



# U.S. Department of Health & Human Services

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Food and Drug Administration

## SAVE REQUEST

**USER:** (jsh)  
**FOLDER:** K110869 - 363 pages  
**COMPANY:** DIAGNOS, INC (DIAGNOS)  
**PRODUCT:** SYSTEM, IMAGE MANAGEMENT, OPHTHALMIC (NFJ)  
**SUMMARY:** Product: CARA

**DATE REQUESTED:** Sep 3, 2015

**DATE PRINTED:** Sep 3, 2015

**Note:** Printed



DIAGNOS, Inc.  
CARA

510(k) Premarket Notification  
March 25, 2011

510(k) summary  
CARA  
March 2011

510(k): K116869

JUL 14 2011

**1. Applicant Information**

Diagnos, Inc.  
7005 Taschereau Boulevard, Suite 340  
Brossard, Québec J4Z 1A7  
Canada  
Contact Person: Housseem Ben Tahar  
VP Development and Business Intelligence  
Telephone No.: 450.678.8882, #231  
Fax No.: 450.678.8119  
E-mail: houssem@diagnos.com

**2. Device Information**

Classification names: Picture Archiving and Communications System  
Device classification: Class II  
Regulation numbers: 21 CFR 892.2050  
Product codes: NFJ  
Proprietary name: CARA

**3. Predicate Device**

The predicate device is the Topcon IMAGEnet Professional PC Software System, cleared under K082364.

**4. Description of device**

CARA is a software platform that collects, enhances, stores, and manages color fundus images. Through the internet, CARA software collects and manages color fundus images from a range of approved computerized digital imaging devices. CARA enables a real-time review of retinal image data (both original and enhanced) from an internet-browser-based user interface to allow authorized users to access and view data saved in a centralized database. The system utilizes state-of-the-art encryption tools to ensure a secure networking environment.

**5. Indications for use**

CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.

DIAGNOS, Inc.  
CARA

510(k) Premarket Notification  
March 25, 2011

## 6. Substantial Equivalence

The claim of substantial equivalence to the Topcon IMAGENet Professional PC Software System is based on similar intended uses to collect, store, enhance and transfer digital retinal images from computerized imaging devices through computerized networks.

The table below provides a comparison between the predicate device and the CARA device.

	Topcon IMAGENet	Diagnos CARA
Software Only	√	√
Web Based Platform	x	√
Non-mydratic Capture Device Images Processing	√	√
Image Data Management	√	√
Fundus Image Only	√	√
File Import	√	√
Color Fundus Image Enhancement	x	√
Black & White Fundus Image Enhancement	√	x
Linear Distance and Area Measurement	√	x
Image Annotation & Measurement	√	x

√ = present

x = absent

CARA shares many similar technological characteristics as the predicate device, both in terms of the manner in which images are captured, processed, and stored, as well as the operation of the device by the intended user.

The results of performance and software validation and verification testing demonstrate that CARA performs as intended and meets the specifications. This supports the claim of substantial equivalence

Any minor difference in operation does not raise additional new questions about safety and effectiveness. CARA raises the same issues of safety and effectiveness as the predicate device.

## 7. Clinical data:

Since the CARA system currently is not a stand-alone tool, does not make any diagnostic claims and does not replace the existing retinal images or the treating physician, the sponsor believes that the software testing and validation presented in this 510(k) are sufficient and that there is no need for a clinical trial.



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

Diagnos, Incorporated  
% Mr. Aron Shapiro  
Vice President  
Ora, Incorporated  
300 Brickstone Square  
Andover, MA 01810

JUL 14 2011

Re: K110869

Trade/Device Name: CARA  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture Archiving and Communications System  
Regulatory Class: Class II  
Product Code: NFJ  
Dated: June 15, 2011  
Received: June 16, 2011

Dear Mr. Shapiro:

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

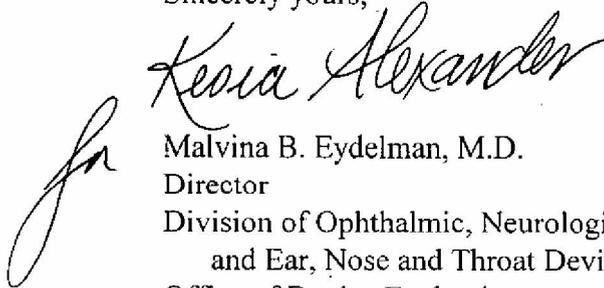
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,



Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

DIAGNOS, Inc.  
CARA

510(k) Premarket Notification  
March 25, 2011

**Indications for Use**

510(k) Number (if known):     K110869    

Device Name:     CARA    

Indications for Use:

CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.

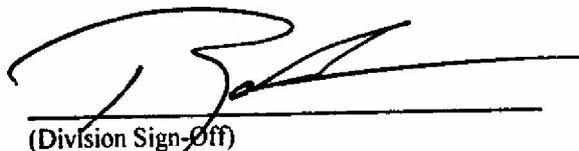
Prescription Use     X      
(Part 21 CFR 801 Subpart D)

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)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

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510(k) Number     K110869    

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

Diagnos, Incorporated  
% Mr. Aron Shapiro  
Vice President  
Ora, Incorporated  
300 Brickstone Square  
Andover, MA 01810

JUL 14 2011

Re: K110869

Trade/Device Name: CARA  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture Archiving and Communications System  
Regulatory Class: Class II  
Product Code: NFJ  
Dated: June 15, 2011  
Received: June 16, 2011

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1

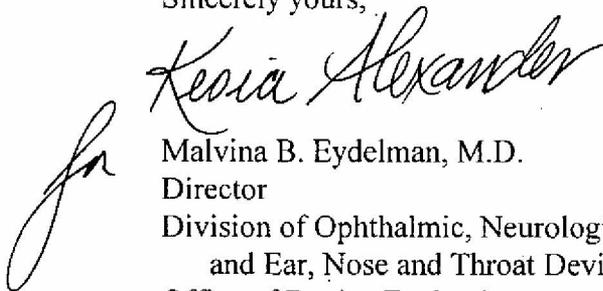
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Sincerely yours,



Malvina B. Eydelman, M.D.  
Director  
Division of Ophthalmic, Neurological,  
and Ear, Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

DIAGNOS, Inc.  
CARA

Indications for Use

510(k) Number (if known): K110869

Device Name: CARA

Indications for Use:

CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.

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)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,  
Nose and Throat Devices

Page 1 of 1

510(k) Number K110869

Page 1-10



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

## Public Health Service

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

June 01, 2011

DIAGNOS, INC  
 C/O ORA, INC.  
 300 BRICKSTONE SQUARE  
 ANDOVER, MASSACHUSETTS 01810  
 ATTN: ARON SHAPIRO

510k Number: K110869

Product: CARA

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center 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

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 30, 2011

DIAGNOS, INC  
C/O ORA, INC.  
300 BRICKSTONE SQUARE  
ANDOVER, MASSACHUSETTS 01810  
ATTN: ARON SHAPIRO

510k Number: K110869

Received: 3/29/2011

Product: CARA

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

KR 869  
OP/OMED  
Ora

March 25, 2011

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

FDA CDRH DMC

MAR 29 2011

Received

RE: Traditional 510(k) Premarket Notification for CARA

Dear Sir or Madam:

Please find enclosed two copies of the above-referenced Premarket Notification (510(k)). One copy is a paper copy and the other is an electronic copy (exact duplicate of the paper copy) provided as per FDA's instructions. An additional paper copy of the cover letter is provided to accompany the electronic copy. The following general information applies to this submission:

**A. Common Name:** Medical Image Management Device

**B. Trade Name:** CARA

**C. Submitter:** Ora, Inc. on behalf of Diagnos, Inc.

Submission Contact: Aron Shapiro  
Vice President  
Office: 978.685.8900 ext. 9443  
Fax: 978.689.0020  
email: [ashapiro@oraclinical.com](mailto:ashapiro@oraclinical.com)

**D. Sponsor/Owner:** Diagnos, Inc.  
7005 Taschereau Boulevard  
Brossard, Québec J4Z 1A7  
Canada

Contact: Housseem Ben Tahar  
Phone: 450.678.8882, #231  
Fax: 450.678.8119  
email: [housseem@diagnos.com](mailto:housseem@diagnos.com)

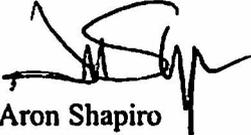
300 Brickstone Square | Andover, MA 01810  
T 978.685.8900 | F 978.689.0020 | [www.oraclinical.com](http://www.oraclinical.com)

Diagnos, Inc.  
Page 2

- E. Confidentiality:** We consider the intent to market this device to be confidential commercial information, and therefore exempt from public disclosure. We request that the existence of this 510(k) remain confidential until it is cleared by the agency (21 CFR 807.95 and 812.38).
- F. Device Class:** Class II ophthalmic
- G. Device Classification:** Picture Archiving and Communications System (892.2050)
- H. Product Codes:** NFJ
- I. Reason for 510(k):** New device
- J. Referenced Submissions:** I100579

Please contact me if you have any questions or comments regarding the enclosed 510(k) submission.

Sincerely,



Aron Shapiro  
Vice President

Enclosures

CARA 510(k)



March 25, 2011

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification for CARA

Dear Sir or Madam:

Please find enclosed two copies of the above-referenced Premarket Notification (510(k)). One copy is a paper copy and the other is an electronic copy (exact duplicate of the paper copy) provided as per FDA's instructions. An additional paper copy of the cover letter is provided to accompany the electronic copy. The following general information applies to this submission:

**A. Common Name:** Medical Image Management Device

**B. Trade Name:** CARA

**C. Submitter:** Ora, Inc. on behalf of Diagnos, Inc.

Submission Contact: Aron Shapiro  
Vice President  
Office: 978.685.8900 ext. 9443  
Fax: 978.689.0020  
email: [ashapiro@oraclinical.com](mailto:ashapiro@oraclinical.com)

**D. Sponsor/Owner:** Diagnos, Inc.

7005 Taschereau Boulevard  
Brossard, Québec J4Z 1A7  
Canada

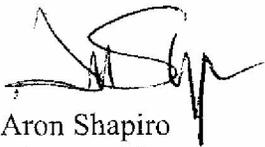
Contact: Housseem Ben Tahar  
Phone: 450.678.8882, #231  
Fax: 450.678.8119  
email: [housseem@diagnos.com](mailto:housseem@diagnos.com)

Diagnos, Inc.  
Page 2

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Please contact me if you have any questions or comments regarding the enclosed 510(k) submission.

Sincerely,



Aron Shapiro  
Vice President

Enclosures

CARA 510(k)

**PREMARKET NOTIFICATION 510(k)**

**CARA**

**March 25, 2010**

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**Cover Letter**

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**PREMARKET NOTIFICATION 510(k)**

**CARA**

**SECTION I: ADMINISTRATIVE DOCUMENTS**

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## 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 <a href="http://www.fda.gov/oc/mdufma/coversheet.html">www.fda.gov/oc/mdufma/coversheet.html</a>	Section I		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf</a>	Section I		
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	<input checked="" type="checkbox"/>		
Indications for Use Statement	Device Advice " Content of a 510(k)" Section D <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_6">www.fda.gov/cdrh/devadvice/314312.html#link_6</a>	Section I		
510(k) Summary or 510(k) Statement	Device Advice " Content of a 510(k)" Section E <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_7">www.fda.gov/cdrh/devadvice/314312.html#link_7</a>	Section I		
Truthful and Accuracy Statement	Device Advice " Content of a 510(k)" Section G <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_9">www.fda.gov/cdrh/devadvice/314312.html#link_9</a>	Section I		
Class III Summary and Certification	Class III Summary and Certification Form <a href="http://www.fda.gov/cdrh/manual/stmnciii.html">www.fda.gov/cdrh/manual/stmnciii.html</a>			<input checked="" type="checkbox"/>
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf</a>  FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf</a>  Financial Disclosure by Clinical Investigators <a href="http://www.fda.gov/oc/guidance/financialdis.html">www.fda.gov/oc/guidance/financialdis.html</a> .			<input checked="" type="checkbox"/>
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations <a href="http://www.fda.gov/cdrh/ode/guidance/1131.html">www.fda.gov/cdrh/ode/guidance/1131.html</a> . FDA Standards program <a href="http://www.fda.gov/cdrh/stdsprog.html">www.fda.gov/cdrh/stdsprog.html</a> . Declaration of conformity <a href="http://www.fda.gov/cdrh/devadvice/3145.html#link_9">www.fda.gov/cdrh/devadvice/3145.html#link_9</a> Required Elements for Declaration of Conformity to Recognized Standard <a href="http://www.fda.gov/cdrh/ode/regrecstand.html">www.fda.gov/cdrh/ode/regrecstand.html</a>			<input checked="" type="checkbox"/>
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	Section II		

Title	Related Information	Present	Inadequate	N/A
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	Section III		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), <a href="http://www.fda.gov/cdrh/k863.html">www.fda.gov/cdrh/k863.html</a>	Section IV		
Proposed Labeling	Device Advice " Content of a 510(k)" Section H <a href="http://www.fda.gov/cdrh/devadvice/314312.html#link_10">www.fda.gov/cdrh/devadvice/314312.html#link_10</a>	Section V		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) <a href="http://www.fda.gov/cdrh/ode/guidance/361.html">www.fda.gov/cdrh/ode/guidance/361.html</a> 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 <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">www.fda.gov/cdrh/ode/guidance/1216.html</a>			<input checked="" type="checkbox"/>
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" <a href="http://www.fda.gov/cdrh/g951.html">www.fda.gov/cdrh/g951.html</a>			<input checked="" type="checkbox"/>
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices <a href="http://www.fda.gov/cdrh/ode/software.html">www.fda.gov/cdrh/ode/software.html</a>	Section III		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program <a href="http://www.fda.gov/cdrh/emc">www.fda.gov/cdrh/emc</a> See also IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			<input checked="" type="checkbox"/>
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	Section VI		
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			<input checked="" type="checkbox"/>
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 <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf</a> <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf">www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf</a>			<input checked="" type="checkbox"/>
Kit Certification	Device Advice <a href="http://www.fda.gov/cdrh/devadvice/314c.html">http://www.fda.gov/cdrh/devadvice/314c.html</a>			<input checked="" type="checkbox"/>

DIAGNOS, Inc.  
CARA

510(k) Premarket Notification  
March 25, 2011

Form Approved: OMB No. 0910-511. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  DIAGNOS INC 7005 Taschereau BLVD suite 340 BROSSARD J4Z 1A7 CA  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Housseem Ben Tahar  2.1 E-MAIL ADDRESS houssem@diagnos.com  2.2 TELEPHONE NUMBER (include Area code) 450-678-8882  2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) Select an application type:		
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates  <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population  <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		18-Mar-2011

Form FDA 3601 (01/2007)

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			Form Approval OMB No. 0910-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
<b>CDRH PREMARKET REVIEW SUBMISSION COVER SHEET</b>				
Date of Submission March 25, 2011	User Fee Payment ID Number MD6054848-956733	FDA Submission Document Number (if known) To be determined		
SECTION A TYPE OF SUBMISSION				
<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Diagnos, Inc.		Establishment Registration Number (if known)		
Division Name (if applicable)		Phone Number (including area code) 450.678.8882 #231		
Street Address 7005 Taschereau Boulevard, Suite 340		FAX Number (including area code) 450.678.8119		
City Brossard	State / Province Québec	ZIP/Postal Code J4Z 1A7	Country Canada	
Contact Name Housseem Ben Tahar				
Contact Title VP Development and Business Intelligence		Contact E-mail Address housseem@diagnos.com		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name Ora, Inc.				
Division Name (if applicable)		Phone Number (including area code) 978.685.8900, ext. 9443		
Street Address 300 Brickstone Square		FAX Number (including area code) 978.689.0020		
City Andover	State / Province MA	ZIP Code 01810	Country USA	
Contact Name Aron Shapiro				
Contact Title Vice President		Contact E-mail Address ashapiro@oraclinical.com		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager  <input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Response to FDA correspondence:		
<input type="checkbox"/> Other Reason (specify):		
SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA  <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		
SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

DIAGNOS, Inc.  
CARA

510(k) Premarket Notification  
March 25, 2011

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

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

Information on devices to which substantial equivalence is claimed (if known)		
510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K082364	1 IMAGEnet Professional PC Software System 1 Topcon Corporation
2		2
3		3
4		4
5		5
6		6

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name  
Picture Archiving and Communications System

Trade or Proprietary or Model Name for This Device	Model Number
1 CARA	1 N/A
2	2
3	3
4	4
5	5

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

Data Included in Submission  
 Laboratory Testing     Animal Trials     Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code NFJ	C.F.R. Section (if applicable) 892.2050	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Ophthalmic		

Indications (from labeling)  
The enhancement, storage and transfer of digital retinal images through computerized networks

<p><b>Note:</b> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.</p>		<p>FDA Document Number <i>(if known)</i> To be determined</p>	
<p><b>SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION</b></p>			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number N/A</p>		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name Diagnos, Inc.</p>		<p>Establishment Registration Number N/A</p>	
<p>Division Name <i>(if applicable)</i></p>		<p>Phone Number <i>(including area code)</i> 450.678.8882, #231</p>	
<p>Street Address 7005 Taschereau Boulevard, Suite 340</p>		<p>FAX Number <i>(including area code)</i> 450.678.8882</p>	
<p>City Brossard</p>		<p>State / Province Québec</p>	<p>ZIP Code J4Z 1A7</p>
<p>Contact Name Houssem Ben Tahar</p>		<p>Contact Title VP Development and Business Intelligence</p>	
		<p>Contact E-mail Address houssem@diagnos.com</p>	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number</p>		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name</p>		<p>Establishment Registration Number</p>	
<p>Division Name <i>(if applicable)</i></p>		<p>Phone Number <i>(including area code)</i></p>	
<p>Street Address</p>		<p>FAX Number <i>(including area code)</i></p>	
<p>City</p>		<p>State / Province</p>	<p>ZIP Code</p>
		<p>Country</p>	
<p>Contact Name</p>		<p>Contact Title</p>	
		<p>Contact E-mail Address</p>	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	<p>Facility Establishment Identifier (FEI) Number</p>		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
<p>Company / Institution Name</p>		<p>Establishment Registration Number</p>	
<p>Division Name <i>(if applicable)</i></p>		<p>Phone Number <i>(including area code)</i></p>	
<p>Street Address</p>		<p>FAX Number <i>(including area code)</i></p>	
<p>City</p>		<p>State / Province</p>	<p>ZIP Code</p>
		<p>Country</p>	
<p>Contact Name</p>		<p>Contact Title</p>	
		<p>Contact E-mail Address</p>	

**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					
2					
3					
4					
5					
6					
7					

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

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

Department of Health and Human Services  
Food and Drug Administration  
Office of the Chief Information Officer (HFA-710)  
5600 Fishers Lane  
Rockville, Maryland 20857

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.

### Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: CARA

Indications for Use:

CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.

Prescription Use \_\_\_\_\_  
(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)

Page 1 of 1

510(k) summary

**CARA**

**March 2011**

**1. Applicant Information**

Diagnos, Inc.

7005 Taschereau Boulevard, Suite 340

Brossard, Québec J4Z 1A7

Canada

Contact Person: Housseem Ben Tahar

VP Development and Business Intelligence

Telephone No.: 450.678.8882, #231

Fax No.: 450.678.8119

E-mail: houssem@diagnos.com

**2. Device Information**

Classification names: Picture Archiving and Communications System

Device classification: Class II

Regulation numbers: 21 CFR 892.2050

Product codes: NFJ

Proprietary name: CARA

**3. Predicate Device**

The predicate device is the Topcon IMAGEnet Professional PC Software System, cleared under K082364.

**4. Description of device**

CARA is a software platform that collects, enhances, stores, and manages color fundus images. Through the internet, CARA software collects and manages color fundus images from a range of approved computerized digital imaging devices. CARA enables a real-time review of retinal image data (both original and enhanced) from an internet-browser-based user interface to allow authorized users to access and view data saved in a centralized database. The system utilizes state-of-the-art encryption tools to ensure a secure networking environment.

**5. Indications for use**

CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.

**6. Substantial Equivalence**

The claim of substantial equivalence to the Topcon IMAGENet Professional PC Software System is based on similar intended uses to collect, store, enhance and transfer digital retinal images from computerized imaging devices through computerized networks.

The table below provides a comparison between the predicate device and the CARA device.

	<b>Topcon IMAGENet</b>	<b>Diagnos CARA</b>
<b>Software Only</b>	√	√
<b>Web Based Platform</b>	x	√
<b>Non-mydratiatic Capture Device Images Processing</b>	√	√
<b>Image Data Management</b>	√	√
<b>Fundus Image Only</b>	√	√
<b>File Import</b>	√	√
<b>Color Fundus Image Enhancement</b>	x	√
<b>Black &amp; White Fundus Image Enhancement</b>	√	x
<b>Linear Distance and Area Measurement</b>	√	x
<b>Image Annotation &amp; Measurement</b>	√	x

√ = present  
 x = absent

CARA shares many similar technological characteristics as the predicate device, both in terms of the manner in which images are captured, processed, and stored, as well as the operation of the device by the intended user.

The results of performance and software validation and verification testing demonstrate that CARA performs as intended and meets the specifications. This supports the claim of substantial equivalence

Any minor difference in operation does not raise additional new questions about safety and effectiveness. CARA raises the same issues of safety and effectiveness as the predicate device.

**7. Clinical data:**

Since the CARA system currently is not a stand-alone tool, does not make any diagnostic claims and does not replace the existing retinal images or the treating physician, the sponsor believes that the software testing and validation presented in this 510(k) are sufficient and that there is no need for a clinical trial.

PREMARKET NOTIFICATION  
TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as VP – Development and Business Intelligence of Diagnos, Inc., that 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.

(b)(6)



\_\_\_\_\_  
Signature

Housseem Ben Tahar  
\_\_\_\_\_  
Typed or Printed Name

March 25, 2011  
\_\_\_\_\_  
Date

510(k) Number: To be determined

## **PREMARKET NOTIFICATION 510(k)**

### **CARA**

#### **SECTION II: EXECUTIVE SUMMARY**

CARA is a Picture Archiving and Communications System (PACS) that performs enhancement and sharing of digital retinal color images using a secure internet connection.

CARA is designed to be used with images from a standard, commonly used fundus camera. The eye care practitioner takes the image and sends it to the CARA processing engine through a dedicated web interface, and then the enhancement process is completed automatically. This processing provides eye care professionals with an enhanced photo that the user reviews in conjunction with the original image.

The claim of substantial equivalence to the Topcon IMAGEnet Professional PC Software System (K082364) is based on similar intended uses to collect, store, enhance and transfer digital retinal images from computerized imaging devices through computerized networks.

The sponsor has provided software information in accordance with the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. Included in this information are descriptions of the software, and information on the development, design verification and validation of the device.

Since the CARA system currently is not a stand-alone tool (i.e., the enhanced images are only intended to be used with the original images), does not make any diagnostic claims and does not replace the existing retinal images or the treating physician, the sponsor believes that the software testing and validation presented in this 510(k) are sufficient and that there is no need for a clinical trial.

The information provided in this 510(k) application supports the claim that the CARA system is as safe and effective as the Topcon IMAGEnet system.

**PREMARKET NOTIFICATION 510(k)**

**CARA**

**SECTION III: DEVICE DESCRIPTION**

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### **SECTION III: DEVICE DESCRIPTION**

#### **A. LEVEL OF CONCERN**

In accordance with the FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005, the LOC questions from Tables 1 and 2 of the guidance have been addressed and included in this submission for FDA review. Copies of the completed Tables 1 and 2 are presented in Appendix III-1.

Based upon the "No" answers to all questions in Table 1, the Sponsor has determined that the Level of Concern (LOC) for this device is not Major.

Regarding the questions in Table 2:

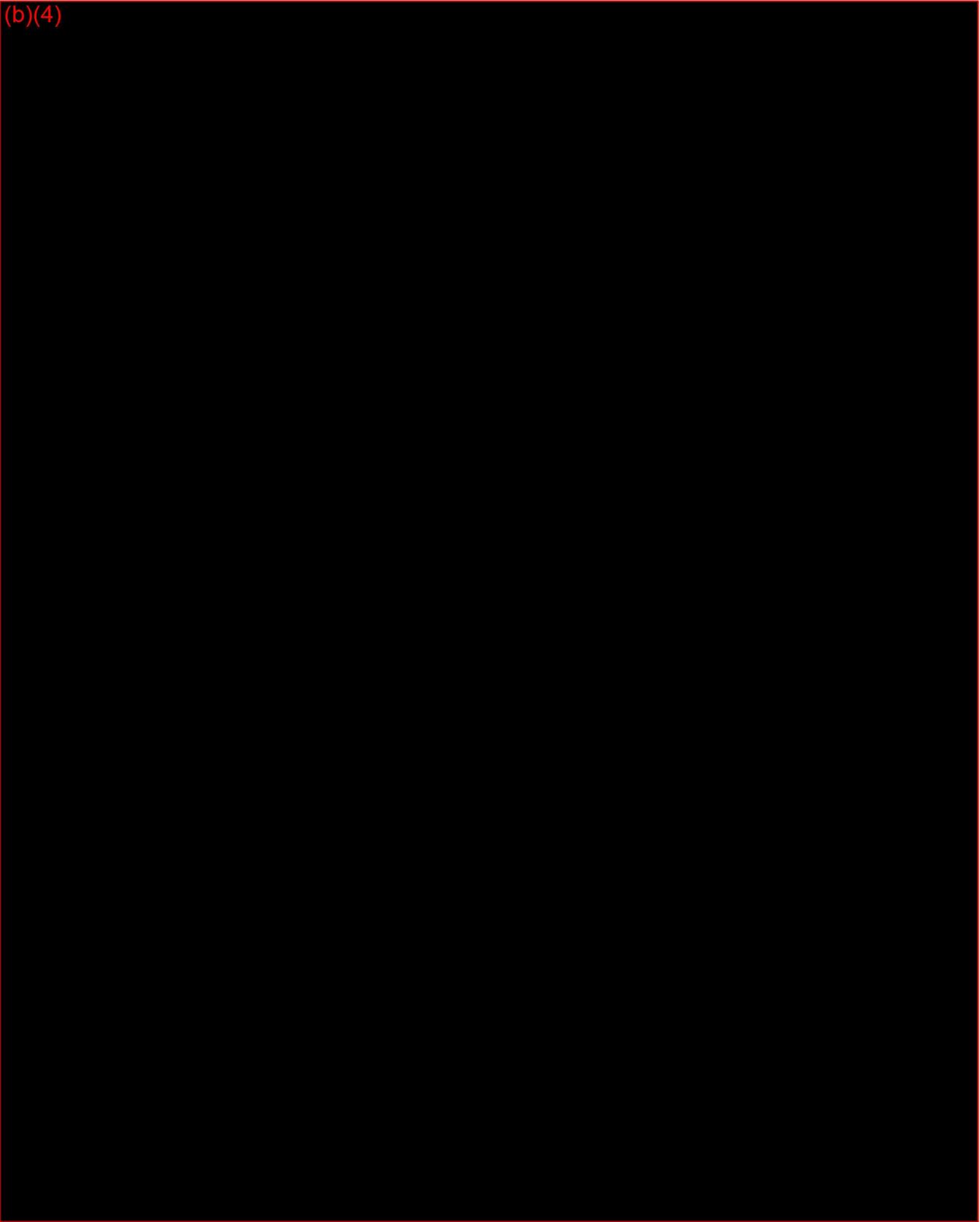
- The device does not come in contact with patients or users and thus poses no physical threat of injury.
- The original images provided by the users (eye care practitioners) are preserved and presented to the user in conjunction with the enhanced images. The user does not review the enhanced image in isolation. Therefore, no information is lost and the doctor is not relying on the enhanced image to make any conclusions about the patient's condition.
- The enhanced image is only providing assistance in enhancing the image so that the user then refers back to the original image for final review. In addition, the electronic images and patient identification information are preserved during the transfer to protect against mix-ups with information between patients.

This would indicate a Minor Level of Concern, however, following discussions with the Agency during the Pre-IDE Meeting (reference I100579), the Sponsor now understands that this type of device is considered to have a Moderate Level of Concern based on the potential for misdiagnosis. The sponsor believes this to be a remote possibility that would be caused by user error due either to a mix-up of the patient's image by the practitioner prior to upload to the CARA system or to the user not relying on the original image for diagnosis as instructed by the labeling.

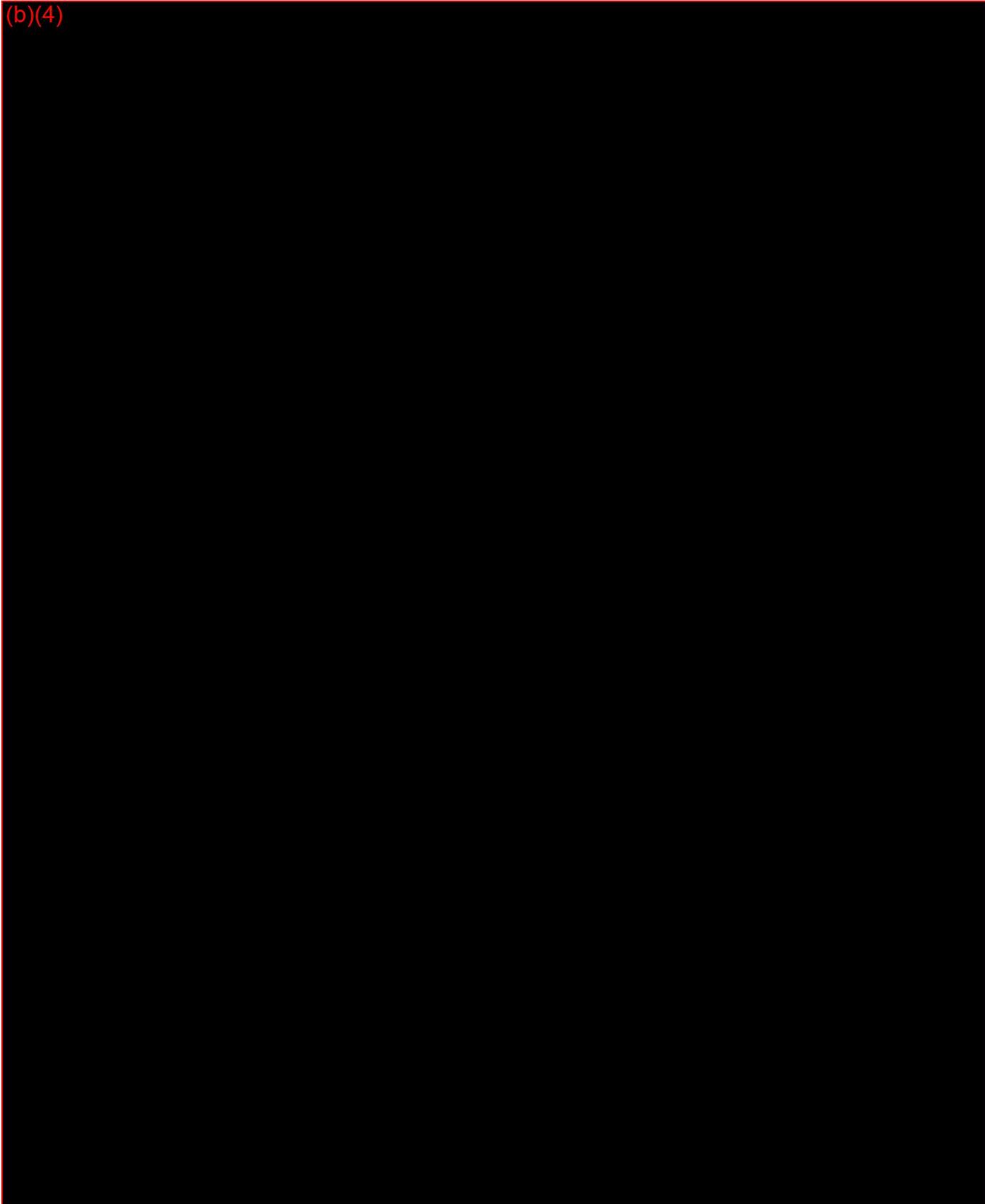
#### **B. SOFTWARE DESCRIPTION**



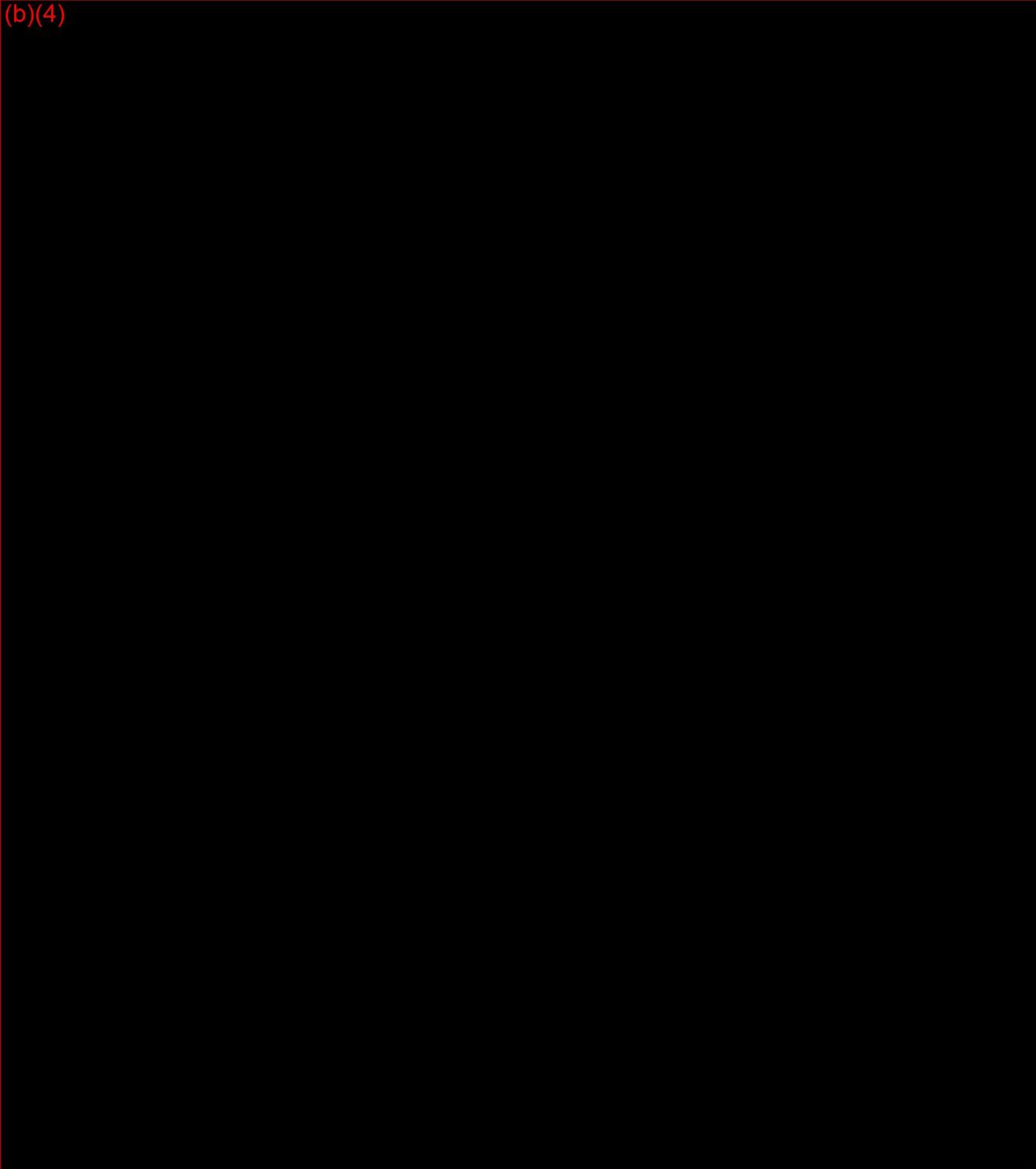
(b)(4)



(b)(4)

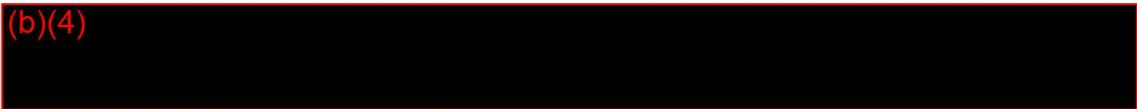


(b)(4)



**C. DEVICE HAZARD ANALYSIS**

(b)(4)



Based upon the function of the device and the controls put in place during the design, the Sponsor believes that potential hazards have been adequately controlled.

#### **D. SOFTWARE REQUIREMENTS SPECIFICATION (SRS)**

The Software Requirements Specification document found in Appendix III-4 documents the functional, interface, performance, design and developmental requirements for the CARA software.

#### **E. ARCHITECTURE DESIGN CHART**

The Architecture Design Chart is included in Appendix III-5.

#### **F. SOFTWARE DESIGN SPECIFICATION (SDS)**

The Software Design Specification document found in Appendix III-6 describes the implementation of the requirements for the CARA software. Details of the image processing algorithms are included in Appendix III-7.

#### **G. TRACEABILITY ANALYSIS**

A traceability matrix is included in Appendix III-8. This document links the user requirements and functional requirements with hazards/mitigations and verification/validation testing requirements for the CARA software.

#### **H. SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION**

The software development process is governed by the Sponsor's Design Control program. A description of the software development environment is included in Appendix III-9.

#### **I. VERIFICATION AND VALIDATION DOCUMENTATION**

Appendix III-10 includes information regarding internet browser compatibility testing that was done to test the CARA web interface.

Software Functionality Testing is described in Appendix III-11.

Appendix III-12 provides additional verification and validation information on the functionality of the CARA enhancement software.

#### **J. REVISION LEVEL HISTORY**

The CARA software revision history log is included in Appendix III-13.

#### **K. UNRESOLVED ANOMALIES (BUGS OR DEFECTS)**

To-date, the sponsor has not detected any unresolved anomalies in the CARA system.

## **APPENDIX III-1**

### **Level of Concern Table**

## Diagnos CARA – Level of Concern Analysis

### Table 1 Major Level of Concern

**If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.**

1. Does the Software Device qualify as Blood Establishment Computer Software?

No.

2. Is the Software Device intended to be used in combination with a drug or biologic?

No.

3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?

No. The device receives images created by other medical devices, but is not an accessory to any device.

4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:

No. The software does not contact patients or users, therefore, there is no potential for direct physical injury.

- a. Does the Software Device control a life supporting or life sustaining function?

No.

- b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?

No.

- c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

No. The device simply enhances images. It does not control delivery of any treatment.

- d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

No. The device simply enhances images. It does not provide any diagnostic information. The original (non-enhanced) image is available to the doctor who evaluates the patient. The doctor will not rely on the enhanced image as the sole or primary information used to make any diagnosis.

- e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

No.

## **Table 2 Moderate Level of Concern**

**If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.**

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

No. The device receives images created by other medical devices, but is not an accessory to any 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?

No. The software does not come in contact with patients or users; therefore, there is no potential for direct physical injury. The original (non-enhanced) image is available to the doctor who evaluates the patient. The doctor will not rely on the enhanced image as the sole or primary information used to make any diagnosis.

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

No. The tools routinely used in diagnosis of retinal pathologies include the eye examination and images of the retina. The device does not perform any diagnosis, grading or analysis of the patient condition or of the images taken. The device does not replace the original images obtained. The original (non-enhanced) image, which is already sufficient and typically used to make a diagnosis, will be available to the doctor who evaluates the patient. The doctor will not rely on the enhanced image as the sole or primary information used to make any diagnosis. The physician will use the enhanced image to help identify areas that he/she should look closer at in the non-enhanced original image.

However, if there is user error by the practitioner (i.e., he or she mixes up the patient's original image or relies on the enhanced image) there is a remote possibility that a misdiagnosis or delay in appropriate medical care could result.

