November 19, 2015

K152402/A001

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

Re: Supplement 2 to – 510(k) K152402/S001
Securus Medical Group, Inc.
IRTS System

Dear Mr. Burdick:

The attached information is submitted for inclusion in the referenced 510(k) Notice for the Securus IRTS System. The information is being provided in response to questions raised by FDA during the review of the subject Notification on 11/14/15. Please direct this response to William Burdick.

Should you have any questions pertaining to these responses please contact me at 978-317-0836. Please send written communications concerning this Notification to:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.

November 19, 2015

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100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.

ADDITIONAL INFORMATION

The following pages contain Additional Information (AI) provided in response to questions raised by FDA during the review of K152402/S001 on November 14, 2015

This response is organized in the sequence of the questions presented in the FDA communication. In each case, the question is repeated (verbatim) in italics, followed by the Securus response. If additional supporting documentation is referenced, it is provided as an Attachment.

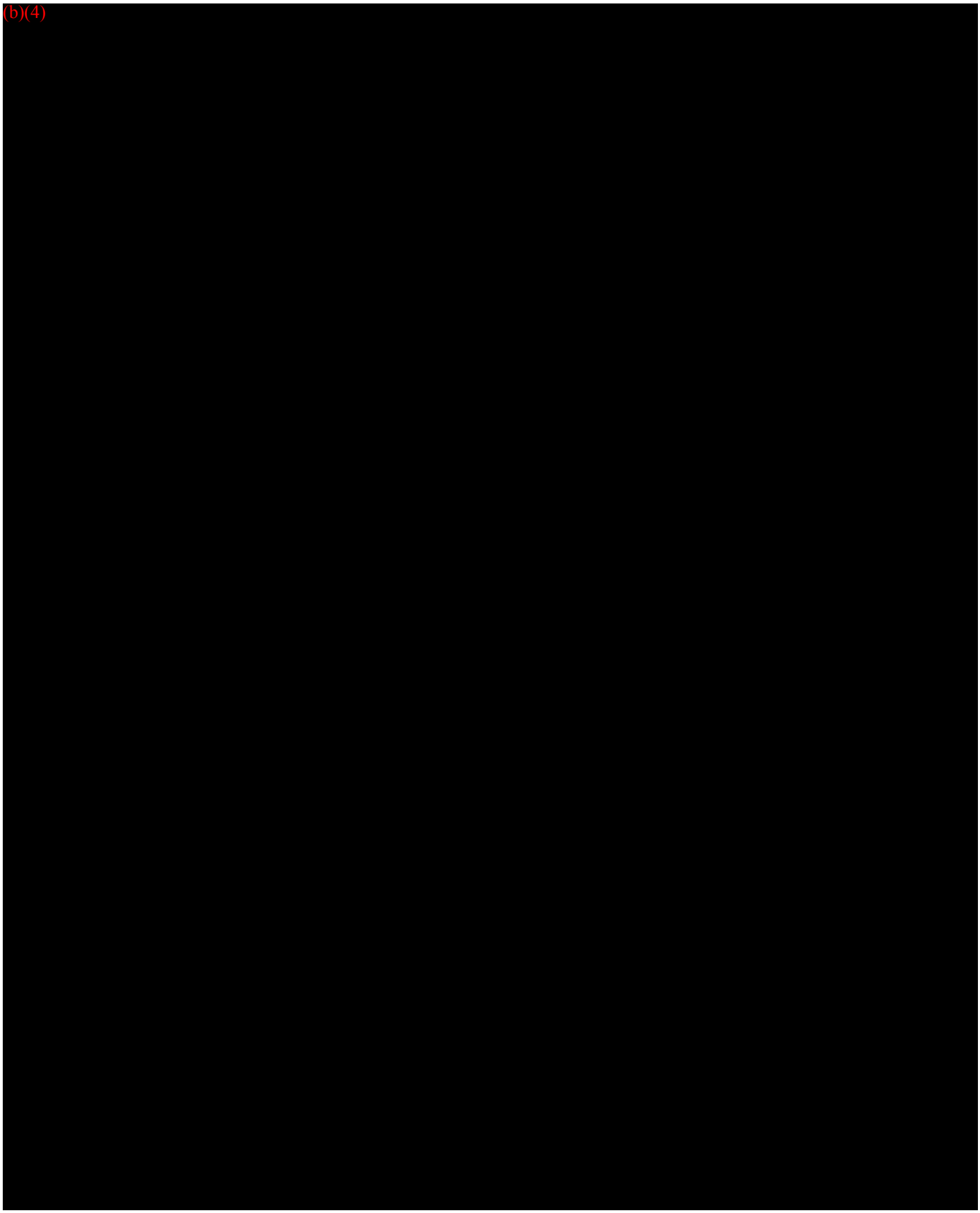
AI K152402/S001
Table of Contents

ATTACHMENTS:

A: SD-10855 - SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION
B: TR-10850 - IRTS UNIT TEST RESULTS
C: TR-10900 - IRTS SOFTWARE TEST REPORT
D: D-10903 - DESIGN REVIEW BOARD MEETING MINUTES

(b)(4)

(b)(4)



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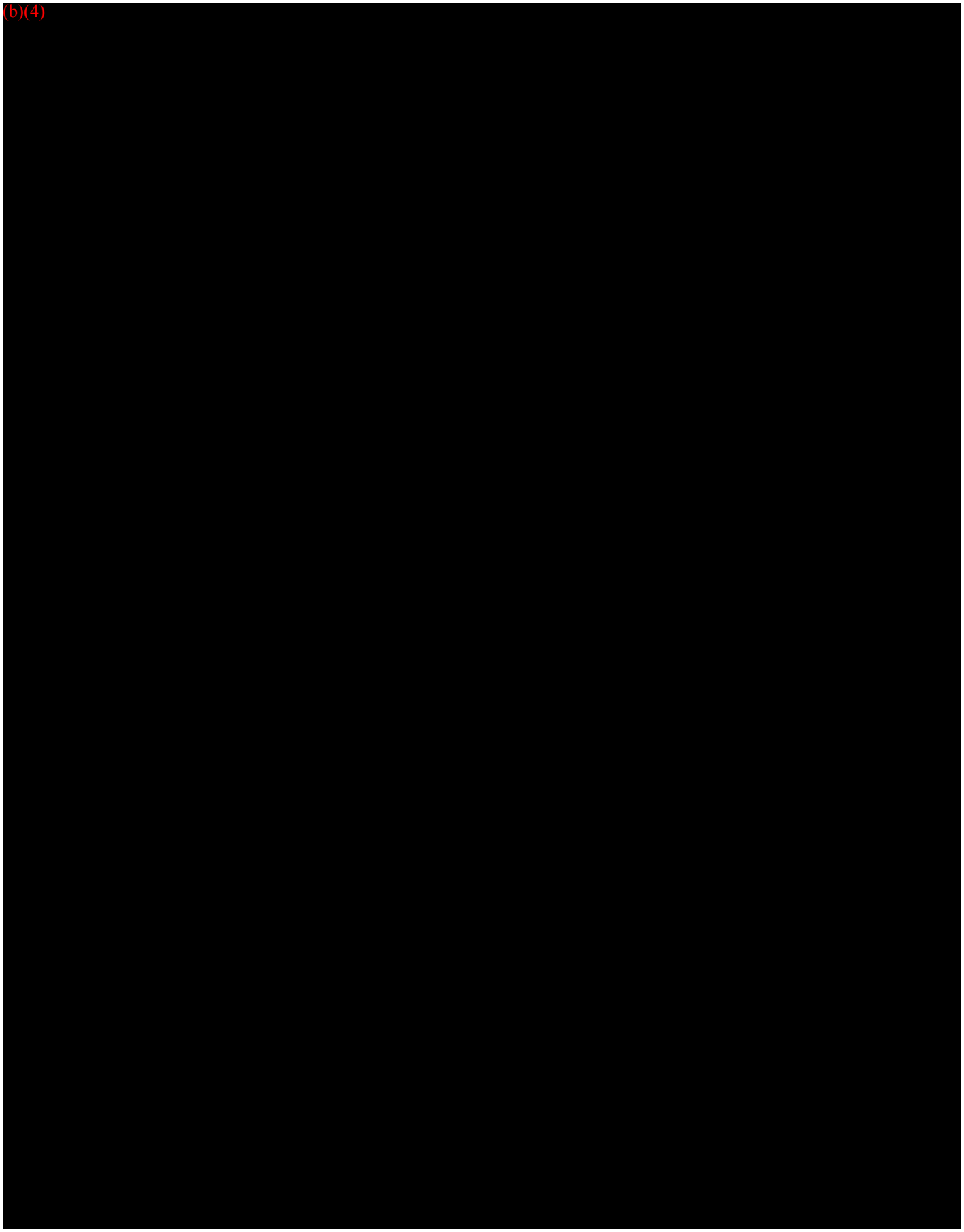

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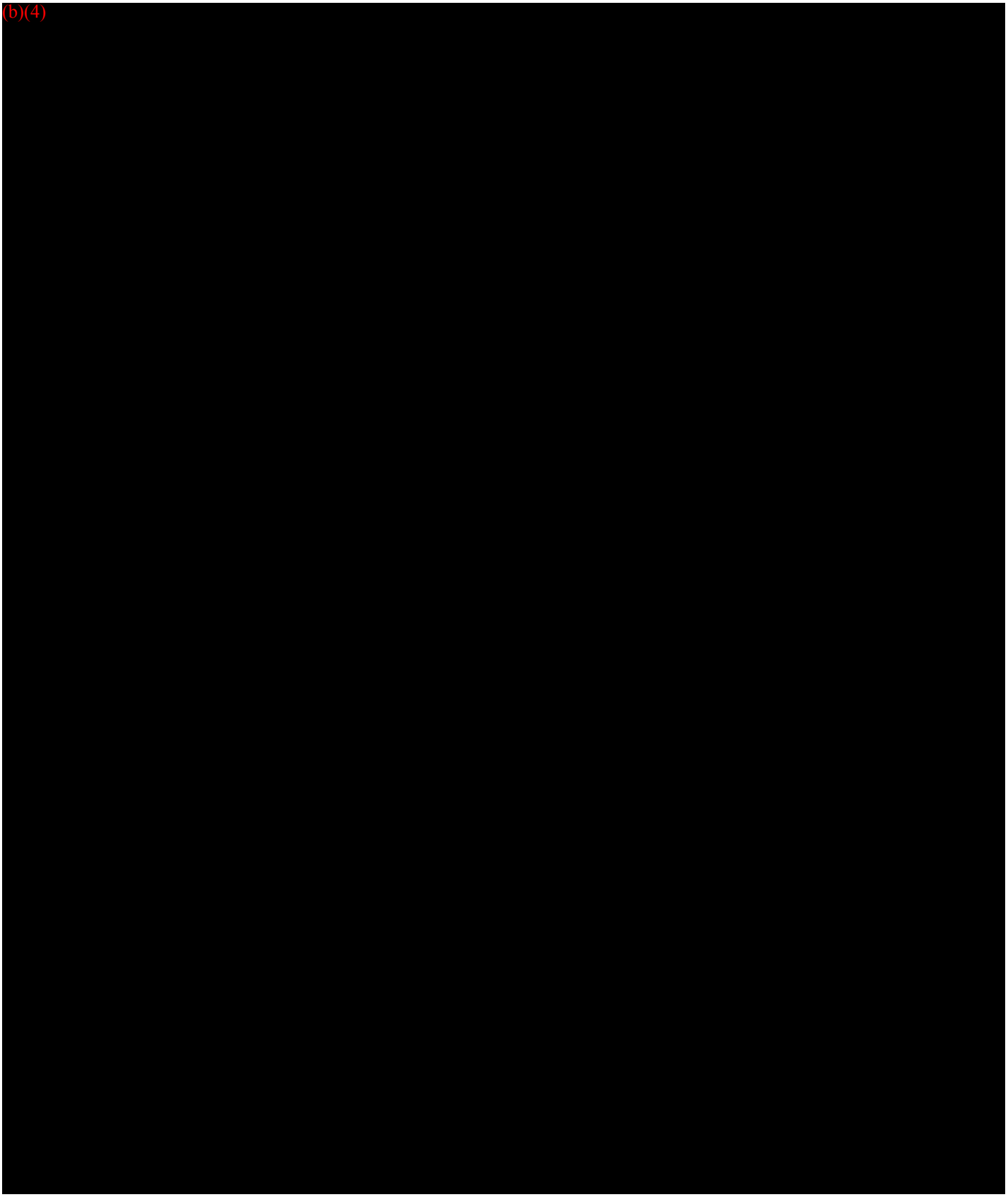
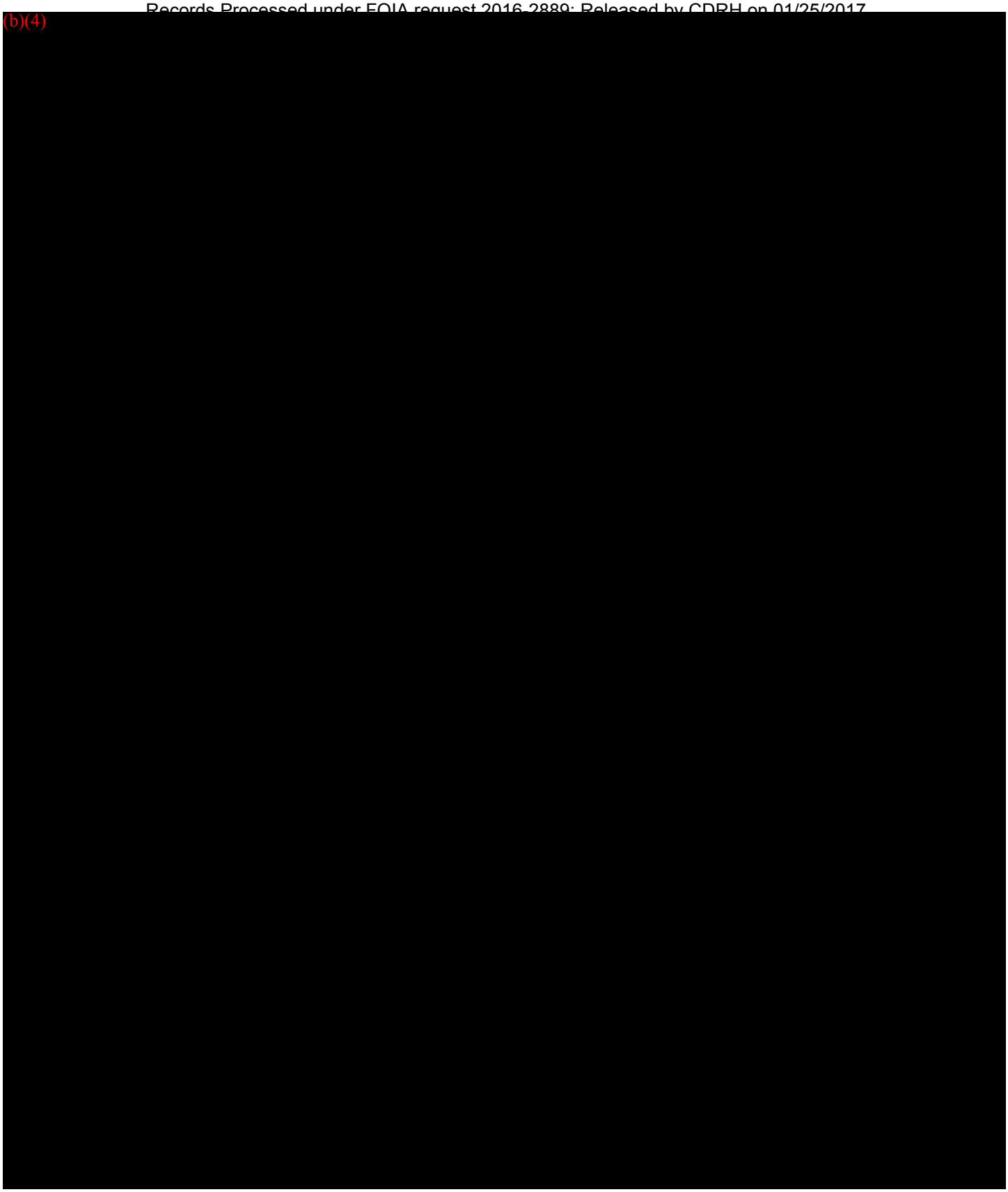


ATTACHMENT A: (b)(4) – SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION

(b)(4)

(b)(4)



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[redacted]

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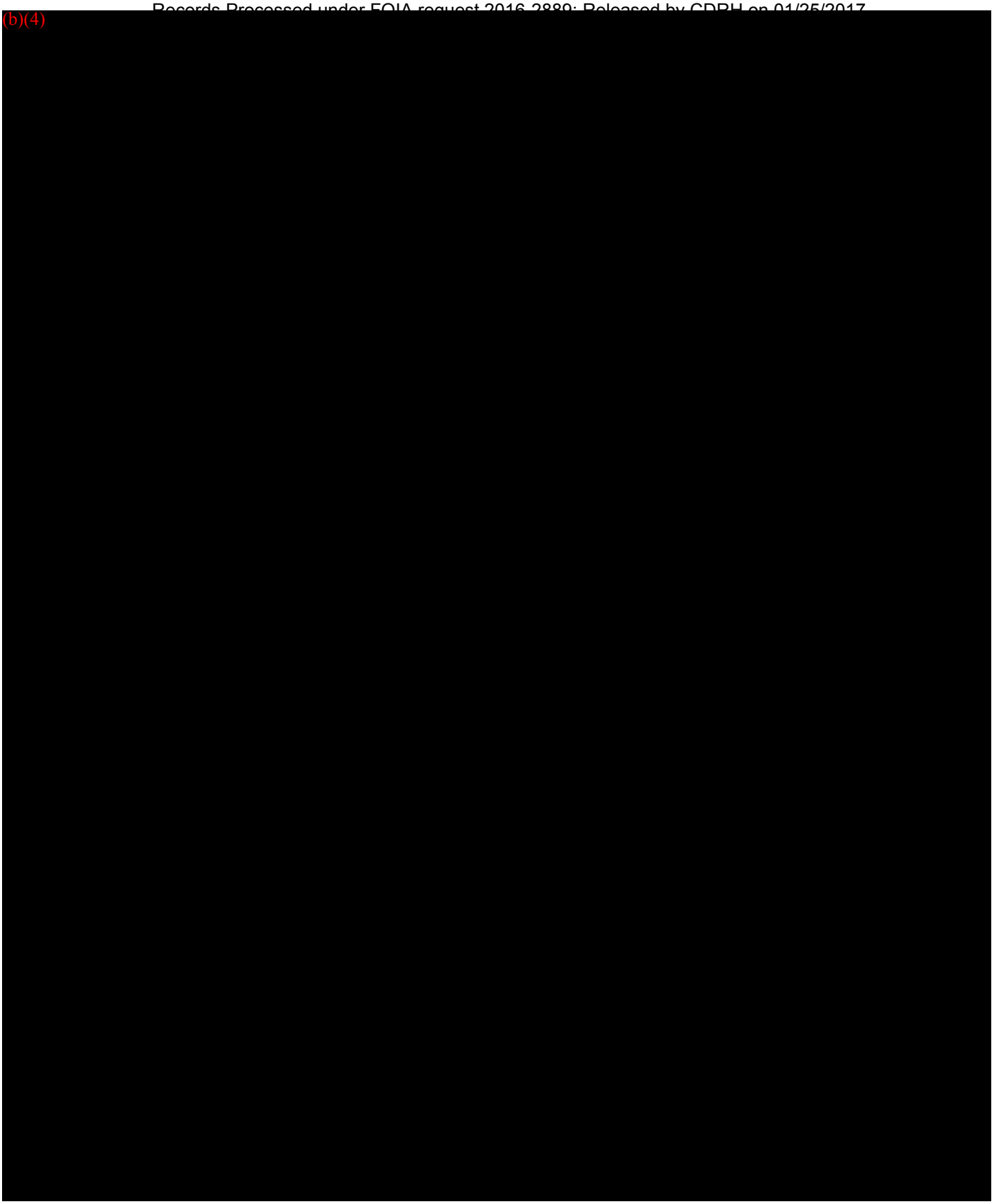
[redacted]

(b)(4)

[redacted]

(b)(4)



ATTACHMENT B: (b)(4) – IRTS UNIT TEST RESULTS

(b)(4) [redacted]

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ATTACHMENT C: (b)(4) – IRTS SOFTWARE TEST REPORT

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ATTACHMENT D: DESIGN REVIEW BOARD MEETING MINUTES

(b)(4)

(b)(4)

1h152402

August 20, 2015

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

Re: Traditional Premarket Notification 510(k) for the InfraRed Thermographic System (IRTS)

510(k) Notification – USER FEE ID -(b)(4) for Securus Medical Group, Inc.

Dear Sir/Madam:

Enclosed are one paper copy and one electronic copy of an original Traditional Premarket Notification 510(k) for the InfraRed Thermographic System (IRTS). This document complies with 21 CFR, part 807, subpart E, providing notice before the date Securus Medical Group, Inc. intends to introduce this device into commercial distribution. Additionally, this submission was prepared in accordance with the following FDA's Guidance documents: "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k) Guidance for Industry and Food and Drug Administration Staff" document issued on: July 28, 2014, "Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers" and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The information contained in this document is confidential and proprietary. Knowledge of this project and product line has been restricted to Securus Medical Group, Inc. employees and agents only. None of this information is public. The complete document should not be released through Freedom of Information Act request or any other way. We request that Securus Medical Group, Inc. be notified by FDA if there is a FOI request filed for this document. Selected confidential and/or proprietary information must be deleted before any part of the document is released.

Per FDA's "eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff" dated December 31, 2012, the electronic copy included in this premarket notification is an exact duplicate of the paper copy.

Appendix XIX includes a completed Acceptance Checklist for Traditional 510(k)s.

There have been no prior regulatory submissions related to this device.

Should you have any questions pertaining to this notification, please contact:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Telephone: 978-317-0836, Email: wgorman@securusmg.com

Sincerely, William J Gorman

Digitally signed by William J Gorman
DN: cn=William J Gorman, o, ou, email=wgorman@securusmg.com, c=US
Date: 2015.08.19 15:38:08 -04'00'

Enclosure: 1 paper copy and 1 electronic copy of this 510(k) notification

Premarket Notification Submission

Traditional 510(k) Application

For

InfraRed Thermographic System (IRTS)

Applicant:

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

August 20, 2015

1 paper copy and 1 electronic copy

510(k) Table of Contents

SECTION 1: MEDICAL DEVICE USER FEE COVER SHEET

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) SECURUS MEDICAL GROUP INC 100 Cummings Center Suite 215F Beverly USA MA 01982 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)	2. CONTACT NAME William Gorman 2.1 E-MAIL ADDRESS wgorman@securusmg.com 2.2 TELEPHONE NUMBER (include Area code) 978-3170836 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
	[ ] 180-day (PMA, PMR, PDP)

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

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

[X] NO, I am not a small business

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

5. 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?

[X] 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.)

[ ] 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/cdrh/mdufma for additional information)

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

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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).

[ ] YES [X] 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, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[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) 30-Jun-2015

Form FDA 3601 (05/13)

"Close Window" Print Cover sheet

SECTION 2: CDRH PREMARKET REVIEW SUBMISSION COVER SHEET, FORM 3514

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/15/2015	(b)(4)	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Securus , Inc.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	978 317 0836		
Street Address	**FAX Number *(including area code)***		
100 Cummings Center, Suite 215F			
City	**State / Province**	**ZIP/Postal Code**	**Country**
Beverly	MA	01915	USA
Contact Name			
William J. Gorman			
Contact Title	**Contact E-mail Address**		
Director of Quality and Regulatory Affairs	wgorman@securusmg.com		

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

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

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PSC Publishing Services (301) 443-6740 EF

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

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Response to FDA correspondence:
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

FORM FDA 3514 (1/13) Page 2 of 5 Pages

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FLL	2	LHQ	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K123361	1	ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB	1	FIAB
2	K073581	2	ICI P and S Series IR Camera(s) and the IR Flash Software	2	Texas Infrared
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Clinical electronic thermometer
Telethermographic system (adjunctive use)

	Trade or Proprietary or Model Name for This Device		Model Number
1	IRTS Thermal Imaging Probe (TIP)	1	A-10734
2	IRTS Patient Monitoring Unit (PMU)	2	A-10395
3	IRTS Patient Interface Unit (PIU)	3	A-10667
4		4	
5		5	

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

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

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FLL and LHQ	21 CFR § 880.2910 and 21 CFR § 884.2980	☒ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
General Hospital Panel and Obstetrical and Gynecological Devices Panel		

Indications *(from labeling)*

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.
The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.
The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

FORM FDA 3514 (1/13) Page 3 of 5 Pages

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.				FDA Document Number *(if known)*
SECTION H	**MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**			
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number			☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name Securus , Inc.				Establishment Registration Number
Division Name *(if applicable)* N/A				Phone Number *(including area code)* 978 317 0836
Street Address 100 Cummings Center, Suite 215F				FAX Number *(including area code)*
City Beverly		State / Province MA	ZIP Code 01915	Country USA
Contact Name William Gorman	Contact Title Director of Quality and Regulatory Affairs		Contact E-mail Address wgorman@securusmg.com	
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number			☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name				Establishment Registration Number
Division Name *(if applicable)*				Phone Number *(including area code)*
Street Address				FAX Number *(including area code)*
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number			☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name				Establishment Registration Number
Division Name *(if applicable)*				Phone Number *(including area code)*
Street Address				FAX Number *(including area code)*
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 5 Pages

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	ES60601-1	AAMI/ANSI	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005/(R)2012 and A1:2012	08/21/2012
	Standards No.	Standards Organization	Standards Title	Version	Date
2	60601-1-2	AAMI/ANSI/IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	Edition 3: 2007-03	5/17/2007
	Standards No.	Standards Organization	Standards Title	Version	Date
3	80601-2-56:	ISO	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	First Edition 2009-10-01	10/1/2009
	Standards No.	Standards Organization	Standards Title	Version	Date
4	10993-1	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009 / (R) 2013	10/15/2009
	Standards No.	Standards Organization	Standards Title	Version	Date
5	10993-5	ISO	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	2009 / (R) 2014	06/01/2009
	Standards No.	Standards Organization	Standards Title	Version	Date
6	10993-10	ISO	Biological evaluation of medical Devices - Part 10: Tests for irritation and skin sensitization	2010	09/04/2010
	Standards No.	Standards Organization	Standards Title	Version	Date
7	14791	ISO	Application of risk management to medical devices	2007	10/01/2007

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

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

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

The burden time for this collection of information is estimated to average 0.5 hour 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
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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SECTION 3: ORIGINAL 510(K) COVER LETTER

August 20, 2015

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

Re: Traditional Premarket Notification 510(k) for the InfraRed Thermographic System (IRTS)

510(k) Notification – USER FEE ID (b)(4) for Securus Medical Group, Inc.

Dear Sir/Madam:

Enclosed are one paper copy and one electronic copy of an original Traditional Premarket Notification 510(k) for the InfraRed Thermographic System (IRTS). This document complies with 21 CFR, part 807, subpart E, providing notice before the date Securus Medical Group, Inc. intends to introduce this device into commercial distribution. Additionally, this submission was prepared in accordance with the following FDA's Guidance documents: "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k) Guidance for Industry and Food and Drug Administration Staff" document issued on: July 28, 2014, "Guidance on the Content of Premarket Notification 510(K) Submissions for Clinical Electronic Thermometers" and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The information contained in this document is confidential and proprietary. Knowledge of this project and product line has been restricted to Securus Medical Group, Inc. employees and agents only. None of this information is public. The complete document should not be released through Freedom of Information Act request or any other way. We request that Securus Medical Group, Inc. be notified by FDA if there is a FOI request filed for this document. Selected confidential and/or proprietary information must be deleted before any part of the document is released.

Per FDA's "eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff" dated December 31, 2012, the electronic copy included in this premarket notification is an exact duplicate of the paper copy.

Appendix XIX includes a completed Acceptance Checklist for Traditional 510(k)s.

There have been no prior regulatory submissions related to this device.

Should you have any questions pertaining to this notification, please contact:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Telephone: 978-317-0836, Email: wgorman@securusmg.com

Sincerely,

Enclosure: 1 paper copy and 1 electronic copy of this 510(k) notification

510(k) Notification (21 CRF 807.90(e))

Submitter:	Securus Medical Group, Inc. 100 Cummings Center Suite 215F Beverly, MA 01915
Registration Number:	Securus will register with FDA upon clearance of the device.

Device name:	InfraRed Thermographic System (IRTS)
Common name:	Thermometer
Classification name:	Clinical electronic thermometer Thermographic system
Classification number:	880.2910, 884.2980
Product code:	FLL, LHQ
Device class:	Class II for FLL, Class I for LHQ
Classification panel:	FLL, General Hospital LHQ, Obstetrical and Gynecological Devices

Confidentiality

The information contained in this document is confidential and proprietary. Knowledge of this project and product line has been restricted to Securus Medical Group, Inc. employees and agents only.

Basis for the submission

☒ New device ☐ Modification of a legally marketed device ☐ New indication for use ☐ Original 510(k) ☐ Special 510(k) ☐ New device design

Design and Use of the Device / Questions	**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**
If yes, does this device type require reprocessed validation data?		
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**

Company contact: William J. Gorman **Signature:**

Telephone: 978-317-0836

Email: wgorman@securusmg.com

SECTION 4: INDICATIONS FOR USE STATEMENT

See Appendix XVIII for FDA form 3881.

Device Name: InfraRed Thermographic System (IRTS)

Indications for Use

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

SECTION 5: 510(K) SUMMARY

This 510(k) Summary is being submitted in accordance with: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)

Common name: Clinical Electronic Thermometer

Thermographic System

Classification Number/ Classification name/Product code:

Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Telethermographic systems intended for adjunctive diagnostic screening are Class I devices under 21 CFR § 884.2980 and are classified by the Obstetrical and Gynecological Devices panel. Product code – LHQ.

Special Controls:

Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers

3) Predicate Devices

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361).

ICI P and S Series IR Camera(s) and the IR Flash Software, Texas Infrared, (K073581).

4) Device Description

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification. Esophageal temperature probes are Class II devices.

A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure,

without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ.

The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition, the Probe incorporates adjunctive infrared thermal imaging to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to the thermocouple temperature and not intended as a diagnostic feature. See Figure 1 for a system overview.

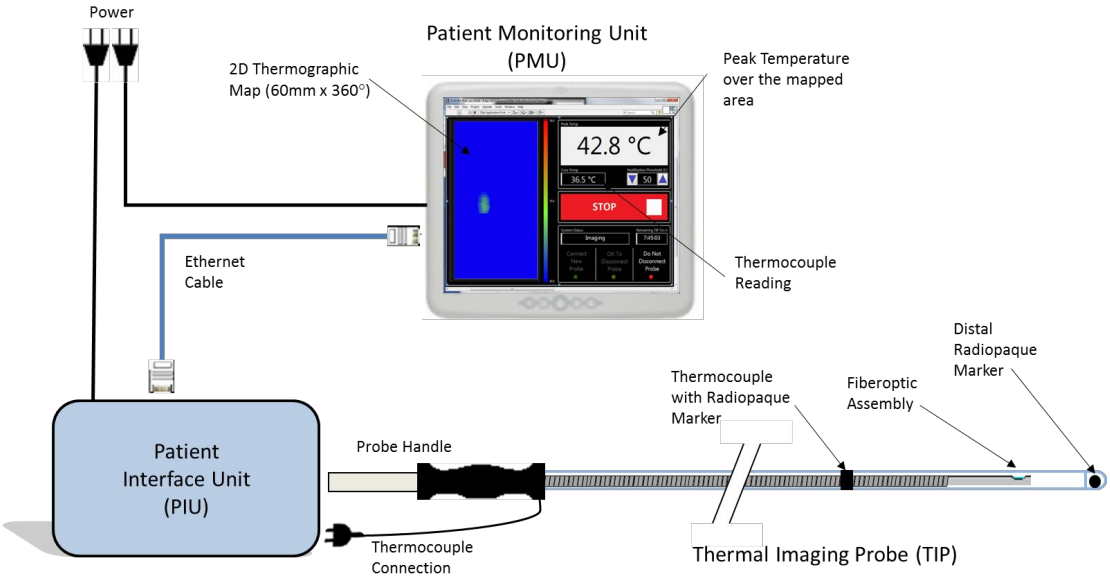


Figure 1: System Overview Diagram

5) Indications for Use

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

6) Comparison to Predicate Device

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification.

Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ. A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The FIAB ESOTEST System is identified as the primary predicate for the esophageal temperature probe. The Texas Infrared IR Camera with Flash Software is identified as the secondary predicate for the adjunctive telethermographic diagnostic screening functionality.

SE SUMMARY TABLE - Comparison to Predicate			
	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., InfraRed Thermographic System (IRTS)
Intended Use	Continuous temperature monitoring of the patients esophagus.	Intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperatures.	Continuous temperature monitoring of the patients esophagus.
Indications for Use	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The ICI Series and S IR Cameras, which provide capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.	The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring. The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe. The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.
System Components	Temperature probe with 3 thermocouple sensors, Interconnect cable, 250cm long, Patient Monitor	Thermographic infrared detector with optical assembly, Flash Software	Temperature probe with 1 thermocouple sensor and infrared fiber optic assembly, Patient Interface Unit (PIU) with thermographic infrared detector, Patient Monitoring Unit (PMU) with software

SE SUMMARY TABLE - Comparison to Predicate			
	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., InfraRed Thermographic System (IRTS)
Probe Material (patient contact)	Polyurethane and stainless steel	N/A	Polyethylene and platinum iridium
Probe size	7 Fr catheter with 11 Fr sensors 95 cm length	N/A	9 Fr catheter with 9 Fr sensor 150 cm length
Route of insertion into Esophagus	Nasal or oral	N/A	Nasal or oral
System Temperature Precision and Resolution	0.1° C	0.1° C	0.1° C
Thermocouple Temperature Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	N/A	± 0.3° C tested in accordance with ISO 80601-2-56
Transient Response Time of Thermocouple	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential.	N/A	Both heating transient response time and cooling transient response time are less than 2 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential.
Infrared Detector Technology	N/A	FPA microbolometer	Stirling cooled MCT
Infrared Temperature Accuracy	N/A	IR: ± 2° C or 2% of reading	IR: ± 2° C
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007

Comparison to Predicate Discussion:

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and an infrared imaging system, onto a single display monitor.

The following differences are noted in the SE table above but do not affect substantial equivalence or safety and effectiveness.

- The Probe material (patient contact): Polyethylene was selected for the exterior catheter shaft of the Probe. Polyethylene has excellent transmissivity to infrared energy which is important for the infrared imaging capability of the IRTS. The material has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The shaft of the Probe is 9 Fr (3.0 mm) with a smooth surface and mainly uniform diameter along its length. The shaft of the FIAB ESOTEST is 7 Fr (2.3 mm) with five 11 Fr (3.6 mm) stainless steel beads protruding at the thermocouple and electrode locations. The Probe diameter falls within the mid-range of the FIAB ESOTEST geometry which is suitable for both nasal and oral insertion.
- The transient response time (heating and cooling) of the Probe was tested in accordance with ISO 80601-2-56. The resulting transient response time is 2 seconds versus the FIAB ESOTEST transient response time reported as approximately 1 second. The 1second difference in response time is not clinically significant for the intended use.
- The way the IRTS collects the infrared energy from the tissue surface and presents that energy to the detector has been adapted to incorporate a fiber optic assembly. The fiber optic assembly is fully contained within the inner lumen of the esophageal temperature Probe. The Texas IR product presents data from the surface of the skin. Both devices collect passively emitted infrared radiation and present that radiation to a detector for determination of surface temperatures.
- The infrared detector used in the Securus product is a Stirling cooled MCT type. The Texas product utilizes an FPA Microbolometer type detector. The majority of IR cameras have a Microbolometer type detector, mainly because of cost considerations. Microbolometers are relatively low sensitivity, exhibit broad (flat) response curves and slow response time (time constant ~ 12 ms). For more demanding applications, MCT type detectors are used, which operate on the basis of an intrinsic photoelectric effect. Stirling cooled MCT detectors are very sensitive to changes in infrared energy and react very quickly to changes in infrared energy levels (i.e., temperatures), having a response time constant on the order of 1 μs. The Securus IRTS system utilizes the more sensitive Stirling cooled MCT type detector.

Testing and development have been performed in accordance with recognized consensus standards. Based on the testing performed on the IRTS the safety and effectiveness of the system has not been affected by the changes required to combine the output of the two temperature monitoring devices onto one display monitor.

7) <u>Performance Data</u>

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical

devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The performance data provided support the substantial equivalence of the InfraRed Thermographic System (IRTS). According to these data we conclude that the IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), and the Patient Interface Unit (PIU) are substantially equivalent to the predicate devices in terms of performance, safety and use. The differences from the predicates do not affect substantial equivalence or performance and do not raise any new safety concerns.

SECTION 6: STATEMENTS

Truthful and Accuracy Certification
As required by 21 CFR 807.87(k)

I certify as the President/CEO of Securus Medical Group, Inc. that I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification for Securus Medical Group, Inc. InfraRed Thermographic System (IRTS) are truthful and accurate and that no material fact has been omitted.

Steven Girouard Date

SECTION 7: CLASS III SUMMARY AND CERTIFICATION

Not applicable, this is a 510(k) for a Class II device.

SECTION 8: FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

Not applicable.

SECTION 9: DECLARATIONS OF CONFORMITY AND SUMMARY REPORT

Performance standards (Consensus Standards) for this type of device have been established. Securus has carried out appropriate testing as recommended in the FDA Guidance Documents "Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers" and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." and has determined that the device is acceptable for its intended use. Supporting data and information are included in Sections 15-20 of this Notice.

This following is a list of standards that were used in the design and development of the InfraRed Thermographic System (IRTS):

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 80601-2-56:2009 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009(E) Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010(E) Biological evaluation of medical Devices - Part 10: Tests for irritation and skin sensitization
- ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes
- ISO 14791:2007 Application of risk management to medical devices

Note: FDA Standard Forms (F-3654) are provided in **Appendix I** of this document.

SECTION 11: DEVICE INFORMATION

11.1 Device Description & Principles of Operation

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification.

Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ. A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

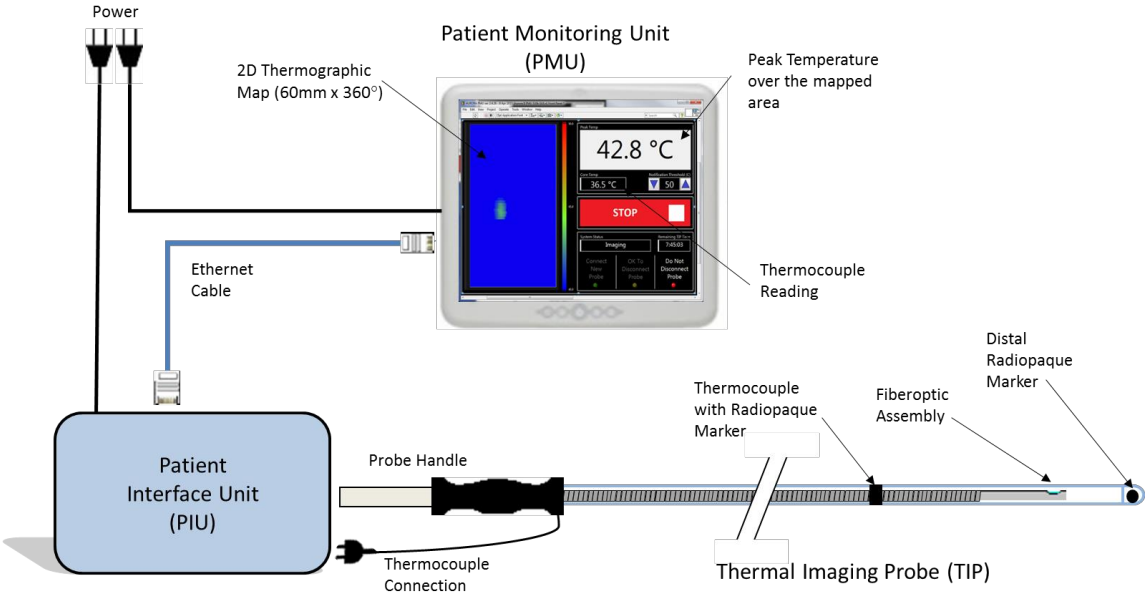


Figure 2: System Overview Diagram

Appendix IX includes drawings with specifications for the system components. The sub-sections below include detailed description of each component.

The InfraRed Thermographic System (IRTS) presented in Figure 2, consists of three components:

a. Patient Monitoring Unit (PMU)

The PMU is an off-the-shelf medical grade computer used to display a custom designed User Interface (UI). The UI is touch screen enabled and designed to be very simple to operate. All user controls and settings are contained in the UI on a single screen. The PMU is designed as a dedicated system limiting all other computer related functionality. In addition to the UI, the software executes high-level control and monitoring of the system as well as signal processing of the data. The PMU presents both a thermocouple reading and the 2-dimensional infrared thermal map including the peak temperature over the mapped area. All temperature readings are displayed in degrees Celsius. The PMU is powered by a 24-volt DC medical grade isolated power supply. See Figure 3 below and Appendix IX.

b. Patient Interface Unit (PIU)

The PIU is a custom medical device containing the thermocouple interface, infrared detector, motion system, custom electronics and software. The thermocouple interface collects the temperature data from the thermocouple of the Probe. The infrared detector converts the self-emanating infrared energy collected from the Probe into an electrical signal (voltage). The motion system provides the means to scan and collect the infrared energy over 360° by 60mm segment of the inner lumen of the esophagus. The custom hardware, electronics and software include all monitoring and control of the system. The PIU connects to the PMU with a standard Ethernet cable. The cable facilitates all communication and data transfer between the devices. The PIU is powered by a 24-volt DC medical grade isolated power supply.

See Figure 4 below and Appendix IX.

c. Thermal Imaging Probe (TIP/Probe)

The Probe is an individually packaged 9 French non-sterile, single-use esophageal catheter. It is designed to be inserted into the esophagus either orally or nasally and positioned under fluoroscopic guidance. The Probe is intended to be used outside the sterile field by clinical professionals familiar with the placement of devices in the esophagus.

The Probe is approximately 1.5 meters long and designed with a smooth and flexible outer shaft with a soft, formable distal tip for atraumatic insertion. The distal tip is closed, encapsulating a radiopaque marker for visualization of the distal tip under fluoroscopy. The entire length of the Probe shaft is made from industry standard medical grade polyethylene.

The Probe handle and thermocouple connector plug into the PIU at the time of use. The Probe incorporates a standard thermocouple for providing continuous temperature readings from the esophagus. The thermocouple is positioned at the proximal platinum iridium marker bank and is under fluoroscopy. See Figure 5 below and Appendix IX.

Sealed within the lumen of the catheter outer shaft is an infrared fiber optic assembly with a torque coil. The torque coil is used to transfer the rotational and translational forces from the motion system in the PIU to the fiber optic assembly over the length of the catheter. The fiber optic assembly passively collects, at a right-angle to the Probe shaft, the infrared energy as it radiates from the esophageal tissue. The fiber optic assembly collects the infrared energy and presents the energy to the detector housed in

the PIU. See Figure 6 below for detailed views of the distal end of the Probe and fiber optic assembly with torque coil. No electrical energy is directed down the Probe. The Probe cannot be disassembled and is single use only. The fiber optic assembly is completely enclosed within the catheter shaft. Only the polyethylene catheter shaft and the radiopaque platinum iridium marker band contact the patient.

During operation the torque coil and fiber optic assembly simultaneously and continuously translate and rotate within the lumen of the outer shaft. This action creates a helical scan covering a 360° by 60mm long segment of the esophageal wall. The collected thermal data is transferred to, and displayed on, the PMU as a color two-dimensional thermal map of the inner surface of the esophagus. The peak temperature over the scanned area is updated each 60mm pass or once every second. See Figure 5 below and Appendix IX.

Figure 3: Patient Monitoring Unit (PMU)

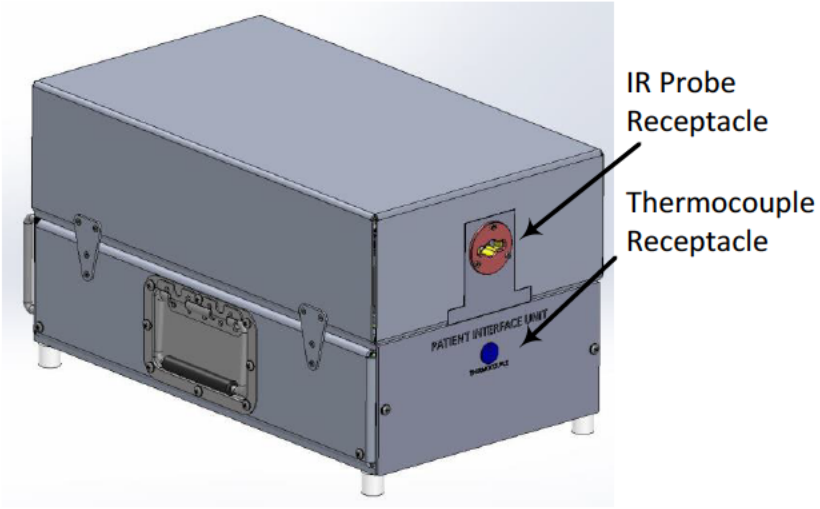


Figure 4: Patient Interface Unit (PIU)

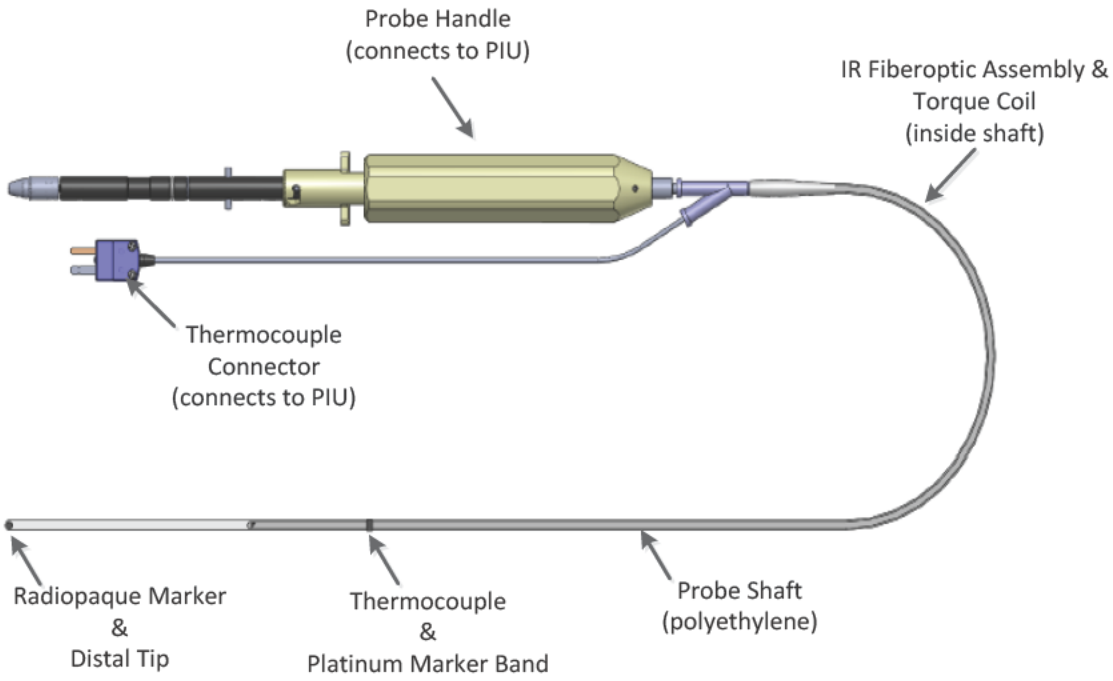
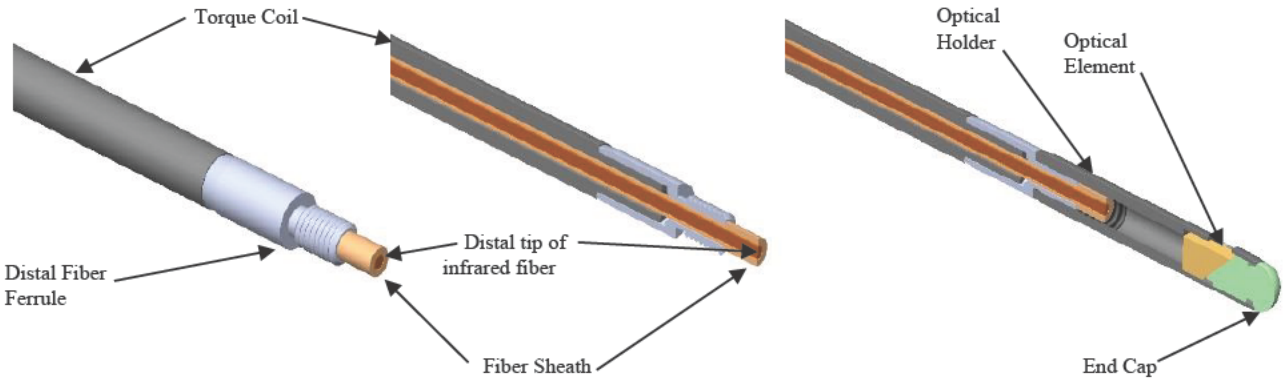


Figure 5: Thermal Imaging Probe (Probe)



6a: Iso view without Optical Element

6b: Cross-section without Optical Element

6c: Cross-section with Optical Element

Figure 6: Distal Probe Detail – Fiber Optic Assembly

SECTION 12: SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1 Substantial Equivalence (SE) Table

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification.

Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ. A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The FIAB ESOTEST System is identified as the primary predicate for the esophageal temperature probe. The Texas Infrared IR Camera with Flash Software is identified as the secondary predicate for the adjunctive telethermographic diagnostic screening functionality.

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., InfraRed Thermographic System (IRTS)
Intended Use	Continuous temperature monitoring of the patients esophagus.	Intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperatures.	Continuous temperature monitoring of the patients esophagus.
Indications for Use	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The ICI Series and S IR Cameras, which provide capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.	The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring. The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe. The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.
System Components	Temperature probe with 3 thermocouple sensors, Interconnect cable, 250cm long, Patient Monitor	Thermographic infrared detector with optical assembly, Flash Software	Temperature probe with 1 thermocouple sensor and Infrared fiber optic assembly. Patient Interface Unit (PIU) with thermographic infrared detector. Patient Monitoring Unit (PMU) with software
Probe Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., InfraRed Thermographic System (IRTS)
Probe Material (patient contact)	Polyurethane and stainless steel	N/A	Polyethylene and platinum iridium
Probe size	7 Fr catheter with 11 Fr sensors 95 cm length	N/A	9 Fr catheter with 9 Fr sensor 150 cm length
Route of insertion into Esophagus	Nasal or oral	N/A	Nasal or oral
System Temperature Precision and Resolution	0.1° C	0.1° C	0.1° C
Thermocouple Sensor Technology	Type-T thermocouple	N/A	Type-T thermocouple
Thermocouple Signal Processing and Display	Temperature is a function of thermocouple voltage 1 input (single probe) available	N/A	Temperature is a function of thermocouple voltage 1 input (single probe) available
Thermocouple Temperature Range	25°-75° C	N/A	25° - 45° C
Thermocouple Temperature Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	N/A	± 0.3° C tested in accordance with ISO 80601-2-56
Transient Response Time of Thermocouple	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential.	N/A	Both heating transient response time and cooling transient response time are less than 2 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential.
Infrared Detector Technology	N/A	FPA microbolometer	Stirling cooled MCT

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., InfraRed Thermographic System (IRTS)
Infrared Signal Processing and display	N/A	Relative display of color graphical image representing infrared radiation emitted from surface of the skin.	Relative display of color graphical image representing infrared radiation emitted from surface of the esophagus.
Infrared Temperature Range	N/A	-20° - +250° C	39° - 60° C
Infrared Temperature Accuracy	N/A	IR: ± 2° C or 2% of reading	IR: ± 2° C
Infrared Temperature Resolution	N/A	0.1° C	0.1° C
Spatial Resolution of Thermal Image	N/A	1.13 mrad	IR: 49 mrad
Power Supply	100-120/230 Vac	AC adaptor power supply 12 VDC	100-240 Vac AC adaptor power supply 24 VDC
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007
Data Output	Data provided to the supplied monitor for display	Digital USB 2.0 to user computer	Data provided to the supplied monitor for display

12.2 SE Discussion

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

The differences between the predicate devices and the IRTS are primarily physical differences required to combine an esophageal temperature probe and an infrared imaging system capable of imaging within the body. The basic technologies and the intended use are equivalent.

The following discussion follows the questions provided in Appendix A. 510(k) Decision-Making Flowchart provided in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k), Guidance for Industry and Food and Drug Administration Staff. Document issued on July 28, 2014.

Decision 1: Is the predicate device a legally marketed device?

Yes. The InfraRed Thermographic System (IRTS) independently presents the thermal output from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor. As such a primary and secondary predicate have been identified. Both the primary and secondary predicate devices are legally marketed devices.

The primary predicate is the FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361). This is a legally marketed device. Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

The secondary predicate identified for the telethermographic infrared imaging capability of the IRTS is the ICI P and S Series IR Camera(s) and the IR Flash Software made by Texas Infrared, (K073581). This is a legally marketed device. Telethermographic Systems (adjunctive use) are Class I devices under 21 CFR § 884.2980 and are classified by the Obstetrical and Gynecological Devices panel. Product code - LHQ.

Decision 2: Do the devices have the same intended use?

Yes. The IRTS has the same intended use as the primary predicate. Both the IRTS and the FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) are intended for continuous temperature monitoring of the patients esophagus.

The IRTS has the same intended use as the second predicate. Both the IRTS and the Texas Infrared ICI P and S Series IR Camera(s) and the IR Flash Software (K073581) are intended to display tissue surface temperatures for use as an adjunct to other clinical diagnostic procedures. The IRTS is intended for the surface of the esophagus while the predicate is intended for the surface of the body.

Decision 3: Do the devices have the same technological characteristics?

No. The IRTS incorporates the same basic components as its primary predicate, the FIAB ESOTEST device. Both are catheter-based esophageal temperature probes with integrated Type-T thermocouples for measuring temperature. Both systems incorporate a monitor to continuously display the esophageal temperature. Both systems are classified as a Clinical Thermometer and tested in accordance with ISO 80601-2-56.

The IRTS also incorporates the same fundamental telethermographic infrared technology as its secondary predicate, the Texas Infrared system. Both are infrared imaging devices that include an optical assembly, an infrared detector and graphical presentation software. Both systems passively collect the infrared energy naturally radiated off tissue surfaces for adjunctive diagnostic screening.

The following differences are noted in the SE table above but do not affect substantial equivalence or safety and effectiveness.

- The Securus Probe material (patient contact): Polyethylene was selected for the exterior catheter shaft of the Probe. Polyethylene has excellent transmissivity to infrared energy which is important for the infrared imaging capability of the IRTS. Polyethylene is available in a variety of grades for flexible catheter manufacturing and has a long history of use in medical devices. The material has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The shaft of the Probe is 9 Fr (3.0 mm) with a smooth surface and mainly uniform diameter along its length. The shaft of the FIAB ESOTEST is 7 Fr (2.3 mm) with five 11 Fr (3.6 mm) stainless steel beads protruding at the thermocouple and electrode locations. The Probe diameter falls within the mid-range of the FIAB ESOTEST geometry which is suitable for both nasal and oral insertion.
- A single thermocouple is used for the Securus Probe to report esophageal temperature where the FIAB ESOTEST has 3 thermocouples spaced apart along the catheter shaft. The FIAB device is configured so that only one thermocouple is used at a time. Numerous esophageal temperature probes are marketed with a single sensor configuration and are tested to the same recognized standards.
- The transient response time (heating and cooling) of the Securus Probe was tested in accordance with ISO 80601-2-56. The resulting transient response time is less than 2 seconds. The FIAB ESOTEST transient response time is reported as approximately 1 second. The response time of the Securus Probe is tested and reported in the product manual in accordance with the standard. The less than 1 second difference in response time between the predicate and the Securus product is not clinically significant for the intended use.
- The infrared detector used in the Securus product is a Stirling cooled MCT type. The Texas product utilizes an FPA Microbolometer type detector. The majority of IR cameras have a Microbolometer type detector, mainly because of cost considerations. Microbolometers are relatively low sensitivity, exhibit broad (flat) response curves and slow response time (time constant ~ 12 ms). For more demanding applications, MCT type detectors are used, which operate on the basis of an intrinsic photoelectric effect. Stirling cooled MCT detectors are very sensitive to changes in infrared energy and react very quickly to changes in infrared energy levels (i.e., temperatures), having a response time constant on the order of 1 μs. The Securus IRTS system utilizes the more sensitive Stirling cooled MCT type detector.

- The way the IRTS collects the infrared energy from the tissue surface and presents that energy to the detector has been adapted to incorporate a fiber optic assembly fully contained within the inner lumen of the Probe. The fiber optic assembly incorporates materials that are transmissive to the infrared energy and transfers that energy from the surface of the esophageal wall to the detector. The esophagus is continuously monitored over a 360° by 60mm long segment. The infrared image is graphically presented on the Patient Monitoring Unit as a 2-dimensional color map along with the peak temperature over the scanned area.

Decision 4: Do the differences in technological characteristics of the devices raise different questions of safety and effectiveness?

No. The technological differences of the devices do not raise different questions of safety and effectiveness. Testing has been successfully performed in accordance with accepted consensus standards and methods to evaluate effects on safety and effectiveness.

- The change in Probe materials has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The esophageal temperature measurement has been tested per ISO 80601-2-56 and meets the basic safety standards and essential performance requirements of a Clinical Thermometer for body temperature measurement. The number of thermocouples (1 versus 3) does not affect the safety and effectiveness for the intended use.
- The core infrared technology of passively collecting and delivering the infrared energy to the detector does not affect the performance of the system. The infrared temperature information is for adjunctive diagnostic screening and has the same accuracy performance as the secondary predicate device and does not affect safety and effectiveness for the intended use.

Decision 5a: Are the methods acceptable?

Yes. Testing and development has been performed in accordance with recognized consensus standards. The InfraRed Thermographic System (IRTS) complies with FDA recognized standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 80601-2-56:2009 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009(E) Biological evaluation of medical devices- Part 5: Tests for in

vitro cytotoxicity

- ISO 10993-10:2010(E) Biological evaluation of medical Devices - Part 10: Tests for irritation and skin sensitization
- ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes
- ISO 14791:2007 Application of risk management to medical devices

Decision 5b: Do the data demonstrate substantial equivalence?

Yes. The data demonstrate substantial equivalence. The IRTS has the same intended use as both predicate devices. Data from the thermocouple temperature sensor shows that the IRTS has identical performance characteristics as the FIAB ESOTEST system when tested in accordance with ISO 80601-2-56 particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

The infrared thermographic information is for adjunctive diagnostic screening and has the same accuracy performance as the Texas Infrared system.

The IRTS therefore demonstrates substantial equivalence to both the primary and secondary predicate devices.

Appendix III to this 510(k) application contains copies of the predicate device labeling and/or FDA 510(k) clearance information.

FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, (K123361)

Texas Infrared, ICI P and S Series IR Camera(s) and the IR Flash Software, (K073581).

SECTION 13: PROPOSED LABELING AND PRODUCT CLAIMS

Appendix XV contains an example product labels, the System Manual and Probe IFU for the InfraRed Thermographic System (IRTS).

SECTION 14: STERILIZATION AND SHELF LIFE

This device is not supplied sterile and is not intended to be sterilized. The Probe is provided packaged, clean and ready for use.

The Probe is constructed of industry standard materials. The Probe is packaged in a pouch and box that protects the device during storage. Storage is not expected to compromise device safety or effectiveness.

The Patient Monitoring Unit (PMU) and the Patient Interface Unit (PIU) are electronic devices that are not affected by storage. The PIU and PMU work together as a system and at start-up perform self-checks to ensure that system components are functioning within expected parameters. The PIU and PMU will be subjected to a routine yearly maintenance cycle that will ensure proper function through the product lifecycle. All maintenance of the system will be performed by qualified Securus Medical Group, Inc. personnel.

SECTION 15: BIOCOMPATIBILITY

The parts of the InfraRed Thermographic System (IRTS) system that contact body tissue are limited to the distal portion of the Probe. The Probe is inserted into the esophagus for the intended monitoring period (less than 24 hours).

The patient contact materials are listed in the following table. Included with each material is the contact type and duration as described in ISO 10993-1. The type of contact is surface, short term (A), mucosal membrane.

Component	Material	Type of Contact	Duration of contact
Marker Band	(b)(4)	Mucosal	Short term
Sheath Shaft		Mucosal	Short term
Sheath Window		Mucosal	Short term
Sheath Tip Assembly		Mucosal	Short term

Based on ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, the following tests are recommended:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Based on the intended use, the Irritation test was performed using the Primary Buccal (Mucosal) method as this is most representative of the device's intended use.

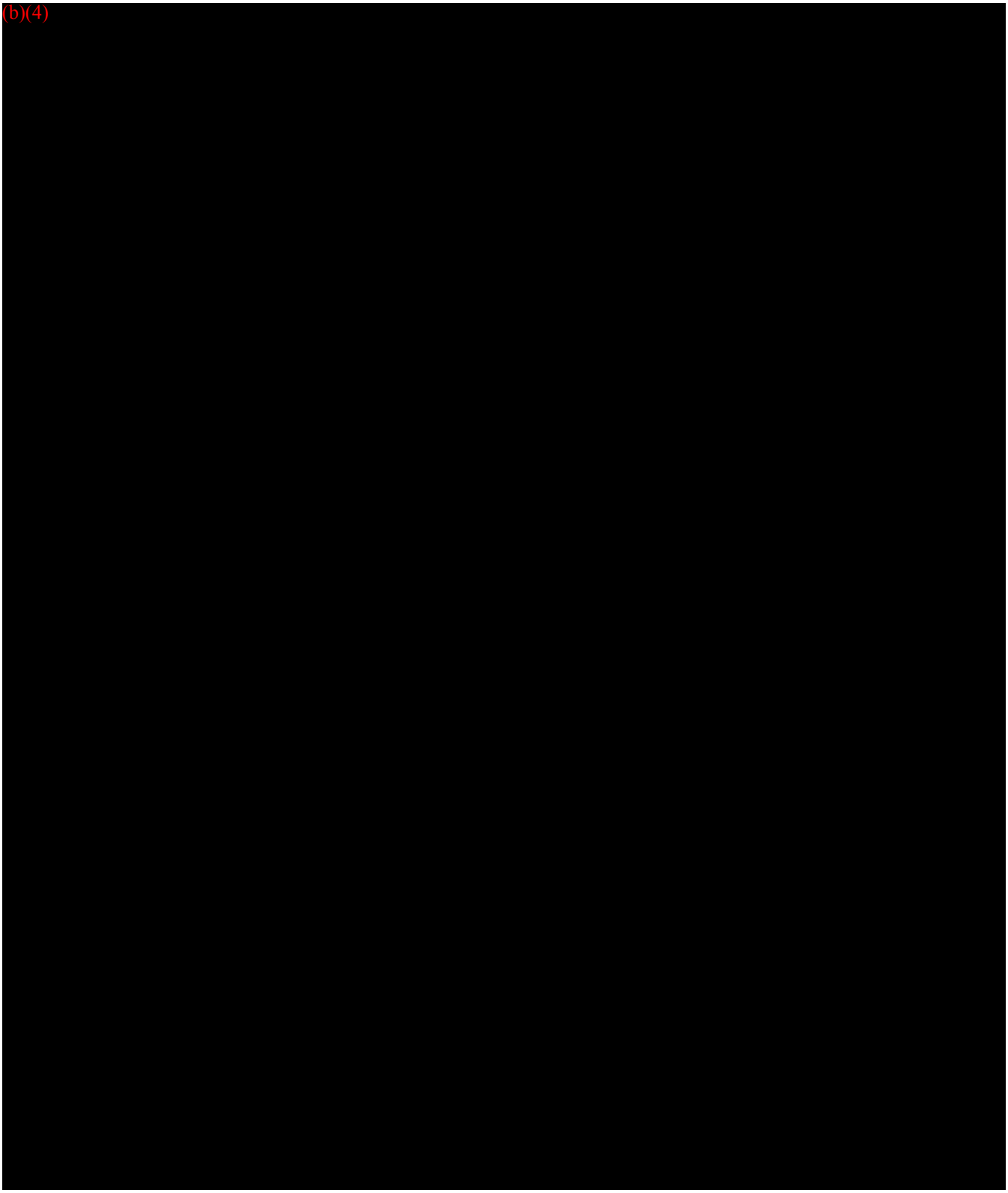
Finished packaged devices were provided to Toxikon for testing to pre-approved GLP protocols. Final reports are provided in Appendix II.

Test results show that the probe meets the requirements of ISO 10993 for its intended use.

Appendix II to this 510(k) application contains biocompatibility test reports from Toxikon Corporation of Bedford Massachusetts.

SECTION 16: SOFTWARE

(b)(4)



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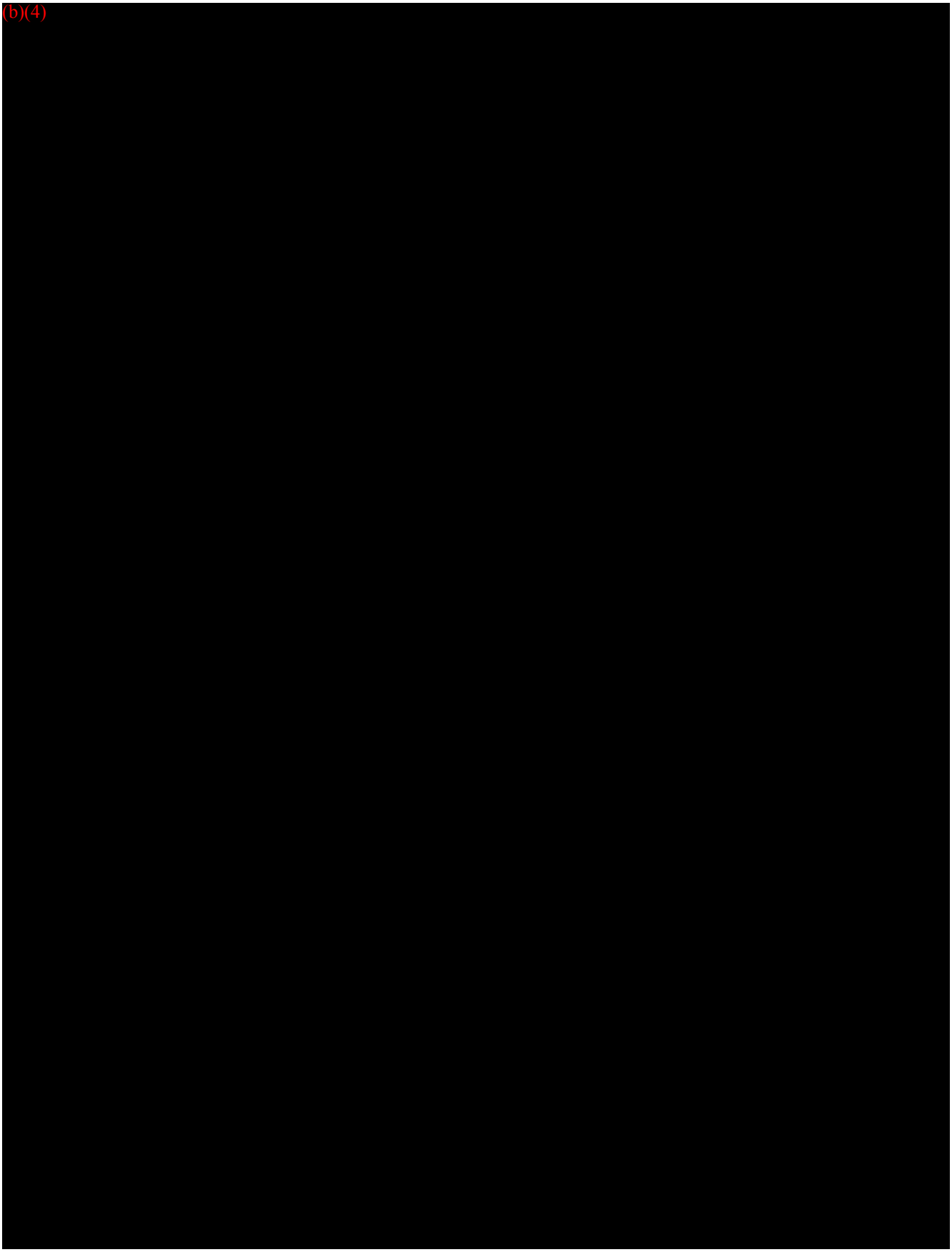

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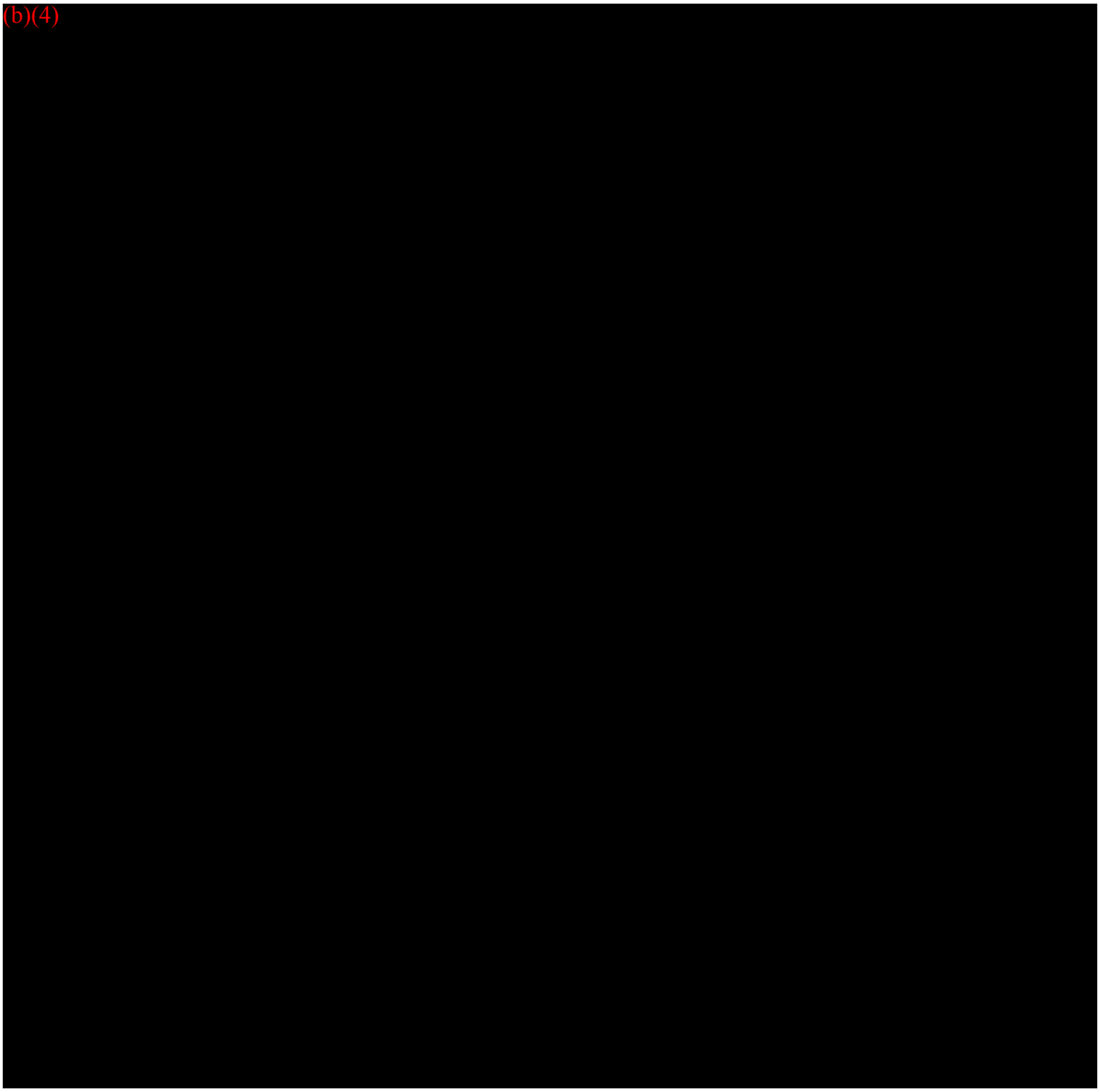
Figure 6: Software Architecture

(b)(4)



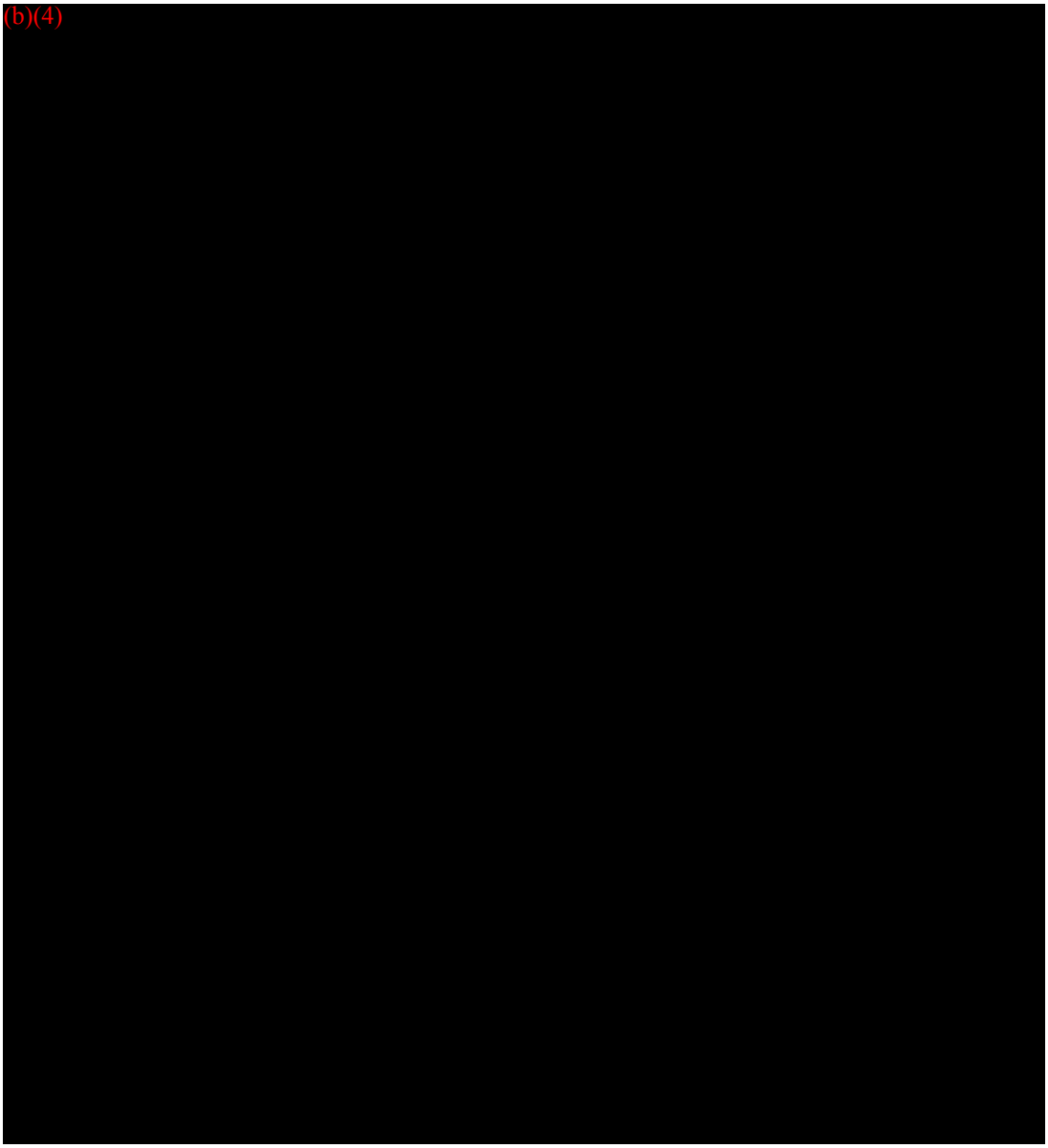
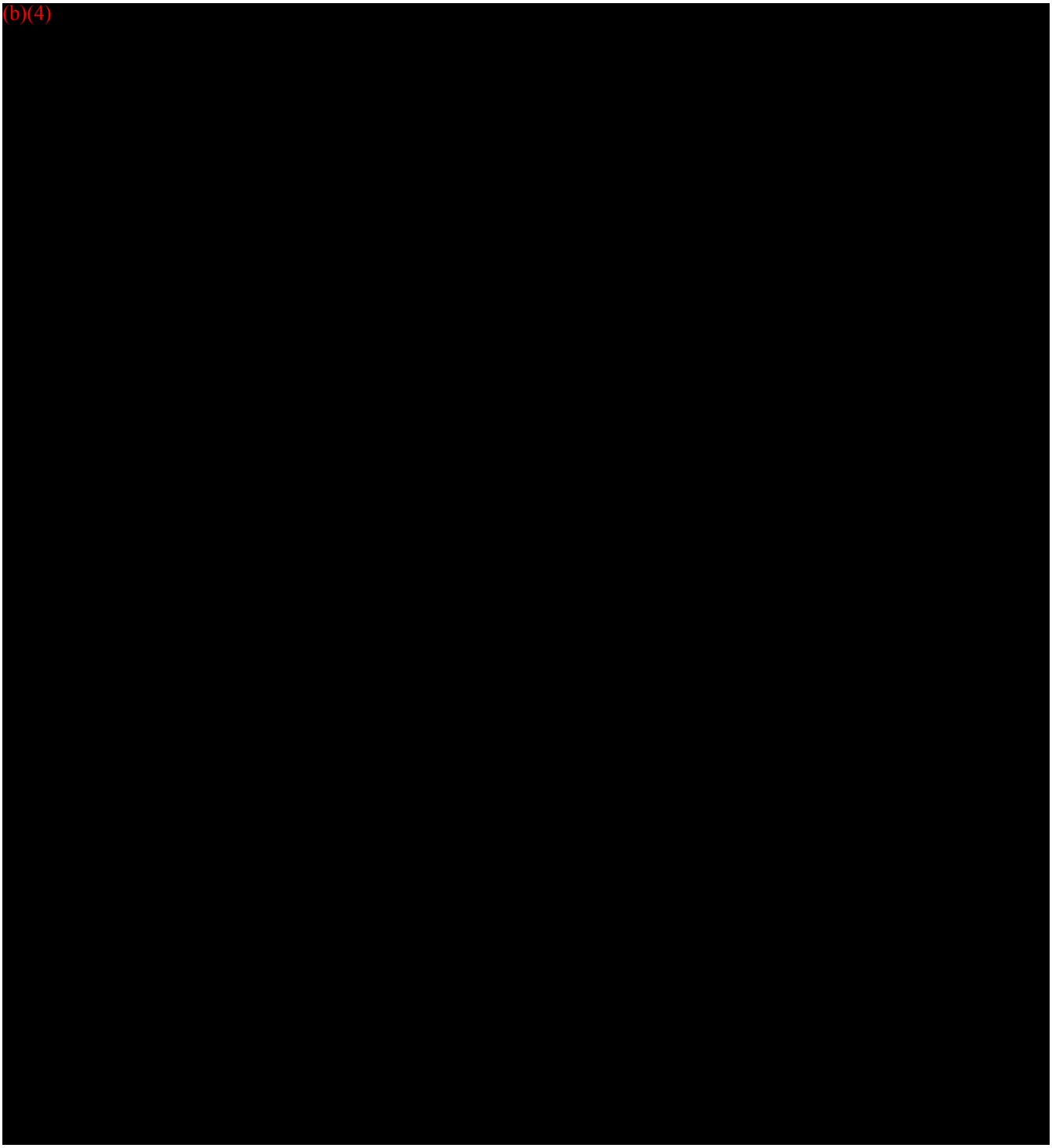


Figure 8: Flow Diagram of InfraRed Thermographic System (IRTS)

(b)(4)



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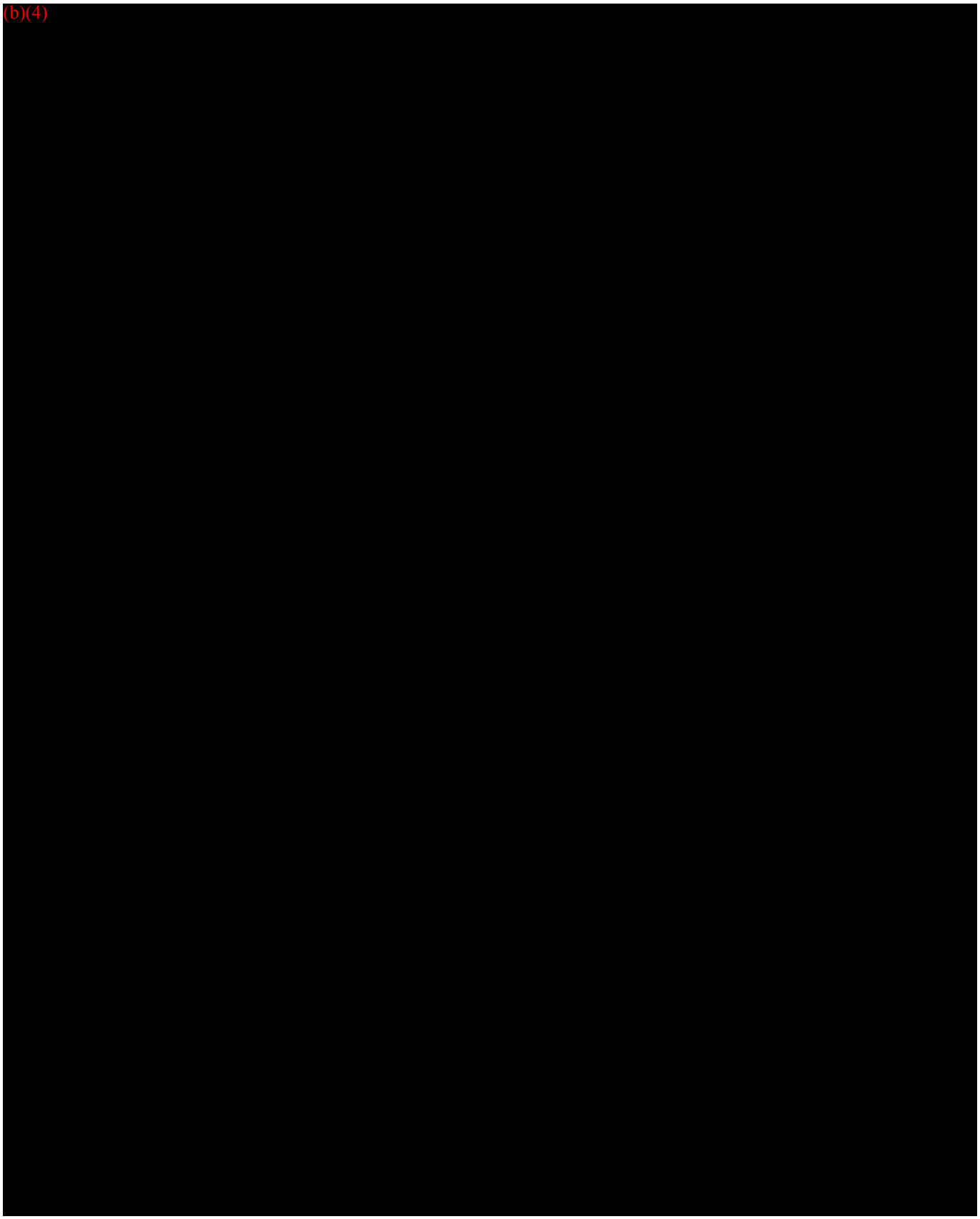


SECTION 17: ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY

Purpose

The purpose of this testing was to demonstrate that the InfraRed Thermographic System (IRTS) meets the requirements for electrical safety and electromagnetic compatibility.

Electrical safety testing was performed in accordance with:

AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Appendix XVI includes the report for testing in accordance with the standard.

Electromagnetic compatibility Testing was performed in accordance with:

IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (3rd Edition).

Appendix XVII includes the protocol and certificate of EMI/EMC Compliance for testing in accordance with the standard.

This testing provides assurance that the InfraRed Thermographic System (IRTS) complies with applicable standards for electrical safety and electromagnetic compatibility and is substantially equivalent.

See reports in Appendix XVI and Appendix XVII.

SECTION 18: PERFORMANCE TESTING BENCH

18.1 InfraRed Thermographic System (IRTS) Bench and Safety Testing

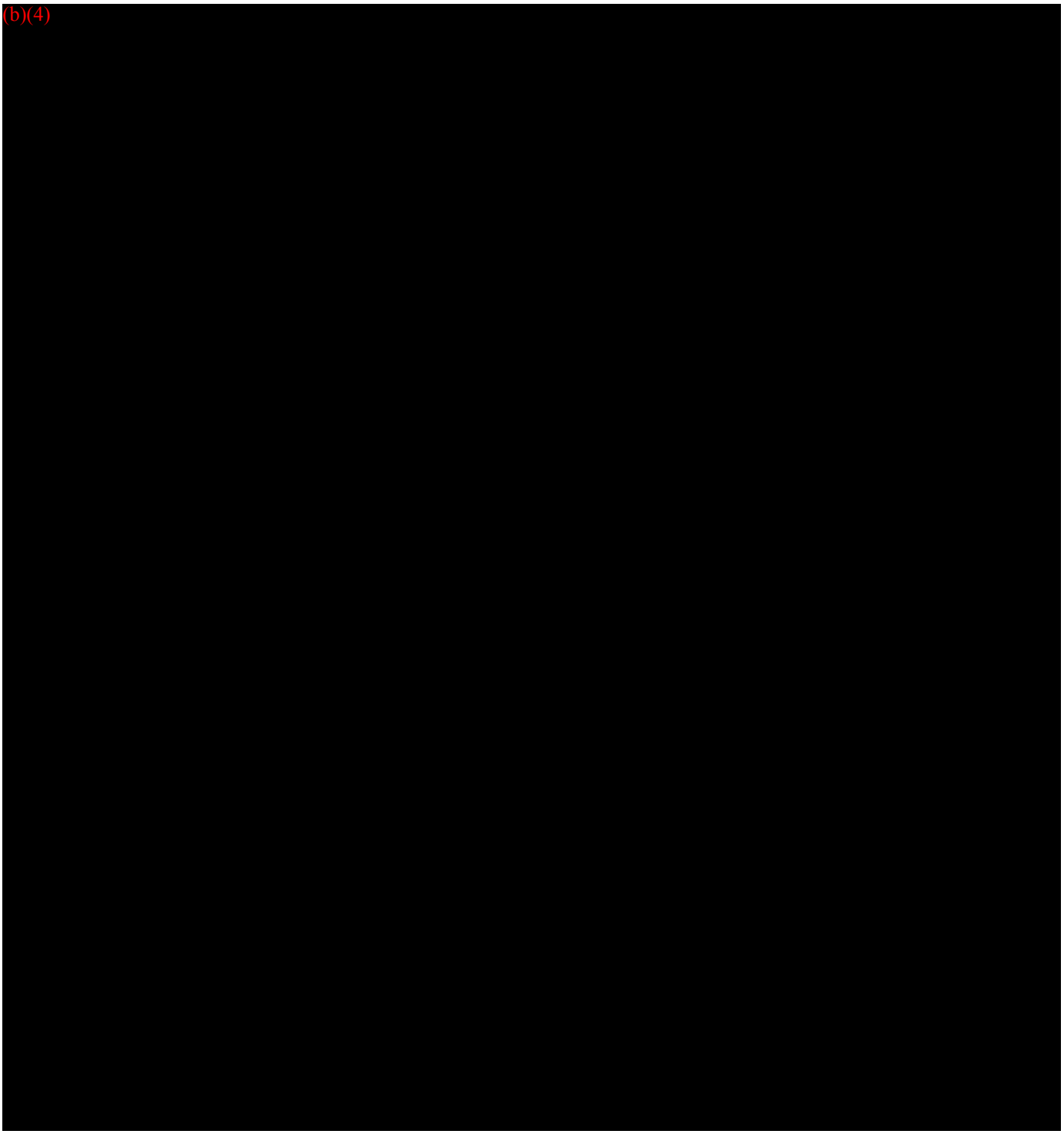
This section of the 510(k) summarizes the results of performance and safety testing of the IRTS. All testing was conducted on finished devices.

The following sections provide a synopsis of the test methods and results for bench testing. Test reports are provided in Appendix as noted in the following table:

Section for synopsis	Name	Appendix for full report
Section 18.2	Accuracy per 80601-2-56	X
Section 18.3	Response Time per 80601-2-56	XI
Section 18.4	Mechanical Testing	XII
Section 18.5	Simulated Use Test	XIII
Section 18.6	Thermographic Accuracy Test	XIV

18.2 Accuracy Testing: *See Appendix X for full report.*

(b)(4)



Continued - Section 18.2 Accuracy Testing

(b)(4)

18.3 Response Time *See Appendix XI for full report.*

(b)(4)

[redacted]

Continued - Section 18.3 Response Time

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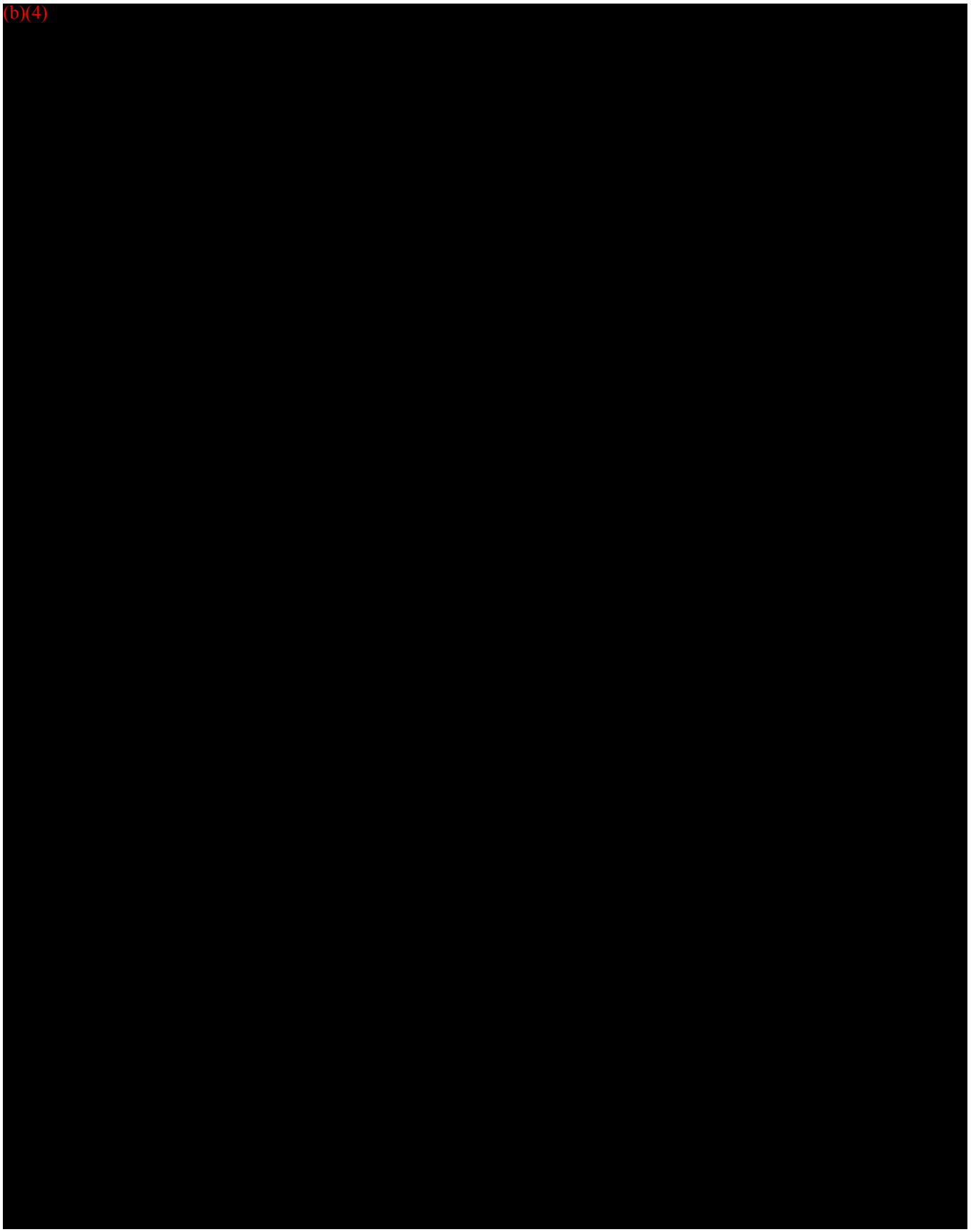
18.4 Mechanical Testing *See Appendix XII for full report.*

(b)(4)



18.5 Simulated Use Test *See Appendix XIII for full report.*

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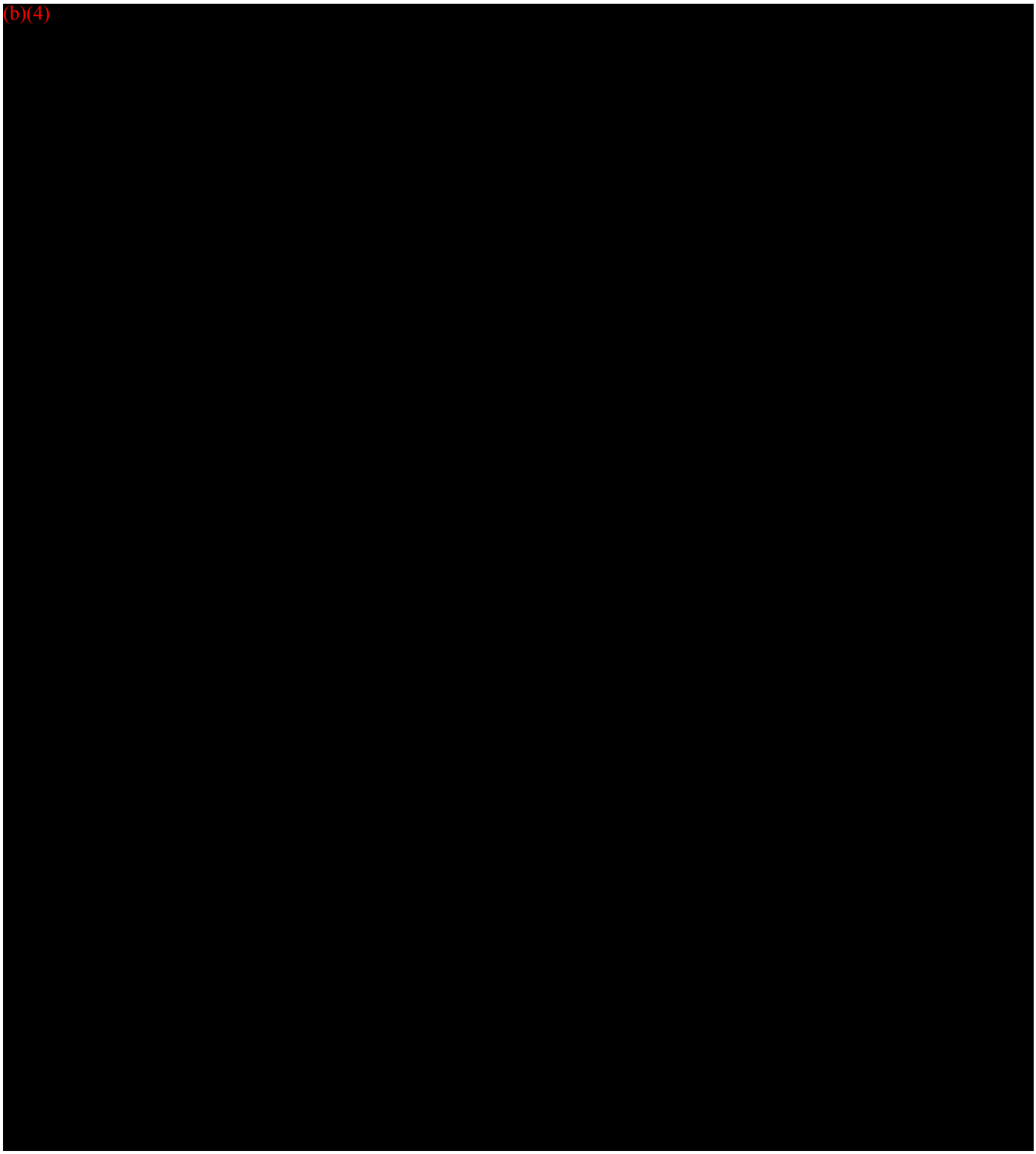

Continued - Section 18.5 Simulated Use Test

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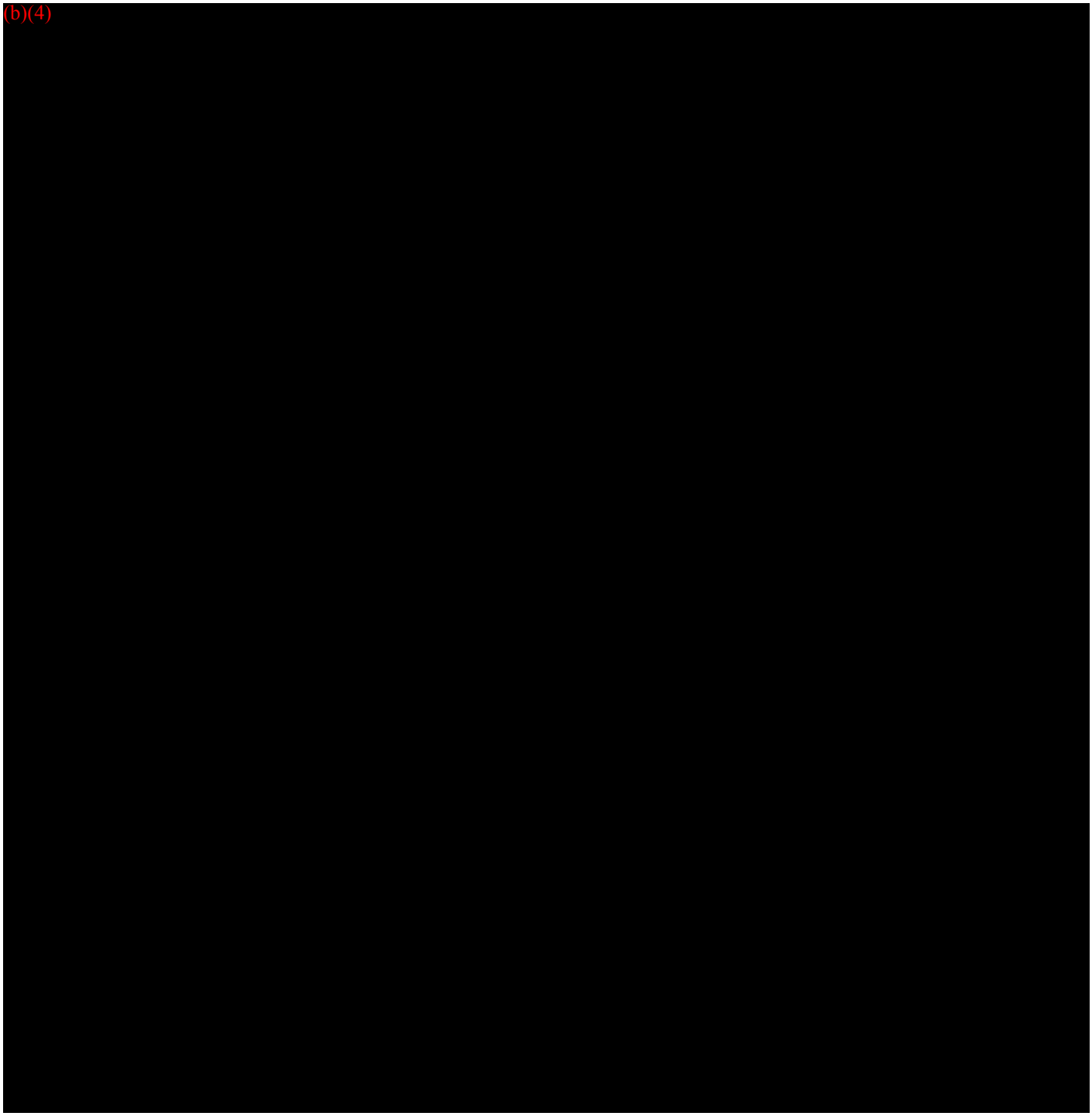

18.6 Thermographic Accuracy Test *See Appendix XIV for full report.*

(b)(4)

[redacted]

SECTION 19: PERFORMANCE TESTING ANIMAL

No animal testing was performed.

SECTION 20: PERFORMANCE TESTING CLINICAL

No clinical testing was performed.

APPENDIX I: STANDARDS FORMS F-3654

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3: 2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 80601-2-56:2009 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009(E) Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010(E) Biological evaluation of medical Devices - Part 10: Tests for irritation and skin sensitization
- ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes
- ISO 14791:2007 Application of risk management to medical devices

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI ES60601-1:2005/(R)2012 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]?	☒	☐
FDA Recognition number [3]	#19-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI / ANSI ES60601-1:2005/(R)2012 Medical electrical equipment -- part 1: general requirements for basic safety and essential performance

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Not applicable per page 1 question 4 (a Summary Report is included)	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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

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

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

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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FORM FDA 3654 (4/14) Page 2 of 2 Add page

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2 Edition 3: 2007-03, Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-1	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☒

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-2 Edition 3: 2007-03, Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	Not applicable per page 1 question 4 (a Summary Report is included)	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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

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

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 80601-2-56 First Edition 2009-10-01, Medical electrical equipment - Part 2-56: Particular requirements for basic safety and esst

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#6-232	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: _____

[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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 80601-2-56 First Edition 2009-10-01, Medical electrical equipment - Part 2-56: Particular requirements for basic safety and esst

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
201.102	Clinical Accuracy Validation	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Clinical investigations were not used to determine clinical accuracy of the device.

DESCRIPTION
N/A

JUSTIFICATION
This section of the standard applies to adjusted mode clinical thermometers. The Securus device is not an adjusted mode thermometer as defined in the standard. The Securus thermometer is a direct mode device.

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
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)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Categorization of medical devices	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Biological evaluation process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Interpretation of biological evaluation data and overall biological safety assess	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5:2009 (R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity. (Biocompatibility)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
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)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 10993-5:2009 (R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity. (Biocompatibility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Sample and control preparation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Cell lines	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Culture medium	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10:2010, biological evaluation of medical devices - part 10: tests for irritation and skin

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
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)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: FDA Bluebook Memorandum G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 10993-10:2010, biological evaluation of medical devices - part 10: tests for irritation and skin

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Irritation tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Delayed hypersensitivity tests	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Key factors in interpretation of test results	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI / ANSI / IEC 62304:2006, medical device software - software life cycle processes. (Software/Informatics)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-32	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidanc

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI / ANSI / IEC 62304:2006, medical device software - software life cycle processes. (Software/Informatics)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Software Development Process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Software Risk Management Process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Software Configuration Management Process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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

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

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 1 hour 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
PRAStaff@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 control number."

FORM FDA 3654 (4/14) Page 2 of 2 Add page

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices. (General I (QS/RM))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance: _____		

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

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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

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

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

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971 Second edition 2007-03-01, medical devices - application of risk management to medical devices. (General I (QS/RM))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	General Requirements	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
4	Risk Analysis	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
6	Risk Control	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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

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FORM FDA 3654 (4/14) Page 2 of 2 Add page

APPENDIX II: BIOCOMPATIBILITY

The following pages include test reports from (b)(4) for the IRTS Probe.

Cytotoxicity report # (b)(4)
Sensitization report # (b)(4) 2
Irritation/Intracutaneous Reactivity report # (b)(4)

Note: (b)(4)
.

(b)(4) Third Party Test Data

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APPENDIX III: PREDICATE LABELING

Texas Infrared, ICI P and S Series IR Camera(s) and the IR Flash Software was reviewed under 510(k) K073581. Labeling could not be obtained.

FIAB ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, was reviewed under 510(k) K123361. Data sheets on following pages.

(b)(4) Third Party Test Data

(b)(4) Third Party Test Data

APPENDIX IV: SOFTWARE RISK ASSESSMENT

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APPENDIX V: SOFTWARE REQUIREMENTS SPECIFICATION

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APPENDIX VI: SOFTWARE DESIGN SPECIFICATION

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APPENDIX VII: SOFTWARE TRACEABILITY ANALYSIS

	Title: IRTS Software Traceability Analysis	(b)(4) [redacted]

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APPENDIX VIII: SOFTWARE VERIFICATION AND VALIDATION REPORT

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APPENDIX IX: DRAWINGS AND SPECIFICATIONS

PATIENT MONITORING UNIT (PMU) SPECIFICATION

CYBERNET
Space Saving Technology

CYBERMED H19
19" Medical Grade All-in-One PC

intel inside CORE i7

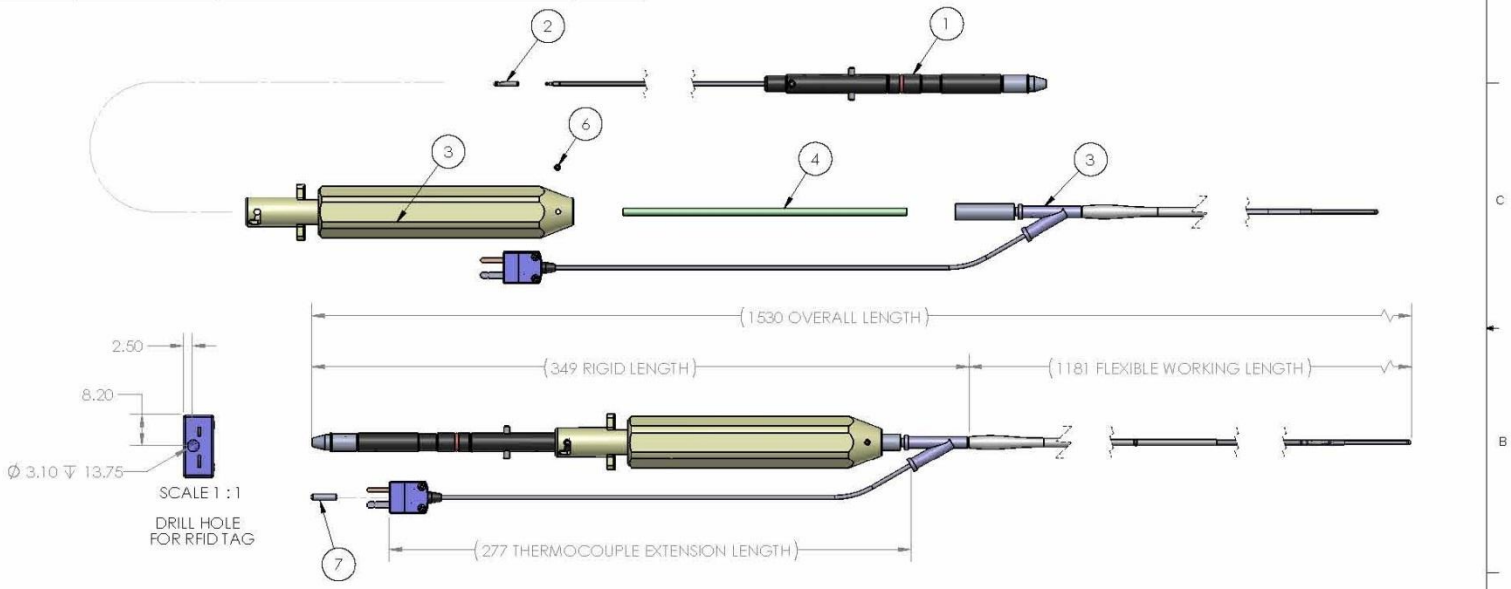
Display	• 19-inch 4:3 TFT LCD (1280x1024)	**Security Lock**	• Security lock slot located on the back of the case
CPU Support	• Intel Core i3, i5 & i7 processors	**Wall Mount**	• Supports 75mm & 100mm VESA mounting holes
I/O Ports	• 2x USB 3.0 Ports, 4x USB 2.0 ports • 1x RS232, option to expand to 5 COM ports • DVI-I Monitor Out Port • HDMI Full 1080p	**HDD Support**	• Integrated Serial ATA controller facilitates high-speed transfers up to 3Gbps for each of the four ports
Chipset	• Intel H61 Express chipset (Sandy Bridge)	**Expansion Slots**	• Two Mini PCI-e (1x Full-Size and 1x Half-Size)
Bios	• AMI Flash BIOS supports ACPI, API, DMI, Plug & Play, and security password. Supports booting from HDD, PXE, LAN, CD-ROM, and ANY USB device. Has BIOS System POST and BIOS setup password protection.	**Audio**	• Realtek ALC892 High Definition Audio enables premium Dolby Digital 5.1 surround sound, 10 channels of enhanced sound quality, and delivers advanced features such as multiple audio streams and jack re-tasking.
Operating System	• Windows 7, Windows 8, Linux	**Weight**	• 18.1 lbs
Video & Graphics	• Intel HD Graphics, Optional NVIDIA GeForce GT630M GPU with 1GB DDR	**Dimensions**	• 17" x 15.8" x 3.2" (L, W, D)
Networking	• Dual Gigabit (Gbe) Fast Ethernet, Realtek RTL 8111E	**Colors**	• White with Antimicrobial Germ Protection
Power Supply	• 135 Watt Medical Grade Adapter 100 ~ 240V AC, 50-60Hz. Supports Output range: DC12V/19V. 5.0A/9.5A Adapters for Energy Star 5.0/UL	**Memory**	• 2 x DDR3 204-pin SO-DIMM sockets, populated up to 8GB Max. Supports PC3-10600 1333MHz SO-DIMM
Environment	• Ambient Temperature: 0°C ~ 50°C (operating)	**Relative Humidity**	• 10% ~ 90% (non-condensing)
Touch Screen	• 5-Wire Resistive Single Touch	**Certifications**	• EN60601-1, FCC CLASS B, CE, UL60950, ES 5.2, RoHS, WEEE, IP64 Front Bezel Waterproof
Wireless	• Intel Centrino 802.11 agn, 2x2, dual band delivers up to 300 Mbps speed, Bluetooth 4.0	**Swivel Base**	• Optional base enables left/right rotation up to 60°. Tilt from -5 to 60°.

Find out more at www.cybernet.us

Global Operations: USA • UK • Taiwan • China
Email: sales@cybernet.us

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	A10726	FINAL PROBE ASSY, ADJUSTABLE	1
2	A10725	DISTAL OPTIC ASSEMBLY, LONG	1
3	P10744	SHEATH HANDLE	1
4	P10720	HANDLE LINER	1
5	A10751	SHEATH ASSEMBLY, LONG	1
6	P10557	PROXIMAL SHEATH SET SCREW, M3 X 0.5	1
7	P10781	RFID TRANSPONDER TAG	1

REVISIONS			
REV.	DESCRIPTION	DATE	APPROVED
01	INITIAL RELEASE	6/10/15	VC



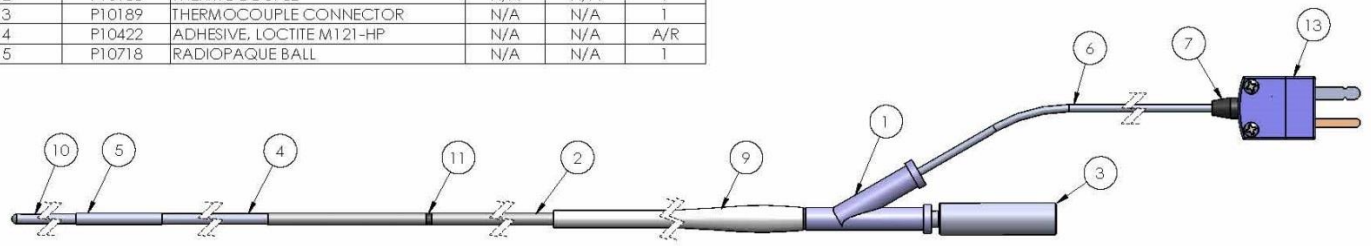
NOTES:
1. DRILL HOLE IN THERMOCOUPLE CONNECTOR FOR RFID TAG.
2. ATTACH DISTAL OPTIC ASSEMBLY TO DISTAL END OF PROBE ASSEMBLY.
3. MEASURE AND CUT LINER SUCH THAT PROBE TIP WILL BE BOTTOMED OUT IN SHEATH.
4. INSERT LINER INTO HANDLE AND INTO THE SHEATH'S ADAPTER BORE.
5. FASTEN SHEATH TO HANDLE USING SET SCREW.
6. INSERT THE PROBE INTO THE ASSEMBLY.
7. TWIST AND LOCK THE PROBE PINS INTO THE L-SHAPED GROOVE.
8. PRESS INSERT RFID TRANSPONDER TAG INTO CONNECTOR.

