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U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(acheng)
FOLDER:	K111346 - 635 pages
COMPANY:	CALGARY SCIENTIFIC, INC. (CALGSCIE)
PRODUCT:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL (LLZ)
SUMMARY:	Product: RESOLUTIONMD MOBILE MODEL RMB-MOB-2X
DATE REQUESTED:	May 17, 2012
DATE PRINTED:	May 17, 2012
Note:	Printed

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

Mr. Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific, Inc.
1210 20th Avenue SE, Suite 208
Calgery, AB T2G 1MB
CANADA

SEP - 9 2011

Re: K111346
Trade/Device Name: ResolutionMD™ Mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2011
Received: August 1, 2011

Dear Mr. Peterson:

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

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use Statement

Applicant: Calgary Scientific, Inc., Suite 208 – 1210 20th Ave. SE, Calgary, Alberta, CANADA T2G 1M8

510(k) Number: ~~K093682~~ K111346

Device Name: ResolutionMD™ Mobile

Indications for Use:

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

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)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111346

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mr. Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific, Inc.
1210 20th Avenue SE, Suite 208
Calgery, AB T2G 1MB
CANADA

SEP - 9 2011

Re: K111346
Trade/Device Name: ResolutionMD™ Mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2011
Received: August 1, 2011

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Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use Statement

Applicant: Calgary Scientific, Inc., Suite 208 – 1210 20th Ave. SE, Calgary, Alberta, CANADA T2G 1M8

510(k) Number: ~~K093682~~ K111346

Device Name: ResolutionMD™ Mobile

Indications for Use:

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The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

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)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111346

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

August 02, 2011

CALGARY SCIENTIFIC, INC.
SUITE 208, 1210 20TH AVENUE SE
CALGARY, ALBERTA
CANADA T2G 1M8
ATTN: KYLE PETERSON

510k Number: K111346

Product: RESOLUTIONMD MOBILE MODEL

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. Pleaseremember 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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific, Inc.
Siute 208, 1210-20th Avenue SE
Calgary, Alberta, T2G 1M8
CANADA

JUN 30 2011

Re: K111346
Trade Name: ResolutionMD™ Mobile
Dated: May 12, 2011
Received: May 13, 2011

Dear Mr. Peterson:

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. To complete the review of your submission, we require the following information:

1. Parts of the submission include specific statements related to the use of the device in emergency situations and for specific conditions (e.g., Section 12, page 16; Section 16.2.5, pages 32-33). As has been noted previously on multiple occasions, FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims related to the use of the device for emergency situations or specific disease conditions, such as stroke. FDA believes that a general indications for use statement is most appropriate for this device based on the information provided. Please confirm that you will not market your device for these or other specific indications.

2. There are concerns with the conclusions that are being drawn from the study in Appendix 16.9.4. As noted on numerous occasions, the purpose of the study was not to compare the resulting primary or secondary diagnosis. FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims that radiologists will be as accurate on the mobile device as on a workstation, or will reach the same diagnosis as on a workstation. The performance study was intended to support that the device offers sufficient image quality for a diagnosis (or image review) on CT and MR under specific lighting conditions when there is no access to a workstation. Much more rigorous studies would be necessary to evaluate the diagnostic effectiveness of using a mobile device compared with a workstation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3. The results from Appendix 16.9.4 suggest that radiologists may have some difficulty using the device under some conditions. Note the comments from Dr. Koles, "Both [iPhone and iPad] were far better in the dark... I'd certainly be reading in the dark". In addition, Dr. Pattison stated, "Subtle findings were better appreciated in the dark on the mobile devices and were best appreciated on the PACS workstation." Please revise the label to reflect the preference for clinicians to review the images in a dark environment.

4. The "Bright" conditions were in the range of 209-220 lux. In the TG18 report, 220 lux was considered as "hospital clinical viewing station," which is much dimmer than regular office lighting. The setting of the ambient luminance (220 and 1.5 lux) may not represent common viewing conditions for mobile display users. The labeling should contain specific language to indicate the limits on the ambient illumination levels in which this product could be used.

5. Page 3 and 12 of the Mobile Device PACS Study (Appendix 16.9.4) indicates that all 12 reviewed cases were neuro cases. Page 5 seems to contradict this. Please clarify this discrepancy.

6. The software documentation suggests that the device is intended to have persistent on-screen indication of the degree of source image compression. It is not clear if this feature has been implemented for the 2D or 3D images. In Appendix 16.11, Item 925 of the list of Unresolved Anomalies indicates that compression information is missing. The User Guide did not contain a description of this indicator. Please clarify if this feature has been implemented for the 2D/3D images and provide the software testing and labeling information.

7. The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss (compression ratio) was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, page 21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

8. The iPad image on page 12 of the user guide lists images from modalities that are not covered by the Indications for Use. Please revise the User Guide to only show modalities that appear in the Indications for Use statement.

9. As required by 21 CFR 801.109(b)(1), please revise your User's Manual to include the Federal prescription statement "Caution: Federal law restricts this device to sale by or on the order of a physician" and provide the revised pages for FDA review.

10. Most of the tests under the "Ambient Lighting User Assessment" in Appendix 16.9.1 were listed as "nd" (not done). Appendix 16.9.2 did not appear to contain any tests related to the ambient lighting user assessment. Please clarify whether the functionality to evaluate the ambient lighting has been implemented. Please provide the software test results that show this feature has been successfully implemented.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11. FDA has comments on the following Unresolved Anomalies (Appendix 16.11).

    a. Item 892 indicates that image corners are rounded on the iPad app unintentionally. Please provide more details on the cause for this anomalies and the potential impact on the safety and effectiveness of the device.

    b. Item 928 indicates that FDA concerns about the User Guide have not been addressed.

    c. Item 919, "As an end-user, I want to be informed when a data type that is displayed is not officially supported so that I can take that into consideration when rendering a medical decision". FDA would like to see this feature incorporated before release.

    d. Item 929, "As an OEM provider, I want to have an extensively tested FDA-approved product..." As previously noted, FDA does not "approve" devices under the 510(k) program; they are only "cleared". Please review 21 CFR 807.97 (Misbranding by reference to premarket notification). Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

12. Please provide documentation for off-the-shelf software used in your device following the "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices".
    http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.htm

13. FDA has comments on the following aspects of the Display Quality Test Reports (Appendix 16.9.3.1, 16.9.3.2, and 16.9.3.3)

    a. The DICOM GSDF measurements appear to have been calculated using ΔL/L; the correct formula is ΔL/average(L)/ΔJND, which could impact the conclusions related to the GSDF measurement on page 9 of Appendix 16.9.3.

    b. The original TG18 test patterns are in 12-bit depth and size of 1k*1k pixels, which do not fit the iPhone4 or iPad screens. In the test reports, the devices were tested with "customized display test patterns," which was not explained. Please explain any difference in the TG18 test patterns, bench test patterns, and those used by the software application.

    c. In the luminance non-uniformity test and the chromaticity variation test, the size of the measured areas was not reported. Because of the smaller display size of iPhone4/iPad, the measurement method needs to be adjusted accordingly when assessing uniformity or the other spatial properties. Please report the measurement method.

    d. In the chromaticity variation test, the test pattern was not specified.

    e. Figure 6 was mislabeled.

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14. Compared with a Windows/Intel-x86-based notebook, which was used in the predicate, the iPhone4/iPad, as an embedded system, is slower in terms of computation and communication speed. In the current submission, such latency-related measurement was not reported. FDA believes that a general discussion of the time required to download images over different network types in the labeling would be useful to users.

15. The Substantial Equivalence Comparison Table (Section 12, page 23) states the client operating system can be the iPhone/iPad OS, other mobile device OS. Items 912 and 913 of the Unresolved Anomalies (Appendix 16.11) reference the Android OS. The submission did not contain any software or bench testing to support the use of the application on other mobile device OS. FDA believes that a new 510(k) submission would be necessary to support the migration of the device to a new operating system, such as the Android OS.

16. In Appendix 16.6, page 15, the following quoted paragraph is inconsistent with the intended use -- "ResolutionMD Mobile was designed to function on smartphone devices that have native hardware providing Wi-Fi and cellular network connectivity. Similarly, these smartphone devices utilize industry-best display technology such as LED or AMOLED LCDs and have large displays that occupy most of the devices' surface (most measuring 3.5" or larger)." Note that iPhone4 and iPad are neither LED nor AMOLED.

17. Please complete the Clinical Trials Form (FDA 3674).
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

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)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

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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 additional information 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/cdrh/mdufma/guidance/1219.html.

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:

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

If you have any questions concerning the contents of the letter, please contact Robert Ochs, Ph.D. at (301) 796-6661. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 796-7100, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara, Ph.D.
Deputy Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K111346 – Calgary Scientific, Inc.

Final: kjh 6.28.2011

Division	Last Name	Date	HFZ #	Last Name	Date	HFZ #	Last Name	Date
DCRD	Ochs	6/28						
DRAD	O'Hara	6/30						

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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May 13, 2011

CALGARY SCIENTIFIC, INC.
SUITE 208, 1210 20TH AVENUE SE
CALGARY, ALBERTA
CANADA T2G 1M8
ATTN: KYLE PETERSON

510k Number: K111346

Received: 5/13/2011

Product: RESOLUTIONMD MOBILE MODEL RMB-

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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

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Calgary Scientific

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May 12, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (W066-G609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA CDRH DMC
MAY 13 2011
Received K2

Re: Attached traditional 510(k) premarket notification

Dear Sir or Madam:

We are submitting the attached traditional 510(k) notification for the ResolutionMD™ Mobile, a new software medical device, and request that you regard this submission as confidential in accordance with 21 CFR 807.95.

The ResolutionMD™ Mobile is a software based Picture Archiving and Communication (PACS) system that is regulated as a Class II device as described in 21 CFR 892.2050. It is intended for prescription use (21 CFR 801 Subpart D). The product code is LLZ under the Radiology Panel.

The ResolutionMD™ Mobile is substantially equivalent to the ResolutionMD™ 2.1 (K082693) which has the same LLZ product code as the ResolutionMD™ Mobile, and conforms to the voluntary DICOM 3.0 and JPEG standards.

Please address communications related to this submission to:

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Suite 208 – 1210 20th Ave. SE
Calgary, Alberta, CANADA T2G 1M8
Voice (403) 767-7945 Fax (403) 270-2771
Kyle.peterson@calgaryscientific.com

Our establishment registration number is 3006123366.

Yours truly,

Kyle Peterson
Director, Regulatory & Corporate Affairs

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resolution MD™ mobile

2.6 (USA Version)
User Guide

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RMDM26-UG215
Release Date: April 30, 2011

Copyright notice

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Calgary, AB T2G1M8
Phone: (403) 270-7159 Fax: (403) 270-2771

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This guide has been produced to assist in providing instruction for the ResolutionMD™ Mobile (ResMD Mobile) product. Every effort has been made to make the information in this guide as accurate as possible. The authors of this guide shall have neither liability nor responsibility to any person or entity with respect to any loss or damages in connection with or arising from the information contained in this guide.

Trademarks

ResolutionMD™ is a trademark of Calgary Scientific Inc. Any additional software products named in this document are claimed as trademarks or registered trademarks of their respective companies.

Regulatory Status

Product: ResolutionMD Mobile
Version: 2.6

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Preface

Intended Use Statement

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0 compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

Intended Audience

There are two profiles for intended users of the ResolutionMD 2.6 solution:

1. Referring physicians who refer their patients to the institution or organization controlling the ResolutionMD solution for imaging studies. Referring physicians wish to review images in addition to reviewing the radiologists' final report of findings to enable them to confirm their treatment plans and communicate with the patient.

2. Diagnostic Imaging specialists and radiologists at the institution or organization controlling the ResolutionMD solution. ResolutionMD 2.6 Mobile must be used in only the context of the approved Indications for Use outlined in this Mobile User Guide.

Training / User Familiarization

It is strongly recommended that user training be conducted by each institution implementing the device. This training should include:

- Institutional on-call process for reviews to be performed using the mobile technology.
- Log-in protocols and security for mobile access to the ResolutionMD server.
- Operation of the software and practice on various uses cases including use of the mobile device under various lighting conditions
- Review of labeling including Intended Use, directions for use, warnings and precautions.

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- Criteria for activation of fall-back procedures should mobile access to imaging data not be available or fail during attempts to access it.
- How to access user and product support through their institution.
- Review of criteria and procedures for reporting adverse events to Calgary Scientific.

Warnings

ResolutionMD Mobile should only be used by professionals qualified to review the pathology relevant to the diagnosis.

Precautions

Lighting - ResolutionMD Mobile should not be used in outdoor lighting or other high ambient light conditions. Users should familiarize themselves with the viewing characteristics of the device under various lighting conditions prior to actual use.

Software features – Users must ensure that the software features available on the device are appropriate for the diagnostic requirement prior to actual use.

Screen size and resolution - Users must ensure that the screen size and resolution of the device are appropriate for the diagnostic requirement prior to actual use.

Brightness settings – The user should be aware that other applications can change the screen brightness setting and ensure the recommended settings are in place prior to each use. Reading sessions must not be interrupted to ensure no changes to the screen brightness are made by other applications.

Battery life – The user should be aware of expected battery life of the mobile device under wireless usage conditions relative to the anticipated duration of usage of the ResolutionMD Mobile application and ensure that the mobile device is adequately charged.

Considerations Prior to Use

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations.

The user should be aware of the limitations in the accuracy and correctness of the output data displayed on the screen, printed, or exported from ResMD Mobile. The quality of the data is dependent on the correctness of the input data, the user's interaction with the data, the quality, characteristics, and settings of the display device or printer, the amount of ambient light in the vicinity and the necessity to interpolate the data for display purposes. For

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example, measurement values in ResMD Mobile are dependent on the calibration information provided by the modality in the DICOM header.

While ResMD Mobile has been tested extensively, it is impossible to completely test any piece of software, and errors may remain in the software. It is possible that an error could manifest as an incorrect measurement or image. Users must be aware of the potential for errors.

Device Settings & Condition

The user should ensure that the automatic brightness feature is turned OFF and the brightness of the display set to maximum. The ambient lighting environment should be assessed such that illumination is equivalent to radiology reading rooms to ensure that image quality is maintained.

The user should ensure that the screen is clean and free from any smudges or marks prior to interpreting a medical image.

Supported Devices

The following devices running iOS 3.2 or higher are tested and approved for use for ResMD Mobile:

- iPhone 4
- iPad

Installing ResMD Mobile

Installation Requirements

1. A properly configured ResolutionMD Server is required.
2. The user requires an account with Apple's App Store.
3. The user will need to have an authorized account on the ResolutionMD Server or be a valid user on the database server.
4. The user requires the IP address or hostname and the port number to connect to the ResolutionMD server.
5. The user needs to know if SSL is being used. If yes, they would need to enable a secure connection option on the mobile devices.
6. The mobile devices require network connectivity to the Internet in order to download ResolutionMD Moblile.
7. The mobile devices will need to be authorized and authenticated on the WiFi network at the using site.

To install ResMD Mobile from the iPhone App Store

1. Tap the App Store icon.
2. Select **Search** from menu at bottom.
3. Enter "ResolutionMD" in the search bar.
4. Select ResMD Mobile from the results list.

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5. Tap **Free.**
6. Tap **Install.**
7. Enter iTunes account credentials if required.

To install ResMD Mobile from iTunes

1. Select **iTunes Store** from the source pane.
2. Enter "ResMD" in the search bar.
3. Select ResMD Mobile from the application results list.
4. Click **Free App.**
5. Enter iTunes account credentials if required.
6. Select your device in iTunes.
7. Click **Sync**.

To verify the installation

1. Ensure you can successfully connect to the ResolutionMD Server, either from the site WiFi network or from the Internet via SSL or VPN connection.
2. Ensure you can successfully authenticate against a user database system.
3. Ensure you can successfully query for studies.
4. Ensure you can successfully view thumbnails.
5. Ensure you are able to successfully open a study/series view the images.
6. Ensure you are able to successfully interact with the images.

Updating

Updates will appear in the App Store when they are available.

To update ResMD Mobile from the iPhone App Store

1. Tap the App Store icon.
2. Select **Updates** from the menu at the bottom of the screen.
3. Select ResMD Mobile from the list of updates.
4. Tap **Update.**
5. Enter your iTunes account credentials if required.

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Configuring ResMD Mobile

You can configure ResMD Mobile in iPhone Settings. The application appears in the list as ResMD.

Setting	Description
Version	Version number for the app.
Prompt for Server	Off by default. The app will access the default server when this setting is off. Enable this setting to be prompted for servers every time you launch the app.
Show Recent Studies	Off by default. For most cases, search is the recommended and more desirable method. Enable this setting to display a list of the most recent studies every time you launch the app.
# Days in Recent Studies	Sets the number of days of recent studies to display. This shows all results from midnight of the last day. E.g. 1d shows all results since midnight of the current day.
Advanced Settings	Settings intended for troubleshooting and support purposes only.

Configuring the Server

On first load, ResMD will prompt you to add a server.

Setting	Description
Server Name	User-selected "friendly" name
Address	Server address and port number
Secure Connection	Ask your system administrator if you will be using a secure connection

To see the server list, do one of the following:

- Enable **Prompt for Server** in iPhone or iPad Settings
- iPad Tap **Servers**
- iPhone Tap **Cancel**

From the server list, you can edit and add servers as well as set the default server. You can also access Help (Instructions, User Guide, and Indications for Use) from here.

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Prerequisites for Using

Ensure that your device and your environment are optimal for using ResMD Mobile.

Your Reading Environment

ResolutionMD Mobile should not be used in outdoor lighting or other high ambient light conditions. You should familiarize yourself with the viewing characteristics of the device under various lighting conditions prior to actual use. To ensure optimal viewing conditions, you must set the display brightness to the maximum value and disable any automatic brightness features on the viewing device. (See *Screen Brightness*) Be aware that other applications can change the screen brightness setting and you must ensure the recommended settings are in place prior to each use. You should also perform a light test to ensure that ambient light conditions are appropriate for use. (See *Ambient Light User Assessment*)

Your Device's Screen

- Your device's screen should be clean and free of dirt and fingerprints when reading.
- Image accuracy degrades with viewing angle, so view the screen within 30 degrees of perpendicular.
- To avoid specular reflections, take special care to move to a location without direct light sources such as windows, light boxes, bright walls, and overhead lighting. Examine the display in your device's sleep or off mode for visible reflections and reorient yourself or the display until they are not present.

Screen Brightness

Your iPhone or iPad's screen should be set to maximum brightness.

To set maximum brightness on your iPhone or iPad

1. Tap to open the **Settings** app.
2. Tap **Brightness**. (**Brightness & Wallpaper** on iPad)
3. Drag the brightness slider all the way to the right.
4. Toggle **Auto-Brightness** to **OFF**.

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Using the Search Interface

The search interface appears after you log in on iPhone and iPad (in landscape orientation).

Note	Tap **Search** to show the search interface on iPad in portrait orientation.

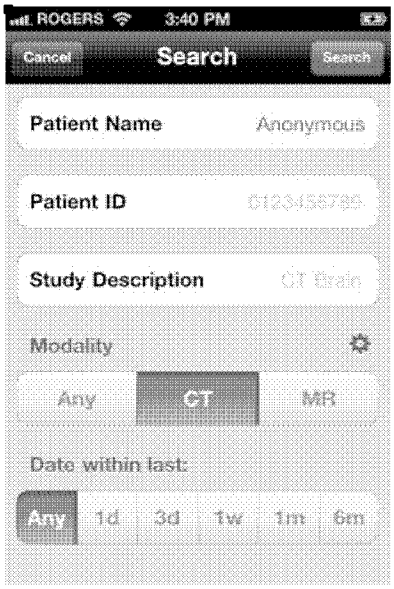

Figure 1: The iPhone Search Interface

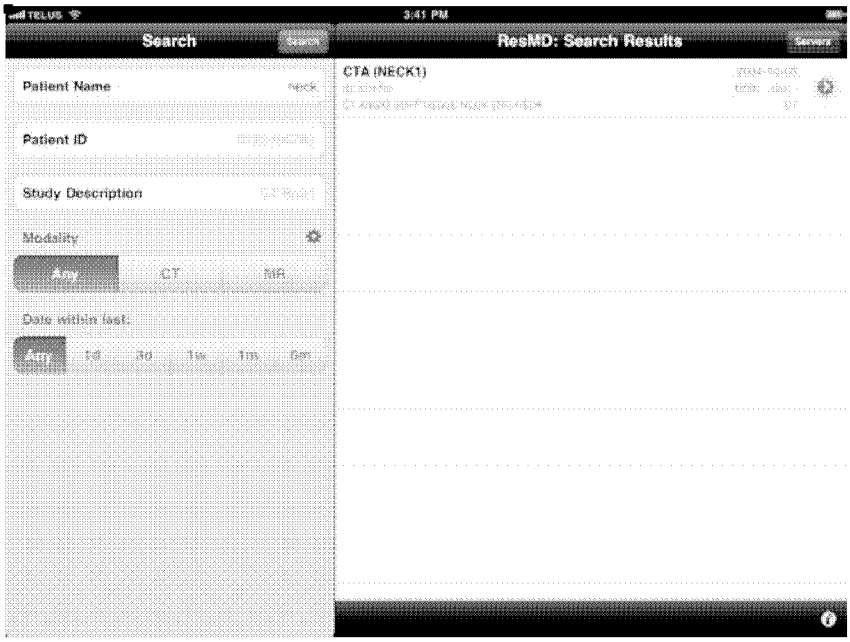

Figure 2: The iPad Search Interface

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To perform a search

1. Enter one or more search criteria.
2. Tap **Search**.

Note	"Date within last" shows all results from midnight of the last day. E.g. 1d shows all results since midnight of the current day.

Sorting Search Results

You can sort the results by your choice of name/ID/date/modality by tapping on their respective column headings.

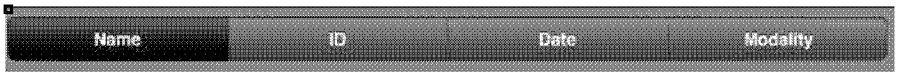

Figure 3: Search Results Column Headings

Loading a Study

To load a study

- **iPhone** Tap the desired study in the search results list. This will display the contents of the study.

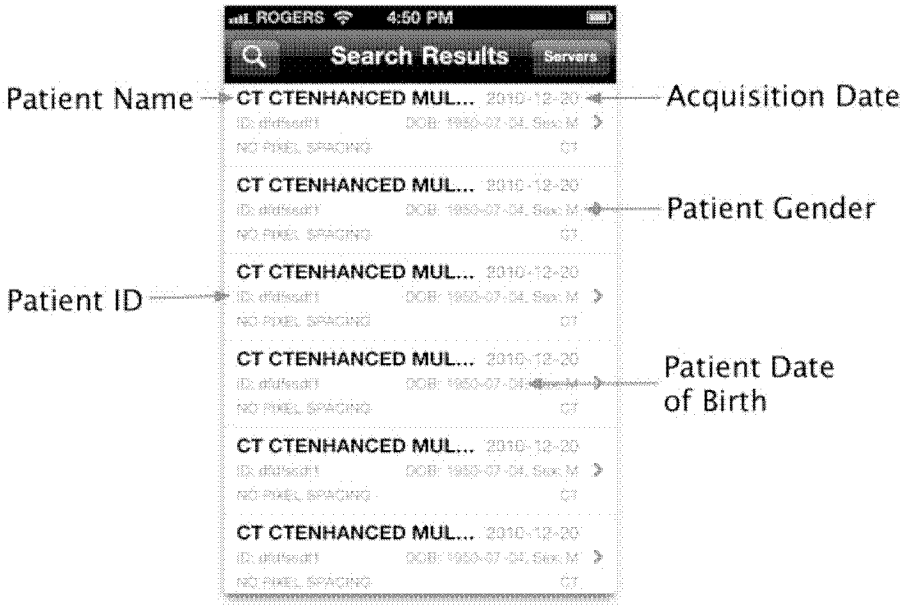

Figure 4: The iPhone Search Results List

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- **iPad**
  Tap the **Study Contents** button in the desired study in the search results list. This will display the study contents popover.

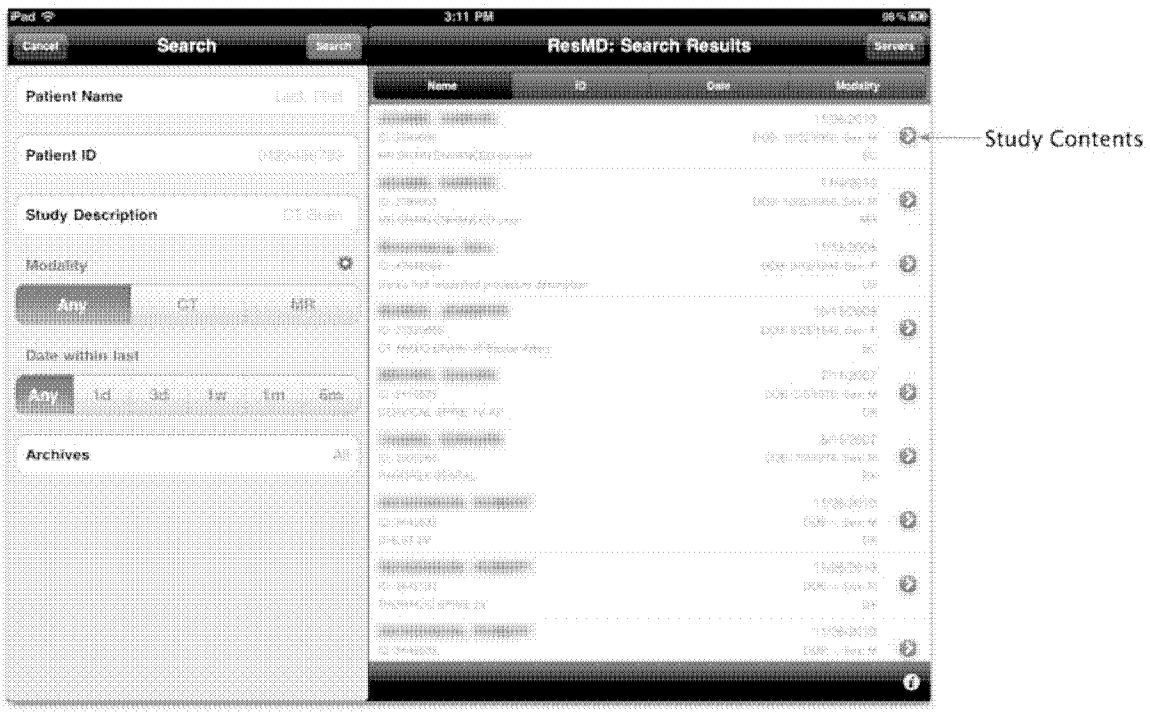

Figure 5: The iPad Search Results List

To load a series

iPhone

- Tap the desired series in the study contents list.

Figure 6: The Study Contents List

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iPad

- Tap the desired series in the study contents popover.

Figure 7: iPad Study Contents Popover

To load a report

- Tap the report in the study contents list.

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If there is more than 1 volume in the series, you will need to choose a volume from the volume list.

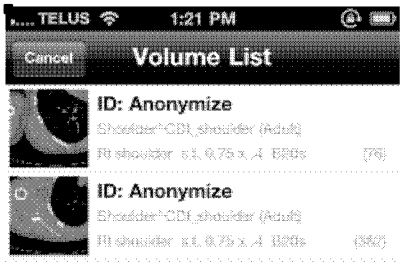

Figure 8: The Volume List

If the volume exceeds the maximum number of slices, you will be presented with the subset selector.

To choose the subset of slices you would like to view

1. Enter the first and last slice numbers of the subset.
2. Tap **Done**.

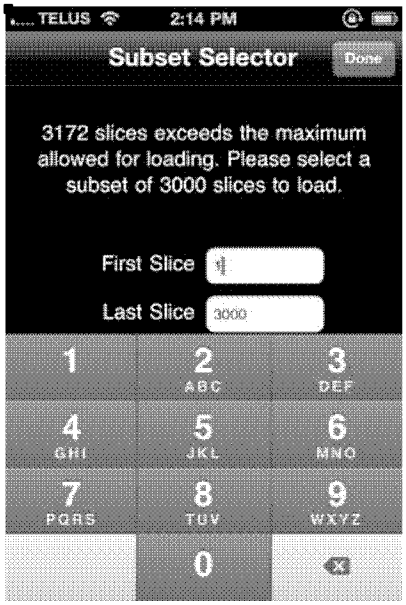

Figure 9: The Subset Selector

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Displaying the Search Interface

- **iPhone**
  You can display the search interface from the search results or recent exams list by tapping the **Search** tool.

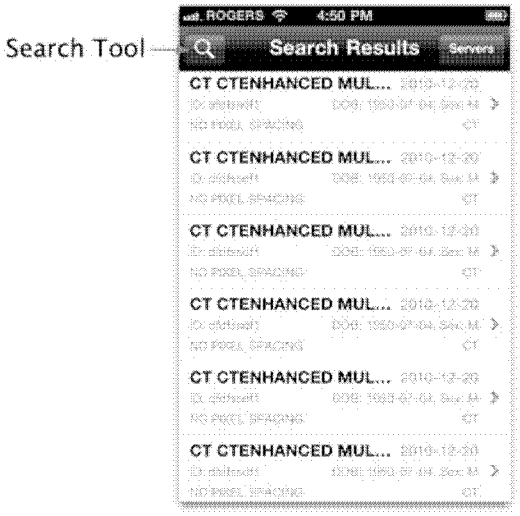

Figure 10: The Search Tool

- **iPad**
  In portrait orientation, you can display the search interface from the search results or recent exams list by tapping **Search**. The search interface is always visible on iPad in landscape orientation.

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Using Views

Your data set opens in the 2D View.

To select a view

1. Tap the **View Selector**.
2. Select the desired view. (2D, 3D or MIP/MPR)
3. Tap **Done**.

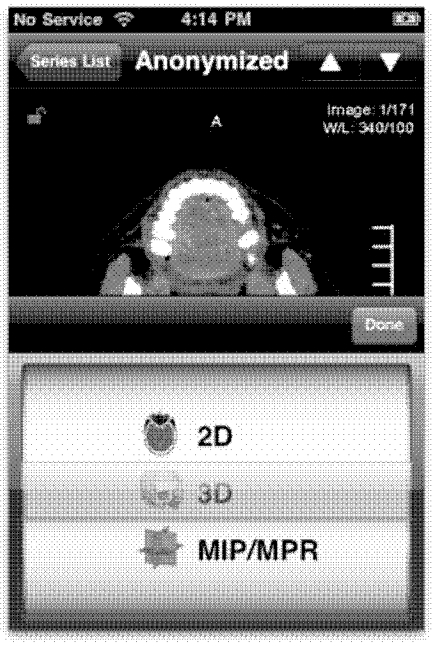

Figure 11: Selecting a View

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2D View

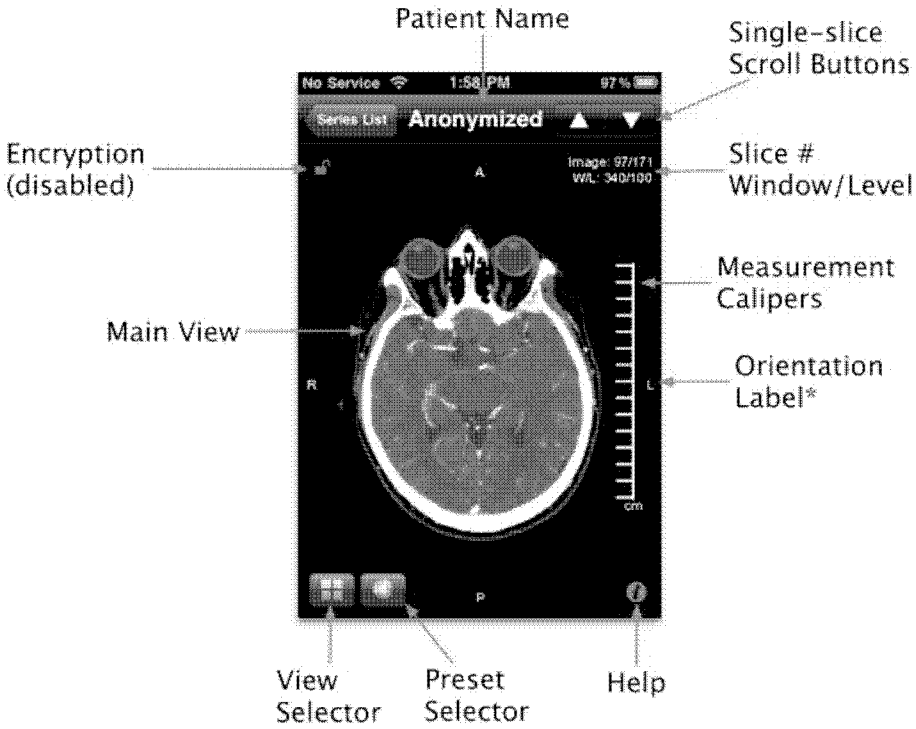

Figure 12: 2D View

*Superior, Inferior, Anterior, Posterior, Left, Right

The Measurement Calipers

The measurement calipers are visible in the 2D and MIP/MPR views. The calipers are a series of marks indicating millimeters or centimeters, depending on the current zoom factor of the image. The spacing of the calipers will adapt to the zoom factor of the image so that measurements are always accurate.

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MIP/MPR View

To change thickness

1. When in MIP/MPR view, tap the **Slab Thickness Selector**.
2. Select the desired thickness.

To change orthogonal view

- Swipe left or right in the main view.

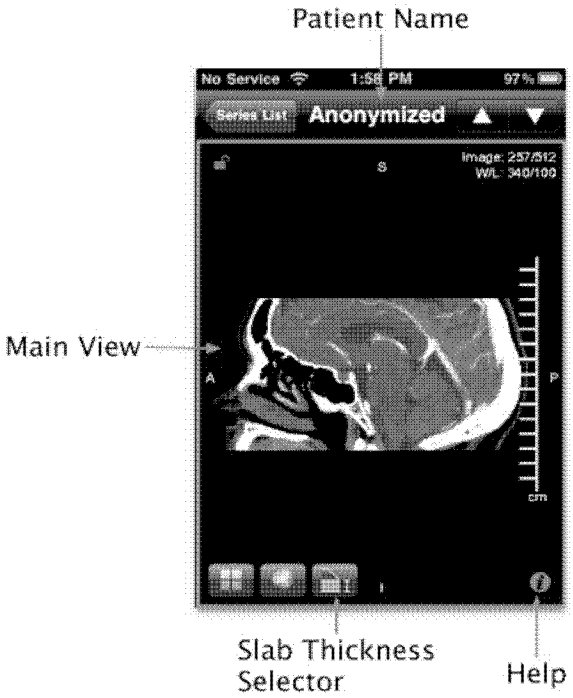

Figure 13: MIP/MPR View

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3D View

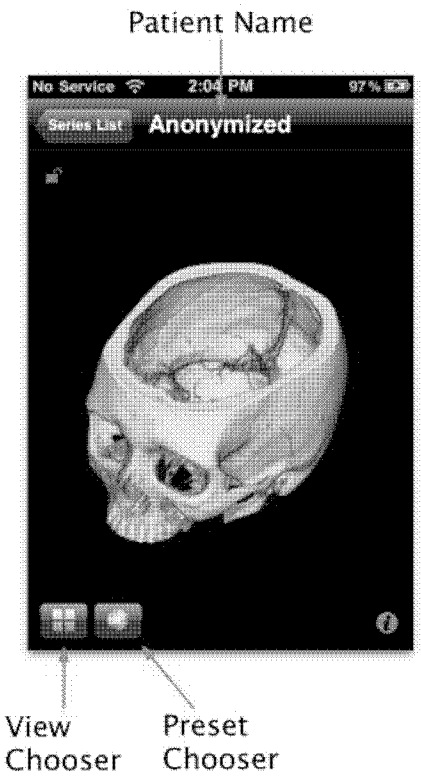

Figure 14: 3D View

Using Presets

To select a preset

1. Tap the **Preset Selector**.
2. Select the desired preset.

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Using the Lens Tool (iPad only)

You can use the Lens tool to magnify a select portion of the volume in the 3D Layout while keeping the entire volume in the Main View. A magnified view is displayed in the upper-right corner.

The Lens tool is made up of a lens and a magnified view. The magnified view shows a close-up of the area covered by the lens.

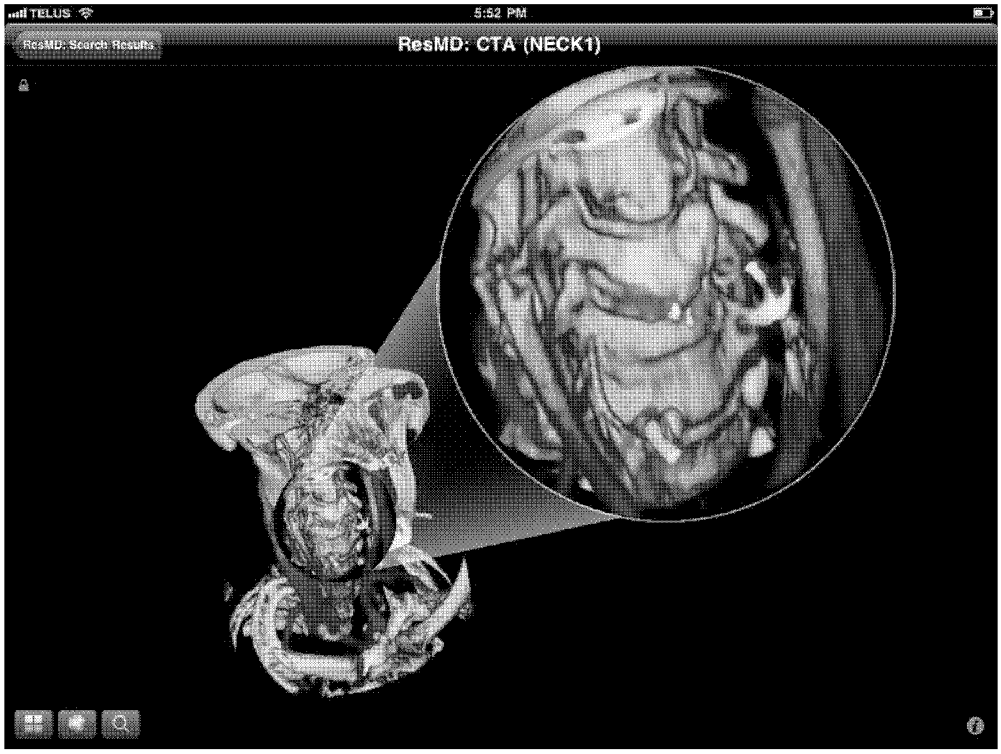
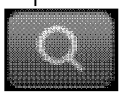


Figure 15: Lens Tool Enabled

To enable the Lens tool, do one of the following:

1. Tap the **Lens** tool.



Note	The Lens tool is only available in 3D Views.

To move the lens over the volume

- Drag the lens.

To adjust the magnification of the lens view

- Pinch or spread two fingers on magnified view.

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Adjusting Image Quality

Depending on the quality of your network connection, you can adjust the image quality to fine tune performance. Your adjustments are saved on your device and will be used in the future.

The interactive quality slider adjusts the image quality during interaction with the volume and reduces the amount of network bandwidth used. The full quality slider adjusts the quality of the image after interaction.

Note	User-selected quality settings may result in information loss from the original imagery. For diagnostic reading, the full quality settings should be set to 100. Diagnostic interpretations should not be formed from the interactive images but only from the static, full-quality resulting image.

To adjust image quality

1. Swipe downwards with three fingers in the main layout to reveal the quality sliders.
2. Adjust the quality sliders.
3. Tap anywhere in the main layout to hide the quality sliders.

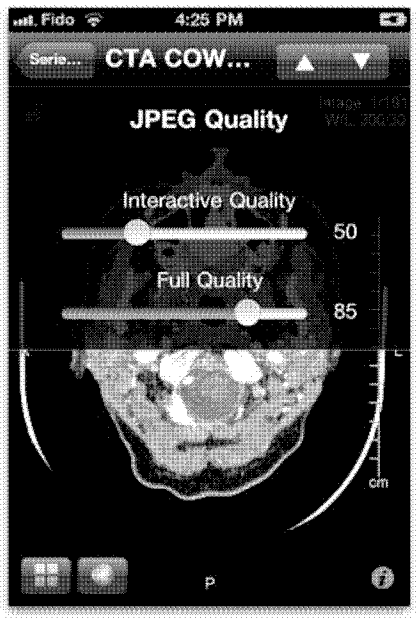

Figure 16: The Quality Sliders

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Interacting with ResMD Mobile

The following tables describe the touchscreen interactions for manipulating the views.

2D View

Functionality	Touchscreen Interaction
Slice Scrolling	Drag up/down (coarse) Tap single-slice scroll buttons (fine)
Win/Level	Tap, drag
Panning	Drag with two fingers
Zooming	Pinch
Reset	Shake

MIP/MPR View

Functionality	Touchscreen Interaction
Slice Scrolling	Drag up/down
Win/Level	Tap, drag
Change Orthogonal View	Swipe left/right
Panning	Drag with two fingers
Zooming	Pinch
Reset	Shake

3D View

Functionality	Touchscreen Interaction
Rotation	Drag
Win/Level	Tap, drag
Panning	Drag with two fingers
Zooming	Pinch
Reset	Shake

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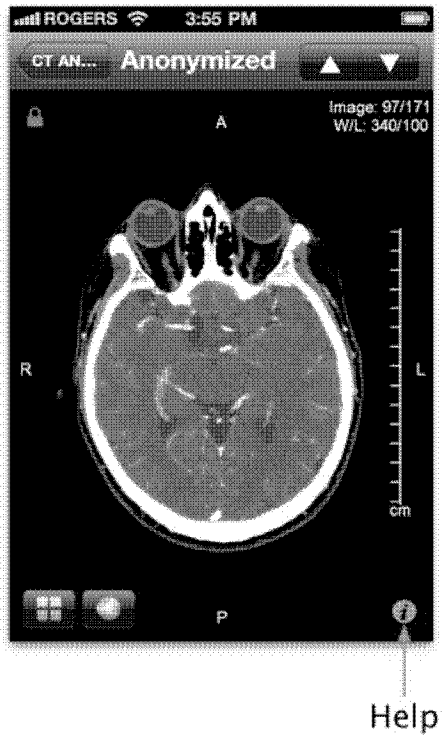
Help

Information is available in the app by tapping **Help**, which also includes this user guide and the Indications for Use.



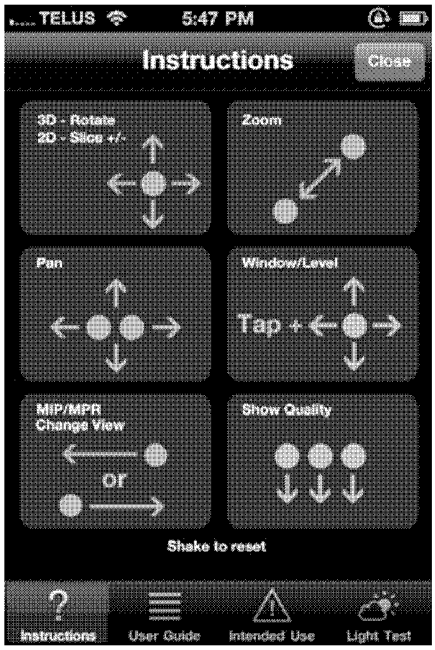


Figure 17: Help

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Assessing Ambient Light

Perform ambient light user assessment to ensure appropriate lighting conditions prior to use.

To perform ambient light user assessment

1. Set your device's display to maximum brightness and disable Auto-Brightness. (See *Screen Brightness*)
2. Tap **Help.**
3. Tap **Light Test.**
4. Tap **Perform Light Test**.

TG18-CT

This pattern is intended to support visual inspection of the luminance response of a display device. It should be evaluated for visibility of the central half-moon targets and the four low-contrast objects at the corners of each of the 16 different luminance regions.

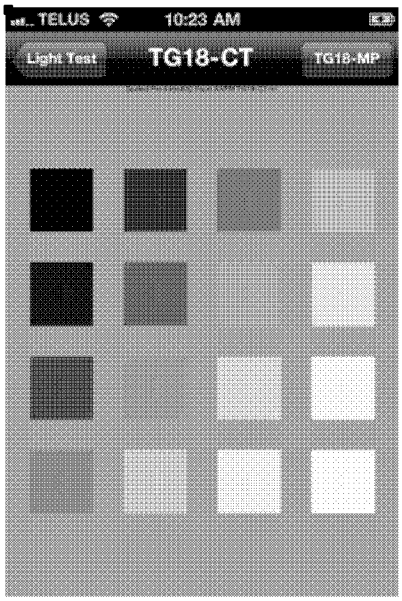

Figure 18: TG18-CT

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TG18-MP

This pattern is intended to support visual inspection of the bit-depth resolution of a display device. It should be evaluated to ascertain the horizontal contouring bands, their relative locations, and grayscale reversals.

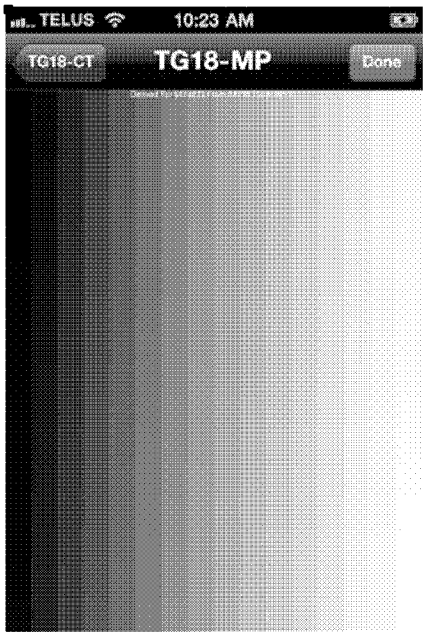

Figure 19: TG18-MP

To assess the suitability of environmental lighting, the user should review these patterns and determine whether their ability to discern the above information is comparable to ideal lighting conditions. If the user indicates that they are not able to perform this task, they will be instructed to find a more appropriate environment before proceeding.

These patterns were developed by the American Association of Physicists in Medicine (AAPM) Task Group 18*, whose purpose is to generate a document that provides guidelines to practicing medical physicists and engineers for in-field performance evaluation of electronic display devices intended for medical use.

* Reference: AAPM ON-LINE REPORT NO. 03: ASSESSMENT OF DISPLAY PERFORMANCE FOR MEDICAL IMAGING SYSTEMS, American Association of Physicists in Medicine, 2005.

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Uninstalling ResMD Mobile

ResMD Mobile can be uninstalled like any other iOS app.

To uninstall ResMD Mobile from your iOS device

1. Hold your finger on the ResMD icon.
2. While the icons are jiggling, tap the X that appears on the icon.

Technical Support - Client Issues

Bad Connection

If you are experiencing problems with your Apple iPhone, examine the connection scenarios below to solve your issue.

Case 1: Both a cellular data connection and a Wi-Fi connection are established.

- The application will function under these conditions.

Case 2: A cellular data connection exists, but no Wi-Fi connection.

- The application will function under these conditions.

Case 3: A Wi-Fi connection exist, but a subscriber identity module (SIM) card is not installed.

- The application will function under these conditions.

Case 4: Searching for a cellular data connection when a Wi-Fi connection is established.

- The application will function under these conditions.

Case 5: Searching for cellular network without a Wi-Fi connection established.

- The application will not function under these conditions.

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Solution:
Allow the device time to connect to the cellular provider.
Connect to a Wi-Fi network.

Case 6: A Wi-Fi connection is not established and a SIM card is not installed.

- The application will not function under these conditions.

Solution:
- Ensure the device is on a Wi-Fi network.
- Insert a SIM card or reseat the SIM card.

Bad Configuration

If you are experiencing problems with your mobile client, ensure that your server credentials are configured correctly on your mobile device.
- Ensure that the hostname is correct.
- Ensure that your port is correct.
- If your server requires SSL, ensure SSL is ON and use port 8443 instead of 8080.

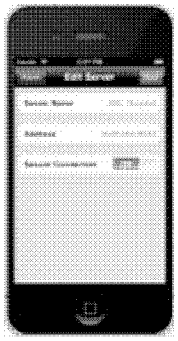

Figure 20: Mobile Device Configuration

Bad Username/Password

1. Ensure that your ResolutionMD plugin is configured to talk to the authentication webservice, knows the hostname/IP of the ResolutionMD Server, and has access to a username and password from the ResolutionMD user management system.
2. Navigate to http://<hostname>:8080/pureweb/server/status.
3. Enter a user/password from a defined user in the system.

If access is granted to the ResolutionMD status page then authentication is working.

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No Images

If you are not able to load or view any images on your mobile client, ensure that the following are configured correctly:

- The back association to the ResMD server is correctly configured.
- Your PACS system is configured correctly with the ResMD server.
- Recent Studies on your mobile device is correctly turned on or off.
- The PACS system has data.

No Reports

If you are unable to load reports, see the troubleshooting details below:
Retrieve an Accession Number/ Exam ID of a recent exam that has a report.
Construct the following URL to test report access:
http://<hostname>:8080/pureweb/resmd/report/<accessionNumber>.

Contacting Calgary Scientific Support

Contact Calgary Scientific Support during the hours of 9:00AM - 5:00PM, Monday - Friday (Mountain Standard Time).

Web Site Telephone E-Mail
http://calgaryscientific.onconfluence.com
(403) 270-7159
support@calgaryscientific.com

Customer and technical support information can be found at www.calgaryscientific.com/contact/customer-technical-support.html.

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Preface

Welcome to the *ResolutionMD 2.6 Service, Installation, and Integration Manual.* Although every effort has been made to make this document clear and easy to understand, it is still very technical in nature.

This document is valid for the 2.5 release of this product.

This preface contains the following sections:

- Intended Audience, page 8
- Making Comments on This Document, page 8
- Contacting Calgary Scientific Support, page 9

Intended Audience

This document is primarily intended for server administrators that plan to install and use ResolutionMD 2.6. It has been written with the assumption that the:

- the server installation will be performed using command lines and a terminal session.
- the server administrator has a general understanding of server configuration and installation.
- the server administrator has a basic understanding of Linux administration from the command line and the use of Secure Shell (SSH).

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Chapter

1 Install and Configure Red Hat Enterprise Linux

This chapter contains the information needed to install configure the Red Hat Enterprise Linux (RHEL) Operating System (OS) for Servers.

This chapter contains the following sections:

- Introducing the RHEL OS, page 10
- Installing and Configuring the RHEL Operating System, page 10

Introducing the RHEL OS

Red Hat Enterprise Linux (RHEL) for Servers is a distribution of the Linux operating system developed for the business market.

For more information about RHEL, visit http://www.redhat.com/rhel/.

Installing and Configuring the RHEL Operating System

Installing the RHEL Server

Purpose: To install the Red Hat Enterprise Linux for Servers operating system.

Prerequisites

- Plug your monitor in to the Digital Visual Interface (DVI) port on one of the Graphics Processor Units (GPU) prior to starting the server.

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Start of procedure

1. Insert the RHEL for Servers 5.5 DVD.
2. Type in linux at the prompt to install in text mode.

Note: If the installer hangs, reboot and type linux irqpoll at the prompt to disable the IRQ polling mechanism.

3. Click Skip to skip the media testing.

Figure 1: Skip Media Test

4. Click Next on the splash screen.

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Figure 2: Splash Screen

5. Select English as your preferred language.
6. Click Next.

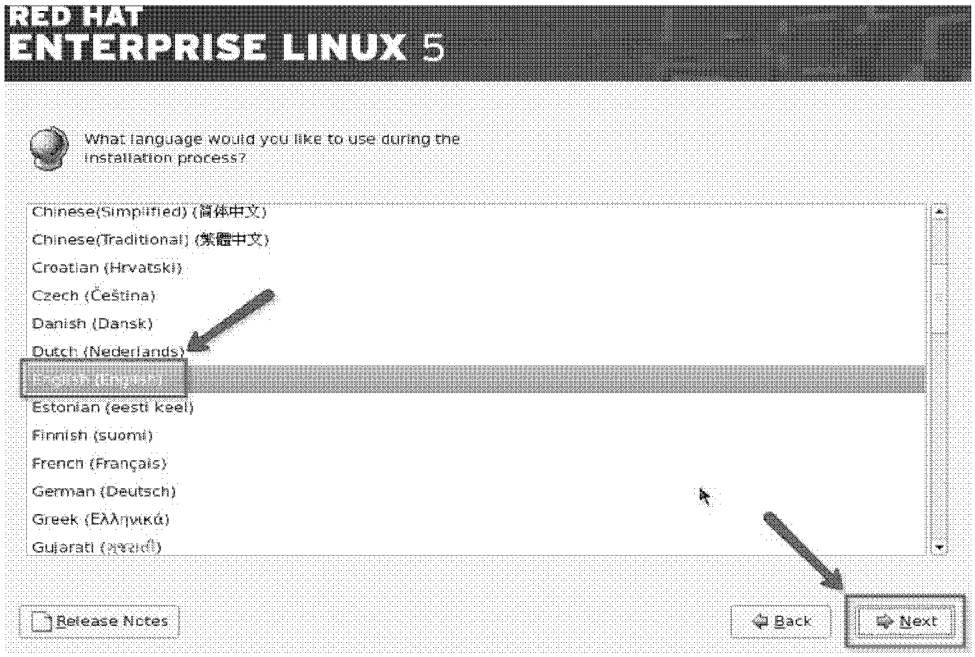

Figure 3: Preferred Language

7. Select U.S. English as your keyboard layout.
8. Click Next.

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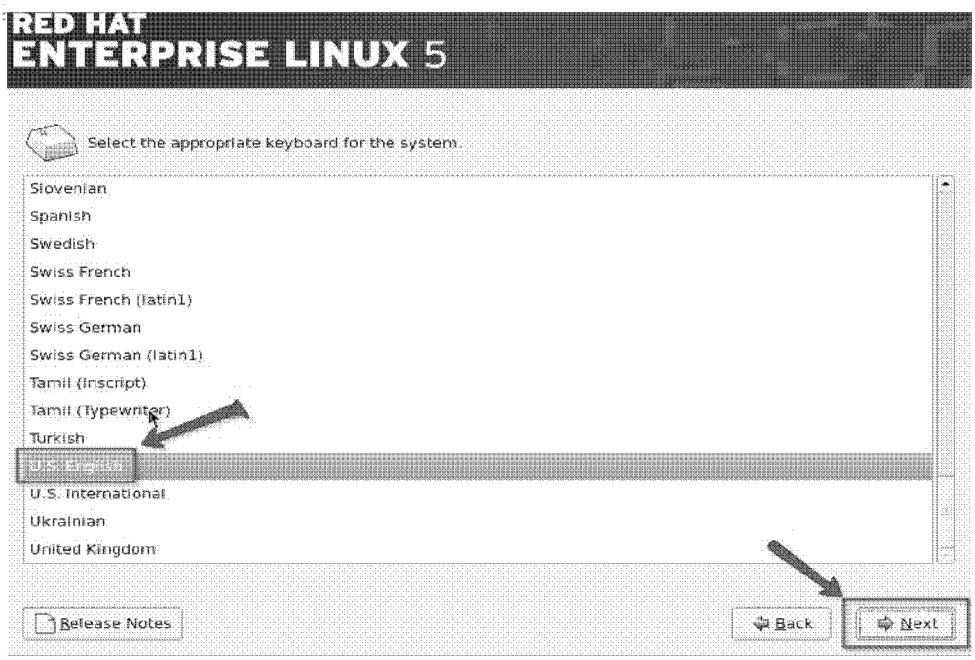

Figure 4: Preferred Keyboard Layout

9. Select the Skip entering Installation Number option and click OK.

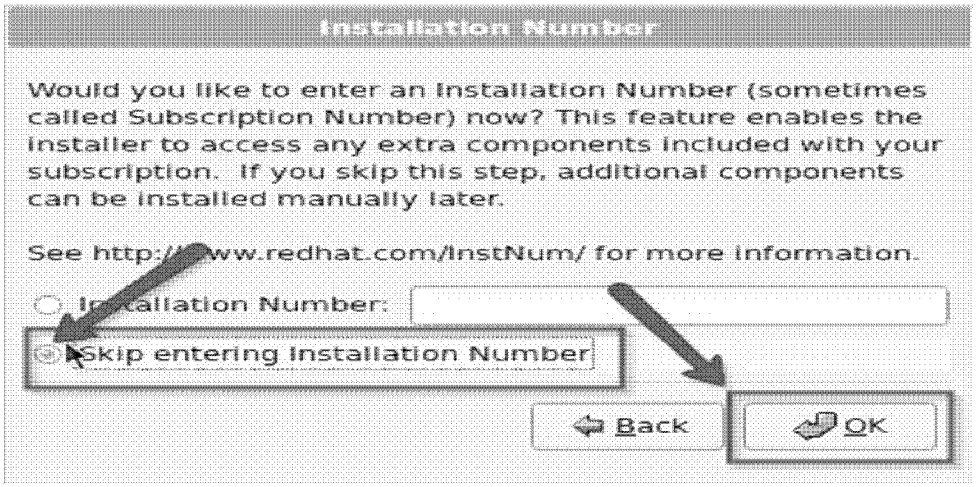

Figure 5: Skip Entering Installation Number

10. Click Skip when the Skip Installation Number dialog is displayed.

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Figure 6: Skip Installation Number Dialog

End of procedure

Next Steps

- Partition your server by following the steps in "Partitioning your HP Server for RHEL" on page 14.

Partitioning your HP Server for RHEL

Purpose: To partition your HP server.

Prerequisites

- Complete the steps in "Installing the RHEL Server" on page 10.

Start of procedure

Note: The HP hardware configuration for ResolutionMD will have a single partition on a RAID5, RAID10, or RAID0+1 array. The recommended Linux partitioning scheme is sufficient for ResolutionMD and no advanced configuration is required.

a. Choose Remove all partitions on selected drives and create default layout option.
b. Uncheck Encrypt System check box.
c. Check the check box next to your selected drive.
d. Click Next.

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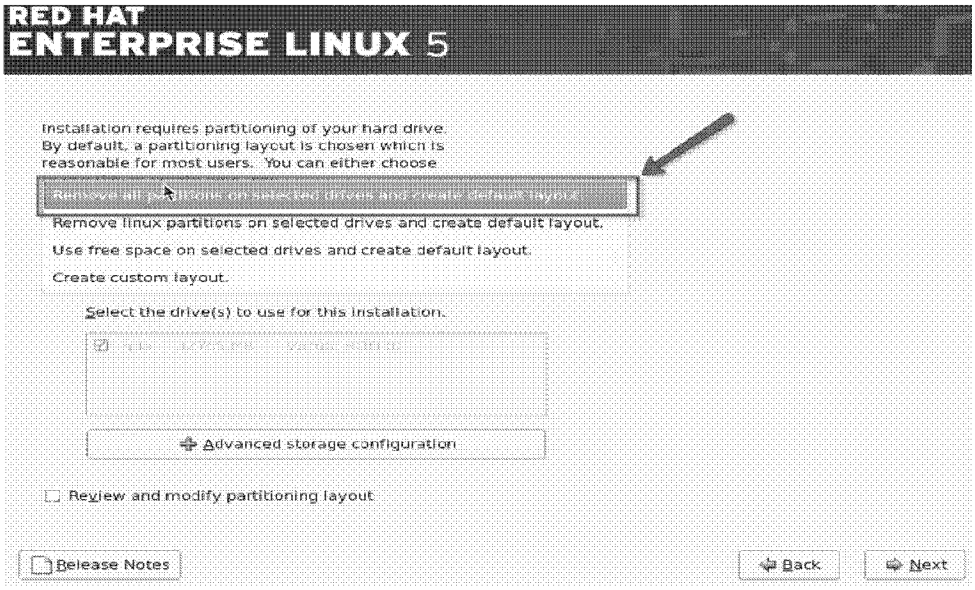

Figure 7: Partitioning Options

e. Click Yes when the Warning dialog is displayed.

Figure 8: Removing All Partitions Warning

Next Steps

- Configure your network device by following the steps in "Configuring your Network Device for RHEL" on page 15.

Configuring your Network Device for RHEL

Purpose: To configure your network device.

Prerequisites

- Complete the steps in "Partitioning your HP Server for RHEL" on page 14.

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Start of procedure

a. Check eth0 active on boot check box.
b. Select the Set the hostname automatically via DHCP option.
c. Click Next.

Figure 9: Networking Configuration

d. Select your time zone from the drop-down box.
e. Click Next.

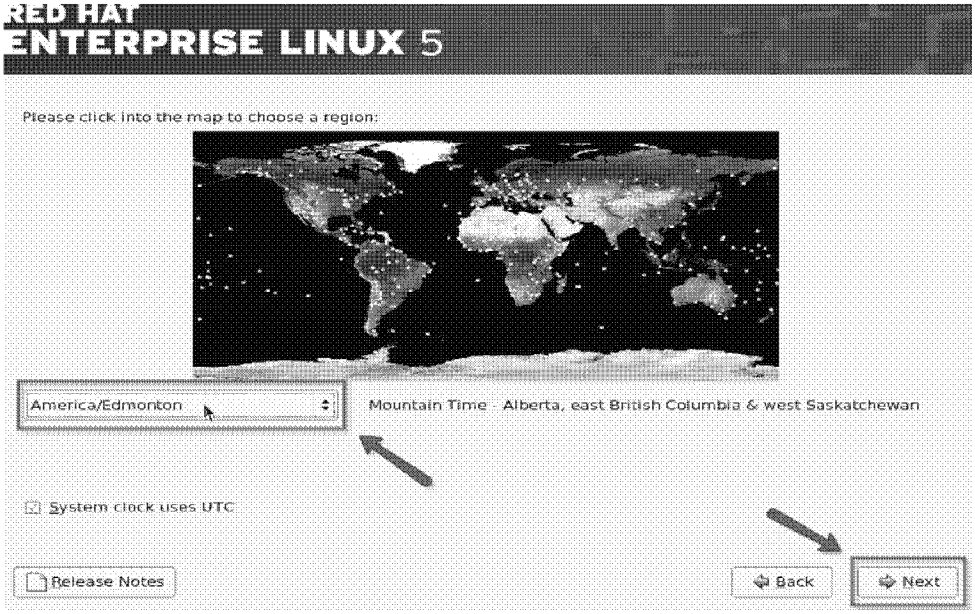

Figure 10: Select Your Time Zone

End of procedure

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Next Steps

- Configure the root account by following the steps in "Configuring the Root Account for RHEL" on page 17.

Configuring the Root Account for RHEL

Purpose: To set the root password.

Prerequisites

- Complete the steps in "Configuring your Network Device for RHEL" on page 15.

Start of procedure

a. Set the root password.

b. Click Next.

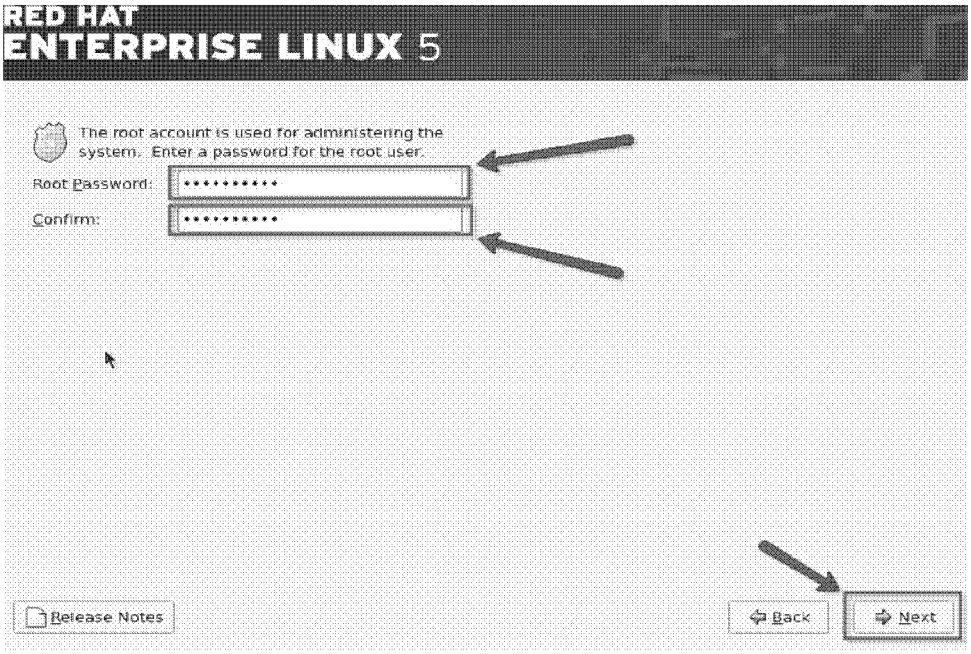

Figure 11: Set the Root Password

End of procedure

Next Steps

- Customize your software selections by following the steps in "Customizing your Software Selections for RHEL" on page 18.

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Customizing your Software Selections for RHEL

Purpose: To customize your software selections.

Prerequisites

- Complete the steps in "Configuring the Root Account for RHEL" on page 17.

Start of procedure

a. Uncheck both the Software Development and Web Server check boxes.
b. Select the Customize Now option.
c. Click Next.

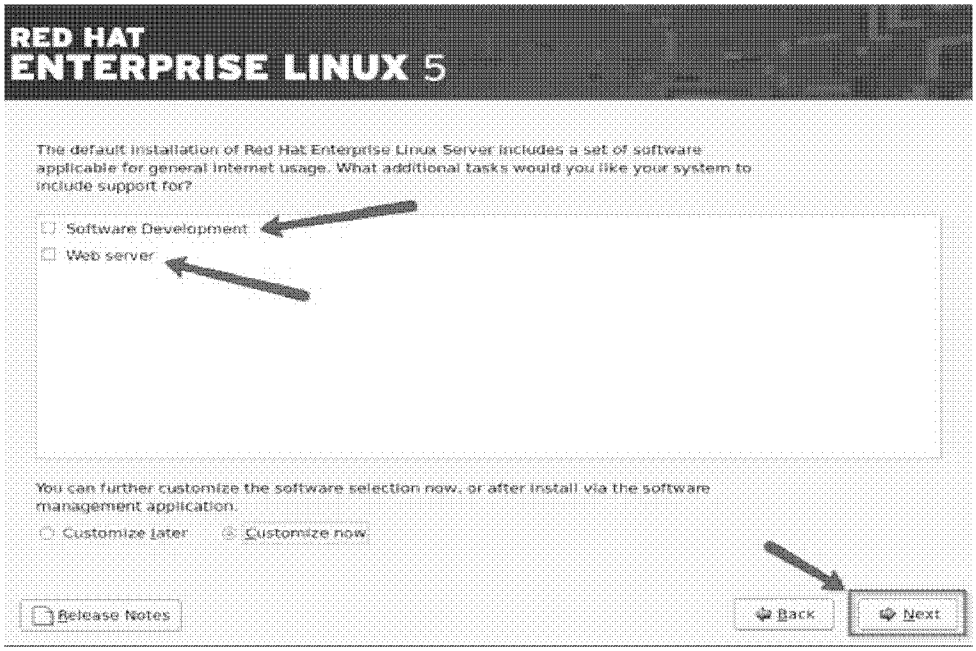

Figure 12: Software Selections

d. Check the GNOME check box.

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Figure 13: Desktop Environments

e. Click Applications in the left pane.

f. Check the Editors check box (all other check boxes are left empty).

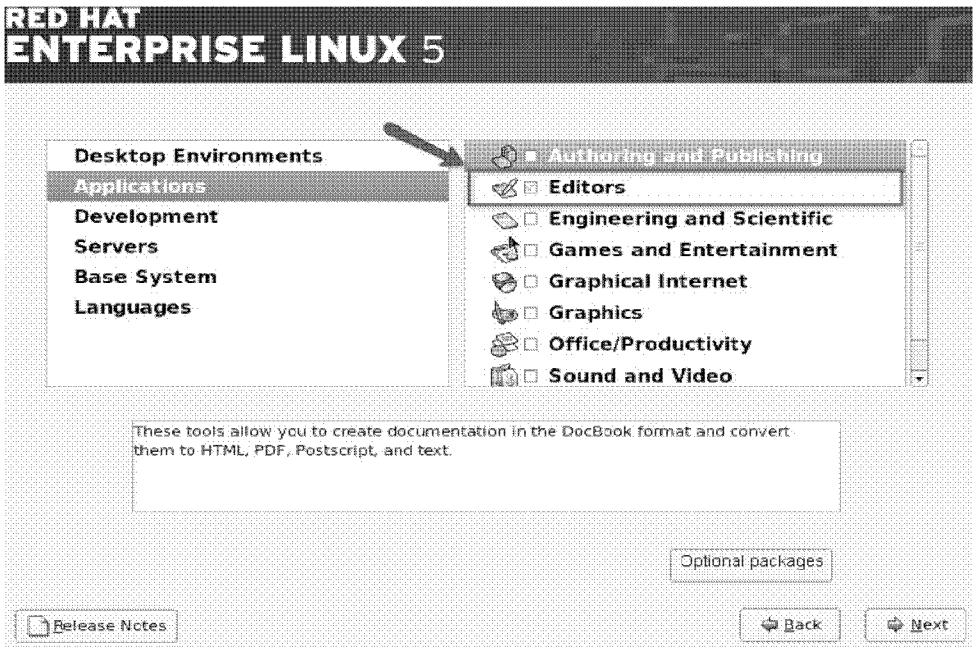

Figure 14: Select Applications

g. Click Development in the left pane.

h. Check the Development Tools and Development Libraries check boxes (all other check boxes are left empty).

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Figure 15: Select Development Tools

i. Click Servers in the left pane.

j. Check the Server Configuration Tools and Windows File Server check boxes (all other check boxes are left empty).

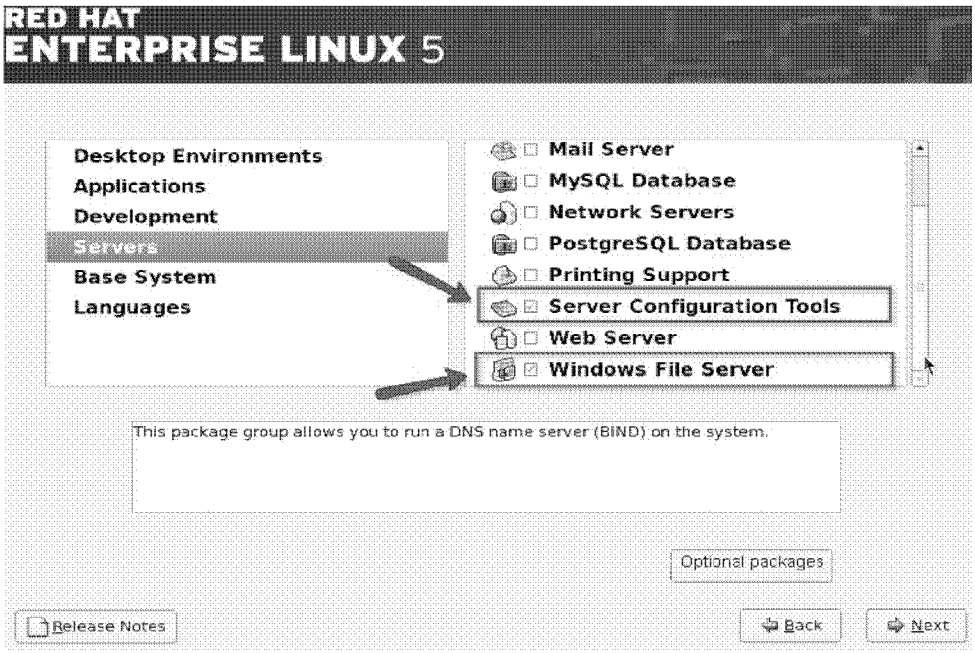

Figure 16: Select Servers

k. Click Base System in the left pane.

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l. Check the Administration Tools, Base, System Tools, and X Windows System check boxes (all other check boxes are left empty).

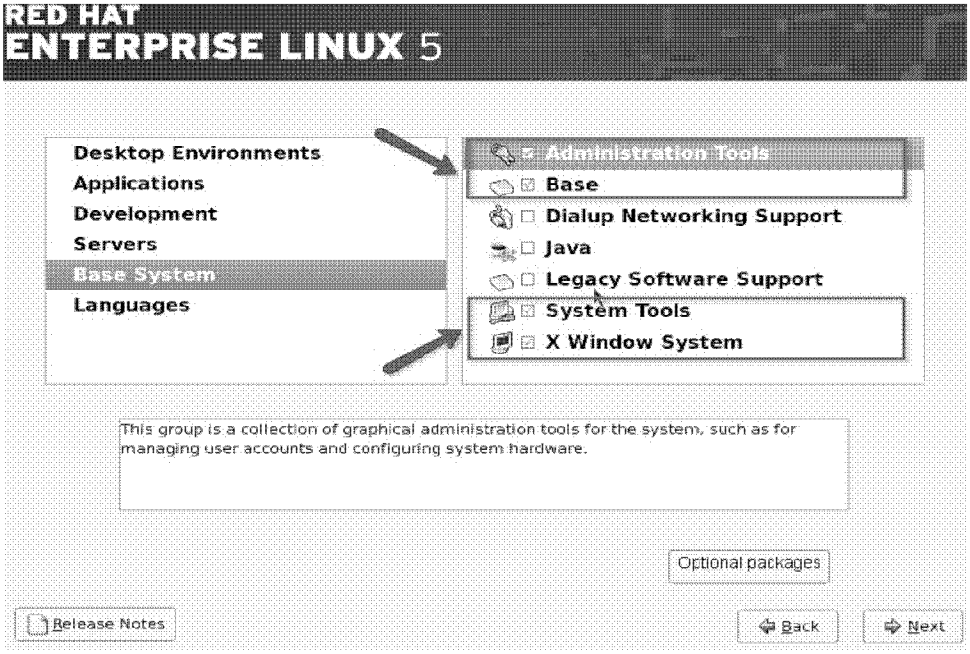

Figure 17: Select Base System

m. Click Languages in the left pane.

n. Uncheck all of the language check boxes.

o. Click Next.

Figure 18: Leave the Language Unselected

End of procedure

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Next Steps

- Install the client application by following the steps in "Installing the RHEL Client Application" on page 22.

Installing the RHEL Client Application

Purpose: To install the client application.

Prerequisites

- Complete the steps in "Customizing your Software Selections for RHEL" on page 18.

Start of procedure

a. Click Next to begin installing the client.

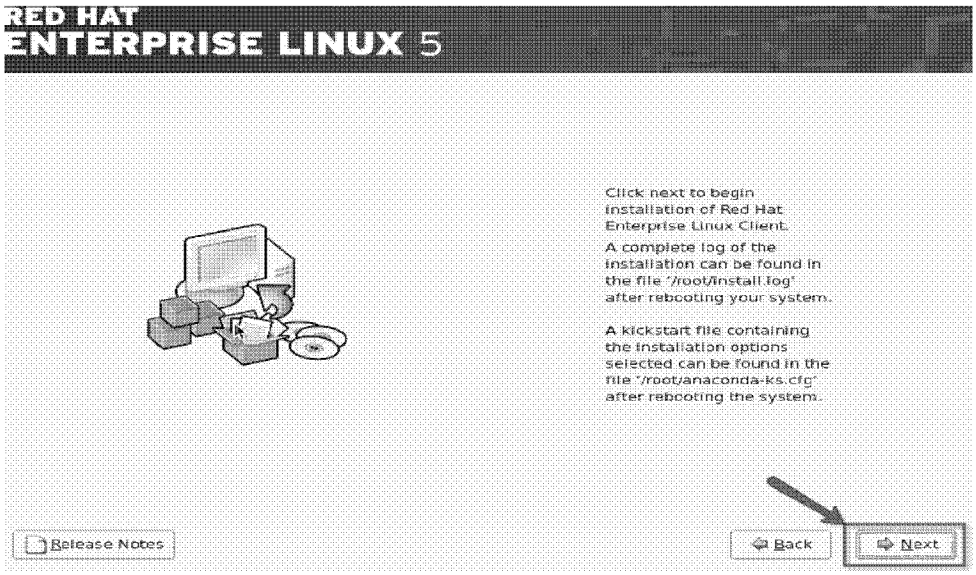

Figure 19: Start Client the Installation

b. Remove DVD and click Reboot.

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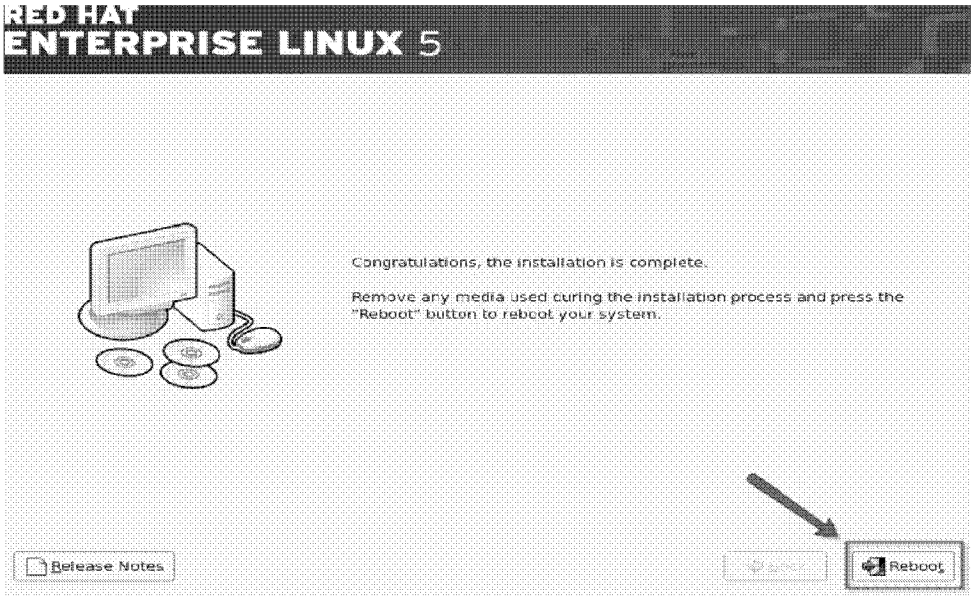

Figure 20: Reboot

c. Click Forward on the Welcome Screen.

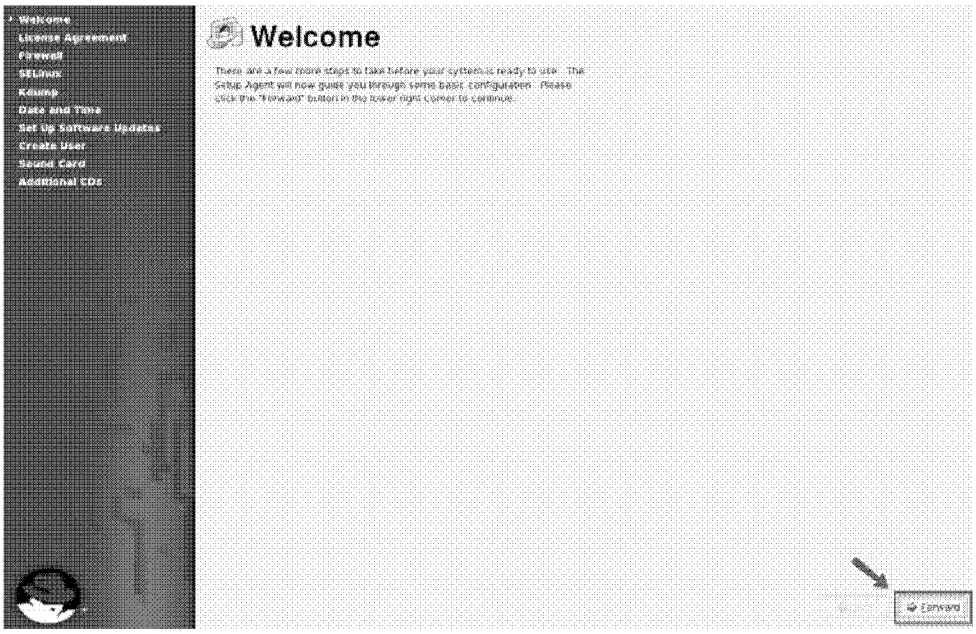

Figure 21: Welcome Screen

d. Select the Yes, I agree to the License Agreement option.

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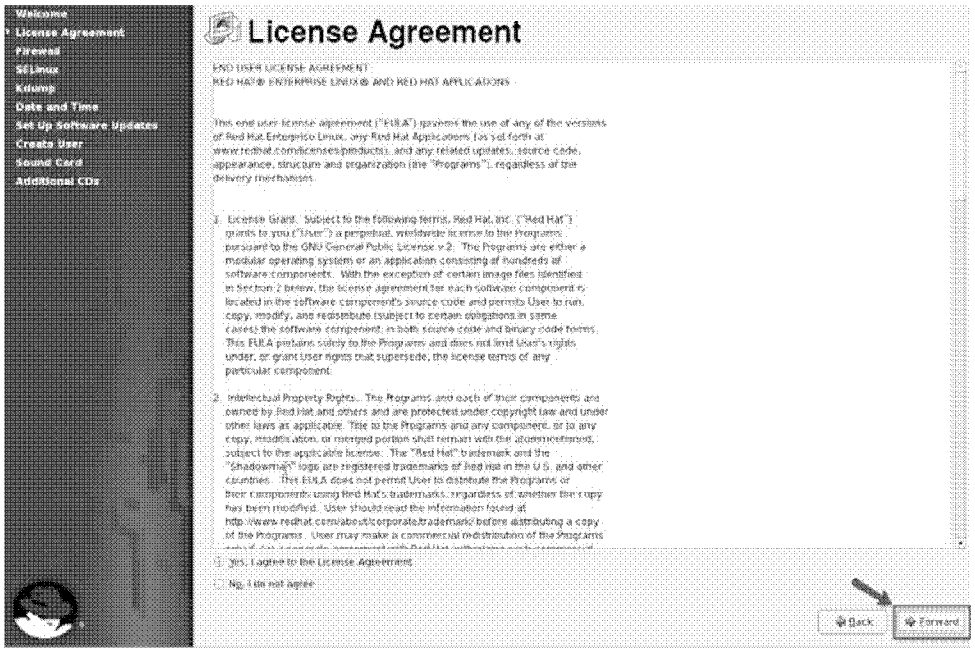

Figure 22: License Agreement

e. Click Forward.

f. Select Disabled from the drop-down box and click Forward.

Figure 23: Disable the Firewall

g. Click Yes, when the Fire Wall Warning dialog is displayed.

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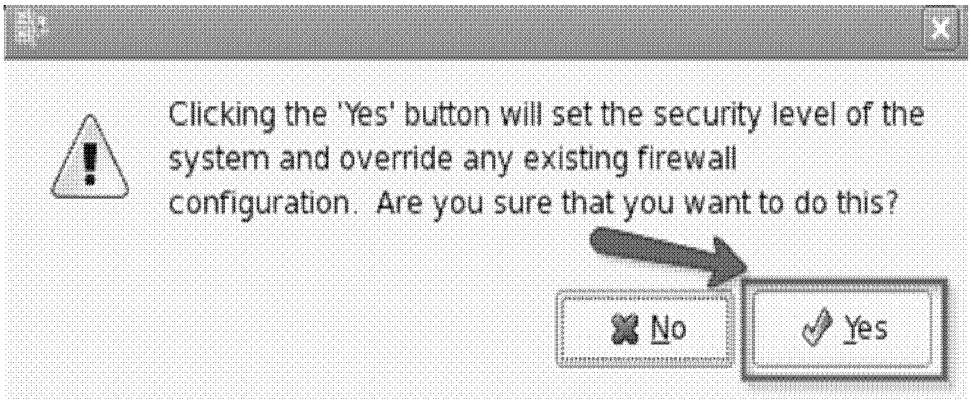

Figure 24: Override Existing Firewall Warning

h. Select Disabled from the drop-down box and click Forward.

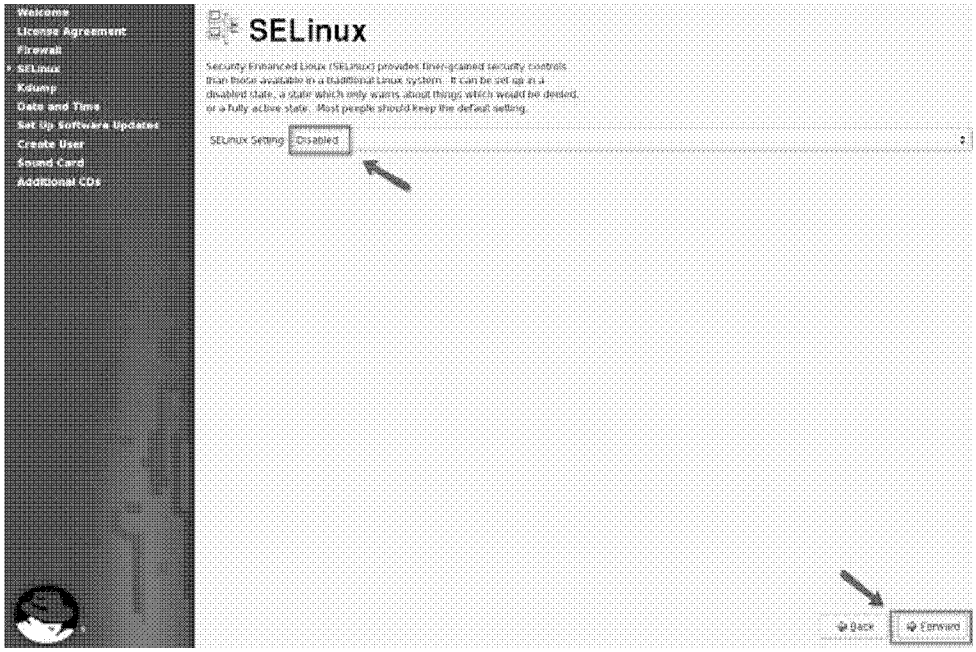

Figure 25: Disable SELinux

i. Click Yes, when the SELinux Reboot Required dialog is displayed.