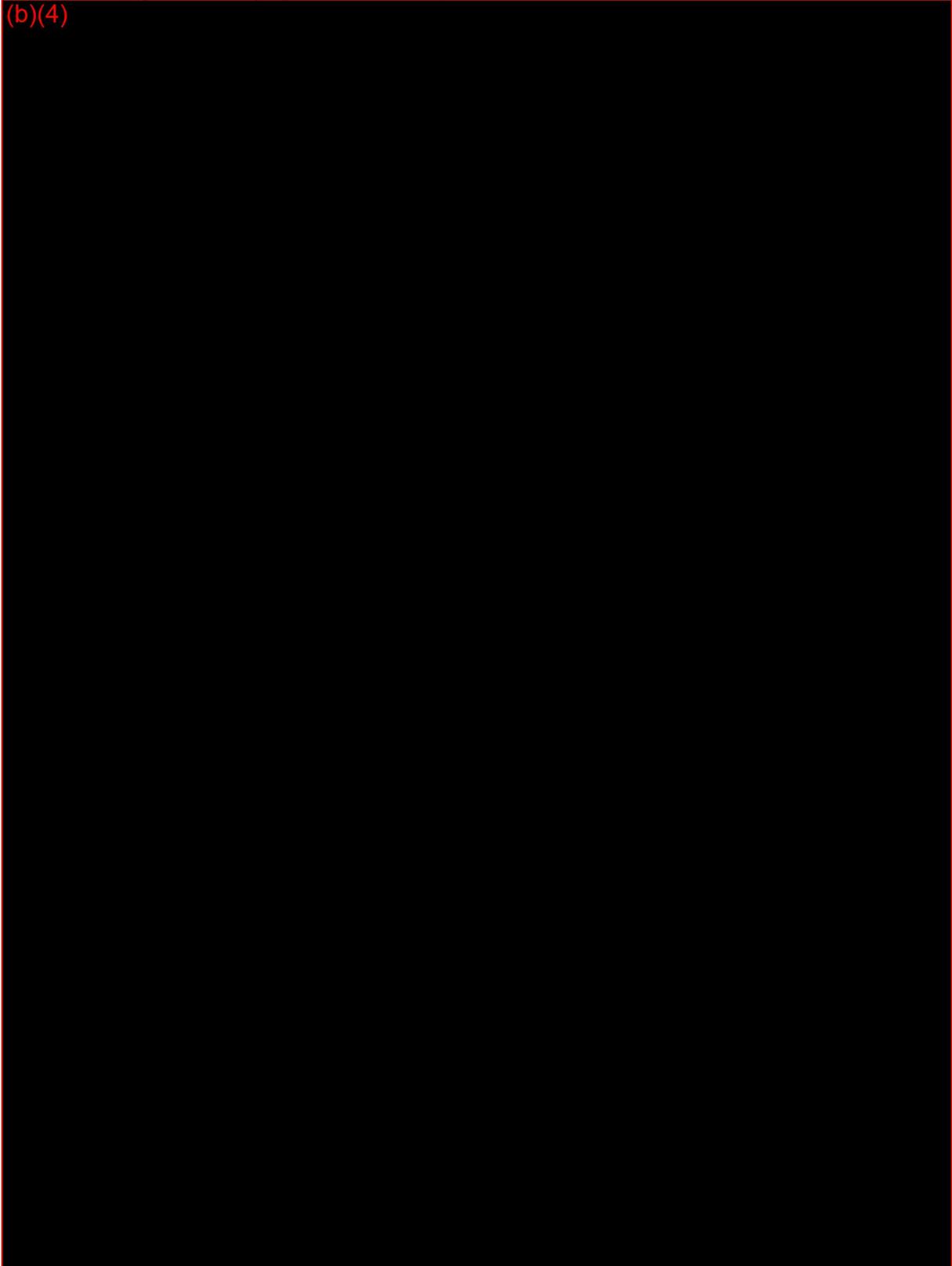
**If the answers to all of the questions in Tables 1 and 2 above are No, the Level of Concern is Minor.**

Based upon discussion with the Agency and the possibility of user error, the Level of Concern is determined to be Moderate.

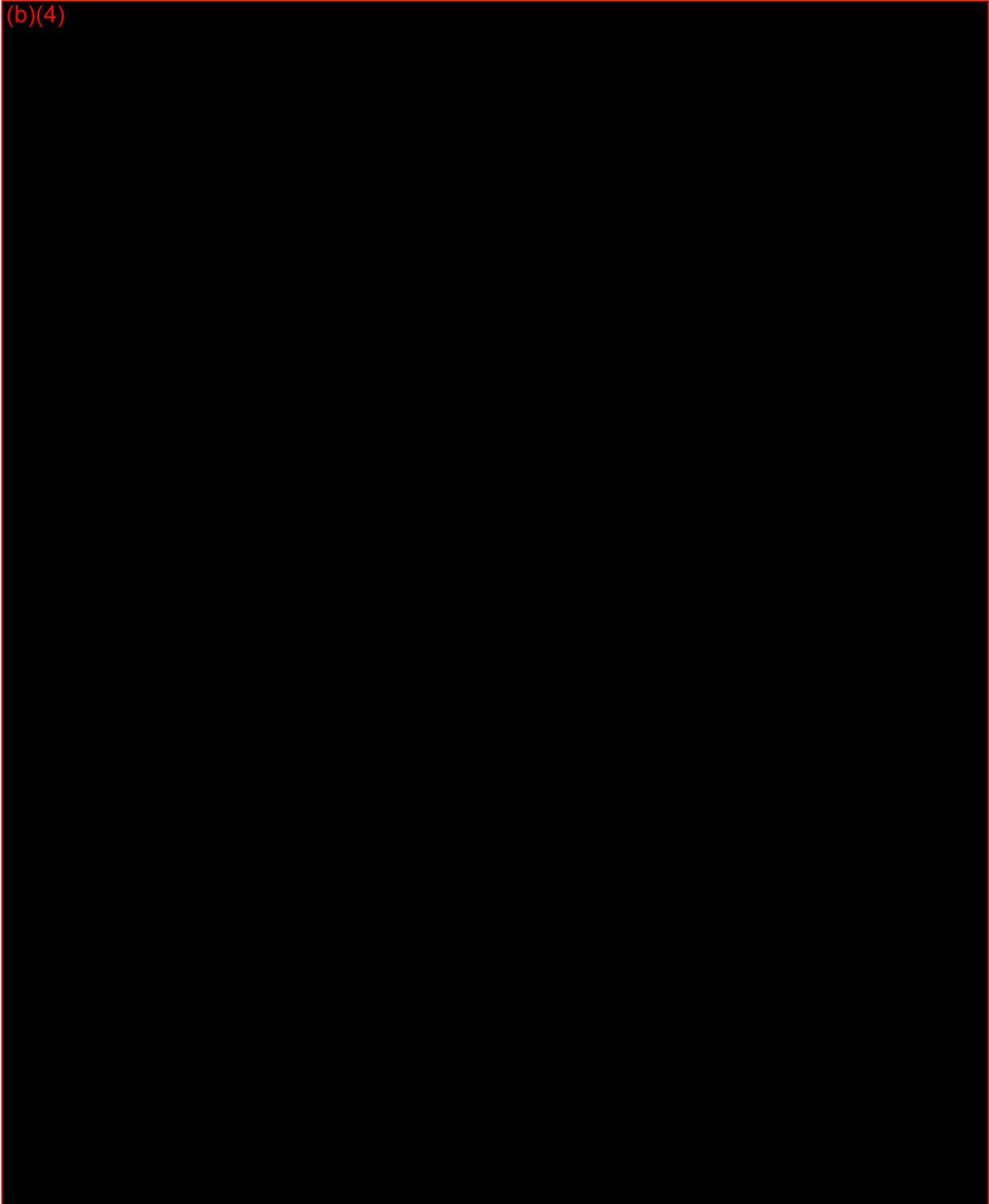
## **APPENDIX III-2**

### **Cybersecurity**

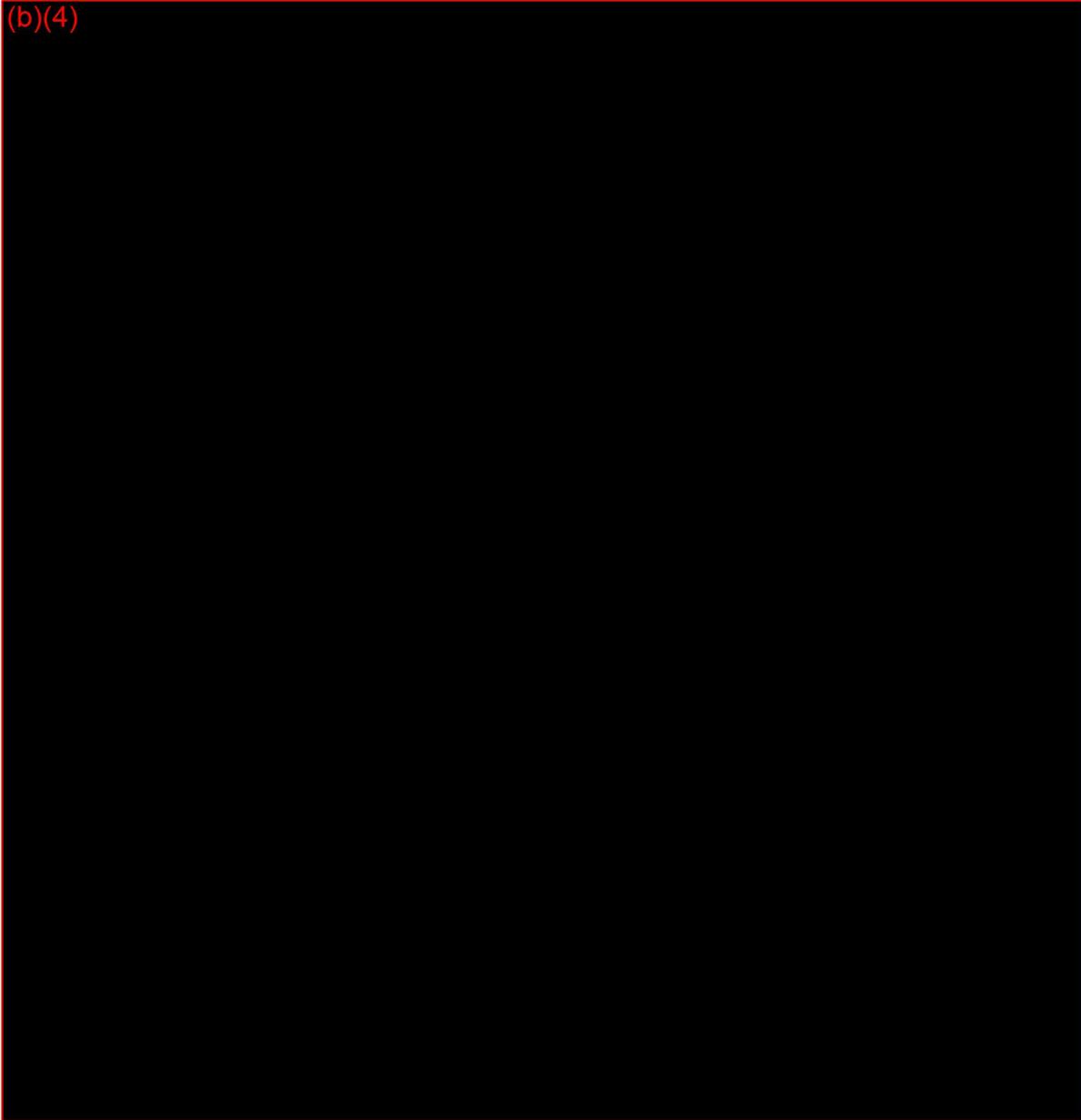
1.1. Cybersecurity system overview



(b)(4)

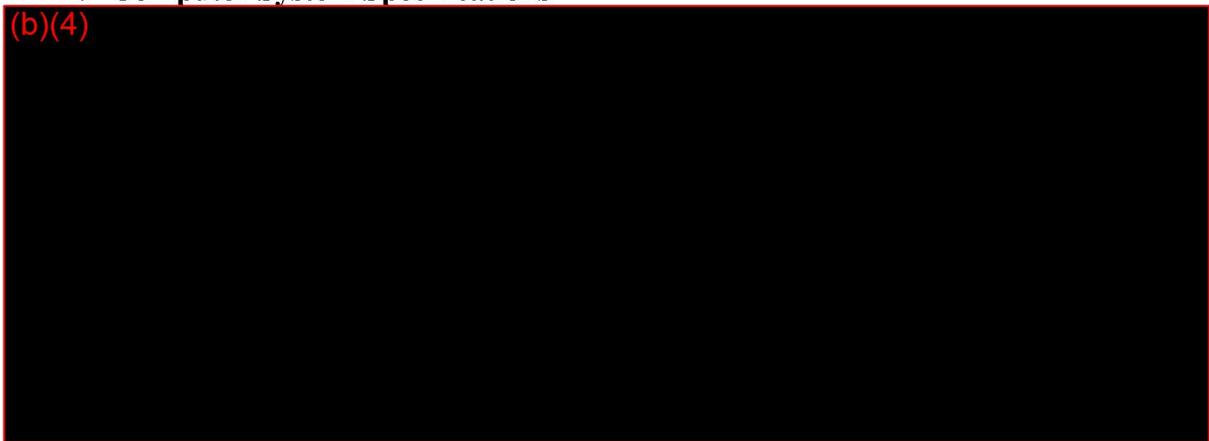


(b)(4)



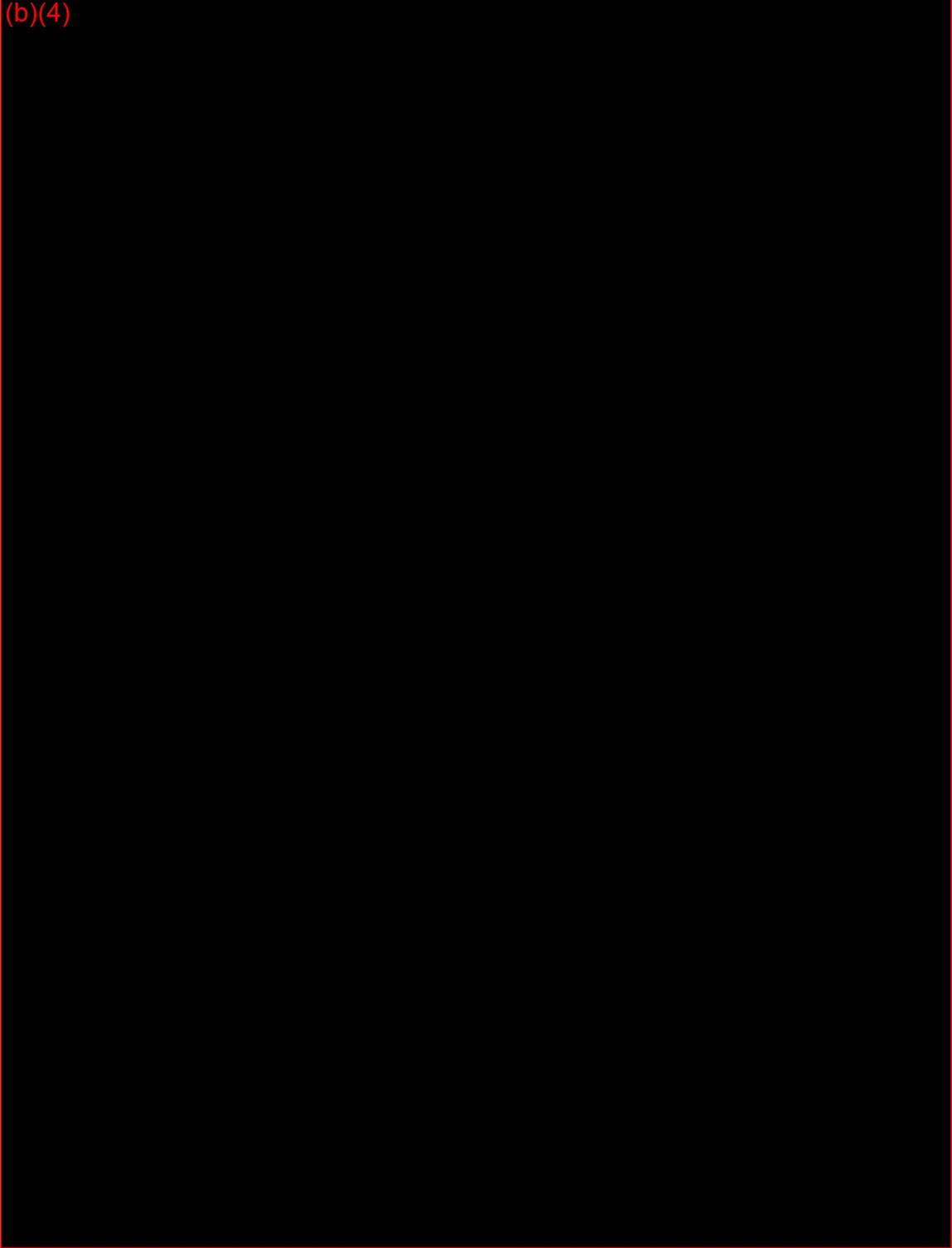
## 2. Computer System Specifications

(b)(4)



*Software*

(b)(4)



(b)(4)



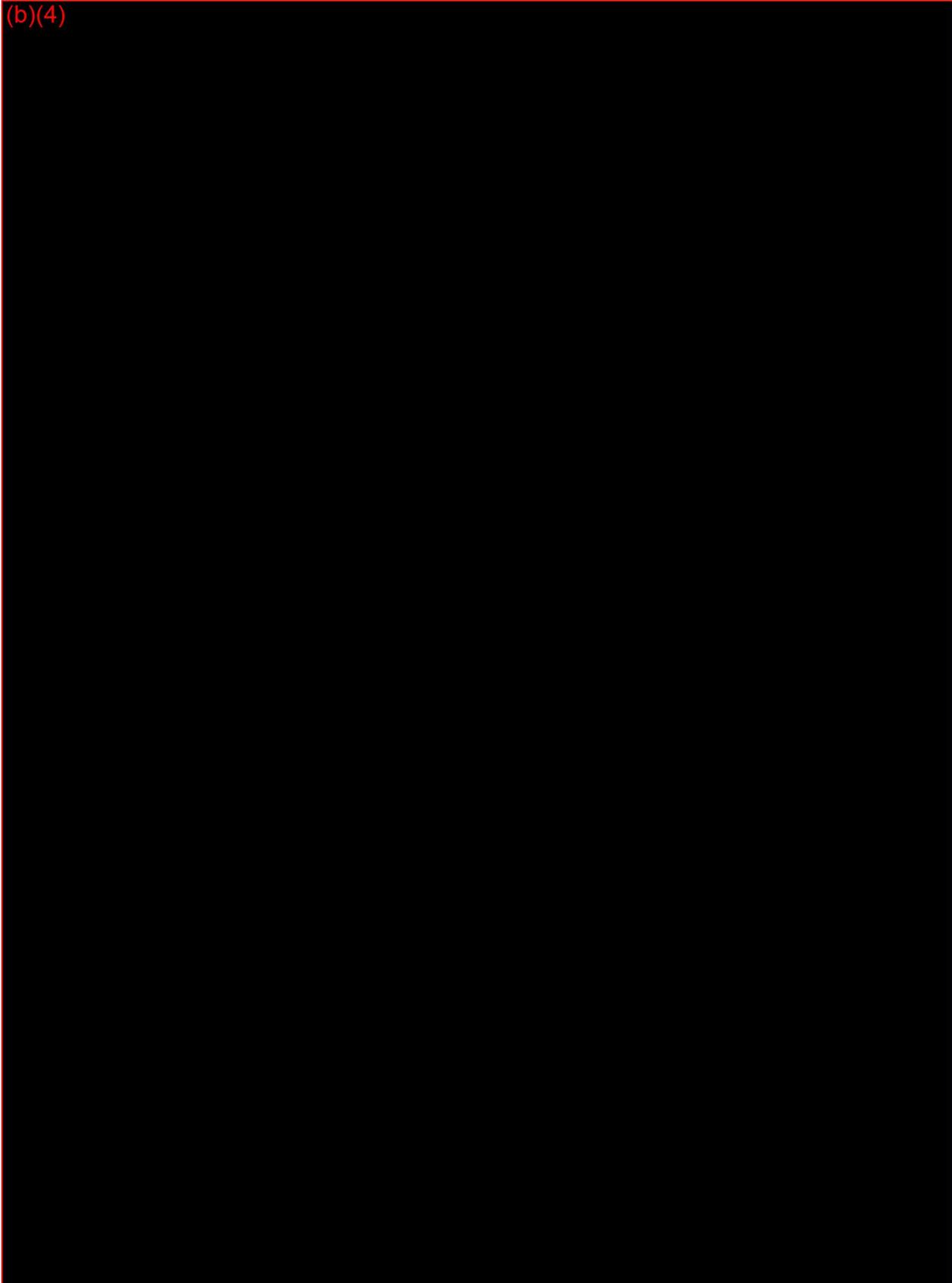
**Cybersecurity**

(b)(4)

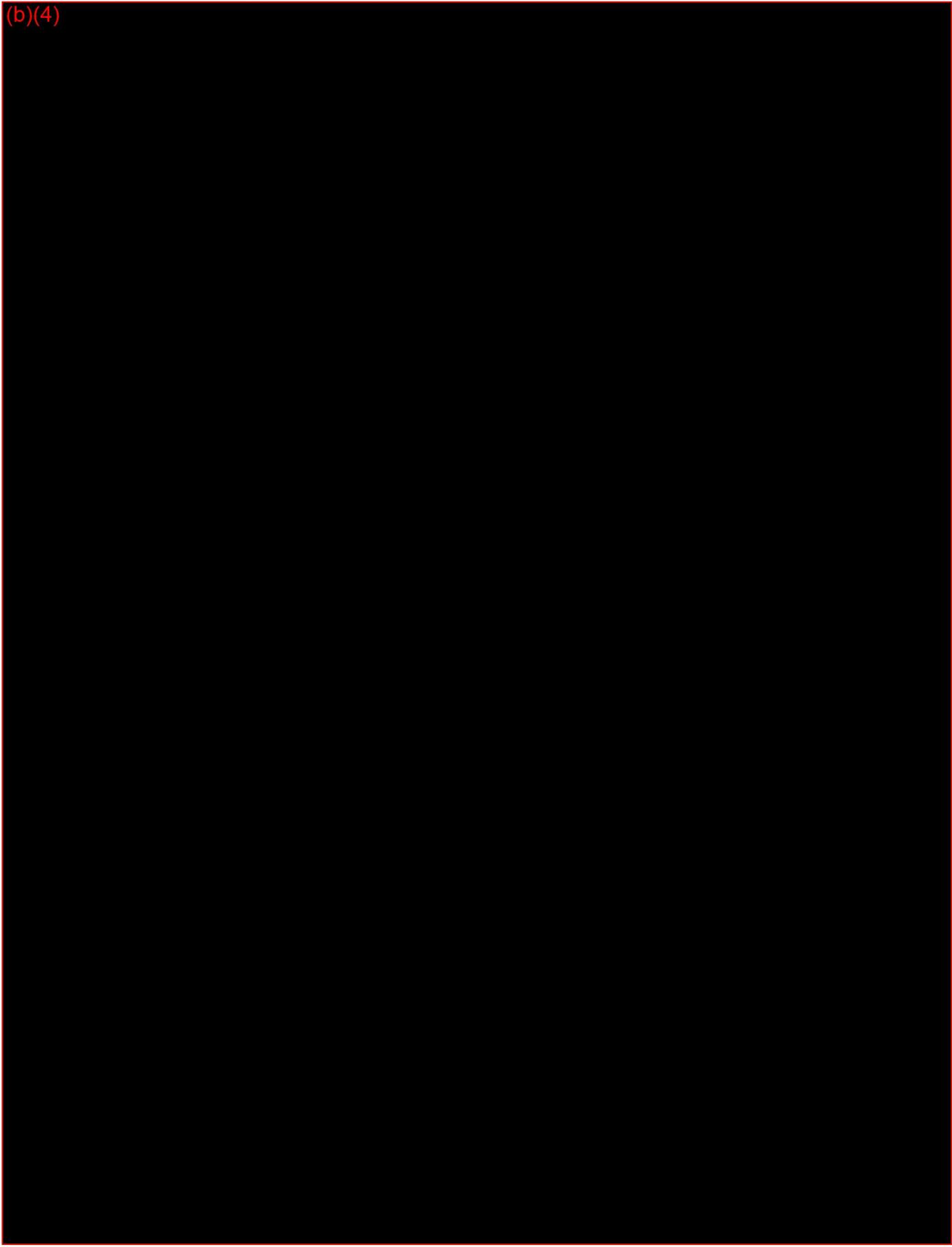


## 2.2 OTS Hazard Analysis and Mitigation

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## **APPENDIX III-3**

### **Hazard Analysis**

DIAGNOS, Inc.  
CARA

510(k) Premarket Notification  
March 25, 2011

CARA Hazard Analysis

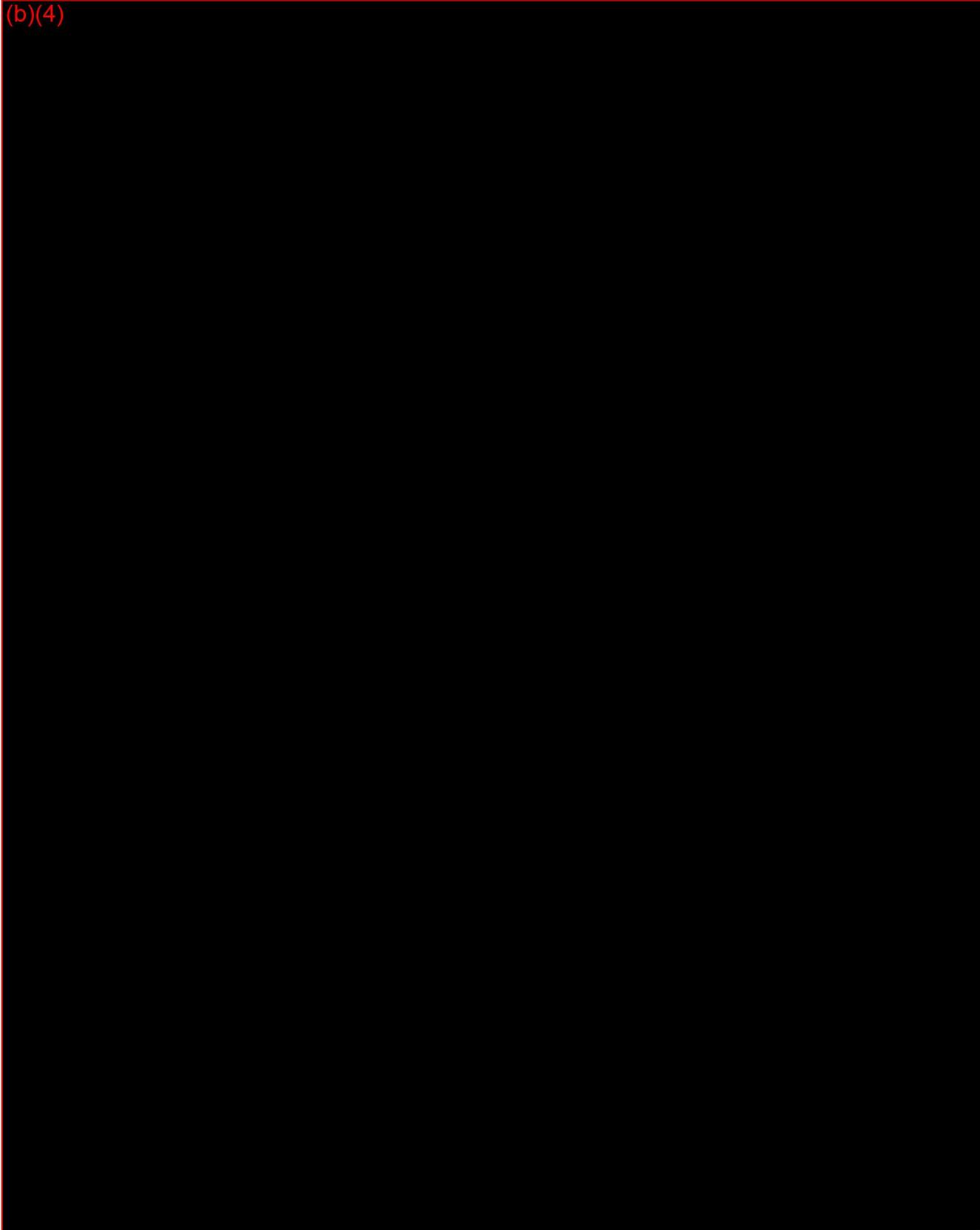
Id.	Hazard	Where Caused	Mitigation
1	Physical harm to user/patient	N/A: device does not contact the user/patient	
2	Misdiagnosis of patient's condition due to artifacts in device output	Medical practice error by doctor	N/A: Device does not perform any diagnostic function (disclaimer). Original image available/presented to user with enhanced image.
3	Misdiagnosis of patient's condition due to poor quality of user display for image output	Hardware used by doctor who submits images for enhancement	Device instructions in the user manual present the minimum requirements for device hardware (image quality) used by the doctor to view images in office
4	Misdiagnosis of patient's condition due to mix-up of images from different patients	Image transfer to/from CARA	To each CARA transaction is assigned a unique transaction key, eight characters in length and whose uniqueness is enforced at the database level (unique primary key). This unique ID is used as a parameter in all CARA subroutines and in all operating system/file system tasks (example: the UID is used as the directory name used to store original and enhanced images on CARA servers). Additionally, all original images are write-protected to assure they are never over-written or modified.
5	Misdiagnosis of patient's condition due to corruption of original image	Doctor's office alters original output files from digital camera	Software rejects images that do not meet quality and size requirements prior to acceptance for enhancement. Moreover, if data flowing across an SSL session is altered, the SSL code in the receiving node will detect this condition and not pass the corrupted data to the application.
6	Compromise of confidential patient information	Image transfer to/from CARA	Image transfer to/from CARA is accomplished with the use of the Secure Socket Layer (SSL). This well established and widely accepted standard assures that data received is identical to data sent with the added advantage of strong encryption.
7	Misidentification of fundus images could lead to misdiagnosis	Mix-up of images from different patients	Use of unique identifier for every request/images sent for analysis. For more information, please refer to section 2.3 OTS Software Hazard Mitigation of Cybersecurity system document in Appendix III-2.

## **APPENDIX III-4**

### **Software Requirements Specification (SRS)**

## SOFTWARE REQUIREMENTS SPECIFICATION

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## **APPENDIX III-5**

### **Architecture Design Chart**



## **APPENDIX III-6**

### **Software Design Specification (SDS)**























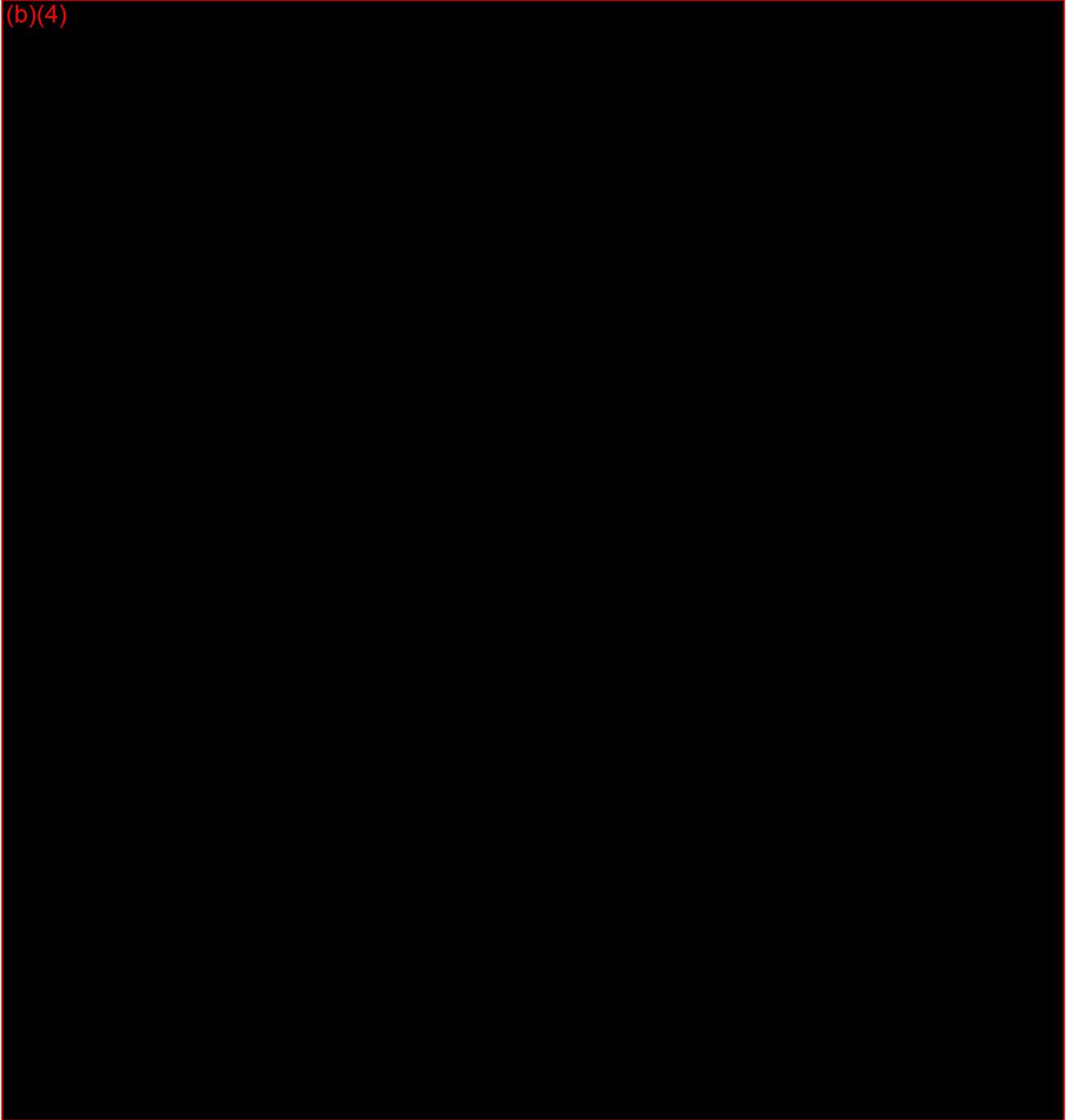


## **APPENDIX III-7**

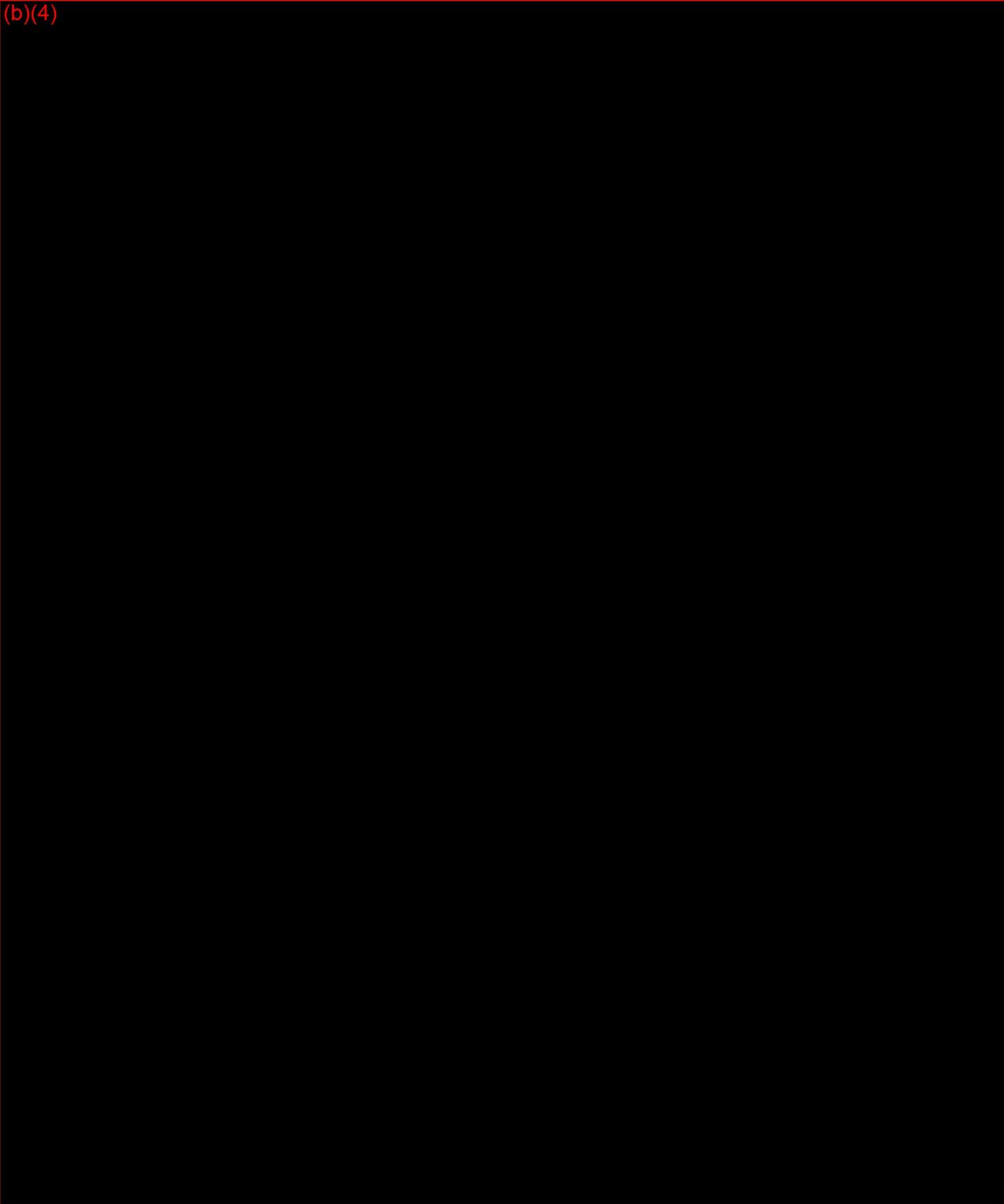
### **Algorithms**

## CARA Enhancement Algorithms Description

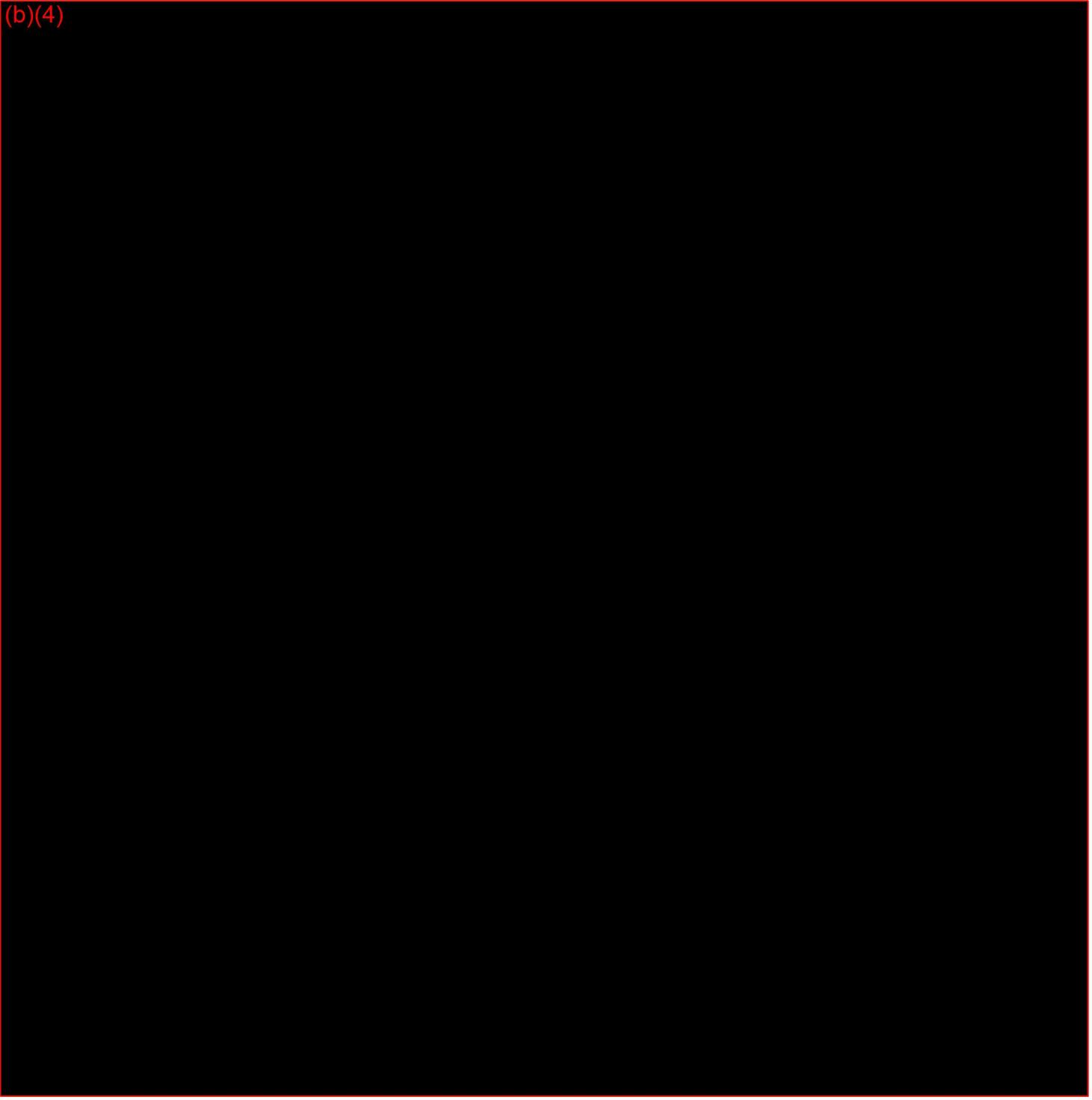
(b)(4)



