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September 8, 2014

US FDA
CDRH
Document Control Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

K133983/A1

FDA CDRH DMC

SEP 09 2014

Received

Subject: K133983/S002 Pre-Market Notification for the Intra.Ox Handheld Tissue Oximeter

Attn: Frank Lacy
Electrical Engineer Cardiac Diagnostic Devices Branch Division of
Cardiovascular Devices
FDA/CDRH/ODE

Dear Mr. Lacy:

Thank you for your contacting us about needing some additional clarifications and changes to our Special 510(k) submission. ViOptix Inc. is enclosing an electronic copy (eCopy) of this submission on a CD in accordance with FDA's "Guidance for Industry and Food and Drug Administration Staff, eCopy Program for Medical Device Submissions", issued October 10, 2013. The eCopy is an exact duplicate of the paper copy.

We have contacted – Joshua Pferer for questions 1 and 2, Tanya Farooque, Ph.D. for question 3 and Jacqueline Francis, M.D., MPH for questions 4 and 5. We have provide each with our response to their questions in writing and have followed up with each by phone to ensure that the responses were satisfactory. We have been assured by each that our responses, as written, were adequate.

Below we have shown the questions from the reviewers with our responses (exactly as had been given to each reviewer). Questions are shown in bold italics.

Thank you for your review, help and phone call follow-ups. Any further questions, please feel free to contact me at any time.

Sincerely,

A handwritten signature in blue ink that reads "Greg Holland". The signature is written in a cursive, flowing style.

Greg Holland
Regulatory Specialists, Inc.
Regulatory Consultant to ViOptix Inc.



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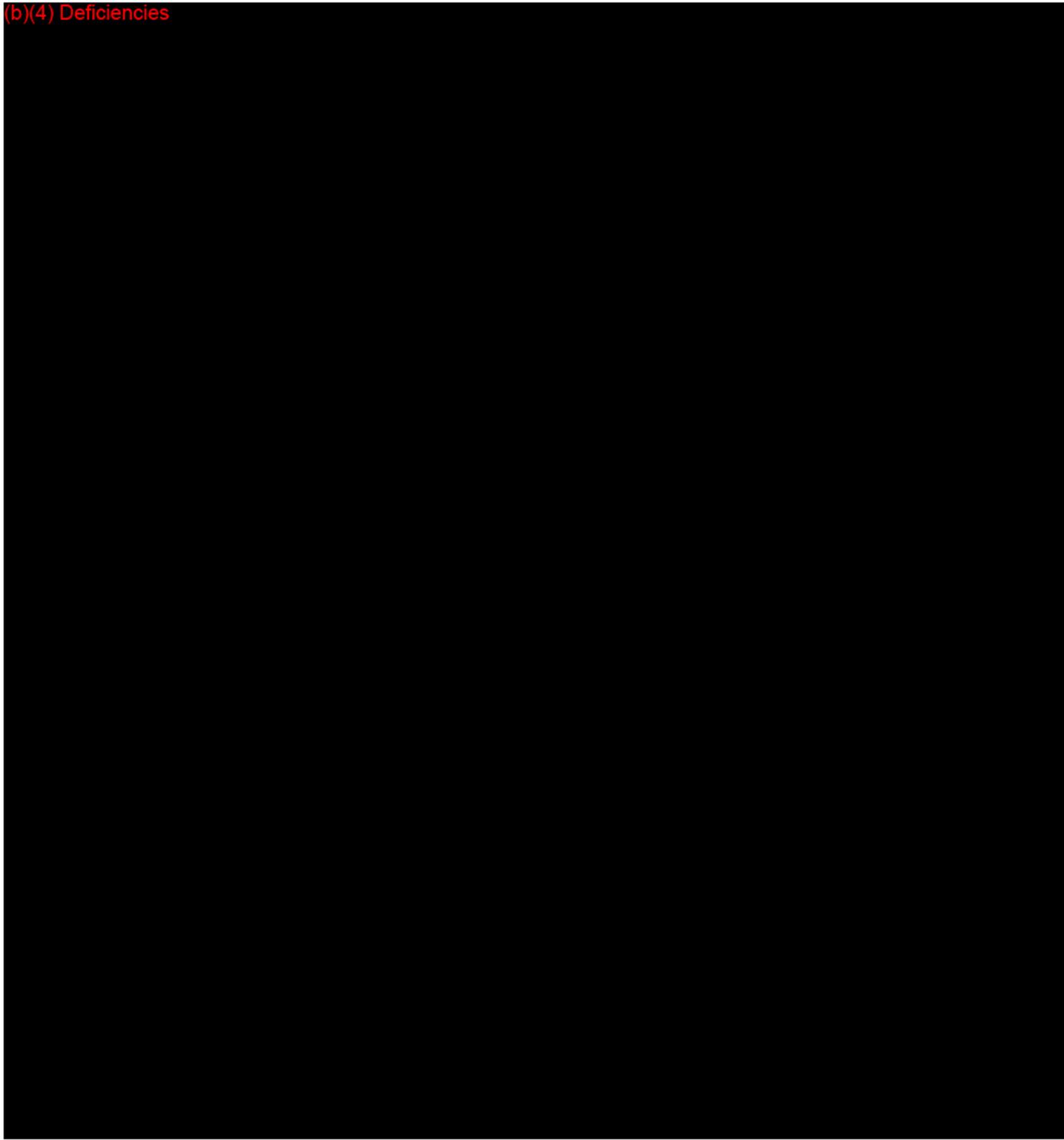
(b)(4) Deficiencies