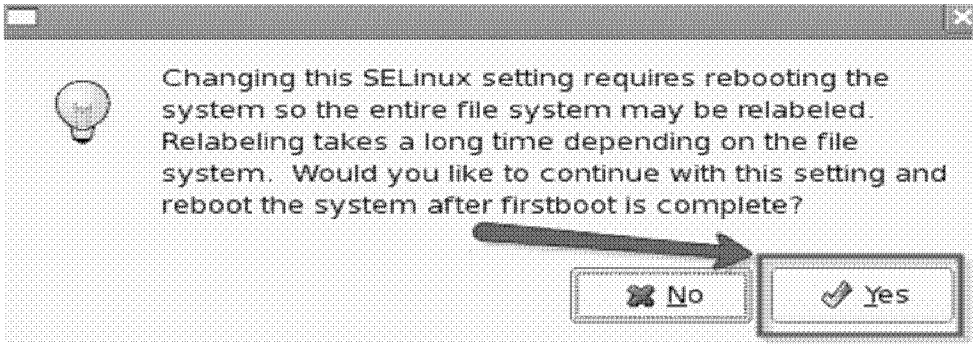

Figure 26: Postpone Reboot Until After the Firstboot

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j. Uncheck the Enable Kdump check box.

k. Click Forward.

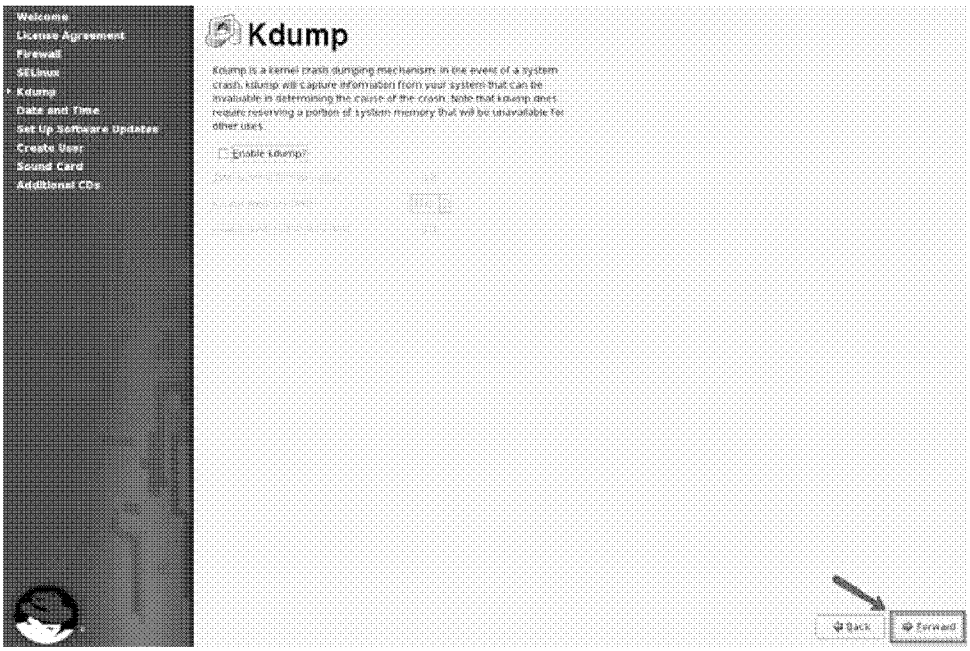

Figure 27: Disable Kdump

l. Select the Network Time Protocol tab and check Enable Network Time Protocol check box.

m. Click Forward.

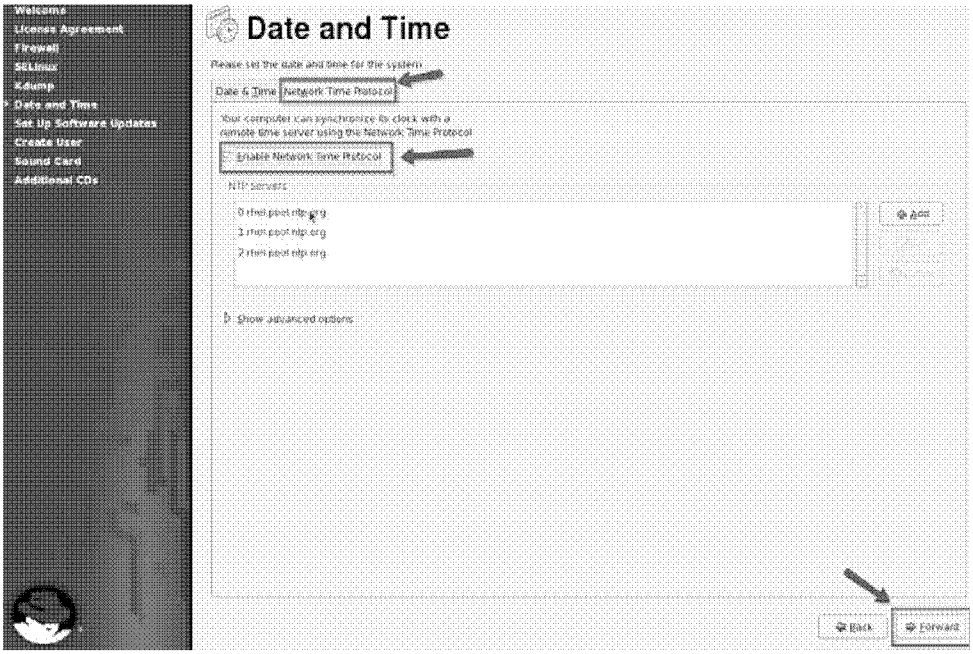

Figure 28: Enable Network Time Protocol

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n. Select the No, I prefer to register at a later time option in the Set Up Software Updates dialog.

o. Click Forward.

Note: If the network is disconnected or external access is disabled you may see a slightly different screen.

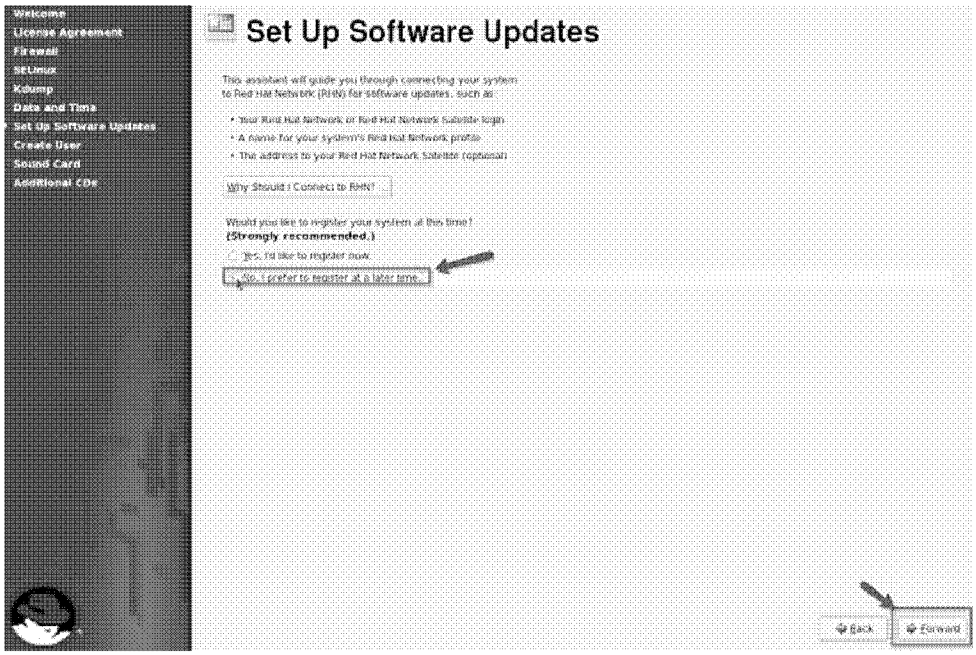

Figure 29: Set Up Software Updates

p. Click Forward on the Create User screen.

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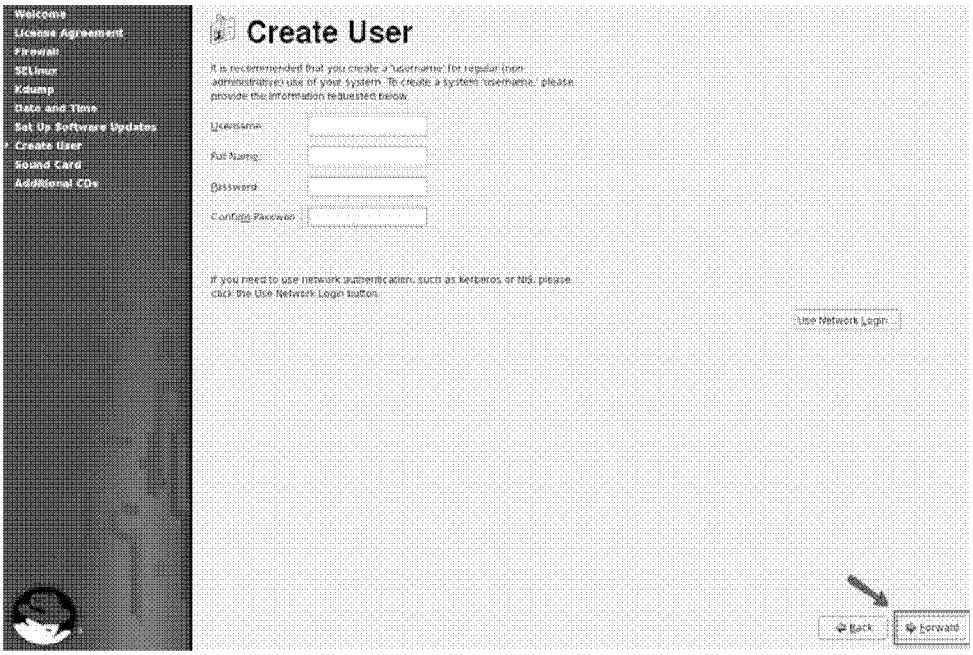

Figure 30: Create a User

q. Test the Sound Card, if one is detected.

r. Click Forward.

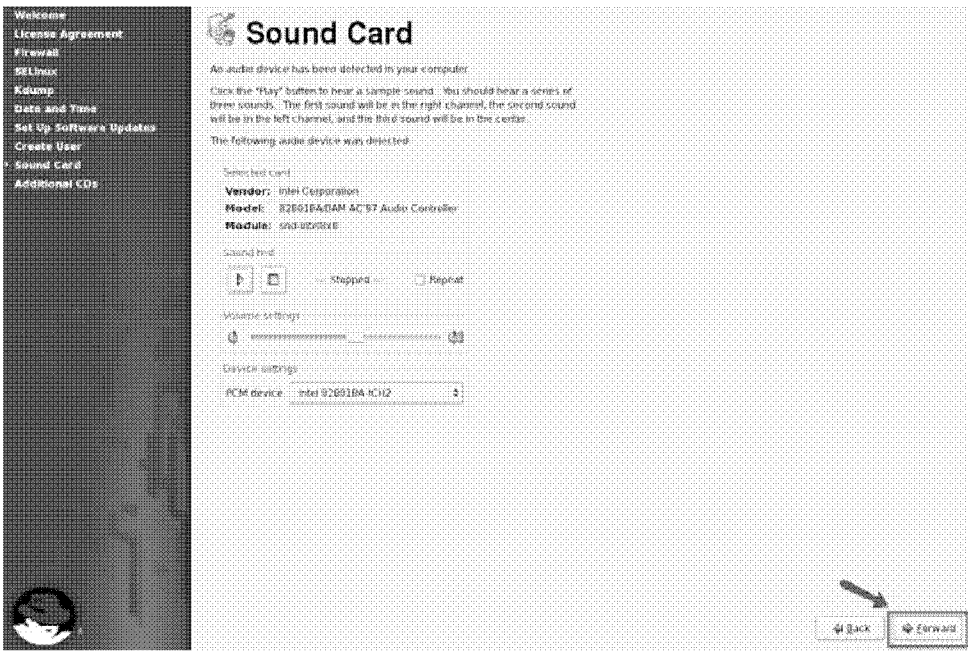

Figure 31: Sound Card Detected

s. Click Finish on the Additional CDs dialog to complete the installation.

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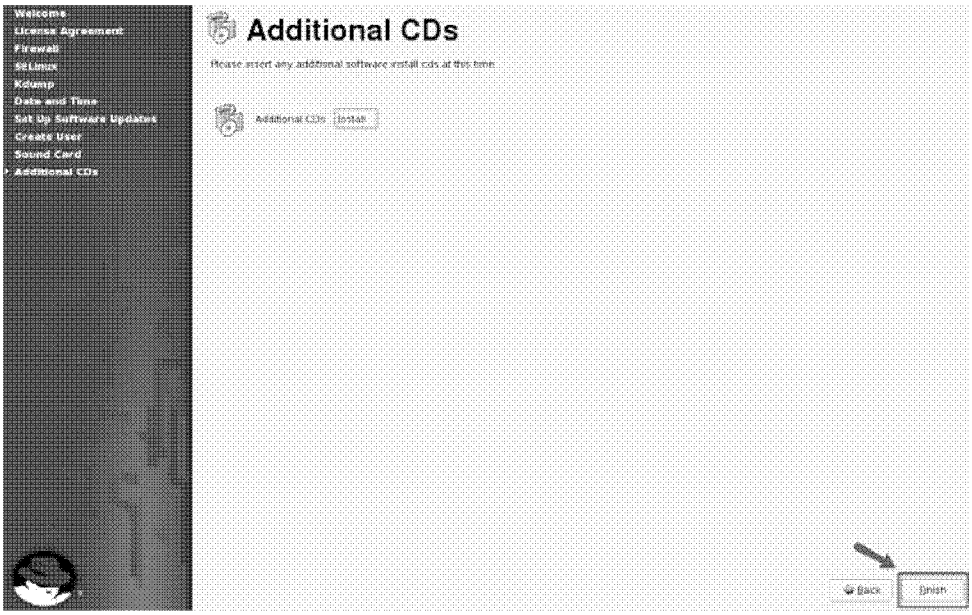

Figure 32: Finished Install

Warning! Before disabling the installation GUI, copy the ResolutionMD Media to /root/.

End of procedure

Next Steps

- Proceed to Chapter 4, "Installing the ResolutionMD Server," on page 42.

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resolution MD

Chapter

2 Configuring Integrated Lights-Out (iLO) 2

This chapter contains the information needed to configure iLO 2 on your server and use it to configure a virtual communication port, and a virtual serial port.

This chapter contains the following sections:

- Introducing iLO 2, page 30
- Configuring iLO 2, page 30

Introducing iLO 2

iLO, is an embedded server management technology exclusive to Hewlett-Packard (HP). iLO 2 provides multiple ways to configure, update, and operate servers remotely. The iLO 2 card has a separate network connection and internet protocol (IP) address that you connect to using HTTPS.

Note: For more information about iLO 2, refer to the HP Integrated Lights-Out 2 User Guide.

Configuring iLO 2

The iLO 2 Administration tab enables you to configure and manage user settings, security settings, licensing, certificate administration, directory settings, and network environment settings. The menu options needed for the steps below are found on the Administration page.

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Configuring iLO 2

Purpose: To configure your HP server.

Start of procedure

1. Turn on the server.
2. During the Power On Self Tests (POST), press F8 to enter the Integrated Lights Configuration Tool.
3. Select the Settings option and confirm that the following settings are configured as indicated.
   - Serial CLI State = ENABLE-AUTH Required.
   - Serial CLI Speed (bits/second) = 57600.

End of procedure

Configuring the iLO 2 Administrator Account/Password

Purpose: To configure your iLO 2 administrator account/password.

Start of procedure

1. Select the Edit option.
2. Change the username and password.

End of procedure

Using iLO 2 to Configure the Network

Purpose: To configure the network.

Start of procedure

1. Select the Network option.
2. Select the NIC and TCP/IP option.
3. Confirm that the Network Interface Adapter = ON.
4. Select the DNS/DHCP option.
5. Confirm that DHCP is ON.
6. Change the DNS Name (optional); otherwise, it will default to the name displayed on the server tag for iLO.

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7. Select the Exit option.

End of procedure

Using iLO 2 to Configure a Virtual Communication Port

Purpose: To configure a virtual communication (COM) port.

Start of procedure

1. After exiting the Integrated Lights Out Configuration Tool, immediately press F9 to enter the BIOS.
2. Select System Options from the menu.
3. Select Serial Port Options from the menu.
4. Select Virtual COM Port from the menu.
5. Select COM 1 from the menu.
6. Select the Exit option.

End of procedure

Configuring RHEL with a Virtual Serial Port Interface

Purpose: To configure RHEL with a virtual serial port interface.

Start of procedure

1. Log in to the RHEL OS.
2. Add the Virtual Serial Port (VSP) to the /etc/inittab file by following the steps below.
   a. Type the command vim /etc/inittab.
   b. Add the following line item to the file.
      - 7:2345:respawn:/sbin/agetty ttyS0 57600 vt100
   c. Select Save and Exit to save the changes and close the file.
3. Type the command telinit q to reload the inittab file.

   In order to accept root login's from the VSP, you will need to add ttyS0 into the /etc/security file by following the steps below.
   a. Type the command vim /etc/security.
   b. Add the following line item to the file.
      - ttyS0
   c. Select Save and Exit to save the changes and close the file.

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Note: To get additional information about the serial port's IRQs and port types, enter the following command: setserial -g /dev/tty*.

End of procedure

Testing the iLO 2 Remote Login

Purpose: To confirm that your remote login is configured correctly.

Start of procedure

1. Open a browser.
2. Enter http://<ILO HOSTNAME> into the URL address text box to navigate to the iLO interface.
3. Enter your iLO Username and Password.
4. Select the Remote Console tab.
5. Select the Remote Serial Console option.
6. Log in as root using your Linux root password.

End of procedure

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Chapter

3 Pre-installation and Deployment Requirements

(b) (4)

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(b) (4)

[redacted]

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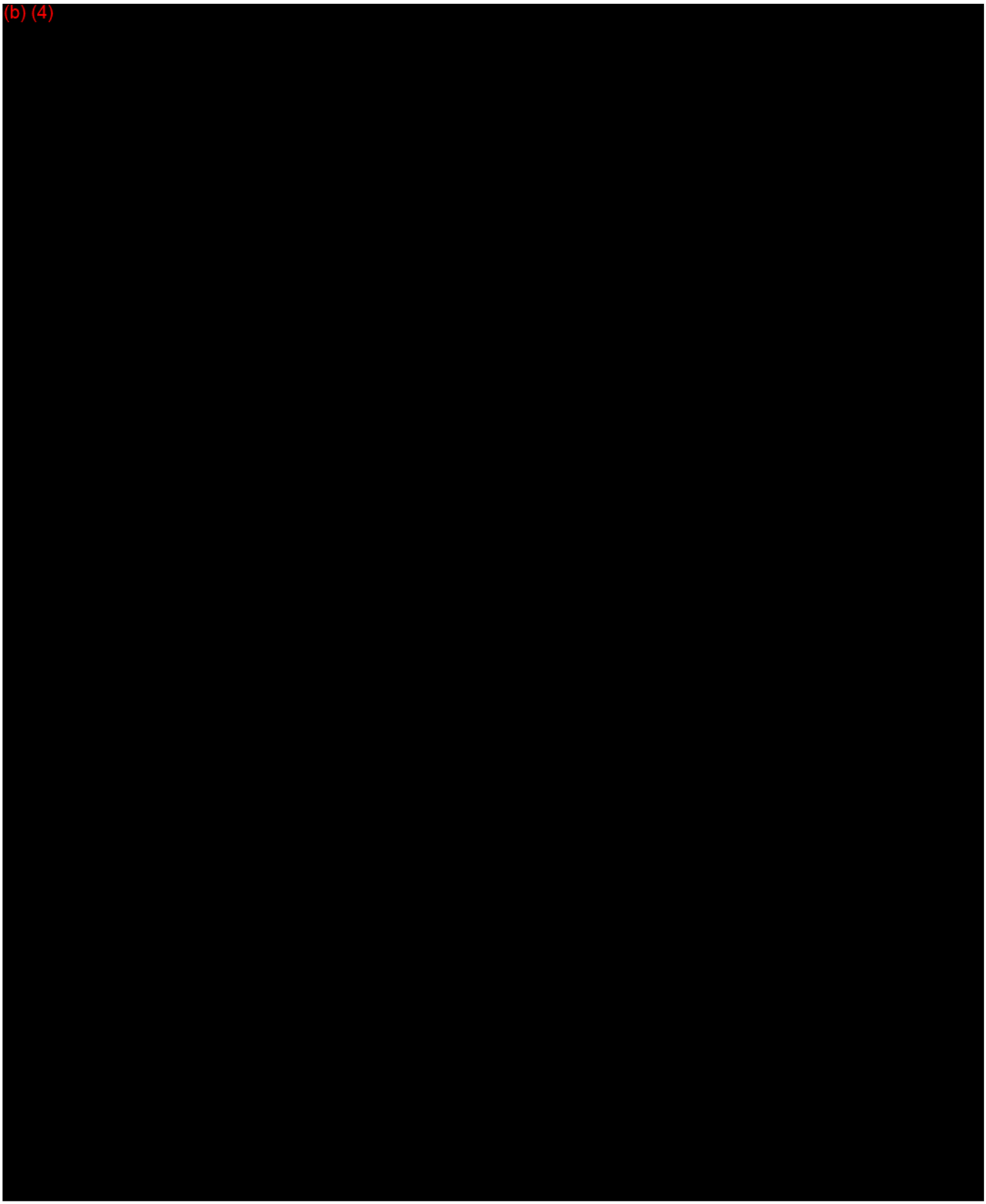

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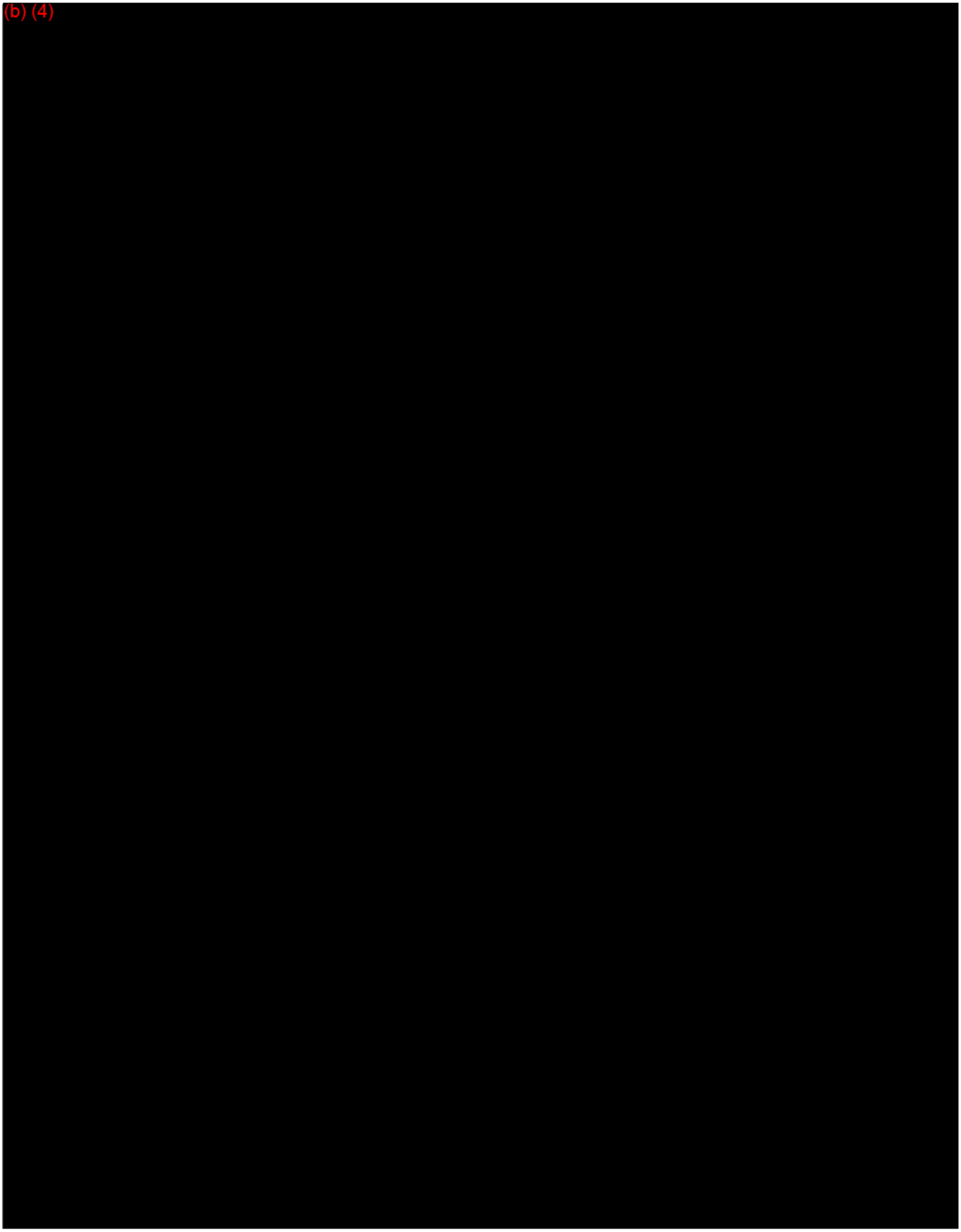
(b) (4)



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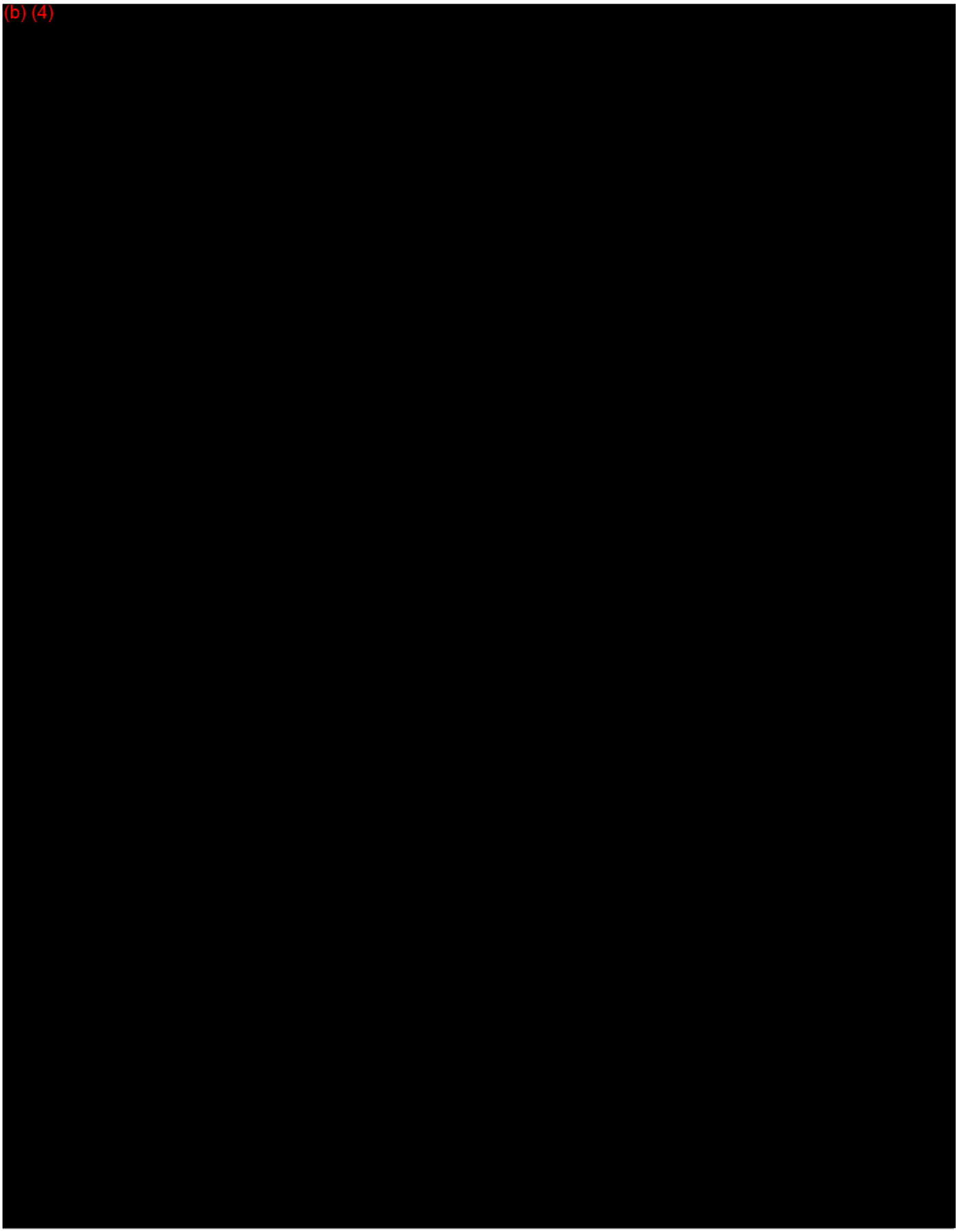
(b) (4)



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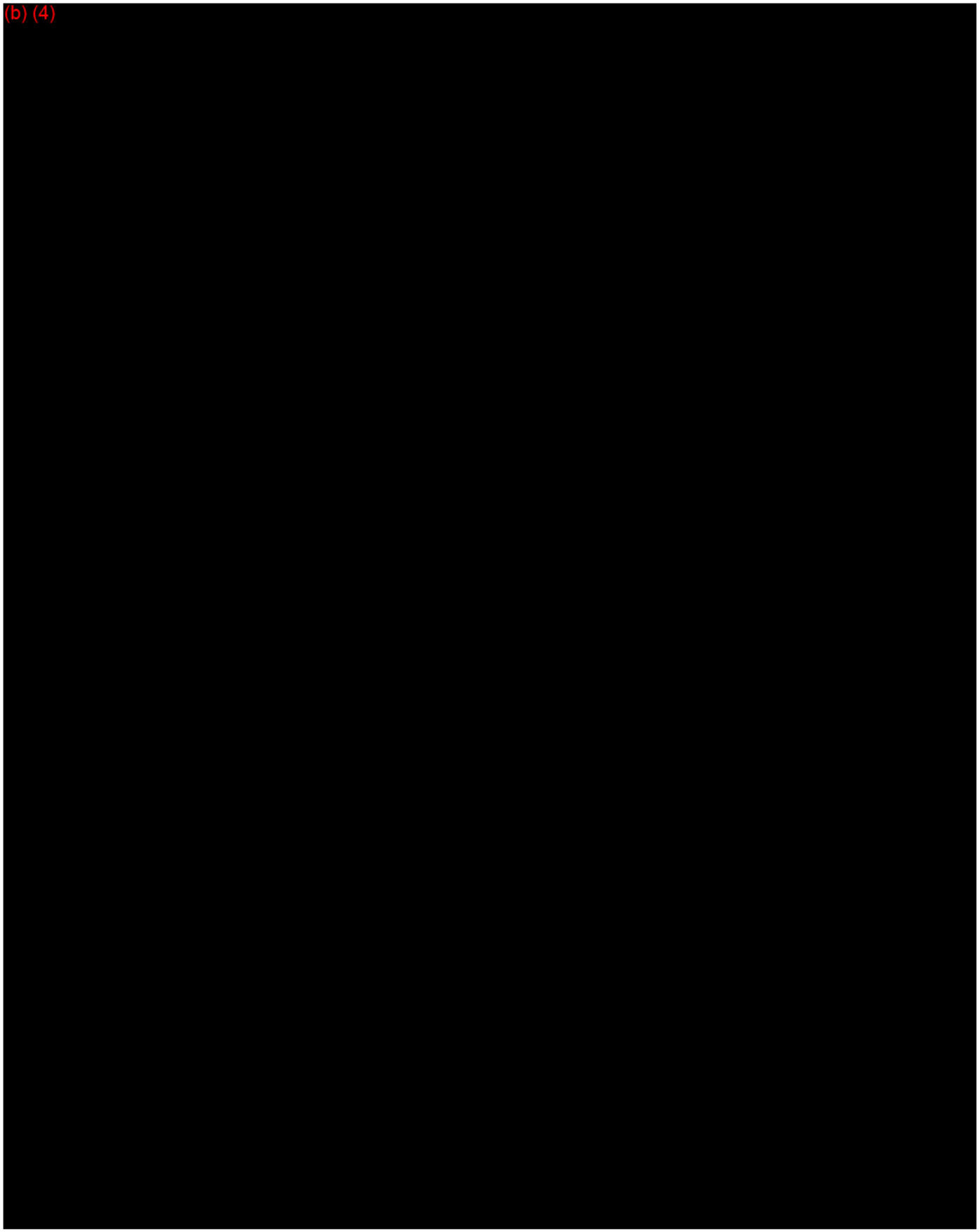

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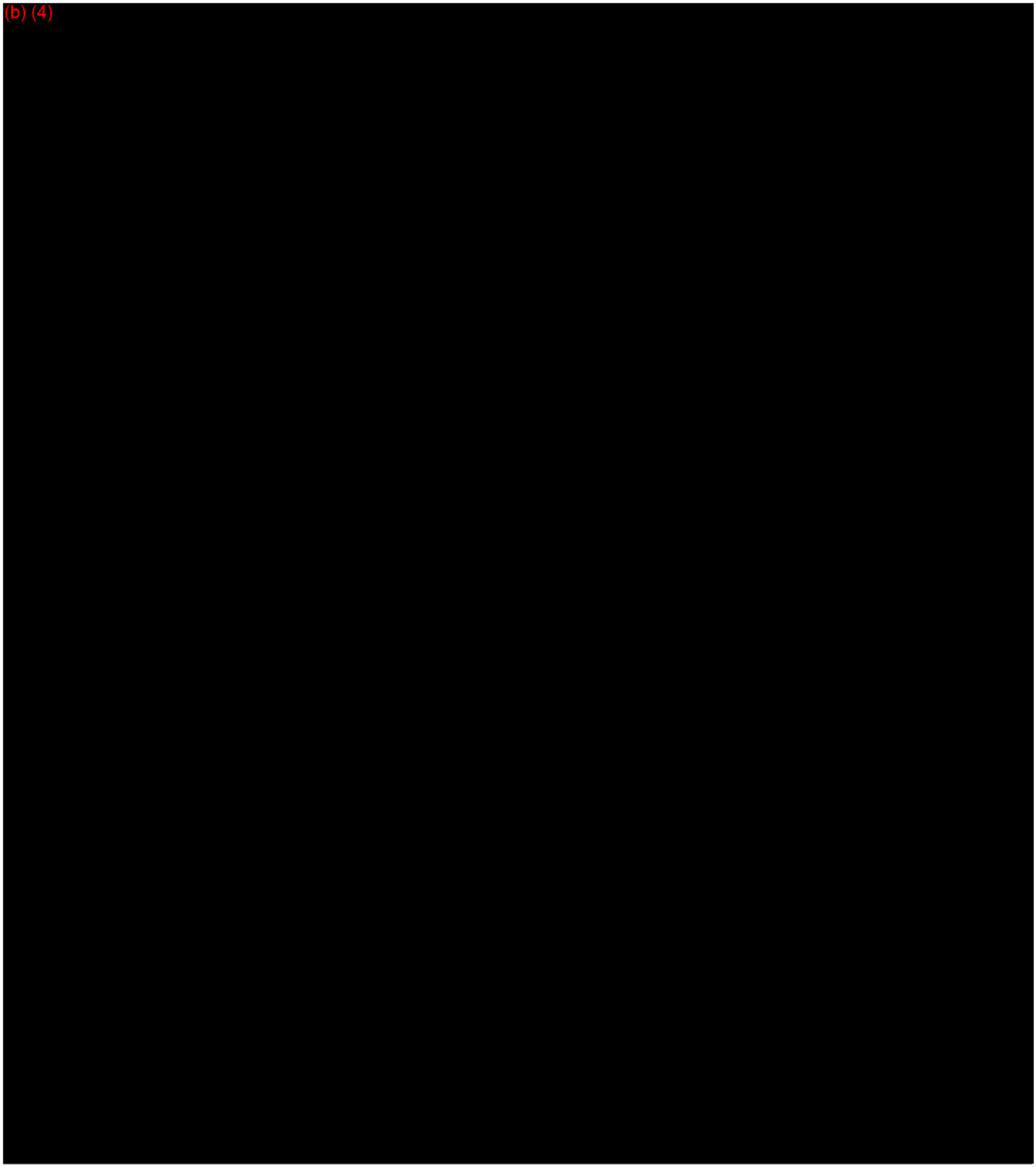

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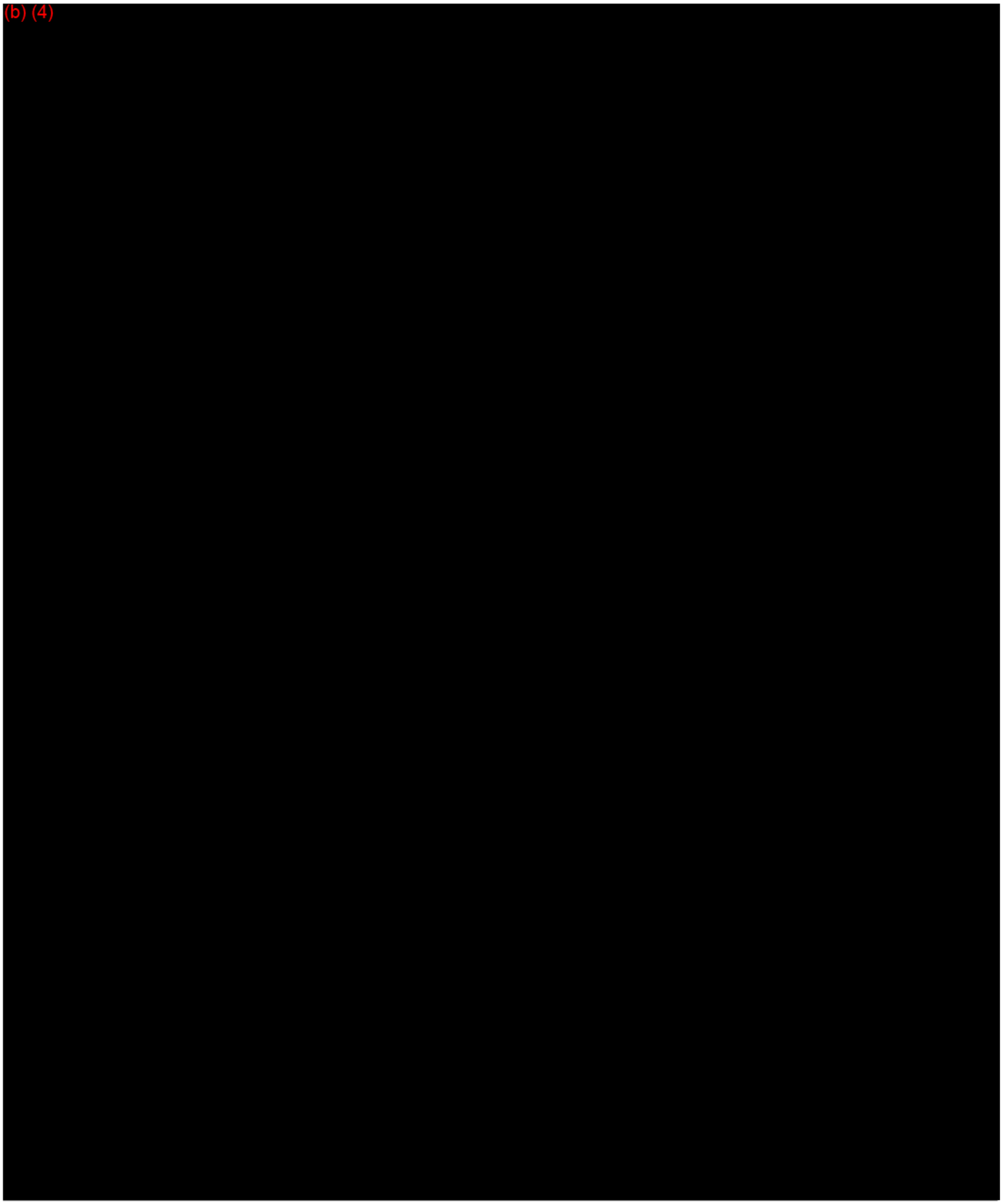
(b) (4)



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resolution MD

Chapter

4 Installing the ResolutionMD Server

This section provides detailed information about installing the server. It includes information about installing the fonts library, the Graphics Processor Unit (GPU) driver, PureWeb, and plugins.

This chapter contains the following sections:

- Server Installation, page 42

Server Installation

When you execute the ResMDInstall.sh script, it performs the following procedure. You only need to perform the steps in the"Installing the ResolutionMD Server" procedure, if you plan to do a manual install.

Installing the ResolutionMD Server

Purpose: To install the ResolutionMD Server.

Prerequisites

- The information required to install the ResolutionMD Server must be complete in the Chapter 11, "Site Survey," on page 84.

Start of procedure

Warning! Before editing files, you should make a copy of the original using the following command: cp -p <filename> <filename>.ORIG.

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Note: Filenames in this document may differ from the files you are provided. Please substitute the actual filenames wherever necessary.

Warning! Executing the init 3 command in step 1 of this procedure will disable the desktop GUI on the next reboot of the server.

1. Change the System run level from 5 to 3 by running the following command:
   sed -i 's/id:5:initdefault:/id:3:initdefault:/g' /etc/inittab
2. Unpack the ResMD-vX.X.X-yyyymmdd.tar.gz or the ResMD-vX.X.X-yyyymmdd.zip file.

Example:

tar -xzvf ResMD-vX.X.X-yyymmdd.tar.gz or unzip ResMD-vX.X.X-yyyymmdd.zip

This creates the following directory structure:

/Server

/Scripts

/Dependencies

3. Install the correct Java Development Kit (JDK) using the following procedure.
   a. In a terminal window, navigate to the /Dependencies/ directory.
   b. Type in sh jdk-6u6-linux-x64-rpm.bin
   c. Type yes to all prompts that follow.
4. Install the correct fonts libraries using the following procedure.
   a. In a terminal window, navigate to the /Dependencies/ directory.
   b. Type in rpm -Uvh xorg-x11-fonts-ISO8859-15-75dpi-7.1-2.1.el5.noarch.rpm
   c. Type in rpm -Uvh xorg-x11-fonts-ISO8859-15-100dpi-7.1-2.1.el5.noarch.rpm.\
5. Install the correct GPU driver using the following procedure.
   a. In a terminal window, run init 3 from the command prompt.
   b. Navigate to the /Dependencies/ directory.

Warning! The commands in the next step are subject to change.

   c. Type in sh NVIDIA-Linux-x86_64-180.51-pkg2.run
   or
   NVIDIA-Linux-x86_64-260.19.36.run for a Q6000 GPU.
      i. Tab until Accept is highlighted in the License Agreement, and press Enter.

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ii. If prompted to uninstall the current driver, highlight Yes, and press Enter.

iii. When prompted for the precompiled kernel interface, highlight Yes, and press Enter.

iv. At the No matching precompiled kernel interface warning, highlight OK, and press Enter.

v. Highlight Yes, and press Enter to install the NVIDIA's 32-bit Compatibility OpenGL Library.

vi. At any warning messages, highlight OK, and press Enter.

vii. When prompted to run the nvidia-config utility, highlight No, and press Enter.

viii. Highlight OK, and press Enter at the update complete message.

6. Edit the /etc/pam.d/xserver file, so that it looks like Figure 34 by using the following commands:

   sed -i 's/required/sufficient/g' /etc/pam.d/xserver

   sed -i 's/pam_console/pam_permit/g' /etc/pam.d/xserver

```
#%PAM-1.0
auth        sufficient  pam_rootok.so
#auth       optional    pam_console.so
#auth       optional    pam_self.so
auth        sufficient  pam_permit.so
account     sufficient  pam_permit.so
session     optional    pam_keyinit.so force revoke
```

Figure 34: PAM 1.0

7. Install PureWeb and plugins using the following procedure:
   a. Stop Existing Services by typing the following:

      service pureweb stop

   b. Install the ResolutionMD Server application by performing the following steps:
      i. Navigate to the /Server directory and run the following commands:

         rpm -Uvh pureweb-server-2.x.y-z.noarch.rpm

         rpm -Uvh pureweb-resmd-plugin-2.x.y-z.x86_64.rpm

         rpm -Uvh pureweb-dicomgr-plugin-2.x.y-z.noarch.rpm.

         chkconfig -level 3 pureweb on

8. Update the xorg.conf file to configure the XServer using the following steps.
   a. Navigate to the /Scripts directory.
   b. Run the XorgConfigure.pl command.
9. Set Hostname by editing the following files.
   a. Edit the /etc/sysconfig/network file to set a suitable hostname.

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b. Edit the /etc/hosts the to add the hostname as a loopback alias.

10. Start the PureWeb Service by typing service pureweb start.

End of procedure

Next Steps

- After completing the ResolutionMD Server installation, you should configure your server by following the procedures in Chapter 7, "Configuring the ResolutionMD Server," on page 50.

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resolution MD

Chapter

5 Upgrading the ResolutionMD Server

This section provides detailed information about upgrading the server.

This chapter contains the following sections:

• Upgrading your Existing ResolutionMD Server, page 46

Upgrading your Existing ResolutionMD Server

Upgrading the ResolutionMD Server

Purpose: To upgrade an existing ResolutionMD Server.

Prerequisites

- The information required to upgrade the ResolutionMD Server must be complete in the Chapter 11, “Site Survey,” on page 84.

Start of procedure

Note: Filenames in this document may differ from the files you are provided. Please substitute the actual filenames wherever necessary.

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1. Copy the ResMD-vX.X.X-yyymmdd.tar.gz or ResMD-vX.X.X-yyyymmdd.zip to the /root directory:

   Server credentials:

   Login: root.

   Password:

2. Use tar -xzvf ResMD-vX.X.X-yyymmdd.tar.gz or unzip ResMD-vX.X.X-yyyymmdd.zip.

   This creates the following directory structure:

   /Server

   /Scripts

   /Dependencies

3. Install the correct fonts libraries using the following procedure.
   a. Browse to the /Dependencies/ directory.
   b. Type in rpm -Uvh xorg-x11-fonts-ISO8859-15-75dpi-7.1-2.1.el5.noarch.rpm
   c. Type in rpm -Uvh xorg-x11-fonts-ISO8859-15-100dpi-7.1-2.1.el5.noarch.rpm
4. Install the build and set the service to autostart with the following commands.
   a. service pureweb stop.
   b. cd /root/ResMD-XXX/Server.
   c. rpm -Uvh pureweb-server-x.y.z-XXXXX.x86_64.rpm
   d. rpm -Uvh pureweb-dicomqr-plugin-2.x.y-z.noarch.rpm
   e. rpm -Uvh pureweb-resmd-plugin-2.x.y-z.noarch.rpm
   f. chkconfig -level 3 pureweb on
5. Start the PureWeb Service by typing service pureweb start.

End of procedure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Chapter

6 Monitoring the ResolutionMD Server

This chapter contains information about the server's monitoring features.

This chapter contains the following sections:

- Monitoring the Server, page 48
- Status Information, page 48
- Server Versions, page 49
- System Information, page 49

Monitoring the Server

Several aspects of the server can me monitored from the administrative pages including:

- "Status Information"
- "Server Versions"
- "System Information"

Status Information

The status page can be accessed at http://<hostname>:8080/pureweb/server/status. The status page details the status of the system, including the number of current users, GPU type, and driver version.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Server Versions

The version details page can be accessed at http://<hostname>:8080/pureweb/server/info or by clicking the Version link on the main status page. The page includes detailed information about your version of the server.

System Information

The server logs page can be accessed at http://<hostname>:8080/pureweb/server/logs or by clicking the Logs link on the main status page. The page includes links to current and archived log files. The current logs can be viewed directly and the compressed archived logs can be downloaded for offline examination.

A list of the location of each log file and its contents is described in Table 20, “Server Log Files,” on page 65.

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Chapter

7 Configuring the ResolutionMD Server

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Pages 96-108 whole page b4

Pages 96-108 whole page b4

Pages 96-108 whole page b4

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Pages 96-108 whole page b4

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Chapter

8 Server Logging Information

(b) (4)

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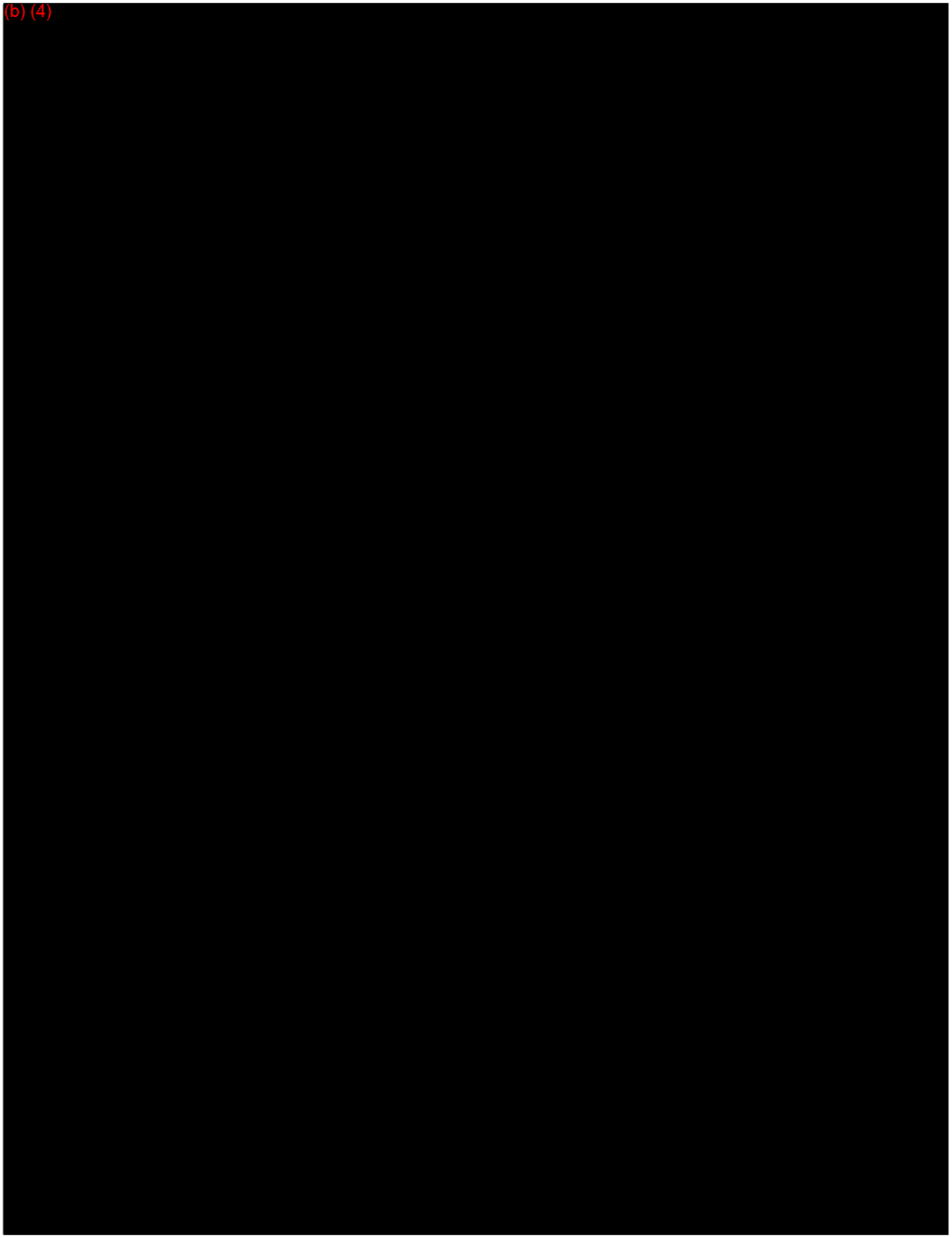

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Chapter

9 Verifying the Installation

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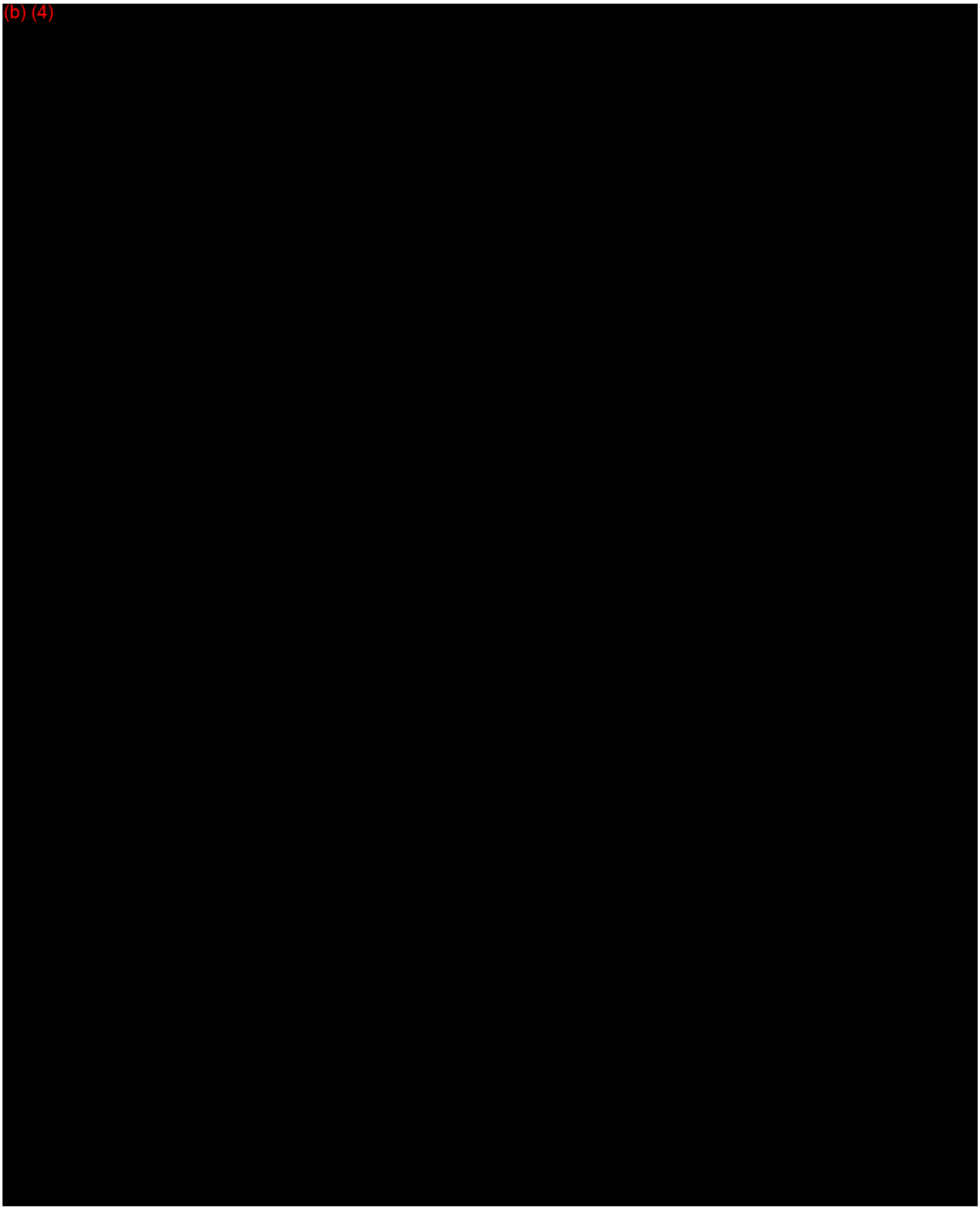

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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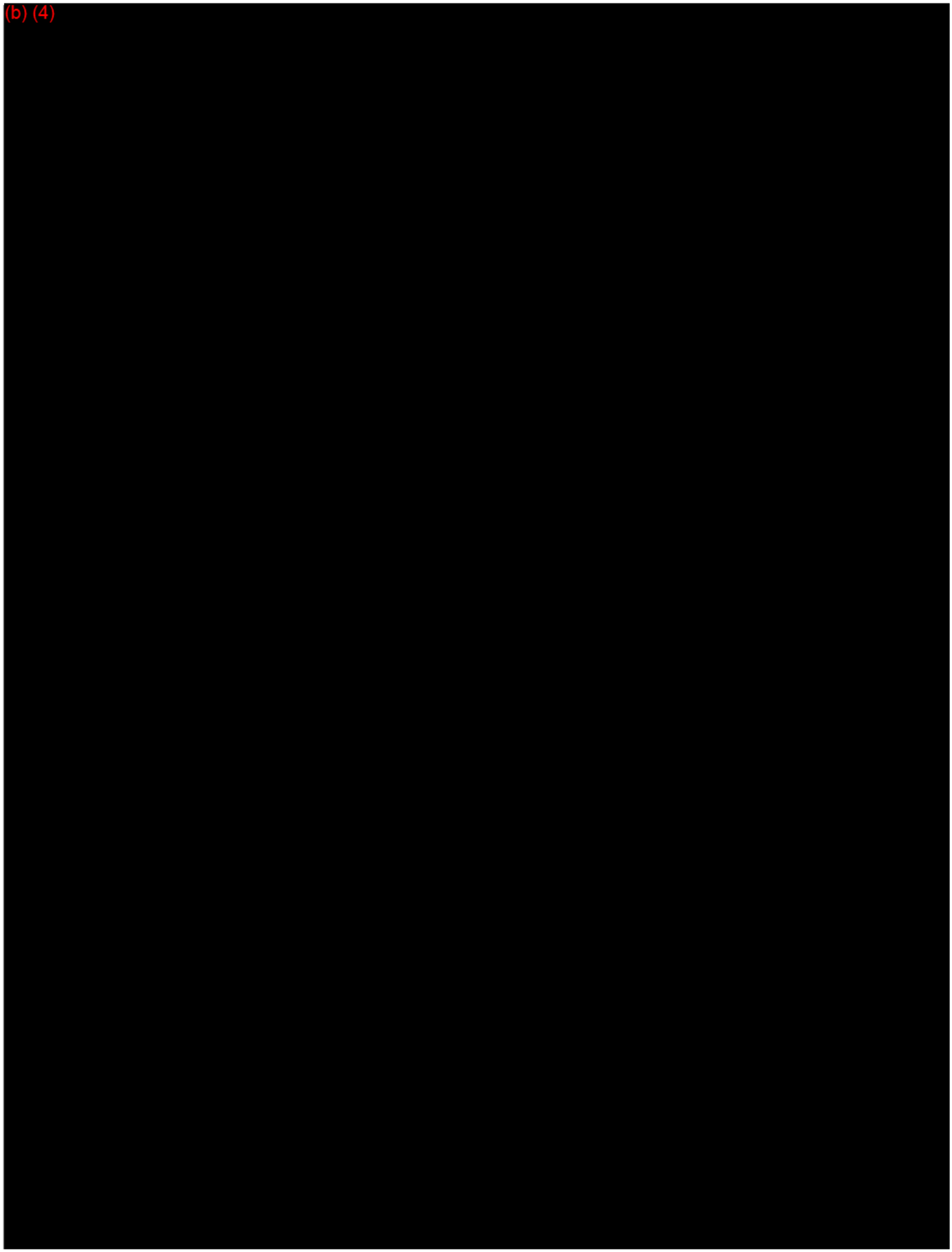

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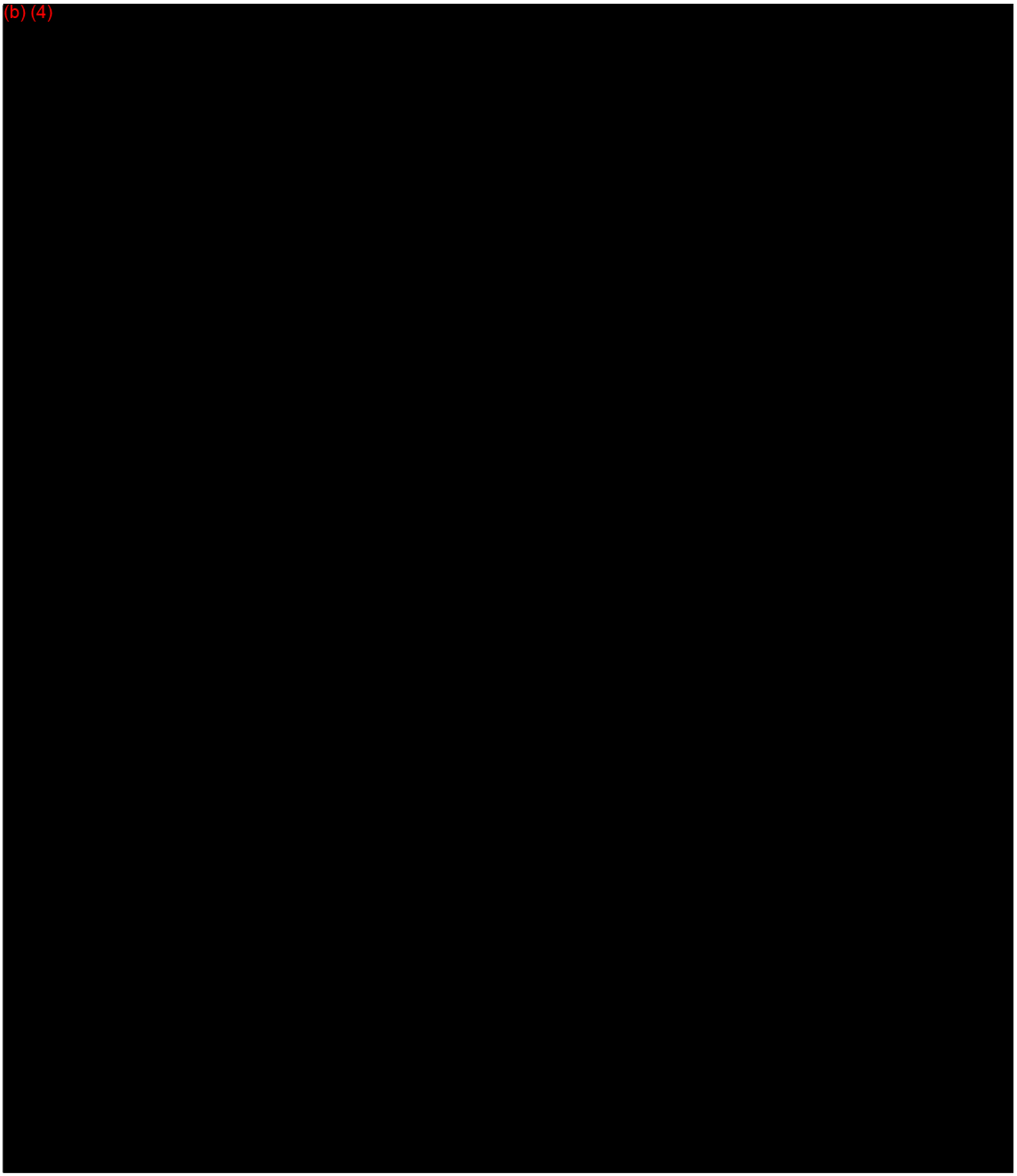

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Chapter

10 Technical Support

This section provides detailed information about accessing technical support for this product.

This chapter contains the following sections:

- The Troubleshooting Support Site, page 70
- The Support Script, page 74
- General Application Troubleshooting, page 77
- The ResolutionMD Salesforce Portal, page 81

The Troubleshooting Support Site

Support teams use the ResolutionMD Troubleshooting Support Site to troubleshoot and resolve issues before reporting them to Calgary Scientific.

Accessing the Troubleshooting Support Site

To access the troubleshooting support site:

1. Open a browser.
2. Navigate to http://calgaryscientific.onconfluence.com.
3. Enter resmd/Calgary as the Username/Password.

In the event that you cannot access the support site, you can email the support site administrator at systems@calgaryscientific.com or contact us by telephone at (403) 270-7159.

Our hours of operation are 9:00AM - 5:00PM, Monday - Friday (Mountain Standard Time).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Using the Troubleshooting Support Site

1. Open a browser.
2. Navigate to http://calgaryscientific.onconfluence.com.
3. Enter resmd/Calgary as the Username/Password.

Figure 40: Support Site Log In Page

4. Click Log In to display the Dashboard.

   The Dashboard contains quick links to popular content and access to your favorite pages. It also has a link to the support space that contains all of the support content to help you find a solution to your problem. You may also use the search functionality to find solutions even quicker.

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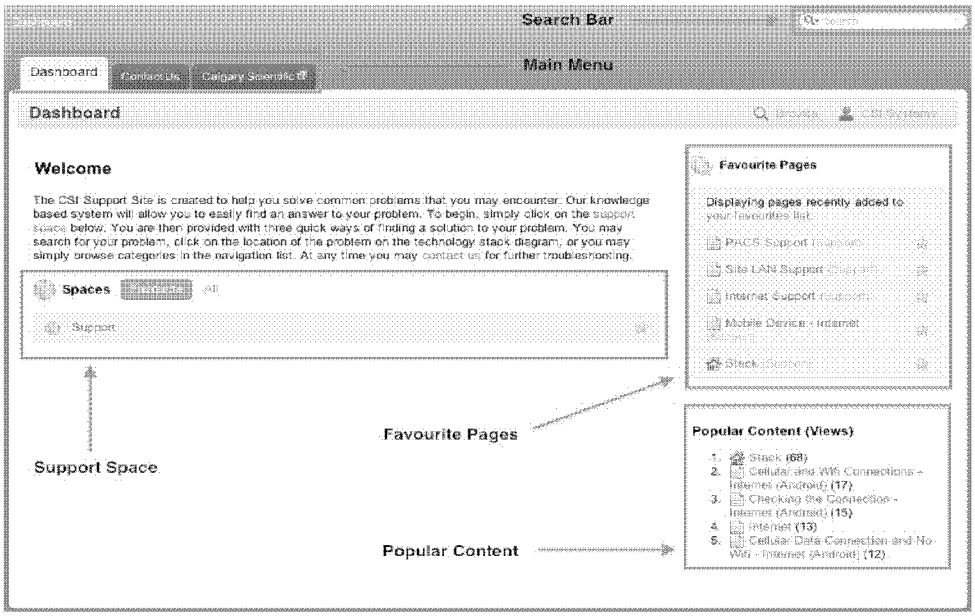

Figure 41: Support Site Dashboard

Tip: You can return to your Dashboard at any time by clicking the Dashboard tab located in the Main Menu.

To help find the solution to your problem as quickly as possible, there are three ways to navigate in the Support Site:

- Using "The Technology Stack" on page 72.
- Using "The Page Tree Panel" on page 73.
- Using "The Search Field" on page 74.

The Technology Stack

Click Support on the Dashboard to display the Technology Stack page.

The Technology Stack depicts our product's architecture. Click on any component in the Technology Stack to access support information specific to that component.

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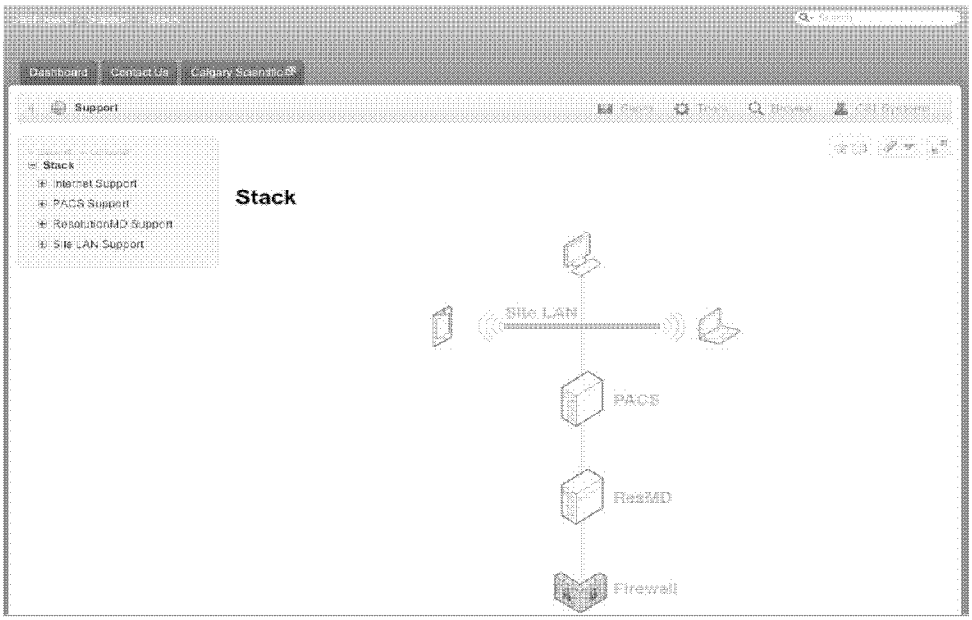

Figure 42: Technology Stack

Tip: Use the Technology Stack to help isolate the location of the problem.

The Page Tree Panel

Every page in the Support Site contains a Page Tree Panel.

Click on a topic in the Page Tree Panel to navigate to the support information about that specific topic.

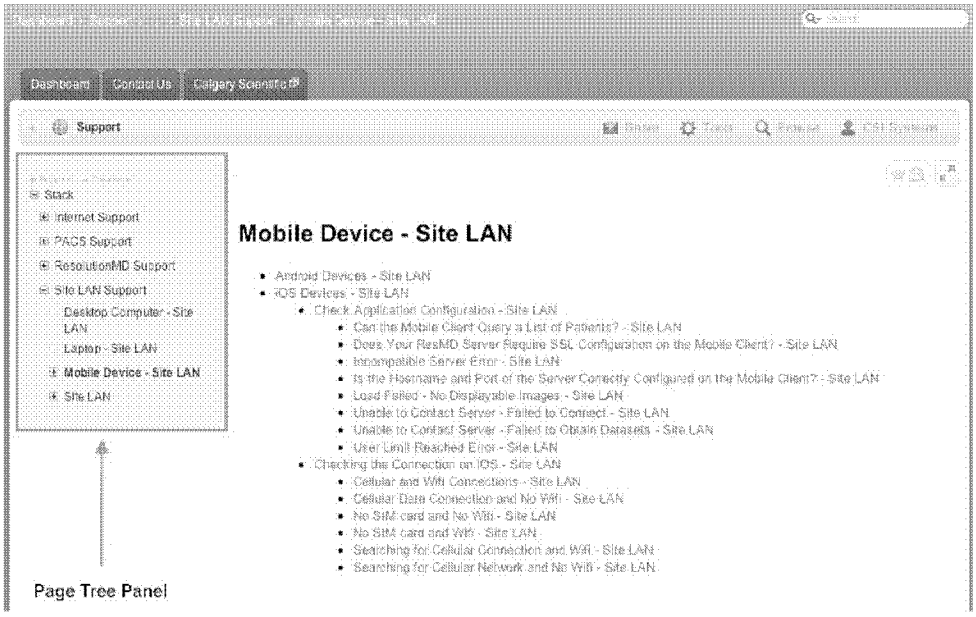

Figure 43: Page Tree Panel

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The Search Field

Every page in the Support Site contains a Search Field.

Type in keywords to display a list of pages that contain content specific to your problem.

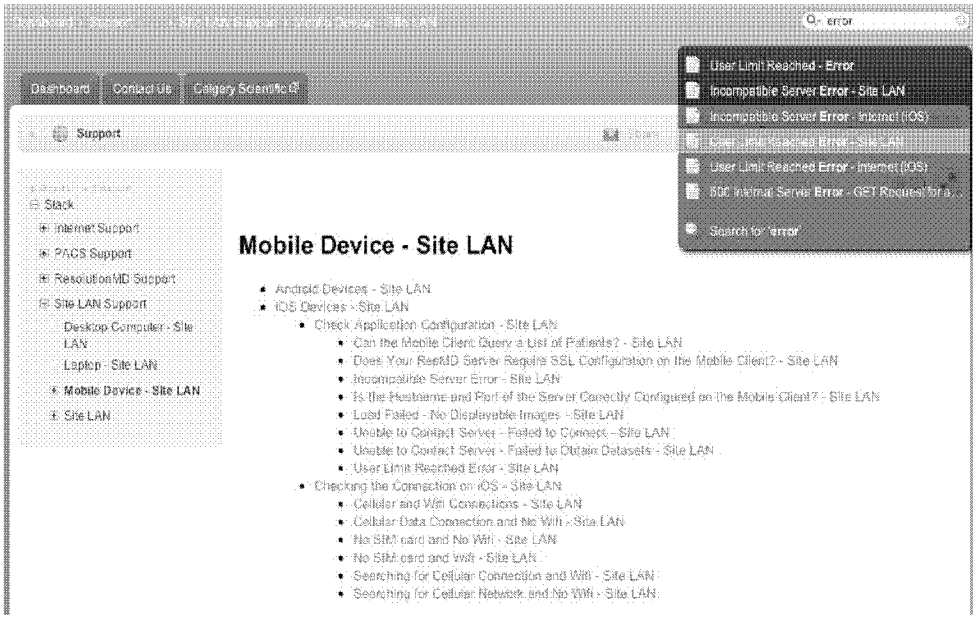

Figure 44: Search Field

The Support Script

Support teams use the ResolutionMD Support Script to generate log files. They analyze these log files to troubleshoot and resolve issues.

Using the Support Script

Purpose: To use the support script to generate a log file.

Start of procedure

1. Navigate to the /Scripts directory on your ResolutionMD Server.
2. Run sh SystemTest.sh.

Figure 45: SystemTest.sh

3. Press the Q key to exit after the script is finished.

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The script will create a log file and display the filename on the screen.

Figure 46: Create and Display Log File

4. Transfer the log file to your computer by "Using an FTP Client" on page 75 or "Using a Terminal" on page 76.
5. Attach the log file to an email and send it to the contact center.

End of procedure

Using an FTP Client

Purpose: To use an FTP client to transfer a log file to your computer.

Start of procedure

Note: In this example we use Cyberduck.

1. Open Cyberduck and click Open Connection.

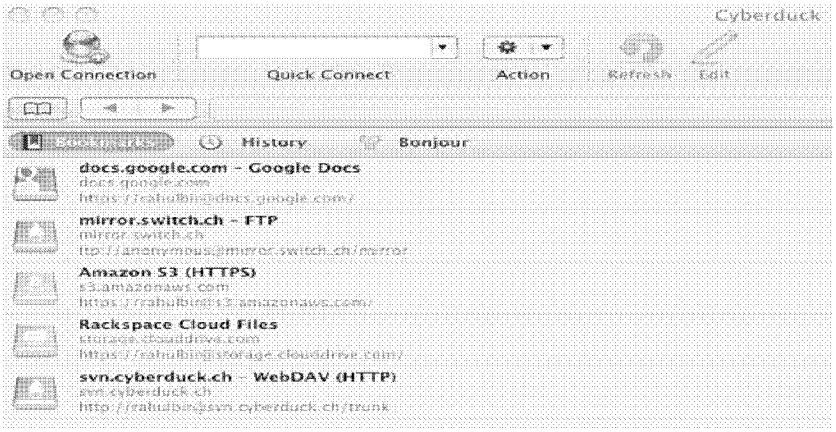

Figure 47: Open Cyberduck

2. Type in your credentials.
3. In the drop down menu, change the type to SFTP.
4. Click Connect.

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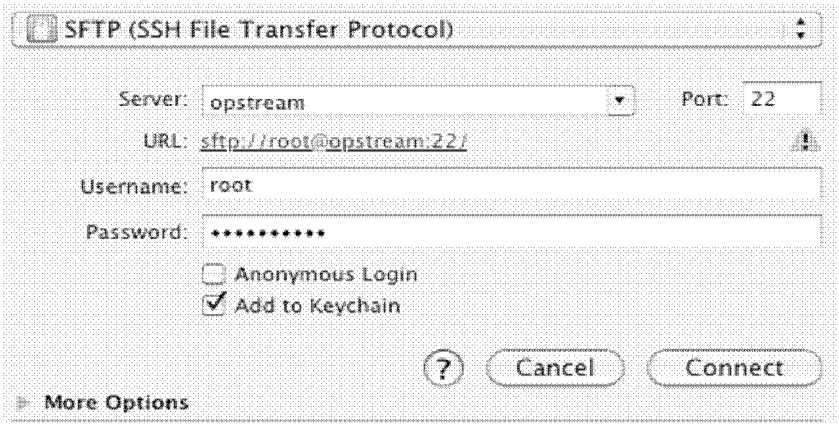

Figure 48: Select FTP Options

5. Navigate to the tools directory and locate the file the script created.

Figure 49: Locate the Log File

6. Right-click on the log file and click Download.

End of procedure

Next Steps

- Return to Step 5 of the "Using the Support Script" procedure.

Using a Terminal

Purpose: To use a terminal to transfer a log file to your computer.

Start of procedure

1. Type the following command:

   scp <Filename> <user>@<hostname or IP>:/<directory>.

   Example: system_test_2011-04-15-1020 root@10.1.10.123:/User/admin/.

End of procedure

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Next Steps

- Return to Step 5 of the "Using the Support Script" procedure.

General Application Troubleshooting

Client Issues

Bad Connection

If you are experiencing problems with your Apple iPhone, examine the connection scenarios below to solve your issue.

Case 1: Both a cellular data connection and a Wi-Fi connection are established.

- The application will function under these conditions.

Case 2: A cellular data connection exists, but no Wi-Fi connection.

- The application will function under these conditions.

Case 3: A Wi-Fi connection exist, but a subscriber identity module (SIM) card is not installed.

- The application will function under these conditions.

Case 4: Searching for a cellular data connection when a Wi-Fi connection is established.

- The application will function under these conditions.

Case 5: Searching for cellular network without a Wi-Fi connection established.

- The application will not function under these conditions.

Solution:

- Allow the device time to connect to the cellular provider.

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- Connect to a Wi-Fi network.

Case 6: A Wi-Fi connection is not established and a SIM card is not installed.

No SIM

- The application will not function under these conditions.

Solution:

- Ensure the device is on a Wi-Fi network.
- Insert a SIM card or reseat the SIM card.

Bad Configuration

If you are experiencing problems with your mobile client, ensure that your server credentials are configured correctly on your mobile device.

- Ensure that the hostname is correct.
- Ensure that your port is correct.
- If your server requires SSL, ensure SSL is ON and use port 8443 instead of 8080.

Figure 50: Mobile Device Configuration

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Bad Username/Password

1. Ensure that your ResolutionMD plugin is configured to talk to the authentication webservice, knows the hostname/IP of the ResolutionMD Server, and has access to a username and password from the ResolutionMD user management system.
2. Navigate to http://<hostname>:8080/pureweb/server/status.
3. Enter a user/password from a defined user in the system.

   If access is granted to the ResolutionMD status page then authentication is working.

No Images

If you are not able to load or view any images on your mobile client, ensure that the following are configured correctly:

- The back association to the ResMD server is correctly configured.
- Your PACS system is configured correctly with the ResMD server.
- Recent Studies on your mobile device is correctly turned on or off.
- The PACS system has data.

Note: For more information refer to Chapter 4, "Installing the ResolutionMD Server," on page 42.

No Reports

If you are unable to load reports, see the troubleshooting details below:

1. Retrieve an Accession Number/ Exam ID of a recent exam that has a report.
2. Construct the following URL to test report access: http://<hostname>:8080/pureweb/resmd/report/<accessionNumber>.

Server Issues

Bad Configuration Dicom

1. Navigate to http://<hostname>:8080/pureweb/config/plugins.
2. Click on the link to open the dicomqr-plugin.properties file.
3. Verify that the dicomqr.query.address property value has the correct AET, IP, and port number.

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4. Verify that the dicomqr.storage.address property value has the correct AET, IP, and port number.

```
################################################################################
### Dicom Q/R config
################################################################################
# The address of the Storage SCP in the form of <ae-title>@<host>:<port>.
# The plugin will issue C-FIND and C-MOVE requests to this address.

dicomqr.query.address=<AE Title>@10.1.20.151:104

# The address of the Storage SCU in the form of <ae-title>@<host>:<port>.
# This is the address that the plugin will listen for storage requests resulting from a C-MOVE.

dicomqr.storage.address=<AET Title>@0.0.0.0:11117
```

If the solution above does not work, make sure the back association is configured correctly.

Note: For more information refer to Chapter 4, "Installing the ResolutionMD Server," on page 42.

Bad Configuration Reports

1. Add the ResolutionMD Server as a node in the system.
2. Configure the ResolutionMD plugin to access the IMS database.
3. Using a ResolutionMD workstation, retrieve the Accession Number or Exam ID of a recent exam that has a report.
4. Construct the following URL to test report access: http://<hostname>:8080/pureweb/resmd/report/<accessionNumber>.

Bad Configuration Authentication

1. Ensure that your ResolutionMD plugin is configured to talk to the authentication webservice, knows the hostname/IP of the ResolutionMD Server, and has access to a username and password from the ResolutionMD user management system.
2. Navigate to http://<hostname>:8080/pureweb/server/status.
3. Enter a user/password from a defined user in the system.

If access is granted to the ResolutionMD status page then authentication is working.

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The ResolutionMD Salesforce Portal

Support teams use the ResolutionMD Salesforce Portal to check the status of issues that they have reported to Calgary Scientific. The ResolutionMD support portal is always available anywhere that you have internet access.

Accessing the Portal

To access the portal:

1. Open a browser.
2. Navigate to https://na1.salesforce.com/secur/login_portal.jsp?orgId=00D30000000iYxE&portalId=06030000000ZMUc.
3. Enter your Username/Password.

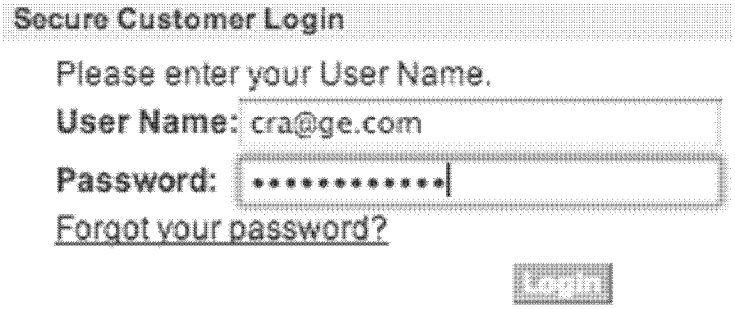

Figure 51: Portal User Name and Password

Using the Portal

1. Open a browser.
2. Navigate to https://na1.salesforce.com/secur/login_portal.jsp?orgId=00D30000000iYxE&portalId=06030000000ZMUc.
3. Enter your Username/Password.
4. Click Login to display the Home page.

   On the Home page, you can check the status of cases (open support issues), browse any posted solutions or announcements, and see any newly posted documents.

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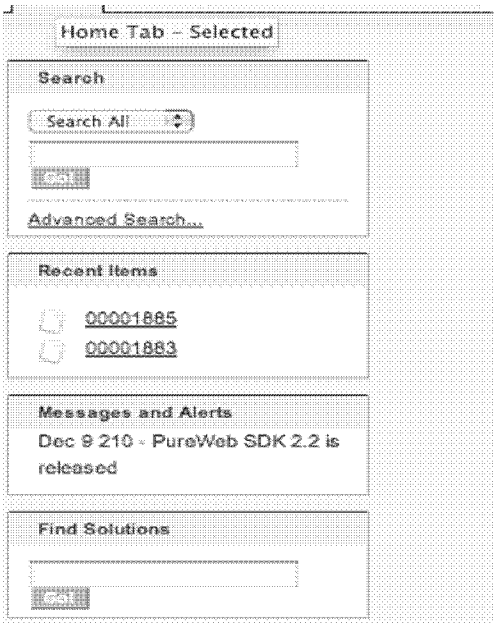

Figure 52: Portal Home

5. Click on the Cases tab to open the Cases Home page.

   This page displays a list of open cases. The External Reference Number represents the ResMD Dispatch Number.

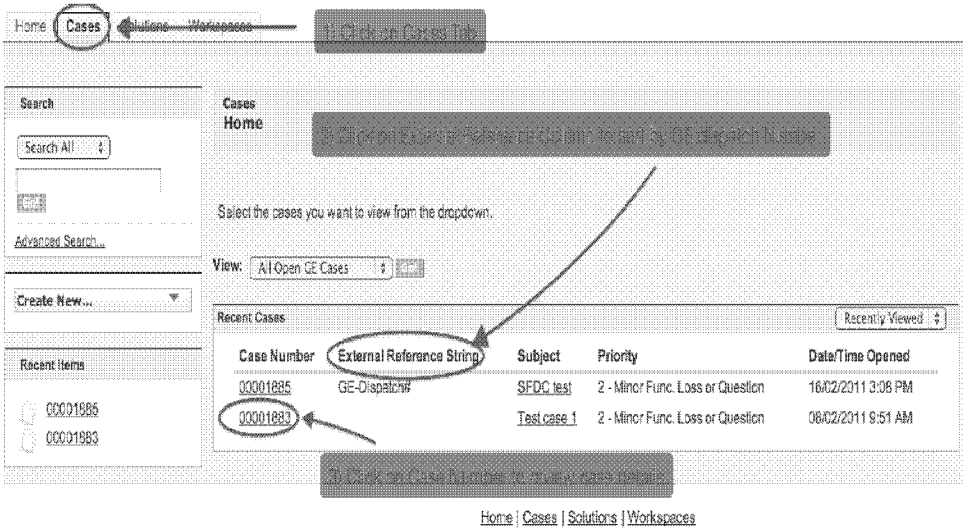

Figure 53: Case Tab View

6. Click on the Case Number to review the Case details.

   On the Case Details page, the support team can review the status, add comments and attach files to an open case.