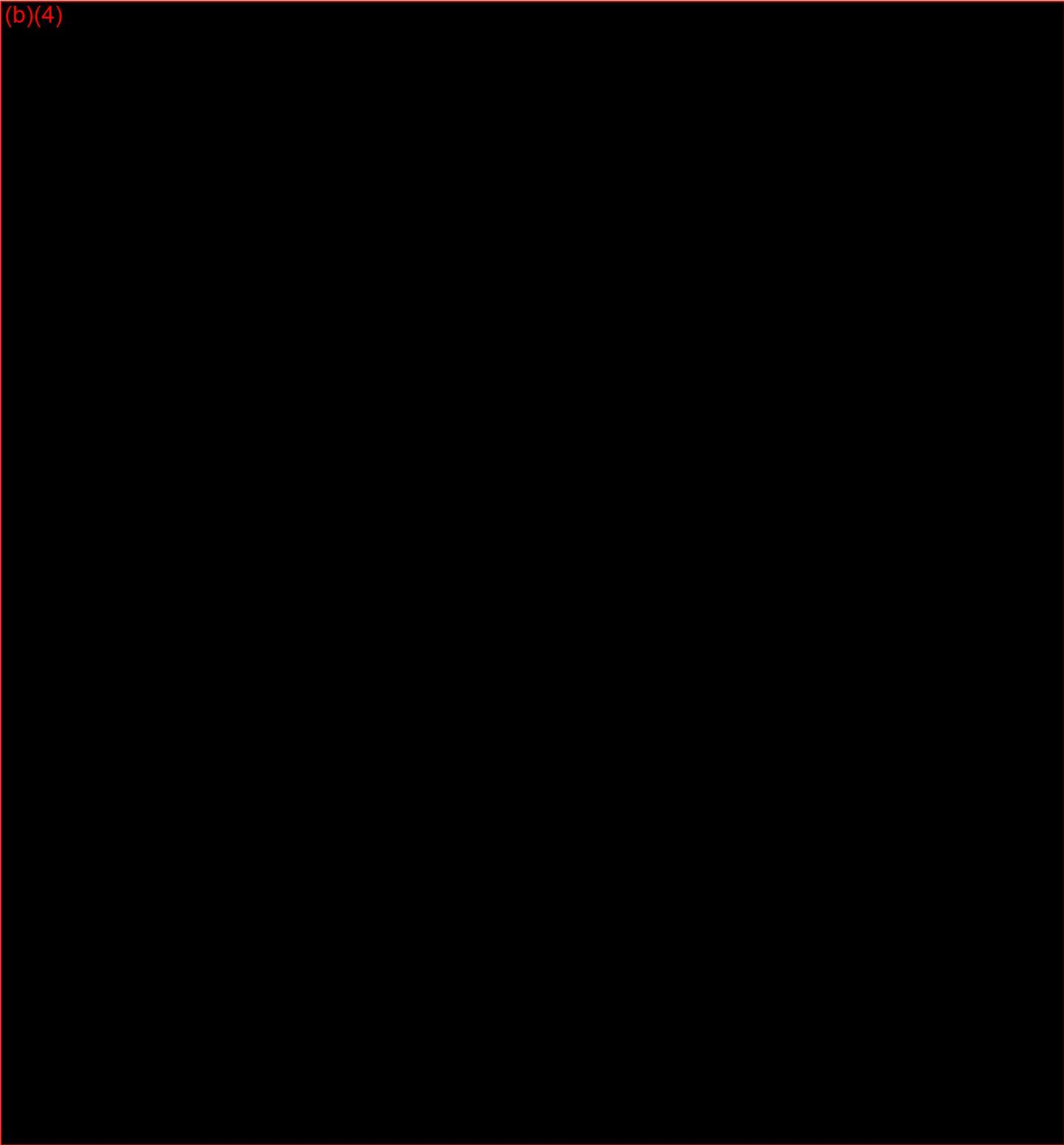
(b)(4)



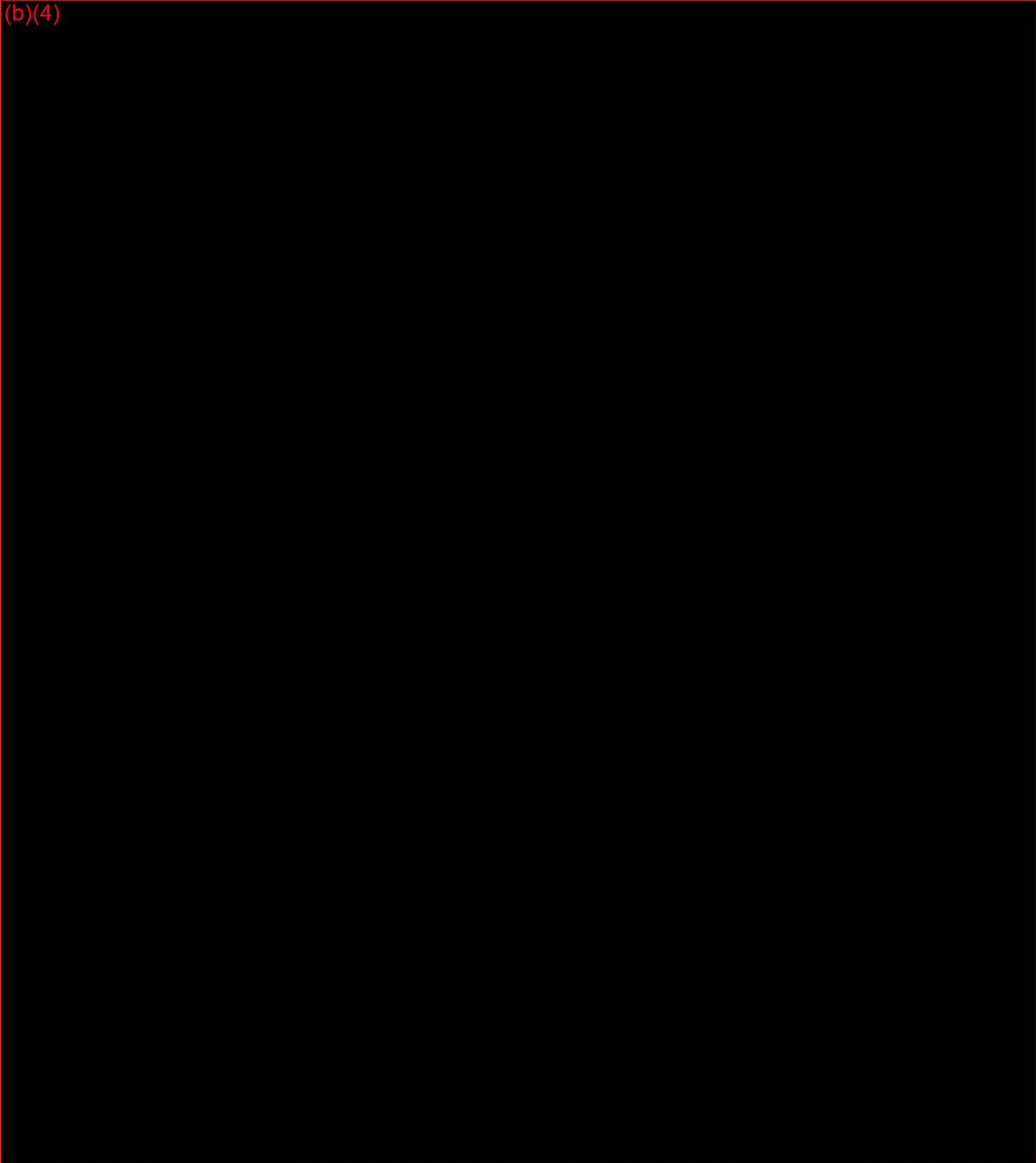
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## **APPENDIX III-8**

### **Traceability Matrix**

DIAGNOS, Inc.  
CARA510(k) Premarket Notification  
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<b>URID</b>	<b>User Requirements Description</b>	<b>Functional Requirements Specification</b>	<b>Hazards and Mitigation</b>	<b>Validation, Verification and Testing</b>
<b>1</b>	The following general security requirements must be met			
1.1	Only an authorized person may modify user account information	Cybersecurity – 1.	Hazard Analysis – 6.	Cybersecurity – 1.
1.3	CARA website connection must be secured and ensure data integrity	Cybersecurity – 5. SRS – 4.3.1 and 4.6.	Hazard Analysis – 5. and 6.	Cybersecurity – 5.
<b>2</b>	The following legal specifications must be met to remain compliant with the regulations			
2.1	CARA must be ISO 13485 certified	SRS – 4.8.	N/A	Audit and certification
2.3	CARA must be FDA approved	SRS – 4.8.	N/A	Currently not FDA certified
<b>3</b>	The following CARA website requirements must be met			
3.1	As a secured website, CARA must have a login page	SRS – 4.6.1 Cybersecurity – 1. and 4.	Hazard Analysis – 4. and 6.	Software Functionality Testing – 1.
3.2	The user must be able to submit new images through a dedicated web page	SRS – 4.6.2	N/A	Software Functionality Testing – 2.
3.3	The user must be able to consult results of enhancement images he has sent	SRS – 4.6.3	Hazard Analysis – 4.	Software Functionality Testing – 3. and 4.

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3.4	The image review page must allow the user to switch from the original and the enhanced image	SRS – 4.6.4	Hazard Analysis – 2.	Software Functionality Testing – 4.
3.5	The image review page must offer a zoom in/out control	SRS – 4.6.5	Hazard Analysis – 3.	Software Functionality Testing – 4.
3.6	The user must be able to navigate through the previous results pages	SRS – 4.6.6	Hazard Analysis – 4.	Software Functionality Testing – 5.
<b>4</b>	The following CARA processing engine specifications must be met to ensure results quality			
4.1	CARA must handle commonly used color fundus image from fundus camera approved by regulatory authorities	SRS – 4.4.2, 4.5.2, 4.5.3 and 4.5.4 Algorithm Description – 1.	N/A	Software Functionality Testing – 6.
4.2	CARA must perform an enhancement of fundus images	SRS – 4.4.1 Algorithm Description – 4.	Hazard Analysis – 2.	Software Functionality Testing – 8.
4.3	CARA must perform an enhancement process quality control	Algorithm Description – 1., 3 and 5.	Hazard Analysis – 2.	Software Functionality Testing – 7. and 8.
<b>5</b>	The following code verification and validation specifications must be met			
5.1	Algorithms must be tested	SRS – 4.7.5 and 4.7.6	Hazard Analysis – 2.	Validation and Verification – 1.
5.2	Algorithm integration must be tested	SRS – 4.7.6	Hazard Analysis – 2.	Validation and Verification – 2.

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## **APPENDIX III-9**

### **Software Development Environment**

## **Software Development Environment**

The following document deals with the way the developers operate to design and manage CARA software.

### ***1 Software Development Life Cycle Plan***

#### **(a) Software Development Plan**

The software development plan is the document the developers can refer to when working on CARA development. It describes the task work flow to create or modify a feature for CARA software.

The software development plan contains

- the different processes uses all along the development
- the deliverables of each activity and task
- the traceability between the software requirements specifications, the tests and the risk management
- the configuration management
- the software problem solving management at each step of the software life cycle

#### **(b) Software development plan update**

When changes are to be applied to the software development process, the software development plan is updated so that the developers can rely on and refer to it to modify or improve the software. To achieve this update, the developers use the AGILE method ([http://en.wikipedia.org/wiki/Agile\\_software\\_development](http://en.wikipedia.org/wiki/Agile_software_development)).

#### **(c) Software requirements analysis**

The software requirements analysis is a really important step that has been done once at the beginning of the project and which is updated each time a modification is to be done on it. The features and functionalities that have to be implemented into CARA are decided at this step and they are written in the Software Specification Requirements (SRS) document.

#### **(d) Software Verification Plan**

The system is based on proprietary algorithms developed using a proprietary digital image processing library. As the algorithms of CARA have to be robust, the verification process must handle both the algorithms themselves and the algorithms contained in the library.

As the algorithms of the library perform basics image processing operations, they are tested with unitary tests that insure that they do correctly what they are intended to do.

The CARA algorithms are more complex and involve too many basics algorithms to be unit tested. Functionality regression tests are thus performed on them to insure that a modification

on any part of the software does not deteriorate the functionalities and the final result. The unitary and functionality tests are designed to evaluate sharply the algorithms and the pass / fail criteria are chosen to be as restrictive as possible. The testing process is detailed in documents: (REF)

### **(e) Risk Management Plan**

The risk management plan is described in the device hazard tabular issued from the Device Hazard Analysis process.

## **2 Configuration / changes management plan**

### **(a) Configuration identification**

CARA configuration elements, such as proprietary elements, external parts and SOUP, are listed in a dedicated file available on company wiki servers. Each element is identified with its version number and if not proprietary, with its origin. The system documentation linking to the configuration documentation is also available on wiki pages on the company servers.

### **(b) Modifications management**

- Modification requests are received from customers for issue troubleshooting or from internal provenance for continuous improvement.
- Each request is analyzed to evaluate if it is appropriate to consider a modification of the software.
- If the software is to be modified, the work is evaluated by company's experts.
- The modifications themselves are then performed documented
- The modifications are then tested to validate that they correctly answer the request.
- The modifications traceability is achieved by two external software : bugzilla (<http://www.bugzilla.org/>) and QIT9000 (<http://www.qit9000.com/>). They both allow modifications records registration and sharing.

### **(c) Configuration related documentation**

The documentation related to CARA configuration state is available on the company wiki server:

<b>CARA-CCE(the system)</b>	<b>v1.0.0 (2009-Jul-31)</b>	<b>v1.0.5 (2009-aou-17)</b>	<b>v1.1(2009-sep-18)</b>	<b>CARA v2.0(2010-Mar-01)</b>
Algorithms CARA	v1.0.0	v1.0.1	v1.0.1.1	v2.0
Algorithms CCE	v1.0	v1.1	v1.2	v1.2
PrognosNG	v0.71	v0.72	v0.80	v0.80
CaraWeb	v1.0	v1.1	v1.2	v2.1.2
518-DOC-SOUP	v1.1	v1.1	v1.2	v1.3

*a - features versions*

<b>Algorithms CCE (analyser)</b>	<b>v1.0 (31-07-09)</b>	<b>v1.1 (17-08-09)</b>	<b>v1.2 (26-08-09)</b>	<b>v1.2 (01-03-10)</b>
oceGetEnhancedColorImage	3058	3285	3285	3285
oceValidateImage	n/a	n/a	3309	3309
oceConvertImage	2612	2612	2612	2612
oceGetThumbnail	3062	3062	3062	3062
oceGetShapeMask	3055	3055	3055	3055

*b - algorithms versions*

*Illustration 1: CARA versions*

#### (d) Software release

CARA development / releases follow a three steps process:

- development
- test
- production

Each component of the system (features, SOUP, external material) has to go through these steps.

This process is applied for

- new features addition
- general upgrade
- bug solving

The software versions and their components information are stored and available on the wiki server with release date (See illustration 1). Thus the composition of each version is perfectly known.

As CARA is a web service, there is no need to provide the user with a new software version. The deployment is then safer and faster.

### **3 Maintenance plan**

#### **(a) Software maintenance plan establishment**

The maintenance plan refers to documentation about the way of handling:

- Reception of correction or improvement requests coming from company's customers or from internal sources.
- Documentation of the corrections or improvements to trace efficiently issues and improvements that occur.
- Evaluation of the request to analyze its causes and the potential lack of the system.
- Answering the request to tackle the issue(s) it raised. This is achieved by correcting the mistake (if any) or designing and implementing a new feature and the related tests into the system. This is done along with the communication with the request sender and the documentation of the problem resolution.

#### **(b) Request evaluation criteria**

Each request is handled and processed by a qualified staff member who determines whether the request is valid or not. He first verifies if it does not meet exclusion criteria that are given in the user's manual. Then, if it's not the case, he

- finds the causes
- evaluates the effort to be done to solve the problem
- evaluates the risks implied by a change in the system
- Designate a person in charge of the documentation (descriptions, reports) and the resolution of the problem.

This process is detailed in the software life cycle documentation.

#### **(c) Archiving**

Once a request has been processed, the whole documentation available for it is archived so that it could help to anticipate or solve a similar issue / improvement.

## **APPENDIX III-10**

### **Internet Browser Capability Testing**

## Internet browser compatibility tests

(b)(4)



















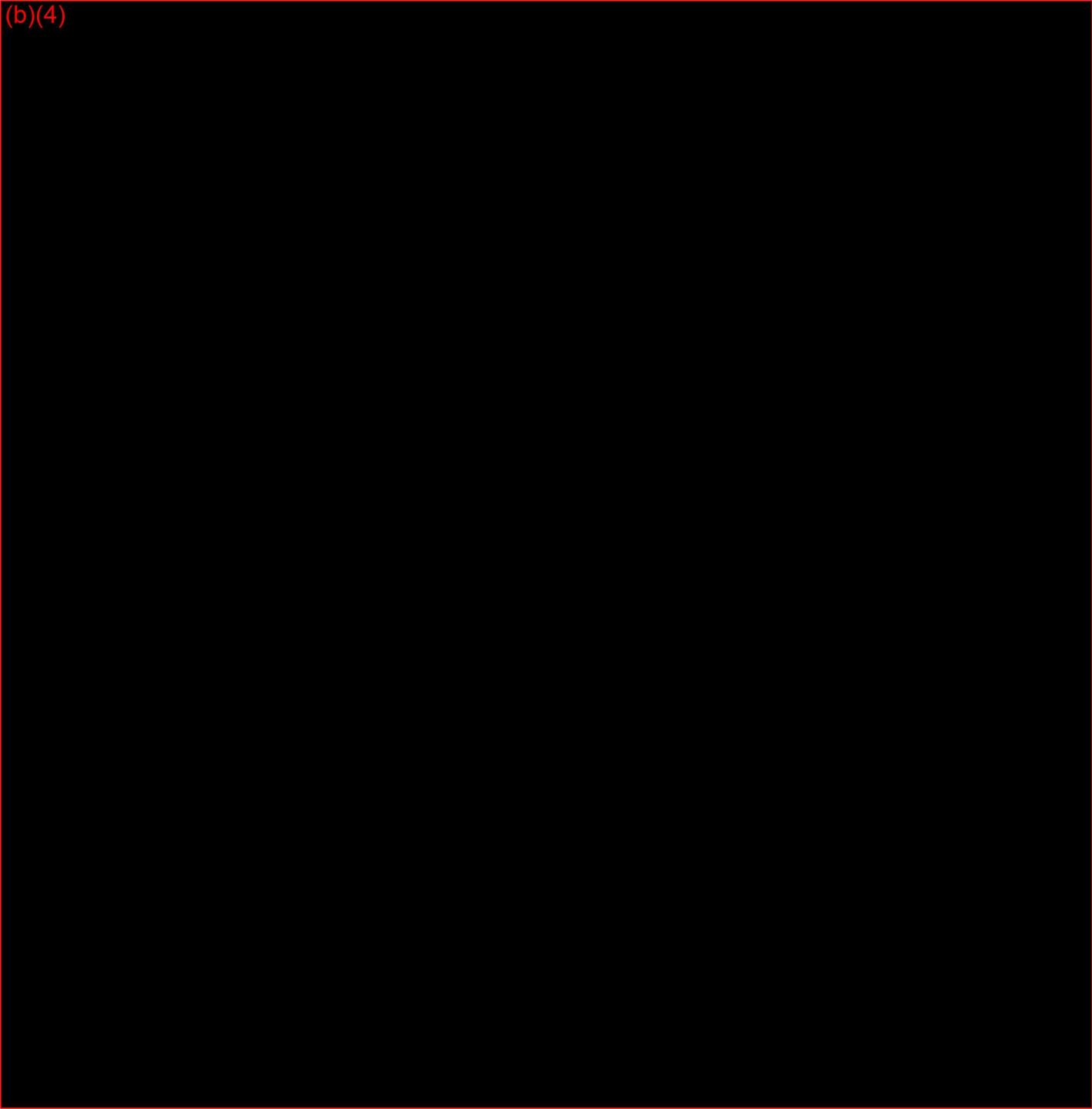


## **APPENDIX III-11**

### **Software Functionality Testing**

## Software Functionality Testing

(b)(4)























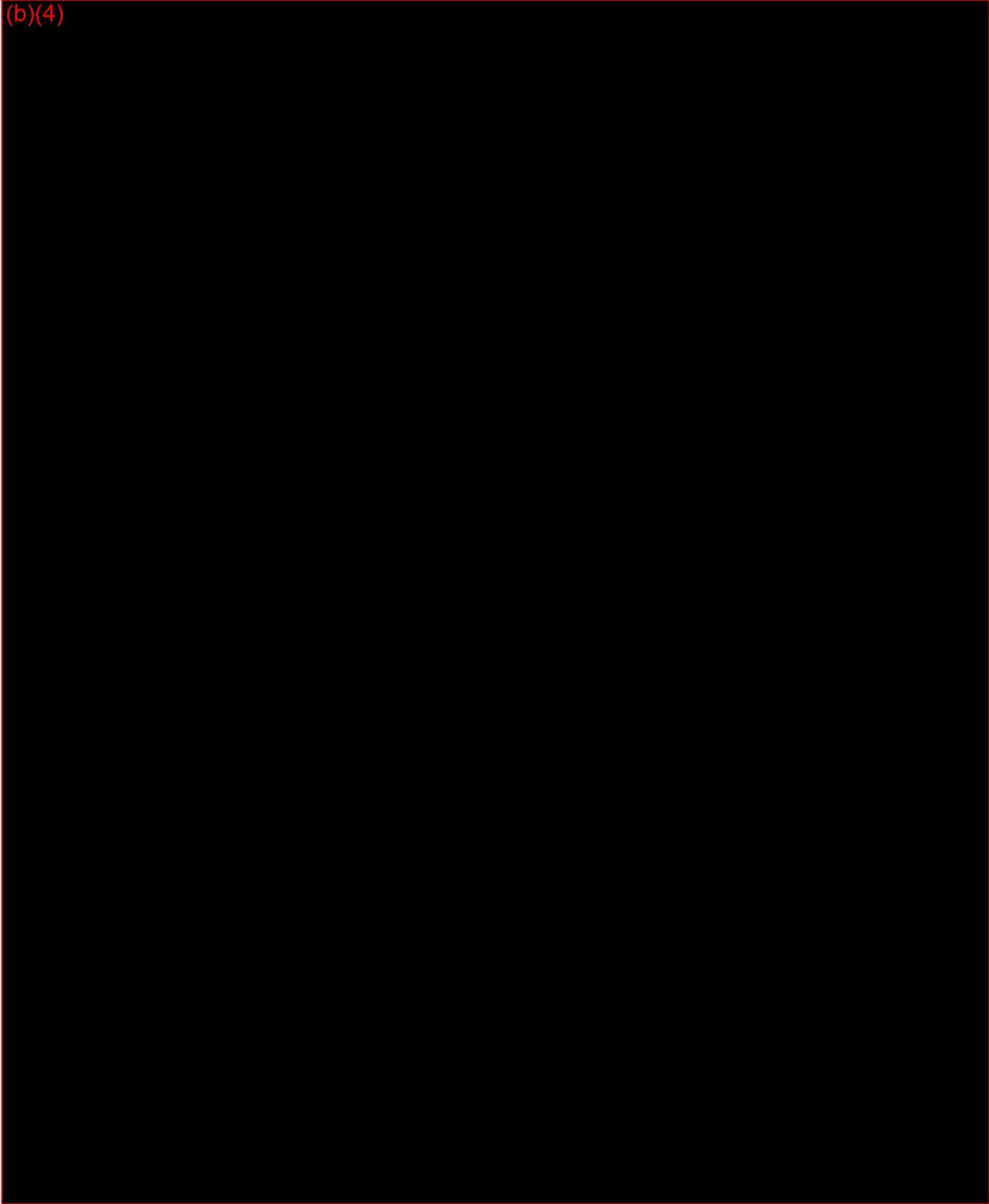


## **APPENDIX III-12**

### **Verification and Validation**

## Validation and Verification

(b)(4)











## **APPENDIX III-13**

### **Revision Level History**



**PREMARKET NOTIFICATION 510(k)**

**CARA**

**SECTION IV: SUBSTANTIAL EQUIVALENCE**

The claim of substantial equivalence to the Topcon IMAGENet Professional PC Software System (K082364) is based on similar intended uses to collect, store, enhance and transfer digital retinal images from computerized imaging devices through computerized networks.

The table below provides a comparison between the predicate device and the CARA device.

	<b>Topcon IMAGENet</b>	<b>Diagnos CARA</b>
<b>Software Only</b>	√	√
<b>Web Based Platform</b>	x	√
<b>Non-mydratic Capture Device Images Processing</b>	√	√
<b>Image Data Management</b>	√	√
<b>Fundus Image Only</b>	√	√
<b>File Import</b>	√	√
<b>Color Fundus Image Enhancement</b>	x	√
<b>Black &amp; White Fundus Image Enhancement</b>	√	x
<b>Linear Distance and Area Measurement</b>	√	x
<b>Image Annotation &amp; Measurement</b>	√	x

√ = present

x = absent

CARA shares many similar technological characteristics as the predicate device, both in terms of the manner in which images are captured, processed, and stored, as well as the operation of the device by the intended user.

The results of software validation and verification testing demonstrate that CARA performs as intended and meets the specifications. This supports the claim of substantial equivalence

Any minor difference in operation does not raise additional new questions about safety and effectiveness. CARA raises the same issues of safety and effectiveness as the predicate device.

**PREMARKET NOTIFICATION 510(k)**

**CARA**

**SECTION V: PROPOSED LABELING**

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	<b><u>Page</u></b>
<b>A. Log-in Page.....</b>	<b>2</b>
<b>B. User Manual .....</b>	<b>2</b>
 <b><u>APPENDICES</u></b>	
<b>Appendix V-1: Log-in Page.....</b>	<b>V-3</b>
<b>Appendix V-2: User Manual .....</b>	<b>V-5</b>

## **SECTION V: PROPOSED LABELING**

### **A. Log-in Page**

A screen shot of the Internet log-in page for the CARA system is provided in Appendix V-1. The user is directed to account-specific pages after this log-in and will thus be prevented from access to parts of the system that are not cleared for use by the FDA.

### **B. User Manual**

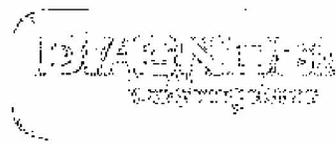
The proposed User Manual for the CARA system is presented in Appendix V-2. The manual describes the use of CARA through the internet interface, including step-by-step user instructions. Descriptions and screen shots of the internet interface screens are provided.

## **APPENDIX V-1**

### **Log-in Page**

DIAGNOS, Inc.  
CARA

510(k) Premarket Notification  
March 25, 2011



CARA  
Computer Assisted Retinal Analysis



English

Username

Password

**Disclaimer:** The CARA system is intended to help the qualified health care professionals in the analysis of the human retina. When using CARA, the user must be aware of the following:

- CARA has been approved by Health Canada and is in the process for the U.S. Food and Drug Administration (FDA) and other international regulatory bodies.
- CARA is not intended to diagnose, treat, cure, or prevent diabetic retinopathy, or any other disease.
- CARA enhanced images should only be used as an ancillary tool by qualified eye care professionals who are qualified to conduct fundus eye exams, assess retinal health and disease and offer treatment in parallel with the original images provided for enhancement.
- DIAGNOS makes no claims as to the effectiveness of CARA to treat or prevent any medical condition.
- CARA is designed to be used with images from a fundus camera approved by the relevant regulatory authorities (e.g. Health Canada in Canada, FDA in the United States).
- It is up to the user to ensure that the fundus camera is well maintained and is free of dust or other particles or reflections in the image that may appear as artifacts on a retinal image, and might cause any potential misinterpretation of such image, etc.
- It is up to the user to ensure that CARA and any other software used to visualize retinal images is used in an appropriate viewing environment (e.g. optimal lighting and free of distraction) so that details in the image may be appropriately viewed.

**Correcting Defects:** In the event that any services furnished by DIAGNOS are incomplete or unavailable, or in the event DIAGNOS temporarily fails to provide the Services (collectively a "Defect"), DIAGNOS may, at their sole discretion, without charge to the Client, effect an immediate reduction of the once paid or payable for the services to which such Defect relates, provided that DIAGNOS has received written notice of the Defect from the Client within 30 days from the date on which the Client became aware of, or should have become aware of, such Defect.

**Force majeure:** A party is not liable for failure to perform the party's obligations if such failure is a result of Acts of God (including fire, flood, earthquake, storm, hurricane or other natural disaster), war, invasion, act of foreign enemies, hostilities (regardless of whether a war is declared), civil war, rebellion, revolution, insurrection, military or usurped power, or confiscation, terrorist activities, national emergency, government sanction, strike, legal embargo, labor dispute, strike, lock-out or interruption or failure of electricity or telecommunication service. No party is entitled to terminate this Agreement under the Termination Clause in such circumstances.

**Limitation of Liability:** Neither of DIAGNOS, directors, officers, employees, agents, contractors, subcontractors or affiliates shall have any liability, in whatever manner, for any, indirect, consequential, exemplary, incidental or punitive damages, even if such parties have been advised of the possibility of such damages.

DIAGNOS inc  
7001 Boulevard Taschereau, bureau 340  
Brossard, Québec, Canada  
J4W 1A7  
[support@diagncs.com](mailto:support@diagncs.com)

© CARA v1.2.1

© 2010 © DIAGNOS inc. All rights reserved.  
Please login to access the Users Manual.

## **APPENDIX V-2**

### **User Manual**



# **CARA USER'S MANUAL**

**V 1.2.1**

CARA User's Manual

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## CARA User's Manual

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### **Introduction**

#### **Important Notices**

Indications for use: CARA is a comprehensive software platform intended for importing, processing, and storing of colour fundus images as well as visualization of original and enhanced image through computerized networks.

Warnings: The CARA system and the enhanced images provided should not be used alone to diagnose or grade any retinal abnormalities. CARA enhanced images should only be used by eye care professionals in parallel with the original images provided for enhancement.

Precautions: CARA should be used only by eye care professionals who are qualified to conduct fundus eye exams, assess retinal health and disease and offer treatment.

#### **CARA Overview**

Computer Assisted Retinal Analysis (CARA) is a web application that interfaces with an image processing engine that performs several treatments on images received from clients over a secure connection.

It has been developed by and is proprietary of DIAGNOS Inc.

#### **CARA Purpose**

CARA performs proprietary contrast enhancements of color retinal fundus images. The enhancement process is completed automatically and only requires that the user sends the image to the processing engine through a dedicated web interface.

#### **CARA User's Manual**

This manual describes how to use CARA through its dedicated web interface.

## CARA User's Manual

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It provides a general overview of the application, describes CARA web application's main pages, provides relevant instructions for their use, and then focuses more specifically on the enhancement and analysis of results.

Should you require additional help, please contact CARA support at **support@diagnos.com**. This manual is also available online at the following address: **<https://cara.diagnos.com/manual>**

## CARA User's Manual

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# 1 General Information

## 1.1 CARA Web Access

### 1.1.1 Web Address

CARA website is accessible at: <https://cara.diagnos.com>

### 1.1.2 Minimum Hardware Requirements

#### **CPU**

As no computation is done on the user's computer, the hardware needs are modest. However, a CPU with a frequency at least equal to 1,6 GHz (as Intel Atom N270 for example) is preferable.

#### **Memory**

To have a nice experience using CARA website, it is recommended to have at least 128 MB free memory.

#### **Hard Drive**

No specific hard drive space is needed to access CARA website.

#### **Display Device**

Whereas the display device is not really important in the image submission process, it has a central role in the image review. Thus the screen must be a color screen with a resolution of at least 1024×600 pixels. The zoom in control of CARA website allowing the user to magnify the image, such a resolution is sufficient. Portable devices like Iphone® or BlackBerry® must not be used to access CARA website because they may not have an adequate resolution and some functionalities may not work properly. The graphic card must be able to handle the minimum resolution of 1024×600 pixels.

#### **Operator Interfaces**

To send and review images on the CARA website, simple computer mouse and keyboard are sufficient.

#### **Printers**

Although CARA offers the possibility to print a report containing

## CARA User's Manual

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the images and some other information, this printing must not be employed to make a diagnosis. It has a simple purpose of archiving or education. In that case, a simple printer with a resolution of 300 dpi is sufficient to have a good picture quality.

### **1.1.3 Software Requirements**

No special software is necessary to access CARA website. A simple web browser allows the user to submit and review images provided it is supported by CARA. CARA supports major web browsers including Firefox, Internet Explorer, Chrome and Safari. The following versions have been tested and are supported:

- Firefox 3 or higher
- Internet Explorer 7 and 8 or higher
- Chrome 3 or higher
- Safari 4 or higher

While other web browsers or browser versions may function properly, they have not been tested and are not officially supported.

Note: javascript must be activated and the cookies must be enabled so that CARA website works properly.

### **1.1.4 Internet Connection Requirements**

The minimum internet connection speed is about 300 kb/s. The faster the connection is, the more comfortable the navigation will be.

## **1.2 Image Requirements**

This section describes the necessary characteristics of a submitted image to ensure a high level of quality in the enhancement process. If the sent image does not meet the following criteria, it will not be processed and an error message will be sent to the user.

## CARA User's Manual

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### 1.2.1 Input Image

CARA can handle images coming from a wide set of cameras provided they can export images in one of the formats listed below. The CARA approved camera brands are Zeiss<sup>®</sup>, Topcon<sup>®</sup>, Canon<sup>®</sup>, Nidek<sup>®</sup> and Kowa<sup>®</sup> and Centervue<sup>®</sup>. Other cameras may also be suitable but they have not been tested yet.

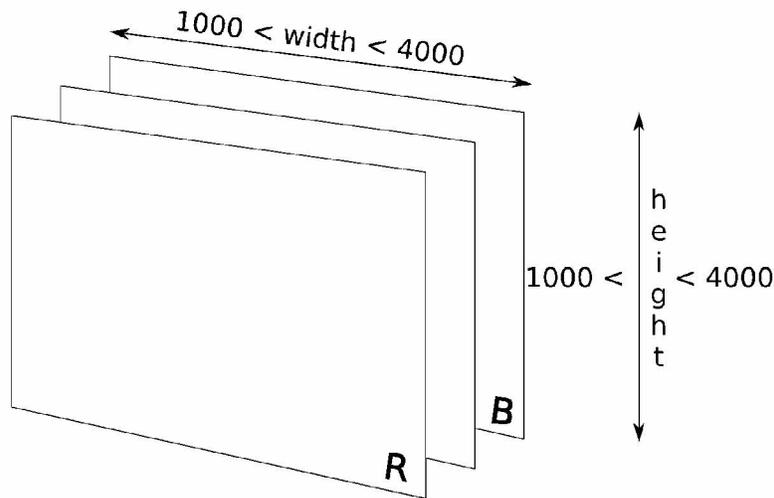


Figure 1: Image characteristics

Images must meet the following requirements:

- Image minimum number of horizontal pixels or vertical pixels must be greater than 1000
- Image maximum number of horizontal pixels or vertical pixels must be lower than 4000
- Image must be a color image in RGB color field (standard output of a digital fundus camera approved by a regulatory agency). Achromatic photos such as fluorescein photos or red-free photos are not accepted to be processed by CARA.
- Image must have one of the following formats (extensions): jpeg/jpg, png, bmp, tiff/tif

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## CARA User's Manual

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### 1.2.2 Comments

For a given image resolution, the size of the corresponding image file is related to the compression ratio. It is important to remember that the image quality is inversely proportional to the compression ratio; hence, it is up to the user to strike the correct balance between resolution, file size, and transfer time.

**Example:**

An image with dimensions of 2496 × 1664 pixels and size on hard drive of 1.1Mb has a compression ratio of 11.3. This image is considered suitable and its file size is adequately small to be easily sent over the internet.

More generally, an image with a compression ratio between 10 and 20 will be considered as adequate to be processed within a reasonable transfer time. Higher compression ratios may deteriorate quality, while lower compression ratios may not necessarily lead to better results, but will increase the transfer time.

---

## CARA User's Manual

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## 2 How To Use CARA Web Interface

CARA Web interface is available at the following url: <https://cara.diagnos.com>  
This section describes how to use the CARA web interface.

### 2.1 CARA website navigation

A CARA website navigation overview is given in the Figure 2. On this illustration, the user can find the links to go from one page to another. This links are displayed at the top of each page:

- "Dashboard", leads to the page displaying the user dashboard (see section 2.3)
- "Browse Request", leads to the page displaying the request list (see section 2.5)
- "New", leads to the page allowing to send a new request (see section 2.6)
- "Logout", ends the user's session and disconnects

CARA website pages are described in the following sections.

### 2.2 Connection page

In order to gain access to CARA, the user must obtain a CARA account username and password from **support@diagnos.com**. The user must use these credentials to log-on to the CARA web site. The CARA login page is shown in Figure 3.

### 2.3 Dashboard

Once logged-on, the user is redirected to his/her personal CARA account web page, where he/she will find his/her personal dashboard. If patients have already been recorded, the dashboard will resemble Figure 4. In that case, the dashboard page will contain the patients list. If no patients have been previously recorded in the system, the patient list is empty. To add a new patient, the user has to submit a new request (see section 2.6), with the relevant informations. Each line of the list gives the following information:





## CARA User's Manual

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- patient name
- last visit date
- rescreen date (if specified)

Above the patients list there are navigation buttons for switching between patients list pages. The button corresponding to the current page is highlighted in blue and clicking the other buttons allows the user to go either to the previous or next page, or jump to the first or last page.

These buttons are also available on the requests list page (see section [2.5](#)).

At the top of the page, CARA account information are summarized in a grey rectangle:

- the user login name
- the CARA account id
- the email address to which communications from CARA will be sent
- the clinic name
- the last submission date
- the number of patients attached to the account

A search function allows the user to find one or more patient according to a given criterion. The result list can also be filtered.

To retrieve a specific patient within the whole patient set, the user has to provide a criterion in the dedicated field and click on the "Search" button. The criterion must be an alphanumeric string. This string can be a word or part of a word the user is searching for (see example in [Figure 5](#)).

The user can apply a filter to the list to narrow the results by selecting the relevant item in the "Conformity" drop-down menu. An example of search with filtering is illustrated in [Figure 5](#). The search criterion is "John" and the results are not filtered. This search functionality is also available within the request list page (see section [2.5](#)).

### **2.4 Patient Panel**

Clicking on the patient name on the dashboard page redirects the user to the related page on which he/she can find information

## CARA User's Manual

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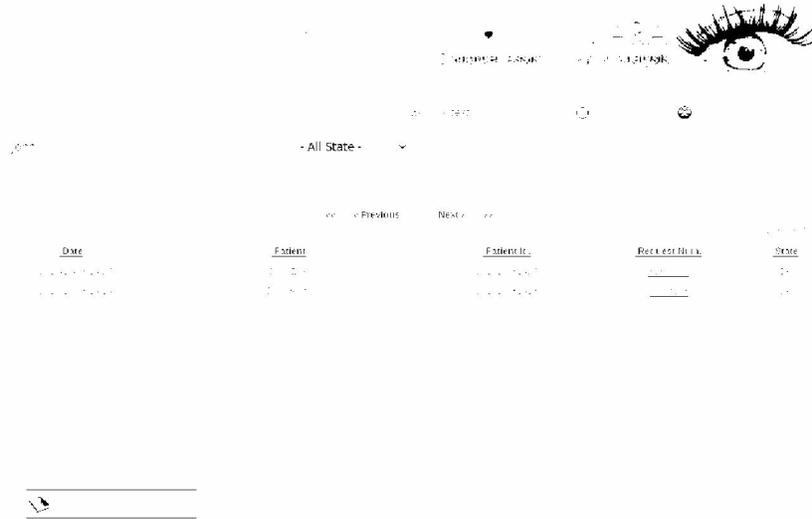


Figure 5: A search result example

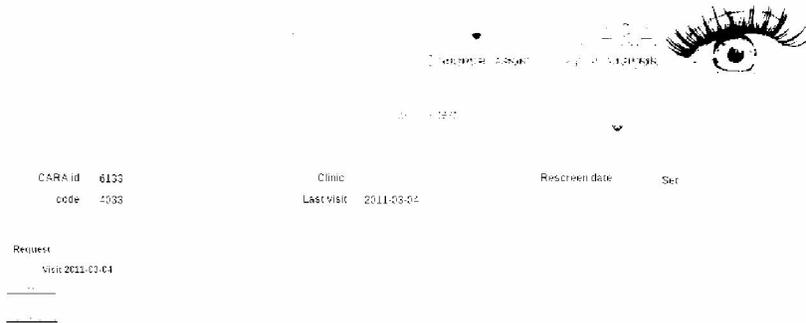


Figure 6: Patient panel

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## CARA User's Manual

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about the patient in a grey area and the list of the corresponding requests. Requests are grouped by visit. The user also has a tool to schedule a new screening date. An example of a patient panel is given in Figure 6. The information about the patient are:

- the CARA user id
- an internal CARA code useful for communication with CARA support
- the clinic where the patient is followed
- the last visit date

### 2.5 Request List

By clicking on the "Browse Requests" link, the user is redirected to a page containing a list of all the request that have been sent through his/her account. This list provides some information related to each request:

- request date and time
- patient name (if provided in request)
- patient id
- request number (unique identifier for CARA)
- conformity: quality degree of the image according to CARA standard specifications.

