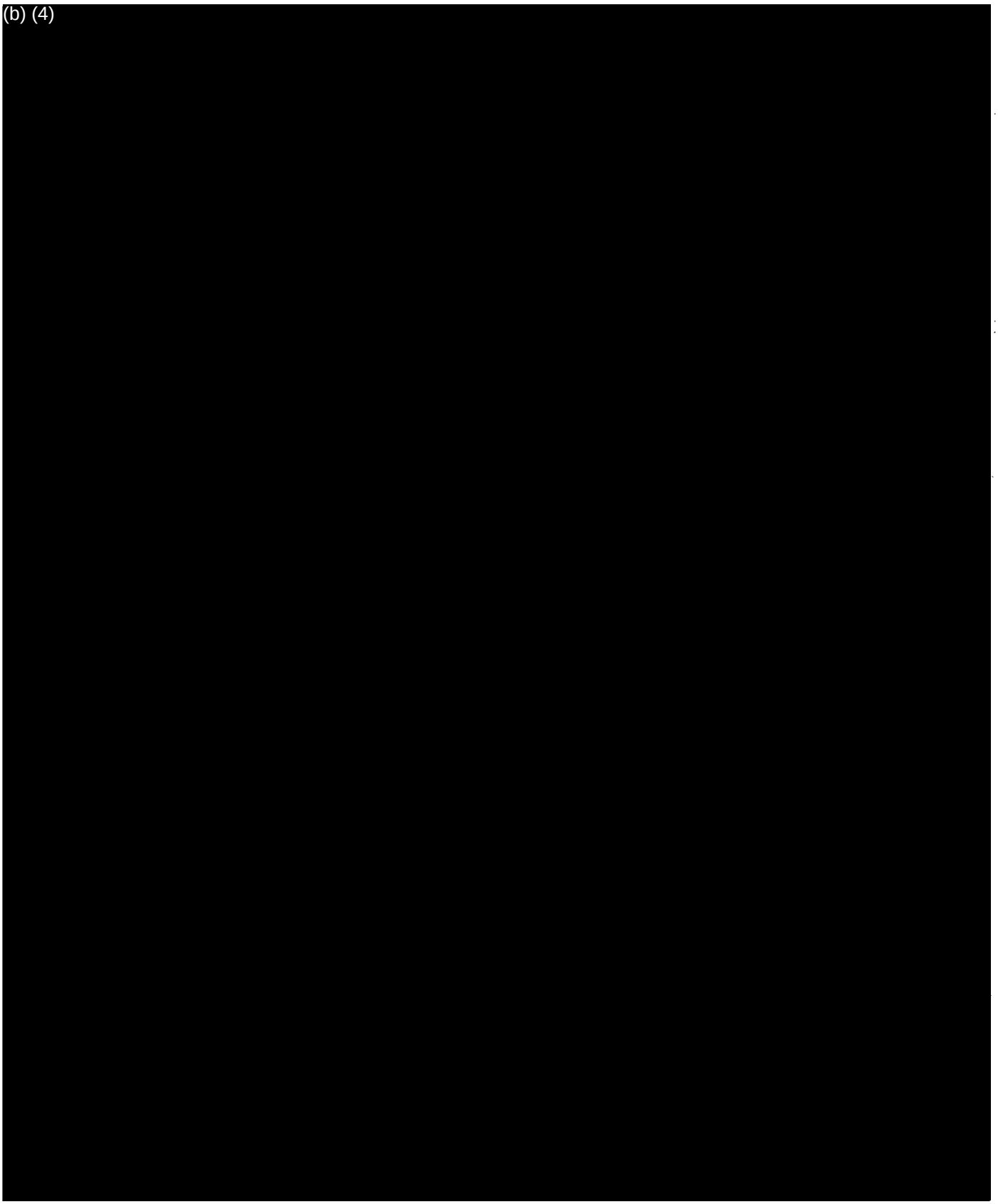
DJA x00424

(b) (4)



Propri
specifi
deliver

(b) (4)



Proprietary rights of Integrated Surgical Systems, Inc., are involved in the subject matter of this material. It is submitted in confidence for a specific purpose and the recipient by accepting this material agrees that it will not be used other than for the express purpose for which it was delivered. Disclosure to others without written permission from Integrated Surgical Systems, Inc., is forbidden.

DJA x00426

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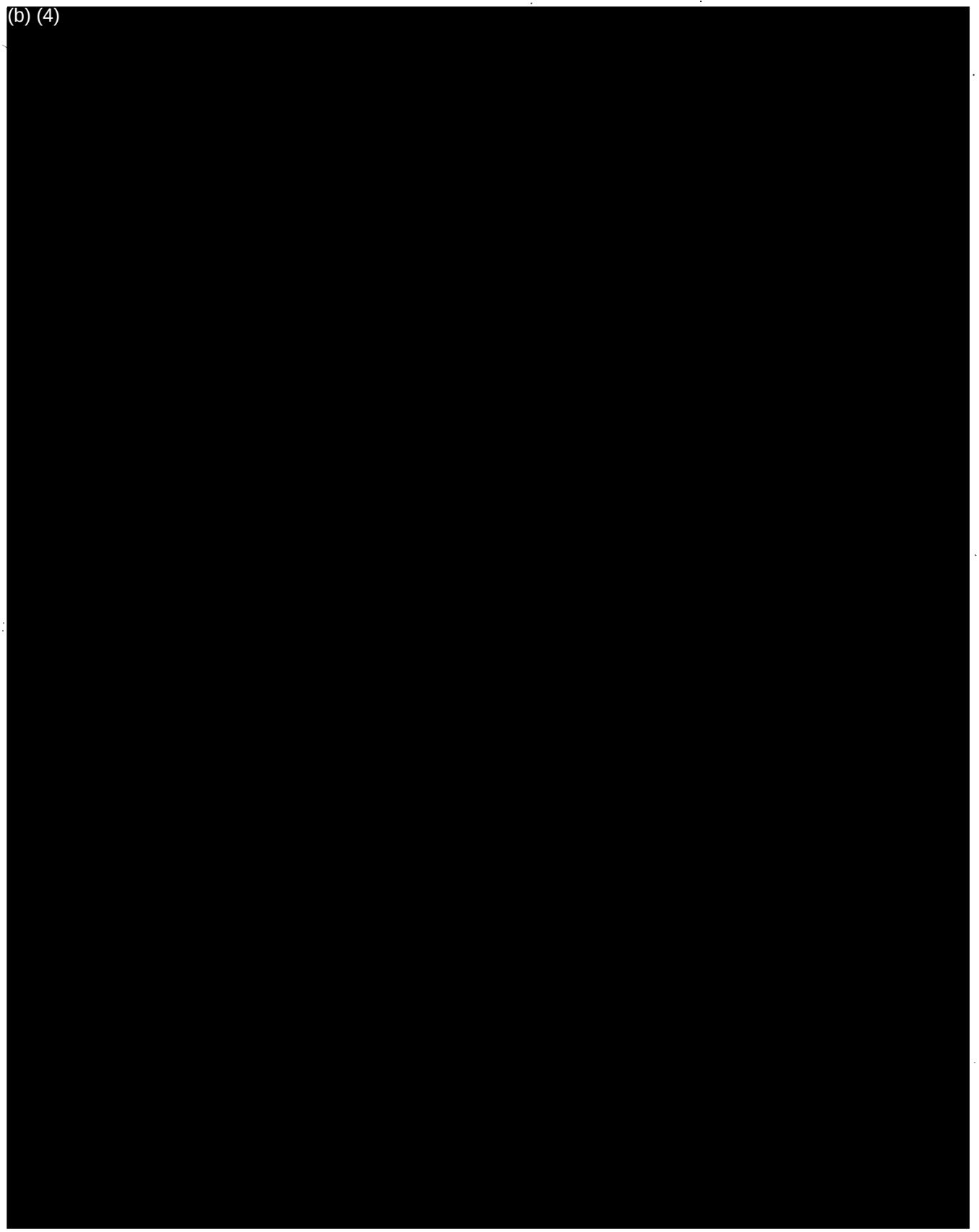

Proprietary rights of Integrated Surgical Systems, Inc., are involved in the subject matter of this material. It is submitted in confidence for a specific purpose and the recipient by accepting this material agrees that it will not be used other than for the express purpose for which it was delivered. Disclosure to others without written permission from Integrated Surgical Systems, Inc., is forbidden.

DJA x00427

(b) (4)

[redacted]

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DJA x00428

Pinless ROBODOC Patient Inclusion Criteria
(Appendix A)

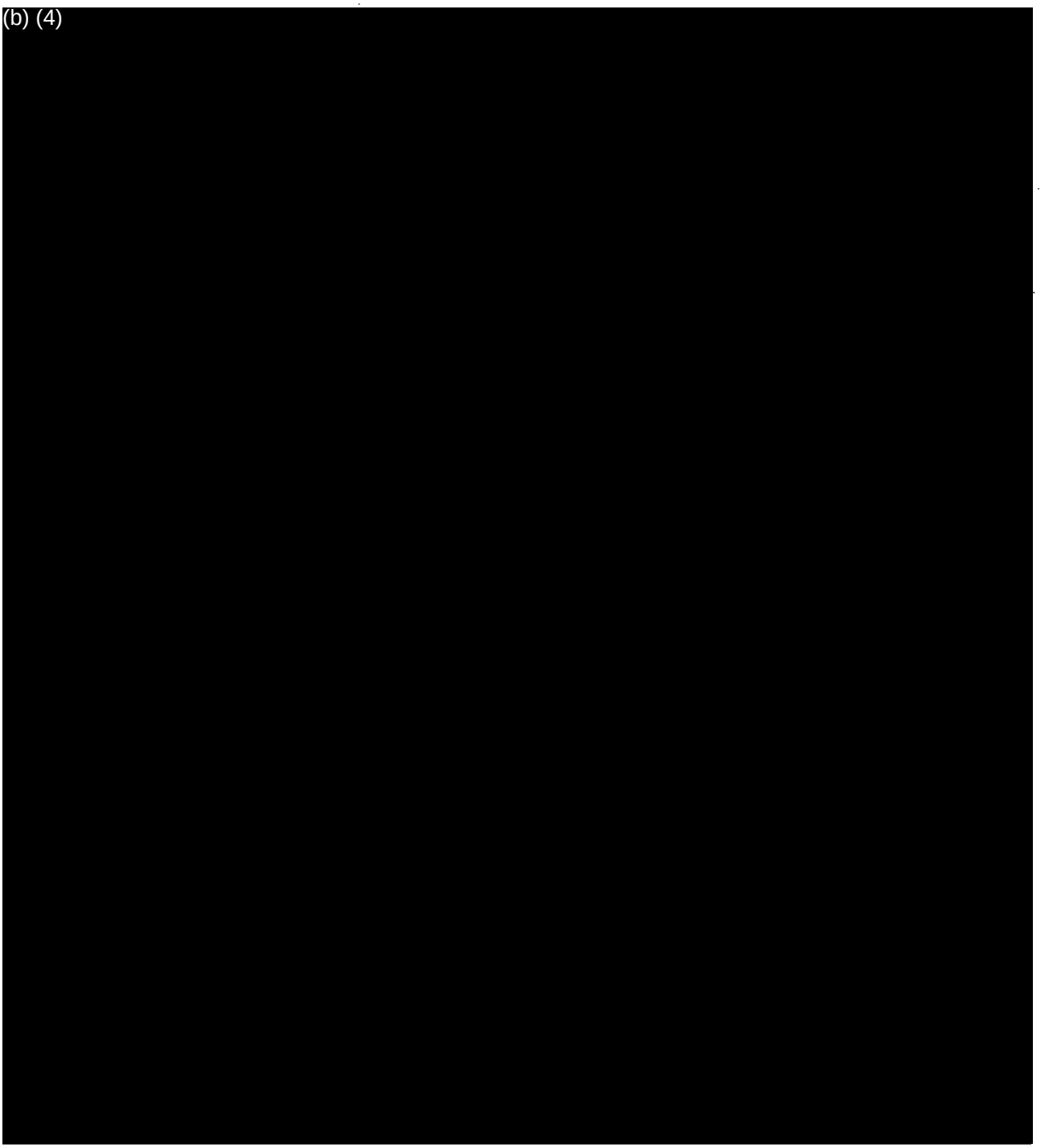
(b) (4)

DJA x00429

Appendix B

Pinless ROBODOC Clinical Evaluation Training Record

(b) (4)



DJA x00430

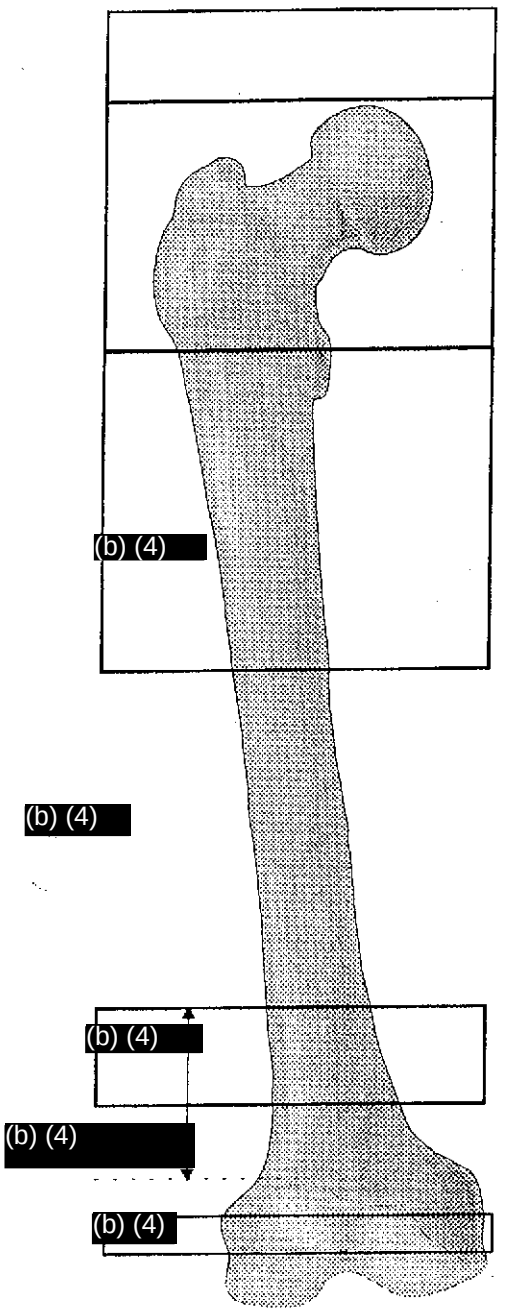
Appendix C

DJA x00431

Pinless ROBODOC® System
CT Scan Protocol
(Appendix D)

(b) (4)

DJA x00432



ROBODOC®
INTEGRATED
SURGICAL SYSTEMS

Pinless ROBODOC® CT Protocol
Anterolateral Approach

DJA x00433

Appendix E

Pin-less Data Collection System Procedure for creation of 3D femur model

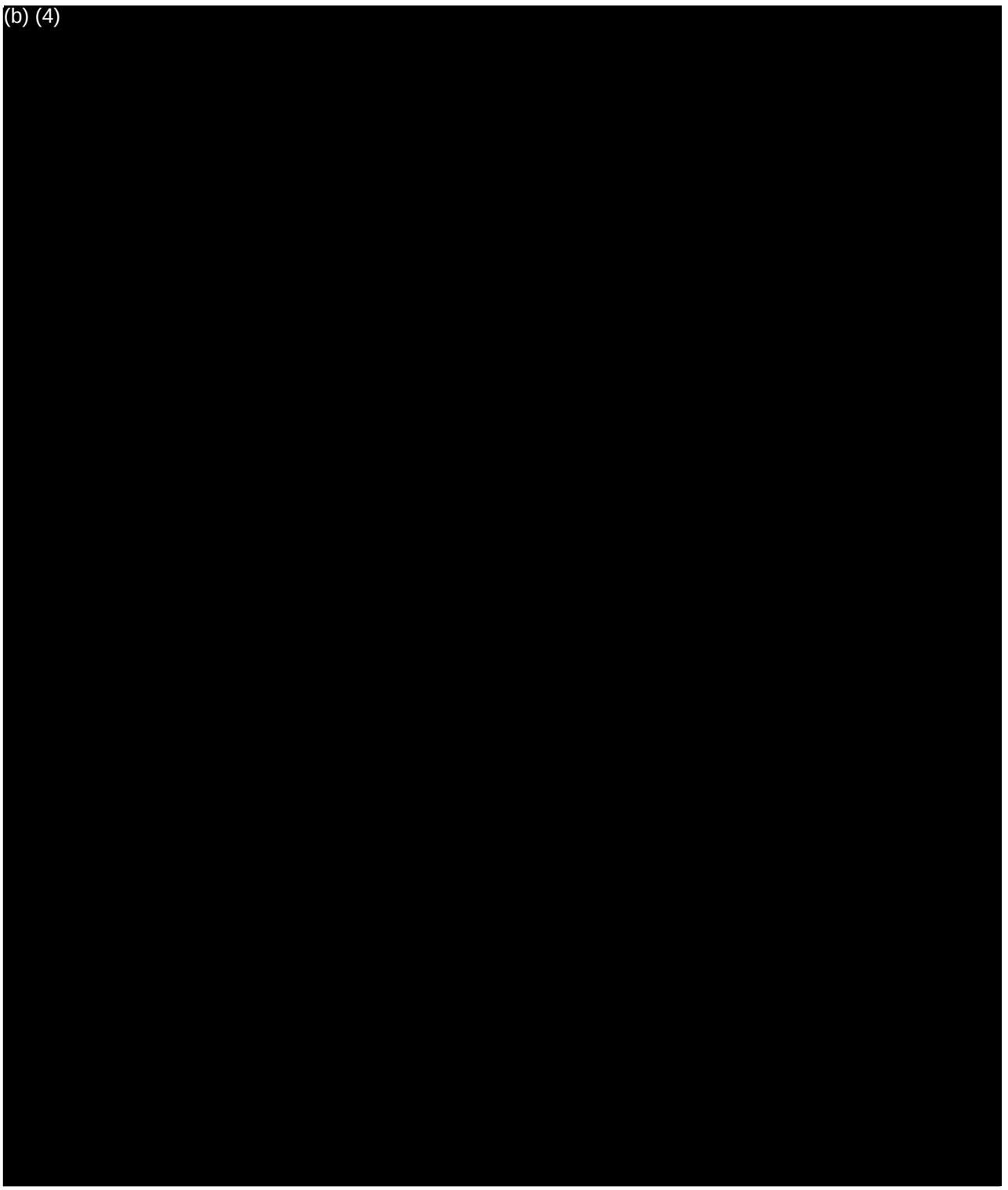
(b) (4)

(b) (4)

DJA x00434

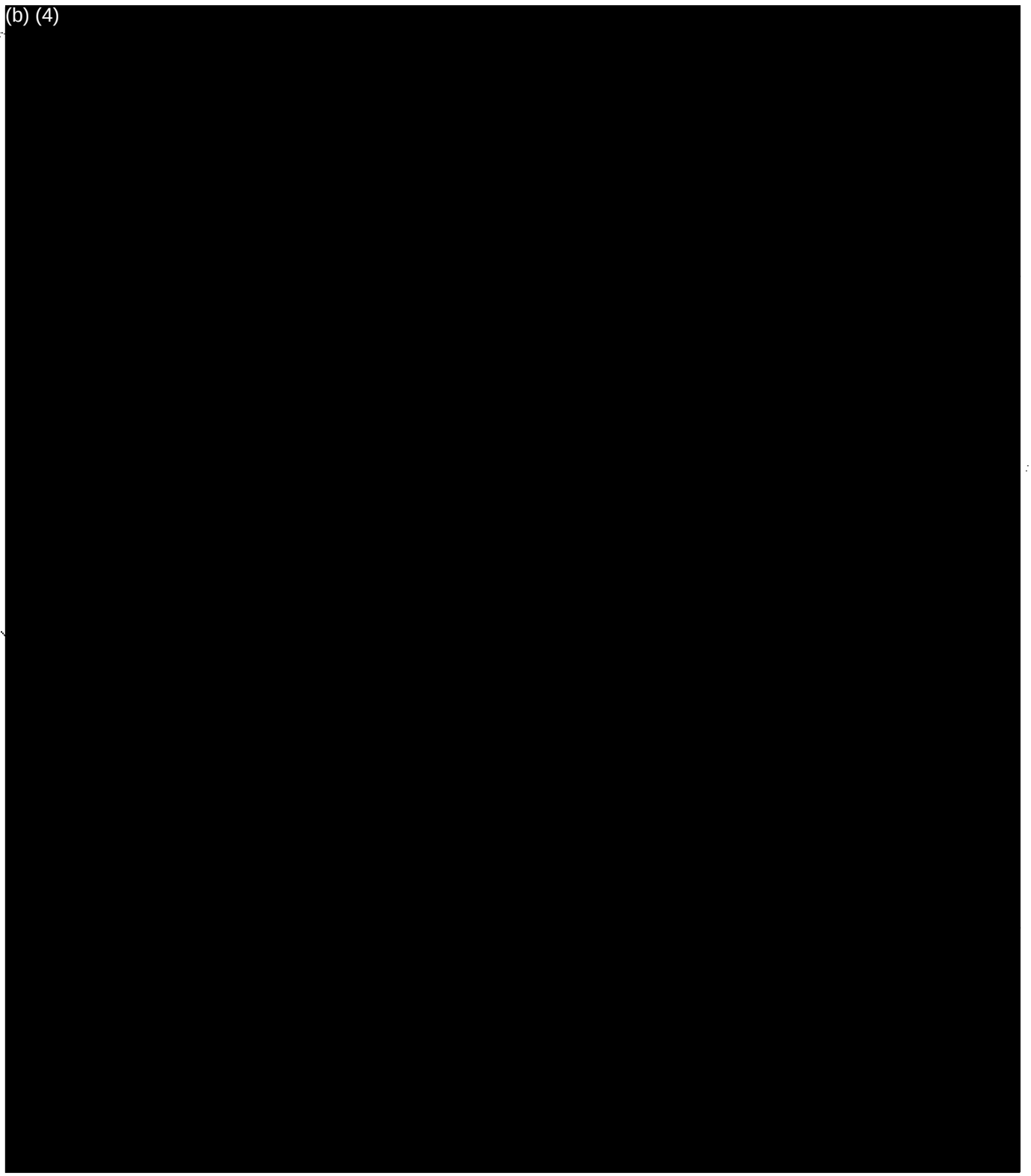
Model Creation Method

(b) (4)



DJA x00435

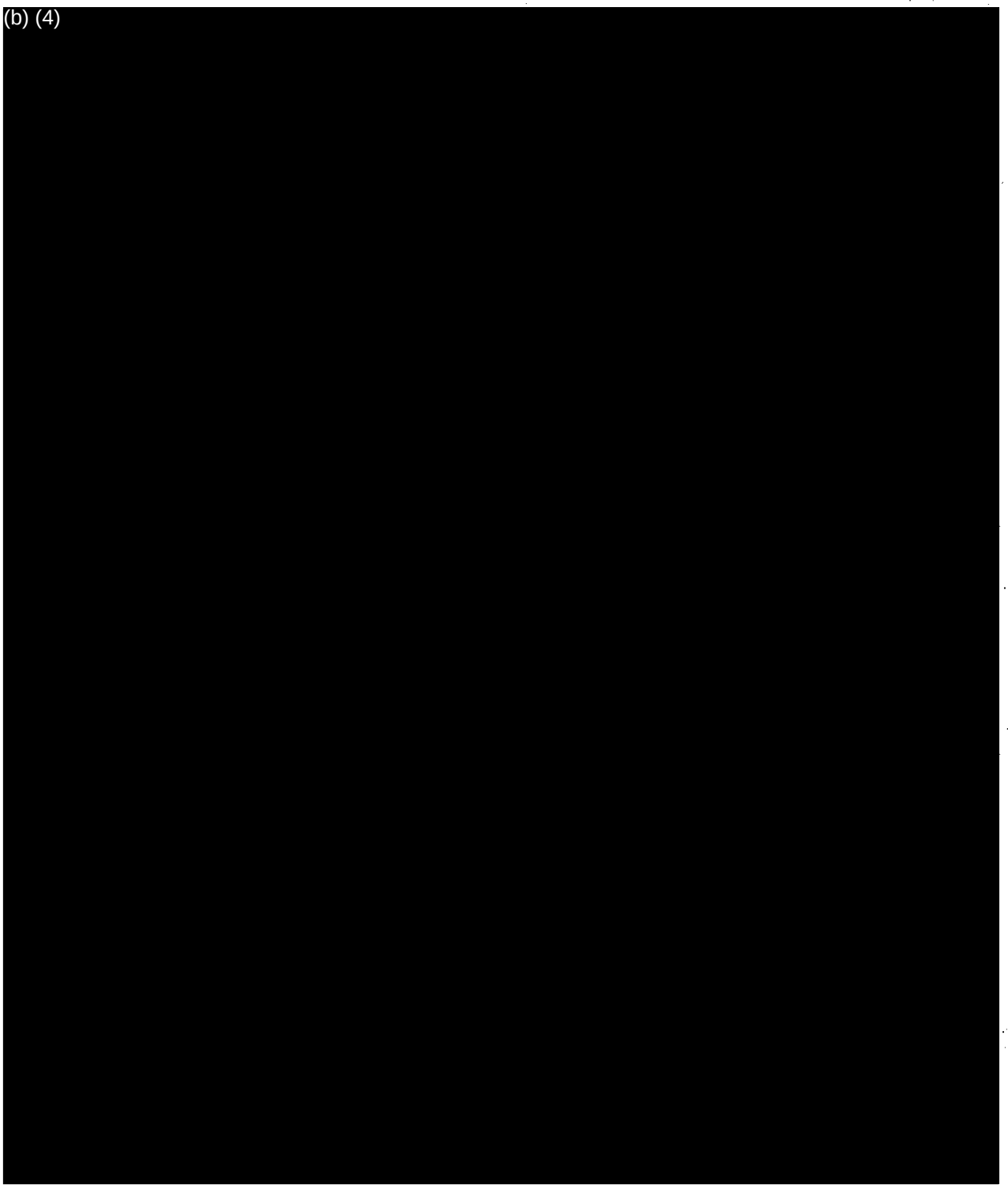
(b) (4)



DJA x00436

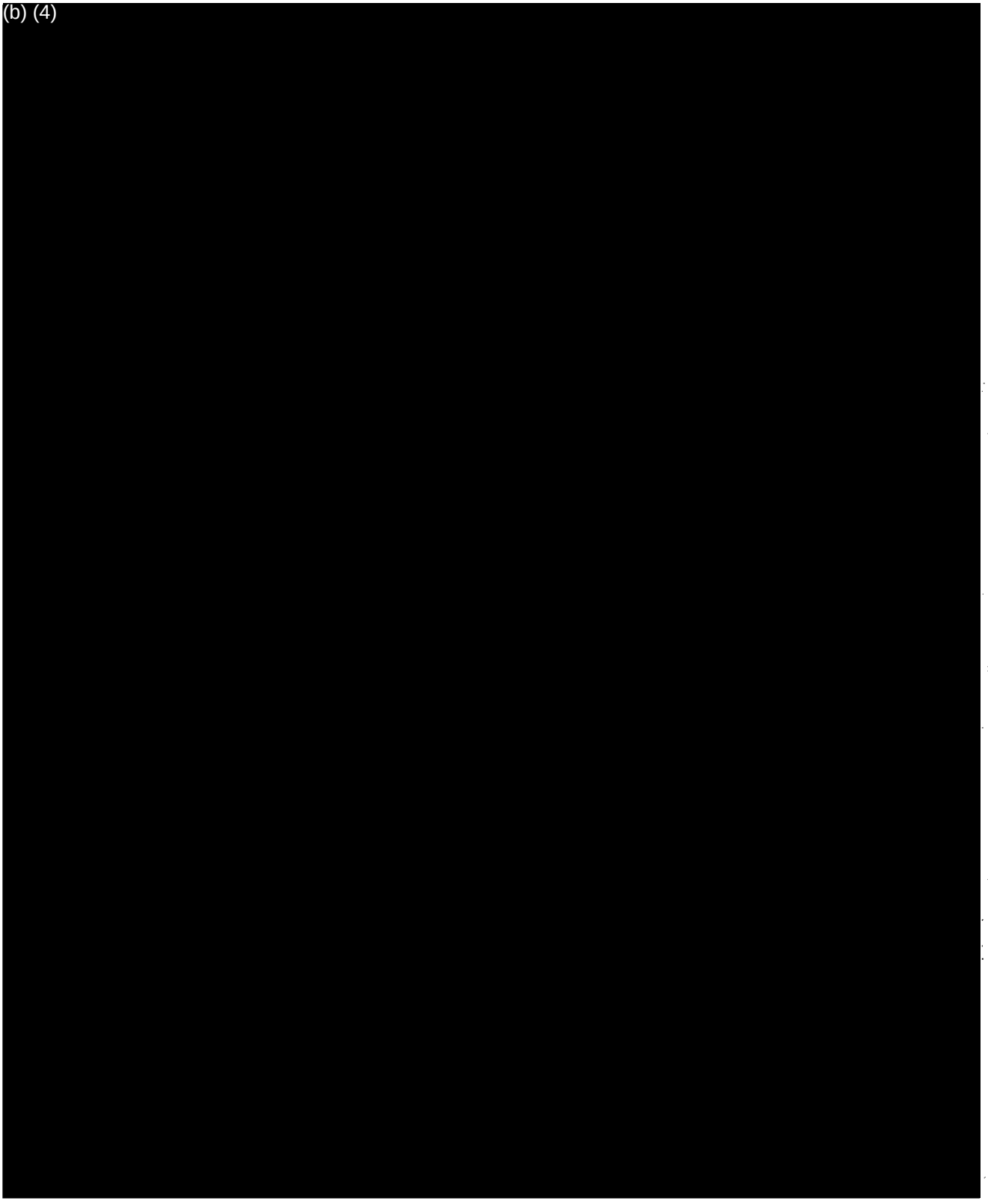
Pinless ROBODOC Clinical Evaluation
Patient Data Collection Form

(b) (4)



DJA x00437

(b) (4)



DJA x00438

PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER: **PV99-007-01** DCO # 1832		PAGE 1 OF 9
KEY WORDS: pinless, digitizer, clinical validation	PROTOCOL REF. NO. (If applicable)	PROJECT NO.: RDE 007 (If applicable)

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[redacted]

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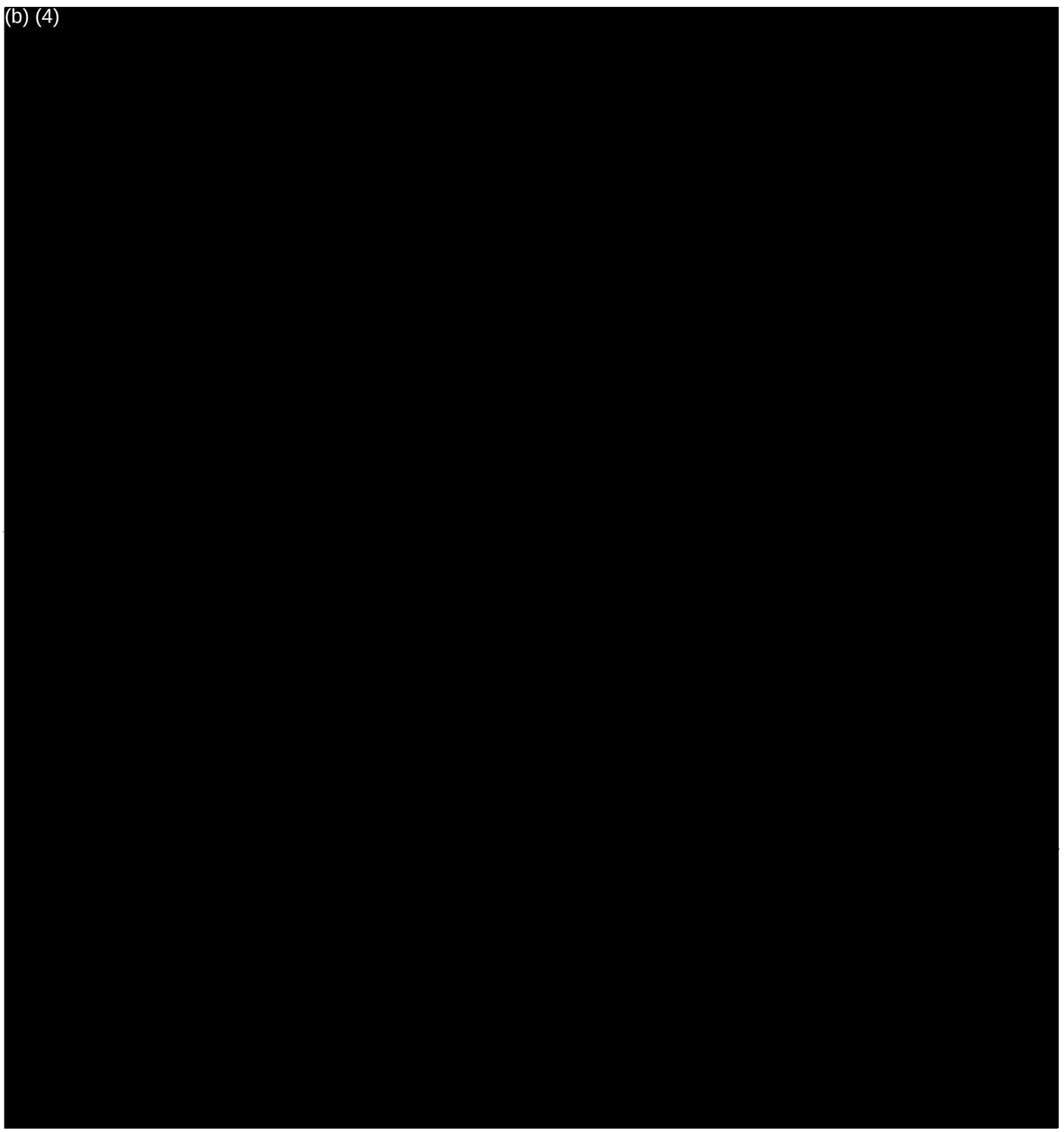
DJA x00439

(b) (4)



DJA x00440

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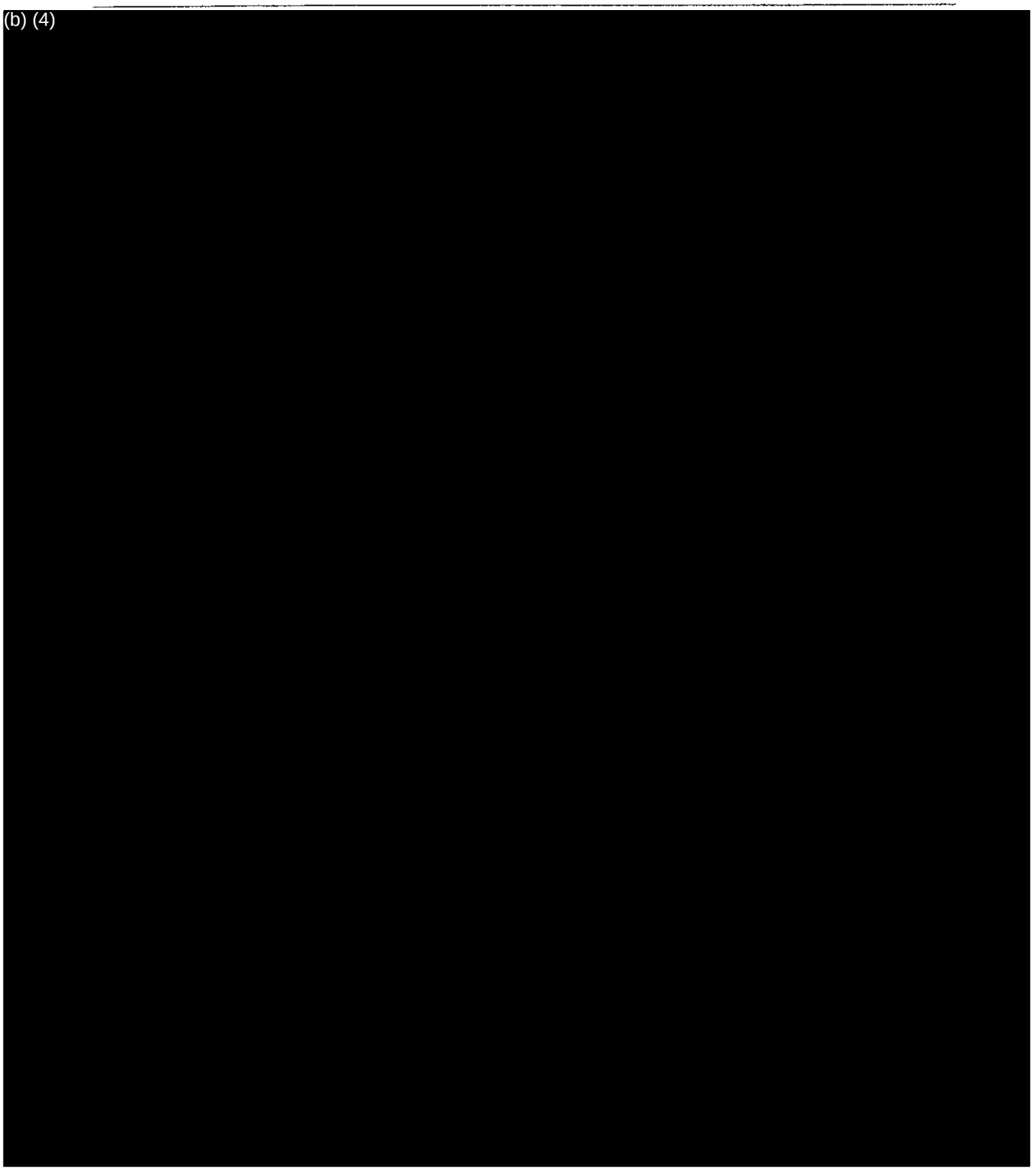

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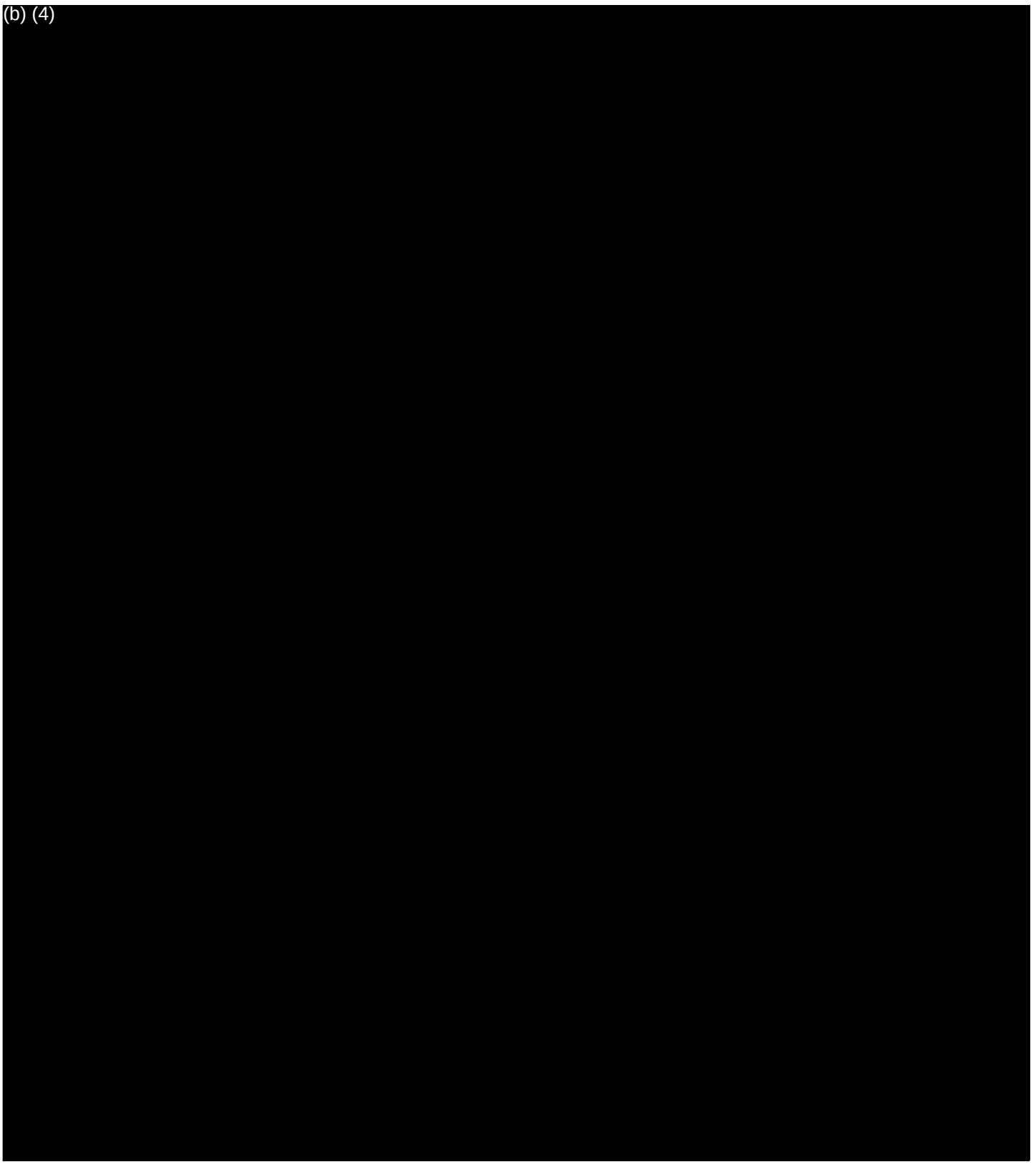


DJA x00442

(b) (4)

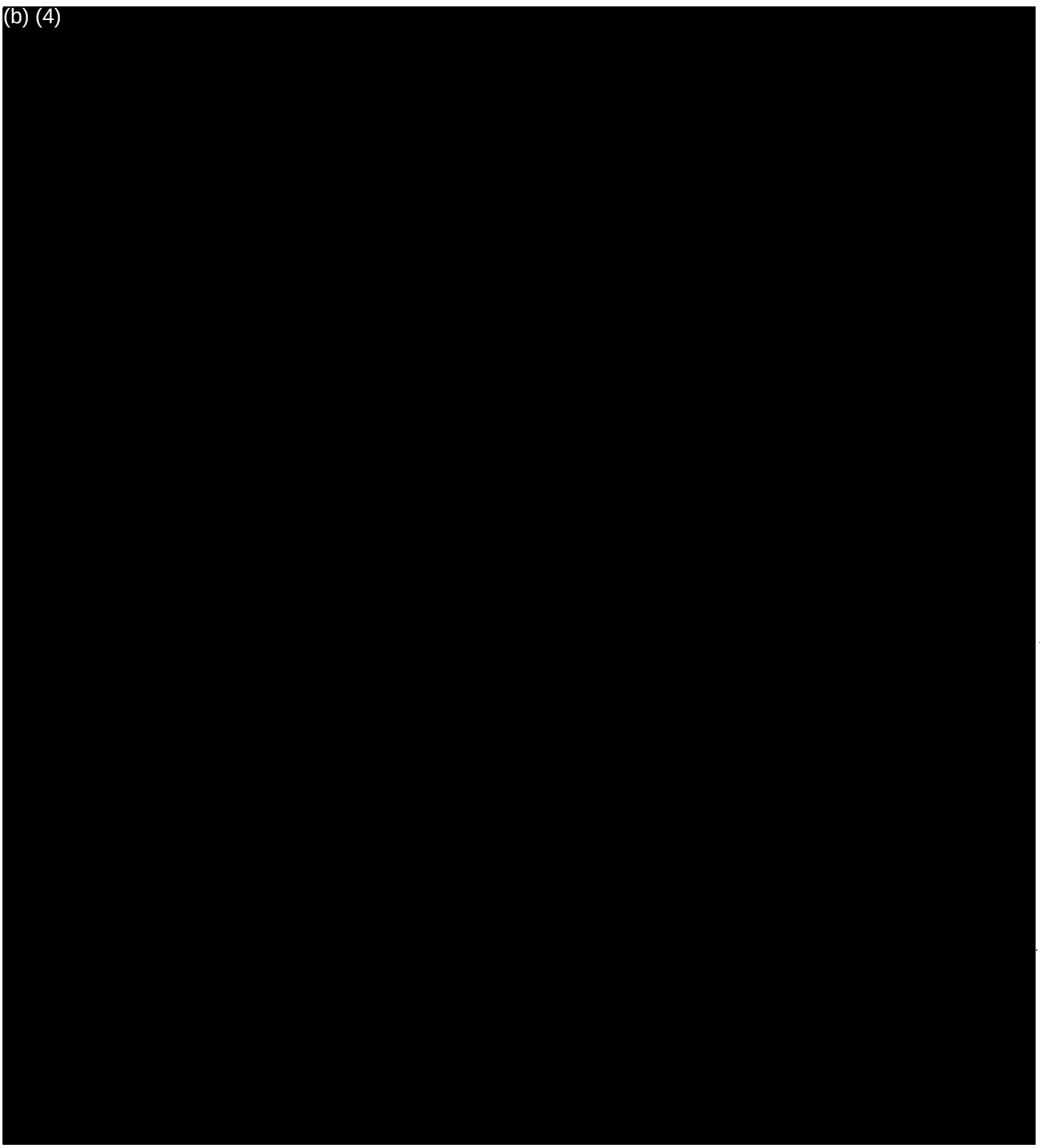
DJA x00443

Appendix A

ROBODOC DigiMatch System Clinical Evaluation

Training Record

(b) (4)



Appendix B

Integrated Surgical Systems, Inc.

INFORMED CONSENT ADDENDUM

DigiMatch System Clinical Testing for Direct Lateral Surgical Approach.

(b) (4)

Appendix C: ROBODOC® DigiMatch™ System Clinical Evaluation

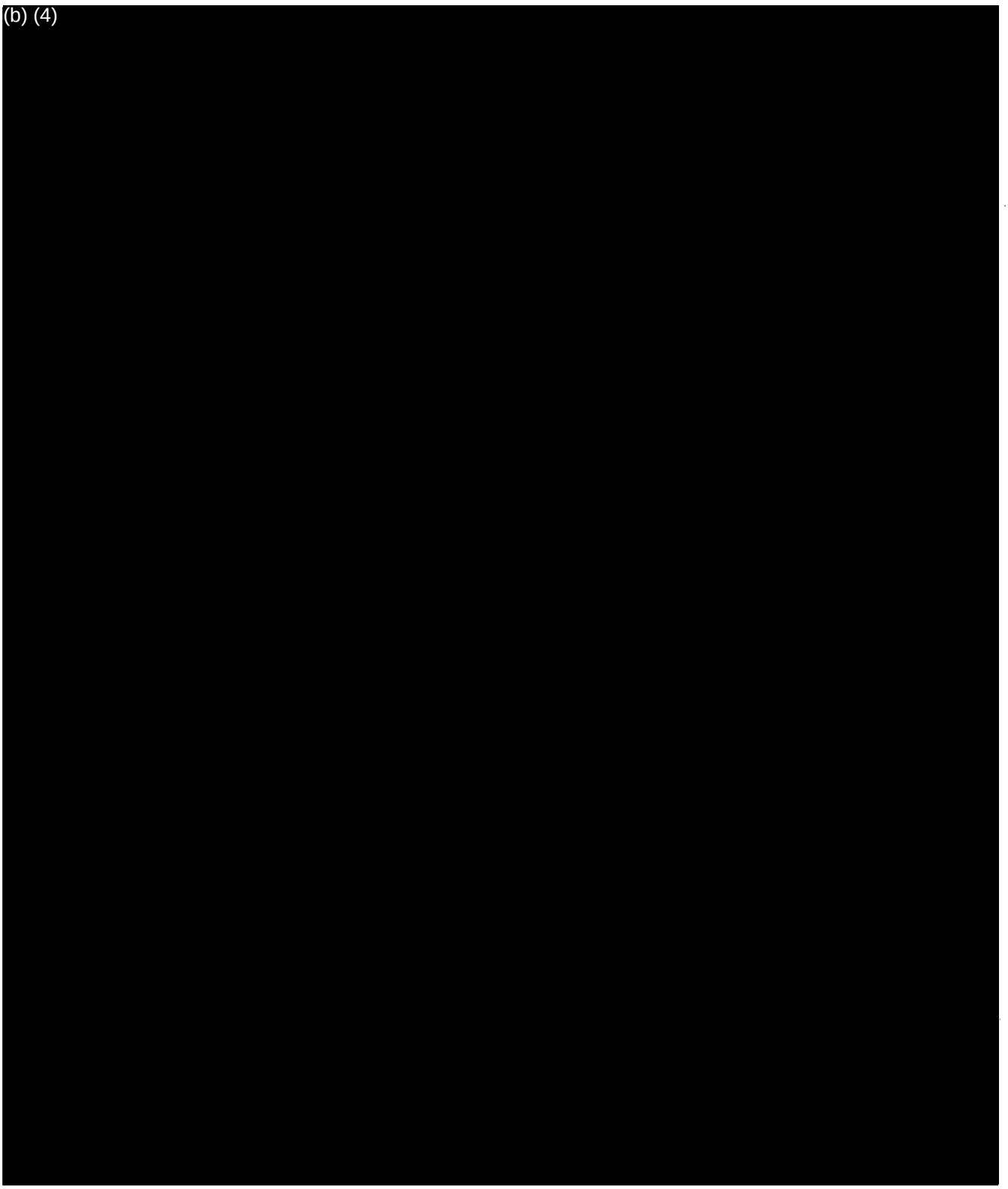
Patient Data Collection Form

(b) (4)

[redacted]

DJA x00446

(b) (4)



DJA x00447

PROTOCOL and TEST REPORT APPROVAL SHEET

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REFERENCE COPY
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DJA x00448

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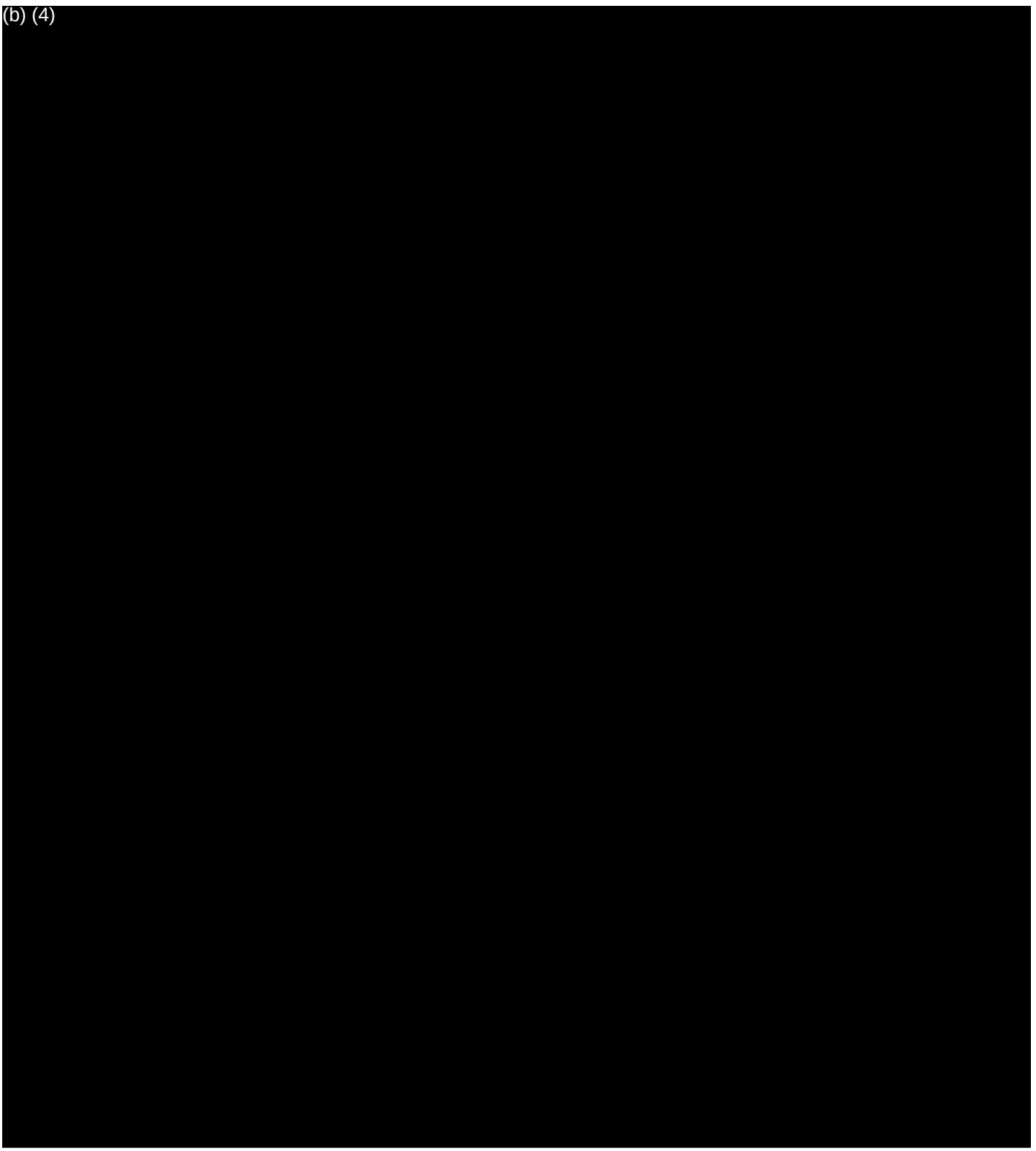

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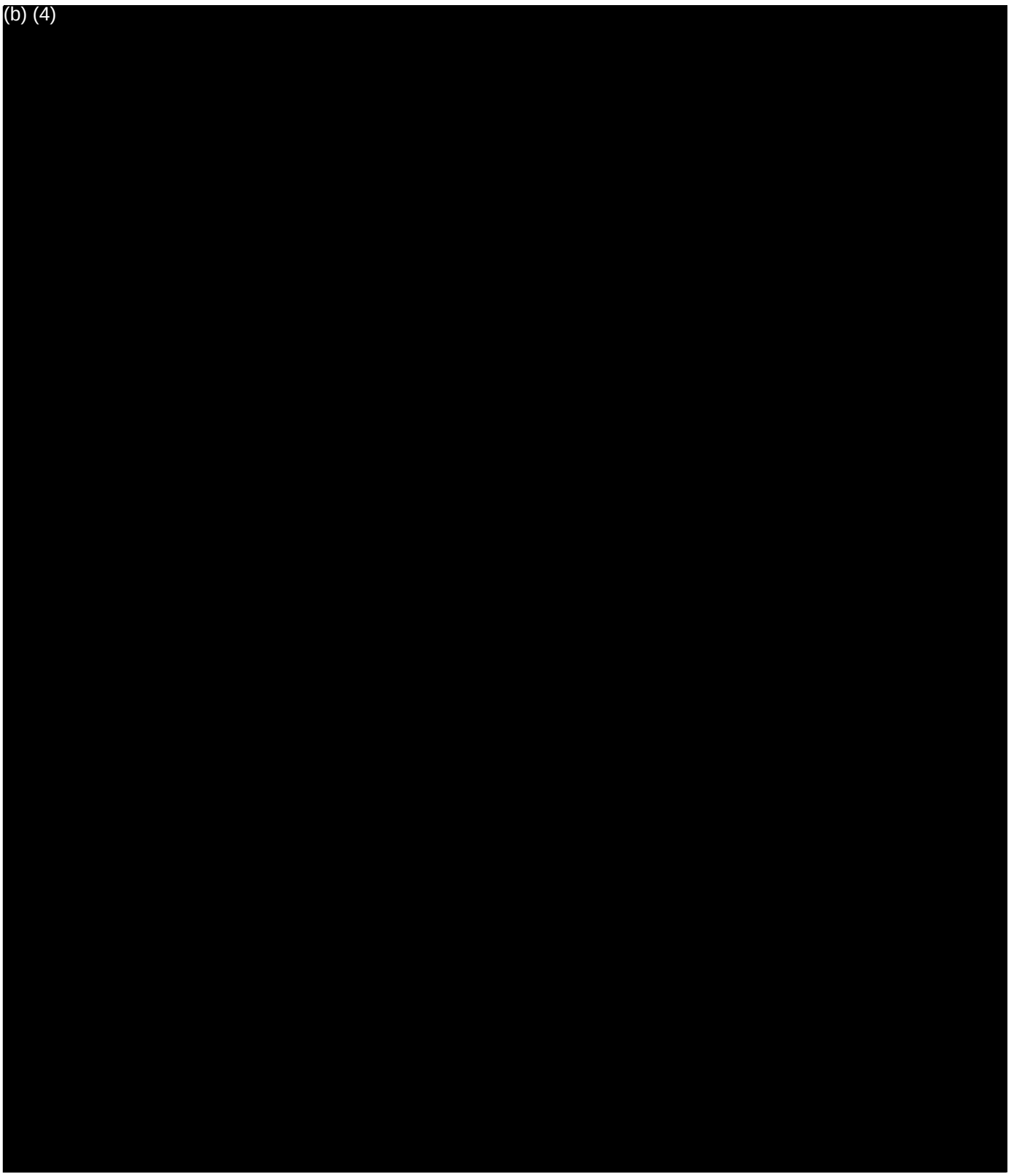

DJA x00450

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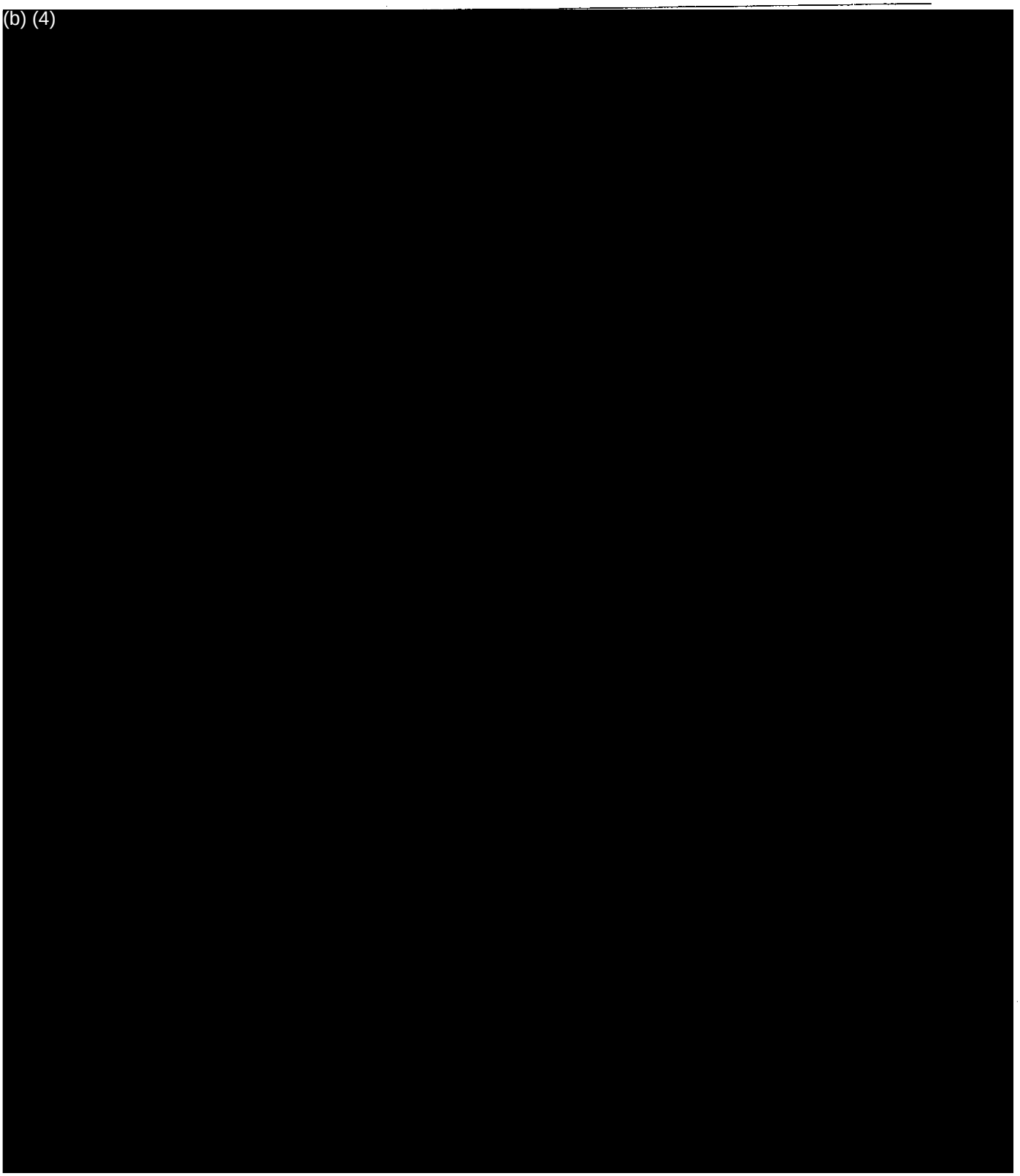

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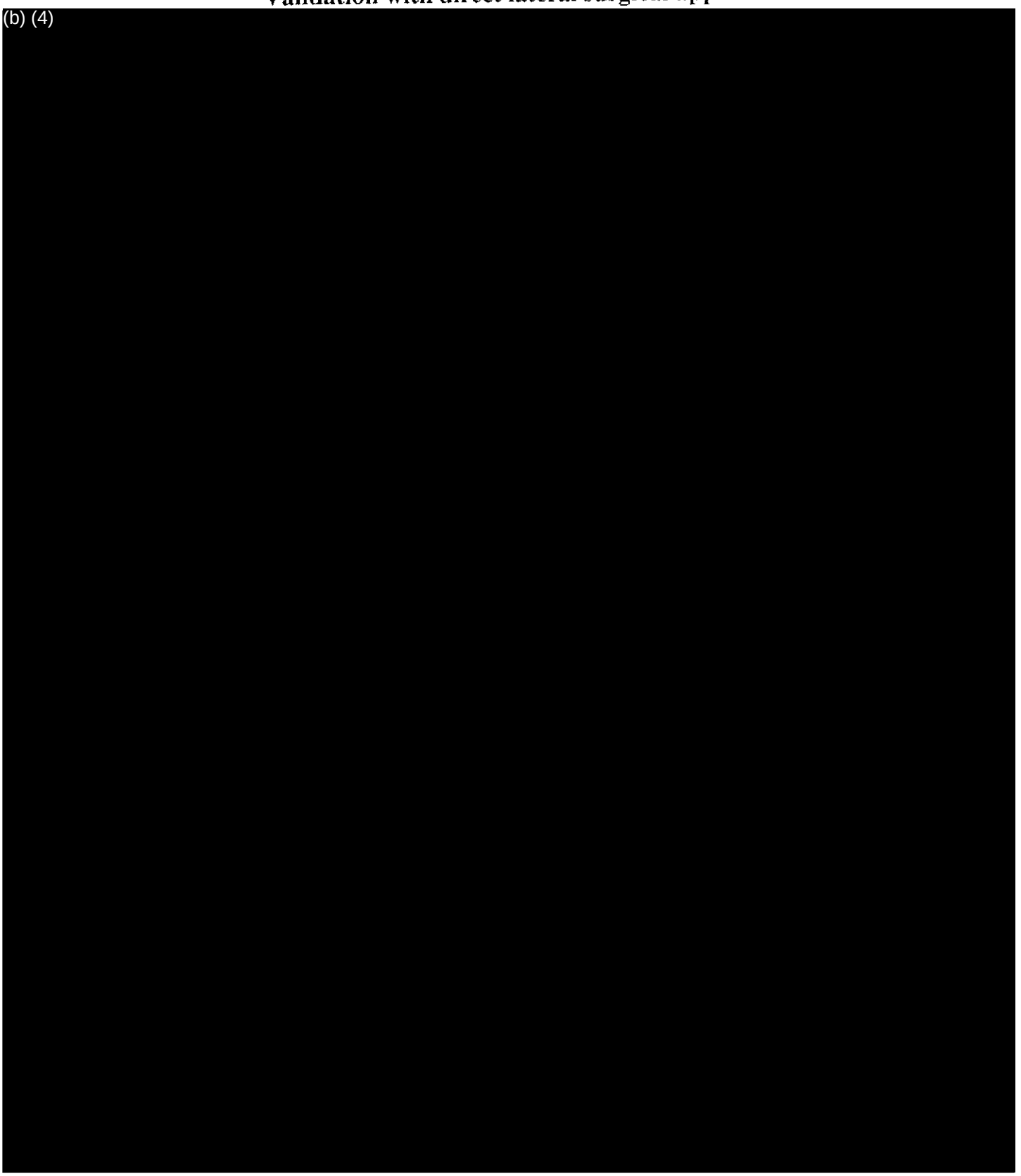

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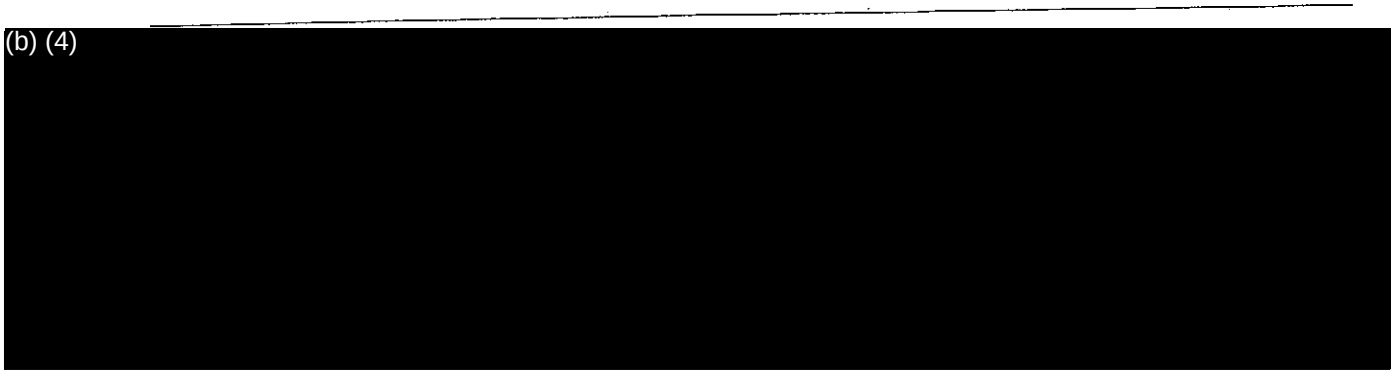

DJA x00453

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COPY
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DJA x004541

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[redacted]

DJA x00455

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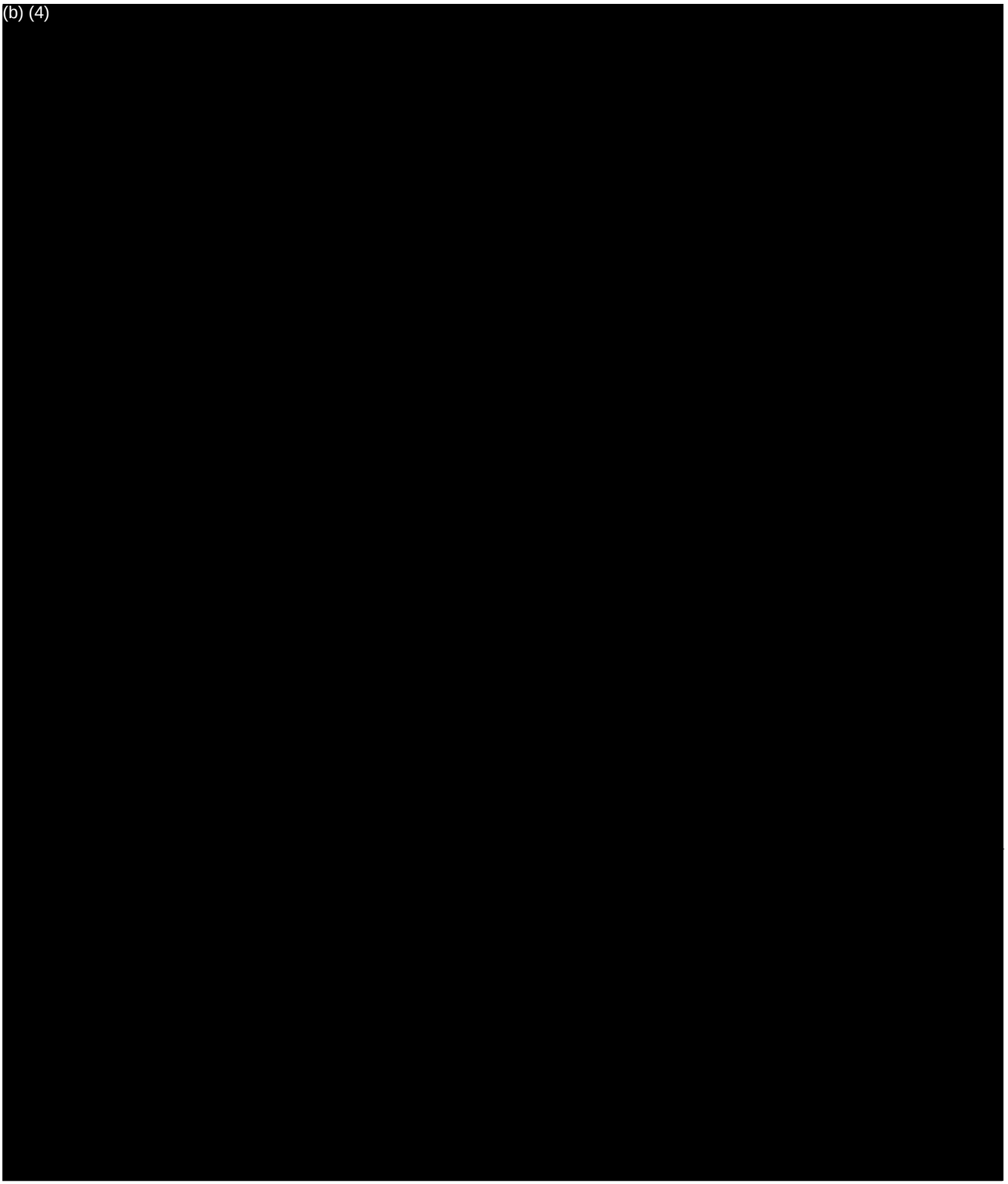
DJA x00456

(b) (4)



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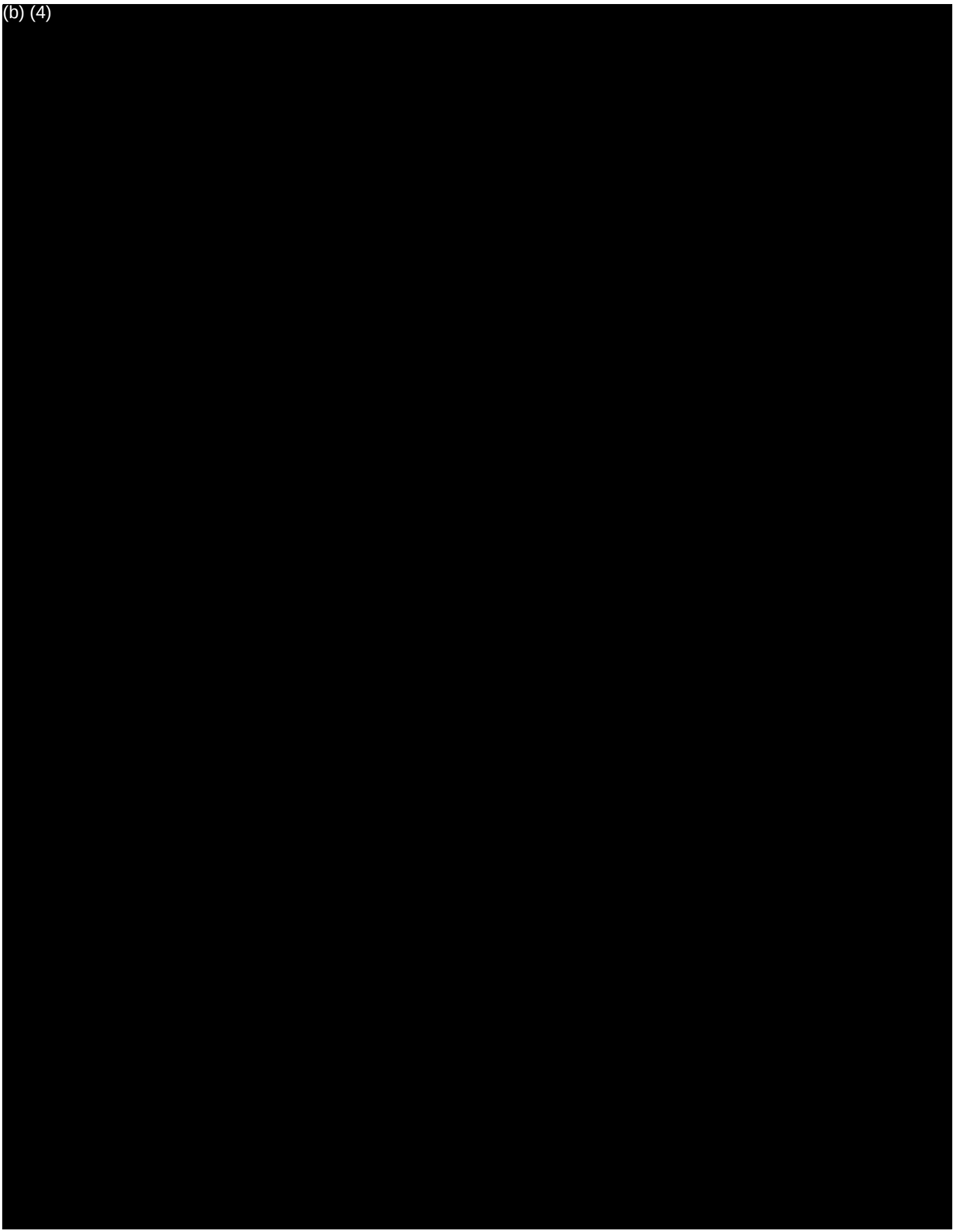

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DJA x00459

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DJA x00460

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(b) (4)

[redacted]

REFERENCE COPY
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DJA x00461

Results (Attach additional sheets if necessary):

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DJA x00462

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(b) (4)

DJA x00463

Results (Attach additional sheets if necessary):

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DJA x00464

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//                        FOR TESTING PURPOSES ONLY                      //
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DJA x00465

DJA x00466

ERROR FIELDS

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[redacted]

BASE MOVE COMMANDS STATUS FIELD STATISTICS

(b) (4)

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COMMANDS

(b) (4)

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DJA x00467

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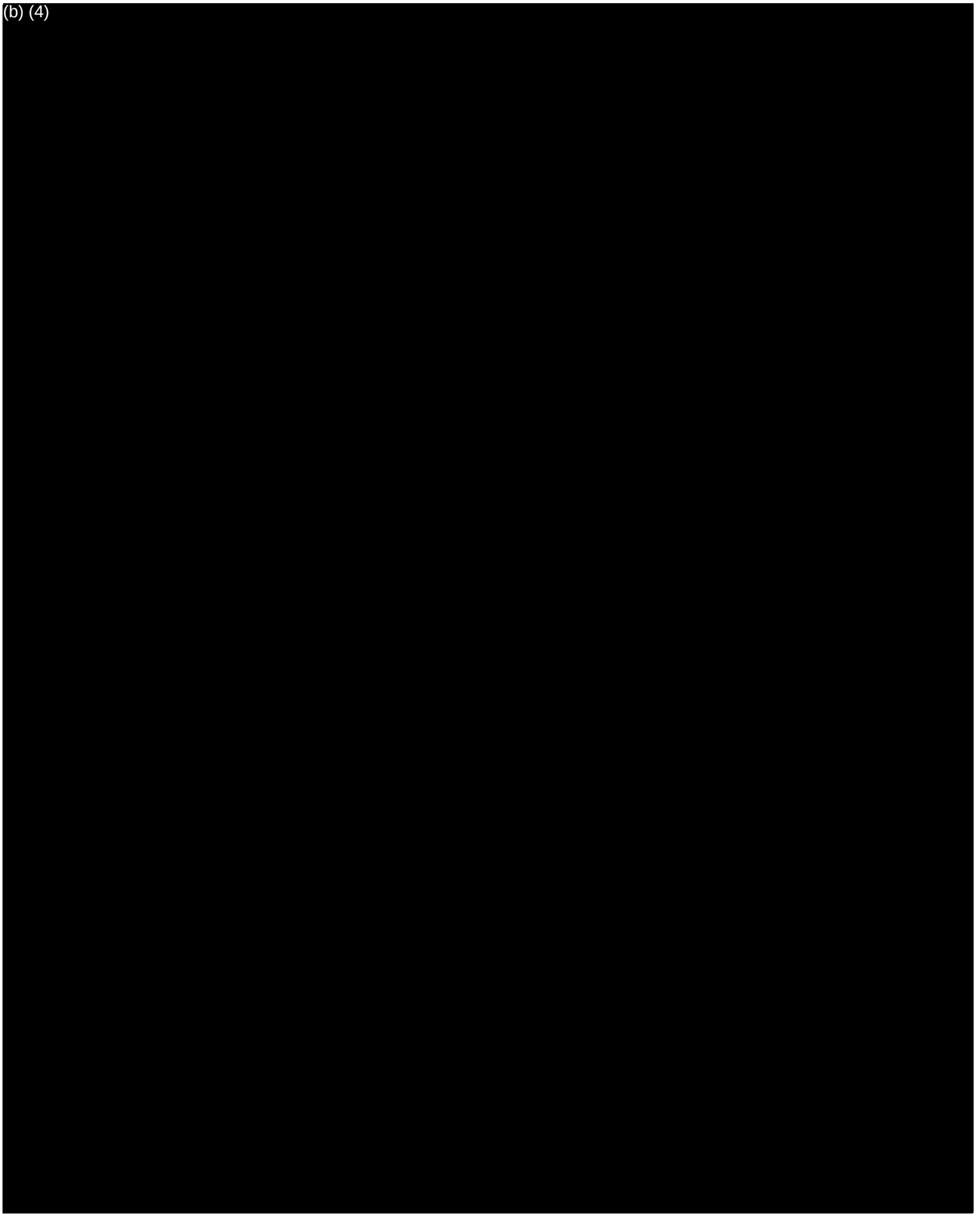
(b) (4)

DJA x00468

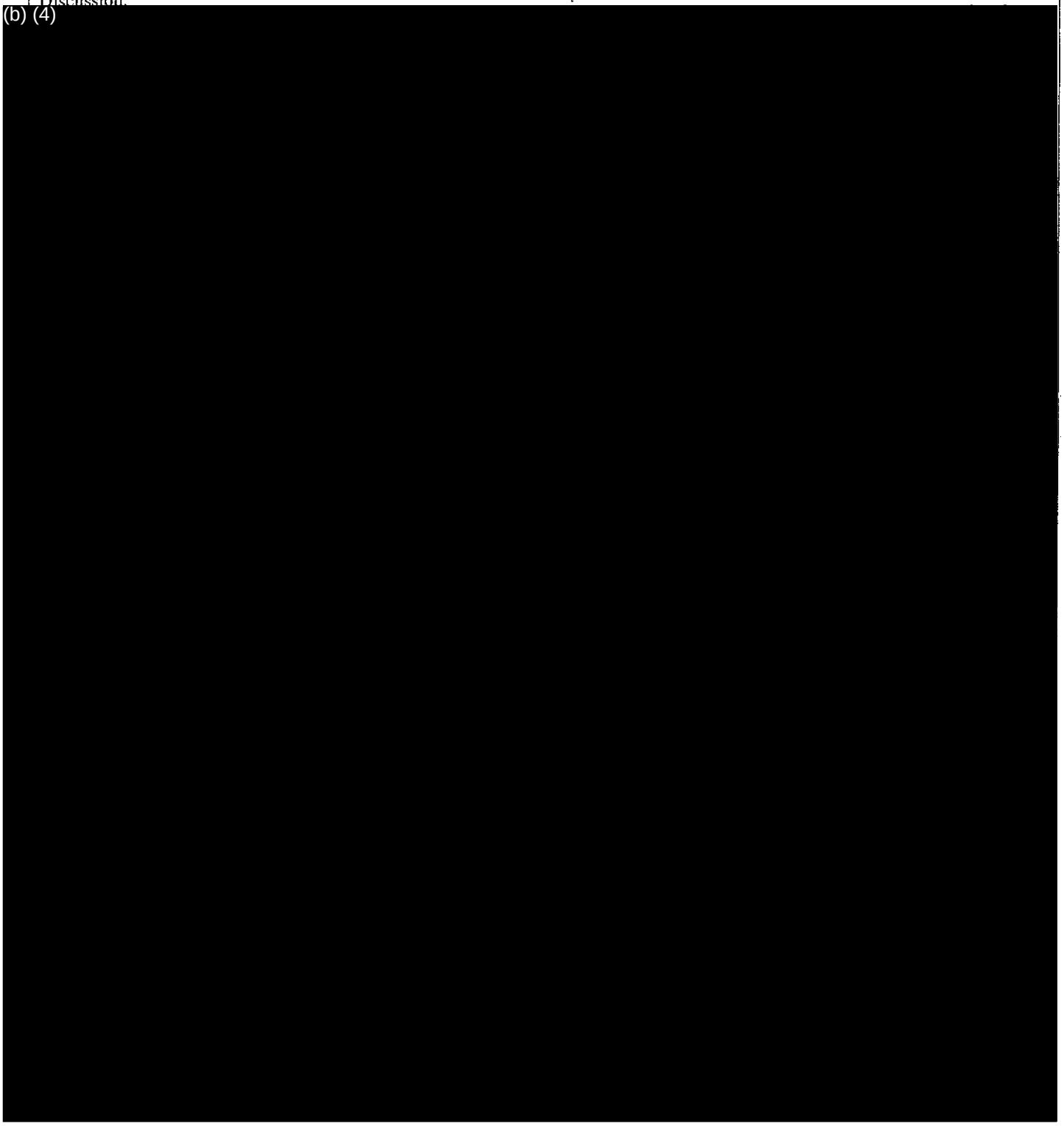
(b) (4)



DJA x00469

Analysis / Calculations:
Discussion:

(b) (4)



DJA x00470

TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1565

(b) (4)

REFERENCE COPY
qc 01/17/08

DJA x00471

Results (Attach additional sheets if necessary):

(b) (4)

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DJA x00472

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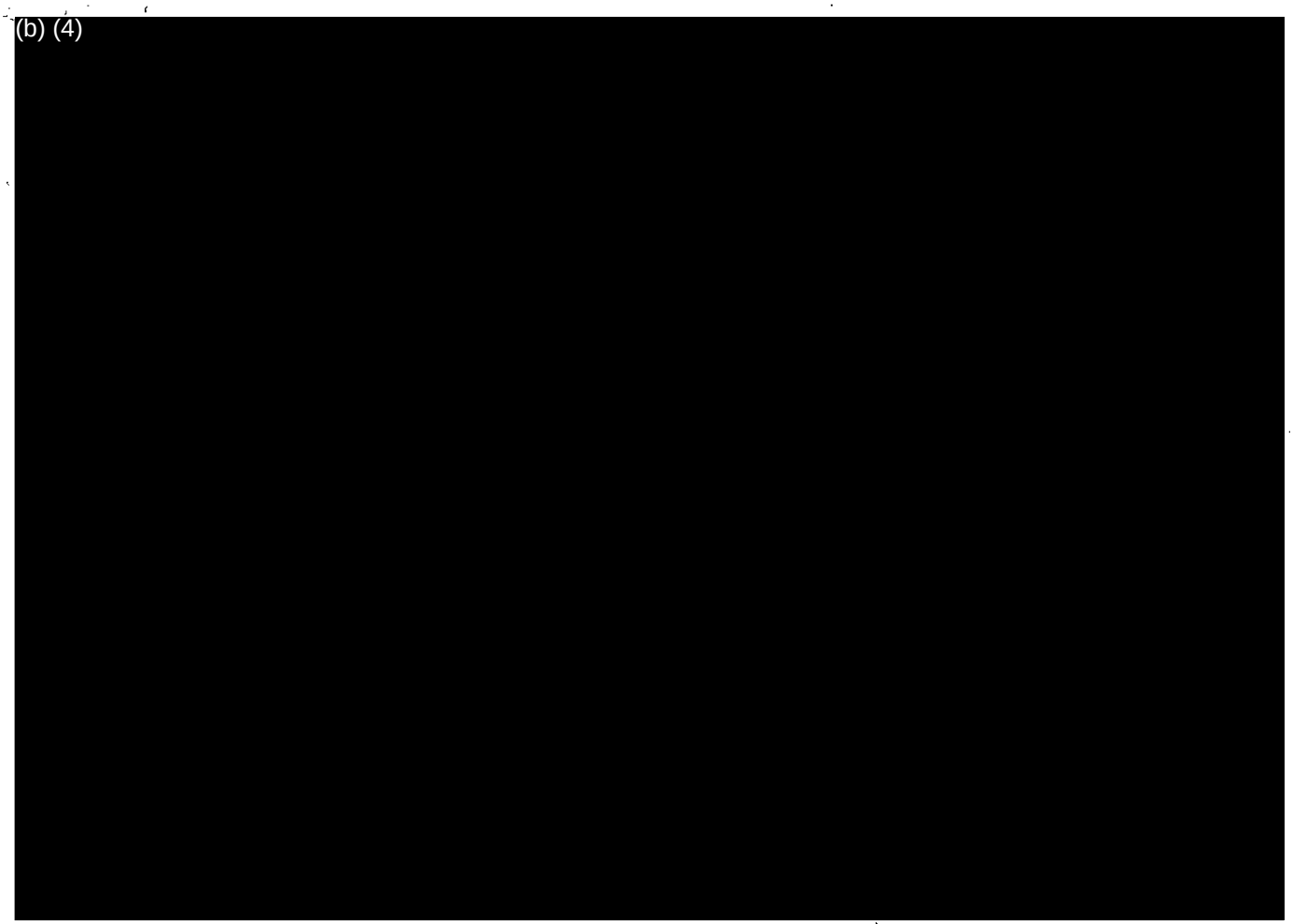

DJA x00474

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BASE MOVE COMMANDS STATUS FIELD STATISTICS

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COMMANDS

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DJA x00475

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(b) (4)

DJA x00476

Supervisor's Approval To Execute Study	Date
(b) (6) [redacted]	4/12/99

DJA x00477

Results (Attach additional sheets if necessary):

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DJA x00478

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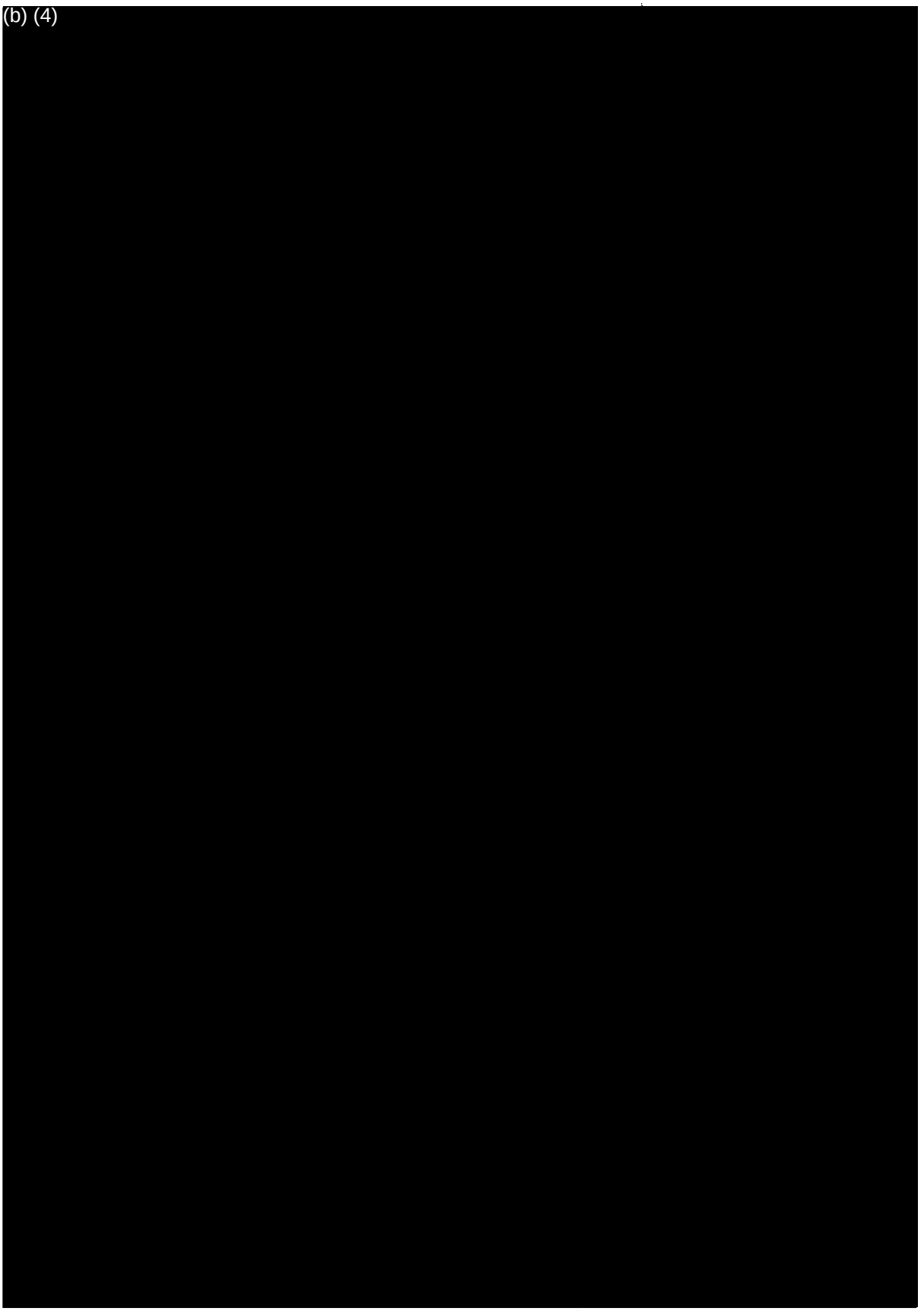

DJA x00479

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CIA X00480

ERROR FIELDS

(b) (4)

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BASE MOVE COMMANDS STATUS FIELD STATISTICS

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COMMANDS

(b) (4)

[redacted]

DJA x00481

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(b) (4)

[redacted]

COPY
gc 01/17/08

DJA x00482

Results (Attach additional sheets if necessary):

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DJA x00483

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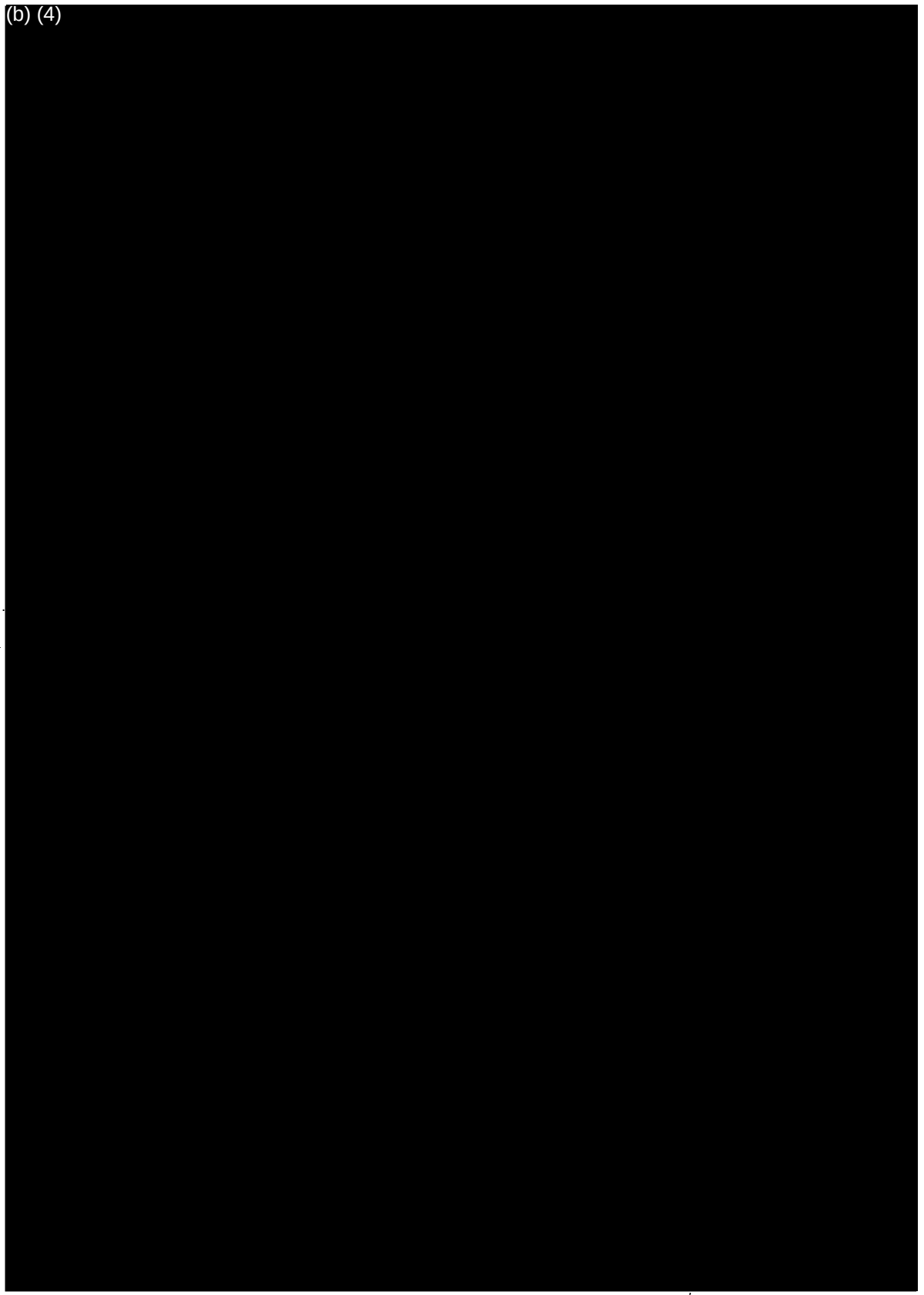

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DJA x00485

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BASE MOVE COMMANDS STATUS FIELD STATISTICS

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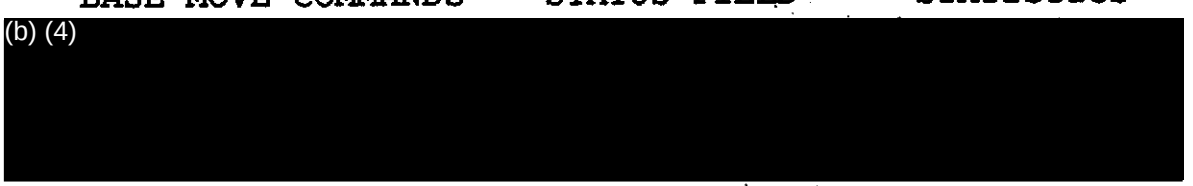

COMMANDS

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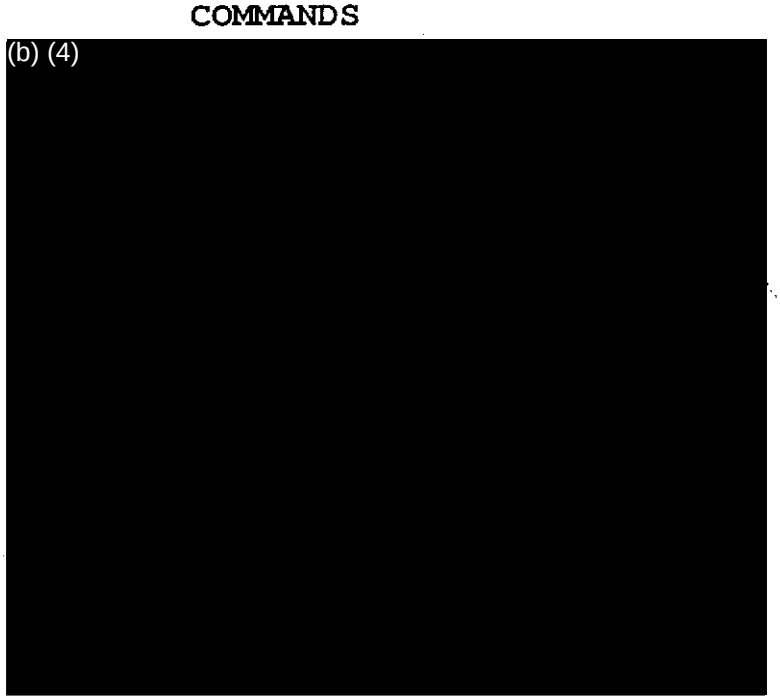

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DJA x00487

Supervisor's Approval To Execute Study	Date
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DJA x00488

Results (Attach additional sheets if necessary):

(b) (4)

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DJA x00489

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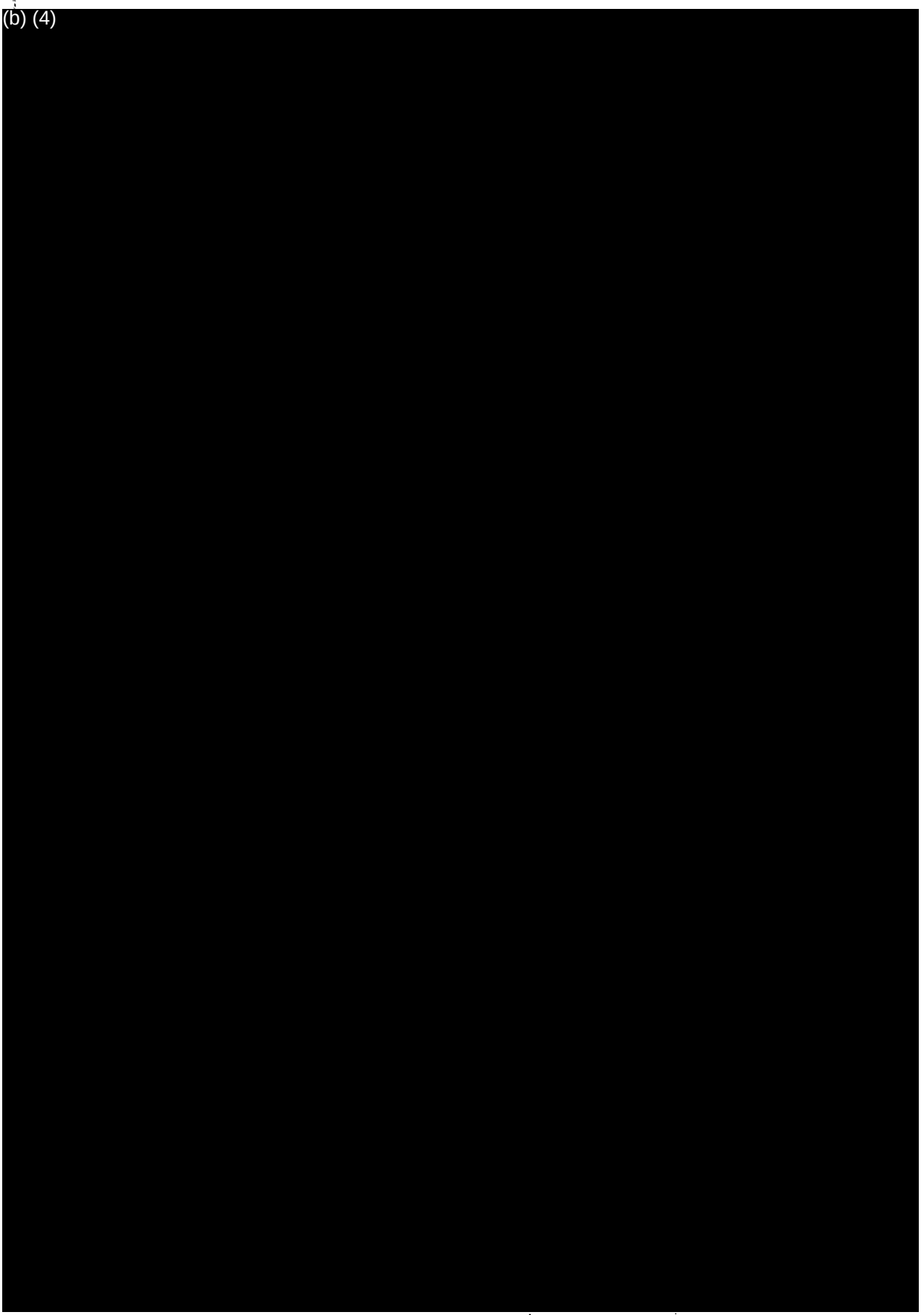

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DJA x00490

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DJA x00491

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BASE MOVE COMMANDS STATUS FIELD STATISTICS

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DJA x00492

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(b) (4)

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gc 01/17/08

DJA x00493

Results (Attach additional sheets if necessary):

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[redacted]

DJA x00494

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

[redacted]

REFERENCE COPY
gc 01/17/08

DJA x00495

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00496

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

[redacted]

DJA x00497

(b) (4)

[redacted]

Supervisor's Approval To Execute Study	Date
[signature]	3/3/99

DJA x00498

Results (Attach additional sheets if necessary):

(b) (4) [redacted]

Discussion:

(b) (4) [redacted]

DJA x00499

Conclusion:

(b) (4) [redacted]

Supervisor's Approval _____ Date 3/31/99

Documentation File Date Ogden Dahl 5/19/99

DJA x00500

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

REFERENCE COPY
qc 01/17/08

DJA x00501

Results (Attach additional sheets if necessary):

(b) (4)

DJA x00502

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

DJA x00503

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00504

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

qc 01/17/08

DJA x00505

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00506

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

[redacted]

2. Current

REFERENCE COPY
gc 01/17/08

DJA x00507

(b) (4)

[redacted]

Supervisor's Approval To Execute Study	Date
[signature]	5/11/99

DJA x00508

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00509

(b) (4)

DJA x00510

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

REFERENCE COPY
qc 01/17/08

DJA x00511

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00512

03/30/99
(b) (4)

ERROR FIELDS

(b) (4)

BASE MOVE COMMANDS STATUS FIELD STATISTICS

(b) (4)

COMMANDS

(b) (4)

DJA x00513

TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1565

(b) (4)

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REFERENCE COPY
gc 01/17/08

DJA x00514

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x005:5

03/30/99

(b) (4)

ERROR FIELDS

(b) (4)

[redacted]

DJA x00516

TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1565

(b) (4)

REFERENCE COPY
qc 01/17/08

DJA x00517

Results (Attach additional sheets if necessary):

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[redacted]

DJA x00518

03/30/99
(b) (4)

ERROR FIELDS

(b) (4)

[redacted]

BASE MOVE COMMANDS STATUS FIELD STATISTICS

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[redacted]

COMMANDS

(b) (4)

[redacted]

DJA x00519

TECHNICAL STUDY (TS)

Study Control Number

(b) (4)

DCO # 1565

(b) (4)

[redacted]

Supervisor's Approval To Execute Study

Date

3/31/99

DJA x00520

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00521

ERROR FIELDS

(b) (4)

[redacted]

BASE MOVE COMMANDS STATUS FIELD STATISTICS

(b) (4)

[redacted]

COMMANDS

(b) (4)

[redacted]

DJA x00522

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[redacted]

REFERENCE COPY
gc 01/17/08

DJA x00523

Results (Attach additional sheets if necessary):

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[redacted]

DJA x00524

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

qc 01/17/08

DJA x00525

(b) (4)

DJA x00526

Results (Attach additional sheets if necessary):

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[redacted]

DJA x00527

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1565

(b) (4)

REFERENCE COPY
gc 01/09/08

DJA x00528

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00529

(b) (4)

[redacted]

DJA x00530

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

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REFERENCE COPY
gc 01/09/08

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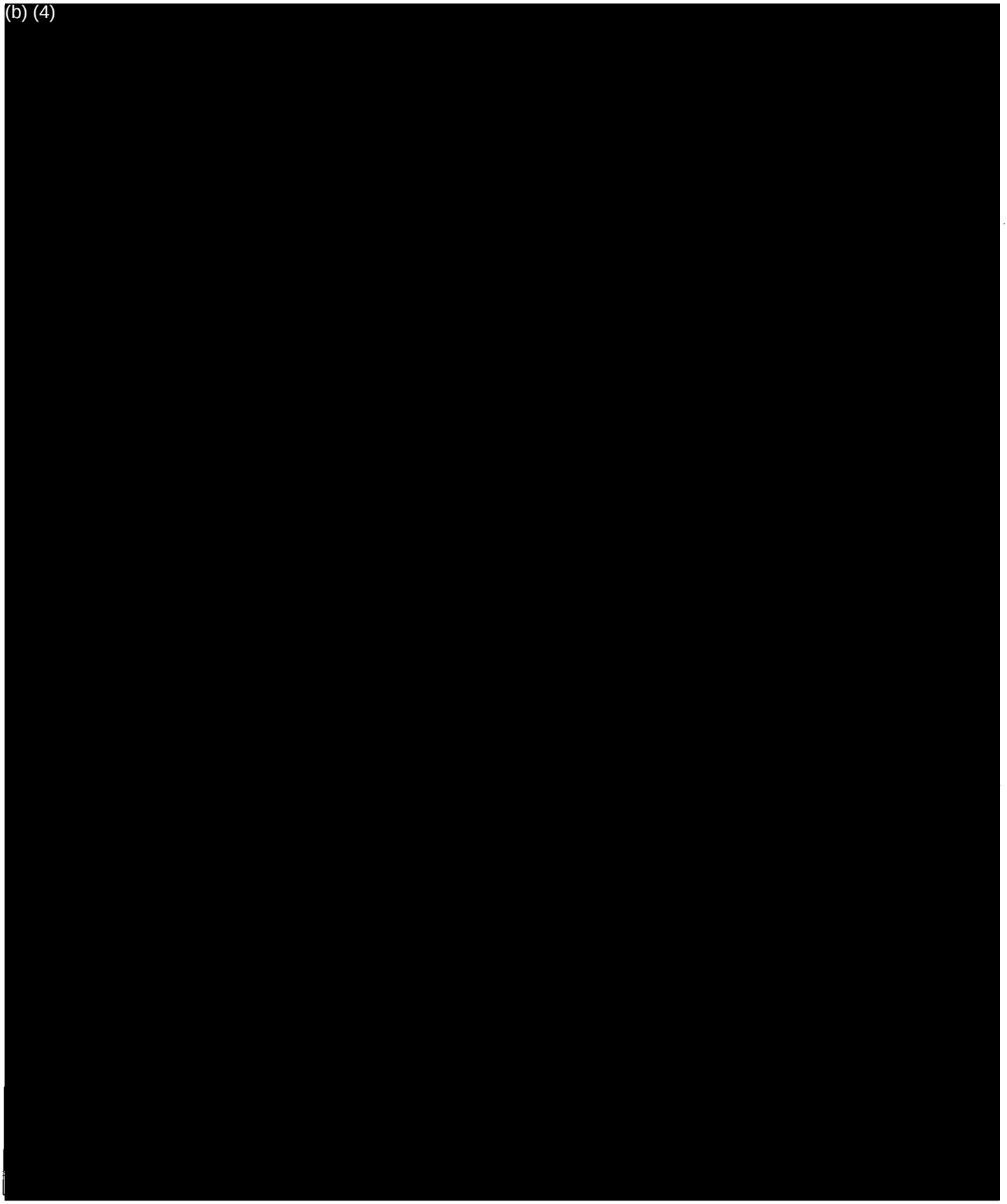

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Results (Attach additional sheets if necessary):

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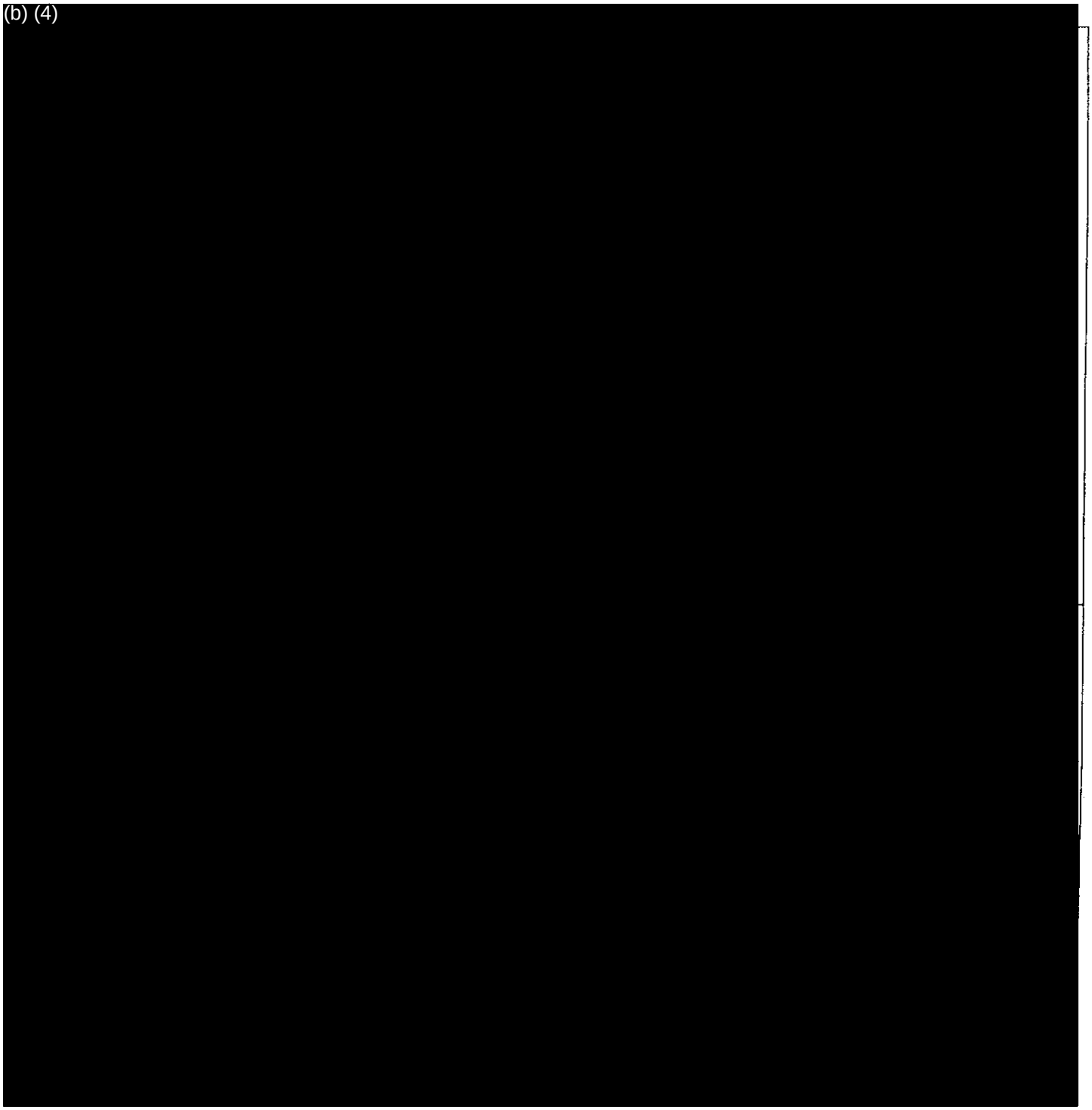
DJA x00533

(b) (4)



DJA x00534

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[redacted]

REFERENCE COPY
gc 01/17/08

DJA x00535

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00536

(b) (4)

DJA x00537

ERROR FIELDS

(b) (6)

[redacted]

BASE MOVE COMMANDS STATUS FIELD STATISTICS

(b) (6)

[redacted]

COMMANDS

(b) (6)

[redacted]

DJA x00538

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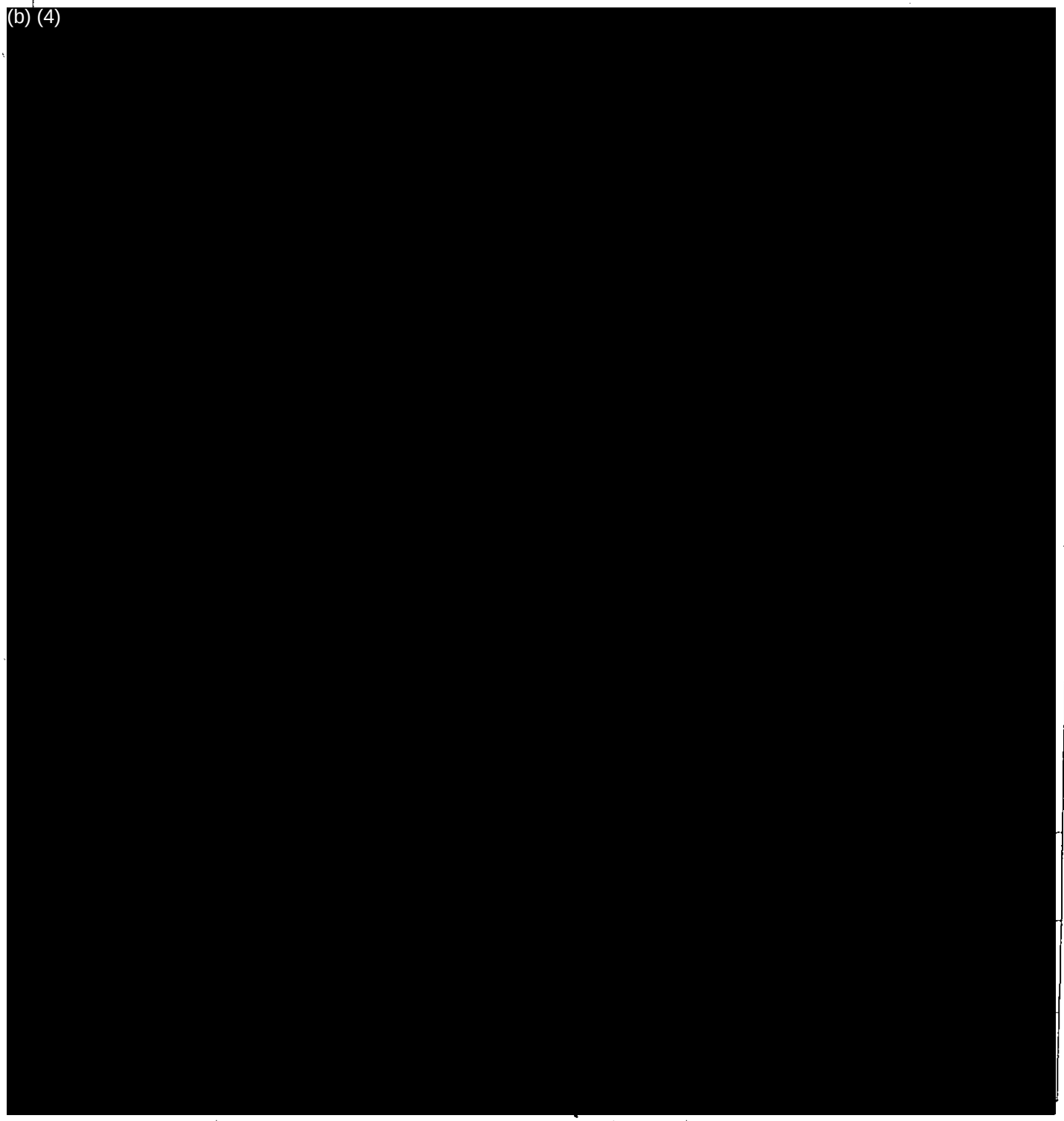
DJA x00539

(b) (4)



DJA x00540

Results (Attach additional sheets if necessary):

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DJA x00541

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1565

(b) (4)

DJA x00542

References:

(b) (4)

[redacted]

DJA x00543

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00544

ERROR FIELDS

(b) (4)

[redacted]

BASE MOVE COMMANDS STATUS FIELD STATISTICS

(b) (4)

[redacted]

COMMANDS

(b) (4)

[redacted]

DJA x00545

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

DJA x00546

Results (Attach additional sheets if necessary):

(b) (4)

DJA x00547

TECHNICAL STUDY (TS)

Study Control Number

(b) (4)

DCO # 1565

(b) (4)

DJA x00548

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00549

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

[redacted]

REFERENCE COPY
gc 01/17/08

DJA x00550

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00551

(b) (4)

[redacted]

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ACTUATE

(b) (4)

[redacted]

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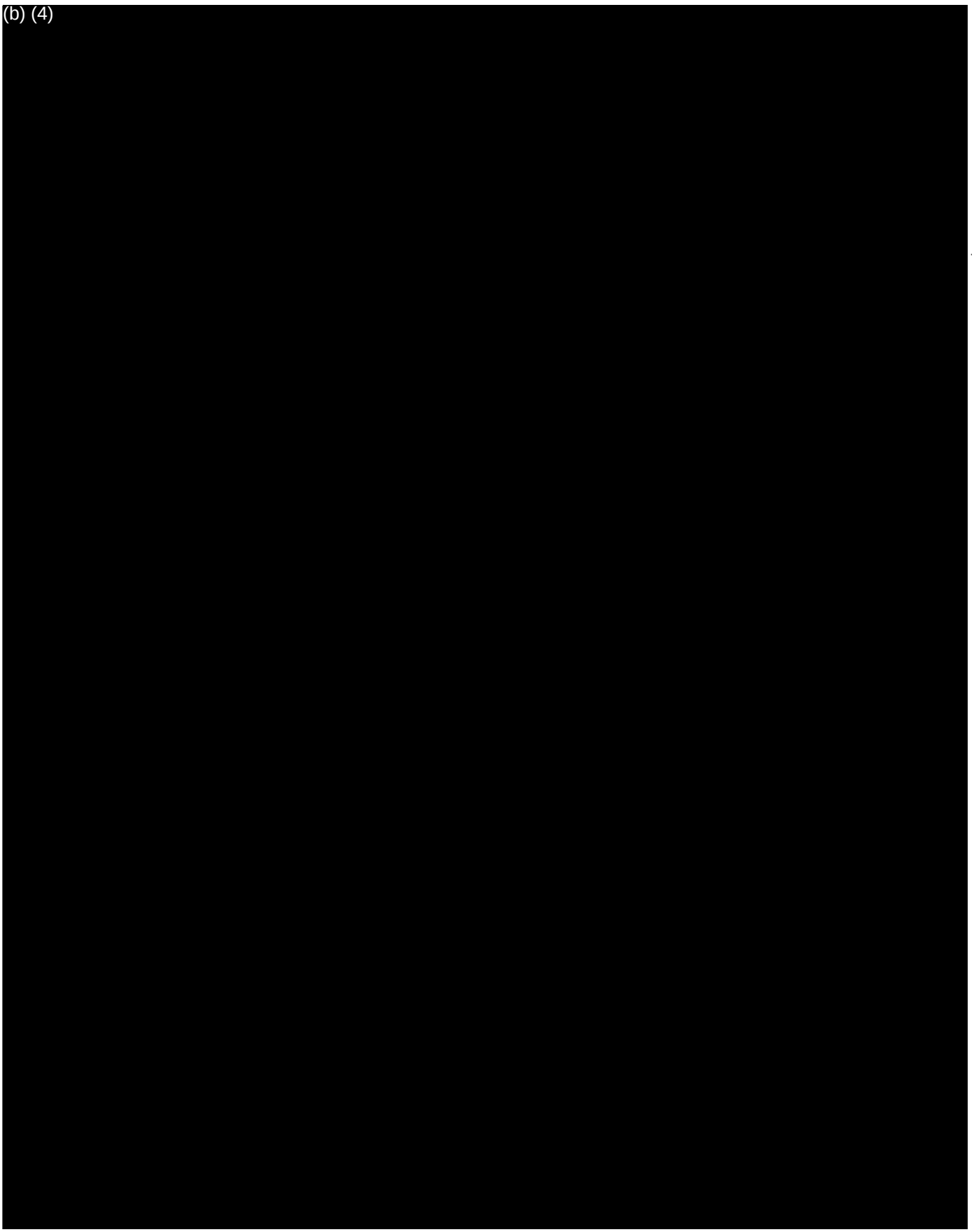
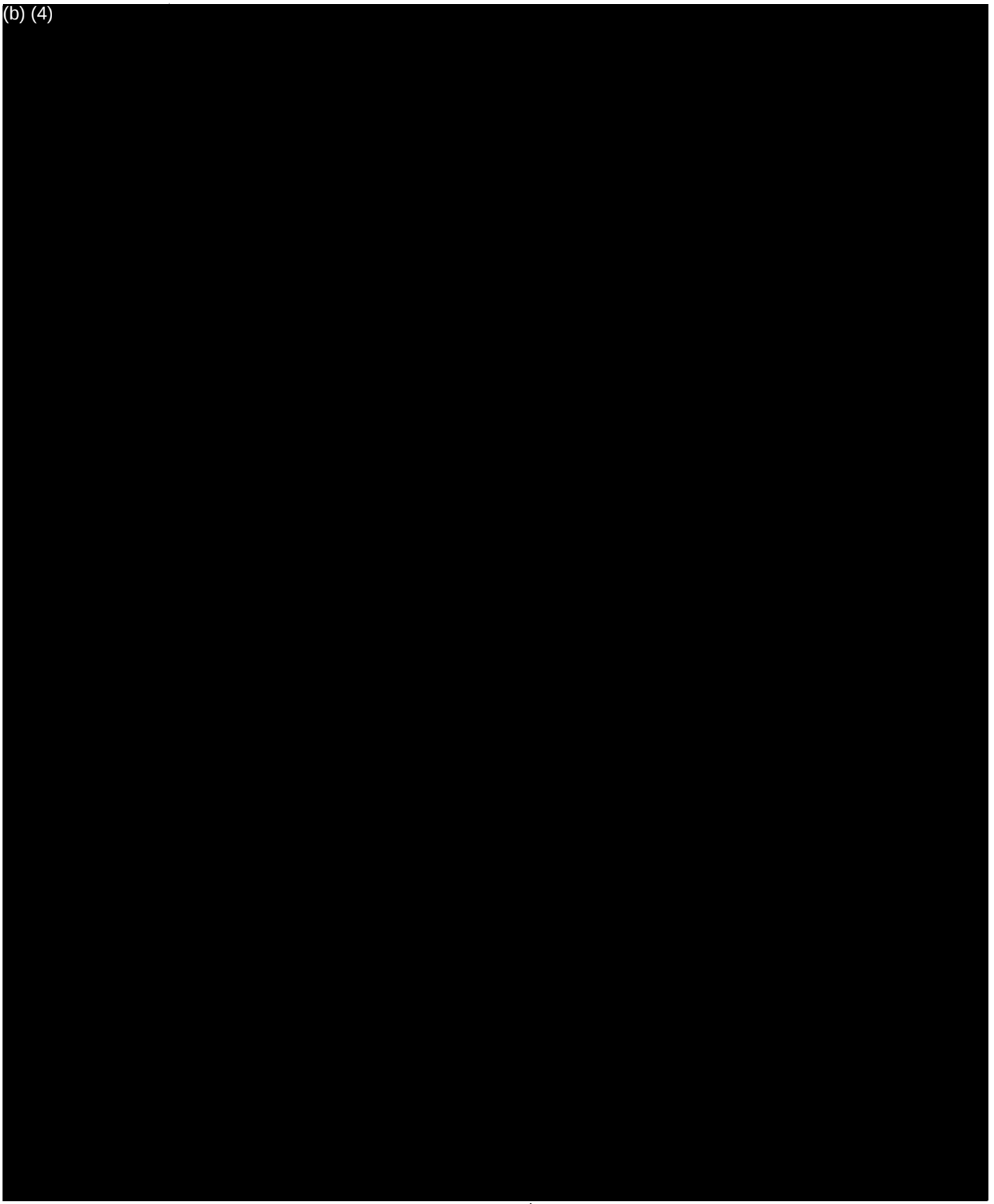
DJA x00552



DJA x00553

(b) (4)



DJA x00554

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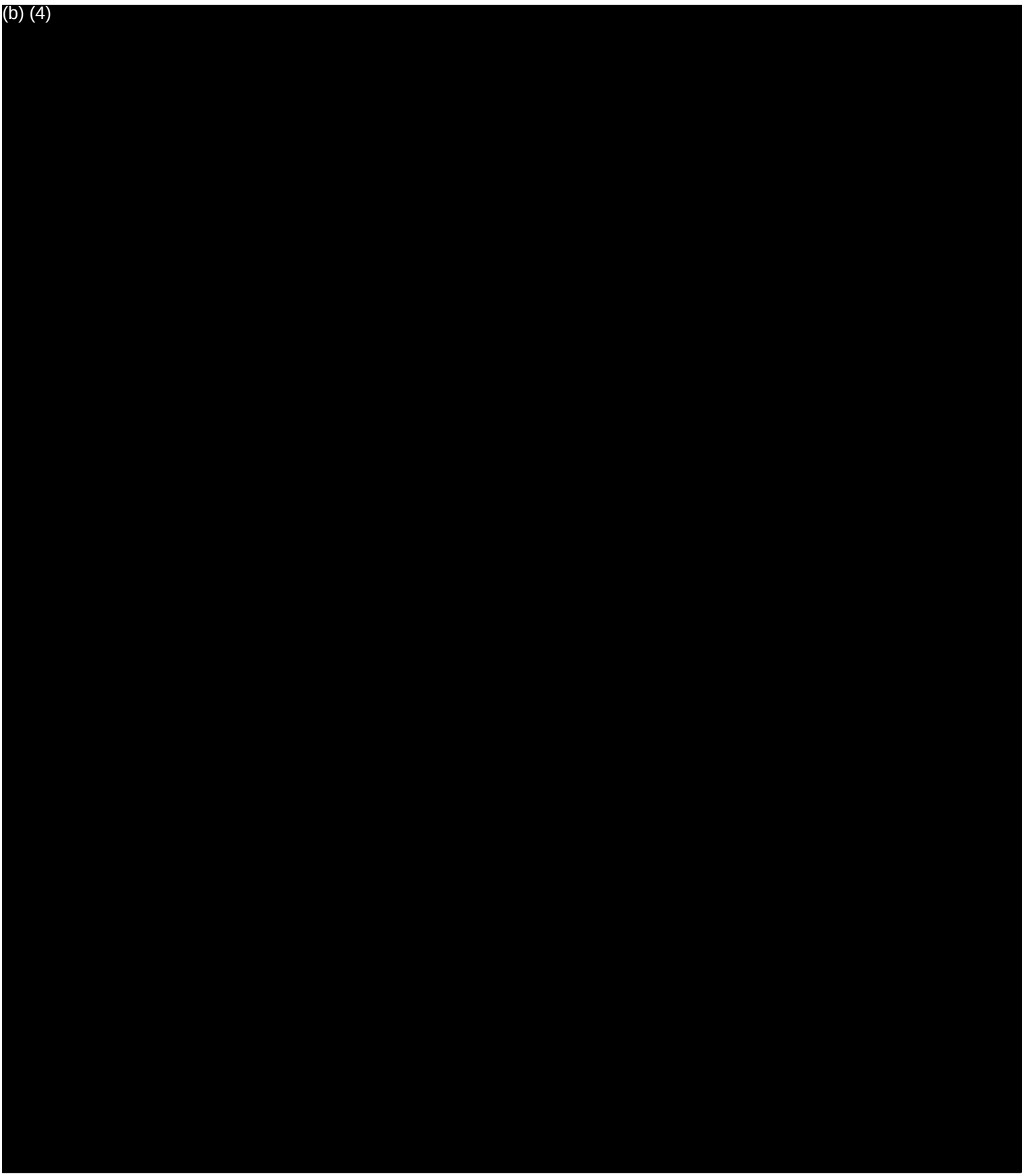

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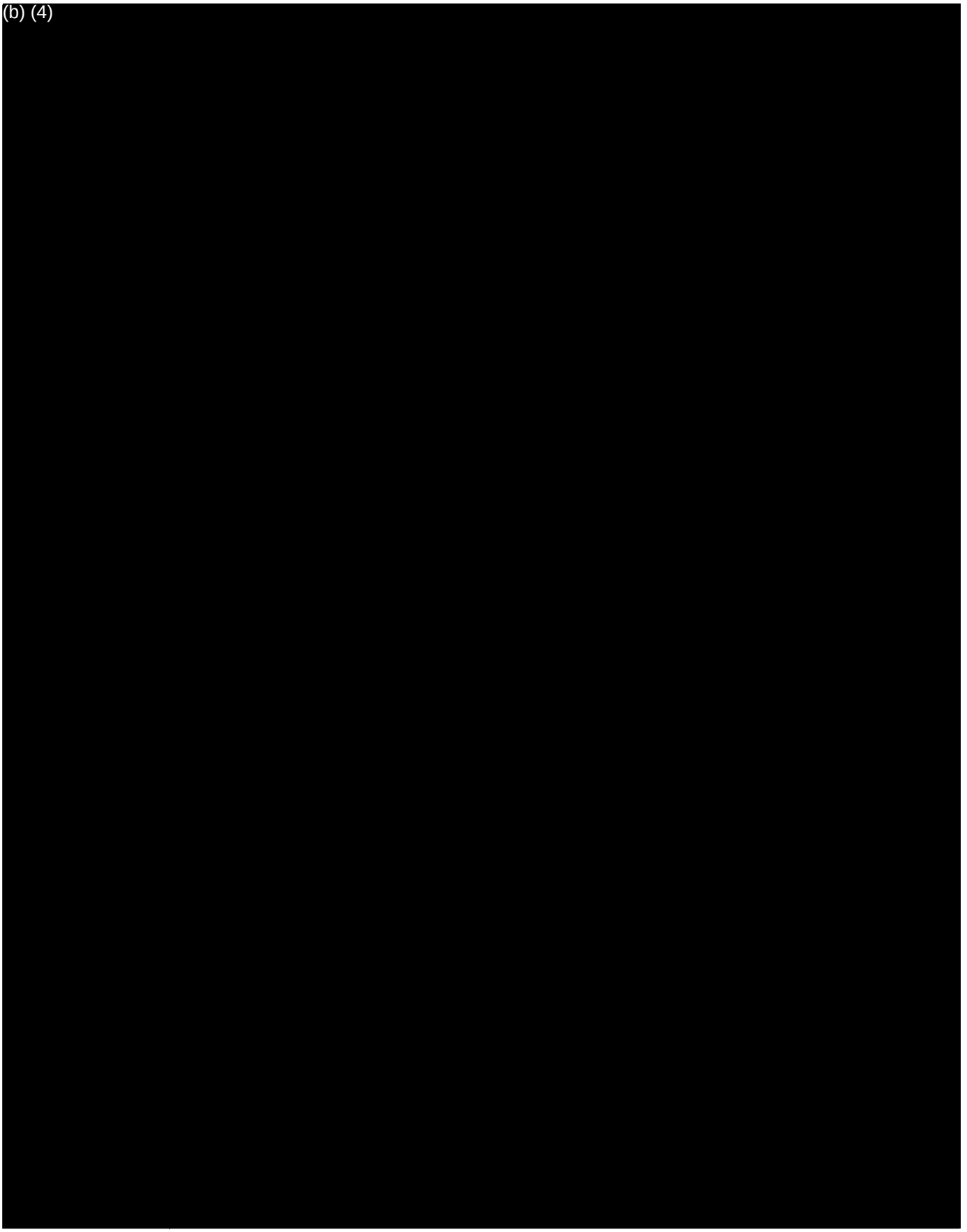
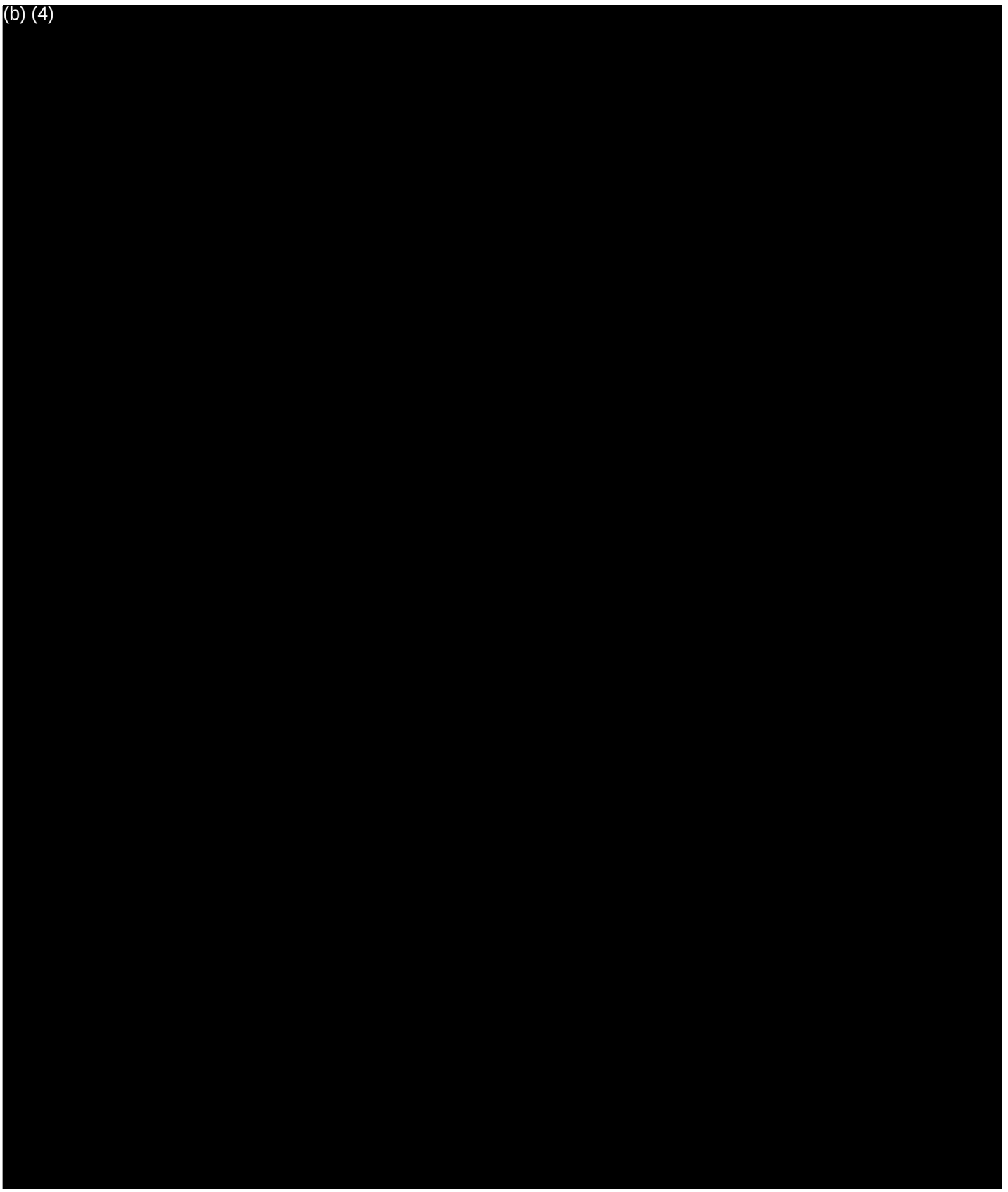


DJA x00556

(b) (4)



DJA x00557

(b) (4)

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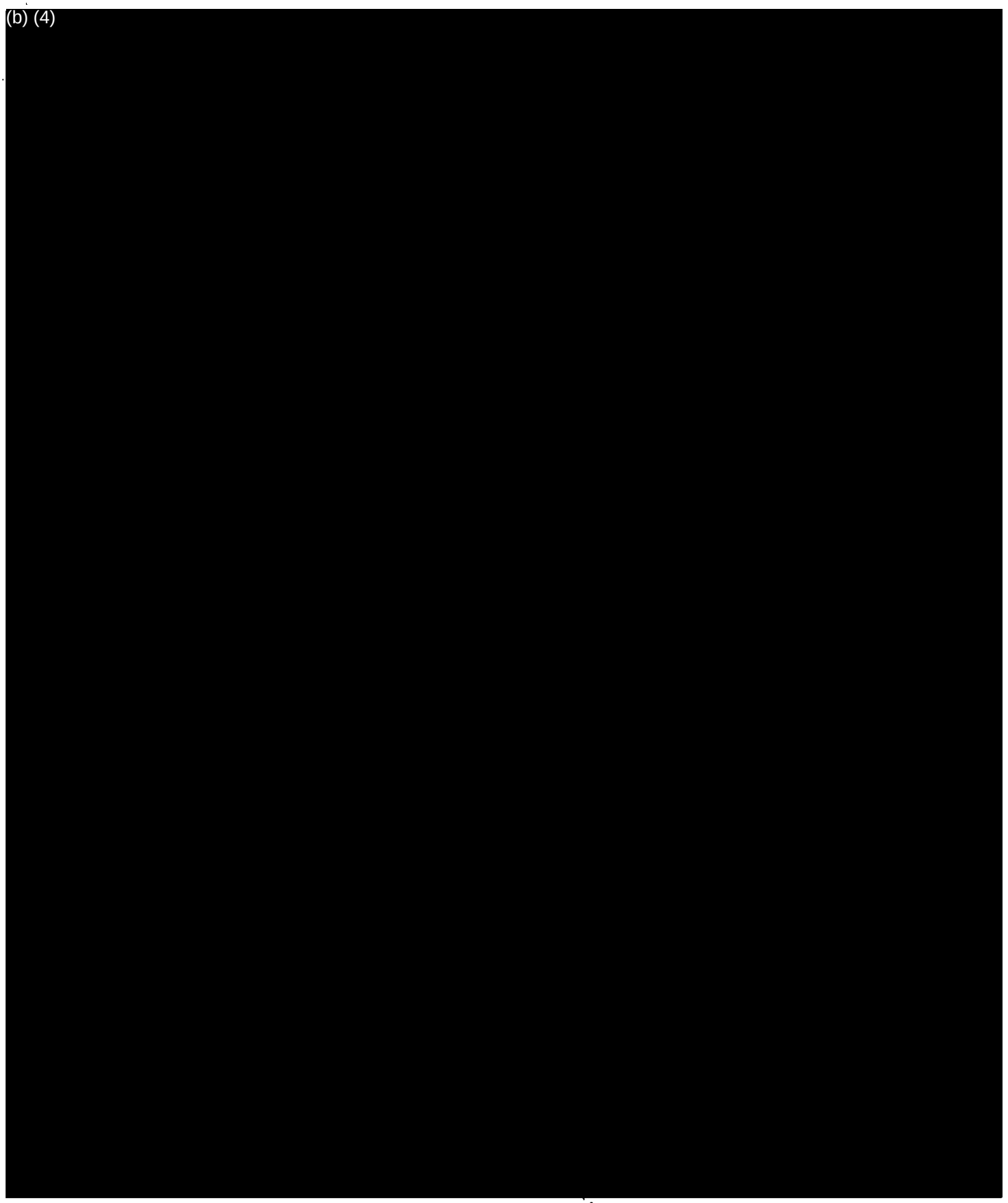
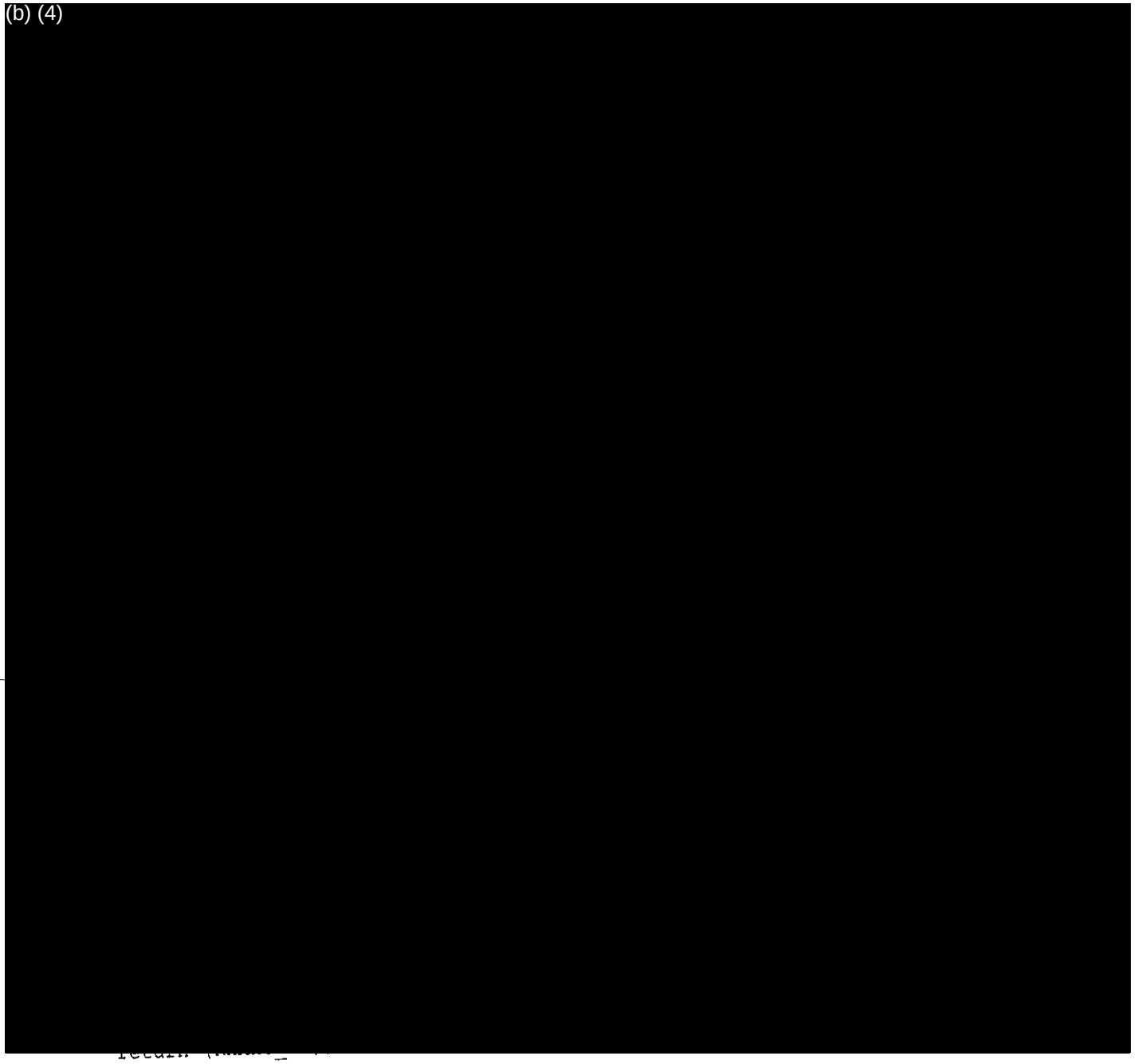
DJA x00558

(b) (4)



DJA x00559

(b) (4)



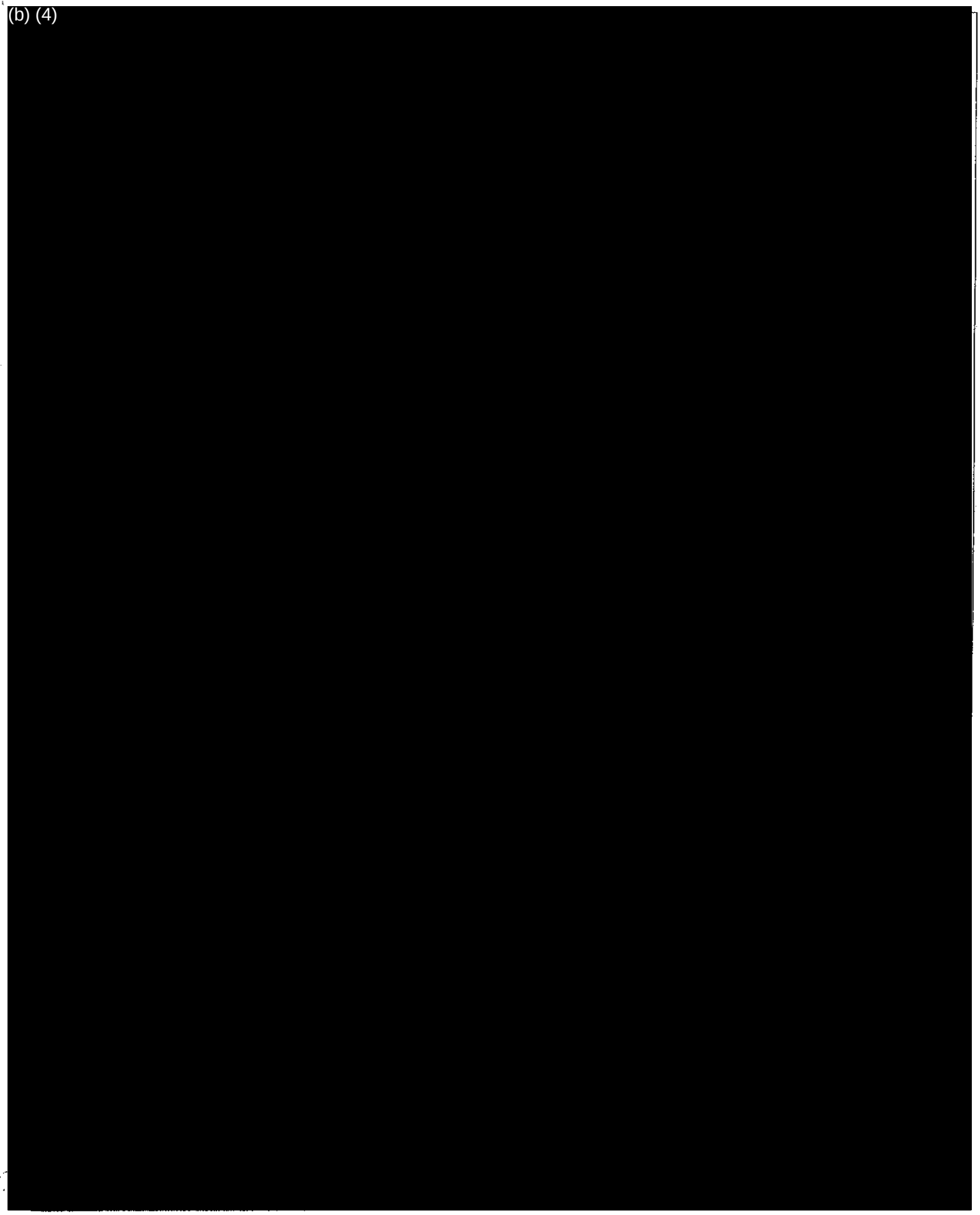
DJA x00560

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

DJA x00561

(b) (4)



DJA x00562

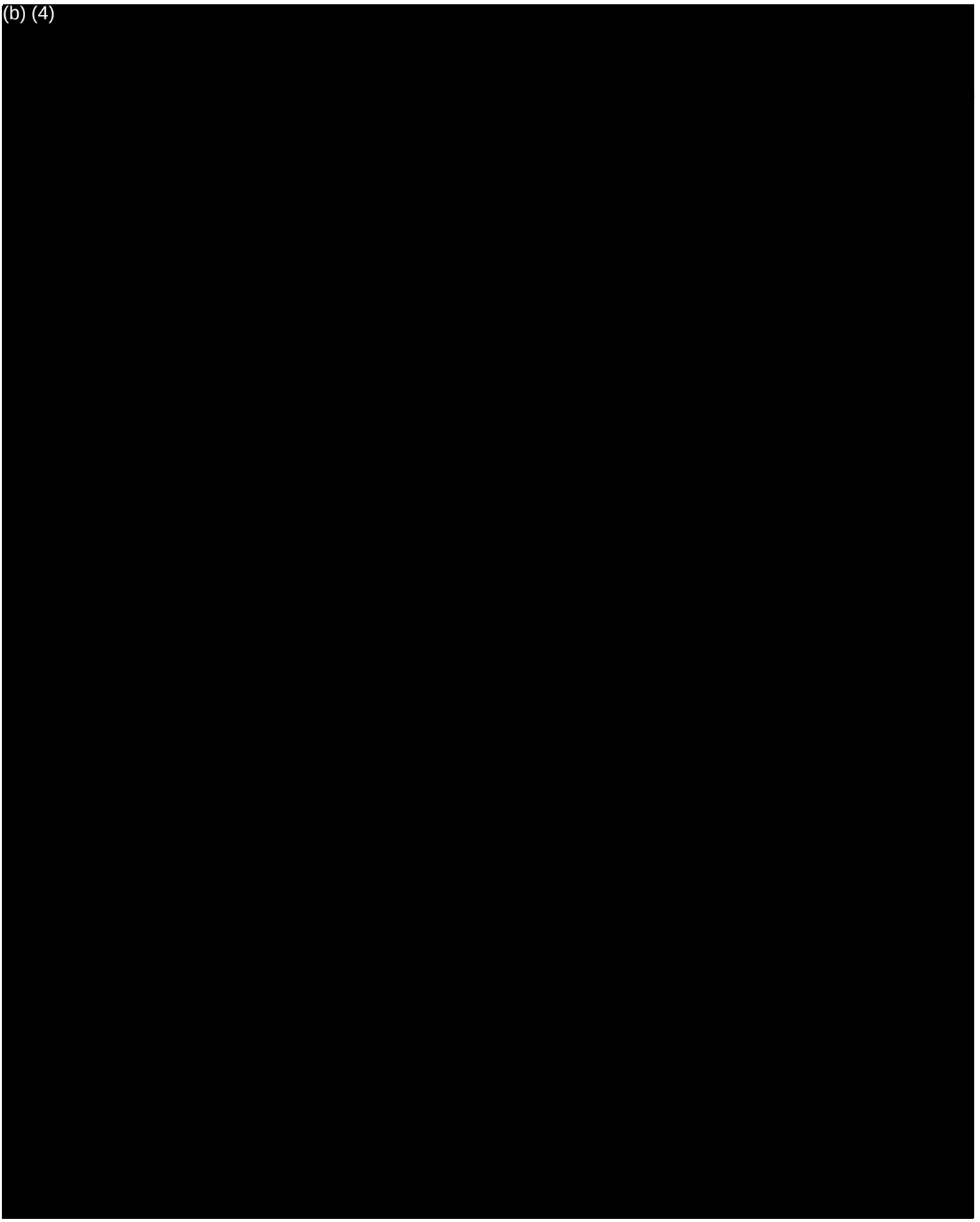
Results (Attach additional sheets if necessary):

(b) (4)