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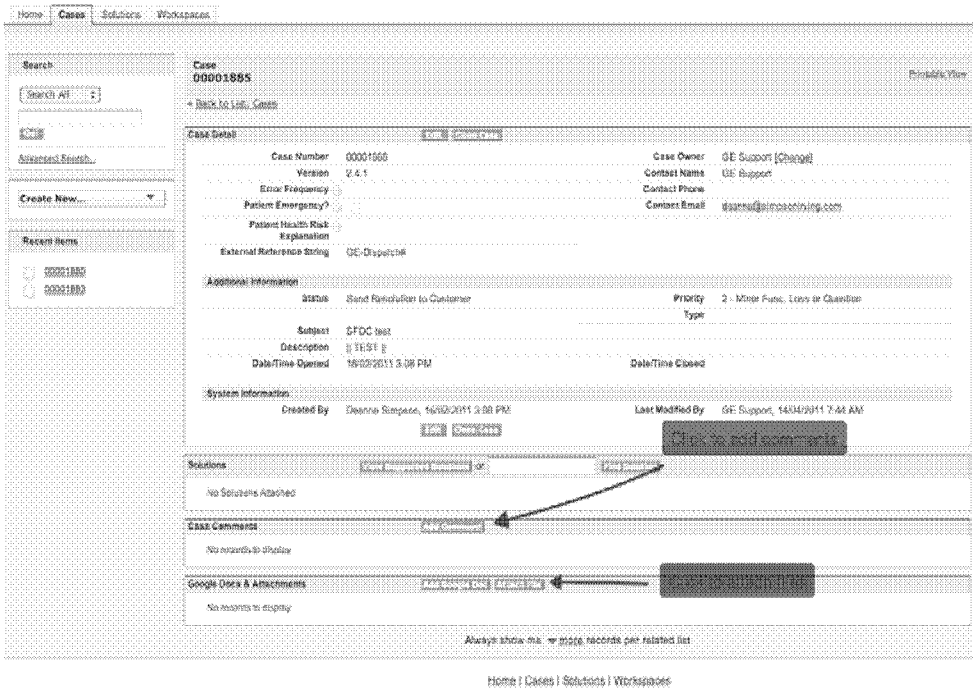

Figure 54: A Case

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resolution MD

Chapter

11 Site Survey

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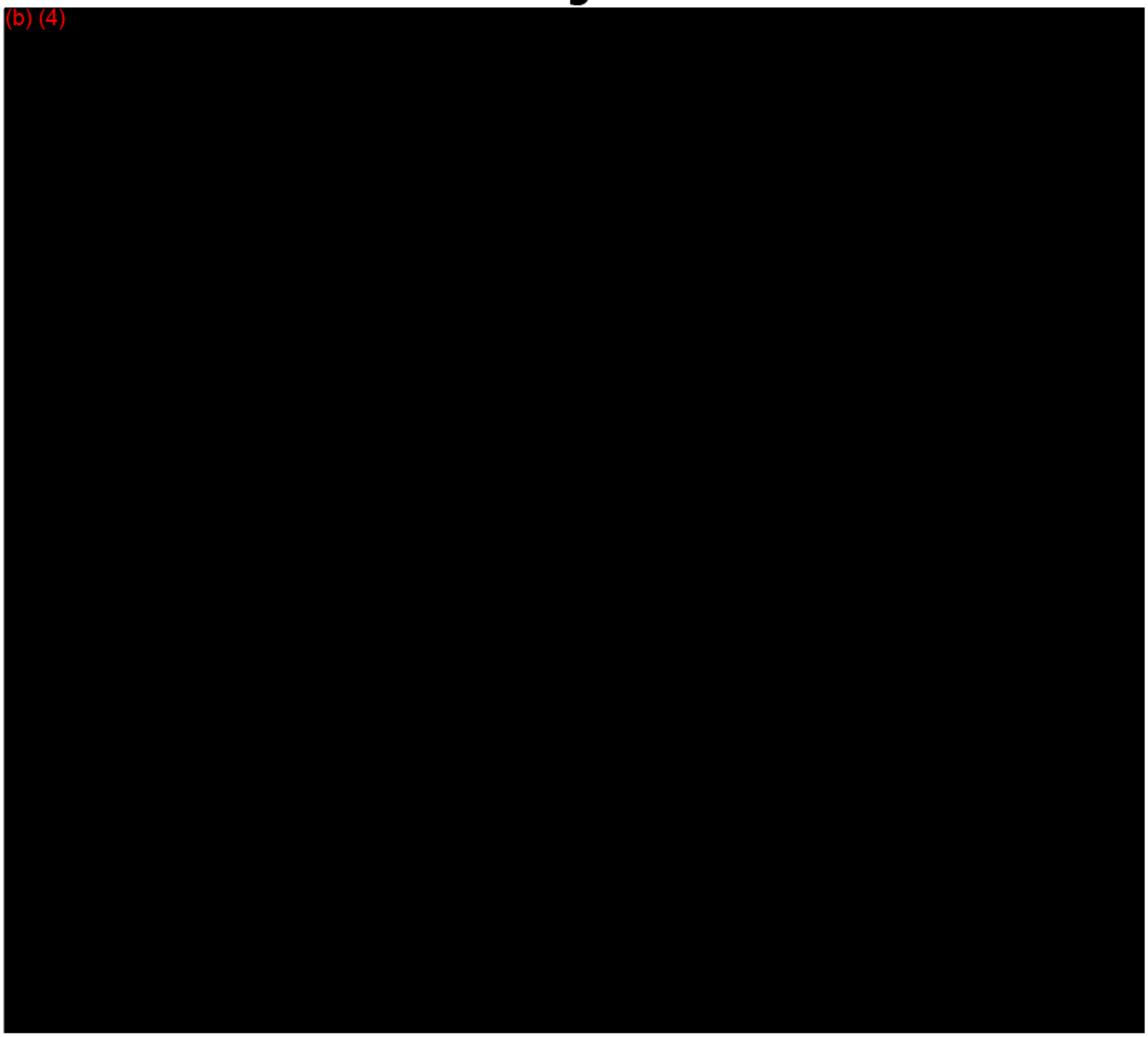

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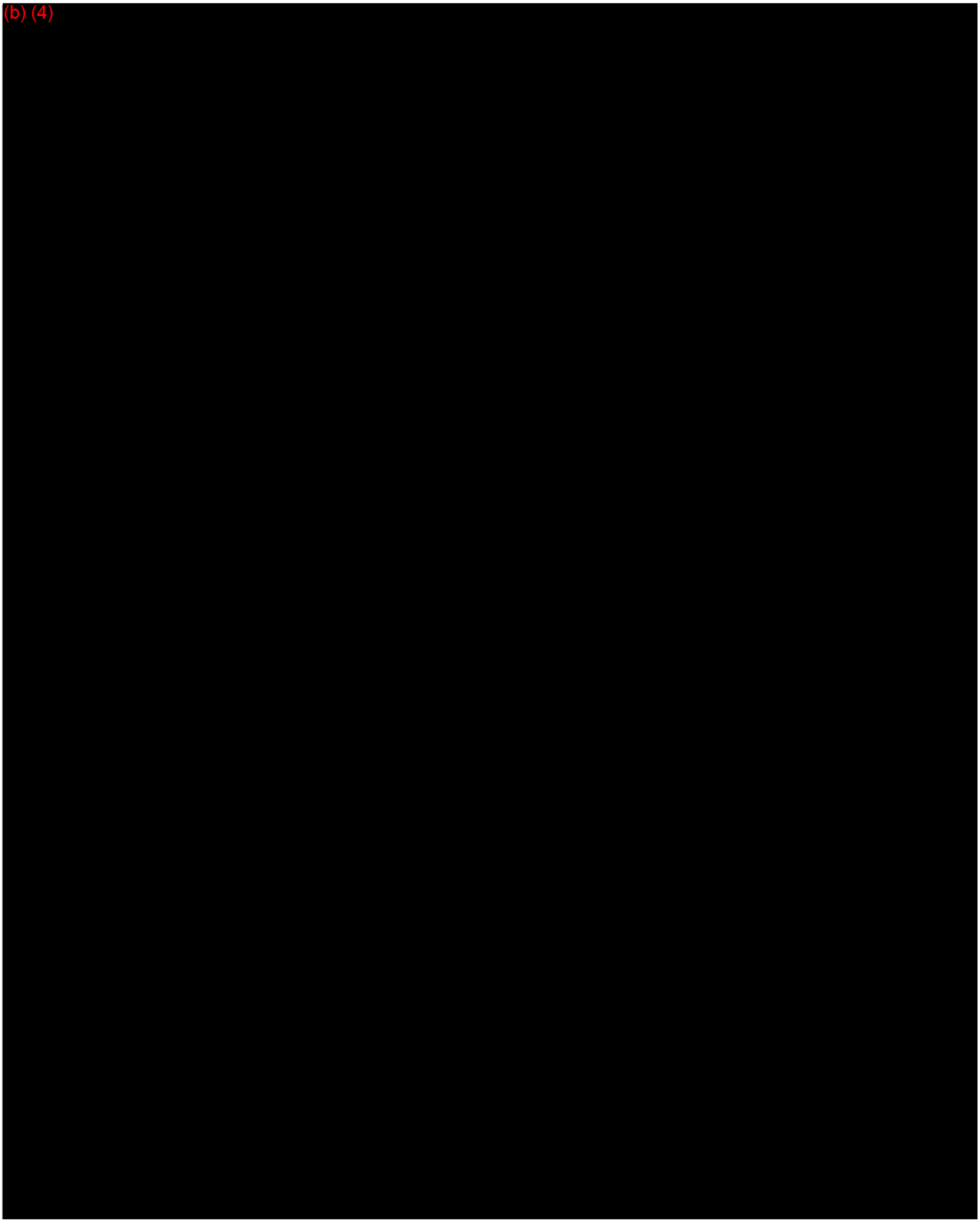

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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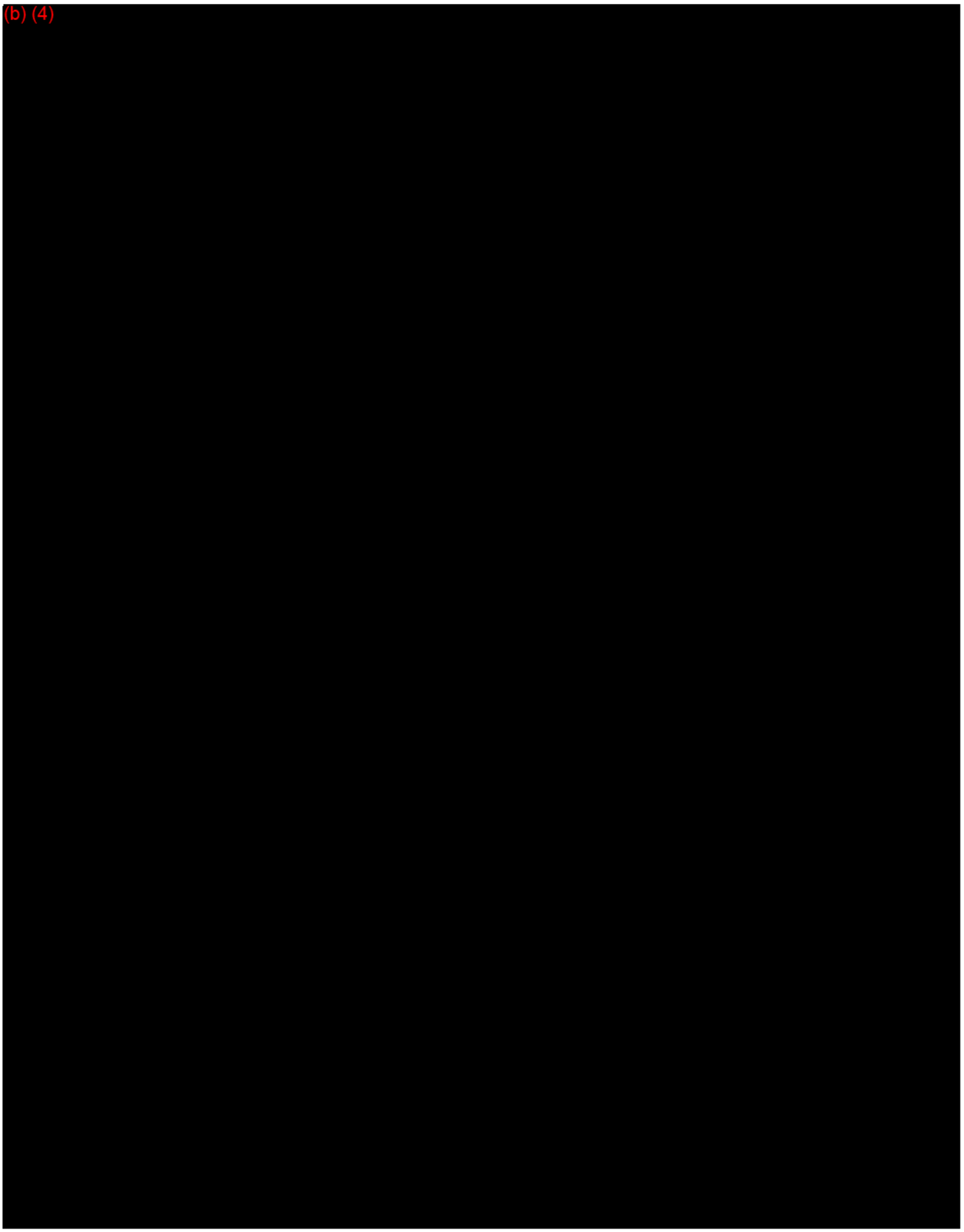

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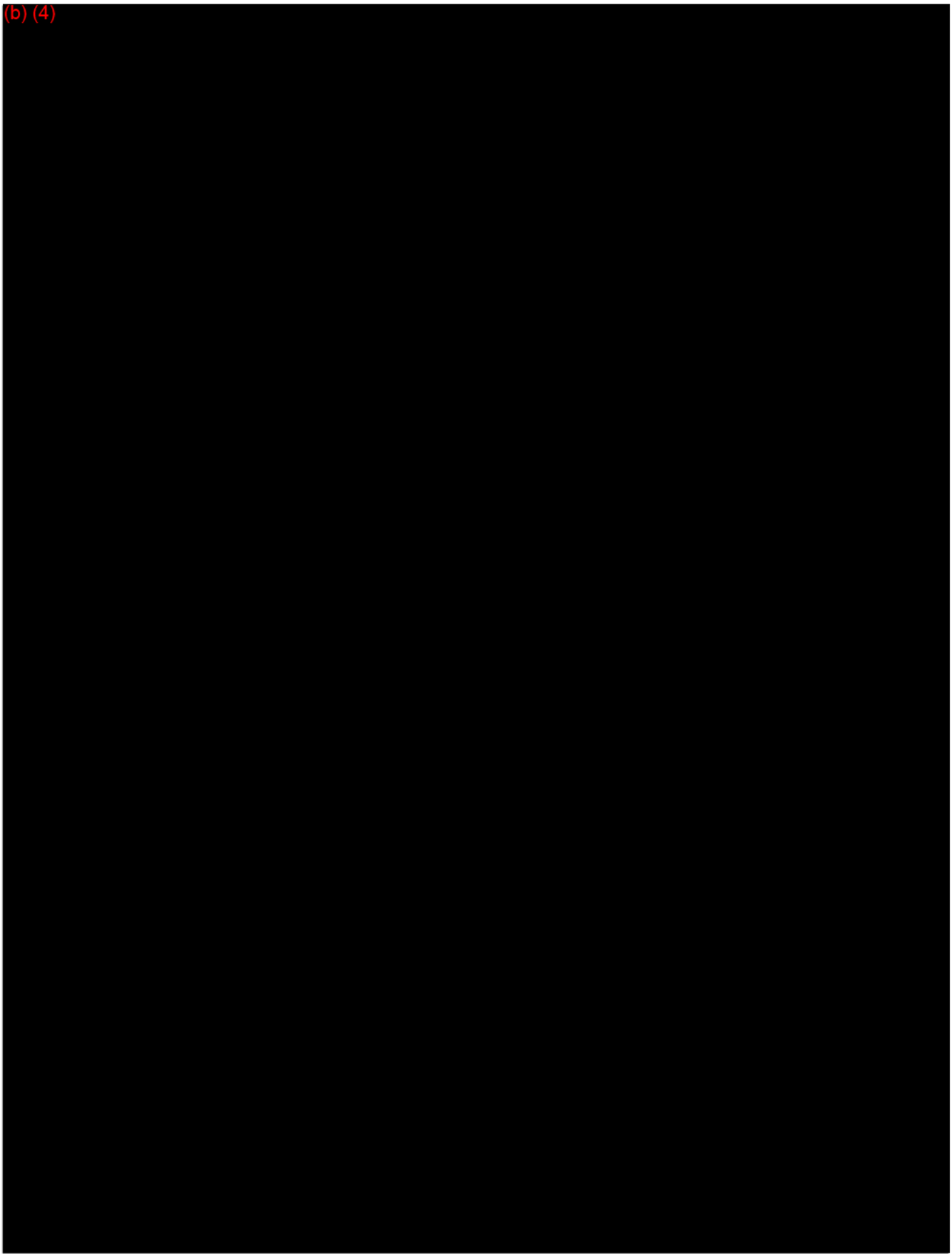

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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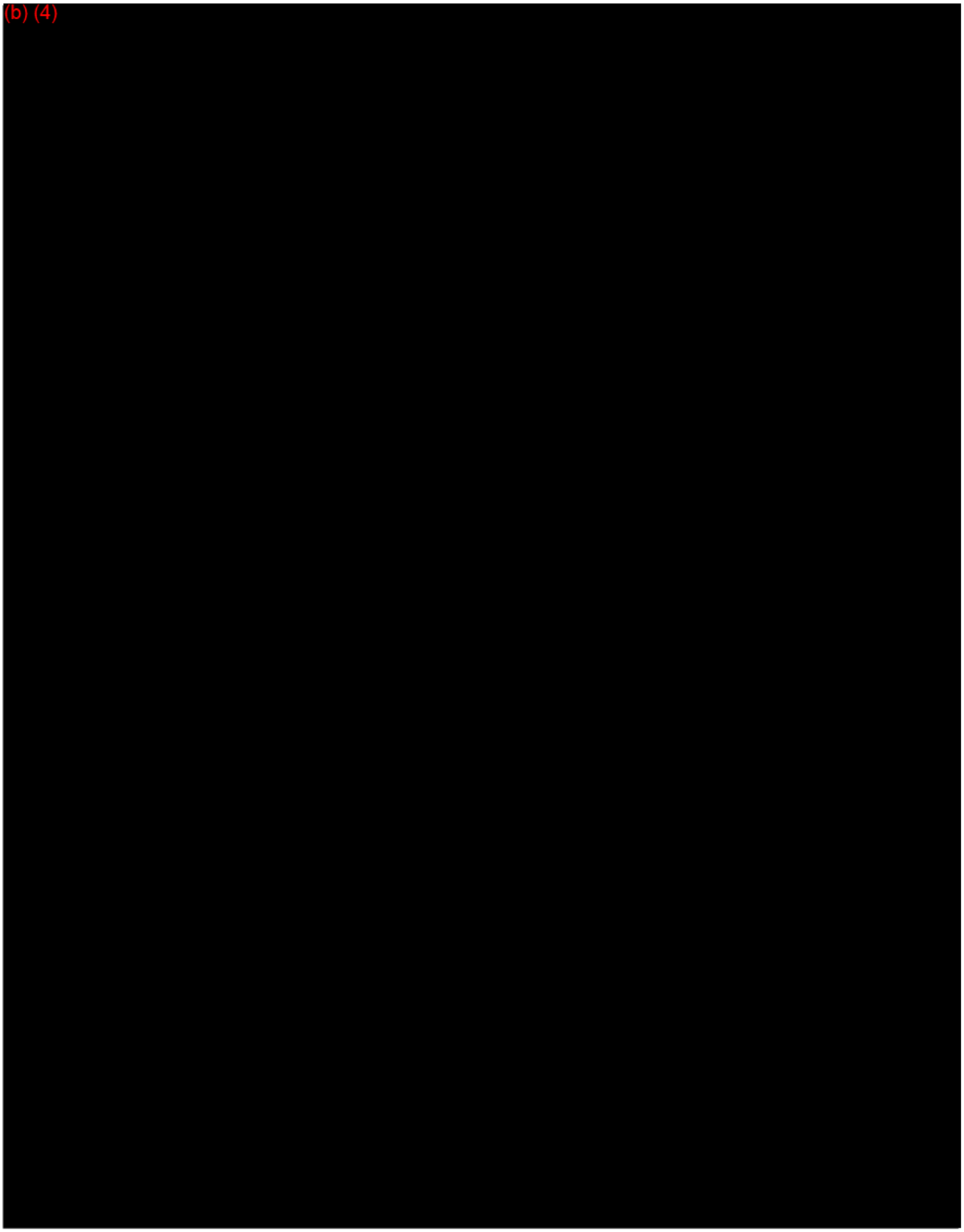

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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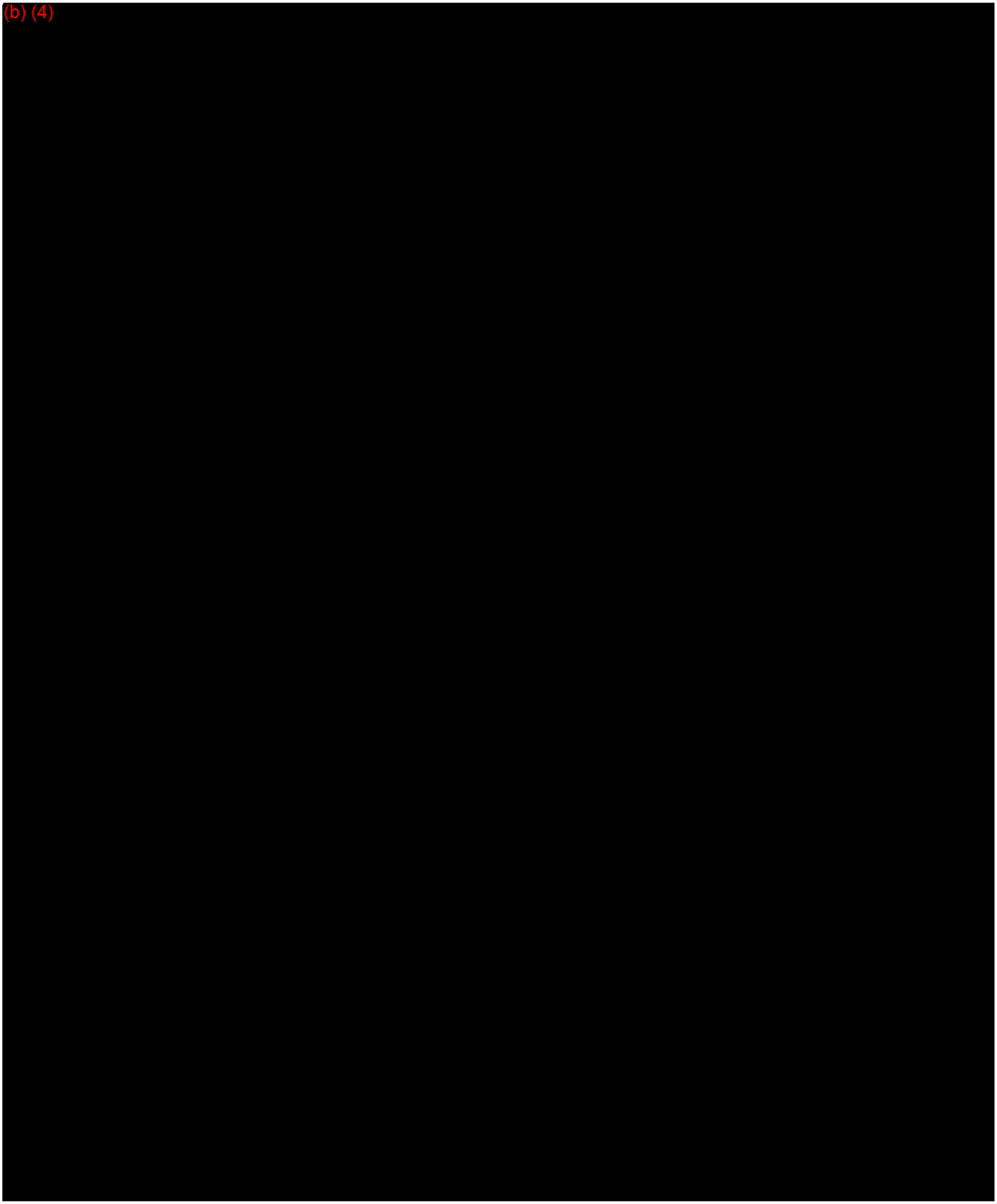

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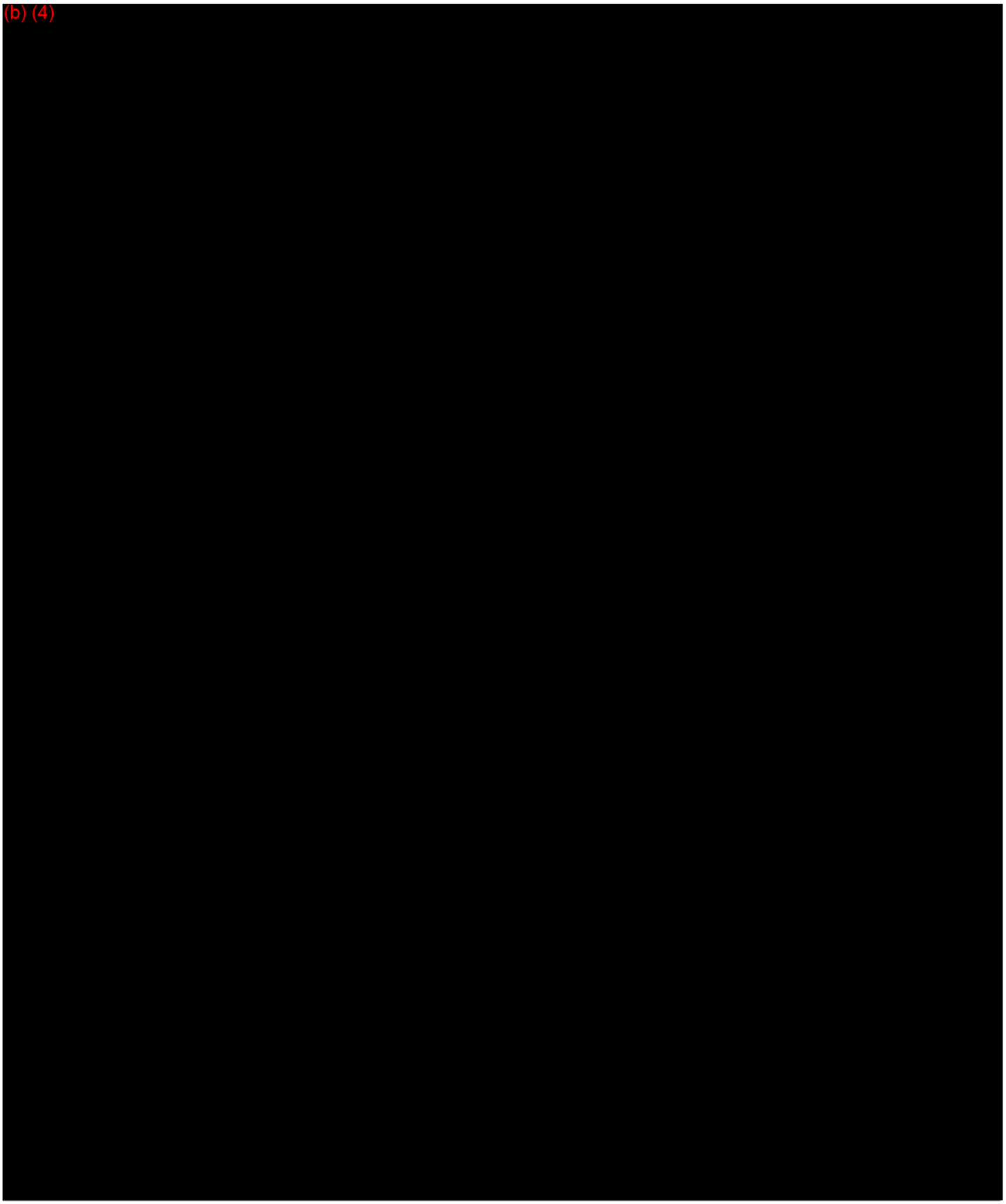

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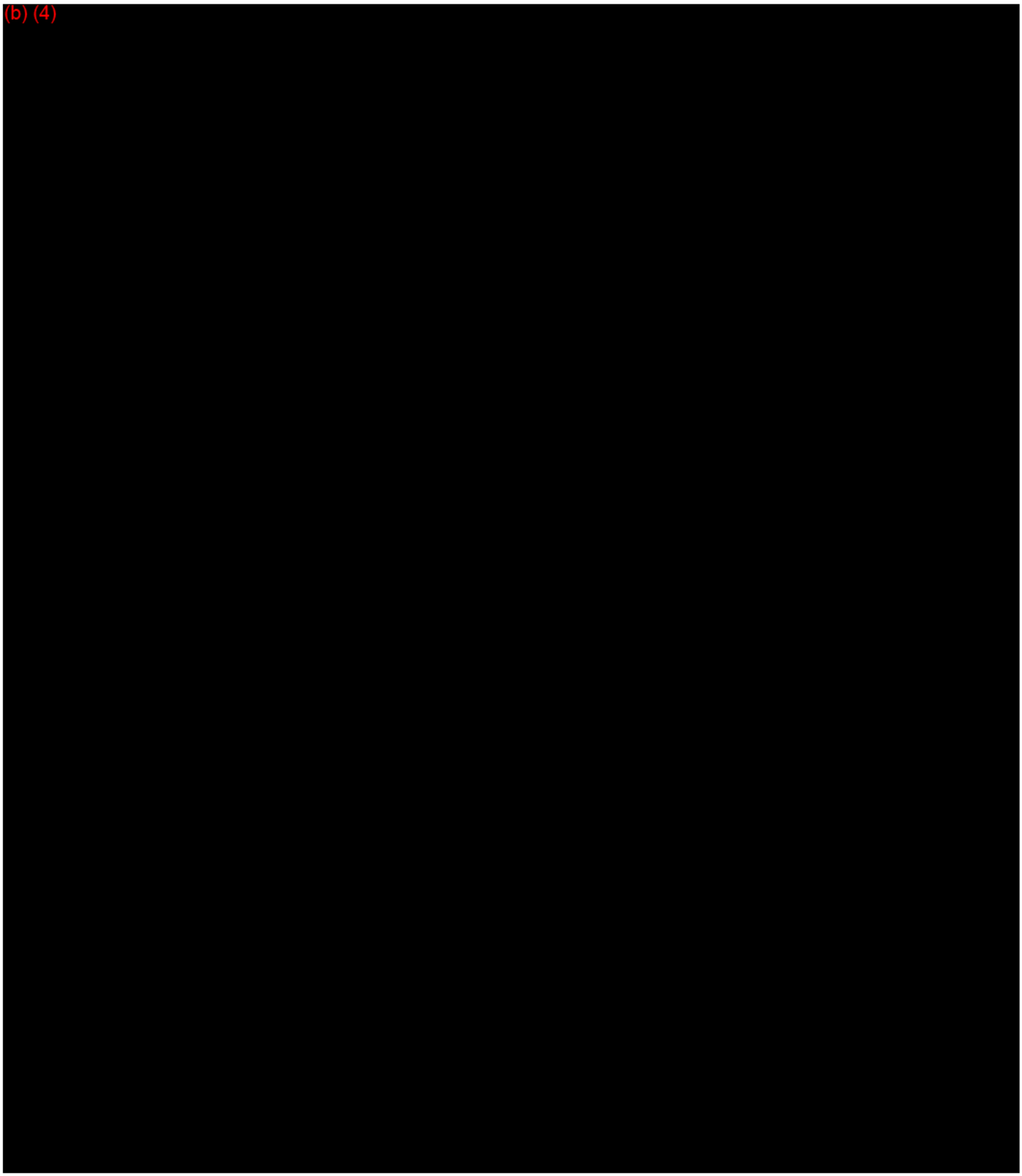
(b) (4)



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Chapter

12 Adding a Dicom Node

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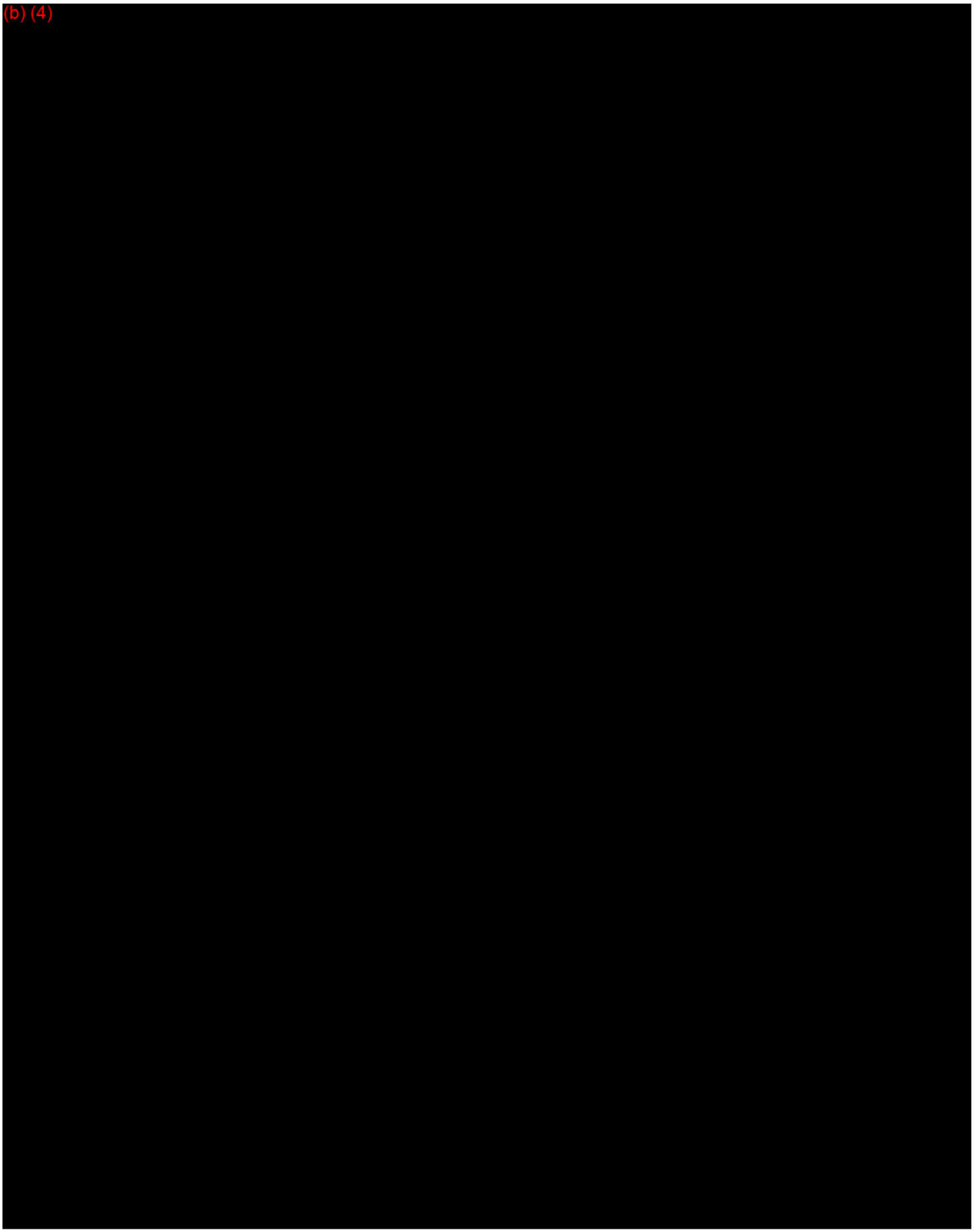
(b) (4)



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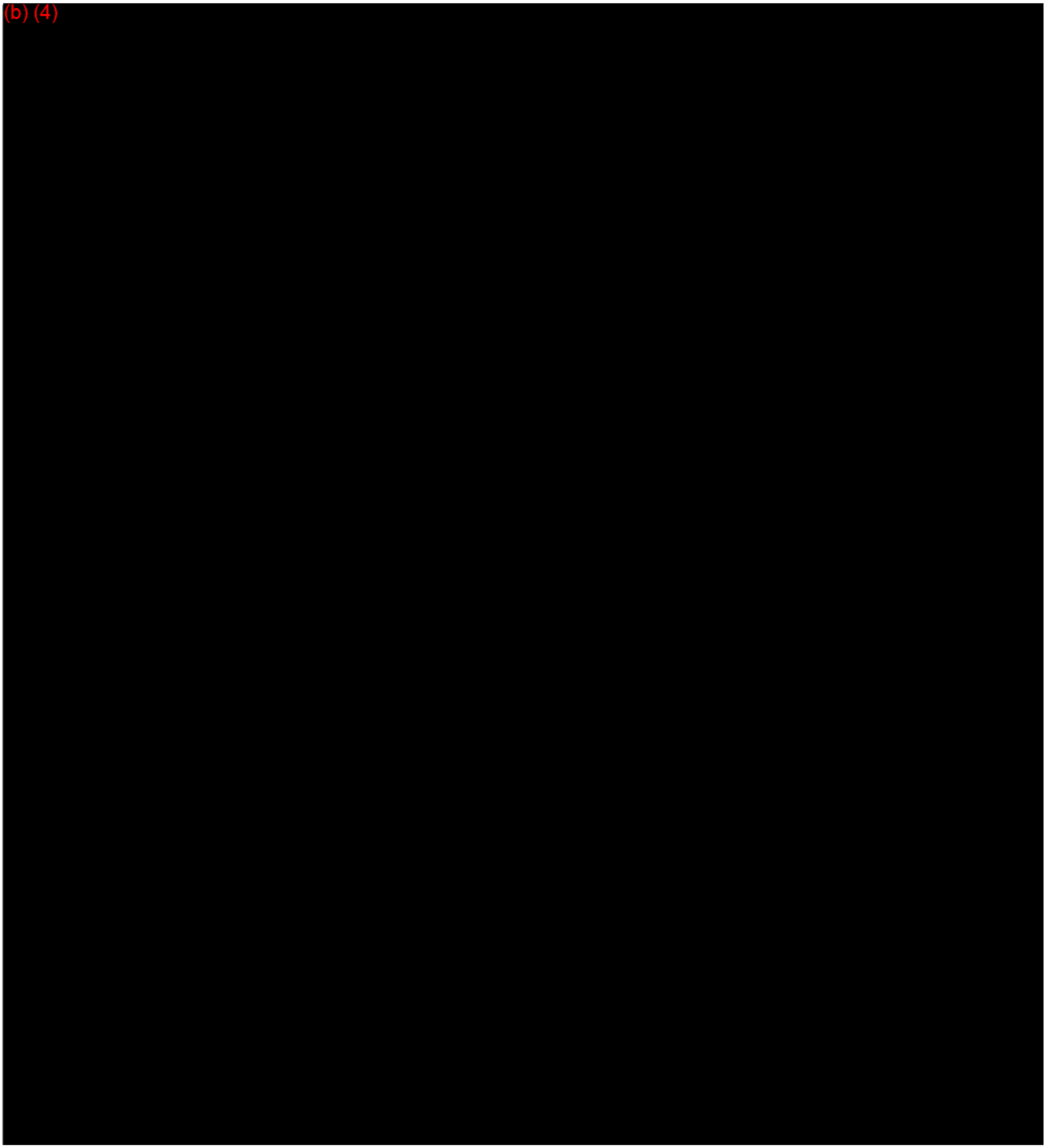
(b) (4)



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Chapter

13 Active Directory Integration

This section provides detailed information about how to create a ResolutionMD organizational unit with several test users in the Domain Controller.

This chapter contains the following sections:

- Windows 2008 Active Directory Server, page 96
- Windows 2003 Active Directory Server, page 97

Windows 2008 Active Directory Server

Follow the procedures below to add a ResolutionMD organizational unit.

Adding a ResolutionMD Organizational Unit

Purpose: Adding a ResolutionMD Organizational Unit to a Microsoft Windows 2008 active directory server.

Prerequisites

- Ensure that Identity Management for Unix is installed as part of the Active Directory role.

Start of procedure

1. Click Start | Administrative Tools | Active Directory Users and Computers.
2. Right-click on the domain name and choose the New | Organizational Unit option.
3. Enter ResMDUsers in the Name field and click OK.

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4. Right-click on the ResMDUsers Organizational Unit and choose New:Group.
5. Enter ResMDAdmin and click OK.
6. Right-click on the ResMDUsers Organizational Unit a second time and choose New:Group.
7. Enter ResMDUsers and click OK.
8. Add your ResolutionMD users to the ResMDUsers group as required.
9. Add your ResolutionMD administrators to the ResMDAdmin group as required.

Next Steps

Windows 2003 Active Directory Server

ResolutionMD is fully compatible with Windows 2003 Active Directory Server via the LDAP v3 protocol.

To support ResolutionMD integration, the Active Directory Sever needs to have LDAP AD/AM (ADAM Service Pack 1) components installed. These components are installed by default with Windows 2003 Server R2, but not with R1.

Warning! The LDAP AD/AM (ADAM Service Pack 1) components are mandatory for Active Directory integration with ResolutionMD.

Verifying the Requirements for Active Directory Integration with ResolutionMD

Purpose: To verify the requirements for active directory integration with ResolutionMD.

Start of procedure

1. Ensure that an Active Directory Server and domain exist.
2. Ensure that the ResolutionMD Server can access the Active Directory Server.
3. Ensure that the ResolutionMD Server is either part of the Active Directory domain or has the ability to communicate with the Active Directory Server.
4. Ensure that there is an Active Directory Account that can authenticate to the Active Directory Server for searching for users.

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5. Ensure that the Active Directory Server uses the LDAP protocol to communicate with the ResolutionMD Server.
6. Ensure that the ResolutionMD solution s *not* installed on the Active Directory Server.

End of procedure

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Chapter

14 Secure Socket Layer (SSL) Certificate

This section is optional and used only for those sites that use SSL connections to access the ResolutionMD 2.6 Server.

This chapter contains the following sections:

- Requesting and Installing an SSL Certificate, page 100
- Architectural Options for Enabling SSL, page 105
- Configuration Options for SSL, page 105
- Secure Socket Layer Requirements, page 108

Requesting and Installing an SSL Certificate

Note: Self-signed certificates are not supported.

SSL Certificates are required for the ResolutionMD Server to support HTTPS connections from ResolutionMD clients. A certificate must be acquired from a recognized. Certificate Authority or generated and configured in the Apache Tomcat container before HTTPS connections are enabled.

Warning! Perform the steps below on the server where the application is running or you will be unable to run the application in the future.

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Generating a Certificate Keystore

Purpose: To generate a certificate keystore.

Prerequisites

- You must have the completed the information in Table 31 on page 108.

Start of procedure

You can request a SSL Certificate from many different internet providers all of which will follow a process similar to the following example.

Note: In this example we use `keytool`, a key and certificate management utility. `Keytool` is included in the Java Development Kit (JDK).

When generating a Certificate. The `Common Name` must be the fully-qualified domain name of the host to which the certificate is applied.

Log in as root using Putty or similar SSH tool and type the following commands:

1. cd /opt/CSI/PureWeb/Server/tomcat
2. `ln` -s /usr/java/jdk1.6.0_23/jre/bin/keytool ./keytool
3. $ ./keytool -genkey -alias tomcat -keyalg RSA **-keysize 2048** -keystore ./tomcat.keystore

You will be prompted for the keystore password.

4. Type resmd at the first prompt.
5. Type resmd at the second prompt.
6. When asked for the first and last name, enter the server name including the fully qualified domain name. For example, resmd.hospitalname.com.
7. Type the name of your organizational unit.
8. Type the name of your organization.
9. Type the name of the city or locality.
10. Type the name of the state or province.
11. Type the two letter country code. For example, US.
12. Type yes.
13. Type the keystore password, resmd.

End of procedure

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Next Steps

- "Generating a Certificate Signing Request (CSR)" on page 102.

Generating a Certificate Signing Request (CSR)

Warning! You must generate the CSR file from the keystore created on the server.

Purpose: To generate a certificate signing request.

Start of procedure

Type in the following commands:

1. cd /opt/CSI/PureWeb/Server/tomcat
2. ./keytool -certreq -keyalg RSA -alias tomcat -file ./resmd.csr -keystore ./tomcat.keystore
3. ./keytool -certreq -keyalg RSA -alias tomcat -keysize 2048 -file resmd.csr -keystore tomcat.keystore
4. Enter the keystore password, resmd.
5. Check for a file called, resmd.csr.
6. Move the file resmd.csr to a location where it can be submitted to the Certificate Authority.

End of procedure

Next Steps

- "Submitting the CSR to the Certificate Authority" on page 102.

Submitting the CSR to the Certificate Authority

Purpose: To submit a Certificate Signing Request to the Certificate Authority.

Start of procedure

There are two options for submitting your CSR to the Certificate Authority.

- You can submit your CSR to the site IT team who will then submit it to the Certificate Authority used by the site.
- You can submit the CSR directly to the service providing the SSL certificate.

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Warning! You must ensure that the SSL is compatible with Apache Tomcat.

Generally, this will involve copying and pasting the CSR generated above into an online enrollment form and possibly indicating that the server software is Apache Tomcat.

Receive the Signed Certificate from the Certificate Authority. This may be in the form of a zip file containing the Signed Certificate along with other certificates to form the Certificate Chain.

End of procedure

Next Steps

- "Importing the Signed Certificate into a Keystore" on page 103.

Importing the Signed Certificate into a Keystore

Warning! You must import all of the .crt files that you received from the SSL certificate provider.

Purpose: To import the signed certificate into a keystore.

Start of procedure

Type the following commands:

1. $ cd /opt/CSI/PureWeb/Server/tomcat
2. ./keytool -import -alias cross -keystore ./tomcat.keystore -trustcacerts -file gd_cross_intermediate.crt.
1. ./keytool -import -alias intermed -keystore ./tomcat.keystore -trustcacerts -file gd_intermediate.crt
2. ./keytool -import -alias tomcat -keystore ./tomcat.keystore -trustcacerts -file tomcat

If prompted for the keystore password, enter resmd.

End of procedure

Next Steps

- "Enabling the HTTPS Connector" on page 104.

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Enabling the HTTPS Connector

Purpose: To enable the HTTP connector to use the Signed Certificate.

Start of procedure

1. Edit the \opt\CSI\Server\tomcat\conf\server.xml must enable the keystoreFile and keystorePass values on line 00010 are set appropriately.

   The set of available ciphers may be restricted to those that are considered to be cryptographically strong by including the ciphers configuration on line 00012 as part of the connector configuration. When complete, restart the Pureweb service.

2. Restart the Pureweb service by typing: service pureweb restart.

```
00001: <!--
00002: <Connector port="8443" address="0.0.0.0"
00003:    maxHttpHeaderSize="8192" emptySessionPath="false"
00004:    maxKeepAliveRequests="-1"
00005:    maxThreads="150" minSpareThreads="25" maxSpareThreads="75"
00007:    enableLookups="false" disableUploadTimeout="true"
00008:    acceptCount="100" scheme="https" secure="true"
00009:    clientAuth="false" sslProtocol="TLS"
00010:    keystoreFile="tomcat.keystore" keystorePass="mypassword"
00011:    useBodyEncodingForURI="true" URIEncoding="UTF-8"
00012:    ciphers="SSL_RSA_WITH_RC4_128_MD5,
                   SSL_RSA_WITH_RC4_128_SHA,
                   TLS_RSA_WITH_AES_128_CBC_SHA,
                   TLS_DHE_RSA_WITH_AES_128_CBC_SHA,
                   TLS_DHE_DSS_WITH_AES_128_CBC_SHA,
                   SSL_RSA_WITH_3DES_EDE_CBC_SHA,
                   SSL_DHE_RSA_WITH_3DES_EDE_CBC_SHA,
                   SSL_DHE_DSS_WITH_3DES_EDE_CBC_SHA"/>
                   00013:->
```

End of procedure

Testing that HTTPS is Enabled on Workstations

Purpose: To ensure that HTTPS is enabled in workstations.

Start of procedure

1. Browse to https://<hostname>:8443/pureweb/server/status.

   If there are no errors upon connecting to the status page then SSL is configured correctly.

End of procedure

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Testing that HTTPS is Enabled on Mobile Devices

Purpose: To ensure that HTTPS is enabled on mobile devices.

Start of procedure

1. Set Secure Connection to ON.
2. Enter the address of hostname:8443.
3. Tap Connect.

End of procedure

Architectural Options for Enabling SSL

Two architectural options exist for enabling SSL:

- To enable SSL for use on both internal and external networks, you require only one client-server configuration.
- To enable SSL for use with an external http on an internal network requires two client configurations. One configuration is to be for the external secure connection and one for the internal network.

Configuration Options for SSL

Two configuration options exist for enabling SSL.

- Option One:

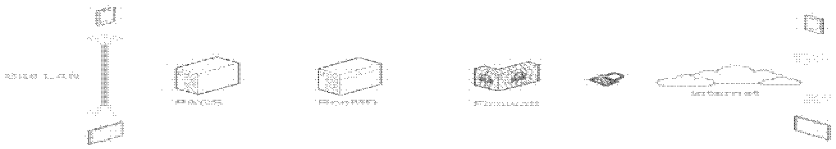

Figure 59: Single Server Entry on Mobile Device

Use a single server that uses port 8443. Both external and internal devices use port 8443. This may slow down a network's performance and can impact the user's experience.

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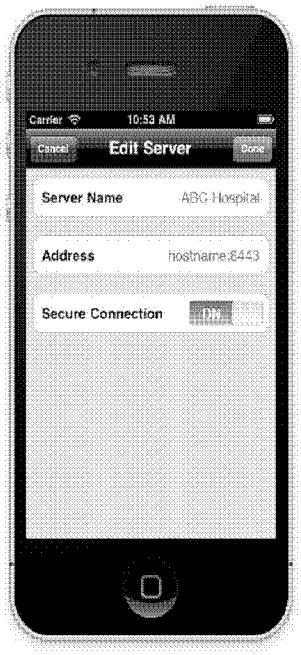

Figure 60: Edit Server Option 1

- Option Two:

Figure 61: Two Server Entries on Mobile Device

Using both port 8080 and 8443 where internal devices use port 8080 and external devices use port 8443. This allows internal users to take advantage of the network performances. This option requires two servers, one internal server that uses port 8080 and an external server that uses port 8443.

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Figure 62: Edit Server Option 2

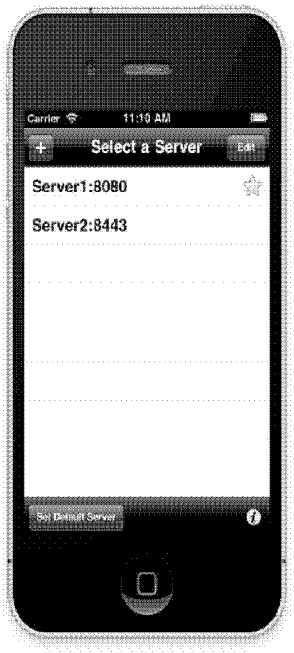

Figure 63: Select a Server

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Secure Socket Layer Requirements

Table 31: Preliminary Secure Socket Layer Elements

Requirement	Details
Fully qualified domain name	
IT SSL contact name/role	
IT SSL contact phone number	
IT SSL contact email	
Customer's choice for Certificate Authority	

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Chapter

15 Using the Network Configuration Editor

This section contains the information needed to use the Network Configuration Editor.

This chapter contains the following sections:

- Configuring the Network, page 110

Configuring the Network

When running the ResMDInstall.sh script, the Network Configuration Editor will open automatically and display the screen seen in Figure 64 on page 111. Follow the "Using the Network Configuration Editor to Configure the Network" procedure.

Enabling Additional Ethernet Interfaces

Purpose: To enable additional ethernet interfaces.

Start of procedure

1. Run the following command, where X equals the number of ethernet interfaces that you want to enable.

   sed -i s/ONBOOT=no/ONBOOT=yes/ /etc/sysconfig/network-scripts/ifcfg-ethX

2. Run the following command to restart the network interfaces:

   service network restart

End of procedure

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Accessing the Network Configuration Editor

Purpose: To access the Network Configuration Editor.

Start of procedure

1. Use SSH to log in to the ResolutionMD Server.
2. Type the following commands:
   a. cd /etc/security/console.apps/.
   b. system-config-network

Or

   a. network.

End of procedure

Next Steps

- Follow the steps in the "Using the Network Configuration Editor to Configure the Network" procedure.

Using the Network Configuration Editor to Configure the Network

Purpose: To successfully configure your network.

Start of procedure

1. Select Edit Devices.

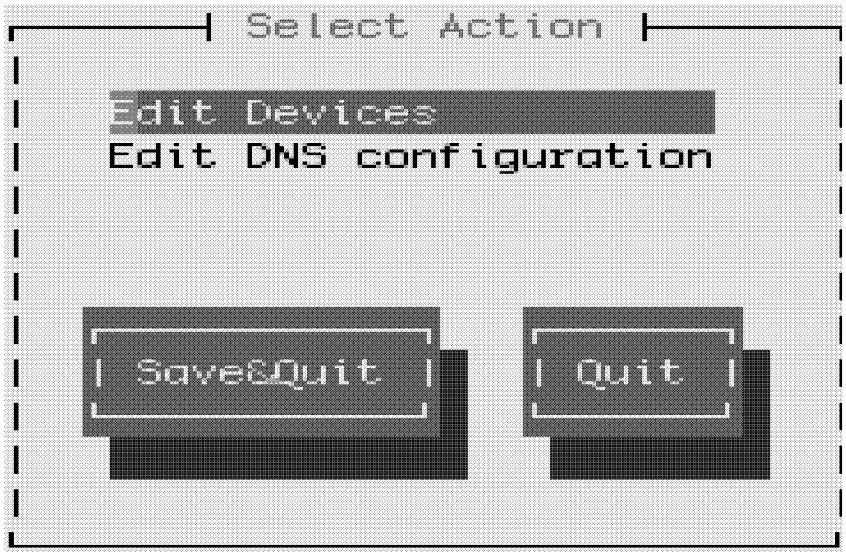

Figure 64: Network Configuration Editor

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2. Select eth0 and enter the IP, Netmask, and Default Gateway IP as seen in Figure 66.

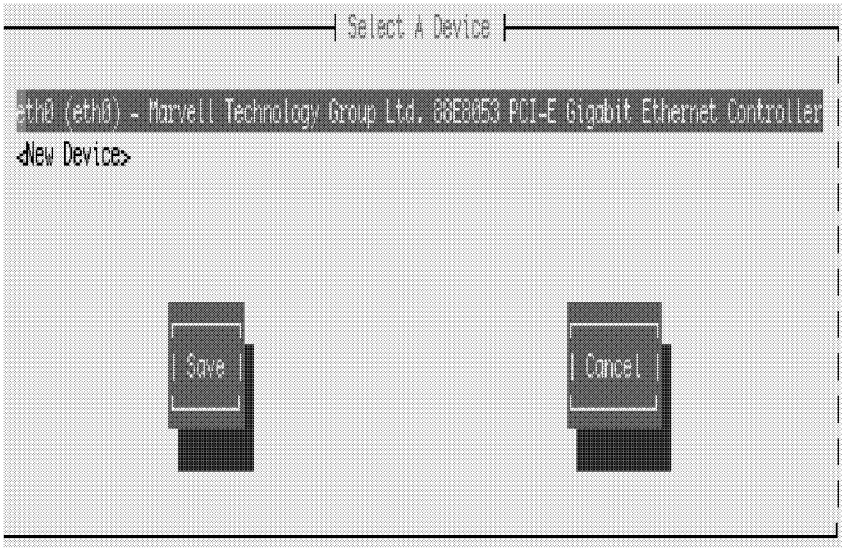

Figure 65: Select a Device

3. Once done editing the IP information, select OK and then OK again to get back to the main screen.

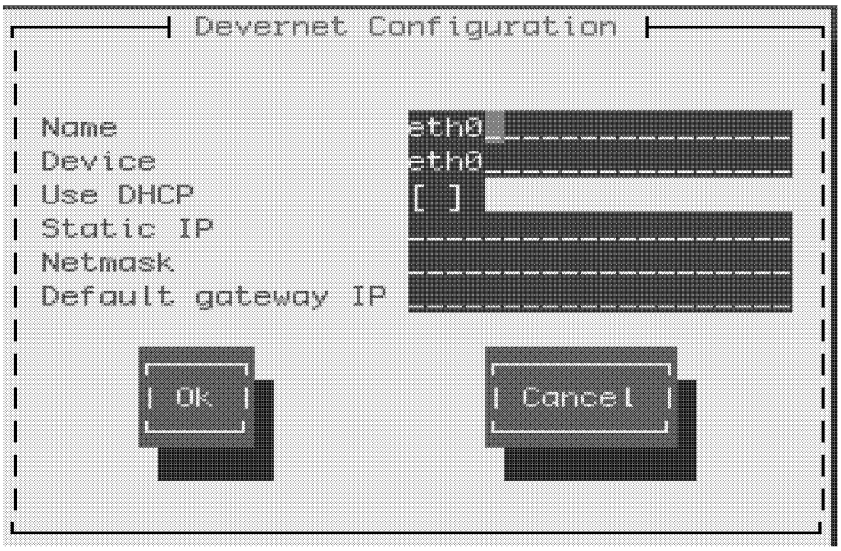

Figure 66: Enter your Network Information

4. Select Edit DNS Configuration. The DNS Configuration screen will be displayed, see Figure 67 on page 113. Here you can edit the hostname, primary, secondary and tertiary DNS servers and the search name.

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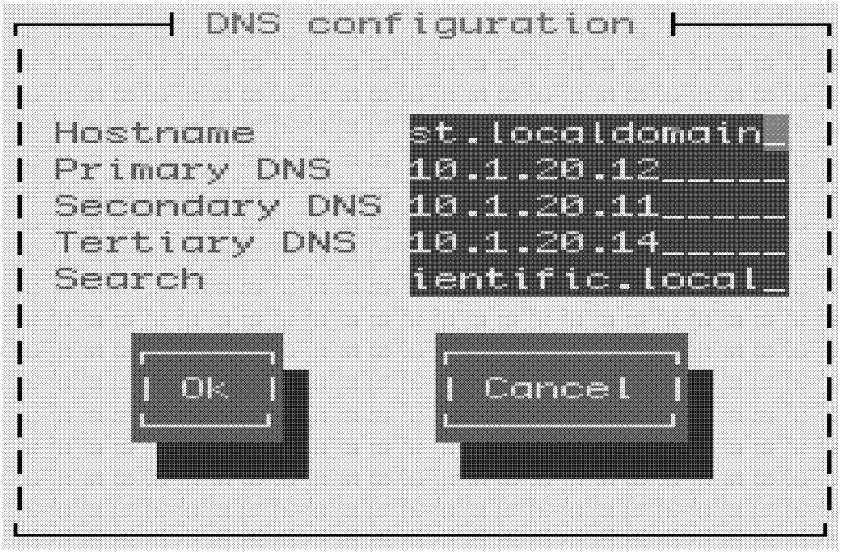

Figure 67: Edit DNS Configuration

5. When you are finished configuring the network, navigate to the main screen and select Save and Exit.

End of procedure

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Appendix 16.10 – Revision Level History

ResolutionMD™ 2.1 and Mobile - Product Family Revision History

Core Product Release 1.0
Release Date: Feb. 17, 2006

- first release
  - full 3D rendering capability
  - Textured, MIP, and Colored view modes
- Lighting and Silhouette enhancements
- 3D controls
- DICOM load
- DICOM listener
- Histogram and basic histogram controls
- Window and leveling
- Image saving
- Viewing plane clipping and orthogonal plane clipping
- Support for non-dicom files - Tiff, mpeg, raw, mayo-analyze
- Lens for extraction of items within view, and magnification
- DICOM study information
- Custom mac version only

Core Product Release 1.1
Release Date: May 24, 2006

- cross platform release, windows and mac
- same core functionality set as release 1.0

Core Product Release 1.2
Release Date: June 23, 2006

- material editor
- custom preset loader and color lookups
- default color preset load
- 3D measurement
- Integrated help
- Surface (nearest visible texture) selection for 3D measurement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Core Product Release 1.3

Testing completion date: July 20, 2006

- startup splash screen
- 2D view, original slice and best fit, and view manipulation
- Annotation in 2D view
- Measurement in 2D view, per slice
- Auto Scroll through slices, and single step through slices

Core Product Release 1.4

Release Date: November 24, 2006

- Tabbed interface
- Floating palettes
- Patient Study Manager (PSM)
- PACS query/retrieve functionality
- Enhanced 2D measurement (point, linear, and area)
- Color presets
- Orthogonal Views
- Orthogonal Feedback Planes

Core Product Release 1.5

Release Date: April 12, 2007

- GUI improvements
- Save to PACS functionality
- Performance enhancements
- Improved PACS connectivity

Cardiac Product Family Release 1.0

Release Date: June 1, 2007

- Calcium Scoring protocol
- Coronary Artery Analysis protocol

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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New Integrated Core Product: ResolutionMD 2.1

Release Date: February 23, 2009

- Software Development Kit (Microsoft .NET)
- Web Server / Browser Client
- Maximum Intensity Projection/Multi-Planar Reformat (MIP/MPR)
- MPR Batch Series / MIP Batch Series
- Cine MIP/MPR review
- Scrolling speed improvements
- Calcium Scoring protocol
- Coronary Artery Analysis protocol

ResolutionMD Mobile (2.6 - USA version)

Release Date: FDA submission pending

- Apple iPhone client application to interface to ResolutionMD Web server component of ResolutionMD 2.1
- Apple iPad client application to interface to ResolutionMD Web server component of ResolutionMD 2.1
- 2D viewing, slice scrolling, window/level, zoom in/out, pan on mobile client
- Client enables 3D volume rendering, manipulation, zoom, pan on mobile client
- MIP/MPR/Slabbing – study reformat to axial, sagittal and coronal views with Maximum Intensity Projection slabbing up to 50 mm
- User-selectable presets
- Secure Log-in, work/study list selection
- Wi-Fi or 3G communication to server via private LAN/WAN or Internet
- Ambient Light Display Test using AAPM TG18 images and 1:1 viewing mode

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 16.11 - Unresolved Anomalies

CSI JIRA

Displaying **56** issues at **11/May/11 2:44 PM**.

Rank	Issue Type	Key	Sub-Tasks	Priority	Status	Resolution	Summary	Assignee	Reporter

(b) (4)

Appendix 16.11 - Unresolved Anomalies

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Appendix 16.11 - Unresolved Anomalies

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CSI JIRA

Displaying **56** issues at **11/May/11 2:44 PM**.

Rank	Issue Type	Key	Sub-Tasks	Priority	Status	Resolution	Summary	Assignee	Reporter

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Appendix 16.11 - Unresolved Anomalies

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Appendix 16.11 - Unresolved Anomalies

CSI JIRA

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Appendix 16.11 - Unresolved Anomalies

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Appendix 16.11 - Unresolved Anomalies

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CSI JIRA

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Appendix 16.11 - Unresolved Anomalies

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Appendix 16.11 - Unresolved Anomalies

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CSI JIRA

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Rank	Issue Type	Key	Sub-Tasks	Priority	Status	Resolution	Summary	Assignee	Reporter
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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

Digital Imaging and Commnications in Medicine (DICOM)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# not in database	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

Digital Imaging and Commnications in Medicine (DICOM)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

None; standard, proven software libraries were used and the application was heavily tested and validated by experts

DESCRIPTION

None

JUSTIFICATION

Not applicable

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO/IEC 10918-1 (1994-02) Digital Compression and Coding of Continuous-Tone Still Images (JPEG)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3]	# not in database	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☑
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☑	☐
If yes, was the guidance document followed in preparation of this 510k?	☑	☐

Title of guidance: Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO/IEC 10918-4:1999 Digital Compression and Coding of Continuous-Tone Still Images (JPEG)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

None; standard, proven software libraries were used and the application was heavily tested and validated by experts

DESCRIPTION

None

JUSTIFICATION

Not applicable

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Appendix 16.14

Certification of Software Information

(Guidance for the Submission of Premarket Notifications for Medical Image Management Devices Issued July 27, 2000, Section IV(G)(5))

I certify in my capacity as President & Chief Technology Officer of Calgary Scientific Inc. that to the best of my knowledge and belief the software information provided in this notification is correct and that the same procedures will be used to retest and revalidate the software when it is revised.

Pierre Lemire
President & Chief Technology Officer

May 12, 2011

Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Risk Analysis Matrix - ResolutionMD 2.6 Mobile Master Excel (b) (4)

SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
1. Functional Requirements								
a. 2D Viewing								
A.1.a.2	Orientation Labels: S, A, L, R, I, P	(b) (4)						
A.1.a.4	Scrolling between slices - coarse & fine scrolling							
A.1.a.9	Image quality panel							

ResolutionMD Mobile 2.6 Risk Analysis.xlsx

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

Risk Analysis Matrix - Resoluti		
SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
1. Functional Requirements		
a. 2D Viewing		
A.1.a.2	(b) (4)	
A.1.a.4		
A.1.a.9		

ResolutionMD Mobile 2.6 Risk Analysis.xlsx

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Risk Analysis Matrix - Resoluti						
SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
1. Functional Requirements						
a. 2D Viewing						
A.1.a.2	Orientation Labels: S, A, L, R, I, P	(b) (4)				
A.1.a.4	Scrolling between slices - coarse & fine scrolling					
A.1.a.9	Image quality panel					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.1.a.9	Image quality panel	(b) (4)						
b. MIP/MPR Viewing								
A.1.b.2	Orientation Labels: S, A, L, R, I, P							
A.1.b.4	Scrolling between slices - coarse & fine scrolling							

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.1.a.9	Image quality panel	
b. MIP/MPR Viewing		
A.1.b.2	Orientation Labels: S, A, L, R, I, P	(b) (4) [redacted]
A.1.b.4	Scrolling between slices - coarse & fine scrolling	

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.1.a.9	Image quality panel	(b) (4)				
b. MIP/MPR Viewing						
A.1.b.2	Orientation Labels: S, A, L, R, I, P					
A.1.b.4	Scrolling between slices - coarse & fine scrolling					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.1.b.8	MIP/MPR Slabbing	(b) (4)						
A.1.b.8	MIP/MPR Slabbing							

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.1.b.8	MIP/MPR Slabbing	(b) (4) [redacted]
A.1.b.8	MIP/MPR Slabbing	

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.1.b.8	MIP/MPR Slabbing	(b) (4)				
A.1.b.8	MIP/MPR Slabbing					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.1.b.8	MIP/MPR Slabbing	(b) (4)						
A.1.b.9	Changing orthogonal view							
A.1.b.11	Image quality panel							

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.1.b.8	MIP/MPR Slabbing	
A.1.b.9	Changing orthogonal view	(b) (4)
A.1.b.11	Image quality panel	

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.1.b.8	MIP/MPR Slabbing	(b) (4)				
A.1.b.9	Changing orthogonal view					
A.1.b.11	Image quality panel					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.1.b.11	Image quality panel	(b) (4)						
c. 3D Viewing								
A.1.c.1	Render							
A.1.c.8	Image Quality Panel							

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.1.b.11	Image quality panel	(b) (4)
c. 3D Viewing		
A.1.c.1	Render	
A.1.c.8	Image Quality Panel	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.1.b.11	Image quality panel	(b) (4)				
c. 3D Viewing						
A.1.c.1	Render					
A.1.c.8	Image Quality Panel					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.1.c.8	Image Quality Panel	(b) (4)						
A.1.c.10	3D Bricking							
III. Computing Environment								

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.1.c.8	Image Quality Panel	
A.1.c.10	3D Bricking	(b) (4) [redacted]
III. Computing Environment		

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.1.c.8	Image Quality Panel	(b) (4)				
A.1.c.10	3D Bricking					
III. Computing Environment						

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.III.b	Client Hardware	(b) (4)						
A.III.b	Client Hardware							
A.III.b	Client Hardware							
A.III.b	Client Hardware							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.III.b	Client Hardware	(b) (4) [redacted]
A.III.b	Client Hardware	
A.III.b	Client Hardware	
A.III.b	Client Hardware	

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.III.b	Client Hardware	(b) (4)				
A.III.b	Client Hardware					
A.III.b	Client Hardware					
A.III.b	Client Hardware					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.III.b	Client Hardware	(b) (4)						
A.III.b	Client Hardware							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.III.b	Client Hardware	(b) (4)
A.III.b	Client Hardware	

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.III.b	Client Hardware	(b) (4) [redacted]				
A.III.b	Client Hardware					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
A.IV (also F.V.2)	Ambient Lighting User Assessment	(b) (4)						
Section B: Software System Inputs and Outputs	*Other: File Data, Exam and Image Support*							
B.I	Supported Modality Types							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
A.IV (also F.V.2)	Ambient Lighting User Assessment	(b) (4) [redacted]
Section B: Software System Inputs and Outputs	*Other: File Data, Exam and Image Support*	
B.I	Supported Modality Types	

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
A.IV (also F.V.2)	Ambient Lighting User Assessment	(b) (4)				
Section B: Software System Inputs and Outputs	*Other: File Data, Exam and Image Support*					
B.I	Supported Modality Types					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
B.I	Supported Modality Types	(b) (4)						
Section F: Usability Engineering Requirements that are Sentive to Human Errors and Training								
I. Non-functional Requirements								
F.I.5.b	Speed of diagnosis							

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section		
Section A: Functional and Capability Requirements	**Feature / Function Name**	**Design Description**
B.I	Supported Modality Types	
Section F: Usability Engineering Requirements that are Sentive to Human Errors and Training		
I. Non-functional Requirements		
F.I.5.b	Speed of diagnosis	(b) (4) [redacted]

ResolutionMD Mobile 2.6 Risk Analysis.xlsx

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
B.I	Supported Modality Types	(b) (4)				
Section F: Usability Engineering Requirements that are Sentive to Human Errors and Training						
I. Non-functional Requirements						
F.I.5.b	Speed of diagnosis					

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SRS Section								
Section A: Functional and Capability Requirements	Feature / Function Name	Requirement Description	Potential Failures / Risks	Severity	Cause of Failure	Probability	Detectability	Reason for Pr Rating
F.V.1	Network connectivity	(b) (4)						
F.V.2 (also A.IV)	Ambient Lighting User Assessment							

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SRS Section		
Section A: Functional and Capability Requirements	Feature / Function Name	Design Description
F.V.1	Network connectivity	(b) (4) [redacted]
F.V.2 (also A.IV)	Ambient Lighting User Assessment	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SRS Section						
Section A: Functional and Capability Requirements	Feature / Function Name	Failure Mitigation	Severity 2	Probability 2	Detectability 2	Risk Priority Number (RPN) Residual
F.V.1	Network connectivity	(b) (4) [redacted]				
F.V.2 (also A.IV)	Ambient Lighting User Assessment					

ResolutionMD Mobile 2.6 Risk Analysis.xlsx

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Appendix 16.4

ResolutionMD Mobile 2.6

Software Requirements Specification

Date: March 16, 2011
Report #: (b) (4)
Version #:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General Solution Description

The client-server architecture of ResolutionMD Mobile requires network connectivity between the server and client for users to view and manipulate patient information. This connectivity can take the form of a Wi-Fi or cellular data network.

The client must have the ability to perform searches using criteria relevant to the data they wish to view. The search results must be returned to the client for display. Finally, the user must be able to select a series from a study/series hierarchy from those results for loading and viewing from the server.

Performing standard viewing operations (ex. Slice scrolling, window/level, pan, zoom, etc.) will be conducted by gesture interactions on the client device, which will be translated to image manipulations on the server and return of the result to the client device for display.

Section A: Functional and Capability Requirements

I. Functional Requirements

a. 2D Viewing

1) Metadata display

(b) (4)

[redacted]

2) Orientation labels

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3) Measurement calipers

(b) (4)

4) Slice scrolling

(b) (4)

5) Pan

(b) (4)

6) Zoom

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

7) Window/level

(b) (4)

8) Encryption Indicator

(b) (4)

9) Image Quality Panel

(b) (4)

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(b) (4)

10) Reset

(b) (4)

b. MIP/MPR Viewing

1) Metadata display

(b) (4)

2) Orientation labels

(b) (4)

3) Measurement calipers

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

4) Slice scrolling

(b) (4)

5) Pan

(b) (4)

6) Zoom

(b) (4)

7) Window/level

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

8) MIP slab viewing

(b) (4)

9) Changing orthogonal view

(b) (4)

10) Encryption Indicator

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11) Image quality panel

(b) (4)

12) Reset

(b) (4)

c. 3D Viewing

1) Render

(b) (4)

2) Volume rotation

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3) Pan

(b) (4)

4) Zoom

(b) (4)

5) Lens

(b) (4)

6) Visualization presets

(b) (4)

7) Encryption Indicator

(b) (4)

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(b) (4)

8) Image quality panel

(b) (4)

9) Reset

(b) (4)

10) 3D Bricking

(b) (4)

II. Physical Characteristics

a. Code Language

1. Client

(b) (4)

2. Server

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

b. Platform

1. Client

(b) (4)

2. Server

(b) (4)

c. Operating System

1. Client

(b) (4)

2. Server

(b) (4)

III. Computing Environment

a. Server Hardware

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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b. Client Hardware

(b) (4)

IV. Ambient Lighting User Assessment

(b) (4)

Section B: Software System Inputs and Outputs

I. Inputs

(b) (4)

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II. Outputs

(b) (4)

Section C. Interfaces between Software System and Other Systems

I. PACS Interface

(b) (4)

II. Authentication Interface

(b) (4)

III. URL Integration

(b) (4)

Section D. Software-driven Alarms, Warnings and Operator Messages

I. End User

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

Section E. Security Requirements

(b) (4)

I. Secure Communication

(b) (4)

II. Server Identity Verification

(b) (4)

III. Client Authentication

(b) (4)

IV. Session Timeout

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

V. Sensitive Data

(b) (4)

[redacted]

Section F. Usability Engineering Requirements that are Sensitive to Human Errors and Training

(b) (4)

[redacted]

Section G. Data Definition and Database Requirements

(b) (4)

[redacted]

Section H. Installation and Acceptance Requirements of the Delivered Medical Device Software at the Operation and Maintenance Site or Sites

I. Installation Requirements

a. **Mobile client**

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

b. Server Application

This section shall cover the broad installation requirements. The ResMD Service and Installation Manual shall provide detailed requirements for the following elements.

(b) (4)

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(b) (4)

II. Acceptance Requirements

In order to qualify an installation as successful, the following items would need to be satisfied.