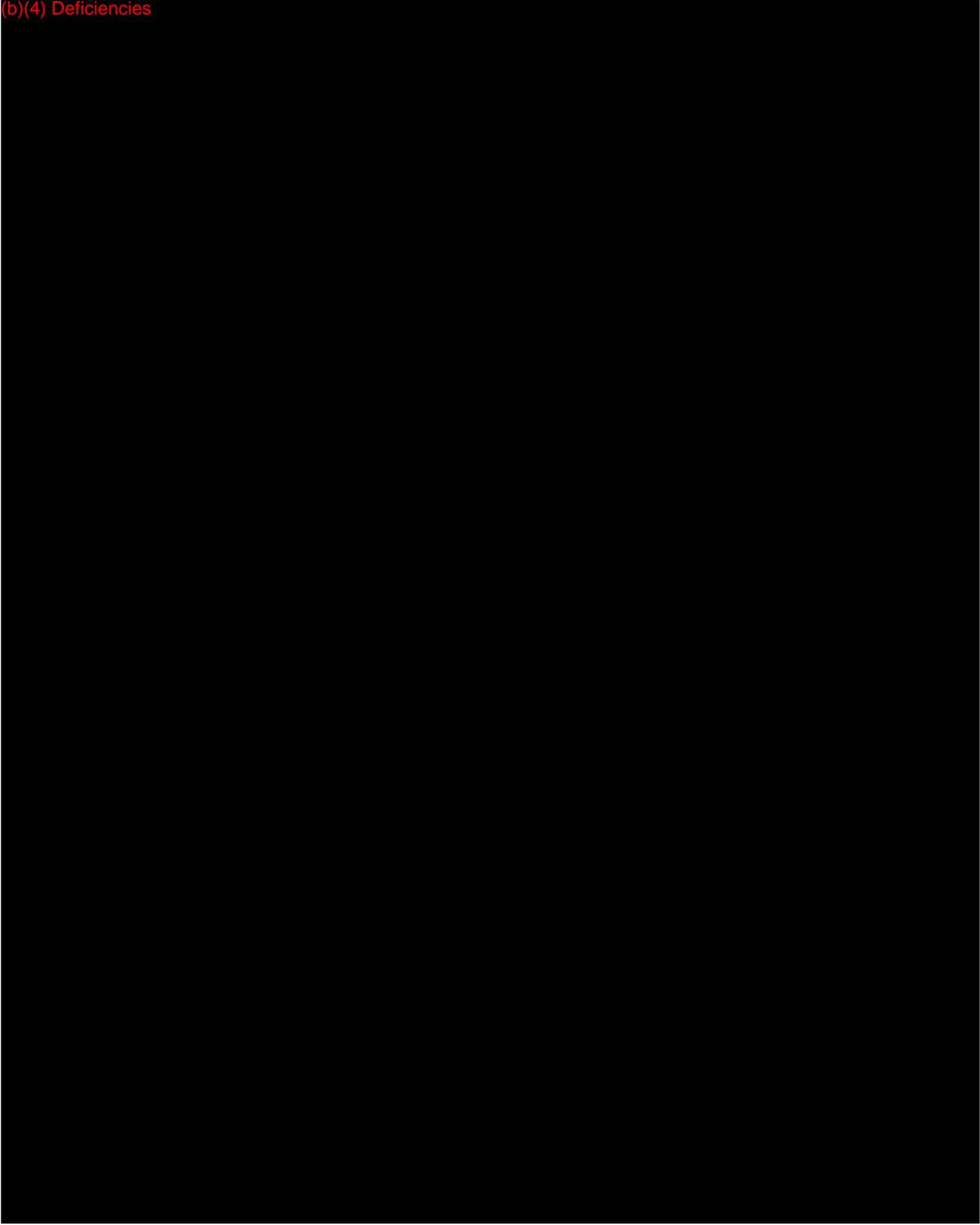
(b)(4) Deficiencies



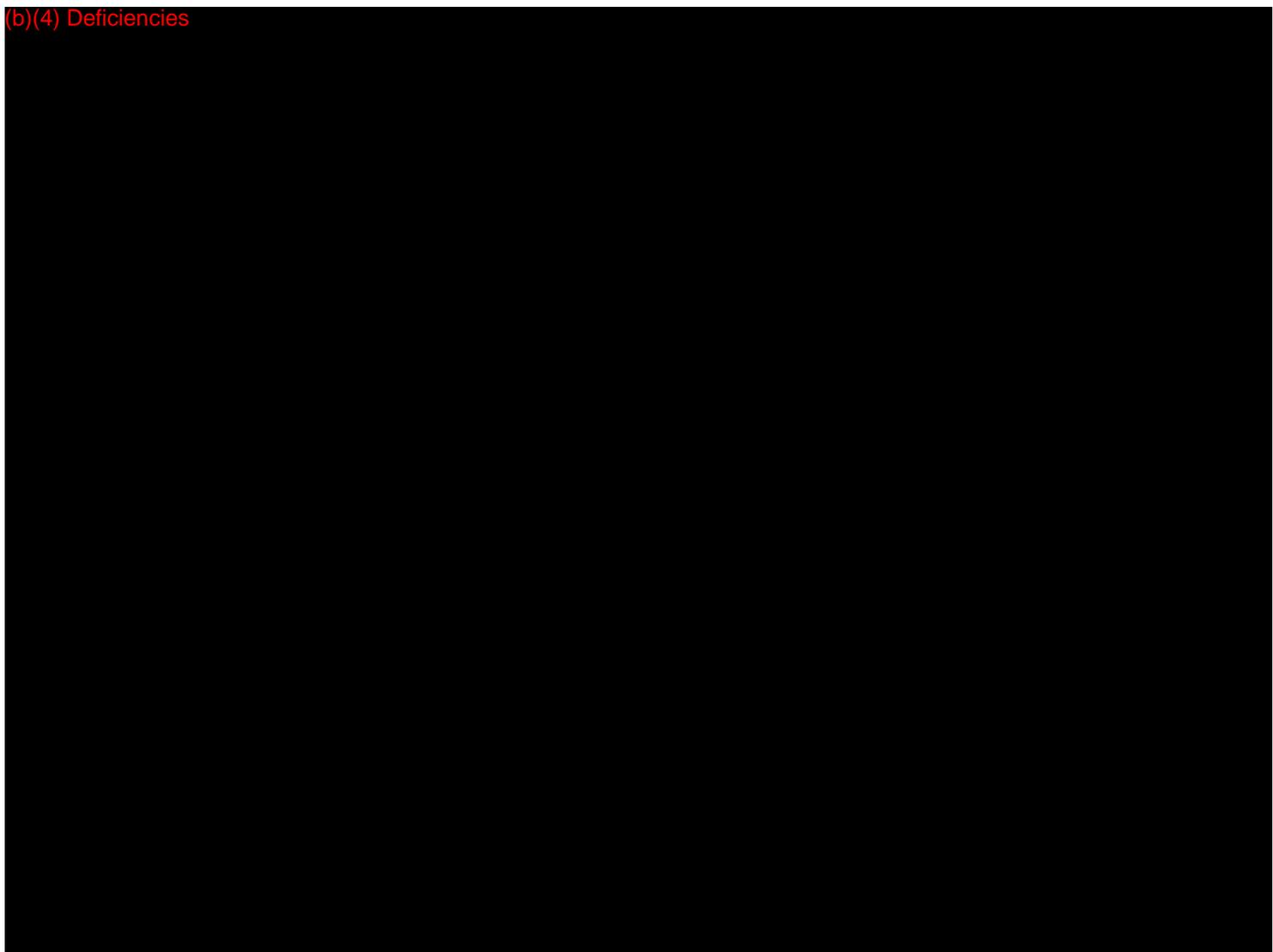
(b)(4) Deficiencies



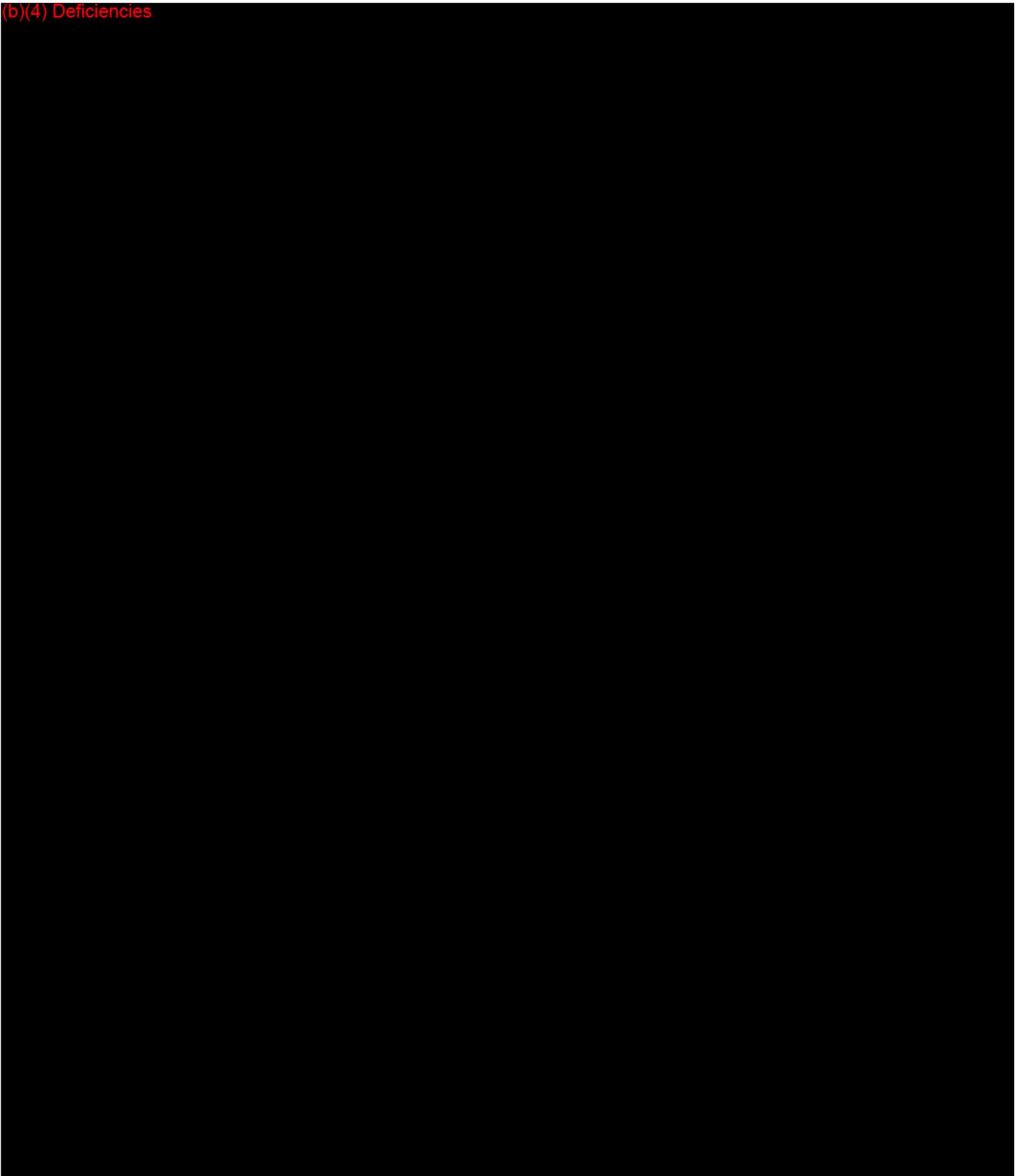
(b)(4) Deficiencies



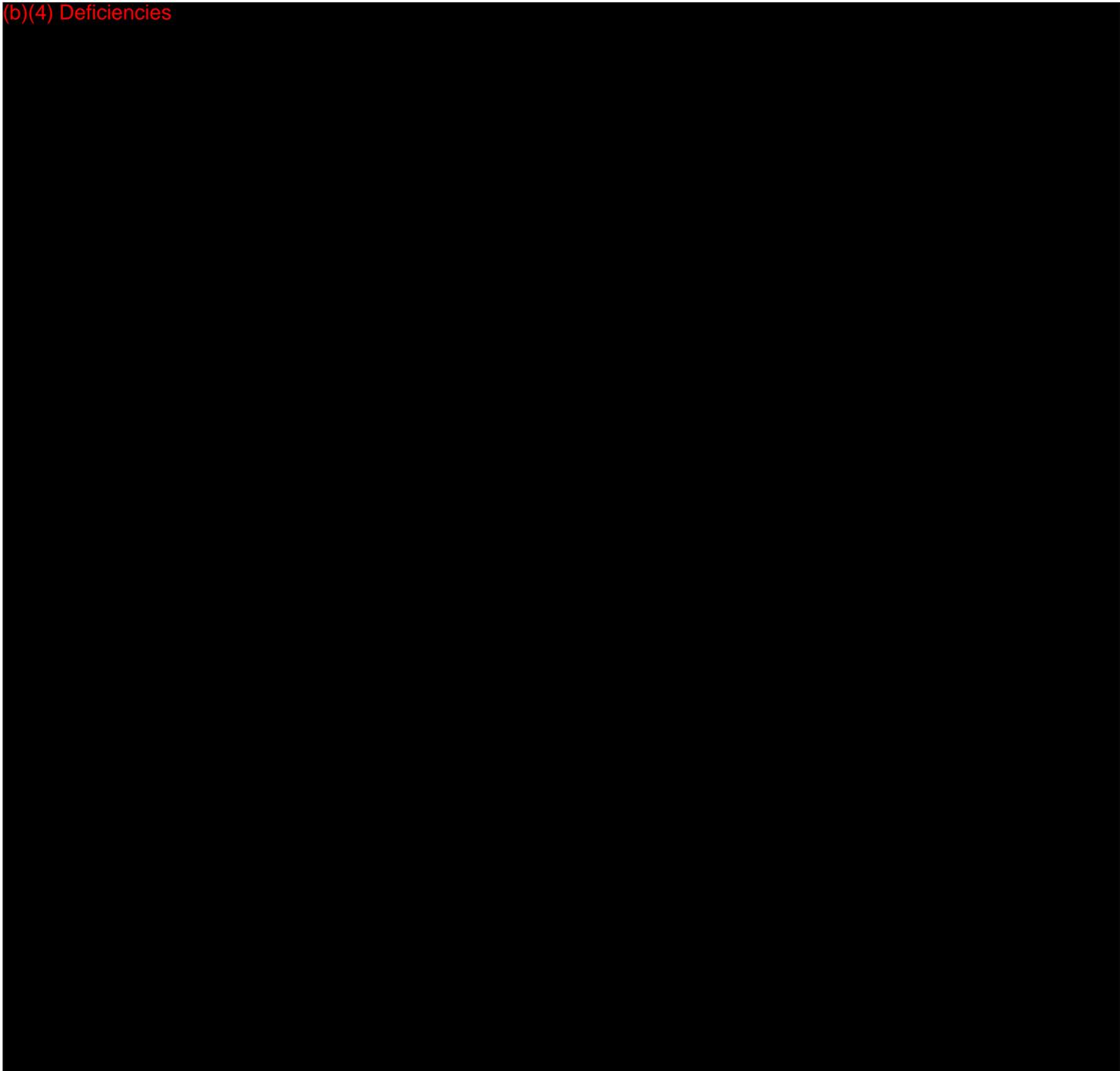
(b)(4) Deficiencies



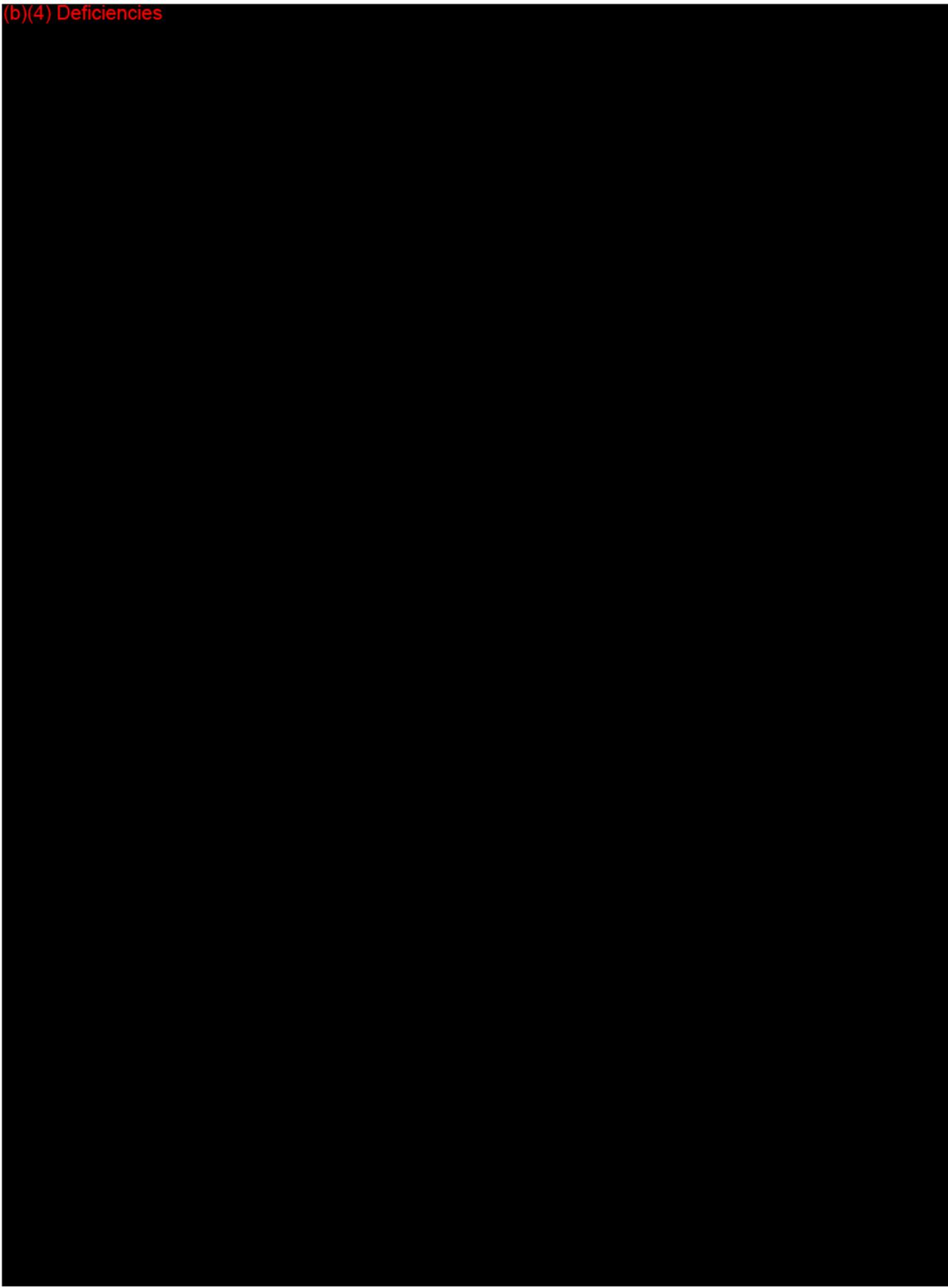
(b)(4) Deficiencies



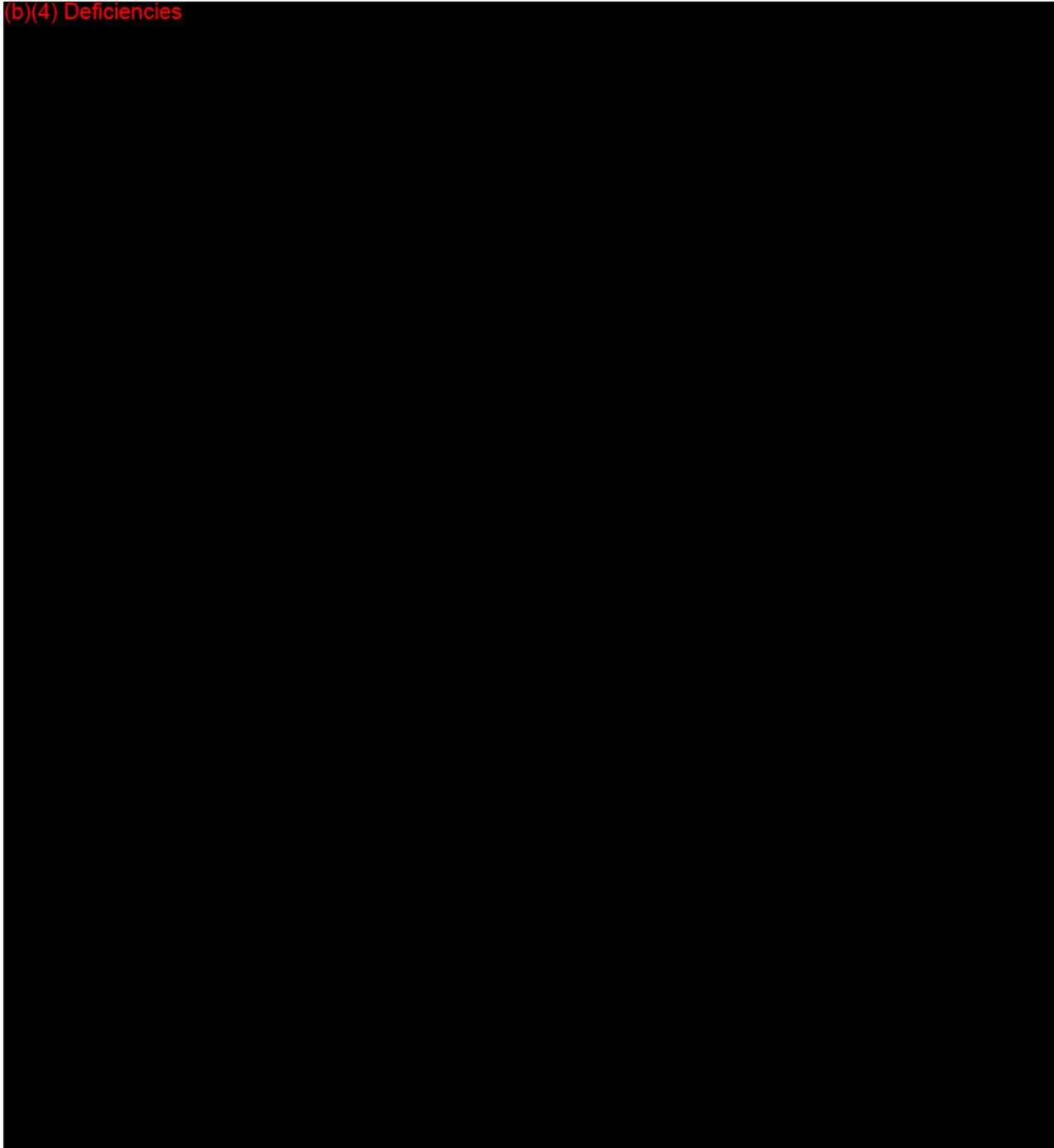
(b)(4) Deficiencies



(b)(4) Deficiencies



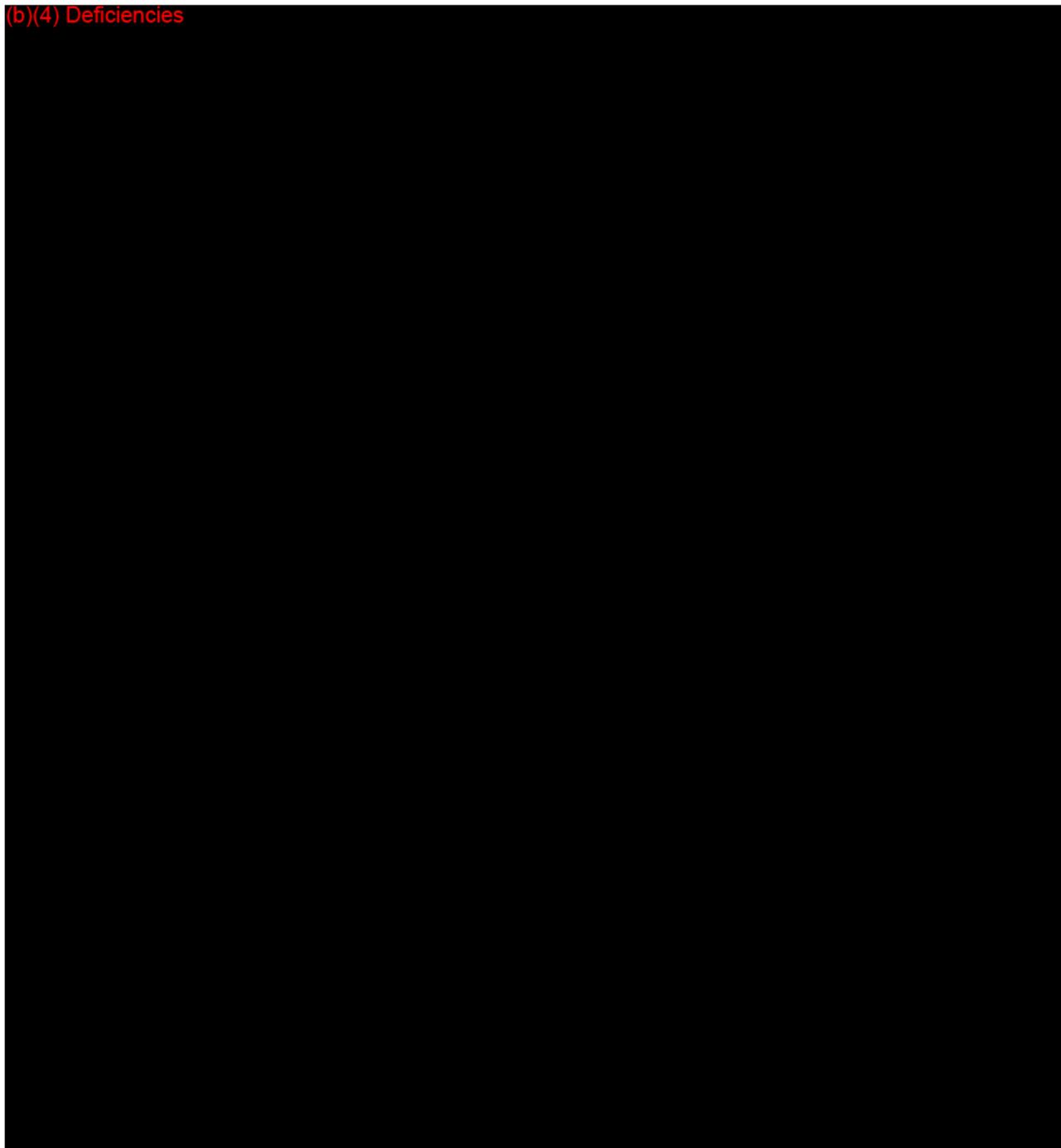
(b)(4) Deficiencies



(b)(4) Deficiencies



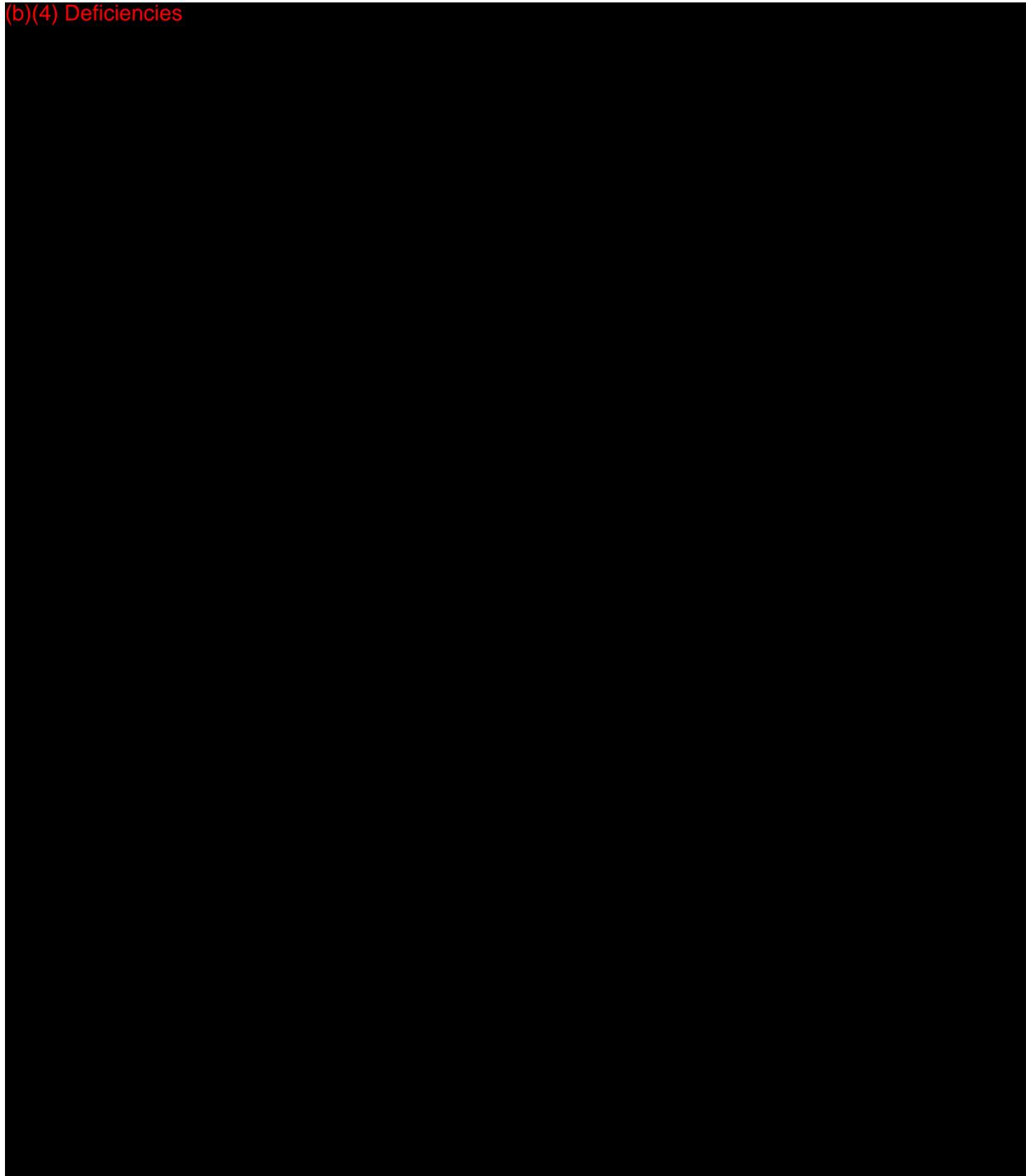
(b)(4) Deficiencies



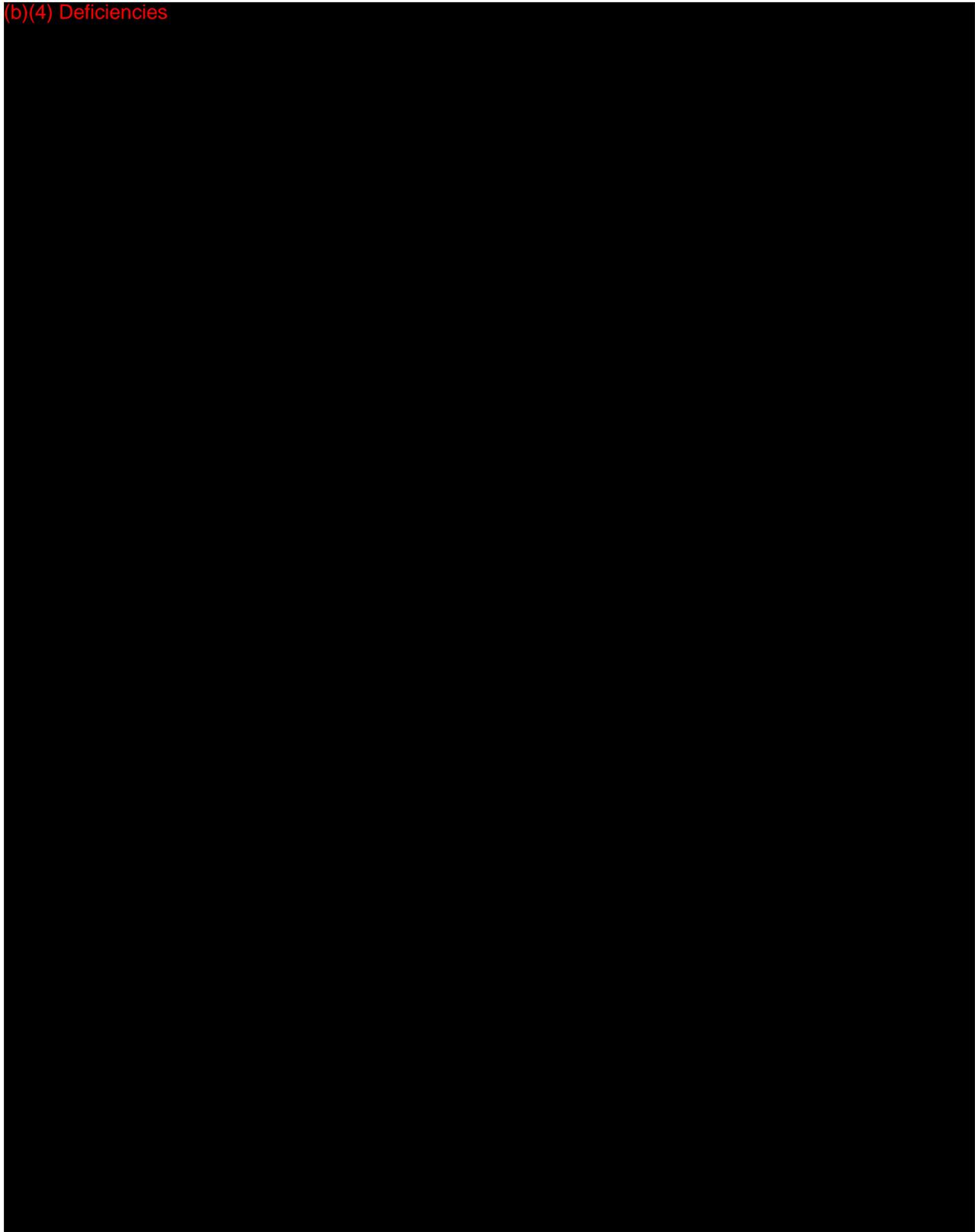
(b)(4) Deficiencies



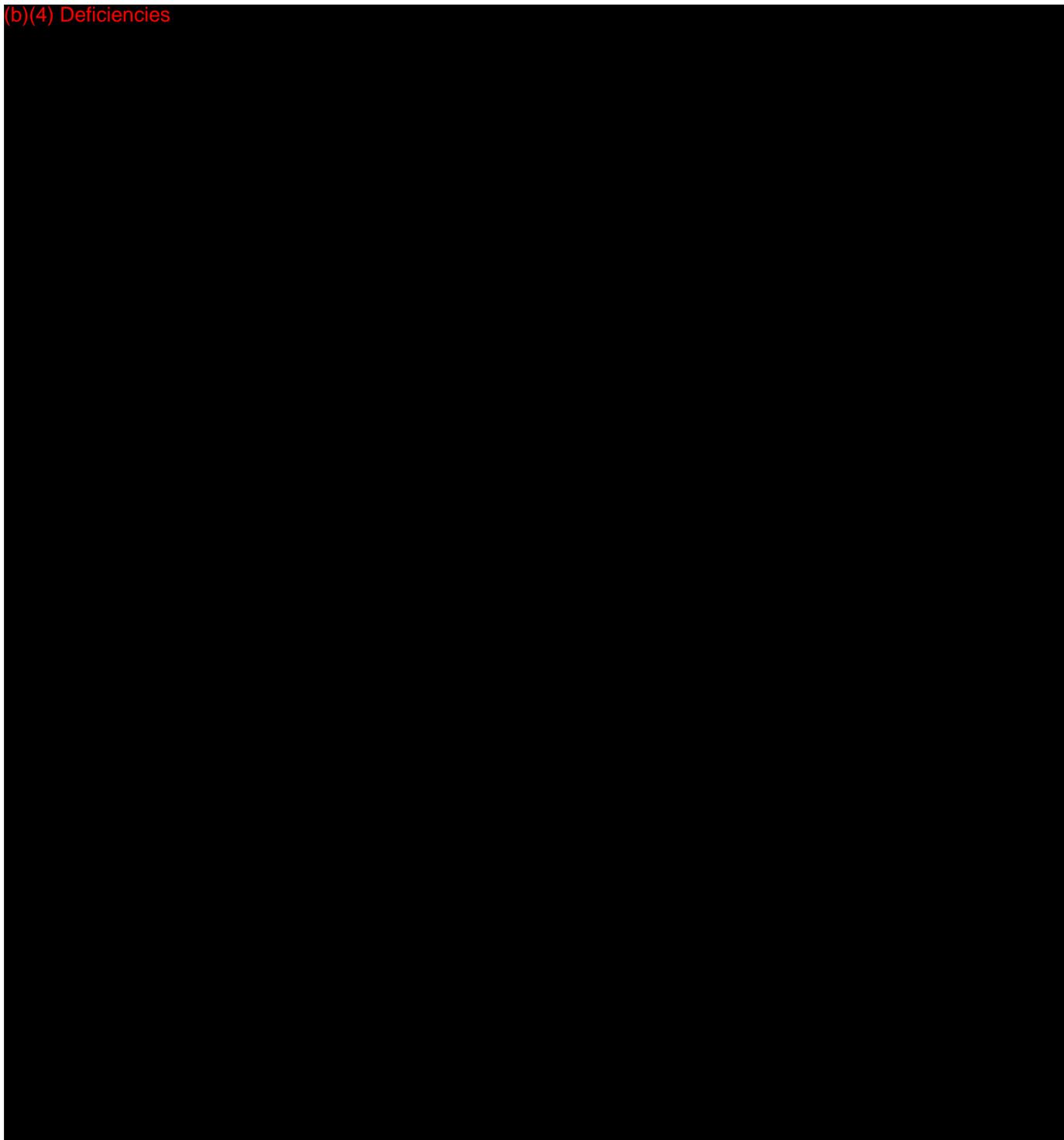
(b)(4) Deficiencies



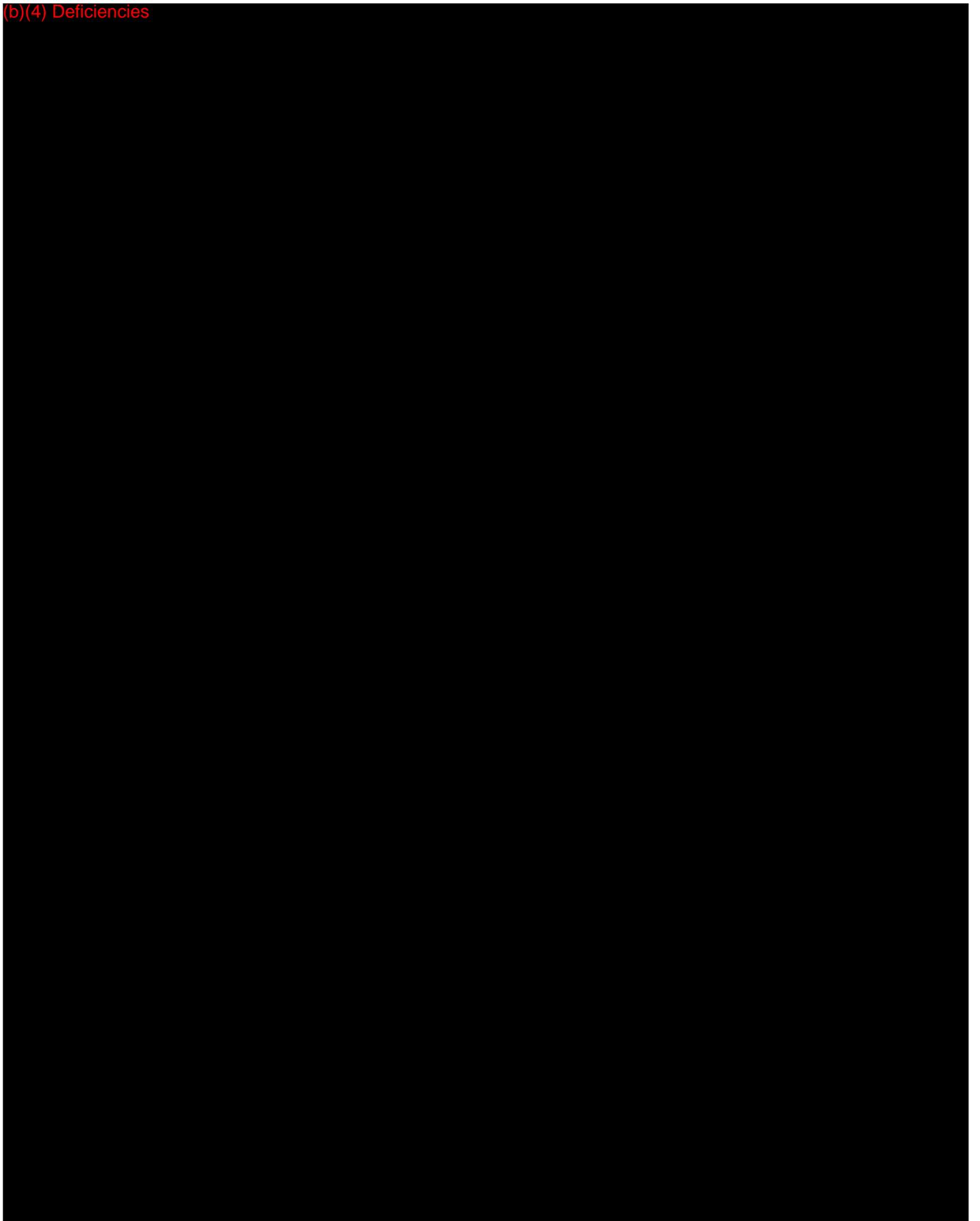
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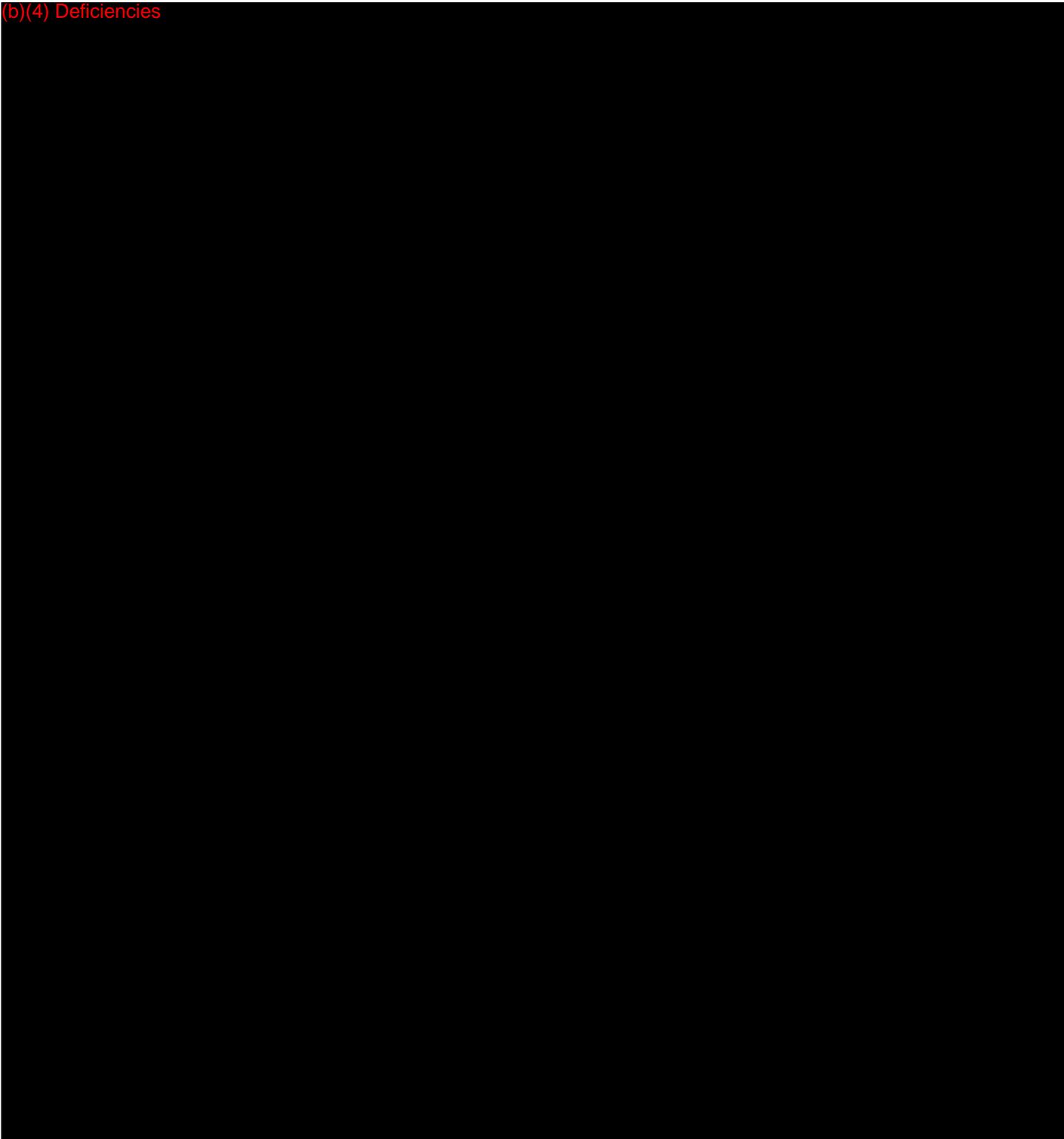
(b)(4) Deficiencies



(b)(4) Deficiencies



(b)(4) Deficiencies



3. 510(k) Cover Letter



47224 Mission Falls Ct.
Fremont, CA 94539
510-226-5860
info@vioptix.com

December 20, 2013

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

Subject: Traditional Premarket Notification (510(k)) for Intra.Ox™ Handheld
Tissue Oximeter

Attention: Document Mail Clerk

Pursuant to section 510(k) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807.87, please find the premarket notification for the Intra.Ox™ Handheld Tissue Oximeter, a new device to be marketed by ViOptix, Inc. There are no prior submissions for the subject device.

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

ViOptix wishes to use its own device, the ODISsey Tissue Oximeter (reference number K042657), as the predicate. The ODISsey Tissue Oximeter was renamed the T.Ox Tissue Oximeter (2009), and is thus referred to as the T.Ox in this submission. The primary differences between the Intra.Ox™ Handheld Tissue Oximeter and the T.Ox Tissue Oximeter are as follows:

- The Intra.Ox™ Handheld Tissue Oximeter is an integrated handheld unit (designed for disposable single-use), whereas the T.Ox Tissue Oximeter is a console with replaceable sensors.
- The Intra.Ox™ Handheld Tissue Oximeter has additional detectors (8 as compared to T.Ox's 4).

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- The Intra.Ox™ Handheld Tissue Oximeter has additional wavelengths of light (4 as compared to T.Ox's 2).
- The Intra.Ox™ Handheld Tissue Oximeter utilizes wavelengths such that methylene blue, a common medical dye, is not an interferent.

Information regarding ViOptix:

Submitter's Name ViOptix, Inc.
Address 47224 Mission Falls Ct., Fremont, CA 94539
Contact at ViOptix Mark Lonsinger
Telephone 510-360-7506
Fax 510-226-5864
Email lonsingerm@vioptix.com

Information regarding Application Correspondent:

Official Correspondent Greg Holland
Address Regulatory Specialists, Inc
3722 Ave. Sausalito
Irvine, CA 92606
Telephone 949-262-0411
Email greg@regulatoryspecialists.com

Information regarding the device classification:

Trade Name: Intra.Ox™ Handheld Tissue Oximeter
Common Name: Tissue Oximeter
Classification regulation: 21 CFR 870.2700
Classification regulation name: Oximeter
Classification Panel: Cardiovascular
Product code: MUD
Device Class: II
Basis for Submission: New Device

The principal factors about the design and use of the device are shown in Table 3-1, below.

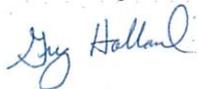
Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

Table 3-1

The eCopy is an exact duplicate of the paper copy.

Please feel free to contact me directly at 949-262-0411 if you have any questions.

Sincerely,



Greg Holland
Regulatory Specialist to ViOptix, Inc.

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- 001_Appendix 16A - V (b)(4) Intra.Ox_Level of Concern Analysis.docx
- 002_Appendix 16B - (b)(4) Risk Analysis.doc
- 003_Appendix 16C - (b)(4) ViOptix Intra.Ox System Requirements Specification VRS.docx

004_Appendix 16D - (b)(4) _Architecture Design and SDS Intra.Ox
VRS
005_Appendix 16E - (b)(4) _Intra.Ox System Traceability
(b)(4) f
006_Appendix 16F - (b)(4) _Intra.Ox Software Build Machine
Configuration (b)(4)
007_Appendix 16G - (b)(4) _Intra.Ox Software Build Instructions
(b)(4)
008_Appendix 16H (b)(4) _Intra Ox Verification and Validation
Plan.docx
009_Appendix 16I - (b)(4) Tissue Oximeter Design Verification
Protocol.pdf
010_Appendix 16J - (b)(4) ScannedVerification Report ReducedSize.pdf
011_Appendix 16K - V (b)(4) _Revision History (b)(4)
012_Appendix 16L - V (b)(4) _Unresolved Anomolies (b)(4)

**RTA Acceptance Checklist for Traditional 510(k)s
Preliminary Questions**

		YES	N/A	NO
1.	Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21CFR3.2 (e)) with a device constituent part?	X Device		
2.	Is the application with the appropriate Center?	X		
3.	If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?		X	
4.	b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?		X	
5.	Is this device type eligible for a 510(k) submission?	X		
6.	Is there a pending PMA for the same device with the same indications for use?			X
7.	If clinical studies have been submitted, is the submitter the subject of the Application Integrity Policy (AIP)?			X

Organizational Elements

		YES	N/A	NO
a.	Submission contains Table of Contents	X		
b.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
c.	All pages of the submission are numbered.	X		
d.	Type of 510(k) is identified – traditional, abbreviated, or special	X		

**Elements of a Complete Submission (RTA Items)
 (21CFR807.87 unless otherwise indicated)**

		Page #	YES	N/A	NO
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		X		
2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		X		
	a. Device trade name or proprietary name	20, 24	X		
	b. Device common name	20, 27	X		
	c. Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	24	X		
3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) in appropriate format.	26			
4.	Submission contains 510(k) Summary or 510(k) Statement	27			
	a. Summary contains all elements per 21CFR807.92		X		
	b. Statement contains all elements per 21 CFR 807.93			X	
5.	Submission Contains Truthful and Accuracy Statement per 21 CFR 807.84(k)	32	X		
6.	Submission contains Class III Summary and Certification	33	X		
7.	Submission Contains clinical data		X		
	a. Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission.	34, 35	X		
	b. Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial	174	X		

		Page #	YES	N/A	NO
	included in the submission. <i>Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)</i>				
8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654)	37-53	X		
9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.			X	
	a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed.			X	
B.	Device Description				
10.	a. If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement			X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or			X	

		Page #	YES	N/A	NO
	regulatory criteria through an alternative approach.				
11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
	a. A description of the principle of operation and mechanism of action for achieving the intended effect.	61	X		
	b. A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	61-81	X		
	c. A list and description of each device for which clearance is requested.	61	X		
12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	61-64	X		
13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system,			X	
	a. Submission includes a list of all components and accessories to be marketed with the subject device.			X	
	b. Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory			X	
	c. A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C.	Substantial Equivalence Discussion				
14.	Submitter has identified a predicate device.	20, 23, 27	X		
	a. Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status.	20, 23, 27	X		

		Page #	YES	N/A	NO
	b. The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.		X		
15.	Submission includes a of the following for the predicate(s) and subject device				
	a. Indications for Use	55	X		
	b. Technology, including features, materials, and principles of operation	56	X		
16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	90-91	X		
D.	Proposed Labeling (see also 21 CFR part 801)				
17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use	97-114	X		
	a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	97	X		
	b. Submission includes directions for use that <ul style="list-style-type: none"> • include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, 	97, 99-100	X		

		Page #	YES	N/A	NO
	contraindications) (21 CFR 801.5) AND • Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D				
18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol	110	X		
19.	General labeling provisions				
	a. Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	110	X		
	b. Labeling includes device common or usual name (21 CFR 801.61)	110		X	
20.	a. If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
	c. If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and			X	

		Page #	YES	N/A	NO
	effectiveness.				
21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E.	Sterilization				
	Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> provided sterile <input type="checkbox"/> provided non-sterile but sterilized by the end user <input type="checkbox"/> non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.	25, 27, 54, 28, 61, 114	X		
22.	Assessment of the need for sterilization information				
	a. Identification of device, and/or accessories, and/or components that are provided sterile.	25	X		
	b. Identification of device, and/or accessories, and/or components that are end user sterilized			X	
	c. Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.			X	
23.	If the device, and/or accessory, and/or a component is provided sterile:				
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	114	X		
	b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.	114-115	X		
	c. For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant	114	X		

		Page #	YES	N/A	NO
	residuals remaining on the device and sterilant residual limits.				
	d. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	114-115	X		
	e. Sterility Assurance Level (SAL) stated	114	X		
24.	If the device, and/or accessory, and/or a component is end user sterilized:			X	
	a. Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)			X	
	b. A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method.			X	
	c. Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)			X	
	d. Submission includes sterilization instructions for end user			X	
25.	a. If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
	c. If there is a special controls document applicable to the device, the submission includes sterility			X	

		Page #	YES	N/A	NO
	information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.				
F.	Shelf Life				
26.	Proposed shelf life/ expiration date stated	115	X		
27	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable.	115	X		
28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	115	X		
G.	Biocompatibility				
	Submission states that there: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> Are <input type="checkbox"/> are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.	116			
29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	119	X		
30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	116	X		

		Page #	YES	N/A	NO
31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	117	X		
H.	Software				
	Submission states that the device: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> does <input type="checkbox"/> does not contain software/firmware.	25, 120	X		
32.	Submission includes a statement of software level of concern and rationale for the software level of concern	Appendix 16A	X		
33.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	Appendix 16A	X		
I.	EMC and Electrical Safety				
	Submission states that the device: <i>(one of the below must be checked)</i> <input checked="" type="checkbox"/> does <input type="checkbox"/> does not require EMC and Electrical Safety evaluation.	122	X		
34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety	130-161	X		

		Page #	YES	N/A	NO
	evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).				
35.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	124-129	X		
L.	Performance Data – General				
36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions and an explanation of how the data generated from the test supports a finding of substantial equivalence.)	162-173	X		
37.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the			X	

		Page #	YES	N/A	NO
	device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach				
	c. If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
37.	If literature is referenced in the submission, submission includes:			X	
	a. Legible reprints or a summary of each article			X	
	b. Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.			X	
39.	For each completed nonclinical (i.e., animal) study conducted,			X	
	a. Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120			X	
	b. Submission includes final study report which includes all elements outlined in 21 CFR 58.185			X	
	c. Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial			X	

		Page #	YES	N/A	NO
	equivalence determination.				
K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))			X	
	Submission indicates that device: (one of the below must be checked) <input type="checkbox"/> is <input checked="" type="checkbox"/> is not an in vitro diagnostic device (IVD).			X	
40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:			X	
	a. Precision/reproducibility			X	
	b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.			X	
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			X	
	d. Analytical specificity			X	
41.	a. If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
	b. If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
	c. If there is a special controls document applicable to the device,			X	

		Page #	YES	N/A	NO
	the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.				

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

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) VIOPTIX INC 47224 Mission Falls Court Fremont USA CA 94539 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****6947	2. CONTACT NAME Mark Lonsinger 2.1 E-MAIL ADDRESS lonsingerm@vioptix.com 2.2 TELEPHONE NUMBER (include Area code) 510-360-7506 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 510-226-5864
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) Select an application type:	
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]	
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)	

Form FDA 3601 (01/2007)

19-Dec-2013

2. CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		Form Approval OMB No 0910-0120 Exp rat on Date: August 31 2010 See OMB Statement on page 5	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			
Date of Submission December 20, 2013	User Fee Payment ID Number (b)(4)	FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION			
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information
		Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):	
		Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):	
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name ViOptix Inc.		Establishment Registration Number (if known) 3003965364	
Division Name (if applicable)		Phone Number (including area code) 510-226-5860 x 7506	
Street Address 47224 Mission Falls Court		FAX Number (including area code) 510-226-5864	
City Fremont	State / Province CA	Z P/Postal Code 94539	Country USA
Contact Name Mark Lonsinger			
Contact Title VP & GM		Contact E mail Address lonsingerm@vioptix.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name Regulatory Specialist, Inc.		Phone Number (including area code) (949) 262-0411	
Division Name (if applicable)		FAX Number (including area code) (949) 552-2821	
Street Address 3722 Ave. Sausalito			
City Irvine	State / Province CA	Z P/Postal Code 92606	Country USA
Contact Name Greg Holland			
Contact Title Regulatory Specialist		Contact E mail Address greg@regulatoryspecialists.com	

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

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed						Summary of, or statement concerning, safety and effectiveness information	
1	MUD	2		3		4	
5		6		7		8	
						<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 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	K042657			1 ODISsey Tissue Oximeter			1 ViOptix
2				2			2
3				3			3
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification Tissue Oximeter							
	Trade or Proprietary or Model Name for This Device						Model Number
1	Intra.Ox™ Handheld Tissue Oximeter						1
2							2
3							3
FDA document numbers of all prior related submissions (regardless of outcome)							
1	2	3	4	5	6		
Data Included in Submission							
<input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input checked="" type="checkbox"/> Human Trials							
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS							
Product Code MUD		C.F.R. Section (if applicable) 870.2700				Device Class	
Classification Panel Cardiovascular						<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Indications (from labeling)							
The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO ₂) in a volume of tissue. The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.							

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name ViOptix, Inc		Establishment Registration Number 3003965364	
Division Name (if applicable)		Phone Number (including area code) 510-226-5860 x 7506	
Street Address 47224 Mission Falls Ct		FAX Number (including area code) 510-226-5864	
City Fremont		State / Province CA	Z P/Postal Code 94536
		Country USA	
Contact Name Mark Lonsinger		Contact Title VP & GM	Contact E mail Address lonsingerm@vioptix.com
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name To be determined		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code)	
City		State / Province	Z P/Postal Code
		Country	
Contact Name		Contact Title	Contact E mail Address
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City		State / Province	Z P/Postal Code
		Country	
Contact Name		Contact Title	Contact E mail Address

SECTION I		UTILIZATION OF STANDARDS			
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. IEC 60601-1:2005 (R2012)	Standards Organization IEC	Standards Title IEC 60601-1:2005 (R2012) with amendments; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Version	Date 2005
2	Standards No. IEC 60601-1-2:2007	Standards Organization IEC	Standards Title IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests: General Requirements for Safety	Version	Date 2007
3	Standards No. ANSI/IESNA RP-27.1-05	Standards Organization ANSI	Standards Title ANSI/IESNA RP-27.1-05, Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements	Version	Date 2005
4	Standards No. ANSI/AAMI/ISO 11135-1:2007	Standards Organization ANSI/AA MI/ISO	Standards Title ANSI/AAMI/ISO 11135-1:2007: Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Version	Date 2007
5	Standards No. ISO 11737-1:2006 (R)2011	Standards Organization ISO	Standards Title ISO 11737-1:2006 (R)2011 Sterilization of Medical Devices - Microbiological Methods - Part 1: Determination of a Population of Microorganisms on Products	Version	Date 2011
6	Standards No. ANSI/AAMI/ISO 10993-5:2009	Standards Organization ANSI/AA MI/ISO	Standards Title ANSI/AAMI/ISO 10993-5:2009: Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Version	Date 2009
7	Standards No. ANSI/AAMI/ISO 10993-1:2009	Standards Organization ANSI/AA MI/ISO	Standards Title ANSI/AAMI/ISO 10993-1:2009: Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Version	Date 2009
8	Standards No. ISO 10993-10:2010	Standards Organization ISO	Standards Title ISO 10993-10:2010: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Version	Date 2010
Please include any additional standards to be cited on a separate page.					
<p>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:</p> <p style="text-align: right;">Food and Drug Administration CDRH (HFZ-342) 9200 Corporate Blvd. Rockville, MD 20850</p>					
<i>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</i>					

3. 510(k) Cover Letter



47224 Mission Falls Ct.
Fremont, CA 94539
510-226-5860
info@vioptix.com

December 20, 2013

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

Subject: Traditional Premarket Notification (510(k)) for Intra.Ox™ Handheld
Tissue Oximeter

Attention: Document Mail Clerk

Pursuant to section 510(k) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807.87, please find the premarket notification for the Intra.Ox™ Handheld Tissue Oximeter, a new device to be marketed by ViOptix, Inc. There are no prior submissions for the subject device.

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

ViOptix wishes to use its own device, the ODISsey Tissue Oximeter (reference number K042657), as the predicate. The ODISsey Tissue Oximeter was renamed the T.Ox Tissue Oximeter (2009), and is thus referred to as the T.Ox in this submission. The primary differences between the Intra.Ox™ Handheld Tissue Oximeter and the T.Ox Tissue Oximeter are as follows:

- The Intra.Ox™ Handheld Tissue Oximeter is an integrated handheld unit (designed for disposable single-use), whereas the T.Ox Tissue Oximeter is a console with replaceable sensors.
- The Intra.Ox™ Handheld Tissue Oximeter has additional detectors (8 as compared to T.Ox's 4).

- The Intra.Ox™ Handheld Tissue Oximeter has additional wavelengths of light (4 as compared to T.Ox's 2).
- The Intra.Ox™ Handheld Tissue Oximeter utilizes wavelengths such that methylene blue, a common medical dye, is not an interferent.

Information regarding ViOptix:

Submitter's Name ViOptix, Inc.
Address 47224 Mission Falls Ct., Fremont, CA 94539
Contact at ViOptix Mark Lonsinger
Telephone 510-360-7506
Fax 510-226-5864
Email lonsingerm@vioptix.com

Information regarding Application Correspondent:

Official Correspondent Greg Holland
Address Regulatory Specialists, Inc
 3722 Ave. Sausalito
 Irvine, CA 92606
Telephone 949-262-0411
Email greg@regulatoryspecialists.com

Information regarding the device classification:

Trade Name: Intra.Ox™ Handheld Tissue Oximeter
Common Name: Tissue Oximeter
Classification regulation: 21 CFR 870.2700
Classification regulation name: Oximeter
Classification Panel: Cardiovascular
Product code: MUD
Device Class: II
Basis for Submission: New Device

The principal factors about the design and use of the device are shown in Table 3-1, below.

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?	X	
Is the device implanted?		X

Table 3-1

The eCopy is an exact duplicate of the paper copy.

Please feel free to contact me directly at 949-262-0411 if you have any questions.

Sincerely,

Greg Holland
Regulatory Specialist to ViOptix, Inc.