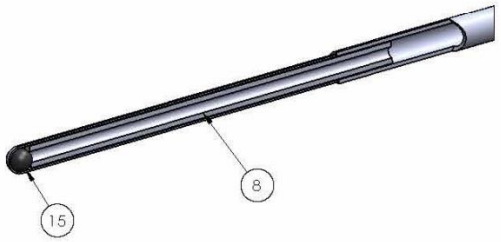
UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS
UNLESS OTHERWISE SPECIFIED TOLERANCES ARE: X ± .5, XX ± .13, X° ± 5°
THIS DRAWING, IN TOTAL OR IN PART, IS PRIVATE AND CONFIDENTIAL AND IS SUPPLIED ONLY ON THE EXPRESS CONDITION THAT IT IS NOT TO BE USED BY, COPIED BY, OR COMMUNICATED TO, ANY OTHER PERSON WITHOUT WRITTEN AUTHORIZATION

DRAWN BY	V.CANGIALOSI
DATE	6/26/156
INTERPRET DIMENSIONS AND TOLERANCES PER ASME Y14.5-2009	
THIRD ANGLE PROJECTION	
SIZE	B
PROJECT CODE	AURORA
DESCRIPTION	FINAL PROBE ASSEMBLY, ADJUSTABLE
PART NO.	A10743
REV	01
SCALE 2:3	SHEET 1 of 1

ITEM NO.	PART NUMBER	DESCRIPTION	NOM. TUBE ID	NOM. TUBE OD	Default/ QTY.
1	P10195	Y-CONNECTOR	N/A	N/A	1
2	P10193	SHEATH SHAFT, DUAL LUMEN, HDPE	2.29mm	3.05mm	1
3	P10729	HANDLE LUER COUPLING	N/A	N/A	1
4 OPTION -01	P10727	SHEATH WINDOW, .010" WALL, LDPE	2.21 mm	2.72mm	1
4 OPTION -02	P10192	SHEATH WINDOW, .007" WALL, LDPE	2.21 mm	2.97mm	1
5	P10191	SHEATH TIP, LLDPE	2.21 mm	2.97mm	1
6	P10414	THERMOCOUPLE WIRE TUBING	1.11mm	1.91mm	1
7	P10457	THERMOCOUPLE LEAD REDUCER	N/A	N/A	1
8	P10455	TIP INSERT, EVA	1.06mm	2.06mm	1
9	P10411	STRAIN RELIEF, Y-CONNECTOR	N/A	N/A	1
10	P10410	SHEATH TIP, LLDPE	2.21 mm	2.57mm	1
11	P10187-03	MARKER BAND	N/A	N/A	1
12	P10188	THERMOCOUPLE	N/A	N/A	1
13	P10189	THERMOCOUPLE CONNECTOR	N/A	N/A	1
14	P10422	ADHESIVE, LOCTITE M121-HP	N/A	N/A	A/R
15	P10718	RADIOPAQUE BALL	N/A	N/A	1

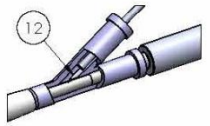
REVISIONS			
REV.	DESCRIPTION	DATE	APPROVED
01	INITIAL RELEASE, BASED ON DESIGN A10190.	3/19/15	VC





TIP OF THERMOCOUPLE UNDER MARKER BAND ITEM 11

THERMOCOUPLE PASSES THRU SKIVED HOLE OF MICRO-LUMEN OF PROXIMAL SHAFT ITEM 2



ASSEMBLY #	ITEM USED	DESCRIPTION
A10751-01	4 OPTION -01	SHEATH ASSEMBLY, LONG, .007" WALL
A10751-02	4 OPTION -02	SHEATH ASSEMBLY, LONG, .010" WALL

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS
UNLESS OTHERWISE SPECIFIED TOLERANCES ARE: X ± .3, XX ± .13, XXX ± .05
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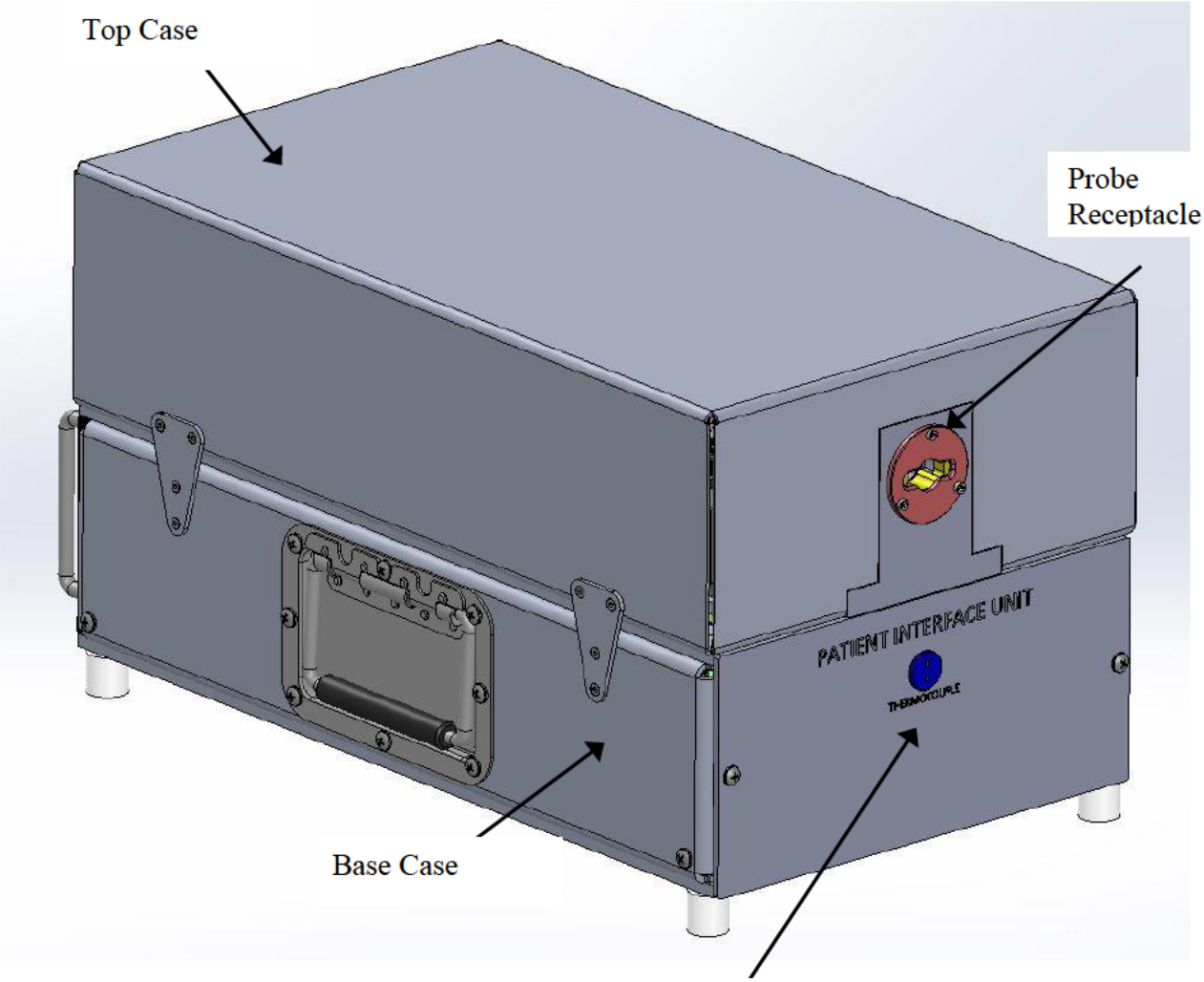
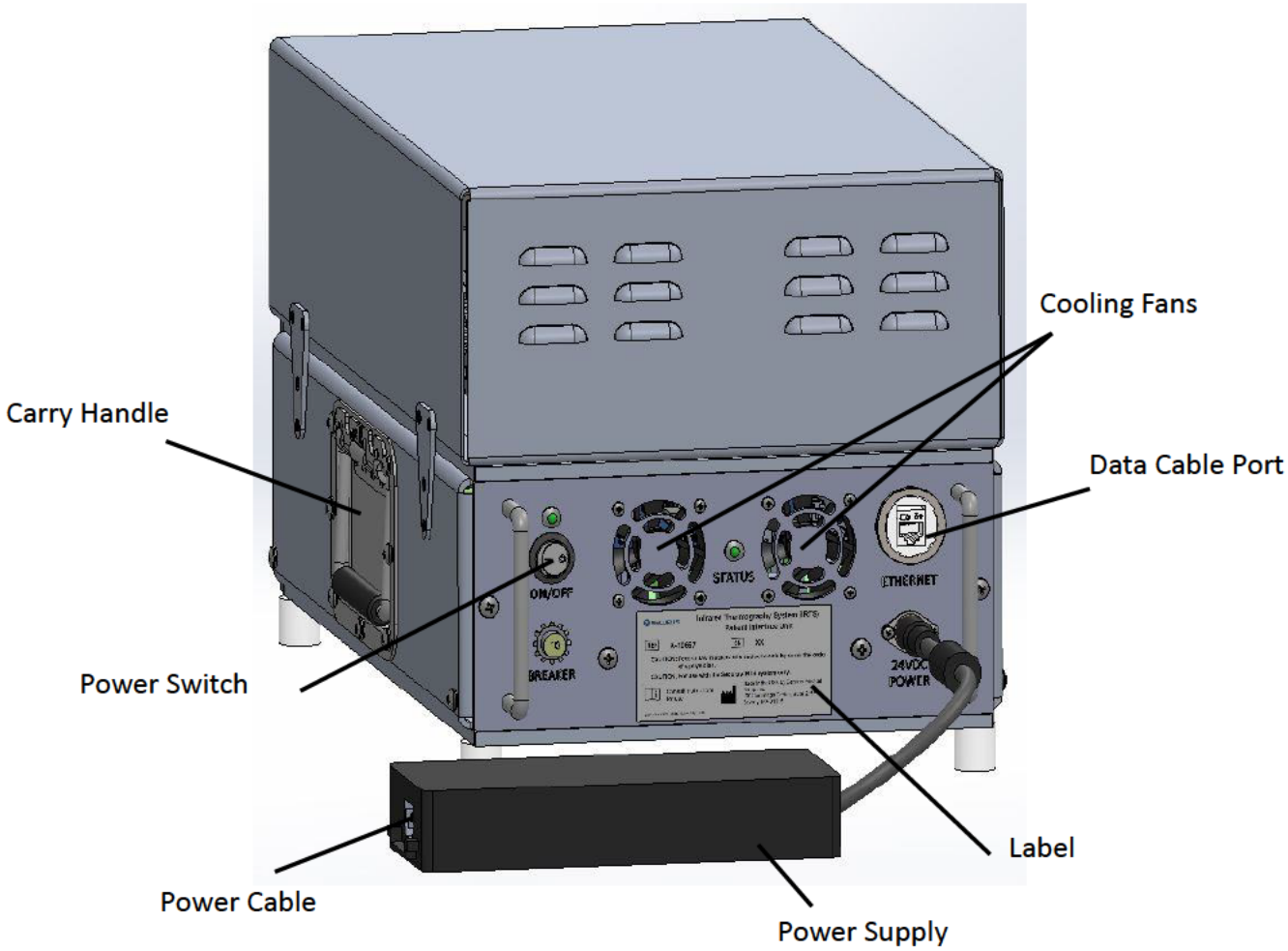
DRAWN BY: V. CANGIALOSI | DATE: 3/19/15
INTERPRET DIMENSIONS AND TOLERANCES PER ASME Y14.5-2009
THIRD ANGLE PROJECTION
SIZE: B | PROJECT CODE: AURORA

DESCRIPTION: SHEATH ASSEMBLY, LONG
PART NO.: A10751-XX | REV: 01
SCALE: 2:1 | SHEET 1 of 4

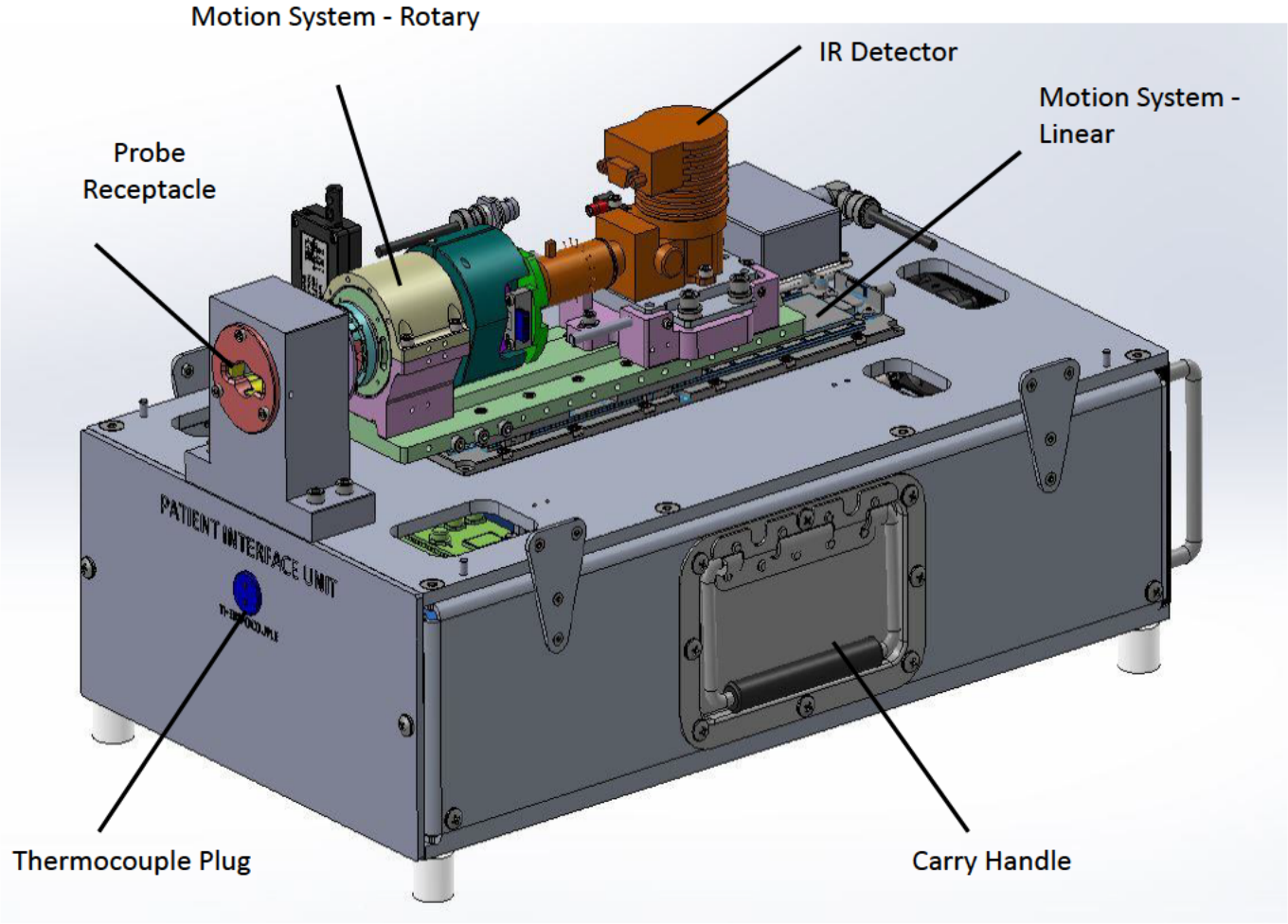
PATIENT INTERFACE UNIT (PIU) DRAWINGS



PIU FRONT VIEW



PIU REAR VIEW



PIU INSIDE VIEW

APPENDIX X: ACCURACY TESTING

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APPENDIX XI: RESPONSE TIME TESTING

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APPENDIX XII: MECHANICAL TESTING

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APPENDIX XIII: SIMULATED USE TEST

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(b)(4)

APPENDIX XIV: THERMOGRAPHIC ACCURACY TEST

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(b)(4)

APPENDIX XV: PROPOSED LABELING

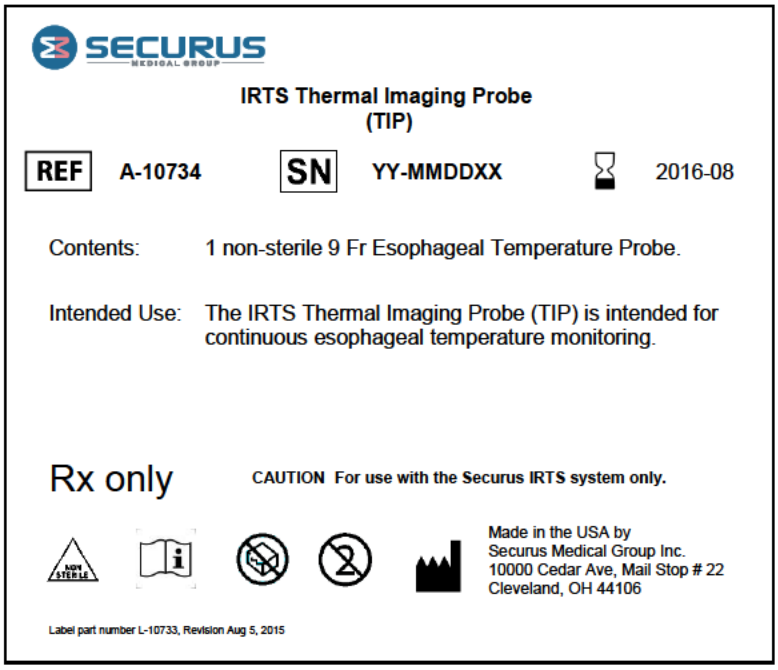


Figure 1: IRTS Probe package label.

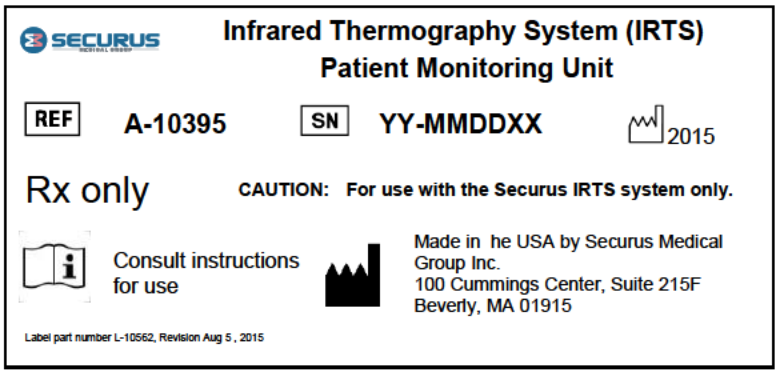


Figure 2: IRTS Patient Monitoring Unit label.

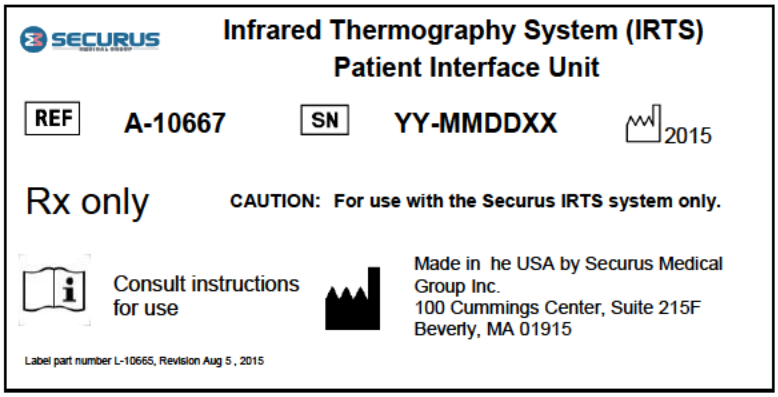


Figure 3: IRTS Patient Interface Unit label.

InfraRed Thermographic System (IRTS)

Instruction Manual

TABLE OF CONTENTS

1. SYSTEM OVERVIEW

The InfraRed Thermographic System (IRTS) consists of three components:

DIAGRAM LETTER	REF #	NAME	DESCRIPTION
A	A-10734	Thermal Imaging Probe (TIP)	Temperature Probe
B	A-10667	Patient Interface Unit (PIU)	Main system control unit
C	A-10395	Patient Monitoring Unit (PMU)	Touchscreen monitor

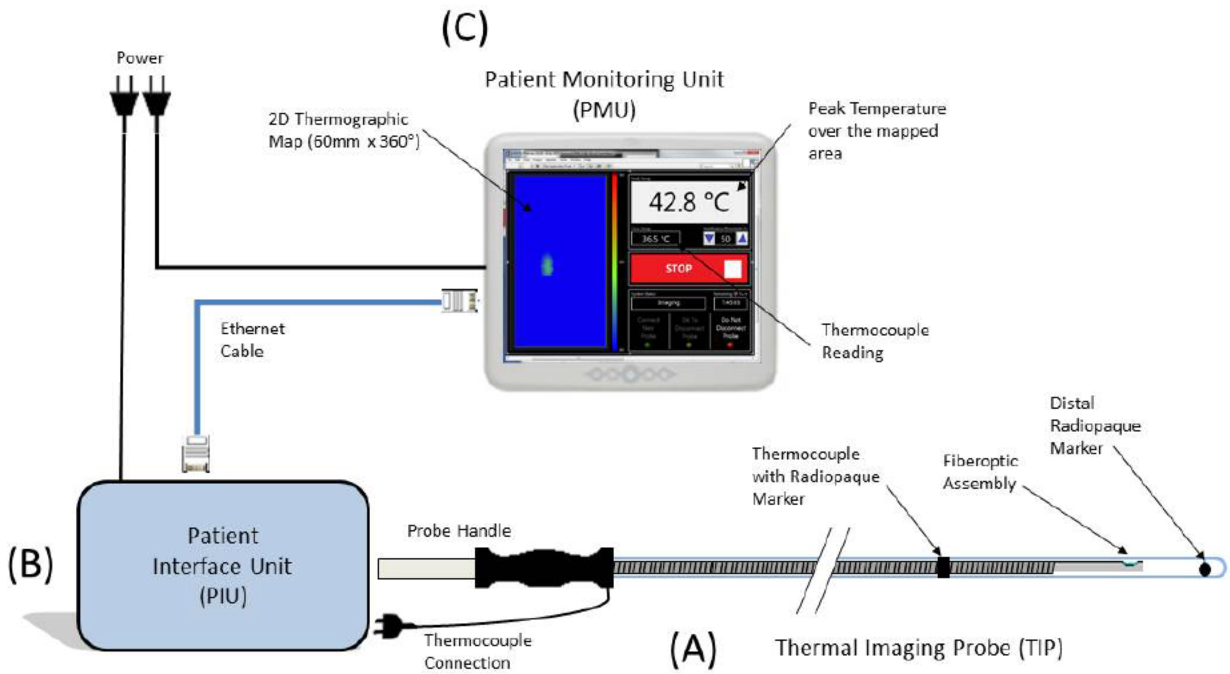


Figure 1: System Overview Diagram

The InfraRed Thermographic System (IRTS) is designed to provide continuous direct mode esophageal temperature monitoring through the use of a standard thermocouple located at the proximal radiopaque marker. In addition, the system incorporates adjunctive infrared thermal imaging technology for quantifying differences in surface temperature changes in the esophagus.

The Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) displays the thermal image and temperature measurements (°C) from the Thermal Imaging Probe (TIP). The thermal image provides a continuous, real-time, non-contact thermal map of a 360° by 60mm long segment of the inner lumen of the esophagus. The thermal image is displayed in a two-dimensional color map. The peak temperature represents the maximum temperature over the scanned area.

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.***

2. INDICATIONS FOR USE

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

3. CONTRAINDICATIONS, WARNINGS and CAUTIONS

CONTRAINDICATIONS

The use of the IRTS is contraindicated for patients who have:

- Symptomatic Esophageal Stricture
- Esophageal Diverticulum
- Esophageal Tumor or Abscess
- Recent Esophageal or Gastric Surgery

WARNINGS

- The Probe is single use only. Do not re-use. Cross-infection to patient may occur and the device may not function properly.
- The Securus IRTS PMU should only be used with Securus IRTS Probes. Use of incompatible components can result in degraded performance or harm.
- Ethernet ports on PMU and PIU components should only be connected to one another.
- Insert Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.
- Do not attempt to reposition Probe while imaging. To reposition always hit “Stop” and wait for the button message “Start Imaging”.
- The Securus IRTS is to be installed and serviced exclusively by Securus technicians. Do not attempt to install, repair, service, or operate the Securus IRTS in any fashion deviating from what is specified in this manual.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- All electrical equipment supporting the patient must be appropriately grounded and must comply with all current regulations and must be of CF type.
- The use of accessories and cables other than those listed above may result in increased EMISSIONS or decreased IMMUNITY of the Securus IRTS.
- The Securus IRTS should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Securus IRTS should be observed to verify normal operation in the configuration in which it will be used.
- Use system only within the indicated operating environment temperature and humidity range. Use outside the specified operating environment may result in inaccurate esophageal temperature readings.

- The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended in Table 4.
- Read and follow all prompts, warnings, errors, and instructions on the IRTS User Interface to ensure proper operation. Failure to follow these instructions can result in degraded performance or harm.

CAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.
- Only physicians trained in esophageal insertion and catheterization procedures should use the IRTS.
- Do not use the IRTS for any purpose other than its intended use.
- Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock.
- Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.
- Do not bend or kink the probe in a sharp angle or a small radius.
- The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
- Avoid touching the proximal tip of the Probe to avoid damaging the Probe.
- The Probe is provided fully assembled. Do not disassemble the Probe. Disassembly will damage the device.
- The system components will not function with equipment from other manufacturers.
- At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.

If you experience any problems with this product please contact Securus at 216-445-4683

4. SET-UP

A Securus Technician will install the system at your facility. The installation will include:

- Initial inspection of the system for shipping damage
- Identifying the proper location and suitable surface for the PMU and PIU in the lab
- Connection and routing of Ethernet cable
- Identification of suitable power sources
- Initializing software, setting local time and date and other relevant software settings
- Confirming system fully operational in the lab environment

Note: The following steps assume that the Securus installation has already occurred.

4.1. Inspect the PMU and PIU for damage. Do not use the system, and contact Securus if damage is evident.

> **CAUTION:** Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock

4.2. Confirm PIU and PMU are placed on a suitable surface in a dry location.

> **CAUTION:** At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.

4.3. Confirm that the correct power supplies and provided Ethernet cable are plugged into the back panel of the PIU and of the PMU. Plug both power supplies into a grounded, 100-240VAC outlet (50/60hz). Only use the Securus issued power supplies for the IRTS system.

> **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Position of equipment should not make it difficult to disconnect the mains plug.

> **CAUTION:** The system components will not function with equipment from other manufacturers.

4.4. Obtain a new Probe. The Instructions for Use (IFU) is supplied with the Probe. Please read and follow the Probe instructions carefully.

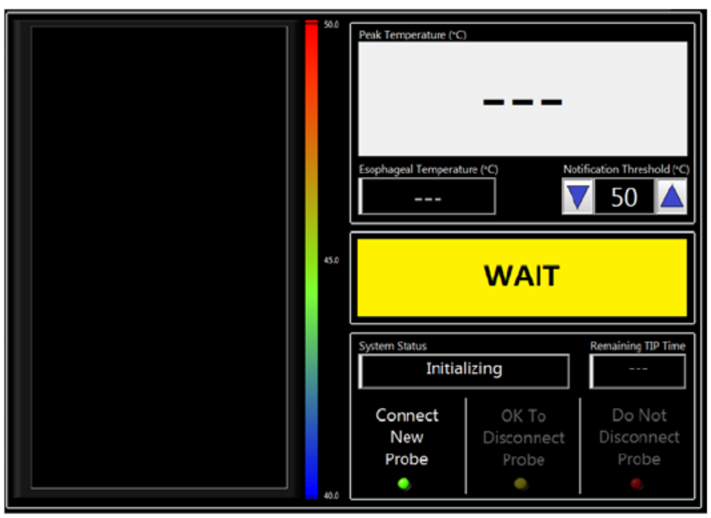
5. SYSTEM OPERATION

5.1. Turn on power to the PMU by pressing the power button located on the lower right-hand side of the unit. The monitor will display the user interface with the following message “WAIT”.

5.2. Turn on power to the PIU by pressing power button on the left side of the back panel. The green power LED will light. The PIU will begin initialization. It requires approximately 5-minutes to complete the initialization process.

5.3. Follow Instructions for Use provided with the Probe. Insert the probe into the patient. Care should be exercised to avoid damaging the probe. Do not kink or clamp Probe at any time.

5.4. The PMU will prompt you when the PIU is ready to accept a new Probe.



5.5. Insert the Probe Connector (1) into the PIU Probe Receptacle (2) and turn it 90 degrees. Plug the Thermocouple Connector (3) into the PIU TC Receptacle (4).

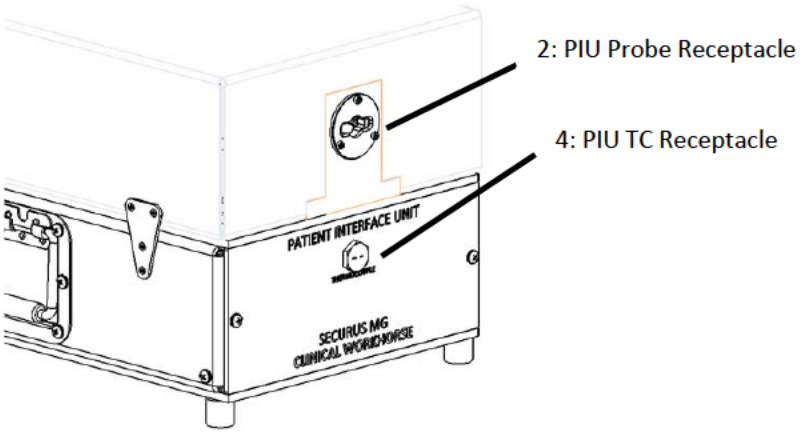


Figure 2: PIU Front

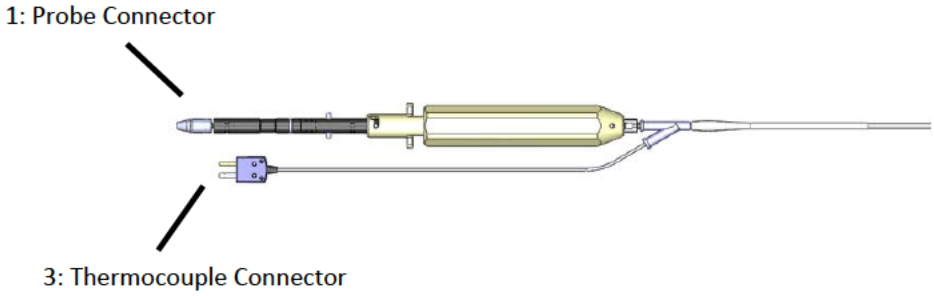


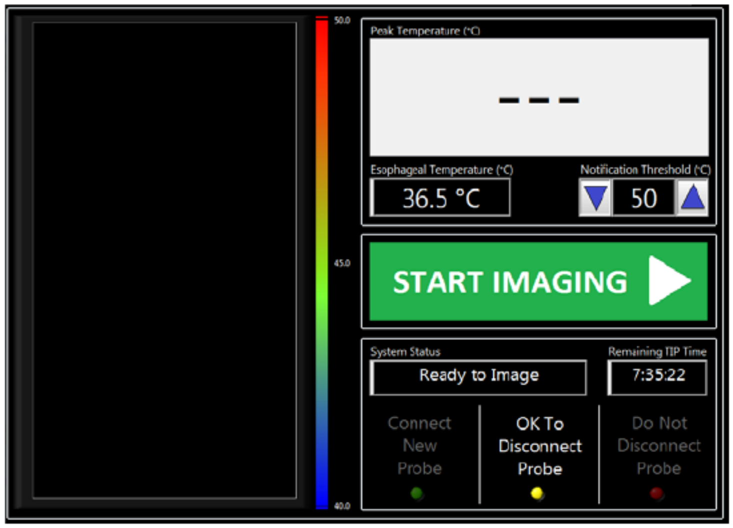
Figure 3: Probe

WARNING: Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging"

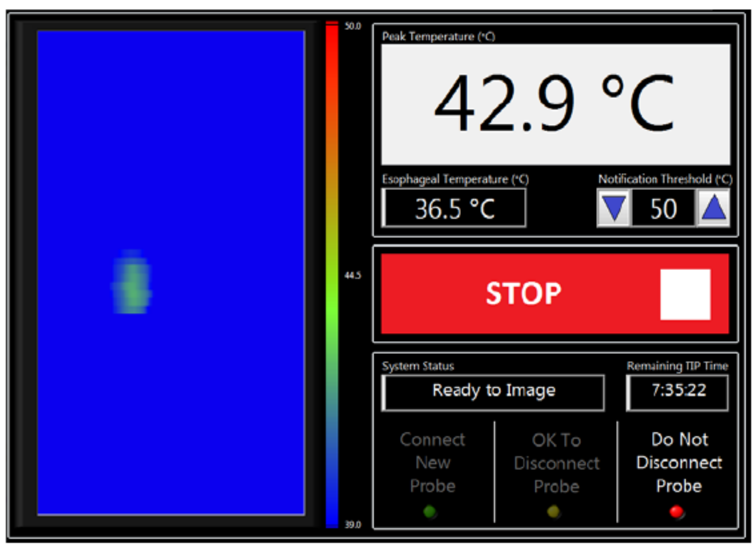
CAUTION: The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.

5.6. To initiate the thermal image and peak temperature Press “Start Imaging” on the user interface.

NOTE: If the peak temperature over the scan area is less than 39°C the Image will be blue and the Peak Temperature will state “< 39°C”.



5.7. Press “Stop” to cease thermal imaging.



5.7.1. System will automatically proceed through Probe docking routine. Press “Stop Docking” to interrupt this process.

5.7.2. When probe is docked, press “Start Imaging” to begin imaging again.

5.8. If the procedure is finished, ensure the status light reads “OK to Disconnect Probe”.

5.9. Remove the probe from the patient.

5.10. Remove the Probe from the PIU by first unplugging the thermocouple. Then turn the handle 90 degrees counter clockwise, remove, and discard.

5.11. Power down the PIU and the PMU. Turn off power to the PMU by pressing the power button located on the lower right-hand side of the unit.

6. ADDITIONAL INFORMATION

6.1. To set a notification temperature, press the (▲) or (▼) key under "Notification Threshold" until you reach the desired value. If the peak temperature is equal to or above this number, an audible and visual notification will sound.

6.1.1. Temporarily disable notification by tapping the "Peak Temperature" indicator. To re-enable notification tap outside the Peak Temperature box.

6.2. Pressing "Stop" or "Stop Docking" will immediately cease all PIU action. If on-screen prompts appear, follow them to continue.

6.3. The Probe is a single use device. Probes have a limited lifetime, which is measured and tracked in the software. Once a probe has reached its defined life it should be discarded. The user interface will inform the user when one hour of useful life remains, and again when a Probe change is necessary.

CAUTION: Do not attempt to operate the Probe beyond its intended service life.

6.4. Initialization is the default status for the system when it is waiting or performing internal status checks. In many cases the system will complete its internal processes and proceed out of Initialization status when ready.

6.5. User Interface States

Button Text	System Status Text	Meaning
Wait	Initializing	When "Core Temp" reads "---" the system is undergoing start-up procedure. Insert a probe when instructed by the User Interface.
		When "Core Temp" reads a numeric value and "Peak Temp" reads "---", probe has been engaged, but system is still initializing.
Play	Ready to Image	System is ready to begin Imaging Session.
Stop	Preparing to Image	System is executing Pre-Imaging routine.
Stop	Imaging	System is Imaging.
Stop Docking	Docking	System is docking probe.
ERROR	TIP Expired	Probe has reached the end of its expected lifespan.
ERROR	ERROR	System has detected an error. Follow additional warnings and instructions on the user interface.

6.6. Cleaning: The PIU and PMU may be cleaned by wiping with a disinfectant soap solution. Suitable disinfectants include bleach or hydrogen peroxide based soap solutions such as Clorox Healthcare Bleach Germicidal Cleaner or Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant. Disinfectants should be applied by wiping or spraying onto the surface and should be allowed to stand wet for a minimum of 1 minute. Wipe with a clean, damp cloth. Allow to air dry. Other suitable cleaners approved by your institution may be used on the PUI and PMU.

The PIU and PMU are not designed for immersion or machine washing techniques. Immersion will damage the electromechanical elements inside of the case.

6.7. Maintenance or Calibration: System cannot be maintained or calibrated by the user. System should be returned to Securus for service after one calendar year of use.

7. SPECIFICATIONS

System	
Esophageal Temperature Accuracy (Thermocouple)	± 0.3°C
Esophageal Temperature Range (Thermocouple)	25°C - 45°C
Transient Response Time of Thermocouple for a 2°C temperature change	2 seconds for both heating and cooling from a reference water bath to a water bath with a 2°C temperature differential
Thermal Sensitivity	0.1°C within temp range
Infrared Temperature Accuracy	± 2°C
Infrared Temperature Range	39°C - 60°C
Ethernet cable length	3 meters (10 feet)
Storage and transportation environmental	Temperature Range -15°C to 40°C (5°F to 104°F) Relative Humidity 10 to 93% Air Pressure 500 to 1060 hPa (15 to 31 in. Hg)
Operating environmental	Temperature Range 15°C to 35°C (59°F to 95°F) Relative Humidity 25 to 85% Air Pressure 700 to 1060 hPa (21 to 31 in. Hg)
Disposal	Dispose of in compliance with all applicable local, state, federal laws and regulations. PIU and PMU should be returned to Securus at end of life.
Patient Monitoring Unit	
Size	43cm x 40cm x 81cm (17" x 15.8" x 3.2")
Weight	8.2kg (18.1 lbs)
AC DC Power Supply	12/19.5 VDC 135W
Patient Interface Unit	
Size	49cm x 28cm x 28cm (19" x 11" x 11")
Weight	18kg (39 lbs)
AC DC Power Supply	24 VDC 250W
Probe	
Probe length (exclude handle)	118 cm
Probe length overall	153 cm
Standards	
Electrical Safety	Tested in compliance with IEC 60601-1:2005+A1:2012(E) (applicable sections)
	Tested in compliance with IEC 60601-1-2:2007
	Tested in compliance with applicable sections of ISO 80601-2-56
Accuracy Thermocouple	Fully complies with ISO 80601-2-56:2009 requirements (applicable sections)
Type and degree of protection, electrical shock	Type CF, Class I
Degree of protection against ingress of water (IEC 529)	IP2X

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.***

8. ELECTROMAGNETIC COMPATIBILITY (EMC) and ELECTROMAGNETIC SAFETY

8.1. The Securus IRTS has been tested and complies with international Standard IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

8.2. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

8.3. Portable and mobile RF communications equipment can affect Medical electrical equipment performance and safe operation. Portable and mobile RF communications equipment should be separated from the Securus IRTS by at least the minimum separation distances listed in Table 4.

8.4. To maintain the Electromagnetic Compatibility of the Securus IRTS, only the following cables and accessories should be used:

Part Number	Description
A-10734	Temperature Probe
P-10800	L-COM TRD855SCR-10 Ethernet cable – 10.0 ft length
P-10259	Patient Interface Unit (PIU) Power Supply (Includes Power Cord)
P-10838	Patient Monitoring Unit (PMU) Power Supply (Includes Power Cord)

8.5. The following tables are to provide information on the electromagnetic compatibility of the Securus IRTS. If interference is observed or the system is not working correctly, the following information may be useful in correcting the problem. In particular Table 4 provides guidance on the distance that a portable transmitter, communications device, and cellular phones should be kept away from the Securus IRTS to avoid interference or adverse operation of the Securus system.

Table 1- Guidance and manufacturer's declaration – Electromagnetic Emissions		
The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions *CISPR 11*	*Group 1*	*The Securus IRTS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
RF emissions CISPR 11	Class A	The Securus IRTS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 - Guidance and manufacturer's declaration – Electromagnetic Immunity			
The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Securus IRTS requires continued operation during power mains interruptions, it is recommended that the Securus IRTS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 - Guidance and manufacturer's declaration – Electromagnetic Immunity

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Securus IRTS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Securus IRTS is used exceeds the applicable RF compliance level above, the Securus IRTS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Securus IRTS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Recommended separation distances between portable and mobile RF communications equipment and the Securus IRTS			
The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** in meters		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. GENERAL INFORMATION

Manufactured and Distributed By:

Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
216-445-4683

SYMBOLS KEY

REF	Catalog number		Manufacturer
LOT	Lot Number	SN	Serial Number
QTY	Quantity	NON STERILE	Non-Sterile
	Use by - year and month		See accompanying documentation
	Consult instructions for use		Do not use if product is broken, damaged or open
	Do not reuse		Defibrillation – Proof Type CF Applied Part

DEVICE DESCRIPTION

INFRARED THERMOGRAPHIC SYSTEM (IRTS)

The InfraRed Thermographic System (IRTS) is designed to provide continuous esophageal temperature monitoring through the use of a standard thermocouple located at the proximal radiopaque marker. In addition, the system incorporates adjunctive infrared thermal imaging technology for quantifying differences in surface temperature changes in the esophagus.

The Probe contained in this package is a 9 French non-sterile, single-use esophageal catheter designed to be inserted into the esophagus either orally or nasally and positioned under fluoroscopic guidance. The Probe is intended to be used outside the sterile field by clinical professionals familiar in the placement of devices in the esophagus. The Probe is approximately 1.5 meters long with a smooth and flexible outer shaft and soft formable distal tip to aid in insertion. The Probe handle and thermocouple connector connect/plug-in to the Patient Interface Unit (PIU) at the time of the procedure. The Probe utilizes a standard thermocouple for providing continuous body temperature readings from the esophagus. The location of the thermocouple is easily visible under fluoroscopy. See Fig. 1.

The Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) displays the thermal image and temperature measurements (°C) from the Thermal Imaging Probe. The thermal image provides a continuous, real-time, non-contact thermal map of a 360° by 60mm long segment of the inner lumen of the esophagus. The thermal image is displayed in a two-dimensional color map. The peak temperature represents the maximum temperature over the scanned area.

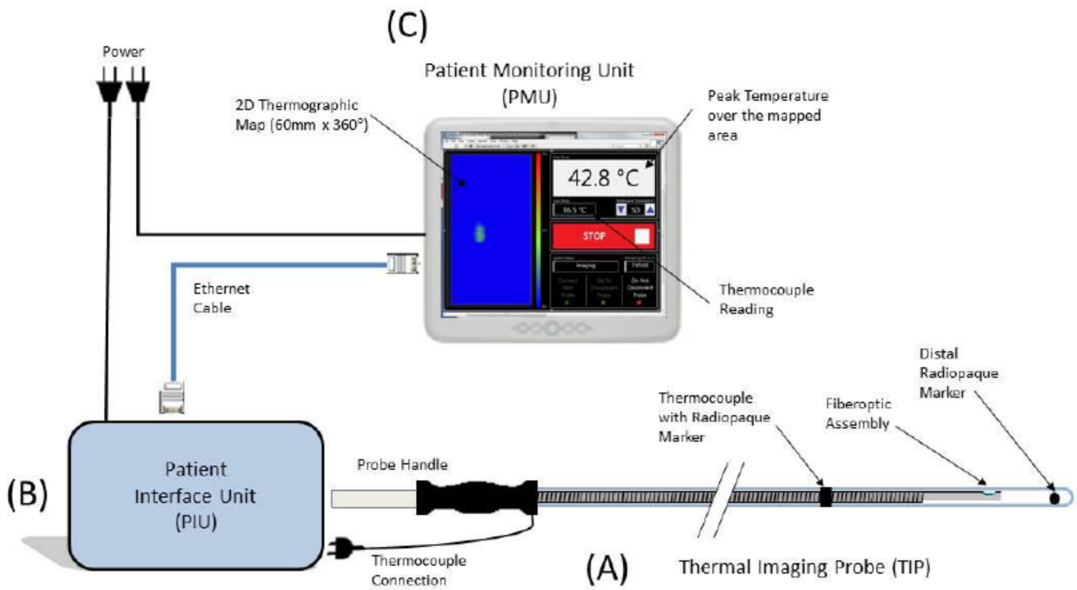


Figure 1: IRTS System Overview Diagram

IRTS SYSTEM COMPONENTS:

DIAGRAM LETTER	REF #	NAME	DESCRIPTION
A	A-10734	TIP	Temperature Probe
B	A-10667	Patient Interface Unit (PIU)	Main system control unit
C	A-10395	Patient Monitoring Unit (PMU)	Touchscreen monitor

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).***

INDICATIONS FOR USE

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

CONTRAINDICATIONS

The use of the IRTS is contraindicated for patients who have:

- Symptomatic Esophageal Stricture
- Esophageal Diverticulum
- Esophageal Tumor or Abscess
- Recent Esophageal or Gastric Surgery

WARNINGS

- The Probe is single use only. Do not re-use. Cross-infection to patient may occur and the device may not function properly.
- Insert Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.
- Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging".
- The Securus IRTS is to be installed and serviced exclusively by Securus technicians. Do not attempt to install, repair, service, or operate the Securus IRTS in any fashion deviating from what is specified in this manual.
- Use system only within the indicated operating environment temperature and humidity range. Use outside the specified operating environment may result in inaccurate esophageal temperature readings.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- All electrical equipment supporting the patient must be appropriately grounded and must comply with all current regulations and must be of CF type.
- The use of accessories and cables other than those listed above may result in increased emissions or decreased immunity of the Securus IRTS.

CAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- See the IRTS Manual provided with Patient Interface Unit and Monitor to operate the system.
- The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.
- Only physicians trained in esophageal insertion and catheterization procedures should use the IRTS.
- Do not use the IRTS for any purpose other than its intended use.
- Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock.
- Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.
- Do not bend or kink the probe in a sharp angle or a small radius.
- The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
- Avoid touching the proximal tip of the Probe to avoid damaging the Probe.
- The Probe is provided fully assembled. Do not disassemble the Probe. Disassembly will damage the device.
- The system components will not function with equipment from other manufacturers.

Instructions for Use
Probe Placement

1. The Probe is provided clean non-sterile. Remove Probe from package and visually inspect it for damage, kinks or broken components. Do not use the Probe if it appears damaged by shipping or handling.

   Always use gloves while handling the probe.

   CAUTION: Avoid touching the proximal tip of the Probe to avoid damaging the Probe.

   CAUTION: The TIP is provided fully assembled. Do not disassemble the TIP. Disassembly will damage the device

   CAUTION: The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.

2. Apply a water-soluble lubricant to the tip of the Probe as desired to aid in insertion.

3. Insert the Probe into the patient (nasal or orally) and position in the esophagus under fluoroscopic X-Ray.

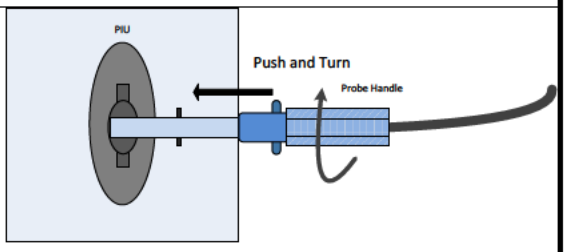
   WARNING: Insert the Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.

   CAUTION: Do not bend or kink the probe in a sharp angle or a small radius.

4. Verify the position of the Probe under fluoroscopic X-Ray. Reposition as required to achieve desired placement.

   WARNING: Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging".

5. Insert the Probe handle into the PIU opening. Firmly push and turn (1/4 turn clockwise) to secure the Probe handle. A proper connection will be accompanied by an audible click as the connector seats in the PIU.



6. Connect the thermocouple temperature connector (blue connector) to the PIU. Ensure that the connector is fully seated.

7. Check the pathway of the Probe to ensure smooth and supported draping. Secure as needed with surgical tape to patient, bed or table to eliminate any movement that might dislodge or otherwise compromise the position of the Probe in the patient. Ensure that the probe is free of kinks or pinch points.

   CAUTION: Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.

   CAUTION: Do not bend the Probe in a sharp angle or a small radius. Excessive bending may damage the Probe.

   WARNING: Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging".

8. Single use device. Discard after use in accordance with institutional rules and regulations.

See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).

If you experience any problems with this product, you should immediately contact Securus at 216-445-4683

MATERIALS (patient contact components)

In Patient Contact	Material
Probe Shaft	Medical grade polyethylene tubing
Thermocouple Marker Band	Platinum Band

SYSTEM SPECIFICATIONS

Characteristic	Specification
Probe OD (patient contact)	9 Fr. (3 mm)
Probe length (exclude handle)	118 cm
Probe length overall	153 cm
Esophageal Temperature Accuracy (Thermocouple) Per ISO 80601-2-56:2009 requirements (applicable sections)	± 0.3°C
Esophageal Temperature Range (Thermocouple)	25°C - 45°C
Transient Response Time of Thermocouple for a 2°C temperature change	2 seconds for both heating and cooling from a reference water bath to a water bath with a 2°C temperature differential
Infrared Temperature Accuracy	± 2°C
Infrared Temperature Range	39°C - 60°C
Thermal Sensitivity	0.1°C within temp range
Operating Environment	Temperature Range 15°C to 35°C (59°F to 95°F) Relative Humidity 25 to 85%

STORAGE & USE

- Store in a cool, dry place and in a manner that protects the integrity of the device and packaging.
- The Probe is intended for single use only.
- Do not use if the package is damaged or opened.
- Do not use the device after the expiration date listed on the package label.
- Contact Customer Service if package has been opened or altered.
- Dispose of in compliance with all applicable local, state federal laws and regulations.

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).***

Manufactured and Distributed By:

Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
216-445-4683

SYMBOLS KEY

Symbol	Meaning	Symbol	Meaning
REF	Catalog number		Manufacturer
LOT	Lot Number		Do not reuse
QTY	Quantity	NON STERILE	Non-Sterile
	Use by - year and month		See accompanying documentation
	Consult instructions for use		Do not use if product is broken, damaged or open
			Defibrillation – Proof Type CF Applied Part

APPENDIX XVI: 60601-1 ELECTRICAL SAFETY TESTING

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APPENDIX XVII: 60601-1-2 EMC TESTING

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APPENDIX XVIII: FDA FORM 3881, INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Infrared Thermographic System (IRTS)

Indications for Use *(Describe)*

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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
PRAStaff@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."

APPENDIX XIX: ACCEPTANCE CHECKLIST FOR TRADITIONAL 510(K)

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: **K** **Date Received by DCC:**

Lead Reviewer:

Branch: **Division:** **Center/Office:**

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

	Yes	No	N/A
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	☐	☐	
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	☐	☐	
Comments:			

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?** **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?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☐
Comments:			
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	☐	☐	
Comments:			
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.	☐	☐	
Comments:			
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm. If no clinical studies have been submitted, mark "N/A."	☐	☐	☐
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.**

- **If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.**
- **If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.**
- **If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.**

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☐	☐	
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☐	☐	
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☐	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☐	☐	
Comments:				

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☐	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
		a.	Device trade/proprietary name	☐	☐		
		b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☐	☐		
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		☐	☐		
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☐	☐		
		Comments:					
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*		☐	☐		
		Comments:					

#	**Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.** ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*	☐		☐	
a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*	☐	☐	☐	
	Comments:				
7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐		☐	
a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators.*	☐	☐	☐	
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 included in the submission. *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)*	☐	☐	☐	
	Comments:				
8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **<u>OR</u>** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514).*	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).					
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☐	☐	☐	
		Comments:					
B.	**Device Description**						
	9.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **<u>OR</u>** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **<u>OR</u>** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☐	☐		
		Comments:					
	11.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☐	☐		
		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.	☐	☐		
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☐	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **<u>OR</u>**	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				**Yes**	**No**	**N/A**	***Page #**
			Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*				
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A"is selected, parts a-c below are omitted from the checklist.*		☐		☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **<u>AND</u>** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☐	☐		
		Comments:					
C.	**Substantial Equivalence Discussion**						
	13.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, de	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).*				
		b.	The identified predicate(s) is consistent throughout the submission (e.g., 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.	☐	☐		
		Comments:					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*					
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☐	☐		
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the*	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.				
		Comments:					
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☐	☐		
		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)	☐	☐		
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☐	☐		
		Comments:					
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		☐	☐		
		Comments:					
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		☐	☐	☐	
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
	19.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.		☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comment:				
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	

	Submission states that the device, and/or accessories, and/or components are: (*one of the below must be checked*)
	☐ Provided sterile, intended to be single-use
	☐ Requires processing during its use-life
	☐ Non-sterile when used (and no processing required)
	☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below)
	    ☐ Sterility status not needed for this device (e.g., software-only device)
	    ☐ Sterility status needed or need unclear
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.
	If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.
	If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."
	The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:
	• *Supplied sterile and requires reprocessing prior to subsequent patient use*
	• *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use*
	• *Reusable medical device (single-user) reprocessed between each use*
	• *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use*
	Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.
					☐		

	Comments:					
	20.	Assessment of the need for cleaning and subsequent disinfection				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				**Yes**	**No**	**N/A**	***Page #**
		or sterilization information.					
		a.	Identification of device, and/or accessories, and/or components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*	☐	☐	☐	
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*	☐	☐	☐	
		c.	Identification of device, and/or accessories, and/or components that are reusable. *Select "N/A" if no part of the device, accessories, or components is reusable.*	☐	☐	☐	
		Comments:					
	21.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*				☐	
		a.	Sterilization method is stated for each component (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☐	
		d.	Sterility Assurance Level (SAL) stated	☐	☐		
		e.	Submission includes description of packaging	☐	☐		
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus	☐	☐	☐	

		Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	*Page #
		amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*				
		Comments:				
	22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*			☐	
		a. Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*	☐	☐	☐	
		b. Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*	☐	☐	☐	
		c. Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*	☐	☐	☐	
		d. Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." *Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐		☐	
		i. If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*	☐	☐	☐	
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	23.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					
F.	**Shelf-Life**						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	24.	Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☐	☐		
		Comments:				
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☐	
		Comments:				
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☐	☐		
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	
	Submission states that there: (*one of the below must be checked*) ☐ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.			☐		

		Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
	If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No." *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*					
	Comments:					
	27.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☐	☐		
		Comments:				
	28.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	☐	☐		
		Comments:				
	29.	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).	☐	☐		
		Comments:				
H.	**Software**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain software/firmware			☐		

		Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	*Page #
	☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*					
	Comments:					
	30.	Submission includes a statement of software level of concern and rationale for the software level of concern	☐	☐		
		Comments:				
	31.	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). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☐	☐		
		Comments:				
I.	**Electrical Safety and EMC**					
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☐ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation			☐		

	Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
	☐ Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*				
	Comments:				
	32. Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **<u>OR</u>** Submission includes electrical safety 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).	☐	☐		
	Comments:				
	EMC: Submission states that the device: (*one of the below must be checked*) ☐ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear		☐		

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*						
	Comments:						
	33.		Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **<u>OR</u>** 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).	☐	☐		
			Comments:				
J.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.*					☐	
	Comments:						
	34.		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. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*	☐	☐	☐	
		a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☐	☐	☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
			Select "N/A" if the submission does not include performance data.				
		Comments:					
	35.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☐	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **<u>OR</u>** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **<u>OR</u>** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		Comments:					

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
	36.		If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A" is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*			☐	
		a.	Legible reprints or a summary of each article.	☐	☐		
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
		Comments:					
	37.		For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A" is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*			☐	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		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 equivalence determination.	☐	☐		
		Comments:					
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	☐ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	38.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
	a.	Precision/reproducibility	☐	☐	☐	
	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.	☐	☐	☐	
	c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
	d.	Analytical specificity	☐	☐	☐	
		Comments:				
	39.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐	☐	☐	
	a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **<u>OR</u>** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
	b.	The submission includes performance data that addresses	☐	☐	☐	

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
			relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **<u>OR</u>** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*				
		Comments:					

<u>Decision:</u> Accept_____ Refuse to Accept_____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

K152402/S1/WD001

December 14, 2015

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

Re: Withdraw Supplement S001 – 510(k) K152402/S001
Securus Medical Group, Inc.
IRTS System

DCC:

We request that supplement K152402/S001 be withdrawn. This supplement was received on 11/17/2015.

We request the ONLY the SUPPLEMENT K152402/S001 be withdrawn. We do not intend to withdraw the entire submission K152402.

Please inform the reviewer, William Burdick, of the receipt of this letter.

Should you have any questions pertaining to these responses please contact me at 978-317-0836. Please send written communications concerning this Notification to:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.
978-317-0836

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K152402/S1

November 11, 2015

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

Re: Supplement 1 to – 510(k) K152402
Securus Medical Group, Inc.
IRTS System

Dear Mr. Burdick:

The attached information is submitted for inclusion in the referenced 510(k) Notice for the Securus IRTS System. The information is being provided in response to questions raised by FDA during the review of the subject Notification on 10/23/15. Please direct this response to William Burdick.

Should you have any questions pertaining to these responses please contact me at 978-317-0836. Please send written communications concerning this Notification to:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.

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Sincerely:

William J. Gorman
Securus Medical Group, Inc.

ADDITIONAL INFORMATION

The following pages contain Additional Information (AI) provided in response to questions raised by FDA during the review of K152402 on October 23, 2015

This response is organized in the sequence of the questions presented in the FDA communication. In each case, the question is repeated (verbatim) in italics, followed by the Securus response. If additional supporting documentation is referenced, it is provided as an Attachment.

AI K152402
Table of Contents

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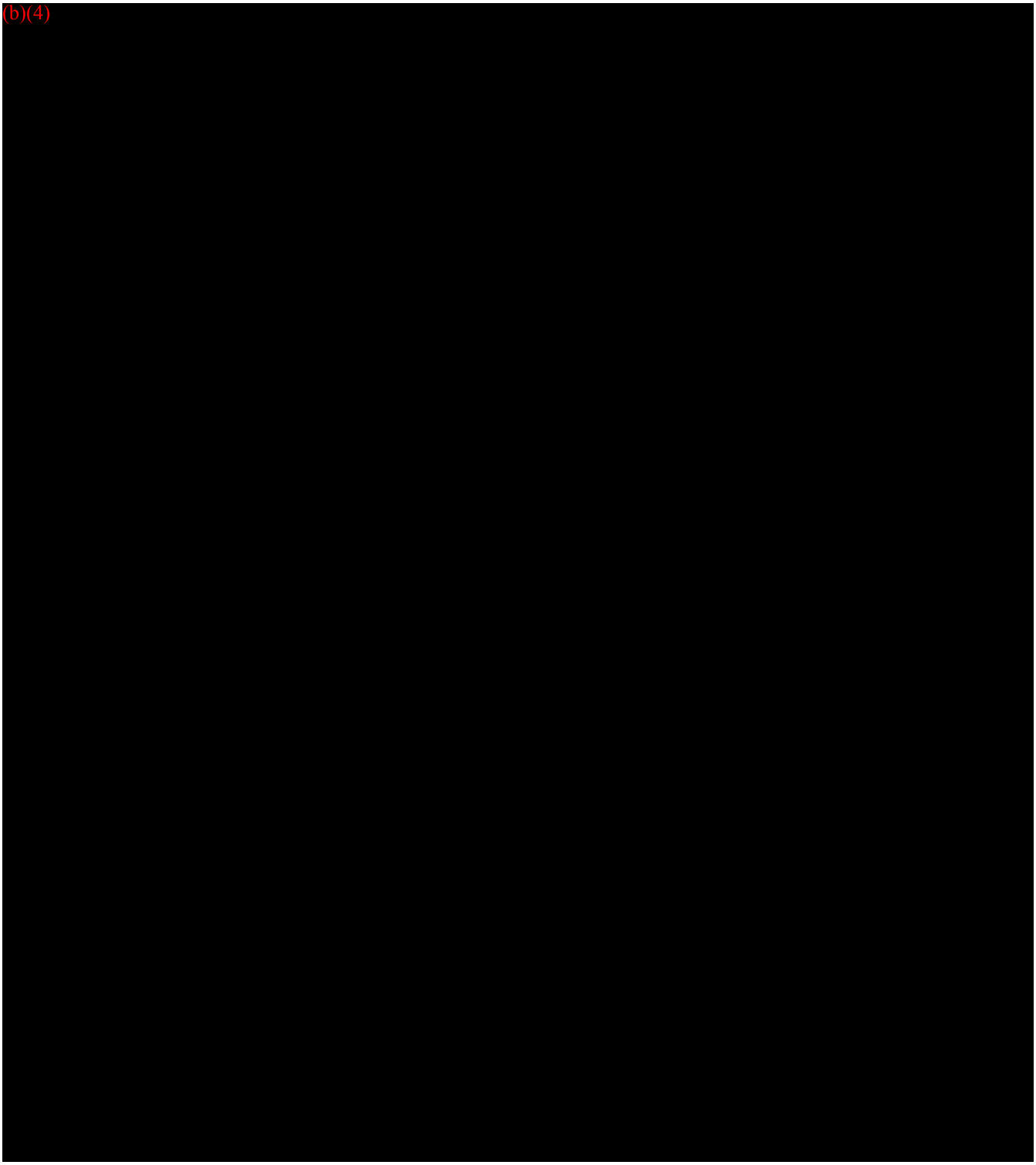

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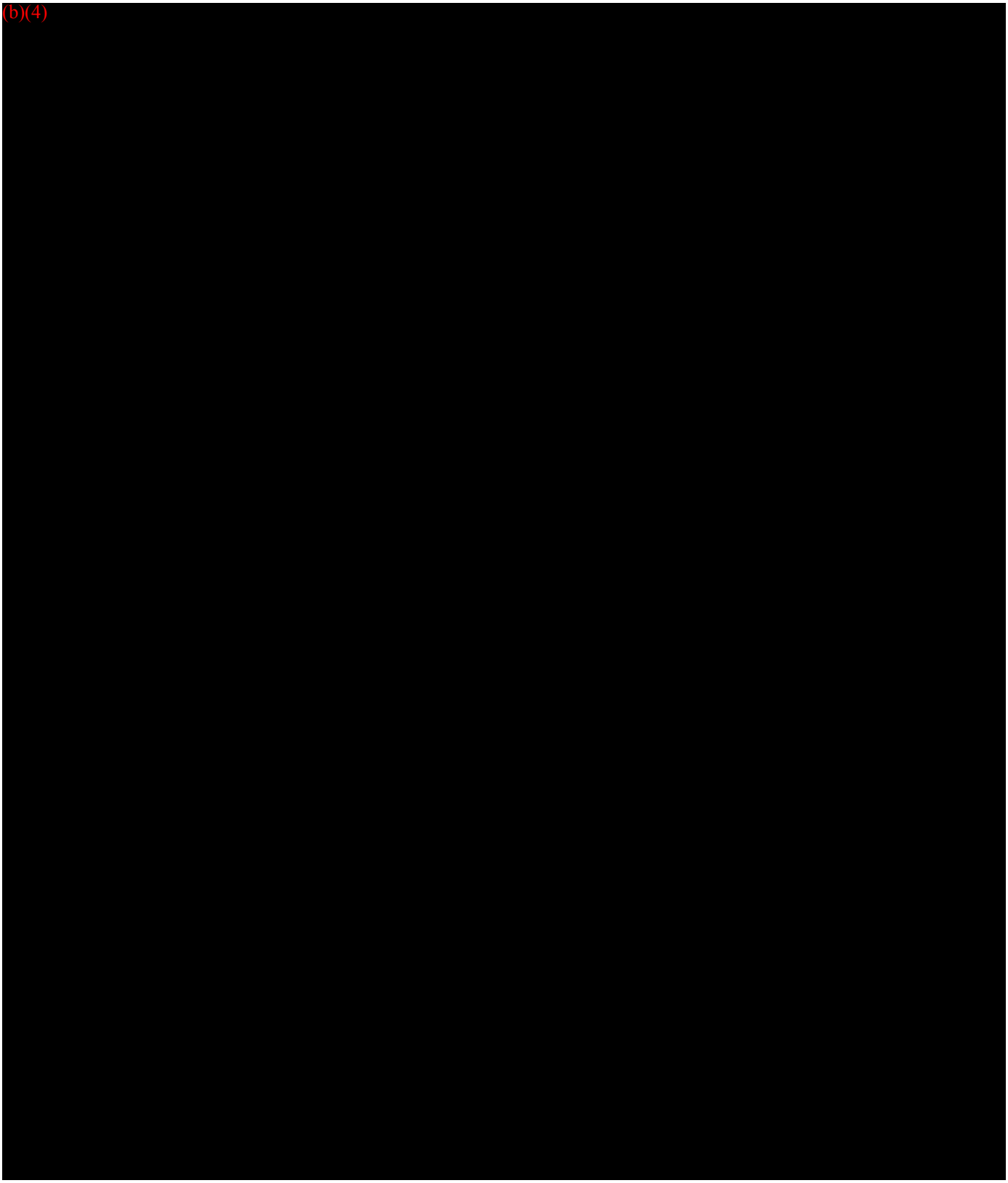

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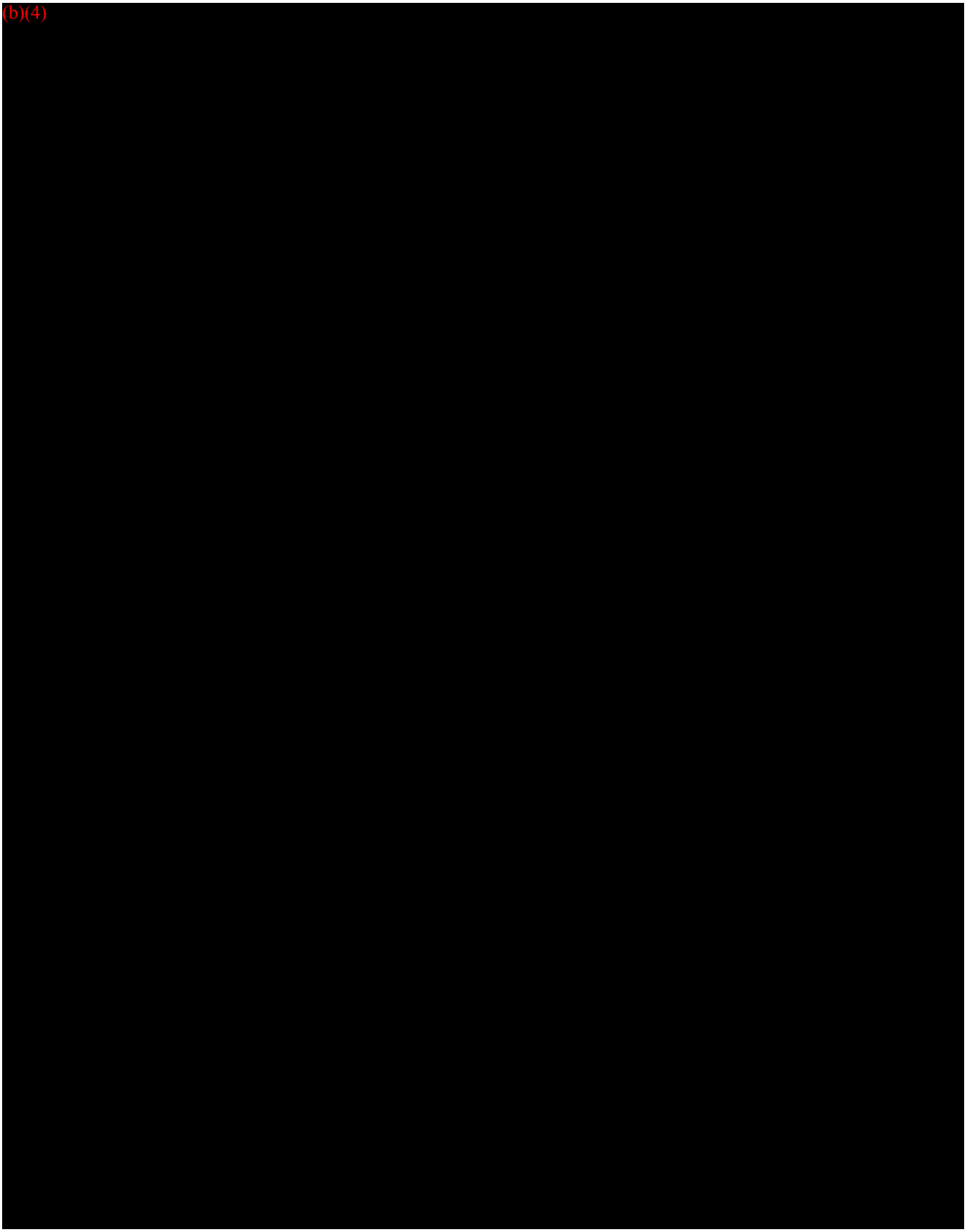

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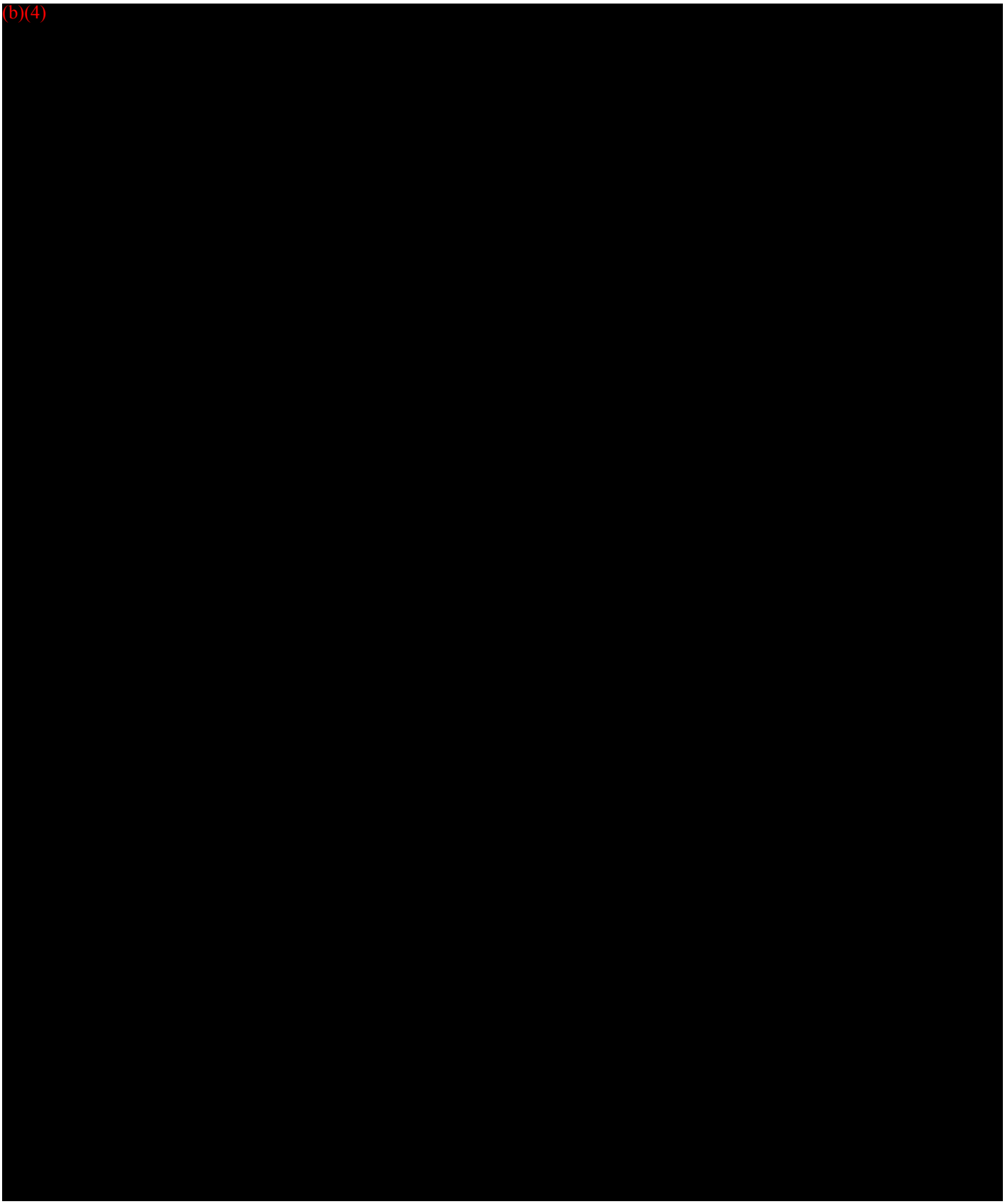

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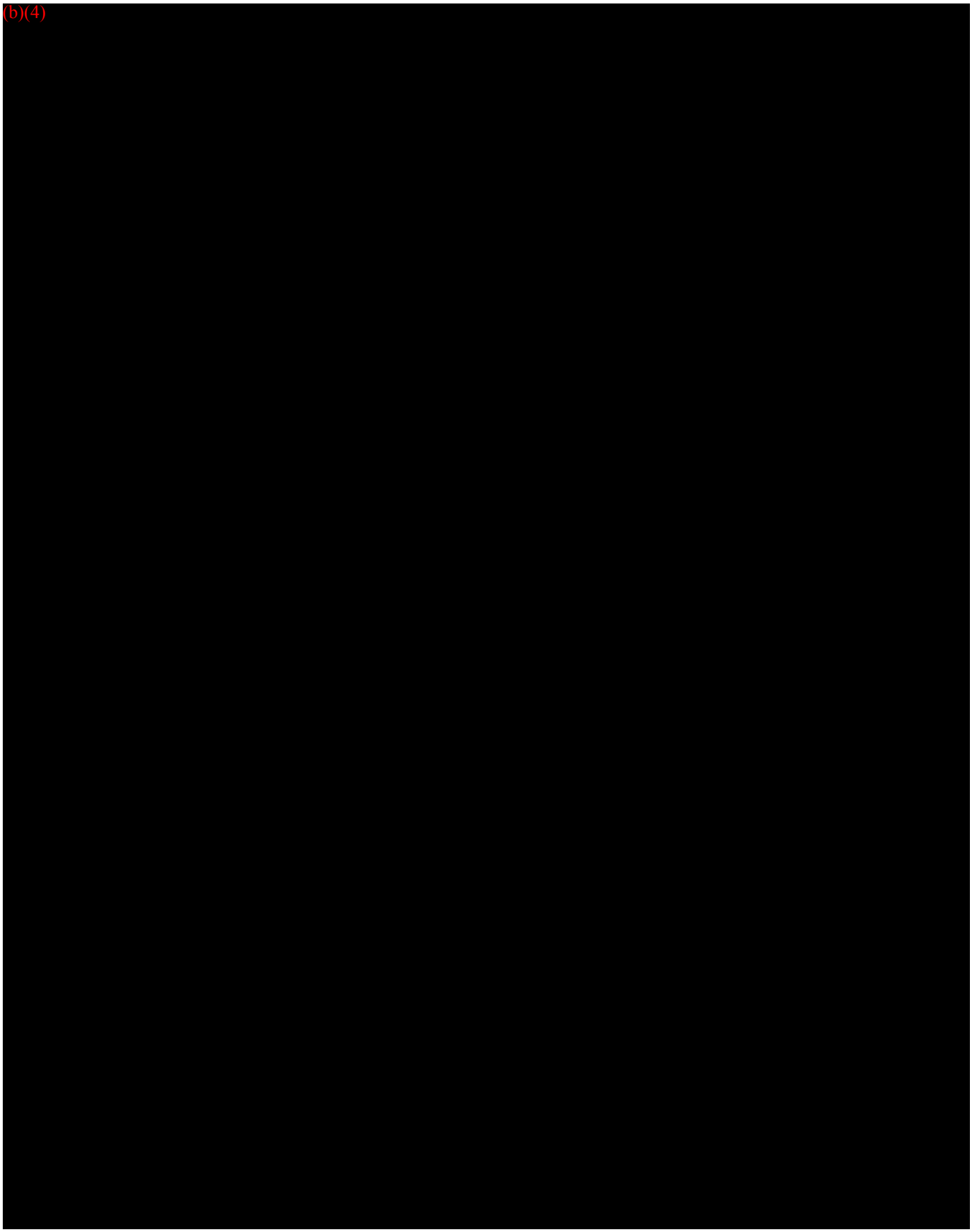

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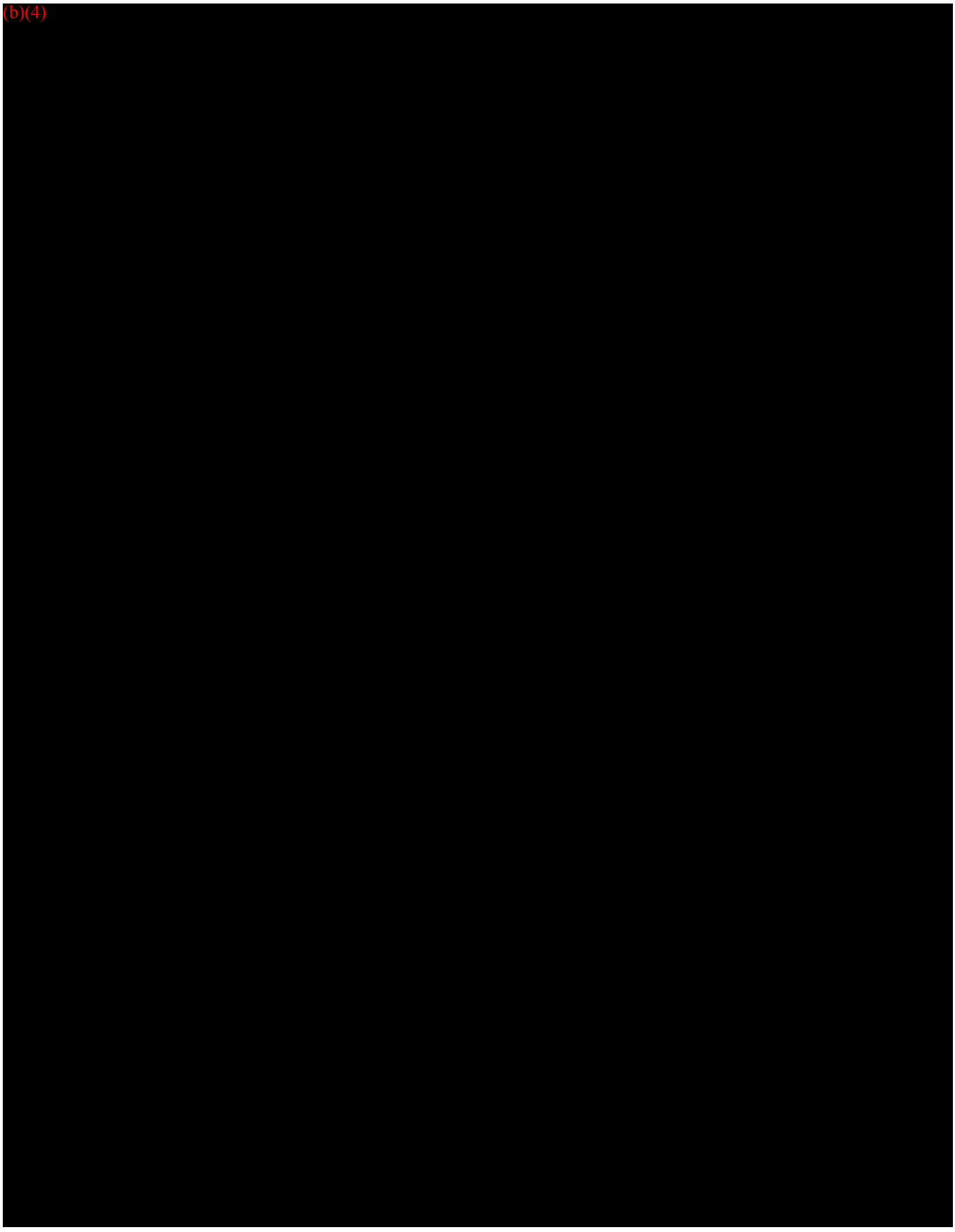

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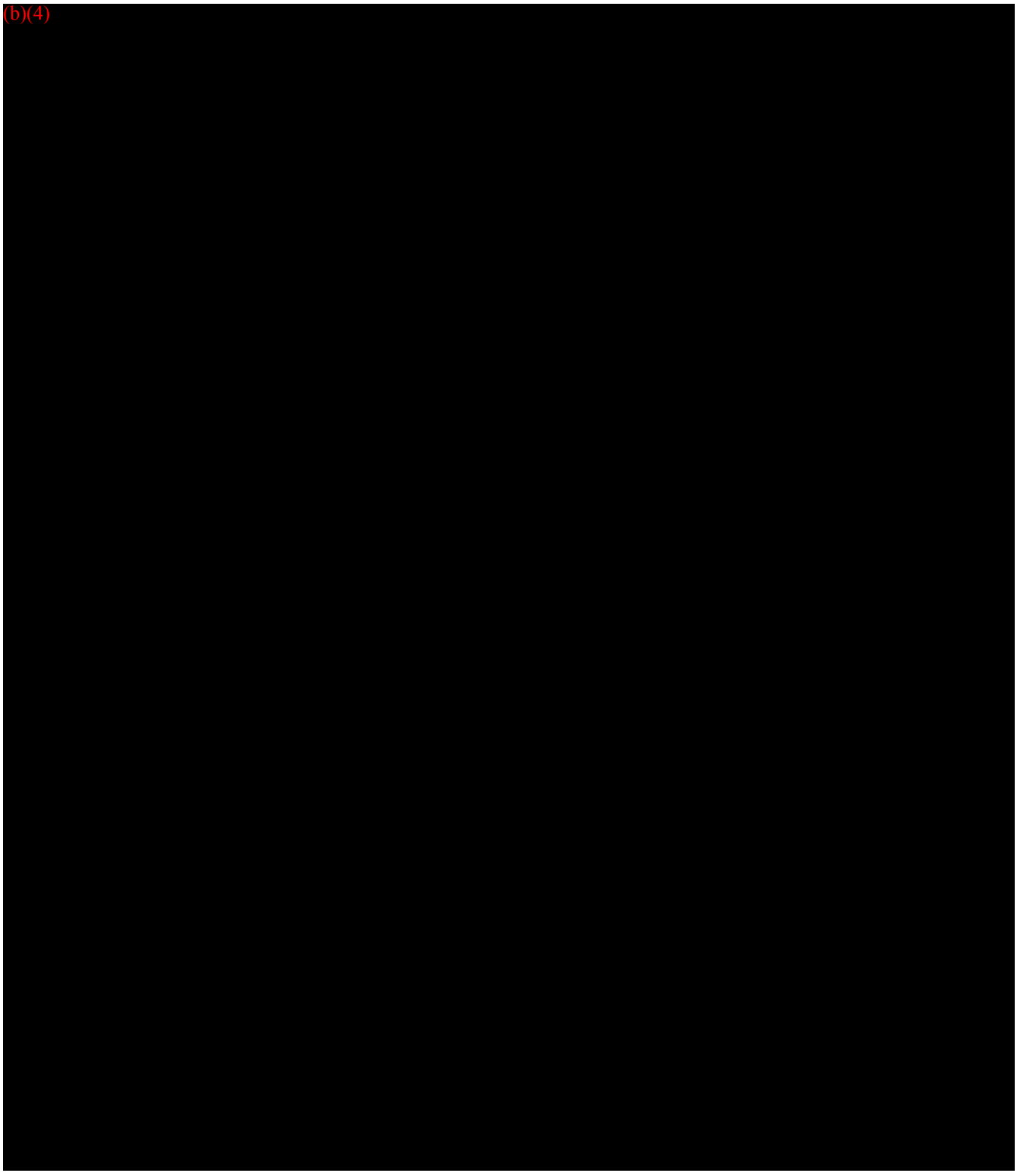

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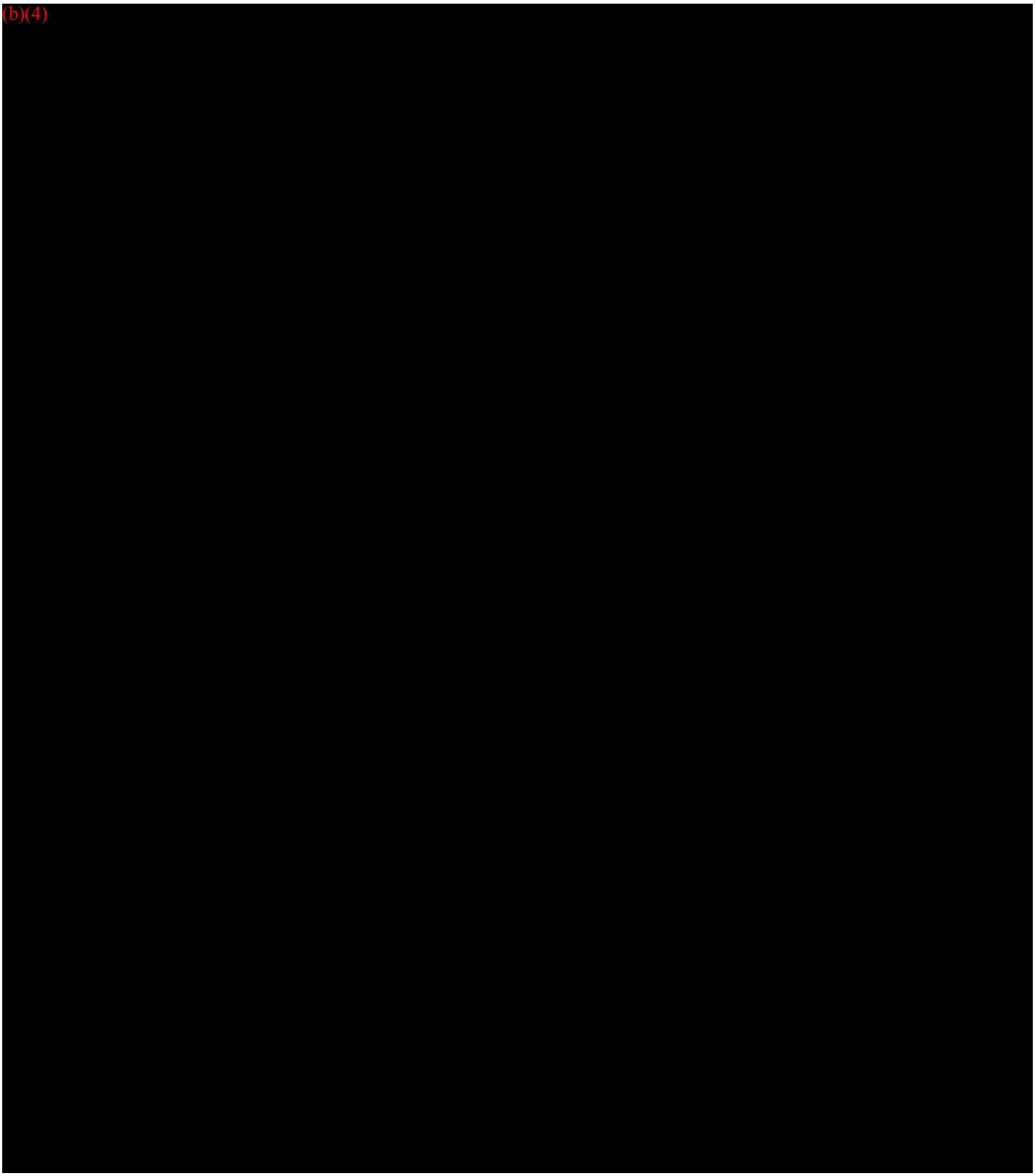

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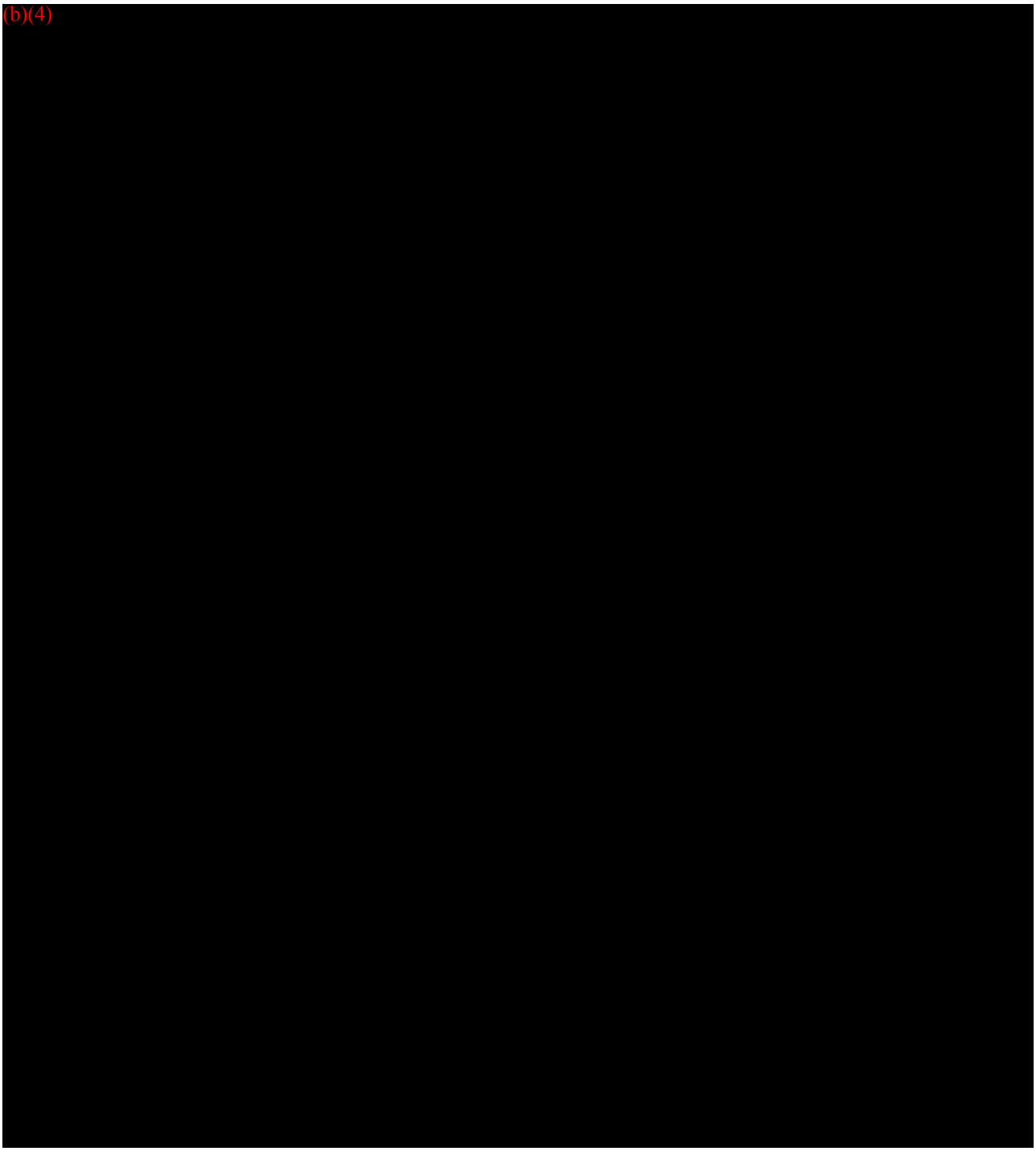

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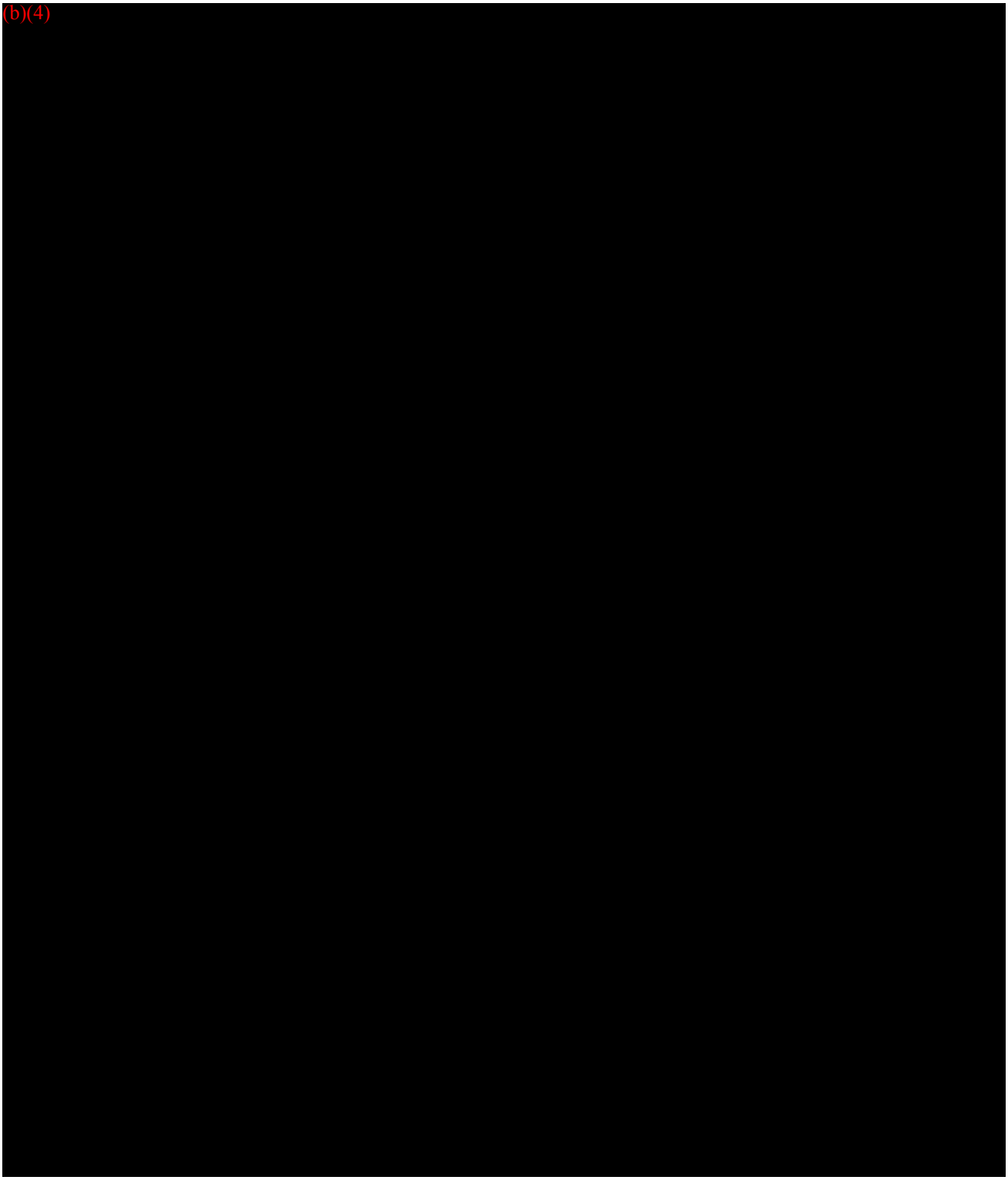

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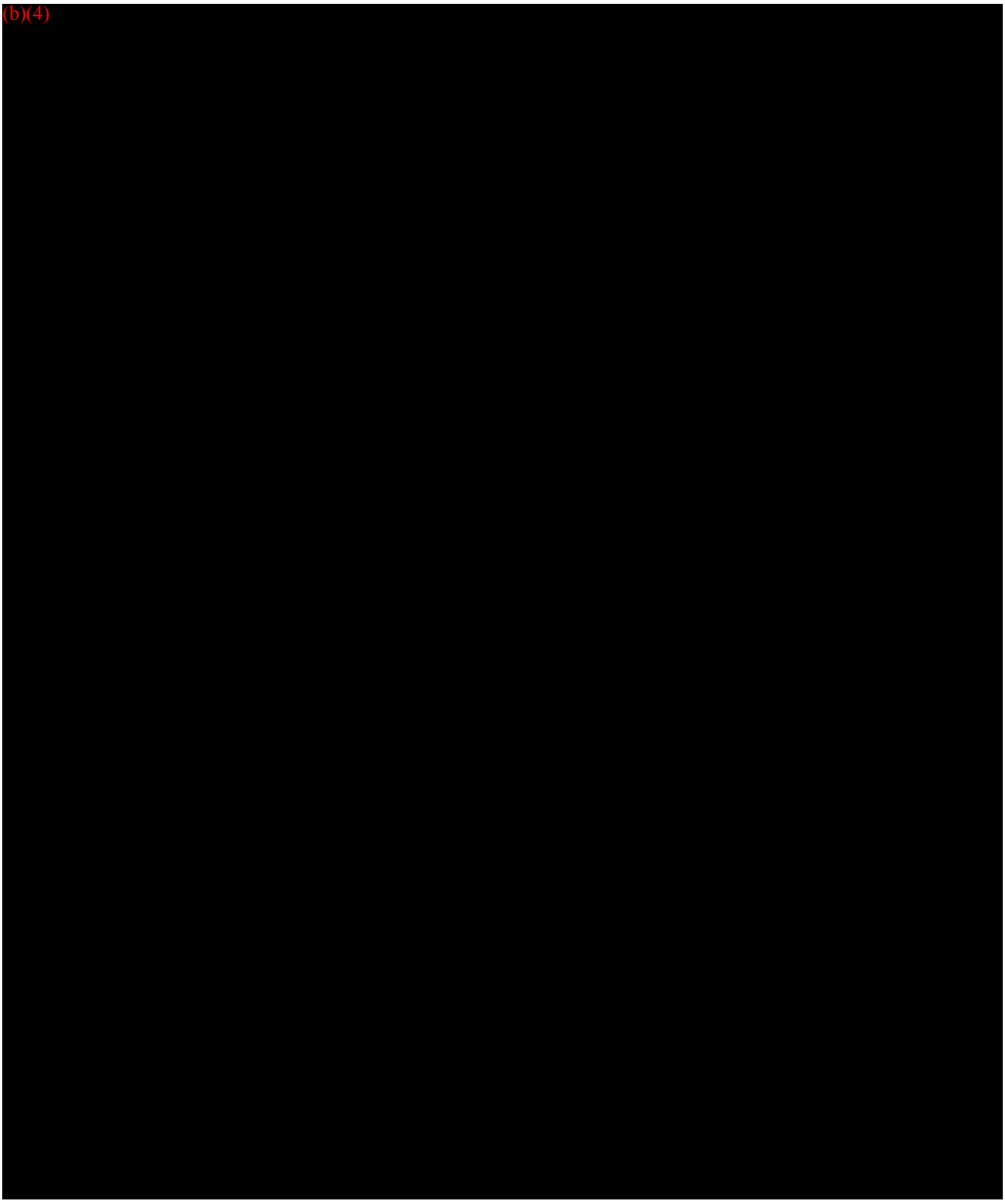

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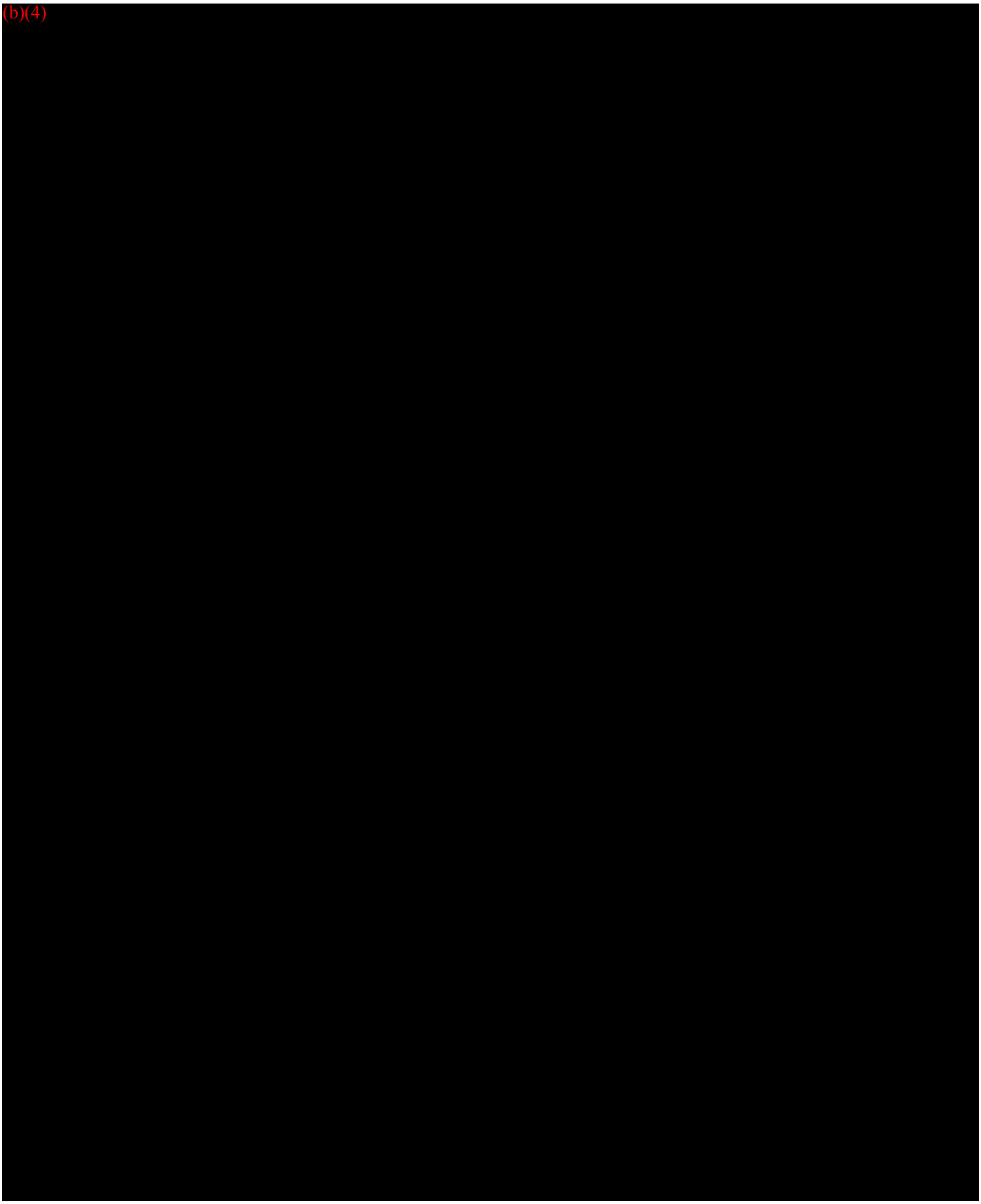

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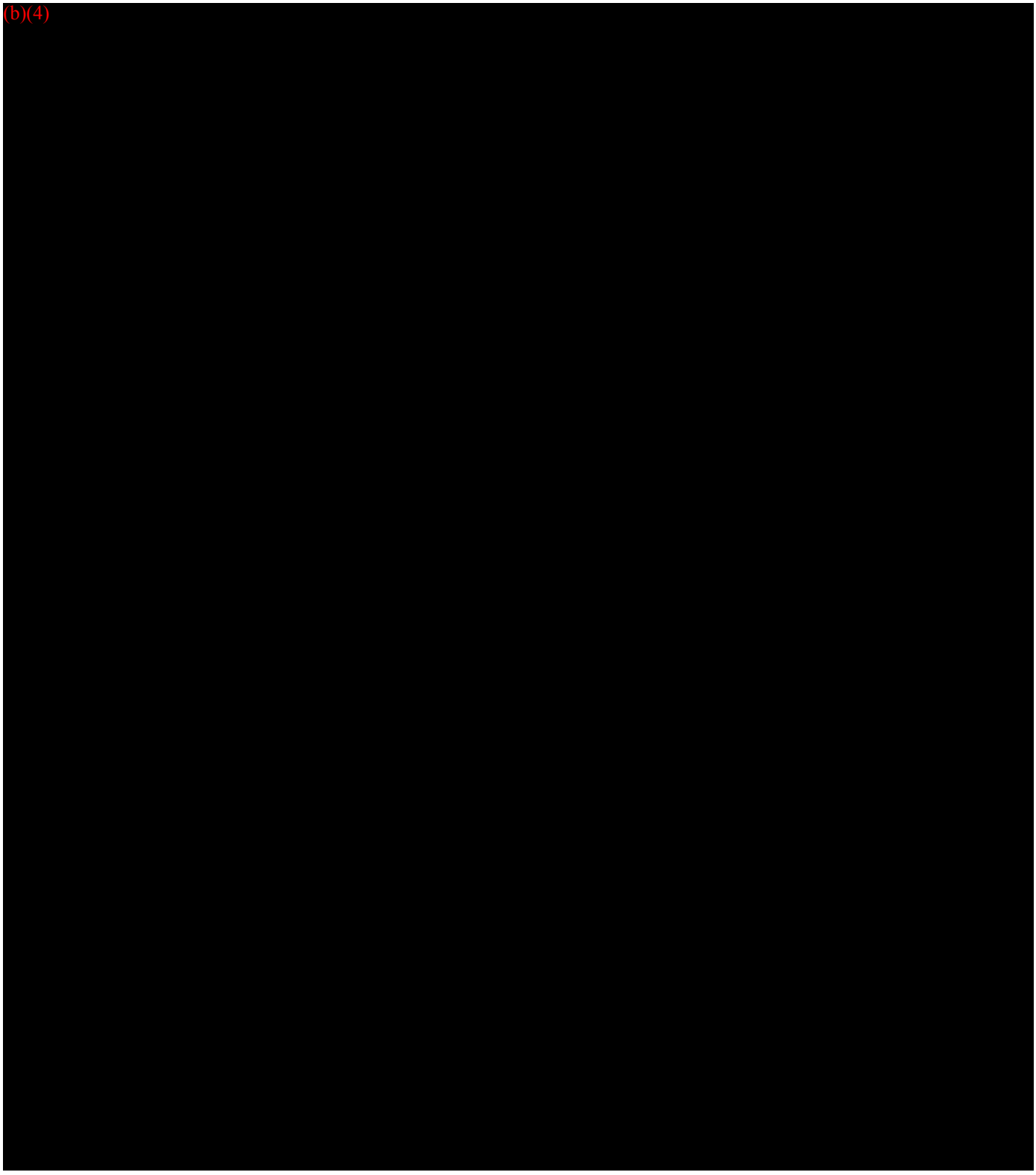


ATTACHMENT A: REVISED SE TABLE & DISCUSSION

SUBSTANTIAL EQUIVALENCE DISCUSSION

1.1 Substantial Equivalence (SE) Table

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

Esophageal temperature probes for continuous temperature monitoring of the patients esophagus are Class II devices under Product Code FLL 21 CFR 880.2910;

(a) A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

The thermocouple sensor of the IRTS Probe is considered a Direct Mode Clinical Thermometer as defined in ISO 80601-2-56.

201.3.207: Direct Mode: Operating mode of a clinical thermometer where the output temperature is an unadjusted temperature that represents the temperature of the measuring site to which the probe is coupled. (see page 4 of ISO 80601-2-56).

The FIAB ESOTEST System is identified as the primary predicate for continuous temperature monitoring of the patients esophagus, (K123361).

Telethermographic systems for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures are Class 1 devices under Product Code LHQ 21 CFR 884.2980;

(a) A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The thermographic sensor of the IRTS Prove is not a Clinical Thermometer as defined in ISO 80601-2-56.

The Texas Infrared IR Camera with Flash Software is identified as the secondary predicate for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures, (K073581). This secondary predicate was included in accordance with the guidance document entitled: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k), Guidance for Industry and Food and Drug Administration Staff, Document issued on: July 28, 2014.

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Intended Use	Continuous temperature monitoring of the patients esophagus.	Intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperatures.	The thermocouple sensor of the IRTS Probe is intended for continuous temperature monitoring of the patients esophagus. The thermographic sensor of the IRTS Probe is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.
Indications for Use	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The ICI Series and S IR Cameras, which provide capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.	The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe. The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
System Components	Temperature probe 7 Fr Interconnect cable Patient Monitor	Thermographic infrared detector with optical assembly Flash Software	Temperature probe 9 Fr Patient Interface Unit (PIU) with thermographic infrared detector with optical assembly. Patient Monitoring Unit (PMU) with software
Probe Sterility	Provided sterile	Provided non-sterile	Provided non-sterile
Route of Insertion	Oral or Nasal	N/A	Oral or Nasal
Probe Material (patient contact)	Polyurethane and stainless steel	N/A	Polyethylene and platinum iridium
Probe Size	7 Fr catheter with 11 Fr sensors 95 cm length	N/A	9 Fr catheter with 9 Fr sensor 150 cm length
System Temperature Precision and Resolution	0.1° C	0.1° C	0.1° C
Temperature Sensor	Type-T thermocouple	N/A	Type-T thermocouple
Thermocouple Sensor Signal Processing and Display	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LED display	N/A	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LCD display
Thermocouple Sensor Range	15° - 75° C	N/A	25° - 45° C
Thermocouple Sensor Accuracy	± 0.5° C tested in accordance with ISO 80601-2-56	N/A	± 0.3° C tested in accordance with ISO 80601-2-56

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Transient Response Time of Thermocouple Sensor	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	N/A	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56
Infrared Detector Technology	N/A	FPA microbolometer	Stirling cooled MCT
Infrared Signal Processing and Display	N/A	Relative display of color graphical image representing infrared radiation emitted from the body.	Relative display of color graphical image representing infrared radiation emitted from the body.
Infrared Temperature Range	N/A	-20° - +250° C	35° - 60° C
Infrared Temperature Accuracy	N/A	IR: ± 2° C or 2% of reading	IR: ± 2° C
Infrared Temperature Resolution	N/A	0.1° C	0.1° C
Infrared Image Field of View	N/A	22°	360°
Spectral Response	N/A	8-14µm	8-11µm
Thermal Image Size	N/A	320 x 240 array	128 x 60 array
Power Supply	100-120/230 Vac	AC adaptor power supply 12 VDC	100-240 Vac AC adaptor power supply 24 VDC
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2	Fully complies with IEC 60601-1-1:2005 +A1:2012 IEC 60601-1-2:2007
Data Output	Data provided to the supplied monitor for display	Digital USB 2.0 to user computer	Data provided to the supplied monitor for display

1.2 SE Discussion

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

There are no significant technological differences between the predicate devices and the IRTS that would raise new questions about safety and effectiveness of the system. Minor modifications to the technological characteristics were necessary to combine the output from the thermocouple sensor for esophageal temperature measurement and the output from the thermographic sensor for adjunctive thermal imaging the esophagus on a single monitor. The fundamental technologies and the intended uses are substantially equivalent.

The following discussion follows the questions provided in Appendix A. 510(k) Decision-Making Flowchart provided in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k), Guidance for Industry and Food and Drug Administration Staff. Document issued on July 28, 2014.

Decision 1: Is the predicate device a legally marketed device?

Yes.

Both the primary and secondary predicate devices are legally marketed devices.

The primary predicate is the FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361). This is a legally marketed device. Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

The secondary predicate identified for the telethermographic infrared imaging capability of the IRTS is the ICI P and S Series IR Camera(s) and the IR Flash Software made by Texas Infrared, (K073581). This is a legally marketed device. Telethermographic Systems (adjunctive use) are Class I devices under 21 CFR § 884.2980 and are classified by the Obstetrical and Gynecological Devices panel. Product code - LHQ.

Decision 2: Do the devices have the same intended use?

Yes.

The IRTS has the same intended use as the primary predicate. Both the IRTS and the FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) are intended for continuous temperature monitoring of the patients esophagus.

The IRTS has the same intended use as the second predicate. Both the IRTS and the Texas Infrared ICI P and S Series IR Camera(s) and the IR Flash Software (K073581) are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

Decision 3: Do the devices have the same technological characteristics?

No.

The IRTS incorporates the same basic components as its primary predicate, the FIAB ESOTEST device. Both are catheter-based esophageal temperature probes with integrated Type-T thermocouples for measuring temperature. Both systems incorporate a monitor to continuously display the esophageal temperature. Both systems are classified as a Direct Mode Clinical Thermometer and tested in accordance with ISO 80601-2-56.

The IRTS also incorporates the same fundamental telethermographic infrared technology as its secondary predicate, the Texas Infrared system. Both are infrared imaging devices that include an optical assembly, an infrared detector and graphical presentation software. Both systems passively collect the infrared energy naturally radiated off tissue surfaces for adjunctive diagnostic screening. Both systems are not Clinical Thermometers as defined by 80601-2-56.

The following differences are noted in the SE table above but do not affect substantial equivalence or safety and effectiveness.

- The Securus Probe material (patient contact): Polyethylene was selected for the exterior catheter shaft of the Probe. Polyethylene has excellent transmissivity to infrared energy which is important for the infrared imaging capability of the IRTS. Polyethylene is available in a variety of grades for flexible catheter manufacturing and has a long history of use in medical devices. The material has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The shaft of the Probe is 9 Fr (3.0 mm) with a smooth surface and mainly uniform diameter along its length. The shaft of the FIAB ESOTEST is 7 Fr (2.3 mm) with five 11 Fr (3.6 mm) stainless steel beads protruding at the thermocouple and electrode locations. The Securus Probe diameter falls within the mid-range of the FIAB ESOTEST geometry which is suitable for both nasal and oral insertion.
- A single thermocouple is used for the Securus Probe to report esophageal temperature where the FIAB ESOTEST has 3 thermocouples spaced apart along the catheter shaft. The FIAB device is configured so that only one thermocouple is used at a time. Numerous esophageal temperature probes are marketed with a single sensor configuration and are tested to the same recognized standards.
- The Securus Probe is supplied non-sterile where the FIAB ESOTEST is provided sterile. There are multiple non-sterile esophageal temperature sensor probes on the market. The choice of sterile versus non-sterile is made by the clinical site and varies depending on the nature of the procedure, institutional protocols and product price. Offering the Securus Probe as a non-sterile product is not clinically significant for the intended use.
- The transient response time (heating and cooling) of the thermocouple sensor was tested in accordance with ISO 80601-2-56. The resulting transient response time is less than 2.5 seconds. The FIAB ESOTEST transient response time is reported as approximately 1 second. The response time of the Securus Probe is tested and reported in the product manual in accordance with the standard. The l.5 second difference in response time between the predicate and the Securus product is not clinically significant for the intended use.
- The infrared detector used in the Securus product is a Stirling cooled MCT type. The Texas product utilizes an FPA Microbolometer type detector. The majority of IR cameras have a Microbolometer type detector, mainly because of cost considerations. Microbolometers are relatively low sensitivity, exhibit broad (flat) response curves and slow response time (time

constant ~ 12 ms). For more demanding applications, MCT type detectors are used, which operate on the basis of an intrinsic photoelectric effect. Stirling cooled MCT detectors are very sensitive to changes in infrared energy and react very quickly to changes in infrared energy levels (i.e., temperatures), having a response time constant on the order of 1 µs. The Securus IRTS system utilizes the more sensitive Stirling cooled MCT type detector.

- The way the IRTS collects the infrared energy from the tissue surface and presents that energy to the detector has been adapted to incorporate a fiberoptic assembly. This fiberoptic accessary is fully contained within the inner lumen of the Probe. The fiberoptic assembly transfers the IR energy from the surface of the esophagus wall to the detector. The Probe continuously scans a 360° by 60mm segment. The infrared image is graphically presented on the Patient Monitoring Unit as a 2-dimensional color map along with the peak temperature over the scanned area. The thermal image has a refresh rate of once every second.

Decision 4: Do the differences in technological characteristics of the devices raise different questions of safety and effectiveness?

No.

The technological differences of the devices do not raise different questions of safety and effectiveness. Testing has been successfully performed in accordance with accepted consensus standards and methods to evaluate effects on safety and effectiveness.

- The change in Probe materials has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The esophageal temperature measurement has been tested per ISO 80601-2-56 and meets the basic safety standards and essential performance requirements of a Clinical Thermometer for body temperature measurement. The number of thermocouples (1 versus 3) does not affect the safety and effectiveness for the intended use.
- The fiberoptic assembly allows the device to passively collect infrared energy from the esophagus and transmit it to the detector. This added accessory does not affect the performance of the system as shown through accuracy testing. The infrared temperature information is for adjunctive diagnostic screening and has the same accuracy performance as the secondary predicate device and does not affect safety and effectiveness for the intended use.

Decision 5a: Are the methods acceptable?

Yes.

Where appropriate, testing and development has been performed in accordance with recognized consensus standards. The InfraRed Thermographic System (IRTS) complies with FDA recognized standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 80601-2-56:2009 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009(E) Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010(E) Biological evaluation of medical Devices - Part 10: Tests for irritation and skin sensitization
- ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes
- ISO 14791:2007 Application of risk management to medical devices

Decision 5b: Do the data demonstrate substantial equivalence?

Yes.

The data demonstrate substantial equivalence. The IRTS has the same intended use as both predicate devices. Data from the thermocouple temperature sensor shows that the IRTS has substantially equivalent performance characteristics as the FIAB ESOTEST system when tested in accordance with ISO 80601-2-56 particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

The infrared thermographic information is for adjunctive diagnostic screening and has the same accuracy performance as the Texas Infrared system.

The IRTS therefore demonstrates substantial equivalence to both the primary and secondary predicate devices.

Appendix III to this 510(k) application contains copies of the predicate device labeling and/or FDA 510(k) clearance information.

FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, (K123361)

Texas Infrared, ICI P and S Series IR Camera(s) and the IR Flash Software, (K073581).

ATTACHMENT B: REVISED SUMMARY

510(K) SUMMARY

This 510(k) Summary is being submitted in accordance with: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)

Common name: Clinical Electronic Thermometer

Thermographic System

Classification Number/ Classification name/Product code:

Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Telethermographic systems intended for adjunctive diagnostic screening are Class I devices under 21 CFR § 884.2980 and are classified by the Obstetrical and Gynecological Devices panel. Product code - LHQ.

Special Controls:

Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers

3) Predicate Devices

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361).

ICI P and S Series IR Camera(s) and the IR Flash Software, Texas Infrared, (K073581).

4) Device Description

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

Esophageal temperature probes for continuous temperature monitoring of the patients esophagus are Class II devices under Product Code FLL 21 CFR 880.2910;

(a) A clinical electronic thermometer is a device used to measure the body temperature of a

patient by means of a transducer coupled with electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

The thermocouple sensor of the IRTS Probe is considered a Direct Mode Clinical Thermometer as defined in ISO 80601-2-56.

201.3.207: Direct Mode: Operating mode of a clinical thermometer where the output temperature is an unadjusted temperature that represents the temperature of the measuring site to which the probe is coupled. (see page 4 of ISO 80601-2-56).

The FIAB ESOTEST System is identified as the primary predicate for continuous temperature monitoring of the patients esophagus, (K123361).

Telethermographic systems for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures are Class 1 devices under Product Code LHQ 21 CFR 884.2980;

A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition, the Probe incorporates adjunctive infrared thermal imaging element to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to other clinical diagnostic procedures. See Figure 1 for a system overview.

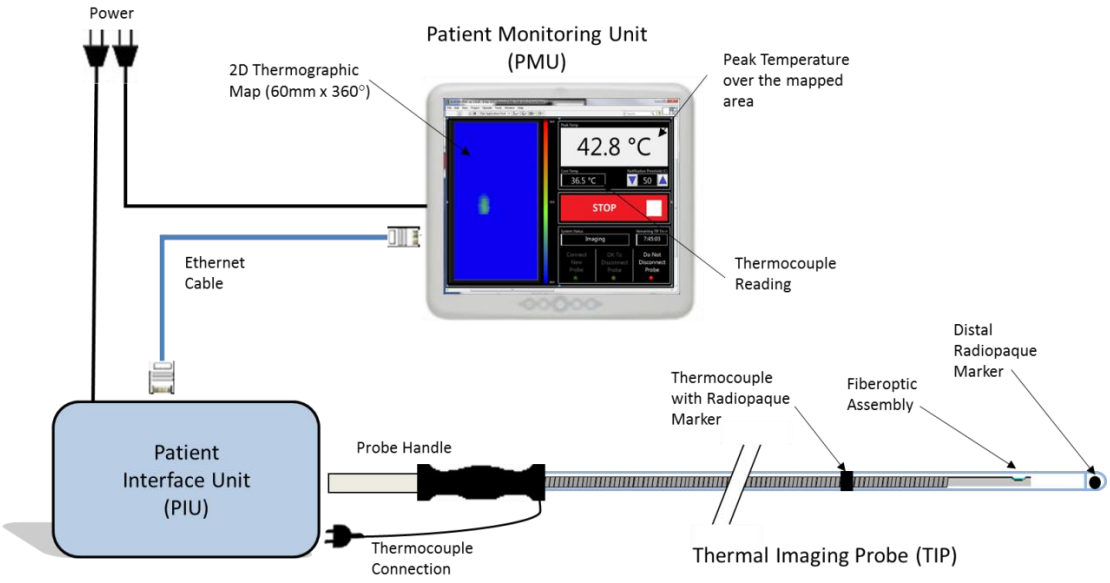


Figure 1: System Overview Diagram

5) Indications for Use

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

6) Comparison to Predicate Device

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

There are no significant technological differences between the predicate devices and the IRTS that would raise new questions about safety and effectiveness of the system. Minor modifications to the technological characteristics were necessary to combine the output from the thermocouple sensor for esophageal temperature measurement and the output from the thermographic sensor for adjunctive thermal imaging the esophagus on a single monitor. The fundamental technologies and the intended uses are substantially equivalent.

The FIAB ESOTEST System is identified as the primary predicate for continuous temperature monitoring of the patients esophagus, (K123361).

Telethermographic systems for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures are Class 1 devices under Product Code LHQ 21 CFR 884.2980;

The Texas Infrared IR Camera with Flash Software is identified as the secondary predicate for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures, (K073581).

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Intended Use	Continuous temperature monitoring of the patients esophagus.	Intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperatures.	The thermocouple sensor of the IRTS Probe is intended for continuous temperature monitoring of the patients esophagus. The thermographic sensor of the IRTS Probe is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.
Indications for Use	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The ICI Series and S IR Cameras, which provide capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.	The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor isintended to display continuous esophageal temperature measurements (°C) from the IRTS Probe. The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
System Components	Temperature probe 7 Fr Interconnect cable Patient Monitor	Thermographic infrared detector with optical assembly Flash Software	Temperature probe 9 Fr Patient Interface Unit (PIU) with thermographic infrared detector. Patient Monitoring Unit (PMU) with software
Probe Material (patient contact)	Polyurethane and stainless steel	N/A	Polyethylene and platinum iridium
Probe size	7 Fr catheter with 11 Fr sensors 95 cm length	N/A	9 Fr catheter with 9 Fr sensor 150 cm length
System Temperature Precision and Resolution	0.1° C	0.1° C	0.1° C
Temperature Sensor	Type-T thermocouple	N/A	Type-T thermocouple
Thermocouple Sensor Range	15°-75° C	N/A	25° - 45° C
Thermocouple Sensor Accuracy	± 0.5° C tested in accordance with ISO 80601-2-56	N/A	± 0.3° C tested in accordance with ISO 80601-2-56
Transient Response Time of Thermocouple	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	N/A	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56
Infrared Detector Technology	N/A	FPA microbolometer	Stirling cooled MCT

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Infrared Temperature Range	N/A	-20° - +250° C	35° - 60° C
Infrared Temperature Accuracy	N/A	IR: ± 2° C or 2% of reading	IR: ± 2° C
Power Supply	100-120/230 Vac	AC adaptor power supply 12 VDC	100-240 Vac AC adaptor power supply 24 VDC
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007

7) Comparison to Predicate Discussion:

The IRTS incorporates the same basic components as its primary predicate, the FIAB ESOTEST device. Both are catheter-based esophageal temperature probes with integrated Type-T thermocouples for measuring temperature. Both systems incorporate a monitor to continuously display the esophageal temperature. Both systems are classified as a Direct Mode Clinical Thermometer and tested in accordance with ISO 80601-2-56.

The IRTS also incorporates the same fundamental telethermographic infrared technology as its secondary predicate, the Texas Infrared system. Both are infrared imaging devices that include an optical assembly, an infrared detector and graphical presentation software. Both systems passively collect the infrared energy naturally radiated off tissue surfaces for adjunctive diagnostic screening. Both systems are not Clinical Thermometers as defined by 80601-2-56.

The following differences are noted in the SE table above but do not affect substantial equivalence or safety and effectiveness.