(b) (4)

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Section I. Requirements Related to Methods of Operation and Maintenance

(b) (4)

(b) (4)

(b) (4)

Section J. User Documentation to be Developed

I. End-User

(b) (4)

II. Administrative User

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

Section K. User Maintenance Requirements

(b) (4)

Section L. Regulatory Requirements

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 16.4.1

Hardware Specification for ResolutionMD Solutions

Date:
Report #:
Version #:
Author:

(b) (4)

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Report Review/Revision History

Date	Version	Description	Author
(b) (4)			

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This specification provides a listing of required, recommended and optional components

(b) (4)

[redacted]

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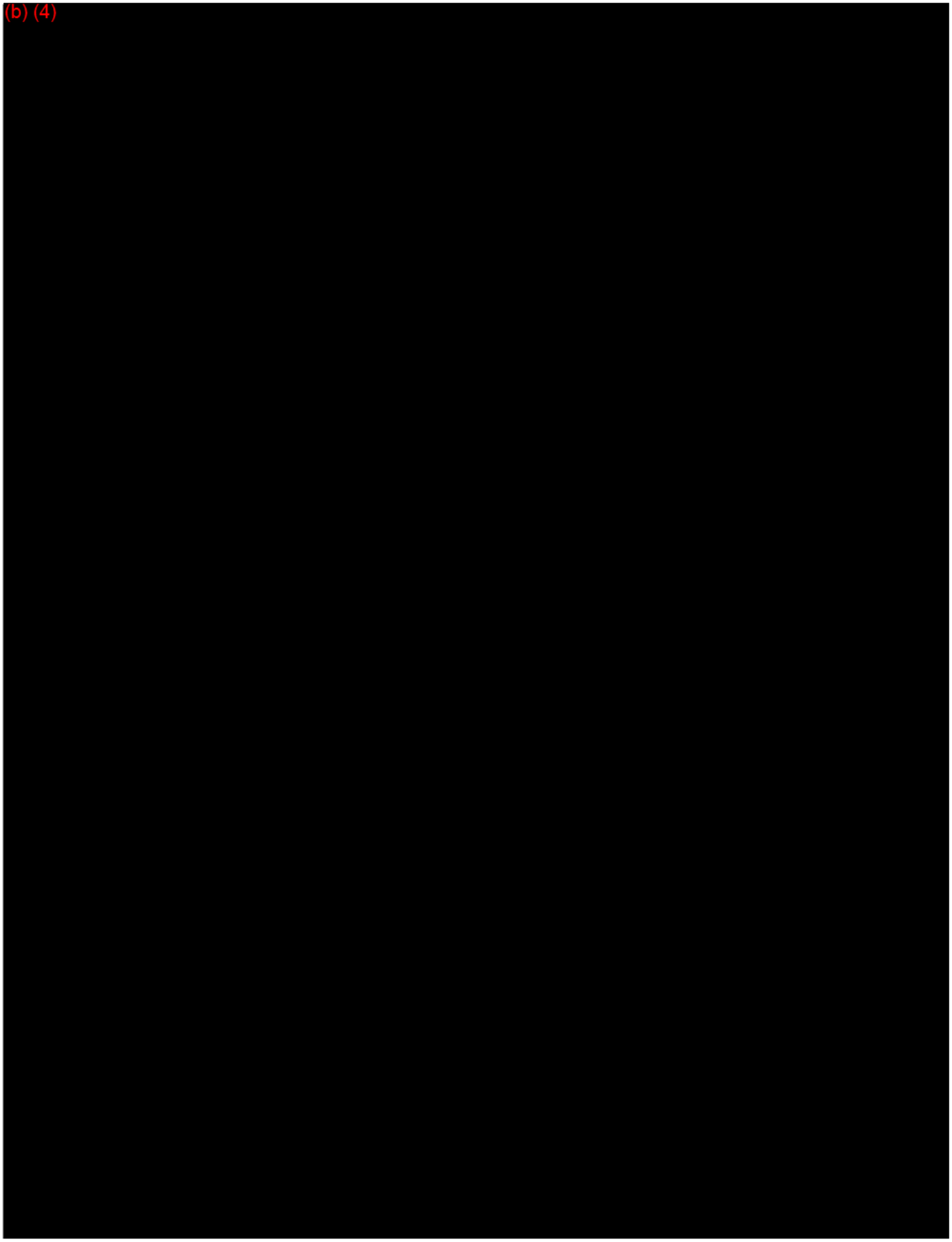
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

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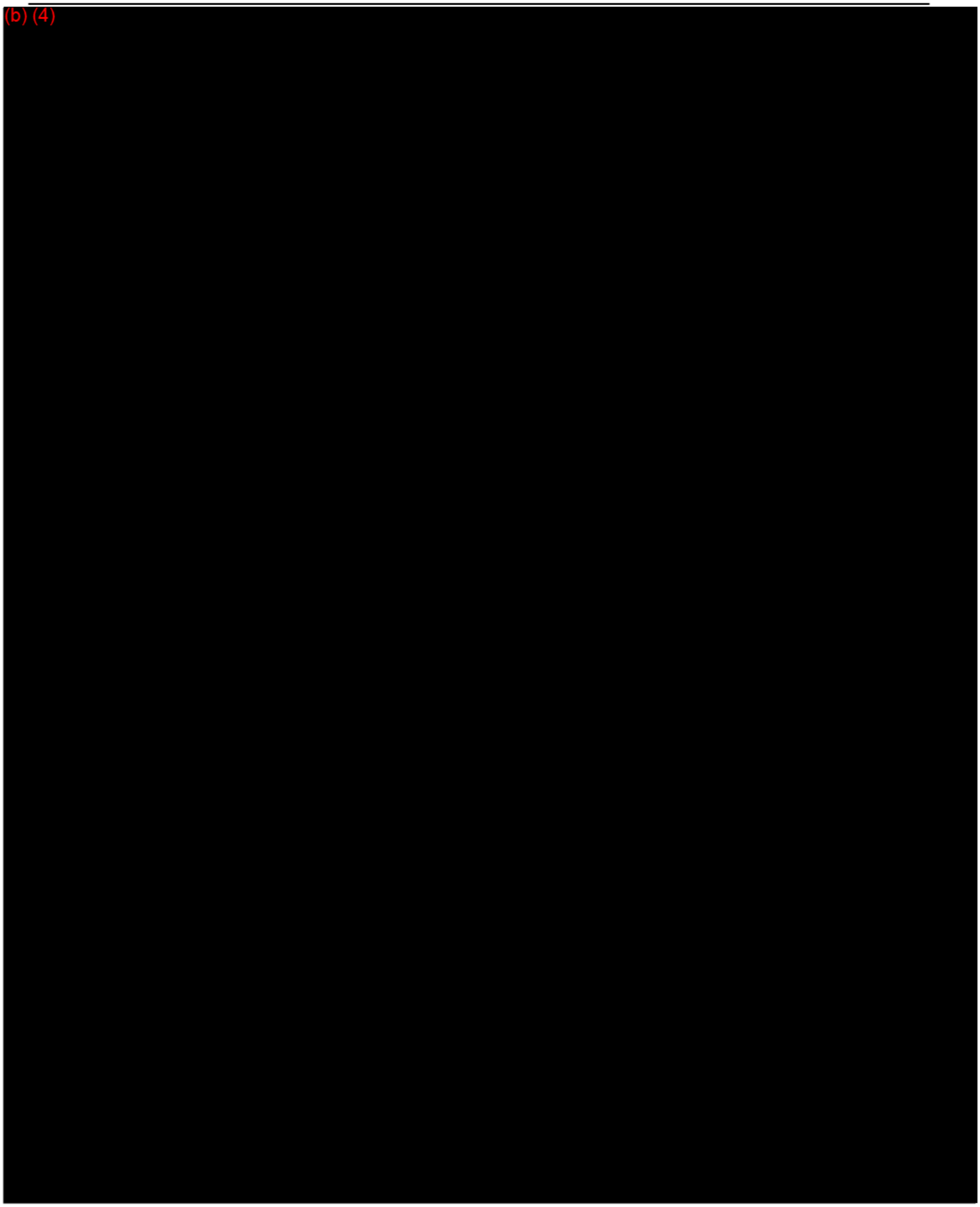
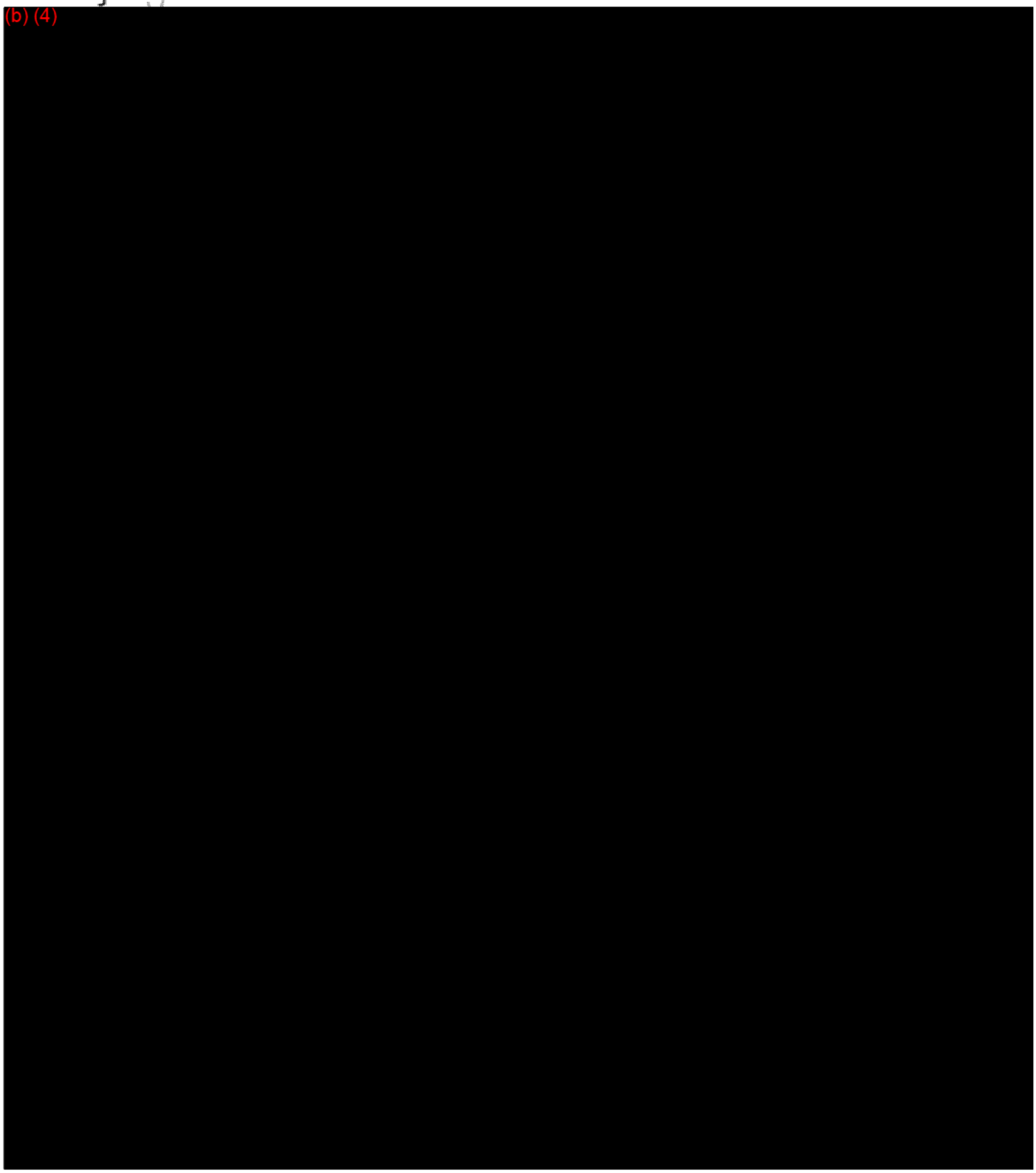
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

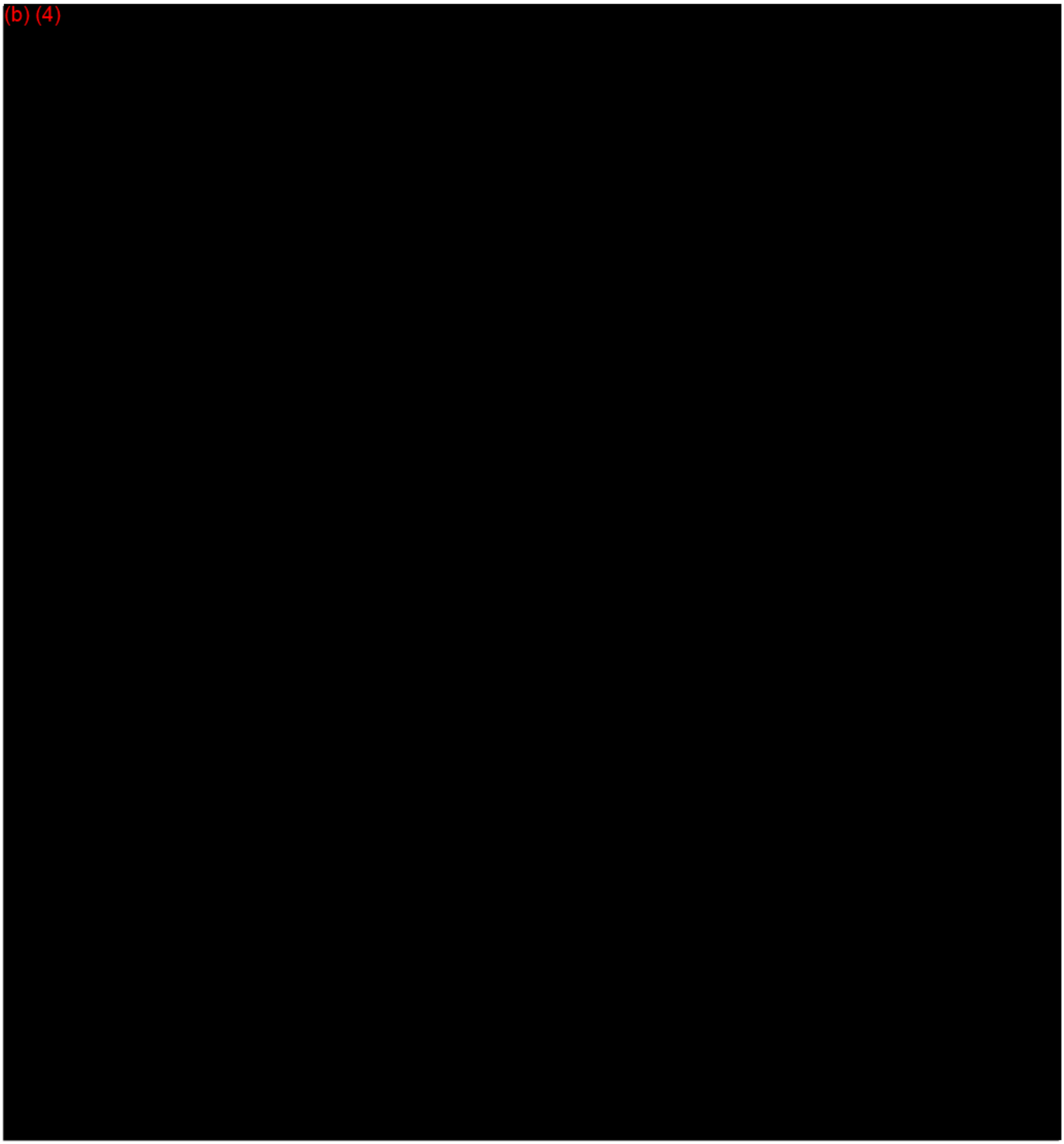
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)



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(b) (4)

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Appendix 16.4.2

ResolutionMD Mobile 2.6

Usability Specification

Date:
Report #:
Version #: (b) (4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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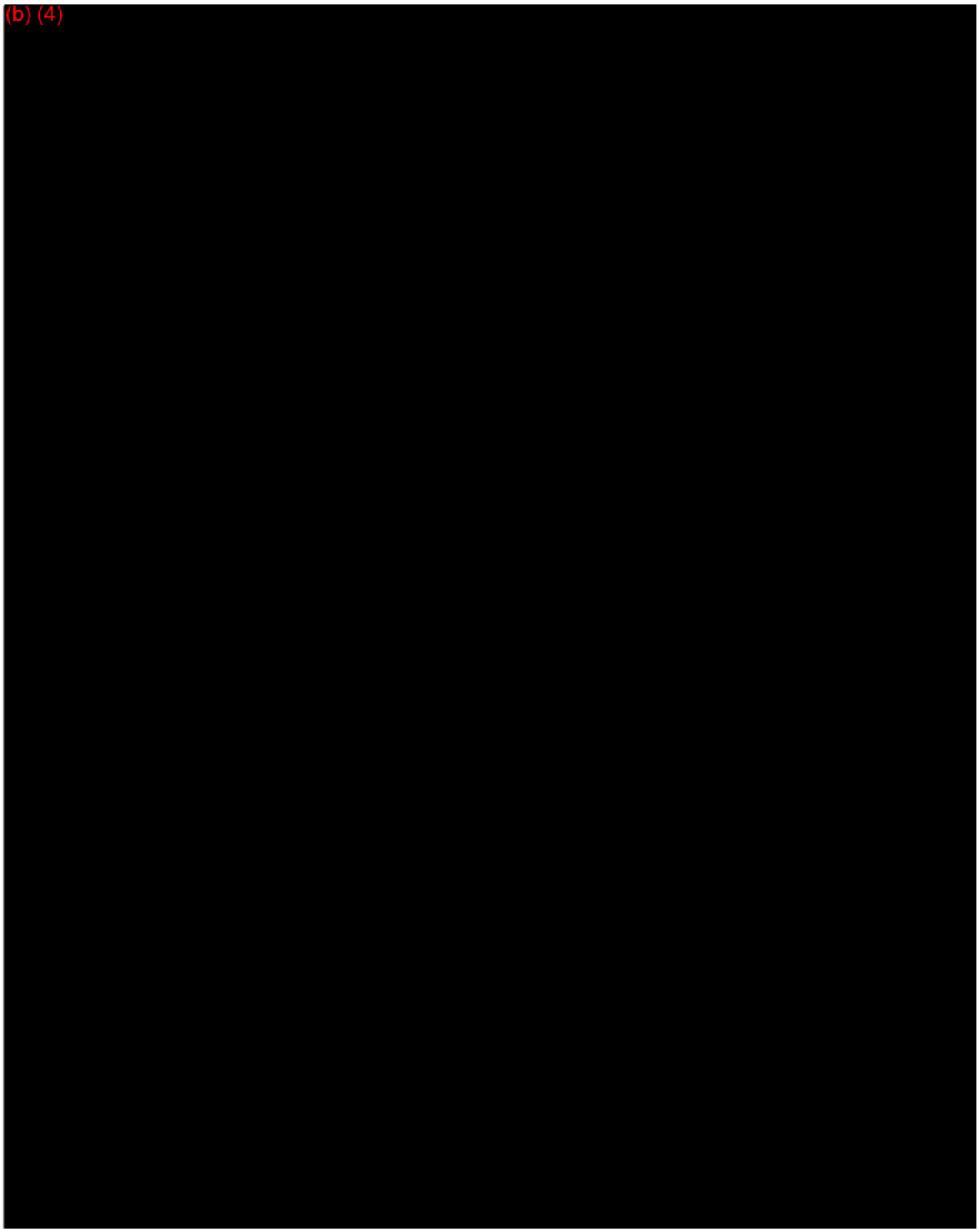
Usability Specification

F.I - Intended Use Specification

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

F.II - Primary Operating Functions (see Functional Requirements section of the Software Requirements Specification)

(b) (4)

F.III - User Interface Requirements for Primary Operating Functions

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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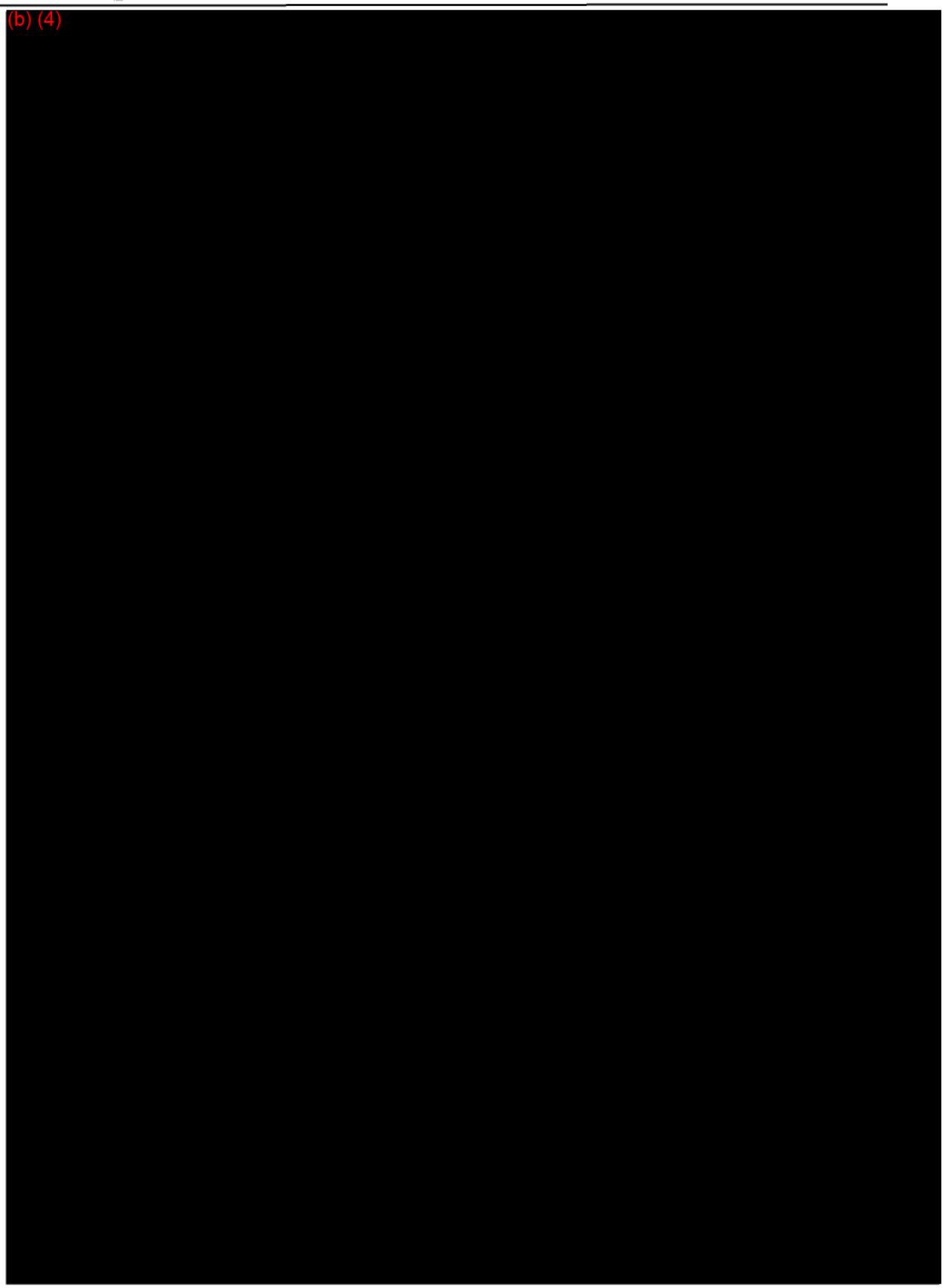
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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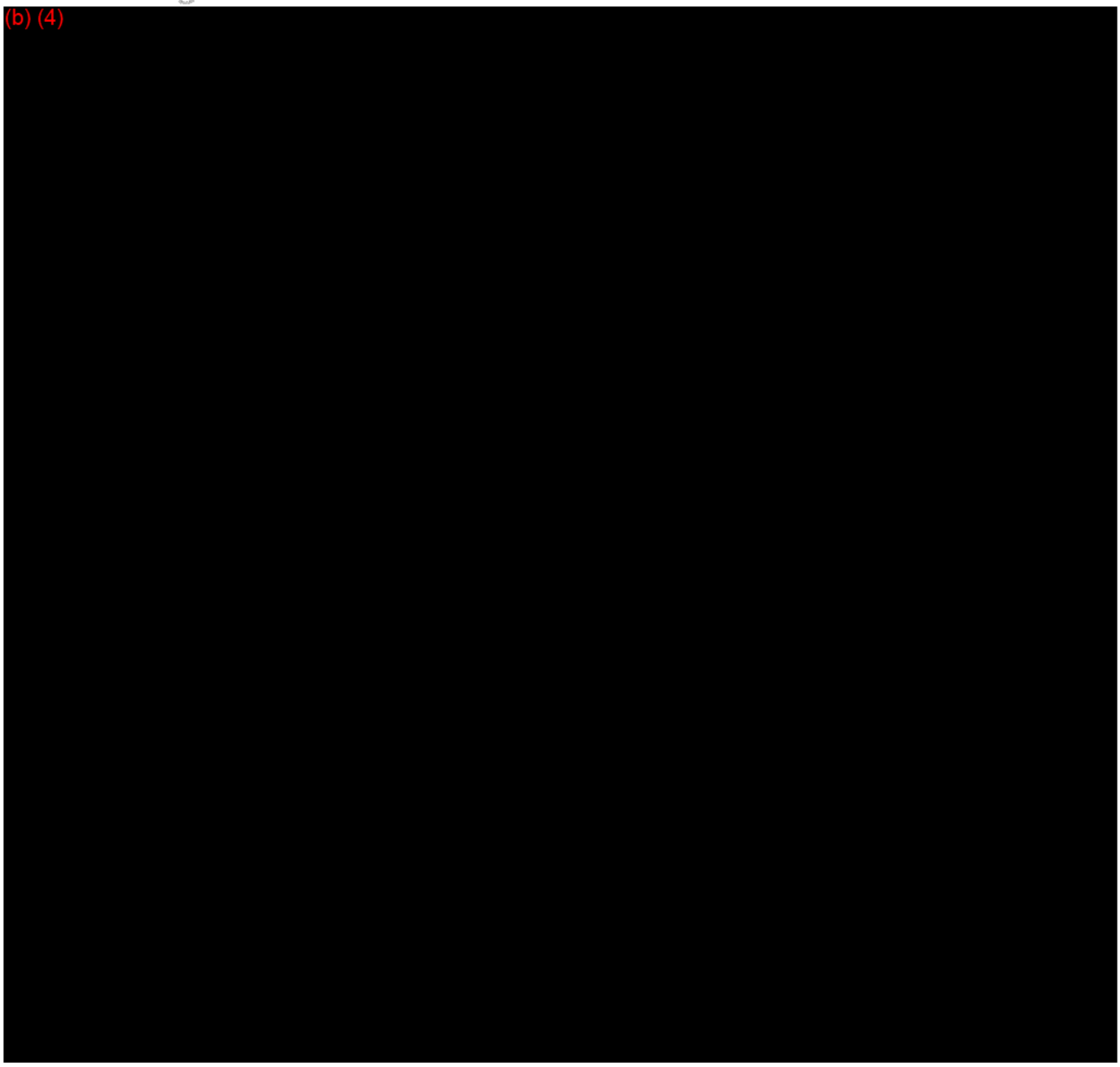
(b) (4)



F.IV - Risk Analysis

(b) (4)

F.V - Use Scenarios (Worst to best case scenario)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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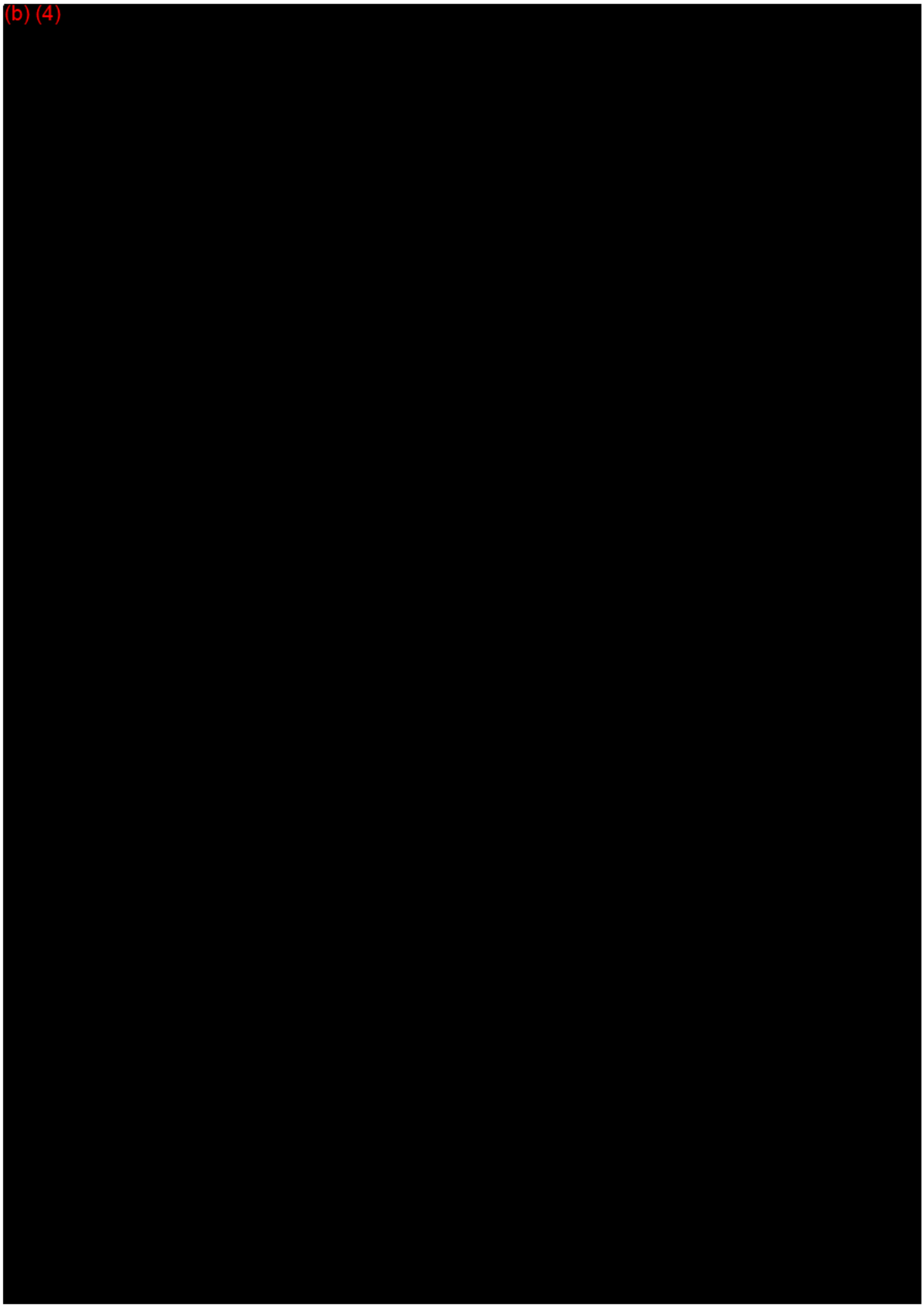
(b) (4)



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Appendix 16.6

ResolutionMD Mobile 2.6

Software Design Specification

Date: (b) (4)
Report #: [redacted]
Version #: [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General Solution Description

The client-server architecture of ResolutionMD Mobile requires network connectivity between the server and client for users to view and manipulate patient information. This connectivity can take the form of a Wi-Fi or cellular data network.

The client must have the ability to perform searches using criteria relevant to the data they wish to view. The search results must be returned to the client for display. Finally, the user must be able to select a series from a study/series hierarchy from those results for loading and viewing from the server.

Performing standard viewing operations (ex. Slice scrolling, window/level, pan, zoom, etc.) will be conducted by gesture interactions on the client device, which will be translated to image manipulations on the server and return of the result to the client device for display.

Section A: Functional and Capability Requirements

I. Functional Requirements

a. 2D Viewing

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2) Orientation labels (b) (4)

(b) (4)

(b) (4)

3) Measurement calipers (b) (4)

(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4) Slice scrolling (b) (4)

(b) (4)

(b) (4)

5) Pan (b) (4)

(b) (4)

(b) (4)

6) Zoom (b) (4)

(b) (4)

(b) (4)

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(b) (4)

7) Window/level (b) (4)

(b) (4)

8) Encryption Indicator (b) (4)

(b) (4)

9) Image Quality Panel (b) (4)

(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

10) Reset

(b) (4)

b. MIP/MPR Viewing

1) Metadata display (b) (4)

(b) (4)

(b) (4)

2) Orientation labels (b) (4)

(b) (4)

(b) (4)

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(b) (4)

3) Measurement calipers (b) (4)

(b) (4)

4) Slice scrolling (b) (4)

(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5) Pan

(b) (4)

6) Zoom (b) (4)

(b) (4)

7) Window/level (b) (4)

(b) (4)

(b) (4)

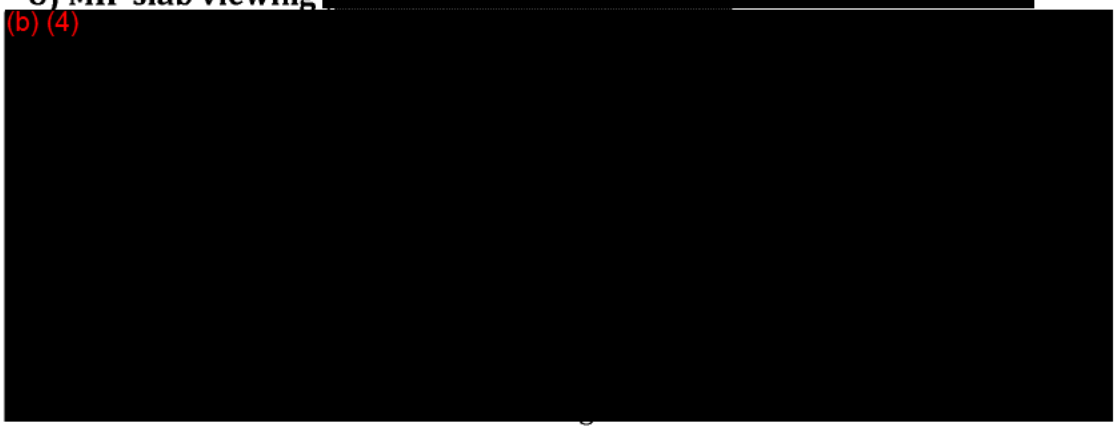
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

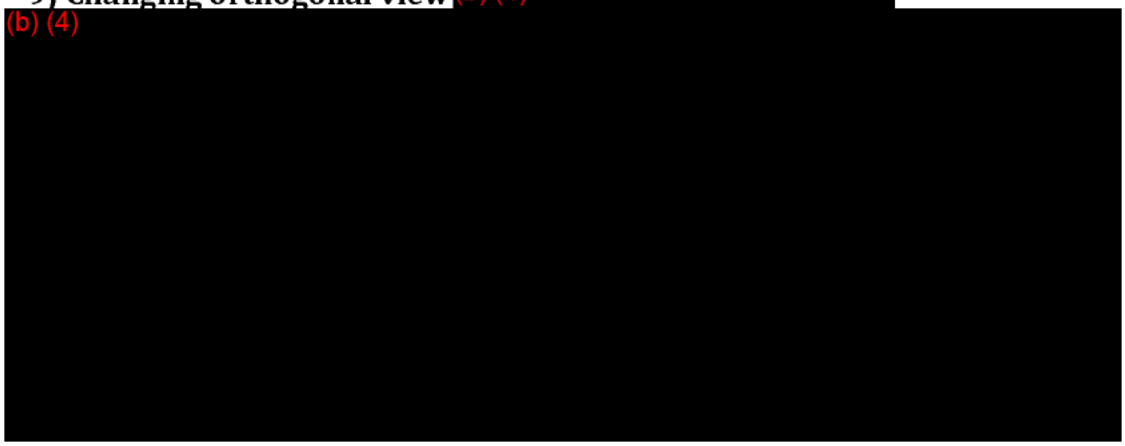
8) MIP slab viewing (b) (4)

(b) (4)



9) Changing orthogonal view (b) (4)

(b) (4)



10) Encryption Indicator

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

11) Image quality panel

(b) (4)

[redacted]

12) Reset

(b) (4)

[redacted]

c. 3D Viewing

1) Render

(b) (4)

[redacted]

2) Volume rotation

(b) (4)

[redacted]

3) Pan

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

4) Zoom (b) (4)

(b) (4)

5) Lens (b) (4)

(b) (4)

6) Visualization presets (b) (4)

(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

7) Encryption Indicator

(b) (4)

8) Image quality panel

(b) (4)

9) Reset

(b) (4)

10) 3D Bricking

(b) (4)

II. Physical Characteristics

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

b. Platform

(b) (4)

c. Operating System

(b) (4)

III. Computing Environment

a. Server Hardware

(b) (4)

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(b) (4)

b. Client Hardware

(b) (4)

IV. Ambient Lighting Testing Function

(b) (4)

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Section B: Software System Inputs and Outputs

I. Inputs

(b) (4)

II. Outputs

(b) (4)

Section C. Interfaces between Software System and Other Systems

I. PACS Interface

(b) (4)

II. Authentication Interface

(b) (4)

III. URL Integration

(b) (4)

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Section D. Software-driven Alarms, Warnings and Operator Messages

(b) (4)

Section E. Security Requirements

(b) (4)

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(b) (4)

I. Secure Communication

(b) (4)

II. Server Identity Verification

(b) (4)

III. Client Authentication

(b) (4)

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IV. Session Timeout

(b) (4)

[redacted]

V. Sensitive Data

(b) (4)

[redacted]

Section F. Usability Engineering Requirements that are Sensitive to Human Errors and Training

See Appendix 16.4.2 – ResolutionMD Mobile Usability Specification

Section G. Data Definition and Database Requirements

(b) (4)

[redacted]

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See Sections B and C above for descriptions of system inputs and outputs, and interfaces with other software systems, respectively.

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calgary scientific

resolution MD™ web

2.5 DICOM Conformance Statement

November 24, 2010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

DCM25-CS15
Release Date: November 24, 2010

1. Overview

This DICOM conformance statement specifies the behavior and functionality of the ResolutionMD (ResMD) application from Calgary Scientific. ResMD is a computer software product used for the anytime and anywhere display and analysis of medical images. It is a server-based application that is accessed from zero-footprint browser based web clients or a mobile smartphone client running on the iPhone, iPad, iPod Touch or Android based devices. The application conforms to aspects of the DICOM 3.0 standard to allow interoperability with other DICOM 3.0 compliant systems. ResMD takes advantage of several network services defined in 3.7 of the DICOM standards for the purpose of loading and rendering the images. Images are not permanently stored within ResMD. ResMD is integrated with other DICOM-compliant PACS (Picture Archiving and Communication System) in order to enable users to display DICOM medical images and is able to save modified versions of those images back to a PACS.

SOP Classes	User of Service (SCU)	Provider of Service (SCP)	Display
Transfer			
CT Image Storage	Yes	Yes	Yes
Enhanced CT Image Storage	Yes	Yes	Yes
MR Image Storage	Yes	Yes	Yes
Enhanced MR Image Storage	Yes	Yes	Yes
Positron Emission Tomography Image Storage	Yes	Yes	Yes
X-Ray Angiographic Image Storage	Yes	Yes	Yes
Computed Radiology Image Storage	Yes	Yes	Yes
Digital X-Ray Image Storage - for Presentation	Yes	Yes	Yes
Digital X-Ray Image Storage - for Processing	Yes	Yes	Yes
Ultrasound Image Storage	Yes	Yes	Yes

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Ultrasound Multi-Frame Image Storage	Yes	Yes	Yes
Nuclear Medicine Image Storage	Yes	Yes	Yes
Secondary Capture Image Storage	Yes	Yes	Yes
Basic Text SR	Yes	Yes	Yes
Query / Retrieve			
Patient Root Query / Retrieve IM - Find	Yes	No	N/A
Patient Root Query / Retrieve IM - Move	Yes	No	N/A
Study Root Query / Retrieve IM - Find	Yes	No	N/A
Study Root Query / Retrieve IM - Move	Yes	No	N/A

Table 1: Supported Network Services

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3. Introduction

ResolutionMD (ResMD) provides interactive, high-quality visualization and display of Dicom medical images. It reads and displays 2D images and transforms them into reconstructed 2D or 3D volumes to display a high-definition, interactive view of medical data. ResMD software supports several image formats, specifically DICOM version 3.0 image files. ResMD reads and displays uncompressed monochrome DICOM images of all major modalities and image SOP classes and can request that modified versions of DICOM objects be stored in an external PACS via the DICOM Storage Service Class.

ResolutionMD 2.4 is primarily intended as an image display and viewing solution. ResolutionMD is able to act as an SCU for the purposes of saving modified image series or secondary captures back to a Dicom image storage system. It is recommended that users leverage their existing PACS system or third party systems such as DCM4Chee to act as a C-Store provider or to provide Dicom Query / Retrieve functionality in conjunction with ResolutionMD 2.4.

This document applies to the ResolutionMD 2.5 release of software.

3.1. Revision History

Revision Number	Date	Reason for Change
2.0	November 30, 2010	Update to reflect current conformance status of ResolutionMD 2.5
1.0	March 5, 2010	Update to reflect current conformance status of ResolutionMD 2.4 (including 2.4.1 and 2.4.2) release

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3.2. Audience

This conformance statement is intended for use to evaluate possible interoperability between ResolutionMD and other applications.

This document is written for the people that need to understand how ResolutionMD will integrate into their healthcare facility. This includes both those responsible for overall imaging network policy and architecture, as well as integrators who need to have a detailed understanding of the DICOM features of the product. Integrators are expected to fully understand all the DICOM terminology, how the tables in this document relate to the product's functionality, and how that functionality integrates with other devices that support compatible DICOM features.

3.3. Remarks

This DICOM Conformance Statement documents the conformance of the ResolutionMD software with the Digital Imaging and Communications in Medicine (DICOM) standard. This document is essential in order to evaluate whether or not another DICOM compliant device can communicate with this software product. This statement is conformant with the recommended format as described in PS 3.2 of the DICOM standard.
The Conformance Statement should be read and understood in conjunction with the DICOM Standard. DICOM by itself does not guarantee interoperability.

The Conformance Statement does, however, facilitate a first-level comparison for interoperability between different applications supporting compatible DICOM functionality. This Conformance Statement is not supposed to replace validation with other DICOM equipment to ensure proper exchange of intended information. In fact, the user should be aware of the following important issues:

- The comparison of different Conformance Statements is just the first step towards assessing interconnectivity and interoperability between the product and other DICOM conformant equipment.

- Test procedures should be defined and executed to validate the required level of interoperability with specific compatible DICOM equipment, as established by the healthcare facility.

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4. Networking

4.1. Implementation Model

4.1.1. Application Data Flow

ResolutionMD implements an Application Entity (AE) which acts either as a Storage Service Class User (SCU) or as a Query / Retrieve Service Class User (SCU). This AE sends queries (C-FIND) initiated from ResolutionMD users to specified or all DICOM servers (Remote AE) identified within the ResolutionMD configuration. The query results are returned to ResolutionMD from the Remote and displayed to the requesting user.

When a user requests images for retrieval (C-MOVE), ResolutionMD sends a move request to specified or all Remote AE, loads the retrieved images into ResolutionMD server memory and displays to the users 2D, 3D or MIP/ MPR representations of the images. No Dicom data is transferred to the user device accessing the ResolutionMD application and image data is never stored persistently on the user device or on the ResolutionMD server.

ResolutionMD also provides a Storage SCU capability.

The application data flow for ResolutionMD 2.5 can be seen in Figure 1.

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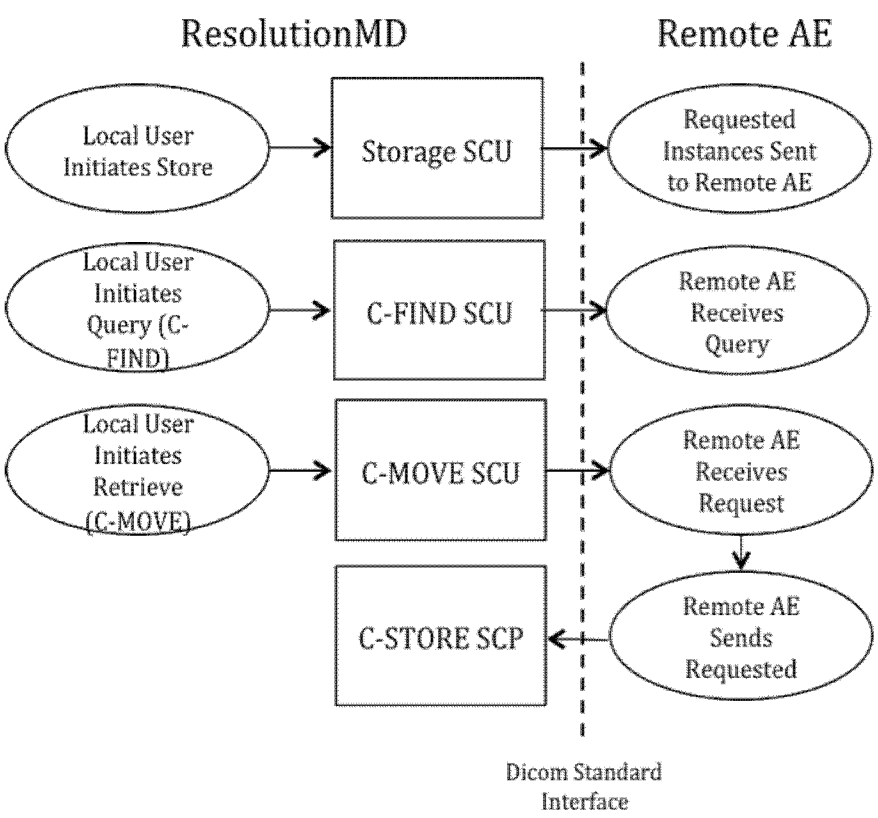

Figure 1: ResolutionMD Data Flow

4.1.2. Function Definition of Application Entities

4.1.2.1. Network Related Functions

1) ResMD supports storage of received SOP instances from remote SCU AE.
2) ResMD storage SCU transmits the stored instances to a remote AE triggered following a user initiated storage request to a pre-programmed remote AE.
3) ResMD acts as an SCU for the C-Find and C-Move.
4) ResMD acts as an SCP for the C-Store service.

4.1.3. Sequencing of Real World Activities

As shown in Figure 1, the local user must initiate the retrieve C-Move before the C-Store.

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4.2. AE Specification

4.2.1. Application Entity Specifications

This section outlines the specifications for each of the Application Entities that are relevant to the ResolutionMD 2.5.

4.2.1.1. Storage SOP Classes

ResMD Application Entity provides Standard Conformance to the following Storage SOP Classes:

SOP Class Name	SOP Class UID	SCU	SCP
CT Image Storage	1.2.840.10008.5.1.4.1.1.2	Yes	Yes
Enhanced CT Image Storage	1.2.840.10008.5.1.4.1.1.2.1	Yes	Yes
MR Image Storage	1.2.840.10008.5.1.4.1.1.4	Yes	Yes
Enhanced MR Image Storage	1.2.840.10008.5.1.4.1.1.4.1	Yes	Yes
Positron Emission Tomography Image Storage	1.2.840.10008.5.1.4.1.1.128	Yes	Yes
X-Ray Angiographic Image Storage	1.2.840.10008.5.1.4.1.1.12.1	Yes	Yes
Computed Radiology Image Storage	1.2.840.10008.5.1.4.1.1.1	Yes	Yes
Digital X-Ray Image Storage - for Presentation	1.2.840.10008.5.1.4.1.1.1.1	Yes	Yes
Digital X-Ray Image Storage - for Processing	1.2.840.10008.5.1.4.1.1.1.1.1	Yes	Yes
Ultrasound Image Storage	1.2.840.10008.5.1.4.1.1.6.1	Yes	Yes
Ultrasound Multi-Frame Image Storage	1.2.840.10008.5.1.4.1.1.3.1	Yes	Yes
Nuclear Medicine Image Storage	1.2.840.10008.5.1.4.1.1.20	Yes	Yes
Secondary Capture Image Storage	1.2.840.10008.5.1.4.1.1.7	Yes	Yes
Basic Text SR	1.2.840.10008.5.1.4.1.1.88.11	Yes	Yes

Table 2-1: Storage SOP Classes

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4.2.1.2. Query/Retrieve SOP Classes

ResMD Application Entity provides Standard Conformance to the following Query/Retrieve SOP Classes:

SOP Class Name	SOP Class UID	SCU	SCP
Patient Root Query / Retrieve IM - Find	1.2.840.10008.5.1.4.1.2.1.1	Yes	No
Patient Root Query / Retrieve IM - Move	1.2.840.10008.5.1.4.1.2.1.2	Yes	No
Study Root Query / Retrieve IM - Find	1.2.840.10008.5.1.4.1.2.2.1	Yes	No
Study Root Query / Retrieve IM – Move	1.2.840.10008.5.1.4.1.2.2.2	Yes	No

Table 2-2 : Query/Retrieve SOP Classes

4.2.1.3. Transfer Syntaxes

ResMD supports the following transfer syntaxes in the listed order for each SOP class:

Full Syntax List	
JPEG Lossless Non-Hierarchical 1st Order Prediction	1.2.840.10008.1.2.4.70
JPEG Lossless Non-Hierarchical (14)	1.2.840.10008.1.2.4.57
JPEG-LS Lossless	1.2.840.10008.1.2.4.80
JPEG-LS Lossy (near lossless)	1.2.840.10008.1.2.4.81
JPEG 2000 Lossless Only	1.2.840.10008.1.2.4.90
JPEG 2000	1.2.840.10008.1.2.4.91
JPEG Baseline	1.2.840.10008.1.2.4.50
JPEG Extended (2 & 4)	1.2.840.10008.1.2.4.51
Deflated Explicit VR Little Endian	1.2.840.10008.1.2.1.99
Explicit VR Big Endian	1.2.840.10008.1.2.2
Explicit VR Little Endian	1.2.840.10008.1.2.1
Implicit VR Little Endian	1.2.840.10008.1.2

Table 2-3: Transfer Syntaxes

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4.2.2. Association Establishment Policies

Association acceptance and establishment policies are described below for ResolutionMD

4.2.2.1. General

4.2.2.2. Number of Associations

The number of simultaneous active associations is limited only by the specifications of the machine running ResolutionMD and by the limits of performance on the network to which it is attached.

4.2.2.3. Asynchronous Nature

The Query / Retrieve function does support multiple outstanding transactions to defined AE. Asynchronous communication is supported.

4.2.2.4. Implementation Identifying Information

Currently, the ResolutionMD DICOM uses the OFFIS DCMTK as a baseline toolkit to support DICOM functionality. The original DCMTK Implementation Class UID and Version Name are being used.

Implementation Class UID	1.2.276.0.7230010.3
Implementation Version Name	OFFIS_DCMTK_354

Table 2-4: DICOM Implementation Class and Version for ResolutionMD

4.2.3. Association Acceptance Policy

This real world activity is used when ResolutionMD wishes to verify connectivity between the ResolutionMD Application Entity and a remote Application Entity.

4.3. Network Interfaces

ResolutionMD operates over the TCP/IP protocol stack of the OS on the server on which it is hosted. ResolutionMD is indifferent to the physical medium over which it operates.

4.4. Configuration

ResolutionMD Application Entities can be configured for Presentation Addresses and Application Entity Titles within the application. This and all other configuration is accessed via the ResolutionMD configuration capabilities that are outlined in the ResolutionMD installation and administration guides.

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4.4.1. AE Title/Presentation Address Mapping

ResolutionMD Application Entities can be configured for Presentation Addresses and Application Entity Titles within the application.

5. Media Interchange

None are supported.

6. Security

ResolutionMD supports SSL connections directly between web or mobile clients and the ResolutionMD application on a centralized server. Organizations should ensure that these as well as other security precautions such as firewalls or virtual private networks are in place to ensure security and privacy of image information. ResolutionMD should be operated in an environment with strong focus and attention to security and it is the responsibility of the deploying organization to ensure their IT network is secure.

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Traceability Analysis Matrix

System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
Section A: Functional and Capability Requirements	Feature/Function Name	(b) (4)					
I. Functional Requirements							
a. 2D Viewing							
A.I.a.1	Metadata display						
A.I.a.2	Orientation labels						
A.I.a.3	Measurement calipers						
A.I.a.4	Slice scrolling						
A.I.a.5	Pan						
A.I.a.6	Zoom						
A.I.a.7	Window/level						

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
A.I.a.8	Encryption indicator	A.I.a.8	(b) (4)				
A.I.a.9	Image Quality Panel	A.I.a.9					
A.I.a.9	Image Quality Panel						
A.I.a.10	Reset	A.I.a.10					
b. MIP/MPR Viewing		b. MIP/MPR Viewing					
A.I.b.1	Metadata display	A.I.b.1					
A.I.b.2	Orientation labels	A.I.b.2					

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
A.I.b.3	Measurement calipers	A.I.b.3	(b) (4)				
A.I.b.4	Slice scrolling	A.I.b.4					
A.I.b.5	Pan	A.I.b.5					
A.I.b.6	Zoom	A.I.b.6					
A.I.b.7	Window/level	A.I.b.7					
A.I.b.8	MIP slab viewing	A.I.b.8					
A.I.b.8	MIP slab viewing						

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
A.I.b.8	MIP slab viewing		(b) (4)				
A.I.b.9	Changing orthogonal view	A.I.b.9					
A.I.b.10	Encryption indicator	A.I.b.10					
A.I.b.11	Image Quality Panel	A.I.b.11					

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
A.I.b.11	Image Quality Panel		(b) (4)				
A.I.b.12	Reset	A.I.b.12					
c. 3D Viewing		c. 3D Viewing					
A.I.c.1	Render	A.I.c.1					

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
A.I.c.2	Volume rotation	A.I.c.2	(b) (4)				
A.I.c.3	Pan	A.I.c.3					
A.I.c.4	Zoom	A.I.c.4					
A.I.c.5	Lens	A.I.c.5					
A.I.c.6	Visualization presets	A.I.c.6					
A.I.c.7	Encryption indicator	A.I.c.7					
A.I.c.8	Image Quality Panel	A.I.c.8					
A.I.c.8	Image Quality Panel						
A.I.c.9	Reset	A.I.c.9					

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
A.I.c.10	3D Bricking	A.I.c.10	(b) (4)				
II. Physical Characteristics		II. Physical Characteristics					
a. Code Language		a. Code Language					
A.II.a.1	Client - written as native application for supported devices	A.II.a.1					
A.II.a.2	Server - languages must support core rendering & image manipulation	A.II.a.2					
b. Platform		b. Platform					
A.II.b.1	Client - Touch-screen Smartphone	A.II.b.1					

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		**Appendix 16.6**	(b) (4)				
A.II.b.2	Server - Well-known, consumable within Healthcare IT market, supports latest workstation graphics cards	A.II.b.2					
c. Operating System		**c. Operating System**					
A.II.c.1	Client - Smartphone OS with programmable touchscreen interface	A.II.c.1					
A.II.c.2	Server - OS support for security, graphics, networking and remote maintenance	A.II.c.2					
III. Computing Environment		**III. Computing Environment**					
a. Server Hardware	Support for graphics and network hardware	**a. Server Hardware**					
b. Client Hardware	Display characterstics	**b. Client Hardware**					

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		**Appendix 16.6**	(b) (4)				
b. Client Hardware	Display luminance profile	**b. Client Hardware**					
b. Client Hardware	Display resolution	**b. Client Hardware**					
b. Client Hardware	Dirty display	**b. Client Hardware**					
b. Client Hardware	Backlight brightness	**b. Client Hardware**					
b. Client Hardware	Battery service time	**b. Client Hardware**					

Appendix 16.7-Traceability Analysis

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
IV. Ambient Lighting User Assessment	View AAPM TG18 test patterns shown pixel for pixel at 100% JPEG quality to enable the user to asses whether their current lighting environment. A Test button will activate this in the client and the User Guide and help will explain how to use the images.	IV. Ambient Lighting User Assessment	(b) (4)				
Section B: Software System Inputs and Outputs	Feature/Function Name	Section B: Software System Inputs and Outputs					
I. Inputs	DICOM support	I. Inputs					
I. Inputs	DICOM support						

Appendix 16.7-Traceability Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
II. Outputs	2D, MIP/MPR, 3D image renderings as per the Functional Requirements	II. Outputs	(b) (4)				
Section C: Interfaces between Software System and Oher Systems	Feature/Function Name	Section C: Interfaces between Software System and Oher Systems					
I. PACS Interface	DICOM Query/Retrieve or direct database integration	I. PACS Interface					
II. Authentication Interface	External authentication service comunication e.g. LDAP	II. Authentication Interface					
III. URL Integration	Launch from RIS/EMR on mobile device	III. URL Integration					
Section D: Software-driven Alarms, Warning and Operator Messages		Section D: Software-driven Alarms, Warning and Operator Messages					
I. End User	Interrupts & Interactions related to battery, calendar, clock, phone, iPod, sleep, accesssibility, cable	I. End User					

Appendix 16.7-Traceability Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
II. Adminstrative User	Web server message log	II. Adminstrative User	(b) (4)				
Section E: Security Requirements	Feature/Function Name	Section E: Security Requirements					
I. Secure Communication		I. Secure Communication					
II. Server Identity Verification		II. Server Identity Verification					
III. Client Authentication		III. Client Authentication					
IV. Session Timeout		IV. Session Timeout					
V. Sensitive Data		V. Sensitive Data					
Section F: Usability Engineering Requirements	Feature/Function Name	Section F: Usability Engineering Requirements					

Appendix 16.7-Traceability Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		**Appendix 16.6**	**Appendix 16.3**				**Appendices 1** Appen
See Appendix 16.4.2 – ResolutionMD Mobile Usability Specification			(b) (4) [redacted]				
I.5.b. Performance	Speed of diagnosis						
V.1. Use Scenario 1	Network connectivity						

Appendix 16.7-Traceability Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
V.2. Use Scenario 2	High Ambient Light		(b) (4)				
Section G: Data Definition and Database Requirements	Feature/Function Name	Section G: Data Definition and Database Requirements					
Data Definition	Load DICOM File Types	DICOM loader as per Appendix 16.6.2- DICOM Conformance Statement, no database					
Section H: Installation and Acceptance Requirements	Feature/Function Name						
I. Installation Requirements							
a. Mobile Client	iTunes installation, uninstall						

Appendix 16.7-Traceability Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		**Appendix 16.6**	**Appendix 16.3**				**Appendices 1 Appen**
b. Server	Logistics, Networking		(b) (4)				
II. Acceptance Requirements							
a. Clinical end-user	Connection, authentication, query, view, open studies, interact						
b. Adminstrative user	Hardware, OS, Networking, Appliction validation						
Section I: Methods of Operation and Maintenance	**Feature/Function Name**						
I. End User	Open app, mode switch, close app, setting dialog						
II. Administrative User	Monitoring and configuration procedures for the server						
Section J: User Documentation	**Feature/Function Name**						
I. End-User	User Guide						
II. Admin User	Installation & Service Manual						

Appendix 16.7-Traceability Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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System Requirements Summary Section		System Design Summary Section	Risk Analysis Potential Failure (Initial RPN > 15)	Initial RPN	Failure Mitigation (Risks with an initial RPN of greater than 15 are required to have a mitigation as per SOP-19)	Final RPN	Verifi (QA Testing Docume
Appendix 16.4		Appendix 16.6	Appendix 16.3				Appendices 1 Appen
Section K: User Maintenance Requirements	Feature/Function Name		(b) (4)				
I. Upgrade Procedures							
II. Monitoring Features							
Section L: Regulatory Requirements	Feature/Function Name						
I. Clinical Evaluations	Benchmark comparison testing by radiologists						
II. Licensing Requirements	FDA 510(k) clearance						
II. Labeling Requirements	Indications for Use, Warnings, Precautions, Directions for Use						

Appendix 16.7-Traceability Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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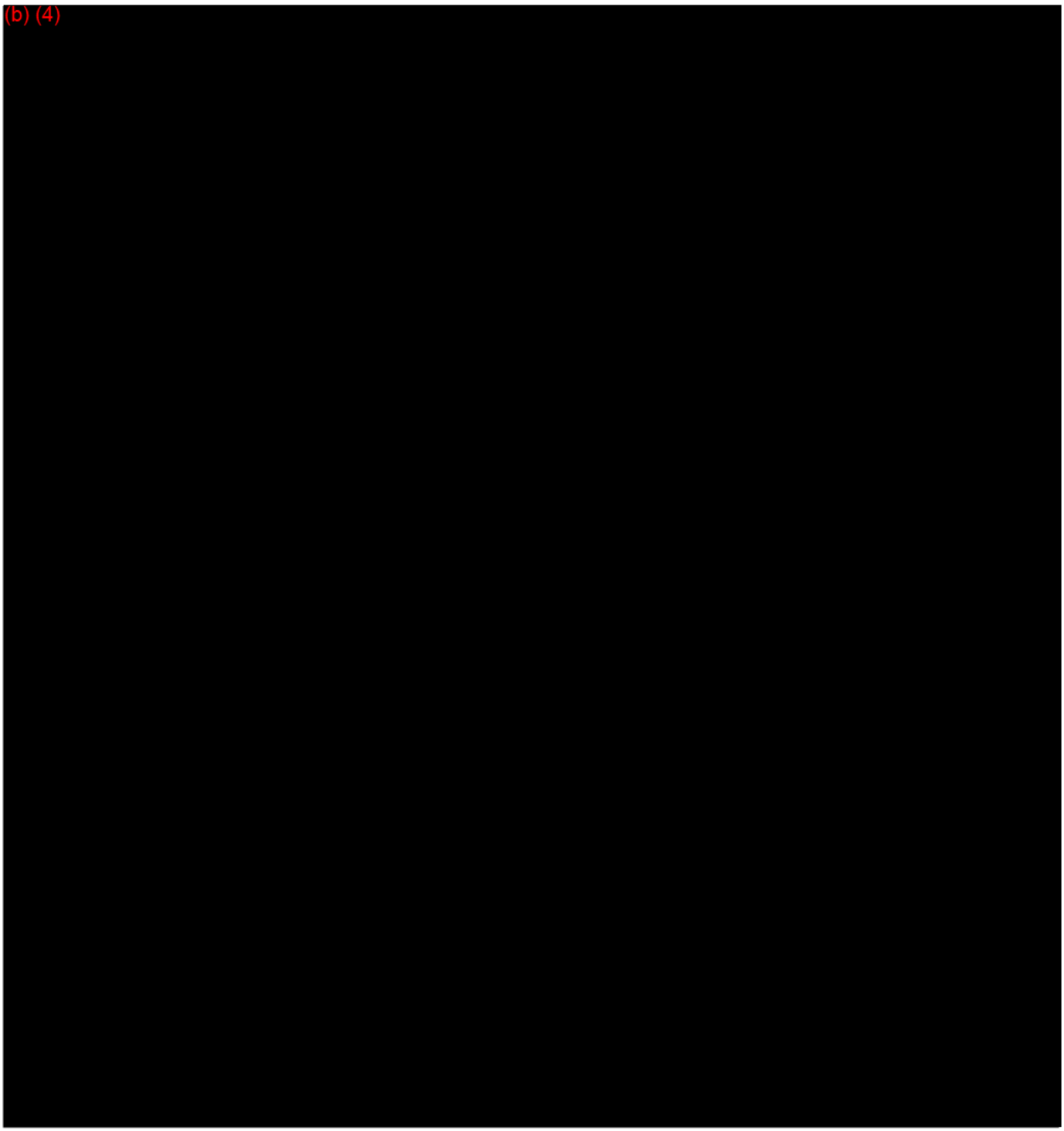
calgary scientific

Software Development Environment Description

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

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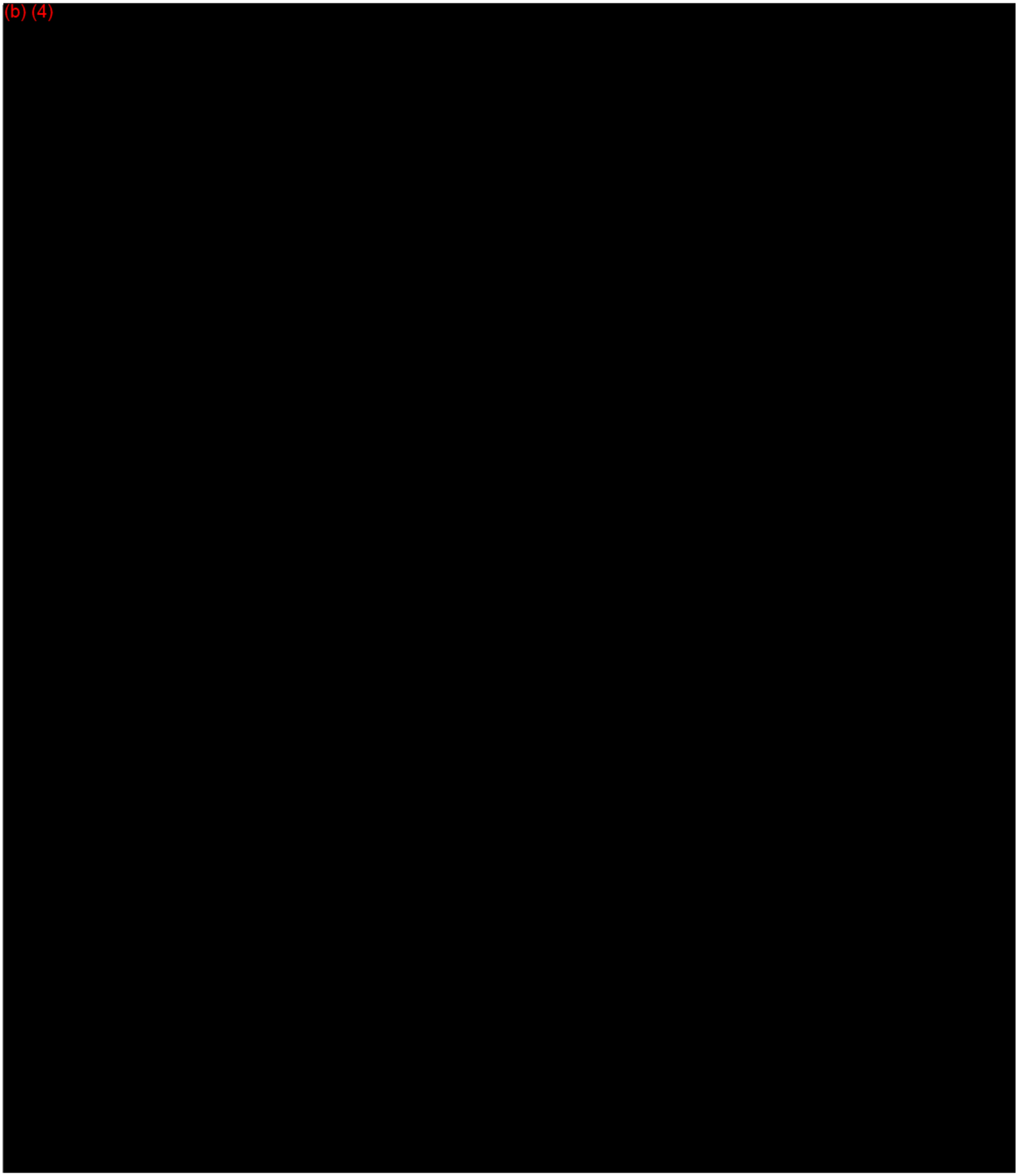
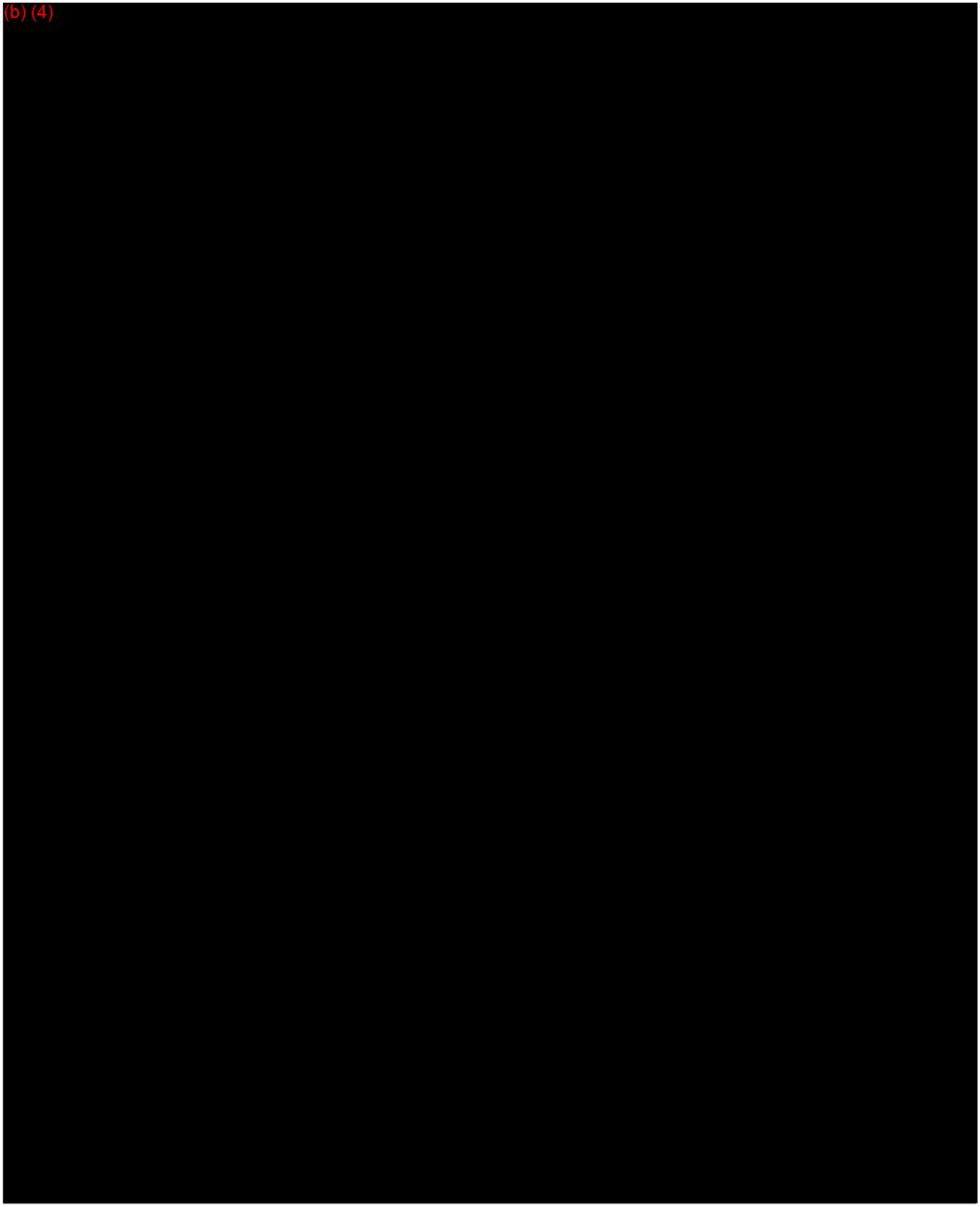
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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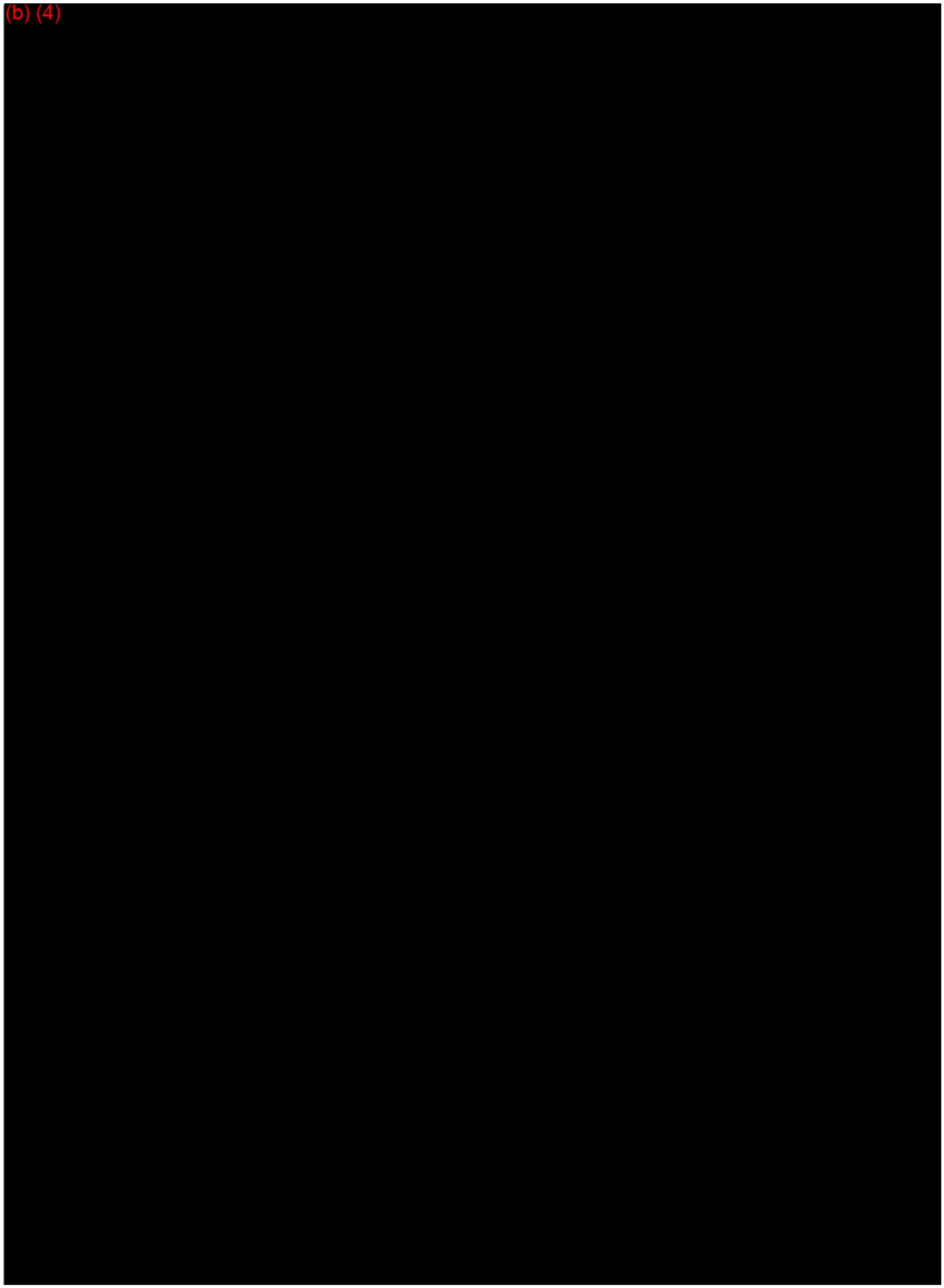
Diagram 2: Documents generated from the design and development process



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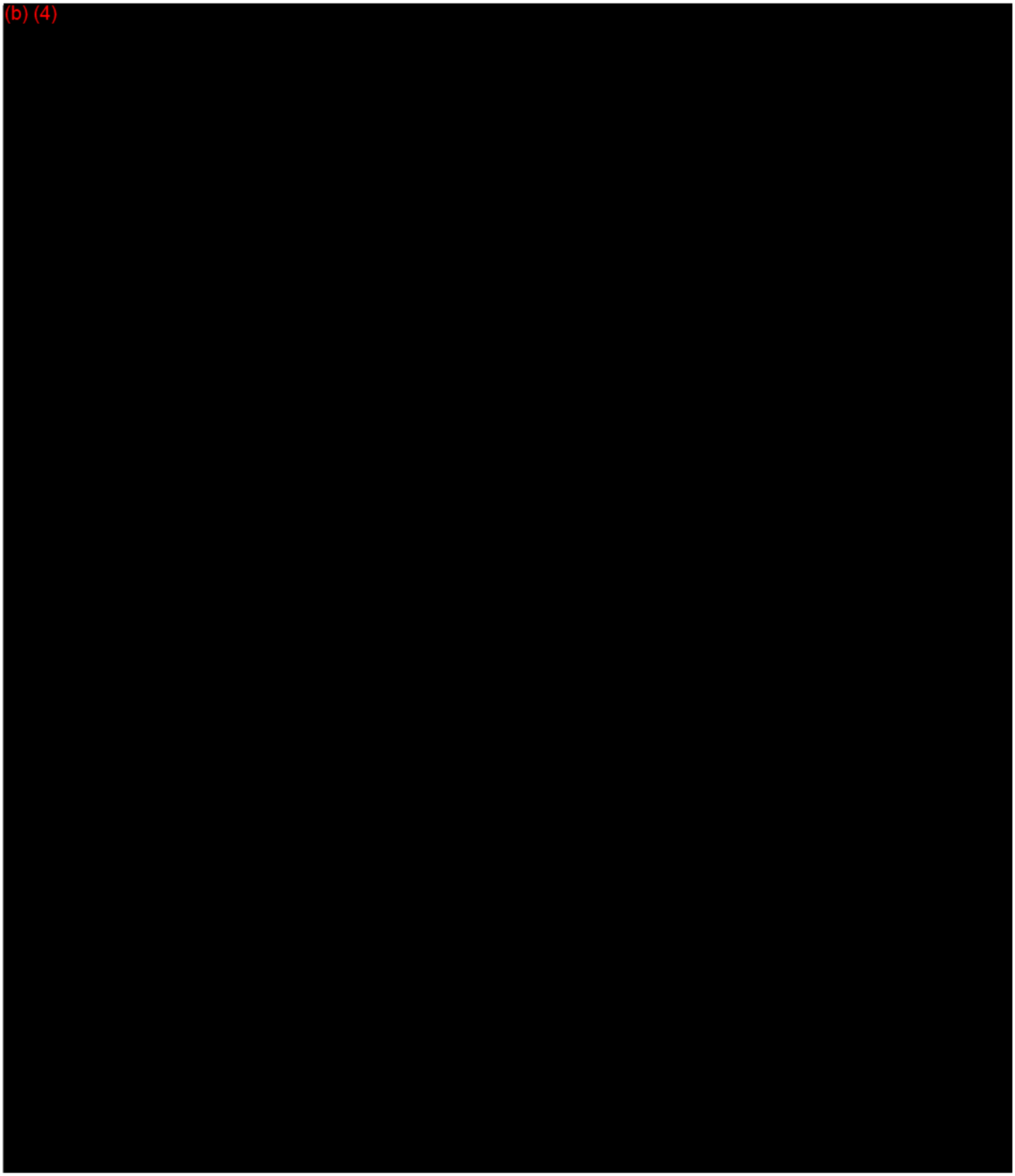
Change Management

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

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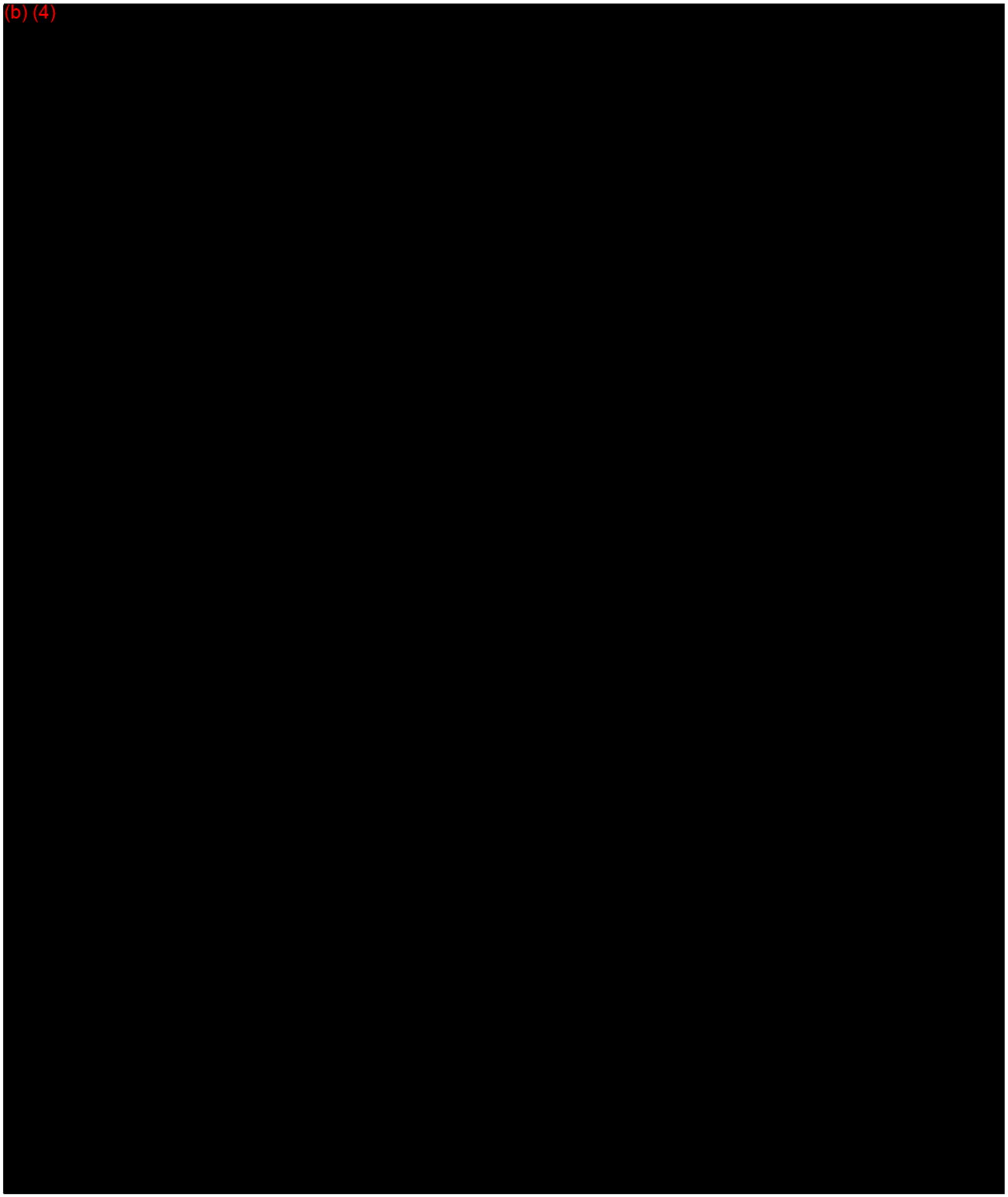
Coding Standards - (b) (4)



(b) (4)

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Records processed under FOIA Request 2011-7341; Released 4/8/13

Coding Standards - (b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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s MUST be filled out in full.

(b) (4)

on

(b) (4)	

ResMD Mobile
(b) (4)

Please Note: This Matrix can only be used to track 1 webserver and 1 software revision. If you are using another webserver, start another Matrix. If you are moving to a new Software revision, start another Matrix.

(b) (4)	

You MUST fill in the Following items for each tester on the Matrix:
<Tester Name> <Browser Type & Version> <Client OS> <Flash/Flex/Silverlight & Version> <Tester Start date mm/dd/yyyy>

(b) (4)		(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

(b) (4)

This matrix is to record the results (P/F) of running the associated test

For any Defects you find please note the Defect Number in the "Ticket Number (New or Reproduced)" column and on the "Ticket Summary" tab

Documentation referenced using the (b) (4)
(b) (4)

Cases referenced using the (b) (4)
(b) (4)

Refer to the case for the specific document and heading

P
F
ND
NA

Records processed under FOIA Request 2011-7341; Released 4/8/13

nality	Guidance Document Reference	Test-case Reference	Notes
RS Section A.I.a)			
ta display (SRS Section A.I.a.1)	S2D - Single2D.doc		
(b) (4)			
tion labels (SRS Section A.I.a.2)	S2D - Single2D.doc		
(b) (4)			
tion labels (SRS Section A.I.a.2)	CAL - Calipers.doc	ResMD_mobile_iPhone.doc	
(b) (4)			
olling (SRS Section A.I.a.4)	PAG – Page.doc	ResMD_mobile_iPhone.doc	
(b) (4)			
S Section A.1.a.5)	PAN – Panning.doc	ResMD_mobile_iPhone.doc	
(b) (4)			
S Section A.1.a.5)	ZTV - ZoomThroughViews.doc	ResMD_mobile_iPhone.doc	
(b) (4)			
v/level (SRS Section A.I.a.7)	WLV - WindowLevelViews.doc	ResMD_mobile_iPhone.doc	
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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nality	Guidance Document Reference	Test-case Reference	Notes
(b) (4)			
ion Indicator (SRS Section A.I.a.8)		\\fnp\QA\General\Projects\2010\ResolutionMD 2.5\FDA Mobile Submis	
(b) (4)			
	ResMD_mobile_iPhone.doc	SET - Settings.doc	
(b) (4)			
uality panel(SRS Section A.I.a.9)		\\fnp\QA\General\Projects\2010\ResolutionMD 2.5\FDA Mobile Submis	
(b) (4)			
	ResMD_mobile_iPhone.doc	SET - Settings.doc	
e/Decrease the "Quality"	Changing ResMD Settings	SET-0006	
RS Section A.I.a.10)			
(b) (4)			

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nality	Guidance Document Reference	Test-case Reference	Notes
MPR (SRS Section A.I.b)			
ta display (SRS Section A.I.b.1)		\\fnp\QA\General\Projects\2010\ResolutionMD 2.5\FDA Mobile Submis	
(b) (4)			
		(b) (4)	
tion labels (SRS Section A.I.b.2)	S2D - Single2D.doc		
(b) (4)			
ement calipers (SRS Section A.I.b.3)	ResMD_mobile_iPhone.doc	CAL - Calipers.doc	
(b) (4)			
olling (SRS Section A.I.b.4)	ResMD_mobile_iPhone.doc	PAG – Page.doc	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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nality	Guidance Document Reference	Test-case Reference	Notes
(b) (4)			
S Section A.I.b.5)	ResMD_mobile_iPhone.doc	PAN – Panning.doc	
(b) (4)			
SRS Section A.I.b.6)	ResMD_mobile_iPhone.doc	WLV - WindowLevelViews.doc	
(b) (4)			
v/level (SRS Section A.I.b.7)	ResMD_mobile_iPhone.doc	PAN – Panning.doc	
(b) (4)			
n viewing (SRS Section A.I.b.8)	ResMD_mobile_iPhone.doc	iMIP - iPhoneMIPMPR.doc	
(b) (4)			
g orthogonal view (SRS Section A.I.b.9)	ResMD_mobile_iPhone.doc	iMIP - iPhoneMIPMPR.doc	
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

nality	Guidance Document Reference	Test-case Reference	Notes
ion Indicator (SRS Section A.I.b.10)		(b) (4)	
(b) (4)			
	ResMD_mobile_iPhone.doc	SET - Settings.doc	
(b) (4)			
uality panel (SRS Section A.I.b.11)		\\fnp\QA\General\Projects\2010\ResolutionMD 2.5\FDA Mobile Submis	
(b) (4)			
	ResMD_mobile_iPhone.doc	SET - Settings.doc	
(b) (4)			
RS Section A.I.b.12)	ResMD_mobile_iPhone.doc	PAN – Panning.doc	
(b) (4)			
RS Section A.I.c)			
(SRS Section A.I.c.1)			
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

nality	Guidance Document Reference	Test-case Reference	Notes
(b) (4)			
rotation (SRS Section A.I.c.2)			
(b) (4)			
S Section A.I.c.3)			
(b) (4)			
RS Section A.I.c.4)	ResMD_mobile_iPhone.doc	ZTV - ZoomThroughViews.doc	
(b) (4)			
S Section A.I.c.5)	ResMD_mobile_iPhone.doc	S3D - Single3D.doc	
(b) (4)			
ation presets (SRS Section A.I.c.6)	ResMD_mobile_iPhone.doc	S3D - Single3D.doc	
(b) (4)			
ion Indicator (SRS Section A.I.c.7)		(b) (4)	
(b) (4)			
	ResMD_mobile_iPhone.doc	SET - Settings.doc	
(b) (4)			

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nality	Guidance Document Reference	Test-case Reference	Notes
uality panel (SRS Section A.I.c.8)		(b) (4)	
(b) (4)			
	ResMD_mobile_iPhone.doc	SET - Settings.doc	
(b) (4)			
RS Section A.I.c.9)	ResMD_mobile_iPhone.doc	S3D - Single3D.doc	
(b) (4)			
ing (SRS Section A.I.c.10)	ResMD_mobile_iPhone.doc	BRK - Bricking.doc	
(b) (4)			
t Lighting User Assessment (SRS Section A.IV)		TCM Case Reference	
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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nality	Guidance Document Reference	Test-case Reference	Notes
(b) (4)			

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	Guidance Document Reference	Test-case Reference	Notes
Worklist enabled.	(b) (4)		
(b) (4)			
		TCM Case #	
(b) (4)			
	ResMD_mobile_iPhone.doc	2DO - 2D Orientation.doc	
(b) (4)			
in MIP/MPR	ResMD_mobile_iPhone.doc	2DO - 2D Orientation.doc	
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Guidance Document Reference	Test-case Reference	Notes
	ResMD_mobile_iPhone.doc	S3D - Single3D.doc	
(b) (4) [redacted]			

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	Guidance Document Reference	Test-case Reference	Notes
tivity (SRS Section A.III.b)	ResMD_mobile_iPhone.doc	DCON - DeviceConnectivity.doc	
(b) (4)			
rkList (Connect to dcm4chee) (SRS Section C.I)	ResMD_mobile_iPhone.doc	SWL - SearchWorkList.doc	
(b) (4)			

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Records processed under FOIA Request 2011-7341; Released 4/8/13

	Guidance Document Reference	Test-case Reference	Notes
tivity (SRS Section A.III.b)	ResMD_mobile_iPhone.doc	DCON - DeviceConnectivity.doc	
(b) (4)			
eractions (SRS Section D.I)	ResMD_mobile_iPhone.doc		
(b) (4)			
S Section D.II)	ResMD_mobile_iPhone.doc	WSE - WebServer.doc	
(b) (4)			

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ty	Guidance Document Reference	Test-case Reference	Notes
(b) (4)			
netion	ResMD_mobile_iPhone.doc	SCON - SecureConnection.doc	
(b) (4)			
	ResMD_mobile_iPhone.doc	SET - Settings.doc	
(b) (4)			
	ResMD_mobile_iPhone.doc	WSE - WebServer.doc	
(b) (4)			

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ty (SRS Section F)	Guidance Document Reference	Test-case Reference	Notes	
				TCM Cases
(b) (4) [redacted]				
Testing	ResMD_mobile_iPhone.doc	MULTICON - MultiUserConcurrency.doc		
(b) (4) [redacted]				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ty (SRS Section F)	Guidance Document Reference	Test-case Reference	Notes	
(b) (4)				
	ResMD_mobile_iPhone.doc	INS - Installation.doc		
(b) (4)				

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ty (SRS Section F)	Guidance Document Reference	Test-case Reference	Notes	
(b) (4)				

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	Guidance Document Reference	Test-case Reference	Notes
(b) (4)			

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Records processed under FOIA Request 2011-7341; Released 4/8/13

	Guidance Document Reference	Test-case Reference	Notes
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

	Guidance Document Reference	Test-case Reference	Notes
S Section I.I)	ResMD_mobile_iPhone.doc	APG - ApplicationGeneric.doc	
(b) (4) [redacted]			
I.I)	ResMD_mobile_iPhone.doc	SET - Settings.doc	
(b) (4) [redacted]			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

	Guidance Document Reference	Test-case Reference	Notes
(b) (4)	ResMD_mobile_iPhone.doc	DOC - Documentation.doc	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

Validation Report

Product Name:	ResolutionMD Mobile 2.6
Project Identifier:	(b) (4) [redacted]
Report #:	
Reported by:	
Date of Report:	

Hard copy without "Controlled Copy" stamp is not authorized to any changes control.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Introduction

The ResolutionMD™ is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices such as Apple devices include the iPhone 4 and the iPad. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0 compliant medical images.