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Intra.Ox™ Handheld Tissue Oximeter

Indications for Use:

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

5. 510(k) Summary



47224 Mission Falls Court · Fremont, CA 94539
Office: (510) 226-5860 · Fax: (510) 226-5864

Submitter's Name ViOptix, Inc.
Address 47224 Mission Falls Ct., Fremont, CA 94539
Contact at ViOptix Mark Lonsinger
Telephone 510-360-7506
Fax 510-226-5864
Email info@vioptix.com
Date the Summary was prepared: December 20, 2013

Information regarding Application Correspondent:

Official Correspondent Greg Holland
Address 3722 Ave. Sausalito
 Irvine, CA 92606
Telephone 949-262-0411
Email greg@regulatoryspecialists.com

Information regarding the device classification:

Trade Name: Intra.Ox™ Handheld Tissue Oximeter
Common Name: Tissue Oximeter
Classification regulation: 21 CFR 870.2700
Classification regulation name: Oximeter
Product code: MUD
Device Class: II

Information regarding the legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

510(k) Reference # K042657
Device Name ODISsey Tissue Oximeter
510(k) Holder ViOptix

Description of the Device:

The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO₂) in a volume of tissue. The device uses spatially-resolved optical measurements at four wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO₂ estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a single-use disposable constructed from

biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

Indications for Use:

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

Intended Use:

The Intra.Ox™ Handheld Tissue Oximeter has the same intended use as the predicate, the T.Ox.

Technological Characteristics:

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)
510K number	This submission	K042657
Manufacturer	ViOptix, Inc.	ViOptix, Inc.
Intended Use		
Indications for Use	<p>The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.</p> <p>The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.</p>	<p>The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.</p> <p>The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.</p>
Measured Parameters	Tissue oxygen saturation (% StO ₂)	Tissue oxygen saturation (% StO ₂) and trend graph
Operating Principle	Spectrophotometric oximetry	Spectrophotometric oximetry
Energy Delivered	Near-infrared light Source: LED chips Wavelengths: 760, 810, 850, 900 nm	Near-infrared light Source: laser diodes Wavelengths: 690, 830 nm
Single Patient Use?	Yes, integrated sensor and control unit is single patient use disposable.	Sensor is single patient use disposable. Control unit is reusable.
Power Source	Battery powered Battery type: 4 Lithium AA Battery voltage: 6 V total	Mains powered with battery backup Battery type: 3-cell Lithium ion
Measurement Range	1-99% StO ₂	1-99% StO ₂

Performance Testing

Bench Tests

The Intra.Ox™ devices were found to measure absorption coefficients with a high degree of correlation to actual absorption coefficients in liquid phantoms prepared with Intralipid and swine whole blood. The correlation coefficient was greater than 0.9 for each of the four wavelengths used in the devices.

The Intra.Ox™ devices were shown to agree well with the predicate device in StO₂% measurements. Over three full-scale (complete oxygenation to complete deoxygenation) blood desaturations, three different Intra.Ox™ devices as compared to two T.Ox devices showed combined limits of agreement of +8.49 and -7.50 percentage points. The acceptance criterion required the limits of agreement to be less than ±10 percentage points. Therefore, the Intra.Ox™ is demonstrated to be substantially equivalent to the T.Ox in estimating StO₂%.

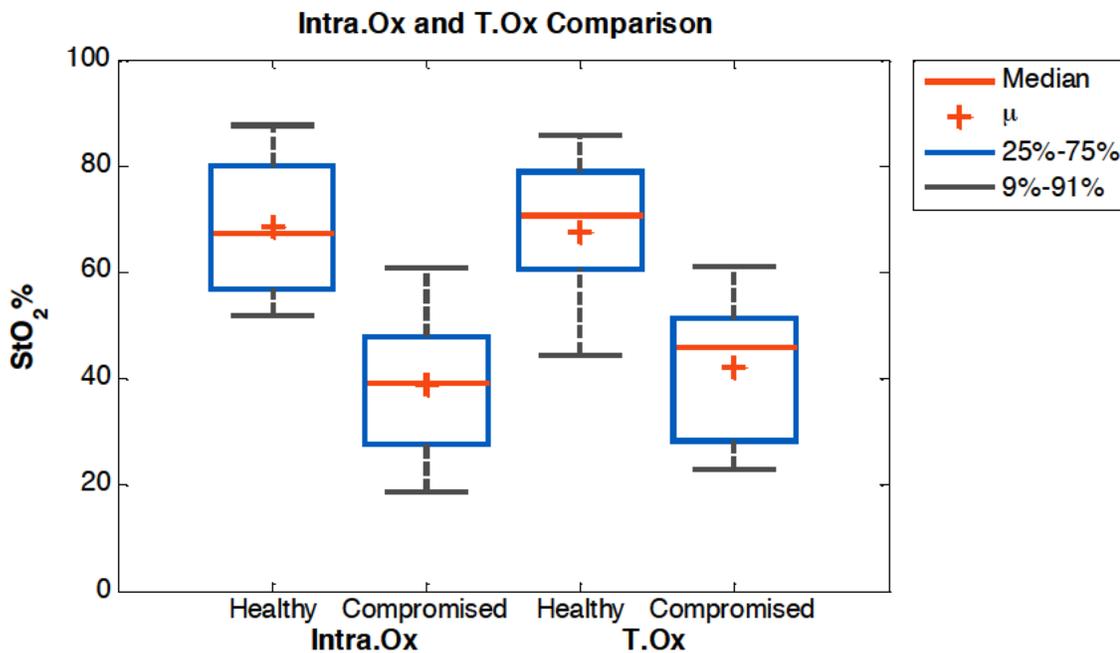
Clinical Study

Performance was determined by measuring tissue oxygen saturation (StO₂) with both devices during transient ischemic events on healthy human volunteers that temporarily mimics compromised tissue. Data from 11 subjects, who were near-evenly distributed over age, gender, and skin color as determined by the Fitzpatrick skin type, were analyzed.

There was excellent agreement in shape of the ischemic events between the Intra.Ox™ and T.Ox devices. A direct comparison with paired data showed good agreement considering the physiological variances inherent between measurement sites.

The mean baseline value of 68% and mean desaturation dynamic range of 30 percentage points agrees well with literature-reported values of skin and muscle transient ischemia.

Importantly, the Intra.Ox™ and T.Ox measure similar ranges of StO₂ values for both healthy and compromised tissue, thus validating substantial equivalence.



Conclusion

The Intra.Ox™ Handheld Tissue Oximeter has the predicate device identified above, has the same intended use as the predicate, has similar technology that does not raise new types of questions of safety or effectiveness, and performance data shows that this device provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.

7. Class III Summary and Certification

Oximeters are class II type devices and therefore **this section does not apply.**

8. Financial Certification or Disclosure Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS	Form Approved: OMB No. 0910-0396 Expiration Date: December 31, 2015
TO BE COMPLETED BY APPLICANT	
<p>With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).</p>	
<div style="border: 1px solid black; padding: 2px; display: inline-block;">Please mark the applicable check box.</div>	
<p><input checked="" type="checkbox"/> (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).</p>	
Clinical Investigators	<div style="background-color: black; color: red; padding: 2px;">(b)(6)</div>
<p><input type="checkbox"/> (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).</p>	
<p><input type="checkbox"/> (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.</p>	
NAME	TITLE
Mark Lonsinger	VP & GM
FIRM/ORGANIZATION	
ViOptix Inc	
SIGNATURE	DATE (mm/dd/yyyy)
	12/19/2013
<p>This section applies only to the requirements of the Paperwork Reduction Act of 1995. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right. *An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.*</p>	
<p>Do NOT send your completed form to the PRA Staff email address below. Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer PRAStaff@fda.hhs.gov</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS	Form Approved: OMB No. 0910-0396 Expiration Date: December 31, 2015												
TO BE COMPLETED BY APPLICANT													
The following information concerning (b)(6) [REDACTED], who participated as a clinical investigator in the submitted study (b)(4) [REDACTED] (b)(4) [REDACTED] submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:													
Please mark the applicable check boxes.													
<input type="checkbox"/> any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;													
<input type="checkbox"/> any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;													
<input type="checkbox"/> any proprietary interest in the product tested in the covered study held by the clinical investigator;													
<input type="checkbox"/> any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.													
Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.													
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">NAME</td> <td style="width: 50%;">TITLE</td> </tr> <tr> <td>Mark Lonsensor</td> <td>VP JGM</td> </tr> <tr> <td colspan="2">FIRM/ORGANIZATION</td> </tr> <tr> <td colspan="2">ViOptix Inc.</td> </tr> <tr> <td>SIGNATURE</td> <td>Date (mm/dd/yyyy)</td> </tr> <tr> <td></td> <td>12/19/2013</td> </tr> </table>	NAME	TITLE	Mark Lonsensor	VP JGM	FIRM/ORGANIZATION		ViOptix Inc.		SIGNATURE	Date (mm/dd/yyyy)		12/19/2013	
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<p>Do NOT send your completed form to the PRA Staff email address below.</p> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer PRAStaff@fda.hhs.gov</p>													

FORM FDA 3455 (4/13)

PSC Publishing Services (301) 443-6740 EF

9. Declarations of Conformity and Summary Reports

Before the Intra.Ox™ Handheld Tissue Oximeter is marketed, testing will be conducted, and the device will meet specified acceptance criteria of the recognized standards listed below:

Electrical Safety and EMC

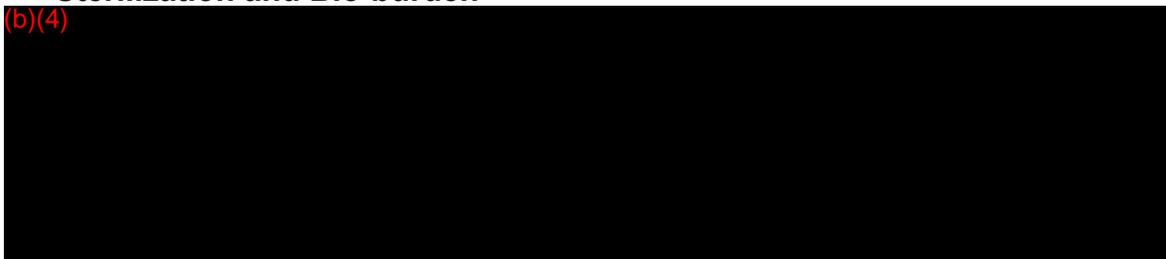
1. IEC 60601-1:2005 (R2012) with amendments; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests: General Requirements for Safety

Light Safety

3. ANSI/IESNA RP-27.1-05, Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements

Sterilization and Bio-burden

(b)(4)



Biocompatibility Standards

6. ANSI/AAMI/ISO 10993-5:2009: Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
7. ANSI/AAMI/ISO 10993-1:2009: Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
8. ISO 10993-10:2010: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

Standards Data Report For 510(K)s for the above listed standards are on the following pages.

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(K)S <i>(To be filled in by applicant)</i>		
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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 60601-1:2005 (R2012) with amendments; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	5-27	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of the standard? ...	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes report these deviations or adaptations in the summary report table		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], 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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE
STANDARD TITLE IEC 60601-1:2005 (R2012) with amendments; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
CONFORMANCE WITH STANDARD SECTIONS*
Please see Appendix 17B – VIO0873_VPL_Electrical Safety Compliance Plan
* 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 <i>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.</i>

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(K)S <i>(To be filled in by applicant)</i>		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests: General Requirements for Safety		
Please answer the following questions		
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	5-60	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of the standard? ...	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
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Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes report these deviations or adaptations in the summary report table		
Were there any exclusions from the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
Title of guidance: _____		
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Please see Appendix 17A – VIO0872_VPL_EMC Compliance Plan
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STANDARD TITLE ¹ Recommended Practice for Photobiological Safety for Lamps and Lamp Systems - General Requirements				
Please answer the following questions				
	Yes	No		
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
FDA Recognition number ³	# 12-153			
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements		
CONFORMANCE WITH STANDARD SECTIONS		
SECTION NUMBER 4.2	SECTION TITLE Ultraviolet Exposure Limits	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED		
DESCRIPTION This section and its subsections describe exposure limits for ultraviolet radiation		
JUSTIFICATION The Intra.Ox device does not emit ultraviolet radiation. Therefore, this section and its subsections are not applicable.		
SECTION NUMBER 4.3.1	SECTION TITLE Retinal Thermal Hazard Exposure Limit	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED None		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 4.3.2	SECTION TITLE Retinal Blue Light Hazard Exposure Limit	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED		
DESCRIPTION This subsection applies to light sources with wavelengths shorter than 700 nm.		
JUSTIFICATION The Intra.Ox device does not contain light sources with wavelengths shorter than 700 nm.		
SECTION NUMBER 4.3.3	SECTION TITLE Retinal Blue Light Hazard Exposure Limit – Small Source	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED		
DESCRIPTION This subsection applies to light sources with wavelengths shorter than 700 nm.		
JUSTIFICATION The Intra.Ox device does not contain light sources with wavelengths shorter than 700 nm.		

SECTION NUMBER 4.3.4	SECTION TITLE The Apathic Eye Hazard Exposure Limit	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED		
DESCRIPTION This subsection applies to light sources with wavelengths shorter than 700 nm.		
JUSTIFICATION The Intra.Ox device does not contain light sources with wavelengths shorter than 700 nm.		
SECTION NUMBER 4.3.5	SECTION TITLE Infrared Radiation Hazard Exposure Limit	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED None		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 4.3.6	SECTION TITLE Infrared Radiation Hazard Exposure Limit – Weak Visual Stimulus	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED		
DESCRIPTION This subsection describes eye exposure limits to near-infrared light for time periods greater than 10 s.		
JUSTIFICATION The Intra.Ox device emits light in the spectral region covered by this subsection. However, the device is intended to be applied to tissue and is not expected to be viewed by eye for any time longer than casual handling (couple of seconds).		
SECTION NUMBER 4.3.7	SECTION TITLE Skin – Thermal Hazard Exposure Limit	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED None		
DESCRIPTION		
JUSTIFICATION		

Department of Health and Human Services Food and Drug Administration STANDARDS DATA REPORT FOR 510(K)S <i>(To be filled in by applicant)</i>		
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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ (b)(4)		
Please answer the following questions		
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
FDA Recognition number ³	14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
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.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Does this standard include more than one option or selection of the standard? ... If yes, report options selected in the summary report table.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
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 ?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
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.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Title of guidance: _____		
<small> 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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html </small>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
(b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All Normative		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
None		
DESCRIPTION		
Testing will demonstrate conformance before device is marketed		
JUSTIFICATION		
Design requirements include conformance to this standard. Compliance to be verified prior to product release.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
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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 <i>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.</i>		

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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ (b)(4)		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		14-
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
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.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria?		<input checked="" type="checkbox"/> <input type="checkbox"/>
If no, include the results of testing in the 510(k).		
Does this standard include more than one option or selection of the standard? ... If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
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 ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?		<input type="checkbox"/> <input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusions from the standard?		<input type="checkbox"/> <input checked="" type="checkbox"/>
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If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
(b)(4)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All Normative	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* None		
DESCRIPTION Testing will demonstrate conformance before device is marketed		
JUSTIFICATION Design requirements include conformance to this standard. Compliance to be verified prior to product release.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
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Paperwork Reduction Act Statement		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ANSI/AAMI/ISO 10993-5:2009: Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity		
Please answer the following questions		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		2-153
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
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.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of the standard? ... If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
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 ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?.....		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
<p>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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html</p>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ANSI/AAMI/ISO 10993-5:2009: Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All Normative	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* None		
DESCRIPTION Testing will demonstrate conformance before device is marketed		
JUSTIFICATION Design requirements include conformance to this standard. Compliance to be verified prior to product release.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>♦ 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</p>		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ANSI/AAMI/ISO 10993-1:2009: Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process		
<i>Please answer the following questions</i>		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		2-156
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
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.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of the standard? ... If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
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 ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], 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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ANSI/AAMI/ISO 10993-1:2009: Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All Normative	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* None		
DESCRIPTION Testing will demonstrate conformance before device is marketed		
JUSTIFICATION Design requirements include conformance to this standard. Compliance to be verified prior to product release.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
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Paperwork Reduction Act Statement		
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TYPE OF 510(K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ANSI/AAMI/ISO 10993-10:2010: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization		
<i>Please answer the following questions</i>		Yes No
Is this standard recognized by FDA ² ?		<input checked="" type="checkbox"/> <input type="checkbox"/>
FDA Recognition number ³		2-173
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
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.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?.....		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).		<input checked="" type="checkbox"/> <input type="checkbox"/>
Does this standard include more than one option or selection of the standard? ... If yes, report options selected in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
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 ?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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		<input type="checkbox"/> <input checked="" type="checkbox"/>
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.		<input type="checkbox"/> <input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?		<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Title of guidance: _____		
¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] ² Authority [21 U.S.C. 360d], 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 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ANSI/AAMI/ISO 10993-10:2010: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER All Normative	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED* None		
DESCRIPTION Testing will demonstrate conformance before device is marketed		
JUSTIFICATION Design requirements include conformance to this standard. Compliance to be verified prior to product release.		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED*		
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Paperwork Reduction Act Statement		
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10. Executive Summary

Device Description:

The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO₂) in a volume of tissue. The device uses spatially-resolved optical measurements at four wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO₂ estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a single-use disposable constructed from biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

Indications for Use:

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

Intended Use:

The Intra.Ox™ Handheld Tissue Oximeter has the same intended use as the predicate.

Device Comparison table:

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
510K number	This submission	K042657	
Manufacturer	ViOptix, Inc.	ViOptix, Inc.	Yes. Identical
Intended Use			
Indications for Use	<p>The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.</p> <p>The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.</p>	<p>The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.</p> <p>The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.</p>	Yes. Overall use is the same.

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Measured Parameters	Tissue oxygen saturation (% StO ₂)	Tissue oxygen saturation (% StO ₂) and trend graph	Yes. Similar to predicate. The Intra.Ox™ is intended for spot checking at various locations and not long-term use in one location.
Design			
Operating Principle	Spectrophotometric oximetry	Spectrophotometric oximetry	Yes. Identical to predicate.
Technology	Spatially-resolved reflectance measurements	Ratiometric spatial reflectance measurements	Yes. Similar to predicate.
Energy Delivered	Near-infrared light Source: LED chips Wavelengths: 760, 810, 850, 900 nm	Near-infrared light Source: laser diodes Wavelengths: 690, 830 nm	Yes. Similar to predicate.
Sources/Detectors	2 source locations with 4 wavelengths at each location / 8 detectors	2 source locations with 2 wavelengths at each location / 4 detectors	Yes. Similar to predicate.
Source-detector spacings	16 spacings from 1 mm – 4 mm	8 spacings from 5 mm – 7.5 mm	Substantially Equivalent.
Single Patient Use?	Yes, integrated sensor and control unit is single patient use disposable.	Sensor is single patient use disposable. Control unit is reusable.	Substantially equivalent.
Power Source	Battery powered Battery type: 4 Lithium AA Battery voltage: 6 V total	Mains powered with battery backup Battery type: 3-cell Lithium ion	Substantially equivalent.

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Biocompatibility	Patient-contacting materials meet the requirements of 10993 Parts 1, 5 and 10	Patient-contacting materials meet the requirements of 10993 Parts 1, 5 and 10 (See page 100 of K042657 submission)	Yes. Identical to predicate.
Performance			
Measurement Range	1-99% StO ₂	1-99% StO ₂	Yes. Identical to predicate.
Measurement Depth (mean photon visitation depth)	0.5 – 2 mm	1 – 3 mm	Substantially equivalent.
Bench testing	Full-range blood desaturation (see Section 18)	Not Performed	Yes. Substantially equivalent. The results of the study show strong agreement between the outputs from both devices.
Animal studies	Not performed	Canine desaturation events	Instead of animal studies, an in-vivo study with human subjects was performed as discussed below.

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Clinical studies	An in-vivo study was performed to compare measurements from the Intra.Ox™ Handheld Tissue Oximeter and the predicate device under similar circumstances.	Not performed	Yes. Substantially equivalent. The results of the study show strong agreement between the outputs from both devices.
Safety			
Sterility	(b)(4)		
Compatibility with intended environments	Conforms to IEC 60601-1-2 for Electromagnetic Interference	Conforms to IEC 60601-1-2 for Electromagnetic Interference	Yes. Identical to predicate.
Electrical safety	Conforms to IEC 60601-1 requirements for electrical safety	Conforms to IEC 60601-1 requirements for electrical safety	Yes. Identical to predicate.
Mechanical safety	Conforms to IEC 60601-1-1, Section 9.3 requirements for mechanical safety	Conforms to IEC 60601-1 requirements for mechanical safety	Yes. Identical to predicate.

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Radiation safety	Conforms to ANSI/IESNA RP-27.1-05 Photobiological Safety for Lamps and Lamp Systems Section 4.3.	Conforms to IEC 60825-1.	Yes. Substantially equivalent. The light source used by the Intra.Ox™ Handheld Tissue Oximeter consists of LEDs which present much lower risk of injury than the predicate device, which uses lasers.

Performance Testing

Bench Tests

The Intra.Ox™ devices were found to measure absorption coefficients with a high degree of correlation to actual absorption coefficients in liquid phantoms prepared with Intralipid and swine whole blood. The correlation coefficient was greater than 0.9 for each of the four wavelengths used in the devices.

The Intra.Ox™ devices were shown to agree well with the predicate device in StO₂% measurements. Over three full-scale (complete oxygenation to complete deoxygenation) blood desaturations, three different Intra.Ox™ devices as compared to two T.Ox devices showed combined limits of agreement of +8.49 and -7.50. The acceptance criterion required the limits of agreement to be less than ±10. Therefore, the Intra.Ox™ is demonstrated to be substantially equivalent to the T.Ox in estimating StO₂%.

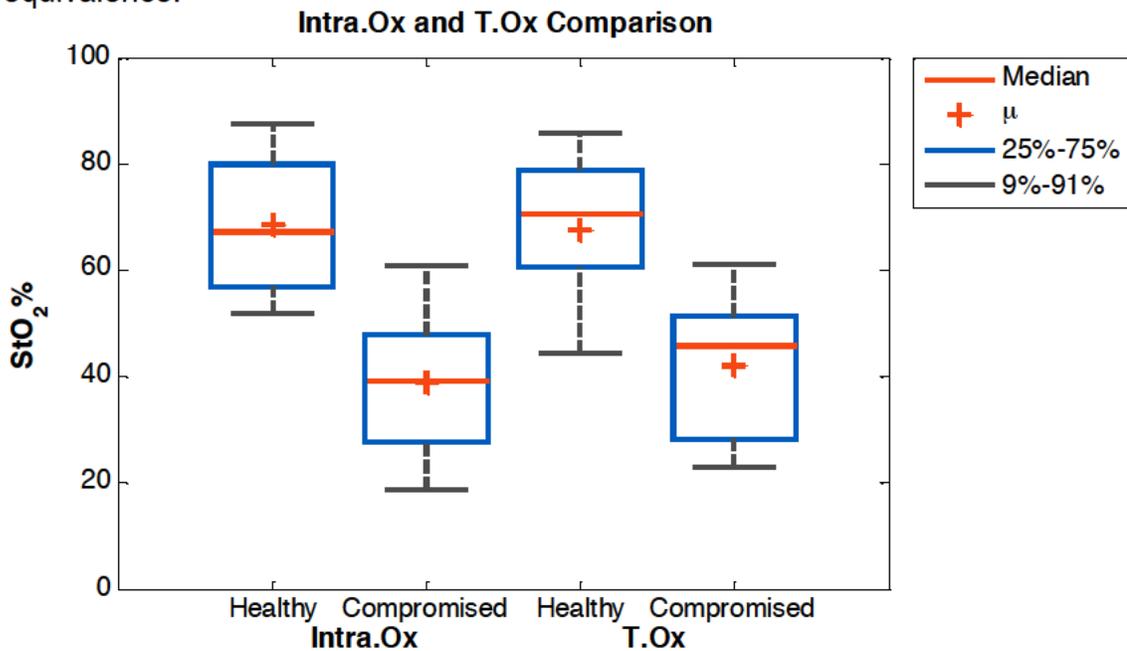
Clinical Study

Performance was determined by measuring tissue oxygen saturation (StO₂) with both devices during transient ischemic events on healthy human volunteers that temporarily mimics compromised tissue. Data from 11 subjects who were near-evenly distributed over age, gender, and skin color as determined by the Fitzpatrick skin type, were analyzed.

There was excellent agreement in shape of the ischemic events between the Intra.Ox™ and T.Ox devices. A direct comparison with paired data showed good agreement considering the physiological variances inherent between measurement sites.

The mean baseline value of 68% and mean desaturation dynamic range of 30 percentage points agrees well with literature-reported values of skin and muscle transient ischemia.

Importantly, the Intra.Ox™ and T.Ox measure similar ranges of StO₂ values for both healthy and compromised tissue, thus validating substantial equivalence.



Conclusion

The Intra.Ox™ Handheld Tissue Oximeter has the predicate device identified above, has the same intended use as the predicate, has similar technology that does not raise new types of questions of safety or effectiveness, and performance data shows that this device provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.

11. Device Description

Device Description:

The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO₂) in a volume of tissue. The device uses spatially-resolved optical measurements at four wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO₂ estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a single-use disposable constructed from biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

Device Configuration:

The device contains light sources, detectors, and processing electronics to convert measurements of reflected light into estimates of StO₂. See Appendix 11A – VIO05178_PRD_Intra.Ox™ Product Requirements Document, at the end of this Section. Figure 11-1 contains an illustration of the complete device.

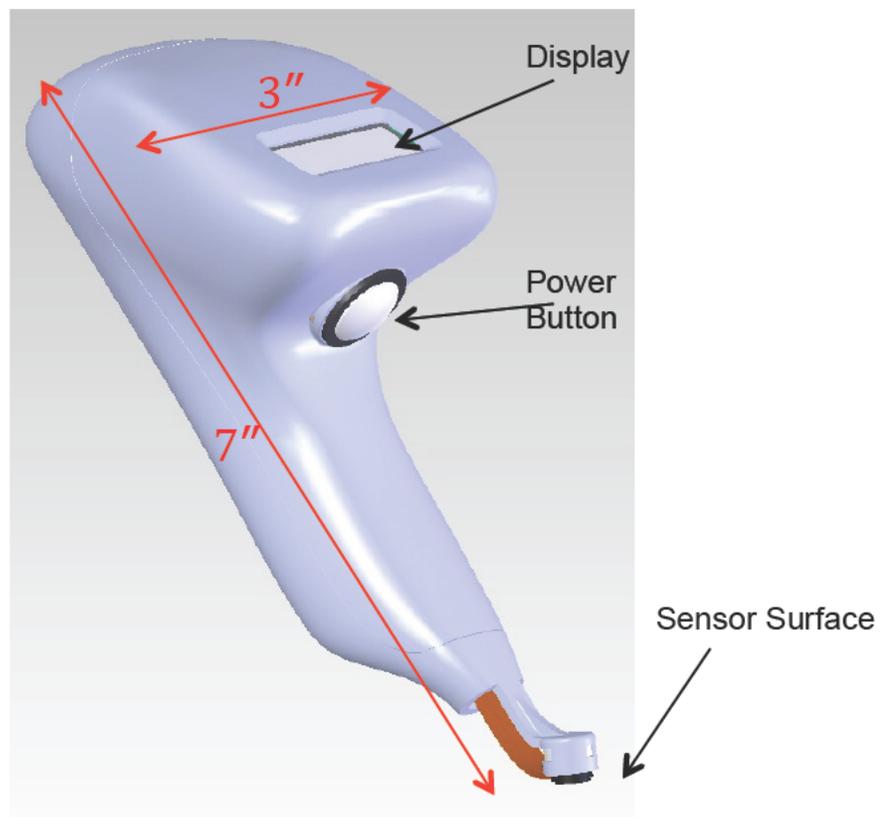


Figure 11-1. External View of Intra.Ox™ Handheld Tissue Oximeter

The device is handheld and operated by positioning the tip on the area of the tissue that is to be measured. The device is packaged sterile for single-patient use and can be used directly in a sterile environment with less than a 5 minute warm-up/boot-up time.

The unit is designed to be comfortable for a range of hand sizes and can be held and operated by either hand. It is lightweight (< 1 pound) and compact, resistant to fluid ingress, and has no awkward protrusions or external wiring or cabling. The device's shape permits targeted positioning over an area of tissue and has a read-out display mounted such that the readings can be viewed easily by the user while positioning it over an area of interest. The sensing face is oriented such that it can address the patient's tissue with a comfortable orientation of the user's hand.

The sensing face, which makes contact with the patient, consists of a small optical head containing multiple-wavelength LEDs and spatially-distributed photosensors (detectors). The optical head forms the tip of the device and is connected by flexible cables to a set of internal acquisition and processing electronics which calculates the StO₂ in real-time.

The user display is a LCD screen that displays StO₂ measurements to the user at a 1-second update rate from a range of 1-99%. Low battery conditions and other error messages are displayed as necessary.

Figure 11-2 shows a block diagram describing the overall physical hardware.

(b)(4)

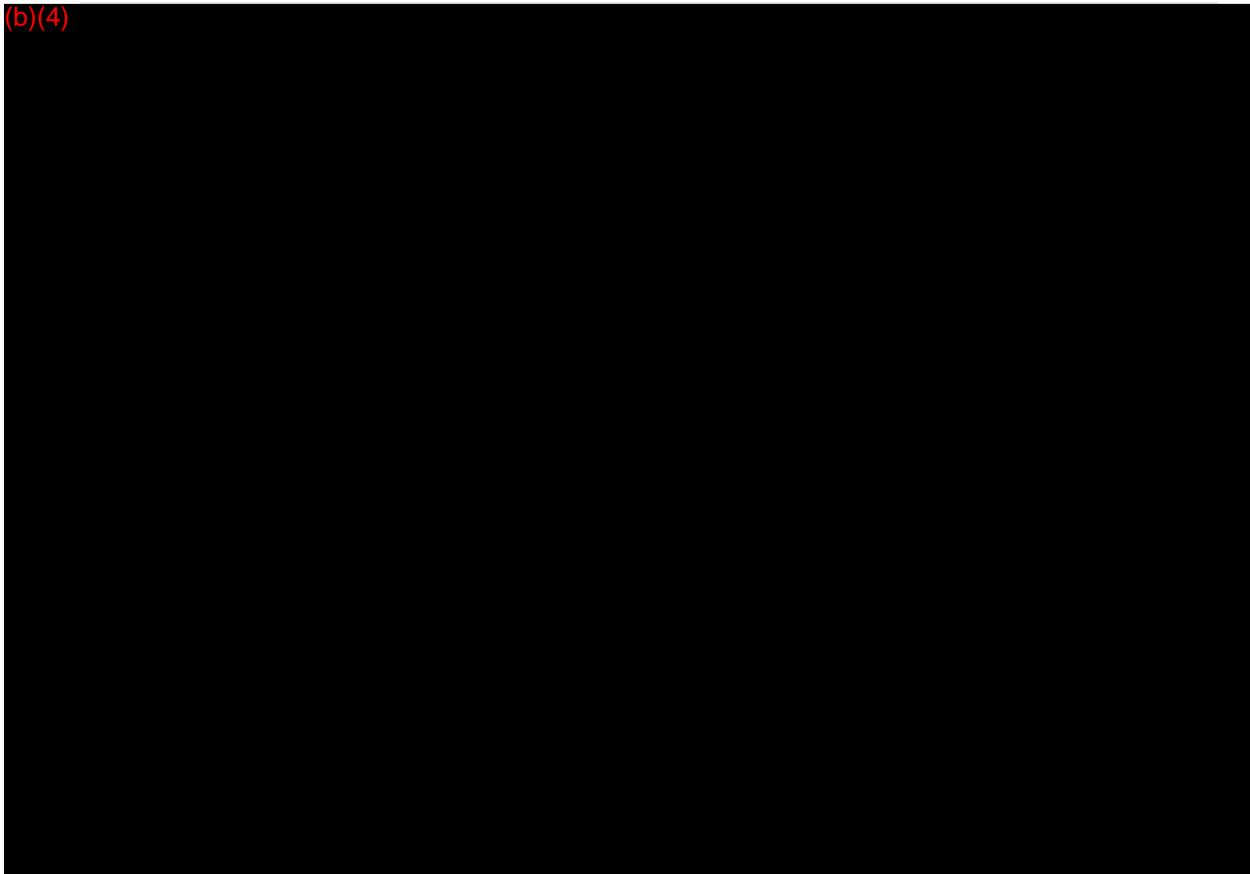


Figure 11-2. Intra.Ox™ Hardware System Description

Mechanical Housing:

The mechanical housing encases the device and provides access to certain internal components. Internal components externally available to the user are the Power Switch and LCD Display. Other internal components include the acquisition module, the measurement module, and 4 AA batteries. The housing case is made of ABS. The outside surface (made of Delrin) of the Sensor Subsystem makes contact with the tissue during operation. Figure 11-3 shows how the internal components are placed within the mechanical housing.

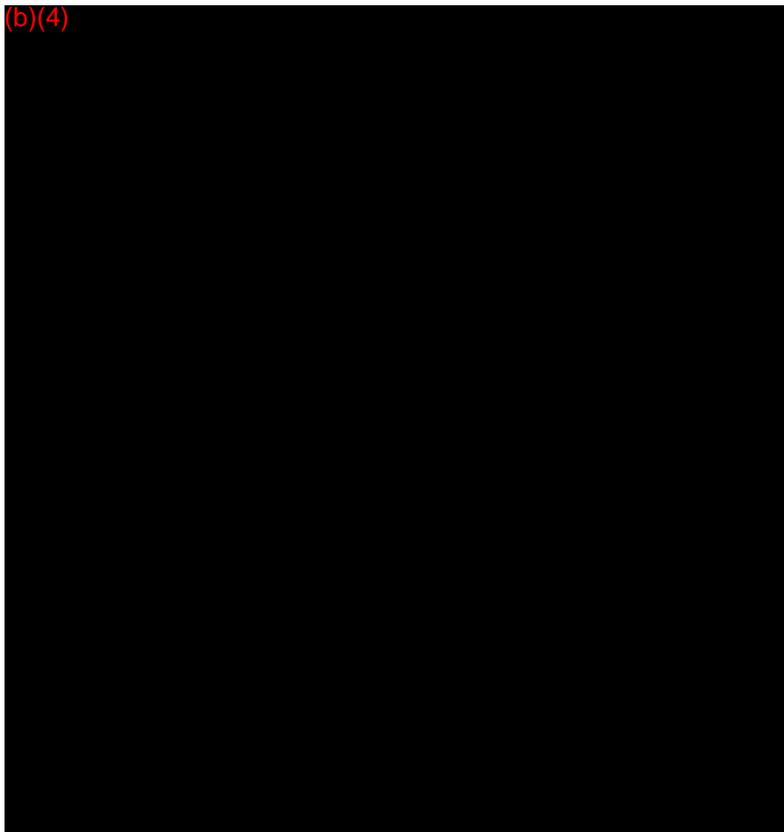


Figure 11-3. Mechanical housing made transparent

Probe Head:

The Intra.Ox™ device contains 8 LEDs that generate 4 different wavelengths of light in the red to near-infrared. This light is directed to the tissue through small lenses and short fiber light pipes. Light reflected back from the tissue is detected by an array of 8 PIN diode detectors mounted behind individual epoxy windows in a circular pattern to achieve varying LED-to-detector distances. Light pipes and detector windows are embedded in an aperture plate and the entire optical sensor assembly is sealed and housed in the Mechanical Housing so that the only part that makes contact with the patient is the aperture plate. The aperture plate itself is made of Delrin. See Figure 11-4 for the layout of the probe head.