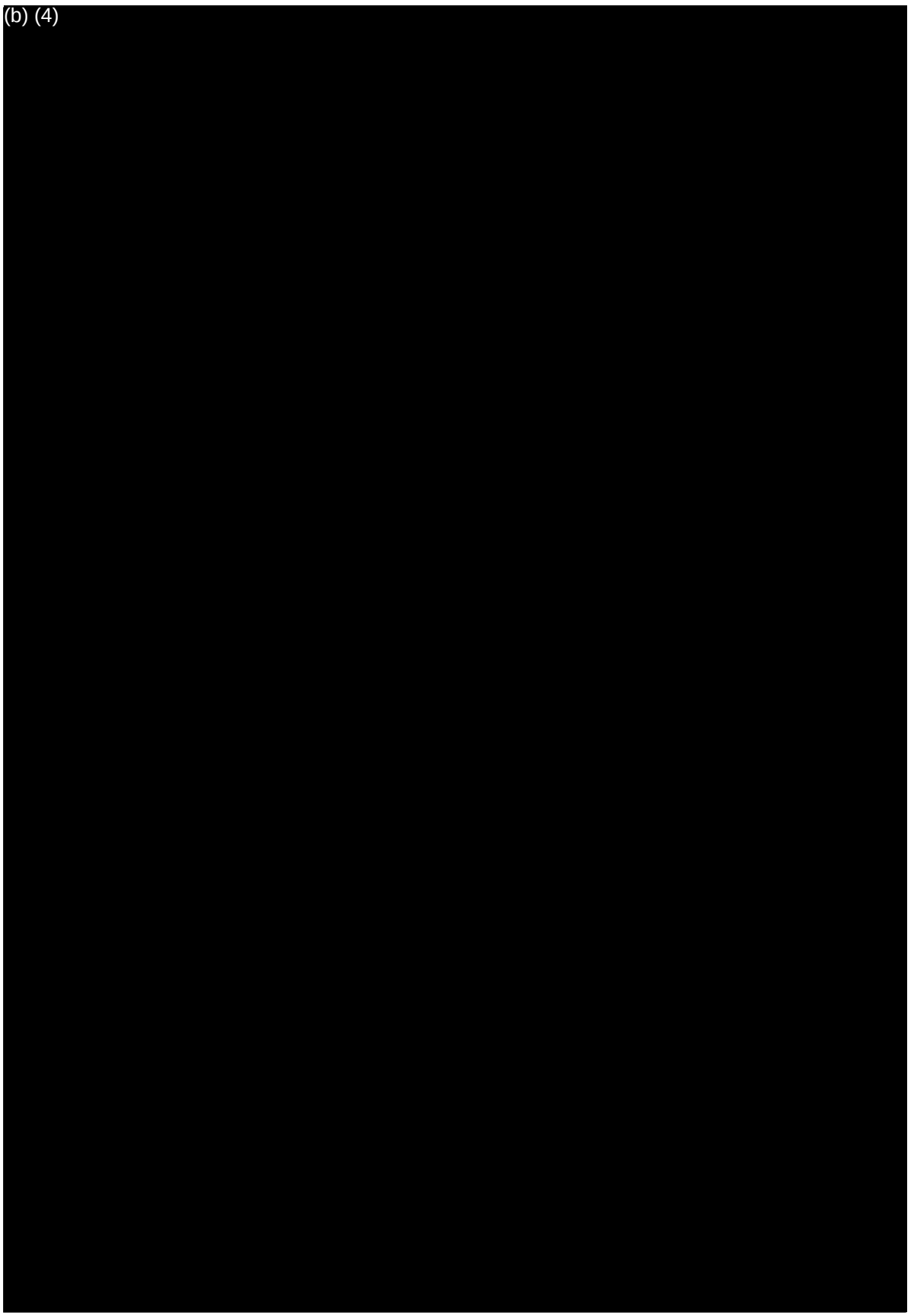
[redacted]

DJA x00563

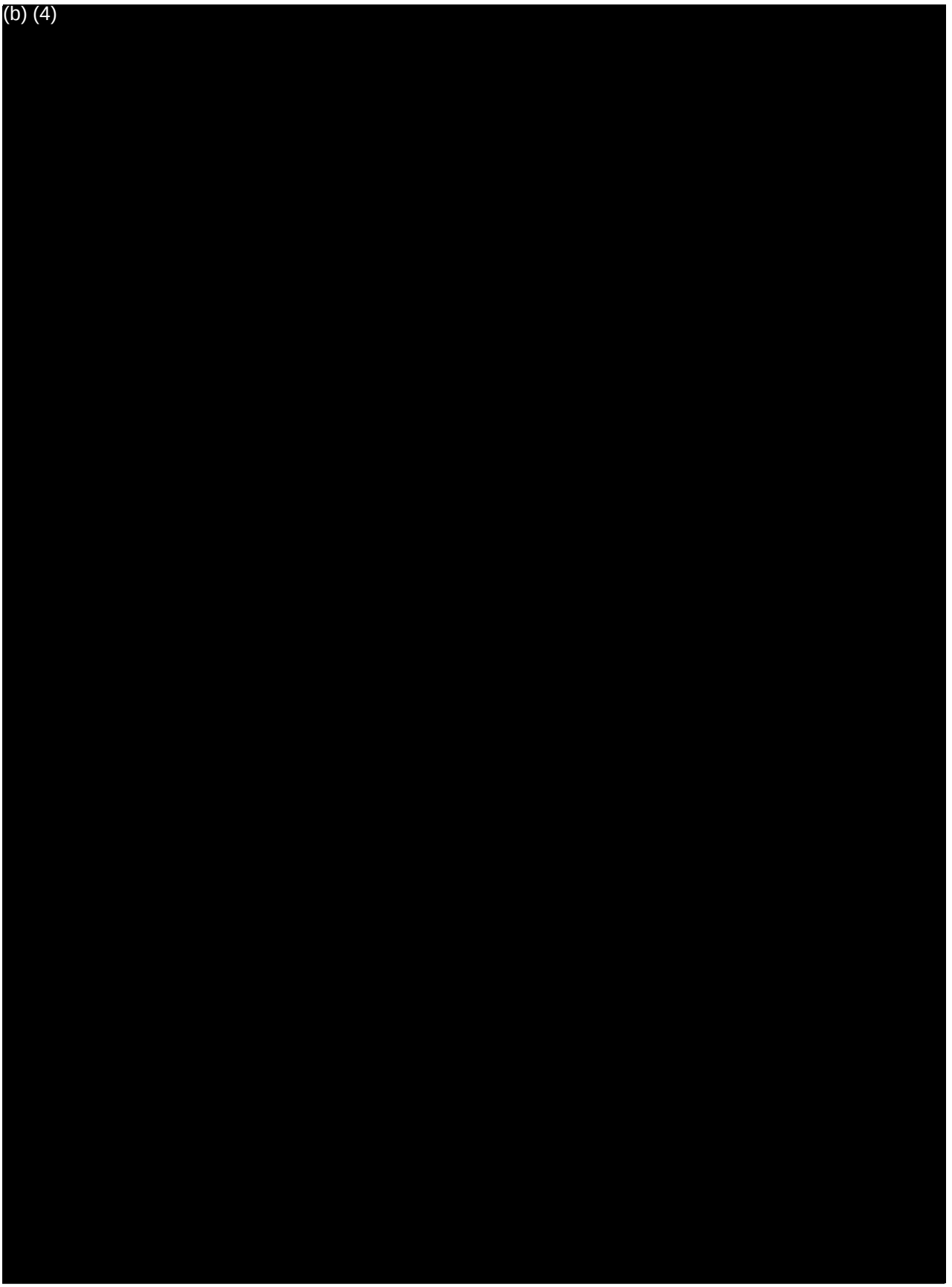
(b) (4)



DJA x00564

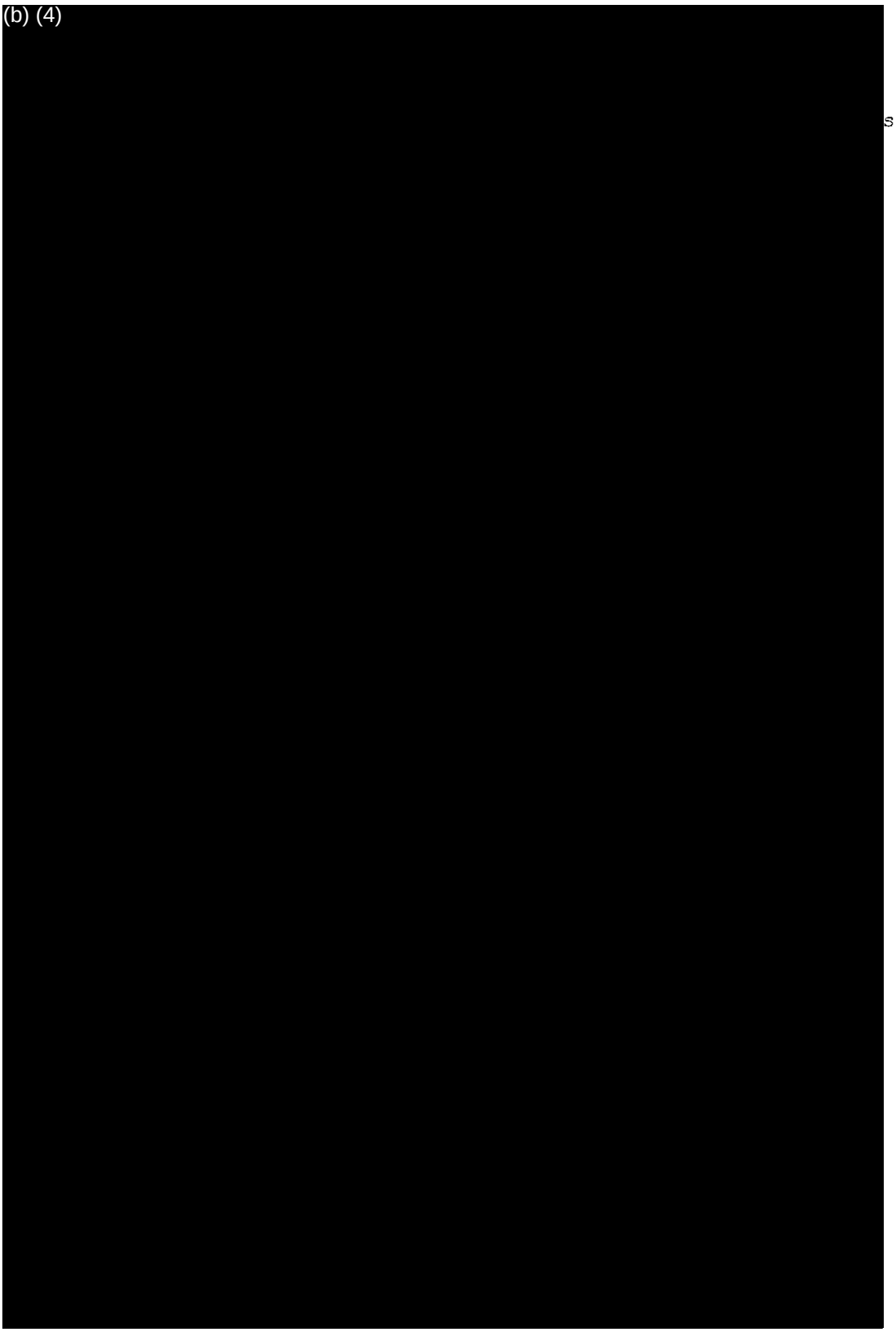


DJA x00565



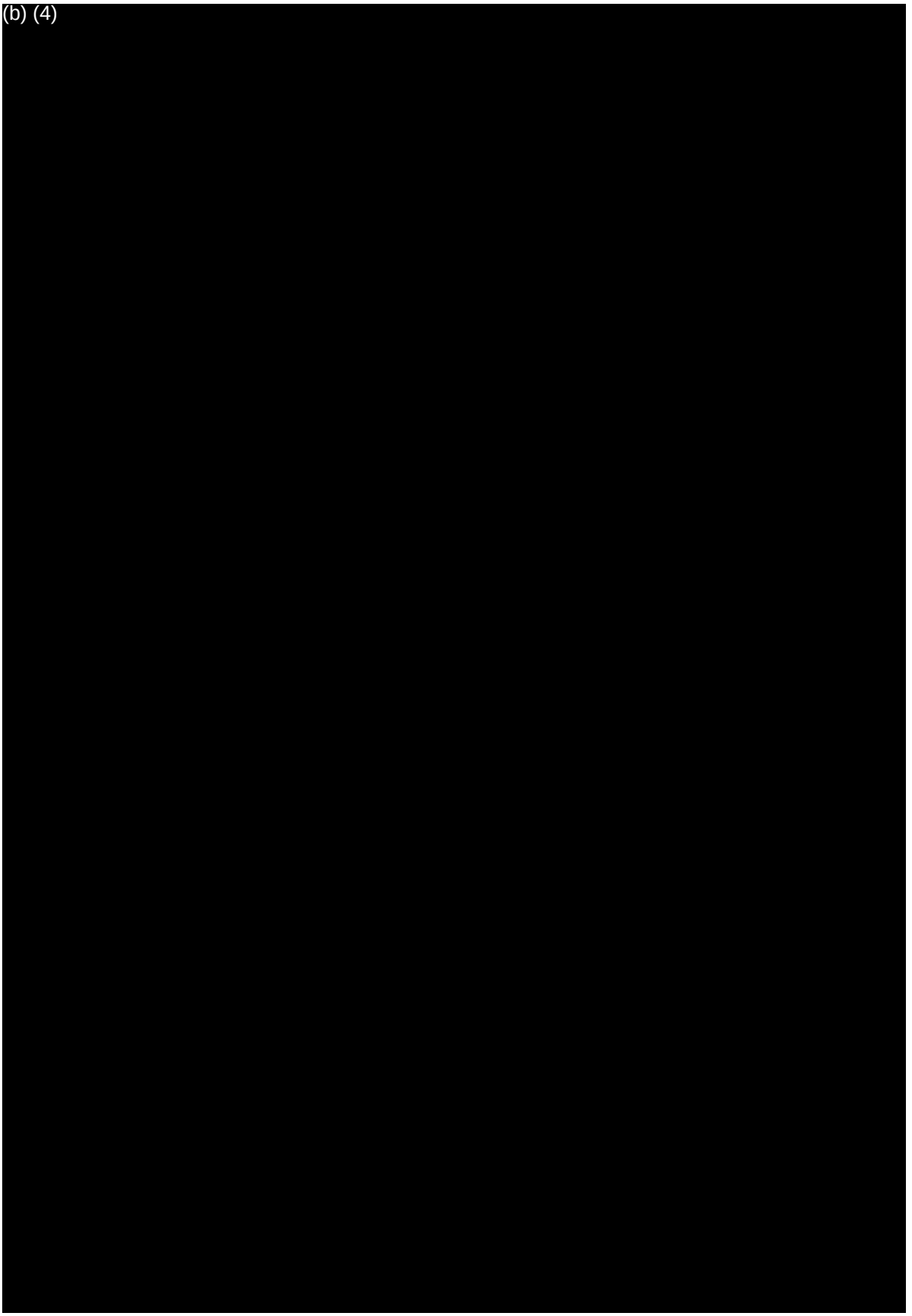
DJA x00566

(b) (4)



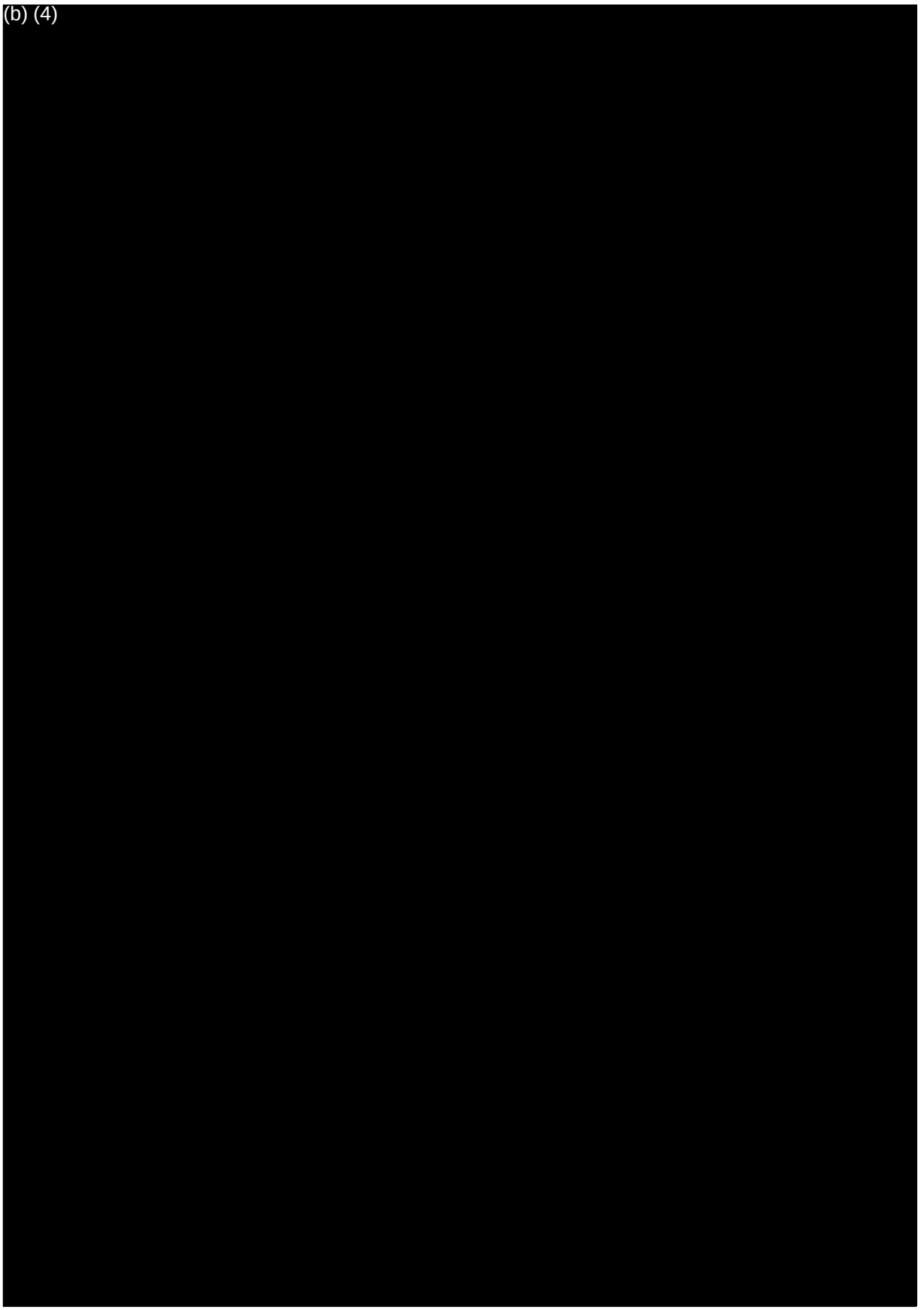
DJA x00567

(b) (4)



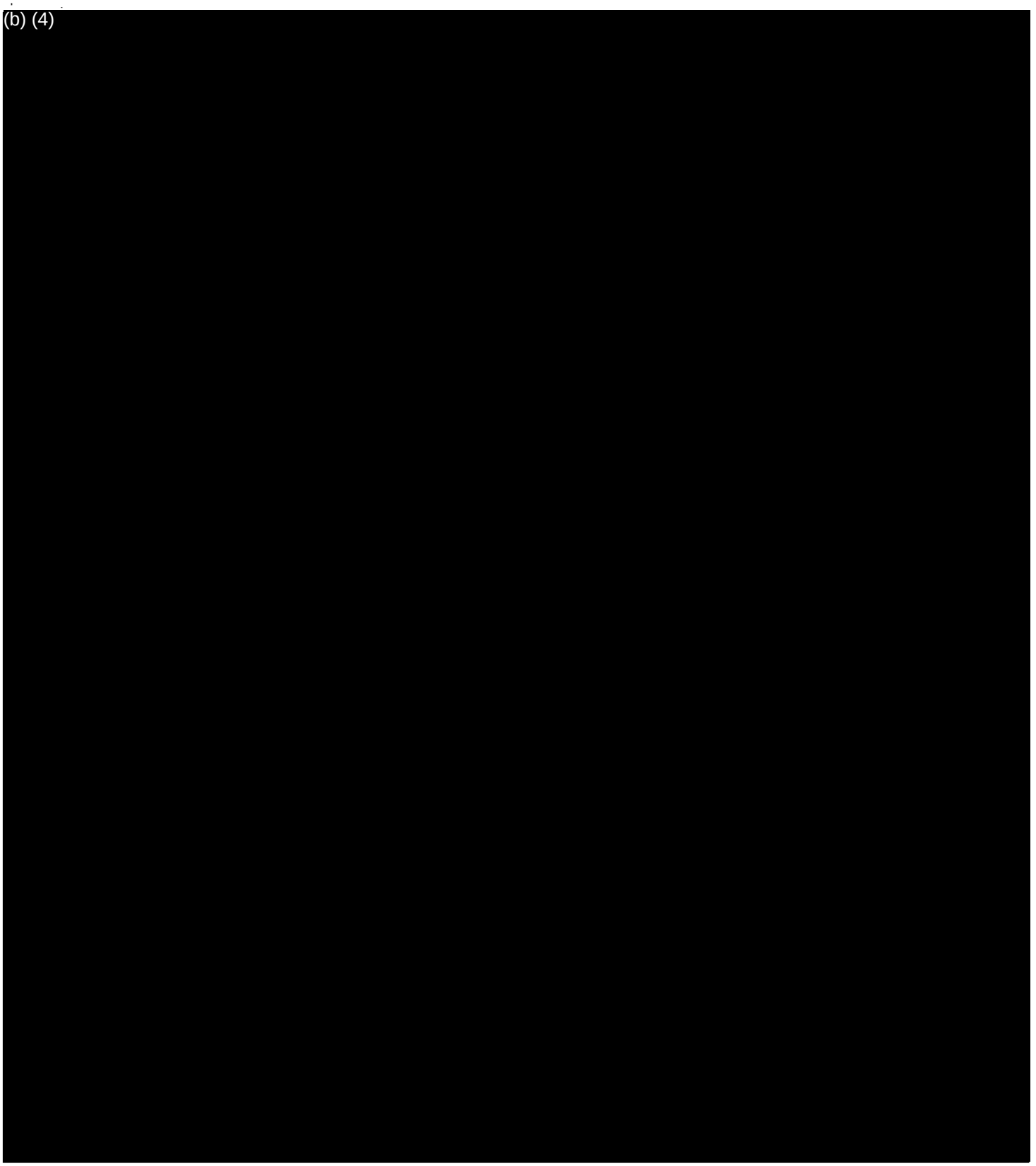
DJA x00568

(b) (4)



DJA x00569

(b) (4)



DJA x00570

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

01/17/08

DJA x00571

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00572

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1565

(b) (4)

DJA x00573

Supervisor's Approval To Execute Study	Date
[signature]	5/13/99

DJA x00574

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

Conclusion:

(b) (4)

[redacted]

DJA x00575

TEST REPORT APPROVAL SHEET

(b) (4)

[redacted]

COPY
qc 01/07/08

DJA X00576

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(b) (4)

[redacted]

DJA X00577

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(b) (4)

[redacted]

DJA x00578

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(b) (4)

[redacted]

DJA x00579

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(b) (4)

DJA x005801

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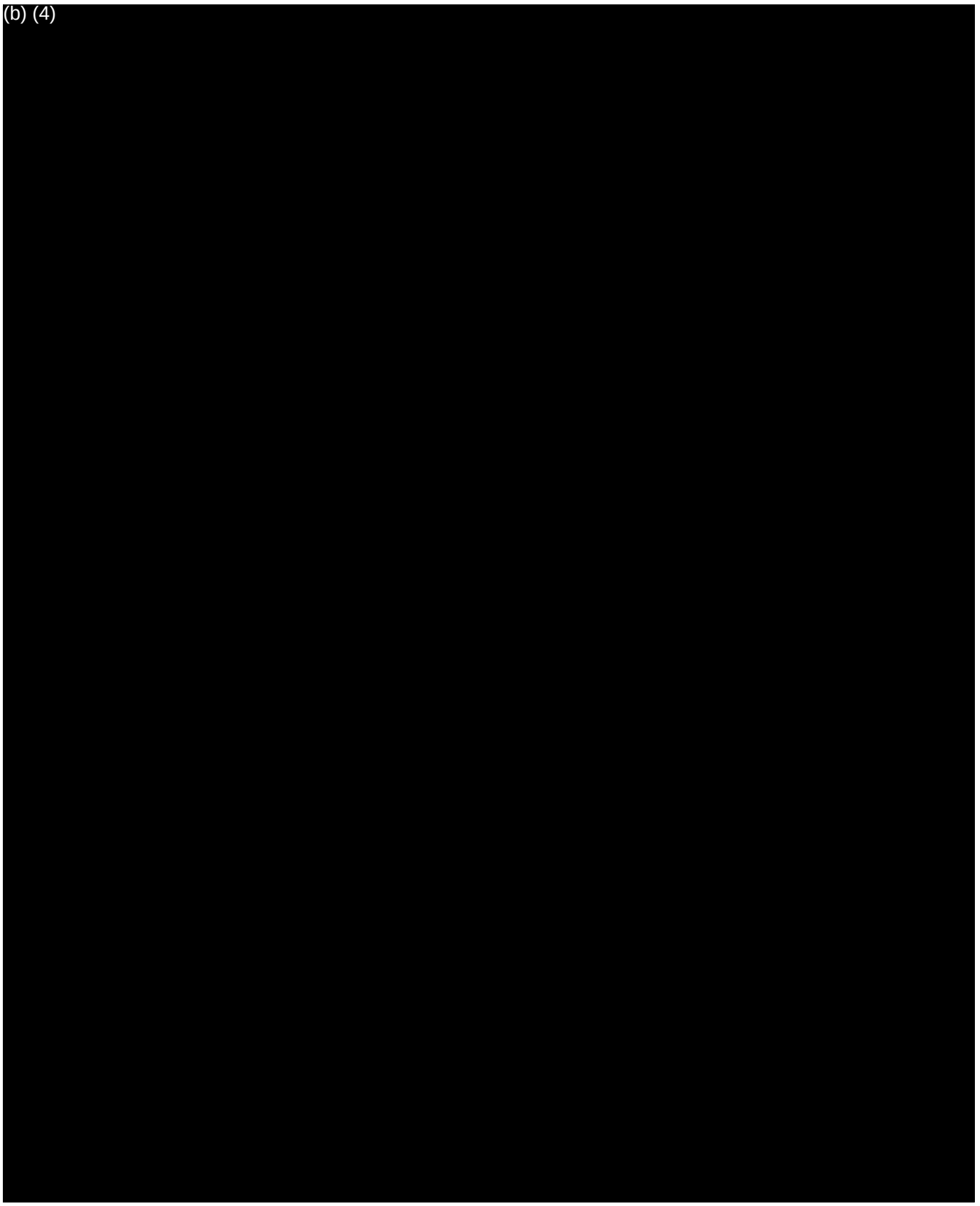
(b) (4)



DJA x00581

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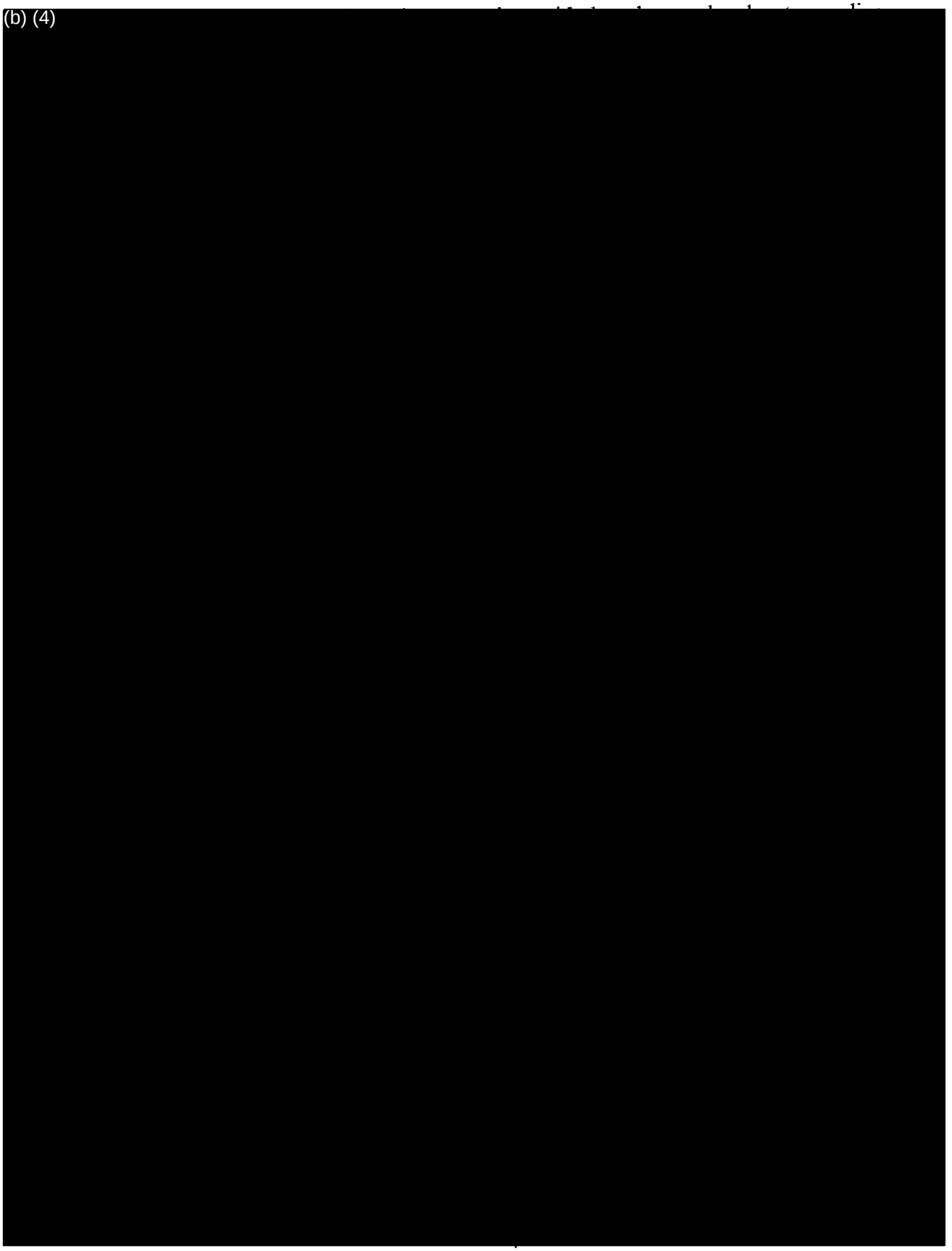
(b) (4)



DJA x00582

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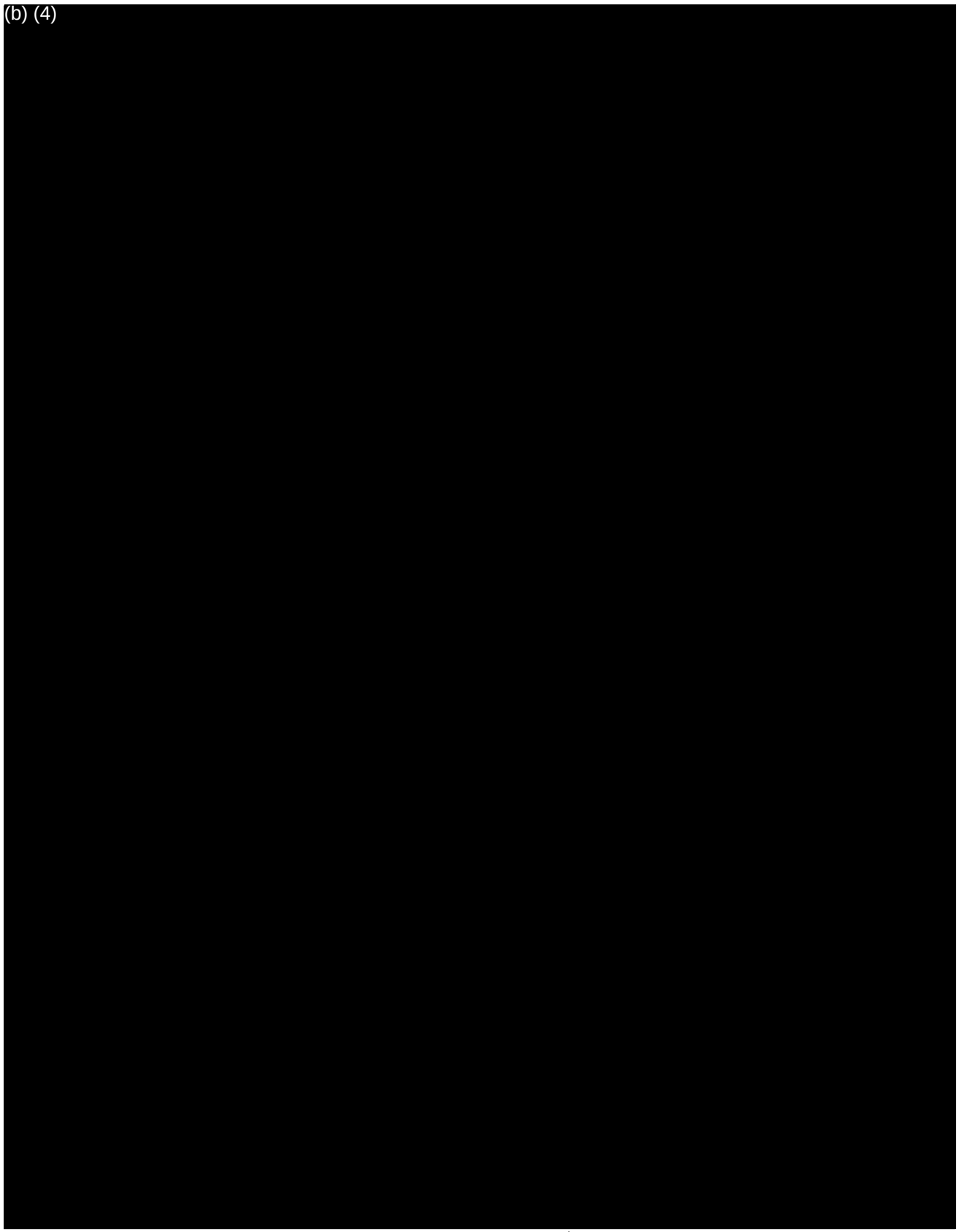
(b) (4)



DJA x00583

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(b) (4)

DJA x00584

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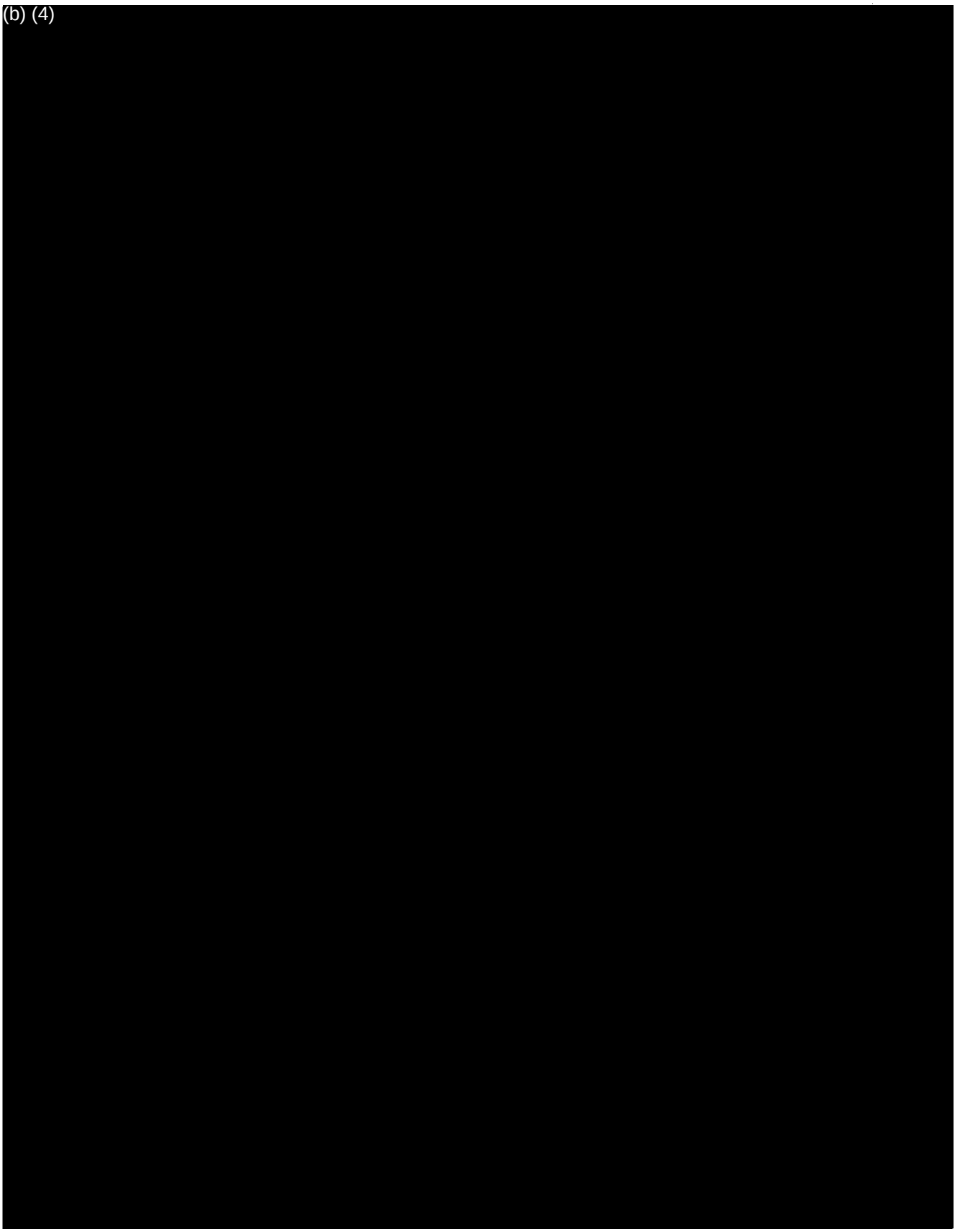
(b) (4)



DJA x00585

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(b) (4)

[redacted]

DJA x00586

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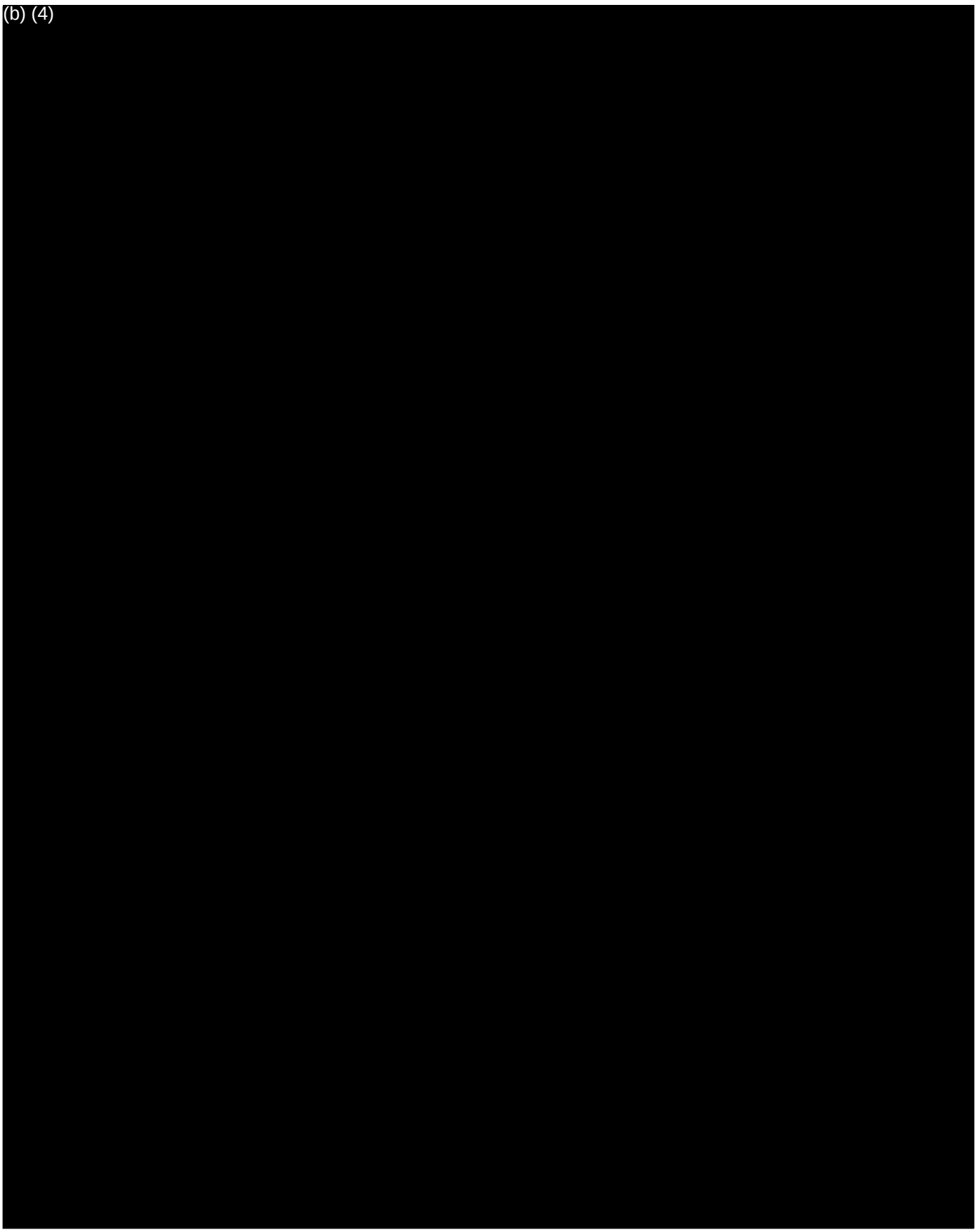
(b) (4)



DJA X00587

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(b) (4)

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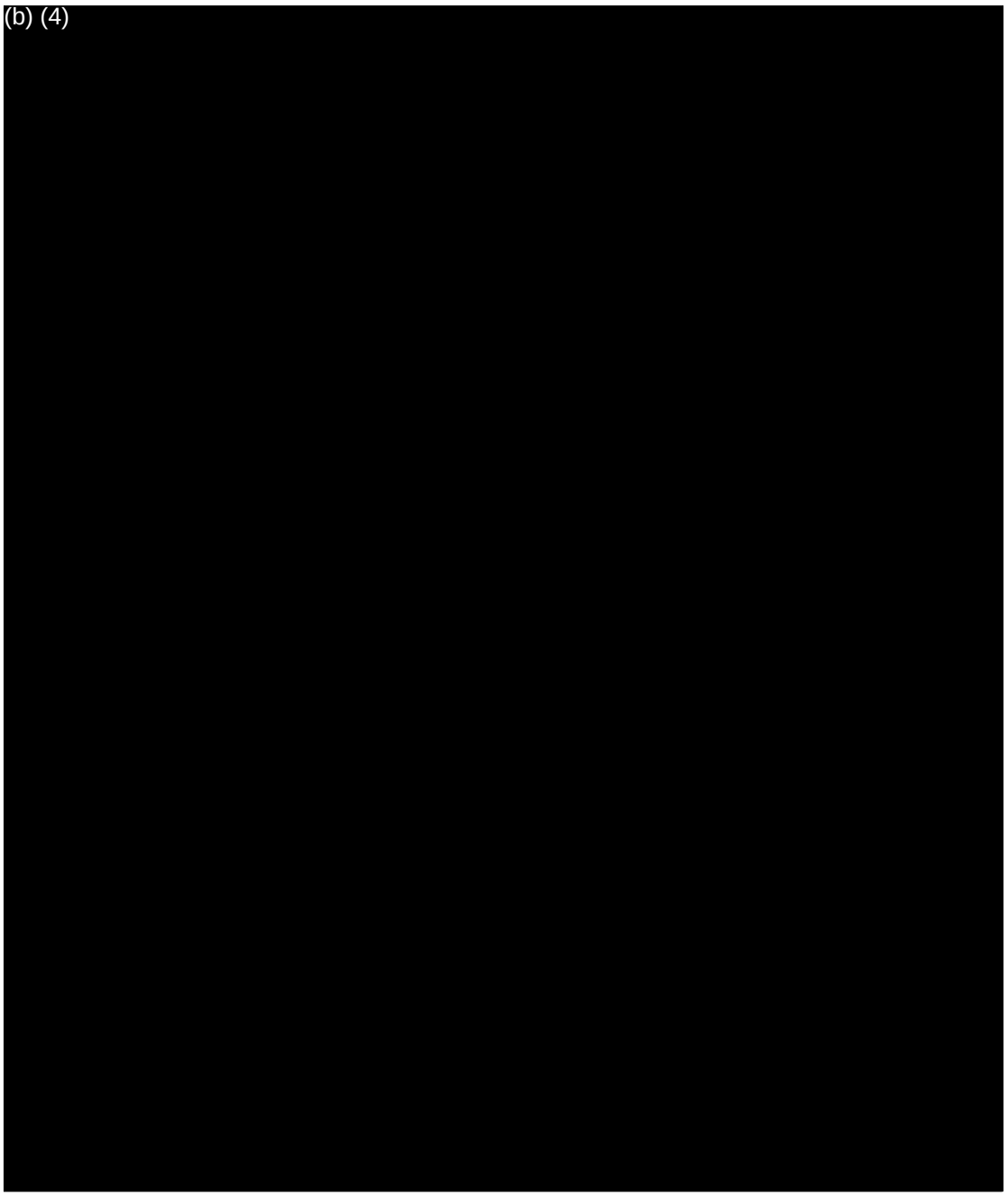
DJA x00588

ATTACHMENT 15.1:

(b) (4)



DJA x005889

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(b) (4)

DJA x00590

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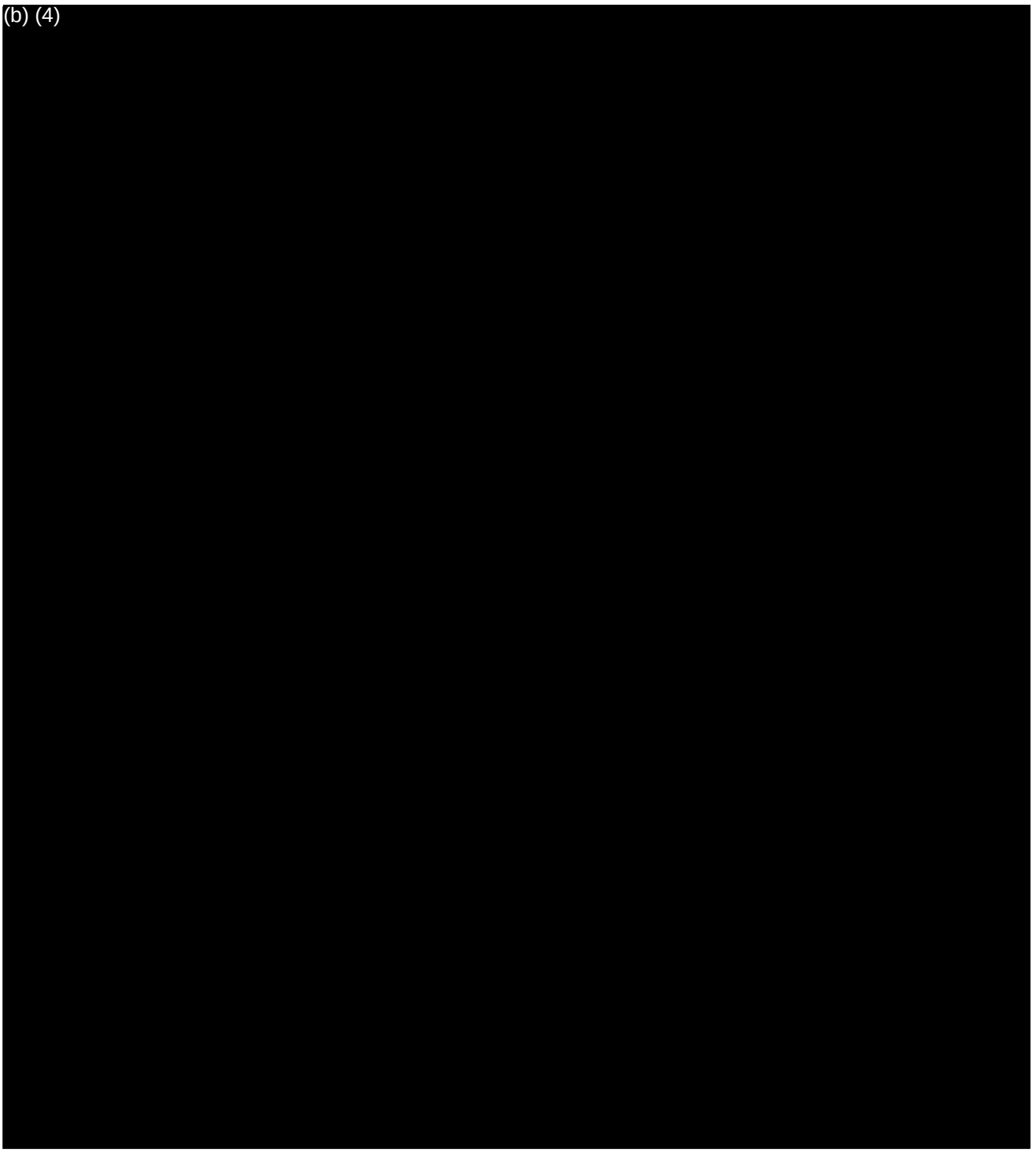
(b) (4)



DJA x00591

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ATTACHMENT 15.3:

(b) (4)

DJA x00592

PROTOCOL APPROVAL SHEET

(b) (4)

[redacted]

DJA x00593

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(b) (4) : Protocol for Verification of Implant Cut File data

(b) (4)

DJA x00594

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(b) (4)

(b) (4)

DJA x00595

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(b) (4)

[redacted]

DJA x00596

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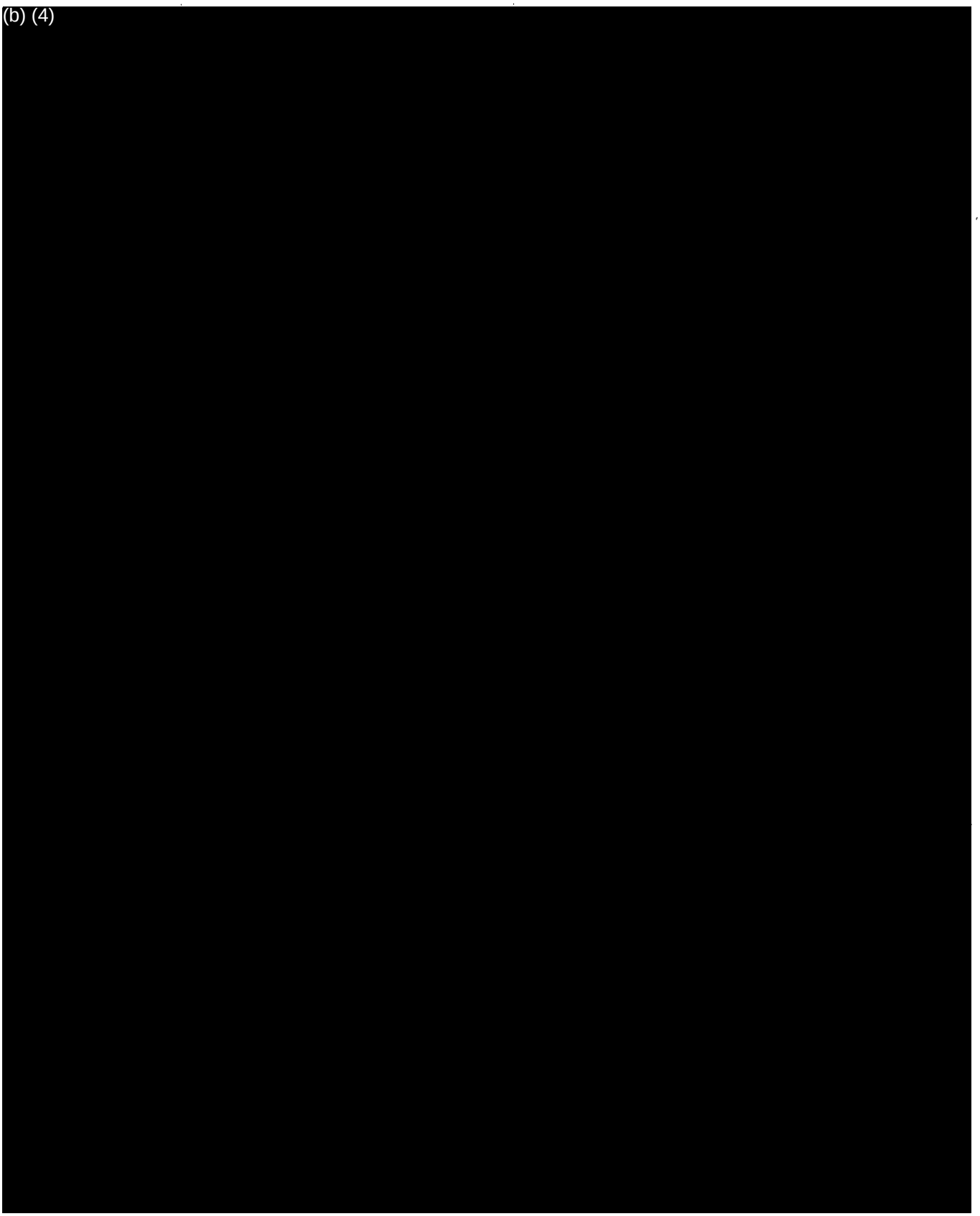
(b) (4)



DJA X00597

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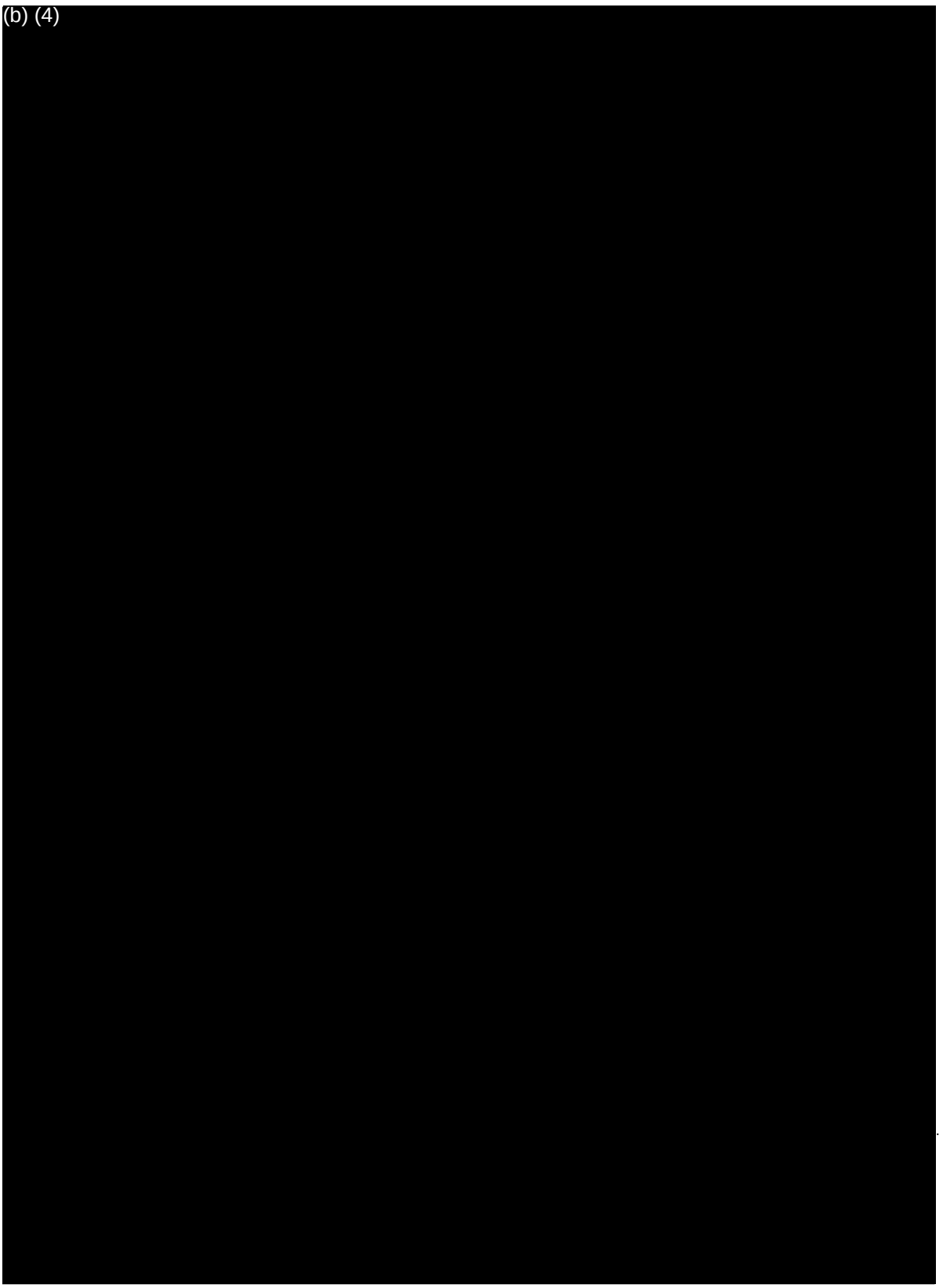

DJA x00598

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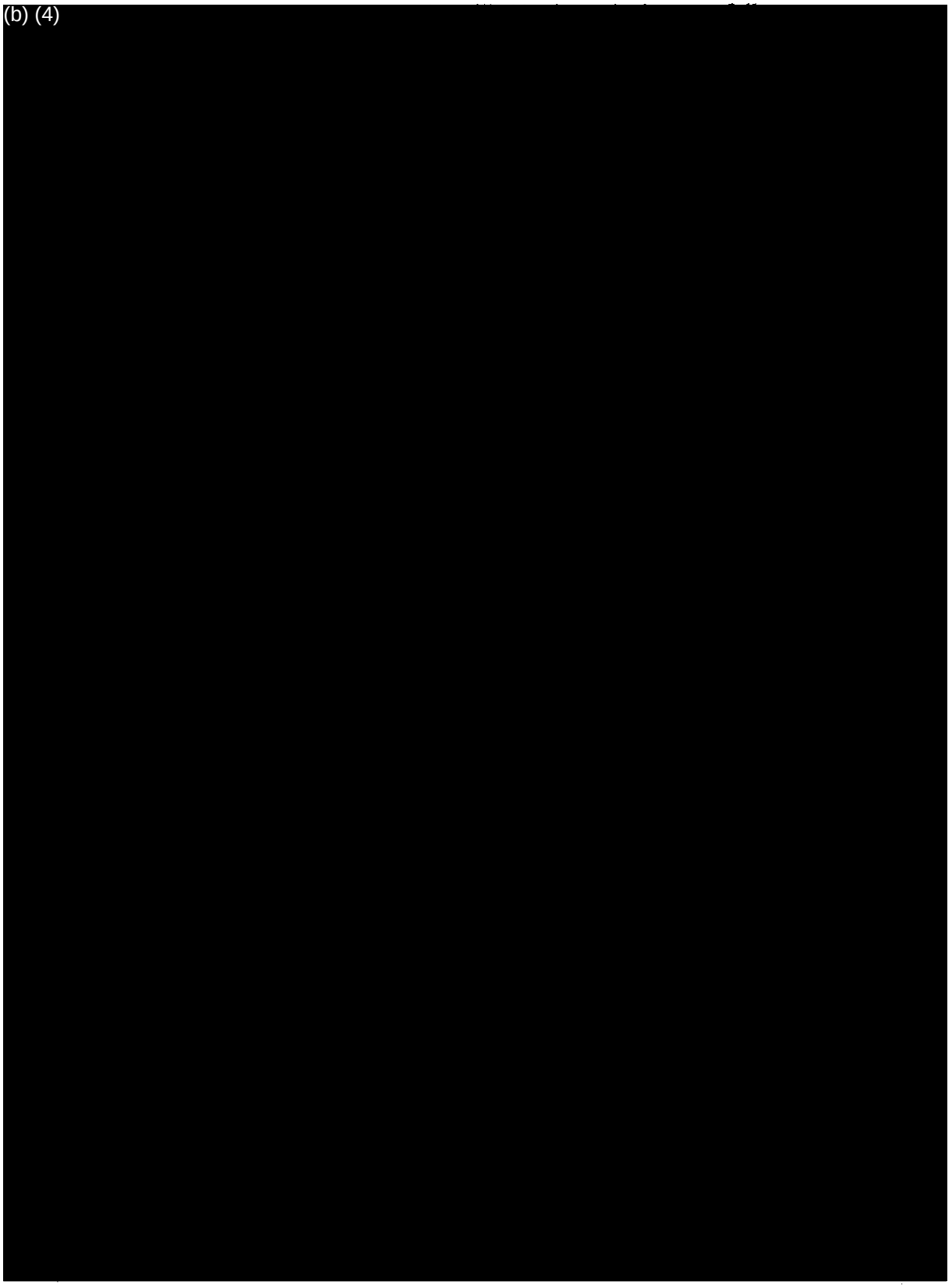

DJA x00599

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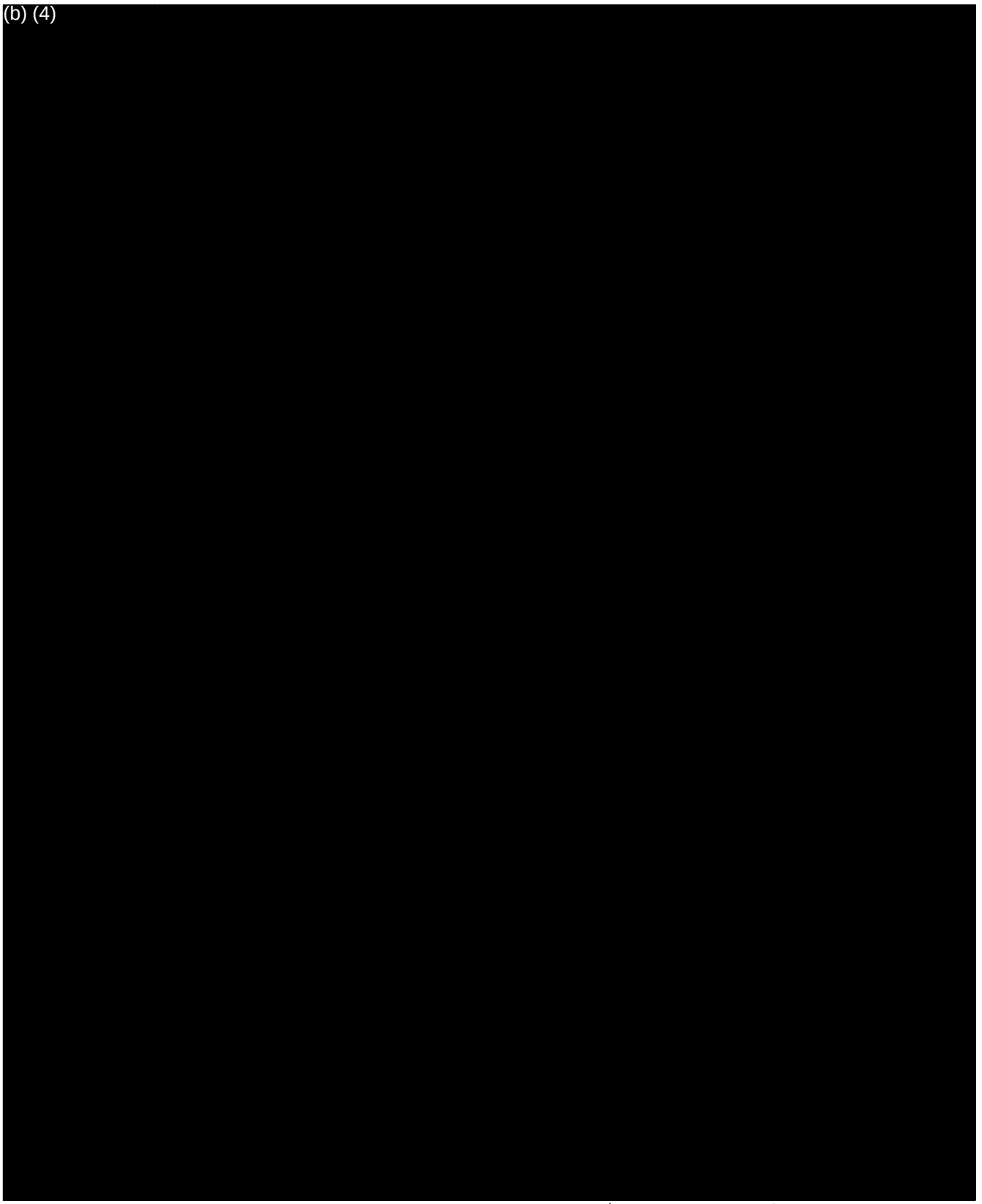

DJA x00600

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11.0 Attachments:

None

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DJA x00602

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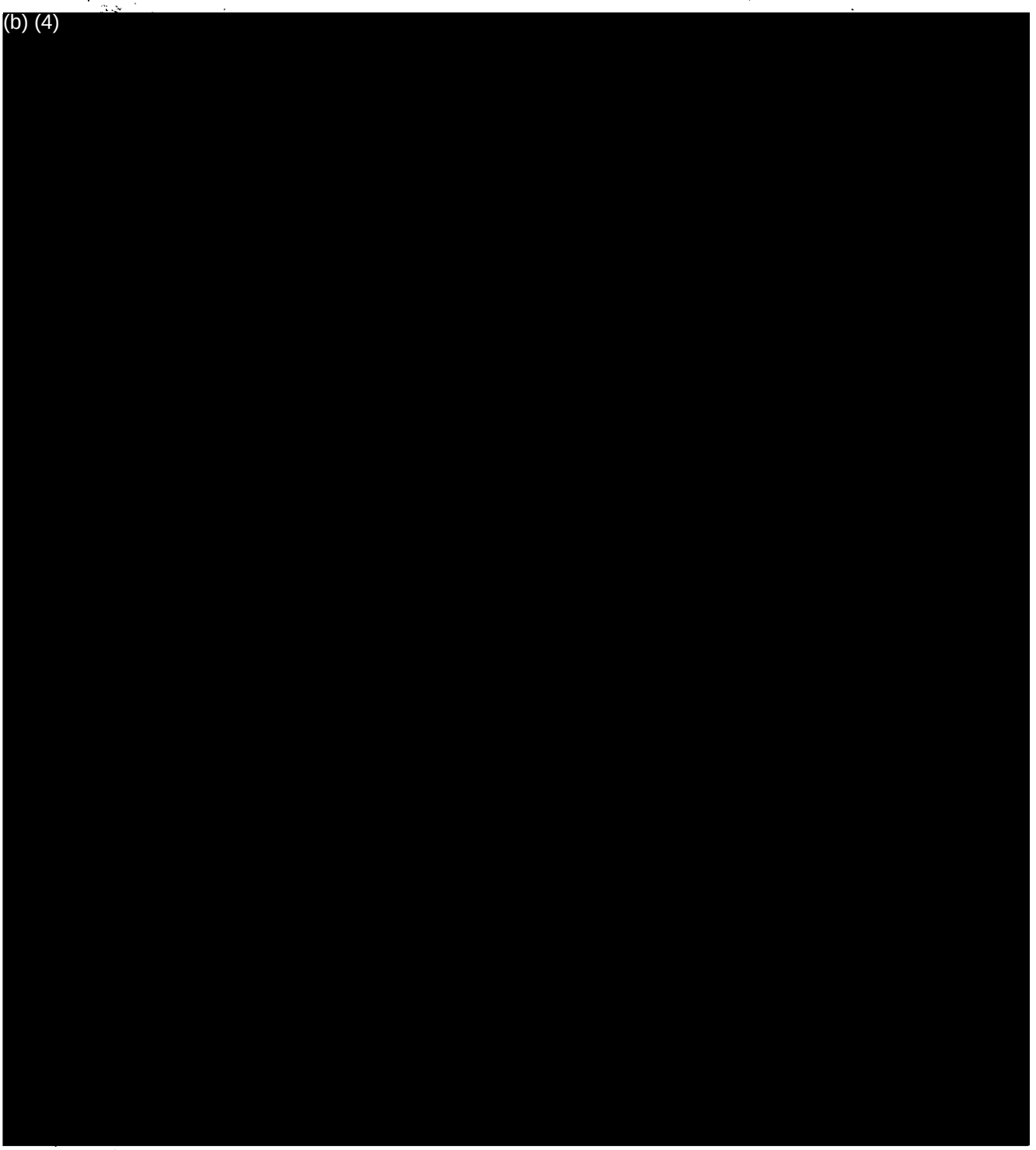

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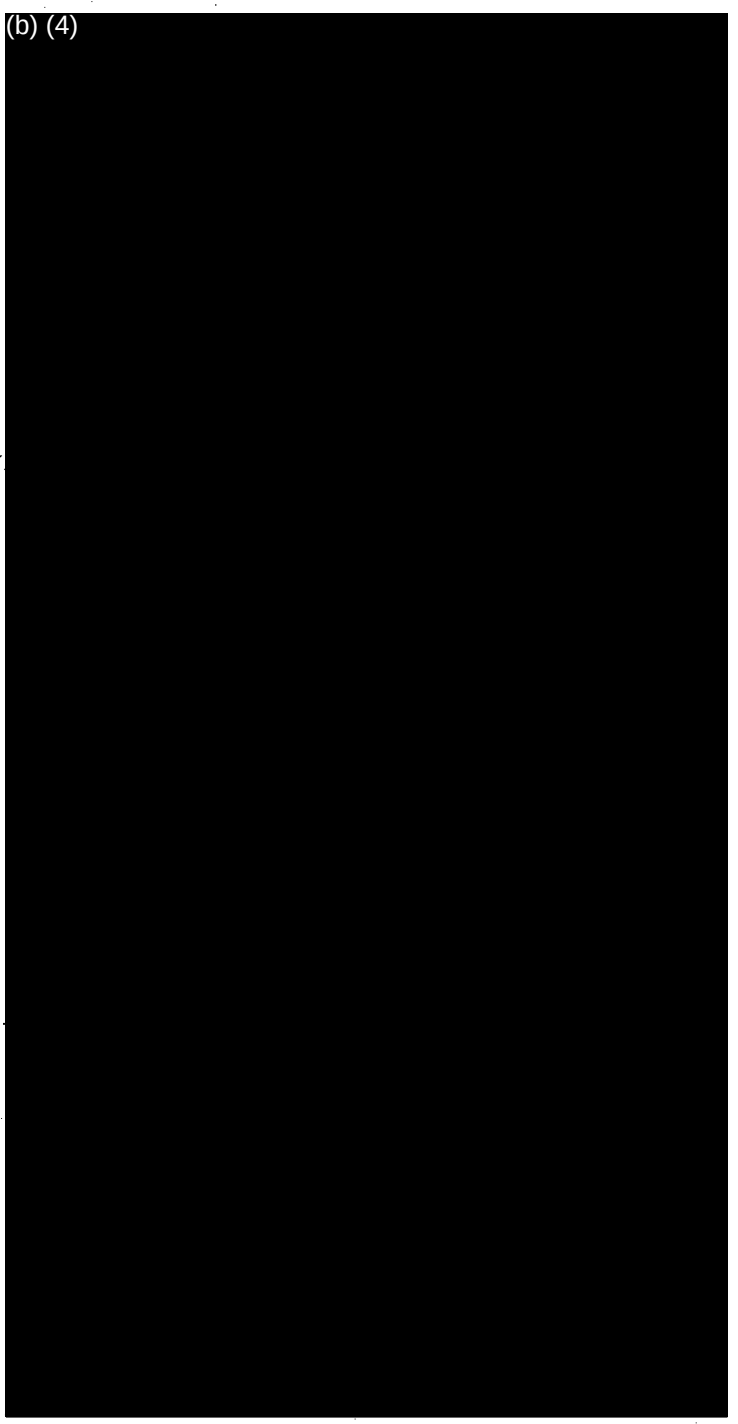

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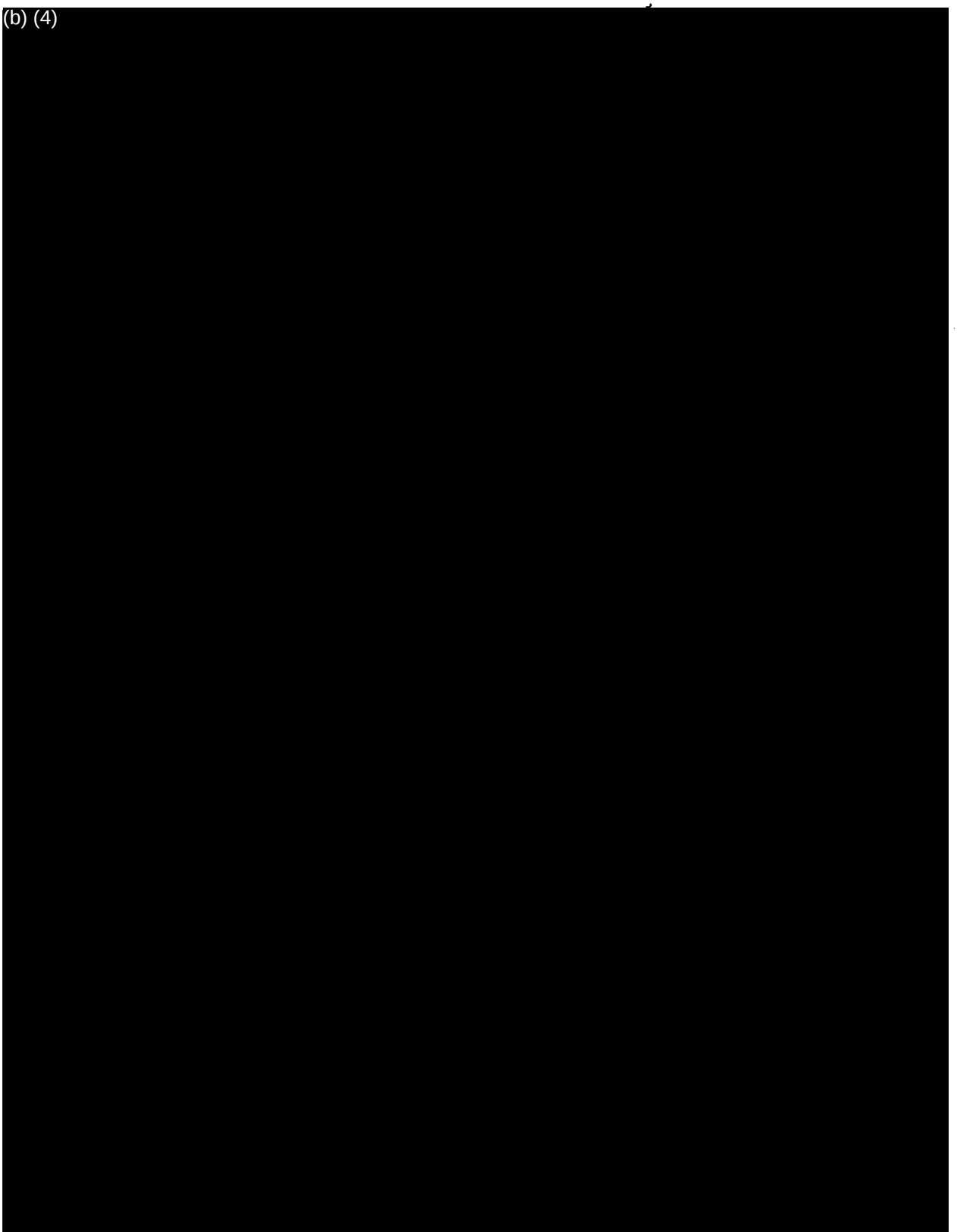

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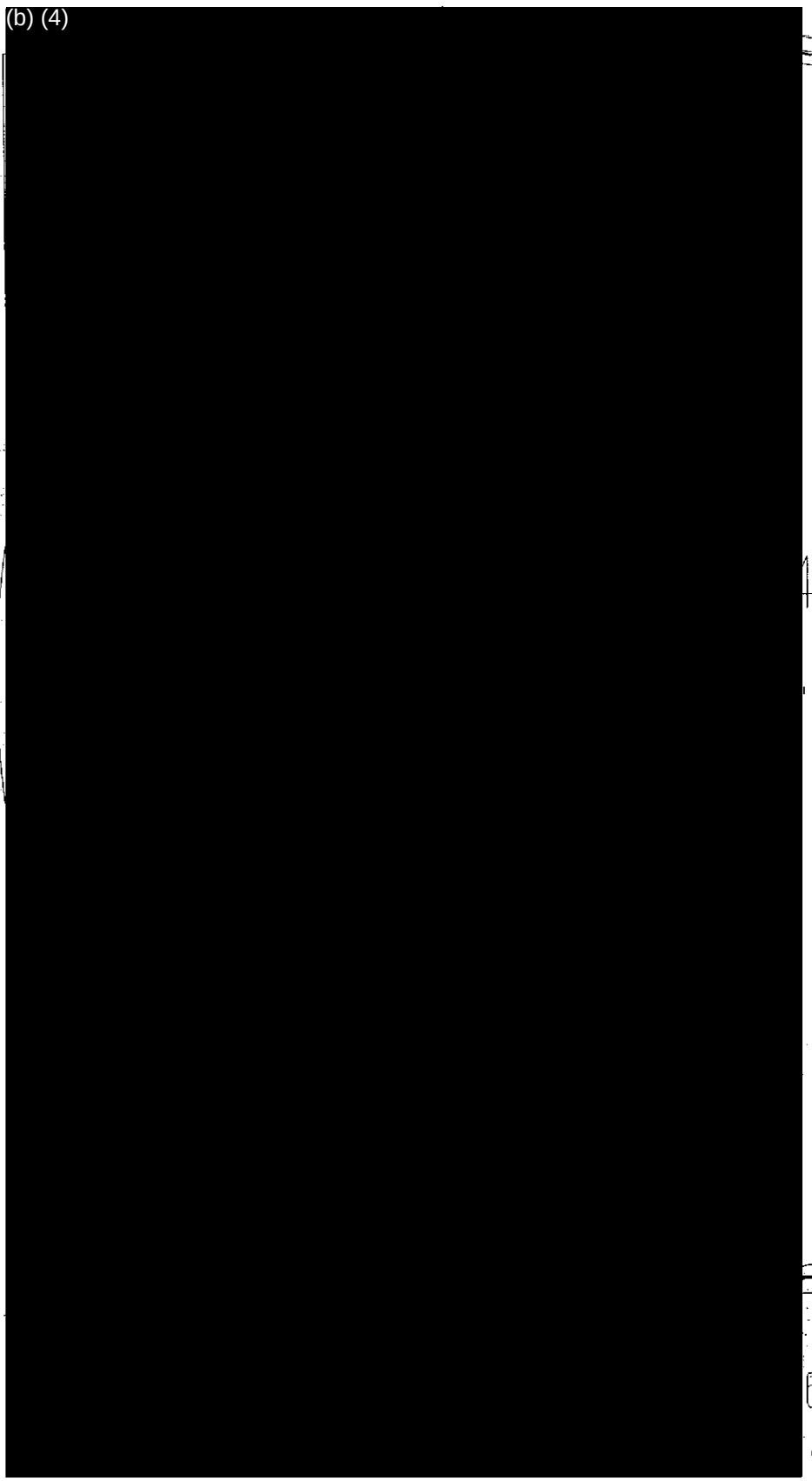

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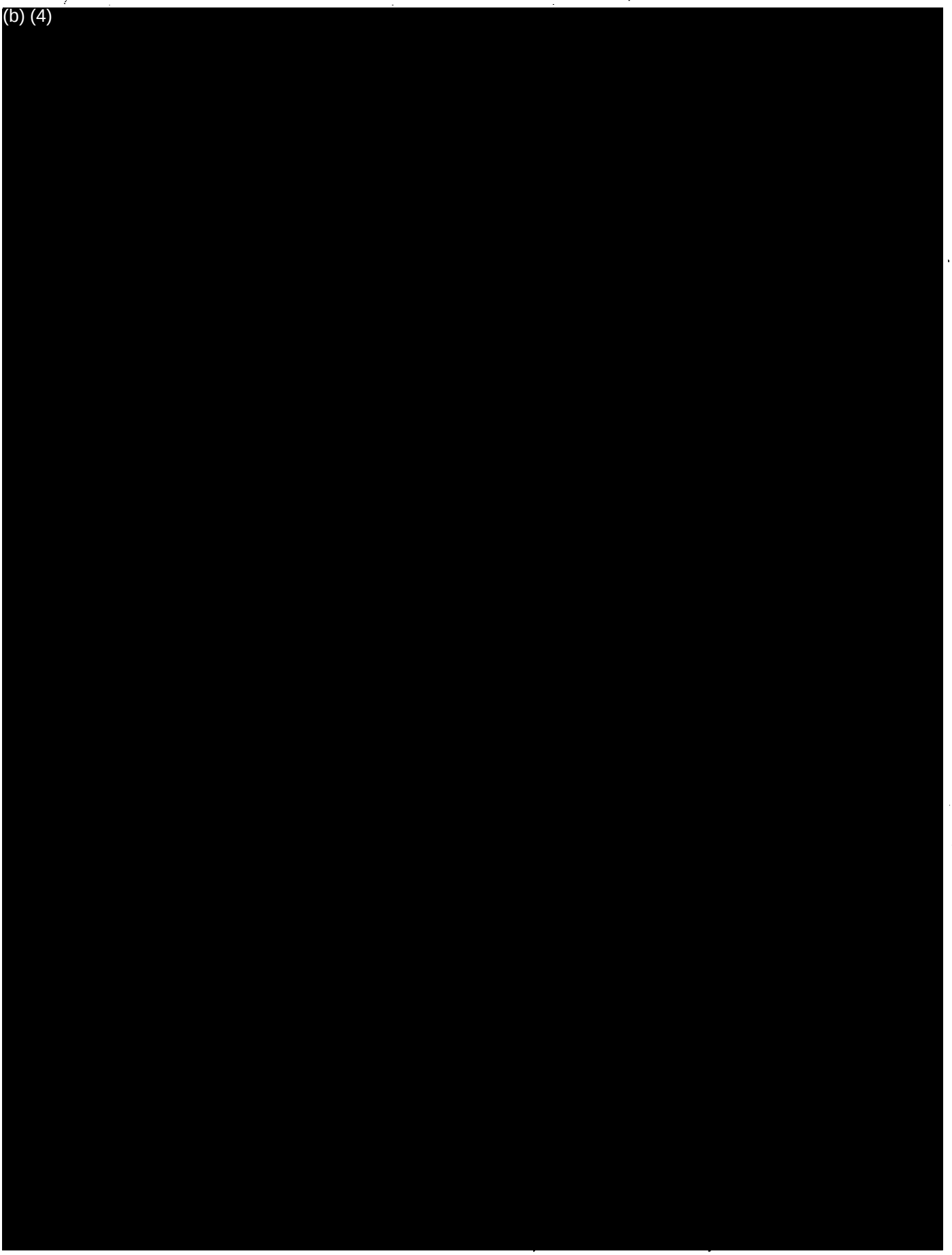

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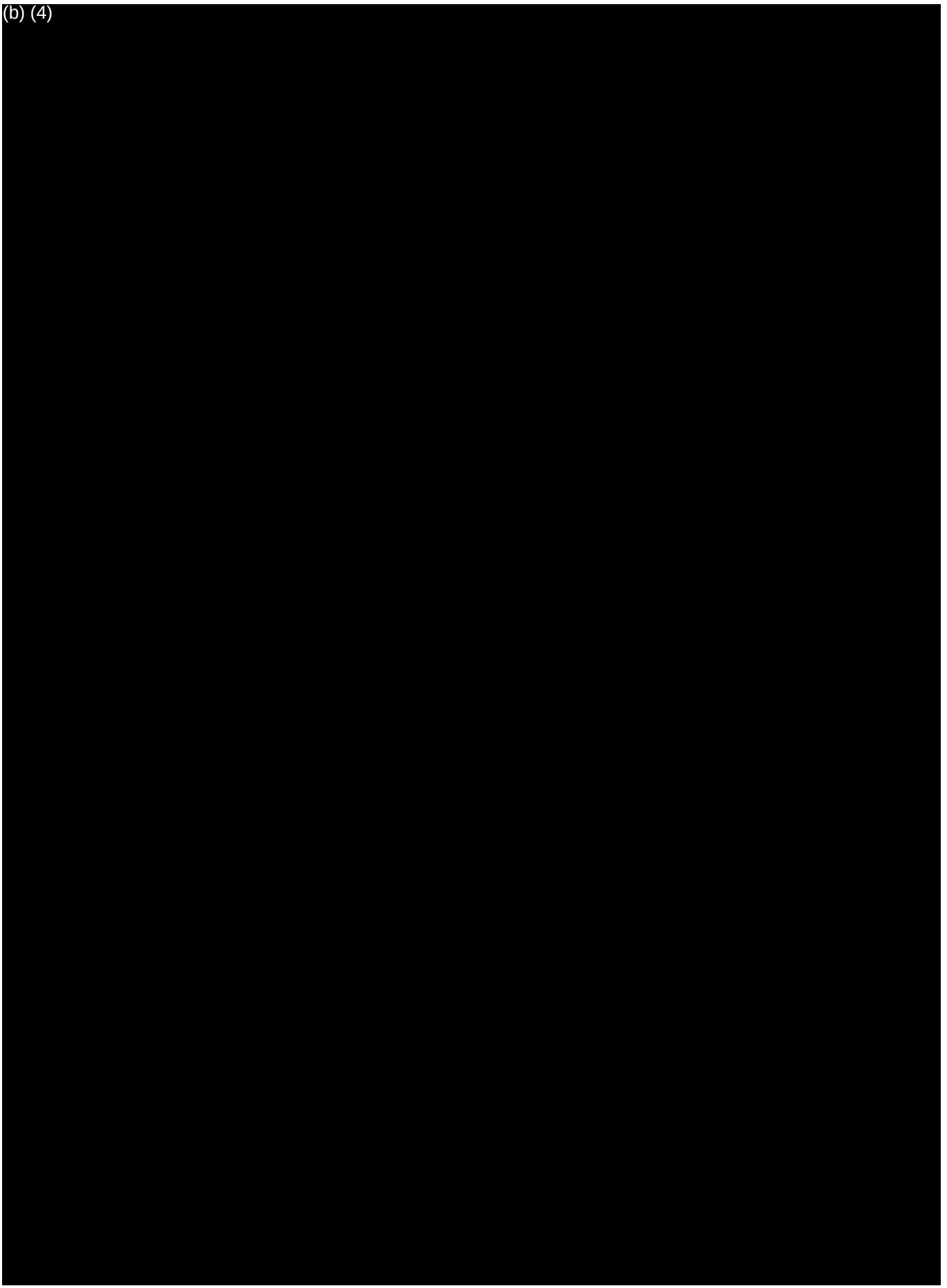

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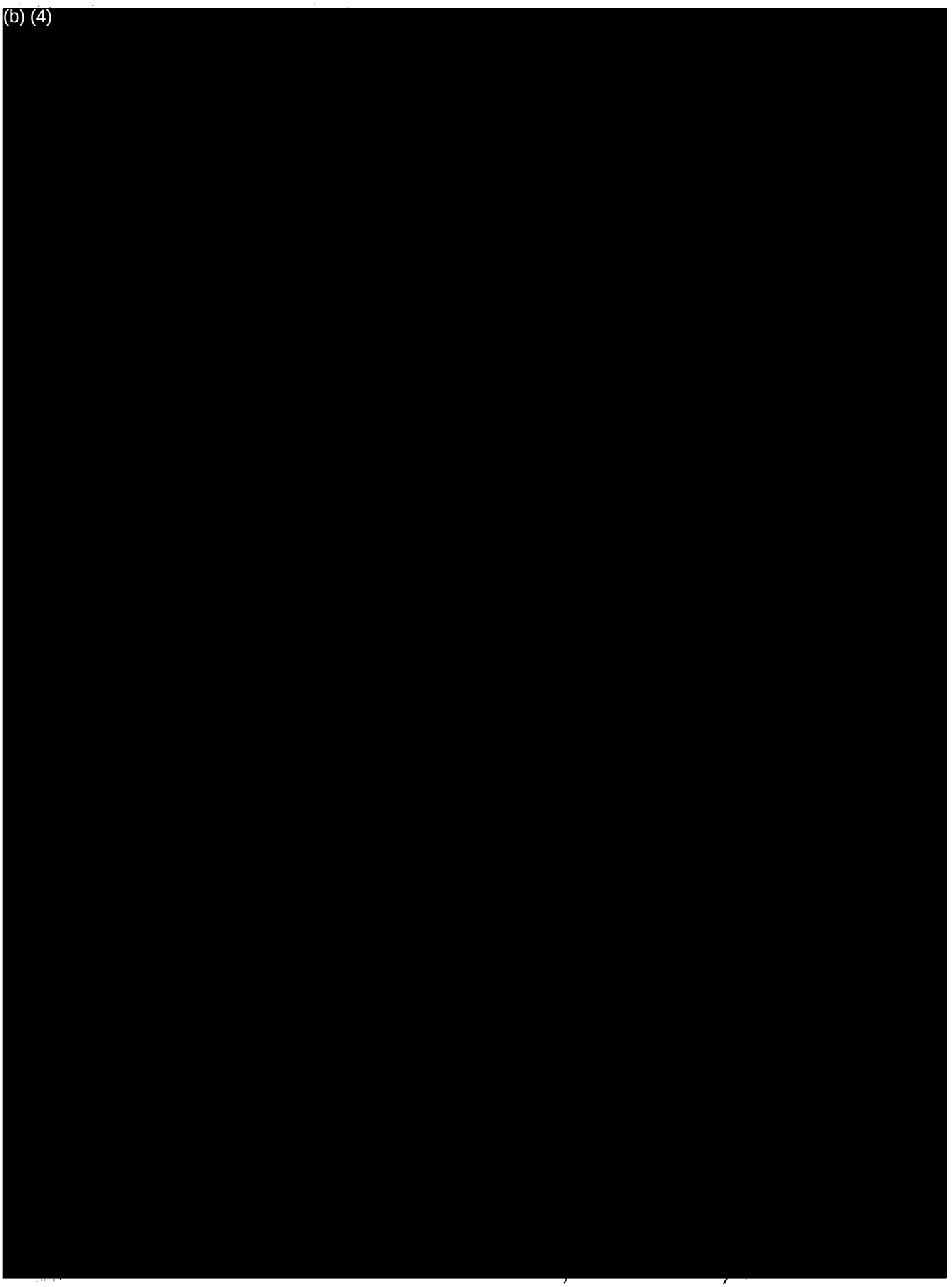

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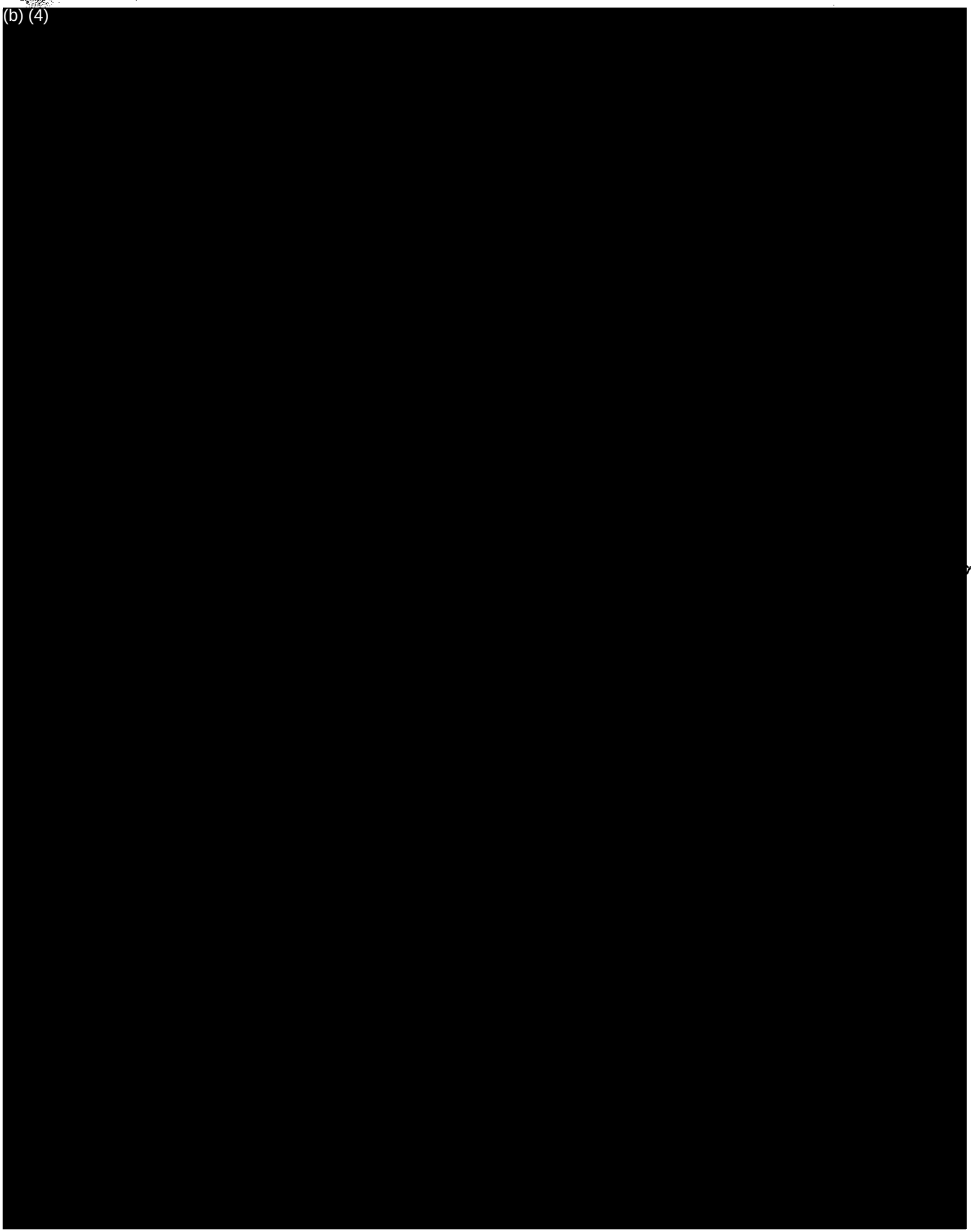

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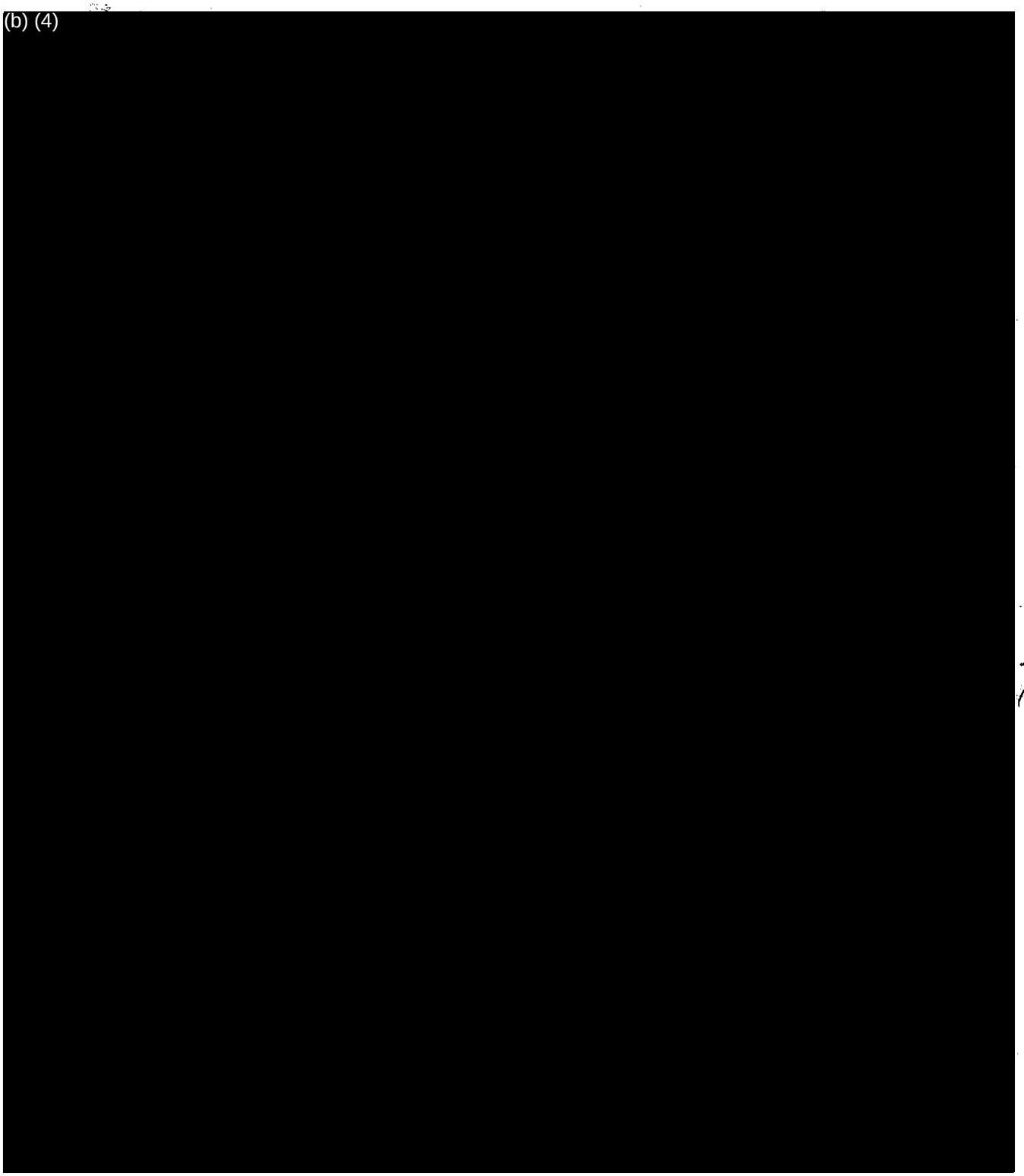

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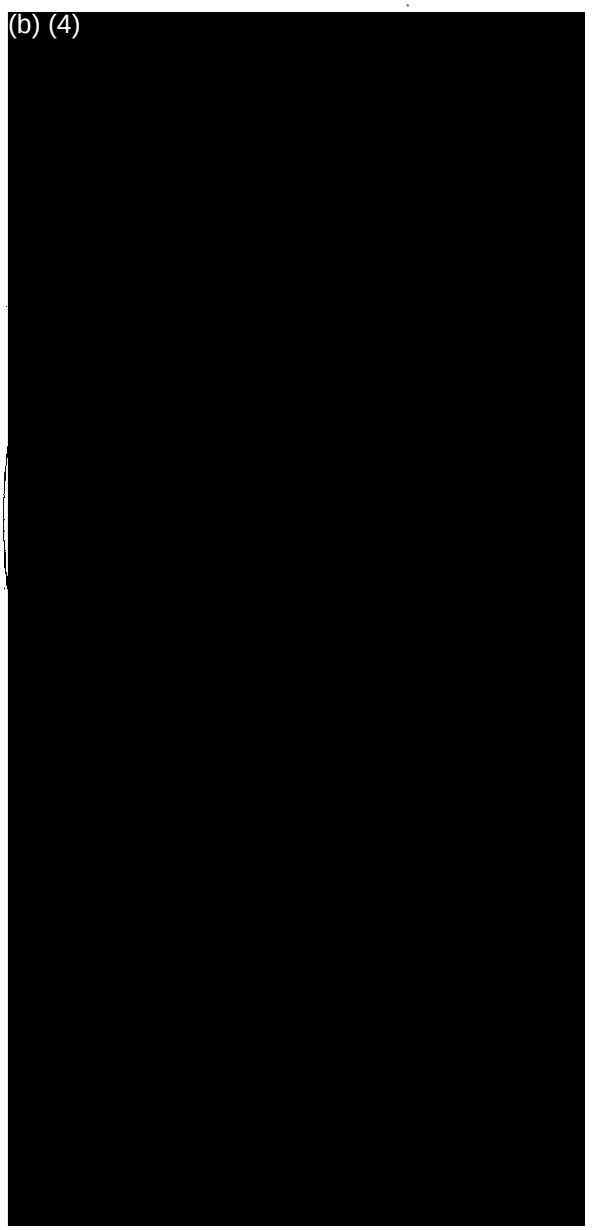

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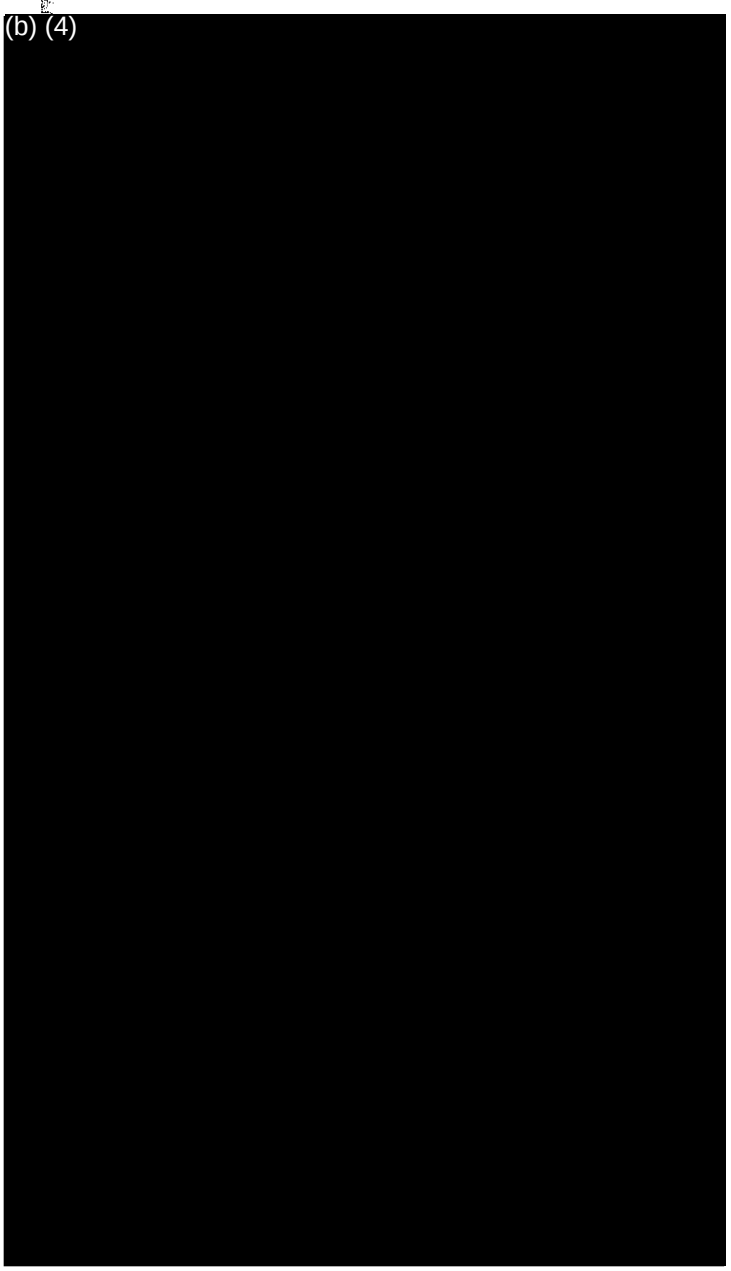

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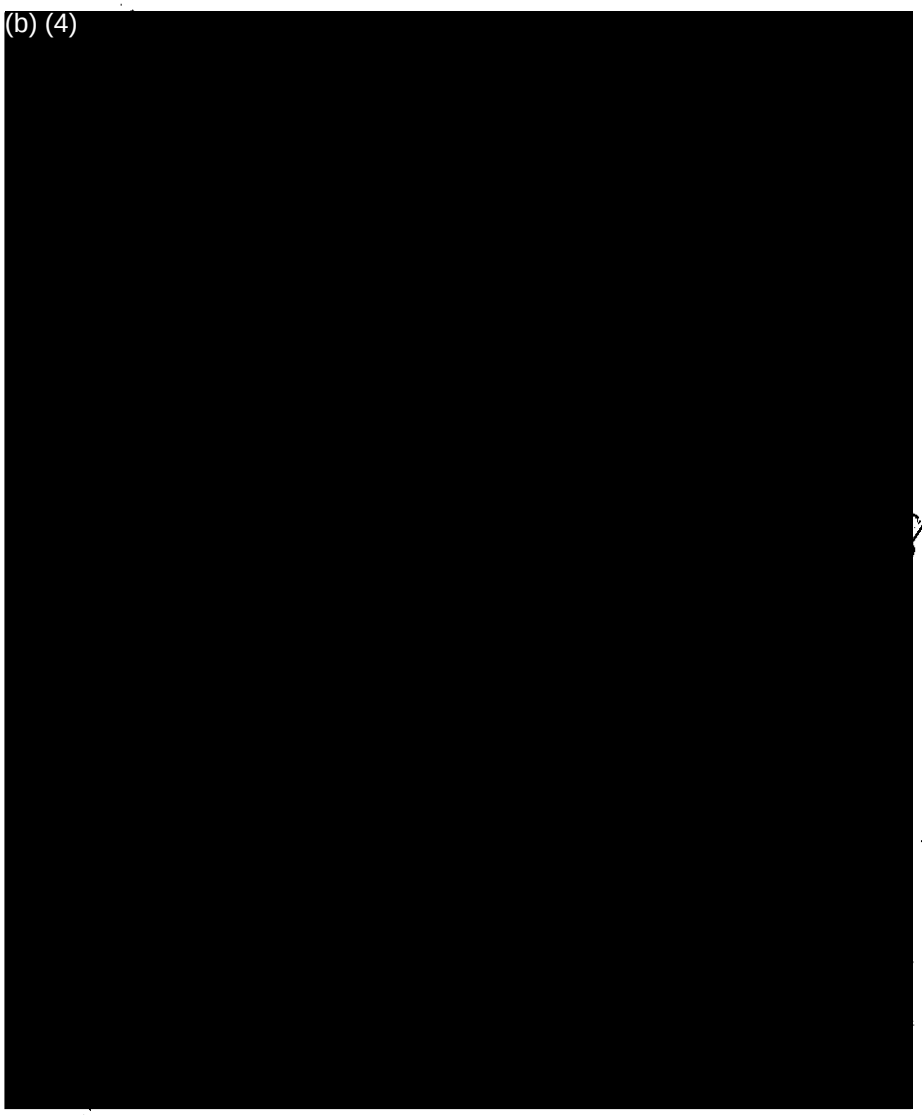

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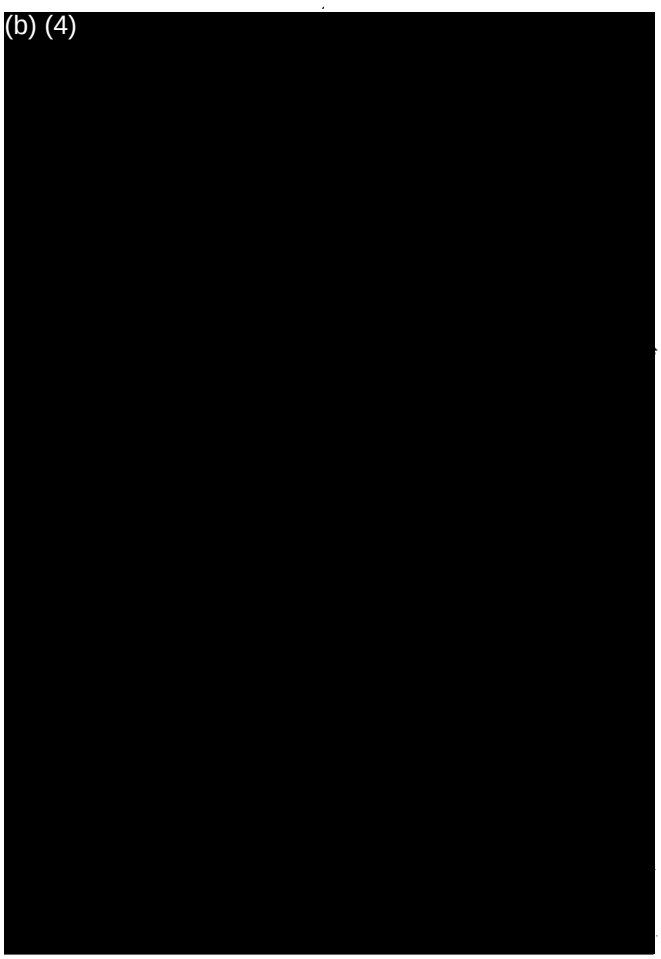

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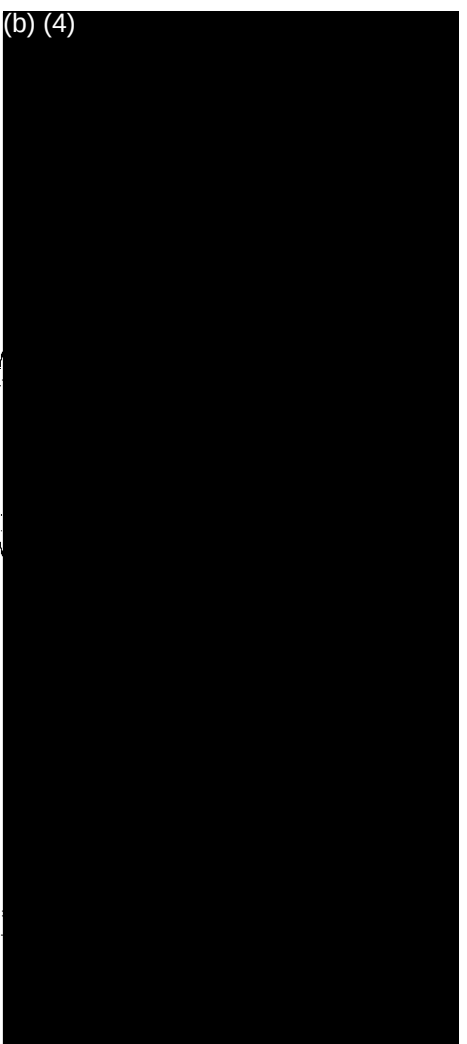

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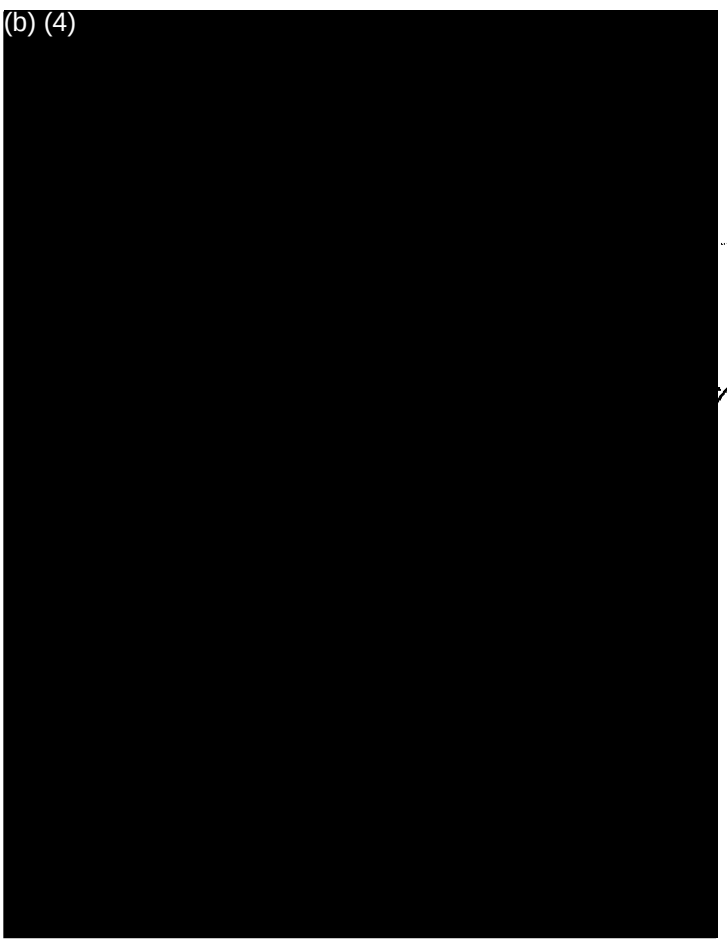

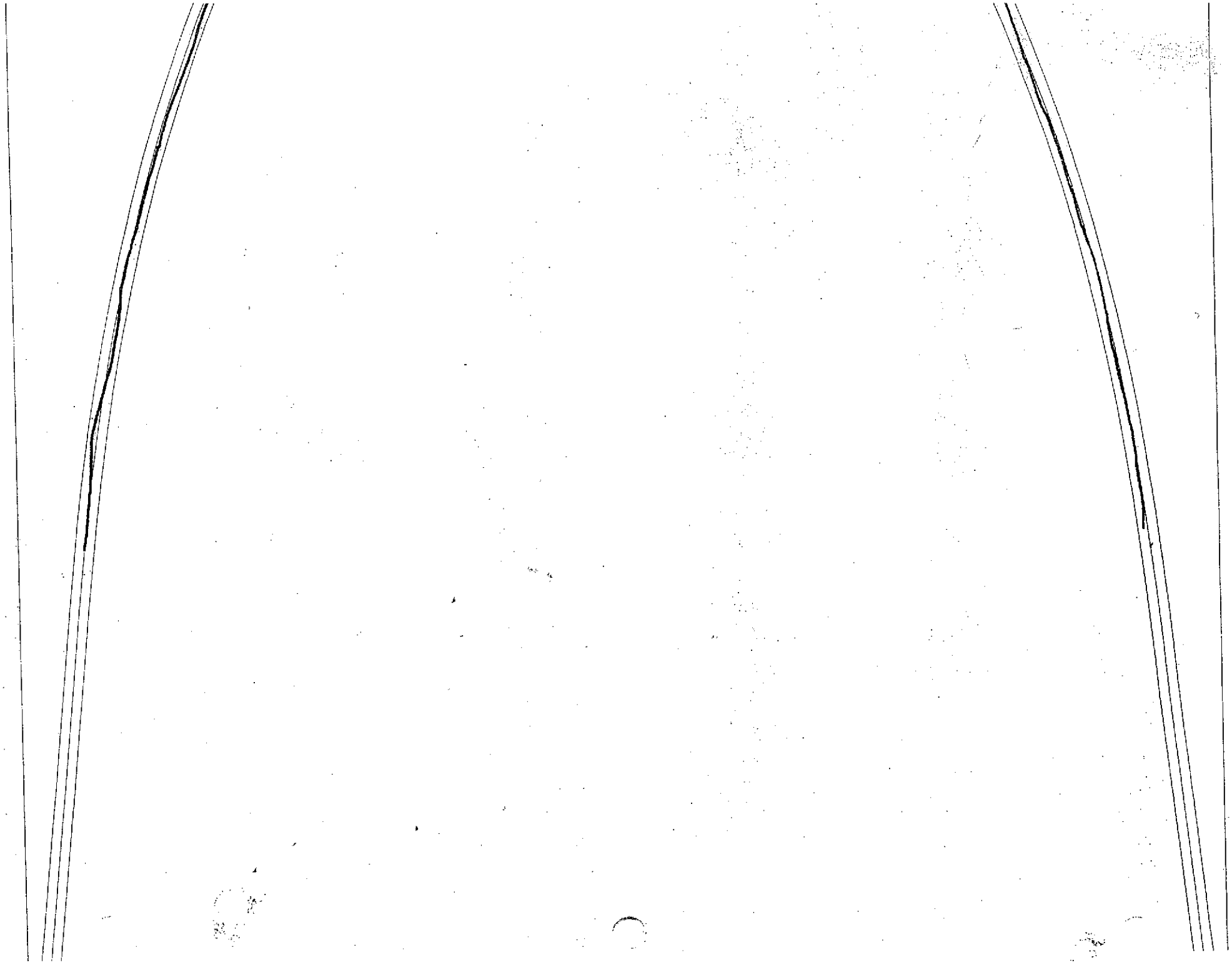

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(b) (4)

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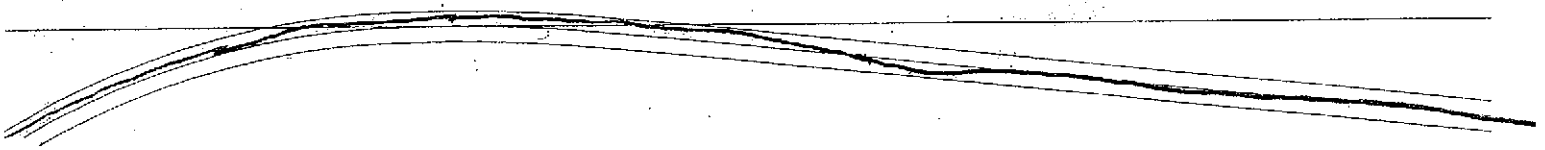

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DJA x00626

DJA x00627

(b) (4)

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(b) (4)

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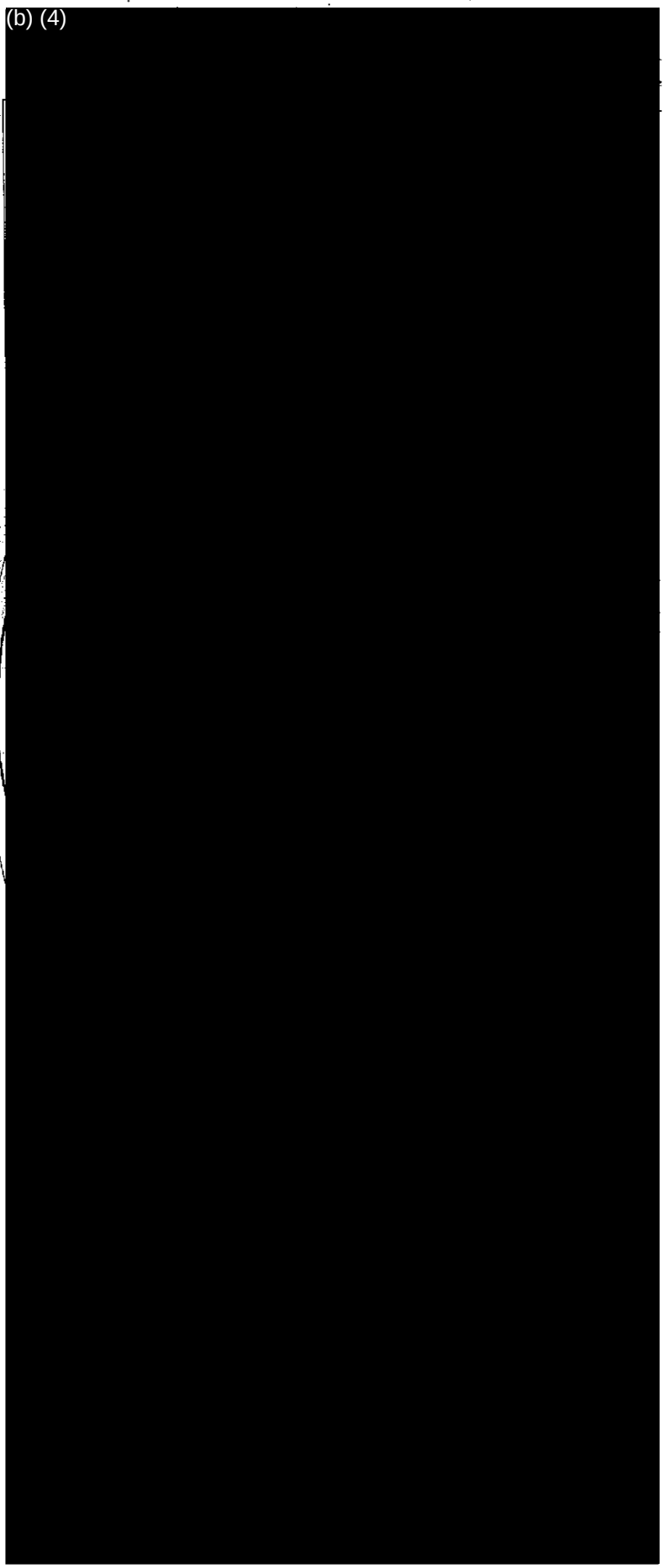
DJA x00629



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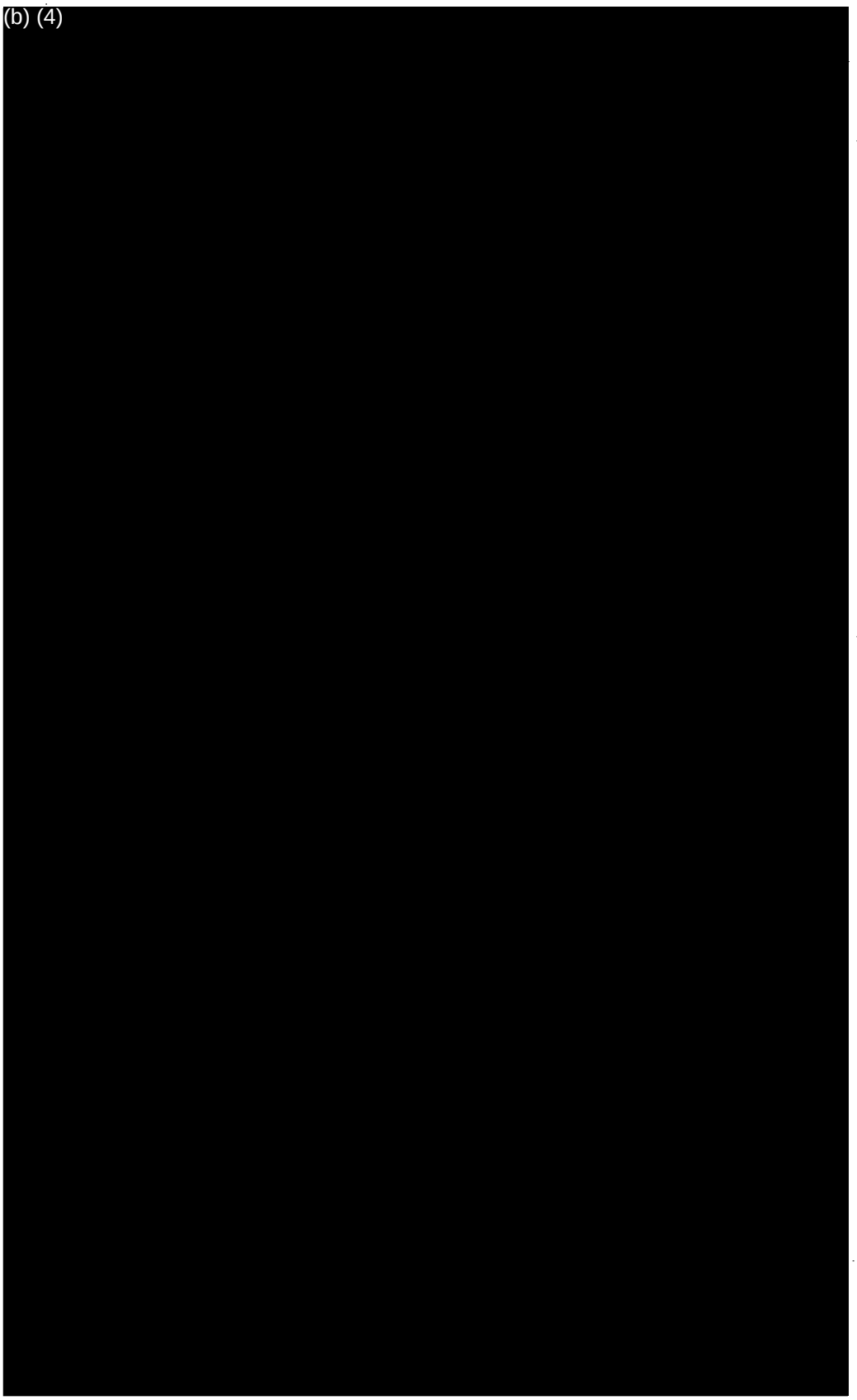

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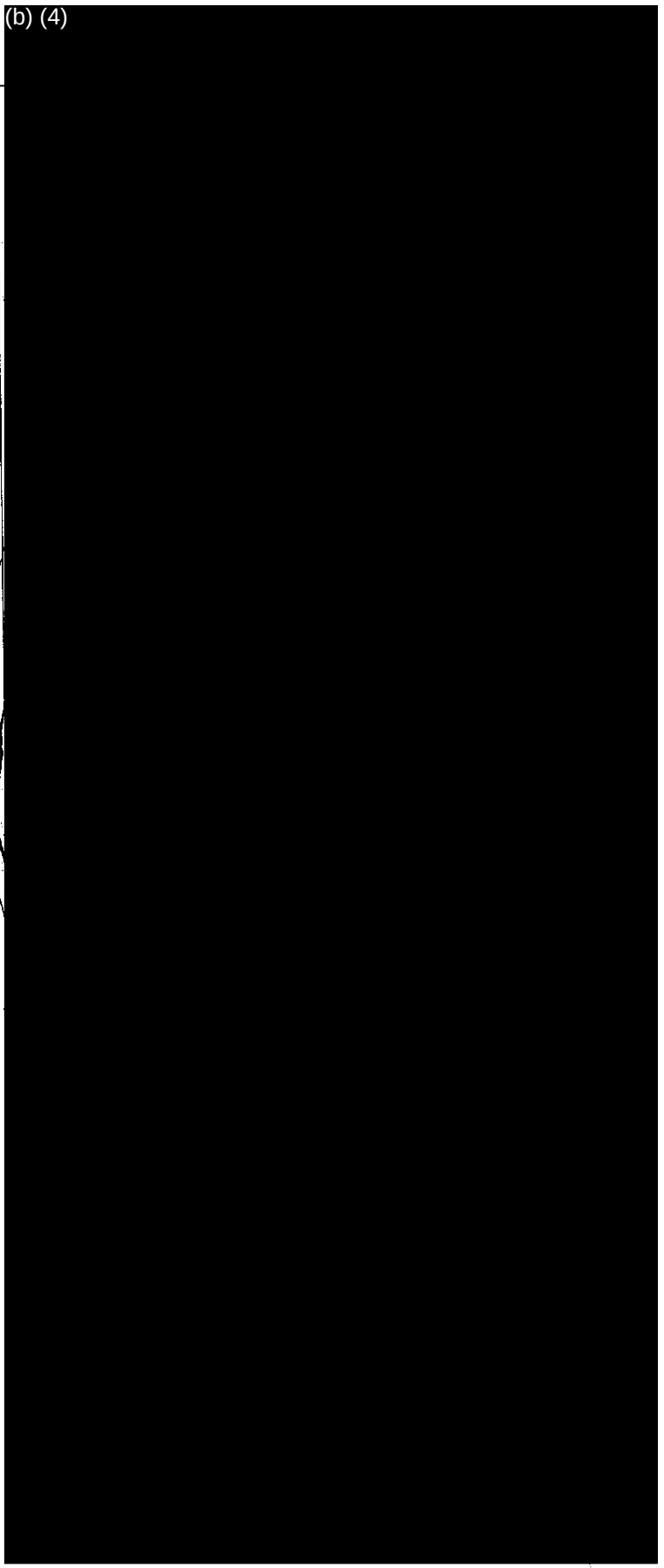

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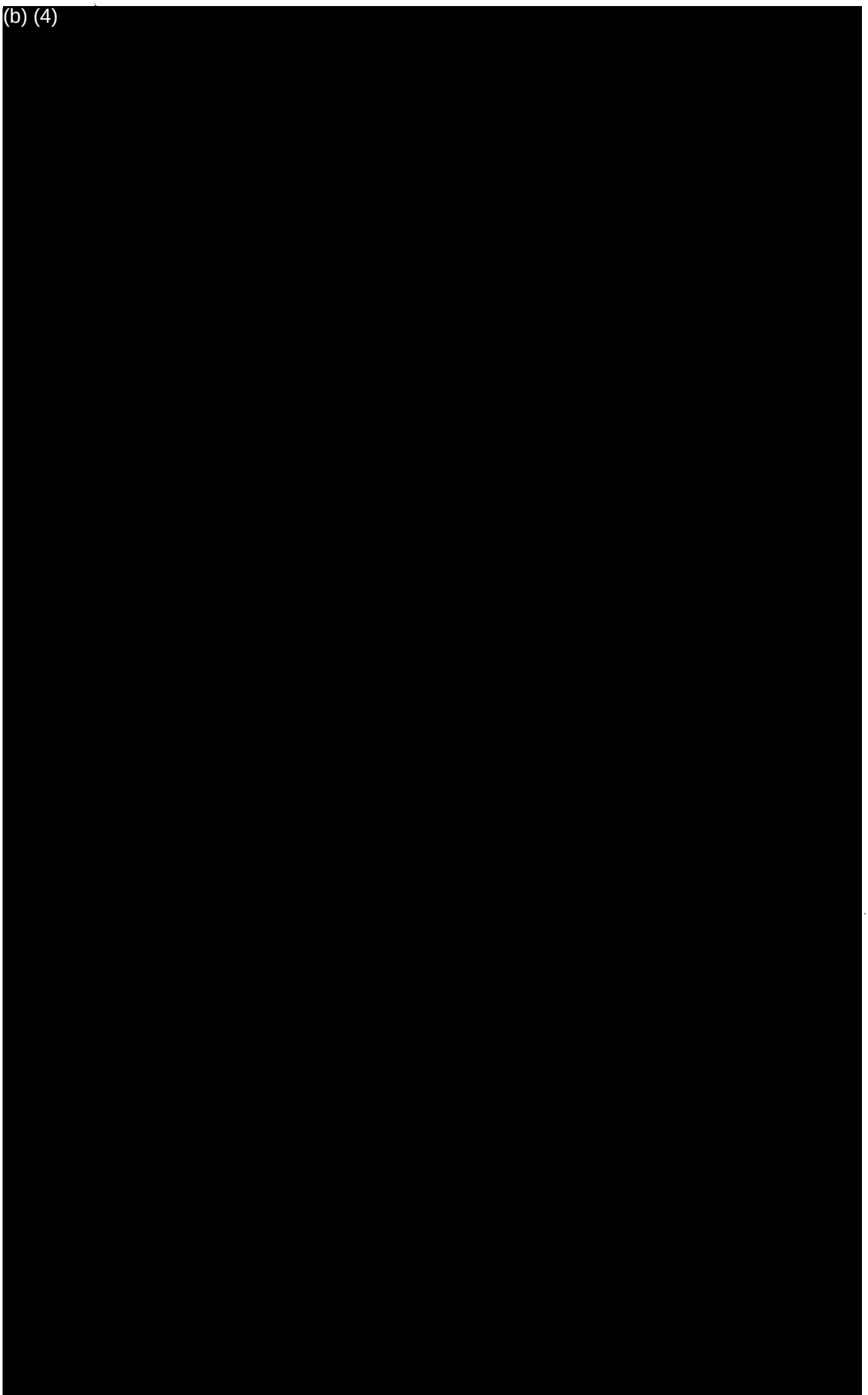

DJA x00633

ATTACHMENT 15.6:

(b) (4) [redacted] **Slice Block Plots**

Implant Cavity Development Report

(b) (4)

DJA x006335

Implant Cavity Development Report

(b) (4)

[redacted]

Implant Cavity Development Report

(b) (4)

Implant Cavity Development Report

(b) (4)

Implant Cavity Development Report

(b) (4)

[redacted]

Implant Cavity Development Report

(b) (4)

[redacted]

DJA x00640

Implant Cavity Development Report

(b) (4)

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(b) (4)

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(b) (4)

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Implant Cavity Development Report

(b) (4)

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Implant Cavity Development Report

(b) (4)

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Implant Cavity Development Report

(b) (4)

[redacted]

DJA x00646

Implant Cavity Development Report

(b) (4)

[redacted]

Implant Cavity Development Report

(b) (4)

Implant Cavity Development Report

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Implant Cavity Development Report

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Implant Cavity Development Report

(b) (4)

[redacted]

Implant Cavity Development Report

(b) (4)

[redacted]

DJA x00652

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1568

(b) (4)

DJA x00653

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00654

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1680

(b) (4)

REFERENCE COPY
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DJA x00655

Results (Attach additional sheets if necessary):

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[redacted]

DJA x00656

PROTOCOL and TEST REPORT APPROVAL SHEET

(b) (4)

[redacted]

REFERENCE
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qc 01/17/08

DJA x00657

PINLESS THR PROCEDURAL TEST

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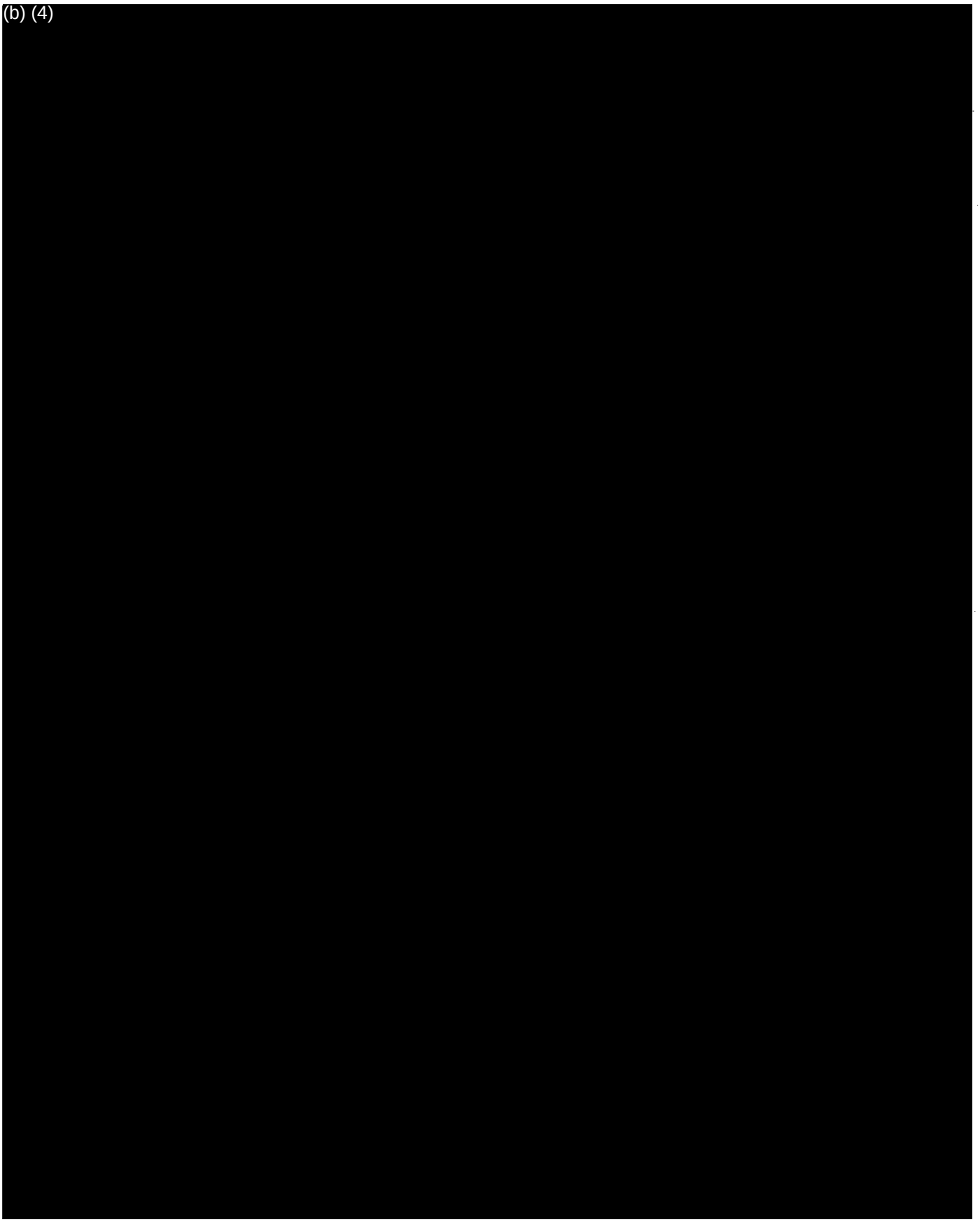

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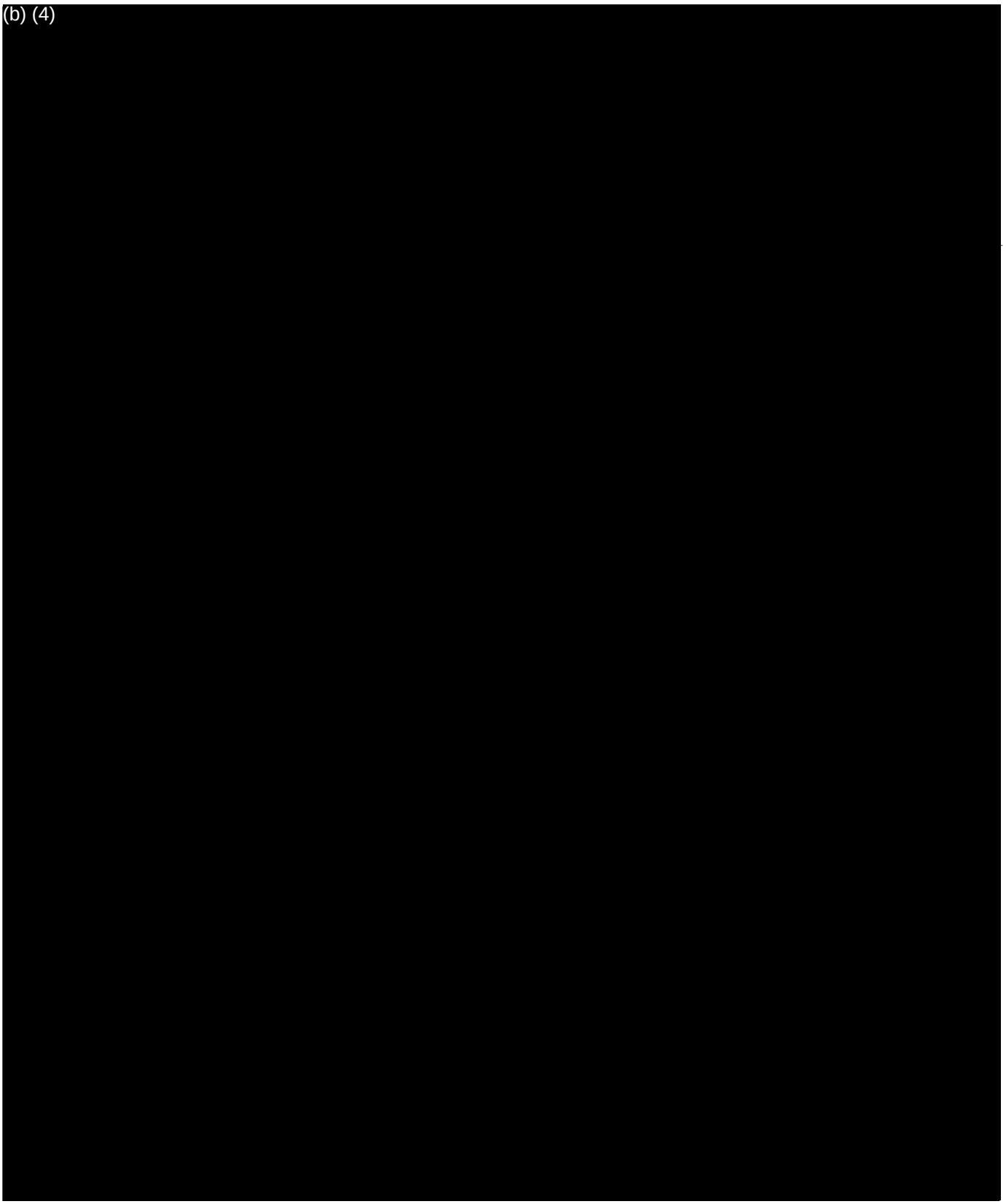

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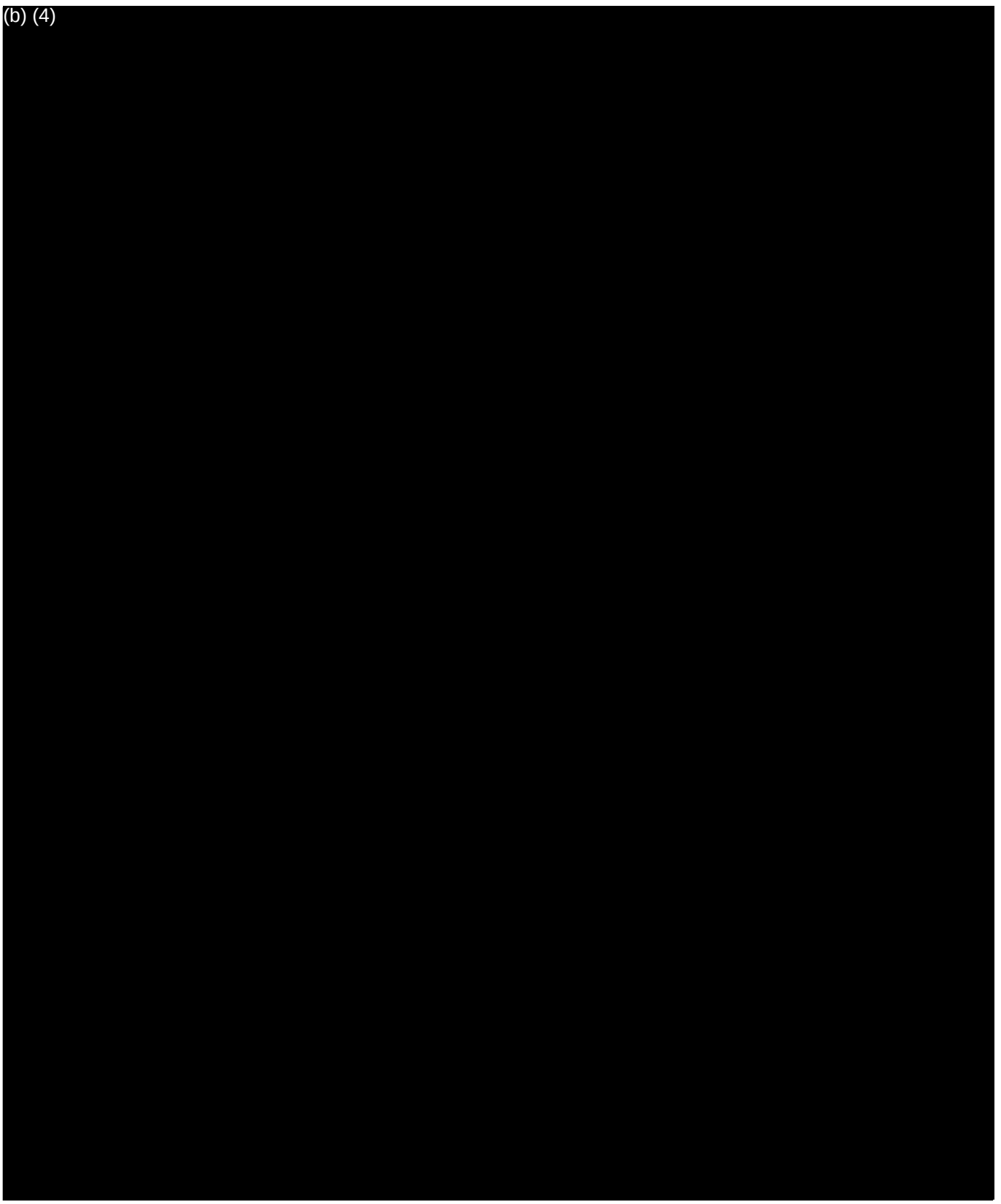

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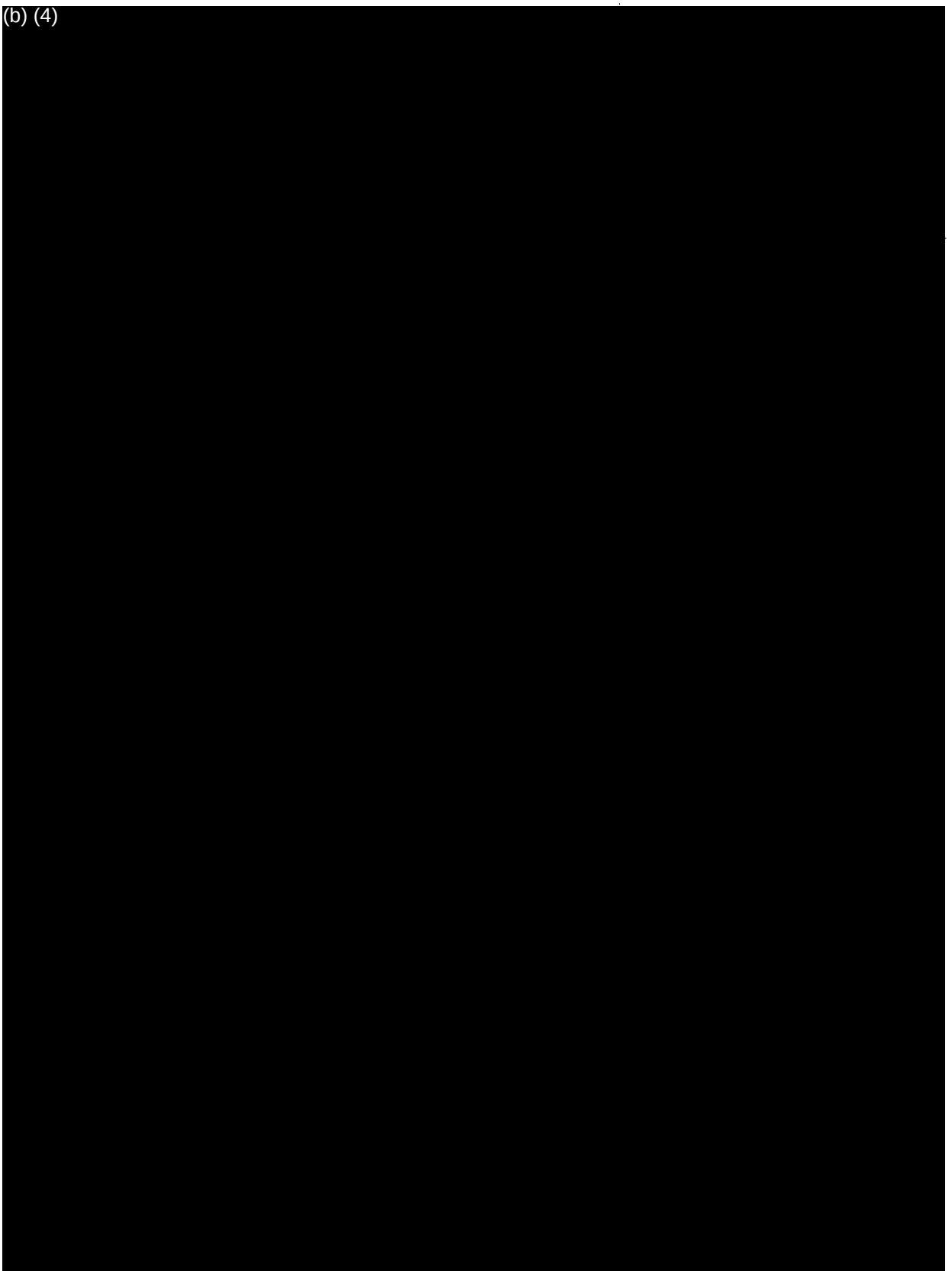

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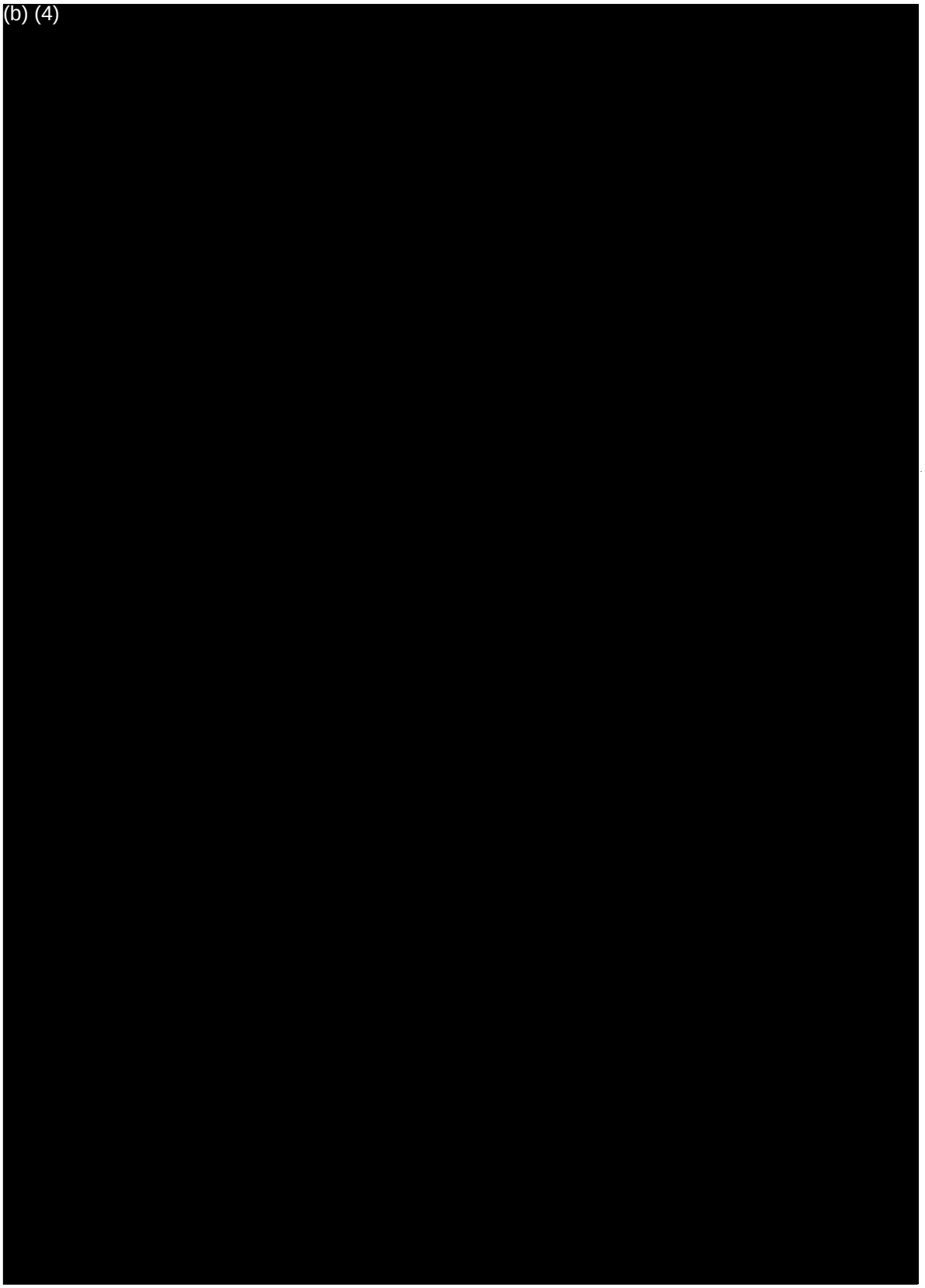