Validation Tester

(b) (4)

[redacted]

Validation Methodology

(b) (4)

[redacted]

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Validation Results

(b) (4) [redacted]

Name of Feature	Expected Outcome	Actual Outcome	Conformity (pick one) Minor –nonconformity or Major-nonconformity?	Follow-up Required? (if yes, write down the ticket #)
(b) (4) [redacted]				

(b) (4) [redacted]

ct to any change control.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118
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Records processed under FOIA Request 2011-7341; Released 4/8/13

Findings

(b) (4) [redacted]

Follow-ups

(b) (4) [redacted]

Conclusion

(b) (4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

Appendix A

Validation results on iPhone 4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

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Appendix B

Validation results on iPad

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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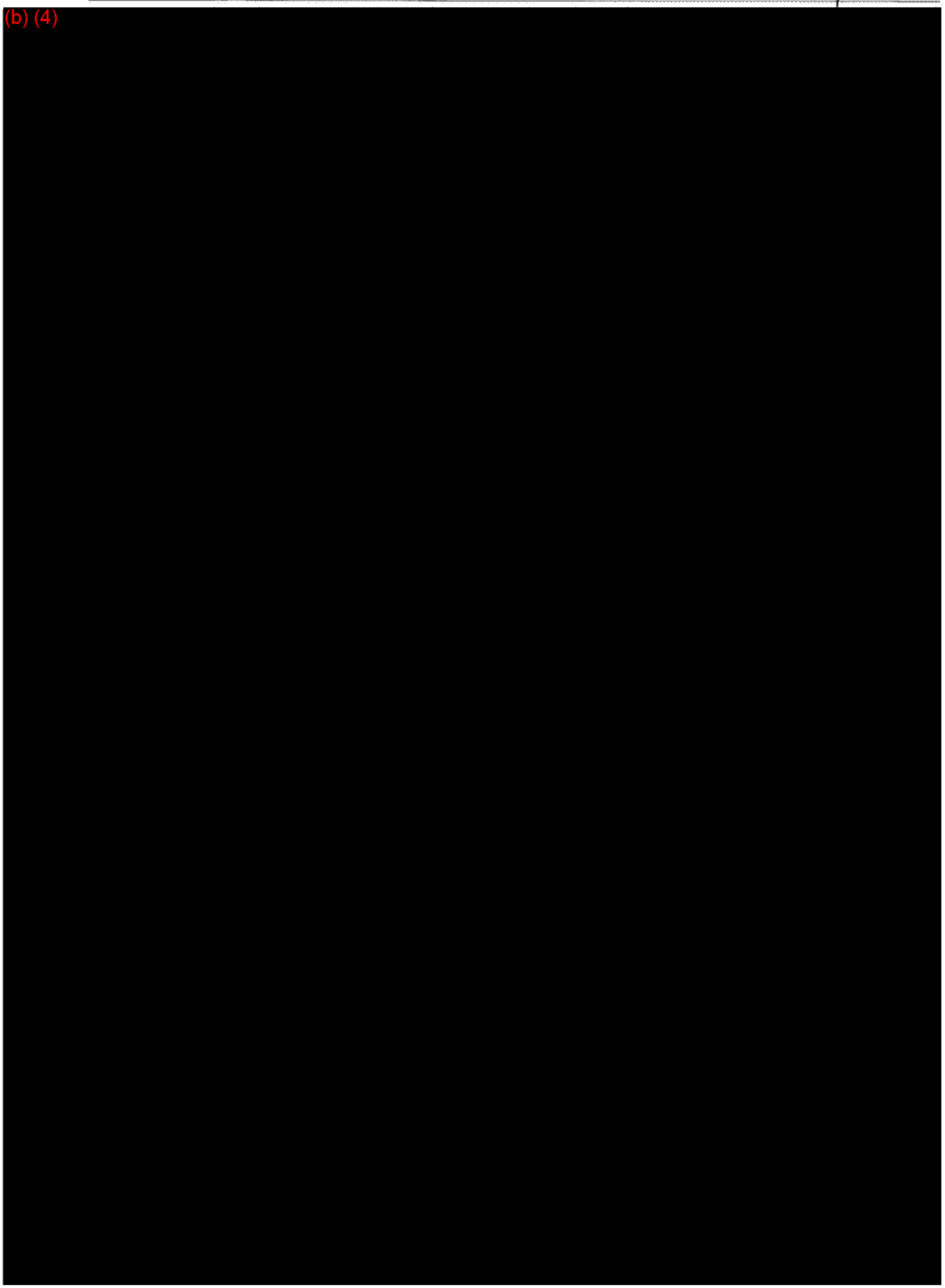
(b) (4)



(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

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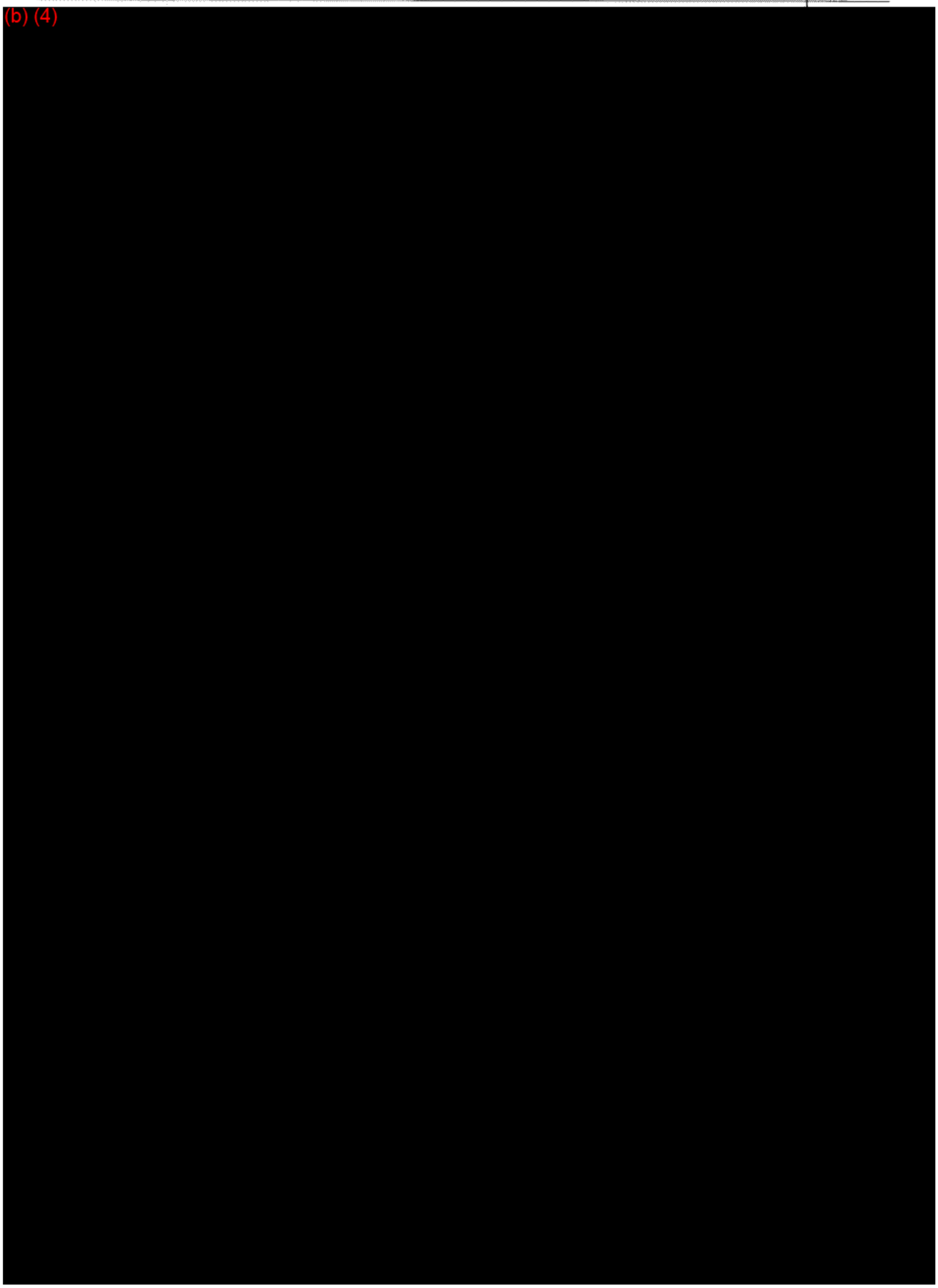

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

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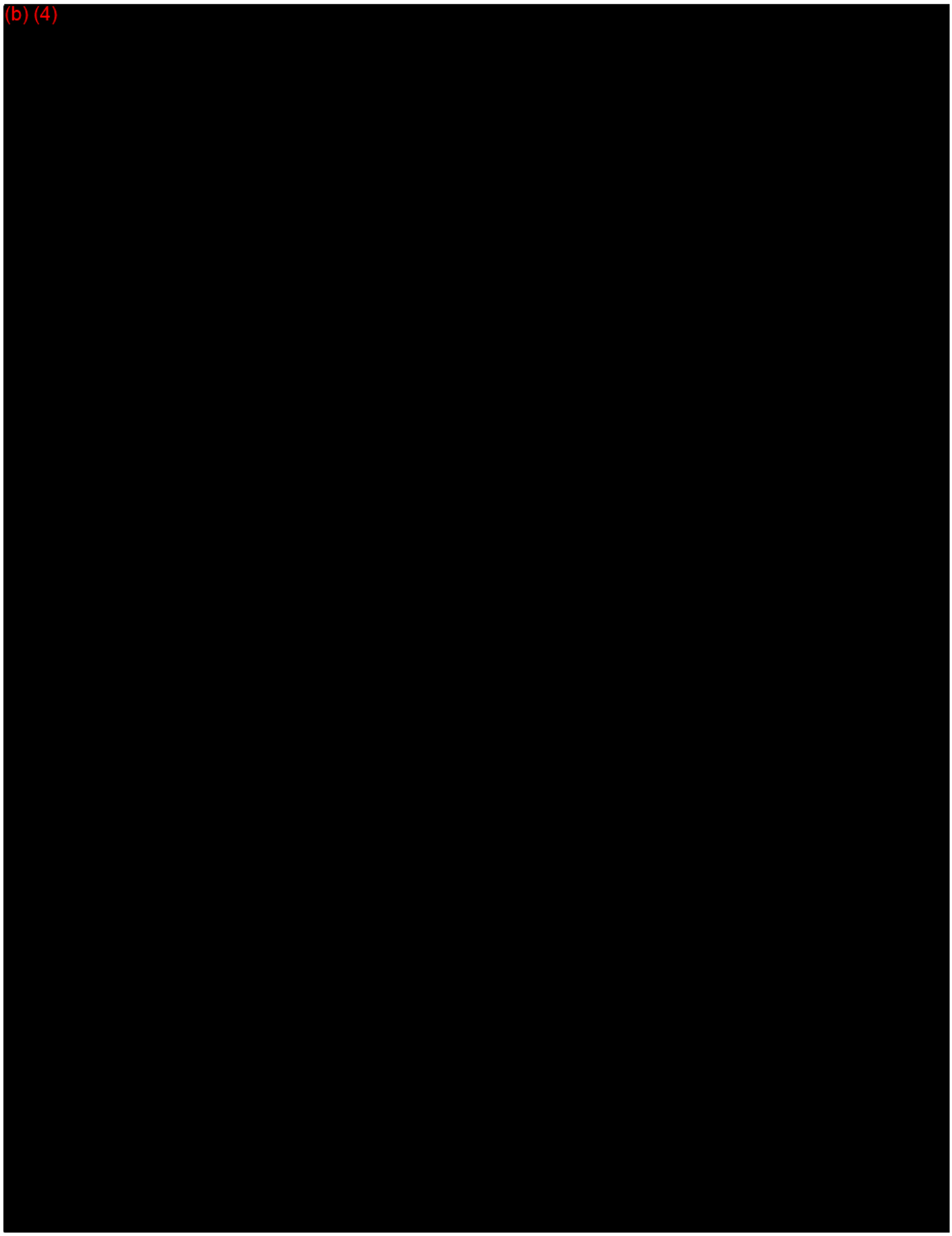

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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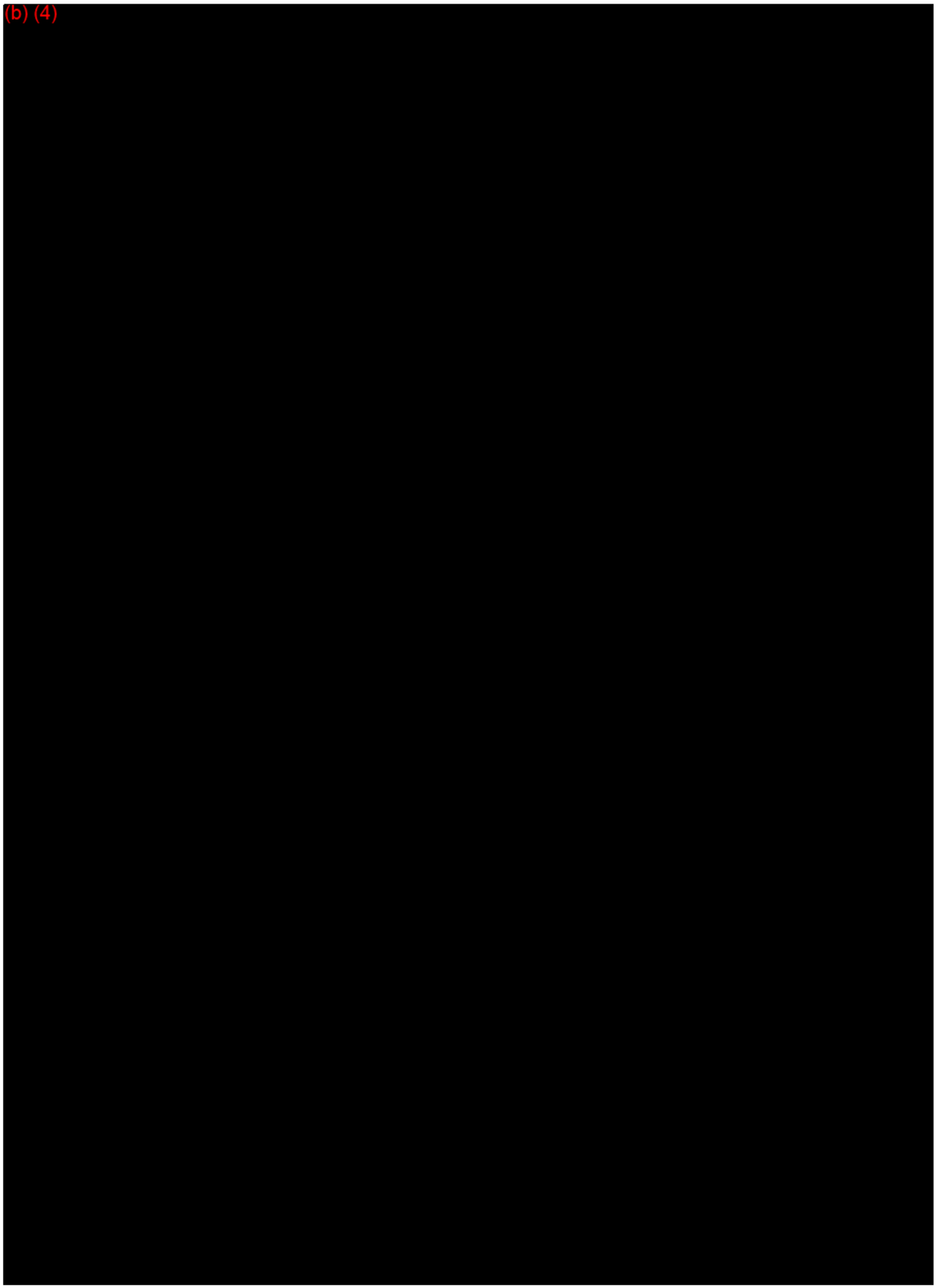
(b) (4)



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Hard copy without 'Controlled Copy' stamp is not subject to any change control

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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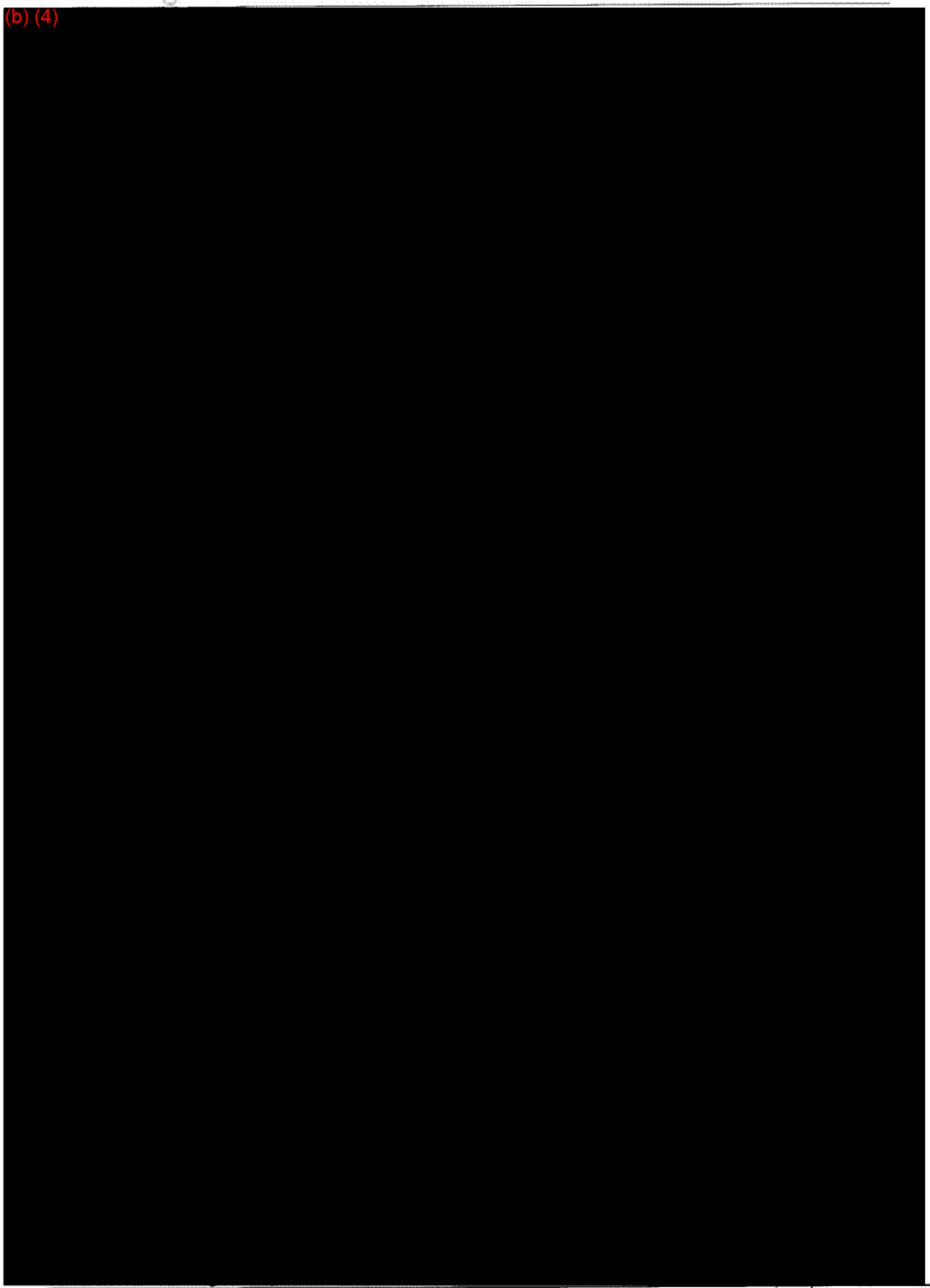
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

(b) (4)

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Appendix 16.9.3 – Mobile Display Lab Testing Results

ResolutionMD Mobile as an Appropriate Radiological Device for Diagnostic Review.

(b) (4)

TG18 Bench Tests for iPhone4 and iPad

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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About the Test Company

(b) (4)

[redacted]

Test Engineer Biography

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table One: TG18 Test Results & Acceptance Criteria for ResolutionMD Mobile clients[iii]

Test	Primary Acceptance	Secondary Acceptance	iPhone4 value	iPad Value	CSI Comments
(b) (4)					

Appendix 16.9.3 – Mobile Display Lab Testing Results

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

Test	Primary Acceptance	Secondary Acceptance	iPhone4 value	iPad Value	CSI Comments
(b) (4)					

Appendix 16.9.3 – Mobile Display Lab Testing Results

Records processed under FOIA Request 2011-7341; Released 4/8/13

Test	Primary Acceptance	Secondary Acceptance	iPhone4 value	iPad Value	CSI Comments
(b) (4)					(b) (4)

Appendix 16.9.3 – Mobile Display Lab Testing Results

Records processed under FOIA Request 2011-7341; Released 4/8/13

ResolutionMD Mobile as an appropriate radiological device.

Table Two: Relevant goals from the ACR[iv] to which the use of ResolutionMD Mobile contributes.

ACR Goal	ResolutionMD Mobile Contribution
4. Transmission of data to remote sites for consultation, review, or formal interpretation.	(b) (4) [redacted]
5. Appropriate compression of image data to facilitate transmission or storage, without loss of clinically significant information.	
7. Promoting efficiency and quality improvement.	
8. Providing interpreted images to referring providers.	
9. Supporting telemedicine by making radiologic consultations available in medical facilities without on-site radiologic support.	

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ACR Goal	ResolutionMD Mobile Contribution
10. Providing supervision of off-site imaging studies.	(b) (4) [redacted]
11. Providing timely availability of radiologic images, image consultation, and image interpretation in emergent and nonemergent clinical care areas by: a. Facilitating radiologic interpretations in on-call situations. b. Providing subspecialty radiologic support as needed.	

Table Three: ACR Guidelines relevant to ResolutionMD Mobile

Guideline	ResolutionMD Mobile
Compression. Several methods, including both reversible and irreversible techniques (lossless and lossy are also common terms), may be used under the direction of a qualified physician **or** practitioner, with minimal if any reduction in clinical diagnostic image quality. If compression is used, algorithms recommended by the DICOM standard such as wavelet or JPEG-2000 compression methods should be used.	(b) (4) [redacted]
In all cases, for official interpretation, the digital data received at the receiving end of any transmission must have negligible if any loss of clinically significant information when compared to uncertainties introduced by the detector and display devices.	
The transmission system shall have adequate error-checking capability.	

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Guideline	ResolutionMD Mobile
The DICOM Transmission and Storage Standard Digital X-ray Image Information Object and relevant substandards should be used for best practice implementation and incorporated by all digital imaging equipment vendors, as appropriate.	(b) (4) [redacted]
The ratio of the maximum luminance to the minimum luminance of a display device for images other than mammography should be at least 50.	
Maximum luminance of the grayscale monitors not used for mammography therefore should be at least 50 foot lamberts (171 cd/m2).	
A minimum of 8-bit luminance resolution (bit depth) is required.	
Window and level adjustment tools must be available since the full dynamic range of most images cannot be displayed on most digital devices. Preset window/level settings (e.g., bone or lung windows using set lookup table [LUT] transformations) are recommended to increase the speed of user interaction with the display device.	
Zoom (magnification) and pan functions capable of meeting guidelines for display at the originally acquired spatial resolutions should be used rather than the user moving closer to the display.	
Rotating or flipping the images, provided labeling of patient orientation is preserved.	
Displaying prior application of irreversible compression ratio, processing, or cropping.	
Matrix size should be as close to the "for processing" image data as possible, or obtainable with magnification (image zoom and pan functionality) without sacrificing too much of the image field of view.	
Bit depth should be at least 8 bits.	

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Guideline	ResolutionMD Mobile
The total number of images acquired in the study needs to be accessible during interpretation.	(b) (4) [redacted]
The FDA requires that any electronic device used within 2.5 meters (about 10.8 feet) or less of a patient must have UL2601 certification.	
Angular performance should not lead to a deviation of the contrast response from the DICOM GSDF by more than 30% within the operating ranges of the viewing angles (<30 degrees usually).	
Color LCD displays are now approaching the luminance output of grayscale LCD displays with similar grayscale rendition accuracy for 3 megapixel and 2 megapixel display formats, and should be acceptable for use as long as minimum luminance requirements are satisfied and the monitor/video card provides capabilities for DICOM calibration.	
Color displays are advantageous for displaying color-encoded functional imaging information from modalities such as positron emission tomography (PET), nuclear medicine (NM), ultrasound (US), and magnetic	
The DICOM GSDF can be applied to color displays for accurate conformance to grayscale rendition, but the issue of color display calibration is still not fully addressed. Monitors displaying images that require strict color rendition accuracy should have alternate methods of color calibration and testing.	

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Guideline	ResolutionMD Mobile
Digital image data management systems should provide network and software security protocols to protect the confidentiality of patients' identification and imaging data as well as appropriate user accessibility and authentication.	(b) (4) [redacted]
Physicians providing emergency interpretations should be immediately available for consultation.	
Performance testing and monitoring of official or primary interpretation display devices should be performed in accordance with any relevant ACR modality accreditation program Quality Control Manual recommendations, the equipment manufacturer specifications, applicable industry guidelines, and state and federal regulations. In the absence of adequate manufacturer procedures, guidelines or standards, the recommendations for the performance evaluation of display devices testing methods and frequencies contained in AAPM Task Group 18: Assessment of Display Performance for Medical Imaging Systems should be followed.	
As a minimum quality check for acquisition workstation, small matrix, and secondary display devices, a test image, such as the SMPTE test pattern should be captured, transmitted, archived, retrieved, and displayed at appropriate intervals to test the overall operation of the system under conditions that simulate its normal operation. As a spatial resolution test, at least 2.5 lp/mm resolutions should be confirmed for both small and large-matrix official interpretation. As a test of the display fidelity, SMPTE pattern data files sized to occupy the full area used to display images on the monitor should be displayed. The overall SMPTE image appearance should be inspected to assure the absence of gross artifacts (e.g., blurring or bleeding of bright display areas into dark areas or aliasing of spatial resolution patterns). All display monitors used for primary interpretation should be tested at least monthly. As a dynamic range test, both the 5% and the 95% areas should be seen as distinct from the respective adjacent 0% and 100% areas.	

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(b) (4)

(b) (4)

Display Quality Evaluation

IPAD #369

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(b) (4) – METROLOGY LABORATORY

DISPLAY QUALITY TEST REPORT

(b) (4)

Display Testing Description

(b) (4)

Device Under Test

(b) (4)

Test Equipment

(b) (4)

Tests Performed

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

[redacted]

Display Quality Evaluation

IPhone #1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

Display Testing Description

(b) (4)

Device Under Test

(b) (4)

Test Equipment

(b) (4)

Tests Performed

(b) (4)

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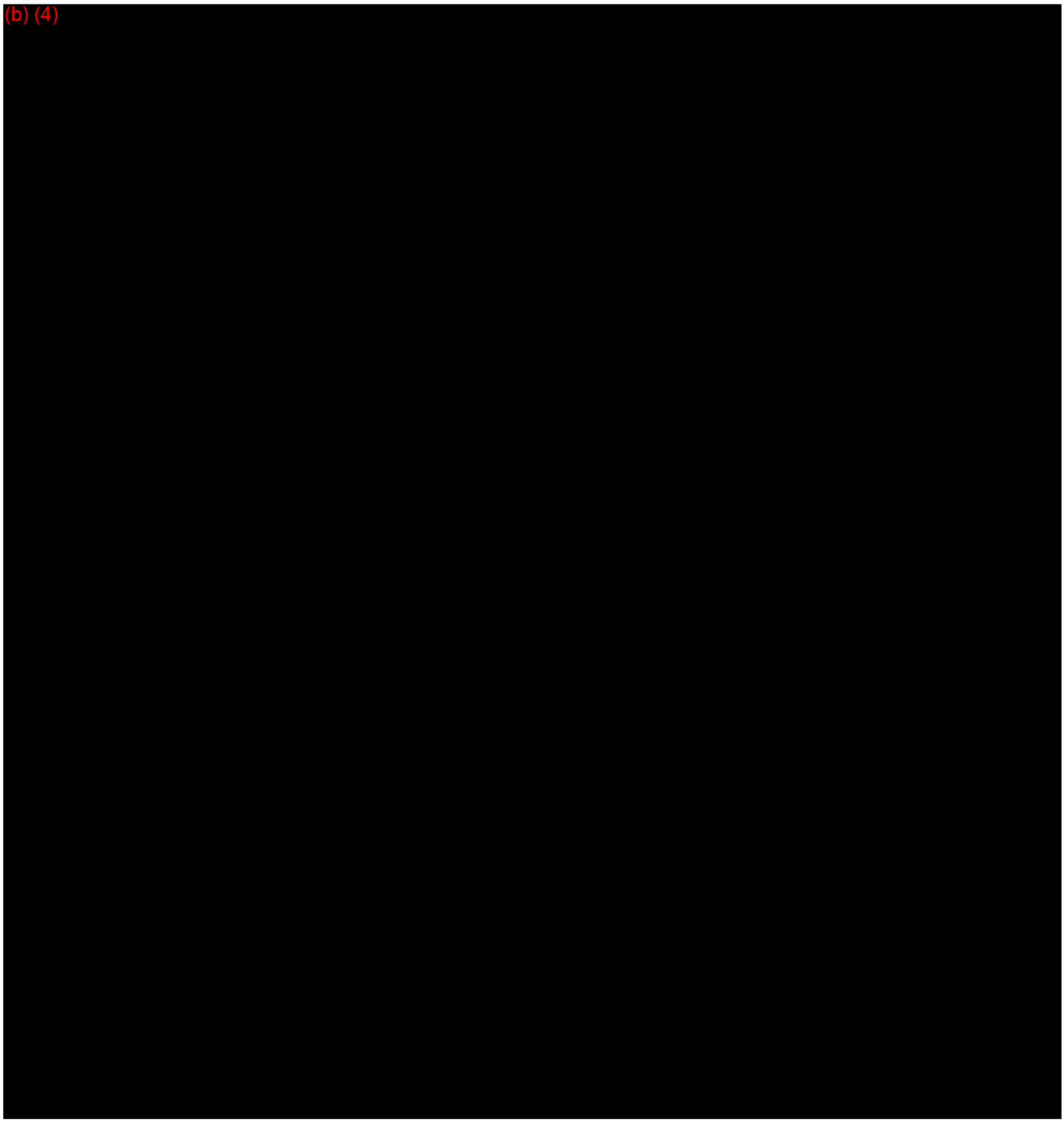
Results Summary

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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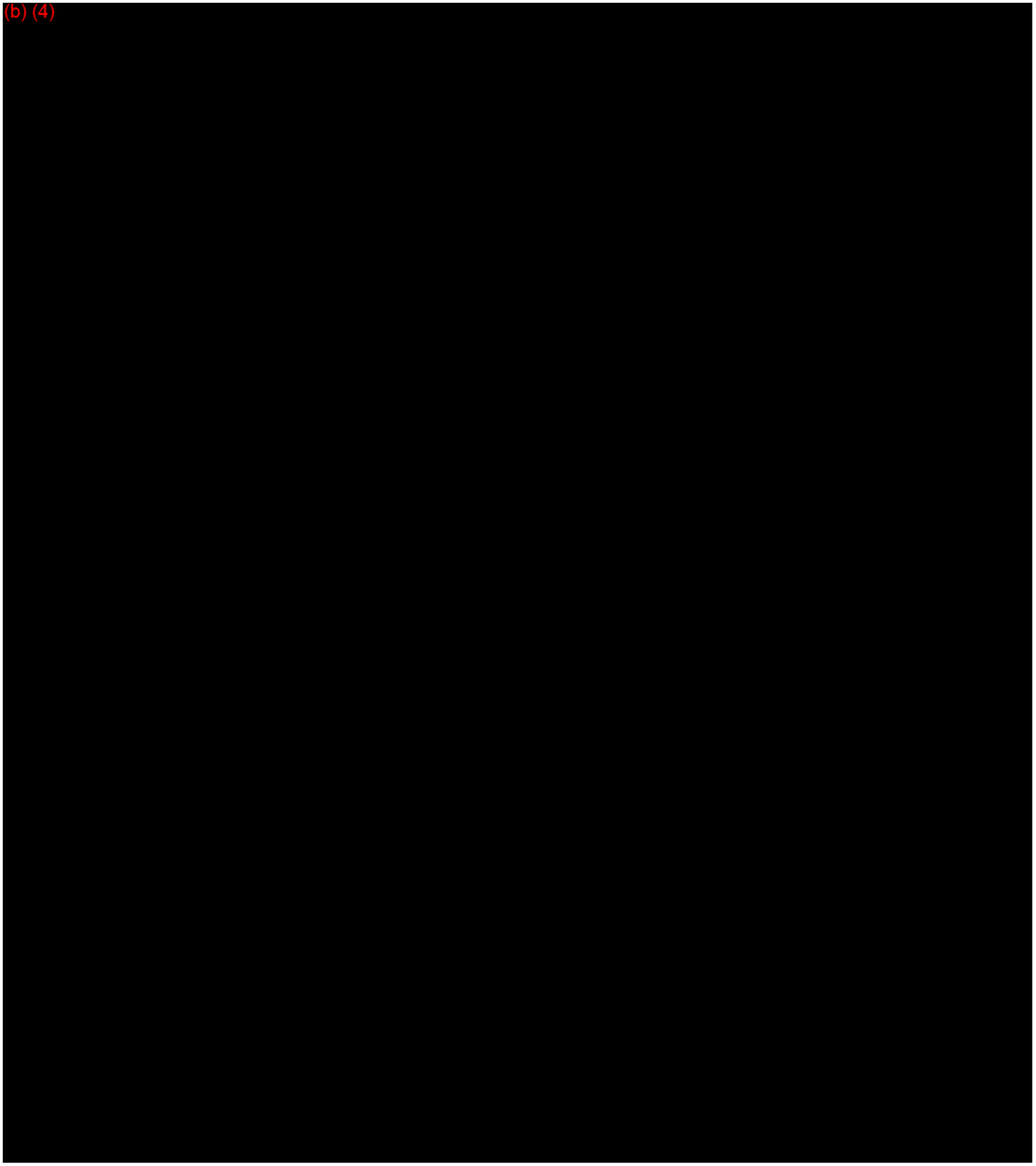
Test Results

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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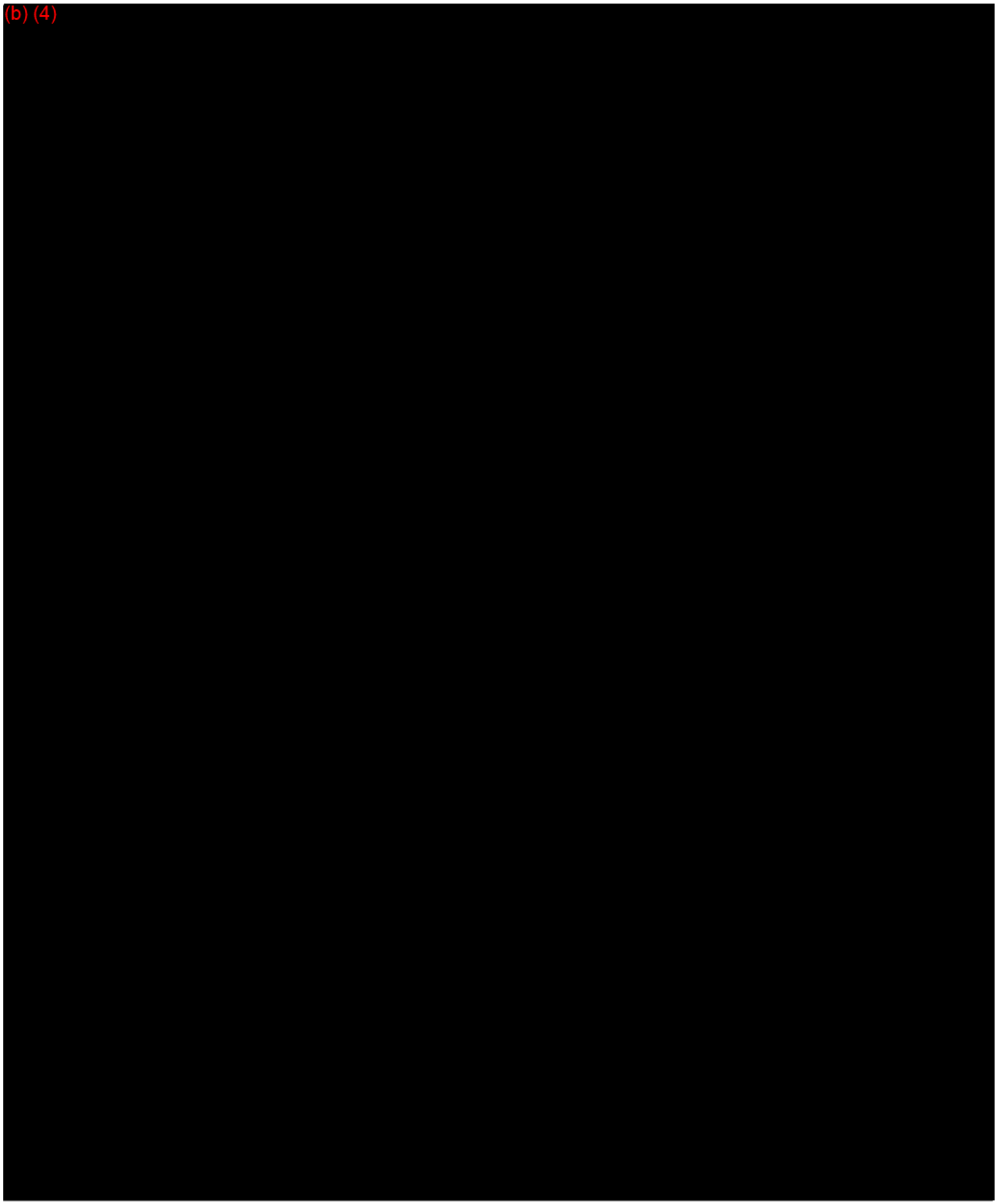
Appendix A

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 16.9.3.3 - ResolutionMD™ Mobile Display Noise Testing for iPhone and iPad

(b) (4)

[redacted]

The results are presented in the following tables.

(b) (4)

[redacted]

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Summary – All tests were passed according to the TG18 criteria on both the iPhone 4 and iPad at both sets of ambient lighting conditions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 16.9.4

Calgary Scientific Inc. – ResolutionMD Mobile

Mobile Device / PACS Diagnostic Effectiveness Comparison

May 10, 2011

By:
Calgary Scientific Inc.
Calgary, Alberta, Canada

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mobile Study 6
Summary of Findings 7
Mobile Device Review Experience Comments 7
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Case Review Summary 8
Results 12
Conclusions 13

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Calgary Scientific Inc. – ResolutionMD Mobile
Mobile Device / PACS Diagnostic Effectiveness Comparison

Abstract

Objective – To show qualitatively that radiological review of mobile devices (iPhone and iPad)

(b) (4)

Methods – An expert panel of radiologists from three U.S.-based institutions described 12

(b) (4)

Results – Both radiologists agreed that the mobile device was adequate quality for clinical use

(b) (4)

Conclusions – We conclude that the ResolutionMD Mobile software running on a mobile device

(b) (4)

Please see Page 13 for a more detailed discussion of results and conclusions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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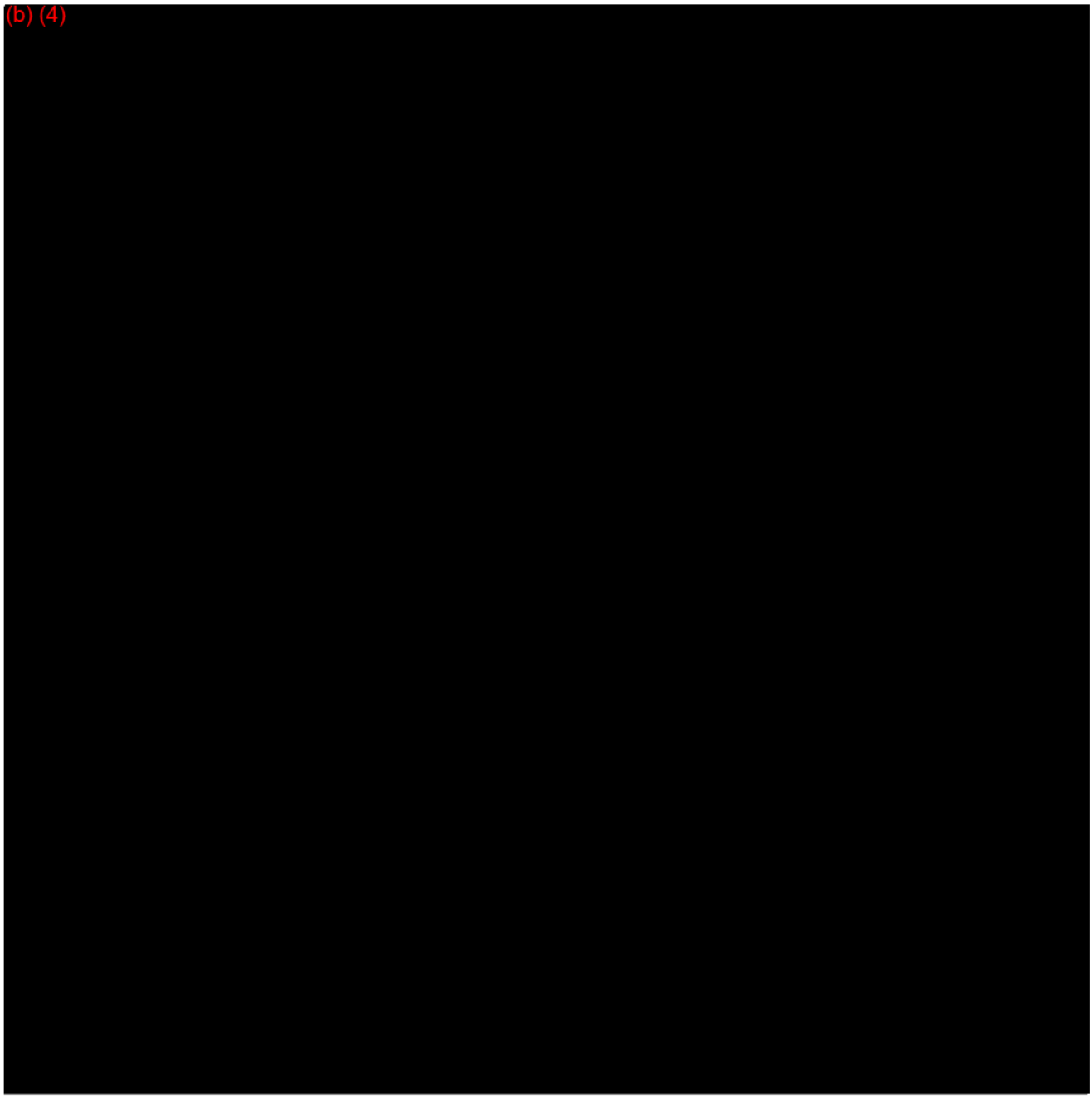
Methodology for Qualitative Study

Objective

To show qualitatively that radiological review of mobile device (smartphone) based images is comparable to the gold standard of review on a standard imaging console. This objective is stratified by image modality (CT & MR) and pathology of interest.

Methods

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Outcomes

The outcomes will be to qualitatively compare the findings from mobile device review (under both lighting conditions) with the gold standard and to compare the overall experience of review relative to the five criteria listed above.

Panel Members

(b) (4)

Types of Cases selected by Panel

(b) (4)

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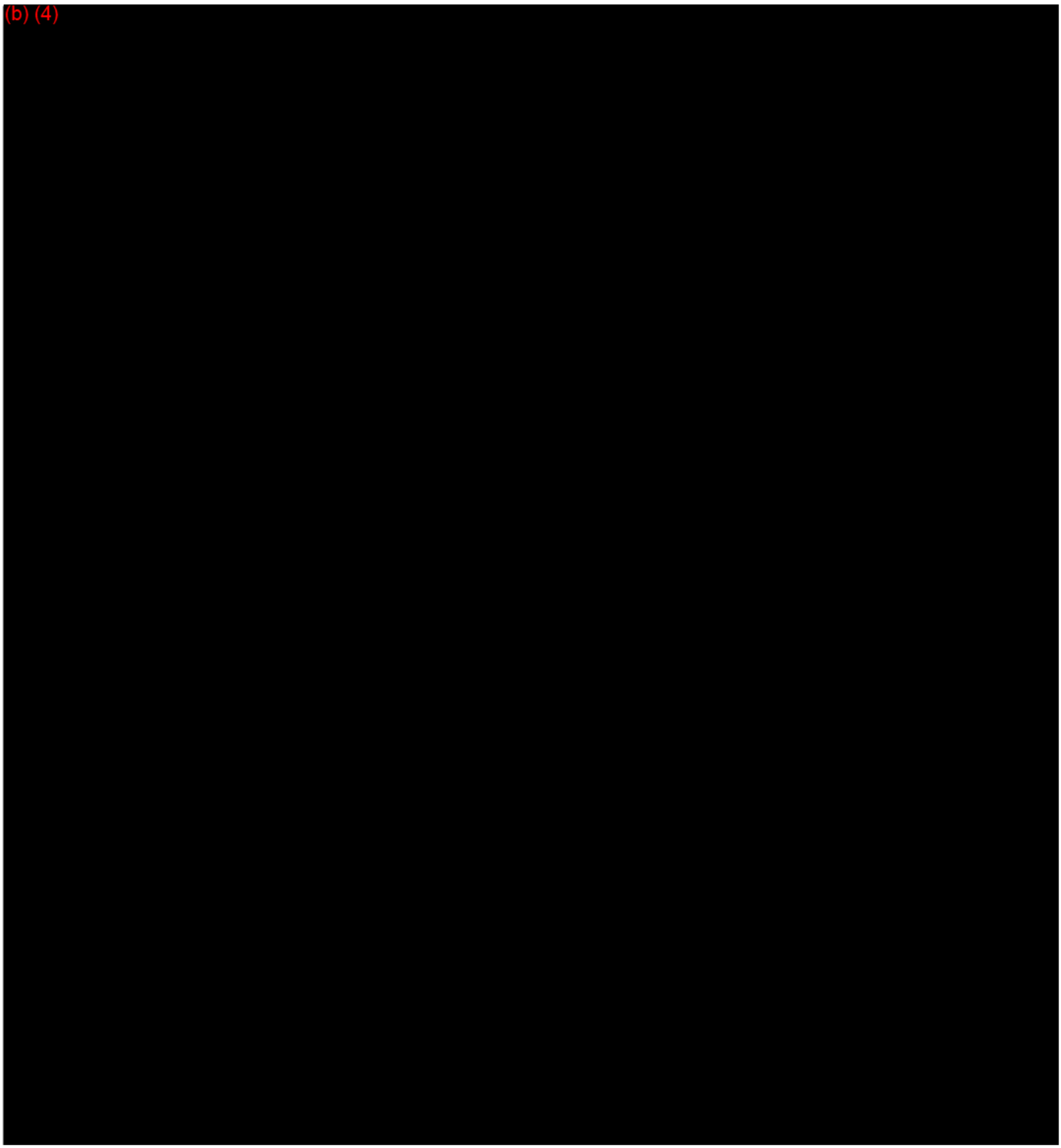
Mobile Study

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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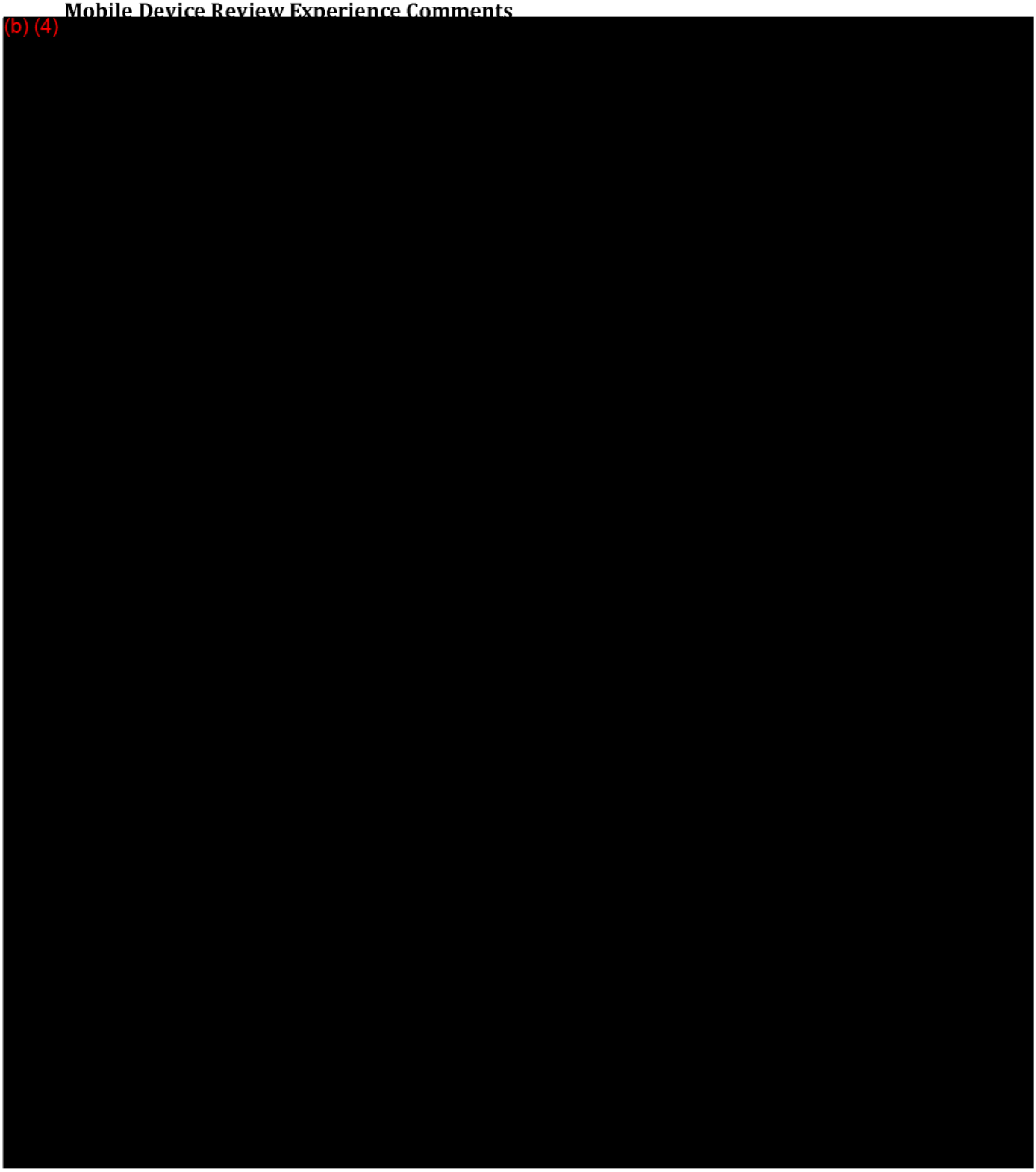
Summary of Findings

Mobile Device Review Experience Comments

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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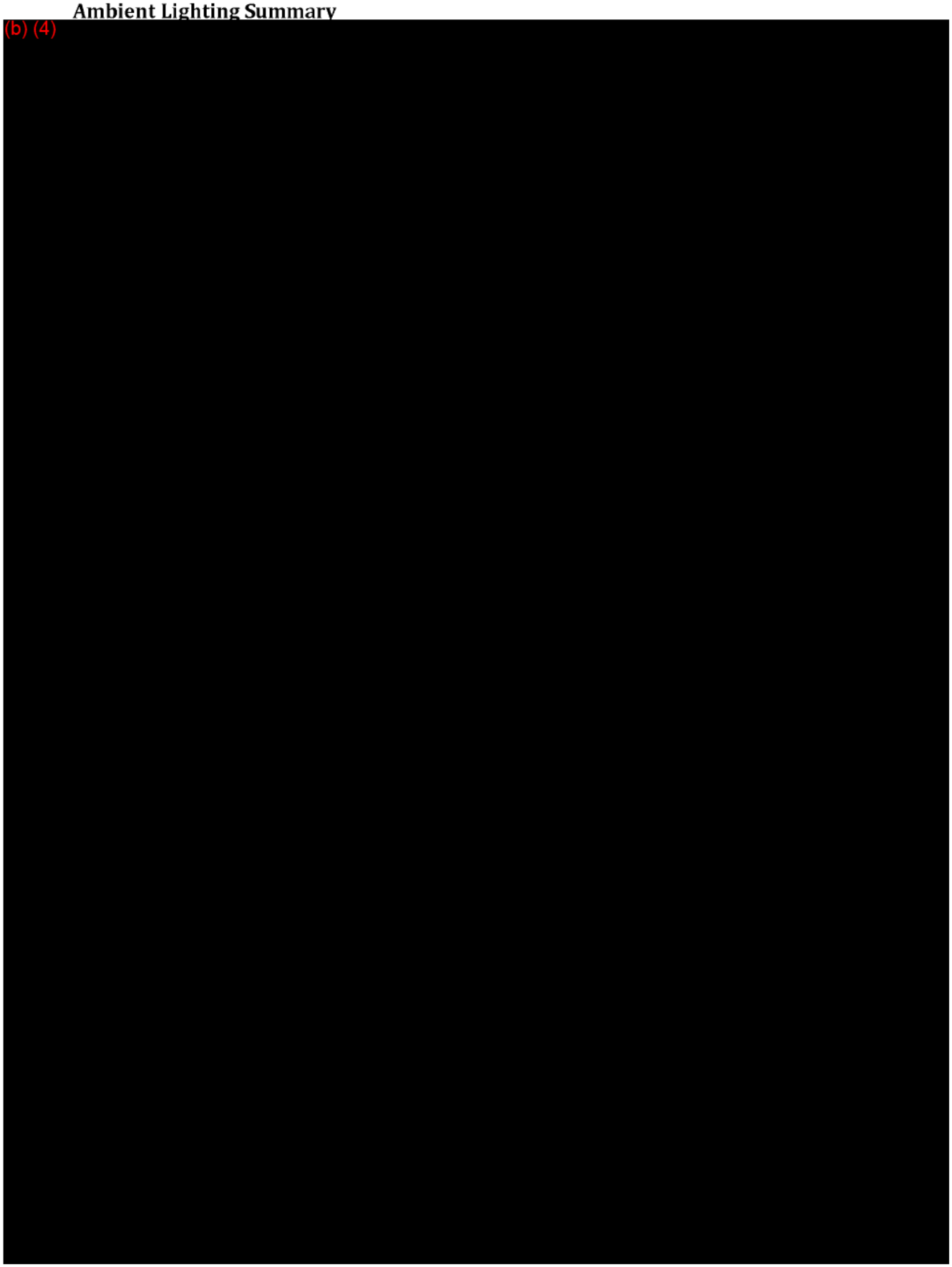
Ambient Lighting Summary

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

(b) (4)

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Conclusions

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03/21/2011	MD6054768-956733	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Calgary Scientific inc.	3006123366		
Division Name *(if applicable)*	**Phone Number** *(including area code)*		
	(403) 767-7945		
Street Address	**FAX Number** *(including area code)*		
Suite 208, 1210 - 20th Avenue SE	(403) 270-2771		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Calgary	Aberta	T2G 1M8	Canada
Contact Name			
Kyle Peterson			
Contact Title	**Contact E-mail Address**		
Director, Regulatory & Corporate Affairs	kyle.peterson@calgaryscientific.com		

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

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

PSC Graphics: (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

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

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

- ☐ Response to FDA correspondence:

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

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LLZ	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached

☒ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K082693	1	ResolutionMD™ 2.1	1	Calgary Scientific Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Picture Archiving and Communications System

	Trade or Proprietary or Model Name for This Device		Model Number
1	ResolutionMD™ Mobile	1	RMB-MOB-2X
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	C.F.R. Section *(if applicable)*	Device Class
LLZ	892.2050	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Radiology

Indications *(from labeling)*

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images on the mobile device. The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. The ResolutionMD Mobile is not to be used for mammography.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 3006123366	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Calgary Scientific Inc.	3006123366
Division Name *(if applicable)*	Phone Number *(including area code)*: (403) 767-7945
Street Address: Suite 208, 1210 - 20th Avenue SE	FAX Number *(including area code)*: (403) 270-2771

City	State / Province	ZIP Code	Country
Calgary	Alberta	T2G 1M8	Canada

Contact Name	Contact Title	Contact E-mail Address
Kyle Peterson	Director, Regulatory & Corporate Affairs	kyle.peterson@calgaryscientific.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

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SECTION I — UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1		NEMA	DICOM	3.0	12/28/2006
2	10918-4	ISO/IEC	Digital Compression and Coding of Continuous-tone Still Images (JPEG)	4	08/15/1999
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 Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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calgary scientific

ResolutionMD™ Mobile – 510(k) Submission

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<<Insert form 3601 here>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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2 CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<<Insert form 3514 here>>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3 510(k) Cover Letter

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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May 12, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (W066-G609)
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Attached traditional 510(k) premarket notification

Dear Sir or Madam:

We are submitting the attached traditional 510(k) notification for the ResolutionMD™ Mobile, a new software medical device, and request that you regard this submission as confidential in accordance with 21 CFR 807.95.

The ResolutionMD™ Mobile is a software based Picture Archiving and Communication (PACS) system that is regulated as a Class II device as described in 21 CFR 892.2050. It is intended for prescription use (21 CFR 801 Subpart D). The product code is LLZ under the Radiology Panel.

The ResolutionMD™ Mobile is substantially equivalent to the ResolutionMD™ 2.1 (K082693) which has the same LLZ product code as the ResolutionMD™ Mobile, and conforms to the voluntary DICOM 3.0 and JPEG standards.

Please address communications related to this submission to:

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Suite 208 – 1210 20th Ave. SE
Calgary, Alberta, CANADA T2G 1M8
Voice (403) 767-7945 Fax (403) 270-2771
Kyle.peterson@calgaryscientific.com

Our establishment registration number is 3006123366.

Yours truly,

Kyle Peterson
Director, Regulatory & Corporate Affairs

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 Indications for Use Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use Statement

Applicant: Calgary Scientific, Inc., Suite 208 – 1210 20th Ave. SE, Calgary, Alberta, CANADA T2G 1M8

510(k) Number: K093682

Device Name: ResolutionMD™ Mobile

Indications for Use:

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

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)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5 510(k) Statement

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510(k) Statement

I certify that, in my capacity as Director, Regulatory & Corporate Affairs, of Calgary Scientific Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
May 12, 2011

Premarket Notification 510(k) Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 Truthful and Accurate Statement

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Truthful and Accurate Statement

(as required by 21 CFR 807.87 (k))

I certify in my capacity as Director, Regulatory & Corporate Affairs of Calgary Scientific Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
May 12, 2011

Premarket Notification 510(k) Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7 Class III Summary and Certification

Not applicable.

8 Financial Certification or Disclosure Statement

Not applicable.

9 Declarations of Conformity and Summary Reports

Not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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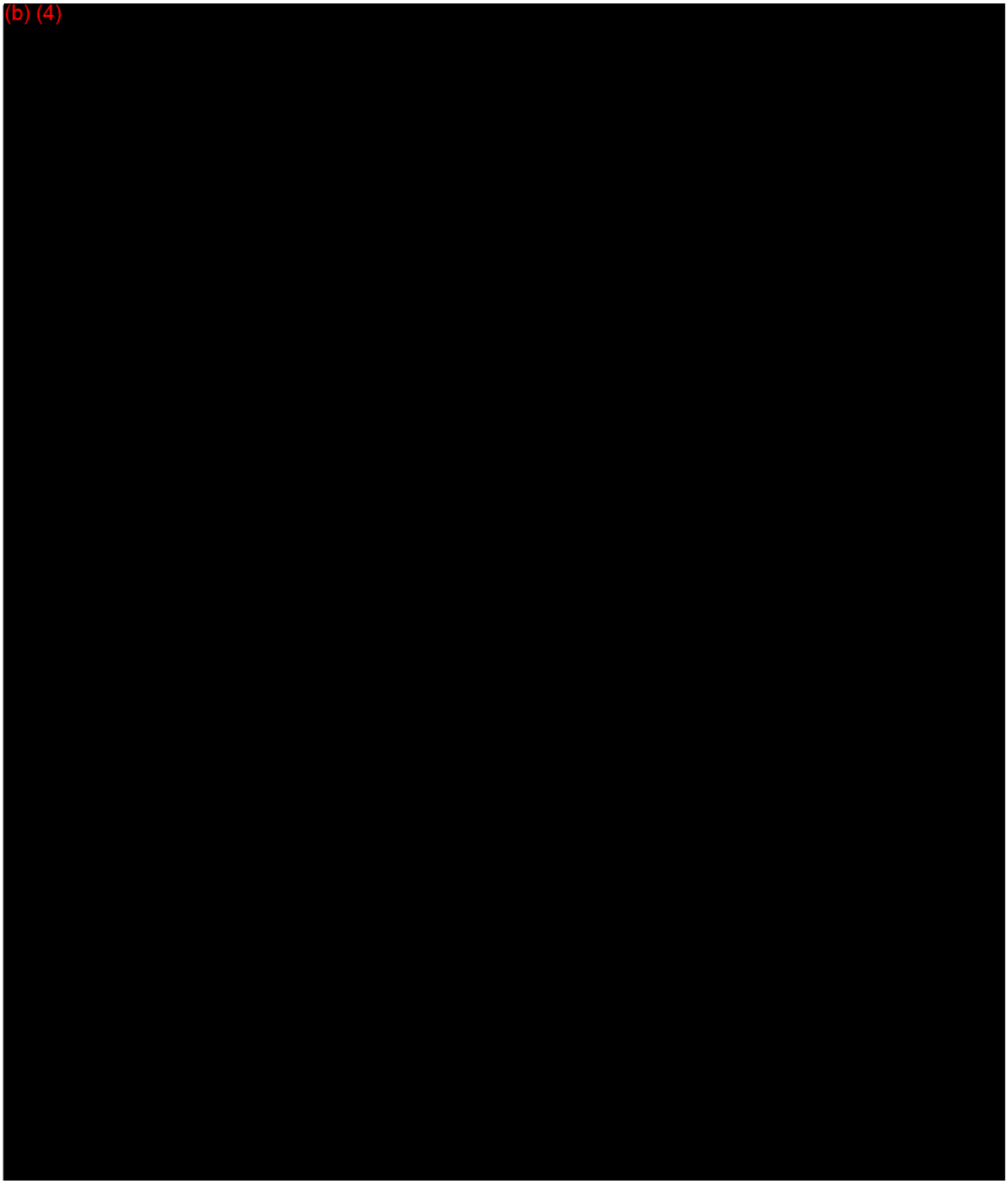
10 Executive Summary

Overview:

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

Device Description:

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and high-resolution wireless mobile devices for the display and advanced visualization of medical image data. It provides for communication, storage, processing, rendering on the server and the display of DICOM 3.0 compliant image data derived from CT and MRI on the mobile device.

It is a software product which enables clinicians to quickly and effectively review, analyze and evaluate medical images in situations where there is no access to a full PACS workstation.

The ResolutionMD Mobile is available in a Microsoft Windows Server version and a Linux Web server version supporting a mobile client running on the Apple iPhone 4 and the Apple iPad qualified as suitable in accordance with our verification and validation procedures. Available functions include study search, DICOM communication, display of 2D images in original planes including zoom, pan and window/level, computation and display of Maximum Intensity Projections/Multi-Planar Reformats (MIP/MPR) and rendered 3D images including zoom, manipulation, lens magnification and various presets.

A risk analysis has been conducted in accordance with the ISO 14971 standard and the level of concern has been classified as moderate. The ResolutionMD™ Mobile software has been extensively tested on supported platforms by members of the development and quality control team prior to validation testing. In addition, laboratory testing by an independent 3rd-party laboratory has been conducted t verify the performance of the mobile device displays. Validation including benchmark clinical comparative effectiveness studies by trained radiologists have been completed and are included in this submission. The software has passed all tests considered critical in terms of patient safety and demonstrated an overall acceptable performance for release as determined by the predefined release criteria. Details are discussed in Section 16 and supporting documents are provided in Appendices 16.3 – 16.13.

The release version of the software will be required to pass all tests considered critical in terms of patient safety and to demonstrate an overall acceptable performance for release as determined by the predefined release criteria.

11 Device Description

As the device is a software product, it is described fully in Section 16.2 – Software Description.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12 Substantial Equivalence Discussion

Both, the ResolutionMD™ Mobile (K093682) and the Calgary Scientific Inc. ResolutionMD™ 2.1 (K082693) are software-based picture archiving and communications systems conforming to the voluntary DICOM 3.0 standard (FDA product category: LLZ). Each of these systems has similar functionality to manage and display DICOM compliant images.

Indications for Use Statement

(b) (4)

Client/Server Architecture

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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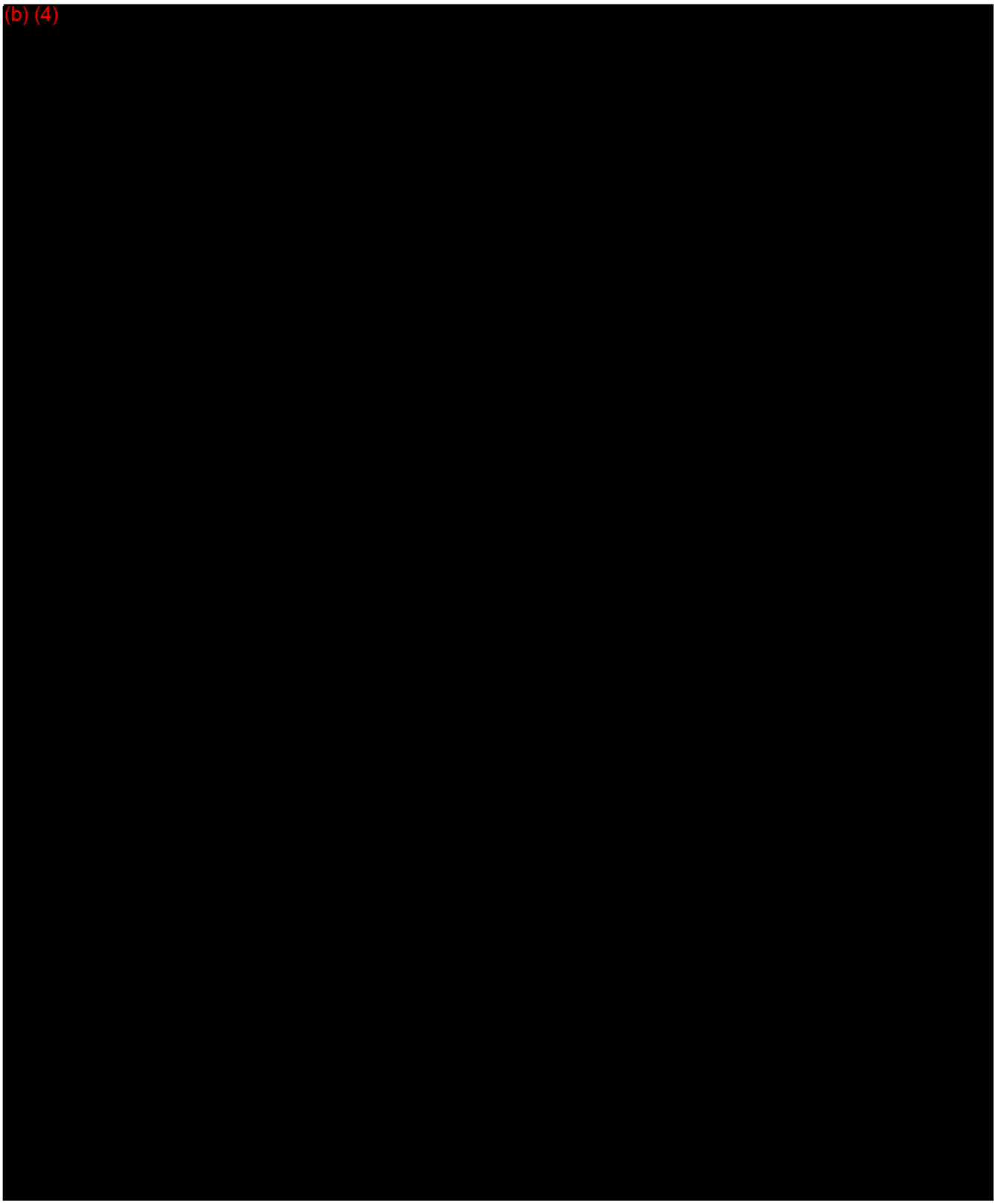
Software Features

(b) (4)



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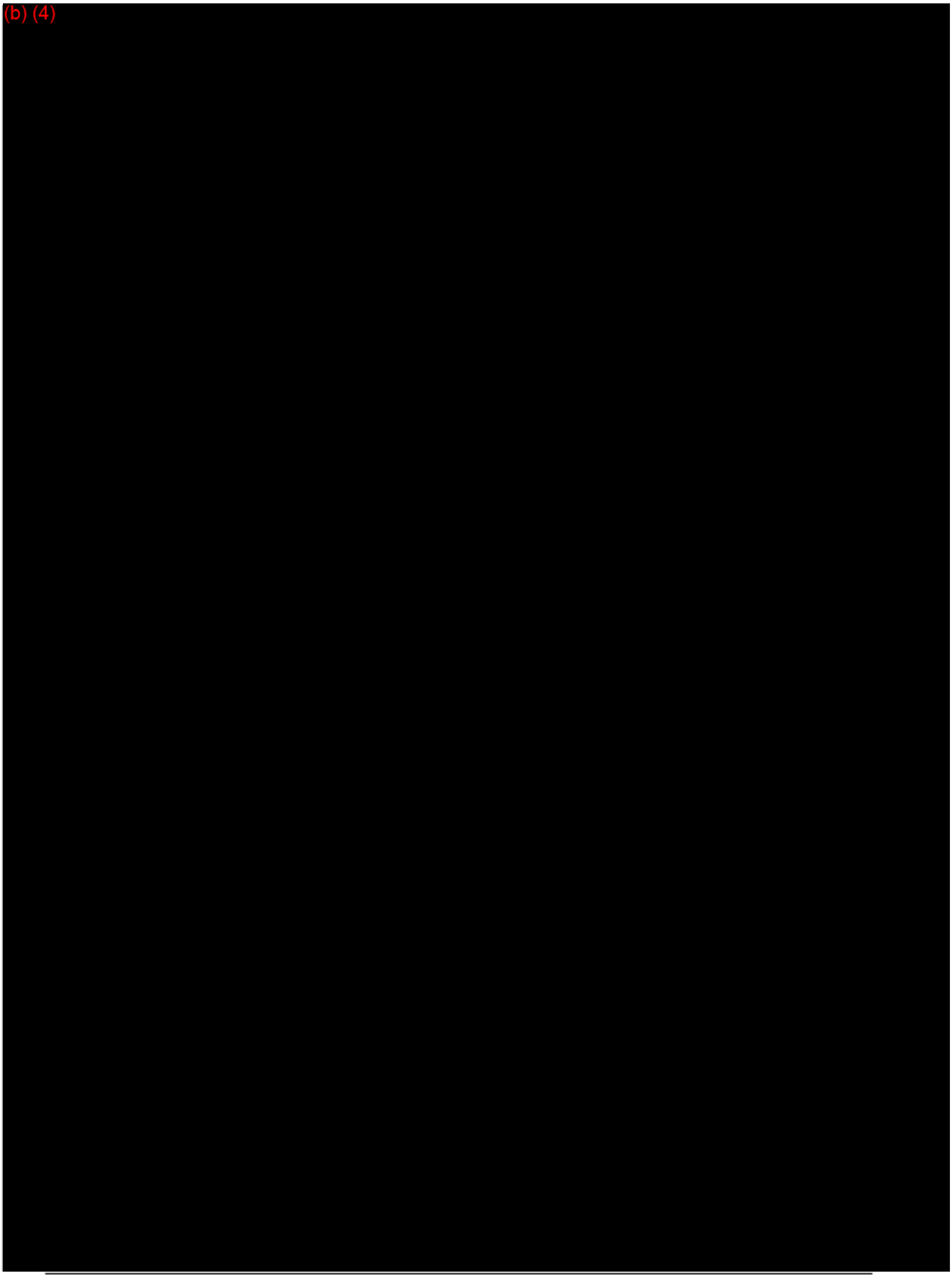
(b) (4)



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(b) (4)

Network Access Transparency

(b) (4)

Client Computer Display/Monitor

(b) (4)

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(b) (4)

Intended Users

(b) (4)

A table of item-by-item comparisons for the substantially equivalent device is included below.

Based on these considerations we conclude that ResolutionMD™ Mobile is substantially equivalent to the Calgary Scientific Inc. ResolutionMD™ 2.1 (K082693).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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calgary scientific

ResolutionMD™ Mobile – 510(k) Submission

Table of Substantial Equivalence Comparisons with Predicate Devices

Introduction: Both the predicate device, ResolutionMD 2.1, and the new device, ResolutionMD Mobile, use a client-serve
server software is the same in both devices, and the same server will support users accessing it with a PC browser or an i
All of the image processing takes place on the server. The browser client or the iPhone/mobile device client is used only
sending commands to the server and receiving the resulting rendered images from the server.

Feature	ResolutionMD™ 2.1 – K082693	ResolutionMD™
Intended Use	(b) (4)	
Computer Operating System Platform - Server		
Computer Operating System Platform – Client		
Computer Display/Monitor – Client		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Feature	ResolutionMD™ 2.1 – K082693	ResolutionMD™
	(b) (4)	
DICOM compliance		
LAN, WAN and Web access		
Data Integrity / Data Security		
2D Imaging		
2D Image Viewer – Interactive User Controls		
2D Image Viewer – Pixel for		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Feature	ResolutionMD™ 2.1 – K082693	ResolutionMD™
pixel representation to original image	(b) (4)	(b) (4)
Measurement		
Maximum Intensity Projection (MIP)		
Multiplanar Reformatting (MPR)		
3D Imaging		
Lens tool		
3D Segmentation		
Server Selection		
Search		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Feature	ResolutionMD™ 2.1 – K082693	ResolutionMD™
Prescription Use	(b) (4)	
Intended Users		
	Optional Cardiac-Specific Functionality included in ResolutionMD 2.1 predicate	
Calcium Score	(b) (4)	
Artery detection		
Curved multi-planar reconstruction		
Reporting		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13 Proposed Labeling

The ResolutionMD™ Mobile is software that will be supplied to users as a download over the internet and thus will not have any physical labeling. The Indications for Use statement in the User Guide will be accessible from the "Info" button when the application is running on the mobile device.

A copy of the User Guide is included as Appendix 13.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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14 Sterilization/Shelf Life

Not applicable.

15 Biocompatibility

Not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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16 Software Description

16.1 Level of Concern

A Risk (hazard) Analysis based on the ISO 14971 standard has been conducted and the potential hazards including traceability to test cases and expert validation have been identified and evaluated (See Appendix 16.3).

The ResolutionMD™ Mobile is a software application that does not contact the patient or control any life sustaining devices. The software receives data from devices that provide diagnostic information, such as CT and MRI scanners. There is ample opportunity for competent human intervention before the information displayed is used to influence patient care. A trained physician interprets the images being displayed, and any diagnostic findings suggested by the MIP/MPR or 3D images rendered by the ResolutionMD™ Mobile software can be confirmed on the original 2D DICOM images provided by the diagnostic modality. In addition, the image interpretation is correlated with other clinical information by a treating physician prior to any patient intervention based on the images, so that a failure of the device is unlikely to lead to an erroneous diagnosis or delay in diagnosis that would result in patient injury.

Based on these factors we consider the level of concern to be moderate.

16.2 Software Description

16.2.1 Overview

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and high-resolution wireless mobile devices for the display and advanced visualization of medical image data. It provides for communication, storage, processing, rendering on the server and the display of DICOM 3.0 compliant image data derived from CT and MRI on the mobile device (iPhone 4 and iPad).

It is a software product which enables clinicians to quickly and effectively review, analyze and evaluate medical images in situations where there is no access to a full PACS workstation.

ResolutionMD Mobile can permit a clinician with a smartphone to access the ResolutionMD server via Wi-Fi or 3G and review the CT or MR scan of the patient. The ability of the iPhone to handle a phone call at the same time provides the ability for the clinician to convey their findings in "real time" through a phone conversation. They may also collaborate with a colleague in reviewing the same images at the same time. In any case, the review of the images in consultation with attending physicians at the hospital will determine the ultimate course of treatment for the patient.

16.2.2 High Level Use Case

Deployment of ResolutionMD Mobile on smartphones will take advantage of the ability of the device to access the ResolutionMD server from either a Wi-Fi network or a 3G network. The advantage is that if Wi-Fi is available, it will afford greater bandwidth for better performance and less cost (not having to pay for cellular access). The 3G network allows the user to obtain broader access to the ResolutionMD server, albeit at a lower bandwidth and performance. As

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4G devices and networks become more widely available and are incrementally upgraded in bandwidth, the performance difference will become moot. Because the ResolutionMD server will be SSL capable, it will be able to support both access modes (see diagram below).

On launch of the application on the smartphone, ResolutionMD Mobile would present a list of studies on the server in a searchable list and the user would select the correct one to examine. They then review the images in a way very similar to what they would do on a PACS workstation in a DI room or in their office. The clinician would typically begin looking at the 2D image stack first, most likely zooming up the image slightly and perhaps adjusting the window/level. Then they would scroll through the stack at varying speeds and direction. When they hit an image containing a Region Of Interest (ROI), they will likely want to adjust the zoom and window/level further for closer examination.

In reviewing the images, ResolutionMD Mobile will also allow viewing in MIP/MPR and 3D modes if the clinician wishes to do so. Additionally, because the device allows the user to conduct a phone call simultaneously, it greatly enhances the user's collaborative experience with a colleague or peer, which ultimately results in better patient care.

16.2.3 High Level Description of Product

The ResolutionMD Mobile product leverages Calgary Scientific's FDA-approved ResolutionMD Web server and client product and architecture. The overall solution will consist of:

1. ResolutionMD Mobile - Thin-client software to load and reside on an iPhone or mobile device with similar characteristics
   - selects sever to connect to (neurologists may need to connect to more than one hospital)
   - initiates authentication
   - communicates via Wi-Fi or 3G with server
   - handles SSL encryption
   - does not require downloading of data
   - software and user information can be remotely erased if lost

2. ResolutionMD Web server software
   - FDA approved under K082693
   - defined subset of ResolutionMD features in PureWeb® architecture
   - receives and stores incoming studies
   - provides worklist for clients
   - manages authentication & audit trails
   - handles SSL security
   - is DICOM compliant as SCP and SCU (does not issue "storage commit", ie. not an archive)
   - performs all image manipulations
   - supports HIPAA compliance

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- remotely serviceable

3. Server hardware
   - capable of running software with specified capacity and performance
   - COTS vendor preferred
   - scalable
   - readily serviceable

16.2.4 Product Environment

16.2.4.1 Server

(b) (4)

[redacted]

16.2.4.2 Client

(b) (4)

[redacted]

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16.2.4.3 New Displays:

(b) (4)

[redacted]

16.2.5 Network Architecture – Local Wi-Fi Configuration

(b) (4)

[redacted]

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Figure 1. iPhone will be enabled for both internal wireless network access and external 3G cell phone wireless access will be available using SSL.

16.2.6 Network Architecture –Remote Wi-Fi/3G Configuration

(b) (4)

Figure 2. This diagram illustrates typical workflow for the assessment of stroke using the iPhone over 3G wireless and SSL.

16.2.7 Requirements and Design Specifications

The Software Requirements Specification and Software Design Specification describe the features of the device and operating environment in considerable detail. These can be found sections 16.4 and 16.6 respectively.

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16.3 Device Risk (Hazard) Analysis

Risk analysis was carried out using the FMEA methodology. Starting from the detailed system requirement, each functional component of the software was assessed for risk and a list of potential hazards was developed and assessed for likelihood and severity. Actions to eliminate, minimize, or mitigate each such hazard have been identified, and a comprehensive testing plan has been developed to confirm proper function of the software.

This plan includes predefined expected behavior and/or pass/fail criteria for each individual test as well as overall acceptance criteria for the released version of the software. All tests designed to identify defects associated with any significant safety risk are defined as critical. The release criteria do not allow release of a software version unless it passes all such critical tests.

A tabulation of the identified hazards and mitigations is included in Appendix 16.3. The Traceability Analysis Matrix (Appendix 16.7) links risks to verification and validation activities.

16.4 Software Requirements Specification

User requirements were assessed and a software requirements specification consistent with user requirements has been generated and is summarized in Appendix 16.4.

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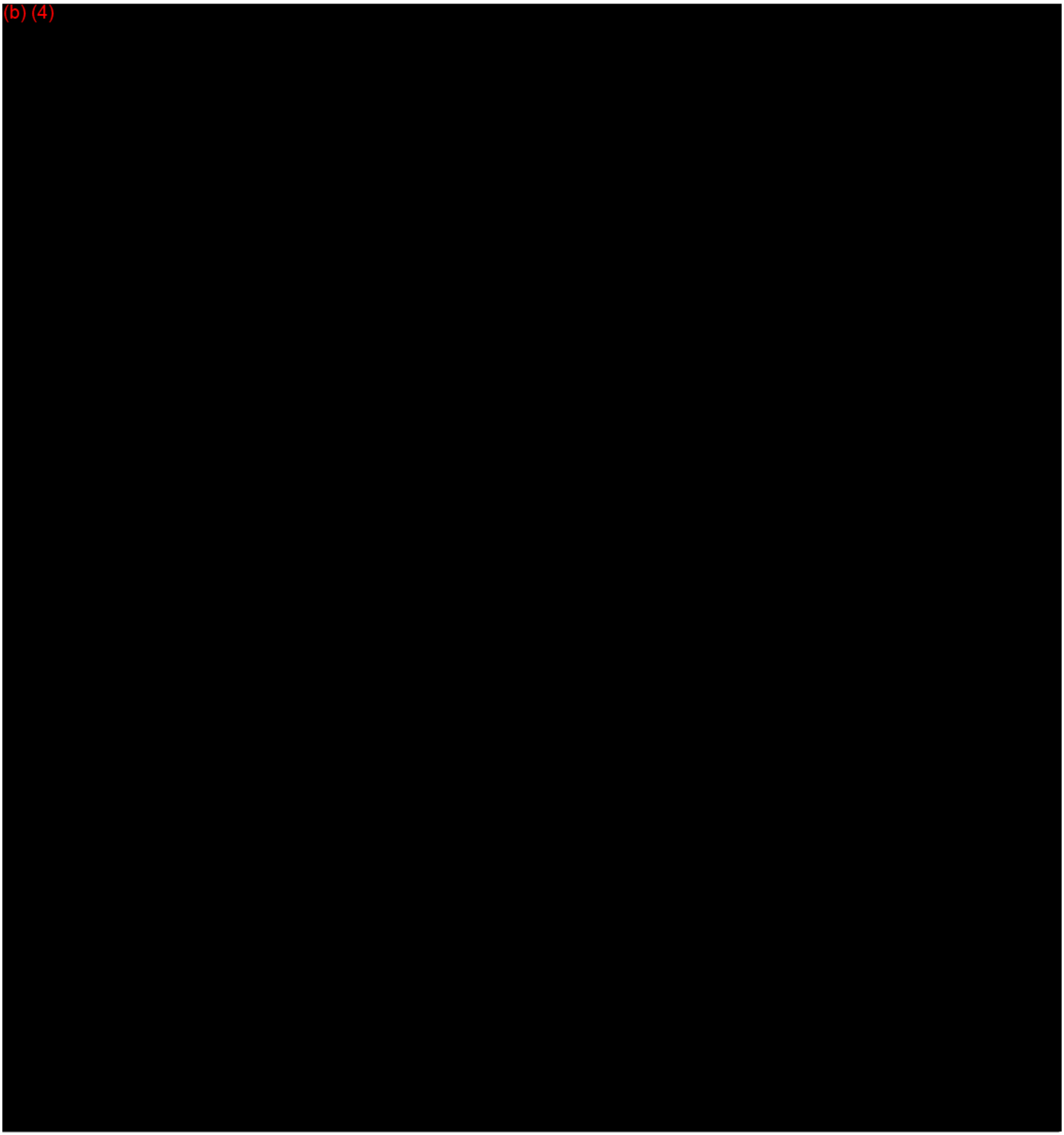
16.5 Architecture Design Chart

(b) (4)



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16.6 Software Design Specification

See Appendix 16.6 for the detailed document. Also see Appendix 16.6.1 for the DICOM Conformance Statement.

16.7 Traceability Analysis

A Traceability Analysis is included as a table that relates items from the Software Requirements Specification (SRS) to the Software Design Specification, Risk Analysis, Verification and Validation Testing and Documentation.

16.8 Software Development Environment Specification

See Appendix 16.8.1, 16.8.2 and 16.8.3 for a description of the software development environment and software coding standards at Calgary Scientific Inc.

16.9 Verification and Validation Documentation

(b) (4)

The test results matrix listing all the test plans and test result performed for the iPhone 4 client and the iPad client is included as Appendix 16.9.1.

Based on satisfactory results of testing of individual components of the software, satisfactory overall performance of the application on multiple hardware platforms, and the requirement for a successful external validation program and passing of all critical tests, the overall risk of the software is considered acceptable for its intended use.

In Appendix 16.9.2, we present an Expert Validation Report that establishes that the functional operation of the software meets the user requirements.

In Appendix 16.9.3 and its sub-appendices, we have provided the results of extensive laboratory testing of the mobile device displays used in the iPhone 4 and the iPad. These tests were intended to characterize the performance of these displays while running our ResolutionMD software to display the AAPM TG18 test images used in the medical monitor industry.

The comparative validation testing conducted with practicing radiologists (presented in Appendix 16.9.4) establishes equivalence to workstation software and describes the radiologists' confidence in using ResolutionMD Mobile on the iPhone and iPad.

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Certification that the same procedures will be used to retest and revalidate the software when it is revised is included in Appendix 16.14.

16.10 Revision Level History

A complete, detailed log of code changes and revisions has been maintained. A tabulation of major changes has been abstracted from this document and is included in Attachment 11.

16.11 Unresolved Anomalies

A listing of the unresolved anomalies from the most recent verification testing including their dispositions is included as Appendix 16.11.

16.12 DICOM Conformance

The ResolutionMD™ platform incorporates DICOM functionality as described previously in section 16.4 and 16.6. A DICOM conformance statement is included in Appendix 16.6.1. Form 3654 is included as Appendix 16.12.

16.13 JPEG Conformance

The ResolutionMD™ platform incorporates JPEG technology as described previously in section 16.4 and 16.6. Form 3654 is included as Appendix 16.13.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17 Electromagnetic Compatibility/Electrical Safety

Not applicable.

18 Performance Testing-Bench

Not applicable.

19 Performance Testing-Animal

Not applicable.

20 Performance Testing-Clinical

Not applicable.

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calgary scientific

K111346

SEP - 9 2011

510(k) Statement

I certify that, in my capacity as Director, Regulatory & Corporate Affairs, of Calgary Scientific Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
May 12, 2011

Premarket Notification 510(k) Number

Questions? Contact CDRH/OSE/DID at CDRH-OISTATUS@fda.hhs.gov or 301-796-5118

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

COVER SHEET MEMORANDUM

From: Reviewer Name Robert Ochs

Subject: 510(k) Number K 111346/S1

To: The Record

Please list CTS decision code SE

x Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

x Hold (Additional Information or Telephone Hold).

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

Not Substantially Equivalent (NSE) Codes

x	NO	NSE for lack of predicate
x	NI	NSE for new intended use
x	NQ	NSE for new technology that raises new questions of safety and effectiveness
x	NP	NSE for lack of performance data
x	NM	NSE requires PMA
x	NS	NSE no response
x	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 Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
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)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓

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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.)		–
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, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	–

Regulation Number	**Class***	**Product Code**
21 CFR § 892.2050	II	LLZ

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) DRAD (Branch Code) 9/19/11 (Date)

Final Review: Mary S Pastel (Division Director) 9 Sept 11 (Date)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. Department of Health and Human Services
Food and Drug Administration

Division of Radiological Devices
Center for Devices and
Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

From: Robert Ochs, PhD
To: The Record
Date: September 8, 2011

Subject: **K111346 S1**
Device: ResolutionMD Mobile (RMB-MOB-2X)
Sponsor: Calgary Scientific Inc.
Contact: Kyle Peterson
kyle.peterson@calgaryscientific.com

I. Summary

Calgary Scientific is submitting a *traditional* 510(k) for a new picture archiving and communications system (ResolutionMD Mobile). The device is intended for the display, visualization, and diagnostic review of medical images using the Apple iPhone 4 or iPad mobile devices.

The device has the same intended use as the predicate as well as other PACS systems. The capability of the device to display the images on a mobile device is a new technological characteristic. However, there are no new types of safety and effectiveness questions. The sponsor provided software documentation, bench testing, and a limited study of the clinical image quality to support the safety and effectiveness of the device.

Submission History:

- March 18, 2011: Calgary received an NSE letter for their prior submission (K093682). The NSE letter was sent for insufficient response after two requests for additional information. Documentation of numerous interactions to address a number of issues related to the submission is included in the record for K093682.
- May 13, 2011: New 510(k) submission received. Calgary was able to address many of the issues that lead to the prior NSE letter. However, there were concerns with the labeling, software documentation, and testing that needed to be resolved.
- August 1, 2011: First supplement received. Calgary addressed most of the prior concerns and the remaining minor deficiencies were resolved interactively.
- August 29, 2011: Interactive request for additional information on the intended use and testing.
- August 31, 2011: The sponsor provided additional information to address the remaining concerns.

Recommendation: The device should be found Substantially Equivalent and regulated under 21 CFR §892.2050; the device is considered a class II device with product code LLZ.

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II. Administrative Requirements

	Sufficient	
	Yes	No
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)	✓	
510(k) Cover Letter	✓	
Indications for Use	Rx	
510(k) Statement according to 21 CFR §807.93	✓	
Truthful and Accuracy Statement	✓	
Class III Summary		N/A
Financial Certification or Disclosure Statement		N/A
Standards Form (FDA 3654) • NEMA PS 3.1-3.18: Digital Image Communication in Medicine (DICOM) • ISO/IEC 10918-1 (1994-02) Digital Compression and Coding of Continuous-Tone Still Images (JPEG)	✓	
Clinical Trials Form (FDA 3674)	✓	

III. Indications for Use / Intended Use

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

The applicant claims substantial equivalence to the following legally marketed predicate device:

K082693, ResolutionMD 2.1 (Calgary Scientific, Inc.)

The ResolutionMDTM 2.1 is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

The ResolutionMDTM 2.1 device incorporates a Calcium Scoring module which is used to identify and quantify calcified plaque within the coronary arteries. This protocol is performed on noncontrast enhanced cardiac CT data sets. It also includes the Coronary Artery Analysis protocol which is used to visually identify and measure stenoses in the coronary arteries. This protocol is performed on contrast-enhanced cardiac CTA data sets.

The ResolutionMDM 2.1 software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists, and nurses. When interpreted by a trained

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physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD TM 2.1 software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Review Comments: Both the subject device and the predicate device are intended for the communication, storage, and display of medical image data. The subject device is intended for a subset of the functionality of the original device, and will not include the optional cardiac analysis module or calcium scoring module available for the predicate. In addition, the subject device is only intended for the review of MR and CT images.

The subject device is not intended for specific diseases or for emergency situations. During the current and prior 510(k) review, the sponsor was informed that they have not submitted sufficient evidence to support labeling claims related to the use of the mobile device in emergency situations or for specific indications for use.

The Indications for Use of the device are also similar to the 510(k) cleared MIM Software mobile application for the iPhone 4 and iPad (K103785).

IV. Device Description

Component	Material(s)	Attributes	Acceptable	
			Yes	No
Software (iOS App)	Software	No Patient Contact No Biocompatibility/Sterilization Issues No Image Contrast Requirements Not Life-Supporting or Life Sustaining	✓	
Mobile Device	iPhone, iPad	Common materials No Biocompatibility/Sterilization Concerns Display Testing	✓	

The ResolutionMD™ Mobile software is a software-based PACS for use with general purpose computing servers and mobile devices for the display and visualization of medical image data. The primary functionalities of the ResolutionMD™ Mobile include DICOM communication, display of 2D images in original planes including window/level controls, computation and display of rendered 3D images and zoom, pan and rotate.

The device will include functionality to allow the user to review test images for evaluating the ambient lighting conditions.

Review Comments: The smaller screen size and potential use of the device under varying ambient lighting conditions increases the concern about the quality of the displayed image data. However, design features and bench testing can be used to mitigate and evaluate these potential risks.