Figure 11-4. Probe Head configuration, S#’s are light-emitting sites. D#’s are light detection sites. S1 and S2 are 4mm apart.

Acquisition Module:

The Acquisition Module is a control board that manages the acquisition process. It provides control to the LEDs in terms of when they are on and off and their light output intensities. It also collects and averages data from the detectors, and converts the measured voltages into the corresponding physical quantities (e.g., light intensity) for further processing by the Measurement Module.

Measurement Module:

The Measurement Module serves two functions: First, it provides overall control of the system, managing system operation (e.g., power) and user interactions. Second, it converts the measured signals from the Acquisition Module into StO₂ and displays this information to the user via the on-board LCD display.

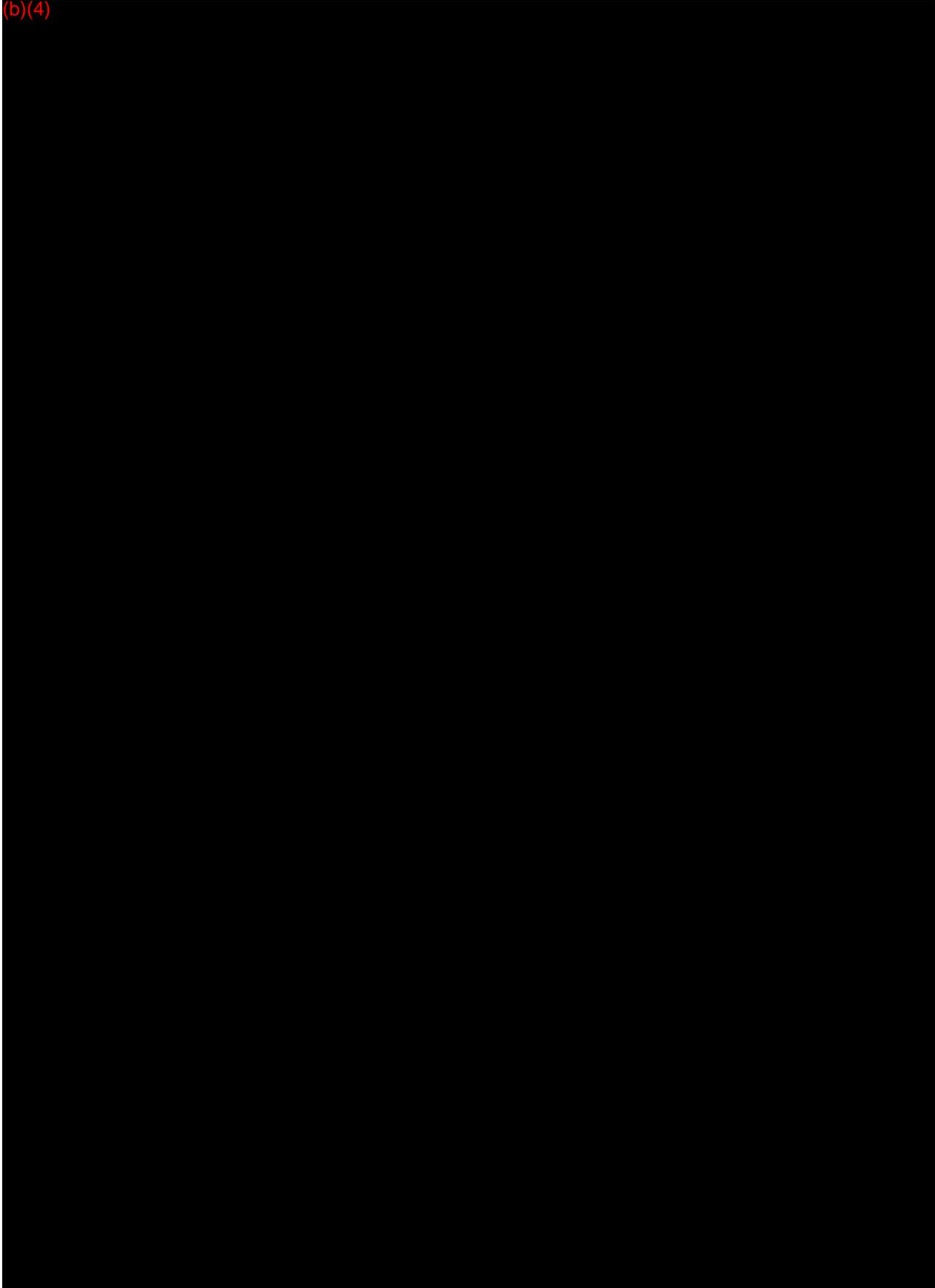
Power:

Power is provided for all components by 4 AA lithium batteries at an overall 6 Volts. Power is managed by the Measurement Module to enable standby, warm-up/boot and normal operations. When the battery voltage dips, a low battery warning is displayed to the user on the on-board display.

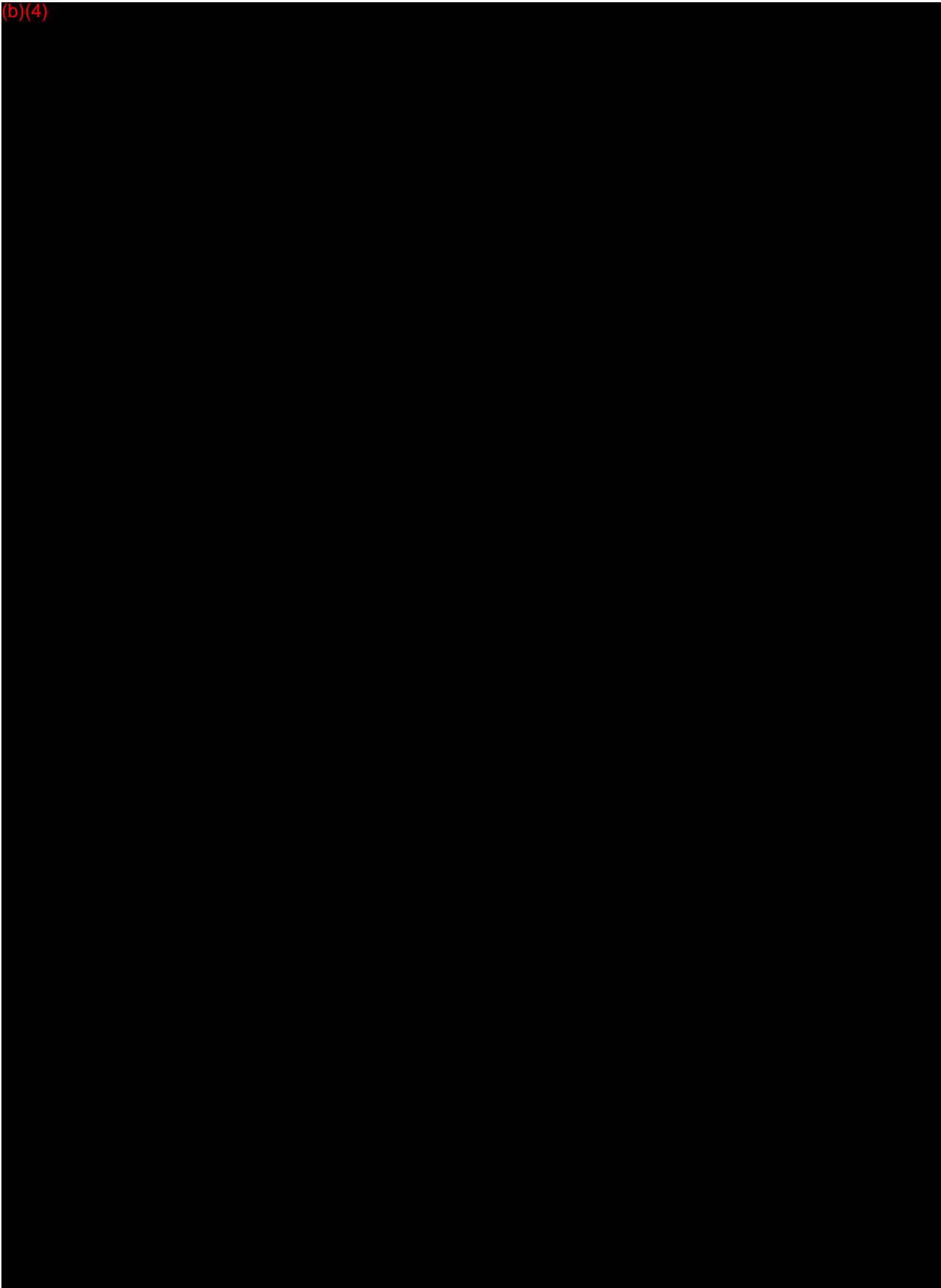
Principles of Operation:

The basic principle of operation of the Intra.Ox™ device, spectrophotometric oximetry, is the same as other oximeters on the market, including the predicate device. Spectrophotometric oximetry entails utilizing red and near-infrared light to measure the color of blood and determine an oxygen saturation value. Specifically, the tissue absorption coefficient, μ_a , is related to the concentration of N absorbing species as follows:

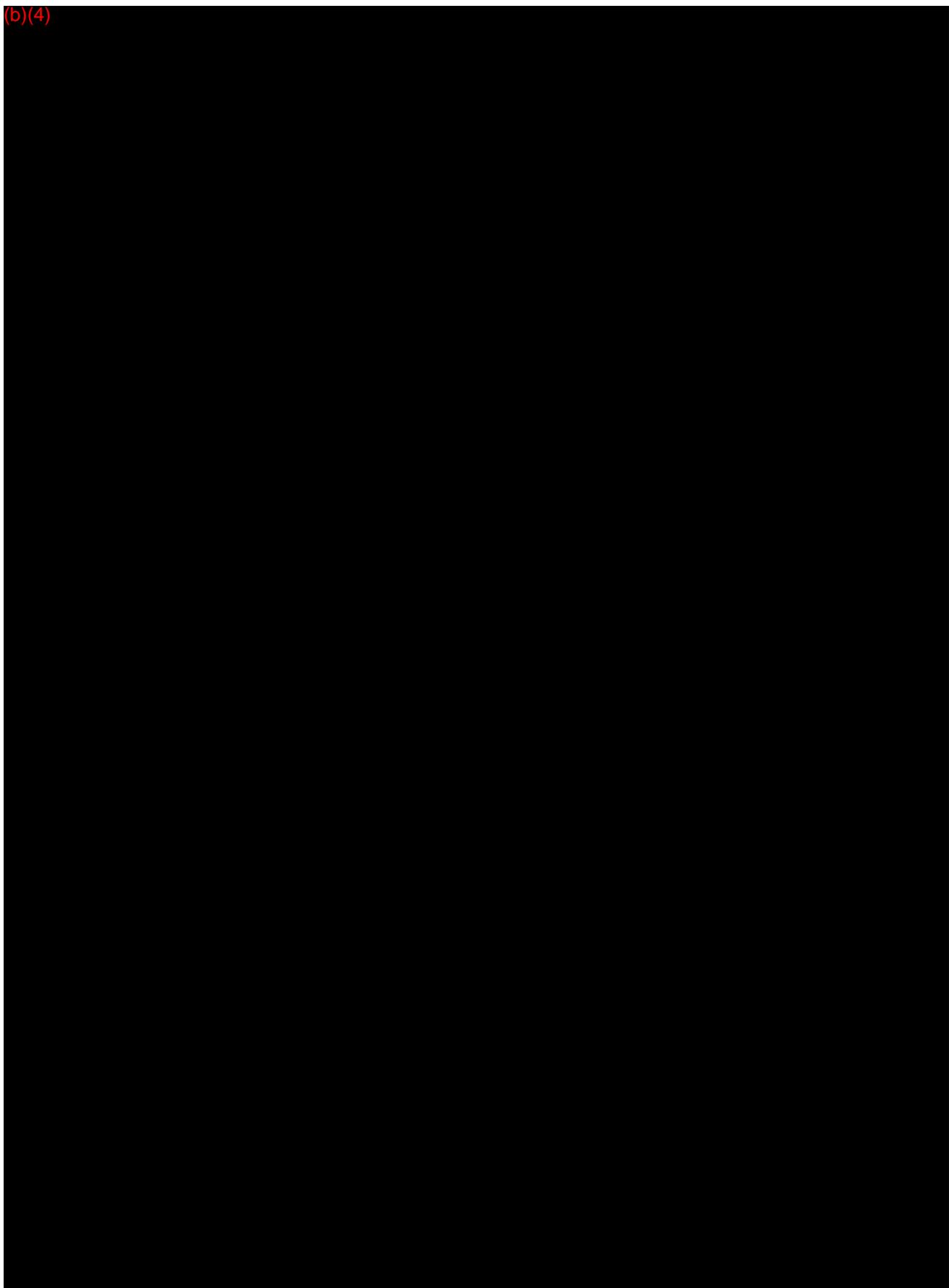
(b)(4)



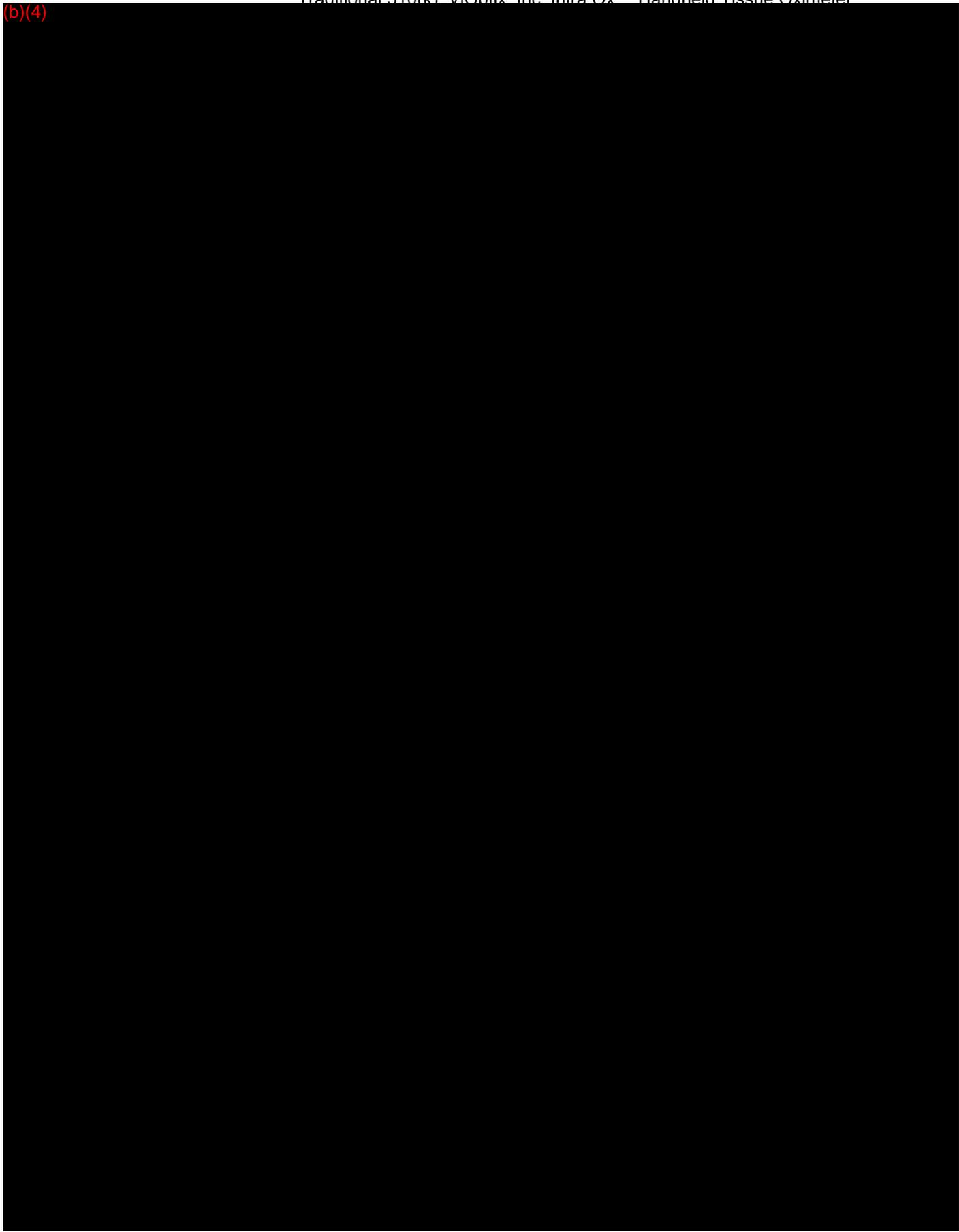
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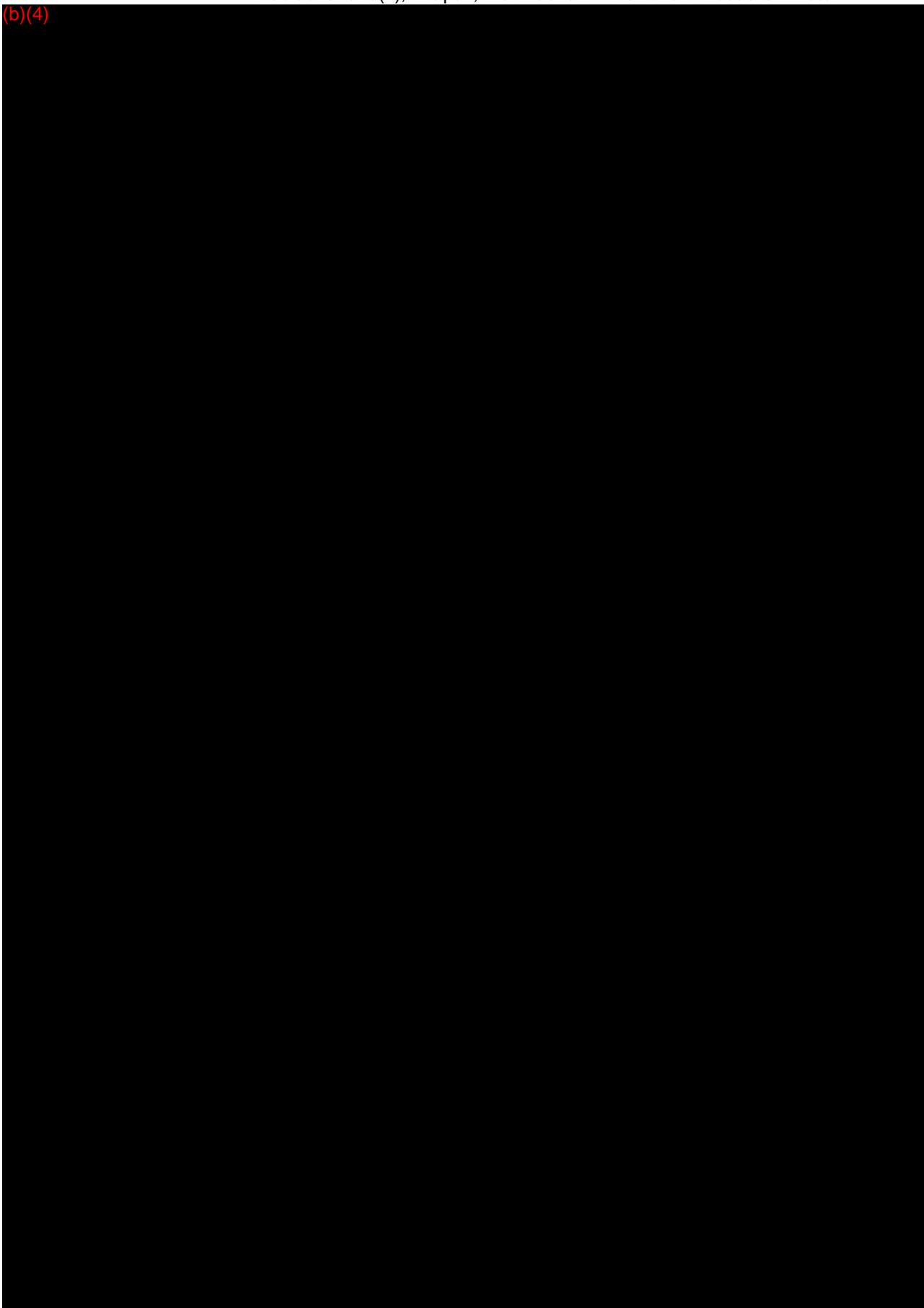
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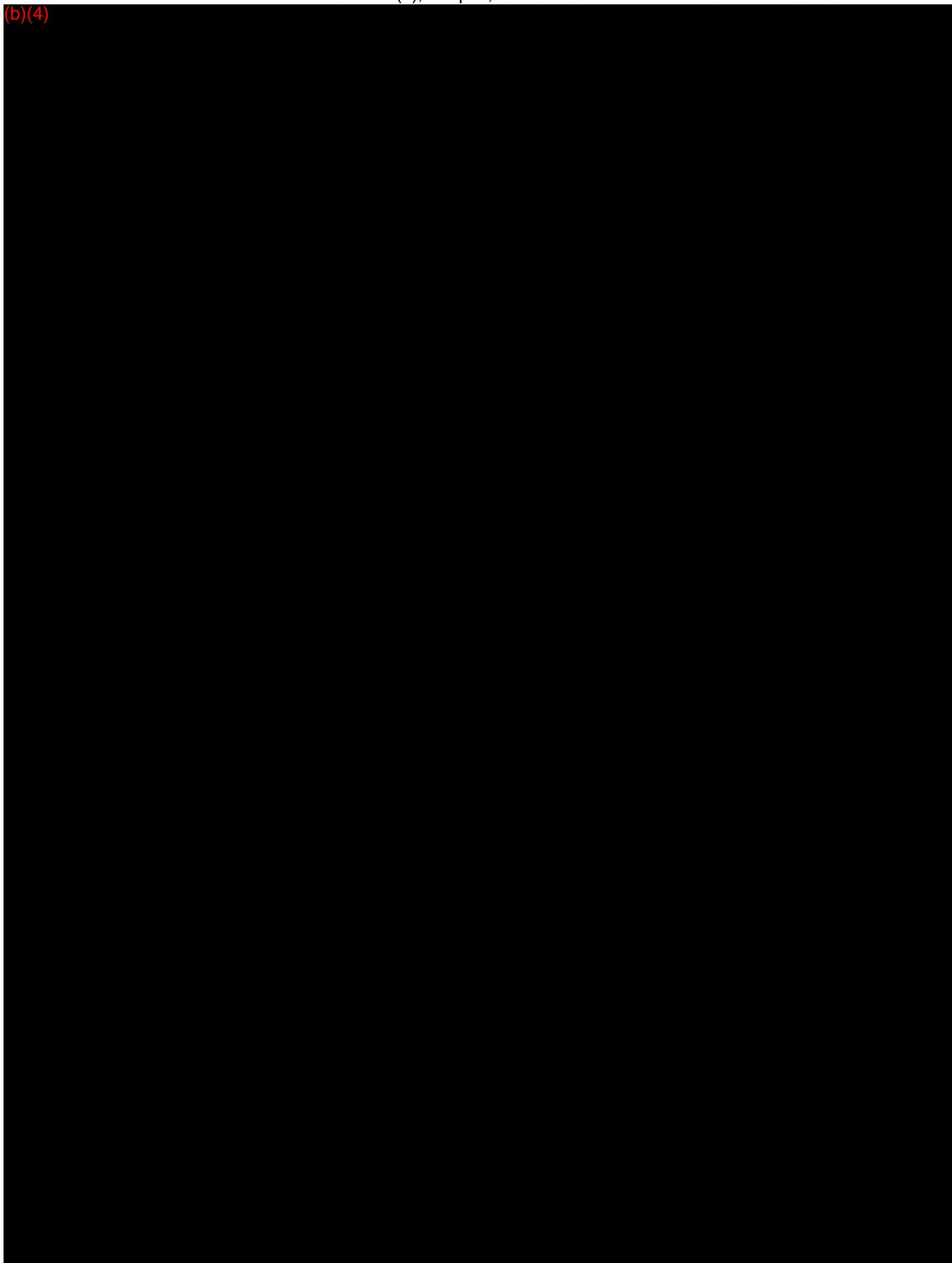
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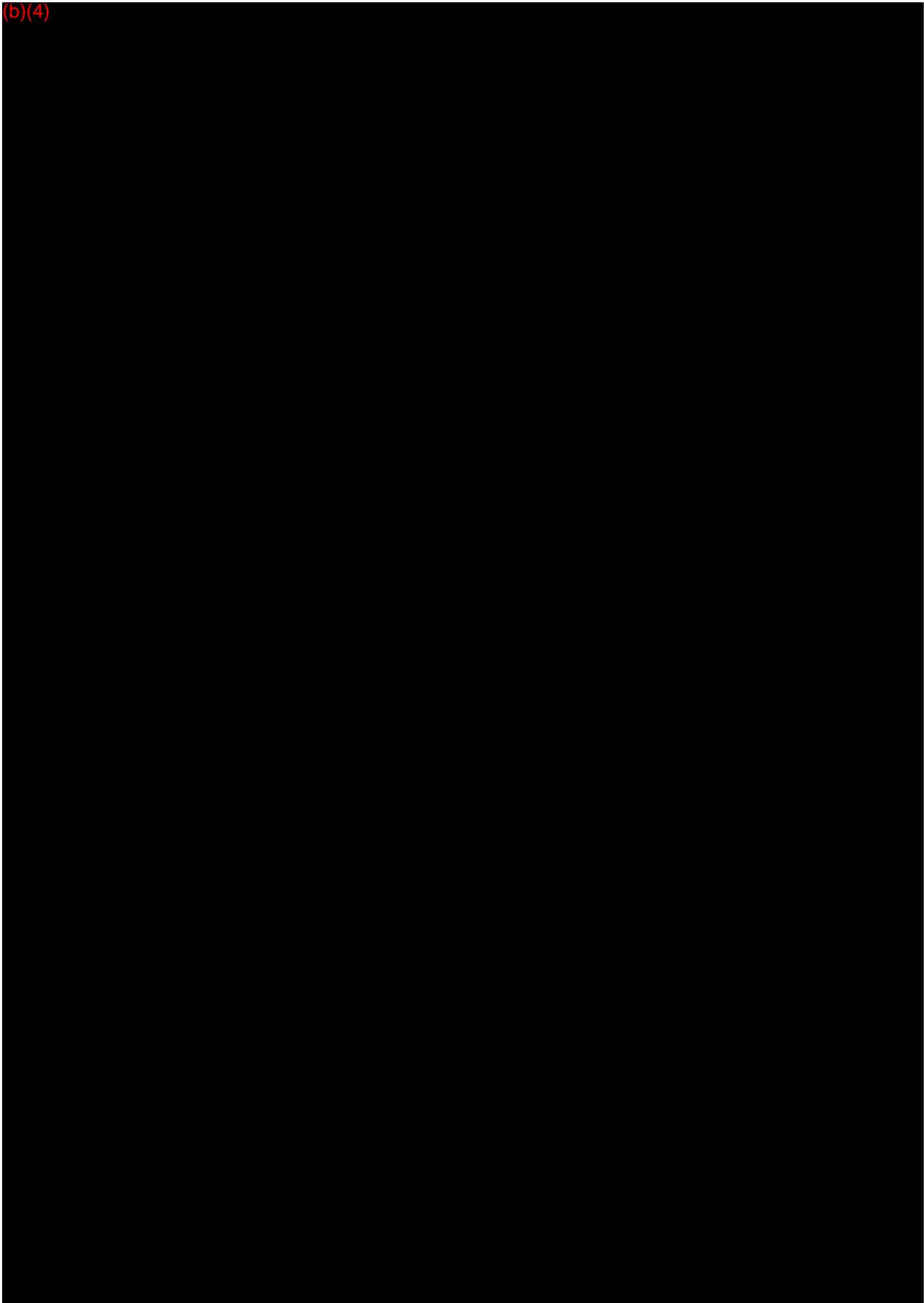
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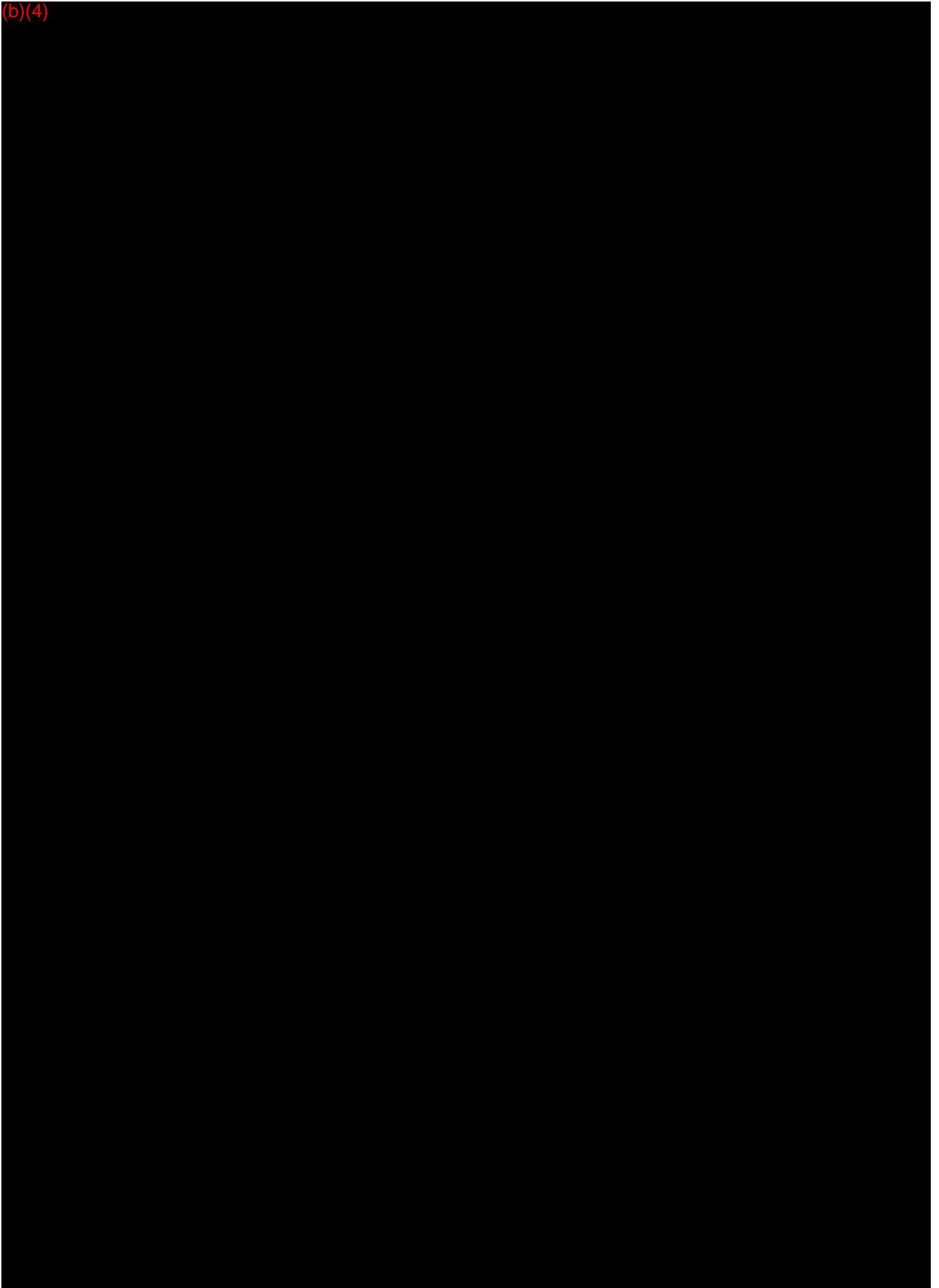
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(b)(4)



(b)(4)



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APPENDIX 11A – VIO05178_PRD_INTRA.OX™
PRODUCT REQUIREMENTS DOCUMENT

(b)(4) Third Party Information

PRD_Intra.Ox Product Requirements Document

<i>Number</i>	(b)(4)
<i>Revision</i>	
<i>State</i>	In Work
<i>Authors</i>	Technical Staff
<i>Project</i>	(b)(4)
<i>Client</i>	ViOptix, Inc.

(b)(4) Third Party Information

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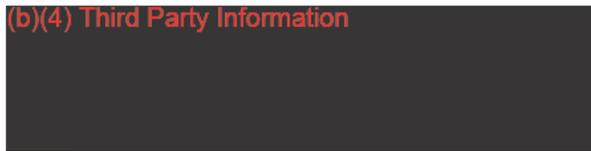


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3. Requirements List	4
4. Revision History	6

Title: PRD, Intra.Ox Product Requirements Document
Part num: (b) (b)(4)
Version: (4)

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(b)(4) Third Party Information



1. Objective

The purpose of this document is to describe the product requirements of the ViOptix Intra.Ox system.

This PRD will define the problems that the product is intended to solve, but will avoid defining technical solutions to or numerical metrics for those problems. The requirements will be distinct and numbered so as to be able to be referenced by the technical requirements documents.

The requirements will be differentiated between

"shall" (critical product requirements)

Indicate requirements which must be satisfied for product viability. These requirements are considered mandatory, and must be validated prior to product release.

"should" (optional features and requirements)

Indicate features or behaviors which are desirable, but not necessary, for product viability. These performance characteristics must be assessed during validation, and any shortfalls with respect to the specification must be reviewed and approved by client prior to product release.

"may" (allowable features and requirements)

Indicate requirements that have no impact on product viability. These provide only clarification, additional guidance to the system developer, or to indicate planned design or implementation strategies. These performance characteristics may be measured during validation, and any shortfalls with respect to the specification will be reviewed and approved by client prior to product release.

