

K033967

MAR 9 2004

Premarket Notification 510(k)

Telethermographic Camera

6.1 510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

Page 1 of 2

December 19, 2003

Flir Systems, Inc.
16 Esquire Road
North Billerica, MA 01862

Tel (978) 901-8227
Fax (978) 901-8532

Official Contact:

Tom Scanlon

Proprietary or Trade Name:

Series A, E, S, and P - IR cameras

Common/Usual Name:

Telethermographic system

Classification Name:

Telethermographic system (adjunctive use)

Predicate Devices:

Technology
Inframetrics, Inc.
Infracam-Med - K982327

Indications of Use
Dorex, Inc.
Spectrum 9000mb - K023434

Device Description:

Flir manufactures a number of IR camera's, they all include the same basis temperature measurement and sensing technology. They are non-contacting and employ passive infrared emissions for sensing temperature variations.

The captured energy is processed by software to produce digital output values of the thermal energy captured by the camera's thermal sensors.

Intended Use:

The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes

Environment of Use:

Hospital, Sub-acute Institutions, public areas, i.e., airports

Premarket Notification 510(k)

Telethermographic Camera

Non-Confidential Summary of Safety and Effectiveness

Page 2 of 2

December 19, 2003

General Technical Characteristics

Attribute	Proposed devices – Series – A, E, S, P
Indications for use	The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes
Prescription	No
Intended population	Not applicable
Intended Environment of Use	Hospital, Sub-acute Institutions, public areas, i.e., airports
Design	
Method of data collection	Non-contacting detection of passive infrared emissions
Data processing	CPU
Detector type	Focal Plane Array
Display	Monitor or LCD
Temperature ranges	-40 °C to + 250 °C
Accuracy	±2 °C or ± 2% of reading
Materials	
Not applicable	Device is non-contacting
Performance Standards	
Under Section 514	None
Complies with various ISO standards	EMC, EMI

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed device is safe, effective, and substantially equivalent when compared to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Flir Systems, Inc.
% Mr. Paul Dryden
President
ProMedic, Inc.
6329 W. Waterview Ct.
MCCORDSVILLE IN 46055-9501

Re: K033967
Trade/Device Name: Telethermographic camera
Series A, E, P, and S
Regulation Number: 21 CFR 884.2980
Regulation Name: Telethermographic system
Regulatory Class: I
Product Code: 90 LHQ
Dated: December 19, 2003
Received: December 22, 2003

Dear Mr. Dryden:

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

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

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

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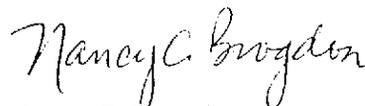
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Premarket Notification 510(k)

Telethermographic Camera

6.3 Indications for Use

Page 1 of 1

510(k) Number: K033967 (To be assigned)

Device Name: Telethermographic camera
Series A, E, P, and S

Intended Use: The Flir devices are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes.

Environment of use: hospital, sub-acute, public areas, i.e., airports

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or Over-the-counter use
(Per CFR 801.109)

Nancy Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033967

Page 16



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Flir Systems, Inc.
% Mr. Paul Dryden
President
ProMedic, Inc.
6329 W. Waterview Ct.
MCCORDSVILLE IN 46055-9501

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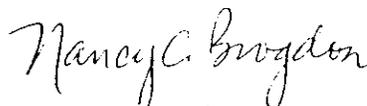
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Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Premarket Notification 510(k)

Telethermographic Camera

6.3 Indications for Use

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(Per CFR 801.109)

Nancy Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033967

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 22, 2003

FLIR SYSTEMS
C/O PROMEDIC, INC.
6329 W. WATERVIEW CT.
MCCORDSVILLE, IN 46055
ATTN: PAUL DRYDEN

510(k) Number: K033967
Received: 22-DEC-2003
Product: TELETHERMOGRAPHIC
CAMERA, SERIES A, E,
S AND P

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

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at <http://www.fda.gov/oc/mdufma>).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

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10033967

Premarket Notification 510(k)

Telethermographic Camera

ProMedic, Inc. 

6329 W. Waterview Ct. - McCordsville, IN 46055-9501
Tel (317) 335-3780 Fax - (317) 335-9270
E-mail - drydenp@promedic.cc Web - www.promedic.cc

December 19, 2003

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

FDA/CDRH/DOH
2003 DEC 22 A 9:43

RE: **510(k) Premarket Notification**
PIN # 012379-956733
Telethermographic camera (adjunctive use)

ATTN: Document Control Clerk

Flir Systems, Inc. intends to market an Infra-red camera for measuring skin temperature as an adjunctive screening and diagnostic tool.

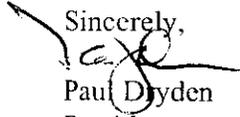
This Premarket Notification 510(k) submission has been prepared in accordance with the Draft Guidance for Format and Content for Premarket Notification 510(k) and MDUFMA. We have provided:

- User Fee cover sheet
- Premarket Notification Submission Cover Sheet,
- 510(k) Safety and Effectiveness Summary,
- Truthful and Accurate Statement, and
- Indications for Use.

ProMedic, Inc. has been retained as the official correspondent for this submission or contact details can be found within.

Please feel free to contact me should you have any questions.

Sincerely,



Paul Dryden
President
Regulatory Consultant for Flir Systems, Inc.

SK-16
RA
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16

Form Approved OMB No. 0910-0511 Expiration Date August 31, 2006 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. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) FLIR SYSTEMS, INC. 16 ESQUIRE ROAD NORTH BILLERICA, MA 01862 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 930708501	2. CONTACT NAME PAUL DRYDEN 2.1 E-MAIL ADDRESS drydenp@promedic.cc 2.2 TELEPHONE NUMBER (Include Area Code) 317-335-3780 2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 317-335-9270
---	---

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/oc/mdufma>)

Select an application type:

- Premarket notification (510(k)), except for third party reviews
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below:

- Original Application
- Supplement Types:
- Efficacy (BLA)
 - Panel Track (PMA, PMR, PDP)
 - 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

NO, I am not a small business

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

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

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b)(4)

Form FDA 3601 (08/2003)

**Document Mail Center
Federal Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Blvd. HFZ 401
Rockville, MD 20850**

510(k) Premarket Notification

Flir Systems, Inc.

ThermaCAM Cameras

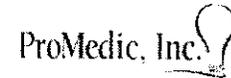
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December 19, 2003

2003 DEC 22 A 9:43
FDA/CDR/11/2003/15000

Premarket Notification 510(k)

Telethermographic Camera



6329 W. Waterview Ct. ~ McCordsville, IN 46055-9501
Tel (317) 335-3780 Fax - (317) 335-9270
E-mail - drydenp@promedic.cc Web - www.promedic.cc

December 19, 2003

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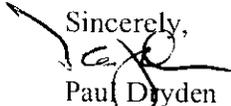
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Sincerely,


Paul Dryden
President

Regulatory Consultant for Flir Systems, Inc.

DEC 22 A 9:43

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Telethermographic Camera

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Premarket Notification 510(k)

Telethermographic Camera

Section 3 – MDUFMA User Fee Cover Sheet

The required MDUFMA has been filed.

The PIN is (b)(4).

Form Approved OMB No. 0910-0511 Expiration Date: August 31, 2006 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. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.htm#3a>. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) FLIR SYSTEMS, INC. 16 ESQUIRE ROAD NORTH BILLERICA, MA 01862 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 930708501	2 CONTACT NAME PAUL DRYDEN 2.1 E-MAIL ADDRESS drydenp@promedic.cc 2.2 TELEPHONE NUMBER (Include Area Code) 317-335-3780 2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 317-335-9270
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- | | |
|---|--|
| Select an application type:
<input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews
<input type="checkbox"/> Biologics License Application (BLA)
<input type="checkbox"/> Premarket Approval Application (PMA)
<input type="checkbox"/> Modular PMA
<input type="checkbox"/> Product Development Protocol (PDP)
<input type="checkbox"/> Premarket Report (PMR) | 3.1 Select one of the types below:
<input checked="" type="checkbox"/> Original Application

Supplement Types:
<input type="checkbox"/> Efficacy (BLA)
<input type="checkbox"/> Panel Track (PMA, PMR, PDP)
<input type="checkbox"/> Real-Time (PMA, PMR, PDP)
<input type="checkbox"/> 180-day (PMA, PMR, PDP) |
|---|--|

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

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

NO, I am not a small business

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

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

<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population
<input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

YES NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

(b)(4)

Form FDA 3601 (08/2003)

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Premarket Notification 510(k)

Telethermographic Camera

Section 4 – 510(k) Submission Cover Sheet

CDRH SUBMISSION COVER SHEET				
Date of Submission: December 19, 2003			FDA Document Number:	
Section A Type of Submission				
PMA <input type="checkbox"/> Original submission <input type="checkbox"/> Modules submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review	PDP <input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original submission <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Additional information <input type="checkbox"/> Traditional <input type="checkbox"/> Special Abbreviated	Meeting <input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify)
IDE <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement Report	Class II Exemption <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Evaluation of Automatic Class III Designation <input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Other Submission Describe submission:
Section B Applicant or Sponsor				
Company / Institution name: Flir Systems, Inc.		Establishment registration number: Filed not yet received		
Division name (if applicable): Thermography		Phone number (include area code): (978) 901-8227		
Street address: 16 Esquire Road		FAX number (include area code): (978) 901-8532		
City: North Billerica	State / Province: MA	Country: USA	ZIP / Postal Code: 01862	
Contact name: Tom Scanlon				
Contact title: Vice President Americas Thermography		Contact e-mail address: tom.scanlon@flir.com		
Section C Submission correspondent (if different from above)				
Company / Institution name: ProMedic, Inc.		Establishment registration number:		
Division name (if applicable):		Phone number (include area code): (317) 335-3780		
Street address: 6329 W. Waterview Ct.		FAX number (include area code): (317) 335-9270		
City: McCordsville	State / Province: IN	Country:	ZIP / Postal Code: 46055-9501	
Contact name: Paul Dryden				
Contact title: President		Contact e-mail address: drydenp@promedic.cc		

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		FDA Document Number:
Section D1 Reason for Submission - PMA, PDP, or HDE		
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Process Change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Response to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site Other reason (specify):	<input type="checkbox"/> Change design, component or specifications: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling Change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submissions: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent
Section D2 Reason for Submission - IDE		
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Compassionate use request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing process <input type="checkbox"/> Protocol - feasibility <input type="checkbox"/> Protocol - other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report Submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approval <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting
Section D3 Reason for Submission - 510(k)		
<input checked="" type="checkbox"/> New device <input type="checkbox"/> Addition or expanded indications Other reasons (specify):	<input type="checkbox"/> Change in technology <input type="checkbox"/> Change in design	<input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process

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				FDA Document Number:	
Section E Additional Information on 510(k) Submission					
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:	
1 LHQ	2	3	4	XX 510(k) Summary attached __ 510(k) Statement	
5	6	7	8		
Information on devices to which substantial equivalence is claimed:					
510(k) Number		Trade or Proprietary or Model Name		Manufacturer	
1 K982327		1 Infracam-Med		1 Inframetrics, Inc. Purchased by Flir Systems, Inc.	
2 K023434		2 Spectrum 9000mb		2 Dorex, Inc.	
3		3		3	
4		4		4	
Section F Product Information - Applicable to ALL Applications					
Common or usual or classification name: System, Telethermographic (adjunctive use)					
Trade or Proprietary or Model Name				Model Number	
1 A, E, S, and P series					
2					
3					
4					
FDA document numbers of all prior related submissions (regardless of outcome):					
1 K982327	2	3	4	5	6
Data included in submission: XX Laboratory testing Animal trials Human trials					
Section G Product Classification - Applicable to ALL Applications					
Product code: LHQ		C.F.R. section: 884.2980		Device class: XX Class I __ Class II Class III Unclassified	
Classification panel: Obstetrics / Gynecology					
Indications (From labeling): The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes					