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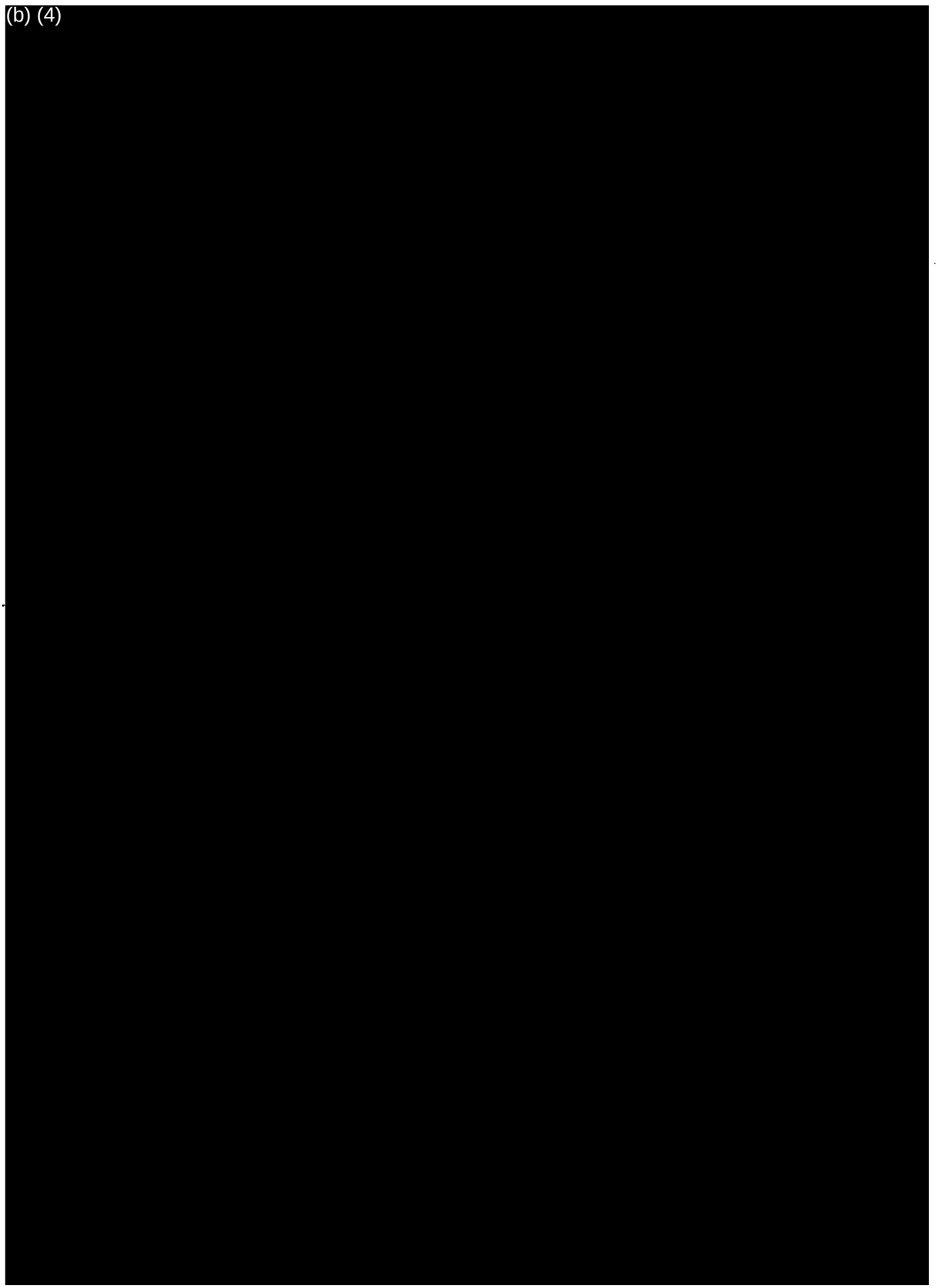
8. (b) (4)



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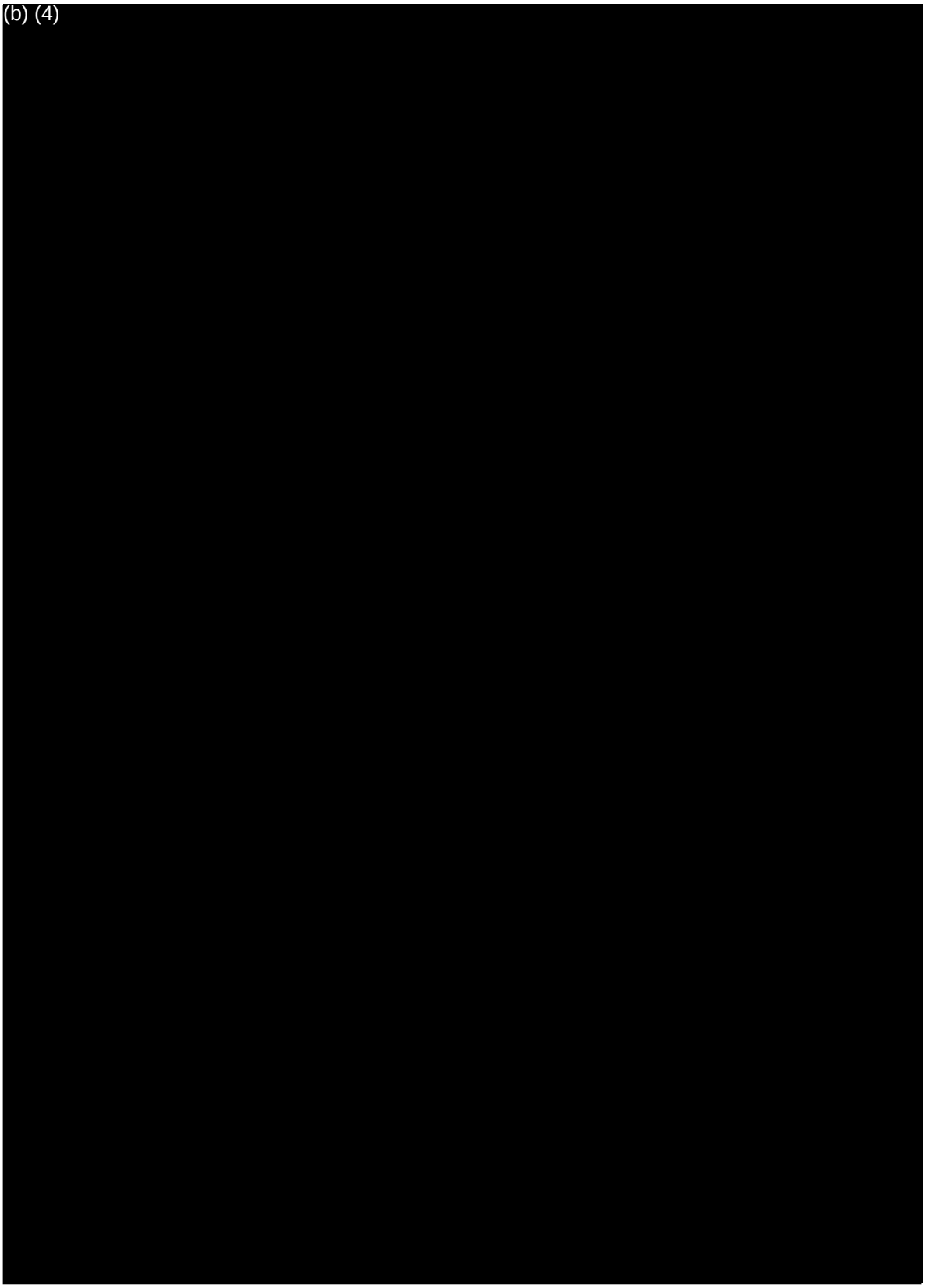

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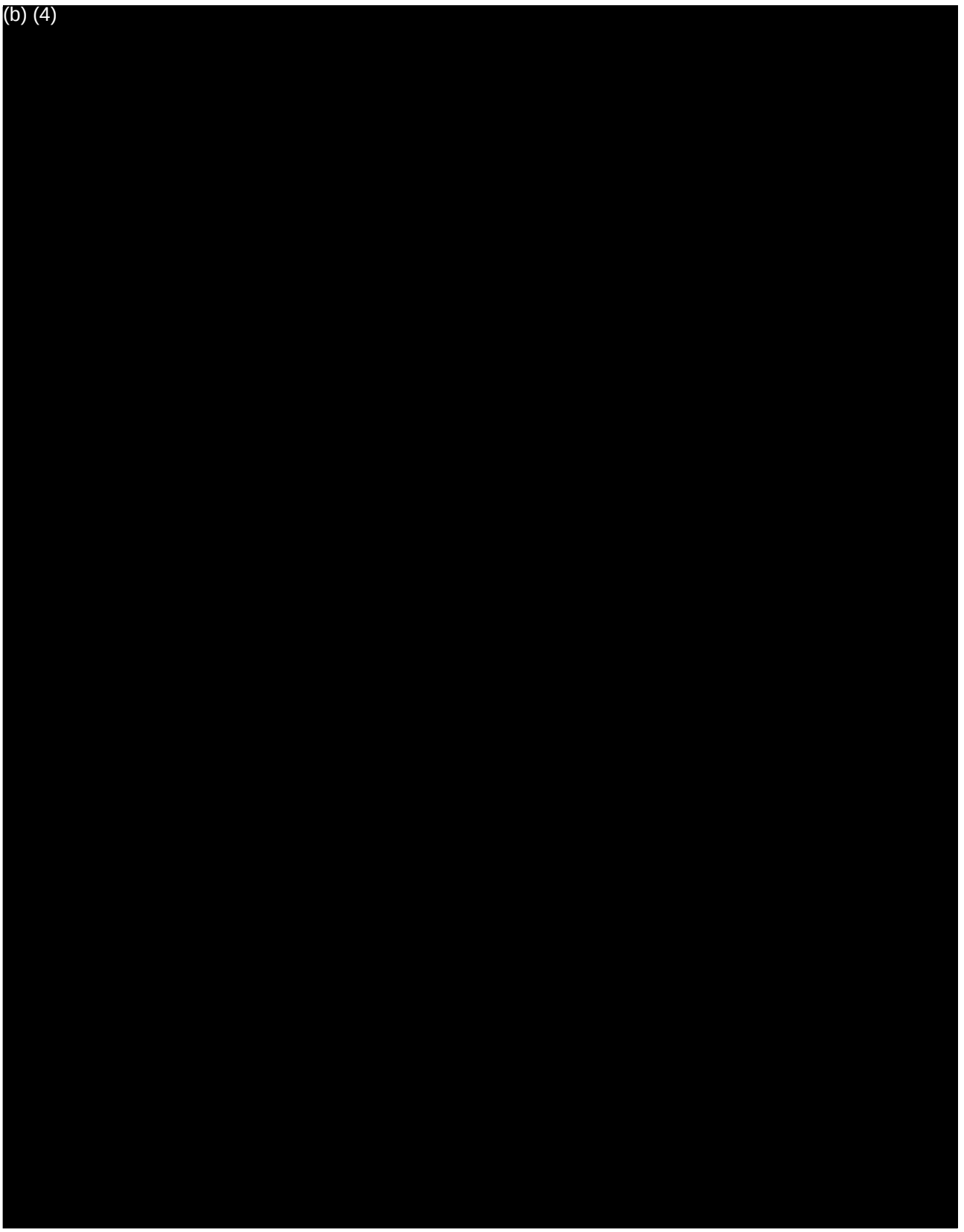

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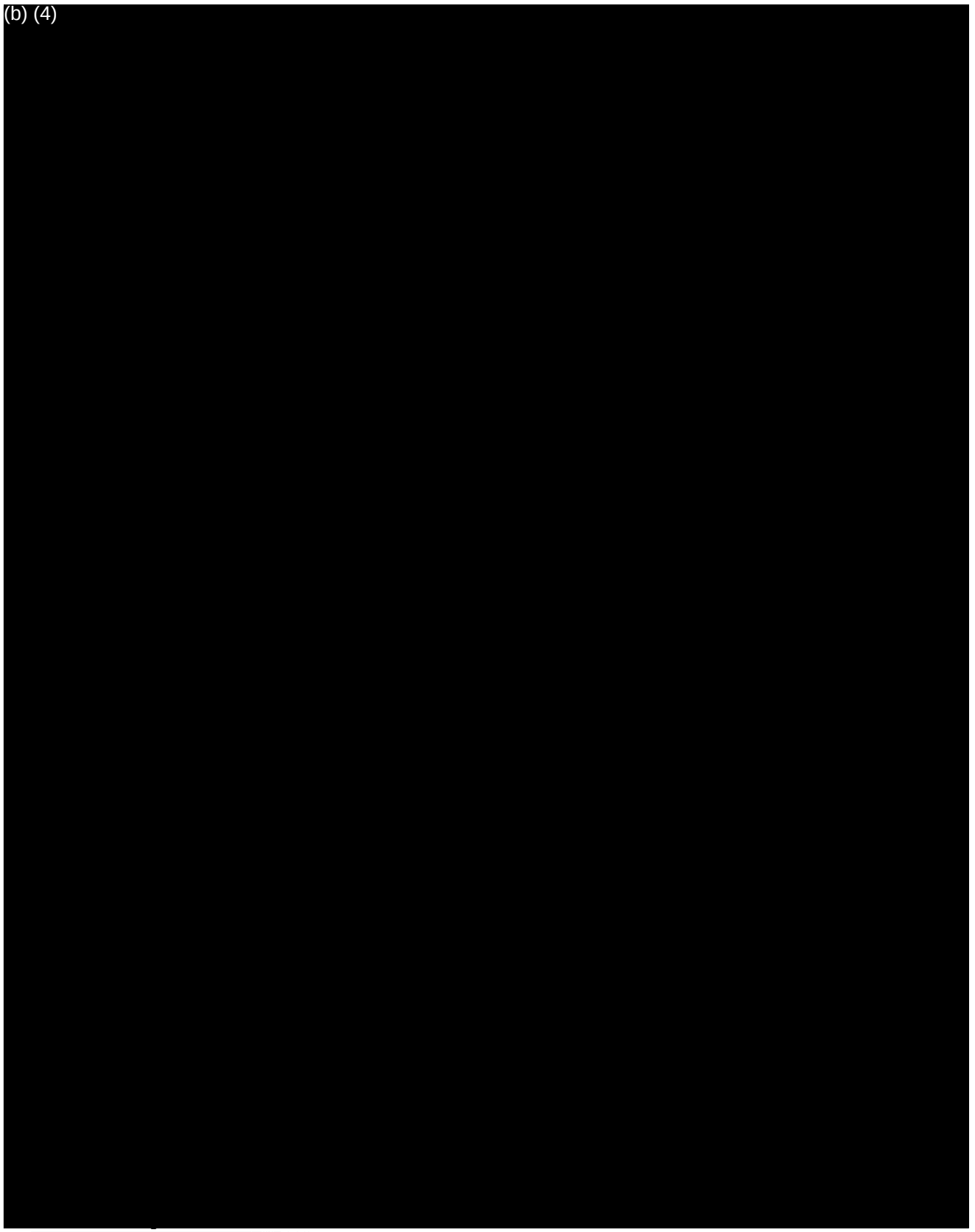

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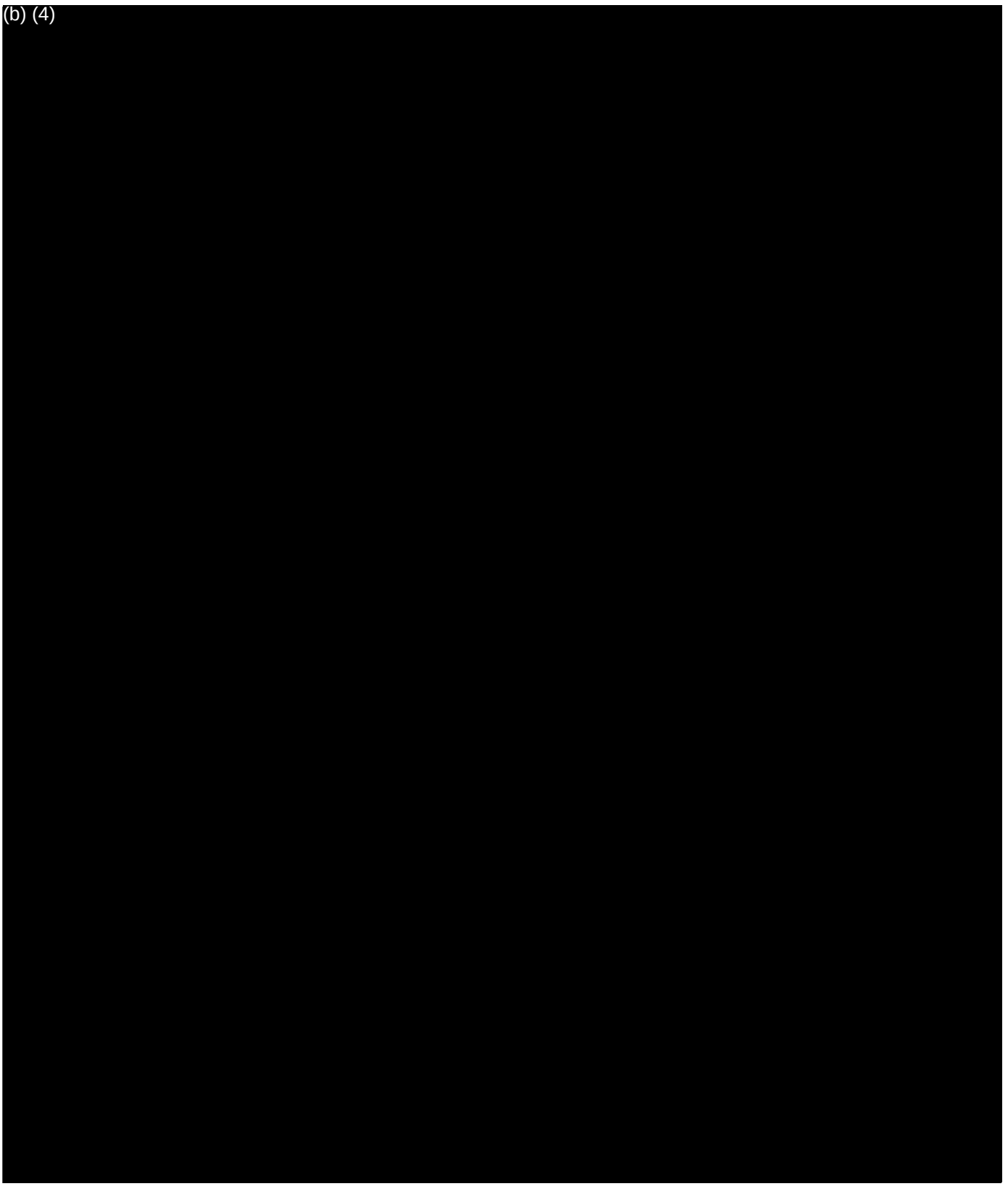

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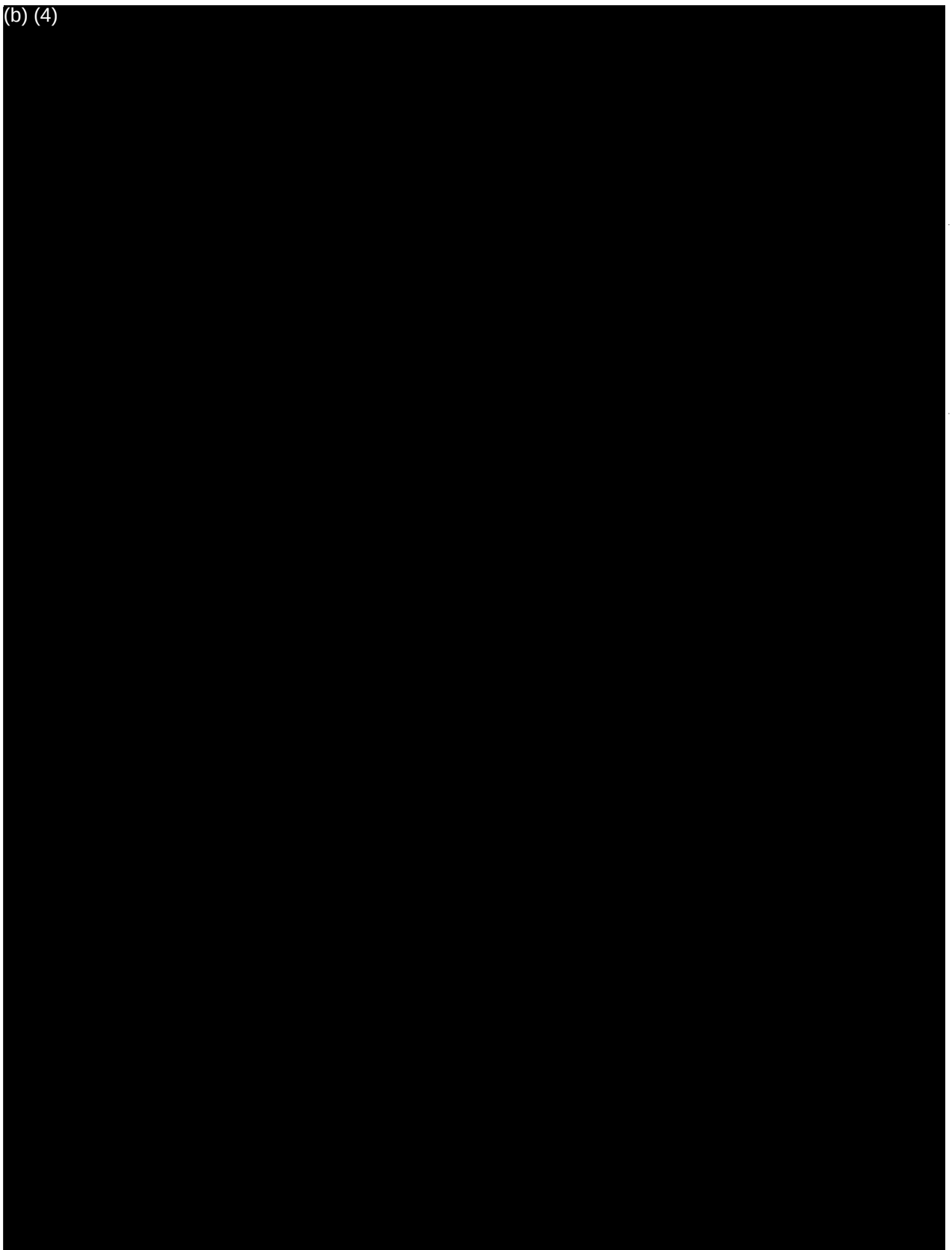


DJA x00668

PINLESS THR PROCEDURAL TEST

(b) (4)

DJA x00669

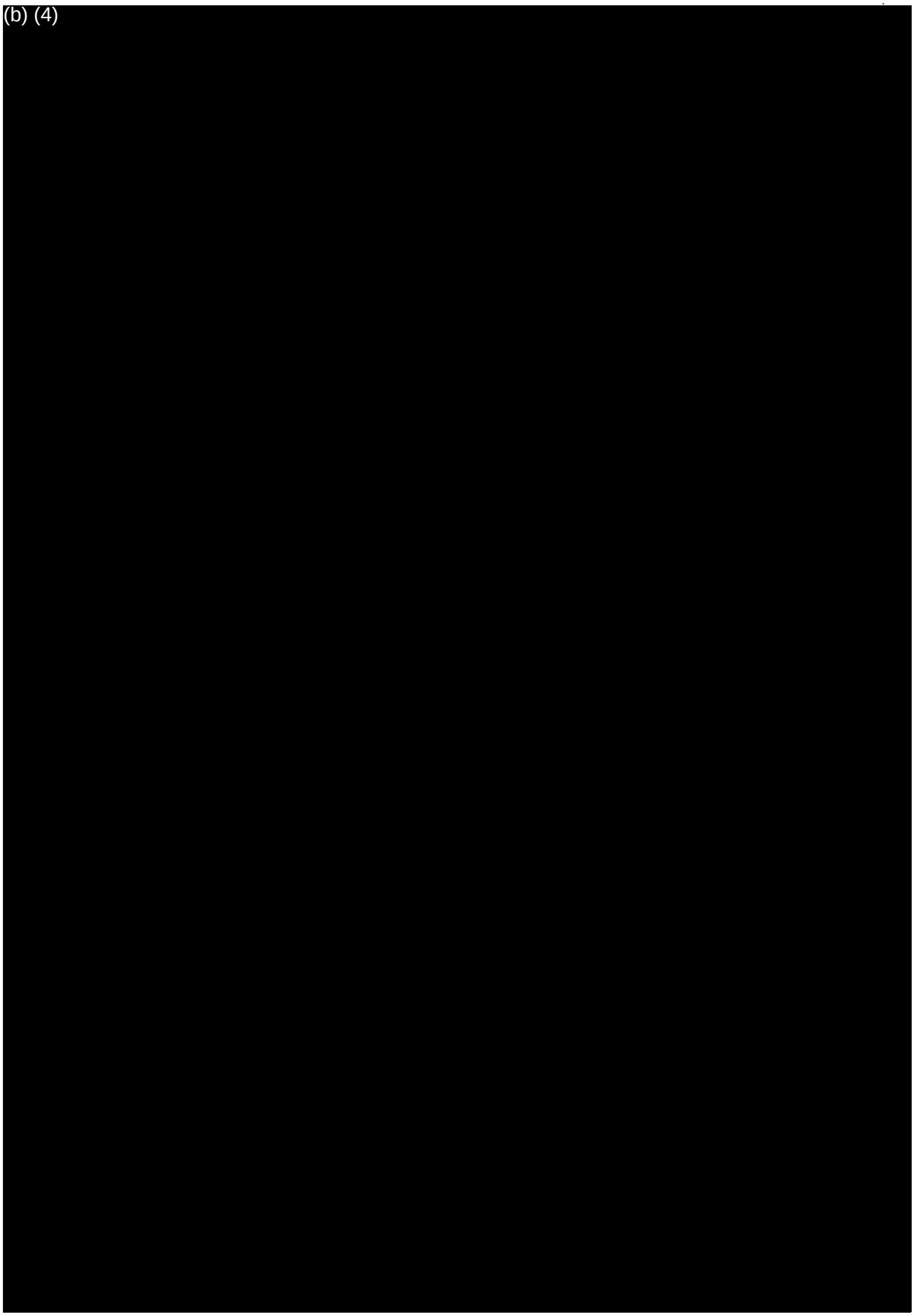
Verification and Validation Plan for
Robot Control Computer (RCC) Software Version 3.6
P/N 103534 Rev 01
May 22, 2000

DCO # 1533

(b) (4)

DJA x00670

(b) (4)



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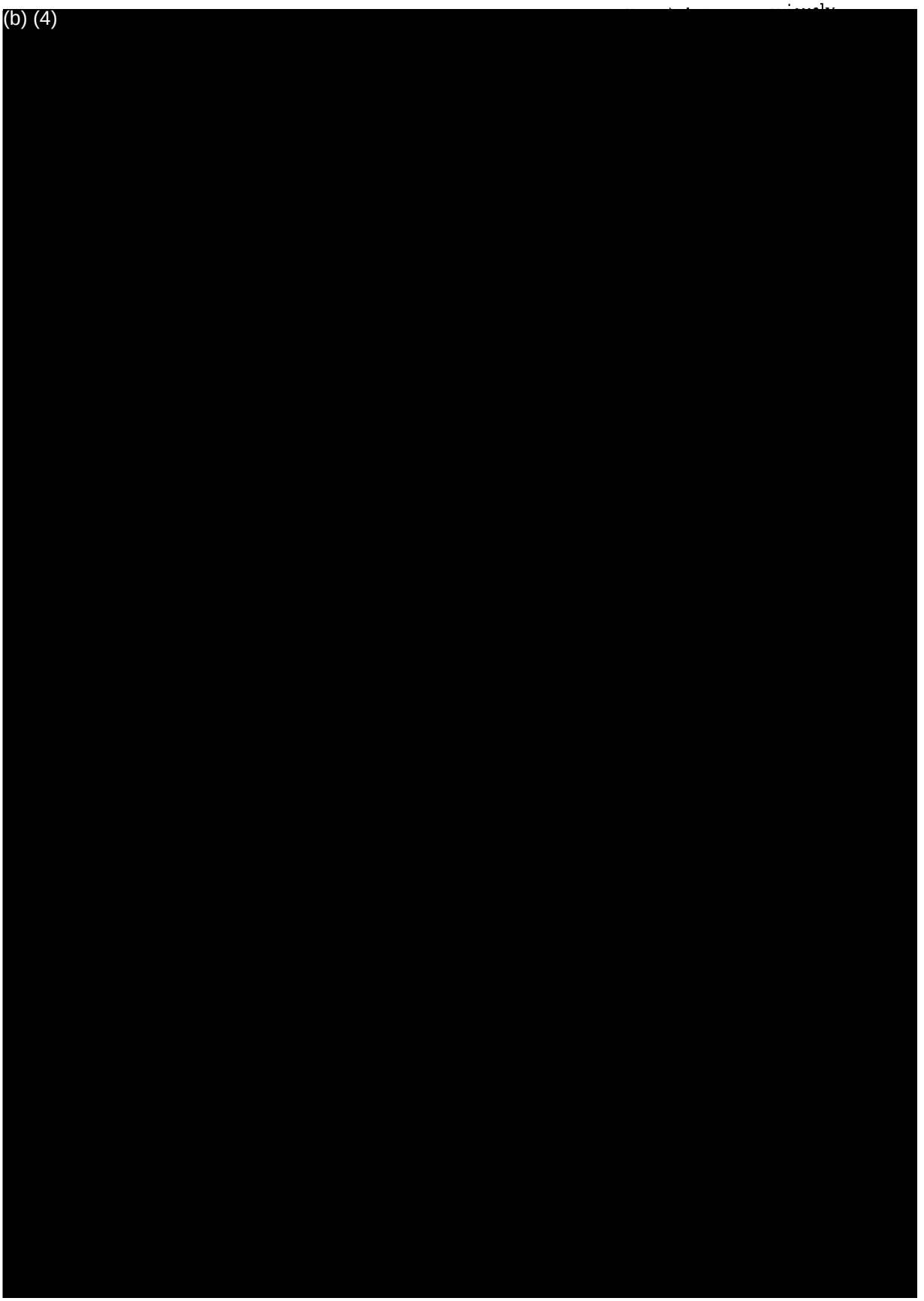

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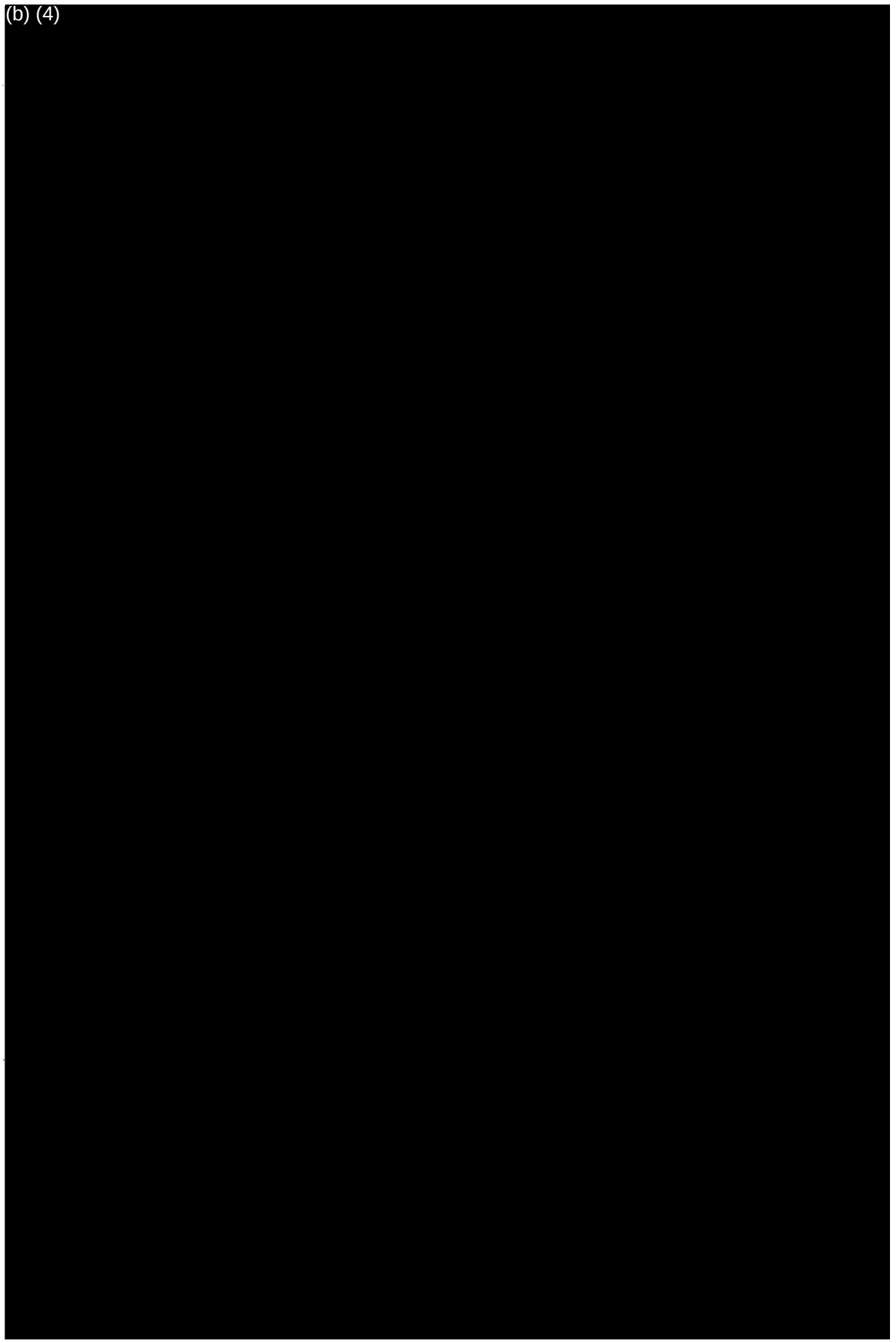

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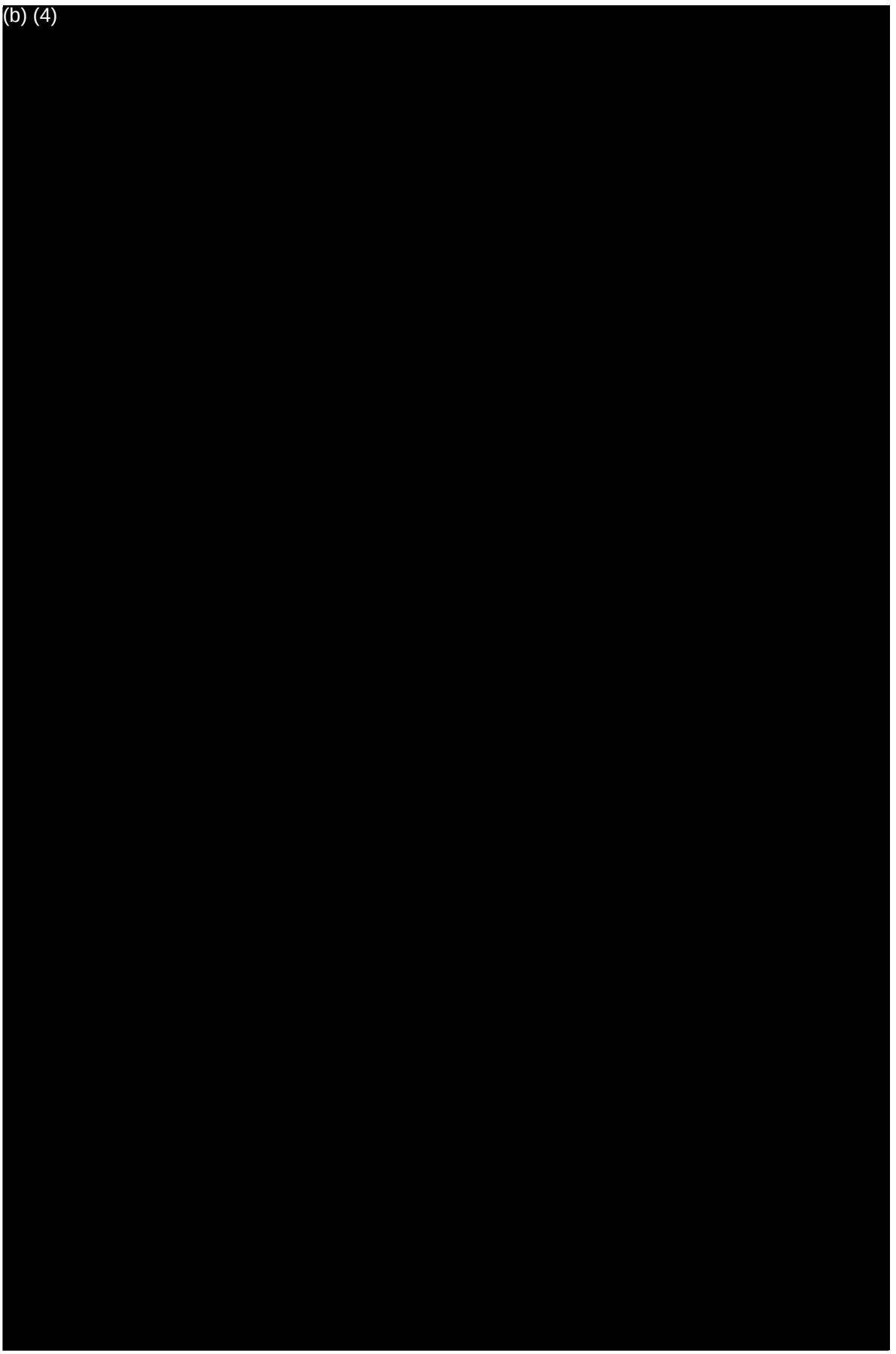

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(b) (4)

42	(b) (4)
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DJA x006?6

Traceability Matrix

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(b) (4)

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DJA x00678

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Section 2: Arranged by Test number

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DCO # 1563

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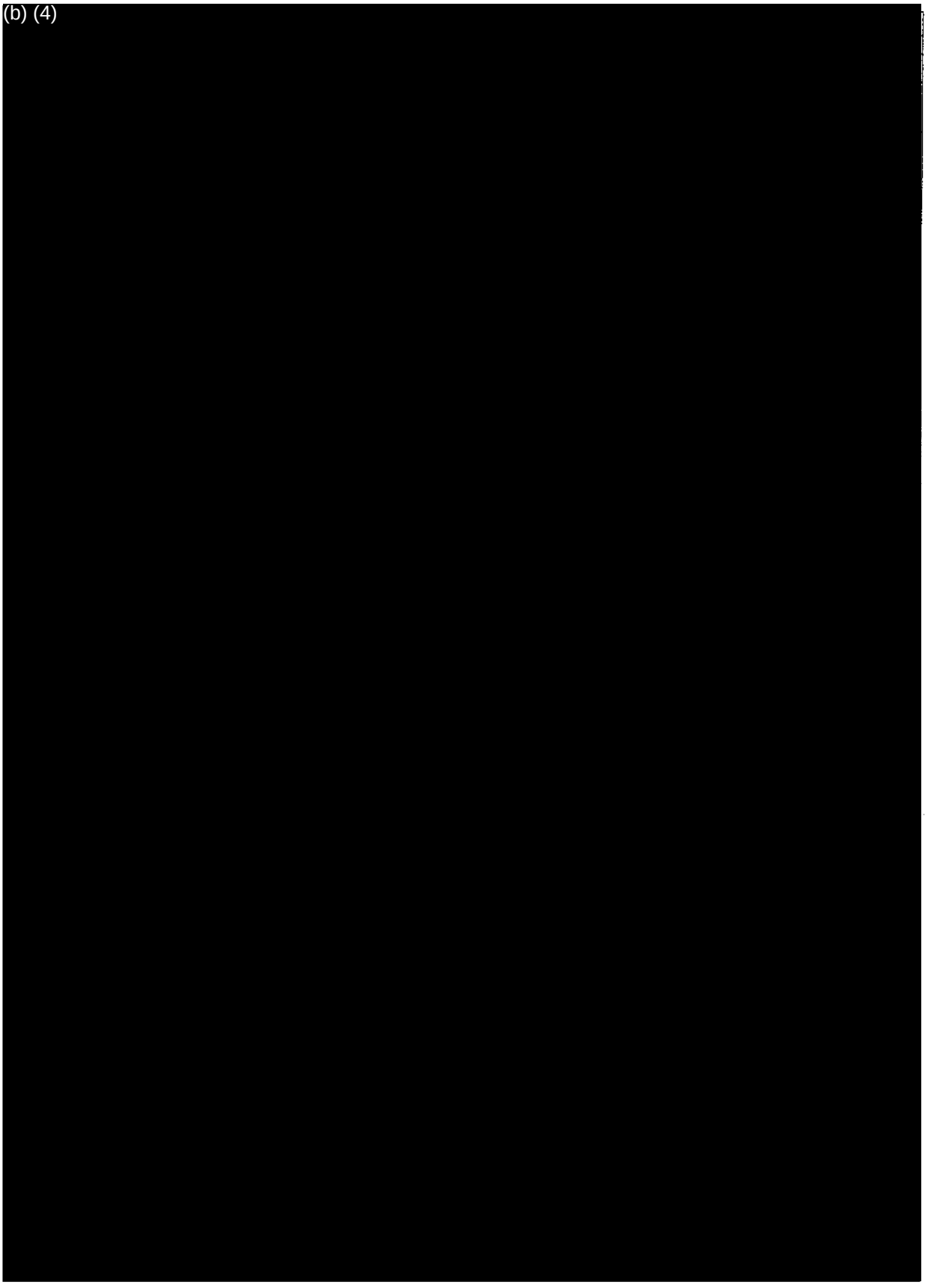

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TEST REPORT APPROVAL SHEET

DCO # 1893

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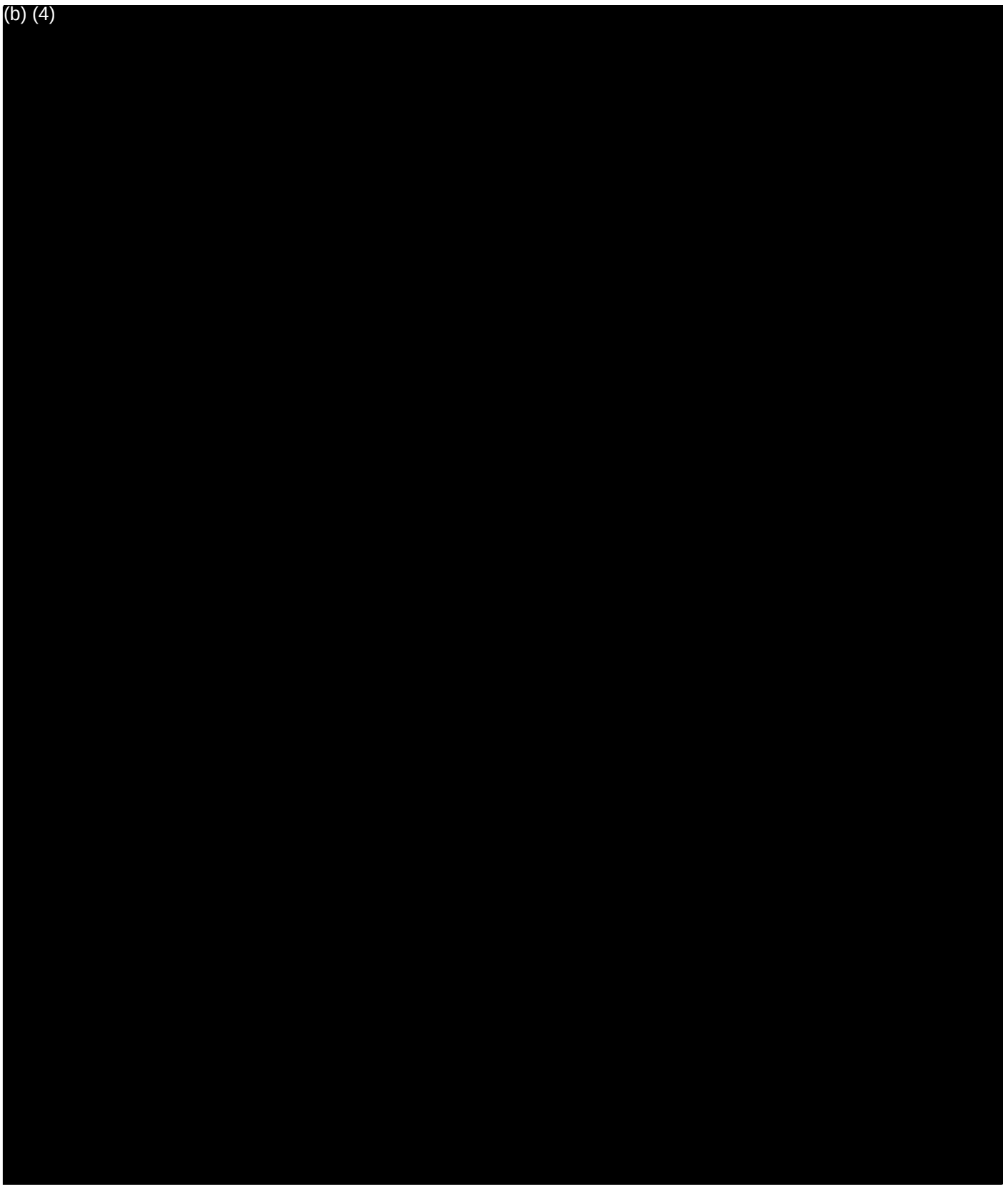

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5.0 Results

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DJA x00685

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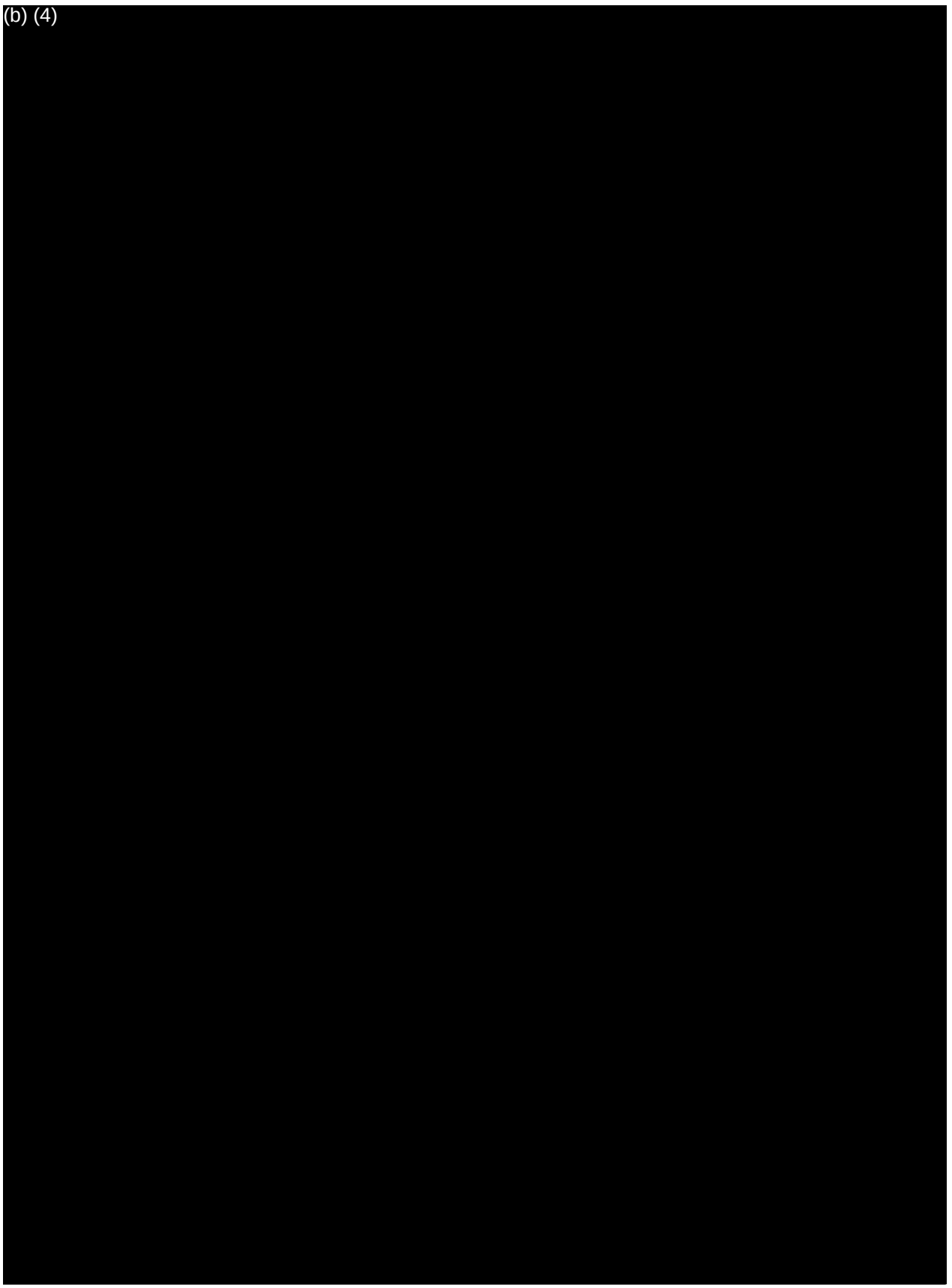

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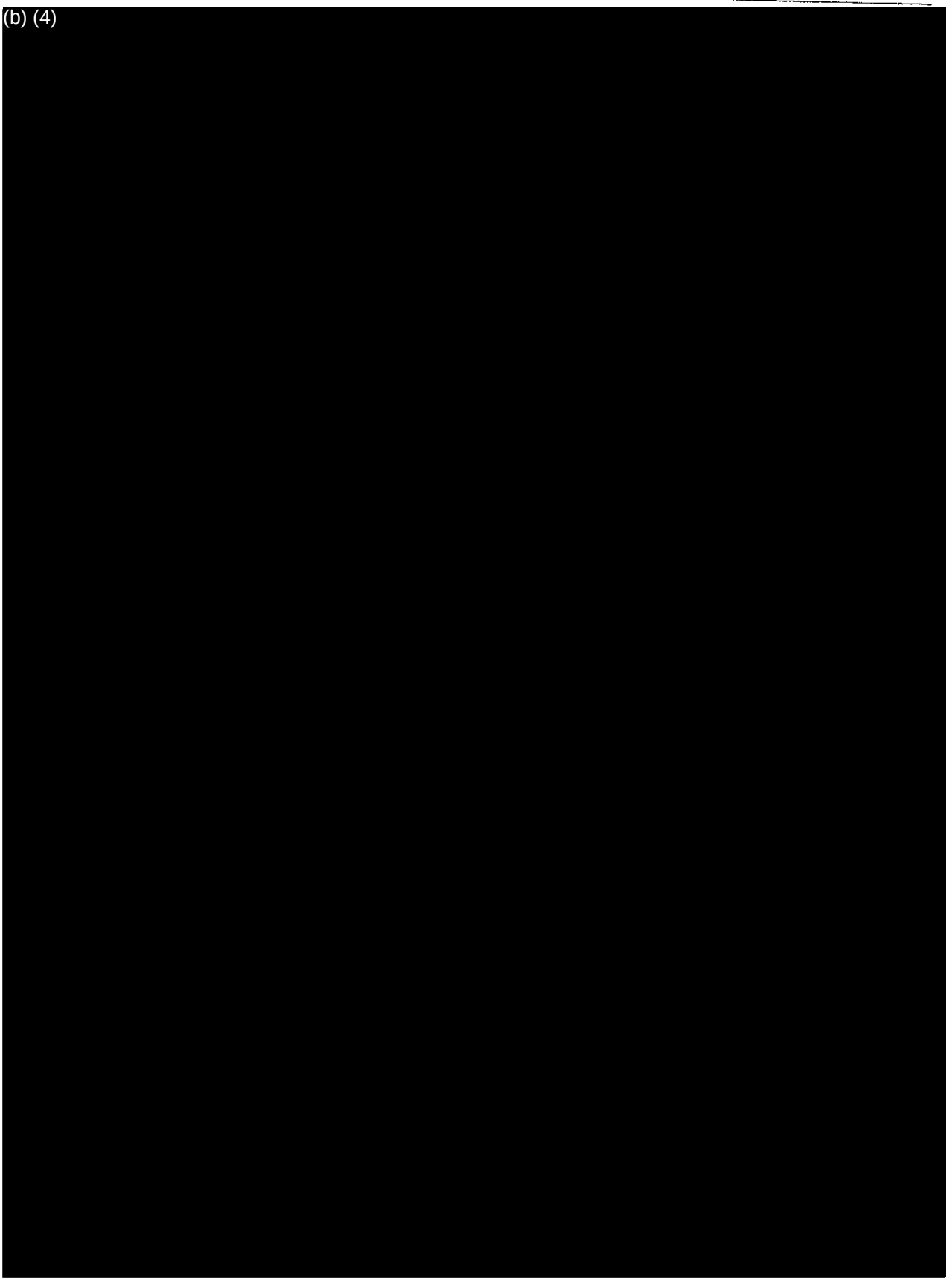

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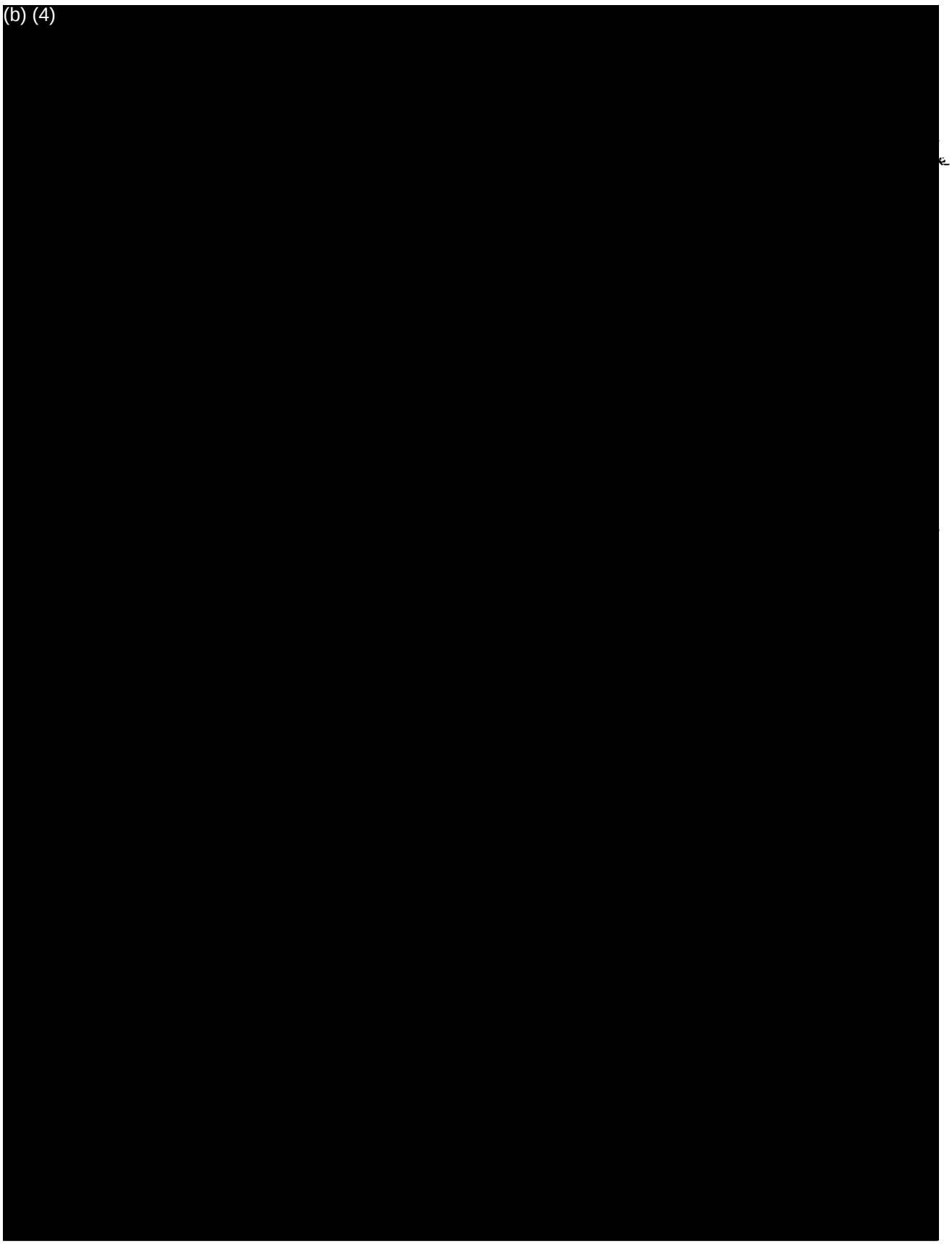

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DJA x00689

(b) (4)

DJA x00690

K072629/S1
FDA CDRH DMC
JAN 31 2008

VOL III
Index for Test Reports

(b) (4)

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DJA x00691

ROBODOC
INTEGRATED SURGICAL SYSTEMS

PROTOCOL and TEST REPORT APPROVAL SHEET

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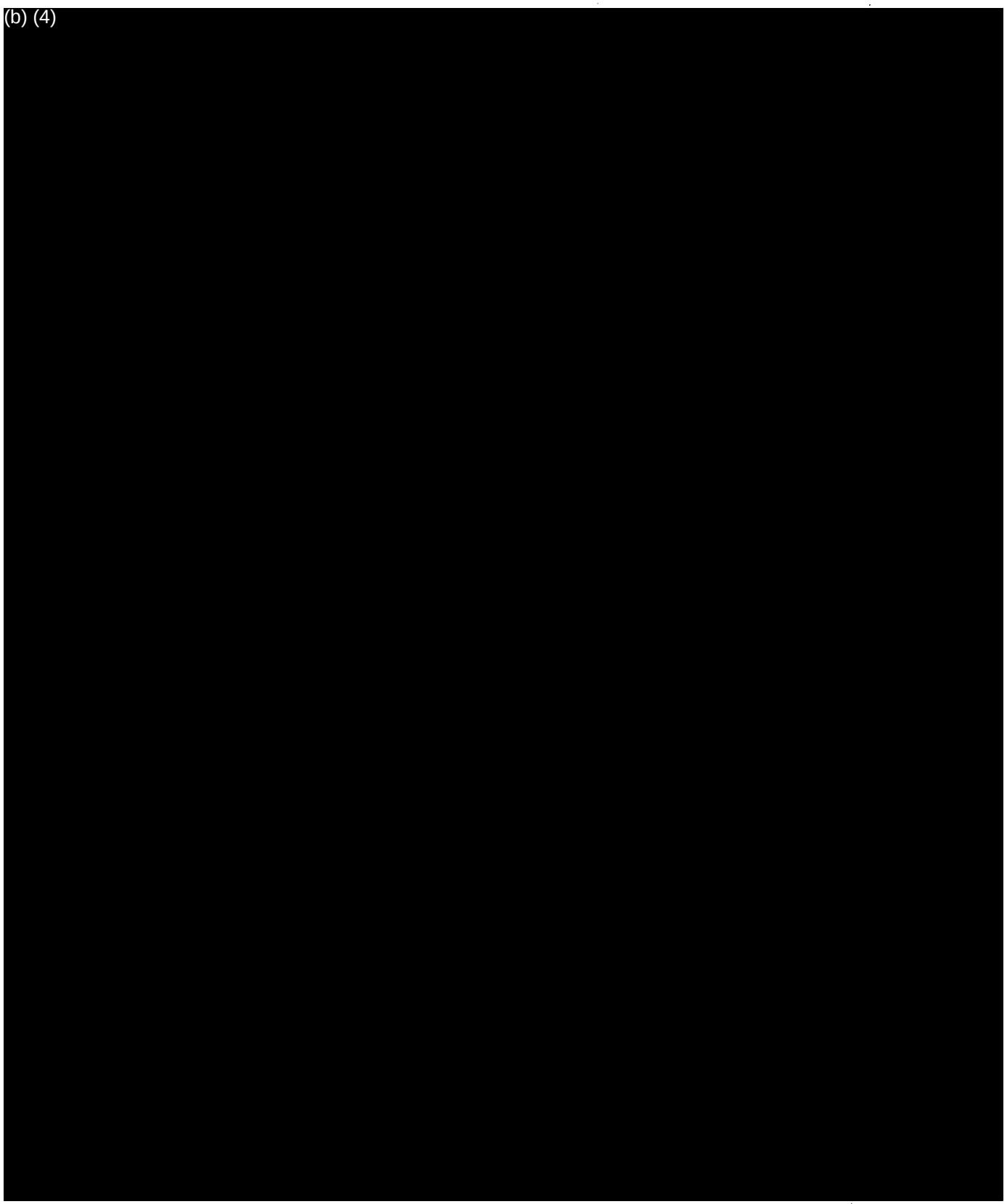
qc 01/17/08

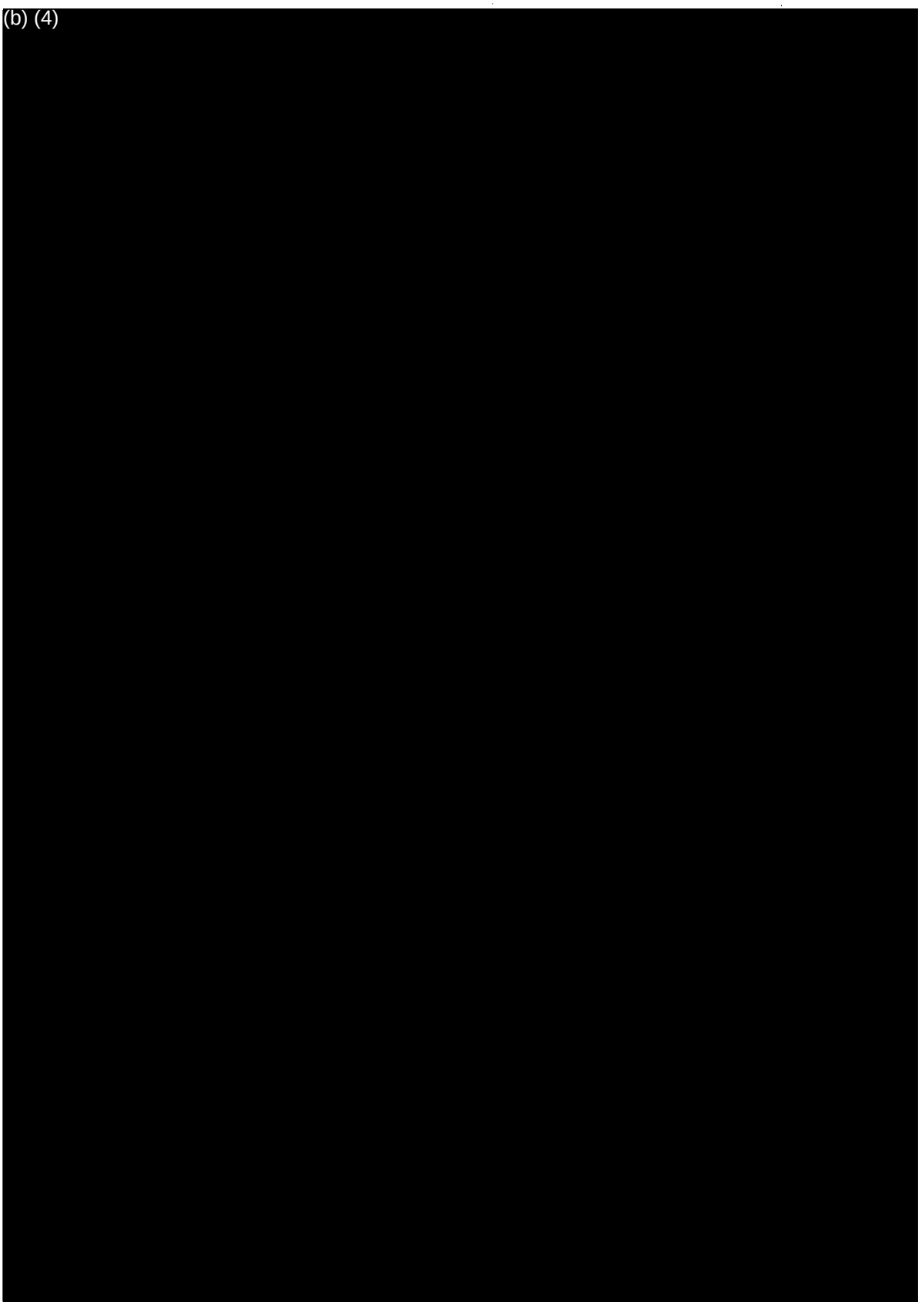
DJA x00692

(b) (4)



DJA x00693

(b) (4)



DJA x00694

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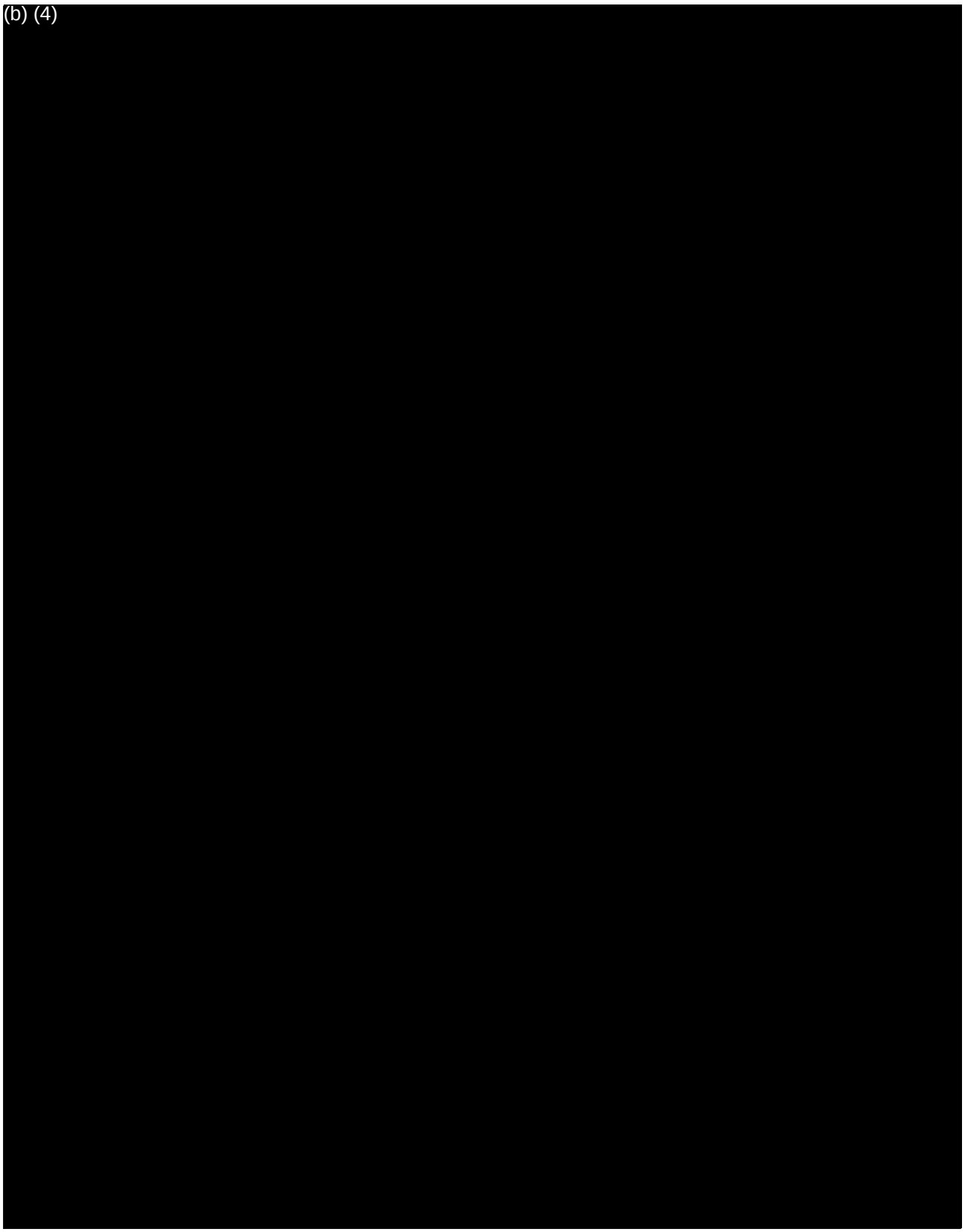

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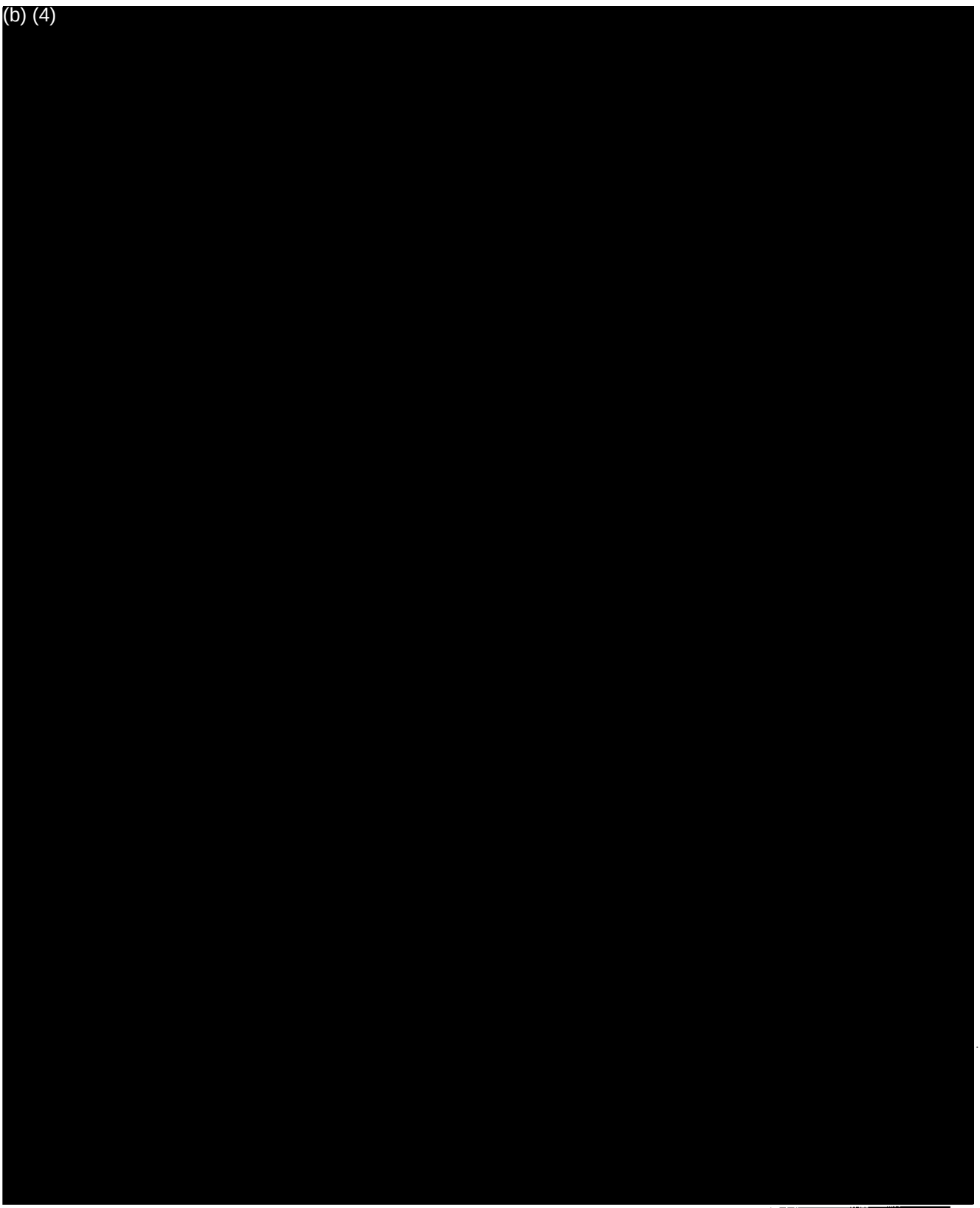

DJA x00696

(b) (4)

DJA x00697

ROBOTICS
INTEGRATED SURGICAL SYSTEMS

TEST REPORT APPROVAL SHEET

DCO # 1833

(b) (4)

[redacted]

REFERENCE COPY
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DJA x00698

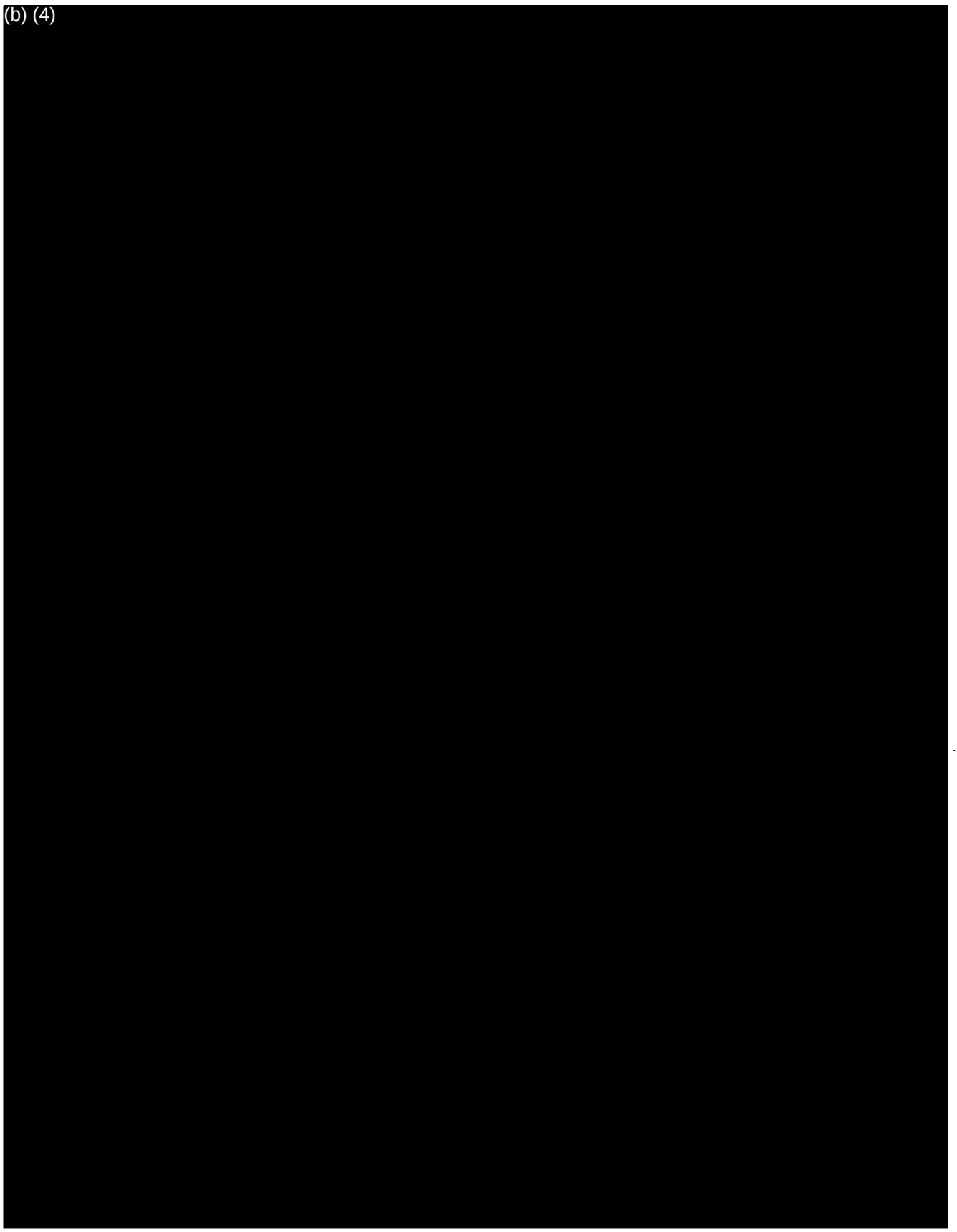
1.0 Deviations from Protocol

(b) (4)

2.0

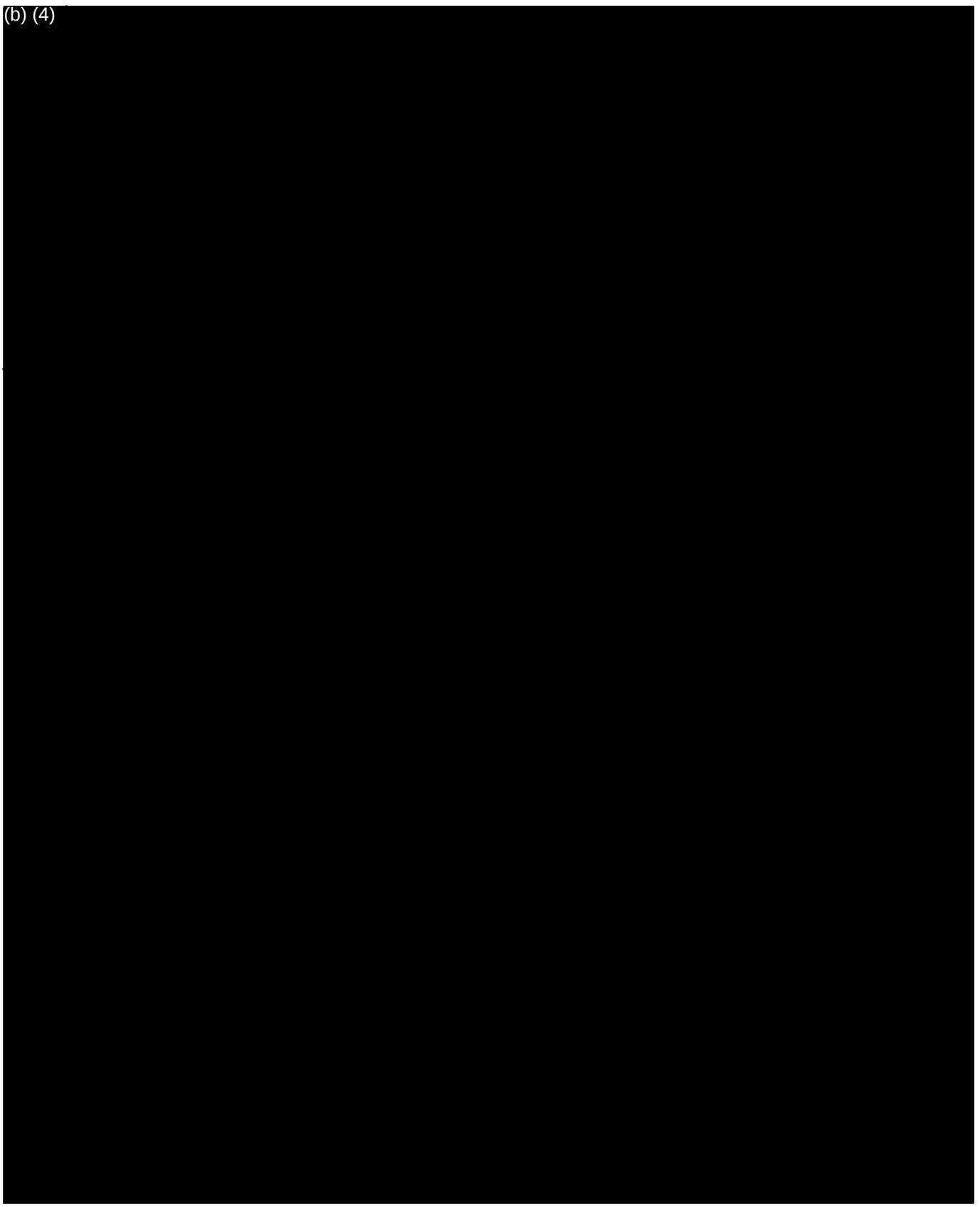
DJA x00699

(b) (4)



DJA x00700

(b) (4)



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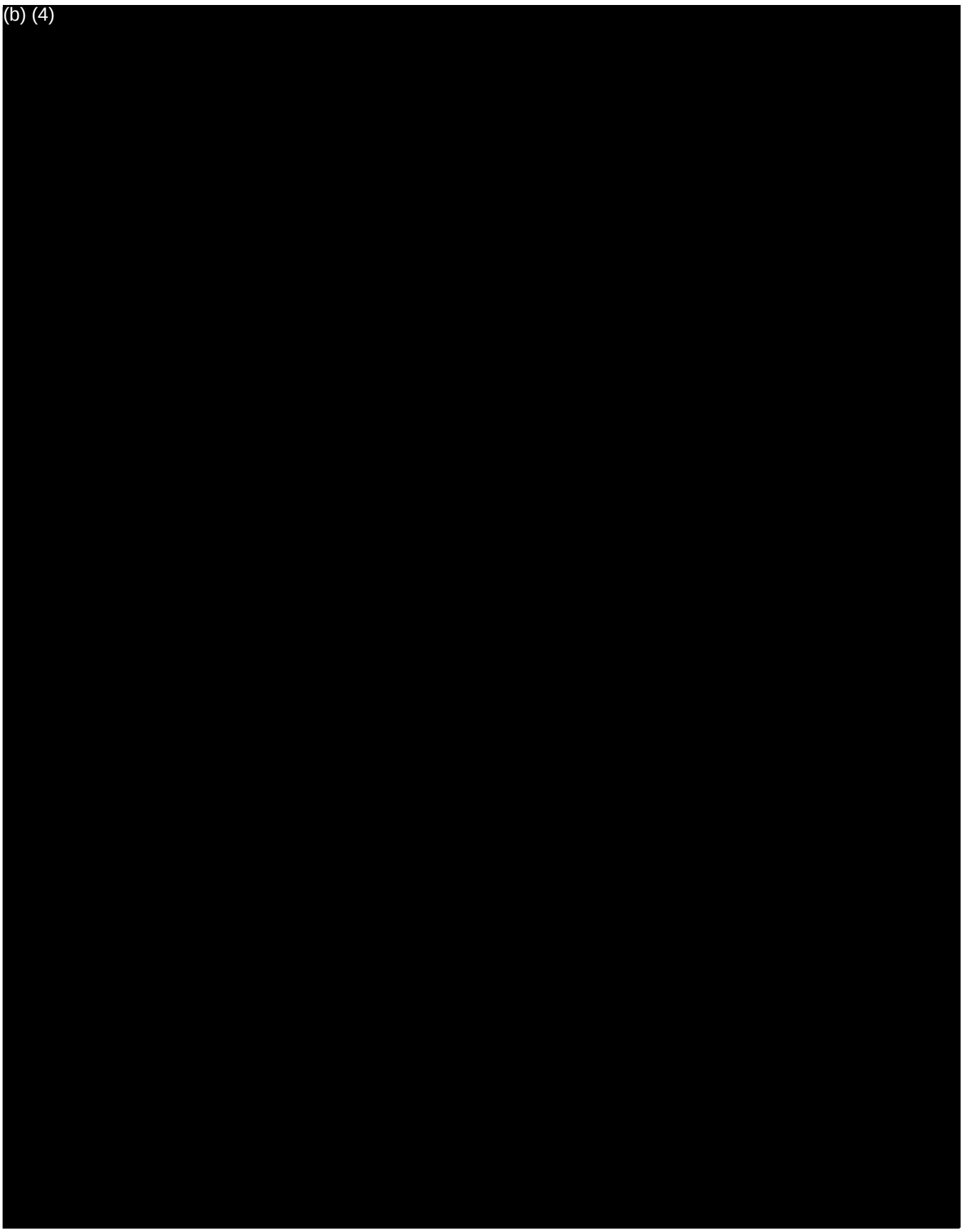
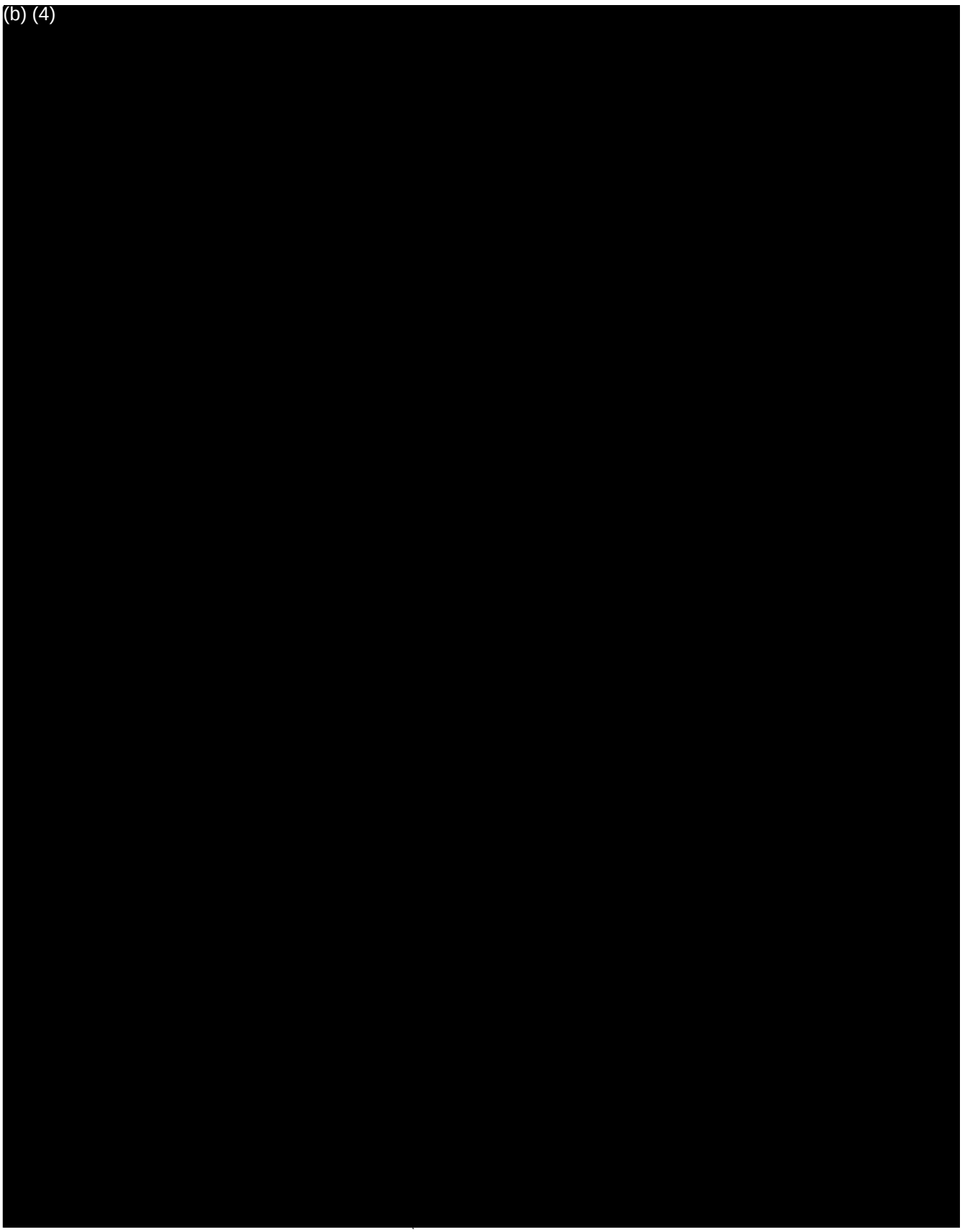
(b) (4)



DJA x00702

(b) (4)



DJA x00703

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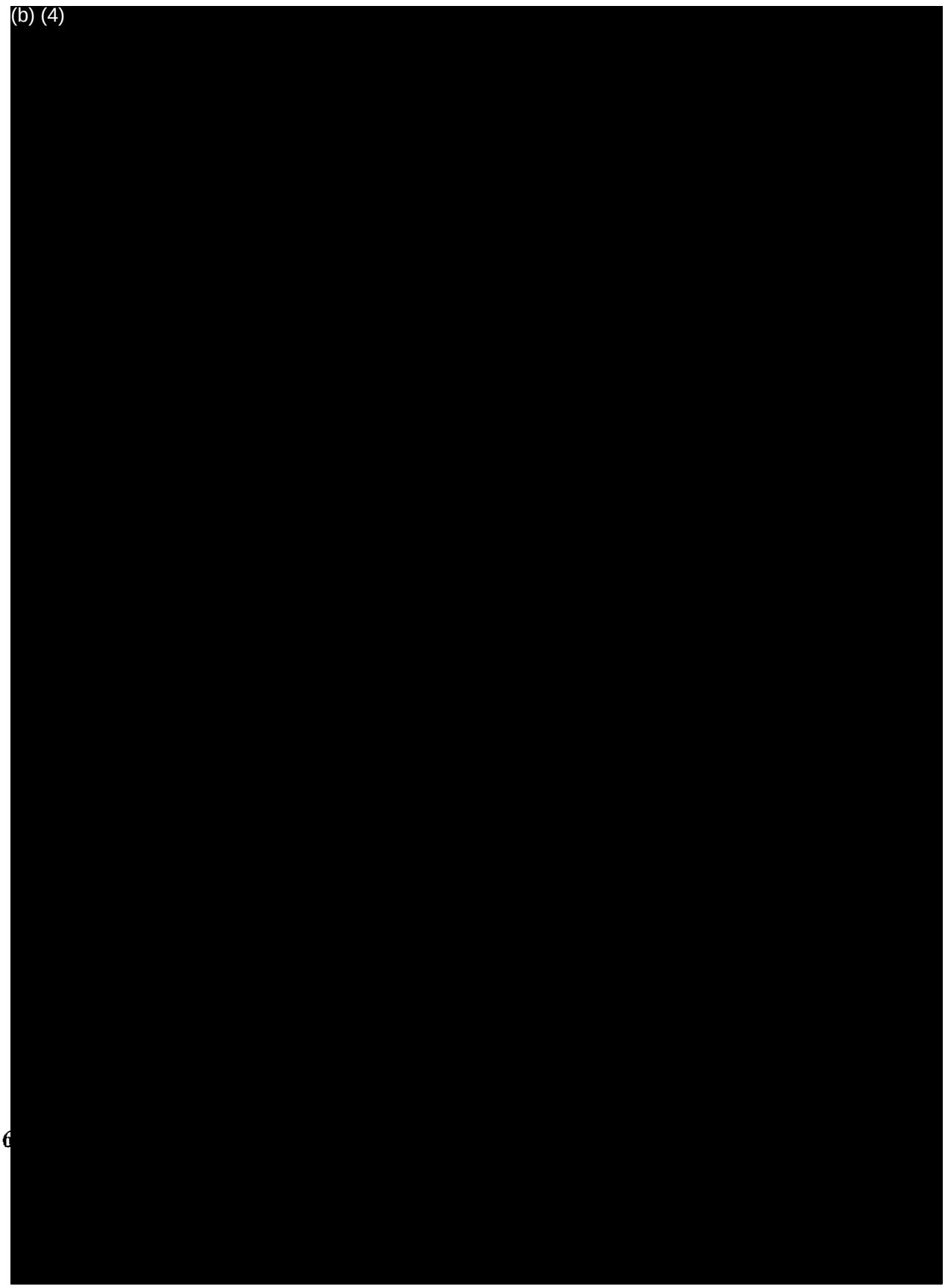
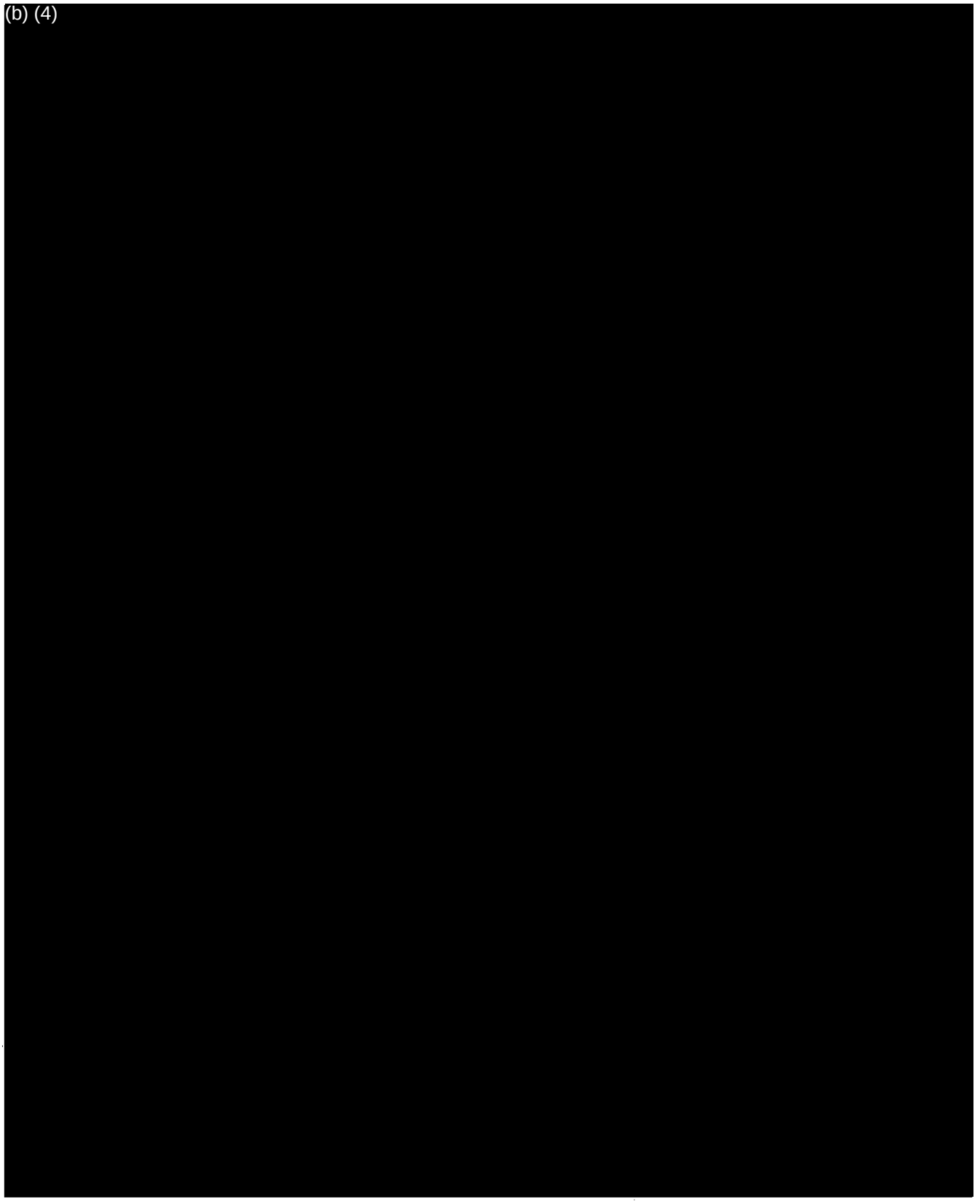


6

DJA x00704

(b) (4)



DJA x00705

DCO # 1912

PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 6
KEY WORDS: THR Procedural Flow Test	PROTOCOL REF. NO. (If applicable)	PROJECT NO.:. (If applicable) RDE-041

(b) (4)

[redacted]

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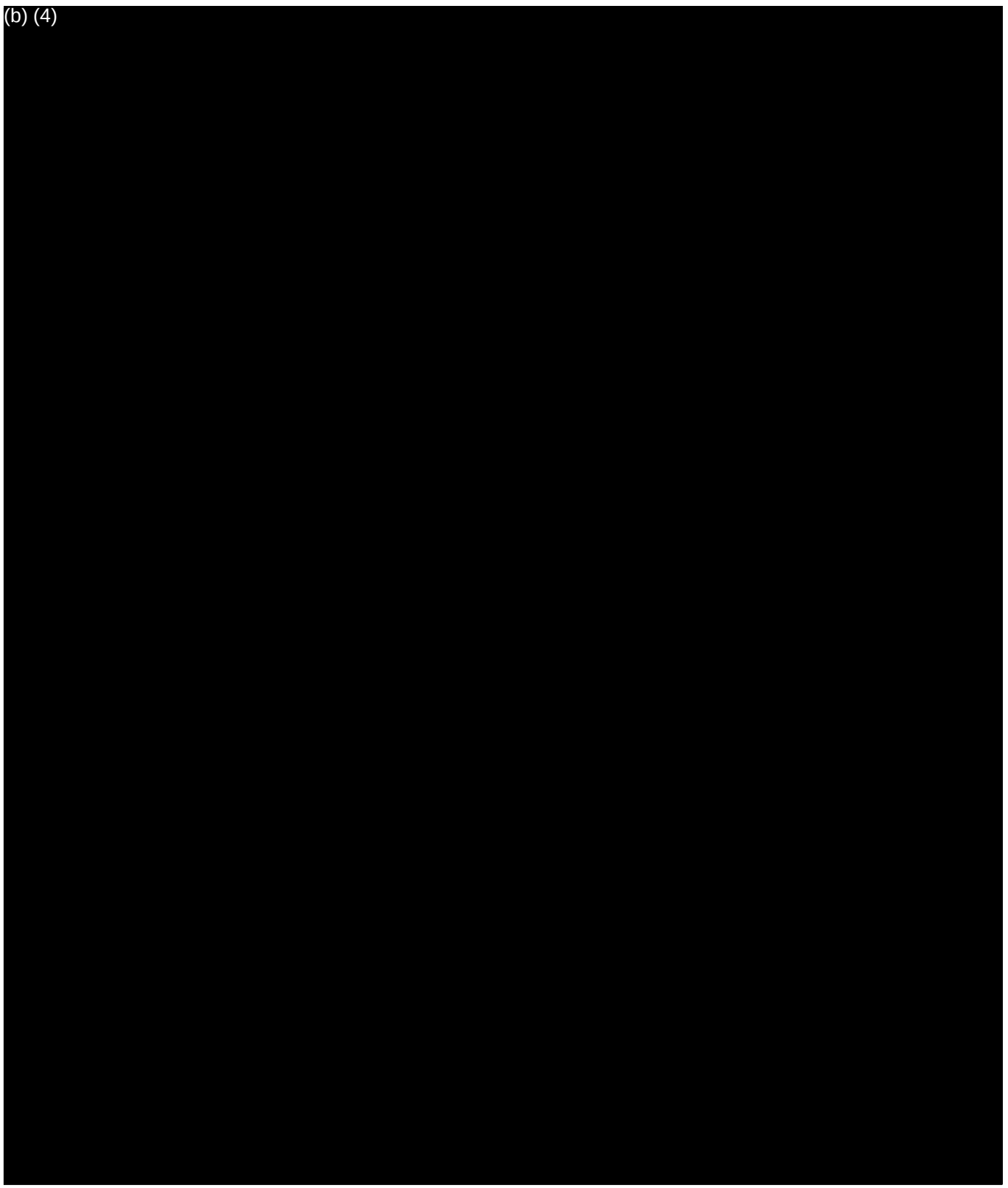
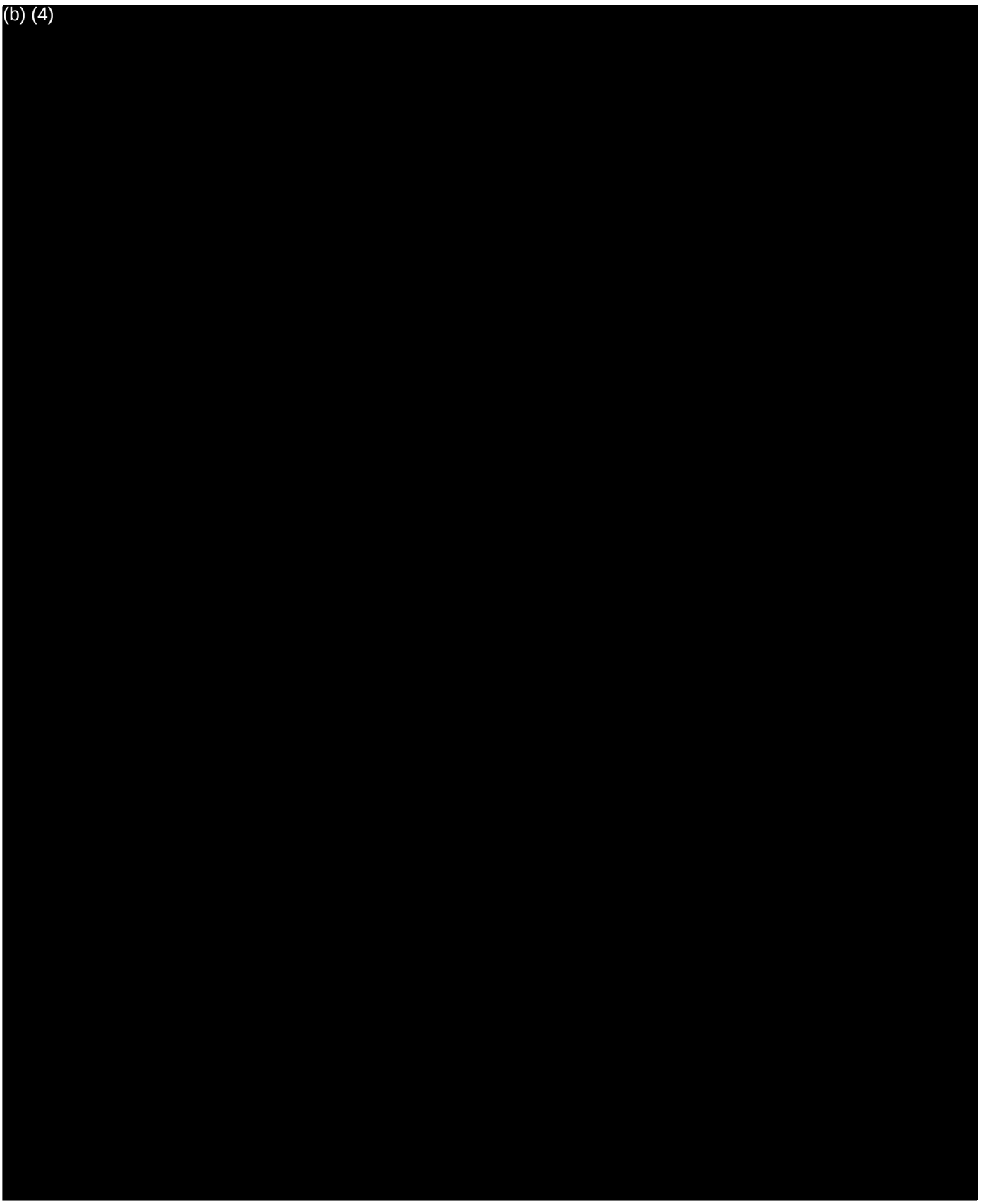
DJA x00706

(b) (4)



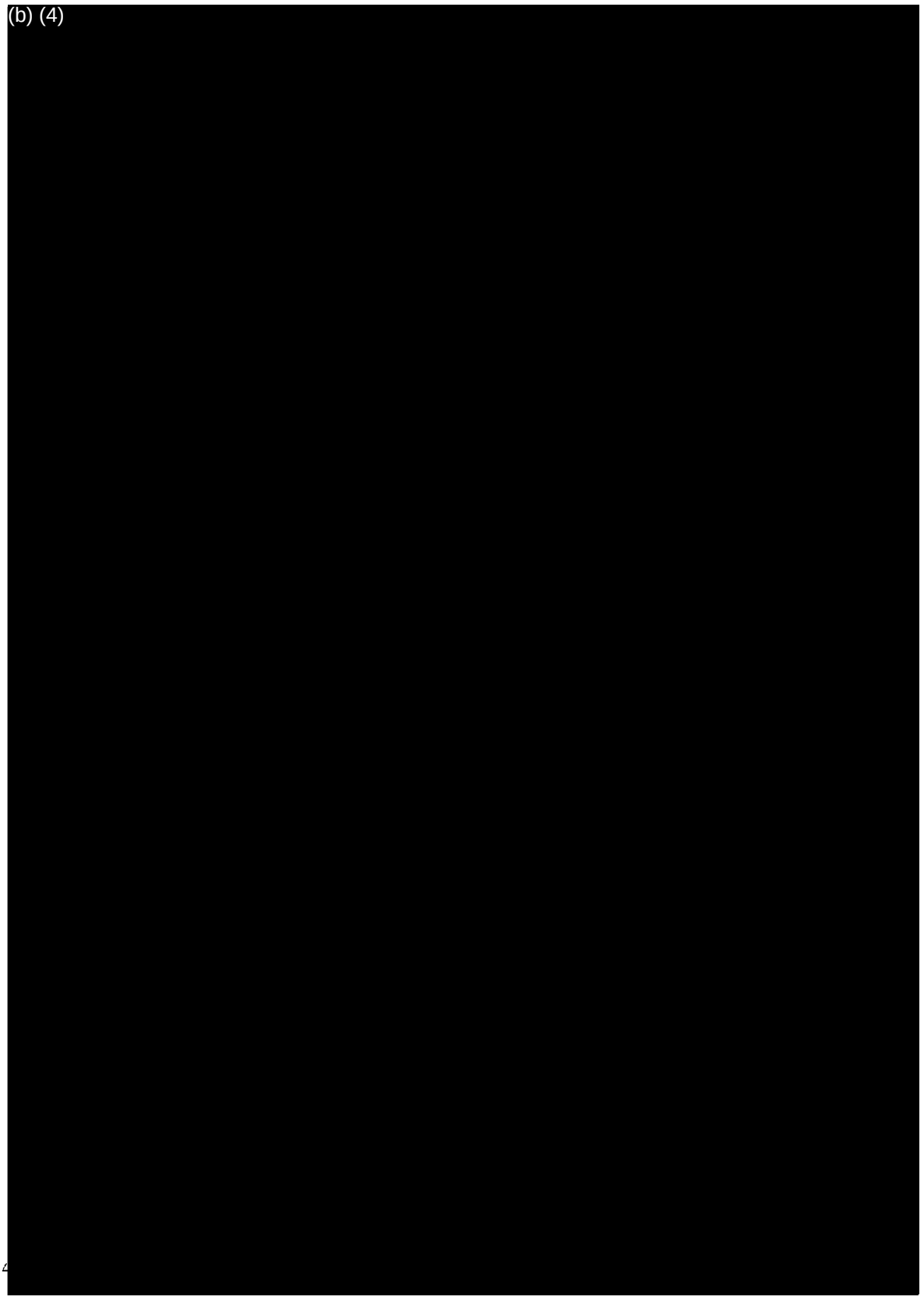
DJA x00707

(b) (4)



DJA x00708

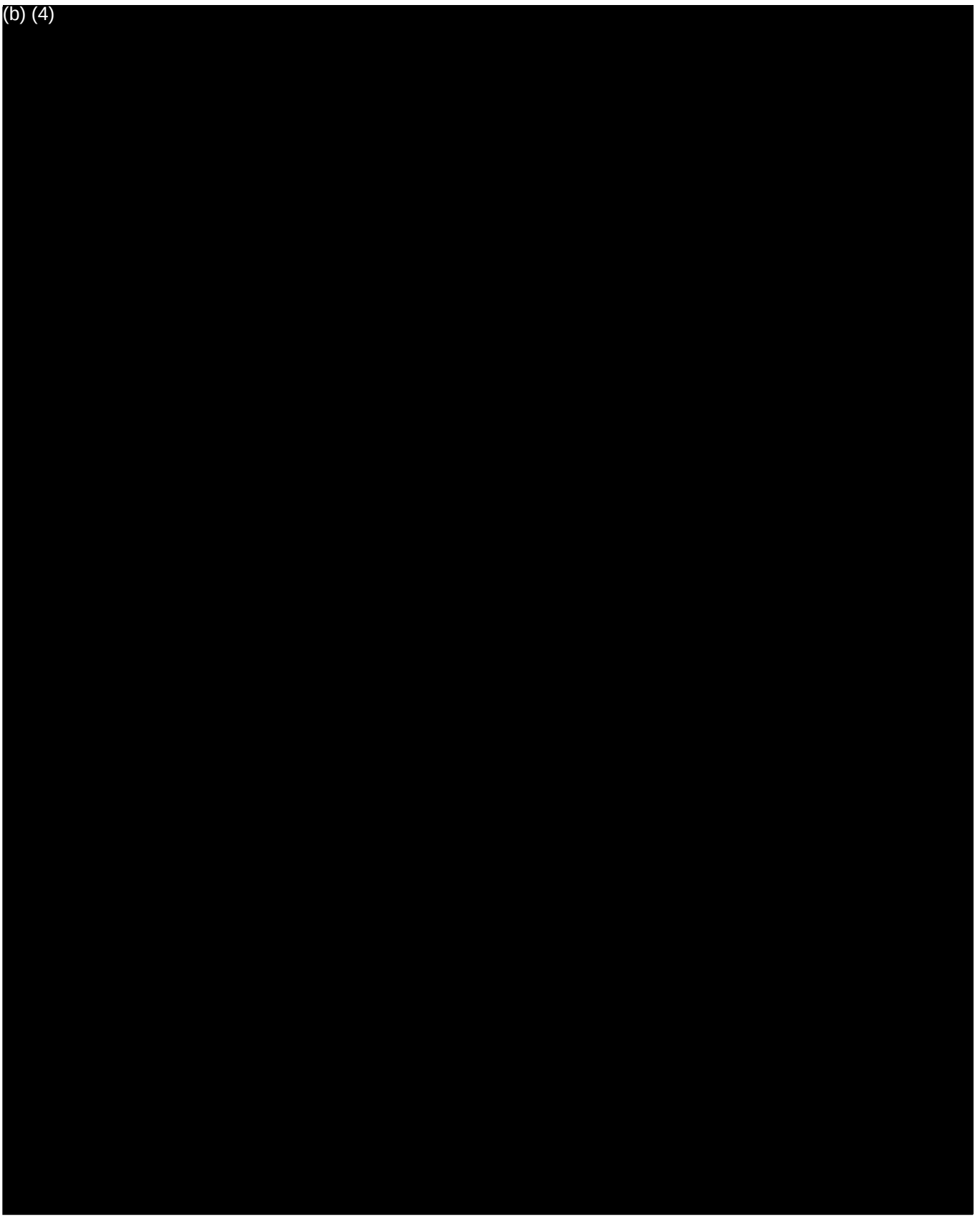
(b) (4)



8.4

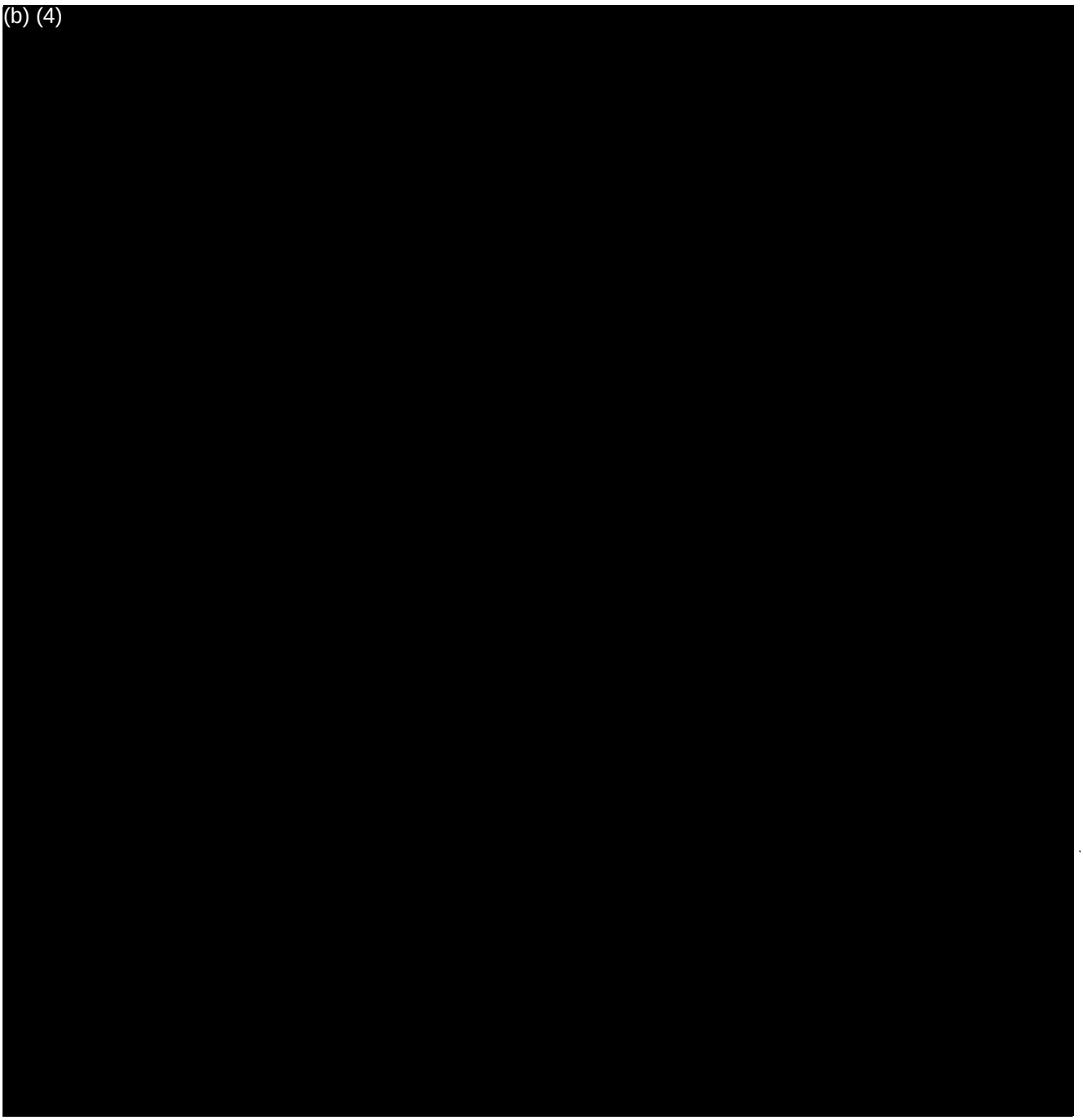
DJA x00709

(b) (4)



DJA x00710

(b) (4)



DJA x00711

DCO # 1912

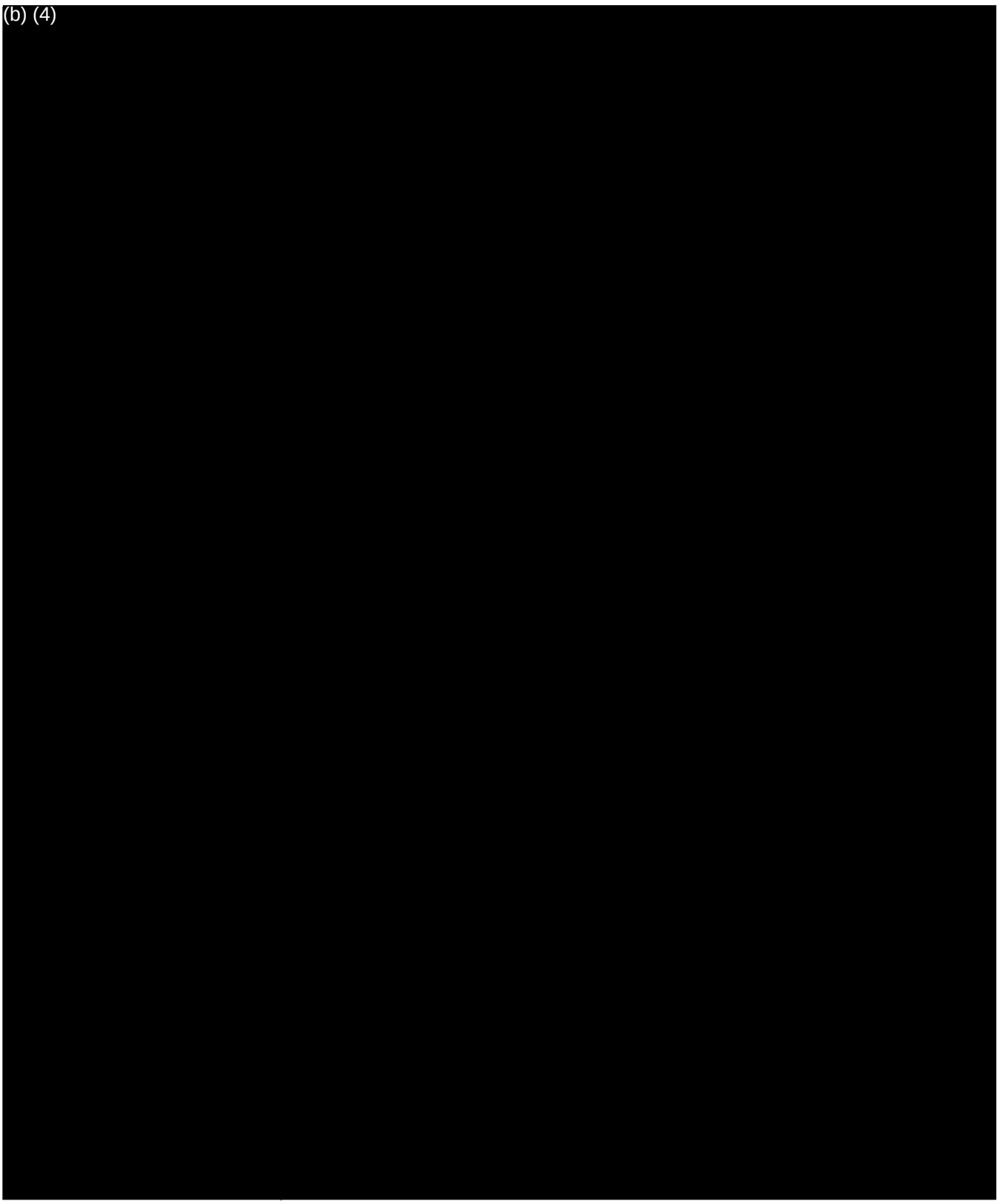
PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 6
KEY WORDS: THR Procedural Flow Test	PROTOCOL REF. NO. (If applicable)	PROJECT NO.: (If applicable) RDE-041

(b) (4)

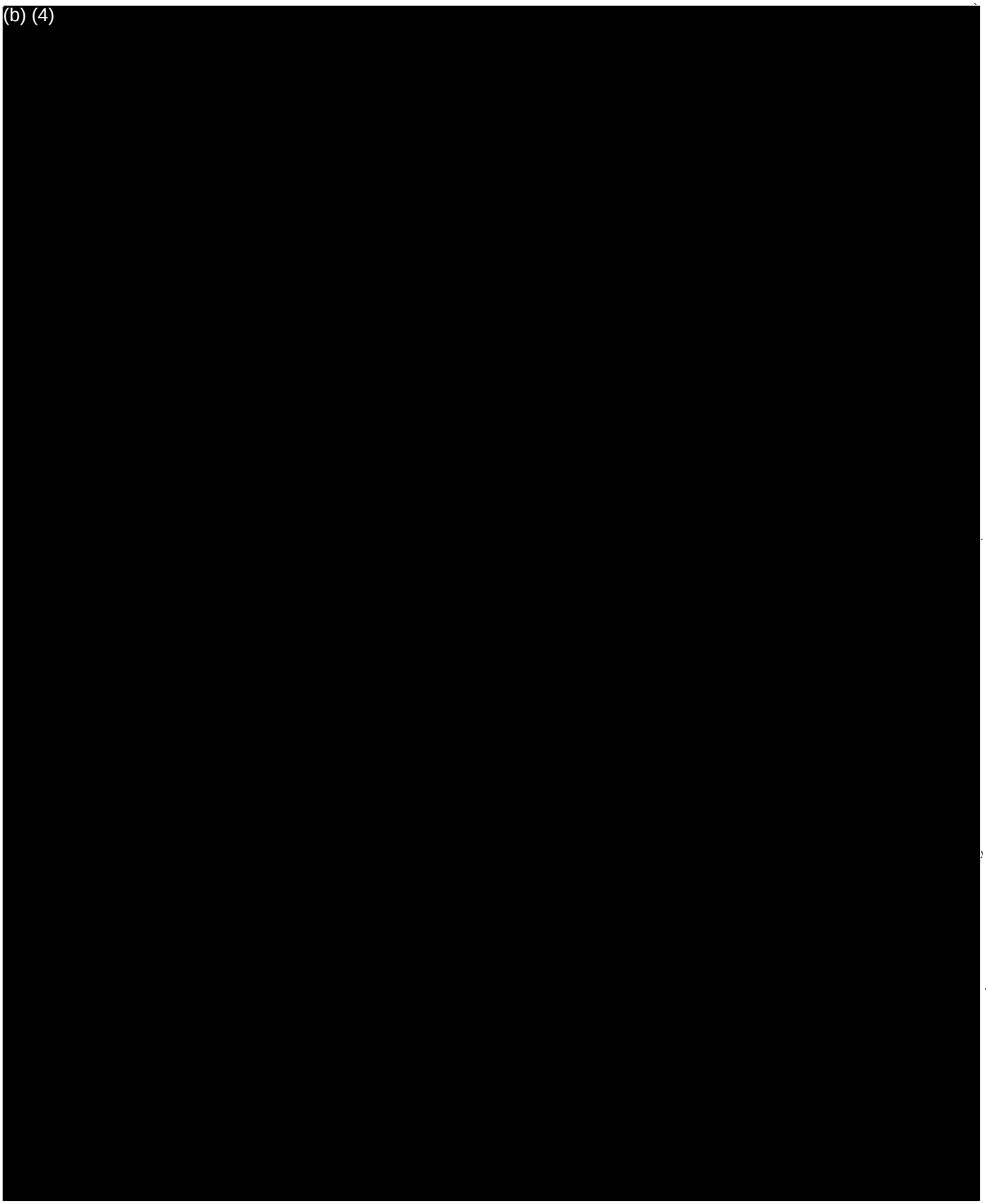
DJA x00712

(b) (4)



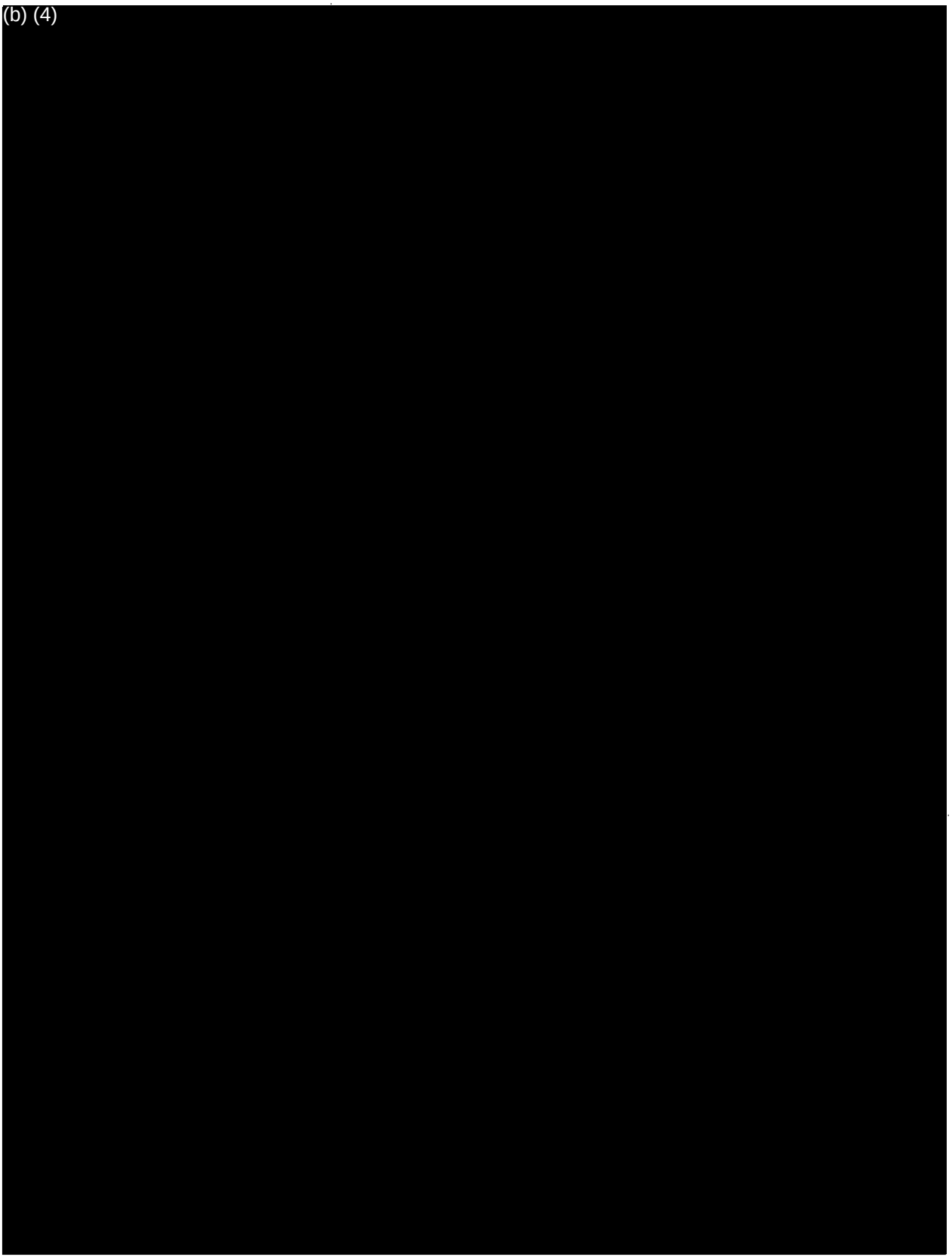
DJA x00713

(b) (4)



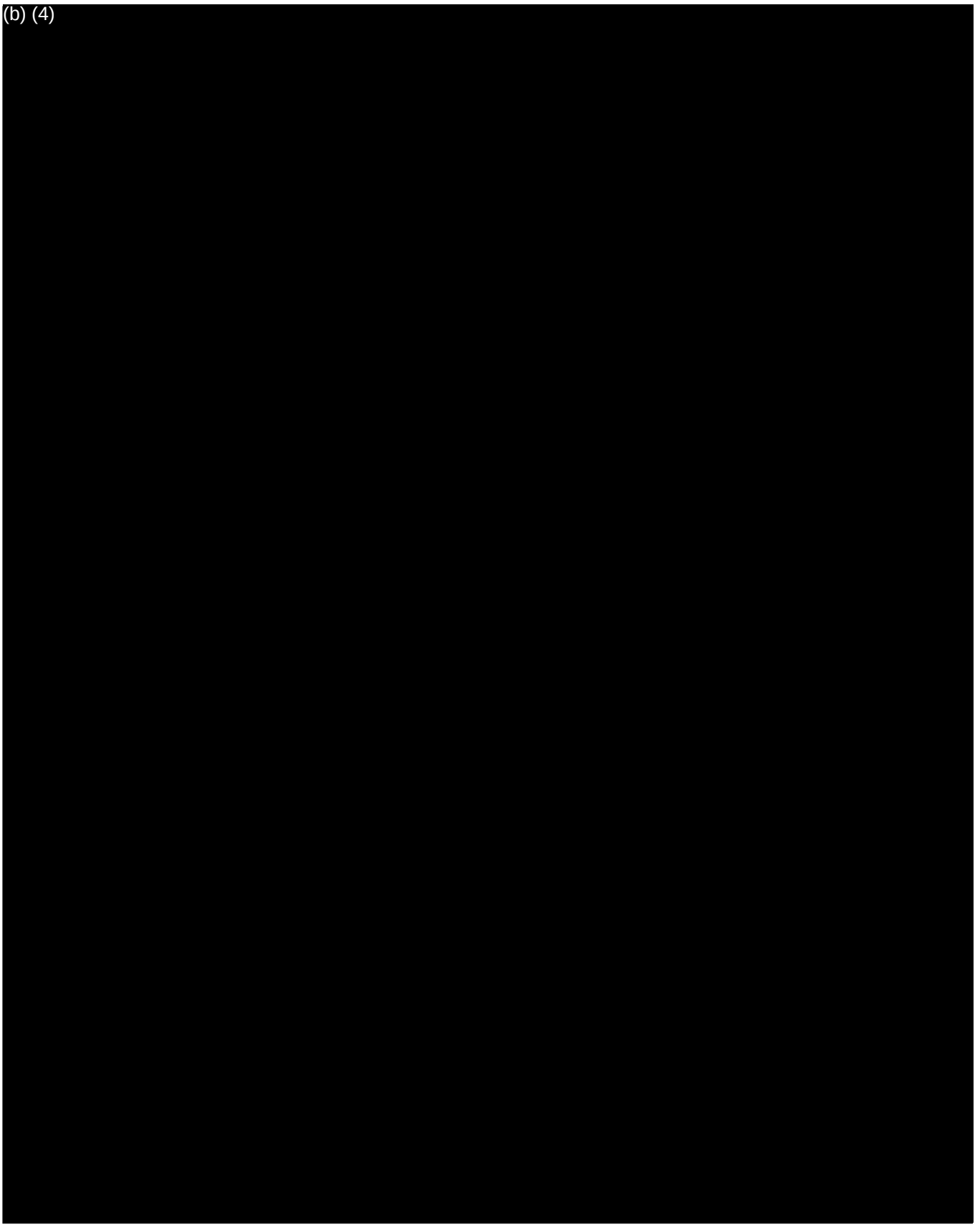
DJA x00714

(b) (4)



DJA x00715

(b) (4)



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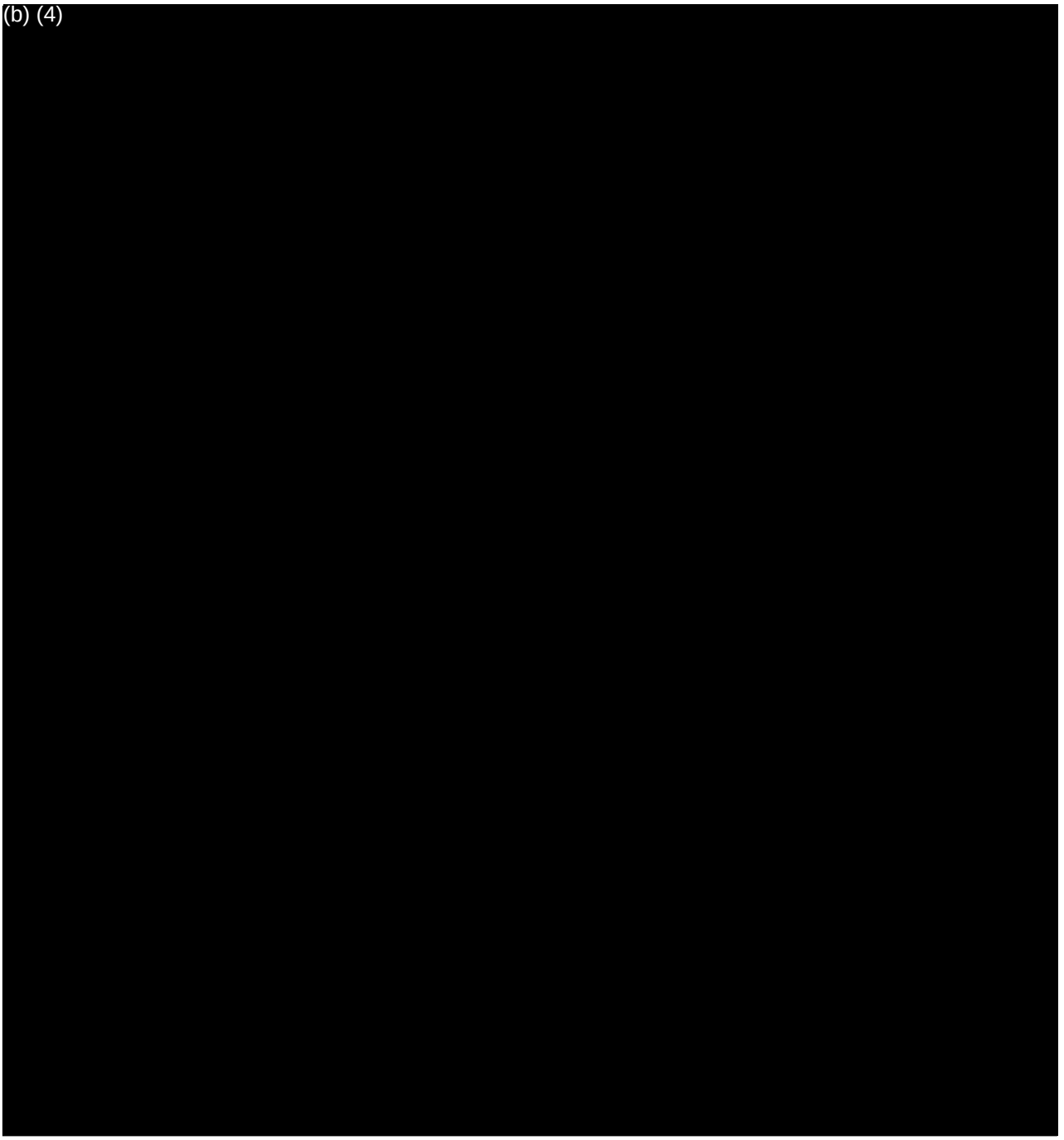

DJA x00717

DCO # 1912

TEST REPORT APPROVAL SHEET

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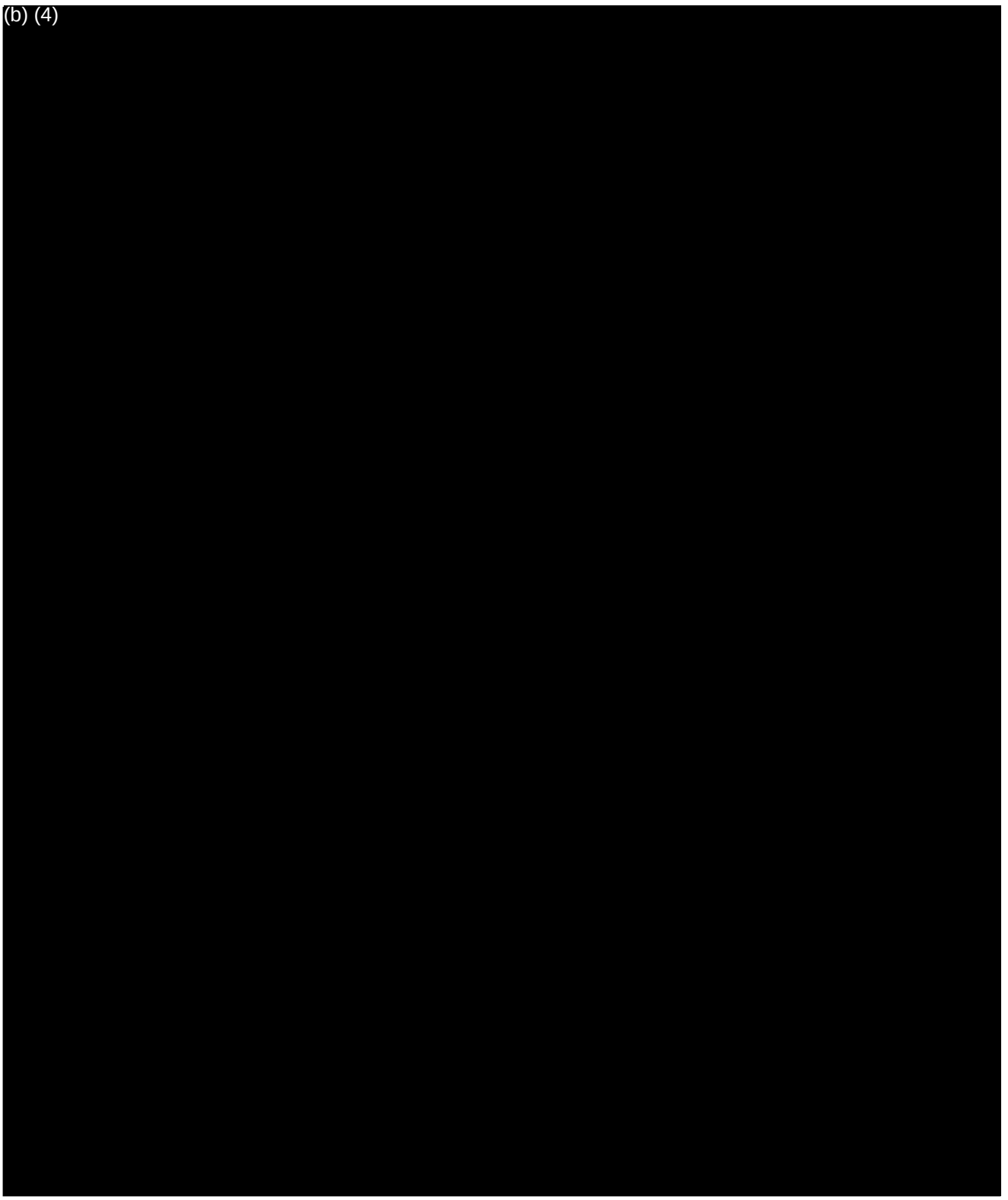
REFERENCE COPY

DJA x00718

(b) (4)



DJA x00719

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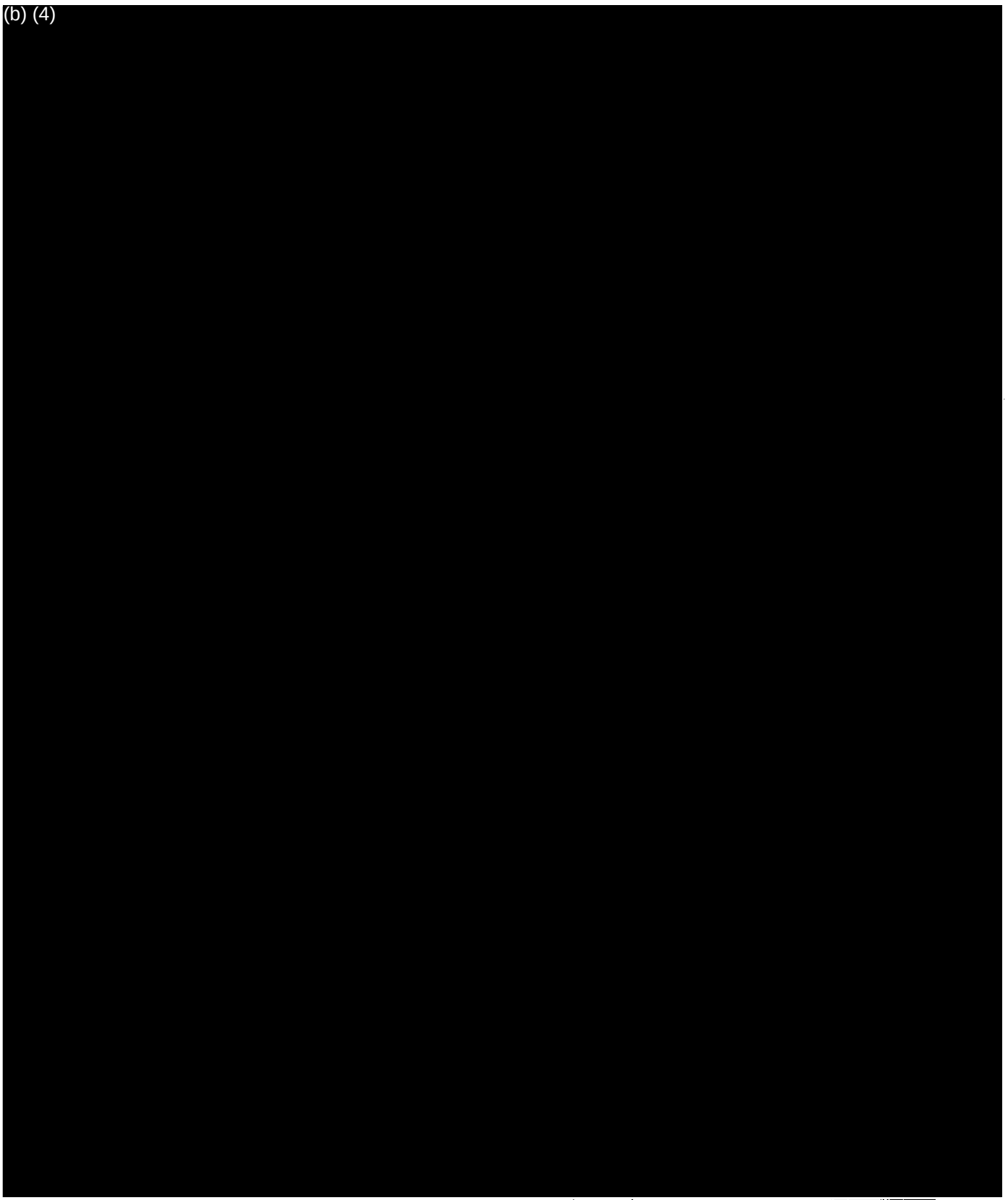
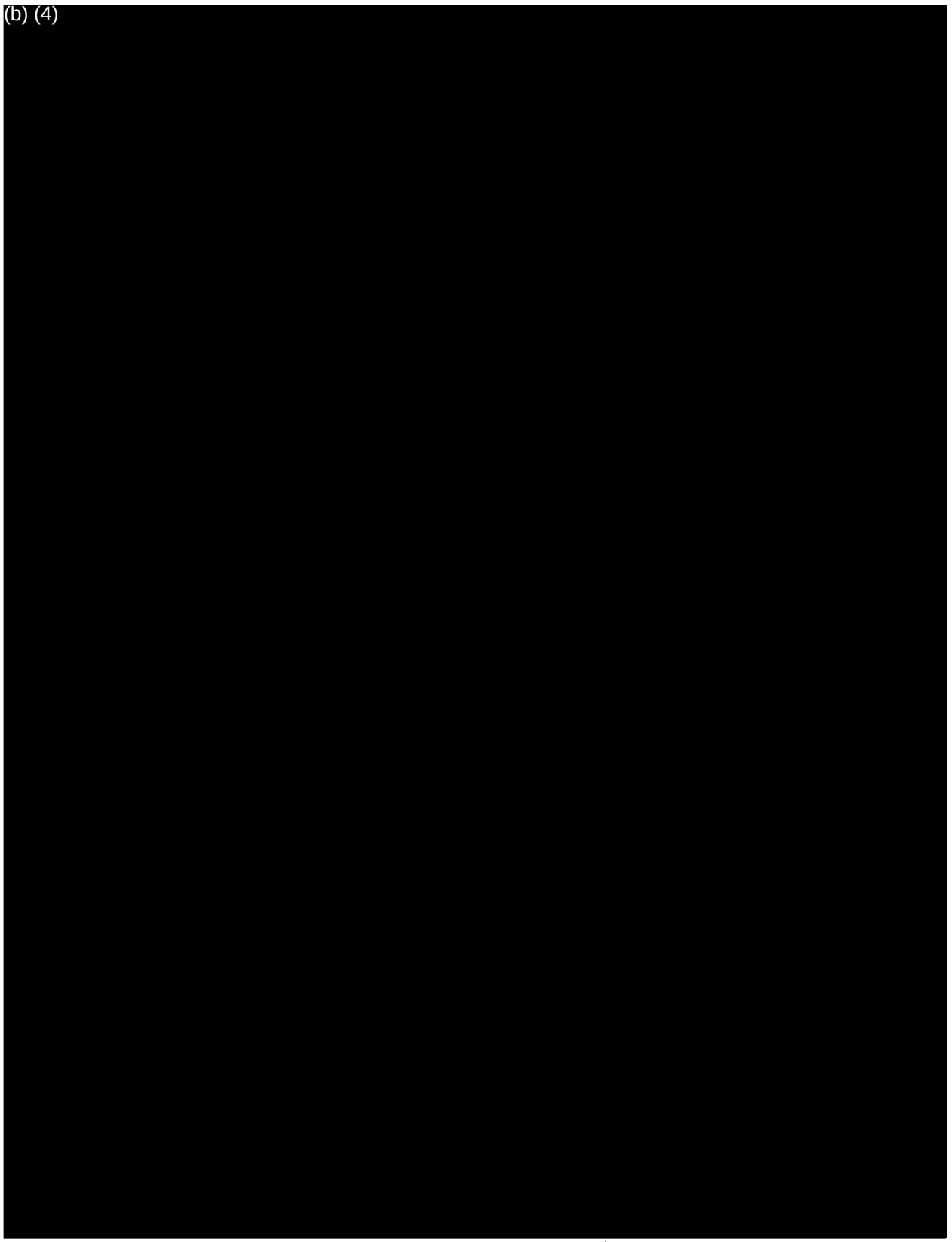


DJA x00720

(b) (4)



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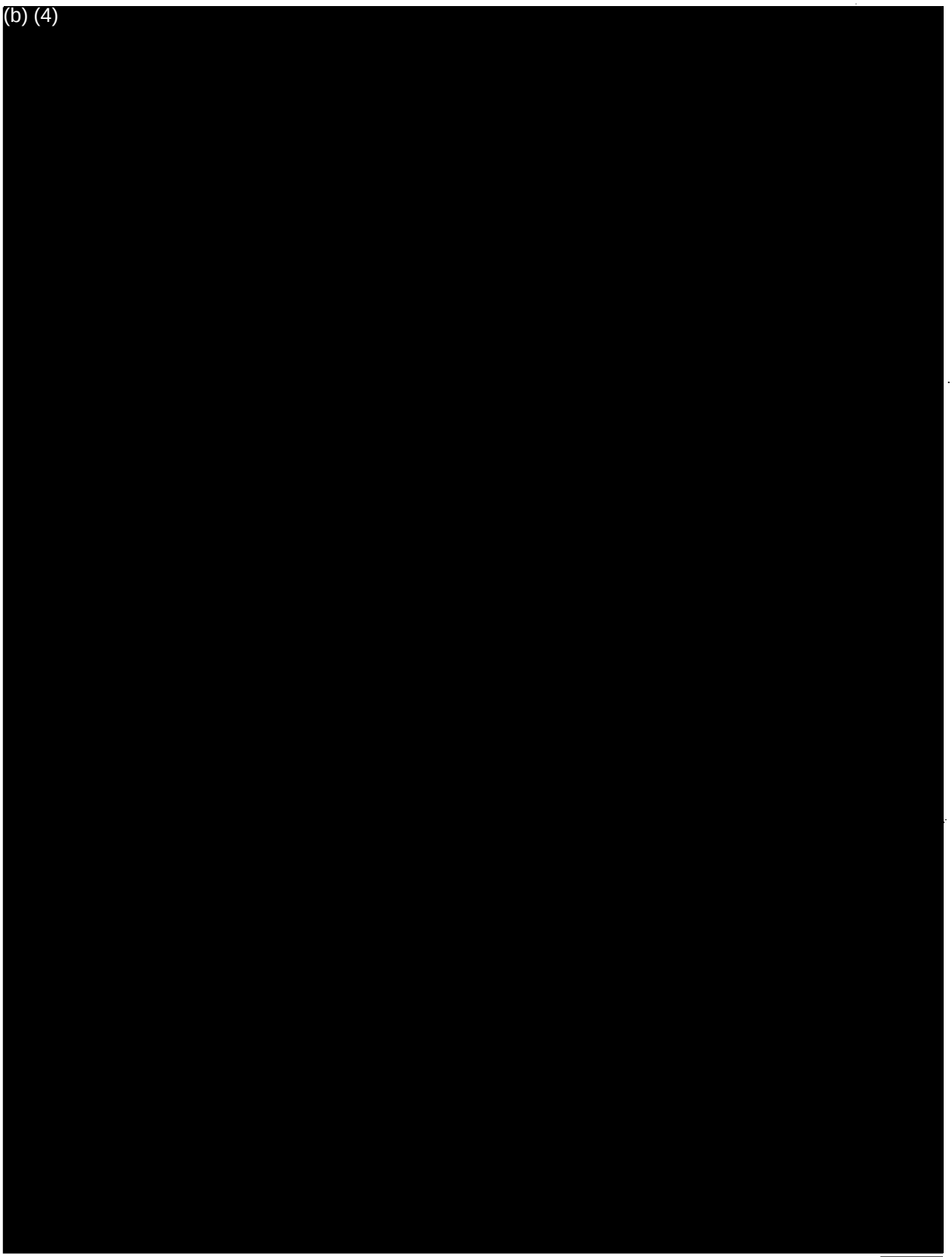