- The Securus Probe material (patient contact): Polyethylene was selected for the exterior catheter shaft of the Probe. Polyethylene has excellent transmissivity to infrared energy which is important for the infrared imaging capability of the IRTS. Polyethylene is available in a variety of grades for flexible catheter manufacturing and has a long history of use in medical devices. The material has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The shaft of the Probe is 9 Fr (3.0 mm) with a smooth surface and mainly uniform diameter along its length. The shaft of the FIAB ESOTEST is 7 Fr (2.3 mm) with five 11 Fr (3.6 mm) stainless steel beads protruding at the thermocouple and electrode locations. The Securus Probe diameter falls within the mid-range of the FIAB ESOTEST geometry which is suitable for both nasal and oral insertion.
- A single thermocouple is used for the Securus Probe to report esophageal temperature where the FIAB ESOTEST has 3 thermocouples spaced apart along the catheter shaft. The FIAB device is configured so that only one thermocouple is used at a time. Numerous esophageal temperature probes are marketed with a single sensor configuration and are tested to the same recognized standards.
- The transient response time (heating and cooling) of the thermocouple sensor was tested in accordance with ISO 80601-2-56. The resulting transient response time is less than 2.5 seconds. The FIAB ESOTEST transient response time is reported as approximately 1 second. The response time of the Securus Probe is tested and reported in the product manual in accordance with the standard. The l.5 second difference in response time between the predicate and the Securus product is not clinically significant for the intended use.
- The infrared detector used in the Securus product is a Stirling cooled MCT type. The Texas product utilizes an FPA Microbolometer type detector. The majority of IR cameras have a Microbolometer type detector, mainly because of cost considerations. Microbolometers are relatively low sensitivity, exhibit broad (flat) response curves and slow response time (time constant ~ 12 ms). For more demanding applications, MCT type detectors are used, which operate on the basis of an intrinsic photoelectric effect. Stirling cooled MCT detectors are very sensitive to changes in infrared energy and react very quickly to changes in infrared energy levels (i.e., temperatures), having a response time constant on the order of 1 µs. The Securus IRTS system utilizes the more sensitive Stirling cooled MCT type detector.
- The way the IRTS collects the infrared energy from the tissue surface and presents that energy to the detector has been adapted to incorporate a fiberoptic assembly. This fiberoptic accessary

is fully contained within the inner lumen of the Probe. The fiberoptic assembly transfers the IR energy from the surface of the esophagus wall to the detector. The Probe continuously scans a 360° by 60mm segment. The infrared image is graphically presented on the Patient Monitoring Unit as a 2-dimensional color map along with the peak temperature over the scanned area. The thermal image has a refresh rate of once every second.

Testing and development have been performed in accordance with recognized consensus standards. Based on the testing performed on the IRTS the safety and effectiveness of the system has not been affected by the changes required to combine the output of the two temperature monitoring devices onto one display monitor.

8) Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body

temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

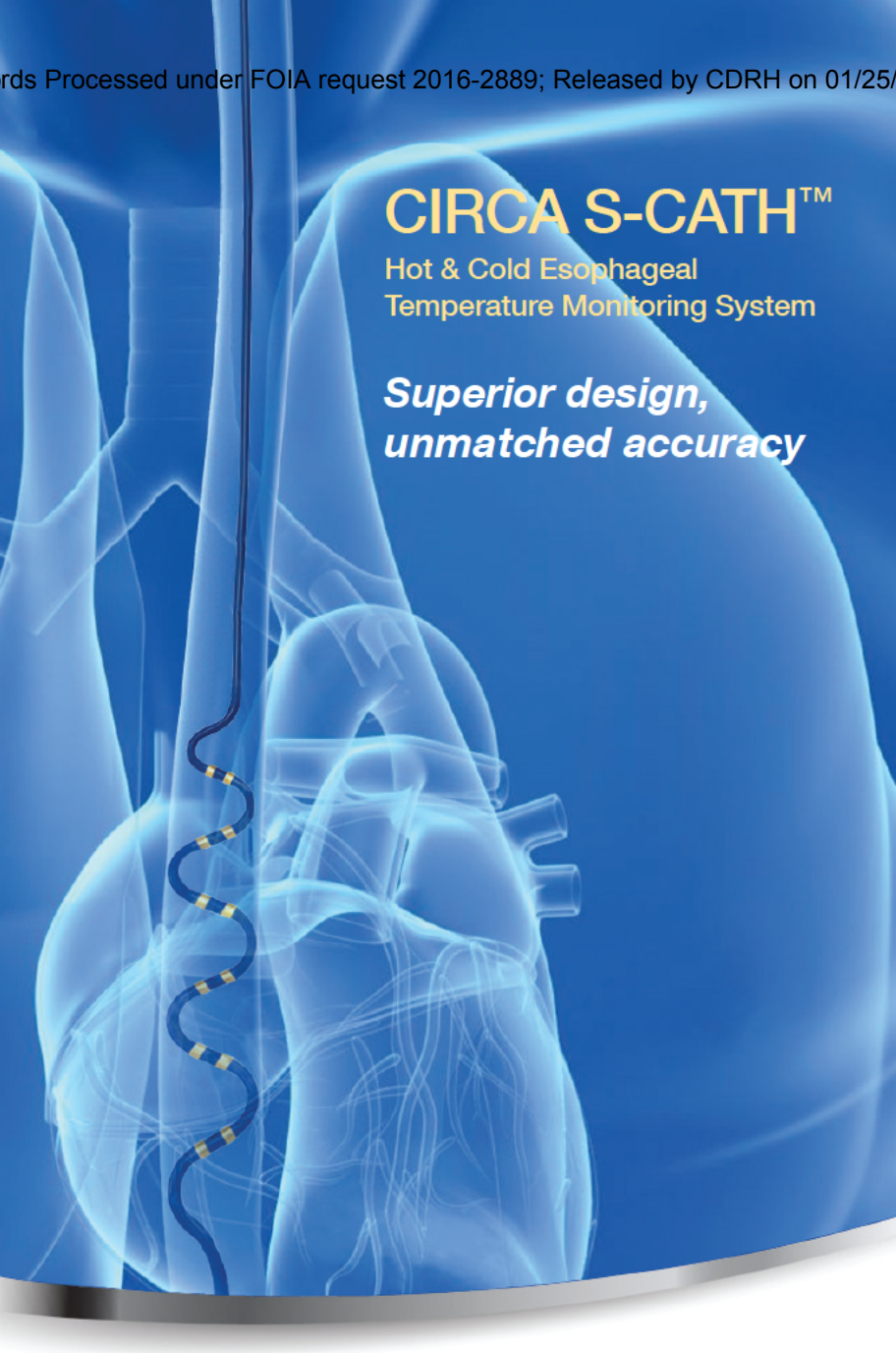
Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The performance data provided support the substantial equivalence of the InfraRed Thermographic System (IRTS). According to these data we conclude that the IRTS Probe (TIP), IRTS Patient Monitoring Unit (PMU), and the Patient Interface Unit (PIU) are substantially equivalent to the predicate devices in terms of performance, safety and use. The differences from the predicates do not affect substantial equivalence or performance and do not raise any new safety concerns.

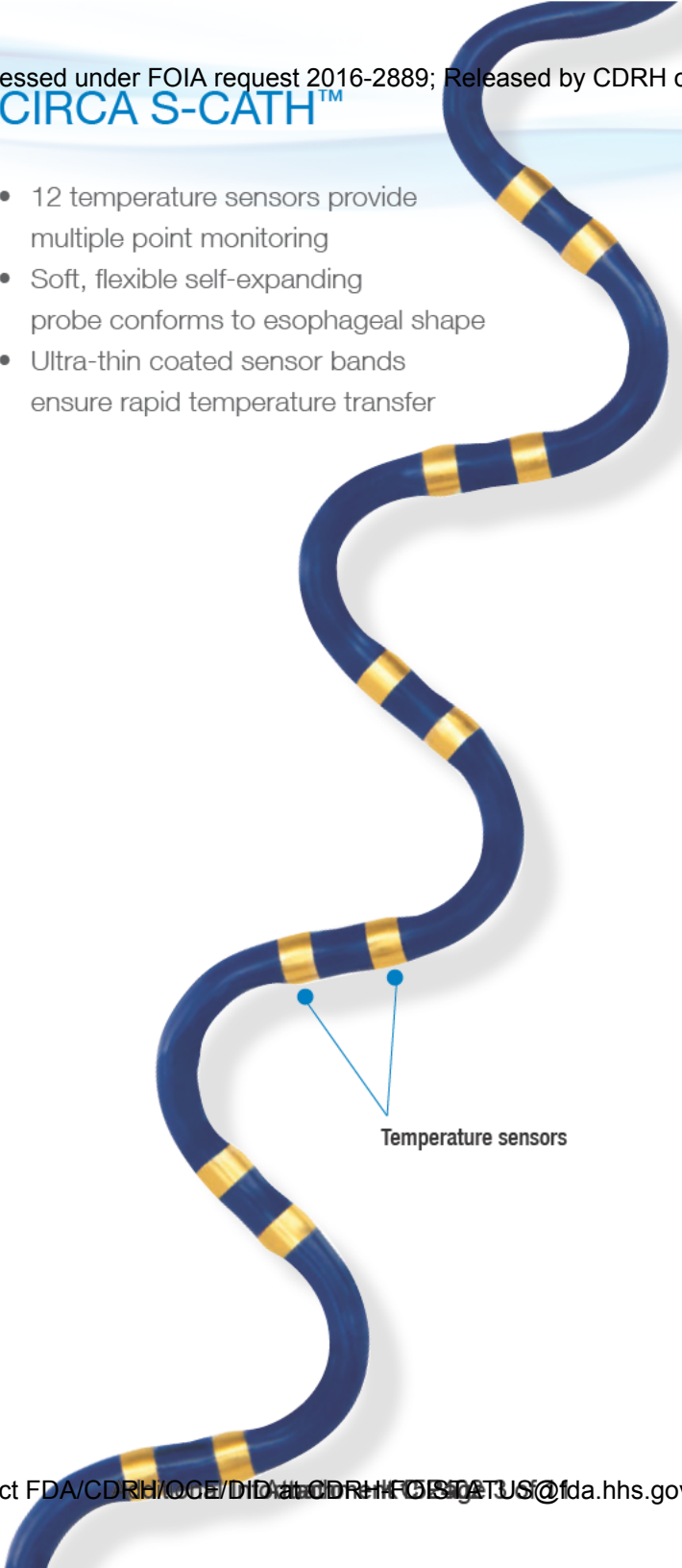
ATTACHMENT C: LABELING, CIRCA



CIRCA SCIENTIFIC

CIRCA S-CATH™

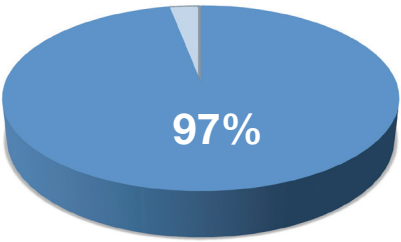
- 12 temperature sensors provide multiple point monitoring
- Soft, flexible self-expanding probe conforms to esophageal shape
- Ultra-thin coated sensor bands ensure rapid temperature transfer



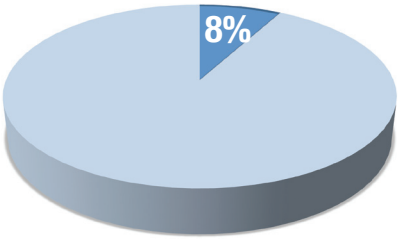
Maximum Esophageal Coverage

Proprietary S-Shape Design provides maximum coverage for more complete monitoring.

S-CATH S-Shape Design
97% coverage



Conventional Probe Design
8% coverage

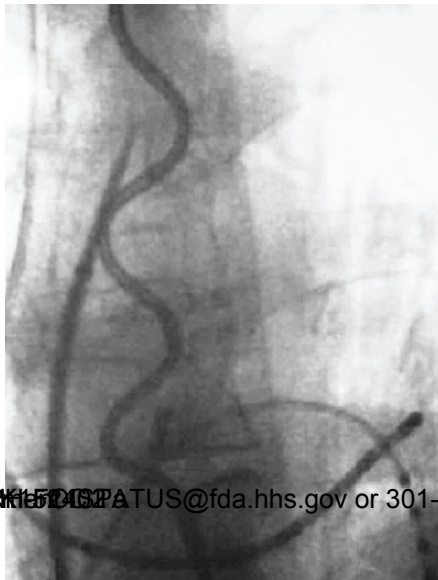


Assumes: Average esophageal width of 18.9mm[1], average esophageal length in contact with left atrium of 42.8mm[2], and each sensor covers 64 sq. mm.

Stationary Placement

Sensor placement ensures proximity to the point of treatment; no need to move the probe once placed.

- Radiopaque shaft provides a visual landmark of the esophagus
- Indicates esophageal width and orientation
- Facilitates reduced use of fluoroscopy

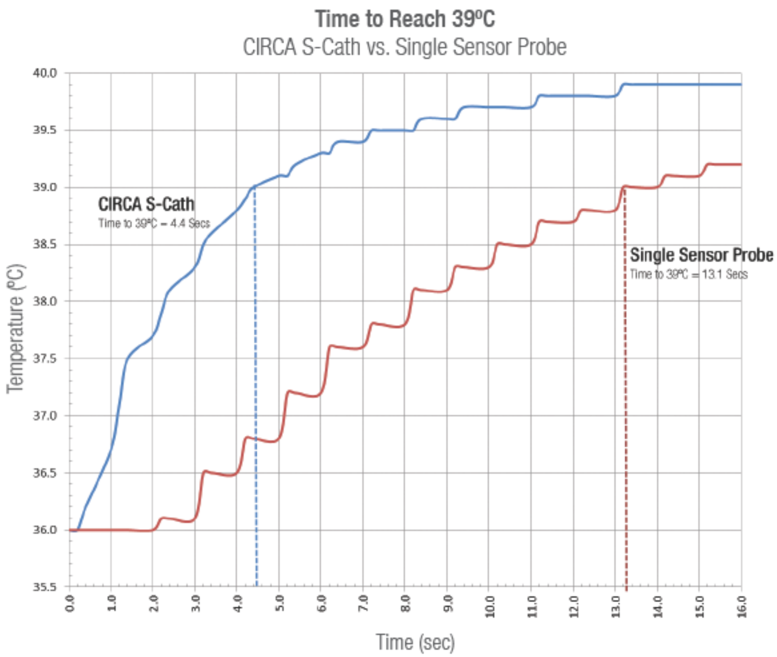


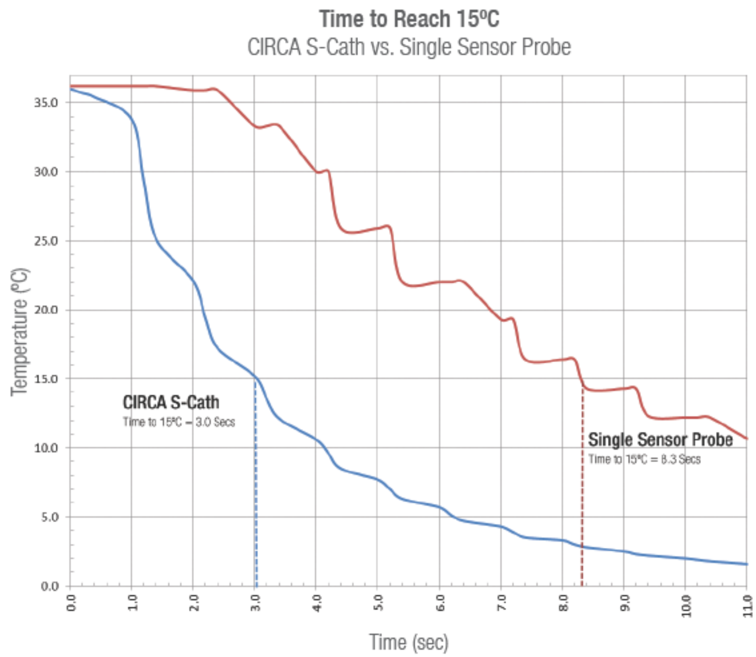
Faster Response to Hot & Cold Temperature Changes

Continuous monitoring software is highly accurate in both hot and cold (down to 0°C) temperatures.[3]

- 12 temperature sensors update 20 times per second
- Four, user selectable low and high temperature alarms
- Temperature is displayed both graphically and numerically

CIRCA's sensor technology displays temperature changes nearly 3 times faster than a single sensor probe.





Test conducted by CIRCA Scientific.

Product Code Description

CS-1000	CIRCA Temperature Monitoring System™ (Touch Screen Display, Pole Mount included)
CS-2001	CIRCA S-CATH™ Esophageal Temperature Probe, (Single Use, 10Fr O.D.,10 units/ Carton), U.S.*
CS-2006	CIRCA S-CATH™ Esophageal Temperature Probe, (Single Use, 10Fr O.D.,10 units/ Carton), International*
CS-2003	CIRCA S-CATH Interconnect Cable (Reusable, 15 Foot Working Length)
CS-1029	CIRCA Temperature Standard (Calibration)

CIRCA SCIENTIFIC

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Englewood, CO 80112
www.CIRCASCIENTIFIC.com
Office: 1.303.951.8767 • Fax: 1.303.951.8769
info@circascientific.com

All products carry the CE mark, comply with Medical Device Directive 93/42/EEC and are manufactured to Quality Systems ISO13485.

This product is listed by CSA International as certified.

Indication for Use: The CIRCA S-CATH Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus. The CIRCA Temperature Monitor is indicated to display continuous temperature measurement (°C) from 12-sensor temperature probe.

[1] Cury RC, Abbara S, Schmidt S, Malchano ZJ, Neuzil P, Weichet J, Ferencik M, et al. Relationship of the esophagus and aorta to the left atrium and pulmonary veins: Implications for catheter ablation of atrial fibrillation. Heart Rhythm 2005; 2:1317-1323.

[2] Sánchez-Quintana D, Cabrera JA, Climent V, Farré J, de Mendonça MC, Ho SY. Anatomic relations between the esophagus and left atrium and relevance for ablation of atrial fibrillation. Circulation. 2005;112: 1400-1405.

[3] Accuracy of the temperature sensors is ± 0.3°C within the rated output range of 25°C to 45°C and ± 0.4°C within the rated extended output range of 0° to 24.9°C.

CE 0470

*US and Foreign Patents Pending

Instructions for Use: S-Cath™ Esophageal Temperature Probe

General warnings and cautions:

- Rx Only: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Single use only. Do not re-use. If re-used, cross-infection to patient may occur.
- Do not rinse, soak, wash, or sterilize. Material degradation and temperature inaccuracy may occur.
- Insert temperature probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction.
- Do not re-insert stylet or attempt to override lock-out feature, probe damage may occur.
- The S-Cath™ Esophageal Temperature Probe is designed for use with CIRCA Scientific Interconnect Cable, CIRCA Scientific Temperature Monitor, and 400 Series Compatible Monitor only. Incompatible components can result in degraded performance and could lead to damage.
- Part of defibrillation proof protection is provided by the S-Cath™ Temperature Probe with the CIRCA Scientific Temperature Monitor (Defibrillation-Proof Type BF Applied Part). When 400 Series Cable Connector is connected to 400 Series Compatible Monitor, consult equipment manufacturer's accompanying documents for the monitor's defibrillation-proof classification.

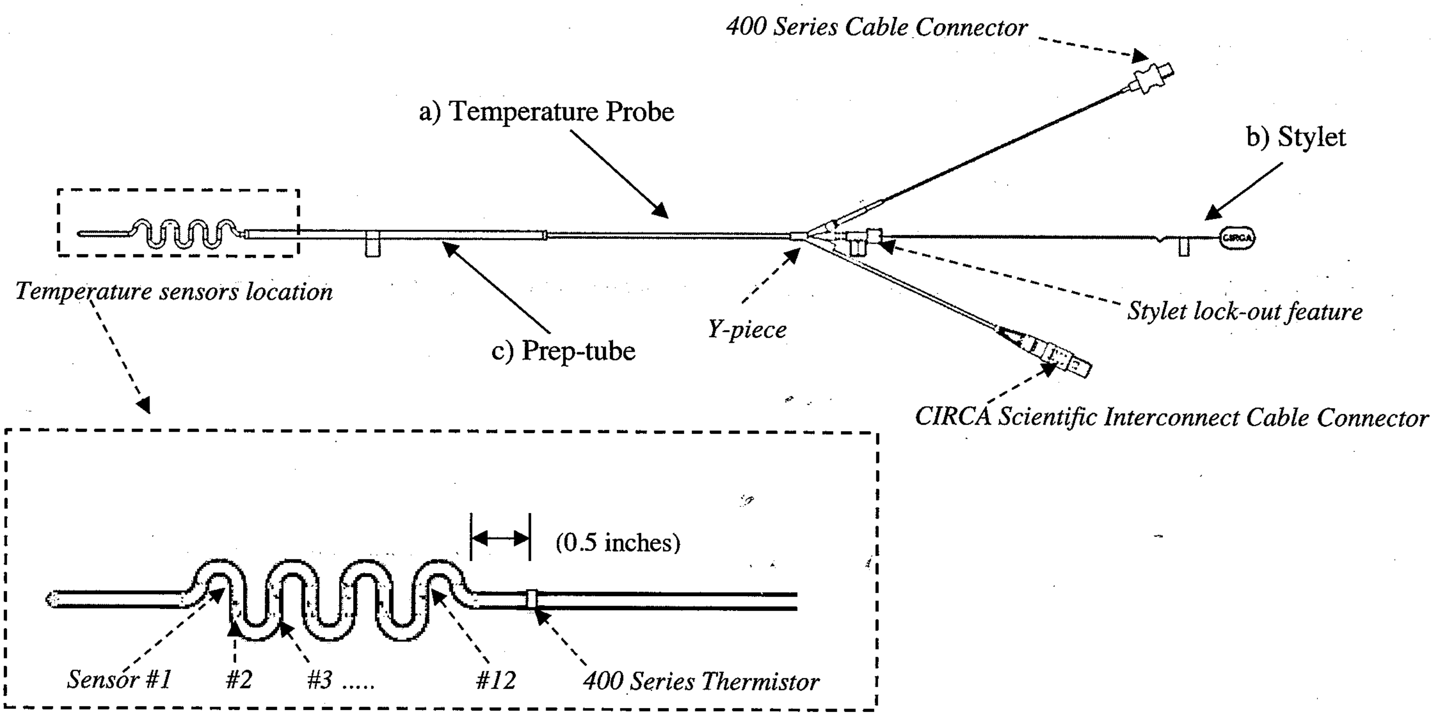
Indications for use:

The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Description:

The S-Cath™ Esophageal Temperature Probe provides continuous temperature measurement (°C) and operates in direct mode.

The components inside package are: a) radiopaque temperature probe; b) stainless steel stylet; and c) plastic prep-tube.



Manufactured for:
CIRCA Scientific, LLC
[illegible]
Englewood, CO 80112
(303) 951-8767

CIRCA SCIENTIFIC

Setup instructions:

The operator is responsible for checking the compatibility of the temperature probe, interconnect cable, and monitor before use. Ensure only CIRCA Scientific components and equipment is connected to CIRCA Scientific cable connector.

S1) Remove device from package.

S2) Visually inspect for damage, kinks, visible debris, and missing components. Do not use if any defects are observed.

S3) Connect CIRCA Scientific Interconnect Cable Connector to CIRCA Scientific monitor via CIRCA Scientific interconnect cable by aligning snap-fit connectors and pushing firmly.

S4) If used, align 400 series cable connector with 400 series compatible temperature monitor cable and push firmly to assure full contact.

S5) Verify temperatures are displayed on monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on monitor.

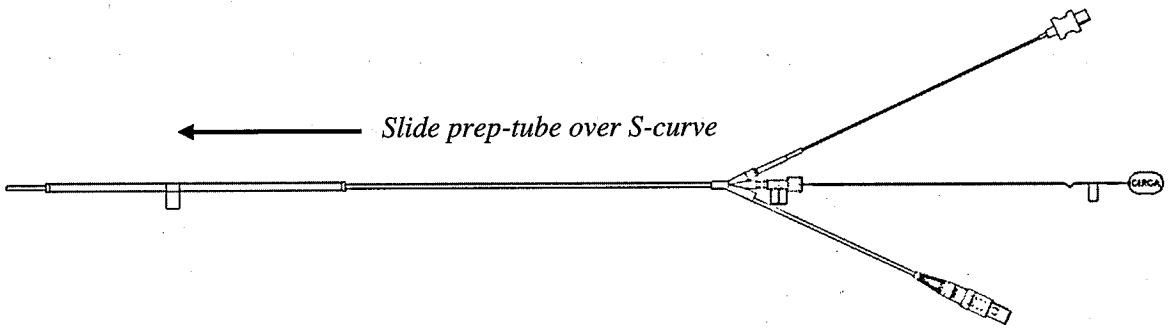
S6) Disconnect temperature probe from interconnect cable by grasping connectors. Do not pull on cable or probe wire to disconnect.

S7) Proceed with operating instructions below.

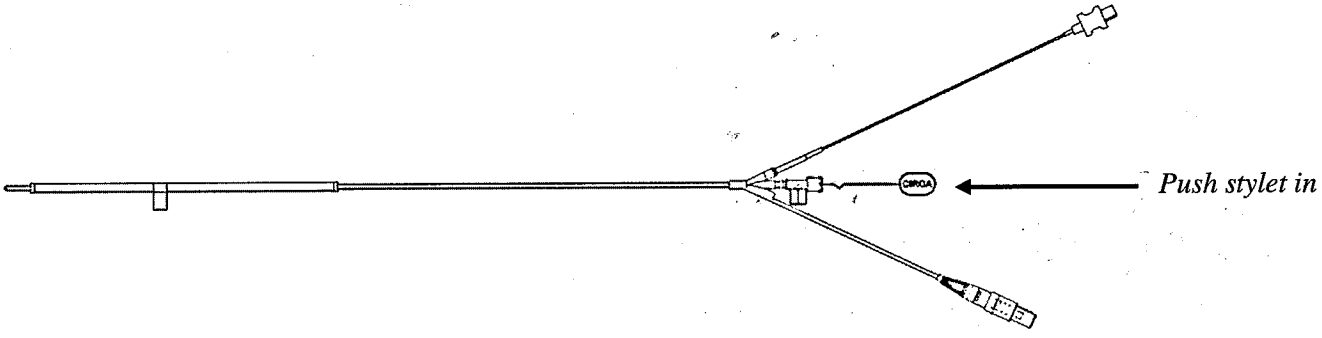
Operating instructions:

O1) Straighten S-Curve Portion of Temperature Probe

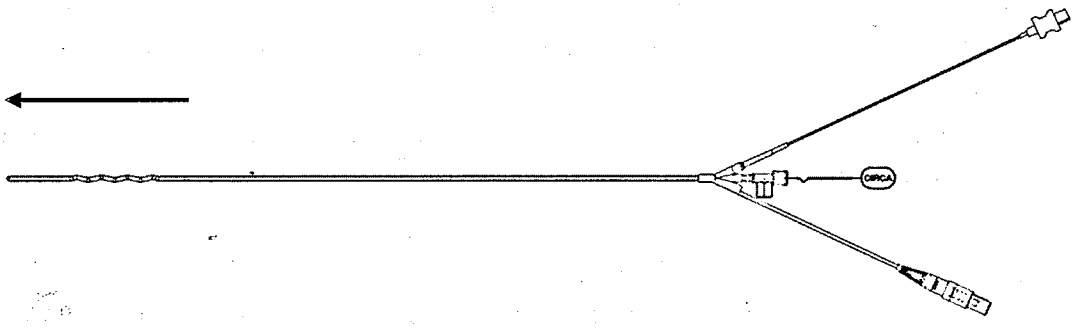
a. Grasp Y-piece of temperature probe with one hand and slide prep-tube over S-curve portion to approximately 20 mm (3/4") from the end with other hand.



b. Grasp Y-piece of temperature probe with one hand and push stainless steel stylet until z-bend of stylet reaches Y-piece.



c. ***Remove prep-tube and discard***



Note: Once prèp-tube is removed and discarded, temperature probe is now ready for insertion; proceed with step O2)

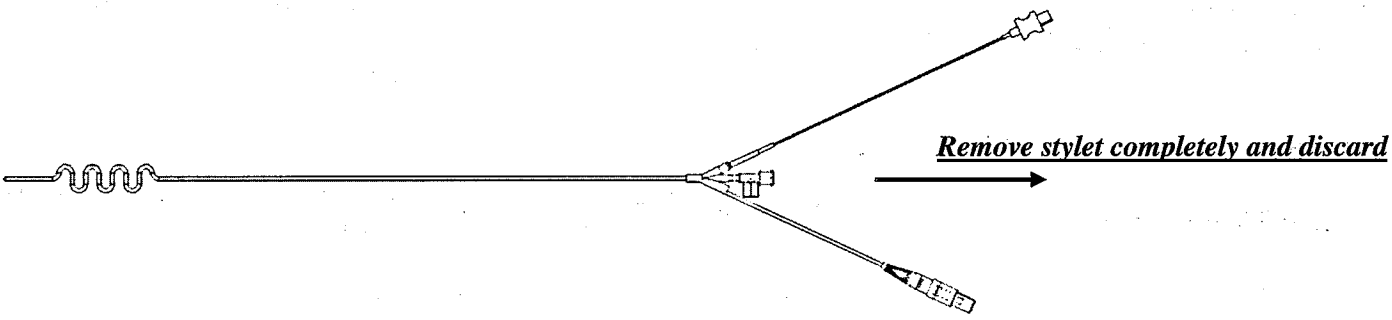
O2) Insert Temperature Probe into Esophagus

a. Apply water-soluble lubricant to outside of temperature probe.

b. Insert temperature probe into esophagus under fluoroscopic x-ray. Advance distal tip to approximately 1 cm (0.4") superior to the gastroesophageal junction.

c. Once temperature probe is placed, grasp finger grip end of stylet and remove completely. Discard stylet.

Caution: do not re-insert stylet or attempt to override lock-out feature, probe damage may occur.



d. Verify position of temperature probe under fluoroscopic x-ray. If probe end does not appear as an S-shape, grasp Y-piece and rotate probe until S-shape is visible. Grasp Y-piece to reposition probe as required for desired placement.

Instructions for Use: S-Cath™ Esophageal Temperature Probe

Setup instructions:

The operator is responsible for checking the compatibility of the temperature probe, interconnect cable, and monitor before use. Ensure only CIRCA Scientific components and equipment is connected to CIRCA Scientific cable connector.

S1) Remove device from package.

S2) Visually inspect for damage, kinks, visible debris, and missing components. Do not use if any defects are observed.

S3) Connect CIRCA Scientific Interconnect Cable Connector to CIRCA Scientific monitor via CIRCA Scientific interconnect cable by aligning snap-fit connectors and pushing firmly.

S4) If used, align 400 series cable connector with 400 series compatible temperature monitor cable and push firmly to assure full contact.

S5) Verify temperatures are displayed on monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on monitor.

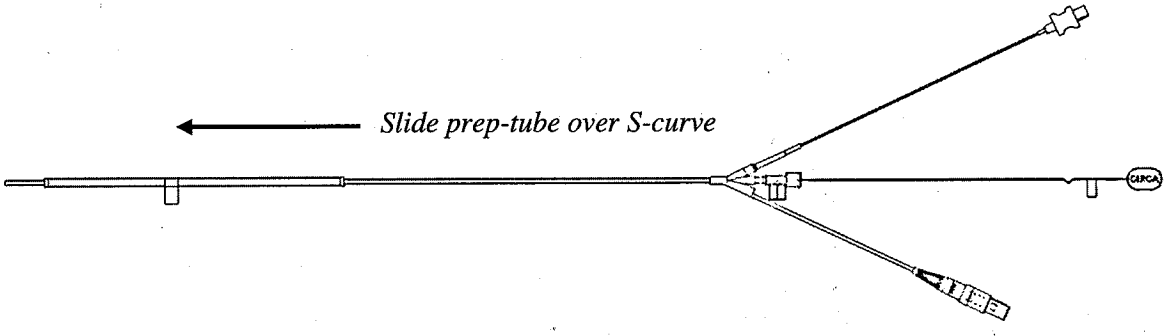
S6) Disconnect temperature probe from interconnect cable by grasping connectors. Do not pull on cable or probe wire to disconnect.

S7) Proceed with operating instructions below.

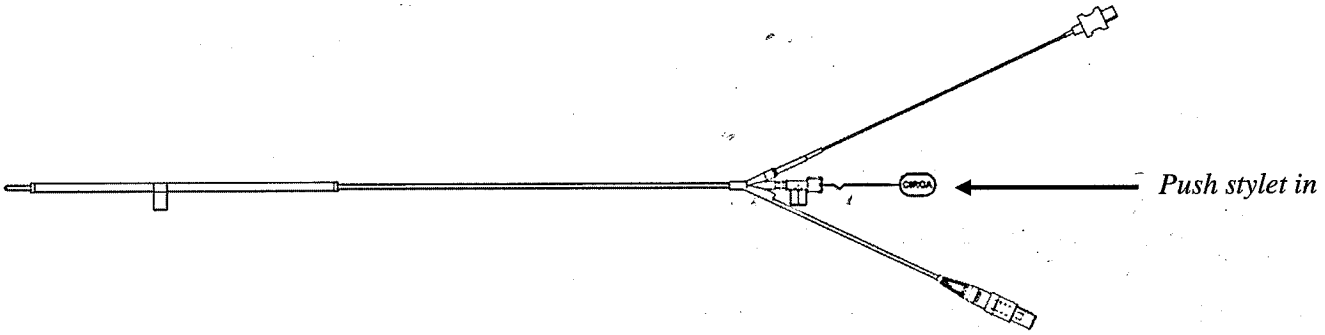
Operating instructions:

O1) Straighten S-Curve Portion of Temperature Probe

a. Grasp Y-piece of temperature probe with one hand and slide prep-tube over S-curve portion to approximately 20 mm (3/4") from the end with other hand.



b. Grasp Y-piece of temperature probe with one hand and push stainless steel stylet until z-bend of stylet reaches Y-piece.



CIRCA SCIENTIFIC

S-Cath™

Esophageal Temperature Probe

Intended Use: The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Size: 10 Fr OD Length: 50cm

REF CS-2001

LOT 026941

QTY 1

2014-05

Rx Only

Manufactured for : CIRCA Scientific, LLC
14 Inverness Drive East, Suite H-136
Englewood, CO 80112 USA
(303) 951-8767

EC REP Medicor Medical Supplies NV/ SA
Timmerik 2, B-3020 Herent, Belgium

CE 0470

CS-ART2001 Rev.03

ATTACHMENT D: REVISED INSTRUCTION MANUAL AND PROBE LABELING

InfraRed Thermographic System (IRTS)

Instruction Manual

TABLE OF CONTENTS

1. SYSTEM OVERVIEW

The InfraRed Thermographic System (IRTS) consists of three components:

DIAGRAM LETTER	REF #	NAME	DESCRIPTION
A	A-10734	Thermal Imaging Probe (TIP)	Temperature Probe
B	A-10667	Patient Interface Unit (PIU)	Main system control unit
C	A-10395	Patient Monitoring Unit (PMU)	Touchscreen monitor

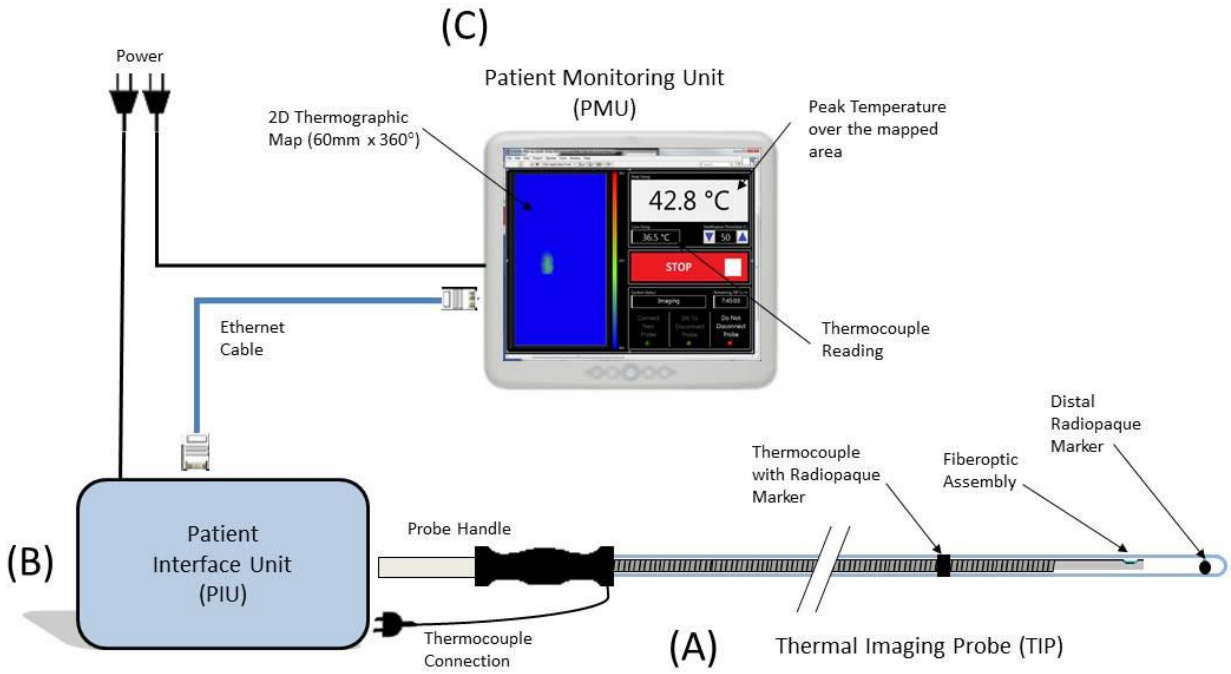


Figure 1: System Overview Diagram

The InfraRed Thermographic System (IRTS) is designed to provide continuous direct mode esophageal temperature monitoring through the use of a standard thermocouple located at the proximal radiopaque marker. In addition, the system incorporates adjunctive infrared thermal imaging technology for quantifying differences in surface temperature changes in the esophagus.

The Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) displays the thermal image and temperature measurements (°C) from the Thermal Imaging Probe (TIP). The thermal image provides a continuous, real-time, non-contact thermal map of a 360° by 60mm long segment of the inner lumen of the esophagus. The thermal image is displayed in a two-dimensional color map. The peak temperature represents the maximum temperature over the scanned area.

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.***

2. INDICATIONS FOR USE

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

3. CONTRAINDICATIONS, WARNINGS and CAUTIONS

CONTRAINDICATIONS

The use of the IRTS is contraindicated for patients who have:

- Symptomatic Esophageal Stricture
- Esophageal Diverticulum
- Esophageal Tumor or Abscess
- Recent Esophageal or Gastric Surgery

WARNINGS

- The Probe is single use only. Do not re-use. Cross-infection to patient may occur and the device may not function properly.
- The Securus IRTS PMU should only be used with Securus IRTS Probes. Use of incompatible components can result in degraded performance or harm.
- Ethernet ports on PMU and PIU components should only be connected to one another.
- Insert Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.
- Do not attempt to reposition Probe while imaging. To reposition always hit “Stop” and wait for the button message “Start Imaging”.
- The Securus IRTS is to be installed and serviced exclusively by Securus technicians. Do not attempt to install, repair, service, or operate the Securus IRTS in any fashion deviating from what is specified in this manual.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- All electrical equipment supporting the patient must be appropriately grounded and must comply with all current regulations and must be of CF type.
- The use of accessories and cables other than those listed above may result in increased EMISSIONS or decreased IMMUNITY of the Securus IRTS.

- The Securus IRTS should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Securus IRTS should be observed to verify normal operation in the configuration in which it will be used.
- Use system only within the indicated operating environment temperature and humidity range. Use outside the specified operating environment may result in inaccurate esophageal temperature readings.
- The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended in Table 4.
- Read and follow all prompts, warnings, errors, and instructions on the IRTS User Interface to ensure proper operation. Failure to follow these instructions can result in degraded performance or harm.

CAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- The thermal image and peak temperature are offered as an adjunct to other clinical diagnostic procedures. Only the thermocouple temperature measurement meets the requirements for essential performance of Clinical Thermometers for body temperature measurement accuracy.
- Only physicians trained in esophageal insertion and catheterization procedures should use the IRTS.
- Do not use the IRTS for any purpose other than its intended use.
- Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock.
- Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.
- Do not bend or kink the probe in a sharp angle or a small radius.
- The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
- Avoid touching the proximal tip of the Probe to avoid damaging the Probe.
- The Probe is provided fully assembled. Do not disassemble the Probe. Disassembly will damage the device.
- The system components will not function with equipment from other manufacturers.
- At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.

If you experience any problems with this product please contact Securus at 216-445-4683

4. SET-UP

A Securus Technician will install the system at your facility. The installation will include:

- Initial inspection of the system for shipping damage
- Identifying the proper location and suitable surface for the PMU and PIU in the lab
- Connection and routing of Ethernet cable
- Identification of suitable power sources
- Initializing software, setting local time and date and other relevant software settings
- Confirming system fully operational in the lab environment

Note: The following steps assume that the Securus installation has already occurred.

4.1. Inspect the PMU and PIU for damage. Do not use the system, and contact Securus if damage is evident.

> **CAUTION:** Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock

4.2. Confirm PIU and PMU are placed on a suitable surface in a dry location.

> **CAUTION:** At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.

4.3. Confirm that the correct power supplies and provided Ethernet cable are plugged into the back panel of the PIU and of the PMU. Plug both power supplies into a grounded, 100-240VAC outlet (50/60hz). Only use the Securus issued power supplies for the IRTS system.

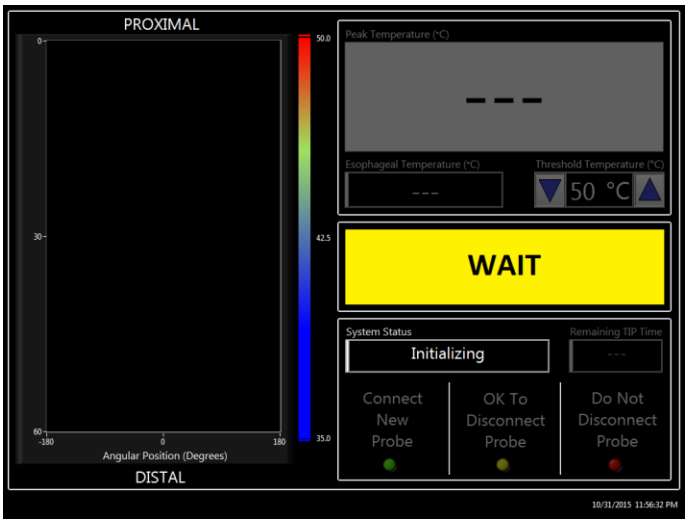
> **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Position of equipment should not make it difficult to disconnect the mains plug.

> **CAUTION:** The system components will not function with equipment from other manufacturers.

4.4. Obtain a new Probe. The Instructions for Use (IFU) is supplied with the Probe. Please read and follow the Probe instructions carefully.

5. SYSTEM OPERATION

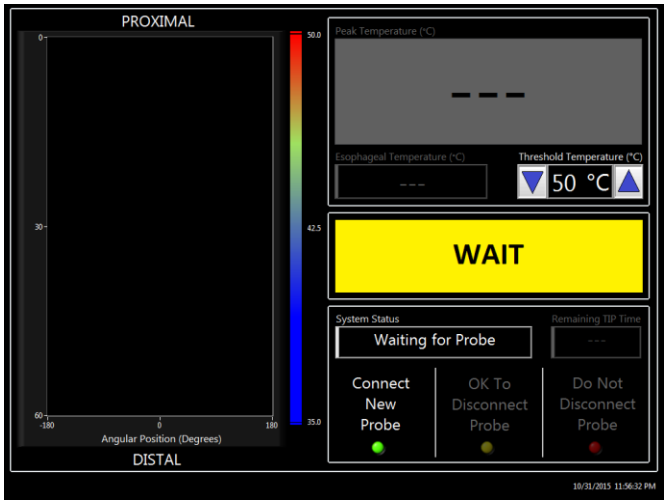
5.1. Turn on power to the PMU by pressing the power button located on the lower right-hand side of the unit. The monitor will display the user interface with the following message “WAIT”.



5.2. Turn on power to the PIU by pressing power button on the left side of the back panel. The green power LED will light. The PIU will begin initialization. It requires approximately 5-minutes to complete the initialization process.

5.3. Follow Instructions for Use provided with the Probe. Insert the probe into the patient. Care should be exercised to avoid damaging the probe. Do not kink or clamp Probe at any time.

5.4. The PMU will prompt you when the PIU is ready to accept a new Probe.



5.5. Insert the Probe Connector (1) into the PIU Probe Receptacle (2) and turn it 90 degrees. Plug the Thermocouple Connector (3) into the PIU TC Receptacle (4).

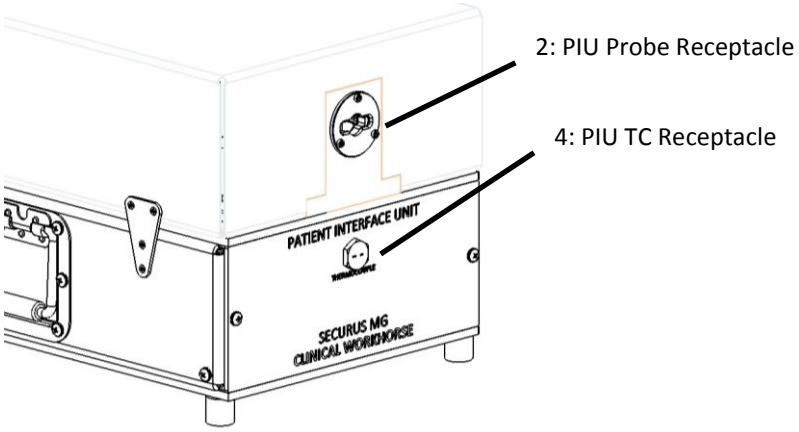


Figure 2: PIU Front

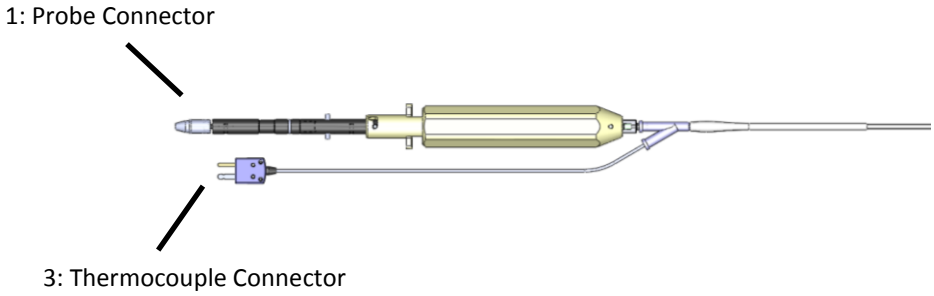


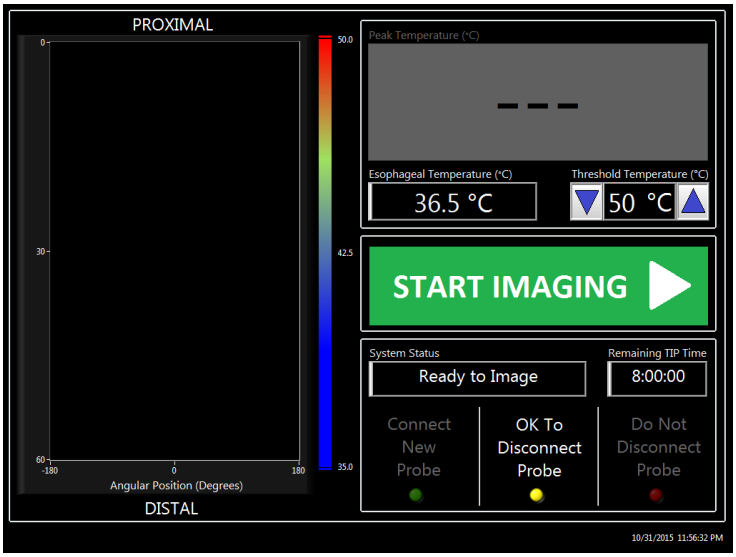
Figure 3: Probe

WARNING: Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging"

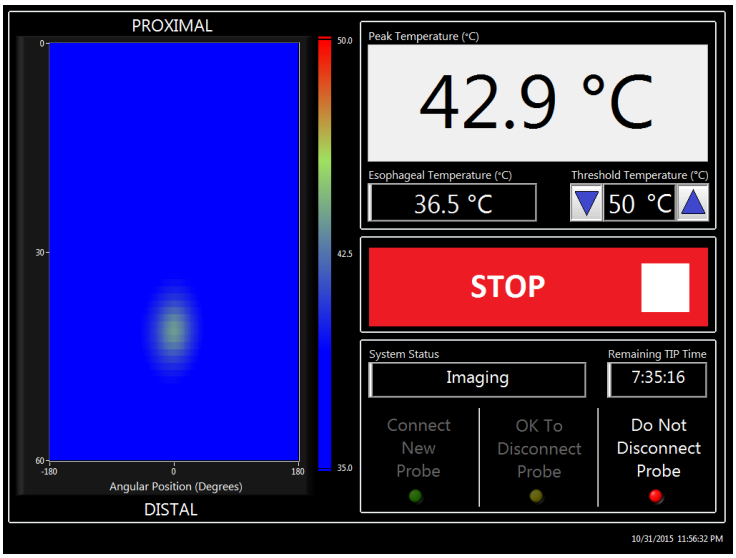
CAUTION: The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.

5.6. To initiate the thermal image and peak temperature Press “Start Imaging” on the user interface.

NOTE: If the peak temperature over the scan area is less than 35°C the Image will be blue and the Peak Temperature will state “< 35°C”.



5.7. Press “Stop” to cease thermal imaging.



5.7.1. System will automatically proceed through Probe docking routine. Press “Stop Docking” to interrupt this process.

5.7.2. When probe is docked, press “Start Imaging” to begin imaging again.

5.8. If the procedure is finished, ensure the status light reads “OK to Disconnect Probe”.

5.9. Remove the probe from the patient.

5.10. Remove the Probe from the PIU by first unplugging the thermocouple. Then turn the handle 90 degrees counter clockwise, remove, and discard.

5.11. Power down the PIU and the PMU. Turn off power to the PMU by pressing the power button located on the lower right-hand side of the unit.

6. ADDITIONAL INFORMATION

6.1. To set a notification temperature, press the (▲) or (▼) key under "Threshold Temperature (°C)" until you reach the desired value. If the peak temperature is equal to or above this number, an audible and visual notification will sound.

6.1.1.Temporarily disable notification by tapping the "Peak Temperature" indicator.

6.2. Pressing "Stop" or "Stop Docking" will immediately cease all PIU action. If on-screen prompts appear, follow them to continue.

6.3. The Probe is a single use device. Probes have a limited lifetime, which is measured and tracked in the software. Once a probe has reached its defined life it should be discarded. The user interface will inform the user when one hour of useful life remains, and again when a Probe change is necessary.

CAUTION: Do not attempt to operate the Probe beyond its intended service life.

6.4. Initialization is the default status for the system when it is waiting or performing internal status checks. In many cases the system will complete its internal processes and proceed out of Initialization status when ready.

6.5. User Interface States

Button Text	System Status Text	Meaning
Wait	Initializing	System is undergoing start-up procedure. Insert a Probe when instructed by the User Interface.
Wait	Waiting for Probe	System is ready for user to engage Probe
Start Imaging	Ready to Image	System is ready to begin Imaging Session.
Stop	Preparing to Image	System is executing Pre-Imaging routine.
Stop	Imaging	System is Imaging.
Stop Docking	Docking	System is docking probe.
ERROR	TIP Expired	Probe has reached the end of its expected lifespan.
ERROR	ERROR	System has detected an error. Follow additional warnings and instructions on the user interface.

6.6. Cleaning: The PIU and PMU may be cleaned by wiping with a disinfectant soap solution. Suitable disinfectants include bleach or hydrogen peroxide based soap solutions such as Clorox Healthcare Bleach Germicidal Cleaner or Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant. Disinfectants should be applied by wiping or spraying onto the surface and should be allowed to stand wet for a minimum of 1 minute. Wipe with a clean, damp cloth. Allow to air dry. Other suitable cleaners approved by your institution may be used on the PUI and PMU.

The PIU and PMU are not designed for immersion or machine washing techniques. Immersion will damage the electromechanical elements inside of the case.

6.7. Maintenance or Calibration: System cannot be maintained or calibrated by the user. System should be returned to Securus for service after one calendar year of use.

7. SPECIFICATIONS

System	
Esophageal Temperature Accuracy (Thermocouple)	± 0.3°C
Esophageal Temperature Range (Thermocouple)	25°C - 45°C
Transient Response Time of Thermocouple for a 2°C temperature change	2.5 seconds for both heating and cooling from a reference water bath to a water bath with a 2°C temperature differential
Thermal Sensitivity	0.1°C within temp range
Infrared Temperature Accuracy	± 2°C
Infrared Temperature Range	35°C - 60°C
Ethernet cable length	3 meters (10 feet)
Storage and transportation environmental	Temperature Range -15°C to 40°C (5°F to 104°F) Relative Humidity 10 to 93% Air Pressure 500 to 1060 hPa (15 to 31 in. Hg)
Operating environmental	Temperature Range 15°C to 35°C (59°F to 95°F) Relative Humidity 25 to 85% Air Pressure 700 to 1060 hPa (21 to 31 in. Hg)
Disposal	Dispose of in compliance with all applicable local, state, federal laws and regulations. PIU and PMU should be returned to Securus at end of life.
Patient Monitoring Unit	
Size	43cm x 40cm x 81cm (17" x 15.8" x 3.2")
Weight	8.2kg (18.1 lbs)
AC DC Power Supply	12/19.5 VDC 135W
Patient Interface Unit	
Size	49cm x 28cm x 28cm (19" x 11" x 11")
Weight	18kg (39 lbs)
AC DC Power Supply	24 VDC 250W
Probe	
Probe length (exclude handle)	118 cm
Probe length overall	153 cm
Standards	
Electrical Safety	Tested in compliance with IEC 60601-1:2005+A1:2012(E) (applicable sections)
	Tested in compliance with IEC 60601-1-2:2007
	Tested in compliance with applicable sections of ISO 80601-2-56
Accuracy Thermocouple	Fully complies with ISO 80601-2-56:2009 requirements (applicable sections)
Type and degree of protection, electrical shock	Type CF, Class I
Degree of protection against ingress of water (IEC 529)	IP2X

See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.

8. ELECTROMAGNETIC COMPATIBILITY (EMC) and ELECTROMAGNETIC SAFETY

8.1. The Securus IRTS has been tested and complies with international Standard IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

8.2. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

8.3. Portable and mobile RF communications equipment can affect Medical electrical equipment performance and safe operation. Portable and mobile RF communications equipment should be separated from the Securus IRTS by at least the minimum separation distances listed in Table 4.

8.4. To maintain the Electromagnetic Compatibility of the Securus IRTS, only the following cables and accessories should be used:

Part Number	Description
A-10734	Temperature Probe
P-10800	L-COM TRD855SCR-10 Ethernet cable – 10.0 ft length
P-10259	Patient Interface Unit (PIU) Power Supply (Includes Power Cord)
P-10838	Patient Monitoring Unit (PMU) Power Supply (Includes Power Cord)

8.5. The following tables are to provide information on the electromagnetic compatibility of the Securus IRTS. If interference is observed or the system is not working correctly, the following information may be useful in correcting the problem. In particular Table 4 provides guidance on the distance that a portable transmitter, communications device, and cellular phones should be kept away from the Securus IRTS to avoid interference or adverse operation of the Securus system.

Table 1- Guidance and manufacturer's declaration – Electromagnetic Emissions

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions *CISPR 11*	*Group 1*	*The Securus IRTS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
RF emissions CISPR 11	Class A	The Securus IRTS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 - Guidance and manufacturer's declaration – Electromagnetic Immunity

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Securus IRTS requires continued operation during power mains interruptions, it is recommended that the Securus IRTS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 3 - Guidance and manufacturer's declaration – Electromagnetic Immunity

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Securus IRTS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Securus IRTS is used exceeds the applicable RF compliance level above, the Securus IRTS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Securus IRTS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Recommended separation distances between portable and mobile RF communications equipment and the Securus IRTS

The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. GENERAL INFORMATION

Manufactured and Distributed By:

Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
216-445-4683

SYMBOLS KEY

REF	Catalog number		Manufacturer
LOT	Lot Number	SN	Serial Number
QTY	Quantity	NON STERILE	Non-Sterile
	Use by - year and month		See accompanying documentation
	Consult instructions for use		Do not use if product is broken, damaged or open
	Do not reuse		Defibrillation – Proof Type CF Applied Part

DEVICE DESCRIPTION

INFRARED THERMOGRAPHIC SYSTEM (IRTS)

The InfraRed Thermographic System (IRTS) is designed to provide continuous esophageal temperature monitoring through the use of a standard thermocouple located at the proximal radiopaque marker. In addition, the system incorporates adjunctive infrared thermal imaging technology for quantifying differences in surface temperature changes in the esophagus.

The Probe contained in this package is a 9 French non-sterile, single-use esophageal catheter designed to be inserted into the esophagus either orally or nasally and positioned under fluoroscopic guidance. The Probe is intended to be used outside the sterile field by clinical professionals familiar in the placement of devices in the esophagus. The Probe is approximately 1.5 meters long with a smooth and flexible outer shaft and soft formable distal tip to aid in insertion. The Probe handle and thermocouple connector connect/plug-in to the Patient Interface Unit (PIU) at the time of the procedure. The Probe utilizes a standard thermocouple for providing continuous body temperature readings from the esophagus. The location of the thermocouple is easily visible under fluoroscopy. See Fig. 1.

The Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) displays the thermal image and temperature measurements (°C) from the Thermal Imaging Probe. The thermal image provides a continuous, real-time, non-contact thermal map of a 360° by 60mm long segment of the inner lumen of the esophagus. The thermal image is displayed in a two-dimensional color map. The peak temperature represents the maximum temperature over the scanned area.

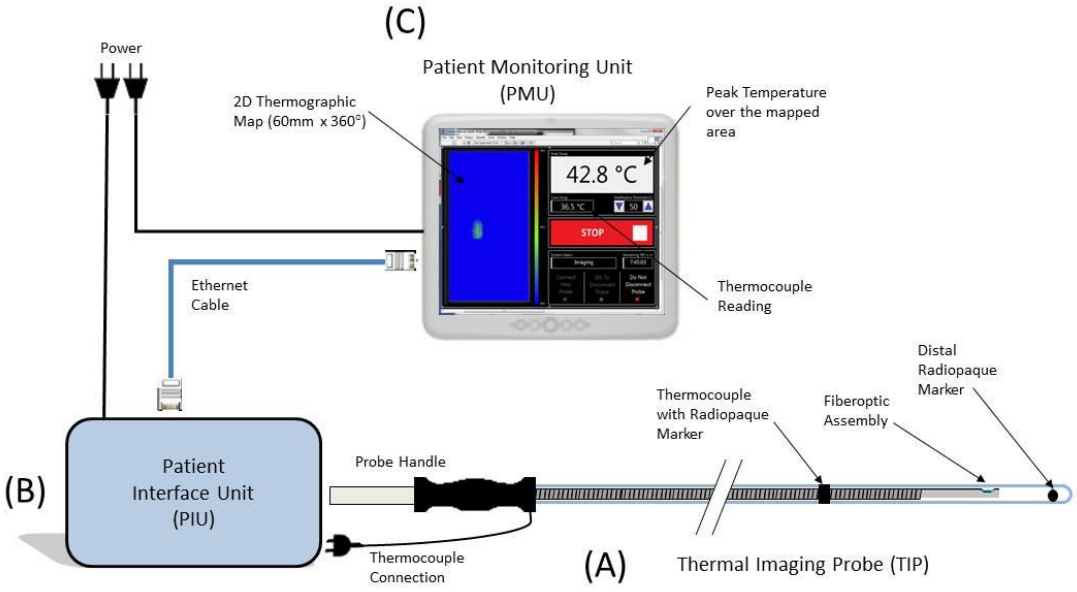


Figure 1: IRTS System Overview Diagram

IRTS SYSTEM COMPONENTS:

DIAGRAM LETTER	REF #	NAME	DESCRIPTION
A	A-10734	TIP	Temperature Probe
B	A-10667	Patient Interface Unit (PIU)	Main system control unit
C	A-10395	Patient Monitoring Unit (PMU)	Touchscreen monitor

See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).

INDICATIONS FOR USE

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

CONTRAINDICATIONS

The use of the IRTS is contraindicated for patients who have:

- Symptomatic Esophageal Stricture
- Esophageal Diverticulum
- Esophageal Tumor or Abscess
- Recent Esophageal or Gastric Surgery

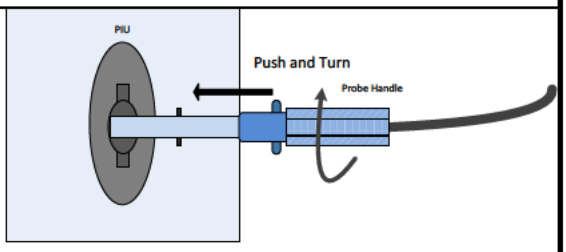
WARNINGS

- The Probe is single use only. Do not re-use. Cross-infection to patient may occur and the device may not function properly.
- Insert Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.
- Do not attempt to reposition Probe while imaging. To reposition always hit “Stop” and wait for the button message “Start Imaging”.
- The Securus IRTS is to be installed and serviced exclusively by Securus technicians. Do not attempt to install, repair, service, or operate the Securus IRTS in any fashion deviating from what is specified in this manual.
- Use system only within the indicated operating environment temperature and humidity range. Use outside the specified operating environment may result in inaccurate esophageal temperature readings.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- All electrical equipment supporting the patient must be appropriately grounded and must comply with all current regulations and must be of CF type.
- The use of accessories and cables other than those listed above may result in increased emissions or decreased immunity of the Securus IRTS.

CAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- See the IRTS Manual provided with Patient Interface Unit and Monitor to operate the system.
- The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.
- Only physicians trained in esophageal insertion and catheterization procedures should use the IRTS.
- Do not use the IRTS for any purpose other than its intended use.
- Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock.
- Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.
- Do not bend or kink the probe in a sharp angle or a small radius.
- The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
- Avoid touching the proximal tip of the Probe to avoid damaging the Probe.
- The Probe is provided fully assembled. Do not disassemble the Probe. Disassembly will damage the device.
- The system components will not function with equipment from other manufacturers.

Instructions for Use **Probe Placement**	
1.	The Probe is provided clean non-sterile. Remove Probe from package and visually inspect it for damage, kinks or broken components. Do not use the Probe if it appears damaged by shipping or handling. Always use gloves while handling the probe. **CAUTION:** Avoid touching the proximal tip of the Probe to avoid damaging the Probe. **CAUTION:** The TIP is provided fully assembled. Do not disassemble the TIP. Disassembly will damage the device **CAUTION:** The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
2.	Apply a water-soluble lubricant to the tip of the Probe as desired to aid in insertion.
3.	Insert the Probe into the patient (nasal or orally) and position in the esophagus under fluoroscopic X-Ray. **WARNING:** Insert the Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury. **CAUTION:** Do not bend or kink the probe in a sharp angle or a small radius.
4.	Verify the position of the Probe under fluoroscopic X-Ray. Reposition as required to achieve desired placement. **WARNING:** Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging".
5.	Insert the Probe handle into the PIU opening. Firmly push and turn (1/4 turn clockwise) to secure the Probe handle. A proper connection will be accompanied by an audible click as the connector seats in the PIU.
6.	Connect the thermocouple temperature connector (blue connector) to the PIU. Ensure that the connector is fully seated.
7.	Check the pathway of the Probe to ensure smooth and supported draping. Secure as needed with surgical tape to patient, bed or table to eliminate any movement that might dislodge or otherwise compromise the position of the Probe in the patient. Ensure that the probe is free of kinks or pinch points. **CAUTION:** Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device. **CAUTION:** Do not bend the Probe in a sharp angle or a small radius. Excessive bending may damage the Probe. **WARNING:** Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging".
8.	Single use device. Discard after use in accordance with institutional rules and regulations.



See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).

If you experience any problems with this product, you should immediately contact Securus at 216-445-4683

MATERIALS (patient contact components)

In Patient Contact	Material
Probe Shaft	Medical grade polyethylene tubing
Thermocouple Marker Band	Platinum Band

SYSTEM SPECIFICATIONS

Characteristic	Specification
Probe OD (patient contact)	9 Fr. (3 mm)
Probe length (exclude handle)	118 cm
Probe length overall	153 cm
Esophageal Temperature Accuracy (Thermocouple) Per ISO 80601-2-56:2009 requirements (applicable sections)	± 0.3°C
Esophageal Temperature Range (Thermocouple)	25°C - 45°C
Transient Response Time of Thermocouple for a 2°C temperature change	2.5 seconds for both heating and cooling from a reference water bath to a water bath with a 2°C temperature differential
Infrared Temperature Accuracy	± 2°C
Infrared Temperature Range	35°C - 60°C
Thermal Sensitivity	0.1°C within temp range
Operating Environment	Temperature Range 15°C to 35°C (59°F to 95°F) Relative Humidity 25 to 85%

STORAGE & USE

- Store in a cool, dry place and in a manner that protects the integrity of the device and packaging.
- The Probe is intended for single use only.
- Do not use if the package is damaged or opened.
- Do not use the device after the expiration date listed on the package label.
- Contact Customer Service if package has been opened or altered.
- Dispose of in compliance with all applicable local, state federal laws and regulations.

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).***

Manufactured and Distributed By:

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SYMBOLS KEY

REF	Catalog number		Manufacturer
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			Defibrillation – Proof Type CF Applied Part

ATTACHMENT E: SITED PUBLICATION

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Temperature Monitoring and Perioperative Thermoregulation

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Abstract

Most clinically available thermometers accurately report the temperature of whatever tissue is being measured. The difficulty is that no reliably core-temperature measuring sites are completely non-invasive and easy to use — especially in patients not having general anesthesia. Nonetheless, temperature can be reliably measured in most patients. Body temperature should be measured in patients having general anesthesia exceeding 30 minutes in duration, and in patients having major operations under neuraxial anesthesia.

Core body temperature is normally tightly regulated. All general anesthetics produce a profound dose-dependent reduction in the core temperature triggering cold defenses including arterio-venous shunt vasoconstriction and shivering. Anesthetic-induced impairment of normal thermoregulatory control, and the resulting core-to-peripheral redistribution of body heat, is the primary cause of hypothermia in most patients. Neuraxial anesthesia also impairs thermoregulatory control, although to a lesser extant than general anesthesia. Prolonged epidural analgesia is associated with hyperthermia whose cause remains unknown.

In previous articles, I've reviewed heat balance in surgical patients,[1] complications associated with perioperative thermal perturbations,[2] and the etiology and treatments of postoperative shivering.[3] Heier and Caldwell have reviewed the effects of hypothermia on the response to neuromuscular blocking drugs.[4] Furthermore, an entire book is devoted to the emerging field of therapeutic hypothermia.[5] In this article, I will belatedly review temperature monitoring and the effects of general and regional anesthesia on thermoregulatory control.

Surgery typically involves exposure to a cold environment, administration of unwarmed intravenous fluids, and evaporation from within surgical incisions. However, these factors alone would not usually cause hypothermia; instead, thermoregulatory defenses would normally maintain core temperature in the face of comparable environmental stress. That hypothermia is typical in unwarmed surgical patients reflects a failure of effective thermoregulatory defenses. Understanding the effects of anesthetics on normal thermoregulatory control is thus the key to perioperative thermal perturbations because ineffective thermoregulation — much more than cold exposure — underlies most temperature changes observed in surgical patients.

I will first briefly review temperature monitoring and normal thermoregulation, and then discuss the effects of general and neuraxial anesthesia on temperature control.

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Dr. Sessler has consulted for MGI Pharma (Bloomington, Minnesota), Cardinal Health (McGraw Park, Illinois), and Johnson and Johnson (Newark, New Jersey).

Summary statement: This article reviews perioperative temperature monitoring and the effects of anesthetic drugs on body temperature control.

Temperature Monitoring

Body temperature is not homogeneous: deep thoracic, abdominal, and central nervous system (i.e., core) temperatures usually range from 2 to 4°C cooler than the arms and legs — and much of the skin surface is cooler yet. Unlike core temperature, which is tightly regulated, skin temperature varies markedly as a function of environmental exposure; temperature of peripheral tissues (mostly the arms and legs) depends on current exposure, exposure history, core temperature, and thermoregulatory vasomotion. Core temperature, while by no means completely characterizing body heat content and distribution, is the best single indicator of thermal status in humans.

Core temperature monitoring (*e.g.*, tympanic membrane, pulmonary artery, distal esophagus, and nasopharynx) is used to monitor intraoperative hypothermia, prevent overheating, and facilitate detection of malignant hyperthermia. Because these sites are not necessarily available or convenient, a variety of “near-core” sites are also used clinically. These include the mouth, axilla, bladder, rectum, and skin surface. Each has distinct limitations but can be used clinically in appropriate circumstances.

What level of accuracy is clinically necessary has yet to be established. But a good rule-of-thumb, one that has been used in many studies, is that the combined inaccuracy of a site/thermometer combination should not exceed 0.5°C. One basis for this choice is that it is the smallest difference that has been shown to be associated with hypothermia-induced complications.[6]

Muscle or skin-surface temperatures may be used to evaluate vasomotion[7] and assure validity of peripheral neuromuscular monitoring.[4] Muscle temperatures are also used to determine peripheral compartment temperatures and regional distribution of body heat.[8-10] Both core and mean skin-surface temperature measurements are required to determine the thermoregulatory effects of different anesthetic drugs[11] and estimate mean-body temperature.[12]

Thermometers

Mercury-in-glass thermometers are slow and cumbersome, and spilt mercury is a biohazard; they have thus all but disappeared from clinical use — although they remain useful for laboratory calibration of other systems. The most common electronic thermometers are thermistors and thermocouples. Thermistors are temperature-sensitive semi-conductors, whereas thermocouples depend on the tiny current generated when dissimilar metals are joined. Both devices are sufficiently accurate for clinical use and inexpensive enough to be disposable. However, the signals from each are inherently non-linear and thus need to be linearized by calibrated compensating units.

Infrared sensors are another type of thermometer that has become popular in the last decade. They work by evaluating infrared energy that is emitted by all surfaces above absolute zero degrees. They can consequently be used without actually touching the surface in question (which is useful for measuring the temperature of molten lava or metals, for example). These thermometers are accurate and relatively inexpensive. Clinical models can measure temperature of the skin surface to within a tenth of a degree or so. When infrared signals are actually obtained from the tympanic membrane, the result is core temperature.[13,14] However, nearly all available systems are intentionally too large to even fit more than a few mm into the aural canal and do not “see” anywhere near the tympanic membrane. As normally used, that is directed into the aural canal[15] or near the temporal artery,[16] infrared systems are insufficiently accurate for clinical use (fig. 1). In light of their poor performance, it seems unfortunate that they have become so popular.

An interesting method of measuring core temperature from the surface of the skin is to use a system originally proposed by Fox[17,18] and refined by Togawa.[19] The technique is to combine a heater with a thermal flux transducer (which is, effectively, two thermometers separated by a known thermal insulator). The heater is then servo-controlled until flux is zero. At this point, heat and skin temperature are, by definition, equal since there would otherwise be a flow of heat. However, the same logic suggests that there is no flow of heat from skin to deeper tissues; otherwise, heat would accumulate, which would violate the Second Law of Thermodynamics. This logic is not quite accurate since it ignores blood-borne lateral convection of heat. But in practice, these thermometers accurately determine the temperature of tissues to about a centimeter below the skin surface. In many parts of the body, notably the chest and forehead, a centimeter is sufficient to approximate core temperature (fig. 2).[20] Unfortunately, these otherwise excellent monitors are not currently available in Europe or the United States.

When Temperature Monitoring Is Required

Core temperature monitoring is appropriate during most general anesthetics both to facilitate detection of malignant hyperthermia and to quantify hyperthermia and hypothermia. Malignant hyperthermia is best detected by tachycardia and an increase in end-tidal PCO_2 out of proportion to minute ventilation.[21] Although increasing core temperature is not the first sign of acute malignant hyperthermia, it certainly helps confirm the diagnosis. More common than malignant hyperthermia is intraoperative hyperthermia having other etiologies including excessive warming, infectious fever, blood in the fourth cerebral ventricle, and mismatched blood transfusions. Because hyperthermia has so many serious etiologies, any perioperative hyperthermia requires diagnostic attention.

By far the most common perioperative thermal disturbance is inadvertent hypothermia. Prospective, randomized trials have shown that even mild hypothermia causes numerous adverse outcomes in a variety of patient populations. Hypothermia-induced complications include morbid myocardial outcomes[22] secondary to sympathetic nervous system activation,[23] surgical wound infection,[24,25] coagulopathy[6,26-33] increased allogeneic transfusions,[6,24,26,27,31,33-37] negative nitrogen balance,[38] delayed wound healing,[24] delayed post-anesthetic recovery,[39] prolonged hospitalization,[24] shivering,[40] and patient discomfort.[41]

The major cause of hypothermia in most patients given general anesthesia is an internal core-to-peripheral redistribution of body heat that usually reduces core temperature by 0.5 to 1.5° C in the first 30 minutes following induction of anesthesia. Hypothermia results from internal redistribution of heat and a variety of other factors whose importance in individual patients is hard to predict.[9] Core temperature perturbations during the first 30 minutes of anesthesia thus are difficult to interpret and measurements not usually required. Body temperature should, however, be monitored in most patients undergoing general anesthesia exceeding 30 minutes in duration and in all patients whose surgery lasts longer than one hour. Measuring body temperature (and maintaining normothermia) is now essentially the standard-of-care during prolonged general anesthesia, especially for large operations where the risk of hypothermia is substantial.

Hypothermia, resulting largely from core-to-peripheral redistribution of body heat,[8] is as common during epidural and spinal anesthesia as it is during general anesthesia, and can be nearly as severe.[42] Because neuraxial anesthesia impairs behavioral thermoregulatory responses (i.e., patient sensation of cold),[43] patients and physicians are both frequently unaware that hypothermia has developed (fig. 3).[42] Core temperature should therefore be measured during regional anesthesia in patients likely to become hypothermic, including those undergoing body cavity surgery — although temperature monitoring during neuraxial anesthesia remains relatively uncommon.[44,45]

Monitoring sites

The core thermal compartment is composed of highly perfused tissues whose temperature is uniform and high compared with the rest of the body. Temperature in this compartment can be evaluated in the pulmonary artery, distal esophagus, tympanic membrane, or nasopharynx.[46,47] Even during rapid thermal perturbations (*e.g.*, cardiopulmonary bypass), these temperature-monitoring sites remain reliable — although there may be transient real differences among them.

Temperature probes incorporated into esophageal stethoscopes must be positioned at the point of maximal heart sounds, or even more distally, to provide accurate readings.[48] Modern tympanic thermocouples are soft and pliable. There is thus little if any risk of perforating the membrane, although it is possible to push a bolus of wax onto the tympanic membrane. Inserting tympanic probes is somewhat more difficult than it sounds, especially in conscious subjects, because the aural canal is several cm long and is not straight. The difficulty is that subjects and people inserting the probes often mistake the bend in the canal for the tympanic membrane and thus do not position the probes on the membrane itself. Once properly positioned, it is helpful to occlude the aural canal with wool to prevent air currents from cooling the thermocouple. Nasopharyngeal probes should be inserted at least a few cm past the nares to obtain core temperature; nasopharyngeal temperature are probably only accurate in patients who are not breathing through their nostrils.

Core temperature can be estimated with reasonable accuracy using oral, axillary, and bladder temperatures except during extreme thermal perturbations.[46,47] Each of these sites is subject to artifact so clinicians should use reasonable judgment in selecting a monitoring site (and type of thermometer) for a given patient. For example, oral temperatures can be inaccurate in patients who breathe through their mouths or have recently ingested hot or cold liquids. Axillary temperatures are reasonably accurate,[49] but work best when the probe is positioned over the axillary artery and the arm is kept at the patient's side. Differences in technique may explain reported differences in accuracy.[50]

Skin-surface temperatures are considerably lower than core temperature[51]; forehead skin temperature, for example, is typically 2°C cooler than core. Perhaps surprisingly, even the intense vasodilation associated with sweating and the intense vasoconstriction associated with shivering only slightly alter the core-to-forehead temperature gradient (fig. 4).[52] Skin temperature is determined by the balance of heat provided by subcutaneous tissues and heat lost to the environment. Dissipation of heat from the skin surface, mostly by radiation and convection, depends on ambient temperature. While each type of heat loss is controlled by different equations, most of which are highly non-linear, cutaneous heat loss is approximately linear over small ranges of ambient temperature. The 1−2°C ambient temperature differences usually observed during surgery thus have little effect on the core-to-forehead temperature gradient (fig. 5).[52] Forehead skin temperature is thus a surprisingly accurate measure of core temperature so long as a +2°C compensation is included.

A special case of skin-temperature monitoring is temporal artery thermometers. These are infrared skin-surface thermometers that record skin temperature at approximately 10 Hz and detect the highest temperature as the device is scanned across the forehead, including the region of the temporal artery. The theory is that the blood in the temporal artery is near core temperature and, therefore, that supervening skin temperature will also approximate core temperature. While the theory is attractive, the devices are much too inaccurate for clinical use.[16,53]

A distinct limitation of skin temperatures is that they fail to reliably confirm the clinical signs of malignant hyperthermia (tachycardia and hypercarbia) in swine (fig. 6)[54] and have not been

evaluated for this purpose in humans. Rectal temperature also normally correlates well with core temperature,[46,47] but fails to increase appropriately during malignant hyperthermia crises[54] and under other documented situations including heat stroke.[55,56] Consequently, rectal and skin-surface temperatures must be used with considerable caution.

The four core temperature monitoring sites (*e.g.*, tympanic membrane, nasopharynx, pulmonary artery, and esophagus) remain useful even during cardiopulmonary bypass. In contrast, rectal temperatures lag behind those measured in core sites. Consequently, rectal temperature is considered an "intermediate" temperature in deliberately cooled patients. During cardiac surgery, bladder temperature is equal to rectal temperature (and therefore intermediate) when urine flow is low, but equal to pulmonary artery temperature (and thus core) when flow is high.[57] Because bladder temperature is strongly influenced by urine flow, it may be difficult to interpret in these patients. The adequacy of rewarming is best evaluated by considering both "core" and "intermediate" temperatures.

Mean-skin Temperature—Mean-skin temperature is the area-weighted average temperature of the skin surface. Mean-skin temperature, while less important than core temperature, is nonetheless important for at least three reasons: 1) cutaneous heat loss is a function of mean-skin and ambient temperatures; 2) central thermoregulatory control is determined by a combination of core and mean-skin temperatures; and 3) the combination of core and mean-skin temperatures can be used to estimate mean-body temperature and, therefore, body heat content.

Unsurprisingly, the accuracy of mean-skin temperature measurements increases with the number of measurement sites. Thus, 15 or more sites are usually used in thermoregulatory studies. For example, the following sites and regional weightings have been used in a hundred or more studies: head—6%, upper arms—9%, forearms—6%, hands—2.5%, fingers—2%, back— 19%, chest—9.5%, abdomen—9.5%, medial thigh—6%, lateral thigh—6%, posterior thigh—7%, anterior calves—7.5%, posterior calves—4%, feet—4%, and toes—2%.[58] This large number of measurement sites results in accurate measurements even in the context of regional thermal manipulations (active heating or cooling) and when different amounts of insulation are used in various areas.

When thermal management (insulation or active heating or cooling) is uniformly distributed over the entire body, simpler formulae can be used without great loss of accuracy. A formula with only four sites was developed by Ramanathan in 1964 and remains in common use [59]: Mean-skin temperature = 0.3(chest + upper arm) + 0.2(thigh + calf)].

Mean-body Temperature—Changes in mean-body temperature over time can be determined by integrating the difference between metabolic heat production (oxygen consumption) and cutaneous heat loss (measured with thermal flux transducers). Mean-body temperature can also be approximated as the mass-weighted sum of regional temperature distributions, which can be determined by integration of radial temperature distributions.[60] However, the technique is invasive and the computations tedious. Its use is consequently restricted to controlled studies in laboratories possessing the necessary equipment.[61]

In 1935 Burton[62] cleverly proposed that mean-body temperature (MBT) could be calculated from a formula: $MBT = a \cdot T_{Core} + (1–a) \cdot T_{Skin}$. The general form of the equation was based on the logic that core tissues are relatively homogeneous, whereas tissue temperature in the peripheral decreases parabolically from core temperature to skin temperature. The value of a, the coefficient describing the contribution of core temperature to mean-body temperature, was then estimated by simultaneously measuring the change in body heat content (in a calorimeter),

core temperature, and mean-skin temperature. The resulting value of the coefficient alpha was 0.64, thus giving the formula: $MBT = 0.64 \cdot T_{Core} + 0.36 \cdot T_{Skin.}$

A similar approach has been used by others, including Hardy and DuBois,[63] who proposed a coefficient, a, of 0.7 for a neutral environment; Stolwijk and Hardy,[64] who proposed a coefficient of 0.7 for a hot environment; and Snellen,[65] who found the coefficient to be ≈0.8 during muscular work in a hot environment. Subsequently, Colin et al.[66] showed in an elegant study that Burton's coefficient was correct for a neutral environment, but that the coefficient increased to 0.79 in an extremely warm environment.

Given all the assumptions about distribution of heat within the body that are necessary to estimate mean-body temperature from core and skin temperatures, it would be surprising if a simple formula based on core and mean-skin temperatures were sufficient. But remarkably, it is. Even during cardiopulmonary bypass, the formula of Colin et al.[66] estimates mean-body temperature reasonably well (fig. 7).

Normal Thermoregulation

Normal Body Temperature Regulation

Body temperature is normally tightly regulated, more so even than blood pressure or heart rate. The control system is complex and involves parallel positive- and negative-feedback systems that are so widely distributed that nearly every part of the autonomic nervous system participates to some extent.

As early as 1912, physiologists recognized that the hypothalamus is the dominant thermoregulatory site in mammals because control was markedly compromised by injury or destruction of the hypothalamus. (The spinal cord serves this function in birds.) Interestingly, it took nearly another half-century before the importance of thermal input from the skin was appreciated. It is now known that thermal signals from a variety of tissues and structures contribute thermal signals to the hypothalamus, and that there is considerable pre-processing of thermal information on the way from peripheral to central tissues.[67] Thus, thermoregulation is based on multiple, redundant signals from nearly every type of tissue. The processing of thermoregulatory information occurs in three phases: *afferent thermal sensing*, *central regulation*, and *efferent responses*.

Afferent Input—While all physiologic processes are, to some extent, temperature dependent, specific cells are markedly activated or inhibited by thermal perturbations. The assumption is that these cells are temperature sensors, and they are referred to as warm- or cold-sensing cells. Cold receptors, for example, increase their activity as tissue cools, whereas the reverse is true for heat-sensors.

Because of its accessibility, cutaneous thermoreception is relatively well understood. (See monograph by Hensel for details).[68] Human skin is phenomenally sensitive to temperature: An increase in forehead temperature of as little as 0.003°C can be detected! Apparent skin temperature and, more importantly, the ability to influence thermoregulatory responses is not uniform across the skin surface. The face is approximately five times as sensitive as other areas. Furthermore, sensitivity at differing sites depends somewhat on whether the skin is being warmed or cooled. The skin is far more sensitive to rapid thermal perturbations than to those occurring slowly. Similarly, the static skin temperature contributes less to thermoregulatory responses than even small changes.

Cold signals from the skin travel primarily *via* A∂ nerve fibers whereas warm signals are transduced by unmyelinated C fibers.[69] Until recently, little was know about how A∂ and C

fibers actually detect cutaneous temperature. However, it now appears that Transient Receptor Potential (TRP) vanilloid (V) and menthol (M) receptors may be the fundamental temperature sensing elements both in skin and the dorsal root ganglia. These receptors, which have only been well characterized in recent years, are a family notable for having unusually high temperature sensitivity. Most change their activity by more than a factor-of-ten over a 10°C range (Q10 > 10). TRPV1−4 receptors are heat activated, whereas TRPM8 and TRPA1 are activated by cold.[70,71]

Most ascending thermal information traverses the spino-thalamic tracts in the anterior spinal cord, but no single spinal tract is critical for conveying thermal information. Recently, for example, an afferent somatosensory pathway via lateral parabrachial neurons has been shown to transmit signals directly to the preoptic thermoregulatory control center.[72] Consequently, the entire anterior cord must be destroyed to ablate thermoregulatory responses. The hypothalamus, other parts of the brain, the spinal cord, deep abdominal and thoracic tissues, and the skin surface each contribute roughly 20 percent of the total thermal input to the central regulatory system.[73,74] Hence although the hypothalamus is the dominant and most precise thermoregulatory controller, its temperature *per se* is not especially important.

Central Control—The simplest thermoregulatory model is the "set-point" system in which all thermoregulatory responses are simultaneously turned on or off in response to hypothalamic temperature. This model is known to be an inadequate representation of the thermoregulatory system because: 1) responses are determined by thermal input from nearly every portion of the body; 2) responses do not occur simultaneously or at similar temperatures; 3) the model does not incorporate a "null zone" in which no thermoregulatory responses occur; and 4) this model cannot explain thermal adaptation and a host of other observed phenomena.

The General Thermoregulatory Model—Consequently, I will review here a model which is somewhat more complicated, but considerably more useful. As with all models, this should be considered a framework from which to analyze thermoregulatory responses, not an actual mechanism by which the body produces those responses. In this model, thermal input from tissues throughout the body are integrated at a variety of centers (including the spinal cord and brain stem), but most importantly the hypothalamus. Individual responses are coordinated on the basis of weighted averages of the diverse inputs.

Temperature is regulated by central structures that compare integrated thermal inputs from the skin surface, neuraxis, and deep tissues with *thresholds* (triggering core temperatures) for each thermoregulatory response. Control is distributed in the sense that thermal input is integrated at various levels within the neuraxis, but the dominant controller in mammals is the hypothalamus, with autonomic control being centered in the anterior hypothalamus and behavioral control being centered in the posterior hypothalamus. This hierarchical arrangement presumably developed when the evolving thermoregulatory control system co-opted previously existing mechanisms.[67] For example, muscles used for shivering were probably developed for posture and locomotion; similarly, thermoregulatory vasomotion is probably an offshoot of systems originally developed for hemodynamic control. It is likely that some thermoregulatory responses can be mounted by the spinal cord alone.[74] For example, animals and patients with high spinal-cord transections regulate temperature much worse than normal — but are not poikilothermic.

The slope of response intensity versus core temperature defines the *gain* of a thermoregulatory response. The *maximum intensity* of the response is defined as when response intensity no longer increases with further deviation in core temperature. Figure 8, for example, shows the normal sweating response as a function of distal esophageal core temperature during surface warming. There is only background insensible water loss from the skin without anesthesia until

the threshold is reached at a core temperature of 36.5°C. The sweating rate then increases quickly as core temperature increases an additional 0.5°C (gain), but remains essentially constant with further hypothermia (maximum response intensity). Although the threshold increases as a function of isoflurane concentration, the gain and maximum intensity remain similar during anesthesia.[75]

Control of autonomic responses is approximately 80 percent determined by thermal input from core structures[76,77] and remains similar during anesthesia (fig. 9). In contrast, fully half of the input controlling behavioral responses is derived from the skin surface.[78]

Humans apparently measure temperature to great precision, but nonetheless tolerate an interthreshold range over which autonomic responses are not activated. This range of temperatures thus defines normal core temperature under given circumstances (*i.e.*, time of day, menstrual phase). Normal core temperatures in humans typically range from 36.5°C to 37.5°C; values <36°C or >38°C usually indicate loss of control or a thermal environment so extreme that it overcomes thermoregulatory defenses.

Thermoregulatory modeling is thus complicated by interactions with other regulatory responses (*i.e.*, vascular volume control) and time-dependent effects. An area of continuing interest to physiologists is how humans handle environmental stress that would normally provoke opposing compensations. Heat stroke, for example, often results from dehydration in an excessively hot environment. Dehydration would normally activate water-retention mechanisms whereas hyperthermia normally provokes sweating. Heat stroke, in fact, usually develops because the body cannot simultaneously compensate effectively for both perturbations.

Most thermoregulatory models (including the one described above) do not adequately account for the rate at which central and peripheral temperatures change. Consequently, they should be applied to vigorously dynamic situations with caution. Similarly, at least under some circumstances thermoregulatory responses are not determined only by instantaneous thermal inputs, but instead reflect the recent history of thermal perturbations. The extent to which time- and temperature-dependent factors contribute to human thermoregulatory responses remains unclear.

Thresholds—How the body determines absolute threshold temperatures is incompletely understood, but appears to involve inhibitory postsynaptic potentials in hypothalamic neurons[79] that are modulated by norepinephrine, dopamine, 5-hydroxytryptamine, acetylcholine, prostaglandin E_1, and neuropeptides. The thresholds vary daily by 0.5−1°C in both sexes (circadian rhythm)[80] and by ≈ 0.5°C with menstrual cycles in women[81]. Exercise, nutrition, infection, hypo- and hyperthyroidism, drugs (including alcohol, sedatives, and nicotine), and cold- and warm-adaptation all alter threshold temperatures. But each of these effects is small compared to the profound impairment induced by general anesthesia.

The *interthreshold range* (core temperatures *not* triggering autonomic thermoregulatory responses) is bounded by the sweating threshold at its upper end and by the vasoconstriction threshold at the lower end. Within this range, temperatures are presumably sensed accurately but do not trigger regulatory responses. Teleologically, sacrificing a small degree of temperature regulation is prudent because energy and nutrients are not wasted aggressively combating small environmental changes. Some animals such as camels and desert rats use this strategy extensively, allowing body temperature to change up to 10 C during a 24-hour period.

The interthreshold range is usually only 0.2−0.4°C in humans,[82] and that range defines normal body temperature. For unclear reasons, control is only half as tight at the circadian nadir near

3:00 AM (fig. 10).[80] Because energy cost and nutrients are conserved without excessive autonomic control or evaporative water loss within the interthreshold range, some animals such as camels and desert rats maintain a wide interthreshold range, allowing core temperature changes up to 10°C each day. However, this is very much the exception and most mammals tightly control core temperature.

Both sweating and vasoconstriction thresholds are 0.3−0.5°C higher in women than men, even during the follicular phase of the menstrual cycle (*i.e.*, first ten days).[75] Differences are even greater during the luteal phase.[83] Central thermoregulatory control is apparently intact even in slightly pre-mature infants,[84] but is presumably immature in less-developed infants such as those weighing less than a kilogram. The shivering threshold is well maintained in some elderly subjects well into their 9th decade, whereas others that age regulate poorly; regulation though appears consistently normal in people aged less than 80 years.[85]

Efferent Responses—Some thermoregulatory responses are rarely, if ever, activated except by thermal perturbations. Such responses include sweating, peripheral cutaneous vasoconstriction, and brown fat metabolism. In other cases, the thermoregulatory system has co-opted effector mechanisms developed for other purposes including shivering (postural and locomotive muscular activity) and vasomotion (blood pressure and osmotic control). Adaptation of preexisting systems for thermoregulatory control is consistent with the hierarchical thermoregulatory model proposed by Satinoff,[67] and may explain why thermoregulatory control is so widely disbursed.

Thermal perturbations, (defined by body temperature difference from a specific threshold) triggers effector responses that actually mediate appropriate increases in environmental heat loss or increases in metabolic heat production. Each response has its own threshold and gain. The control system is thus able to activate responses in an efficient order (i.e., vasoconstriction before shivering which is metabolically costly) and only to the extent actually necessary to maintain core temperature.

Behavioral Regulation—Behavioral regulation (intentional manipulation of heat exchange with the environment) is the most powerful thermoregulatory effector. It is such modification that allows humans to live in the warmest and coldest climates on earth. Animals also use behavioral modification to alter heat balance with the environment. Behavioral regulation is most dramatic in reptiles and amphibians. These animals, often referred to as “cold-blooded,” actually regulate their temperatures remarkably well and even develop behavioral “fever.”[86] Given access to a reasonable range of environmental temperatures, they will position themselves to maintain a central temperature within a few degrees of “normal.” Interestingly, the temperatures maintained as optimal by most reptiles is similar to that in mammals, near 37 C. Similarly, fish provided with a thermal gradient will position themselves to maintain a nearly constant central temperature.[87] One investigator was even able to train a goldfish to maintain his water (and therefore body) temperature nearly constant by pushing a button![88] Even bacteria, given an opportunity, will position themselves to maintain optimal temperature.

Aggressive behavioral modification of environmental heat loss is not necessary in mammals exposed to reasonable environments. This has the evolutionary advantage of maintaining a nearly constant central temperature (presumably necessary for optimal enzyme function) without requiring behavioral modifications that might compromise survival. Nonetheless, when autonomic thermoregulatory responses are insufficient for maintaining central temperature, behavioral responses become critical for survival. Behavioral adaptations take many forms, but most commonly involve simple maneuvers such as moving from direct sun into shade, dressing more warmly, or altering ambient temperature using a heating/air conditioning system. Behavioral responses require a conscious perception of body temperature.

Intriguingly, humans appear to poorly sense changes in central temperature; in contrast, minute changes in skin-surface temperature are easily perceived. Thus, behavioral thermoregulation is about half mediated by skin temperature[78] whereas mean-skin temperature contributes only 10−20% to the control of autonomic thermoregulatory defenses.[76,89]

Vasomotion—Most metabolic heat is lost from the skin surface and cutaneous and vasoconstriction, the most consistently used autonomic effector mechanism, reduces this loss. Total digital skin blood flow is divided into nutritional (mostly capillary) and thermoregulatory (mostly arterio-venous shunt) components.[90] Shunts are typically 100 μm in diameter, which means that one shunt can convey 10,000-fold as much blood as a comparable length of capillary 10-μm in diameter. Arterio-venous shunt flow tends to be “on” or “off” which is simply a way of saying that the gain of this response is high. Roughly 10 percent of cardiac output traverses arterio-venous shunts; consequently, shunt vasoconstriction increases mean arterial pressure ≈15 mmHg.[91]

Arterio-venous shunts are located only in acral regions (fingers, toes, nose, *etc*.). These specialized thermoregulatory vessels are under alpha adrenergic control and are constricted by norepinephrine released from sympathetic nerves. Circulating factors appear to have little direct influence on arterio-venus shunts, although hormones such as angiotensin are known to facilitate the response to a given sympathetic stimulus. Most blood vessels constrict in response to local hypothermia, but arterio-venus shunts are relatively resistant regional temperature perturbations and appear to be almost exclusively controlled by central thermoregulatory status. In a thermoneutral environment (*e.g.*, body temperature within the interthreshold range) or in a denervated extremity, arterio-venus shunts are fully dilated. However, at typical ambient temperatures tonic sympathetic stimulation maintains minimal shunt flow.

Non-shivering Thermogenesis—Non-shivering thermogenesis is defined as an increase in metabolic heat production not associated with muscular activity. This increase occurs largely in specialized fat called brown adipose tissue located largely in the intrascapular and perirenal areas. Brown fat has a dark hue because it is loaded with mitochondria. When stimulated, this tissue has by far the highest metabolic rate of any organ (up to 0.5 W/g). Ordinarily, mitochondrial metabolism produces a proton which is secreted outside the sarcoplasmic reticulum. The proton gradient across this membrane subsequently activates the sodium-potassium ATPase, producing ATP from ADP. When stimulated by norepinephrine released from sympathetic nerves, mitochondrial respiration in brown ATPase tissue proceeds normally. However, production of ATP is prevented by an “uncoupling protein” which allow protons to reenter the sarcoplasmic reticulum without driving the sodium-potassium ATPase.[92]

Nonshivering thermogenesis is the primary defense against cold in small mammalian species such as mice and rats, and can easily double or triple metabolic heat production (measured as whole-body oxygen consumption) without producing mechanical work. Nonshivering thermogenesis also doubles heat production in infants.[93] The intensity of nonshivering thermogenesis is a linear function of the difference between mean body temperature and its threshold.

But despite its importance in small animals and human infants, non-shivering thermogenesis is relatively unimportant or non existent in species having a relatively large body size (*i.e.*, greater than fifty kg). In adult humans, non-shivering thermogenesis is poorly developed[94] and contributes little to thermal balance in adult humans.

Shivering—Sustained shivering augments metabolic heat production 50 to 100 percent in adults. This increase is small compared with that produced by exercise (which can, at least

briefly, increase metabolism five-fold) and is, thus, surprisingly ineffective. Shivering is manifested as an irregular tremor which on electromyographic analysis consists of randomly overlapping myofibril depolarization spikes. Superimposed on this rapid and apparently disorganized local activity, is a 4 − 10 cycles/minute waxing-and-waning activity. Notably, this slow amplitude modulation is synchronous and occurs simultaneously in all muscles throughout the body.[95] Shivering does not occur in newborn infants and probably is not fully effective until children are several years old. Because the shivering threshold is a full degree less than the vasoconstriction threshold,[82] shivering appears to be a "last resort" response to extreme cold.

Sweating—Sweating is mediated by post-ganglionic, cholinergic nerves.[96] It thus is an active process that is prevented by nerve block or atropine administration.[97] Even untrained individuals can sweat up to one liter/hour, and athletes can sweat at twice that rate. Sweating is the only mechanism by which the body can dissipate heat in an environment exceeding core temperature. Fortunately, the process is remarkably effective: each gram of evaporated sweat dissipates 0.58 kcal. In a dry, convective environment, individuals can thus easily dissipate many times their basal metabolic rate which is very roughly a $kcal \cdot kg^{-1} \cdot h^{-1}$. Of course sweat which drips off the skin without evaporating contributes nothing to heat balance, but does promote dehydration.

During exercise, muscle blood flow increases enormously and blood pressure can only be maintained by vigorous vasoconstriction. Furthermore, exercise produces considerable heat which in most environments must be dissipated by increased capillary blood flow and sweating (a liter/hour or more). Both these thermoregulatory compensations compete with the needs of muscle for increased blood flow. Consequently, it is unsurprising that maximum capillary blood flow and sweating rate are impaired by insufficient vascular volume and cardiovascular compromise. In light of the huge cardiovascular stresses imposed by exercise and the thermoregulatory compensation for the attendant increase in metabolic heat production, it is remarkable that humans can perform vigorously in a warm environment and maintain a reasonable blood pressure.

In contrast to shunt flow, capillary blood flow is minimal both at typical ambient temperatures and at thermoneutral temperatures. During heat stress, active dilation of pre-capillary arterials increases capillary blood flow enormously. This dilation certainly involves withdrawal of tonic sympathetic stimulation but also likely involves release of the yet-to-be identified factor from sweat glands; the mediator may be nitric oxide or neuropeptide Y.[98] Because active vasodilation requires intact sweat gland function, it also is largely inhibited by nerve block. During extreme heat stress, blood flow through the top millimeter of skin can reach 7.5 liters/minute — equaling the entire resting cardiac output.[99] The threshold for active vasodilation usually is similar to the sweating threshold, but maximum cutaneous vasodilation usually is delayed until sweating intensity is at its maximum.

Response Activation Strategy—All potential thermoregulatory responses are ideally available and used in a specific order depending on their respective thresholds and response gains. However, one or more effectors may be disabled by circumstances. For example, social convention may restrict voluntary movement or the ability to seek a warmer or cooler environment. Or a muscle relaxant may prevent shivering or a vasodilator may restrict vasoconstriction. In such circumstances, remaining effectors compensate to the limit of their abilities. The result is that core temperature is usually nonetheless maintained, although the range of tolerated environments decreases.

Hyperthermia

Hyperthermia is a generic term simply indicating a core body temperature exceeding normal values. In contrast, fever is a regulated increase in the core temperature targeted by the thermoregulatory system. Hyperthermia can result from a variety of causes and, unlike perioperative hypothermia, usually requires diagnosis and often intervention.

Passive Hyperthermia and Excessive Heat Production—Passive intraoperative hyperthermia results from excessive patient heating and is most common in infants and children. Hyperthermia was common in the tropics, before air conditioning became routine, and was aggravated by the frequent use of atropine.[100] Passive hyperthermia, by definition, does not result from thermoregulatory intervention. Consequently, it can easily be treated by discontinuing active warming and removing excessive insulation.

The increase in body temperature during malignant hyperthermia results from an enormous increase in metabolic heat produced by both internal organs and skeletal muscles. Central thermoregulation presumably remains intact during acute crises, but efferent heat loss mechanisms may be compromised by intense peripheral vasoconstriction resulting from circulating catecholamine concentrations 20 times normal.[101]

Fever—Body temperature is minimally influenced by circulating factors such as thyroid hormones; instead it is normally maintained by neuronal systems. In contrast, fever is mediated by endogenous pyrogens which increase the thermoregulatory target temperature ("setpoint"). Endogenous pyrogens include interleukin-1, tumor necrosis factor, interferon alpha, endothelin-1, and macrophage inflammatory protein-1.[102,103] There is increasing evidence that vagal afferents mediate between systemic pyrogens and the hypothalamus[104], although several systems probably contribute.[105] Most endogenous pyrogens have peripheral actions (e.g., immune system activation) in addition to their central generating capabilities. The relative contributions of fever *per se* and the systemic action of endogenous pyrogens remains unclear; however, it appears that fever itself is an important immune defense.[106]

Fever is relatively rare during general anesthesia, considering how many patients presumably experience febrile stimuli, including surgical tissue injury. The reason intraoperative fever is rare is that volatile anesthetics per se inhibit expression of fever,[107] as do opioids.[108,109] Infection is by far the most common cause of fever. Such fevers may reflect pre-existing infection or result, for example, from urological manipulations. However, perioperative fever also occurs in response to mis-matched blood transfusions, blood in the fourth cerebral ventricle, drug toxicity, and allergic reactions.[110,111] Some degree of fever is also typical after surgery, and presumably results from the inflammatory response to surgery.[112] There is no evidence to support the common attribution of postoperative fever to atelectasis. Instead, the causes of fever are sufficiently diverse — and potentially serious — that physicians caring for febrile patients should consider potential etiologies.

Treatment of hyperthermia depends on the etiology; the critical distinction is between actively maintained fever and hyperthermia that results from excessive heating, inadequate dissipation of metabolic heat, or excessive heat production. A simple way to distinguish the etiologies is that patients with fever and increasing core temperature will have constricted, cold fingertips whereas those with other types of hyperthermia will be vasodilated and have warm fingertips. It is always appropriate to treat underlying causes, but non-febrile hyperthermia will also improve with cooling.

The first- and second-line treatments for fever are amelioration of the underlying cause and administration of anti-pyretic medications.[113] The first treatment strategy often fails because the etiology of fever remains either unknown or unresponsive. The second strategy also often

fails or is only partially effective, perhaps because some fever is mediated by mechanisms that bypass conventional anti-pyretics.[102] It is in these patients that third-line treatment is most likely to be implemented: active cooling. Active cooling of febrile patients is a natural response. However, it often fails to reduce core temperature — while simultaneously worsening the situation by triggering thermoregulatory defenses including intense discomfort, shivering, and autonomic nervous system activation.[114,115]

Active cooling should thus be used with considerable caution in febrile patients, with great attention to the metabolic and vasomotor consequences — to say nothing of the resulting thermal discomfort. Systems that directly cool the core[116-118] provoke less thermoregulatory stress than surface-based systems,[115] especially when intense core cooling is combined with gentle surface warming. A general clinical guideline is that cooling which maintains or decreases oxygen consumption is likely to be helpful[119], whereas an increasing metabolic rate indicates a potentially harmful activation of thermoregulatory responses.

Thermoregulation During General Anesthesia

Anesthetized patients cannot activate behavioral responses, leaving them to rely on autonomic defenses and external thermal management. All general anesthetics so far tested markedly impair normal autonomic thermoregulatory control. Anesthetic-induced impairment has a specific form: warm-response thresholds are elevated slightly, if at all, whereas cold-response thresholds are markedly reduced. Consequently, the interthreshold range increases ten-fold to approximately 2–4°C.[109,120-123] The gain and maximum intensity of some responses remain normal,[75] whereas general anesthesia reduces others.[124,125]

Response Thresholds

Propofol,[120] alfentanil,[109] dexmedetomidine,[121] isoflurane,[123] and desflurane[122] all increase the sweating threshold only slightly, if at all. Warm defenses are thus well preserved even during general anesthesia. A consequence is that inadvertent hyperthermia during forced-air warming is relatively rare because patients are usually able to dissipate excess heat into their dry, convective micro-environment. They are less protected against hyperthermia with the newer circulating-water garments that not only transfer more heat,[61] but are impervious to moisture, thus preventing evaporative heat loss.

Propofol,[120] alfentanil,[109] and dexmedetomidine,[121] produce a marked and linear decrease in the vasoconstriction and shivering thresholds. In contrast, isoflurane[123] and desflurane[122] decrease the cold-response thresholds non-linearly. Consequently, the volatile anesthetics inhibit vasoconstriction and shivering less than propofol at low concentrations, but more than propofol at typical anesthetic doses.

Interestingly, the normal approximately 1°C difference between the vasoconstriction and shivering thresholds is maintained even when patients are given sedatives or general anesthesia. That the relationship between these two thresholds is so precisely maintained under a large variety of circumstances suggests that both major autonomic cold defenses are similarly controlled, perhaps by an identical central regulator. The only exceptions to comparable control identified to date are nefopam[126] and meperidine, which reduces the shivering threshold twice as much as the vasoconstriction threshold[127] — explaining the drug's potent anti-shivering action.[128,129]

The dose-dependent response thresholds for four anesthetic drugs are shown in figure 11. These responses are characteristic of the drugs and drug combinations that have so far been tested. The combination of increased sweating thresholds and reduced vasoconstriction thresholds increases the interthreshold range ten-fold, from its normal value near 0.2−0.4°C to

approximately 2−4°C. Temperatures within this range do *not* trigger thermoregulatory defenses; by definition, patients are thus poikilothermic within this temperature range.

Halothane[130], enflurane,[131] and the combination of nitrous oxide and fentanyl[132] decrease the vasoconstriction threshold 2 − 4°C from its normal value near 37°C. The effects of these drugs on sweating or shivering remain unknown, but experience with other drugs suggests that they are unlikely to have much effect on sweating, but have a profound effect on shivering. Clonidine synchronously decreases cold-response thresholds,[133] while slightly increasing the sweating threshold.[134] Nitrous oxide decreases the vasoconstriction[135] and shivering[136] thresholds less than equi-potent concentrations of volatile anesthetics.

Midazolam, in typical clinical doses, minimally influences thermoregulatory control.[137, 138] Painful stimulation slightly increases vasoconstriction thresholds[131] just as pain has an anti-anesthetic effect[139] and regional anesthesia has a pro-anesthetic action.[140] Consequently, thresholds will be somewhat lower when surgical pain is prevented by simultaneous local or regional anesthesia. Both amino acid[141] and fructose[142] infusions increase the vasoconstriction threshold by ≈0.5°C.

The effects of vascular volume on thermoregulatory vasoconstriction have not been evaluated during anesthesia. But, positive end-expiratory pressure increases the vasoconstriction threshold while increasing central blood volume by leg raising reduces the threshold.[143] Baroreceptor unloading augments the peripheral vasoconstrictor and catecholamine response to core hypothermia while simultaneously reducing thermogenesis — which consequently aggravates hypothermia in the upright position. Upright posture attenuates the thermogenic response to core hypothermia but augments peripheral vasoconstriction. This divergent result suggests that input from the baroreceptor modifies the individual thermoregulatory efferent pathway at a site distal to the common thermoregulatory center or neural pathway.[144]

Gain and Maximum Response Intensity

Both the gain and maximum intensity of sweating remain normal during isoflurane (Fig. 8)[75] and enflurane anesthesia.[145] However, the gain of arterio-venous shunt vasoconstriction is reduced three-fold during desflurane anesthesia (fig. 12),[124] even though the maximum vasoconstriction intensity remains normal.[146] Volatile anesthetics thus not only markedly decrease the vasoconstriction threshold,[122,123] but once triggered, three times as much additional hypothermia as normal is required to reach maximum vasoconstriction. Fortunately, maximum intensity is finally reached and once reached, is effective, usually preventing further core hypothermia.[10]

Shivering is rare with surgical doses of general anesthesia, which is consistent with its threshold being roughly 1°C less than the vasoconstriction threshold.[109,120-123] The reason is that vasoconstriction is effective, constraining metabolic heat to the core thermal compartment, thus usually preventing additional hypothermia.[10] Consequently, it is rare even for unwarmed patients to become cold enough to induce shivering. Nonetheless, sufficient active cooling can induce shivering.

Gain and maximum shivering intensity remain normal during both meperidine and alfentanil administration.[147] Gain also remains nearly intact during nitrous oxide administration, although maximum intensity is reduced.[148] Isoflurane changes the macroscopic pattern of shivering to such an extent that it is no longer possible to easily determine gain. The drug does, however, reduce maximum shivering intensity.[125]

To sum up, sweating is the thermoregulatory defense that is best preserved during anesthesia. Not only is the threshold only slightly increased, but also the gain and maximum intensity are

well preserved. In contrast, the thresholds for vasoconstriction and shivering are markedly reduced, and furthermore, these responses are less effective than normal even after being activated.

It would be intuitive to conclude that surgical patients become hypothermic because they are minimally covered, exposed to a cold environment, washed with cold fluids that are allowed to evaporate, because surgery per se increases heat loss from within incisions, and because general anesthesia reduces metabolic rate. However, even the combination of all these factors would rarely produce hypothermia in subjects with intact thermoregulatory defenses. Anesthetic-induced thermoregulatory impairment is thus by far the most important cause of perioperative hypothermia.

Responses in Infants and the Elderly

As we have seen, thermoregulatory control is profoundly impaired by most any type of general anesthesia in adults, resulting in a large interthreshold range (i.e. 2−4°C) over which core temperature perturbations fail to trigger regulatory defenses. Thermoregulatory control is equally bad in anesthetized infants and children, but does not appear to be worse. For example, thermoregulatory vasoconstriction is comparably impaired in infants, children, and adults given isoflurane[149] or halothane[150] (fig. 13). In contrast, the vasoconstriction threshold is about 1°C less in patients aged 60−80 years than in those between 30 and 50 years old (fig. 14).[151,152] Infants are nonetheless at special risk of hypothermia because their large surface area-to-mass ratio increases the relative difference between heat loss to heat production.

Nonshivering thermogenesis does not occur in anesthetized adults,[153] which is hardly surprising since this response is not particularly important in unanesthetized adults.[94] In contrast to adult humans, nonshivering thermogenesis is an important thermoregulatory response in animals and human infants. However, nonshivering thermogenesis in animals is inhibited by volatile anesthetics,[154] and it fails to increase the metabolic rate in infants anesthetized with propofol.[155] It thus appears that nonshivering thermogenesis is relatively unimportant in perioperative patients and certainly has a small effect compared with the approximately 30% reduction in metabolic rate associated with general anesthesia.

Thermoregulation During Neuraxial Anesthesia

Central thermoregulatory control is slightly impaired by neuraxial anesthesia, but this is combined with reduced gain and maximum response intensity of shivering. Autonomic impairment is compounded by an impairment of behavioral regulation so that patients do not recognize that they are hypothermic. And finally, core temperature is not usually monitored during neuraxial anesthesia.

The result is that patients undergoing neuraxial anesthesia typically become hypothermic and do not sense the hypothermia. In addition, the anesthesiologist does not detect the hypothermia. This is problematic because there is little reason to believe that patients having neuraxial anesthesia are protected from the well-established complications of hypothermia.

Response Thresholds

Epidural[43,156] and spinal[156,157] anesthesia each decrease the thresholds triggering vasoconstriction and shivering (above the level of the block) about 0.6°C (fig. 15). Although the magnitude is less, the pattern of impairment is thus similar to that observed with general anesthetics and opioids, suggesting an alteration in central, rather than peripheral control seems most likely. The mechanism by which peripheral administration of local anesthesia impairs centrally mediated thermoregulation remains unknown, but is proportional to the number of spinal segments blocked (fig. 16).[158]

Reduced thresholds during neuraxial anesthesia does not result from recirculation of neuraxially administered local anesthetic because impairment is similar during epidural and spinal anesthesia,[43,156,157] although the amount and location of administered local anesthetic differs substantially. Furthermore, lidocaine administered intravenously in doses producing plasma concentrations similar to those occurring during epidural anesthesia has no thermoregulatory effect.[159] Finally, neuraxial administration of 2-chloroprocaine, a local anesthetic which has a plasma half life well under a minute, also impairs thermoregulatory control.[160]

Since neuraxial anesthesia prevents vasoconstriction and shivering in blocked regions, it is unsurprising that epidural anesthesia decreases the maximum intensity of shivering. However, epidural anesthesia also reduces the gain of shivering which suggests that the regulatory system is unable to compensate for lower body paralysis (fig. 17).[125] Thermoregulatory defenses, once triggered, are thus less effective than usual during regional anesthesia.

Sedative and analgesic medications all impair thermoregulatory control to some extent.[109, 127,137,161] Such inhibition may be severe when combined with the intrinsic impairment produced by regional anesthesia and other factors, including advanced age or pre-existing illness (fig. 18).[85]

Interestingly, core hypothermia during regional anesthesia may not trigger a perception of cold.[43,162] The reason is that thermal perception (behavioral regulation) is largely determined by skin rather than core temperature.[78] During regional anesthesia, core hypothermia is accompanied by a real increase in skin temperature. The paradoxical result is often a perception of continued or increased warmth, accompanied by autonomic thermoregulatory responses including shivering (fig. 19).[43,162]

Taken together, these data indicate that neuraxial anesthesia inhibits numerous aspects of thermoregulatory control. The vasoconstriction and shivering thresholds are reduced by regional anesthesia,[43,156-158,163] and further reduced by adjuvant drugs[109,137] and advanced age.[85] Even once triggered, the gain and maximum response intensity of shivering are about half normal.[164] Finally, behavioral thermoregulation is impaired.[162] The result is that cold-defenses are triggered at a lower temperature than normal during regional anesthesia, defenses are less effective once triggered, and patients frequently do not recognize that they are hypothermic. Because core-temperature monitoring remains rare during regional anesthesia,[44] substantial hypothermia often goes undetected in these patients.[42]

Shivering During Neuraxial Anesthesia

Shivering-like tremor is common during neuraxial anesthesia and has at least four potential etiologies: 1) normal thermoregulatory shivering in response to core hypothermia; 2) normal shivering in normothermic or even hyperthermic patients who are developing a fever; 3) direct stimulation of cold receptors in the neuraxis by injected local anesthetic; and, 4) non-thermoregulatory muscular activity that resembles thermoregulatory shivering. However, other etiologies remain possible. For example, a convincing cause has yet to be identified for the intense shivering that so often occurs immediately after induction of spinal or epidural anesthesia for cesarean delivery — well before core temperature has had time to decrease.

Most shivering associated with neuraxial anesthesia appears to be normal shivering, the expected response to hypothermia. And at least in volunteers given neuraxial anesthesia, shivering is always preceded by core hypothermia and vasoconstriction (above the level of the block).[43] Furthermore, electromyographic analysis indicates that the tremor has the 4−8 cycles/minute waxing-and-waning pattern that characterizes normal shivering.[160] Fever is defined by a regulated increase in thermoregulatory response thresholds and can thus provoke

shivering even in normothermic individuals. Nonetheless, perioperative fever is probably a relatively rare cause of shivering.

All mammals and birds have spinal thermoreceptors. There is thus the theoretical possibility that injection of relatively cool (i.e., ambient temperature) local anesthetic into the epidural space might provoke shivering by stimulating local temperature sensors. Consistent with this possibility, the incidence of shivering in pregnant women was reported to be greater when they are given refrigerated epidural anesthetic than when the anesthetic is warmed before injection.[165] However, epidural administration of large amounts of ice-cold saline does not trigger shivering in non-pregnant volunteers.[166] Furthermore, the incidence of shivering is comparable in volunteers[43] and non-pregnant patients[167] given warm or cold epidural anesthetic injections. These data indicate that temperature of injected local anesthetic rarely provokes shivering during major conduction anesthesia.

Not all shivering-like tremor is thermoregulatory. It is possible to detect low-intensity shivering-like muscular activity in both surgical patients[168] and during labor.[169] The cause of this muscular activity remains unknown, but it is associated with pain and may thus result from sympathetic nervous system activation.[170]

Since skin temperature contributes to control of thermoregulatory responses, shivering of any type can be treated by warming the skin surface.[171] This is why shivering so often stops in a matter of seconds after entering a warm room even though core temperature hasn't had time to change at all. However, the entire skin surface contributes 20% to thermoregulatory control[76,89] and the lower body contributes about 10%,[163] sentient skin warming is likely to only compensate for small reductions in core temperature. As might thus be expected, skin warming is only effective in a fraction of patients.

Most often, pharmacologic treatments will be required for moderate or severe shivering. The same drugs that are effective for shivering after general anesthesia can be used to treat shivering during neuraxial anesthesia: these include meperidine (25 mg, IV or epidurally),[172] clonidine (75 μg, IV),[173] ketanserin (10 mg, IV),[173] and magnesium sulfate (30 mg/kg, IV).[174]

Hyperthermia During Epidural Analgesia

Prolonged epidural analgesia for labor and delivery is occasionally associated with hyperthermia, typically to 38.5−39.5°C. Hyperthermia develops only in a sub-set of women.[175] Hyperthermia typically develops after at least five hours of labor, and then increases over time.[176-179] The clinical consequence of this hyperthermia is that women given epidural analgesia for labor are more often given antibiotics than in those treated conventionally, and their offspring are more commonly treated for sepsis.[177,180,181]

Although best studied and most concerning in the context of labor, the association between epidural analgesia and hyperthermia is by no means restricted to labor; it also occurs in non-pregnant post-operative patients.[182] It is thus apparent that this hyperthermia is not restricted to pregnancy and must have a more general etiology.

There are several potential explanations for hyperthermia during labor analgesia. For example, it could simply be passive hyperthermia resulting from excessive heat production and inadequate heat dissipation to the environment. Labor certainly involves muscular effort that increases metabolic rate; furthermore, maternal metabolism is already increased by the fetus. Nonetheless, maternal metabolic rate remains small compared with even gentle exercise which perhaps doubles metabolic rate, and does not provoke hyperthermia in any but the most extreme environments. There is not reason to believe that epidural analgesia per se alters whatever

increase in metabolic rate might normally accompany labor. And of course metabolic rate is near-normal in postoperative patients who also develop hyperthermia with epidural analgesia.

A dense epidural block would inhibit sweating, which is sympathetically mediated, in the blocked region; but epidural analgesia for labor does not normally produce a sufficiently dense block. Furthermore, in a relatively dry and cool hospital environment, patients could easily dissipate many times their basal metabolic rates just from the upper body. It thus seems unlikely that an imbalance between heat production and loss is the explanation for hyperthermia during labor analgesia. A corollary is that hyperthermia during labor analgesia is a regulated fever rather than simple passive hyperthermia.

Hyperthermia during labor could just be the normal febrile response to infection. “Fever work-ups” and antibiotic treatments are common responses to maternal hyperthermia, and some hyperthermia surely is infectious fever.[183] Nonetheless, typical epidural-associated hyperthermia seems unlikely to result from infection and the current consensus is that infection is rarely the cause.