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:	
Section H Manufacturing / Packaging / Sterilization Sites			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number: Not yet filed	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name: Flir Systems AB		Establishment registration number: Not yet filed	
Division name (if applicable):		Phone number (include area code): 011-46-8 753 2755	
Street address: Rinkebyvagen 19, PO Box 3		FAX number (include area code): 011-46-8 755 0752	
City: Danderyd	State / Province:	Country: Sweden	ZIP / Postal Code: SE-182 11
Contact name: Olof Gawell			
Contact title: Director, Quality Assurance		Contact e-mail address: ogawell@flir.se	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:		Contact e-mail address:	

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Section 5 – General Information

- 5.1 Establishment name** Flir Systems, Inc.
- 5.2 Establishment Number** Filed, to be assigned
- 5.3 Official Correspondent** Paul Dryden
ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055-9501
- 5.4 Device Name** Telethermographic camera
Series (A, E, S, and P)
- 5.5 Classification** Class I
- 5.6 Classification Reference** 21 CFR 884.2980
- 5.7 FDA Classification code** LHQ
- 5.8 Classification panel** Obstetrics / Gynecology
- 5.9 Classification name** Telethermographic system (adjunctive use)
- 5.10 Reason for Submission** New device
- 5.11 Predicate devices** Technology
Inframetrics, Inc.
Infracam-Med -- K982327
- Indications of Use
Dorex, Inc.
Spectrum 9000mb -- K023434

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Telethermographic Camera

- 5.12 Performance standards** None applicable under Section 514
- 5.13 Intended use** The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes.
- 5.14 Intended Population** Not applicable
- 5.15 Environments of use** Hospital
Sub-acute institutions
Public areas, such as airports

Section 6 - Certifications and Summaries

Section	Description
6.1	510(k) Summary of Safety and Effectiveness
6.2	Truthful and Accurate Statement
6.3	Indications for Use

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6.1 510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

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December 19, 2003

Flir Systems, Inc.
16 Esquire Road
North Billerica, MA 01862

Tel (978) 901-8227
Fax (978) 901-8532

Official Contact: Tom Scanlon

Proprietary or Trade Name: Series A, E, S, and P - IR cameras

Common/Usual Name: Telethermographic system

Classification Name: Telethermographic system (adjunctive use)

Predicate Devices: Technology
Inframetrics, Inc.
Infracam-Med - K982327

Indications of Use
Dorex, Inc.
Spectrum 9000mb - K023434

Device Description: Flir manufactures a number of IR camera's, they all include the same basis temperature measurement and sensing technology. They are non-contacting and employ passive infrared emissions for sensing temperature variations.

The captured energy is processed by software to produce digital output values of the thermal energy captured by the camera's thermal sensors.

Intended Use: The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes

Environment of Use: Hospital, Sub-acute Institutions, public areas, i.e.. airports

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Telethermographic Camera

Non-Confidential Summary of Safety and Effectiveness

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General Technical Characteristics	
Attribute	Proposed devices – Series – A, E, S, P
Indications for use	The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes
Prescription	No
Intended population	Not applicable
Intended Environment of Use	Hospital, Sub-acute Institutions, public areas, i.e., airports
Design	
Method of data collection	Non-contacting detection of passive infrared emissions
Data processing	CPU
Detector type	Focal Plane Array
Display	Monitor or LCD
Temperature ranges	-40 °C to + 250 °C
Accuracy	+2 °C or + 2% of reading
Materials	
Not applicable	Device is non-contacting
Performance Standards	
Under Section 514	None
Complies with various ISO standards	EMC, EMI

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed device is safe, effective, and substantially equivalent when compared to the predicate devices.

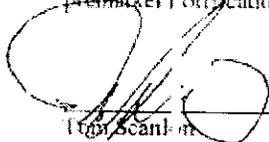
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Telethermographic Camera

6.2 Pre market Notification - Truthful and Accurate Statement

I certify that, in my capacity as Vice President Americas Thermography for Flir Systems, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Tom Scanlon
Vice President Americas Thermography
Flir Systems, Inc.
December 9, 2003

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Telethermographic Camera

6.3 Indications for Use

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510(k) Number: K033967 (To be assigned)

Device Name: Telethermographic camera
Series A, E, P, and S

Intended Use: The Flir devices are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes.

Environment of use: hospital, sub-acute, public areas, i.e., airports

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-counter use** _____
(Per CFR 801.109)

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Section 7 - Labeling

7.1 General Labeling Content

The labeling will include this basic content.

- Part / reorder number
- Lot / control number placed on the label or device
- Description and contents
- Intended use
- Cautions, Warnings
- Directions for Use
- Manufacturer's name

Section 15 contains a sample of a typical User Manual.

Section 8 – Device Description

8.1 Background

Using Infrared technology to measure temperature variation of the surface of the body is common place.

These devices use self-emulating infrared radiation technology to detect, measure and quantify patient skin temperatures. They are battery or AC power and do not touch the patient.

Some devices use the technique as an adjunctive diagnostic screening tooling for a number of procedures including:

- Skin temperature variation,
- Viewing heat patterns of heart tissue and vessels during coronary artery bypass surgery.

The Flir Systems' IR cameras are intended for skin temperature only.

8.2 Device Description

FLIR manufactures a number of IR cameras; they all include the same basic temperature measurement and sensing technology. They are non-contacting and employ passive infrared emissions for sensing temperature variations.

The captured energy is processed by software to produce digital output values of the thermal energy captured by the camera's thermal sensors.

Table 1 lists the basic technological feature and characteristics for the different cameras and **Table 2** discusses the differences.

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Telthermographic Camera

Table 1 – General Features and Specifications

Feature	Specifications
Imaging performance	
Field of view	24° to 25°
Means of focusing	Manual, automatic or motor drive
Thermal sensitivity	0.08 °C to 0.12 °C and 80-120 mK
Detector	
Focal Plane Array	160 x 120 pixel or 320 x 240 pixel
Spectral range	7.5 – 13 um
Temperature range	
Temperature ranges	-40 °C to + 250 °C
Accuracy	±2 °C or ± 2% of reading
Power and operating conditions	
Power Input	Battery or AC
Operating temperature range	-15 °C to + 45 - 55 °C
Storage temperature range	- 40 °C to + 70 °C
Humidity	20-95% non-condensing
Physical specifications	
Weight range	0.70 kg to 1.40 kg
Size (LxWxH)	Typically - 207 mm x 92 mm x 109 mm or 265 mm x 80 mm x 105 mm
Video display and interface	
Video Interface	Built-in LCD RS 232 port to monitor USB to computer monitor
Mounting	Handheld / portable and fixed mounted

Table 2 – Differences of the various series

Feature	A series	E series	P series	S series
Mounting	Fixed	Fixed / portable	Portable	Portable
Method of focusing	Manual Motor	Manual	Automatic or manual	Automatic or manual
Focal Plane Array	160 x 120 320 x 240	160 x 120	320 x 240	320 x 240
Imaging viewing	External monitor	LCD	LCD	LCD
Weight	0.8 to 1.4 kg	0.7 kg	1.4 kg	1.4 kg
Thermal sensitivity	0.08 - 0.12°C	0.12 °C	0.08 °C	0.08 °C

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Telethermographic Camera

8.3 Intended Use

The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes

8.4 Patient Population

As indicated by the clinician.

8.5 Environments of use

Hospital, Sub-acute Institutions, public areas, i.e., airports.

8.6 Materials

There are no materials which come in contact the patient.

8.7 Performance Testing

There are no performance standards for these devices under Section 514.

Flir Systems as part of their ISO 9001 certification and requirements for CE marking in the European Union have had the devices tested to a number of international standards.

The standards to which the various models and their components have been tested and comply are listed below.

Standard	Complies or Passed
(b)(4)	

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Section 9 – Comparison to Predicates the Establishment of Substantial Equivalence

9.1 Comparison to Other Legally Marketed Predicate Devices

The following comparison table details the primary attributes of the intended device and legally marketed predicate devices. The most significant attributes have been listed.

Attribute	Proposed Device	Predicates Inframetrics K982327	Dorex Spectrum 9000mb K023434
Indications for use – Adjunctive diagnosis for measuring temperature patterns and changes	Yes	Yes but for cardiac applications	Yes
Method of data collection Non-contacting, passive infrared	Yes	Yes	Yes
Collection instrument – IR camera	Yes	Yes	Yes
Data Processing – CPU and software	Yes	Yes	Yes
Detector type Focal Plane Array	Yes	Yes	Yes
Temperature ranges	-40 °C to + 250 °C	Not stated	+ 15 °C to 40 °C
Accuracy	±2 °C or ± 2% of reading	Not stated	Not stated
Display	Monitor / LCD	Monitor	Monitor
None applicable under Section 514	Yes	Yes	Yes

9.2 Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the proposed devices and the predicates.

9.3 Substantial Equivalency

The Flir IR cameras are viewed as substantially equivalent to the predicate devices since they:

- Have the same intended uses –
 - Dorex Spectrum 9000mb - K023434
- Have the same environments for use –
 - No listed restrictions on the environments of use

- Are of the same design –
 - Dorex and Inframetrics
- They utilize the same technologies –
 - Inframetrics
- No materials come in contact with the patient skin.
 - Dorex and Inframetrics

9.4 Predicate Information

Section 14 includes predicate information for the Inframetrics – Infracam-Med, K982327 and Dorex – Spectrum 9000mb – K023434.

Section 10 - Biocompatibility

10.1 Biocompatibility

The proposed device and its components never come in contact with the patient's skin; therefore no biocompatibility testing is required.

Section 11- Sterilization Information

11.1 Sterilization

The device is not provided sterile.

Section 12- Hazard Analysis and Software

12.1 Hazard Analysis

We have included a hazard analysis for the basic E series camera as an example. The Hazard Analysis follows this section.

12.2 Software

The software incorporated in the ThermoCAM cameras captures and records the temperatures from the internal temperature sensors and then store and displays the data.

The software is considered a low level of concern.

FLIR Systems

Thermography, Danderyd

Product Name: ThermaCAM E Series

Document Title: Hazard Analysis Plan

Document Number: (b)(4)
 Document Filename: (b)(4)

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Revision Level	Revision Date	DCO/ECO Number	Description of Revision	Revision Author
(b)(4)	11/11/03	(b)(4)	Draft	(b)(6)
	19/11/03	(b)(4)	Initial Release	



COMPANY PROPRIETARY AND CONFIDENTIAL

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FLIR Systems
Thermography Danderyd
ThermaCAM E Series

Hazard Analysis Plan
(b)(4)
19/11/03

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 1.2 Description of Hardware 1
 1.3 Description of Software 1
2.0 Hazard Analysis 3