2. Indications for Use

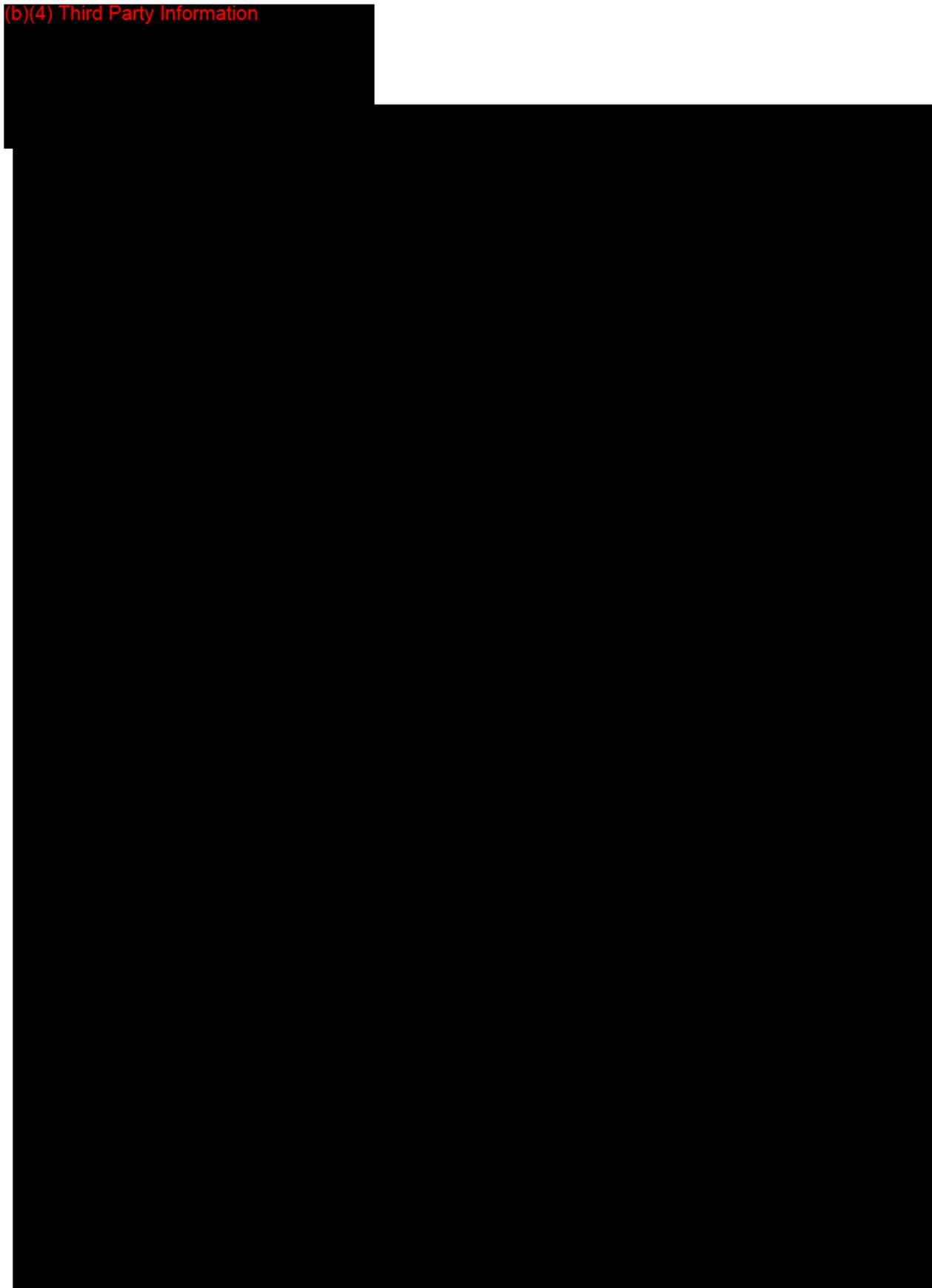
The Intra.Ox Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

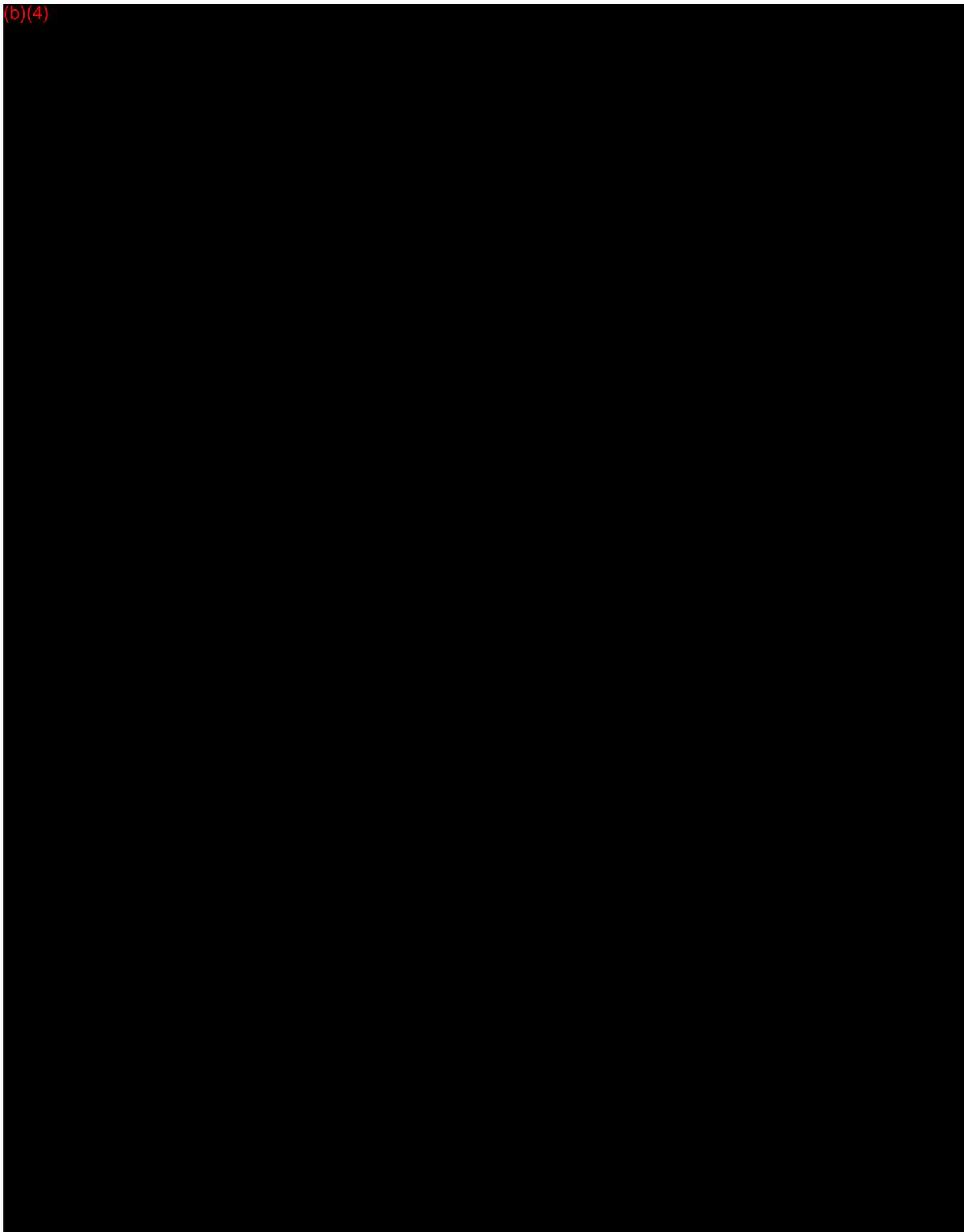
Title: PRD, Intra.Ox Product Requirements Document
Part number: (b)(4)
Version: 1.1

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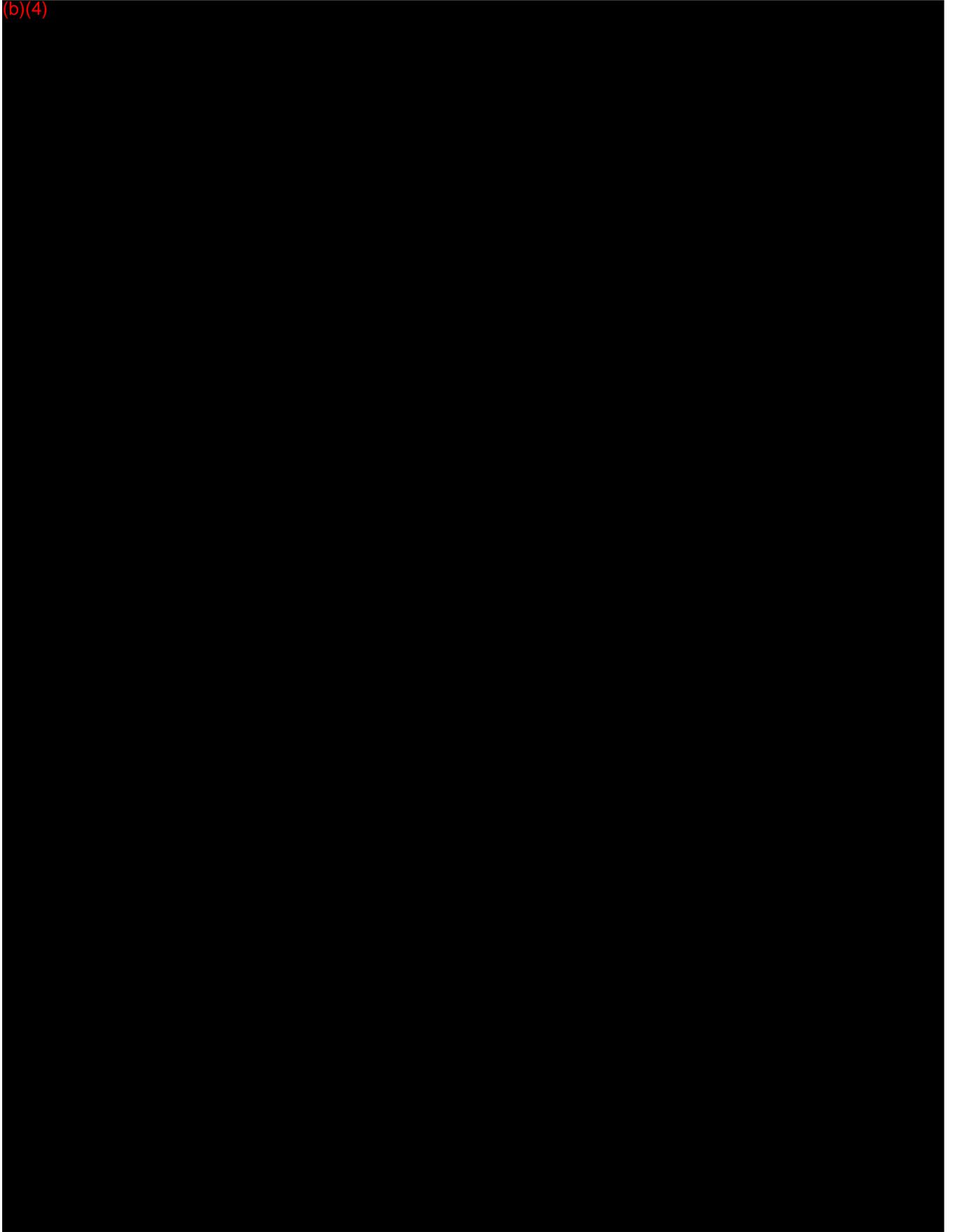
(b)(4) Third Party Information



(b)(4)



(b)(4)



12. Substantial Equivalence Discussion

Substantial Equivalence Overview:

The ViOptix Intra.Ox™ Handheld Tissue Oximeter device is substantially equivalent in intended use and technological characteristics to the following legally marketed predicate device:

- T.Ox Tissue Oximeter (formerly known as ODISsey, ViOptix, Inc., K042657)

Provided below is a detailed comparison of the Intra.Ox™ device to its predicate (See

Substantial Equivalence Table), which includes attributes identified for comparison in guidance documents provided by the FDA. This is followed by a narrative discussion.

In summary, the Intra.Ox™ device is similar to the ViOptix T.Ox predicate device in that:

- Both have the same intended use. Both are oximeters that non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.
- Both use the same general operating principle, specifically using red and near-infrared wavelengths of light to measure the color of the blood in a volume of tissue.
- Both have sensors that are disposable single patient use.

The devices are different in that:

- The Intra.Ox™ device has an updated form factor designed to improve the user experience. Specifically, the proposed device is a single-use, cordless, handheld unit as compared to the predicate, which consists of a console plus single-use sensor.
- The Intra.Ox™ device has additional detectors (8 as compared to predicate's 4), which increases the information available to the oxygen saturation determination. Specifically, tissue absorption can now be determined independently from tissue scattering as discussed in the Device Description section. Typically, the effects of tissue scattering and absorption are entangled; for example, light may not reach a detector due to either being absorbed or by being scattered away. The Intra.Ox™ device disentangles these effects through use of the additional detectors at different distances from the source and therefore does not need an assumption of fixed tissue scattering that the predicate device required.

This concept is discussed in more detail in the Device Description and in the following narrative.

- The Intra.Ox™ device has additional wavelengths (4 as compared to predicate's 2; 760 nm, 810 nm, 850 nm, and 900 nm as compared to predicate's 690 nm and 830 nm), which increases the information available to the oxygen saturation determination. The minimum number of wavelengths necessary to determine oxygen saturation is 2, which stems from the assumption that oxygenated and deoxygenated hemoglobin are the primary absorbers in tissue. Therefore, in order to solve the 2-equation, 2-unknown problem for the concentrations of

oxygenated and deoxygenated hemoglobin, at least 2 wavelengths are needed.

- In order to avoid interference from methylene blue, a common medical dye, the Intra.Ox™ device has its shortest wavelength (760 nm) longer than (beyond) the absorption curve of methylene blue (strong absorption up to 730 nm).

Substantial Equivalence Table

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
510K number	This submission	K042657	
Manufacturer	ViOptix, Inc.	ViOptix, Inc.	Yes. Identical
Intended Use			
Indications for Use	<p>The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.</p> <p>The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.</p>	<p>The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.</p> <p>The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.</p>	Yes. Overall use is the same.

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Measured Parameters	Tissue oxygen saturation (% StO ₂)	Tissue oxygen saturation (% StO ₂) and trend graph	Yes. Similar to predicate. The Intra.Ox™ is intended for spot checking at various locations and not long-term use in one location.
Design			
Operating Principle	Spectrophotometric oximetry	Spectrophotometric oximetry	Yes. Identical to predicate.
Technology	Spatially-resolved reflectance measurements	Ratiometric spatial reflectance measurements	Yes. Similar to predicate.* *see narrative below
Energy Delivered	Near-infrared light Source: LED chips Wavelengths: 760, 810, 850, 900 nm	Near-infrared light Source: laser diodes Wavelengths: 690, 830 nm	Yes. Similar to predicate.* *see narrative below
Sources/Detectors	2 source locations with 4 wavelengths at each location / 8 detectors	2 source locations with 2 wavelengths at each location / 4 detectors	Yes. Similar to predicate.* *see narrative below
Source-detector spacings	16 spacings from 1 mm – 4 mm	8 spacings from 5 mm – 7.5 mm	Substantially Equivalent.* *see narrative below

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Single Patient Use?	Yes, integrated sensor and control unit is single patient use disposable.	Sensor is single patient use disposable. Control unit is reusable.	Substantially equivalent.
Power Source	Battery powered Battery type: 4 Lithium AA Battery voltage: 6 V total	Mains powered with battery backup Battery type: 3-cell Lithium ion	Substantially equivalent.
Biocompatibility	Patient-contacting materials meet the requirements of 10993 Parts 1, 5 and 10	Patient-contacting materials meet the requirements of 10993 Parts 1, 5 and 10 (See page 100 of K042657 submission)	Yes. Identical to predicate.
Performance			
Measurement Range	1-99% StO ₂	1-99% StO ₂	Yes. Identical to predicate.
Measurement Depth (mean photon visitation depth)	0.5 – 2 mm	1 – 3 mm	Substantially equivalent. * *see narrative below
Bench testing	Full-range blood desaturation (see Section 18)	Not Performed	Yes. Substantially equivalent. The results of the study show strong agreement between the outputs from both devices.

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Animal studies	Not performed	Canine desaturation events	Instead of animal studies, an in-vivo study with human subjects was performed as discussed below.
Clinical studies	An in-vivo study was performed to compare measurements from the Intra.Ox™ Handheld Tissue Oximeter and the predicate device under similar circumstances.	Not performed	Yes. Substantially equivalent. The results of the study show strong agreement between the outputs from both devices.
Safety			
Sterility	(b)(4)		
Compatibility with intended environments	Conforms to IEC 60601-1-2 for Electromagnetic Interference	Conforms to IEC 60601-1-2 for Electromagnetic Interference	Yes. Identical to predicate.
Electrical safety	Conforms to IEC 60601-1 requirements for electrical safety	Conforms to IEC 60601-1 requirements for electrical safety	Yes. Identical to predicate.
Mechanical safety	Conforms to IEC 60601-1-1, Section 9.3 requirements for mechanical safety	Conforms to IEC 60601-1 requirements for mechanical safety	Yes. Identical to predicate.

Parameter	Subject Device: Intra.Ox™	Predicate Device: T.Ox (formerly known as ODISsey)	Substantial Equivalence?
Radiation safety	Conforms to ANSI/IESNA RP-27.1-05 Photobiological Safety for Lamps and Lamp Systems Section 4.3.	Conforms to IEC 60825-1.	Yes. Substantially equivalent. The light source used by the Intra.Ox™ Handheld Tissue Oximeter consists of LEDs which present much lower risk of injury than the predicate device, which uses lasers.

Substantial Equivalence Discussion:

The Intra.Ox™ Handheld Tissue Oximeter, as well as the predicate device, are both intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue and indicated for use in monitoring patients during circulatory or perfusion examinations. The basic theory of operations, spectrophotometric oximetry, is the same for both devices – utilizing red and near-infrared wavelengths of light to measure the color of blood and determining an oxygen saturation value. The Intra.Ox™ Handheld Tissue Oximeter has a more convenient form factor by incorporating all functions within one single-use handheld unit, as opposed to a reusable console and single-use handheld sensor.

Technology

The Intra.Ox™ device and the predicate T.Ox device use very similar technology, but with some differences that primarily relate to the different form factors of the devices. In order to estimate the oxygen saturation in tissue, the effective attenuation coefficient of the tissue needs to be measured. The effective attenuation coefficient is a function of both tissue absorption and scattering.

The predicate device comprises a touch screen console and separately-sold sensors that connect to the console. Because the sensors are sold separately from the console, an autocalibration method is used to ensure reproducible results from sensor to sensor. The autocalibration method involves ratioing the outputs from two different detectors that use the same source and also ratioing the outputs from the same detector that uses different sources. In the first case the source power variation is removed and in the second case the detector gain variation is removed. The multiplication of these ratios then gives a stable value that is independent of source power and detector gain. Multiple such ratiometric pairings are compared to values in a lookup table to determine the effective attenuation coefficient of the tissue. The lookup table uses tissue scattering at a set value, although some patients may have skin that is much lower scattering or much higher scattering than the majority of patients.

The Intra.Ox™ Handheld Tissue Oximeter is contained in a single handheld unit. Each device is individually factory calibrated with the calibration table stored in the device flash memory, eliminating the need for autocalibration. The device uses a multitude of source-detector separations ranging from very close to the source (~ 1 mm) to further away (~ 4 mm) that provides enough information to compare to curves in a look-up table and determine tissue absorption and scattering independently of one another and determine the tissue attenuation coefficient without assuming a set value for tissue scattering. This change does not raise new questions of safety or effectiveness.

Energy delivered / Light sources

The predicate device utilizes laser diodes, which occupy more physical space and require more hardware to operate than LEDs. The Intra.Ox™ device utilizes LED chips in its very compact sensor head. Because tissue is highly scattering, spatially coherent laser light becomes randomized within 1 mm of the source. Therefore, there is no functional difference between using lasers or LEDs for tissue oximetry measurements; all that matters to the tissue reading is wavelength (see below).

Wavelength

The wavelength selection for both the predicate and subject devices follow the same general principles as all oximetry devices. The minimum number of wavelengths necessary to determine oxygen saturation is 2, which stems from the assumption that oxygenated and deoxygenated hemoglobin are the primary absorbers in tissue. Therefore, in order to solve the 2-equation, 2-unknown problem for the concentrations of oxygenated and deoxygenated hemoglobin, at least 2 wavelengths are needed.

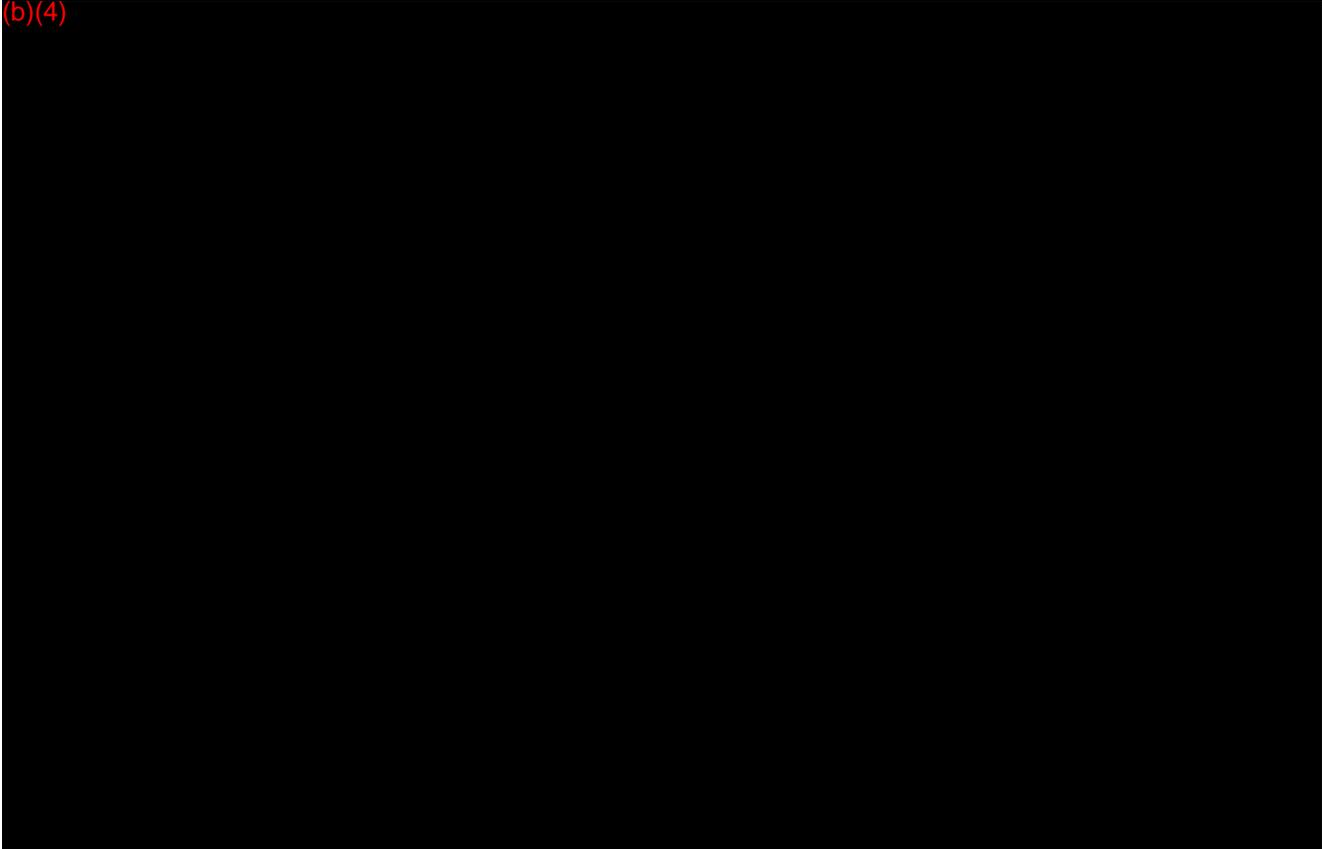
For measurement depth reasons, wavelengths in the near-infrared region (700-900 nm) are preferred because tissue scattering is lower in this region and light penetrates farther into tissue. For statistical reasons, in a two-wavelength system it is beneficial to select wavelengths on either side of an

oxygenated-deoxygenated hemoglobin spectral crossing point called an isosbestic point. Consequently, when one chromophore has high absorption, the other has low absorption and vice versa. Both the predicate and Intra.Ox™ devices use wavelengths longer and shorter than the 810 nm isosbestic point of hemoglobin. The predicate device uses 690 nm and 830 nm whereas the proposed device utilizes at a minimum 760 nm and 850 nm. In an effort to avoid the absorption curve of methylene blue, a common medical dye that interferes with the predicate device, the Intra.Ox™ device utilizes wavelengths longer than about 730 nm. 760 nm was selected as it is the peak of the deoxyhemoglobin spectrum in the 720-900 nm range; 850 nm is functionally no different than 830 nm as the spectral profiles are fairly flat in that region.

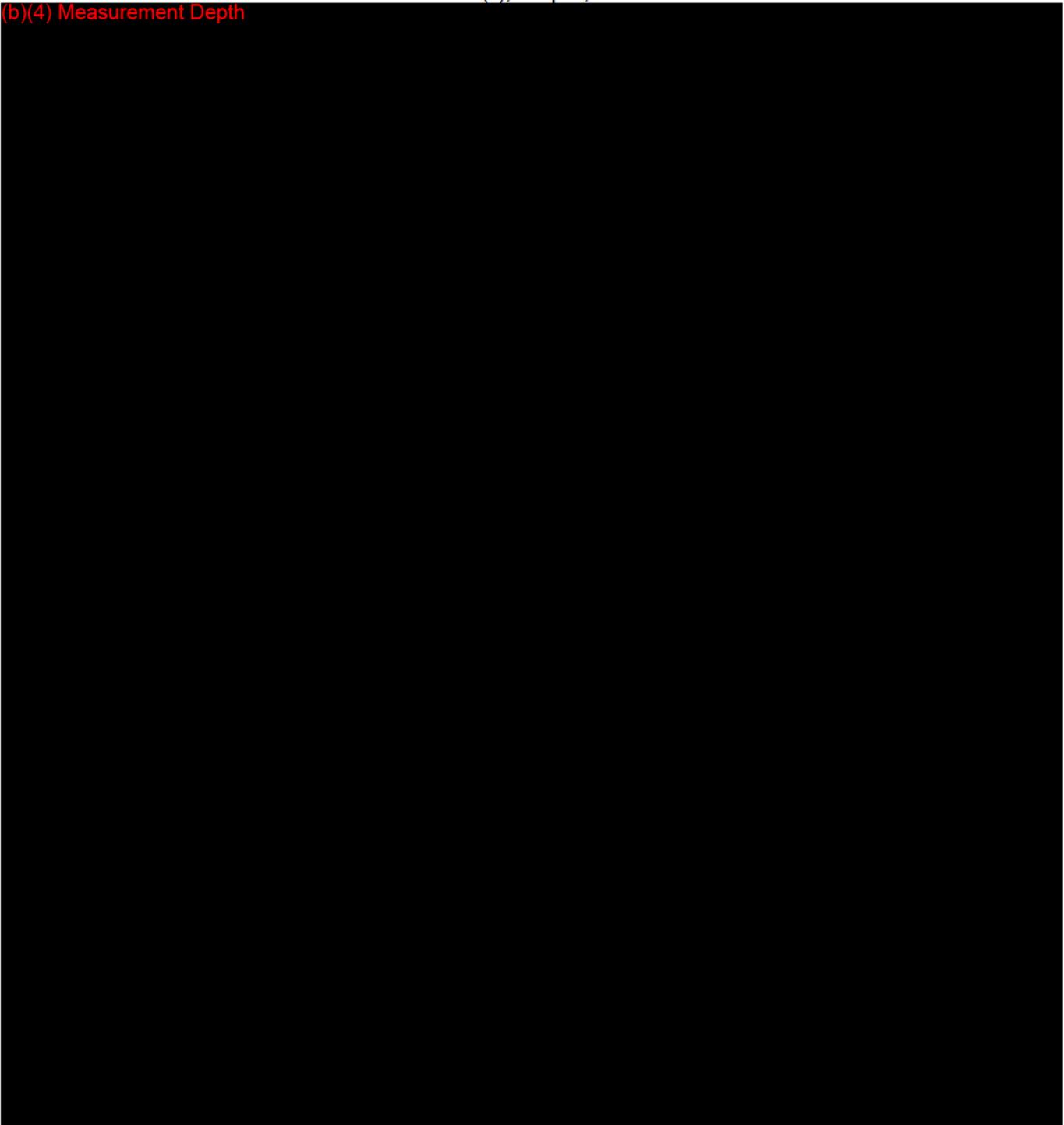
In the presence of noise, additional wavelengths may be utilized to improve accuracy. The Intra.Ox™ device includes two additional wavelengths: 810 nm and 900 nm. The isosbestic point itself, at 810 nm, is selected as at this point the absorption of oxy- and deoxyhemoglobin are equivalent and it provides a stable reference. 900 nm is chosen in order to better distinguish the deoxyhemoglobin absorption curve from the melanin absorption curve.

Measurement Depth

(b)(4)



(b)(4) Measurement Depth



Substantial Equivalence Summary:

The Intra.Ox™ device is substantially equivalent to the T.Ox device predicate (K042657) based on the data and narrative presented here. The subject device, while having potential improvements in user experience and reliability among different tissue types, has the same overall intended use and does not raise new types of questions of safety or effectiveness. The performance of the Intra.Ox™ device is validated with a bench test and in-vivo test, as described in Sections 18 and 20.

510(k) “Substantial Equivalence” Decision-Making Process Flowchart Analysis:

This section includes a direct answer to each of the pertinent questions included in the flowchart attached to FDA’s guidance on the premarket notification review program (K86-3) [“510(k) ‘Substantial Equivalence’ Decision-making process (detailed)”].

New device is compared to marketed device?

Yes. The ViOptix Intra.Ox™ device is compared to the legally marketed T.Ox device (formerly known as ODISsey, ViOptix, Inc., K042657).

Does new device have same intended use?

Yes. Both are intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

Does new device have same technological characteristics?

Very similar. Differences are as described in the above narrative.

Could the new characteristics affect safety or effectiveness?

Yes, but the new characteristics do not raise a new type of safety or effectiveness question.

Are the descriptive characteristics precise enough to ensure equivalence?

Yes. All relevant aspects of the subject and predicate devices have been considered and listed in the Substantial Equivalence Table. In addition, performance data obtained from bench testing and in vivo shows that this device provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.

References:

Patterson 1995

Patterson MS, et al. "Absorption spectroscopy in tissue-simulating materials: a theoretical and experimental study of photon paths." *Appl. Opt.* 34(1):22-30 (1995).

Sussman C and Bates-Jensen B

Wound Care: A collaborative practice manual for health professionals.
ISBN-13: 978-1608317158, Fourth Edition

13. Proposed Labeling

Proposed labeling for the Intra.Ox™ Handheld Tissue Oximeter, including instructions for use and device label, is found in Appendix 13A – VIO06283_Proposed Labeling, in the following pages.

APPENDIX 13A – VIO06283_PROPOSED LABELING

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DOC_Proposed Labeling

<i>Number</i>	(b)(4)
<i>Revision</i>	(b)(4)
<i>State</i>	In Work
<i>Authors</i>	Technical Staff
<i>Project</i>	(b)(4)
<i>Client</i>	ViOptix, Inc.

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1 General Information

1.1 Overview

The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO₂) in a volume of tissue. The device uses spatially-resolved optical measurements at four wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO₂ estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is constructed from biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

This manual has been prepared to assist medical personnel in the operation the ViOptix Intra.Ox™ Handheld Tissue Oximeter. Prior to operating this device, all personnel must read this manual and gain a thorough understanding of its proper operation. Special attention should be directed to all cautions and warnings regarding the use of the product.

ViOptix cannot, and does not intend within this manual, to give medical advice.

1.2 Indications For Use

The Intra.Ox Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

(b)(4) Third Party Information



1.3 References

Trademarks

Intra.Ox™ Handheld Tissue Oximeter is a registered trademark of ViOptix, Inc.

References

References to "ViOptix" in this manual shall imply ViOptix, Inc.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, ViOptix reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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

Copyright 2013

Covered by one or more of the following US Patents and foreign equivalents:

6,516,209

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ViOptix, Incorporated

47224 Mission Falls Court

Fremont, CA 94539

Tel: 510-226-5860

Fax: 510-226-5864

2 Safety

2.1 Contraindications, Warnings, and Cautions

2.1.1 Contraindications

There are no known contraindications for the use of the Intra.Ox™ Handheld Tissue Oximeter.

2.1.2 Warnings

Warnings are identified by a label or symbol. Refer to the Glossary of Symbols at the end of this document. Warnings alert the operator to potential serious outcomes to the patient or operator.

- The Intra.Ox™ Handheld Tissue Oximeter comes packaged sterile and is a one time use device, DO NOT RE-STERILIZE this device.
- Inspect the sensors before each use for visible damage. Do not use the sensor if it has visible damage.
- To prevent damage, do not bend or apply torque to the sensor head
- Hard knocks, particularly at the distal end of the sensor, may result in damage to the delicate fiber-optic cables, which could affect instrument performance. Do not use if there is visible damage to the Handheld Tissue Oximeter.
- Do not allow any liquid to pass into any electrical connections. **Allow wet surfaces to thoroughly dry before use**
- Do not immerse or soak sensors in liquid solutions.
- Avoid extreme changes in temperature and/or humidity.
- To reduce the risk of electrical shock, do not open the equipment's inner housing. Refer servicing to qualified personnel only. Removal of panels by unauthorized personnel will void the unit's warranty.
- This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.
- Dispose of used Intra.Ox™ Handheld Tissue Oximeter using appropriate biohazard precautions.
- Dispose of an Intra.Ox™ Handheld Tissue Oximeter battery in accordance with local requirements and regulations.

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2.1.3 Precautions

- Check the sensor application site frequently to assess positioning, circulation, and skin sensitivity of the patient. If required, reposition the sensor to a new site or if redness or skin irritation is noted. If irritation continues, discontinue use.
- Avoid placement directly over bony prominences, scar tissue, dark birthmarks or other visibly non-homogenous tissue, as it could provide improper reading.
- If tissue is uneven, gently flatten tissue or move to a new location.
- When repositioning device, pick up sensor and replace; do not drag.
- Use extra caution when placing on thin or delicate skin.

3 Installation and Setup

The Intra.Ox™ Handheld Tissue Oximeter is a prescription-only device that comes fully assembled and packaged in a protective box which contains one device in a sterile double pouched configuration. The device is designed for single use, is handheld and battery powered and requires no external power source. The unit is sealed and is not designed to be disassembled or repaired by the user. The unit cannot be opened and the batteries cannot be replaced by the user.