Inflammation is a different matter, though. There are many potential sources of non-infectious inflammation in laboring patients, to say nothing of postoperative patients who obviously have injured tissues. For example, Dashe et al concluded: “Epidural analgesia is associated with intrapartum fever, but only in the presence of placental inflammation.”[184] It seems likely that inflammation provokes a regulated febrile response during labor (and in postoperative patients). Consistent with this theory, high-dose steroids — powerful antiinflammatory drugs — nearly eliminate fever during labor.[185] In contrast, acetaminophen did not prevent hyperthermia, although the drug is usually an effective antipyretic.[186] That prolonged labor is associated with a greater risk of hyperthermia is consistent with a longer period in which to develop inflammation, especially placental inflammation which is likely to release a variety of pyrogenic cytokines. And of course longer labor is associated with factors that promote inflammation.[187]

The difficulty is that epidural analgesia surely does not augment the general inflammatory response to labor or surgery. Nor does it increase the risk of fetal malposition or need for cesarean delivery.[188] It thus remains unclear why epidural analgesia augments the risk of hyperthermia during labor and in postoperative patients. The conventional assumption is that hyperthermia is somehow caused by the technique; although no even slightly convincing mechanism has been proposed.

It is worth remembering, though, that when hyperthermia during labor is studied, pain in the “control” patients is usually treated with opioids — which themselves blunts thermoregulatory defenses[109,127] and specifically attenuates fever.[108] Fever associated with infection or tissue injury might then be suppressed by low doses of opioids that are usually given to the “control” patients while being expressed normally in patients given epidural analgesia.[189] The extent to which this mechanism contributes remains to be determined, and the theory is controversial.[190] However, no convincing alternative explanation has been advanced.

Summary

Core temperature, while by no means completely characterizing body heat content and distribution, is the best single indicator of thermal status in humans. Core temperature can be accurately monitored at the tympanic membrane, pulmonary artery, distal esophagus, and nasopharynx. Under appropriate circumstances, core temperature can also be reliably estimated from the mouth, axilla, and bladder. In contrast, infrared aural canal (“tympanic”) and temporal artery systems are insufficiently accurate for clinical use.

Body temperature should be monitored in most patients undergoing general anesthesia exceeding 30 minutes in duration and in all patients whose surgery lasts longer than one hour. Measuring body temperature (and maintaining normothermia) is now the standard-of-care during prolonged general anesthesia, especially for large operations where the risk of hypothermia is substantial. Core temperature should also be measured during regional anesthesia in patients likely to become hypothermic, including those undergoing body cavity surgery.

The processing of thermoregulatory information occurs in three phases: *afferent thermal sensing*, *central regulation*, and *efferent responses*. Transient Receptor Potential (TRP) vanilloid (V) and menthol (M) receptors may be the fundamental temperature sensing elements. Most ascending thermal information traverses the spino-thalamic tracts in the anterior spinal cord, but no single spinal tract is critical for conveying thermal information. The hypothalamus, other parts of the brain, the spinal cord, deep abdominal and thoracic tissues, and the skin surface each contribute roughly a fifth of the total thermal input to the central regulatory system.

Temperature is regulated by central structures that compare integrated thermal inputs from the skin surface, neuraxis, and deep tissues with *thresholds* (triggering core temperatures) for each thermoregulatory response. The slope of response intensity versus core temperature defines the *gain* of a thermoregulatory response. The *maximum intensity* of the response is defined as when response intensity no longer increases with further deviation in core temperature. The *interthreshold range* (core temperatures *not* triggering autonomic thermoregulatory responses) is bounded by the sweating threshold at its upper end and by the vasoconstriction threshold at the lower end. The interthreshold range is usually only 0.2−0.4°C in humans, and that range defines normal body temperature.

Behavioral regulation is the most powerful thermoregulatory effector, and it is behavioral regulation that allows humans to tolerate extreme environments. However, surgical patients much largely depend on autonomic responses including sweating, vasoconstriction, and shivering. Among these defenses, vasoconstriction is the most important and accounts for most perioperative thermal perturbations.

Hyperthermia is any increase in core temperature; in contrast, fever is a regulated increase in the core temperature targeted by the thermoregulatory system. Fever is mediated by circulating endogenous pyrogens and is an active process. Hyperthermia can result from a variety of causes, many of which are serious including infection, mis-matched blood transfusion, allergic reactions, and malignant hyperthermia. Perioperative hyperthermia thus deserves a serious diagnostic effort, and often intervention.

General anesthetics and opioids have little influence on sweating, but profoundly reduce the vasoconstriction and shivering thresholds. The results is a 10−20-fold increase in the interthreshold range. In contrast, general anesthetics have relatively little effect on the gain and maximum intensity of thermoregulatory responses. It is thermoregulatory impairment not — as one might assume — exposure to a cool operating room environment that causes most perioperative thermal perturbations. Thermoregulatory defenses are reasonably well maintained in infants and children, but somewhat impaired in the elderly.

Central thermoregulatory control is slightly impaired by neuraxial anesthesia, but this is combined with reduced gain and maximum response intensity of shivering. Autonomic impairment is compounded by an impairment of behavioral regulation so that patients do not recognize that they are hypothermic. The result is that patients undergoing neuraxial anesthesia typically become hypothermic and do not sense the hypothermia. Temperature should thus be measured in patients having major surgery under regional anesthesia, and they should be actively warmed as necessary to maintain normothermia.

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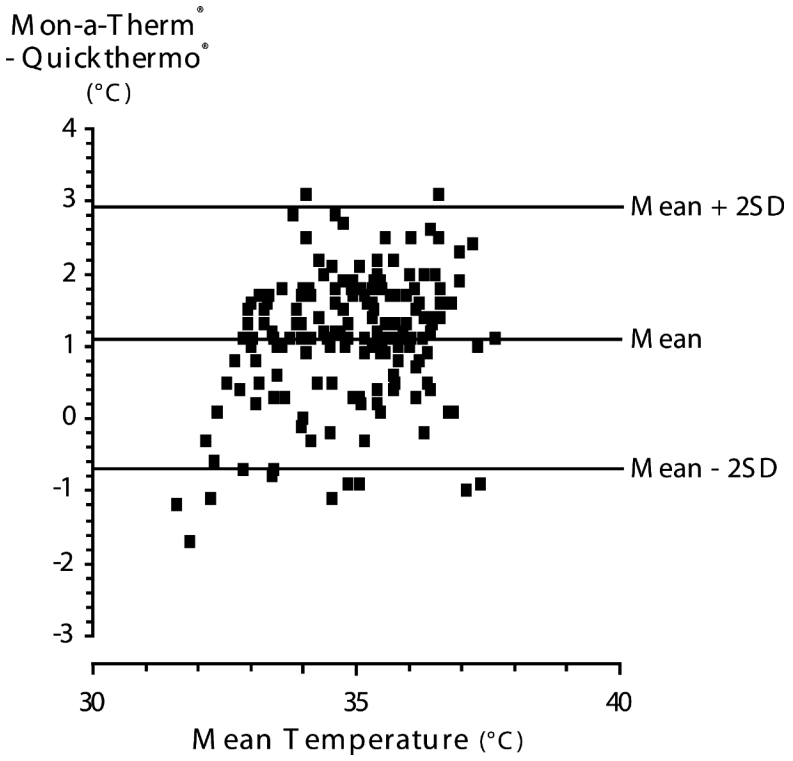

Figure 1.

The differences between the tympanic membrane thermocouple (Mon-a-therm) and aural canal temperature measured by a Quickthermo infrared thermometer. The mean difference between core temperature and the infrared monitor was 1.1°C. Three other infrared monitors were evaluated in this study, but none proved sufficiently accurate for clinical use. SD = standard deviation. Reprinted with permission[15].

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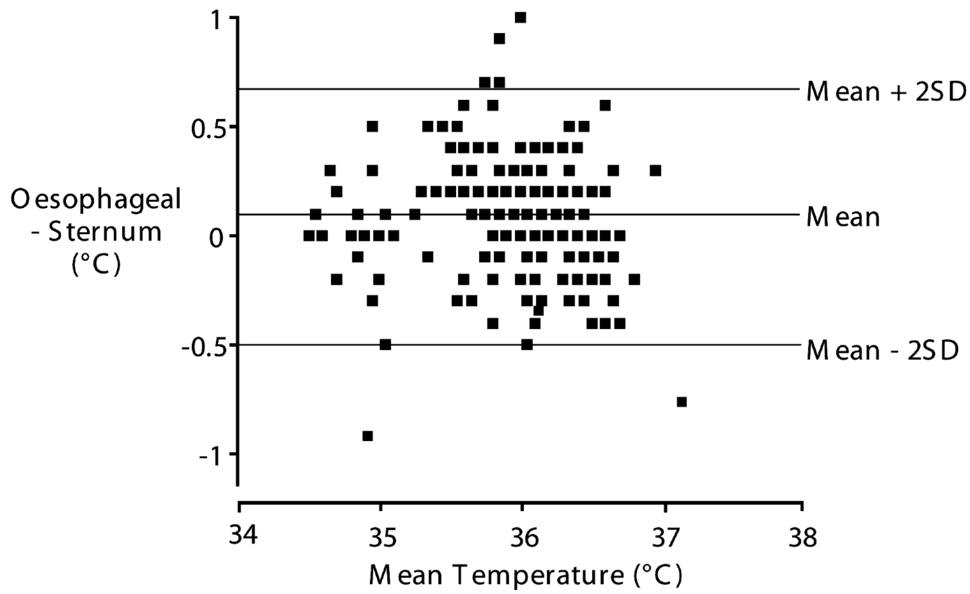

Figure 2.
Bland and Altman comparison of distal esophageal temperature and “deep sternal” temperatures. The vertical axis is the difference between esophageal and deep sternal temperatures. Mean temperature on the horizontal axis refers to the average between esophageal and deep sternal temperatures at each measurement time. The mean offset was 0.1°C, with a standard deviations of 0.3°C. This accuracy is perfectly adequate for clinical use. Reprinted with permission[20].

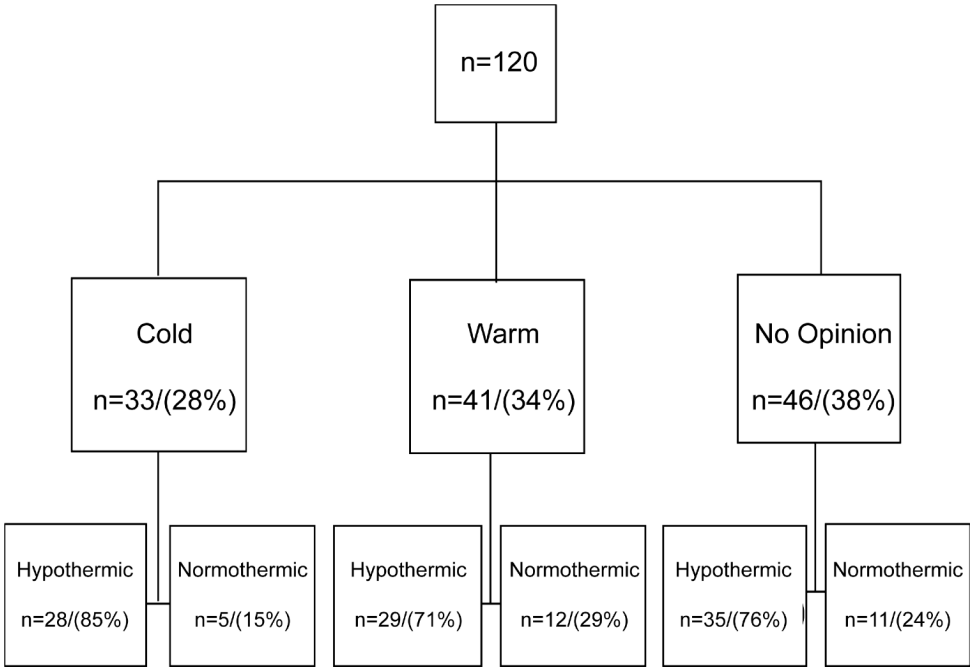

Figure 3.
All patients were divided by anesthesiologists' impression of thermal status. There was no difference in the number of hypothermic (<36°C) and normothermic patients (P = 0.36) when divided by anesthesiologists' impression. Anesthesiologists were unable to reliably estimate their patients' thermal status. Reprinted with permission[42].

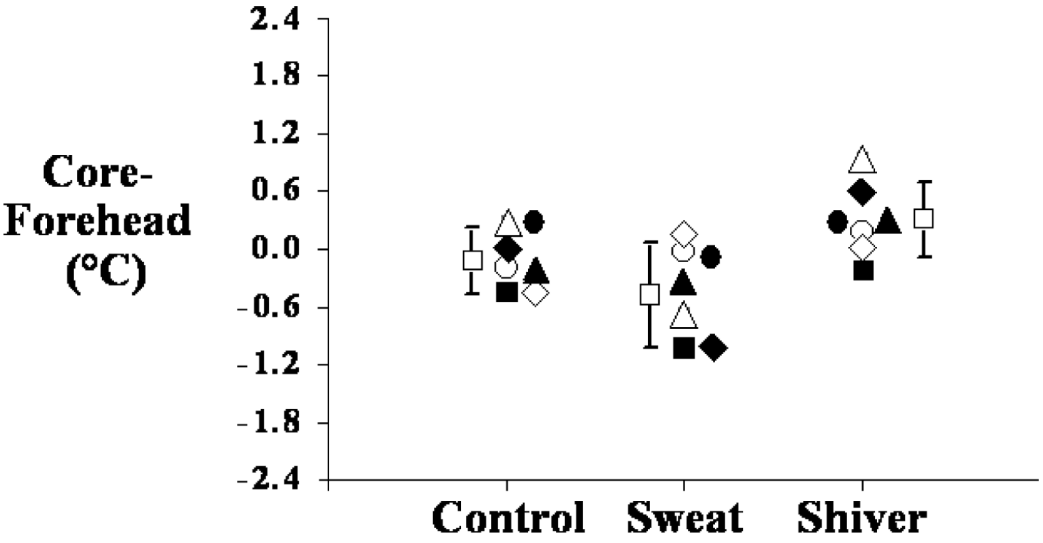

Figure 4.

Tympanic membrane (core) minus forehead skin-surface temperature difference during a thermoneutral control period was 0.1 ± 0.3°C. This difference did not change significantly during vasodilation associated with sweating or vasoconstriction associated with shivering. Results are presented as mean ± SD. Reprinted with permission[52].

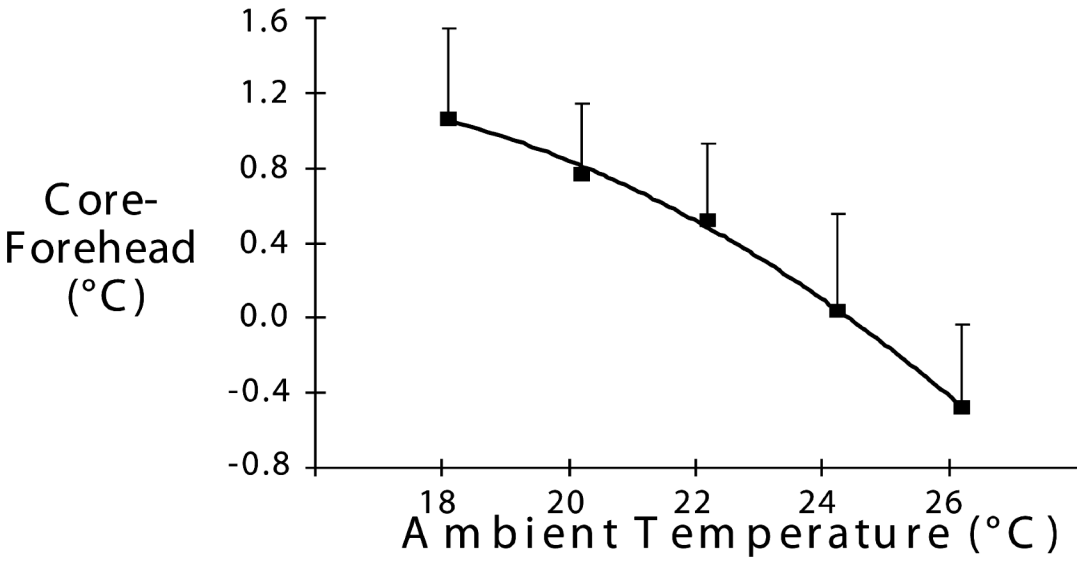

Figure 5.

The difference between tympanic membrane (core) and forehead skin-surface temperatures (ΔT) at ambient temperatures ($T_{ambient}$) between 18 and 26°C. The data were fit to a second-order regression: $\Delta T = -0.58 + 0.29(T_{ambient}) - 0.01(T_{ambient})^2$, $r^2 = 0.999$. Each 1°C change in ambient temperature, starting near 22°C, thus altered skin temperature ≈0.16°C. Results are presented as mean ± SD. Horizontal error bars (variation in ambient temperatures) are not displayed because they were smaller than the size of the markers. Reprinted with permission[52].

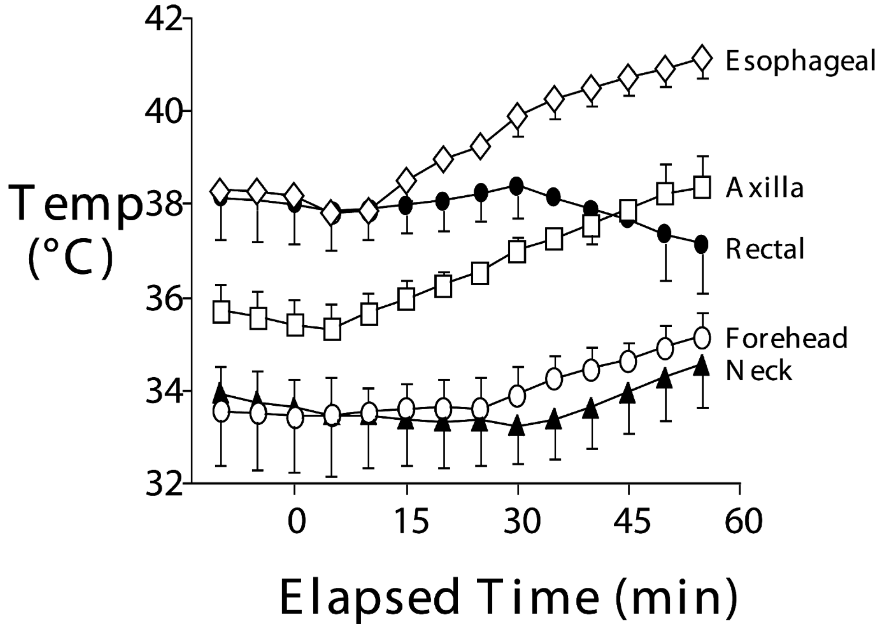

Figure 6.
Axillary and esophageal temperatures correlated well during acute malignant hyperthermia in swine, but forehead and neck skin temperatures did not. Rectal temperature also failed to promptly identify onset of malignant hyperthermia. Elapsed time zero indicates an end-tidal PCO2 = 70 mmHg. These data indicate that forehead and neck skin-surface temperatures will not adequately confirm other clinical signs of malignant hyperthermia. Valid core temperature monitoring sites include the distal esophagus, pulmonary artery, nasopharynx, and tympanic membrane. Except during cardiopulmonary bypass, body temperature also can be measured in the mouth, axilla, and bladder. Data presented as means ± SDs. Modified and reprinted with permission[54].

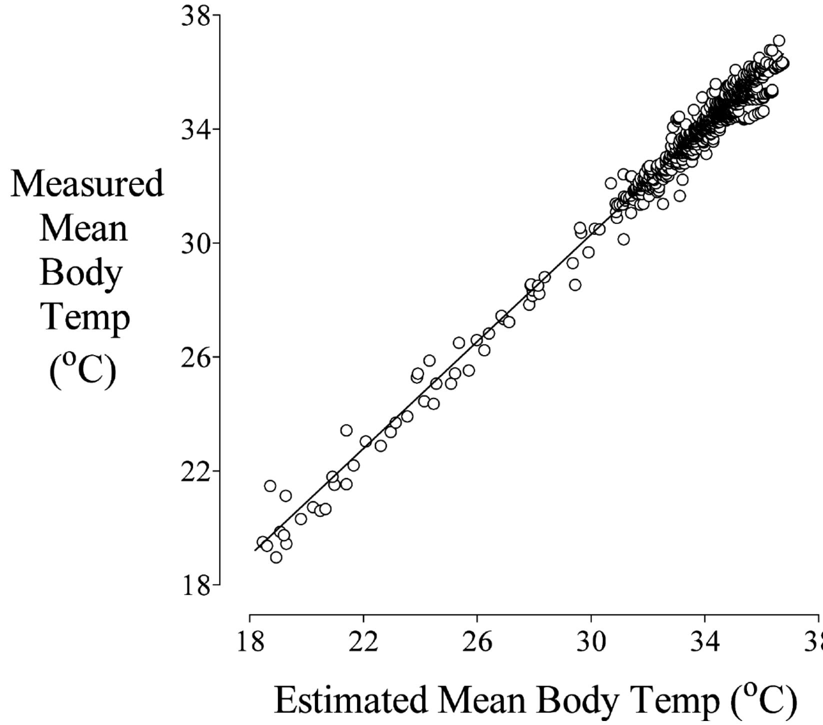

Figure 7.

Linear regression including 913 data pairs from 44 subjects who participated in four heat-balance studies. Mean-body temperature (MBT) was estimated from core (Tcore) and mean-skin (TSkin) temperature and compared to directly measured values. There was a remarkably good relationship between measured and estimated mean-body temperatures: $MBT_{estimated} = 0.94 . MBT_{Measured} + 2.15$, $r^2 = 0.98$. Reprinted with permission[12].

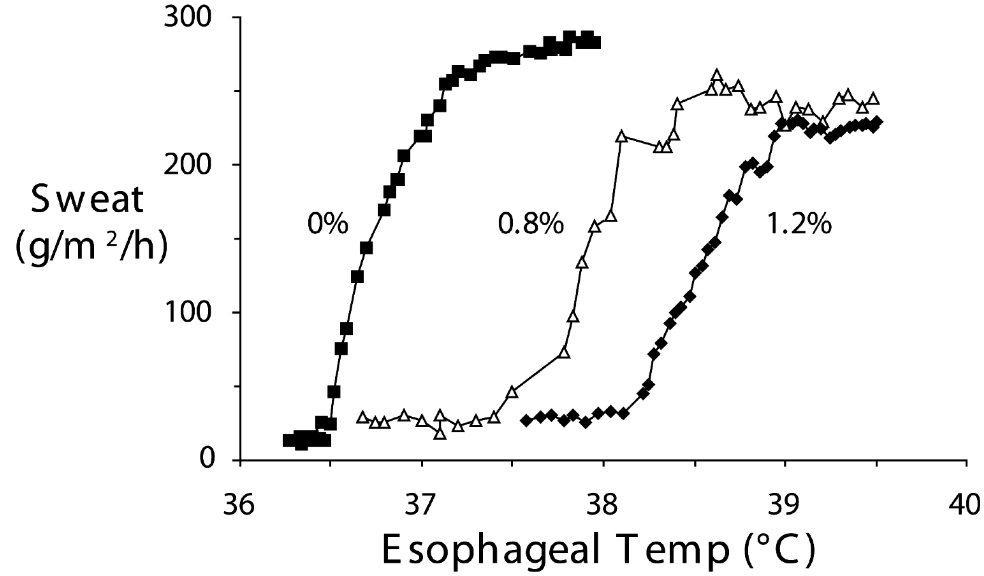

Figure 8.
The sweating rate from the unwarmed site in a single typical male volunteer shows the threshold, gain, and maximum intensity during hyperthermia alone (0%) and at 0.8%, and 1.2% end-tidal isoflurane concentration. The thresholds were markedly increased by anesthesia; in contrast, gains and maximum sweating rates were relatively well preserved. Reprinted with permission[75].

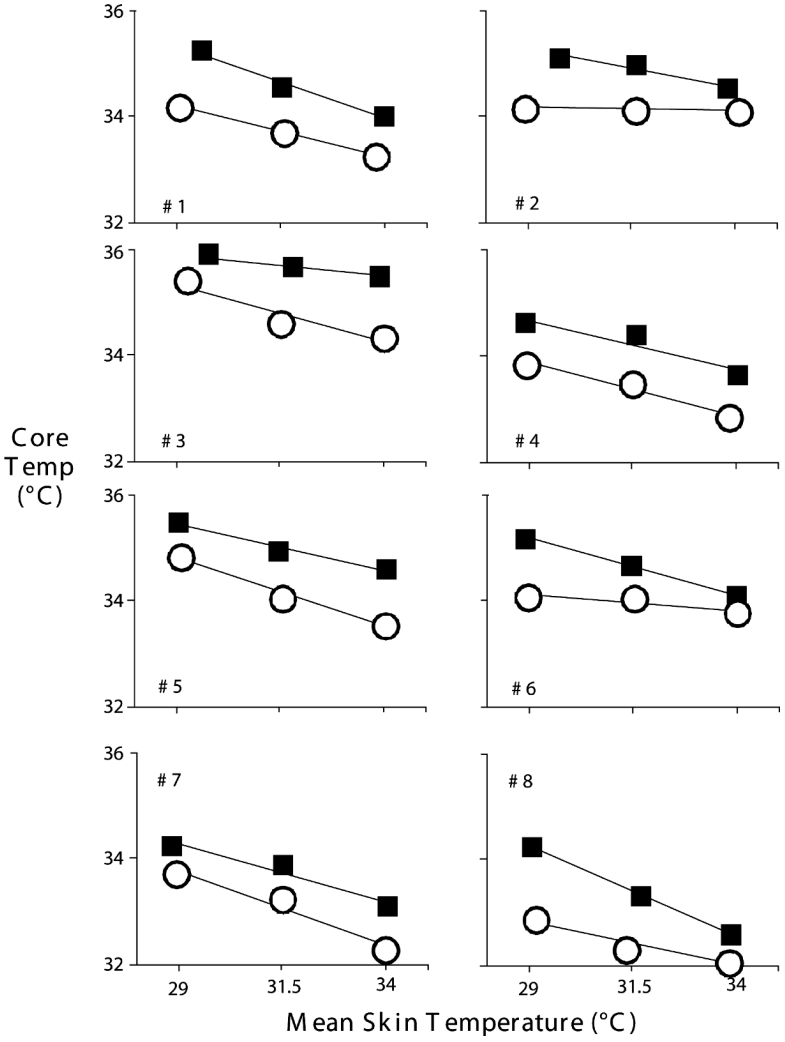

Figure 9.

Individual mean-skin and core temperatures at the vasoconstriction (squares) and shivering (circles) thresholds in the eight volunteers. There was a linear relation between mean skin and core temperatures at the vasoconstriction and shivering thresholds in each volunteer (lines): $r^2 = 0.98 \pm 0.02$ for vasoconstriction, and 0.96 ± 0.04 for shivering. Relative contributions of skin and core temperatures varied from subject to subject, but on average skin temperature contributed $21 \pm 8\%$ to vasoconstriction, and $18 \pm 10\%$ to shivering. Reprinted with permission[89].

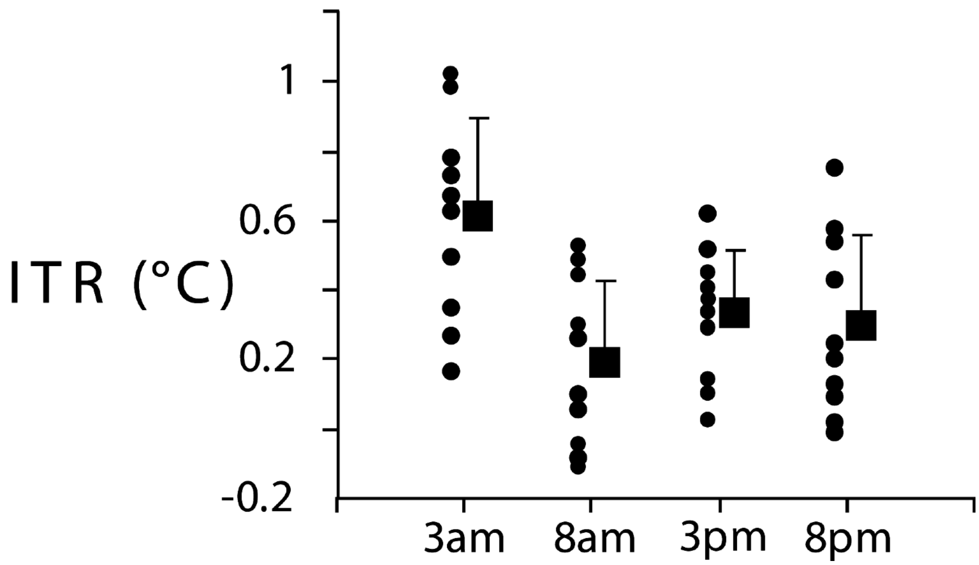

Figure 10.
The sweating-to-vasoconstriction interthreshold range at each time of day. Data presented as means ± SDs. Values at 3 AM differed significantly from those at other times. Reprinted with permission[80].

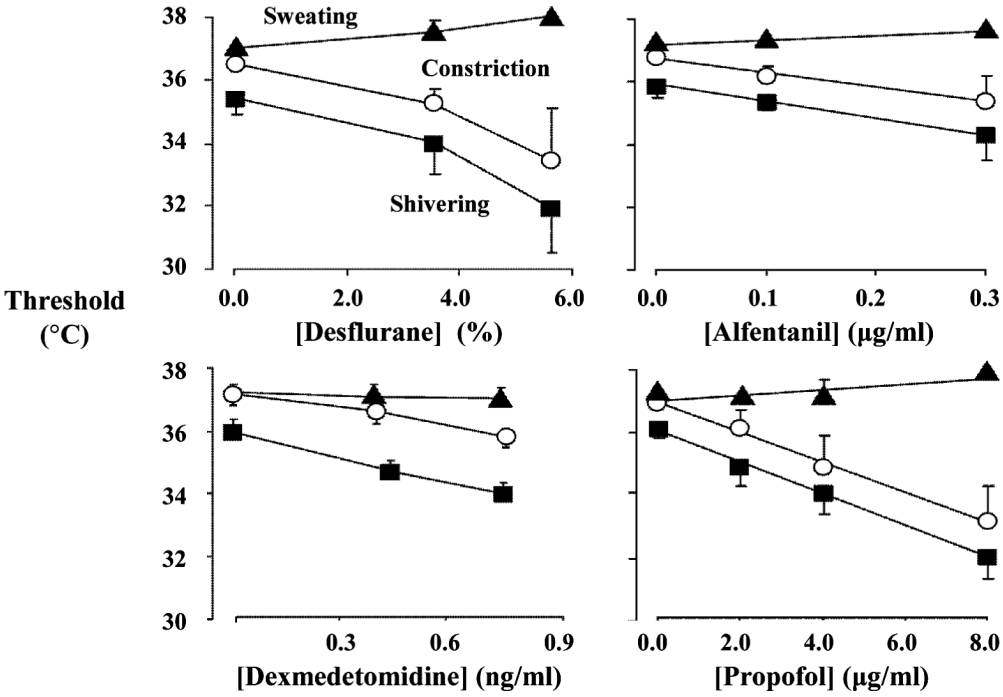

Figure 11.

The major autonomic thermoregulatory response thresholds in volunteers given desflurane, alfentanil, dexmedetomidine, or propofol. All the anesthetics slightly increase the sweating threshold (triggering core temperature), while markedly and synchronously decreasing the vasoconstriction and shivering thresholds. Standard deviation bars smaller than the data markers have been deleted. Reprinted with permission[109, 120, 121, 122].

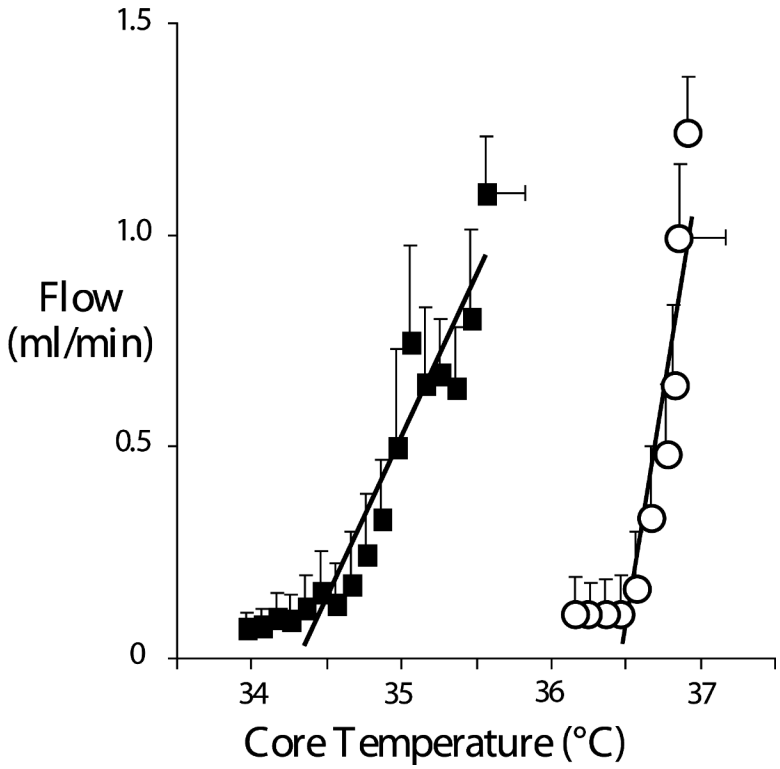

Figure 12.
Finger blood flow without (open circles) and with (filled squares) desflurane administration. Values were computed relative to the thresholds (finger flow = 1.0 ml/min) in each subject. Flows of exactly 1.0 ml/min are not shown because flows in each individual were averaged over 0.1 or 0.05°C increments; each data point thus includes both higher and lower flows. The horizontal standard deviation bars indicate variability in the thresholds among the volunteers; although errors bars are shown only at a flow near 1.0 ml/min, the same temperature variability applies to each data point. The slopes of the flow vs. core temperature relationships (1.0 to ≈0.15 ml/min) were determined using linear regression. These slopes defined the gain of vasoconstriction with and without desflurane anesthesia. Gain was reduced by a factor of three, from 2.4 to 0.8 ml min-1.°C-1 ($P < 0.01$). Reprinted with permission[124].

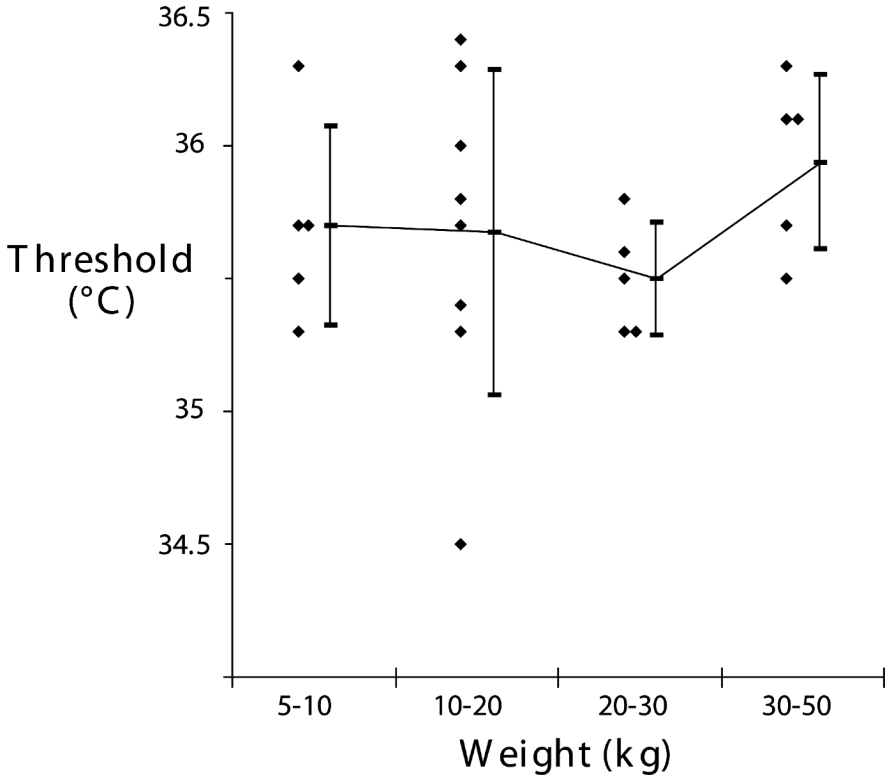

Figure 13.
The core thermoregulatory threshold in 23 healthy children and infants undergoing abdominal surgery with halothane anesthesia. Differences among the groups are not statistically significant. Results are presented as means ± SDs. Reprinted with permission[150].

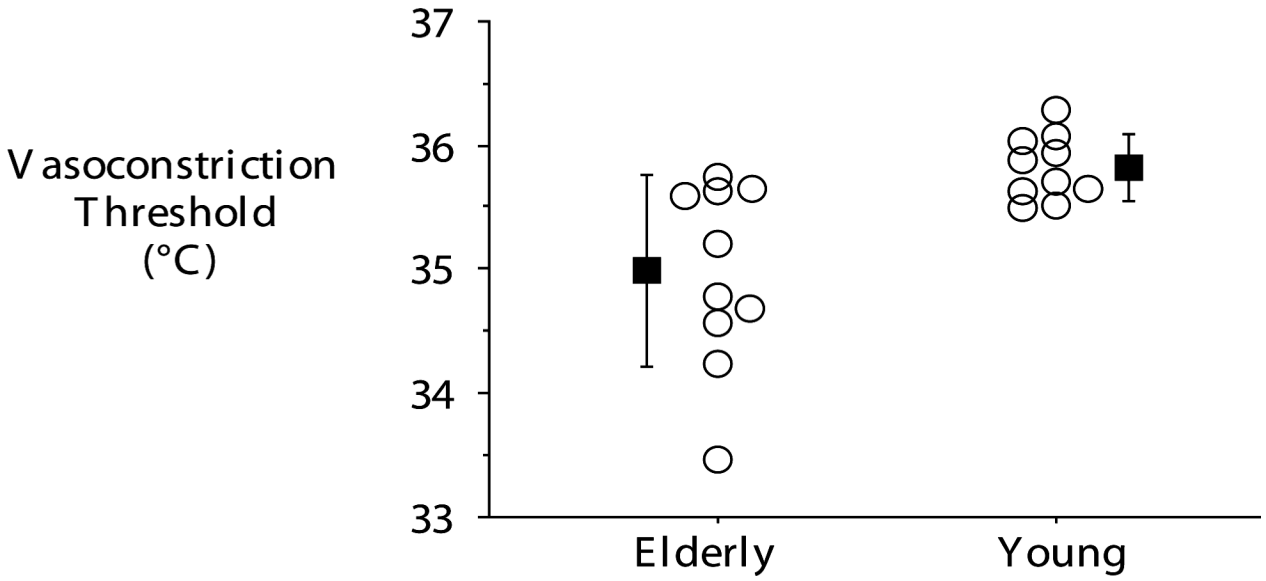

Figure 14.
The vasoconstriction threshold during light sevoflrurane anesthesia was significantly less in elderly (35.8 ± 0.3°C, n = 10) than in younger patients (35.0 ± 0.5°C, n = 10) ($P < 0.01$). Open circles indicate the vasoconstriction threshold in each patient; filled squares the show the mean and standard deviations in each group. Reprinted with permission[152].

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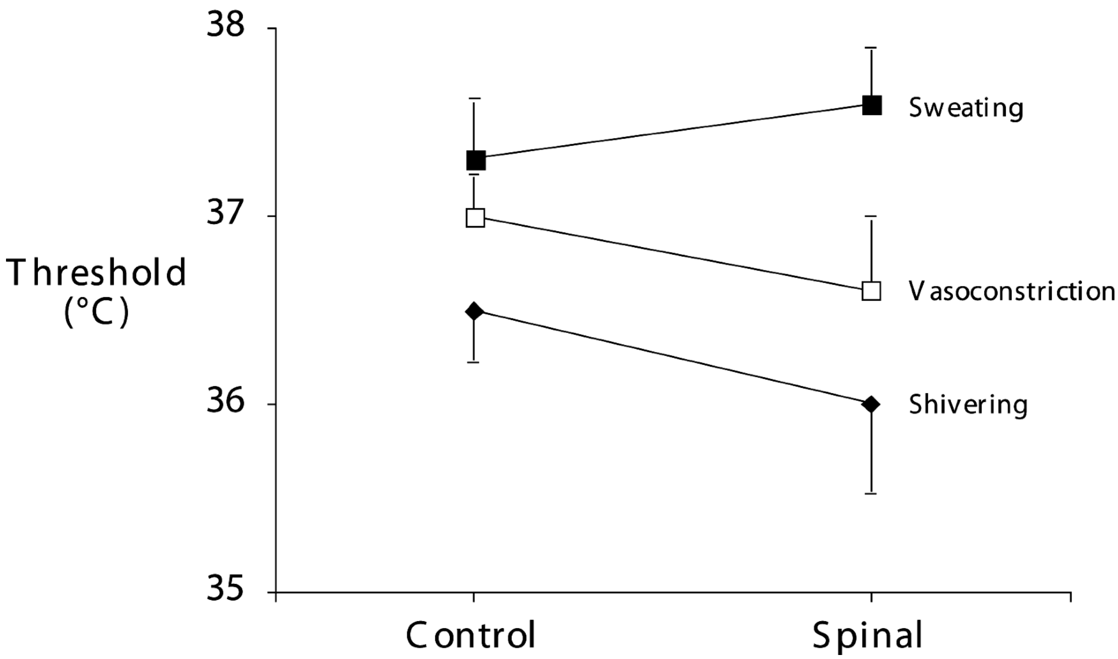

Figure 15.
Spinal anesthesia increased the sweating threshold but reduced the thresholds for vasoconstriction and shivering. Consequently, the interthreshold range increased substantially. The vasoconstriction-to-shivering range, however, remained normal during spinal anesthesia. Results are presented as means ± SDs. Reprinted with permission[157].

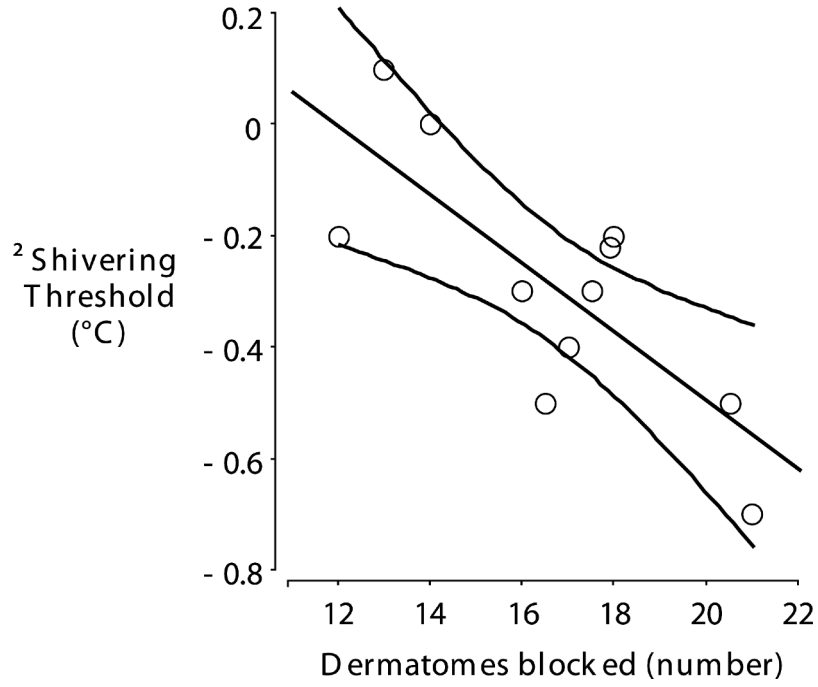

Figure 16.
The number of dermatomes blocked (sacral segments = 5; lumbar segments = 5; thoracic segments = 12) versus reduction in the shivering threshold (difference between the control shivering threshold and spinal shivering threshold). The shivering threshold was reduced more by extensive spinal blocks than by less extensive ones (Δ threshold = 0.74 − 0.06(dermatomes blocked); $r^2 = 0.58$, $P < 0.006$). The curved lines indicate the 95% confidence intervals for the slope. Reprinted with permission[158].

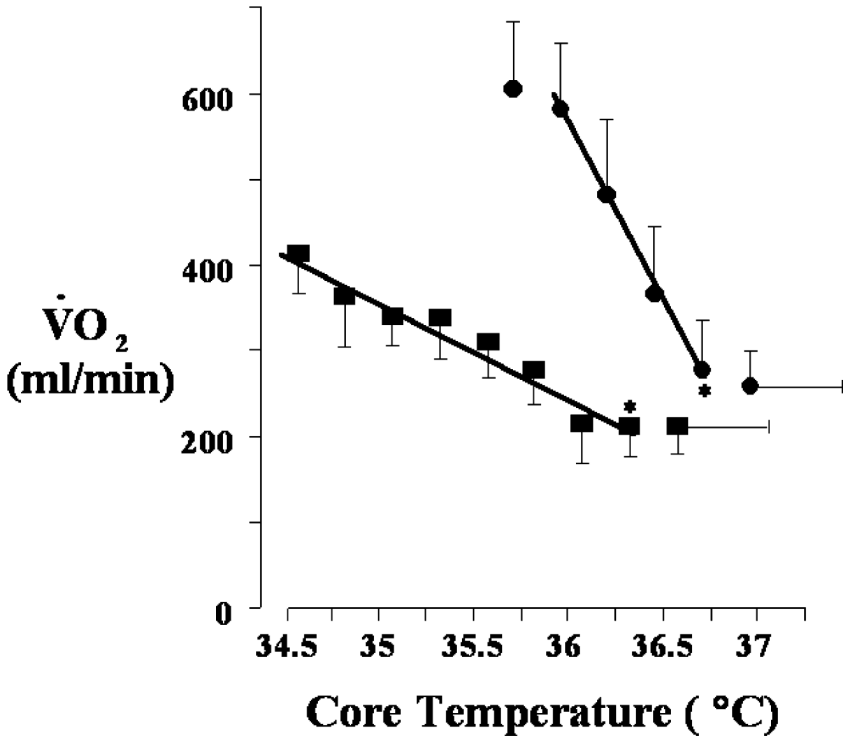

Figure 17.

Systemic oxygen consumption without (circles) and with (squares) epidural anesthesia. The horizontal standard deviation bars indicate variability in the thresholds among the volunteers; although errors bars are shown only once in each series, the same temperature variability applies to each data point. The slopes of the oxygen consumption versus core temperature relationships (solid lines) were determined using linear regression. These slopes defined the gain of shivering with and without epidural anesthesia. Gain was reduced 3.7-fold, from −412 ml·min-1·°C^{-1} (r^2 = 0.99) to −112 ml·min-1·°C-1 (r^2 = 0.96). Reprinted with permission[164].

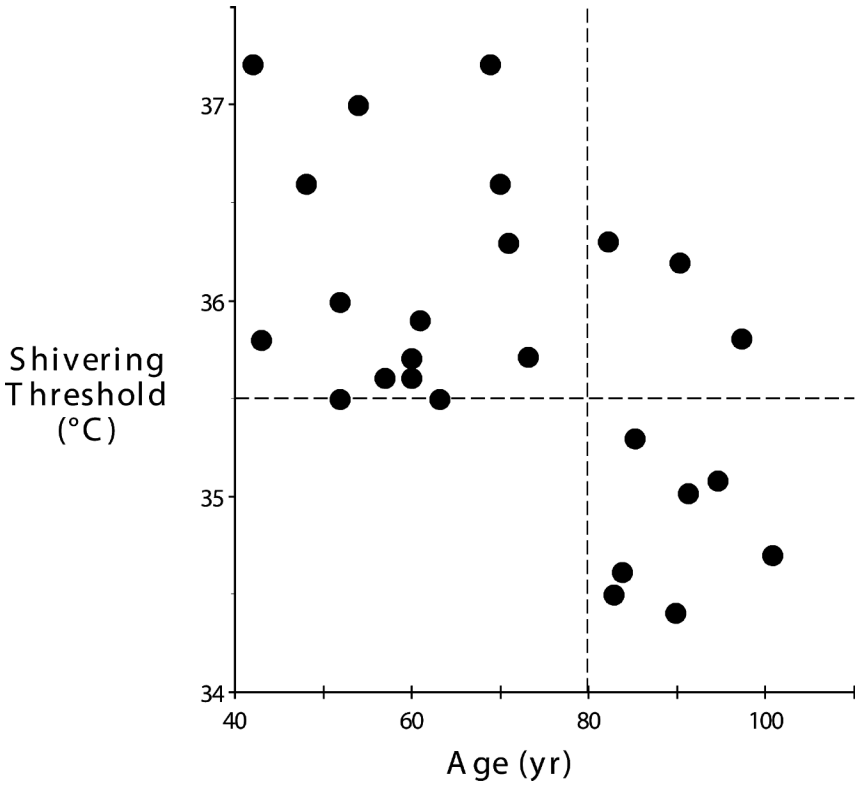

Figure 18.
Fifteen patients aged <80 yr (58 ± 10 yr) shivered at 36.1 ± 0.6°C during spinal anesthesia; in contrast, eight patients aged ≥80 yr (89 ± 7 yr) shivered at a significantly lower mean temperature, 35.2 ± 0.8°C. The shivering thresholds in five of the eight patients aged more than 80 yr was less than 35.5°C, whereas the threshold equaled or exceeded this value in all the younger patients. Results presented as means ± SDs. Reprinted with permission[85].

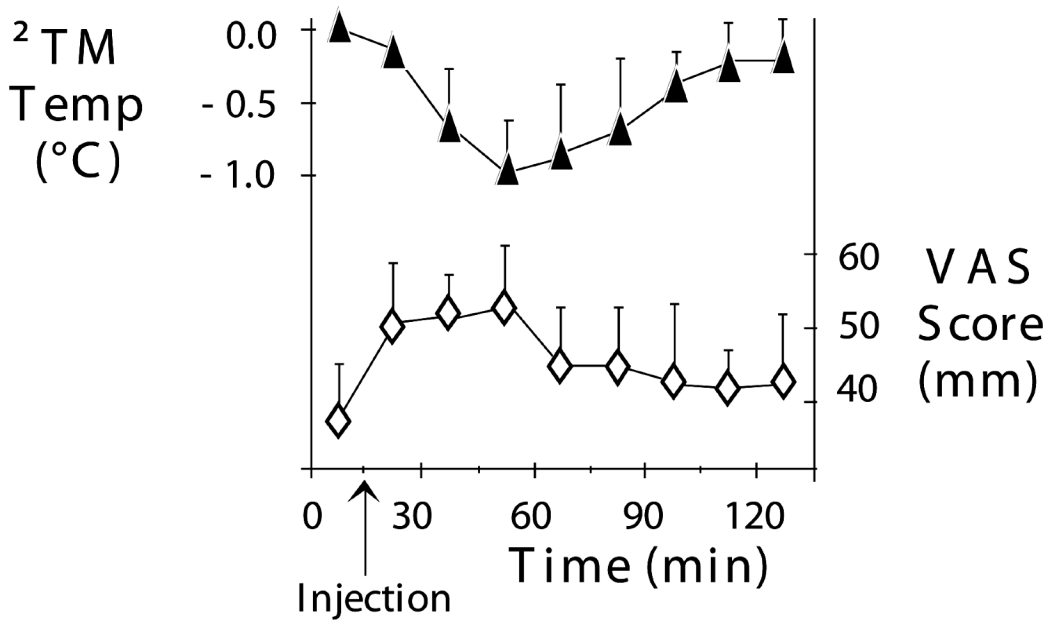

Figure 19.
Changes in tympanic membrane temperatures and thermal comfort (mm on a visual analog scale) following epidural lidocaine injections in 6 volunteers in a cool operating room environment. Epidural injections were given after a 15-min control period. Shivering (not shown) started when tympanic temperature decreased about 0.5°C and continued until core temperature returned to within 0.5°C of control. Thermal comfort increased following epidural injections in each volunteer; maximal comfort occurred at the lowest core temperature. Results presented as means ± SDs. Reprinted with permission[43].

ATTACHMENT F: RESPONSE TIME TEST REPORT

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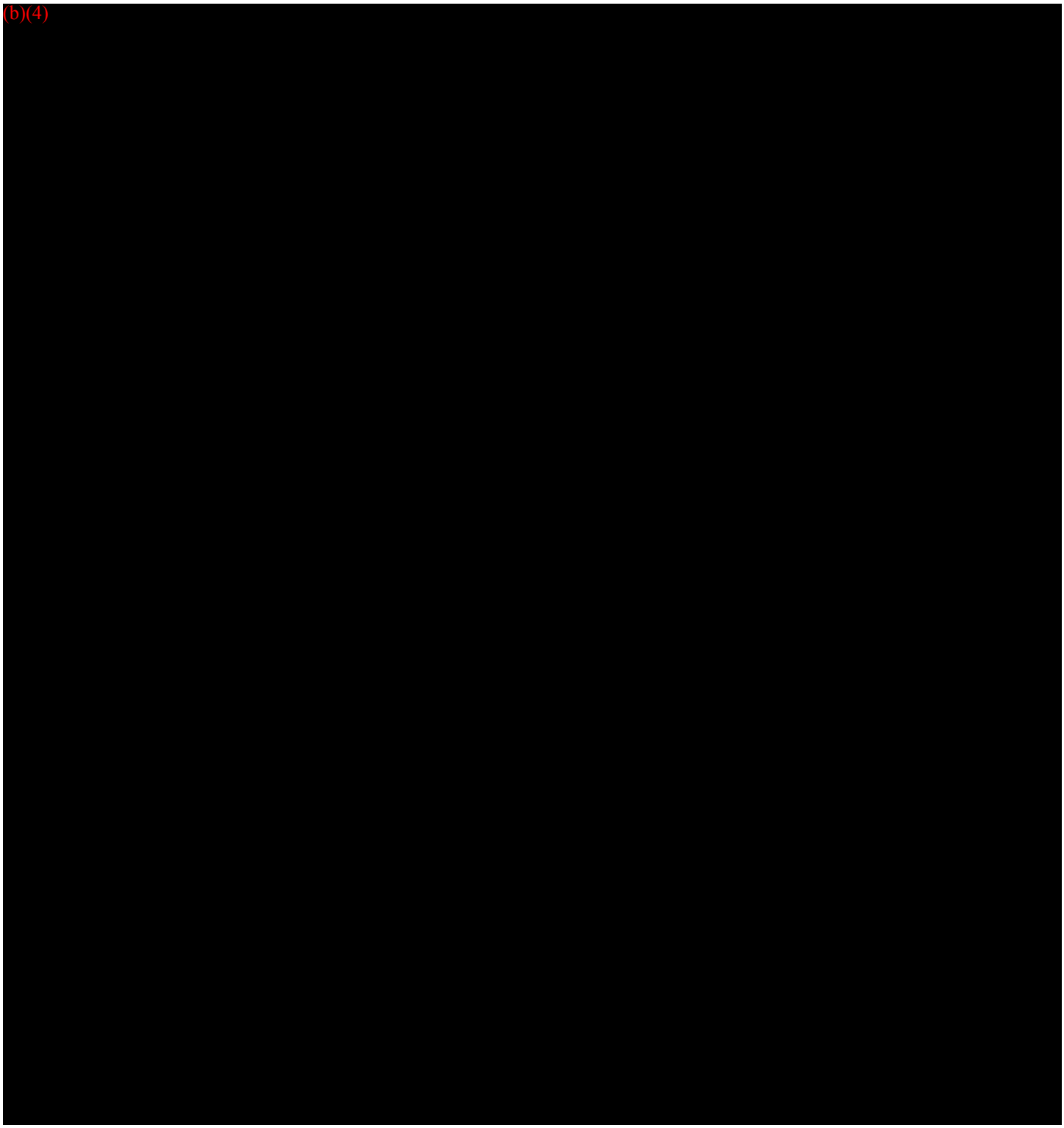

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ATTACHMENT G: IR TEMPERATURE ACCURACY REPORT

	Title: IRTS IR Temperature Accuracy Study	Doc (b)(4) Rev

(b)(4)

(b)(4)

(b)(4)

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ATTACHMENT H: IRTS SPATIAL RESOLUTION & ACCURACY STUDY

	Title: IRTS Spatial Resolution & Accuracy Study	Doc Rev (b)(4)

(b)(4)

[redacted]

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	Title: IRTS Spatial Resolution & Accuracy Study	Do Re

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K152402/S002

January 27, 2016

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

Re: Supplement to – 510(k) K152402
Securus Medical Group, Inc.
InfraRed Thermographic System

Dear Mr. Burdick:

The attached information is submitted for inclusion in the referenced 510(k) Notice for the Securus Medical Group ("the company" or "Securus") InfraRed Thermographic System ("IRTS"). The information is being provided in response to Food and Drug Administration's ("FDA" or "the agency") Request for Additional Information (AI) letter dated October 23, 2015. This response also addresses FDA's additional requests through various interactive correspondences as outlined below. Securus believes that it has provided all information requested by the agency in support of a substantial equivalence determination for the IRTS.

(b)(4)

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(b)(4)

[redacted]

Securus is submitting this supplement response to address the three outstanding issues requested in FDA's e-mail dated December 13, 2015. The company trusts that it has adequately addressed all outstanding concerns regarding the IRTS in order for the agency to make a substantial equivalence determination.

Should you have any questions pertaining to these responses please contact me at 978-317-0836. Please send written communications concerning this Notification to:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.

January 27, 2016

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

Re: Supplement to – 510(k) K152402
Securus Medical Group, Inc.
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William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.

ADDITIONAL INFORMATION

The following pages contain the company responses to FDA's request for additional information in its letter dated October 23, 2015, and in an interactive e-mail dated December 13, 2015, regarding the IRTS proposed in 510(k) notice K152042.

This response is organized in the sequence of the questions presented in the FDA communication. In each case, the question is repeated (verbatim) in italics, followed by the Securus response. If additional supporting documentation is referenced, it is provided as an Attachment.

AI K152402
Table of Contents

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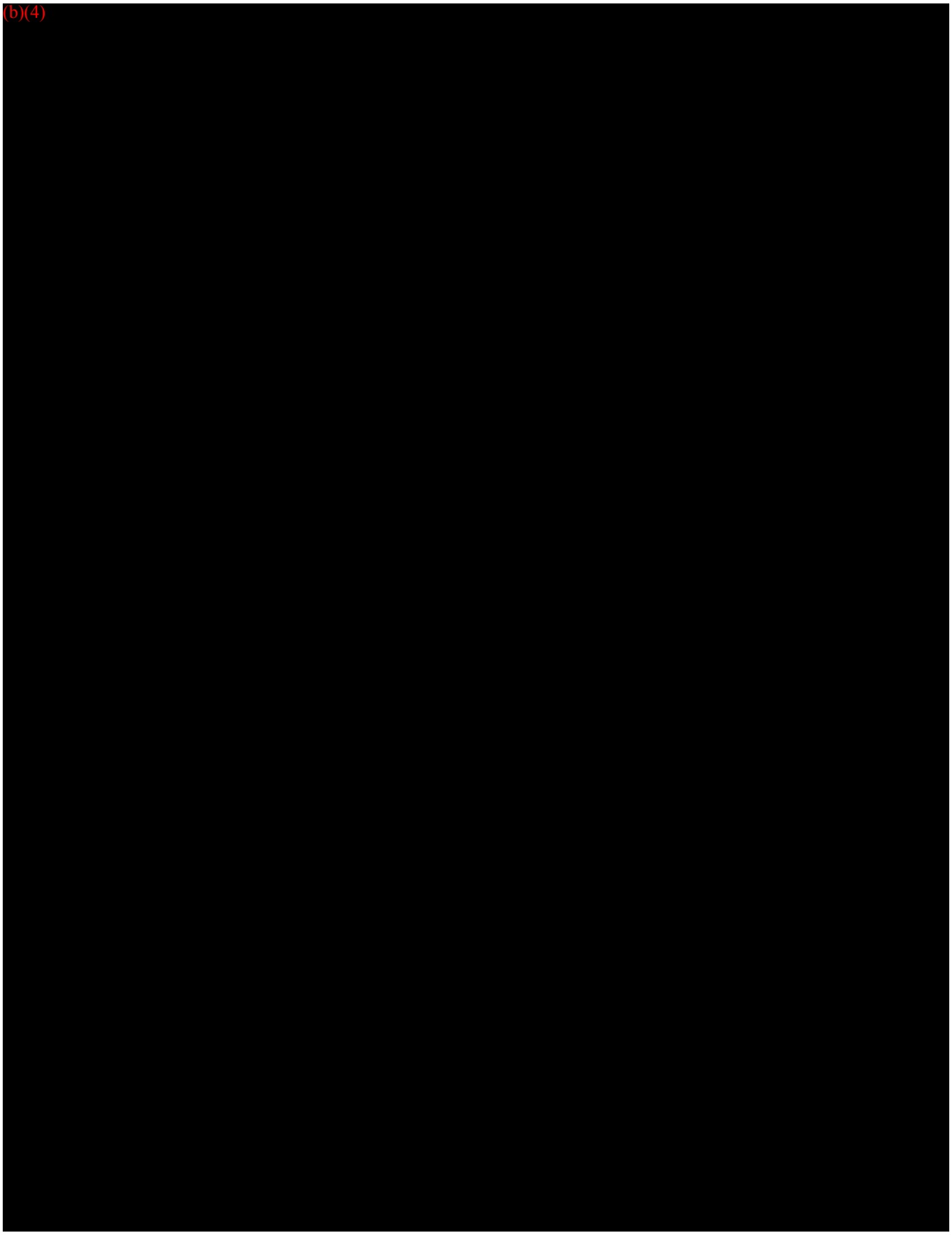

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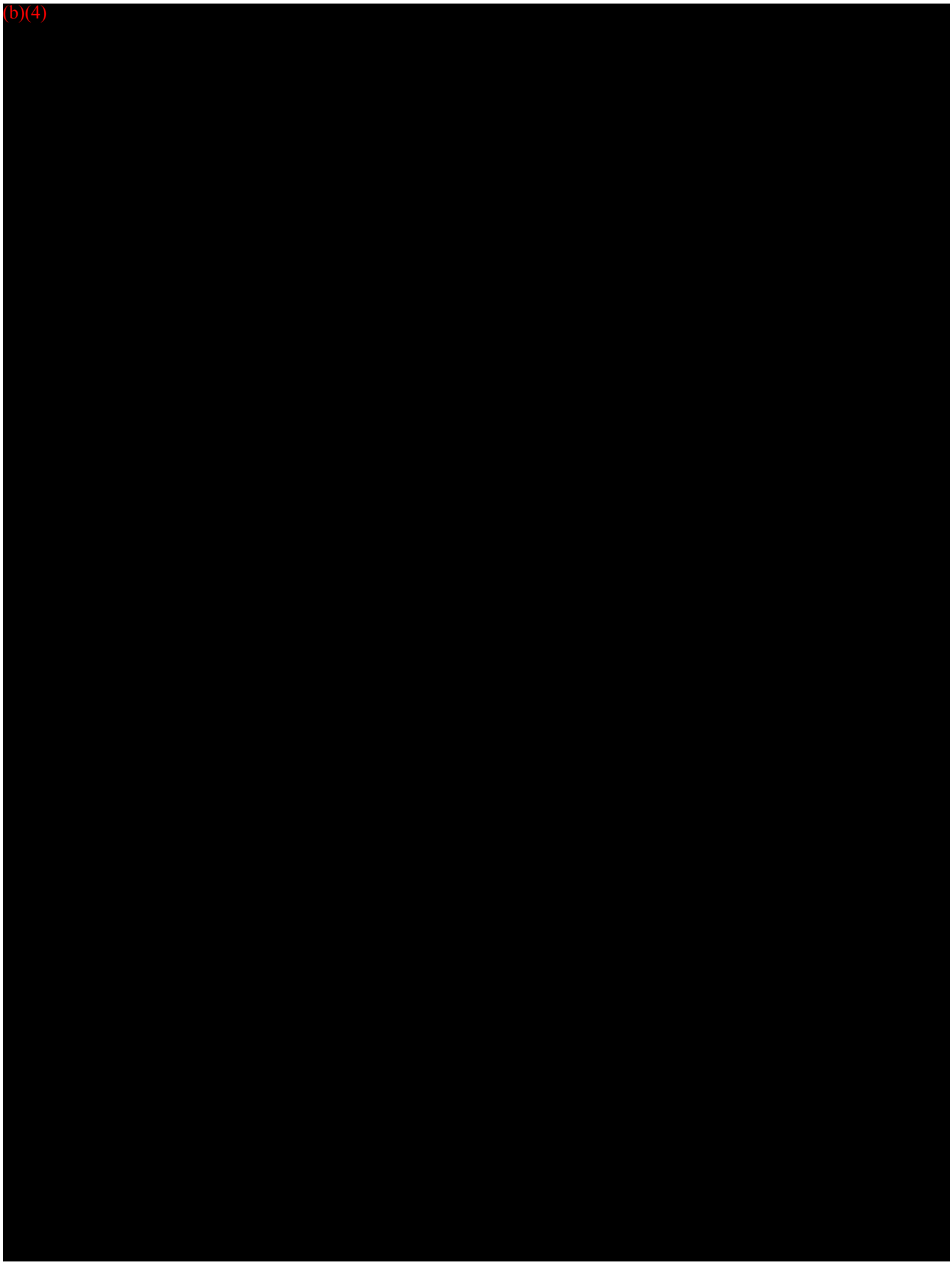

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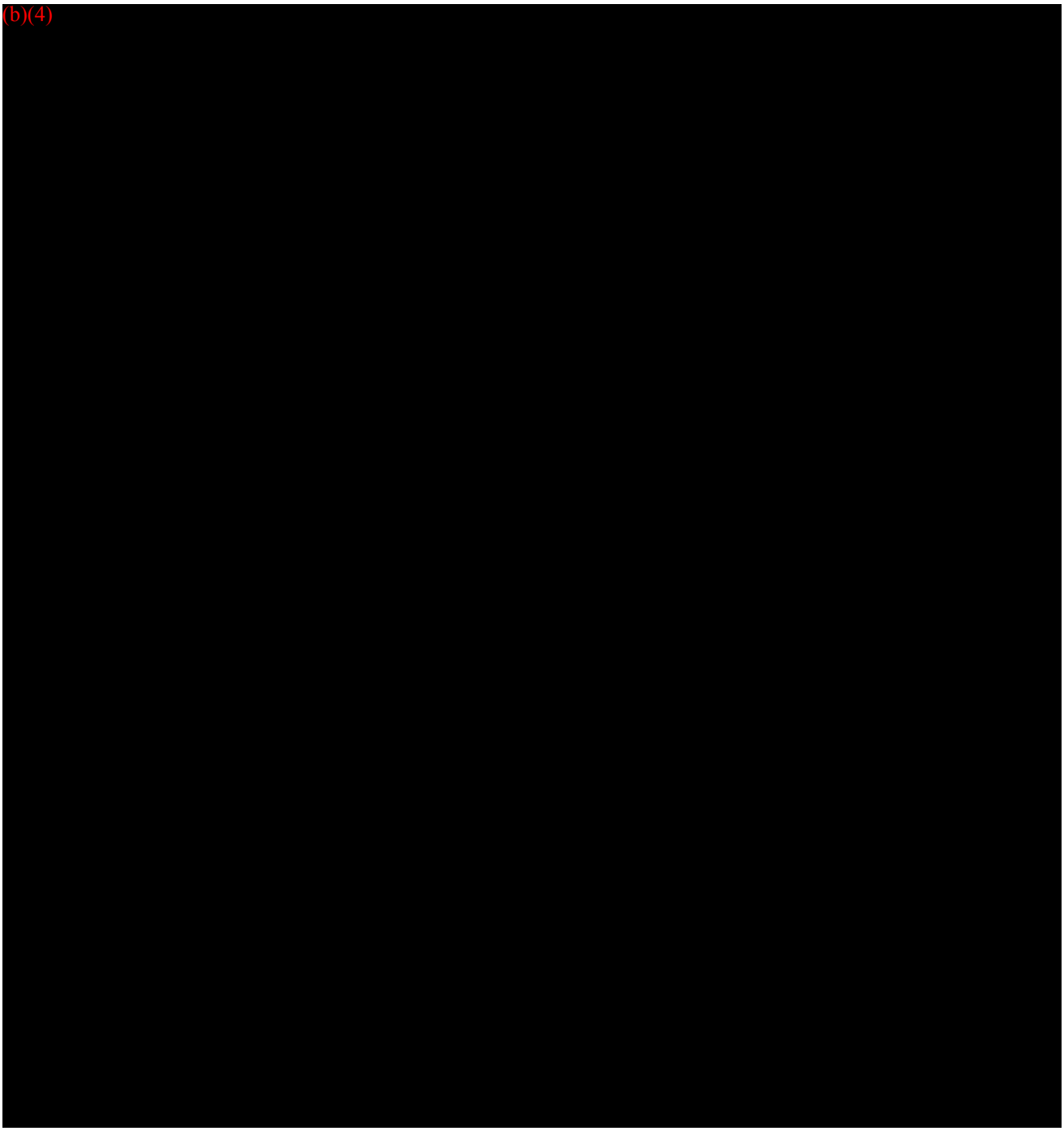

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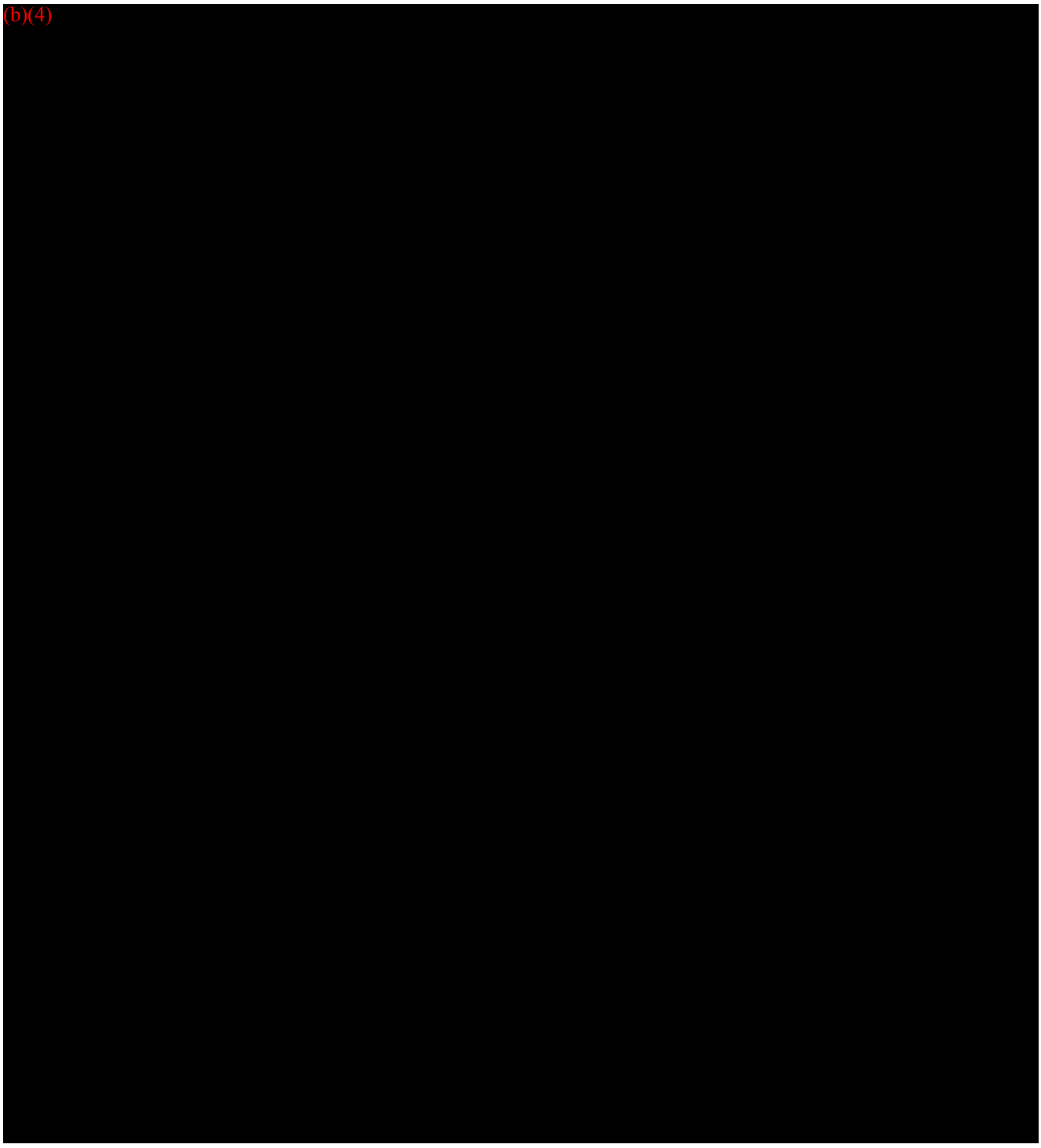


ATTACHMENT A: REVISED SE TABLE & DISCUSSION

SUBSTANTIAL EQUIVALENCE DISCUSSION

As explained in detail below, the IRTS is substantially equivalent to other legally marketed clinical electronic thermometers. Specifically, the IRTS is substantially equivalent to primary predicate device FIAB ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361). As explained in more detail below, the IRTS has the same intended use and indications for use and similar technological characteristics as the previously cleared predicate K123361. A substantial equivalence chart comparing the similarities and differences between the IRTS and its primary predicate device is provided below. As also explained in more detail below, the differences in the technological characteristics do not raise new questions of safety or efficacy. Performance bench testing demonstrated that the IRTS is substantially equivalent to its primary predicate device.

A. Intended Use/ Indications for Use

The IRTS has the same intended use as the primary predicate device K123361 as an esophageal temperature probe and monitoring system intended for continuous temperature monitoring of the patient's esophagus. Both devices also have identical indications for use:

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

Thus, the IRTS satisfies the first criterion of intended use for substantial equivalence.

B. Technological Characteristics

Both the IRTS and the primary predicate device K123361 are catheter-based esophageal temperature probes with integrated Type-T thermocouples for measuring temperature. Both systems incorporate a monitor to continuously display the esophageal temperature. A single thermocouple is used for the subject device to report esophageal temperature. In comparison, the predicate device has 3 thermocouples spaced apart along the catheter shaft. The subject device is configured so that only one thermocouple is used at a time. However, this difference does not raise different questions of safety or effectiveness since other esophageal temperature probes are marketed with a single sensor configuration and are tested to the same FDA recognized consensus standard ISO 80601-2-56 for clinical thermometers. The IRTS also incorporates a thermographic infrared technology to provide thermal imaging as an additional feature for temperature monitoring. The sensor passively collects the infrared energy naturally radiated off tissue surfaces. Although this feature is not provided in the predicate device, it does not raise different questions of safety or effectiveness as it provides additional information about the patient's esophageal temperature. Finally, the IRTS is provided non-sterile while the predicate device K123361 is provided sterile. However, FDA has cleared the reference device Circa Scientific's Esophageal Temperature Probe and Temperature Monitoring System (K112376) as a non-sterile device with the same intended use and indications for use. In addition, the target tissue in the esophagus is a non-sterile environment and does not require sterile devices. As such, there are no different questions of safety or effectiveness regarding the device sterility. As stated above, both the subject and primary predicate devices were validated using consensus standard ISO 80601-2-56 along with biocompatibility, EMC, and electrical safety testing. Thus, the IRTS satisfies the second criterion of technological characteristics for substantial equivalence.

C. Conclusion

The IRTS and the primary predicate device K123361 have the same intended use and indications for use and similar technological characteristics as described above. The primary technological differences between the IRTS and its predicate are the sensor configuration, thermal imaging and provided non-sterile. These differences do not present any new issues of safety or effectiveness because both the IRTS and the primary predicate have been validated using FDA recognized consensus standard ISO 80601-2-56 for clinical thermometers, the thermal imaging feature provides additional information about the esophageal temperature, and the reference device has been cleared for non-sterile use. Thus, the IRTS is substantially equivalent to the primary predicate device K123361.

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) **Primary Predicate**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System (K112376) **Reference Device**
Intended Use	Continuous temperature monitoring of the patients esophagus.	Continuous temperature monitoring of the patients esophagus.	Continuous esophageal temperature monitoring.
Indications for Use	The IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.
System Components	Temperature probe 9 Fr Patient Interface Unit (PIU) Patient Monitoring Unit (PMU)	Temperature probe 7 Fr Interconnect cable Patient Monitor	Temperature probe 10 Fr Interconnect cable Monitor
Probe Sterility	Provided non-sterile	Provided sterile	Provided non-sterile
Route of Insertion	Oral or Nasal	Oral or Nasal	Oral or Nasal
Probe Material (patient contact)	Polyethylene and platinum iridium	Polyurethane and stainless steel	Flexible Polyester and Rigid Pebax
Probe Size	9 Fr catheter with 9 Fr sensor 150 cm length	7 Fr catheter with 11 Fr sensors 95 cm length	10 Fr, 50 cm length (tip to Y connector) Interconnect Cable 10' long
System Temperature Precision and Resolution	0.1° C	0.1° C	0.2° C

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) **Primary Predicate**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System (K112376) **Reference Device**
Temperature Sensor	Type-T thermocouple	Type-T thermocouple	Thermistor
Thermocouple Sensor Signal Processing and Display	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LCD display	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LED display	Temperature is a function of thermistor voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LCD display
Thermocouple Sensor Range	25° - 45° C	15° - 75° C	25° - 45° C
Thermocouple Sensor Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	± 0.5° C tested in accordance with ISO 80601-2-56	± 0.3° C tested in accordance with ISO 80601-2-56
Transient Response Time of Temperature Sensor	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Heating transient 7 seconds, cooling transient 4.5 seconds tested in accordance with ISO 80601-2-56
Infrared Detector Technology	Stirling cooled MCT	N/A	N/A
Infrared Signal Processing and Display	Relative display of color graphical image representing infrared radiation emitted from the body.	N/A	N/A
Infrared Temperature Range	35° - 60° C	N/A	N/A
Infrared Temperature Accuracy	IR: ± 2° C	N/A	N/A
Infrared Temperature Resolution	0.1° C	N/A	N/A
Infrared Image Field of View	360°	N/A	N/A

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) **Primary Predicate**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System (K112376) **Reference Device**
Spectral Response	8-11µm	N/A	N/A
Thermal Image Size	128 x 60 array	N/A	N/A
Power Supply	100-240 Vac AC adaptor power supply 24 VDC	100-120/230 Vac	AC adaptor power supply 12 VDC
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2
Data Output	Data provided to the supplied monitor for display	Data provided to the supplied monitor for display	Digital USB 2.0 to user computer

ATTACHMENT B: REVISED SUMMARY

510(K) SUMMARY

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)

Common name: Clinical Electronic Thermometer

Classification Number/ Classification name/Product code:
Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Special Controls:
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers, March 1993

3) Predicate Device

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361)

4) Device Description

The Securus InfraRed Thermographic System (IRTS) is an esophageal temperature probe and monitoring system intended for continuous temperature monitoring of the patient's esophagus. The Probe includes a thermocouple sensor for temperature monitoring and a thermographic sensor for thermal imaging. Data from both sensors are displayed on a monitor for the user.

The InfraRed Thermographic System (IRTS) consists of three components:

- **A.** Thermal Imaging Probe (TIP or Probe)
- **B.** Patient Interface Unit (PIU)
- **C.** Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature monitoring through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. In addition, the IRTS incorporates a thermographic sensor and fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding esophageal tissue surface. The thermal data is presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak

temperature are offered as additional temperature monitoring features. The thermal data of the IRTS is not classified under the Clinical Thermometer designation of ISO 80601-2-56.

5) Indications for Use

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

6) Comparison to Predicate Device

The IRTS is substantially equivalent to the primary predicate device FIAB ESOTEST System (K123361). Both the subject device and the primary predicate device have the same intended use and indications for use as a continuous esophageal temperature monitor. Both use thermocouple sensors for temperature monitoring of the patients esophagus. The subject device also includes a thermographic sensor for displaying thermal images as an additional temperature monitoring feature. This feature does not raise different questions of safety or effectiveness as it provides additional information about the temperature in the patient's esophagus. Similar to reference device Circa Scientific, Esophageal Temperature Probe and Temperature Monitoring System (K112376), the subject device is provided non-sterile. Thus, the subject device has the same intended use and similar technological characteristics as the primary predicate device K123361. Any differences in technological characteristics do not raise different questions of safety or effectiveness. A summary comparison between the subject, primary predicate and reference devices is provided in the following table:

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Intended Use	Continuous temperature monitoring of the patients esophagus	Continuous temperature monitoring of the patients esophagus.	Continuous esophageal temperature monitoring	Same intended use

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Indications for Use	The IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.	Same indications as primary predicate
System Components	Temperature probe Patient Interface Unit Patient Monitoring Unit	Temperature probe Interconnect cable Patient Monitor	Temperature probe Interconnect cable Monitor	Similar components
Probe Sterility	Provided Non-sterile	Provided Sterile	Provided Non-sterile	Same as reference device
Probe Material (patient contact)	Polyethylene and platinum iridium	Polyurethane and stainless steel	Flexible Polyester and Rigid Pebax	Similar materials, tested for biocompatibility
Probe size	9 Fr catheter with 9 Fr sensor 150 cm length	7 Fr catheter with 11 Fr sensors 95 cm length	10 Fr OD, 30.5" total length. Interconnect Cable 10' long	Similar sizes
System Temperature Precision and Resolution	0.1° C	0.1° C	0.2° C	Similar precision and resolution.
Temperature Sensor	Type-T thermocouple	Type-T thermocouple	Thermistor	Similar sensor
Temperature Sensor Range	25° - 45° C	15°-75° C	25° - 45° C	Same range as reference device

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Temperature Sensor Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	± 0.5° C tested in accordance with ISO 80601-2-56	± 0.3° C tested in accordance with ISO 80601-2-56	Better accuracy than primary predicate device
Transient Response Time of Temperature Sensor	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Heating transient 7 seconds, cooling transient 4.5 seconds tested in accordance with ISO 80601-2-56	Insignificant time differential.
Power Supply	100-240 Vac AC adaptor power supply 24 VDC	100-120/230 Vac	100-240 Vac	Compliant to US power supply
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1:1998 (applicable sections)	Same standards

7) Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and

a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

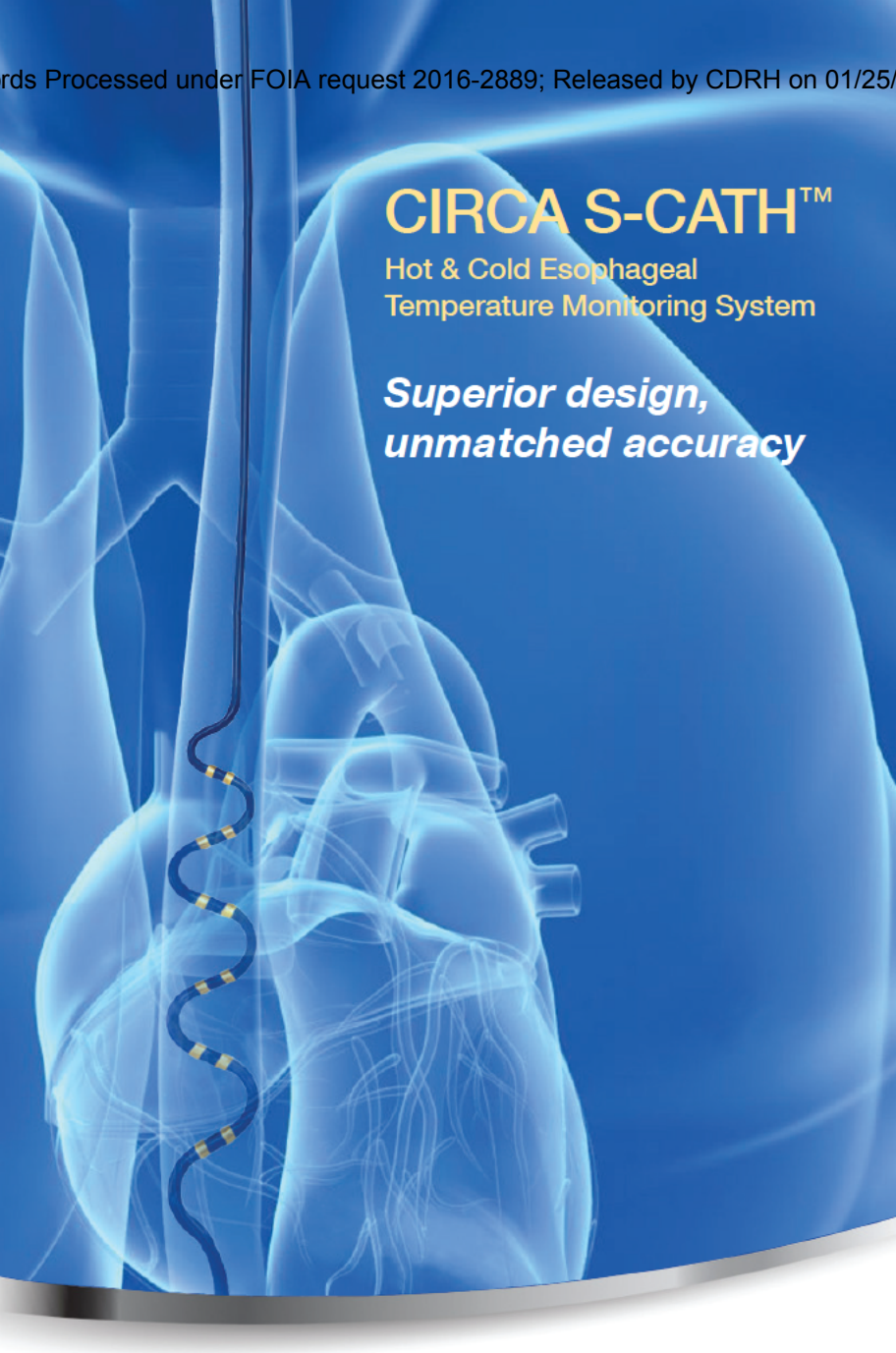
Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The IRTS has the same intended use, indications for use and similar technological characteristics as the primary predicate device K123361. Any difference in technological characteristics does not raise different questions of safety or effectiveness. The thermal imaging feature of the IRTS provides additional temperature monitoring of the patient's esophagus. The performance testing supports substantial equivalence of the IRTS to the predicate.

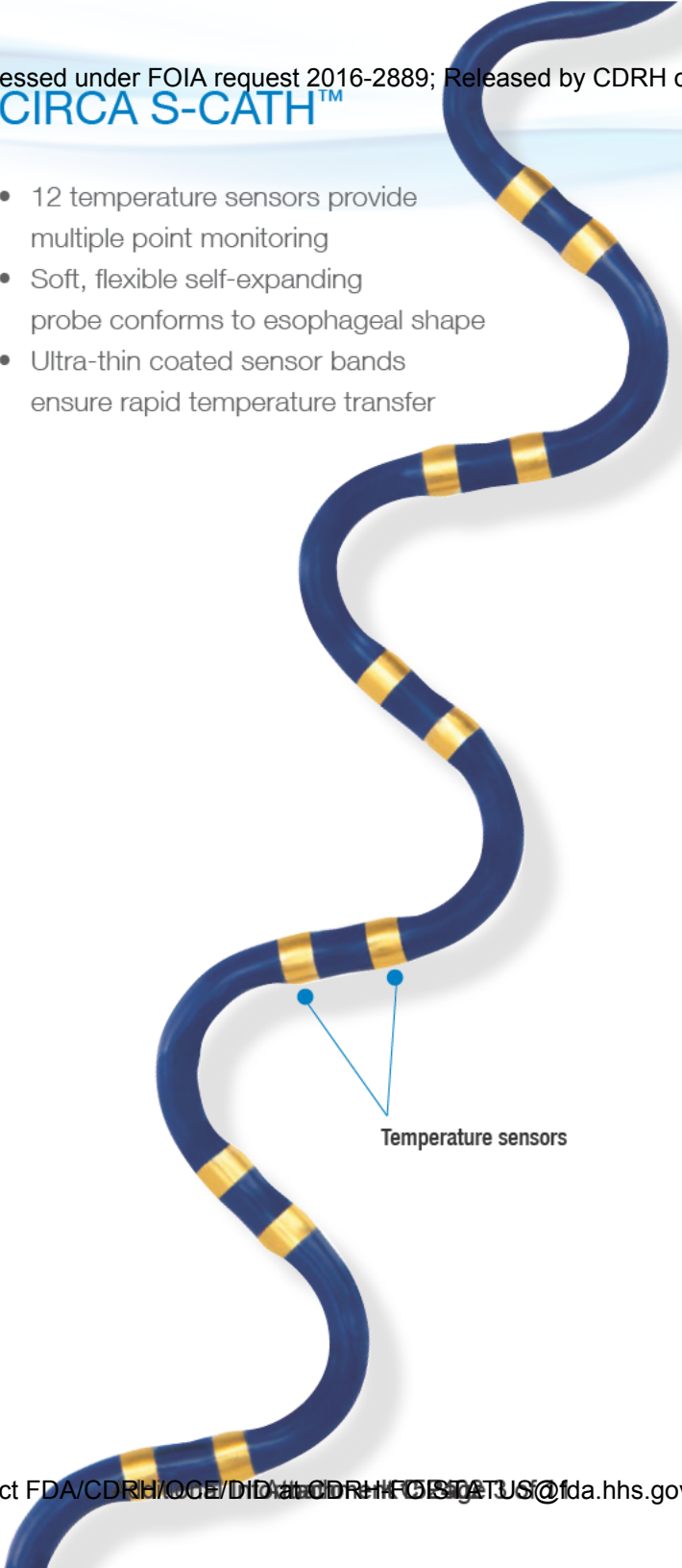
ATTACHMENT C: LABELING, CIRCA



CIRCA SCIENTIFIC

CIRCA S-CATH™

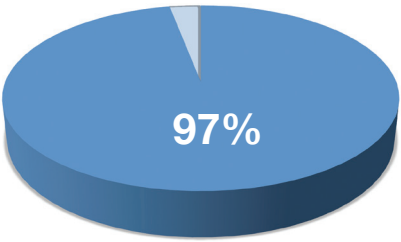
- 12 temperature sensors provide multiple point monitoring
- Soft, flexible self-expanding probe conforms to esophageal shape
- Ultra-thin coated sensor bands ensure rapid temperature transfer



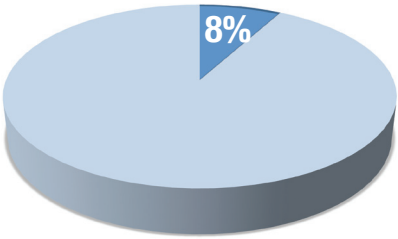
Maximum Esophageal Coverage

Proprietary S-Shape Design provides maximum coverage for more complete monitoring.

S-CATH S-Shape Design
97% coverage



Conventional Probe Design
8% coverage

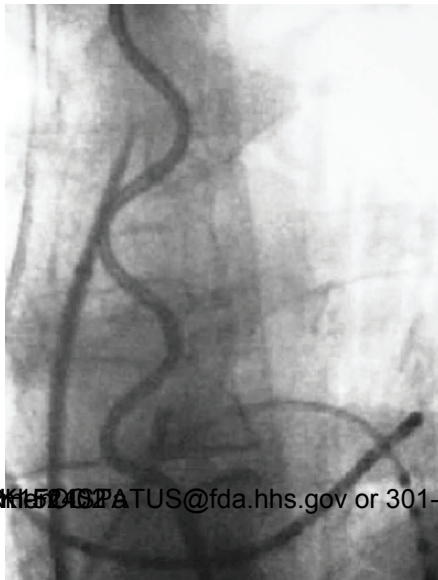


Assumes: Average esophageal width of 18.9mm[1], average esophageal length in contact with left atrium of 42.8mm[2], and each sensor covers 64 sq. mm.

Stationary Placement

Sensor placement ensures proximity to the point of treatment; no need to move the probe once placed.

- Radiopaque shaft provides a visual landmark of the esophagus
- Indicates esophageal width and orientation
- Facilitates reduced use of fluoroscopy



Faster Response to Hot & Cold Temperature Changes

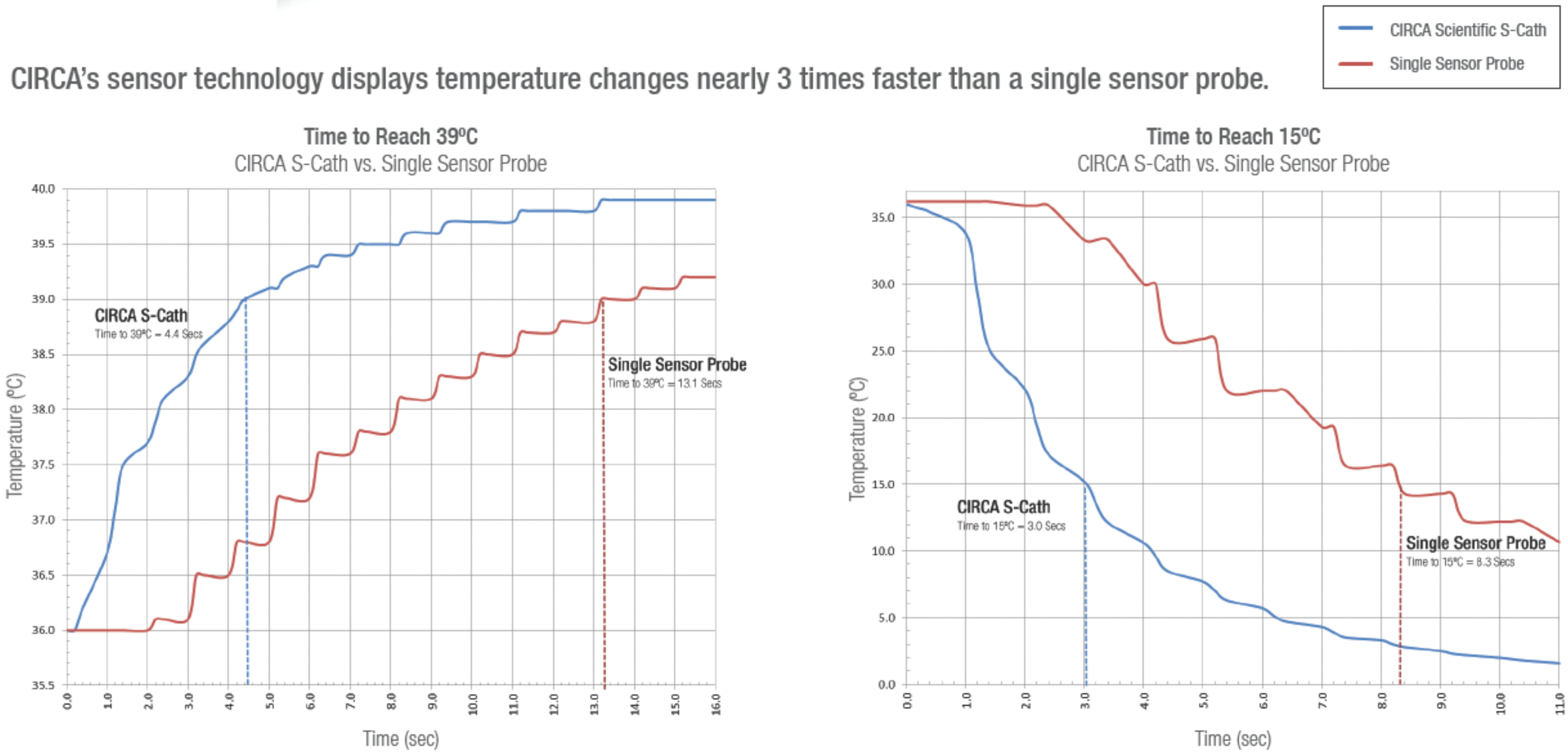
Continuous monitoring software is highly accurate in both hot and cold (down to 0°C) temperatures.[3]

- 12 temperature sensors update 20 times per second
- Four, user selectable low and high temperature alarms
- Temperature is displayed both graphically and numerically

CIRCA's sensor technology displays temperature changes nearly 3 times faster than a single sensor probe.

Time to Reach 39ºC
CIRCA S-Cath vs. Single Sensor Probe

Time to Reach 15ºC
CIRCA S-Cath vs. Single Sensor Probe



...positioning.
Test conducted by CIRCA Scientific.

Product Code Description

CS-1000	CIRCA Temperature Monitoring System™ (Touch Screen Display, Pole Mount included)
CS-2001	CIRCA S-CATH™ Esophageal Temperature Probe, (Single Use, 10Fr O.D.,10 units/ Carton), U.S.*
CS-2006	CIRCA S-CATH™ Esophageal Temperature Probe, (Single Use, 10Fr O.D.,10 units/ Carton), International*
CS-2003	CIRCA S-CATH Interconnect Cable (Reusable, 15 Foot Working Length)
CS-1029	CIRCA Temperature Standard (Calibration)

CIRCA SCIENTIFIC

Corporate Office
14 Inverness Drive East, Suite H-136
Englewood, CO 80112
www.CIRCASCIENTIFIC.com
Office: 1.303.951.8767 • Fax: 1.303.951.8769
info@circascientific.com

All products carry the CE mark, comply with Medical Device Directive 93/42/EEC and are manufactured to Quality Systems ISO13485.

This product is listed by CSA International as certified.

Indication for Use: The CIRCA S-CATH Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus. The CIRCA Temperature Monitor is indicated to display continuous temperature measurement (°C) from 12-sensor temperature probe.

[1] Cury RC, Abbara S, Schmidt S, Malchano ZJ, Neuzil P, Weichet J, Ferencik M, et al. Relationship of the esophagus and aorta to the left atrium and pulmonary veins: Implications for catheter ablation of atrial fibrillation. Heart Rhythm 2005; 2:1317-1323.

[2] Sánchez-Quintana D, Cabrera JA, Climent V, Farré J, de Mendonça MC, Ho SY. Anatomic relations between the esophagus and left atrium and relevance for ablation of atrial fibrillation. Circulation. 2005;112: 1400-1405.

[3] Accuracy of the temperature sensors is ± 0.3°C within the rated output range of 25°C to 45°C and ± 0.4°C within the rated extended output range of 0° to 24.9°C.

CE 0470

*US and Foreign Patents Pending

Instructions for Use: S-Cath™ Esophageal Temperature Probe

General warnings and cautions:

- Rx Only: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Single use only. Do not re-use. If re-used, cross-infection to patient may occur.
- Do not rinse, soak, wash, or sterilize. Material degradation and temperature inaccuracy may occur.
- Insert temperature probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction.
- Do not re-insert stylet or attempt to override lock-out feature, probe damage may occur.
- The S-Cath™ Esophageal Temperature Probe is designed for use with CIRCA Scientific Interconnect Cable, CIRCA Scientific Temperature Monitor, and 400 Series Compatible Monitor only. Incompatible components can result in degraded performance and could lead to damage.
- Part of defibrillation proof protection is provided by the S-Cath™ Temperature Probe with the CIRCA Scientific Temperature Monitor (Defibrillation-Proof Type BF Applied Part). When 400 Series Cable Connector is connected to 400 Series Compatible Monitor, consult equipment manufacturer's accompanying documents for the monitor's defibrillation-proof classification.

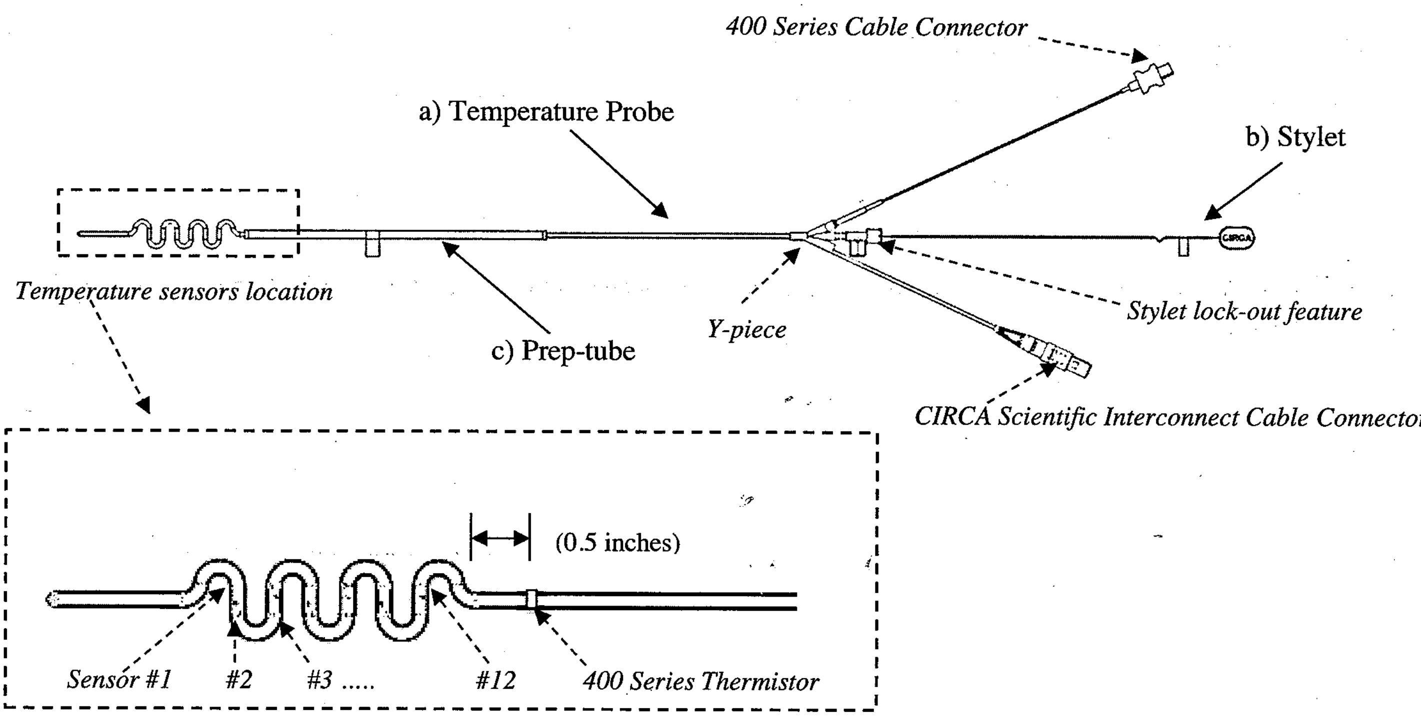
Indications for use:

The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Description:

The S-Cath™ Esophageal Temperature Probe provides continuous temperature measurement (°C) and operates in direct mode.

The components inside package are: a) radiopaque temperature probe; b) stainless steel stylet; and c) plastic prep-tube.



Manufactured for:
CIRCA Scientific, LLC
[illegible]
Englewood, CO 80112
(303) 951-8767

Setup instructions:

The operator is responsible for checking the compatibility of the temperature probe, interconnect cable, and monitor before use. Ensure only CIRCA Scientific components and equipment is connected to CIRCA Scientific cable connector.

S1) Remove device from package.

S2) Visually inspect for damage, kinks, visible debris, and missing components. Do not use if any defects are observed.

S3) Connect CIRCA Scientific Interconnect Cable Connector to CIRCA Scientific monitor via CIRCA Scientific interconnect cable by aligning snap-fit connectors and pushing firmly.

S4) If used, align 400 series cable connector with 400 series compatible temperature monitor cable and push firmly to assure full contact.

S5) Verify temperatures are displayed on monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on monitor.

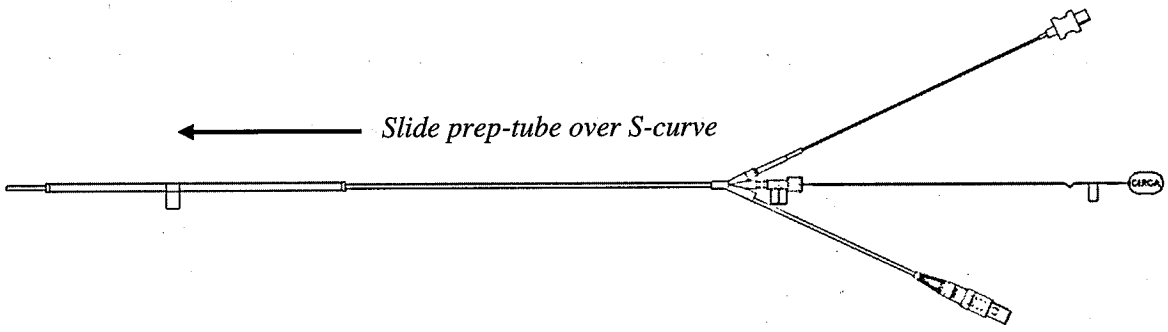
S6) Disconnect temperature probe from interconnect cable by grasping connectors. Do not pull on cable or probe wire to disconnect.

S7) Proceed with operating instructions below.

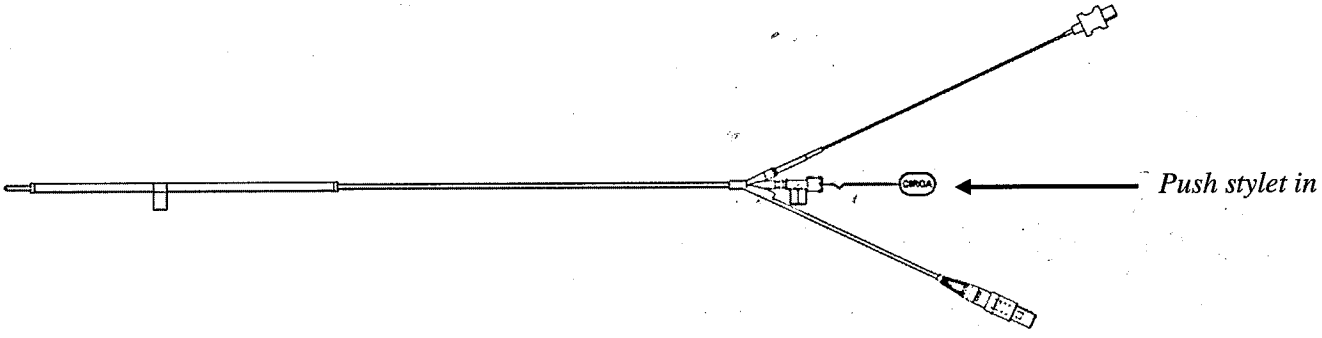
Operating instructions:

O1) Straighten S-Curve Portion of Temperature Probe

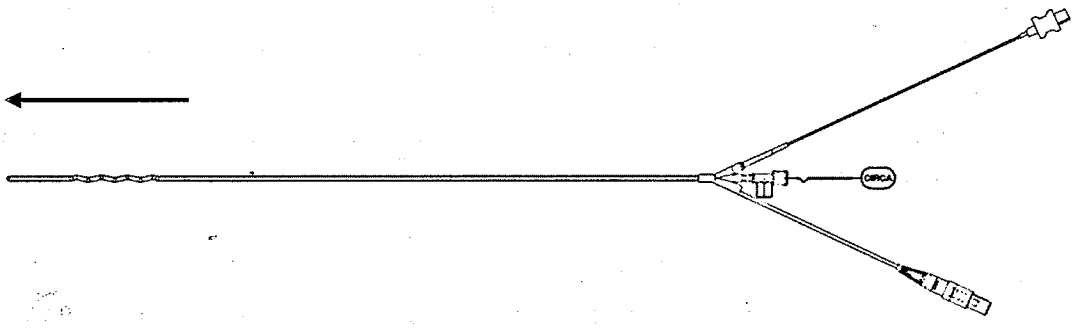
a. Grasp Y-piece of temperature probe with one hand and slide prep-tube over S-curve portion to approximately 20 mm (3/4") from the end with other hand.



b. Grasp Y-piece of temperature probe with one hand and push stainless steel stylet until z-bend of stylet reaches Y-piece.



c. ***Remove prep-tube and discard***



Note: Once prèp-tube is removed and discarded, temperature probe is now ready for insertion; proceed with step O2)

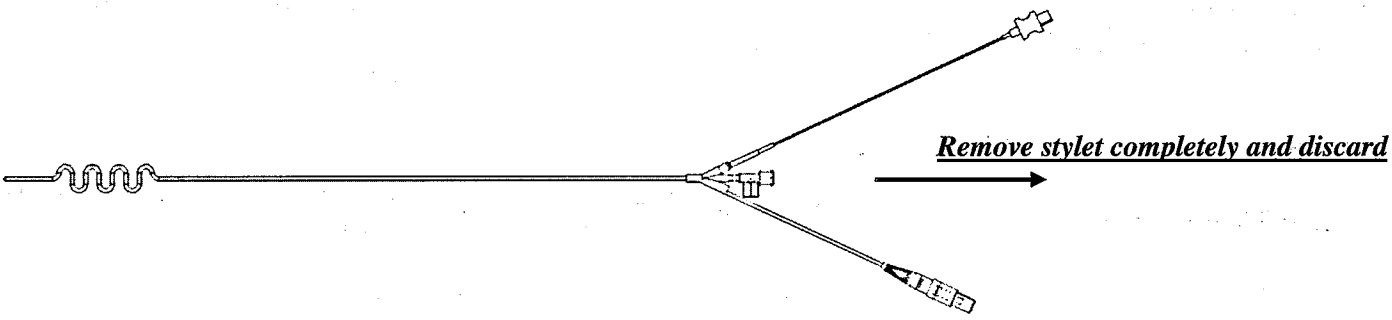
O2) Insert Temperature Probe into Esophagus

a. Apply water-soluble lubricant to outside of temperature probe.

b. Insert temperature probe into esophagus under fluoroscopic x-ray. Advance distal tip to approximately 1 cm (0.4") superior to the gastroesophageal junction.

c. Once temperature probe is placed, grasp finger grip end of stylet and remove completely. Discard stylet.

Caution: do not re-insert stylet or attempt to override lock-out feature, probe damage may occur.



d. Verify position of temperature probe under fluoroscopic x-ray. If probe end does not appear as an S-shape, grasp Y-piece and rotate probe until S-shape is visible. Grasp Y-piece to reposition probe as required for desired placement.

Instructions for Use: S-Cath™ Esophageal Temperature Probe

Setup instructions:

The operator is responsible for checking the compatibility of the temperature probe, interconnect cable, and monitor before use. Ensure only CIRCA Scientific components and equipment is connected to CIRCA Scientific cable connector.

S1) Remove device from package.

S2) Visually inspect for damage, kinks, visible debris, and missing components. Do not use if any defects are observed.

S3) Connect CIRCA Scientific Interconnect Cable Connector to CIRCA Scientific monitor via CIRCA Scientific interconnect cable by aligning snap-fit connectors and pushing firmly.

S4) If used, align 400 series cable connector with 400 series compatible temperature monitor cable and push firmly to assure full contact.

S5) Verify temperatures are displayed on monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on monitor.

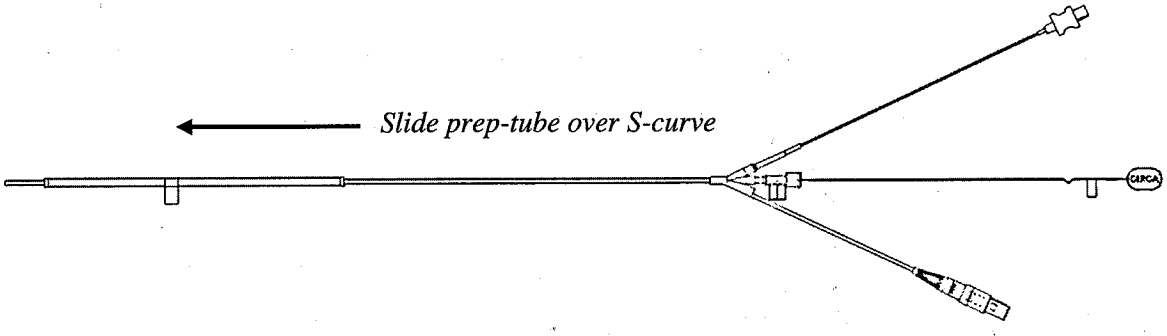
S6) Disconnect temperature probe from interconnect cable by grasping connectors. Do not pull on cable or probe wire to disconnect.

S7) Proceed with operating instructions below.

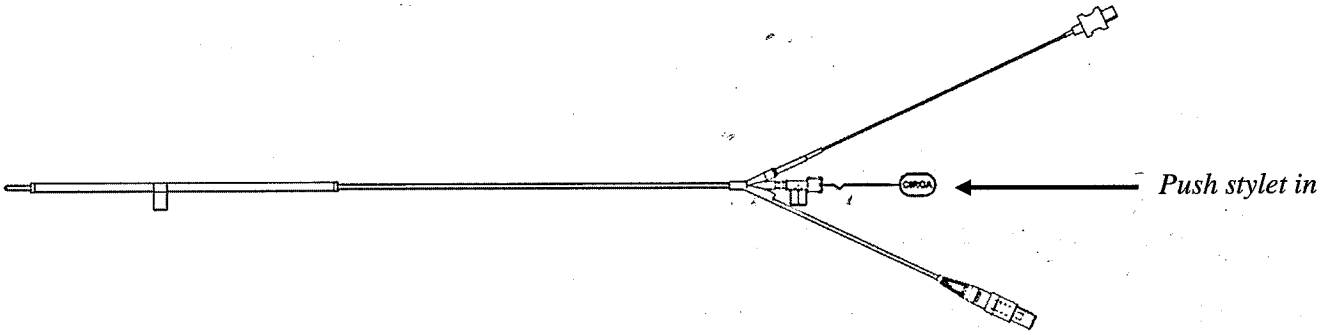
Operating instructions:

O1) Straighten S-Curve Portion of Temperature Probe

a. Grasp Y-piece of temperature probe with one hand and slide prep-tube over S-curve portion to approximately 20 mm (3/4") from the end with other hand.



b. Grasp Y-piece of temperature probe with one hand and push stainless steel stylet until z-bend of stylet reaches Y-piece.



CIRCA SCIENTIFIC

S-Cath™

Esophageal Temperature Probe

Intended Use: The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Size: 10 Fr OD Length: 50cm

REF CS-2001

LOT 026941

QTY 1

2014-05

Rx Only

Manufactured for : CIRCA Scientific, LLC
14 Inverness Drive East, Suite H-136
Englewood, CO 80112 USA
(303) 951-8767

EC REP Medicor Medical Supplies NV/ SA
Timmerik 2, B-3020 Herent, Belgium

CE 0470

CS-ART2001 Rev.03

ATTACHMENT D: REVISED INSTRUCTION MANUAL

InfraRed Thermographic System (IRTS)

Instruction Manual

TABLE OF CONTENTS

1. SYSTEM OVERVIEW

The InfraRed Thermographic System (IRTS) consists of three components:

DIAGRAM LETTER	REF #	NAME	DESCRIPTION
A	A-10734	Thermal Imaging Probe (TIP)	Temperature Probe
B	A-10667	Patient Interface Unit (PIU)	Main system control unit
C	A-10395	Patient Monitoring Unit (PMU)	Touchscreen monitor

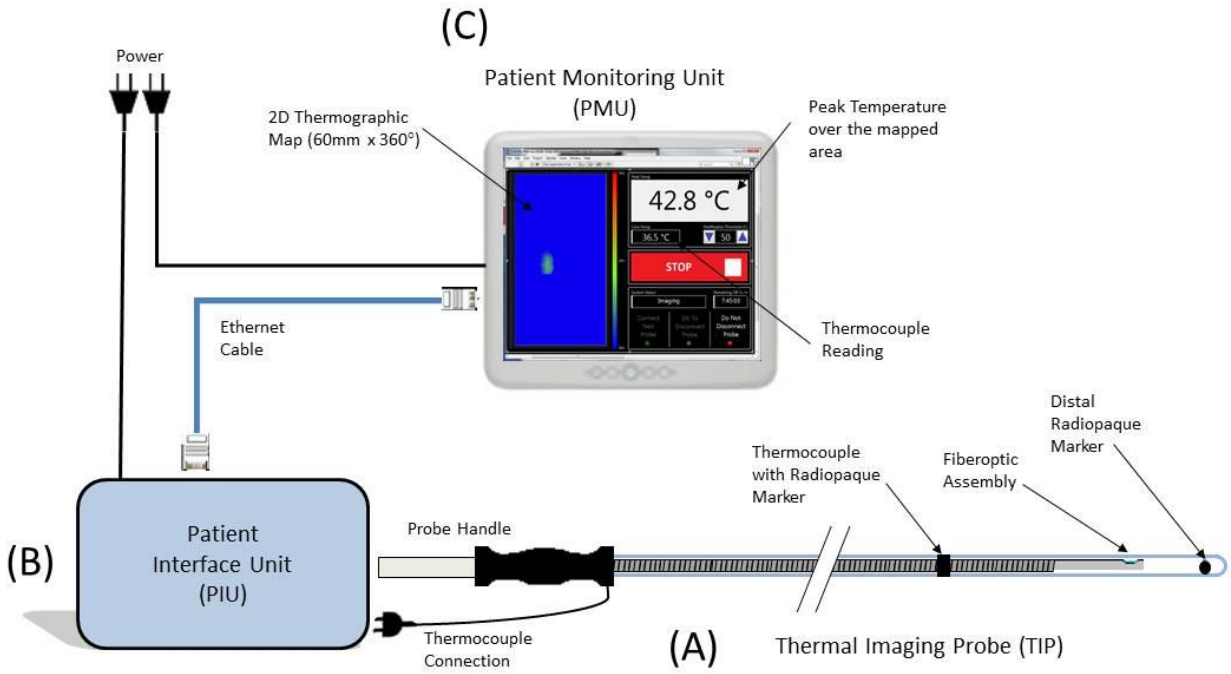


Figure 1: System Overview Diagram

The InfraRed Thermographic System (IRTS) is designed to provide continuous direct mode esophageal temperature monitoring through the use of a standard thermocouple located at the proximal radiopaque marker. In addition, the system incorporates adjunctive infrared thermal imaging technology for quantifying differences in surface temperature changes in the esophagus.

The Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) displays the thermal image and temperature measurements (°C) from the Thermal Imaging Probe (TIP). The thermal image provides a continuous, real-time, non-contact thermal map of a 360° by 60mm long segment of the inner lumen of the esophagus. The thermal image is displayed in a two-dimensional color map. The peak temperature represents the maximum temperature over the scanned area.

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.***

2. INDICATIONS FOR USE

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

3. CONTRAINDICATIONS, WARNINGS and CAUTIONS

CONTRAINDICATIONS

The use of the IRTS is contraindicated for patients who have:

- Symptomatic Esophageal Stricture
- Esophageal Diverticulum
- Esophageal Tumor or Abscess
- Recent Esophageal or Gastric Surgery

WARNINGS

- The Probe is single use only. Do not re-use. Cross-infection to patient may occur and the device may not function properly.
- The Securus IRTS PMU should only be used with Securus IRTS Probes. Use of incompatible components can result in degraded performance or harm.
- Ethernet ports on PMU and PIU components should only be connected to one another.
- Insert Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.
- Do not attempt to reposition Probe while imaging. To reposition always hit “Stop” and wait for the button message “Start Imaging”.
- The Securus IRTS is to be installed and serviced exclusively by Securus technicians. Do not attempt to install, repair, service, or operate the Securus IRTS in any fashion deviating from what is specified in this manual.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- All electrical equipment supporting the patient must be appropriately grounded and must comply with all current regulations and must be of CF type.
- The use of accessories and cables other than those listed above may result in increased EMISSIONS or decreased IMMUNITY of the Securus IRTS.
- The Securus IRTS should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Securus IRTS should be observed to verify normal operation in the configuration in which it will be used.
- Use system only within the indicated operating environment temperature and humidity range. Use outside the specified operating environment may result in inaccurate esophageal temperature readings.