The requests list can be filtered with the search tool thus the user can access any request quickly.

By selecting the "Visit view" checkbox, the requests are displayed grouped by patient and by date (see Figure 7). Otherwise, they appear in a simple list ordered by date.

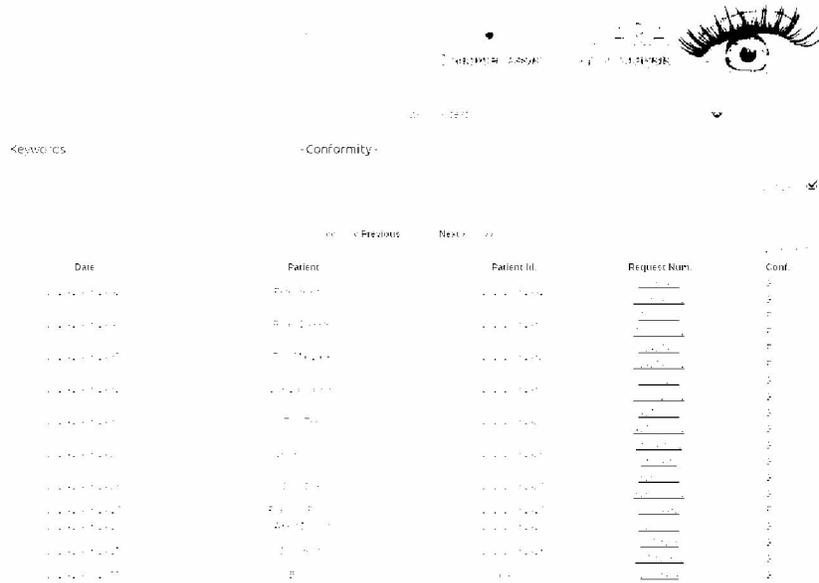
### 2.6 New Request Submission

Request submission via the web interface requires clicking the "New" link, which redirects the user to the request submission page (illustrated in Figure 8).

To send a request, the user has to fill-in the following fields:

## CARA User's Manual

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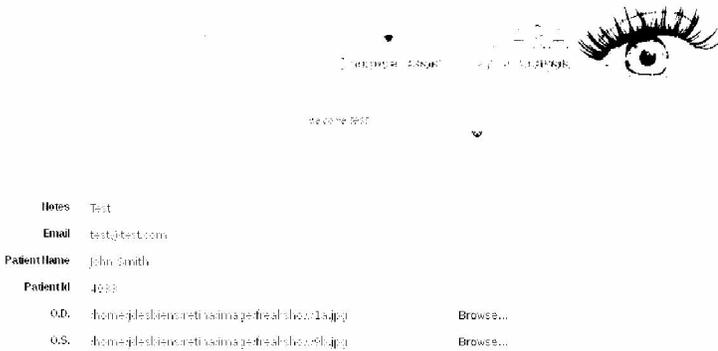


Keywords:  - Conformity -

Previous Next

Date	Patient	Patient ID	Request Num.	Conf.
2/22/2011	John Smith	123456789	1	2
2/22/2011	John Smith	123456789	2	2
2/22/2011	John Smith	123456789	3	2
2/22/2011	John Smith	123456789	4	2
2/22/2011	John Smith	123456789	5	2
2/22/2011	John Smith	123456789	6	2
2/22/2011	John Smith	123456789	7	2
2/22/2011	John Smith	123456789	8	2
2/22/2011	John Smith	123456789	9	2
2/22/2011	John Smith	123456789	10	2
2/22/2011	John Smith	123456789	11	2
2/22/2011	John Smith	123456789	12	2
2/22/2011	John Smith	123456789	13	2
2/22/2011	John Smith	123456789	14	2
2/22/2011	John Smith	123456789	15	2
2/22/2011	John Smith	123456789	16	2
2/22/2011	John Smith	123456789	17	2
2/22/2011	John Smith	123456789	18	2
2/22/2011	John Smith	123456789	19	2
2/22/2011	John Smith	123456789	20	2

Figure 7: Requests list grouped by patient and date



KEYWORD SEARCH REQUEST SEARCH

Notes: Test

Email: test@bert.com

Patient Name: John Smith

Patient ID: 123456789

O.D.: d:\ome-jple-stabenc-ret\usima-jedre-ah-shloco-1a.jpg Browse...

O.S.: d:\ome-jple-stabenc-ret\usima-jedre-ah-shloco-1b.jpg Browse...

Figure 8: Request submission page

## CARA User's Manual

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- notes (optional - if any, notes will be attached to the request)
- email address (mandatory)
- patient name (mandatory)
- patient id (mandatory)

After completing the above fields the user has to select the images to be sent for processing by clicking the "Browse" button on the right of the "O.D." (right eye) and "O.S." (left eye) fields. A request will normally comprise two images (one for each eye) but sending only one image will not cause an error. Once all the required fields have been filled in, the user clicks on the "Submit" button to send the request.

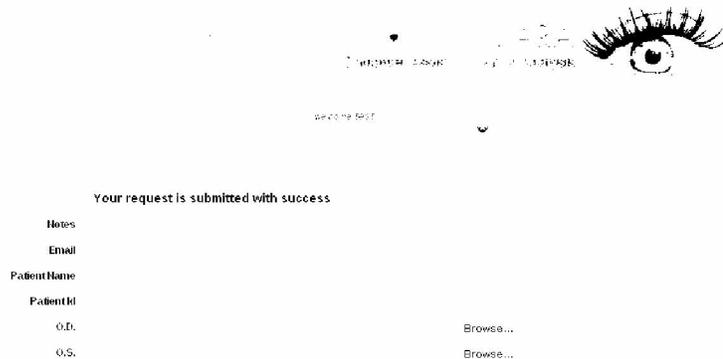


Figure 9: Sent request confirmation page

The "sent request confirmation" screen is then displayed as shown in Figure 9. Then, the user can submit another request by filling again the request fields and selecting other images. The user can also either go back to his/her dashboard or quit his/her CARA account by clicking on the corresponding link.

## 2.7 Request Panel

By clicking on a request number either on the patient panel or the requests list, the user is redirected to the related request panel.

## CARA User's Manual

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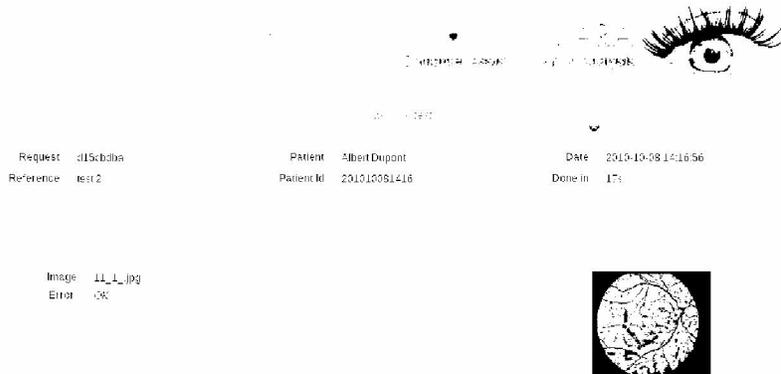


Figure 10: Request results review page

An example of the request panel is shown in Figure 10. The top of the page reminds the user of the information provided when the request was sent and gives information about the request processing. These information are:

- request number
- request reference (given during request submission see section 2.6)
- patient name
- patient id
- request date and time
- processing time

Under these information, the user can find the request results. The submitted image name and the processing status of the request are recalled on the left hand side of the page. Normally, a thumbnail of the processed image is displayed on the right part, unless an error occurred during the processing, in which case, a generic error image is shown in place of the final image. Clicking on the thumbnail opens the image review page. See Section 3 for more details on enhancement review page.

## 2.8 Logout

The user can logout from CARA website anytime by clicking on the "Logout" link. He/She is then redirected to the CARA login page.

CARA User's Manual

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## 2.9 Error Message Interpretation

Should image processing fail, an error code is returned and displayed on the results page (Figure 10). The comment in parentheses provides brief information on the error and its possible cause. The following table lists error codes and their message:

<b>Error code</b>	<b>Meaning and comment</b>
0	<u>File does not exist</u> : the file can not be found.
10	<u>File is not a supported image</u> : the image format is not supported by CARA.
11	<u>File compression too high</u> : the compration rate of the image is too high to provide good level results.
20	<u>Not a color image</u> : image is monochromatic instead of color.
30 & 31	<u>Width/Height too small</u> : one of the dimensions (width or height) does not meet the minimum required size.
40 & 41	<u>Width/Height too large</u> : one of the dimensions (width or height) exceeds the maximum allowed size.
110 to 152	CARA contrast enhancement quality criteria are not met by the resulting enhanced image.
410	<u>Non regular contour</u> : the corner mask has not a regular contour. That may affect the results.
420	<u>Corner mask volume is too small</u> : the volume of the corner mask is too small. This is a often caused by a bad quality image.

## CARA User's Manual

### 3 Enhancement Review

Once the user has clicked on the image thumbnail on the request panel, a new window opens up and displays the required information. Review page is illustrated in Figure 11.



Figure 11: View page

#### 3.1 View Window

##### 3.1.1 View Selection

As shown on Figure 11, some relevant information about the processed image are displayed at the top of the page, below which are two controls that allow the user to zoom in and out or to select the image to be displayed - original image or enhanced image - as illustrated by the small pictures on the right of Figure 11.



**PREMARKET NOTIFICATION 510(k)**

**CARA**

**SECTION VI: PERFORMANCE TESTING**

The Diagnos CARA system would receive retinal images, taken by approved fundus cameras. An algorithm would be applied to enhance the image, allowing for a different color scheme to be used. The original image is kept intact, and is always available. The enhanced image is then sent back with the original image to the eye care professional.

The Diagnos CARA system does not automatically grade, diagnose or suggest a therapeutic or diagnostic approach. The Diagnos CARA system does not replace the diagnostic or treatment decisions made by the clinician, and is intended as an ancillary tool available only to eye care professionals who are qualified to conduct fundus eye exams, assess retinal health and disease, and offer treatment and who use the original image in parallel.

Since the CARA system currently intended for sale in the U.S. is not a stand-alone tool, does not make any diagnostic claims and does not replace the existing retinal images or the treating physician, the sponsor believes that the software testing and validation presented in Section III are sufficient and that there is no need for a clinical trial.



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

**COVER SHEET MEMORANDUM**

**From:** Rahul Ram  
**Subject:** 510(k) Traditional Supplement- K110869 / S1  
**To:** The Record

*[Handwritten Signature]*  
*7/11/2014*

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](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))

Hold (Additional Information or Telephone Hold).

**X Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)**

Not Substantially Equivalent (NSE) Codes

- NO NSE for lack of predicate
- NI NSE for new intended use
- NQ NSE for new technology that raises new questions of safety and effectiveness
- NP NSE for lack of performance data
- NC NSE call for PMAs
- NS NSE no response
- NH NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Pages	<i>Attach IFU</i>	Yes	
<b>510(k) Summary / 510(k) Statement</b>	<i>Attach Summary</i>	Yes	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	Yes	
Is the device Class III? If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		No
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			No
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			No
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for			No





DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Center for Devices & Radiological Health

Division of Ophthalmic, Neurologic, Ear, Nose, and Throat Devices  
Ophthalmic Lasers, Neurostimulators, and Diagnostic Devices Branch  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002  
(301) 796-6620

SUPPLEMENT (S1) PREMARKET NOTIFICATION [510(K)] REVIEW

DATE: July 7<sup>th</sup>, 2011  
TO: RECORD  
FROM: Rahul Ram  
SUBJECT: Traditional, K110869 / S1

*Handwritten signature and date: 7/7/2011*

--

<b>510(K) HOLDER<sup>1</sup>:</b> Diagnos, Inc. 7005 Taschereau Boulevard Brossard, Quebec J4Z 1A7	<b>OFFICIAL CORRESPONDENT<sup>1</sup>:</b>  Mr. Aron Shapiro Vice President Ora, Inc. 300 Brickstone Square Andover, MA 01810  Email: <a href="mailto:ashapiro@oraclinical.com">ashapiro@oraclinical.com</a> Phone: (978) 685-8900 x9443 Fax: (978) 689-0020
<b>DEVICE TRADE NAME<sup>1</sup>:</b> CARA	
<b>DESCRIPTION:</b> Ophthalmic Image Management Software as Service	
<b>510(K) DATED DATE:</b> June 15, 2011	
<b>510(K) RECEIVED DATE:</b> June 16, 2011	

**APPLICANT-IDENTIFIED PREDICATE DEVICE:**

510(K) NUMBER <sup>2</sup>	PRODUCT CODE <sup>3</sup>	DEVICE NAME <sup>3</sup>	510(K) HOLDER <sup>3</sup>
K082364	NFJ	IMAGEnet Professional PC Software System	Topcon Corp.

**RECOMMENDATION:**

GIVEN THAT ALL DEFICIENCIES HAVE BEEN RESOLVED, I RECOMMEND THAT CARA BE FOUND SUBSTANTIALLY EQUIVALENT.

Regulation Number: 21 CFR 892.2050  
 Regulation Name: **Picture archiving and communications system**  
 Regulatory Class: **Class II**  
 Product Code: **NFJ**

<sup>1</sup> K110869/S0, Cover Letter  
<sup>2</sup> K110869/S0, Page I-7 ("FDA Form 3514")  
<sup>3</sup> 510(k) Database

Produce Code Description: **System, Image Management, Ophthalmic**

Additional Product Codes: **n/a**

INDICATIONS FOR USE (IFU) STATEMENT<sup>4</sup>:  Prescription  
 Over-the-Counter

“CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced images through computerized networks.”

#### **I SUBMISSION REVIEWERS**

- Rahul Ram (ODE/DONED/ONDB) – Lead Reviewer
- Thomas Radman (ODE/DONED/ONDB) – Consulting Software Reviewer for S0
- Rahul Ram (ODE/DONED/ONDB) – Consulting Software Reviewer for S1
- Bradley Cunningham (ODE/DONED/ONDB) – Branch-Level Concurrence

Please note that although Tom did a review for the original submission (S0), due to workload concerns and my expertise in reviewing software, I have reviewed and evaluated the responses to his deficiencies. This plan of action was discussed with Tom and he concurred.

#### **II PURPOSE OF SUBMISSION**

As per the submission cover letter<sup>1</sup>, the applicant has submitted this 510(k) premarket notification to solicit marketing clearance for **CARA**.

#### **III REGULATORY HISTORY**

- I100579 (received in FDA on 7/2/2010) – comments conveyed to applicant on August 31, 2010
- I100579 / S1 (received in FDA on 10/2/2010) – comments conveyed to applicant on December 10, 2010
- Email in Response to FDA Comments of I100579 / S1 (received in FDA on 12/10/2010) – comments, as applicable, shall be conveyed to the applicant as deficiencies in the telephone hold memorandum in review of this 510(k) submission (K110869 / S0)
- K110869 / S0 (received in FDA on March 29, 2011)
- Telephone Hold Memorandum Conveyed to Applicant (dated May 26, 2011)
- **K110869 / S1 (received in FDA on June 16, 2011)**

#### **IV FORMAT OF REVIEW**

<sup>4</sup> K110869/S0, Page I-10 (“Indications for Use”)

To ensure that this review is wholly inclusive of all pertinent information, it contains almost all the information from the review of the original submission (S0). Please note the following conventions in this review:

1. Updated information as per the current submission (S1) is included as **bold text**, and indicated by the following symbol: “**▲**”.
2. New, S1 Review Comments are bolded.
3. Review Comments from S0 are un-bolded.

## V INTRODUCTION

This device consists of local (via internet browser) and non-local (server-based) software that allows for importation, “enhancement,” storage, reporting and analysis of human fundus images.

## VI OVERALL ADMINISTRATIVE REQUIREMENTS (AS PER<sup>5,6</sup>)

REQUIREMENT	S0 SUBMISSION LOCATION
MDUFMA Cover Sheet (FDA Form 3601)	Page I-4
CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)	Pages I-5 – I-9
Cover Letter	YES
Indications for Use Page	Page I-10
510(k) Summary	Pages I-11, I-12
Truthful and Accuracy Statement	Page I-13
Class III Summary or Certification	N/A
Financial Certification or Disclosure Statement	N/A
Clinical Certification Statement (FDA Form 3674)	N/A
Standards Data Report(s) (FDA Form 3654)	N/A
Executive Summary	Page II-1

S0 REVIEW COMMENT: Administrative requirements appear to have been met.

SECTION RECOMMENDATION: ADEQUATE

## VII INDICATIONS FOR USE

The Indications for Use (IFU) statement as reported on Page I-10 of the original submission (S0), is the following:

*“CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.”*

### A CONSISTENCY THROUGHOUT SUBMISSION

Aside from Page I-10 of the original submission (S0), the applicant provided the IFU statement in the following original submission locations:

- Page I-11 (510(k) Summary)

<sup>5</sup> FDA Guidance Document, “Format for Traditional and Abbreviated 510(k)s”

<sup>6</sup> 21 CFR 807.87

- Page V-8 (Page 3 of the CARA User's Manual)

~~SO REVIEW COMMENT:~~ The IFU statements in these multiple locations appear to be consistent.

**B COMPARISON TO PREDICATE DEVICES**

The following is the IFU statement of the predicate device, the Topcon IMAGEnet Professional PC Software System (cleared under K082364)<sup>3</sup>:

*The IMAGEnet Professional PC Software System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from computerized diagnostic imaging devices through direct connection with the instruments or through computerized networks.*

*The software system is indicated for use with retinal camera or digital camera imaging devices, including retinal cameras, non-mydratic retinal cameras, and slit lamps.*

	<b>CARA CLAIMS</b>	<b>CORRESPONDING PREDICATE CLAIMS</b>	<b>COMMENTS</b>
<b>PERFORMANCE CLAIMS</b>	Importing, Processing, Storage, Visualization	Collection, Storage, Management	<i>SYNONYMOUS LANGUAGE</i>
<b>CLAIMS OF DATA TYPE</b>	(Original, Enhanced) Color Fundus Images	Digital Images, Patient Data, Diagnostic Data, Clinical Information	<i>CARA CLAIMS ARE INCLUDED IN PREDICATE CLAIMS</i>
<b>CLAIMS OF METHOD</b>	Via Computerized Networks	Direct connection with instrument, computerized networks	<i>SYNONYMOUS LANGUAGE</i>

**C DECISION-MAKING**

- **SAME INDICATIONS FOR USE?**

**NO.** The predicate devices use different syntax and language to describe their claims. Furthermore, claims made in the IFU of the predicate device are more expansive than those of CARA.

- **DO THE DIFFERENCES ALTER THE EFFECT OR RAISE NEW QUESTIONS OF SAFETY AND/OR EFFECTIVENESS?**

**NO.** The claims are essentially the same between those of the CARA and the predicate device; the language between them is at least synonymous, if not identical.

**D ADDITIONAL NOTES FROM CONSULTING SOFTWARE REVIEWER**

On Page 2/19 of Tom's consulting software review from the original submission (S0), he stated the following:

*I suggest the name "Diagnos" (510(k) Holder Company Name) be evaluated by management for it's implication towards the indications for use of the device.*

S0 REVIEW COMMENT: Regarding Tom's comment (above), to the best of my knowledge there are no regulations in 21 CFR or guidance documents that convey or indicate authority regarding a company's name. Therefore, there are no concerns regarding the Indications for Use of CARA.

SECTION RECOMMENDATION: ADEQUATE

### VIII SOFTWARE (AS PER<sup>7</sup>)

S0 REVIEW COMMENT: Because the device is only software, this section serves to describe the technological characteristics of the device *in toto*.

To review the software documentation in detail, Dr. Thomas Radman was recruited to provide a consulting review. Tom's consulting review is attached with the review of the original submission (S0).

As per the FDA software guidance<sup>7</sup>, the applicant provided software documentation in Section III ("Device Description") of the original submission. The following table summarizes each of the documents provided, including whether each is adequate. Each document is described in detail, below, with comments from Tom's review.

SOFTWARE REQUIREMENT	S0 SUBMISSION LOCATION	ADEQUATE?
Level of Concern	Pages III-8 – III-10	YES
Software Description	Pages III-2 – III-6	YES
Device Hazard Analysis	Page III-21	<b>/</b> YES
Software Requirements Specification	Pages III-23 – III-25	YES
Architecture Design Chart	Page III-27	YES
Software Design Specification	Pages III-29 – III-40	<b>/</b> YES
Traceability Analysis	Pages III-48, III-49	YES
Software Development Environment Description	Pages III-51 – III-54	YES
Verification & Validation Documentation	Pages III-56 – III-65, III-67 – III-78, III-80 – III-84	<b>/</b> YES
Revision Level History	Page III-86	YES
Unresolved Anomalies	None	YES

#### A LEVEL OF CONCERN (MODERATE)

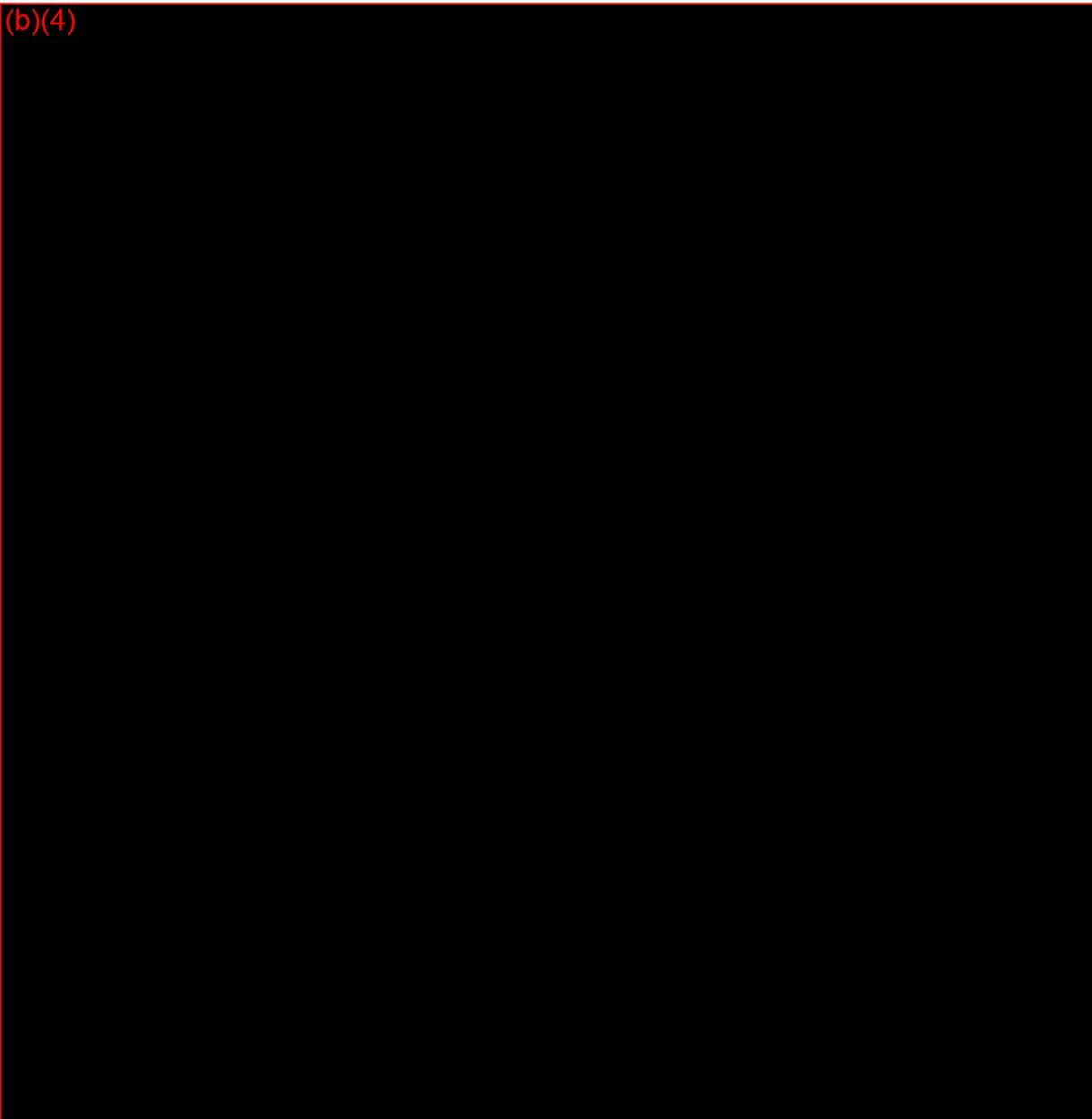
<sup>7</sup> FDA Guidance Document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

(b)(4)

A large rectangular area of the document is completely redacted with a solid black fill. The text "(b)(4)" is written in red at the top left corner of this redacted area.

B SOFTWARE DESCRIPTION

(b)(4)

A very large rectangular area of the document is completely redacted with a solid black fill, covering most of the page's content. The text "(b)(4)" is written in red at the top left corner of this redacted area.

(b)(4)

C HAZARD ANALYSIS

The applicant provided a device hazard analysis on Page III-21 of the original submission (S0). In review of this hazard analysis, Tom noted the following deficiency<sup>9</sup>:

*Original Deficiency: In Appendix III-3 entitled CARA Hazard Analysis, you provide some risk analysis, but it is insufficient. Please provide a description of the hazards (including clinical 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.*

**// To that end, Deficiency 1 was conveyed to the applicant in the May 26, 2011 hold memorandum:**

**// In Appendix III-3 of the submission ("CARA Hazard Analysis"), you provide a risk analysis. However, this information is insufficient. Specifically, you have not provided a description of the hazards (including clinical 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. Please provide this information.**

**// In the current submission (S1), the applicant responds by providing a revised risk analysis in Appendix 1.**

**// S1 REVIEW COMMENT: In review of this risk analysis, the following is noted:**

- // The verification testing for hazard R1 refers to Appendix 11 of the current submission (S1). This document includes a statement that a future release of CARA will be used for "automatically annotating abnormal findings." Given that the current version of the software does not include this feature, no concerns are raised**
- // Overall, the risk analysis provides a description of the potential hazards, ratings of probability, severity, and detectability, control methods, and verification of those control methods.**

**// The response to Deficiency 1 is ADEQUATE.**

<sup>9</sup> Consulting Review of Dr. Thomas Radman, Page 6/19

validation, corner mask calculation, enhancement, and output validation) and the Prognos NG (which organizes and executes system tasks)) and Infrastructure Cluster (consisting of the Web Interface and database which stores image information). The client side consists of an off-the-shelf internet browser and off-the-shelf operating system (non-specific).

C HAZARD ANALYSIS

The applicant provided a device hazard analysis on Page III-21 of the original submission (S0). In review of this hazard analysis, Tom noted the following deficiency<sup>9</sup>:

*Original Deficiency: In Appendix III-3 entitled CARA Hazard Analysis, you provide some risk analysis, but it is insufficient. Please provide a description of the hazards (including clinical 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.*

**// To that end, Deficiency 1 was conveyed to the applicant in the May 26, 2011 hold memorandum:**

**// In Appendix III-3 of the submission ("CARA Hazard Analysis"), you provide a risk analysis. However, this information is insufficient. Specifically, you have not provided a description of the hazards (including clinical 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. Please provide this information.**

**// In the current submission (S1), the applicant responds by providing a revised risk analysis in Appendix 1.**

**// S1 REVIEW COMMENT: In review of this risk analysis, the following is noted:**

- // The verification testing for hazard R1 refers to Appendix 11 of the current submission (S1). This document includes a statement that a future release of CARA will be used for "automatically annotating abnormal findings." Given that the current version of the software does not include this feature, no concerns are raised**
- // Overall, the risk analysis provides a description of the potential hazards, ratings of probability, severity, and detectability, control methods, and verification of those control methods.**

**// The response to Deficiency 1 is ADEQUATE.**

<sup>9</sup> Consulting Review of Dr. Thomas Radman, Page 6/19

D SOFTWARE REQUIREMENTS SPECIFICATION (SRS)

The applicant provided documentation to describe software requirements between Pages III-23 and III-25 of the original submission (S0).

S0 REVIEW COMMENT: Given the lack of concerns noted in this regard in Tom's review, the provided SRS documentation is ADEQUATE.

E ARCHITECTURE DESIGN CHART

The applicant provided an architecture design chart on Page III-27 of the original submission (S0).

S0 REVIEW COMMENT: This information was the subject of a concern noted in review of I100579 (the applicant did not originally submit an architecture design chart). In review of the architecture design chart provided, given the lack of concerns noted in this regard in Tom's review, the provided information is ADEQUATE.

F SOFTWARE DESIGN SPECIFICATION (SRS)

The applicant provided documentation to describe software requirements between Pages III-29 and III-40 of the original submission (S0). In review of this information, Tom noted the following concerns and deficiencies in his review<sup>10,11</sup>:

*Review Comment: The SDS, beginning on p.50 of the submission, expands the documentation of functionality described in the SRS, but does not document how the requirements of the SRS are implemented as is specified in the FDA Software Guidance for Moderate LOC devices. Joe Jorgens, software reviewer for pre-IDE I100579 was consulted for concurrence. If he concurs, the following deficiency should be sent:*

*Original Deficiency: Please provide a software design specification (SDS) document which describes how the requirements in the Software Requirements Specifications (SRS) are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the software device was clear and unambiguous, with minimal ad hoc design decisions. The document that you submit should provide adequate information to allow for the review of the implementation plan for the software requirements in terms of intended use, functionality, safety and effectiveness. These should be presented in an enumerated manner, referencing the associated Software Requirements.*

**Regarding Tom's comment and deficiency above, I noted the following comment in my S0 review:**

S0 REVIEW COMMENT: Because Joe Jorgens (OSEL/DESE) was not available to

<sup>10</sup> Consulting Review of Dr. Thomas Radman, Page 9/19

<sup>11</sup> Consulting Review of Dr. Thomas Radman, Page 11/19

comment, and given my experience with reviewing such software devices, I determined that the above concern is, in fact, warranted. The SDS documentation provided is not specific enough to explain specific design considerations; THE ABOVE DEFICIENCY SHOULD BE CONVEYED TO THE APPLICANT AS DEFICIENCY 2.

**// To that end, Deficiency 2 was conveyed to the applicant in the May 26, 2011  
// hold memorandum:**

**// You provide a software design specification (SDS) document in Appendix III-6 of the  
// submission. However, this information is incomplete. Specifically, you have not described how  
// the requirements in the software requirements specification (SRS) document are implemented  
// via design specifications. The information presented in the SDS should be sufficient to ensure  
// that the work performed by the software engineers who created the software device was clear and  
// unambiguous, with minimal ad hoc design decisions. The document that you submit should  
// provide adequate information to allow for the review of the implementation plan for the software  
// requirements in terms of intended use, functionality, safety and effectiveness. These should be  
// presented in an enumerated manner, referencing the associated software requirements. Please  
// provide this information.**

**// In the current submission (S1), the applicant responds to Deficiency 2 by  
// providing a revised SRS document (Appendix 2), a revised SDS document  
// (Appendix 3), and traceability between the two documents ("Requirements vs.  
// Design Grid," Appendix 4).**

**// S1 REVIEW COMMENT: In review of the provided information, it is noted  
// that the SRS and SDS documents are clear and descriptive, and the  
// traceability grid clearly links the software requirements to the design  
// specifications. The response to Deficiency 2 is ADEQUATE.**

**// The following deficiency was noted in Tom's review, in review of the original  
// submission (S0):**

*Original Deficiency: In the software design specification, you provide a qualitative overview of your image enhancement algorithm. However, it is unclear which parameters of the algorithm may be adjusted by the user. Please clarify if each color channel be individually enhanced or are the channels enhanced as separate channels, but at the same time? Please provide the numerical algorithms responsible for the enhancement. This information is necessary to understand the safety and effectiveness of your device compared to your cited predicate.*

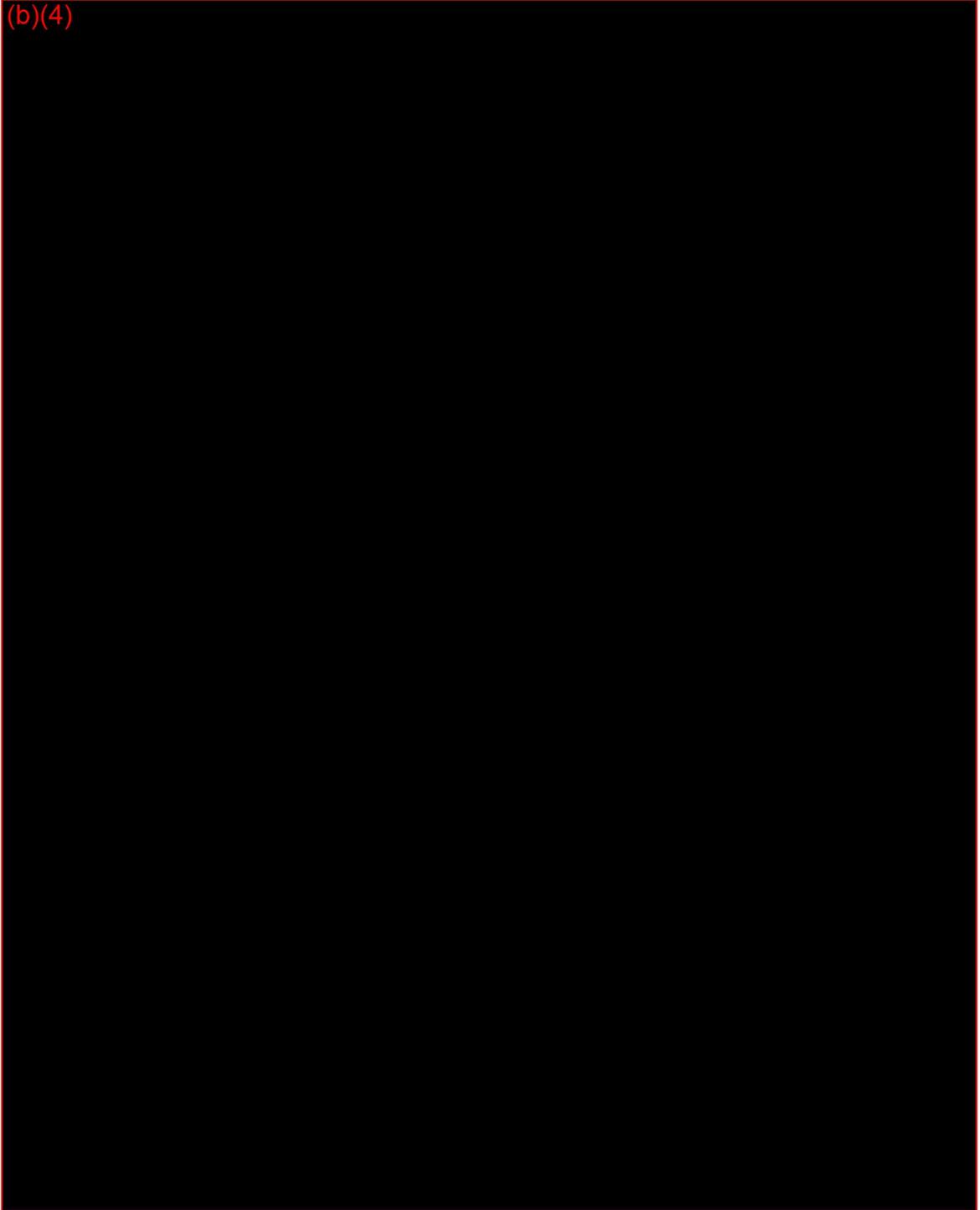
**// To that end, Deficiency 3 was conveyed to the applicant in the May 26, 2011  
// hold memorandum:**

**// In the software design specification, you provide a qualitative overview of your image  
// enhancement algorithm. However, it is unclear which parameters of the algorithm may be  
// adjusted by the user. Please clarify if each color channel be individually enhanced or are the  
// channels enhanced as separate channels, and whether these changes can be made simultaneously.**

*Furthermore, please provide the numerical algorithms responsible for the enhancement. This information is necessary to understand the safety and effectiveness of your device compared to your cited predicate.*

**In response, the applicant states the following in the current submission (S1):**

(b)(4)



**To that end, Deficiency 4 was conveyed to the applicant in the May 26, 2011 hold memorandum:**

*You state a high compression level of JPEG images can result in deterioration of image quality and the enhancement result and provide Illustration 4 ("Dependence of enhancement quality to file format to validate the similarity of the JPEG enhancement to the raw image formats"). This is a qualitative measure on a single sample image that does may not be representative on the worst case scenario. Please establish a quantitative measure of image quality, and provide test data evaluating changes to this quality at varying compression levels. Furthermore, please provide sample images representing a spectrum of images of worst case quality and highest potential to mischaracterize the structure of the eye. Please include your test procedures and results.*

**In response, the applicant states the following in the current submission (S1):**

*Illustration 4 shows the enhancement process behavior on different file formats with either lossless or lossy compression (Appendix 5 CARA Enhancement Algorithms Description, Paragraph 6, Page 4). It addresses the question of file format support and it concludes that if lossy compression is not too high, the results are quite similar. Tests have been done on a set of 150 images. The Illustration 4 shows one of them. Illustration 5 addresses the issue of compression level versus image quality. Enhancement algorithm does not modify anything in geometry and compression of the image.*

**S1 REVIEW COMMENT: The applicant did not provide a quantitative measure of image quality, but instead uses compression ratio ( $Q = \text{theoretical image size} / \text{real image size}$ ) as a surrogate for image quality. The algorithm warns the user if  $Q > 100$  that the image is of poor quality. Furthermore, the applicant has shown that subjectively, image quality deteriorates when  $Q$  is increased. Given that no diagnostic decision-making is preempted by the software, and that judgement is reserved to the user as to whether the image is of good quality, the applicant's response to Deficiency 4 is ADEQUATE.**

#### G TRACEABILITY ANALYSIS

The applicant provided a traceability analysis on Pages III-48 and III-49 of the original submission (S0). In review of this information, Tom noted in his review that *"this document links the user requirements and functional requirements with hazards/mitigations and verification/validation testing requirements for the CARA software."*<sup>12</sup>

**S0 REVIEW COMMENT: Given the lack of concerns noted in this regard in Tom's review, the provided traceability analysis is ADEQUATE.**

#### H SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION

<sup>12</sup> Consulting Review of Dr. Thomas Radman, Page 12/19

The applicant provided a description of the software development environment between Pages III-51 and III-54 in the original submission (S0).

S0 REVIEW COMMENT: Given the lack of concerns noted in this regard in Tom's review, the provided description of the software development environment is ADEQUATE.

I VERIFICATION & VALIDATION INFORMATION

The applicant provided verification and validation information in various places in the original submission (S0):

- Pages III-56 – III-65 (“Internet Browser Capability Testing”)
- Pages III-67 – III-78 (“Software Functionality Testing”)
- Pages III-80 – III-84 (“Validation and Verification”)

Additionally, regarding verification and validation, FDA provided comments to the applicant in review of I100579 / S1. As meeting materials for a teleconference, the applicant attempted to address these comments (email, 12/10/2010, located in the administrative file for I100579 / S1). The relevant applicant responses that were not adequate are below:

FDA Comment: In a 510(k) submission, validation examples should include actual system output pictures, i.e., with the full spatial resolution and color range provided to the user. The validation section should include examples of worst-case acceptable original image quality, as well as examples of original images that generate various error messages.

Applicant Response to Above Comment: All the validation examples presented are actual system output pictures. The spatial resolution of these images is the same as the original images submitted. The color range provided to the user could not be interpreted. The color range is input dependent (Camera type, etc.).

In review of the applicant's response above, Tom noted the following in his review:

Review Comment: the validation section does not contain examples of worst-case image quality, or examples of original images that generate the systems's error messages. This response was reviewed by Bruce Drum (Vision Scientist, DONED/ONDB).

Original Deficiency: You provide a validation section with your submission. However, you do not provide worst-case image quality sample output images. Please provide the worst-case image quality sample output images and examples of images that would generate any error messages possible due to the input image. Please provide these images in the full spatial resolution and size as perceived by the device operator. This information is necessary to determine the effective use of your device as compared to your cited predicate.