Table of Figures

Table 1. System Hardware Requirements 1
Table 2. Potential Hazards 3

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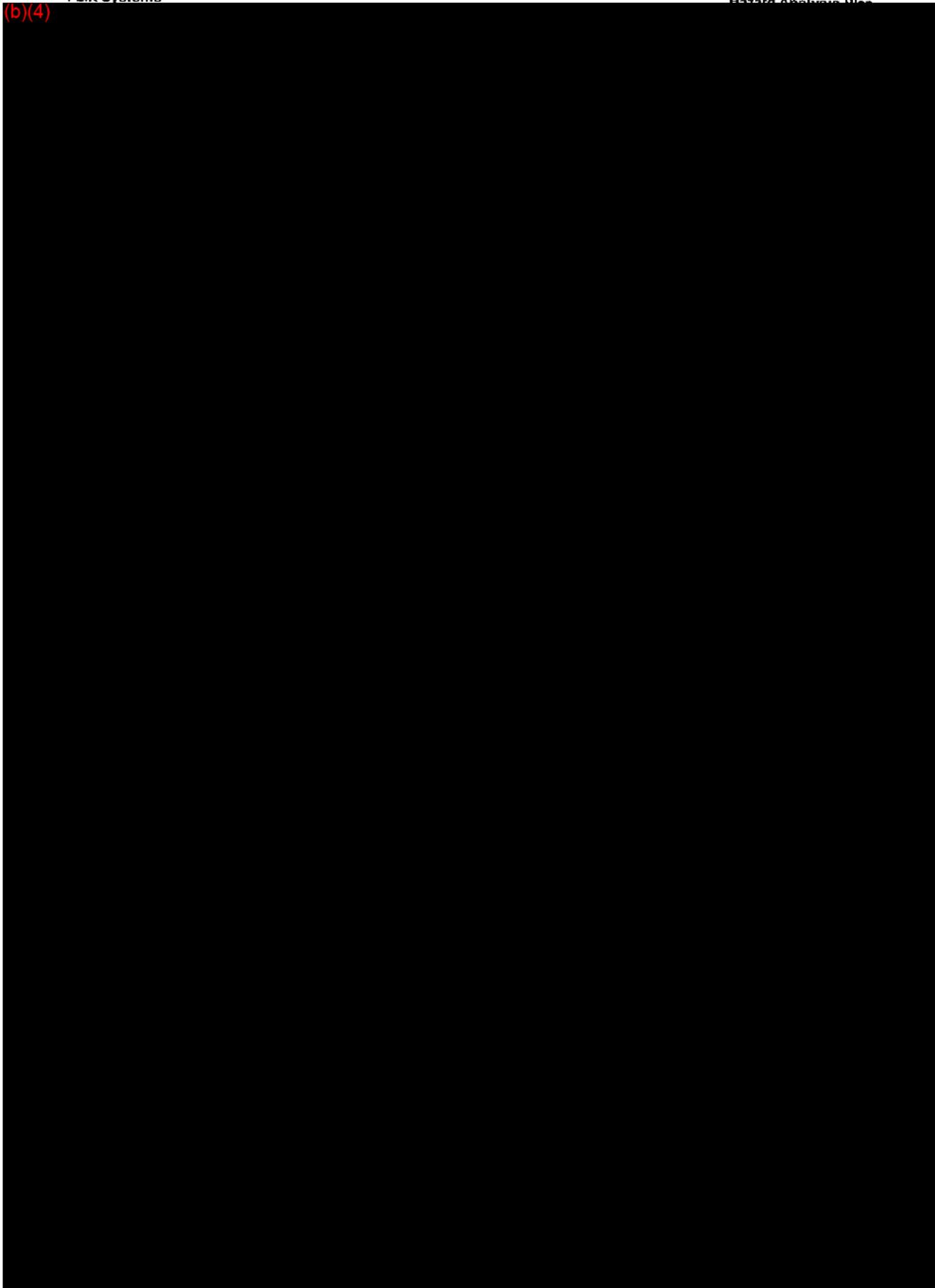
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FLIR Systems

Hazard Analysis Plan

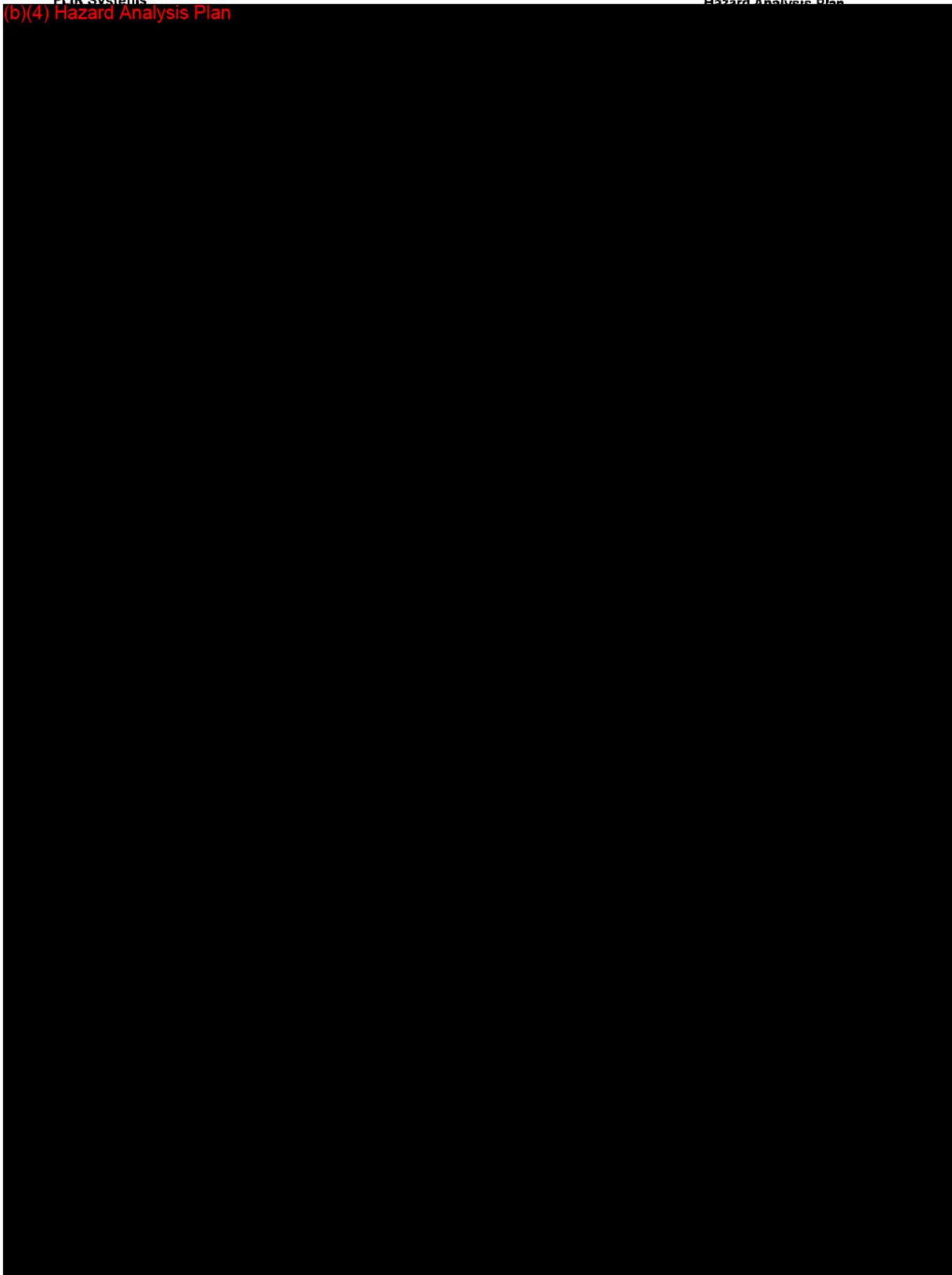
(b)(4)