- The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended in Table 4.
- Read and follow all prompts, warnings, errors, and instructions on the IRTS User Interface to ensure proper operation. Failure to follow these instructions can result in degraded performance or harm.

CAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- The thermal image and peak temperature are offered as an adjunct to other clinical diagnostic procedures. Only the thermocouple temperature measurement meets the requirements for essential performance of Clinical Thermometers for body temperature measurement accuracy.
- Due to Non-Uniform Rotational Distortion (NURD) of the device, some distortion of the thermal image may occur. Numerical temperature measurements are not affected by this phenomenon.
- Only physicians trained in esophageal insertion and catheterization procedures should use the IRTS.
- Do not use the IRTS for any purpose other than its intended use.
- Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock.
- Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.
- Do not bend or kink the probe in a sharp angle or a small radius.
- The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
- Avoid touching the proximal tip of the Probe to avoid damaging the Probe.
- The Probe is provided fully assembled. Do not disassemble the Probe. Disassembly will damage the device.
- The system components will not function with equipment from other manufacturers.
- At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.
- The Probe is not recommended for use in combination with a barium esophagram.

If you experience any problems with this product please contact Securus at 216-445-4683

4. SET-UP

A Securus Technician will install the system at your facility. The installation will include:

- Initial inspection of the system for shipping damage
- Identifying the proper location and suitable surface for the PMU and PIU in the lab
- Connection and routing of Ethernet cable
- Identification of suitable power sources
- Initializing software, setting local time and date and other relevant software settings
- Confirming system fully operational in the lab environment

Note: The following steps assume that the Securus installation has already occurred.

4.1. Inspect the PMU and PIU for damage. Do not use the system, and contact Securus if damage is evident.

> **CAUTION:** Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock

4.2. Confirm PIU and PMU are placed on a suitable surface in a dry location.

> **CAUTION:** At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.

4.3. Confirm that the correct power supplies and provided Ethernet cable are plugged into the back panel of the PIU and of the PMU. Plug both power supplies into a grounded, 100-240VAC outlet (50/60hz). Only use the Securus issued power supplies for the IRTS system.

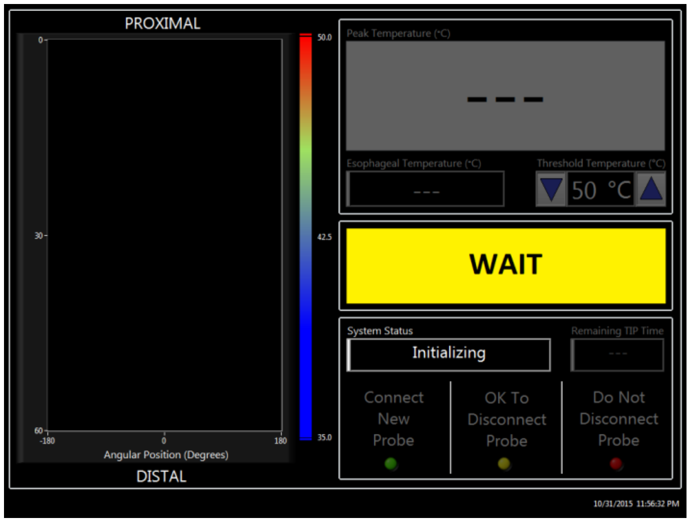
> **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Position of equipment should not make it difficult to disconnect the mains plug.

> **CAUTION:** The system components will not function with equipment from other manufacturers.

4.4. Obtain a new Probe. The Instructions for Use (IFU) is supplied with the Probe. Please read and follow the Probe instructions carefully.

5. SYSTEM OPERATION

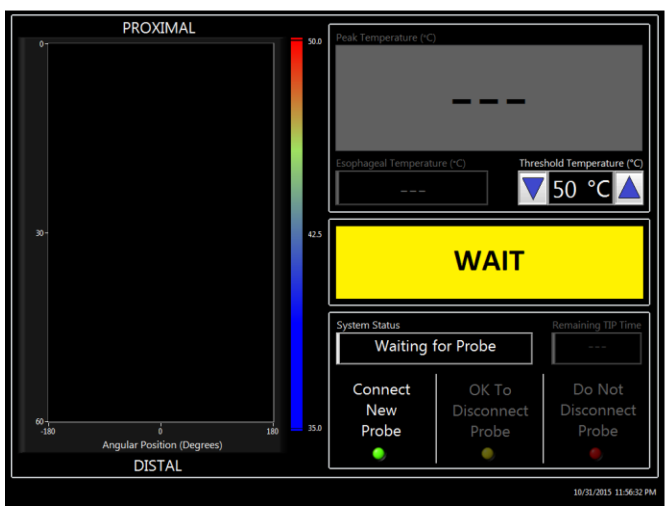
5.1. Turn on power to the PMU by pressing the power button located on the lower right-hand side of the unit. The monitor will display the user interface with the following message "WAIT".



5.2. Turn on power to the PIU by pressing power button on the left side of the back panel. The green power LED will light. The PIU will begin initialization. It requires approximately 5-minutes to complete the initialization process.

5.3. Follow Instructions for Use provided with the Probe. Insert the probe into the patient. Care should be exercised to avoid damaging the probe. Do not kink or clamp Probe at any time.

5.4. The PMU will prompt you when the PIU is ready to accept a new Probe.



5.5. Insert the Probe Connector (1) into the PIU Probe Receptacle (2) and turn it 90 degrees. Plug the Thermocouple Connector (3) into the PIU TC Receptacle (4).

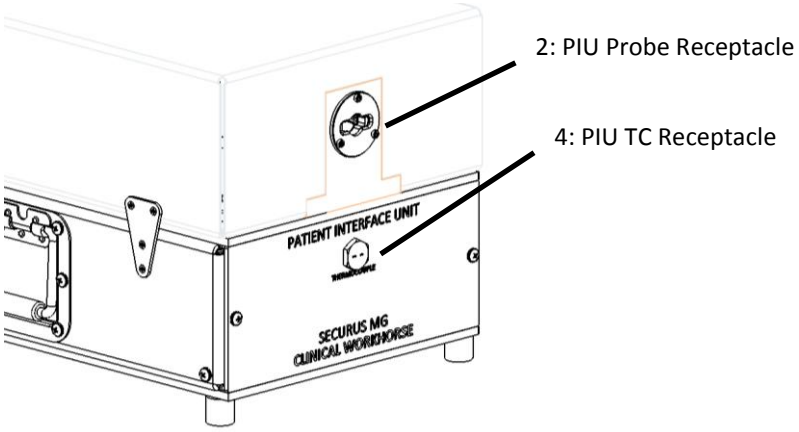


Figure 2: PIU Front

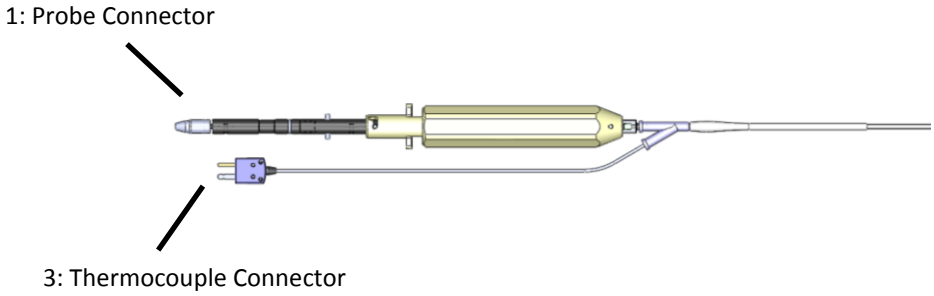


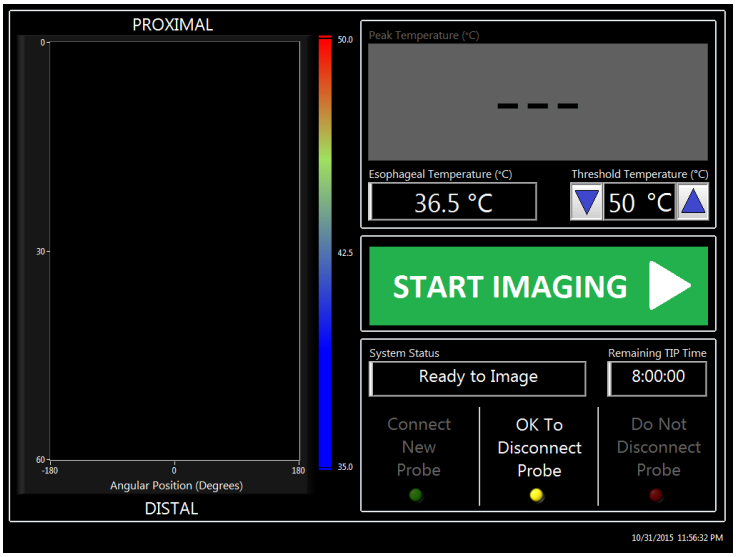
Figure 3: Probe

WARNING: Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging"

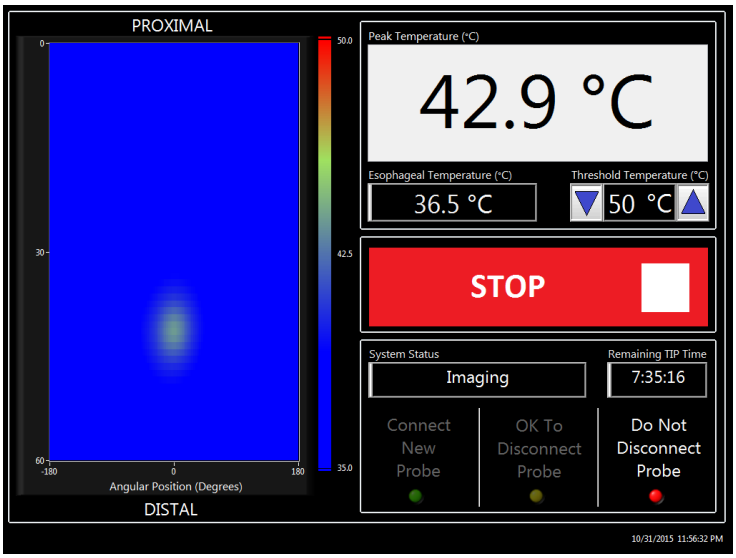
CAUTION: The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.

5.6. To initiate the thermal image and peak temperature Press “Start Imaging” on the user interface.

NOTE: If the peak temperature over the scan area is less than 35°C the Image will be blue and the Peak Temperature will state “< 35°C”.



5.7. Press “Stop” to cease thermal imaging.



5.7.1. System will automatically proceed through Probe docking routine. Press “Stop Docking” to interrupt this process.

5.7.2. When probe is docked, press “Start Imaging” to begin imaging again.

5.8. If the procedure is finished, ensure the status light reads “OK to Disconnect Probe”.

5.9. Remove the probe from the patient.

5.10. Remove the Probe from the PIU by first unplugging the thermocouple. Then turn the handle 90 degrees counter clockwise, remove, and discard.

5.11. Power down the PIU and the PMU. Turn off power to the PMU by pressing the power button located on the lower right-hand side of the unit.

6. ADDITIONAL INFORMATION

6.1. To set a notification temperature, press the (▲) or (▼) key under "Threshold Temperature (°C)" until you reach the desired value. If the peak temperature is equal to or above this number, an audible and visual notification will sound.

6.1.1. Temporarily disable notification by tapping the "Peak Temperature" indicator.

6.2. Pressing "Stop" or "Stop Docking" will immediately cease all PIU action. If on-screen prompts appear, follow them to continue.

6.3. The Probe is a single use device. Probes have a limited lifetime, which is measured and tracked in the software. Once a probe has reached its defined life it should be discarded. The user interface will inform the user when one hour of useful life remains, and again when a Probe change is necessary.

CAUTION: Do not attempt to operate the Probe beyond its intended service life.

6.4. Initialization is the default status for the system when it is waiting or performing internal status checks. In many cases the system will complete its internal processes and proceed out of Initialization status when ready.

6.5. User Interface States

Button Text	System Status Text	Meaning
Wait	Initializing	System is undergoing start-up procedure. Insert a Probe when instructed by the User Interface.
Wait	Waiting for Probe	System is ready for user to engage Probe
Start Imaging	Ready to Image	System is ready to begin Imaging Session.
Stop	Preparing to Image	System is executing Pre-Imaging routine.
Stop	Imaging	System is Imaging.
Stop Docking	Docking	System is docking probe.
ERROR	TIP Expired	Probe has reached the end of its expected lifespan.
ERROR	ERROR	System has detected an error. Follow additional warnings and instructions on the user interface.

6.6. Cleaning: The PIU and PMU may be cleaned by wiping with a disinfectant soap solution. Suitable disinfectants include bleach or hydrogen peroxide based soap solutions such as Clorox Healthcare Bleach Germicidal Cleaner or Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant. Disinfectants should be applied by wiping or spraying onto the surface and should be allowed to stand wet for a minimum of 1 minute. Wipe with a clean, damp cloth. Allow to air dry. Other suitable cleaners approved by your institution may be used on the PUI and PMU.

The PIU and PMU are not designed for immersion or machine washing techniques. Immersion will damage the electromechanical elements inside of the case.

6.7. Maintenance or Calibration: System cannot be maintained or calibrated by the user. System should be returned to Securus for service after one calendar year of use.

7. SPECIFICATIONS

System	
Esophageal Temperature Accuracy (Thermocouple)	± 0.3°C
Esophageal Temperature Range (Thermocouple)	25°C - 45°C
Transient Response Time of Thermocouple for a 2°C temperature change	2.5 seconds for both heating and cooling from a reference water bath to a water bath with a 2°C temperature differential
Thermal Sensitivity	0.1°C within temp range
Infrared Temperature Accuracy	± 2°C
Infrared Temperature Range	35°C - 60°C
Infrared Thermal Image Resolution, Longitudinal	1 Sample / mm over 60 mm
Infrared Thermal Image Resolution, Rotational	1 Sample / 2.8125° over 360°
Ethernet cable length	3 meters (10 feet)
Storage and transportation environmental	Temperature Range -15°C to 40°C (5°F to 104°F) Relative Humidity 10 to 93% Air Pressure 500 to 1060 hPa (15 to 31 in. Hg)
Operating environmental	Temperature Range 15°C to 35°C (59°F to 95°F) Relative Humidity 25 to 85% Air Pressure 700 to 1060 hPa (21 to 31 in. Hg)
Disposal	Dispose of in compliance with all applicable local, state, federal laws and regulations. PIU and PMU should be returned to Securus at end of life.
Patient Monitoring Unit	
Size	43cm x 40cm x 81cm (17" x 15.8" x 3.2")
Weight	8.2kg (18.1 lbs)
AC DC Power Supply	12/19.5 VDC 135W
Patient Interface Unit	
Size	49cm x 28cm x 28cm (19" x 11" x 11")
Weight	18kg (39 lbs)
AC DC Power Supply	24 VDC 250W
Probe	
Probe length (exclude handle)	118 cm
Probe length overall	153 cm
Standards	
Electrical Safety	Tested in compliance with IEC 60601-1:2005+A1:2012(E) (applicable sections)
	Tested in compliance with IEC 60601-1-2:2007
	Tested in compliance with applicable sections of ISO 80601-2-56
Accuracy Thermocouple	Fully complies with ISO 80601-2-56:2009 requirements (applicable sections)
Type and degree of protection, electrical shock	Type CF, Class I
Degree of protection against ingress of water (IEC 529)	IP2X

See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.

8. ELECTROMAGNETIC COMPATIBILITY (EMC) and ELECTROMAGNETIC SAFETY

8.1. The Securus IRTS has been tested and complies with international Standard IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

8.2. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

8.3. Portable and mobile RF communications equipment can affect Medical electrical equipment performance and safe operation. Portable and mobile RF communications equipment should be separated from the Securus IRTS by at least the minimum separation distances listed in Table 4.

8.4. To maintain the Electromagnetic Compatibility of the Securus IRTS, only the following cables and accessories should be used:

Part Number	Description
A-10734	Temperature Probe
P-10800	L-COM TRD855SCR-10 Ethernet cable – 10.0 ft length
P-10259	Patient Interface Unit (PIU) Power Supply (Includes Power Cord)
P-10838	Patient Monitoring Unit (PMU) Power Supply (Includes Power Cord)

8.5. The following tables are to provide information on the electromagnetic compatibility of the Securus IRTS. If interference is observed or the system is not working correctly, the following information may be useful in correcting the problem. In particular Table 4 provides guidance on the distance that a portable transmitter, communications device, and cellular phones should be kept away from the Securus IRTS to avoid interference or adverse operation of the Securus system.

Table 1- Guidance and manufacturer's declaration – Electromagnetic Emissions

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions *CISPR 11*	*Group 1*	*The Securus IRTS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
RF emissions CISPR 11	Class A	The Securus IRTS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 - Guidance and manufacturer's declaration – Electromagnetic Immunity

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Securus IRTS requires continued operation during power mains interruptions, it is recommended that the Securus IRTS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 3 - Guidance and manufacturer's declaration – Electromagnetic Immunity

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Securus IRTS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Securus IRTS is used exceeds the applicable RF compliance level above, the Securus IRTS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Securus IRTS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Recommended separation distances between portable and mobile RF communications equipment and the Securus IRTS

The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. GENERAL INFORMATION

Manufactured and Distributed By:

Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
216-445-4683

SYMBOLS KEY

REF	Catalog number		Manufacturer
LOT	Lot Number	SN	Serial Number
QTY	Quantity	NON STERILE	Non-Sterile
	Use by - year and month		See accompanying documentation
	Consult instructions for use		Do not use if product is broken, damaged or open
	Do not reuse		Defibrillation – Proof Type CF Applied Part

ATTACHMENT E: CITED PUBLICATIONS

Print this Page

Web Review of Todar's Online Textbook of Bacteriology. *"The Good, the Bad, and the Deadly"*

Tag words: bacteriology, bacteria, m crobiology, microbe, normal flora, indigenous bacteria, E. coli, Staphylococcus, Streptococcus, Enterococcus, Lactobacillus, Bif dobacterium, corynebacteria, clostridium, neisseria, bacteroides, Haemophilus, b ofilm, dental plaque, dental caries, per odontal disease.

The Normal Bacterial Flora of Humans (page 3)

(This chapter has 5 pages)

The Composition of the Normal Flora

The normal flora of humans are exceedingly complex and consist of more than 200 species of bacteria. The makeup of the normal flora may be influenced by various factors, including genetics, age, sex, stress, nutrition and diet of the individual.

Three developmental changes in humans, weaning, the eruption of the teeth, and the onset and cessation of ovarian functions, invariably affect the composition of the normal flora in the intestinal tract, the oral cavity, and the vagina, respectively. However, within the limits of these fluctuations, the bacterial flora of humans is sufficiently constant to a give general description of the situation.

A human first becomes colonized by a normal flora at the moment of birth and passage through the birth canal. In utero, the fetus is sterile, but when the mother's water breaks and the birth process begins, so does colonization of the body surfaces. Handling and feeding of the infant after birth leads to establishment of a stable normal flora on the skin, oral cavity and intestinal tract in about 48 hours.

It has been calculated that a human adult houses about 10^{12} bacteria on the skin, 10^{10} in the mouth, and 10^{14} in the gastrointestinal tract. The latter number is far in excess of the number of eucaryotic cells in all the tissues and organs which comprise a human. The predominant bacteria on the surfaces of the human body are listed in Table 3. Informal names identify the bacteria in this table. Formal taxonomic names of organisms are given in Table 1.

Table 3. Predominant bacteria at various anatomical locations in adults.

Anatomical Location	Predominant bacteria
Skin	staphylococci and corynebacteria
Conjunctiva	sparse, Gram-positive cocci and Gram-negative rods
Oral cavity	
teeth	streptococci, lactobacilli
mucous membranes	streptococci and lactic acid bacteria
Upper respiratory tract	
nares (nasal membranes)	staphylococci and corynebacteria
pharynx (throat)	streptococci, neisseria, Gram-negative rods and cocci

Lower respiratory tract	**none**
Gastrointestinal tract	
stomach	***Helicobacter pylori* (up to 50%)**
small intestine	**lactics, enterics, enterococci, bifidobacteria**
colon	**bacteroides, lactics, enterics, enterococci, clostridia, methanogens**
Urogenital tract	
anterior urethra	**sparse, staphylococci, corynebacteria, enterics**
vagina	**lactic acid bacteria during child-bearing years; otherwise mixed**

Normal Flora of the Skin The adult human is covered with approximately 2 square meters of skin. The density and composition of the normal flora of the skin varies with anatomical locale. The high moisture content of the axilla, groin, and areas between the toes supports the activity and growth of relatively high densities of bacterial cells, but the density of bacterial populations at most other sites is fairly low, generally in 100s or 1000s per square cm. Most bacteria on the skin are sequestered in sweat glands.

The skin microbes found in the most superficial layers of the epidermis and the upper parts of the hair follicles are Gram-positive cocci (*Staphylococcus epidermidis* and *Micrococcus* sp.) and corynebacteria such as *Propionibacterium* sp. These are generally nonpathogenic and considered to be commensal, although mutualistic and parasitic roles have been assigned to them. For example, staphylococci and propionibacteria produce fatty acids that inhibit the growth of fungi and yeast on the skin. But, if *Propionibacterium acnes,* a normal inhabitant of the skin, becomes trapped in hair follicle, it may grow rapidly and cause inflammation and acne.

Sometimes potentially pathogenic *Staphylococcus aureus* is found on the face and hands in individuals who are nasal carriers. This is because the face and hands are likely to become inoculated with the bacteria on the nasal membranes. Such individuals may autoinoculate themselves with the pathogen or spread it to other individuals or foods.

Normal Flora of the Conjunctiva A variety of bacteria may be cultivated from the normal conjunctiva, but the number of organisms is usually small. *Staphylococcus epidermidis* and certain coryneforms (*Propionibacterium acnes*) are dominant. *Staphylococcus aureus, some* streptococci, *Haemophilus* sp. and *Neisseria* sp. are occasionally found. The conjunctiva is kept moist and healthy by the continuous secretions from the lachrymal glands. Blinking wipes the conjunctiva every few seconds mechanically washing away foreign objects including bacteria. Lachrymal secretions (tears) also contain bactericidal substances including lysozyme. There is little or no opportunity for microorganisms to colonize the conjunctiva without special mechanisms to attach to the epithelial surfaces and some ability to withstand attack by lysozyme.

Pathogens which do infect the conjunctiva (e.g. *Neisseria gonorrhoeae* and *Chlamydia trachomatis*) are thought to be able to specifically attach to the conjunctival epithelium. Newborn infants may be especially prone to bacterial attachment. Since *Chlamydia* and *Neisseria* might be present on the cervical and vaginal epithelium of an infected mother, silver nitrate or an antibiotic may be put into the newborn's eyes to avoid infection after passage through the birth canal.

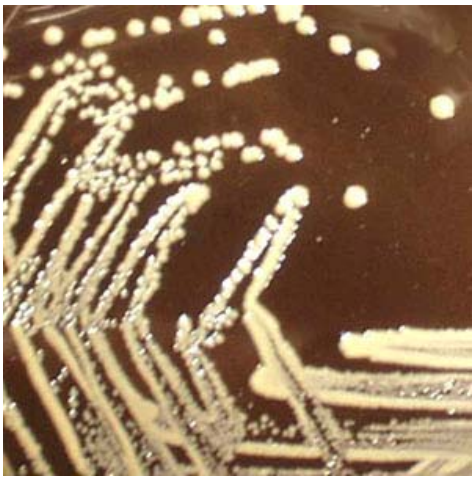


Figure 4. Colonies of *Propionibacterium acnes,* found on skin and the conjunctiva.

Normal Flora of the Respiratory Tract A large number of bacterial species colonize the upper respiratory tract (nasopharynx). The nares (nostrils) are always heavily colonized, predominantly with *Staphylococcus epidermidis* and corynebacteria, and often (in about 20% of the general population) with *Staphylococcus aureus,* this being the main carrier site of this important pathogen. The healthy sinuses, in contrast are sterile. The pharynx (throat) is normally colonized by streptococci and various Gram-negative cocci. Sometimes pathogens such as *Streptococcus pneumoniae, Streptococcus pyogenes, Haemophilus influenzae* and *Neisseria meningitidis* colonize the pharynx.

The lower respiratory tract (trachea, bronchi, and pulmonary tissues) is virtually free of microorganisms, mainly because of the efficient cleansing action of the ciliated epithelium which lines the tract. Any bacteria reaching the lower respiratory tract are swept upward by the action of the mucociliary blanket that lines the bronchi, to be removed subsequently by coughing, sneezing, swallowing, etc. If the respiratory tract epithelium becomes damaged, as in bronchitis or viral pneumonia, the individual may become susceptible to infection by pathogens such as *H influenzae* or *S pneumoniae* descending from the nasopharynx.

Normal Flora of the Urogenital Tract Urine is normally sterile, and since the urinary tract is flushed with urine every few hours, microorganisms have problems gaining access and becoming established. The flora of the anterior urethra, as indicated principally by urine cultures, suggests that the area my be inhabited by a relatively consistent normal flora consisting of S*taphylococcus epidermidis, Enterococcus faecalis* and some alpha-hemolytic streptococci. Their numbers are not plentiful, however. In addition, some enteric bacteria (e.g. *E coli, Proteus*) and corynebacteria, which are probably contaminants from the skin, vulva or rectum, may occasionally be found at the anterior urethra.

The vagina becomes colonized soon after birth with corynebacteria, staphylococci, streptococci, *E coli*, and a lactic acid bacterium historically named "Doderlein's bacillus" (*Lactobacillus acidophilus*). During reproductive life, from puberty to menopause, the vaginal epithelium contains glycogen due to the actions of circulating estrogens. Doderlein's bacillus predominates, being able to metabolize the glycogen to lactic acid. The lactic acid and other products of metabolism inhibit colonization by all except this lactobacillus and a select number of lactic acid bacteria. The resulting low pH of the vaginal epithelium prevents establishment by most other bacteria as well as the potentially-pathogenic yeast, *Candida albicans* This is a striking example of the protective effect of the normal bacterial flora for their human host.

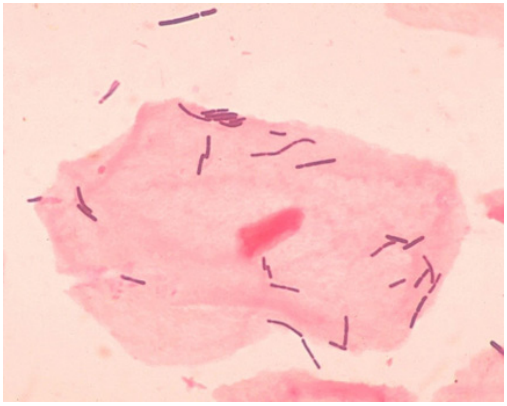


Figure 5. A *Lactobacillus* species, possibly Doderlein's bacillus, in association with a vaginal epithelial cell.

Normal Flora of the Oral Cavity The presence of nutrients, epithelial debris, and secretions makes the mouth a favorable habitat for a great variety of bacteria. Oral bacteria include streptococci, lactobacilli, staphylococci and corynebacteria, with a great number of anaerobes, especially bacteroides.

The mouth presents a succession of different ecological situations with age, and this corresponds with changes in the composition of the normal flora. At birth, the oral cavity is composed solely of the soft tissues of the lips, cheeks, tongue and palate, which are kept moist by the secretions of the salivary glands. At birth the oral cavity is sterile but rapidly becomes colonized from the environment, particularly from the mother in the first feeding. *Streptococcus salivarius* is dominant and may make up 98% of the total oral flora until the appearance of the teeth (6 - 9 months in humans). The eruption of the teeth during the first year leads to colonization by *S mutans* and *S sanguis*. These bacteria require a nondesquamating (nonepithelial) surface in order to colonize. They will persist as long as teeth remain. Other strains of streptococci adhere strongly to the gums and cheeks but not to the teeth. The creation of the gingival crevice area (supporting structures of the teeth) increases the habitat for the variety of anaerobic species found. The complexity of the oral flora continues to increase with time, and bacteroides and spirochetes colonize around puberty.

Figure 6. Various streptococci in a biofilm in the oral cavity.

The normal bacterial flora of the oral cavity clearly benefit from their host who provides nutrients and habitat. There may be benefits, as well, to the host. The normal flora occupy available colonization sites which makes it more difficult for other microorganisms (nonindigenous species) to become established. Also, the oral flora contribute to host nutrition through the synthesis of vitamins, and they contribute to immunity by inducing low levels of circulating and secretory antibodies that may cross react with pathogens. Finally, the oral bacteria exert

microbial antagonism against nonindigenous species by production of inhibitory substances such as fatty acids, peroxides and bacteriocins.

On the other hand, the oral flora are the usual cause of various oral diseases in humans, including abscesses, dental caries, gingivitis, and periodontal disease. If oral bacteria can gain entrance into deeper tissues, they may cause abscesses of alveolar bone, lung, brain, or the extremities. Such infections usually contain mixtures of bacteria with *Bacteroides melaninogenicus* often playing a dominant role. If oral streptococci are introduced into wounds created by dental manipulation or treatment, they may adhere to heart valves and initiate subacute bacterial endocarditis.

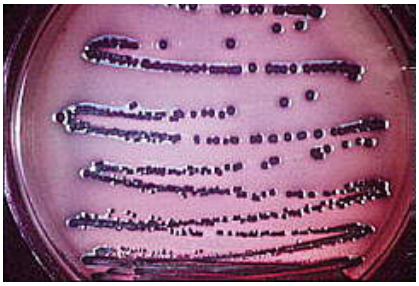


Figure 7. Colonies of *E. coli* growing on EMB agar.

Normal Flora of the Gastrointestinal Tract The bacterial flora of the gastrointestinal (GI) tract of animals has been studied more extensively than that of any other site. The composition differs between various animal species, and within an animal species. In humans, there are differences in the composition of the flora which are influenced by age, diet, cultural conditions, and the use of antibiotics. The latter greatly perturbs the composition of the intestinal flora.

In the upper GI tract of adult humans, the esophagus contains only the bacteria swallowed with saliva and food. Because of the high acidity of the gastric juice, very few bacteria (mainly acid-tolerant lactobacilli) can be cultured from the normal stomach. However, at least half the population in the United States is colonized by a pathogenic bacterium, *Helicobacter pylori* Since the 1980s, this bacterium has been known to be the cause of gastric ulcers, and it is probably a cause of gastric and duodenal cancer as well. The Australian microbiologist, Barry Marshall, received the Nobel Prize in Physiology and Medicine in 2005, for demonstrating the relationship between *Helicobacter* and gastric ulcers.

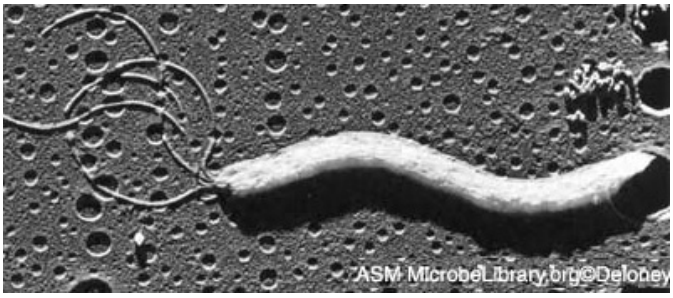


Figure 8. *Helicobacter pylori.* ASM

The proximal small intestine has a relatively sparse Gram-positive flora, consisting mainly of lactobacilli and *Enterococcus faecalis* This region has about 10^5 - 10^7 bacteria per ml of fluid. The distal part of the small intestine contains greater numbers of bacteria (10^8/ml) and additional species, including coliforms (*E coli* and relatives) and *Bacteroides,* in addition to lactobacilli and enterococci.

The flora of the large intestine (colon) is qualitatively similar to that found in feces. Populations of bacteria in the colon reach levels of 10^{11}/ml feces. Coliforms become more prominent, and enterococci, clostridia and lactobacilli can be regularly found, but the predominant species are anaerobic *Bacteroides* and

anaerobic lactic acid bacteria in the genus *Bifidobacterium* (*Bifidobacterium bifidum*). These organisms may outnumber *E coli* by 1,000:1 to 10,000:1. Sometimes, significant numbers of anaerobic methanogens (up to 10^{10}/gm) may reside in the colon of humans. This is our only direct association with archaea as normal flora. The range of incidence of certain bacteria in the large intestine of humans is shown in Table 4 below.

Table 4. Bacteria found in the large intestine of humans.

BACTERIUM	RANGE OF INCIDENCE
Bacteroides fragilis	**100**
Bacteroides melaninogenicus	**100**
Bacteroides oralis	**100**
Lactobacillus	**20-60**
Clostridium perfringens	**25-35**
Clostridium septicum	**5-25**
Clostridium tetani	**1-35**
Bifidobacterium bifidum	**30-70**
Staphylococcus aureus	**30-50**
Enterococcus faecalis	**100**
Escherichia coli	**100**
Salmonella enteritidis	**3-7**
Klebsiella sp.	**40-80**
Enterobacter sp.	**40-80**
Proteus mirabilis	**5-55**
Pseudomonas aeruginosa	**3-11**
Peptostreptococcus sp.	**?common**
Peptococcus sp.	**?common**

At birth the entire intestinal tract is sterile, but bacteria enter with the first feed. The initial colonizing bacteria vary with the food source of the infant. In breast-fed infants, bifidobacteria account for more than 90% of the total intestinal bacteria. *Enterobacteriaceae* and enterococci are regularly present, but in low proportions, while bacteroides, staphylococci, lactobacilli and clostridia are practically absent. In bottle-fed infants, bifidobacteria are not predominant. When breast-fed infants are switched to a diet of cow's milk or solid food, bifidobacteria are progressively joined by enterics, bacteroides, enterococci lactobacilli and clostridia. Apparently, human milk contains a growth factor that enriches for growth of bifidobacteria, and these bacteria play an important role in preventing colonization of the infant intestinal tract by non indigenous or pathogenic species.

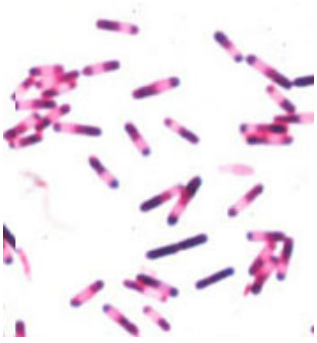


Figure 9. *Clostridium difficile.* Gram stain. The growth of "C. diff" in the intestinal tract is normally held in check by other members of the normal flora. When antibiotics given for other infections cause collateral damage to the normal intestinal flora, the clostridium may be able to "grow out" and produce a serious diarrheal syndrome called pseudomembranous colitis. This is an example of an "antibiotic induced diarrheal disease".

The composition of the flora of the gastrointestinal tract varies along the tract (at

longitudinal levels) and across the tract (at horizontal levels) where certain bacteria attach to the gastrointestinal epithelium and others occur in the lumen. There is frequently a very close association between specific bacteria in the intestinal ecosystem and specific gut tissues or cells (evidence of tissue tropism and specific adherence). Gram-positive bacteria, such as the streptococci and lactobacilli, are thought to adhere to the gastrointestinal epithelium using polysaccharide capsules or cell wall teichoic acids to attach to specific receptors on the epithelial cells. Gram-negative bacteria such as the enterics may attach by means of specific fimbriae which bind to glycoproteins on the epithelial cell surface.

It is in the intestinal tract that we see the greatest effect of the bacterial flora on their host. This is due to their large mass and numbers. Bacteria in the human GI tract have been shown to produce vitamins and may otherwise contribute to nutrition and digestion. But their most important effects are in their ability to protect their host from establishment and infection by alien microbes and their ability to stimulate the development and the activity of the immunological tissues.

On the other hand, some of the bacteria in the colon (e.g. *Bacteroides*) have been shown to produce metabolites that are carcinogenic, and there may be an increased incidence of colon cancer associated with these bacteria. Alterations in the GI flora brought on by poor nutrition or perturbance with antibiotics can cause shifts in populations and colonization by nonresidents that leads to gastrointestinal disease.

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chapter continued

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Candida concentrations determined following concentrated oral rinse culture reflect clinical oral signs

Hiroaki Tooyama, Takehisa Matsumoto, Kiyonori Hayashi, Kenji Kurashina, Hiroshi Kurita, Mitsuo Uchida, Eriko Kasuga, and Takayuki Honda

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Abstract

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Background

Oral candidiasis is a common opportunistic infection of the oral cavity and is caused by yeast of the *Candida*genus, primarily *Candida albicans*. It presents clinically in many forms, including pseudomembranous (acute/chronic), erythematous (acute/chronic), plaque-like (chronic), and nodular (chronic) forms [1]. However, *Candida* species are frequently isolated from the oral cavity in healthy individuals of all ages, with a reported prevalence of 15–75 % [2–4], and it is therefore difficult to differentiate oral candidiasis from the commensal state by microbiological detection of the *Candida* species in the oral cavity. Furthermore, oral candidiasis has often been diagnosed on the basis of clinical findings, regardless of whether a *Candida*species was detected. Therefore, additional microbiological criteria are required to diagnose oral *Candida*infection correctly.

Various methods can be used to isolate *Candida* from the oral cavity, including smears, plain swabs, imprint cultures, whole saliva collection, concentrated oral rinses, and mucosal biopsies [5, 6]. Of these, the concentrated oral rinse method is one of the most suitable techniques for determining *Candida* concentrations in the oral cavity [7]; however, this method is inadequate for detecting the *Candida* infection site. *Candida*concentrations under 600 CFU/mL in concentrated rinse samples have been reported for healthy commensal carriage [8], whereas individuals with *Candida* concentrations above 2–3 × 10^3 CFU/mL are predisposed to oral *Candida* infection [7]. However, White et al. reported that *Candida* levels up to 9 × 10^3 CFU/mL were observed in healthy controls and that these levels were occasionally higher than those in patients with oral candidiasis [9].

Oral candidiasis frequently occurs in immunocompromised individuals, including HIV-positive and AIDS patients, organ transplant recipients, and chemotherapy patients [10]. In fact, the disease is often the initial sign of several immunodeficiency diseases, and its clinical significance

as a biomarker has been recognized in recent years [11]. However, it is difficult to correctly and satisfactorily diagnose oral candidiasis because currently no microbiological or laboratory standards based on samples from the oral cavity are available. In this study, we examined associations between clinical oral findings and difference methods for obtaining samples from the oral cavity to determine which criteria could help differentiate oral candidiasis from the presence of *Candida* in the commensal state.

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Methods

Samples obtained from 200 consecutive outpatients (103 male patients and 97 female patients; mean age, 47.2 years; age range, 9–89 years) who consulted a dentist at Aizawa Hospital from March 2011 to June 2011 were participated in this study. Samples from 30 volunteers (17 men and 13 women; mean age, 30.1 years; age range, 23–43 years) without clinical oral symptoms and signs of candidiasis were also used. In all of them, one tooth was not broken and the decayed teeth were completely treated. Informed consent was obtained from all patients, the parents of minors, and volunteers. The Committee for Ethics at Aizawa Hospital approved this study protocol with approval number H22-14.

Sample preparation and determination of CFU

The 3 sample methods used in the study were as follows.

1. Swab method: The materials were obtained by swabbing the dorsal surface of the tongue with 5 strokes (about 2 cm in length) of a cotton swab (Hakujuji Co Ltd. Tokyo, Japan), and then the swab was directly inoculated onto CHROMagar Candida medium (Kanto Chemical Co. Ltd., Tokyo, Japan).

2. Rinse method: After a sample had been obtained using the swab method, a sample of oral rinse solution was collected by rinsing the mouth with 10 mL sterile saline, which was held in the mouth for 5 s before being collected in a sterile container. One hundred microliters of the rinse solution was inoculated onto the CHROMagar Candida medium.

3. Concentrated rinse method: The oral cavity is rinsed with 10 mL of sterile saline, and 7 to 10 mL was collected as the rinse solution. The concentrated rinse solution was prepared by centrifuging it at 2300 × *g* for 20 min. After the supernatant was removed, the cell pellet was resuspended in 500 μL, which was inoculated onto CHROMagar Candida medium in 100 μL aliquots. *Candida* colonies were counted after incubation at 37 °C for 48 h. If there were too many *Candida* colonies to be counted, the *Candida* solutions were diluted tenfold.

Associations between the presence of *Candida* species and clinical oral signs

We then examined associations between the presence of *Candida* species and clinical oral signs using samples obtained via the swab method and the concentrated rinse method. Associations between *Candida*colony counts (*Candida* concentrations) and clinical oral signs were then determined using samples obtained via the concentrated rinse method. Table 1 shows the clinical oral signs used in this study and their grading.

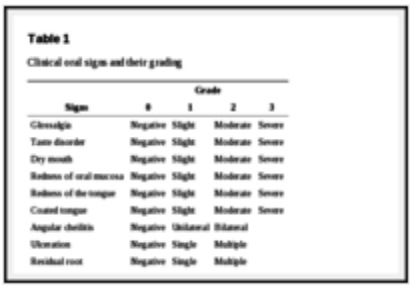

Table 1

Clinical oral signs and their grading

Sign	Grade 0	1	2	3
Glossalgia	Negative	Slight	Moderate	Severe
Taste disorder	Negative	Slight	Moderate	Severe
Dry mouth	Negative	Slight	Moderate	Severe
Redness of oral mucosa	Negative	Slight	Moderate	Severe
Redness of the tongue	Negative	Slight	Moderate	Severe
Coated tongue	Negative	Slight	Moderate	Severe
Angular cheilitis	Negative	Unilateral	Bilateral	
Ulceration	Negative	Single	Multiple	
Residual root	Negative	Single	Multiple	

Table 1

Clinical oral signs and their grading

Oral assessments

Clinical oral signs were graded as follows. Glossalgia was graded using the Visual Analog Scale (negative: 0 mm; slight: 1 mm; moderate: 30 mm; severe: over 54 mm) [12, 13]. Taste disorder was graded using the Common Terminology Criteria for Adverse Events v3.0 published by the National Cancer Institute (negative: no change in taste; slight: altered taste but no change in diet; moderate: altered taste with change in diet or noxious or unpleasant taste; severe: loss of taste) [14]. Dry mouth was graded using the classification provided by Kakinoki et al. (negative: non-dry; slight: saliva shows viscosity; moderate: saliva showing tiny bubbles on tongue; severe: dry tongue without viscosity, little or no saliva) [15]. Redness of oral mucosa was graded using the Eilers Oral Assessment Guide (negative: no redness on the oral mucosa; slight: localized redness areas without ulcerations; moderate: redness on the whole oral mucosa without ulcerations; severe: ulcerations with or without bleeding) [16].

Tongue coating was graded using the visual scores developed by Kojima et al. (negative: less than 1/3 of the tongue slightly coated; slight: about 2/3 of the tongue slightly coated or about 1/3 of the tongue thickly coated; moderate: about 2/3 of the tongue thickly coated; severe: more than 2/3 of the tongue thickly coated [17]. Redness of the tongue was graded similarly (negative: less than 1/3 of the tongue showing slight redness; slight: about 2/3 of the tongue showing slight redness or about 1/3 of the tongue showing strong redness; moderate: about 2/3 of the tongue showing strong redness; severe: more than 2/3 of the tongue showing strong redness).

Determining the normal range of healthy commensal carriage

We examined 30 volunteers without clinical oral signs of candidiasis for the presence of *Candida* species. We used the highest colony count obtained from their swab and

concentrated rinse samples as the threshold for distinguishing oral candidiasis from the oral commensal state of *Candida* species. The *Candida* detection ratio, the associations between clinical oral signs and *Candida* detection, and the associations between clinical signs and the number of *Candida* colonies obtained using the swab method and the concentrated rinse method were then determined. The sensitivity and specificity of each clinical sign were examined when*Candida* species were detected.

Statistical analysis

The $\chi 2$ test was used to determine the significance of the difference between the rates of positive *Candida*detection using the oral swab method and the concentrated oral rinse method. The median values of the number of detected *Candida* which were obtained from identical individuals were compared using the non-parametric Wilcoxon signed rank test. The significance of the relationships between the median *Candida*concentrations and the grades of each clinical oral sign was analyzed using the nonparametric Kruskal-Wallis test.

Statistical significance was set at $p < 0.05$ for all the analysis methods. In addition, Bonferroni test was used to adopt multiple comparison. All statistical analyses were performed using the SPSS software version 22 (SPSS, Chicago, IL, USA).

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Results

In order to establish the required methods before the whole analysis, a pilot test was conducted on the first 10 samples. The colony counts obtained from the first 10 outpatients using the swab, rinse, and concentrated rinse methods are shown in Fig. 1. The median and interquartile range were 23 CFU (interquartile range, 3 to 96 CFU)/swab for the swab method, 56 CFU (interquartile range, 11 to 900 CFU)/100 μL for the rinse method, and 485 CFU (interquartile range, 210 to 6981 CFU)/100 μL for the concentrated rinse method in the first 10 outpatients. The first 10 outpatients were tested using all three methods; however, we used the concentrated rinse method for subsequent examinations because it yielded more *Candida* colonies. The median counts of the *Candida* colonies obtained using the concentrated rinse method were significantly higher than those obtained using the other two methods, respectively ($p < 0.01$, Wilcoxon signed-rank test with Bonferroni test). The concentrated rinse method was the most sensitive, because it could detect *Candida*species when the swab method or the rinse method did not. Thus, we understood that the concentrated rinse method was appropriate for subsequent examinations.

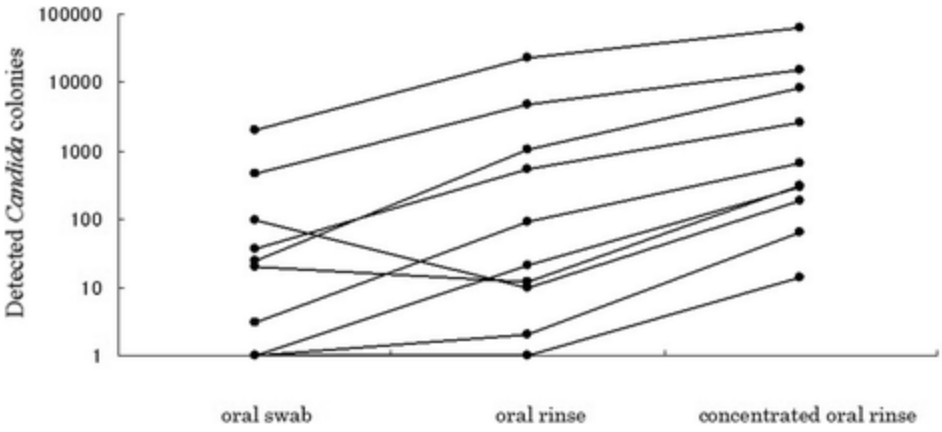

Fig. 1

Comparison of the sensitivities of the swab method, the rinse method, and the concentrated rinse method ($n = 10$). Dots representing data from the same patient are connected by lines

We presumptively identified *Candida* species from the color of colonies grown on CHROMagar Candida. Using this method, the following *Candida* profiles were observed in 68 patients, 12 patients, one patient, nine patients, seven patients, five patients, one patient, and one patient, respectively: *C. albicans*, *C. tropicalis*, *C. glabrata*, *C. albicans* + *C. glabrata*, *C. albicans* + *C. tropicalis*, *C. albicans* + *C. glabrata* + *C. tropicalis*, *C. albicans* + *C. krusei* + unidentified *Candida* species, and *C. glabrata* + *C. tropicalis* + unidentified *Candida* species. There were no significant differences in clinical oral signs between the 68 patients with *C. albicans* and the 12 with *C. tropicalis*.

Detection rates and colony counts obtained using the swab method and the concentrated oral rinse method are shown in Table 2. *Candida* species were detected in the oral cavity in 67 of 200 patients (33.5 %) by the swab method and in 104 of 200 (52 %) by the concentrated rinse method. The median colony count was 7 CFU (interquartile range, 2 to 37 CFU)/swab for the swab method and 141 CFU (interquartile range, 14 to 1001 CFU)/100 μL for the concentrated rinse method. The detection ratios ($p < 0.01$, χ^2 test) and colony counts ($p < 0.01$, Wilcoxon signed-rank test) obtained using the concentrated rinse method were significantly higher than those obtained using the swab method.

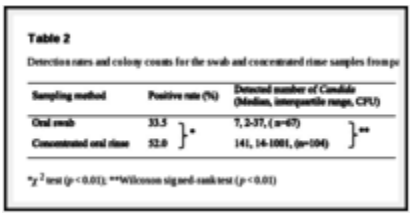

Table 2

Detection rates and colony counts for the swab and concentrated rinse samples from pa

Sampling method	Positive rate (%)		Detected number of *Candida* (Median, interquartile range, CFU)	
Oral swab	33.5	*	7, 2-37, (n=67)	**
Concentrated oral rinse	52.0		141, 14-1001, (n=104)	

*χ^2 test ($p < 0.01$); **Wilcoxon signed-rank test ($p < 0.01$)

Table 2

Detection rates and colony counts for the swab and concentrated rinse samples from patients ($n = 200$)

Associations between clinical oral signs and *Candida* detection using the swab method are summarized in Tables 3 and and4.4. When *Candida* was detected using the swab method, the sensitivities of coated tongue, dry mouth, denture, redness of the tongue, and residual root were 41.8, 46.3, 40.3, 34.3, and 29.9 %, respectively, and the specificities of redness of the oral mucosa, angular cheilitis, residual root, glossalgia, taste disorder, denture, and ulceration were 97.7, 99.2, 92.5, 94.0, 93.2, 88.0, and 92.5 %, respectively. The positive predictive values of residual root, redness of the oral mucosa, denture, glossalgia, dry mouth, and taste disorder were 66.7, 66.7, 62.8, 52.9, 54.4, and 35.7 %, respectively.

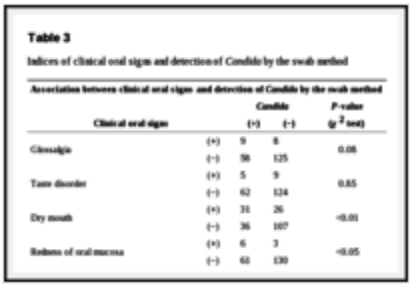

Table 3

Indices of clinical oral signs and detection of *Candida* by the swab method

Association between clinical oral signs and detection of Candida by the swab method				
Clinical oral signs		Candida (+)	Candida (-)	*P* value (χ^2 test)
Glossalgia	(+)	9	8	0.08
	(-)	58	125	
Taste disorder	(+)	5	9	0.85
	(-)	62	124	
Dry mouth	(+)	31	26	<0.01
	(-)	36	107	
Redness of oral mucosa	(+)	6	3	<0.05
	(-)	61	130	

Table 3

Indices of clinical oral signs and detection of *Candida* by the swab method

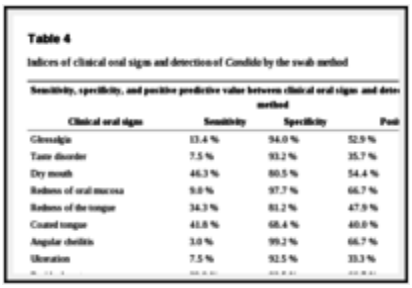

Table 4

Indices of clinical oral signs and detection of *Candida* by the swab method

Sensitivity, specificity, and positive predictive value between clinical oral signs and dete method			
Clinical oral signs	Sensitivity	Specificity	Posi
Glossalgia	13.4 %	94.0 %	52.9 %
Taste disorder	7.5 %	93.2 %	35.7 %
Dry mouth	46.3 %	80.5 %	54.4 %
Redness of oral mucosa	9.0 %	97.7 %	66.7 %
Redness of the tongue	34.3 %	81.2 %	47.9 %
Coated tongue	41.8 %	68.4 %	40.0 %
Angular cheilitis	3.0 %	99.2 %	66.7 %
Ulceration	7.5 %	92.5 %	33.3 %

Table 4

Indices of clinical oral signs and detection of *Candida* by the swab method

Associations between clinical oral signs and *Candida* detection using the concentrated rinse method are summarized in Tables 5 and and6.6. When *Candida* was detected using the concentrated rinse method, the sensitivities of coated tongue, dry mouth, denture, redness of the tongue, and residual root were 45.2, 42.3, 34.6, 29.8, and 26.0 %, respectively, and the specificities of redness of the oral mucosa, angular cheilitis, residual root, glossalgia, taste disorder, denture, and ulceration were 99.0, 99.0, 96.9, 96.9, 95.8, 92.7, and 91.7 %, respectively. The positive predictive values of residual root, redness of the oral mucosa, denture, glossalgia, dry mouth, and taste disorder were 90.0, 88.9, 83.7, 82.4, 77.2, and 71.4 %, respectively.

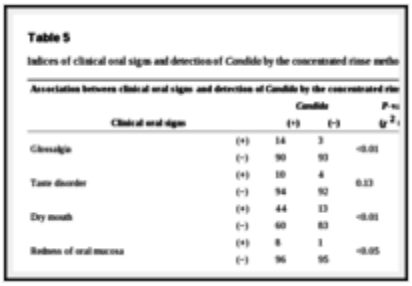

Table 5

Indices of clinical oral signs and detection of *Candida* by the concentrated rinse method

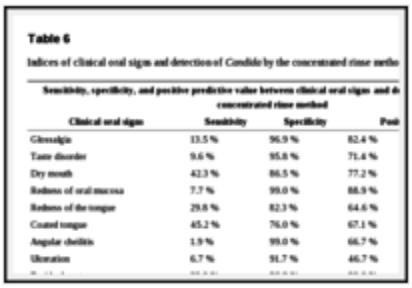

Table 6

Indices of clinical oral signs and detection of *Candida* by the concentrated rinse method

Differences between the grades of each clinical oral sign and colony numbers obtained using the swab method are shown in Table 7. High *Candida* counts were significantly associated with dry mouth. Differences between the grades of each clinical oral sign and colony concentrations obtained using the concentrated rinse method are shown in Table 8. High *Candida* counts were significantly associated with dry mouth, redness of the tongue, coated tongue, and denture.

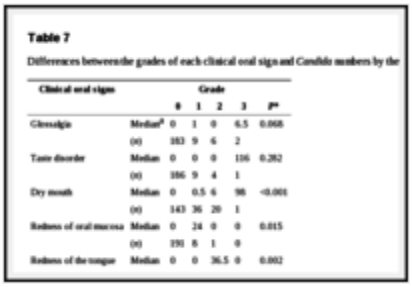

Table 7

Differences between the grades of each clinical oral sign and *Candida* numbers by the swab method

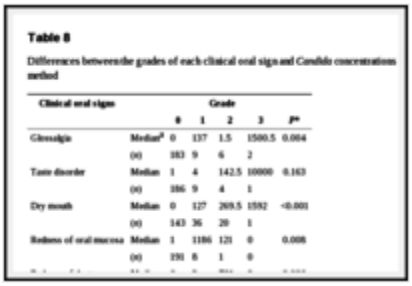

Table 8

Differences between the grades of each clinical oral sign and *Candida*concentrations by the concentrated rinse method

When *Candida* counts were determined in healthy volunteers, the swab method yielded colonies for 3/30 of the volunteers (1, 4, and 5 colonies, respectively), whereas the concentrated rinse method yielded colonies for 8/30 volunteers (1, 1, 2, 22, 25, 36, 38, and 67 colonies, respectively). Based on these results, we defined 0–5 CFU/swab and 0–67 CFU/100 μL as the reference ranges for healthy commensal carriages detected by the swab method and the concentrated rinse method, respectively. In contrast, among outpatients with no clinical oral signs, the highest counts obtained using the swab method and the concentrated rinse method were 23 CFU/swab and 90 CFU/100 μL, respectively.

Go to:

Discussion

In this study, *Candida* species were detected in the oral cavity in dental clinic outpatients with a frequency of 52.0 and 33.5 % using the concentrated rinse method and the swab method, respectively. Therefore, the concentrated rinse method was more sensitive than the swab method for detecting *Candida* species in the oral cavity. Some of the oral clinical signs (e.g., coated tongue, dry mouth, denture, redness of the tongue, and residual root) were relatively robust predictors for oral candidiasis. However, the positive predictive values of residual root, redness of the oral mucosa, denture, glossalgia, dry mouth, and taste disorder were high, and only these clinical oral signs were frequently associated with the presence of *Candida* species.

The concentrated rinse method is more suitable for the detection of *Candida* species in the oral cavity than the swab method. However, the number of colonies in the concentrated rinse samples was smaller than the theoretically predicted value of a 20-fold increase in the rinse samples. This might be related to the low centrifugal force of 2300 × *g*. In addition, the concentrated rinse method showed the same sensitivity as the rinse method when high numbers of colonies were present; however, the concentrated rinse method was more sensitive when only a few colonies could be obtained from the sample. For the first 10 outpatients examined in this study, the concentrated rinse method yielded more *Candida* colonies than the standard rise method, and the concentrated rinse method might generally show a higher sensitivity for detecting *Candida*in the

oral cavity than the standard rinse method; therefore, we used results obtained via the concentrated rinse method rather than the standard rinse method for comparisons in the current study. Several sampling methods are available, including imprints, oral rinses, swabs, whole saliva collection [18], biopsies, and smears, and each method has both advantages and disadvantages [5]. Although the concentrated rinse method does not detect the localized site of infection, it enables quantitation of other microbes in addition to*Candida* species [5]. The concentrated rinse method is also easy to perform and is more sensitive than the imprint culture technique. Hence, it is suggested that the concentrated rinse method be preferentially employed in future investigations to obtain comparable data from different centers [8].

Candida counts may correspond to the severity of several clinical findings. Dry mouth was observed in 44 of 104 patients for whom *Candida* was detected by the concentrated rinse method, and the sensitivity, specificity, and positive predictive values of this characteristic were 42.3, 86.5, and 77.2 %, respectively. The*Candida* concentrations obtained using the concentrated rinse method showed some significant differences in the severity of dry mouth, redness of the tongue, residual root, coated tongue, and denture.

Similarly, the absence of a number of clinical signs (oral mucosa redness, angular cheilitis, residual root, glossalgia, taste disorder, denture, and ulceration) was a robust indicator for the absence of *Candida*.Similarly, low densities of *Candida* may not cause coated tongue, dry mouth, denture, redness of the tongue, and residual root, which are often observed in outpatients with *Candida* in the oral cavity; indeed, the*Candida* density showed a significant difference between the severities of each of these signs.

Taste disorder, redness of the oral mucosa, angular cheilitis, and ulceration were observed in less than 10 % of the outpatients diagnosed with candidiasis using the concentrated rinse method, and glossalgia was noted in 13.5 % of the outpatients diagnosed with candidiasis using the concentrated rinse method. In any case, all the above clinical oral signs were likely to be related to other oral diseases rather than to *Candida* infection. Concentrations of less than 90 CFU/100 μL obtained with the concentrated rinse method were not associated with any oral signs of candidiasis in outpatients and volunteers. The patients showing *Candida* colony numbers under 90 CFU/100 μL in the concentrated rinse method might have been in the stage before apparent candidiasis.

Candida species are often detected in the oral cavity in healthy individuals, and their presence does not necessarily indicate *Candida* infection. A threshold *Candida* concentration is required in order to separate individuals with commensal *Candida* from those with infection-associated *Candida*. Most healthy Thai adolescents carry *Candida* at a low level, that is, below 50 CFU/100 μL [19], and *Candida* levels of 60 CFU/100 μL in concentrated rinse culture samples are associated with healthy commensal carriage [8]. On the other hand, individuals with conditions that predispose them to infection harbor higher numbers (2×10^2 to

3×10^2 CFU/100 μL). *Candida* levels up to 9×10^2 CFU/100 μL have been observed in healthy controls without clinical oral signs in other studies [7, 9].

Quantitative analysis may be important for the assessment of oral candidiasis, including differentiation from the commensal carriage of *Candida*. Oral candidiasis is a particularly significant problem with respect to the morbidity of immunocompromised individuals, including HIV-positive and AIDS patients, organ transplant recipients, and chemotherapy patients [10, 20, 21]. In addition, there have been several reports on the relationships between oral *Candida* and diabetes mellitus [22], oral *Candida* and Sjögren's syndrome [23], and oral *Candida* and a combination of chronic renal failure and hemodialysis [24].

Go to:

Conclusions

In this study, the *Candida* concentration associated with several clinical oral signs in the infected patients and may be closely related to the patient's current clinical status and prognosis. We have shown that quantitative analysis of *Candida* is required in order to correctly differentiate commensal forms of infection from those requiring treatment due to *Candida* infection. Such analysis may also be suitable for monitoring the time-dependent changes and quantitative analysis of *Candida* concentration. Adoption of the concentrated rinse method in independent locations around the globe is relatively straightforward since the method is simple. This will greatly facilitate direct comparisons between studies on *Candida* that originate in distinct geographic locations and involve diverse subject populations.

Go to:

Acknowledgements

The authors wish to thank the participating patients and staff of the Department of Dentistry and Oral Surgery, Shinshu University School of Medicine, Shinshu University Hospital and the Department of Dentistry and Oral Surgery, Aizawa Hospital for their support in this study.

Go to:

Abbreviations

CFU colony forming unit

SD standard deviation

Go to:

Footnotes

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

HT performed the experiments and wrote the manuscript; TM contributed to planning and designing the study; KH, KK and EK helped in the data collection; MU performed all the statistical analyses; HK and TH corrected the paper and supervised the study. All authors read and approved the final manuscript.

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ATTACHMENT F: K152402

COPY OF S001, NOVEMBER 11, 2015 ADDITIONAL INFORMATION

November 11, 2015

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

Re: Supplement 1 to – 510(k) K152402
Securus Medical Group, Inc.
IRTS System

Dear Mr. Burdick:

The attached information is submitted for inclusion in the referenced 510(k) Notice for the Securus IRTS System. The information is being provided in response to questions raised by FDA during the review of the subject Notification on 10/23/15. Please direct this response to William Burdick.

Should you have any questions pertaining to these responses please contact me at 978-317-0836. Please send written communications concerning this Notification to:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.

ADDITIONAL INFORMATION

The following pages contain Additional Information (AI) provided in response to questions raised by FDA during the review of K152402 on October 23, 2015

This response is organized in the sequence of the questions presented in the FDA communication. In each case, the question is repeated (verbatim) in italics, followed by the Securus response. If additional supporting documentation is referenced, it is provided as an Attachment.

AI K152402
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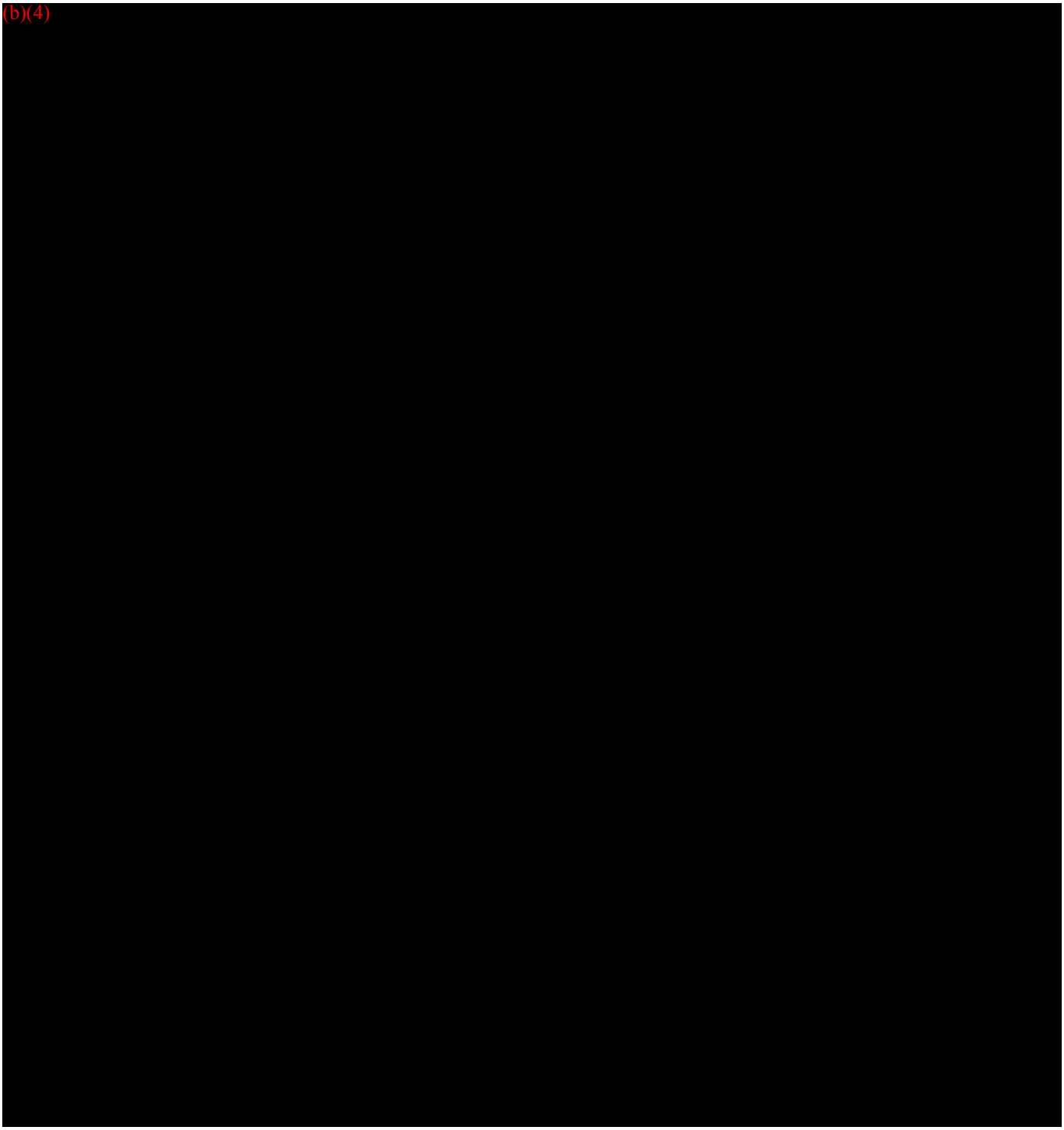

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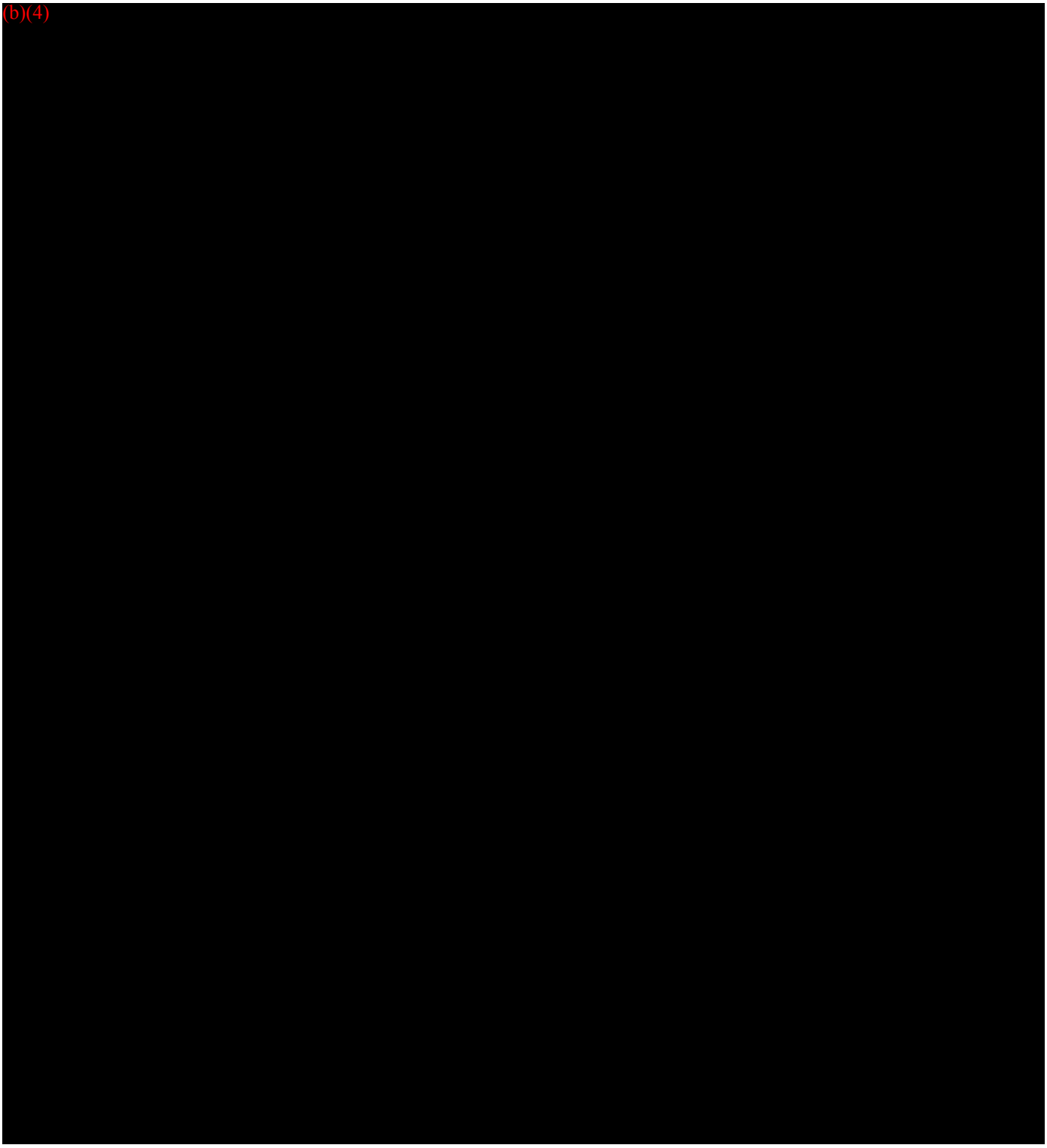

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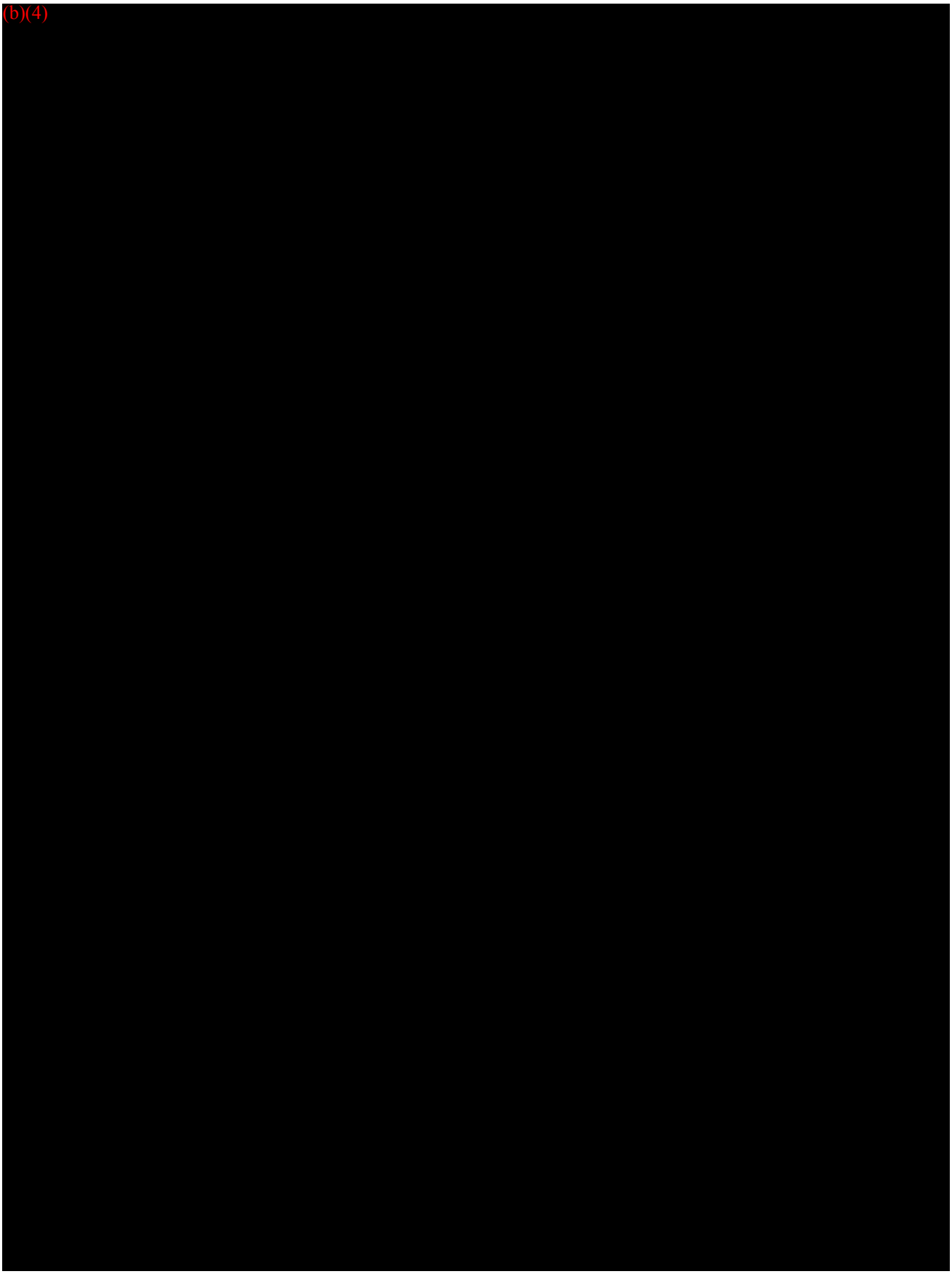

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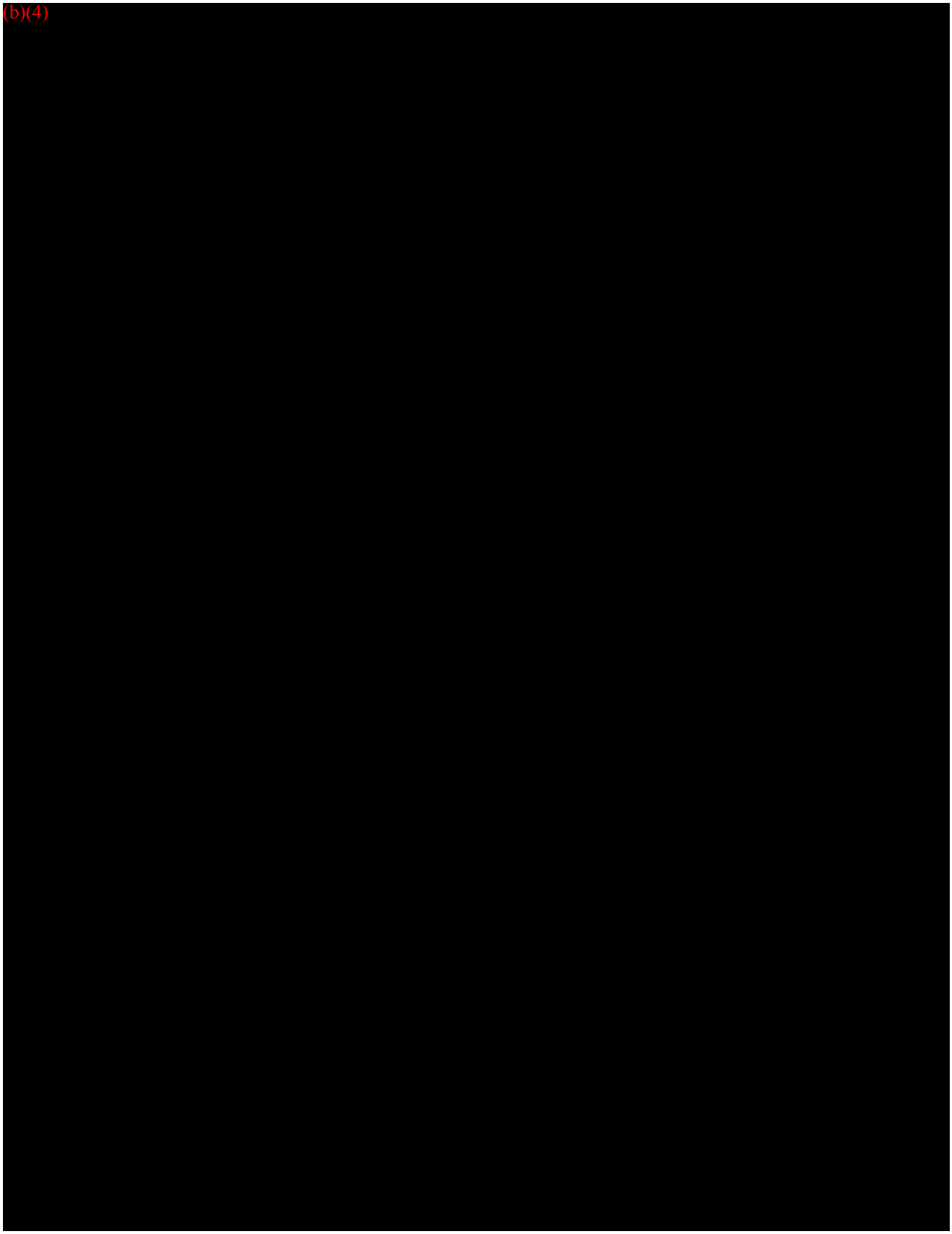

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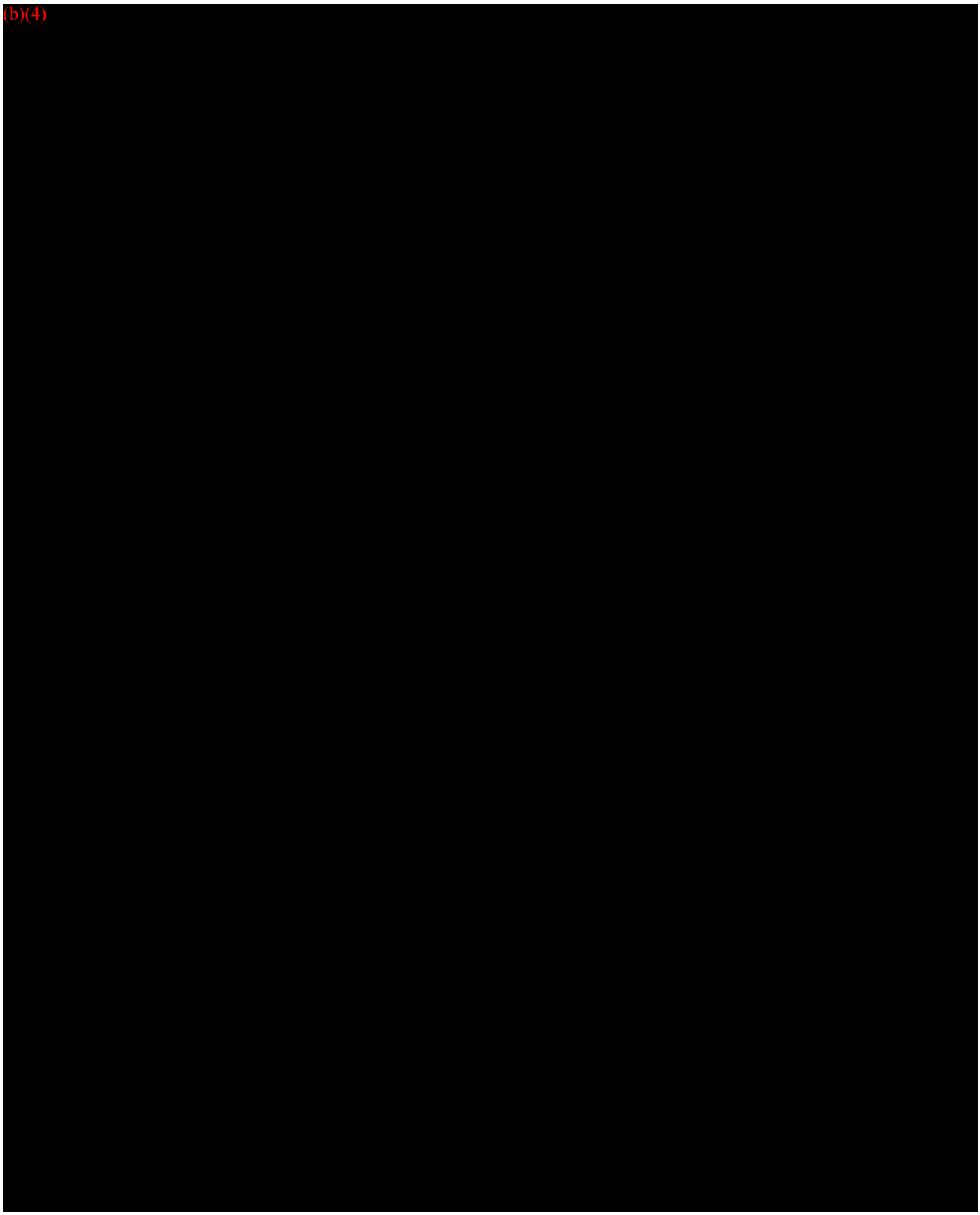

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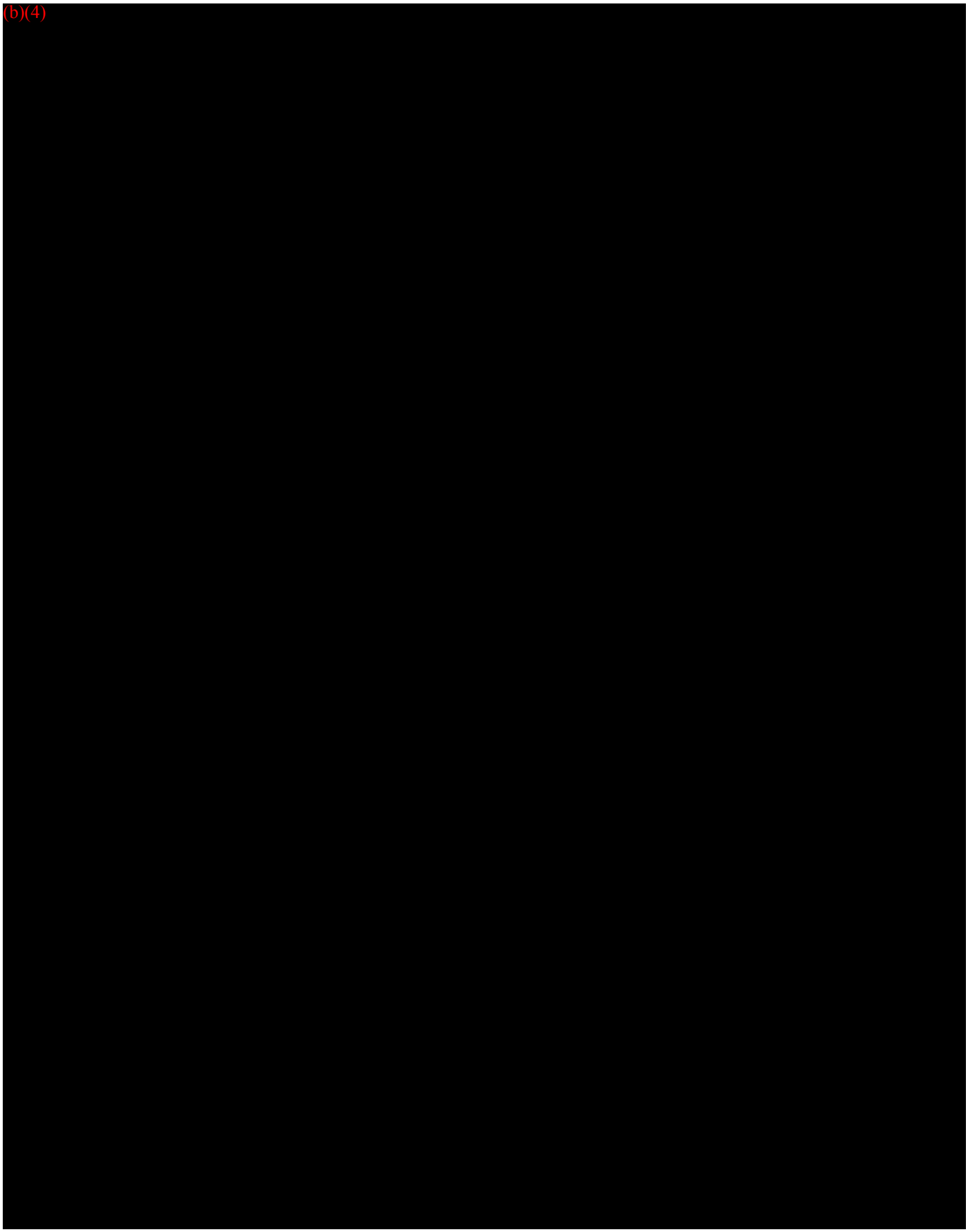

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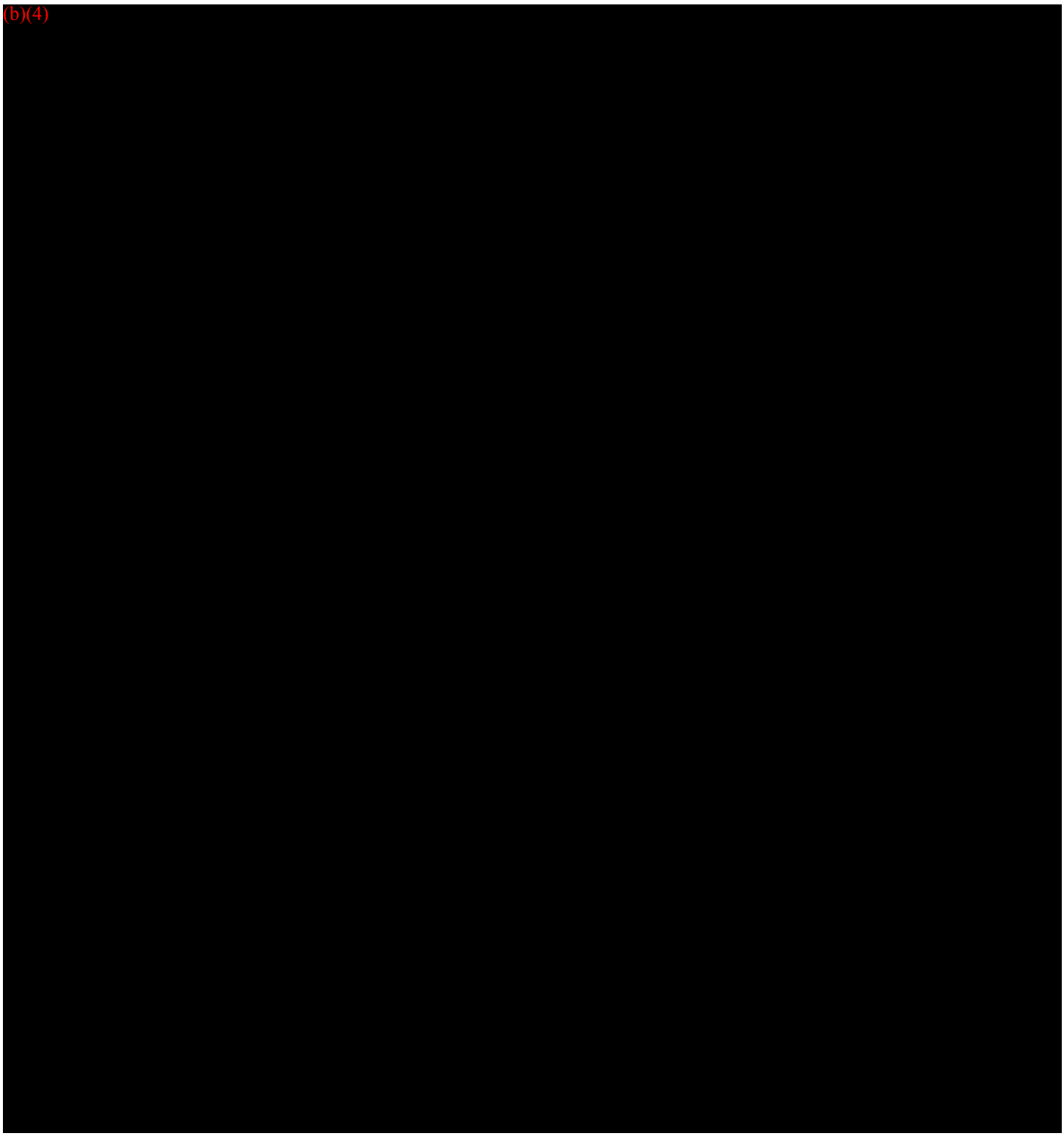

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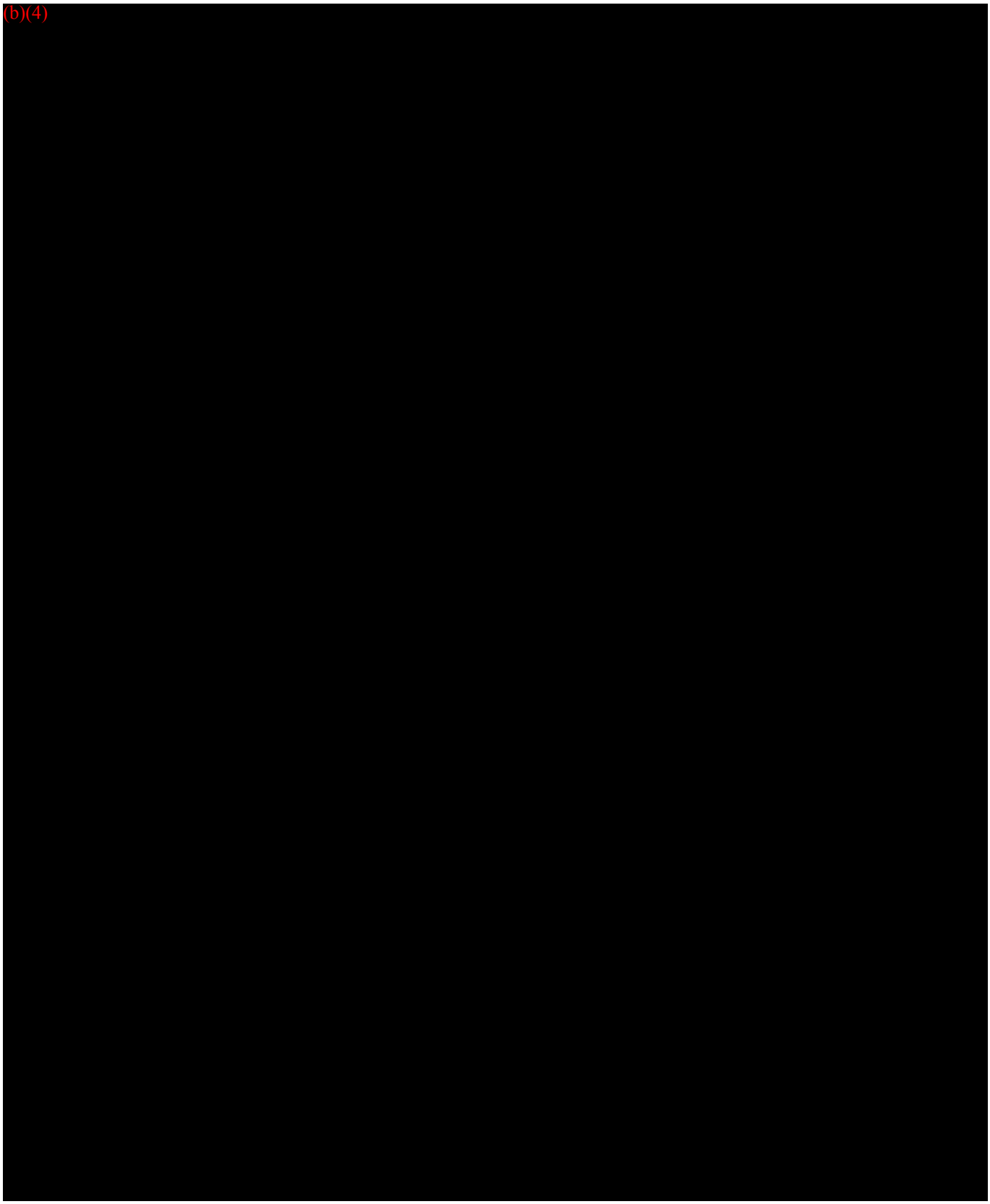

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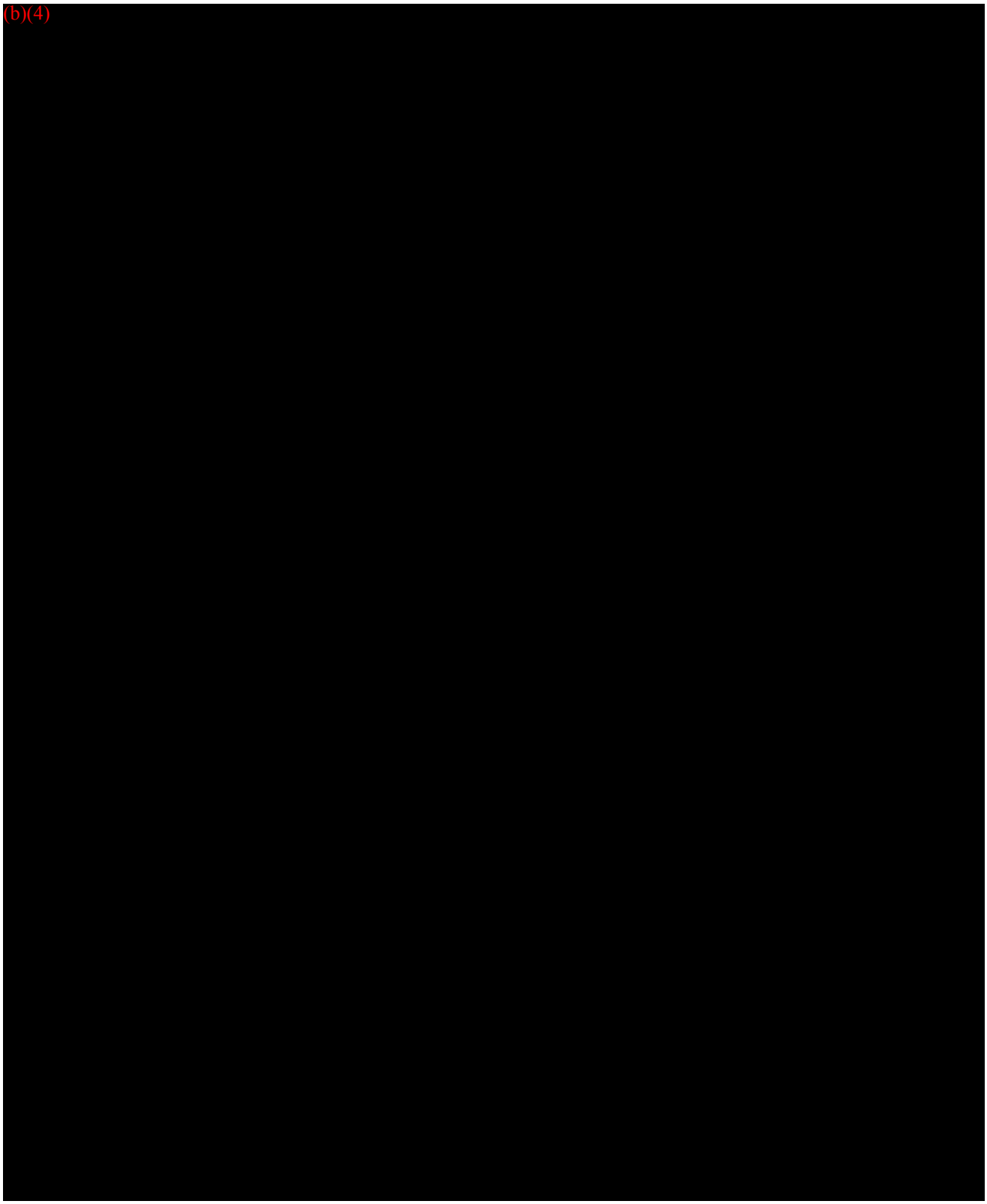

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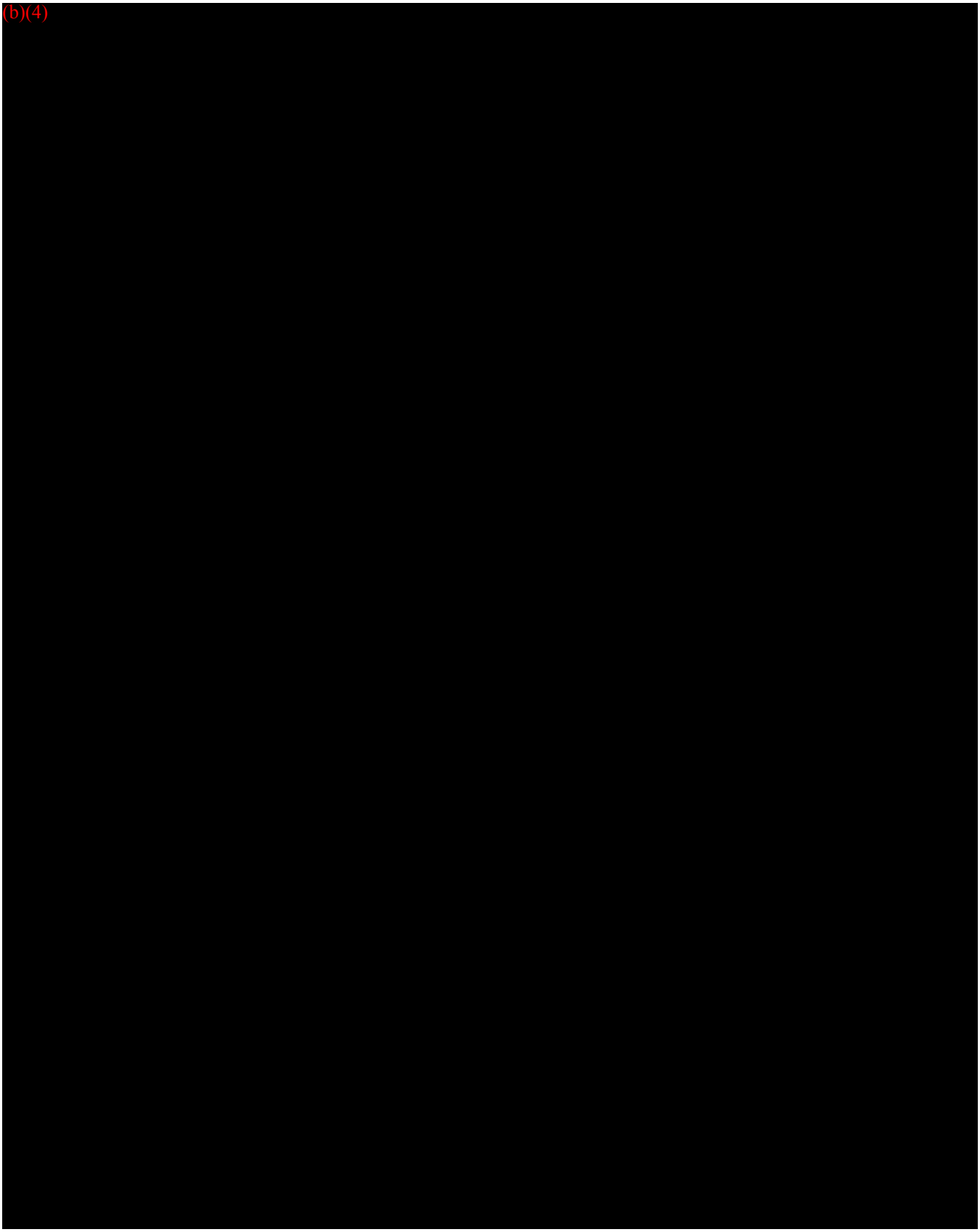

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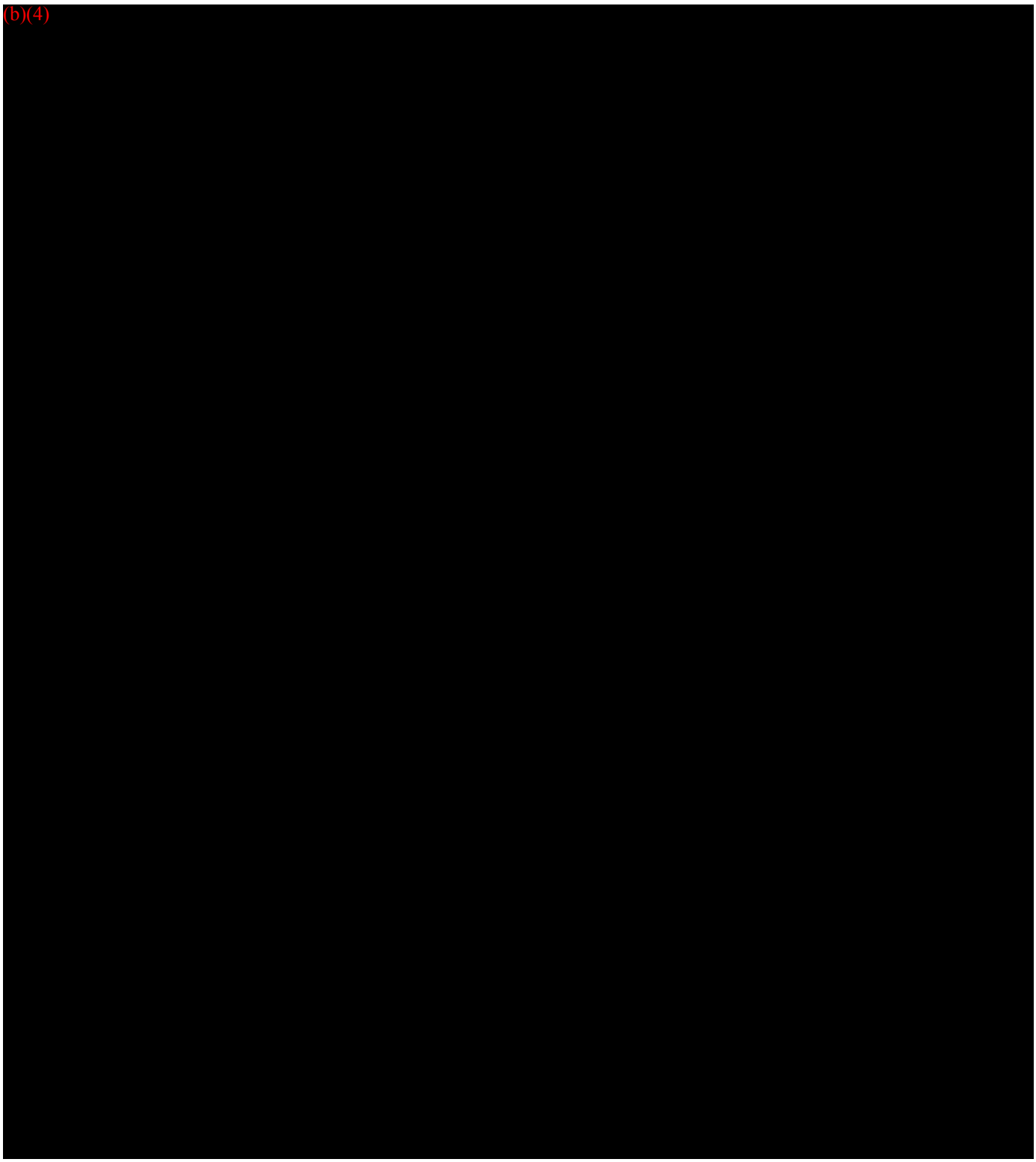

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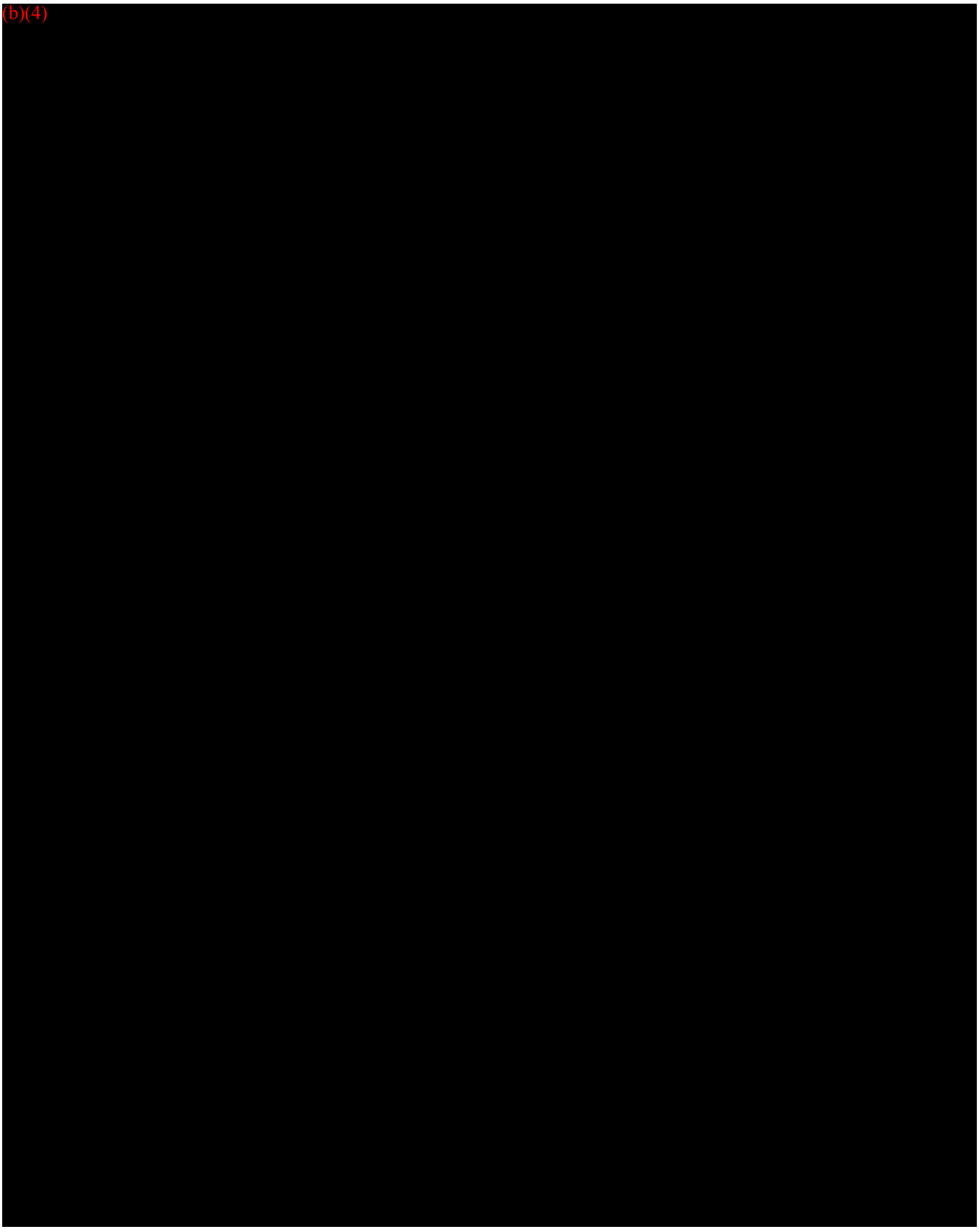

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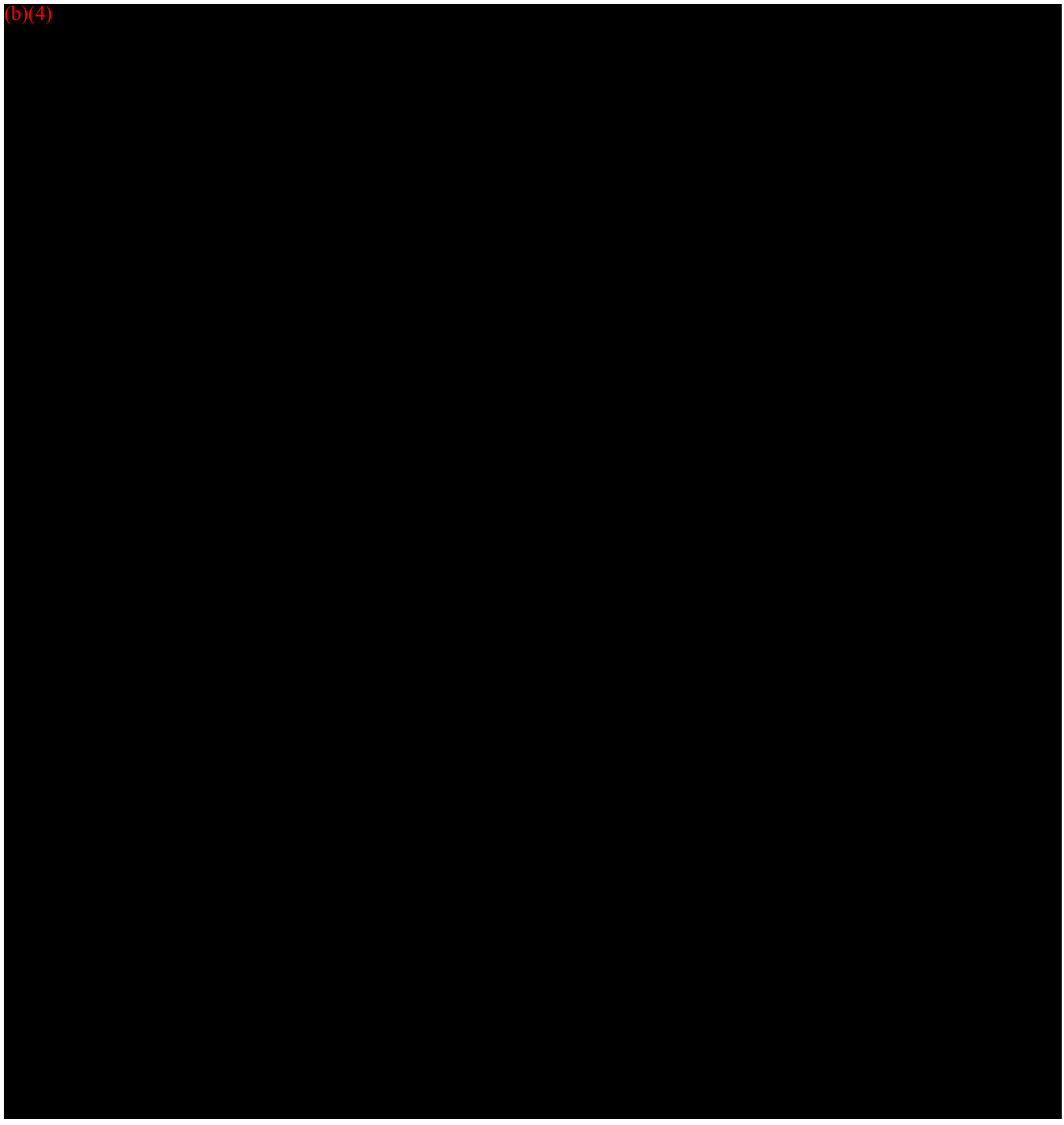


ATTACHMENT A: REVISED SE TABLE & DISCUSSION

SUBSTANTIAL EQUIVALENCE DISCUSSION

1.1 Substantial Equivalence (SE) Table

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

Esophageal temperature probes for continuous temperature monitoring of the patients esophagus are Class II devices under Product Code FLL 21 CFR 880.2910;

(a) A clinical electronic thermometer is a device used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

The thermocouple sensor of the IRTS Probe is considered a Direct Mode Clinical Thermometer as defined in ISO 80601-2-56.

201.3.207: Direct Mode: Operating mode of a clinical thermometer where the output temperature is an unadjusted temperature that represents the temperature of the measuring site to which the probe is coupled. (see page 4 of ISO 80601-2-56).

The FIAB ESOTEST System is identified as the primary predicate for continuous temperature monitoring of the patients esophagus, (K123361).

Telethermographic systems for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures are Class 1 devices under Product Code LHQ 21 CFR 884.2980;

(a) A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The thermographic sensor of the IRTS Prove is not a Clinical Thermometer as defined in ISO 80601-2-56.

The Texas Infrared IR Camera with Flash Software is identified as the secondary predicate for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures, (K073581). This secondary predicate was included in accordance with the guidance document entitled: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k), Guidance for Industry and Food and Drug Administration Staff, Document issued on: July 28, 2014.

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Intended Use	Continuous temperature monitoring of the patients esophagus.	Intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperatures.	The thermocouple sensor of the IRTS Probe is intended for continuous temperature monitoring of the patients esophagus. The thermographic sensor of the IRTS Probe is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.
Indications for Use	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The ICI Series and S IR Cameras, which provide capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.	The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe. The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
System Components	Temperature probe 7 Fr Interconnect cable Patient Monitor	Thermographic infrared detector with optical assembly Flash Software	Temperature probe 9 Fr Patient Interface Unit (PIU) with thermographic infrared detector with optical assembly. Patient Monitoring Unit (PMU) with software
Probe Sterility	Provided sterile	Provided non-sterile	Provided non-sterile
Route of Insertion	Oral or Nasal	N/A	Oral or Nasal
Probe Material (patient contact)	Polyurethane and stainless steel	N/A	Polyethylene and platinum iridium
Probe Size	7 Fr catheter with 11 Fr sensors 95 cm length	N/A	9 Fr catheter with 9 Fr sensor 150 cm length
System Temperature Precision and Resolution	0.1° C	0.1° C	0.1° C
Temperature Sensor	Type-T thermocouple	N/A	Type-T thermocouple
Thermocouple Sensor Signal Processing and Display	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LED display	N/A	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LCD display
Thermocouple Sensor Range	15° - 75° C	N/A	25° - 45° C
Thermocouple Sensor Accuracy	± 0.5° C tested in accordance with ISO 80601-2-56	N/A	± 0.3° C tested in accordance with ISO 80601-2-56

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Transient Response Time of Thermocouple Sensor	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	N/A	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56
Infrared Detector Technology	N/A	FPA microbolometer	Stirling cooled MCT
Infrared Signal Processing and Display	N/A	Relative display of color graphical image representing infrared radiation emitted from the body.	Relative display of color graphical image representing infrared radiation emitted from the body.
Infrared Temperature Range	N/A	-20° - +250° C	35° - 60° C
Infrared Temperature Accuracy	N/A	IR: ± 2° C or 2% of reading	IR: ± 2° C
Infrared Temperature Resolution	N/A	0.1° C	0.1° C
Infrared Image Field of View	N/A	22°	360°
Spectral Response	N/A	8-14µm	8-11µm
Thermal Image Size	N/A	320 x 240 array	128 x 60 array
Power Supply	100-120/230 Vac	AC adaptor power supply 12 VDC	100-240 Vac AC adaptor power supply 24 VDC
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2	Fully complies with IEC 60601-1-1:2005 +A1:2012 IEC 60601-1-2:2007
Data Output	Data provided to the supplied monitor for display	Digital USB 2.0 to user computer	Data provided to the supplied monitor for display

1.2 SE Discussion

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

There are no significant technological differences between the predicate devices and the IRTS that would raise new questions about safety and effectiveness of the system. Minor modifications to the technological characteristics were necessary to combine the output from the thermocouple sensor for esophageal temperature measurement and the output from the thermographic sensor for adjunctive thermal imaging the esophagus on a single monitor. The fundamental technologies and the intended uses are substantially equivalent.

The following discussion follows the questions provided in Appendix A. 510(k) Decision-Making Flowchart provided in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k), Guidance for Industry and Food and Drug Administration Staff. Document issued on July 28, 2014.

Decision 1: Is the predicate device a legally marketed device?

Yes.

Both the primary and secondary predicate devices are legally marketed devices.

The primary predicate is the FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361). This is a legally marketed device. Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

The secondary predicate identified for the telethermographic infrared imaging capability of the IRTS is the ICI P and S Series IR Camera(s) and the IR Flash Software made by Texas Infrared, (K073581). This is a legally marketed device. Telethermographic Systems (adjunctive use) are Class I devices under 21 CFR § 884.2980 and are classified by the Obstetrical and Gynecological Devices panel. Product code - LHQ.

Decision 2: Do the devices have the same intended use?

Yes.

The IRTS has the same intended use as the primary predicate. Both the IRTS and the FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) are intended for continuous temperature monitoring of the patients esophagus.

The IRTS has the same intended use as the second predicate. Both the IRTS and the Texas Infrared ICI P and S Series IR Camera(s) and the IR Flash Software (K073581) are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

Decision 3: Do the devices have the same technological characteristics?

No.

The IRTS incorporates the same basic components as its primary predicate, the FIAB ESOTEST device. Both are catheter-based esophageal temperature probes with integrated Type-T thermocouples for measuring temperature. Both systems incorporate a monitor to continuously display the esophageal temperature. Both systems are classified as a Direct Mode Clinical Thermometer and tested in accordance with ISO 80601-2-56.

The IRTS also incorporates the same fundamental telethermographic infrared technology as its secondary predicate, the Texas Infrared system. Both are infrared imaging devices that include an optical assembly, an infrared detector and graphical presentation software. Both systems passively collect the infrared energy naturally radiated off tissue surfaces for adjunctive diagnostic screening. Both systems are not Clinical Thermometers as defined by 80601-2-56.

The following differences are noted in the SE table above but do not affect substantial equivalence or safety and effectiveness.

- The Securus Probe material (patient contact): Polyethylene was selected for the exterior catheter shaft of the Probe. Polyethylene has excellent transmissivity to infrared energy which is important for the infrared imaging capability of the IRTS. Polyethylene is available in a variety of grades for flexible catheter manufacturing and has a long history of use in medical devices. The material has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The shaft of the Probe is 9 Fr (3.0 mm) with a smooth surface and mainly uniform diameter along its length. The shaft of the FIAB ESOTEST is 7 Fr (2.3 mm) with five 11 Fr (3.6 mm) stainless steel beads protruding at the thermocouple and electrode locations. The Securus Probe diameter falls within the mid-range of the FIAB ESOTEST geometry which is suitable for both nasal and oral insertion.
- A single thermocouple is used for the Securus Probe to report esophageal temperature where the FIAB ESOTEST has 3 thermocouples spaced apart along the catheter shaft. The FIAB device is configured so that only one thermocouple is used at a time. Numerous esophageal temperature probes are marketed with a single sensor configuration and are tested to the same recognized standards.
- The Securus Probe is supplied non-sterile where the FIAB ESOTEST is provided sterile. There are multiple non-sterile esophageal temperature sensor probes on the market. The choice of sterile versus non-sterile is made by the clinical site and varies depending on the nature of the procedure, institutional protocols and product price. Offering the Securus Probe as a non-sterile product is not clinically significant for the intended use.
- The transient response time (heating and cooling) of the thermocouple sensor was tested in accordance with ISO 80601-2-56. The resulting transient response time is less than 2.5 seconds. The FIAB ESOTEST transient response time is reported as approximately 1 second. The response time of the Securus Probe is tested and reported in the product manual in accordance with the standard. The l.5 second difference in response time between the predicate and the Securus product is not clinically significant for the intended use.
- The infrared detector used in the Securus product is a Stirling cooled MCT type. The Texas product utilizes an FPA Microbolometer type detector. The majority of IR cameras have a Microbolometer type detector, mainly because of cost considerations. Microbolometers are relatively low sensitivity, exhibit broad (flat) response curves and slow response time (time

constant ~ 12 ms). For more demanding applications, MCT type detectors are used, which operate on the basis of an intrinsic photoelectric effect. Stirling cooled MCT detectors are very sensitive to changes in infrared energy and react very quickly to changes in infrared energy levels (i.e., temperatures), having a response time constant on the order of 1 µs. The Securus IRTS system utilizes the more sensitive Stirling cooled MCT type detector.