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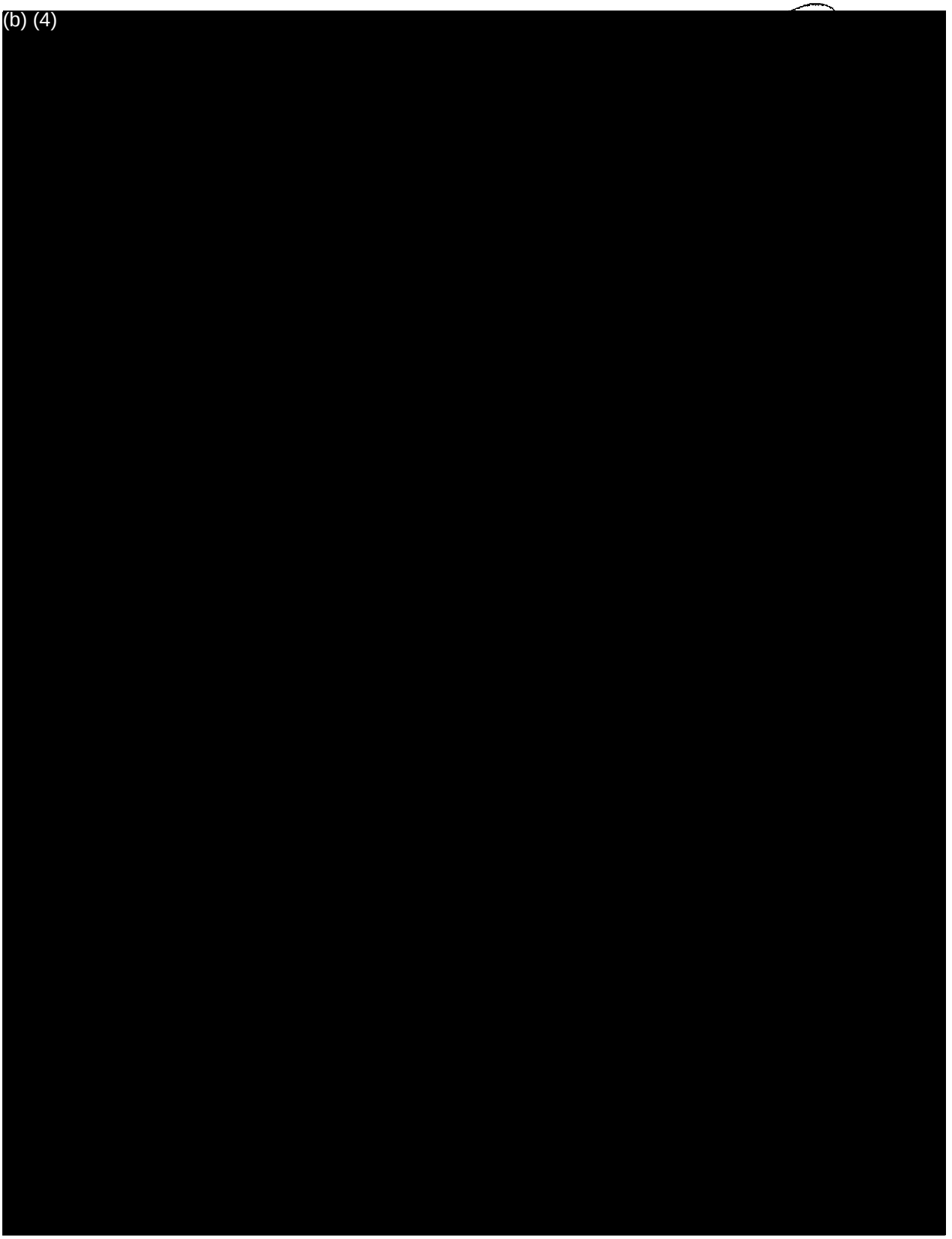

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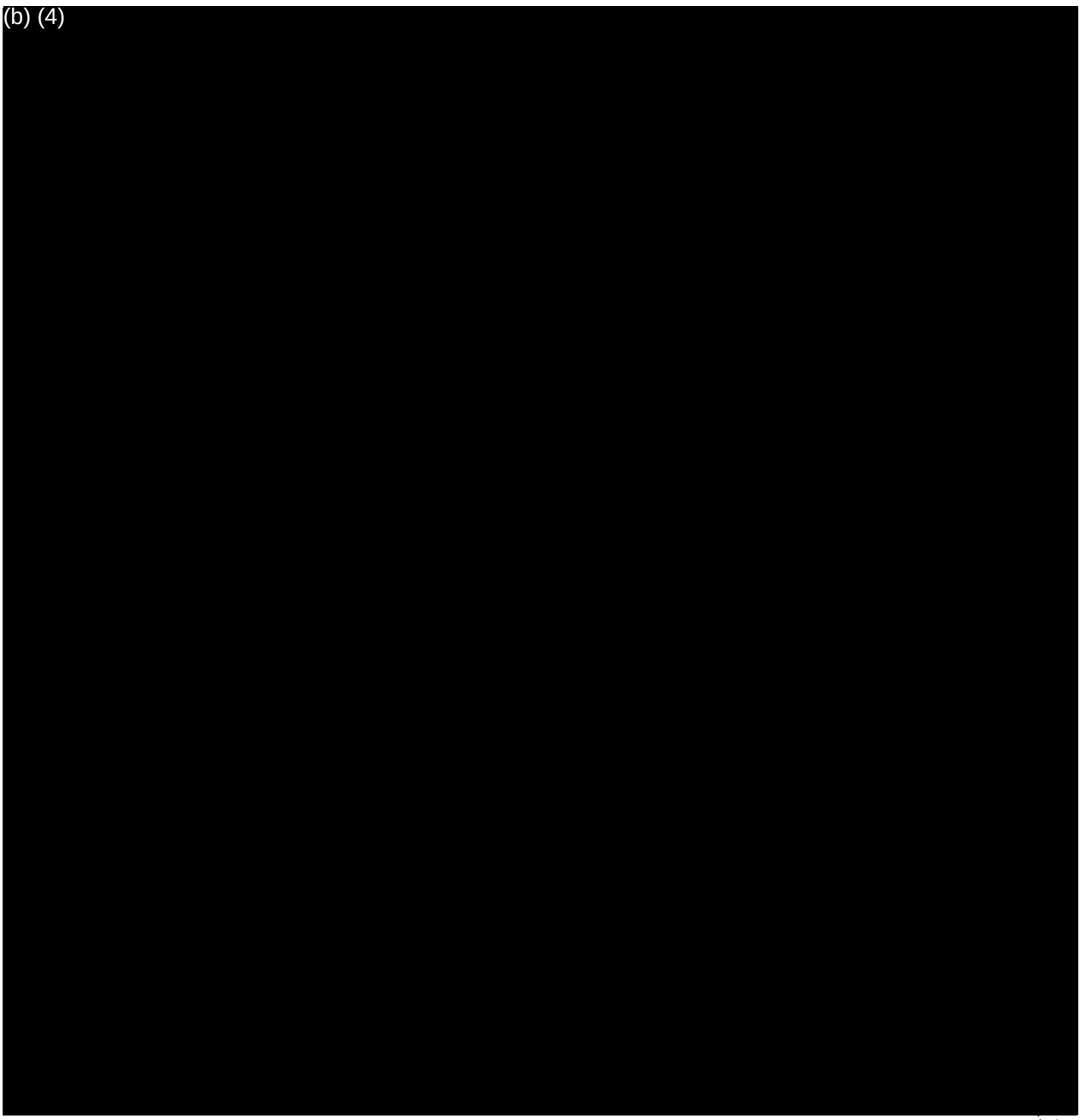

DJA x00724

DCO # 1912

TEST REPORT APPROVAL SHEET

(b) (4)

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REFERENCE COPY
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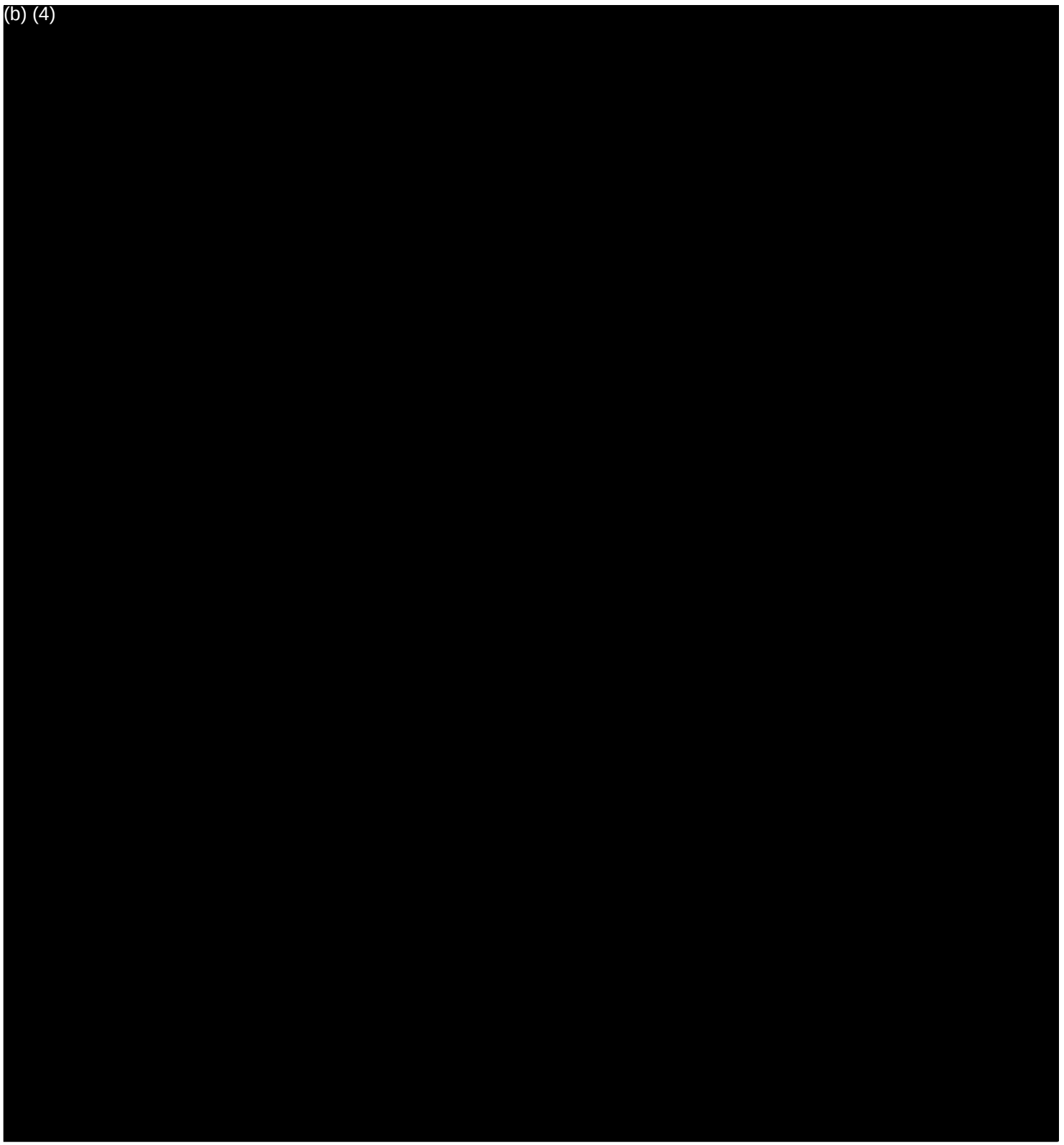
DJA x00725

(b) (4)



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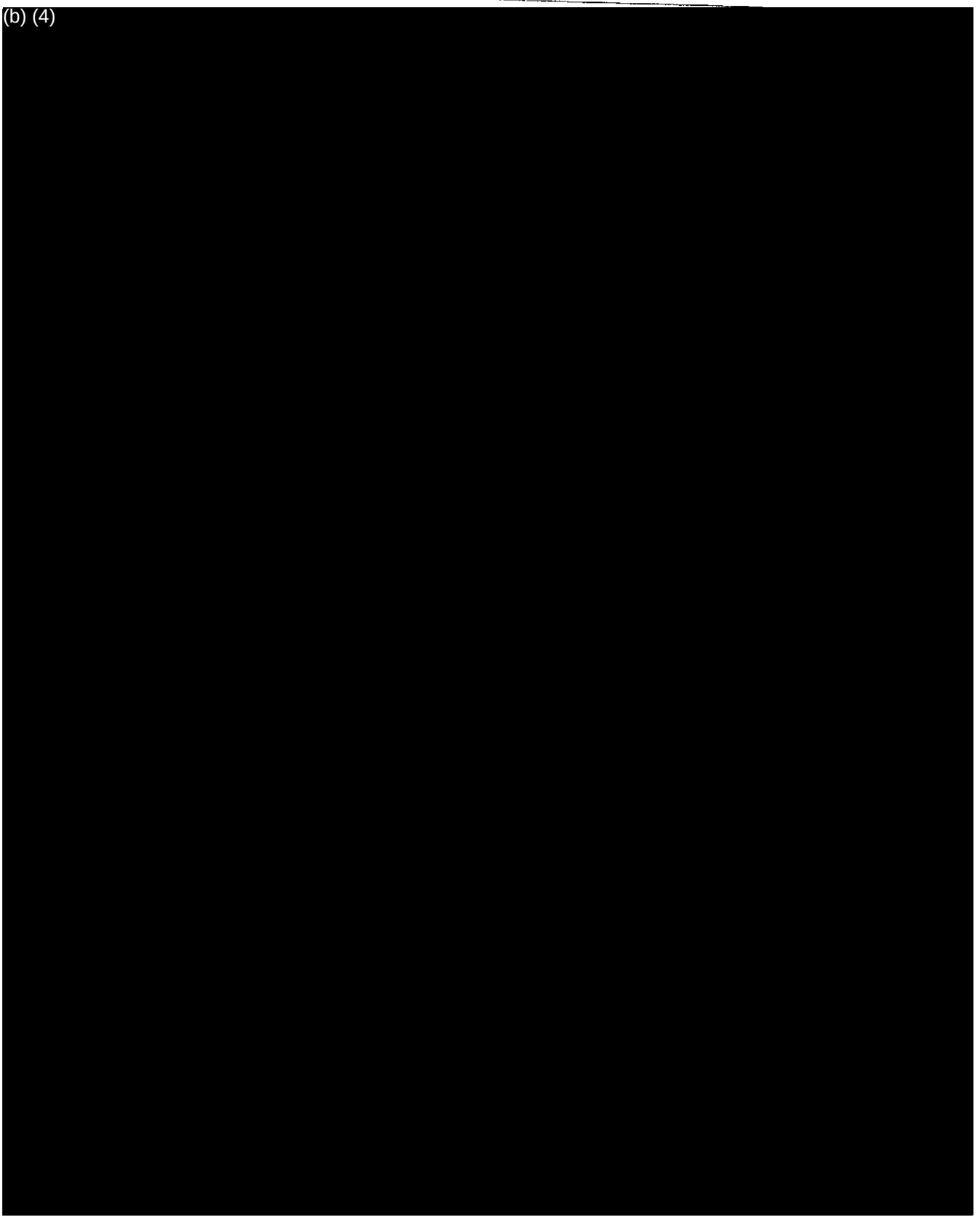

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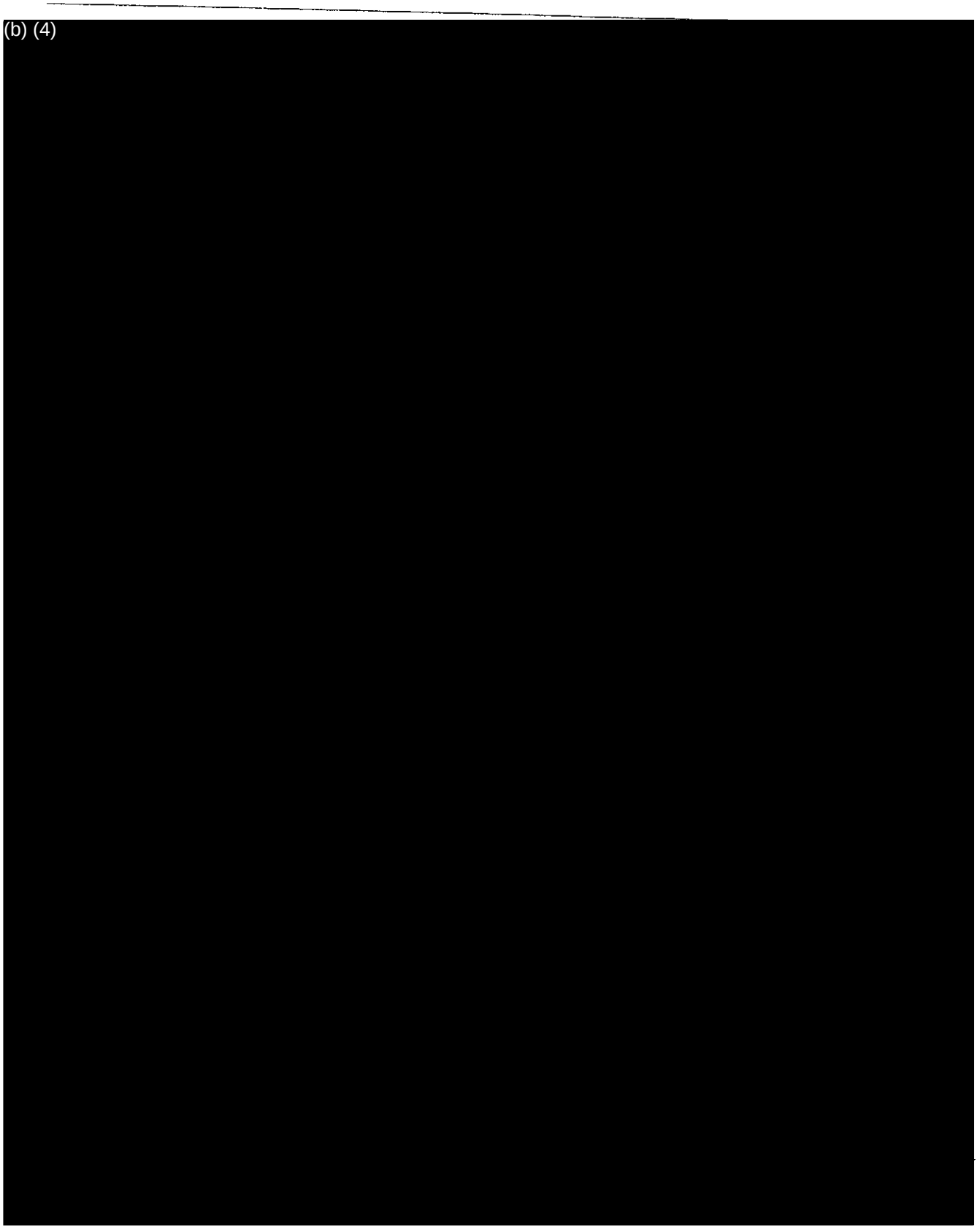
(b) (4)



DJA x00728

(b) (4)

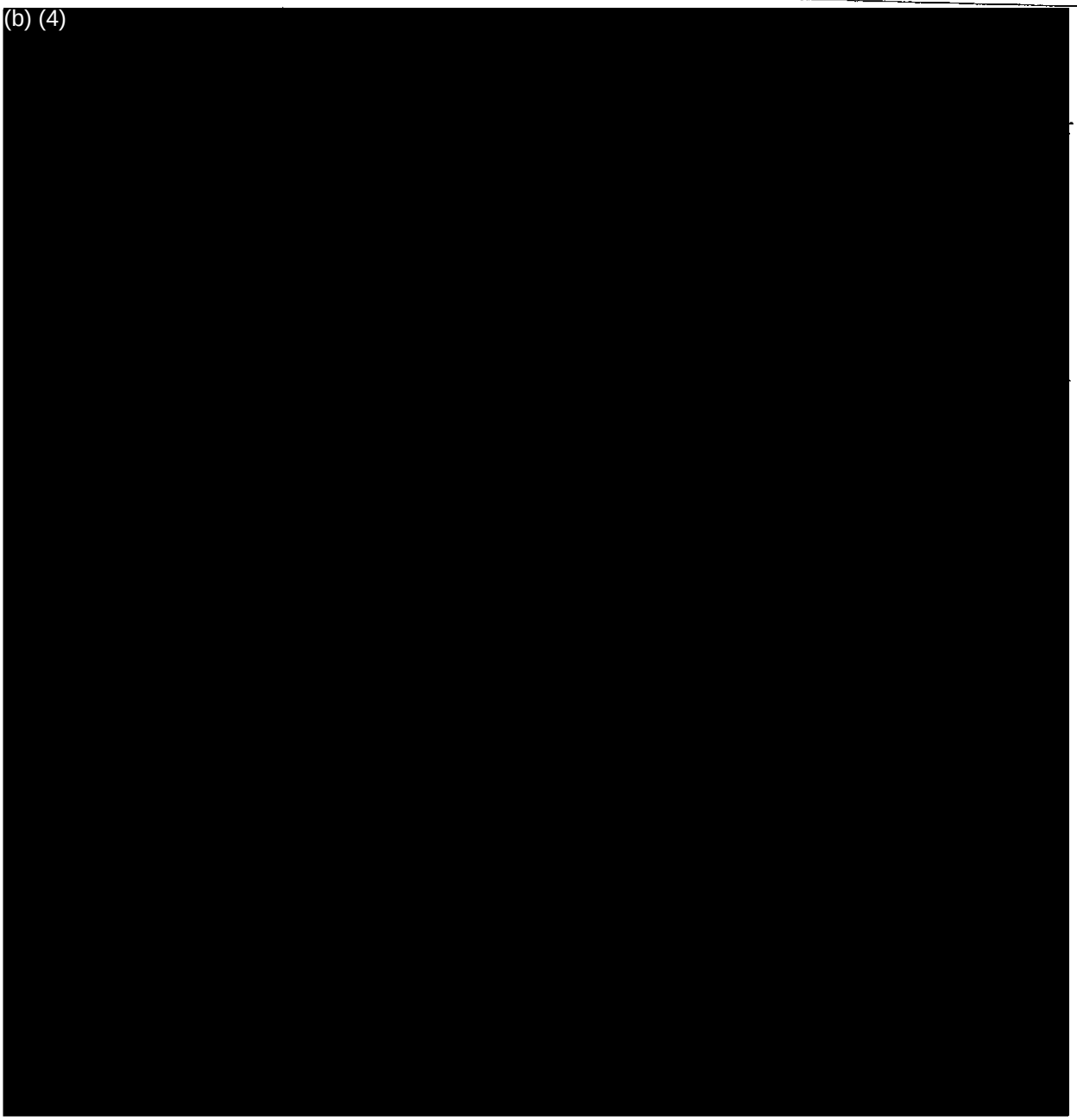
DJA x00729

(b) (4)

6

DJA x00730

(b) (4)



DJA x00731

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1767

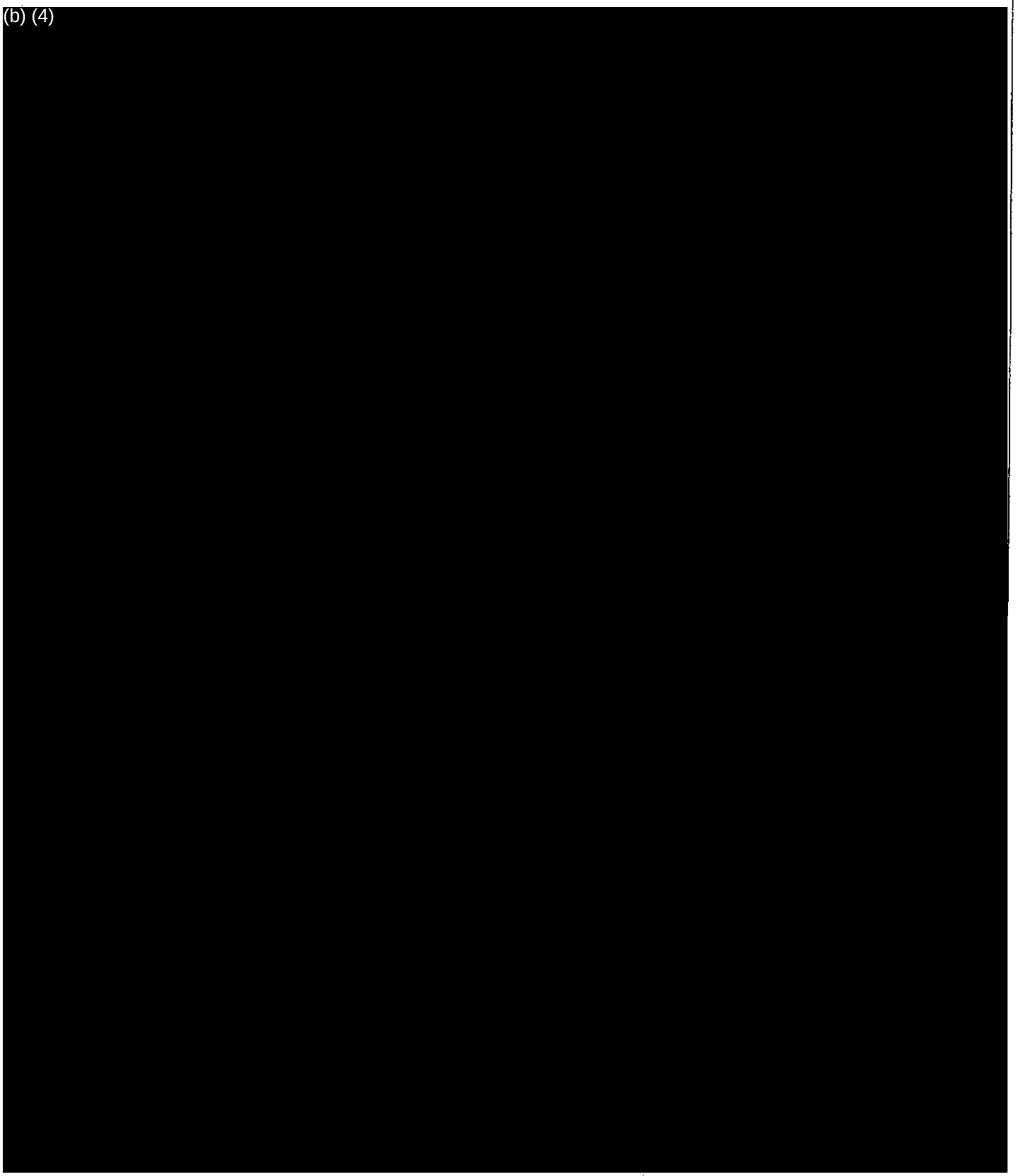
(b) (4)

REFERENCE COPY
qc 01/17/08

DJA x00732

Results (Attach additional sheets if necessary):

(b) (4)



DJA x00733

TECHNICAL STUDY (TS)

Study Control Number

(b) (4)

DCO # 1767

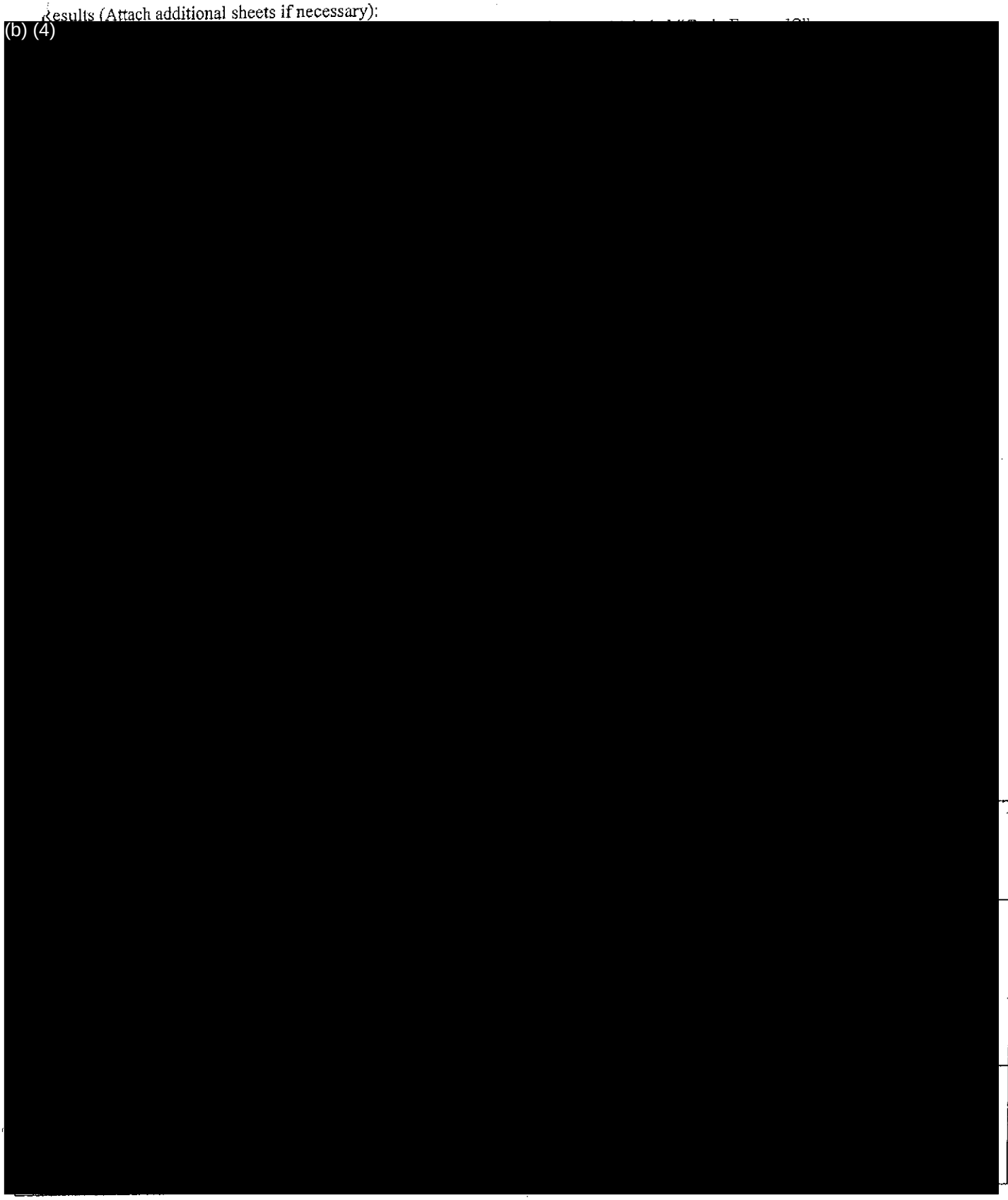
(b) (4)

[redacted]

DJA x00734

Results (Attach additional sheets if necessary):

(b) (4)



DJA x00735

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1767

(b) (4)

REFERENCE COPY
gc 01/17/08

DJA x00736

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

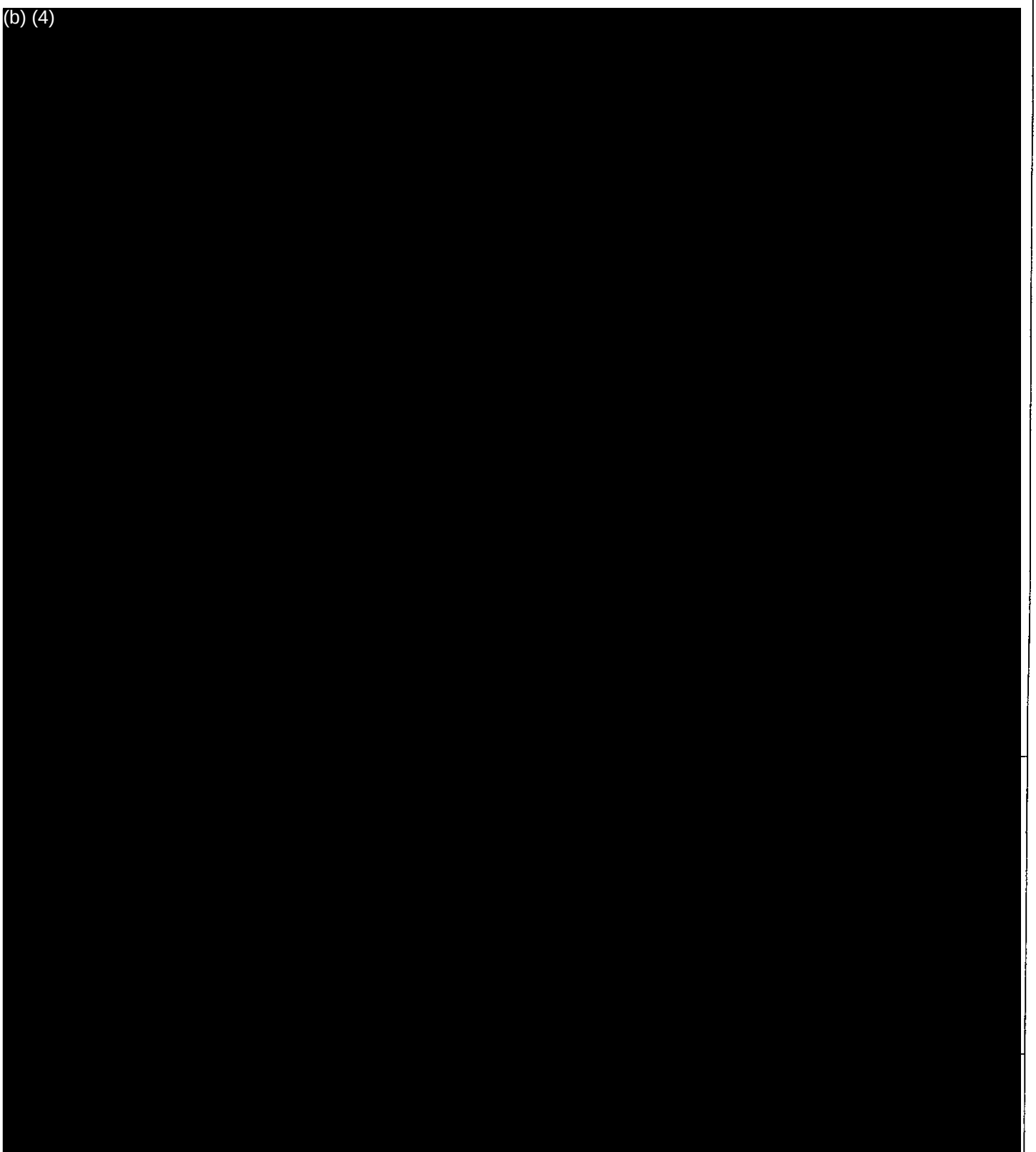
DJA x00737

(b) (4)

DJA x00738

Discussion:

(b) (4)



DJA x00739

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1767

(b) (4)

[redacted]

DJA x00740

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00741

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1767

(b) (4)

REFERENCE COPY
gf 01/17/08

DJA x00742

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00743

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1353

(b) (4)

DJA x00744

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00745

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1833

(b) (4)

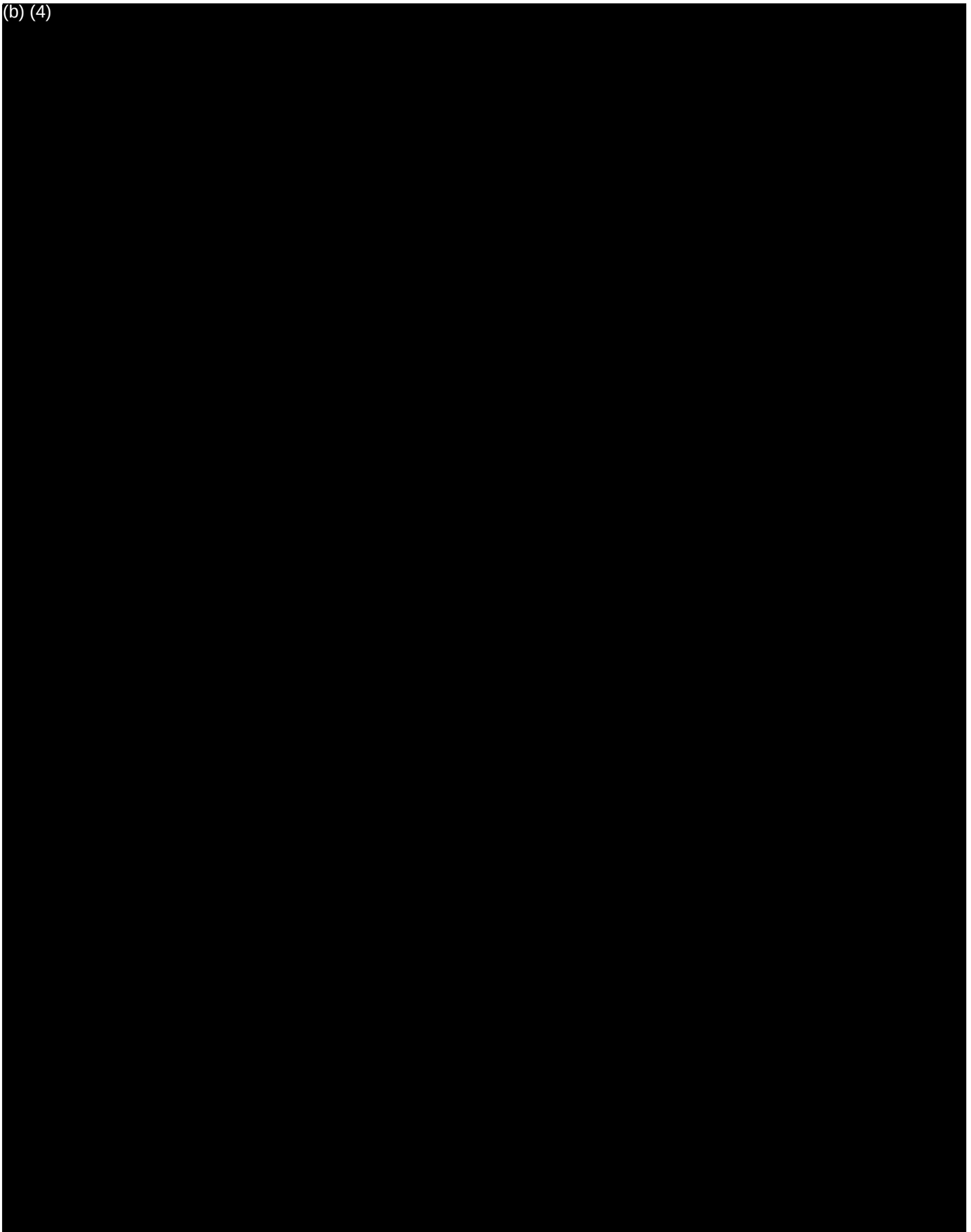
DJA x00746

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1833

(b) (4)

DJA x00747

(b) (4)



DJA x00748

(b) (4)

DJA x00749

Results (Attach additional sheets if necessary):

(b) (4)

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DJA x00750

Discussion:

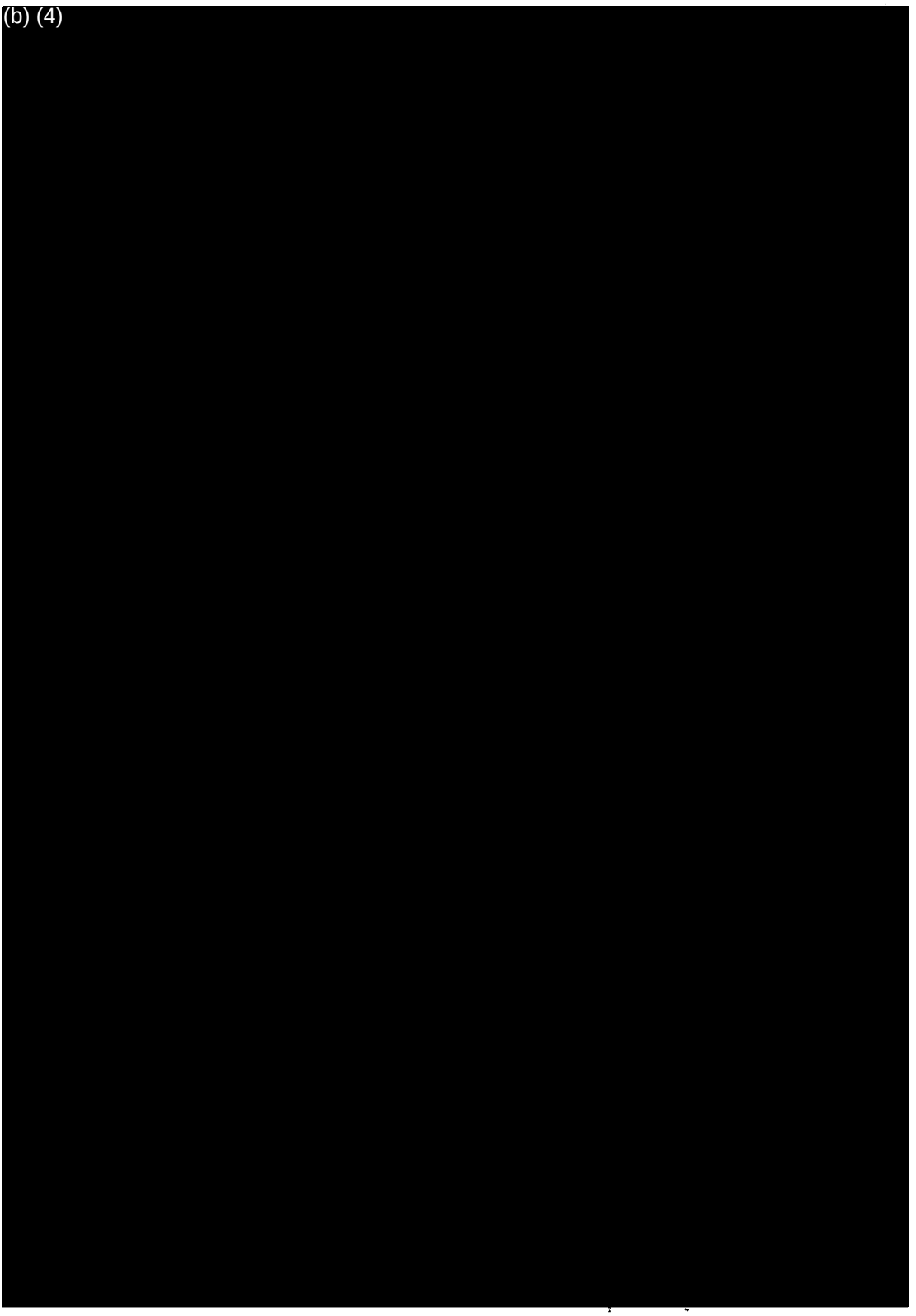
(b) (4)

[redacted]

DJA x00751

This is from SENSORS.LOG

(b) (4)



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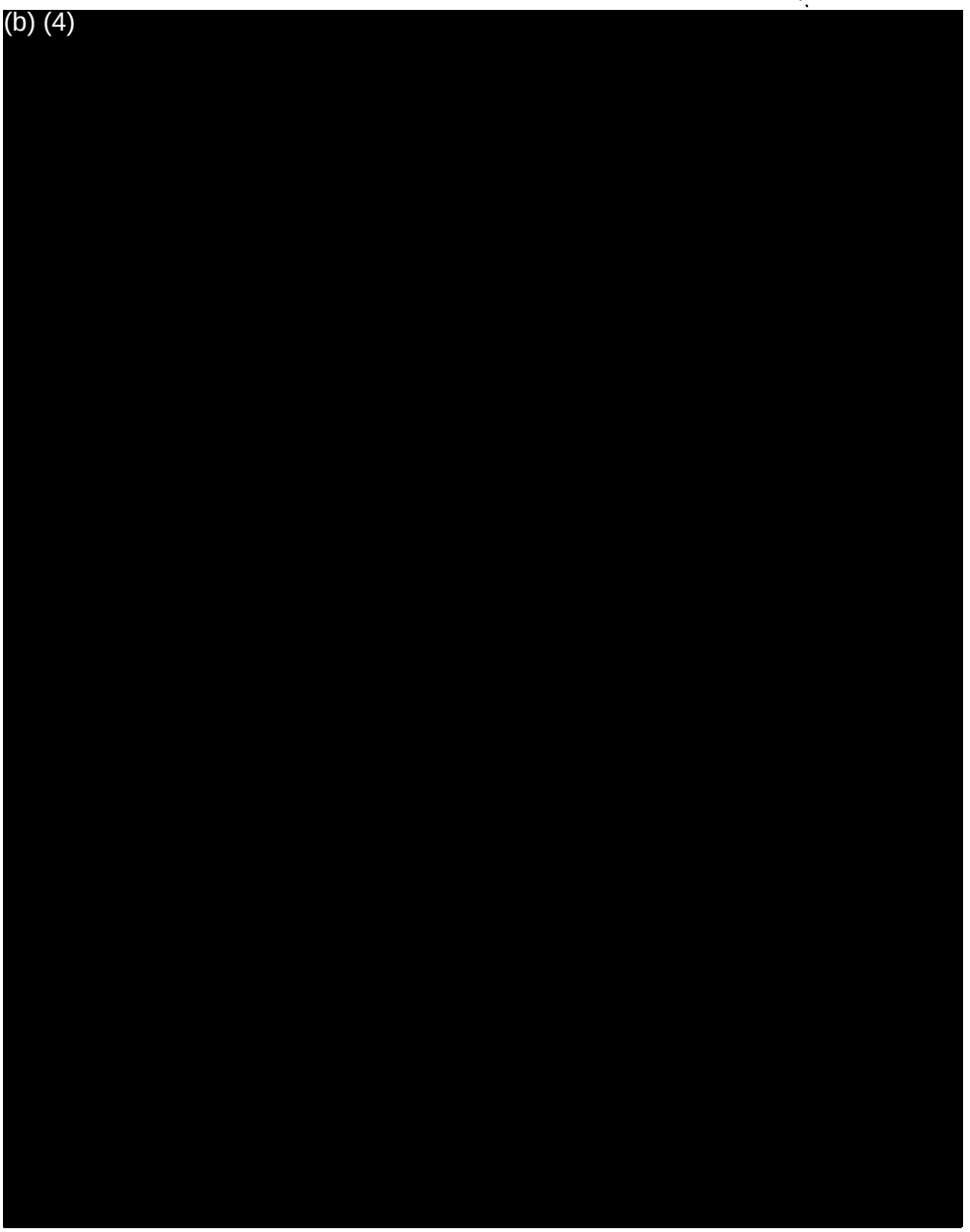

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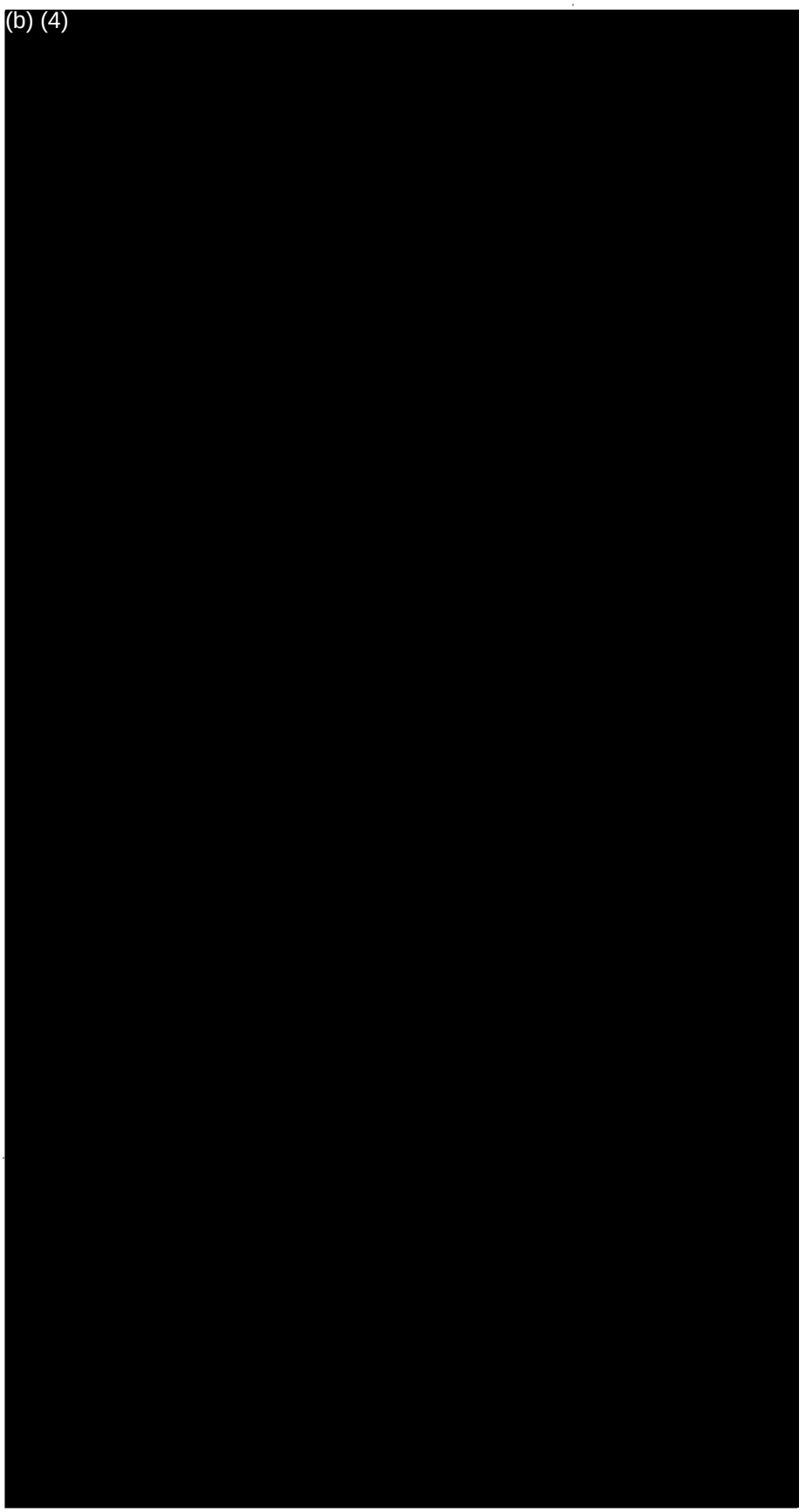

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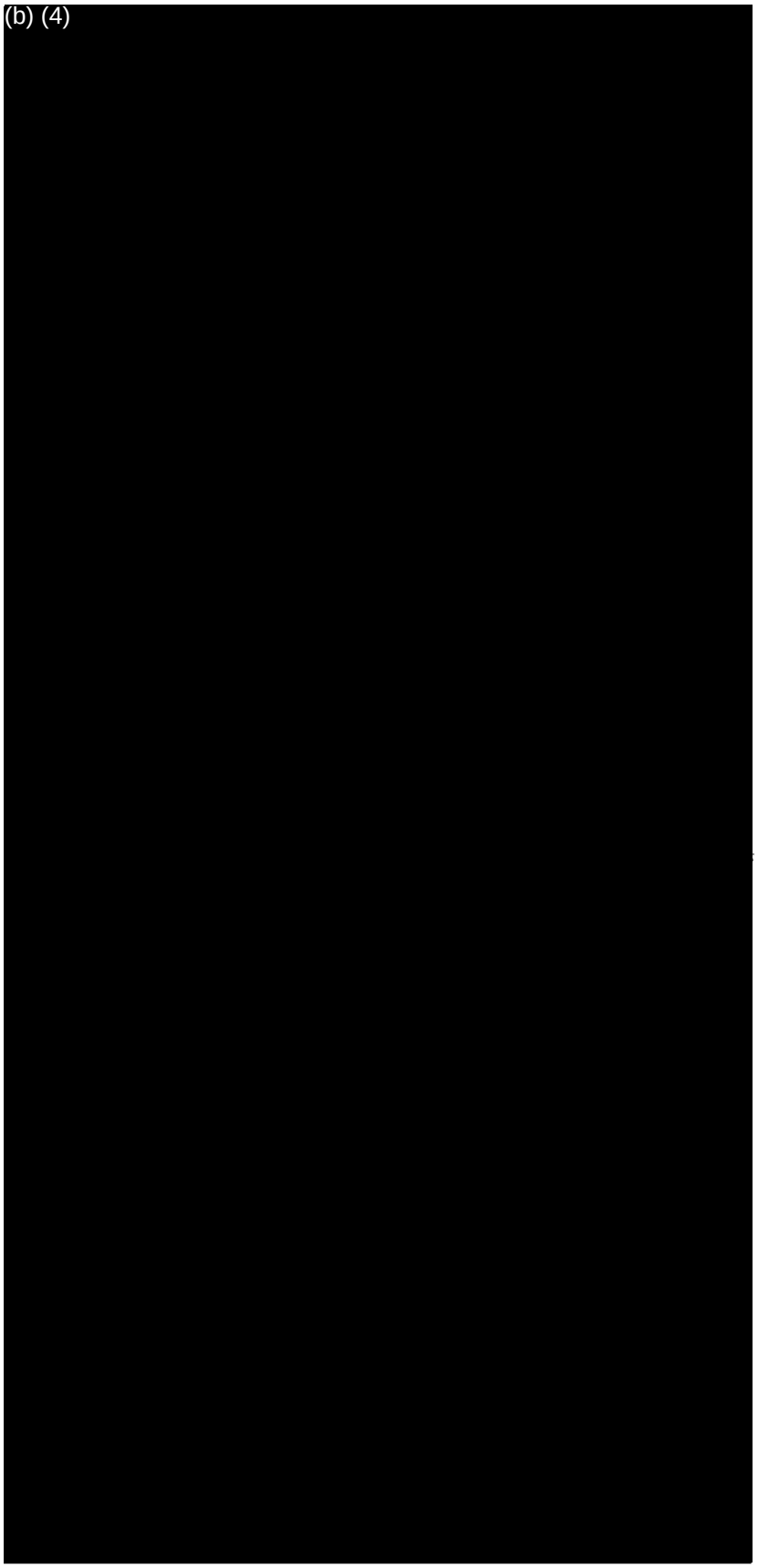

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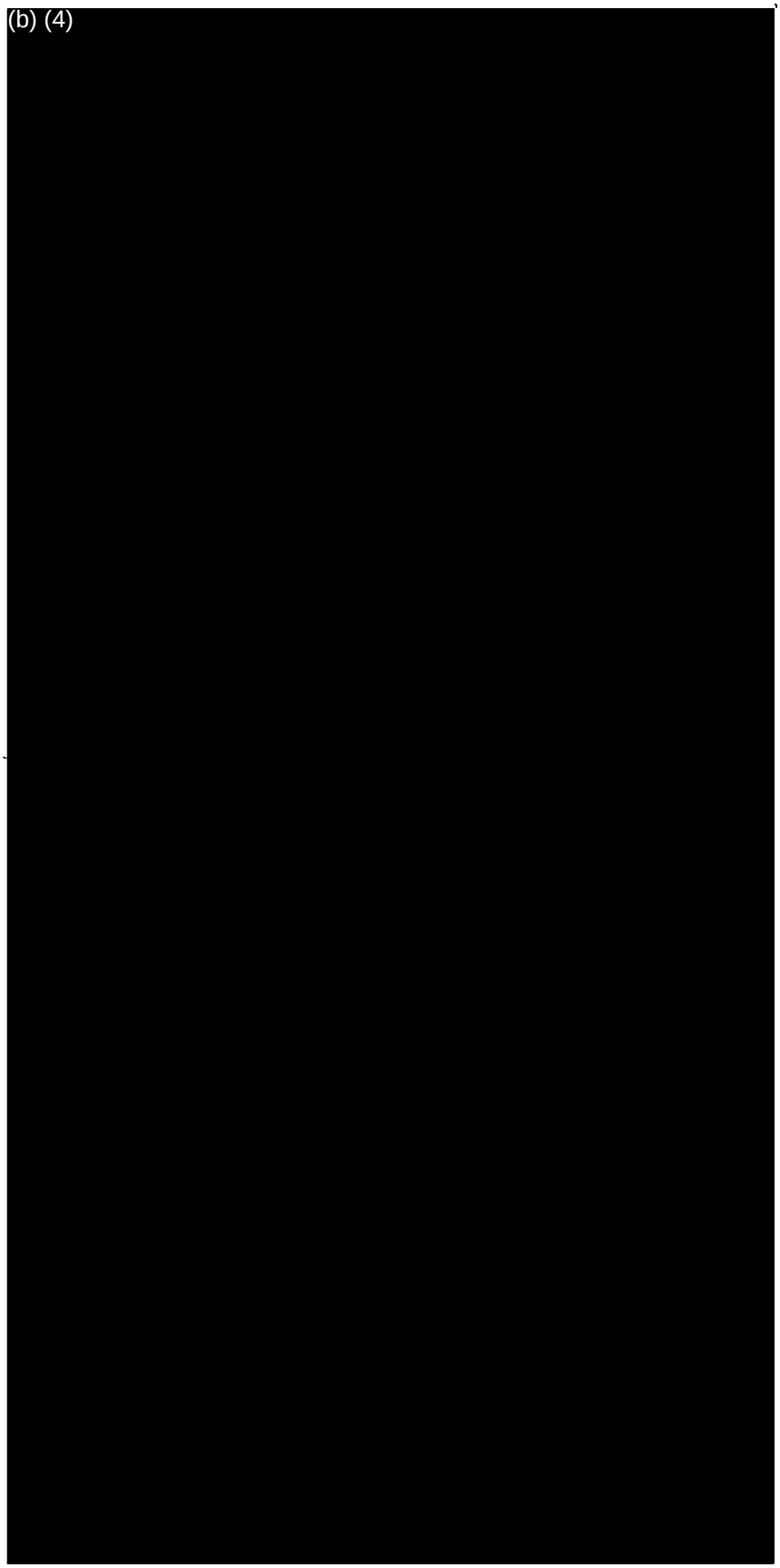

DJA x00756

(b) (4)

DJA x00757

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1533

(b) (4)

DJA x00758

Results (Attach additional sheets if necessary):

(b) (4)

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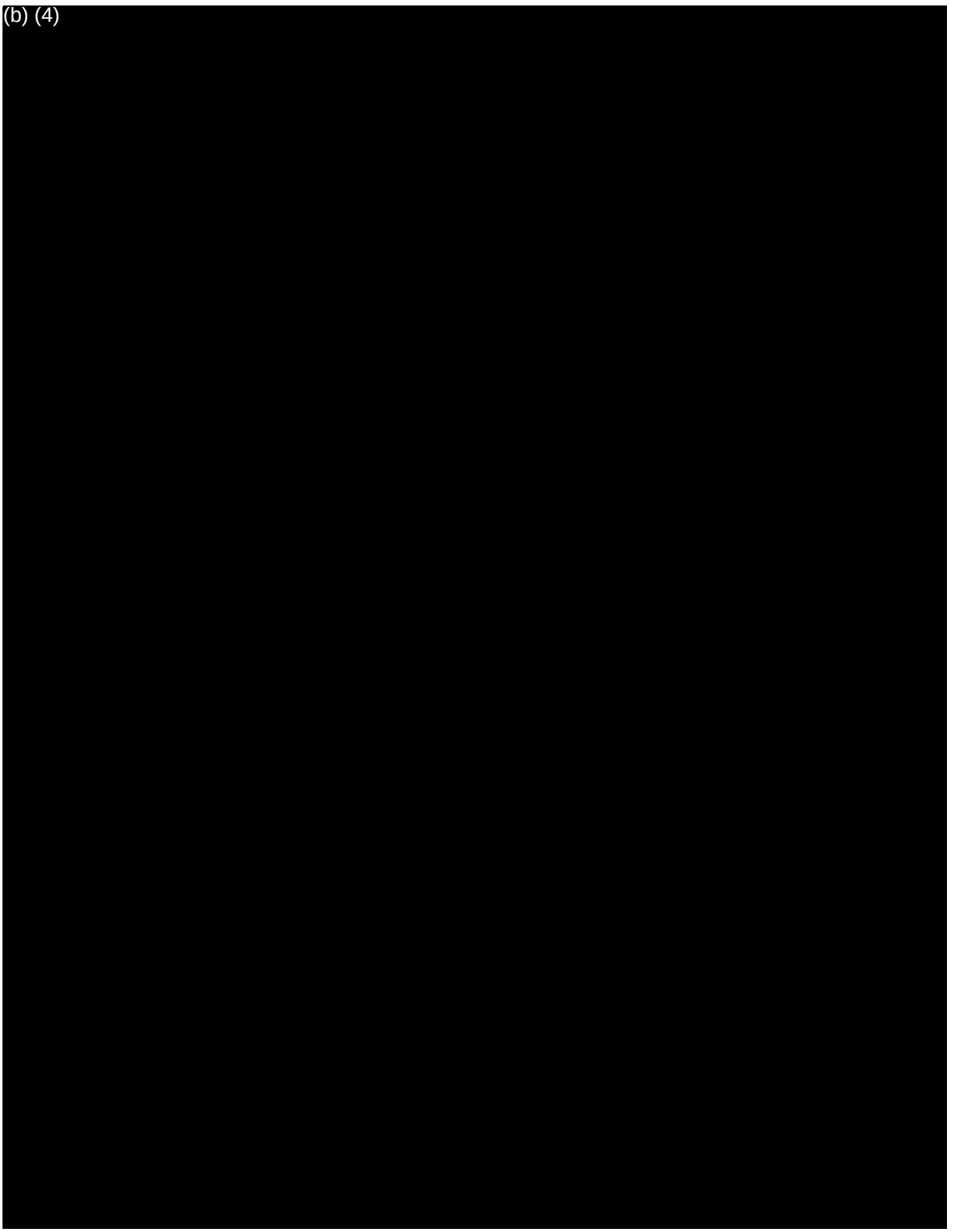
DJA x00759

ATTACHMENT TO T(b) (4)

(b) (4)



DJA x00760

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1833

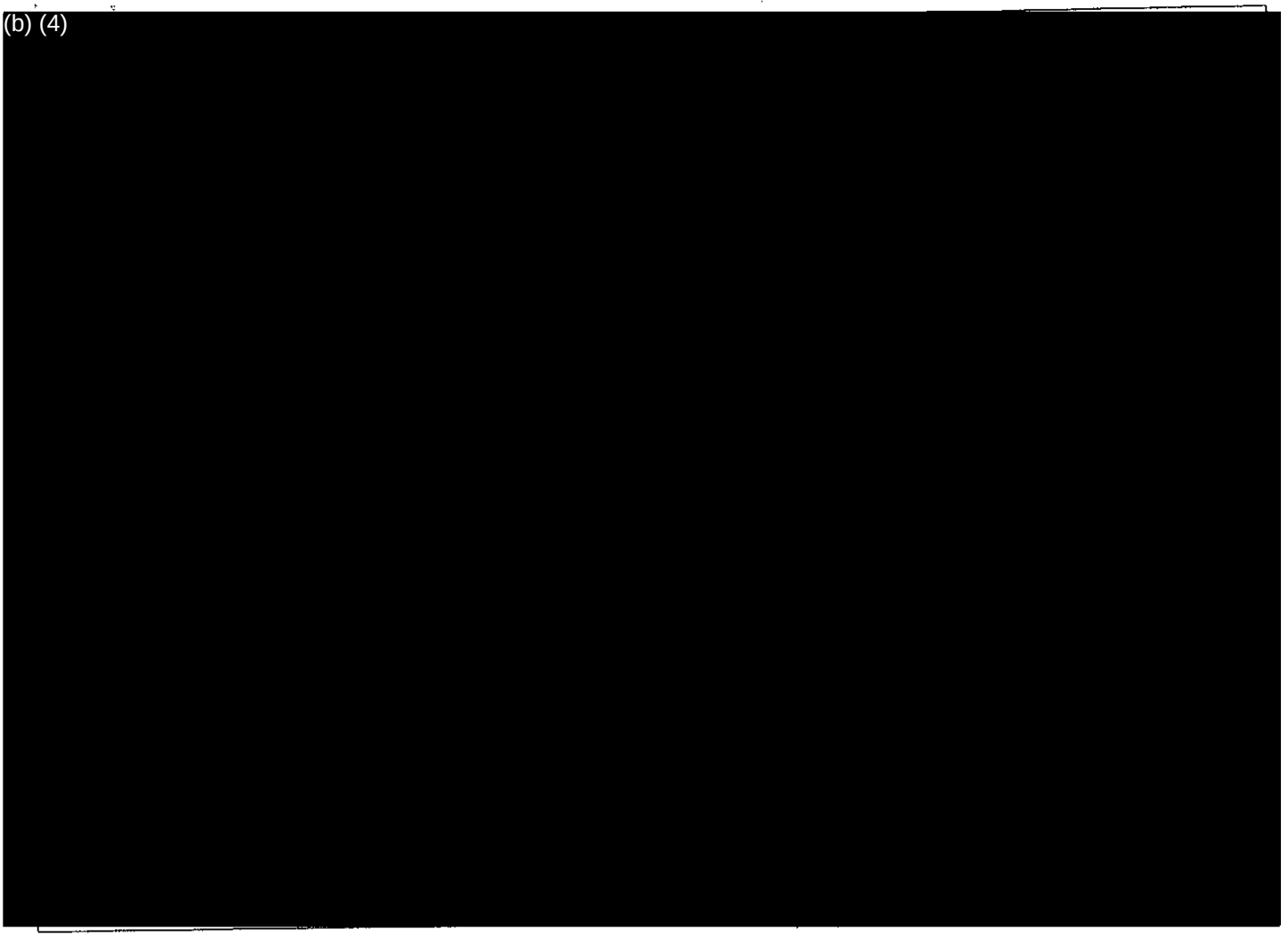
(b) (4)

[redacted]

COPY

DJA x00761

(b) (4)



DJA x00762

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00763

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 1833

(b) (4)

DJA x00764

(b) (4)

[redacted]

DJA x00765

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00766

Conclusion:

(b) (4)

[redacted]

DJA x00767

DCO # 1912

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)

(b) (4)

[redacted]

REFERENCE COPY
qc 01/17/08

DJA x00768

Project Manager Approval To Execute Study	Date
[signature]	8/21/00

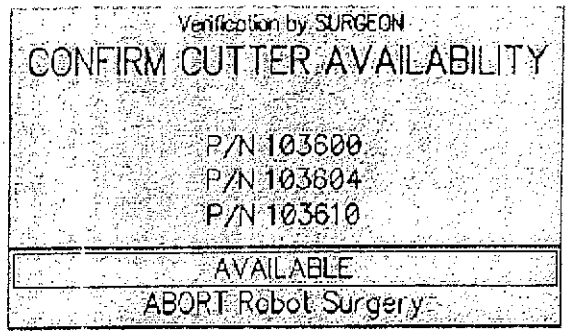
DJA x00769

RESULTS (Attach additional sheets if necessary):

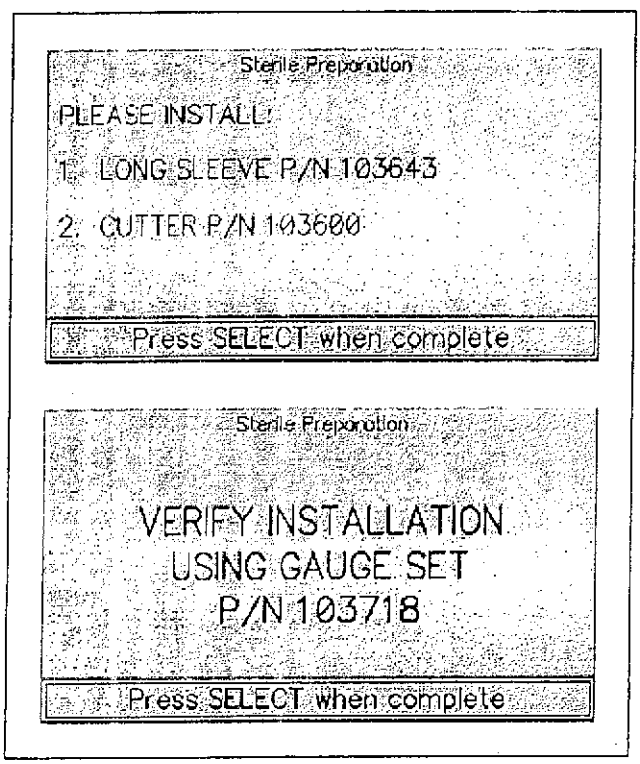
(b) (4)

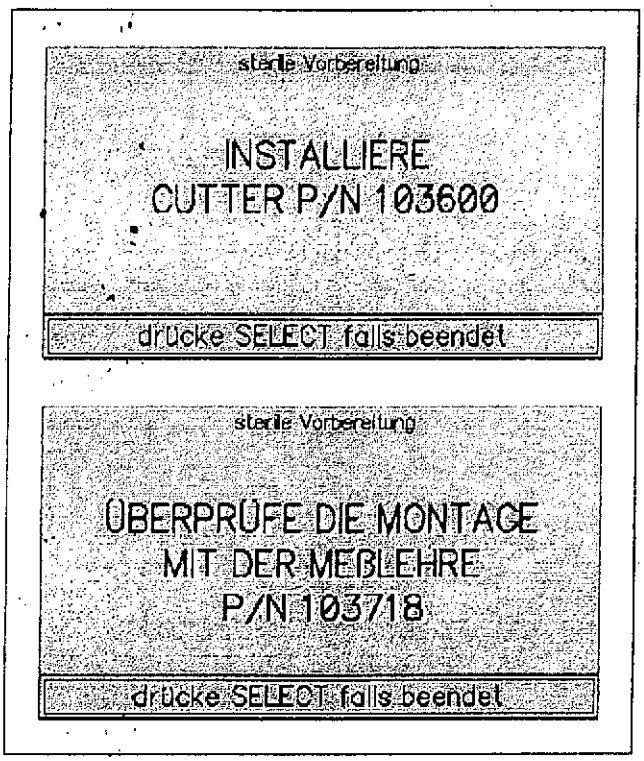
[redacted]

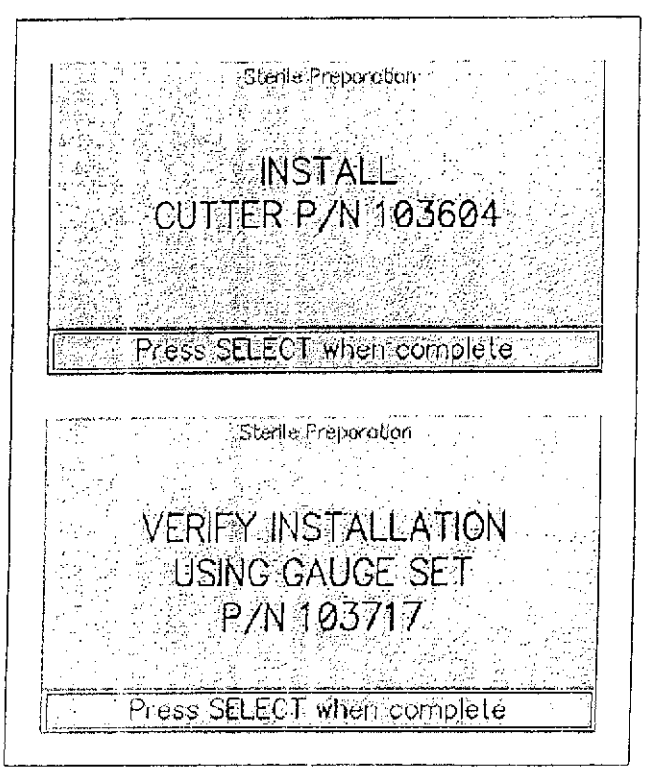
DJA x00770

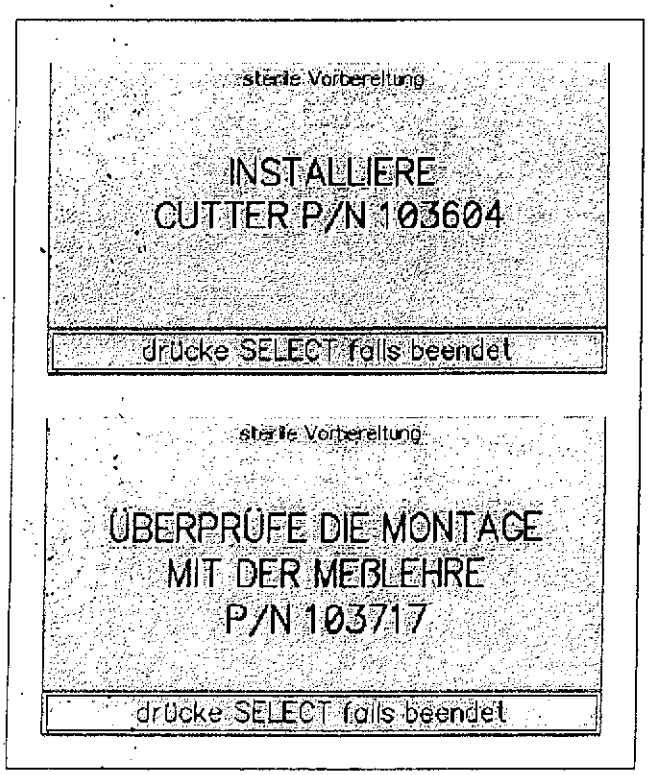

Verification by SURGEON
CONFIRM CUTTER AVAILABILITY
P/N 103600
P/N 103604
P/N 103610
AVAILABLE
ABORT Robot Surgery

Überprüfung durch den Arzt
ÜBERPRÜFE DAS VORHANDENSEIN DES FRÄSERS
P/N 103600
P/N 103604
P/N 103610
VORHANDEN
ABBRUCH der Roboter Operation

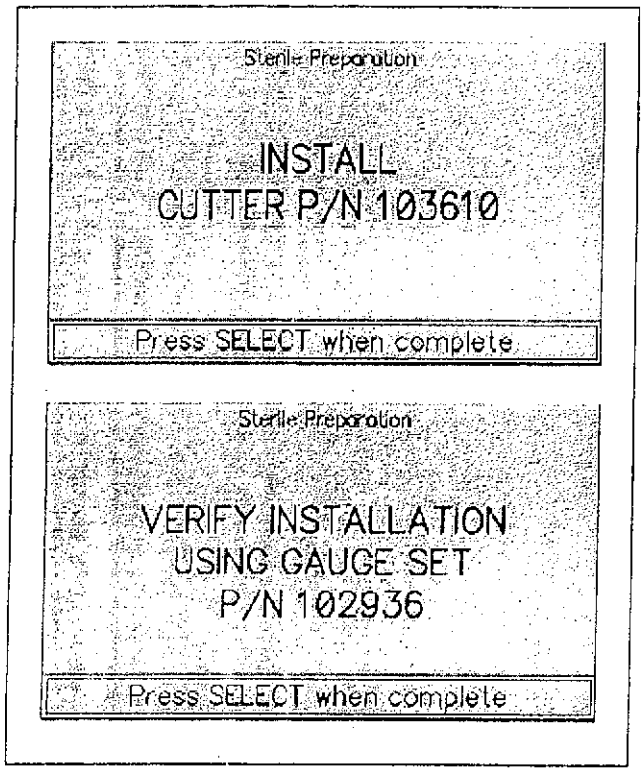

Sterile Preparation
PLEASE INSTALL:
1. LONG SLEEVE P/N 103643
2. CUTTER P/N 103600
Press SELECT when complete
Sterile Preparation
VERIFY INSTALLATION USING GAUGE SET P/N 103718
Press SELECT when complete


sterile Vorbereitung
INSTALLIERE CUTTER P/N 103600
drücke SELECT falls beendet
sterile Vorbereitung
ÜBERPRÜFE DIE MONTAGE MIT DER MEßLEHRE P/N 103718
drücke SELECT falls beendet

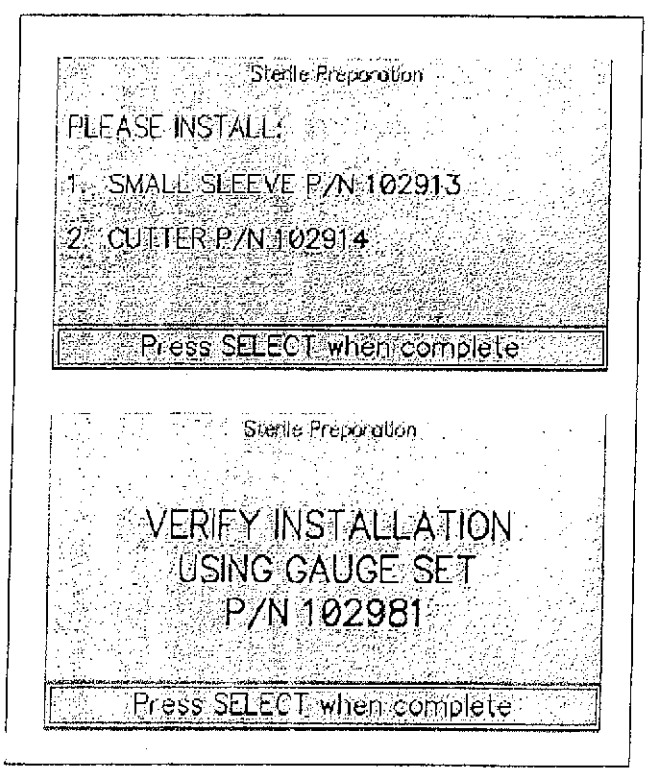

Sterile Preparation
INSTALL CUTTER P/N 103604
Press SELECT when complete
Sterile Preparation
VERIFY INSTALLATION USING GAUGE SET P/N 103717
Press SELECT when complete

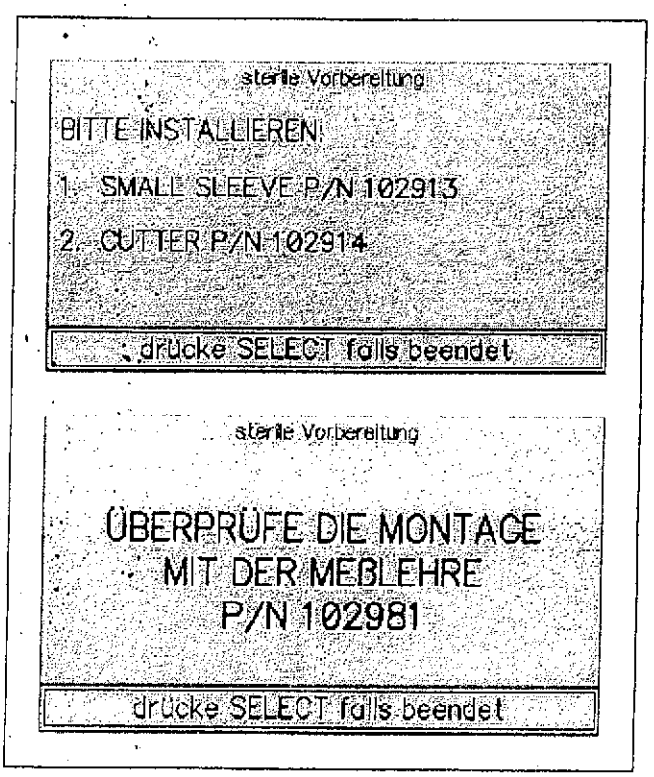

sterile Vorbereitung
INSTALLIERE CUTTER P/N 103604
drücke SELECT falls beendet
sterile Vorbereitung
ÜBERPRÜFE DIE MONTAGE MIT DER MEßLEHRE P/N 103717
drücke SELECT falls beendet

DJA x00771

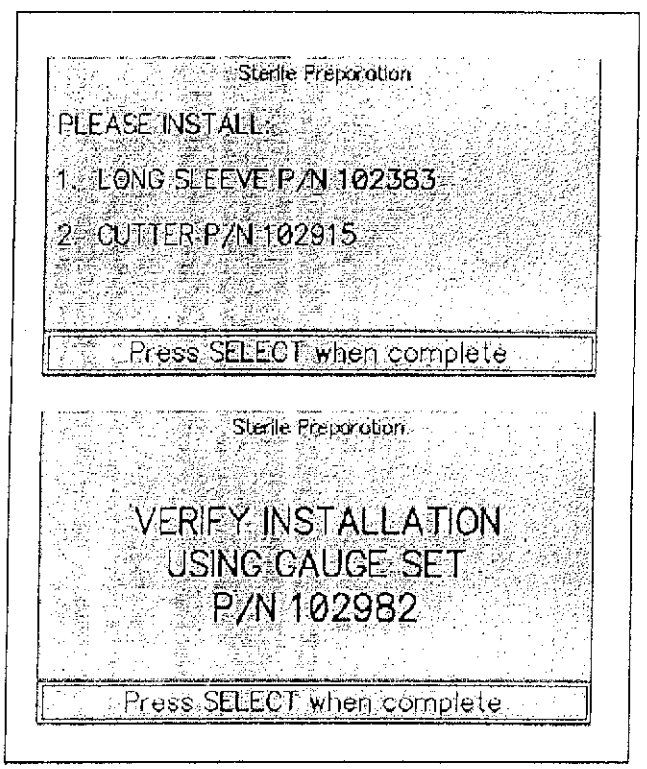

Sterile Preparation
INSTALL
CUTTER P/N 103610
Press SELECT when complete
Sterile Preparation
VERIFY INSTALLATION
USING GAUGE SET
P/N 102936
Press SELECT when complete

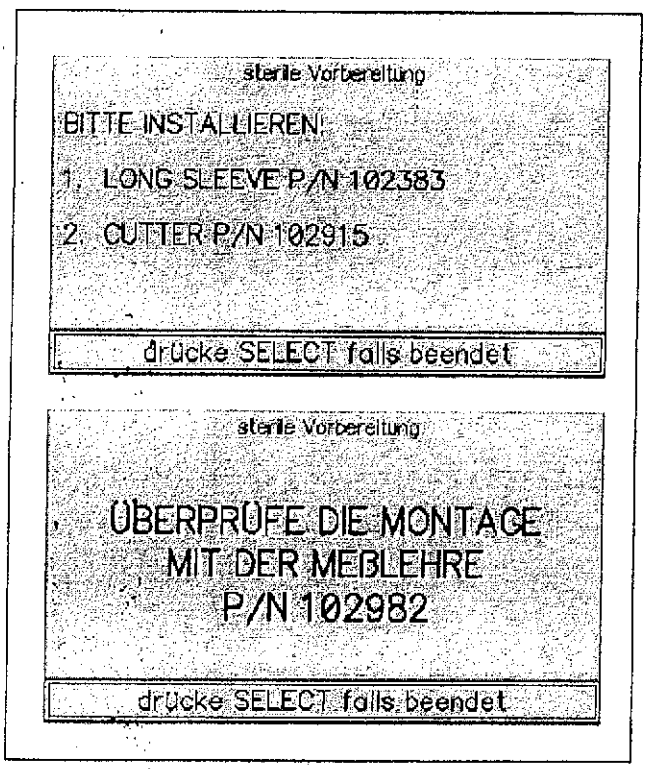
sterile Vorbereitung
INSTALLIERE
CUTTER P/N 103610
drücke SELECT falls beendet
sterile Vorbereitung
ÜBERPRÜFE DIE MONTAGE
MIT DER MEßLEHRE
P/N 102936
drücke SELECT falls beendet


Sterile Preparation
PLEASE INSTALL:
1. SMALL SLEEVE P/N 102913
2. CUTTER P/N 102914
Press SELECT when complete
Sterile Preparation
VERIFY INSTALLATION
USING GAUGE SET
P/N 102981
Press SELECT when complete


sterile Vorbereitung
BITTE INSTALLIEREN:
1. SMALL SLEEVE P/N 102913
2. CUTTER P/N 102914
drücke SELECT falls beendet
sterile Vorbereitung
ÜBERPRÜFE DIE MONTAGE
MIT DER MEßLEHRE
P/N 102981
drücke SELECT falls beendet

DJA x00772


Sterile Preparation
PLEASE INSTALL:
1. LONG SLEEVE P/N 102383
2. CUTTER P/N 102915
Press SELECT when complete
Sterile Preparation
VERIFY INSTALLATION
USING GAUGE SET
P/N 102982
Press SELECT when complete


sterile Vorbereitung
BITTE INSTALLIEREN:
1. LONG SLEEVE P/N 102383
2. CUTTER P/N 102915
drücke SELECT falls beendet
sterile Vorbereitung
ÜBERPRÜFE DIE MONTAGE
MIT DER MEßLEHRE
P/N 102982
drücke SELECT falls beendet

DJA x00773

DCO # 1912

TECHNICAL STUDY (TS)	Study Control Number (b) (4)

(b) (4)

DJA x00774

(b) (4)

[redacted]

DJA x00775

(b) (4)

DJA x00776

RESULTS (Attach additional sheets if necessary):

(b) (4)

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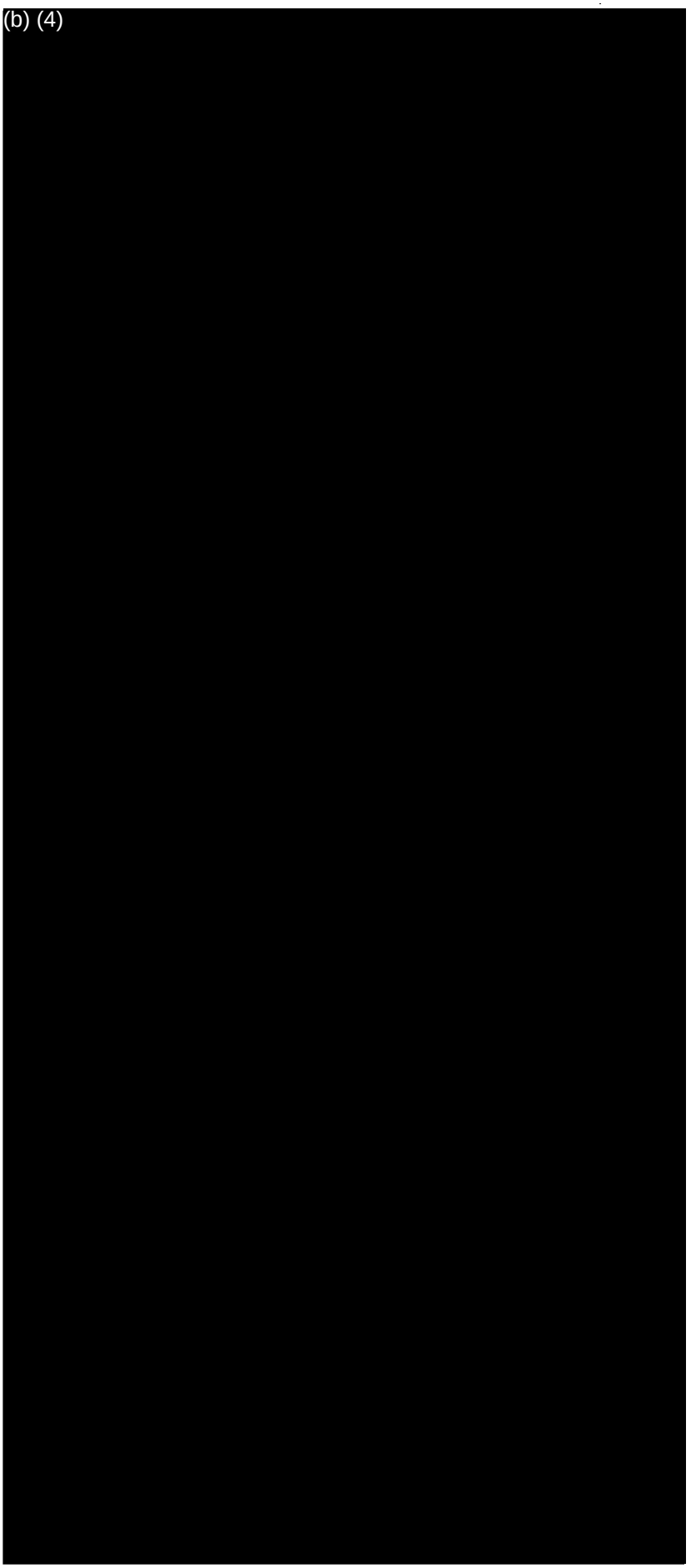
DJA x00777

(b) (4)



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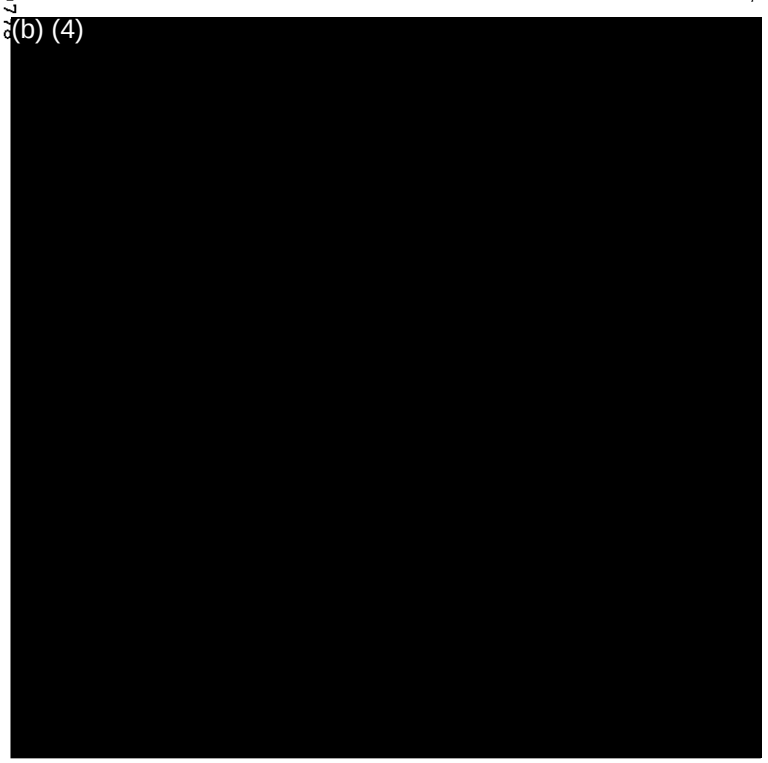
(b) (4)



DJA x00779

DCO # 1912

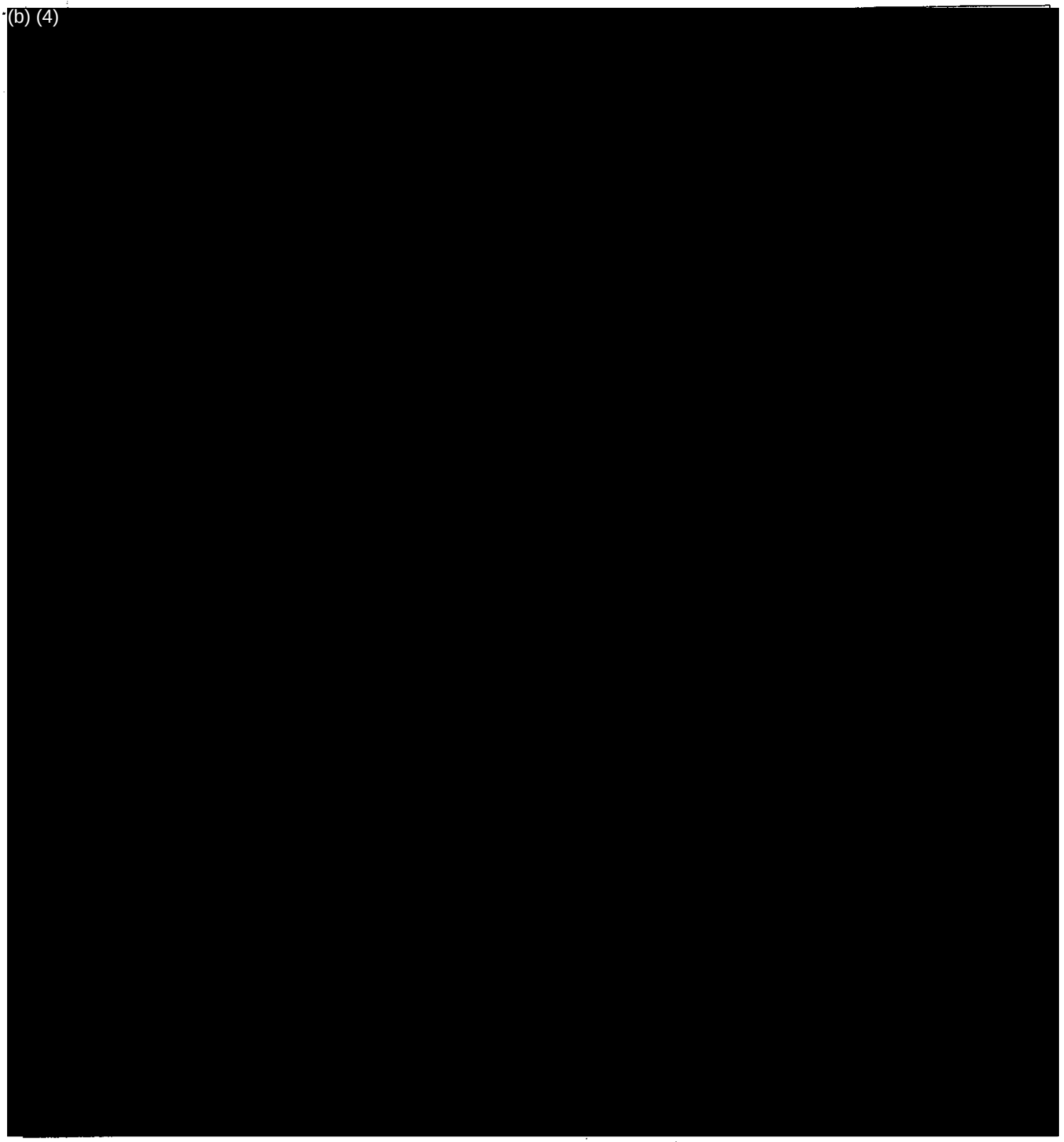
TECHNICAL STUDY (TS)	Study Control Number T(b) (4)

(b) (4)

COPY
gc 01/17/08

DJA x00780

(b) (4)



DJA x00781

RESULTS (Attach additional sheets if necessary):

(b) (4)

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DJA x00782

Discussion:

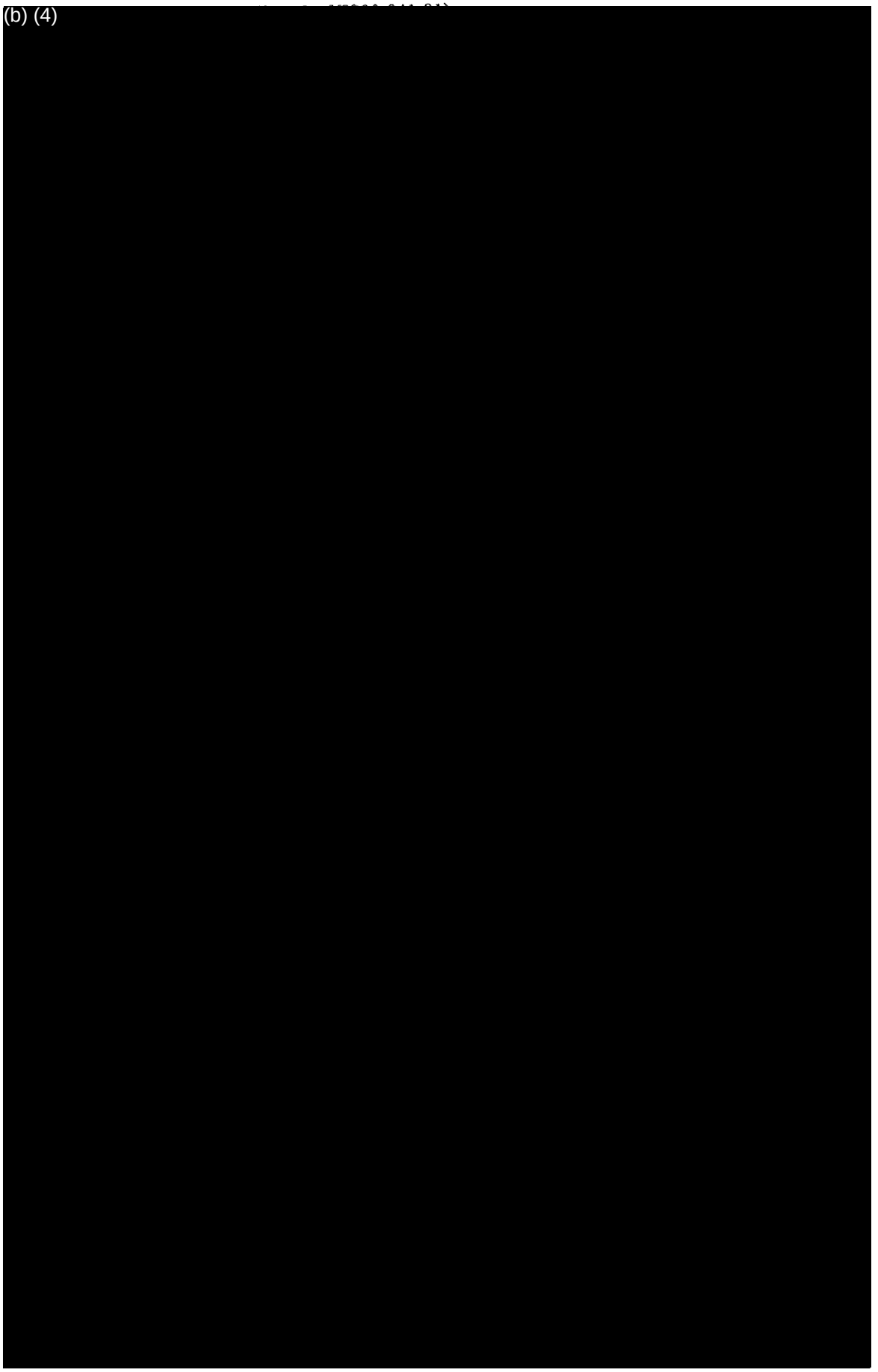
All test steps proceeded as specified.

(b) (4)

[redacted]

DJA x00783

(b) (4)



DJA x00784

(b) (4)

DJA x00785

DCO # 1912

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) 6

(b) (4)

[redacted]

REFERENCE COPY
gc 01/17/08

DJA x00786

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

File C:\thr.pro

DJA x007B7

(b) (4)

DJA x00788

Excerpts from: C:\ROBODOC\recover.rbt

(b) (4)

DJA x00789

DCO # 19/2

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)

(b) (4)

qp 01/17/08 1 of 1

DJA x00790

Results (Attach additional sheets if necessary):

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DJA x00791

TECHNICAL STUDY (TS)

Study Control Number

(b) (4)

DCO # 152

(b) (4)

DJA x00792

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00793

ROBODOC
INTEGRATED SURGICAL SYSTEMS

PROTOCOL and TEST REPORT APPROVAL SHEET

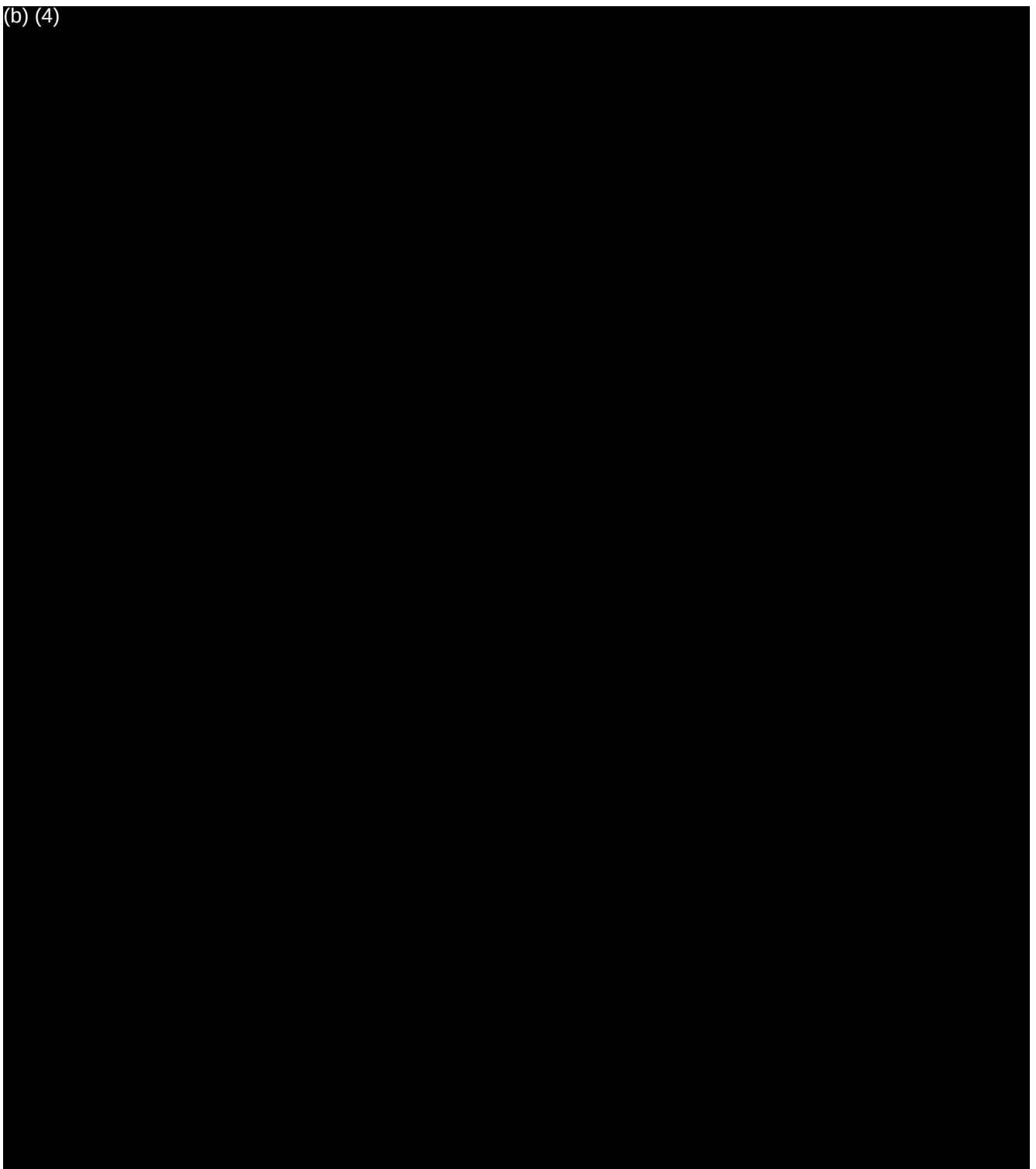
DCO # 1849

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 49
KEY WORDS: ORTHODOC TEST REPORT	PROTOCOL REF. NO. (If applicable) (b) (4)	PROJECT NO.: (If applicable) 42

(b) (4)

DJA x00794

(b) (4)



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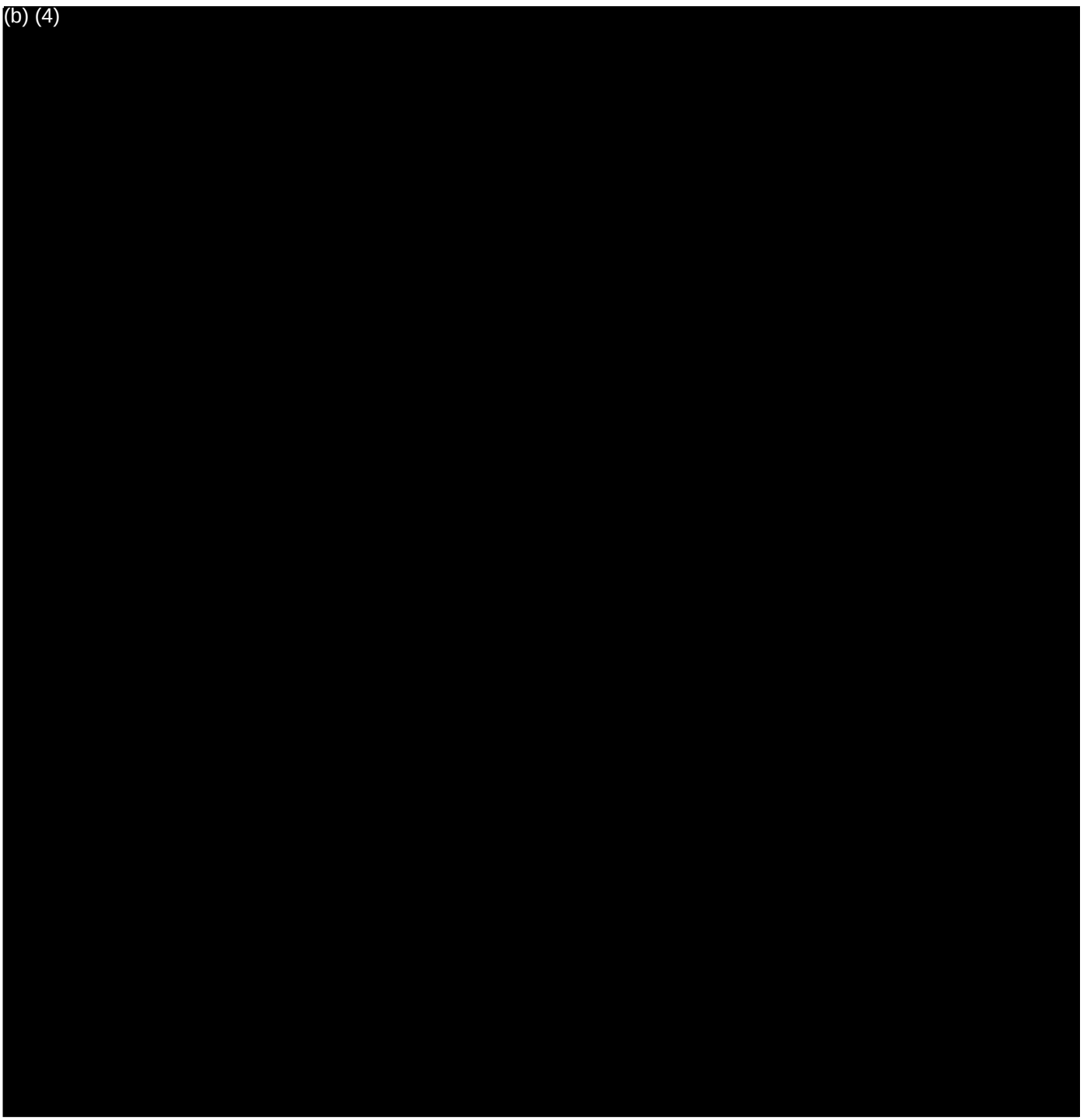

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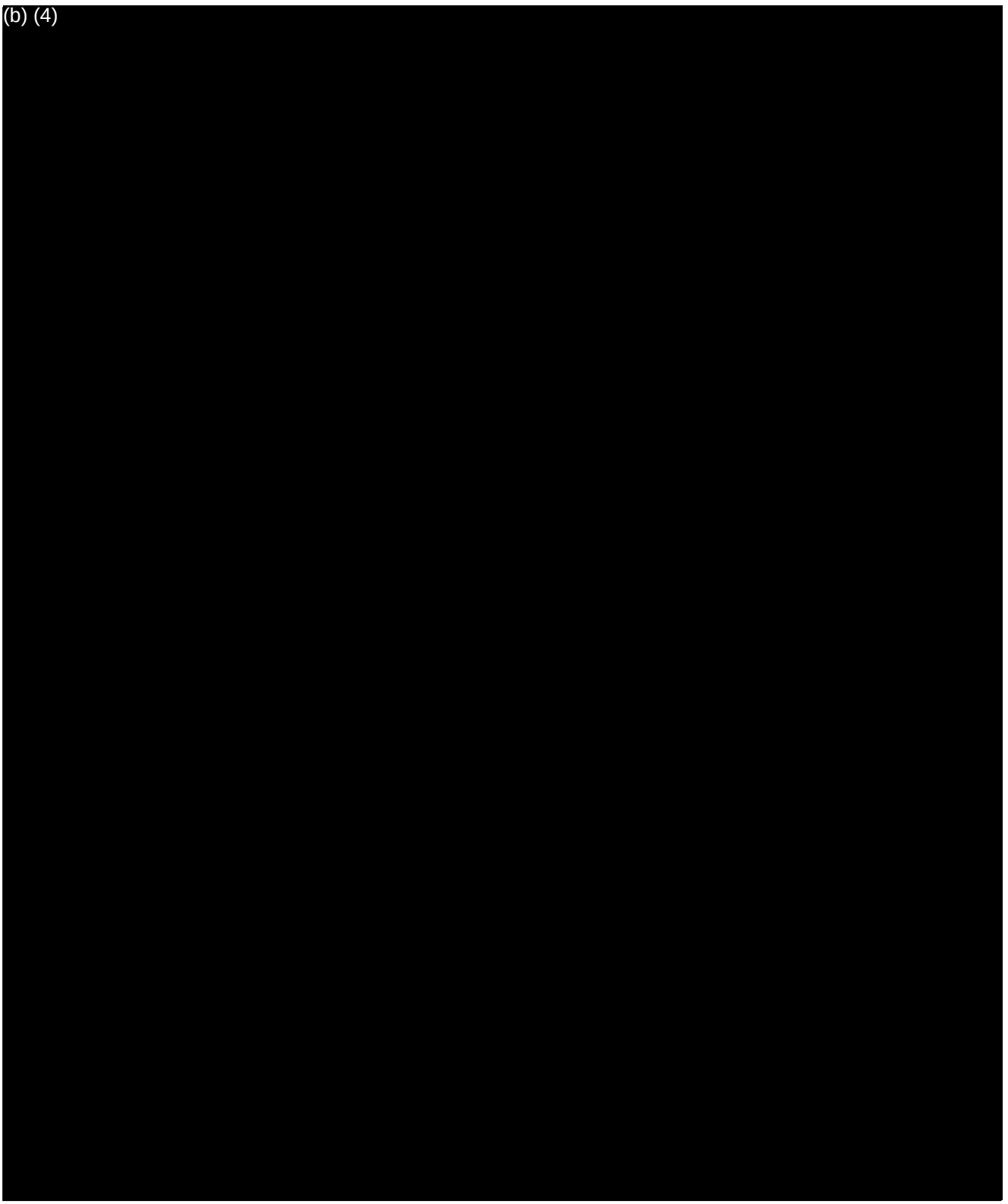

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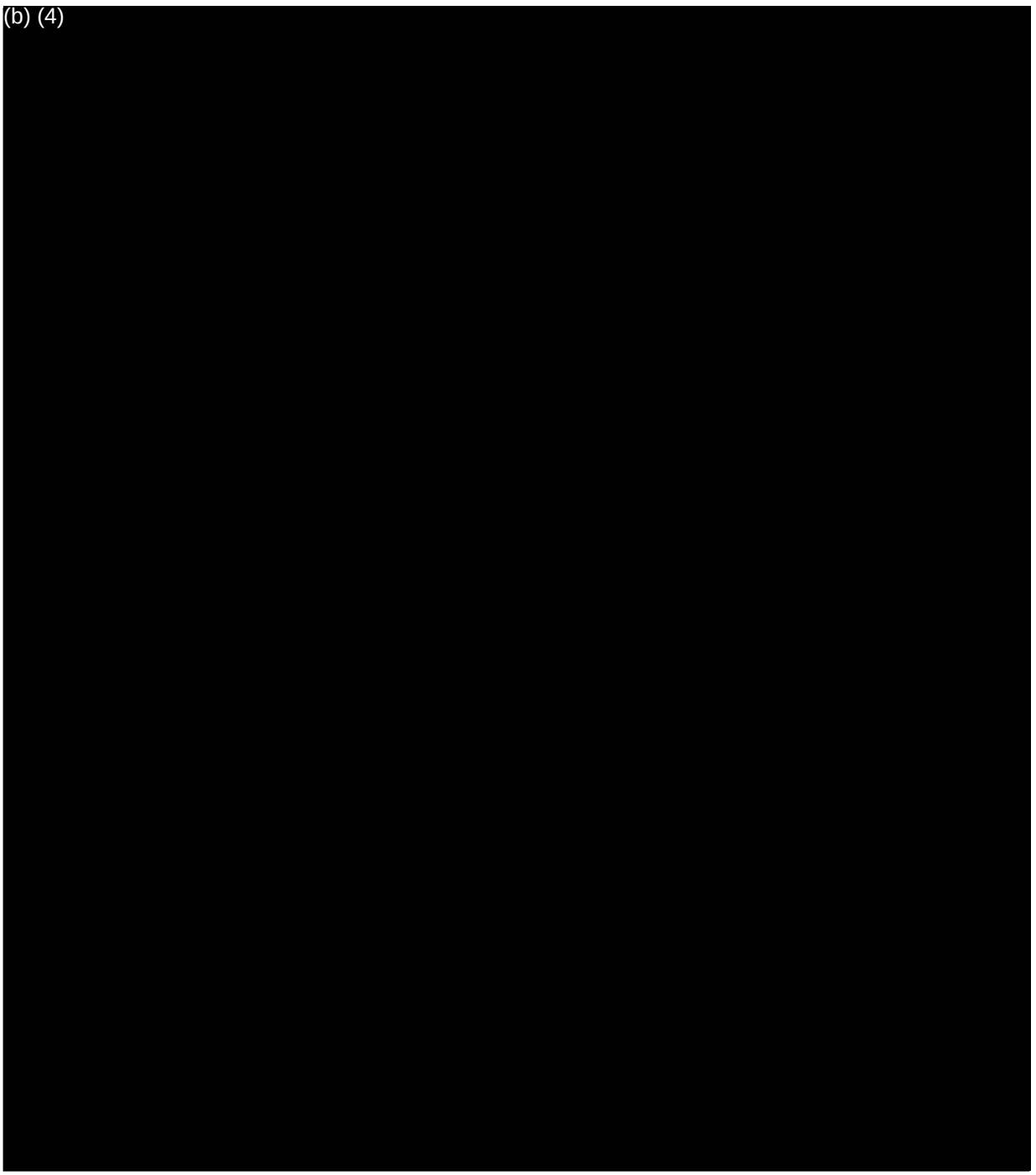

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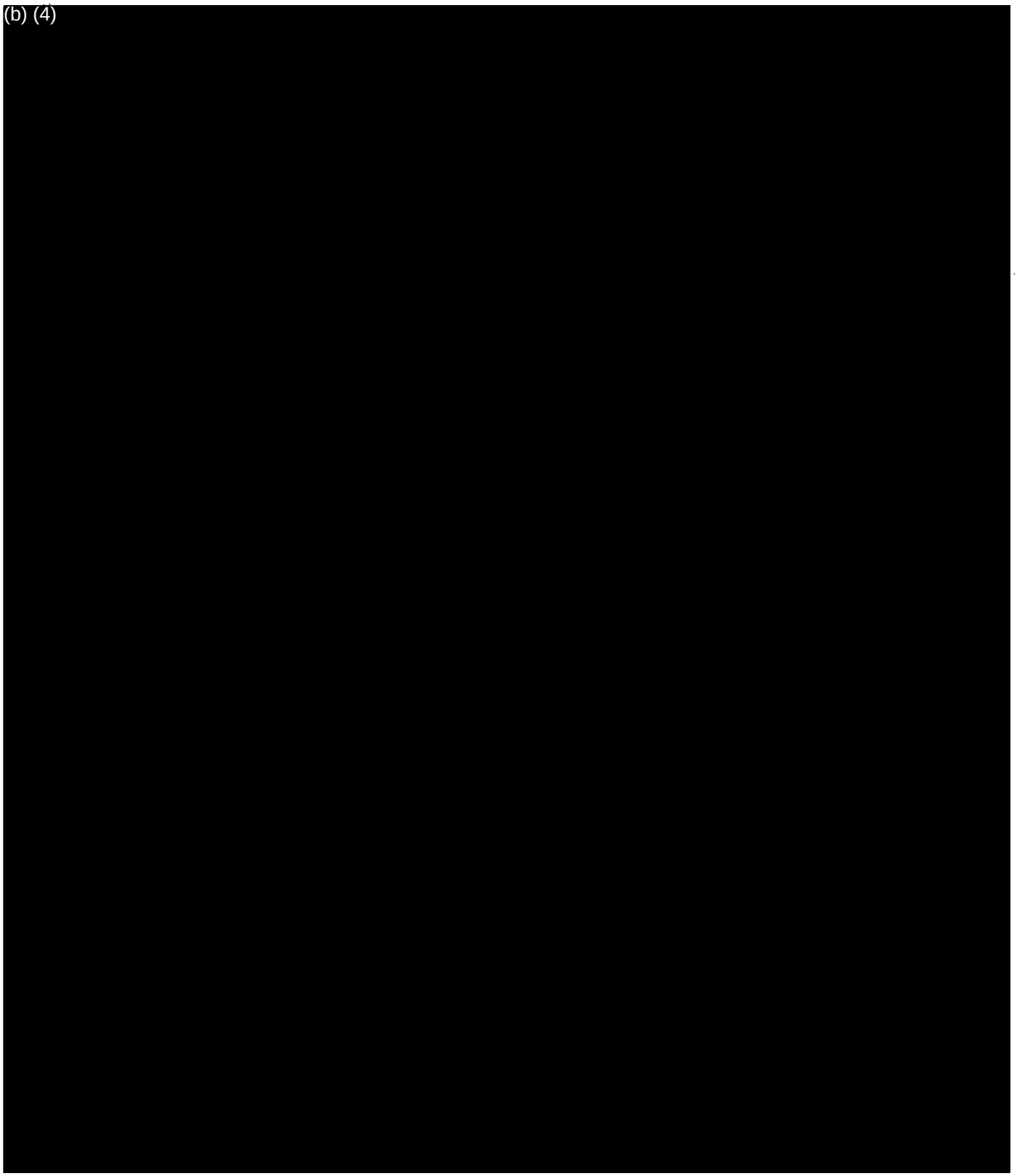
DJA x00799

Dicom - Jpeg & normal
Siemens

ORTHODOC MODEL 500
SOFTWARE TEST REPORT

(b) (4)



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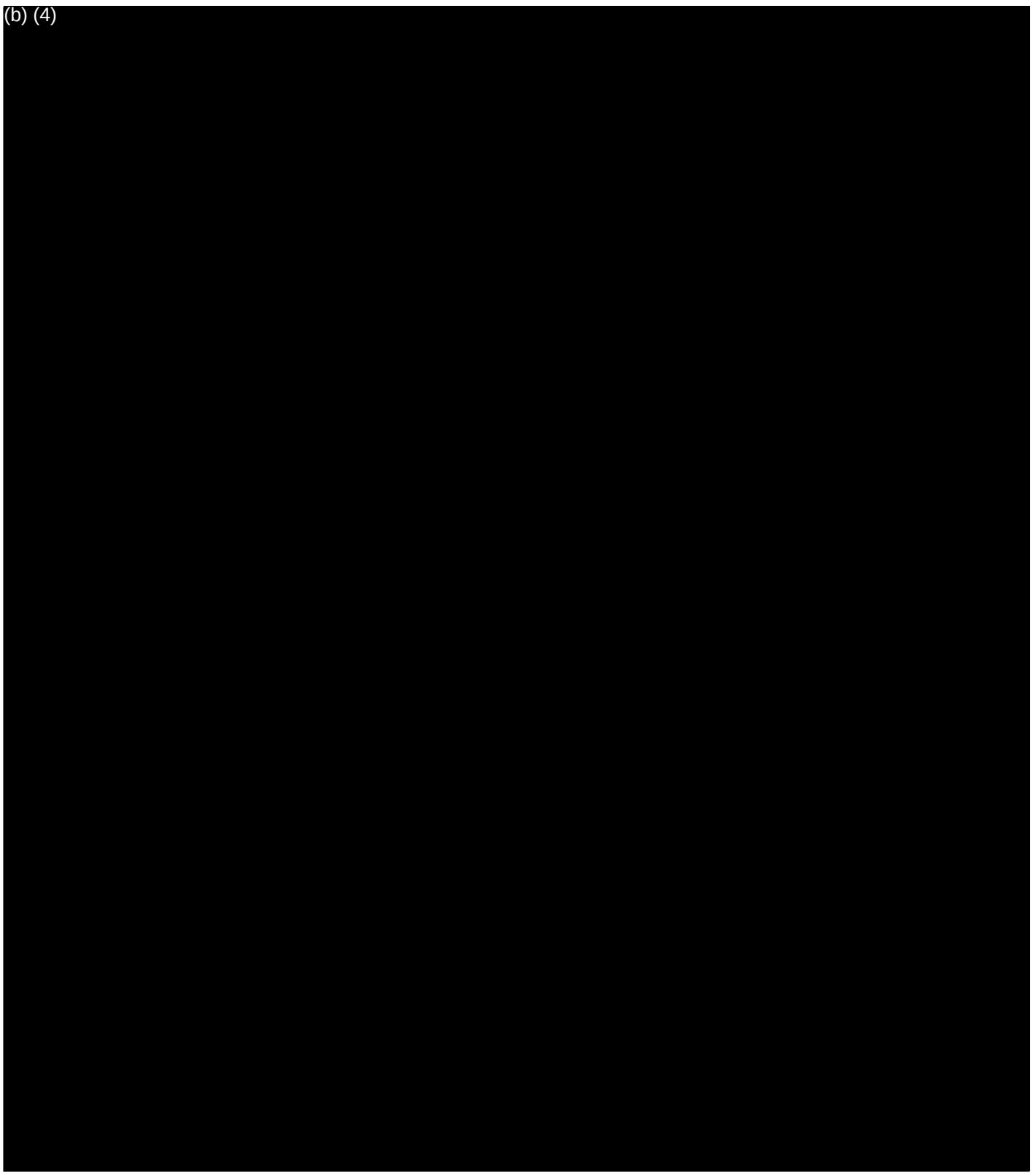
(b) (4)

Dicom - Jpeg & normal
Siemens

DJA x000801

(b) (4)



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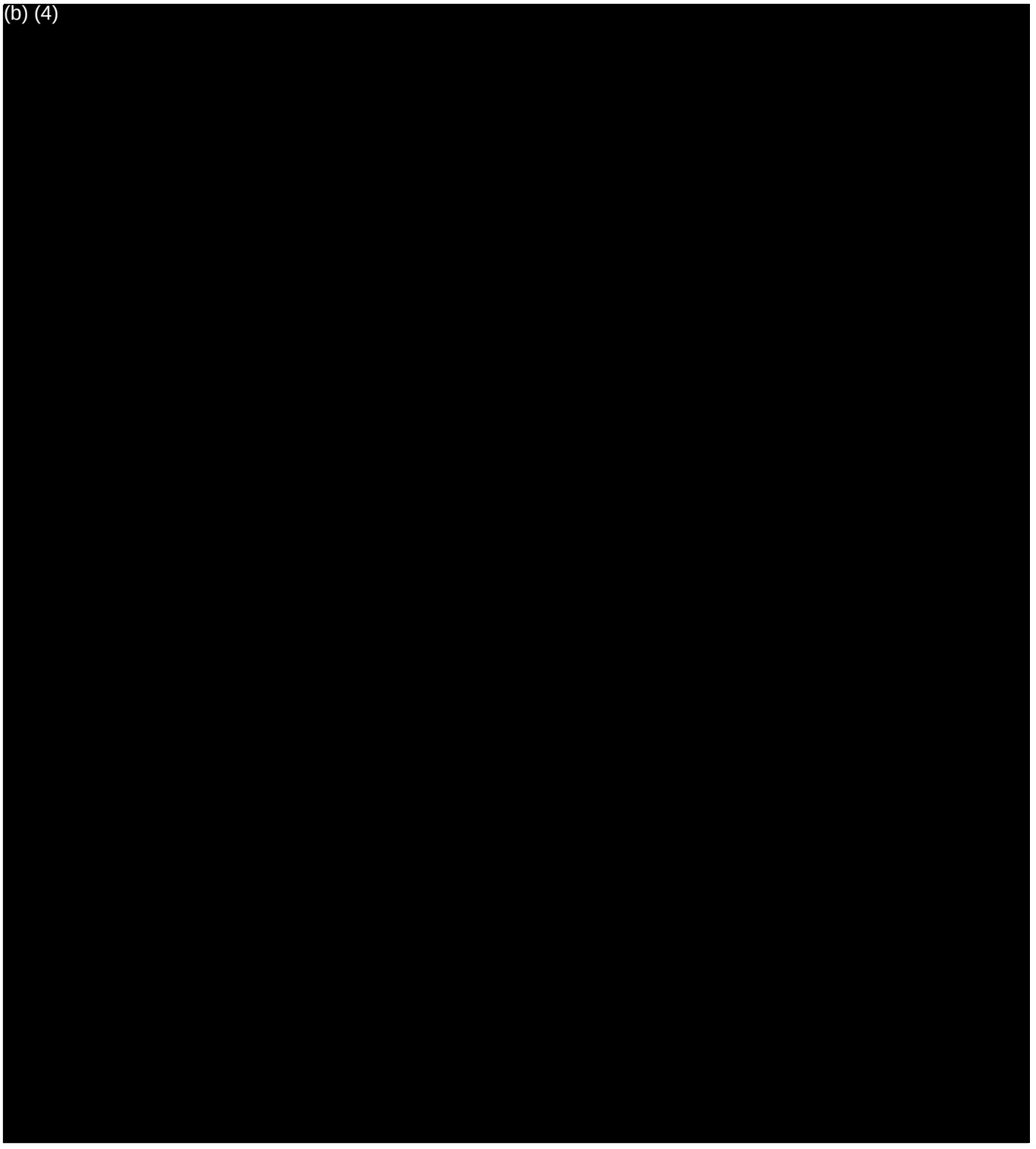
(b) (4)

DJA x000803

(b) (4)



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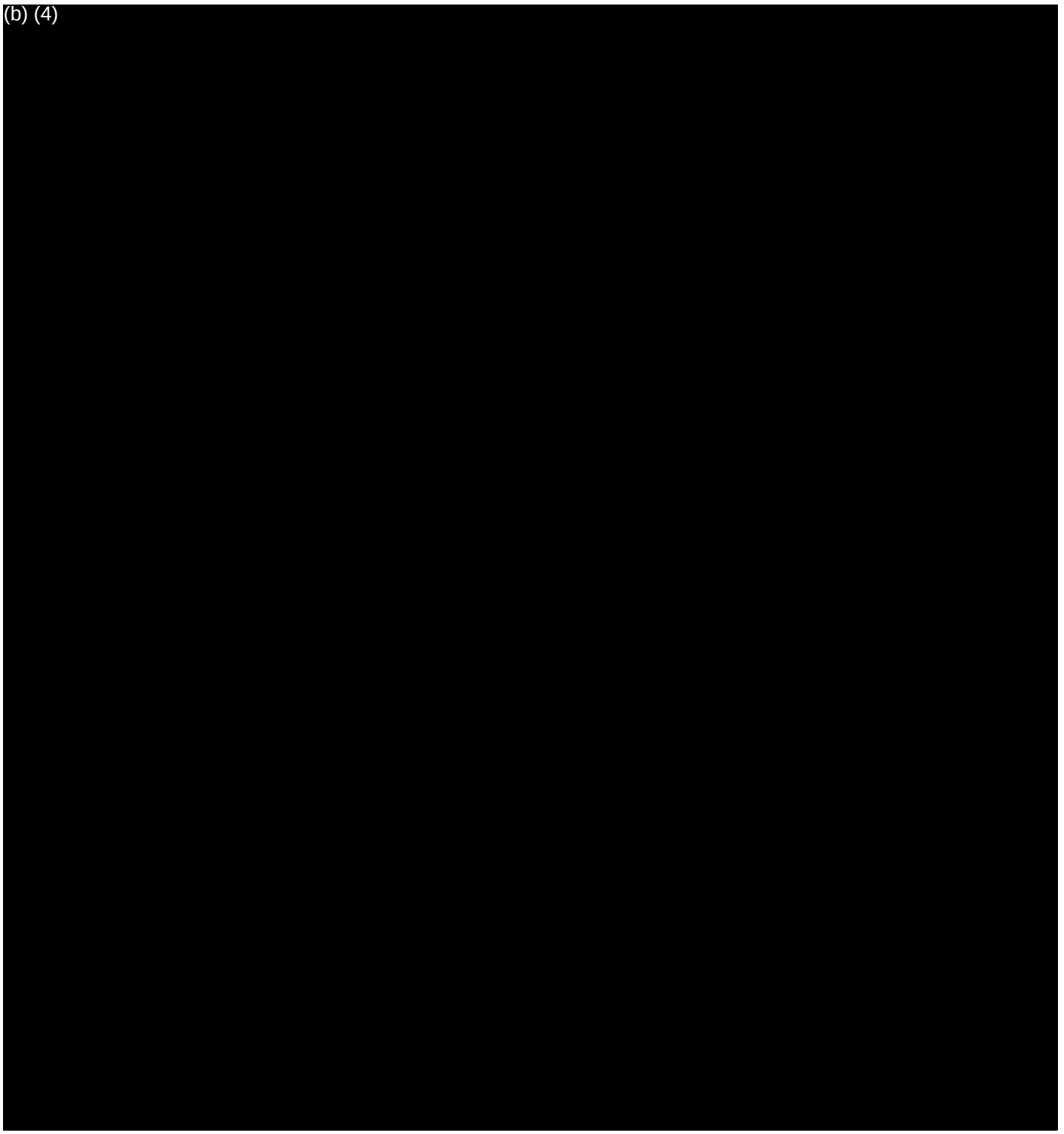
(b) (4)



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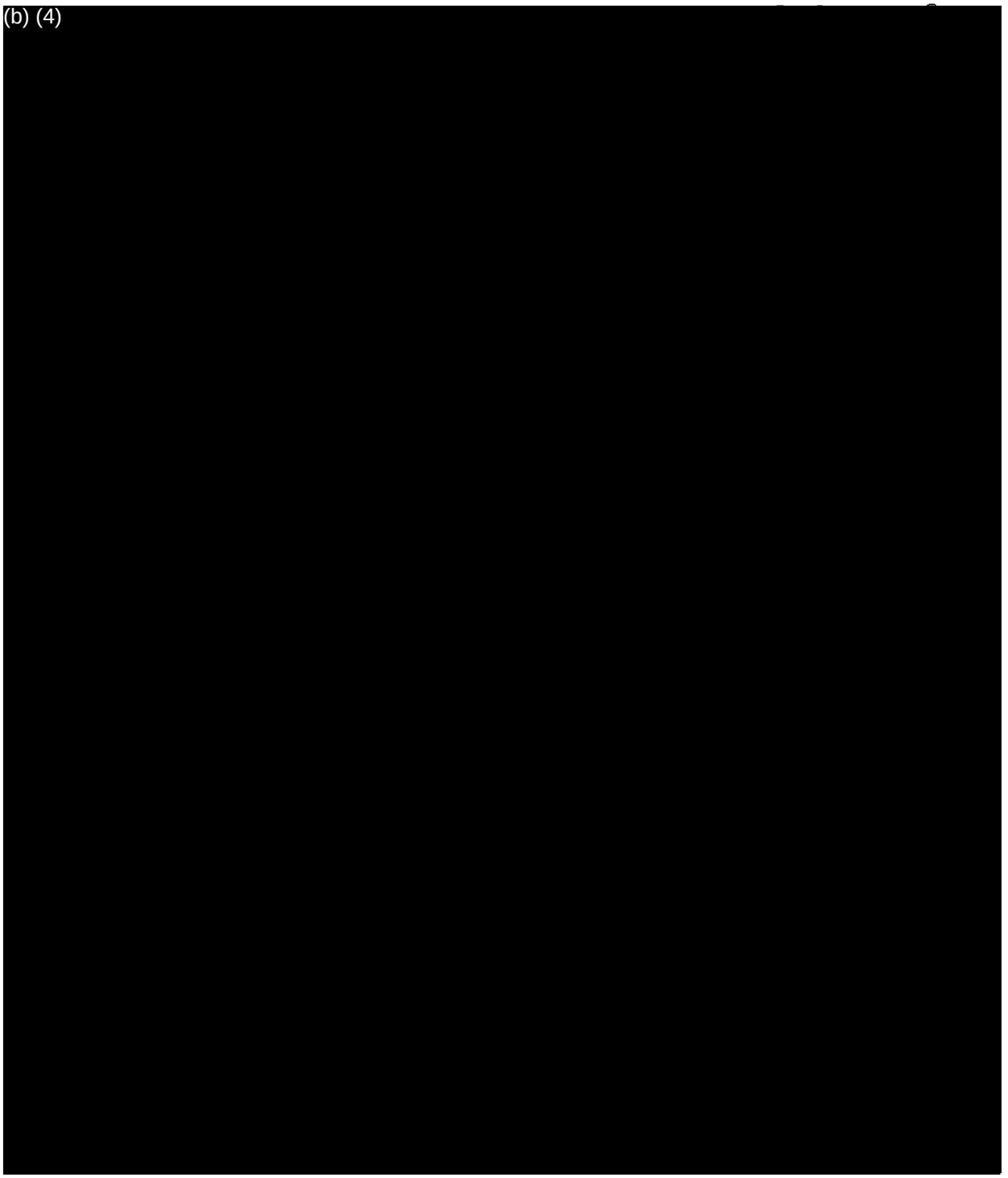

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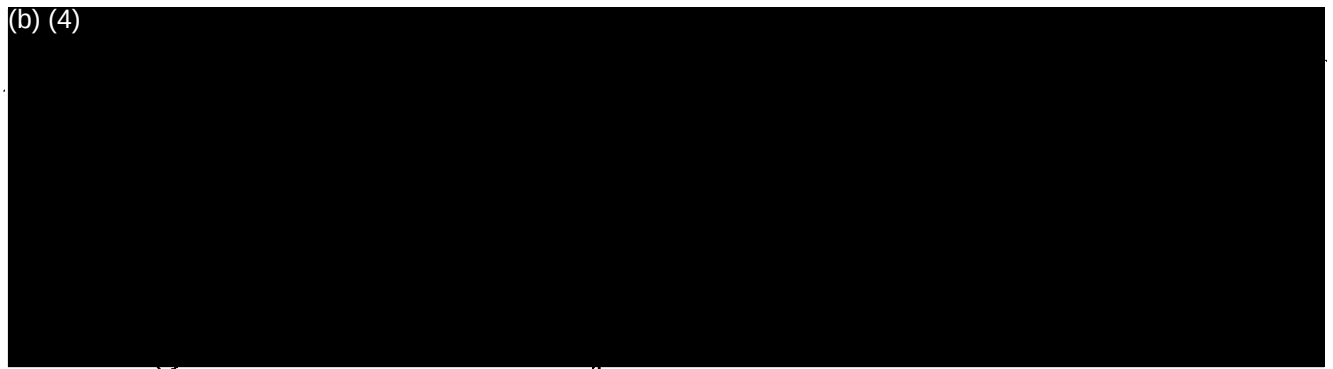

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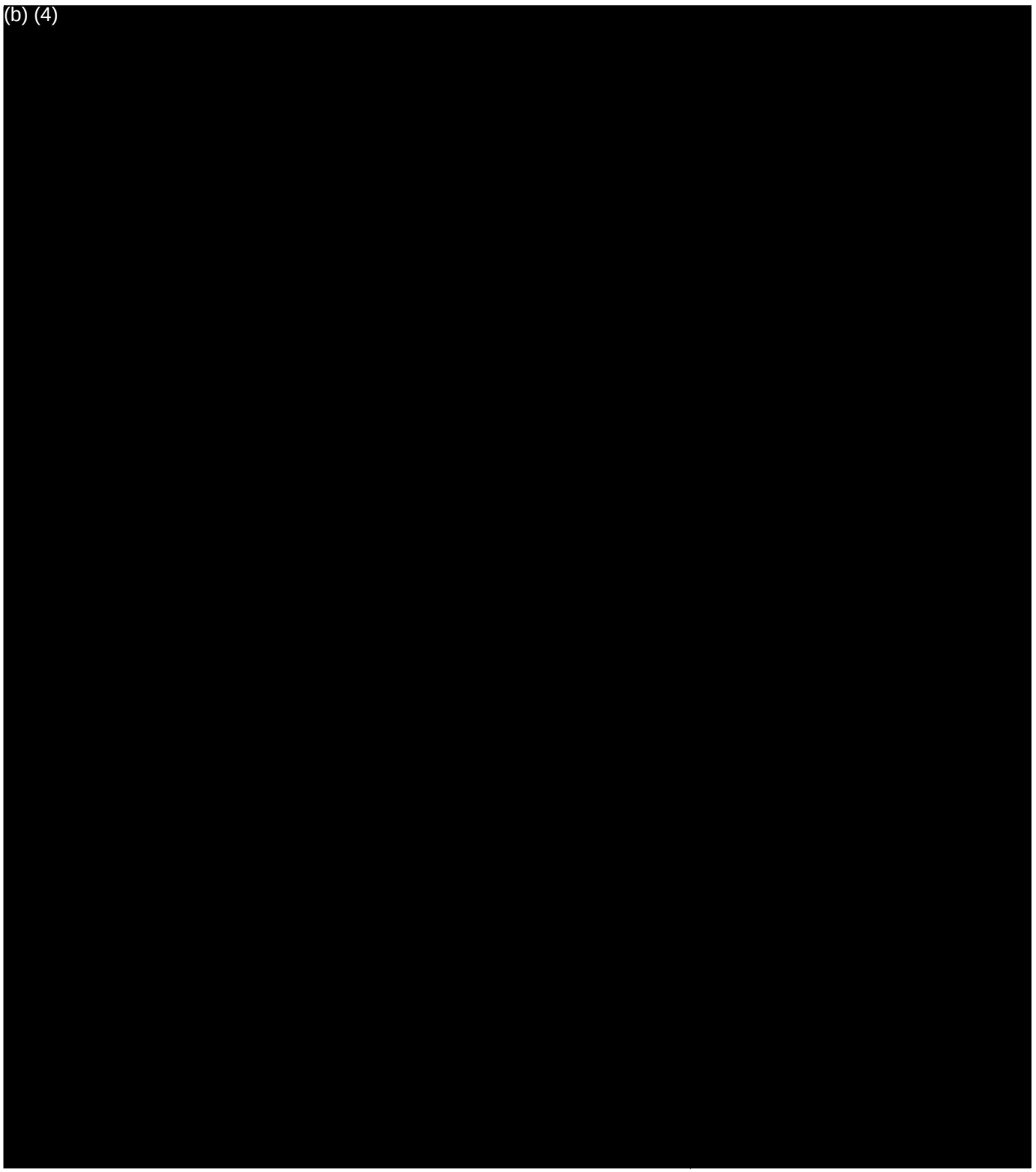

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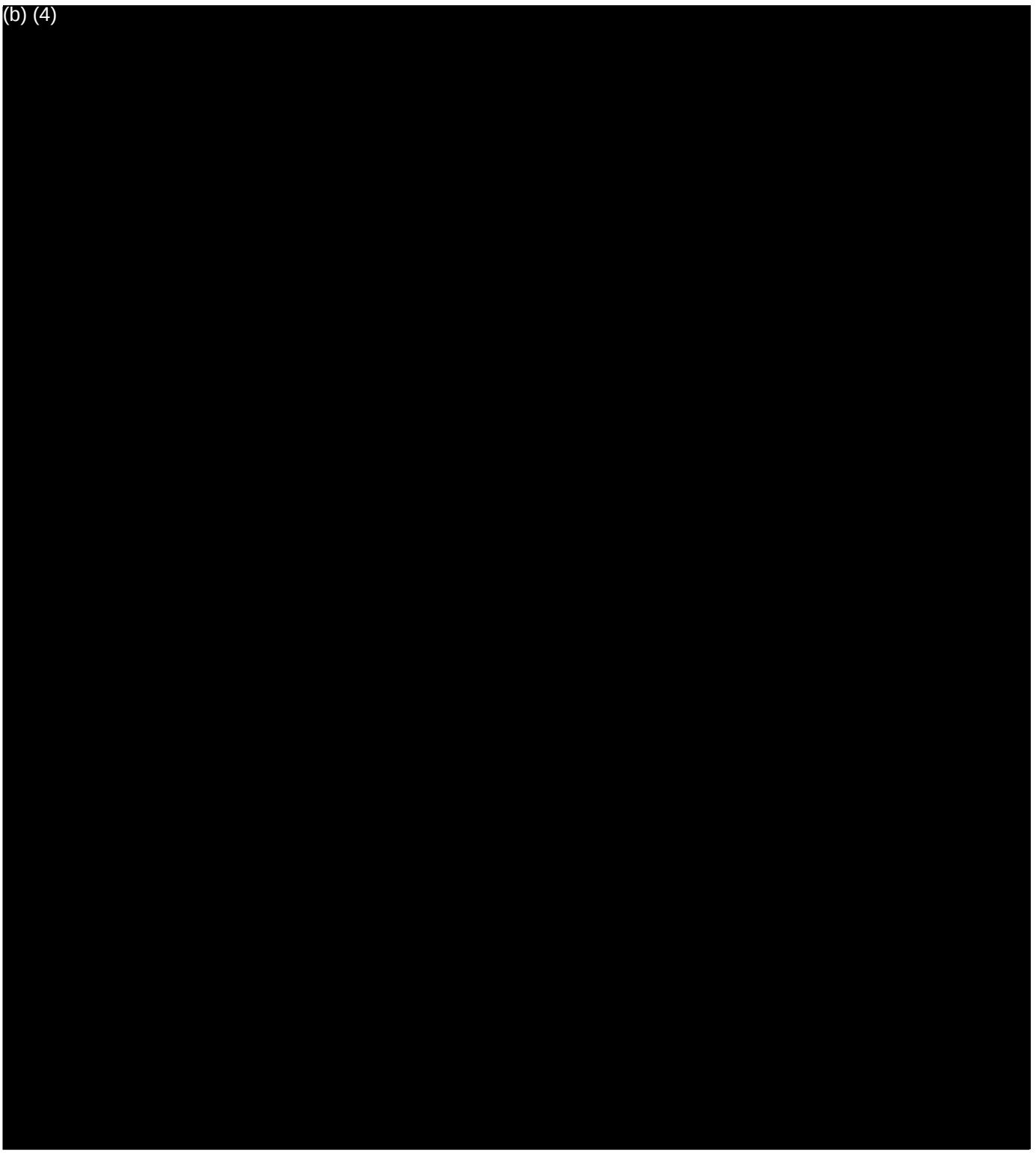

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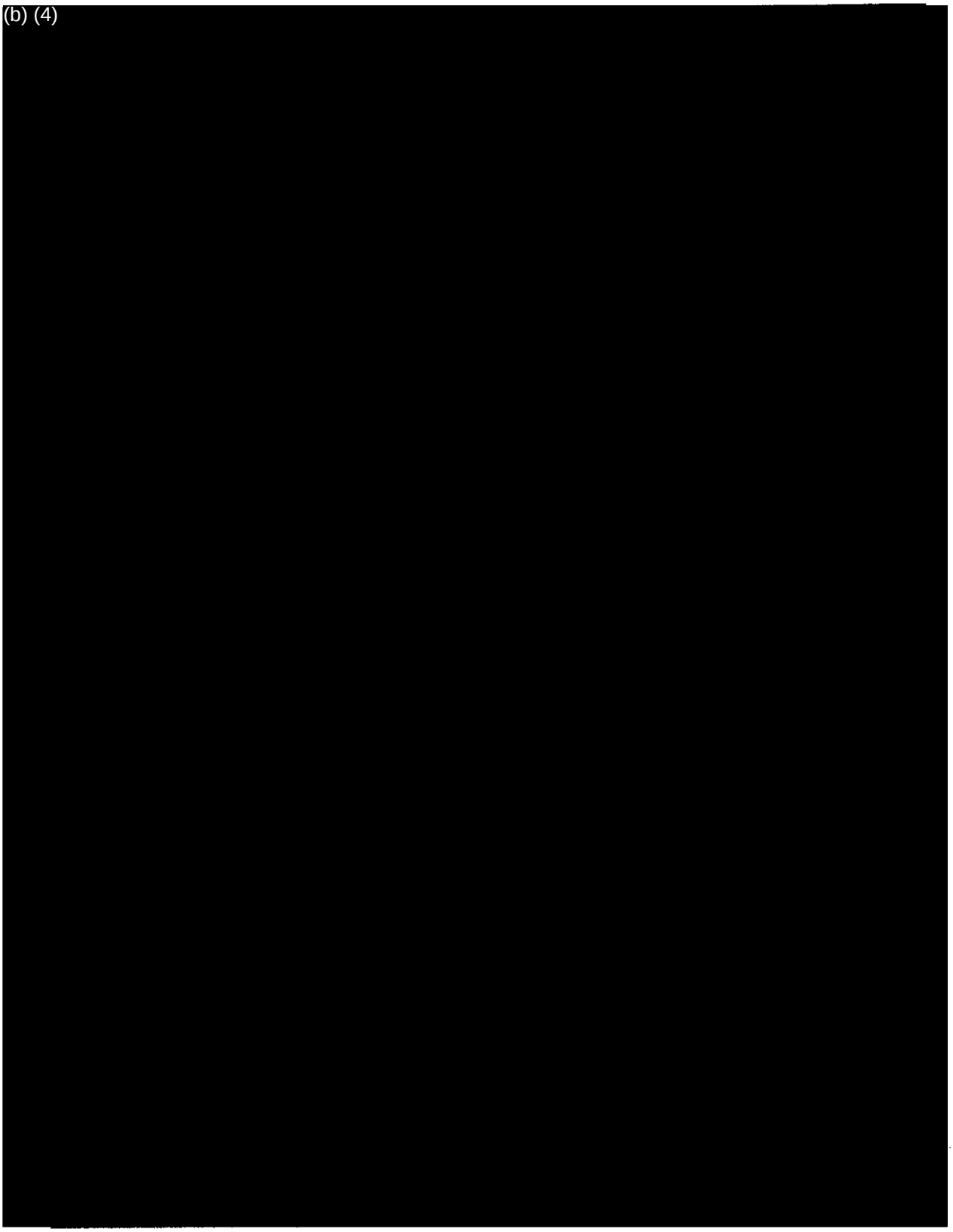

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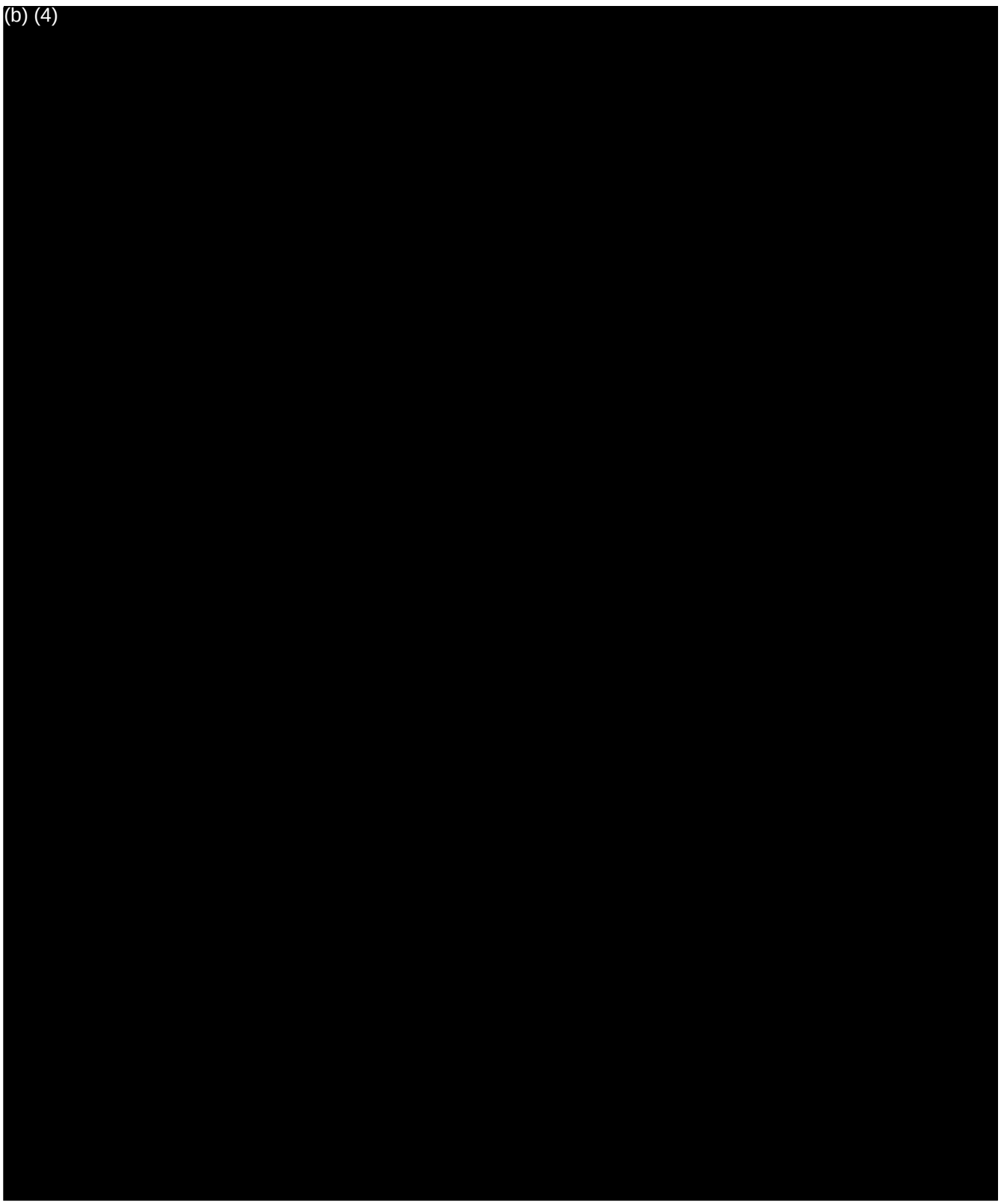

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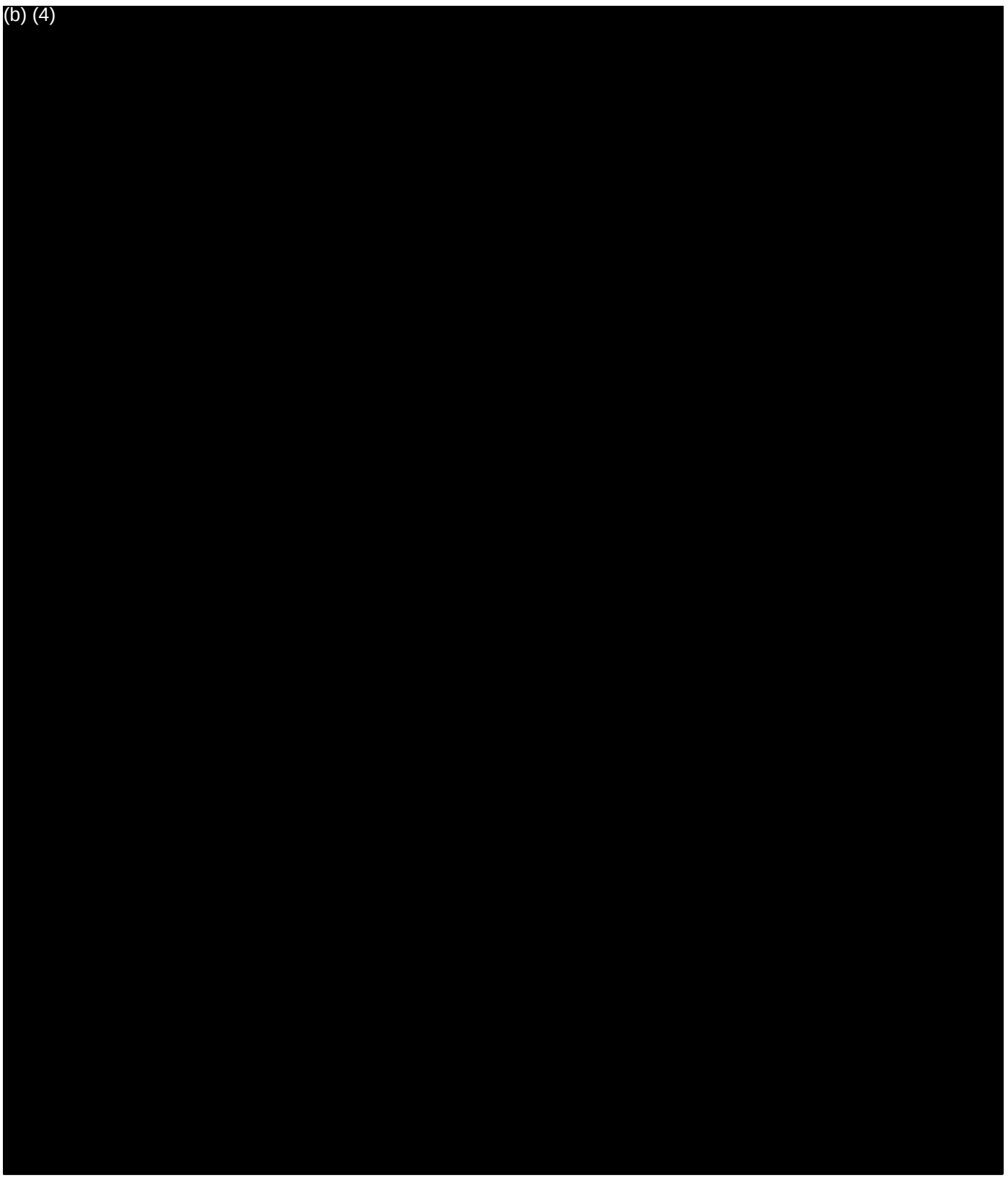