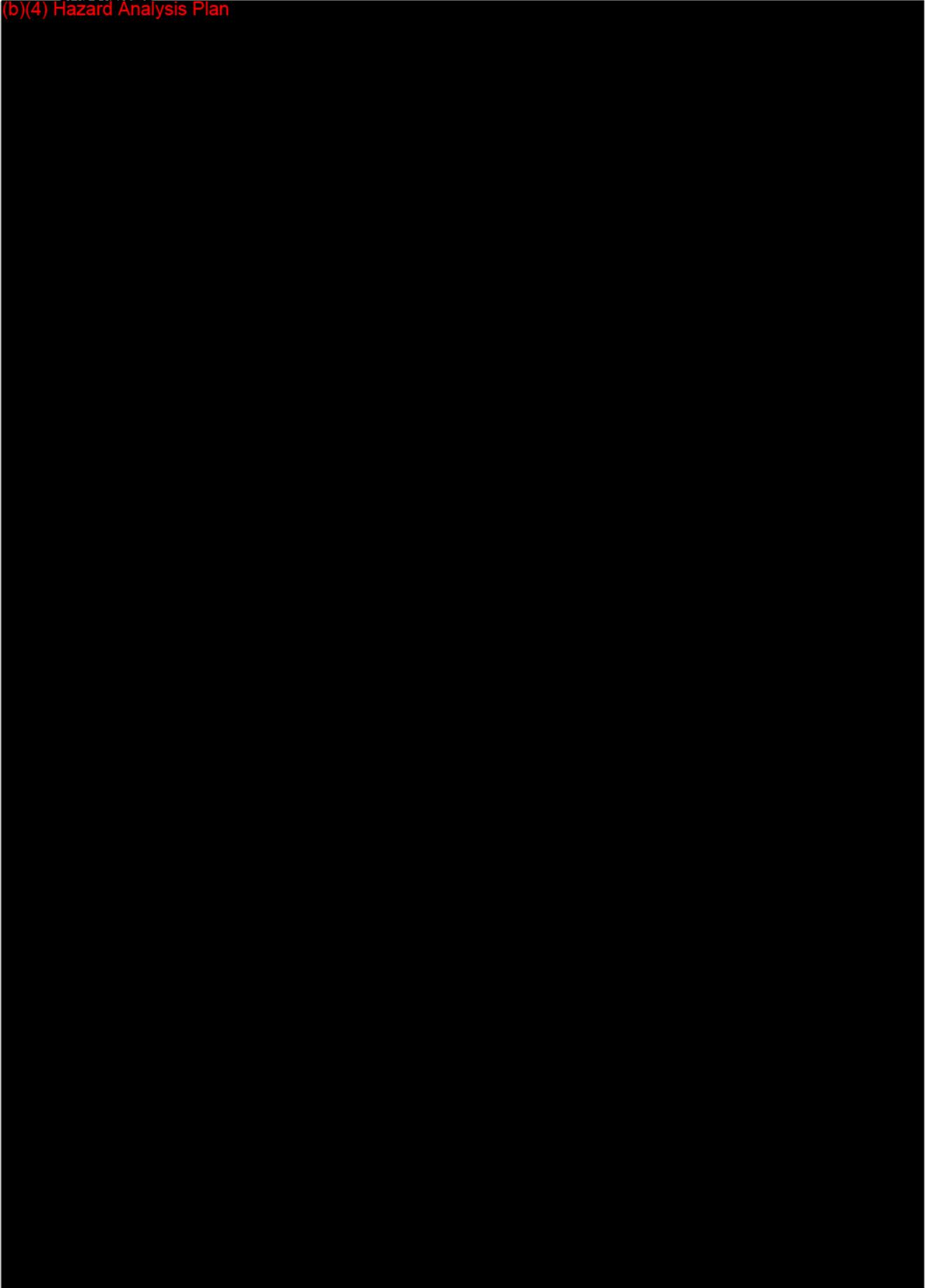
FLIR Systems

Hazard Analysis Plan

(b)(4) Hazard Analysis Plan



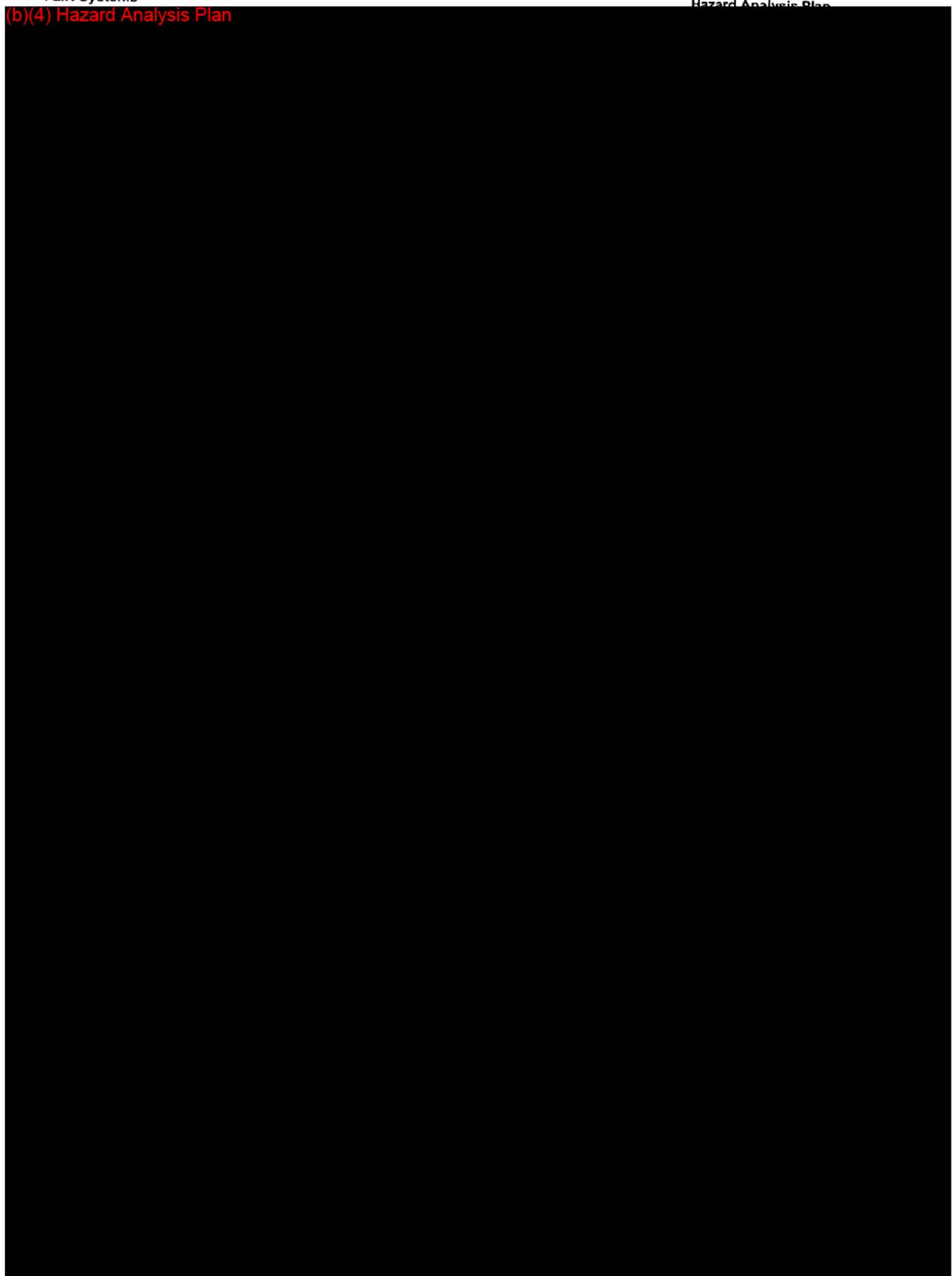
(b)(4) Hazard Analysis Plan



FLIR Systems

Hazard Analysis Plan

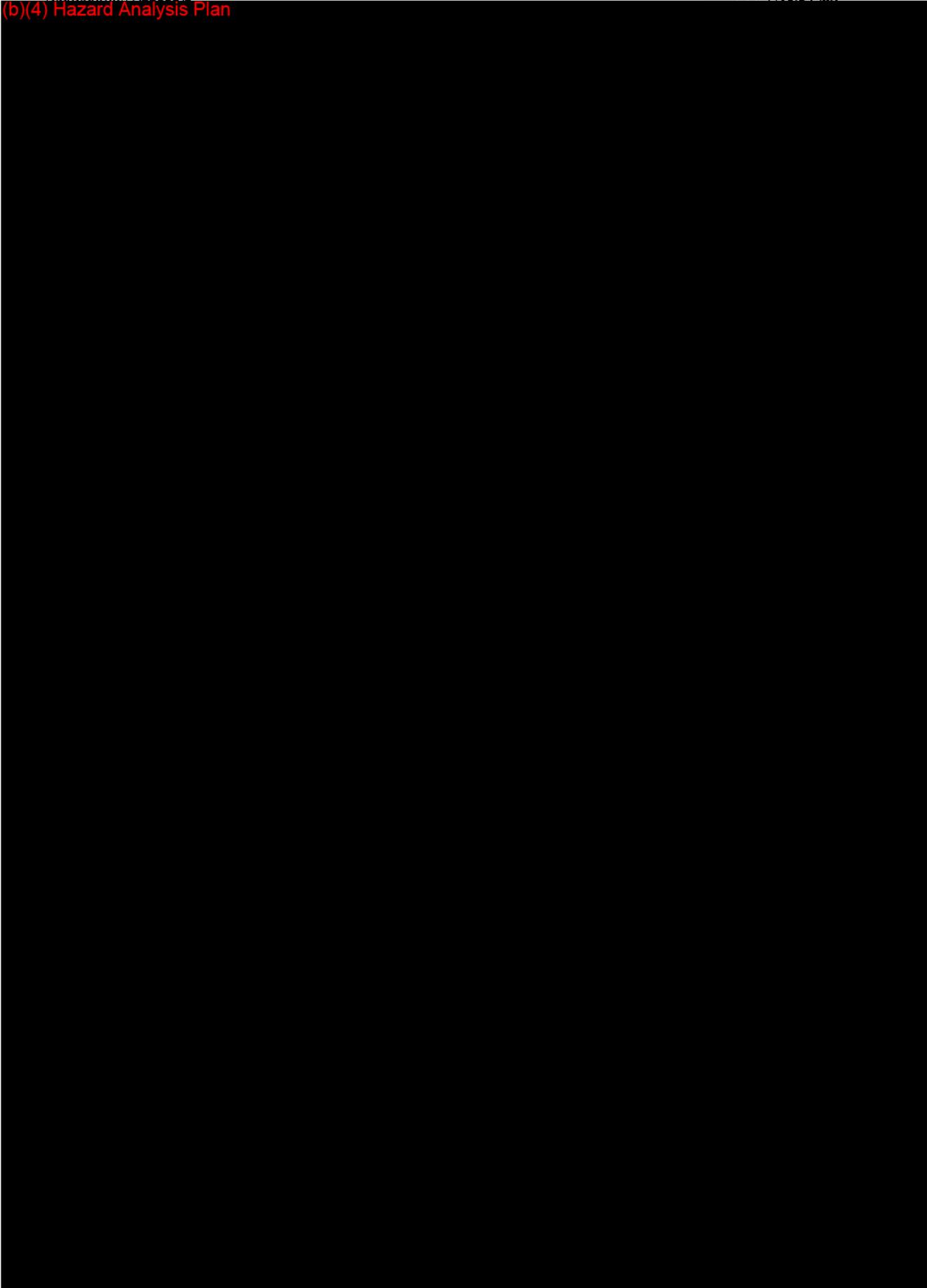
(b)(4) Hazard Analysis Plan



FLIR Systems

Hazard Analysis Plan

(b)(4) Hazard Analysis Plan



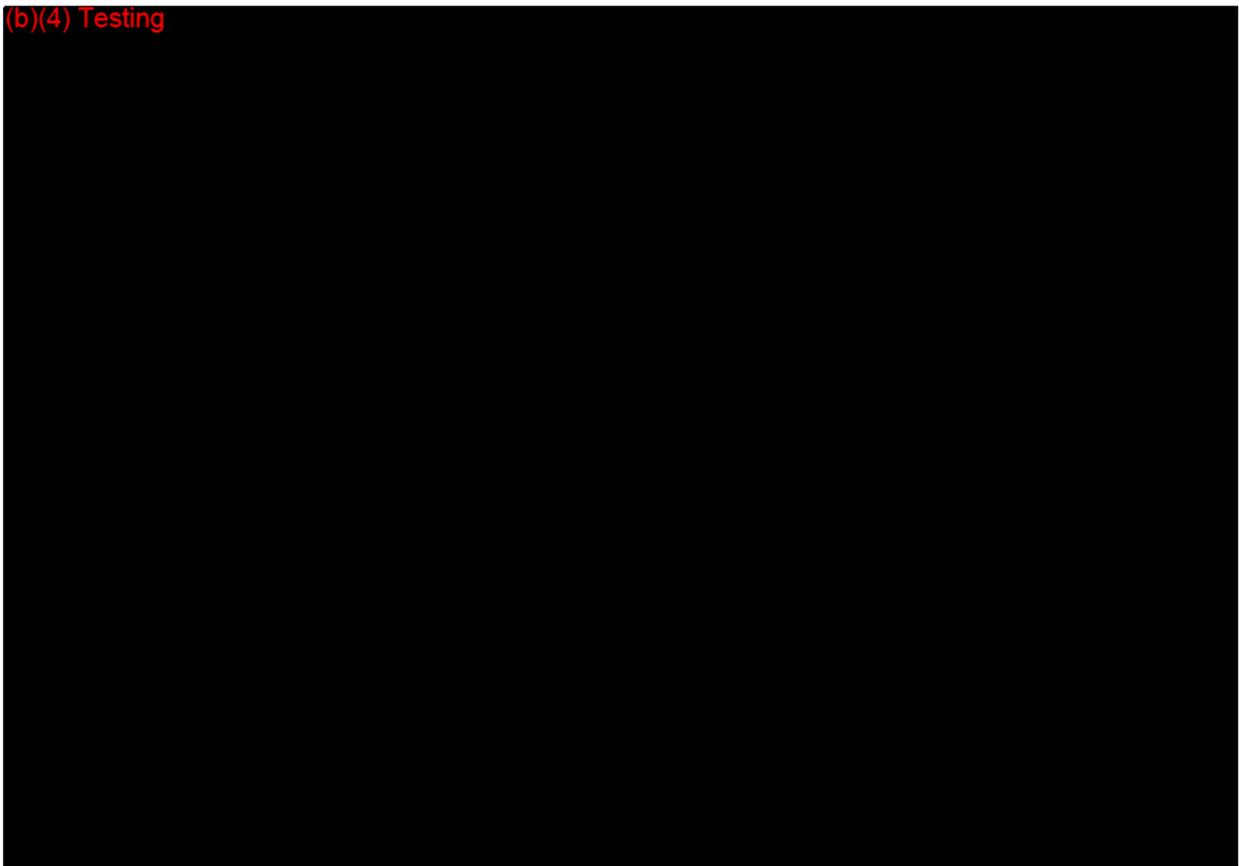
Section 13 - Performance Standards

13.1 Performance Standards

There is no performance standards established under Section 514.

As part of Flir's compliance with CE marking for the European Union and ISO 9001 certification the devices have been tested to a number of international standards.

(b)(4) Testing





(b)(4)

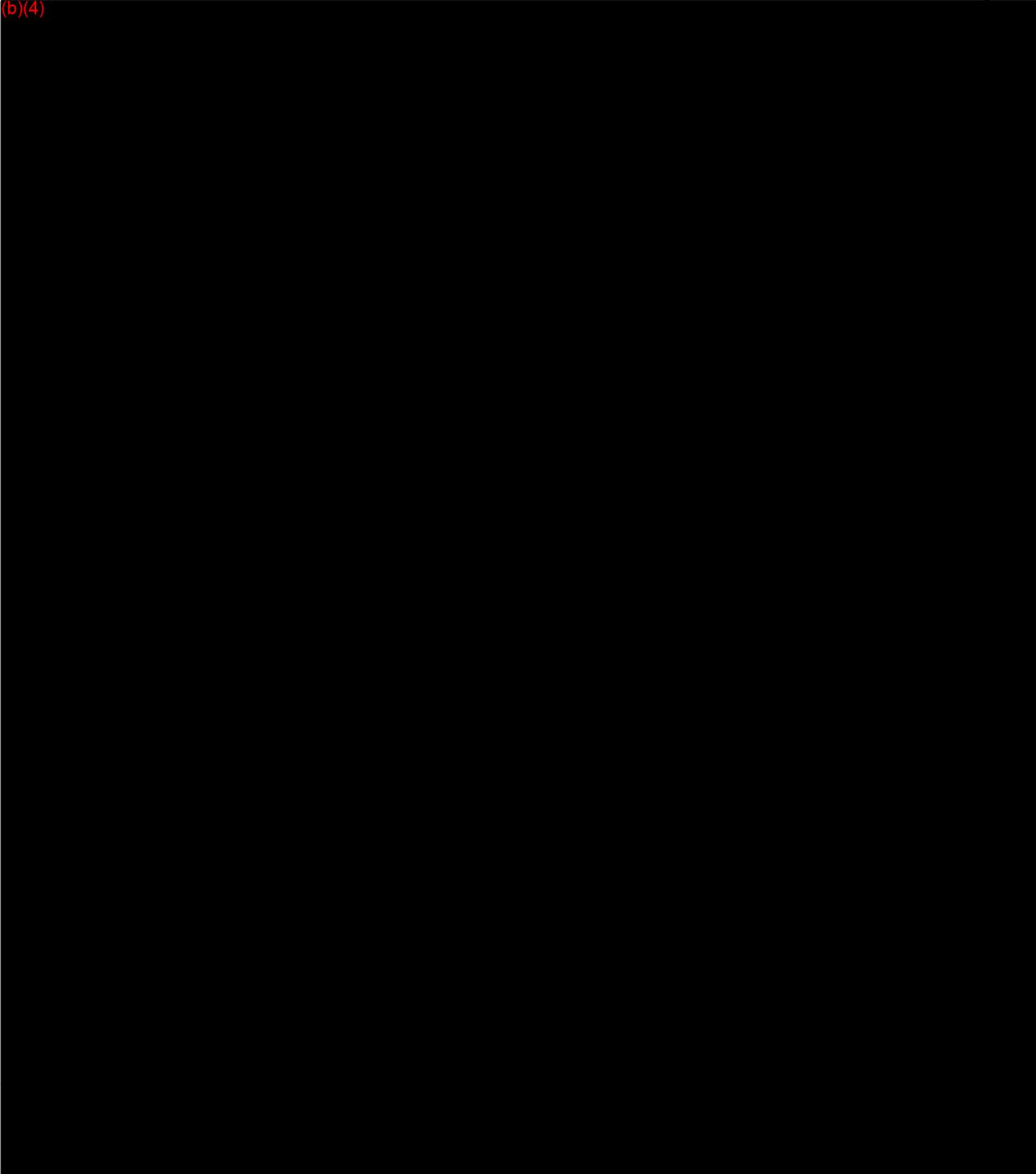
**Calibration and traceability of the measurement accuracy of
Thermal Imaging Systems manufactured by FLIR Systems AB**