No Installation is required.

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4 Device Configuration and Interface Elements

The ViOptix Intra.Ox™ tissue oximeter has three main interface elements:

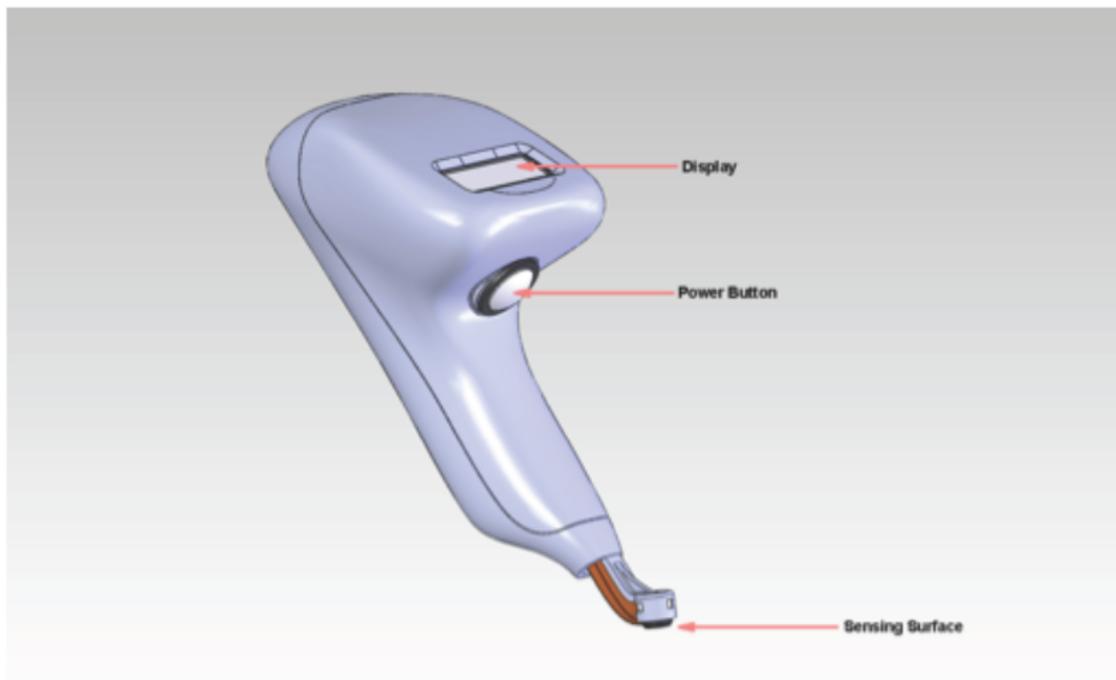


Figure 1: Device Configuration and Interface Elements

4.1 Display

The LCD display shows

- Powering up indicator
- Current oxygen saturation value in percent
- Total powered-up time
- Low battery indicator
- Error messages

4.2 Power Button

The power button is used to:

- Power up the device

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- Put the device into standby mode
- Bring the device out of standby mode
- Clear error messages
- Power down the device

4.3 Sensing Surface

The sensing surface contacts the patient and includes:

- Light sources
- Light detectors

All elements are discussed in greater detail later in this manual.

5 Operating The ViOptix Intra.Ox™

5.1 Holding the Device

Hold the tip of the Intra.Ox™ device similarly to a pen, with the wrist in a neutral position. Lightly rest hand on the patient and use fingers to brace the device for maximum stability. Sensing face should be parallel to tissue and in gentle contact.

5.2 Powering Up

To power up the Intra.Ox™ tissue oximeter, momentarily press the power button and then release it. The LCD backlight comes on, and the startup display depicted below is shown briefly:



Figure 2: Startup Display

If an error condition exists, an error display is shown. See section 5.7 for instructions on how to clear the error.

5.3 Measuring Percent Oxygen Saturation

Once power-up is complete, place the sensing surface on the patient, and apply very light pressure to the tissue of interest. Do not apply firm pressure as this will blanch the tissue.

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Continue to hold the device against the tissue for a few seconds until an Oxygen Saturation Percentage appears on the display. The display is organized as depicted below:

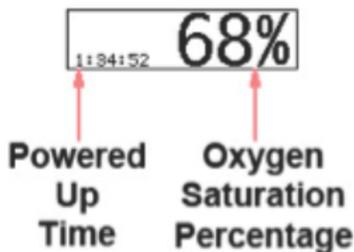


Figure 3: Normal Display Layout

5.3.1 Powered Up Time Display

The total elapsed time that the device has been powered up is displayed in hours, minutes and seconds in the lower left of the display.

Battery life is expected to last 5 hours of operating time.

5.3.2 Percent Oxygen Saturation Display

The oxygen saturation estimate at the sensing surface location is indicated in percent on the right side of the display and is updated several times per second.

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If the oxygen saturation value is invalid for any reason, the digits are replaced by dashes:



Figure 4: Invalid Percent Oxygen Saturation Value Display

If the sensing surface is not in contact with tissue or is in contact with inappropriate pressure, the invalid percent oxygen saturation value indication is displayed. A dirty sensing face can also cause the unit display dashes. If the Intra.Ox™ is positioned properly and no oxygen saturation value appears, gently wipe the sensing surface with a soft cloth, moistened with water or alcohol, to remove any debris. Alternately, cup hand around sensor to reduce potential interference from ambient light.

5.3.3 Temperature Out Of Range Error

If the sensor temperature is out of range, a "Low Temp" or "High Temp" error is displayed in addition to the invalid percent oxygen saturation dashes:

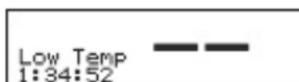


Figure 5: Temperature Out Of Range Display

If a "High Temp" error is displayed, move the Intra.Ox™ away from heat sources such as warming blankets or direct OR light exposure. If a "Low Temp" error is displayed, move the device away from cold sources such as ice packs and air-conditioning vents.

(b)(4) Third Party Information

5.3.4 Low Battery Indicator Display

When remaining battery capacity is low, a battery indicator flashes on the display.

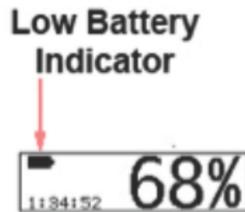


Figure 6: Low Battery Indicator

The Intra.Ox™ tissue oximeter can continue to be used as long as battery life remains. The battery is not rechargeable, so the low battery indicator indicates remaining product usage time is limited. Standby mode (section 5.4) can be used to maximize remaining battery life during the current procedure.

5.4 Requesting Standby

In order to reduce power consumption and maximize battery life, you may wish to put the Intra.Ox™ tissue oximeter in standby mode when it is not actively in use during a procedure. This is done by momentarily pressing and releasing the power button (press for less than two seconds).

The LCD backlight turns off, and the invalid percent oxygen saturation display is shown. The device can be quickly reactivated.

5.5 Coming Out Of Standby

To return to normal operating mode from standby mode, momentarily press and release the power button (press for less than two seconds).

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The LCD backlight comes on, and percent oxygen saturation values are displayed as soon as appropriate contact is made with the tissue of interest.

5.6 Powering Down

At any time, the Intra.Ox™ tissue oximeter can be powered down completely by pressing the power button for more than two seconds and then releasing it. Release the power button as soon as the "powering down" message is displayed.

The LCD turns off completely as the device powers down.

If for any reason the device does not power down as expected, press and hold the power button until it does. This effects a hardware-mediated power-down without software control. If the device is powered down in this manner, you may see an improper shutdown error message the next time you power up.

5.7 Resolving Errors

Error conditions may occur that require the display of an error message on the display. Error messages are displayed as text that may use up to 4 lines on the display. Error messages may be recoverable or non-recoverable.

5.7.1 Recoverable Error Messages

To clear a recoverable error message, momentarily press and release the power button (press for less than two seconds).

Recoverable Messages:

Improper Shutdown Logs/Time Corrupted

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The device was powered down by pressing and holding the power button to effect a hardware shutdown (i.e. the device was powered down without software control). In this case, elapsed time from the most recent operating session will not be reflected in the powered-up time. The displayed powered-up time will underestimate actual device powered-up time. In addition, some operating log entries may have been lost.

5.7.2 Non-Recoverable Error Messages

Any message with the prefix FATAL is a non-recoverable error. Attempt to power-cycle the device by powering down completely and then powering up as described earlier.

If the error persists, the device is not operable. Use a new Intra.Ox™ Handheld Tissue Oximeter and contact your ViOptix sales representative to report the error.

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⊕ **6 Specifications**

Component	Specification
Tissue Oxygen Saturation Range	0 – 99%
Wavelengths	760, 810, 850, 900 nm LED
Accuracy	StO ₂ measurement shall be within +/-10 points
System Control	System will perform self-test when power is turned on
Alarms (visual)	Display Low Battery Condition Display Measurement Error Conditions of Insufficient Data Quality
Battery Life	4 Hours of continuous use (including 2 hours of measurement)
Operating Mode	Spot Measurement Mode
Transport and Storage	<p><u>Temperature</u></p> <ul style="list-style-type: none"> • Device shall operate normally at ambient temperatures of 20°C to 35°C, provided the sensor head temperature is 37.0 ± 0.5° C. • Device (packaged) shall operate normally after storage at -20°C to 60°C. <p><u>Humidity</u></p> <ul style="list-style-type: none"> • Device shall operate normally in a humidity environment of 20% to 80% (non-condensing). • Device (packaged) shall operate normally after storage at 10% to 100% (condensing).
Dimensions	5" x 5" x 10"
Weight	1 LB

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[Redacted]

Sensor Specifications	IEC 60601-1. Any surface of the system that comes into contact with a patient for a time of 1 minute shall not exceed 45°C. The device shall comply with ANSI/IESNA RP-27.1-05 (Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements) for light output.
------------------------------	---

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7 Labels



Contents: (1) Disposable Intra.Ox™ Handheld Tissue Oximeter

ViOptix P/N: OXY-2-INT-1

STERILE EO

EC REP

CE 0085

Emergo Europe
Molenstraat 15
2513 BH The Hague
The Netherlands
Phone: +31.70.345.8570
Fax: +31.70.346.7299

S/N

Do not re-use

Use by:
YYYY-MM

Consult instructions for use

ViOptix, Inc.
47224 Mission Falls Ct.
Fremont, CA 94539
www.vioptix.com

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of a physician.

Patents pending

Label P/N: 89708 Rev A

Manufactured in the USA for ViOptix, Inc.
47224 Mission Falls Court, Fremont, CA 94539

To Reorder: Fax 510.226.5864

www.vioptix.com



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7.1 Glossary of Symbols

Symbols

 Do not re-use	Sterile Disposable Small Patch Sensor –are intended for single-patient one-time use . DO NOT REUSE, DO NOT RE-STERILIZE
	Sterilized by Ethelyne Oxide
 Use by	Use by expiration date stamped
	Attention, consult accompanying documents
	Non-ionizing radiation
ViOptix P/N:	Model Number (Catalog Number)
	Serial Number
	DANGER: Explosion risk if used with flammable anesthetics
	Manufactured By

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+ 8 Revision History

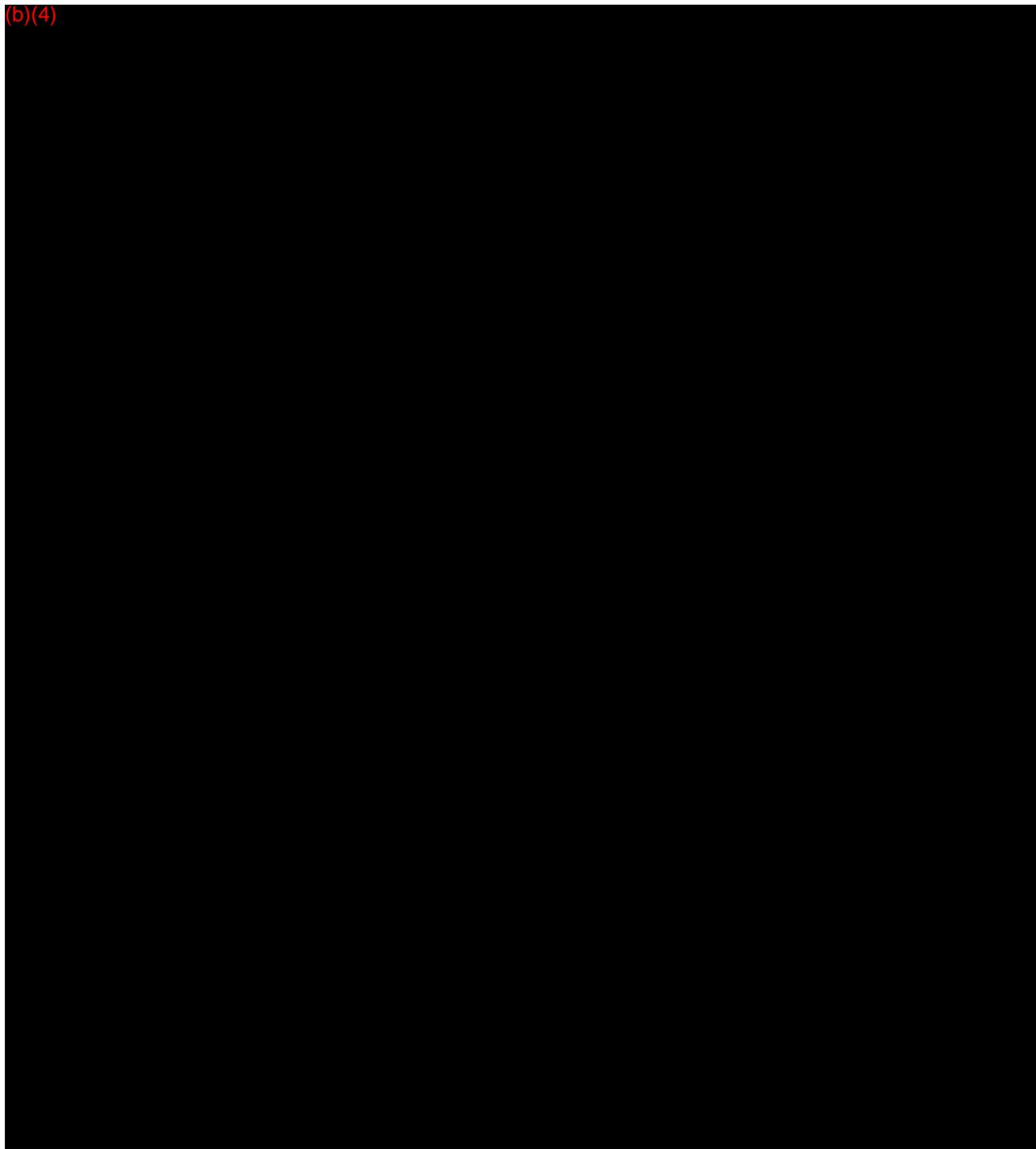
<i>Rev</i>	<i>Description of Change</i>	<i>Project No.</i>	<i>Originator</i>	<i>Date</i>
01	Initial Release	(b)(4)	Technical Staff	3/1/2013
02	Updated for current design	(b)(4)	Technical Staff	8/30/2013
03	ViOptix Updates	(b)(4)	Technical Staff	10/17/2013

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14. Sterilization and Shelf Life

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Pyrogenicity:

Product will not be labeled as “non-pyrogenic,” is not a permanent implant, and will not be contacting blood or cerebrospinal fluid.

The Sterility Assurance Level (SAL):

The validated SAL will be 10⁻⁶

Radiation dose:

N/A: Product will not be sterilized with radiation.

Shelf Life:

The Intra.Ox™ will be labeled with a 12-month shelf-life.

- The packaging has been validated by the pouch manufacturer per ASTM F1980-07: Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Devices to maintain sterility over the specified shelf life
- System requirement SRS0801 states “The device shall have a shelf-life of at least 12 months” and is verified per VIO08223_VPL_Intra.Ox™ Verification Plan

15. Biocompatibility

Overview:

The following information is submitted in accordance with FDA 510(k) Memorandum G95-1.

Typically, an individual device will contact the patient intermittently for a few minutes at a time, several times over a period of up to a few hours. The device is discarded after that. There is also the possibility of the device being used on breached or compromised skin. Based on Table 15-1, below, the device may be characterized as shown in the shaded area (Surface device, Contact duration A-Limited, Breached or compromised surfaces).

Device Categories			Biological Effect							
Body Contact	Contact duration		Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	System Toxicity (Acute)	Sub chronic toxicity (Sub acute toxicity)	Genotoxicity	Implantation	Haemocompatibility
	A-limited (24h)									
	B-prolonged (24h to 30 days)									
	C-permanent (>30 days)									
Surface devices	Skin	A	x	x	x
		B	x	x	x
		C	x	x	x
	Mucosal membrane	A	x	x	x
		B	x	x	x	o	o	.	o	.
		C	x	x	x	o	x	x	o	.
	Breached or compromised surfaces	A	x	x	x	o
		B	x	x	x	o	o	.	o	.
		C	x	x	x	o	x	x	o	.

x = ISO Evaluation Tests for Consideration

o = Additional Tests which may be applicable

Table 15-1

Accordingly, recommended initial evaluation tests for consideration include:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

Additional Tests:

- System Toxicity (Acute)

The above tests will be addressed by the requirements of either FDA-modified ISO 10993, or a combination of both of ISO 10993 and USP Class VI.

All materials that can come into contact with the patient will meet biocompatibility requirements. For surfaces which are likely to have the most contact, only materials that have a Master file on record will be selected. These materials will be considered to have met biocompatibility requirements based on G95-1 Attachment C, see Flowchart in Figure 15-1, below.

General Program Memorandum

(b)(4)

Attachment C

Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s

(b)(4)

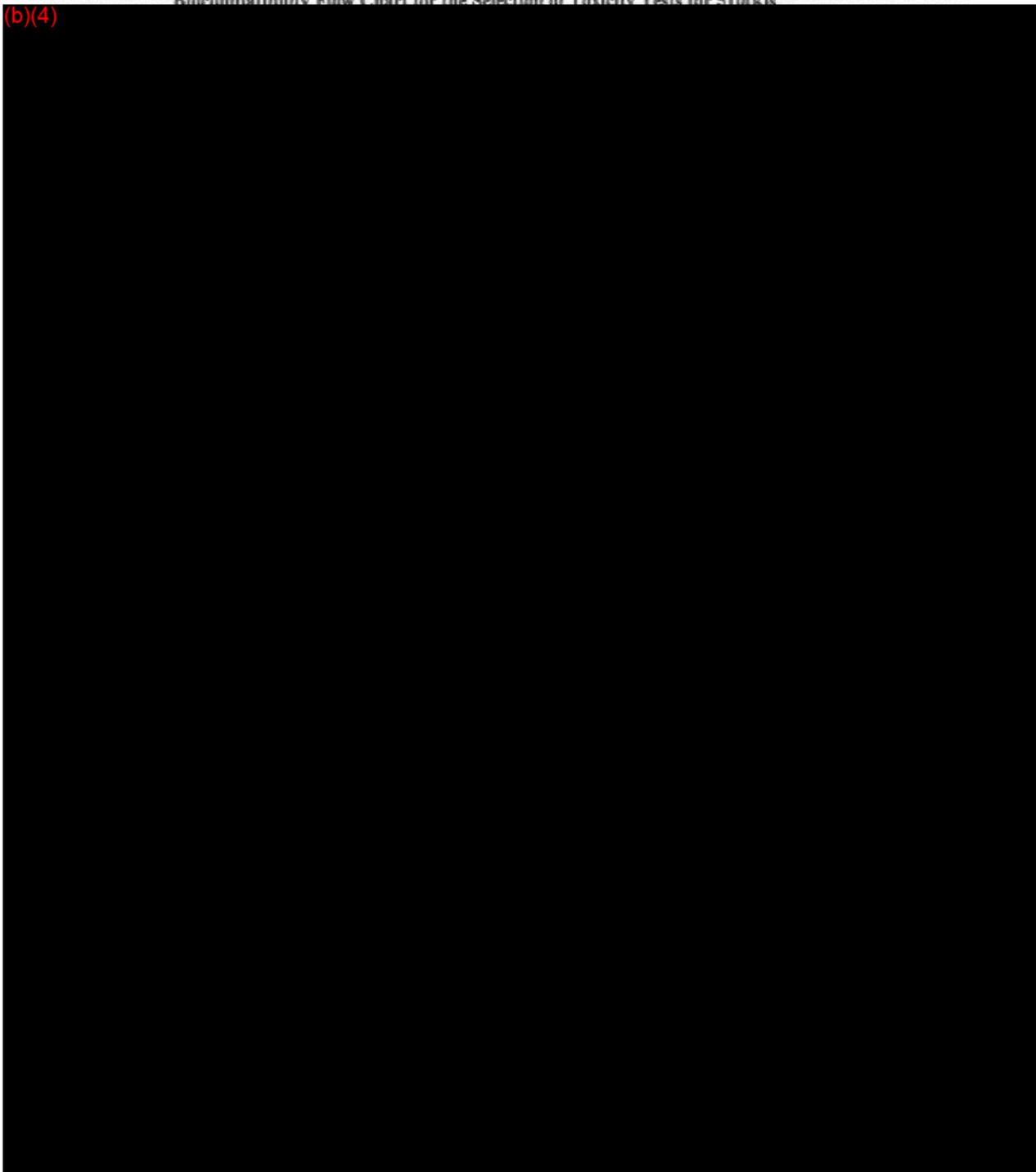


Figure 15-1

Externally Facing Components:

(b)(4)

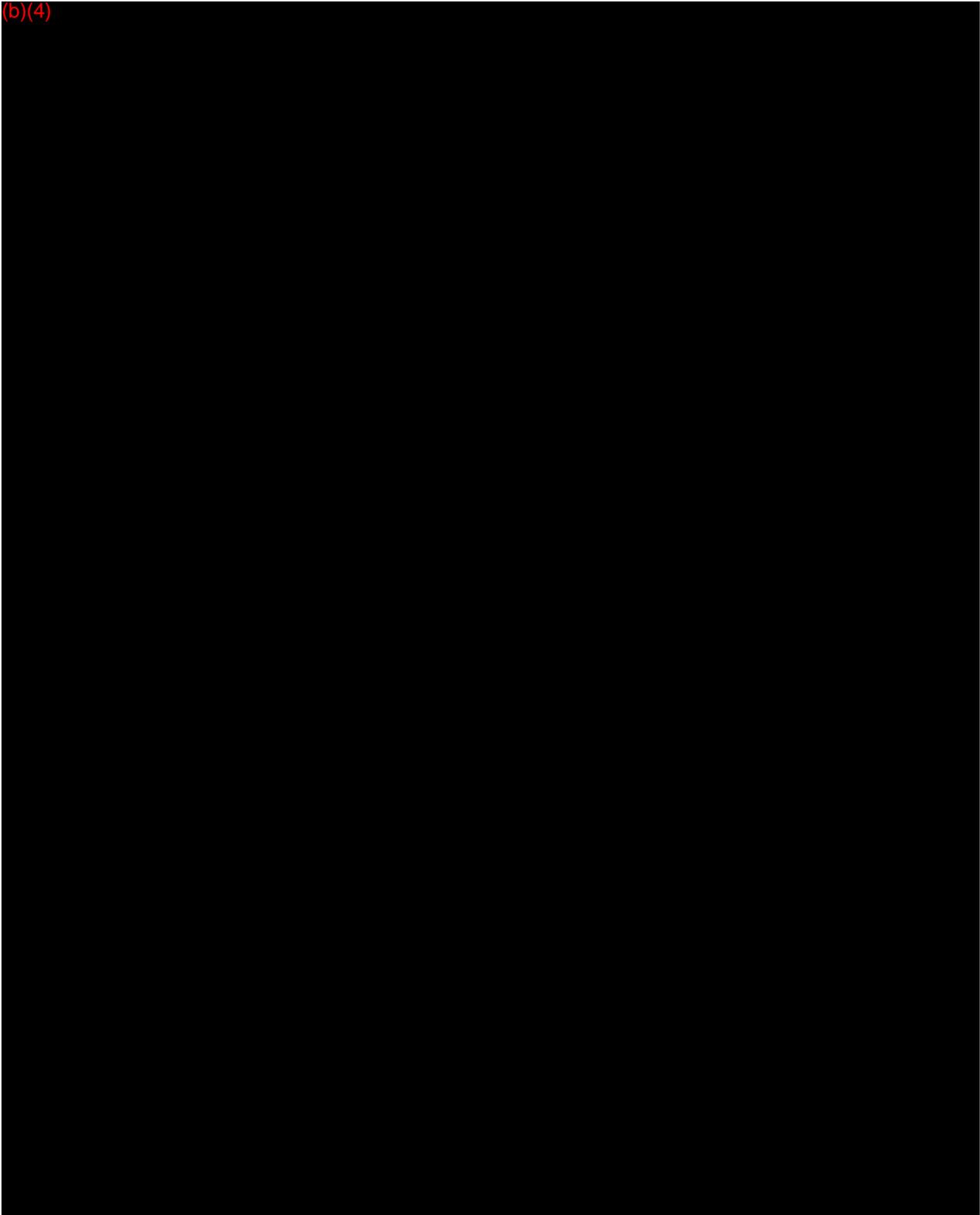


Table 15-2

16. Software

ViOptix has reviewed the FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and has determined that the software in the Intra.Ox product has a moderate level of concern. The level of concern was not formally established for the predicate device. However, the rationale for determining a level of concern would be identical and result in the same level of concern.

The software documentation recommended in Table 3 of the FDA Guidance is submitted as shown in Table 16-1, below. Please note that some documents are used for multiple sections of the guidance.

Appendix Number	Software Documentation per Table 3 of Guidance	Document Name
16A	Level of Concern	(b)(4)
16D	Software Description	(b)(4)
16B	Device Hazard Analysis	(b)(4)
16C	Software Requirements Specification	(b)(4)
16D	Architecture Design Chart	(b)(4)
16D	Software Design Specification	(b)(4)
16E	Traceability Analysis	(b)(4)
16F	Software Development Environment Description	(b)(4)
16G	“	(b)(4)
16H	Verification & Validation Documentation	(b)(4)
16I	“	(b)(4)
16J	“	(b)(4)
16K	Revision Level History	(b)(4)
16L	Unresolved Anomalies	(b)(4)

Table 16-1

17. EMC and Electrical Safety

Electromagnetic Compatibility:

The Intra.Ox™ device will meet applicable requirements for electromagnetic compatibility in accordance with IEC 60601-1-2. The compliance plan is shown in Appendix 17A – V (b)(4) _EMC Compliance Plan.

Electrical Safety:

The Intra.Ox™ device will meet applicable requirements for electrical safety in accordance with IEC 60601-1-1. The compliance plan is shown in Appendix 17B – (b)(4) _Electrical Safety Compliance Plan.

APPENDIX 17A – VIO08742_VPL_EMCCOMPLIANCE PLAN.

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Title: VPL_EMC Compliance Plan

(b)(4)

(b)(4)

Revision:

State: In Work

Prepared For: ViOptix

(b)(4), (b)(6)



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Information

VPL V&V Plan
VPL EMC Compliance Plan
P/N: (b)(4) Third Party

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VPL V&V Plan
 VPL EMC Compliance Plan
 (b)(4)

1 Scope

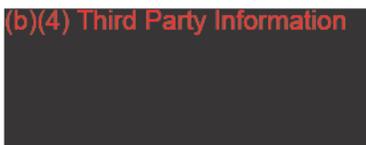
This document covers the plan for the compliance of the Intra.Ox Handheld Tissue Oximeter to electromagnetic compatibility specified in IEC60601-1-2.

2 Electromagnetic Compatibility Compliance Plan

IEC 60601-1, ed 3, Requirements	How addressed
1.1.1 Defibrillation	Not Applicable. Device is hand held with no patient connections.
1.1.2 ESD Contact Discharge Immunity	Not Applicable. The device has no exposed metal parts and deeply recessed screws.
1.1.3 ESD Air Discharge Immunity	
The device shall conform to IEC 60601-1-2 for air discharge ESD immunity test levels of +/-2 kV, +/-4 kV and +/-8 kV applied to non-conductive accessible parts in accordance with IEC 61000-4-2.	Functional testing verifies insulation properties of the case and spacing to the electronics
Air discharge immunity test levels will generally break through wiring insulation. For air discharge tests into cables, any connector pin may become energized. Cable shielding and circuitry protection must be considered to ensure adequate immunity.	Not Applicable. Device has no external wiring.
The device shall maintain safe operation during exposure to an air electrostatic discharge of 8 kVDC within 1 m of any exposed surface or part and/or within 1m of any connected cable or sensor.	Functional testing verifies insulation properties of the case and spacing to the electronics
The device is not required to operate through exposure to such discharges with no disruption to its measurement functions.	Not Applicable. Exercising the device trigger offers cycling power to re-initialize the device and thus clear any disruption.
The device shall function correctly when restored to its normal configuration within 10 seconds after cessation of such discharges.	Functional testing verifies insulation properties of the case and spacing to the electronics
1.1.4 Electro-surgery	Not Applicable. Device is hand held with no patient connections.
1.1.5 Magnetic Field Immunity	
The device shall conform to IEC 60601-1-2 the Magnetic Field Immunity requirement per IEC 61000-4-8 at 50 Hz and at 60 Hz.	Device to withstand 3 A/m. Power frequency (50/60 Hz) magnetic field IEC 61000-4-8. Note: The device will not be used near, "Power frequency magnetic fields,"
1.1.6 Conducted RF Immunity	
The device shall conform to IEC 60601-1-2 the Conducted RF Immunity requirements.	Exempt. The device is both small and internally powered, thus it is exempt, see section 6.2.6.1e

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(b)(4) Third Party Information



VPL V&V Plan
 VPL EMC Compliance Plan
 (b)(4)

Fast Transient immunity test levels of ± 2 kV for a.c. and d.c. power lines and ± 1 kV for signal and interconnecting cables per IEC 61000-4-4.	Exempt. There is no Mains cord.
Surge immunity test levels of ± 0.5 kV, ± 1 kV and ± 2 kV for a.c. power line(s) to earth and ± 0.5 kV and ± 1 kV for a.c. power line(s) to line(s) per IEC 61000-4-5.	Exempt. There is no Mains cord.
Voltage dip immunity test levels per IEC 60601-1-2 Table 10.	Exempt. There is no Mains cord.
Voltage interruption; to remain safe, experience no component failures, and meet all specifications with operator intervention complies at the immunity test levels per IEC 60601-1-2 Table 11.	Exempt. There is no Mains cord.
1.1.7 Radiated RF Immunity	
The device shall conform to IEC 60601-1-2 the Radiated RF Immunity requirement.	Certification testing verifies that externally generated RF energy will not cause failures or malfunctions. IMMUNITY TEST LEVEL of 3 V/m over the frequency range 80 MHz to 2.5 GHz, per IEC 61000-4-6.
1.1.8 Electromagnetic Interference (EMI)	
The device shall conform to IEC 60601-1-2 CISPR 11 Group 1 Class B limits for Radiated Emissions without exemption.	Certification testing verifies that the device does not radiate excessive RF energy in prescribed frequency bands. (clocks, data transmission, switching power supplies, pulse width modulated power)

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 Version: (b)(4)

(b)(4) Third Party Information



VPL V&V Plan
VPL EMC Compliance Plan
(b)(4)

3 Revision History



Rev	Description of Change	Originator	Date
00	Initial Release	Sophia Berger	11/17/2013

Proprietary
Version: (b)(4)

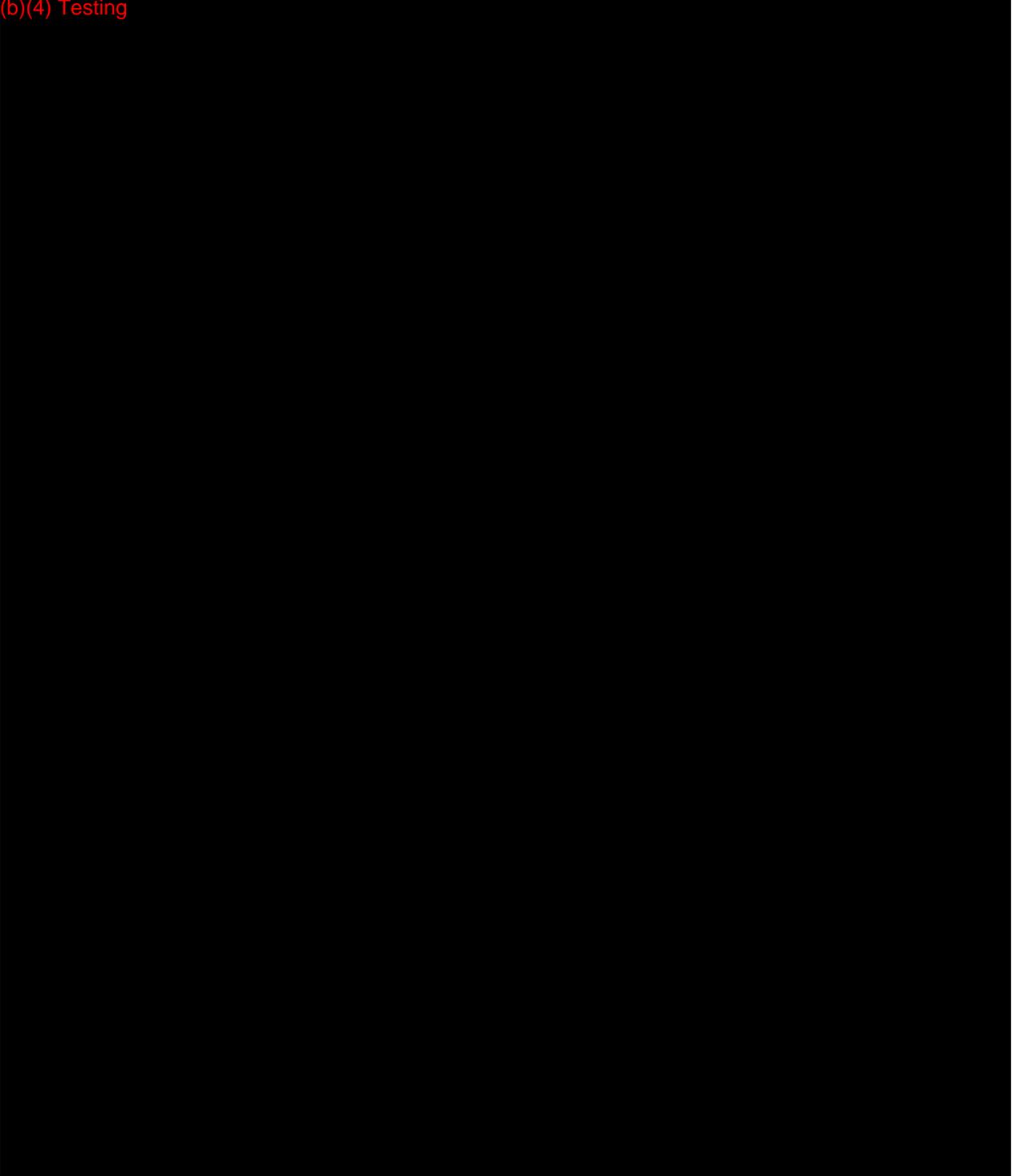
APPENDIX 17B – (b)(4) L ELECTRICAL SAFETY COMPLIANCE
PLAN

18. Performance Testing – Bench

Purpose:

Bench tests were performed to verify device performance over a wide range of optical conditions, with varying oxygen saturation and total hemoglobin content. Measurements were made using the Intra.Ox™ Handheld Tissue Oximeter and the predicate (T.Ox) device in order to demonstrate substantial equivalence in performance.