**Regarding Tom's concern above, Deficiency 5 was conveyed to the applicant in the May 26, 2011 hold memorandum:**

*You provide a validation section with your submission. However, you do not provide worst-case image quality sample output images. Please provide the worst-case image quality sample output images and examples of images that would generate any error messages possible due to the input image. Please provide these images in the full spatial resolution and size as perceived by the device operator. This information is necessary to determine the effective use of your device as compared to your cited predicate.*

**In response to the deficiency, the applicant provides worst case images in Appendix 8 of the submission. Furthermore, the applicant stated the errors generated by use of each image.**

***SI REVIEW COMMENT:* The applicant's response to Deficiency 5 is ADEQUATE; the behavior of the software during worst case does not raise any new concerns.**

**The next applicant comment from the 12/10/2010 email is below:**

*FDA Comment: It seems that the CARA algorithm keeps evolving with each enhancement failure because required modification may be made when an error occurs. Please clarify what modifications are made based on the enhancement failure and the effect of the modifications on the algorithms.*

*Applicant Response to Above Comment: The modifications are made to make the algorithms more robust and powerful.*

In review of the applicant's response above, Tom noted the following in his review:

*Review Comment: This response was reviewed by Bruce Drum (Vision Scientist, ONDB/DONED). He stated the response was not adequate, and the deficiency should be repeated in the 510k request for additional information.*

*Original Deficiency: Prior to the pre-teleconference for pre-IDE I100579, you had sent an email dated December 7, 2010 responding to our request for additional information. We requested clarification on what modifications were made based on the enhancement failure and the effect of the modifications on the algorithms. You responded "The modifications are made to make the algorithms more robust and powerful." Please provide the numerical algorithms, and a theory of operations for the modifications made to the algorithm relevant to its current iteration. This is necessary to understand if the current algorithm is safe and effective, or if it is also not a stable iteration resulting in bugs in the image processing.*

**Regarding Tom's concern above, Deficiency 6 was conveyed to the applicant in the May 26, 2011 hold memorandum:**

*Prior to the teleconference for pre-IDE I100579, you sent an email (dated December 7, 2010) which attempted to respond to our request for additional information. We requested clarification on what modifications were made based on the enhancement failure and the effect of the modifications on the algorithms. In response, you stated that "the modifications are made to*

*make the algorithms more robust and powerful." However, this information is incomplete. Please provide the numerical algorithms, and a theory of operations for the modifications made to the algorithm relevant to its current iteration. This is necessary to understand if the current algorithm is safe and effective, or if it is also not a stable iteration resulting in errors in the image processing.*

**In response to the deficiency, the applicant states the following:**

*The changes in the numerical algorithms are described in the Appendix 10. The attached revision number is linked to the theory of operations that is explained in the changes column in the revision history in the Appendix 9.*

*The revision level history is the log of the developed software and the most important revisions are highlighted in yellow. The accompanying text describes in few words the objective of the revision.*

*There were two main revisions of the enhancement. The rest of the code had only one initial revision.*

*The revision history shows that the code (in Appendix 10) is very stable and had a very small number of modifications.*

***S1 REVIEW COMMENT:*** Appendix 9 documents modifications made to the enhancement algorithms. The applicant has also provided source code for these changes. These changes, as noted in Appendix 9, are clear and consistent do not raise any new concerns.

**The next applicant comment from the 12/10/2010 email is below:**

*FDA Comment: You conclude that "the CARA algorithms are robust; therefore the rejection rate is less than 0.1 %." Was the robustness derived from the rejection rate? An interpretation on the rejection criteria is required. Please provide rationale and interpretation on how the validation criteria are chosen and what problems the images may have associated with failure in meeting each criterion.*

*Applicant Response to Above Comment: Yes, the robustness was derived from the rejection rate. The validation criteria are chosen based on the characteristics of an acceptable enhanced image. An interpretation of the rejection criteria will be provided in the 510(k) submission.*

In review of the applicant's response above, Tom noted the following in his review:

*Review Comment: The rejection rate is listed on p.96 of the submission as 0.3% with a confidence interval of [0, 0.008875]. The sponsor should be asked to clarify why the rejection rate is outside of the confidence interval.*

*Original Deficiency: On p.96 of your submission, the rejection rate is listed as 0.3% with a confidence interval of [0 0.008875]. Please clarify how the rejection rate may be outside the confidence interval, or if this is a typo.*

**Regarding the potential typographical error, Deficiency 7 was conveyed to the applicant in the May 26, 2011 hold memorandum:**

**On Page III-74 of the submission, you state that “the rejection rate is as 0.3% with a confidence interval of [0, 0.008875]...” Please clarify how the rejection rate may be outside the confidence interval, or if this is a typographical error.**

**In response to Deficiency 7, the applicant states the following:**

*We indeed stated on Page III-74 of the submission, that the “rejection rate is as 0.3% with a confidence interval of [0, 0.008875].*

*The rejection rate is not outside the confidence interval because it is  $0.3\% = 0.003$  and falls within the confidence interval of [0, 0.008875].*

***S1 REVIEW COMMENT:* The applicant’s response to Deficiency 7 is ADEQUATE.**

J DECISION-MAKING

• **SAME TECHNOLOGICAL CHARACTERISTICS?**

• **NO.** Though technological features of the device are similar, the specific organization of the software and design-level specifications is completely different.

• **COULD THE NEW CHARACTERISTICS AFFECT SAFETY AND/OR EFFECTIVENESS?**

**YES.** If the software fails or produces an inaccurate report/image, there is a safety and effectiveness risk of misdiagnosis / limited diagnostic utility.

• **ARE THERE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?**

**NO.** These types of questions are common to those in the product code ‘NFJ.’

• **DO ACCEPTED SCIENTIFIC METHODS EXIST FOR ASSESSING THE EFFECTS OF THE NEW CHARACTERISTICS?**

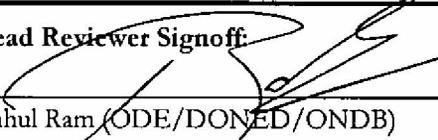
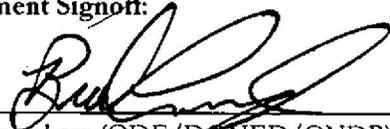
**YES.** Bench or clinical validation may be performed to verify and validate software specifications.

• **ARE PERFORMANCE DATA AVAILABLE TO ALLOW FOR ASSESSMENT OF EQUIVALENCE?**

YES,  and the information provided is sufficient to characterize performance  
 of the software to display retinal images.

**IX**    RECOMMENDATION

GIVEN THAT ALL DEFICIENCIES HAVE BEEN RESOLVED, I RECOMMEND THAT  
 K110869 / S1 BE FOUND SUBSTANTIALLY EQUIVALENT.

Lead Reviewer Signoff:	
	7/7/11
Rahul Ram (ODE/DONED/ONDB)	
Management Signoff:	
	
Brad Cunningham (ODE/DONED/ONDB)	
Date: 7/12/11	Concur: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Division Level _____	
Date _____	Concur: Yes <input type="checkbox"/> No <input type="checkbox"/>



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

## COVER SHEET MEMORANDUM

**From:** Reviewer Name Rahul Ram  
**Subject:** 510(k) Number K110869 / S0  
**To:** The Record

Please list CTS decision code TH

- 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](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	<i>Attach IFU</i>	✓	
510(k) Summary /510(k) Statement	<i>Attach Summary</i>	✓	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			✓
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			✓
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, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
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.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21		✓	
Neonate/Newborn (Birth to 28 days)		✓	
Infant (29 days -< 2 years old)		✓	
Child (2 years -< 12 years old)		✓	
Adolescent (12 years -< 18 years old)		✓	
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.)		✓	

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Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)		✓	
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )		Contact OC.	✓

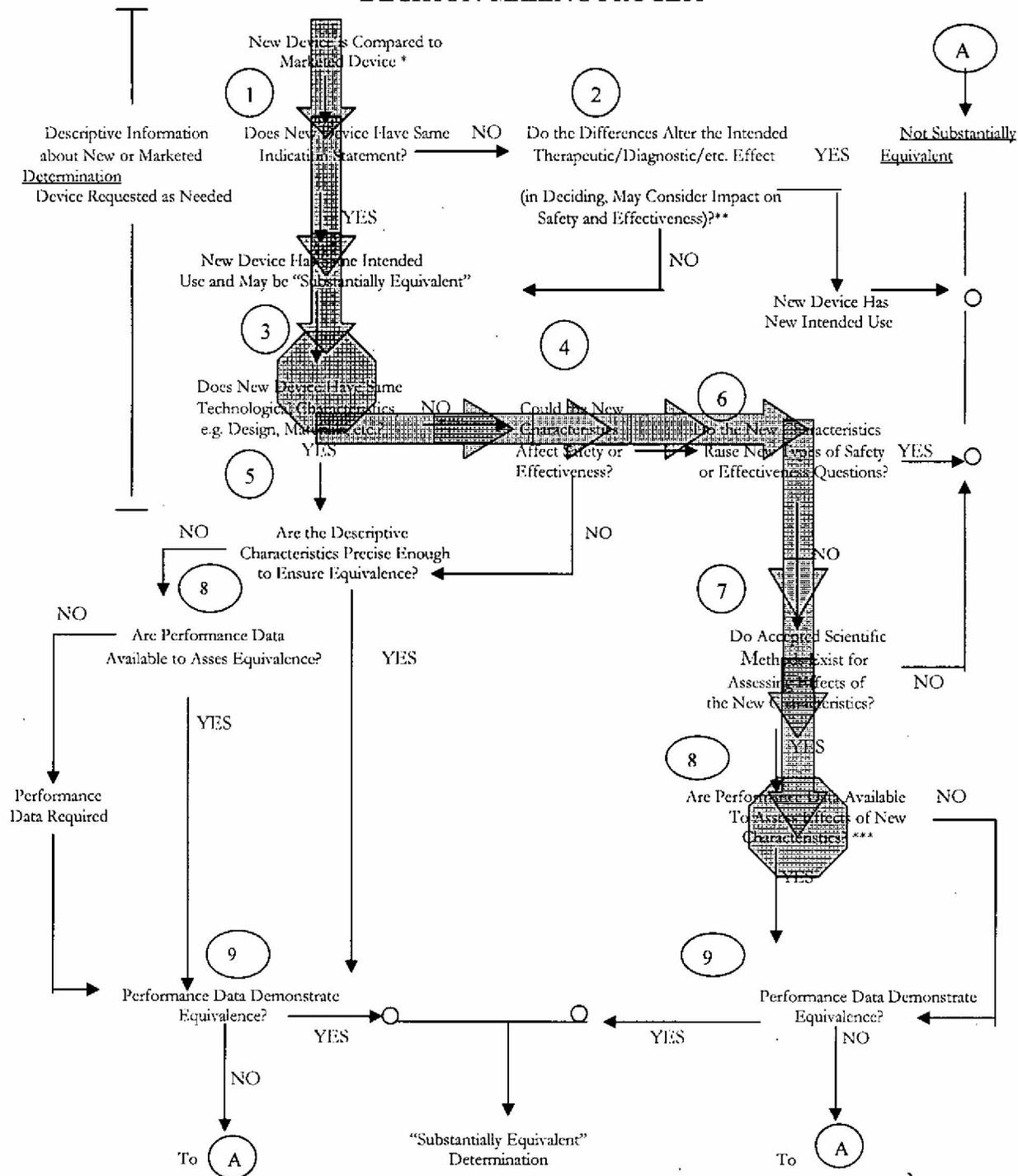
Regulation Number	Class*	Product Code
21 CFR 892.2050	II	NFJ

Additional Product Codes: \_\_\_\_\_

Review: \_\_\_\_\_  
 (Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
 (Division Director) (Date)

**DECISION-MAKING PROCESS**



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

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

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



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Food and Drug Administration  
Center for Devices & Radiological Health

Division of Ophthalmic, Neurologic, Ear, Nose, and Throat Devices  
Ophthalmic Lasers, Neurostimulators, and Diagnostic Devices Branch  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002  
(301) 796-6620

ORIGINAL (S0) PREMARKET NOTIFICATION [510(K)] REVIEW

DATE: May 25, 2011  
TO: RECORD  
FROM: Rahul Ram  
SUBJECT: Traditional, K110869 / S0

*[Signature]*  
5/26/2011

<b>510(K) HOLDER<sup>1</sup>:</b> Diagnos, Inc. 7005 Taschereau Boulevard Brossard, Quebec J4Z 1A7		<b>OFFICIAL CORRESPONDENT<sup>1</sup>:</b> Mr. Aron Shapiro Vice President Ora, Inc. 300 Brickstone Square Andover, MA 01810  Email: <a href="mailto:ashapiro@oraclinical.com">ashapiro@oraclinical.com</a> Phone: (978) 685-8900 x9443 Fax: (978) 689-0020	
<b>DEVICE TRADE NAME<sup>1</sup>:</b> CARA			
<b>DESCRIPTION:</b> Ophthalmic Image Management Software as Service			
<b>510(K) DATED DATE<sup>1</sup>:</b> March 25, 2011			
<b>510(K) RECEIVED DATE<sup>1</sup>:</b> March 29, 2011			
<b>APPLICANT-IDENTIFIED PREDICATE DEVICE:</b>			
<b>510(K) NUMBER<sup>2</sup></b>	<b>PRODUCT CODE<sup>3</sup></b>	<b>DEVICE NAME<sup>3</sup></b>	<b>510(K) HOLDER<sup>3</sup></b>
K082364	NFJ	IMAGEnet Professional PC Software System	Topcon Corp.

**RECOMMENDATION:**

CARA requires additional information in order to proceed with the review. Therefore, I recommend that the submission be placed on **telephone hold (TH)**.

Regulation Number: **21 CFR 892.2050**

Regulation Name: **Picture archiving and communications system**

<sup>1</sup> K110869/S0, Cover Letter

<sup>2</sup> K110869/S0, Page I-7 ("FDA Form 3514")

<sup>3</sup> 510(k) Database

Regulatory Class: **Class II**  
Product Code: **NFJ**  
Produce Code Description: **System, Image Management, Ophthalmic**  
Additional Product Codes: **n/a**

INDICATIONS FOR USE (IFU) STATEMENT<sup>4</sup>:  **Prescription**  
 **Over-the-Counter**

“CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced images through computerized networks.”

**I** SUBMISSION REVIEWERS

- Rahul Ram (ODE/DONED/ONDB) – Lead Reviewer
- Thomas Radman (ODE/DONED/ONDB) – Consulting Software Reviewer
- Bruce Drum (ODE/DONED/ONDB) – *Ad-Hoc* Consulting Engineering Reviewer
- Bradley Cunningham (ODE/DONED/ONDB) – Branch-Level Concurrence

**II** PURPOSE OF SUBMISSION

As per the submission cover letter<sup>1</sup>, the applicant has submitted this 510(k) premarket notification to solicit marketing clearance for **CARA**.

**III** REGULATORY HISTORY

- I100579 (received in FDA on 7/2/2010) – comments conveyed to applicant on August 31, 2010
- I100579 / S1 (received in FDA on 10/2/2010) – comments conveyed to applicant on December 10, 2010
- Email in Response to FDA Comments of I100579 / S1 (received in FDA on 12/10/2010) – comments, as applicable, shall be conveyed to the applicant as deficiencies in the telephone hold memorandum in review of this 510(k) submission (K110869 / S0)
- **K110869 / S1 (received in FDA on March 29, 2011)**

**IV** INTRODUCTION

This device consists of local (via internet browser) and non-local (server-based) software that allows for importation, “enhancement,” storage, reporting and analysis of human fundus images.

<sup>4</sup> K110869/S0, Page I-10 (“Indications for Use”)

V OVERALL ADMINISTRATIVE REQUIREMENTS (AS PER<sup>5,6</sup>)

REQUIREMENT	SUBMISSION LOCATION
MDUFMA Cover Sheet (FDA Form 3601)	Page I-4
CDRH Premarket Review Submission Cover Sheet (FDA Form 3514)	Pages I-5 – I-9
Cover Letter	YES
Indications for Use Page	Page I-10
510(k) Summary	Pages I-11, I-12
Truthful and Accuracy Statement	Page I-13
Class III Summary or Certification	N/A
Financial Certification or Disclosure Statement	N/A
Clinical Certification Statement (FDA Form 3674)	N/A
Standards Data Report(s) (FDA Form 3654)	N/A
Executive Summary	Page II-1

***S0 REVIEW COMMENT:*** Administrative requirements appear to have been met.

**SECTION RECOMMENDATION:** ADEQUATE

VI INDICATIONS FOR USE

The Indications for Use (IFU) statement as reported on Page I-10 of the submission (S0), is the following:

*“CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.”*

A CONSISTENCY THROUGHOUT SUBMISSION

Aside from Page I-10, the applicant provides the IFU statement in the following submission locations:

- Page I-11 (510(k) Summary)
- Page V-8 (Page 3 of the CARA User’s Manual)

***S0 REVIEW COMMENT:*** The IFU statements in these multiple locations appear to be consistent.

B COMPARISON TO PREDICATE DEVICES

The following is the IFU statement of the predicate device, the Topcon IMAGEnet Professional PC Software System (cleared under K082364)<sup>3</sup>:

<sup>3</sup> FDA Guidance Document, “Format for Traditional and Abbreviated 510(k)s”

<sup>6</sup> 21 CFR 807.87

*The IMAGENet Professional PC Software System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from computerized diagnostic imaging devices through direct connection with the instruments or through computerized networks.*

*The software system is indicated for use with retinal camera or digital camera imaging devices, including retinal cameras, non-mydratic retinal cameras, and slit lamps.*

	CARA CLAIMS	CORRESPONDING PREDICATE CLAIMS	COMMENTS
PERFORMANCE CLAIMS	Importing, Processing, Storage, Visualization	Collection, Storage, Management	<i>SYNONYMOUS LANGUAGE</i>
CLAIMS OF DATA TYPE	(Original, Enhanced) Color Fundus Images	Digital Images, Patient Data, Diagnostic Data, Clinical Information	<i>CARA CLAIMS ARE INCLUDED IN PREDICATE CLAIMS</i>
CLAIMS OF METHOD	Via Computerized Networks	Direct connection with instrument, computerized networks	<i>SYNONYMOUS LANGUAGE</i>

#### C DECISION-MAKING

- **SAME INDICATIONS FOR USE?**

**NO.** The predicate devices use different syntax and language to describe their claims. Furthermore, claims made in the IFU of the predicate device are more expansive than those of CARA.

- **DO THE DIFFERENCES ALTER THE EFFECT OR RAISE NEW QUESTIONS OF SAFETY AND/OR EFFECTIVENESS?**

**NO.** The claims are essentially the same between those of the CARA and the predicate device; the language between them is at least synonymous, if not identical.

#### D ADDITIONAL NOTES FROM CONSULTING SOFTWARE REVIEWER

On Page 2/19 of Tom's consulting software review, he states the following:

*I suggest the name "Diagnos" (510(k) Holder Company Name) be evaluated by management for it's implication towards the indications for use of the device.*

**S0 REVIEW COMMENT: Regarding Tom's comment (above), to the best of my knowledge there are no regulations in 21 CFR or guidance documents that convey or indicate authority regarding a company's name. Therefore, there are no concerns regarding the Indications for Use of CARA.**

**SECTION RECOMMENDATION: ADEQUATE****VII SOFTWARE (AS PER<sup>7</sup>)**

***S0 REVIEW COMMENT:*** Because the device is only software, this section serves to describe the technological characteristics of the device *in toto*.

To review the software documentation in detail, Dr. Thomas Radman was recruited to provide a consulting review. Tom's consulting review is attached behind the lead review (this document).

As per the FDA software guidance<sup>7</sup>, the applicant has provided software documentation in Section III of the submission ("Device Description"). The following table summarizes each of the documents provided, including whether each is adequate. Each document is described in detail, below, with comments from Tom's review.

SOFTWARE REQUIREMENT	SUBMISSION LOCATION	ADEQUATE?
Level of Concern	Pages III-8 – III-10	YES
Software Description	Pages III-2 – III-6	YES
Device Hazard Analysis	Page III-21	NO
Software Requirements Specification	Pages III-23 – III-25	YES
Architecture Design Chart	Page III-27	YES
Software Design Specification	Pages III-29 – III-40	NO
Traceability Analysis	Pages III-48, III-49	YES
Software Development Environment Description	Pages III-51 – III-54	YES
Verification & Validation Documentation	Pages III-56 – III-65, III-67 – III-78, III-80 – III-84	NO
Revision Level History	Page III-86	YES
Unresolved Anomalies	None	YES

**A LEVEL OF CONCERN (MODERATE)**

The applicant states<sup>8</sup> that the Level of Concern of the CARA is Moderate, based on the potential for misdiagnosis.

***S0 REVIEW COMMENT:*** Level of Concern was an issue which was raised in review of I100579. In the original Pre-510(k) and Pre-510(k) supplement, it was resolved that the Level of Concern should be Moderate and an appropriate rationale should be provided.

**In review of the provided information, given the lack of concerns noted in**

<sup>7</sup> FDA Guidance Document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

<sup>8</sup> K110869 / S0, Page III-2

**this regard in Tom's review, the device Level of Concern is ADEQUATE.**

## B SOFTWARE DESCRIPTION

The applicant provides a description of the software between pages III-2 and III-6 in the current submission (S0). On Page 2/19 of his review, Tom provides a brief description of the device overall:

*CARA is a Picture Archiving and Communications System (PACS) that performs enhancement and sharing of digital fundus color images using a secure internet connection. Through the internet, CARA software collects and manages color fundus images from a range of approved computerized digital imaging devices. CARA enables a real-time review of retinal image data (both original and enhanced) from an internet-browser-based user interface to allow authorized users to access and view data saved in a centralized database. The system utilizes state-of-the-art encryption tools to ensure a secure networking environment.*

*CARA is designed to be used with images from a standard, commonly used fundus camera. The eye care practitioner takes the image and sends it to the CARA processing engine through a dedicated web interface, and then the enhancement process is completed automatically. This processing provides eye care professionals with an enhanced photo that the user reviews in conjunction with the original image.*

*CARA is Software as a Service (SaaS). The user needs a computer with a web browser and an internet connection to use CARA service. Further information regarding the minimal computer hardware, software and internet connection requirements, on the user side, can be found in the CARA User's Manual. It is up to the user to assure that CARA and any other software used to visualize retinal images is used in an appropriate viewing environment, e.g., optimal lighting and free of distraction, so that details in the image may be appropriately viewed.*

*When a user account is created for practitioners using the CARA system, the user's country is specified to provide the appropriate version of CARA approved for use in that country. When the user logs in, the system redirects them to a specific dashboard related to their user account.*

CARA is segregated into a server side and client side. The server side consists of the Processing Cluster (further composed of the CARA processor (which performs input validation, corner mask calculation, enhancement, and output validation) and the Prognos NG (which organizes and executes system tasks)) and Infrastructure Cluster (consisting of the Web Interface and database which stores image information). The client side consists of an off-the-shelf internet browser and off-the-shelf operating system (non-specific).

## C HAZARD ANALYSIS

The applicant provides a device hazard analysis on Page III-21 of the current submission (S0). In review of this hazard analysis, Tom notes the following deficiency<sup>9</sup>:

<sup>9</sup> Consulting Review of Dr. Thomas Radman, Page 6/19

*Original Deficiency:* In Appendix III-3 entitled CARA Hazard Analysis, you provide some risk analysis, but it is insufficient. Please provide a description of the hazards (including clinical 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.

***S0 REVIEW COMMENT:* The hazard analysis is NOT ADEQUATE; THE ABOVE DEFICIENCY SHALL BE CONVEYED TO THE APPLICANT AS DEFICIENCY 1.**

D SOFTWARE REQUIREMENTS SPECIFICATION (SRS)

The applicant provides documentation to describe software requirements between Pages III-23 and III-25 of the current submission (S0).

***S0 REVIEW COMMENT:* Given the lack of concerns noted in this regard in Tom's review, the provided SRS documentation is ADEQUATE.**

E ARCHITECTURE DESIGN CHART

The applicant provides an architecture design chart on Page III-27 of the current submission (S0).

***S0 REVIEW COMMENT:* This information was the subject of a concern noted in review of I100579 (the applicant did not originally submit an architecture design chart). In review of the architecture design chart provided, given the lack of concerns noted in this regard in Tom's review, the provided information is ADEQUATE.**

F SOFTWARE DESIGN SPECIFICATION (SRS)

The applicant provides documentation to describe software requirements between Pages III-29 and III-40 of the current submission (S0). In review of this information, Tom notes the following concerns and deficiencies in his review<sup>10,11</sup>:

*Review Comment:* The SDS, beginning on p.50 of the submission, expands the documentation of functionality described in the SRS, but does not document how the requirements of the SRS are implemented as is specified in the FDA Software Guidance for Moderate LOC devices. Joe Jorgens, software reviewer for pre-IDE I100579 was consulted for concurrence. If he concurs, the following deficiency should be sent:

*Original Deficiency:* Please provide a software design specification (SDS) document which describes how the requirements in the Software Requirements Specifications (SRS) are implemented. The

<sup>10</sup> Consulting Review of Dr. Thomas Radman, Page 9/19

<sup>11</sup> Consulting Review of Dr. Thomas Radman, Page 11/19

*information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the software device was clear and unambiguous, with minimal ad hoc design decisions. The document that you submit should provide adequate information to allow for the review of the implementation plan for the software requirements in terms of intended use, functionality, safety and effectiveness. These should be presented in an enumerated manner, referencing the associated Software Requirements.*

***SO REVIEW COMMENT:*** Because Joe Jorgens (OSEL/DESE) was not available to comment, and given my experience with reviewing such software devices, I determined that the above concern is, in fact, warranted. The SDS documentation provided is not specific enough to explain specific design considerations; THE ABOVE DEFICIENCY SHOULD BE CONVEYED TO THE APPLICANT AS DEFICIENCY 2.

*Original Deficiency:* In the software design specification, you provide a qualitative overview of your image enhancement algorithm. However, it is unclear which parameters of the algorithm may be adjusted by the user. Please clarify if each color channel be individually enhanced or are the channels enhanced as separate channels, but at the same time? Please provide the numerical algorithms responsible for the enhancement. This information is necessary to understand the safety and effectiveness of your device compared to your cited predicate.

***SO REVIEW COMMENT:*** THE ABOVE DEFICIENCY SHALL BE CONVEYED TO THE APPLICANT AS DEFICIENCY 3.

*Review Comment:* The sponsor states a high compression level of jpeg images can result in deterioration of image quality and the enhancement result. The level of compression is noted in the User's Manual 1.2.2. Joe Jorgens software reviewer for pre-IDE I100579, or Rongping Ze (DLAM), image processing reviewer of the pre-IDE I100579, should be consulted for concurrence. If they concur, a deficiency should be sent:

*Original Deficiency:* You state a high compression level of jpeg images can result in deterioration of image quality and the enhancement result and provide illustration 4: Dependence of enhancement quality to file format to validate the similarity of the jpeg enhancement to the raw image formats. This is a qualitative measure on a single sample image that may not be representative on the worst case scenario. Please provide quantitative test data validating the use of the jpeg format of identified varying compression levels and sample images. Please include your test procedures and results.

***SO REVIEW COMMENT:*** Again, because Joe Jorgens (OSEL/DESE) was not available to comment, and given my experience with reviewing such software devices, I determined that the above concern is warranted. The applicant has not yet characterized worst case image quality that may be experienced; THE ABOVE DEFICIENCY SHOULD BE CONVEYED TO THE APPLICANT AS DEFICIENCY 4.

#### G TRACEABILITY ANALYSIS

The applicant provides a traceability analysis on Pages III-48 and III-49 of the submission. In review of this information, Tom notes in his review that *"this document links the user requirements and functional requirements with hazards/mitigations and verification/validation testing requirements for the CARA software."*<sup>12</sup>

***S0 REVIEW COMMENT:*** Given the lack of concerns noted in this regard in Tom's review, the provided traceability analysis is ADEQUATE.

#### H SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION

The applicant provides a description of the software development environment between Pages III-51 and III-54 in the current submission (S0).

***S0 REVIEW COMMENT:*** Given the lack of concerns noted in this regard in Tom's review, the provided description of the software development environment is ADEQUATE.

#### I VERIFICATION & VALIDATION INFORMATION

The applicant provides verification and validation information in various places in the submission:

- Pages III-56 – III-65 ("Internet Browser Capability Testing")
- Pages III-67 – III-78 ("Software Functionality Testing")
- Pages III-80 – III-84 ("Validation and Verification")

Additionally, regarding verification and validation, FDA provided comments to the applicant in review of I100579 / S1. As meeting materials for a teleconference, the applicant attempted to address these comments (email, 12/10/2010, located in the administrative file for I100579 / S1). The relevant applicant responses that are not adequate are below:

*FDA Comment: In a 510(k) submission, validation examples should include actual system output pictures, i.e., with the full spatial resolution and color range provided to the user. The validation section should include examples of worst-case acceptable original image quality, as well as examples of original images that generate various error messages.*

*Applicant Response to Above Comment: All the validation examples presented are actual system output pictures. The spatial resolution of these images is the same as the original images submitted. The color range provided to the user could not be interpreted. The color range is input dependent (Camera type, etc.).*

In review of the applicant's response above, Tom notes the following in his review:

<sup>12</sup> Consulting Review of Dr. Thomas Radman, Page 12/19

Review Comment: the validation section does not contain examples of worst-case image quality, or examples of original images that generate the systems's error messages. This response was reviewed by Bruce Drum (Vision Scientist, DONED/ONDB).

Original Deficiency: You provide a validation section with your submission. However, you do not provide worst-case image quality sample output images. Please provide the worst-case image quality sample output images and examples of images that would generate any error messages possible due to the input image. Please provide these images in the full spatial resolution and size as perceived by the device operator. This information is necessary to determine the effective use of your device as compared to your cited predicate.

**S0 REVIEW COMMENT: THE ABOVE DEFICIENCY SHALL BE CONVEYED TO THE APPLICANT AS DEFICIENCY 5.**

FDA Comment: It seems that the CARA algorithm keeps evolving with each enhancement failure because required modification may be made when an error occurs. Please clarify what modifications are made based on the enhancement failure and the effect of the modifications on the algorithms.

Applicant Response to Above Comment: The modifications are made to make the algorithms more robust and powerful.

In review of the applicant's response above, Tom notes the following in his review:

Review Comment: This response was reviewed by Bruce Drum (Vision Scientist, ONDB/DONED). He stated the response was not adequate, and the deficiency should be repeated in the 510k request for additional information.

Original Deficiency: Prior to the pre-teleconference for pre-IDE I100579, you had sent an email dated December 7, 2010 responding to our request for additional information. We requested clarification on what modifications were made based on the enhancement failure and the effect of the modifications on the algorithms. You responded "The modifications are made to make the algorithms more robust and powerful." Please provide the numerical algorithms, and a theory of operations for the modifications made to the algorithm relevant to its current iteration. This is necessary to understand if the current algorithm is safe and effective, or if it is also not a stable iteration resulting in bugs in the image processing.

**S0 REVIEW COMMENT: THE ABOVE DEFICIENCY SHALL BE CONVEYED TO THE APPLICANT AS DEFICIENCY 6.**

FDA Comment: You conclude that "the CARA algorithms are robust; therefore the rejection rate is less than 0.1 %." Was the robustness derived from the rejection rate? An interpretation on the rejection criteria is required. Please provide rationale and interpretation on how the validation criteria are chosen and what problems the images may have associated with failure in meeting each criterion.

*Applicant Response to Above Comment:* Yes, the robustness was derived from the rejection rate. The validation criteria are chosen based on the characteristics of an acceptable enhanced image. An interpretation of the rejection criteria will be provided in the 510(k) submission.

In review of the applicant's response above, Tom notes the following in his review:

*Review Comment:* The rejection rate is listed on p.96 of the submission as 0.3% with a confidence interval of [0, 0.008875]. The sponsor should be asked to clarify why the rejection rate is outside of the confidence interval.

*Original Deficiency:* On p.96 of your submission, the rejection rate is listed as 0.3% with a confidence interval of [0 0.008875]. Please clarify how the rejection rate may be outside the confidence interval, or if this is a typo.

***SO REVIEW COMMENT:* THE ABOVE DEFICIENCY SHALL BE CONVEYED TO THE APPLICANT AS DEFICIENCY 7.**

#### J DECISION-MAKING

- **SAME TECHNOLOGICAL CHARACTERISTICS?**

- **NO.** Though technological features of the device are similar, the specific organization of the software and design-level specifications is completely different.

- **COULD THE NEW CHARACTERISTICS AFFECT SAFETY AND/OR EFFECTIVENESS?**

**YES.** If the software fails or produces an inaccurate report/image, there is a safety and effectiveness risk of misdiagnosis / limited diagnostic utility.

- **ARE THERE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?**

**NO.** These types of questions are common to those in the product code 'NFJ.'

- **DO ACCEPTED SCIENTIFIC METHODS EXIST FOR ASSESSING THE EFFECTS OF THE NEW CHARACTERISTICS?**

**YES.** Bench or clinical validation may be performed to verify and validate software specifications.

- **ARE PERFORMANCE DATA AVAILABLE TO ALLOW FOR ASSESSMENT OF EQUIVALENCE?**

**YES, HOWEVER...** the information provided is neither entirely clear nor complete. The following deficiencies attempt to obtain clarifying information and substantiating data.

### **VIII RECOMMENDATION**

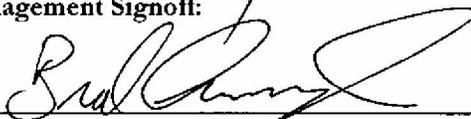
**I RECOMMEND THAT K110869 / S0 BE PLACED ON HOLD, AND THAT THE DEFICIENCIES BELOW BE CONVEYED TO THE APPLICANT.**

### **IX DEFICIENCIES**

1. In Appendix III-3 of the submission ("CARA Hazard Analysis"), you provide a risk analysis. However, this information is insufficient. Specifically, you have not provided a description of the hazards (including clinical 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. Please provide this information.
2. You provide a software design specification (SDS) document in Appendix III-6 of the submission. However, this information is incomplete. Specifically, you have not described how the requirements in the software requirements specification (SRS) document are implemented via design specifications. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the software device was clear and unambiguous, with minimal ad hoc design decisions. The document that you submit should provide adequate information to allow for the review of the implementation plan for the software requirements in terms of intended use, functionality, safety and effectiveness. These should be presented in an enumerated manner, referencing the associated software requirements. Please provide this information
3. In the software design specification, you provide a qualitative overview of your image enhancement algorithm. However, it is unclear which parameters of the algorithm may be adjusted by the user. Please clarify if each color channel be individually enhanced or are the channels enhanced as separate channels, and whether these changes can be made simultaneously. Furthermore, please provide the numerical algorithms responsible for the enhancement. This information is necessary to understand the safety and effectiveness of your device compared to your cited predicate.
4. You state a high compression level of JPEG images can result in deterioration of image quality and the enhancement result and provide illustration 4: Dependence of enhancement quality to file format to validate the similarity of the jpeg enhancement to the raw image formats. This is a qualitative measure on a single sample image that may not be representative on the worst case scenario. Please provide quantitative test data validating the use of the JPEG format of identified varying compression levels and sample images. Please include your test procedures and results.
5. You provide a validation section with your submission. However, you do not provide worst-case image quality sample output images. Please provide the worst-case image

quality sample output images and examples of images that would generate any error messages possible due to the input image. Please provide these images in the full spatial resolution and size as perceived by the device operator. This information is necessary to determine the effective use of your device as compared to your cited predicate.

6. Prior to the teleconference for pre-IDE I100579, you sent an email (dated December 7, 2010) which attempted to respond to our request for additional information. We requested clarification on what modifications were made based on the enhancement failure and the effect of the modifications on the algorithms. In response, you stated that "the modifications are made to make the algorithms more robust and powerful." However, this information is incomplete. Please provide the numerical algorithms, and a theory of operations for the modifications made to the algorithm relevant to its current iteration. This is necessary to understand if the current algorithm is safe and effective, or if it is also not a stable iteration resulting in errors in the image processing.
  
7. On Page III-74 of the submission, you state that "the rejection rate is as 0.3% with a confidence interval of [0, 0.008875]..." Please clarify how the rejection rate may be outside the confidence interval, or if this is a typographical error.

<b>Lead Reviewer Signoff:</b>	
	5/26/2011
Rahul Ram (ODE/DONED/ONDB)	
<b>Management Signoff:</b>	
	
Brad Cunningham (ODE/DONED/ONDB)	
Date 5/26/11	Concur: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Division Level _____	
Date _____	Concur: Yes <input type="checkbox"/> No <input type="checkbox"/>

**Ram, Rahul**

---

**From:** Ram, Rahul  
**sent:** Thursday, May 26, 2011 3:30 PM  
**to:** 'ashapiro@oraclinical.com'  
**Cc:** Cunningham, Bradley; Radman, Thomas  
**Subject:** K110869 - CARA

**Attachments:** Telephone Hold Memorandum.pdf

Mr. Shapiro:

Thank you for your submission regarding CARA (K110869). The submission has been placed on hold.

Please refer to the attached PDF for an explanation of the deficiencies.



Telephone Hold  
Memorandum.pdf ...

Thank you,

Rahul Ram

**Rahul K. Ram**

LT, USPHS-CC

DA \ CDRH \ ODE

*Division of Ophthalmic, Neurologic & ENT Devices (DONED),*

*Ophthalmic Lasers, Neurostimulators & Diagnostic Devices Branch (ONDB)*

**rahul.ram@fda.hhs.gov**

**301-796-6610 (v)**

**301-847-8126 (f-1)**

**301-847-8127 (f-2)**



Public Health Service  
DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
Memorandum

**Date:** May 26, 2011

**From:** Rahul K. Ram  
Lead Reviewer, K110869  
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch  
Division of Ophthalmic, Neurologic and ENT Devices  
Center for Devices and Radiological Health

**To:** Diagnos, Inc.  
c/o Mr. Aron Shapiro  
Vice President  
Ora, Inc.  
300 Brickstone Square  
Andover, MA 01810  
[ashapiro@oraclinical.com](mailto:ashapiro@oraclinical.com)

**Subject:** 510(k): K110869  
Trade Name: CARA  
Dated: March 25, 2011  
Received: March 29, 2011

Mr. Shapiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. This 510(k) submission is being placed on HOLD pending the submission of responses to the following deficiencies:

1. In Appendix III-3 of the submission ("CARA Hazard Analysis"), you provide a risk analysis. However, this information is insufficient. Specifically, you have not provided a description of the hazards (including clinical 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. Please provide this information.
2. You provide a software design specification (SDS) document in Appendix III-6 of the submission. However, this information is incomplete. Specifically, you have not described how the requirements in the software requirements specification (SRS) document are implemented via design specifications. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the

Mr. Aron Shapiro

Page 2

software device was clear and unambiguous, with minimal ad hoc design decisions. The document that you submit should provide adequate information to allow for the review of the implementation plan for the software requirements in terms of intended use, functionality, safety and effectiveness. These should be presented in an enumerated manner, referencing the associated software requirements. Please provide this information

3. In the software design specification, you provide a qualitative overview of your image enhancement algorithm. However, it is unclear which parameters of the algorithm may be adjusted by the user. Please clarify if each color channel be individually enhanced or are the channels enhanced as separate channels, and whether these changes can be made simultaneously. Furthermore, please provide the numerical algorithms responsible for the enhancement. This information is necessary to understand the safety and effectiveness of your device compared to your cited predicate.
4. You state a high compression level of JPEG images can result in deterioration of image quality and the enhancement result and provide Illustration 4 ("Dependence of enhancement quality to file format to validate the similarity of the JPEG enhancement to the raw image formats"). This is a qualitative measure on a single sample image that does may not be representative on the worst case scenario. Please establish a quantitative measure of image quality, and provide test data evaluating changes to this quality at varying compression levels. Furthermore, please provide sample images representing a spectrum of images of worst case quality and highest potential to mischaracterize the structure of the eye. Please include your test procedures and results.
5. You provide a validation section with your submission. However, you do not provide worst-case image quality sample output images. Please provide the worst-case image quality sample output images and examples of images that would generate any error messages possible due to the input image. Please provide these images in the full spatial resolution and size as perceived by the device operator. This information is necessary to determine the effective use of your device as compared to your cited predicate.
6. Prior to the teleconference for pre-IDE I100579, you sent an email (dated December 7, 2010) which attempted to respond to our request for additional information. We requested clarification on what modifications were made based on the enhancement failure and the effect of the modifications on the algorithms. In response, you stated that "the modifications are made to make the algorithms more robust and powerful." However, this information is incomplete. Please provide the numerical algorithms, and a theory of operations for the modifications made to the algorithm relevant to its current iteration. This is necessary to understand if the current algorithm is safe and effective, or if it is also not a stable iteration resulting in errors in the image processing.
7. On Page III-74 of the submission, you state that "the rejection rate is as 0.3% with a confidence interval of [0, 0.008875]..." Please clarify how the rejection rate may be outside the confidence interval, or if this is a typographical error.

The deficiencies identified above represents the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the

203

Mr. Aron Shapiro

Page 3

deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to the Document Control Center at the Center for Devices and Radiological Health (CDRH):

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center (WO66-G609)  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993-0002

If you have any questions concerning the contents of this memorandum, please contact Rahul Ram at (301) 796-6620.

204



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service  
Food and Drug Administration

## Memorandum

Date: April 6, 2011  
From: Thomas C. Radman, PhD.  
DONED/ONDB  
Subject: K110869; CARA  
Diagnos, Inc.  
Brossard, Quebec  
Canada  
To: The Record

### Purpose/Scope of Review

The applicant seeks 510(k) clearance for the Reletex Nerve Diagnos CARA Device. This review is intended to address the software aspects of the device. The device is proposed to be classified as Picture Archiving and Communications System (21 CFR 892.2050), product code NFJ.

The sponsor references pre-IDE I100579, received July 2, 2010, resulting in guidance for adequate device testing for this 510(k). A list of FDA comments was sent to the sponsor electronically on August 31, 2010. The sponsor submitted a response in Supplement I received October 20, 2010. FDA sent additional comments in an e-mail dated December 7, 2010. The sponsor provided a response via e-mail dated December 10, 2010 the day of our scheduled teleconference with them.