(b)(4)



4 Camera calibration

(b)(4)



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Section 14 – Predicate Information

Section	Description
14.1	Inframetrics – Infracam-Med – K982327
14.2	Dorex, Inc. – Spectrum 9000mb – K023434

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[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

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510(k) Premarket Notification Database

Device Classification Name	System, Telethermographic (Adjunctive Use)
Regulation Number	884.2980
510(K) Number	K982327
Device Name	Inframetrics Infracam-Med
Applicant	Inframetrics, Inc. 49 Plain St. North Attleboro, MA 02760 4153
Contact	Mary Mcnamara-Culli
Product Code	LHQ
Date Received	07/02/1998
Decision Date	08/18/1998
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	Radiology
Statement/Summary/Purged Status	Summary/Purged 510(K)
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 12/09/2003

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K982327

AUG 18 1998

510(k) Summary
for
Inframetrics InfraCAM-MED

1. COMPANY NAME AND ADDRESS

Applicant Name and Address

Inframetrics, Inc.
16 Esquire Road
North Billerica, MA 01862-2598

Contact Person

Michael Paulding, Medical Products Manager
781-670-5555

Date of Summary Preparation

July 1, 1998

2. DEVICE NAME

Proprietary Name:	Inframetrics InfraCAM-MED
Common/Usual Name:	Thermographic Camera System
Classification Name:	Telethermographic System Surgical Camera and Accessories

3. IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) TO WHICH EQUIVALENCE IS BEING CLAIMED

The Inframetrics InfraCAM-MED is substantially equivalent to several legally marketed infrared thermography systems, such as the Opgal IVA-2000 distributed by OPGAL (K951806), and the Inframetrics Model 535 Infrared Medical Thermography System (K822729).

Inframetrics, Inc. 510(k)
Inframetrics InfraCAM-MED

7/1/98

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4. DEVICE DESCRIPTION

The InfraCAM-MED is a small infrared camera with integral high-resolution CRT viewfinder. It is a battery operated thermal imaging system that is completely self contained with integral TV compatible display. The InfraCAM-MED is qualified to MIL STD 810E. The camera head houses the thermal image camera. During surgery, the camera is situated outside the sterile field therefore it is not covered by a sterile drape.

5. INTENDED USE

The InfraCAM-MED is a non-contact, non-invasive, non-radiating, thermal (infrared) imaging video camera intended as an adjunctive diagnostic device for viewing heat patterns generated by the relative surface temperature of human heart tissue and vessels during coronary artery bypass graft surgery. Images of the exposed heart may be captured as a black/white video image using VHS/SVHS videotape, or a black/white still image using a thermal image printer. The InfraCAM-MED Thermal Coronary Angiography imaging camera may be used to perform the following:

- Viewing and documenting temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by the injection of cold or warm fluid into the proximal end of a vein graft.
- Viewing and documenting temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by blood flow after release of the cross clamp(s) on a arterial graft.
- Viewing and documenting temperature changes to the myocardium during the retrograde or antegrade perfusion of warm or cold cardioplegia.

6. A Statement of How the Technological Characteristics of the Device Compare to Those of the Predicate or Legally Marketed Device(s) Cited

The Inframetrics InfraCAM-MED is substantially equivalent to the Opgal IVA-2000 and the Inframetrics Model 535 Infrared Medical Thermography System in intended use in that they all are intended to visualize and document temperature

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patterns and temperature changes in tissue temperature during coronary artery bypass surgeries. In addition, the InfraCAM-MED is intended to view and document temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by the injection of cold or warm fluid into the proximal end of a vein graft, view and document temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by blood flow after release of the cross clamp(s) on an arterial graft, and view and document temperature changes to the myocardium during the retrograde or antegrade perfusion of warm or cold cardioplegia.

All three systems have various design features in common. Neither the InfraCAM-MED, the Model 535 Infrared Medical Thermography System nor the IVA-2000 is in direct contact with the patient. The systems vary in components and accessories. All three include a thermal image camera. The IVA-2000 and Model 535 include a CCD camera, videocassette recorder, and thermal printer while the InfraCAM-MED includes only the camera.

Unlike the IVA-2000 and the Model 535, the Inframetrics InfraCAM-MED does not allow image capture and storage for subsequent retention and/or review. The Inframetrics InfraCAM-MED and both predicate devices display images in real time with the capability for printing and recording. The IVA-2000 and the Model 535 use keyboard entry of relevant procedural data, such as patient identifiers. The Inframetrics InfraCAM-MED does not provide for data entry or overlay of information on the image whereas both the Model 535 and the IVA-2000 do both.

The InfraCAM-MED displays the thermal image in 256 shades of Black and White, whereas the IVA 2000 uses 256 shades of Black/White or Red/White. No color bar is utilized. The Model 535 is color selectable in 6, 10, 14, or 20 colors. Neither the proposed InfraCAM-MED nor the IVA-2000 displays the temperature of the target whereas the Model 535 displays temperature in degrees. The IVA-2000 is software controlled. The Inframetrics InfraCAM-MED and the Model 535 do not utilize a microprocessor for any function.

Additionally, both animal and clinical testing were performed using the InfraCAM-MED which showed that the InfraCAM-MED performs as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 18 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Inframetrics, Inc.
c/o Mary McNamara-Cullinane
Medical Device Consultants
49 Plain Street
North Attleboro, MA 02760

Re: K982327
Inframetrics InfraCAM-MED
Dated: July 1, 1998
Received: July 2, 1998
Regulatory class: I
21 CFR 884.2980/Procode: 90 LQH

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): _____

Device Name: Inframetrics InfraCAM-MED

Indications For Use:

The InfraCAM-MED is a non-contact, non-invasive, non-radiating, thermal (infrared) imaging video camera intended for viewing heat patterns generated by the relative surface temperature of human heart tissue and vessels during coronary artery bypass surgery. Images of the exposed heart may be captured as black/white video images using VHS/SVHS videotape, or black/white still images using a thermal image printer. The InfraCAM-MED may be used to perform the following:

- Viewing and documenting temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by the injection of cold or warm fluid into the proximal end of a vein graft.
- Viewing and documenting temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by blood flow after release of the cross clamp(s) on an arterial graft.
- Viewing and documenting temperature changes to the myocardium during the retrograde or antegrade perfusion of warm or cold cardioplegia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Samuel G. Segura
 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K982327

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

Inframetrics, Inc. 510(k)
Inframetrics InfraCAM-MED

7/1/98

CONFIDENTIAL

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Records

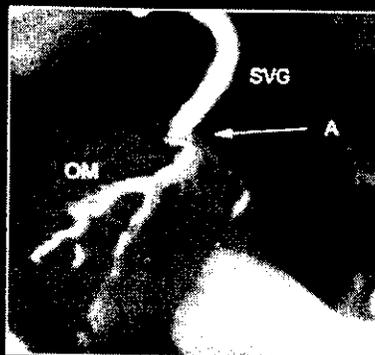
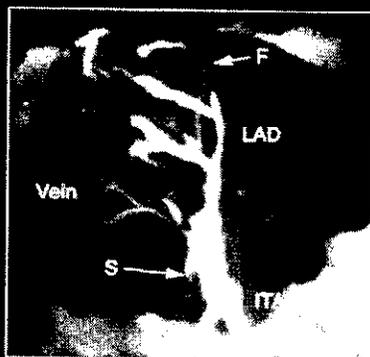
inframetrics

InfraCAM - MED

*Thermal Coronary
Angiography*



Inframetrics Thermal Coronary Angiography System

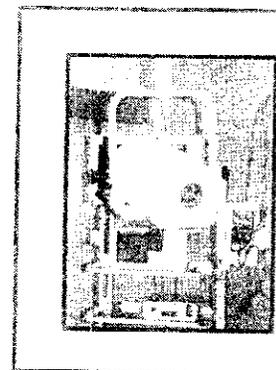


Inframetrics Focal Plane Array Thermal Imagers allow clear visualization of both SV and ITA grafts. Occlusions, particularly anatomic sites, are seen instantly. Leaks are visible as well. TCA is performed in under two minutes without disruption to the surgical procedure. Inframetrics' superb image quality allows even retrograde venous flow to be seen.

Thermal Coronary Angiography (TCA) is the use of an infrared thermal imaging camera to obtain a real-time "heat picture" of the heart. All objects emit photons at various excited states in accordance with their temperature. As an infrared detector is impacted by these photons, it converts their energy into electrical impulses that are assembled into a video image.

TCA can help the surgeon immediately identify and document problems during bypass surgery, and can produce real-time video of blood flow at, and distal to, the anastomotic site without the use of contrast agents or ionizing radiation. In TCA, as tissue warms it appears brighter (whiter), and as it cools it appears darker. The temperature differences produced by warmer blood flowing through an internal thoracic artery (ITA) graft or by injecting cold cardioplegic solution into the proximal end of a vein graft produce a black and white contrast video image.

All thermal coronary angiography Images from *Thermal Coronary Angiography: A Method For Assessing Graft Patency And Coronary Anatomy In Coronary Bypass Surgery*. Volkmar Falk M.D., Friedrich W. Mohr, M.D., Ann Thorac Surg 1997 May 63:5 1506-7. Drs. Mohr and Falk are located at Universitaet Leipzig, Herzzentrumr, Klinik fuer Herzchirurgie, Leipzig Germany.



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From left to right: Images show progression of injection of cold cardioplegia which cools (darkens) vein graft.

CABG Applications

Pre-Graft Placement:

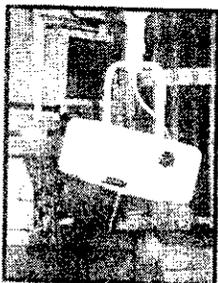
- ◆ Helps locate native coronary arteries.
- ◆ Visualizes and documents perfusion of cardioplegia and ensures myocardial protection
- ◆ Helps locate intramuscular coronary arteries in re-operation patients.