(b)(4) Testing



(b)(4)



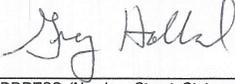
19. Performance Testing – Animal

No animal test results are being submitted to support substantial equivalence; therefore, **this section does not apply.**

20. Performance Testing – Clinical

An Evaluative Study To Compare Intra.Ox® And T.Ox® Performance In The Fingertips is not an applicable clinical trial to be registered on clinicaltrials.gov, because the human research study was intended to demonstrate proof of concept only.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

 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 ViOptix, Inc	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES December 20, 2013	
3. ADDRESS (Number, Street, State, and ZIP Code) 47224 Mission Falls Court Fremont, CA 94539	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 510-226-5860 (Fax) 510-360-7506	
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) Intra.Ox Handheld Tissue Oximeter, CFR 870.2700		
APPLICATION / SUBMISSION INFORMATION		
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other		
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)		
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) <input type="checkbox"/> 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. <input checked="" type="checkbox"/> 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. <input type="checkbox"/> 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 PERON WHO SIGNED IN NO. 11 (Name) Greg Holland (Title) Regulatory Specialist	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 3722 Ave. Sausalito Irvine, CA 92606	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 949-262-0411 (Fax) 949-552-2821	15. DATE OF CERTIFICATION 12/20/2013



Risk Analysis			
Document Number: (b)(4)	Date Effective: 11/14/13	Rev: (b)	Page 1 of 25

DCO #	Revision Level	Effective Date	Originator	Process Owner	Change Description
(b)(4)	(b) b	11/13/13	M. Lonsinger	(b)(4)	Initial Release

K133983/S1



FDA CDRH DMC

AUG 07 2014

Received

August 5, 2014

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

RE: K133983/S001 – Amendment to 510(k) for the Intra.Ox Handheld Tissue Oximeter

Dear Madam:

In response to FDA's request for additional information letter dated February 11, 2014, ViOptix Inc. ("ViOptix") is herein submitting an Amendment to 510(k) K133983 for the Intra.Ox Handheld Tissue Oximeter.

ViOptix Inc. is also enclosing an electronic copy (eCopy) of this submission on a CD in accordance with FDA's "Guidance for Industry and Food and Drug Administration Staff, eCopy Program for Medical Device Submissions", issued October 10, 2013. The eCopy is an exact duplicate of the paper copy except that the raw data contained in the "STATISTICAL DATA" volume is not included in the paper copy. Placeholders are included in the paper copy that refer to the raw data found in the eCopy. In addition, minor formatting changes may have been introduced as a result of the PDF conversions. Following this cover letter is a response to the FDA request. For the reviewer's convenience, each FDA question is provided in bold italic font, followed by ViOptix Inc.'s response.

Thank you in advance for your review of this amendment. If you have any questions, you may contact me by phone at 949-262-0411, by fax at 510-226-5864, or by email at greg@regulatoryspecialists.com.

Sincerely,

Greg Holland
Regulatory Specialist
ViOptix Inc.
Enclosures

CC: Mark Longsinger
Vice President and General Manager
ViOptix, Inc.

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K133983/S001


ViOptix

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August 5, 2014

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Sincerely,



Greg Holland
Regulatory Specialist
ViOptix Inc.
Enclosures

CC: Mark Longsinger
Vice President and General Manager
ViOptix, Inc.

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115



August 5, 2014

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Greg Holland
Regulatory Specialist
ViOptix Inc.
Enclosures

CC: Mark Longsinger
Vice President and General Manager
ViOptix, Inc.

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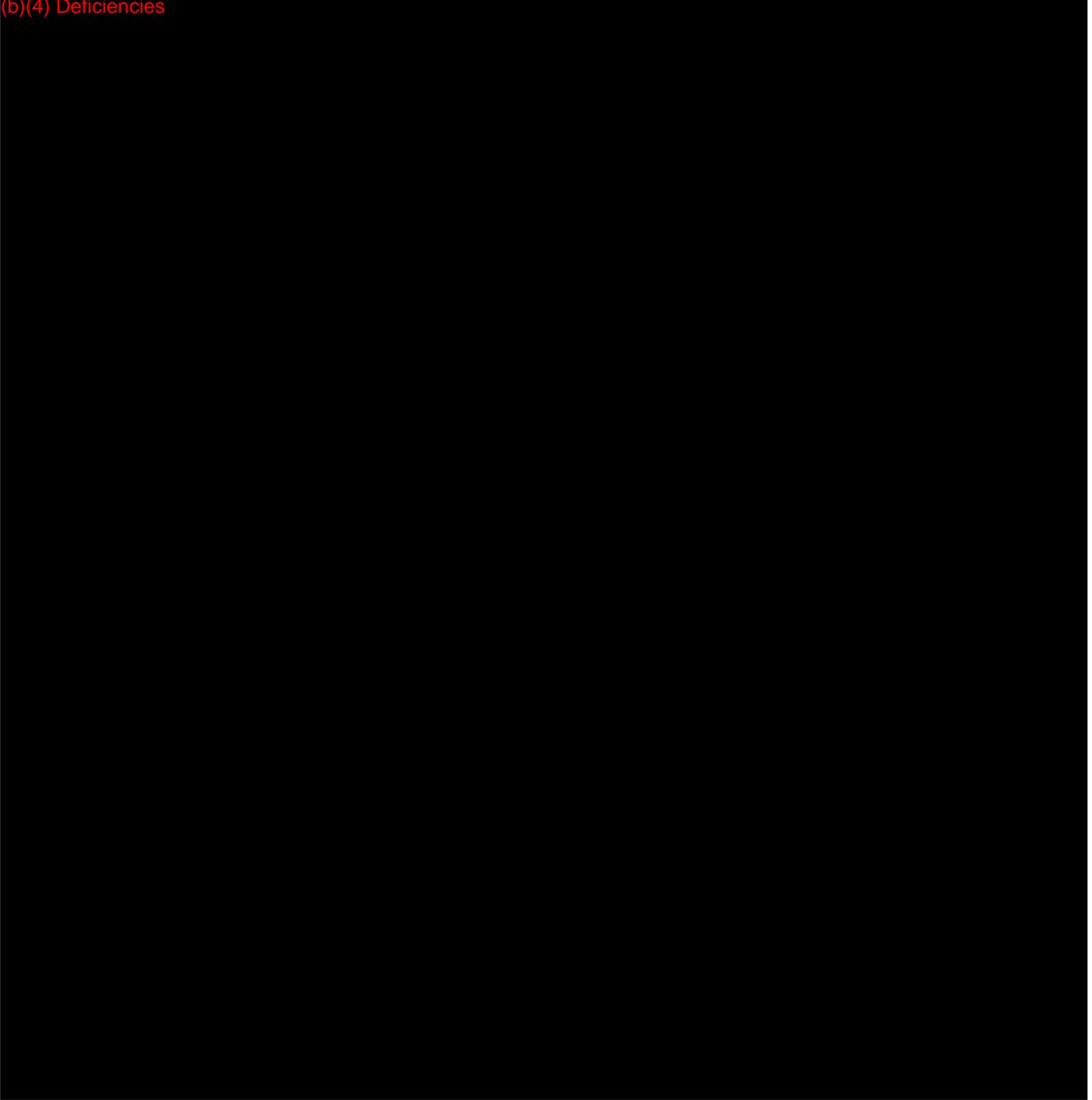
Response to FDA's Letter dated February 11, 2014

(b)(4) Deficiencies



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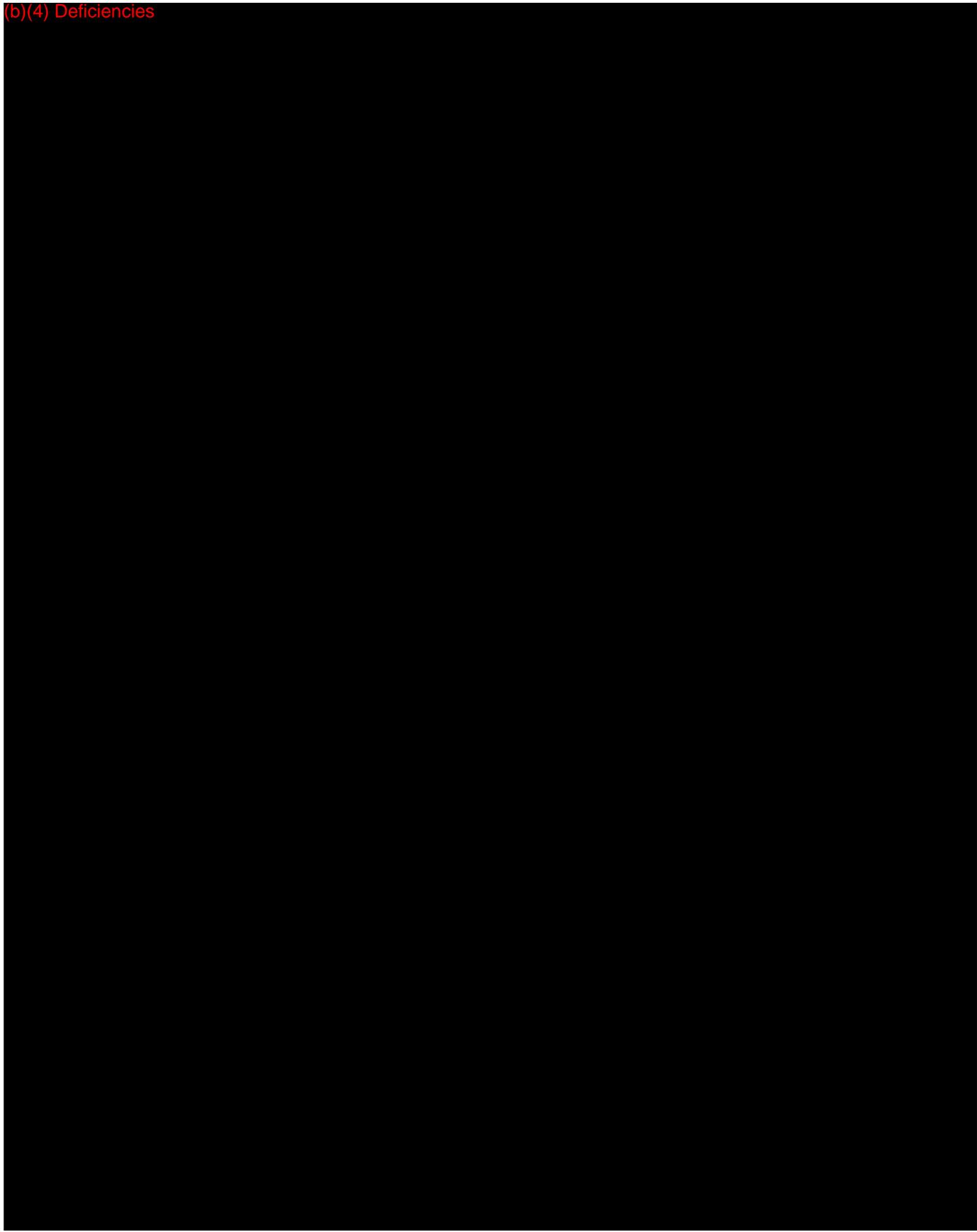
(b)(4) Deficiencies



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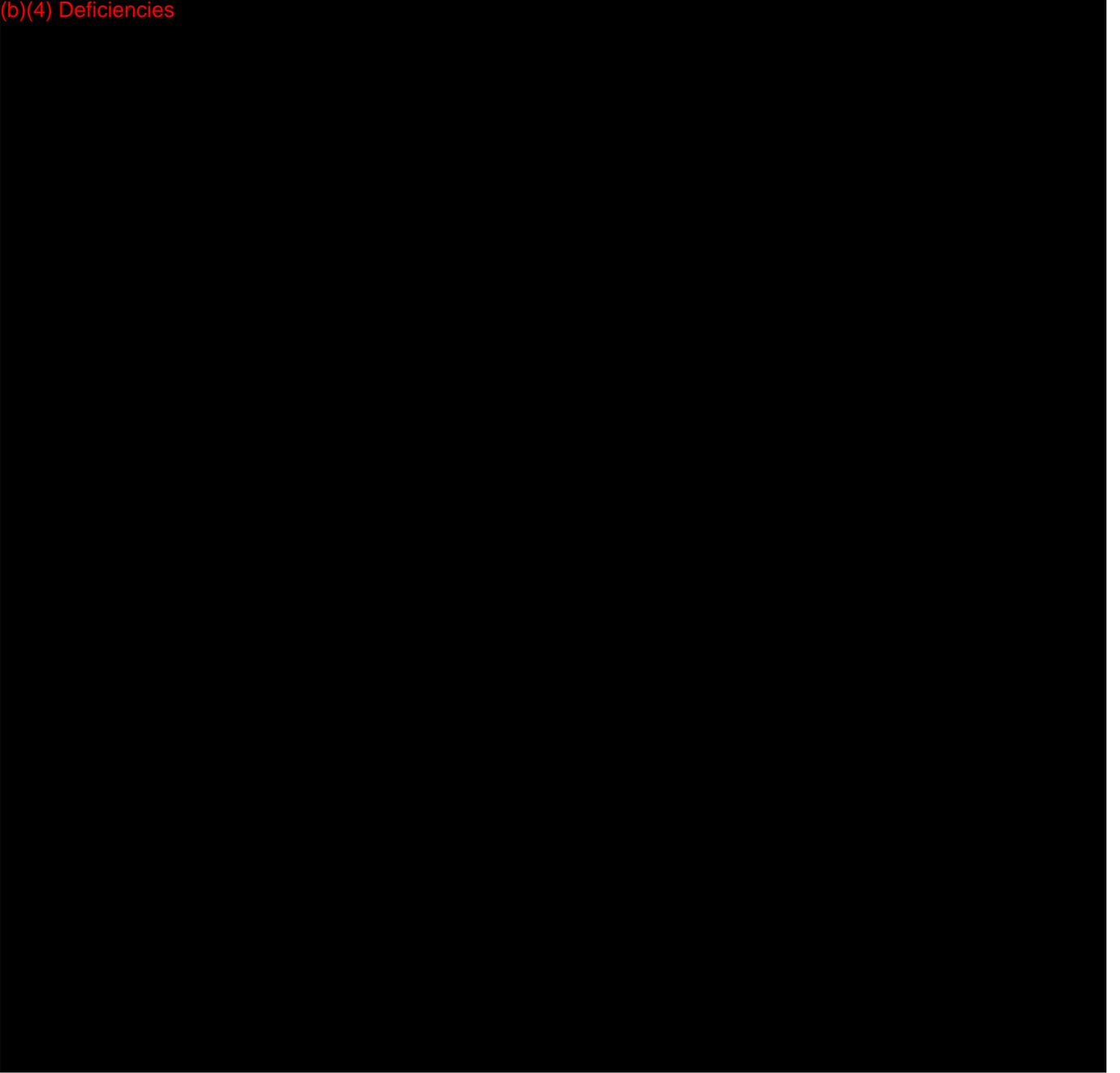
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies



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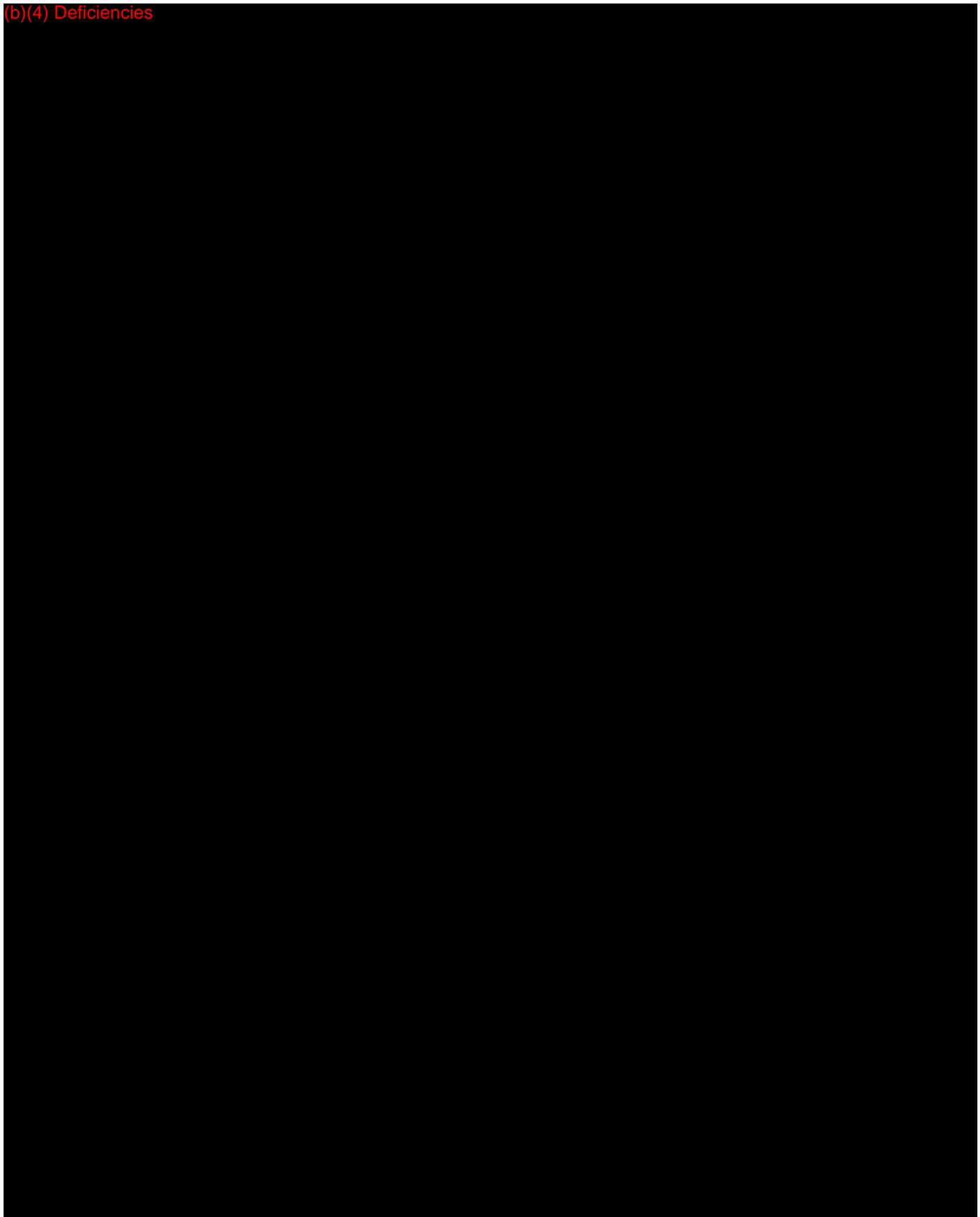
(b)(4) Deficiencies



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(b)(4) Deficiencies



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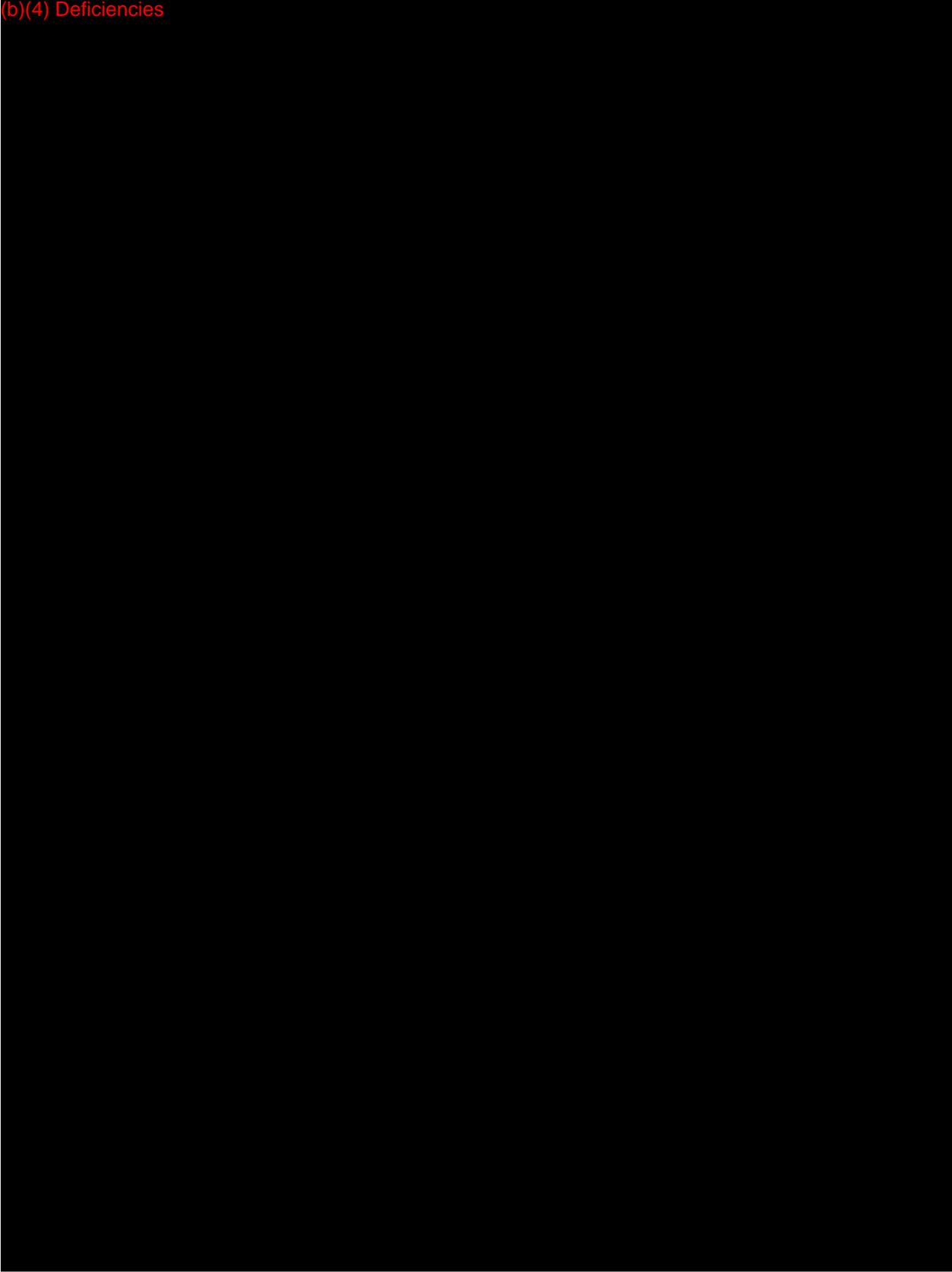
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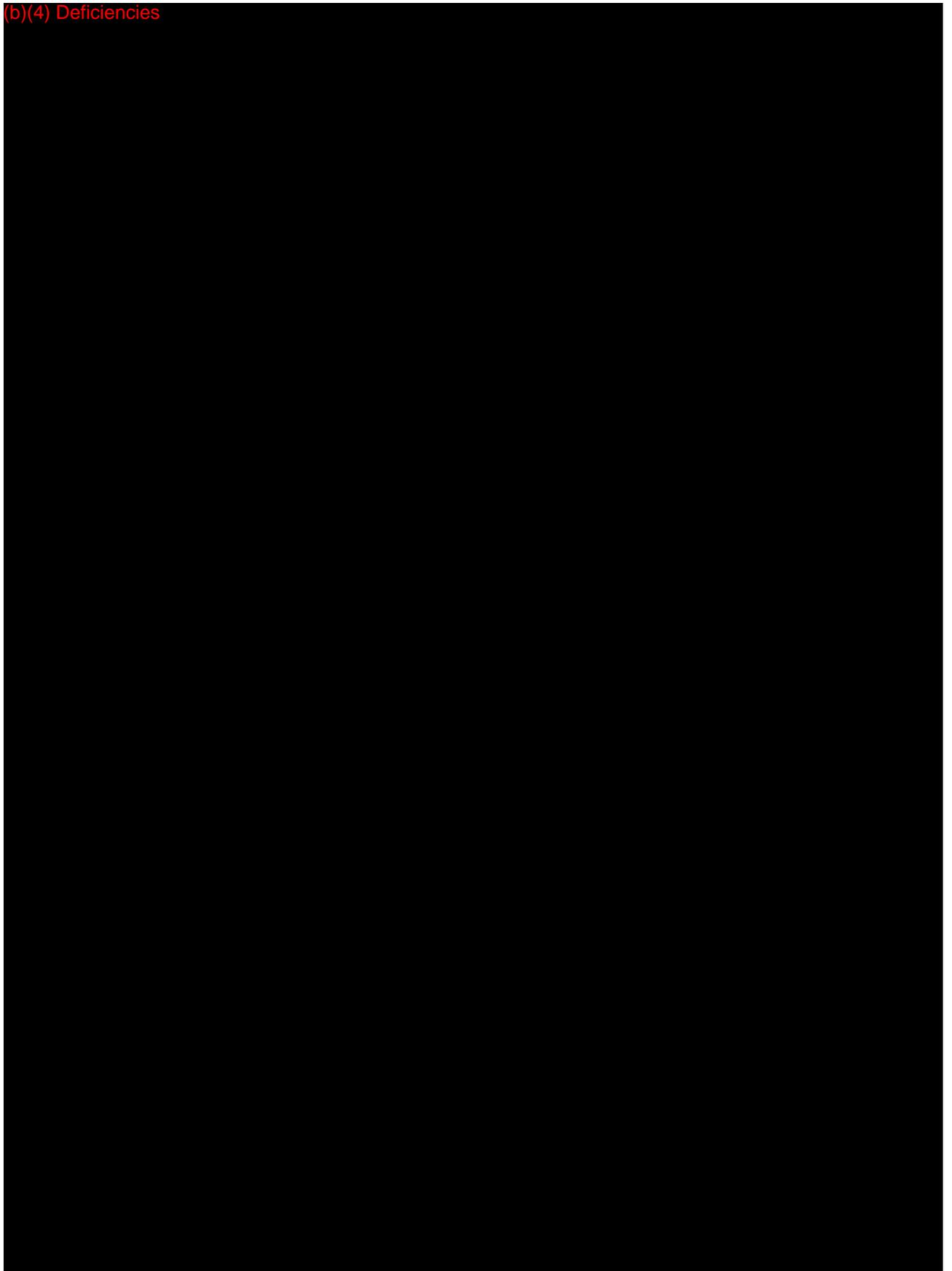
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(b)(4) Deficiencies



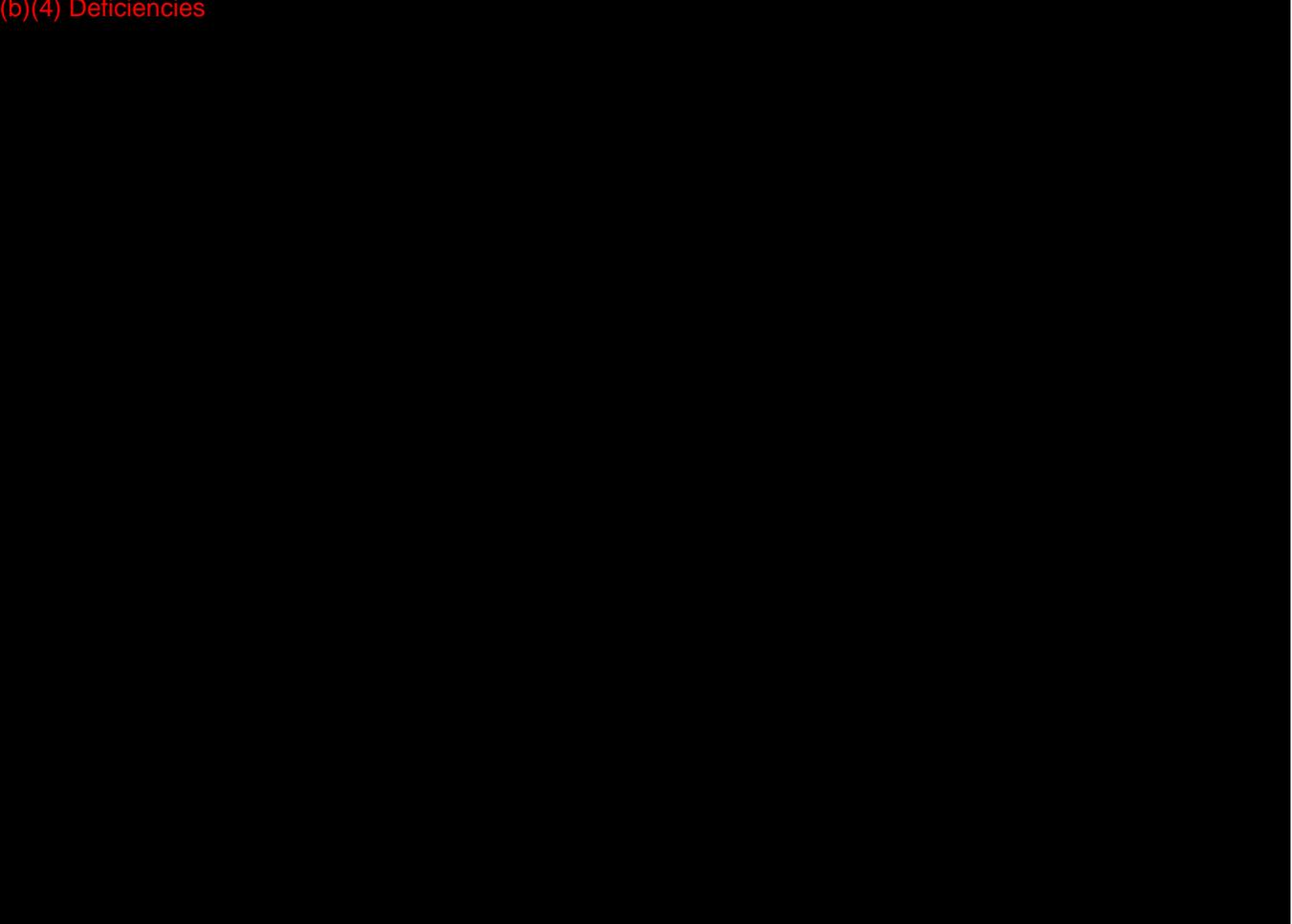
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(b)(4) Deficiencies



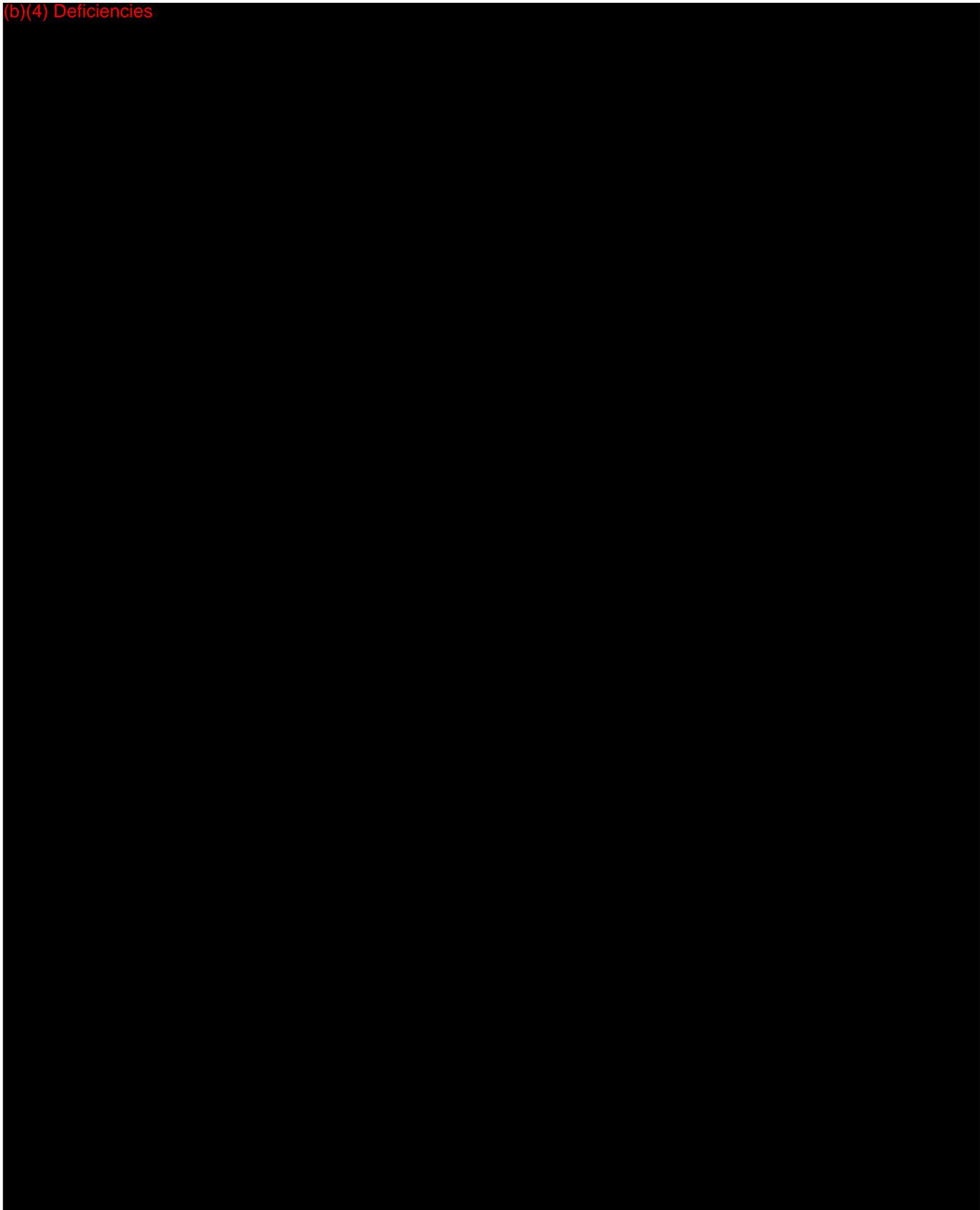
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(b)(4) Deficiencies