- The way the IRTS collects the infrared energy from the tissue surface and presents that energy to the detector has been adapted to incorporate a fiberoptic assembly. This fiberoptic accessary is fully contained within the inner lumen of the Probe. The fiberoptic assembly transfers the IR energy from the surface of the esophagus wall to the detector. The Probe continuously scans a 360° by 60mm segment. The infrared image is graphically presented on the Patient Monitoring Unit as a 2-dimensional color map along with the peak temperature over the scanned area. The thermal image has a refresh rate of once every second.

Decision 4: Do the differences in technological characteristics of the devices raise different questions of safety and effectiveness?

No.

The technological differences of the devices do not raise different questions of safety and effectiveness. Testing has been successfully performed in accordance with accepted consensus standards and methods to evaluate effects on safety and effectiveness.

- The change in Probe materials has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The esophageal temperature measurement has been tested per ISO 80601-2-56 and meets the basic safety standards and essential performance requirements of a Clinical Thermometer for body temperature measurement. The number of thermocouples (1 versus 3) does not affect the safety and effectiveness for the intended use.
- The fiberoptic assembly allows the device to passively collect infrared energy from the esophagus and transmit it to the detector. This added accessory does not affect the performance of the system as shown through accuracy testing. The infrared temperature information is for adjunctive diagnostic screening and has the same accuracy performance as the secondary predicate device and does not affect safety and effectiveness for the intended use.

Decision 5a: Are the methods acceptable?

Yes.

Where appropriate, testing and development has been performed in accordance with recognized consensus standards. The InfraRed Thermographic System (IRTS) complies with FDA recognized standards:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO 80601-2-56:2009 Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009(E) Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010(E) Biological evaluation of medical Devices - Part 10: Tests for irritation and skin sensitization
- ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes
- ISO 14791:2007 Application of risk management to medical devices

Decision 5b: Do the data demonstrate substantial equivalence?

Yes.

The data demonstrate substantial equivalence. The IRTS has the same intended use as both predicate devices. Data from the thermocouple temperature sensor shows that the IRTS has substantially equivalent performance characteristics as the FIAB ESOTEST system when tested in accordance with ISO 80601-2-56 particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

The infrared thermographic information is for adjunctive diagnostic screening and has the same accuracy performance as the Texas Infrared system.

The IRTS therefore demonstrates substantial equivalence to both the primary and secondary predicate devices.

Appendix III to this 510(k) application contains copies of the predicate device labeling and/or FDA 510(k) clearance information.

FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, (K123361)

Texas Infrared, ICI P and S Series IR Camera(s) and the IR Flash Software, (K073581).

ATTACHMENT B: REVISED SUMMARY

510(K) SUMMARY

This 510(k) Summary is being submitted in accordance with: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)

Common name: Clinical Electronic Thermometer

Thermographic System

Classification Number/ Classification name/Product code:

Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Telethermographic systems intended for adjunctive diagnostic screening are Class I devices under 21 CFR § 884.2980 and are classified by the Obstetrical and Gynecological Devices panel. Product code - LHQ.

Special Controls:

Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers

3) Predicate Devices

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361).

ICI P and S Series IR Camera(s) and the IR Flash Software, Texas Infrared, (K073581).

4) Device Description

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

Esophageal temperature probes for continuous temperature monitoring of the patients esophagus are Class II devices under Product Code FLL 21 CFR 880.2910;

(a) A clinical electronic thermometer is a device used to measure the body temperature of a

patient by means of a transducer coupled with electronic signal amplification, conditioning, and display unit. The transducer may be in a detachable probe with or without a disposable cover.

The thermocouple sensor of the IRTS Probe is considered a Direct Mode Clinical Thermometer as defined in ISO 80601-2-56.

201.3.207: Direct Mode: Operating mode of a clinical thermometer where the output temperature is an unadjusted temperature that represents the temperature of the measuring site to which the probe is coupled. (see page 4 of ISO 80601-2-56).

The FIAB ESOTEST System is identified as the primary predicate for continuous temperature monitoring of the patients esophagus, (K123361).

Telethermographic systems for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures are Class 1 devices under Product Code LHQ 21 CFR 884.2980;

A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition, the Probe incorporates adjunctive infrared thermal imaging element to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to other clinical diagnostic procedures. See Figure 1 for a system overview.

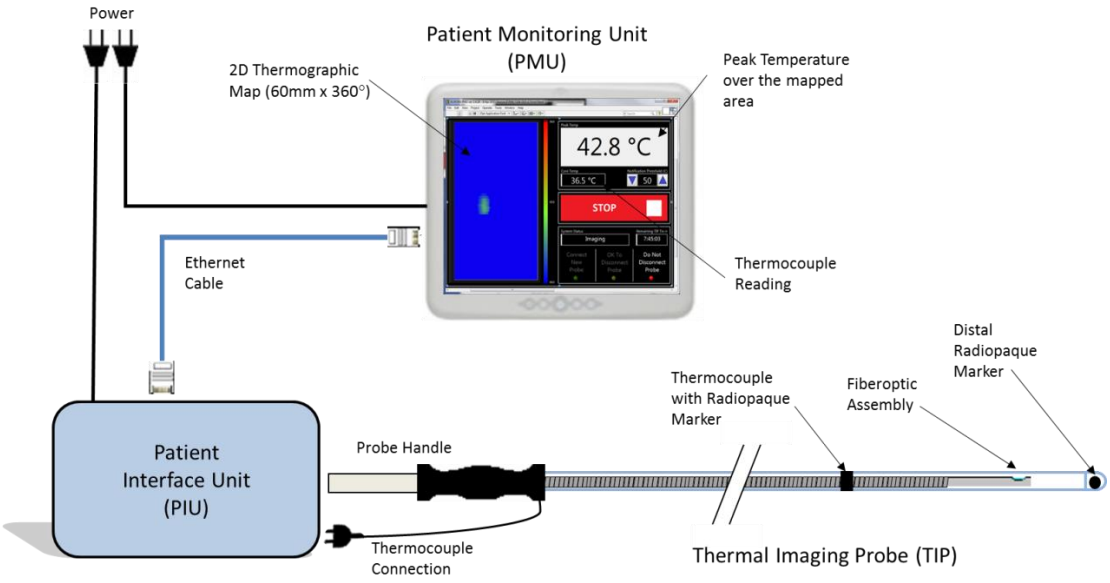


Figure 1: System Overview Diagram

5) Indications for Use

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

6) Comparison to Predicate Device

The Securus InfraRed Thermographic System (IRTS) combines two different temperature sensing technologies and displays the output on a single monitor.

The temperature sensing technologies incorporated into the IRTS Probe include, a thermocouple sensor for continuous temperature monitoring of the patients esophagus and a thermographic sensor for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.

There are no significant technological differences between the predicate devices and the IRTS that would raise new questions about safety and effectiveness of the system. Minor modifications to the technological characteristics were necessary to combine the output from the thermocouple sensor for esophageal temperature measurement and the output from the thermographic sensor for adjunctive thermal imaging the esophagus on a single monitor. The fundamental technologies and the intended uses are substantially equivalent.

The FIAB ESOTEST System is identified as the primary predicate for continuous temperature monitoring of the patients esophagus, (K123361).

Telethermographic systems for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures are Class 1 devices under Product Code LHQ 21 CFR 884.2980;

The Texas Infrared IR Camera with Flash Software is identified as the secondary predicate for displaying thermal images as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures, (K073581).

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Intended Use	Continuous temperature monitoring of the patients esophagus.	Intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperatures.	The thermocouple sensor of the IRTS Probe is intended for continuous temperature monitoring of the patients esophagus. The thermographic sensor of the IRTS Probe is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperatures.
Indications for Use	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The ICI Series and S IR Cameras, which provide capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature. Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.	The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor isintended to display continuous esophageal temperature measurements (°C) from the IRTS Probe. The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
System Components	Temperature probe 7 Fr Interconnect cable Patient Monitor	Thermographic infrared detector with optical assembly Flash Software	Temperature probe 9 Fr Patient Interface Unit (PIU) with thermographic infrared detector. Patient Monitoring Unit (PMU) with software
Probe Material (patient contact)	Polyurethane and stainless steel	N/A	Polyethylene and platinum iridium
Probe size	7 Fr catheter with 11 Fr sensors 95 cm length	N/A	9 Fr catheter with 9 Fr sensor 150 cm length
System Temperature Precision and Resolution	0.1° C	0.1° C	0.1° C
Temperature Sensor	Type-T thermocouple	N/A	Type-T thermocouple
Thermocouple Sensor Range	15°-75° C	N/A	25° - 45° C
Thermocouple Sensor Accuracy	± 0.5° C tested in accordance with ISO 80601-2-56	N/A	± 0.3° C tested in accordance with ISO 80601-2-56
Transient Response Time of Thermocouple	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	N/A	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56
Infrared Detector Technology	N/A	FPA microbolometer	Stirling cooled MCT

	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361	Texas Infrared, ICI P and S Series IR Camera with Flash Software K073581	Securus Medical Group, Inc., IRTS System
Infrared Temperature Range	N/A	-20° - +250° C	35° - 60° C
Infrared Temperature Accuracy	N/A	IR: ± 2° C or 2% of reading	IR: ± 2° C
Power Supply	100-120/230 Vac	AC adaptor power supply 12 VDC	100-240 Vac AC adaptor power supply 24 VDC
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007

7) Comparison to Predicate Discussion:

The IRTS incorporates the same basic components as its primary predicate, the FIAB ESOTEST device. Both are catheter-based esophageal temperature probes with integrated Type-T thermocouples for measuring temperature. Both systems incorporate a monitor to continuously display the esophageal temperature. Both systems are classified as a Direct Mode Clinical Thermometer and tested in accordance with ISO 80601-2-56.

The IRTS also incorporates the same fundamental telethermographic infrared technology as its secondary predicate, the Texas Infrared system. Both are infrared imaging devices that include an optical assembly, an infrared detector and graphical presentation software. Both systems passively collect the infrared energy naturally radiated off tissue surfaces for adjunctive diagnostic screening. Both systems are not Clinical Thermometers as defined by 80601-2-56.

The following differences are noted in the SE table above but do not affect substantial equivalence or safety and effectiveness.

- The Securus Probe material (patient contact): Polyethylene was selected for the exterior catheter shaft of the Probe. Polyethylene has excellent transmissivity to infrared energy which is important for the infrared imaging capability of the IRTS. Polyethylene is available in a variety of grades for flexible catheter manufacturing and has a long history of use in medical devices. The material has been evaluated per ISO 10993-1 and meets biocompatibility requirements for the intended use.
- The shaft of the Probe is 9 Fr (3.0 mm) with a smooth surface and mainly uniform diameter along its length. The shaft of the FIAB ESOTEST is 7 Fr (2.3 mm) with five 11 Fr (3.6 mm) stainless steel beads protruding at the thermocouple and electrode locations. The Securus Probe diameter falls within the mid-range of the FIAB ESOTEST geometry which is suitable for both nasal and oral insertion.
- A single thermocouple is used for the Securus Probe to report esophageal temperature where the FIAB ESOTEST has 3 thermocouples spaced apart along the catheter shaft. The FIAB device is configured so that only one thermocouple is used at a time. Numerous esophageal temperature probes are marketed with a single sensor configuration and are tested to the same recognized standards.
- The transient response time (heating and cooling) of the thermocouple sensor was tested in accordance with ISO 80601-2-56. The resulting transient response time is less than 2.5 seconds. The FIAB ESOTEST transient response time is reported as approximately 1 second. The response time of the Securus Probe is tested and reported in the product manual in accordance with the standard. The l.5 second difference in response time between the predicate and the Securus product is not clinically significant for the intended use.
- The infrared detector used in the Securus product is a Stirling cooled MCT type. The Texas product utilizes an FPA Microbolometer type detector. The majority of IR cameras have a Microbolometer type detector, mainly because of cost considerations. Microbolometers are relatively low sensitivity, exhibit broad (flat) response curves and slow response time (time constant ~ 12 ms). For more demanding applications, MCT type detectors are used, which operate on the basis of an intrinsic photoelectric effect. Stirling cooled MCT detectors are very sensitive to changes in infrared energy and react very quickly to changes in infrared energy levels (i.e., temperatures), having a response time constant on the order of 1 µs. The Securus IRTS system utilizes the more sensitive Stirling cooled MCT type detector.
- The way the IRTS collects the infrared energy from the tissue surface and presents that energy to the detector has been adapted to incorporate a fiberoptic assembly. This fiberoptic accessary

is fully contained within the inner lumen of the Probe. The fiberoptic assembly transfers the IR energy from the surface of the esophagus wall to the detector. The Probe continuously scans a 360° by 60mm segment. The infrared image is graphically presented on the Patient Monitoring Unit as a 2-dimensional color map along with the peak temperature over the scanned area. The thermal image has a refresh rate of once every second.

Testing and development have been performed in accordance with recognized consensus standards. Based on the testing performed on the IRTS the safety and effectiveness of the system has not been affected by the changes required to combine the output of the two temperature monitoring devices onto one display monitor.

8) Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body

temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

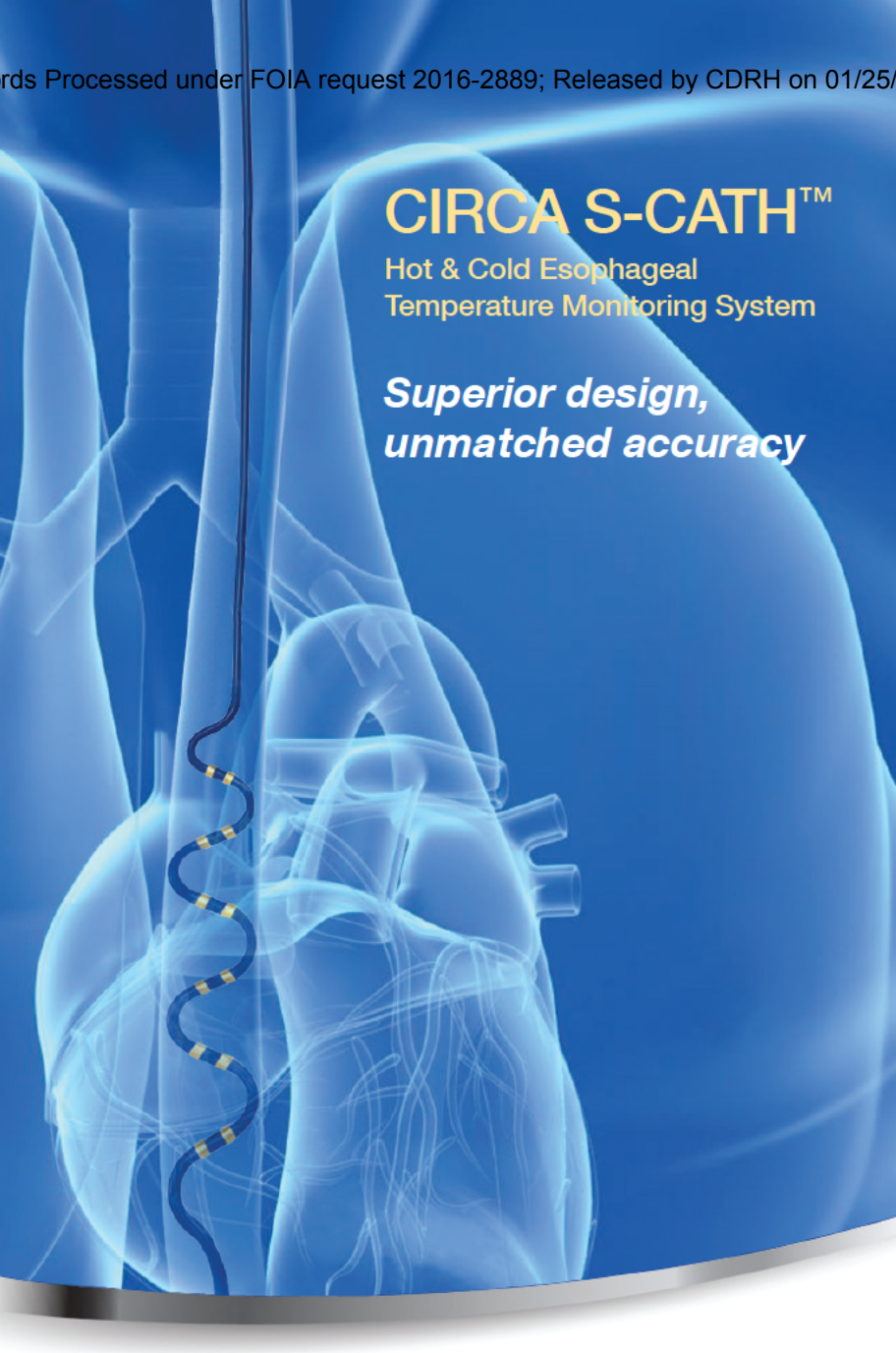
Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The performance data provided support the substantial equivalence of the InfraRed Thermographic System (IRTS). According to these data we conclude that the IRTS Probe (TIP), IRTS Patient Monitoring Unit (PMU), and the Patient Interface Unit (PIU) are substantially equivalent to the predicate devices in terms of performance, safety and use. The differences from the predicates do not affect substantial equivalence or performance and do not raise any new safety concerns.

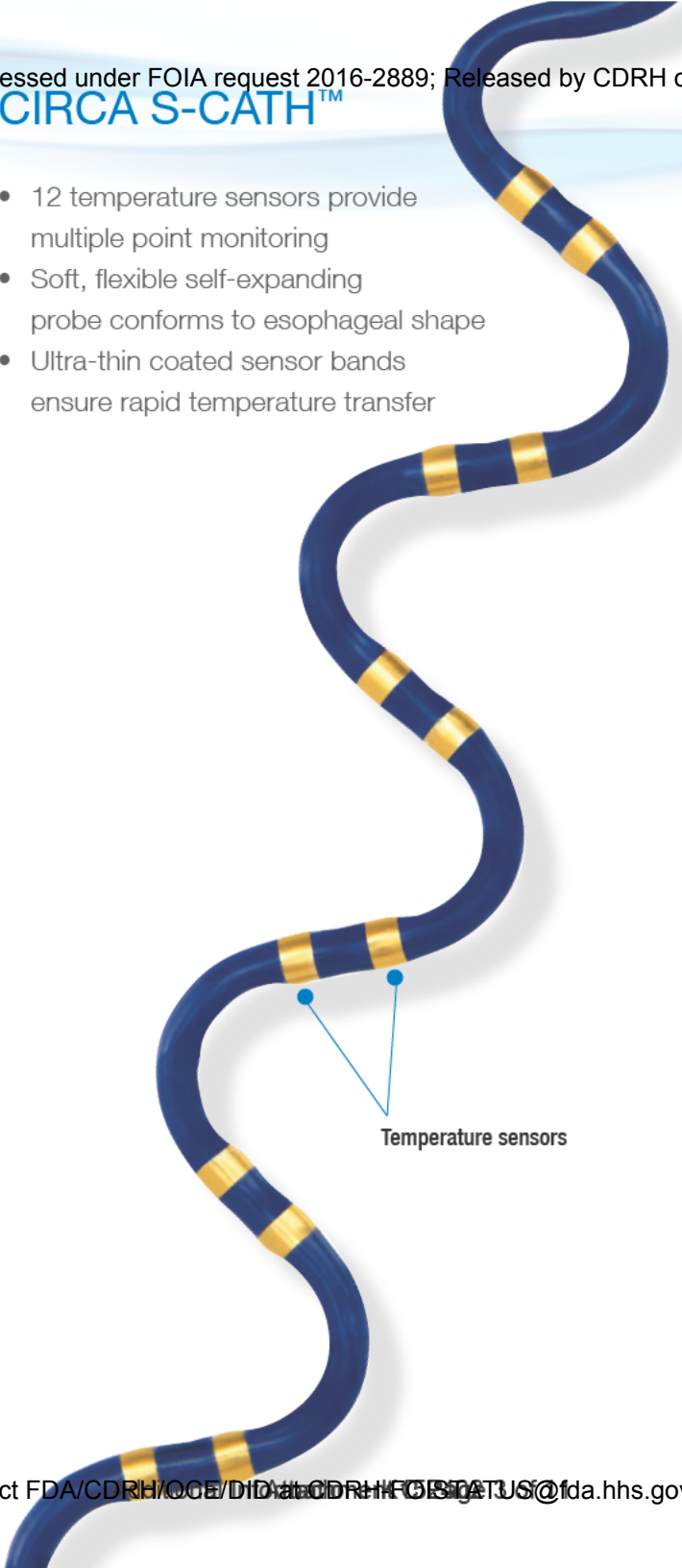
ATTACHMENT C: LABELING, CIRCA



CIRCA SCIENTIFIC

CIRCA S-CATH™

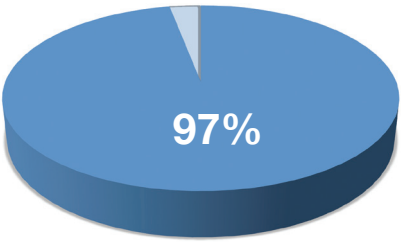
- 12 temperature sensors provide multiple point monitoring
- Soft, flexible self-expanding probe conforms to esophageal shape
- Ultra-thin coated sensor bands ensure rapid temperature transfer



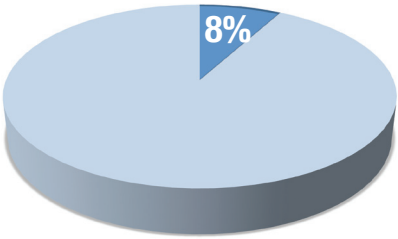
Maximum Esophageal Coverage

Proprietary S-Shape Design provides maximum coverage for more complete monitoring.

S-CATH S-Shape Design
97% coverage



Conventional Probe Design
8% coverage

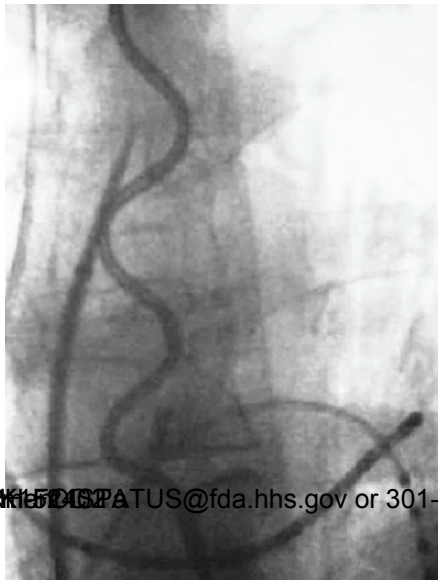


Assumes: Average esophageal width of 18.9mm[1], average esophageal length in contact with left atrium of 42.8mm[2], and each sensor covers 64 sq. mm.

Stationary Placement

Sensor placement ensures proximity to the point of treatment; no need to move the probe once placed.

- Radiopaque shaft provides a visual landmark of the esophagus
- Indicates esophageal width and orientation
- Facilitates reduced use of fluoroscopy

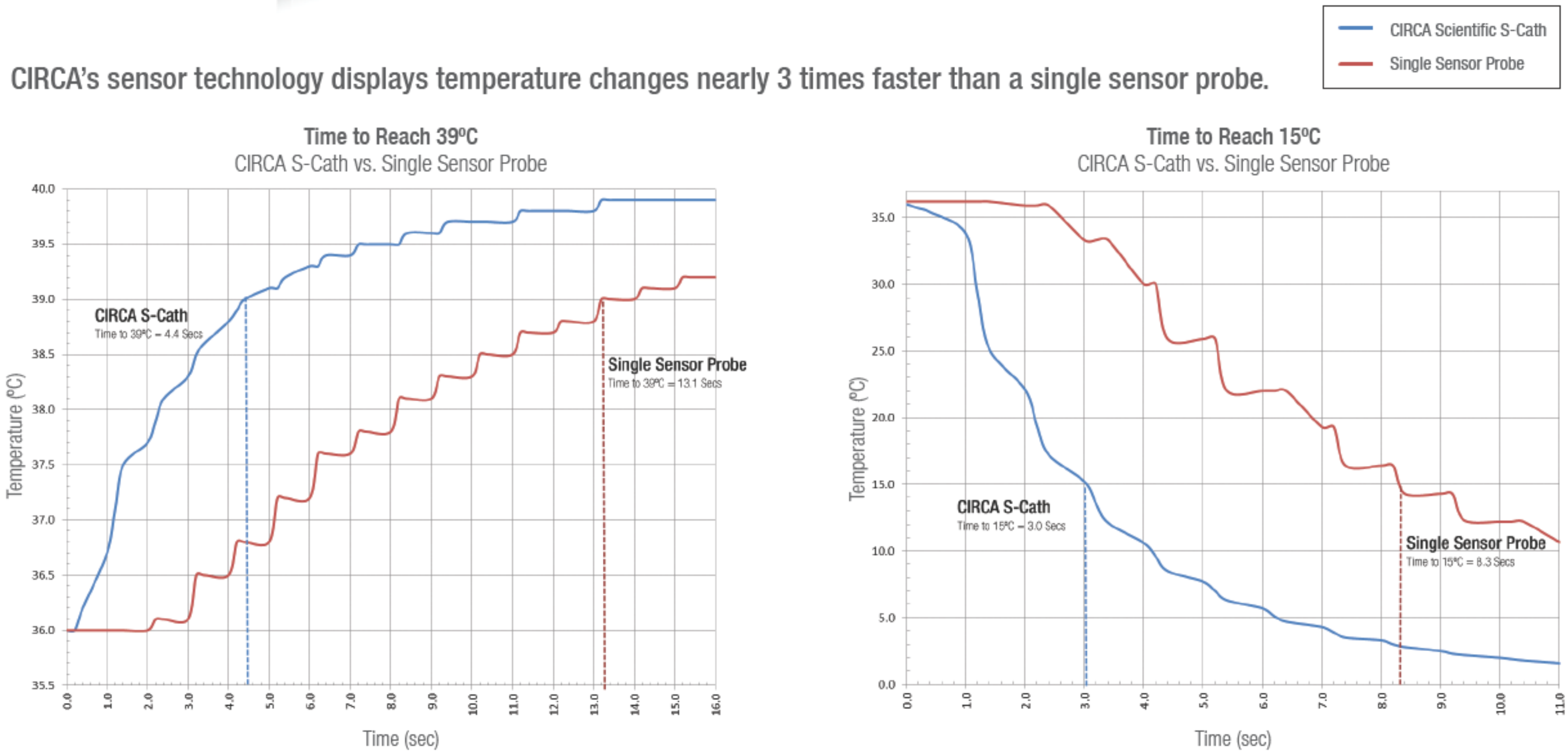


Faster Response to Hot & Cold Temperature Changes

Continuous monitoring software is highly accurate in both hot and cold (down to 0°C) temperatures.[3]

- 12 temperature sensors update 20 times per second
- Four, user selectable low and high temperature alarms
- Temperature is displayed both graphically and numerically

CIRCA's sensor technology displays temperature changes nearly 3 times faster than a single sensor probe.



Test conducted by CIRCA Scientific.

Product Code Description

CS-1000	CIRCA Temperature Monitoring System™ (Touch Screen Display, Pole Mount included)
CS-2001	CIRCA S-CATH™ Esophageal Temperature Probe, (Single Use, 10Fr O.D.,10 units/ Carton), U.S.*
CS-2006	CIRCA S-CATH™ Esophageal Temperature Probe, (Single Use, 10Fr O.D.,10 units/ Carton), International*
CS-2003	CIRCA S-CATH Interconnect Cable (Reusable, 15 Foot Working Length)
CS-1029	CIRCA Temperature Standard (Calibration)

CIRCA SCIENTIFIC

Corporate Office
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Englewood, CO 80112
www.CIRCASCIENTIFIC.com
Office: 1.303.951.8767 • Fax: 1.303.951.8769
info@circascientific.com

All products carry the CE mark, comply with Medical Device Directive 93/42/EEC and are manufactured to Quality Systems ISO13485.

This product is listed by CSA International as certified.

Indication for Use: The CIRCA S-CATH Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus. The CIRCA Temperature Monitor is indicated to display continuous temperature measurement (°C) from 12-sensor temperature probe.

[1] Cury RC, Abbara S, Schmidt S, Malchano ZJ, Neuzil P, Weichet J, Ferencik M, et al. Relationship of the esophagus and aorta to the left atrium and pulmonary veins: Implications for catheter ablation of atrial fibrillation. Heart Rhythm 2005; 2:1317-1323.

[2] Sánchez-Quintana D, Cabrera JA, Climent V, Farré J, de Mendonça MC, Ho SY. Anatomic relations between the esophagus and left atrium and relevance for ablation of atrial fibrillation. Circulation. 2005;112: 1400-1405.

[3] Accuracy of the temperature sensors is ± 0.3°C within the rated output range of 25°C to 45°C and ± 0.4°C within the rated extended output range of 0° to 24.9°C.

CE 0470

*US and Foreign Patents Pending

Instructions for Use: S-Cath™ Esophageal Temperature Probe

General warnings and cautions:

- Rx Only: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Single use only. Do not re-use. If re-used, cross-infection to patient may occur.
- Do not rinse, soak, wash, or sterilize. Material degradation and temperature inaccuracy may occur.
- Insert temperature probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction.
- Do not re-insert stylet or attempt to override lock-out feature, probe damage may occur.
- The S-Cath™ Esophageal Temperature Probe is designed for use with CIRCA Scientific Interconnect Cable, CIRCA Scientific Temperature Monitor, and 400 Series Compatible Monitor only. Incompatible components can result in degraded performance and could lead to damage.
- Part of defibrillation proof protection is provided by the S-Cath™ Temperature Probe with the CIRCA Scientific Temperature Monitor (Defibrillation-Proof Type BF Applied Part). When 400 Series Cable Connector is connected to 400 Series Compatible Monitor, consult equipment manufacturer's accompanying documents for the monitor's defibrillation-proof classification.

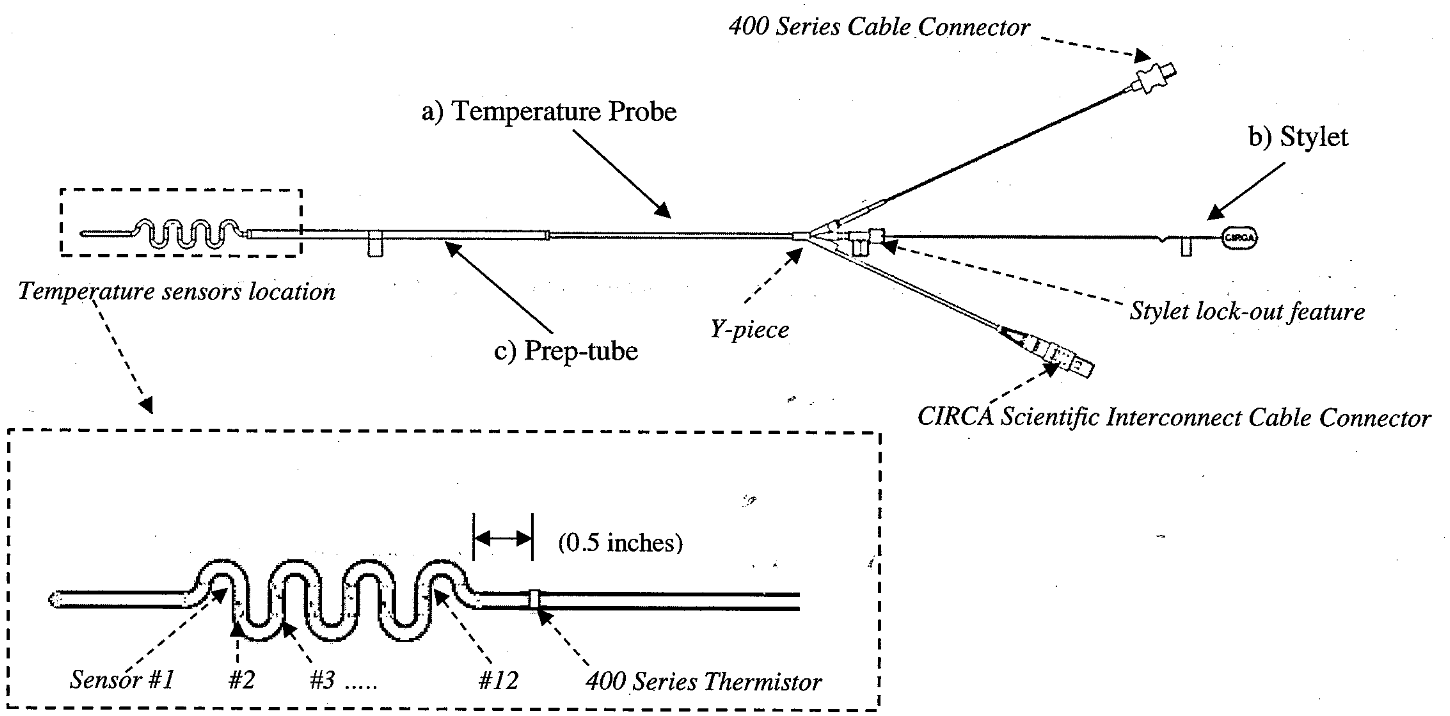
Indications for use:

The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Description:

The S-Cath™ Esophageal Temperature Probe provides continuous temperature measurement (°C) and operates in direct mode.

The components inside package are: a) radiopaque temperature probe; b) stainless steel stylet; and c) plastic prep-tube.



Manufactured for:
CIRCA Scientific, LLC
[illegible]
Englewood, CO 80112
(303) 951-8767

Setup instructions:

The operator is responsible for checking the compatibility of the temperature probe, interconnect cable, and monitor before use. Ensure only CIRCA Scientific components and equipment is connected to CIRCA Scientific cable connector.

S1) Remove device from package.

S2) Visually inspect for damage, kinks, visible debris, and missing components. Do not use if any defects are observed.

S3) Connect CIRCA Scientific Interconnect Cable Connector to CIRCA Scientific monitor via CIRCA Scientific interconnect cable by aligning snap-fit connectors and pushing firmly.

S4) If used, align 400 series cable connector with 400 series compatible temperature monitor cable and push firmly to assure full contact.

S5) Verify temperatures are displayed on monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on monitor.

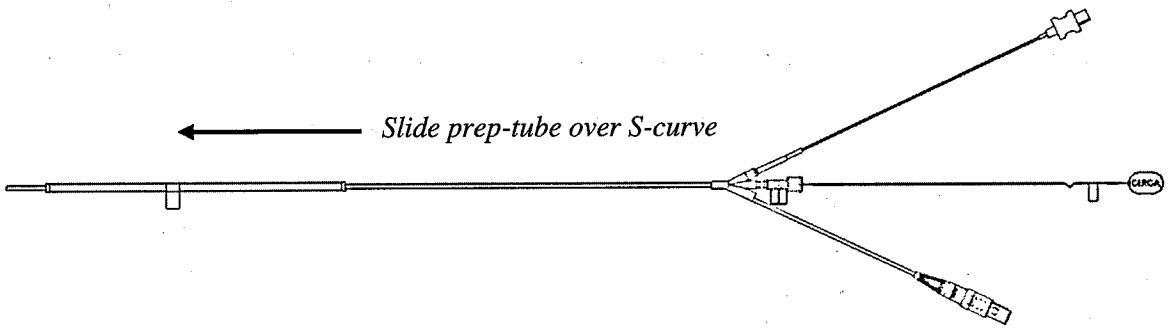
S6) Disconnect temperature probe from interconnect cable by grasping connectors. Do not pull on cable or probe wire to disconnect.

S7) Proceed with operating instructions below.

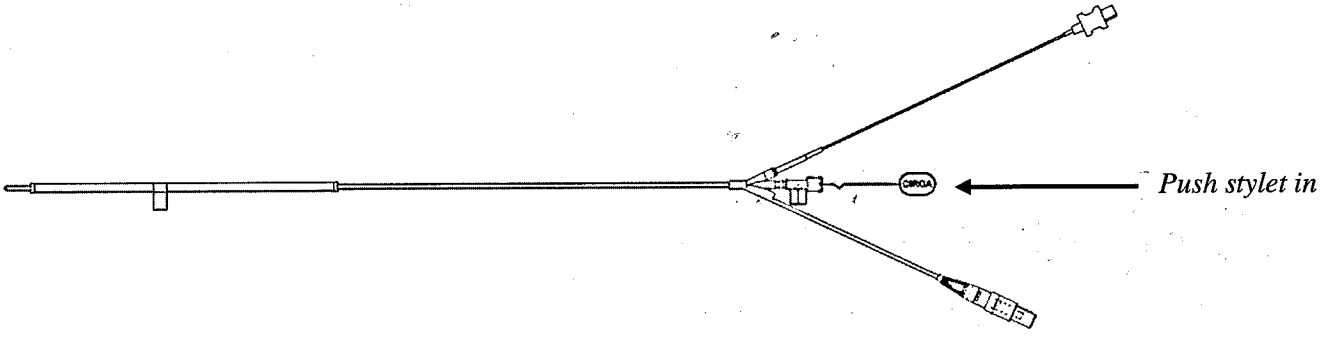
Operating instructions:

O1) Straighten S-Curve Portion of Temperature Probe

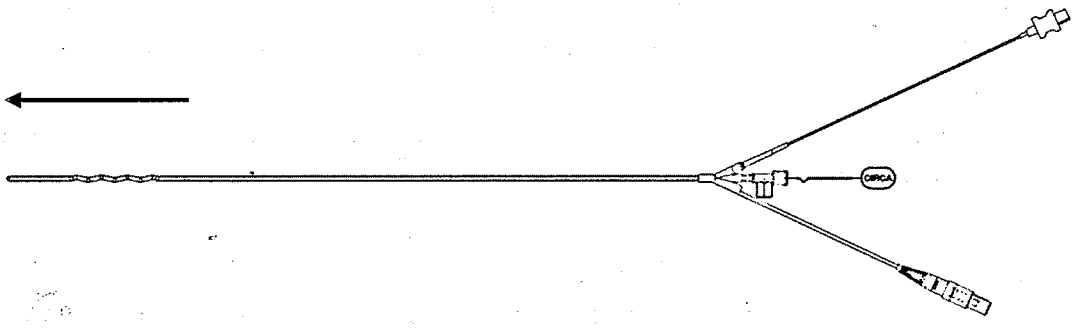
a. Grasp Y-piece of temperature probe with one hand and slide prep-tube over S-curve portion to approximately 20 mm (3/4") from the end with other hand.



b. Grasp Y-piece of temperature probe with one hand and push stainless steel stylet until z-bend of stylet reaches Y-piece.



c. ***Remove prep-tube and discard***



Note: Once prèp-tube is removed and discarded, temperature probe is now ready for insertion; proceed with step O2)

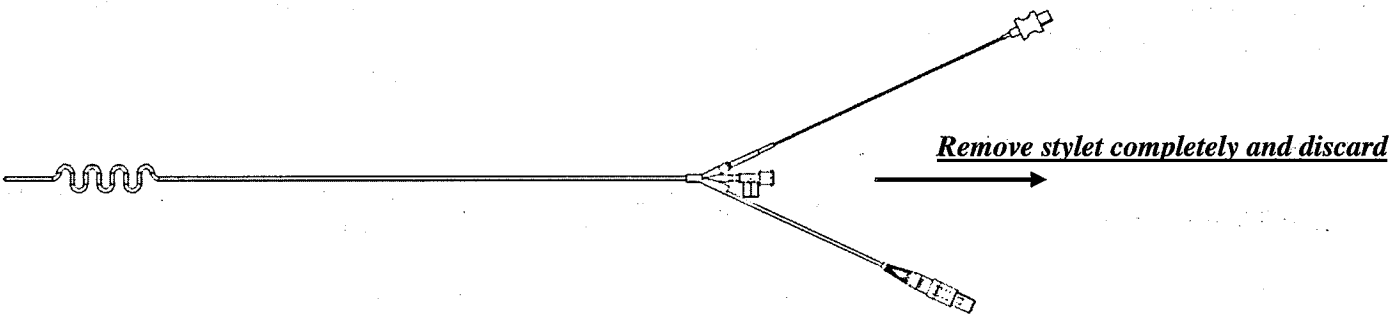
O2) Insert Temperature Probe into Esophagus

a. Apply water-soluble lubricant to outside of temperature probe.

b. Insert temperature probe into esophagus under fluoroscopic x-ray. Advance distal tip to approximately 1 cm (0.4") superior to the gastroesophageal junction.

c. Once temperature probe is placed, grasp finger grip end of stylet and remove completely. Discard stylet.

Caution: do not re-insert stylet or attempt to override lock-out feature, probe damage may occur.



d. Verify position of temperature probe under fluoroscopic x-ray. If probe end does not appear as an S-shape, grasp Y-piece and rotate probe until S-shape is visible. Grasp Y-piece to reposition probe as required for desired placement.

Instructions for Use: S-Cath™ Esophageal Temperature Probe

Setup instructions:

The operator is responsible for checking the compatibility of the temperature probe, interconnect cable, and monitor before use. Ensure only CIRCA Scientific components and equipment is connected to CIRCA Scientific cable connector.

S1) Remove device from package.

S2) Visually inspect for damage, kinks, visible debris, and missing components. Do not use if any defects are observed.

S3) Connect CIRCA Scientific Interconnect Cable Connector to CIRCA Scientific monitor via CIRCA Scientific interconnect cable by aligning snap-fit connectors and pushing firmly.

S4) If used, align 400 series cable connector with 400 series compatible temperature monitor cable and push firmly to assure full contact.

S5) Verify temperatures are displayed on monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on monitor.

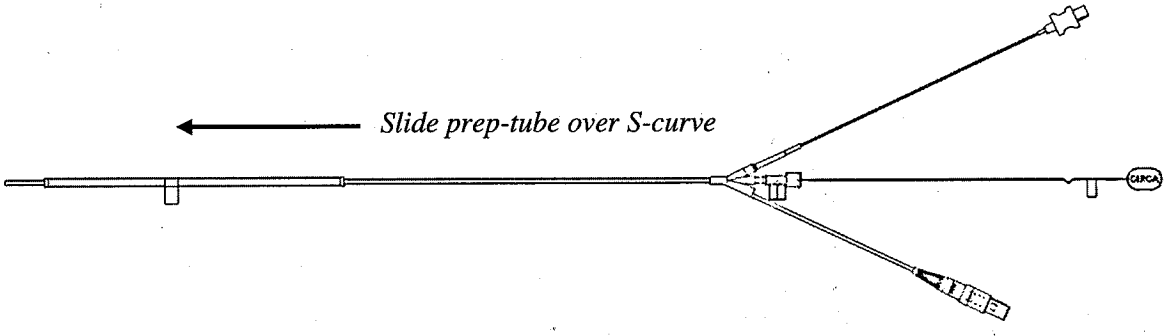
S6) Disconnect temperature probe from interconnect cable by grasping connectors. Do not pull on cable or probe wire to disconnect.

S7) Proceed with operating instructions below.

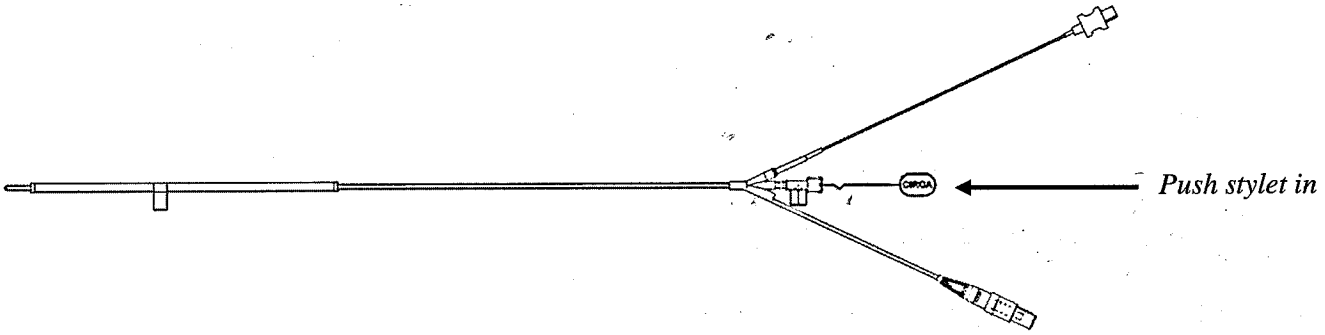
Operating instructions:

O1) Straighten S-Curve Portion of Temperature Probe

a. Grasp Y-piece of temperature probe with one hand and slide prep-tube over S-curve portion to approximately 20 mm (3/4") from the end with other hand.



b. Grasp Y-piece of temperature probe with one hand and push stainless steel stylet until z-bend of stylet reaches Y-piece.



CIRCA SCIENTIFIC

S-Cath™

Esophageal Temperature Probe

Intended Use: The Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus.

Size: 10 Fr OD Length: 50cm

REF CS-2001

LOT 026941

QTY 1

2014-05

Rx Only

Manufactured for : CIRCA Scientific, LLC
14 Inverness Drive East, Suite H-136
Englewood, CO 80112 USA
(303) 951-8767

EC REP Medicor Medical Supplies NV/ SA
Timmerik 2, B-3020 Herent, Belgium

CE 0470

CS-ART2001 Rev.03

ATTACHMENT D: REVISED INSTRUCTION MANUAL AND PROBE LABELING

InfraRed Thermographic System (IRTS)

Instruction Manual

TABLE OF CONTENTS

1. SYSTEM OVERVIEW

The InfraRed Thermographic System (IRTS) consists of three components:

DIAGRAM LETTER	REF #	NAME	DESCRIPTION
A	A-10734	Thermal Imaging Probe (TIP)	Temperature Probe
B	A-10667	Patient Interface Unit (PIU)	Main system control unit
C	A-10395	Patient Monitoring Unit (PMU)	Touchscreen monitor

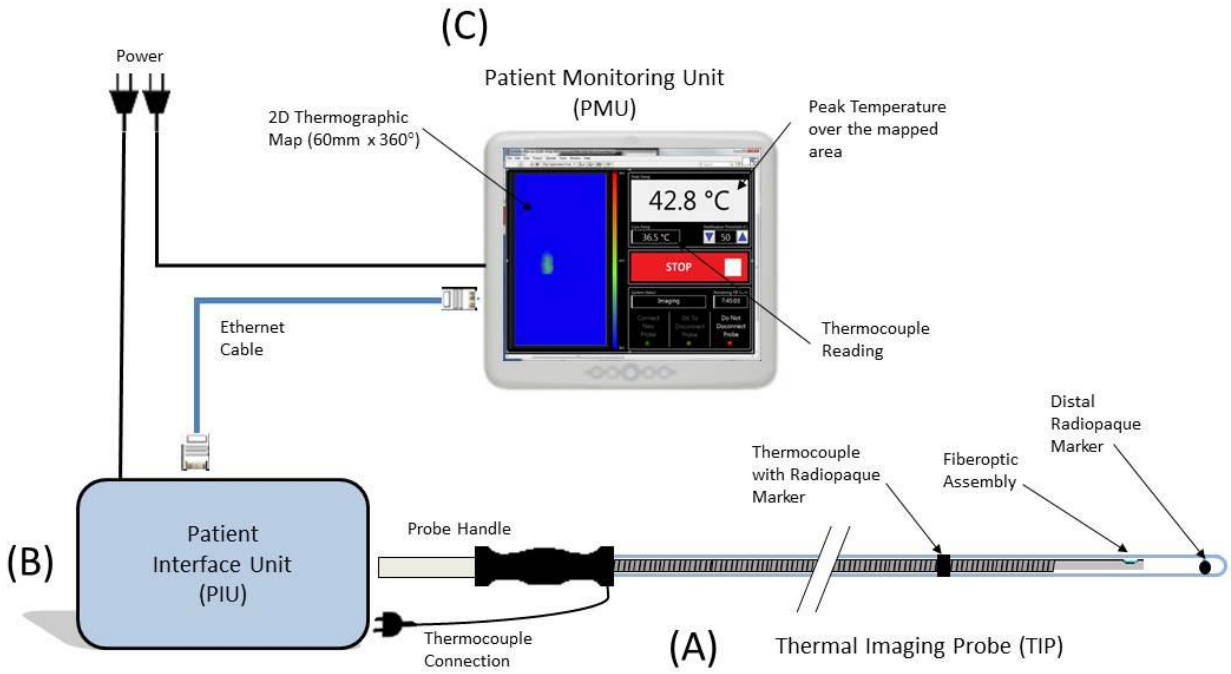


Figure 1: System Overview Diagram

The InfraRed Thermographic System (IRTS) is designed to provide continuous direct mode esophageal temperature monitoring through the use of a standard thermocouple located at the proximal radiopaque marker. In addition, the system incorporates adjunctive infrared thermal imaging technology for quantifying differences in surface temperature changes in the esophagus.

The Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) displays the thermal image and temperature measurements (°C) from the Thermal Imaging Probe (TIP). The thermal image provides a continuous, real-time, non-contact thermal map of a 360° by 60mm long segment of the inner lumen of the esophagus. The thermal image is displayed in a two-dimensional color map. The peak temperature represents the maximum temperature over the scanned area.

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.***

2. INDICATIONS FOR USE

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

3. CONTRAINDICATIONS, WARNINGS and CAUTIONS

CONTRAINDICATIONS

The use of the IRTS is contraindicated for patients who have:

- Symptomatic Esophageal Stricture
- Esophageal Diverticulum
- Esophageal Tumor or Abscess
- Recent Esophageal or Gastric Surgery

WARNINGS

- The Probe is single use only. Do not re-use. Cross-infection to patient may occur and the device may not function properly.
- The Securus IRTS PMU should only be used with Securus IRTS Probes. Use of incompatible components can result in degraded performance or harm.
- Ethernet ports on PMU and PIU components should only be connected to one another.
- Insert Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.
- Do not attempt to reposition Probe while imaging. To reposition always hit “Stop” and wait for the button message “Start Imaging”.
- The Securus IRTS is to be installed and serviced exclusively by Securus technicians. Do not attempt to install, repair, service, or operate the Securus IRTS in any fashion deviating from what is specified in this manual.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- All electrical equipment supporting the patient must be appropriately grounded and must comply with all current regulations and must be of CF type.
- The use of accessories and cables other than those listed above may result in increased EMISSIONS or decreased IMMUNITY of the Securus IRTS.

- The Securus IRTS should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Securus IRTS should be observed to verify normal operation in the configuration in which it will be used.
- Use system only within the indicated operating environment temperature and humidity range. Use outside the specified operating environment may result in inaccurate esophageal temperature readings.
- The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended in Table 4.
- Read and follow all prompts, warnings, errors, and instructions on the IRTS User Interface to ensure proper operation. Failure to follow these instructions can result in degraded performance or harm.

CAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- The thermal image and peak temperature are offered as an adjunct to other clinical diagnostic procedures. Only the thermocouple temperature measurement meets the requirements for essential performance of Clinical Thermometers for body temperature measurement accuracy.
- Only physicians trained in esophageal insertion and catheterization procedures should use the IRTS.
- Do not use the IRTS for any purpose other than its intended use.
- Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock.
- Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.
- Do not bend or kink the probe in a sharp angle or a small radius.
- The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
- Avoid touching the proximal tip of the Probe to avoid damaging the Probe.
- The Probe is provided fully assembled. Do not disassemble the Probe. Disassembly will damage the device.
- The system components will not function with equipment from other manufacturers.
- At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.

If you experience any problems with this product please contact Securus at 216-445-4683

4. SET-UP

A Securus Technician will install the system at your facility. The installation will include:

- Initial inspection of the system for shipping damage
- Identifying the proper location and suitable surface for the PMU and PIU in the lab
- Connection and routing of Ethernet cable
- Identification of suitable power sources
- Initializing software, setting local time and date and other relevant software settings
- Confirming system fully operational in the lab environment

Note: The following steps assume that the Securus installation has already occurred.

4.1. Inspect the PMU and PIU for damage. Do not use the system, and contact Securus if damage is evident.

> **CAUTION:** Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock

4.2. Confirm PIU and PMU are placed on a suitable surface in a dry location.

> **CAUTION:** At no time should the PIU or PMU units be placed directly on a bed or other soft surface. Placing the units on a soft surface may cause them to overheat or fall.

4.3. Confirm that the correct power supplies and provided Ethernet cable are plugged into the back panel of the PIU and of the PMU. Plug both power supplies into a grounded, 100-240VAC outlet (50/60hz). Only use the Securus issued power supplies for the IRTS system.

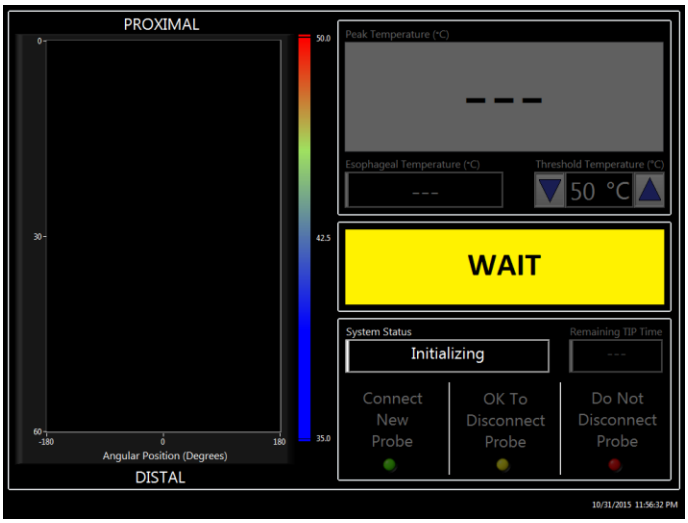
> **WARNING:** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth. Position of equipment should not make it difficult to disconnect the mains plug.

> **CAUTION:** The system components will not function with equipment from other manufacturers.

4.4. Obtain a new Probe. The Instructions for Use (IFU) is supplied with the Probe. Please read and follow the Probe instructions carefully.

5. SYSTEM OPERATION

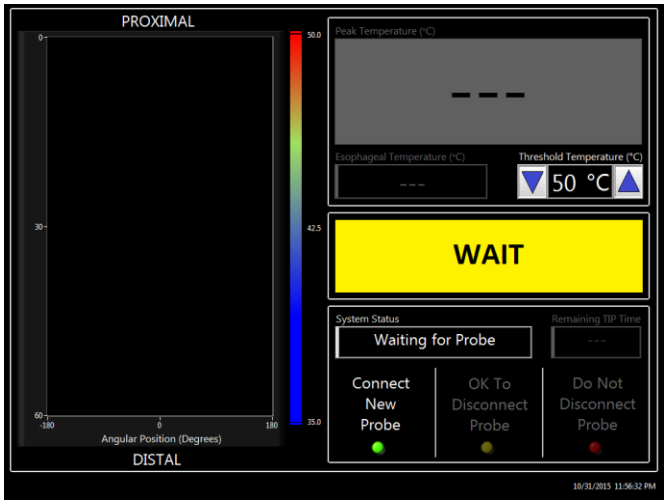
5.1. Turn on power to the PMU by pressing the power button located on the lower right-hand side of the unit. The monitor will display the user interface with the following message “WAIT”.



5.2. Turn on power to the PIU by pressing power button on the left side of the back panel. The green power LED will light. The PIU will begin initialization. It requires approximately 5-minutes to complete the initialization process.

5.3. Follow Instructions for Use provided with the Probe. Insert the probe into the patient. Care should be exercised to avoid damaging the probe. Do not kink or clamp Probe at any time.

5.4. The PMU will prompt you when the PIU is ready to accept a new Probe.



5.5. Insert the Probe Connector (1) into the PIU Probe Receptacle (2) and turn it 90 degrees. Plug the Thermocouple Connector (3) into the PIU TC Receptacle (4).

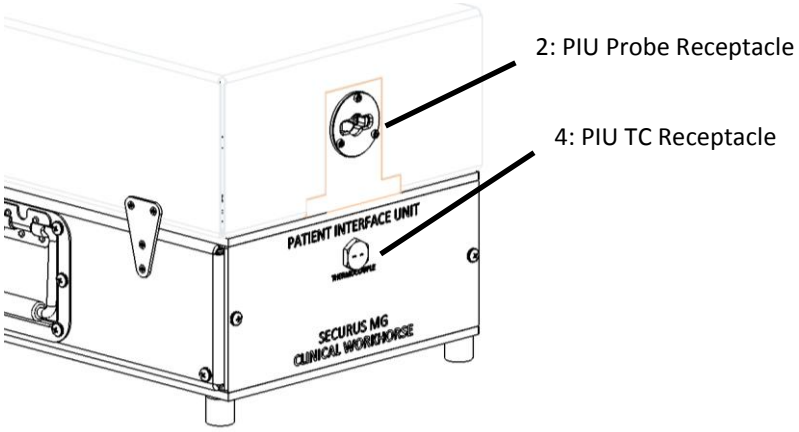


Figure 2: PIU Front

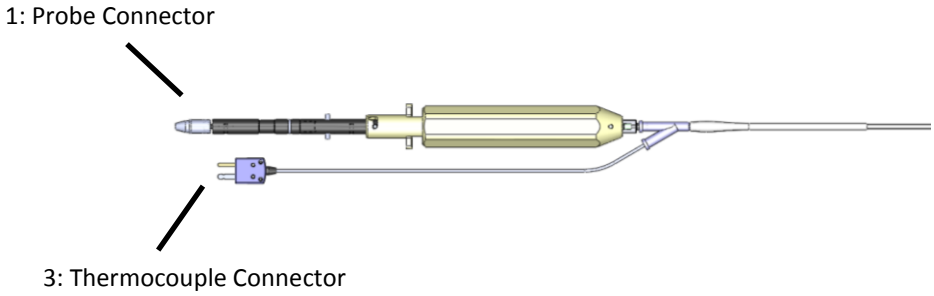


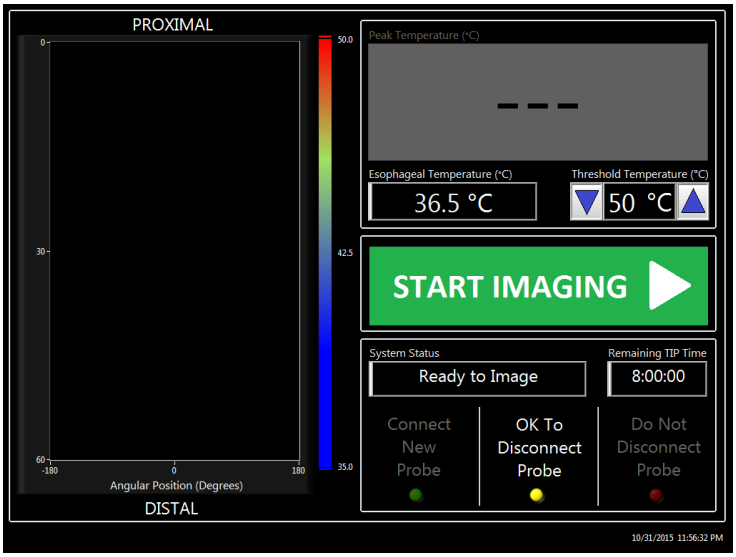
Figure 3: Probe

WARNING: Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging"

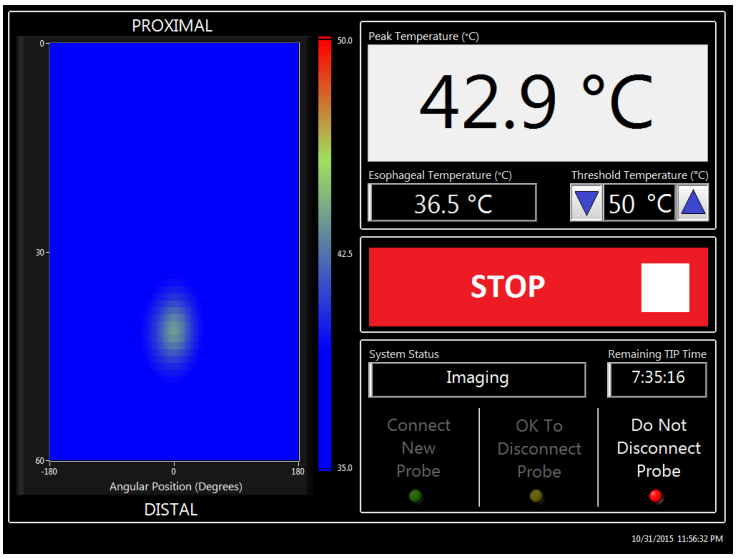
CAUTION: The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.

5.6. To initiate the thermal image and peak temperature Press “Start Imaging” on the user interface.

NOTE: If the peak temperature over the scan area is less than 35°C the Image will be blue and the Peak Temperature will state “< 35°C”.



5.7. Press “Stop” to cease thermal imaging.



5.7.1. System will automatically proceed through Probe docking routine. Press “Stop Docking” to interrupt this process.

5.7.2. When probe is docked, press “Start Imaging” to begin imaging again.

5.8. If the procedure is finished, ensure the status light reads “OK to Disconnect Probe”.

5.9. Remove the probe from the patient.

5.10. Remove the Probe from the PIU by first unplugging the thermocouple. Then turn the handle 90 degrees counter clockwise, remove, and discard.

5.11. Power down the PIU and the PMU. Turn off power to the PMU by pressing the power button located on the lower right-hand side of the unit.

6. ADDITIONAL INFORMATION

6.1. To set a notification temperature, press the (▲) or (▼) key under "Threshold Temperature (°C)" until you reach the desired value. If the peak temperature is equal to or above this number, an audible and visual notification will sound.

6.1.1. Temporarily disable notification by tapping the "Peak Temperature" indicator.

6.2. Pressing "Stop" or "Stop Docking" will immediately cease all PIU action. If on-screen prompts appear, follow them to continue.

6.3. The Probe is a single use device. Probes have a limited lifetime, which is measured and tracked in the software. Once a probe has reached its defined life it should be discarded. The user interface will inform the user when one hour of useful life remains, and again when a Probe change is necessary.

CAUTION: Do not attempt to operate the Probe beyond its intended service life.

6.4. Initialization is the default status for the system when it is waiting or performing internal status checks. In many cases the system will complete its internal processes and proceed out of Initialization status when ready.

6.5. User Interface States

Button Text	System Status Text	Meaning
Wait	Initializing	System is undergoing start-up procedure. Insert a Probe when instructed by the User Interface.
Wait	Waiting for Probe	System is ready for user to engage Probe
Start Imaging	Ready to Image	System is ready to begin Imaging Session.
Stop	Preparing to Image	System is executing Pre-Imaging routine.
Stop	Imaging	System is Imaging.
Stop Docking	Docking	System is docking probe.
ERROR	TIP Expired	Probe has reached the end of its expected lifespan.
ERROR	ERROR	System has detected an error. Follow additional warnings and instructions on the user interface.

6.6. Cleaning: The PIU and PMU may be cleaned by wiping with a disinfectant soap solution. Suitable disinfectants include bleach or hydrogen peroxide based soap solutions such as Clorox Healthcare Bleach Germicidal Cleaner or Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant. Disinfectants should be applied by wiping or spraying onto the surface and should be allowed to stand wet for a minimum of 1 minute. Wipe with a clean, damp cloth. Allow to air dry. Other suitable cleaners approved by your institution may be used on the PUI and PMU.

The PIU and PMU are not designed for immersion or machine washing techniques. Immersion will damage the electromechanical elements inside of the case.

6.7. Maintenance or Calibration: System cannot be maintained or calibrated by the user. System should be returned to Securus for service after one calendar year of use.

7. SPECIFICATIONS

System	
Esophageal Temperature Accuracy (Thermocouple)	± 0.3°C
Esophageal Temperature Range (Thermocouple)	25°C - 45°C
Transient Response Time of Thermocouple for a 2°C temperature change	2.5 seconds for both heating and cooling from a reference water bath to a water bath with a 2°C temperature differential
Thermal Sensitivity	0.1°C within temp range
Infrared Temperature Accuracy	± 2°C
Infrared Temperature Range	35°C - 60°C
Ethernet cable length	3 meters (10 feet)
Storage and transportation environmental	Temperature Range -15°C to 40°C (5°F to 104°F) Relative Humidity 10 to 93% Air Pressure 500 to 1060 hPa (15 to 31 in. Hg)
Operating environmental	Temperature Range 15°C to 35°C (59°F to 95°F) Relative Humidity 25 to 85% Air Pressure 700 to 1060 hPa (21 to 31 in. Hg)
Disposal	Dispose of in compliance with all applicable local, state, federal laws and regulations. PIU and PMU should be returned to Securus at end of life.
Patient Monitoring Unit	
Size	43cm x 40cm x 81cm (17" x 15.8" x 3.2")
Weight	8.2kg (18.1 lbs)
AC DC Power Supply	12/19.5 VDC 135W
Patient Interface Unit	
Size	49cm x 28cm x 28cm (19" x 11" x 11")
Weight	18kg (39 lbs)
AC DC Power Supply	24 VDC 250W
Probe	
Probe length (exclude handle)	118 cm
Probe length overall	153 cm
Standards	
Electrical Safety	Tested in compliance with IEC 60601-1:2005+A1:2012(E) (applicable sections)
	Tested in compliance with IEC 60601-1-2:2007
	Tested in compliance with applicable sections of ISO 80601-2-56
Accuracy Thermocouple	Fully complies with ISO 80601-2-56:2009 requirements (applicable sections)
Type and degree of protection, electrical shock	Type CF, Class I
Degree of protection against ingress of water (IEC 529)	IP2X

See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Thermal Imaging Probe Instructions for Use.

8. ELECTROMAGNETIC COMPATIBILITY (EMC) and ELECTROMAGNETIC SAFETY

8.1. The Securus IRTS has been tested and complies with international Standard IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

8.2. Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

8.3. Portable and mobile RF communications equipment can affect Medical electrical equipment performance and safe operation. Portable and mobile RF communications equipment should be separated from the Securus IRTS by at least the minimum separation distances listed in Table 4.

8.4. To maintain the Electromagnetic Compatibility of the Securus IRTS, only the following cables and accessories should be used:

Part Number	Description
A-10734	Temperature Probe
P-10800	L-COM TRD855SCR-10 Ethernet cable – 10.0 ft length
P-10259	Patient Interface Unit (PIU) Power Supply (Includes Power Cord)
P-10838	Patient Monitoring Unit (PMU) Power Supply (Includes Power Cord)

8.5. The following tables are to provide information on the electromagnetic compatibility of the Securus IRTS. If interference is observed or the system is not working correctly, the following information may be useful in correcting the problem. In particular Table 4 provides guidance on the distance that a portable transmitter, communications device, and cellular phones should be kept away from the Securus IRTS to avoid interference or adverse operation of the Securus system.

Table 1- Guidance and manufacturer's declaration – Electromagnetic Emissions

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions *CISPR 11*	*Group 1*	*The Securus IRTS uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
RF emissions CISPR 11	Class A	The Securus IRTS is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 - Guidance and manufacturer's declaration – Electromagnetic Immunity

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Securus IRTS requires continued operation during power mains interruptions, it is recommended that the Securus IRTS be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Table 3 - Guidance and manufacturer's declaration – Electromagnetic Immunity

The Securus IRTS is intended for use in the electromagnetic environment specified below. The customer or the user of the Securus IRTS should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Securus IRTS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Securus IRTS is used exceeds the applicable RF compliance level above, the Securus IRTS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Securus IRTS.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 - Recommended separation distances between portable and mobile RF communications equipment and the Securus IRTS

The Securus IRTS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Securus IRTS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Securus IRTS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. GENERAL INFORMATION

Manufactured and Distributed By:

Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
216-445-4683

SYMBOLS KEY

REF	Catalog number		Manufacturer
LOT	Lot Number	SN	Serial Number
QTY	Quantity	NON STERILE	Non-Sterile
	Use by - year and month		See accompanying documentation
	Consult instructions for use		Do not use if product is broken, damaged or open
	Do not reuse		Defibrillation – Proof Type CF Applied Part

DEVICE DESCRIPTION

INFRARED THERMOGRAPHIC SYSTEM (IRTS)

The InfraRed Thermographic System (IRTS) is designed to provide continuous esophageal temperature monitoring through the use of a standard thermocouple located at the proximal radiopaque marker. In addition, the system incorporates adjunctive infrared thermal imaging technology for quantifying differences in surface temperature changes in the esophagus.

The Probe contained in this package is a 9 French non-sterile, single-use esophageal catheter designed to be inserted into the esophagus either orally or nasally and positioned under fluoroscopic guidance. The Probe is intended to be used outside the sterile field by clinical professionals familiar in the placement of devices in the esophagus. The Probe is approximately 1.5 meters long with a smooth and flexible outer shaft and soft formable distal tip to aid in insertion. The Probe handle and thermocouple connector connect/plug-in to the Patient Interface Unit (PIU) at the time of the procedure. The Probe utilizes a standard thermocouple for providing continuous body temperature readings from the esophagus. The location of the thermocouple is easily visible under fluoroscopy. See Fig. 1.

The Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) displays the thermal image and temperature measurements (°C) from the Thermal Imaging Probe. The thermal image provides a continuous, real-time, non-contact thermal map of a 360° by 60mm long segment of the inner lumen of the esophagus. The thermal image is displayed in a two-dimensional color map. The peak temperature represents the maximum temperature over the scanned area.

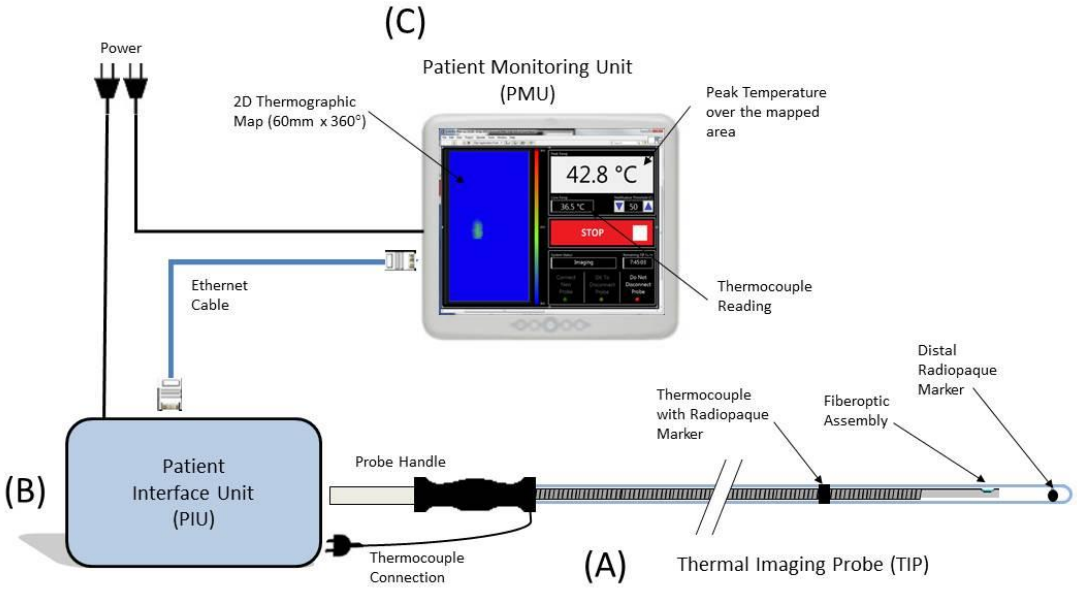


Figure 1: IRTS System Overview Diagram

IRTS SYSTEM COMPONENTS:

DIAGRAM LETTER	REF #	NAME	DESCRIPTION
A	A-10734	TIP	Temperature Probe
B	A-10667	Patient Interface Unit (PIU)	Main system control unit
C	A-10395	Patient Monitoring Unit (PMU)	Touchscreen monitor

See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).

INDICATIONS FOR USE

The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.

CONTRAINDICATIONS

The use of the IRTS is contraindicated for patients who have:

- Symptomatic Esophageal Stricture
- Esophageal Diverticulum
- Esophageal Tumor or Abscess
- Recent Esophageal or Gastric Surgery

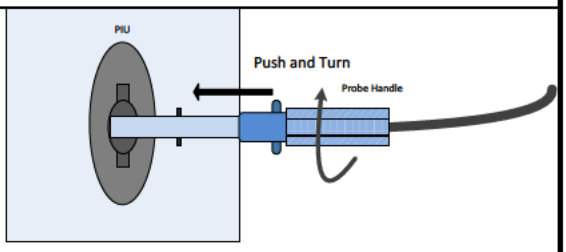
WARNINGS

- The Probe is single use only. Do not re-use. Cross-infection to patient may occur and the device may not function properly.
- Insert Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury.
- Do not attempt to reposition Probe while imaging. To reposition always hit “Stop” and wait for the button message “Start Imaging”.
- The Securus IRTS is to be installed and serviced exclusively by Securus technicians. Do not attempt to install, repair, service, or operate the Securus IRTS in any fashion deviating from what is specified in this manual.
- Use system only within the indicated operating environment temperature and humidity range. Use outside the specified operating environment may result in inaccurate esophageal temperature readings.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- All electrical equipment supporting the patient must be appropriately grounded and must comply with all current regulations and must be of CF type.
- The use of accessories and cables other than those listed above may result in increased emissions or decreased immunity of the Securus IRTS.

CAUTIONS

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- See the IRTS Manual provided with Patient Interface Unit and Monitor to operate the system.
- The thermal image and peak temperature are offered as an adjunct to the esophageal temperature measurement. Only the thermocouple temperature measurement meets the requirements for essential performance of clinical thermometers for body temperature measurement accuracy.
- Only physicians trained in esophageal insertion and catheterization procedures should use the IRTS.
- Do not use the IRTS for any purpose other than its intended use.
- Do not use the IRTS if it appears damaged. Damaged equipment may not provide accurate data and may pose a risk of electrical shock.
- Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device.
- Do not bend or kink the probe in a sharp angle or a small radius.
- The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
- Avoid touching the proximal tip of the Probe to avoid damaging the Probe.
- The Probe is provided fully assembled. Do not disassemble the Probe. Disassembly will damage the device.
- The system components will not function with equipment from other manufacturers.

Instructions for Use **Probe Placement**	
1.	The Probe is provided clean non-sterile. Remove Probe from package and visually inspect it for damage, kinks or broken components. Do not use the Probe if it appears damaged by shipping or handling. Always use gloves while handling the probe. **CAUTION:** Avoid touching the proximal tip of the Probe to avoid damaging the Probe. **CAUTION:** The TIP is provided fully assembled. Do not disassemble the TIP. Disassembly will damage the device **CAUTION:** The Probe may not be sterilized by any means. Sterilizing the Probe will cause damage.
2.	Apply a water-soluble lubricant to the tip of the Probe as desired to aid in insertion.
3.	Insert the Probe into the patient (nasal or orally) and position in the esophagus under fluoroscopic X-Ray. **WARNING:** Insert the Probe into esophagus under fluoroscopic x-ray. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction or injury. **CAUTION:** Do not bend or kink the probe in a sharp angle or a small radius.
4.	Verify the position of the Probe under fluoroscopic X-Ray. Reposition as required to achieve desired placement. **WARNING:** Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging".
5.	Insert the Probe handle into the PIU opening. Firmly push and turn (1/4 turn clockwise) to secure the Probe handle. A proper connection will be accompanied by an audible click as the connector seats in the PIU.
6.	Connect the thermocouple temperature connector (blue connector) to the PIU. Ensure that the connector is fully seated.
7.	Check the pathway of the Probe to ensure smooth and supported draping. Secure as needed with surgical tape to patient, bed or table to eliminate any movement that might dislodge or otherwise compromise the position of the Probe in the patient. Ensure that the probe is free of kinks or pinch points. **CAUTION:** Do not clamp the Probe. Clamping may cause damage that may result in a non-functional device. **CAUTION:** Do not bend the Probe in a sharp angle or a small radius. Excessive bending may damage the Probe. **WARNING:** Do not attempt to reposition Probe while imaging. To reposition always hit "Stop" and wait for the button message "Start Imaging".
8.	Single use device. Discard after use in accordance with institutional rules and regulations.



See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).

If you experience any problems with this product, you should immediately contact Securus at 216-445-4683

MATERIALS (patient contact components)

In Patient Contact	Material
Probe Shaft	Medical grade polyethylene tubing
Thermocouple Marker Band	Platinum Band

SYSTEM SPECIFICATIONS

Characteristic	Specification
Probe OD (patient contact)	9 Fr. (3 mm)
Probe length (exclude handle)	118 cm
Probe length overall	153 cm
Esophageal Temperature Accuracy (Thermocouple) Per ISO 80601-2-56:2009 requirements (applicable sections)	± 0.3°C
Esophageal Temperature Range (Thermocouple)	25°C - 45°C
Transient Response Time of Thermocouple for a 2°C temperature change	2.5 seconds for both heating and cooling from a reference water bath to a water bath with a 2°C temperature differential
Infrared Temperature Accuracy	± 2°C
Infrared Temperature Range	35°C - 60°C
Thermal Sensitivity	0.1°C within temp range
Operating Environment	Temperature Range 15°C to 35°C (59°F to 95°F) Relative Humidity 25 to 85%

STORAGE & USE

- Store in a cool, dry place and in a manner that protects the integrity of the device and packaging.
- The Probe is intended for single use only.
- Do not use if the package is damaged or opened.
- Do not use the device after the expiration date listed on the package label.
- Contact Customer Service if package has been opened or altered.
- Dispose of in compliance with all applicable local, state federal laws and regulations.

⚠ ***See accompanying documentation. To ensure proper use of the IRTS, it is important to carefully read these instructions and the IRTS Manual provided with Patient Interface Unit (PIU) and Patient Monitoring Unit (PMU).***

Manufactured and Distributed By:

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SYMBOLS KEY

REF	Catalog number		Manufacturer
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			Defibrillation – Proof Type CF Applied Part

ATTACHMENT E: SITED PUBLICATION

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Temperature Monitoring and Perioperative Thermoregulation

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Abstract

Most clinically available thermometers accurately report the temperature of whatever tissue is being measured. The difficulty is that no reliably core-temperature measuring sites are completely non-invasive and easy to use — especially in patients not having general anesthesia. Nonetheless, temperature can be reliably measured in most patients. Body temperature should be measured in patients having general anesthesia exceeding 30 minutes in duration, and in patients having major operations under neuraxial anesthesia.

Core body temperature is normally tightly regulated. All general anesthetics produce a profound dose-dependent reduction in the core temperature triggering cold defenses including arterio-venous shunt vasoconstriction and shivering. Anesthetic-induced impairment of normal thermoregulatory control, and the resulting core-to-peripheral redistribution of body heat, is the primary cause of hypothermia in most patients. Neuraxial anesthesia also impairs thermoregulatory control, although to a lesser extant than general anesthesia. Prolonged epidural analgesia is associated with hyperthermia whose cause remains unknown.

In previous articles, I've reviewed heat balance in surgical patients,[1] complications associated with perioperative thermal perturbations,[2] and the etiology and treatments of postoperative shivering.[3] Heier and Caldwell have reviewed the effects of hypothermia on the response to neuromuscular blocking drugs.[4] Furthermore, an entire book is devoted to the emerging field of therapeutic hypothermia.[5] In this article, I will belatedly review temperature monitoring and the effects of general and regional anesthesia on thermoregulatory control.

Surgery typically involves exposure to a cold environment, administration of unwarmed intravenous fluids, and evaporation from within surgical incisions. However, these factors alone would not usually cause hypothermia; instead, thermoregulatory defenses would normally maintain core temperature in the face of comparable environmental stress. That hypothermia is typical in unwarmed surgical patients reflects a failure of effective thermoregulatory defenses. Understanding the effects of anesthetics on normal thermoregulatory control is thus the key to perioperative thermal perturbations because ineffective thermoregulation — much more than cold exposure — underlies most temperature changes observed in surgical patients.

I will first briefly review temperature monitoring and normal thermoregulation, and then discuss the effects of general and neuraxial anesthesia on temperature control.

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Dr. Sessler has consulted for MGI Pharma (Bloomington, Minnesota), Cardinal Health (McGraw Park, Illinois), and Johnson and Johnson (Newark, New Jersey).

Summary statement: This article reviews perioperative temperature monitoring and the effects of anesthetic drugs on body temperature control.

Temperature Monitoring

Body temperature is not homogeneous: deep thoracic, abdominal, and central nervous system (i.e., core) temperatures usually range from 2 to 4°C cooler than the arms and legs — and much of the skin surface is cooler yet. Unlike core temperature, which is tightly regulated, skin temperature varies markedly as a function of environmental exposure; temperature of peripheral tissues (mostly the arms and legs) depends on current exposure, exposure history, core temperature, and thermoregulatory vasomotion. Core temperature, while by no means completely characterizing body heat content and distribution, is the best single indicator of thermal status in humans.

Core temperature monitoring (*e.g.*, tympanic membrane, pulmonary artery, distal esophagus, and nasopharynx) is used to monitor intraoperative hypothermia, prevent overheating, and facilitate detection of malignant hyperthermia. Because these sites are not necessarily available or convenient, a variety of “near-core” sites are also used clinically. These include the mouth, axilla, bladder, rectum, and skin surface. Each has distinct limitations but can be used clinically in appropriate circumstances.

What level of accuracy is clinically necessary has yet to be established. But a good rule-of-thumb, one that has been used in many studies, is that the combined inaccuracy of a site/thermometer combination should not exceed 0.5°C. One basis for this choice is that it is the smallest difference that has been shown to be associated with hypothermia-induced complications.[6]

Muscle or skin-surface temperatures may be used to evaluate vasomotion[7] and assure validity of peripheral neuromuscular monitoring.[4] Muscle temperatures are also used to determine peripheral compartment temperatures and regional distribution of body heat.[8-10] Both core and mean skin-surface temperature measurements are required to determine the thermoregulatory effects of different anesthetic drugs[11] and estimate mean-body temperature.[12]

Thermometers

Mercury-in-glass thermometers are slow and cumbersome, and spilt mercury is a biohazard; they have thus all but disappeared from clinical use — although they remain useful for laboratory calibration of other systems. The most common electronic thermometers are thermistors and thermocouples. Thermistors are temperature-sensitive semi-conductors, whereas thermocouples depend on the tiny current generated when dissimilar metals are joined. Both devices are sufficiently accurate for clinical use and inexpensive enough to be disposable. However, the signals from each are inherently non-linear and thus need to be linearized by calibrated compensating units.

Infrared sensors are another type of thermometer that has become popular in the last decade. They work by evaluating infrared energy that is emitted by all surfaces above absolute zero degrees. They can consequently be used without actually touching the surface in question (which is useful for measuring the temperature of molten lava or metals, for example). These thermometers are accurate and relatively inexpensive. Clinical models can measure temperature of the skin surface to within a tenth of a degree or so. When infrared signals are actually obtained from the tympanic membrane, the result is core temperature.[13,14] However, nearly all available systems are intentionally too large to even fit more than a few mm into the aural canal and do not “see” anywhere near the tympanic membrane. As normally used, that is directed into the aural canal[15] or near the temporal artery,[16] infrared systems are insufficiently accurate for clinical use (fig. 1). In light of their poor performance, it seems unfortunate that they have become so popular.

An interesting method of measuring core temperature from the surface of the skin is to use a system originally proposed by Fox[17,18] and refined by Togawa.[19] The technique is to combine a heater with a thermal flux transducer (which is, effectively, two thermometers separated by a known thermal insulator). The heater is then servo-controlled until flux is zero. At this point, heat and skin temperature are, by definition, equal since there would otherwise be a flow of heat. However, the same logic suggests that there is no flow of heat from skin to deeper tissues; otherwise, heat would accumulate, which would violate the Second Law of Thermodynamics. This logic is not quite accurate since it ignores blood-borne lateral convection of heat. But in practice, these thermometers accurately determine the temperature of tissues to about a centimeter below the skin surface. In many parts of the body, notably the chest and forehead, a centimeter is sufficient to approximate core temperature (fig. 2).[20] Unfortunately, these otherwise excellent monitors are not currently available in Europe or the United States.

When Temperature Monitoring Is Required

Core temperature monitoring is appropriate during most general anesthetics both to facilitate detection of malignant hyperthermia and to quantify hyperthermia and hypothermia. Malignant hyperthermia is best detected by tachycardia and an increase in end-tidal PCO_2 out of proportion to minute ventilation.[21] Although increasing core temperature is not the first sign of acute malignant hyperthermia, it certainly helps confirm the diagnosis. More common than malignant hyperthermia is intraoperative hyperthermia having other etiologies including excessive warming, infectious fever, blood in the fourth cerebral ventricle, and mismatched blood transfusions. Because hyperthermia has so many serious etiologies, any perioperative hyperthermia requires diagnostic attention.

By far the most common perioperative thermal disturbance is inadvertent hypothermia. Prospective, randomized trials have shown that even mild hypothermia causes numerous adverse outcomes in a variety of patient populations. Hypothermia-induced complications include morbid myocardial outcomes[22] secondary to sympathetic nervous system activation,[23] surgical wound infection,[24,25] coagulopathy[6,26-33] increased allogeneic transfusions,[6,24,26,27,31,33-37] negative nitrogen balance,[38] delayed wound healing,[24] delayed post-anesthetic recovery,[39] prolonged hospitalization,[24] shivering,[40] and patient discomfort.[41]

The major cause of hypothermia in most patients given general anesthesia is an internal core-to-peripheral redistribution of body heat that usually reduces core temperature by 0.5 to 1.5° C in the first 30 minutes following induction of anesthesia. Hypothermia results from internal redistribution of heat and a variety of other factors whose importance in individual patients is hard to predict.[9] Core temperature perturbations during the first 30 minutes of anesthesia thus are difficult to interpret and measurements not usually required. Body temperature should, however, be monitored in most patients undergoing general anesthesia exceeding 30 minutes in duration and in all patients whose surgery lasts longer than one hour. Measuring body temperature (and maintaining normothermia) is now essentially the standard-of-care during prolonged general anesthesia, especially for large operations where the risk of hypothermia is substantial.

Hypothermia, resulting largely from core-to-peripheral redistribution of body heat,[8] is as common during epidural and spinal anesthesia as it is during general anesthesia, and can be nearly as severe.[42] Because neuraxial anesthesia impairs behavioral thermoregulatory responses (i.e., patient sensation of cold),[43] patients and physicians are both frequently unaware that hypothermia has developed (fig. 3).[42] Core temperature should therefore be measured during regional anesthesia in patients likely to become hypothermic, including those undergoing body cavity surgery — although temperature monitoring during neuraxial anesthesia remains relatively uncommon.[44,45]

Monitoring sites

The core thermal compartment is composed of highly perfused tissues whose temperature is uniform and high compared with the rest of the body. Temperature in this compartment can be evaluated in the pulmonary artery, distal esophagus, tympanic membrane, or nasopharynx.[46,47] Even during rapid thermal perturbations (*e.g.*, cardiopulmonary bypass), these temperature-monitoring sites remain reliable — although there may be transient real differences among them.

Temperature probes incorporated into esophageal stethoscopes must be positioned at the point of maximal heart sounds, or even more distally, to provide accurate readings.[48] Modern tympanic thermocouples are soft and pliable. There is thus little if any risk of perforating the membrane, although it is possible to push a bolus of wax onto the tympanic membrane. Inserting tympanic probes is somewhat more difficult than it sounds, especially in conscious subjects, because the aural canal is several cm long and is not straight. The difficulty is that subjects and people inserting the probes often mistake the bend in the canal for the tympanic membrane and thus do not position the probes on the membrane itself. Once properly positioned, it is helpful to occlude the aural canal with wool to prevent air currents from cooling the thermocouple. Nasopharyngeal probes should be inserted at least a few cm past the nares to obtain core temperature; nasopharyngeal temperature are probably only accurate in patients who are not breathing through their nostrils.

Core temperature can be estimated with reasonable accuracy using oral, axillary, and bladder temperatures except during extreme thermal perturbations.[46,47] Each of these sites is subject to artifact so clinicians should use reasonable judgment in selecting a monitoring site (and type of thermometer) for a given patient. For example, oral temperatures can be inaccurate in patients who breathe through their mouths or have recently ingested hot or cold liquids. Axillary temperatures are reasonably accurate,[49] but work best when the probe is positioned over the axillary artery and the arm is kept at the patient's side. Differences in technique may explain reported differences in accuracy.[50]

Skin-surface temperatures are considerably lower than core temperature[51]; forehead skin temperature, for example, is typically 2°C cooler than core. Perhaps surprisingly, even the intense vasodilation associated with sweating and the intense vasoconstriction associated with shivering only slightly alter the core-to-forehead temperature gradient (fig. 4).[52] Skin temperature is determined by the balance of heat provided by subcutaneous tissues and heat lost to the environment. Dissipation of heat from the skin surface, mostly by radiation and convection, depends on ambient temperature. While each type of heat loss is controlled by different equations, most of which are highly non-linear, cutaneous heat loss is approximately linear over small ranges of ambient temperature. The 1−2°C ambient temperature differences usually observed during surgery thus have little effect on the core-to-forehead temperature gradient (fig. 5).[52] Forehead skin temperature is thus a surprisingly accurate measure of core temperature so long as a +2°C compensation is included.

A special case of skin-temperature monitoring is temporal artery thermometers. These are infrared skin-surface thermometers that record skin temperature at approximately 10 Hz and detect the highest temperature as the device is scanned across the forehead, including the region of the temporal artery. The theory is that the blood in the temporal artery is near core temperature and, therefore, that supervening skin temperature will also approximate core temperature. While the theory is attractive, the devices are much too inaccurate for clinical use.[16,53]

A distinct limitation of skin temperatures is that they fail to reliably confirm the clinical signs of malignant hyperthermia (tachycardia and hypercarbia) in swine (fig. 6)[54] and have not been

evaluated for this purpose in humans. Rectal temperature also normally correlates well with core temperature,[46,47] but fails to increase appropriately during malignant hyperthermia crises[54] and under other documented situations including heat stroke.[55,56] Consequently, rectal and skin-surface temperatures must be used with considerable caution.

The four core temperature monitoring sites (*e.g.*, tympanic membrane, nasopharynx, pulmonary artery, and esophagus) remain useful even during cardiopulmonary bypass. In contrast, rectal temperatures lag behind those measured in core sites. Consequently, rectal temperature is considered an "intermediate" temperature in deliberately cooled patients. During cardiac surgery, bladder temperature is equal to rectal temperature (and therefore intermediate) when urine flow is low, but equal to pulmonary artery temperature (and thus core) when flow is high.[57] Because bladder temperature is strongly influenced by urine flow, it may be difficult to interpret in these patients. The adequacy of rewarming is best evaluated by considering both "core" and "intermediate" temperatures.

Mean-skin Temperature—Mean-skin temperature is the area-weighted average temperature of the skin surface. Mean-skin temperature, while less important than core temperature, is nonetheless important for at least three reasons: 1) cutaneous heat loss is a function of mean-skin and ambient temperatures; 2) central thermoregulatory control is determined by a combination of core and mean-skin temperatures; and 3) the combination of core and mean-skin temperatures can be used to estimate mean-body temperature and, therefore, body heat content.

Unsurprisingly, the accuracy of mean-skin temperature measurements increases with the number of measurement sites. Thus, 15 or more sites are usually used in thermoregulatory studies. For example, the following sites and regional weightings have been used in a hundred or more studies: head—6%, upper arms—9%, forearms—6%, hands—2.5%, fingers—2%, back— 19%, chest—9.5%, abdomen—9.5%, medial thigh—6%, lateral thigh—6%, posterior thigh—7%, anterior calves—7.5%, posterior calves—4%, feet—4%, and toes—2%.[58] This large number of measurement sites results in accurate measurements even in the context of regional thermal manipulations (active heating or cooling) and when different amounts of insulation are used in various areas.

When thermal management (insulation or active heating or cooling) is uniformly distributed over the entire body, simpler formulae can be used without great loss of accuracy. A formula with only four sites was developed by Ramanathan in 1964 and remains in common use [59]: Mean-skin temperature = 0.3(chest + upper arm) + 0.2(thigh + calf)].

Mean-body Temperature—Changes in mean-body temperature over time can be determined by integrating the difference between metabolic heat production (oxygen consumption) and cutaneous heat loss (measured with thermal flux transducers). Mean-body temperature can also be approximated as the mass-weighted sum of regional temperature distributions, which can be determined by integration of radial temperature distributions.[60] However, the technique is invasive and the computations tedious. Its use is consequently restricted to controlled studies in laboratories possessing the necessary equipment.[61]

In 1935 Burton[62] cleverly proposed that mean-body temperature (MBT) could be calculated from a formula: $MBT = a \cdot T_{Core} + (1–a) \cdot T_{Skin}$. The general form of the equation was based on the logic that core tissues are relatively homogeneous, whereas tissue temperature in the peripheral decreases parabolically from core temperature to skin temperature. The value of a, the coefficient describing the contribution of core temperature to mean-body temperature, was then estimated by simultaneously measuring the change in body heat content (in a calorimeter),

core temperature, and mean-skin temperature. The resulting value of the coefficient alpha was 0.64, thus giving the formula: $MBT = 0.64 \cdot T_{Core} + 0.36 \cdot T_{Skin.}$

A similar approach has been used by others, including Hardy and DuBois,[63] who proposed a coefficient, a, of 0.7 for a neutral environment; Stolwijk and Hardy,[64] who proposed a coefficient of 0.7 for a hot environment; and Snellen,[65] who found the coefficient to be ≈0.8 during muscular work in a hot environment. Subsequently, Colin et al.[66] showed in an elegant study that Burton's coefficient was correct for a neutral environment, but that the coefficient increased to 0.79 in an extremely warm environment.

Given all the assumptions about distribution of heat within the body that are necessary to estimate mean-body temperature from core and skin temperatures, it would be surprising if a simple formula based on core and mean-skin temperatures were sufficient. But remarkably, it is. Even during cardiopulmonary bypass, the formula of Colin et al.[66] estimates mean-body temperature reasonably well (fig. 7).

Normal Thermoregulation

Normal Body Temperature Regulation

Body temperature is normally tightly regulated, more so even than blood pressure or heart rate. The control system is complex and involves parallel positive- and negative-feedback systems that are so widely distributed that nearly every part of the autonomic nervous system participates to some extent.

As early as 1912, physiologists recognized that the hypothalamus is the dominant thermoregulatory site in mammals because control was markedly compromised by injury or destruction of the hypothalamus. (The spinal cord serves this function in birds.) Interestingly, it took nearly another half-century before the importance of thermal input from the skin was appreciated. It is now known that thermal signals from a variety of tissues and structures contribute thermal signals to the hypothalamus, and that there is considerable pre-processing of thermal information on the way from peripheral to central tissues.[67] Thus, thermoregulation is based on multiple, redundant signals from nearly every type of tissue. The processing of thermoregulatory information occurs in three phases: *afferent thermal sensing*, *central regulation*, and *efferent responses*.

Afferent Input—While all physiologic processes are, to some extent, temperature dependent, specific cells are markedly activated or inhibited by thermal perturbations. The assumption is that these cells are temperature sensors, and they are referred to as warm- or cold-sensing cells. Cold receptors, for example, increase their activity as tissue cools, whereas the reverse is true for heat-sensors.

Because of its accessibility, cutaneous thermoreception is relatively well understood. (See monograph by Hensel for details).[68] Human skin is phenomenally sensitive to temperature: An increase in forehead temperature of as little as 0.003°C can be detected! Apparent skin temperature and, more importantly, the ability to influence thermoregulatory responses is not uniform across the skin surface. The face is approximately five times as sensitive as other areas. Furthermore, sensitivity at differing sites depends somewhat on whether the skin is being warmed or cooled. The skin is far more sensitive to rapid thermal perturbations than to those occurring slowly. Similarly, the static skin temperature contributes less to thermoregulatory responses than even small changes.

Cold signals from the skin travel primarily *via* A∂ nerve fibers whereas warm signals are transduced by unmyelinated C fibers.[69] Until recently, little was know about how A∂ and C

fibers actually detect cutaneous temperature. However, it now appears that Transient Receptor Potential (TRP) vanilloid (V) and menthol (M) receptors may be the fundamental temperature sensing elements both in skin and the dorsal root ganglia. These receptors, which have only been well characterized in recent years, are a family notable for having unusually high temperature sensitivity. Most change their activity by more than a factor-of-ten over a 10°C range (Q10 > 10). TRPV1−4 receptors are heat activated, whereas TRPM8 and TRPA1 are activated by cold.[70,71]

Most ascending thermal information traverses the spino-thalamic tracts in the anterior spinal cord, but no single spinal tract is critical for conveying thermal information. Recently, for example, an afferent somatosensory pathway via lateral parabrachial neurons has been shown to transmit signals directly to the preoptic thermoregulatory control center.[72] Consequently, the entire anterior cord must be destroyed to ablate thermoregulatory responses. The hypothalamus, other parts of the brain, the spinal cord, deep abdominal and thoracic tissues, and the skin surface each contribute roughly 20 percent of the total thermal input to the central regulatory system.[73,74] Hence although the hypothalamus is the dominant and most precise thermoregulatory controller, its temperature *per se* is not especially important.

Central Control—The simplest thermoregulatory model is the "set-point" system in which all thermoregulatory responses are simultaneously turned on or off in response to hypothalamic temperature. This model is known to be an inadequate representation of the thermoregulatory system because: 1) responses are determined by thermal input from nearly every portion of the body; 2) responses do not occur simultaneously or at similar temperatures; 3) the model does not incorporate a "null zone" in which no thermoregulatory responses occur; and 4) this model cannot explain thermal adaptation and a host of other observed phenomena.

The General Thermoregulatory Model—Consequently, I will review here a model which is somewhat more complicated, but considerably more useful. As with all models, this should be considered a framework from which to analyze thermoregulatory responses, not an actual mechanism by which the body produces those responses. In this model, thermal input from tissues throughout the body are integrated at a variety of centers (including the spinal cord and brain stem), but most importantly the hypothalamus. Individual responses are coordinated on the basis of weighted averages of the diverse inputs.

Temperature is regulated by central structures that compare integrated thermal inputs from the skin surface, neuraxis, and deep tissues with *thresholds* (triggering core temperatures) for each thermoregulatory response. Control is distributed in the sense that thermal input is integrated at various levels within the neuraxis, but the dominant controller in mammals is the hypothalamus, with autonomic control being centered in the anterior hypothalamus and behavioral control being centered in the posterior hypothalamus. This hierarchical arrangement presumably developed when the evolving thermoregulatory control system co-opted previously existing mechanisms.[67] For example, muscles used for shivering were probably developed for posture and locomotion; similarly, thermoregulatory vasomotion is probably an offshoot of systems originally developed for hemodynamic control. It is likely that some thermoregulatory responses can be mounted by the spinal cord alone.[74] For example, animals and patients with high spinal-cord transections regulate temperature much worse than normal — but are not poikilothermic.

The slope of response intensity versus core temperature defines the *gain* of a thermoregulatory response. The *maximum intensity* of the response is defined as when response intensity no longer increases with further deviation in core temperature. Figure 8, for example, shows the normal sweating response as a function of distal esophageal core temperature during surface warming. There is only background insensible water loss from the skin without anesthesia until

the threshold is reached at a core temperature of 36.5°C. The sweating rate then increases quickly as core temperature increases an additional 0.5°C (gain), but remains essentially constant with further hypothermia (maximum response intensity). Although the threshold increases as a function of isoflurane concentration, the gain and maximum intensity remain similar during anesthesia.[75]

Control of autonomic responses is approximately 80 percent determined by thermal input from core structures[76,77] and remains similar during anesthesia (fig. 9). In contrast, fully half of the input controlling behavioral responses is derived from the skin surface.[78]

Humans apparently measure temperature to great precision, but nonetheless tolerate an interthreshold range over which autonomic responses are not activated. This range of temperatures thus defines normal core temperature under given circumstances (*i.e.*, time of day, menstrual phase). Normal core temperatures in humans typically range from 36.5°C to 37.5°C; values <36°C or >38°C usually indicate loss of control or a thermal environment so extreme that it overcomes thermoregulatory defenses.

Thermoregulatory modeling is thus complicated by interactions with other regulatory responses (*i.e.*, vascular volume control) and time-dependent effects. An area of continuing interest to physiologists is how humans handle environmental stress that would normally provoke opposing compensations. Heat stroke, for example, often results from dehydration in an excessively hot environment. Dehydration would normally activate water-retention mechanisms whereas hyperthermia normally provokes sweating. Heat stroke, in fact, usually develops because the body cannot simultaneously compensate effectively for both perturbations.

Most thermoregulatory models (including the one described above) do not adequately account for the rate at which central and peripheral temperatures change. Consequently, they should be applied to vigorously dynamic situations with caution. Similarly, at least under some circumstances thermoregulatory responses are not determined only by instantaneous thermal inputs, but instead reflect the recent history of thermal perturbations. The extent to which time- and temperature-dependent factors contribute to human thermoregulatory responses remains unclear.

Thresholds—How the body determines absolute threshold temperatures is incompletely understood, but appears to involve inhibitory postsynaptic potentials in hypothalamic neurons[79] that are modulated by norepinephrine, dopamine, 5-hydroxytryptamine, acetylcholine, prostaglandin E_1, and neuropeptides. The thresholds vary daily by 0.5−1°C in both sexes (circadian rhythm)[80] and by ≈ 0.5°C with menstrual cycles in women[81]. Exercise, nutrition, infection, hypo- and hyperthyroidism, drugs (including alcohol, sedatives, and nicotine), and cold- and warm-adaptation all alter threshold temperatures. But each of these effects is small compared to the profound impairment induced by general anesthesia.

The *interthreshold range* (core temperatures *not* triggering autonomic thermoregulatory responses) is bounded by the sweating threshold at its upper end and by the vasoconstriction threshold at the lower end. Within this range, temperatures are presumably sensed accurately but do not trigger regulatory responses. Teleologically, sacrificing a small degree of temperature regulation is prudent because energy and nutrients are not wasted aggressively combating small environmental changes. Some animals such as camels and desert rats use this strategy extensively, allowing body temperature to change up to 10 C during a 24-hour period.

The interthreshold range is usually only 0.2−0.4°C in humans,[82] and that range defines normal body temperature. For unclear reasons, control is only half as tight at the circadian nadir near

3:00 AM (fig. 10).[80] Because energy cost and nutrients are conserved without excessive autonomic control or evaporative water loss within the interthreshold range, some animals such as camels and desert rats maintain a wide interthreshold range, allowing core temperature changes up to 10°C each day. However, this is very much the exception and most mammals tightly control core temperature.

Both sweating and vasoconstriction thresholds are 0.3−0.5°C higher in women than men, even during the follicular phase of the menstrual cycle (*i.e.*, first ten days).[75] Differences are even greater during the luteal phase.[83] Central thermoregulatory control is apparently intact even in slightly pre-mature infants,[84] but is presumably immature in less-developed infants such as those weighing less than a kilogram. The shivering threshold is well maintained in some elderly subjects well into their 9th decade, whereas others that age regulate poorly; regulation though appears consistently normal in people aged less than 80 years.[85]

Efferent Responses—Some thermoregulatory responses are rarely, if ever, activated except by thermal perturbations. Such responses include sweating, peripheral cutaneous vasoconstriction, and brown fat metabolism. In other cases, the thermoregulatory system has co-opted effector mechanisms developed for other purposes including shivering (postural and locomotive muscular activity) and vasomotion (blood pressure and osmotic control). Adaptation of preexisting systems for thermoregulatory control is consistent with the hierarchical thermoregulatory model proposed by Satinoff,[67] and may explain why thermoregulatory control is so widely disbursed.

Thermal perturbations, (defined by body temperature difference from a specific threshold) triggers effector responses that actually mediate appropriate increases in environmental heat loss or increases in metabolic heat production. Each response has its own threshold and gain. The control system is thus able to activate responses in an efficient order (i.e., vasoconstriction before shivering which is metabolically costly) and only to the extent actually necessary to maintain core temperature.

Behavioral Regulation—Behavioral regulation (intentional manipulation of heat exchange with the environment) is the most powerful thermoregulatory effector. It is such modification that allows humans to live in the warmest and coldest climates on earth. Animals also use behavioral modification to alter heat balance with the environment. Behavioral regulation is most dramatic in reptiles and amphibians. These animals, often referred to as “cold-blooded,” actually regulate their temperatures remarkably well and even develop behavioral “fever.”[86] Given access to a reasonable range of environmental temperatures, they will position themselves to maintain a central temperature within a few degrees of “normal.” Interestingly, the temperatures maintained as optimal by most reptiles is similar to that in mammals, near 37 C. Similarly, fish provided with a thermal gradient will position themselves to maintain a nearly constant central temperature.[87] One investigator was even able to train a goldfish to maintain his water (and therefore body) temperature nearly constant by pushing a button![88] Even bacteria, given an opportunity, will position themselves to maintain optimal temperature.

Aggressive behavioral modification of environmental heat loss is not necessary in mammals exposed to reasonable environments. This has the evolutionary advantage of maintaining a nearly constant central temperature (presumably necessary for optimal enzyme function) without requiring behavioral modifications that might compromise survival. Nonetheless, when autonomic thermoregulatory responses are insufficient for maintaining central temperature, behavioral responses become critical for survival. Behavioral adaptations take many forms, but most commonly involve simple maneuvers such as moving from direct sun into shade, dressing more warmly, or altering ambient temperature using a heating/air conditioning system. Behavioral responses require a conscious perception of body temperature.

Intriguingly, humans appear to poorly sense changes in central temperature; in contrast, minute changes in skin-surface temperature are easily perceived. Thus, behavioral thermoregulation is about half mediated by skin temperature[78] whereas mean-skin temperature contributes only 10−20% to the control of autonomic thermoregulatory defenses.[76,89]

Vasomotion—Most metabolic heat is lost from the skin surface and cutaneous and vasoconstriction, the most consistently used autonomic effector mechanism, reduces this loss. Total digital skin blood flow is divided into nutritional (mostly capillary) and thermoregulatory (mostly arterio-venous shunt) components.[90] Shunts are typically 100 μm in diameter, which means that one shunt can convey 10,000-fold as much blood as a comparable length of capillary 10-μm in diameter. Arterio-venous shunt flow tends to be “on” or “off” which is simply a way of saying that the gain of this response is high. Roughly 10 percent of cardiac output traverses arterio-venous shunts; consequently, shunt vasoconstriction increases mean arterial pressure ≈15 mmHg.[91]

Arterio-venous shunts are located only in acral regions (fingers, toes, nose, *etc*.). These specialized thermoregulatory vessels are under alpha adrenergic control and are constricted by norepinephrine released from sympathetic nerves. Circulating factors appear to have little direct influence on arterio-venus shunts, although hormones such as angiotensin are known to facilitate the response to a given sympathetic stimulus. Most blood vessels constrict in response to local hypothermia, but arterio-venus shunts are relatively resistant regional temperature perturbations and appear to be almost exclusively controlled by central thermoregulatory status. In a thermoneutral environment (*e.g.*, body temperature within the interthreshold range) or in a denervated extremity, arterio-venus shunts are fully dilated. However, at typical ambient temperatures tonic sympathetic stimulation maintains minimal shunt flow.

Non-shivering Thermogenesis—Non-shivering thermogenesis is defined as an increase in metabolic heat production not associated with muscular activity. This increase occurs largely in specialized fat called brown adipose tissue located largely in the intrascapular and perirenal areas. Brown fat has a dark hue because it is loaded with mitochondria. When stimulated, this tissue has by far the highest metabolic rate of any organ (up to 0.5 W/g). Ordinarily, mitochondrial metabolism produces a proton which is secreted outside the sarcoplasmic reticulum. The proton gradient across this membrane subsequently activates the sodium-potassium ATPase, producing ATP from ADP. When stimulated by norepinephrine released from sympathetic nerves, mitochondrial respiration in brown ATPase tissue proceeds normally. However, production of ATP is prevented by an “uncoupling protein” which allow protons to reenter the sarcoplasmic reticulum without driving the sodium-potassium ATPase.[92]

Nonshivering thermogenesis is the primary defense against cold in small mammalian species such as mice and rats, and can easily double or triple metabolic heat production (measured as whole-body oxygen consumption) without producing mechanical work. Nonshivering thermogenesis also doubles heat production in infants.[93] The intensity of nonshivering thermogenesis is a linear function of the difference between mean body temperature and its threshold.

But despite its importance in small animals and human infants, non-shivering thermogenesis is relatively unimportant or non existent in species having a relatively large body size (*i.e.*, greater than fifty kg). In adult humans, non-shivering thermogenesis is poorly developed[94] and contributes little to thermal balance in adult humans.

Shivering—Sustained shivering augments metabolic heat production 50 to 100 percent in adults. This increase is small compared with that produced by exercise (which can, at least

briefly, increase metabolism five-fold) and is, thus, surprisingly ineffective. Shivering is manifested as an irregular tremor which on electromyographic analysis consists of randomly overlapping myofibril depolarization spikes. Superimposed on this rapid and apparently disorganized local activity, is a 4 − 10 cycles/minute waxing-and-waning activity. Notably, this slow amplitude modulation is synchronous and occurs simultaneously in all muscles throughout the body.[95] Shivering does not occur in newborn infants and probably is not fully effective until children are several years old. Because the shivering threshold is a full degree less than the vasoconstriction threshold,[82] shivering appears to be a "last resort" response to extreme cold.

Sweating—Sweating is mediated by post-ganglionic, cholinergic nerves.[96] It thus is an active process that is prevented by nerve block or atropine administration.[97] Even untrained individuals can sweat up to one liter/hour, and athletes can sweat at twice that rate. Sweating is the only mechanism by which the body can dissipate heat in an environment exceeding core temperature. Fortunately, the process is remarkably effective: each gram of evaporated sweat dissipates 0.58 kcal. In a dry, convective environment, individuals can thus easily dissipate many times their basal metabolic rate which is very roughly a $kcal \cdot kg^{-1} \cdot h^{-1}$. Of course sweat which drips off the skin without evaporating contributes nothing to heat balance, but does promote dehydration.

During exercise, muscle blood flow increases enormously and blood pressure can only be maintained by vigorous vasoconstriction. Furthermore, exercise produces considerable heat which in most environments must be dissipated by increased capillary blood flow and sweating (a liter/hour or more). Both these thermoregulatory compensations compete with the needs of muscle for increased blood flow. Consequently, it is unsurprising that maximum capillary blood flow and sweating rate are impaired by insufficient vascular volume and cardiovascular compromise. In light of the huge cardiovascular stresses imposed by exercise and the thermoregulatory compensation for the attendant increase in metabolic heat production, it is remarkable that humans can perform vigorously in a warm environment and maintain a reasonable blood pressure.

In contrast to shunt flow, capillary blood flow is minimal both at typical ambient temperatures and at thermoneutral temperatures. During heat stress, active dilation of pre-capillary arterials increases capillary blood flow enormously. This dilation certainly involves withdrawal of tonic sympathetic stimulation but also likely involves release of the yet-to-be identified factor from sweat glands; the mediator may be nitric oxide or neuropeptide Y.[98] Because active vasodilation requires intact sweat gland function, it also is largely inhibited by nerve block. During extreme heat stress, blood flow through the top millimeter of skin can reach 7.5 liters/minute — equaling the entire resting cardiac output.[99] The threshold for active vasodilation usually is similar to the sweating threshold, but maximum cutaneous vasodilation usually is delayed until sweating intensity is at its maximum.

Response Activation Strategy—All potential thermoregulatory responses are ideally available and used in a specific order depending on their respective thresholds and response gains. However, one or more effectors may be disabled by circumstances. For example, social convention may restrict voluntary movement or the ability to seek a warmer or cooler environment. Or a muscle relaxant may prevent shivering or a vasodilator may restrict vasoconstriction. In such circumstances, remaining effectors compensate to the limit of their abilities. The result is that core temperature is usually nonetheless maintained, although the range of tolerated environments decreases.

Hyperthermia

Hyperthermia is a generic term simply indicating a core body temperature exceeding normal values. In contrast, fever is a regulated increase in the core temperature targeted by the thermoregulatory system. Hyperthermia can result from a variety of causes and, unlike perioperative hypothermia, usually requires diagnosis and often intervention.

Passive Hyperthermia and Excessive Heat Production—Passive intraoperative hyperthermia results from excessive patient heating and is most common in infants and children. Hyperthermia was common in the tropics, before air conditioning became routine, and was aggravated by the frequent use of atropine.[100] Passive hyperthermia, by definition, does not result from thermoregulatory intervention. Consequently, it can easily be treated by discontinuing active warming and removing excessive insulation.

The increase in body temperature during malignant hyperthermia results from an enormous increase in metabolic heat produced by both internal organs and skeletal muscles. Central thermoregulation presumably remains intact during acute crises, but efferent heat loss mechanisms may be compromised by intense peripheral vasoconstriction resulting from circulating catecholamine concentrations 20 times normal.[101]

Fever—Body temperature is minimally influenced by circulating factors such as thyroid hormones; instead it is normally maintained by neuronal systems. In contrast, fever is mediated by endogenous pyrogens which increase the thermoregulatory target temperature ("setpoint"). Endogenous pyrogens include interleukin-1, tumor necrosis factor, interferon alpha, endothelin-1, and macrophage inflammatory protein-1.[102,103] There is increasing evidence that vagal afferents mediate between systemic pyrogens and the hypothalamus[104], although several systems probably contribute.[105] Most endogenous pyrogens have peripheral actions (e.g., immune system activation) in addition to their central generating capabilities. The relative contributions of fever *per se* and the systemic action of endogenous pyrogens remains unclear; however, it appears that fever itself is an important immune defense.[106]

Fever is relatively rare during general anesthesia, considering how many patients presumably experience febrile stimuli, including surgical tissue injury. The reason intraoperative fever is rare is that volatile anesthetics per se inhibit expression of fever,[107] as do opioids.[108,109] Infection is by far the most common cause of fever. Such fevers may reflect pre-existing infection or result, for example, from urological manipulations. However, perioperative fever also occurs in response to mis-matched blood transfusions, blood in the fourth cerebral ventricle, drug toxicity, and allergic reactions.[110,111] Some degree of fever is also typical after surgery, and presumably results from the inflammatory response to surgery.[112] There is no evidence to support the common attribution of postoperative fever to atelectasis. Instead, the causes of fever are sufficiently diverse — and potentially serious — that physicians caring for febrile patients should consider potential etiologies.

Treatment of hyperthermia depends on the etiology; the critical distinction is between actively maintained fever and hyperthermia that results from excessive heating, inadequate dissipation of metabolic heat, or excessive heat production. A simple way to distinguish the etiologies is that patients with fever and increasing core temperature will have constricted, cold fingertips whereas those with other types of hyperthermia will be vasodilated and have warm fingertips. It is always appropriate to treat underlying causes, but non-febrile hyperthermia will also improve with cooling.

The first- and second-line treatments for fever are amelioration of the underlying cause and administration of anti-pyretic medications.[113] The first treatment strategy often fails because the etiology of fever remains either unknown or unresponsive. The second strategy also often

fails or is only partially effective, perhaps because some fever is mediated by mechanisms that bypass conventional anti-pyretics.[102] It is in these patients that third-line treatment is most likely to be implemented: active cooling. Active cooling of febrile patients is a natural response. However, it often fails to reduce core temperature — while simultaneously worsening the situation by triggering thermoregulatory defenses including intense discomfort, shivering, and autonomic nervous system activation.[114,115]

Active cooling should thus be used with considerable caution in febrile patients, with great attention to the metabolic and vasomotor consequences — to say nothing of the resulting thermal discomfort. Systems that directly cool the core[116-118] provoke less thermoregulatory stress than surface-based systems,[115] especially when intense core cooling is combined with gentle surface warming. A general clinical guideline is that cooling which maintains or decreases oxygen consumption is likely to be helpful[119], whereas an increasing metabolic rate indicates a potentially harmful activation of thermoregulatory responses.

Thermoregulation During General Anesthesia

Anesthetized patients cannot activate behavioral responses, leaving them to rely on autonomic defenses and external thermal management. All general anesthetics so far tested markedly impair normal autonomic thermoregulatory control. Anesthetic-induced impairment has a specific form: warm-response thresholds are elevated slightly, if at all, whereas cold-response thresholds are markedly reduced. Consequently, the interthreshold range increases ten-fold to approximately 2–4°C.[109,120-123] The gain and maximum intensity of some responses remain normal,[75] whereas general anesthesia reduces others.[124,125]

Response Thresholds

Propofol,[120] alfentanil,[109] dexmedetomidine,[121] isoflurane,[123] and desflurane[122] all increase the sweating threshold only slightly, if at all. Warm defenses are thus well preserved even during general anesthesia. A consequence is that inadvertent hyperthermia during forced-air warming is relatively rare because patients are usually able to dissipate excess heat into their dry, convective micro-environment. They are less protected against hyperthermia with the newer circulating-water garments that not only transfer more heat,[61] but are impervious to moisture, thus preventing evaporative heat loss.

Propofol,[120] alfentanil,[109] and dexmedetomidine,[121] produce a marked and linear decrease in the vasoconstriction and shivering thresholds. In contrast, isoflurane[123] and desflurane[122] decrease the cold-response thresholds non-linearly. Consequently, the volatile anesthetics inhibit vasoconstriction and shivering less than propofol at low concentrations, but more than propofol at typical anesthetic doses.

Interestingly, the normal approximately 1°C difference between the vasoconstriction and shivering thresholds is maintained even when patients are given sedatives or general anesthesia. That the relationship between these two thresholds is so precisely maintained under a large variety of circumstances suggests that both major autonomic cold defenses are similarly controlled, perhaps by an identical central regulator. The only exceptions to comparable control identified to date are nefopam[126] and meperidine, which reduces the shivering threshold twice as much as the vasoconstriction threshold[127] — explaining the drug's potent anti-shivering action.[128,129]

The dose-dependent response thresholds for four anesthetic drugs are shown in figure 11. These responses are characteristic of the drugs and drug combinations that have so far been tested. The combination of increased sweating thresholds and reduced vasoconstriction thresholds increases the interthreshold range ten-fold, from its normal value near 0.2−0.4°C to

approximately 2−4°C. Temperatures within this range do *not* trigger thermoregulatory defenses; by definition, patients are thus poikilothermic within this temperature range.