Post-Graft Placement:

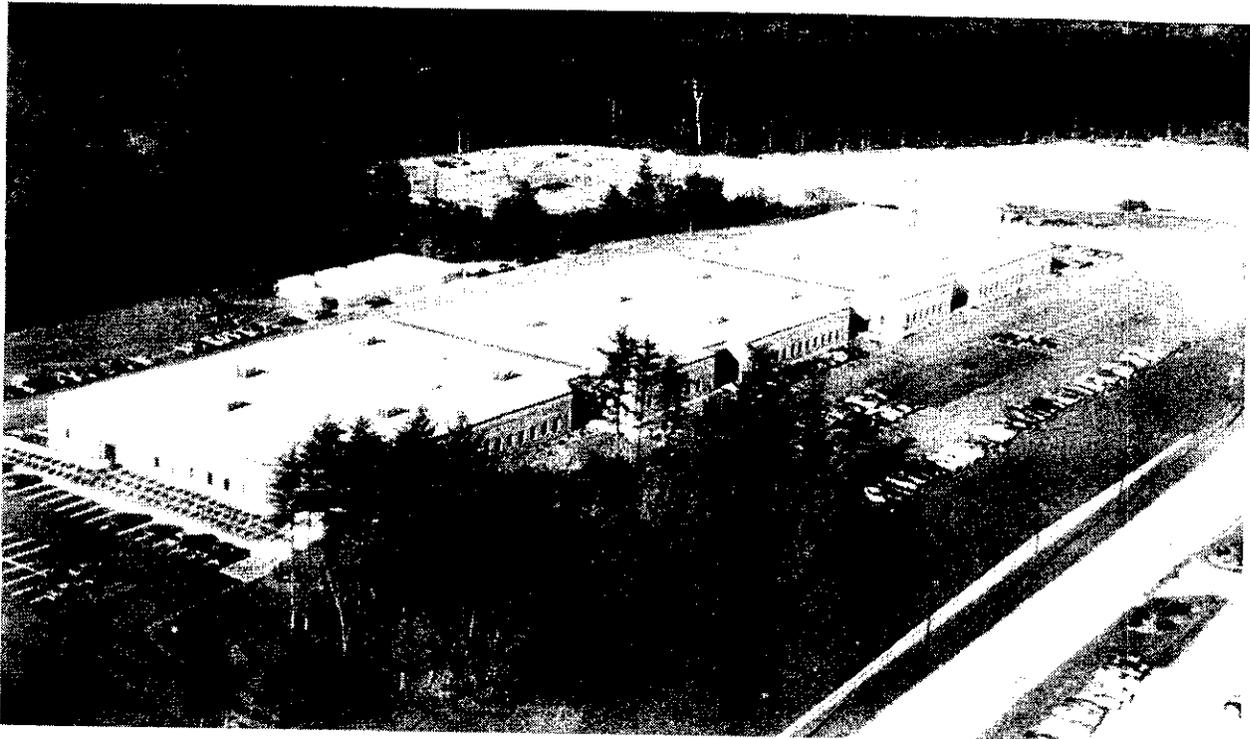
- ◆ Verifies and documents graft patency.
- ◆ Verifies and documents myocardial perfusion.
- ◆ Visualizes and documents blood flow distal to the anastomotic site to check for distal occlusions.

System Benefits

- ◆ Immediate documentation of the success or failure of revascularization prior to wound closure.
- ◆ Requires no contact with the patient.
- ◆ No ionizing radiation.
- ◆ No need for contrast agents.
- ◆ No interference with the surgical procedure.
- ◆ Ceiling-mounted configuration for space optimization.



The Inframetrics InfraCAM - MED TCA video camera uses a focal plane array detector to produce high-resolution images of the heart during CABG procedures. It can be connected to standard operating room video recording equipment and monitors with a video cable. The InfraCAM - MED is designed to be ceiling-mounted (left image) or wall-mounted on a camera arm, and positioned above and perpendicular to the chest cavity. Additionally, its lightweight construction and small size (8.25" x 3.75" x 1.0" L x W x H) allow a hand-held use option if the system is placed in a sterile bag.



ABOUT INFRAMETRICS

Inframetrics is a world leader in the design and manufacture of infrared thermal imaging and measurement systems. Since our founding in 1975, we have introduced a broad scope of new products based upon continuing innovation and proven performance. We continue to pioneer, advance, and refine IR technology. Today, an array of Inframetrics' user-friendly IR systems are being applied in such diverse fields as: predictive maintenance, product research and development, aerospace research, nondestructive evaluation, process monitoring and control/QC, electronics design and manufacturing, navigation, search and rescue, surveillance, law enforcement, and the military. Through our international sales network, Inframetrics serves a worldwide customer base that includes Fortune 500 companies, small to medium sized manufacturers, universities and research organizations, electric utilities, and government agencies. A focus on "real world" research, applications engineering, customer training and highly responsive on-site field applications support has built a customer loyalty for Inframetrics unmatched in the infrared industry.

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510(k) Premarket Notification Database

Device Classification Name	System, Telethermographic (Adjunctive Use)
Regulation Number	884.2980
510(K) Number	K023434
Device Name	Dorex Spectrum 9000mb Thermography System
Applicant	Dorex, Inc. 954 North Lemon St. Orange, CA 92867
Contact	Mel Kutas
Product Code	LHQ
Date Received	10/15/2002
Decision Date	11/14/2002
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	Radiology
Statement/Summary/Purged Status	Statement Only
Statement Type	Statement Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 12/09/2003

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and limiting moving parts to a single unit. The inherent simplicity of the staring focal plane architecture makes true IR portability a reality. Room-temperature operation eliminates the need for cryocooling, which improves sensor reliability while reducing sensor power and cost.

System Architecture:

Versatile software that puts control in your hands with Dorex™, Windows™ software. All the imaging power of focal plane technology is at your command through a simple interface. In moments you can open several windows for comparison views, develop databases automatically, create instant charts and make 3D graphs to highlight areas of special interest. Dorex also develops customized software for specialized applications.

Flexible Data Output

Dorex Spectrum 9000 camera offers digital output, allowing direct interface with a computer. This allows easy archiving of data for future retrieval and analysis.

Compact Camera Components

Dorex has streamlined components within the camera. The Image Processor is the heart of the system, operating the FPA, providing calibration, gain and offset control, and output to a computer using proprietary Dorex Digital Output Board.

Sensor Head - Uncooled Microbolometer:	Specifications
Focus Distance	3" - Inf.
Lens f/#	0.8
Number of detectors (Az)	320
Number of detectors (Ei)	240
FOV (deg), Az	24.86
FOV (deg), Ei	18.65
IFOV (mrad)	1.02
Spectral band (microns)	8-14
Frame rate (Hz)	30 (Real-time)
Number of samples	76,800

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Temperature range	15-40°C
Sensor ambient temperature calibration	Internal / automatic
Output	100% digital output
Software:	
Continuous Imaging & Image Capture	3D Topography w/rotation
Real Time Image Comparison	Image Magnifier
Thermal Density (Histogram)	Text Mode
Selectable Area Temperature - Single/Multiple	Patient Data Base
Isotherm/Subtherm Display	Color/Monochrome Display
Multiple Image Display	Video Reverse Polarity
2D, 3D, or Line Temperature Graphing	256 Colors
* Optional Network Capability	

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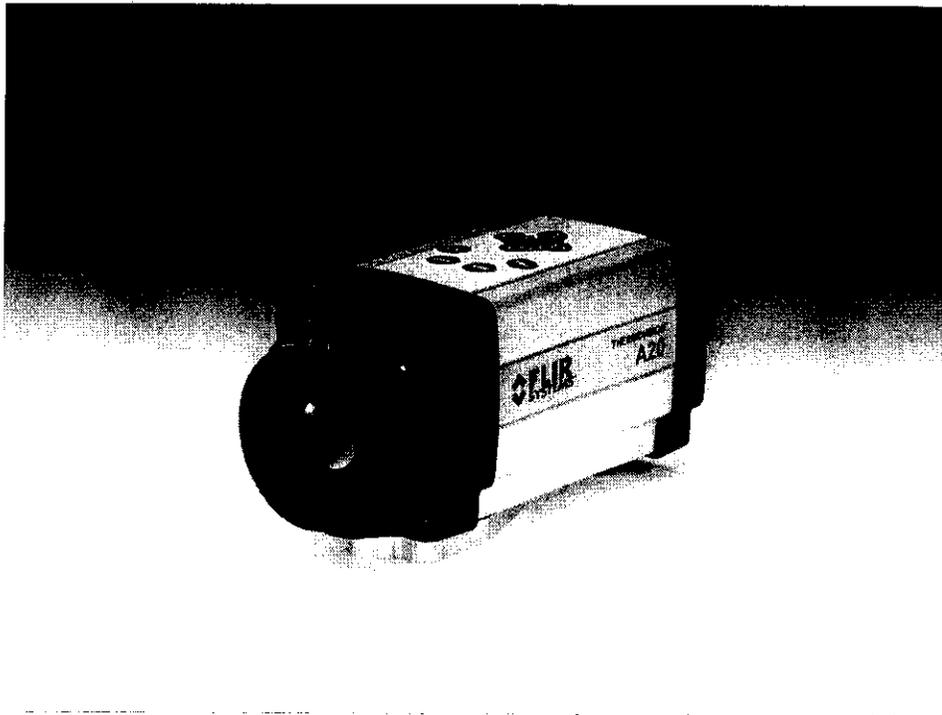
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Section 15 – User Manual

ThermoVision™ A20 V

Operator's manual



Composite video configuration

Publ. No.	1 557 736
Revision	a24
Language	English (EN)
Issue date	November 17, 2003

ThermoVision™ A20 V

Operator's manual



Publ. No. 1 557 736 Rev. a24 – ENGLISH (EN) – November 17, 2003

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All products manufactured by FLIR Systems AB are warranted against defective materials and workmanship for a period of one (1) year from the delivery date of the original purchase, provided such products have been under normal storage, use and service, and in accordance with FLIR Systems AB's instruction.

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This product is protected by patents, design patents, patents pending, or design patents pending.

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2 Welcome!

Thank you for choosing ThermoVision™ A20 V!

ThermoVision™ A20 V is the obvious choice for customers looking for a small and reliable infrared camera for security applications where a higher resolution than 160 × 120 pixels is not necessary. ThermoVision™ A20 V has an integral keypad for control and set-up of the camera, and CVBS output (composite video) for viewing and analyzing the infrared image on an external video monitor.

For customers who want to develop their own applications, FLIR Systems offers ThermoVision SDK (software developer's kit).

2.1 About FLIR Systems

With over 30 years experience in IR systems and applications development, and over 30 000 infrared cameras in use worldwide, FLIR is the undisputed global commercial IR industry leader.

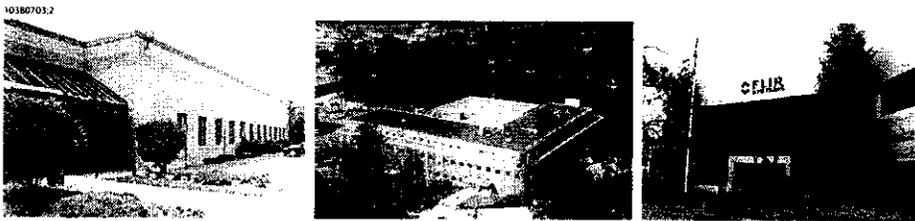


Figure 2.1 FLIR Systems, Boston, USA, FLIR Systems, Danderyd, Sweden, and FLIR Systems, Portland, USA.

As pioneers in the IR industry, FLIR Systems has a long list of 'firsts' in the world of infrared thermography:

- 1965: 1st thermal imaging system for predictive maintenance (Model 650).
- 1973: 1st battery-operated portable IR scanner for industrial applications predictive maintenance (Model 750).
- 1975: 1st TV compatible system (Model 525).
- 1978: 1st dual-wavelength scanning system capable of real-time analog recording of thermal events (Model 780). Instrumental in R & D market development.
- 1983: 1st thermal imaging and measurement system with on-screen temperature measurement.
- 1986: 1st TE (thermo-electrically) cooled system.
- 1989: 1st single-piece infrared camera system for PM (predictive maintenance) and R & D (research & development) with on-board digital storage.
- 1991: 1st Windows-based thermographic analysis and reporting system.
- 1993: 1st Focal Plane Array (FPA) system for PM and R & D applications.