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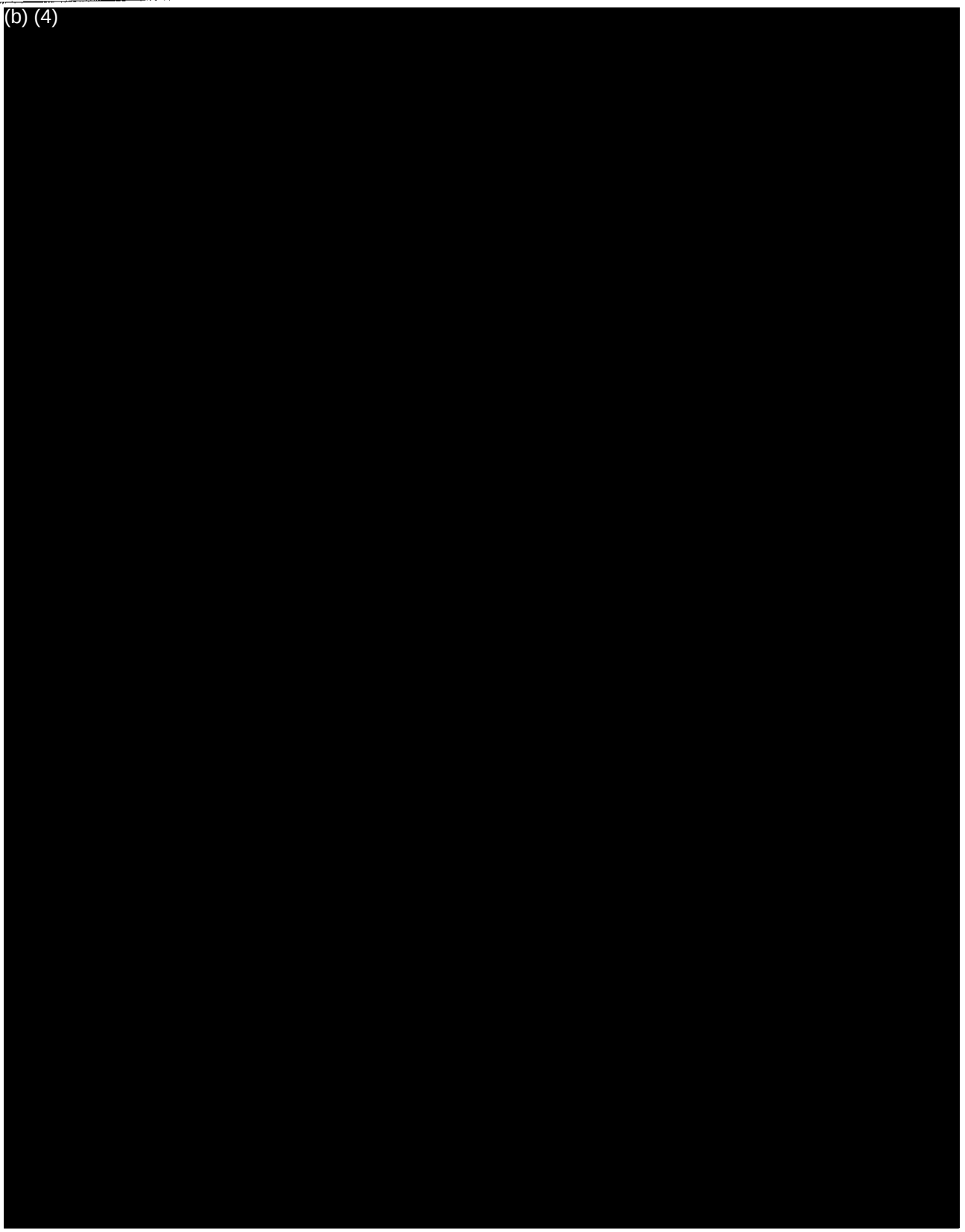

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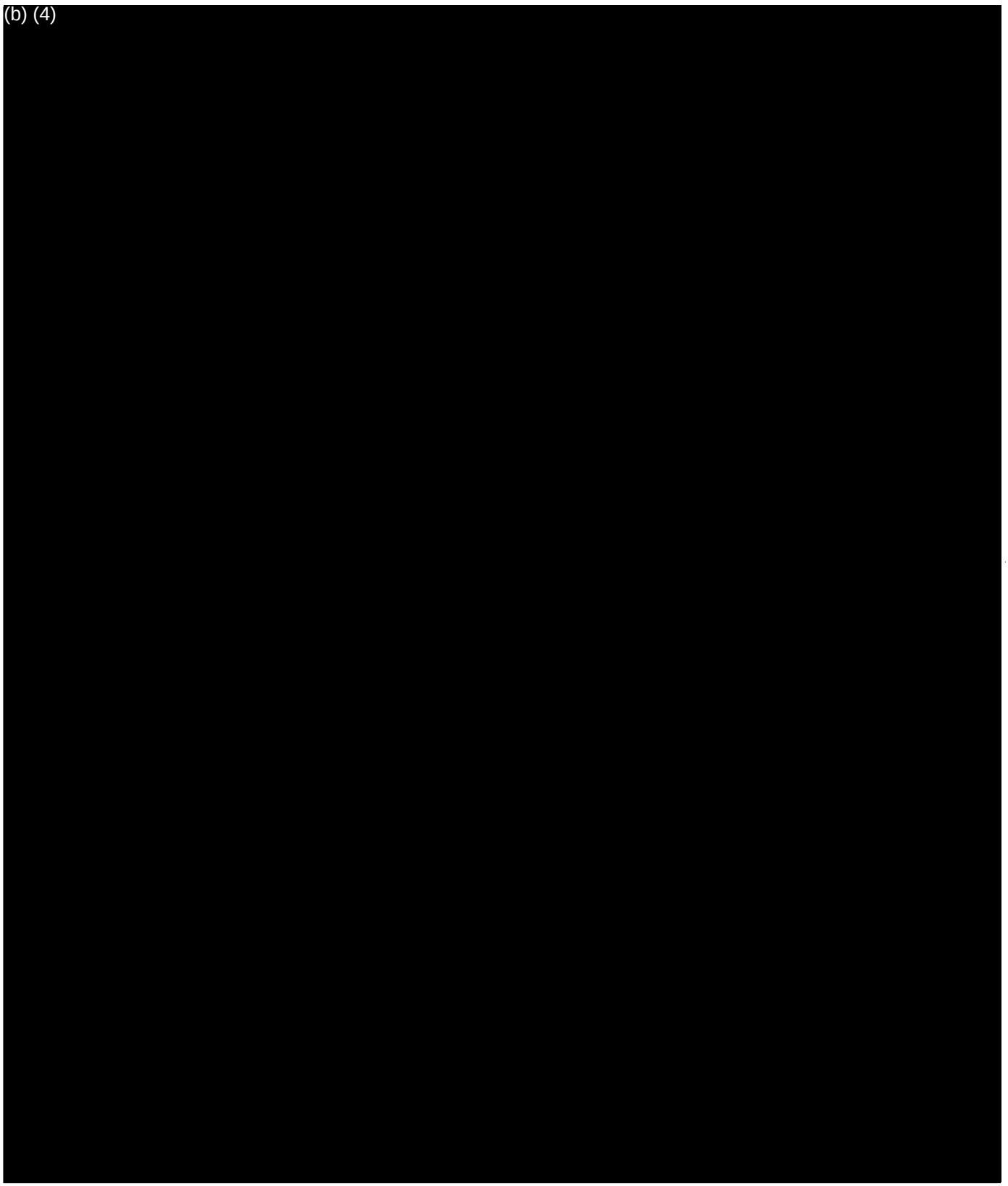

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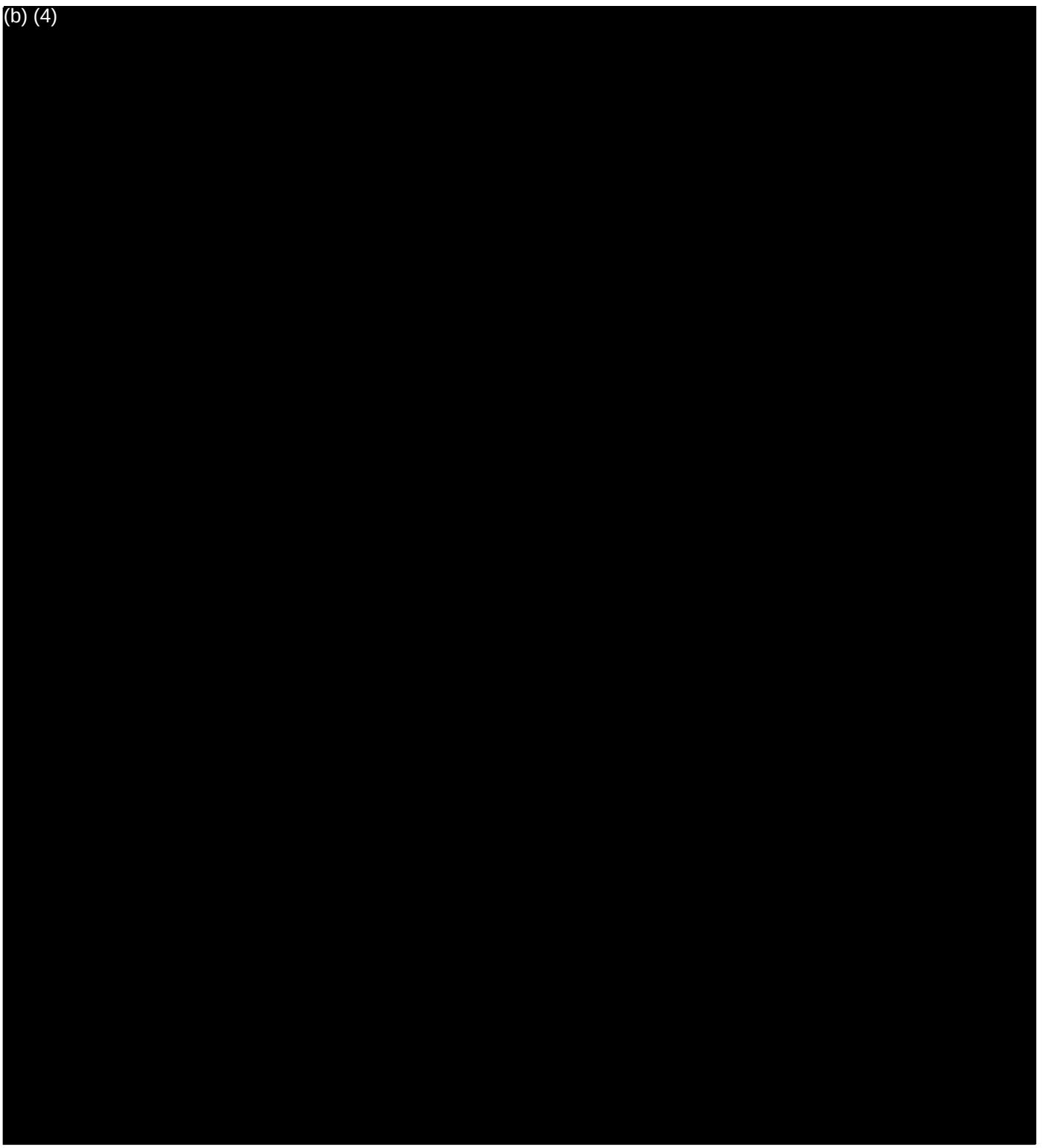

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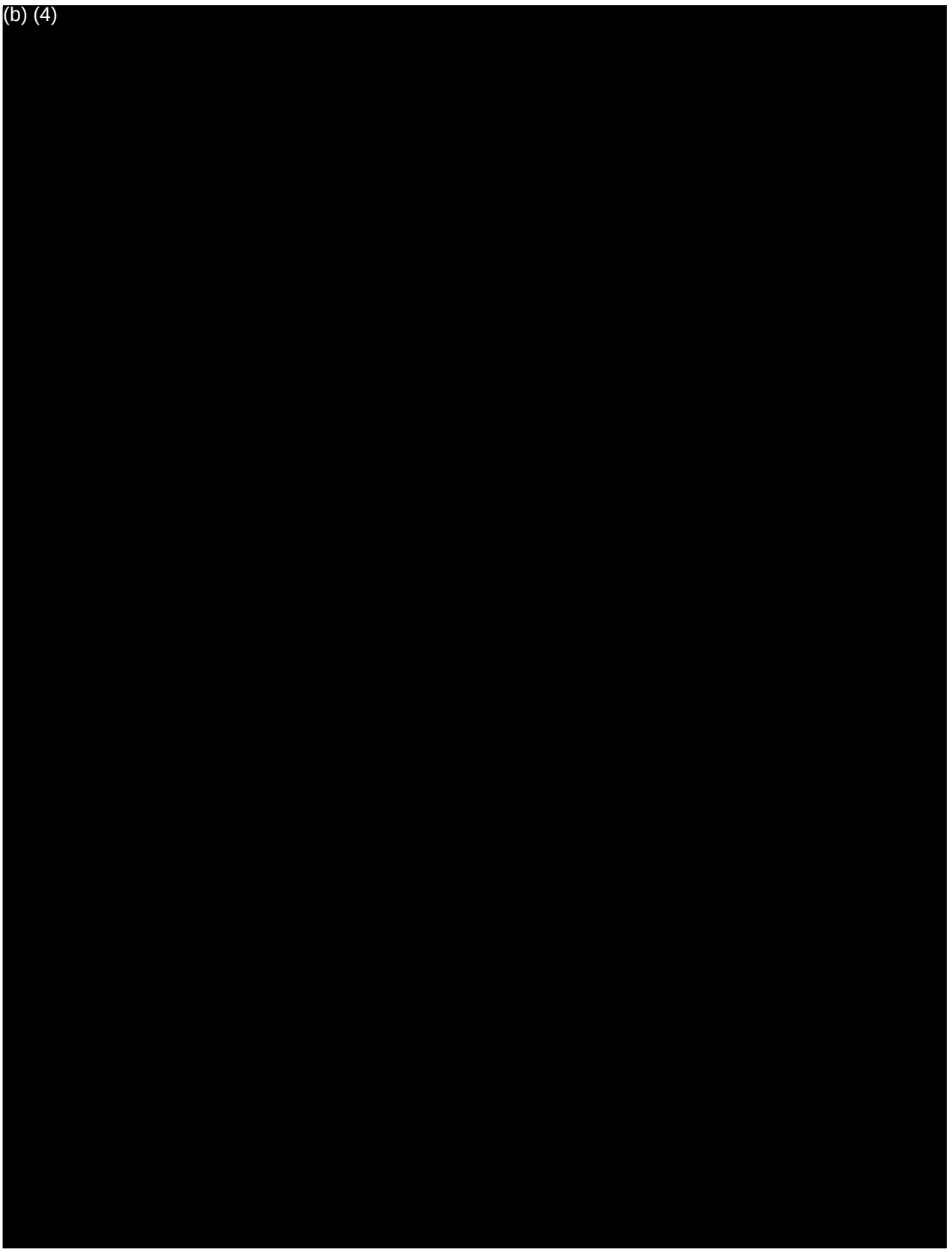

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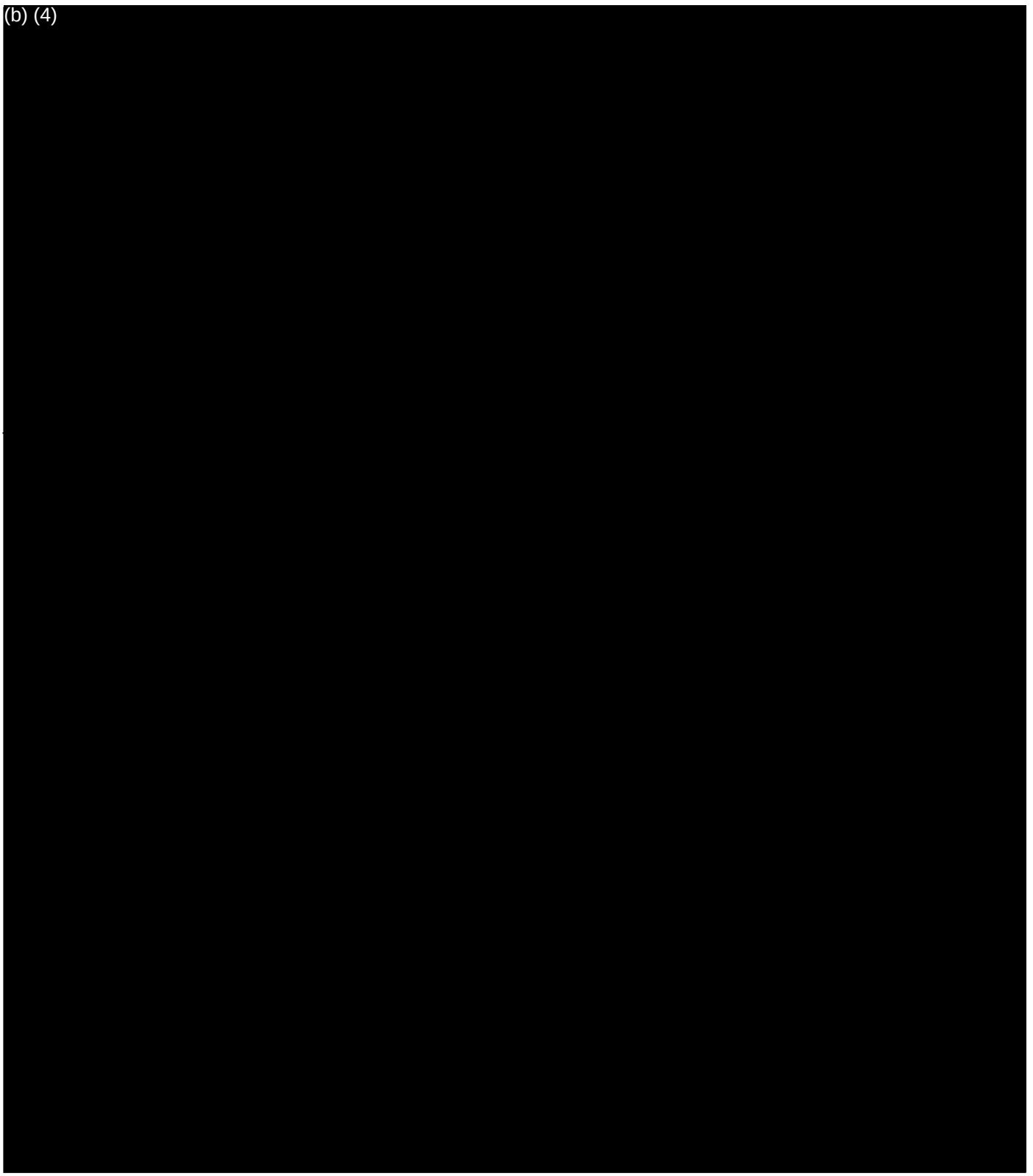

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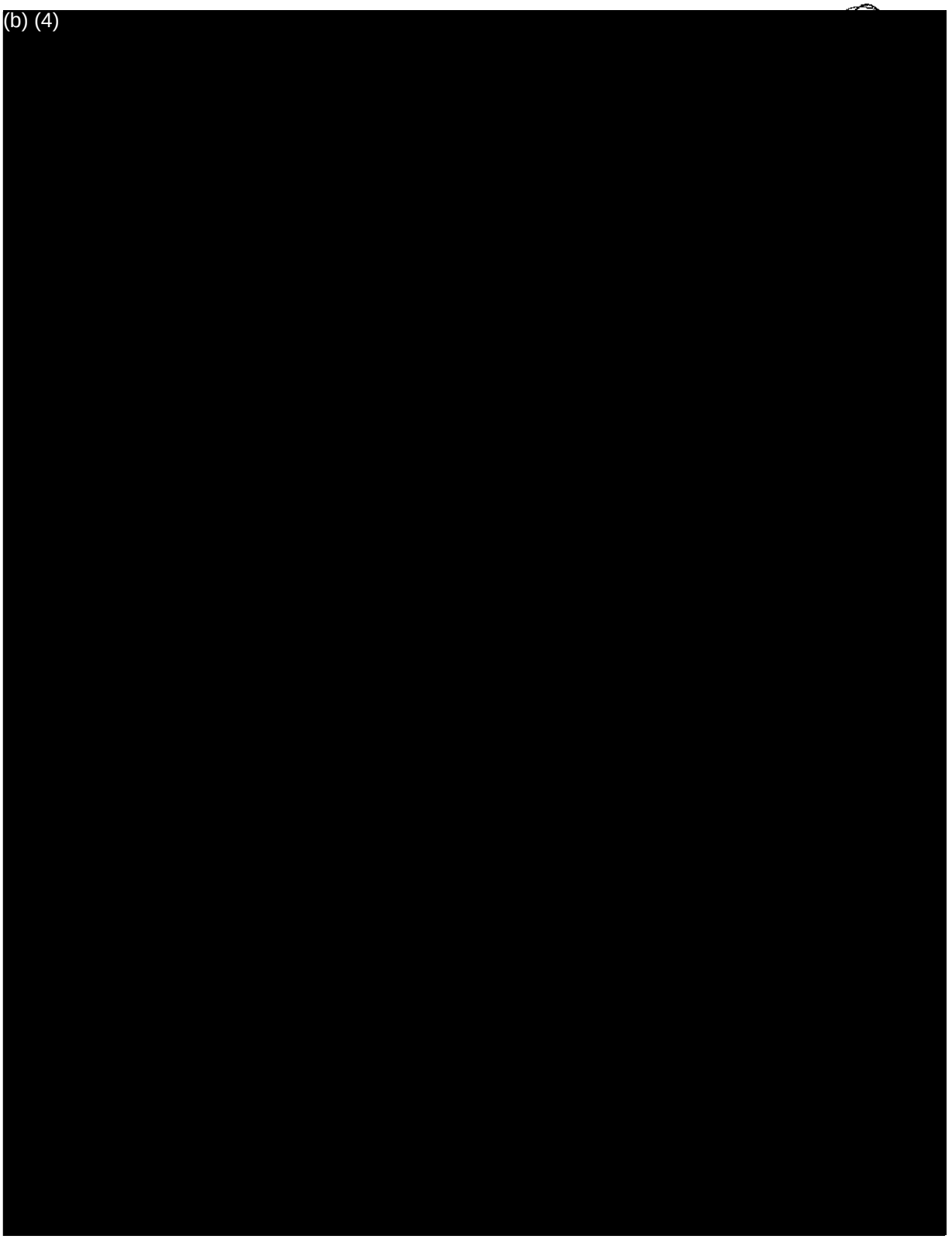

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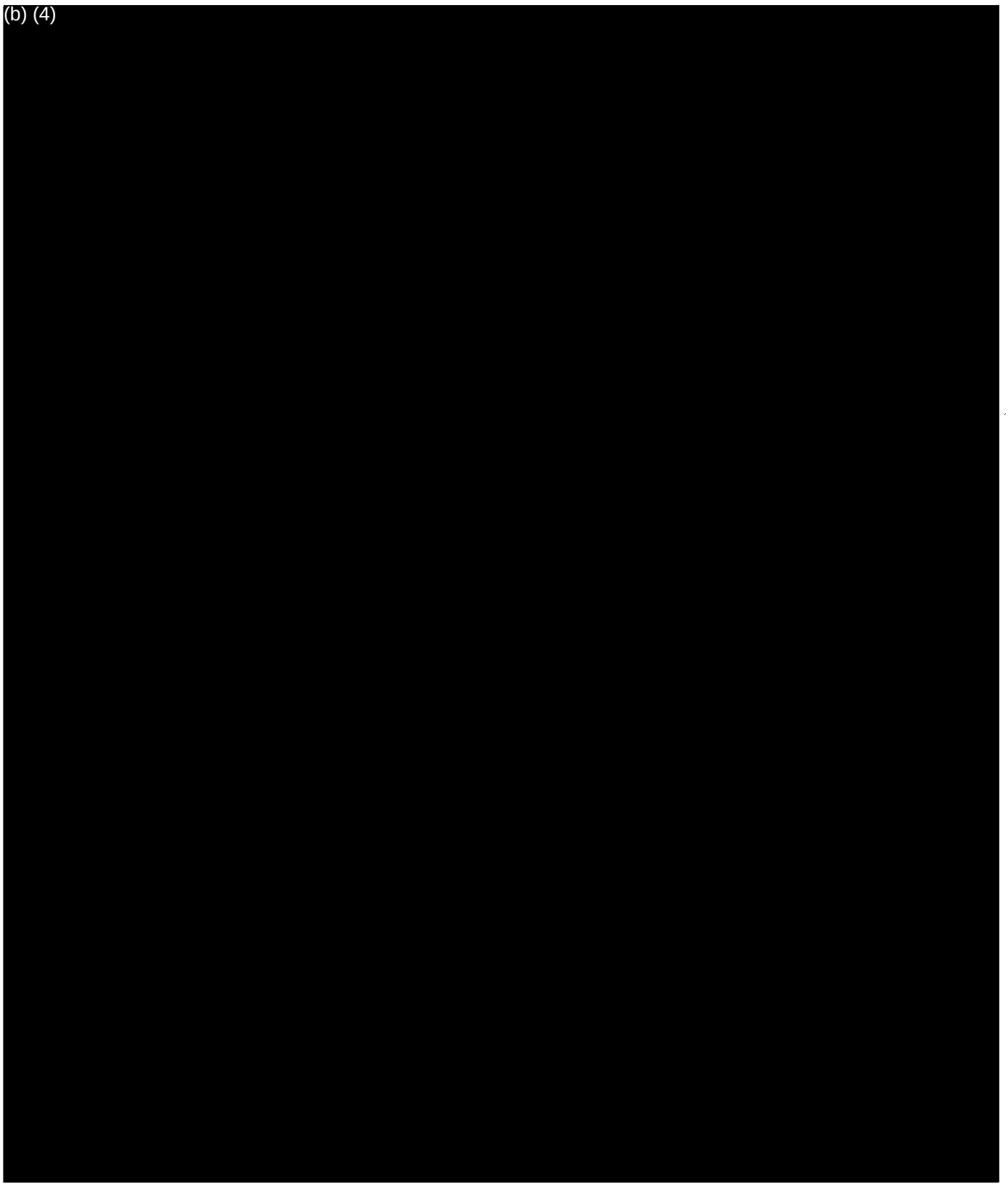

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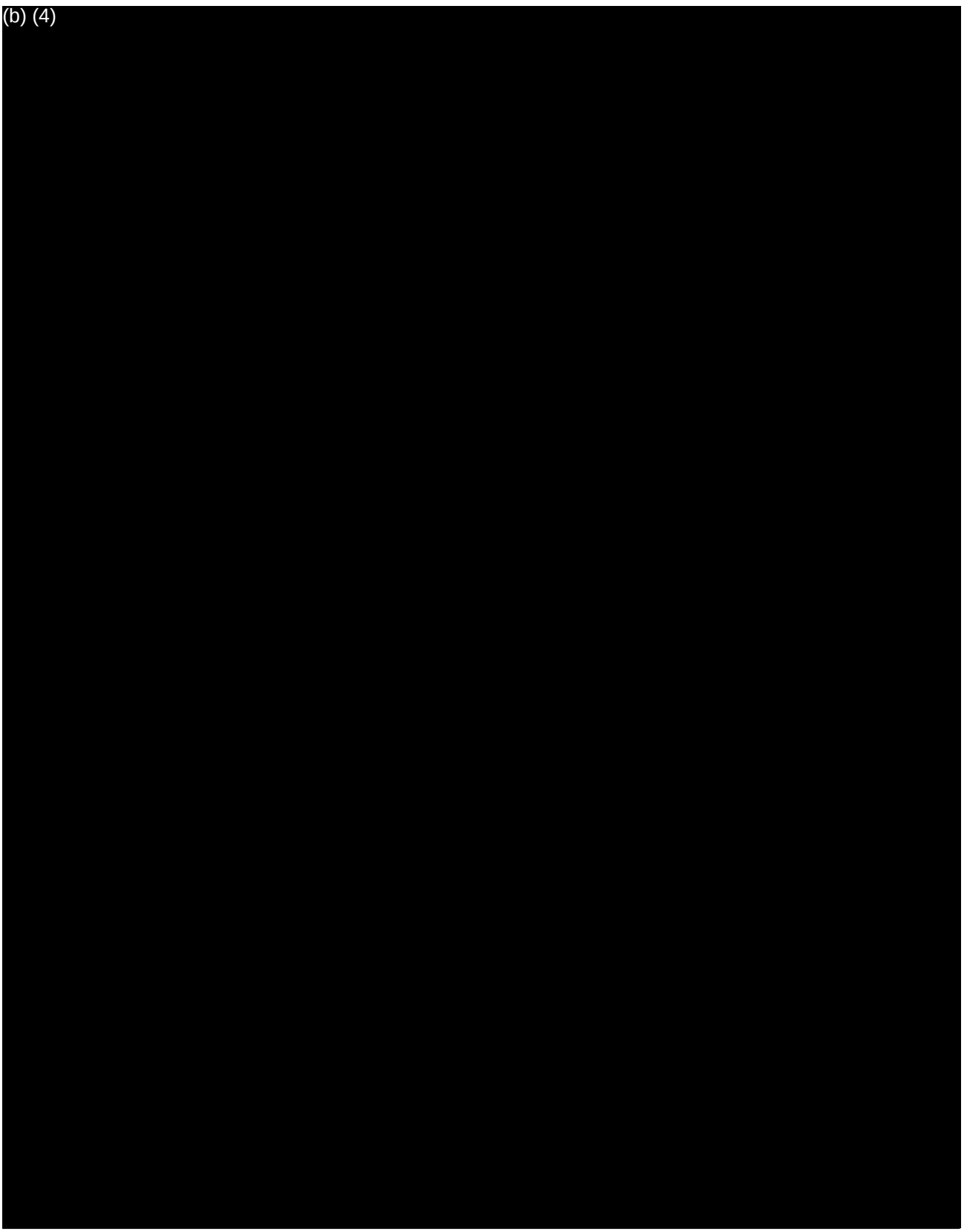

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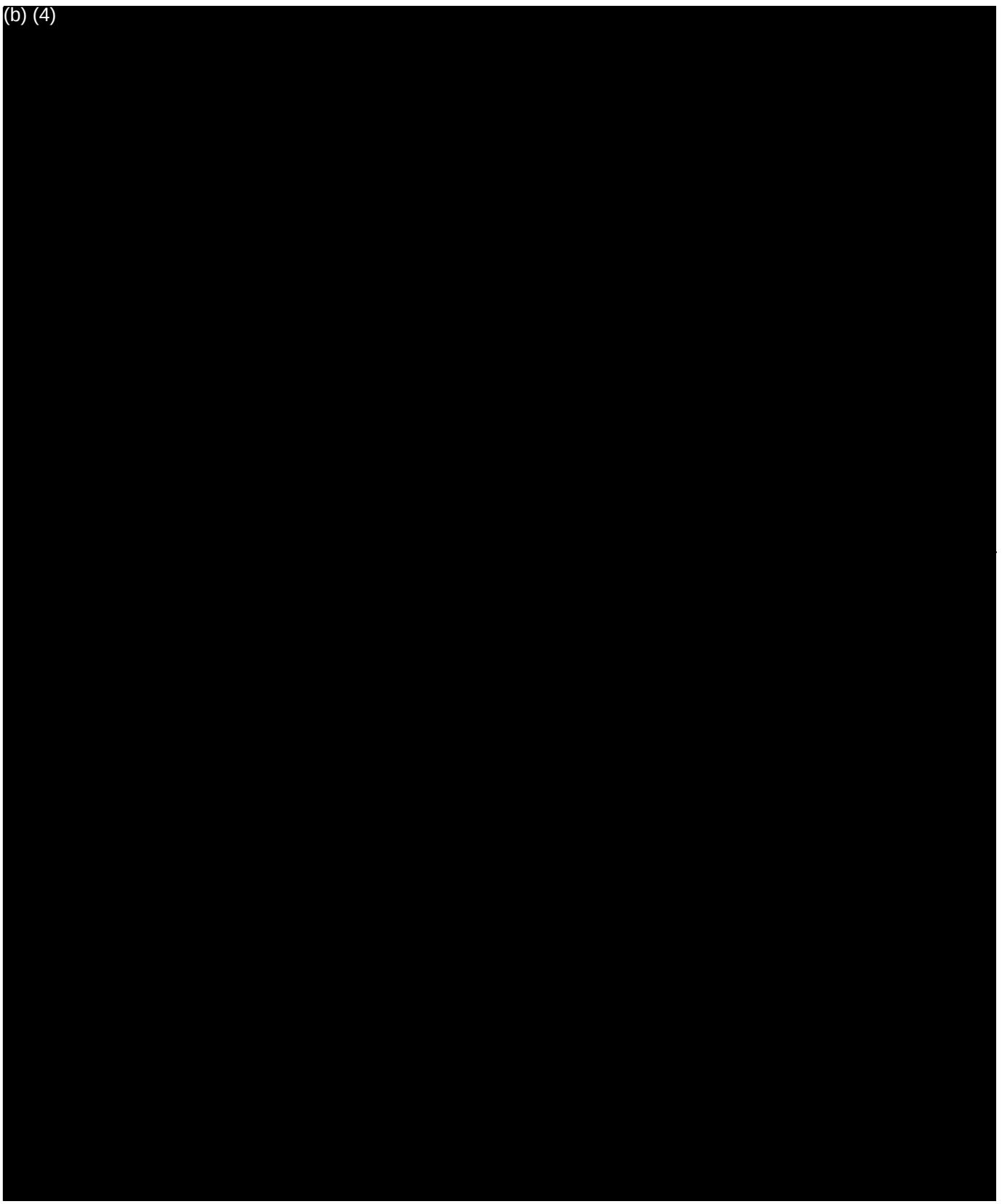

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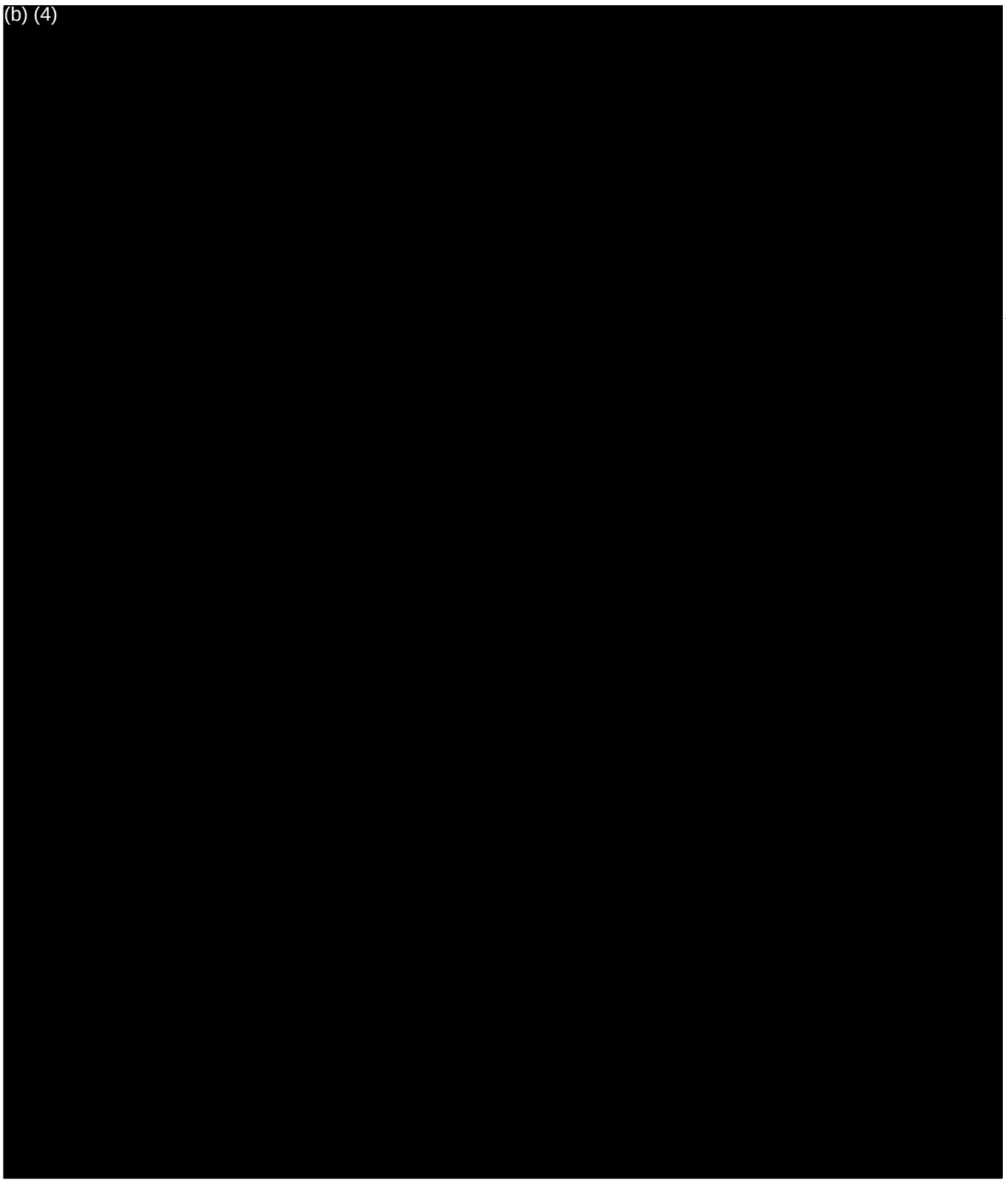

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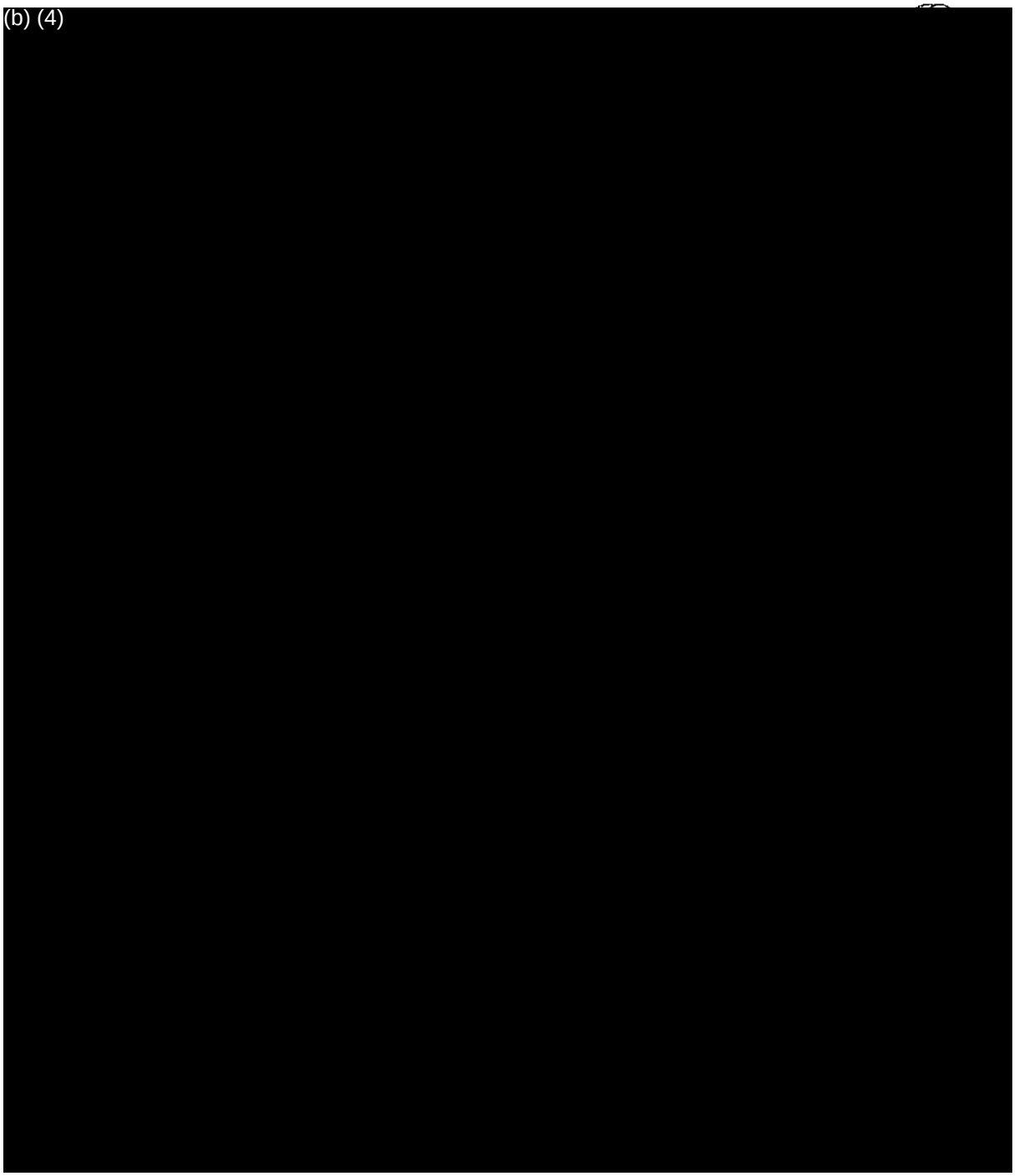

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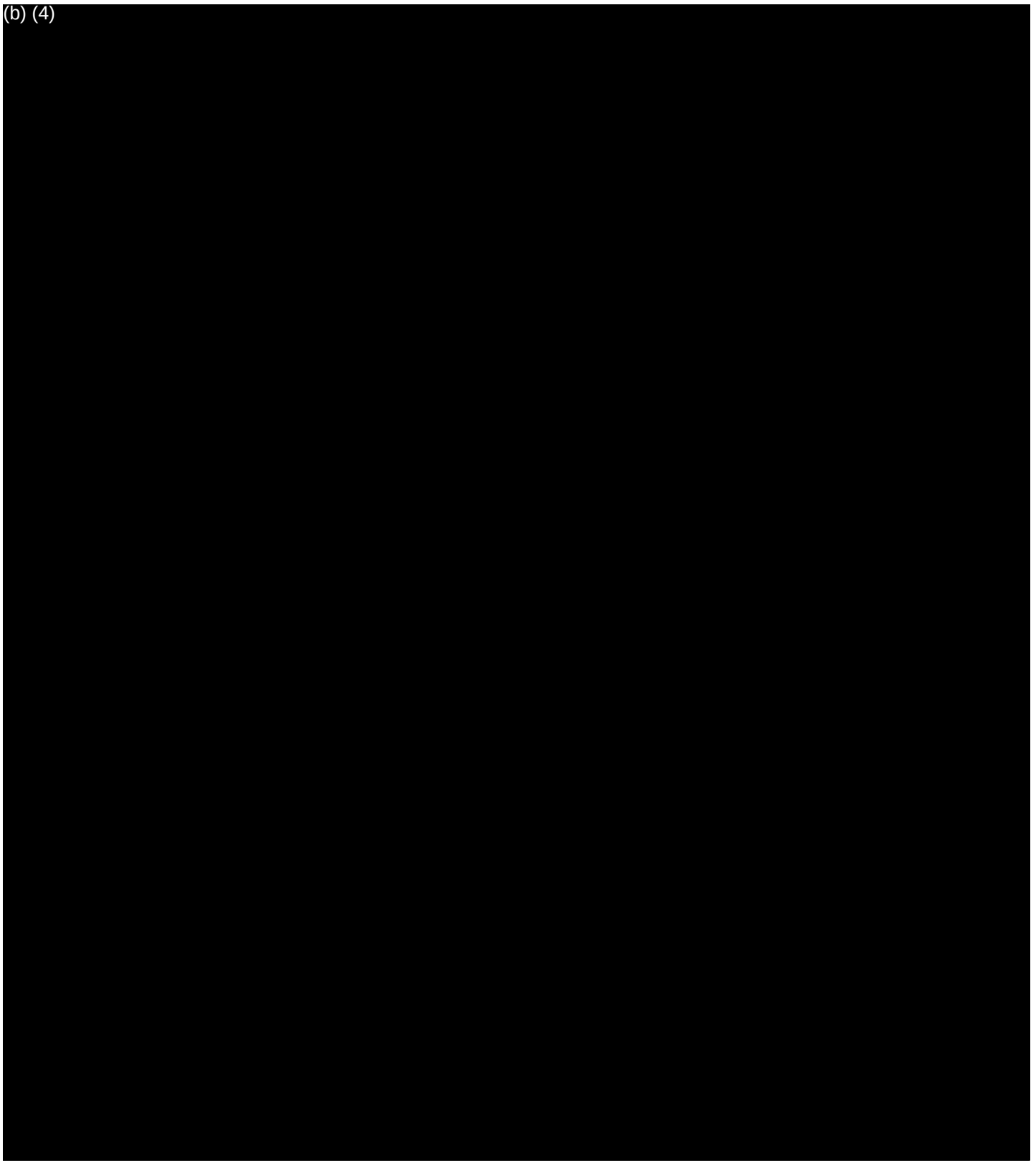

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DJA x00836

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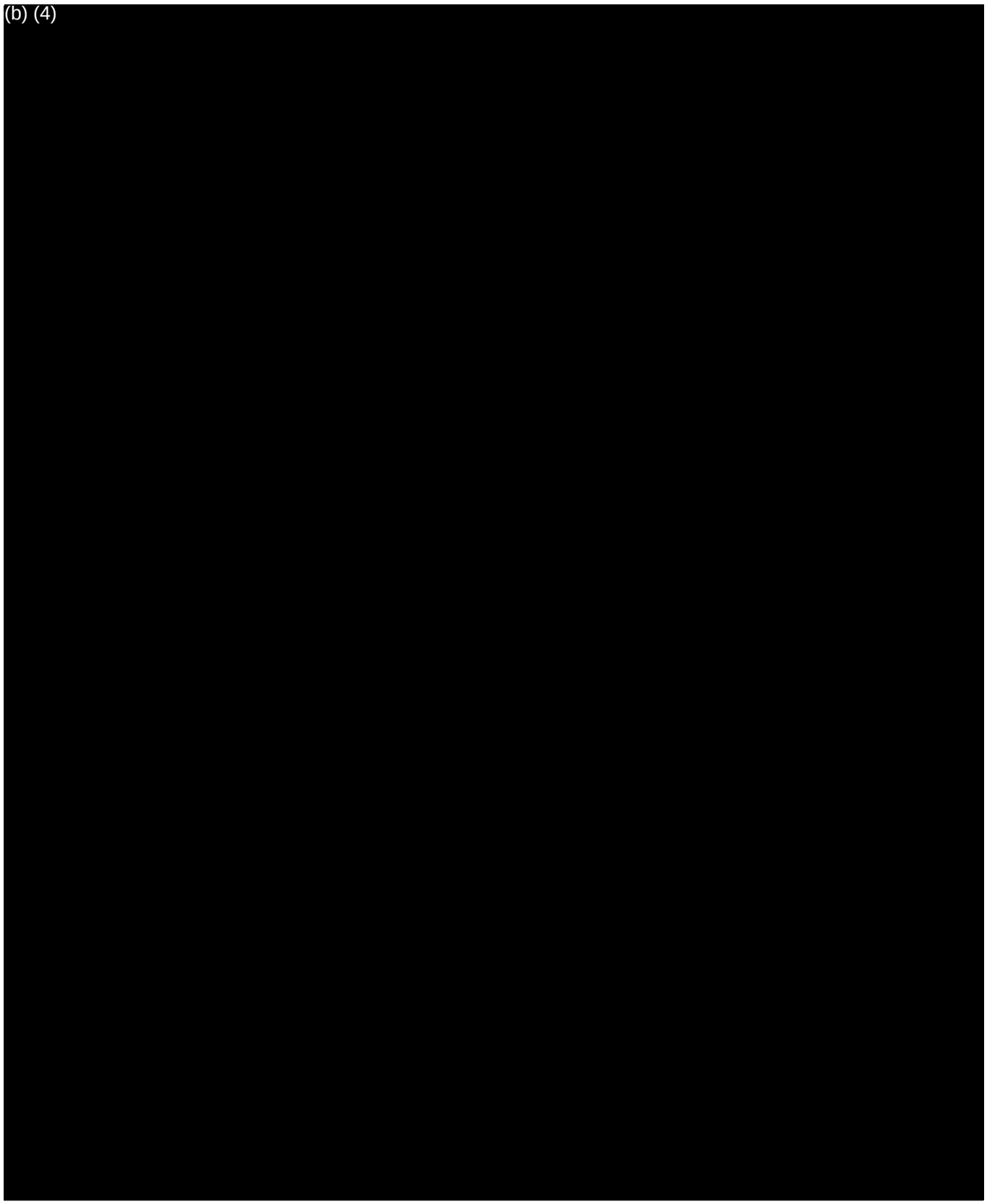

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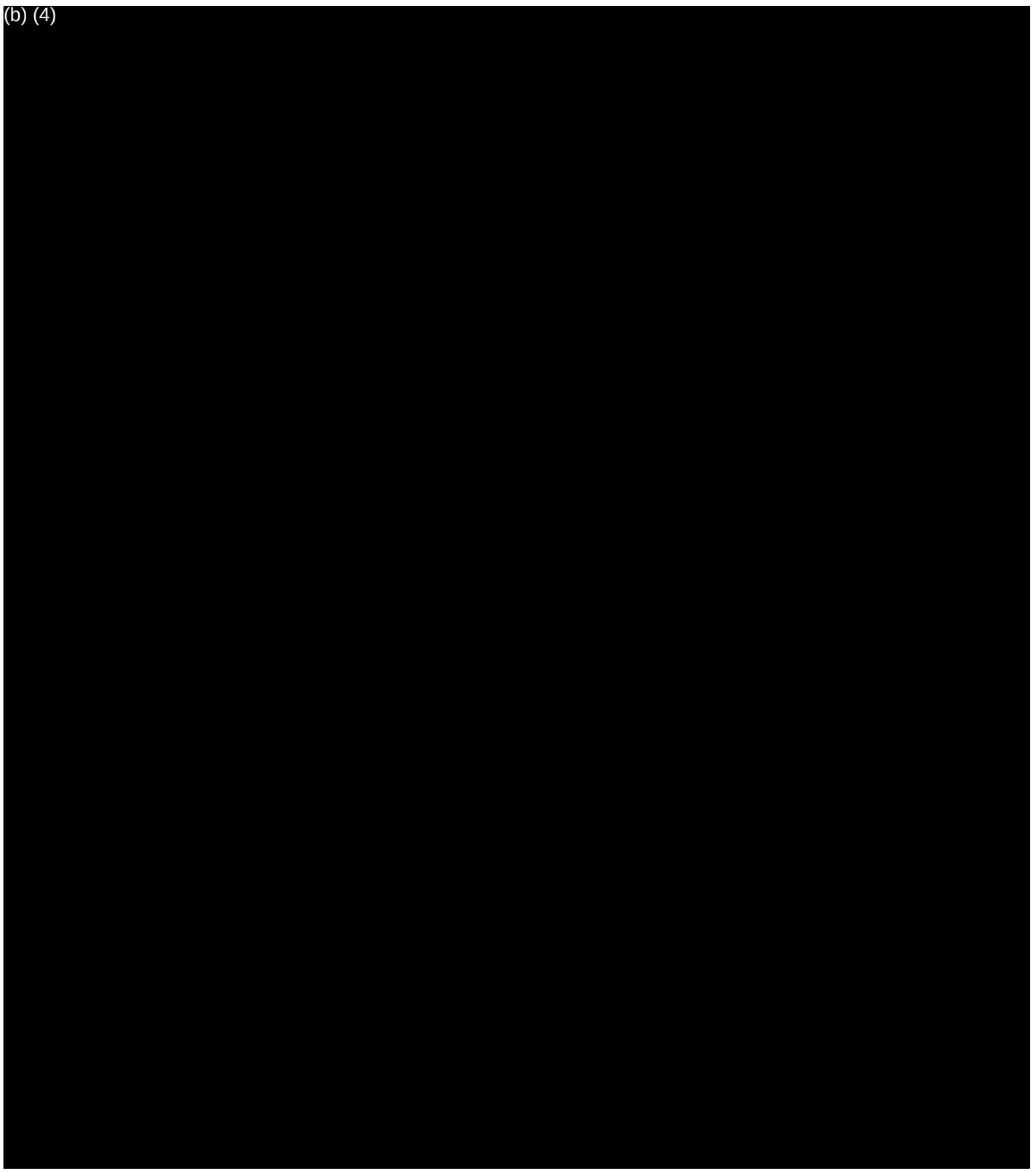

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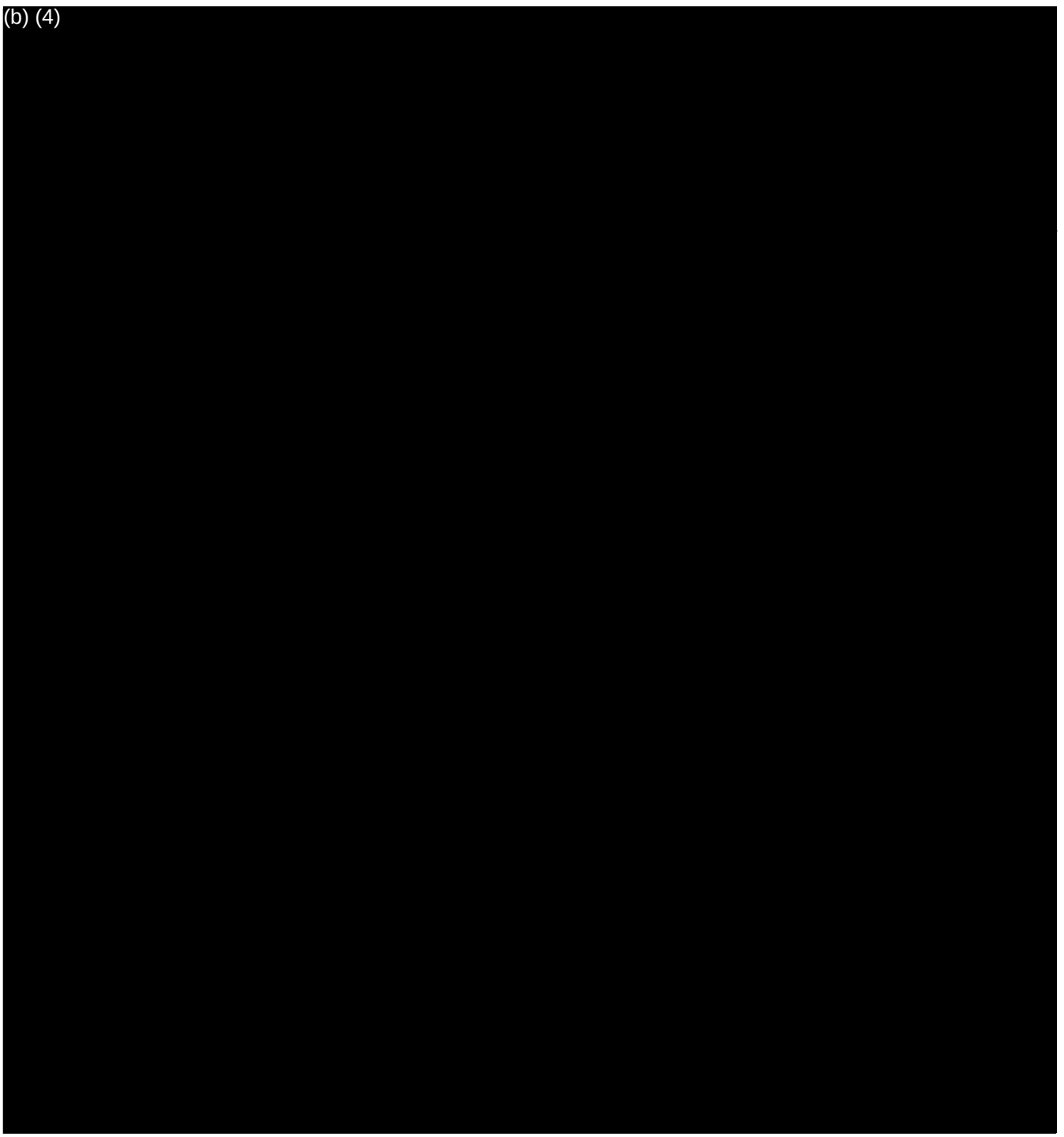

DJA x00841

(b) (4)

DJA x00842

(b) (4)

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DJA x00843

PROTOCOL and TEST REPORT APPROVAL SHEET

DCO # 1849

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 49
KEY WORDS: ORTHODOC PROTOCOL VALIDATION	PROTOCOL REF. NO. (If applicable)	PROJECT NO.: (If applicable) 42

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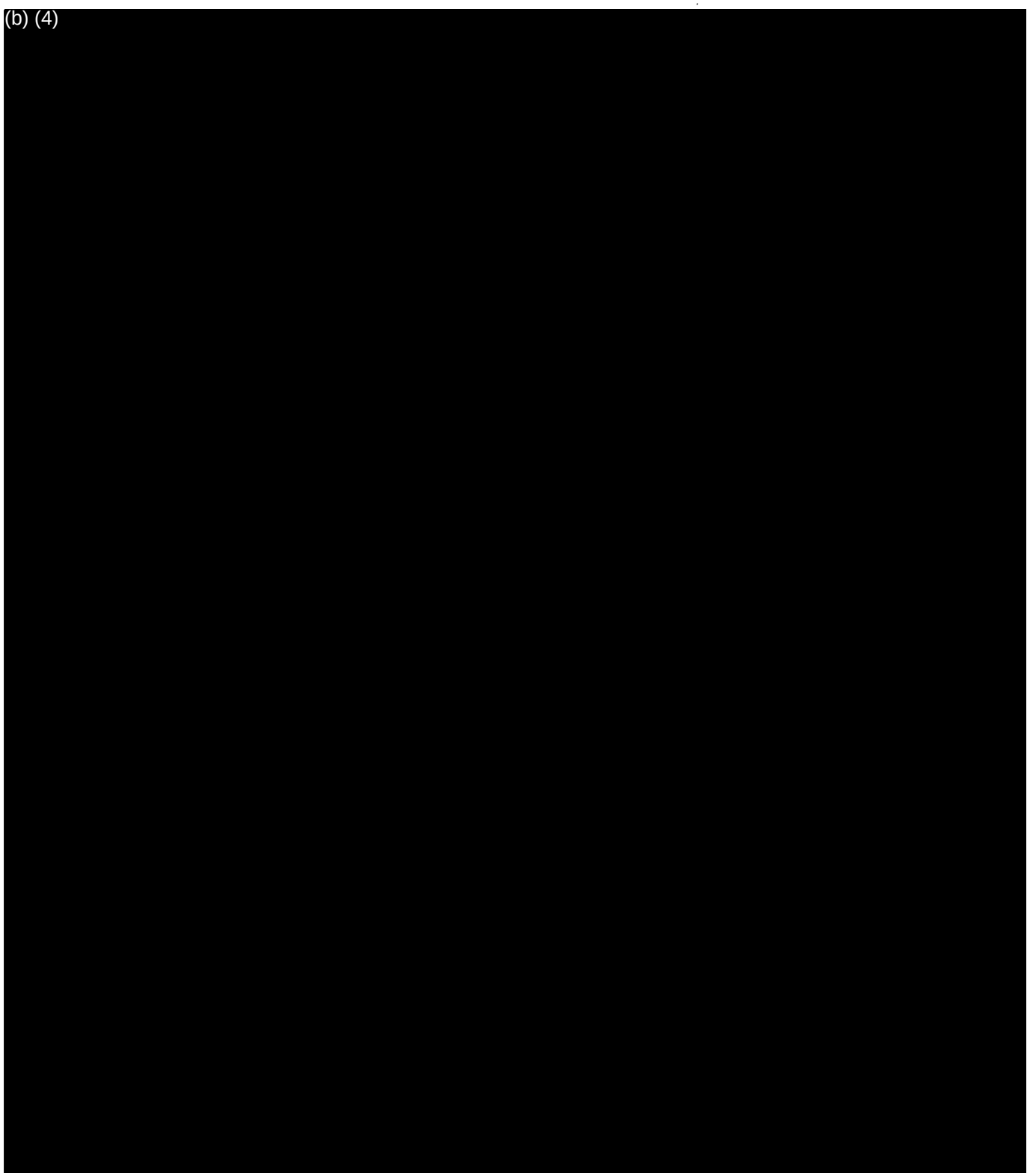
DJA x00844

(b) (4)



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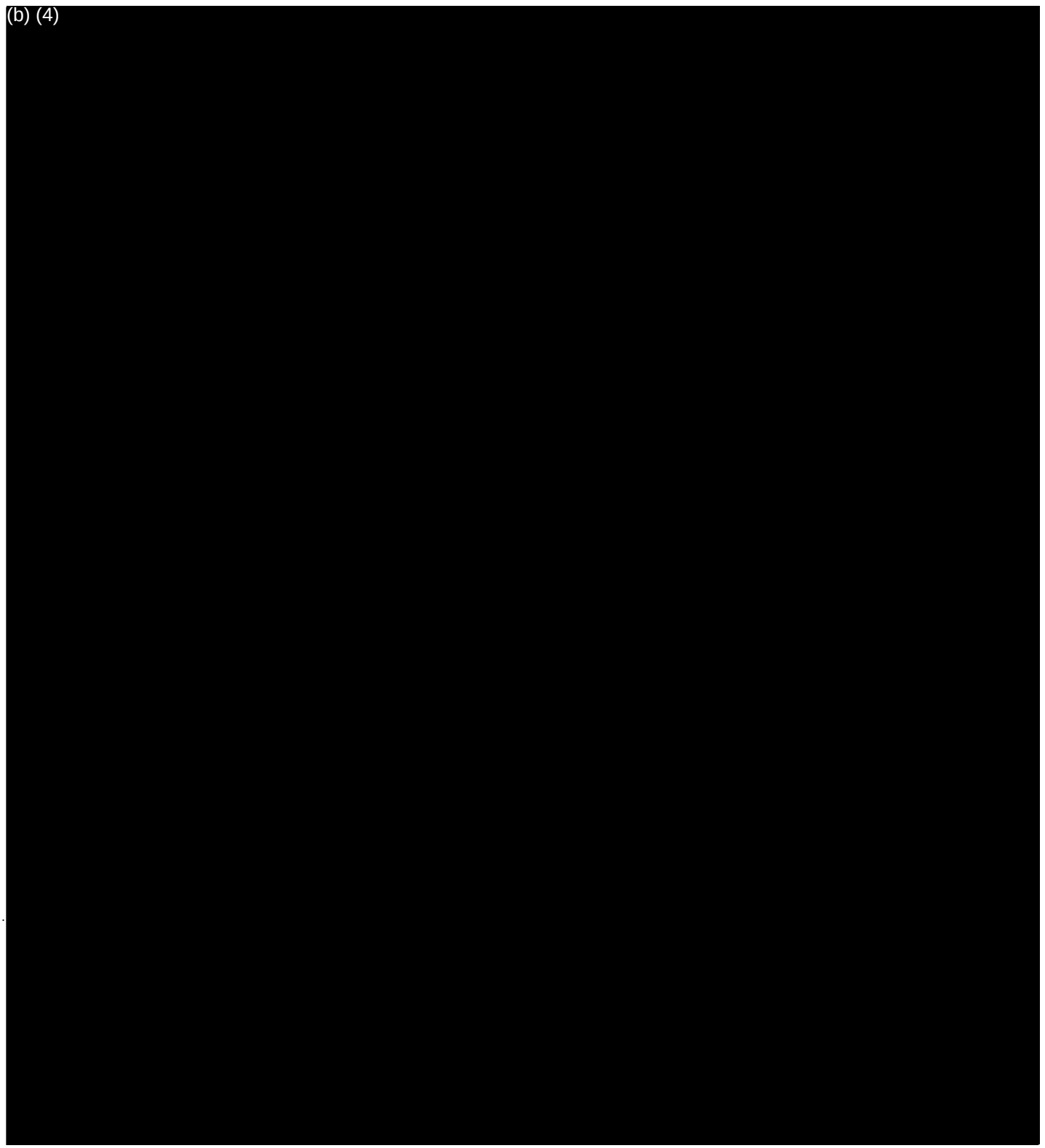

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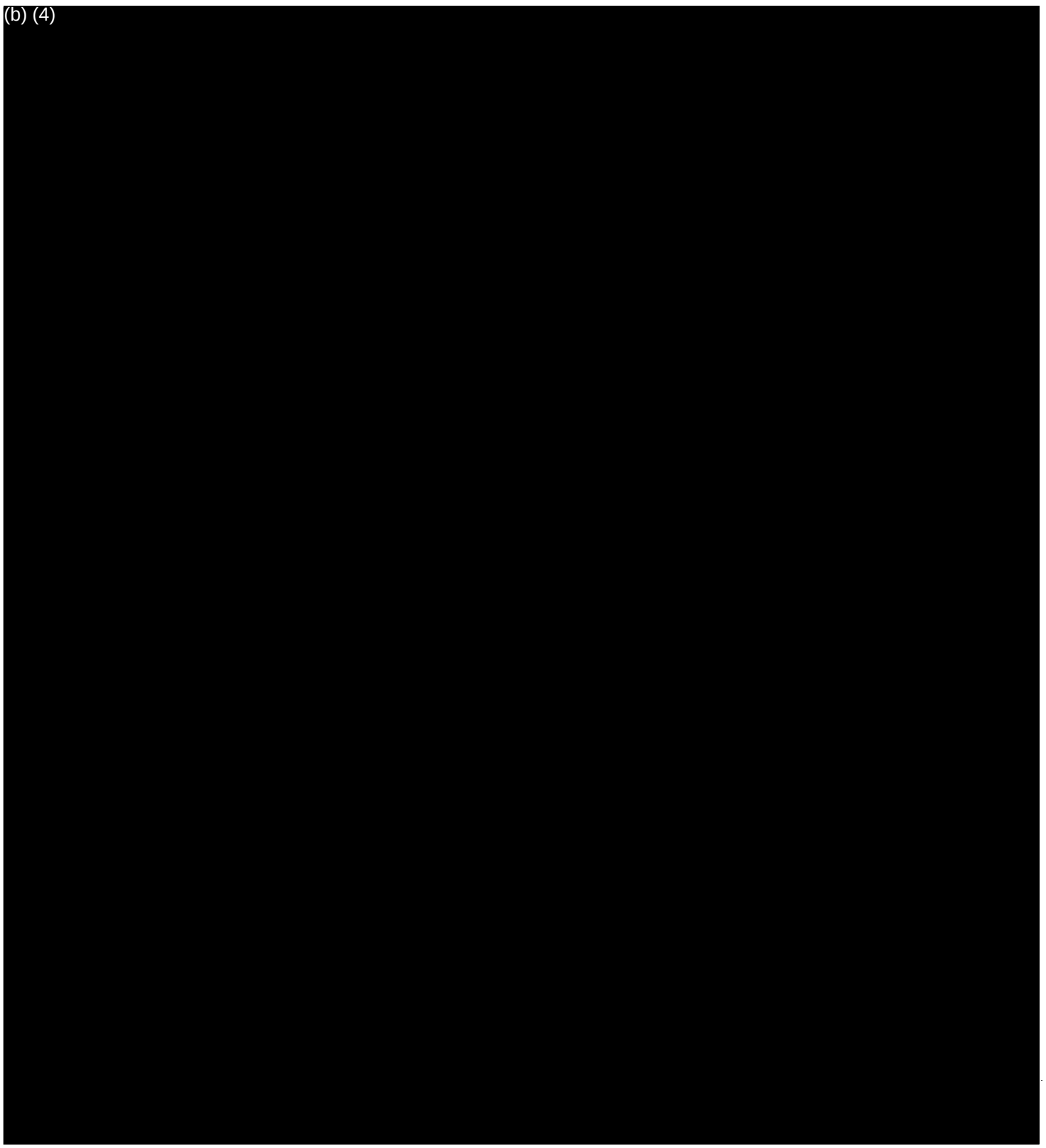

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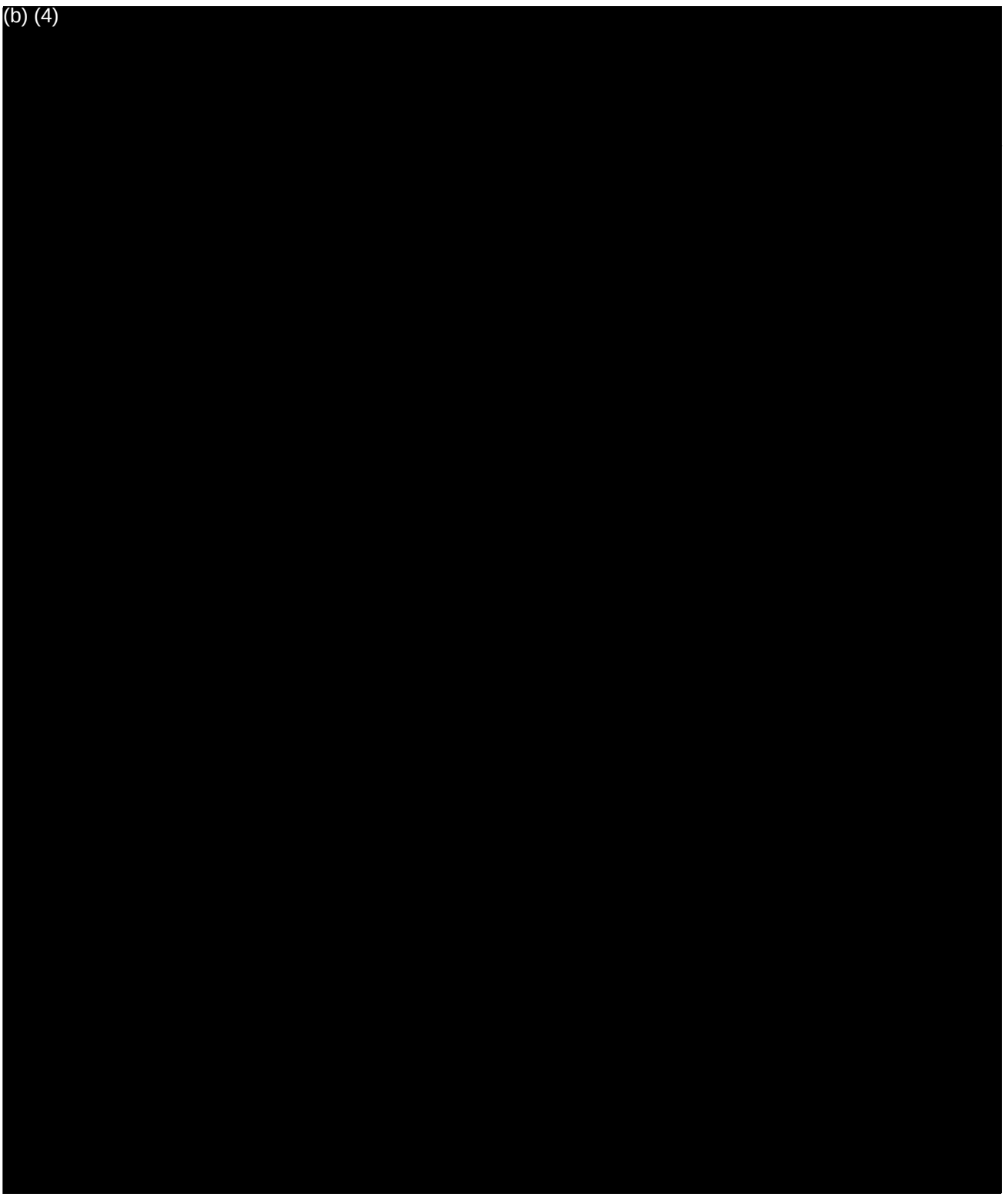
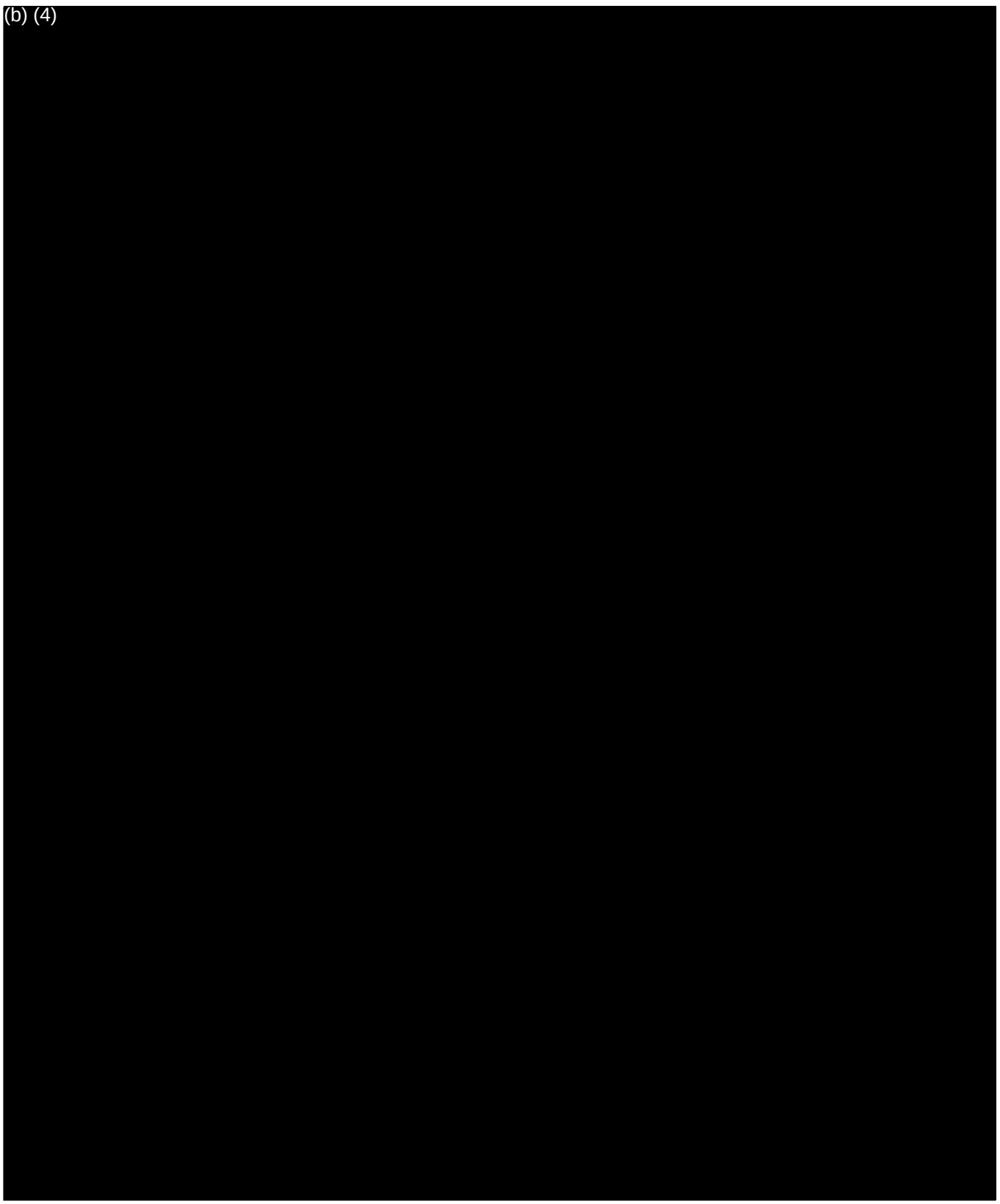


DJA x00848

(b) (4)

DJA x000849

(b) (4)



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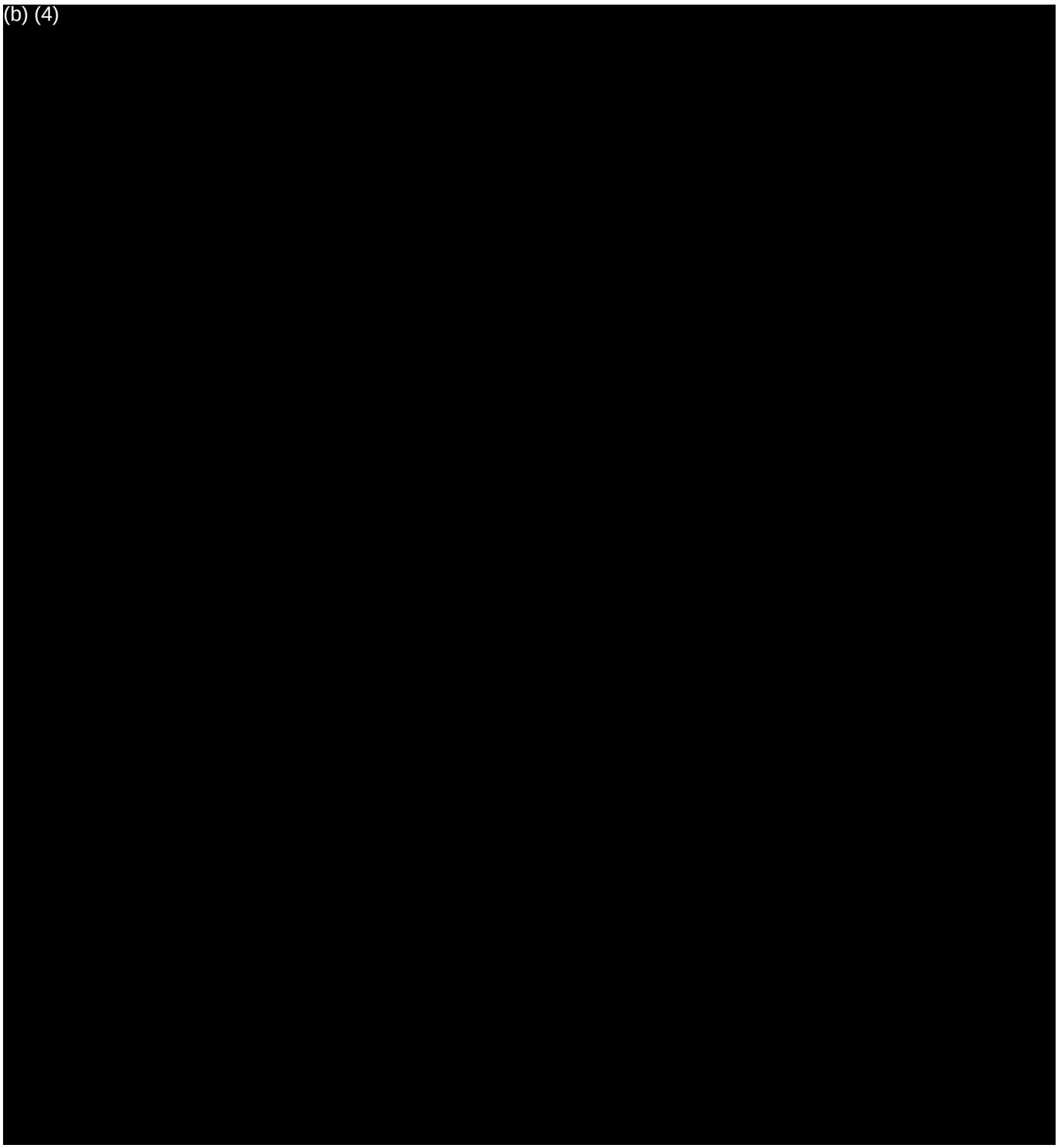
(b) (4)

DJA x00851

(b) (4)



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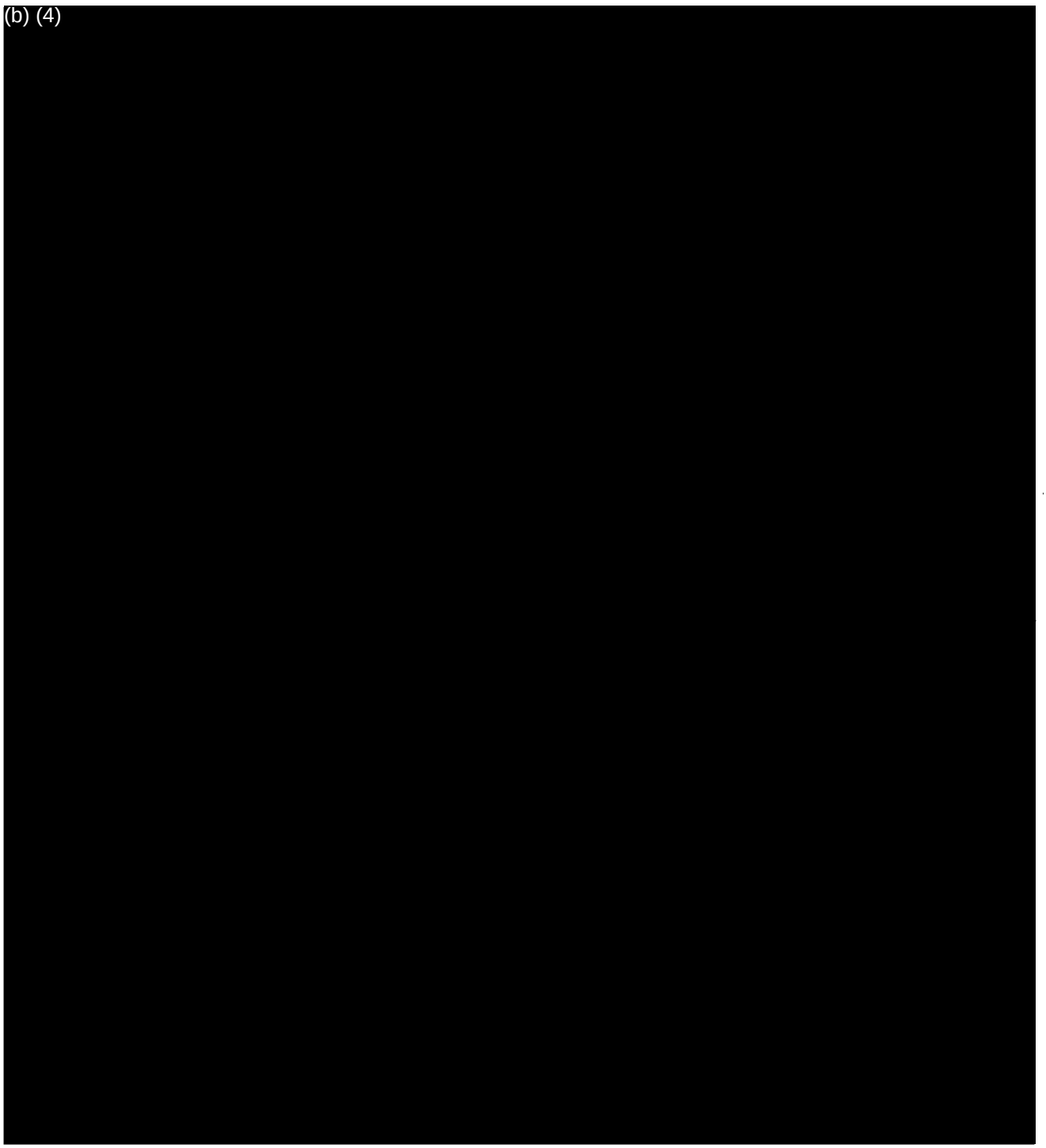
(b) (4)



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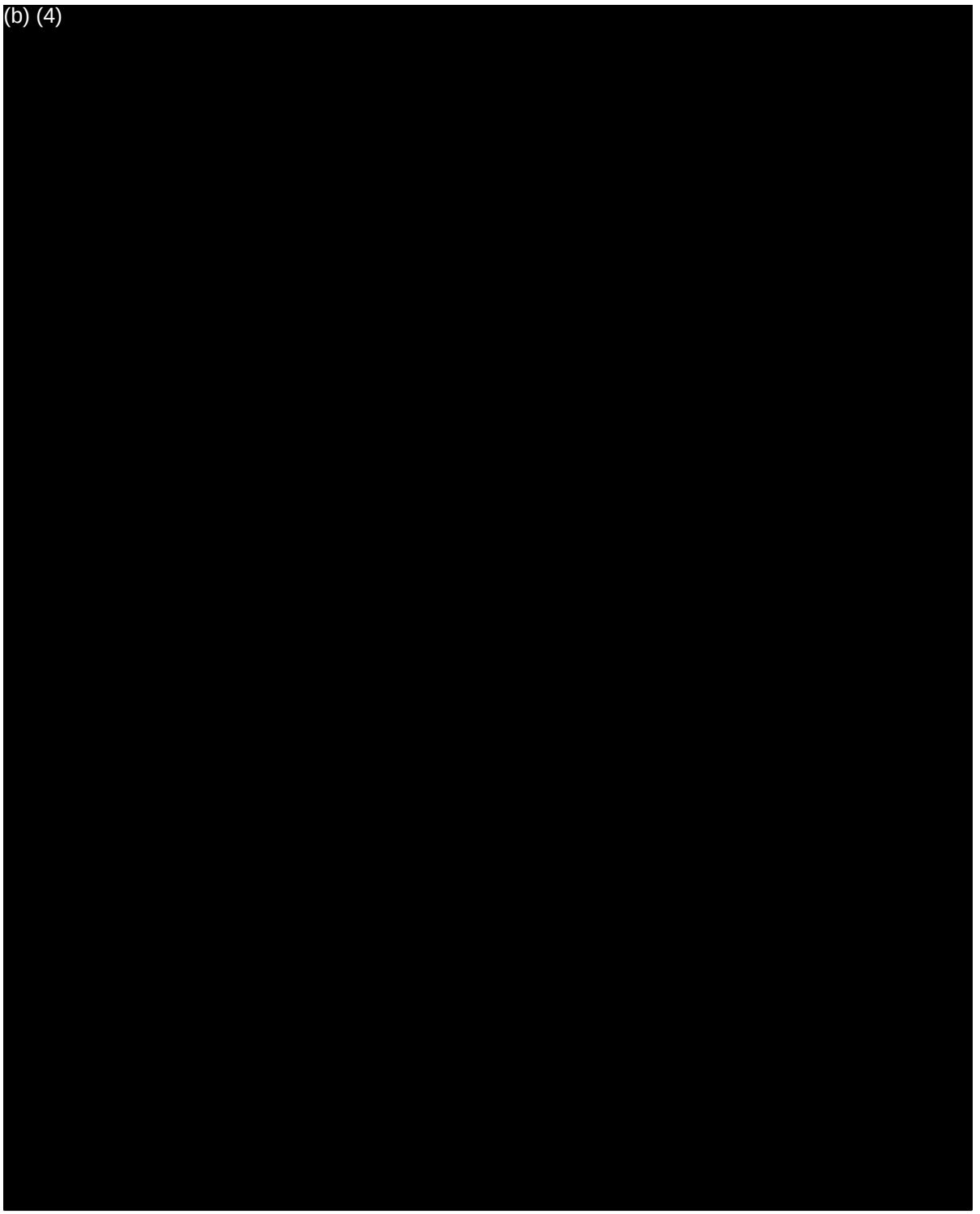

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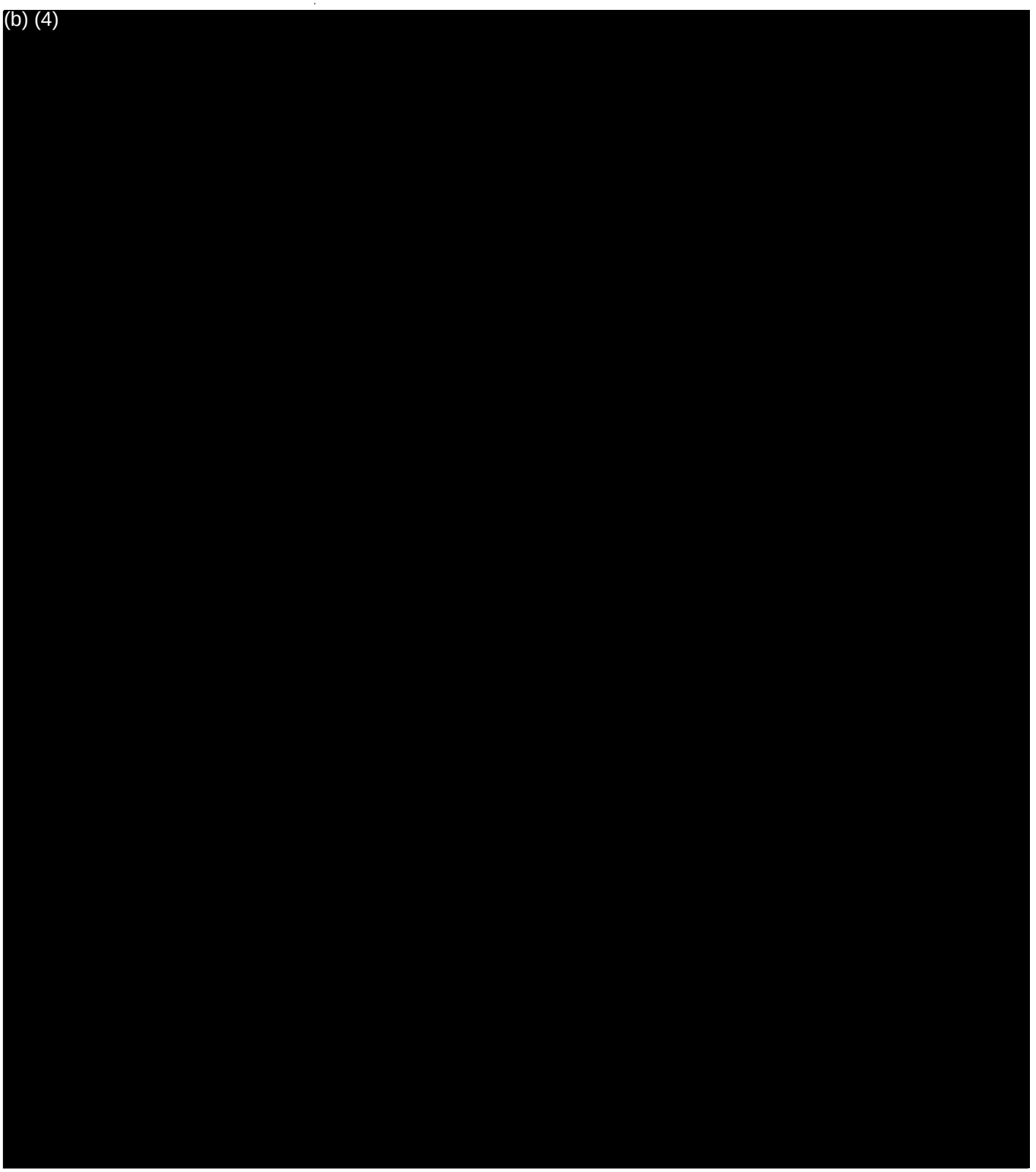
(b) (4)

DJA x00856

(b) (4)



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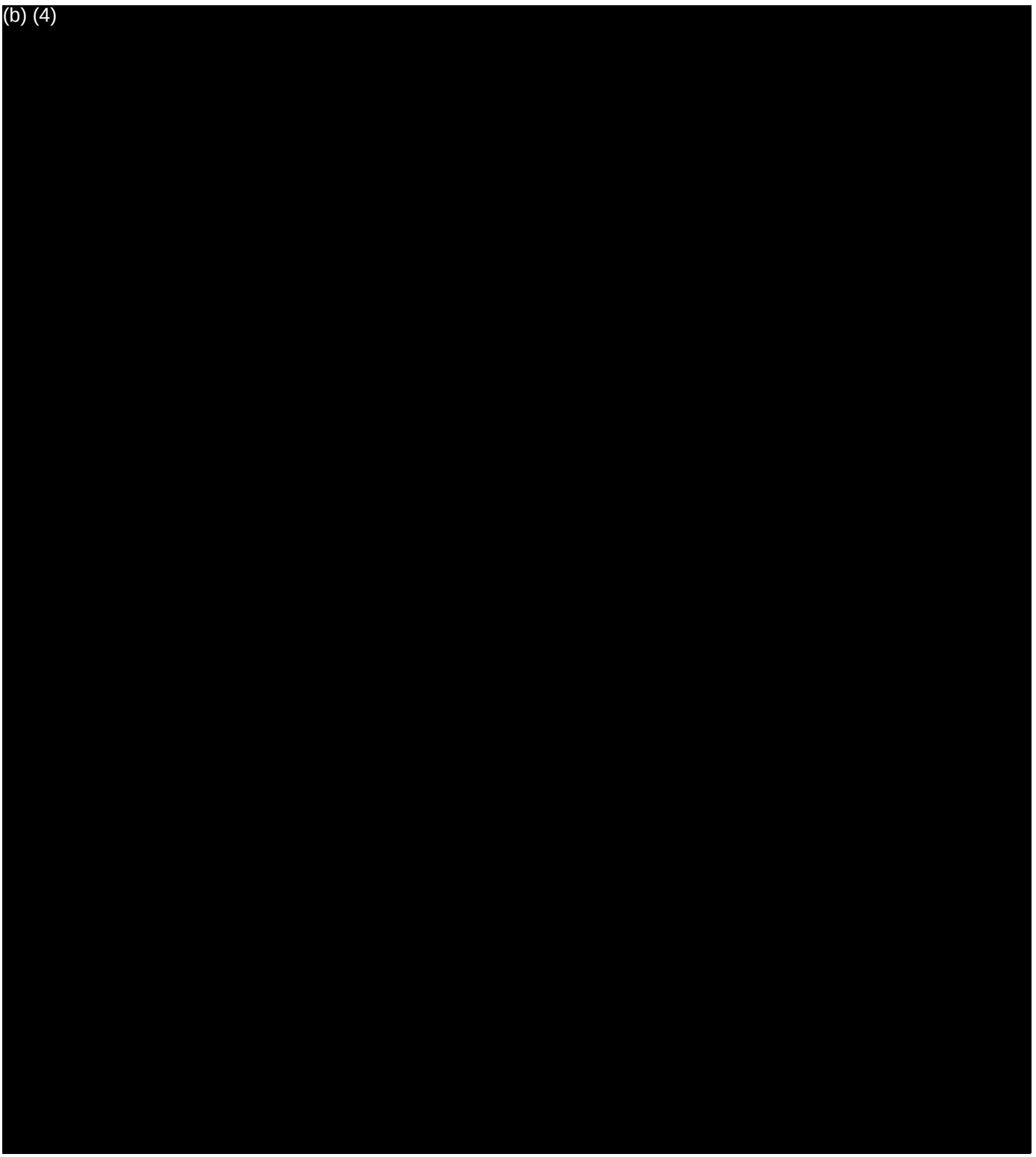

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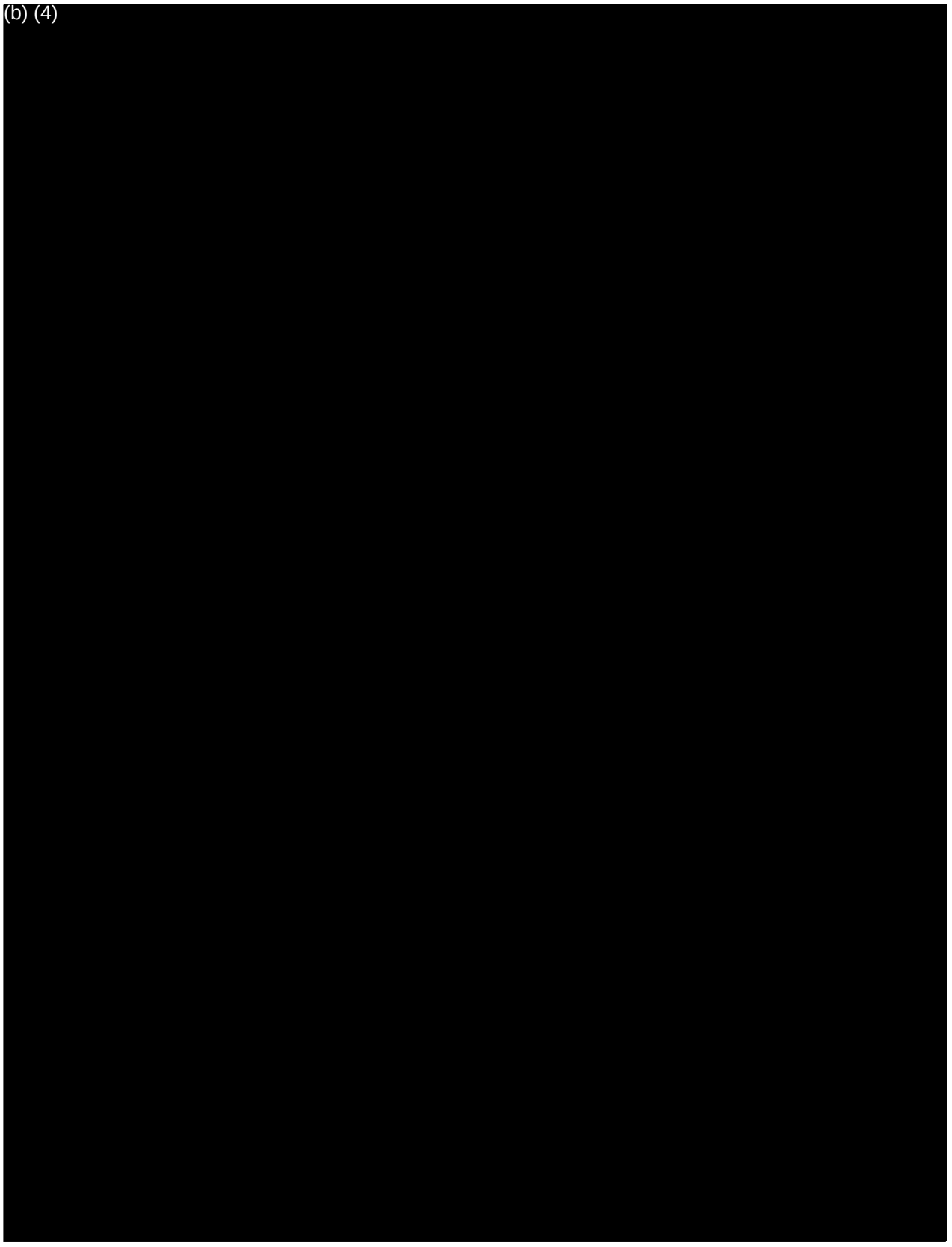

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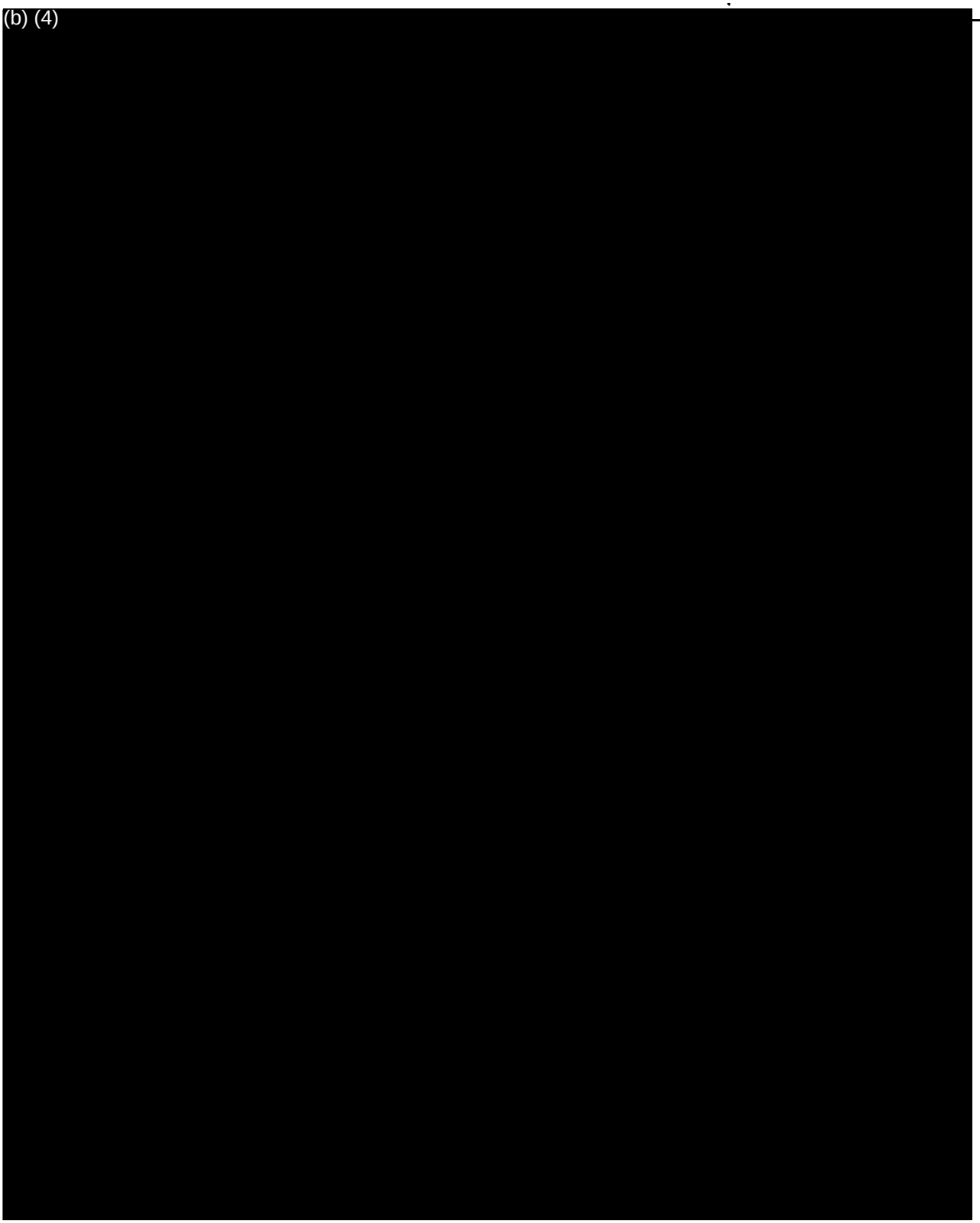

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(b) (4)

DJA x00862

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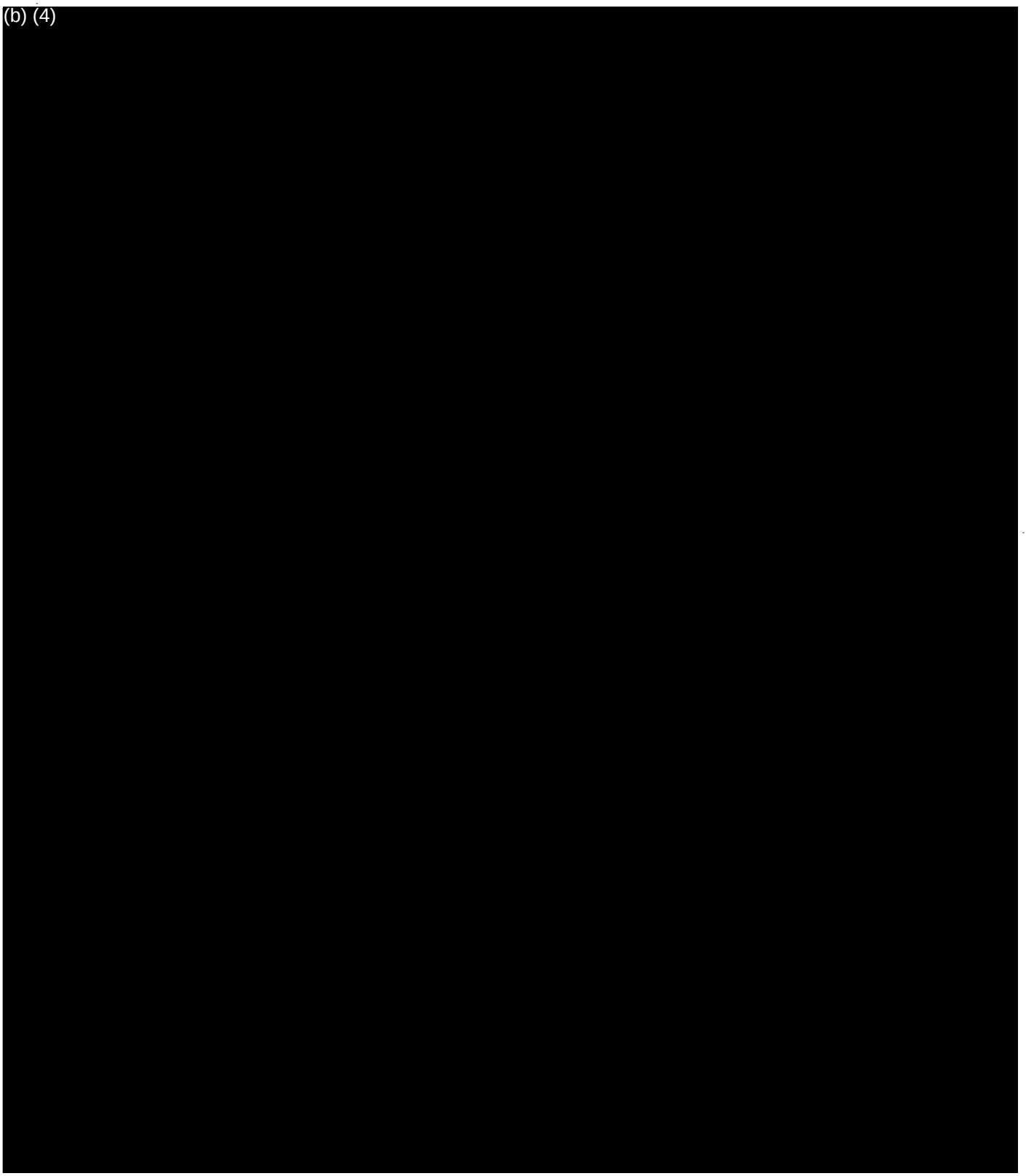

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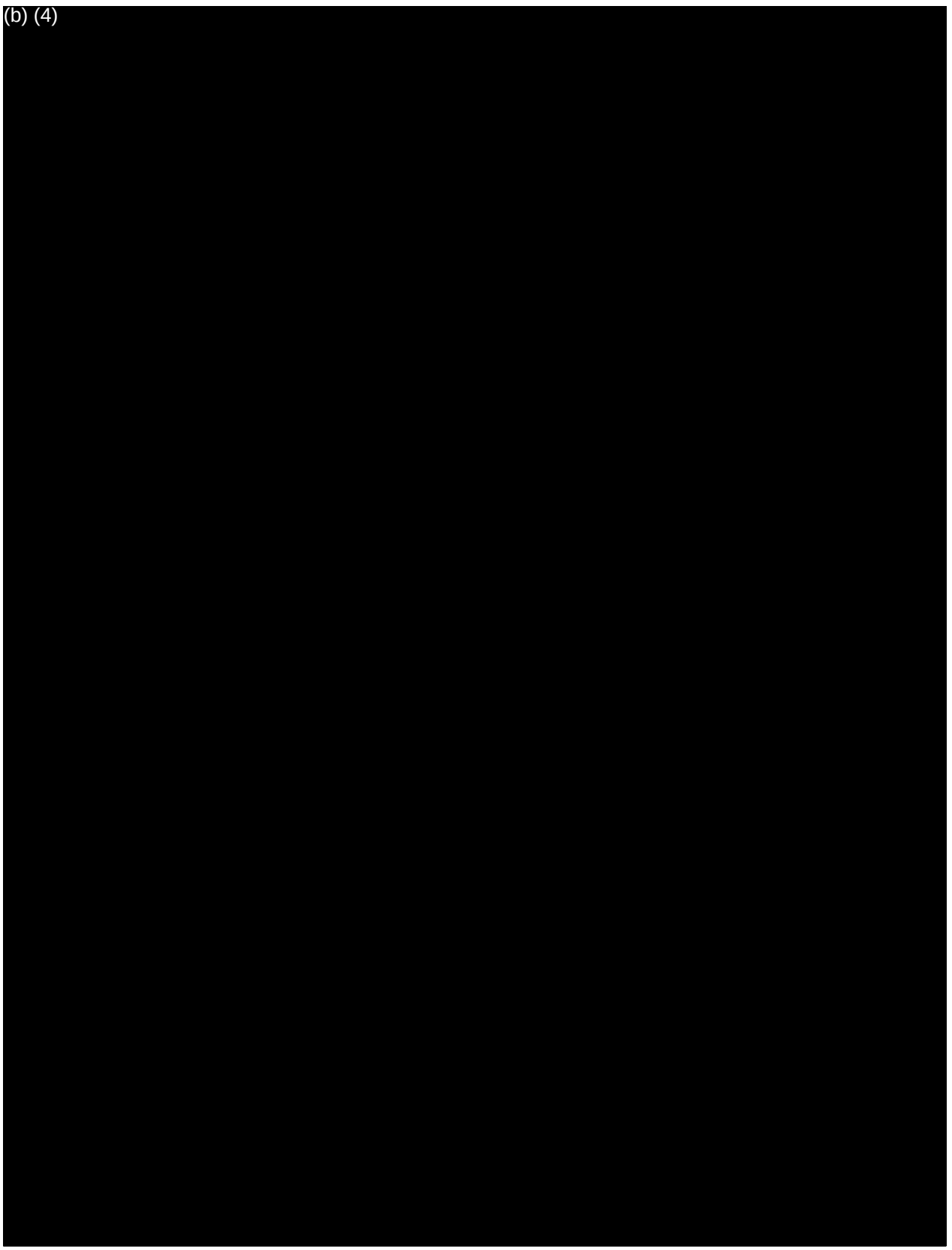

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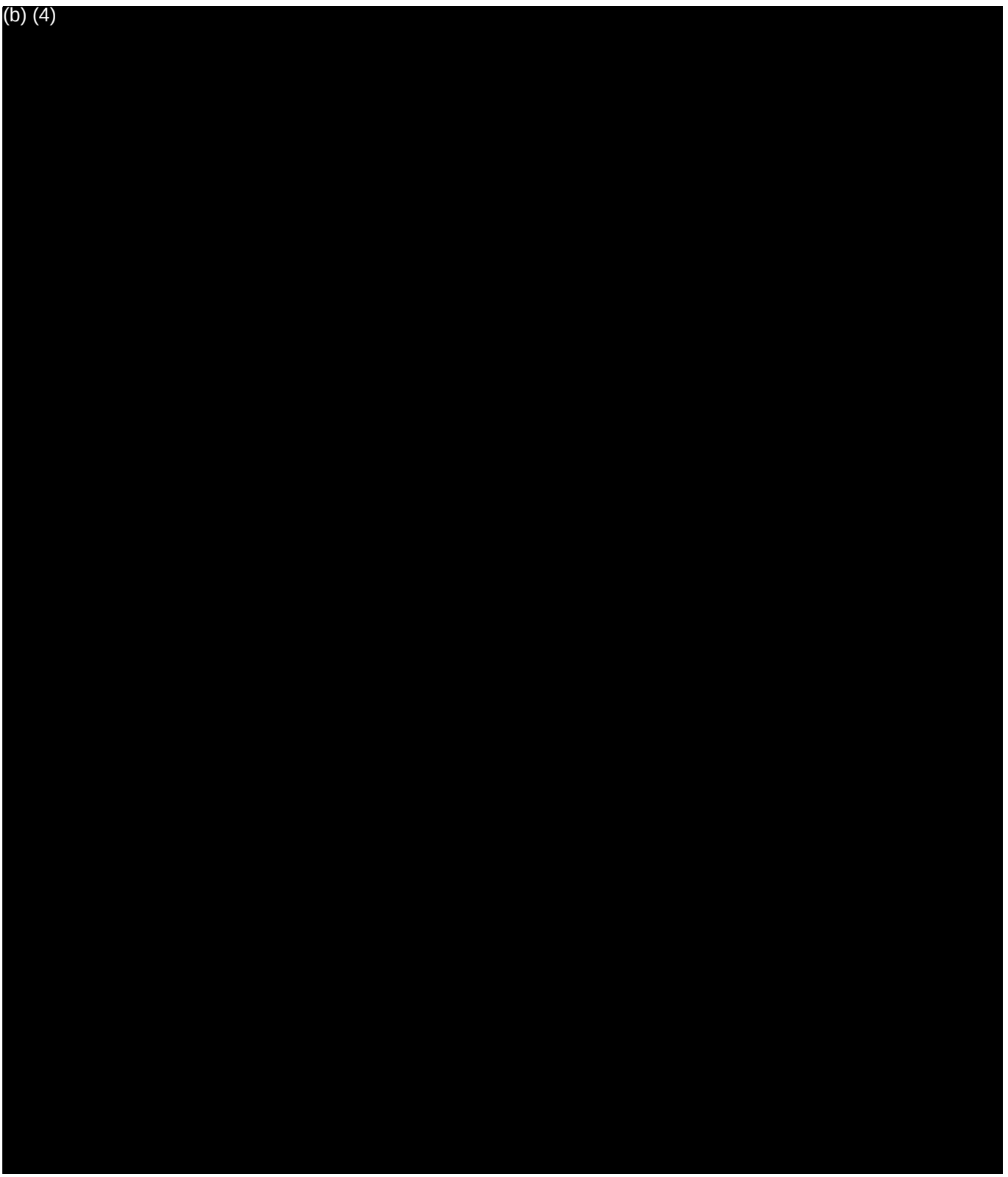
(b) (4)

DJA x00865

(b) (4)



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(b) (4)

DJA x00867

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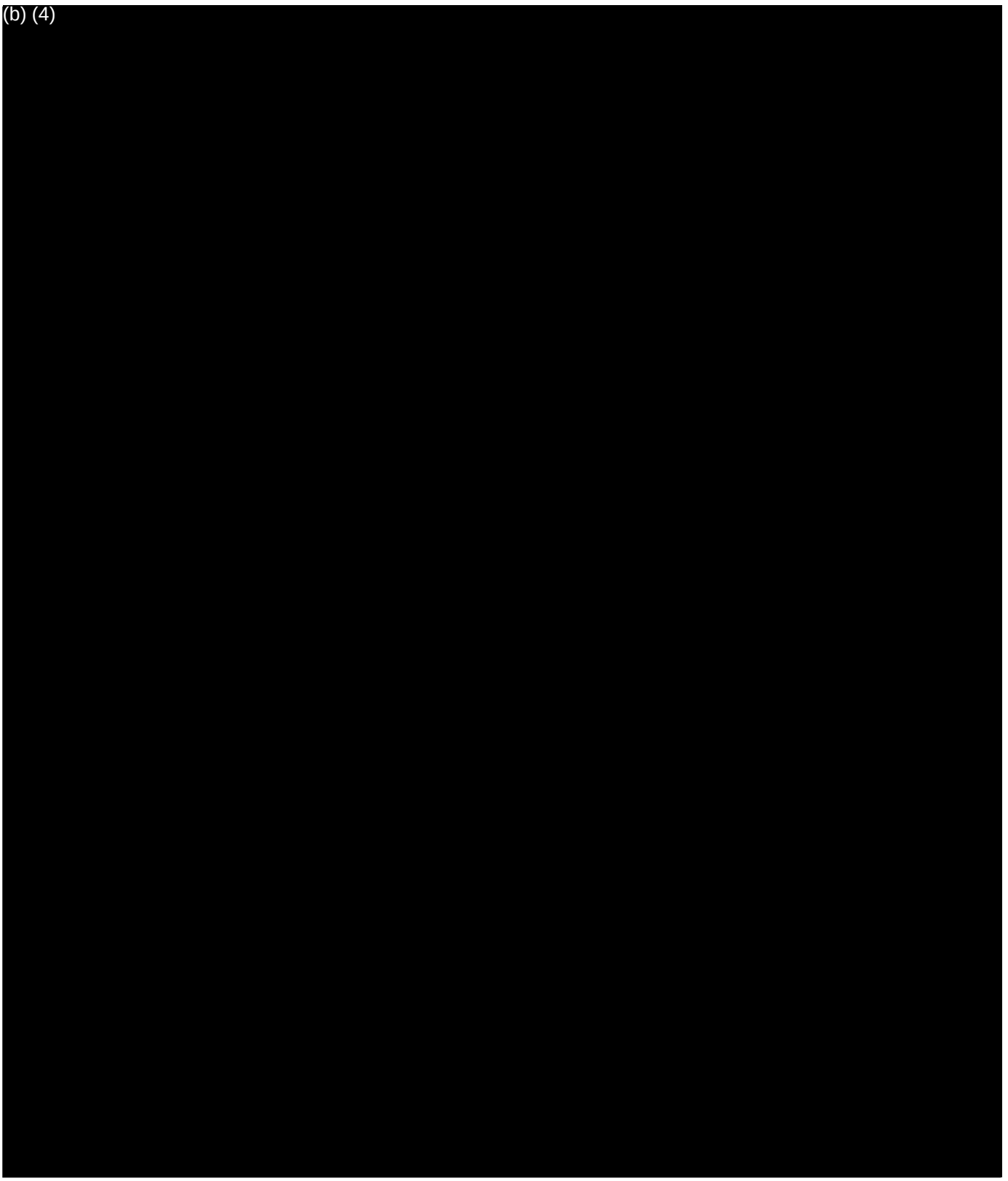

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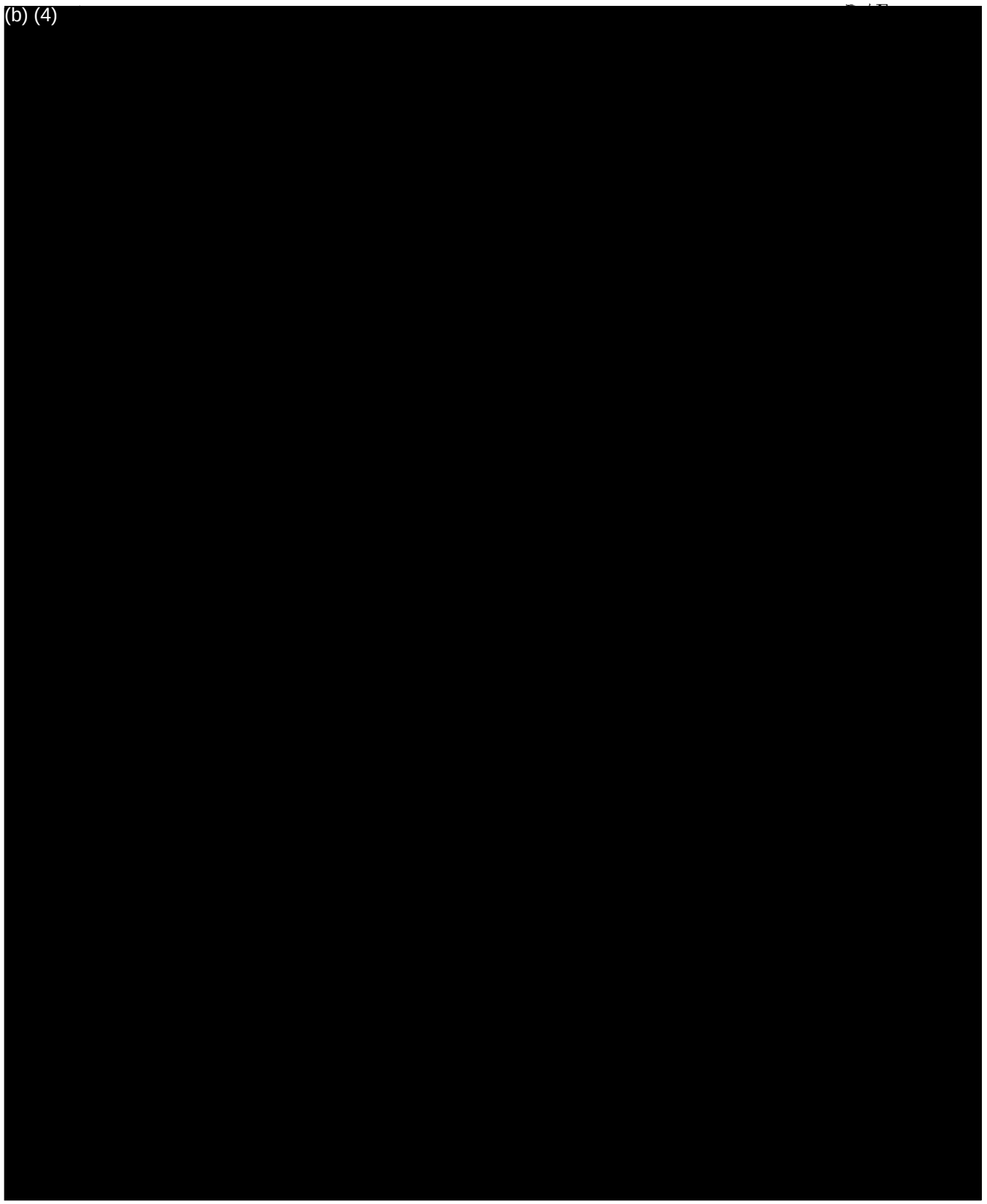

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(b) (4)

DJA x000870

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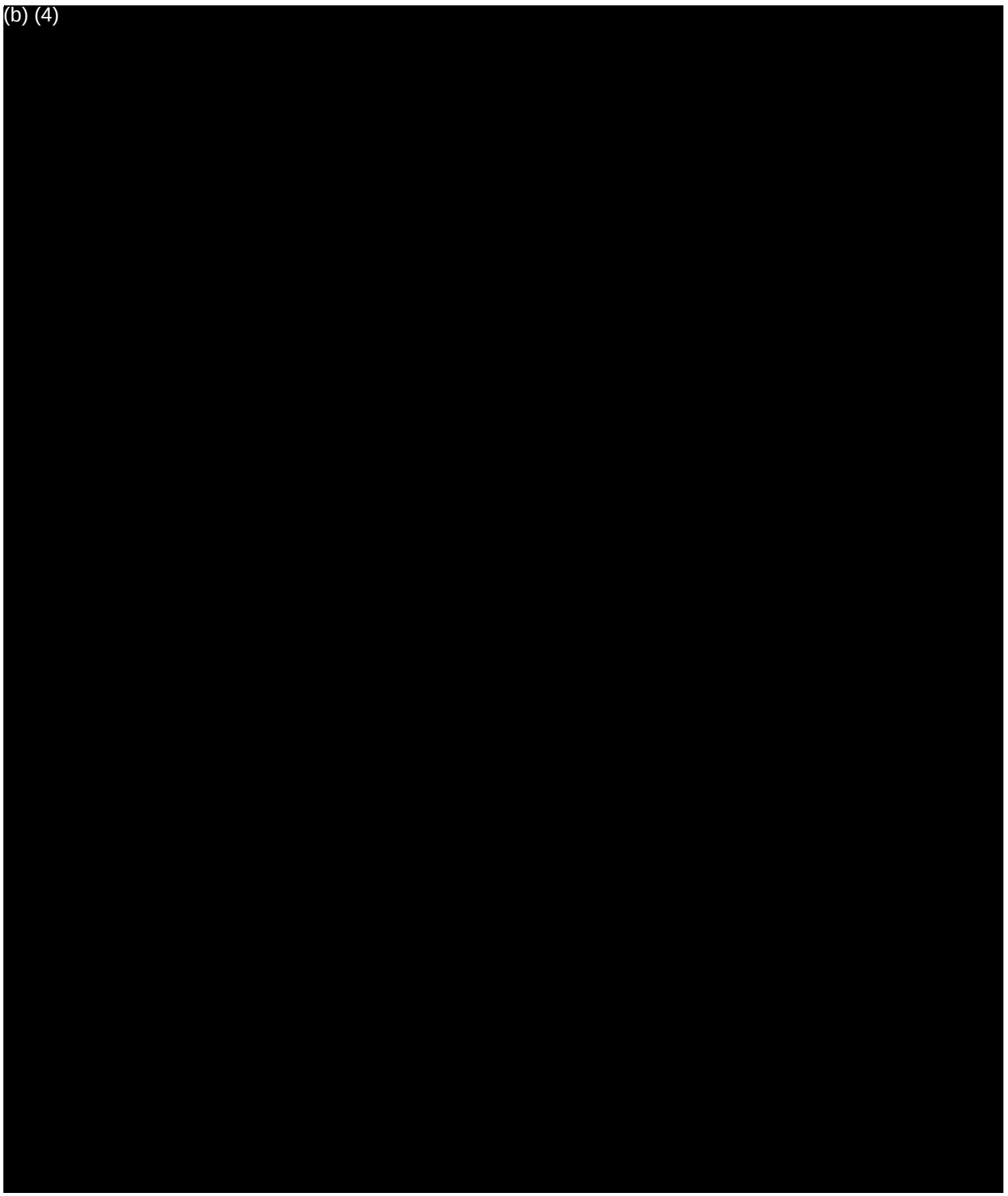

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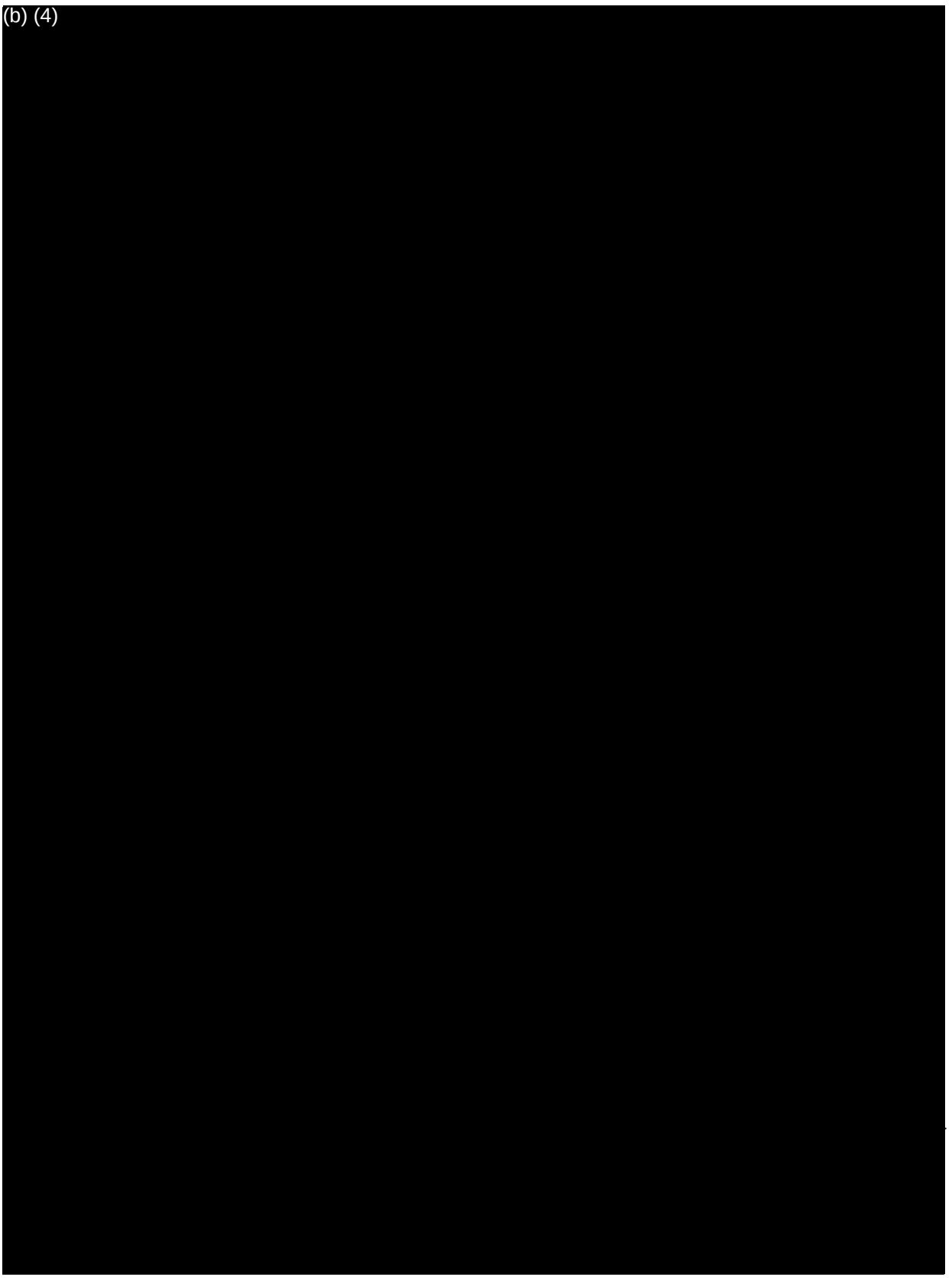

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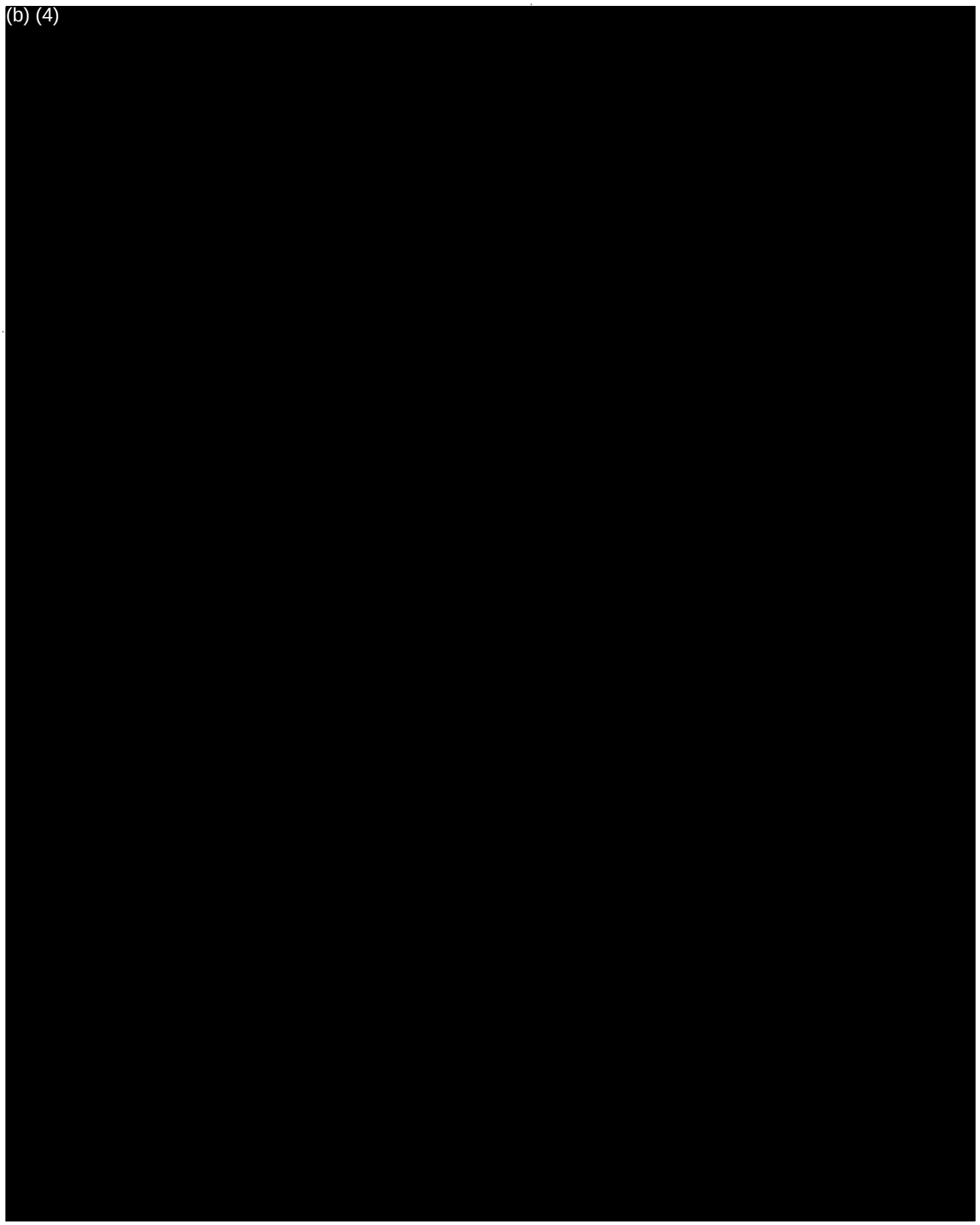

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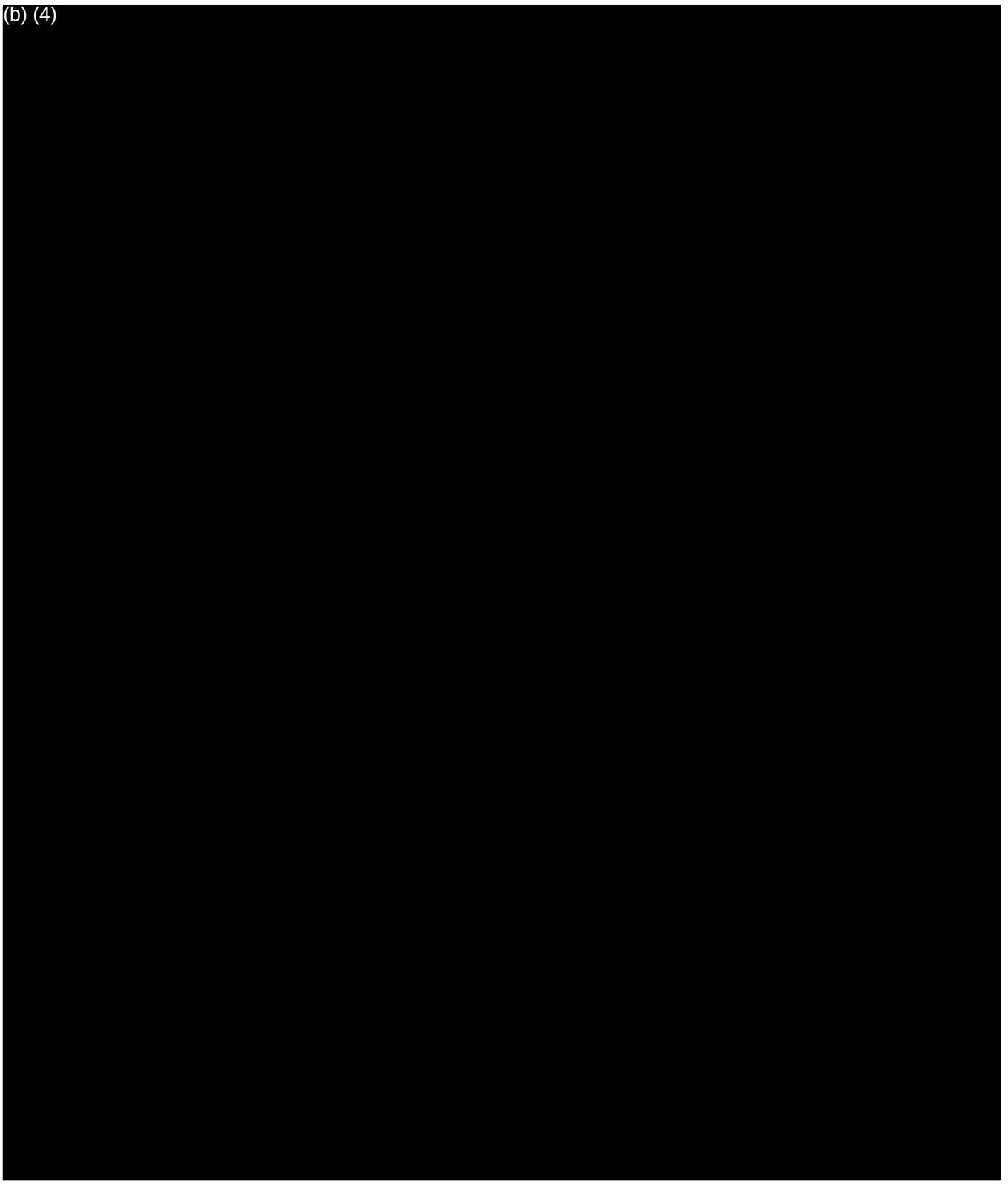

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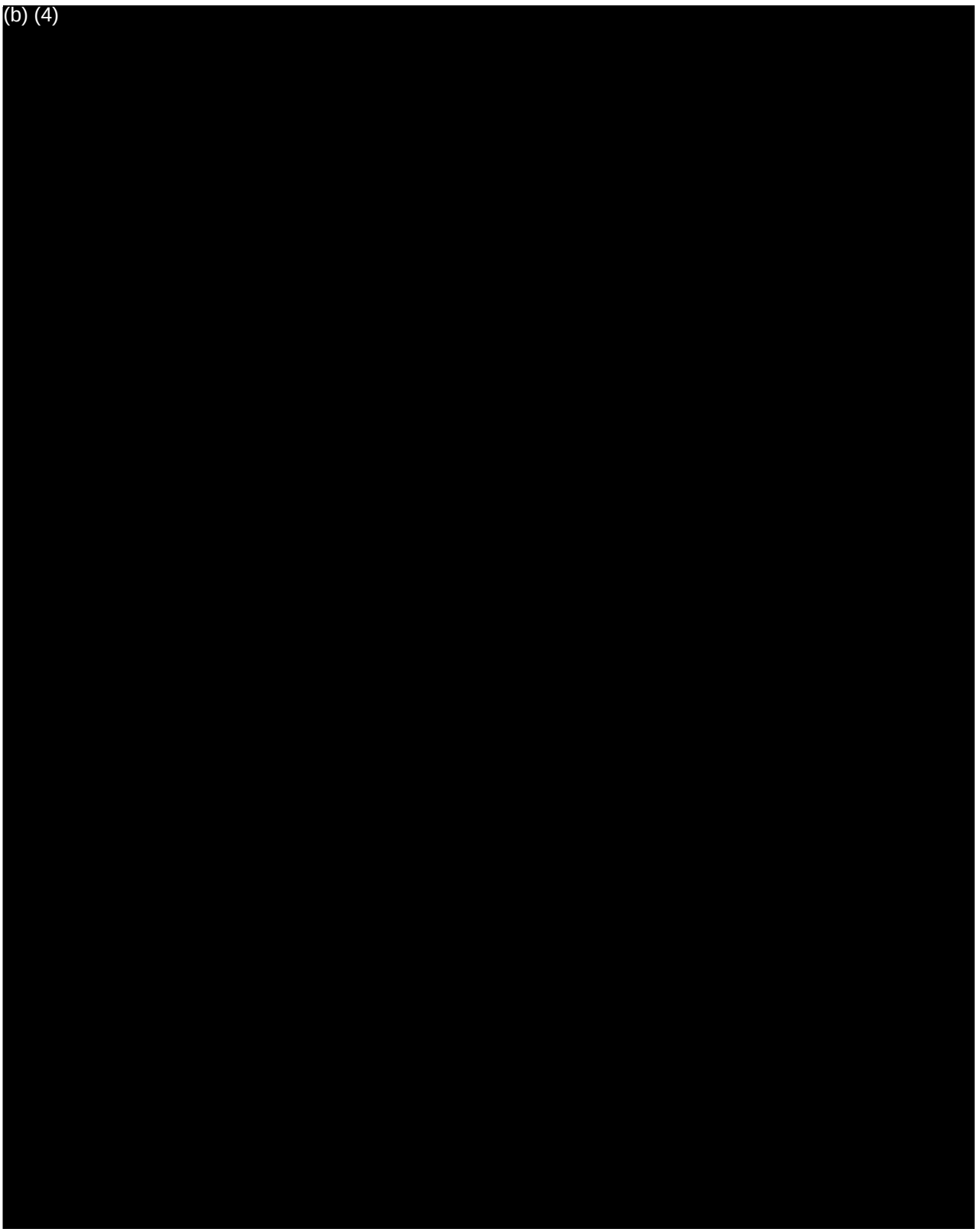

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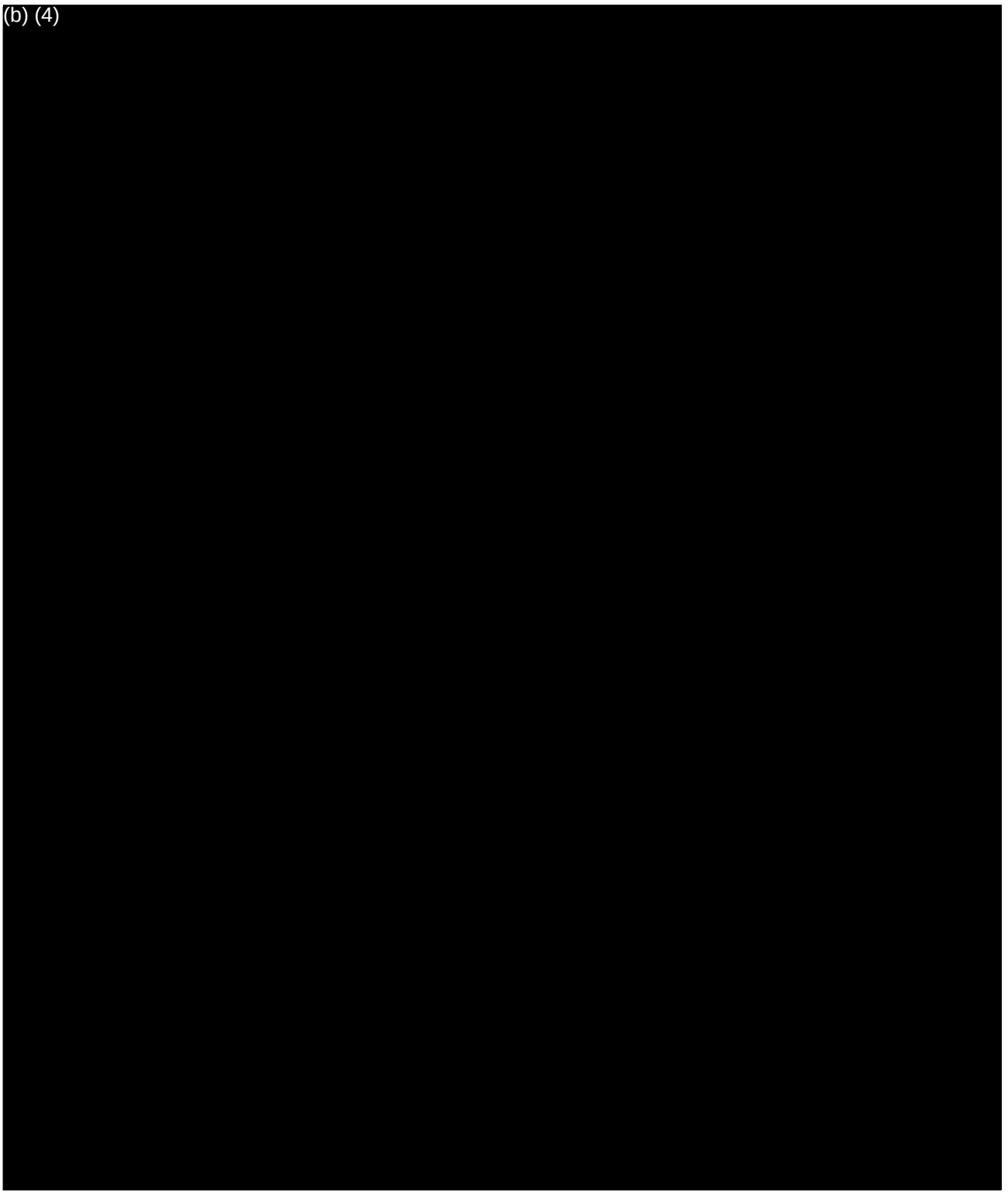

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DJA x000877

(b) (4)

DJA x000878

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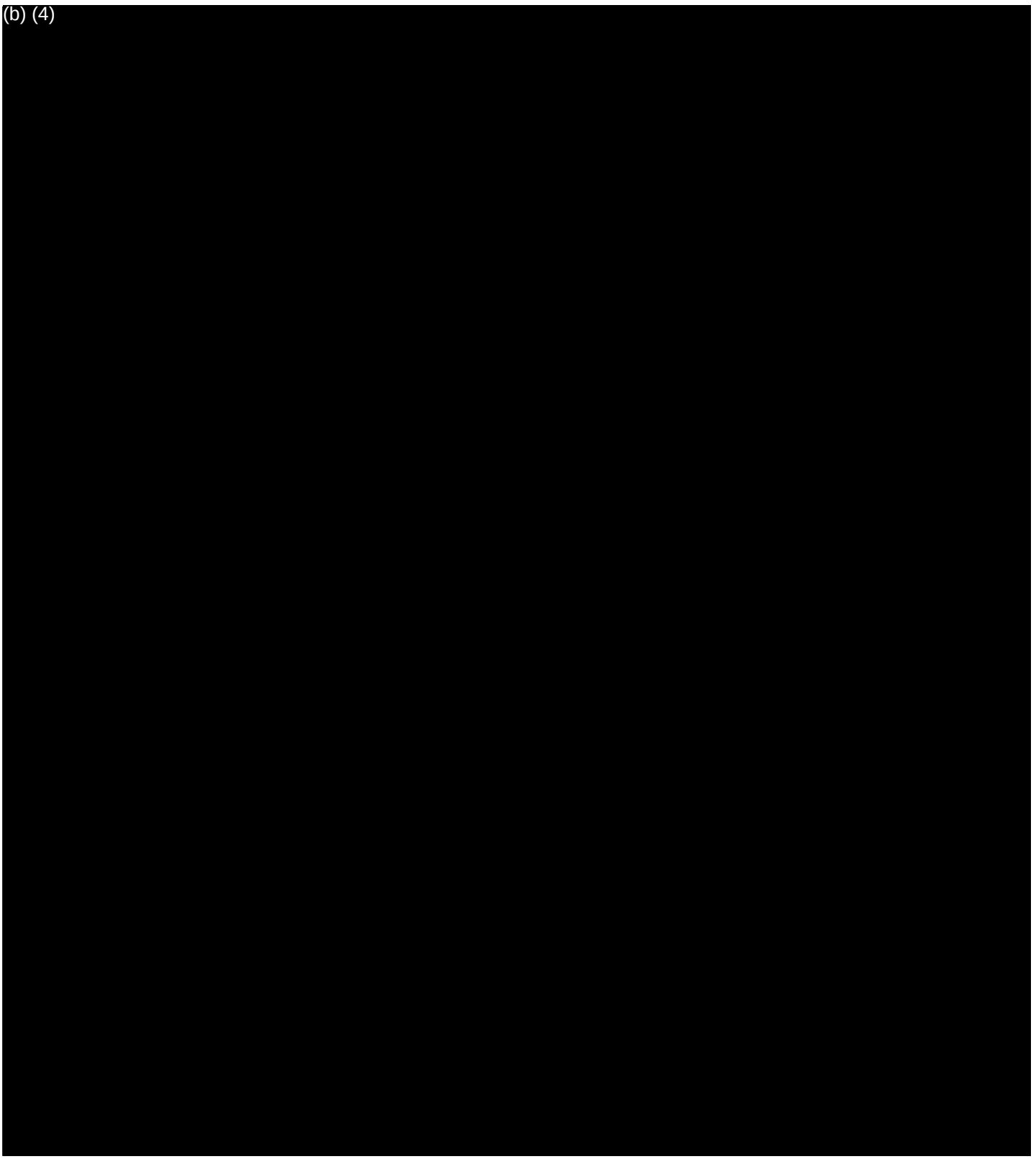

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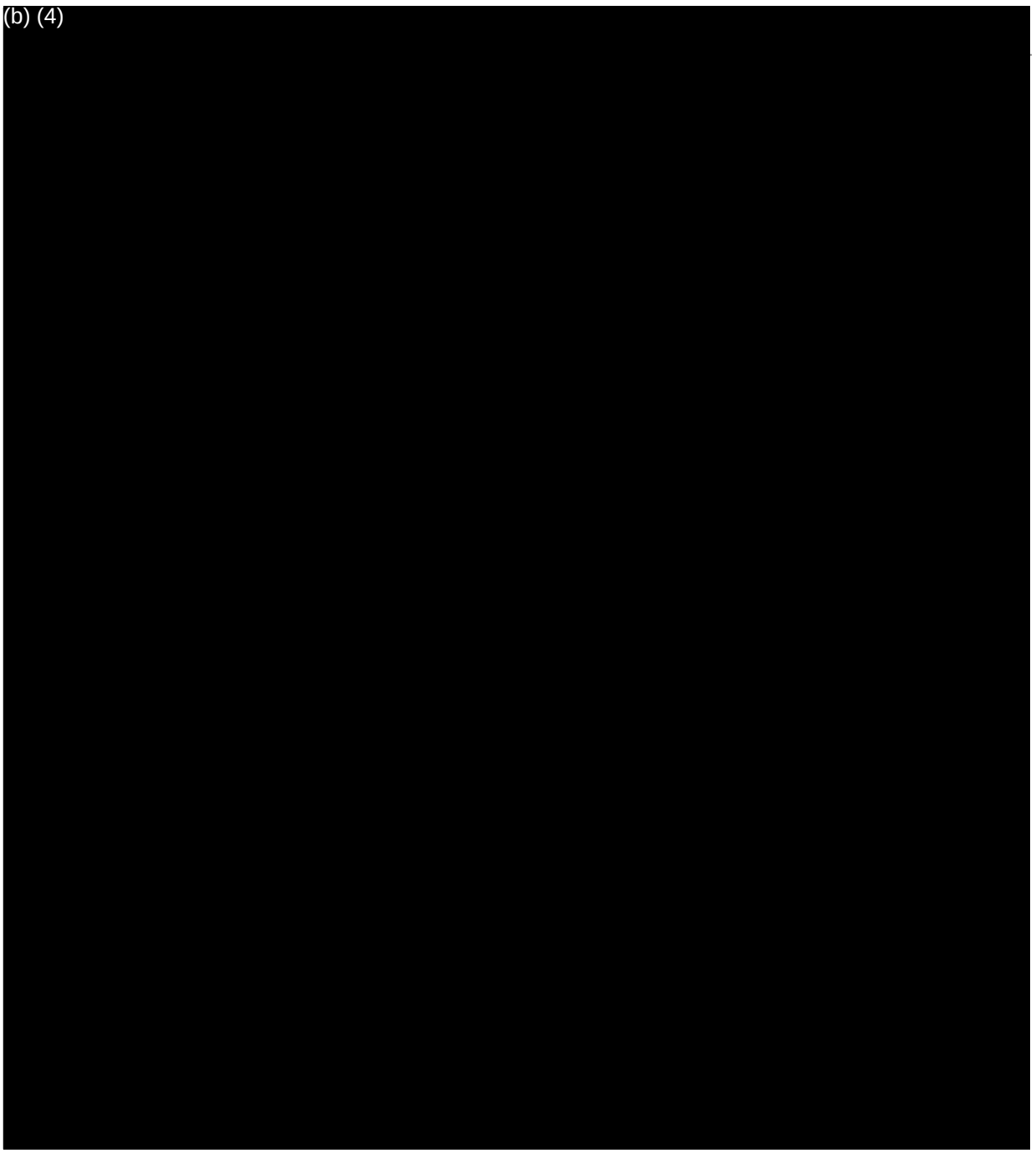