Halothane[130], enflurane,[131] and the combination of nitrous oxide and fentanyl[132] decrease the vasoconstriction threshold 2 − 4°C from its normal value near 37°C. The effects of these drugs on sweating or shivering remain unknown, but experience with other drugs suggests that they are unlikely to have much effect on sweating, but have a profound effect on shivering. Clonidine synchronously decreases cold-response thresholds,[133] while slightly increasing the sweating threshold.[134] Nitrous oxide decreases the vasoconstriction[135] and shivering[136] thresholds less than equi-potent concentrations of volatile anesthetics.

Midazolam, in typical clinical doses, minimally influences thermoregulatory control.[137, 138] Painful stimulation slightly increases vasoconstriction thresholds[131] just as pain has an anti-anesthetic effect[139] and regional anesthesia has a pro-anesthetic action.[140] Consequently, thresholds will be somewhat lower when surgical pain is prevented by simultaneous local or regional anesthesia. Both amino acid[141] and fructose[142] infusions increase the vasoconstriction threshold by ≈0.5°C.

The effects of vascular volume on thermoregulatory vasoconstriction have not been evaluated during anesthesia. But, positive end-expiratory pressure increases the vasoconstriction threshold while increasing central blood volume by leg raising reduces the threshold.[143] Baroreceptor unloading augments the peripheral vasoconstrictor and catecholamine response to core hypothermia while simultaneously reducing thermogenesis — which consequently aggravates hypothermia in the upright position. Upright posture attenuates the thermogenic response to core hypothermia but augments peripheral vasoconstriction. This divergent result suggests that input from the baroreceptor modifies the individual thermoregulatory efferent pathway at a site distal to the common thermoregulatory center or neural pathway.[144]

Gain and Maximum Response Intensity

Both the gain and maximum intensity of sweating remain normal during isoflurane (Fig. 8)[75] and enflurane anesthesia.[145] However, the gain of arterio-venous shunt vasoconstriction is reduced three-fold during desflurane anesthesia (fig. 12),[124] even though the maximum vasoconstriction intensity remains normal.[146] Volatile anesthetics thus not only markedly decrease the vasoconstriction threshold,[122,123] but once triggered, three times as much additional hypothermia as normal is required to reach maximum vasoconstriction. Fortunately, maximum intensity is finally reached and once reached, is effective, usually preventing further core hypothermia.[10]

Shivering is rare with surgical doses of general anesthesia, which is consistent with its threshold being roughly 1°C less than the vasoconstriction threshold.[109,120-123] The reason is that vasoconstriction is effective, constraining metabolic heat to the core thermal compartment, thus usually preventing additional hypothermia.[10] Consequently, it is rare even for unwarmed patients to become cold enough to induce shivering. Nonetheless, sufficient active cooling can induce shivering.

Gain and maximum shivering intensity remain normal during both meperidine and alfentanil administration.[147] Gain also remains nearly intact during nitrous oxide administration, although maximum intensity is reduced.[148] Isoflurane changes the macroscopic pattern of shivering to such an extent that it is no longer possible to easily determine gain. The drug does, however, reduce maximum shivering intensity.[125]

To sum up, sweating is the thermoregulatory defense that is best preserved during anesthesia. Not only is the threshold only slightly increased, but also the gain and maximum intensity are

well preserved. In contrast, the thresholds for vasoconstriction and shivering are markedly reduced, and furthermore, these responses are less effective than normal even after being activated.

It would be intuitive to conclude that surgical patients become hypothermic because they are minimally covered, exposed to a cold environment, washed with cold fluids that are allowed to evaporate, because surgery per se increases heat loss from within incisions, and because general anesthesia reduces metabolic rate. However, even the combination of all these factors would rarely produce hypothermia in subjects with intact thermoregulatory defenses. Anesthetic-induced thermoregulatory impairment is thus by far the most important cause of perioperative hypothermia.

Responses in Infants and the Elderly

As we have seen, thermoregulatory control is profoundly impaired by most any type of general anesthesia in adults, resulting in a large interthreshold range (i.e. 2−4°C) over which core temperature perturbations fail to trigger regulatory defenses. Thermoregulatory control is equally bad in anesthetized infants and children, but does not appear to be worse. For example, thermoregulatory vasoconstriction is comparably impaired in infants, children, and adults given isoflurane[149] or halothane[150] (fig. 13). In contrast, the vasoconstriction threshold is about 1°C less in patients aged 60−80 years than in those between 30 and 50 years old (fig. 14).[151,152] Infants are nonetheless at special risk of hypothermia because their large surface area-to-mass ratio increases the relative difference between heat loss to heat production.

Nonshivering thermogenesis does not occur in anesthetized adults,[153] which is hardly surprising since this response is not particularly important in unanesthetized adults.[94] In contrast to adult humans, nonshivering thermogenesis is an important thermoregulatory response in animals and human infants. However, nonshivering thermogenesis in animals is inhibited by volatile anesthetics,[154] and it fails to increase the metabolic rate in infants anesthetized with propofol.[155] It thus appears that nonshivering thermogenesis is relatively unimportant in perioperative patients and certainly has a small effect compared with the approximately 30% reduction in metabolic rate associated with general anesthesia.

Thermoregulation During Neuraxial Anesthesia

Central thermoregulatory control is slightly impaired by neuraxial anesthesia, but this is combined with reduced gain and maximum response intensity of shivering. Autonomic impairment is compounded by an impairment of behavioral regulation so that patients do not recognize that they are hypothermic. And finally, core temperature is not usually monitored during neuraxial anesthesia.

The result is that patients undergoing neuraxial anesthesia typically become hypothermic and do not sense the hypothermia. In addition, the anesthesiologist does not detect the hypothermia. This is problematic because there is little reason to believe that patients having neuraxial anesthesia are protected from the well-established complications of hypothermia.

Response Thresholds

Epidural[43,156] and spinal[156,157] anesthesia each decrease the thresholds triggering vasoconstriction and shivering (above the level of the block) about 0.6°C (fig. 15). Although the magnitude is less, the pattern of impairment is thus similar to that observed with general anesthetics and opioids, suggesting an alteration in central, rather than peripheral control seems most likely. The mechanism by which peripheral administration of local anesthesia impairs centrally mediated thermoregulation remains unknown, but is proportional to the number of spinal segments blocked (fig. 16).[158]

Reduced thresholds during neuraxial anesthesia does not result from recirculation of neuraxially administered local anesthetic because impairment is similar during epidural and spinal anesthesia,[43,156,157] although the amount and location of administered local anesthetic differs substantially. Furthermore, lidocaine administered intravenously in doses producing plasma concentrations similar to those occurring during epidural anesthesia has no thermoregulatory effect.[159] Finally, neuraxial administration of 2-chloroprocaine, a local anesthetic which has a plasma half life well under a minute, also impairs thermoregulatory control.[160]

Since neuraxial anesthesia prevents vasoconstriction and shivering in blocked regions, it is unsurprising that epidural anesthesia decreases the maximum intensity of shivering. However, epidural anesthesia also reduces the gain of shivering which suggests that the regulatory system is unable to compensate for lower body paralysis (fig. 17).[125] Thermoregulatory defenses, once triggered, are thus less effective than usual during regional anesthesia.

Sedative and analgesic medications all impair thermoregulatory control to some extent.[109, 127,137,161] Such inhibition may be severe when combined with the intrinsic impairment produced by regional anesthesia and other factors, including advanced age or pre-existing illness (fig. 18).[85]

Interestingly, core hypothermia during regional anesthesia may not trigger a perception of cold.[43,162] The reason is that thermal perception (behavioral regulation) is largely determined by skin rather than core temperature.[78] During regional anesthesia, core hypothermia is accompanied by a real increase in skin temperature. The paradoxical result is often a perception of continued or increased warmth, accompanied by autonomic thermoregulatory responses including shivering (fig. 19).[43,162]

Taken together, these data indicate that neuraxial anesthesia inhibits numerous aspects of thermoregulatory control. The vasoconstriction and shivering thresholds are reduced by regional anesthesia,[43,156-158,163] and further reduced by adjuvant drugs[109,137] and advanced age.[85] Even once triggered, the gain and maximum response intensity of shivering are about half normal.[164] Finally, behavioral thermoregulation is impaired.[162] The result is that cold-defenses are triggered at a lower temperature than normal during regional anesthesia, defenses are less effective once triggered, and patients frequently do not recognize that they are hypothermic. Because core-temperature monitoring remains rare during regional anesthesia,[44] substantial hypothermia often goes undetected in these patients.[42]

Shivering During Neuraxial Anesthesia

Shivering-like tremor is common during neuraxial anesthesia and has at least four potential etiologies: 1) normal thermoregulatory shivering in response to core hypothermia; 2) normal shivering in normothermic or even hyperthermic patients who are developing a fever; 3) direct stimulation of cold receptors in the neuraxis by injected local anesthetic; and, 4) non-thermoregulatory muscular activity that resembles thermoregulatory shivering. However, other etiologies remain possible. For example, a convincing cause has yet to be identified for the intense shivering that so often occurs immediately after induction of spinal or epidural anesthesia for cesarean delivery — well before core temperature has had time to decrease.

Most shivering associated with neuraxial anesthesia appears to be normal shivering, the expected response to hypothermia. And at least in volunteers given neuraxial anesthesia, shivering is always preceded by core hypothermia and vasoconstriction (above the level of the block).[43] Furthermore, electromyographic analysis indicates that the tremor has the 4−8 cycles/minute waxing-and-waning pattern that characterizes normal shivering.[160] Fever is defined by a regulated increase in thermoregulatory response thresholds and can thus provoke

shivering even in normothermic individuals. Nonetheless, perioperative fever is probably a relatively rare cause of shivering.

All mammals and birds have spinal thermoreceptors. There is thus the theoretical possibility that injection of relatively cool (i.e., ambient temperature) local anesthetic into the epidural space might provoke shivering by stimulating local temperature sensors. Consistent with this possibility, the incidence of shivering in pregnant women was reported to be greater when they are given refrigerated epidural anesthetic than when the anesthetic is warmed before injection.[165] However, epidural administration of large amounts of ice-cold saline does not trigger shivering in non-pregnant volunteers.[166] Furthermore, the incidence of shivering is comparable in volunteers[43] and non-pregnant patients[167] given warm or cold epidural anesthetic injections. These data indicate that temperature of injected local anesthetic rarely provokes shivering during major conduction anesthesia.

Not all shivering-like tremor is thermoregulatory. It is possible to detect low-intensity shivering-like muscular activity in both surgical patients[168] and during labor.[169] The cause of this muscular activity remains unknown, but it is associated with pain and may thus result from sympathetic nervous system activation.[170]

Since skin temperature contributes to control of thermoregulatory responses, shivering of any type can be treated by warming the skin surface.[171] This is why shivering so often stops in a matter of seconds after entering a warm room even though core temperature hasn't had time to change at all. However, the entire skin surface contributes 20% to thermoregulatory control[76,89] and the lower body contributes about 10%,[163] sentient skin warming is likely to only compensate for small reductions in core temperature. As might thus be expected, skin warming is only effective in a fraction of patients.

Most often, pharmacologic treatments will be required for moderate or severe shivering. The same drugs that are effective for shivering after general anesthesia can be used to treat shivering during neuraxial anesthesia: these include meperidine (25 mg, IV or epidurally),[172] clonidine (75 μg, IV),[173] ketanserin (10 mg, IV),[173] and magnesium sulfate (30 mg/kg, IV).[174]

Hyperthermia During Epidural Analgesia

Prolonged epidural analgesia for labor and delivery is occasionally associated with hyperthermia, typically to 38.5−39.5°C. Hyperthermia develops only in a sub-set of women.[175] Hyperthermia typically develops after at least five hours of labor, and then increases over time.[176-179] The clinical consequence of this hyperthermia is that women given epidural analgesia for labor are more often given antibiotics than in those treated conventionally, and their offspring are more commonly treated for sepsis.[177,180,181]

Although best studied and most concerning in the context of labor, the association between epidural analgesia and hyperthermia is by no means restricted to labor; it also occurs in non-pregnant post-operative patients.[182] It is thus apparent that this hyperthermia is not restricted to pregnancy and must have a more general etiology.

There are several potential explanations for hyperthermia during labor analgesia. For example, it could simply be passive hyperthermia resulting from excessive heat production and inadequate heat dissipation to the environment. Labor certainly involves muscular effort that increases metabolic rate; furthermore, maternal metabolism is already increased by the fetus. Nonetheless, maternal metabolic rate remains small compared with even gentle exercise which perhaps doubles metabolic rate, and does not provoke hyperthermia in any but the most extreme environments. There is not reason to believe that epidural analgesia per se alters whatever

increase in metabolic rate might normally accompany labor. And of course metabolic rate is near-normal in postoperative patients who also develop hyperthermia with epidural analgesia.

A dense epidural block would inhibit sweating, which is sympathetically mediated, in the blocked region; but epidural analgesia for labor does not normally produce a sufficiently dense block. Furthermore, in a relatively dry and cool hospital environment, patients could easily dissipate many times their basal metabolic rates just from the upper body. It thus seems unlikely that an imbalance between heat production and loss is the explanation for hyperthermia during labor analgesia. A corollary is that hyperthermia during labor analgesia is a regulated fever rather than simple passive hyperthermia.

Hyperthermia during labor could just be the normal febrile response to infection. “Fever work-ups” and antibiotic treatments are common responses to maternal hyperthermia, and some hyperthermia surely is infectious fever.[183] Nonetheless, typical epidural-associated hyperthermia seems unlikely to result from infection and the current consensus is that infection is rarely the cause.

Inflammation is a different matter, though. There are many potential sources of non-infectious inflammation in laboring patients, to say nothing of postoperative patients who obviously have injured tissues. For example, Dashe et al concluded: “Epidural analgesia is associated with intrapartum fever, but only in the presence of placental inflammation.”[184] It seems likely that inflammation provokes a regulated febrile response during labor (and in postoperative patients). Consistent with this theory, high-dose steroids — powerful antiinflammatory drugs — nearly eliminate fever during labor.[185] In contrast, acetaminophen did not prevent hyperthermia, although the drug is usually an effective antipyretic.[186] That prolonged labor is associated with a greater risk of hyperthermia is consistent with a longer period in which to develop inflammation, especially placental inflammation which is likely to release a variety of pyrogenic cytokines. And of course longer labor is associated with factors that promote inflammation.[187]

The difficulty is that epidural analgesia surely does not augment the general inflammatory response to labor or surgery. Nor does it increase the risk of fetal malposition or need for cesarean delivery.[188] It thus remains unclear why epidural analgesia augments the risk of hyperthermia during labor and in postoperative patients. The conventional assumption is that hyperthermia is somehow caused by the technique; although no even slightly convincing mechanism has been proposed.

It is worth remembering, though, that when hyperthermia during labor is studied, pain in the “control” patients is usually treated with opioids — which themselves blunts thermoregulatory defenses[109,127] and specifically attenuates fever.[108] Fever associated with infection or tissue injury might then be suppressed by low doses of opioids that are usually given to the “control” patients while being expressed normally in patients given epidural analgesia.[189] The extent to which this mechanism contributes remains to be determined, and the theory is controversial.[190] However, no convincing alternative explanation has been advanced.

Summary

Core temperature, while by no means completely characterizing body heat content and distribution, is the best single indicator of thermal status in humans. Core temperature can be accurately monitored at the tympanic membrane, pulmonary artery, distal esophagus, and nasopharynx. Under appropriate circumstances, core temperature can also be reliably estimated from the mouth, axilla, and bladder. In contrast, infrared aural canal (“tympanic”) and temporal artery systems are insufficiently accurate for clinical use.

Body temperature should be monitored in most patients undergoing general anesthesia exceeding 30 minutes in duration and in all patients whose surgery lasts longer than one hour. Measuring body temperature (and maintaining normothermia) is now the standard-of-care during prolonged general anesthesia, especially for large operations where the risk of hypothermia is substantial. Core temperature should also be measured during regional anesthesia in patients likely to become hypothermic, including those undergoing body cavity surgery.

The processing of thermoregulatory information occurs in three phases: *afferent thermal sensing*, *central regulation*, and *efferent responses*. Transient Receptor Potential (TRP) vanilloid (V) and menthol (M) receptors may be the fundamental temperature sensing elements. Most ascending thermal information traverses the spino-thalamic tracts in the anterior spinal cord, but no single spinal tract is critical for conveying thermal information. The hypothalamus, other parts of the brain, the spinal cord, deep abdominal and thoracic tissues, and the skin surface each contribute roughly a fifth of the total thermal input to the central regulatory system.

Temperature is regulated by central structures that compare integrated thermal inputs from the skin surface, neuraxis, and deep tissues with *thresholds* (triggering core temperatures) for each thermoregulatory response. The slope of response intensity versus core temperature defines the *gain* of a thermoregulatory response. The *maximum intensity* of the response is defined as when response intensity no longer increases with further deviation in core temperature. The *interthreshold range* (core temperatures *not* triggering autonomic thermoregulatory responses) is bounded by the sweating threshold at its upper end and by the vasoconstriction threshold at the lower end. The interthreshold range is usually only 0.2−0.4°C in humans, and that range defines normal body temperature.

Behavioral regulation is the most powerful thermoregulatory effector, and it is behavioral regulation that allows humans to tolerate extreme environments. However, surgical patients much largely depend on autonomic responses including sweating, vasoconstriction, and shivering. Among these defenses, vasoconstriction is the most important and accounts for most perioperative thermal perturbations.

Hyperthermia is any increase in core temperature; in contrast, fever is a regulated increase in the core temperature targeted by the thermoregulatory system. Fever is mediated by circulating endogenous pyrogens and is an active process. Hyperthermia can result from a variety of causes, many of which are serious including infection, mis-matched blood transfusion, allergic reactions, and malignant hyperthermia. Perioperative hyperthermia thus deserves a serious diagnostic effort, and often intervention.

General anesthetics and opioids have little influence on sweating, but profoundly reduce the vasoconstriction and shivering thresholds. The results is a 10−20-fold increase in the interthreshold range. In contrast, general anesthetics have relatively little effect on the gain and maximum intensity of thermoregulatory responses. It is thermoregulatory impairment not — as one might assume — exposure to a cool operating room environment that causes most perioperative thermal perturbations. Thermoregulatory defenses are reasonably well maintained in infants and children, but somewhat impaired in the elderly.

Central thermoregulatory control is slightly impaired by neuraxial anesthesia, but this is combined with reduced gain and maximum response intensity of shivering. Autonomic impairment is compounded by an impairment of behavioral regulation so that patients do not recognize that they are hypothermic. The result is that patients undergoing neuraxial anesthesia typically become hypothermic and do not sense the hypothermia. Temperature should thus be measured in patients having major surgery under regional anesthesia, and they should be actively warmed as necessary to maintain normothermia.

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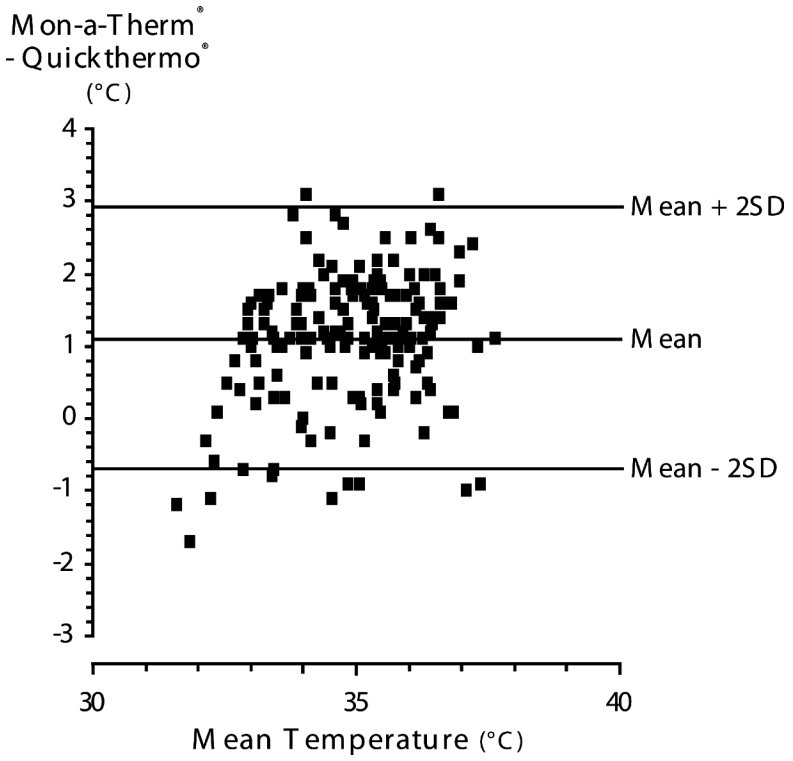

Figure 1.

The differences between the tympanic membrane thermocouple (Mon-a-therm) and aural canal temperature measured by a Quickthermo infrared thermometer. The mean difference between core temperature and the infrared monitor was 1.1°C. Three other infrared monitors were evaluated in this study, but none proved sufficiently accurate for clinical use. SD = standard deviation. Reprinted with permission[15].

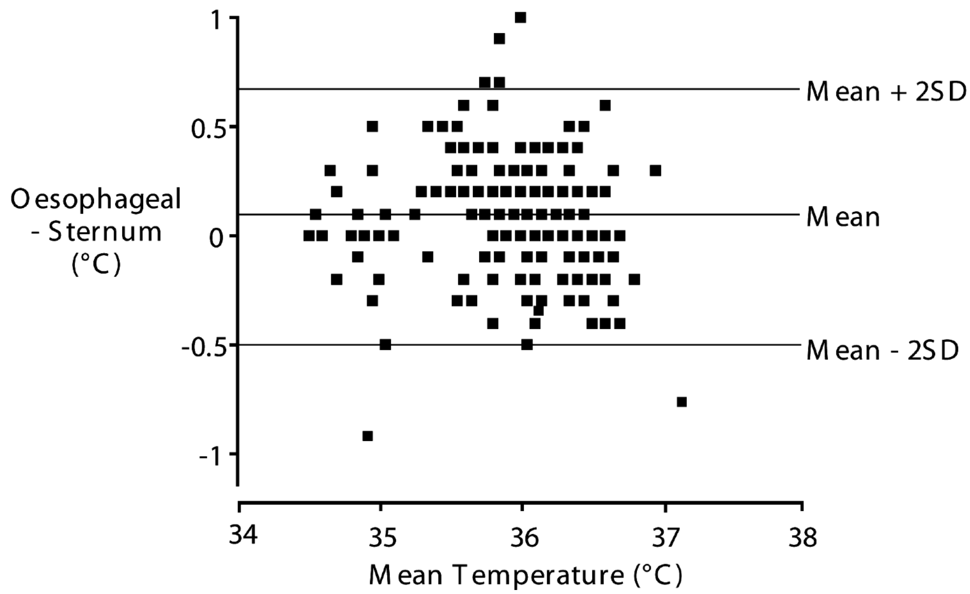

Figure 2.
Bland and Altman comparison of distal esophageal temperature and “deep sternal” temperatures. The vertical axis is the difference between esophageal and deep sternal temperatures. Mean temperature on the horizontal axis refers to the average between esophageal and deep sternal temperatures at each measurement time. The mean offset was 0.1° C, with a standard deviations of 0.3°C. This accuracy is perfectly adequate for clinical use. Reprinted with permission[20].

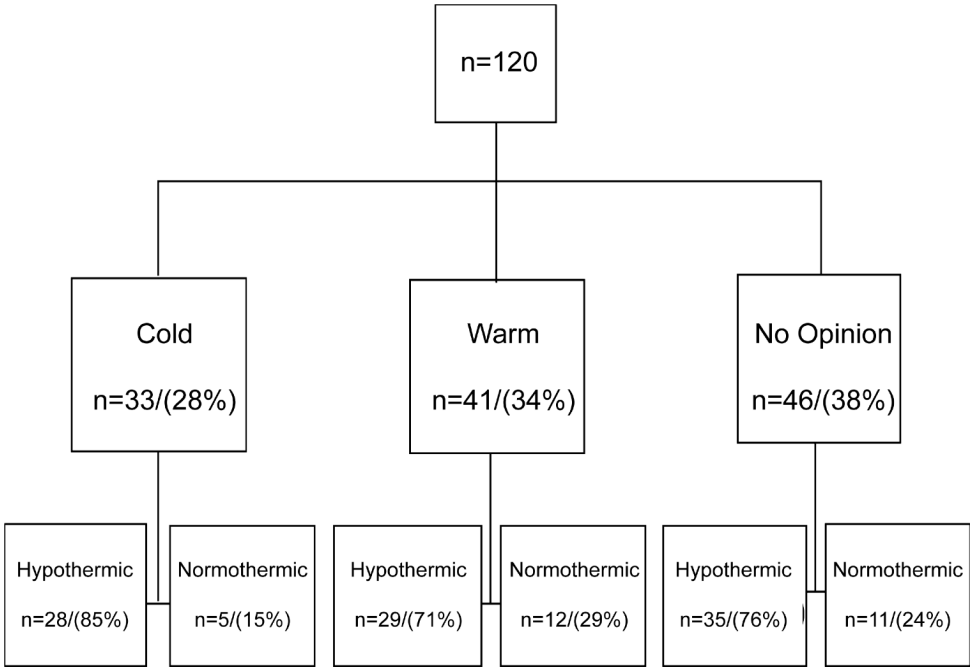

Figure 3.
All patients were divided by anesthesiologists' impression of thermal status. There was no difference in the number of hypothermic (<36°C) and normothermic patients (P = 0.36) when divided by anesthesiologists' impression. Anesthesiologists were unable to reliably estimate their patients' thermal status. Reprinted with permission[42].

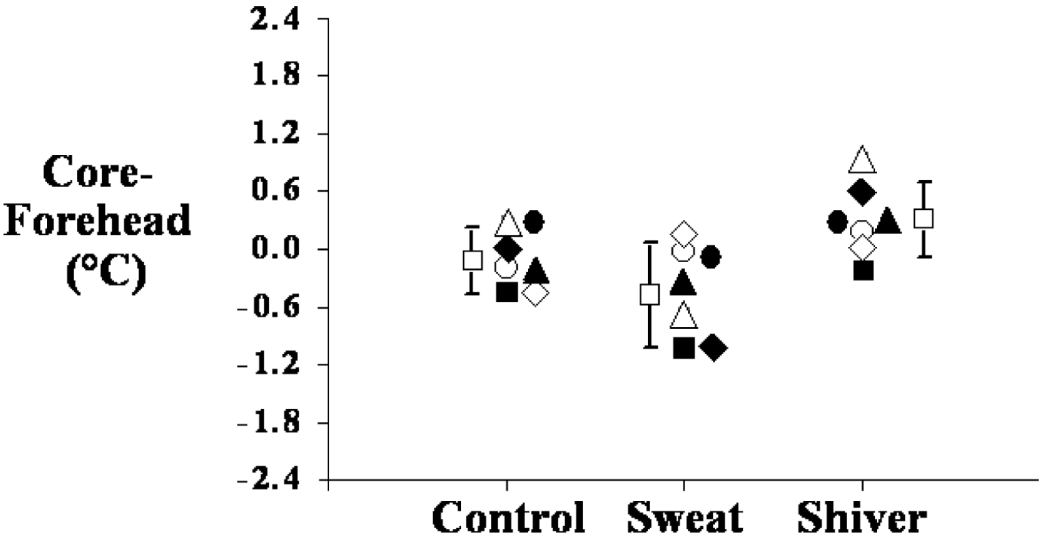

Figure 4.

Tympanic membrane (core) minus forehead skin-surface temperature difference during a thermoneutral control period was 0.1 ± 0.3°C. This difference did not change significantly during vasodilation associated with sweating or vasoconstriction associated with shivering. Results are presented as mean ± SD. Reprinted with permission[52].

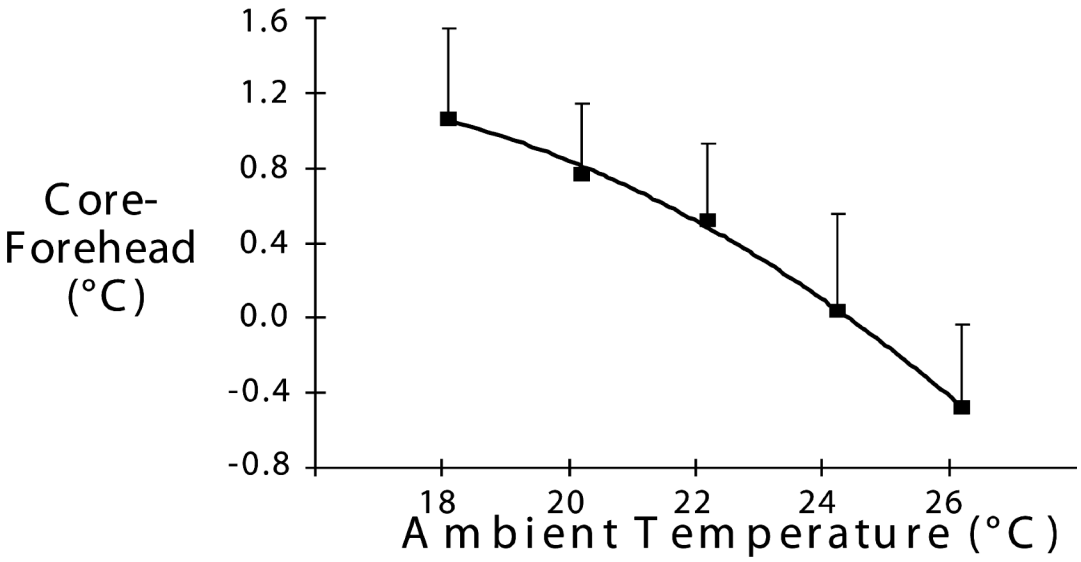

Figure 5.

The difference between tympanic membrane (core) and forehead skin-surface temperatures (ΔT) at ambient temperatures ($T_{ambient}$) between 18 and 26°C. The data were fit to a second-order regression: $\Delta T = -0.58 + 0.29(T_{ambient}) - 0.01(T_{ambient})^2$, $r^2 = 0.999$. Each 1°C change in ambient temperature, starting near 22°C, thus altered skin temperature ≈0.16°C. Results are presented as mean ± SD. Horizontal error bars (variation in ambient temperatures) are not displayed because they were smaller than the size of the markers. Reprinted with permission[52].

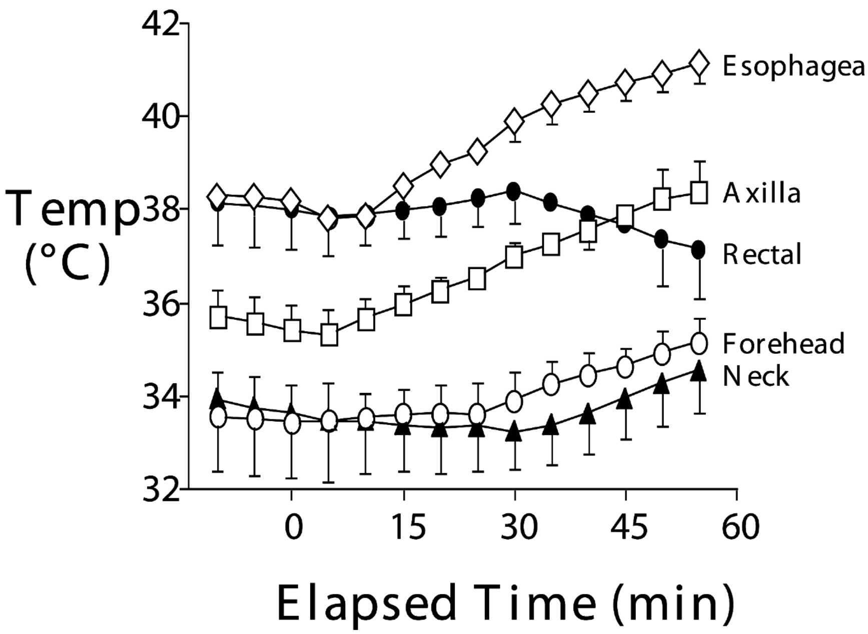

Figure 6.

Axillary and esophageal temperatures correlated well during acute malignant hyperthermia in swine, but forehead and neck skin temperatures did not. Rectal temperature also failed to promptly identify onset of malignant hyperthermia. Elapsed time zero indicates an end-tidal PCO2 = 70 mmHg. These data indicate that forehead and neck skin-surface temperatures will not adequately confirm other clinical signs of malignant hyperthermia. Valid core temperature monitoring sites include the distal esophagus, pulmonary artery, nasopharynx, and tympanic membrane. Except during cardiopulmonary bypass, body temperature also can be measured in the mouth, axilla, and bladder. Data presented as means ± SDs. Modified and reprinted with permission[54].

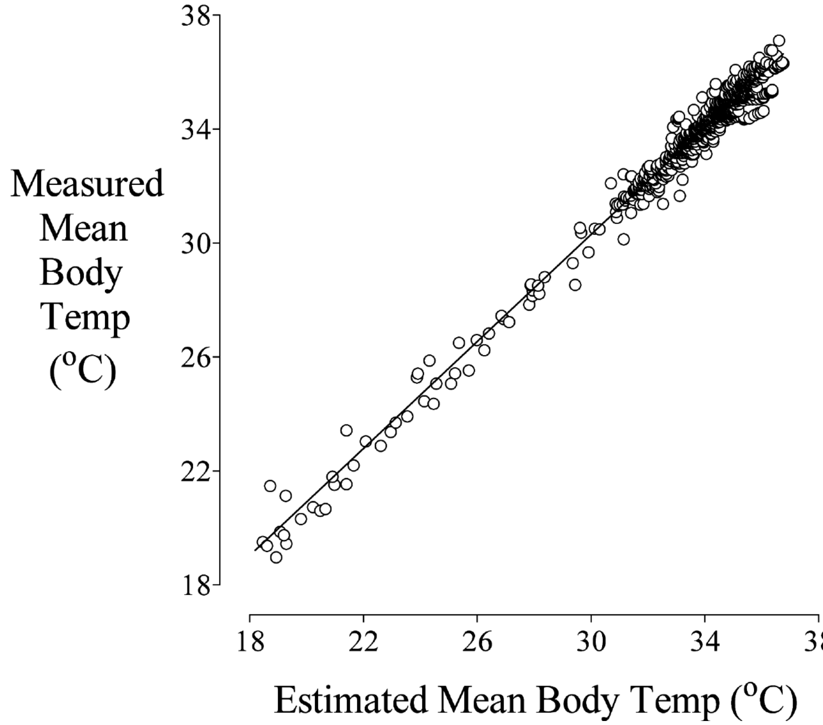

Figure 7.

Linear regression including 913 data pairs from 44 subjects who participated in four heat-balance studies. Mean-body temperature (MBT) was estimated from core (Tcore) and mean-skin (TSkin) temperature and compared to directly measured values. There was a remarkably good relationship between measured and estimated mean-body temperatures: $MBT_{estimated} = 0.94 . MBT_{Measured} + 2.15$, $r^2 = 0.98$. Reprinted with permission[12].

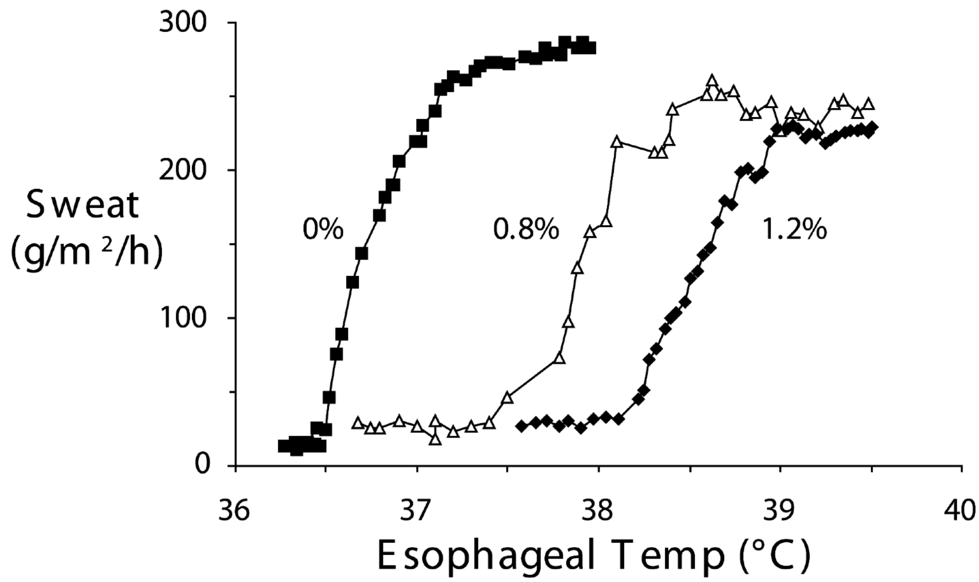

Figure 8.
The sweating rate from the unwarmed site in a single typical male volunteer shows the threshold, gain, and maximum intensity during hyperthermia alone (0%) and at 0.8%, and 1.2% end-tidal isoflurane concentration. The thresholds were markedly increased by anesthesia; in contrast, gains and maximum sweating rates were relatively well preserved. Reprinted with permission[75].

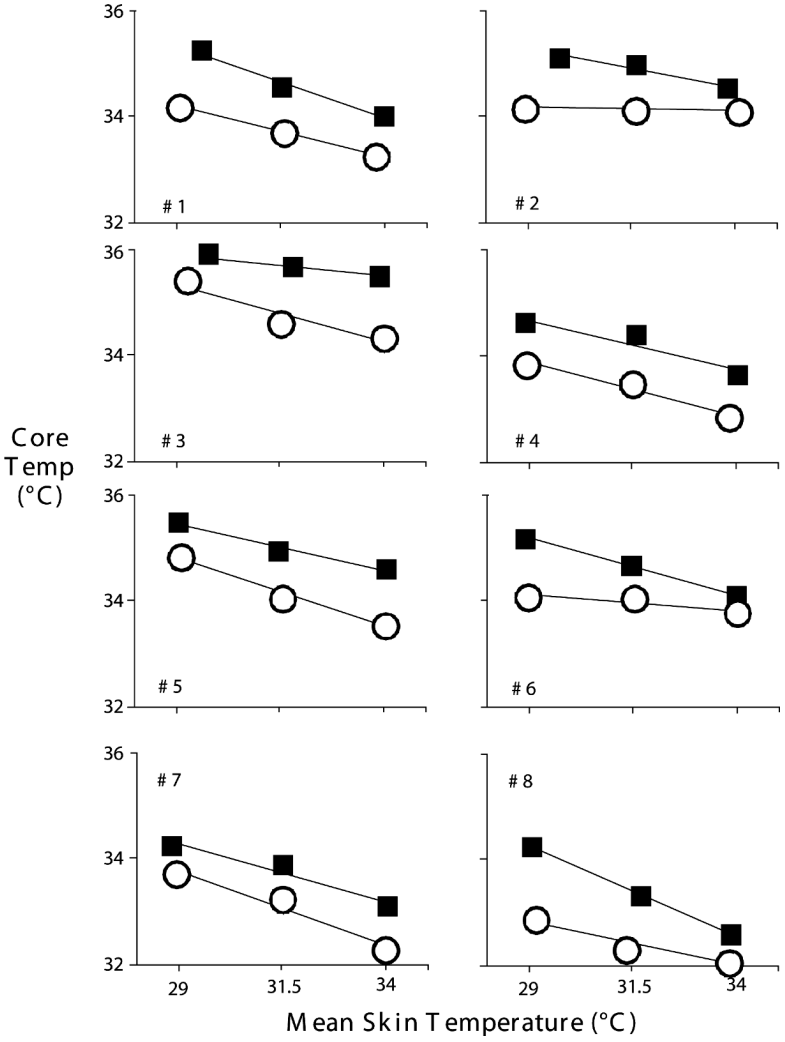

Figure 9.

Individual mean-skin and core temperatures at the vasoconstriction (squares) and shivering (circles) thresholds in the eight volunteers. There was a linear relation between mean skin and core temperatures at the vasoconstriction and shivering thresholds in each volunteer (lines): $r^2 = 0.98 \pm 0.02$ for vasoconstriction, and 0.96 ± 0.04 for shivering. Relative contributions of skin and core temperatures varied from subject to subject, but on average skin temperature contributed $21 \pm 8\%$ to vasoconstriction, and $18 \pm 10\%$ to shivering. Reprinted with permission[89].

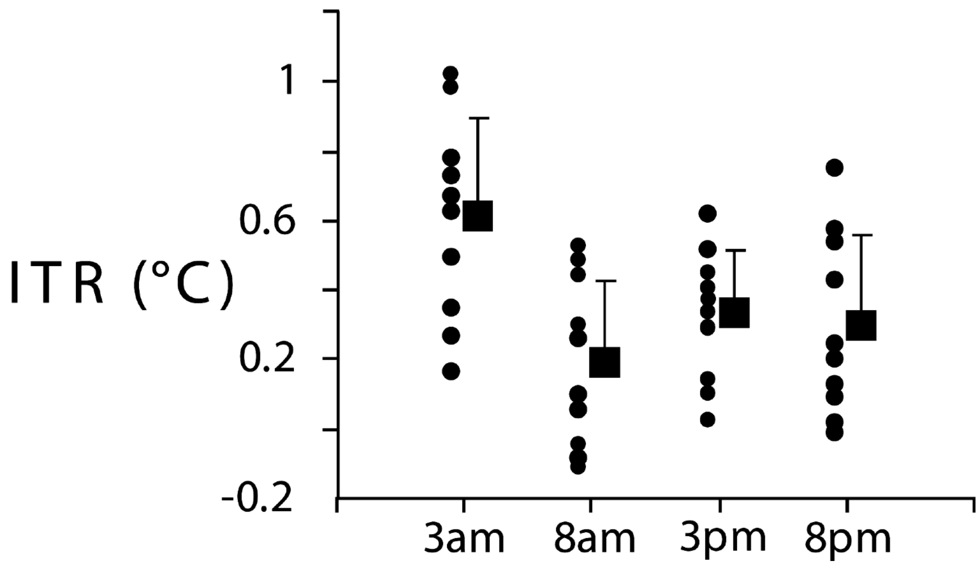

Figure 10.
The sweating-to-vasoconstriction interthreshold range at each time of day. Data presented as means ± SDs. Values at 3 AM differed significantly from those at other times. Reprinted with permission[80].

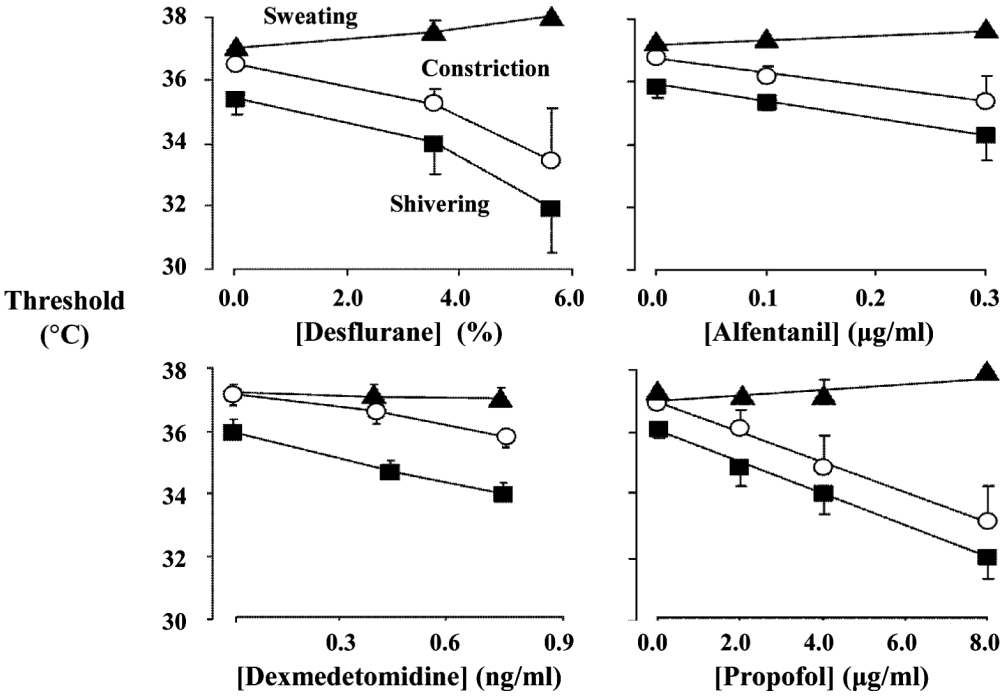

Figure 11.

The major autonomic thermoregulatory response thresholds in volunteers given desflurane, alfentanil, dexmedetomidine, or propofol. All the anesthetics slightly increase the sweating threshold (triggering core temperature), while markedly and synchronously decreasing the vasoconstriction and shivering thresholds. Standard deviation bars smaller than the data markers have been deleted. Reprinted with permission[109, 120, 121, 122].

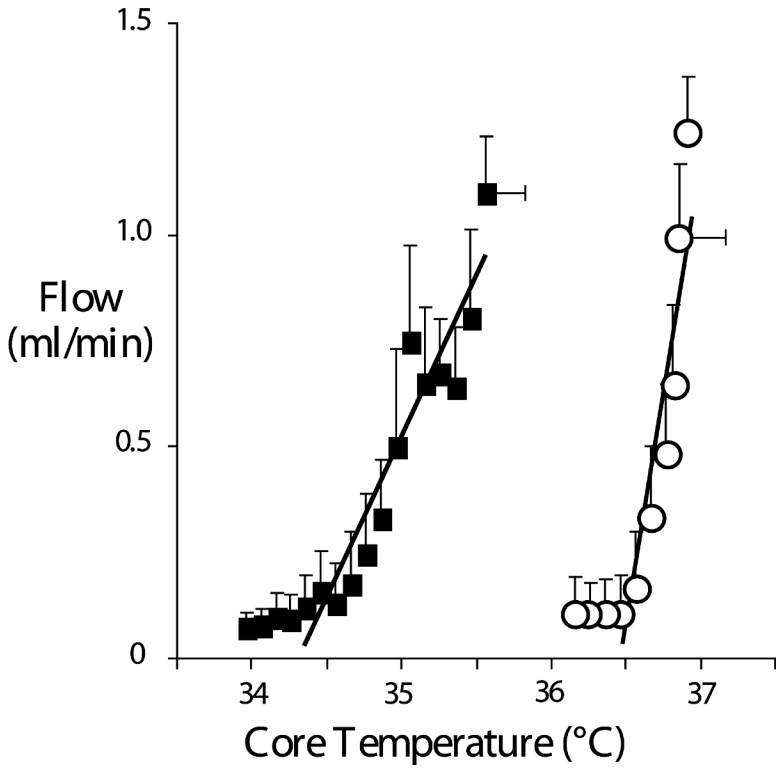

Figure 12.
Finger blood flow without (open circles) and with (filled squares) desflurane administration. Values were computed relative to the thresholds (finger flow = 1.0 ml/min) in each subject. Flows of exactly 1.0 ml/min are not shown because flows in each individual were averaged over 0.1 or 0.05°C increments; each data point thus includes both higher and lower flows. The horizontal standard deviation bars indicate variability in the thresholds among the volunteers; although errors bars are shown only at a flow near 1.0 ml/min, the same temperature variability applies to each data point. The slopes of the flow vs. core temperature relationships (1.0 to ≈0.15 ml/min) were determined using linear regression. These slopes defined the gain of vasoconstriction with and without desflurane anesthesia. Gain was reduced by a factor of three, from 2.4 to 0.8 ml min-1.°C-1 ($P < 0.01$). Reprinted with permission[124].

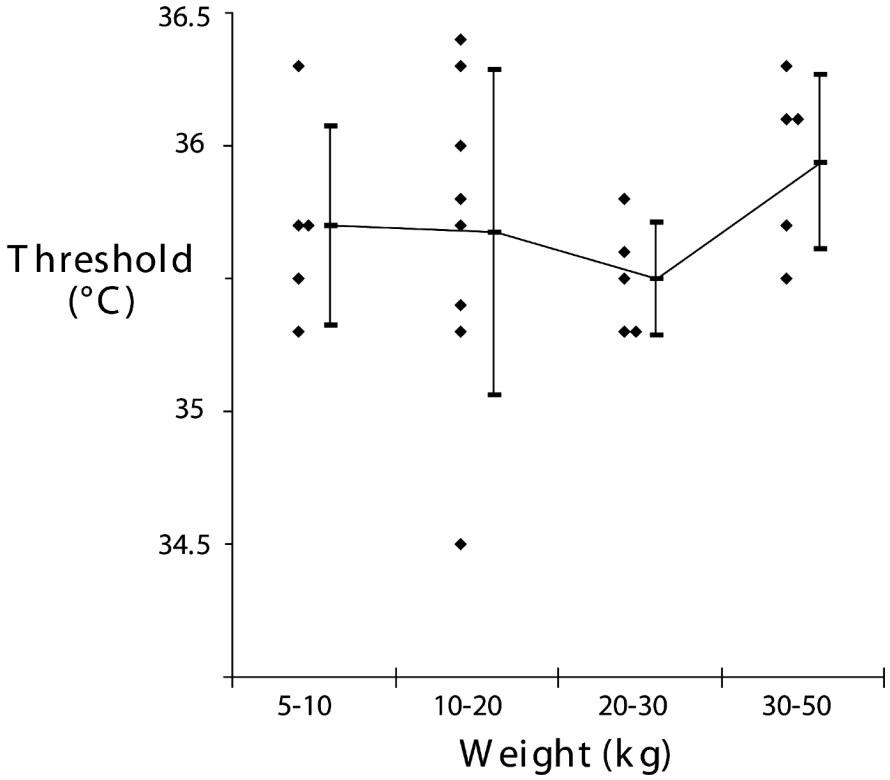

Figure 13.
The core thermoregulatory threshold in 23 healthy children and infants undergoing abdominal surgery with halothane anesthesia. Differences among the groups are not statistically significant. Results are presented as means ± SDs. Reprinted with permission[150].

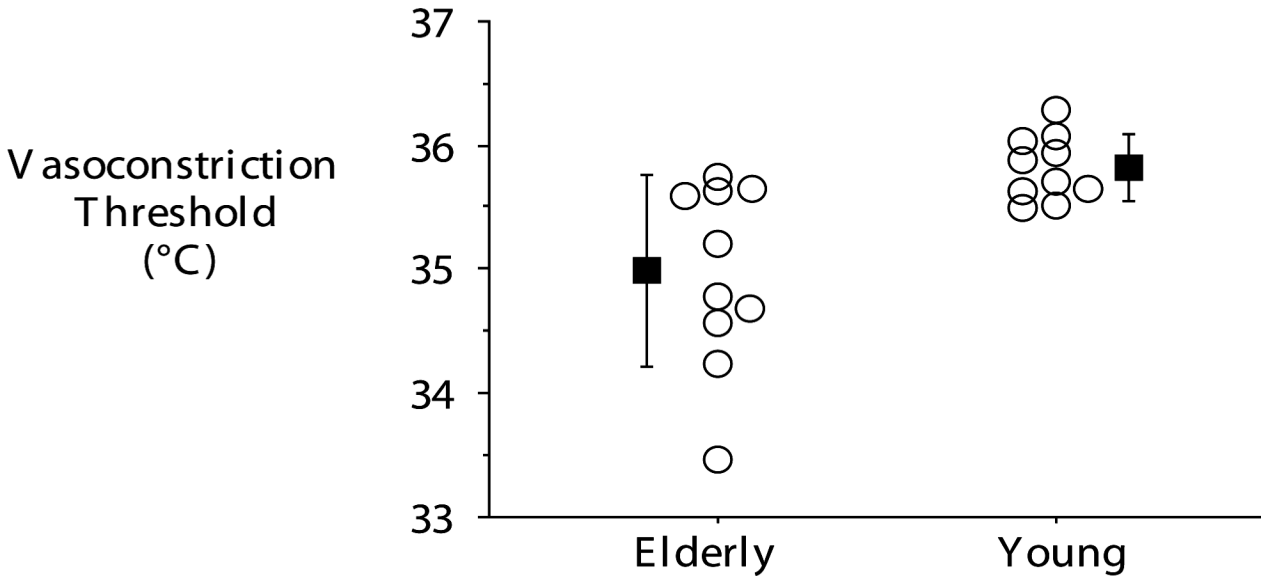

Figure 14.
The vasoconstriction threshold during light sevoflrurane anesthesia was significantly less in elderly (35.8 ± 0.3°C, n = 10) than in younger patients (35.0 ± 0.5°C, n = 10) ($P < 0.01$). Open circles indicate the vasoconstriction threshold in each patient; filled squares the show the mean and standard deviations in each group. Reprinted with permission[152].

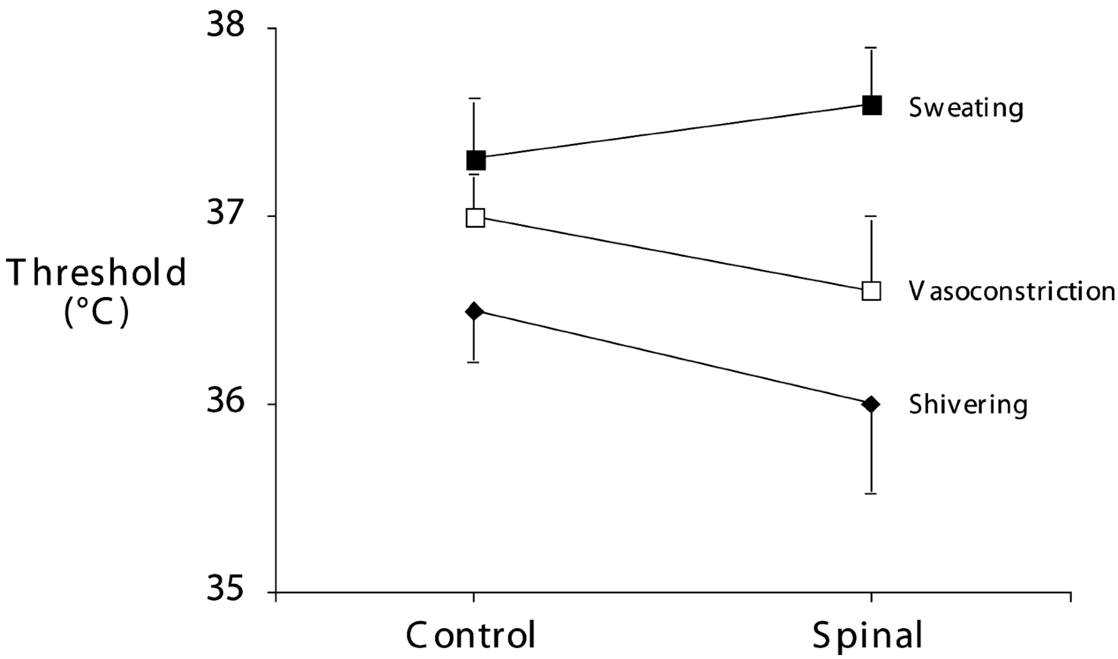

Figure 15.
Spinal anesthesia increased the sweating threshold but reduced the thresholds for vasoconstriction and shivering. Consequently, the interthreshold range increased substantially. The vasoconstriction-to-shivering range, however, remained normal during spinal anesthesia. Results are presented as means ± SDs. Reprinted with permission[157].

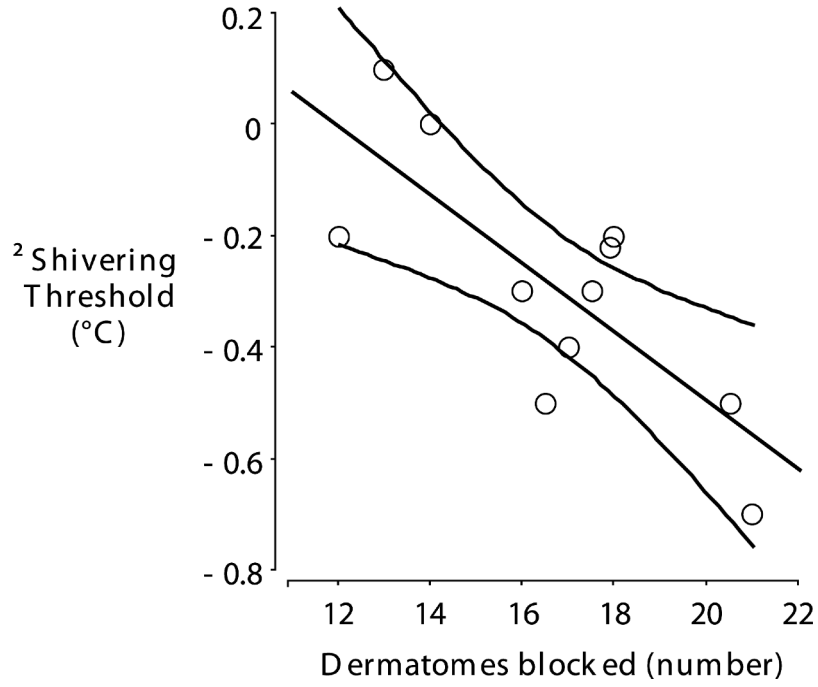

Figure 16.
The number of dermatomes blocked (sacral segments = 5; lumbar segments = 5; thoracic segments = 12) versus reduction in the shivering threshold (difference between the control shivering threshold and spinal shivering threshold). The shivering threshold was reduced more by extensive spinal blocks than by less extensive ones (Δ threshold = 0.74 − 0.06(dermatomes blocked); $r^2 = 0.58$, $P < 0.006$). The curved lines indicate the 95% confidence intervals for the slope. Reprinted with permission[158].

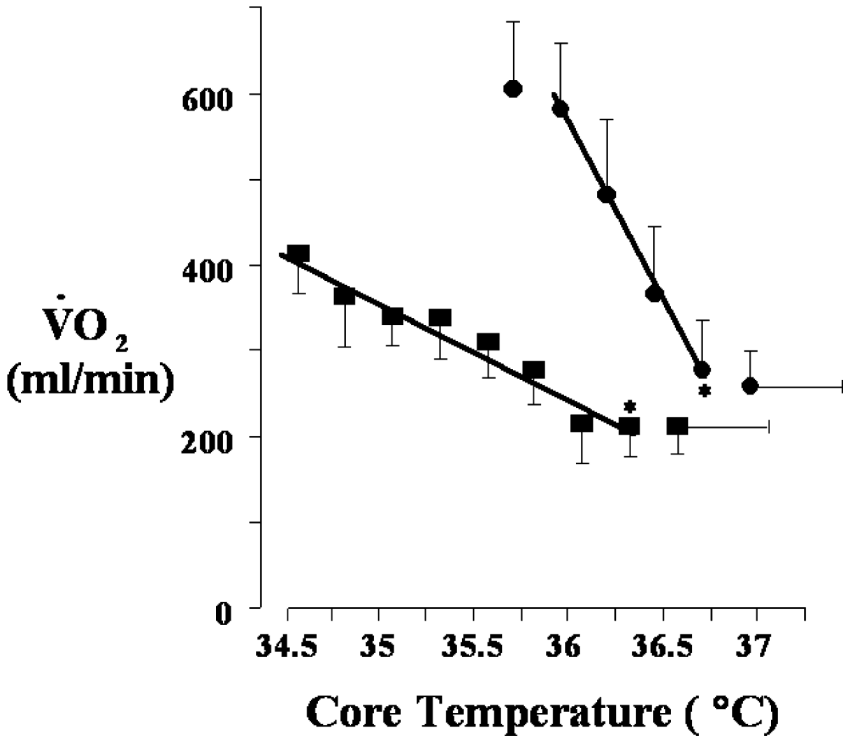

Figure 17.

Systemic oxygen consumption without (circles) and with (squares) epidural anesthesia. The horizontal standard deviation bars indicate variability in the thresholds among the volunteers; although errors bars are shown only once in each series, the same temperature variability applies to each data point. The slopes of the oxygen consumption versus core temperature relationships (solid lines) were determined using linear regression. These slopes defined the gain of shivering with and without epidural anesthesia. Gain was reduced 3.7-fold, from −412 ml·min-1·°C^{-1} (r^2 = 0.99) to −112 ml·min-1·°C-1 (r^2 = 0.96). Reprinted with permission[164].

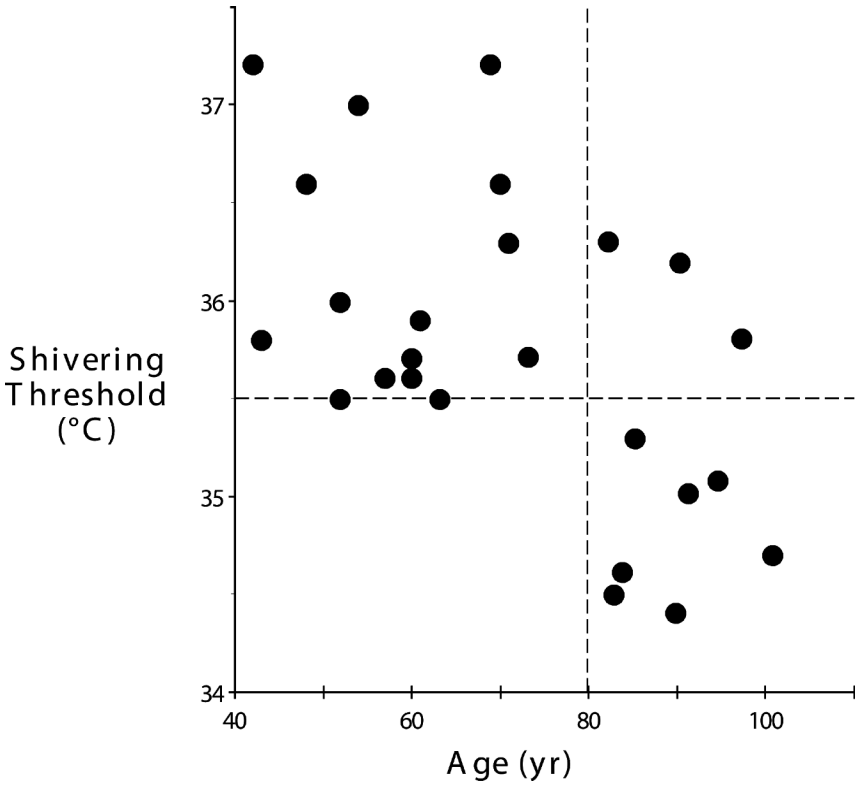

Figure 18.
Fifteen patients aged <80 yr (58 ± 10 yr) shivered at 36.1 ± 0.6°C during spinal anesthesia; in contrast, eight patients aged ≥80 yr (89 ± 7 yr) shivered at a significantly lower mean temperature, 35.2 ± 0.8°C. The shivering thresholds in five of the eight patients aged more than 80 yr was less than 35.5°C, whereas the threshold equaled or exceeded this value in all the younger patients. Results presented as means ± SDs. Reprinted with permission[85].

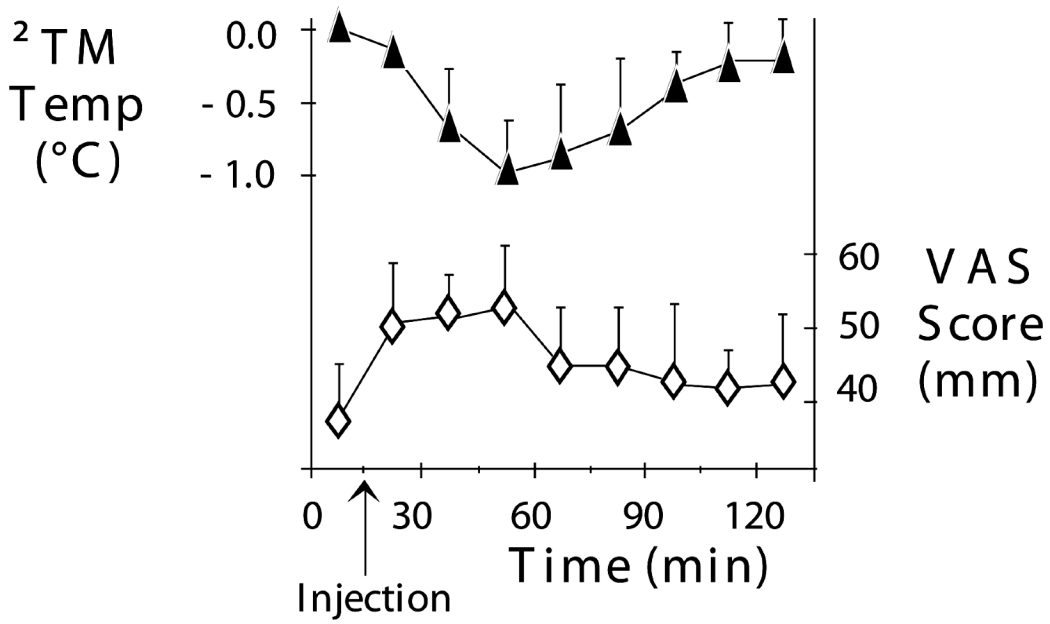

Figure 19.
Changes in tympanic membrane temperatures and thermal comfort (mm on a visual analog scale) following epidural lidocaine injections in 6 volunteers in a cool operating room environment. Epidural injections were given after a 15-min control period. Shivering (not shown) started when tympanic temperature decreased about 0.5°C and continued until core temperature returned to within 0.5°C of control. Thermal comfort increased following epidural injections in each volunteer; maximal comfort occurred at the lowest core temperature. Results presented as means ± SDs. Reprinted with permission[43].

ATTACHMENT F: RESPONSE TIME TEST REPORT

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ATTACHMENT G: IR TEMPERATURE ACCURACY REPORT

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The acceptance criteria was defined in section 7.15 as ± 2˚C probe measurement accuracy with 95/95% confidence per SRS-10212 requirement # A.11. All groupings of probe and temperature met the established acceptance criteria as demonstrated by the data above. Temperature accuracy was evaluated over the operating range per system measurement requirements. Based on these results, the accuracy of the IRTS system is acceptable.

10. ACCEPTANCE CRITERIA

10.1. Temperature measurements made by the IRTS must match the TTG temperature to within +/- 2.0 °C with a 95%/95% confidence interval. **PASS**

11. CONCLUSION

11.1. All temperature measurements made by the IRTS meet the acceptance criteria for accuracy.

Appendix I

Test Materials

Test Element	Details	
Optikos Test Target Generator	Test Fixture #	T-10701
Phase I		
PIU	Serial #	12
TIP 1	Serial #	316
	Slope	5.240
TIP 2	Serial #	317
	Slope	6.290
TIP 3	Serial #	318
	Slope	4.840
PMU Software	Revision #	6.0.1
PIU Software	Revision #	6.0.1
Phase II		
PIU (Phase II)	Serial #	12
TIP 1*	Serial #	341
	Slope	15.00
TIP 2*	Serial #	342
	Slope	12.37
TIP 3*	Serial #	343
	Slope	14.33
PMU Software	Revision #	6.0.1
PIU Software	Revision #	6.0.1

ATTACHMENT H: IRTS SPATIAL RESOLUTION & ACCURACY STUDY

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ATTACHMENT G: K152402

COPY OF A001, NOVEMBER 19, 2015 ADDITIONAL INFORMATION

November 19, 2015

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

Re: Supplement 2 to – 510(k) K152402/S001
Securus Medical Group, Inc.
IRTS System

Dear Mr. Burdick:

The attached information is submitted for inclusion in the referenced 510(k) Notice for the Securus IRTS System. The information is being provided in response to questions raised by FDA during the review of the subject Notification on 11/14/15. Please direct this response to William Burdick.

Should you have any questions pertaining to these responses please contact me at 978-317-0836. Please send written communications concerning this Notification to:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:

William J. Gorman
Securus Medical Group, Inc.

ADDITIONAL INFORMATION

The following pages contain Additional Information (AI) provided in response to questions raised by FDA during the review of K152402/S001 on November 14, 2015

This response is organized in the sequence of the questions presented in the FDA communication. In each case, the question is repeated (verbatim) in italics, followed by the Securus response. If additional supporting documentation is referenced, it is provided as an Attachment.

AI K152402/S001
Table of Contents

ATTACHMENTS:

A: SD-10855 - SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION
B: TR-10850 - IRTS UNIT TEST RESULTS
C: TR-10900 - IRTS SOFTWARE TEST REPORT
D: D-10903 - DESIGN REVIEW BOARD MEETING MINUTES

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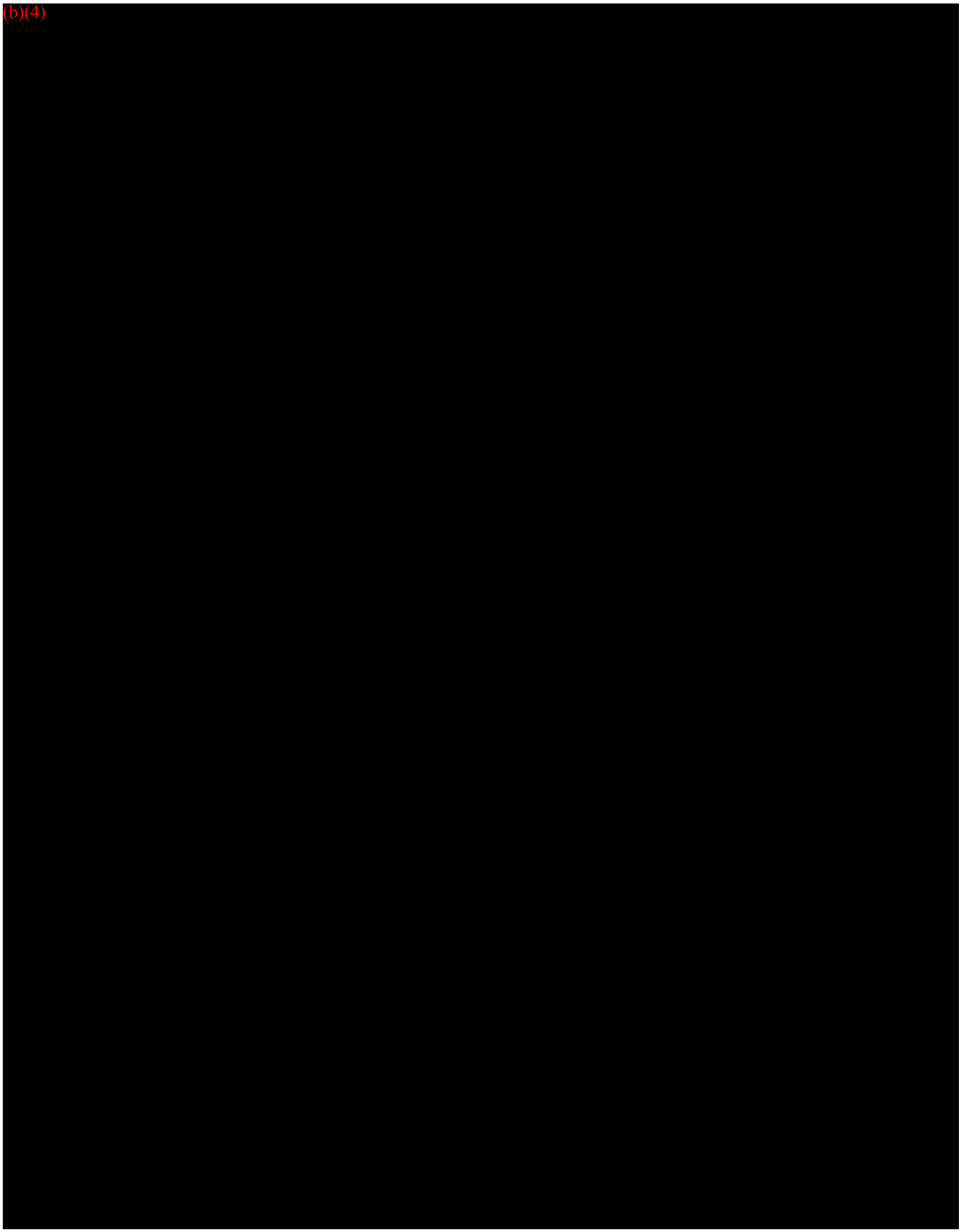

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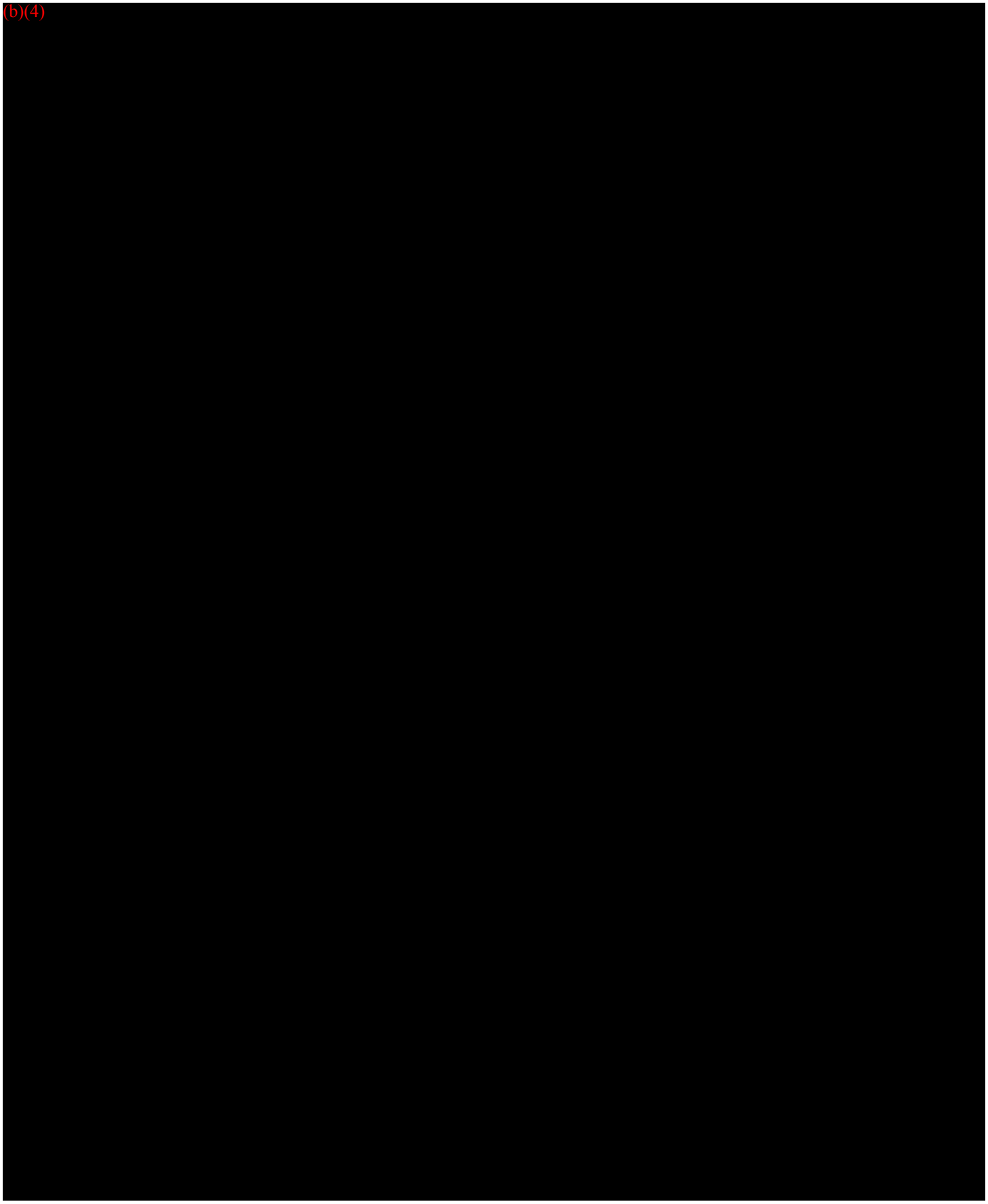

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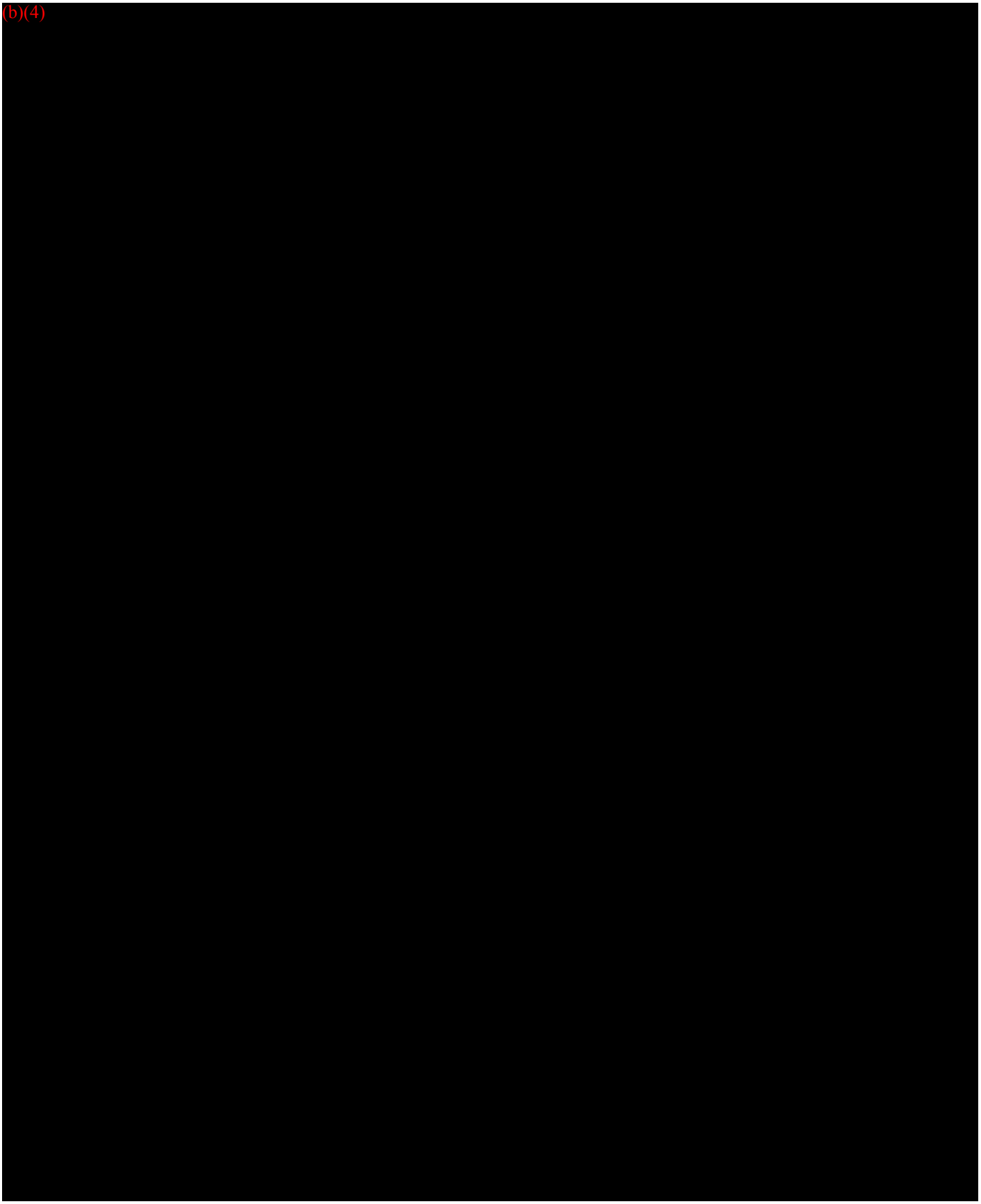

ATTACHMENT A: (b)(4) – SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION

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ATTACHMENT B: (b)(4) – IRTS UNIT TEST RESULTS

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ATTACHMENT C: (b)(4) – IRTS SOFTWARE TEST REPORT

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ATTACHMENT D: DESIGN REVIEW BOARD MEETING MINUTES

(b)(4)Third Party Test Data

(b)(4)

ATTACHMENT H: FDA FORM 3881, INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Infrared Thermographic System (IRTS)

Indications for Use *(Describe)*

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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
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PRAStaff@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 I: LETTER 12/14/15 S001 WITHDRAWAL

December 14, 2015

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

Re: Withdraw Supplement S001 – 510(k) K152402/S001
Securus Medical Group, Inc.
IRTS System

DCC:

We request that supplement K152402/S001 be withdrawn. This supplement was received on 11/17/2015.

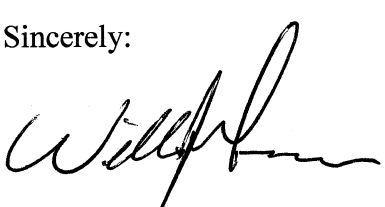
We request the ONLY the SUPPLEMENT K152402/S001 be withdrawn. We do not intend to withdraw the entire submission K152402.

Please inform the reviewer, William Burdick, of the receipt of this letter.

Should you have any questions pertaining to these responses please contact me at 978-317-0836. Please send written communications concerning this Notification to:

William J. Gorman
Securus Medical Group, Inc.
100 Cummings Center, Suite 215F
Beverly, MA 01915
Email: wgorman@securusmg.com

Sincerely:



William J. Gorman
Securus Medical Group, Inc.
978-317-0836

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

K152402
Securus Medical Group, Inc.
Trade Name: InfraRed Thermographic System (IRTS)

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

1. What is the purpose of employing a sensing probe to continually measure the surface temperature of the interior of the esophagus? Normally, a skin surface thermometer employed to measure **BODY TEMPERATURE** is placed at a site on the body surface to avoid having to be sterilized. If your product is intended to measure body temperature, please provide a peer-reviewed reference acceptable to the medical and scientific community that supports esophageal skin temperature as indicative of body temperature.

2. Please specify how your product is measuring body temperature. Is the probe in contact with the external skin of the esophagus and, thus, measures the temperature skin and correlates such a measurement to a body temperature measurement? Does it, instead, measure the temperature of the air in the esophagus and correlate that measurement to a body temperature?

3. You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.

4. You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of esophagitis in patients that use your device. In addition, the predicate device (K123361) you cited is provided sterile. Hence it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

5. Please provide the results from a clinical investigation that validates the accuracy of your device in measuring body temperature. The Agency is not aware of any clinical electronic thermometer that senses temperature from the esophagus and correlates these readings to that of patient body temperature. You may follow the specifications of the clinical investigation as cited in ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature.

6. You provided a specification for the temporal response for your thermometer of 2 °C in 2 s. However, the test measured the response time for the device to change 1.7 °C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend, instead, choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptancle criteria that will not create artificial bias, and discuss how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.

7. Your device labeling states the temperature range for your infrared temperature measurement is 39˚ C – 60˚ C. However, this entire range is higher than the typical core temperature for a human, approximately 37˚ C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.

8. You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency, and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

9. You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Indications for Use

10. The following are the indications for use you cited in your 510(k) submission for your product:

    The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature
measurement by quantifying differences in surface temperatures.

In none of these indications is there an actual medical indication for use. Your IRTS Thermal Imaging Probe (TIP) monitors esophageal temperature; however, what is not cited is if such temperature readings are associated with patient body temperature or the diagnosis or treatment of some other medical condition. The same can be said for the thermographic detector since quantifying the differences in esophageal surface temperature are not related to the diagnosis, treatment, or, even, medical condition of patients.

11. You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device; in other words, a device is not adjunctive to itself. To say so could create a false impression about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.

12. Your Indications for Use as cited in your 510(k) submission are not substantially equivalent (SE) to the indications for the legal predicates you cited in your 510(k) submission. Please either revise your indications for use or compare your current indications to that of a legally marketed medical device.

510(K) SUMMARY

K152402, INFRARED THERMOGRAPHIC SYSTEM (IRTS)

PREPARED: MARCH 3, 2016

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP)
IRTS Patient Monitoring Unit (PMU)
IRTS Patient Interface Unit (PIU)

Common name: Clinical Electronic Thermometer

Classification Number/ Classification name/Product code:
Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Special Controls:
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers, March 1993

3) Predicate Device

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361)

4) Reference Device

S-Cath Esophageal Temperature Probe and Temperature Monitoring System, Circa Scientific, (K112376)

5) Device Description

The Securus InfraRed Thermographic System (IRTS) is an esophageal temperature probe and monitoring system intended for continuous temperature monitoring of the patient's esophagus. The Probe includes a thermocouple sensor for temperature monitoring and a thermographic sensor for thermal imaging. Data from both sensors are displayed on a monitor for the user.

The InfraRed Thermographic System (IRTS) consists of three components:

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature monitoring through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. In addition, the IRTS incorporates a thermographic sensor and fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding esophageal tissue surface. The thermal data is presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as additional temperature monitoring features. The thermal data of the IRTS is not classified under the Clinical Thermometer designation of ISO 80601-2-56.

6) Indications for Use

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

7) Comparison to Predicate Device

The IRTS is substantially equivalent to the primary predicate device FIAB ESOTEST System (K123361). Both the subject device and the primary predicate device have the same intended use and indications for use as a continuous esophageal temperature monitor. Both use thermocouple sensors for temperature monitoring of the patients esophagus. The subject device also includes a thermographic sensor for displaying thermal images as an additional temperature monitoring feature. This feature does not raise different questions of safety or effectiveness as it provides additional information about the temperature in the patient's esophagus. Similar to reference device Circa Scientific, Esophageal Temperature Probe and Temperature Monitoring System (K112376), the subject device is provided non-sterile. Thus, the subject device has the same intended use and similar technological characteristics as the primary predicate device K123361. Any differences in technological characteristics do not raise different questions of safety or effectiveness. A summary comparison between the subject, primary predicate and reference devices is provided in the following table:

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Intended Use	Continuous temperature monitoring of the patients esophagus	Continuous temperature monitoring of the patients esophagus.	Continuous esophageal temperature monitoring	Same intended use

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Indications for Use	The IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.	Same indications as primary predicate
System Components	Temperature probe Patient Interface Unit Patient Monitoring Unit	Temperature probe Interconnect cable Patient Monitor	Temperature probe Interconnect cable Monitor	Similar components
Probe Sterility	Provided Non-sterile	Provided Sterile	Provided Non-sterile	Same as reference device
Probe Material (patient contact)	Polyethylene and platinum iridium	Polyurethane and stainless steel	Flexible Polyester and Rigid Pebax	Similar materials, tested for biocompatibility
Probe size	9 Fr catheter with 9 Fr sensor 150 cm length	7 Fr catheter with 11 Fr sensors 95 cm length	10 Fr OD, 30.5" total length. Interconnect Cable 10' long	Similar sizes
System Temperature Precision and Resolution	0.1° C	0.1° C	0.2° C	Similar precision and resolution.
Temperature Sensor	Type-T thermocouple	Type-T thermocouple	Thermistor	Similar sensor
Temperature Sensor Range	25° - 45° C	15°-75° C	25° - 45° C	Same range as reference device

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Temperature Sensor Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	± 0.5° C tested in accordance with ISO 80601-2-56	± 0.3° C tested in accordance with ISO 80601-2-56	Better accuracy than primary predicate device
Transient Response Time of Temperature Sensor	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Heating transient 7 seconds, cooling transient 4.5 seconds tested in accordance with ISO 80601-2-56	Insignificant time differential.
Power Supply	100-240 Vac AC adaptor power supply 24 VDC	100-120/230 Vac	100-240 Vac	Compliant to US power supply
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1:1998 (applicable sections)	Same standards

8) Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and

a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The IRTS has the same intended use, indications for use and similar technological characteristics as the primary predicate device K123361. Any difference in technological characteristics does not raise different questions of safety or effectiveness. The thermal imaging feature of the IRTS provides additional temperature monitoring of the patient's esophagus. The performance testing supports substantial equivalence of the IRTS to the predicate.

510(K) SUMMARY

K152402, INFRARED THERMOGRAPHIC SYSTEM (IRTS)

PREPARED: MARCH 3, 2016

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP)
IRTS Patient Monitoring Unit (PMU)
IRTS Patient Interface Unit (PIU)

Common name: Clinical Electronic Thermometer

Classification Number/ Classification name/Product code:
Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Special Controls:
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers, March 1993

3) Predicate Device

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361)

4) Reference Device

S-Cath Esophageal Temperature Probe and Temperature Monitoring System, Circa Scientific, (K112376)

5) Device Description

The Securus InfraRed Thermographic System (IRTS) is an esophageal temperature probe and monitoring system intended for continuous temperature monitoring of the patient's esophagus. The Probe includes a thermocouple sensor for temperature monitoring and a thermographic sensor for thermal imaging. Data from both sensors are displayed on a monitor for the user.

The InfraRed Thermographic System (IRTS) consists of three components:

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature monitoring through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. In addition, the IRTS incorporates a thermographic sensor and fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding esophageal tissue surface. The thermal data is presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as additional temperature monitoring features. The thermal data of the IRTS is not classified under the Clinical Thermometer designation of ISO 80601-2-56.

6) Indications for Use

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

7) Comparison to Predicate Device

The IRTS is substantially equivalent to the primary predicate device FIAB ESOTEST System (K123361). Both the subject device and the primary predicate device have the same intended use and indications for use as a continuous esophageal temperature monitor. Both use thermocouple sensors for temperature monitoring of the patients esophagus. The subject device also includes a thermographic sensor for displaying thermal images as an additional temperature monitoring feature. This feature does not raise different questions of safety or effectiveness as it provides additional information about the temperature in the patient's esophagus. Similar to reference device Circa Scientific, Esophageal Temperature Probe and Temperature Monitoring System (K112376), the subject device is provided non-sterile. Thus, the subject device has the same intended use and similar technological characteristics as the primary predicate device K123361. Any differences in technological characteristics do not raise different questions of safety or effectiveness. A summary comparison between the subject, primary predicate and reference devices is provided in the following table:

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Intended Use	Continuous temperature monitoring of the patients esophagus	Continuous temperature monitoring of the patients esophagus.	Continuous esophageal temperature monitoring	Same intended use

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Indications for Use	The IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.	Same indications as primary predicate
System Components	Temperature probe Patient Interface Unit Patient Monitoring Unit	Temperature probe Interconnect cable Patient Monitor	Temperature probe Interconnect cable Monitor	Similar components
Probe Sterility	Provided Non-sterile	Provided Sterile	Provided Non-sterile	Same as reference device
Probe Material (patient contact)	Polyethylene and platinum iridium	Polyurethane and stainless steel	Flexible Polyester and Rigid Pebax	Similar materials, tested for biocompatibility
Probe size	9 Fr catheter with 9 Fr sensor 150 cm length	7 Fr catheter with 11 Fr sensors 95 cm length	10 Fr OD, 30.5" total length. Interconnect Cable 10' long	Similar sizes
System Temperature Precision and Resolution	0.1° C	0.1° C	0.2° C	Similar precision and resolution.
Temperature Sensor	Type-T thermocouple	Type-T thermocouple	Thermistor	Similar sensor
Temperature Sensor Range	25° - 45° C	15°-75° C	25° - 45° C	Same range as reference device

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Temperature Sensor Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	± 0.5° C tested in accordance with ISO 80601-2-56	± 0.3° C tested in accordance with ISO 80601-2-56	Better accuracy than primary predicate device
Transient Response Time of Temperature Sensor	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Heating transient 7 seconds, cooling transient 4.5 seconds tested in accordance with ISO 80601-2-56	Insignificant time differential.
Power Supply	100-240 Vac AC adaptor power supply 24 VDC	100-120/230 Vac	100-240 Vac	Compliant to US power supply
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1:1998 (applicable sections)	Same standards

8) Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and

a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

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This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The IRTS has the same intended use, indications for use and similar technological characteristics as the primary predicate device K123361. Any difference in technological characteristics does not raise different questions of safety or effectiveness. The thermal imaging feature of the IRTS provides additional temperature monitoring of the patient's esophagus. The performance testing supports substantial equivalence of the IRTS to the predicate.

510(K) SUMMARY

K152402, INFRARED THERMOGRAPHIC SYSTEM (IRTS)

PREPARED: MARCH 3, 2016

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

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- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and

a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

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Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The IRTS has the same intended use, indications for use and similar technological characteristics as the primary predicate device K123361. Any difference in technological characteristics does not raise different questions of safety or effectiveness. The thermal imaging feature of the IRTS provides additional temperature monitoring of the patient's esophagus. The performance testing supports substantial equivalence of the IRTS to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

K152402/S001
Securus Medical Group, Inc.
Trade Name: InfraRed Thermographic System (IRTS)

Dear Mr. Gorman:

We have reviewed your supplemental response to the deficiencies we sent to on October 23, 2015. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on your responses to the deficiencies. To complete the review of your submission, we require the following additional information:

1. You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of esophagitis in patients that use your device. In addition, the predicate device (K123361) that you have stated that the subject device be in substantial equivalence provides their device in sterile form. Hence, it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

2. You explained your reasoning for using the LHQ product code and the device K073581 as a second predicate. We continue to believe there is a significant difference in intended use and technology between your device, which is implied internally, and the prior device, which is for an external thermal picture, as are the examples you cited. Please remove references to this product code and device from your 510(k) Summary as they are not appropriate and do not support substantial equivalence.

3. In your response to deficiency 9, you stated that one of the probes you tested showed signs of NURD. If significant distortion is possible for your device, the user should be made aware of the possibility and how it could affect their interpretation of the data. Please add a statement to your labeling describing the spatial accuracy and possible distortion to the user. This is needed so they can accurately evaluate the possible uses of the tool.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

K152402/S001
Securus Medical Group, Inc.
Trade Name: InfraRed Thermographic System (IRTS)

Dear Mr. Gorman:

This is to acknowledge receipt of your December 14, 2015 email requesting withdrawal of supplement S001 of K152402. Please also send a formal paper copy to the Agency (Document Control Center) requesting withdrawal of your supplement. Your submission will remain on HOLD status until the letter is received by the Agency.

You will receive another email informing you of your HOLD status with a Deficiencies List attached. The text of the email will also inform you that you have 180 days to submit your responses to the Agency. Please dismiss this statement since it is incorrect. This is an automatic email over which we have no control.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

March 4, 2016

Securus, Inc.
Mr. William Gorman
Director of Quality and Regulatory Affairs
100 Cummings Center, Suite 215f
Beverly, Massachusetts 01915

Re: K152402
Trade/Device Name: InfraRed Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), IRTS Patient Interface Unit (PIU)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometers
Regulatory Class: II
Product Code: FLL
Dated: January 27, 2016
Received: February 2, 2016

Dear Mr. Gorman:

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

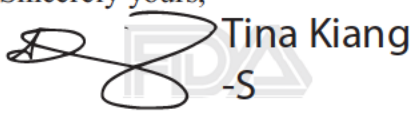
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,



for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152402

Device Name

Infrared Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), IRTS Patient Interface Unit (PIU)

Indications for Use *(Describe)*

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@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."

510(K) SUMMARY

K152402, INFRARED THERMOGRAPHIC SYSTEM (IRTS)

PREPARED: MARCH 3, 2016

1) Submitter

Securus Medical Group, Inc.
100 Cummings Center
Suite 215F
Beverly, MA 01915

Phone: 978-317-0836
Contact: William J. Gorman

2) Device

Trade name: InfraRed Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP)
IRTS Patient Monitoring Unit (PMU)
IRTS Patient Interface Unit (PIU)

Common name: Clinical Electronic Thermometer

Classification Number/ Classification name/Product code:
Clinical Electronic Thermometers are Class II devices under 21 CFR § 880.2910 and are classified by the General Hospital Panel. Product code - FLL.

Special Controls:
Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers, March 1993

3) Predicate Device

ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361)

4) Reference Device

S-Cath Esophageal Temperature Probe and Temperature Monitoring System, Circa Scientific, (K112376)

5) Device Description

The Securus InfraRed Thermographic System (IRTS) is an esophageal temperature probe and monitoring system intended for continuous temperature monitoring of the patient's esophagus. The Probe includes a thermocouple sensor for temperature monitoring and a thermographic sensor for thermal imaging. Data from both sensors are displayed on a monitor for the user.

The InfraRed Thermographic System (IRTS) consists of three components:

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature monitoring through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. In addition, the IRTS incorporates a thermographic sensor and fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding esophageal tissue surface. The thermal data is presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as additional temperature monitoring features. The thermal data of the IRTS is not classified under the Clinical Thermometer designation of ISO 80601-2-56.

6) Indications for Use

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

7) Comparison to Predicate Device

The IRTS is substantially equivalent to the primary predicate device FIAB ESOTEST System (K123361). Both the subject device and the primary predicate device have the same intended use and indications for use as a continuous esophageal temperature monitor. Both use thermocouple sensors for temperature monitoring of the patients esophagus. The subject device also includes a thermographic sensor for displaying thermal images as an additional temperature monitoring feature. This feature does not raise different questions of safety or effectiveness as it provides additional information about the temperature in the patient's esophagus. Similar to reference device Circa Scientific, Esophageal Temperature Probe and Temperature Monitoring System (K112376), the subject device is provided non-sterile. Thus, the subject device has the same intended use and similar technological characteristics as the primary predicate device K123361. Any differences in technological characteristics do not raise different questions of safety or effectiveness. A summary comparison between the subject, primary predicate and reference devices is provided in the following table:

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Intended Use	Continuous temperature monitoring of the patients esophagus	Continuous temperature monitoring of the patients esophagus.	Continuous esophageal temperature monitoring	Same intended use

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Indications for Use	The IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.	Same indications as primary predicate
System Components	Temperature probe Patient Interface Unit Patient Monitoring Unit	Temperature probe Interconnect cable Patient Monitor	Temperature probe Interconnect cable Monitor	Similar components
Probe Sterility	Provided Non-sterile	Provided Sterile	Provided Non-sterile	Same as reference device
Probe Material (patient contact)	Polyethylene and platinum iridium	Polyurethane and stainless steel	Flexible Polyester and Rigid Pebax	Similar materials, tested for biocompatibility
Probe size	9 Fr catheter with 9 Fr sensor 150 cm length	7 Fr catheter with 11 Fr sensors 95 cm length	10 Fr OD, 30.5" total length. Interconnect Cable 10' long	Similar sizes
System Temperature Precision and Resolution	0.1° C	0.1° C	0.2° C	Similar precision and resolution.
Temperature Sensor	Type-T thermocouple	Type-T thermocouple	Thermistor	Similar sensor
Temperature Sensor Range	25° - 45° C	15°-75° C	25° - 45° C	Same range as reference device

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System K123361 **Primary Predicate Device**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System K 112376 **Reference Device**	SE Discussion
Temperature Sensor Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	± 0.5° C tested in accordance with ISO 80601-2-56	± 0.3° C tested in accordance with ISO 80601-2-56	Better accuracy than primary predicate device
Transient Response Time of Temperature Sensor	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Heating transient 7 seconds, cooling transient 4.5 seconds tested in accordance with ISO 80601-2-56	Insignificant time differential.
Power Supply	100-240 Vac AC adaptor power supply 24 VDC	100-120/230 Vac	100-240 Vac	Compliant to US power supply
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1:1998 (applicable sections)	Same standards

8) Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility:

Probes were tested in accordance with ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. Testing included:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity

Test results show that the device meets the requirements of ISO 10993 for its intended use.

Electrical Safety and EMC:

The InfraRed Thermographic System (IRTS) was tested in accordance with:

- AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and

a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

This testing demonstrates that the InfraRed Thermographic System (IRTS) meets the recognized standards for electrical safety and compatibility.

Software Verification and Validation:

Per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", Securus has provided appropriate software documentation based on Level of Concern. A system level software verification and validation protocol was developed to test each requirement. This protocol includes a cross-reference matrix to map each requirement with a test activity and a pass/fail criteria. Results of each test are recorded and compared to the pass/fail criteria. All software verification and validation activities show that the software meets product requirements documentation.

Performance Testing:

The InfraRed Thermographic System (IRTS) was tested in accordance with the requirements of ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. Testing included accuracy and response time. All performance testing data shows that the IRTS system meets the requirements of ISO 80601-2-56.

Mechanical Testing:

Finished devices were tested in accordance with pre-approved protocols based on design input requirements for mechanical strength and service life (simulated use). This testing shows that the IRTS system meets pre-established design input requirements for mechanical strength and service life when tested in simulated worst case conditions.

Conclusions

The IRTS has the same intended use, indications for use and similar technological characteristics as the primary predicate device K123361. Any difference in technological characteristics does not raise different questions of safety or effectiveness. The thermal imaging feature of the IRTS provides additional temperature monitoring of the patient's esophagus. The performance testing supports substantial equivalence of the IRTS to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

K152402
Securus Medical Group, Inc.
Trade Name: InfraRed Thermographic System (IRTS)

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

1. What is the purpose of employing a sensing probe to continually measure the surface temperature of the interior of the esophagus? Normally, a skin surface thermometer employed to measure **BODY TEMPERATURE** is placed at a site on the body surface to avoid having to be sterilized. If your product is intended to measure body temperature, please provide a peer-reviewed reference acceptable to the medical and scientific community that supports esophageal skin temperature as indicative of body temperature.

2. Please specify how your product is measuring body temperature. Is the probe in contact with the external skin of the esophagus and, thus, measures the temperature skin and correlates such a measurement to a body temperature measurement? Does it, instead, measure the temperature of the air in the esophagus and correlate that measurement to a body temperature?

3. You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.

4. You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of esophagitis in patients that use your device. In addition, the predicate device (K123361) you cited is provided sterile. Hence it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

5. Please provide the results from a clinical investigation that validates the accuracy of your device in measuring body temperature. The Agency is not aware of any clinical electronic thermometer that senses temperature from the esophagus and correlates these readings to that of patient body temperature. You may follow the specifications of the clinical investigation as cited in ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature.

6. You provided a specification for the temporal response for your thermometer of 2 °C in 2 s. However, the test measured the response time for the device to change 1.7 °C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend, instead, choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptancle criteria that will not create artificial bias, and discuss how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.

7. Your device labeling states the temperature range for your infrared temperature measurement is 39˚ C – 60˚ C. However, this entire range is higher than the typical core temperature for a human, approximately 37˚ C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.

8. You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency, and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

9. You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Indications for Use

10. The following are the indications for use you cited in your 510(k) submission for your product:

    The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature
measurement by quantifying differences in surface temperatures.

In none of these indications is there an actual medical indication for use. Your IRTS Thermal Imaging Probe (TIP) monitors esophageal temperature; however, what is not cited is if such temperature readings are associated with patient body temperature or the diagnosis or treatment of some other medical condition. The same can be said for the thermographic detector since quantifying the differences in esophageal surface temperature are not related to the diagnosis, treatment, or, even, medical condition of patients.

11. You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device; in other words, a device is not adjunctive to itself. To say so could create a false impression about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.

12. Your Indications for Use as cited in your 510(k) submission are not substantially equivalent (SE) to the indications for the legal predicates you cited in your 510(k) submission. Please either revise your indications for use or compare your current indications to that of a legally marketed medical device.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/15/2015	MD6082465	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Securus , Inc.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	978 317 0836		
Street Address	**FAX Number *(including area code)***		
100 Cummings Center, Suite 215F			
City	**State / Province**	**ZIP/Postal Code**	**Country**
Beverly	MA	01915	USA
Contact Name			
William J. Gorman			
Contact Title	**Contact E-mail Address**		
Director of Quality and Regulatory Affairs	wgorman@securusmg.com		

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

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

PSC Publishing Services (301) 443-6740 EF

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	FLL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K123361	1	ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB	1	FIAB
2	K112376	2	S-Cath Esophageal Temperature Probe and Temperature Monitoring System	2	Circa Scientific
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Clinical electronic thermometer
Telethermographic system (adjunctive use)

	Trade or Proprietary or Model Name for This Device		Model Number
1	IRTS Thermal Imaging Probe (TIP)	1	A-10734
2	IRTS Patient Monitoring Unit (PMU)	2	A-10395
3	IRTS Patient Interface Unit (PIU)	3	A-10667
4	InfraRed Thermographic System (IRTS)	4	A-10734, A-10395, A-10667
5		5	

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

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

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
FLL	21 CFR § 880.2910 and 21 CFR § 884.2980	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

General Hospital Panel and Obstetrical and Gynecological Devices Panel

Indications *(from labeling)*

The IRTS Probe is intended for continuous esophageal temperature monitoring

The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

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

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Securus , Inc.		Establishment Registration Number	
Division Name *(if applicable)*: N/A		Phone Number *(including area code)*: 978 317 0836	
Street Address: 100 Cummings Center, Suite 215F		FAX Number *(including area code)*	
City: Beverly	State / Province: MA	ZIP Code: 01915	Country: USA
Contact Name: William Gorman	Contact Title: Director of Quality and Regulatory Affairs	Contact E-mail Address: wgorman@securusmg.com	

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

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

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ES60601-1	AAMI/ANSI	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	2005/(R)2012 and A1:2012	08/21/2012
2	60601-1-2	AAMI/ANSI/IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests	Edition 3: 2007-03	5/17/2007
3	80601-2-56:	ISO	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	First Edition 2009-10-01	10/1/2009
4	10993-1	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009 / (R) 2013	10/15/2009
5	10993-5	ISO	Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity	2009 / (R) 2014	06/01/2009
6	10993-10	ISO	Biological evaluation of medical Devices - Part 10: Tests for irritation and skin sensitization	2010	09/04/2010
7	14791	ISO	Application of risk management to medical devices	2007	10/01/2007

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

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

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

The burden time for this collection of information is estimated to average 0.5 hour 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
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K152402 Date Received by DCC: Aug 25, 2015

Lead Reviewer: William M. Burdick

Branch: GHDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation 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? 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 ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
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	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist)	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	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. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.			X	
B. Device Description				
10)				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
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 regulatory criteria through an alternative approach.	X			
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.	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.	X			
c) A list and description of each device for which clearance is requested.			X	
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	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. *Information regarding documenting preamendment status is available online.*	X			
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 comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	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))	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
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.	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).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)	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 effectiveness.			X	
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				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
× provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	×			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.				
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.				
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.).	×			
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. *Note, the sterilization validation report is not required.*	×			
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant 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.)	×			
e) Sterility Assurance Level (SAL) is stated.	×			
24) If the device, and/or accessory, and/or a component is end user sterilized:			×	
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.			×	
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.	×			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes sterility 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.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.				
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
X are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	X			
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)	X			
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).	X			
H. Software				
Submission states that the device: (one of the below must be checked)				
X does contain software/firmware.				
does not contain software/firmware.				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	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 submitter has provided an alternative approach with a rationale.	X			
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
X does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
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 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).	X			
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).	X			
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
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.	X			
37)				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
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, 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	
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
is an in vitro diagnostic device.				
X is not an in vitro diagnostic device.				

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	William M. Burdick -S Digitally signed by William M. Burdick -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300046193, cn=William M. Burdick -S Date: 2015.09.08 13:15:56 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Ave.
Silver Spring, MD 20993

Premarket Notification [510(k)] Consult (CON1519747)

K152402

Date: 10/14/2015
To: William Burdick — Office/Division: ODE/DAGRID/GHDB
From: Jessica Lamb — Office/Division: OIR/DRH/MUIS

Sponsor: Securus, Inc.
Device Name: IRTS Thermal Imaging Probe (TIP);IRTS Patient Monitoring Unit (PMU);IRTS Patient Interface Unit (PIU)

I. Purpose and Consult Summary

Securus, Inc would like to introduce the *InfraRed Thermographic system* into interstate commerce. The sponsor has listed the IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU) and IRTS Patient Interface Unit (PIU) as subject devices. They have listed two predicates, ESOTEST Esophageal Temperature Probe and Temperture monitoring system, (K123361) with product code FLL is the primary. ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ is secondary.

I was asked to provide a consult based on my experience with thermography devices. I reviewed the device description, the predicate comparison, and the labeling for descriptive information about the thermal performance. I also reviewed the testing in Appendices X, XI and XIV.

II. Indications for use and device description

Indications for use:

> *The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.*
> *The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.*
> *The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.*

The device consists of an internally applied single use probe that has two types of sensors; a temperature sensor and a thermal imaging probe. The sponsor combines these sensors, which they identify as belonging to two product codes/regulations, into a single device, as show in "Multiple Predicates Examples 4 and 5 in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]." I have not seen a thermal imaging device intended to be inserted in the esophagus before. Our branch reviews trans-esophageal diagnostic ultrasound devices. These are primarily used for cardiac measurements. They have a thermometer, similar to the subject device, but the purpose is to monitor the instrument temperature for safety reasons, not provide a diagnostic measurement that is complimentary to the imaging. I am less familiar with endoscopes intended for optical imaging in the esophagus; I have been told these may be used in cases of gastro-esophageal reflux disease and related conditions.

Since FLL is a class II product code and LHQ is class I, the sponsor has appropriately identified K123361 as the primary predicate. Also, the thermal imaging measurement is identified as adjunctive. However, the device description weights both components nearly equally. LHQ devices require 510(k) despite being class I because the diagnostic utility of the thermal image is easily misrepresented, and they are often improperly marketed. The lead reviewer should be aware that use of a thermography device as a primary diagnostic device is a *class III* indication for use under 21 CFR 884.2980.

The thermal imaging component of this device is sufficiently different than that used in K073581, and other devices I am aware of in LHQ, that it could not be found SE to the secondary predicate (LHQ) if it were standing alone, and it is not a good technological comparison to support substantial equivalence. The implication that such a standalone device could belong in that product code is undesirable. Since this is not the primary predicate, the deficiency will only require the sponsor to remove the secondary product code and predicate. It is up to the sponsor to demonstrate and lead reviewer to decide if substantial equivalence can be established with only the primary predicate. See DEFICIENCY 1.

It is not appropriate to indicate the thermal imaging is adjunctive to the thermal measurement. It is unusual to state directly what a diagnostic device is adjunctive to, although it is usually strongly implied to be a method or technology that is well established and understood. The thermal measurement does not have known diagnostic value, and does not provide any complimentary imaging information. It is better to indicate the whole device as adjunctive to other diagnostic tests. See DEFICIENCY 2.

III. Review of temperature measurement and imaging technology

Temperature sensor

The sponsor describes the temperature sensor as a "standard thermocouple" on page 16 of the submission. The display shows the temperature to a precision of 0.1° C; the device is not

expected to operate to this level of accuracy, but the expected accuracy is stated in the specification within the labeling. They state it has been tested in compliance with ISO 80601-2-56:2009, "Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement." I am not familiar with this standard, but the sponsor did provide a test report.

The test involved submerging three test probes and a reference thermometer in a water bath. The temperature bath was set to 26° C, 37° C and 44° C ±0.5° C. The temperature and humidity of the environment for the monitoring unit were also varied for a total of 45 measurement points. The acceptance criteria was for each measurement to be within ±0.3° C, the specification. All measurements passed. They were not statistically analyzed, but with 45 measurements this is acceptable. Enough measurements were collected to make a small amount of positive bias evident, but this is less than the specified accuracy.

The sponsor also measured the speed of the sensor response by transferring the device between water baths that differed by 2° C. The indicated response time is 2 s for a 2° C change in temperature. However, in order to measure this they recorded the time it took for the temperature to change by 1.7° C, since the device specification is within 3° C. This is not appropriate. DEFICIENCY 3.

Thermal imaging

The device contains an additional thermal imaging element. As stated above, a direct comparison between this feature and the devices in the LHQ product code is not supportable. However, I am not familiar with the breadth of the FLL product code or 21 CFR 880.2910, so I do not know if this could be SE to that regulation alone. To that end, these deficiencies in the thermal imaging specifications and performance data should be considered.

The infrared temperature range stated in the labeling is 39° C - 60° C. The range tested in Appendix XIV "Thermographic Accuracy Test" is slightly less. Given that human body temperature is 37° C, this range is not appropriate. DEFICIENCY 4.

From the information in the submission, spatial imaging is achieved by using a single imaging element, which is rotated and translated, so each time-point for data collection also corresponds to a different spatial location. The sponsor has not provided information about how these spatial locations are mapped, or the expected resolution of the device. DEFICIENCY 5. Although spatial imaging is depicted in the manual (page 18) it does not seem to have been tested directly. DEFICIENCY 6.

The sponsor tested the thermal accuracy using three different probes at three different target temperatures. They state the total data collection amounted to 9000 data points. They demonstrate that the 95% confidence intervals for the various groups are well within the target ±2° C specification. The thermal accuracy of the element does appear to be demonstrated, although for a high temperature range.

IV. Conclusions

I recommend the lead reviewer request additional information from the sponsor to address the deficiencies listed below. In particular, I do not believe the thermal imaging in this device is technologically similar to devices in the LHQ product code which are universally camera-like devices intended to measure external surface temperature patterns.

V. Deficiencies

1) You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.
2) You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device; in other words, a device is not adjunctive to itself. To say so could create a false impression about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.
3) You provided a specification for the temporal response for your thermometer of 2° C in 2 s. However, the test measured the response time for the device to change 1.7° C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend instead choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptance criteria that will not create artificial bias, and discuss how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.
4) Your device labeling states the temperature range for your infrared temperature measurement is 39° C – 60° C. However, this entire range is higher than the typical core temperature for a human, approximately 37° C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.
5) You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency,

and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

6) You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Digital Signature	
Jessica S. Lamb	Jessica S. Lamb -S (Affiliate) 2015.10.14 14:22:52 -04'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

CON1519748 for K152402
Biocompatibility Consult Review

Date: October 14, 2015

To: William Burdick

From: Kiros Hailemariam, Ph.D.

Through: Commander Elizabeth Claverie-Williams, MS, Branch Chief, Infection Control Devices Branch, DAGRID/ODE

Recommendations:

After review of the biocompatibility information in the 510(k) submission request for InfraRed Thermographic System (IRTS), a surface device with mucosal contact of limited exposure of <24 hours, we concluded that there are no outstanding issues (the results of the biocompatibility tests are acceptable).

Indications for use:

The InfraRed Thermographic System (IRTS) Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

Device Description:

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification. Esophageal temperature probes are Class II devices.

A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the

temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ.

The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition, the Probe incorporates adjunctive infrared thermal imaging to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to thethermocouple temperature and not intended as a diagnostic feature.

Reviewer Comment:

We have reviewed the biocompatibility data and information in the submission. The sponsor stated the parts of the IRTS system that contact body tissue are limited to the distal portion of the probe (distal sheath), which was used as a test article in the biocompatibility testing. The results of the cytotoxicity, irritation, and sensitization tests are acceptable.

Kiros Hailemariam, Ph.D.
Reviewer

Kiros F. Hailemariam -S

Digitally signed by Kiros F. Hailemariam -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300424723, cn=Kiros F. Hailemariam -S
Date: 2015.10.14 19:07:42 -04'00'

October 14, 2015
Date

Commander Elizabeth Claverie-Williams, MS
Branch Chief

Clarence W. Murray III -S

October 14, 2015
Date

CON1519748

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152402

Device Name

Infrared Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), IRTS Patient Interface Unit (PIU)

Indications for Use *(Describe)*

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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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:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152402

Device Name

Infrared Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), IRTS Patient Interface Unit (PIU)

Indications for Use *(Describe)*

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe.

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K152402

Date: March 3, 2016
To: The Record
From: William M. Burdick and Robert Meyer

Office: HFZ-480
Division: DAGRID/GHDB

510(k) Holder: Securus Medical Group, Inc.
Device Name: InfraRed Thermographic System (IRTS)
Contact: William Gorman
Phone: 978-317-0836
Fax: N/A
Email: wgorman@securusmg.com

I, Robert Meyer, presumed responsibility for this file on February 2, 2016 and at this point was on day 59 of the submission process. After review of the information provided by William M. Burdick and the consults he assigned I conclude the Sponsor has adequately demonstrated that the proposed device is substantially equivalent to the predicate device which they have noted.

I. Purpose and Submission Summary

Securus Medical Group, Inc would like to introduce the InfraRed Thermographic System (IRTS) into interstate commerce.

Appropriate information addressing electromagnetic compatibility (EMC), and electrical, mechanical, and thermal safety is provided.

Acceptable protocols, pass/fail criteria, and results for bench testing are provided.

No clinical information is submitted. Please refer to the Deficiencies section. **After review of the AINN response received on November 11, 2015 I, Robert Meyer, have determined Clinical data is not necessary because the device is considered a Direct Thermometer, which per ISO 80601-2-56 does not require clinical testing for compliance.**

Descriptions of the packaging as well as the labeling on the packaging are provided. A copy of the Directions for Use (DFU) is also provided.

The sponsor claims that the legal predicates and references are the following:

- ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361).
- Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System (K113376)

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form	x		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted shorter than 30 days)?	x		
Does the device design use software?	x		
Is the device sterile?		x	
Is the device reusable (not reprocessed single use)? *Are "cleaning" instructions included for the end user?*		x	

Device Description & Principles of Operation
The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, a single use esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification.

Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ. A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

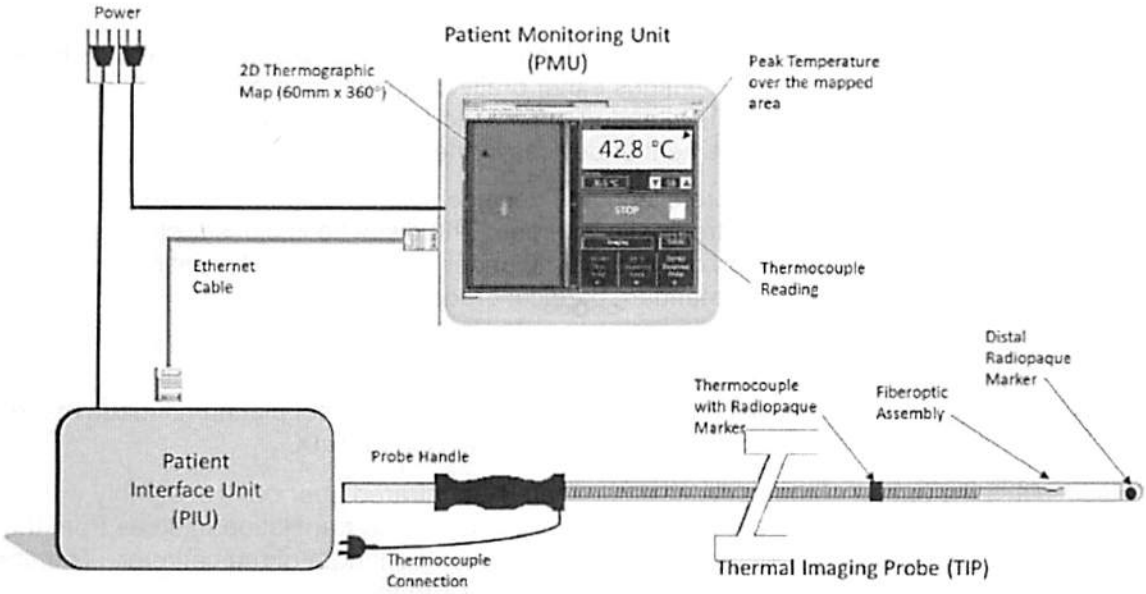


Figure 2: System Overview Diagram

Appendix IX includes drawings with specifications for the system components. The sub-sections below include detailed description of each component.