### Recommendation

Based upon my review of the device, I recommend clearance of the device upon adequate resolution of the requested additional information.

### Indications for Use

*CARA is a comprehensive software platform intended for importing, processing, and storing of color fundus images as well as visualization of original and enhanced image through computerized networks.*

**Review Comment:** I suggest the name "Diagnos" be evaluated by management for it's implication towards the indications for use of the device.

**Device Description and Intended Use**

CARA is a Picture Archiving and Communications System (PACS) that performs enhancement and sharing of digital fundus color images using a secure internet connection. Through the internet, CARA software collects and manages color fundus images from a range of approved computerized digital imaging devices. CARA enables a real-time review of retinal image data (both original and enhanced) from an internet-browser-based user interface to allow authorized users to access and view data saved in a centralized database. The system utilizes state-of-the-art encryption tools to ensure a secure networking environment.

CARA is designed to be used with images from a standard, commonly used fundus camera. The eye care practitioner takes the image and sends it to the CARA processing engine through a dedicated web interface, and then the enhancement process is completed automatically. This processing provides eye care professionals with an enhanced photo that the user reviews in conjunction with the original image.

CARA is Software as a Service (SaaS). The user needs a computer with a web browser and an internet connection to use CARA service. Further information regarding the minimal computer hardware, software and internet connection requirements, on the user side, can be found in the CARA User's Manual. It is up to the user to assure that CARA and any other software used to visualize retinal images is used in an appropriate viewing environment, e.g., optimal lighting and free of distraction, so that details in the image may be appropriately viewed.

When a user account is created for practitioners using the CARA system, the user's country is specified to provide the appropriate version of CARA approved for use in that country. When the user logs in, the system redirects them to a specific dashboard related to their user account.

**Substantial Equivalence Discussion**

The Predicate Devices listed are:

- 1) K082364 Topcon IMAGEnet Professional PC Software System NFJ

The sponsor provides the following comparison table:

	Topcon IMAGENet	Diagnos CARA
Software Only	√	√
Web Based Platform	x	√
Non-mydratiac Capture Device Images Processing	√	√
Image Data Management	√	√
Fundus Image Only	√	√
File Import	√	√
Color Fundus Image Enhancement	x	√
Black & White Fundus Image Enhancement	√	x
Linear Distance and Area Measurement	√	x
Image Annotation & Measurement	√	x

√ = present

x = absent

**Reviewer Comment:** The predicate device is integrated with the compatible fundus camera, while the subject device is cloud based (fundus images are transferred to a remote server via the internet). The predicate device controls some aspects of the fundus camera, and includes the risk of a software error subjecting the user to hazardous light levels. The subject device does not control any functions of the compatible fundus camera.

**Software**

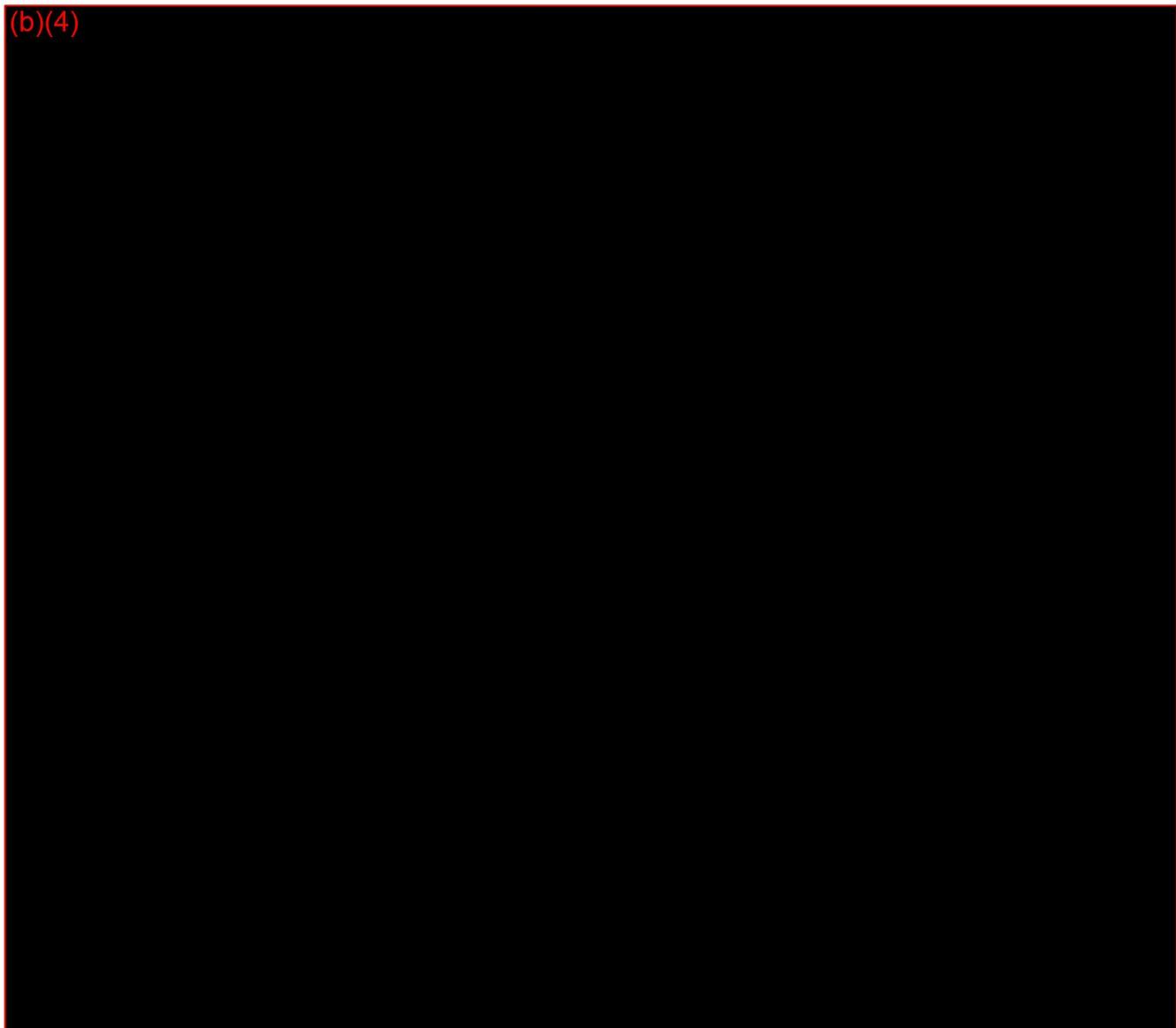
Version: evVision PR v1.1.0		
Level of Concern: Identified as Moderate		
	Yes	No
Software/Firmware description:	✓	
Device Hazard Analysis:	✓	
Software Requirements Specifications:	✓	
Architecture Design Chart: <sup>B</sup>	✓	

Software Design Specifications: <sup>B</sup>	✓	
Traceability Analysis/Matrix:	✓	
Software Development Environment Description: <sup>B</sup>	✓	
Verification & Validation Testing:	✓	
Revision level history:	✓	
Unresolved anomalies: <sup>B</sup>	✓	

Table 5: Summary of the appropriateness of different aspects of the ✓ software. These were evaluated in accordance with the guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued in 2005.

<sup>B</sup> If Minor Level of Concern, no documentation is necessary in the submission

(b)(4)























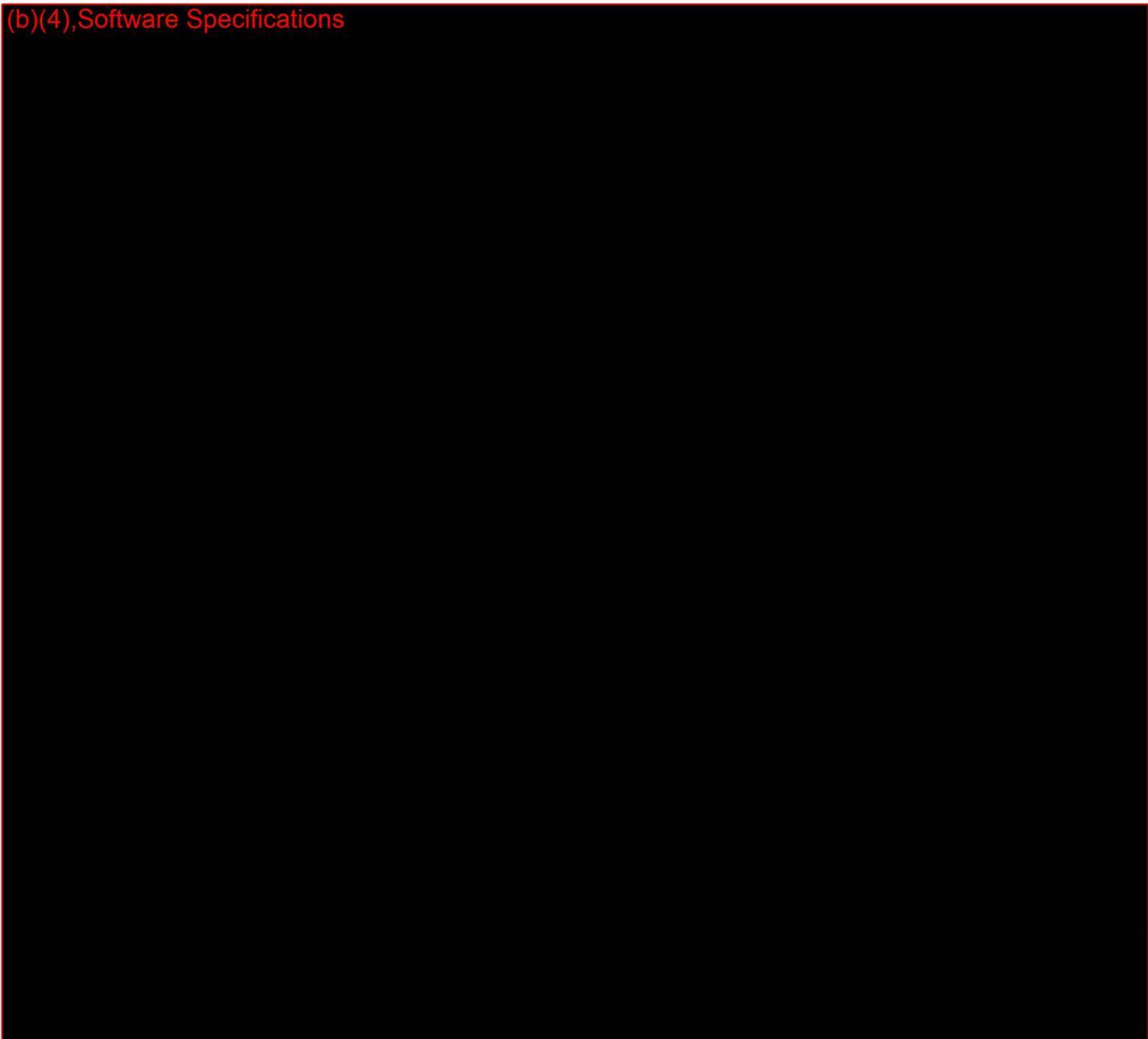






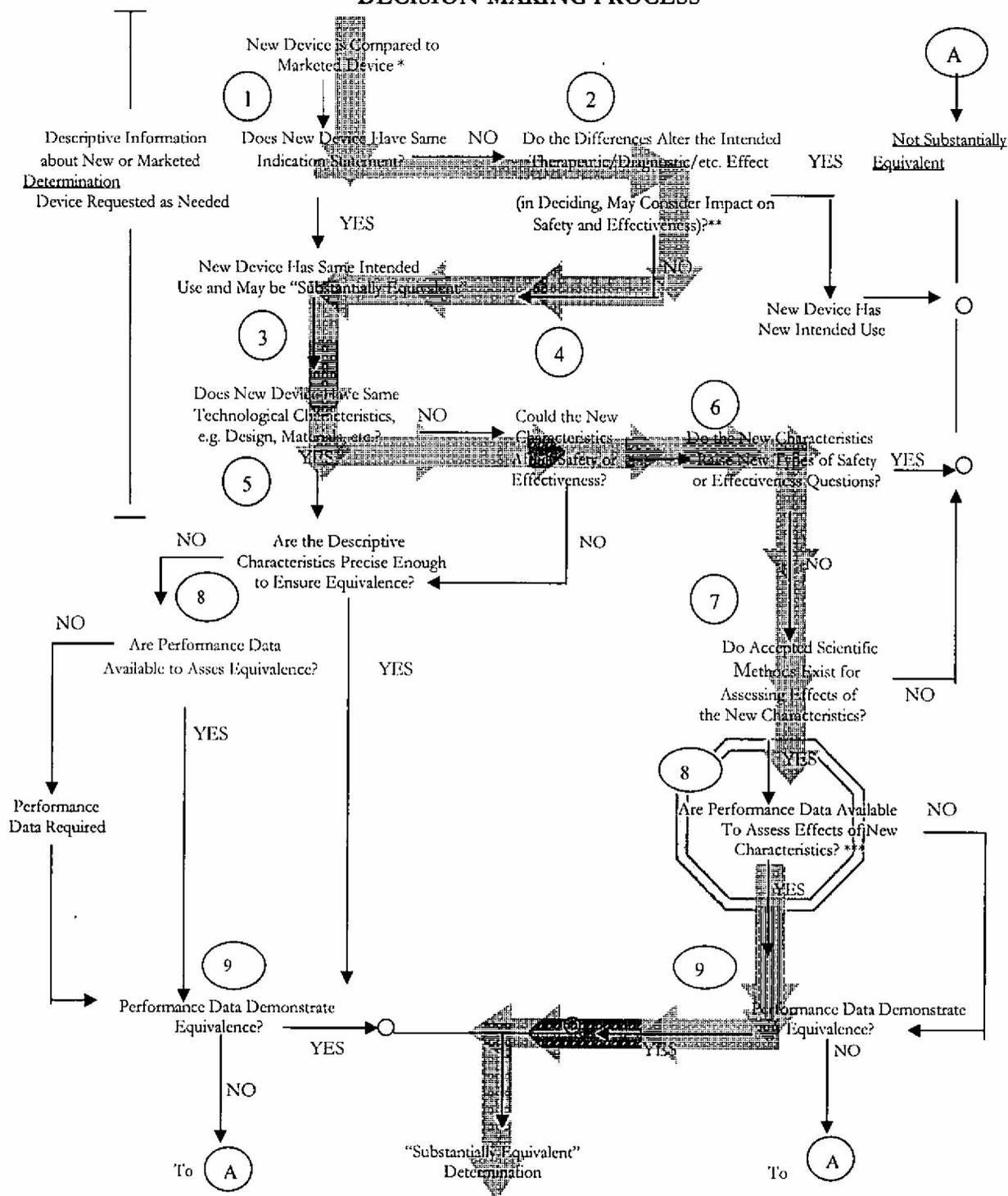


(b)(4), Software Specifications



  
Thomas C. Radman, Ph.D. Date  
Biomedical Engineering, DONED/ONDB

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



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

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

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 16, 2011

DIAGNOS, INC  
C/O ORA, INC.  
300 BRICKSTONE SQUARE  
ANDOVER, MASSACHUSETTS 01810  
ATTN: ARON SHAPIRO

510k Number: K110869

Product: CARA

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 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. 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.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

K110869/51

FDA CDRH DIV



JUN 16 2011

RECEIVED

June 15, 2011

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-0609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Attention: Rahul K. Ram, Lead Reviewer

**Subject: 510(k) No. K110869 – Response to request for additional information.**

Dear Mr. Ram,

We refer to our March 29, 2011 Premarket Notification Submission (510(k) No. K110869, Trade Name: CARA). We also refer to the May 26, 2011 communication from Rahul K. Ram, Lead Reviewer, which included comments and request for additional information. Please find enclosed our response to the FDA comments. The enclosures include a Table of Contents, a point by point response to the FDA comments, and Appendix material.

Please contact me if you have any questions or comments regarding the enclosed 510(k) response submission.

Sincerely,

Aron Shapiro  
Vice President

Enclosures

KA

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Response regarding FDA comments about our submission, K110869, received May 26, 2011

**Date:** June 14, 2011

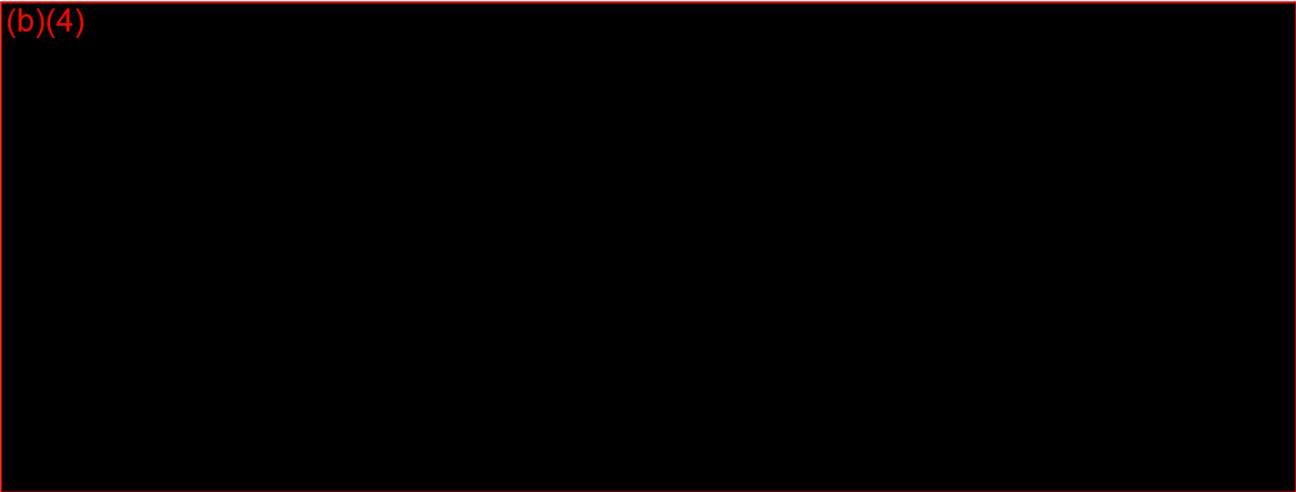
**From :** Diagnos, Inc.

**To:** Rahul K. Ram  
Lead Reviewer, K110869  
Ophthalmic Lasers, Neuromuscular Stimulators, & Diagnostic Devices Branch  
Division of Ophthalmic, Neurologic and ENT Devices  
Center for Devices and Radiological Health

**Subject:** 510(k): K110869  
Trade Name: CARA  
Dated: March 25, 2011  
Received: March 29, 2011

Question 1:

(b)(4)



Question 2:

(b)(4)



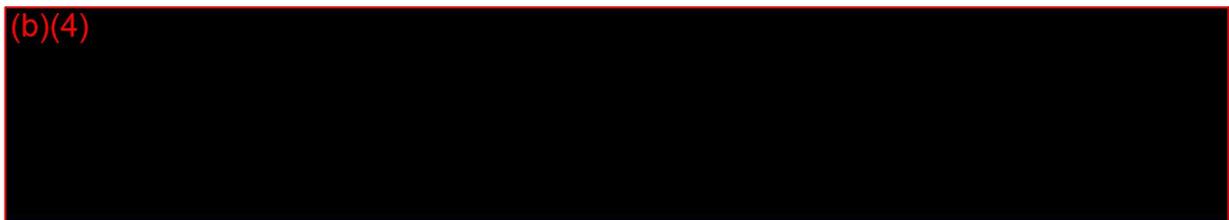
**Diagnos' response regarding question 2:**

(b)(4)

A large black rectangular redaction box covering the entire response to question 2.

Question 3:

(b)(4)

A large black rectangular redaction box covering the entire response to question 3.

**Diagnos' response regarding question 3:**

(b)(4)

A large black rectangular redaction box covering the entire response to question 3.

Question 4:

(b)(4)

A large black rectangular redaction box covering the entire response to question 4.

**Diagnos' response regarding question 4:**

(b)(4)

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(b)(4)



Question 5:

(b)(4)



**Diagnos' response regarding question 5:**

(b)(4)



Question 6:

(b)(4)



**Diagnos' response regarding question 6:**

(b)(4)



Question 7:

(b)(4)

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**Diagnos' response regarding question 7:**

(b)(4)

A large black rectangular redaction box covering the response to Question 7.

**Appendix 1**  
**Hazard Analysis**

Failure Mode	Severity of the Hazard	Hazard Probability	Exposability	Method of Control	Testing	Residual Hazard Probability	Control Measure Effectiveness
R1 Misdiagnosis of patient's condition due to artifacts in device output	Critical	Improbable	High	Device does not perform any diagnostic function (disclaimer). Original image available/presented to user with enhanced image.	Critical image enhancement Test report in the appendix 11	0.000001	99.99%
R2 Misdiagnosis of patient's condition due to poor quality of user display for image output	Critical	Improbable	Systematic	Device instructions in the user manual present the minimum requirements for device hardware (image quality) used by the doctor to view images in office. Moreover, the device does not perform any diagnostic function (disclaimer). Original image available/presented to user with enhanced image.	Please refer to Section Test plan results of appendix III-10 page III-65 of the 510(k)	0	99.99%
R3 Misdiagnosis of patient's condition due to mix-up of images from different patients	Critical	Improbable	Systematic	To each CARA transaction is assigned a unique transaction key, eight characters in length and whose uniqueness is enforced at the database level (unique primary key). This unique ID is used as a parameter in all CARA subroutines and in all operating system/file system tasks (example: the UID is used as the directory name used to store original and enhanced images on CARA servers). Additionally, all original images are write-protected to assure they are never over-written or modified. Moreover, the device does not perform any diagnostic function (disclaimer). Original image available/presented to user with enhanced image.	Please refer to section 2.3 and 2.4 of OIS Software Hazard Mitigation of Cybersecurity system document in appendix III-2 of the 510(k)	0.000001	99.99%
R4 Misdiagnosis of patient's condition due to corruption of original image	Minor	Remote	Systematic	Software rejects images that do not meet quality and size requirements prior to acceptance for enhancement. Moreover, if data flowing across an SSL session is altered, the SSL code in the receiving node will detect this condition and not pass the corrupted data to the application. Moreover, the device does not perform any diagnostic function (disclaimer). Original image available/presented to user with enhanced image.	Please refer to Section Test plan results of appendix III-10 page III-65 and to section 2.3 and 2.4 of OIS Software Hazard Mitigation of Cybersecurity system document in appendix III-2 of the 510(k)	0	99.99%
R5 Compromise of confidential patient information	Critical	Improbable	Systematic	Image transfer to/from CARA is accomplished with the use of the Secure Socket Layer (SSL). This well established and widely accepted standard assures that data received is identical to data sent with the added advantage of strong encryption.	Please refer to section 2.3 and 2.4 of OIS Software Hazard Mitigation of Cybersecurity system document in appendix III-2 of the 510(k)	0.000001	99.99%
R6 Misidentification of fundus images could lead to misdiagnosis	Critical	Improbable	Systematic	Use of unique identifier for every request/images sent for analysis. For more information,	Please refer to section 2.3 and 2.4 of OIS Software Hazard Mitigation of Cybersecurity system document in appendix III-2 of the 510(k)	0.000001	99.99%
R7 Irregular contours of enhanced image	Negligible	Remote	Systematic	Exact on rules in analysis and transformation algorithm with feedback to the user	Please refer to ICD in Section Test plan results of appendix III-10 page III-65 of the 510(k)	0	99.99%

The device does not contact the patient. No harm (physical injury, damage, or both to the health of people or damage to property or the environment) could happen to the patient.

Semi-quantitative risk matrix

	Qualitative severity levels					
	No Effects	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Controlled risk	Controlled risk	Controlled risk	Unacceptable risk	Unacceptable risk	Unacceptable risk
Probable	Controlled risk	Controlled risk	Controlled risk	Unacceptable risk	Unacceptable risk	Unacceptable risk
Occasional	Controlled risk	Controlled risk	Controlled risk	Unacceptable risk	Unacceptable risk	Unacceptable risk
Remote	Controlled risk	Controlled risk	R4	Unacceptable risk	Unacceptable risk	Unacceptable risk
Improbable	Controlled risk	R7	R4	Unacceptable risk	R1, R2, R3, R5, R6	Unacceptable risk

Semi-Quantitative Probability levels

Controlled risk  
 Unacceptable risk  
 Acceptable risk



































**Appendix 4**  
**Requirements vs. Design Grid**

## Requirements vs Design Grid

## 2 General System

Req. #	Description	Design Features	Category
R0101	Support for unlimited number of submitted images	D0107 - CARA is able to receive appropriate transaction volume D0108 - FS component allows for the storage of large volumes of images	Effectiveness
R0102	Single image processing < 1 min.	D0205 - The I/O library is able to read well-known file formats D0219 - Enhance each channel separately in parallel	Effectiveness
R0103	Global speed >= 10 images per min.	D0250 - Current grid can process 720 images per hour	Effectiveness
R0104	Store computation history for each request	D0305 - All user transactions are recorded in a log file D0306 - Unsuccessful log in attempts are monitored and reviewed.	Functionality

## 3 Platform

Req. #	Description	Design Features	Category
R0201	Highly secured platform	D0702 - platform = LINUX	Safety
R0202	Web interface accessible only to authorized users	D0304 - user must log-on to use the system using the assigned user identification / password	Safety
R0203	Users may not access other users data	D0350, D0351 - Authorization system	Safety
R0204	All user data accesses must be logged	D0305 - All user transactions are recorded in a log file D0306 - Unsuccessful log in attempts are monitored and reviewed	Functionality
R0205	Secured communication between user's computer and CARA servers	D0302 - Secure communication system through the HTTPS protocol	Safety
R0206	Must support Firefox 3+, IE 7+, Chrome 3+, Safari 4+	D0301 - list of supported web browsers	Functionality

## 4 Software - Functional Requirements

Req. #	Description	Design Features	Category
R0301	Must perform enhancement of fundus colour images	D0201 - MOD1-CCE: Colour Contrast Enhancement	Intended use
R0302	Supported input file formats = PNG, JPEG, BMP	D0205 - The I/O library is able to read well-known file formats	Effectiveness
R0303	Must handle compressed input images	D0205, D0206 – Handles compressed JPEG images	Functionality
R0304	Supported output file formats = PNG, JPEG, BMP	D0206 - The I/O library is able to handle compressed image file formats such as JPEG, PNG, or TIFF	Functionality
R0305	Rejection of bad quality images and no generation of artifacts	D0210 through D0223	Intended use
R0306	Submission using any of the standard web browsers	D0301 – list of supported web browsers	Intended use
R0307	Result accessible / viewable using any of the standard web browsers	D0301 – list of supported web browsers	Intended use
R0308	System supervisors must be able to add notes or annotations to the requests of any user account	D0323 – Allows the system administrators to add notes/annotations	Intended use

## 5 Software Performance

Req. #	Description	Design Features	Category
R0401	Must enhance images on-line + batch modes	D0503 - Images can be sent to CARA for automated processing as well as for archival and recall	Intended use
R0402	Must handle non compressed large input images	D0213 - Image maximum size (height and width) is lower than 4000 pixels	Functionality

**6 User Interface**

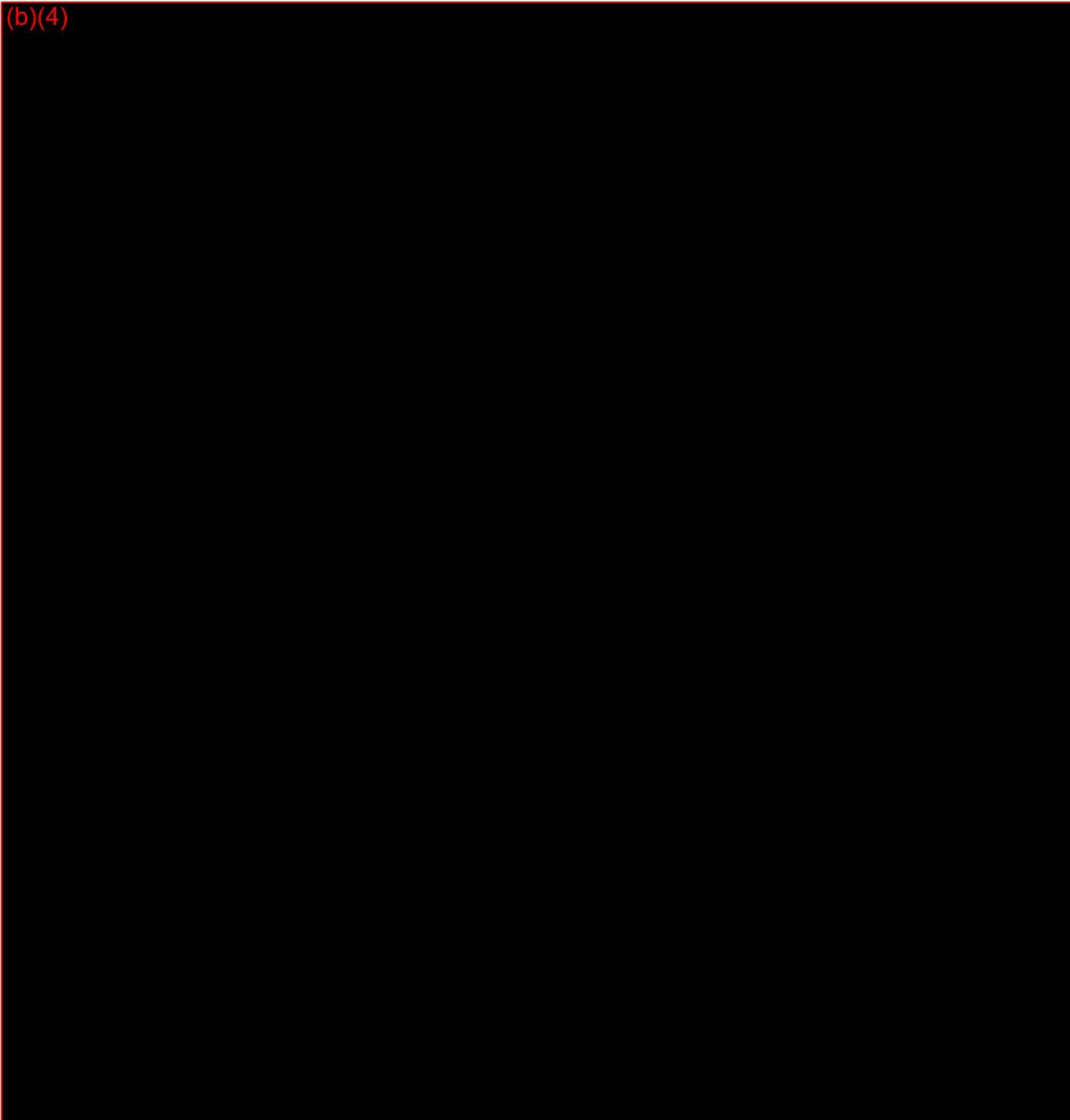
Req. #		Description	Design Features	Category
R0501	High data integrity		D0109 – A unique number is given to every request received	Safety
R0502	Images must be archived after 6 months		D0108 - FS component allows for the storage of images D0501 - Long-term storage and retrieval	Functionality
R0503	Web interface text in English		D0303 - In the log in page, English is the initial language offered to the user	Intended use

**Appendix 5**

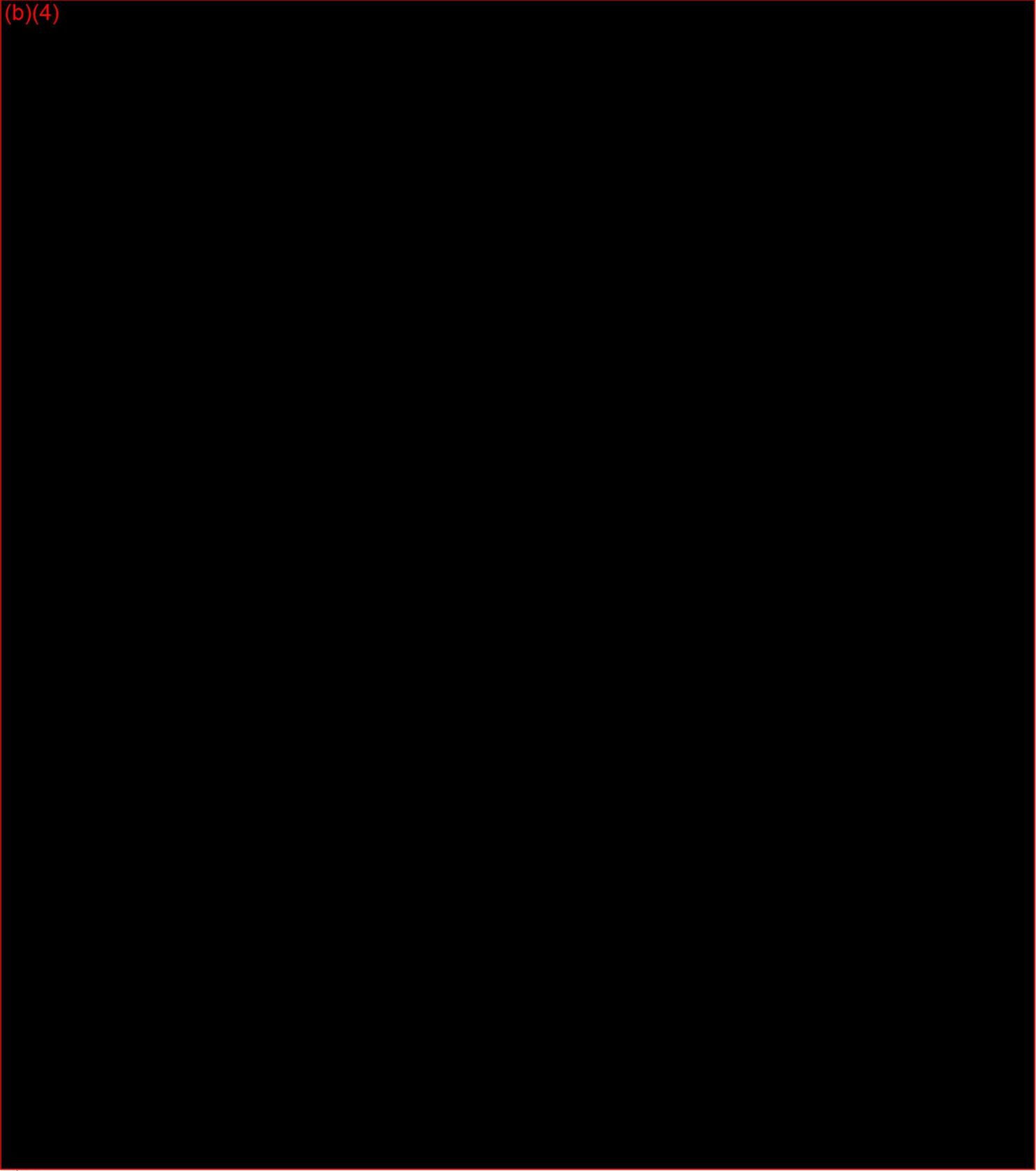
**CARA Enhancement Algorithms Description**

## CARA Enhancement Algorithms Description

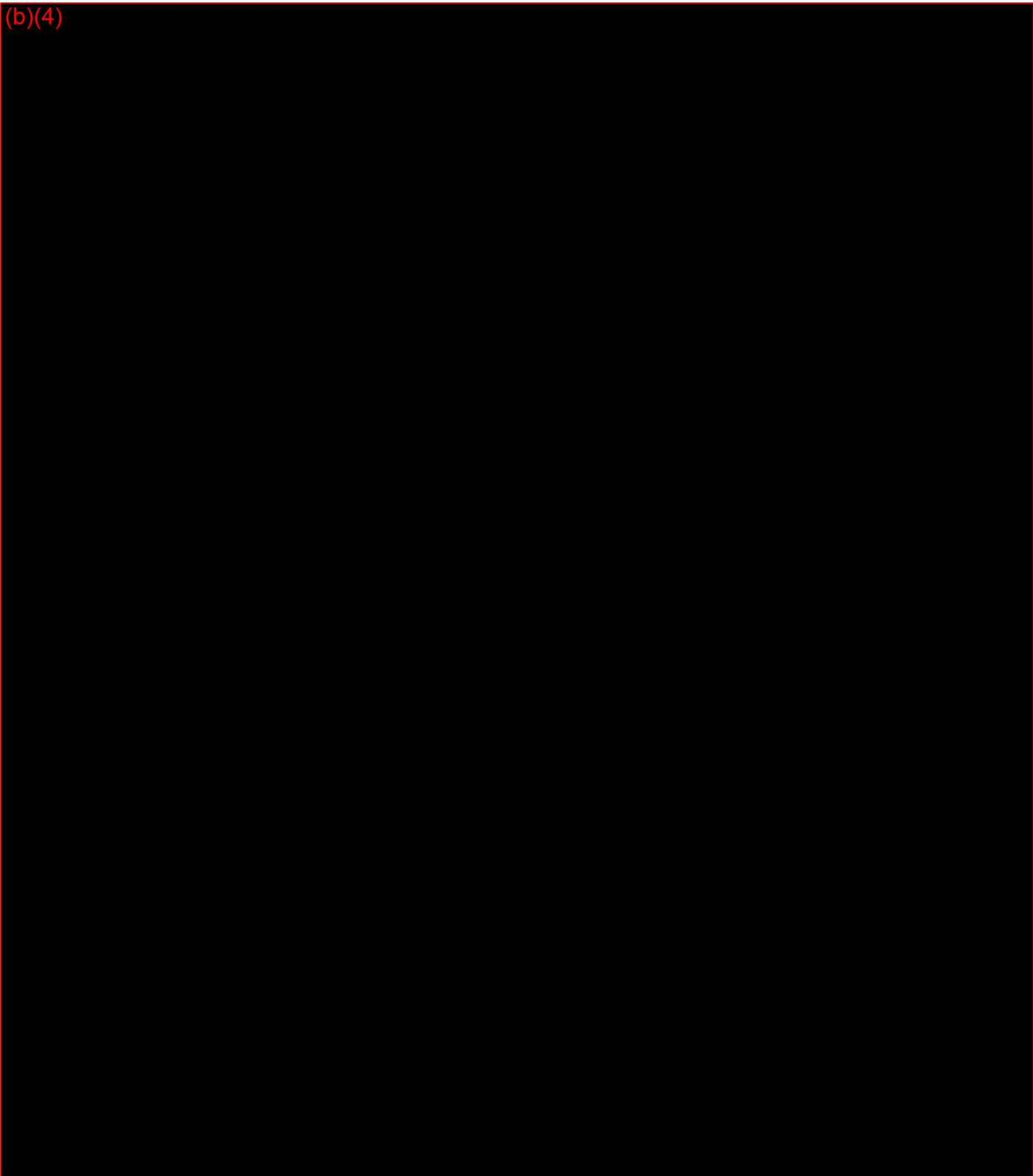
(b)(4)



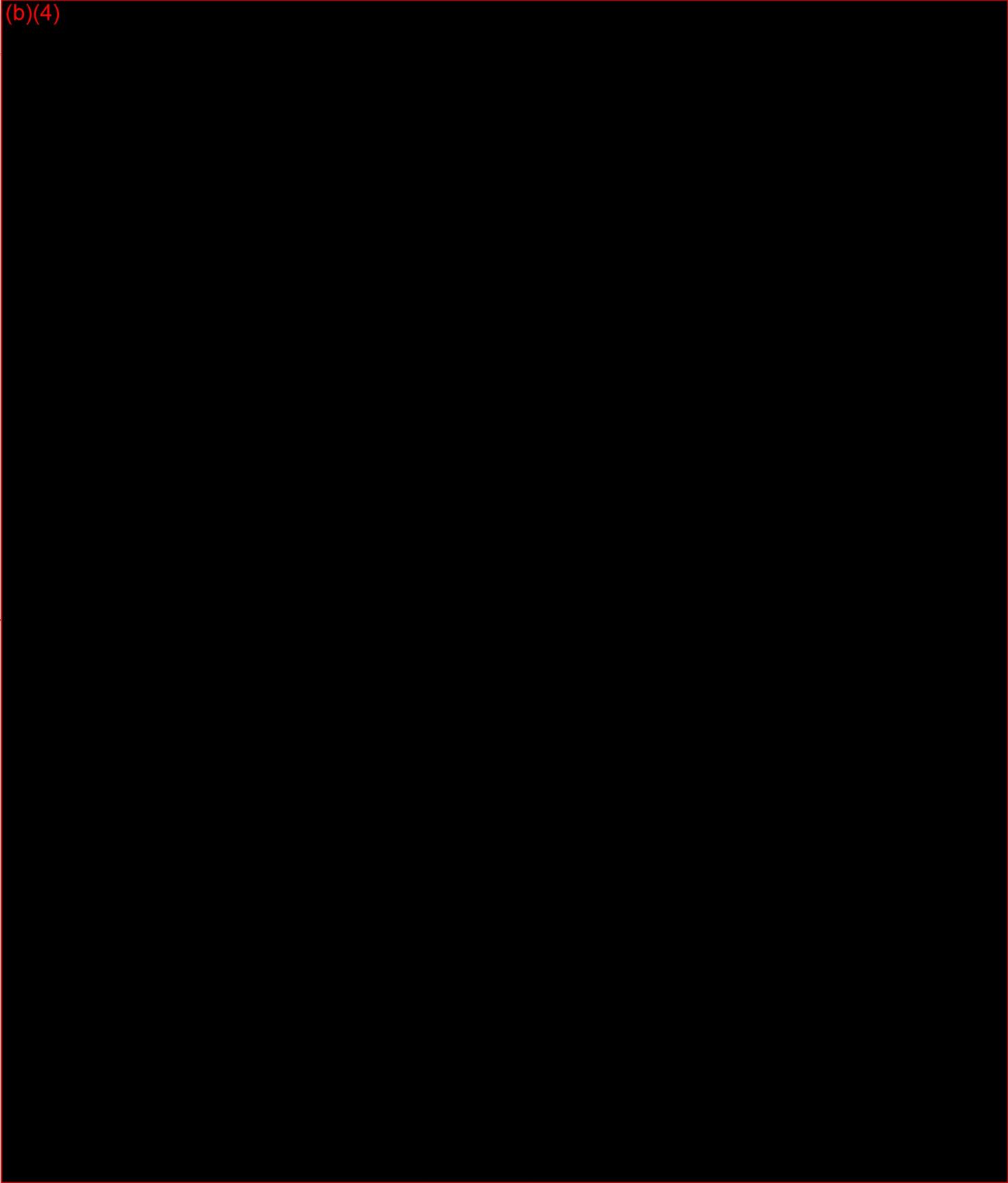
(b)(4)