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DJA x000881

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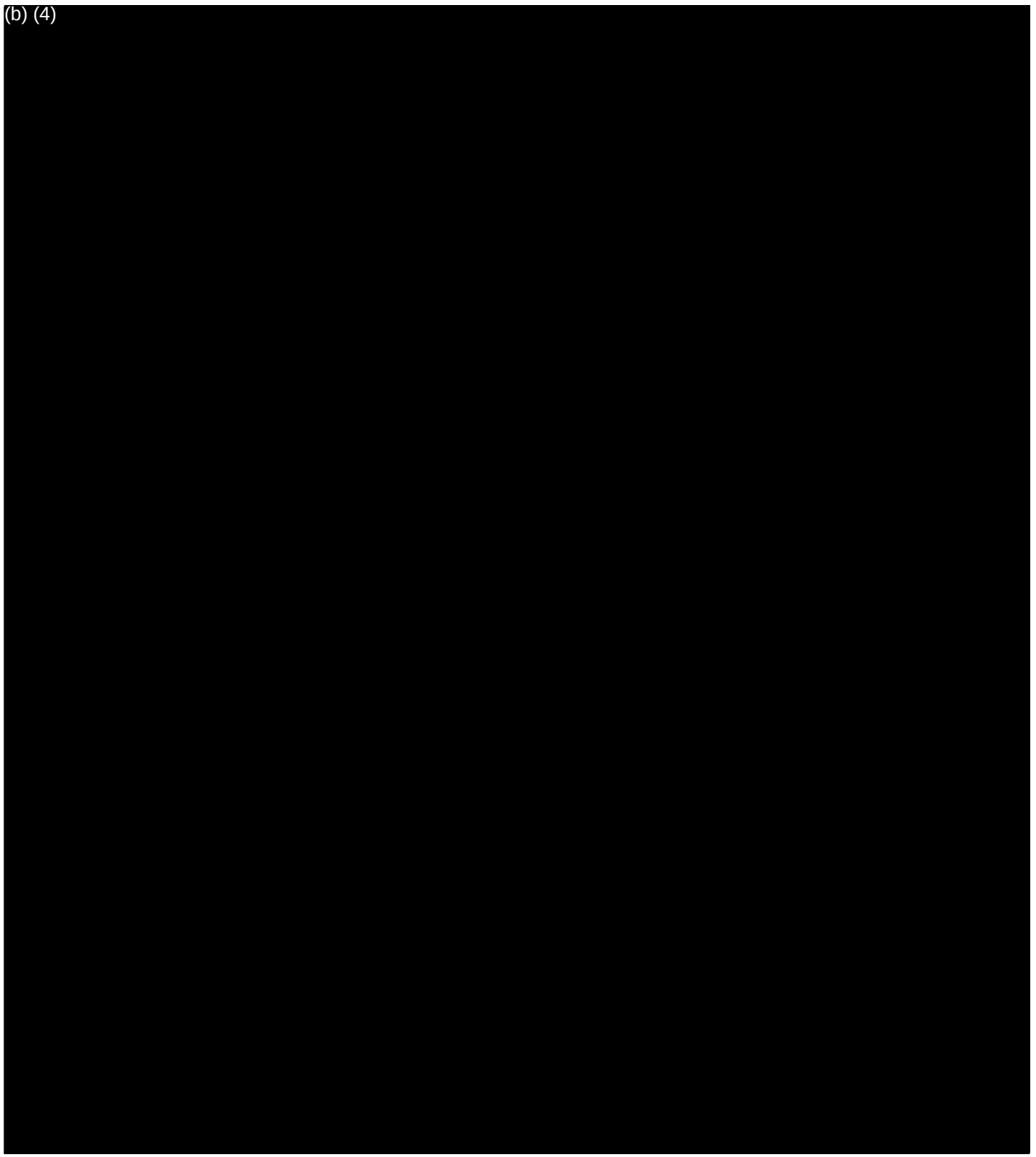

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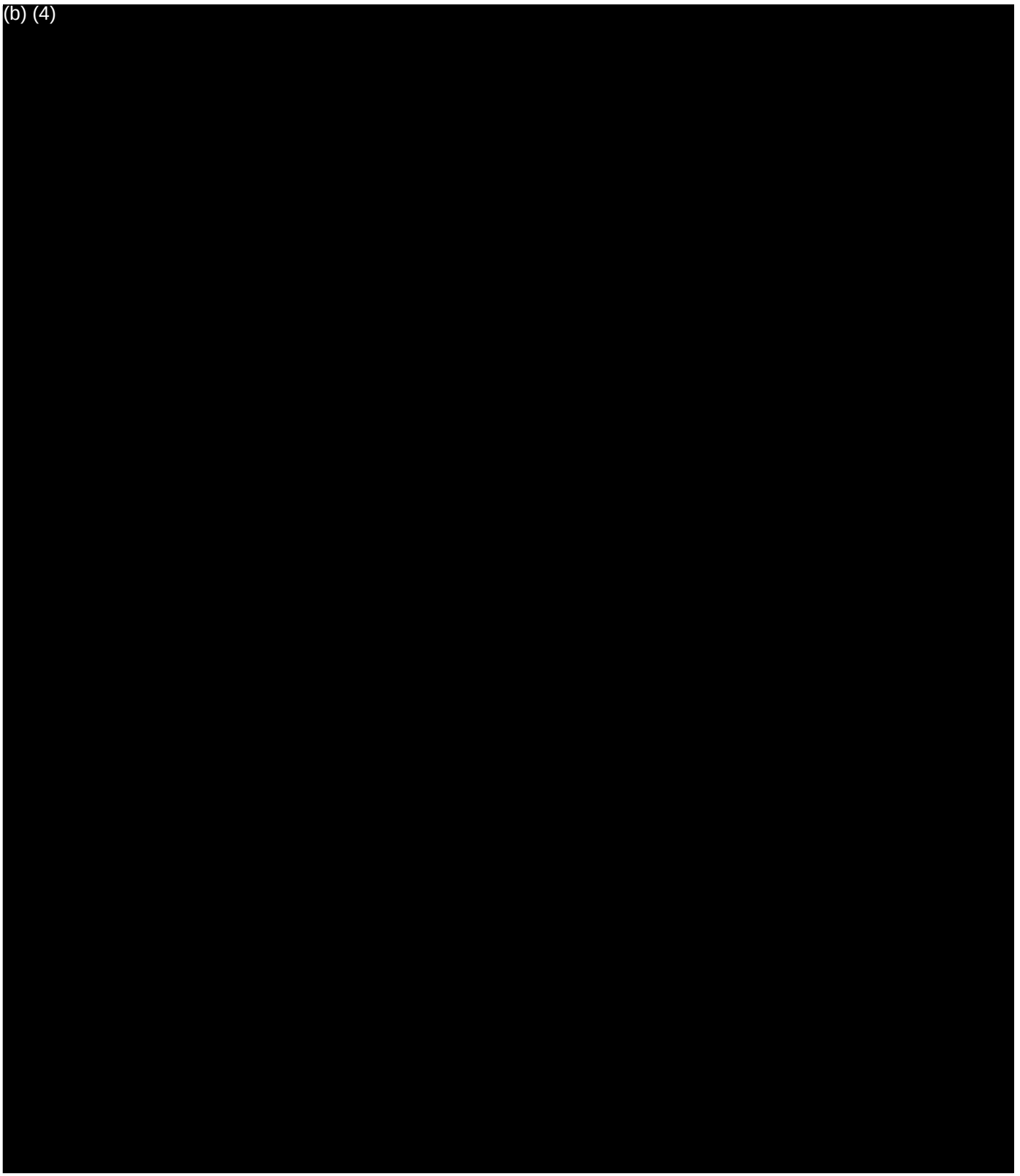

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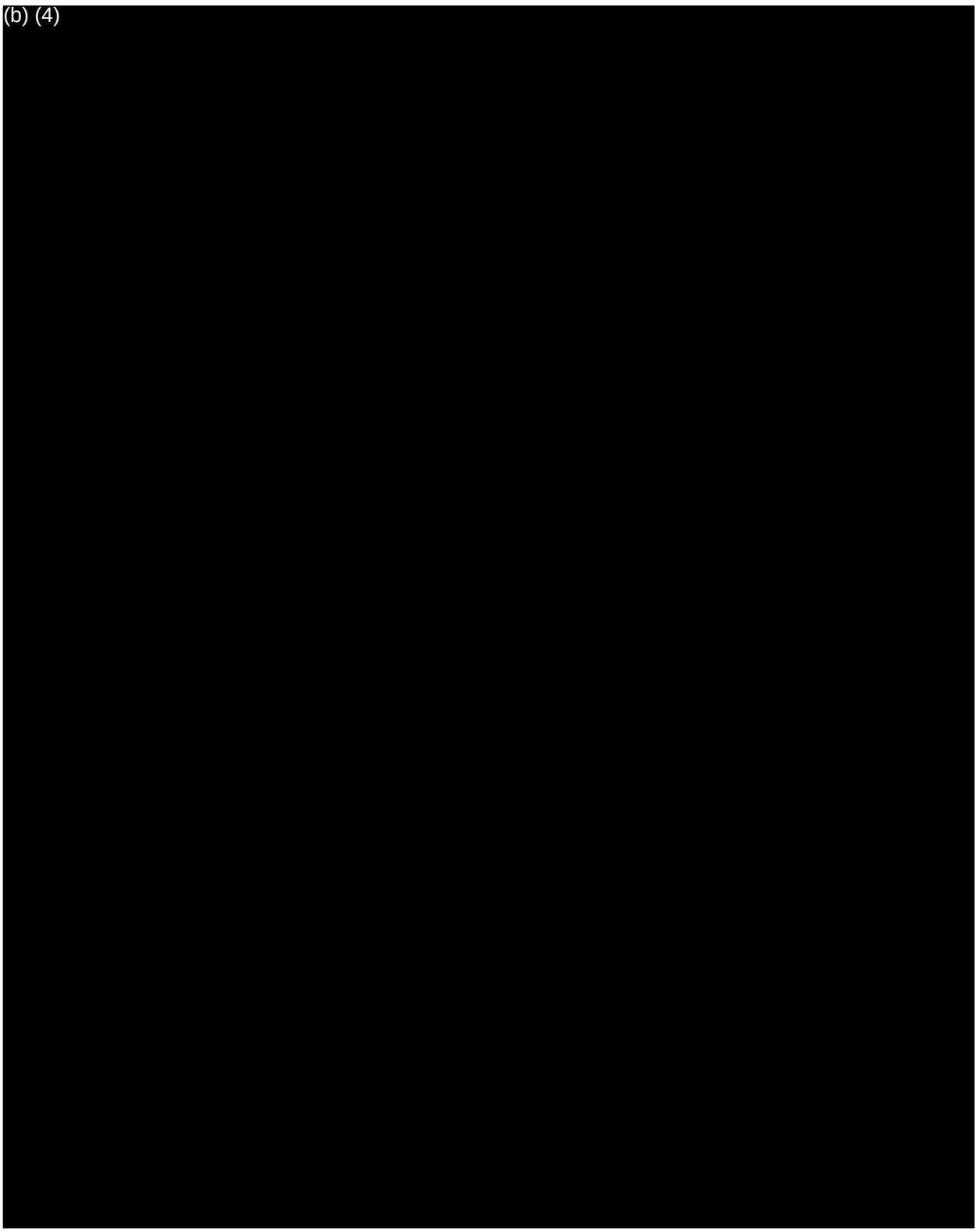

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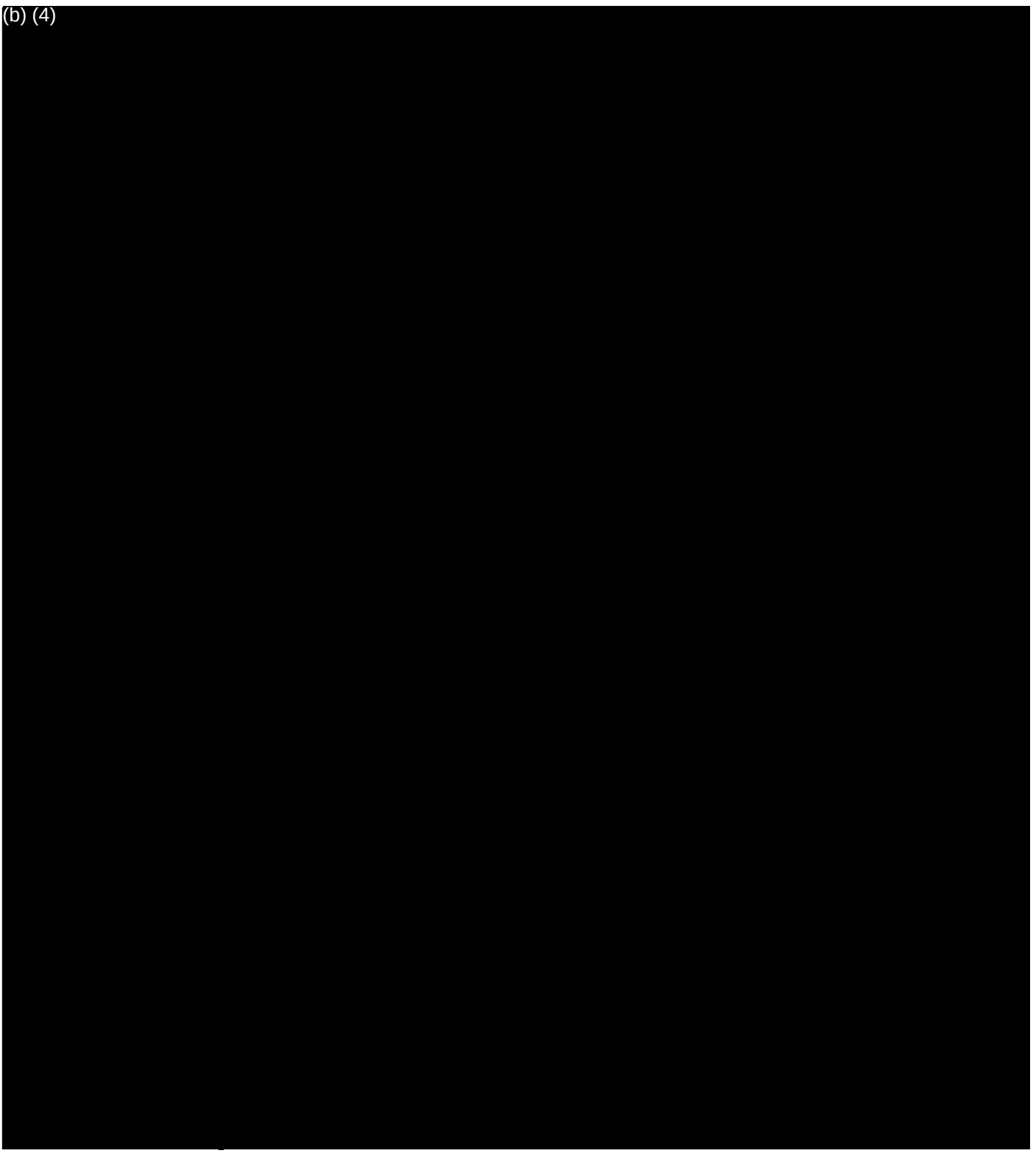

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ORTHODOC MODEL 500
SOFTWARE PROTOCOL VALIDATION

(b) (4)

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DJA x00889

(b) (4)

DJA x00890

QUALITY POLICY AND PROCEDURE APPROVAL AND REVISION RECORD

(b) (4)

DJA x00891

PROTOCOL APPROVAL SHEET

DCO # 2158

(b) (4)

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DJA x00892

PINLESS THR FULL PROCEDURAL TEST (BMM/DIGITIZER)

(b) (4)

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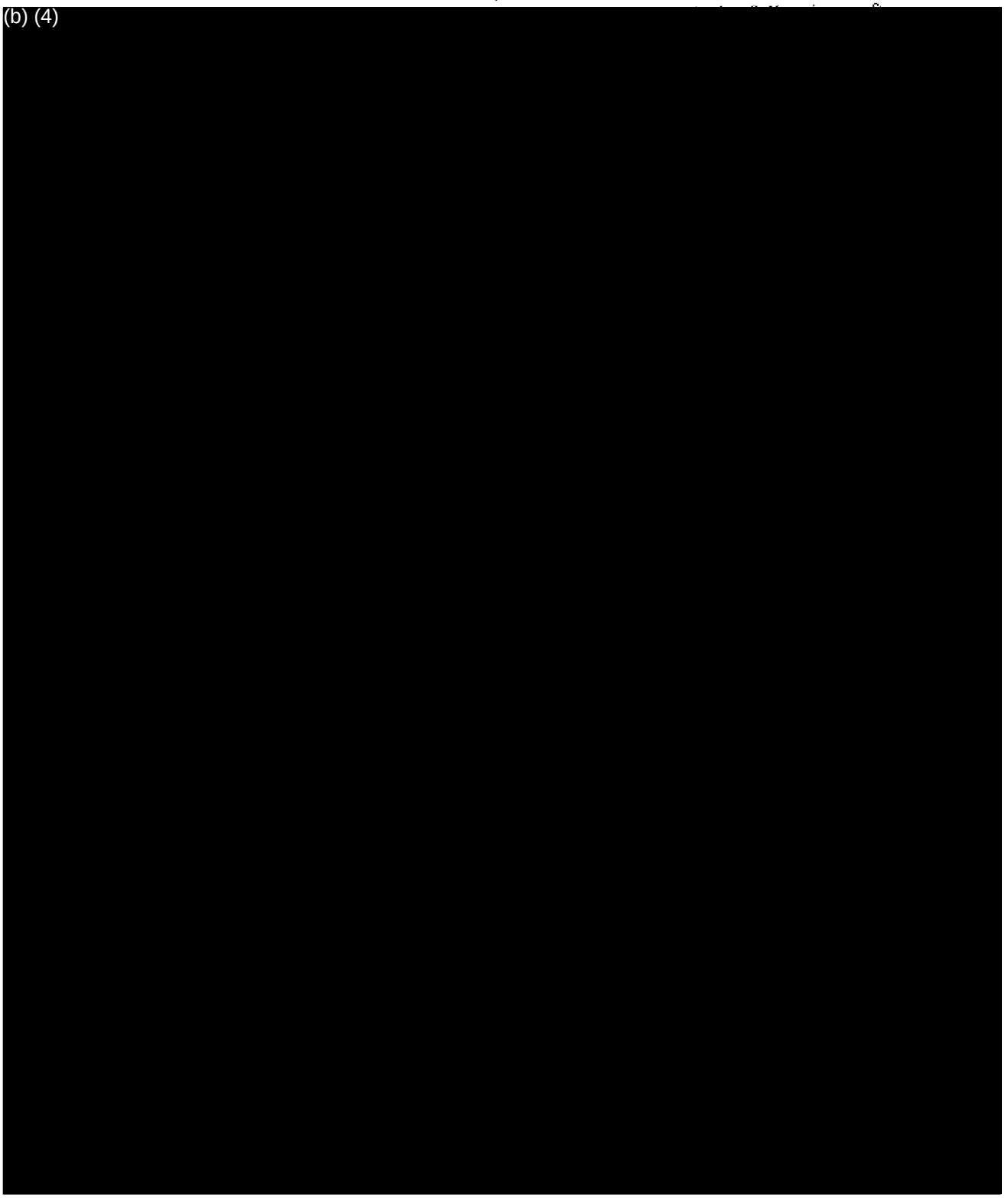
(b) (4)



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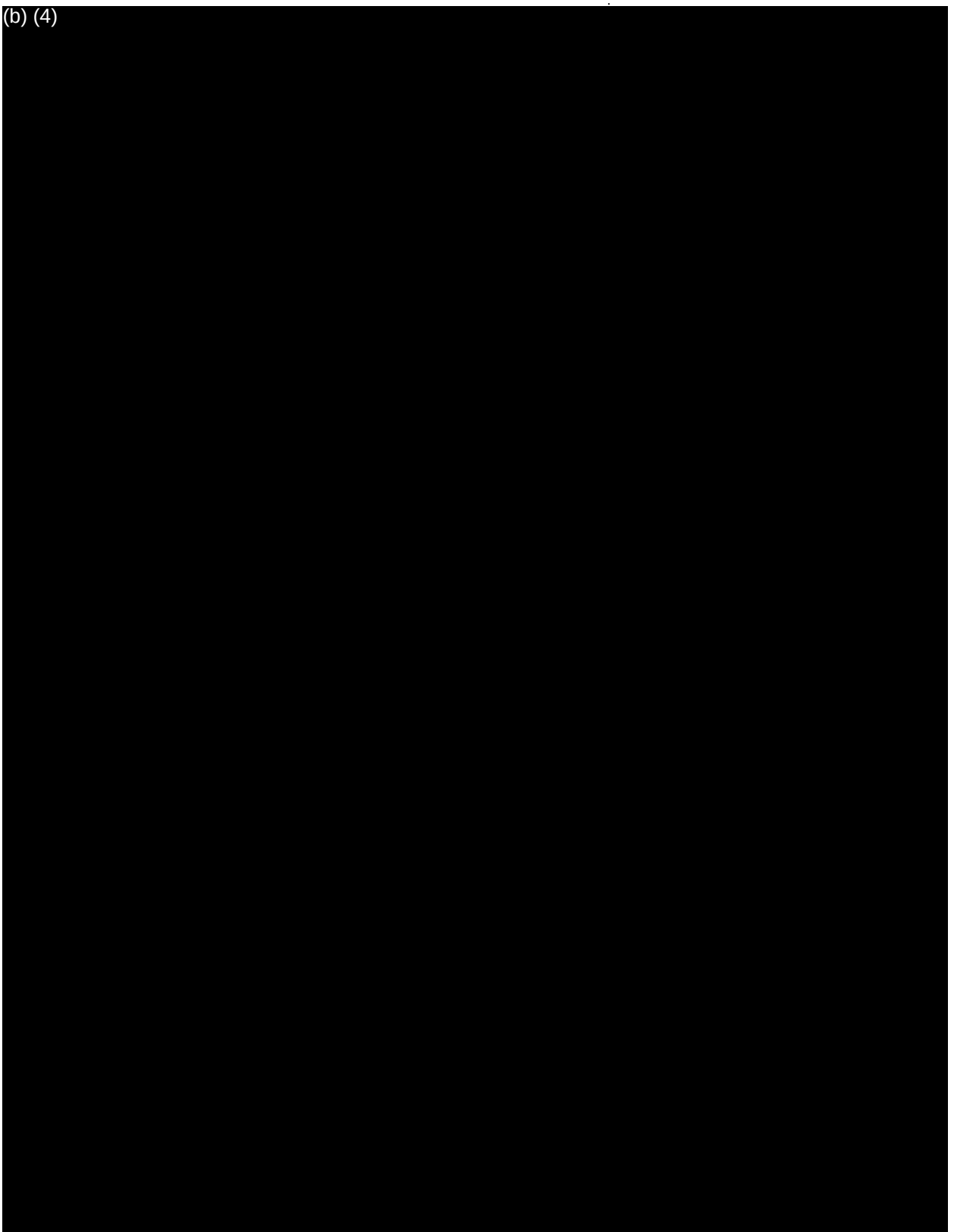

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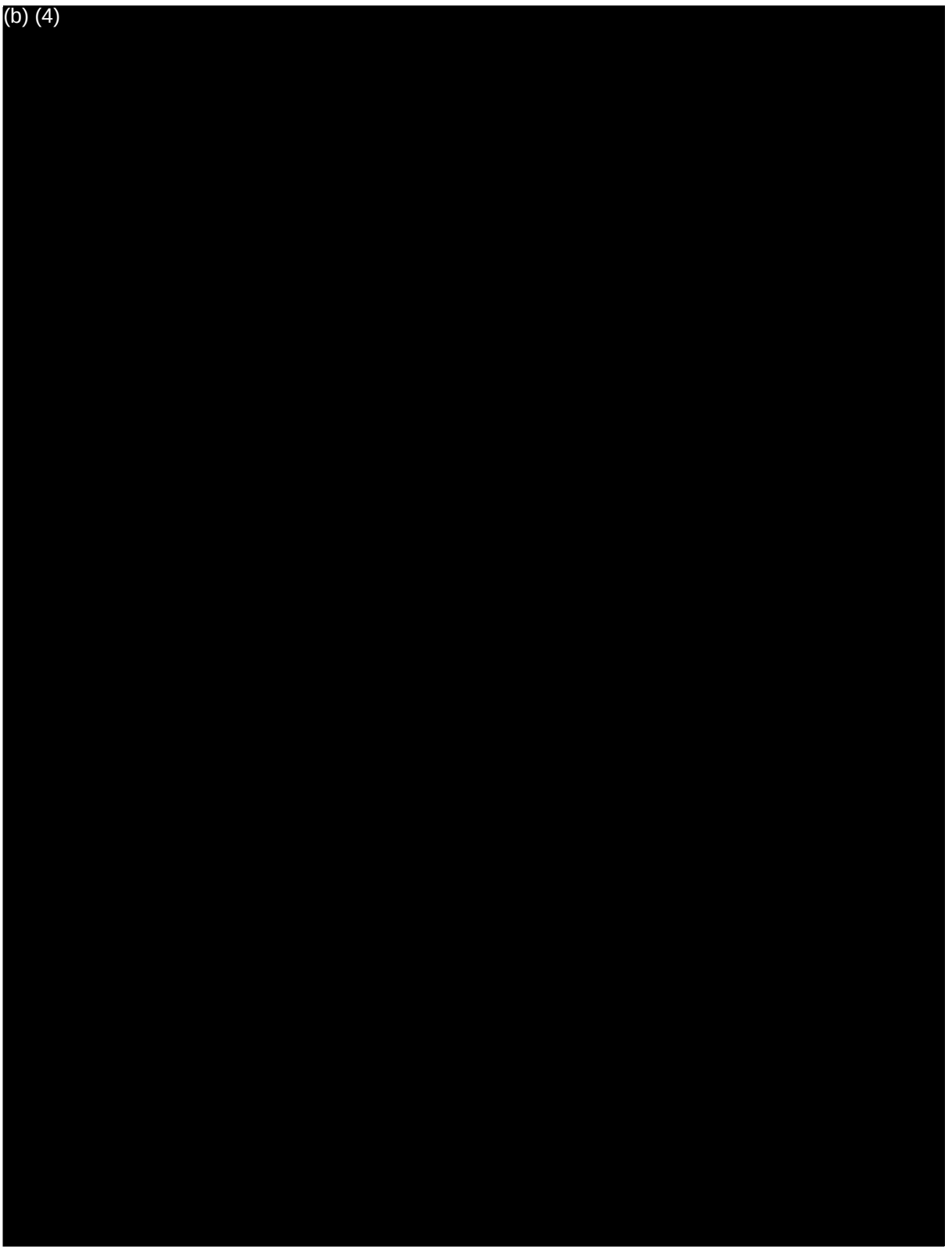

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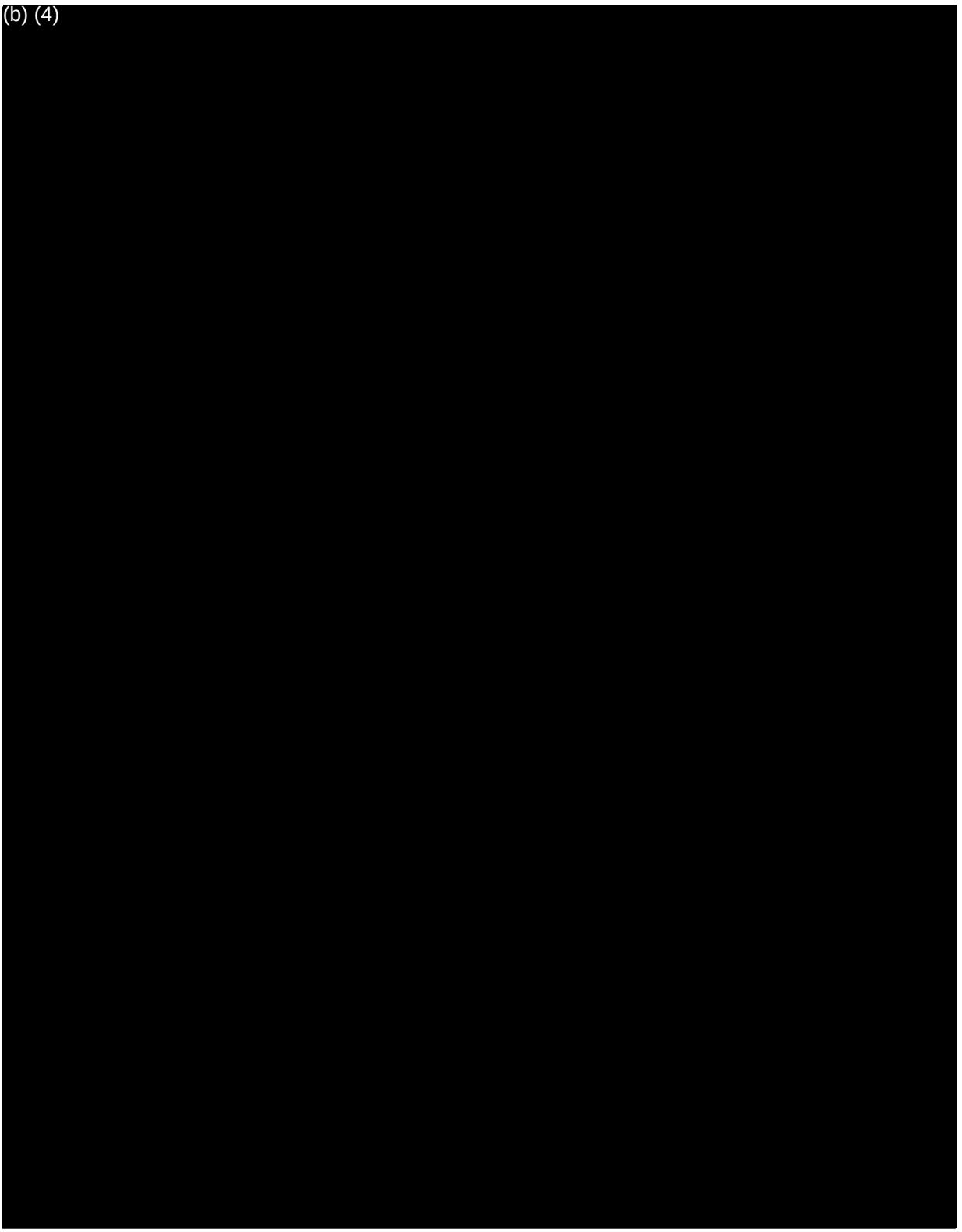

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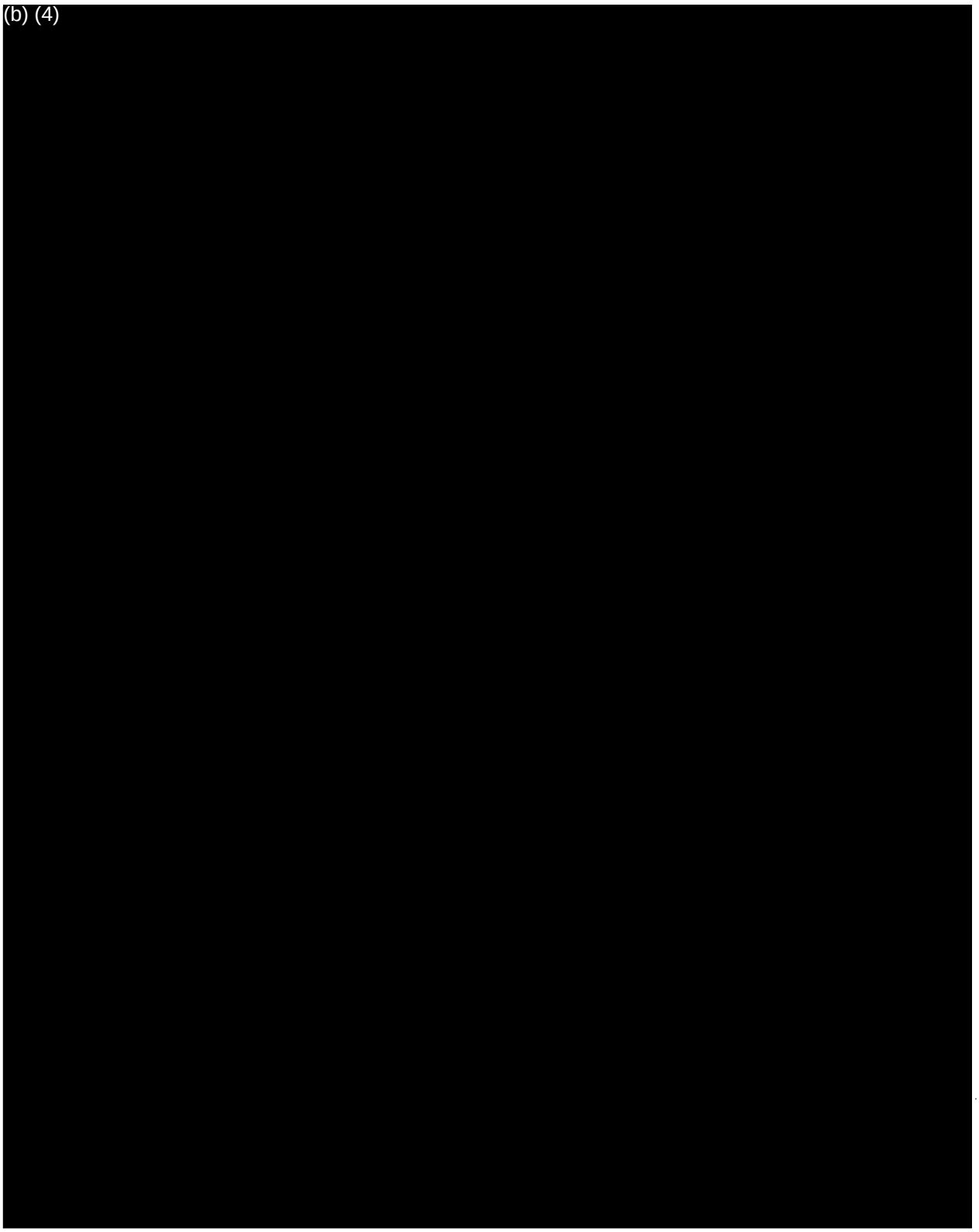

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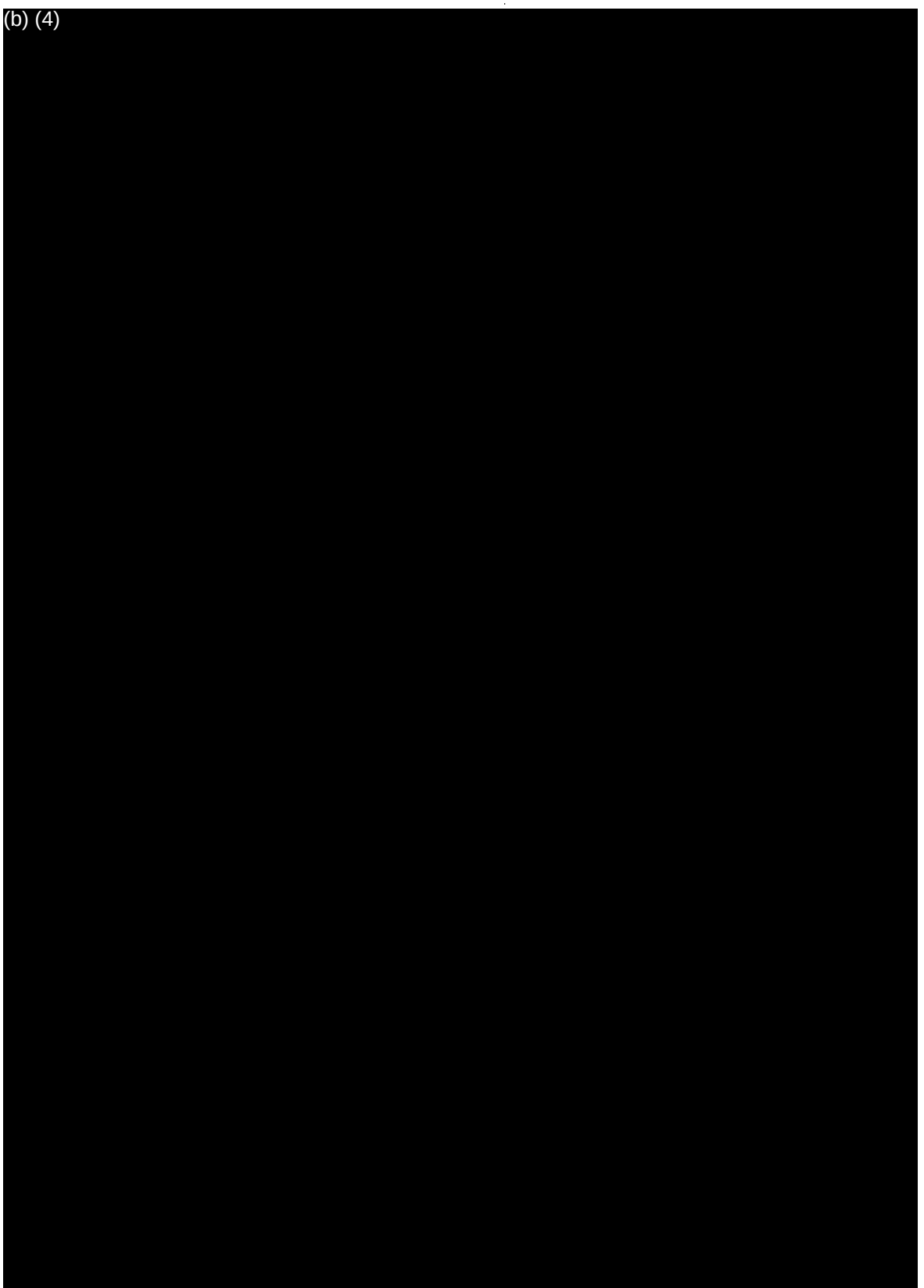

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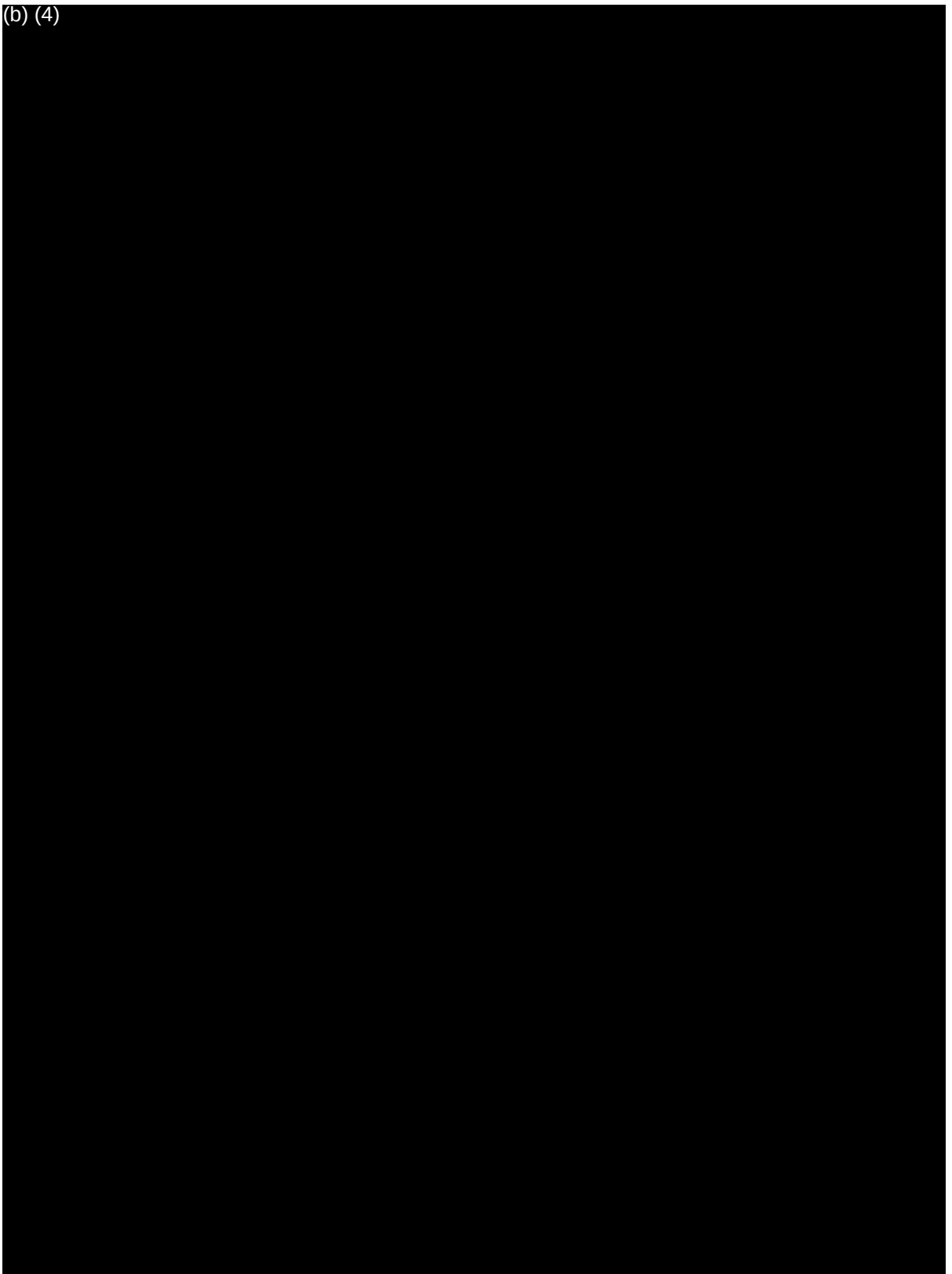

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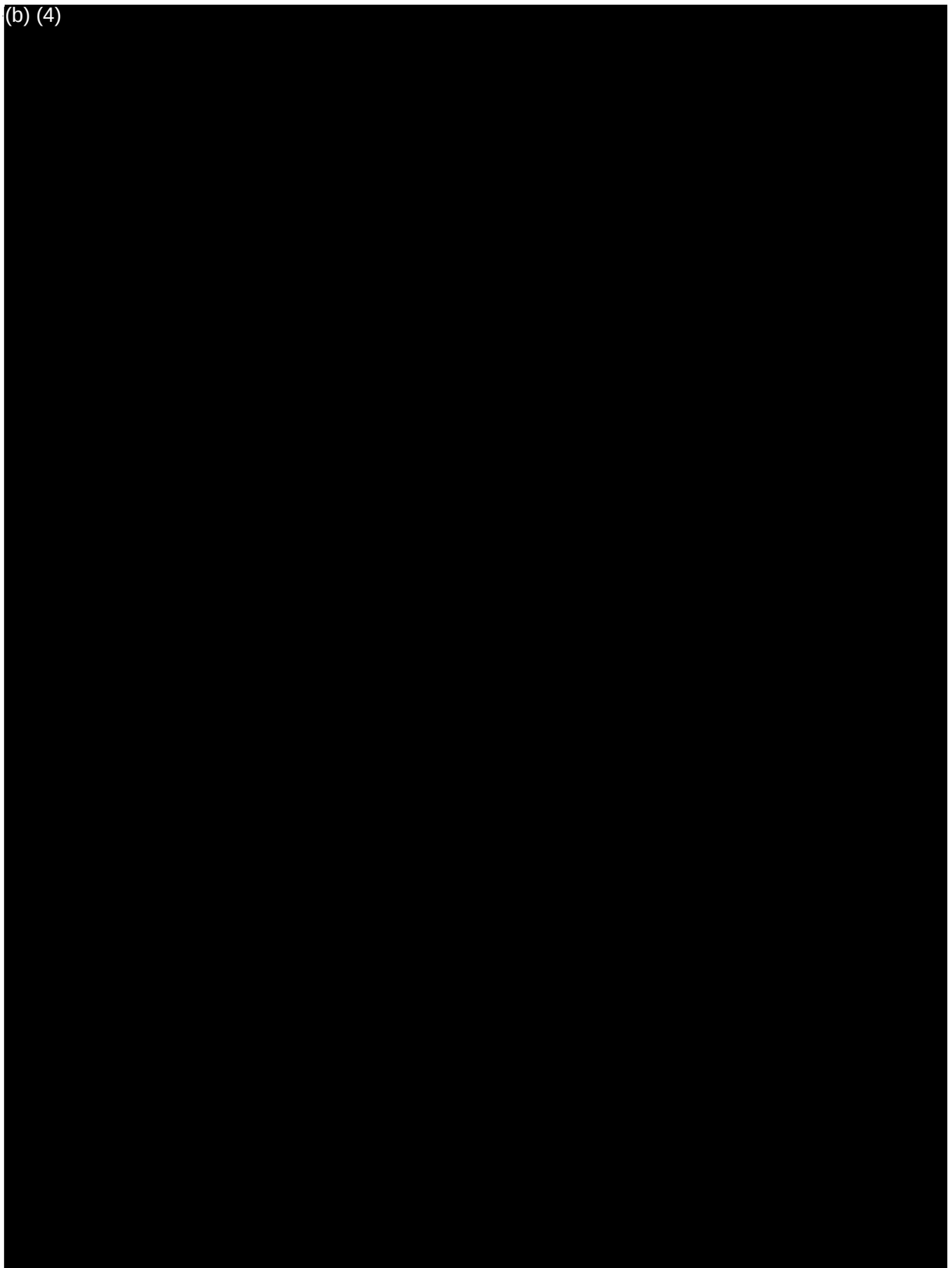

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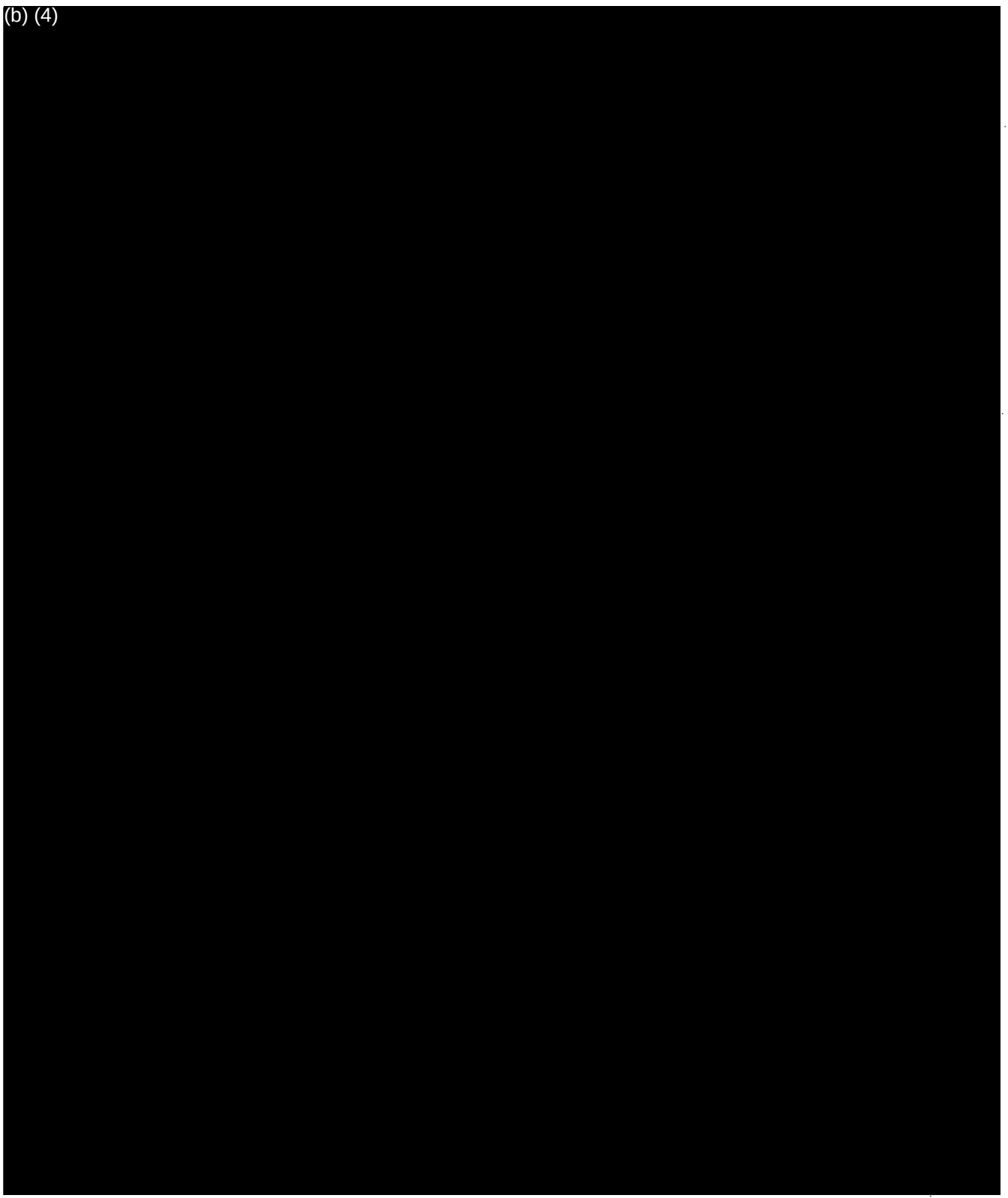

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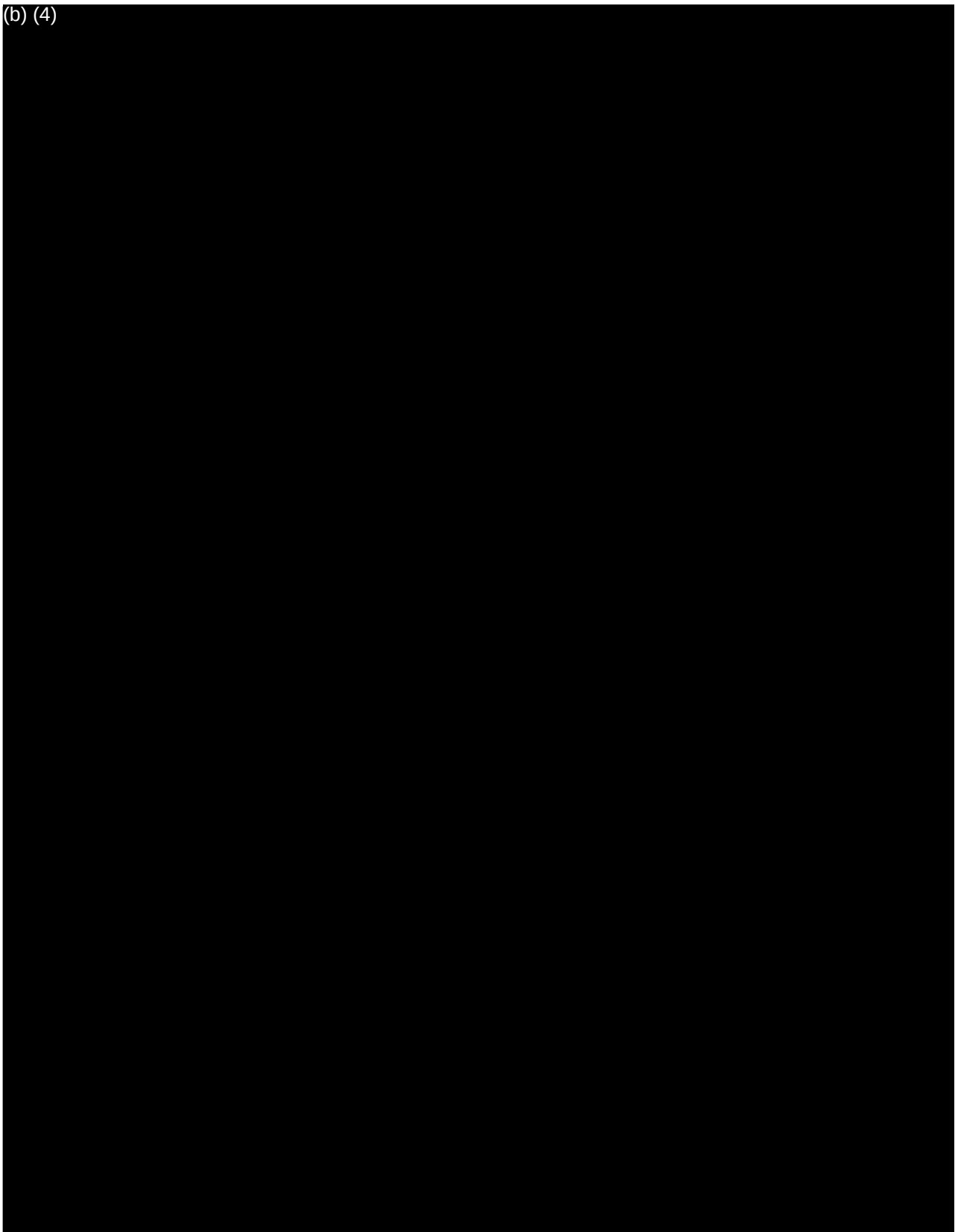

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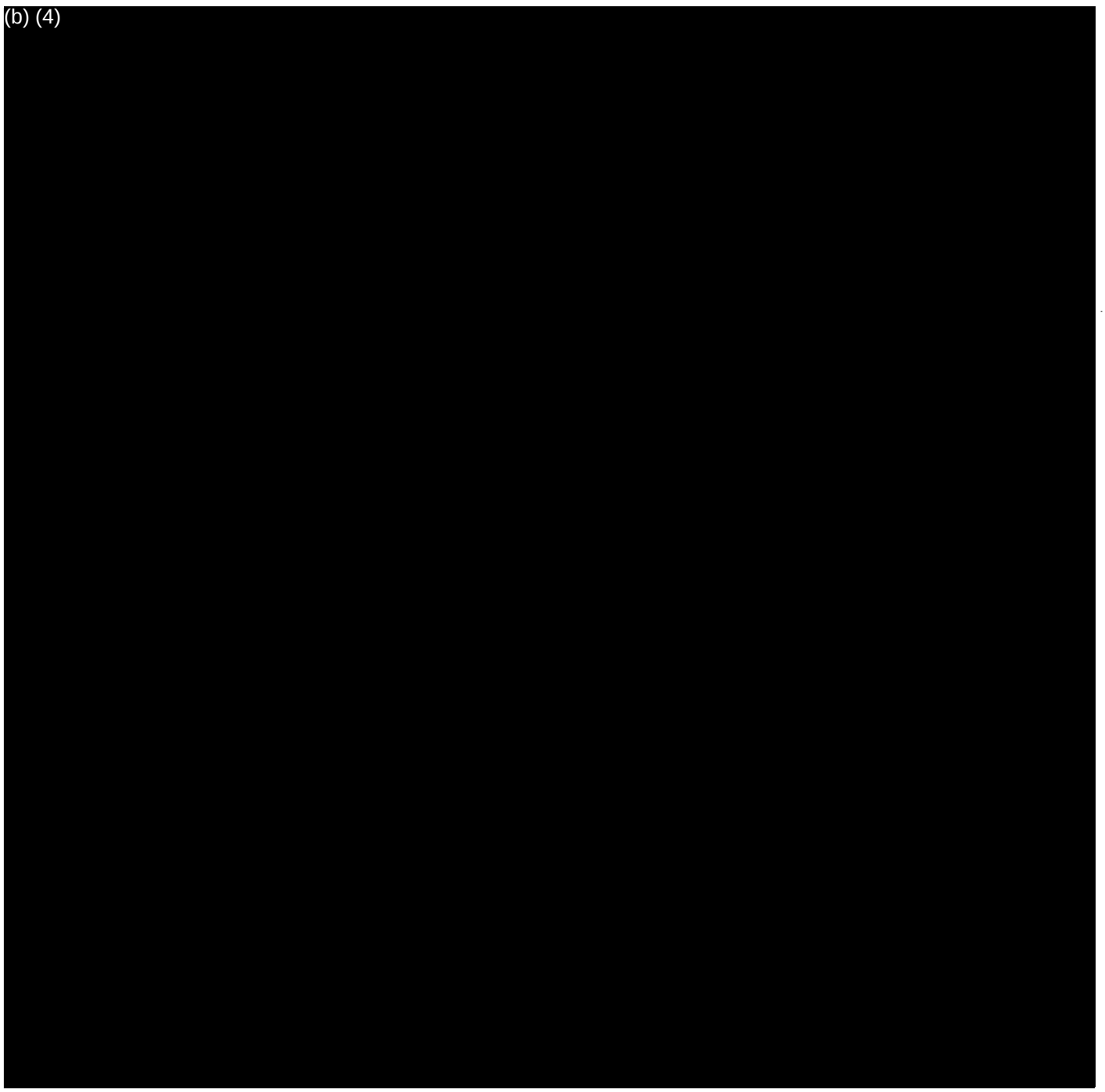

DJA x00905

DCO # 2158

TEST REPORT APPROVAL SHEET

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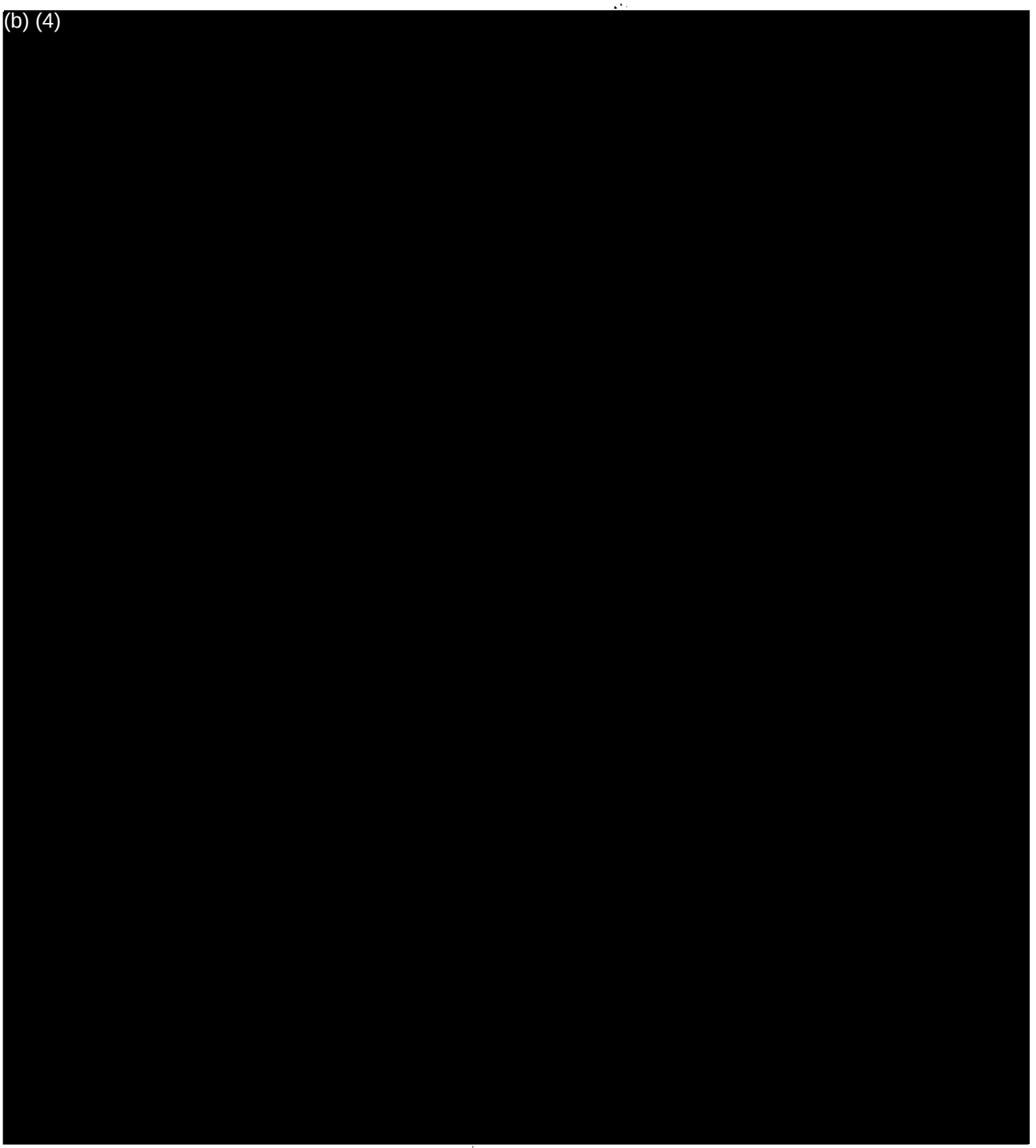
Integrated Surgical Systems, Inc.
1850 Research Park Dr., Davis, CA 95616-4884

DJA x00906

(b) (4)



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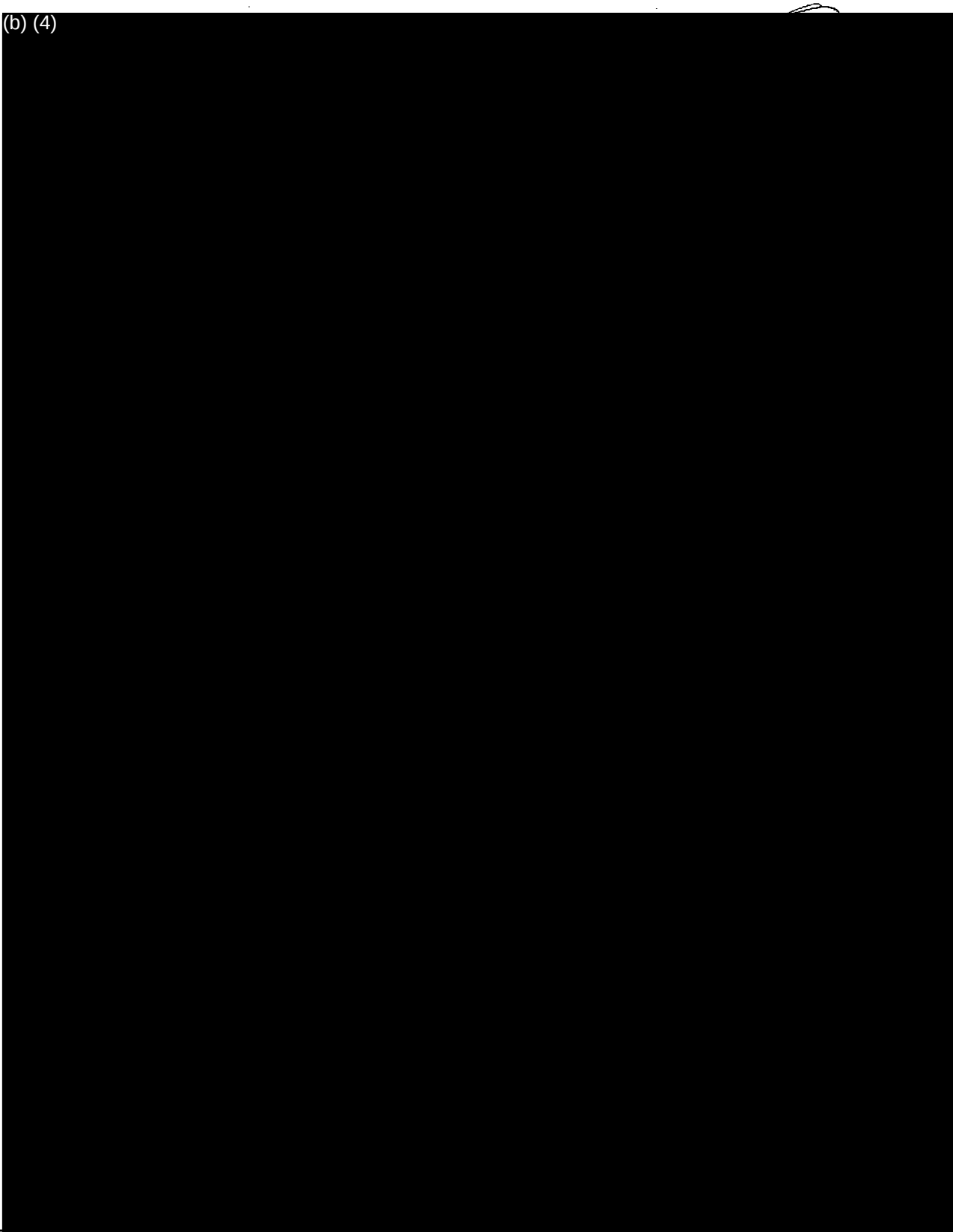
11.0 Attachments

(b) (4)

DJA x00908

(b) (4)



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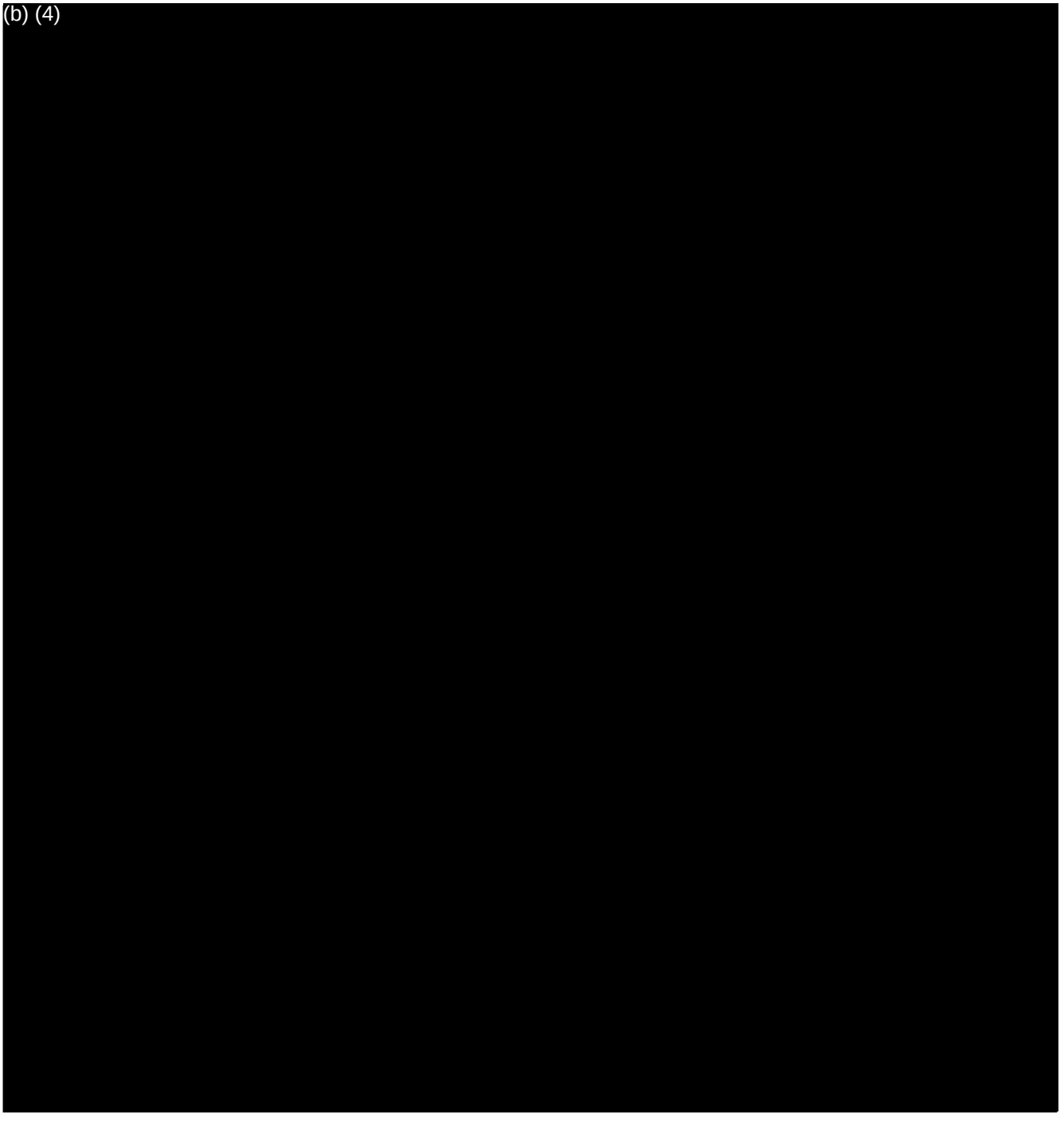

DJA x00910

TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 1984

(b) (4)

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DJA x00911

Results (Attach additional sheets if necessary):

(b) (4)

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DJA x00912

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 269

(b) (4)

DJA x00913

Data Collection / Analysis Method:

(b) (4)

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DJA x00914

TECHNICAL STUDY (TS)

Study Control Number

(b) (4) DCO # 2158

(b) (4)

DJA x00915

(b) (4)

DJA x00916

Results (Attach additional sheets if necessary):

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[redacted]

DJA x00917

(b) (4)

[redacted]

DJA x00918

Discussion:

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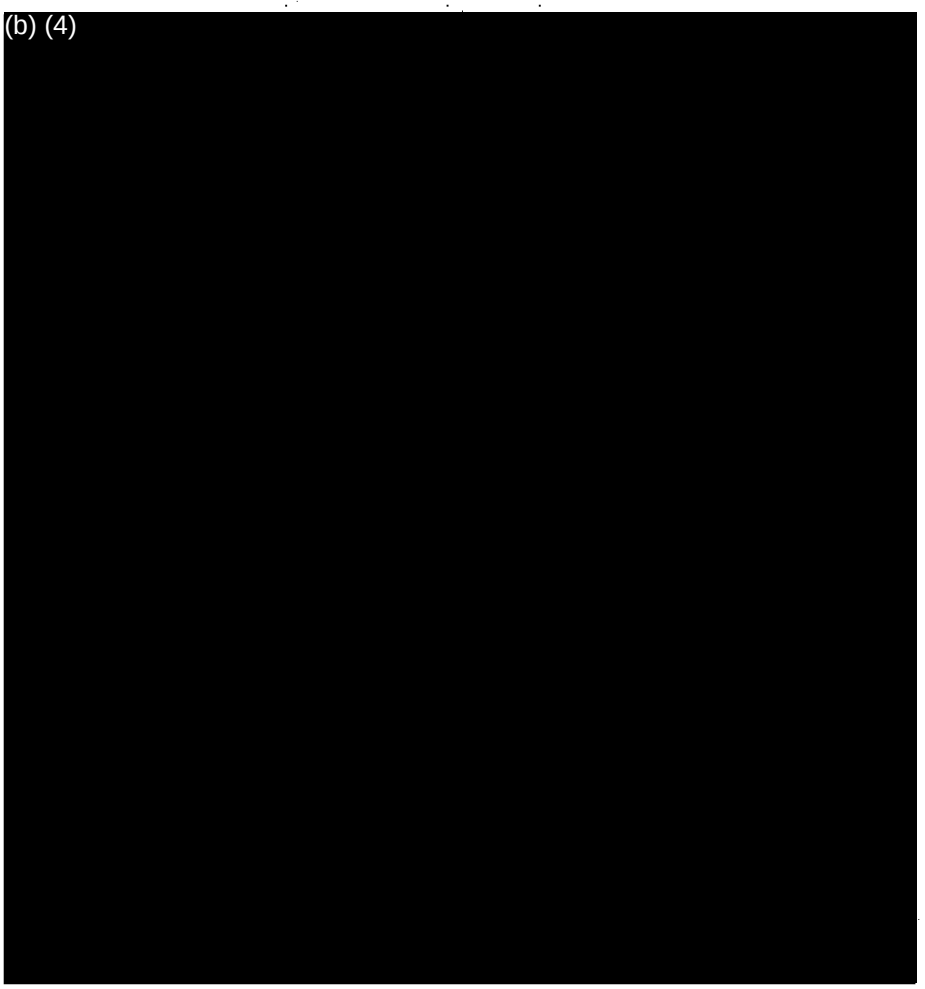
[redacted]

DJA x00919

DJA x00920

Natural Move

(b) (4)



DJA x00921

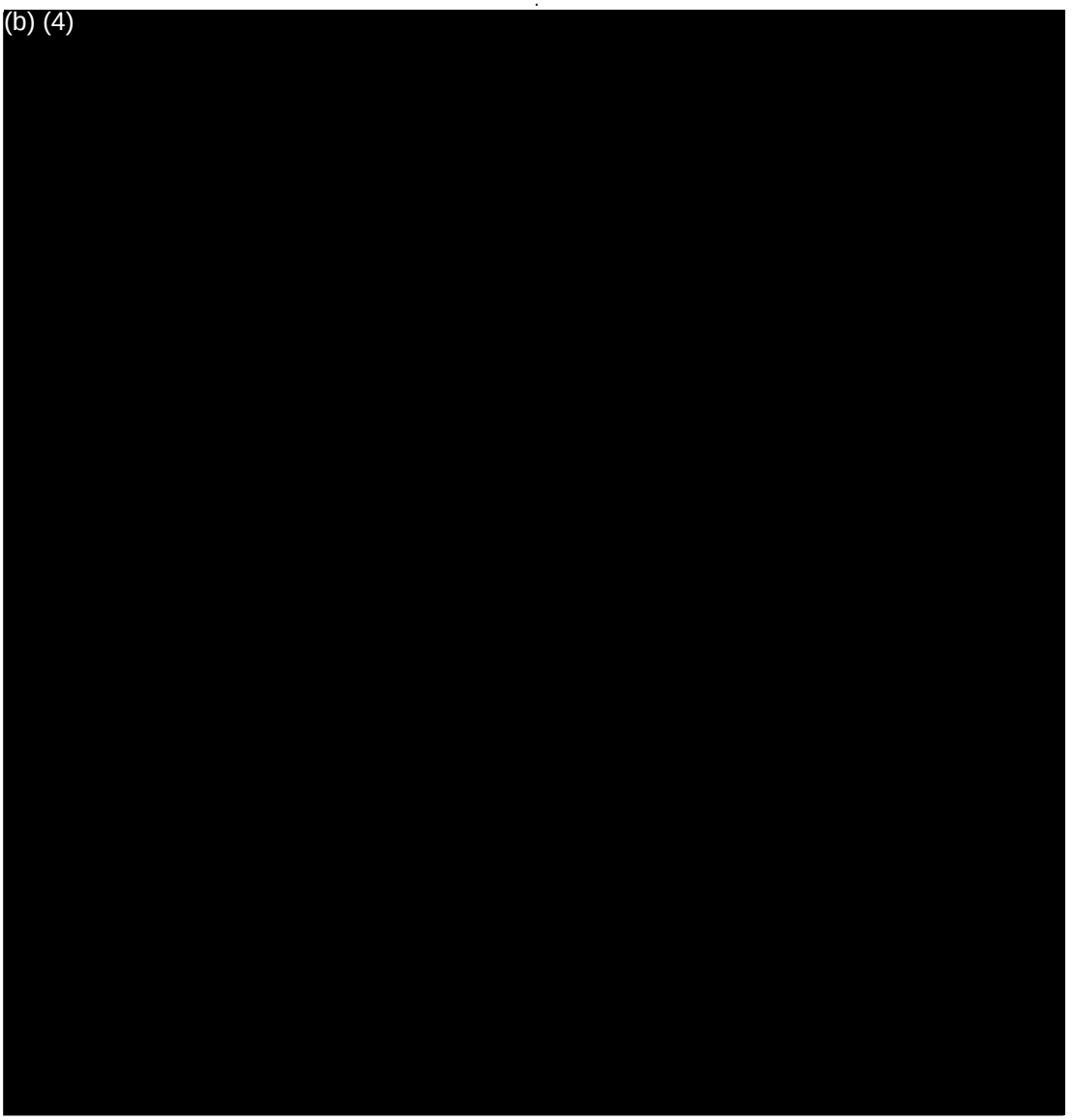
Natural Move

(b) (4)

DJA x00922

DJA x00923

(b) (4)



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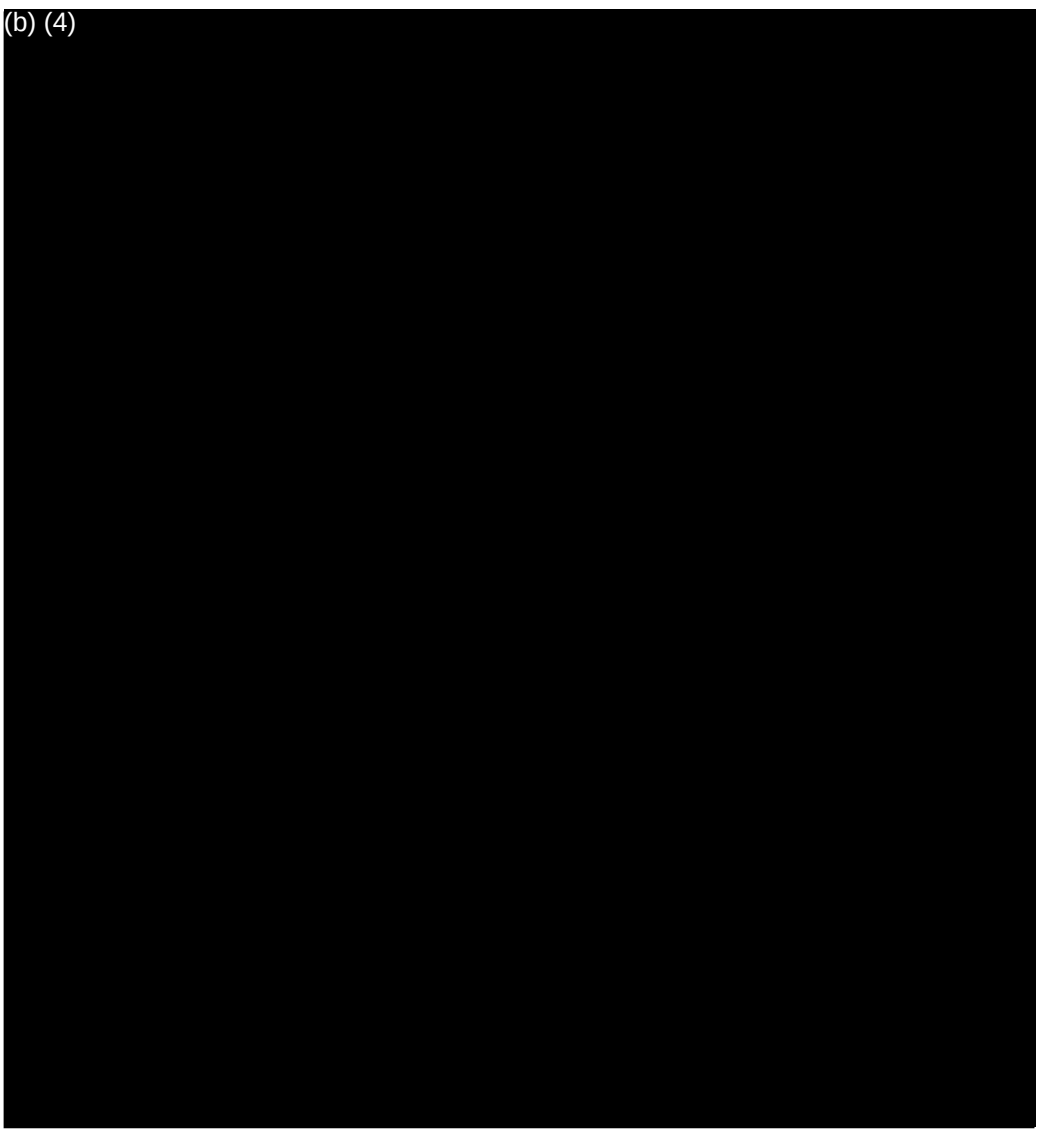

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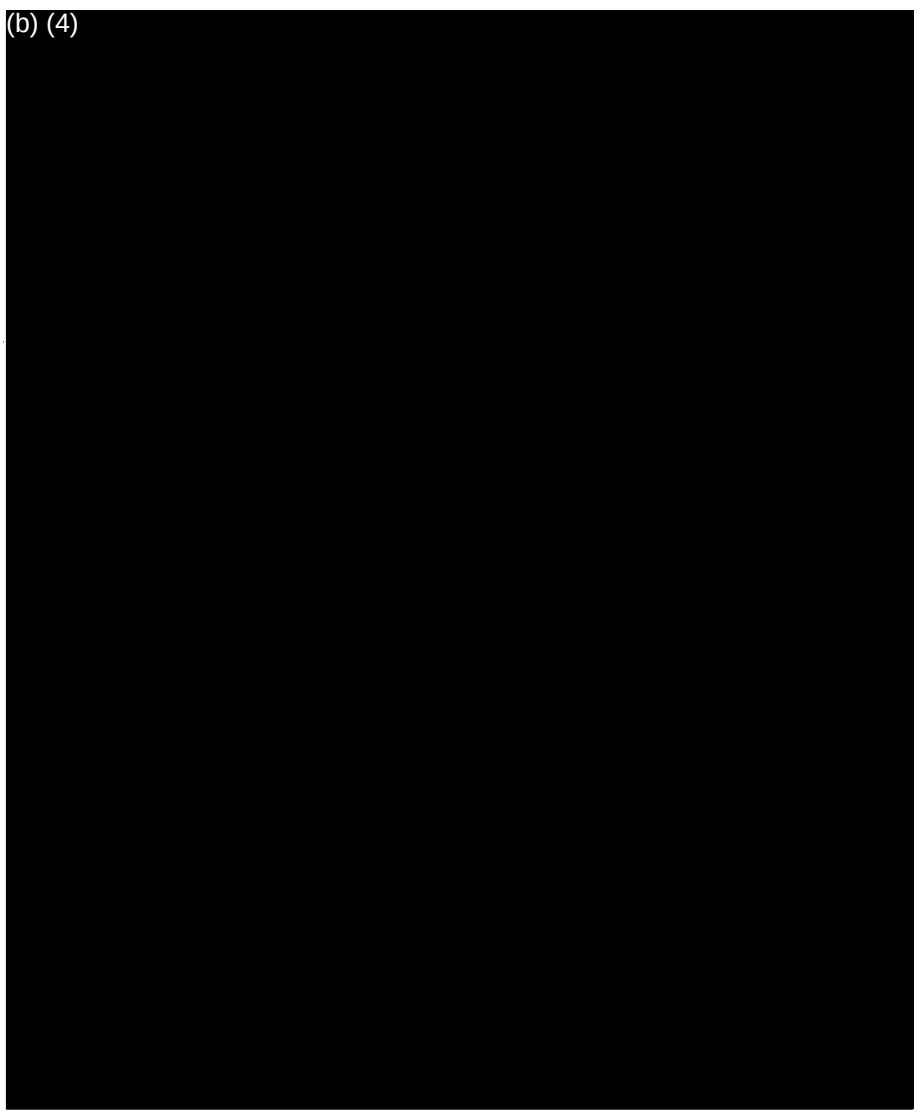

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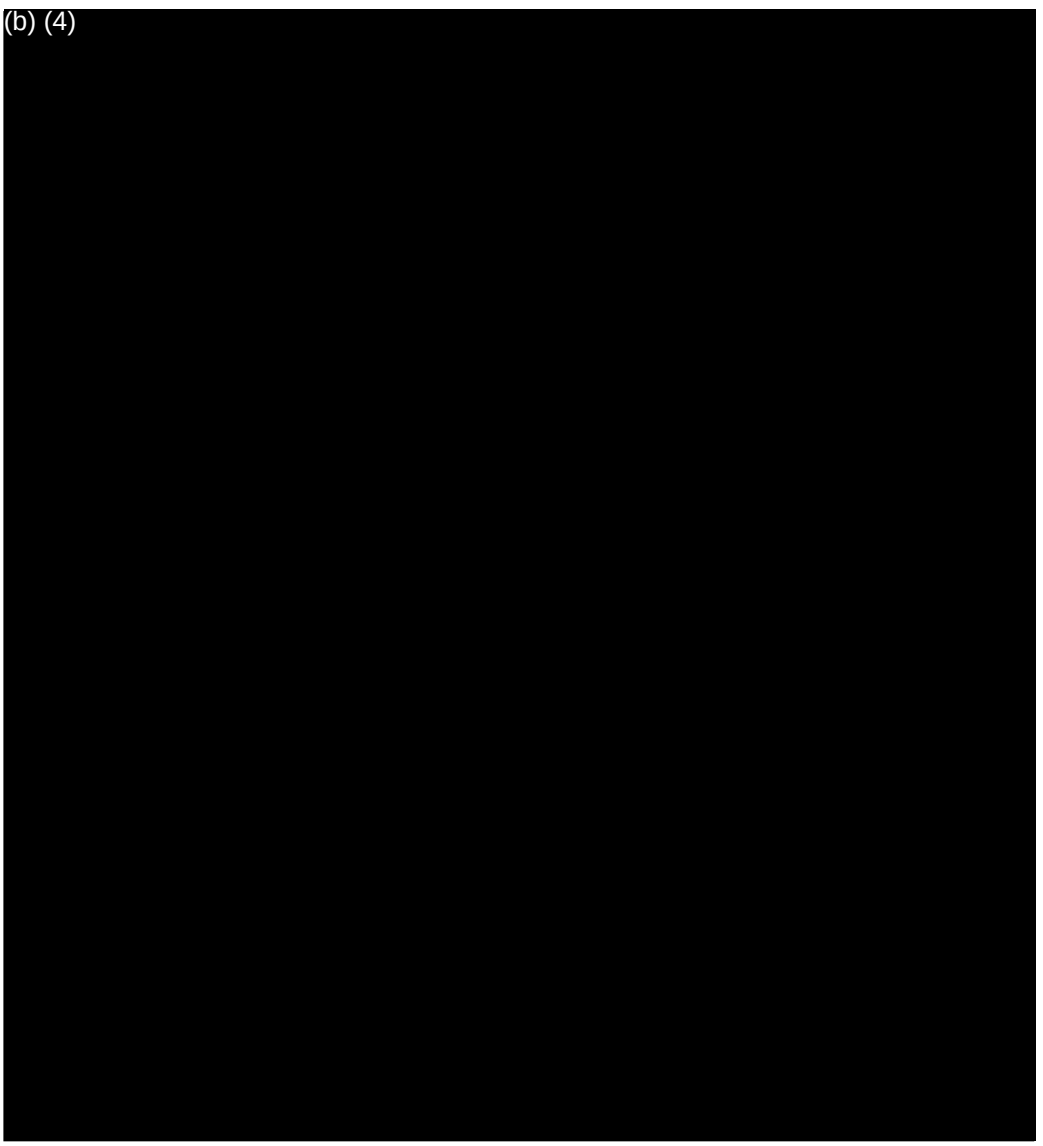
(b) (4)

DJA x00927

(b) (4)

DJA x00928

(b) (4)



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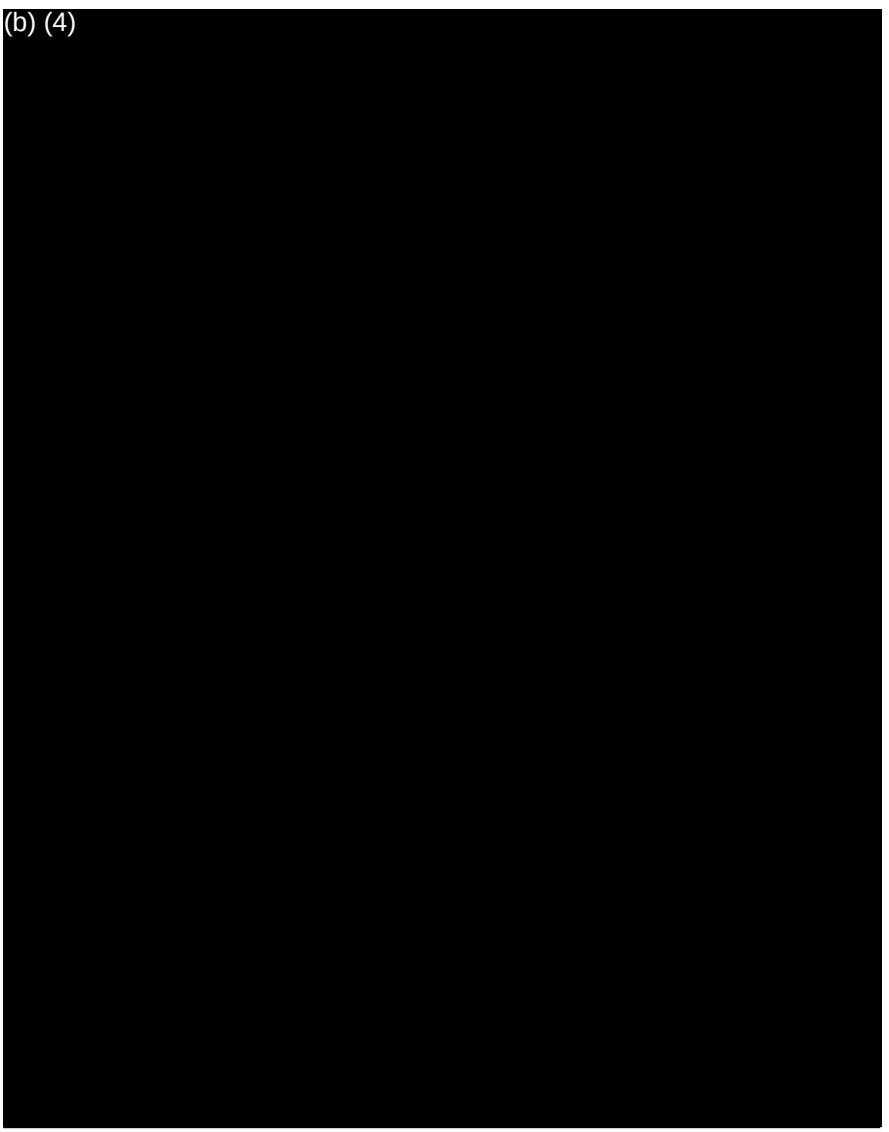

DJA x00930

(b) (4)

DJA x00931

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DJA x00932

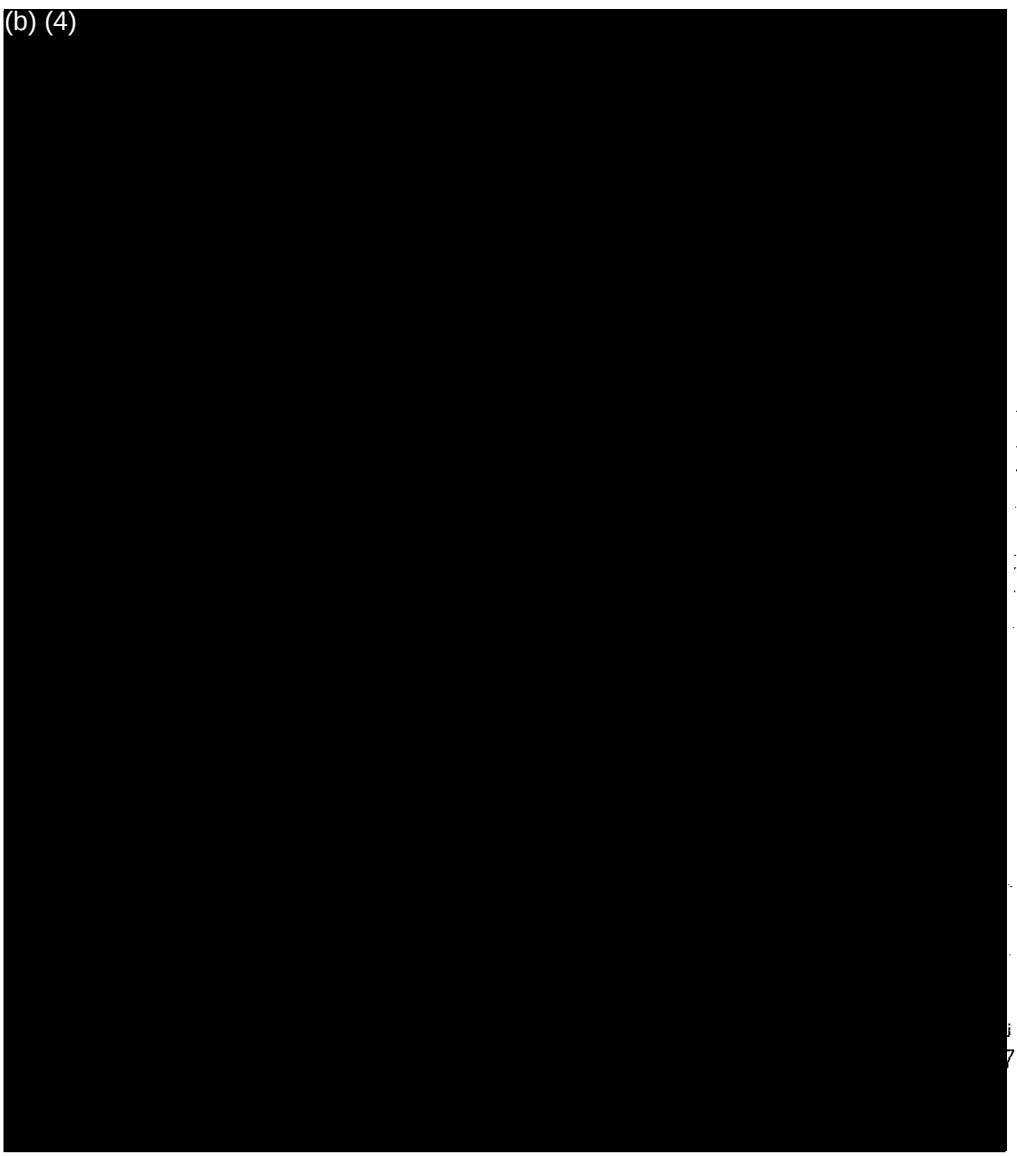
(b) (4)

DJA x00933

DJA x00934

(b) (4)

DJA x00935



DJA x00936

(b) (4)

DJA x00937

(b) (4)

DJA x00938

Tool Circle #4

(b) (4)

CJTA x00939

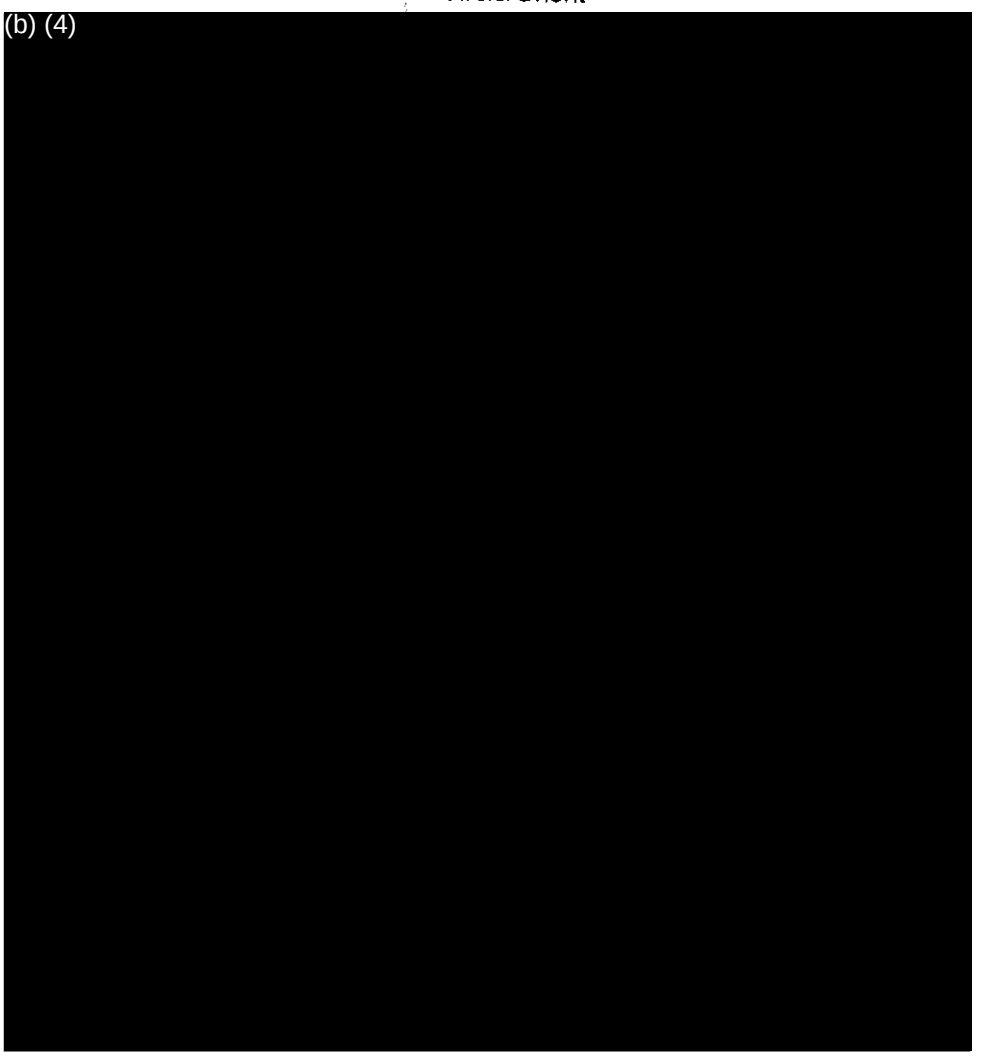
Tool Circle/Orient

(b) (4)

DJA x00940

Tool Circle/Orient

(b) (4)

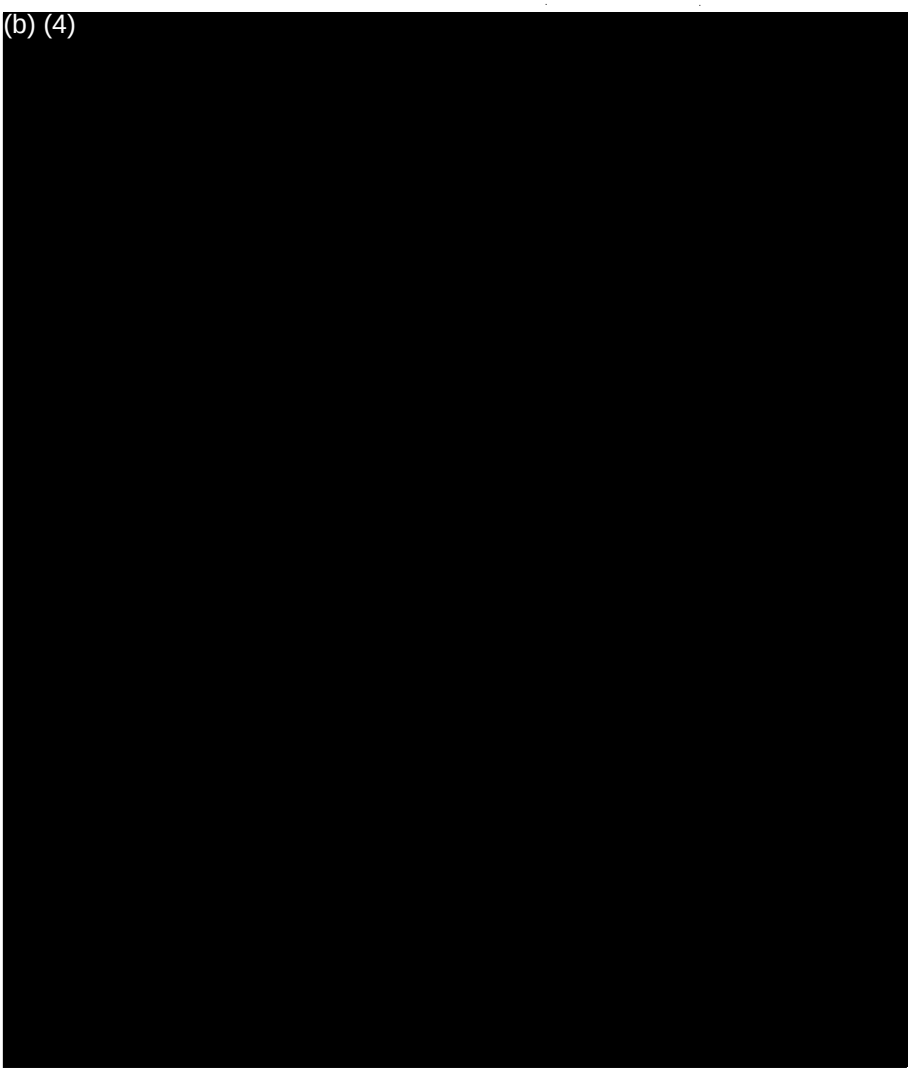


DJA x00941

Tool Circle/Orient (Approach Vector)

DJA x00942

Tool Helix #1



DJA x00943

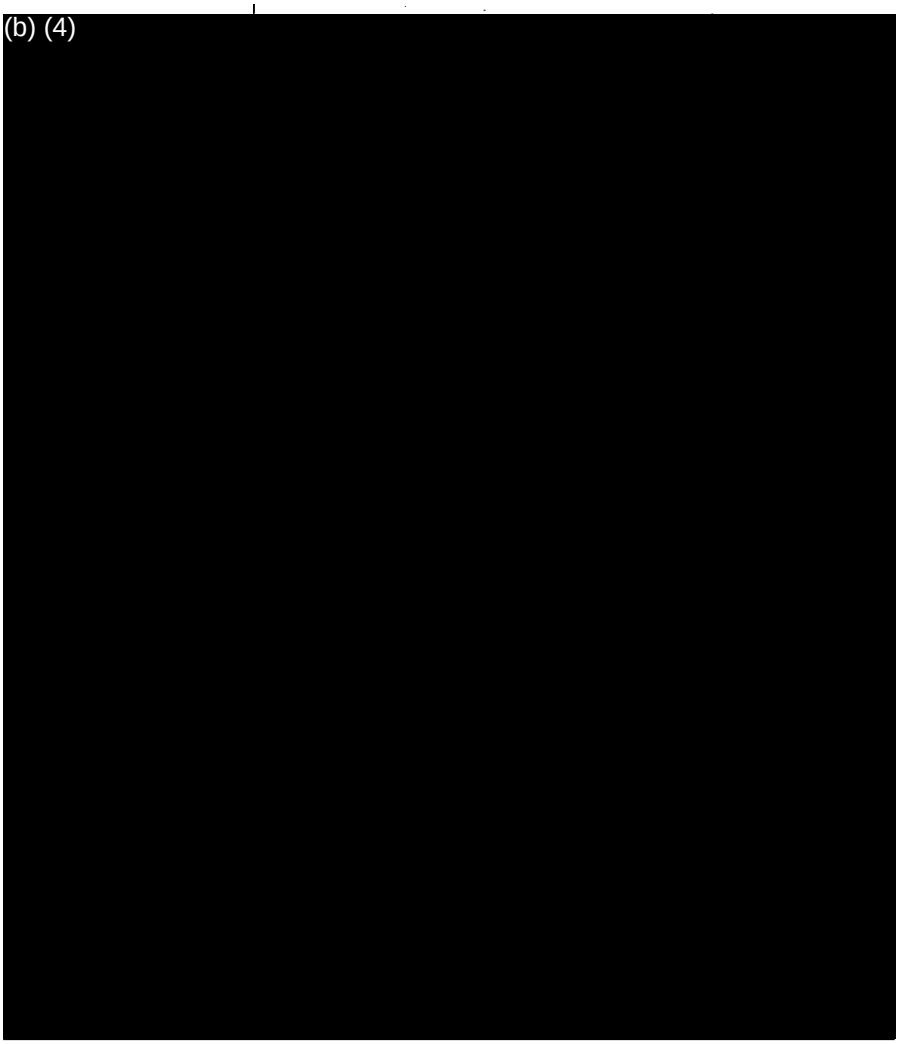
Tool Helix #1

(b) (4)

DJA x00944

Tool Helix #1

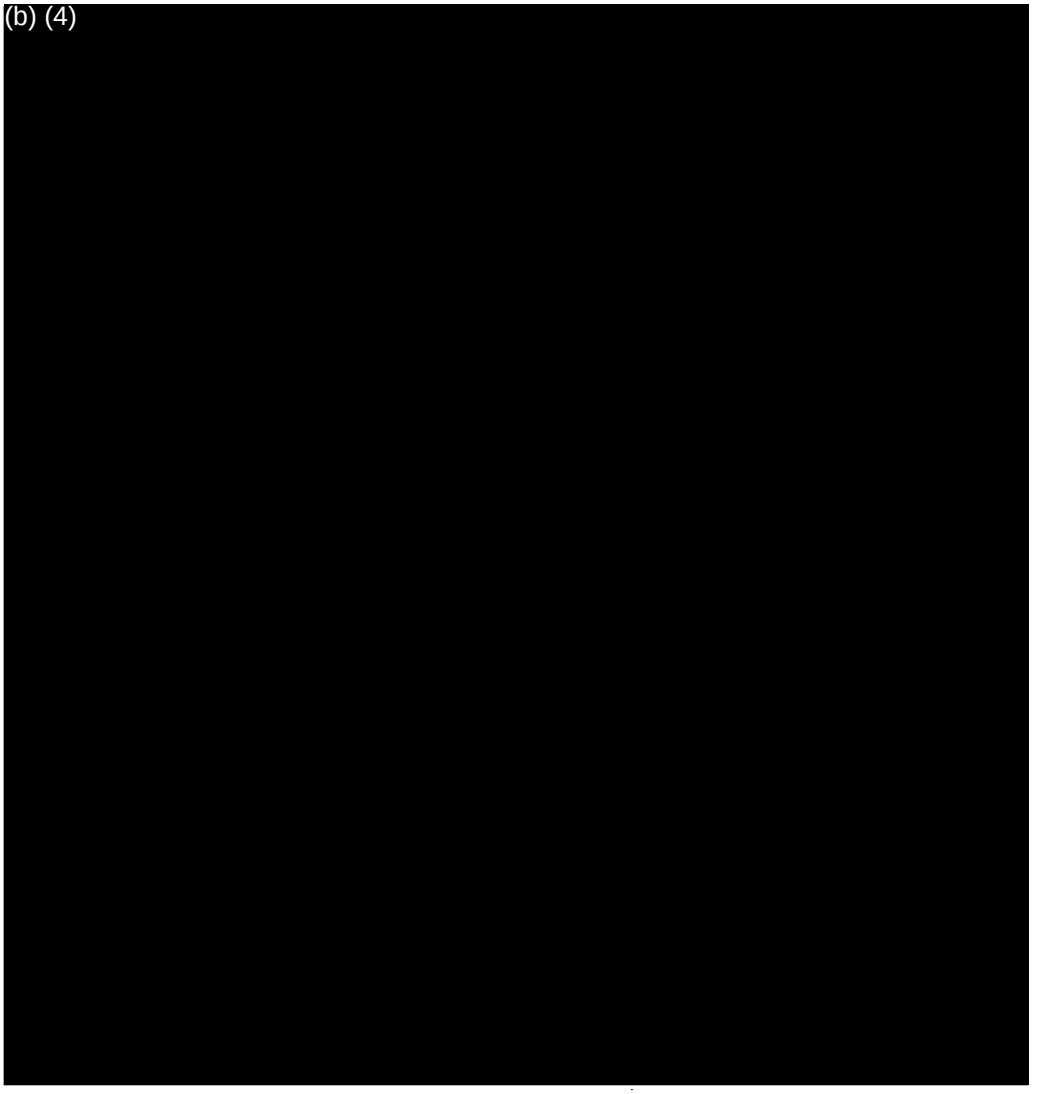
(b) (4)



DJA x00945

Tool Helix #2

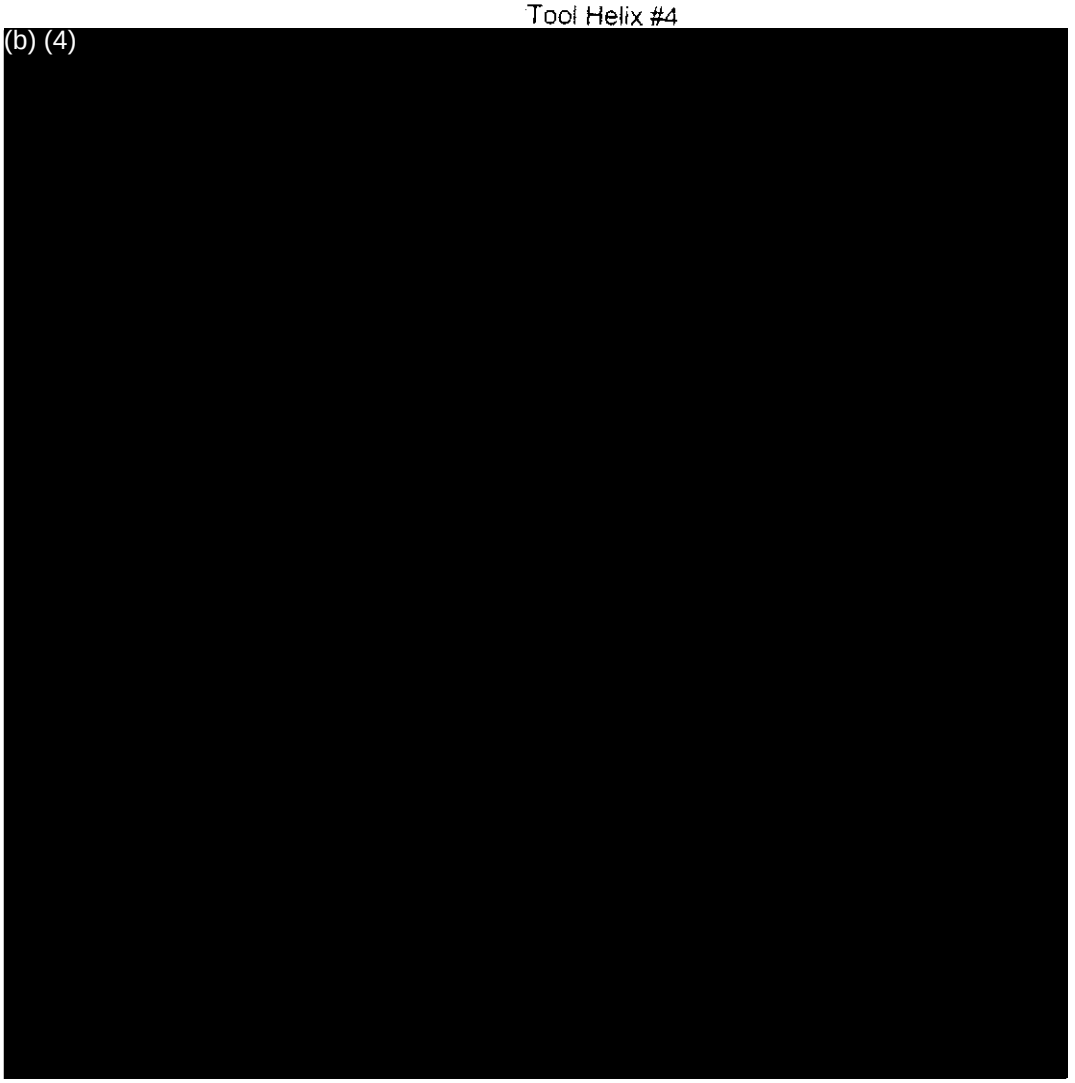
(b) (4)



DJA x00946

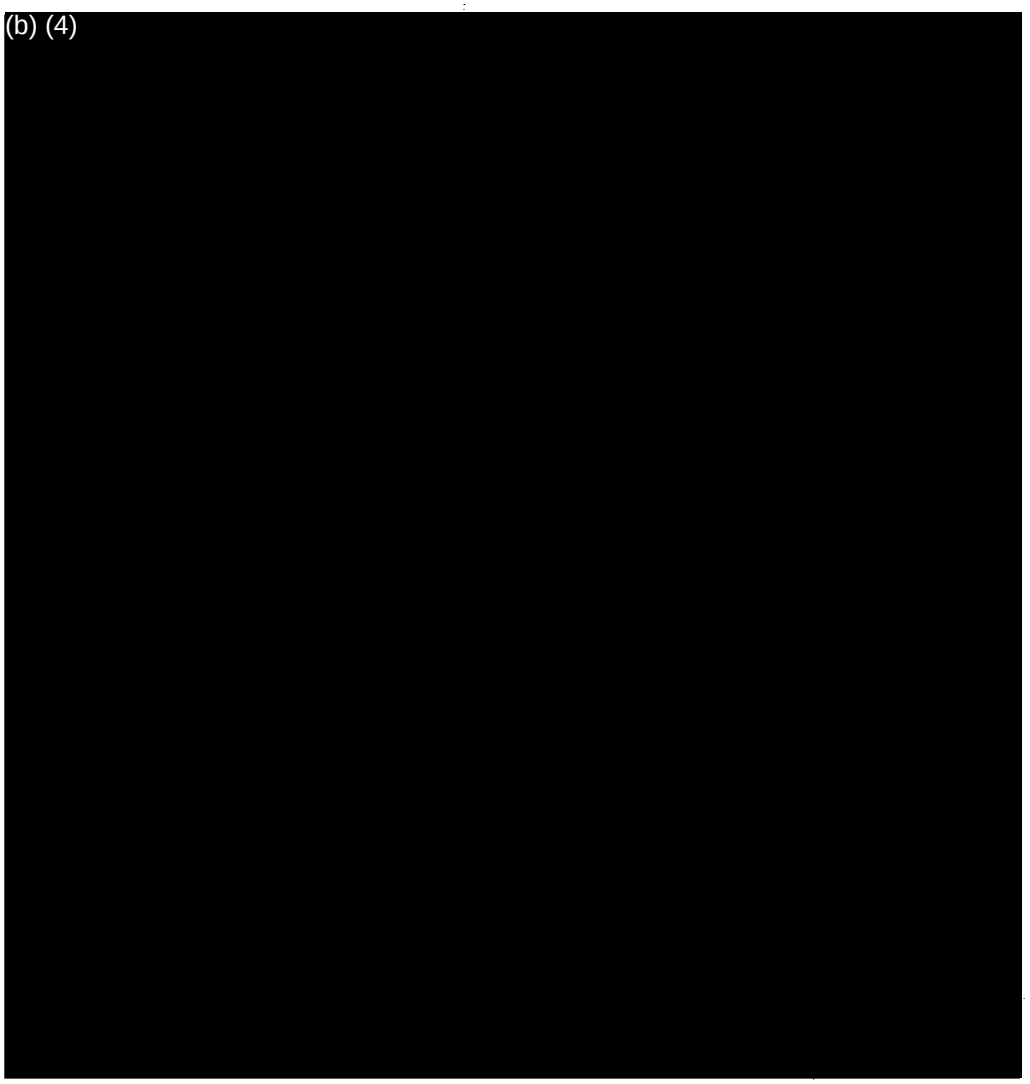
Tool Helix #4

(b) (4)



DJA x00947

Tool Helix #5



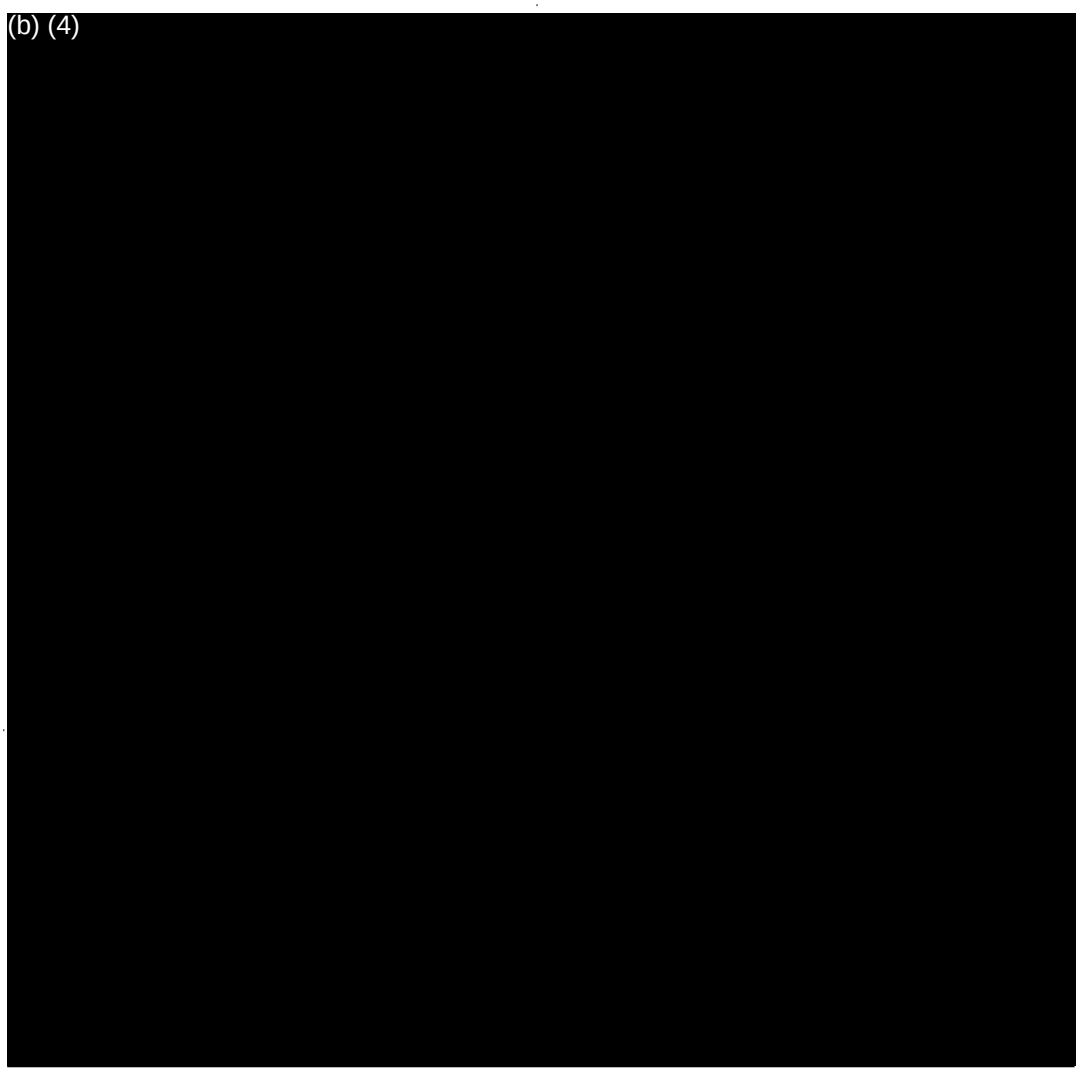
DJA x00948

(b) (4)

DJA x00949

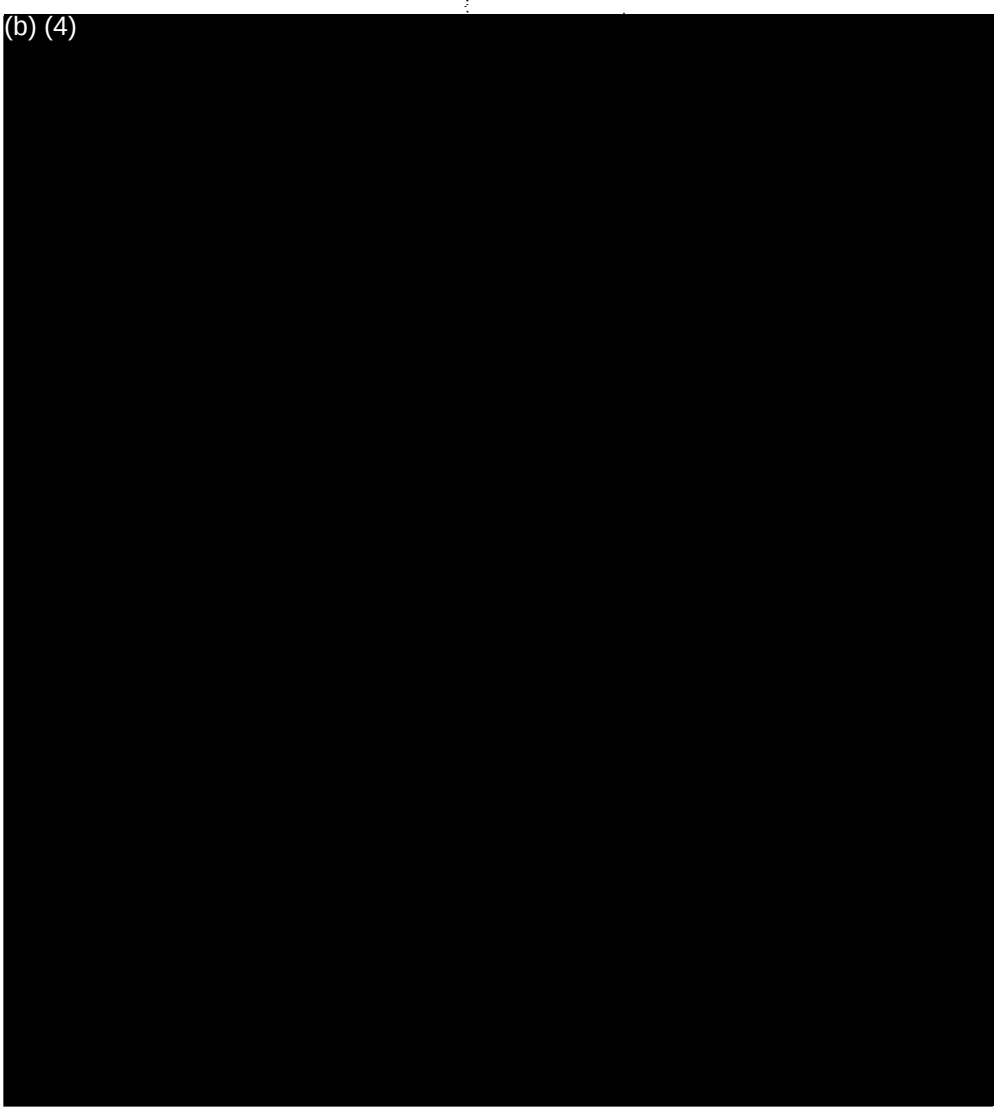
Tool Helix #5

(b) (4)



DJA x00950

Tool Helix #6



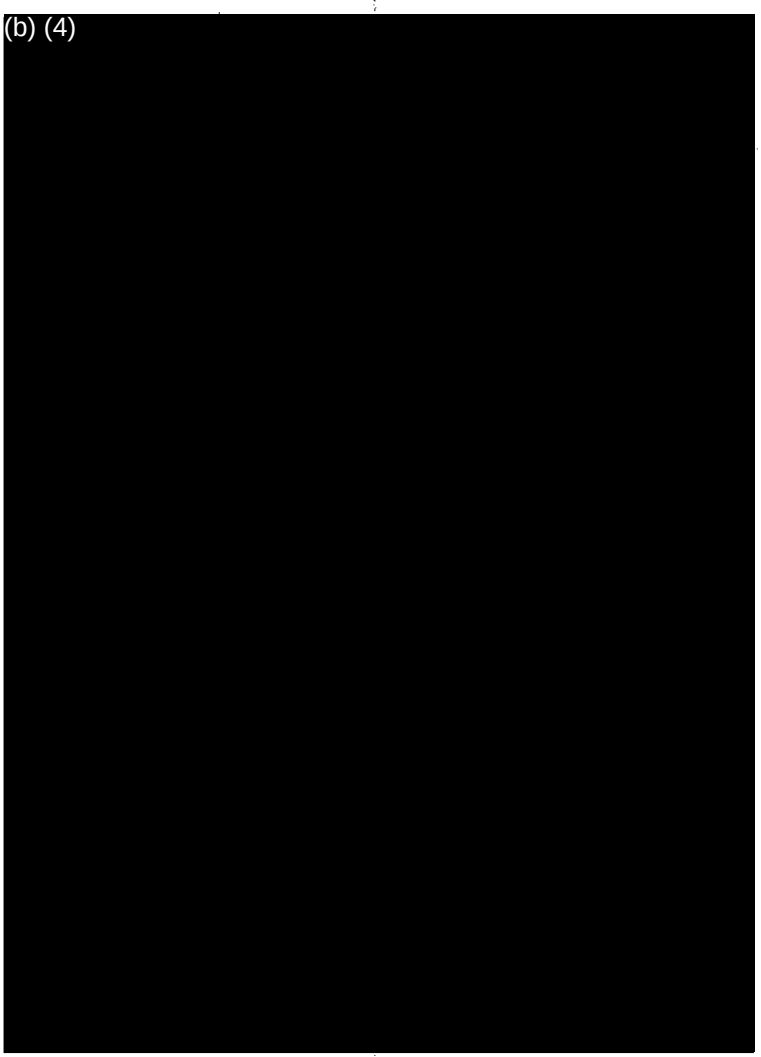
DJA x00951

Tool Helix #6

(b) (4)

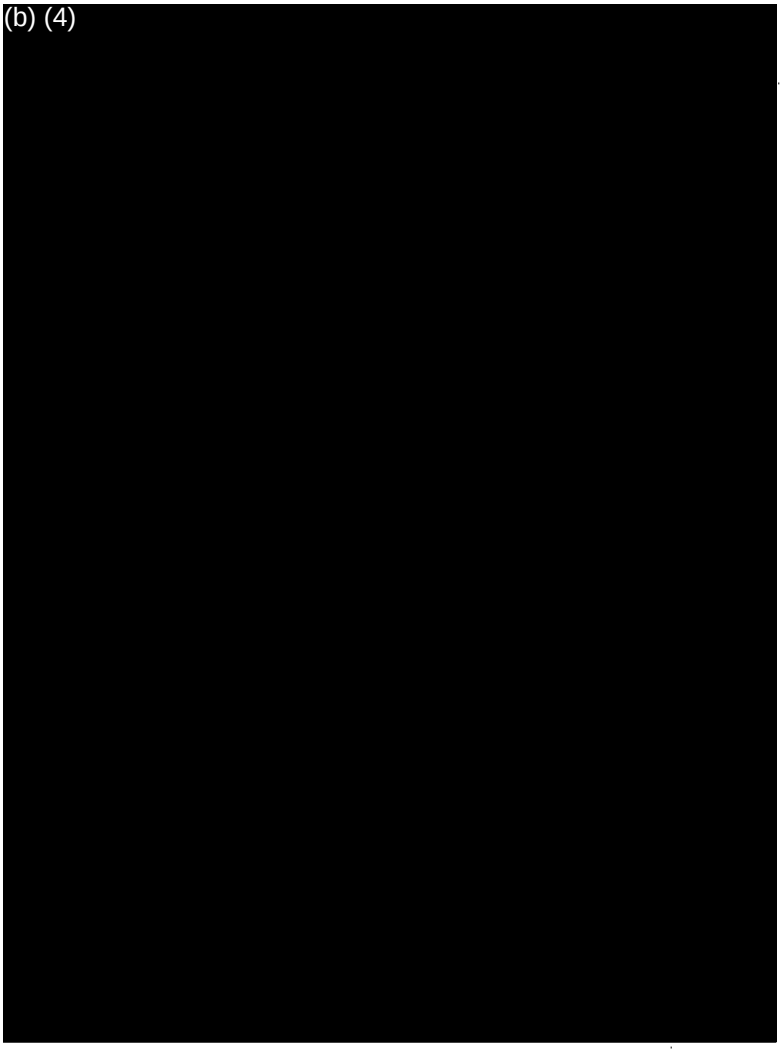
DJA x00952

Tool Helix #6



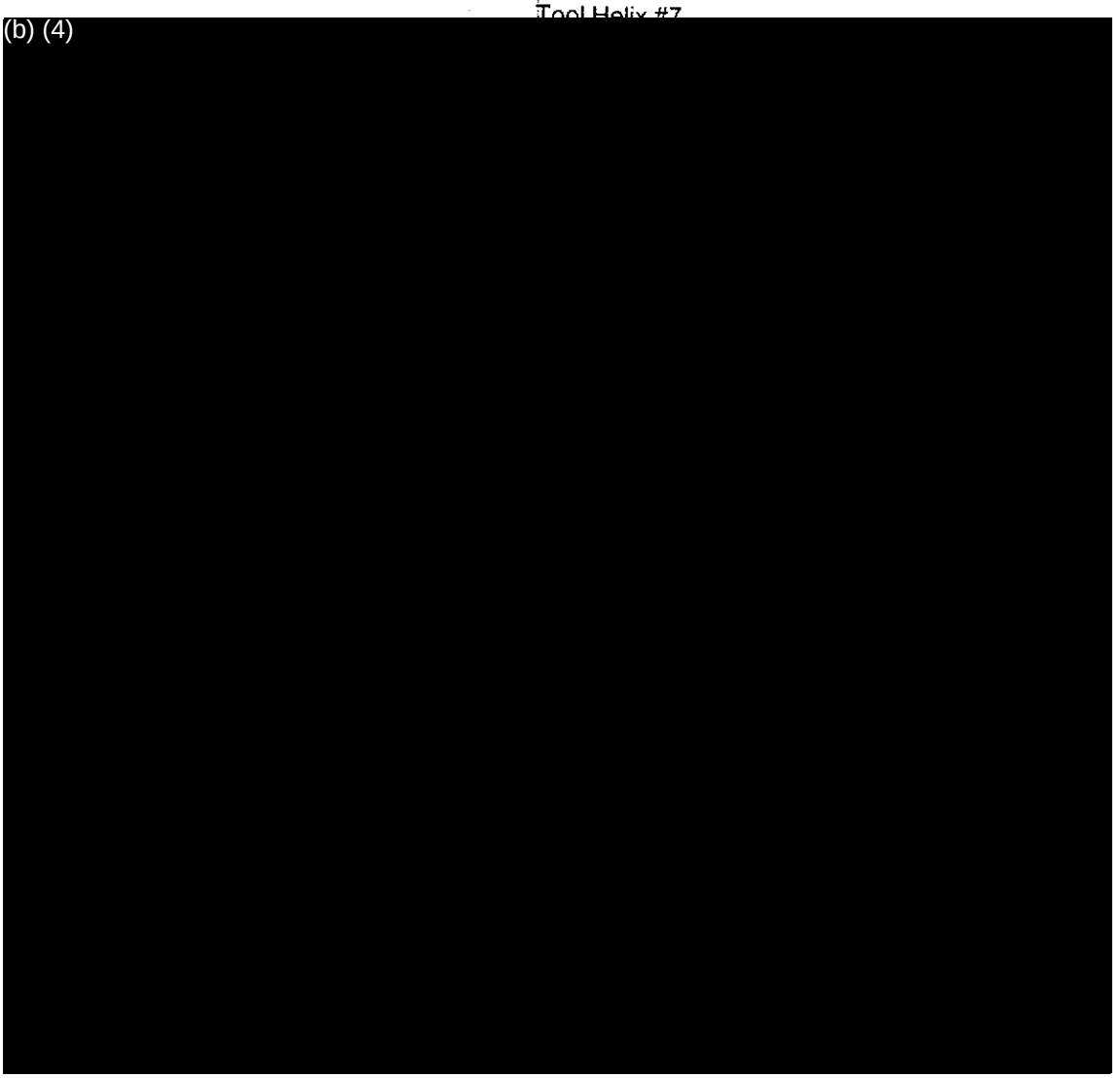
DJA x00953

Tool Helix #7



DJA x00954

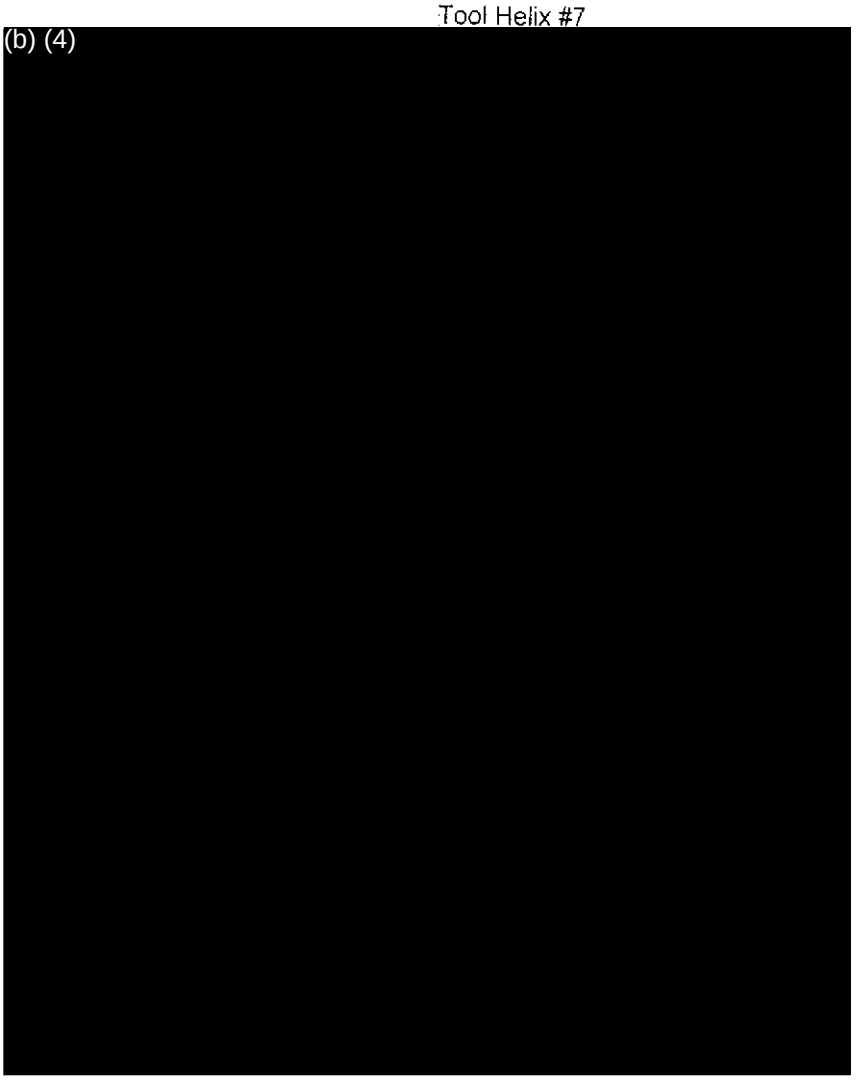
Tool Helix #7



DJA x00955

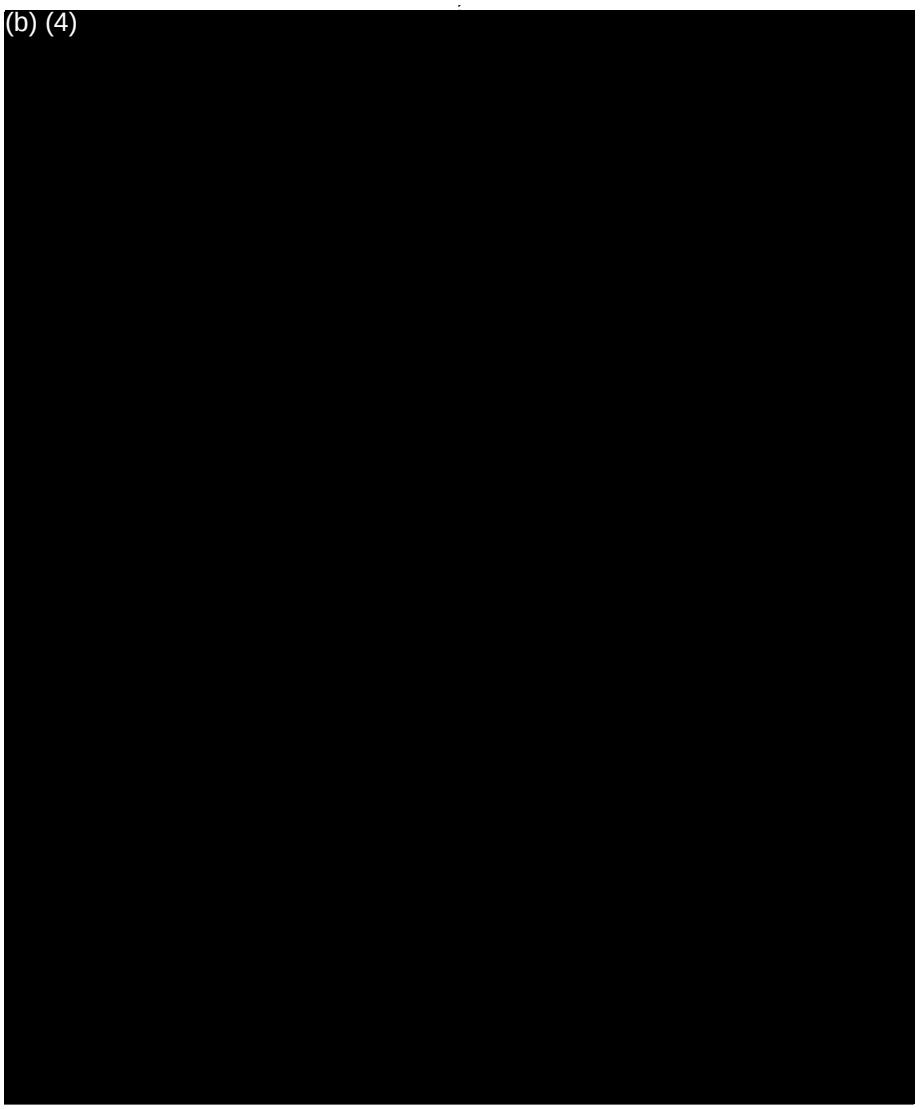
Tool Helix #7

(b) (4)



DJA x00956

Tool Helix #8



DJA x00957

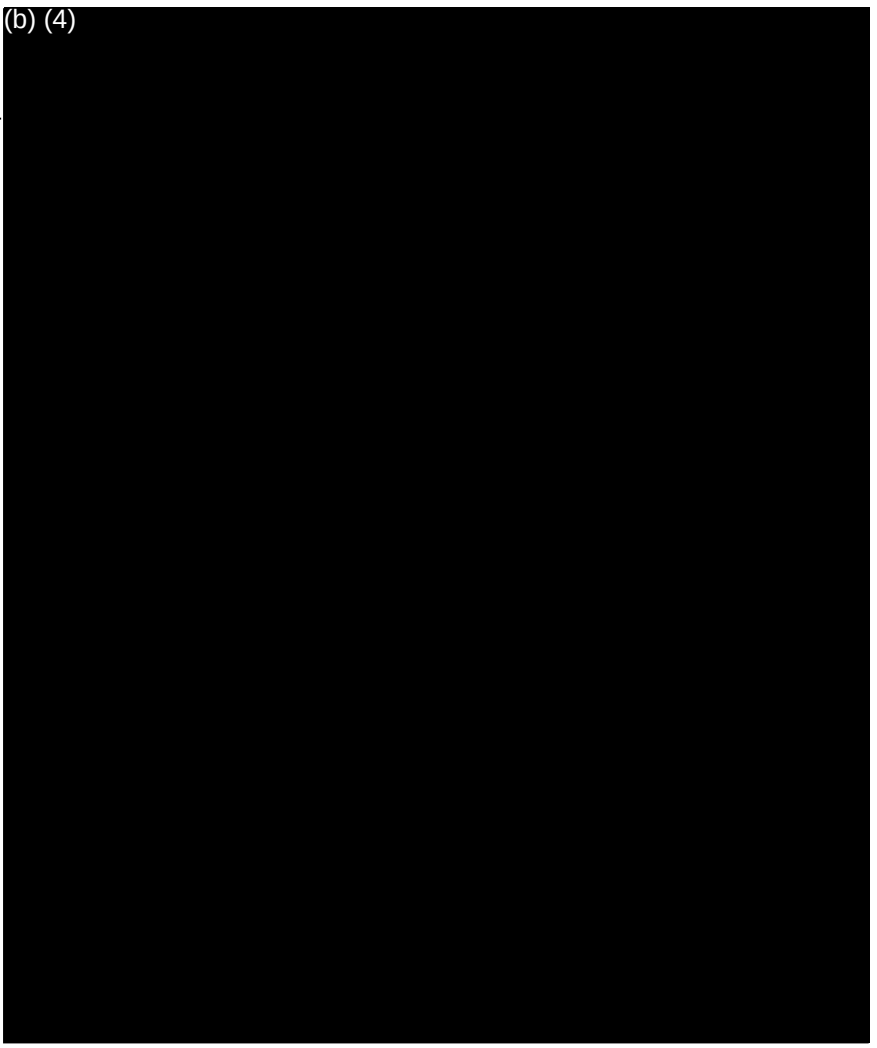
Tool Helix #8

(b) (4)

DJA x00958

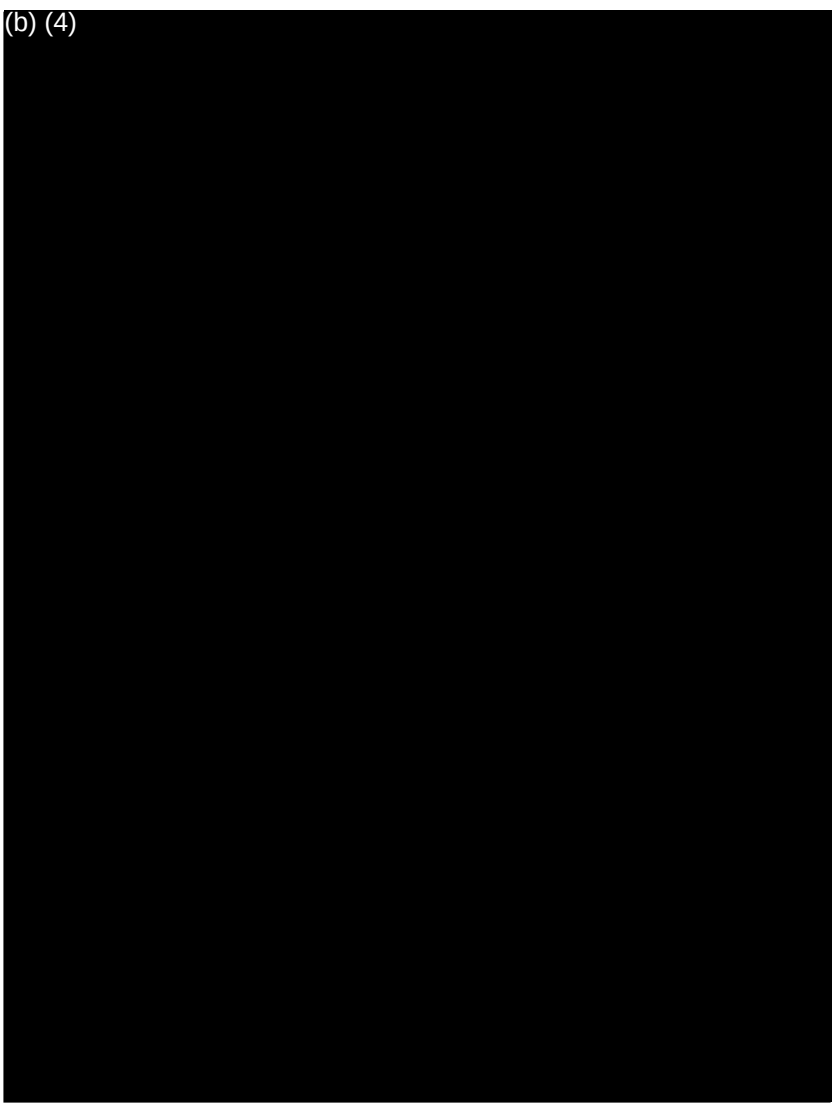
Tool Helix #8

(b) (4)



DJA x00959

Tool Helix/Orient



DJA x00960

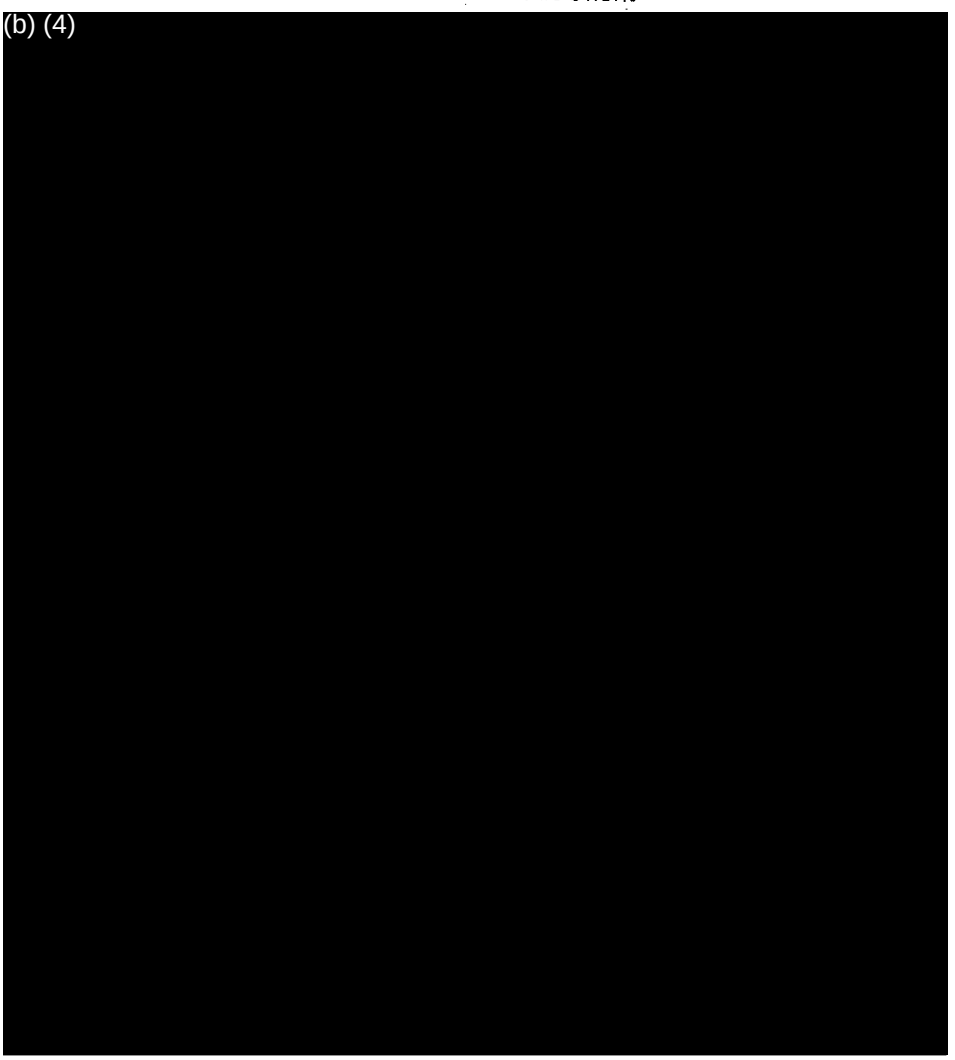
Tool Helix/Orient

(b) (4)

DJA x00961

Tool Helix/Orient

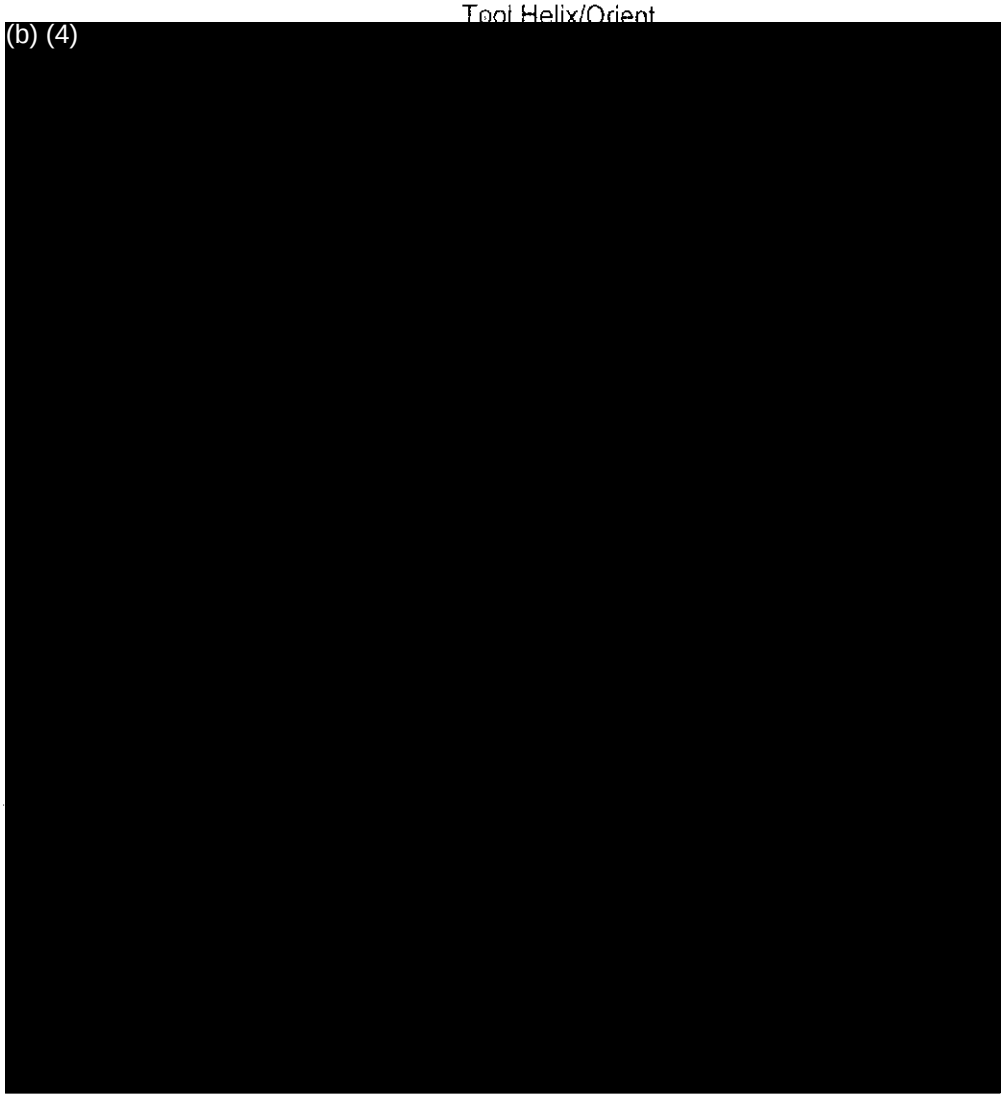
(b) (4)



DJA x00962

Tool Helix/Orient

(b) (4)



DJA x00963

Tool Helix/Orient (Approach Vector)