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V. Predicate Device Comparison

Category	Predicate (ResolutionMD, K082693)	New Device (ResolutionMD Mobile, K093682)
Intended Use		
Diagnostic image review and analysis	Yes	Yes
Anatomy/Disease	General	General
Intended User	Trained Professionals	Same
Environment/Setting	Hospital	No access to a workstation.
Functions		
Client / Server Architecture	Yes	Same
Server Platform	Windows OS, Microsoft .NET SDK, Linux OS	Same
Client Platform	Windows OS, Mac OS, Linux OS – any browser supporting Flash	**iPhone 4/iPad OS**; the client is only used for user interaction (i.e., sending commands to the server and receiving the resulting images from the server).
Data Integrity / Data Security	DICOM images remain on the server. Only JPEG renderings generated by the server software are sent to client browser for viewing. No source image data is ever stored on the client and all JPEG renderings transmitted are deleted when the client application is closed.	
Image Processing	Both devices rely on the same server software to perform the image processing.	
DICOM 3.0	Yes	Yes
Modalities	Not-specified	CT, MR
2D Image Review	Window/level, zoom, pan, scroll	Same
3D Image Review	3D volume rendering, zoom, pan, rotate, window/level, MIP, MPR	Same
Segmentation	Yes	No
Cardiac - Specific, Functionality	Yes	No

Review Comments: The subject device is intended for the communication, display, and interpretation of medical images; this is the same intended use as the predicate device and numerous other PACS systems. The primary difference between the subject and predicate (K082693) is that the subject device is intended for reviewing images on the iPhone 4 and iPad.

The subject device is designed for use with touch-screen mobile devices that have a display size and resolution much smaller than diagnostic review workstations. This is a new technological characteristic that could affect safety or effectiveness. For instance, 1) the small screen size does not allow for the side-by-side review of images from prior exams, reconstructions, anatomical planes, etc... 2) the screen resolution is much smaller than most full-field images, and 3) the reading environment, connection, and lighting conditions may be highly variable. The lower image quality, reduced functionality, and variable reading environment could affect the ability of radiologists to view images.

However, the new technological characteristics do not raise new types of safety and effectiveness questions. The types of questions considered when reviewing other PACS systems and display monitors still apply (e.g., does the design of the device allow safe and effective interpretation of medical images?).

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Existing scientific methods are appropriate for evaluating the safety and effectiveness of the device. FDA has issued guidance for software verification and validation testing. The mobile image display can be evaluated following AAPM and IEC test standards.

FDA requests testing of the image display characteristics of monitors. The image display for PACS software is typically not considered during the 510(k) review since the PACS systems are not labeled for specific displays. There are numerous cleared displays available as well as there are guidelines from the American College of Radiology (ACR) on selecting and testing display equipment for use with PACS systems.

Unlike other PACS, the subject device has been designed (and is labeled) specifically for the iPhone 4 and iPad mobile devices. These mobile displays are being considered as a component of the ResolutionMD Mobile system. Bench testing and a limited clinical image evaluation are considered necessary since there is greater concern that the interaction between the ResolutionMD Mobile software and mobile display could impact image quality.

Note: although not cited as a predicate, the intended use and technological characteristics are similar to the cleared Mobile MIM software (K103785). There are some differences in the client-server architecture and the functionality to allow users to evaluate the ambient lighting conditions. The general approach for requiring software documentation, bench testing of the mobile display, and a limited clinical image evaluation are the same.

VI. Labeling

The submission included the ResolutionMD Mobile Users Guide (Appendix 13) and the Installation Service Guide (Appendix 13.1).

	Sufficient	
	Yes	No
Manufacturer's Contact Information	✓	
Prescription use statement	✓	
Intended Use / Indications for Use	✓	
Relevant cautions, warnings, and/or contraindications	✓	
Symbols *(with description)*	✓	
Device Description	✓	
Hardware Requirements (for software)	✓	
Accessories		N/A
Directions for Use	✓	
Performance Specifications (summary of physical laboratory testing)		N/A
Cleaning instructions	✓	
Description of quality assurance tests (and action limits)	✓	
Conformity to voluntary standards	✓	
Marketing brochures/flyers/claims		N/A

Review Comments: During the review of the sponsor's prior 510(k) submission, there were numerous concerns that the labeling was promoting the use of the device for emergency situations and specific disease conditions without any valid scientific evidence to support such claims. The sponsor was also asked to provide more information to help the users evaluate the ambient lighting. The new 510(k) submission resolved the prior issues.

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VII. Software

	Sufficient	
	Yes	No
Level of Concern: Moderate. A malfunction or a latent design flaw in the software device could lead to erroneous diagnosis or a delay in delivery of appropriate medical care that may lead to a minor injury. This level of concern is consistent with other radiological software products.	✓	
Software Description: The device description and labeling provided sufficient details of the device features, operating environment, and intended use.	✓	
Device Hazard Analysis: Section 16.3 of the submission presented the risk analysis associated with the device features and use (e.g., screen size, ambient lighting, communication, image quality, etc...). The sponsor analyzed the potential cause of the hazard and the impact of the mitigation on the severity of the risk.	✓	
Software Requirements Specifications: Appendix 16.4 of the submission contained the system requirements specifications, the hardware requirements, and the usability specifications. The documents enumerated the functionality, interface, hardware, communication, and other requirements related to the operation of the device.	✓	
Architecture Design Chart: Section 16 of the submission provided sufficient detail of the software architecture and client/server features.	✓	
Design Specifications: Appendix 16.6 of the submission provided details of the design specifications. The document enumerated the functionality, interface, security, usability, and other requirements related to the operation of the device.	✓	
Traceability Analysis/Matrix: Appendix 16.7 of the submission provided traceability among the requirements specifications, design specifications, risk analysis, verification, and validation testing.	✓	
Development Environment: Appendix 16.8.1, 16.8.2 and 16.8.3 of the submission contained a sufficient description of the development environment. The sponsor also stated that they utilize ISO 13485 and FDA QSR-compliant processes (incorporating other related standards) for software verification and validation (Section 16, page 32).	✓	
Verification & Validation Testing: Appendix 16.9.1 of the submission included a summary of the system level testing for the iPhone and iPad. Appendix 16.9.2 of the submission included an expert "validation" report for the iPhone and iPad; the purpose of the testing was to verify the device functionality. In the S1 response, the sponsor provided additional information to demonstrate that specific features have been implemented and tested.	✓	
Revision Level History: Appendix 16.10 of the submission summarized the device modifications that have occurred starting with the core software functionality of the ResolutionMD predicate.	✓	

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	Sufficient	
	Yes	No
Unresolved Anomalies: Appendix 16.11 of the submission summarized the unresolved anomalies. In the S1 response, the sponsor provided additional information on the anomalies and/or documentation that they have been resolved.	✓	
Off the Shelf Software: This documentation was provided in the S1 response.	✓	
Cyber security: The software documentation (Section 16, pg. 28-32; Section 16.4) contained information and requirements related to cyber security.	✓	
DICOM Conformance Statement: Appendix 16.6.1 contained the DICOM Conformance Statement for version 2.5 of the software. Numerous sections of the submission (FDA Form 3514, pg. 5; Section 12) states that the device complies with DICOM 3.0.	✓	

VIII. Performance Testing – Display

Review Comments: Please see the review comments from Dr. Wei-Chung Cheng for the bench testing; additional information on some the tests and results was requested and provided in the follow-up supplement and interactive review.

IX. Qualitative Evaluation – Image Quality

The sponsor submitted the results of a small reader study with two radiologists, who were asked to review images on the iPhone 4, iPad, and diagnostic workstation under varying lighting conditions. The clinicians were asked to provide a primary diagnosis, subtle findings, and evaluate characteristics of the image.

The study design is comparable to the study used to support the cleared Mobile MIM software (K103785).

Review Comments: Overall, the results support that the device can be used to review images under varying lighting conditions. However, the clinicians did note lower connection speed as well as the lack of multiple monitors/views. The clinicians also stated preference for reviewing the images in low lighting. In S1, the sponsor revised the labeling to include the radiologists preference for darker reading conditions.

X. TPLC Review Analysis

Search Items	Results
Network Signals and Issues	None
MDRs	None
Recalls	None
Inspections	None

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XI. Substantial Equivalence Discussion

	Yes	No	
1. Same Indications for Use statement?		✓	If **YES** = Go To 3
2. Do differences alter the effect or raise new issues of safety or effectiveness?		✓	If **YES** = Stop **NSE**
3. Same technological characteristics?		✓	If **YES** = Go To 5
4. Could the new characteristics affect safety or effectiveness?	✓		If **YES** = Go To 6
5. Descriptive characteristics precise enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New types of safety or effectiveness questions?		✓	If **YES** = Stop **NSE**
7. Accepted scientific methods exist?	✓		If **NO** = Stop **NSE**
8. Performance data available?	✓		If **NO** = Request Data
9. Data demonstrate equivalence?	✓		Final Decision: **SE**

1. Explain how the new indication differs from the predicate device's indication:
   The subject device is intended for reviewing images on mobile devices, such as the iPhone; the predicate device is intended as a web based viewer.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
   The new indication for use statement reflects the different technological characteristics of the mobile devices. The device is still intended for the communication, display, and interpretation of medical images, which is the same intended use as numerous other PACS systems.

   The indications for use are also similar to the cleared Mobile MIM software (K103785).

3. Describe the new technological characteristics:
   The subject device is designed for use with touch-screen mobile devices that have a display size and resolution smaller than diagnostic review workstations.

4. Explain how the new characteristics could or could not affect safety or effectiveness:
   Reviewing diagnostic images with mobile device could potentially impact the safety and effectiveness since: 1) the small screen size does not allow for the side-by-side review of images from prior exams and/or different anatomical planes, etc... 2) the screen resolution is much smaller than most full-field images, and 3) the reading environment, connection, and lighting conditions may be highly variable.

5. Explain how descriptive characteristics are not precise enough: N/A

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
   The types of questions posed by this device are not different than the types of questions posed for previous PACS systems and display monitors (e.g., does the PACS system offer sufficient image quality for reviewing medical images?).

7. Explain why existing scientific methods can not be used:
   N/A: The image display and environmental conditions can be evaluated using standard equipment and test procedures. Reader studies can be designed to evaluate if the device provides sufficient diagnostic image quality.

8. Explain what performance data is needed:

Questions? Contact CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8116

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The sponsor needs to provide software test and bench data for all mobile devices that are intended to be used with their software.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The sponsor provided software documentation, bench testing, and a limited clinical image evaluation to support the safety and effectiveness of the device.

XII. Comments to Sponsor

Appendix A documents the initial request for additional information.

Appendix B documents the interactive requests for additional information.

XIII. Recommendation

The subject device is substantially equivalent to predicate devices under the following classification:

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

Robert A Ochs
Robert Ochs, PhD

September 8, 2011
Date

Michael O'Hara, PhD
Deputy Division Director

9/19/11
Date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix A

Request for Additional Information (June 30, 2011)
and
Comments on Response (August 1, 2011)

1. Parts of the submission include specific statements related to the use of the device in emergency situations and for specific conditions (e.g., Section 12, page 16; Section 16.2.5, pages 32-33). As has been noted previously on multiple occasions, FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims related to the use of the device for emergency situations or specific disease conditions, such as stroke. FDA believes that a general indications for use statement is most appropriate for this device based on the information provided. Please confirm that you will not market your device for these or other specific indications.

   Review Comments: (Resolved) The sponsor stated: "In accordance with the submitted Indications for Use statement which has previously been discussed with the FDA, the device is not indicated for any specific situations or disease conditions. Calgary Scientific Inc. does not intend to market the device for any specific situations or disease conditions. ... The diagrams on pages 32-33 have been deleted and replaced with generic diagrams properly reflecting the IFU statement as shown below. We will use such generic diagrams in any other material we produce. We will use generic scenario descriptions which do not imply any specific disease conditions. ..." This response is considered adequate.

2. There are concerns with the conclusions that are being drawn from the study in Appendix 16.9.4. As noted on numerous occasions, the purpose of the study was not to compare the resulting primary or secondary diagnosis. FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims that radiologists will be as accurate on the mobile device as on a workstation, or will reach the same diagnosis as on a workstation. The performance study was intended to support that the device offers sufficient image quality for a diagnosis (or image review) on CT and MR under specific lighting conditions when there is no access to a workstation. Much more rigorous studies would be necessary to evaluate the diagnostic effectiveness of using a mobile device compared with a workstation.

   Review Comments: (Resolved) The sponsor explained the rationale for the study and the conclusions. The sponsor stated: "We are not suggesting that this study, as reported, result in a different IFU statement than that already agreed."

3. The results from Appendix 16.9.4 suggest that radiologists may have some difficulty using the device under some conditions. Note the comments from Dr. Koles, "Both [iPhone and iPad] were far better in the dark... I'd certainly be reading in the dark". In addition, Dr. Pattison stated, "Subtle findings were better appreciated in the dark on the mobile devices and were best appreciated on the PACS workstation." Please revise the label to reflect the preference for clinicians to review the images in a dark environment.

   Review Comments: (Resolved) The sponsor revised the labeling to state: "... It is preferable for clinicians to review images in a dark environment, similar to a radiology reading room. Users should familiarize themselves with the viewing characteristics of the device under various lighting conditions and are encouraged to use the built-in ambient light test to test the suitability of their current lighting environment prior to actual use."

4. The "Bright" conditions were in the range of 209-220 lux. In the TG18 report, 220 lux was considered as "hospital clinical viewing station," which is much dimmer than regular office lighting. The setting of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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the ambient luminance (220 and 1.5 lux) may not represent common viewing conditions for mobile display users. The labeling should contain specific language to indicate the limits on the ambient illumination levels in which this product could be used.

Review Comments: (Resolved) The sponsor provided a copy of the AAPM chart, which showed the lux used for testing falls within a range of viewing conditions (e.g., staff offices, hospital viewing workstations). The user manual includes information on ambient lighting.

5. Page 3 and 12 of the Mobile Device PACS Study (Appendix 16.9.4) indicates that all 12 reviewed cases were neuro cases. Page 5 seems to contradict this. Please clarify this discrepancy.

   Review Comments: (Resolved) The sponsor stated: "This was an error in the document. The 12 cases reviewed were a mix of neuro and body/musculo-skeletal cases as per the panel's selections on Page 5."

6. The software documentation suggests that the device is intended to have persistent on-screen indication of the degree of source image compression. It is not clear if this feature has been implemented for the 2D or 3D images. In Appendix 16.11, Item 925 of the list of Unresolved Anomalies indicates that compression information is missing. The User Guide did not contain a description of this indicator. Please clarify if this feature has been implemented for the 2D/3D images and provide the software testing and labeling information.

   Review Comments: (Resolved) The sponsor provided documentation that this issue has been resolved.

7. The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, page 21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

   Review Comments: (Resolved) The slider has been renamed to "Final Quality" to avoid confusion.

8. The iPad image on page 12 of the user guide lists images from modalities that are not covered by the Indications for Use. Please revise the User Guide to only show modalities that appear in the Indications for Use statement.

   Review Comments: (Resolved) The user manual has been revised to show only CT and MR images.

9. As required by 21 CFR 801.109(b)(1), please revise your User's Manual to include the Federal prescription statement "Caution: Federal law restricts this device to sale by or on the order of a physician" and provide the revised pages for FDA review.

   Review Comments: (Resolved) The labeling was revised.

10. Most of the tests under the "Ambient Lighting User Assessment" in Appendix 16.9.1 were listed as "nd" (not done). Appendix 16.9.2 did not appear to contain any tests related to the ambient lighting user assessment. Please clarify whether the functionality to evaluate the ambient lighting has been implemented. Please provide the software test results that show this feature has been successfully implemented.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Review Comments: (Resolved) The sponsor provided additional documentation to support that the capability for ambient light testing has been implemented.

11. FDA has comments on the following Unresolved Anomalies (Appendix 16.11).
    (a) Item 892 indicates that image corners are rounded on the iPad app unintentionally. Please provide more details on the cause for this anomalies and the potential impact on the safety and effectiveness of the device.
    (b) Item 928 indicates that FDA concerns about the User Guide have not been addressed.
    (c) Item 919, "As an end-user, I want to be informed when a data type that is displayed is not officially supported so that I can take that into consideration when rendering a medical decision". FDA would like to see this feature incorporated before release.
    (d) Item 929, "As an OEM provider, I want to have an extensively tested FDA-approved product..." As previously noted, FDA does not "approve" devices under the 510(k) program; they are only cleared. Please review 21 CFR 807.97 (Misbranding by reference to premarket notification). Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

    Review Comments: (Resolved) (a) The sponsor clarified this is an issued with the iOS. (b) A revised User Manual for the US was included in the response. (c) This feature has been implemented. (d) The sponsor clarified that this ticket does not reflect labeling.

12. Please provide documentation for off-the-shelf software used in your device following the "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices". http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.htm

    Review Comments: (Resolved) This documentation was provided.

13. FDA has comments on the following aspects of the Display Quality Test Reports (Appendix 16.9.3.1, 16.9.3.2, and 16.9.3.3)
    (a) The DICOM GSDF measurements appear to have been calculated using ΔL/L; the correct formula is ΔL/average(L)/ΔJND, which could impact the conclusions related to the GSDF on page 9 of Appendix 16.9.3.
    (b) The original TG18 test patterns are in 12-bit depth and size of 1k*1k pixels, which do not fit the iPhone 4 or iPad screens. In the test reports, the devices were tested with "customized display test patterns," which was not explained. Please explain any difference in the TG18 test patterns, bench test patterns, and those used by the software application.
    (c) In the luminance non-uniformity test and the chromaticity variation test, the size of the measured areas was not reported. Because of the smaller display size of iPhone4/iPad, the measurement method needs to be adjusted accordingly when assessing uniformity or the other spatial properties. Please report the measurement method.
    (d) In the chromaticity variation test, the test pattern was not specified.
    (e) Figure 6 was mislabeled.

    Review Comments: (Resolved) Most of the issues were resolved. The sponsor was notified of potential areas of improvement for future versions; specifically, the DICOM GSDF calculations, which are optional for non-mammography systems, but may still improve the image quality.

14. Compared with a Windows/Intel-x86-based notebook, which was used in the predicate, the iPhone4/iPad, as an embedded system, is slower in terms of computation and communication speed. In the current submission, such latency-related measurement was not reported. FDA believes that a

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general discussion of the time required to download images over different network types in the labeling would be useful to users.

Review Comments: (Resolved) The user manual was revised to include a discussion of the download time as well as recommendation to discuss with an IT professional. The sponsor provided bench test results.

15. The Substantial Equivalence Comparison Table (Section 12, page 23) states the client operating system can be the iPhone/iPad OS, other mobile device OS. Items 912 and 913 of the Unresolved Anomalies (Appendix 16.11) reference the Android OS. The submission did not contain any software or bench testing to support the use of the application on other mobile device OS. FDA believes that a new 510(k) submission would be necessary to support the migration of the device to a new operating system, such as the Android OS.

    Review Comments: (Resolved) The sponsor stated: "This submission is intended only to cover the Apple iOS devices, specifically iPhone 4 and iPad. Any references to Android or other mobile operating systems were unintentional and not meant to imply their inclusion in the submission for FDA clearance. (b) (4)
    (b) (4)

16. In Appendix 16.6, page 15, the following quoted paragraph is inconsistent with the intended use -- "ResolutionMD Mobile was designed to function on smartphone devices that have native hardware providing Wi-Fi and cellular network connectivity. Similarly, these smartphone devices utilize industry-best display technology such as LED or AMOLED LCDs and have large displays that occupy most of the devices' surface (most measuring 3.5" or larger)." Note that iPhone4 and iPad are neither LED nor AMOLED.

    Review Comments: (Resolved) The sponsor stated: "... The SDS document has been edited on Page15 to remove this unintended anomaly."

17. Please complete the Clinical Trials Form (FDA 3674).
    http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf

    Review Comments: (Resolved) This form was provided.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix B

Request for Additional Information (Email, August 29, 2011)
Response Received (Email, August 31, 2011)

1. The response to comments #1 and #2 clarify that Calgary is not trying to modify the Indications for Use statement. FDA was looking for a simple confirmation that Calgary will not make emergency use claims, and that Calgary will not claim that clinicians using a mobile device will be as accurate or will reach the same diagnosis as they would be when using a workstation.

   Review Comments: (Resolved) This sponsor confirmed.

2. FDA's comment #14 was not fully addressed. The original comment was about "different network types" such as a good Wi-Fi connection versus a poor 3G connection. The response assumes ideal conditions and uses description such as "in only a few seconds". The results of actual testing would provide some insight into the potential variation. For example, the download time required for a 50 slice CT series from a good Wi-Fi connection, good 3G connection, and a poor 3G connection with the "Final Quality" at 100%. There is no minimum or maximum requirement; this information is to help characterize the variation.

   Review Comments: (Resolved) The sponsor revised the user manual and provided details for the expected performance under different scenarios.

3. As part of the response to comment 13(c), the table on page 11 of the "Response to FDA AI Letter" includes the measurement setup. Please clarify why the area of measurement is the same (0.006283165 m^2) even though the measurement distances and pixel diameter/area are different for the iPad and iPhone 4. Is this a typo, or does is reflect additional problems with the test methods or results?

   Review Comments: (Resolved) This discrepancy was a typographical mistake.

The following comments were meant as considerations for a future release.

4. The concern with the JPEG compression was not about the wording between "Full Quality" vs. "Final Quality" but the numerical representation. The terms "Low - High - Full" may be more appropriate since the actual impact of the compression parameters on image quality is non-linear and difficult to predict. Numbers could give the wrong impression to users; for example, users may think that at the 75 setting they only lose 25% of image quality.

   Review Comments: The sponsor is using the JPEG standard. The suggested revision may be more accurate, but is not required for SE.

5. Calgary should consider alerting users when the final quality is reached during download.

   Review Comments: A progress bar is displayed across the screen as the data set is loading. Should the connection being lost during transmission, an error message will be displayed.

6. The correct formula for the DICOM GSDF should be delta-L/average(L)/JND, not delta-L/average(L)/delta-JND as previously stated. There may be a larger deviation in the lower luminance JNDs that may be important to consider when designing the device for lower-contrast modalities.

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Review Comments: The deviation from DICOM may be more than 30%, which is acceptable because the iPad and iPhone4 are not designed for DICOM. The DICOM GSDF report is optional for non-mammo modalities.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ochs, Robert

From: Kyle Peterson [kyle.peterson@calgaryscientific.com]
Sent: Wednesday, August 31, 2011 2:36 PM
To: Ochs, Robert
Subject: RE: K111346 S1 - Calgary - ResolutionMD Mobile
Importance: High
Attachments: K111346-Response to August 29 , 2011 email-August 31, 2011.pdf

Robert,

Thanks for your time on the phone this morning. Attached is our response to your email.

As mentioned in the response, we will do the iPad performance testing before market release. Doing so now would have held up this response as we need to develop a reproducible method of creating the poor 3G connection. There's a documented (and easy) one for the iPhone 4 but we'll have to devise one for the iPad.

Please let me know if there are any further questions. If you are able to let me know when your review is complete and the clearance has gone out for sign-off, I would sure appreciate the advance notice.

Best regards,

Kyle

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

From: Ochs, Robert [mailto:Robert.Ochs@fda.hhs.gov]
Sent: Monday, August 29, 2011 8:23 AM
To: 'Kyle Peterson'
Subject: K111346 S1 - Calgary - ResolutionMD Mobile

Hello Kyle,

There are still a few minor issues that need to be resolved in order to complete our review. Please email your response by September 1, 2011. If you need more time, I can place the submission on hold.

1. The response to comments #1 and #2 clarify that Calgary is not trying to modify the Indications for Use statement. FDA was looking for a simple confirmation that Calgary will not make emergency use claims, and that Calgary will not claim that clinicians using a mobile device will be as accurate or will reach the same diagnosis as they would be when using a workstation.

2. FDA's comment #14 was not fully addressed. The original comment was about "different network types" such as a good Wi-Fi connection versus a poor 3G connection. The response assumes ideal conditions and uses description such as "in only a few seconds". The results of actual testing would provide some insight into the potential variation. For example, the download time required for a 50 slice CT series from a good Wi-Fi connection, good 3G connection, and a poor 3G connection with the "Final Quality" at 100%. There is no

minimum or maximum requirement; this information is to help characterize the variation.

3. As part of the response to comment 13(c), the table on page 11 of the "Response to FDA AI Letter" includes the measurement setup. Please clarify why the area of measurement is the same (0.006283165 m^2) even though the measurement distances and pixel diameter/area are different for the iPad and iPhone 4. Is this a typo, or does is reflect additional problems with the test methods or results?

The following comments are meant as considerations for a future release.

4. The concern with the JPEG compression was not about the wording between "Full Quality" vs. "Final Quality" but the numerical representation. The terms "Low - High - Full" may be more appropriate since the actual impact of the compression parameters on image quality is non-linear and difficult to predict. Numbers could give the wrong impression to users; for example, users may think that at the 75 setting they only lose 25% of image quality.

5. Calgary should consider alerting users when the final quality is reached during download.

6. The correct formula for the DICOM GSDF should be delta-L/average(L)/JND, not delta-L/average(L)/delta-JND as previously stated. There may be a larger deviation in the lower luminance JNDs that may be important to consider when designing the device for lower-contrast modalities.

Thank you,
Robert

Robert Ochs, PhD
Lead Reviewer / Physicist
Division of Radiological Devices
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66 Room G242
Silver Spring, MD 20993-0002
(301) 796-6661
Robert.Ochs@fda.hhs.gov

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Robert.Ochs@fda.hhs.gov

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K111346 Trade name: ResolutionMD™ Mobile

Response to FDA – Robert Ochs email of August 29, 2011
Date of Response: August 31, 2011

Introduction

This response is organized using the same numbering as the items in the email sent by Dr. Robert Ochs of the FDA to Kyle Peterson of Calgary Scientific Inc., dated August 29, 2011.

Items and Response

Item 1 - The response to comments #1 and #2 clarify that Calgary is not trying to modify the Indications for Use statement. FDA was looking for a simple confirmation that Calgary will not make emergency use claims, and that Calgary will not claim that clinicians using a mobile device will be as accurate or will reach the same diagnosis as they would be when using a workstation.

Response:

In marketing ResolutionMD Mobile, Calgary Scientific Inc. (CSI) will not make emergency use claims nor will we claim that clinicians using a mobile device will be as accurate or reach the same diagnosis as they would using a workstation.

In preparation for the launch of the device into the United States market, we are undertaking several actions to ensure that our marketing messages respect the above statement and are consistently represented during our marketing activities. These actions include:

- Development of marketing materials and messaging focused on product capabilities and clearly reflecting the Intended Use statement
- Retention of a Washington, DC-based medical device regulatory attorney to review our materials and messaging strategy.
- Professional education for our regulatory staff on medical device marketing and promotion.
- Internal training for our executive, sales, marketing and product management staff on the appropriate messaging to be used at trade shows, sales presentations, press interviews, etc.
- Training for our distributors and resellers on the appropriate messaging to be used in their marketing.
- Compliance monitoring of these activities via our internal QMS audit process.

We are confident that these measures will ensure that we deliver on our commitment. We would appreciate any feedback you may have on best practices in this regard.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item 2 - FDA's comment #14 was not fully addressed. The original comment was about "different network types" such as a good Wi-Fi connection versus a poor 3G connection. The response assumes ideal conditions and uses description such as "in only a few seconds". The results of actual testing would provide some insight into the potential variation. For example, the download time required for a 50 slice CT series from a good Wi-Fi connection, good 3G connection, and a poor 3G connection with the "Final Quality" at 100%. There is no minimum or maximum requirement; this information is to help characterize the variation.

Response:

Calgary Scientific has conducted performance testing using ResolutionMD Mobile on the iPhone 4 in order to provide the user with a more definitive indication of the actual image loading times they will experience. As a result of this testing, CSI proposes to reword the Expected Performance section of the User Guide to communicate this testing information.

This section on Page 5 of the User Guide submitted for review on August 2 currently reads:

Expected Performance

Because ResolutionMD Mobile is not required to download full DICOM images to your mobile viewing device, the delivery of rendered images from the server to the mobile device over different network types will vary somewhat depending on bandwidth availability i.e. raw speed of the network, either Wi-Fi or 3G cellular, and network latency, i.e. inherent delays on the network. In any case, we have observed that once communication is established to the server, the requested image will be fully loaded on the server and available for initial viewing on the mobile device in only a few seconds. Please work with your IT provider or service provider to connect your device with higher bandwidth / lower latency network options to optimize performance.

We propose to change this wording to the following:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

A Progress bar is displayed across the screen as the data set is loading. Should the connection being lost during transmission, an error message will be displayed.

For reference for your technical reviewers, since the signal strength formula was "corrected" for the iPhone 4 the following signal strengths (in dBm) correspond to each of the "bar" designations (the values for which Apple indicates they use on the advice of AT&T).

(b) (4)

Also for your information, it will be several weeks following receipt of the FDA clearance before we formally launch the ResolutionMD Mobile product. Having done the above testing, we will also develop and include testing data for the iPad device in the released version of the User Guide. From informal tests, we can state it is not much different than the iPhone 4. We will add these tests to our formal test suite and include updated performance information for future releases of the software in the User Guide.

Item 3 - As part of the response to comment 13(c), the table on page 11 of the "Response to FDA AI Letter" includes the measurement setup. Please clarify why the area of measurement is the same (0.006283165 m^2) even though the measurement distances and pixel diameter/area are different for the iPad and iPhone 4. Is this a typo, or does is reflect additional problems with the test methods or results?

Response: In the August 2 response, a typographical mistake was made in the second and fifth columns. The errors have been corrected. The corrected table should read:

(b) (4)

Please accept our apologies for this oversight.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Summary:

We hope that we have addressed the points in your email of August 29, 2011 to your satisfaction. We look forward to receiving clearance to bring this innovative technology to market in the United States.

Calgary Scientific Inc.
August 31, 2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ochs, Robert

From: Ochs, Robert
Sent: Wednesday, August 31, 2011 9:49 AM
To: 'Kyle Peterson'
Subject: RE: K111346 S1 - Calgary - ResolutionMD Mobile

You can just send the content and proposed wording, if that was the only question. I'll be back in my office around 10 am if you have any additional questions.

Thanks,
Robert

From: Kyle Peterson [mailto:kyle.peterson@calgaryscientific.com]
Sent: Tuesday, August 30, 2011 10:19 AM
To: Ochs, Robert
Subject: RE: K111346 S1 - Calgary - ResolutionMD Mobile

Robert,

Thanks for your note. I was out of the office yesterday but I was able to forward your note to my colleagues who began work on the items. I expect that we will be able to respond by Thursday as requested but I will know more later today.

Thank you for the additional comments. We will address those in the next release and for our next planned 510 (k) submission for the Android platform. We may have some additional questions or clarification regarding that submission that we will forward as well once the current submission receives clearance.

And, thanks once more for all your patience and guidance as we navigated through all the issues over the last 21 months.

Best regards,

Kyle

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

From: Ochs, Robert [mailto:Robert.Ochs@fda.hhs.gov]
Sent: Monday, August 29, 2011 8:23 AM
To: 'Kyle Peterson'
Subject: K111346 S1 - Calgary - ResolutionMD Mobile

Hello Kyle,

29

There are still a few minor issues that need to be resolved in order to complete our review. Please email your response by September 1, 2011. If you need more time, I can place the submission on hold.

1. The response to comments #1 and #2 clarify that Calgary is not trying to modify the Indications for Use statement. FDA was looking for a simple confirmation that Calgary will not make emergency use claims, and that Calgary will not claim that clinicians using a mobile device will be as accurate or will reach the same diagnosis as they would be when using a workstation.

2. FDA's comment #14 was not fully addressed. The original comment was about "different network types" such as a good Wi-Fi connection versus a poor 3G connection. The response assumes ideal conditions and uses description such as "in only a few seconds". The results of actual testing would provide some insight into the potential variation. For example, the download time required for a 50 slice CT series from a good Wi-Fi connection, good 3G connection, and a poor 3G connection with the "Final Quality" at 100%. There is no minimum or maximum requirement; this information is to help characterize the variation.

3. As part of the response to comment 13(c), the table on page 11 of the "Response to FDA AI Letter" includes the measurement setup. Please clarify why the area of measurement is the same (0.006283165 m^2) even though the measurement distances and pixel diameter/area are different for the iPad and iPhone 4. Is this a typo, or does is reflect additional problems with the test methods or results?

The following comments are meant as considerations for a future release.

4. The concern with the JPEG compression was not about the wording between "Full Quality" vs. "Final Quality" but the numerical representation. The terms "Low - High - Full" may be more appropriate since the actual impact of the compression parameters on image quality is non-linear and difficult to predict. Numbers could give the wrong impression to users; for example, users may think that at the 75 setting they only lose 25% of image quality.

5. Calgary should consider alerting users when the final quality is reached during download.

6. The correct formula for the DICOM GSDF should be delta-L/average(L)/JND, not delta-L/average(L)/delta-JND as previously stated. There may be a larger deviation in the lower luminance JNDs that may be important to consider when designing the device for lower-contrast modalities.

Thank you,
Robert

Robert Ochs, PhD
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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Robert.Ochs@fda.hhs.gov

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Ochs, Robert

From: Ochs, Robert
Sent: Wednesday, July 27, 2011 11:16 AM
To: 'Kyle Peterson'
Subject: RE: K111346 - Calgary Scientific - clarification requested on your letter

Hi Kyle,

I think that your proposed responses are reasonable. I do not think that revised documentation is necessary for some of the figure/wording edits as long as your response addresses the issue.

The main purpose of questions #1 and #2 was to try and make our opinion as clear as possible on what we believe will be appropriate marketing claims given the data submitted. We understand you comment about radiologists wanting to provide information on a diagnosis when reading under the different conditions. There is nothing wrong with collecting this information if you or the radiologists think that it may be useful as part of your product development. However, we just wanted to clarify what claims we thought would or would not be supported by the study.

A post-market study is not required in order to obtain 510(k) clearance. Your post-market plans will likely provide you with valuable information on where to focus future study to support more specific marketing claims for review by FDA.

I think for #7, we were also looking for a change of the slider name form "Full Quality" to something else, perhaps "Compression" or "Image Quality". This may be a minor issue, but it seems like the name should only be "Full Quality" when there is no compression. There may have been confusion since you may use "Full" to refer to the mode, while users may think "Full" describes the quality of the image.

Thank you,
Robert

From: Kyle Peterson [mailto:kyle.peterson@calgaryscientific.com]
Sent: Monday, July 25, 2011 9:54 AM
To: Ochs, Robert
Subject: RE: K111346 - Calgary Scientific - clarification requested on your letter

Robert,

Thanks for the note. We received the letter in the mail on Friday, July 15. It was dated June 30. Normally, with these letters, we receive it by fax on the day it is dated. No fax was received on this occasion.

I will send it an extension request later today.

I look forward to your reply to my questions.

Best regards,

Kyle

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.

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Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

From: Ochs, Robert [mailto:Robert.Ochs@fda.hhs.gov]
Sent: Monday, July 25, 2011 7:03 AM
To: 'Kyle Peterson'
Subject: RE: K111346 - Calgary Scientific - clarification requested on your letter

I just returned after being out of the office, so it may take a day or two to go through your email.

If possible, can you send me the exact date that you received the letter/fax? Nobody benefits from these type of delays, so I'll make sure our management and the 510(k) management is notified. In my experience, the 510(k) staff does not not extend the 30 day date, although they are unlikely to delete the submission on day 30. I would recommend that you submit an extension request.

Thanks,
Robert

From: Kyle Peterson [mailto:kyle.peterson@calgaryscientific.com]
Sent: Friday, July 22, 2011 2:16 PM
To: Ochs, Robert
Subject: K111346 - Calgary Scientific - clarification requested on your letter
Importance: High

Robert,

Thanks for sending on the contents of your AI request last week. We finally received the hard copy in the mail last Friday. I have left a message on the DSMICA voice mail about not receiving the fax and the effective date of the letter (which was actually June 30). I wanted to find out if they are going to adjust the start date of the 30 day response period or whether I need to file for an extension should we not get our response in next week. So far they have not returned my call.

Anyway, I think we understand most of your letter. Most of the items are either straight-forward answers, small fixes or clarifications on a few items that may have been taken out of context. Two items (#9 and #17) were not requested on the prior submission but are easy to do.

I did want to get further clarification on items 1, 2 and 7 as follows:

Item 1 - Parts of the submission include specific statements related to the use of the device in emergency situations and for specific conditions (e.g., Section 12, page 16; Section 16.2.5, pages 32-33). As has been noted previously on multiple occasions, FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims related to the use of the device for emergency situations or specific disease conditions, such as stroke. FDA believes that a general indications for use statement is most appropriate for this device based on the information provided. Please confirm that you will not market your device for these or other specific indications.

Here is the response I was thinking we should submit:

In accordance with the submitted Indications for Use statement which has previously been discussed with the FDA, the device is not indicated for any specific situations or disease conditions. Calgary Scientific Inc. does not intend to market the device for any specific situations or disease conditions. As discussed, the IFU states that the device

is only to be used when there is no access to a full workstation.

The comment on Page 16, "... especially in emergency situations", was not intended to modify the agreed IFU statement. If anything, it was predictive rather than prescriptive since the impetus to create the device came from physicians involved in emergency care. The diagrams on pages 32-33 have been deleted and replaced with generic diagrams properly reflecting the IFU statement. (Note: We have also fixed the footers in this document.)

Calgary Scientific will institute a post-market monitoring program to document the actual use of the device by physicians.

My questions are: Does this work? Do you want my commentary or should I take out the second paragraph? Do you want us to clean up that particular document and submit a new version or just provide this response?

Item 2 - There are concerns with the conclusions that are being drawn from the study in Appendix 16.9.4. As noted on numerous occasions, the purpose of the study was not to compare the resulting primary or secondary diagnosis. FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims that radiologists will be as accurate on the mobile device as on a workstation, or will reach the same diagnosis as on a workstation. The performance study was intended to support that the device offers sufficient image quality for a diagnosis (or image review) on CT and MR under specific lighting conditions when there is no access to a workstation. Much more rigorous studies would be necessary to evaluate the diagnostic effectiveness of using a mobile device compared with a workstation.

My question is: Is this just a comment, do you want us to change the conclusions or do you want to a response explain why we wrote it this way?

If it's the latter, my response would be the following:

The study design suggested by the FDA was essentially a three-step process. First, a panel of expert radiologists was asked to nominate the typical types of cases read for each modality. Second, a senior radiologist at the institution conducting the study was asked to find challenging examples of cases of each of the nominated types. The challenging element was typically either a subtle finding related to the type of case or an incidental, unrelated secondary finding. Third, typical radiologists were asked to compare reading these studies on mobile devices in normal office lighting, again in a dark radiology reading room, and finally on a PACS workstation.

Although the primary assessment the radiologists were asked to make was one of general comparison and confidence level on the mobile device, the radiologists' instinctive reaction to the methodology was to try to read the case on the mobile device and report their findings as they would for any diagnosis. They then proceeded to re-read the case in dark conditions and then on the PACS to see whether their diagnosis held up or what additional details they might see on the mobile device in the darkened conditions or on the PACS workstation. Only after they had completed a series of reads could they draw their general observations and answer the general questions requested by the FDA.

Our feeling is that this study, conducted both with iPad and the iPhone 4, and our previous study submitted with our previous 510(k), conducted with a mixture of iPhone 4 and iPhone 3GS, are supportive of the notion that a range of diagnoses could be made on the mobile devices that are comparable to PACS workstations. We acknowledge that this notion does not translate into "valid scientific evidence" as the FDA points out. We felt it was important to report the radiologists' actual reaction to the methodology, their verbatim comments, and draw the conclusions that the data suggested. In the study, we did report the general observations and confidence levels requested by the FDA. We are not suggesting that this study, as reported, result in a different IFU statement than that already agreed.

If it's a response you want, does this resonate or would you rather see something different?

Robert, based on the direction that mobile technology is going in terms of hardware, networks and user acceptance/demand, we believe that the post-market phase will generate a great of deal of data on safe and effective use cases and clinical demand for greater functionality and expanded/liberalized IFUs. Our strategy is to let it play it out and see how the physicians actually use it and then come back to you in time to ask "what do we need to show to prove out X?".

Item 7 - The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss (compression ratio) was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, page 21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

What we are thinking to do to respond here is to create a table for the User Guide that shows the compression ratio for each setting on quality slider. We will also explain what Full Quality means in terms of compression ratio. Will this be adequate or do you see something further as beign required to address this item?

Also, I should apologize for the stray references to the Android platform. I thought I had scrubbed all of these but a few were in the List of Unresolved Anomalies. This list was an unfiltered, unedited report run from our ticketing system. We think it's important to give you data in the same way an FDA or ISO auditor would see it. I specificied iOS issues for the report but a few of the tickets related to bugs seen on both iOS and Android, which I did not notice. (b) (4)

(b) (4)

I am hopeful that we can answer all your concerns in one iteration. If any other questions arise during the drafting of our response, I will contact you.

Best regards,

Kyle

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ochs, Robert

From: Kyle Peterson [kyle.peterson@calgaryscientific.com]
Sent: Tuesday, July 12, 2011 10:05 AM
To: Ochs, Robert
Subject: RE: Calgary Scientific 510(k) - Radiologist Benchmark testing

Robert,

Thanks for your reply. We did not receive any faxes from the FDA in the last week or so. We will start digging into these issues and get back to you with any questions.

Best regards,

Kyle

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

From: Ochs, Robert [mailto:Robert.Ochs@fda.hhs.gov]
Sent: Tuesday, July 12, 2011 5:37 AM
To: 'Kyle Peterson'
Subject: RE: Calgary Scientific 510(k) - Radiologist Benchmark testing

The letter should have been faxed at the end of June or last week. I asked our document center to resend the fax yesterday. Here are the comments from the initial review.

- Robert

1. Parts of the submission include specific statements related to the use of the device in emergency situations and for specific conditions (e.g., Section 12, page 16; Section 16.2.5, pages 32-33). As has been noted previously on multiple occasions, FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims related to the use of the device for emergency situations or specific disease conditions, such as stroke. FDA believes that a general indications for use statement is most appropriate for this device based on the information provided. Please confirm that you will not market your device for these or other specific indications.

2. There are concerns with the conclusions that are being drawn from the study in Appendix 16.9.4. As noted on numerous occasions, the purpose of the study was not to compare the resulting primary or secondary diagnosis. FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims that radiologists will be as accurate on the mobile device as on a workstation, or will reach the same diagnosis as on a workstation. The performance study was intended to support that the device offers sufficient image quality for a diagnosis (or image review) on CT and MR under specific lighting conditions when there is no access to a workstation. Much more rigorous studies would be necessary to evaluate the diagnostic effectiveness of using a mobile device compared with a workstation.

3. The results from Appendix 16.9.4 suggest that radiologists may have some difficulty using the device under some conditions. Note the comments from Dr. Koles, "Both [iPhone and iPad] were far better in the dark... I'd certainly be reading in the dark". In addition, Dr. Pattison stated, "Subtle findings were better appreciated in the dark on the mobile devices and were best appreciated on the PACS workstation." Please revise the label to reflect the preference for

clinicians to review the images in a dark environment.

4. The "Bright" conditions were in the range of 209-220 lux. In the TG18 report, 220 lux was considered as "hospital clinical viewing station," which is much dimmer than regular office lighting. The setting of the ambient luminance (220 and 1.5 lux) may not represent common viewing conditions for mobile display users. The labeling should contain specific language to indicate the limits on the ambient illumination levels in which this product could be used.

5. Page 3 and 12 of the Mobile Device PACS Study (Appendix 16.9.4) indicates that all 12 reviewed cases were neuro cases. Page 5 seems to contradict this. Please clarify this discrepancy.

6. The software documentation suggests that the device is intended to have persistent on-screen indication of the degree of source image compression. It is not clear if this feature has been implemented for the 2D or 3D images. In Appendix 16.11, Item 925 of the list of Unresolved Anomalies indicates that compression information is missing. The User Guide did not contain a description of this indicator. Please clarify if this feature has been implemented for the 2D/3D images and provide the software testing and labeling information.

7. The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss (compression ratio) was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, page 21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

8. The iPad image on page 12 of the user guide lists images from modalities that are not covered by the Indications for Use. Please revise the User Guide to only show modalities that appear in the Indications for Use statement.

9. As required by 21 CFR 801.109(b)(1), please revise your User's Manual to include the Federal prescription statement "Caution: Federal law restricts this device to sale by or on the order of a physician" and provide the revised pages for FDA review.

10. Most of the tests under the "Ambient Lighting User Assessment" in Appendix 16.9.1 were listed as "nd" (not done). Appendix 16.9.2 did not appear to contain any tests related to the ambient lighting user assessment. Please clarify whether the functionality to evaluate the ambient lighting has been implemented. Please provide the software test results that show this feature has been successfully implemented.

11. FDA has comments on the following Unresolved Anomalies (Appendix 16.11).
(a) Item 892 indicates that image corners are rounded on the iPad app unintentionally. Please provide more details on the cause for this anomalies and the potential impact on the safety and effectiveness of the device.
(b) Item 928 indicates that FDA concerns about the User Guide have not been addressed.
(c) Item 919, "As an end-user, I want to be informed when a data type that is displayed is not officially supported so that I can take that into consideration when rendering a medical decision". FDA would like to see this feature incorporated before release.
(e) Item 929, "As an OEM provider, I want to have an extensively tested FDA-approved product..." As previously noted, FDA does not "approve" devices under the 510(k) program; they are only "cleared". Please review 21 CFR 807.97 (Misbranding by reference to premarket notification). Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

12. Please provide documentation for off-the-shelf software used in your device following the "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices".
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.htm

13. FDA has comments on the following aspects of the Display Quality Test Reports (Appendix 16.9.3.1, 16.9.3.2, and 16.9.3.3)
(a) The DICOM GSDF measurements appear to have been calculated using $\Delta L/L$; the correct formula is $\Delta L/\text{average}(L)/\Delta JND$, which could impact the conclusions related to the GSDF measurement on page 9 of Appendix 16.9.3.
(b) The original TG18 test patterns are in 12-bit depth and size of 1k*1k pixels, which do not fit the iPhone4 or iPad screens. In the test reports, the devices were tested with "customized display test patterns," which was not explained. Please explain any difference in the TG18 test patterns, bench test patterns, and those used by the software application.
(c) In the luminance non-uniformity test and the chromaticity variation test, the size of the measured areas was not reported. Because of the smaller display size of iPhone4/iPad, the measurement method needs to be adjusted accordingly when assessing uniformity or the other spatial properties. Please report the measurement method.
(d) In the chromaticity variation test, the test pattern was not specified.
(e) Figure 6 was mislabeled.

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14. Compared with a Windows/Intel-x86-based notebook, which was used in the predicate, the iPhone4/iPad, as an embedded system, is slower in terms of computation and communication speed. In the current submission, such latency-related measurement was not reported. FDA believes that a general discussion of the time required to download images over different network types in the labeling would be useful to users.

15. The Substantial Equivalence Comparison Table (Section 12, page 23) states the client operating system can be the iPhone/iPad OS, other mobile device OS. Items 912 and 913 of the Unresolved Anomalies (Appendix 16.11) reference the Android OS. The submission did not contain any software or bench testing to support the use of the application on other mobile device OS. FDA believes that a new 510(k) submission would be necessary to support the migration of the device to a new operating system, such as the Android OS.

16. In Appendix 16.6, page 15, the following quoted paragraph is inconsistent with the intended use -- "ResolutionMD Mobile was designed to function on smartphone devices that have native hardware providing Wi-Fi and cellular network connectivity. Similarly, these smartphone devices utilize industry-best display technology such as LED or AMOLED LCDs and have large displays that occupy most of the devices' surface (most measuring 3.5" or larger)." Note that iPhone4 and iPad are neither LED nor AMOLED.

17. Please complete the Clinical Trials Form (FDA 3674).
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf

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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Robert.Ochs@fda.hhs.gov

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From: Kyle Peterson [mailto:kyle.peterson@calgaryscientific.com]
Sent: Friday, July 08, 2011 10:28 AM
To: Ochs, Robert
Subject: Calgary Scientific 510(k) - Radiologist Benchmark testing

Hello, Robert:

I hope you are well and enjoying a nice summer. How is your review of our recent 510(k) submission going? We are hoping that no news is good news and that a clearance letter is coming our way soon. If you do have questions on this submission, please email me and we'll answer them quickly.

In the meantime, if you have completed your review of our radiologist benchmark testing on the iPhone and iPad, could you please comment on the adequacy of our methodology and presentation of the results? The reason I ask is that we have completed the lab testing on several (b) (4)

(b) (4)

Your comments would be helpful in expeditiously proceeding on this testing.

Thanks and best regards,

Kyle

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Director, Regulatory & Corporate Affairs
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Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

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Ochs, Robert

From: Ochs, Robert
Sent: Tuesday, September 06, 2011 10:06 AM
To: Cheng, Wei-Chung; O'Leary, Brendan
Subject: RE: K111346 - Calgary - ResolutionMD

The device is only intended for the iPhone 4 or iPad. I'll make sure that it is clear in my review memo.
Thanks,
- Robert

From: Cheng, Wei-Chung
Sent: Tuesday, September 06, 2011 9:58 AM
To: O'Leary, Brendan; Ochs, Robert
Subject: RE: K111346 - Calgary - ResolutionMD

Hi Robert,

Can this software be used on iPhone 3G? In the original submission, it is very clear that this software is to be used on iPhone4 or iPad. However, in the final memo, it became "The sponsor stated: "This submission is intended only to cover the Apple iOS devices, specifically iPhone 4 and iPad." Based on this statement, this software can be used on iPhone 3, iPhone 5, or even iPod.

Maybe the wording of "iPhone/iPad" can be qualified as "iPhone4/iPad"?

Wei-Chung

From: O'Leary, Brendan
Sent: Tuesday, September 06, 2011 9:23 AM
To: Ochs, Robert; Cheng, Wei-Chung
Subject: RE: K111346 - Calgary - ResolutionMD

Looks good to me.

From: Ochs, Robert
Sent: Tuesday, September 06, 2011 8:58 AM
To: Cheng, Wei-Chung; O'Leary, Brendan
Subject: K111346 - Calgary - ResolutionMD

Hello,

Here is my final review memo recommending SE. Please let me know if you have any comments by Wednesday afternoon (Sept. 7th).

<< File: K111346 S1 - Review.doc >>

Thank you,
Robert

Robert Ochs, PhD
Lead Reviewer / Physicist
Division of Radiological Devices
Center for Devices and Radiological Health

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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Robert.Ochs@fda.hhs.gov

4.0

Ochs, Robert

From: O'Leary, Brendan
Sent: Wednesday, August 31, 2011 2:54 PM
To: Ochs, Robert; Cheng, Wei-Chung
Cc: Badano, Aldo G
Subject: RE: K111346 S1 - Calgary - ResolutionMD Mobile

Robert,

Looks good to me.

Thanks,
Brendan

From: Ochs, Robert
Sent: Wednesday, August 31, 2011 2:48 PM
To: Cheng, Wei-Chung; O'Leary, Brendan
Cc: Badano, Aldo G
Subject: FW: K111346 S1 - Calgary - ResolutionMD Mobile

Hello,

Please see the sponsor's response to our latest set of questions. Please let me know if you have any additional comments by Friday afternoon (Sept. 2, 2011).

Thank you,
Robert

From: Kyle Peterson [mailto:kyle.peterson@calgaryscientific.com]
Sent: Wednesday, August 31, 2011 2:36 PM
To: Ochs, Robert
Subject: RE: K111346 S1 - Calgary - ResolutionMD Mobile
Importance: High

Robert,

Thanks for your time on the phone this morning. Attached is our response to your email.

As mentioned in the response, we will do the iPad performance testing before market release. Doing so now would have held up this response as we need to develop a reproducible method of creating the poor 3G connection. There's a documented (and easy) one for the iPhone 4 but we'll have to devise one for the iPad.

Please let me know if there are any further questions. If you are able to let me know when your review is complete and the clearance has gone out for sign-off, I would sure appreciate the advance notice.

Best regards,

Kyle

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

From: Ochs, Robert [mailto:Robert.Ochs@fda.hhs.gov]
Sent: Monday, August 29, 2011 8:23 AM
To: 'Kyle Peterson'
Subject: K111346 S1 - Calgary - ResolutionMD Mobile

Hello Kyle,

There are still a few minor issues that need to be resolved in order to complete our review. Please email your response by September 1, 2011. If you need more time, I can place the submission on hold.

1. The response to comments #1 and #2 clarify that Calgary is not trying to modify the Indications for Use statement. FDA was looking for a simple confirmation that Calgary will not make emergency use claims, and that Calgary will not claim that clinicians using a mobile device will be as accurate or will reach the same diagnosis as they would be when using a workstation.

2. FDA's comment #14 was not fully addressed. The original comment was about "different network types" such as a good Wi-Fi connection versus a poor 3G connection. The response assumes ideal conditions and uses description such as "in only a few seconds". The results of actual testing would provide some insight into the potential variation. For example, the download time required for a 50 slice CT series from a good Wi-Fi connection, good 3G connection, and a poor 3G connection with the "Final Quality" at 100%. There is no minimum or maximum requirement; this information is to help characterize the variation.

3. As part of the response to comment 13(c), the table on page 11 of the "Response to FDA AI Letter" includes the measurement setup. Please clarify why the area of measurement is the same (0.006283165 m^2) even though the measurement distances and pixel diameter/area are different for the iPad and iPhone 4. Is this a typo, or does is reflect additional problems with the test methods or results?

The following comments are meant as considerations for a future release.

4. The concern with the JPEG compression was not about the wording between "Full Quality" vs. "Final Quality" but the numerical representation. The terms "Low - High - Full" may be more appropriate since the actual impact of the compression parameters on image quality is non-linear and difficult to predict. Numbers could give the wrong impression to users; for example, users may think that at the 75 setting they only lose 25% of image quality.

5. Calgary should consider alerting users when the final quality is reached during download.

6. The correct formula for the DICOM GSDF should be delta-L/average(L)/JND, not delta-L/average(L)/delta-JND as previously stated. There may be a larger deviation in the lower luminance JNDs that may be important to consider when designing the device for lower-contrast modalities.

Thank you,
Robert

Robert Ochs, PhD
Lead Reviewer / Physicist
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This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Robert.Ochs@fda.hhs.gov

Ochs, Robert

From: Cheng, Wei-Chung *
Sent: Friday, August 26, 2011 2:53 PM
To: Ochs, Robert
Cc: Badano, Aldo G; O'Leary, Brendan
Subject: RE: K111346 - Calgary - ResolutionMD

OK. I understand the background and don't need to ask further questions.

However, please note that mobile display is not a conventional PACS display accessory due to the size difference. When JPEG compression is necessary, at least the parameters should be adjusted. For example, when using 4x4 macroblocks to compress images for an iPhone4 (960x640) and for a full HD display (1902x1080). When both fill the same field of view, a macroblock will look 9 times larger on iPhone4 than full HD. In other words, the artifacts will be more pronounced.

Wei-Chung

From: Ochs, Robert
Sent: Friday, August 26, 2011 11:49 AM
To: Cheng, Wei-Chung *
Cc: Badano, Aldo G; O'Leary, Brendan
Subject: RE: K111346 - Calgary - ResolutionMD

We can ask them to change the scale to "low" to "high", since that would seem to make more sense than the 0-100 scale, which as you note may not be linear. We pretty much have to accept the use of the JPEG standard since, it is an FDA recognized standard and is used by numerous PACS systems.

Thanks,
Robert

From: Cheng, Wei-Chung *
Sent: Friday, August 26, 2011 11:39 AM
To: O'Leary, Brendan; Ochs, Robert
Cc: Badano, Aldo G
Subject: RE: K111346 - Calgary - ResolutionMD

4. The device recommends that the "Final Quality" is set to 100 for diagnostic reading. In a future release, Calgary should consider alerting users when the final quality is reached during download

My concern about the JPEG compression is not about the wording between "Full Quality" vs. "Final Quality" but the numerical representation. I prefer using "Low - High - Full" instead of 0-100. Based on psychophysics, it matters between ordinal scale and ratio scale. I don't want the user to get the impression that "When I use the 75 setting, I only lose 25% of image quality".

Basically I am against JPEG compression because the image loss is very difficult to predict. The sponsor has no base to claim "The observed differences in image quality from the lowest to highest settings for typical CT and MR images are very subtle". For such a small mobile display, the compression is not meaningful. The Sponsor also said in Item 14 "An iPhone 4 requires much smaller images to be sent from the server than does a full screen browser on the predicate notebook." If so, why is JPEG compression necessary? It also puts computational load on the mobile device.

I asked them to clarify where they plugged the 0-100 parameter in the compression stages because the effects of image quality loss will not be linear.

Wei-Chung

From: O'Leary, Brendan
Sent: Thursday, August 25, 2011 4:11 PM
To: Ochs, Robert; Cheng, Wei-Chung *
Cc: Badano, Aldo G
Subject: RE: K111346 - Calgary - ResolutionMD

Looks good. I am relatively confident that the iPhone does not connect to 4G networks. (iPhone 4G stands for 4th generation.)

From: Ochs, Robert
Sent: Thursday, August 25, 2011 3:35 PM
To: Cheng, Wei-Chung *; O'Leary, Brendan
Cc: Badano, Aldo G
Subject: RE: K111346 - Calgary - ResolutionMD

Hi,

It seems like there are only a few minor comments to resolve. I have put together the follow draft deficiencies. Please let me know if you have any comments or questions by tomorrow afternoon (Friday, the 25th).

1. The response to comments #1 and #2 state that Calgary is not trying to modify the Indications for Use statement. FDA was looking for a simple confirmation that Calgary will not make emergency use claims, and that Calgary will not claim that clinicians using a mobile device will be as accurate or will reach the same diagnosis as they would be when using a workstation.

2. FDA's comment #14 was not fully addressed. The original comment was about "different network types" such as a good Wi-Fi connection versus a poor 3G connection. The response assumes ideal conditions and uses description such as "in only a few seconds". The results of actual testing would provide some insight into the potential variation. For example, the download time required for a 50 slice CT series from a good Wi-Fi connection, good 4G connection, and a poor 3G connection with the "Final Quality" at 100%.

3. The test report on page 11 of the "Response to FDA AI Letter" shows that the measurement distance for the iPhone 4 was 0.3 m. Please clarify why the area of measurement is the same (0.006283165 m^2) even though the iPad and iPhone 4 were at two different distances (0.2 m and 0.3 m) and different pixel diameter/area. Is this a typo, or does is reflect problems with the test methods or results?

I will also pass along the following comments as future considerations.

4. The device recommends that the "Final Quality" is set to 100 for diagnostic reading. In a future release, Calgary should consider alerting users when the final quality is reached during download.

5. The correct formula for the DICOM GSDF should be delta-L/average(L)/JND, not delta-L/average(L)/delta-JND as previously stated. There may be a larger deviation in the lower luminance JNDs that may be important to consider when designing the device for lower-contrast modalities.

Thank you,
Robert

From: Cheng, Wei-Chung *
Sent: Wednesday, August 24, 2011 4:45 PM
To: Ochs, Robert
Cc: O'Leary, Brendan; Badano, Aldo G; Petrick, Nicholas A
Subject: RE: K111346 - Calgary - ResolutionMD

Hi Robert,

Attached is my consult for Calgary ResolutionMD Mobile K111346/S001. Many of the responses are just handwaving and require clarification.

Thanks,
Wei-Chung

From: O'Leary, Brendan
Sent: Monday, August 22, 2011 2:14 PM
To: Ochs, Robert
Cc: Cheng, Wei-Chung *
Subject: RE: K111346 - Calgary - ResolutionMD

Robert,

Sorry I didn't have a chance to put this down in an email last week. I recommend the following questions:

1. Please confirm that you will make no emergency use claims.
2. Please confirm that you will make no claims that clinicians using a mobile device will be as accurate as they would be when using a workstation.

-Brendan

From: Ochs, Robert
Sent: Wednesday, August 03, 2011 8:03 AM
To: O'Leary, Brendan; Cheng, Wei-Chung *
Subject: K111346 - Calgary - ResolutionMD

Hello,

I have attached Calgary's response to our latest request for additional information. I would appreciate you comments on whether the response has adequately addressed your concerns. I have assigned a CTS due date of August 19, 2011.

<< File: K111346 S1.zip >>

Thank you,
Robert

Robert Ochs, PhD
Lead Reviewer / Physicist
Division of Radiological Devices
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66 Room G242
Silver Spring, MD 20993-0002
(301) 796-6661
Robert.Ochs@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

Document: Medical imaging and display review of K111364/S001
Division: CDRH/OIVD/DRAD/RADB
Lead Reviewer: Robert Ochs
Applicant: Calgary Scientific
Description: ResolutionMD Mobile -- A remote PACS viewer for iPhone4 and iPad
Reviewer: Wei-Chung Cheng
COD: CDRH/OSEL/DIAM
Through: Nicholas Petrick, Deputy Director, DIAM
Date: August 24, 2011

Review scope:

This review covers the Sponsor's responses to item 4, 7, 13, 14, and 16.

Technical comments:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item 4 - The "Bright" conditions were in the range of 209-220 lux. In the TG18 report, 220 lux was considered as "hospital clinical viewing station," which is much dimmer than regular office lighting. The setting of the ambient luminance (220 and 1.5 lux) may not represent common viewing conditions for mobile display users. The labeling should contain specific language to indicate the limits on the ambient illumination levels in which this product could be used.

Response:

(b) (4)

Reviewer's comment: I have difficulty in understanding the Sponsor's rationale. If the current device can only be used when the ambient lighting is less than 220 lux, then the indications for use statement should be changed accordingly.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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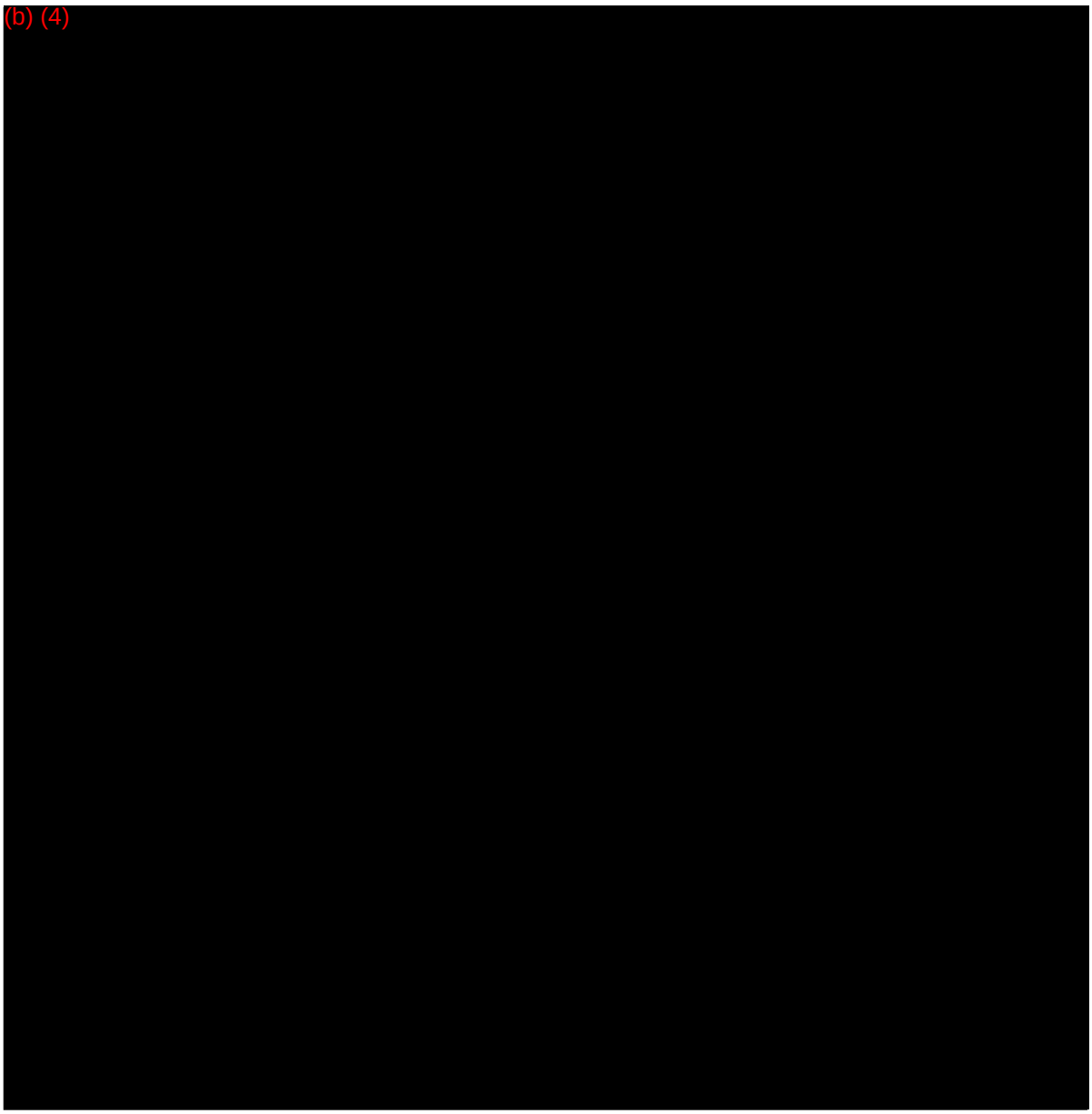
Item 7 - The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss (compression ratio) was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, page 21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

Response:

(b) (4)



Reviewer's comment: Please explain the "JPEG Encoding Quality" parameter, which "usually varies between 1 and 100", and how it controls the downsampling, discrete cosine transform, and quantization stages in the JPEG encoding process.

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Item 13(a) - The DICOM GSDF measurements appear to have been calculated using ΔL/L; the correct formula is ΔL/average(L)/ΔJND, which could impact the conclusions related to the GSDF measurement on page 9 of Appendix 16.9.3.

Response:

(b) (4)

[redacted]

Item 13(b) - The original TG18 test patterns are in 12-bit depth and size of 1k*1k pixels, which do not fit the iPhone4 or iPad screens. In the test reports, the devices were tested with "customized display test patterns," which was not explained. Please explain any difference in the TG18 test patterns, bench test patterns, and those used by the software application.

Response:

Creation of customized test images.

Reviewer's comment: OK.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item 13(c) - In the luminance non-uniformity test and the chromaticity variation test, the size of the measured areas was not reported. Because of the smaller display size of iPhone4/iPad, the measurement method needs to be adjusted accordingly when assessing uniformity or the other spatial properties. Please report the measurement method.

Response:

(b) (4)

Reviewer's comment: The test report is questionable because for the same spectroradiometer it measures the same area (0.006283165 m^2) for different distances (0.20m for iPad and 0.30m for iPhone4). Please clarify the measurement data.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item 13(d) - In the chromaticity variation test, the test pattern was not specified.

Response:

(b) (4)

[redacted]

Reviewer's comment: OK.

Item 13(e) - Figure 6 was mislabeled.

Response: The word "Contrast" was deleted from the figure titles of Figure 6 in Appendices 16.9.3.1 and 16.9.3.2.

Reviewer's comment: OK.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item 14- Compared with a Windows/Intel-x86-based notebook, which was used in the predicate, the iPhone4/iPad, as an embedded system, is slower in terms of computation and communication speed. In the current submission, such latency-related measurement was not reported. FDA believes that a general discussion of the time required to download images over different network types in the labeling would be useful to users.

Response:

(b) (4)

Reviewer's comment: FDA's comment #14 was not properly addressed by the Sponsor. The original comment was about "different network types" such as a good Wi-Fi connection versus a poor 3G connection. The response assumes ideal conditions and uses description such as "in only a few seconds," which is an empty statement. Please perform lab tests and report test results.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item 16 - In Appendix 16.6, page 15, the following quoted paragraph is inconsistent with the intended use -- "ResolutionMD Mobile was designed to function on smartphone devices that have native hardware providing Wi-Fi and cellular network connectivity. Similarly, these smartphone devices utilize industry-best display technology such as LED or AMOLED LCDs and have large displays that occupy most of the devices' surface (most measuring 3.5" or larger)." Note that iPhone4 and iPad are neither LED nor AMOLED.

Response:

(b) (4)

[redacted]

Reviewer's comment: OK.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

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

COVER SHEET MEMORANDUM

From: Reviewer Name ROBERT OCHS

Subject: 510(k) Number K111346

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☑ Hold (Additional Information or Telephone Hold).

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

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NT	NSE for new technology
☐	NI	NSE for new intended use
☐	NP	NSE for lack of performance data
☐	NN	NSE raises new types of safety and effectiveness questions
☐	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 Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
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 ages <=21			

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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.)			
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, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ DRAD 6/30/11
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. Department of Health and Human Services
Food and Drug Administration

Division of Radiological Devices
Center for Devices and
Radiological Health
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

From: Robert Ochs, PhD
To: The Record
Date: June 28, 2011

Subject: K111346
Device: ResolutionMD Mobile (RMB-MOB-2X)
Sponsor: Calgary Scientific Inc.
Contact: Kyle Peterson
kyle.peterson@calgaryscientific.com

I. Summary

Calgary Scientific is submitting a *traditional* 510(k) for a new picture archiving and communications system (ResolutionMD Mobile). The device is intended for the display, visualization, and diagnostic review of medical images using the Apple iPhone or iPad mobile devices.

Submission History:

- March 18, 2011: The sponsor received an NSE letter for their prior submission (K093682). The NSE letter was sent for insufficient response after two requests for additional information. Documentation of numerous interactions with the sponsor to address a number of issues related to the submission is included in the record for K093682.

- There are still some issues with the labeling, software documentation, and testing that should be resolved.

Recommendation: There is inadequate information to determine substantial equivalence; additional information is requested via an additional information letter.

II. Administrative Requirements

	Sufficient	
	Yes	No
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)	✓	
510(k) Cover Letter	✓	
Indications for Use	Rx	
510(k) Statement according to 21 CFR §807.93	✓	
Truthful and Accuracy Statement	✓	
Class III Summary		N/A
Financial Certification or Disclosure Statement		N/A
Standards Form (FDA 3654) • NEMA PS 3.1-3.18: Digital Image Communication in Medicine (DICOM) • ISO/IEC 10918-1 (1994-02) Digital Compression and Coding of Continuous-Tone Still Images (JPEG)	✓	
Clinical Trials Form (FDA 3674)		✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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III. Indications for Use / Intended Use

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

The applicant claims substantial equivalence to the following legally marketed predicate device:

K082693, ResolutionMD 2.1 (Calgary Scientific, Inc.)

The ResolutionMDTM 2.1 is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing hardware for the display and 3D visualization of medical image data. It provides for communication, storage, reformatting, rendering, and display of DICOM 3.0 compliant image data derived from various sources including CT and MRI.

The ResolutionMDTM 2.1 device incorporates a Calcium Scoring module which is used to identify and quantify calcified plaque within the coronary arteries. This protocol is performed on noncontrast enhanced cardiac CT data sets. It also includes the Coronary Artery Analysis protocol which is used to visually identify and measure stenoses in the coronary arteries. This protocol is performed on contrast-enhanced cardiac CTA data sets.

The ResolutionMDM 2.1 software is intended for use as a diagnostic, review, and analysis tool by trained professionals such as physicians, technologists, and nurses. When interpreted by a trained physician, reviewed images may be used as an element for diagnosis. It is the user's responsibility to ensure that the software is installed on appropriate hardware and that image quality is suitable for the clinical application. Calgary Scientific recommends that users of the ResolutionMD TM 2.1 software consult the appropriate American College of Radiology Practice Guidelines pertaining to the anatomy and pathology being studied.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Review Comments: Both the subject device and the predicate device are intended for the communication, storage, and display of medical image data. The subject device is intended for a subset of the functionality of the original device, and will not include the optional cardiac analysis module or calcium scoring module available for the predicate. In addition, the subject device is only intended for the review of MR and CT images.

The subject device is not intended for specific diseases or for emergency situations. During the prior 510(k) review, the sponsor was repeatedly informed that they have not submitted sufficient evidence to support labeling claims related to the use of the mobile device in emergency situations or for specific indications for use.

The Indications for Use of the device are similar to the 510(k) cleared MIM Software mobile application (K103785).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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IV. Device Description

Component	Material(s)	Attributes	Acceptable Yes	Acceptable No
Software (iOS App)	Software	No Patient Contact No Biocompatibility/Sterilization Issues No Image Contrast Requirements Not Life-Supporting or Life Sustaining	✓	
Mobile Device	iPhone, iPad	Common materials; no Biocompatibility/Sterilization Concerns	✓	

The ResolutionMD™ Mobile software is a software-based PACS for use with general purpose computing servers and mobile devices for the display and visualization of medical image data. The primary functionalities of the ResolutionMD™ Mobile include DICOM communication, display of 2D images in original planes including window/level controls, computation and display of rendered 3D images and zoom, pan and rotate.

The device will include functionality to allow the user to review test images to help evaluate the ambient lighting conditions.

Review Comments: There is some concern about the review of medical images on mobile devices. Specifically, the smaller screen size and potential use of the device under varying lighting conditions. However, it was decided that design features and bench testing could be used to mitigate and evaluate these potential risks.

V. Predicate Device Comparison

Category	Predicate (ResolutionMD, K082693)	New Device (ResolutionMD Mobile, K093682)
Intended Use		
Diagnostic image review and analysis	Yes	Yes
Anatomy/Disease	General	General
Intended User	Trained Professionals	Same
Environment/Setting	Hospital	No access to a workstation.
Functions		
Server Platform	Windows OS, Microsoft .NET SDK, Linux OS	Same
Client Platform	Windows OS, Mac OS, Linux OS – any browser supporting Flash	iPhone/iPad OS, other mobile device OS
Data Integrity / Data Security	DICOM images remain on the server. Only JPEG renderings generated by the server software are sent to client browser for viewing. No source image data is ever stored on the client and all JPEG renderings transmitted are deleted when the client application is closed.	
DICOM 3.0	Yes	Yes
Modalities	Not-specified	CT, MR
2D Image Review	Window/level, zoom, pan, scroll	Same
3D Image Review	3D volume rendering, zoom, pan, rotate, window/level, MIP, MPR	Same
Segmentation	Yes	No
Cardiac - Specific Functionality	Yes	No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Both the predicate device and the new device use a client-server architecture; the server software is the same for both devices and performs all of the image processing. The browser client or the mobile device client is used only for user interaction (i.e., sending commands to the server and receiving the resulting images from the server).

Review Comments: Compared to the predicate, the primary difference is that the subject device is intended for reviewing images on mobile devices, such as the iPhone. The device is still intended for the communication, display, and interpretation of medical images, which is the same intended use as numerous other PACS systems.

The subject device is designed for use with touch-screen mobile devices that have a display size and resolution much smaller than diagnostic review workstations. This is a new technological characteristic that could affect safety or effectiveness. For instance, 1) the small screen size does not allow for the side-by-side review of images from prior exams, reconstructions, anatomical planes, etc... 2) the screen resolution is much smaller than most full-field images, and 3) the reading environment, connection, and lighting conditions may be highly variable. The lower image quality, functionality, and ability to visualize images could affect the ability of radiologists to view images compared with current clinical practice.

However, the types of questions posed by this device are not different than the types of questions posed for previous PACS systems and display monitors (e.g., does the design of the device allow safe and effective interpretation of medical images?).

Existing scientific methods are appropriate for evaluating the safety and effectiveness of the device. The image display and environmental conditions can be evaluated using standard equipment and bench testing of the mobile display.

FDA regulates medical image display devices as Class II under 21 CFR §892.2050. Since the sponsor is specifically labeling the device for use with the iPhone and iPad mobile devices, which have not been cleared, the mobile display is being considered a component of the mobile application.

FDA informed the sponsor that bench testing of the mobile device display would also be necessary for the 510(k) review. FDA typically does not request bench testing for other PACS software, since there are numerous FDA cleared monitors as well as American College of Radiology (ACR) guidelines for the selection and testing of radiological display equipment. However, bench testing of the mobile devices is currently considered necessary since FDA is unaware of the potential impact of the interaction between the display software and hardware on the resulting image quality.

Although not cited as a predicate, the intended use and technological characteristics are similar to the cleared Mobile MIM software (K103785). There are some differences in the client-server architecture and the functionality to allow users to evaluate the ambient lighting conditions.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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VI. Labeling

The submission included the ResolutionMD Mobile Users Guide (Appendix 13) and the Installation Service Guide (Appendix 13.1).

	Sufficient	
	Yes	No
Manufacturer's Contact Information	✓	
Prescription use statement		✓
Intended Use / Indications for Use	✓	
Relevant cautions, warnings, and/or contraindications	✓	
Symbols *(with description)*	✓	
Device Description	✓	
Hardware Requirements (for software)	✓	
Accessories		N/A
Directions for Use	✓	
Performance Specifications (summary of physical laboratory testing)		N/A
Cleaning instructions	✓	
Description of quality assurance tests (and action limits)	✓	
Conformity to voluntary standards	✓	
Marketing brochures/flyers/claims		N/A

Review Comments: During the review of the sponsor's prior 510(k) submission, there were numerous concerns that the labeling was promoting the use of the device for emergency situations and specific disease conditions without any valid scientific evidence to support such claims. The sponsor was asked to provide more information to help the users evaluate the ambient lighting. The new 510(k) submission resolved most of the prior issues, but a few minor modifications are considered necessary.

VII. Software

	Sufficient	
	Yes	No
Level of Concern: Moderate. A malfunction or a latent design flaw in the software device could lead to erroneous diagnosis or a delay in delivery of appropriate medical care that may lead to a minor injury. This level of concern is consistent with other radiological software products.	✓	
Software Description: The device description and labeling provided sufficient details of the device features, operating environment, and intended use.	✓	
Device Hazard Analysis: Section 16.3 of the submission presented the risk analysis associated with the device features and use (e.g., screen size, ambient lighting, communication, image quality, etc...). The sponsor analyzed the potential cause of the hazard and the impact of the mitigation on the severity of the risk.	✓	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Sufficient	
	Yes	No
Software Requirements Specifications: Appendix 16.4 of the submission contained the system requirements specifications, the hardware requirements, and the usability specifications. The documents enumerated the functionality, interface, hardware, communication, and other requirements related to the operation of the device.	✓	
Architecture Design Chart: Section 16 of the submission provided sufficient detail of the software architecture and client/server features.	✓	
Design Specifications: Appendix 16.6 of the submission provided details of the design specifications. The document enumerated the functionality, interface, security, usability, and other requirements related to the operation of the device.	✓	
Traceability Analysis/Matrix: Appendix 16.7 of the submission provided traceability among the requirements specifications, design specifications, risk analysis, verification, and validation testing.	✓	
Development Environment: Appendix 16.8.1, 16.8.2 and 16.8.3 of the submission contained a sufficient description of the development environment. The sponsor also stated that they utilize ISO 13485 and FDA QSR-compliant processes (incorporating other related standards) for software verification and validation (Section 16, page 32).	✓	
Verification & Validation Testing: Appendix 16.9.1 of the submission included a summary of the system level testing for the iPhone and iPad. Appendix 16.9.2 of the submission included an expert "validation" report for the iPhone and iPad; the purpose of the testing was to verify the device functionality. (Deficiency) Most of the tests under the "Ambient Lighting User Assessment" have not been completed. The sponsor should clarify whether the functionality to evaluate ambient lighting has been implemented. The expert "validation" report also did not test the ambient lighting features.		✓
Revision Level History: Appendix 16.10 of the submission summarized the device modifications that have occurred starting with the core software functionality of the ResolutionMD predicate.	✓	
Unresolved Anomalies: Appendix 16.11 of the submission summarized the unresolved anomalies. (Deficiency) Some of the software anomalies require clarification to understand their potential impact on the safety and effectiveness of the device.		✓
Off the Shelf Software: Not provided.		✓

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Cyber security: The software documentation (Section 16, pg. 28-32; Section 16.4) contained information and requirements related to cyber security.	✓	
DICOM Conformance Statement: Appendix 16.6.1 contained the DICOM Conformance Statement for version 2.5 of the software. Numerous sections of the submission (FDA Form 3514, pg. 5; Section 12) states that the device complies with DICOM 3.0.	✓	

VIII. Performance Testing – Display

Review Comments: (Deficiency) Please see the review comments from Dr. Wei-Chung Cheng for the bench testing; additional information on some of the tests and results is requested.

IX. Qualitative Evaluation – Image Quality

The sponsor submitted the results of a small reader study with two radiologists, who were asked to review images on the iPhone, iPad, and diagnostic workstation under varying lighting conditions. The clinicians were asked to provide a primary diagnosis, subtle findings, and evaluate characteristics of the image.

The study design is comparable to the study used to support the cleared Mobile MIM software (K103785).

Review Comments: Overall, the results support that the device can be used to review images under varying lighting conditions. However, the clinicians did note lower connection speed as well as the lack of multiple monitors/views. The clinicians also stated preference for reviewing the images in low lighting.

(Deficiency) There are concerns with the conclusions that the sponsor is trying to draw from their study. For instance, the sponsor states: "We further conclude that subtle findings can be appreciated on the mobile device in normal office lighting in most cases. We also conclude that difficult cases are not necessarily more difficult to diagnose on the mobile device than on the PACS." (Appendix 16.9.4, pg. 3)

During the prior 510(k) review, the sponsor was told repeatedly, that the purpose of the study was not to compare the resulting primary or secondary diagnosis. The sponsor was told that the purpose of the study was make conclusions on the image quality, not the final diagnosis.

X. TPLC Review Analysis

Search Items	Results
Network Signals and Issues	None
MDRs	None
Recalls	None
Inspections	None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XI. Substantial Equivalence Discussion

	Yes	No	
1. Same Indications for Use statement?		✓	If **YES** = Go To 3
2. Do differences alter the effect or raise new issues of safety or effectiveness?		✓	If **YES** = Stop **NSE**
3. Same technological characteristics?		✓	If **YES** = Go To 5
4. Could the new characteristics affect safety or effectiveness?	✓		If **YES** = Go To 6
5. Descriptive characteristics precise enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New types of safety or effectiveness questions?		✓	If **YES** = Stop **NSE**
7. Accepted scientific methods exist?	✓		If **NO** = Stop **NSE**
8. Performance data available?	✓		If **NO** = Request Data
9. Data demonstrate equivalence?			Final Decision: **SE**

1. Explain how the new indication differs from the predicate device's indication:
   The subject device is intended for reviewing images on mobile devices, such as the iPhone; the predicate device is intended as a web based viewer.

2. Explain why there is or is not a new effect or safety or effectiveness issue:
   The new indication for use statement reflects the different technological characteristics of the mobile devices. The device is still intended for the communication, display, and interpretation of medical images, which is the same intended use as numerous other PACS systems.

   The indications for use are also similar to the cleared Mobile MIM software (K103785).

3. Describe the new technological characteristics:
   The subject device is designed for use with touch-screen mobile devices that have a display size and resolution smaller than diagnostic review workstations.

4. Explain how the new characteristics could or could not affect safety or effectiveness:
   Reviewing diagnostic images with mobile device could potentially impact the safety and effectiveness since: 1) the small screen size does not allow for the side-by-side review of images from prior exams and/or different anatomical planes, etc... 2) the screen resolution is much smaller than most full-field images, and 3) the reading environment, connection, and lighting conditions may be highly variable.

5. Explain how descriptive characteristics are not precise enough: N/A

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
   The types of questions posed by this device are not different than the types of questions posed for previous PACS systems and display monitors (e.g., does the PACS system offer sufficient image quality for reviewing medical images?).

7. Explain why existing scientific methods can not be used:
   N/A: The image display and environmental conditions can be evaluated using standard equipment and test procedures. Reader studies can be designed to evaluate if the device provides sufficient diagnostic image quality.

8. Explain what performance data is needed:

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The sponsor needs to provide software test and bench data for all mobile devices that are intended to be used with their software.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
Some aspects of the bench and software testing require clarification.

XII. Requests for Additional Information

1. Parts of the submission include specific statements related to the use of the device in emergency situations and for specific conditions (e.g., Section 12, page 16; Section 16.2.5, pages 32-33). As has been noted previously on multiple occasions, FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims related to the use of the device for emergency situations or specific disease conditions, such as stroke. FDA believes that a general indications for use statement is most appropriate for this device based on the information provided. Please confirm that you will not market your device for these or other specific indications.

2. There are concerns with the conclusions that are being drawn from the study in Appendix 16.9.4. As noted on numerous occasions, the purpose of the study was not to compare the resulting primary or secondary diagnosis. FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims that radiologists will be as accurate on the mobile device as on a workstation, or will reach the same diagnosis as on a workstation. The performance study was intended to support that the device offers sufficient image quality for a diagnosis (or image review) on CT and MR under specific lighting conditions when there is no access to a workstation. Much more rigorous studies would be necessary to evaluate the diagnostic effectiveness of using a mobile device compared with a workstation.

3. The results from Appendix 16.9.4 suggest that radiologists may have some difficulty using the device under some conditions. Note the comments from Dr. Koles, "Both [iPhone and iPad] were far better in the dark... I'd certainly be reading in the dark". In addition, Dr. Pattison stated, "Subtle findings were better appreciated in the dark on the mobile devices and were best appreciated on the PACS workstation." Please revise the label to reflect the preference for clinicians to review the images in a dark environment.

4. The "Bright" conditions were in the range of 209-220 lux. In the TG18 report, 220 lux was considered as "hospital clinical viewing station," which is much dimmer than regular office lighting. The setting of the ambient luminance (220 and 1.5 lux) may not represent common viewing conditions for mobile display users. The labeling should contain specific language to indicate the limits on the ambient illumination levels in which this product could be used.

5. Page 3 and 12 of the Mobile Device PACS Study (Appendix 16.9.4) indicates that all 12 reviewed cases were neuro cases. Page 5 seems to contradict this. Please clarify this discrepancy.

6. The software documentation suggests that the device is intended to have persistent on-screen indication of the degree of source image compression. It is not clear if this feature has been implemented for the 2D or 3D images. In Appendix 16.11, Item 925 of the list of Unresolved Anomalies indicates that compression information is missing. The User Guide did not contain a description of this indicator. Please clarify if this feature has been implemented for the 2D/3D images and provide the software testing and labeling information.