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2.1 – About FLIR Systems

- 1995: 1st full-featured camcorder style FPA infrared system (ThermaCAM).
- 1997: 1st uncooled microbolometer-based PM/R & D system.
- 2000: 1st thermography system with both thermal and visual imaging.
- 2000: 1st thermography system to incorporate thermal/visual/voice and text data logging.
- 2002: 1st automated thermography system (model P60) to feature detachable remotely controllable LCD, JPEG image storage, enhanced connectivity including USB and IrDA wireless, thermal/visual/voice and text data logging.
- 2002: 1st low-cost ultra-compact hand-held thermography camera (E series). Revolutionary, ergonomic design, lightest IR measurement camera available.

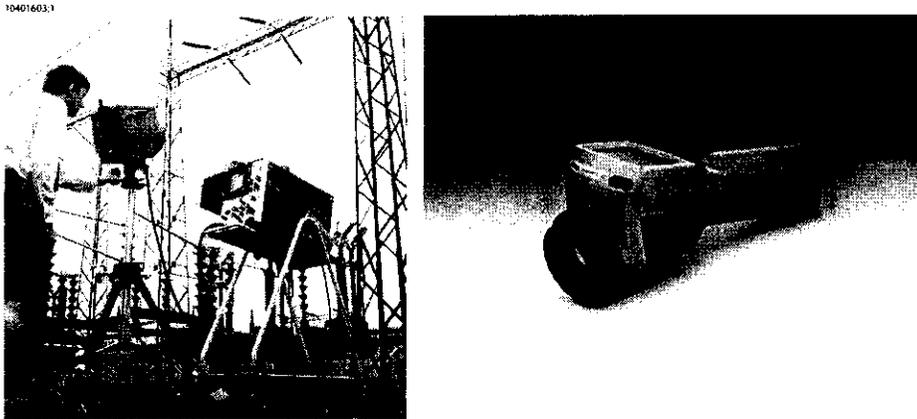


Figure 2.2 LEFT: FLIR Systems' Thermovision® Model 661. The photo is taken on May 30th, 1969 at the distribution plant near Beckomberga, in Stockholm, Sweden. The camera weighed approx. 25 kg (55 lb), the oscilloscope 20 kg (44 lb), the tripod 15 kg (33 lb). The operator also needed a 220 VAC generator set, and a 10 L (2.6 US gallon) jar with liquid nitrogen. To the left of the oscilloscope the Polaroid attachment (6 kg/13 lb) can be seen. **RIGHT:** FLIR Systems' ThermaCAM Model E2 from 2002 – weight: 0.7 kg (1.54 lb), including battery.

With this tradition of unparalleled technical excellence and innovative achievements, FLIR continues to develop new infrared products, educational venues and applications expertise to meet the diverse demands of thermographers worldwide.

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2.1 – About FLIR Systems

2.1.1 A few images from our facilities

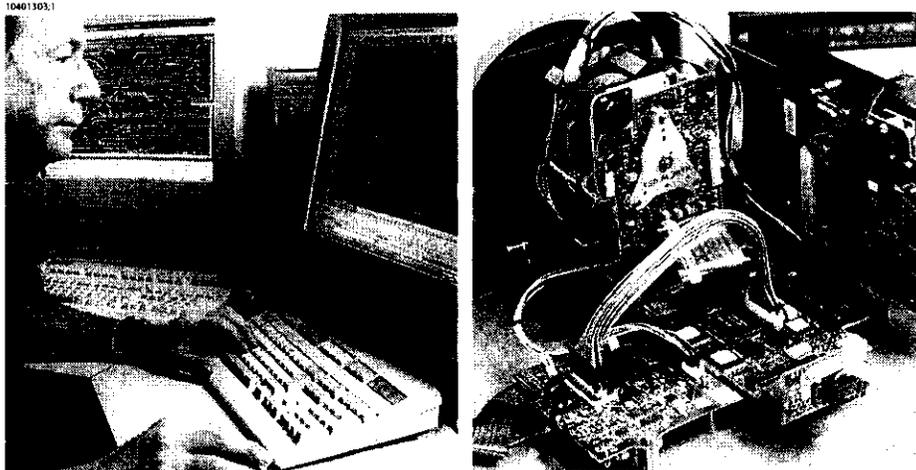


Figure 2.3 LEFT: Development of system electronics; RIGHT: Testing of an FPA detector



Figure 2.4 LEFT: Diamond turning machine; RIGHT: Lens polishing

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Figure 2.5 LEFT: Testing of IR cameras in the climatic chamber; RIGHT: Robot for camera testing and calibration

2.2 Comments & questions

FLIR Systems is committed to a policy of continuous development, and although we have tested and verified the information in this manual to the best of our ability, you may find that features and specifications have changed since the time of printing. Please let us know about any errors you find, as well as your suggestions for future editions, by sending an e-mail to:

documentation@flir.se

NOTE: Do not use this e-mail address for technical support questions. Technical support is handled by FLIR Systems local sales offices.

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3 Key features

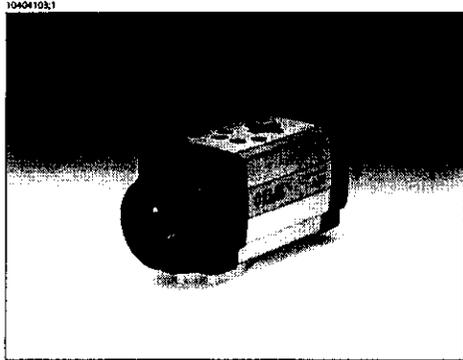


Figure 3.1 ThermoVision™ A20V

3.1 *Typical applications*

- Security & surveillance

3.2 *Main features & functions*

- Rugged
- Affordable
- CVBS output (composite video)
- Externally mounted motor focus (extra option)
- Changed settings are automatically saved

3.3 *Analysis functions*

- Isotherm signal (above, below, interval)

3.4 *Image storage*

- By using menu system and/or keypad

3.5 *Image out*

- CVBS (composite video)

3.6 *Camera control*

- Keypad
- RS-232

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4 Packing list

The ThermoVision™ A20 V and its accessories are delivered in a box which typically contains the items below. On receipt of the box, inspect all items and check them against the delivery note. Any damaged items must be reported to the local FLIR Systems representative immediately.

No.	Description	Part number	Qty
1	Video cable	908 929	1
2	Power supply	1 909 528	1
3	Installation CD for ThermoCAM Connect 3	1 195 850	1
4	Operator's manual	1 557 736	1
5	ThermoVision™ A20 V	Configuration-dependent	1

NOTE: The packing list is, to some degree, subject to customer configuration and may contain more or less items.

NOTE: FLIR Systems reserves the right to discontinue models, parts and accessories, and other items, or change specifications at any time without prior notice.

SEE: For information about installing ThermoCAM Connect 3, see section 6 – Installation & operation of ThermoCAM Connect 3 on page 9.

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5 List of accessories

No.	Description
1 195 642	Hard case
1 195 271	25° IR lens with case
1 195 272	12° IR lens with case
1 195 273	45° IR lens with case
1 122 048	Spring for 25° IR lens
1 122 059	Spring for 12° IR lens
1 122 060	Spring for 45° IR lens
1 195 027	25° IR lens without case
1 195 269	12° IR lens without case
1 195 270	45° IR lens without case
1 909 528	Power supply, incl. cable
1 195 436	High temperature option to +900° C (+1652° F)

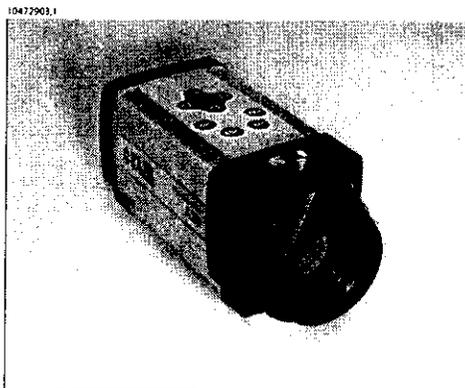


Figure 5.1 When exposed to severe vibrations, the focus ring on the camera may show a tendency to move. To prevent this, FLIR Systems AB has developed a spring which locks the focus ring on the infrared lens. The spring is mounted on top of the camera housing by using a metric M3 screw. See table above for part numbers and sizes.

6 Installation & operation of ThermaCAM Connect 3

6.1 Introduction

FLIR Systems AB's software ThermaCAM Connect 3 lets you download images from your infrared camera to your desktop or laptop computer.

6.2 Installation

NOTE: This installation tutorial applies to ThermaCAM Connect 3 only.

6.2.1 Software requirements

6.2.1.1 Camera

ThermaCAM Connect 3 will only work with these camera configurations:

- A series cameras: boot2 version 1.0.2.1 (or higher)
- A series cameras: appl version 1.0.2.1 (or higher)

To check the version of boot2/appl, select **Setup** → **Camera Info** in the camera. Make sure the version number of the module 'boot2'/'appl' is as stated above.

6.2.1.2 PC

Serial communication (RS-232) between PC and camera is supported on the following operating systems:

- Windows 98 Second Edition
- Windows Me
- Windows NT 4, Service Pack 6
- Windows 2000
- Windows XP

USB and connections between PC and camera is supported on the following operating systems:

- Windows 98 Second Edition
- Windows Me
- Windows 2000
- Windows XP

NOTE: Before you install the application, please close all other programs on the computer. Make sure ThermaCAM Connect 3 is installed before connecting the camera to the USB or port.

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6.2 - Installation

6.2.2 Installing ThermaCAM Connect 3

Step	Action
1	Make sure the IR camera is switched off and the cable between the IR camera and the computer is not connected.
2	Insert the ThermaCAM Connect 3 installation CD into the CD-ROM drive.
3	Select the preferred language and follow the on screen instructions.

NOTE: If the installation program doesn't start when you insert the installation CD, please start the program manually by following the steps below.

Step	Action
1	Double-click My Computer on the Desktop.
2	Right-click on your CD-ROM drive and click Explore .
3	Double-click SETUP.EXE
4	Select the preferred language and follow the on screen instructions.

6.2.3 Installing drivers

When the ThermaCAM Connect 3 installation is finished, you have to install the drivers depending on how you connect the infrared camera to your computer. If you are using serial communication, you can skip this part and continue with section 6.3.1 – Transferring the images from the camera to the computer on page 14. Before you continue with the installation, have your Windows installation CDs available. Make sure that the ThermaCAM Connect 3 installation CD is inserted into your CD-ROM drive.

You find the appropriate installations procedure on the following pages, matching your Windows operating system and communication protocols.

6.2.3.1 FireWire/1394 Driver Installation Procedure for Microsoft Windows XP

Step	Action
1	When the system has detected the ThermaCAM, the Welcome to the Found New Hardware Wizard window appears. The wizard asks: What do you want the wizard to do? Select Install from a list or specific location .
2	Click Next .

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6.2 – Installation

Step	Action
3	The next wizard window is displayed: Please choose your search and installation options. <ul style="list-style-type: none"> ▪ Select Search for the best driver in these locations ▪ Clear Search removable media ▪ Select Include this location in the search ▪ Click Browse and locate folder "C:\Program Files\FLIR Systems\Device drivers" ▪ Click Ok
4	Click Next .
5	The next wizard window is displayed: The driver has not passed Windows Logo testing to verify its compatibility with Windows XP. Click Continue Anyway .
6	The wizard copies the necessary driver files to your system.
7	The first driver installation procedure is completed. Click Finish .
8	Welcome to the Found New Hardware Wizard window appears again. Repeat step 1 to 7. After that the driver installation is complete.
9	Reboot your computer if prompted to do so.

6.2.3.2 *FireWire/1394 Driver Installation Procedure for Microsoft Windows 2000*

Step	Action
1	When the system has detected the ThermoCAM, the Welcome to the Found New Hardware Wizard window appears. Click Next .
2	The next wizard window is displayed: This wizard will complete the installation for this device: FLIR 1394 Network Adapter. The wizard asks: What do you want the wizard to do? Select Search for a suitable driver for my device .
3	Click Next .
4	The wizard asks: Where do you want Windows to search for driver files? Select Specify a location , clear all other options.
5	Click Next .
6	<ul style="list-style-type: none"> ▪ Click Browse and locate folder "C:\Program Files\FLIR Systems\Device drivers" ▪ Click Ok.