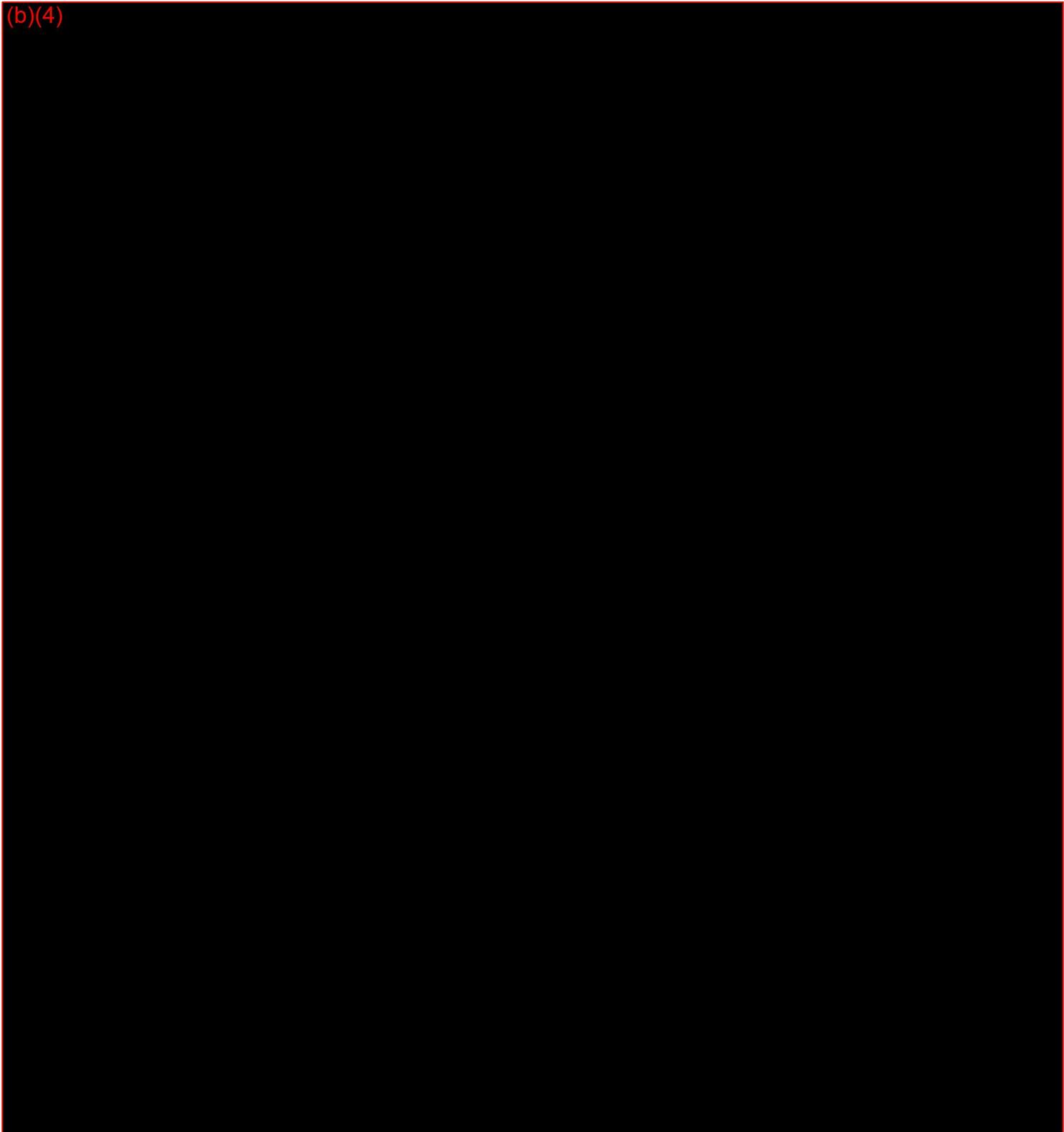
(b)(4)



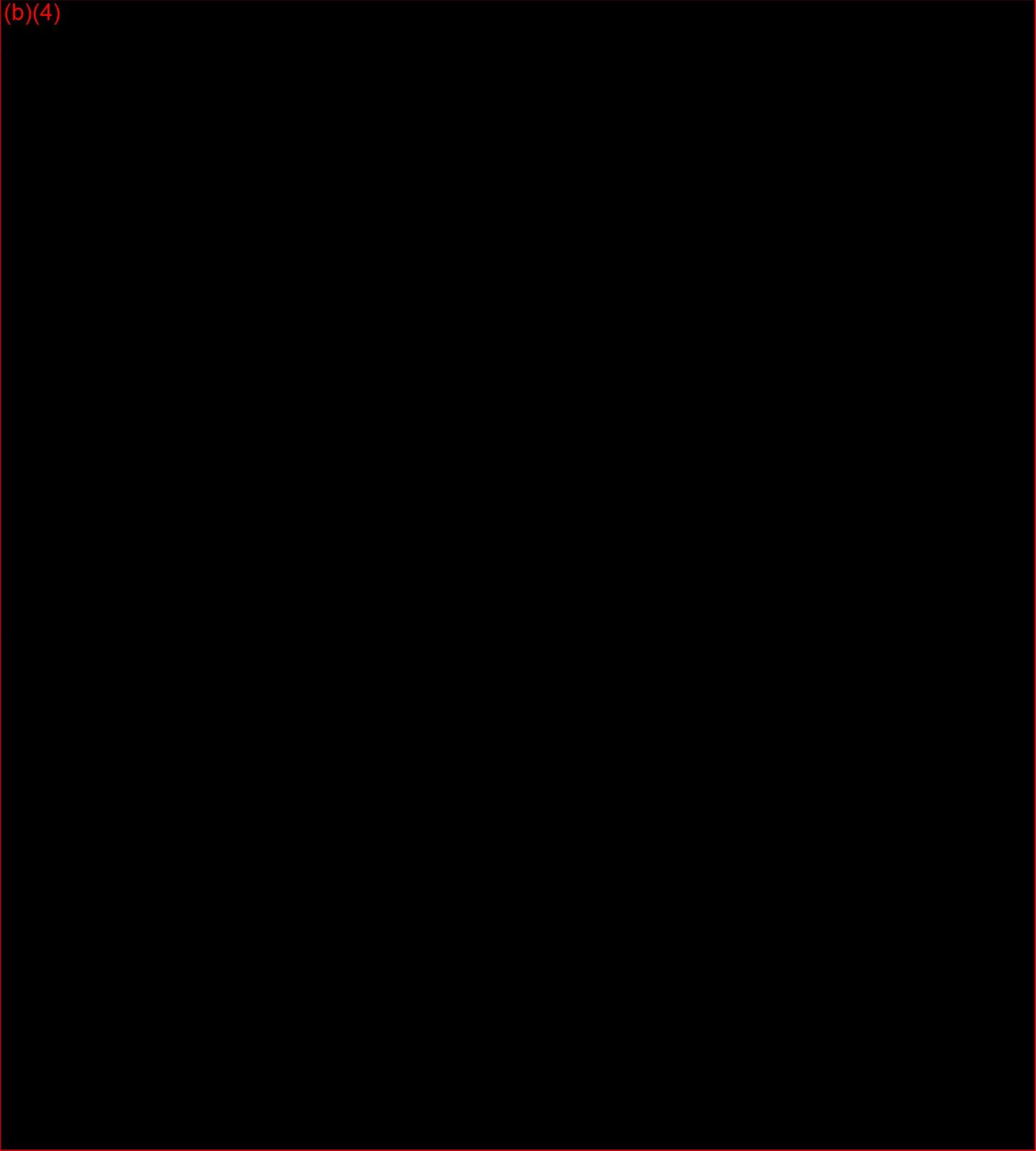
(b)(4)



(b)(4)



(b)(4)



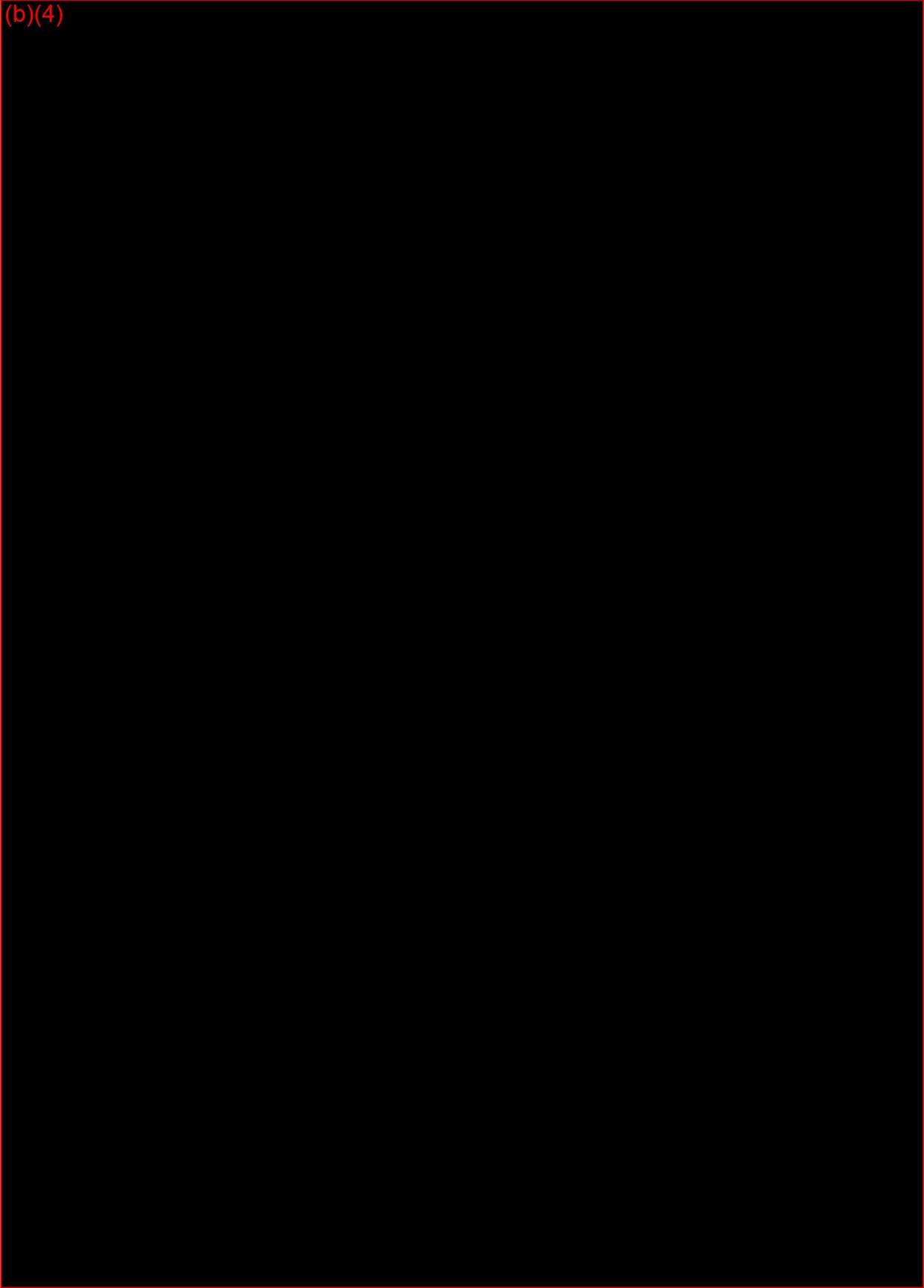
(b)(4)



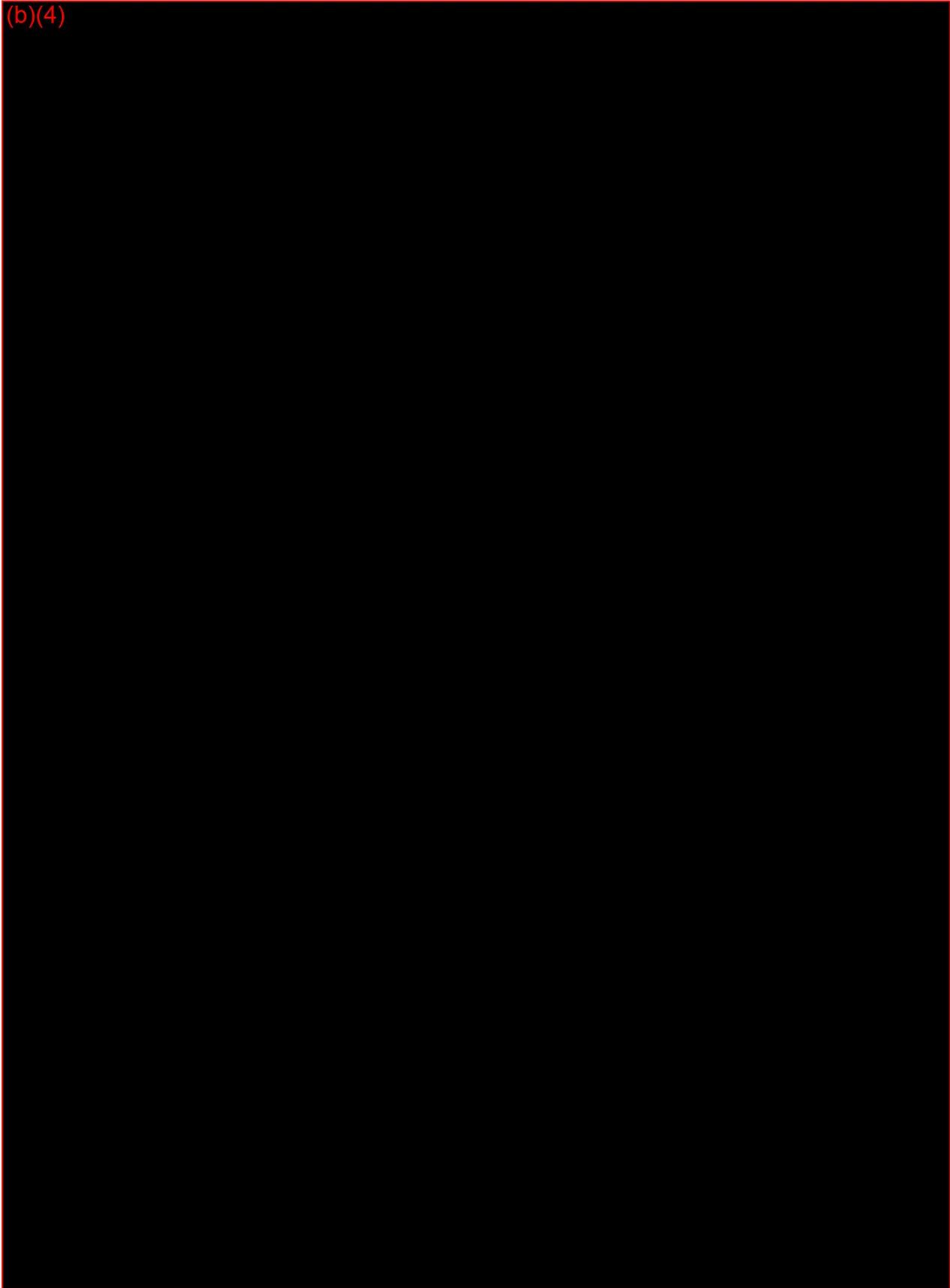
**Appendix 6**

**The numerical algorithm responsible for the enhancement**

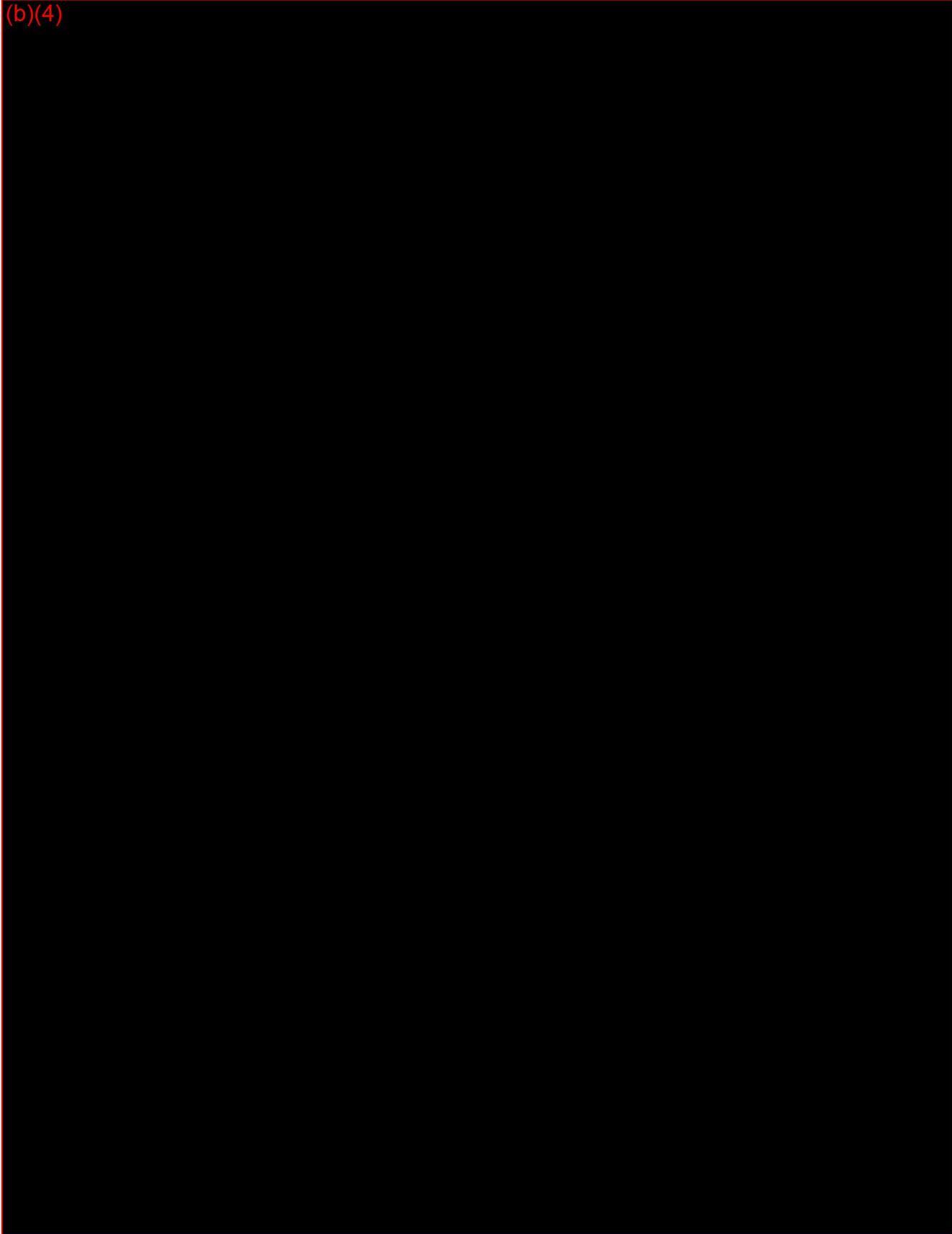
(b)(4)



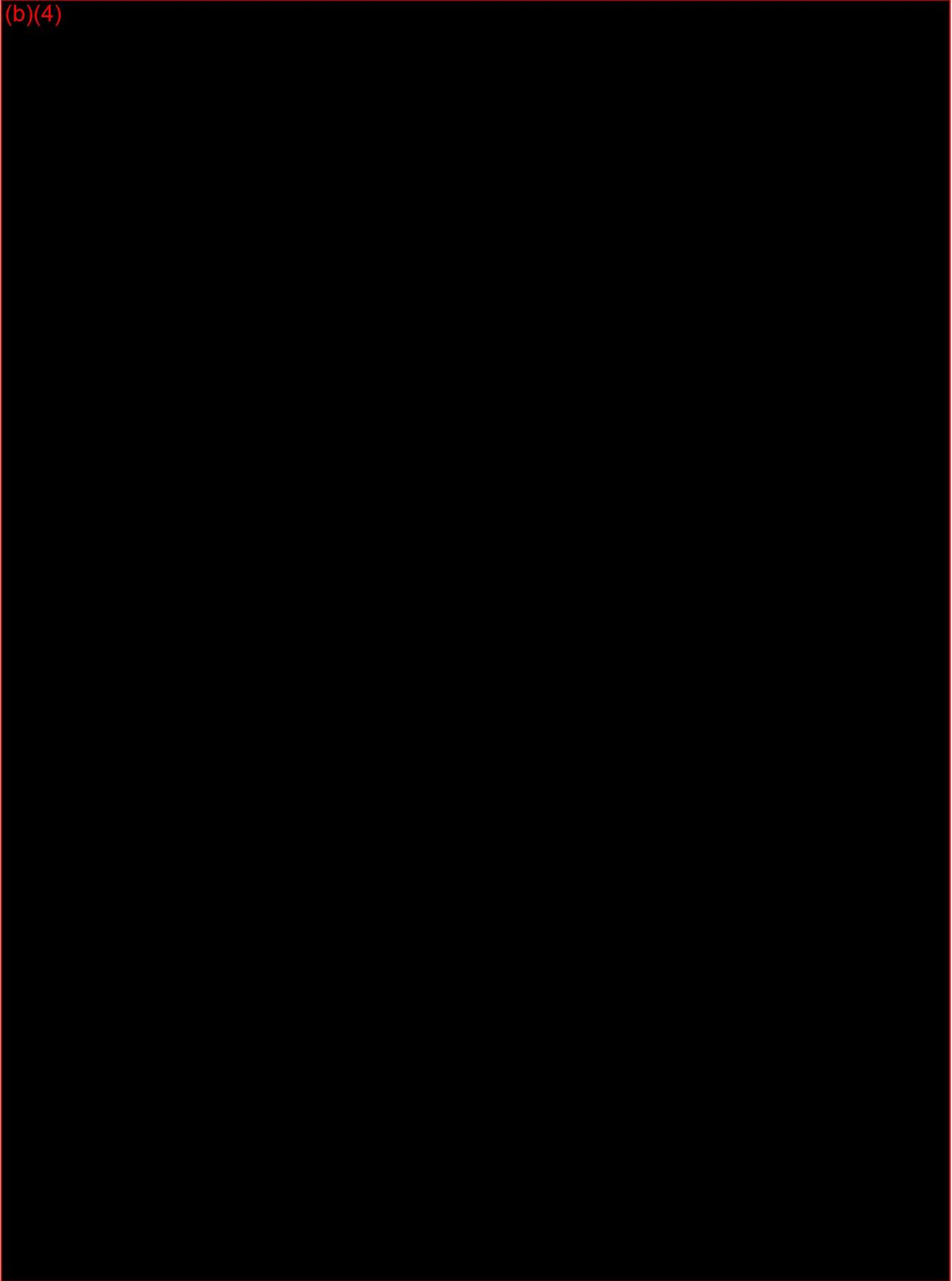
(b)(4)



(b)(4)



(b)(4)



(b)(4)



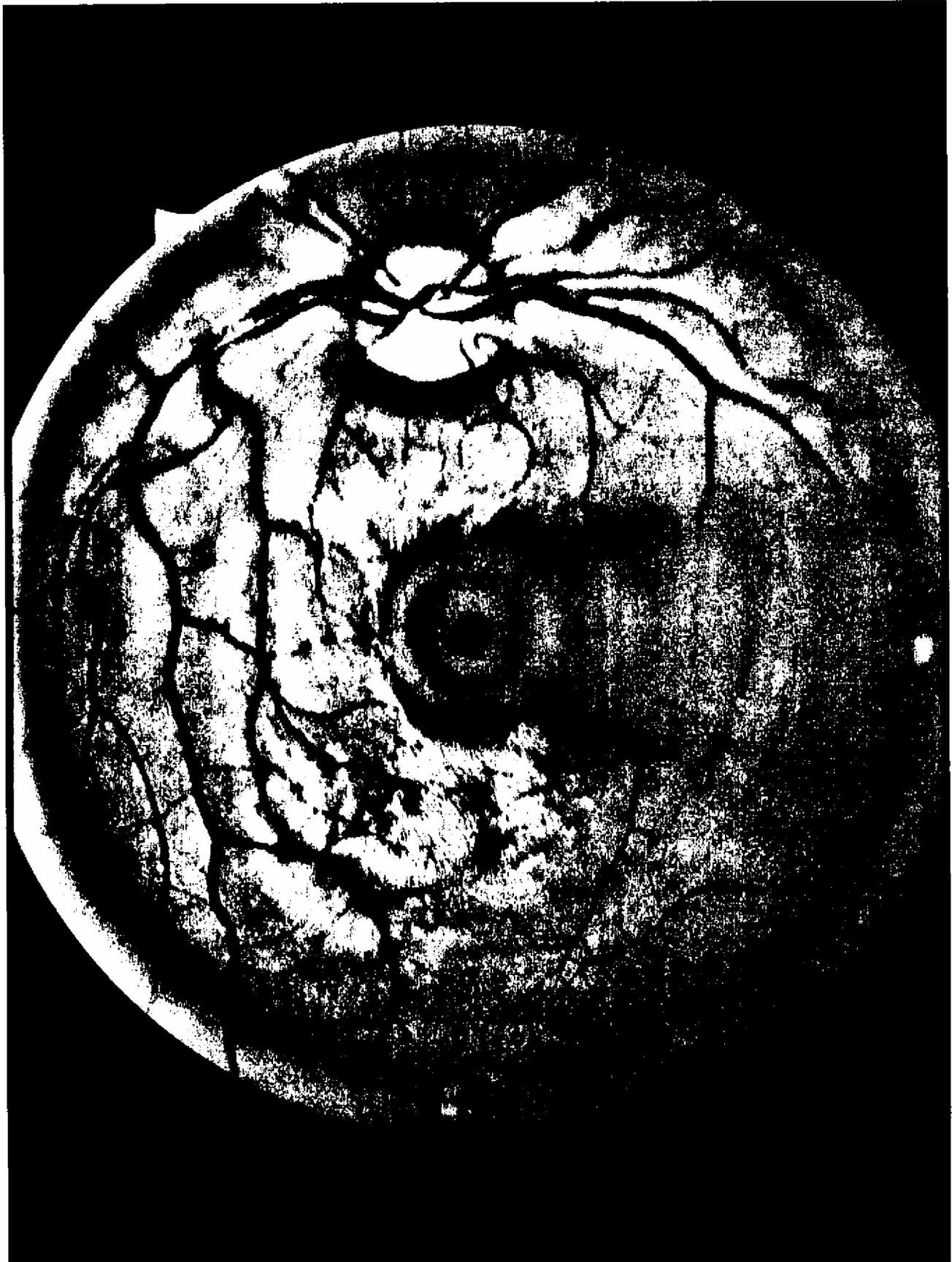
**Appendix 7**  
**Worst Case Images**

### **Worst-case images**

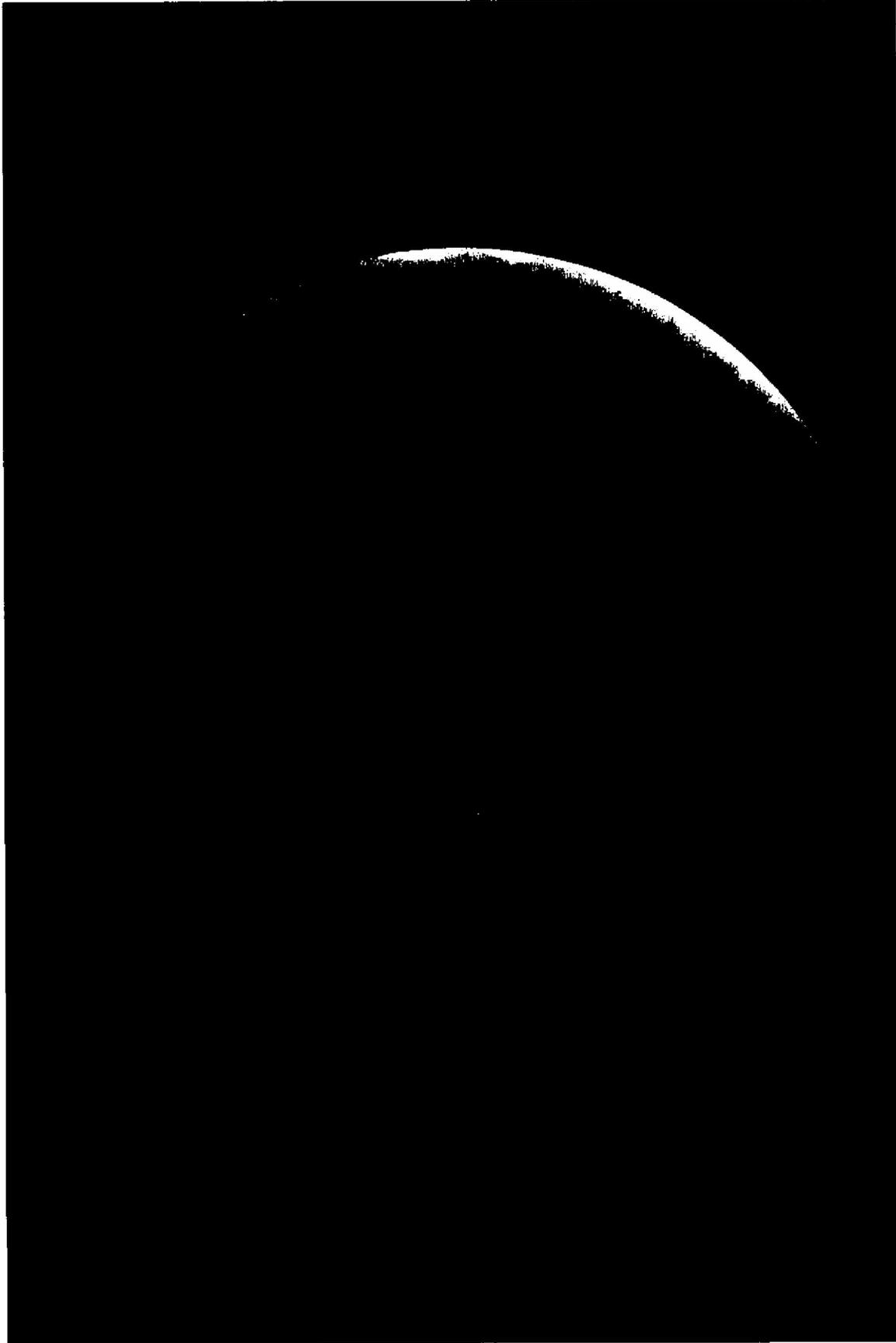
Many factors can deteriorate image quality: high and low illumination, reflection, eye blinking for example. The following images constitute a review of the worst images processed by CARA and their related enhanced image.