7. The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, page 21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. The iPad image on page 12 of the user guide lists images from modalities that are not covered by the Indications for Use. Please revise the User Guide to only show modalities that appear in the Indications for Use statement.

9. As required by 21 CFR 801.109(b)(1), please revise your User's Manual to include the Federal prescription statement "Caution: Federal law restricts this device to sale by or on the order of a physician" and provide the revised pages for FDA review.

10. Most of the tests under the "Ambient Lighting User Assessment" in Appendix 16.9.1 were listed as "nd" (not done). Appendix 16.9.2 did not appear to contain any tests related to the ambient lighting user assessment. Please clarify whether the functionality to evaluate the ambient lighting has been implemented. Please provide the software test results that show this feature has been successfully implemented.

11. FDA has comments on the following Unresolved Anomalies (Appendix 16.11).

(a) Item 892 indicates that image corners are rounded on the iPad app unintentionally. Please provide more details on the cause for this anomalies and the potential impact on the safety and effectiveness of the device.

(b) Item 928 indicates that FDA concerns about the User Guide have not been addressed.

(c) Item 919, "As an end-user, I want to be informed when a data type that is displayed is not officially supported so that I can take that into consideration when rendering a medical decision". FDA would like to see this feature incorporated before release.

(e) Item 929, "As an OEM provider, I want to have an extensively tested FDA-approved product..." As previously noted, FDA does not "approve" devices under the 510(k) program; they are only cleared. Please review 21 CFR 807.97 (Misbranding by reference to premarket notification). Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

12. Please provide documentation for off-the-shelf software used in your device following the "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices". http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.htm

13. FDA has comments on the following aspects of the Display Quality Test Reports (Appendix 16.9.3.1, 16.9.3.2, and 16.9.3.3)

(a) The DICOM GSDF measurements appear to have been calculated using $\Delta L/L$; the correct formula is $\Delta L/\text{average}(L)/\Delta JND$, which could impact the conclusions related to the GSDF on page 9 of Appendix 16.9.3.

(b) The original TG18 test patterns are in 12-bit depth and size of 1k*1k pixels, which do not fit the iPhone4 or iPad screens. In the test reports, the devices were tested with "customized display test patterns," which was not explained. Please explain any difference in the TG18 test patterns, bench test patterns, and those used by the software application.

(c) In the luminance non-uniformity test and the chromaticity variation test, the size of the measured areas was not reported. Because of the smaller display size of iPhone4/iPad, the measurement method needs to be adjusted accordingly when assessing uniformity or the other spatial properties. Please report the measurement method.

(d) In the chromaticity variation test, the test pattern was not specified.

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(e) Figure 6 was mislabeled.

14. Compared with a Windows/Intel-x86-based notebook, which was used in the predicate, the iPhone4/iPad, as an embedded system, is slower in terms of computation and communication speed. In the current submission, such latency-related measurement was not reported. FDA believes that a general discussion of the time required to download images over different network types in the labeling would be useful to users.

15. The Substantial Equivalence Comparison Table (Section 12; page 23) states the client operating system can be the iPhone/IPad OS, other mobile device OS. Items 912 and 913 of the Unresolved Anomalies (Appendix 16.11) reference the Android OS. The submission did not contain any software or bench testing to support the use of the application on other mobile device OS. FDA believes that a new 510(k) submission would be necessary to support the migration of the device to a new operating system, such as the Android OS.

16. In Appendix 16.6, page 15, the following quoted paragraph is inconsistent with the intended use -- "ResolutionMD Mobile was designed to function on smartphone devices that have native hardware providing Wi-Fi and cellular network connectivity. Similarly, these smartphone devices utilize industry-best display technology such as LED or AMOLED LCDs and have large displays that occupy most of the devices' surface (most measuring 3.5" or larger)." Note that iPhone4 and iPad are neither LED nor AMOLED.

17. Please complete the Clinical Trials Form (FDA 3674).
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf

XIII. Recommendation

There is inadequate information to determine substantial equivalence; additional information is requested via an additional information letter.

Robert A Ochs
Robert Ochs, PhD

June 28, 2011
Date

Michael O'Hara
Deputy Division Director

June 30, 2011
Date

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Ochs, Robert

From: Kyle Peterson [kyle.peterson@calgaryscientific.com]
Sent: Monday, April 18, 2011 10:02 AM
To: Ochs, Robert
Subject: RE: Questions from your letter re: K093682 - ResolutionMD Mobile, request for pre-IDE meeting

Robert,

Thanks very much for your quick answer. Your explanations are understood. I will take this back tour team as we work to complete our testing. We will definitely be testing with multiple Apple and Android devices.

Best regards,

Kyle

From: Ochs, Robert [mailto:Robert.Ochs@fda.hhs.gov]
Sent: Monday, April 18, 2011 6:46 AM
To: 'Kyle Peterson'
Subject: RE: Questions from your letter re: K093682 - ResolutionMD Mobile, request for pre-IDE meeting

Hi Kyle,

The use of test images may be acceptable. The 510(k) should include a description of the test routine, and when the testing occurs once or every time the application is initialized. User's should be alerted to the potential impact of changing ambient lighting. User's should also be able to review the test images at will if there is a change in lighting. If the application determines that there has been a change in the backlight, or a change in the background processes that impact the display, the application could display a "for reference only" until the user has confirmed the reading conditions are acceptable.

For the pre-market review, we would prefer to see testing from a couple of Apple and Android devices to understand the potential variation in image quality with your application.

We can not give definitive recommendations on when a new 510(k) will be required, since this decision is suppose to be made by the sponsor and will likely depend on a number of factors. I will only refer you to guidance on when to submit a new 510(k). I would image that having knowledge of the performance from a few devices that have been cleared with your application will help you make this decision.

Thank you,
Robert

From: Kyle Peterson [mailto:kyle.peterson@calgaryscientific.com]
Sent: Thursday, April 14, 2011 11:44 AM
To: Ochs, Robert
Subject: RE: Questions from your letter re: K093682 - ResolutionMD Mobile, request for pre-IDE meeting

Robert,

Thanks very much for the quick reply. Since the official response from the FDA to our previous 510(k) was signed by Mary, I sent the questions to her first. I thought it was likely that you would continue to work on our

file but I didn't want to be presumptive.

Thanks for your explanation on the TG18 display testing. In regard to the Android devices, I agree that there's variation in models of devices and versions of OS among the various phones and tablets. I agree that testing is necessary and we would conduct the technical TG18 testing and a review by radiologists following the methodology we established for the benchmark testing conducted for the iPhone whether or not a new 510(k) was submitted.

I have read the guidance document you mentioned many times as we use it as the basis of deciding on filing or not whenever we have a new release of our software. In reference to Android devices, once we establish a test regimen (including TG18 and expert comparison by radiologists) and clear our software under a 510(k) on some Android devices, my interpretation of the guidance doc is that we should be able to qualify new Android devices using this testing regimen without submitting new 510(k)s for each new device. I see no specific trigger in the guidance doc that would require a new 510(k).

Does this logic match your interpretation of the guidance? The records of all testing would be maintained in our QMS as per the QSR and ISO 13485 requirements.

My other question relates to an ambient light test for users of the software. You indicated that we could implement TG18 test images as solution to this requirement or we could put a specific routine into the product as was done by MIM Software. My question is if we choose to implement TG18 test images, document the use of these in the User Guide in a "Before You Start" section and mention the issue also in the Precautions, will the FDA accept this as being adequate?

These are the two most urgent questions we have at the moment. We have triaged the 19 points in the list of issues from our previous 510(k). There are some other questions arising from this but I going to gather everyone's feedback before submitting them. We may not need an in-person meeting to resolve these. The request was opportunistic as I was trying to combine this with the West Wireless Institute Health Care Innovation Day which is a full day conference with FDA officials in DC on April 28.

Robert, thanks again for your patience and diligence in working with us. I look forward to your reply.

Best regards,

Kyle

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

From: Ochs, Robert [mailto:Robert.Ochs@fda.hhs.gov]
Sent: Wednesday, April 13, 2011 3:12 PM
To: 'Kyle Peterson'
Subject: RE: Questions from your letter re: K093682 - ResolutionMD Mobile, request for pre-IDE meeting

Hello Kyle,

Mary forwarded your questions to me.

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The visual tests recommended by TG18 with the luminance response measurements would be appropriate. This is also consistent with the IEC 62563-1 standard on Image Displays which may be a better description of the techniques and methods. (IEC 62563-1. Medical electrical equipment - Medical image display systems – Part 1: Evaluation methods)

Testing using a single sample of a model/version may be appropriate, unless there is reason to believe that performance varies significantly in a model/version.

The purpose of the bench testing is to help characterize the software-display system. You could use this in conjunction with the radiologists' review of the image quality to help identify the display requirements for your application.

There will likely be large differences in the display components of Android phones and tablets, so it will be difficult to know what is a representative device. Thus, testing on each model/version that is being indicated for use with the application will likely be necessary. If there are no changes to the display and OS from model to model, then the testing may not be necessary.

For additional guidance on when to submit a new 510(k), please review "Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)"
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm

Currently, there are no 1-hour slots available on either March 27th or 29th where everyone on the review team is available. If you would like a face-to-face meeting, I would recommend mailing a request to the FDA document and mail center. This will help FDA better track the request and allocate resources. It usually takes at least 30-days to schedule a pre-IDE meeting due to the available of members of the review team. The request should include any necessary background material and specific questions for the FDA. Without specific questions, you will likely receive only limited feedback since members of a review team usually will not venture to answer questions that have not previously been discussed amongst the review team.

Thank you,
Robert

Robert Ochs, PhD
Lead Reviewer / Physicist
Division of Radiological Devices
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66 Room G242
Silver Spring, MD 20993-0002
(301) 796-6661
Robert.Ochs@fda.hhs.gov
This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion; does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed. This message is intended for the exclusive use of the recipient named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at Robert.Ochs@fda.hhs.gov

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From: Kyle Peterson [mailto:kyle.peterson@calgaryscientific.com]
Sent: Monday, April 11, 2011 10:47 AM
To: Pastel, Mary
Subject: Questions from your letter re: K093682 - ResolutionMD Mobile, request for pre-IDE meeting

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Importance: High

Dear Dr. Pastel:

We received the formal copy of your letter of March 18, 2011 just last week. As we are actively working on a new 510(k) submission to address the issues previously communicated by email, I wanted to contact you with the most urgent of our questions regarding the issues raised in your letter. If it is at all possible to answer these questions this week, we would be most appreciative.

Also, we would like to request a pre-IDE meeting to discuss the issues more broadly. If your schedule can accommodate either April 27 (anytime) or 29 (prefer morning), this would allow me to attend the Health Care Innovation Day sponsored by the West Wireless Institute in Washington on April 28. Several speakers from the FDA including Jeff Shuren, William Maisel and Bakul Patel will be speaking that day. Please let me know if this is possible and I will forward a list of topics we would like to discuss.

As to our immediate questions, we are embarking on technical display testing and further clinical benchmark studies within the next week. It is important that we have your guidance on the amount of testing required as these are expensive and time-consuming exercises. Our questions are:

1. Bench testing according to AAPM TG18 -- This issue deals mainly with point 19 in your letter. The letter mention testing for visual noise and reflectance, both diffuse and specular. In our conference call on March 9, one of your colleagues mentioned that he wanted to see testing for the luminance response curve. So, our question what is the set of APPM TG18 display tests that the FDA is requesting we provide? Further, can these test be conducted on one sample of each model of device or is there a need to test more than one sample e.g. do we need to test 3 iPhone 4 devices, 3 iPads, etc.? Also, given that these devices are not medical monitors, what is the criteria for acceptability of these test results?
2. Other Mobile platforms – This relates to point 17 in your letter where you mention that the FDA wants to see complete testing information for each mobile platform. Further you mention that migration of the device to other mobile platforms and operating systems may require a separate 510(k). We are planning to make our software device available on the Android platform. As you know, there are many such devices already in the market. The steady stream of new Android devices this year will turn into a torrent over the next few years. This is an issue I would like to discuss with you at greater length but for now we have this question. Will the FDA accept our testing for a representative Android phone device and a representative Android tablet device (both AAPM TG18 and clinician comparison to PACS) in the 510(k) and allow us to qualify other Android devices using our internal V&V procedures and comparison to the approved devices?

My last item for this note was in response to point 8 in your letter which I interpreted as not an issue with our 510(k) submission but rather a direct question to us. The wording of the labeling was based on the previously-mentioned misunderstanding between diagnosis on a mobile devices and review of images for other purposes. Had we understood your definition of a Class II use of the images, we would have reworded this section to read "only non-significant risk studies". Calgary Scientific is not marketing ResolutionMD Mobile in the United States. It is not available for sale and no orders have been taken. We have supplied our server and the mobile client at no cost to sites such as (b) (4) [redacted] to run comparative effectiveness studies. These sites conducted their studies by reading in parallel on a PACS workstation and mobile device. As non-significant risk studies, they did not require an Investigational Device Exemption.

Dr. Pastel, thank you very much for your time and diligent follow-up on our submission. We want to make the next one go as smoothly as possible. If you could get back to us this week on our questions and suggested date

for a meeting at the agency later in the month, this will help us greatly to complete our new submission.

Best regards,

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Tel: (403) 767-7945
Fax: (403) 270-2771
Email: kyle.peterson@calgaryscientific.com
Web: www.calgaryscientific.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Ochs, Robert

From: Ochs, Robert
Sent: Thursday, June 23, 2011 1:18 PM
To: Cheng, Wei-Chung *; O'Leary, Brendan
Cc: Badano, Aldo G
Subject: RE: K111346 - Calgary - ResolutionMD Mobile

Thanks for the comments.

I'll take a closer look at the GSDF comments and modify the deficiency.

I think a general discussion of the time required to download images over different network types in the labeling would be useful to users.

I agree that the device should indicate if an image is compressed. However, I believe that mammography is the only modality where FDA says lossy images cannot be used for diagnosis. I am not aware of another instance where we have required a statement that uncompressed images cannot be used for diagnosis; if we require this statement, then it seems like we would have to define "diagnosis".

Thanks,
- Robert

From: Cheng, Wei-Chung *
Sent: Thursday, June 23, 2011 1:00 PM
To: O'Leary, Brendan; Ochs, Robert
Cc: Badano, Aldo G
Subject: RE: K111346 - Calgary - ResolutionMD Mobile

Of course the plot is for your reference only.

The latency is just one of the issues that I enumerated. It's your call to decide whether it is relevant.

Wei-Chung

From: O'Leary, Brendan
Sent: Thursday, June 23, 2011 12:54 PM
To: Cheng, Wei-Chung *; Ochs, Robert
Cc: Badano, Aldo G
Subject: RE: K111346 - Calgary - ResolutionMD Mobile

We cannot send MIM's data (GSDF plot) in a deficiency letter to Calgary.

I don't know that I would be too concerned about deficiency 14 personally. As long as the compression ratio is displayed and the labeling appropriately indicates that diagnoses should only be made from uncompressed images (actually, does the labeling say this?), then what the physician decides to do based on network speed, advisable or not, may be outside of our purview. Still, a general discussion of the time required to download images over different network types in the labeling may be useful to users.

-Brendan

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Cheng, Wei-Chung *
Sent: Thursday, June 23, 2011 12:42 PM
To: Ochs, Robert
Cc: Badano, Aldo G; O'Leary, Brendan
Subject: RE: K111346 - Calgary - ResolutionMD Mobile

Hi Robert,

Please find my answers in the comments.
I am also attaching a GSDF comparison plot.

Wei-Chung

From: O'Leary, Brendan
Sent: Wednesday, June 22, 2011 2:33 PM
To: Ochs, Robert; Cheng, Wei-Chung *
Cc: Badano, Aldo G
Subject: RE: K111346 - Calgary - ResolutionMD Mobile

Just 2 sentences you can consider adding to the first deficiency and one typo in the third:
Looks good to me.

Thanks,
Brendan

From: Ochs, Robert
Sent: Wednesday, June 22, 2011 2:11 PM
To: Cheng, Wei-Chung *; O'Leary, Brendan
Cc: Badano, Aldo G
Subject: K111346 - Calgary - ResolutionMD Mobile

Hi,

I have attached my review of this 510(k). I would appreciate any comments you may have on the list of comments to the sponsor. Please let me know if you have any comments or suggestions by Friday, June 24, 2011.

<< File: K111346 - Review.doc >>

Thank you,
Robert

Robert Ochs, PhD
Lead Reviewer / Physicist
Division of Radiological Devices
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mail the sender immediately at Robert.Ochs@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of In Vitro Diagnostics
10903 New Hampshire Avenue
Silver Spring, MD 20993

Consulting Review

K111346

Date: Thursday, June 09, 2011
To: Robert Ochs, PhD
From: Brendan O'Leary

Sponsor: Calgary Scientific
Device: ResolutionMD Mobile Model RMB-MOB-2x

I. Device Description

This is a web viewer for mobile devices. It currently supports the Apple iPhone 4 and Apple iPad. It is for CT and MR images. The sponsor indicates that an ambient light test using TG-18 test patterns is included in the software.

II. Intended Use

The indications for use statement is acceptable.

III. Concerns and Deficiencies (for consideration of lead reviewer)

1. In the executive summary the sponsor notes, "The release version of the software will be required to pass all tests considered critical in terms of patient safety and to demonstrate an overall acceptable performance for release as determined by the predefined release criteria." This implies that the device is not complete and has not completed testing. FDA does not review incomplete devices.

2. The executive summary references emergency use. This specific indication should be avoided.

3. Minimum specifications/test pass fail criteria for qualifying additional devices.

4. Calgary indicates that the server is "agnostic" to the client device and responds to the same commands whether they originate from a PC browser or an iPhone/mobile device client. This would seem to conflict with their statements that it is only for use with "specific mobile devices".

5. The discussion of intended audience on page 4 of the user guide should be removed. I believe this was discussed in a conference call.

6. The only currently listed supported devices are iOS devices. A change in the OS could affect safety/effectiveness and should result in a 510(k).

7. The iPad image on page 12 of the user guide lists images from modalities that are not covered by the IFU (cervical spine x-ray, panoramic dental, etc).

8. It is not clear whether or not there is a persistent on-screen indication when lossy images are displayed.

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9. Bugs:

   (a) Bug 892 indicates that image corners are rounded on the iPad app unintentionally. This raises concerns that image data are not being transmitted properly.

   (b) Bug 928 indicates that the sponsor has not addressed our concerns about the user guide.

   (c) Bug 919, "As an end-user, I want to be informed when a data type that is displayed is not officially supported so that I can take that into consideration when rendering a medical decision" is an excellent idea and should be incorporated before release.

   (d) Bug 925 indicates that compression ratio info is missing for 3D images.

   (e) Bugs 912 and 913 references Android.

10. Page 3 of the mobile device PACS study seems to indicate that all 12 reviewed cases were neuro cases. Page 5 seems to contradict this. Page 12 again indicates that 12 neuro cases were reviewed.

11. The study found that subtle findings were found or better observed in darker lighting conditions but concluded that "subtle findings can be appreciated on the mobile device in normal office lighting in most cases". It is not clear that there is sufficient data to support this conclusion. Note the comments from Dr. Koles, "Both [iPhone and iPad] were far better in the dark... I'd certainly be reading in the dark". In addition, Dr. Pattison says, "Subtle findings were better appreciated in the dark on the mobile devices and were best appreciated on the PACS workstation."

12. The "Bright" conditions were not particularly bright: only 209-220 lux.

IV. Recommendation

I recommend AI for this device.

Brendan O'Leary

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8015

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Document: Medical imaging and display review of K111364
Division: CDRH/OIVD/DRAD/RADB
Lead Reviewer: Robert Ochs
Applicant: Calgary Scientific
Description: ResolutionMD Mobile -- A remote PACS viewer for iPhone4 and iPad
Reviewer: Wei-Chung Cheng
COD: CDRH/OSEL/DIAM
Through: Nicholas Petrick, Deputy Director, DIAM
Date: June 09, 2011

Review scope:

This review looks into the display aspect of an iOS application for viewing grayscale CT and MR medical images on an iPhone4 or iPad device.

Overall comments:

Compared with its predicate, although the current submission also uses a client-server design, the client side is fundamentally different in terms of hardware and software. In hardware, the iPhone4 and iPad have less computation and communication power than the Windows/Intel-x86-based notebook used by its predicate. Such performance difference introduces extra transmission latency, which may affect the diagnostic accuracy. In software, the iOS exposes very limited low-level control to the developers, which increases the difficulty in controlling the display hardware.

Compared with the predicate ResolutionMD (K082693), the current submission differs in the following ways:

(1) Processing speed: The iPhone4 and iPad are slower than most Windows/Intel x86-based notebooks in terms of computation and communication speed. The extended data transmission latency may encourage the user to reduce image quality by using compressed JPEG, which may compromise diagnostic accuracy. Therefore, the latency of data transmission for Wi-Fi and 3G needs to be tested in stressed conditions and reported.

(2) Display size: The display size of iPhone4/iPad is much smaller, so the TG18 test patterns need to be tailored to obtain meaningful bench test results. In the bench test report of the current submission, there are a number of questions that need to be clarified. Please see technical comments below.

(3) PACS study for mobile display: The design and results of the reader's study are insufficient. Please see technical comments below.

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For consistency in regulatory decisions, this review also compares the current submission with the first FDA-cleared mobile display device Mobile MIM (K103785). The current submission differs in the following ways:

(1) Bit-depth: The Mobile MIM uses the "bit-stealing" technique to increase the number of graylevels to 1,021, which makes luminance calibration possible. The current submission uses the native 8-bit depth of iPhone4 and iPad.

(2) Calibration: The Mobile MIM uses 1,021 graylevels to calibrate the display for 8-bit images. No calibration was performed or reported in the current submission.

(3) Change of viewing conditions: The Mobile MIM enforces the user to go through a visual check every 20 minutes in order to assure a proper viewing environment. The current submission offers the function of "ambient light user assessment" by showing a test pattern. However, the application and user guide do not instruct the user how to evaluate the test result and how to improve the viewing conditions.

Technical comments:

1. Display quality test reports (Appendix 16.9.3.1, 16.9.3.2, and 16.9.3.3)

   a. The DICOM GSDF measurement is missing.

   b. Test patterns: The original TG18 test patterns are in 12-bit depth and size of 1k*1k pixels, which do not fit the iPhone4 or iPad screens. In the test reports, the devices were tested with "*customized display test patterns*," which was not explained. The Sponsor needs to show that both the software application and the bench test use the same display mechanism.

   c. In the *luminance non-uniformity test* and the *chromaticity variation test*, the size of the measured areas was not reported. Because of the smaller display size of iPhone4/iPad, the measurement method needs to be adjusted accordingly when assessing uniformity or the other spatial properties. The Sponsor needs to report the measurement method.

   d. In the *chromaticity variation test*, the test pattern was not specified.

   e. Figure 6 was mislabeled.

2. PACS study summary (Appendix 16.9.4)

   The study design is insufficient for the following reasons:

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a. The setting of the ambient luminance (220 and 1.5 lux) was too low to represent common viewing conditions for mobile display users. In the TG18 report, 220 lux was considered as "hospital clinical viewing station," which is much dimmer than regular office lighting.

b. The "ambient light user assessment" function (Appendix 13, p24) was not used in this study.

c. The fact that both subjects performed better in the darker 1.5 lux environment may indicate a bad calibration of the display. Note that the DICOM GSDF measurement is missing.

d. The terms -- *contrast*, *sharpness*, and *image quality* – may sound vague or ambiguous for subjects with little training of imaging science. It is not appropriate to ask subjects to assess these measures directly.

3. Impact of transmission latency

   Compared with a Windows/Intel-x86-based notebook, which was used in the predicate, the iPhone4/iPad, as an embedded system, is slower in terms of computation and communication speed. In the current submission, such latency-related measurement was not reported. As pointed out in the Executive Summary, the current submission is likely to be used in emergent situations, where ideal network connection may not be available. Extended latency in the TCP/IP layer may interrupt the application in an unexpected way or encourage the user to reduce image quality with JPEG compression at the cost of diagnostic accuracy.

4. JPEG quality adjustment (Appendix 13, p21)

   The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, p21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

5. In Appendix 16.6, p15, the following quoted paragraph is inconsistent with the intended use -- "ResolutionMD Mobile was designed to function on smartphone devices that have native hardware providing Wi-Fi and cellular network connectivity. Similarly, these smartphone devices utilize industry-best display technology such as LED or AMOLED LCDs and have large displays that occupy most of the devices' surface (most measuring 3.5" or larger)." Note that iPhone4 and iPad are neither LED nor AMOLED.

6. In Appendix 16.6.1 "2.5 DICOM Conformance Statement," it is not clear whether the submission conforms to 3.0 DICOM or 2.5 DICOM.

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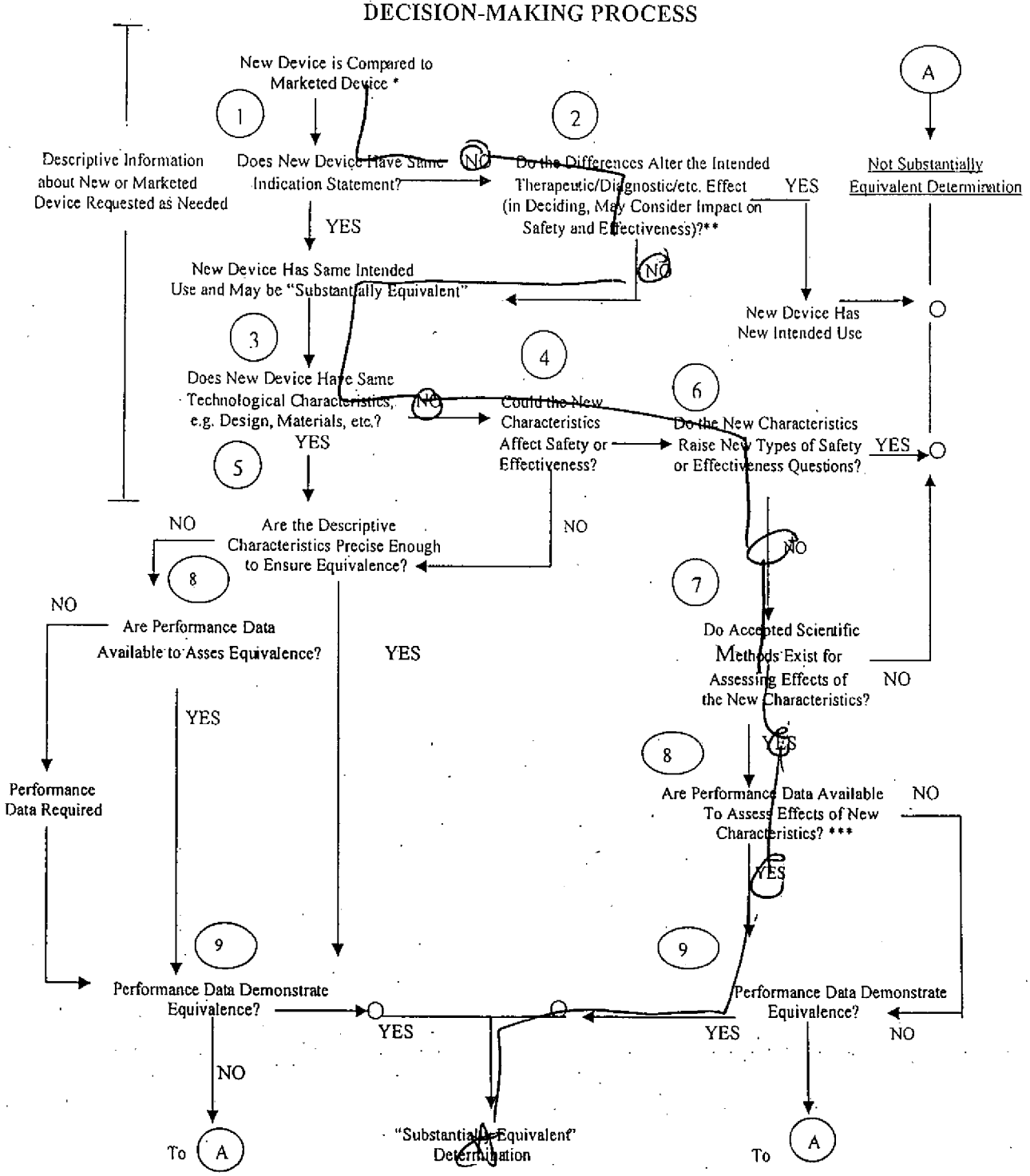
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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

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

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RA/ DRAD

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V-6

July 29, 2011

FDA CDRH DMC

AUG 1 2010

Received

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

Dear Sir/Madam:

Re: K111346 Trade name: ResolutionMD™ Mobile
Response to Letter of June 30, 2011

We received your letter of June 30, 2011 requesting Additional Information to support the above-mentioned Section 510(k) application to market ResolutionMD™ Mobile.

After discussions with the reviewer, Dr. Roberts Ochs, we have assembled a comprehensive package of information with is contained in the enclosed documents and on the enclosed CD.

Please confirm your receipt of this information at your earliest convenience.

Sincerely,

Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific Inc.
Email: kyle.peterson@calgaryscientific.com
Tel: 403-767-7945
Fax: 403-270-2771

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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July 29, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
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Attachments

Labeling – ResolutionMD Mobile U.S. User Guide (revised)

Item 6 - Ticket MOB-1057 for Missing source compression info

Item 10-iOS Ambient Light Test Results

Item 10.1- Ticket MOB-1051 for Ambient Light Test

Item 11(c) - Unsupported data indicator-Ticket MOB-1052

Item 12 - ResolutionMD Mobile-Off-the-shelf Software

Item 13-iPhone 4 and iPad Fit to GSDF Luminance Response

Item-17-Form FDA 3674-Clinical Trials-signed

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FDA Ambient Light Test

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ResMD Mobile (b) (4)

Application frozen when user times out on Ambient Light test

Details

Type:	Defect	Status:	Closed
Priority:	(b) (4)	Resolution:	Fixed
Affects Version/s:	ResMD 2.6 (FDA)	Fix Version/s:	None
Component/s:	iOS		
Labels:	None		
Environment:	iPad dev build for Ambient Light test rev (b) (4)		

(b) (4)

Description

When the user times out from the imaging session > Ambient Light, with either popup vieawable the user is returned to the search screen in a frozen state

Tempo

Activity

All Comments Work Log History Activity Case Attachments Source Reviews Builds

(b) (4)

(b) (4)

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ResMD Mobile (b) (4)

As an end-user, I want to be informed when a data type that is displayed is not officially supported so that I can take that into consideration when rendering a medical decision

Details

Type:	Story	Status:	Closed
Priority:	(b) (4)	Resolution:	Fixed
Affects Version/s:	None	Fix Version/s:	Conuscant, ResMD 2.5
Component/s:	iOS		
Labels:	PIT		

Description

(b) (4)

Tempo

Issue Links

(b) (4)

Activity

(b) (4)

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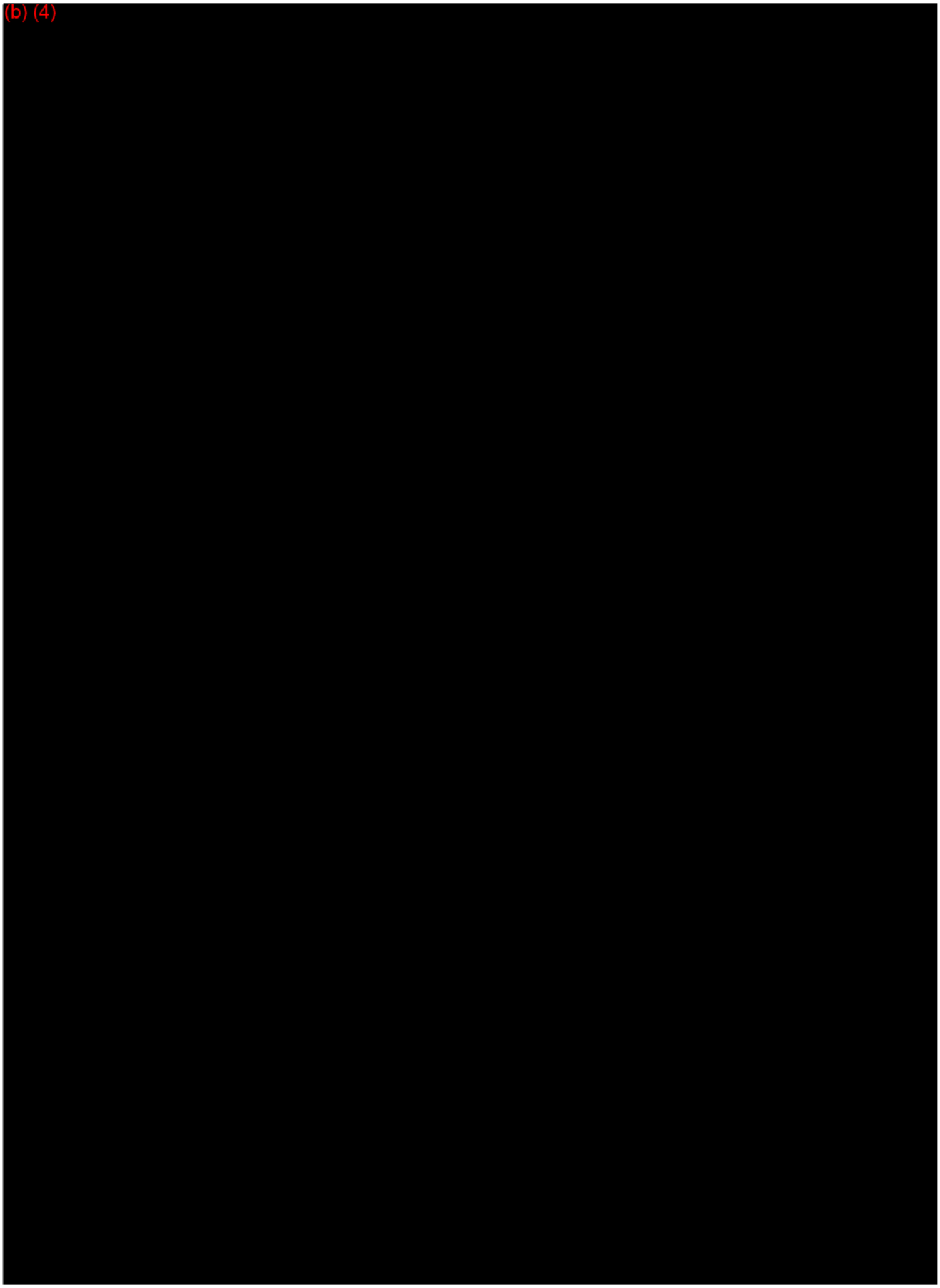
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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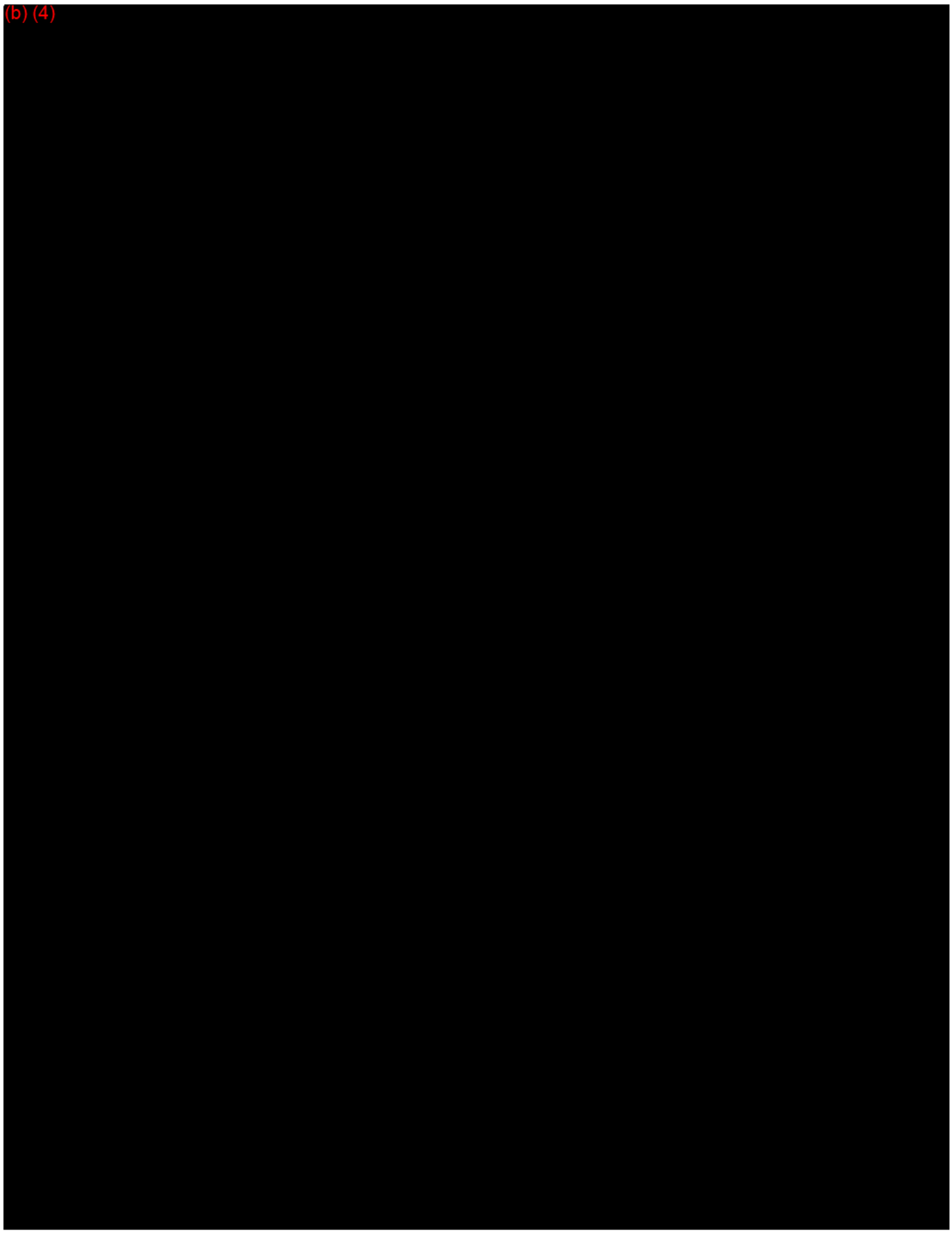
(b) (4)



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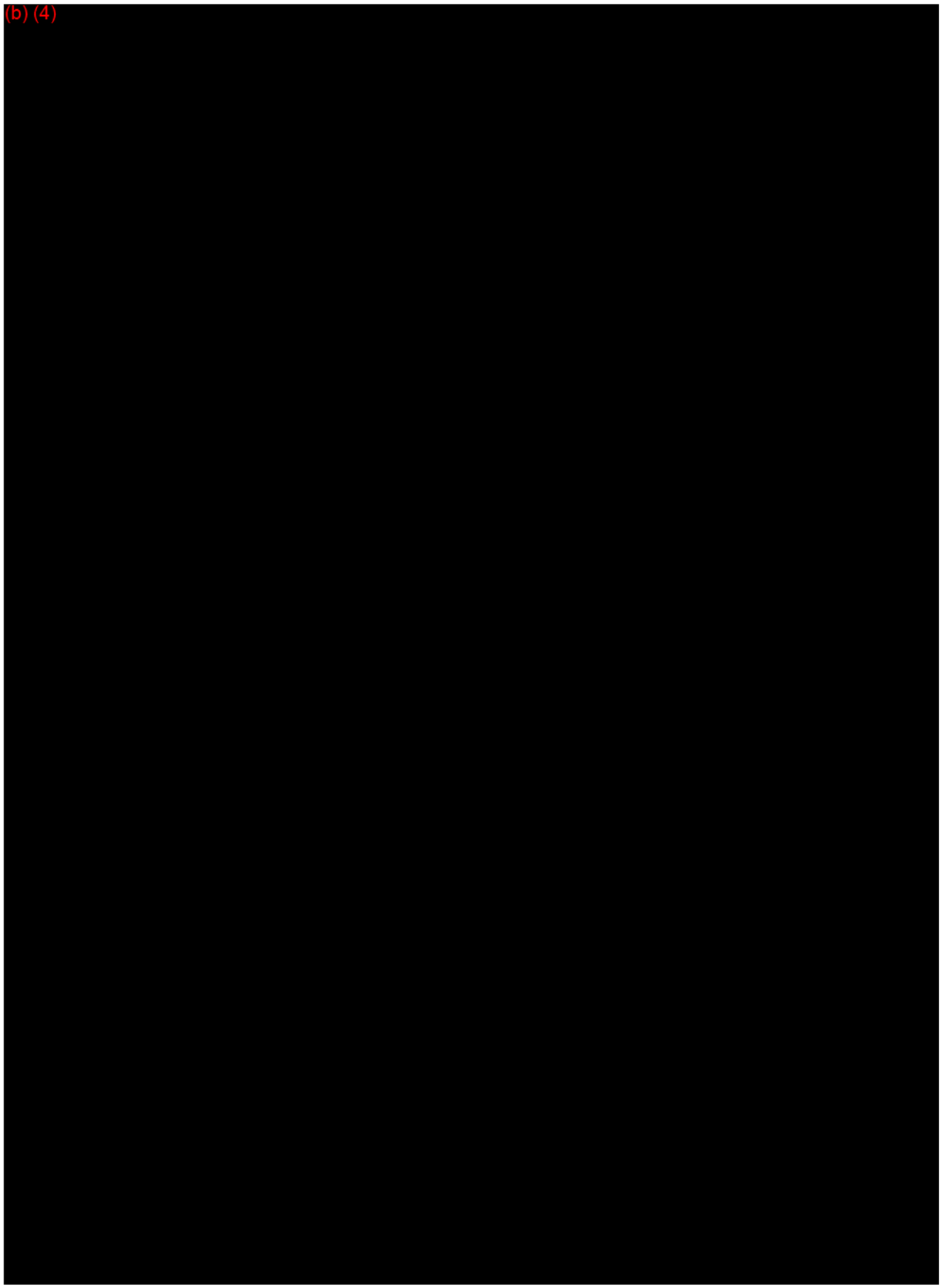

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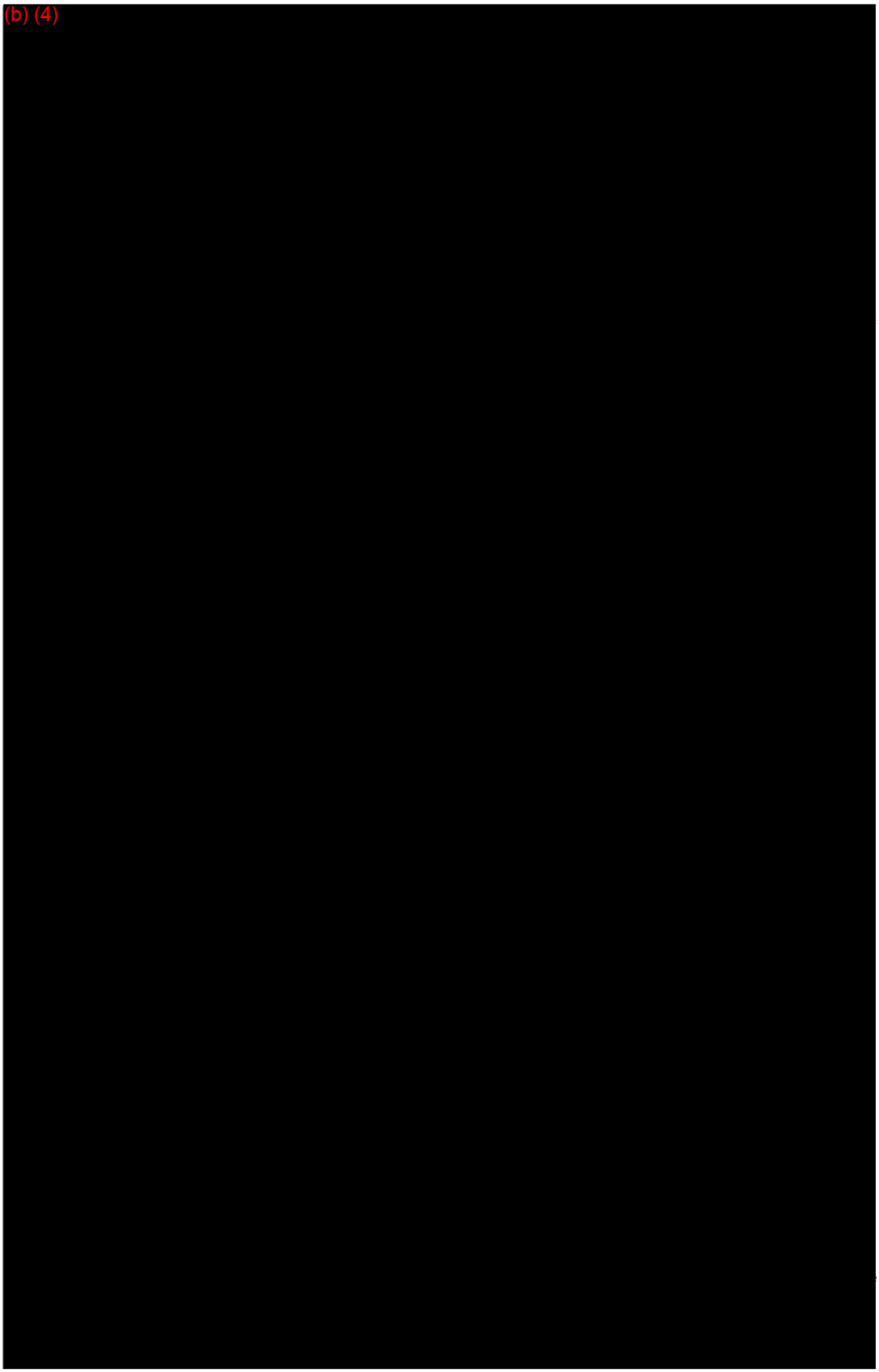

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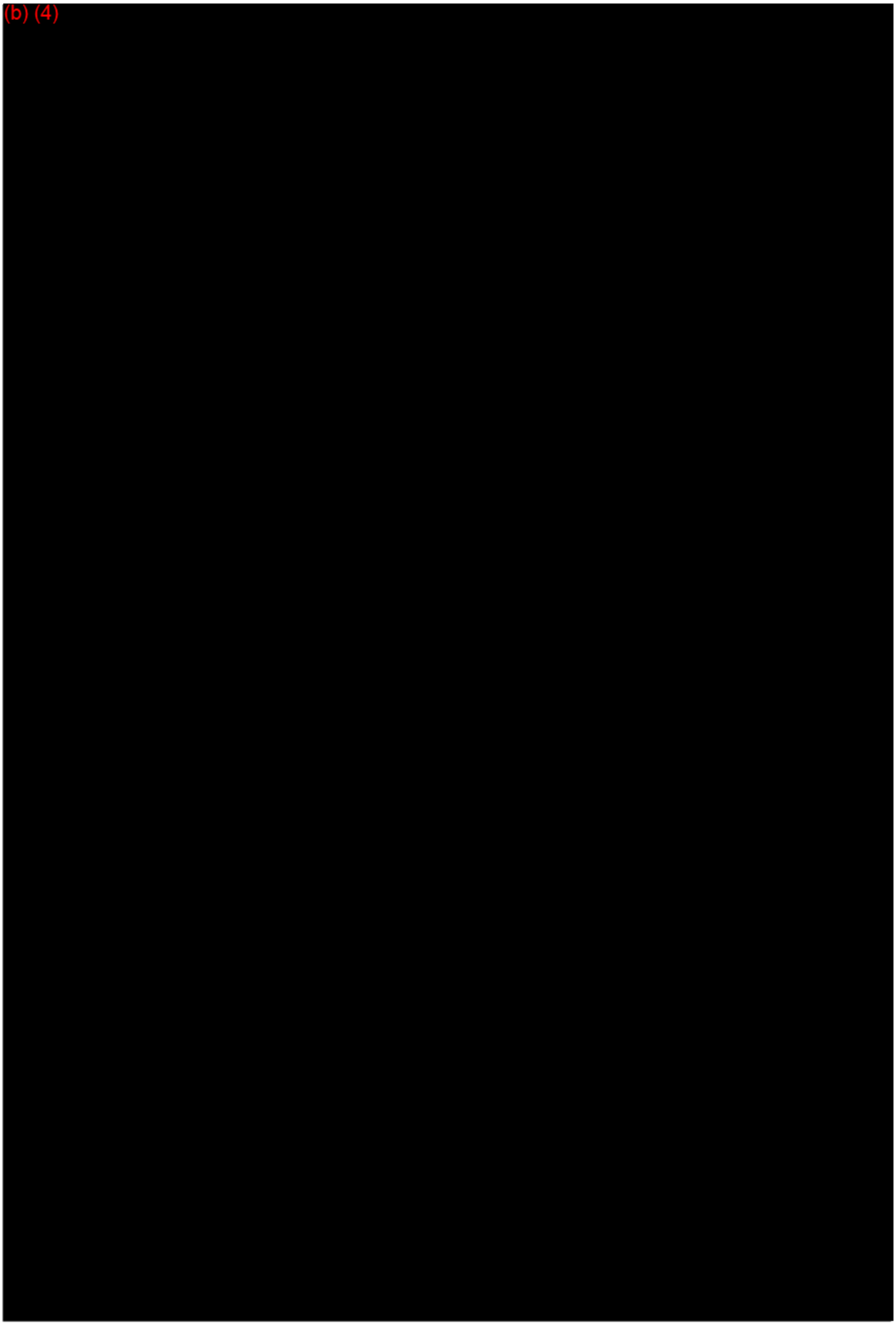

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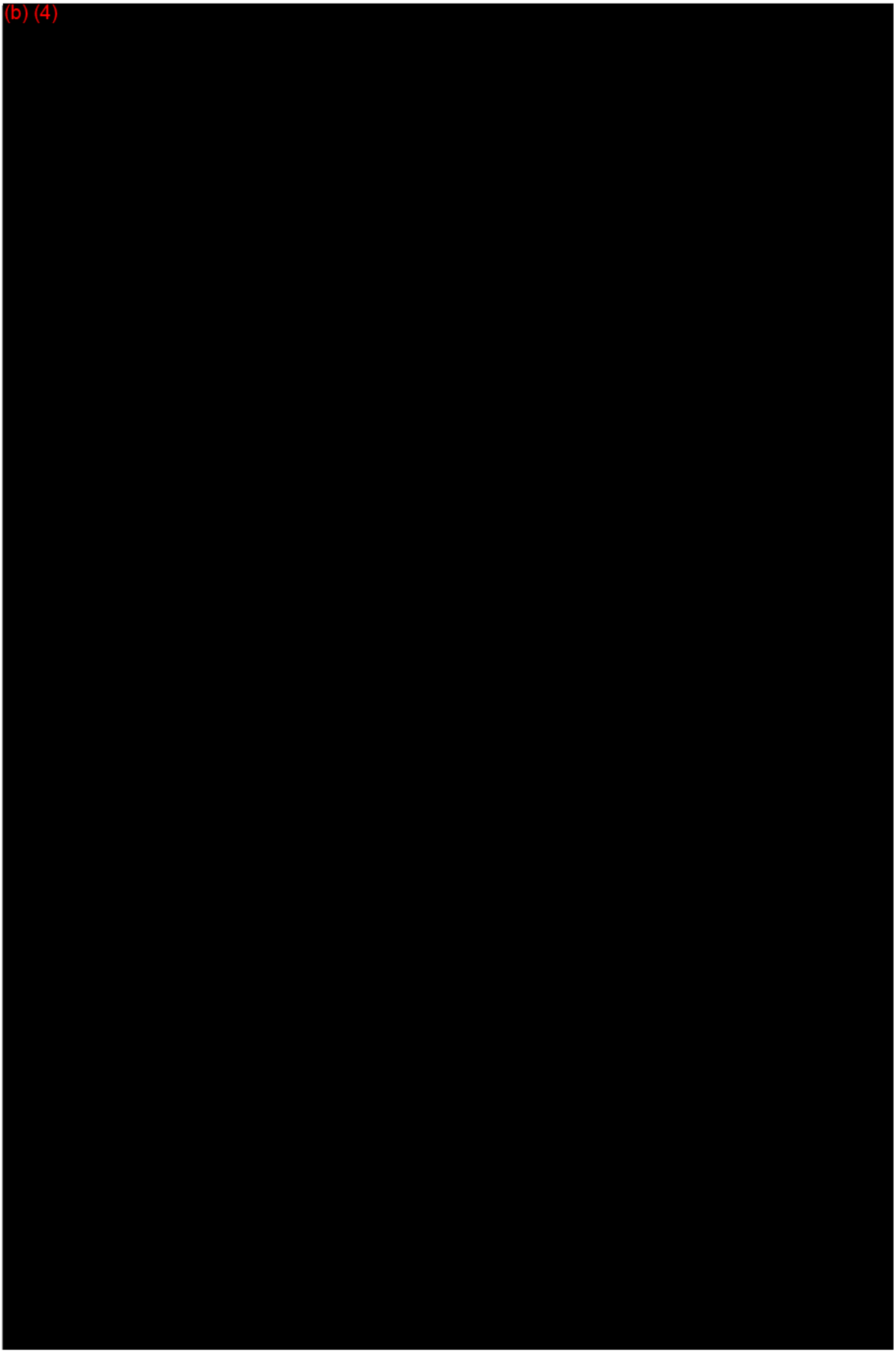

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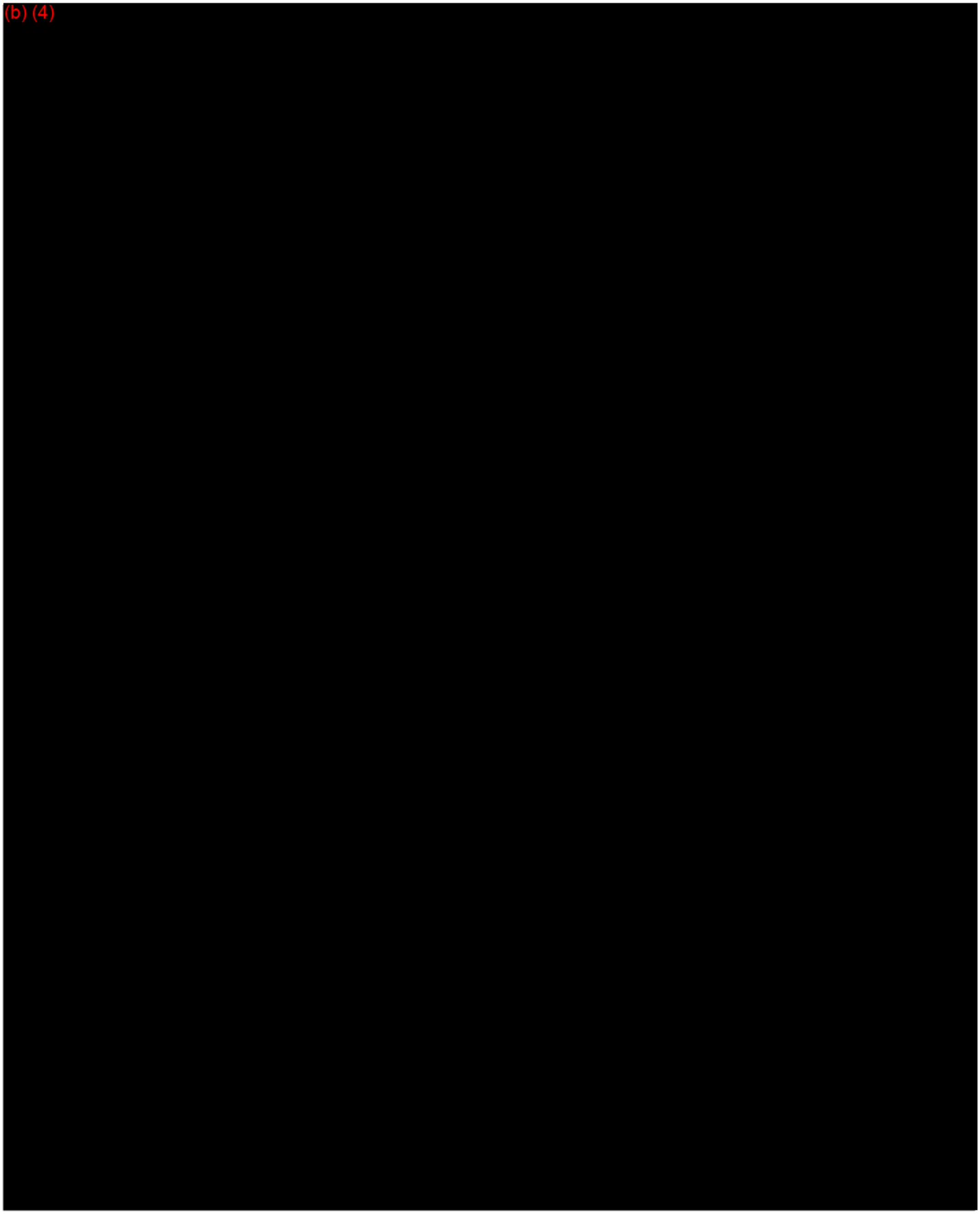

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calgary scientific

ResolutionMD Mobile – Off-the-Shelf Software Overview

This document contains a summary of the usage of the off-the-shelf (OTS) software at Calgary Scientific as well as a detailed review of the OTS software that is incorporated in ResolutionMD , iOS clients, and PureWeb.

Summary

(b) (4)

[redacted]

Detailed Review of the OTS Software

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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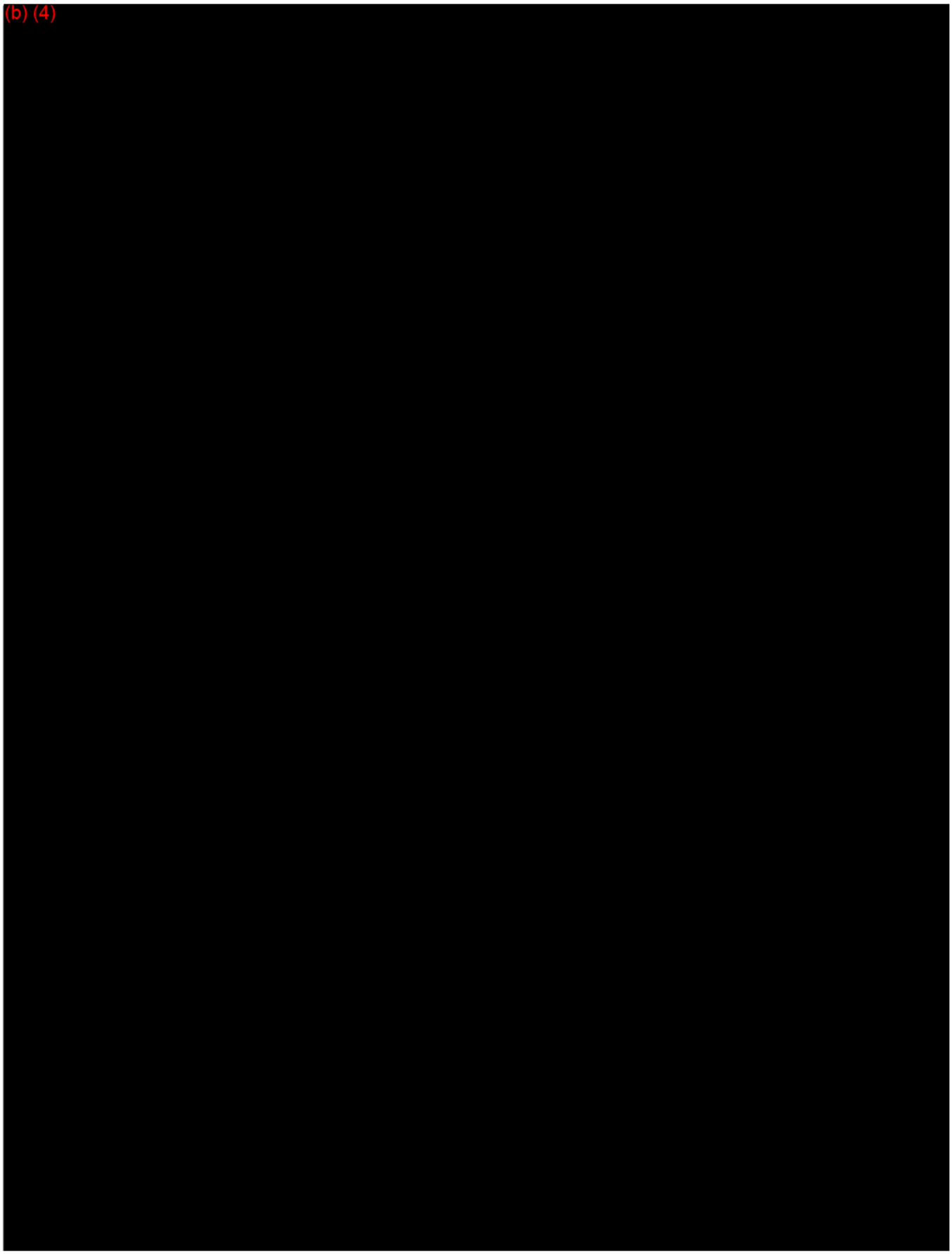

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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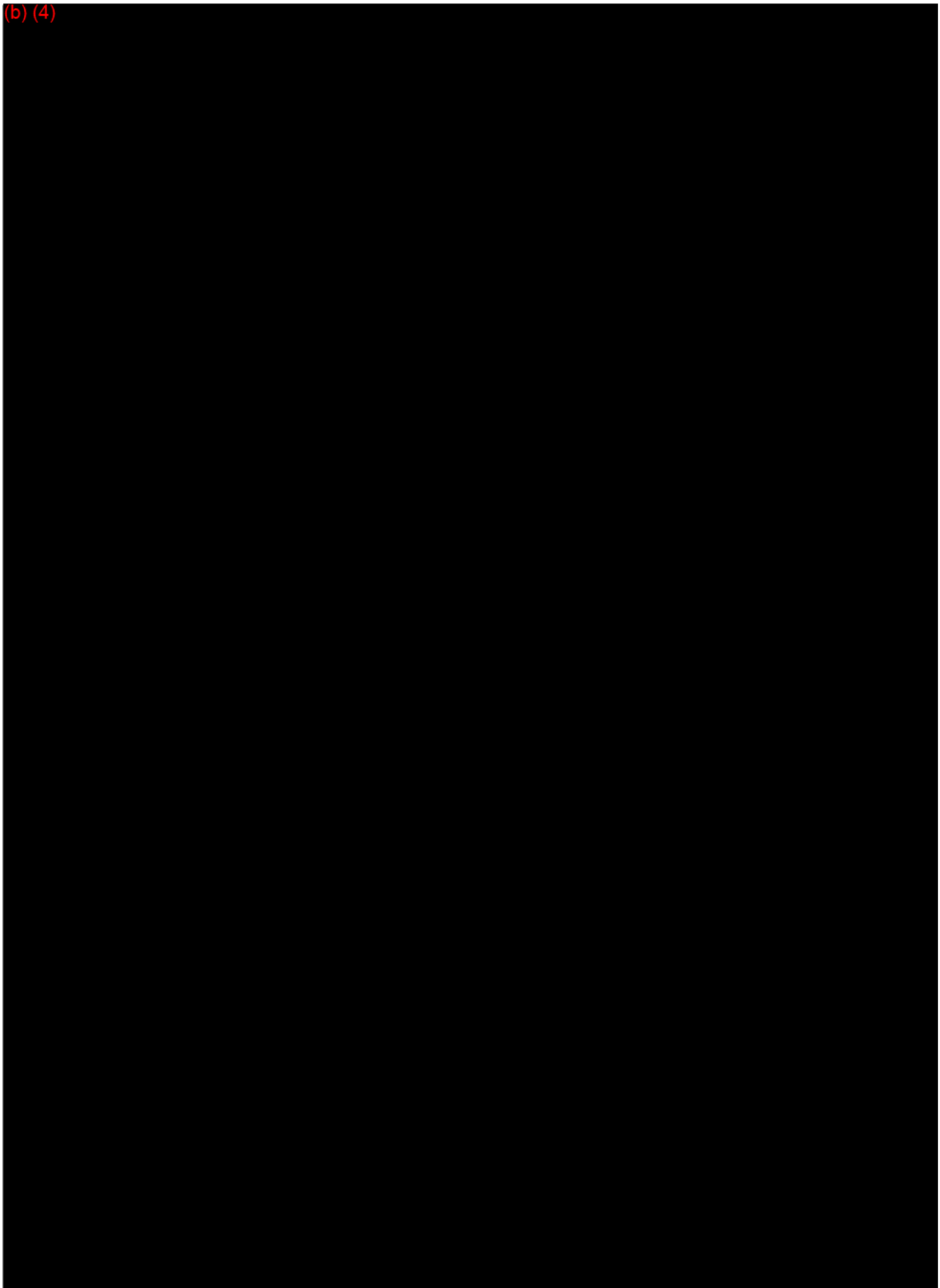
(b) (4)



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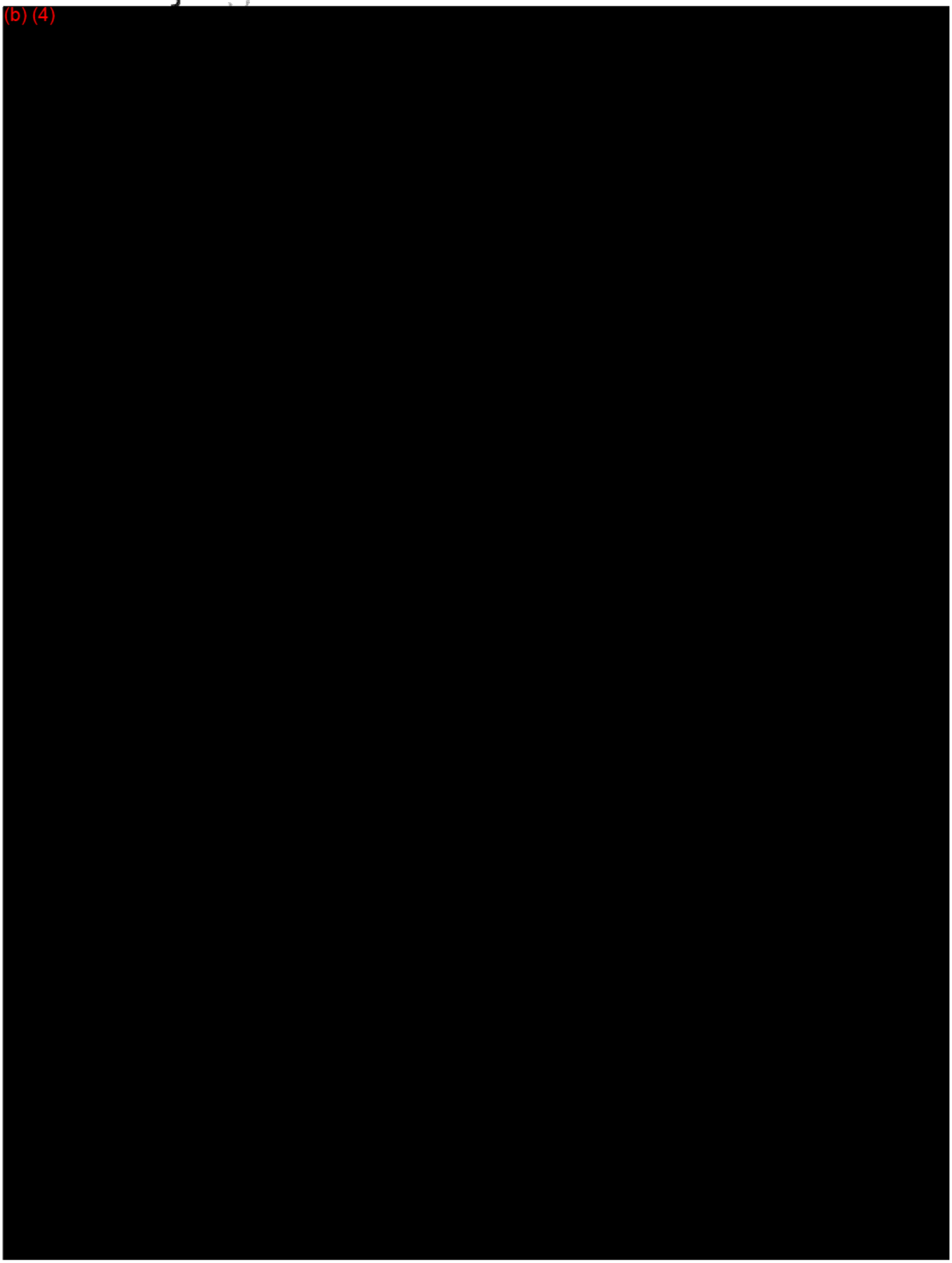

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Usage: Used for string parsing and evaluation to pre-determined patterns.

License: BSD

License URL: http://www.pcre.org/licence.txt

1.16. zlib

Project: http://www.zlib.net/

Description: This library provides data compression and decompression utilities.

Usage: Used for general data compression.

License: zlib

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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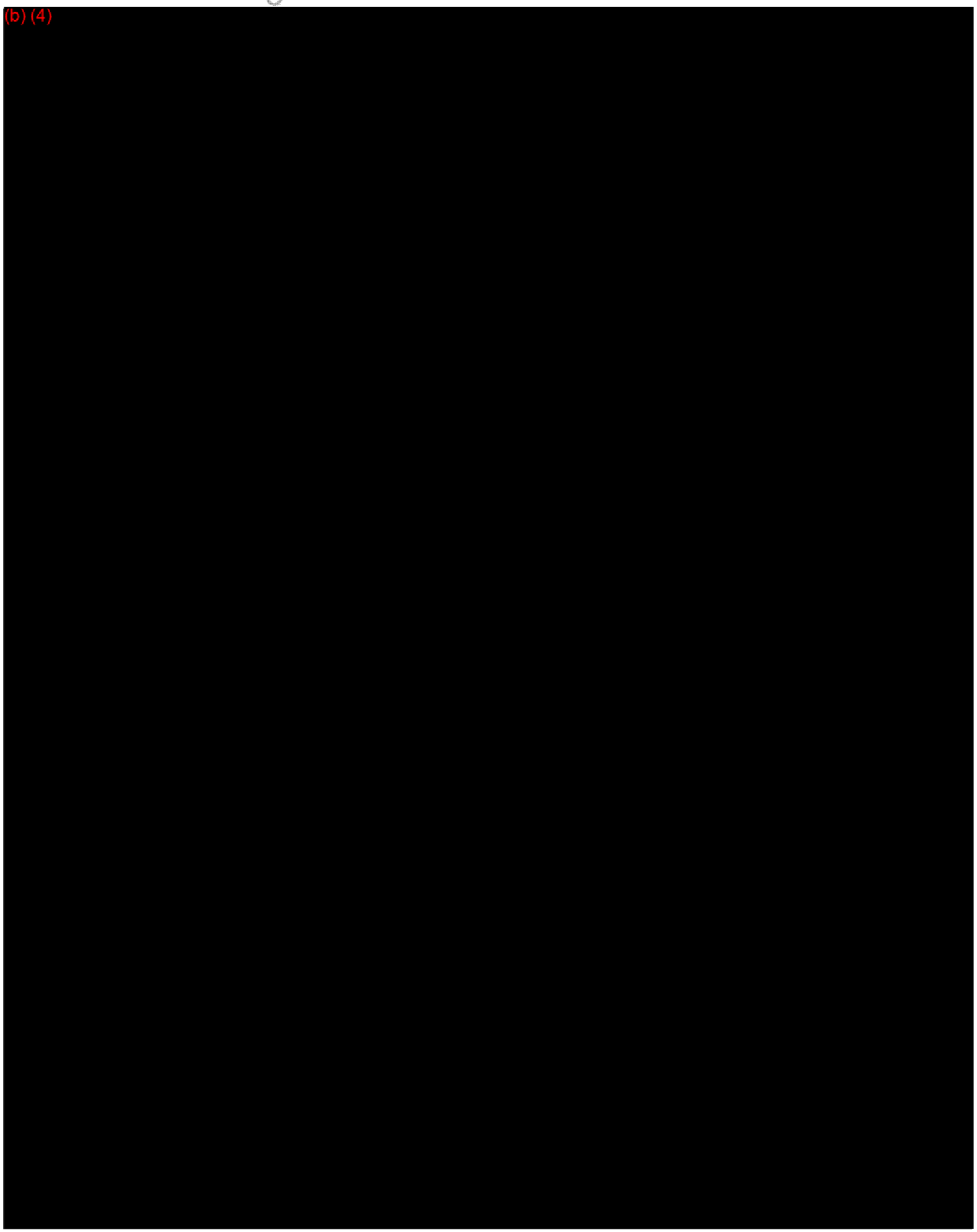

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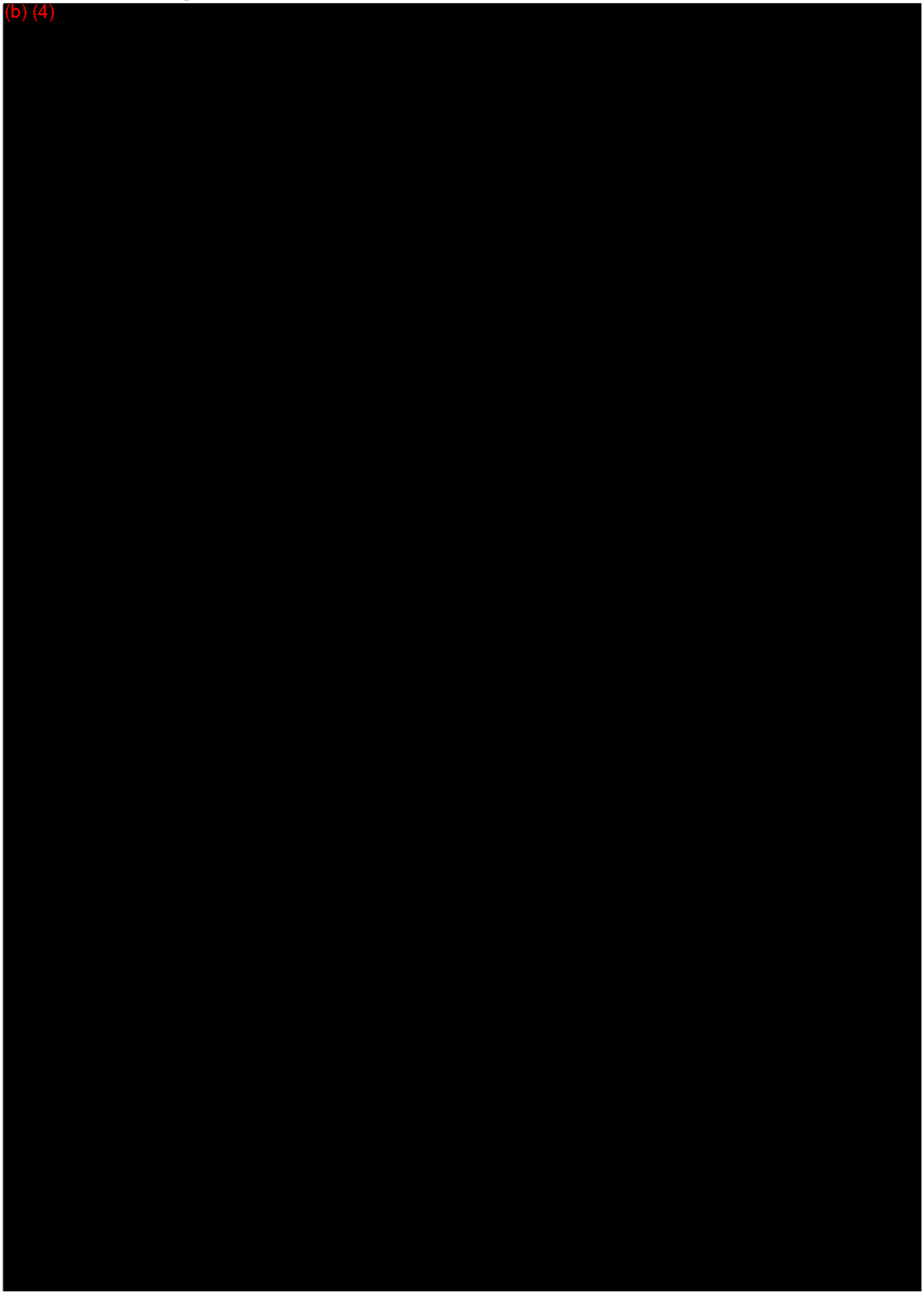

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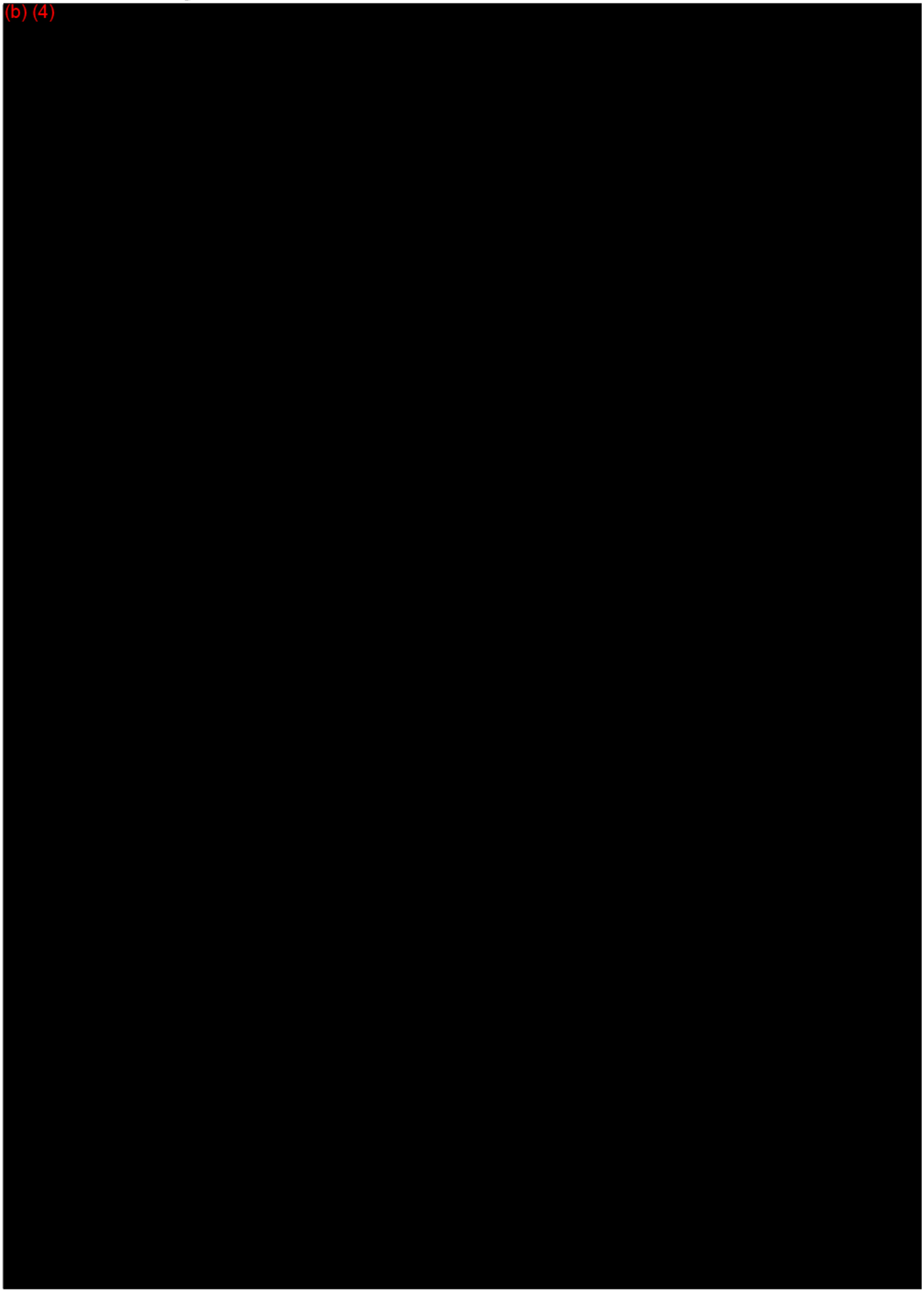

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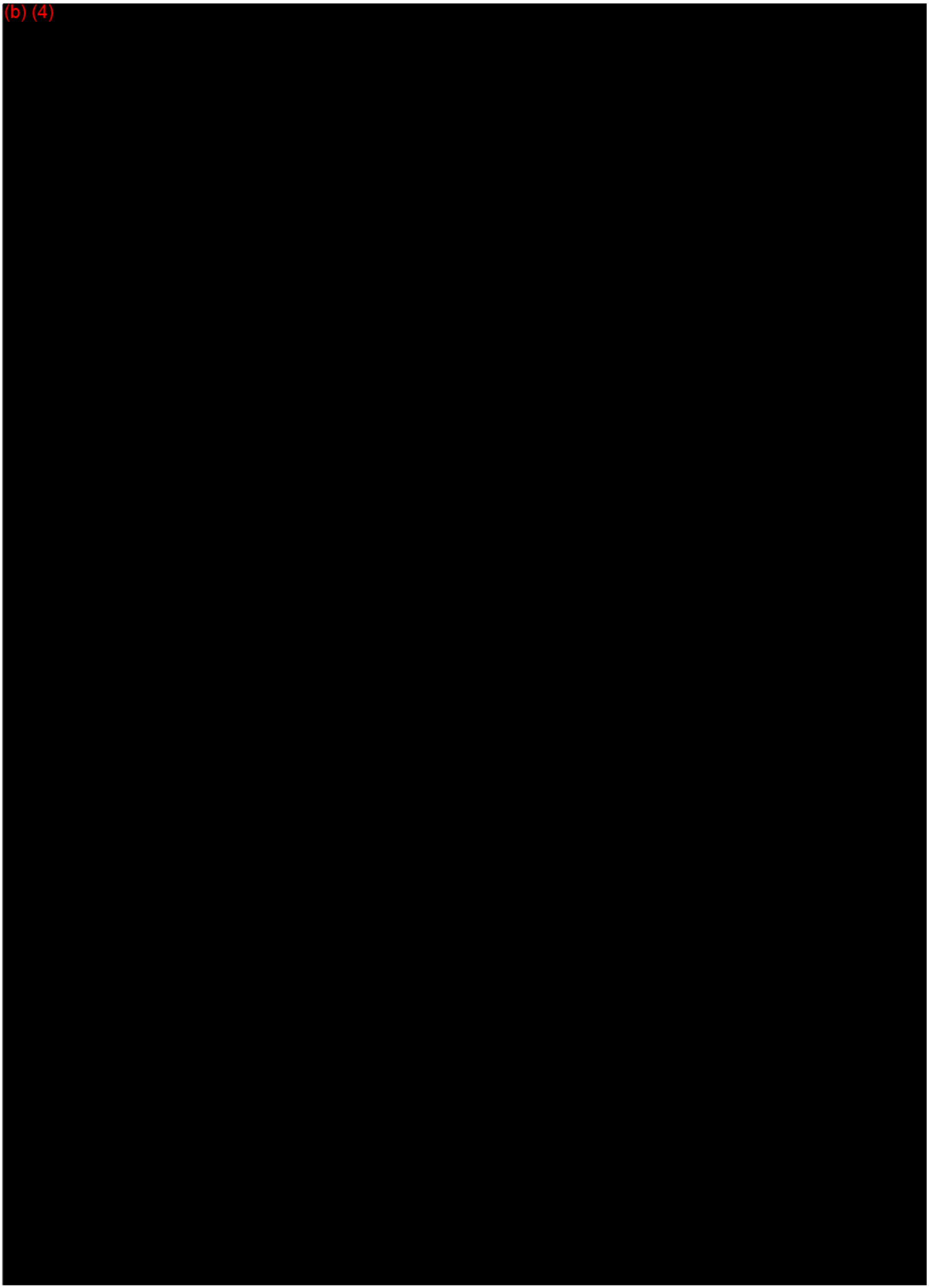

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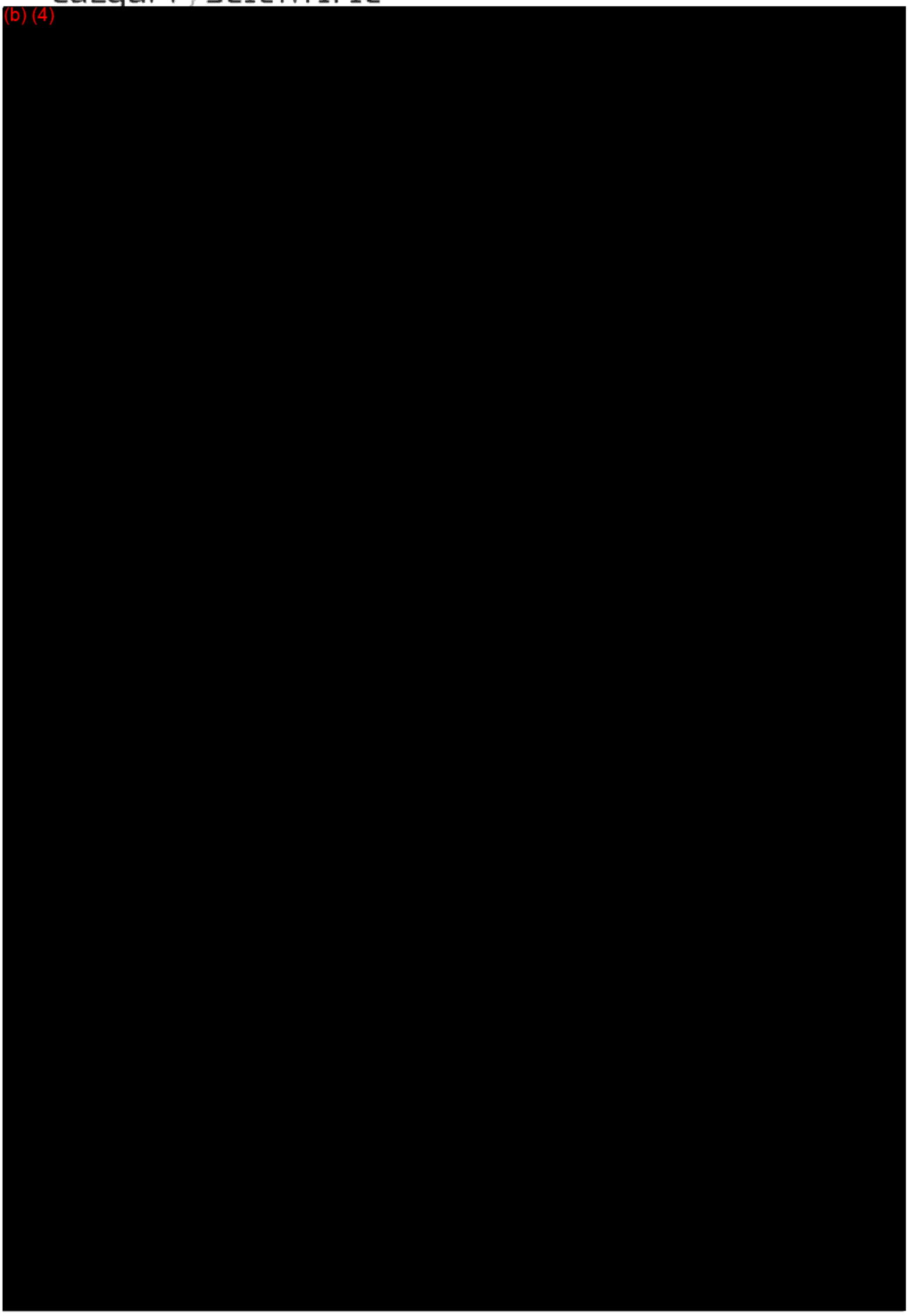
(b) (4)