DJA x00964

TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 2153

(b) (4)

COPY
gc 01/17/08

DJA x00965

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00966

(b) (4)

DJA x00967

Acceleration = 0.01 - Distance

(b) (4)

DJA x00968

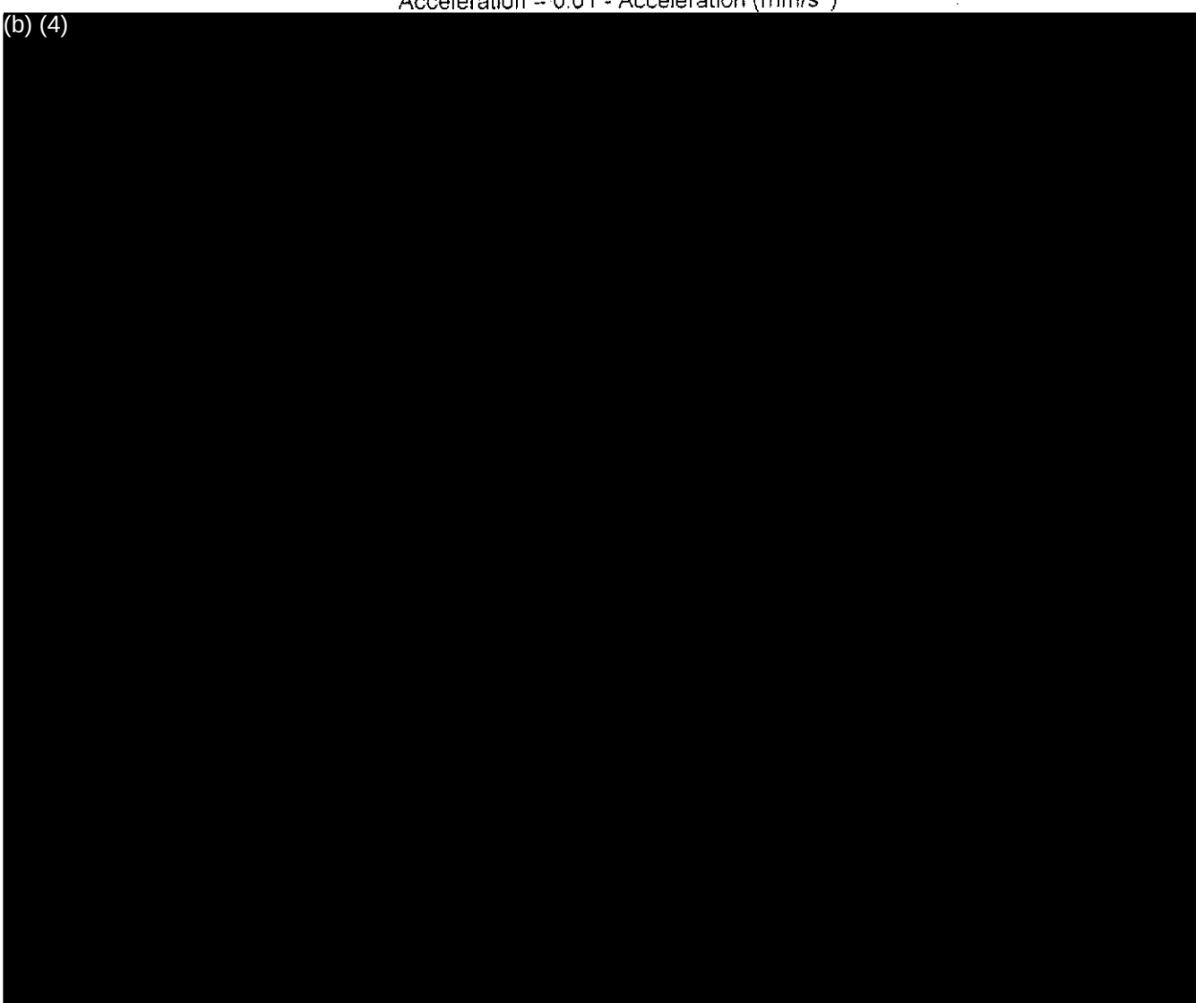
Acceleration = 0.01 - Velocity (mm/s)

(b) (4)

DJA x00969

Acceleration = 0.01 - Acceleration (mm/s^2)

(b) (4)



DJA x00970

Acceleration = 0.02 - Distance

(b) (4)

DJA x00971

Acceleration = 0.02 - Velocity (mm/s)

(b) (4)

DJA x00972

Acceleration = 0.02 - Acceleration (mm/s^2)

(b) (4)

DJA x00973

Acceleration = 0.05 - Distance

(b) (4)

DJA x00974

Acceleration = 0.05 - Velocity (mm/s)

(b) (4)

DJA x00975

Acceleration = 0.05 - Acceleration (mm/s^2)

(b) (4)

DJA x00976

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)	DCO # 2158

(b) (4)

[redacted]

DJA x00977

Results (Attach additional sheets if necessary):

(b) (4)

[redacted]

DJA x00978

	TECHNICAL STUDY (TS)	Study Control Number (b) (4) DCO # 2158

(b) (4)

DJA x00979

Results (Attach additional sheets if necessary):

(b) (4)

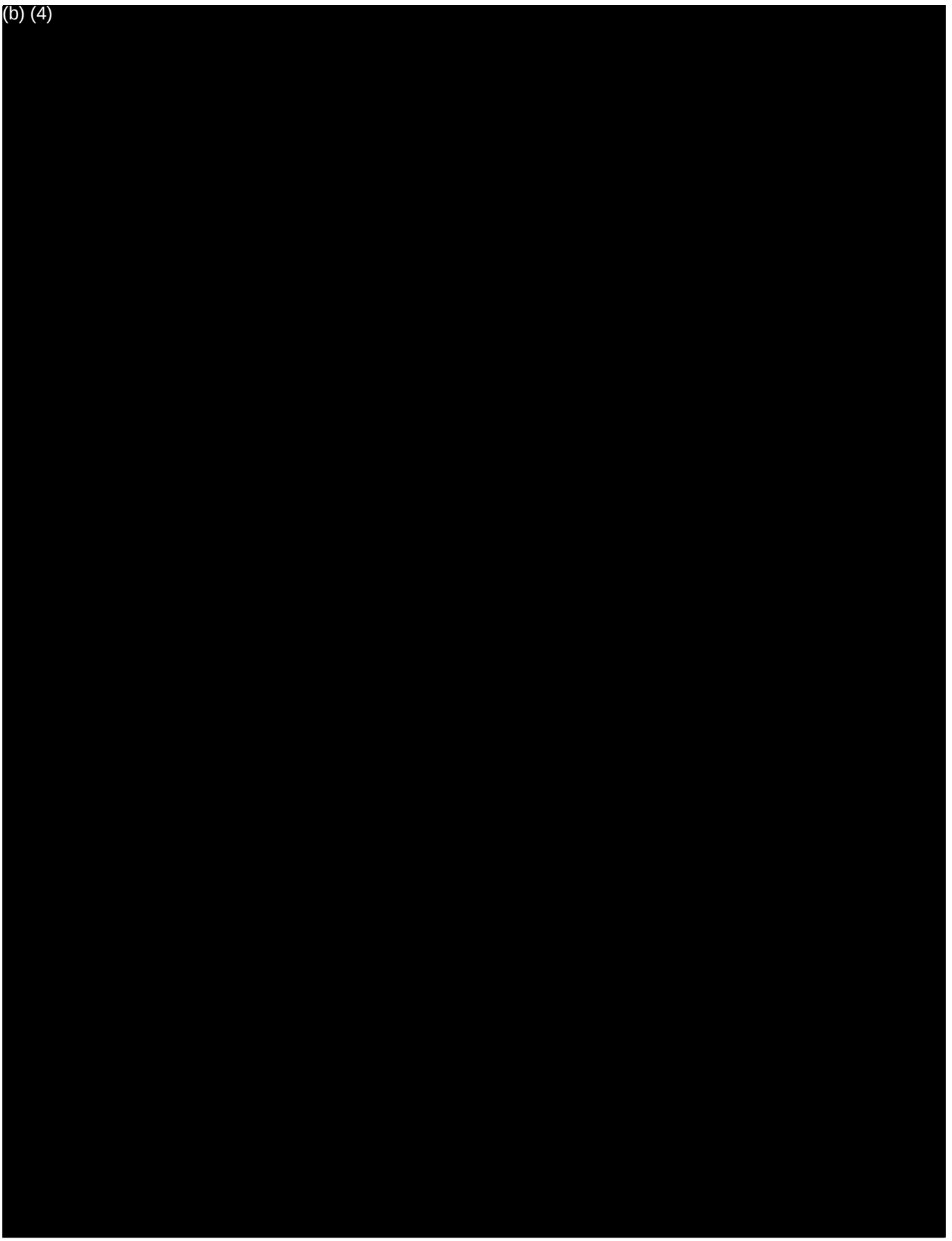
[redacted]

DJA x009B0

(b) (4)

DJA x00981

(b) (4)



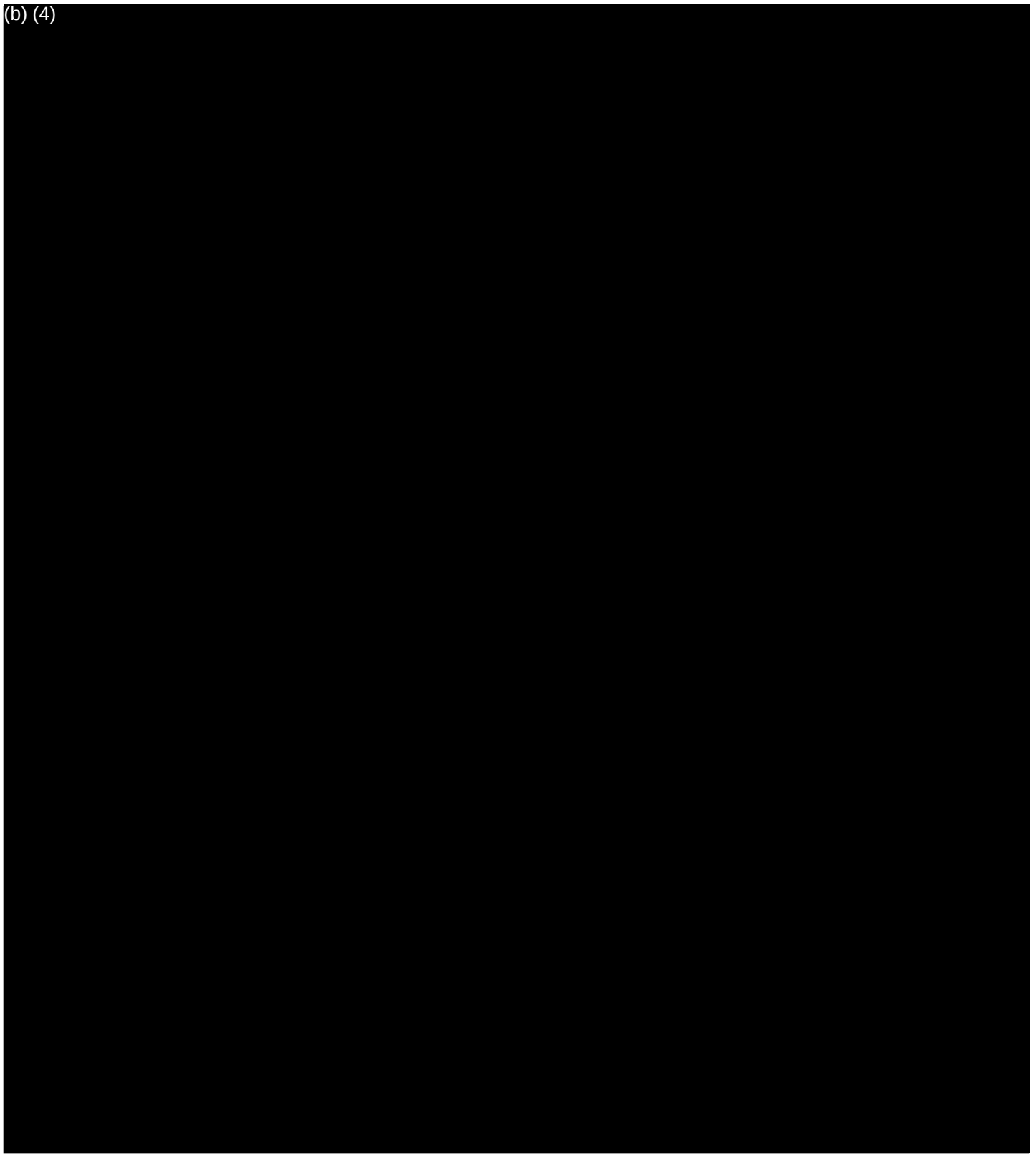
DJA x00982

Attachment to (b) (4)

(b) (4)

DJA x00983

(b) (4)



DJA x00984

(b) (4)

DJA x00985

(b) (4)

DJA x00986

(b) (4)

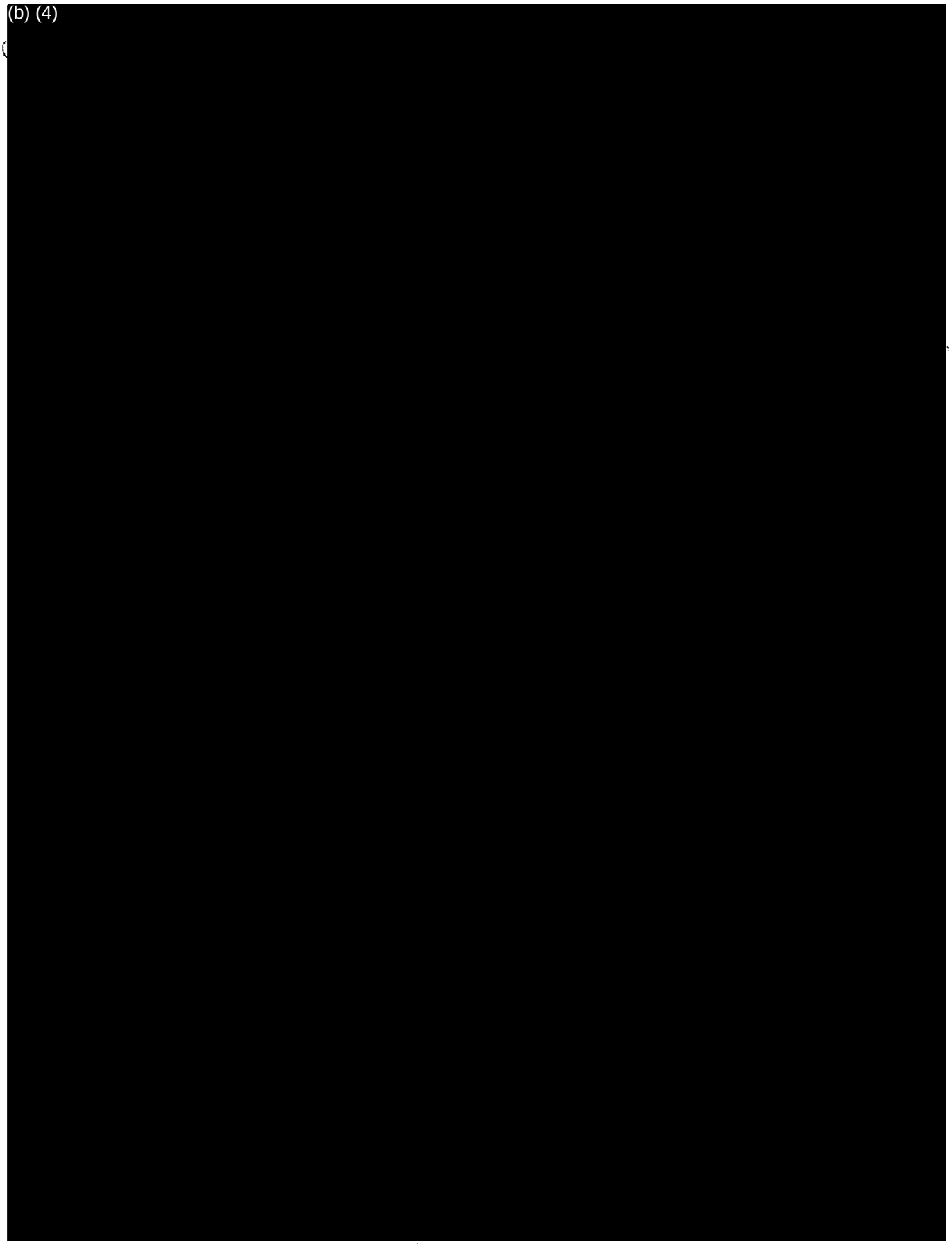
[redacted]

DJA x00987

(b) (4)

DJA x00988

(b) (4)



DJA x00989

(b) (4)

DJA x00990

ROBODOC
INTEGRATED SURGICAL SYSTEMS

PROTOCOL APPROVAL SHEET

DCO # 2221

(b) (4)

[redacted]

REFERENCE COPY

DJA x00991

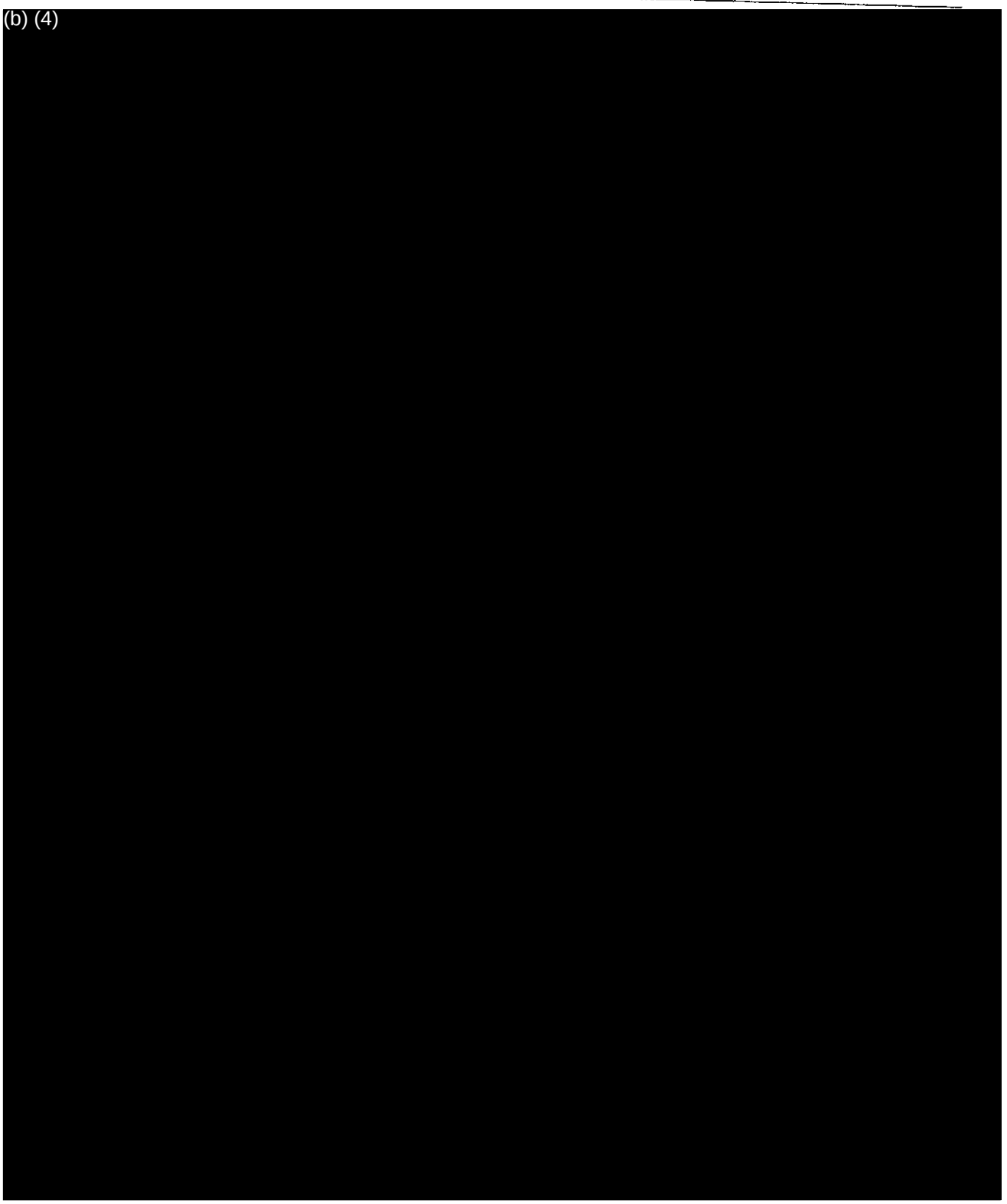
PINLESS THR FULL PROCEDURAL TEST (BMM/DIGITIZER)

(b) (4)

DJA x00992

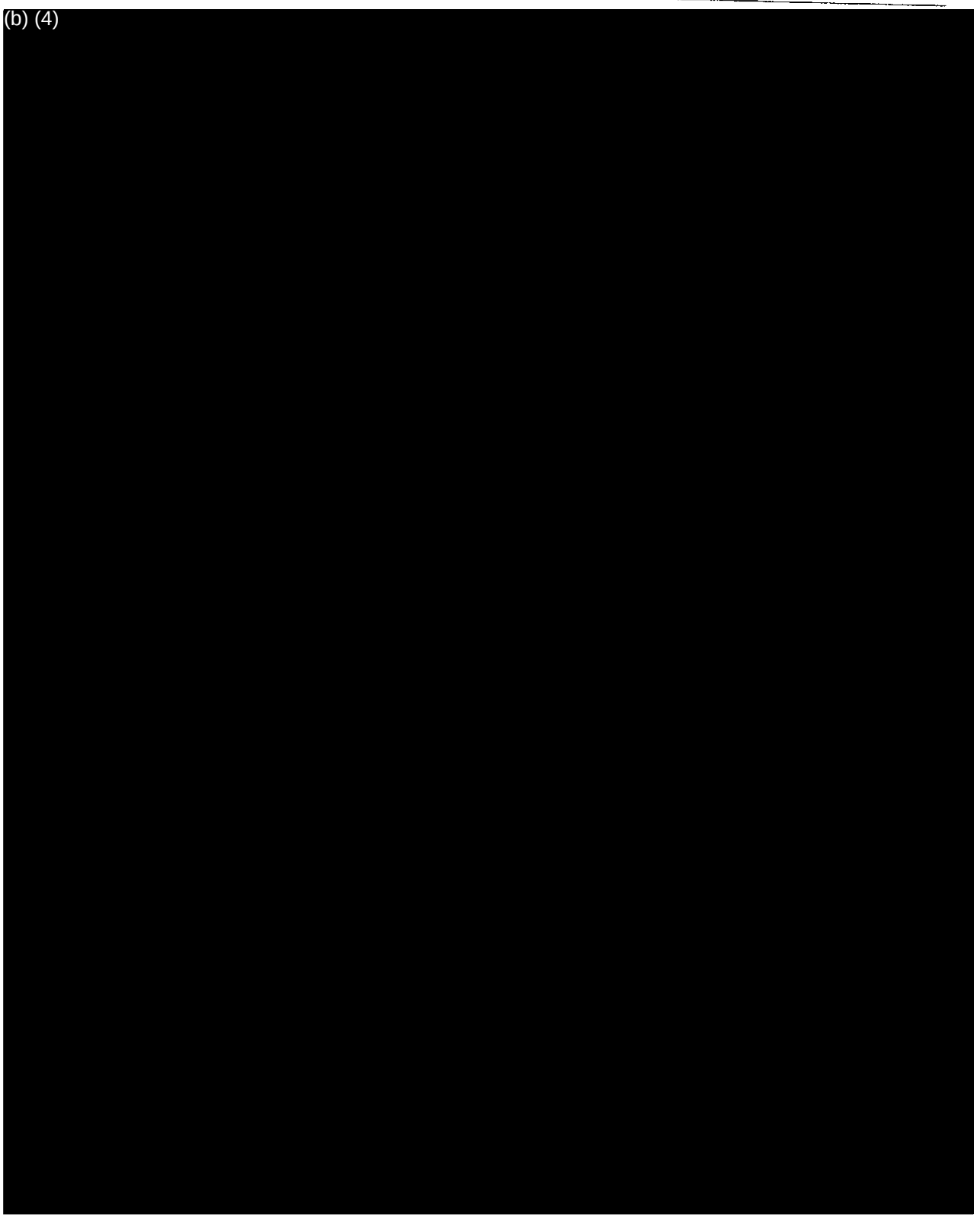
PINLESS THR PROCEDURAL TEST (BMM/DIGITIZER)

(b) (4)



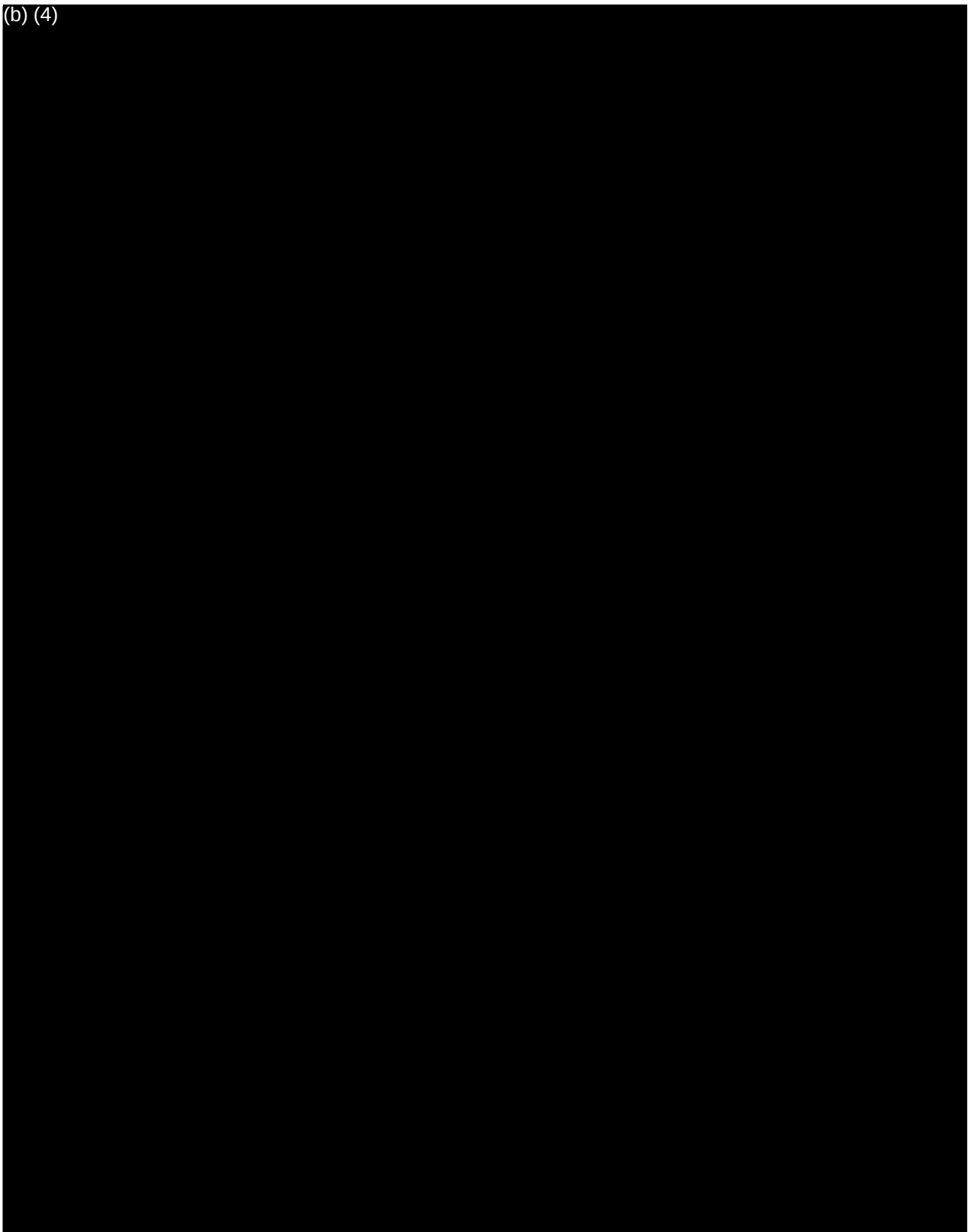
DJA x00993

(b) (4)



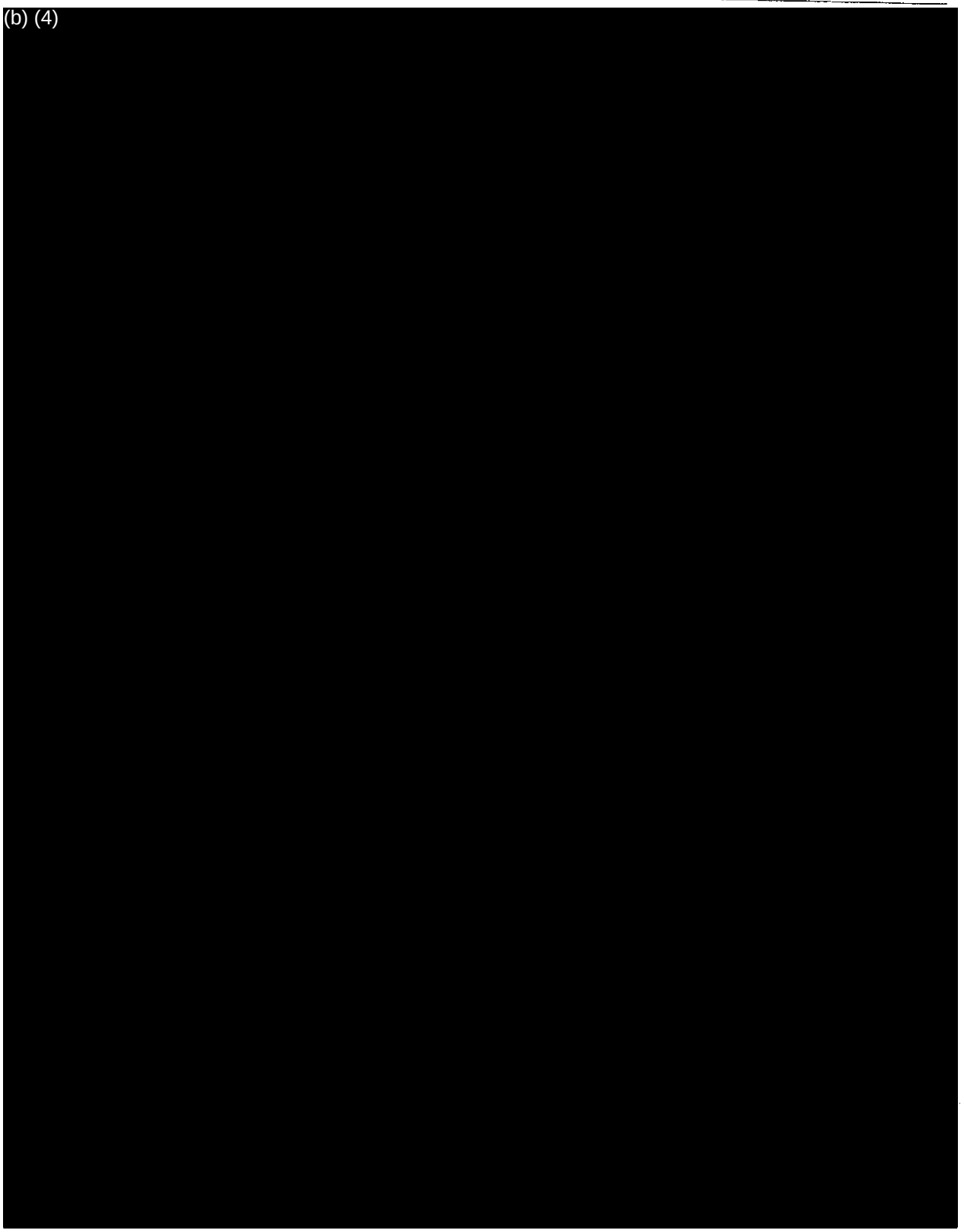
DJA x00994

(b) (4)



DJA x00995

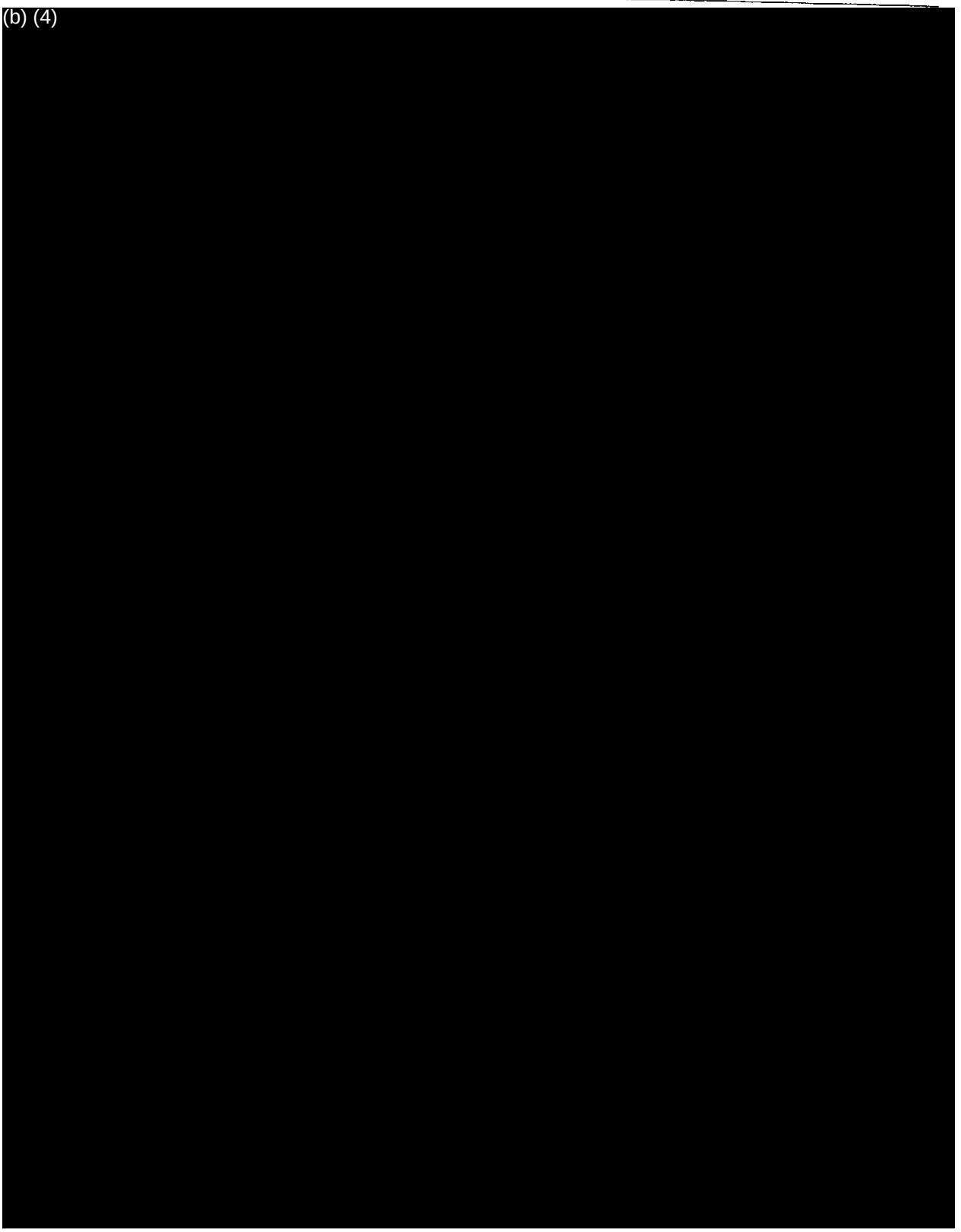
(b) (4)



DJA x00996

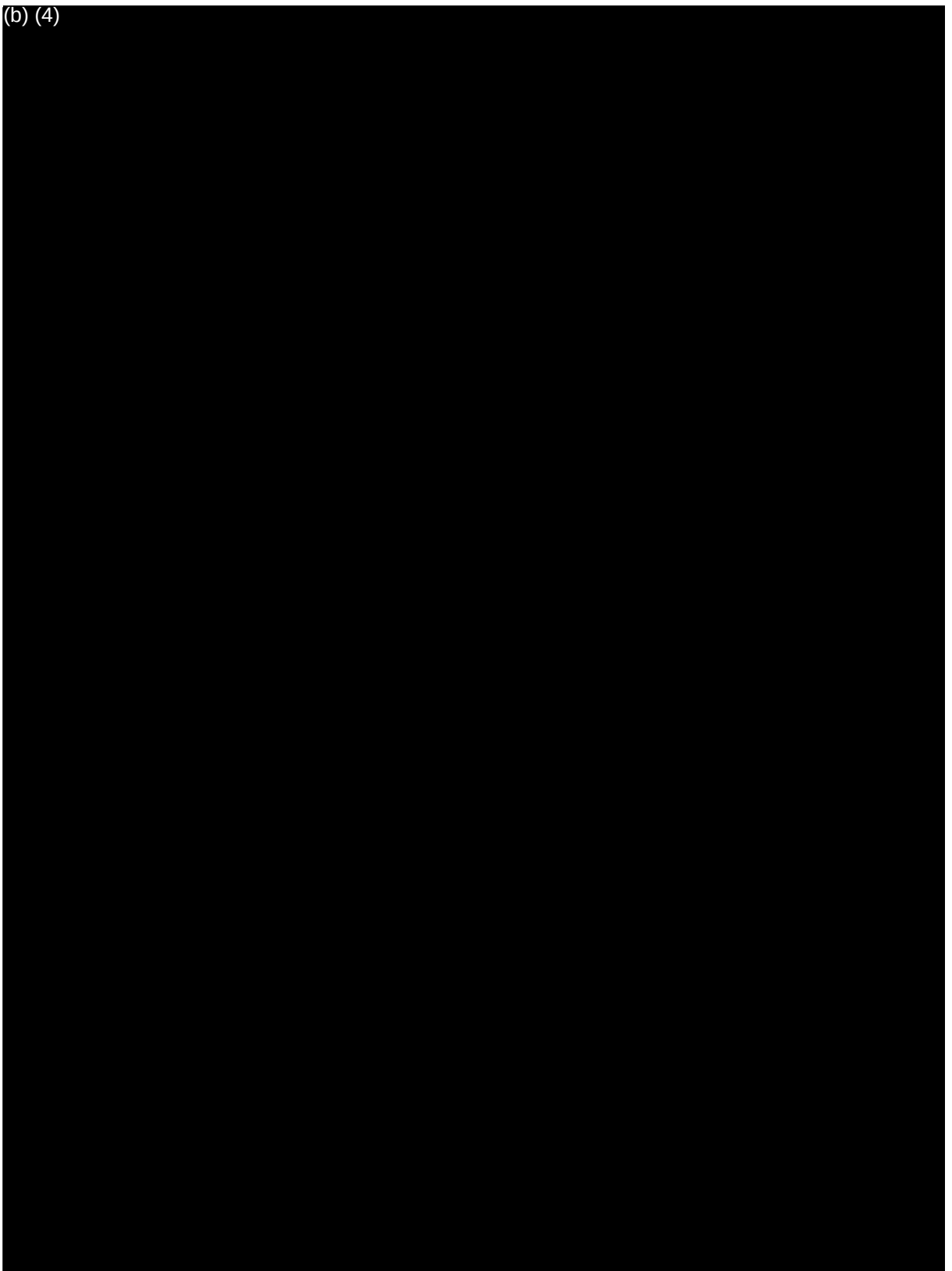
PINLESS THR PROCEDURAL TEST (BMM/DIGITIZER)

(b) (4)



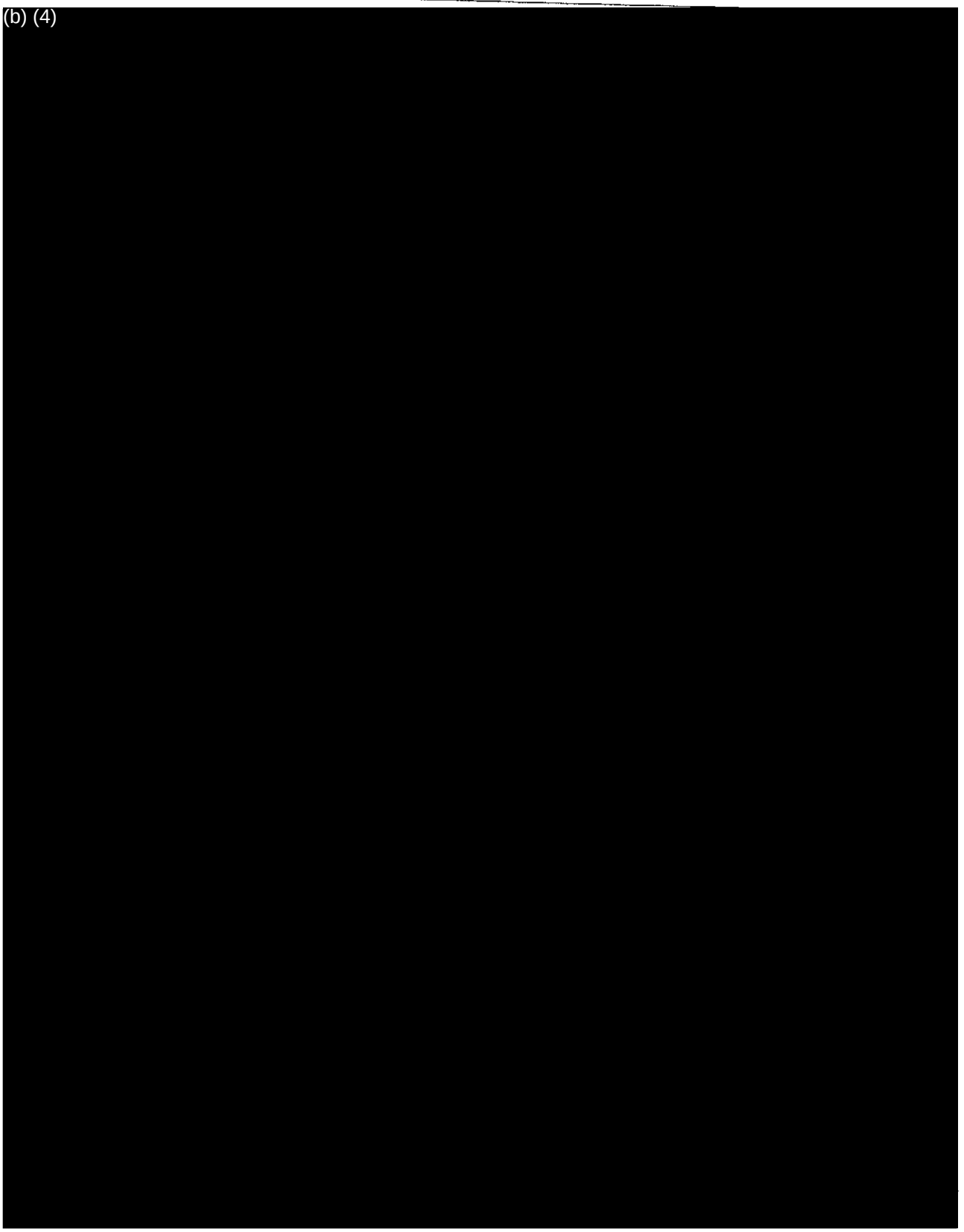
DJA x00997

(b) (4)



DJA x00998

(b) (4)



DJA x00999

(b) (4)

8

DJA x01000

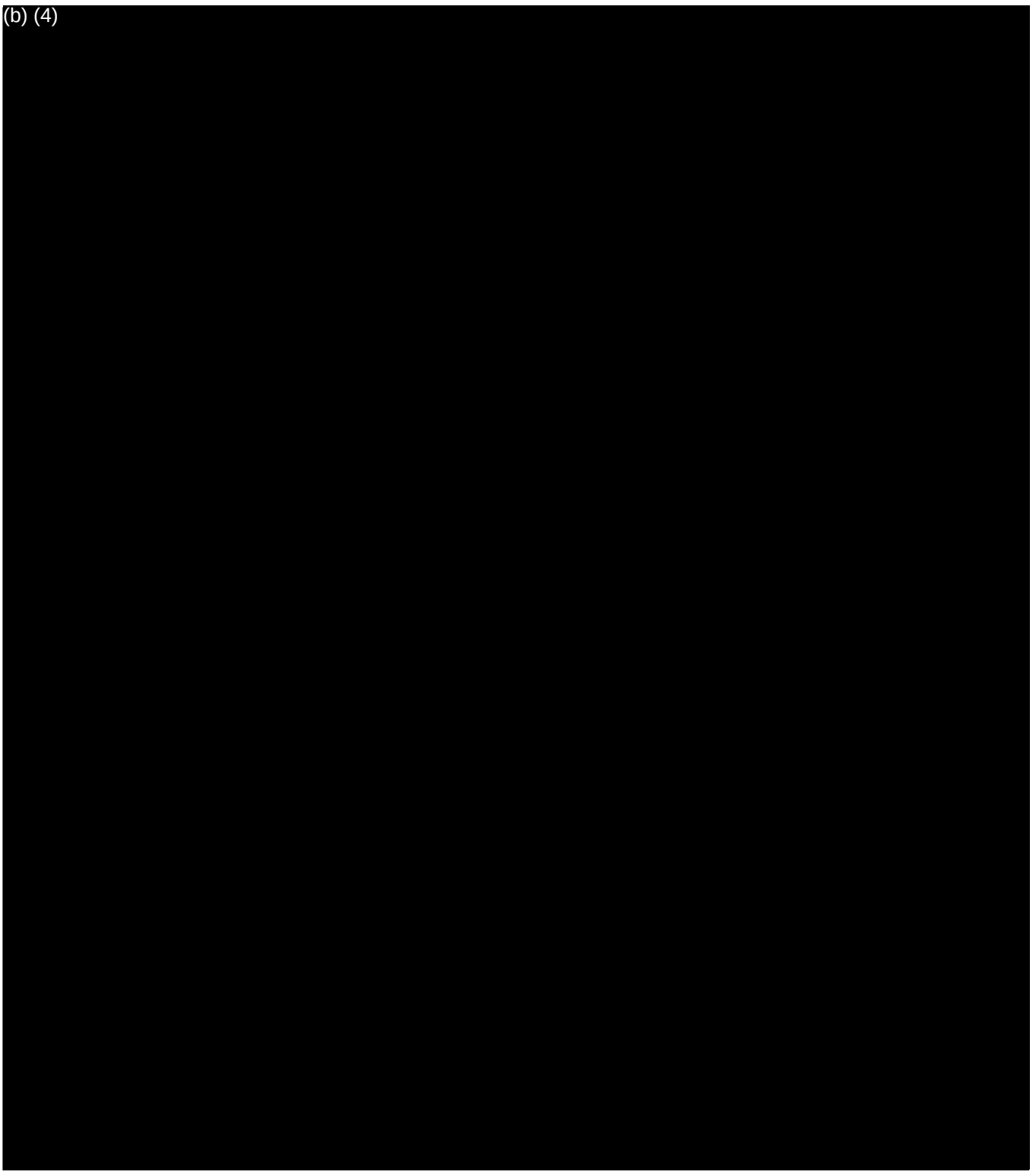
PINLESS THR PROCEDURAL TEST (BMM/DIGITIZER)

(b) (4)

DJA x01001

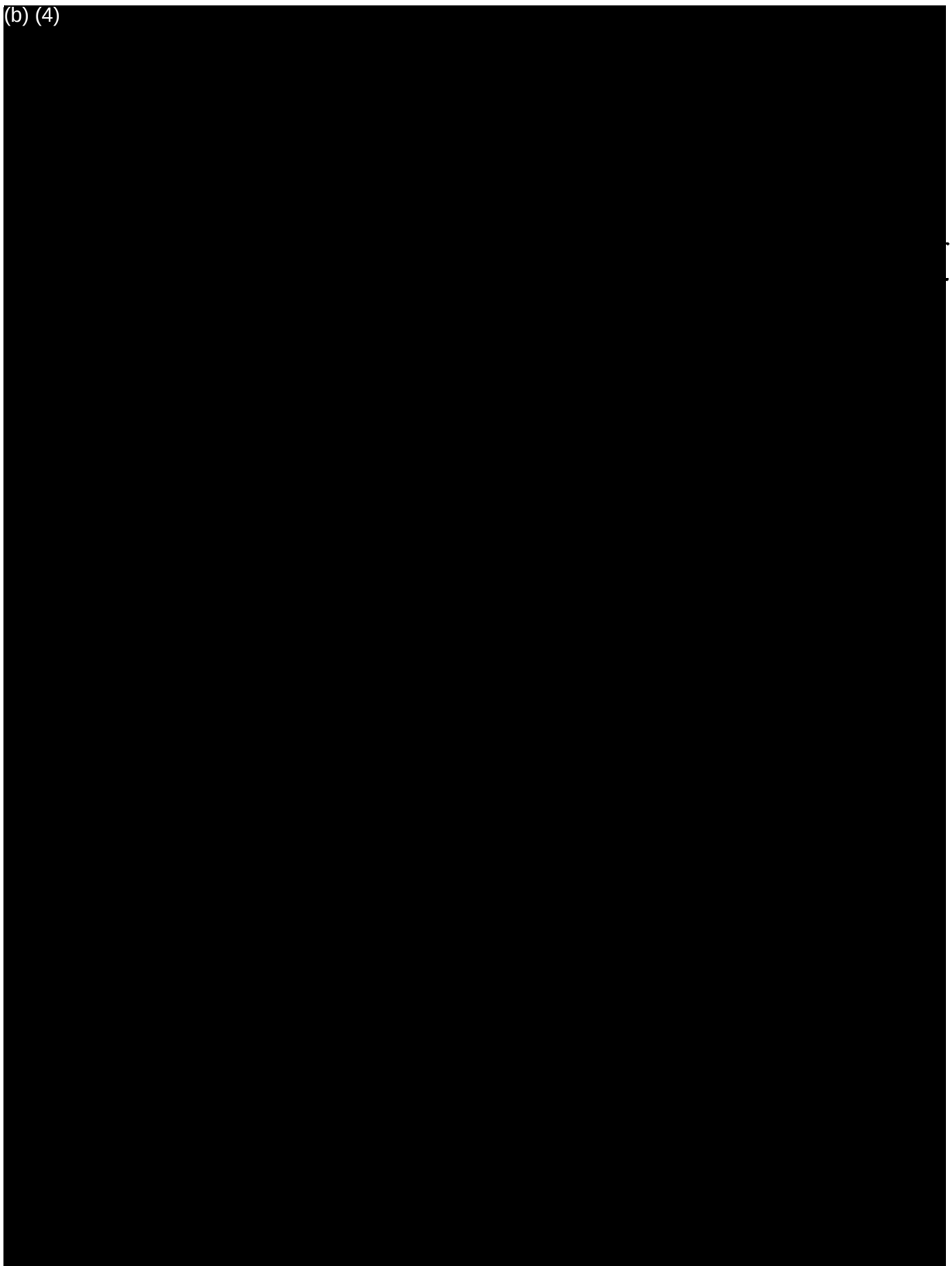
11.0 Attachments

(b) (4)



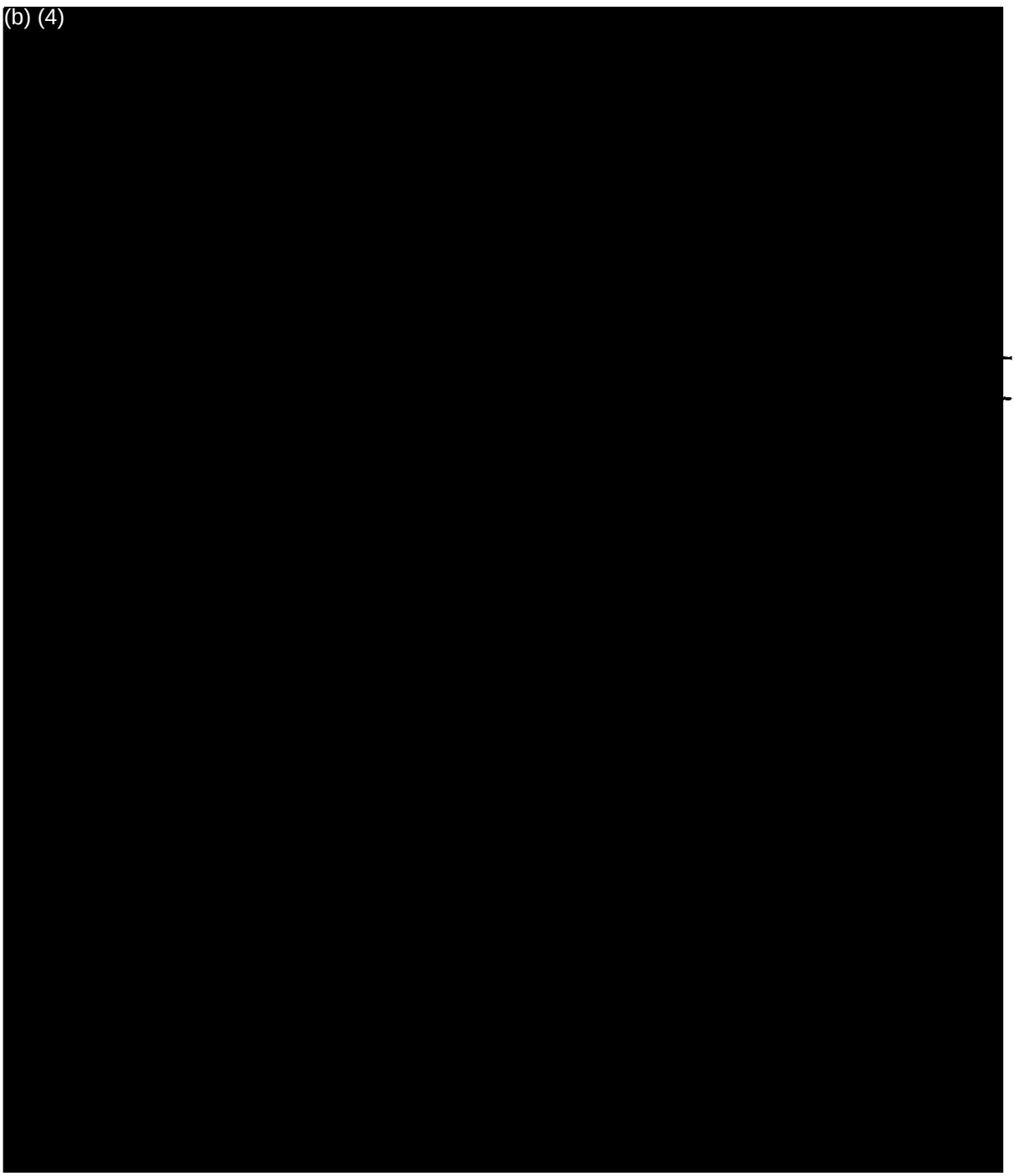
DJA x01002

(b) (4)



DJA x01003

(b) (4)



DJA x01004

QUALITY POLICY AND PROCEDURE APPROVAL AND REVISION RECORD

Document #	Title
D-008-1-3	Validation Protocol (PV) Format

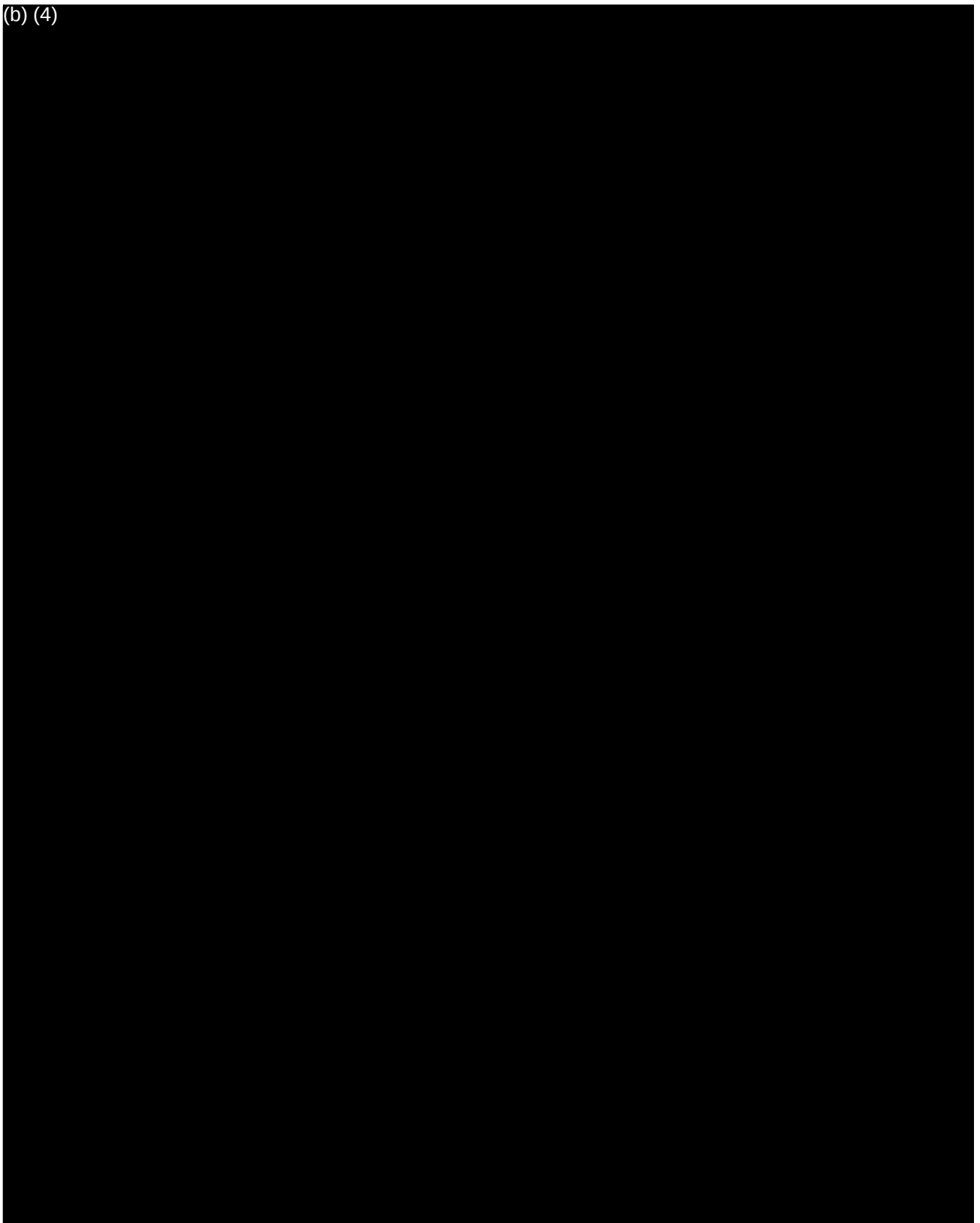
REVISION RECORD

(b) (4)

[redacted]

DJA x01005

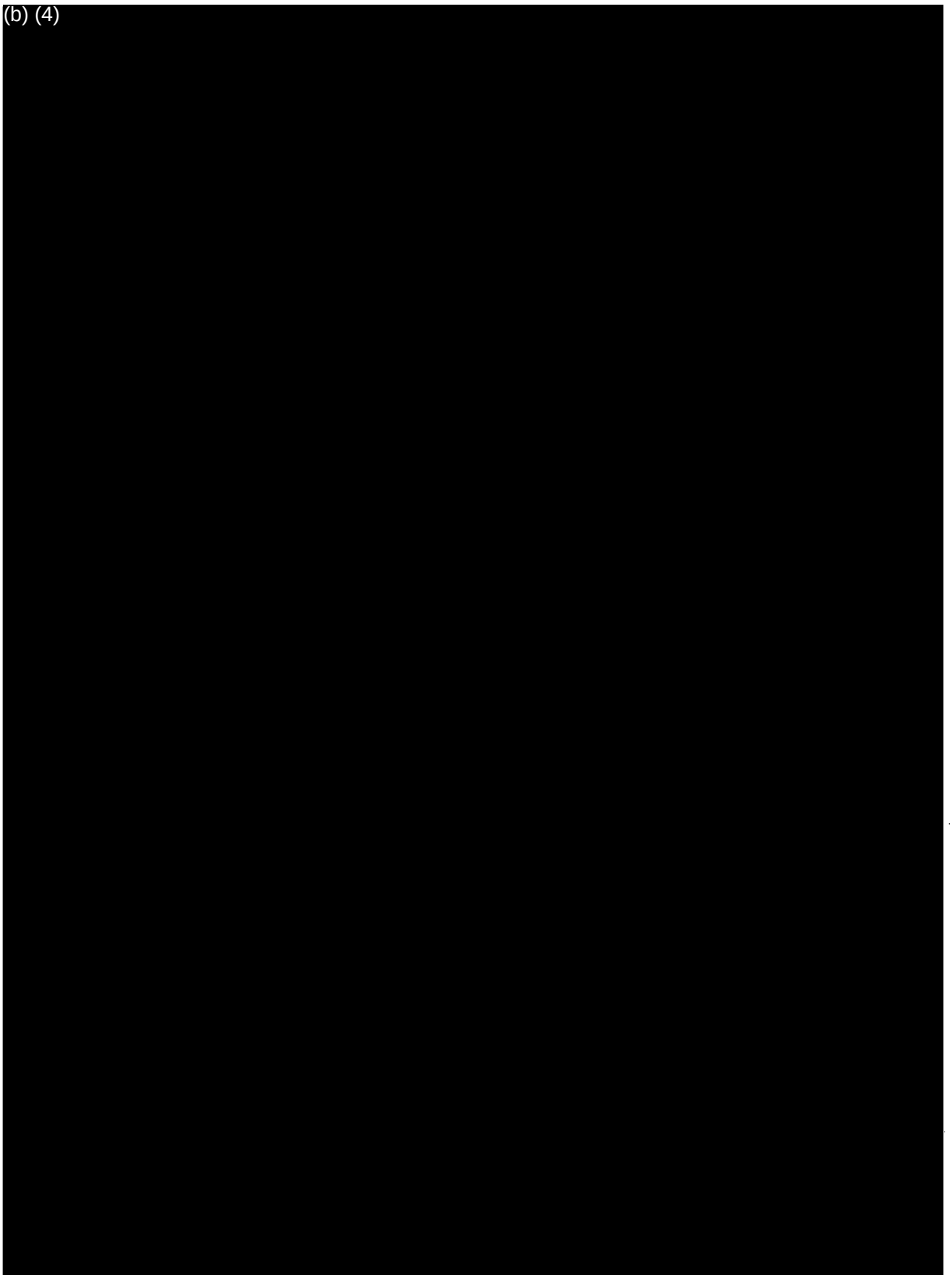
(b) (4)



DJA x01006

PINLESS THR PROCEDURAL TEST (BMM/DIGITIZER)

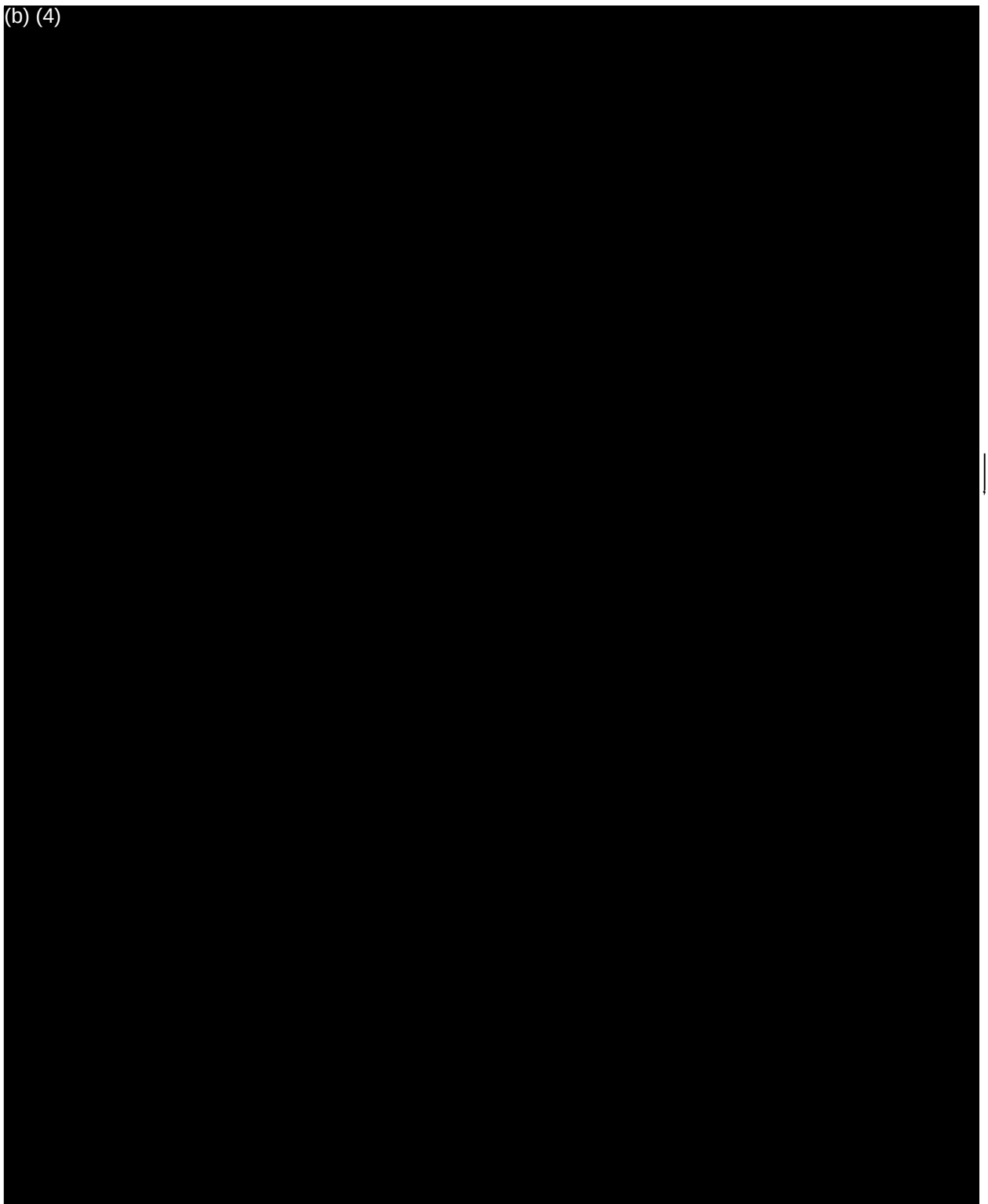
(b) (4)



DJA x01007

11.0 Attachments

(b) (4)



DJA x01008

TEST REPORT APPROVAL SHEET

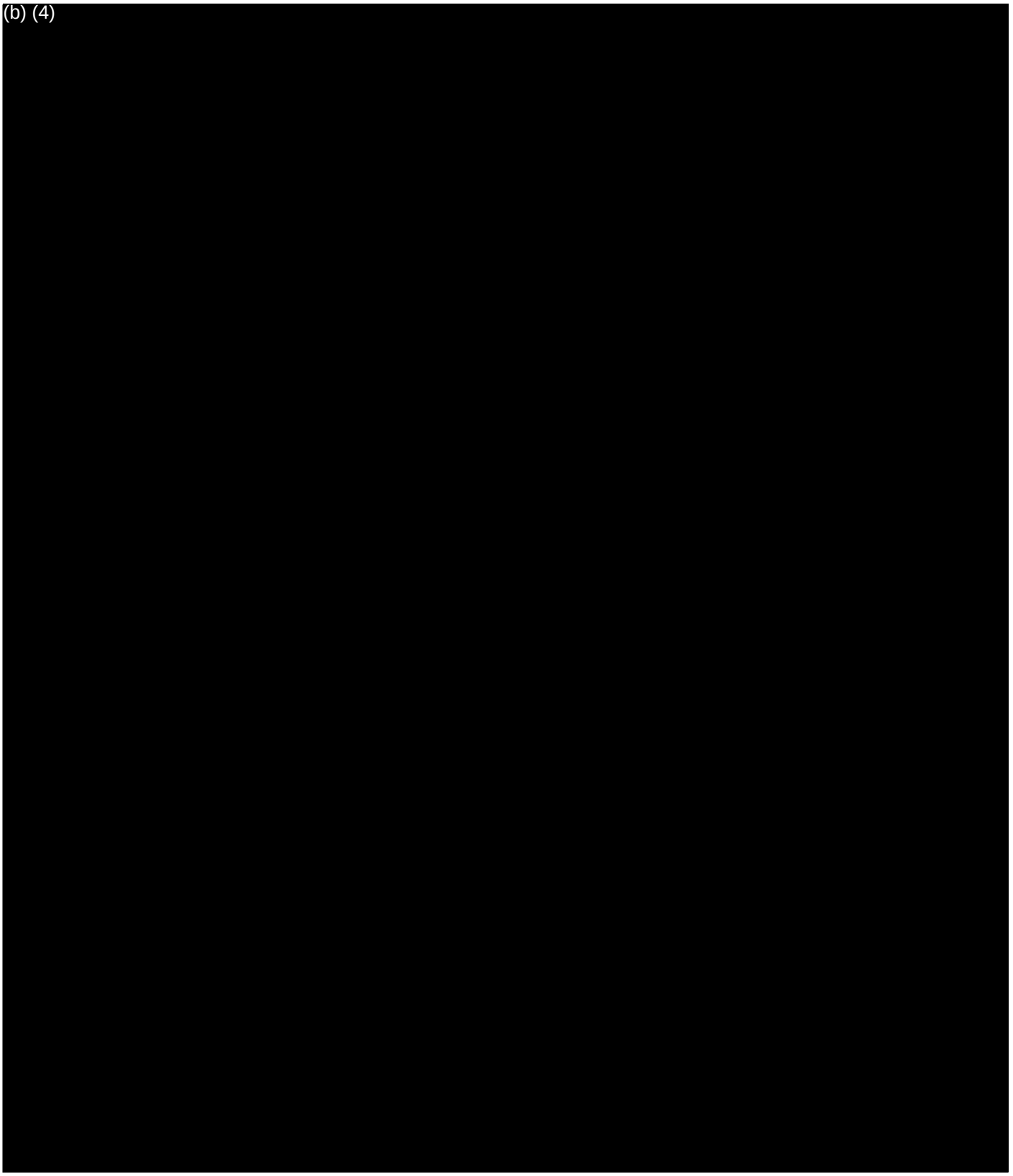
DOCUMENT NUMBER: (b) (4)

(b) (4)

[redacted]

DJA x01009

(b) (4)



DJA x01010

(b) (4)

DJA x01011

QUALITY POLICY AND PROCEDURE APPROVAL AND REVISION RECORD

Document #	Title
D-008-1-4	Test Report (TR) Format

REVISION RECORD

(b) (4)

[redacted]

DJA x01012

ORTHODOC PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 2
KEY WORDS: Protocol ORTHODOC Model 500 Preoperative Planning Station Module Unit Testing	PROTOCOL REF. NO. (If applicable)	PROJECT NO.: (If applicable) 42

(b) (4)

[redacted]

DJA x01013

(b) (4)

[redacted]

DJA x01014

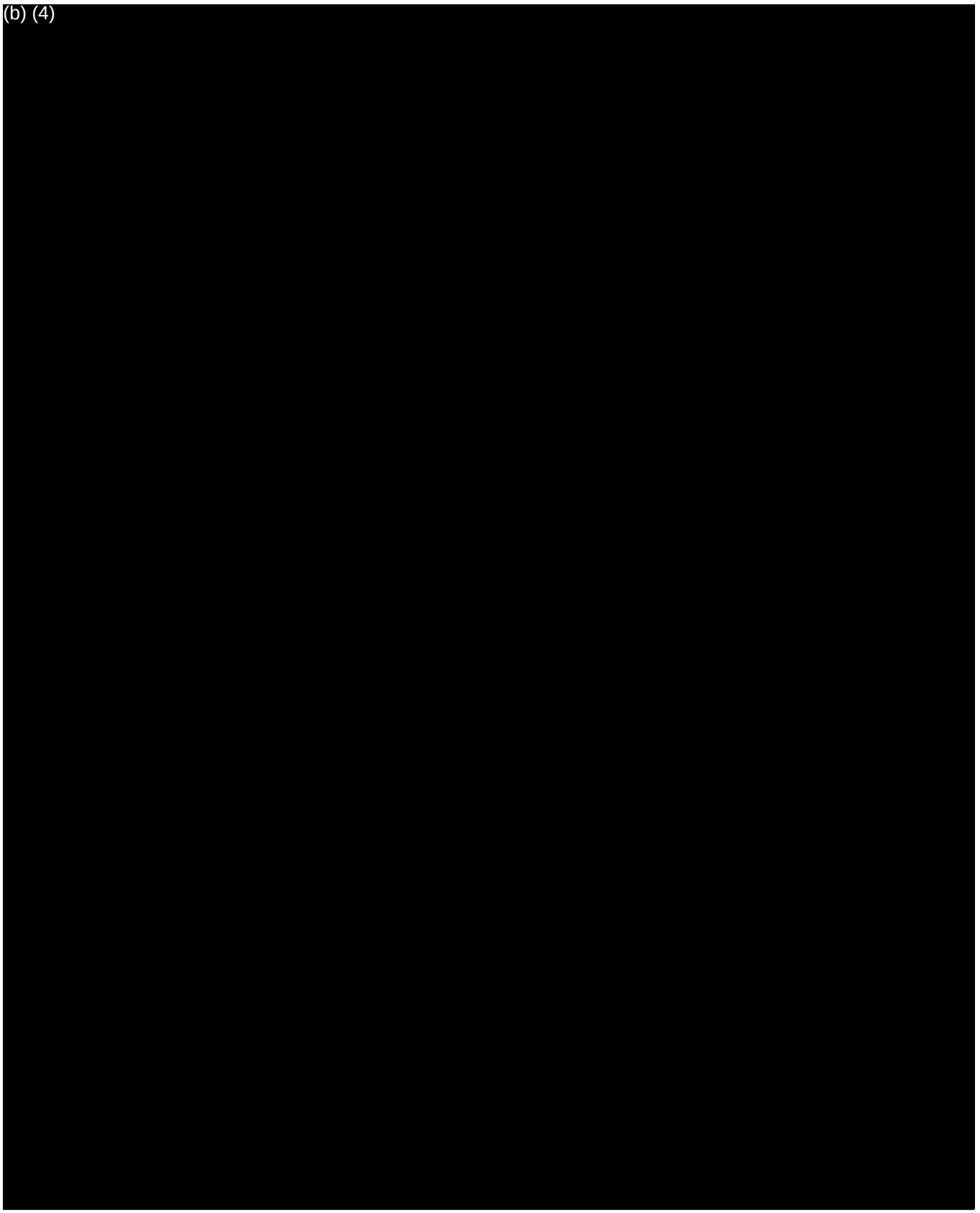
ORTHODOC PROTOCOL and TEST REPORT APPROVAL SHEET

DOCUMENT NUMBER: (b) (4)		PAGE 1 OF 6
KEY WORDS: ORTHODOC Model 500 Preoperative Planning Station Module UnitTest Report	PROTOCOL REF. NO. (If applicable) (b) (4)	PROJECT NO.: (If applicable) 42

(b) (4)

DJA x01015

(b) (4)



DJA x01016

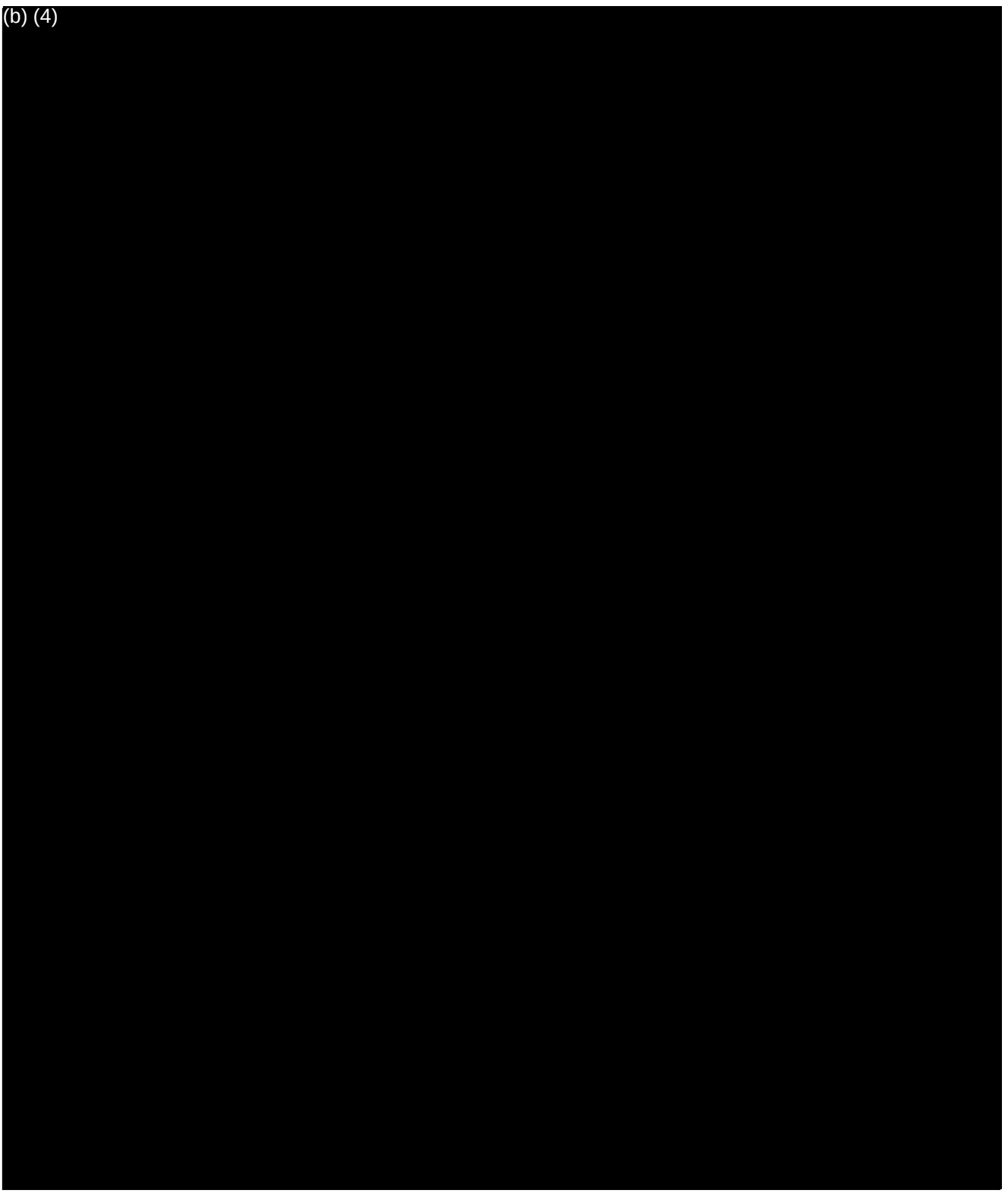
(b) (4)

5.

DJA x01017

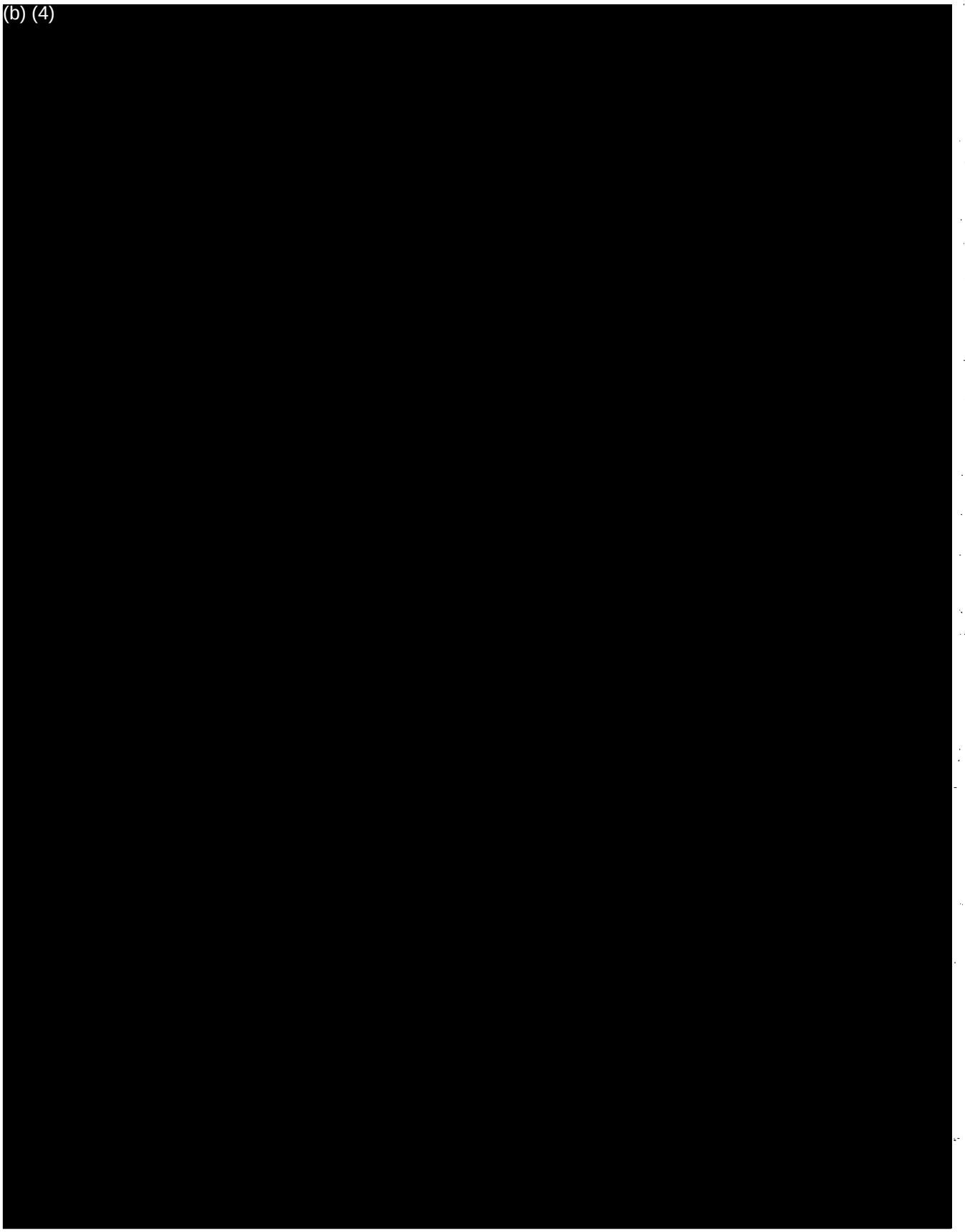
6.0 Results

(b) (4)



DJA x01018

(b) (4)



DJA x01019

(b) (4)

DJA x01020

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)
Title: ReadTape Unit Testing.		**Originator**: (b) (6)

(b) (4)

DJA x01021

Results :

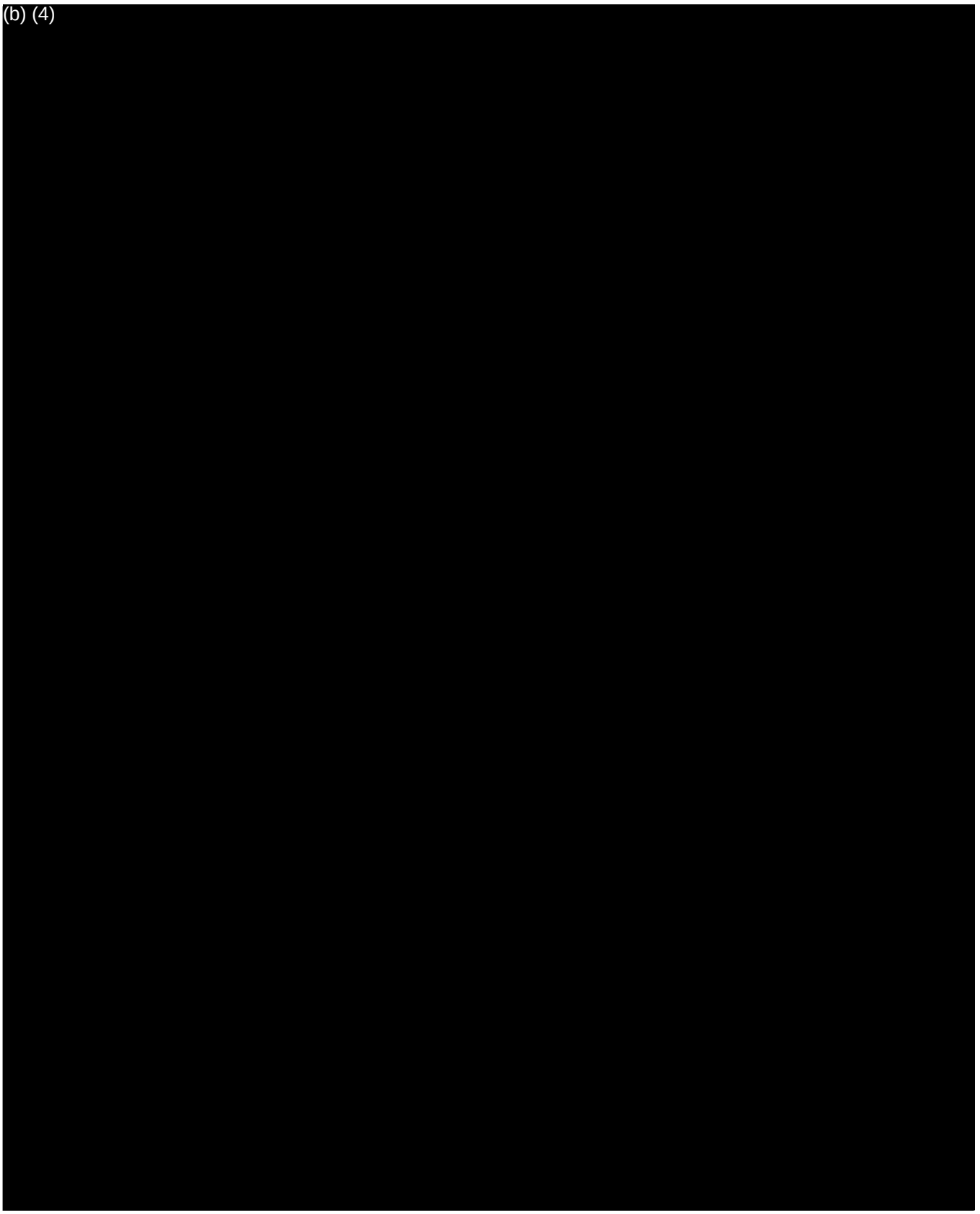
(b) (4)

[redacted]

DJA x01022

Appendix : ReadTape Unit Testing

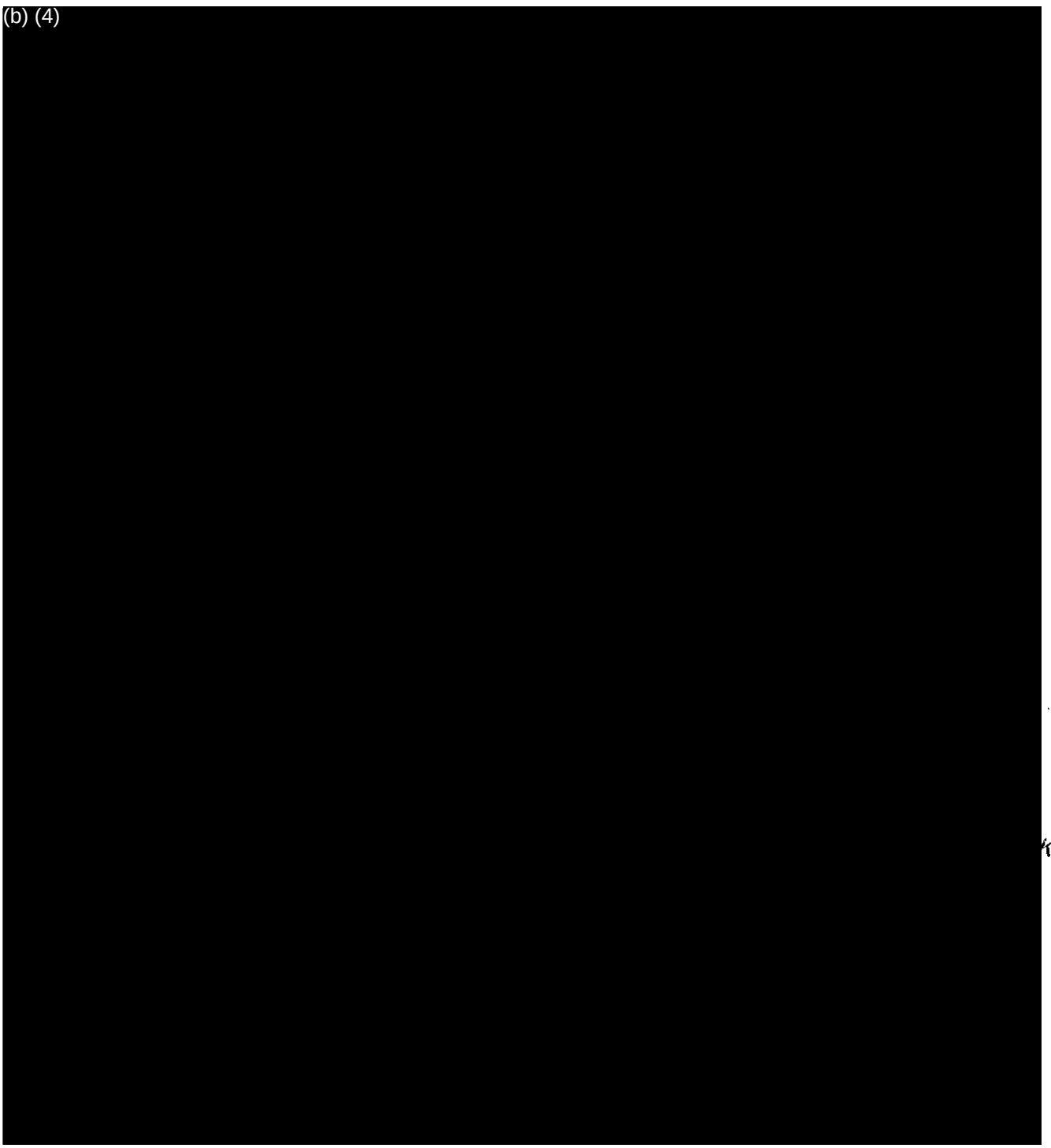
(b) (4)



DJA x01023

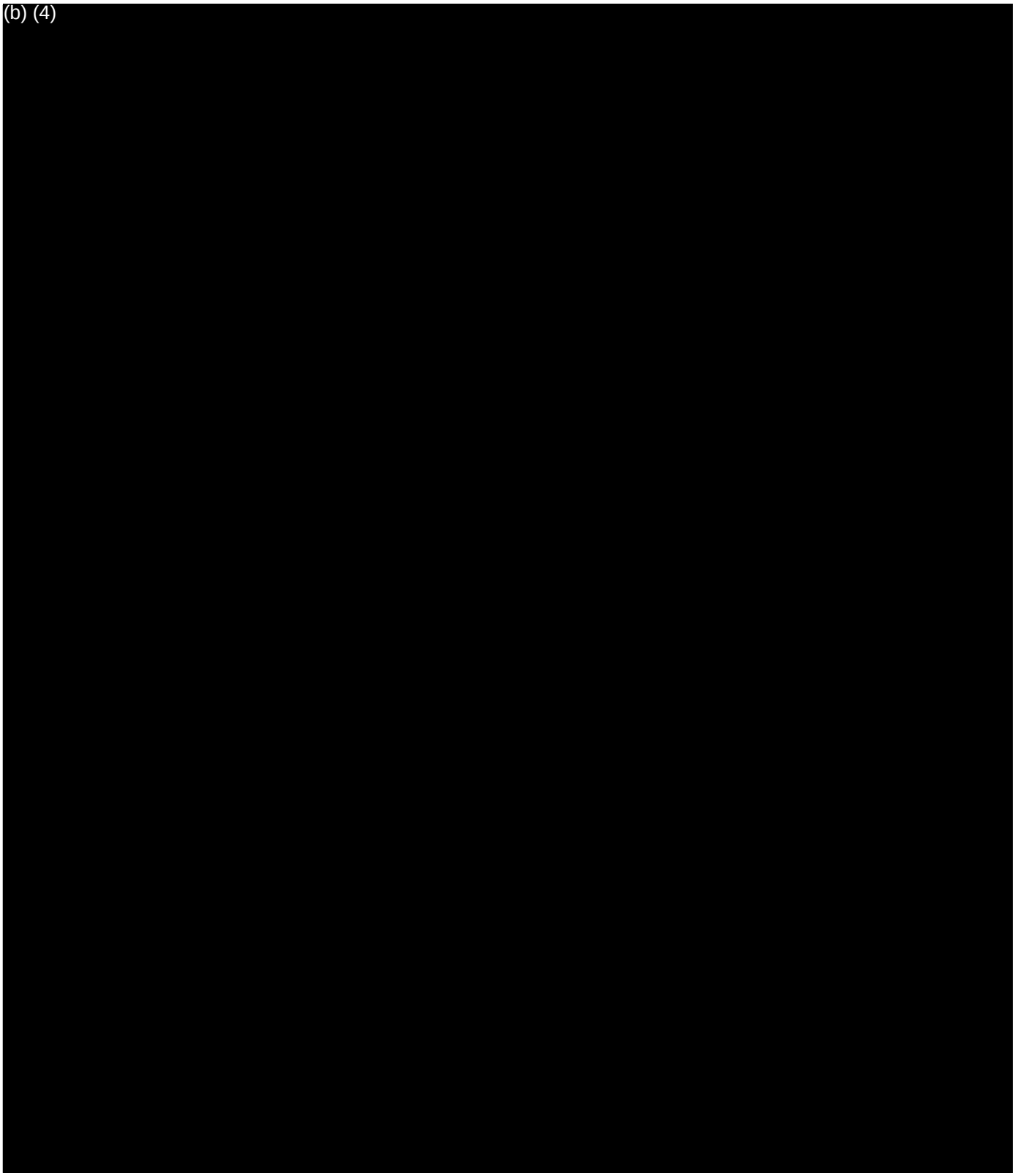
1.3 Test with Network:

(b) (4)



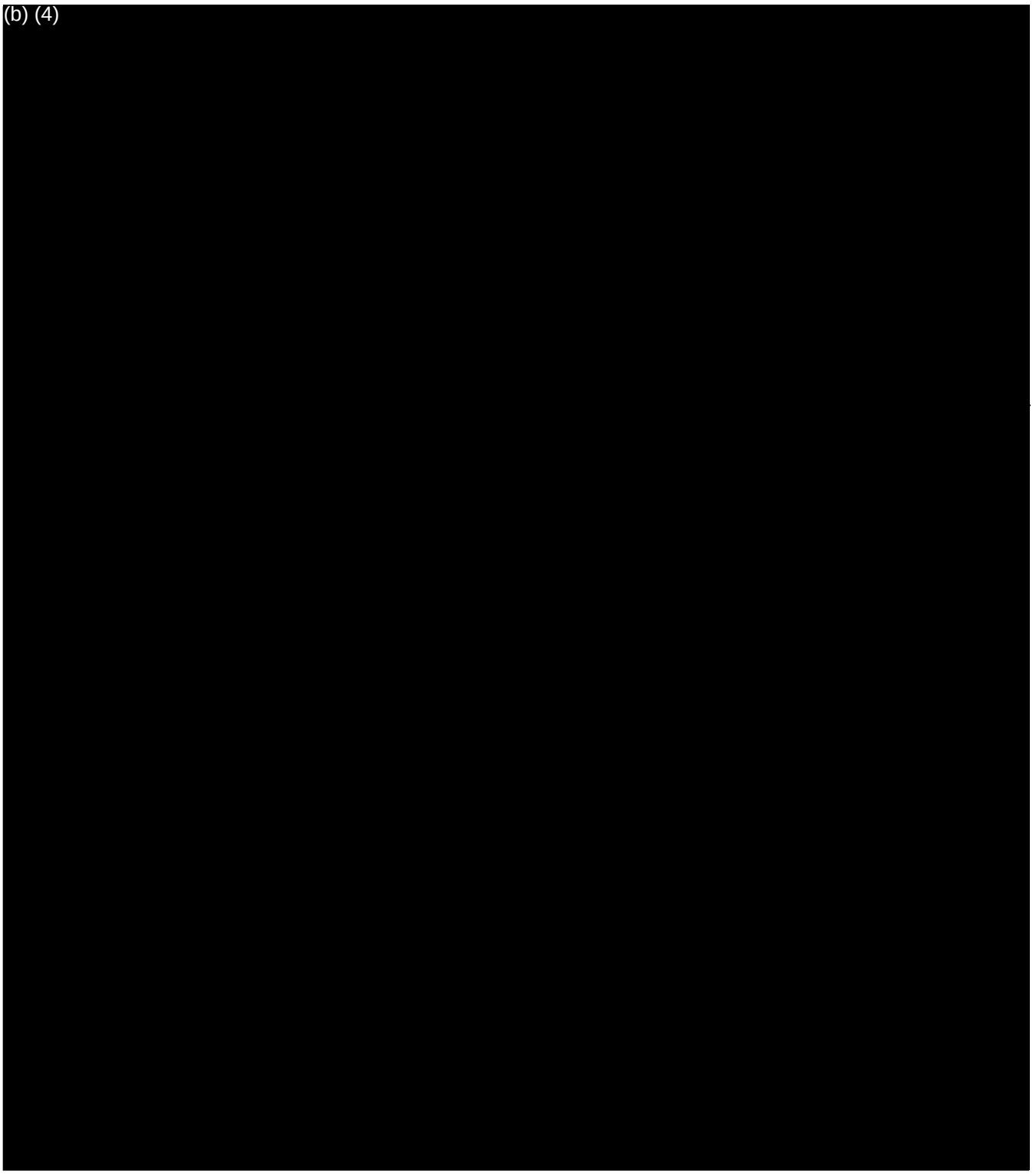
DJA x01024

(b) (4)



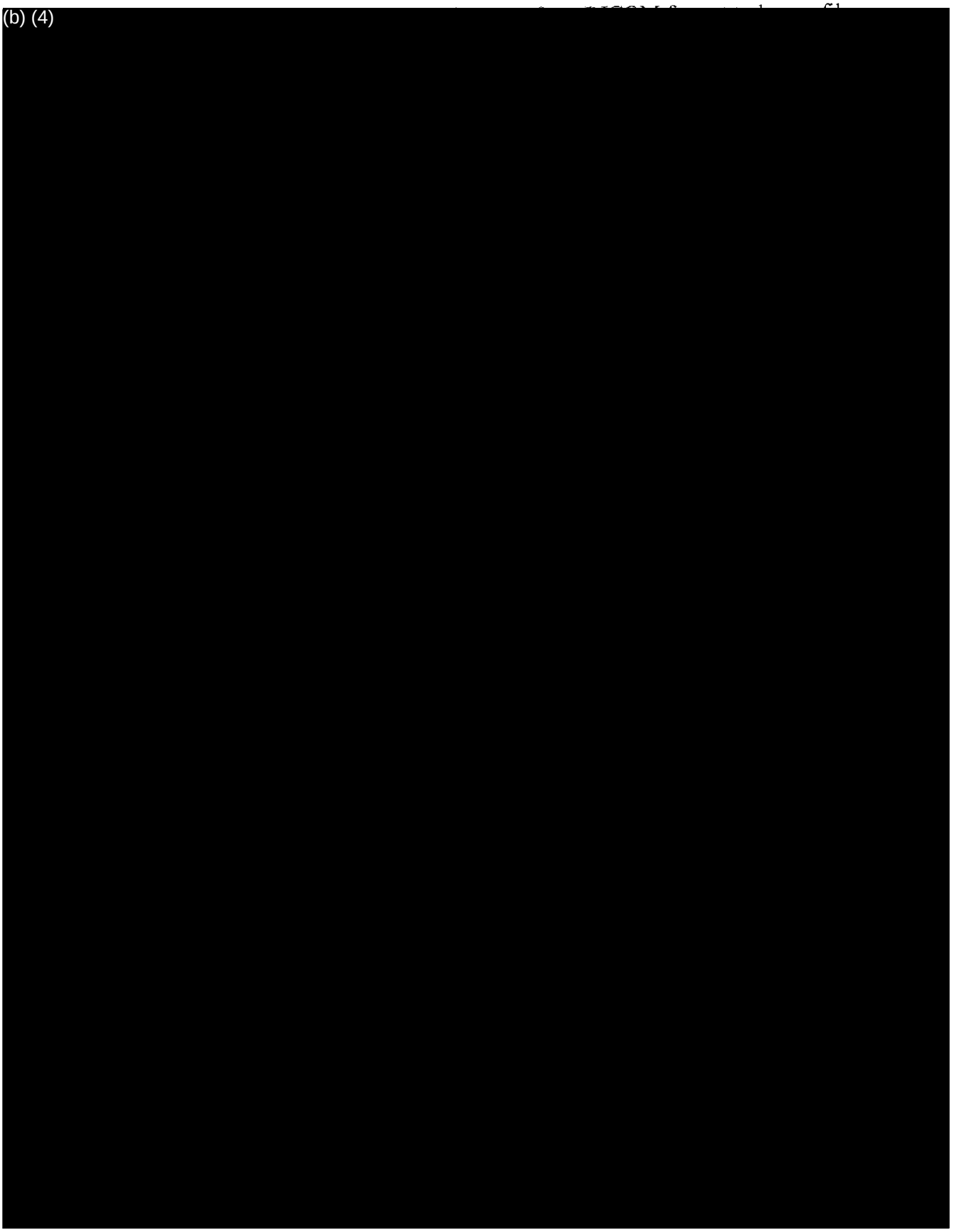
DJA x01025

(b) (4)



DJA x01026

(b) (4)



DJA x01027

3.3 Test corrupted scan data

(b) (4)

DJA x01028

	TECHNICAL STUDY (TS)	Study Control Number (b) (4)

(b) (4)

DJA x01029

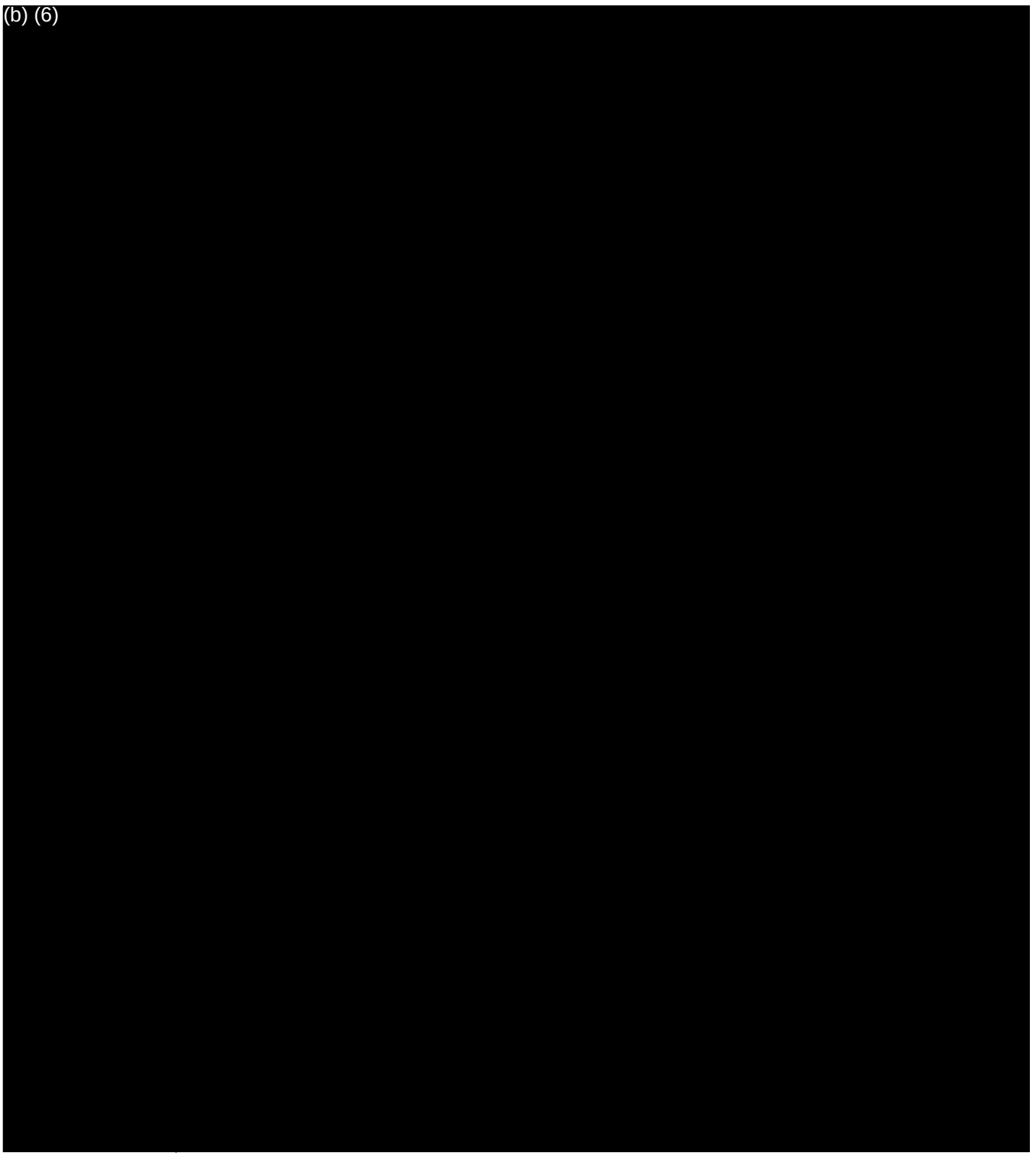
Results :

(b) (4)

DJA x01030

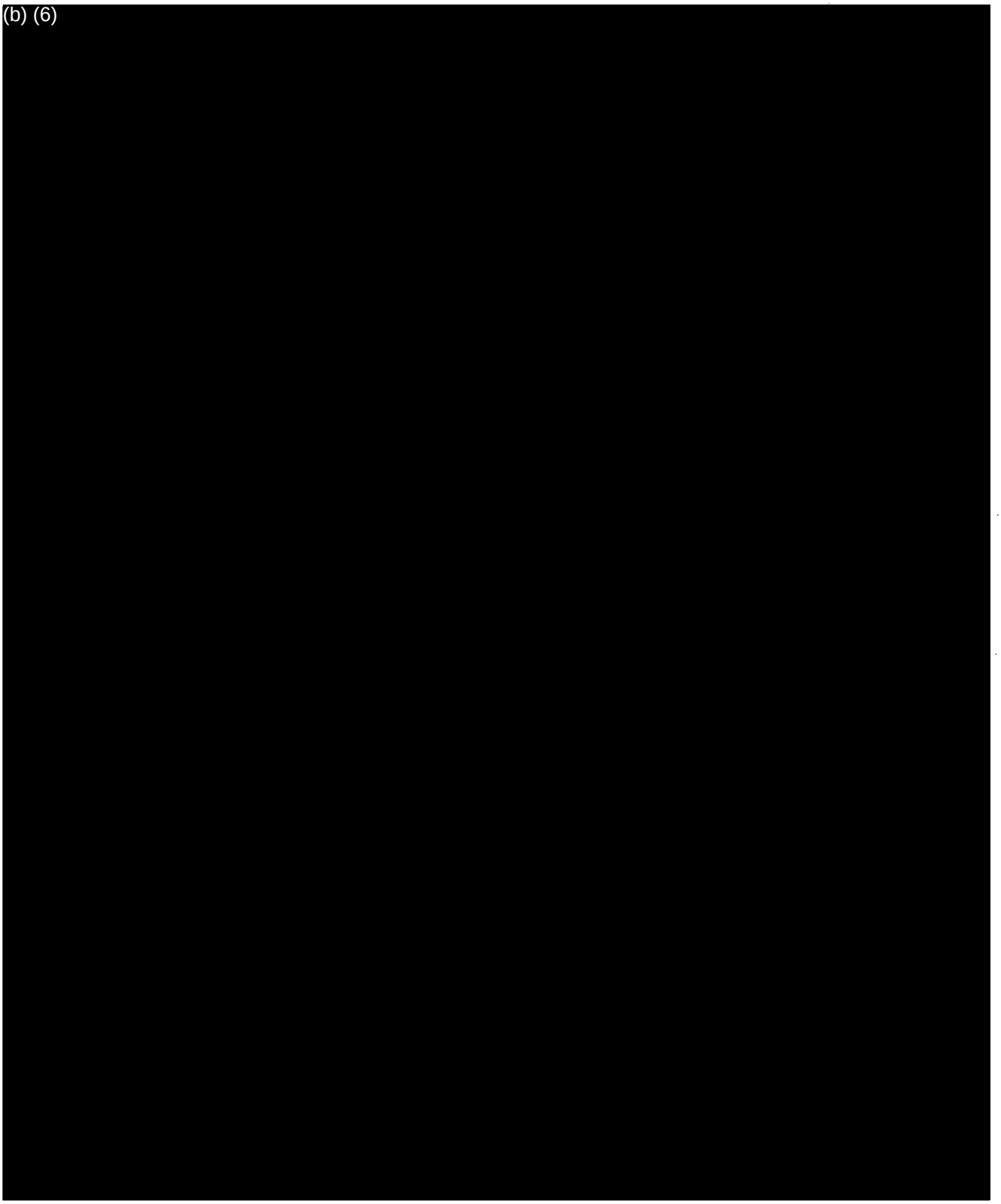
Appendix : FindRod Unit Testing

(b) (6)



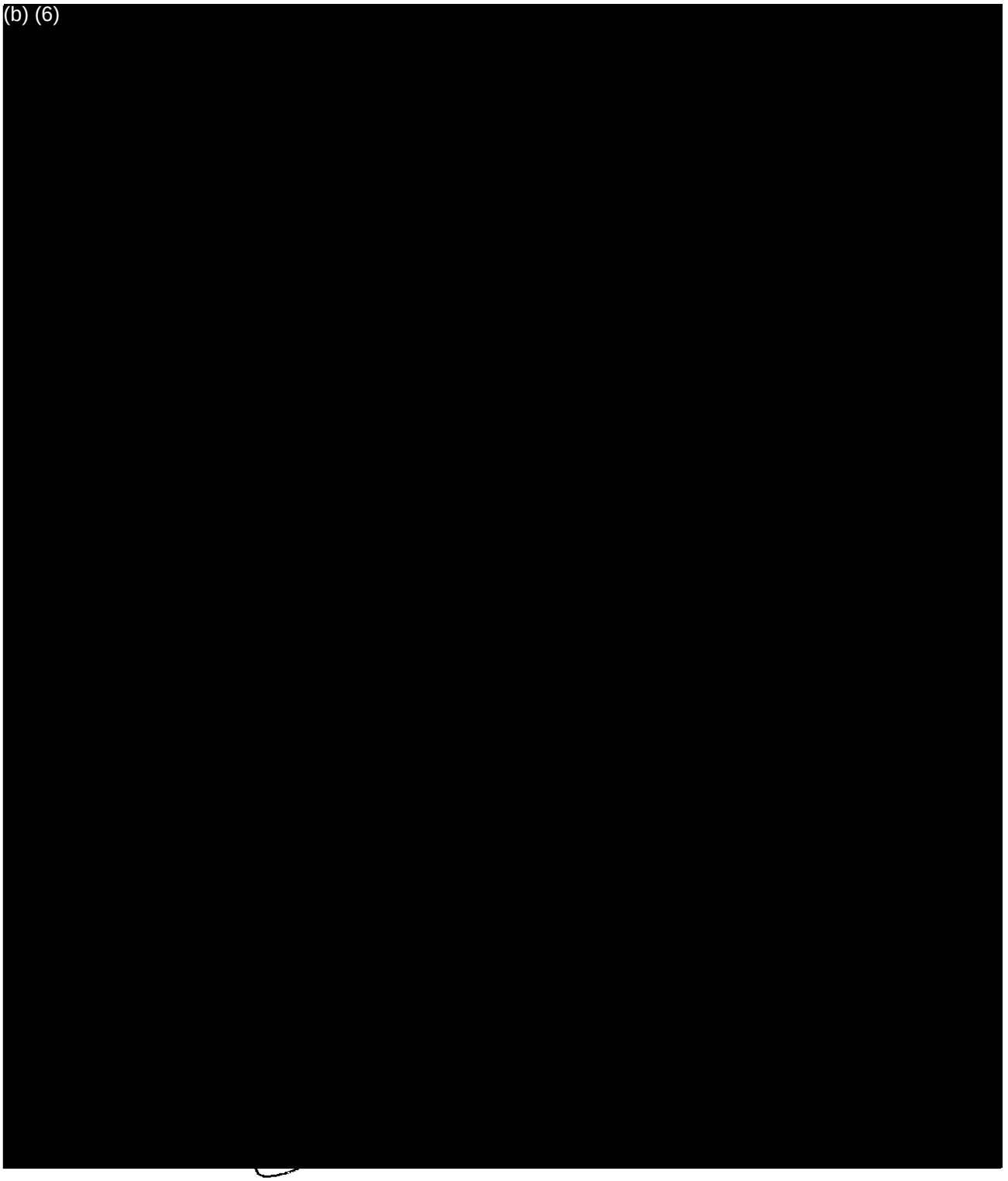
DJA x01031

(b) (6)



DJA x01032

(b) (6)



DJA x01033

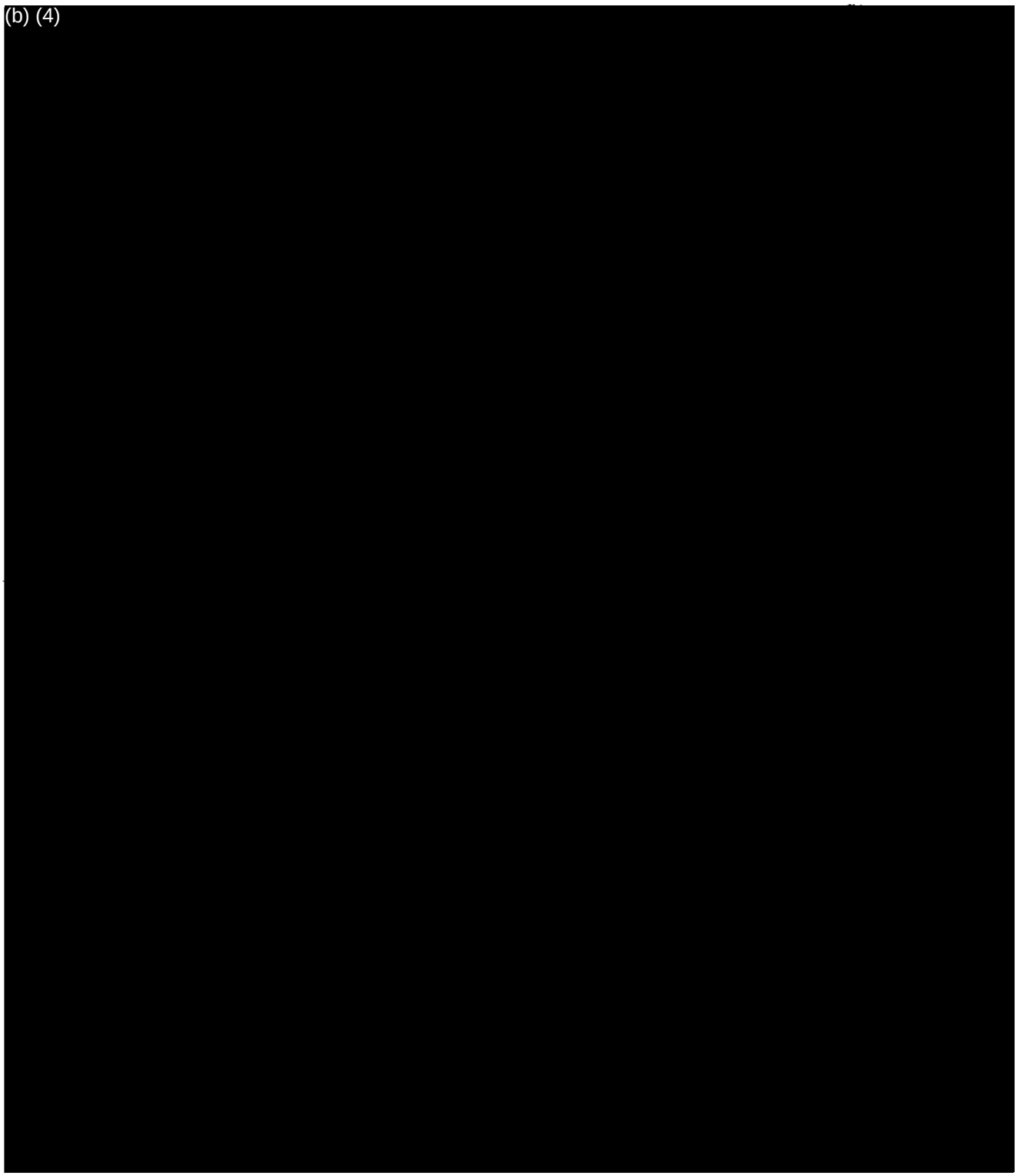
2.3 Test Patient Case with noise in the scan data:

(b) (4)

DJA x01034

(b) (4)

[redacted]



DJA x01035

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(b) (4)

DJA x01036

Results :

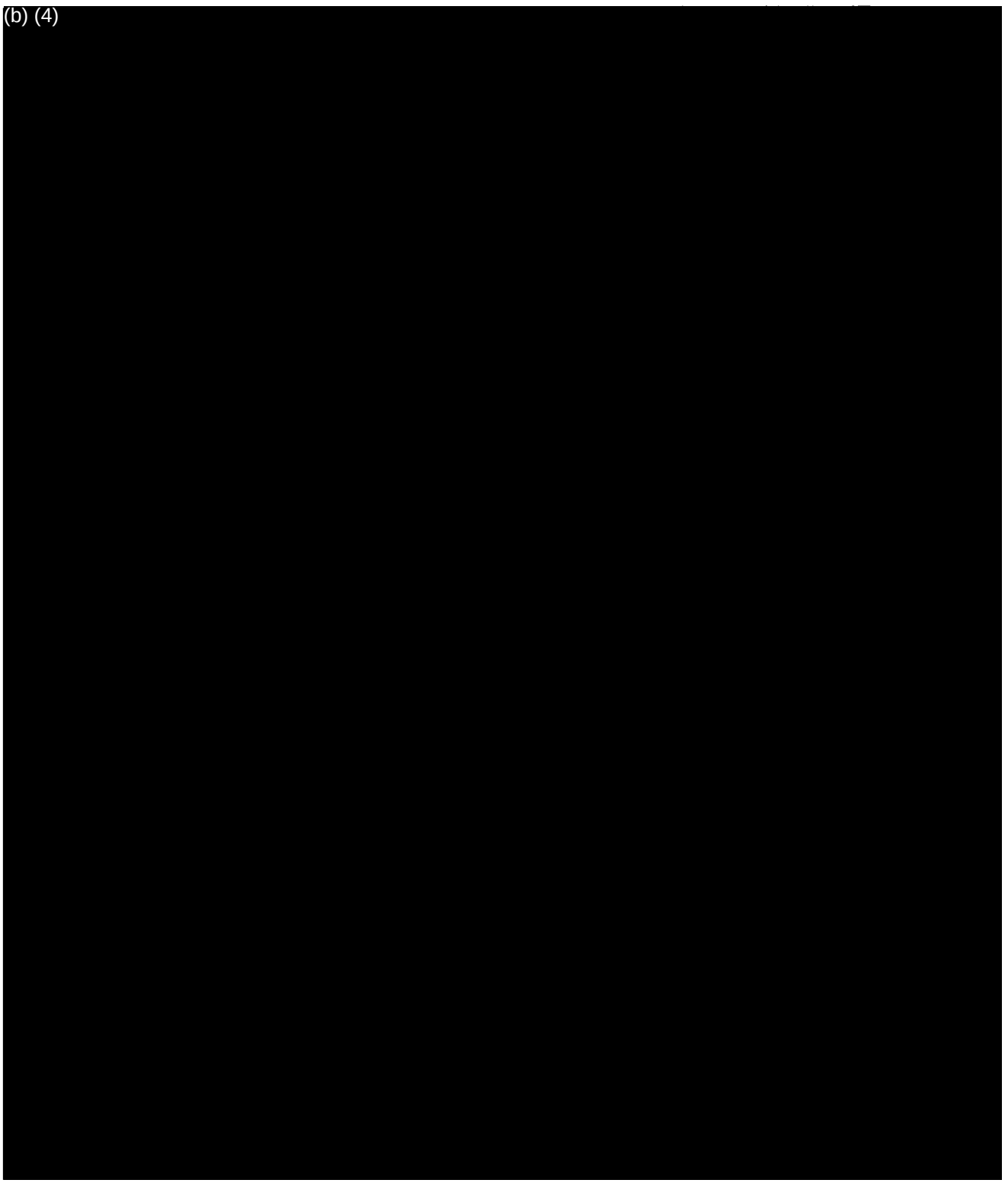
(b) (4)

[redacted]

DJA x01037

Appendix (b) (4) [redacted]

(b) (4)



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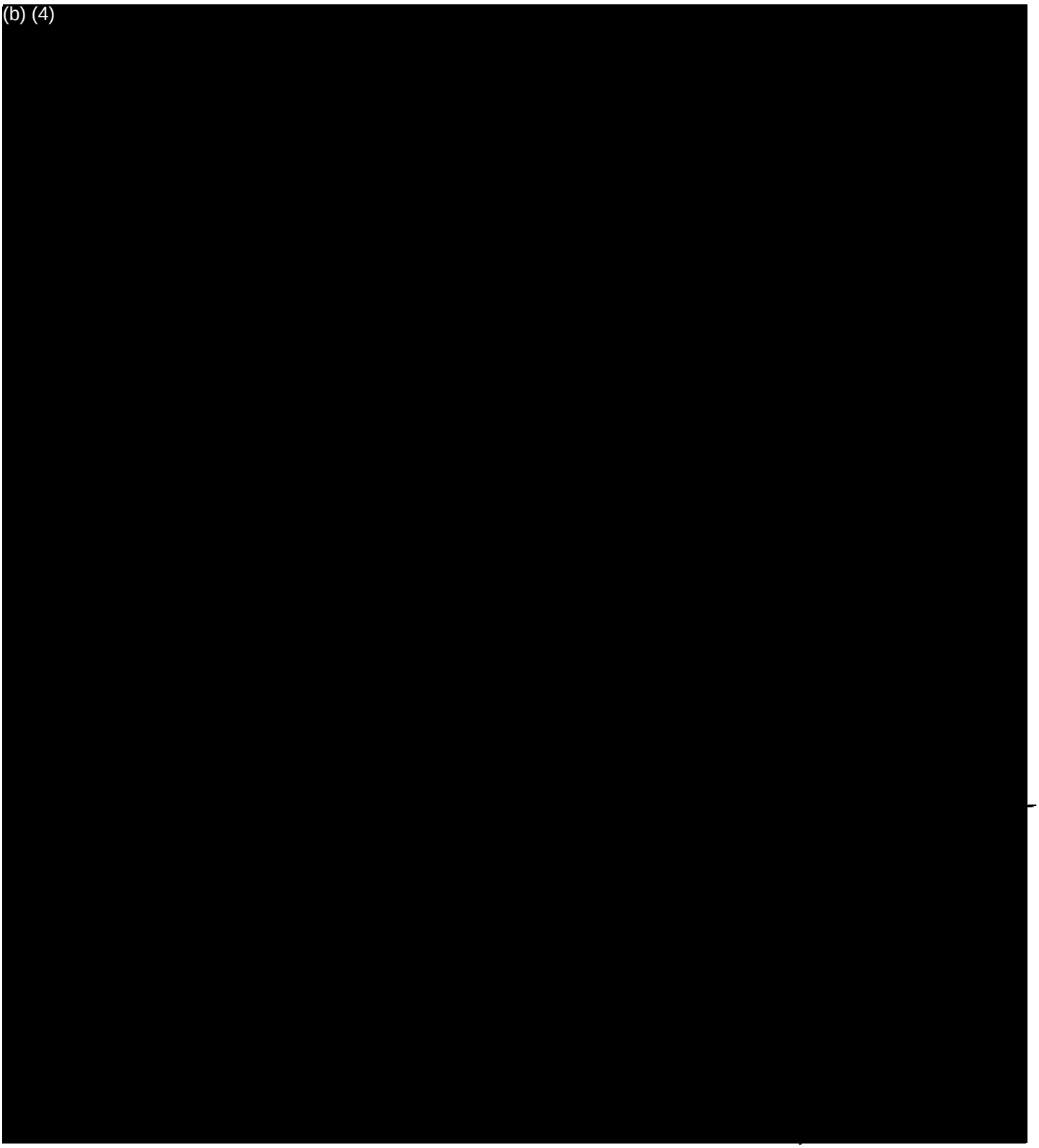
(b) (4)



DJA x01039

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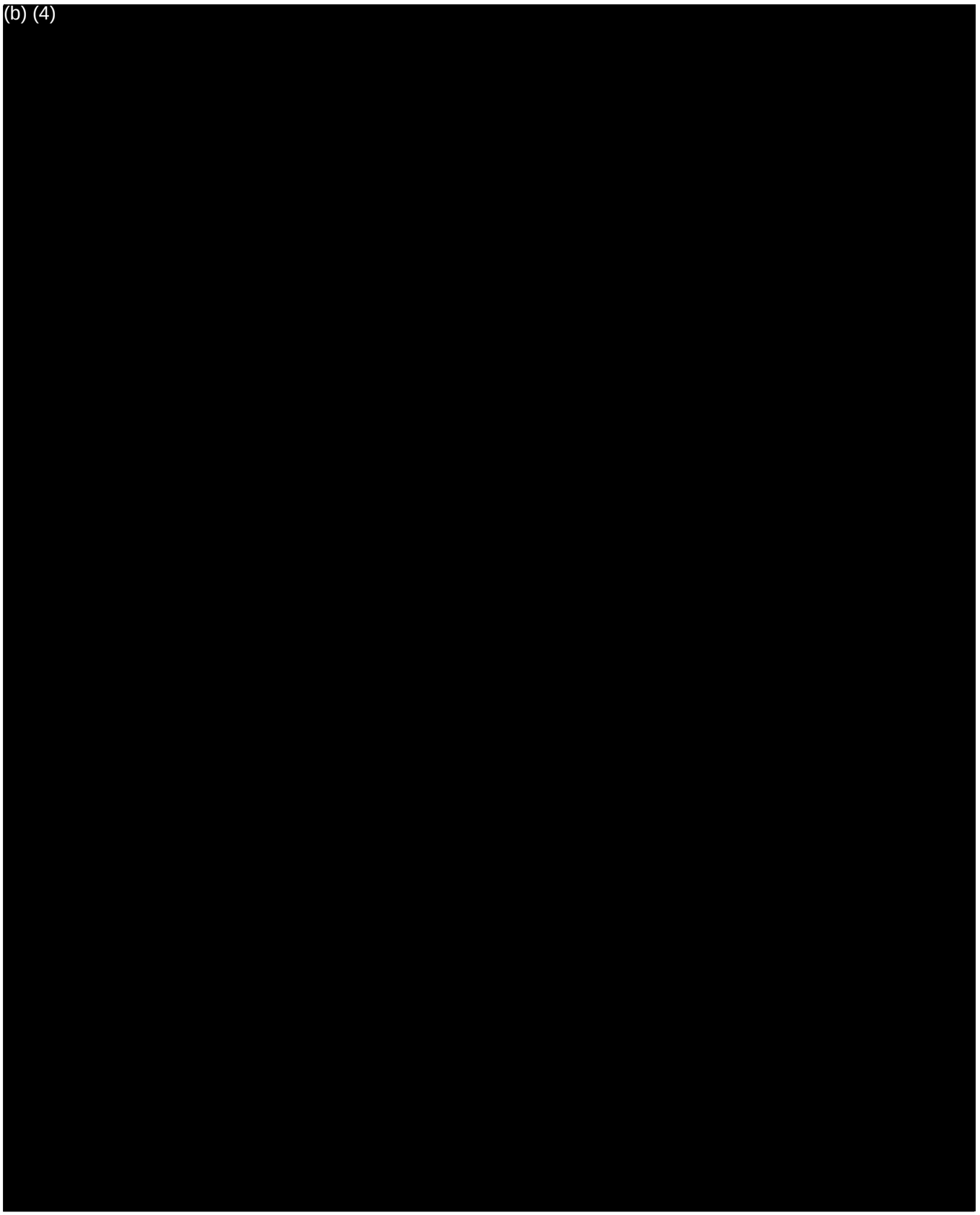

DJA x01040

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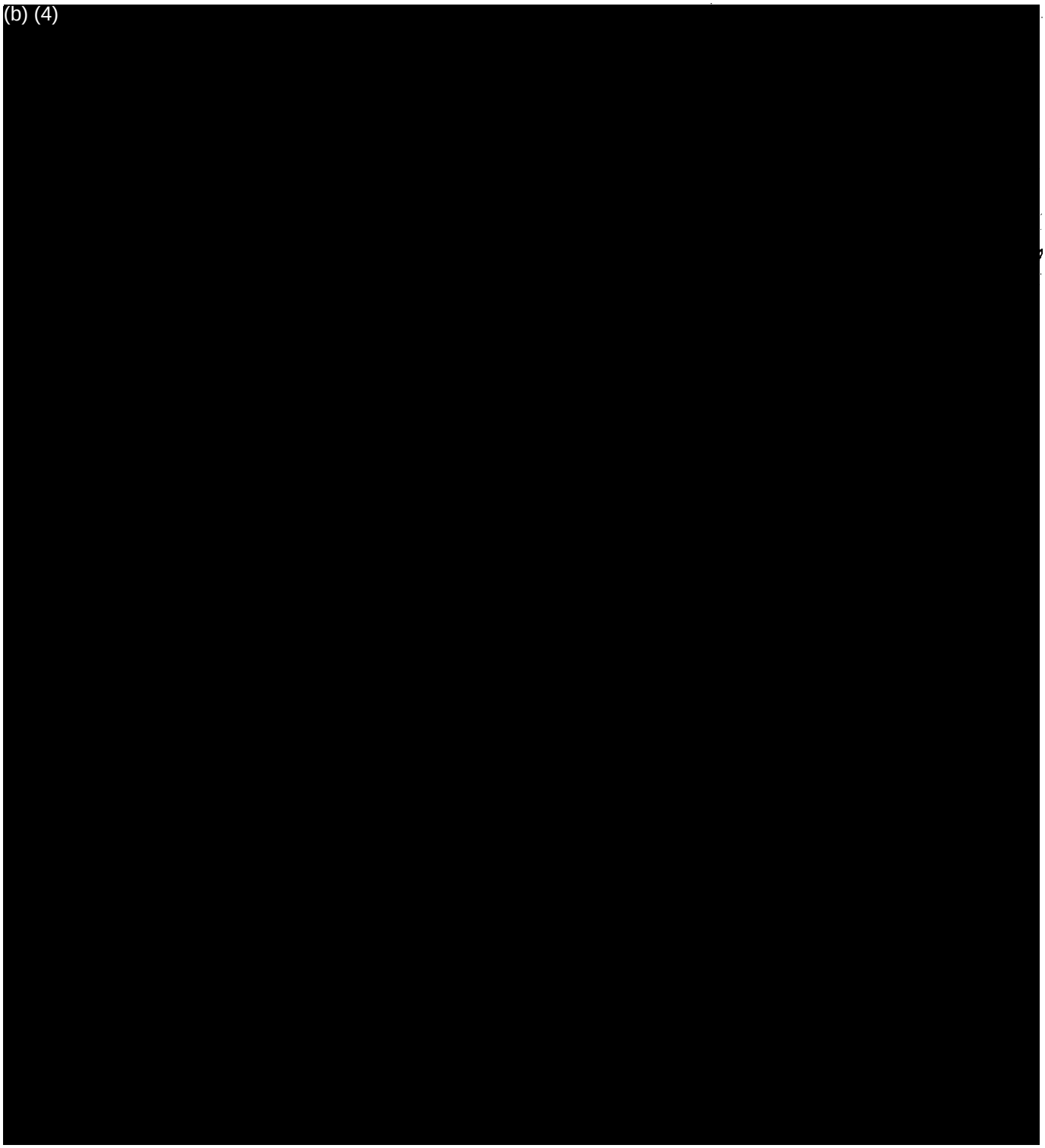
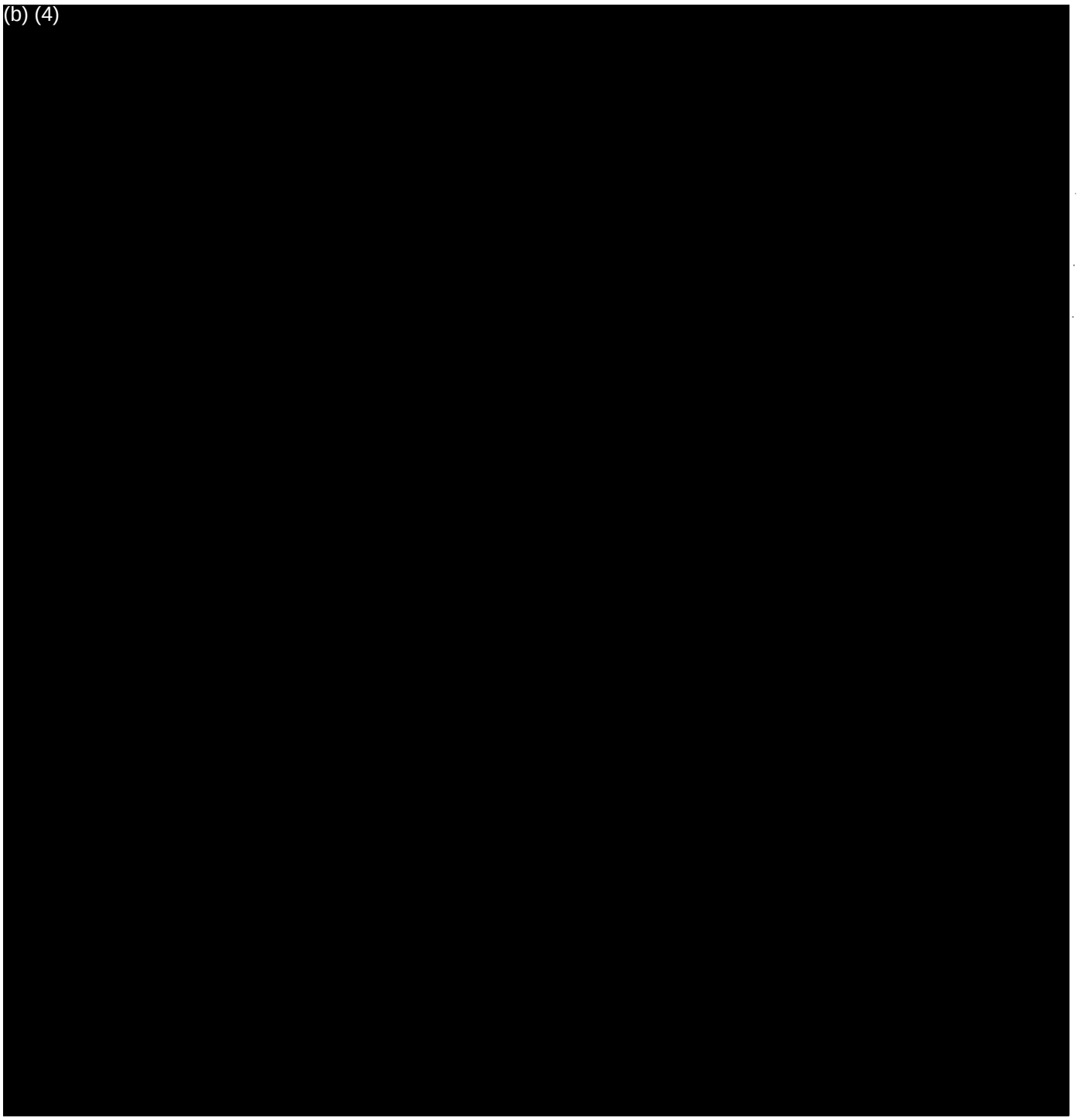


DJA x01041

(b) (4)

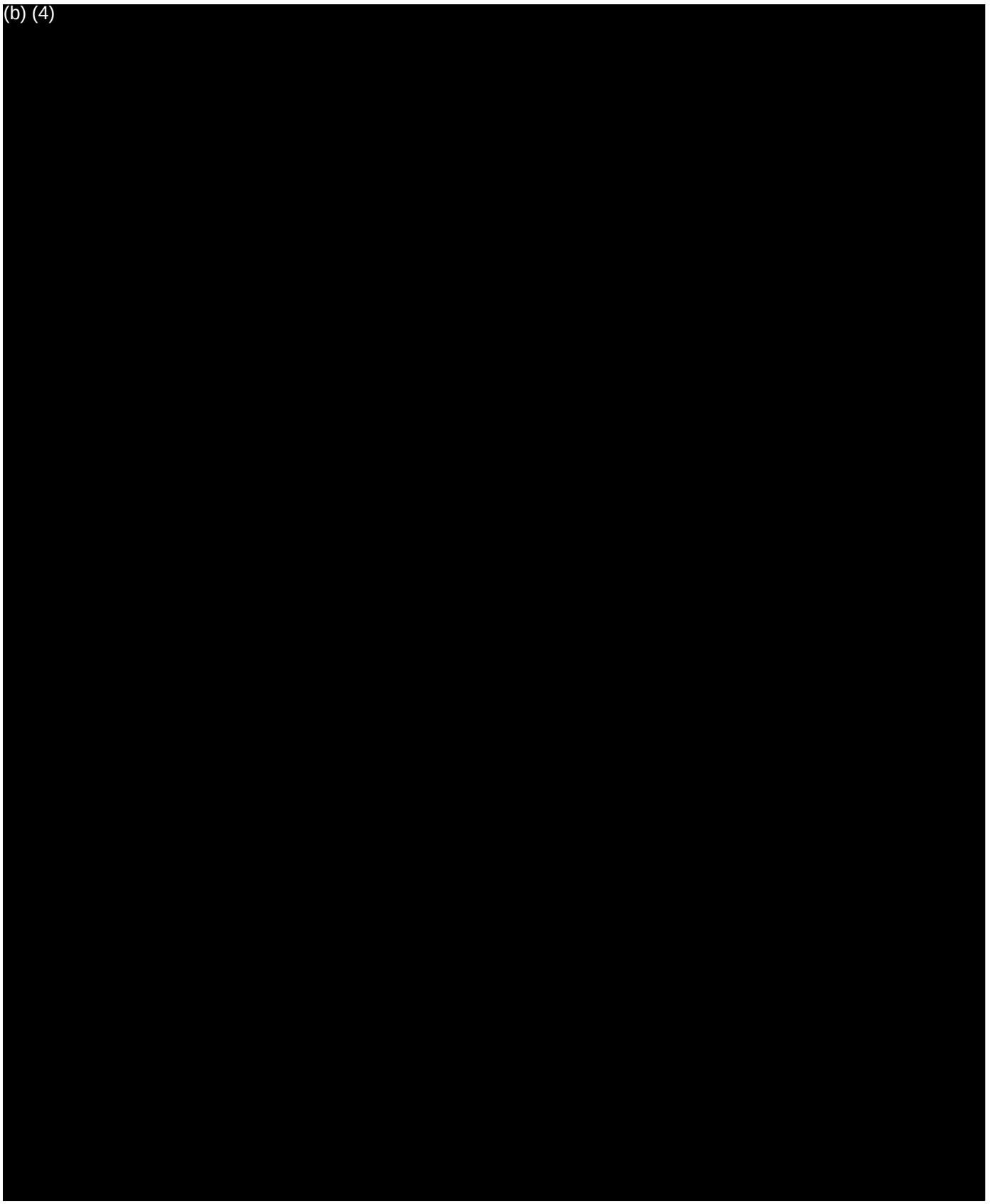


DJA x01042

(b) (4)

DJA x01043

(b) (4)



DJA x01044

TECHNICAL STUDY (TS)	Study Control Number (b) (4)
Title: ORTHODOC Unit Testing	**Originator:** (b) (4)

(b) (4)

DJA x01045

Results :

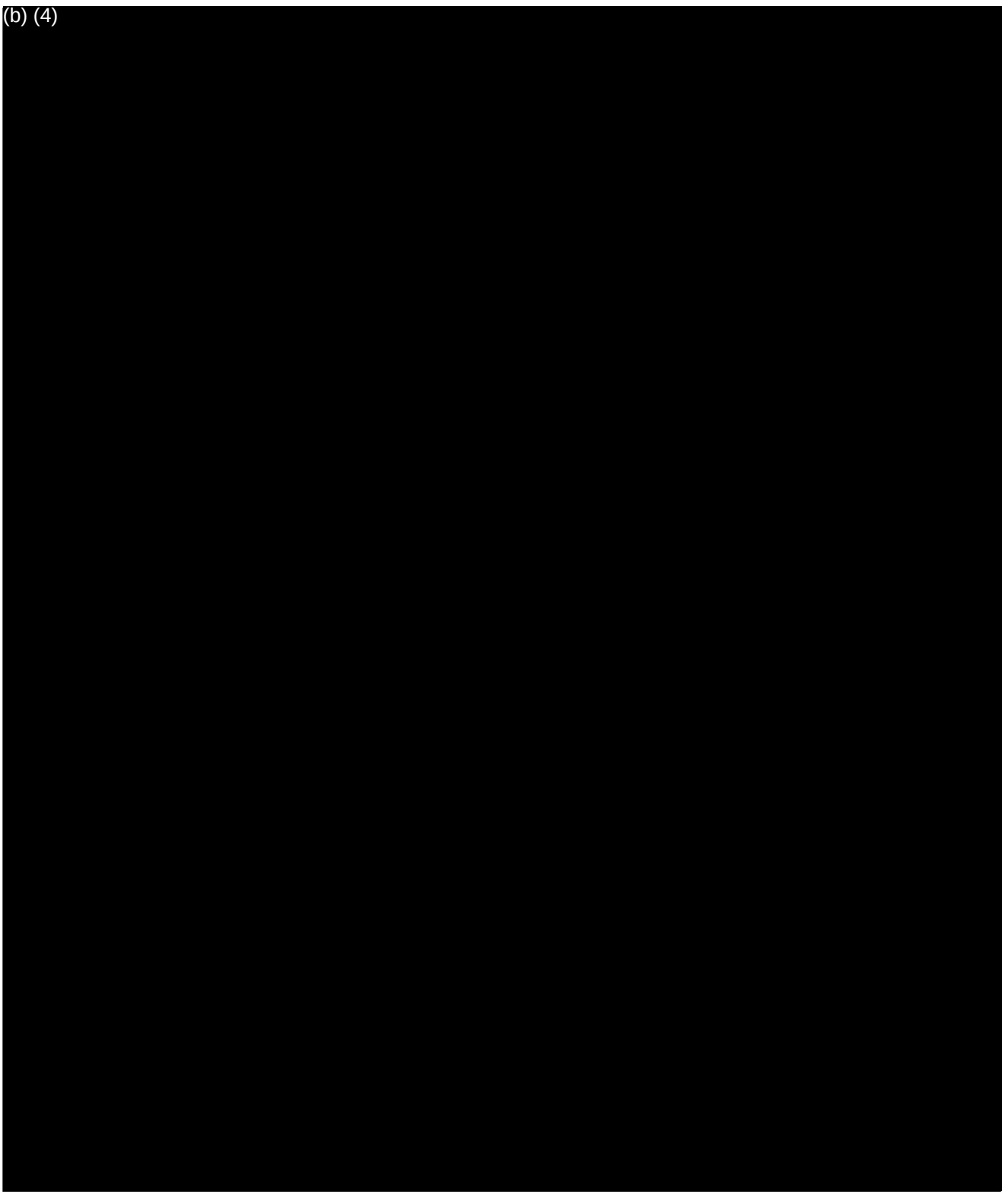
(b) (4)

[redacted]

DJA x01046

Appendix D : ORTHODOC Unit Testing

(b) (4)



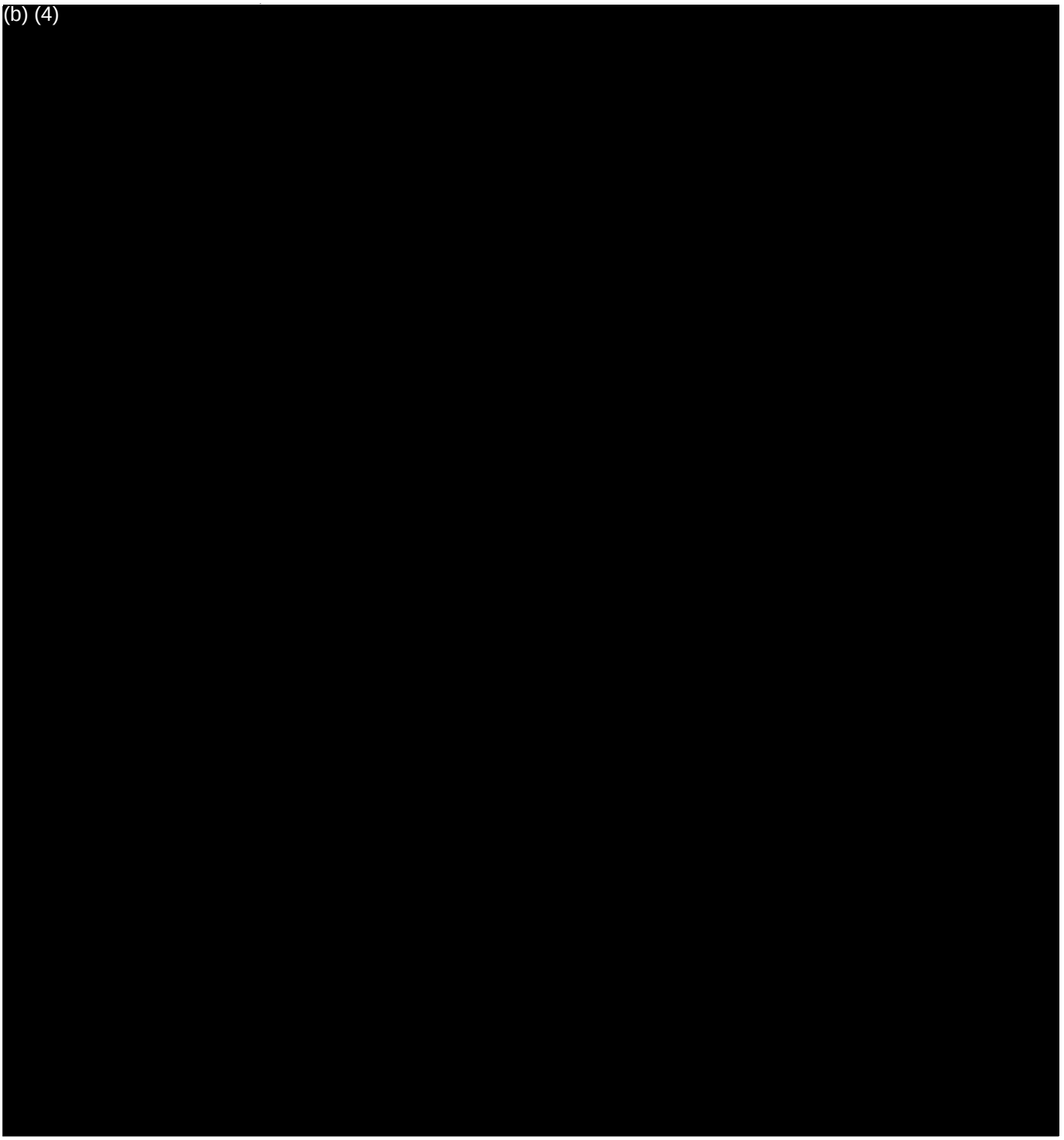
DJA x01047

1.3 Test Corrupted Patient Case:

(b) (4)

DJA x01048

(b) (4)



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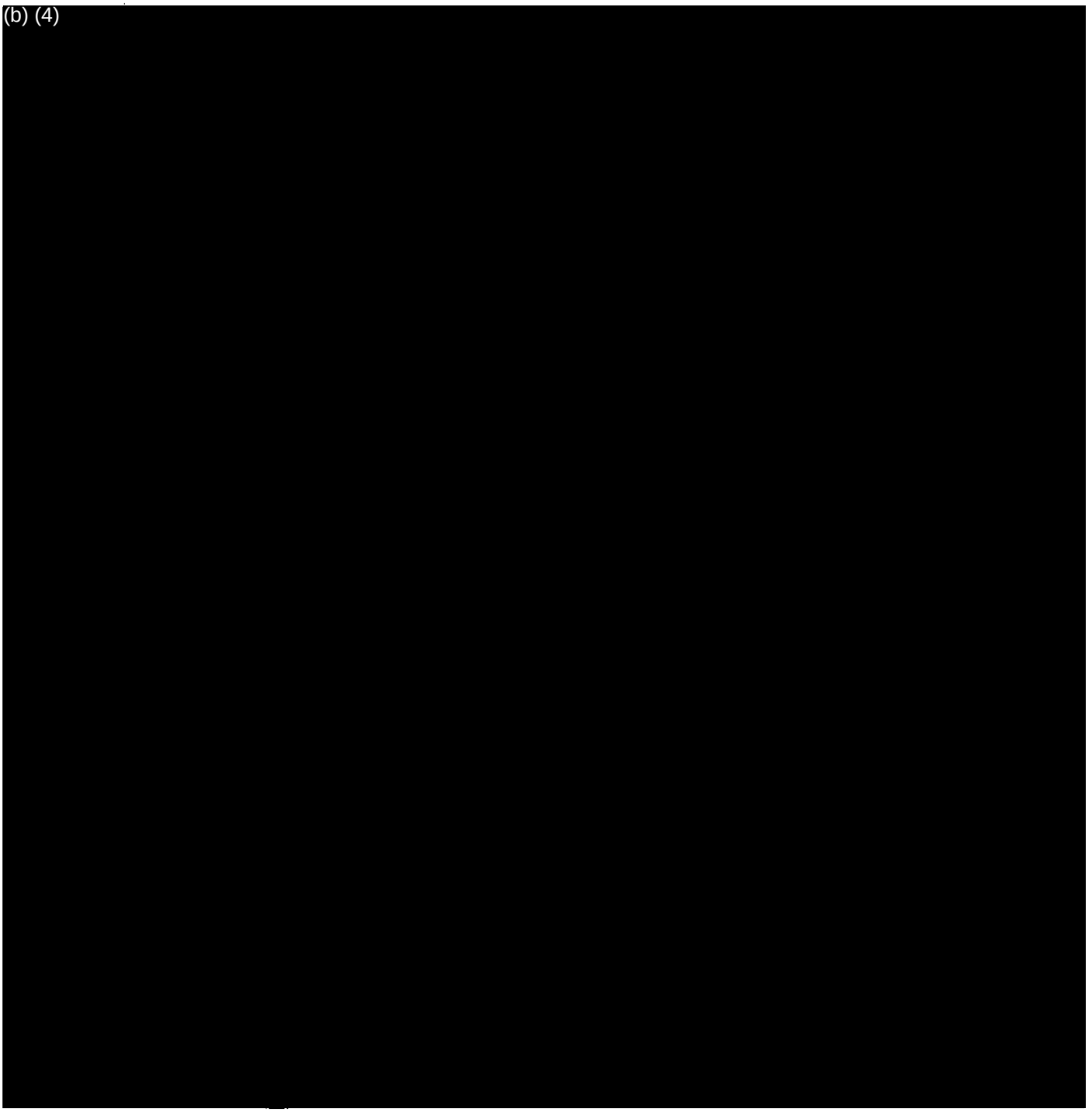