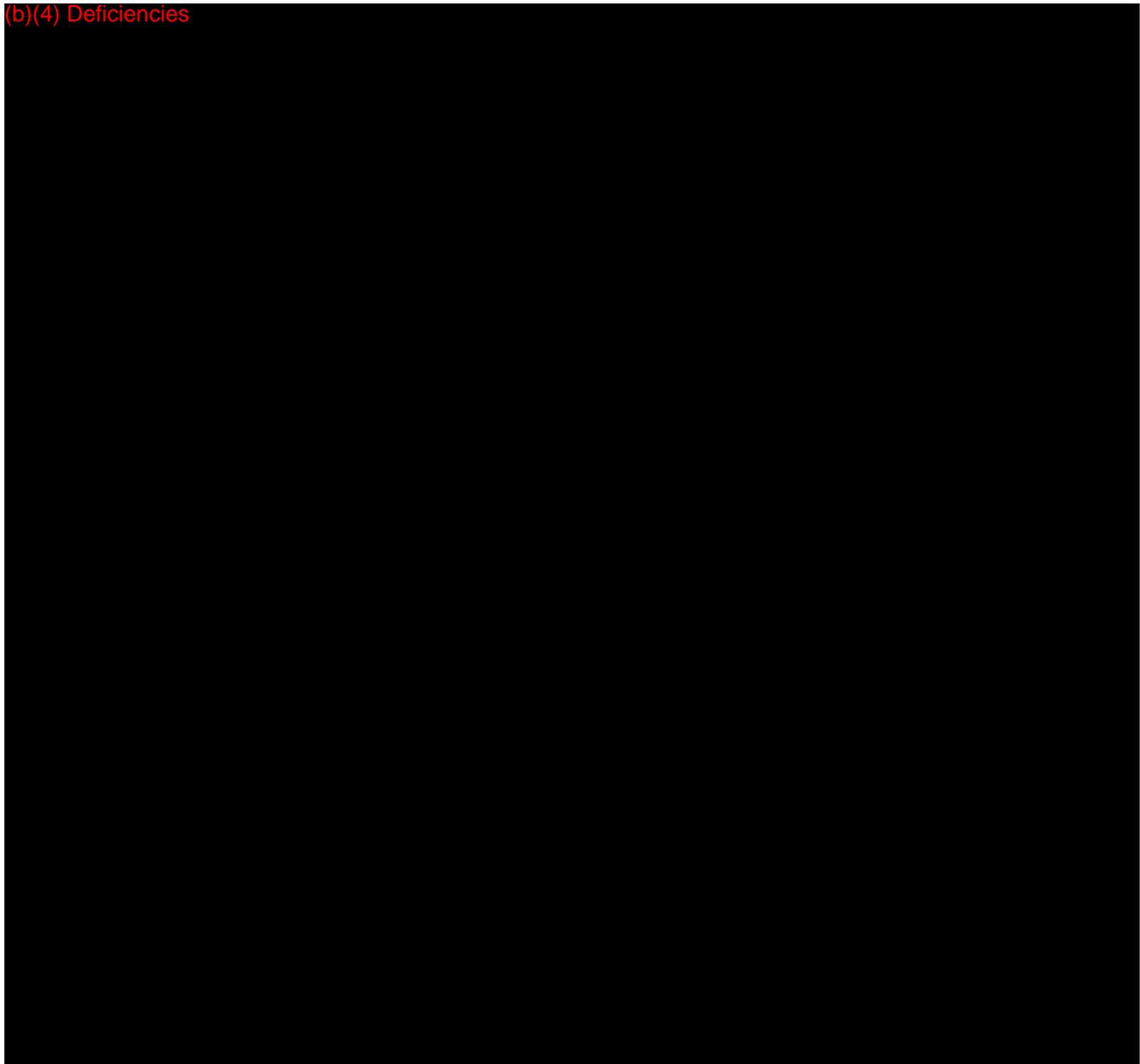
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(b)(4) Deficiencies



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(b)(4) Deficiencies



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ATTACHMENT 1
BIOCOMPATIBILITY

Attachment 1.1:

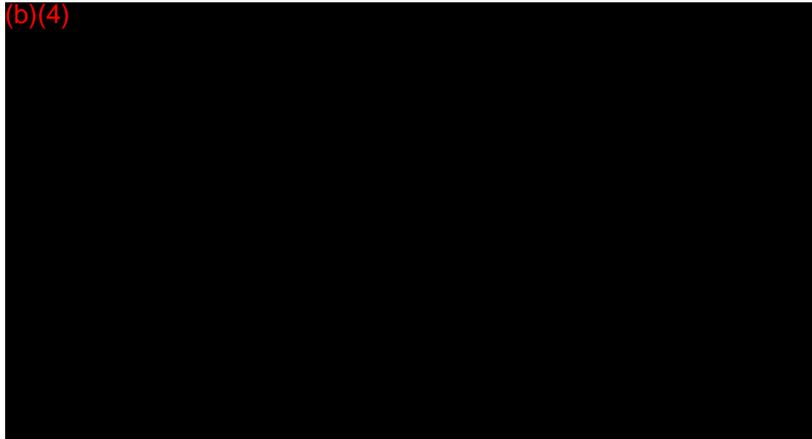
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-

Attachment 1.2:

-
-

Attachment 1.3:

-
-



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ATTACHMENT 3
RPT_INTRA.OX LIGHT SAFETY ANALYSIS

Attachment 3: (b) (4) "RPT_Intra.Ox Light Safety Analysis"

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ATTACHMENT 7
PROPOSED LABELING

Attachment 7.1: (b)(4) : “DOC_Proposed Labeling” (Clean)

- Instructions for Use
- Labels

Attachment 7.2: (b)(4) : “DOC_Proposed Labeling” (Redline)

- Instructions for Use
- Labels

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DOC_Proposed Labeling

Number (b)(4)
Revision **01**
State **Engineering Released**

Authors **Technical Staff**

Project **VI005**
Client **ViOptix, Inc.**

(b)(4) Third Party Information

(b)(4) Third Party Information

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1 General Information

1.1 Overview

The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO₂) in a volume of tissue. The device uses spatially-resolved optical measurements at four wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO₂ estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is constructed from biocompatible materials that can tolerate bodily fluids and other liquids such as disinfectants and marking materials.

This manual has been prepared to assist medical personnel in the operation the ViOptix Intra.Ox™ Handheld Tissue Oximeter. Prior to operating this device, all personnel must read this manual and gain a thorough understanding of its proper operation. Special attention should be directed to all cautions and warnings regarding the use of the product.

ViOptix cannot, and does not intend within this manual, to give medical advice.

1.2 Indications For Use

The Intra.Ox Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.



(b)(4) Third Party Information

Request # 2015-7558; Released by CDRH on 02-12-2016

1.3 References

Trademarks

Intra.Ox™ Handheld Tissue Oximeter is a registered trademark of ViOptix, Inc.

References

References to "ViOptix" in this manual shall imply ViOptix, Inc.

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, ViOptix reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation.

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

Copyright 2013

Covered by one or more of the following US Patents and foreign equivalents:

6,516,209

ViOptix, Incorporated

47224 Mission Falls Court

Fremont, CA 94539

Tel: 510-226-5860

Fax: 510-226-5864

2 Safety

2.1 Contraindications, Warnings, and Cautions

2.1.1 Contraindications

There are no known contraindications for the use of the Intra.Ox™ Handheld Tissue Oximeter.

2.1.2 Warnings

Warnings are identified by a label or symbol. Refer to the Glossary of Symbols at the end of this document. Warnings alert the operator to potential serious outcomes to the patient or operator.

- The Intra.Ox™ Handheld Tissue Oximeter comes packaged sterile and is a one-time use device, DO NOT RE-STERILIZE this device.
- Inspect the sensors before each use for visible damage. Do not use the sensor if it has visible damage.
- To prevent damage, do not bend or apply torque to the sensor head

Title: DOC_Proposed Labeling

Part Number: VIO06282
Questions: Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Version: (b)

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Page 4 of 16

(b)(4) Third Party Information

- Hard knocks, particularly at the distal end of the sensor, may result in damage to the delicate fiber-optic cables, which could affect instrument performance. Do not use if there is visible damage to the Handheld Tissue Oximeter.
- Do not allow any liquid to pass into any electrical connections. **Allow wet surfaces to thoroughly dry before use**
- Do not immerse or soak sensors in liquid solutions.
- Avoid extreme changes in temperature and/or humidity.
- To reduce the risk of electrical shock, do not open the equipment's inner housing. Refer servicing to qualified personnel only. Removal of panels by unauthorized personnel will void the unit's warranty.
- This device is not to be used in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants.
- Dispose of used Intra.Ox™ Handheld Tissue Oximeter using appropriate biohazard precautions.
- This equipment has been tested and found to comply with the limits of the standard for medical devices, IEC 60601-1-2 for Class A equipment. The limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy, and, if not installed and used in accordance with the manufacturer's instructions may cause harmful interference to other devices in the vicinity. Portable and mobile RF communications equipment can affect medical electrical equipment. There is no guarantee that interference will not occur in a particular installation. If this equipment causes interference with other devices, which may be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:
 - Reorient or relocate the device receiving the interference
 - Increase the separation between the equipment
 - Consult the manufacturer or field service technician for help

2.1.3 Precautions

- Check the sensor application site frequently to assess positioning, circulation, and skin sensitivity of the patient. If required, reposition the sensor to a new site or if redness or skin irritation is noted. If irritation continues, discontinue use.
- Avoid placement directly over bony prominences, scar tissue, dark birthmarks or other visibly non-homogenous tissue, as it could provide improper reading.
- If tissue is uneven, gently flatten tissue or move to a new location.
- When repositioning device, pick up sensor and replace; do not drag.
- Use extra caution when placing on thin or delicate skin.

2.1.4 Disposal

- The sensor contains a Lithium battery and should only be disposed of with electrically hazardous medical waste and in accordance with all local and hospital

disposal procedures. Contact the hospital or local environmental control agency for additional instructions. The sensor should not be incinerated.

3 Installation and Setup

The Intra.Ox™ Handheld Tissue Oximeter is a prescription-only device that comes fully assembled and packaged in a protective box which contains one device in a sterile double pouched configuration. The device is designed for single use, is handheld and battery powered and requires no external power source. The unit is sealed and is not designed to be disassembled or repaired by the user. The unit cannot be opened and the batteries cannot be replaced by the user.

Before using, inspect the device and packaging for any sign of damage. Do not use if unit has been compromised. No Installation is required.

4 Device Configuration and Interface Elements

The ViOptix Intra.Ox™ tissue oximeter has three main interface elements:

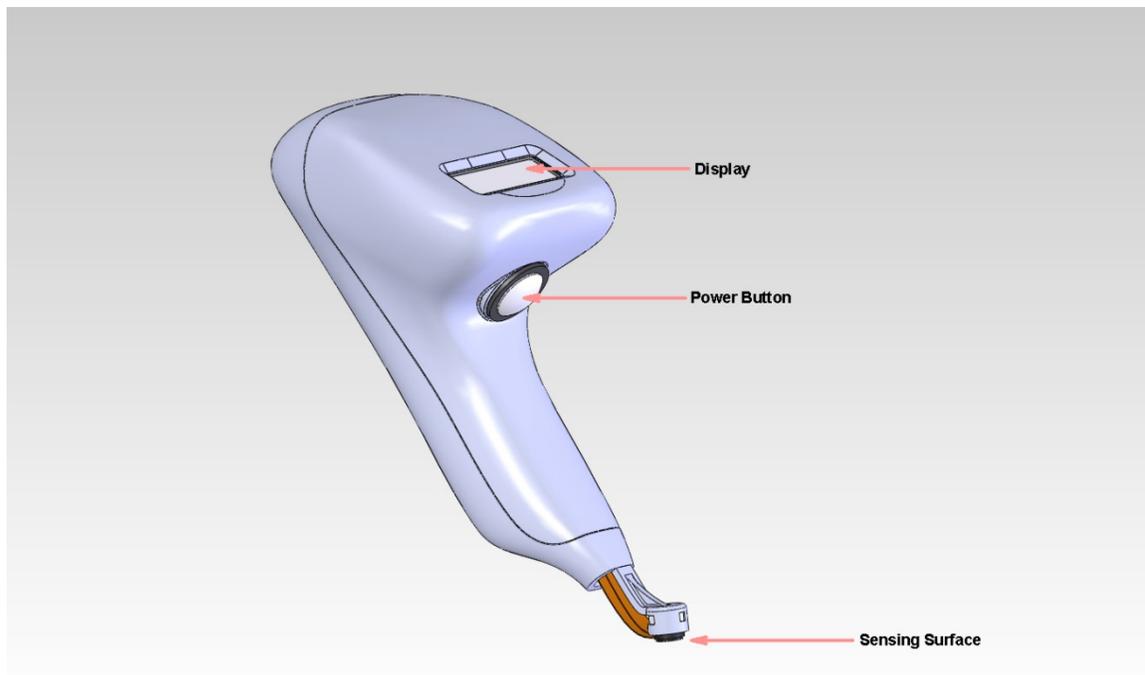


Figure 1: Device Configuration and Interface Elements

4.1 Display

The LCD display shows

- Powering up indicator
- Current oxygen saturation value in percent
- Total powered-up time

(b)(4) Third Party Information

request # 2015-7558; Released by CDRH on 02-12-2016

- Low battery indicator
- Error messages

4.2 Power Button

The power button is used to:

- Power up the device
- Put the device into standby mode
- Bring the device out of standby mode
- Clear error messages
- Power down the device

4.3 Sensing Surface

The sensing surface contacts the patient and includes:

- Light sources
- Light detectors

All elements are discussed in greater detail later in this manual.

5 Operating The ViOptix Intra.Ox™

5.1 Holding the Device

Hold the tip of the Intra.Ox™ device similarly to a pen, with the wrist in a neutral position. Lightly rest hand on the patient and use fingers to brace the device for maximum stability. Sensing face should be parallel to tissue and in gentle contact.

5.2 Powering Up

To power up the Intra.Ox™ tissue oximeter, momentarily press the power button and then release it. The LCD backlight comes on, and the startup display depicted below is shown briefly:



Figure 2: Startup Display

(b)(4) Third Party Information

If an error condition exists, an error display is shown. See section 5.7 for instructions on how to clear the error.

5.3 Measuring Percent Oxygen Saturation

Once power-up is complete, place the sensing surface on the patient, and apply very light pressure to the tissue of interest. Do not apply firm pressure as this will blanch the tissue. Continue to hold the device against the tissue for a few seconds until an Oxygen Saturation Percentage appears on the display. The display is organized as depicted below:

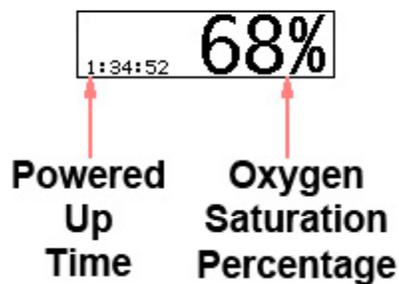


Figure 3: Normal Display Layout

5.3.1 Powered Up Time Display

The total elapsed time that the device has been powered up is displayed in hours, minutes and seconds in the lower left of the display.

Battery life is expected to last 4 hours of operating time.

5.3.2 Percent Oxygen Saturation Display

The oxygen saturation estimate at the sensing surface location is indicated in percent on the right side of the display and is updated several times per second.

If the oxygen saturation value is invalid for any reason, the digits are replaced by dashes:

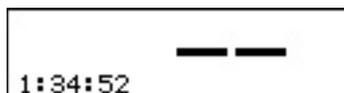


Figure 4: Invalid Percent Oxygen Saturation Value Display

If the sensing surface is not in contact with tissue or is in contact with inappropriate pressure, the invalid percent oxygen saturation value indication is displayed. A dirty sensing face can also cause the unit display dashes. If the Intra.Ox™ is positioned properly and no oxygen saturation value appears, gently wipe the sensing surface with a soft cloth, moistened with water or alcohol, to remove any debris. Alternately, cup hand around sensor to reduce potential interference from ambient light.

5.3.3 Temperature Out Of Range Error

If the sensor temperature is out of range, a “Low Temp” or “High Temp” error is displayed in addition to the invalid percent oxygen saturation dashes:

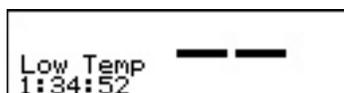


Figure 5: Temperature Out Of Range Display

If a “High Temp” error is displayed, move the Intra.Ox™ away from heat sources such as warming blankets or direct OR light exposure. If a “Low Temp” error is displayed, move the device away from cold sources such as ice packs and air-conditioning vents.

5.3.4 Low Battery Indicator Display

When remaining battery capacity is low, a battery indicator flashes on the display.

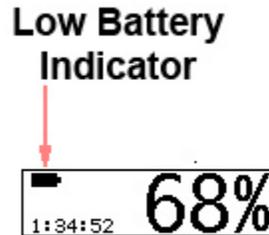


Figure 6: Low Battery Indicator

The Intra.Ox™ tissue oximeter can continue to be used as long as battery life remains. The battery is not rechargeable, so the low battery indicator indicates remaining product usage time is limited. Standby mode (section 5.4) can be used to maximize remaining battery life during the current procedure.

5.4 Requesting Standby

In order to reduce power consumption and maximize battery life, you may wish to put the Intra.Ox™ tissue oximeter in standby mode when it is not actively in use during a procedure. This is done by momentarily pressing and releasing the power button (press for less than two seconds).

The LCD backlight turns off, and the invalid percent oxygen saturation display is shown. The device can be quickly reactivated.

5.5 Coming Out Of Standby

To return to normal operating mode from standby mode, momentarily press and release the power button (press for less than two seconds).

The LCD backlight comes on, and percent oxygen saturation values are displayed as soon as appropriate contact is made with the tissue of interest.

(b)(4) Third Party Information



5.6 Powering Down

At any time, the Intra.Ox™ tissue oximeter can be powered down completely by pressing the power button for more than two seconds and then releasing it. Release the power button as soon as the “powering down” message is displayed.

The LCD turns off completely as the device powers down.

If for any reason the device does not power down as expected, press and hold the power button until it does. This effects a hardware-mediated power-down without software control. If the device is powered down in this manner, you may see an improper shutdown error message the next time you power up.

5.7 Resolving Errors

Error conditions may occur that require the display of an error message on the display. Error messages are displayed as text that may use up to 4 lines on the display. Error messages may be recoverable or non-recoverable.

5.7.1 Recoverable Error Messages

To clear a recoverable error message, momentarily press and release the power button (press for less than two seconds).

Recoverable Messages:

Improper Shutdown Logs/Time Corrupted

The device was powered down by pressing and holding the power button to effect a hardware shutdown (i.e. the device was powered down without software control). In this case, elapsed time from the most recent operating session will not be reflected in the powered-up time. The displayed powered-up time will underestimate actual device powered-up time. In addition, some operating log entries may have been lost.

(b)(4) Third Party Information

FOIA Request # 2015-7558; Released by CDRH on 02-12-2016

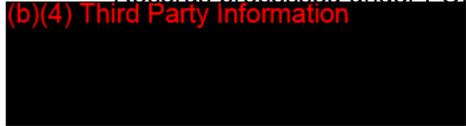


5.7.2 Non-Recoverable Error Messages

Any message with the prefix FINAL is a non-recoverable error. Attempt to power-cycle the device by powering down completely and then powering up as described earlier.

If the error persists, the device is not operable. Use a new Intra.Ox™ Handheld Tissue Oximeter and contact your ViOptix sales representative to report the error.

(b)(4) Third Party Information



6 Specifications

Component	Specification
Tissue Oxygen Saturation Range	0 – 99%
Wavelengths	760, 810, 850, 900 nm LED
Accuracy	StO ₂ measurement shall be within +/-10 points
System Control	System will perform self-test when power is turned on
Alarms (visual)	Display Low Battery Condition Display Measurement Error Conditions of Insufficient Data Quality
Battery Life	4 Hours of continuous use (including 2 hours of measurement)
Operating Mode	Spot Measurement Mode
Transport and Storage	<p><u>Temperature</u></p> <ul style="list-style-type: none"> • Device shall operate normally at ambient temperatures of 20°C to 35°C, provided the sensor head temperature is 37.0 ± 0.5° C. • Device (packaged) shall operate normally after storage at -20°C to 60°C. <p><u>Humidity</u></p> <ul style="list-style-type: none"> • Device shall operate normally in a humidity environment of 20% to 80% (non-condensing). • Device (packaged) shall operate normally after storage at 10% to 100% (condensing).
Dimensions	5" x 5" x 10"
Weight	1 LB
Sensor Specifications	IEC 60601-1. Any surface of the system that comes into contact with a patient for a time of 1 minute shall not exceed 45°C. The device shall comply with ANSI/IESNA RP-27.1-05 (Recommended Practice for Photobiological Safety for Lamps and Lamp Systems – General Requirements) for light output.



7 Labels

7.1 Box label



Contents: (1) Disposable Intra.Ox™ Hand Held Tissue Oximeter

ViOptix P/N: OXY-2-INT-1

STERILE EO

S/N

Do not re-use

Use by: YYYY-MM

Consult instructions for use

ViOptix, Inc. 47224 Mission Falls Ct. Fremont, CA 94539 www.vioptix.com

CAUTION: Federal (USA) law restricts this device for sale and use by, or on the order of a physician.

Patents pending

Label P/N: 89708 Rev A

Manufactured in the USA for ViOptix, Inc. 47224 Mission Falls Court, Fremont, CA 95539

To Reorder: Fax 510.226.5864

www.vioptix.com ViOptix



(b)(4) Third Party information

DIA Request # 2015-7558; Released by CDRH on 02-12-2016



7.2 Device label

ViOptix
 P/N: OXY-2-INT-1
 SN:



7.3 Glossary of Symbols

 Do not re-use	Sterile Disposable Small Patch Sensor –are intended for single-patient one-time use. DO NOT REUSE, DO NOT RE-STERILIZE
	Sterilized by Ethelyne Oxide
 Use by	Use by expiration date stamped
	Attention, consult accompanying documents
ViOptix P/N:	Model Number (Catalog Number)
	Serial Number
	Manufactured By
	Applied part type BF

(b)(4) Third Party Information
[Redacted]

8 Revision History

<i>Rev</i>	<i>Description of Change</i>	<i>Project No.</i>	<i>Originator</i>	<i>Date</i>
(b)	Initial Release	(b)(4)	Technical Staff	8/1/2014

ATTACHMENT 8
CLINICAL DATA

Attachment 8: (b)(4) : “ANL_Clinical Data”

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ATTACHMENT 8
CLINICAL DATA

Attachment 8 is the full clinical data, including patient line listings. Please refer to (b)(4) within the “STATISTICAL DATA” volume of the eCopy of this submission.

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ATTACHMENT 9
INDICATIONS FOR USE

Attachment 9: FDA Form 3881: Indications for Use

CONFIDENTIAL

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

Indications for Use

510(k) Number (if known)

K133983

Device Name

Intra.Ox™ Handheld Tissue Oximeter

Indications for Use (Describe)

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

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

FOR FDA USE ONLY

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

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

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

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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

ATTACHMENT 10
510(k) SUMMARY

Attachment 10.1: (b)(4) "510(k) Summary" (Clean)

Attachment 10.2: (b)(4) "510(k) Summary" (Redline)

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Office: (510) 226-5860 · Fax: (510) 226-5864

Submitter's Name ViOptix, Inc.
Address 47224 Mission Falls Ct., Fremont, CA 94539
Contact at ViOptix Mark Lonsinger
Telephone 510-360-7506
Fax 510-226-5864
Email info@vioptix.com
Date the Summary was prepared: August 7, 2014

Information regarding Application Correspondent:

Official Correspondent Greg Holland
Address 3722 Ave. Sausalito
 Irvine, CA 92606
Telephone 949-262-0411
Email greg@regulatoryspecialists.com

Information regarding the device classification:

Trade Name: Intra.Ox Handheld Tissue Oximeter
Common Name: Tissue Oximeter
Classification regulation: 21 CFR 870.2700
Classification regulation name: Oximeter
Product code: MUD
Device Class: II

Information regarding the legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

510(k) Reference # K042657
Device Name ODISsey Tissue Oximeter
510(k) Holder ViOptix

Description of the Device:

The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a sterile, cordless, battery-powered device that non-invasively estimates the percent oxygen saturation (StO₂) in a volume of tissue. The device uses spatially-resolved optical measurements at four wavelengths. The device performs measurements on the patient by direct physical contact to the patient's tissue and displays the StO₂ estimate on the built-in screen. The ViOptix Intra.Ox™ Handheld Tissue Oximeter is a single-use disposable constructed from biocompatible materials that can



tolerate bodily fluids and other liquids such as disinfectants and marking materials.

Indications for Use:

The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.

The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.

Intended Use:

The Intra.Ox™ Handheld Tissue Oximeter has the same intended use as the predicate, the T.Ox.



Technological Characteristics:

Parameter	Subject Device: Intra.Ox	Predicate Device: T.Ox (formerly known as ODISsey)
510K number	K133983	K042657
Manufacturer	ViOptix, Inc.	ViOptix, Inc.
Intended Use		
Indications for Use	<p>The Intra.Ox™ Handheld Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue.</p> <p>The Intra.Ox™ Handheld Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations.</p>	<p>The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation (StO₂) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.</p> <p>The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.</p>
Measured Parameters	Tissue oxygen saturation (% StO ₂)	Tissue oxygen saturation (% StO ₂) and trend graph
Operating Principle	Spectrophotometric oximetry	Spectrophotometric oximetry



Parameter	Subject Device: Intra.Ox	Predicate Device: T.Ox (formerly known as ODISsey)
Energy Delivered	Near-infrared light Source: LED chips Wavelengths: 760, 810, 850, 900 nm	Near-infrared light Source: laser diodes Wavelengths: 690, 830 nm
Single Patient Use?	Yes, integrated sensor and control unit is single patient use disposable.	Sensor is single patient use disposable. Control unit is reusable.
Power Source	Battery powered Battery type: 4 Lithium AA Battery voltage: 6 V total	Mains powered with battery backup Battery type: 3-cell Lithium ion
Measurement Range	1-99% StO ₂	1-99% StO ₂

Testing in Support of Substantial Equivalence

All necessary testing was conducted on the Intra.Ox™ Handheld Tissue Oximeter to support a determination of substantial equivalence. The tests performed include:

- Biocompatibility
- Software Verification and Validation
- Electrical Safety and Electromagnetic Compatibility
- LED Light Safety Testing
- Homogeneous Phantom Study (Summary of results provided)
- Heterogeneous Phantom Study
- Isolated Limb Animal Study (Summary of results provided)
- Non-significant Risk Clinical Study (Summary of results provided)

The collective performance testing demonstrates that the Intra.Ox™ Handheld Tissue Oximeter does not raise any new question of safety or effectiveness when compare to the predicate device. The results of performance testing demonstrate that the Intra.Ox™ Handheld Tissue Oximeter performs as intended.



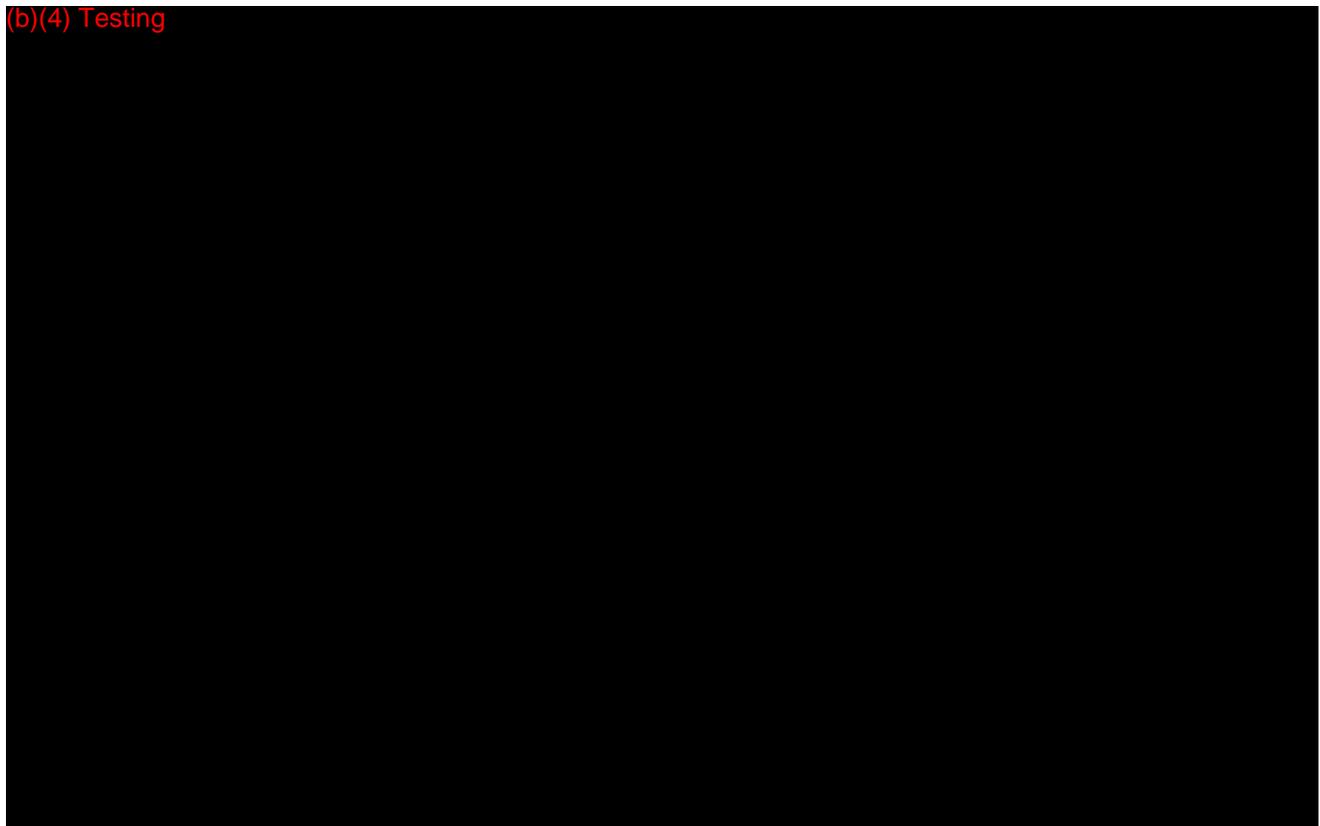
Bench Tests

Homogenous Phantom Study

The Intra.Ox devices were found to measure absorption coefficients with a high degree of correlation to actual absorption coefficients in liquid phantoms prepared with Intralipid and swine whole blood. The correlation coefficient was greater than 0.9 for each of the four wavelengths used in the devices.

The Intra.Ox devices were shown to agree well with the predicate device in StO₂% measurements. Over three full-scale (complete oxygenation to complete deoxygenation) blood desaturations, three different Intra.Ox devices as compared to two T.Ox devices showed combined limits of agreement of +8.49 and -7.50 percentage points. The acceptance criterion required the limits of agreement to be less than ± 10 percentage points. Therefore, the Intra.Ox is demonstrated to be substantially equivalent to the T.Ox in estimating StO₂%.

(b)(4) Testing





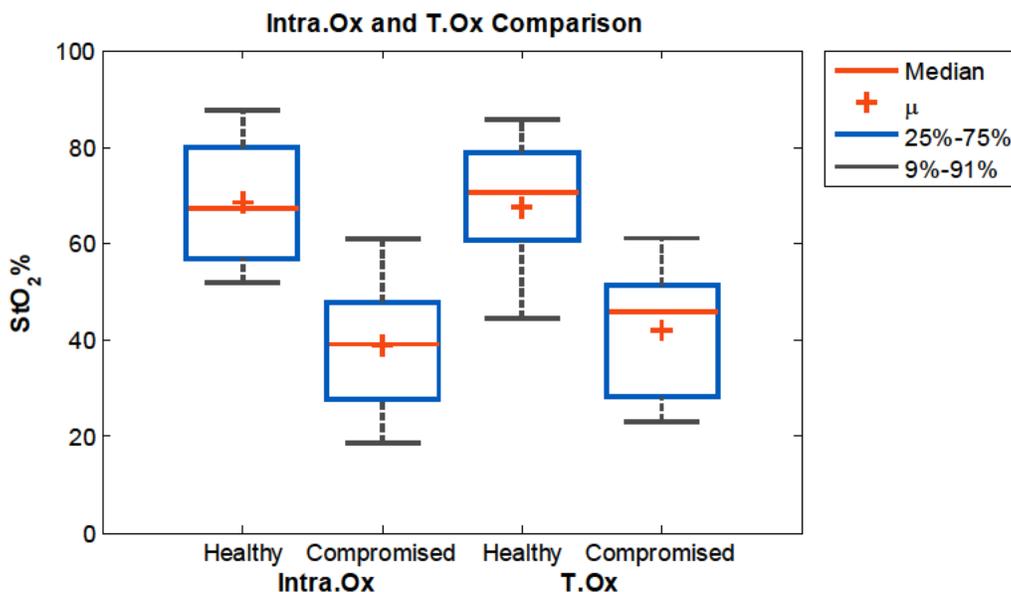
Clinical Study

Performance was determined by measuring tissue oxygen saturation (StO₂) with both devices during transient ischemic events on healthy human volunteers that temporarily mimics compromised tissue. Data from 11 subjects, who were near-evenly distributed over age, gender, and skin color as determined by the Fitzpatrick skin type, were analyzed.

There was excellent agreement in shape of the ischemic events between the Intra.Ox and T.Ox devices. A direct comparison with paired data showed good agreement considering the physiological variances inherent between measurement sites.

The mean baseline value of 68% and mean desaturation dynamic range of 30 percentage points agrees well with literature-reported values of skin and muscle transient ischemia.

Importantly, the Intra.Ox and T.Ox measure similar ranges of StO₂ values for both healthy and compromised tissue, thus validating substantial equivalence.



Conclusion

The Intra.Ox™ Handheld Tissue Oximeter and the predicate device have the same intended use and has similar technology that does not raise new types of questions of safety or effectiveness. The performance data shows that the Intra.Ox provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.