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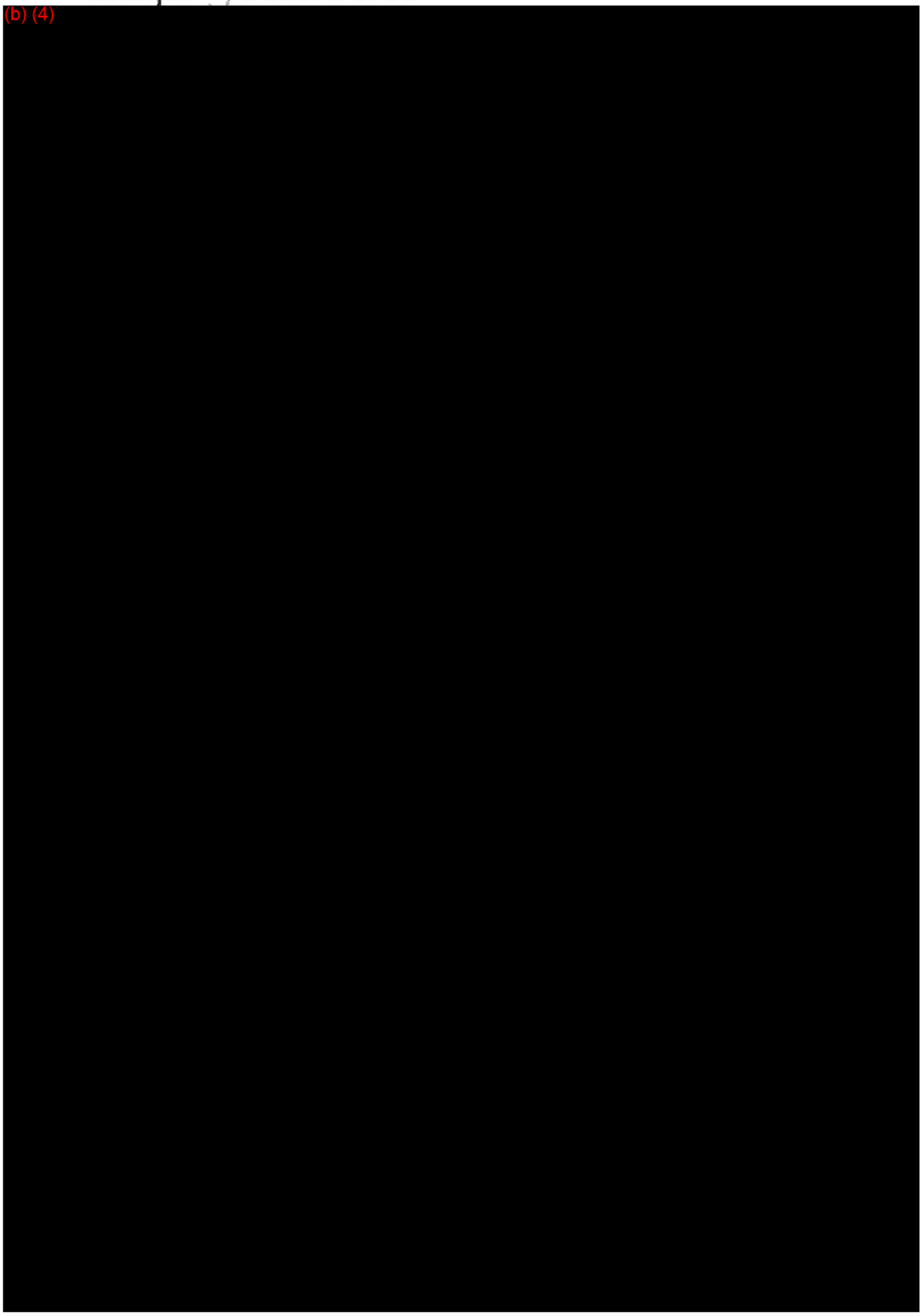

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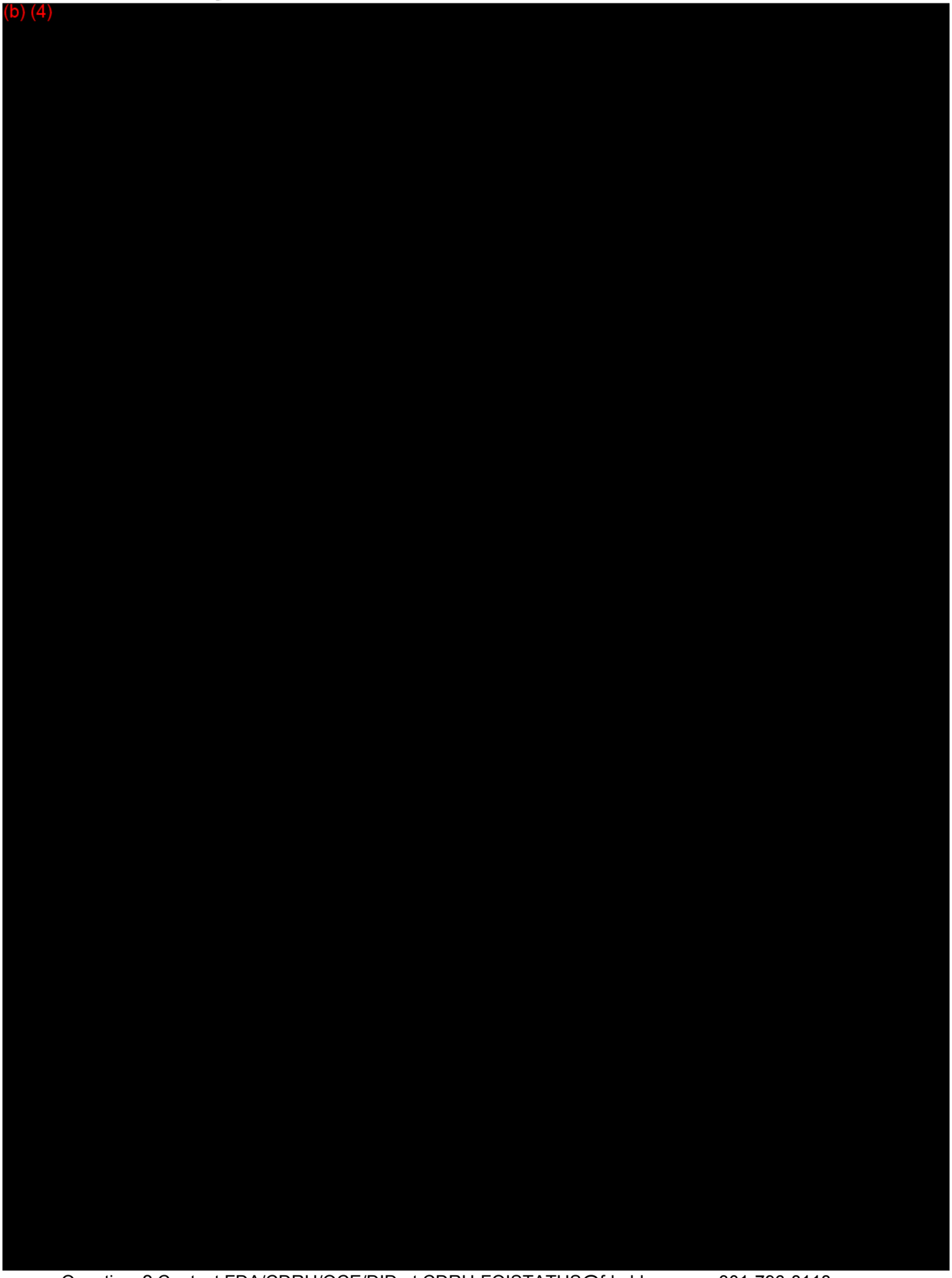

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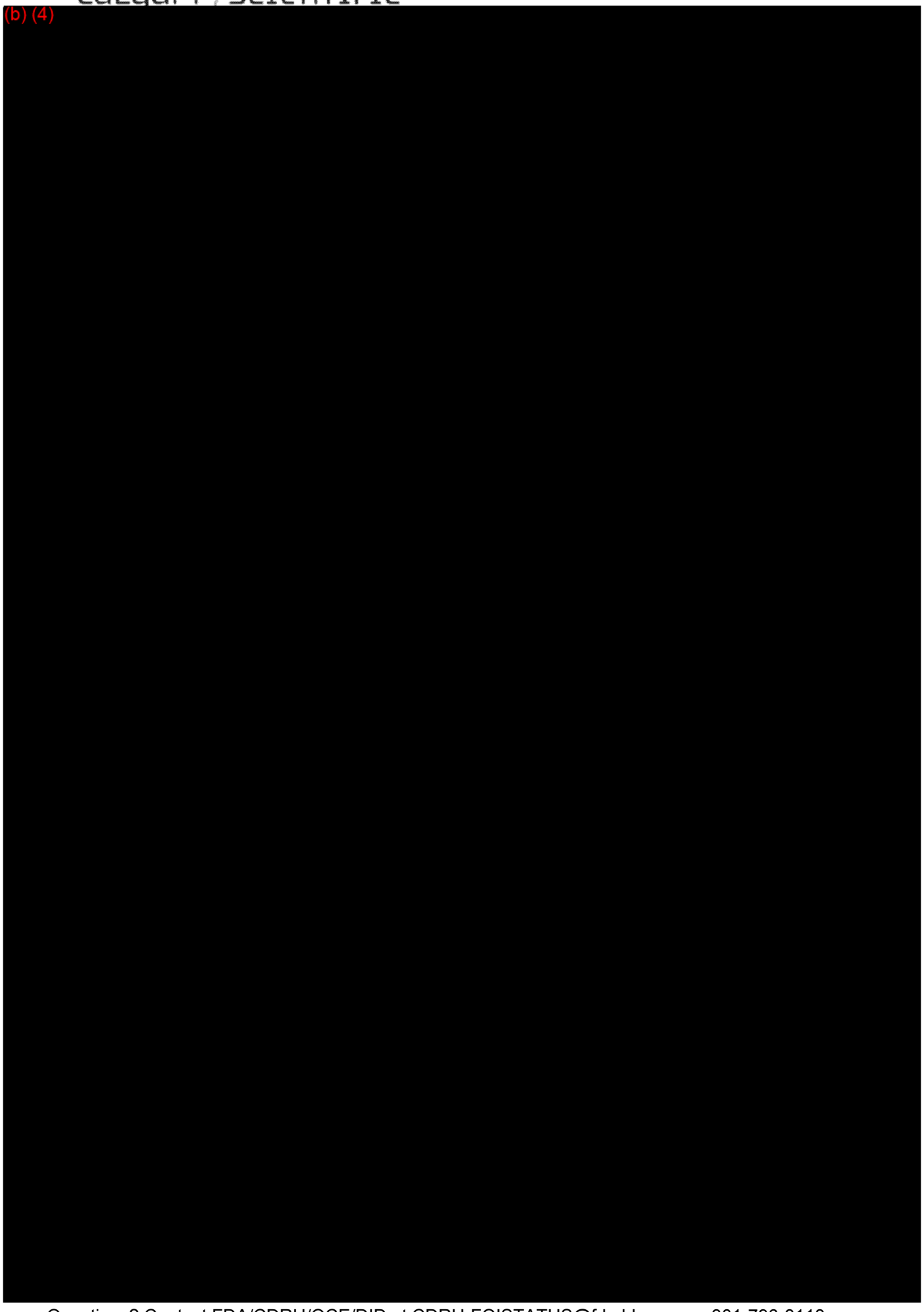

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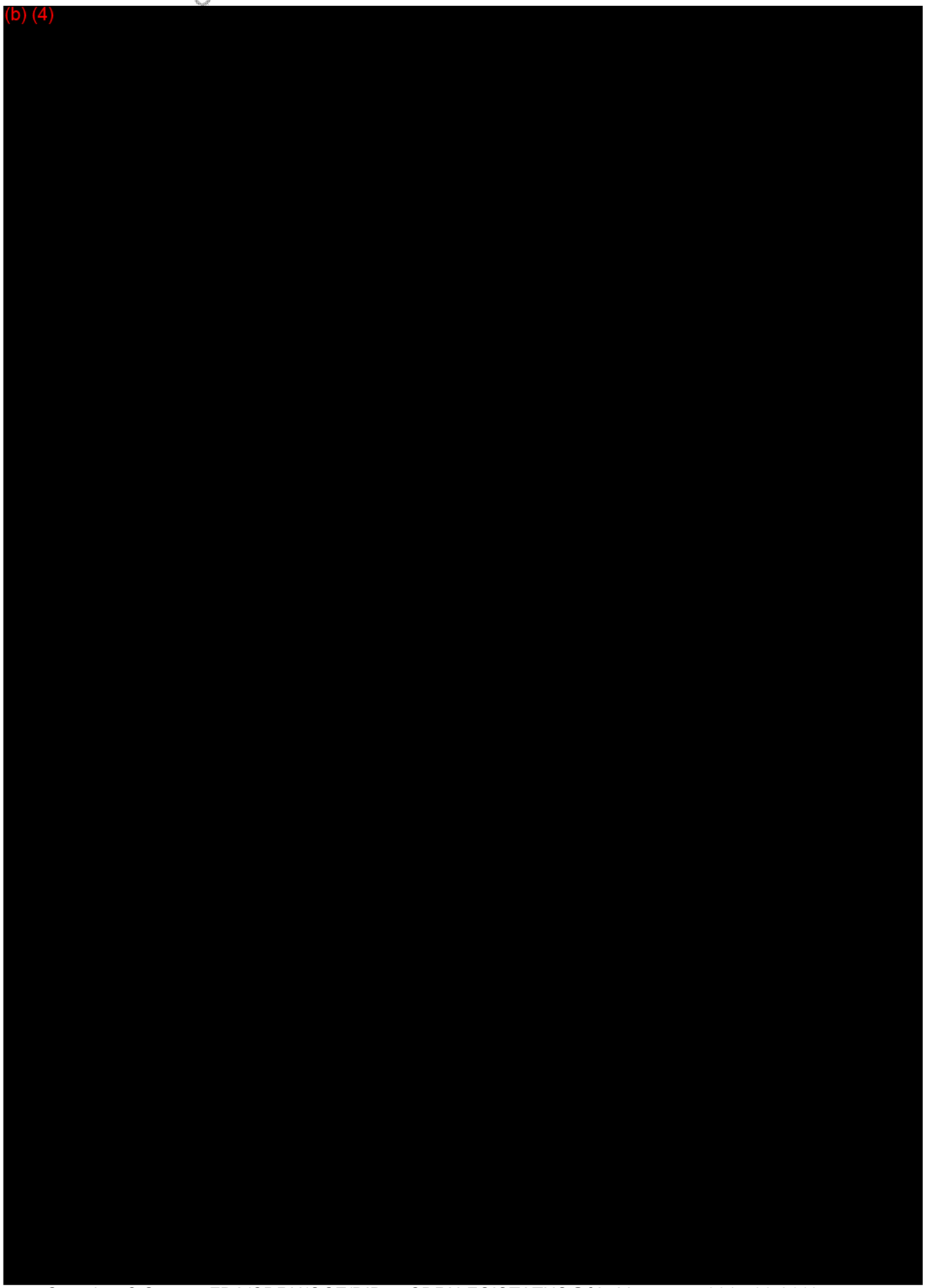

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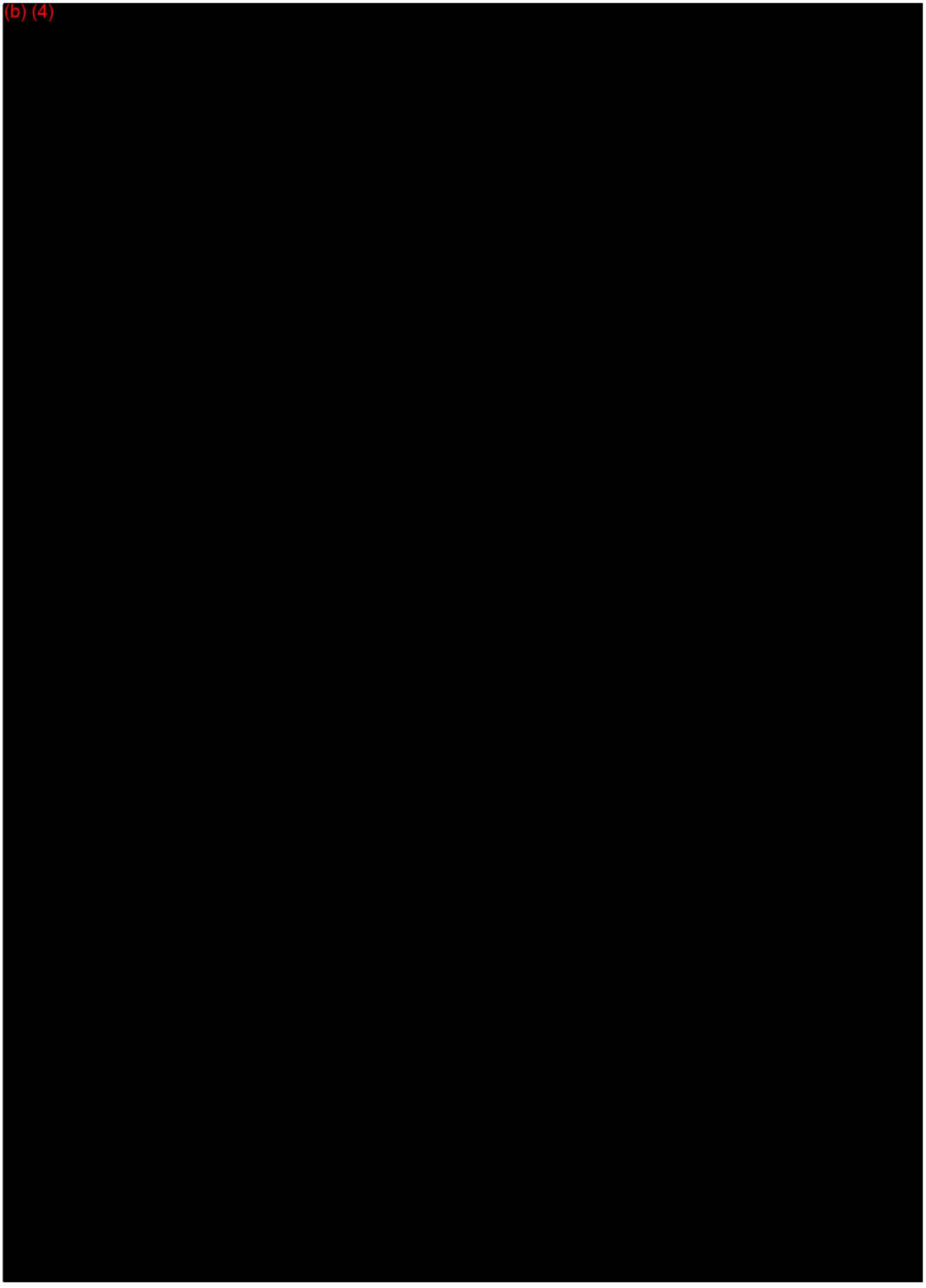

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Item 13 - iPhone 4 Fit to GSDF Luminance Response

Grey Level	Measured Luminance (cd/m^2) L_n	JND Observe	Change in Luminanc		change in	Delta(L) / avg(L)/delta(J	DICOM JND	DICOM JND Uppe	DICOM	DICOM	Change in Luminanc		c e
(b) (4)													

Item 13 – iPhone 4 and iPad Fit to GSDF Luminance Response

Item 13 - iPad Fit to GSDF Luminance Response

Grey Level	Measured Luminance (cd/m^2) L_n	JND Observ	Change in Luminanc		change in	Delta(L) / avg(L)/delta(J	DICOM JND	DICOM JND Uppe	DICOM	DICOM	Change in Luminan		c e J
(b) (4)													

Item 13 – iPhone 4 and iPad Fit to GSDF Luminance Response

Records processed under FOIA Request 2011-7341; Released 4/8/13

ResMD Mobile (b) (4)

Missing compression info on 3D and MIP/MPR

Details

Type:	Defect	Status:	Closed
Priority:	(b) (4)	Resolution:	Fixed
Affects Version/s:	Coruscant	Fix Version/s:	None
Component/s:	Android, iOS		
Labels:	PIT		
Environment:	iPhone, iPad		

Steps to Reproduce: (b) (4)

Description

(b) (4)

Tempo

Issue Links

(b) (4)

Activity

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)

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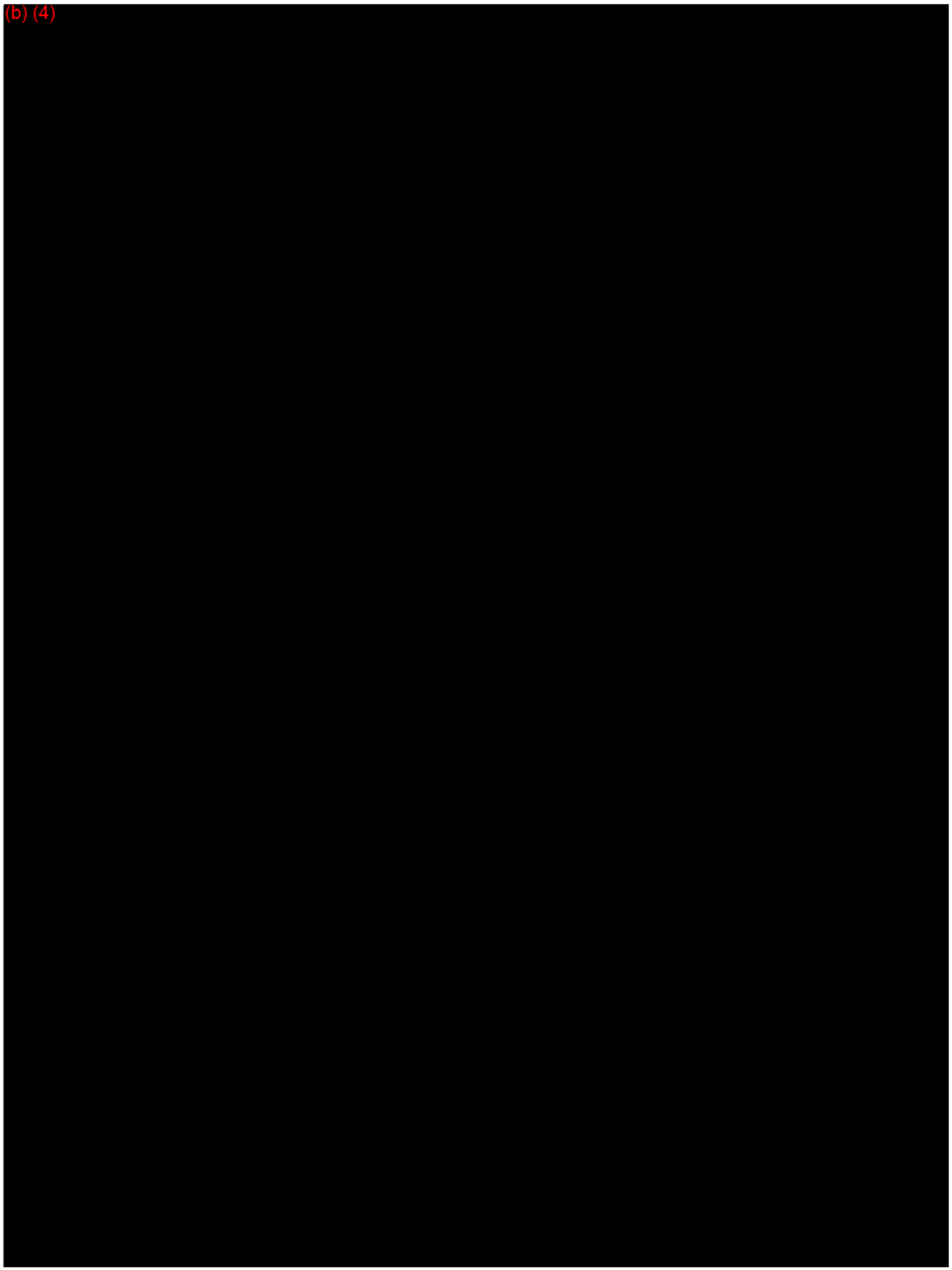
(b) (4)



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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Calgary Scientific Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
May 12, 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
1210 - 20th Avenue SW, Suite 208
Calgary, AB T2G 1M8
Canada

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 403-270-7159
(Fax) 403-270-2771

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

ResolutionMD Mobile, Class II Medical Device (892.2050)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*
K111346

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

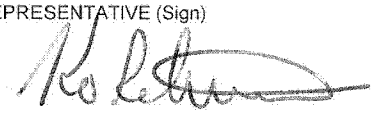
☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)



12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Kyle Peterson
(Title) Director, Regulatory & Corporate Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
1210 - 20th Avenue SW, Suite 208
Calgary, AB T2G 1M8
Canada

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 403-767-7945
(Fax) 403-270-2771

15. DATE OF CERTIFICATION
Jul 27, 2011

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

Records processed under FOIA Request 2011-7341; Released 4/8/13

K111346 Trade name: ResolutionMD™ Mobile

Response to FDA Additional Information request letter of June 30, 2011
Date of Response: July 29, 2011

Introduction

This response is organized using the same numbering as the items in the letter signed by Michael D. O'Hara of the FDA to Kyle Peterson of Calgary Scientific Inc., dated June 30, 2011. Some sections of this response will refer to new or revised documents, identified by the item addressed, which are appended to this document.

Items and Response

Item 1 - Parts of the submission include specific statements related to the use of the device in emergency situations and for specific conditions (e.g., Section 12, page 16; Section 16.2.5, pages 32-33). As has been noted previously on multiple occasions, FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims related to the use of the device for emergency situations or specific disease conditions, such as stroke. FDA believes that a general indications for use statement is most appropriate for this device based on the information provided. Please confirm that you will not market your device for these or other specific indications.

Response:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

Item 2 - There are concerns with the conclusions that are being drawn from the study in Appendix 16.9.4. As noted on numerous occasions, the purpose of the study was not to compare the resulting primary or secondary diagnosis. FDA does not believe that Calgary Scientific has provided any valid scientific evidence to support specific labeling/marketing claims that radiologists will be as accurate on the mobile device as on a workstation, or will reach the same diagnosis as on a workstation. The performance study was intended to support that the device offers sufficient image quality for a diagnosis (or image review) on CT and MR under specific lighting conditions when there is no access to a workstation. Much more rigorous studies would be necessary to evaluate the diagnostic effectiveness of using a mobile device compared with a workstation.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

Item 3 - The results from Appendix 16.9.4 suggest that radiologists may have some difficulty using the device under some conditions. Note the comments from Dr. Koles, "Both [iPhone and iPad] were far better in the dark... I'd certainly be reading in the dark". In addition, Dr. Pattison stated, "Subtle findings were better appreciated in the dark on the mobile devices and were best appreciated on the PACS workstation." Please revise the label to reflect the preference for clinicians to review the images in a dark environment.

Response:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

Item 4 - The "Bright" conditions were in the range of 209-220 lux. In the TG18 report, 220 lux was considered as "hospital clinical viewing station," which is much dimmer than regular office lighting. The setting of the ambient luminance (220 and 1.5 lux) may not represent common viewing conditions for mobile display users. The labeling should contain specific language to indicate the limits on the ambient illumination levels in which this product could be used.

Response:

(b) (4)

[redacted]

Item 5 - Page 3 and 12 of the Mobile Device PACS Study (Appendix 16.9.4) indicates that all 12 reviewed cases were neuro cases. Page 5 seems to contradict this. Please clarify this discrepancy.

Response:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item 6 - The software documentation suggests that the device is intended to have persistent on-screen indication of the degree of source image compression. It is not clear if this feature has been implemented for the 2D or 3D images. In Appendix 16.11, Item 925 of the list of Unresolved Anomalies indicates that compression information is missing. The User Guide did not contain a description of this indicator. Please clarify if this feature has been implemented for the 2D/3D images and provide the software testing and labeling information.

Response:

(b) (4)

Item 7 - The user can adjust the JPEG quality between 30 and 100. However, the assessment of quality loss (compression ratio) was not reported in the submission. In addition, a slider named "Full Quality" associated with a number between 0 and 100 (Appendix 13, page 21) may mislead the user by giving the wrong hint of a quantitative measure of image quality.

Response:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

Item 8 - The iPad image on page 12 of the user guide lists images from modalities that are not covered by the Indications for Use. Please revise the User Guide to only show modalities that appear in the Indications for Use statement.

(b) (4)

Item 9- As required by 21 CFR 801.109(b)(1), please revise your User's Manual to include the Federal prescription statement "Caution: Federal law restricts this device to sale by or on the order of a physician" and provide the revised pages for FDA review.

(b) (4)

Item 10 - Most of the tests under the "Ambient Lighting User Assessment" in Appendix 16.9.1 were listed as "nd" (not done). Appendix 16.9.2 did not appear to contain any tests related to the ambient lighting user assessment. Please clarify whether the functionality to evaluate the ambient lighting has been implemented. Please provide the software test results that show this feature has been successfully implemented.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2011-7341; Released 4/8/13

(b) (4)

Item 11 - FDA has comments on the following Unresolved Anomalies (Appendix 16.11).

Item 11(a) - Item 892 indicates that image corners are rounded on the iPad app unintentionally. Please provide more details on the cause for this anomalies and the potential impact on the safety and effectiveness of the device.

Response:

(b) (4)

Item 11(b) - Item 928 indicates that FDA concerns about the User Guide have not been addressed.

Response:

(b) (4)

Item 11(c) - Item 919, "As an end-user, I want to be informed when a data type that is displayed is not officially supported so that I can take that into consideration when

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rendering a medical decision". FDA would like to see this feature incorporated before release.

Response:

(b) (4)

[redacted]

Item 11(e) - Item 929, "As an OEM provider, I want to have an extensively tested FDA-approved product..." As previously noted, FDA does not "approve" devices under the 510(k) program; they are only "cleared". Please review 21 CFR 807.97 (Misbranding by reference to premarket notification). Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

Response:

(b) (4)

[redacted]

Item 12 - Please provide documentation for off-the-shelf software used in your device following the "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices".
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073779.htm

Response:

(b) (4)

[redacted]

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Item 13 - FDA has comments on the following aspects of the Display Quality Test Reports (Appendix 16.9.3.1, 16.9.3.2, and 16.9.3.3)

Item 13(a) - The DICOM GSDF measurements appear to have been calculated using ΔL/L; the correct formula is ΔL/average(L)/ΔJND, which could impact the conclusions related to the GSDF measurement on page 9 of Appendix 16.9.3.

Response:

(b) (4)

[redacted]

Item 13(b) - The original TG18 test patterns are in 12-bit depth and size of 1k*1k pixels, which do not fit the iPhone4 or iPad screens. In the test reports, the devices were tested with "customized display test patterns," which was not explained. Please explain any difference in the TG18 test patterns, bench test patterns, and those used by the software application.

Response:

Creation of customized test images.

(b) (4)

[redacted]

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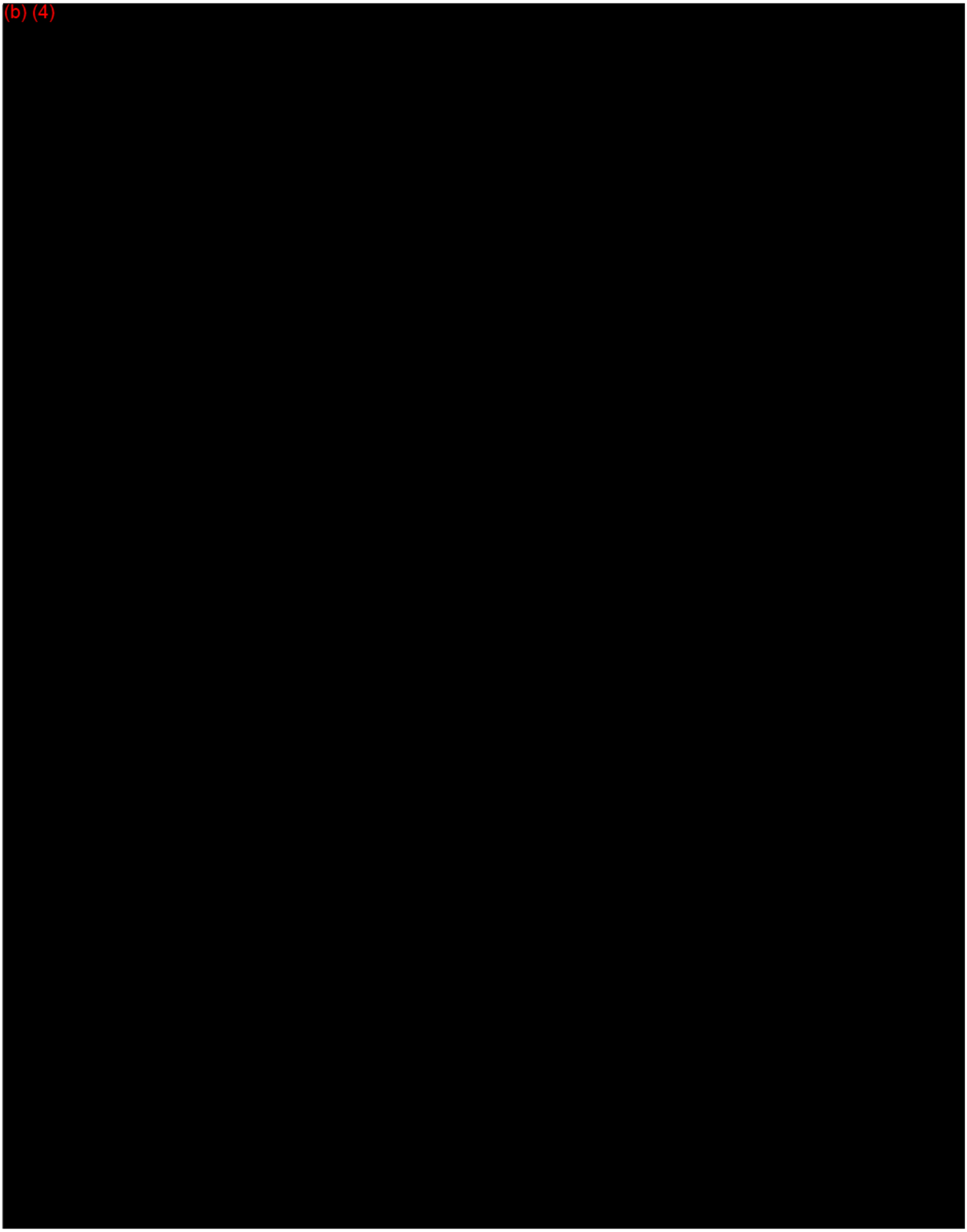
(b) (4)



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(b) (4)

[redacted]

Item 13(c) - In the luminance non-uniformity test and the chromaticity variation test, the size of the measured areas was not reported. Because of the smaller display size of iPhone4/iPad, the measurement method needs to be adjusted accordingly when assessing uniformity or the other spatial properties. Please report the measurement method.

Response:

(b) (4)

[redacted]

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Item 13(d) - In the chromaticity variation test, the test pattern was not specified.

Response:

(b) (4)

[redacted]

Item 13(e) - Figure 6 was mislabeled.

(b) (4)

[redacted]

Item 14- Compared with a Windows/Intel-x86-based notebook, which was used in the predicate, the iPhone4/iPad, as an embedded system, is slower in terms of computation and communication speed. In the current submission, such latency-related measurement was not reported. FDA believes that a general discussion of the time required to download images over different network types in the labeling would be useful to users.

Response:

(b) (4)

[redacted]

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Item 15 - The Substantial Equivalence Comparison Table (Section 12, page 23) states the client operating system can be the iPhone/iPad OS, other mobile device OS. Items 912 and 913 of the Unresolved Anomalies (Appendix 16.11) reference the Android OS. The submission did not contain any software or bench testing to support the use of the application on other mobile device OS. FDA believes that a new 510(k) submission would be necessary to support the migration of the device to a new operating system, such as the Android OS.

Response:

(b) (4)

Item 16 - In Appendix 16.6, page 15, the following quoted paragraph is inconsistent with the intended use -- "ResolutionMD Mobile was designed to function on smartphone devices that have native hardware providing Wi-Fi and cellular network connectivity. Similarly, these smartphone devices utilize industry-best display technology such as LED or AMOLED LCDs and have large displays that occupy most of the devices' surface (most measuring 3.5" or larger)." Note that iPhone4 and iPad are neither LED nor AMOLED.

(b) (4)

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Item 17 - Please complete the Clinical Trials Form (FDA 3674).
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf

Response:

(b) (4)

[redacted]

Summary:

We hope that we have addressed the points in your letter of June 30, 2011 to your satisfaction. We look forward to receiving clearance to bring this innovative technology to market in the United States.

Calgary Scientific Inc.
July 29, 2011

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calgary scientific

resolution MD mobile

2.6 (USA Version)
User Guide

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RMDM26-UG215
Release Date: April 30, 2011

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This guide has been produced to assist in providing instruction for the ResolutionMD™ Mobile (ResMD Mobile) product. Every effort has been made to make the information in this guide as accurate as possible. The authors of this guide shall have neither liability nor responsibility to any person or entity with respect to any loss or damages in connection with or arising from the information contained in this guide.

Trademarks

ResolutionMD™ is a trademark of Calgary Scientific Inc. Any additional software products named in this document are claimed as trademarks or registered trademarks of their respective companies.

Regulatory Status

Product: ResolutionMD Mobile
Version: 2.6

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Preface

Federal Prescription Statement

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

Intended Use Statement

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0 compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

Intended Audience

There are two profiles for intended users of the ResolutionMD 2.6 solution:

1. Referring physicians who refer their patients to the institution or organization controlling the ResolutionMD solution for imaging studies. Referring physicians wish to review images in addition to reviewing the radiologists' final report of findings to enable them to confirm their treatment plans and communicate with the patient.

2. Diagnostic Imaging specialists and radiologists at the institution or organization controlling the ResolutionMD solution. ResolutionMD 2.6 Mobile must be used in only the context of the approved Indications for Use outlined in this Mobile User Guide.

Training / User Familiarization

It is strongly recommended that user training be conducted by each institution implementing the device. This training should include:

- Institutional on-call process for reviews to be performed using the mobile technology.
- Log-in protocols and security for mobile access to the ResolutionMD server.

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- Operation of the software and practice on various uses cases including use of the mobile device under various lighting conditions
- Review of labeling including Intended Use, directions for use, warnings and precautions.
- Criteria for activation of fall-back procedures should mobile access to imaging data not be available or fail during attempts to access it.
- How to access user and product support through their institution.
- Review of criteria and procedures for reporting adverse events to Calgary Scientific.

Expected Performance

Because ResolutionMD Mobile is not required to download full DICOM images to your mobile viewing device, the delivery of rendered images from the server to the mobile device over different network types will vary somewhat depending on bandwidth availability i.e. raw speed of the network, either Wi-fi or 3G cellular, and network latency, i.e. inherent delays on the network. In any case, we have observed that once communication is established to the server, the requested image will be fully loaded on the server and available for initial viewing on the mobile device in only a few seconds. Please work with your IT provider or service provider to connect your device with higher bandwidth / lower latency network options to optimize performance.

Warnings

ResolutionMD Mobile should only be used by professionals qualified to review the pathology relevant to the diagnosis.

Precautions

Lighting - ResolutionMD Mobile should not be used in outdoor lighting or other high ambient light conditions. User testing has been conducted validating the use of the ResolutionMD Mobile in lighting conditions up to 220 lux. It is preferable for clinicians to review images in a dark environment, similar to a radiology reading room. Users should familiarize themselves with the viewing characteristics of the device under various lighting conditions and are encouraged to use the built-in ambient light test to test the suitability of their current lighting environment prior to actual use.

Software features – Users must ensure that the software features available on the device are appropriate for the diagnostic requirement prior to actual use.

Screen size and resolution - Users must ensure that the screen size and resolution of the device are appropriate for the diagnostic requirement prior to actual use.

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Brightness settings – The user should be aware that other applications can change the screen brightness setting and ensure the recommended settings are in place prior to each use. Reading sessions must not be interrupted to ensure no changes to the screen brightness are made by other applications.

Battery life – The user should be aware of expected battery life of the mobile device under wireless usage conditions relative to the anticipated duration of usage of the ResolutionMD Mobile application and ensure that the mobile device is adequately charged.

Rounding of bottom corners — Due to system software constraints specific to the iPad client device, about six extreme bottom corner pixels may not be displayed (in order to produce a rounded corner effect) in some zoomed views, particularly when the zoomed image is larger than the display space. Pixels that are not displayed at the corners can be seen by translating the image to bring the corner of interest into the active display area or by reducing the magnification until the entire image lies within the active display area.

Considerations Prior to Use

The software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people who have been appropriately trained in the software's functions, capabilities and limitations.

The user should be aware of the limitations in the accuracy and correctness of the output data displayed on the screen, printed, or exported from ResMD Mobile. The quality of the data is dependent on the correctness of the input data, the user's interaction with the data, the quality, characteristics, and settings of the display device or printer, the amount of ambient light in the vicinity and the necessity to interpolate the data for display purposes. For example, measurement values in ResMD Mobile are dependent on the calibration information provided by the modality in the DICOM header.

While ResMD Mobile has been tested extensively, it is impossible to completely test any piece of software, and errors may remain in the software. It is possible that an error could manifest as an incorrect measurement or image. Users must be aware of the potential for errors.

Device Settings & Condition

The user should ensure that the automatic brightness feature is turned OFF and the brightness of the display set to maximum. The ambient lighting environment should be assessed such that illumination is equivalent to radiology reading rooms to ensure that image quality is maintained.

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The user should ensure that the screen is clean and free from any smudges or marks prior to interpreting a medical image.

Supported Devices

The following devices running iOS 4.3 or higher are tested and approved for use for ResMD Mobile:

- iPhone 4
- iPad

Installing ResMD Mobile

Installation Requirements

1. A properly configured ResolutionMD Server is required.
2. The user requires an account with Apple's App Store.
3. The user will need to have an authorized account on the ResolutionMD Server or be a valid user on the database server.
4. The user requires the IP address or hostname and the port number to connect to the ResolutionMD server.
5. The user needs to know if SSL is being used. If yes, they would need to enable a secure connection option on the mobile devices.
6. The mobile devices require network connectivity to the Internet in order to download ResolutionMD Moblile.
7. The mobile devices will need to be authorized and authenticated on the WiFi network at the using site.

To install ResMD Mobile from the iPhone App Store

1. Tap the App Store icon.
2. Select **Search** from menu at bottom.
3. Enter "ResolutionMD" in the search bar.
4. Select ResMD Mobile from the results list.
5. Tap **Free.**
6. Tap **Install.**
7. Enter iTunes account credentials if required.

To install ResMD Mobile from iTunes

1. Select **iTunes Store** from the source pane.
2. Enter "ResMD" in the search bar.
3. Select ResMD Mobile from the application results list.
4. Click **Free App.**
5. Enter iTunes account credentials if required.
6. Select your device in iTunes.
7. Click **Sync**.

To verify the installation

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1. Ensure you can successfully connect to the ResolutionMD Server, either from the site WiFi network or from the Internet via SSL or VPN connection.
2. Ensure you can successfully authenticate against a user database system.
3. Ensure you can successfully query for studies.
4. Ensure you can successfully view thumbnails.
5. Ensure you are able to successfully open a study/series view the images.
6. Ensure you are able to successfully interact with the images.

Updating

Updates will appear in the App Store when they are available.

To update ResMD Mobile from the iPhone App Store

1. Tap the App Store icon.
2. Select **Updates** from the menu at the bottom of the screen.
3. Select ResMD Mobile from the list of updates.
4. Tap **Update.**
5. Enter your iTunes account credentials if required.

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Configuring ResMD Mobile

You can configure ResMD Mobile in iPhone Settings. The application appears in the list as ResMD.

Setting	Description
Version	Version number for the app.
Prompt for Server	Off by default. The app will access the default server when this setting is off. Enable this setting to be prompted for servers every time you launch the app.
Show Recent Studies	Off by default. For most cases, search is the recommended and more desirable method. Enable this setting to display a list of the most recent studies every time you launch the app.
# Days in Recent Studies	Sets the number of days of recent studies to display. This shows all results from midnight of the last day. E.g. 1d shows all results since midnight of the current day.
Advanced Settings	Settings intended for troubleshooting and support purposes only.

Configuring the Server

On first load, ResMD will prompt you to add a server.

Setting	Description
Server Name	User-selected "friendly" name
Address	Server address and port number
Secure Connection	Ask your system administrator if you will be using a secure connection

To see the server list, do one of the following:

- Enable **Prompt for Server** in iPhone or iPad Settings
- iPad Tap **Servers**
- iPhone Tap **Cancel**

From the server list, you can edit and add servers as well as set the default server. You can also access Help (Instructions, User Guide, and Indications for Use) from here.

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Using ResMD Mobile

Prerequisites for Using

Ensure that your device and your environment are optimal for using ResMD Mobile.

Your Reading Environment

ResolutionMD Mobile should not be used in outdoor lighting or other high ambient light conditions. You should familiarize yourself with the viewing characteristics of the device under various lighting conditions prior to actual use. To ensure optimal viewing conditions, you must set the display brightness to the maximum value and disable any automatic brightness features on the viewing device. (See *Screen Brightness*) Be aware that other applications can change the screen brightness setting and you must ensure the recommended settings are in place prior to each use. You should also perform a light test to ensure that ambient light conditions are appropriate for use. (See *Ambient Light User Assessment*)

Your Device's Screen

- Your device's screen should be clean and free of dirt and fingerprints when reading.
- Image accuracy degrades with viewing angle, so view the screen within 30 degrees of perpendicular.
- To avoid specular reflections, take special care to move to a location without direct light sources such as windows, light boxes, bright walls, and overhead lighting. Examine the display in your device's sleep or off mode for visible reflections and reorient yourself or the display until they are not present.

Screen Brightness

Your iPhone or iPad's screen should be set to maximum brightness.

To set maximum brightness on your iPhone or iPad

1. Tap to open the **Settings** app.
2. Tap **Brightness**. (**Brightness & Wallpaper** on iPad)
3. Drag the brightness slider all the way to the right.
4. Toggle **Auto-Brightness** to **OFF**.

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Using the Search Interface

The search interface appears after you log in on iPhone and iPad (in landscape orientation).

Note	Tap **Search** to show the search interface on iPad in portrait orientation.

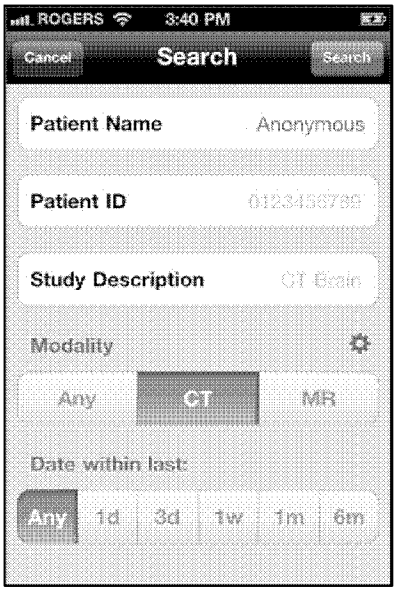

Figure 1: The iPhone Search Interface

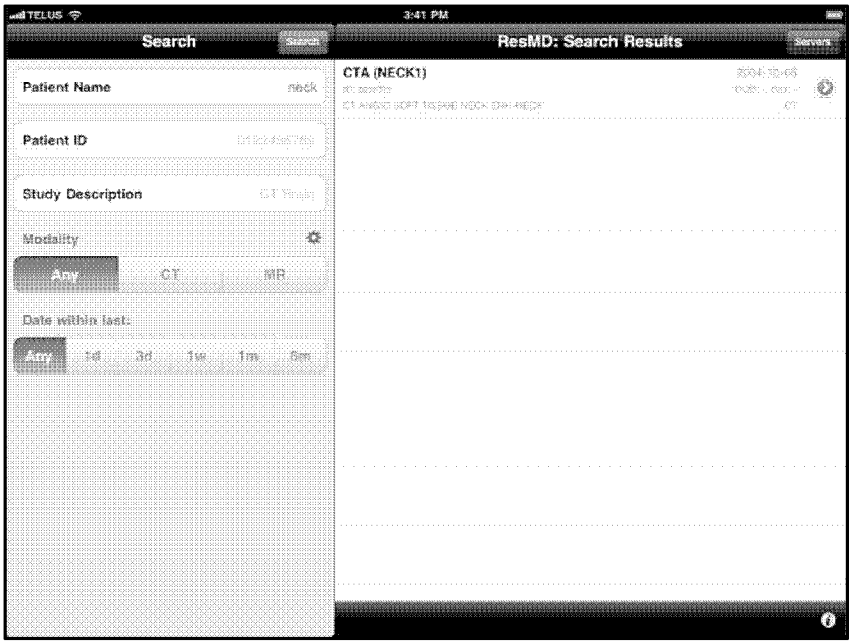

Figure 2: The iPad Search Interface

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To perform a search

1. Enter one or more search criteria.
2. Tap **Search**.

Note	"Date within last" shows all results from midnight of the last day. E.g. 1d shows all results since midnight of the current day.

Sorting Search Results

You can sort the results by your choice of name/ID/date/modality by tapping on their respective column headings.

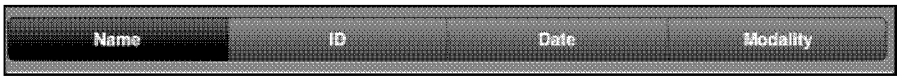

Figure 3: Search Results Column Headings

Loading a Study

To load a study

- **iPhone** Tap the desired study in the search results list. This will display the contents of the study.

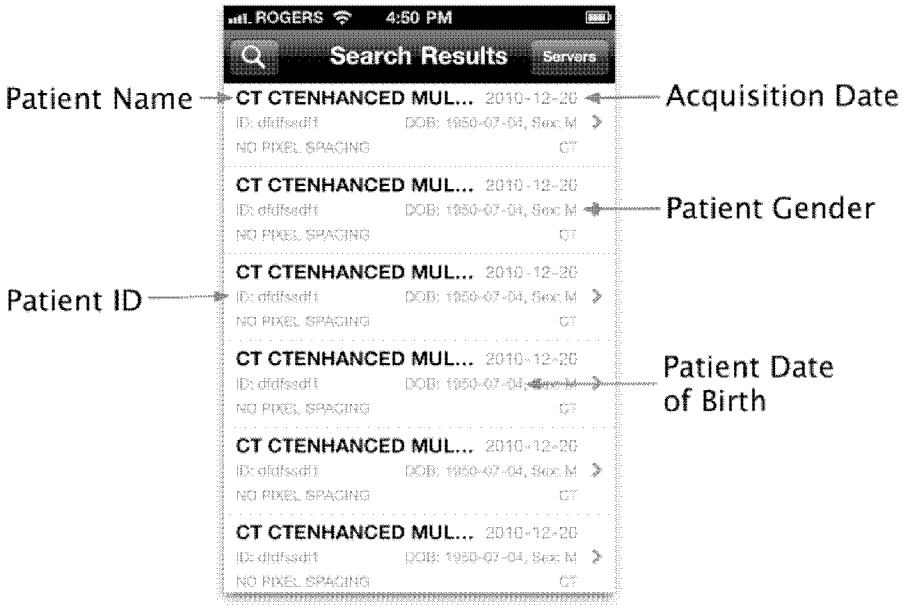

Figure 4: The iPhone Search Results List

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- **iPad**

  Tap the **Study Contents** button in the desired study in the search results list. This will display the study contents popover.

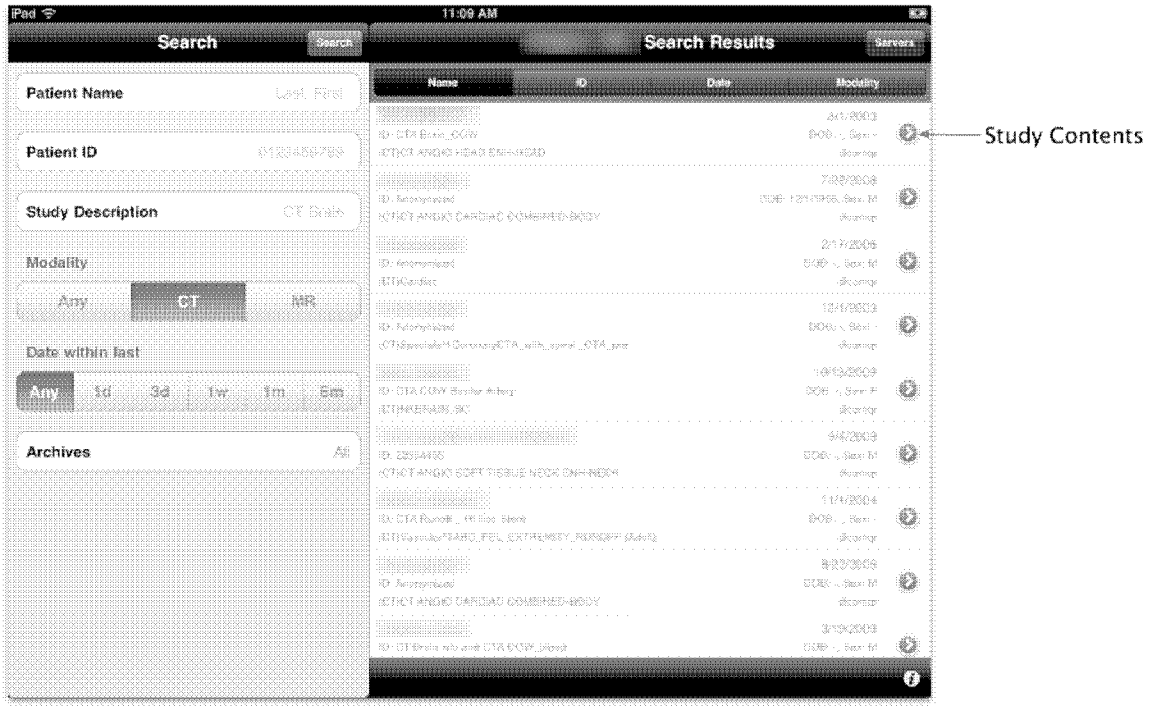

Figure 5: The iPad Search Results List

To load a series

iPhone

- Tap the desired series in the study contents list.

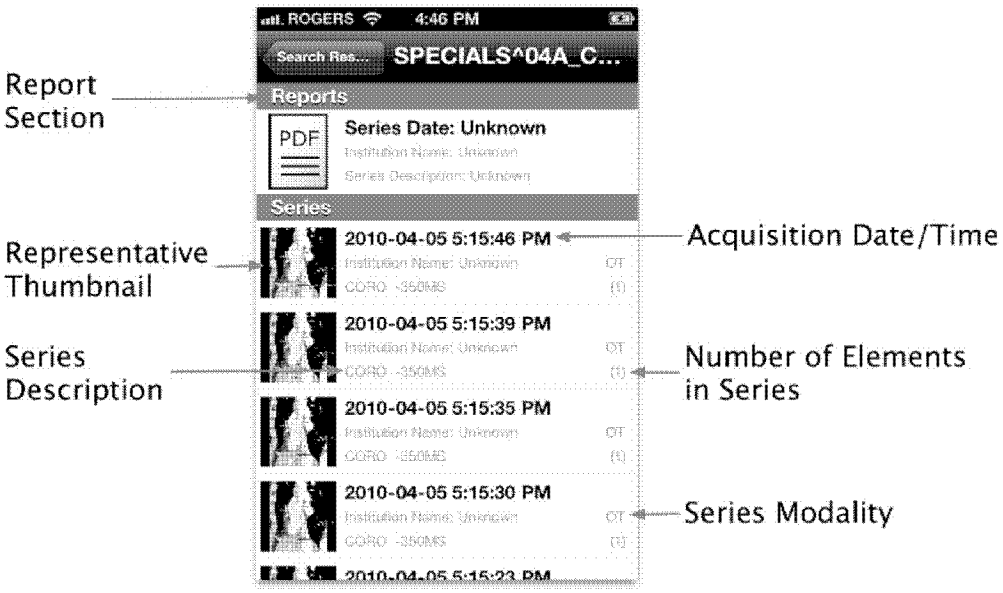

Figure 6: The Study Contents List

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iPad

- Tap the desired series in the study contents popover.

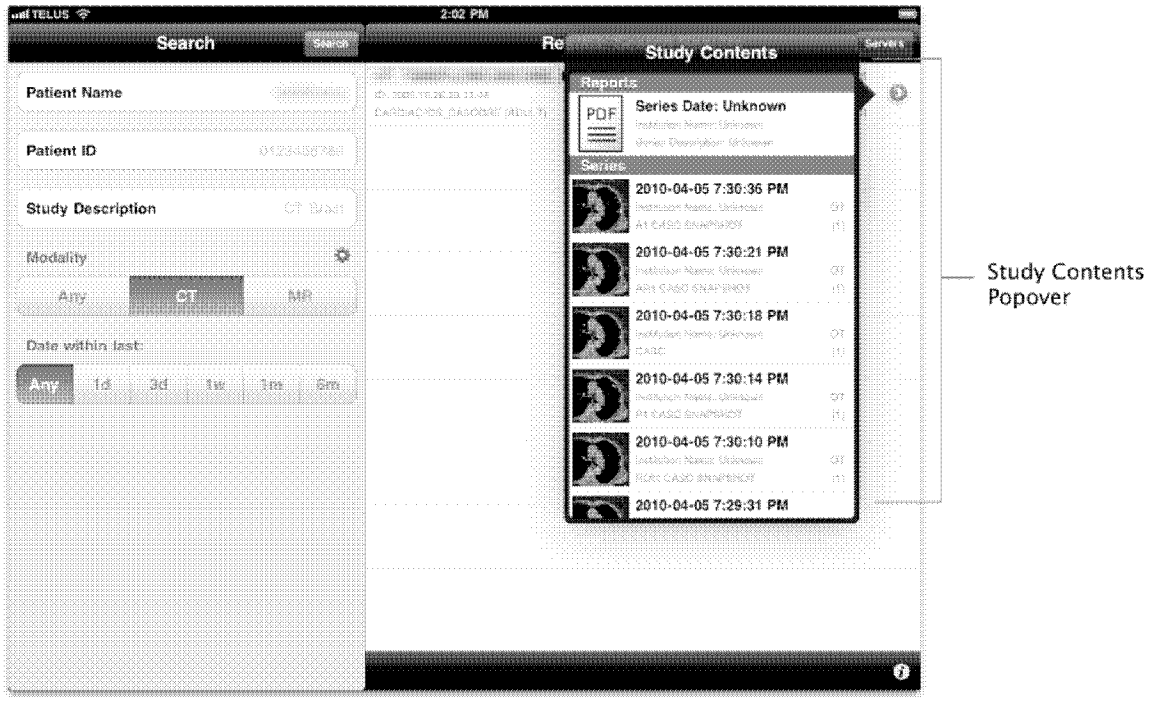

Figure 7: iPad Study Contents Popover

To load a report

- Tap the report in the study contents list.

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If there is more than 1 volume in the series, you will need to choose a volume from the volume list.

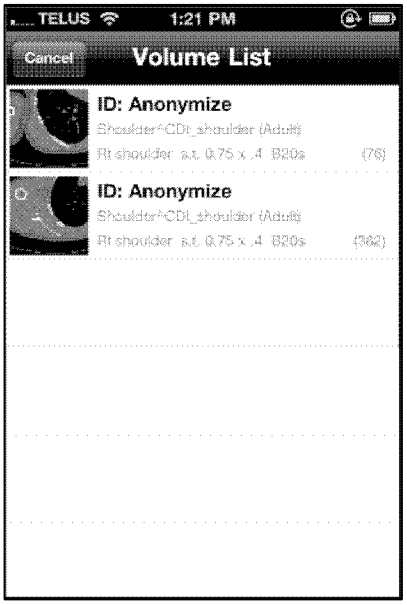

Figure 8: The Volume List

If the volume exceeds the maximum number of slices, you will be presented with the subset selector.

To choose the subset of slices you would like to view

1. Enter the first and last slice numbers of the subset.
2. Tap **Done**.

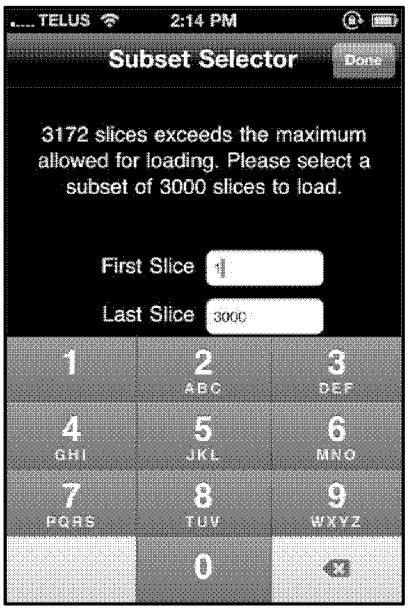

Figure 9: The Subset Selector

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About Source Image Compression

A persistent indication will appear in all views if source images are compressed. In 2D layout, the compression ratio will also be displayed.

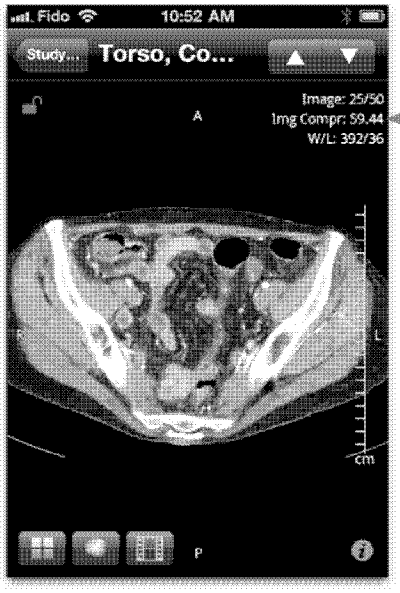

Figure 10: Compressed Source Images in 2D Layout

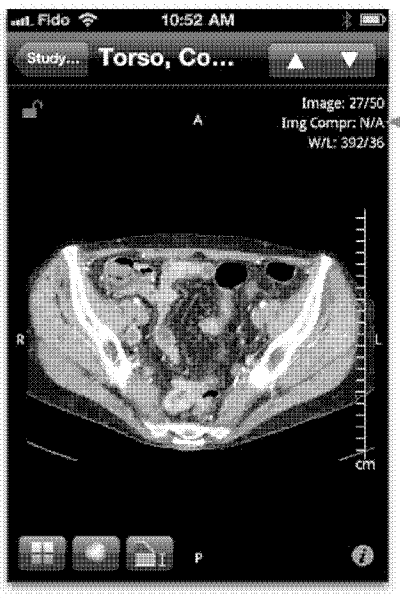

Figure 11: Compressed Source Images in MIP-MPR Layout

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Loading Unsupported Data

ResMD Mobile will notify you if you attempt to load unsupported data. You will be able to view the data, but there will be a persistent warning in red that you are viewing unsupported data.

Figure 12: Unsupported Data Notification

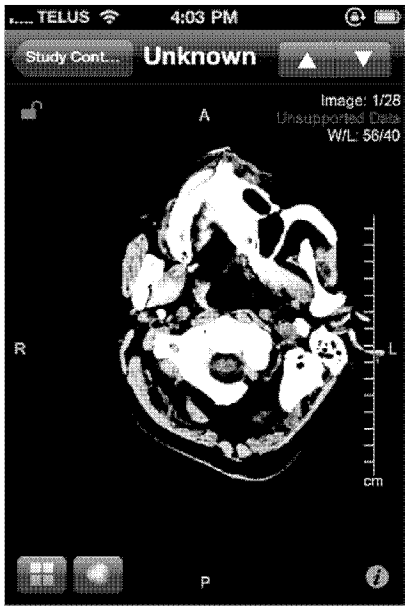

Figure 13: Viewing Unsupported Data

Displaying the Search Interface

- **iPhone**
  You can display the search interface from the search results or recent exams list by tapping the **Search** tool.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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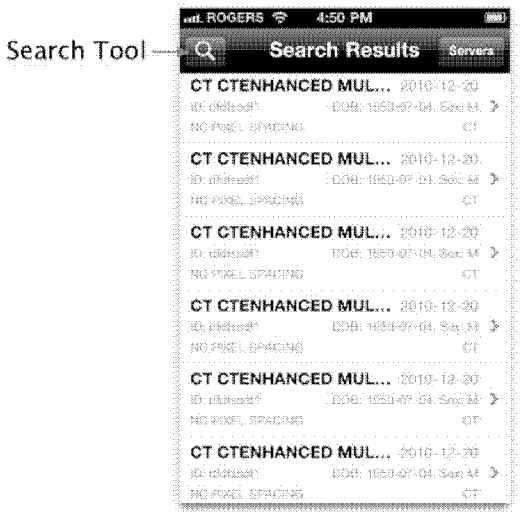

Figure 14: The Search Tool

- **iPad**
  In portrait orientation, you can display the search interface from the search results or recent exams list by tapping **Search**. The search interface is always visible on iPad in landscape orientation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Using Views

Your data set opens in the 2D View.

To select a view

1. Tap the **View Selector**.
2. Select the desired view. (2D, 3D or MIP/MPR)
3. Tap **Done**.

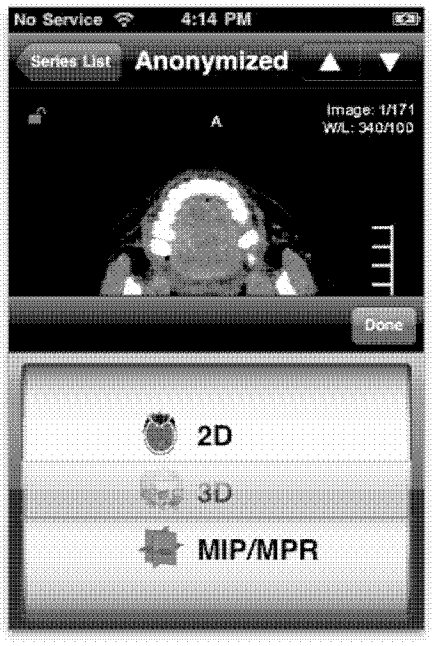

Figure 15: Selecting a View

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2D View

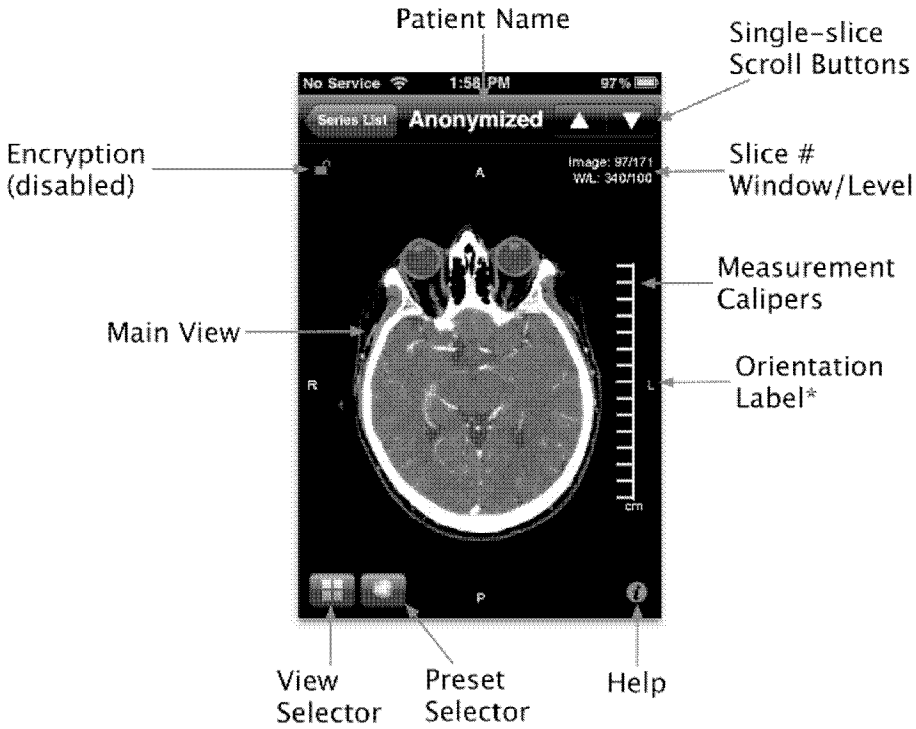

Figure 16: 2D View

*Superior, Inferior, Anterior, Posterior, Left, Right

The Measurement Calipers

The measurement calipers are visible in the 2D and MIP/MPR views. The calipers are a series of marks indicating millimeters or centimeters, depending on the current zoom factor of the image. The spacing of the calipers will adapt to the zoom factor of the image so that measurements are always accurate.

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MIP/MPR View

To change thickness

1. When in MIP/MPR view, tap the **Slab Thickness Selector**.
2. Select the desired thickness.

To change orthogonal view

- Swipe left or right in the main view.

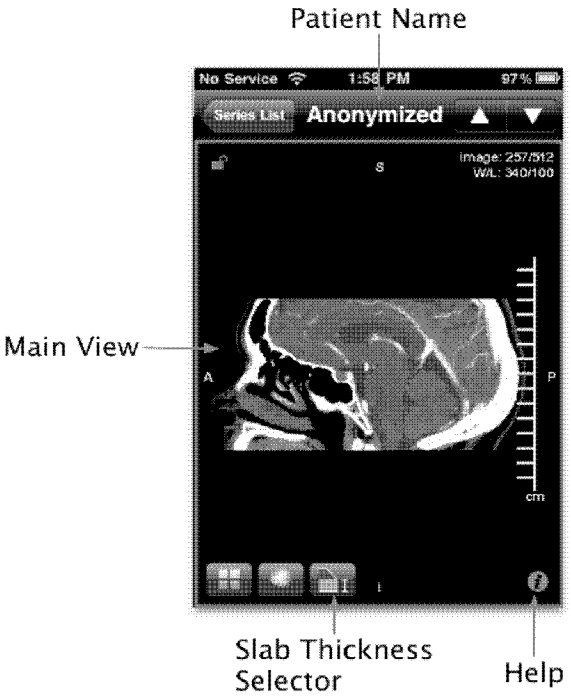

Figure 17: MIP/MPR View

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3D View

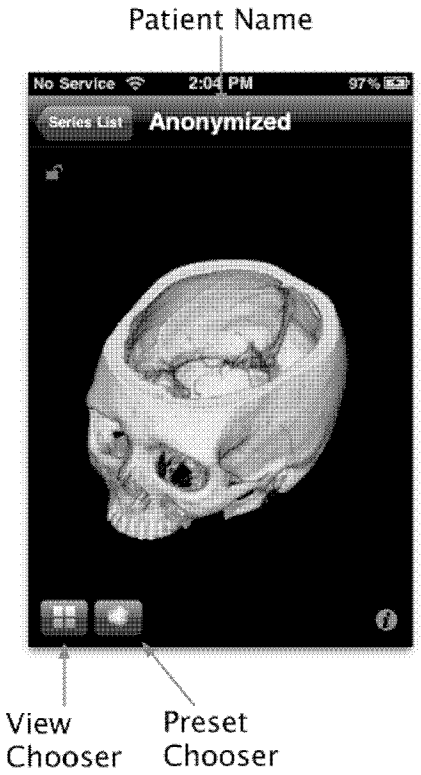

Figure 18: 3D View

Using Presets

To select a preset

1. Tap the **Preset Selector**.
2. Select the desired preset.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Using the Lens Tool (iPad only)

You can use the Lens tool to magnify a select portion of the volume in the 3D Layout while keeping the entire volume in the Main View. A magnified view is displayed in the upper-right corner.

The Lens tool is made up of a lens and a magnified view. The magnified view shows a close-up of the area covered by the lens.

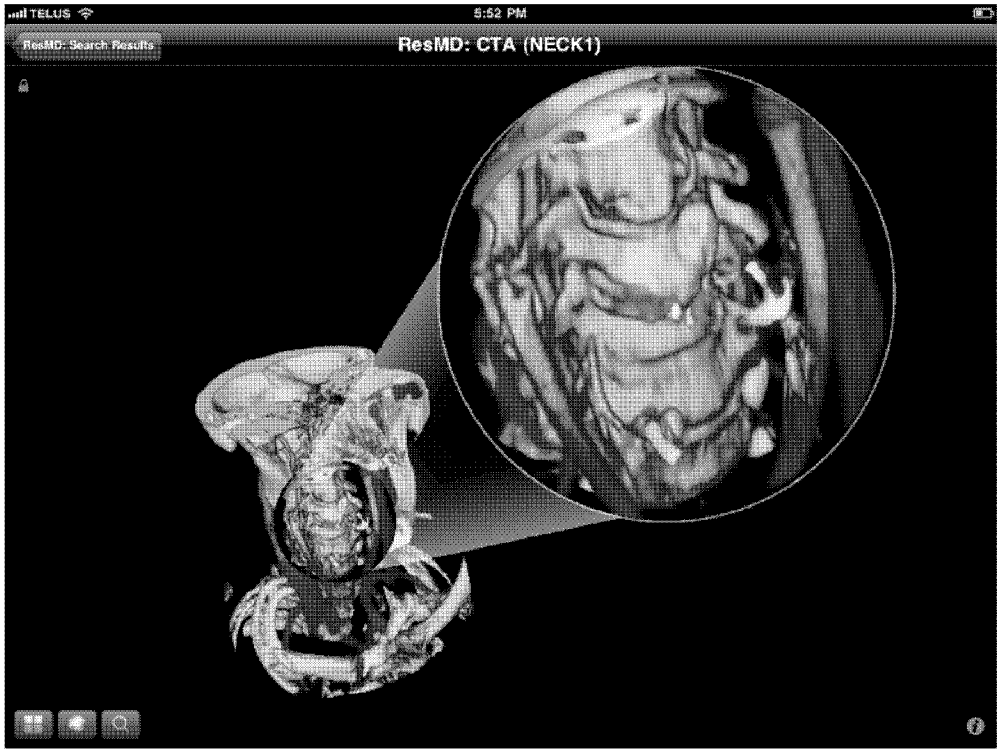
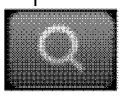


Figure 19: Lens Tool Enabled

To enable the Lens tool, do one of the following:

1. Tap the **Lens** tool.



Note	The Lens tool is only available in 3D Views.

To move the lens over the volume

- Drag the lens.

To adjust the magnification of the lens view

- Pinch or spread two fingers on magnified view.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Adjusting Image Quality

Depending on the quality of your network connection, you can adjust the image quality to fine tune performance. Your adjustments are saved on your device and will be used in the future.

The interactive quality slider adjusts the image quality during interaction with the volume and reduces the amount of network bandwidth used. The final quality slider adjusts the quality of the image after interaction.

Note	User-selected quality settings may result in information loss from the original imagery. For diagnostic reading, the final quality settings should be set to 100. Diagnostic interpretations should not be formed from the interactive images but only from the static, final-quality resulting image.

To adjust image quality

1. Swipe downwards with three fingers in the main layout to reveal the quality sliders.
2. Adjust the quality sliders.
3. Tap anywhere in the main layout to hide the quality sliders.

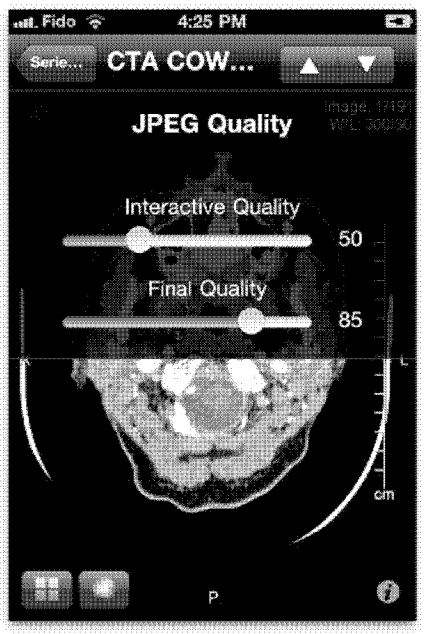

Figure 20: The Quality Sliders

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Interacting with ResMD Mobile

The following tables describe the touchscreen interactions for manipulating the views.

2D View

Functionality	Touchscreen Interaction
Slice Scrolling	Drag up/down (coarse) Tap single-slice scroll buttons (fine)
Win/Level	Tap, drag
Panning	Drag with two fingers
Zooming	Pinch
Reset	Shake

MIP/MPR View

Functionality	Touchscreen Interaction
Slice Scrolling	Drag up/down
Win/Level	Tap, drag
Change Orthogonal View	Swipe left/right
Panning	Drag with two fingers
Zooming	Pinch
Reset	Shake

3D View

Functionality	Touchscreen Interaction
Rotation	Drag
Win/Level	Tap, drag
Panning	Drag with two fingers
Zooming	Pinch
Reset	Shake

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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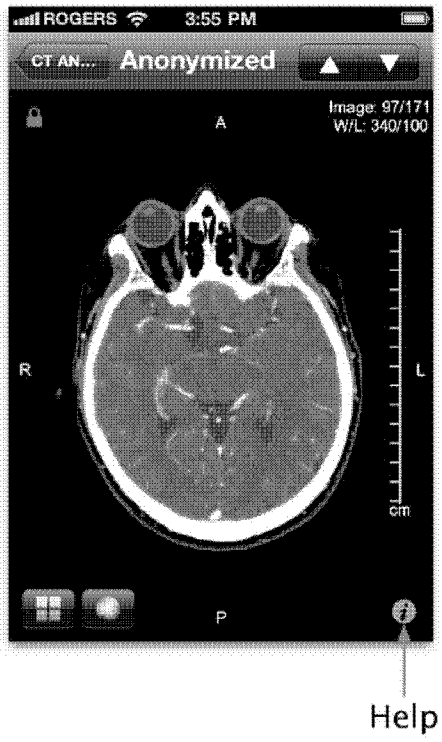
Help

Information is available in the app by tapping **Help**, which also includes this user guide and the Indications for Use.



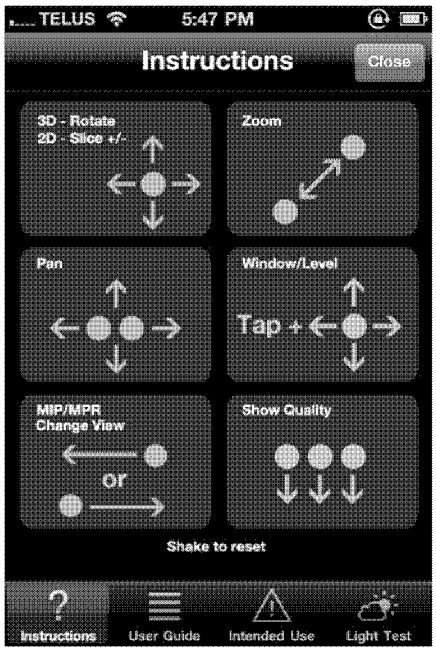


Figure 21: Help

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Assessing Ambient Light

Perform ambient light user assessment to ensure appropriate lighting conditions prior to use.

To perform ambient light user assessment

1. Set your device's display to maximum brightness and disable Auto-Brightness. (See *Screen Brightness*)
2. Tap **Help.**
3. Tap **Light Test.**
4. Tap **Perform Light Test**.

TG18-CT

This pattern is intended to support visual inspection of the luminance response of a display device. It should be evaluated for visibility of the central half-moon targets and the four low-contrast objects at the corners of each of the 16 different luminance regions.

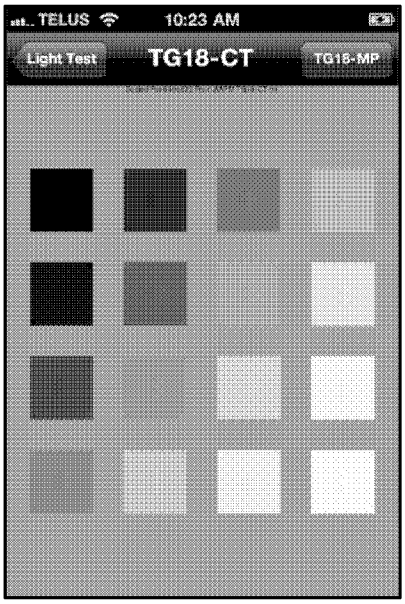

Figure 22: TG18-CT

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TG18-MP

This pattern is intended to support visual inspection of the bit-depth resolution of a display device. It should be evaluated to ascertain the horizontal contouring bands, their relative locations, and grayscale reversals.

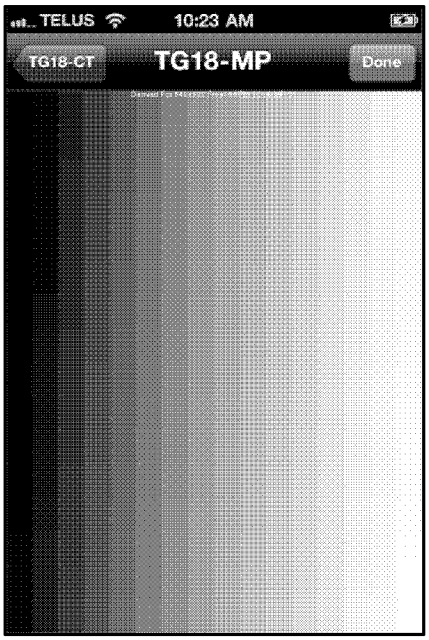

Figure 23: TG18-MP

To assess the suitability of environmental lighting, the user should review these patterns and determine whether their ability to discern the above information is comparable to ideal lighting conditions. If the user indicates that they are not able to perform this task, they will be instructed to find a more appropriate environment before proceeding.

These patterns were developed by the American Association of Physicists in Medicine (AAPM) Task Group 18*, whose purpose is to generate a document that provides guidelines to practicing medical physicists and engineers for in-field performance evaluation of electronic display devices intended for medical use.

* Reference: AAPM ON-LINE REPORT NO. 03: ASSESSMENT OF DISPLAY PERFORMANCE FOR

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Uninstalling ResMD Mobile

ResMD Mobile can be uninstalled like any other iOS app.

To uninstall ResMD Mobile from your iOS device

1. Hold your finger on the ResMD icon.
2. While the icons are jiggling, tap the X that appears on the icon.

Technical Support - Client Issues

Bad Connection

If you are experiencing problems with your Apple iPhone, examine the connection scenarios below to solve your issue.

Case 1: Both a cellular data connection and a Wi-Fi connection are established.

- The application will function under these conditions.

Case 2: A cellular data connection exists, but no Wi-Fi connection.

- The application will function under these conditions.

Case 3: A Wi-Fi connection exist, but a subscriber identity module (SIM) card is not installed.

- The application will function under these conditions.

Case 4: Searching for a cellular data connection when a Wi-Fi connection is established.

- The application will function under these conditions.

Case 5: Searching for cellular network without a Wi-Fi connection established.

- The application will not function under these conditions.

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Solution:
Allow the device time to connect to the cellular provider.
Connect to a Wi-Fi network.

Case 6: A Wi-Fi connection is not established and a SIM card is not installed.

No SIM

- The application will not function under these conditions.

Solution:
- Ensure the device is on a Wi-Fi network.
- Insert a SIM card or reseat the SIM card.

Bad Configuration

If you are experiencing problems with your mobile client, ensure that your server credentials are configured correctly on your mobile device.
- Ensure that the hostname is correct.
- Ensure that your port is correct.
- If your server requires SSL, ensure SSL is ON and use port 8443 instead of 8080.

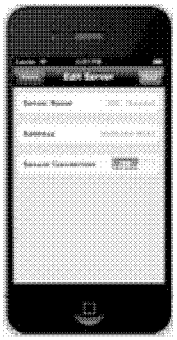

Figure 24: Mobile Device Configuration

Bad Username/Password

1. Ensure that your ResolutionMD plugin is configured to talk to the authentication webservice, knows the hostname/IP of the ResolutionMD Server, and has access to a username and password from the ResolutionMD user management system.
2. Navigate to http://<hostname>:8080/pureweb/server/status.
3. Enter a user/password from a defined user in the system.

If access is granted to the ResolutionMD status page then authentication is working.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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No Images

If you are not able to load or view any images on your mobile client, ensure that the following are configured correctly:

- The back association to the ResMD server is correctly configured.
- Your PACS system is configured correctly with the ResMD server.
- Recent Studies on your mobile device is correctly turned on or off.
- The PACS system has data.

No Reports

If you are unable to load reports, see the troubleshooting details below:
Retrieve an Accession Number/ Exam ID of a recent exam that has a report.
Construct the following URL to test report access:
http://<hostname>:8080/pureweb/resmd/report/<accessionNumber>.

Contacting Calgary Scientific Support

Contact Calgary Scientific Support during the hours of 9:00AM - 5:00PM, Monday - Friday (Mountain Standard Time).

Web Site Telephone E-Mail
http://calgaryscientific.onconfluence.com
(403) 270-7159
support@calgaryscientific.com

Customer and technical support information can be found at www.calgaryscientific.com/contact/customer-technical-support.html.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118