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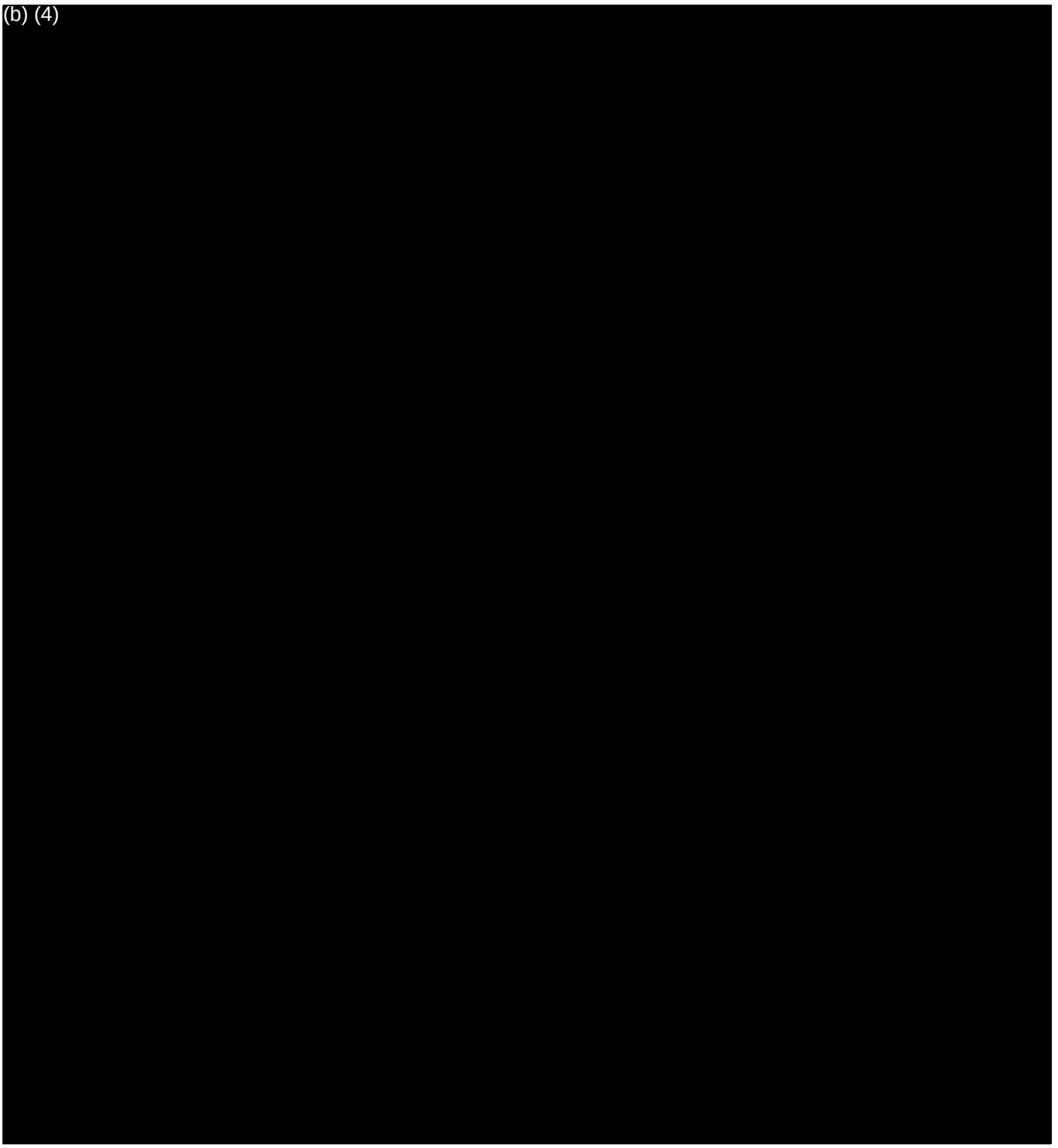

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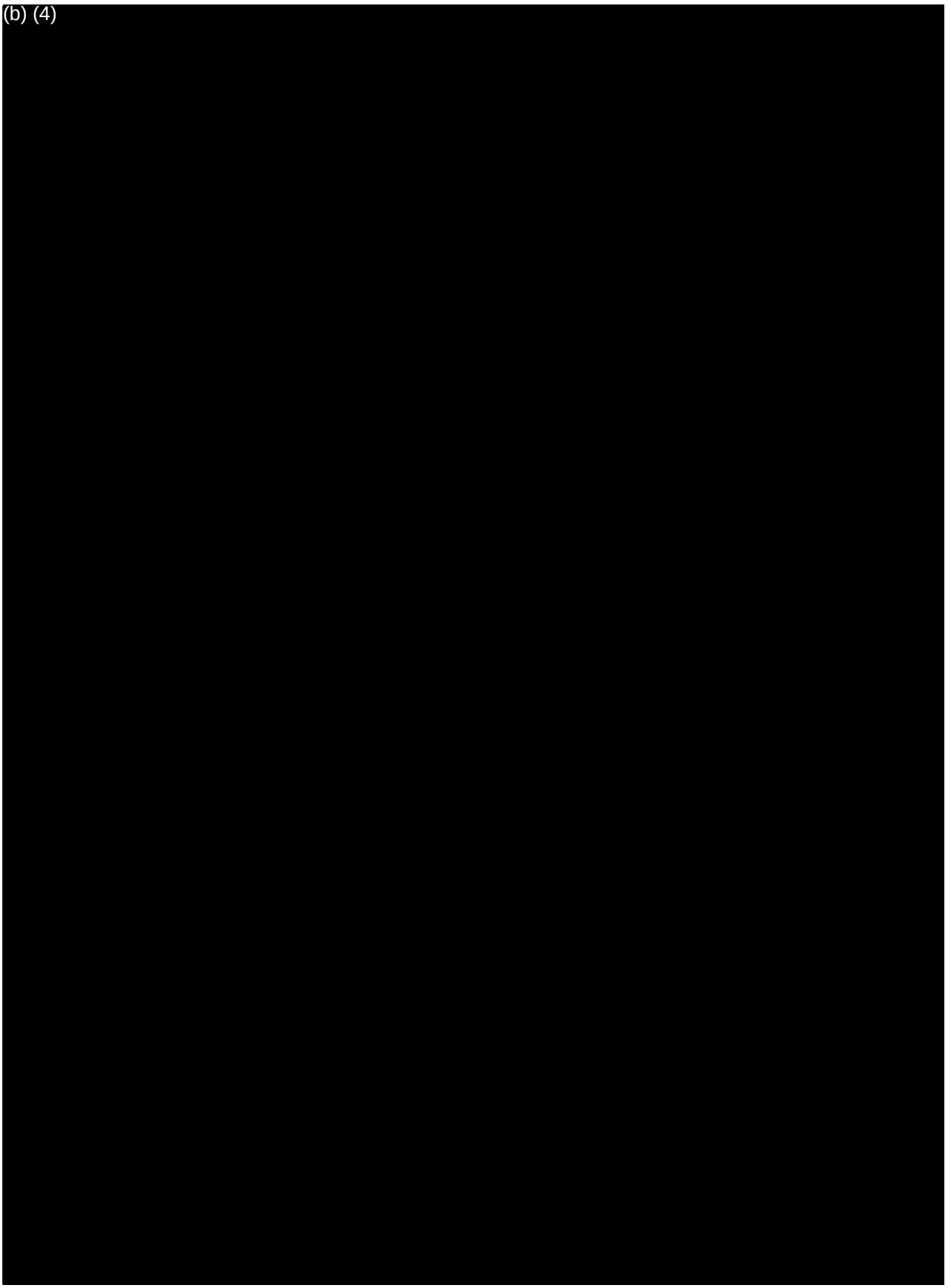

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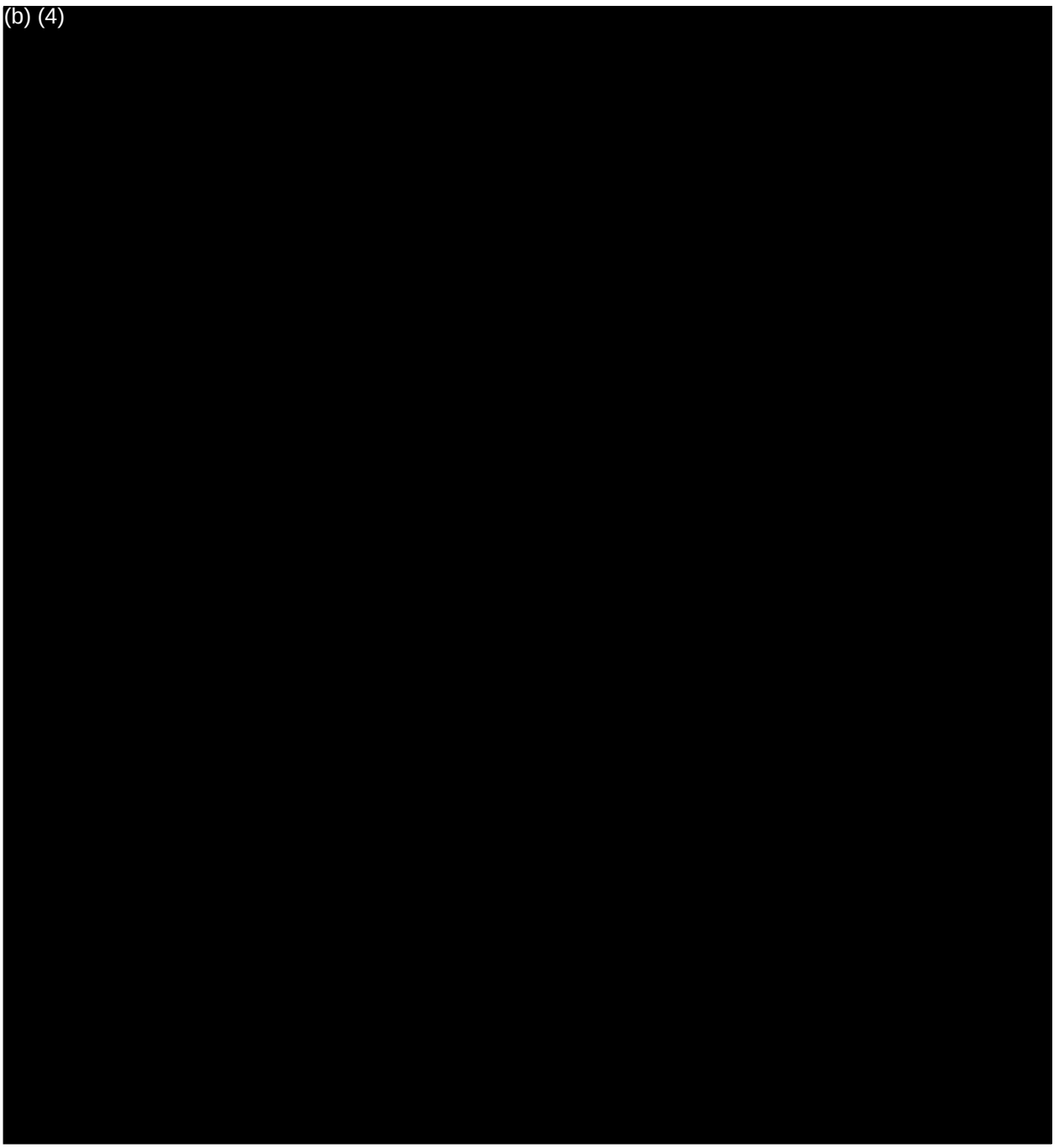

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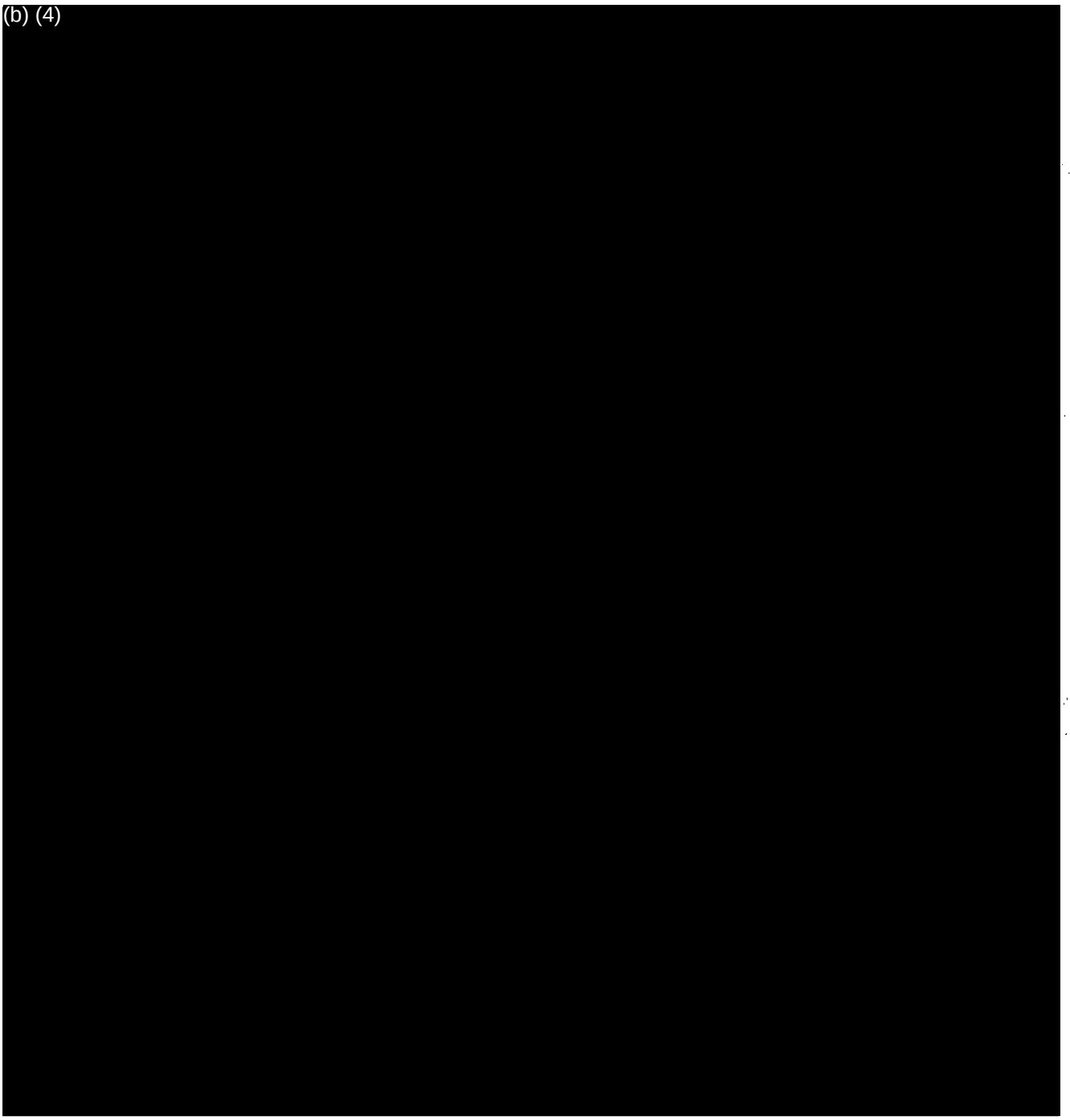

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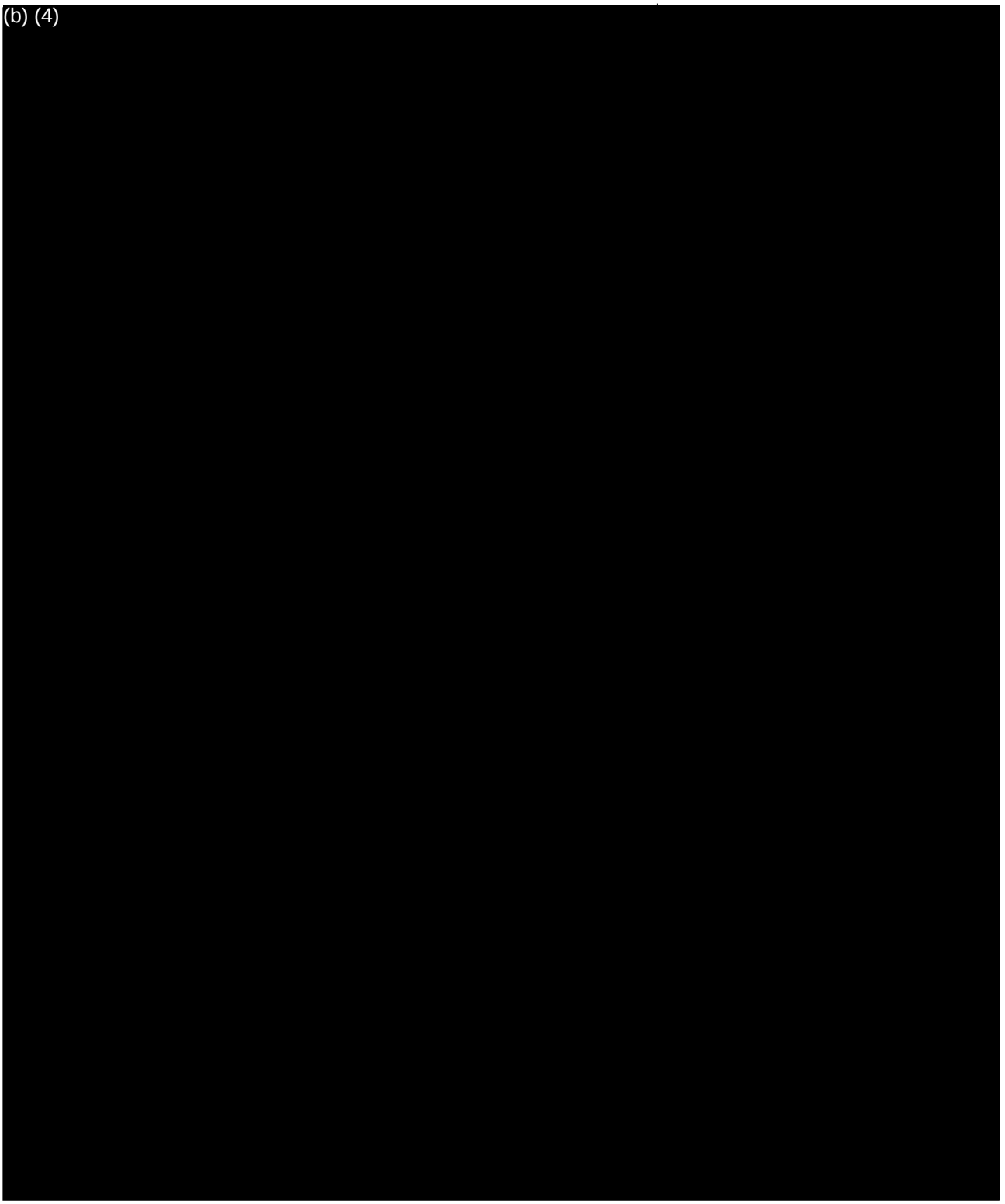

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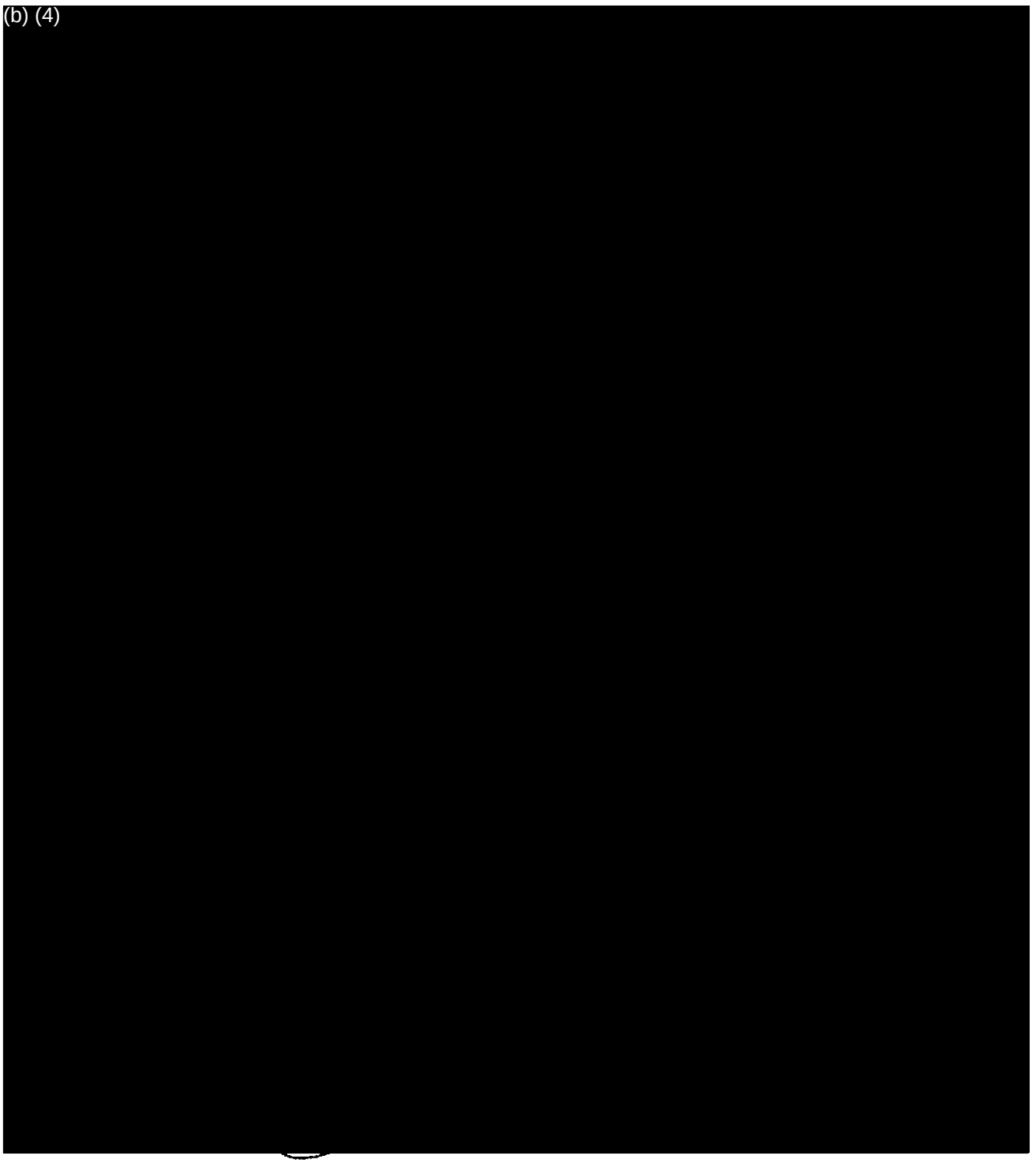

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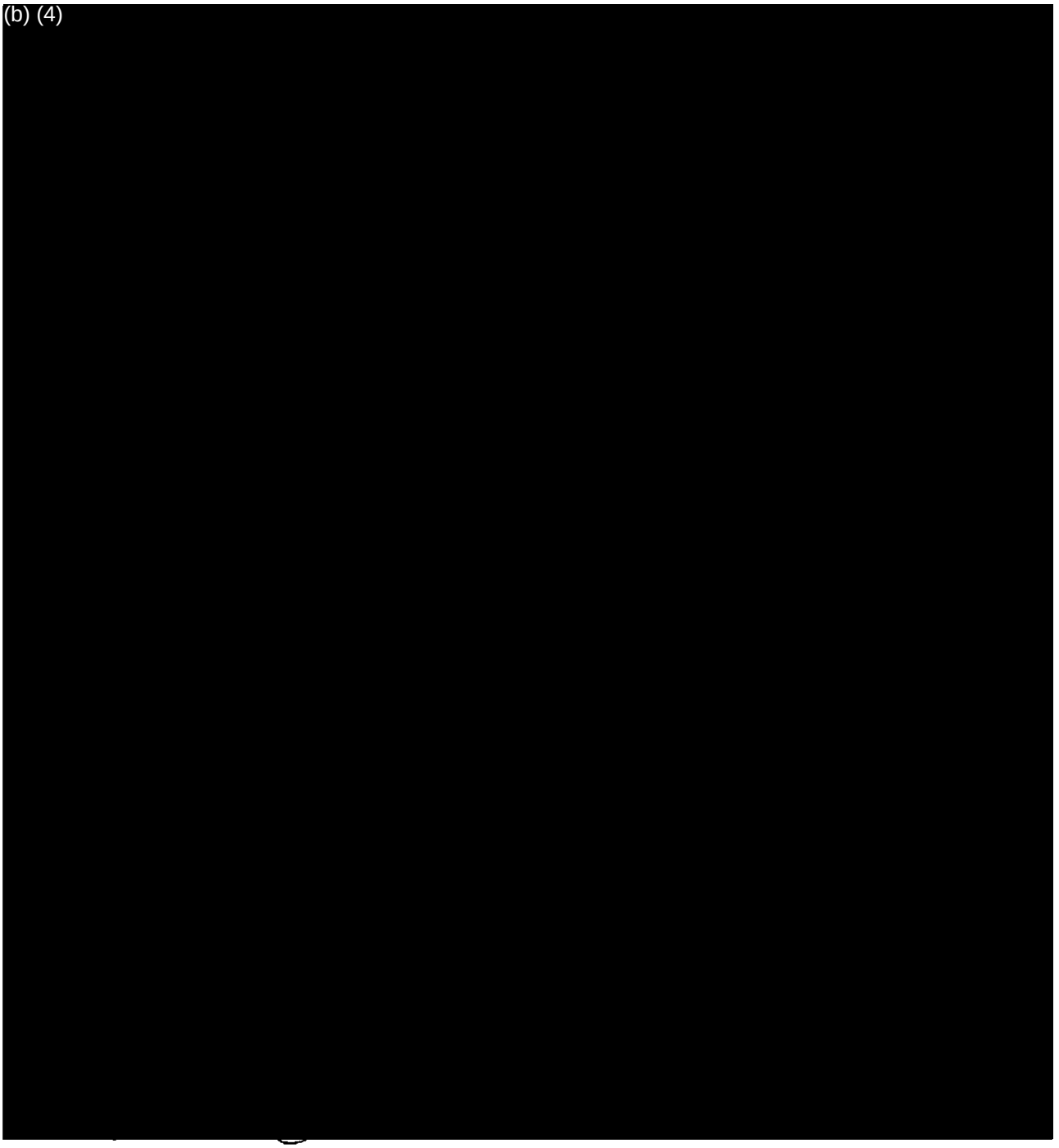

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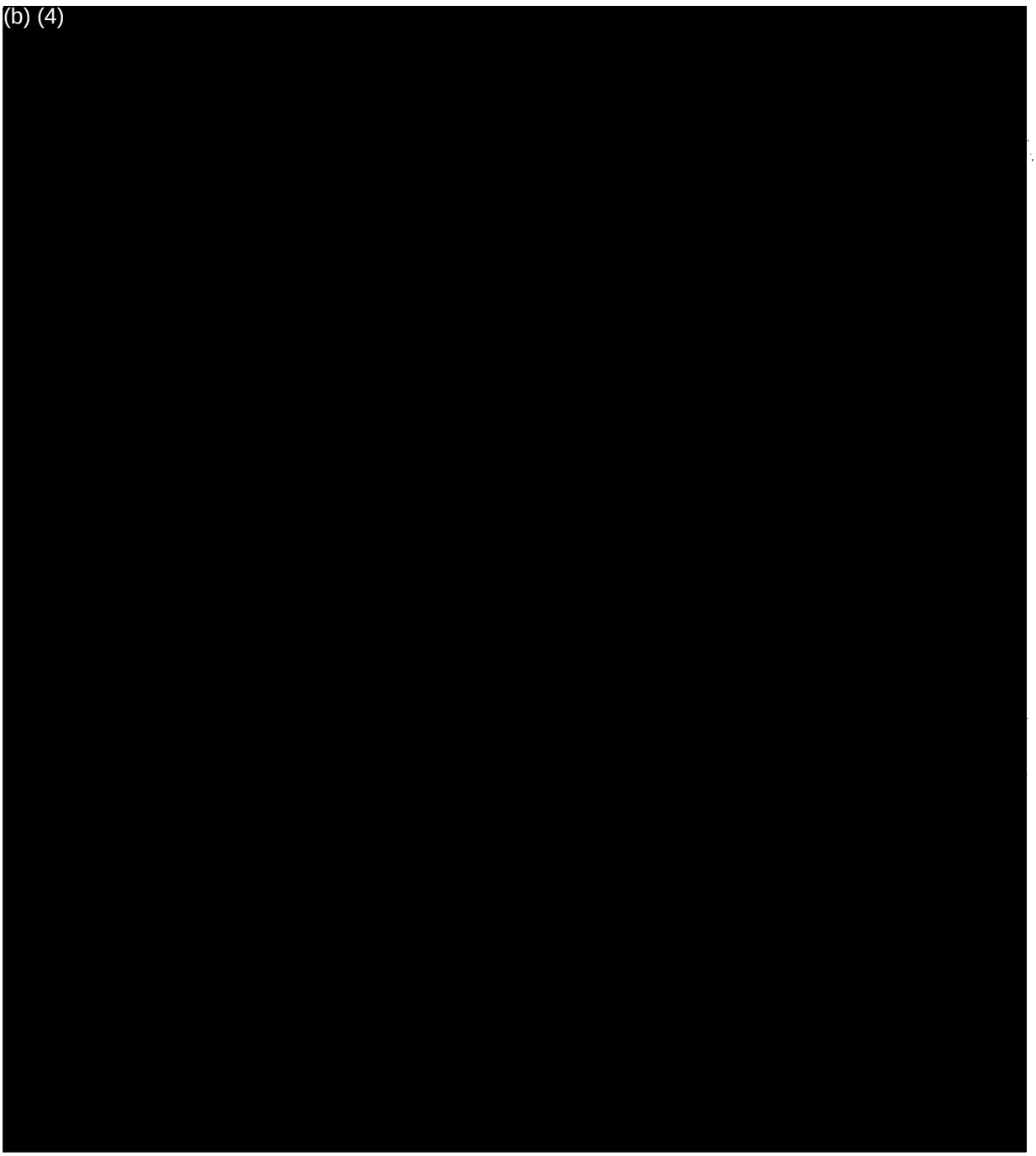

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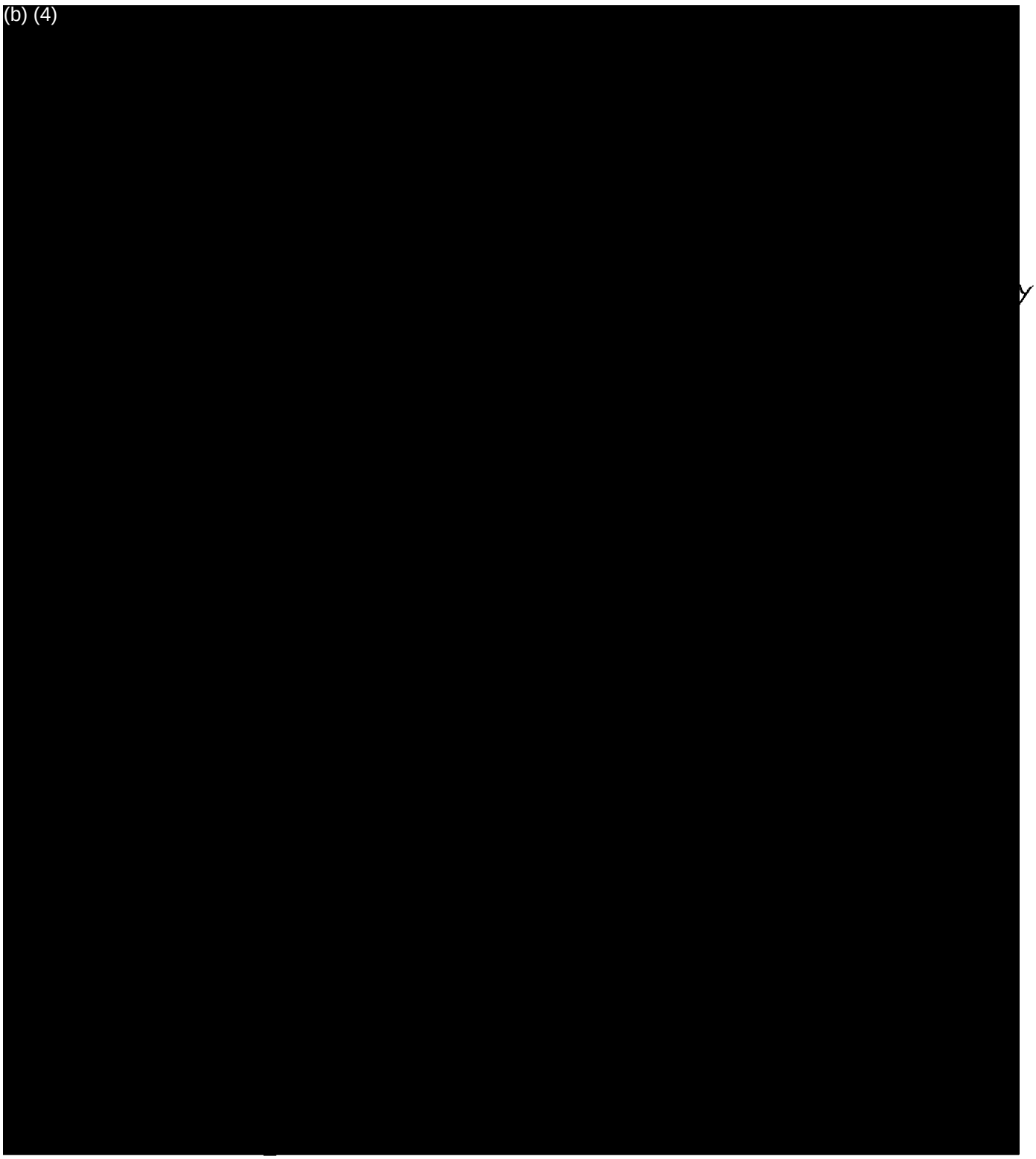

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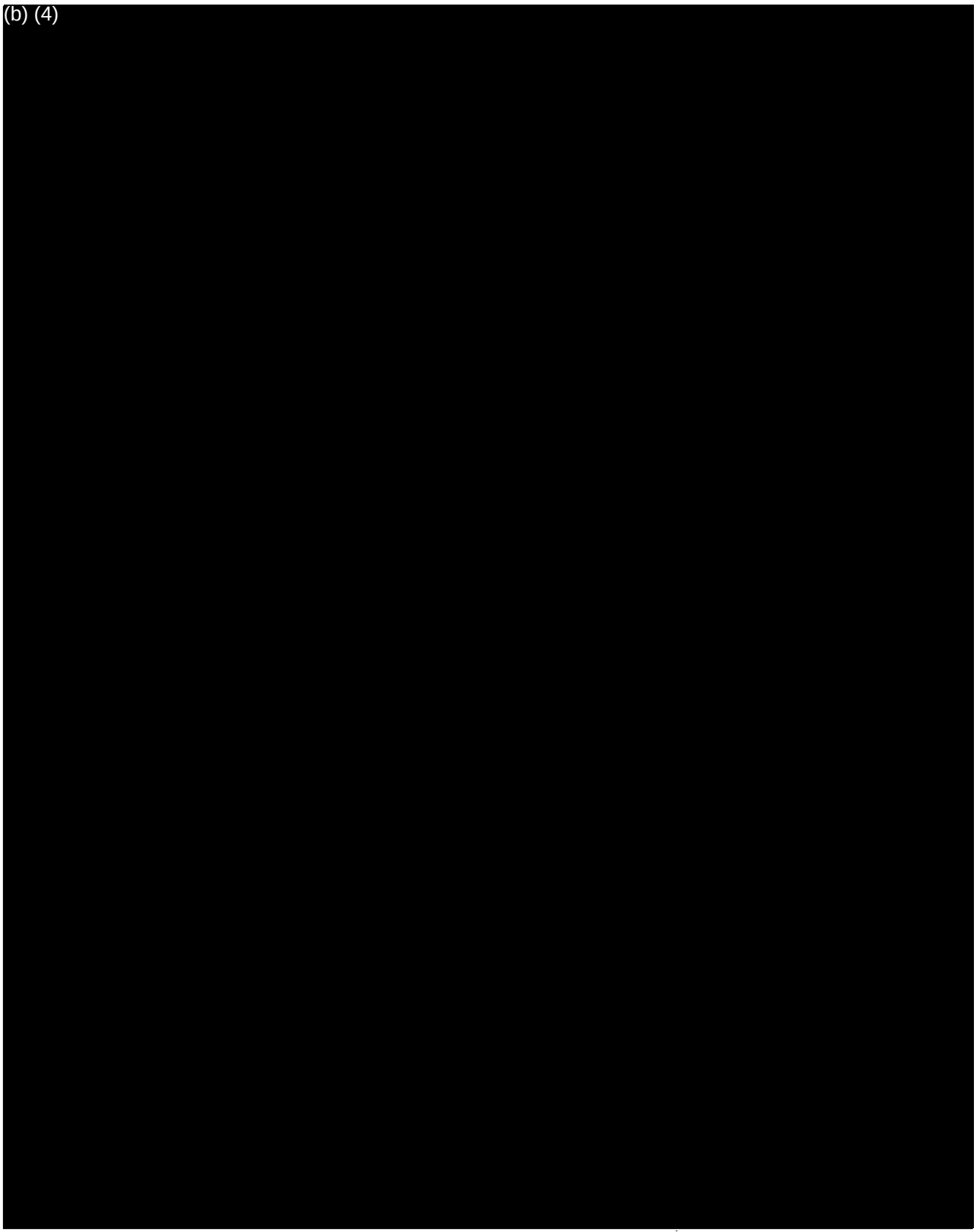

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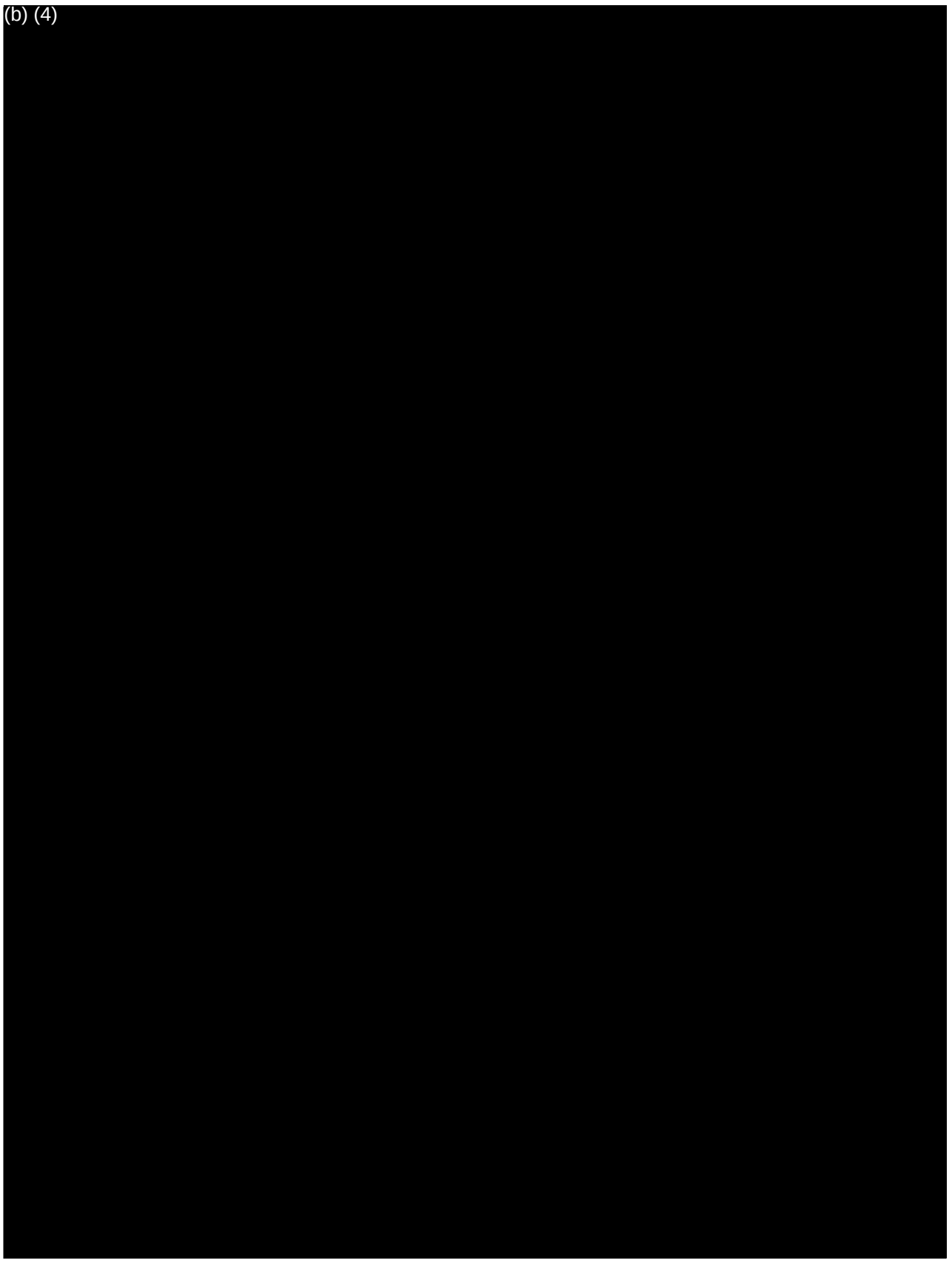

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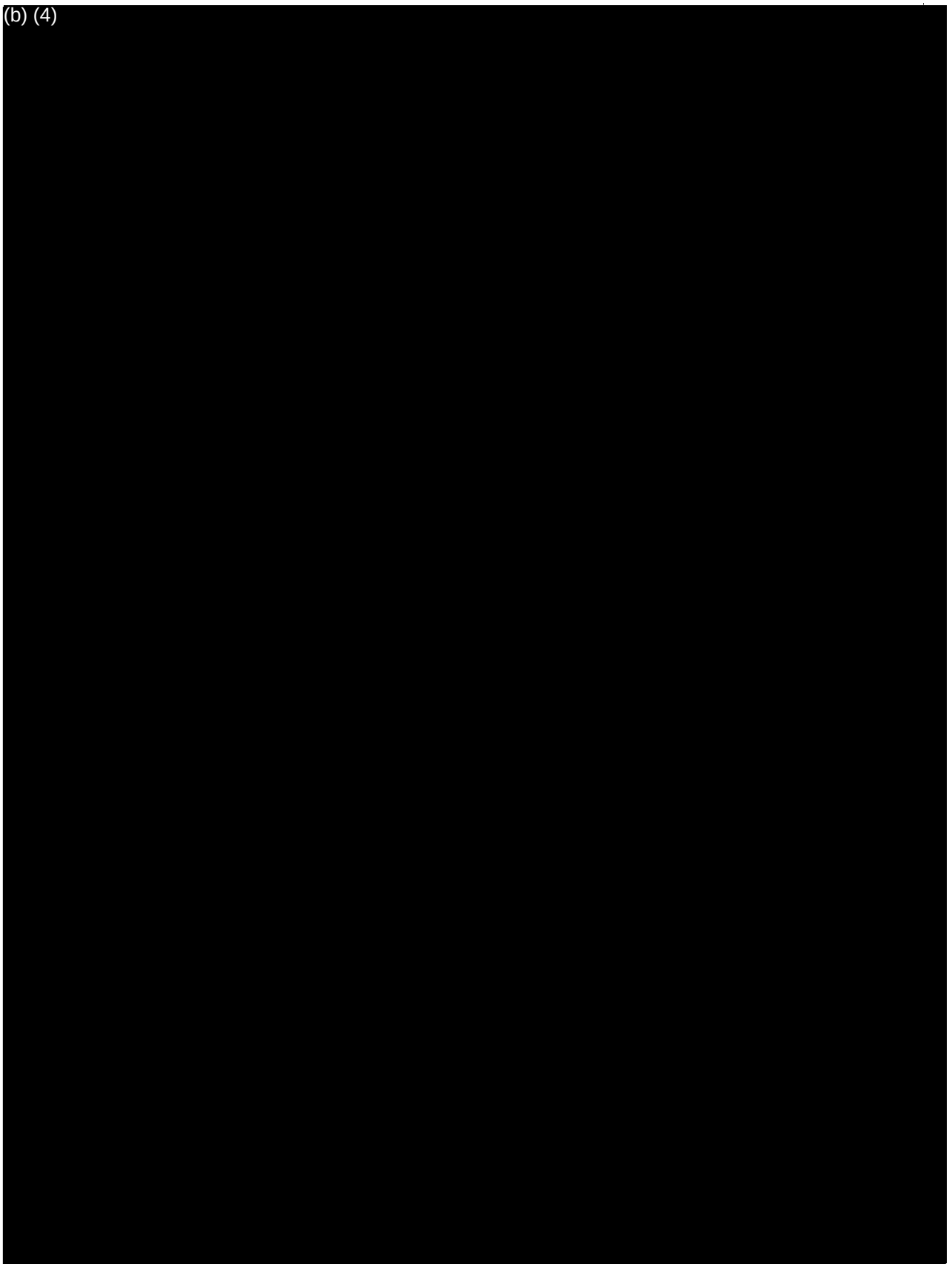

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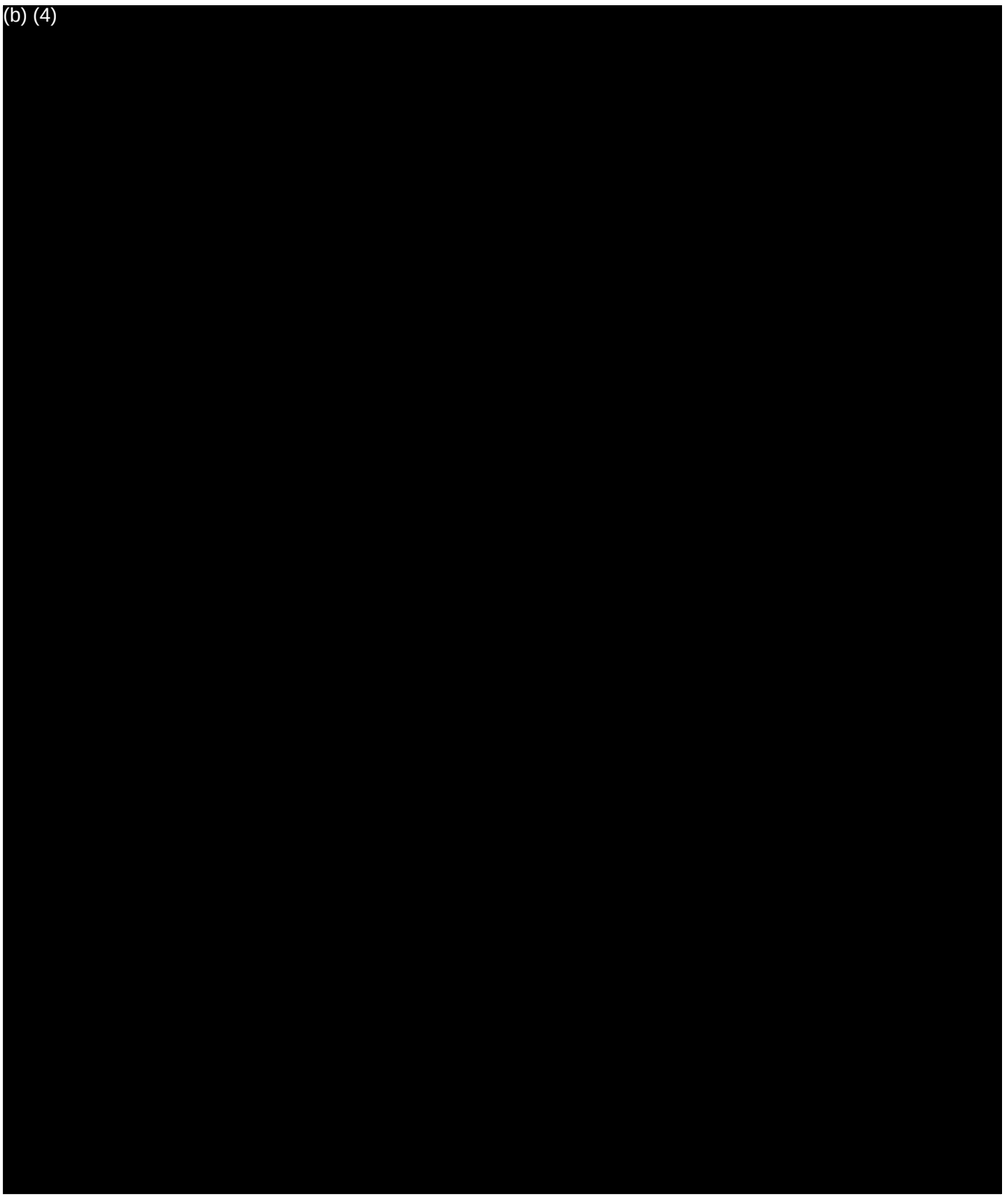

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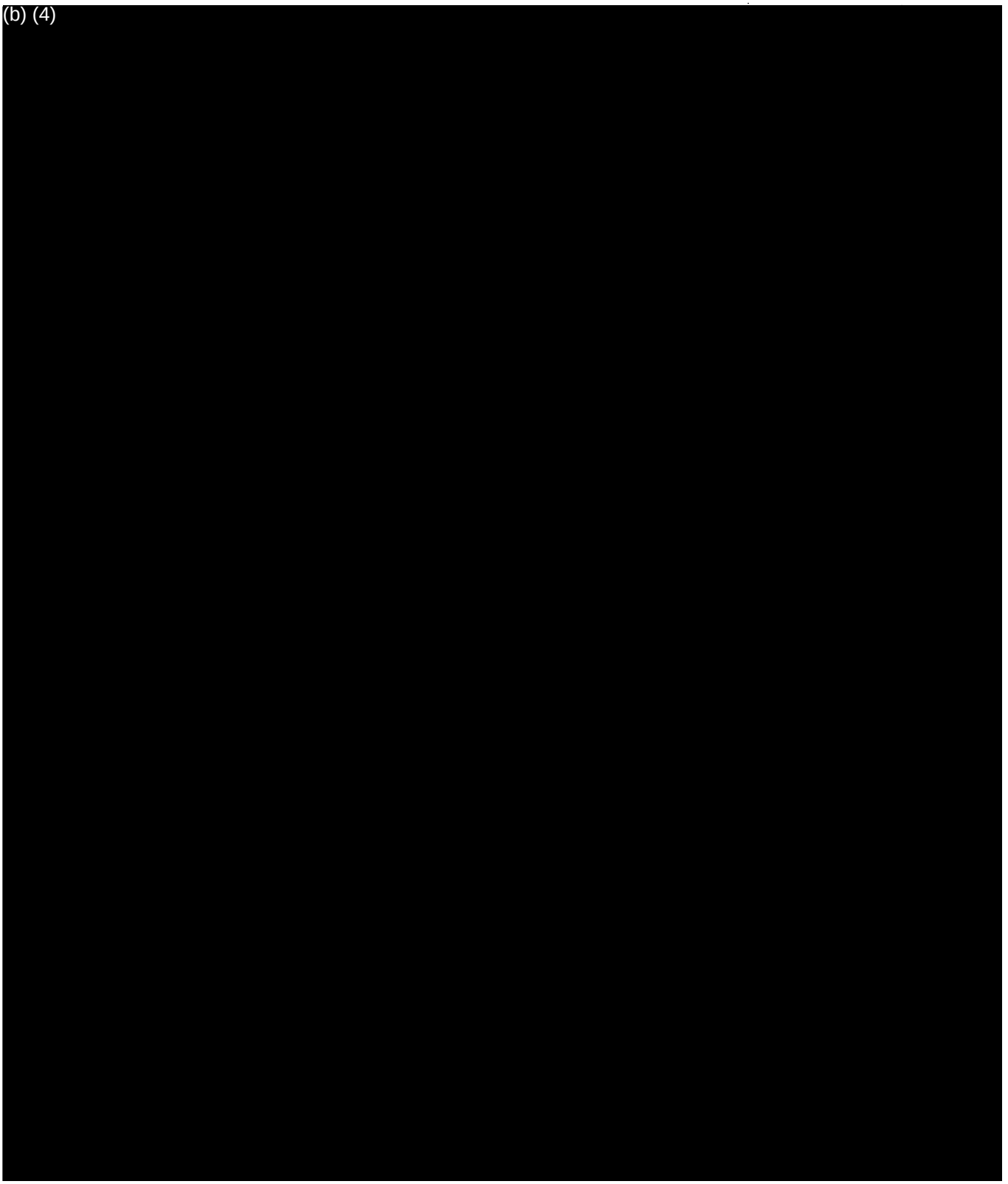

DJA x01:064

(b) (4)

DJA x00045

K072629/S2

ROBODOC®
INTEGRATED SURGICAL SYSTEMS

FDA CDRH DMC

APR - 3 2008

Received

March 31, 2008

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

Attention: Michel D. Janda

Re: Supplement 2: Response to FDA's Review Comments regarding the DigiMatch™ ROBODOC® Surgical System 510(k) Premarket Notification (K072629)

Dear Mr. Janda:

This submission provides the responses to the Food and Drug Administration's ("FDA") February 29, 2008, review comments regarding the DigiMatch™ ROBODOC® Surgical System 510(k) Premarket Notification (K072629). The deficiency letter items are provided on the following pages. For convenience of review, each of the questions raised in the agency's letter is repeated in italics, followed by the company's response.

We trust that the information contained in this response will address the outstanding issues related to this 510(k) review and will provide the information required for the Orthopedic Panel Member to complete the ROBODOC System Benefit/Risk Analysis homework assignment. If you have any questions regarding this response, please contact me at the below number.

Sincerely,

RD Hibbert
Director, Clinical & Regulatory Affairs
Integrated Surgical Systems
1433 N. Market Blvd., #1
Sacramento, CA 95834
Cell: 801-455-0807
Office Phone: 916-285-9943 x 522
Office Fax: 916-285-9104
E-mail: rdhibbert@robodoc.com

cc: Dr. Ramesh Trivedi, President and CEO
Leland Witherspoon, CTO
Howard Holstein, Esq., Hogan & Hartson L.L.P.

Attachments enclosed

K14

DJA x00046

FDA Comment

1. *The purpose of the second IDE clinical trial (G000071) was to validate the new pinless technology and demonstrate that the risk factors seen in the prior clinical trial had been mitigated or eliminated. These risk factors included longer surgical times and greater blood loss. During a January 18, 2007 meeting, FDA indicated that the data collected within the second IDE clinical trial would be reviewed to determine if the risk factors were properly mitigated and for validation of the new pinless technology. As such FDA requested that summary statistical analysis be performed on the available data. After reviewing the submitted analysis it appears that the risks of longer surgical times and greater blood loss were not fully mitigated. Therefore, FDA will be seeking the assistance of our expert panel members to judge the acceptability of these risks in relation to the potential benefit of your system. FDA believes that the recommendation of our expert panel is necessary in order to judge the risk/benefit profile of the subject device as compared to manual broaching and reaming as well as computer assisted surgery.*

   In order to enable this comparison, FDA is requesting that you provide additional formal statistical analysis of the study results. Possible analysis could include a comparison to data generated from the first clinical trial or a comparison to standard of care. Please provide additional information to demonstrate that the known risks of longer surgical times and greater blood loss have been fully mitigated or are acceptable given the device's potential benefit.

ISS Response

ISS will show through statistical and comparative analyses of the data from its clinical trials and the standard of care, as represented in published literature, that the DigiMatch™ ROBODOC® System is substantially equivalent and safe and effective for its intended use. To this end, ISS has completed an in-depth Benefit/Risk Analysis, which is provided in **Attachment 1**. The Benefit/Risk Analysis demonstrates that the potential risks identified in the first clinical trial, namely, of two surgical procedures, ipsilateral knee pain, longer surgical time and increased blood loss have been substantially mitigated or eliminated with the pinless registration (DigiMatch™) ROBODOC® technology. The Benefit/Risk Analysis also demonstrates that the device's benefits outweigh the potential risks.

Based on the results of the Benefit/Risk Analysis, ISS believes that FDA will find the DigiMatch™ ROBODOC® System substantially equivalent and safe and effective for its intended use.

DJA x00047

FDA Comment

2. *As previously indicated, assessment of the device risk/benefit profile remains as the primary concern. In order to allow this assessment, the FDA believes that additional information is needed regarding longer-term outcomes. Possible sources of long term data could include the first IDE clinical trial and Outside of the United States (OUS) studies. As the pooling of this data is likely to be problematic, summary information and analysis is appropriate. Please provide additional long term data (2 year and beyond) to support the potential benefit of the subject device.*

ISS Response

There has been one controlled, FDA-reviewed IDE study and two controlled, peer-reviewed, published studies that follow the ROBODOC patients and manual hand-rasping control subjects out to two years. To date there have been no controlled, published studies reporting results of ROBODOC patients followed for more than two years.

Study One

The first study to report two-year follow-up data on the ROBODOC® System technology was the First IDE Trial (G920035). This trial included two-year follow-up using Harris Hip Score, Hip Society evaluations (Johnson) and the SF-36 scores for quality of life measures. These measures assessed functionality and pain as indicators of the clinical outcome. The results showed no statistical difference between the ROBODOC and control groups at two-year follow-up for these self-assessment measures.

There were less intraoperative fractures reported in the ROBODOC group (0%) compared to the control group (5%). Additionally, the quantitative radiographic assessment performed by an independent radiologist in the First IDE Trial revealed significantly better radiographic outcomes for the ROBODOC group compared to the control group. Specifically:

- Fit – closer cortical bone to prosthesis distance (chi-square, p=0.001)
- Fill – canal filling of the prosthesis (chi-square, p=0.01)
- Alignment – varus-valgus, anterior-posterior (unpaired t-test, AP film: p=0.02; lateral film: p=0.04)
- Axial Seating – prosthesis distance from neck cut (unpaired t-test, p=0.01).
- Proximal Medial Fit (chi-square, p=0.001).

The results of the functionality and pain assessment, and the radiographic assessment are provided in **Section 3** of the Benefit/Risk Analysis, contained in **Attachment 1**.

DJA x00048

Study Two

The second study to report two-year follow-up data on the ROBODOC® System technology was conducted by Nishihara, et al., and was published on the Journal of Arthroplasty, Vol. 21, No. 7, 2006. This study reports that Merle D'Aubigne hip scores at two-year follow-up were statistically better for the ROBODOC group compared to the hand-rasping group (Mann-Whitney *U* test, $p < 0.05$). This demonstrates a functional benefit in using the ROBODOC® System technology.

Study Three

The third study to report two-year follow-up data on the ROBODOC® System technology was conducted by Hananouchi a, et al., and was published on the Journal of Orthopaedic Research, Vol. 25, 2007. This study reports that the better fit and fill of the femoral stem and less destruction of the bony architecture provided by the ROBODOC® System, compared to manual broaching, may have a beneficial affect on femoral periprosthetic bone remodeling. The authors evaluated the effects of robotic milling in cementless total hip arthroplasty (THA) in a longitudinal 24-month follow-up study using dual energy X-ray absorptiometry (DEXA) and plain radiographs of 29 patients (31 hips) after ROBODOC THA and 24 patients (27 hips) after manual THA with the same stem design. To minimize the influence of other factors on bone remodeling, only female osteoarthritis patients, who did not take drugs that might affect bone metabolism, were enrolled. Significantly less bone loss occurred at the proximal periprosthetic areas in the ROBODOC group. In zone 1, the decrease was 15.5% versus 29.9% using conventional rasping; in zone 7, the loss was 17.0% with ROBODOC compared to 30.5% with conventional rasping ($p < 0.05$). On radiographs, endosteal spot welds in the proximal medial portion were more pronounced in the ROBODOC group (48% vs. 11% in the conventional group, $p < 0.05$). The results suggest that robotic milling is effective in facilitating proximal load transfer around the femoral component and minimizing bone loss after cementless THA.

Integrated Surgical Systems
1433 N. Market Boulevard, #1 • Sacramento, CA 98534
916.285.9943 phone • 916-575-7918 fax • www.robodoc.com

DJA x00049

FDA Comment

3. *The submission includes an indication for use statement which appears to differ from that studied within first and secondary IDE studies. Specifically, the indication for use statement includes a paragraph which makes safety and effectiveness claims regarding other orthopedic procedures (Paragraph #3). Please revise the indications for use statement and device labeling where appropriate to remove this reference or provide additional clinical data to support this claim*

ISS Response

The Indication for Used Statement has been revised to address this comment. The revised statement is provided below:

Indication for Used Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

Attachment 2 of this submission contains the FDA formatted Indication for Use Statement.

DJA x00050

Attachment 1 – Benefit/Risk Analysis

DigiMatch™ ROBODOC® Surgical System (K072629)

Table of Contents

1. Introduction
2. Background
3. Summary and Statistical Analysis of First IDE Clinical Trial (G920035); Pin-Based ROBODOC System
4. Summary and Statistical Analysis of Second IDE Clinical Trial (G000071); Pinless ROBODOC System
5. Practices and Procedures Comparison
6. Potential Benefits; Review and Discussion of Clinical Data
7. Potential Risks; Comparison and Analysis of First IDE Trial, Second IDE Trial and Standard of Care
8. Benefit/Risk Analysis
9. Conclusions
10. References

DJA x00051

1. Introduction

1.1 Purpose

The purpose of this document is to:

- Demonstrate that the four potential risks that were identified by FDA following the First Clinical Trial (IDE #G920035), which used the 3-pin registration ROBODOC® System, have been substantially mitigated or eliminated;
- Demonstrate that the risks associated with the use of the DigiMatch™ ROBODOC® System are outweighed by the benefits; and
- Demonstrate that the DigiMatch™ ROBODOC® System is substantially equivalent, safe and effective for its intended use.

1.1.1 Potential Risks

The potential risks associated with the 3-pin registration ROBODOC® System used in the First IDE Trial were:

- Two surgical procedures;
- Ipsilateral knee pain associated with implantation of locator (fiducial) pins;
- Longer surgical time, compared to the manual control group; and
- Increased blood loss, compared to the manual control group.

The Second Clinical Trial, conducted under IDE #G0000710, used the pinless registration DigiMatch™ ROBODOC® System. The pinless registration ROBODOC technology (DigiMatch™) was designed to address the issues related to the pin-based registration ROBODOC technology. A detailed discussion of how the DigiMatch™ ROBODOC® System has mitigated or eliminated these potential risks is provided in **Section 7**.

1.1.2 Identified Benefits

FDA has stated that the First IDE Trial demonstrated that the ROBODOC® System is effective for its intended use as an alternative to conventional template planning and manual reaming/broaching methods for Total Hip Arthroplasty (THA) procedures.

A review of the medical literature of independent clinical studies further confirm the results of the First and Second IDE clinical trials and identify additional benefits. These benefits are discussed in detail in **Section 6** of this document and include:

- Better Fit
- Better Fill
- Better Alignment
- Reduction in Leg Length Discrepancy
- Reduction in Intra-operative Fractures
- Reduction in reported Pulmonary Emboli

DJA x00052

1.2 Development of ROBODOC® Surgical System

The ROBODOC® Surgical System is a surgical tool intended for use in primary cementless Total Hip Arthroplasty (THA) procedures. It was developed as an alternative to the use of conventional manual tools to accurately and reliably implement a preoperative plan developed by the surgeon on the FDA cleared ORTHODOC® (510K# K960685) Preoperative Planning Workstation. The ROBODOC® System is a tool which enables the precise milling of a femoral cavity in the location specified in the preoperative plan by the surgeon, thereby enabling optimal execution of the restorative surgical procedure.

Since the development of the first (1st) generation ROBODOC® Surgical System, which used three preoperative placed locator (fiduciary) pins for registration, one placed in the operative hip and two placed in the area of the operative knee, ISS developed a second (2nd) generation ROBODOC® Surgical System, which used two preoperative placed locator (fiduciary) pins, one placed in the operative hip and one placed in the area of the operative knee. The third (3rd) generation ROBODOC® Surgical System, which is the subject of this 510(k) Premarket Notification, uses a patented (DigiMatch™) intraoperative registration technique that eliminates the preoperative placement of locator (fiduciary) pins.

1.3 Additional Information Required to Support 510(k) Clearance

After reviewing the DigiMatch™ ROBODOC® System Premarket Notification (K072629) FDA has requested that ISS provide:

1- Additional statistical analyses of the study results.

2- Such analyses to include a comparison to data generated from the First IDE Clinical Trial or a comparison to standard of care.

3- Additional information to demonstrate that the potential risks of longer surgical times and greater blood loss have been fully mitigated or are acceptable.

4- A risk/benefit analysis demonstrating that the potential benefits outweigh the potential risks.

1.4 Intent of Benefit/Risk Analysis

This submission will show through statistical and comparative analysis of the data from these trials and the standard of care, as represented in published literature, that the DigiMatch™ ROBODOC® System is substantially equivalent, and is safe and effective for its intended use. ISS believes that this Benefit/Risk Analysis demonstrates the device's benefits outweigh the potential risks identified by FDA.

DJA x00053

2. Background

2.1 General Information

Device Name:	DigiMatch™ ROBODOC® Surgical System
Applicant:	Integrated Surgical Systems, Inc. 1433 N. Market Boulevard, #1 Sacramento, CA 95834
Contact Person:	Russ Hibbert Director, Clinical & Regulatory Affairs Phone: 916-285-9943, ext. 522 Fax: 916-285-9104 E-mail: **rdhibbert@robodoc.com**

2.2 Indications for Use Statement

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch™ ROBODOC® Surgical System is indicated for orthopaedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

2.3 Device Description

The DigiMatch™ ROBODOC® Surgical System (System) consists of the 510(k)-cleared (K960685) ORTHODOC® Preoperative Planning Workstation (ORTHODOC), and a robot composed of an electromechanical arm, electronics control cabinet, display monitor and miscellaneous accessories (ROBODOC). The System (ORTHODOC and ROBODOC) is a three-dimensional graphical preoperative planner and implementation tool and is indicated as an alternative to template planning and manual broaching for treatment of patients who require primary total hip arthroplasty (THA). The ORTHODOC component of the System allows a surgeon to preoperatively assess a patient's femoral anatomy and state of hip disease, select an optimally sized femoral stem implant from a library of prostheses, and determine where the implant should be positioned within the femur. Then ROBODOC component of the System, under direct control of the surgeon, will precisely implement the preoperative plan.

DJA x00054

2.4 Regulatory Background

FDA concluded that the First IDE Clinical Trial, conduced under IDE # G920035, demonstrated efficacy of the ROBODOC technology. This was accomplished by showing that the preoperative plan that was planned by the surgeon using the ORTHODOC®, can be precisely implemented by the ROBODOC®. Thus the ROBODOC technology can achieve better fit, fill and alignment than can be attained using conventional THA procedures.

FDA also identified four, related potential risks: 1) two surgical procedures required for the pin-registration system; 2) postoperative ipsilateral knee pain; 3) longer surgical time; and 4) greater blood loss. The Second IDE Trial, conducted under IDE # G000071, was implemented at the request of FDA to demonstrate that the technological improvements of the pinless registration DigiMatch™ ROBODOC® Surgical System had substantially mitigated or eliminated these potential risks The technological improvements in the ROBODOC® System included the development of a patented registration technique (DigiMatch™), which eliminated the need for preoperative placement of locator (fiduciary) pins and new patented cutting technology that significantly improved the bone cutting performance of the System.

3.0 Summary and Statistical Analysis of First IDE Trial (G920035); Pin-Based ROBODOC System

The information presented in this section is a summary of the Final Report for IDE G920035, which was submitted to FDA in October 2000. This information was also provided to FDA in the March 15, 2007 submission.

3.1 Background

This multi-center clinical trial began in 1993 and ended in February 1996. It was performed with the 1st generation ROBODOC® Surgical System, which used 3 locator (fiduciary) pins. The 3 pins were placed in the patient's operative hip and knee during a separate surgery prior to the total hip arthroplasty (THA) surgery. These pins were used for spatial registration of the robot to the patient for subsequent bone cavity milling.

3.2 Objectives

The objectives of this clinical trial were to demonstrate that the ROBODOC® System was safe and effective for its intended use as an alternative to conventional manual surgical broaching techniques for femoral canal preparation in patients receiving cementless prostheses for primary THA. Occurrence of adverse events, measurements of radiographic parameters (i.e., fit, fill, position, precision and consistency) and clinical outcomes data were to be evaluated in all enrolled subjects to demonstrate clinical efficacy and safety of the surgical robot.

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3.3 Study Design

This study was a randomized (1:1), controlled trial conducted at three U.S. medical centers: Sutter General Hospital (Sacramento, CA), New England Baptist Hospital (Boston, MA), and Shadyside Hospital (Pittsburgh, PA). The trial consisted of 119 patients (136 hips) randomly assigned to either the ROBODOC® study group (n=71) or the manual broaching control group (n=65) for femoral canal preparation. Subjects were monitored for two years following surgery.

3.4 Effectiveness and Safety Endpoints

The primary endpoints intended to demonstrate system effectiveness were: fit, fill, and alignment of the femoral stem implant. These parameters were chosen as the best practical means of assessing the consistency and accuracy of femoral stem canal preparation and were evaluated by radiographic assessment. Other radiographic assessments included parameters that are widely recognized as indicators of a good clinical outcome for a cementless THA implant, including incidence and location of radiolucent lines, bone ingrowth, sclerotic lines, osteolysis, subsidence, hypertrophy, and stress shielding. The evaluation of efficacy also included an assessment of functionality and pain as measured by Harris Hip Score, Hip Society evaluations (Johnson) and the SF-36 scores for quality of life measures, which provide a measure of the clinical outcome.

The safety endpoints included the rate of intra-operative fractures, intra-operative and postoperative complications, and adverse events.

3.4.1 Effectiveness Results

The effectiveness of the ROBODOC® System was measured by assessment of qualitative radiographs (primarily to detect radiolucencies) and non-radiographic clinical data (Harris Hip Score, Hip Society evaluations, and SF-36 quality of life scores). The data were collected at 3, 6, 12, and 24 months. Results of the endpoint outcomes are discussed below.

3.4.1.1 Radiographic Review

Discussion

Quantitative radiographic assessment revealed significantly better fit and fill for the ROBODOC group. The ROBODOC group prostheses were seated significantly closer to the proximal femoral neck osteotomy than prostheses for the control group. The ROBODOC group also had significantly better alignment (varus-valgus, anterior-posterior). No difference was detected between the two groups in the location (centering) of the distal prosthesis tip. Quantitatively, there was significantly less radiolucency for the ROBODOC group in five of the Gruen Zones (predefined measurement areas). The quantitative and qualitative assessments were performed by an independent radiologist.

Results – Three-Month Follow-up

Fit (Closer Cortical Bone to Prosthesis Distance)
Analysis of the frequency of levels with ≤ 2mm fit demonstrated a statistically better fit in the ROBODOC group compared to the control group (chi-square, p=0.001).

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Fill (Canal Filling of the Prosthesis)
Analysis of the frequency of levels with ≥ 90 percent fill demonstrated statistically better fill in the ROBODOC group compared to the control group (chi-square, p=0.01).

Alignment (Varus-Valgus, Anterior-Posterior)
The average alignment (in absolute value) for the ROBODOC group demonstrated statistically better alignment in the ROBODOC group compared to the control group (unpaired t-test, AP film: p=0.02; lateral film: p=0.04).

Axial Seating (Prosthesis Distance from Neck Cut)
The average axial seating distance for the ROBODOC group was significantly less that the control group's average (unpaired t-test, p=0.01).

Neocortex (Radiolucency)
There was no evidence of a neocortex present for any patient.

Distal Tip Displacement and Direction
There was no statistical difference in the displacement of the distal tip of the prosthesis and the center of the canal, between the ROBODOC and control groups.

Proximal Medial Fit
The proximal medial fit of the ROBODOC group was statistically higher than the control group (chi-square, p=0.001).

Femoral Fractures
Three intraoperative fractures were reported in the control group (5%), while no intraoperative fractures were reported in the ROBODOC group. The three-month radiographic review detected one additional femoral fracture in the control group and no femoral fractures in the ROBODOC group.

Conclusion

The radiographic review demonstrated that the ROBODOC® Surgical System provides a significant improvement in femoral stem implant fit, femoral cavity fill and implant alignment in the femoral canal compared to manual reaming and broaching procedures. This improvement is clinically relevant because it helps surgeons achieve better fit, fill and position more reliably, accurately and consistently. Currently, surgeons strive to achieve these objectives with manual broaching techniques as well. Additionally, the data demonstrate that the robot can precisely and reliably implement the preoperative plan.

3.4.1.2 Non-Radiographic Clinical Data

The non-radiographic clinical endpoint for the First IDE Trial was the Harris Hip Score (HHS), which is designed to evaluate outcomes after primary THA. Additionally, the Hip Society (Johnson) Scores and the SF-36® Health Survey self-assessment scores were collected as secondary efficacy endpoints. For the Harris Hip Score, Hip Society (Johnson) Scores and SF-36® Health Survey, a higher score indicates a better outcome. These clinical measures were collected at baseline (prior to surgery) and at 3, 6, 12, and 24 months after surgery. Data from these assessments are discussed below.

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3.4.1.2.1 Harris Hip Scores

The Harris Hip Score showed that postoperatively the ROBODOC and control groups had similar outcomes. The mean Harris Hip Score at 3 months averaged 79.9 for the ROBODOC group and 80.3 for the control group. At 6 and 12 months the average score was 85.3 and 89.4 for the ROBODOC group and 85.5 and 86.5 for the control group, respectively. Additionally, the average improvement from baseline at 6 and 12 months was 35.5 and 39.1 for the ROBODOC group and 33.6 and 34.8 for the control group, respectively. Similar improvements from baseline at 2 years were observed in both groups. The ROBODOC group had slightly better overall improvement than was seen in the control group.

3.4.1.2.2 Hip Society (Johnson) Scores

Comparable results were demonstrated in the Hip Society Scores between the ROBODOC and control group. The data show that 94% (44/47) of the ROBODOC group and 88% (38/43) of the control group patients rated their pain index lower at 12 months after the surgery. The ROBODOC® System shows slightly better results.

3.4.1.2.3 SF-36 Quality of Life Scores

SF-36 data were collected at 3, 6, 12, and 24 months. The mean scores at 3, 6, 12, and 24-months for the ROBODOC group were 65.7, 72.8, 78.6 and 78.1 respectively. The mean scores at 3, 6, 12 and 24-months for the control group were 68.2, 76.1, 76.3 and 76.7 respectively. The ROBODOC group showed slightly better results than the control group.

3.4.2 Safety Results

Although there were four potential surgical risks identified with the use of the ROBODOC® System in the First Clinical Trial, the study nevertheless demonstrated that the investigational device was effective and generally safe for its intended use. There were no serious ROBODOC related complications. There were no intra-operative fractures in the study group, however, there were 3 intra-operative fractures reported in the control group. The four identified potential risks associated with the ROBODOC procedure were:

1. Need to perform a separate preoperative procedure to implant the locator pins for registration of the affected femur;

2. Post-surgical ipsilateral knee pain;

3. Longer surgical time; and

4. Increased intraoperative blood loss.

There were no significant adverse events or sequelae attributed to the identified risks. The safety results, including potential risks and adverse events, are discussed below.

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3.4.2.1 Locator Pin Implantation

Patients in the ROBODOC group were required to undergo a preoperative procedure to implant the locator pins for registration of the affected femur. This procedure was usually performed under local anesthesia in an outpatient surgical setting within 24 hours of the THA. There were no reported adverse events attributed to this additional procedure. To address this issue, ISS developed the "pinless" registration technology that eliminated the need for two surgical procedures.

3.4.2.2 Postoperative Ipsilateral Knee Pain

Ipsilateral knee pain has been reported for patients requiring THA. Some knee pain reported in this Clinical Trial may also be associated with pin implantation. **Table 1** shows the incidence of ipsilateral knee pain in the First IDE Trial.

Table 1: Ipsilateral Knee Pain

	6 wks.	3 mos.	6 mos.	12 mos.	24 mos.
ROBODOC®	57%	46%	28%	28%	22%
Control Group	12%	22%	20%	16%	17%
Difference	45%	24%	8%	12%	5%

To address this issue, ISS developed the "pinless" registration technology (DigiMatch™), which was designed to eliminate the potential risk of ipsilateral knee pain attributed to locator pin implantation.

3.4.2.3 Longer Surgical Time

Data collected on the clinical systems showed mean length of primary THA surgery to be 258 minutes for the ROBODOC group and 134 minutes for the manually broached group. The First Clinical Trial was not specifically controlled for surgical time. The surgeons preceded with the ROBODOC procedures in a manner that focused on procedure and outcome, rather than overall surgical time. The increased surgical time associated with the ROBODOC® System primarily can be attributed to pin-based registration technology, inadequate emphasis on controlling the surgical time and the "intrigue" with the innovative robotic technology. There were no complications or adverse events associated with the increased surgical time in this Clinical Trial.

3.4.2.4 Increased Estimated Blood Loss

The mean estimated rate of blood loss for the ROBODOC group was 4.5 ml/min (1189.4 ml total) compared to 4.8 ml/min (644 ml total) for the control group. This indicates that the rate of blood loss is similar for both methods. The increased amount of total estimated blood loss in the ROBODOC group was related to the longer surgical time. There were no complications or adverse events associated with blood loss in this Clinical Trial.

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3.4.2.5 Complications and Adverse Events

In reviewing the data it was noted that the ROBODOC group had lower intraoperative fracture and postoperative hip dislocation rates than the control group. It was also noted that in the ROBODOC and control groups had similar rates of complications and adverse events. Intraoperative and postoperative complications and adverse events are summarized in **Table 2**.

Table 2: Surgery-Related Events Resulting in Complications and Adverse Effects

Complication	ROBODOC®	Control Group
Intraoperative fractures	0 (0%)	3 (5%)
Postoperative hip dislocation	3 (4%)	5 (10%)
Infection	2 (3%)	1 (2%)
Deep vein thrombosis (DVT)	1 (2%)	1 (2%)
Pulmonary embolism	0 (0%)	1 (2%)
Over-reaming*	1 (1%)	0 (0%)
Detachment of implant coating†	1 (1%)	0 (0%)

* In the case where over-reaming was reported, the medical monitor's investigation suggests that during preoperative planning the surgeon may have chosen an implant that was too large for the canal size. The ROBODOC® System executed the preoperative plan as designed. There was no device malfunction.

† Not device related as failure of implant coating was not caused by or due to the ROBODOC® device.

3.4.2.6 Device Malfunctions

Two of the ROBODOC surgeries were completed manually because of device malfunctions: a tool cone/pin extender error occurred in one case and a pin-finding problem occurred in the other case. Several other minor device malfunctions occurred, but the surgeries were not aborted. These problems included: 1) the proximal locator pin required re-insertion preoperatively; 2) the proximal pin was relocated; 3) vein laceration occurred during "halo pin" installation; 4) the proximal pin stripped out of the bone; 5) the pin driver became stuck in the locator pin head and had to be forcefully separated; 6) computer problems occurred during pin finding; 7) and the robot required pin recalibration during surgery. All of these malfunctions were related to the pin-based registration technology. Since the DigiMatch™ system does not use pins; these malfunctions are no longer a concern.

Two-year follow-up data showed that there was no statistical difference in operative complications or outcome parameters between the study and the control groups.

3.5 Reduction in Intraoperative Fracture Rate

Intraoperative fracture is a potential complication of THA surgery. The medical literature reports fracture rates ranging from 3% to 28%, but clinical outcome results are likely to be worse for low-volume surgeons. (Refs. 1-13). The ROBODOC group had an intraoperative fracture rate of 0% (0/71), compared to 5% (3/65) for the manually broached group. This difference was not statistically significant. There was also one additional fracture noted by the radiologist at 3 months post-op in the control group. None were identified in the ROBODOC group. The total number of fractures in the control group was four (4); however there were no intra-operative or post-operative fractures in the ROBODOC group.

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3.6 Discussion

In the First IDE Trial functionality and pain, as measured by Harris Hip Score, Hip Society evaluations, and SF-36 quality of life scores, showed that there were no statistically significant differences between the ROBODOC and control group at two years.

The ROBODOC® System demonstrated that it accurately, precisely, reliably and consistently implements the preoperative surgical plan. Results showed fewer intraoperative fractures in the ROBODOC group (0%) compared to the control group (5%). Radiographic assessment also showed that the ROBODOC group had significantly better fit, fill and alignment of the femoral stem implant, significantly better axial seating, and significantly better proximal medial fit compared to the control group. These assessments are widely recognized as indicators of a good clinical outcome for a cementless THA implant, including incidence and location of radiolucent lines, bone in-growth, sclerotic lines, osteolysis, subsidence, hypertrophy, and stress shielding. Achieving precise femoral canal preparation is clinically relevant because most surgeons strive for optimal fit and alignment as an objective of manual broaching.

3.7 Conclusions

1. Results of the First IDE Clinical Trial demonstrate that the ROBODOC® System was effective in performing its intended use.
2. There were four potential risks identified by FDA:
    1. Need to perform a separate preoperative procedure to implant the locator pins for registration of the affected femur;
    2. Postoperative ipsilateral knee pain;
    3. Longer surgical time; and
    4. Increased intraoperative blood loss.
3. There were no significant adverse events or sequelae associated to those identified potential risks.
4. There were no significant adverse events or sequelae reported in the trial.
5. Function and pain assessments, using the ROBODOC® technology, compare favorably to manual broaching.
6. The ROBODOC group had a reduction in intraoperative fracture rates compared to the control group (0% vs. 5%, respectively).
7. The ROBODOC® technology provided significantly better postoperative fit of the femoral stem implant (chi-square, $p=0.001$).
8. The ROBODOC® technology provided significantly better postoperative fill of the femoral canal (chi-square, $p=0.01$).
9. The ROBODOC® technology provided significantly better postoperative alignment of the femoral stem implant (unpaired t-test, AP film: $p=0.02$; lateral film: $p=0.04$).

The ROBODOC® System performed effectively during its intended use.

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4. Summary and Statistical Analysis of Second IDE Trial (G000071); Pinless ROBODOC® System

4.1 Background

Results from the ROBODOC® System's First IDE Clinical Trial identified four potential risks associated with the use of the pin-based registration technology. There were no long-term complications or sequelae associated with the potential risks. After discussions with FDA, ISS designed and conducted the Second IDE Trial (G000071) to demonstrate that the pinless registration technology, called DigiMatch™, had substantially mitigated or eliminated the potential risks identified in the First IDE Trial. During subsequent discussions with FDA, ISS was informed that results from the First IDE Trial were considered sufficient to demonstrate the ROBODOC® System performed effectively during its intended use.

4.2 Objective

The primary objective of the Second IDE Clinical Trial was to show that the pinless registration DigiMatch™ ROBODOC® Surgical System is safe for its intended use as a surgical tool indicated for preoperative planning and femoral canal preparation in primary THA. The secondary objective was to demonstrate that potential risks identified in the First IDE Trial had been eliminated or mitigated. The third objective was to confirm efficacy of the ROBODOC® technology by comparing results of Harris Hip Score outcomes.

4.3 Study Design

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[redacted]

4.4 Patient Population and Disposition

(b) (4)

[redacted]

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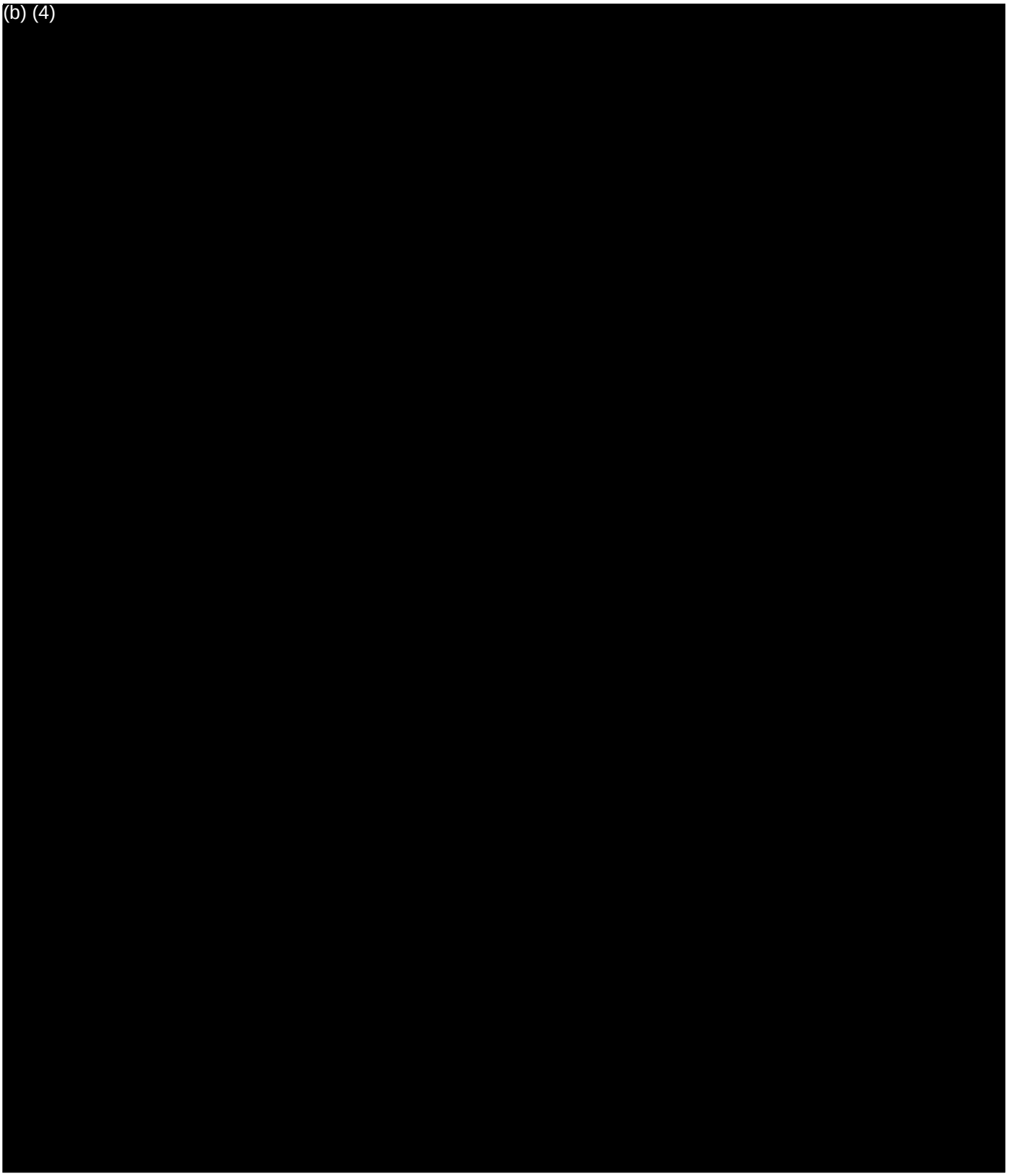

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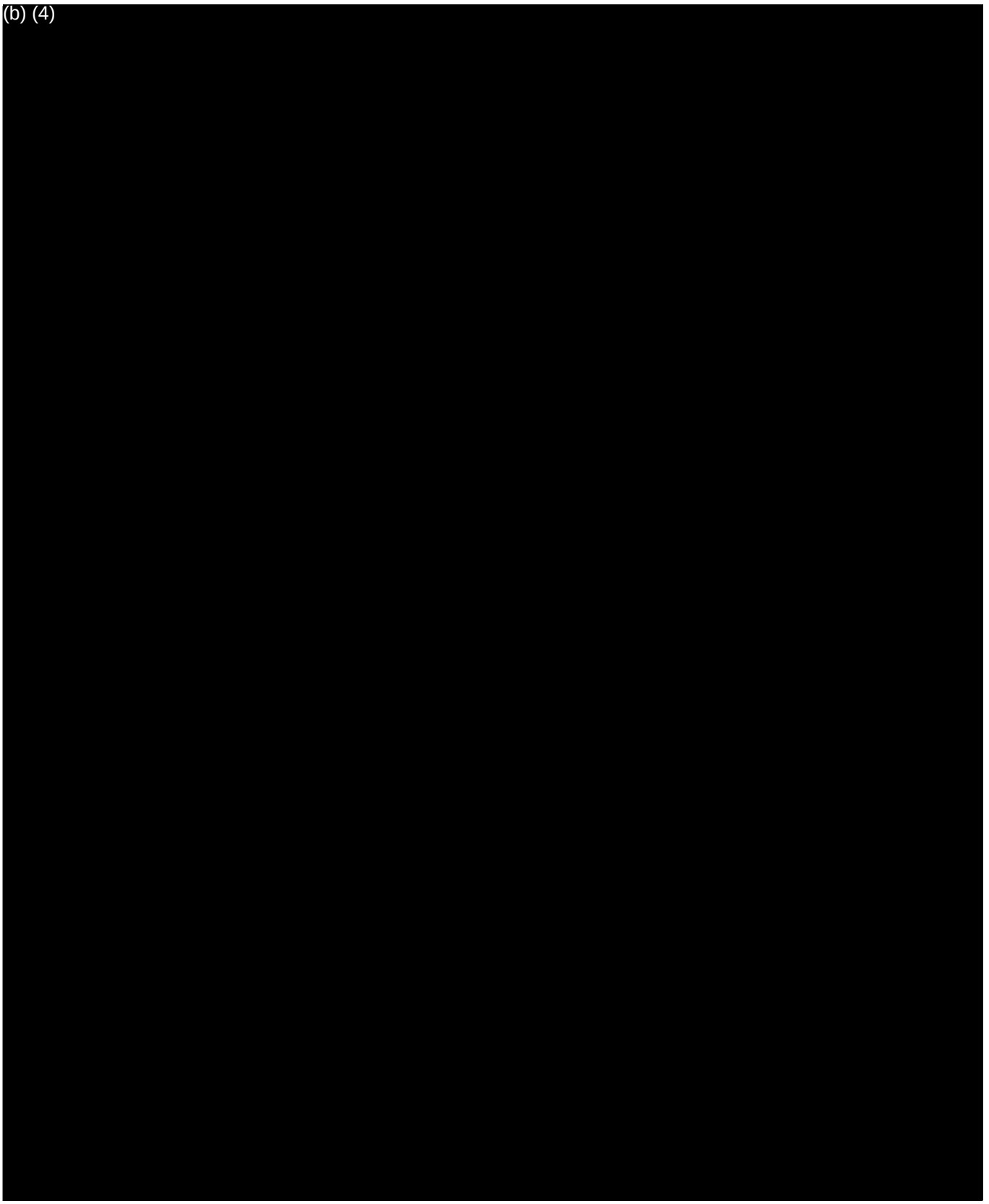

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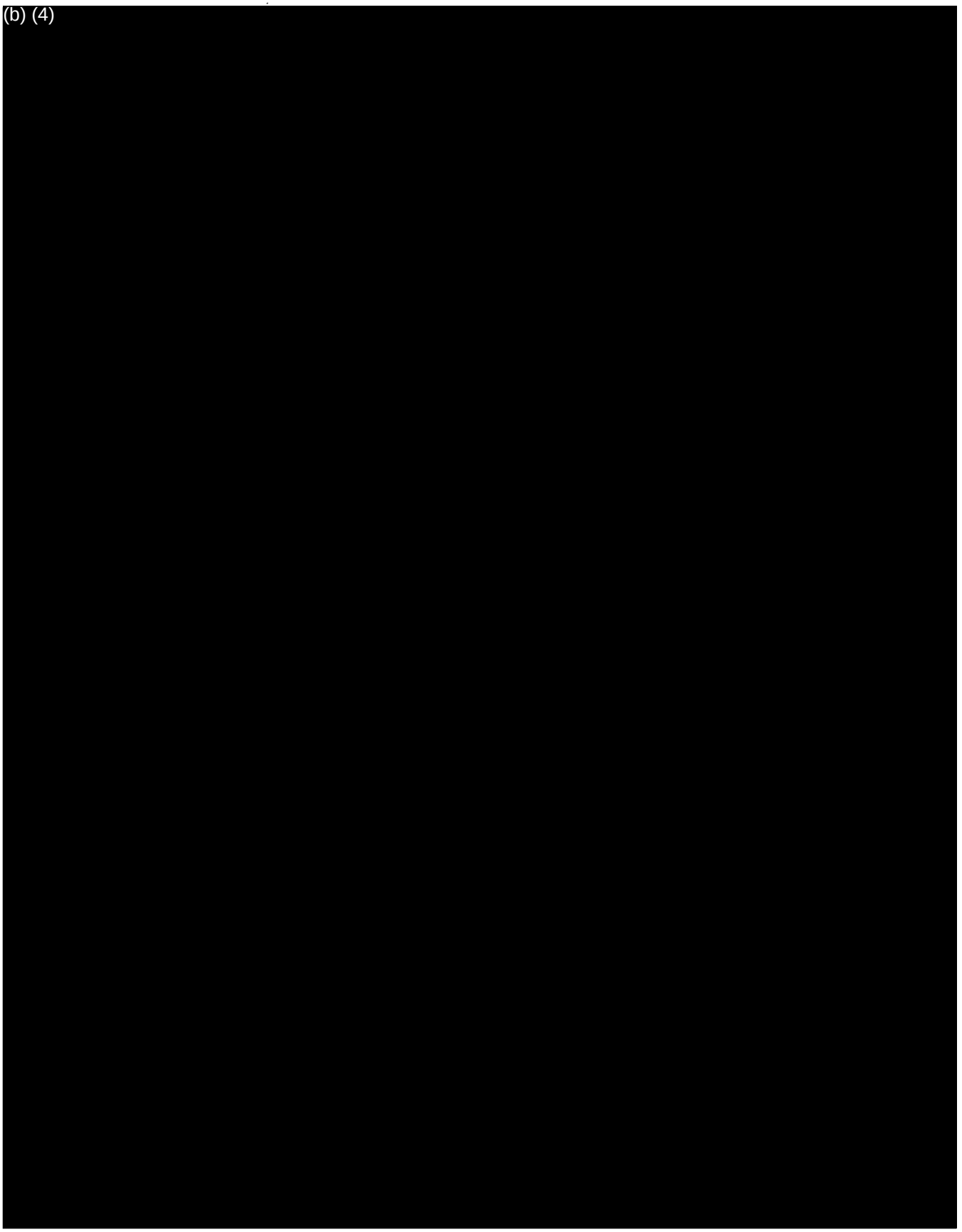

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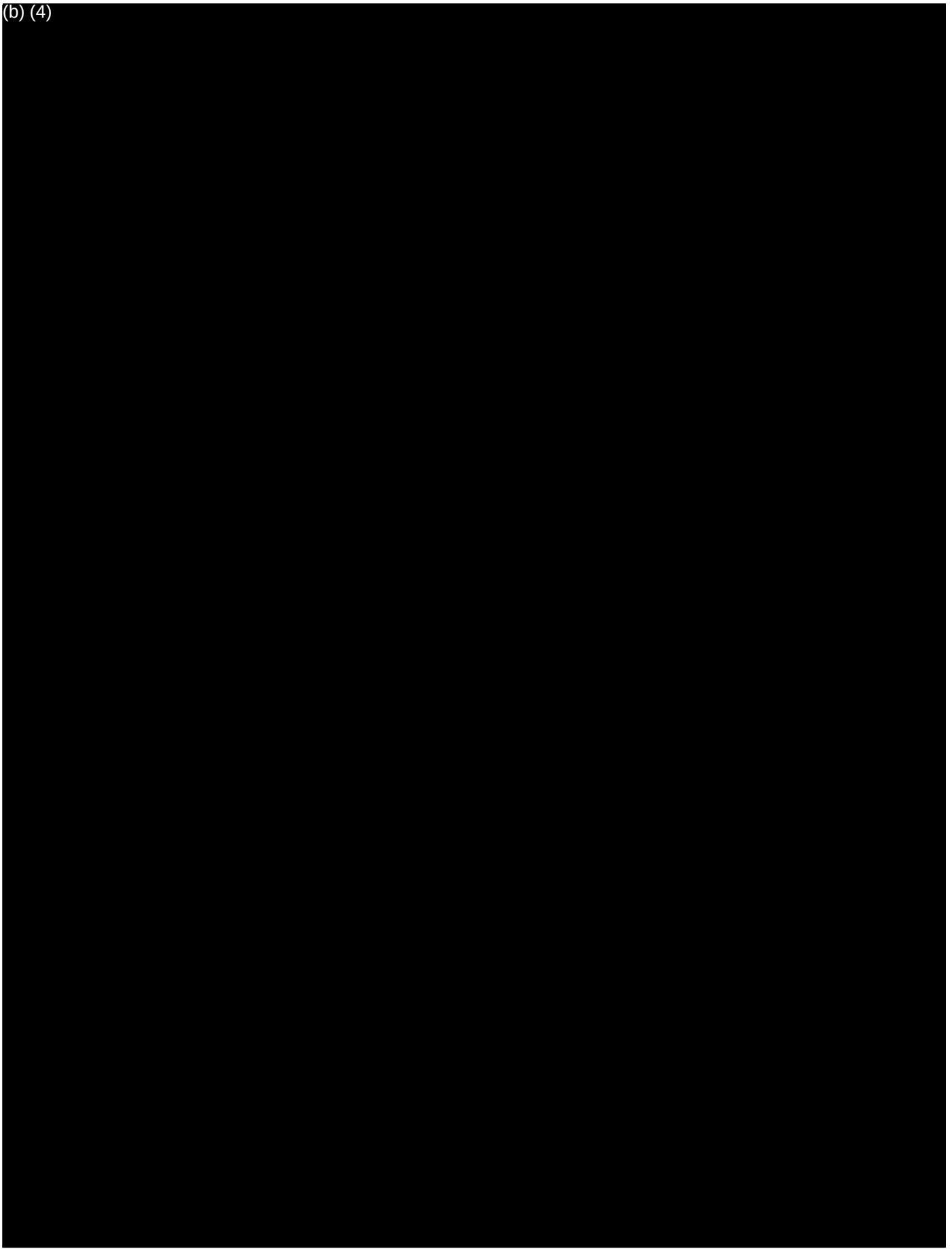

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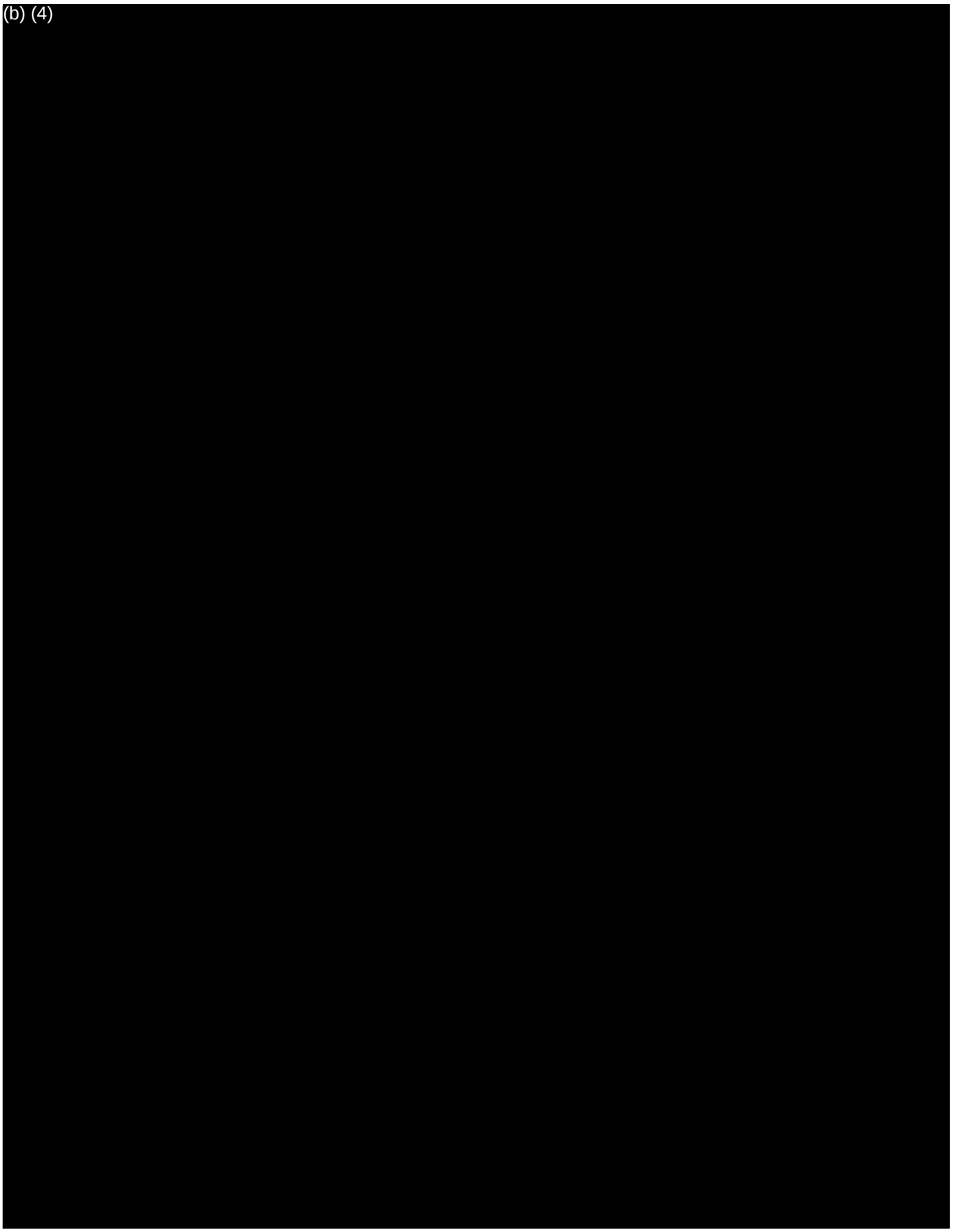

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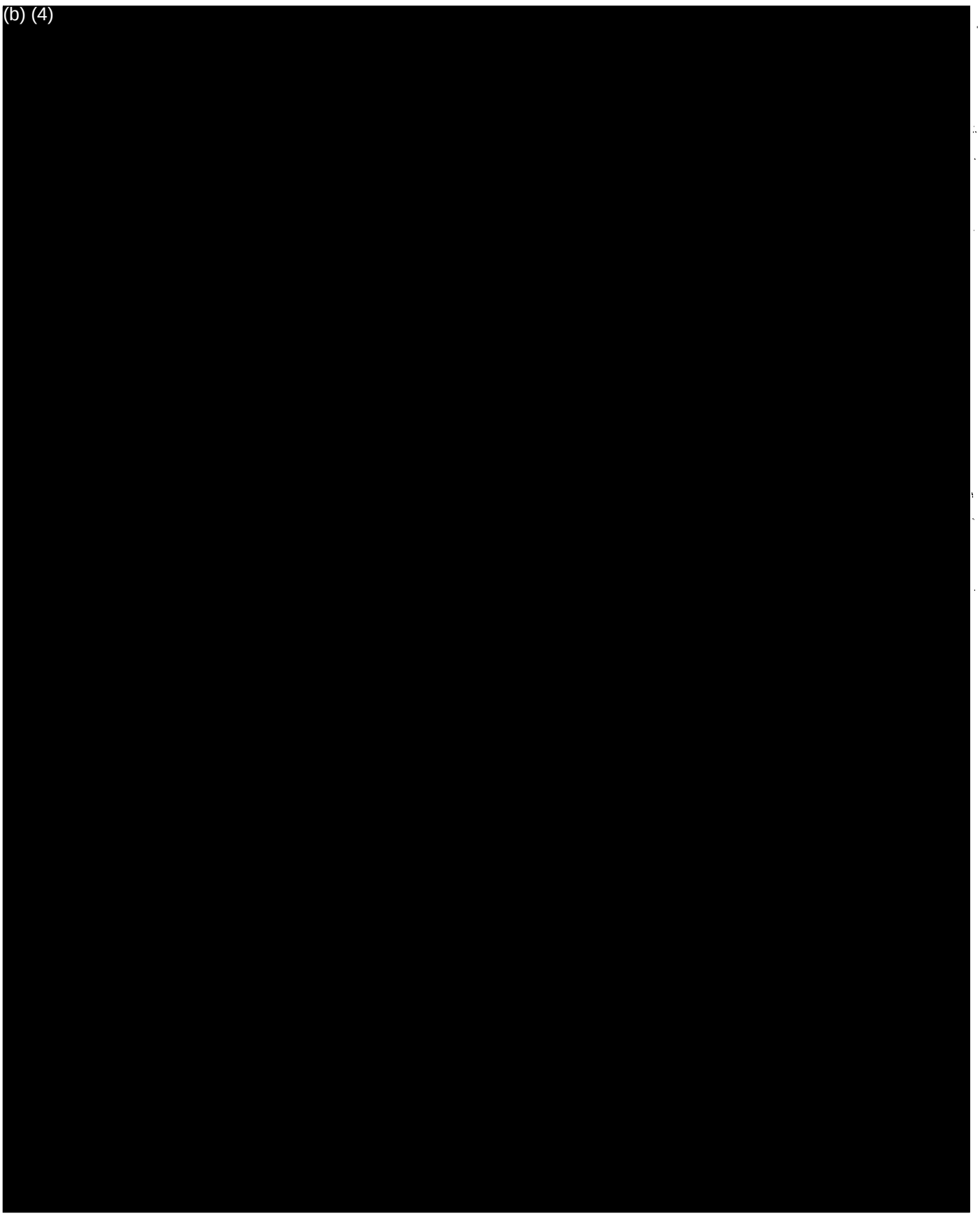

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(b) (4)

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5. Practices and Procedures Comparison

Primary total hip arthroplasty is conducted fundamentally in the same manner with conventional tools or computer added tools such as the DigiMatch™ ROBODOC® System. All computer guide systems add a few extra steps and time to the procedure [14, 15]. While these steps add time to the procedure, they can reduce intra-operative complications and help ensure predictable outcomes. This is fundamentally accomplished by requiring some sort of pre-surgical planning which alerts the surgeon to possible complications, as well as helping the surgeon achieve the desired outcome from the surgical procedure based upon that plan.

5.1 Conventional Primary Total Hip Arthroplasty

Conventional primary total hip arthroplasty (THA) has traditionally been planned using radiographs with film acetate overlays and performed using manual tools. The major steps of the procedure can be defined as follows:

1. Planning
2. Patient Set Up
3. Surgical Exposure
4. Stem Cavity Preparation
5. Cup Preparation
6. Surgical Verification
7. Implantation
8. Exposure Close

1. Planning

The surgeon formulates a surgical plan prior to the operation. This is usually done using 2D acetate overlays provided by the implant manufacturer. These acetates are selected and matched up against x-ray images of the patients' femur for size that appears to fit well in the medullar canal. Optimal implant (stem and cup) selection, placement and orientation cannot be precisely determined using this 2D method and therefore much depends upon the surgeons' re-evaluations and judgment during the surgery.

2. Patient Set Up

The surgical staff prepares the OR by setting up the equipment to be used during surgery and then the patient is brought to the operating room, prepared, anesthetized and positioned for surgery.

3. Surgical Exposure

The surgeon makes the appropriate incisions exposing the patient's operative femur.

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4. Stem Cavity Preparation

Using manual tools and battery powered tools such as saws, reamers, drills and broaches the surgeon removes the femoral head and creates the implant (stem) cavity to accept the chosen implant. Generally speaking most surgeons attempt to create a cavity that achieves a reasonable fit while maximizing surface contact between the implant and bone. In addition they attempt to place the cavity such that the implant when placed into that cavity is positioned and aligned properly maintaining the patient's natural anatomical relationships. Consistently achieving the "best fit", sizing, placement and orientation is difficult using conventional tools.

5. Cup Preparation

After completing the stem cavity the surgeon prepares the Acetabulum. The acetabular cavity is created using battery powered cutting tools designed to prepare the pelvis to accept the acetabular prosthesis component.

6. Surgical Verification

The final broach is used as a trial. The trial implant femoral (stem) and acetabular (cup shell) components are placed. The surgeon evaluates these components for size, fit, placement, and evaluates the hip for range of motion, overall alignment, and leg length. The surgeon makes any required adjustments based upon his assessment.

7. Implantation

The final trial component is removed and the new femoral component set and acetabular insert are fixed into position. With the replacement implants in place the surgeon revaluates the hip prostheses for size, fit, placement, and revaluates the hip for range of motion, overall alignment, and leg length.

8. Exposure Close

The surgeon makes any required adjustments based upon his assessment and then closes the incision.

To address the difficulties in achieving proper implant selection, fit, position and alignment for the stem as well as placement of the acetabular component the surgeon may elect to use one of the many FDA cleared pre-surgical planning and computer-assisted, image-guided navigation systems.

5.2 THA Procedure using the DigiMatch™ ROBODOC® System.

Using the DigiMatch™ ROBODOC® System the surgeon can optimally select and achieve precise fit, position and alignment of the implant cavity to plan.

When using the DigiMatch™ ROBODOC® System in primary THA the surgeon follows the same major procedural steps. However, use of the system, as with any FDA cleared computer-assisted, image-guided systems, does add a few extra steps. The major THA procedural steps using the DigiMatch™ ROBODOC® System are as follows:

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1. Planning
2. Patient Set Up
3. Surgical Exposure
4. Fixation
5. Registration
6. Stem Cavity Preparation
7. Cup Preparation
8. Surgical Verification
9. Implantation
10. Exposure Close

1. Planning

Precisely plans the surgical procedure using 3D patient specific images and 3D implant templates

2. Patient Set Up

The surgical staff prepares the OR by setting up the equipment to be used during surgery.

Setting the robot up for surgery is and additional step that consists of a verification of robot operation directly before use. This is done both in the non-sterile and sterile system state. The non-sterile steps must always be completed prior to the start of surgery. The patient is brought to the operating room, prepared, anesthetized and positioned for surgery. The sterile system checks may be done before during or after surgical exposure depending on the OR staff and their intra-operative routines. However, all checks must be completed before use of the system is allowed.

3. Surgical Exposure

The surgeon makes the appropriate incisions exposing the patient's femur.

4. Fixation

Dislocating the femoral head from the Acetabulum the surgeon brings the ROBODOC system to the patient on the operating table. The position of the Robot and the patient are stabilized. Safety devices are attached and verified.

5. Registration

This step can be sub divided into two parts: 1- Finding where the patient (femur) is, then 2- Verifying the system has correctly found the patient (femur). These two parts are called registration and registration verification.

Registration is achieved by gathering a series of points on the operative femur. Then using those points the software determines the exact position of the patient (femur) on the operating table.

Registration Verification is determined by asking the surgeon to find points on the femur, having the system display where it has calculated those points are and then having the surgeon verify if

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the system calculation is correct. If the surgeon verifies that the system has calculated correctly registration is verified and complete. The surgeon can now proceed to cavity preparation.

6. Stem Cavity Preparation

Instead of using manual tools such as battery powered electric saws, reamers, drills and broaches to create the implant cavity the surgeon guides the Robot to top of bone to be cut. Then under direct surgeon control the robot precisely mills the cavity as planned to accept the chosen implant eliminating concerns about proper fit, fill and alignment to plan. When cavity preparation is completed the robot is removed from the surgical field and the femoral head is removed in the conventional manner.

7. Cup Preparation

After completing the stem cavity preparation the surgeon prepares the acetabulum. The acetabular cavity is created using battery powered cutting tools designed to prepare the pelvis to accept the acetabular prosthesis component.

8. Surgical Verification

Trial components are removed and the new femoral and acetabular prostheses are fixed into position. With the replacement implants in place the surgeon revaluates the hip prostheses for size, fit, placement, and revaluates the hip for range of motion, overall alignment, and leg length.

9. Implantation

Trial components are removed and the new femoral and acetabular prostheses are fixed into position.

10. Exposure Close

The surgeon closes the incision.

The DigiMatch™ ROBODOC® System is designed to allow the surgeon to precisely and consistently plan and implement his surgical intent. Because the exact femoral implant size and femoral implant location was selected and determined preoperatively, using the 3D images of the implant and the patients anatomy on the ORTHODOC component of the system the surgeon can plan with greater accuracy and detail. The ROBODOC component of the system precisely and gently implements the surgical plan with minimal trauma, less risk of cavity preparation factures, and significantly reduced risk of implant mal-alignment or positioning.

5.3 Surgical Time Breakdown

Table 8 compares the surgical times of the First and Second IDE Clinical Trials. In the First Clinical Trial the mean difference in surgical time between ROBODOC and control (manual) group was 124 minutes. In the Second Clinical Trial the mean difference between ROBODOC and control group was reduced substantially to (b) (4) primarily as a result of the elimination of pins and improvements in cutting (cavity preparation) time.

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Table 8 Comparison of Surgical Times: First and Second IDE Clinical Trials

	First IDE Trial			Second IDE Trial		
	ROBODOC n=71	Control n=65	Difference	ROBODOC n=79	Control n=25	Difference
Length of Surgery (min.)	258	134	124	(b) (4)		

Comparing the time differences for each of the major steps between DigiMatch™ ROBODOC® and controls (conventional manual) groups in the Second IDE Trial (**Table 9**) it is seen that the actual difference in mean cutting time is (b) (4) Most of the extra time is consumed in setup, fixation and registration.

Table 9 Comparison: Incremental Times of Major ROBODOC and Manual THA Procedures Steps (Second IDE Clinical Trial)

	ROBODOC n=79	Manual n=25	Difference
Set Up Time	(b) (4)		
Fixation			
Registration			
Milling (Cutting)			
Total Time			

The following discusses further each of these incremental times:

Set-Up Time

Setting the robot up for surgery is a step that does not exist using manual tools and consists of a verification of robot operation each time before use. This is done both in the non-sterile and sterile system state. During this clinical trial the sterile system checks were not routinely completed prior to surgical incision and thus this step added a mean of (b) (4) extra to surgery time.

Fixation

Fixation is a step that does not exist when using manual tools. This step involves moving the robot to table and then docking it with the patient on the OR table. This process often requires adjusting of the OR table and patient positioning.

Registration

Registration is a step you do not have in manual procedures, however it is a required step for all FDA cleared computer-assisted, and image-guided navigation systems. While these procedures typically add 10 to 20 minutes [14, 15] to surgery time the ROBODOC system added on average (b) (4)

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Milling (Cutting)

The cavity milling (cutting) times between the ROBODOC and control groups were similar a(b) (4) minutes respectively. The difference was (b) (4).

6. Potential Benefits; Review and Discussion of Clinical Data

There are a number of clinical studies in the US, Europe and Asia, that have been conducted using the ROBODOC® System. These studies establish the medical suitability of the ROBODOC® System and also provide an understanding of the benefit/risk for patients that elect ROBODOC assisted THR surgery. The medical benefits of the ROBODOC® System are clear and well documented. The following is a brief summary of the clinical data establishing the medical suitability of the ROBODOC® System.

6.1 *Summary: Report of U.S. Multi-center Clinical Trial IDE#G920035. Submitted to FDA, October 20, 2000.*

In the first multi-center clinical trial conducted in the U.S. from 1992-1996, 136 hips were randomly assigned to either the ROBODOC test group (n=71) or the manual broaching control group (n=65). The follow-up period was 2 years. The result from this trial show similar complication rates between the two groups:

	Robot n=71	Control n=65
DVT	2%	2%
Nerve Palsy	1%	4%
Dislocation Rate	4%	10%
Fractures	0%	5%

However, ipsilateral knee pain was higher for the ROBDOC group (22% at 12 months) compared to the control group (17% at 12 months), probably due to the early placement of the pre-surgical registration pins. Estimated blood loss was higher for the ROBODOC group (Mean 1189.4 ml) compared to the control group (Mean 644 ml), probably due to the longer surgery times encountered during the early trials for the ROBODOC group (mean 258 min.) as compared to the control group (Mean 134 min). The ROBODOC group had zero intra-operative fractures, where as the control group had a 5% fracture rate. The ROBODOC group had significantly higher scores for proximal fit and fill ($p<0.002$) and for alignment ($p<0.04$). Finally, at 24 months, there was no significant difference between ROBODOC and control group Harris hip scores.

Summary: Results at 24 months showed that hips from the ROBODOC group had significantly better fit, fill and alignment; however Harris hip scores were about the same for both groups. Intra-operative complications (side effects) were about the same for both groups; with the ROBODOC group reporting no intra-operative fractures as compared 3 for the control group. There were no adverse events reported related to increased surgical times or blood loss.

DJA x00078

6.2 *Rechnerunterstutzter Robetereisatz in der Huftendoprothetik. M. Boerner, A. Bauer and A. Lahmer, Orthopade (1997) 26:251-257*

A independent retrospective follow-up study of 465 patients operated using the 3-pin based ROBODOC system was completed by BGU Frankfurt which also reported a 0 fracture rate and no specific complications related to ROBODOC assisted surgery. The surgeons were able to realize exact execution of the pre-operative plan using the ROBODOC system. Follow-up evaluations using Harris hip scores were similar to the 1st U.S. IDE Trial (IDE#G920035). Surgery time declined rapidly, from 205 minutes initially, to about 90 minutes at the end of the study.

Summary: This study also showed no additional complications (side effects) related to the use of ROBODOC system for THR. The disadvantage reported was the additional surgery required for pin-implantation. Surgery time, using the ROBODOC system, at the end of the study was 90 minutes, which is comparable to manual operating times. There were no intro-operative fractures reported in this large series of 465 patients.

6.3 *Primary and Revision Total Hip Replacement Using the ROBODOC® System. William L. Bargar, MD Andre Bauer MD and Martin Boerner, MD, Clinical Orthopedics and Related Research, 1998, No 345 pp82-91*

Another independent larger retrospective follow-up study of 900 patients was completed by BGU-Frankfurt. The results showed exact execution of the pre-operative plan by the ROBODOC system (deviations less than 1 mm and 1 degree) with zero intra-operative fractures.

At the 24-month follow-up point of 61 patients, the mean Harris hip score was 91.5. Final surgery times at the end of the study were reported to be from 90 to 100 minutes – about 30 minutes longer then manual THR at the hospital.

Summary: This study also showed that complications (side-effects) related to the use of the ROBODOC system for THR were no different than for manual THR surgery. The disadvantage reported was the additional surgery required for pin-implantation. Surgery time, using the ROBODOC system, at the end of the study was 90 minutes, which is comparable to routine manual operating times. There were no intra-operative fractures reported.

6.4 *Stress Shielding in Cementless THR; A DEXA study comparing ROBODOC vs. Conventional Surgical Techniques. W Bargar, T. Blumenfeld, Abstract from Poster presented at ISTA 1999 Symposium*

An independent retrospective study on 40 patients that underwent THA surgery in the First IDE clinical trial using the ROBODOC system at Sutter General Hospital U.S. was completed by Dr. W. Bargar. In this study, BMD (bone mineral density) was measured using a DEXA scanner at patient discharge time and at 2 years follow-up. There were 20 patients each in the ROBODOC and control groups. In proximal Gruen zones 1 and 7, the BMD Ratio at 2 years follow up was found to be higher for the ROBODOC group (0.80 and 0.84) than for the control group (0.92 and 0.68). The values were statistically significant for zone 1 ($p= 0.03$) and for one of the implant types for zone 2 ($p=0.006$). For all other zones, the BMD measured was always higher for the ROBODOC group than for the manual group.

DJA x000079

Summary: Use of the ROBODOC for THR achieves significantly less stress shielding in the proximal Gruen zones 1 and 7.

6.5 ***Effect of robotic milling on periprosthetic bone remodeling; Takehito Hananouchi [1]*, Nobuhiko Sugano [1], Takashi Nishii [1], Nobuo Nakamura [2], Hidenobu Miki [1], Akihiro Kakimoto [2], Mitsuyoshi Yamamura [2], Hideki Yoshikawa [1]***
[1]Department of Orthopedic Surgery, Osaka University Graduate School of Medicine, Osaka, Japan [2]Center of Arthroplasty, Kyowakai hospital, Osaka, Japan
J Orthop Res 25:1062-1069, 2007

The ROBODOC system has provided better fit and fills of the stem and less destruction of the bony architecture than with manual surgery. These benefits might affect femoral periprosthetic bone remodeling. We evaluated the effects of robotic milling in cementless total hip arthroplasty (THA) in a longitudinal 24-month follow-up study using dual energy X-ray absorptiometry (DEXA) and plain radiographs of 29 patients (31 hips) after ROBODOC THA and 24 patients (27 hips) after manual THA with the same stem design. To minimize the influence of other factors on bone remodeling, only female osteoarthritis patients, who had no drugs that might affect bone metabolism were enrolled. Significantly less bone loss occurred at the proximal periprosthetic areas in the ROBODOC group. In zone 1, the decrease was 15.5 versus 29.9% using conventional rasping; in zone 7, the loss was 17.0% with ROBODOC compared to 30.5% with conventional rasping ($p < 0.05$). On radiographs, endosteal spot welds in the proximal medial portion were more pronounced in the ROBODOC group (48 vs. 11% in the conventional group, $p < 0.05$). Our results suggest that robotic milling is effective in facilitating proximal load transfer around the femoral component and minimizing bone loss after cementless THA.

Summary: Use of the ROBODOC for THR achieves significantly better load transfers minimizing bone loss after cementless THA.

6.6 ***Comparison of robotic assisted and manual implantation of a primary total hip replacement. A prospective study. Honl M, Dierk O, Gauck C, Carrero V, Dries s, Quante M, Schwieger K, Hille E, Morlock MM, J Bone Joint Surg. Am 2003 Aug; 85-A(8):1470-8***

A independent prospective study using 154 hips surgeries was completed by Honl et al. In this study there were 80 patients in the manual group and 74 patients in the ROBODOC group. This study showed an unusually high rate of dislocation (18%) for the patients in the ROBODOC group. Also, this site has an unusually high rate of surgery aborts and conversion to manuals for the ROBODOC group (17.6%). There was a high revision rate for the ROBODOC group, as many of the dislocations had to be revised. Other complication rates were not significantly different between the groups. The ROBODOC group had significantly smaller leg length difference (mean of 0.18 cm compared to 0.96 cm for manual surgery) and significantly smaller prosthesis-femur angle (mean of 0.34 degrees compared to mean of 0.84 degrees for manual preparation). Additionally, the ROBODOC group showed significantly better numbers at 6 months for the Merle d' Aubigne and Mayo hip scores, and significantly better numbers at 12 months for the Mayo and Harris hip scores.

DJA x000080

Summary: This study reported a high dislocation rate for the ROBODOC group which is not consistent with other published studies. Given those complications all other complications between the two groups was not significantly different. However, the ROBODOC group had significantly better implant placement accuracy and less leg length variation. The ROBODOC group also had significantly better Merle d' Aubigne, Mayo and Harris hip scores than the manual group.

ISS determined that the high dislocation rate at this site was caused by critical soft tissue damage due to incorrect or inappropriate pre-surgical planning and surgical application of the ROBODOC system. As described in the paper, the ORTHODOC (pre-surgical planning) system clearly displayed for the surgeon all the information regarding the cut path for the implant chosen onto the CT image of the patient for templating. It was observed that the surgeon failed to adequately review the pre-surgical plans and failed to act on the information displayed in that plan. The surgeon did not adequately review that information, and did not take the appropriate intra-operative steps detailed in the pre-surgical plan to preserve critical soft tissue. As a direct result of this study ISS has taken appropriate steps to further improve the templating displays and added additional warnings to the user manual and training materials re-enforcing the requirement that surgeons must review and approve of the pre-surgical plan before executing it and, if required, take actions to preserve critical soft tissue.

6.7 *Effectiveness of the ROBODOC system in preventing intra-operative pulmonary embolism. Hagio K. , Sugano N., Takashina M., Nishii T, Toshikawa H., Ochi T., Acta Orthop Scand 2003 Jun; 74(3): 264-9*

An independent prospective study using 75 hips was conducted by Hagio et al to determine the effectiveness of the ROBODOC system in preventing intra-operative pulmonary embolism during cementless THA, as indicated by results of transesophageal echocardiography and hemodynamic monitoring. In this study, the ROBODOC group had 50 hips and the manual group had 25 hips. The incidence of grade 2 and grade 3 emboli was found to be significantly lower in the ROBODOC group.

Frequency and Grade of Embolic Events

	ROBODOC N=50			Conventional N=25			P-value*
Grade of PE	1	2	3	1	2	3	
Femur Preparation	4 (8%)	0	0	16 (64%)	8 (32%)	1 (4%)	P<0.001
Stem Insertion	18 (36%)	0	0	17 (68%)	4 (16%)	1 (4%)	P<0.001
Relocation	29 (58%)	4 (8%)	0	13 (52%)	11 (44%)	1 (4%)	P<0.001

*Mann-Whitney U test

The authors conclude that the ROBODOC system may reduce the risk of clinically significant pulmonary embolism in cementless THA.

Summary: The finding of this study is consistent with those of other studies most of which have reported lower rates of pulmonary embolism for the ROBODOC groups.

DJA x00081

6.8 *The Incidence of Limp Following ROBODOC Assisted Total Hip Replacement. Ref: 1736, poster presentation at ISTA symposium, September 2003 – San Francisco, CA, USA*

In a follow-up study conducted by Dr. Bargar, 24 month Harris Hip scores surveys were reviewed for patients from the pin-based U.S. multi-center clinical trial. Limp scores were analyzed for 108 patients, 53 in the ROBODOC group and 55 in the control group. The average Harris limp score was found to be slightly higher (better) for the ROBODOC group (10.49 compared to 10.24), though the difference was not statistically significant. In the ROBODOC group 45 patients had no limp and 8 patients had slight to moderate limp. In the control group 44 patients had no limp and 11 patients had slight to moderate limp. The author concludes that there is no significant difference in the incidence of limp between the two groups.

Summary: The results show that there is not increased limp complication (side effect) due to use of the ROBODOC system for THR surgery.

6.9 *Comparison of radiographic evaluation between pinned and pinless methods in total hip arthroplasty using the ROBODOC system. Sugano N., Yamamura M., Nakamura N., Kakimoto A., Nishii T, and Miki H., in 3rd Annual Meeting of CAOS – International Proceedings, Marabella, Spain: June 18-21, 2003*

In a study conducted by Sugano et al the accuracy of the ROBODOC pinless pin system was performed on 31 hips and with the pinless systems on 24 hips. For both groups, final post-operative results were measured and compared to the preoperative plans. For the pin group, the mean difference in alignment was 0.6 degrees and the mean difference in axial seating position was 1.1 mm. For the pinless group, the mean difference in alignment was 0.6 degrees and the mean difference in axial seating position was 1.3 mm.

Summary: The authors conclude that there were no significant differences.

6.10 *Nishihara S, Sugano N, Nishii T, Miki H, Nakamura N, Yoshikawa H. Comparison Between Hand and Robotic Milling for Stem Implantation in Cementless Total Hip Arthroplasty. J Arthroplasty, 21(7):957-66, 2006*

Using the ORTHODOC™ pre-surgical planning Workstation this study compared the clinical and radiographic results of the use of the ROBODOC® Surgical Assistant system as an alternative to conventional manual surgical broaching techniques for femoral canal preparation in patients receiving cementless prostheses for primary THA. The rate of intra-operative fractures, intra-operative and postoperative complications, and adverse events were used to evaluate safety. Fit, fill, position, precision and consistency were determined by Computer Aided Tomography and were used to evaluate clinical efficacy. Other outcomes measured were, *Japanese Orthopedic Association or* JOA scores *(JOA hip scores include pain 40 points, ROM 20 points, walking ability 20 points, and ADL 20 points. A full mark is 100 points.)*, Merle D'Aubigne hip scores, number of days until the patient could walk more than 6 blocks without a cane, and thigh pain at 1 and 3 months after the procedure.

This study of 140 patients provides evidence that the ROBODOC® system can safely and effectively perform its intended use. Mean surgery time in the ROBODOC® group was 122 minutes compared to a mean surgery time of 102 minutes for the manual (hand rasped) group.

DJA x00082

Associated blood loss was significantly less in the ROBODOC® group (527 ml) than the manual (hand rasped) group (694 ml). The JOA scores for ROBODOC® were significantly better than the manually broached group at 6 months and 24 months post procedure. There were no significant adverse events or sequelae attributed to the ROBODOC® system.

There were no serious device-related complications, including no intra-operative fractures using the ROBODOC® System. There were 5 intra-operative femoral factures in the hand rasping group that occurred during insertion of the implant. The difference is reported as statistically significant ($P<.05$). The quantitative radiographic assessments using CT revealed significantly better fit and fill for the ROBODOC®. The differences in operative times ($P<.0001$) and estimated blood loss (unpaired t test, $P<.01$) were statistically significant.

Summary: The multi-center Japanese clinical trial provides evidence that the ROBODOC® System is safe for its intended use and effective in milling a cavity that precisely matches the implant's shape and dimensions and that the ROBODOC® is not associated with long-term unanticipated adverse effects or sequelae and accurately, precisely and reliably implements the preoperative plan.

7. Potential Risks; Comparison and Analysis of First IDE Trial, Second IDE Trial and Standard of Care

The Second Clinical Trial, conducted under IDE # G000071, was implemented in agreement with FDA to demonstrate that the technological improvements of the pinless registration DigiMatch™ ROBODOC® Surgical System have eliminated or substantially mitigated the potential risks identified in the First Clinical Trial, conduced under IDE # G920035. These potential risks were:

1. Two surgical procedures required for the pin-registration system;
2. Postoperative ipsilateral knee pain;
3. Longer surgical time; and
4. Increased blood loss.

The technological improvements in the ROBODOC System included the development of a patented registration technique (DigiMatch™), which eliminated the need for preoperative placement of locator (fiduciary) pins and new patented cutting technology that significantly improved the bone cutting performance of the System. There were no significant adverse events or sequelae attributed to the identified risks in the First Clinical Trial. Each of these potential risks and how they were eliminated or mitigated is discussed below.

7.1 Two Surgical Procedures for Pin-Registration System – DigiMatch Technology has Eliminated this Potential Risk

The First IDE Trial used a ROBODOC® Surgical System that was designed for 3-pin registration of the operative femur to the surgical robot. Patients in the ROBODOC group were required to undergo a preoperative procedure to implant 3 locator pins for registration of the affected femur. This procedure was usually performed under local anesthesia in an outpatient surgical setting within 24 hours of the THA. There were no reported adverse events attributed to this additional procedure.

DJA x00083

To address this issue, ISS developed the DigiMatch™ or "pinless" registration technology that uses anatomical reference points collected on the operative femur to register the femur to the surgical robot. By eliminating the need to implant the locator pins in a separate procedure this potential risk has been eliminated.

7.2 Registration Pin-Related Ipsilateral Knee Pain – DigiMatch Technology has Eliminated this Potential Risk

Ipsilateral knee pain has been reported for patients requiring THA. Some knee pain was reported in the First IDE Trial. It was thought that the increased incidence of postoperative ipsilateral knee pain reported in ROBODOC subjects in the First IDE Trial was due to the requirement to preoperatively place 3 locator or fiducial pins in the operative knee for registration purposes. It follows that by eliminating the need to implant the registration pins, any associated postoperative ipsilateral knee pain would be eliminated. **Table 10** shows the incidence of ipsilateral knee pain in the First IDE Trial. **Table 11** shows the incidence of ipsilateral knee pain in the Second IDE Trial. **Table 12** shows a comparison of ipsilateral knee pain between the First and Second IDE Trials.

Table 10 Postoperative Ipsilateral Knee Pain – First IDE Trial

	ROBODOC	Control Group
6-week follow-up	40 (57%) (n=70)	7 (12%) (n=58)
3-month follow-up	31 (46%) (n=67)	14 (22%) (n=64)
6-month follow-up	16 (28%) (n=57)	11 (20%) (n=55)

Table 11 Postoperative Ipsilateral Knee Pain – Second IDE Trial

	ROBODOC	**Control**
6-week follow-up	(b) (4) [redacted]	
3-month follow-up		
6-month follow-up		

Table 12 Comparison of Ipsilateral Knee Pain – First and Second IDE Trials

	First IDE Trial ROBODOC	**Second IDE Trial ROBODOC**
6-week follow-up	(b) (4) [redacted]	
3-month follow-up		
6-month follow-up		

DJA x00084

Based on the similarity of responses of ipsilateral knee pain between the ROBODOC and the control groups at baseline and 6-weeks, and an actual decrease of reported ipsilateral knee pain in the ROBODOC group at both 3-months and 6-months, it has been demonstrated that this potential risk has been mitigated. Additionally, since the DigiMatch™ technology requires no pin implantation in the knee for registration purposes, the DigiMatch™ ROBODOC® Surgical System has eliminated any pin-based registration related postoperative ipsilateral knee pain.

7.3 Surgical Time – DigiMatch Technology has Mitigated this Potential Risk

One of the potential risks of the pin-based registration ROBODOC® System identified in the First IDE Trial was longer surgical time in the ROBODOC group (mean = (b) (4)) compared to the manual control group (mean = (b) (4)). In agreement with FDA, ISS designed a clinical trial protocol based on the pinless registration DigiMatch™ ROBODOC® System technology. It was agreed with the FDA, prior to the start of the Second IDE Trial, that the goal for surgical times should be less than (b) (4) . FDA requested more details, including any time-related adverse events, for any THA procedure lasting more than (b) (b) (4)

7.3.1 Comparison of Mean Surgical Time: First Trial, Second Trial and Reported Literature

As previously stated, data collected in the First IDE Clinical Trial showed mean surgical time to be (b) (4) for the ROBODOC group and (b) (4) for the manually broached. The increased surgical time associated with the ROBODOC® was primarily attributed to the pin-based registration method, inadequate emphasis on controlling the surgical time and the "intrigue" with the innovative robotic technology. There were no complications or adverse events associated with the increased surgical time in the First IDE Trial.

The mean surgical times for the ROBODOC and the Control groups in the Second IDE Trial were (b) (4) , respectively. The mean surgical time for the ROBODOC group was (b) (4) longer than the control in the Second IDE Trial (b) (4) . This clinical trial attempted to control surgical time to less (b) (4) . There were no complications or adverse events associated with the increased surgical time in the Second IDE Trial.

By comparing the results of the First and Second IDE Clinical Trial (**Table 13**) it can be seen that ROBODOC group mean surgical time was significantly reduced (b) (4) n., respectively). This reduction of (b) (4) shows a highly significant reduction in surgical time using the pinless registration DigiMatch™ technology (p=0.0001).

Table 13 Comparison of ROBODOC Surgical Times: First and Second IDE Trials

	First IDE Trial	Second IDE Trial	Difference
	ROBODOC n=71 hips	**ROBODOC n=79 hips**	
Mean Surgery Time (min.)	(b) (4)		

DJA x00085

Table 14 demonstrates an important fact; namely, the mean surgical time of the ROBODOC group in the Second IDE Trial (b) (4)) is shorter than the mean surgical time of the control group in the First IDE Trial (134 minutes). During discussions with FDA regarding the First IDE Trial results, and FDA's concern of the longer surgical times of the ROBODOC group, FDA did not express a concern about the mean surgical time of 134 minutes reported for the Control group. ISS understands this to mean that FDA considers surgical times in the range of (b) (4) to be acceptable for traditional, manual primary THA procedures.

Table 14 Surgical Time Comparison: Control of First Trial vs. ROBODOC of Second Trial

	First IDE Trial	Second IDE Trial
	Control n=65 hips	**ROBODOC n=79 hips**
Mean Surgery Time (min.)	**134**	(b) (4)

There were no complications or adverse events associated with surgical time in either the First or Second IDE Clinical Trials. The improvement in surgical time is attributed to the elimination of the pin-based registration and an improvement in the bone cutting performance of the DigiMatch™ ROBODOC® Surgical System.

A review of the medical literature looked at mean surgical time for manual THA procedures (not including procedures using FDA cleared computer-assisted, image-guided systems which are know to add time [14, 15] to the procedure) during the years that most subjects were enrolled in either the First or Second IDE Trials. In the United States, Bellabarba et al. [16] reports that average operative time in his institution is 122 minutes, while Woolson et al. [17] reports an average surgical time of 105 minutes at his institution. In Japan, Nishihara et al. [18] report an average surgical time of 122 minutes at their institutions.

Comparing the results of the Second IDE Trial to the First IDE Trial, and peer reviewed papers **(Table 15)**, it can be seen that the mean surgical time using the ROBODOC was significantly less than that in the First IDE Trial. The data demonstrates that the mean surgical time using the ROBODOC in the Second IDE Trial was (b) (4) than the First IDE Trial. The data also demonstrates that surgical times in the Second IDE trial are substantially equivalent to times reported for manual THA procedures at leading U.S. and Japanese orthopaedic centers.

DJA x00086

Table 15 Comparison of ROBODOC Surgical Time: First IDE Trial, Second Trial, Medical Literature

THA Procedure Tool	Source of Clinical Data	Mean Surgery Time (min)
ROBODOC®	First IDE Trial	**258**
ROBODOC®	Second IDE Trial	(b)
Manual	St. Luke's Medical Center Chicago, IL (Ref. 14)	**122**
Manual	Stanford University Hospital Stanford, CA (Ref. 15)	**105**
Manual	University Medical Center and Kyowakai Hospital Osaka, Japan (Ref. 16)	**122**

The data show that there were no complications or adverse events associated with the increased surgical time in either the First or Second IDE clinical trials. The data also show that mean surgical time has been significantly reduced to a range comparable to the standard of care reported in the published literature. Finally, the mean surgical time for the ROBODOC group in the Second clinical trial was less than the original goal of 180 minutes. ISS concludes that the potential risk of surgical time has been mitigated.

7.3.2 Discussion of Effects of Surgical Times Less Than or Equal to 240 minutes

Procedure Time vs. THA Implant Survivorship

A study to examine the association between procedure duration with primary THA and TKA survivorship at 8 years in the Medicare population was conducted by S. Kurtz, E. Lau and Kevin L Ong of Exponent Inc., and M. Manely of the Homer Stryker Center for Orthopaedic Education & Research.

This study used information on elective primary THA procedures identified from 1997-2004 in the Medicare claims database (representing a 5% nationwide sample). It excluded patients younger than 65 years old, not enrolled in both Parts A and B, enrolled in a HMO, or diagnosed with fractures, bone cancer, metastatic cancer, or joint infections. The Kaplan-Meier method and Cox regression were used to determine the 8-year implant survivorship (revision end-point) and hazard ratios associated with procedure duration (using 120-150 min as reference group), respectively. Differences in survival experience for patients stratified by procedure duration were also evaluated by the log-rank test.

The study concluded that median procedure duration for primary THA procedures in 2004 was 143 minutes and that THA procedures lasting more than 240 minutes were significantly associated with higher revision rates compared to 120-150 minutes ($p \leq 0.035$)

DJA x00087

	THA		
Procedure duration (min)	Adjusted odds ratio	95% CI	p-value
,90	1.01	0.68-1.50	0.963
90-120	1.16	0.92-1.47	0.205
120-150	1	-	-
150-180	1.00	0.82-1.22	0.979
180-210	1.21	0.98-1.50	0.081
210-240	1.09	0.85-1.42	0.496
>240	1.28	1.02-1.60	0.035*

*Significant ($p<0.05$)

ISS can draw the following conclusions based on results of the Second IDE Trial and the data presented in this Medicare population study:

- The mean surgical time for the DigiMatch™ ROBODOC® System in the Second IDE Trial was less than 240 minutes.
- Patients undergoing THA surgery using the DigiMatch™ ROBODOC® System can be expected to have no higher rates of revision hip arthroplasty.

This data provides further evidence that the ROBODOC surgical time in the second IDE Trial has been mitigated. It also provides evidence that the DigiMatch™ ROBODOC® System creates no greater risk of revision hip surgery than in the Medicare THA patient population.

7.3.3 DigiMatch Technology has Mitigated the Potential Risk of Longer Surgical Time

The DigiMatch™ ROBODOC® System has reduced mean surgical time from (b) minutes in the First Clinical Trial to (b) (4) in the Second Clinical Trial. The mean surgical time for the DigiMatch™ ROBODOC® in the Second Clinical Trial was less than the manual controls of the First Clinical Trial (135 minutes) and significantly less than the protocol targeted of 180 minutes. The mean surgical time using the DigiMatch™ ROBODOC® System is comparable to routine manual surgeries done in several centers around the world (See **Table 15**).

The study done by Exponent, discussed in **Section 7.3.2**, has shown no effect on long term implant survivorship for procedures lasting less than 240 minutes. The DigiMatch™ ROBODOC® mean procedure times were less than 240 minutes.

While the Second Clinical Trial showed the mean surgical time for the DigiMatch™ ROBODOC® System was longer than the control group (b) (4)) the difference of (b) (4) was demonstrated not to be clinically significant since there was:

1- No statistical difference in blood loss;
2- Significantly less blood loss than controls from the First IDE Clinical Trial;
3- Significantly less time than either the study or control groups from the First Clinical Trial;
4- No surgical time related adverse events or sequelae; and
5- No intraoperative complications or adverse events attributed to surgical or anesthesia time.

DJA x00088

7.3.4 Additiona (b) (4) of Surgical Time

Most of the (b) (4) was spend on setup fixation and registration. The system was milling the patient for only (b) (4) longer than manual. The beneficial tradeoffs of this longer surgical time are that the DigiMatch™ ROBODOC® System produced better clinical result with respect to:

- Better Fit
- Better Fill
- Better Alignment
- Reduction in Leg Length Discrepancy
- Reduction in Intra-operative Fractures
- Reduction in reported Pulmonary Emboli

Based on the information discussed in **Section 7.3** ISS concludes that the use DigiMatch™ ROBODOC® System does not pose any increased risk. Thus, the risk of surgical time has been mitigated.

7.4 Blood Loss

The other potential risk of the pin-based registration ROBODOC® System that concerned FDA was the increased amount of estimated blood loss reported in the First IDE Trial. FDA did not express an opinion about what was an acceptable amount of blood loss other than to state that it should be similar to that of traditional, manual primary THA. FDA did acknowledge the fact that there is a direct correlation of surgical time to blood loss.

7.4.1 Comparison of Mean Estimated Blood Loss: First and Second IDE Trials

As discussed in **Section 3**, the data from the First IDE Clinical Trial show a direct correlation between surgical time and blood loss. **Table 16** shows that the mean total estimated blood loss for ROBODOC® was (b) (4) compared to (b) (4) for the control group. Additionally, the table shows that when compared on a cc/min blood loss rate, the blood loss for the ROBODOC group is essentially the same as the control group (b) (4), respectively). This equivalence of cc/min blood loss demonstrates that the rate of blood loss is similar for ROBODOC and manual THA methods. There were no complications or adverse events associated with blood loss in the First IDE Clinical Trial.

Table 16 ROBODOC Blood Loss in First IDE Trial

	First IDE Trial	
	ROBODOC n=71	**Control n=65**
Blood Loss (cc)	(b) (4)	
Blood Loss Rate (cc/min)		

DJA x00089

As seen by comparing the results of the First and Second IDE Clinical Trial (**Table 17**), the mean estimated blood loss was significantly reduced in the ROBODOC group (b) (4) (b) (4) respectively). This represents a (b) (4) in blood loss from the First to the Second IDE Trial.

Table 17 Comparison of ROBODOC Blood Loss: First and Second IDE Trials

	First IDE Trial	Second IDE Trial	Difference
	ROBODOC n=71	ROBODOC n=79	
Mean Blood Loss (cc)	(b) (4)		
Blood Loss Rate (cc/min)			

Additionally, as discussed in **Section 4**, the mean total estimated blood loss from the Second IDE Trial shows that the control group had only (b) (4) loss than the ROBODOC group ((b) (4) , respectively). This difference of (b) (4) statistically significant (b) (4) . This data also show that the greater blood loss reported in the First IDE Clinical Trial has been reduced by (b) using the DigiMatch™ pinless registration technology.

Another way to consider the reduction in estimated blood loss from the pin-based registration system to the pinless registration DigiMatch™ is that blood loss in the Second Trial was over one unit of blood less than in the First Trial ((b) (4) . Additionally, it is important to note that the mean blood loss of the ROBODOC group in the Second IDE Trial (b) (4)) is less than the mean blood loss of the Control group in the First IDE Trial (b) (4)

Since there were no complications or adverse events associated with blood loss in either the First or Second Clinical Trial, and the mean difference of blood loss was not significantly different, the potential risk associated with blood loss has been mitigated.

8. Benefit/Risk Analysis

This Benefit/Risk Analysis is a systematic approach to the evaluation of the comparative benefits and risks associated with the use of the ROBODOC system. More specifically, this analysis compares the statistically significant results from the First and Second IDE clinical trials of DigiMatch™ ROBODOC® System to the standard of care, as established by the clinical trial controls and the published literature. A check mark indicates a statistically significant difference. The parameters are evaluated as less or more risky and less or more beneficial when compared to that specified standard.

For the purposes of this analysis, benefits and/or risks that are common or equivalent to either the IDE trial control group or to the standard of care, as defined by the literature, are not considered.

DJA x00090

Table 18 Risk and Benefit Comparison DigiMatch™ ROBODOC® to Conventional Manual THA

	DigiMatch™ ROBODOC® System	
Parameter	**Risk**	**Benefit**
Implant Cavity Fit	---	√
Implant Canal Fill	---	√
Alignment	---	√
Leg Length Discrepancy	---	√
Intra-operative Fractures	---	√
Surgical Time	√	---
Total Blood Loss (ml)	---	---
Blood Loss (ml/min)	---	√
Device related A.E.	---	---
DVT	---	---
Pulmonary Emboli	---	√

The results shown in **Table 18** demonstrate that the number of potential benefits of the DigiMatch™ ROBODOC® System is greater than the identified risk. This demonstrates that the benefits associated with the use of DigiMatch™ ROBODOC® System clearly exceed the mitigated, residual risk of surgical time, thus establishing the medical suitability of the ROBODOC® System.

9. Conclusion of Benefit/Risk Analysis

The benefit/risk analysis demonstrates that the number of benefits associated with the use of DigiMatch™ ROBODOC® System clearly outweigh the risks. Taking in to account:

a. The results of the First and Second IDE clinical trials demonstrated no adverse events or sequelae associated with surgery time.
b. The mean surgical time was reduced by (b) (4) minutes from the First IDE Trial to the Second IDE Tria(b) (4)).
c. The 8-year review of Medicare data for THA procedures demonstrating no statistical relation of implant survivorship time <240 minutes. ROBODOC is less.
d. The mean difference in cavity preparation time was only(b) (4) .
e. Lower blood loss rates (ROBODOC < blood loss for similar surgery times).
f. No statistical difference in blood loss using the ROBODOC (b) (4)
g. Reduced risk of cavity preparation fractures.
h. Statistically better cavity Fit using the ROBODOC (chi-square, p=0.001).
i. Statistically better cavity Filling using the ROBODOC (chi-square, p=0.01).
j. Statistically significant improvements in alignment using the ROBODOC (unpaired t-test, AP: p=0.02; lateral: p=0.04).
k. Statistically significant improvements in Leg Length using the ROBODOC (P-value using Exact 2-tailed Pearson Chi-Squared test, p=0.045).
l. Decreased risk of pulmonary embolic events using the ROBODOC.

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Use of the DigiMatch™ ROBODOC® System offers a significant advantage when compared to manual methods.

Based upon comparing current clinical practices and the statistical analysis of the First and Second IDE clinical trials, all identified potential risks have been mitigated or eliminated. The benefits associated with the use of DigiMatch™ ROBODOC® System outweigh the single residual risk, thus establishing the system's efficacy, safety and medical suitability.

Integrated Surgical Systems believes that, through its U.S. clinical trials (IDE #G920035 and IDE# G000071) and the independent clinical studies reported in the medical literature, it has demonstrated consistency of performance and safety of the ROBODOC® system and that the Confirmatory trial sufficiently demonstrates that it has effectively mitigated or eliminated the risks identified in the Primary clinical trial. Given that there is agreement that clinical efficacy was demonstrated in the Primary clinical trial (meeting minutes with FDA January 18, 2007) and that the device has been reclassified as a 510(k) device, ISS has presented adequate data demonstrating the device is safe and effective for its intended use.

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Attachment 2 – Revised Indications for Use Statement

FDA Comment

3. *The submission includes an indication for use statement which appears to differ from that studied within first and secondary IDE studies. Specifically, the indication for use statement includes a paragraph which makes safety and effectiveness claims regarding other orthopedic procedures (Paragraph #3). Please revise the indications for use statement and device labeling where appropriate to remove this reference or provide additional clinical data to support this claim*

ISS Response

The Indication for Used Statement has been revised to address this comment. The revised statement is provided below.

DJA x00095

Indications for Use

510(k) Number (if known): Unknown at this time K072629

Device Name: DigiMatch™ ROBODOC® Surgical System

Indications for Use:

The DigiMatch™ ROBODOC® Surgical System is intended for use as a device, which uses diagnostic images of the patient acquired specifically to assist the physician with presurgical planning and to provide orientation and reference information during intra-operative procedures. The robotic surgical tool, under the direction of the surgeon, precisely implements the presurgical software plan.

The preoperative planning software and robotic surgical tool is used as an alternative to manual planning and broaching/reaming techniques for femoral canal preparation in primary total hip arthroplasty (THA).

The DigiMatch ROBODOC Surgical System is indicated for Orthopedic procedures in which the broaching/reaming in primary total hip arthroplasty (THA) may be considered to be safe and effective and where references to rigid anatomical structures may be made.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)