The InfraRed Thermographic System (IRTS) presented in Figure 2, consists of three components:

a. Patient Monitoring Unit (PMU)

The PMU is an off-the-shelf medical grade computer used to display a custom designed User Interface (UI). The UI is touch screen enabled and designed to be very simple to operate. All user controls and settings are contained in the UI on a single screen. The PMU is designed as a dedicated system limiting all other computer related functionality. In addition to the UI, the software executes high-level control and monitoring of the system as well as signal processing of the data. The PMU presents both a thermocouple reading and the 2-dimensional infrared thermal map including the peak temperature over the mapped area. All temperature readings are displayed in degrees Celsius. The PMU is powered by a 24-volt DC medical grade isolated power supply. See Figure 3 on the following pages and Appendix IX.

b. Patient Interface Unit (PIU)

The PIU is a custom medical device containing the thermocouple interface, infrared detector, motion system, custom electronics and software. The thermocouple interface collects the temperature data from the thermocouple of the Probe. The infrared detector converts the self-emanating infrared energy collected from the Probe into an electrical signal (voltage). The motion system provides the means to scan and collect the infrared energy over 360° by 60mm segment of the inner lumen of the esophagus. The custom hardware, electronics and software include all monitoring and control of the system. The PIU connects to the PMU with a standard Ethernet cable. The cable facilitates all communication and data transfer between the devices. The PIU is powered by a 24-volt DC medical grade isolated power supply.

See Figure 4 on the following pages and Appendix IX.

c. Thermal Imaging Probe (TIP/Probe)

The Probe is an individually packaged 9 French non-sterile, single-use esophageal catheter. It is designed to be inserted into the esophagus either orally or nasally and positioned under fluoroscopic guidance. The Probe is intended to be used outside the sterile field by clinical professionals familiar with the placement of devices in the esophagus.

The Probe is approximately 1.5 meters long and designed with a smooth and flexible outer shaft with a soft, formable distal tip for atraumatic insertion. The distal tip is closed, encapsulating a radiopaque marker for visualization of the distal tip under fluoroscopy. The entire length of the Probe shaft is made from industry standard medical grade polyethylene.

The Probe handle and thermocouple connector are plugged into the PIU at the time of use. The Probe incorporates a standard thermocouple for providing continuous temperature readings from the esophagus. The thermocouple is positioned at the proximal platinum iridium marker bank and is under fluoroscopy. See Figure 5 below and Appendix IX.

Sealed within the lumen of the catheter outer shaft is an infrared fiber optic assembly with a torque coil. The torque coil is used to transfer the rotational and translational forces from the motion system in the PIU to the fiber optic assembly over the length of the catheter. The fiber optic assembly passively collects, at a right-angle to the Probe shaft, the infrared energy as it radiates from the esophageal tissue. The fiber optic assembly collects the infrared energy and presents the energy to the detector housed in the PIU. See Figure 6 below for detailed views of the distal end of the Probe and fiber optic assembly with torque coil. No electrical energy is directed down the Probe. The Probe cannot be disassembled and is single use only. The fiber optic assembly is completely enclosed within the catheter shaft. Only the polyethylene catheter shaft and the radiopaque platinum iridium marker band contact the patient.

During operation the torque coil and fiber optic assembly simultaneously and continuously translate and rotate within the lumen of the outer shaft. This action creates a helical scan covering a 360° by 60mm long segment of the esophageal wall. The collected thermal data is transferred to, and displayed on, the PMU as a color two- dimensional thermal map of the inner surface of the esophagus. The peak temperature over the scanned area is updated each 60mm pass or once every second. See Figure 5 on the following page and Appendix IX.

Figure 3: Patient Monitoring Unit (PMU)

Figure 4: Patient Interface Unit (PIU)

Figure 5: Thermal Imaging Probe (Probe)

Figure 6: Distal Probe Detail – Fiber Optic Assembly

IVa. Indications for Use

Subject Device:

The IRTS Probe is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (C°) from the IRTS Thermal Imaging Probe

Predicate Device:
K123361

ESOTEST Probe
Esotest probe is intended for continuous esophageal temperature monitoring.

ESOTEST Monitor
Esotest monitor is intended for display continuous temperature measurement (°C) from 3 sensors temperature probe.

Reference Device:
K112376

S-Cath Esophageal Temperature Probe and Temperature Monitoring System, Circa Scientific

Indications for Use: The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.

Comparison:

The Indications for Use of the noted predicate and reference are comparable, with exception to the note of the utilization of 3 and 12 sensors respectively in the temperature probe.

IVb. 510(k) Summary / 510(k) Statement

The Sponsor has worked interactively with the review team on March 2, 2016 and ultimately has provided a 510(k) Summary which is deemed acceptable.

V. Predicate Device Comparison

	Securus Medical Group, Inc., IRTS System **Subject Device**	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) **Primary Predicate**	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System (K112376) **Reference Device**
Intended Use	Continuous temperature monitoring of the patients esophagus.	Continuous temperature monitoring of the patients esophagus.	Continuous esophageal temperature monitoring.
Indications for Use	The IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe.	The ESOTEST Probe is intended for continuous esophageal temperature monitoring. ESOTEST Monitor is intended to display continuous temperature measurement (°C) from 3 sensors temperature probe.	The Esophageal Temperature Probe is intended for continuous patient temperature monitoring. The radiopaque probe is designed for placement in the esophagus. Temperature Monitor: Display continuous temperature measurement (°C) from 12-sensor temperature probe.
System Components	Temperature probe 9 Fr Patient Interface Unit (PIU) Patient Monitoring Unit (PMU)	Temperature probe 7 Fr Interconnect cable Patient Monitor	Temperature probe 10 Fr Interconnect cable Monitor
Probe Sterility	Provided non-sterile	Provided sterile	Provided non-sterile
Route of Insertion	Oral or Nasal	Oral or Nasal	Oral or Nasal
Probe Material (patient contact)	Polyethylene and platinum iridium	Polyurethane and stainless steel	Flexible Polyester and Rigid Pebax
Probe Size	9 Fr catheter with 9 Fr sensor 150 cm length	7 Fr catheter with 11 Fr sensors 95 cm length	10 Fr, 50 cm length (tip to Y connector) Interconnect Cable 10' long
System Temperature Precision and Resolution	0.1° C	0.1° C	0.2° C

	Securus Medical Group, Inc., IRTS System Subject Device	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) Primary Predicate	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System (K112376) Reference Device
Temperature Sensor	Type-T thermocouple	Type-T thermocouple	Thermistor
Thermocouple Sensor Signal Processing and Display	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LCD display	Temperature is a function of thermocouple voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LED display	Temperature is a function of thermistor voltage Temperature displayed in 0.1° C increments User selected alarm limit displayed on LCD display
Thermocouple Sensor Range	25° - 45° C	15° - 75° C	25° - 45° C
Thermocouple Sensor Accuracy	± 0.3° C tested in accordance with ISO 80601-2-56	± 0.5° C tested in accordance with ISO 80601-2-56	± 0.3° C tested in accordance with ISO 80601-2-56
Transient Response Time of Temperature Sensor	Both heating transient response time and cooling transient response time are less than 2.5 seconds: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Both heating transient response time and cooling transient response time are approximately 1 second: time for probe plunged from reference bath to a water bath with a 2° C differential. tested in accordance with ISO 80601-2-56	Heating transient 7 seconds, cooling transient 4.5 seconds tested in accordance with ISO 80601-2-56
Infrared Detector Technology	Stirling cooled MCT	N/A	N/A
Infrared Signal Processing and Display	Relative display of color graphical image representing infrared radiation emitted from the body.	N/A	N/A
Infrared Temperature Range	35° - 60° C	N/A	N/A
Infrared Temperature Accuracy	IR: ± 2° C	N/A	N/A
Infrared Temperature Resolution	0.1° C	N/A	N/A
Infrared Image Field of View	360°	N/A	N/A

	Securus Medical Group, Inc., IRTS System Subject Device	FIAB, ESOTEST Esophageal Temperature Probe and Temperature Monitoring System (K123361) Primary Predicate	Circa Scientific, Esophageal Rectal Temperature Probe and Temperature Monitoring System (K112376) Reference Device
Spectral Response	8-11μm	N/A	N/A
Thermal Image Size	128 x 60 array	N/A	N/A
Power Supply	100-240 Vac AC adaptor power supply 24 VDC	100-120/230 Vac	AC adaptor power supply 12 VDC
Electrical Safety and Electromagnetic Compatibility	Fully complies with IEC 60601-1:2005 +A1:2012 IEC 60601-1-2:2007	Fully complies with IEC UL 60601-1: 2006 IEC 60601-1-2:2007	Fully complies with IEC 60601-1-1 IEC 60601-1-2
Data Output	Data provided to the supplied monitor for display	Data provided to the supplied monitor for display	Digital USB 2.0 to user computer

After review, I Robert Meyer have concluded that the predicate comparison table provided by the Sponsor is adeqaute. The not applicable notes are acceptable, as the predicate and references devices do not utilize infrared features, yet these features meet ISO 80601-2-56 standard specifications.

VI. Labeling

Acceptable labeling and packaging information is provided. Please refer to Appendix XV.

VII. Sterilization/Shelf Life/Reuse

I solicited a sterility consult from Dr. Kapil Panguluri. We discussed the issues over the telephone, came to certain conclusions, and Dr. Panguluri summarized the final issues and his assessment in the following email:

Dear Bill,
In the subject device submission the sponsor did not provide any sterilization validation information. I believe the oral cavity and to some extent the esophageal region would contain bacteria and as such non-sterile areas. However, introduction of other microbes such as yeast into the esophageal region through the use of non-sterile devices could lead to esophagitis and hence the firm should provide the device sterile. Moreover the predicate device (K123361) is provided sterile and hence it is an expectation that the subject device be provided sterile as well.

The subject device is stated to have Telethermographic system for diagnostic screening for the detection of breast cancer. In addition the probe is used to thermal map of the surrounding esophageal tissues by infrared fiber optic assembly to collect the radiation emanating from surrounding tissue surface. The firm further states that the probe scans 360^0 by 60 mm long segment of the esophagus and the thermal data is presented as a two dimensional color map with peak temperature over the mapped area. Although the firm states that this data is offered as an adjunct to the thermocouple temperature and not intended as a diagnostic feature, this reviewer believes that this claim alone trips the limits of present classification for such devices.

Please see my deficiency with regards to sterilization:

- You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of esophagitis in patients that use your device. In addition, the predicate device (K123361) that you have stated that the subject device be in substantial equivalence provides their device in sterile form. Hence it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

Thanks for discussing this issue in length in today's telecom meeting and I can be available for further discussions, if you have any on my review above.

Thanks

Regards

Kapil

Agency Assessment

Dr. Panguluri's deficiency will be conveyed to the sponsor.

On March 2, 2016 Dr. Panguluri completed his review of the Sponsors response regarding the aforementioned sterility deficiency, and deems the response adequate.

Shelf Life

The sponsor has not provided any shelf life claims in the labeling or elsewhere in the submission.

Reuse

The device is not reusable.

VIII. Biocompatibility

I solicited a biocompatibility consult from Dr. Kiros Hailemariam. His consult review is provided verbatim on the following pages.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

CON1519748 for K152402
Biocompatibility Consult Review

Date: October 14, 2015
To: William Burdick
From: Kiros Hailemariam, Ph.D.
Through: Commander Elizabeth Claverie-Williams, MS, Branch Chief, Infection Control Devices Branch, DAGRID/ODE

Recommendations:

After review of the biocompatibility information in the 510(k) submission request for InfraRed Thermographic System (IRTS), a surface device with mucosal contact of limited exposure of <24 hours, we concluded that there are no outstanding issues (the results of the biocompatibility tests are acceptable).

Indications for use:

The InfraRed Thermographic System (IRTS) Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

Device Description:

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification. Esophageal temperature probes are Class II devices.

A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the

temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ.

The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition, the Probe incorporates adjunctive infrared thermal imaging to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to thethermocouple temperature and not intended as a diagnostic feature.

Reviewer Comment:

We have reviewed the biocompatibility data and information in the submission. The sponsor stated the parts of the IRTS system that contact body tissue are limited to the distal portion of the probe (distal sheath), which was used as a test article in the biocompatibility testing. The results of the cytotoxicity, irritation, and sensitization tests are acceptable.

Kiros Hailemariam, Ph.D.
Reviewer

Kiros F. Hailemariam -S

Digitally signed by Kiros F. Hailemariam -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300424723, cn=Kiros F. Hailemariam -S
Date: 2015.10.14 19:07:42 -04'00'

October 14, 2015
Date

Commander Elizabeth Claverie-Williams, MS
Branch Chief

Clarence W. Murray III -S

October 14, 2015
Date

Agency Assessment

The Agency concurs with Dr. Hailemariam's review. There are no outstanding biocompatibility issues regarding this submission.

IX. Software

William Burdick consulted Weihong Gu for assistance in reviewing the provided software documentation. Below is the consults review; the deficiencies from the first review appear to be sent to the Sponsor interactively and are included the consults memo. The Sponsor responded to all of the software deficiencies, and this information was reviewed again by Weihong Gu. After review it has been concluded that the provided software verification and validation is adequate for demonstrating the software will allow the device to function as intended.

Software Description:

The software controls PIU operations and interfaces with the PMU. The software controls all functions and the User Interface (UI).

The software is divided into several modules that each serves specific functions. Together the SW modules interpret data from the thermocouple and IR detector and display the data on the monitor. The GUI allows the clinician to control the system, set notifications, read temperature thermocouple data and visualize surface temperature variations graphically.

Specific input features include:

- Start imaging
- Stop imaging
- Stop movement of motors
- Threshold of user defined notification

Specific output features include

- Primary patient temperature measurement
- Peak infrared temperature measurement
- Adjunct 2-D color representation of thermal data
- System status
- Probe status

• Audible and visual notifications, triggered when peak infrared temperature exceeds user defined threshold.
• Audible and visual notifications, triggered when the system enters an error state.

The system software is installed on the Patient Monitoring Unit (PMU) and conducts high-level control of the system. It interacts with the firmware installed on the Patient Interface Unit (PIU). In general, the PMU software is the master, while the PIU firmware is the slave. The PMU software is responsible for:
• Handling input from the user
• Sending commands to the PIU
• Providing the user with thermal data and system status
• Verifying communication with the PIU
• Monitoring state-of-health of the PIU

Communication between the PIU and the PMU is 2-way, where:
• The PMU software sends high level commands to the PIU firmware.
• The PIU firmware receives and acts on these commands, initiating and monitoring hardware activities and status.
• The PIU firmware collects and sends status, thermal data, and state-of-device-health data to the PMU software.
• A heartbeat is shared between the two, verifying the communication channel is open and active.

The PIU firmware interfaces with the PIU hardware, controlling mechanical systems, collecting thermocouple and IR temperature data, and monitoring for hardware state-of-health and failures.

The sponsor has provided the software documentation in Section 16 of the submission for our review:
1. Level of Concern – Section 16.1, Moderate level of concern

The sponsor provided moderate level of concern. A failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. It is consistent with the predicate K073581.
2. Software Description – Section 16.2 *(Adequate)*

3. Device Hazard Analysis – Section 16.3 and Appendix IV *(Adequate)*

4. Software Requirements Specifications (SRS) – Section 16.4 and Appendix V *(Acceptable)*

5. Software Design Specification (SDS) – Section 16.6 and Appendix VI *(Adequate)*

6. Architecture Design Chart – Section 16.5 and Appendix VI *(Acceptable)*

7. Traceability Analysis – Section 16.7 and Appendix VII *(Acceptable)*

8. Verification and Validation Documentation – Section 16.9 and Appendix VIII ***(Inadequate)***

System level verification and validation (V&V) activities were conducted based on the Software Requirements Specification (SRS). Testing of the integration was performed at the module and at the system level. The software testing was performed on latest version 6.0.1 for both PIU and PMU. The

test report includes procedures, pass/fail criteria and results of each test were provided in Appendix VIII. All tests met the requirements.

It is not clear whether they have adequately tested for run-time errors such as buffer overruns, null pointer dereferences, race conditions, resource or memory leaks, and dangerous casts that are usually identified through static analysis. They need to provide results of software testing using a static analysis tool.

9. Development Environment Description – Section 16.8 ***(Inadequate)***

The sponsor stated the software has been developed and validated in accordance with medical device standards including ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes. However, they did not provide a summary of software life cycle development plan.
10. Revision Level History – Section 16.10 *(Adequate)*

11. Unresolved Anomalies (bugs) – Section 16.11 ***(Inadequate)***
The sponsor provided three unresolved anomalies. They have not provided the detailed information regarding these anomalies in the submission.

12. Release Version Number – Section 16.10 *(Adequate)*

Software PIU and PMU version: V6.0.1, 8/4/2015
S001/A001 modified:
The most current IRTS Software Version is 6.1.0.
Software deficiencies are listed in the following section. Lead reviewer is encouraged to include it in his additional information letter.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Electrical Safety and EMC

The purpose of this testing was to demonstrate that the InfraRed Thermographic System (IRTS) meets the requirements for electrical safety and electromagnetic compatibility.

Electrical safety testing was performed in accordance with:

AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Appendix XVI includes the report for testing in accordance with the standard. Electromagnetic compatibility Testing was performed in accordance with:

IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (3rd Edition).

Appendix XVII includes the protocol and certificate of EMI/EMC Compliance for testing in accordance with the standard.

This testing provides assurance that the InfraRed Thermographic System (IRTS) complies with applicable standards for electrical safety and electromagnetic compatibility.

See reports in Appendix XVI and Appendix XVII.

Mechanical and thermal safety are not concerns for this product.

XI. Performance Testing – Bench

The following sections provide a synopsis of the test methods and results for bench testing. Test reports are provided in Appendix as noted in the following table:

Section for synopsis	Name	Appendix for full report
Section 18.2	Accuracy per 80601-2-56	X
Section 18.3	Response Time per 80601-2-56	XI
Section 18.4	Mechanical Testing	XII
Section 18.5	Simulated Use Test	XIII
Section 18.6	Thermographic Accuracy Test	XIV

Accuracy Testing: *See Appendix X for full report.*

Purpose

To demonstrate the accuracy of the IRTS Probe is in compliance with (a) ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature and (b) Securus design input requirements.

Design Input Requirements

The accuracy requirements for the IRTS are derived from ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement: ± 0.3° in the range 25° to 45° C.

Procedure

Probes used in this design verification testing were manufactured in accordance with Securus product specifications.

The indicated temperature range is 25°C - 45°C. Testing was conducted at multiple temperature points inside the indicated range to ensure the accuracy at the range limits in accordance with the standard.

Temperature 1: 26°C (within 1°C of the lower limit of the indicated range)
Temperature 2: 37°C (approximate mid-point of the indicated range) Temperature 3: 44°C (within 1°C of the upper limit of the indicated range)

The indicated operating environment of the equipment is 15°C - 35°C and a relative humidity of 25% - 85%. Testing was be performed with the PIU at a range of environmental combinations in a controlled chamber in accordance with the standard. Five combinations of environmental conditions were tested.

Three (3) units were tested at each temperature point (3) and at each environmental condition (5) resulting in 45 data points.

Each thermocouple measurement was compared to the known water bath temperature.

Error was calculated in accordance with 80601-2-56-2009, 201.101.1 i. The error of an individual output temperature measurement is indicated by the equation error = IRTStemp – PRTtemp where IRTStemp is the output of the IRTS system and PRTtemp is the output of the reference thermometer.

Results
All 45 data points met the ISO standard for accuracy, ± 0.3° in the range 25° to 45° C. Environmental conditions tested did not affect the accuracy of the equipment.

Conclusion
The test data demonstrates that the IRTS meets ISO 80601-2-56 standards for accuracy in the intended operating environment. Additionally, the pre-established, clinically relevant, design input requirements for accuracy have been satisfied.

See Appendix X for full report.

Response Time Test *See Appendix XI for full report.*

Purpose
To demonstrate the response time of the IRTS Probe is in compliance with (a) ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature and (b) Securus Design Input Requirements.

Design Input Requirements

According to ISO 80601-2-56 the response time must be measured using the method described and must be specified on the product labeling (accompanying documents). The response time for the IRTS specified in the manual is 2 seconds.

ISO 80601-2-56 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement indicates the use of a calibrated water bath in a controlled laboratory test situation. Testing was conducted using two temperature-controlled water baths in accordance with the standard test method.

Procedure
Probes used in this design verification testing were manufactured in accordance with Securus product specifications.

Testing was performed using 3 calibrated water baths set at 35°, 37°, and 39° C in accordance with the ISO standard test method.

The probes were placed into the 37° bath and allowed to stabilize. Response time was measured from the time that the probe was removed from the 37° bath, placed into the 35° or

39° degree bath (for heating or cooling) and the monitoring system reported the new temperature.

Response time testing was performed using three units. Each unit was tested for 3 replicate runs in each direction (rising and lowering temperature) creating a data set of nine data points for each transition and a total of 18 data points. 9 data points is sufficient to perform basic statistical analysis and capture test variability.

Results

The testing resulted in a range of response times, from 1.2 – 1.9 seconds for heating and 0.5 – 1.5 seconds for cooling.

The average response time for heating was 1.49 seconds with a standard deviation of 0.2 seconds (n=9).

The average response time for cooling was 0.8 seconds with a standard deviation of 0.3 seconds (n=9).

Conclusion

The test data demonstrates that the InfraRed Thermographic System (IRTS) meets the response time specified on the labeling accordance with ISO 80601-2-56 standards for response time. The pre-established, clinically relevant, design input requirements for response time have been satisfied.

The InfraRed Thermographic System (IRTS) response time is less than 2 seconds when tested in accordance with the ISO 80601-2-56 standard.

See Appendix XI for full report.

Mechanical Testing *(See Appendix XII for full report.)*

Purpose

The purpose of this study was to tensile test the joints in the IRTS Probe to ensure compliance with design input requirements.

Design Input Requirements

The IRTS probe is made up of a fiber optic assembly contained within an outer Sheath Assembly. The Sheath assembly contacts the patient and provides mechanical integrity for the IRTS probe. The inner fiber-optic assembly does not provide strength to the IRTS Probe. For this reason mechanical testing was be performed on the outer Sheath Assembly. The design of the Sheath Assembly is captured by part number A-10751 rev 01.

Tensile testing was performed with a crosshead speed of 20mm/min/mm. This speed is consistent with test methods used for indwelling catheters and provides time for observation of the failure mode during the test. All joints must withstand 3.37 lbs of force. This force represents the required minimum load for segments of single-use catheters with center lumen.

A T-Test was performed to ensure that the data supports a 95% confidence that the joints meet the required specification.

Procedure
Probes used in this design verification testing were manufactured in accordance with Securus product specifications.

This test involves applying tensile loads to specific joints in the Sheath Assembly (A-10751) and determining the break load. Each joint in the Sheath Assembly was subjected to tensile load until failure. All 7 joints were tested.

Ten units were tested to provide 70 data points (7 joints x 10 units).

Results

All 70 data points met the 3.37 lb force specification.

The T-Test shows that the data supports a 95 % confidence that each joint can meet the 3.37 lb. force specification.

Conclusion
The test data demonstrates that the IRTS probe meets mechanical requirements for tensile strength specified in the design input requirements.

See Appendix XII for full report.

Simulated Use Test *(See Appendix XIII for full report.)*

Purpose
The purpose of this test was to simulate the use of the InfraRed Thermography System (IRTS). The simulated use will be conducted with the latest versions of the TIP, PIU, and PMU used in accordance with the Instructions for Use.

Design Input Requirements
The IRTS consists of components listed below:

REF #	NAME	DESCRIPTION
A-10743	Probe Final Assembly (TIP)	Infrared imaging probe
A-10667	Patient Interface Unit (PIU)	Main system control unit
A-10395	Monitor (PMU)	Touchscreen monitor

This testing is designed to provide verification of design input requirements related to the simulated use of TIP A-10743, PIU A-10667 and PMU A-10395. Specifically, execution of the protocol verifies the requirements listed below:

x The TIP shall be designed for nasal or oral insertion.

- x The TIP shall be flexible enough to allow connection to the PIU.
- x The TIP shall endure the forces of insertion and removal.
- x The TIP shall have a functional life of 8hrs.
- x The distal tip of the TIP shall be flexible and formable.
- x The TIP shall scan with translate minimum of 5cm and rotate continuously.

To simulate anatomical positioning of the Probe in the patient a fixture called the Simulated Use Track has been developed. The Simulated Use Track is designed to simulate nasal insertion.

The probe is designed to display relative differences in surface temperature within the esophagus. To simulate a temperature range within the scanned area, a fixture has been built with capability of creating a temperature differential. This fixture will be set at designated differentials to test the basic performance and function of the device before and after the 8 hour run.

Reference temperatures will be set to simulate body temperature (approximately 37°C). For the purposes of this test, the reference temperature will be the temperature of a water bath.

Procedure
Obtain a PIU. Record PIU serial number and software revision. Set the water bath temperature to approximately 37°C.

Set up the system in accordance with the Manual, L-10730.

Insert the probe into the simulated use path and through the test fixture entrance hole. Position the probe such that the distal optic translating path is centered in the test fixture.

Connect probe in accordance with the IFU. Once prompted, press *Start Imaging* on the user interface shown on the PMU. Verify that there is an appropriate thermal image on the PMU.

Ensure the IRTS system continuously operates properly for the designated time (8 hours). Record any anomalies.

When system completes its scheduled duration of continuous operation, record total run-time and confirm Probe function at 5°C ΔT, 10°C ΔT, 20°C ΔT from nominal.

Results

The IRTS Probe demonstrated 8 hours of endurance including:

- The IRTS functioned properly after 8 hours in simulated use conditions.
- The peak temperature as reported by the IRTS did not drift more than +/- 2°C over the test temperature range.

The system operated in simulated use conditions when used in accordance with the Manual and IFU.

Conclusion

This test provides evidence that the IRTS functions in accordance with the Instructions For Use in simulated use conditions for the specified probe design life (8 hours).

See Appendix XIII for full report.

Thermographic Accuracy Test *See Appendix XIV for full report.*

Purpose
The purpose of this testing was to demonstrate that the Infrared Thermographic System (IRTS) meets the design input requirements related to IR Temperature Accuracy.

Design Input Requirements

The InfraRed Thermography System (IRTS) provides body temperature through the use of a standard thermocouple. In addition, the IRTS incorporates an infrared thermal imaging technology to provide a continuous, real-time, non-contact thermal map of the surrounding tissues. This thermal map is offered as an adjunct to the thermocouple temperature. The predicate device reports an accuracy of ±2° C.

The adjunctive thermographic IR temperature differential measurement must be accurate to ± 2° C in the operating range of 39-60° C.

Procedure
Probes used in this testing were manufactured and packaged in accordance with Securus product specifications.

The probes were placed into high precision Optikos Test Target Generator (TTG), where target temperature can be held to within +/- 0.001°C. Temperature representing the top, bottom and middle of the operating range were tested.

Testing was performed using 3 probes. Each combination of probe and temperature was repeated 10 times to create 90 data points. Each combination of Temperature and Probe will result in 1000 data points (9000 data points total).

Data was analyzed for each combination of Temperature and Probe including Mean and Standard Deviation.

A 95%/95% confidence interval was calculated for peak IR temperatures measured.

Results
All 9000 data points met the +/- 2.0 °C accuracy requirement.

Temperature measurements made by the IRTS matched the TTG temperature to within +/- 2.0 °C
with a 95%/95% confidence interval.

Conclusion
The test data demonstrates that the InfraRed Thermographic System (IRTS) thermographic camera meets the design input requirements related to IR Temperature Accuracy (+/- 2.0 °C).

See Appendix XIV for full report.

Thermal Scanning function
I solicited a consult from Dr. Jessica Lamb, physicist, to assess the thermal scanning function of the subject product. Below is her consult review provided verbatim.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Ave.
Silver Spring, MD 20993

Premarket Notification [510(k)] Consult (CON1519747)

K152402

Date: 10/14/2015
To: William Burdick — Office/Division: ODE/DAGRID/GHDB
From: Jessica Lamb — Office/Division: OIR/DRH/MUIS

Sponsor: Securus, Inc.
Device Name: IRTS Thermal Imaging Probe (TIP);IRTS Patient Monitoring Unit (PMU);IRTS Patient Interface Unit (PIU)

I. Purpose and Consult Summary

Securus, Inc would like to introduce the *InfraRed Thermographic system* into interstate commerce. The sponsor has listed the IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU) and IRTS Patient Interface Unit (PIU) as subject devices. They have listed two predicates, ESOTEST Esophageal Temperature Probe and Temperture monitoring system, (K123361) with product code FLL is the primary. ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ is secondary.

I was asked to provide a consult based on my experience with thermography devices. I reviewed the device description, the predicate comparison, and the labeling for descriptive information about the thermal performance. I also reviewed the testing in Appendices X, XI and XIV.

II. Indications for use and device description

Indications for use:

> *The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.*
> *The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.*
> *The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.*

The device consists of an internally applied single use probe that has two types of sensors; a temperature sensor and a thermal imaging probe. The sponsor combines these sensors, which they identify as belonging to two product codes/regulations, into a single device, as show in "Multiple Predicates Examples 4 and 5 in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]." I have not seen a thermal imaging device intended to be inserted in the esophagus before. Our branch reviews trans-esophageal diagnostic ultrasound devices. These are primarily used for cardiac measurements. They have a thermometer, similar to the subject device, but the purpose is to monitor the instrument temperature for safety reasons, not provide a diagnostic measurement that is complimentary to the imaging. I am less familiar with endoscopes intended for optical imaging in the esophagus; I have been told these may be used in cases of gastro-esophageal reflux disease and related conditions.

Since FLL is a class II product code and LHQ is class I, the sponsor has appropriately identified K123361 as the primary predicate. Also, the thermal imaging measurement is identified as adjunctive. However, the device description weights both components nearly equally. LHQ devices require 510(k) despite being class I because the diagnostic utility of the thermal image is easily misrepresented, and they are often improperly marketed. The lead reviewer should be aware that use of a thermography device as a primary diagnostic device is a *class III* indication for use under 21 CFR 884.2980.

The thermal imaging component of this device is sufficiently different than that used in K073581, and other devices I am aware of in LHQ, that it could not be found SE to the secondary predicate (LHQ) if it were standing alone, and it is not a good technological comparison to support substantial equivalence. The implication that such a standalone device could belong in that product code is undesirable. Since this is not the primary predicate, the deficiency will only require the sponsor to remove the secondary product code and predicate. It is up to the sponsor to demonstrate and lead reviewer to decide if substantial equivalence can be established with only the primary predicate. See DEFICIENCY 1.

It is not appropriate to indicate the thermal imaging is adjunctive to the thermal measurement. It is unusual to state directly what a diagnostic device is adjunctive to, although it is usually strongly implied to be a method or technology that is well established and understood. The thermal measurement does not have known diagnostic value, and does not provide any complimentary imaging information. It is better to indicate the whole device as adjunctive to other diagnostic tests. See DEFICIENCY 2.

III. Review of temperature measurement and imaging technology

Temperature sensor

The sponsor describes the temperature sensor as a "standard thermocouple" on page 16 of the submission. The display shows the temperature to a precision of 0.1° C; the device is not

expected to operate to this level of accuracy, but the expected accuracy is stated in the specification within the labeling. They state it has been tested in compliance with ISO 80601-2-56:2009, "Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement." I am not familiar with this standard, but the sponsor did provide a test report.

The test involved submerging three test probes and a reference thermometer in a water bath. The temperature bath was set to 26° C, 37° C and 44° C ±0.5° C. The temperature and humidity of the environment for the monitoring unit were also varied for a total of 45 measurement points. The acceptance criteria was for each measurement to be within ±0.3° C, the specification. All measurements passed. They were not statistically analyzed, but with 45 measurements this is acceptable. Enough measurements were collected to make a small amount of positive bias evident, but this is less than the specified accuracy.

The sponsor also measured the speed of the sensor response by transferring the device between water baths that differed by 2° C. The indicated response time is 2 s for a 2° C change in temperature. However, in order to measure this they recorded the time it took for the temperature to change by 1.7° C, since the device specification is within 3° C. This is not appropriate. DEFICIENCY 3.

Thermal imaging

The device contains an additional thermal imaging element. As stated above, a direct comparison between this feature and the devices in the LHQ product code is not supportable. However, I am not familiar with the breadth of the FLL product code or 21 CFR 880.2910, so I do not know if this could be SE to that regulation alone. To that end, these deficiencies in the thermal imaging specifications and performance data should be considered.

The infrared temperature range stated in the labeling is 39° C - 60° C. The range tested in Appendix XIV "Thermographic Accuracy Test" is slightly less. Given that human body temperature is 37° C, this range is not appropriate. DEFICIENCY 4.

From the information in the submission, spatial imaging is achieved by using a single imaging element, which is rotated and translated, so each time-point for data collection also corresponds to a different spatial location. The sponsor has not provided information about how these spatial locations are mapped, or the expected resolution of the device. DEFICIENCY 5. Although spatial imaging is depicted in the manual (page 18) it does not seem to have been tested directly. DEFICIENCY 6.

The sponsor tested the thermal accuracy using three different probes at three different target temperatures. They state the total data collection amounted to 9000 data points. They demonstrate that the 95% confidence intervals for the various groups are well within the target ±2° C specification. The thermal accuracy of the element does appear to be demonstrated, although for a high temperature range.

IV. Conclusions

I recommend the lead reviewer request additional information from the sponsor to address the deficiencies listed below. In particular, I do not believe the thermal imaging in this device is technologically similar to devices in the LHQ product code which are universally camera-like devices intended to measure external surface temperature patterns.

V. Deficiencies

1) You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.

2) You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device; in other words, a device is not adjunctive to itself. To say so could create a false impression

about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.

3) You provided a specification for the temporal response for your thermometer of 2° C in 2 s. However, the test measured the response time for the device to change 1.7° C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend instead choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptance criteria that will not create artificial bias, and discuss how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.

4) Your device labeling states the temperature range for your infrared temperature measurement is 39° C – 60° C. However, this entire range is higher than the typical core temperature for a human, approximately 37° C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.

5) You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency, and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

6) You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Digital Signature	
Jessica S. Lamb	Jessica S. Lamb -S (Affiliate) 2015.10.14 14:22:52 -04'00'

XII. Performance Testing – Animal

Not applicable

XIII. Performance Testing – Clinical

Not applicable

XV. Original Deficiencies sent October 23, 2015

The Sponsors has resolved deficiencies one (1) through twelve (12) listed below via documentation sent on November 17, 2015. The software deficiency response has been reviewed by Lening Shen who identified the deficiency, and he has confirmed the revisions are sufficient. Deficiencies three (3) through nine (9) were provided by consultant Jessica Lamb, and the associated responses were deemed acceptable by her according to her memo to Bill Burdick. Two additional deficiencies were provided in response by Jessica Lamb, and they are in the following deficiency section.

The following deficiencies will be sent to the sponsor via email.

1. What is the purpose of employing a sensing probe to continually measure the surface temperature of the interior of the esophagus? Normally, a skin surface thermometer employed to measure **BODY TEMPERATURE** is placed at a site on the body surface to avoid having to be sterilized. If your product is intended to measure body temperature, please provide a peer-reviewed reference acceptable to the medical and scientific community that supports esophageal skin temperature as indicative of body temperature.

2. Please specify how your product is measuring body temperature. Is the probe in contact with the external skin of the esophagus and, thus, measures the temperature skin and correlates such a measurement to a body temperature measurement? Does it, instead, measure the temperature of the air in the esophagus and correlate that measurement to a body temperature?

3. You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.

4. You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of esophagitis in patients that use your device. In addition, the predicate device (K123361) you

cited is provided sterile. Hence it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

5. Please provide the results from a clinical investigation that validates the accuracy of your device in measuring body temperature. The Agency is not aware of any clinical electronic thermometer that senses temperature from the esophagus and correlates these readings to that of patient body temperature. You may follow the specifications of the clinical investigation as cited in ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature.

6. You provided a specification for the temporal response for your thermometer of 2° Cin 2 s. However, the test measured the response time for the device to change 1.7° C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend instead choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptance criteria that will not create artificial bias, and discuss how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.

7. Your device labeling states the temperature range for your infrared temperature measurement is 39° C – 60° C. However, this entire range is higher than the typical core temperature for a human, approximately 37° C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.

8. You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency, and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

9. You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Indications for Use

10. The following are the indications for use you cited in your 510(k) submission for your product:

    The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

    The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

    The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

    In none of these indications is there an actual medical indication for use. Your IRTS Thermal Imaging Probe (TIP) monitors esophageal temperature; however, what is not cited is if such temperature readings are associated with patient body temperature or the diagnosis or treatment of some other medical condition. The same can be said for the thermographic detector since quantifying the differences in esophageal surface temperature are not related to the diagnosis, treatment, or, even, medical condition of patients.

11. You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device; in other words, a device is not adjunctive to itself. To say so could create a false impression about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.

12. Your Indications for Use as cited in your 510(k) submission are not substantially equivalent (SE) to the indications for the legal predicates you cited in your 510(k) submission. Please either revise your indications for use or compare your current indications to that of a legally marketed medical device.

XVI. Deficiencies sent December 13, 2015

The Sponsors has resolved the deficiencies listed below via documentation sent on February 2, 2015. The sterility deficiency response has been reviewed by Kapil Panguluri who identified the deficiency, and he has confirmed the revisions are sufficient. The response to deficiencies two (2) and three are adequate; the Sponsor is no longer referencing the noted predicate, and has thoroughly demonstrated equivalence to another referenced device. In response to deficiency #3 the Sponsor has noted associated additions to the product labeling which acceptably negate the deficiency concerns, thus they are considered acceptable to me, Robert Meyer.

1. You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of esophagitis in patients that use your device. In addition, the predicate device (K123361) that you have stated that the subject device be in substantial equivalence provides their device in sterile form. Hence, it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

2. You explained your reasoning for using the LHQ product code and the device K073581 as a second predicate. We continue to believe there is a significant difference in intended use and technology between your device, which is implied internally, and the prior device, which is for an external thermal picture, as are the examples you cited. Please remove references to this product code and device from your 510(k) Summary as they are not appropriate and do not support substantial equivalence.

3. In your response to deficiency 9, you stated that one of the probes you tested showed signs of NURD. If significant distortion is possible for your device, the user should be made aware of the possibility and how it could affect their interpretation of the data. Please add a statement to your labeling describing the spatial accuracy and possible distortion to the user. This is needed so they can accurately evaluate the possible uses of the tool.

XVII. Contact History

By way of background, a summary of the regulatory history for the IRTS is provided below:

- Securus submitted the current 510(k) notice K152402 for the IRTS on August 20, 2015. There were no prior submissions for the IRTS.
- FDA placed the file on administrative hold on October 23, 2015, and requested additional information from the company.
- The company responded to FDA's requests in its supplement submission K152402/S001 dated November 11, 2015. A copy of this response is provided in Attachment F.
- In an interactive review e-mail dated November 14, 2015, FDA requested additional information about the software in the IRTS.
- On November 19, 2105, the company provided its response to FDA's request as an amendment K152402/A001. A copy of this response is provided in Attachment G.
- In an e-mail dated December 13, 2015, FDA stated that the company would need to address three outstanding issues regarding the IRTS before the agency can make a substantial equivalence determination for the IRTS. However, given the limited time left to meet the target MDUFA III goal of 90 days on FDA's review clock, the agency provided four options:

    1) respond to FDA's requests for the three outstanding issues by close of business on December 14, 2015;
    2) officially request the withdrawal of supplement K152402/S001 and place the submission back on hold as of November 11, 2015;
    3) officially request the withdrawal of the entire 510(k) notice;
    4) May receive a Not Substantially Equivalent (NSE) decision.

- In order to adequately address the three outstanding issues and to avoid an adverse outcome, Securus officially requested the withdrawal of supplement K152402/S001 on December 14, 2015. A copy of this request is provided in Attachment I.

The Sponsor's latest response to the three (3) deficiencies noted above was received on February 2, 2016.

XVII. Recommendation

After reviewing the provided information and the Lead Reviewer's and consults thoughts it appears that the submission is substantially equivalent to the identified predicate and reference devices, thus the Sponsor should be notified accordingly.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Robert Meyer -S 2016.03.04 15:40:11 -05'00'
Branch Chief Sign-Off	

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K152402

Date: October 22, 2015
To: The Record
From: William M. Burdick

Office: HFZ-480
Division: DAGID/GHDB

510(k) Holder: Securus Medical Group, Inc.
Device Name: InfraRed Thermographic System (IRTS)
Contact: William Gorman
Phone: 978-317-0836
Fax: N/A
Email: wgorman@securusmg.com

I. Purpose and Submission Summary

Securus Medical Group, Inc would like to introduce the InfraRed Thermographic System (IRTS) into interstate commerce.

Appropriate information addressing electromagnetic compatibility (EMC), and electrical, mechanical, and thermal safety is provided.

Acceptable protocols, pass/fail criteria, and results for bench testing are provided.

No clinical information is submitted. Please refer to the Deficiencies section.

Descriptions of the packaging as well as the labeling on the packaging are provided. A copy of the Directions for Use (DFU) is also provided.

The sponsor claims that the legal predicates are the following:

- ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB, (K123361).
- ICI P and S Series IR Camera(s) and the IR Flash Software, Texas Infrared, (K073581).

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form	x		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted shorter than 30 days)?	x		
Does the device design use software?	x		
Is the device sterile?		x	
Is the device reusable (not reprocessed single use)? *Are "cleaning" instructions included for the end user?*		x	

Device Description & Principles of Operation

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, a single use esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification.

Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ. A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

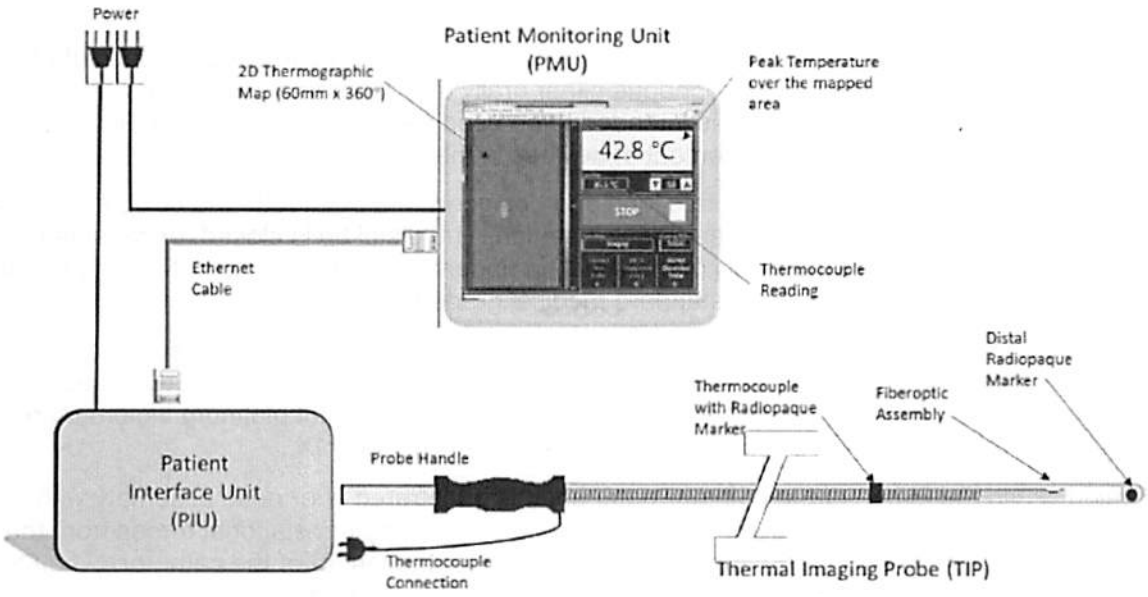


Figure 2: System Overview Diagram

Appendix IX includes drawings with specifications for the system components. The sub-sections below include detailed description of each component.

The InfraRed Thermographic System (IRTS) presented in Figure 2, consists of three components:

a. Patient Monitoring Unit (PMU)

The PMU is an off-the-shelf medical grade computer used to display a custom designed User Interface (UI). The UI is touch screen enabled and designed to be very simple to operate. All user controls and settings are contained in the UI on a single screen. The PMU is designed as a dedicated system limiting all other computer related functionality. In addition to the UI, the software executes high-level control and monitoring of the system as well as signal processing of the data. The PMU presents both a thermocouple reading and the 2-dimensional infrared thermal map including the peak temperature over the mapped area. All temperature readings are displayed in degrees Celsius. The PMU is powered by a 24-volt DC medical grade isolated power supply. See Figure 3 on the following pages and Appendix IX.

b. Patient Interface Unit (PIU)

The PIU is a custom medical device containing the thermocouple interface, infrared detector, motion system, custom electronics and software. The thermocouple interface collects the temperature data from the thermocouple of the Probe. The infrared detector converts the self-emanating infrared energy collected from the Probe into an electrical signal (voltage). The motion system provides the means to scan and collect the infrared energy over 360° by 60mm segment of the inner lumen of the esophagus. The custom hardware, electronics and software include all monitoring and control of the system. The PIU connects to the PMU with a standard Ethernet cable. The cable facilitates all communication and data transfer between the devices. The PIU is powered by a 24-volt DC medical grade isolated power supply.

See Figure 4 on the following pages and Appendix IX.

c. Thermal Imaging Probe (TIP/Probe)

The Probe is an individually packaged 9 French non-sterile, single-use esophageal catheter. It is designed to be inserted into the esophagus either orally or nasally and positioned under fluoroscopic guidance. The Probe is intended to be used outside the sterile field by clinical professionals familiar with the placement of devices in the esophagus.

The Probe is approximately 1.5 meters long and designed with a smooth and flexible outer shaft with a soft, formable distal tip for atraumatic insertion. The distal tip is closed, encapsulating a radiopaque marker for visualization of the distal tip under fluoroscopy. The entire length of the Probe shaft is made from industry standard medical grade polyethylene.

The Probe handle and thermocouple connector are plugged into the PIU at the time of use. The Probe incorporates a standard thermocouple for providing continuous temperature readings from the esophagus. The thermocouple is positioned at the proximal platinum iridium marker bank and is under fluoroscopy. See Figure 5 below and Appendix IX.

Sealed within the lumen of the catheter outer shaft is an infrared fiber optic assembly with a torque coil. The torque coil is used to transfer the rotational and translational forces from the motion system in the PIU to the fiber optic assembly over the length of the catheter. The fiber optic assembly passively collects, at a right-angle to the Probe shaft, the infrared energy as it radiates from the esophageal tissue. The fiber optic assembly collects the infrared energy and presents the energy to the detector housed in the PIU. See Figure 6 below for detailed views of the distal end of the Probe and fiber optic assembly with torque coil. No electrical energy is directed down the Probe. The Probe cannot be disassembled and is single use only. The fiber optic assembly is completely enclosed within the catheter shaft. Only the polyethylene catheter shaft and the radiopaque platinum iridium marker band contact the patient.

During operation the torque coil and fiber optic assembly simultaneously and continuously translate and rotate within the lumen of the outer shaft. This action creates a helical scan covering a 360° by 60mm long segment of the esophageal wall. The collected thermal data is transferred to, and displayed on, the PMU as a color two- dimensional thermal map of the inner surface of the esophagus. The peak temperature over the scanned area is updated each 60mm pass or once every second. See Figure 5 on the following page and Appendix IX.

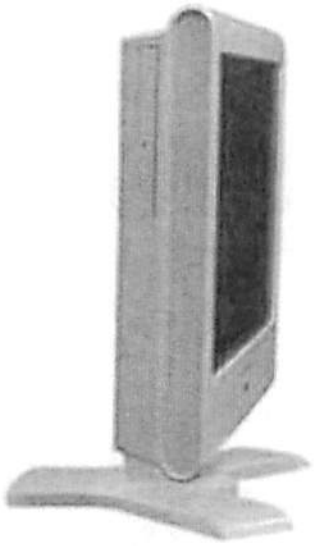


Figure 3: Patient Monitoring Unit (PMU)

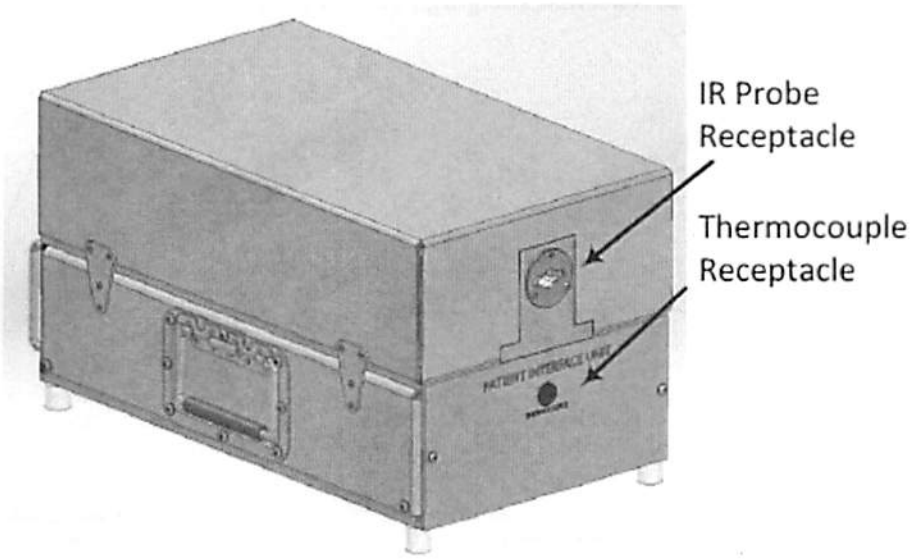


Figure 4: Patient Interface Unit (PIU)

Figure 5: Thermal Imaging Probe (Probe)

Figure 6: Distal Probe Detail – Fiber Optic Assembly

IVa. Indications for Use

Subject Device:

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring. The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

Predicate Devices:

K123361

ESOTEST Probe
Esotest probe is intended for continuous esophageal temperature monitoring.

ESOTEST Monitor
Esotest monitor is intended for display continuous temperature measurement (°C) from 3 sensors temperature probe.

K073581

The ICI Series P and S IR Cameras, which provides capture of skin surface temperature of any part of the body, and the IR Flash Software version1.0, which provides visualization and reporting functionalities, are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature.

Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.

Comparison:

The indications for the use of the subject product are not the same as for either of the predicates. Furthermore, the indications for use of the subject device does not specify a MEDICAL use. Please refer to the Deficiencies section.

IVb. 510(k) Summary / 510(k) Statement

The sponsor has provided its 510(k) Statement in Section 4 of the submission:

			YES	NO	N/A
Required Elements for 510(k) Summary (21 CFR 807.92)					
	Clearly labeled "510(k) Summary"		X		
	Submitter' s name, address, phone #, a contact person		X		
	Date the summary was prepared		X		
	The name of the device/trade name/common name/classification name		X		
	An identification of the legally marketed Predicate		X		
	Description of the subject device				
	Statement of intended use(identical to indications for use)				
	Tec hnol	*if same, a summary of comparison of technological characters*			X

			YES	NO	N/A
		If different, a summary of how do they compare to the Predicate	X		
	Performance Data	*Brief discussion of non-clinical data submitted, referenced, or relied on*	X		
		Brief discussion of clinical data submitted, referenced, or relied on, including: ▪ *Description upon whom the device was tested,* ▪ *Data obtained from the tests and especially:* ▪ *Adverse events and complications* ▪ *Other information for SE determination*			X
		Conclusion that data demonstrate SE	X		
Required Elements for 510(k) Statement (21 CFR 807.93)					
	Signed verbatim statement				X

V. Predicate Device Comparison

Not applicable since deficiencies exist.

VI. Labeling

Acceptable labeling and packaging information is provided. Please refer to Appendix XV.

VII. Sterilization/Shelf Life/Reuse

I solicited a sterility consult from Dr. Kapil Panguluri. We discussed the issues over the telephone, came to certain conclusions, and Dr. Panguluri summarized the final issues and his assessment in the following email:

Dear Bill,
In the subject device submission the sponsor did not provide any sterilization validation information. I believe the oral cavity and to some extent the esophageal region would contain bacteria and as such non-sterile areas. However, introduction of other microbes such as yeast into the esophageal region through the use of non-sterile devices could lead to esophagitis and hence the firm should provide the device sterile. Moreover the predicate device (K123361) is provided sterile and hence it is an expectation that the subject device be provided sterile as well.

The subject device is stated to have Telethermographic system for diagnostic screening for the detection of breast cancer. In addition the probe is used to thermal map of the surrounding esophageal tissues by infrared fiber optic assembly to collect the radiation emanating from surrounding tissue surface. The firm further states that the probe scans 360^0 by 60 mm long segment of the esophagus and the thermal data is presented as a two dimensional color map with peak temperature over the mapped area. Although the firm states that this data is offered as an adjunct to the thermocouple temperature and not intended as a diagnostic feature, this reviewer believes that this claim alone trips the limits of present classification for such devices.

Please see my deficiency with regards to sterilization:

- You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of

esophagitis in patients that use your device. In addition, the predicate device (K123361) that you have stated that the subject device be in substantial equivalence provides their device in sterile form. Hence it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

Thanks for discussing this issue in length in today's telecom meeting and I can be available for further discussions, if you have any on my review above.

Thanks

Regards

Kapil

Agency Assessment

Dr. Panguluri's deficiency will be conveyed to the sponsor.

Shelf Life

The sponsor has not provided any shelf life claims in the labeling or elsewhere in the submission.

Reuse

The device is not reusable.

VIII. Biocompatibility

I solicited a biocompatibility consult from Dr. Kiros Hailemariam. His consult review is provided verbatim on the following pages.

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

CON1519748 for K152402
Biocompatibility Consult Review

Date: October 14, 2015
To: William Burdick
From: Kiros Hailemariam, Ph.D.
Through: Commander Elizabeth Claverie-Williams, MS, Branch Chief, Infection Control Devices Branch, DAGRID/ODE

Recommendations:

After review of the biocompatibility information in the 510(k) submission request for InfraRed Thermographic System (IRTS), a surface device with mucosal contact of limited exposure of <24 hours, we concluded that there are no outstanding issues (the results of the biocompatibility tests are acceptable).

Indications for use:

The InfraRed Thermographic System (IRTS) Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) is intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

Device Description:

The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.

Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification. Esophageal temperature probes are Class II devices.

A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the

temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment. patient and equipment supports. component parts. and accessories. Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ.

The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)

B. Patient Interface Unit (PIU)

C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition. the Probe incorporates adjunctive infrared thermal imaging to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to thethermocouple temperature and not intended as a diagnostic feature.

Reviewer Comment:

We have reviewed the biocompatibility data and information in the submission. The sponsor stated the parts of the IRTS system that contact body tissue are limited to the distal portion of the probe (distal sheath). which was used as a test article in the biocompatibility testing. The results of the cytotoxicity. irritation. and sensitization tests are acceptable.

Kiros Hailemariam, Ph.D. Kiros F. Hailemariam -S Digitally signed by Kiros F. Hailemariam -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000424723, cn=Kiros F. Hailemariam -S Date: 2015.10.14 19:07:42 -04'00' October 14, 2015
Reviewer Date

Commander Elizabeth Claverie-Williams, MS Clarence W. Murray III III -S October 14, 2015
Branch Chief Date

Agency Assessment

The Agency concurs with Dr. Hailemariam's review. There are no outstanding biocompatibility issues regarding this submission.

IX. Software

Unfortunately, I did not realize that software is a component of the subject product, so a consult review is not provided. A consult request will be forwarded to the appropriate expert, shortly.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Electrical Safety and EMC

The purpose of this testing was to demonstrate that the InfraRed Thermographic System (IRTS) meets the requirements for electrical safety and electromagnetic compatibility.

Electrical safety testing was performed in accordance with:

AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Appendix XVI includes the report for testing in accordance with the standard. Electromagnetic compatibility Testing was performed in accordance with:

IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (3rd Edition).

Appendix XVII includes the protocol and certificate of EMI/EMC Compliance for testing in accordance with the standard.

This testing provides assurance that the InfraRed Thermographic System (IRTS) complies with applicable standards for electrical safety and electromagnetic compatibility.

See reports in Appendix XVI and Appendix XVII.

Mechanical and thermal safety are not concerns for this product.

XI. Performance Testing – Bench

The following sections provide a synopsis of the test methods and results for bench testing. Test reports are provided in Appendix as noted in the following table:

Section for synopsis	Name	Appendix for full report
Section 18.2	Accuracy per 80601-2-56	X
Section 18.3	Response Time per 80601-2-56	XI
Section 18.4	Mechanical Testing	XII
Section 18.5	Simulated Use Test	XIII
Section 18.6	Thermographic Accuracy Test	XIV

Accuracy Testing: *See Appendix X for full report.*

Purpose

To demonstrate the accuracy of the IRTS Probe is in compliance with (a) ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature and (b) Securus design input requirements.

Design Input Requirements

The accuracy requirements for the IRTS are derived from ISO 80601-2-56 first Edition 2009-10-01: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement: ± 0.3° in the range 25° to 45° C.

Procedure

Probes used in this design verification testing were manufactured in accordance with Securus product specifications.

The indicated temperature range is 25°C - 45°C. Testing was conducted at multiple temperature points inside the indicated range to ensure the accuracy at the range limits in accordance with the standard.

Temperature 1: 26°C (within 1°C of the lower limit of the indicated range)
Temperature 2: 37°C (approximate mid-point of the indicated range) Temperature 3: 44°C (within 1°C of the upper limit of the indicated range)

The indicated operating environment of the equipment is 15°C - 35°C and a relative humidity of 25% - 85%. Testing was be performed with the PIU at a range of environmental combinations in a controlled chamber in accordance with the standard. Five combinations of environmental conditions were tested.

Three (3) units were tested at each temperature point (3) and at each environmental condition (5) resulting in 45 data points.

Each thermocouple measurement was compared to the known water bath temperature.

Error was calculated in accordance with 80601-2-56-2009, 201.101.1 i. The error of an individual output temperature measurement is indicated by the equation error = IRTStemp – PRTtemp where IRTStemp is the output of the IRTS system and PRTtemp is the output of the reference thermometer.

Results
All 45 data points met the ISO standard for accuracy, ± 0.3° in the range 25° to 45° C. Environmental conditions tested did not affect the accuracy of the equipment.

Conclusion
The test data demonstrates that the IRTS meets ISO 80601-2-56 standards for accuracy in the intended operating environment. Additionally, the pre-established, clinically relevant, design input requirements for accuracy have been satisfied.

See Appendix X for full report.

Response Time Test *See Appendix XI for full report.*

Purpose
To demonstrate the response time of the IRTS Probe is in compliance with (a) ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature and (b) Securus Design Input Requirements.

Design Input Requirements

According to ISO 80601-2-56 the response time must be measured using the method described and must be specified on the product labeling (accompanying documents). The response time for the IRTS specified in the manual is 2 seconds.

ISO 80601-2-56 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement indicates the use of a calibrated water bath in a controlled laboratory test situation. Testing was conducted using two temperature-controlled water baths in accordance with the standard test method.

Procedure
Probes used in this design verification testing were manufactured in accordance with Securus product specifications.

Testing was performed using 3 calibrated water baths set at 35°, 37°, and 39° C in accordance with the ISO standard test method.

The probes were placed into the 37° bath and allowed to stabilize. Response time was measured from the time that the probe was removed from the 37° bath, placed into the 35° or 39° degree bath (for heating or cooling) and the monitoring system reported the new temperature.

Response time testing was performed using three units. Each unit was tested for 3 replicate runs in each direction (rising and lowering temperature) creating a data set of nine data points for each transition and a total of 18 data points. 9 data points is sufficient to perform basic statistical analysis and capture test variability.

Results

The testing resulted in a range of response times, from 1.2 – 1.9 seconds for heating and 0.5 – 1.5 seconds for cooling.

The average response time for heating was 1.49 seconds with a standard deviation of 0.2 seconds (n=9).

The average response time for cooling was 0.8 seconds with a standard deviation of 0.3 seconds (n=9).

Conclusion

The test data demonstrates that the InfraRed Thermographic System (IRTS) meets the response time specified on the labeling accordance with ISO 80601-2-56 standards for response time. The pre-established, clinically relevant, design input requirements for response time have been satisfied.

The InfraRed Thermographic System (IRTS) response time is less than 2 seconds when tested in accordance with the ISO 80601-2-56 standard.

See Appendix XI for full report.

Mechanical Testing *(See Appendix XII for full report.)*

Purpose

The purpose of this study was to tensile test the joints in the IRTS Probe to ensure compliance with design input requirements.

Design Input Requirements

The IRTS probe is made up of a fiber optic assembly contained within an outer Sheath Assembly. The Sheath assembly contacts the patient and provides mechanical integrity for the IRTS probe. The inner fiber-optic assembly does not provide strength to the IRTS Probe. For this reason mechanical testing was be performed on the outer Sheath Assembly. The design of the Sheath Assembly is captured by part number A-10751 rev 01.

Tensile testing was performed with a crosshead speed of 20mm/min/mm. This speed is consistent with test methods used for indwelling catheters and provides time for observation of the failure mode during the test. All joints must withstand 3.37 lbs of force. This force represents the required minimum load for segments of single-use catheters with center lumen.

A T-Test was performed to ensure that the data supports a 95% confidence that the joints meet the required specification.

Procedure
Probes used in this design verification testing were manufactured in accordance with Securus product specifications.

This test involves applying tensile loads to specific joints in the Sheath Assembly (A-10751) and determining the break load. Each joint in the Sheath Assembly was subjected to tensile load until failure. All 7 joints were tested.

Ten units were tested to provide 70 data points (7 joints x 10 units).

Results

All 70 data points met the 3.37 lb force specification.

The T-Test shows that the data supports a 95 % confidence that each joint can meet the 3.37 lb. force specification.

Conclusion
The test data demonstrates that the IRTS probe meets mechanical requirements for tensile strength specified in the design input requirements.

See Appendix XII for full report.

Simulated Use Test *(See Appendix XIII for full report.)*

Purpose
The purpose of this test was to simulate the use of the InfraRed Thermography System (IRTS). The simulated use will be conducted with the latest versions of the TIP, PIU, and PMU used in accordance with the Instructions for Use.

Design Input Requirements
The IRTS consists of components listed below:

REF #	NAME	DESCRIPTION
A-10743	Probe Final Assembly (TIP)	Infrared imaging probe
A-10667	Patient Interface Unit (PIU)	Main system control unit
A-10395	Monitor (PMU)	Touchscreen monitor

This testing is designed to provide verification of design input requirements related to the simulated use of TIP A-10743, PIU A-10667 and PMU A-10395. Specifically, execution of the protocol verifies the requirements listed below:

- x The TIP shall be designed for nasal or oral insertion.
- x The TIP shall be flexible enough to allow connection to the PIU.
- x The TIP shall endure the forces of insertion and removal.
- x The TIP shall have a functional life of 8hrs.

x The distal tip of the TIP shall be flexible and formable.
x The TIP shall scan with translate minimum of 5cm and rotate continuously.

To simulate anatomical positioning of the Probe in the patient a fixture called the Simulated Use Track has been developed. The Simulated Use Track is designed to simulate nasal insertion.

The probe is designed to display relative differences in surface temperature within the esophagus. To simulate a temperature range within the scanned area, a fixture has been built with capability of creating a temperature differential. This fixture will be set at designated differentials to test the basic performance and function of the device before and after the 8 hour run.

Reference temperatures will be set to simulate body temperature (approximately 37°C). For the purposes of this test, the reference temperature will be the temperature of a water bath.

Procedure
Obtain a PIU. Record PIU serial number and software revision. Set the water bath temperature to approximately 37°C.

Set up the system in accordance with the Manual, L-10730.

Insert the probe into the simulated use path and through the test fixture entrance hole. Position the probe such that the distal optic translating path is centered in the test fixture.

Connect probe in accordance with the IFU. Once prompted, press *Start Imaging* on the user interface shown on the PMU. Verify that there is an appropriate thermal image on the PMU.

Ensure the IRTS system continuously operates properly for the designated time (8 hours). Record any anomalies.

When system completes its scheduled duration of continuous operation, record total run-time and confirm Probe function at 5°C ΔT, 10°C ΔT, 20°C ΔT from nominal.

Results

The IRTS Probe demonstrated 8 hours of endurance including:

- The IRTS functioned properly after 8 hours in simulated use conditions.
- The peak temperature as reported by the IRTS did not drift more than +/- 2°C over the test temperature range.

The system operated in simulated use conditions when used in accordance with the Manual and IFU.

Conclusion

This test provides evidence that the IRTS functions in accordance with the Instructions For Use in simulated use conditions for the specified probe design life (8 hours).

See Appendix XIII for full report.

Thermographic Accuracy Test *See Appendix XIV for full report.*

Purpose
The purpose of this testing was to demonstrate that the Infrared Thermographic System (IRTS) meets the design input requirements related to IR Temperature Accuracy.

Design Input Requirements

The InfraRed Thermography System (IRTS) provides body temperature through the use of a standard thermocouple. In addition, the IRTS incorporates an infrared thermal imaging technology to provide a continuous, real-time, non-contact thermal map of the surrounding tissues. This thermal map is offered as an adjunct to the thermocouple temperature. The predicate device reports an accuracy of ±2° C.

The adjunctive thermographic IR temperature differential measurement must be accurate to ± 2° C in the operating range of 39-60° C.

Procedure
Probes used in this testing were manufactured and packaged in accordance with Securus product specifications.

The probes were placed into high precision Optikos Test Target Generator (TTG), where target temperature can be held to within +/- 0.001°C. Temperature representing the top, bottom and middle of the operating range were tested.

Testing was performed using 3 probes. Each combination of probe and temperature was repeated 10 times to create 90 data points. Each combination of Temperature and Probe will result in 1000 data points (9000 data points total).

Data was analyzed for each combination of Temperature and Probe including Mean and Standard Deviation.

A 95%/95% confidence interval was calculated for peak IR temperatures measured.

Results
All 9000 data points met the +/- 2.0 °C accuracy requirement.

Temperature measurements made by the IRTS matched the TTG temperature to within +/- 2.0 °C
with a 95%/95% confidence interval.

Conclusion
The test data demonstrates that the InfraRed Thermographic System (IRTS) thermographic camera meets the design input requirements related to IR Temperature Accuracy (+/- 2.0 °C).

See Appendix XIV for full report.

Thermal Scanning function

I solicited a consult from Dr. Jessica Lamb, physicist, to assess the thermal scanning function of the subject product. Below is her consult review provided verbatim.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Ave.
Silver Spring, MD 20993

Premarket Notification [510(k)] Consult (CON1519747)

K152402

Date: 10/14/2015
To: William Burdick — Office/Division: ODE/DAGRID/GHDB
From: Jessica Lamb — Office/Division: OIR/DRH/MUIS

Sponsor: Securus, Inc.
Device Name: IRTS Thermal Imaging Probe (TIP);IRTS Patient Monitoring Unit (PMU);IRTS Patient Interface Unit (PIU)

I. Purpose and Consult Summary

Securus, Inc would like to introduce the *InfraRed Thermographic system* into interstate commerce. The sponsor has listed the IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU) and IRTS Patient Interface Unit (PIU) as subject devices. They have listed two predicates, ESOTEST Esophageal Temperature Probe and Temperture monitoring system, (K123361) with product code FLL is the primary. ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ is secondary.

I was asked to provide a consult based on my experience with thermography devices. I reviewed the device description, the predicate comparison, and the labeling for descriptive information about the thermal performance. I also reviewed the testing in Appendices X, XI and XIV.

II. Indications for use and device description

Indications for use:

> *The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.*
> *The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.*
> *The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.*

The device consists of an internally applied single use probe that has two types of sensors; a temperature sensor and a thermal imaging probe. The sponsor combines these sensors, which they identify as belonging to two product codes/regulations, into a single device, as show in "Multiple Predicates Examples 4 and 5 in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]." I have not seen a thermal imaging device intended to be inserted in the esophagus before. Our branch reviews trans-esophageal diagnostic ultrasound devices. These are primarily used for cardiac measurements. They have a thermometer, similar to the subject device, but the purpose is to monitor the instrument temperature for safety reasons, not provide a diagnostic measurement that is complimentary to the imaging. I am less familiar with endoscopes intended for optical imaging in the esophagus; I have been told these may be used in cases of gastro-esophageal reflux disease and related conditions.

Since FLL is a class II product code and LHQ is class I, the sponsor has appropriately identified K123361 as the primary predicate. Also, the thermal imaging measurement is identified as adjunctive. However, the device description weights both components nearly equally. LHQ devices require 510(k) despite being class I because the diagnostic utility of the thermal image is easily misrepresented, and they are often improperly marketed. The lead reviewer should be aware that use of a thermography device as a primary diagnostic device is a *class III* indication for use under 21 CFR 884.2980.

The thermal imaging component of this device is sufficiently different than that used in K073581, and other devices I am aware of in LHQ, that it could not be found SE to the secondary predicate (LHQ) if it were standing alone, and it is not a good technological comparison to support substantial equivalence. The implication that such a standalone device could belong in that product code is undesirable. Since this is not the primary predicate, the deficiency will only require the sponsor to remove the secondary product code and predicate. It is up to the sponsor to demonstrate and lead reviewer to decide if substantial equivalence can be established with only the primary predicate. See DEFICIENCY 1.

It is not appropriate to indicate the thermal imaging is adjunctive to the thermal measurement. It is unusual to state directly what a diagnostic device is adjunctive to, although it is usually strongly implied to be a method or technology that is well established and understood. The thermal measurement does not have known diagnostic value, and does not provide any complimentary imaging information. It is better to indicate the whole device as adjunctive to other diagnostic tests. See DEFICIENCY 2.

III. Review of temperature measurement and imaging technology

Temperature sensor

The sponsor describes the temperature sensor as a "standard thermocouple" on page 16 of the submission. The display shows the temperature to a precision of 0.1° C; the device is not

expected to operate to this level of accuracy, but the expected accuracy is stated in the specification within the labeling. They state it has been tested in compliance with ISO 80601-2-56:2009, "Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement." I am not familiar with this standard, but the sponsor did provide a test report.

The test involved submerging three test probes and a reference thermometer in a water bath. The temperature bath was set to 26° C, 37° C and 44° C ±0.5° C. The temperature and humidity of the environment for the monitoring unit were also varied for a total of 45 measurement points. The acceptance criteria was for each measurement to be within ±0.3° C, the specification. All measurements passed. They were not statistically analyzed, but with 45 measurements this is acceptable. Enough measurements were collected to make a small amount of positive bias evident, but this is less than the specified accuracy.

The sponsor also measured the speed of the sensor response by transferring the device between water baths that differed by 2° C. The indicated response time is 2 s for a 2° C change in temperature. However, in order to measure this they recorded the time it took for the temperature to change by 1.7° C, since the device specification is within 3° C. This is not appropriate. DEFICIENCY 3.

Thermal Imaging

The device contains an additional thermal imaging element. As stated above, a direct comparison between this feature and the devices in the LHQ product code is not supportable. However, I am not familiar with the breadth of the FLL product code or 21 CFR 880.2910, so I do not know if this could be SE to that regulation alone. To that end, these deficiencies in the thermal imaging specifications and performance data should be considered.

The infrared temperature range stated in the labeling is 39° C - 60° C. The range tested in Appendix XIV "Thermographic Accuracy Test" is slightly less. Given that human body temperature is 37° C, this range is not appropriate. DEFICIENCY 4.

From the information in the submission, spatial imaging is achieved by using a single imaging element, which is rotated and translated, so each time-point for data collection also corresponds to a different spatial location. The sponsor has not provided information about how these spatial locations are mapped, or the expected resolution of the device. DEFICIENCY 5. Although spatial imaging is depicted in the manual (page 18) it does not seem to have been tested directly. DEFICIENCY 6.

The sponsor tested the thermal accuracy using three different probes at three different target temperatures. They state the total data collection amounted to 9000 data points. They demonstrate that the 95% confidence intervals for the various groups are well within the target ±2° C specification. The thermal accuracy of the element does appear to be demonstrated, although for a high temperature range.

IV. Conclusions

I recommend the lead reviewer request additional information from the sponsor to address the deficiencies listed below. In particular, I do not believe the thermal imaging in this device is technologically similar to devices in the LHQ product code which are universally camera-like devices intended to measure external surface temperature patterns.

V. Deficiencies

1) You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.

2) You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device; in other words, a device is not adjunctive to itself. To say so could create a false impression

about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.

3) You provided a specification for the temporal response for your thermometer of 2° C in 2 s. However, the test measured the response time for the device to change 1.7° C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend instead choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptance criteria that will not create artificial bias, and discuss how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.

4) Your device labeling states the temperature range for your infrared temperature measurement is 39° C – 60° C. However, this entire range is higher than the typical core temperature for a human, approximately 37° C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.

5) You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency, and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

6) You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Digital Signature	
Jessica S. Lamb	Jessica S. Lamb -S (Affiliate) 2015.10.14 14:22:52 -04'00'

XII. Performance Testing – Animal

Not applicable.

XIII. Performance Testing – Clinical

Clinical testing was not provided. Please refer to the Deficiencies section.

XIV. Substantial Equivalence Discussion

Not applicable at this time since deficiencies exist.

XV. Deficiencies

The following deficiencies will be sent to the sponsor via email.

1. What is the purpose of employing a sensing probe to continually measure the surface temperature of the interior of the esophagus? Normally, a skin surface thermometer employed to measure **BODY TEMPERATURE** is placed at a site on the body surface to avoid having to be sterilized. If your product is intended to measure body temperature, please provide a peer-reviewed reference acceptable to the medical and scientific community that supports esophageal skin temperature as indicative of body temperature.

2. Please specify how your product is measuring body temperature. Is the probe in contact with the external skin of the esophagus and, thus, measures the temperature skin and correlates such a measurement to a body temperature measurement? Does it, instead, measure the temperature of the air in the esophagus and correlate that measurement to a body temperature?

3. You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.

4. You have stated that the subject InfraRed Thermographic System is not provided sterile. The Agency believes that the subject device should be provided sterile as there is a possibility of introducing extraneous organisms such as Yeast into the esophageal region which may contribute to the development of esophagitis in patients that use your device. In addition, the predicate device (K123361) you cited is provided sterile. Hence it is expected that the subject device is provided the same with respect to sterility. Please provide sterility validation studies for the subject device.

5. Please provide the results from a clinical investigation that validates the accuracy of your device in measuring body temperature. The Agency is not aware of any clinical electronic thermometer that senses temperature from the esophagus and correlates these readings to that of patient body temperature. You may follow the specifications of the clinical investigation as cited in ISO 80601-2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature.

6. You provided a specification for the temporal response for your thermometer of 2° Cin 2 s. However, the test measured the response time for the device to change 1.7° C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend instead choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptance criteria that will not create artificial bias, and discuss how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.

7. Your device labeling states the temperature range for your infrared temperature measurement is 39° C – 60° C. However, this entire range is higher than the typical core temperature for a human, approximately 37° C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.

8. You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency, and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

9. You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Indications for Use

10. The following are the indications for use you cited in your 510(k) submission for your product:

    The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

    The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe.

    The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

    In none of these indications is there an actual medical indication for use. Your IRTS Thermal Imaging Probe (TIP) monitors esophageal temperature; however, what is not cited is if such temperature readings are associated with patient body temperature or the diagnosis or treatment of some other medical condition. The same can be said for the thermographic detector since quantifying the differences in esophageal surface temperature are not related to the diagnosis, treatment, or, even, medical condition of patients.

11. You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device; in other words, a device is not adjunctive to itself. To say so could create a false impression about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.

12. Your Indications for Use as cited in your 510(k) submission are not substantially equivalent (SE) to the indications for the legal predicates you cited in your 510(k) submission. Please either revise your indications for use or compare your current indications to that of a legally marketed medical device.

XVI. Contact History

The sponsor will be sent an AI email with the deficiencies cited above.

XVII. Recommendation

Send the sponsor an AI email with the deficiencies cited above and place the submission on HOLD status.

_____ _____

Reviewer Date

_____ _____

Branch Chief Date

Digital Signature Concurrence Table	
Reviewer Sign-Off William M. Burdick	William M. Burdick -S Digitally signed by William M. Burdick -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300046193, cn=William M. Burdick -S Date: 2015.10.23 14:01:23 -04'00'
Branch Chief Sign-Off Richard Chapman	

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

March 4, 2016

Securus, Inc.
Mr. William Gorman
Director of Quality and Regulatory Affairs
100 Cummings Center, Suite 215f
Beverly, Massachusetts 01915

Re: K152402
Trade/Device Name: InfraRed Thermographic System (IRTS)
IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU), IRTS Patient Interface Unit (PIU)
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometers
Regulatory Class: II
Product Code: FLL
Dated: January 27, 2016
Received: February 2, 2016

Dear Mr. Gorman:

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MEMO OF SOFTWARE REVIEW

510(K): K152402/S001/A001
InfraRed Thermographic System (IRTS)

FROM: Weihong Gu (ODE/DAGRID/GHDB)

THROUGH: Richard Chapman, Branch Chief, ODE/DAGRID/GHDB

TO: William Burdick, ODE/DAGRID/GHDB

DATE: December 8, 2015

SUBJECT: CON1524156 Software Review for InfraRed Thermographic System (IRTS)

Name of the device: Podimetrics Remote Temperature Monitoring System™
Classification: Class II, 880.2910
Product Code: FLL
Applicant: Securus Medical Group, Inc.

Note: The original software consult was assigned as an off-the-clock review on 10/24/2015. The responses of the software issues were provided in Amendment 001 of Supplement 001.

General Description of Device:
The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.
Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification. Esophageal temperature probes are Class II devices.
A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ.
The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)
B. Patient Interface Unit (PIU)
C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition, the Probe incorporates adjunctive infrared thermal imaging to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to the thermocouple temperature and not intended as a diagnostic feature.

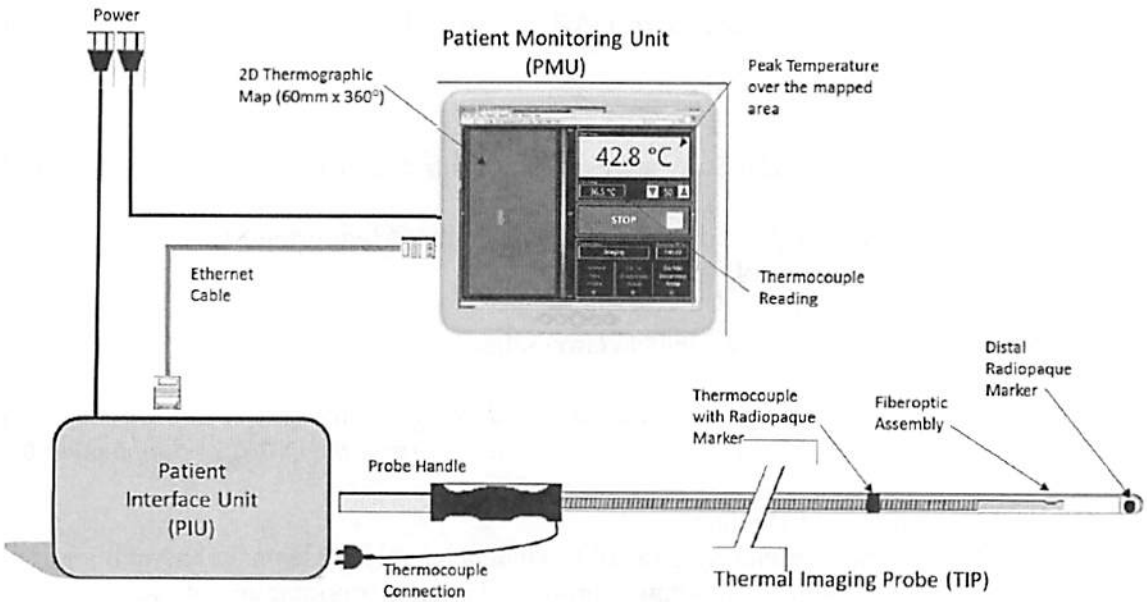


Figure 1 for a system overview

Indications for Use:

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe. The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

Predicate Device:

K123361: ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB SPA

K073581: ICI P and S Series IR Camera(s) and the IR Flash Software, Texas Infrared

Software Consultation (including Description, Comments, Deficiencies):

Software Description:

The software controls PIU operations and interfaces with the PMU. The software controls all functions and the User Interface (UI).

The software is divided into several modules that each serves specific functions. Together the

modules interpret data from the thermocouple and IR detector and display the data on the monitor.
The GUI allows the clinician to control the system, set notifications, read temperature thermocouple data and visualize surface temperature variations graphically.
Specific input features include:

- Start imaging
- Stop imaging
- Stop movement of motors
- Threshold of user defined notification

Specific output features include

- Primary patient temperature measurement
- Peak infrared temperature measurement
- Adjunct 2-D color representation of thermal data
- System status
- Probe status
- Audible and visual notifications, triggered when peak infrared temperature exceeds user defined threshold.
- Audible and visual notifications, triggered when the system enters an error state.

The system software is installed on the Patient Monitoring Unit (PMU) and conducts high-level control of the system. It interacts with the firmware installed on the Patient Interface Unit (PIU).
In general, the PMU software is the master, while the PIU firmware is the slave. The PMU software is responsible for:

- Handling input from the user
- Sending commands to the PIU
- Providing the user with thermal data and system status
- Verifying communication with the PIU
- Monitoring state-of-health of the PIU

Communication between the PIU and the PMU is 2-way, where:

- The PMU software sends high level commands to the PIU firmware.
- The PIU firmware receives and acts on these commands, initiating and monitoring hardware activities and status.
- The PIU firmware collects and sends status, thermal data, and state-of-device-health data to the PMU software.
- A heartbeat is shared between the two, verifying the communication channel is open and active.

The PIU firmware interfaces with the PIU hardware, controlling mechanical systems, collecting thermocouple and IR temperature data, and monitoring for hardware state-of-health and failures.

To meet FDA requirements, manufacturer should provide documentation listed in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

Guidance document. Sections below are required information that needs to be provided by the manufacturer for the Moderate level of concern.

The sponsor has provided the software documentation in Section 16 of the submission for our review:

1. Level of Concern – Section 16.1, Moderate level of concern
   The sponsor provided moderate level of concern. A failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider. It is consistent with the predicate K073581.

2. Software Description – Section 16.2 *(Adequate)*

3. Device Hazard Analysis – Section 16.3 and Appendix IV *(Adequate)*

4. Software Requirements Specifications (SRS) – Section 16.4 and Appendix V *(Acceptable)*

5. Software Design Specification (SDS) – Section 16.6 and Appendix VI *(Adequate)*

6. Architecture Design Chart – Section 16.5 and Appendix VI *(Acceptable)*

7. Traceability Analysis – Section 16.7 and Appendix VII *(Acceptable)*

8. Verification and Validation Documentation – Section 16.9 and Appendix VIII ***(Inadequate)***
   System level verification and validation (V&V) activities were conducted based on the Software Requirements Specification (SRS). Testing of the integration was performed at the module and at the system level. The software testing was performed on latest version 6.0.1 for both PIU and PMU. The test report includes procedures, pass/fail criteria and results of each test were provided in Appendix VIII. All tests met the requirements.
   It is not clear whether they have adequately tested for run-time errors such as buffer overruns, null pointer dereferences, race conditions, resource or memory leaks, and dangerous casts that are usually identified through static analysis. They need to provide results of software testing using a static analysis tool.

9. Development Environment Description – Section 16.8 ***(Inadequate)***
   The sponsor stated the software has been developed and validated in accordance with medical device standards including ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes. However, they did not provide a summary of software life cycle development plan.

10. Revision Level History – Section 16.10 *(Adequate)*

11. Unresolved Anomalies (bugs) – Section 16.11 ***(Inadequate)***

The sponsor provided three unresolved anomalies. They have not provided the detailed information regarding these anomalies in the submission.

12. Release Version Number – Section 16.10 *(Adequate)*
    Software PIU and PMU version: V6.0.1, 8/4/2015

    S001/A001 modified:
    The most current IRTS Software Version is 6.1.0.

Software deficiencies are listed in the following section. Lead reviewer is encouraged to include it in his additional information letter.

Deficiencies:

1. In section 16.8, you stated the software has been developed and validated in accordance with medical device standards including ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes. However, you have not provided a summary of software life cycle development plan. The Software Development Environment Description documentation should be submitted to satisfy the moderate level of concern as described in the FDA Guidance document for Software Contained in Medical Devices. Hence, please provide the Agency with Software Development Environment Description document to include a summary of software life cycle development plan. It should describe the software development life cycle and the processes that are in place to manage the various life cycle activities including a summary of the configuration management and maintenance plan.

   S001/A001 Sponsor's Response:
   Please see Attachment A for SD-10855, Software Development Environment Description.

   Reviewer's Note (Adequate): *The firm submitted a summary of their software development life cycle plan including a summary of the configuration management and maintenance activities as per Attachment A of the Amendment 001. I believe it is acceptable.*

2. It is not clear whether you have adequately tested for run-time errors such as buffer overruns, null pointer dereferences, race conditions, resource or memory leaks, and dangerous casts that are usually identified through static analysis. Please provide a description of the static analysis you have conducted, including portions of code which were challenged and results of tool usage, identify the criteria for correcting or not correcting coding errors/warnings and conclusion.

   S001/A001 Sponsor's Response:
   In order to prevent run-time errors that may reduce efficacy or safety of the software, the following activities were performed:
   1. LabVIEW Built-In Static Analysis. The LabVIEW IDE has built-in, standard edit-time static analysis functions. The information produced by static analysis, along with adherence to style guidelines and risk mitigation requirements, was used to

inform design decisions that prevent run-time errors that could otherwise compromise safety and/or efficacy. These decisions are not documented outside of the FMEA but are clearly reflected in the design. The primary static analysis functions that were used in development of the IRTS Software were:

a. Information About Illegal Casts. The LabVIEW IDE is constantly compiling in the background throughout the application hierarchy (all sub-functions opened in the project are analyzed at edit-time and compile-time). Any inconsistencies in syntax or broken references are brought to the attention of the developer. This provides value by preventing design decisions that are destructive, or indicating the impact of a proposed design change.

b. Information About Potentially Dangerous Casts. This capability is built into the LabVIEW environment. LabVIEW is able to 'promote' data types of variables, but each time this is done, the user is made aware with a red dot (A.K.A. Coercion Dots) in graphical code indicating that a data type has automatically been cast and where the discrepancy is located. These casts must either be avoided by manually handling data casts, or data integrity must be confirmed after the cast. Unit testing was also used to ensure that casts will not cause errors.

c. Show Buffer Allocations. This is a standard LabVIEW analysis function available to developers at the menu location Tools >> Profile >> Show Buffer Allocations. This permits developers to see where array or cluster data is copied to a new memory location, which usually is only considered a performance concerns, and only with large arrays or clusters of data.

2. FMEA. A thorough software FMEA informed the software architecture, which separates Class A and Class B modules and data variables. Class B modules and critical variables were reviewed for design decisions that protect functionality.

3. Unit Testing of Class B Modules. Unit testing was performed for all Class B functions. All unit test results including portions of code which were challenged and results of tool usage and conclusions are recorded in TR-10850 Unit Test Results IRTS.

4. Protection of Critical Data. Critical data was identified in the FMEA and protected by using a CRC. Code inspections were conducted as part of the software verification test protocol with test SCR001-TC-76.

5. White-Box Testing of Critical Functions. White-box testing was conducted to confirm the protections put in place to protect critical data, as well as functions such as software version checks, application integrity checks, and watchdog testing. These tests were executed as part of the software verification test protocol and include specific tests SCR001-TC-77 and SCR001-TC-79.

Direct Response to Specific Items

1. Buffer overruns. Buffers were designed into the code only in Class A modules. These buffers are monitored at run-time according to design decisions to monitor

them. Errors handling in LabVIEW also provide information about whether a function that manages a buffer has detected an error. The publicly available documentation for these data buffering functions indicates that they are appropriate for the IRTS application.

2. Null pointer dereferences. While LabVIEW does provide the ability to use pointers, use of pointers was not necessary for this design. The LabVIEW compiler makes a copy of all data used in sub-functions, which was deemed acceptable if critical data is protected and unit testing confirms appropriate behavior. Developers implemented design decisions that were intended to protect all critical data.
3. Race conditions. All critical variable references were individually reviewed according to the 'Risk Mitigations Tests' section of the Test Protocol, specifically SCR001-TC-76. Good programming practice prevents common race conditions usually by ensuring that variables are written from a single location in the program.
4. Resource or memory leaks. According to the FMEA, any malfunctions caused by memory leaks or subsequent crashes would be protected through a series of risk requirements. Memory used in Class B modules is protected through the use of a CRC for all critical data. Verification testing provided ample opportunity to observe correct operation of system reliability & safety functions. Static analysis was not expected to prevent run-time resource or memory leaks as much as adherence to good development practices.
5. Dangerous casts. Per the explanation provided in the previous section about 'coercion dots,' casts are considered dangerous only if they may effect critical data. These risks can be easily identified and removed. Unit testing is then used to confirm overall functionality and appropriate handling of out-of-range data.

Please see Attachment B for TR-10850 Unit Test Results IRTS

Reviewer's Note (Adequate): *The static analysis was conduct by using LabVIEW Static Analysis. The primary static analysis functions of illegal casts, potentially dangerous casts and show buffer allocations were used in development of the IRTS. They provided description of the static analysis conducted, including buffer overruns, null pointer dereferences, race conditions, resource or memory leaks and dangerous casts. The unite test report was provided in Attachment B of the Amendment all tests resulted in a verdict of Passed. I believe it is acceptable.*

3. You have identified 3 open anomalies in Section 16.11 of the submission. You stated the severity determination for each open anomaly is classified as a Minor. However, you have not provided any detailed information regarding these anomalies for us to verify your claim. The Agency is concerned about the number of open anomalies in your device. We recommend that you fix all your open anomalies because we believe that any deviation from your specifications could result in unmitigated risks. At a minimum, this could reflect a lack of understanding of the behavior of your device. If you still believe there are open anomalies that do not affect the safety and effectiveness of your device, please provide the following information for each anomaly.
    a. A description of the anomaly from a symptom point of view. How it is

manifested and severity determination.

b. The location in the code where the anomaly occurs.
c. A description of how to fix the code.
d. A search of the software source code for other possible instances of the anomaly. For example, if the problem was an off-by-one error in an array, you should provide evidence that all arrays were checked for off-by-one errors.
e. Evidence that a coupling analysis was performed to identify all parts of the software that accessed the errant code and that no problems would arise because of accessing this code.
f. An acceptable rationale for why the anomaly is not fixed in this release.
g. A description of the workarounds.
h. A release schedule indicating which future release will contain a correction for the anomaly.

Please also include a list of all open anomalies and possible workarounds in the labeling.

S001/A001 Sponsor's Response:

Version 6.0.1 of the IRTS Software has been updated since the original submission. The updated IRTS Software, version 6.1.0, addresses the three open software discrepancies (SCAR 476, 499 & 502) noted in TR-10797 and identified in Section 16.11 of the submission. The anomalies were reviewed and a trace analysis was performed linking each anomaly to its related specifications in the SRS and specific software tests in TP-10797 and then compiled into a new software test protocol (TP-10900). Software testing per TP-10900 has been completed on version 6.1.0 of the software and no new anomalies were identified.
Please see Attachment C for Version 6.1.0 Software Test Report TR-10900 and Attachment D for D-10903 Design Review Board Meeting Minutes.

Reviewer's Note (Adequate): *The IRTS software version 6.0.1 has been updated to fix the three open anomalies. The most current version of IRTS software is 6.1.0.The verification testing was performed in September, 2015. They stated results of testing show that no new software discrepancies were found. The remaining 3 discrepancies in version 6.0.1 were all found to be remedied and have been closed. They provided software test report and review board meeting minutes in Attachment C and D respectively. I believe it is acceptable.*

Recommendation:

I have completed a review of software documentation in the submission. Based on the information provided by the sponsor, I believe that the software review issues have been resolved.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Weihong Gu -S Digitally signed by Weihong Gu -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Weihong Gu -S, 0.9.2342.19200300.100.1.1=2000380818 Date: 2015.12.08 17:09:22 -05'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

K152402/S001
Securus Medical Group, Inc.
Trade Name: InfraRed Thermographic System (IRTS)

Dear Mr. Gorman:

This is to acknowledge receipt of your December 14, 2015 email requesting withdrawal of supplement S001 of K152402. Please also send a formal paper copy to the Agency (Document Control Center) requesting withdrawal of your supplement. Your submission will remain on HOLD status until the letter is received by the Agency.

You will receive another email informing you of your HOLD status with a Deficiencies List attached. The text of the email will also inform you that you have 180 days to submit your responses to the Agency. Please dismiss this statement since it is incorrect. This is an automatic email over which we have no control.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of In Vitro Diagnostics and Radiological Health
10903 New Hampshire Ave.
Silver Spring, MD 20993

Premarket Notification [510(k)] Consult (CON1524162)

K152402/S001

Date: 12/4/2015
To: William Burdick — Office/Division: ODE/DAGRID/GHDB
From: Jessica Lamb — Office/Division: OIR/DRH/MUIS

Sponsor: Securus, Inc.
Device Name: IRTS Thermal Imaging Probe (TIP);IRTS Patient Monitoring Unit (PMU);IRTS Patient Interface Unit (PIU)

I. Purpose and Consult Summary

Securus, Inc would like to introduce the *InfraRed Thermographic system* into interstate commerce. The sponsor has listed the IRTS Thermal Imaging Probe (TIP), IRTS Patient Monitoring Unit (PMU) and IRTS Patient Interface Unit (PIU) as subject devices. They have listed two predicates, ESOTEST Esophageal Temperature Probe and Temperture monitoring system, (K123361) with product code FLL is the primary. ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ is secondary.

I was asked to provide a consult on the original submission based on my experience with thermography devices. The purpose of this consult is to review the response to prior deficiencies.

II. Indications for use and device description

Indications for use:

> *The thermocouple sensor of the IRTS Probe is intended for continuous esophageal temperature monitoring. The IRTS Monitor is intended to display continuous esophageal temperature measurements (°C) from the IRTS Probe. The thermographic sensor of the IRTS Probe which provides surface temperature from the esophagus and the IRTS Monitor which provides visualization and reporting functionalities are intended as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative surface temperature.*

The device consists of an internally applied single use probe that has two types of sensors; a temperature sensor and a thermal imaging probe. The sponsor combines these sensors, which they identify as belonging to two product codes/regulations, into a single device, as show in "Multiple Predicates Examples 4 and 5 in The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]." I have not seen a thermal imaging device intended to be inserted in the esophagus before. Our branch reviews trans-esophageal diagnostic ultrasound devices. These are primarily used for cardiac measurements. They have a thermometer, similar to the subject device, but the purpose is to monitor the instrument temperature for safety reasons, not provide a diagnostic measurement that is complimentary to the imaging. I am less familiar with endoscopes intended for optical imaging in the esophagus; I have been told these may be used in cases of gastro-esophageal reflux disease and related conditions.

III. Review of response to deficiencies

Deficiency 3: You proposed ICI P and S Series IR Camera(s) and the IR Flash software (K073581) with product code LHQ as a secondary predicate for your device. However, there are substantial technological differences between the thermal camera on this external device and the thermal imaging element part of your trans-esophageal device. This second predicate does not apply to your device. Please remove the LHQ product code and the second predicate from your 510(k) summary and make your substantial equivalence discussion based on the primary predicate alone.

Review of response: The sponsor argued that they were using multiple predicates in a way consistent with "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" by including the second predicate and LHQ product code. They provided examples of LHQ devices that were cleared for thermal imaging of the exposed heart and blood vessels during surgery. However, that is still external monitoring and the switch from external to trans-esophageal would be a change in indications for use/technology. The mobile fiberoptic assembly would also raise technological questions. The comparison they are making is similar to comparing an optical camera to an endoscope.

In the response to deficiency 9 the sponsor also says "The peak temperature which represents the highest measured temperature over the thermal image is the primary feature provided by the thermal data. The thermal image simply provides an indication of the relative magnitude of any surface temperature variation...." The intention to provide an estimate of the variation of the temperature, rather than an accurate thermal image may be an indication more consistent with the primary regulation. LHQ should be removed. SEE DEFICIENCY 1.

Deficiency 6: You provided a specification for the temporal response for your thermometer of 2 °C in 2 s. However, the test measured the response time for the device to change 1.7 °C due to the accuracy margin for the device. This criteria could create artificial bias towards short response times in your analysis. We recommend, instead, choosing acceptance criteria that demonstrates the temperature has stabilized after the change. Please provide acceptance

criteria that will not create artificial bias, and assure how your data shows that this does not affect your conclusion that the specification has been met, in order to provide performance data that supports the tool claims for your device.

Review of response: The sponsor provided additional testing that relied on stabilization of temperature. As a result, they changed their claim about the response time to 2 °C in 2.5 s. This has been changed in the labeling. There are no concerns.

Deficiency 7: Your device labeling states the temperature range for your infrared temperature measurement is 39 °C – 60 °C. However, this entire range is higher than the typical core temperature for a human, approximately 37 °C. Please either specify and test a temperature range that includes human body temperature, or explain why this range does not raise questions about the effectiveness of the device. This is so we can ensure the specifications are appropriate for safe and effective clinical use.

Review of response: The sponsor changed their stated temperature range to go down to 35 °C and provided a plot of their testing for the entire range. This consisted of a measurements during two complete translations of the probe (>1000 points) repeated with three different probes at each target temperature. The lowest two test temperatures are 35 °C and 41 °C.

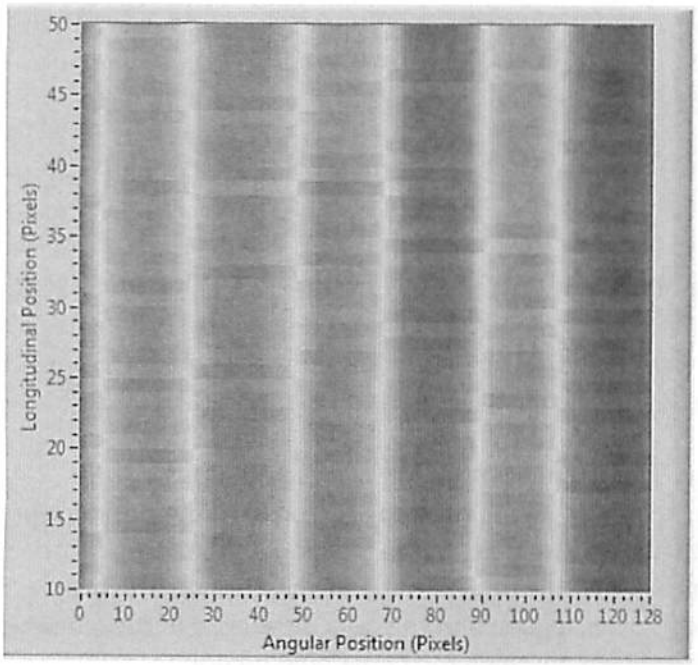
The sponsor specified the measurements should be within of ±2 °C, which seems large for clinical use. It would make it hard to correlate any temperature variation with the temperature provided by the thermocouple. The data appears to indicate the individual probes are more reproducible, but there is some bias which is variable between the probes. Given that the device does not make claims about specific clinical uses, and this specification is in the labeling, I will leave it to the lead reviewer to determine if anything further should be done.

Deficiency 8: You state your device is for thermal imaging or thermal mapping of the inner esophageal wall, and your manual depicts a spatial image. Your device description makes it clear this map is achieved by moving a single element, rather than relying on some sort of sensor array. However, you did not provide any information about the specification of this element map, such as spatial resolution, refresh frequency, and user knowledge of spatial orientation. Understanding the intended specifications is important for us to determine if your device has been tested sufficiently to be safe and effective. Please provide additional descriptive details about the spatial mapping functions of your device.

Review of response: The sponsor provided the needed description. It is acceptable.

Deficiency 9: You tested the thermal accuracy of your infrared sensor. However, you do not appear to have tested the spatial accuracy of the thermal plot displayed by the software. While the exact specifications you intend to adhere to are not clearly spelled out (see above) spatial mapping of thermal information is clearly a major feature of your device. Please demonstrate with testing that this feature functions as intended, to show the safety and effectiveness of one of your device's major functions.

Review of response: The sponsor provided the spatial image testing. A copy of their sample image is below. The image is not ideal, but does depict the thermal phantom. Without a better idea of a clinical function, it could be enough to support a tool claim. However, the sponsor also described some distortion (which they did not show) in one of the three test probes. They claimed the distortion was a common (and implied acceptable) side effect of the type of motion they are using. At least, the user should be made aware of the possibility of distortion through labeling.



Deficiency 11. You state in your indications for use the thermal imaging part of your device is intended to be an adjunctive measurement to the primary sensor. The word "adjunctive" has not been used to apply to other parts of the same device: in other words, a device is not adjunctive to itself. To say so could create a false impression about what information is needed to form a complete clinical picture. Please rephrase the indications for use, so the whole device is adjunctive to other diagnostic tools and information, in order to correctly label your device.

Review of response: The sponsor proposed revised wording of their indications for use to address this deficiency. They adequately address the issue.

IV. Conclusions

There are outstanding issues with this file. Following are deficiencies which reflect minimum issues I believe need to be addressed prior to clearing the file. However, given the nature of the issues, the lead reviewer may decide to revise or disregard these in favor of more significant related issues.

As stated, LHQ should not be used as a secondary product code for this device; the thermal imaging component of this device is different than that used in K073581. The deficiency simply asks the sponsor to remove the code. The sponsor is using this as a significant part of their substantial equivalence argument discussion. I am not familiar with the primary device type; it is up to the lead reviewer to decide if the sponsor also needs to further improve their substantial equivalence discussion. See DEFICIENCY 1.

The performance of the infrared sensor leaves something to be desired; both in terms of measurement bias (see response to Deficiency 7) and image distortion (see response to Deficiency 9). Without a clear clinical purpose or similar devices to compare to, it could be acceptable if the performance characteristics are presented to the user as tool claims. Therefore, I have asked the labeling be improved with regards to image distortion. If the lead reviewer's understanding of the clinical utility is different, he may decide the performance is not acceptable and replace the deficiency with a request for clarification or performance data. See DEFICIENCY 2.

V. Deficiencies

1) You explained your reasoning for using the LHQ product code and the device K073581 as a second predicate. We continue to believe there is a significant difference in intended use and technology between your device, which is implied internally, and the prior device, which is for an external thermal picture, as are the examples you cited. Please remove references to this product code and device from your 510(k) Summary as they are not appropriate and do not support substantial equivalence.
2) In your response to deficiency 9, you stated that one of the probes you tested showed signs of NURD. If significant distortion is possible for your device, the user should be made aware of the possibility and how it could affect their interpretation of the data. Please add a statement to your labeling describing the spatial accuracy and possible distortion to the user. This is needed so they can accurately evaluate the possible uses of the tool.

Digital Signature	
Jessica S. Lamb	Jessica S. Lamb -S (Affiliate) 2015.12.04 11:38:32 -05'00'

MEMO OF SOFTWARE REVIEW

510(K): K152402/S001/A001
InfraRed Thermographic System (IRTS)

FROM: Weihong Gu (ODE/DAGRID/GHDB)

THROUGH: Richard Chapman, Branch Chief, ODE/DAGRID/GHDB

TO: William Burdick, ODE/DAGRID/GHDB

DATE: December 8, 2015

SUBJECT: CON1524156 Software Review for InfraRed Thermographic System (IRTS)

Name of the device: Podimetrics Remote Temperature Monitoring System™
Classification: Class II, 880.2910
Product Code: FLL
Applicant: Securus Medical Group, Inc.

Note: The original software consult was assigned as an off-the-clock review on 10/24/2015. The responses of the software issues were provided in Amendment 001 of Supplement 001.

General Description of Device:
The InfraRed Thermographic System (IRTS) independently presents the thermal input from two devices, an esophageal temperature probe and a telethermographic infrared imaging system, onto a single display monitor.
Esophageal temperature probes fall into product code FLL, a clinical electronic thermometer used to measure the body temperature of a patient by means of a transducer coupled with electronic signal amplification. Esophageal temperature probes are Class II devices.
A telethermographic system for adjunctive diagnostic screening for the detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. Telethermographic systems for adjunctive diagnostic screening are Class 1 devices under Product Code LHQ.
The InfraRed Thermographic System (IRTS) consists of three components (Figure 1):

A. Thermal Imaging Probe (TIP or Probe)
B. Patient Interface Unit (PIU)
C. Patient Monitoring Unit (PMU)

The Probe provides esophageal temperature through the use of a standard thermocouple mounted in a flexible 9 French catheter. This design is standard for esophageal temperature probes commonly used in the industry. The Probe has been tested in compliance with ISO 80601-2-56:2009, Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

In addition, the Probe incorporates adjunctive infrared thermal imaging to provide a non-contact thermal map of the surrounding esophageal tissue. The Probe incorporates an infrared fiber optic assembly to passively collect the infrared radiation that is self-emanating from the surrounding tissue surface. The Probe scans a 360° by 60 mm long segment of the esophagus. The thermal data is transduced by an infrared detector contained in the Patient Interface Unit and presented on the Patient Monitoring Unit as a two-dimensional color map with peak temperature over the mapped area. The thermal image and peak temperature are offered as an adjunct to the thermocouple temperature and not intended as a diagnostic feature.

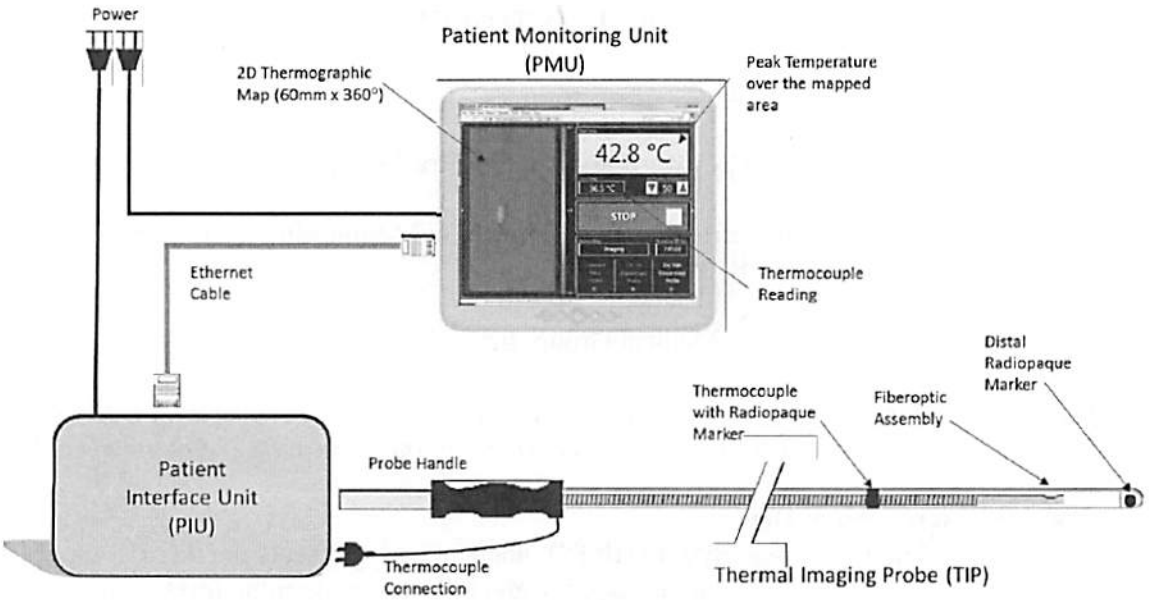


Figure 1 for a system overview

Indications for Use:

The IRTS Thermal Imaging Probe (TIP) is intended for continuous esophageal temperature monitoring.

The IRTS Patient Monitoring Unit (PMU) with Patient Interface Unit (PIU) are intended to display continuous temperature measurements (°C) from the IRTS Thermal Imaging Probe. The IRTS with thermographic detector is intended as an adjunct to the esophageal temperature measurement by quantifying differences in surface temperatures.

Predicate Device:

K123361: ESOTEST Esophageal Temperature Probe and Temperature Monitoring System, FIAB SPA

K073581: ICI P and S Series IR Camera(s) and the IR Flash Software, Texas Infrared

Software Consultation (including Description, Comments, Deficiencies):

Software Description:

The software controls PIU operations and interfaces with the PMU. The software controls all functions and the User Interface (UI).

The software is divided into several modules that each serves specific functions. Together the

modules interpret data from the thermocouple and IR detector and display the data on the monitor.
The GUI allows the clinician to control the system, set notifications, read temperature thermocouple data and visualize surface temperature variations graphically.
Specific input features include:

- Start imaging
- Stop imaging
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- Threshold of user defined notification

Specific output features include

- Primary patient temperature measurement
- Peak infrared temperature measurement
- Adjunct 2-D color representation of thermal data
- System status
- Probe status
- Audible and visual notifications, triggered when peak infrared temperature exceeds user defined threshold.
- Audible and visual notifications, triggered when the system enters an error state.

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- Handling input from the user
- Sending commands to the PIU
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- A heartbeat is shared between the two, verifying the communication channel is open and active.

The PIU firmware interfaces with the PIU hardware, controlling mechanical systems, collecting thermocouple and IR temperature data, and monitoring for hardware state-of-health and failures.

To meet FDA requirements, manufacturer should provide documentation listed in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

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1. Level of Concern – Section 16.1, Moderate level of concern
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2. Software Description – Section 16.2 *(Adequate)*

3. Device Hazard Analysis – Section 16.3 and Appendix IV *(Adequate)*

4. Software Requirements Specifications (SRS) – Section 16.4 and Appendix V *(Acceptable)*

5. Software Design Specification (SDS) – Section 16.6 and Appendix VI *(Adequate)*

6. Architecture Design Chart – Section 16.5 and Appendix VI *(Acceptable)*

7. Traceability Analysis – Section 16.7 and Appendix VII *(Acceptable)*

8. Verification and Validation Documentation – Section 16.9 and Appendix VIII ***(Inadequate)***
   System level verification and validation (V&V) activities were conducted based on the Software Requirements Specification (SRS). Testing of the integration was performed at the module and at the system level. The software testing was performed on latest version 6.0.1 for both PIU and PMU. The test report includes procedures, pass/fail criteria and results of each test were provided in Appendix VIII. All tests met the requirements.
   It is not clear whether they have adequately tested for run-time errors such as buffer overruns, null pointer dereferences, race conditions, resource or memory leaks, and dangerous casts that are usually identified through static analysis. They need to provide results of software testing using a static analysis tool.

9. Development Environment Description – Section 16.8 ***(Inadequate)***
   The sponsor stated the software has been developed and validated in accordance with medical device standards including ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes. However, they did not provide a summary of software life cycle development plan.

10. Revision Level History – Section 16.10 *(Adequate)*

11. Unresolved Anomalies (bugs) – Section 16.11 ***(Inadequate)***

The sponsor provided three unresolved anomalies. They have not provided the detailed information regarding these anomalies in the submission.

12. Release Version Number – Section 16.10 *(Adequate)*
    Software PIU and PMU version: V6.0.1, 8/4/2015

    S001/A001 modified:
    The most current IRTS Software Version is 6.1.0.

Software deficiencies are listed in the following section. Lead reviewer is encouraged to include it in his additional information letter.

Deficiencies:

1. In section 16.8, you stated the software has been developed and validated in accordance with medical device standards including ANSI/AAMI/IEC 62304:2006 Medical device software - Software life cycle processes. However, you have not provided a summary of software life cycle development plan. The Software Development Environment Description documentation should be submitted to satisfy the moderate level of concern as described in the FDA Guidance document for Software Contained in Medical Devices. Hence, please provide the Agency with Software Development Environment Description document to include a summary of software life cycle development plan. It should describe the software development life cycle and the processes that are in place to manage the various life cycle activities including a summary of the configuration management and maintenance plan.

   S001/A001 Sponsor's Response:
   Please see Attachment A for SD-10855, Software Development Environment Description.

   Reviewer's Note (Adequate): *The firm submitted a summary of their software development life cycle plan including a summary of the configuration management and maintenance activities as per Attachment A of the Amendment 001. I believe it is acceptable.*

2. It is not clear whether you have adequately tested for run-time errors such as buffer overruns, null pointer dereferences, race conditions, resource or memory leaks, and dangerous casts that are usually identified through static analysis. Please provide a description of the static analysis you have conducted, including portions of code which were challenged and results of tool usage, identify the criteria for correcting or not correcting coding errors/warnings and conclusion.

   S001/A001 Sponsor's Response:
   In order to prevent run-time errors that may reduce efficacy or safety of the software, the following activities were performed:
   1. LabVIEW Built-In Static Analysis. The LabVIEW IDE has built-in, standard edit-time static analysis functions. The information produced by static analysis, along with adherence to style guidelines and risk mitigation requirements, was used to

inform design decisions that prevent run-time errors that could otherwise compromise safety and/or efficacy. These decisions are not documented outside of the FMEA but are clearly reflected in the design. The primary static analysis functions that were used in development of the IRTS Software were:

a. Information About Illegal Casts. The LabVIEW IDE is constantly compiling in the background throughout the application hierarchy (all sub-functions opened in the project are analyzed at edit-time and compile-time). Any inconsistencies in syntax or broken references are brought to the attention of the developer. This provides value by preventing design decisions that are destructive, or indicating the impact of a proposed design change.
b. Information About Potentially Dangerous Casts. This capability is built into the LabVIEW environment. LabVIEW is able to 'promote' data types of variables, but each time this is done, the user is made aware with a red dot (A.K.A. Coercion Dots) in graphical code indicating that a data type has automatically been cast and where the discrepancy is located. These casts must either be avoided by manually handling data casts, or data integrity must be confirmed after the cast. Unit testing was also used to ensure that casts will not cause errors.
c. Show Buffer Allocations. This is a standard LabVIEW analysis function available to developers at the menu location Tools >> Profile >> Show Buffer Allocations. This permits developers to see where array or cluster data is copied to a new memory location, which usually is only considered a performance concerns, and only with large arrays or clusters of data.

2. FMEA. A thorough software FMEA informed the software architecture, which separates Class A and Class B modules and data variables. Class B modules and critical variables were reviewed for design decisions that protect functionality.

3. Unit Testing of Class B Modules. Unit testing was performed for all Class B functions. All unit test results including portions of code which were challenged and results of tool usage and conclusions are recorded in TR-10850 Unit Test Results IRTS.

4. Protection of Critical Data. Critical data was identified in the FMEA and protected by using a CRC. Code inspections were conducted as part of the software verification test protocol with test SCR001-TC-76.

5. White-Box Testing of Critical Functions. White-box testing was conducted to confirm the protections put in place to protect critical data, as well as functions such as software version checks, application integrity checks, and watchdog testing. These tests were executed as part of the software verification test protocol and include specific tests SCR001-TC-77 and SCR001-TC-79.

Direct Response to Specific Items

1. Buffer overruns. Buffers were designed into the code only in Class A modules. These buffers are monitored at run-time according to design decisions to monitor

them. Errors handling in LabVIEW also provide information about whether a function that manages a buffer has detected an error. The publicly available documentation for these data buffering functions indicates that they are appropriate for the IRTS application.

2. Null pointer dereferences. While LabVIEW does provide the ability to use pointers, use of pointers was not necessary for this design. The LabVIEW compiler makes a copy of all data used in sub-functions, which was deemed acceptable if critical data is protected and unit testing confirms appropriate behavior. Developers implemented design decisions that were intended to protect all critical data.
3. Race conditions. All critical variable references were individually reviewed according to the 'Risk Mitigations Tests' section of the Test Protocol, specifically SCR001-TC-76. Good programming practice prevents common race conditions usually by ensuring that variables are written from a single location in the program.
4. Resource or memory leaks. According to the FMEA, any malfunctions caused by memory leaks or subsequent crashes would be protected through a series of risk requirements. Memory used in Class B modules is protected through the use of a CRC for all critical data. Verification testing provided ample opportunity to observe correct operation of system reliability & safety functions. Static analysis was not expected to prevent run-time resource or memory leaks as much as adherence to good development practices.
5. Dangerous casts. Per the explanation provided in the previous section about 'coercion dots,' casts are considered dangerous only if they may effect critical data. These risks can be easily identified and removed. Unit testing is then used to confirm overall functionality and appropriate handling of out-of-range data.

Please see Attachment B for TR-10850 Unit Test Results IRTS

Reviewer's Note (Adequate): *The static analysis was conduct by using LabVIEW Static Analysis. The primary static analysis functions of illegal casts, potentially dangerous casts and show buffer allocations were used in development of the IRTS. They provided description of the static analysis conducted, including buffer overruns, null pointer dereferences, race conditions, resource or memory leaks and dangerous casts. The unite test report was provided in Attachment B of the Amendment all tests resulted in a verdict of Passed. I believe it is acceptable.*

3. You have identified 3 open anomalies in Section 16.11 of the submission. You stated the severity determination for each open anomaly is classified as a Minor. However, you have not provided any detailed information regarding these anomalies for us to verify your claim. The Agency is concerned about the number of open anomalies in your device. We recommend that you fix all your open anomalies because we believe that any deviation from your specifications could result in unmitigated risks. At a minimum, this could reflect a lack of understanding of the behavior of your device. If you still believe there are open anomalies that do not affect the safety and effectiveness of your device, please provide the following information for each anomaly.
    a. A description of the anomaly from a symptom point of view. How it is

manifested and severity determination.

b. The location in the code where the anomaly occurs.
c. A description of how to fix the code.
d. A search of the software source code for other possible instances of the anomaly. For example, if the problem was an off-by-one error in an array, you should provide evidence that all arrays were checked for off-by-one errors.
e. Evidence that a coupling analysis was performed to identify all parts of the software that accessed the errant code and that no problems would arise because of accessing this code.
f. An acceptable rationale for why the anomaly is not fixed in this release.
g. A description of the workarounds.
h. A release schedule indicating which future release will contain a correction for the anomaly.

Please also include a list of all open anomalies and possible workarounds in the labeling.

S001/A001 Sponsor's Response:

Version 6.0.1 of the IRTS Software has been updated since the original submission. The updated IRTS Software, version 6.1.0, addresses the three open software discrepancies (SCAR 476, 499 & 502) noted in TR-10797 and identified in Section 16.11 of the submission. The anomalies were reviewed and a trace analysis was performed linking each anomaly to its related specifications in the SRS and specific software tests in TP-10797 and then compiled into a new software test protocol (TP-10900). Software testing per TP-10900 has been completed on version 6.1.0 of the software and no new anomalies were identified.
Please see Attachment C for Version 6.1.0 Software Test Report TR-10900 and Attachment D for D-10903 Design Review Board Meeting Minutes.

Reviewer's Note (Adequate): *The IRTS software version 6.0.1 has been updated to fix the three open anomalies. The most current version of IRTS software is 6.1.0.The verification testing was performed in September, 2015. They stated results of testing show that no new software discrepancies were found. The remaining 3 discrepancies in version 6.0.1 were all found to be remedied and have been closed. They provided software test report and review board meeting minutes in Attachment C and D respectively. I believe it is acceptable.*

Recommendation:

I have completed a review of software documentation in the submission. Based on the information provided by the sponsor, I believe that the software review issues have been resolved.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Weihong Gu -S Digitally signed by Weihong Gu -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Weihong Gu -S, 0.9.2342.19200300.100.1.1=2000380818 Date: 2015.12.08 17:09:22 -05'00'