*Image 1: Dark and shadowed image*



*Image 2: Enhancement of image 1*



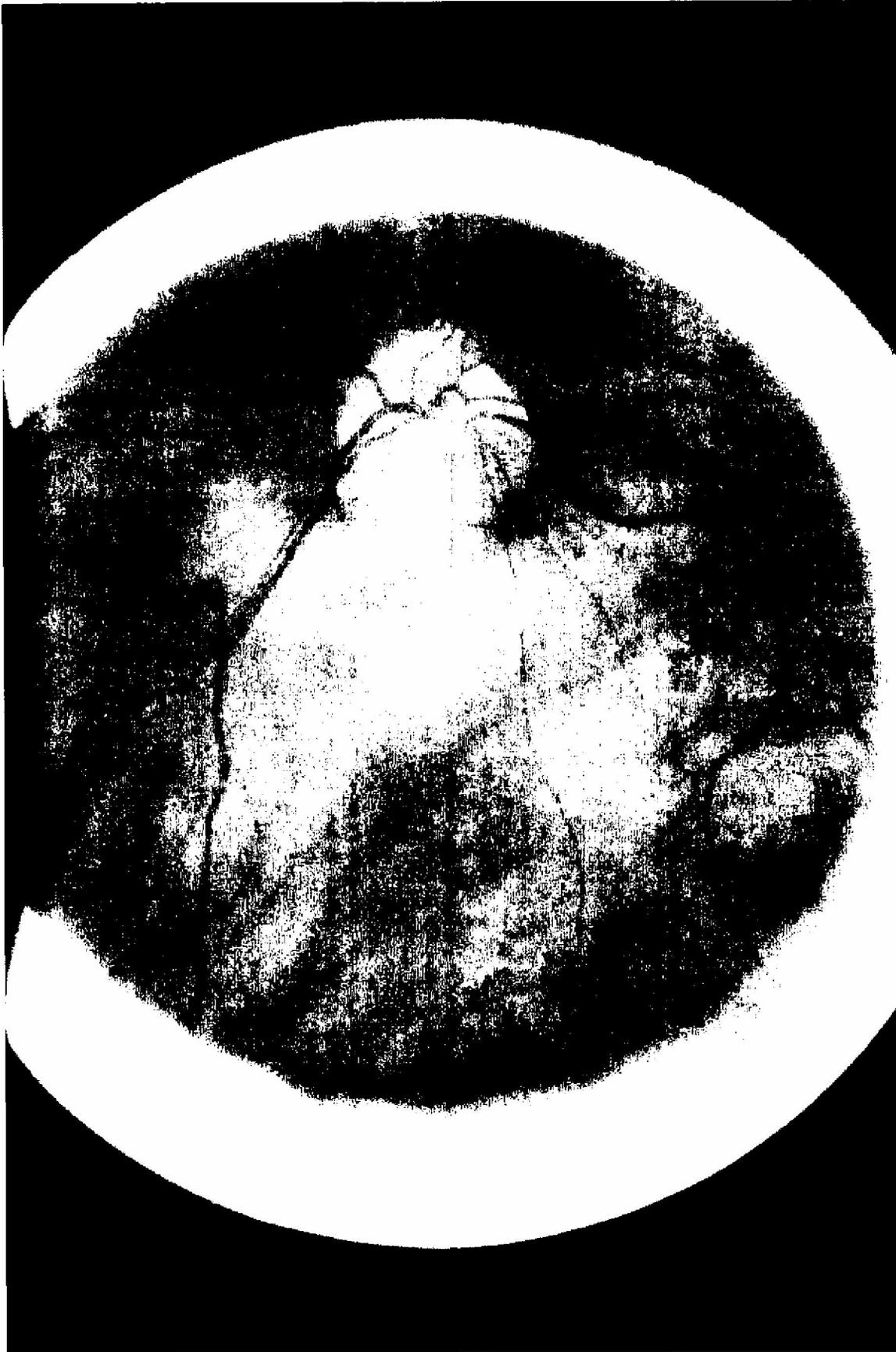
47

*Image 3: Dark image with peripheral flush halo*

73



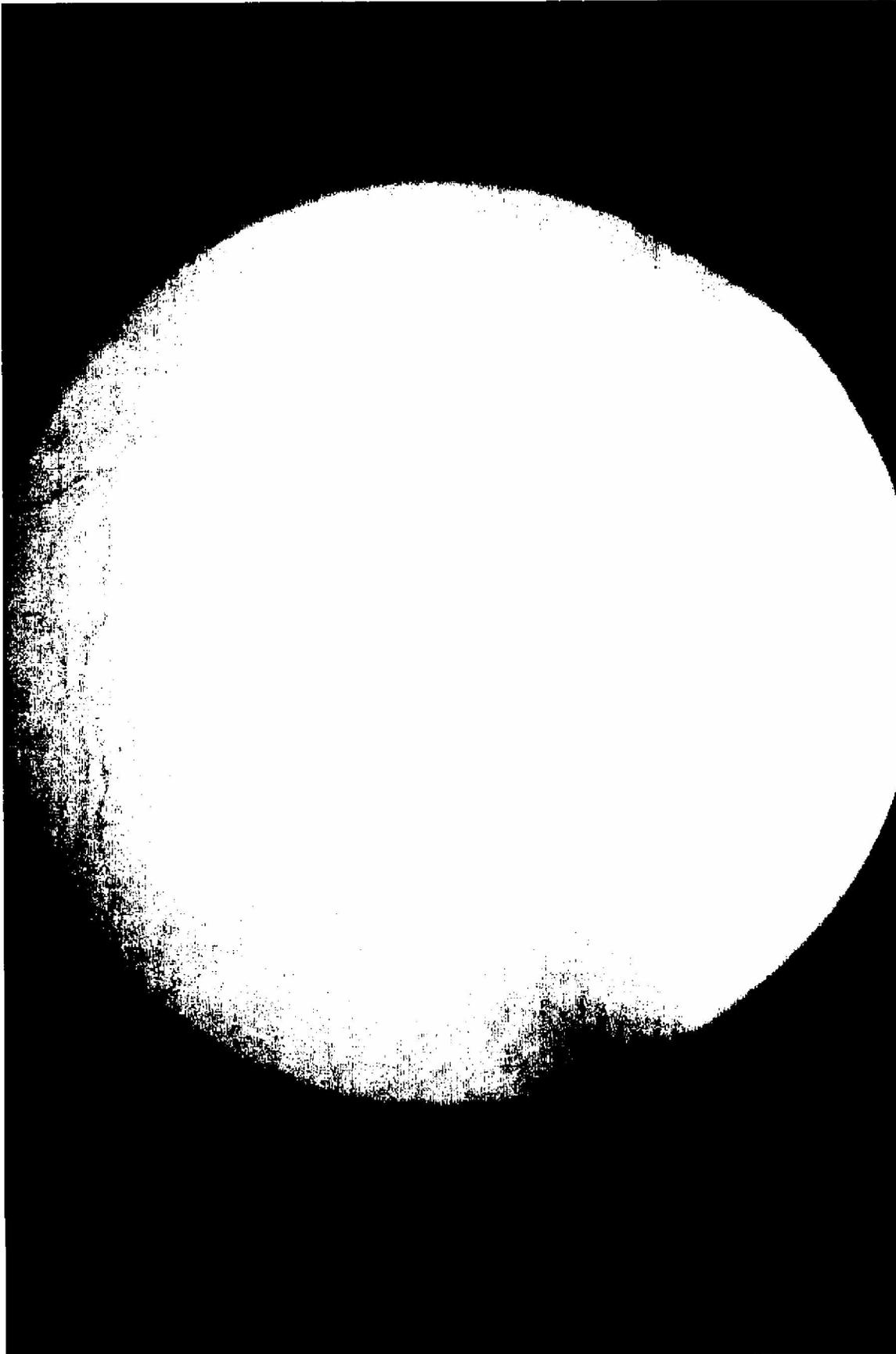
*Image 1: Enhancement of image 3*



*Image 5: Image with huge peripheral dust halo and eyelashes prints*



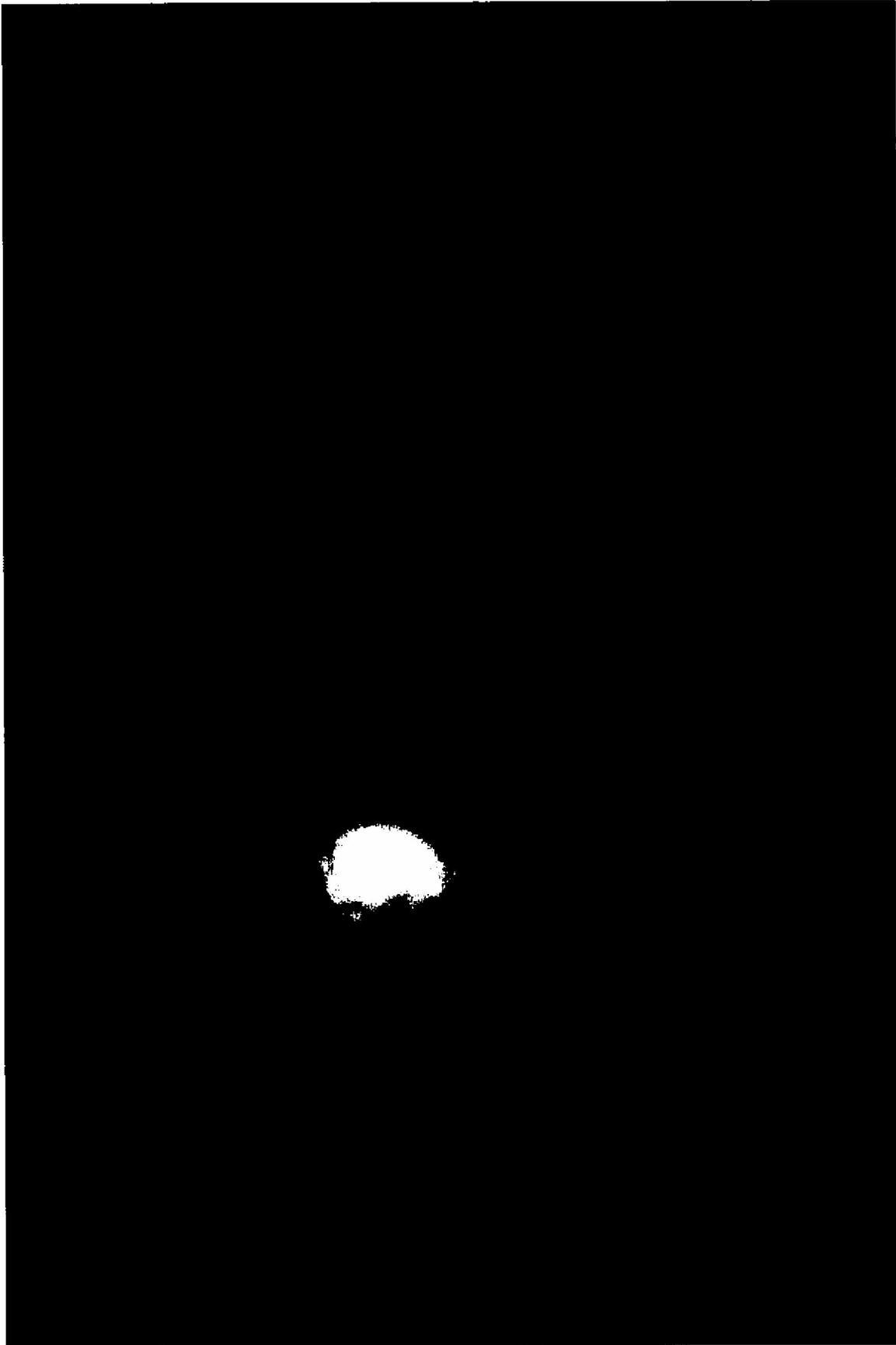
*Image 6: Enhancement of image 5*



*Image 7: Blurred an hazed image with eyelashes prints*



*Image 8: Enhancement of image 7*



*Image 9: Dark images with artifacts due to dust on lens*

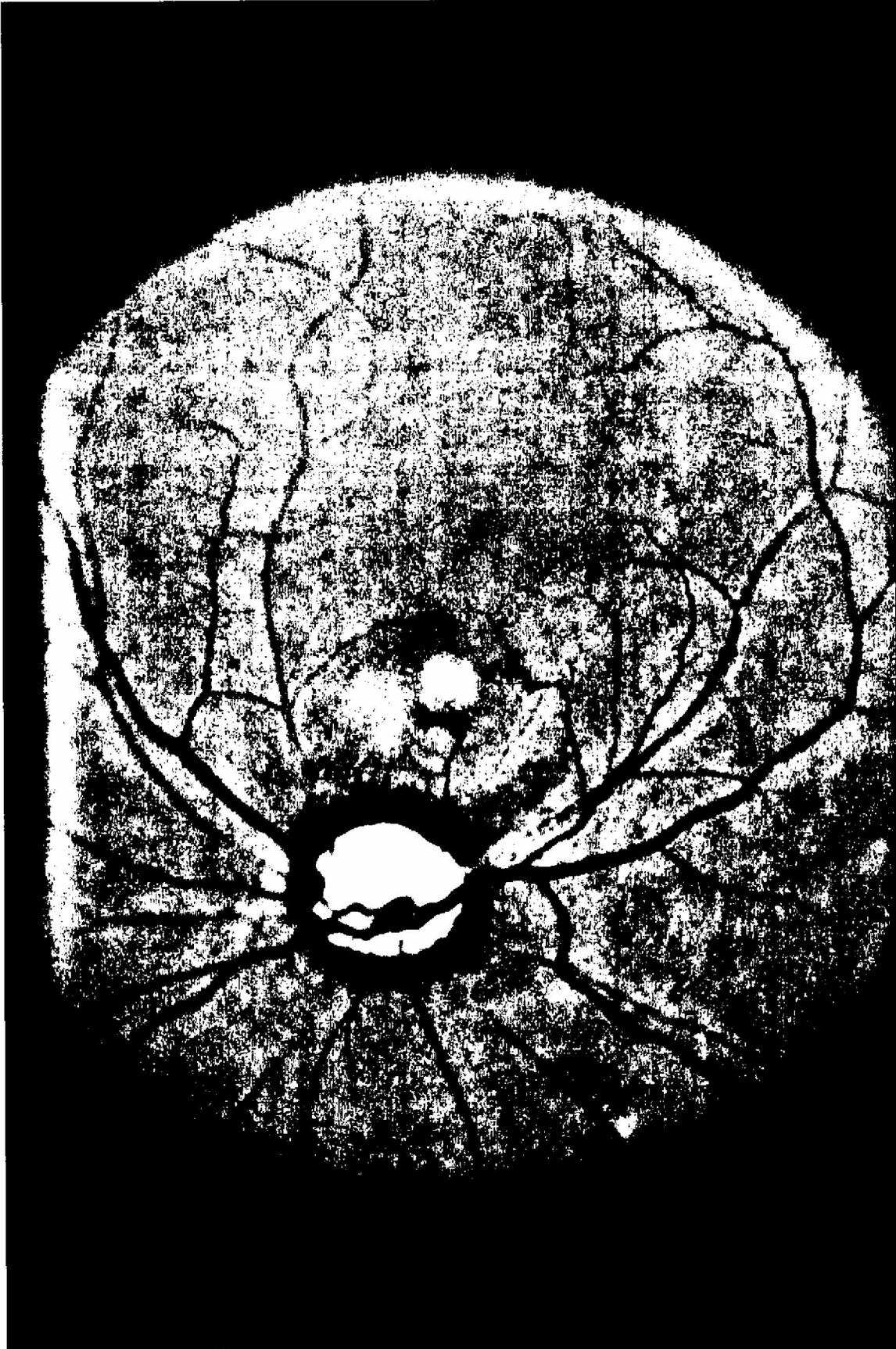


Image 10: Enhancement of image 9



*Image 11: Image highly compressed with jpeg artifacts*

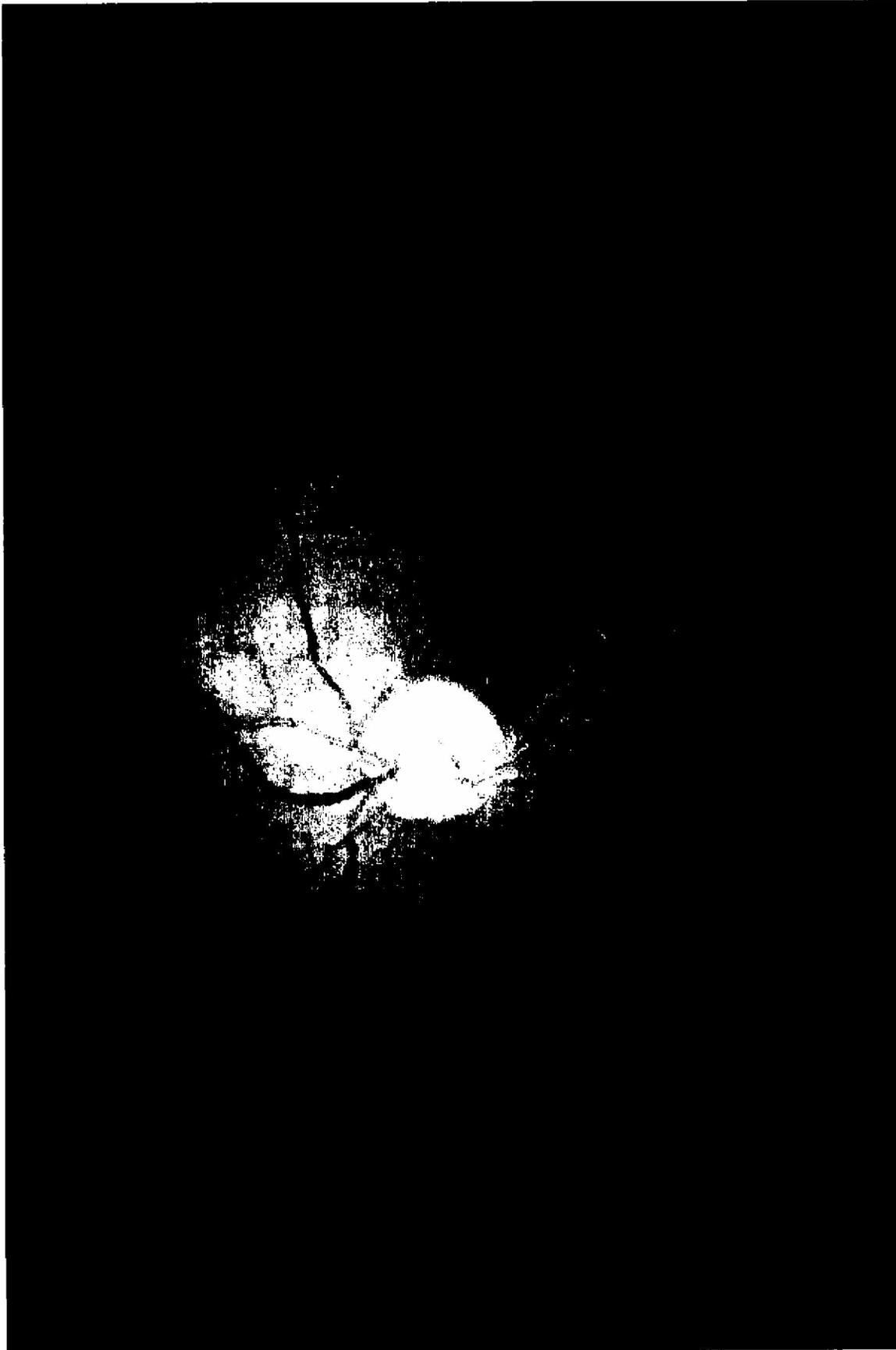


*Image 12: Enhancement of image 11*

**Appendix 8**  
**Images Generating Errors**

The following images generate error messages when they are processed for enhancement by CARA.

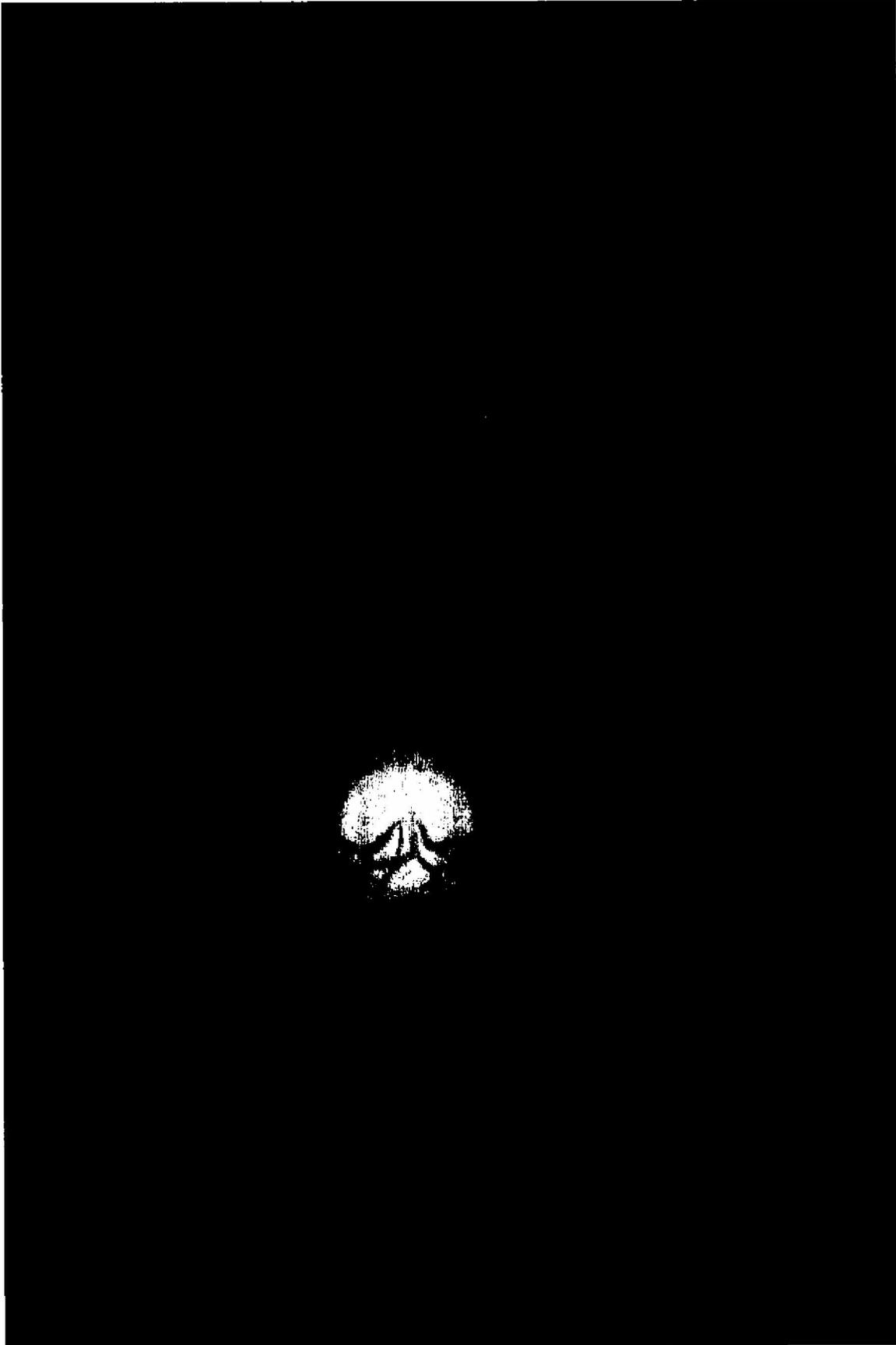
1. The first image, page 59, produces an enhanced image which histogram in blue channel is not wide enough to conform to CARA requirements.
2. In the second image page 60, the enhancement has a red channel histogram which shape is not adequate to CARA requirements.
3. In the third image page 61, the enhanced blue channel histogram is not centered as it should be to fulfill CARA requirements.
4. The fourth image, page 62, generates an error concerning the regularity of the interest area boundaries which has to be circular.
5. The fifth image, page 63, corner mask is not big enough to satisfy CARA requirements thus it leads to the related error.



*Enhanced histogram in blue channel is not wide enough*



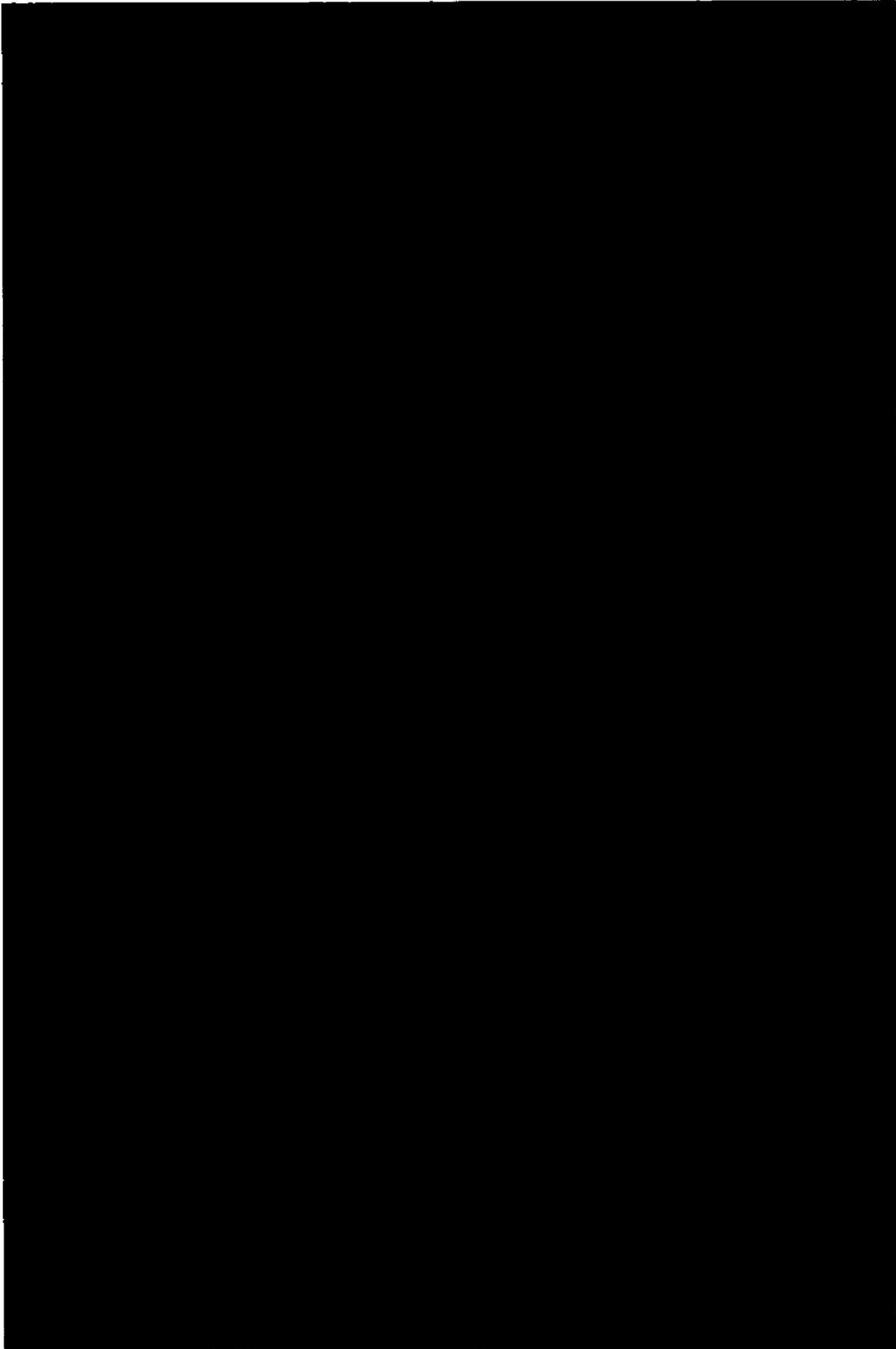
*Enhanced red channel histogram shape is not in acquisition with CARA requirements*



61

*Enhanced blue channel histogram is not centered*

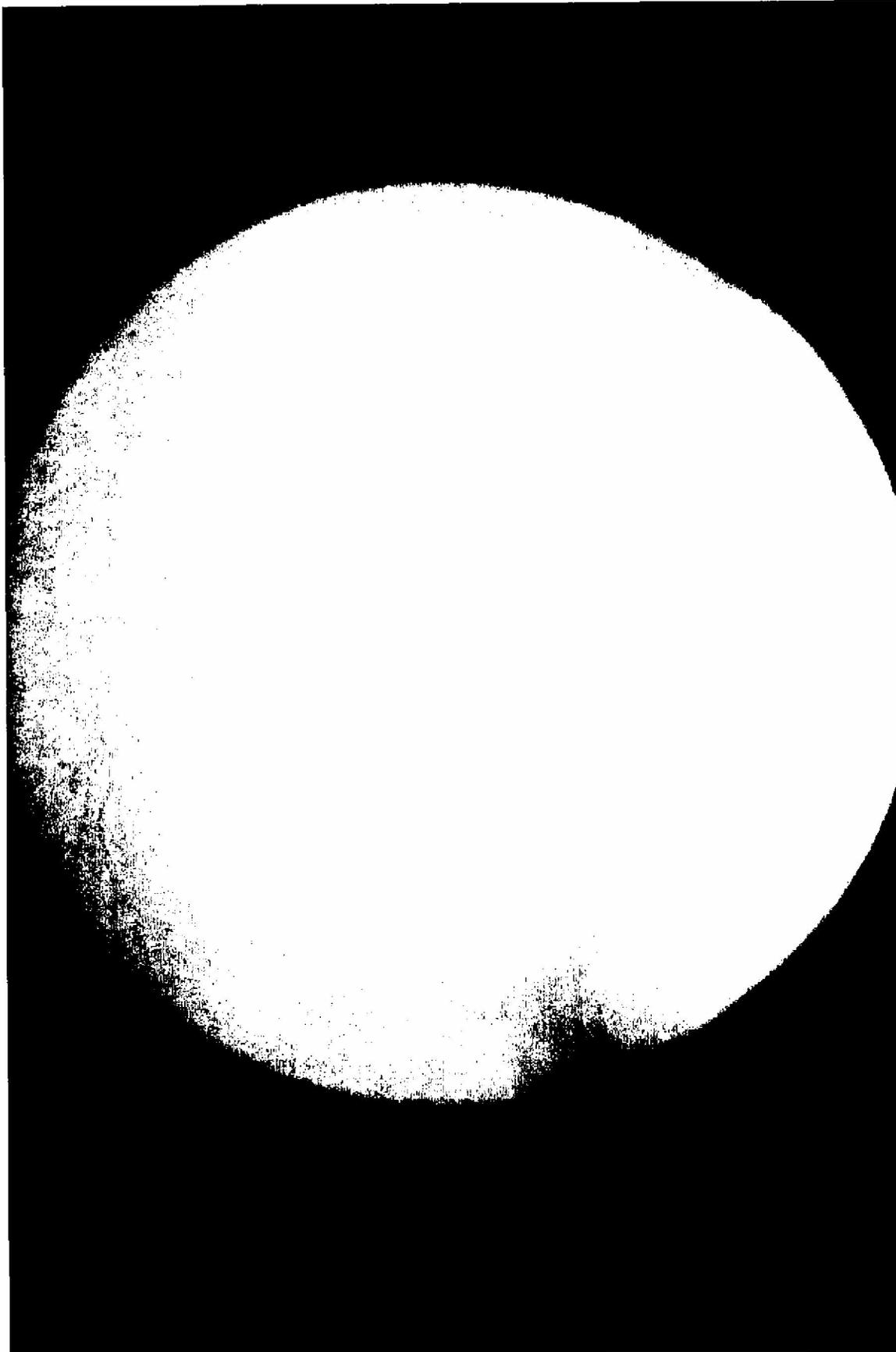
87



62

*Shape mask has a non circular contour*

88



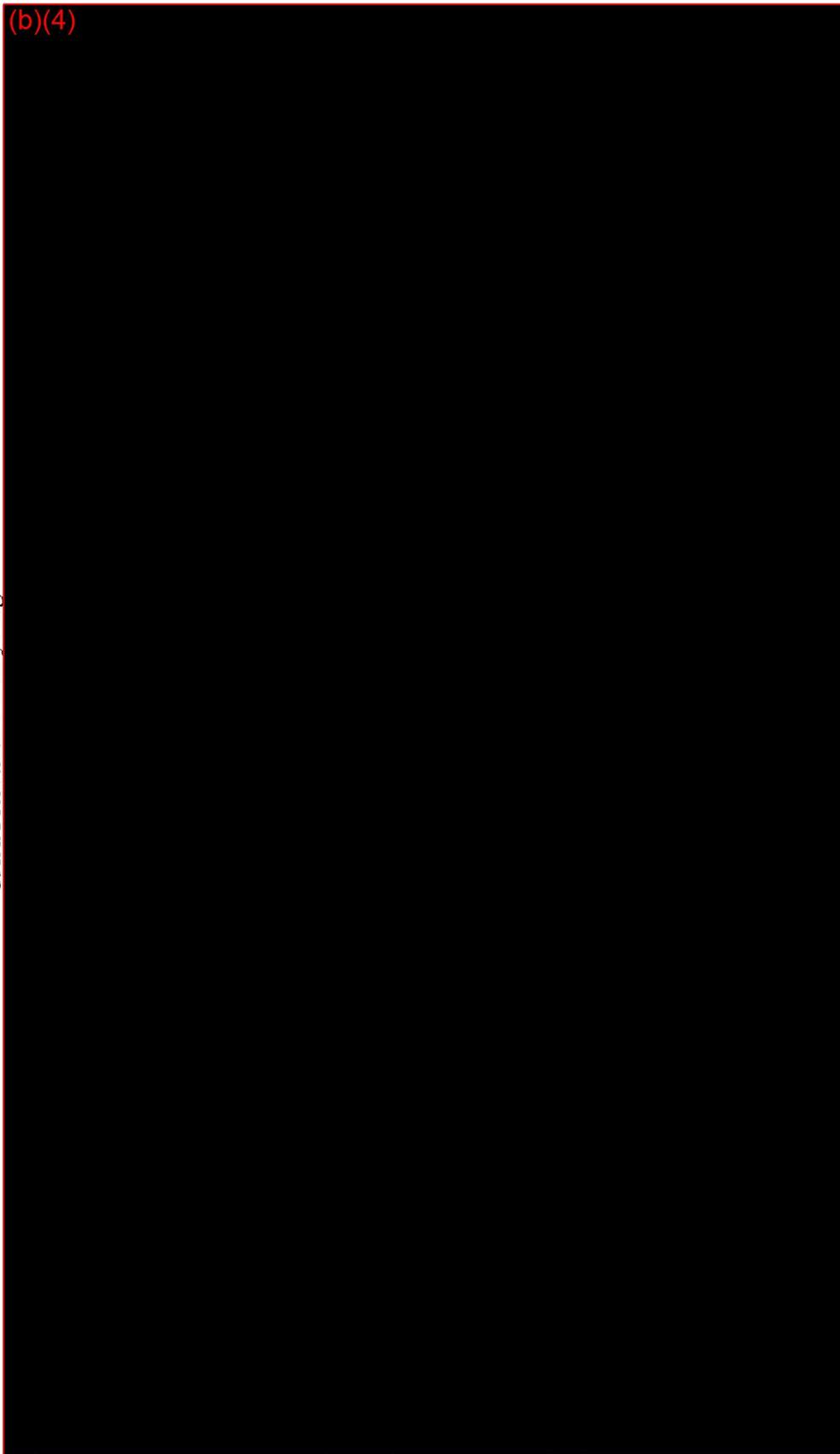
63

*Shape mask volume is too small*

89

**Appendix 9**  
**The revision Level History**

CARA Revision History Log



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**Appendix 10**

**The Changes in the numerical algorithms**









































































































































































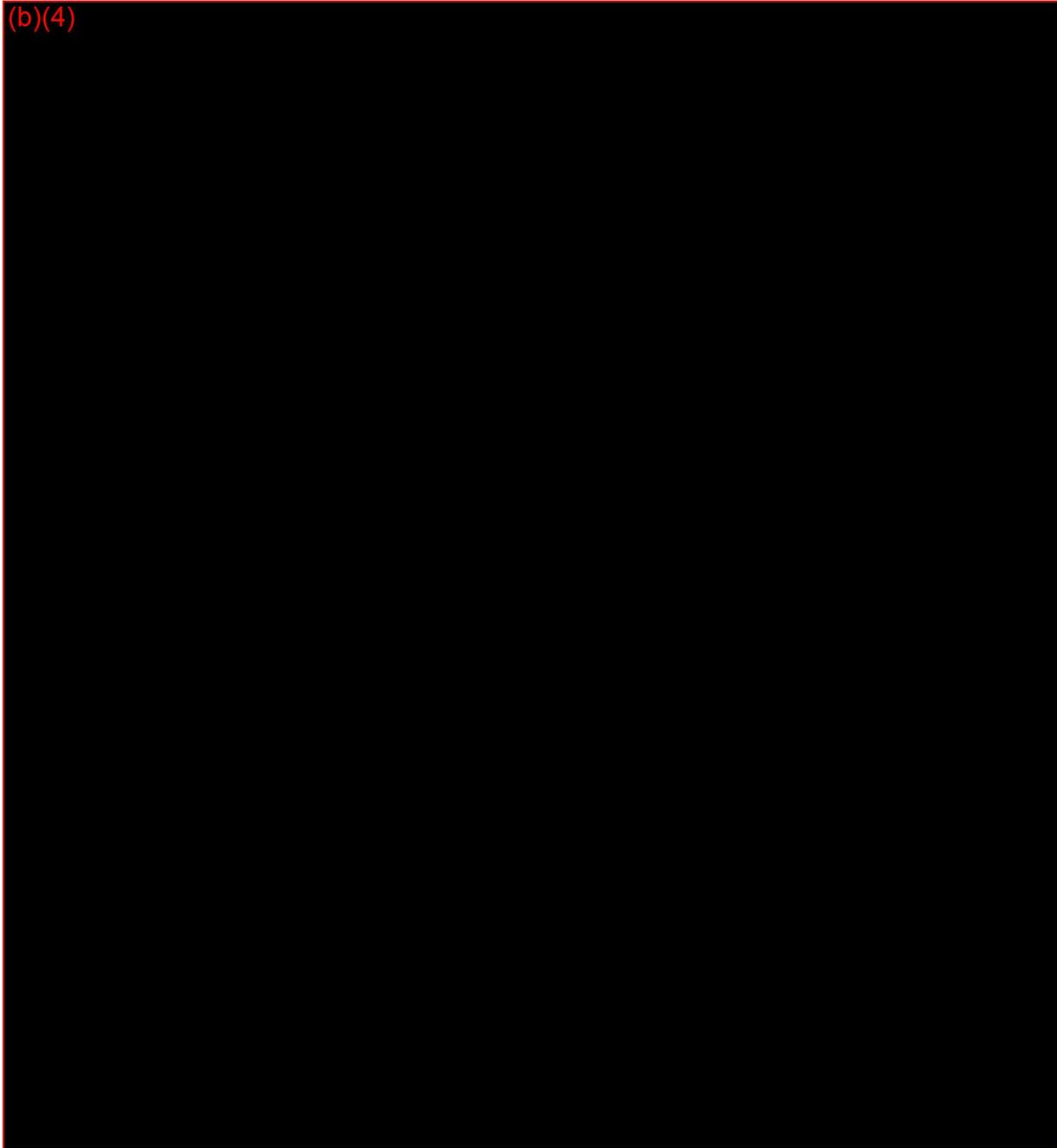


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**DIAGNOS**

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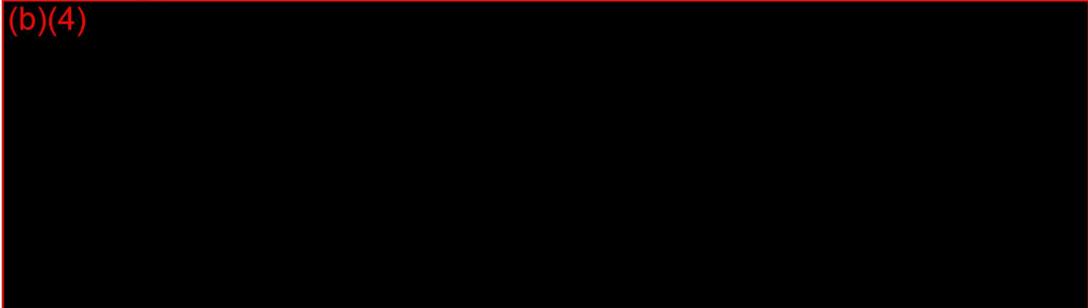
**Summary**

(b)(4)

A large black rectangular redaction box covers the entire content of the Summary section.

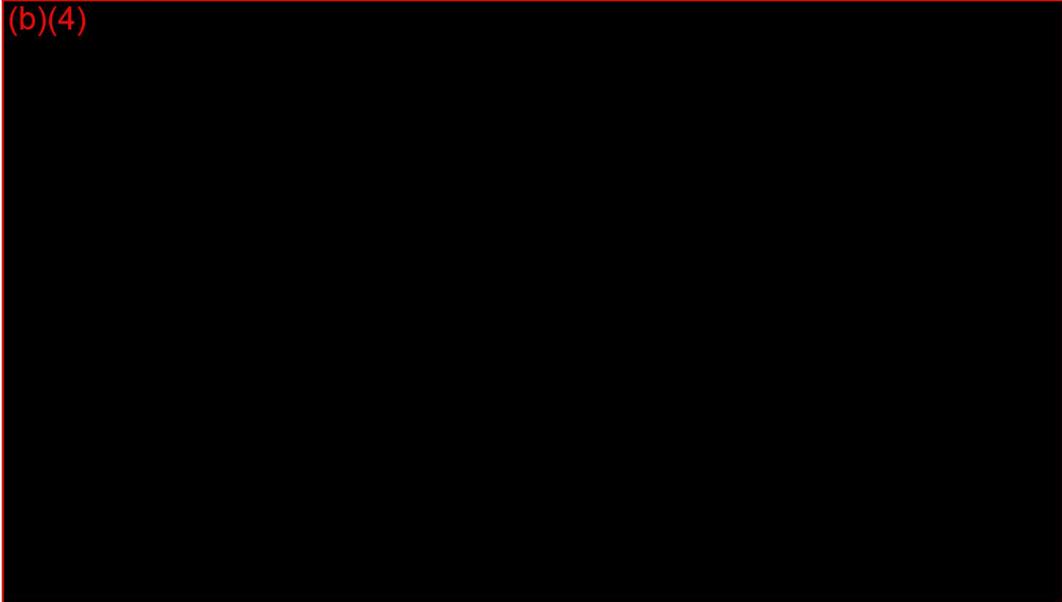
**Testing process**

(b)(4)

A large black rectangular redaction box covers the entire content of the Testing process section.

**Results**

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A large black rectangular redaction box covers the entire content of the Results section.

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**DIAGNOS**

**Conclusion**

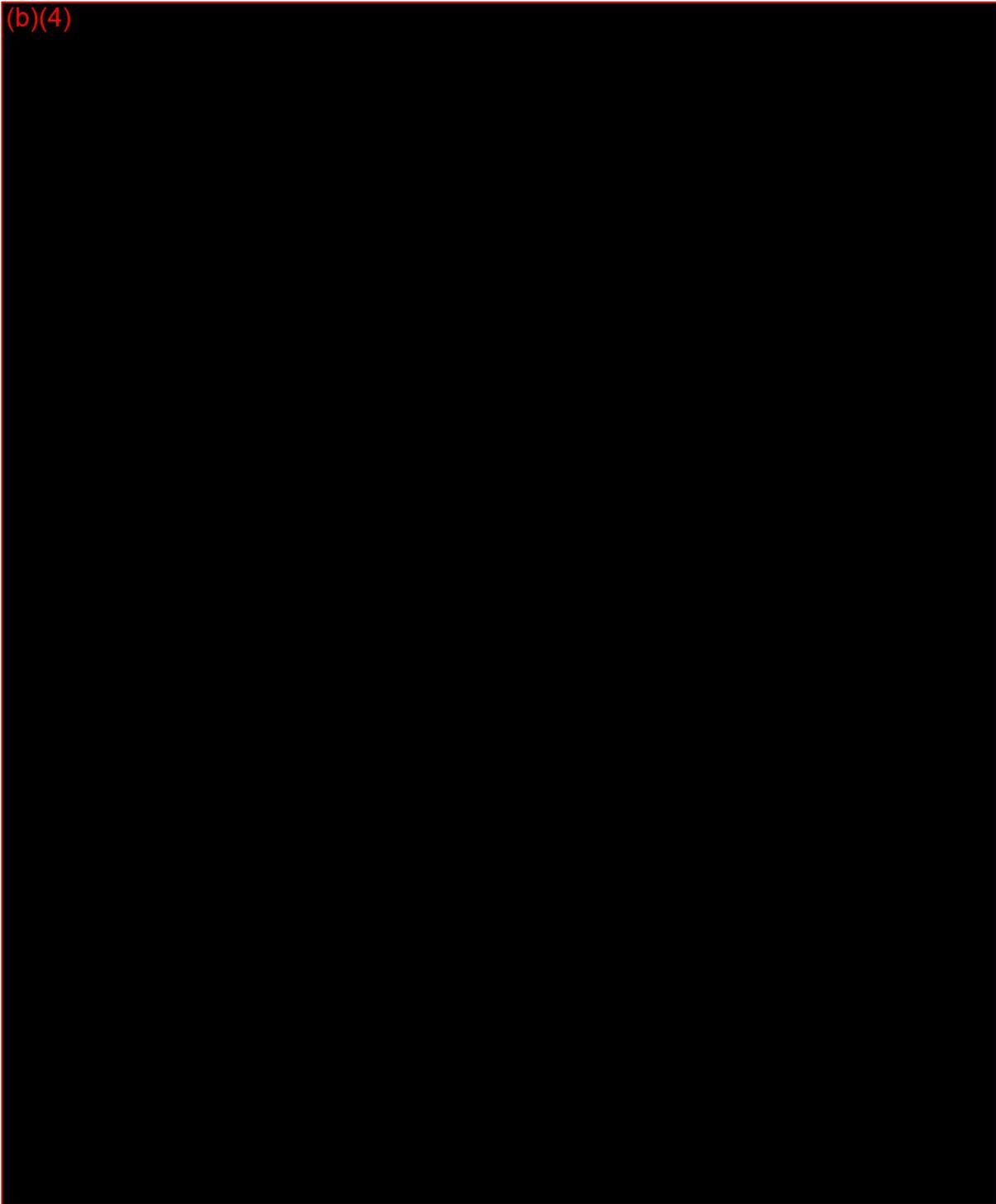
(b)(4)



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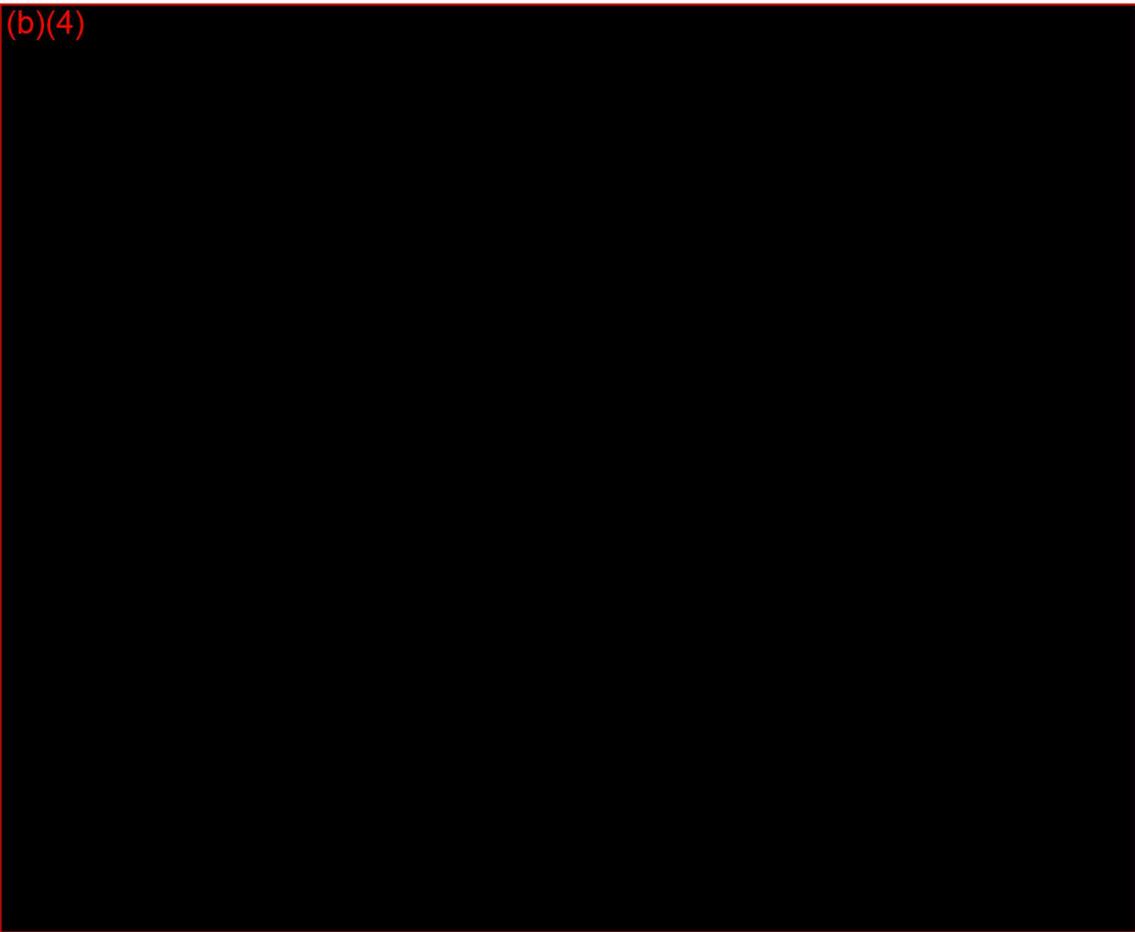
(b)(4)



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2009-10-09, 16:24:00



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