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6.2 - Installation

Step	Action
7	The wizard has now found a driver for the device. Click Next .
8	The next wizard window is displayed; Microsoft has not digitally signed the driver. Click Yes to continue
9	The wizard copies the necessary driver files to your system.
10	The first driver installation procedure is completed. Click Finish .
11	Welcome to the Found New Hardware Wizard window appears again. Repeat step 1 to 10. After that the driver installation is complete.

6.2.3.3 FireWire/1394 Driver Installation Procedure for Microsoft Windows ME

Step	Action
1	When the system has detected the ThermaCAM, the Windows has found the following new hardware: FLIR ThermaCAM_R3 . What would you like to do? window appears. Select Specify the location of the driver .
2	Click Next .
3	<ul style="list-style-type: none"> ▪ Select Search for the best driver for your device ▪ Clear Removable media ▪ Select Specify a location ▪ Click Browse and locate folder "C:\Program Files\FLIR Systems\Device drivers" ▪ Click Ok
4	Click Next
5	Click Next
6	If you get version conflict questions, click Yes .
7	Click Finish .
8	Windows has found the following new hardware: FLIR ThermaNET_R2 window appears.
9	Repeat Step 1-4, 6-7
10	Reboot your computer if prompted to do so.

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6.2.3.4 FireWire/1394 Driver Installation Procedure for Microsoft Windows 98

Windows 98 doesn't support Plug and Play for FireWire. After you have connected the camera follow the instructions below.

Step	Action
1	Click Start → Settings → Control Panel in order to display the Control Panel
2	Double-click Add New Hardware .
3	Click Next .
4	Click Next .
5	Select Yes, the device is in the list and select the FLIR ThermoCAM_R3 device. Click Next .
6	Click Finish .
7	Click Reinstall Driver .
8	Click Next .
9	Select Search for a better drive than the one your device is using now . Click Next .
10	Select Specify a location . Clear all other options.
11	Click Browse and select folder C:\Program Files\FLIR Systems\Device drivers . Click Ok .
12	Click Next .
13	Click Next .
14	Insert Windows 98 CD-ROM if prompted to do so.
15	If you get version conflict questions, click Yes .
16	Click Finish .
17	Click Close .
18	Repeat Step 1–17 for the FLIR ThermoNET_R2 device.
19	Reboot your computer if prompted to do so.



6.3 - Operation

6.3 Operation

6.3.1 Transferring the images from the camera to the computer

ThermaCAM Connect 3 transfer application is started automatically when you connect the infrared camera using USB or FireWire. If you connect the infrared camera using serial communication (RS-232), you have to start ThermaCAM Connect 3 transfer application manually. You will find ThermaCAM Connect 3 in the Start menu.

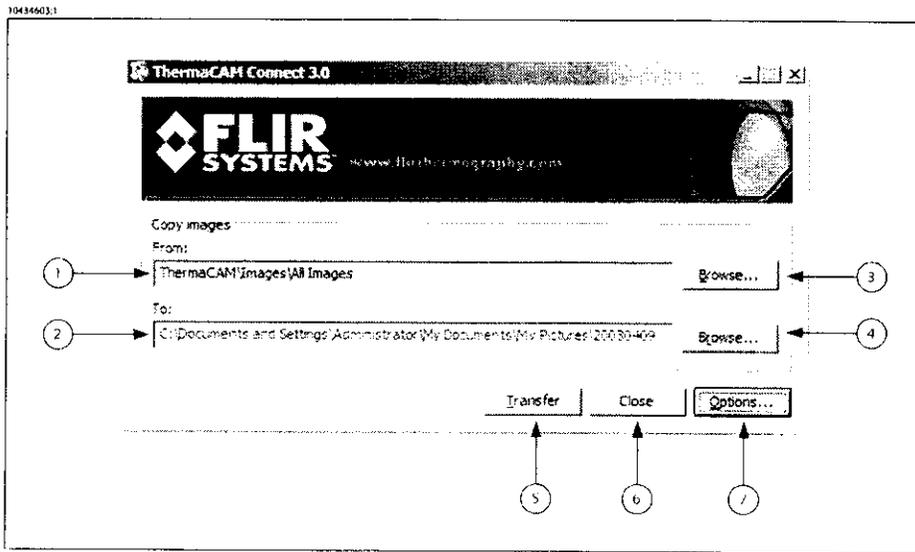


Figure 6.1 Image transfer application

The ThermaCAM Connect 3 transfer application makes it possible to transfer all images from the camera by clicking on the **Transfer** button. Below is a more detailed description of the different controls.

Callout	Explanation
1	Where the images are copied from in the camera. By default all images in the internal camera memory will be copied.
2	Folder on your computer to which the images will be transferred.
3	Click here to select images you want to transfer.
4	Click here to browse for a folder on your computer where the transferred images will be stored.
5	Click here to transfer images from the infrared camera to your computer.
6	Click here to close the application.

Callout	Explanation
7	Click here to open an Options dialog where different options, controlling how the application operates, can be chosen.

6.3.2 Transferring all images from the internal camera memory

When the application starts all images in the internal camera memory (but not sub-folders) are selected for transfer.

- If you want to transfer all images, the only thing you have to do is to click the **Transfer** button and the transfer of images from the infrared camera will begin.
- If you want to change folder on your computer to which the images are copied, click the **Browse** button.
- When you click the **Transfer** button, a new window will open indicating the transfer process and show a preview of the transferred images.

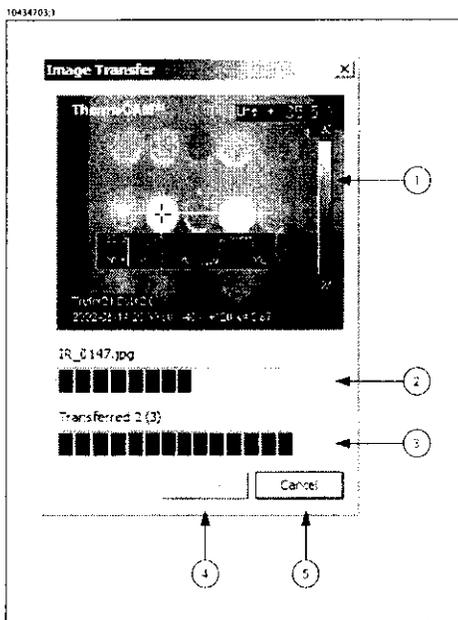


Figure 6.2 Image transfer

Callout	Explanation
1	Preview of images transferred to your computer.
2	Progress indicator for current image.
3	Progress indicator for all images.

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6.3 – Operation

Callout	Explanation
4	Click here to start Windows Explorer showing images transferred to your computer. This button will be enabled when image transfer is completed.
5	Click here interrupt the image transfer..

If you click the **Open Folder** button, the application will terminate and a Windows Explorer window will open showing you all files in the folder you transferred your images.

6.3.3 Transferring a selection of images or images from another folder

If you want to transfer only a selection of images or images from another folder, you can click **Browse** and select images.

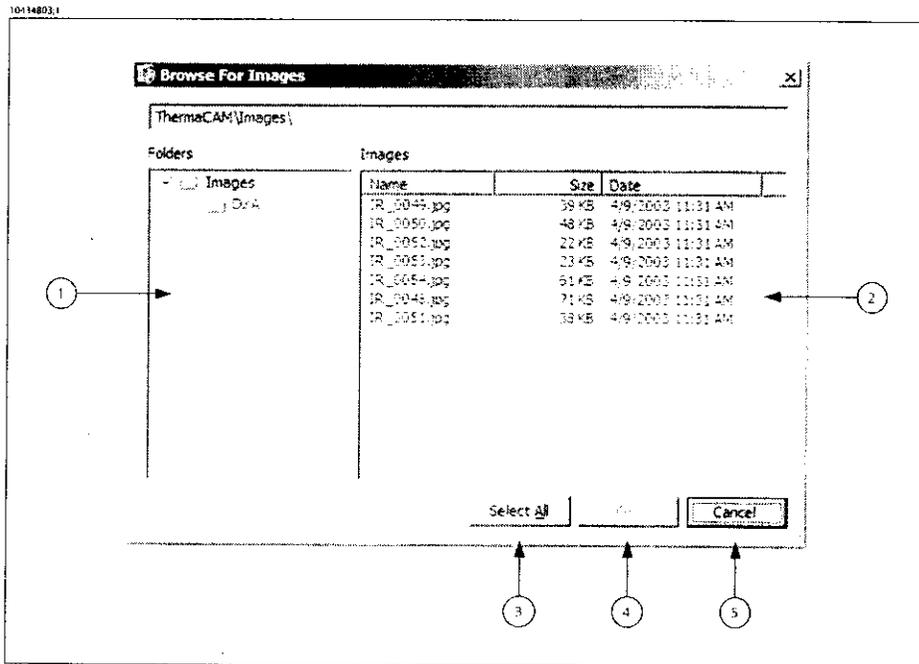


Figure 6.3 Browse for images

Callout	Explanation
1	Folders in the camera memory.
2	Images in the selected folder.
3	Click here to select all images in the list.

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Callout	Explanation
4	Click here close this window and return to the application main window. The images you selected will be marked for transfer and copied to your computer when you click the Transfer-button.
5	Click here to close this window without selecting any images.

In the **Browse For Images** window you can see all the folders in the camera and select the images you want to transfer. It is possible to click on the **Name**, **Size** and **Date** columns to sort the images.

To select more than one image do the following:

- Pressing SHIFT and clicking the mouse, or pressing SHIFT and one of the arrow keys, extends the selection from the previously selected item to the current item.
- Pressing CTRL and clicking the mouse selects or deselects an item.

When you finished selecting images click **OK** to close the **Browse for images** dialog. You can click the **Transfer** button to start transferring the selected images.

6.3.4 Program options

There are a few options in ThermaCAM Connect 3 that you can change. Click on the **Options** button in the main window to open the **Options** dialog box.

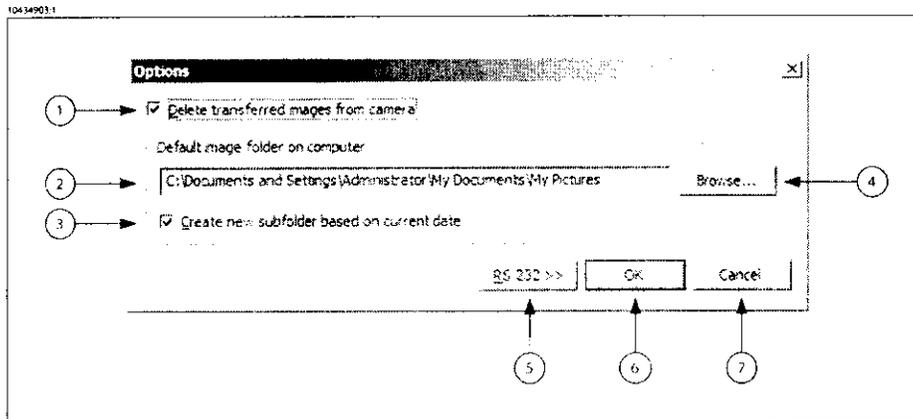


Figure 6.4 Options

Callout	Explanation
1	If this option is selected transferred images will be deleted from the infrared camera.
2	Default folder on your computer to which the images will be transferred.

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6.3 – Operation

Callout	Explanation
3	If this option is selected a subfolder to the default image folder will be created. The subfolder will have the same name as the current date and your images will be transferred to that subfolder.
4	Click here to browse for a new destination folder.
5	Click here to expand the dialog and show serial communication settings.
6	Click here to close the dialog and save the options.
7	Click here to close the dialog and discard all changes you have made in the dialog.

If you are using serial communication (RS-232) click the RS-232 button in order to expand the **Options** dialog box and set options for serial communication (RS-232).

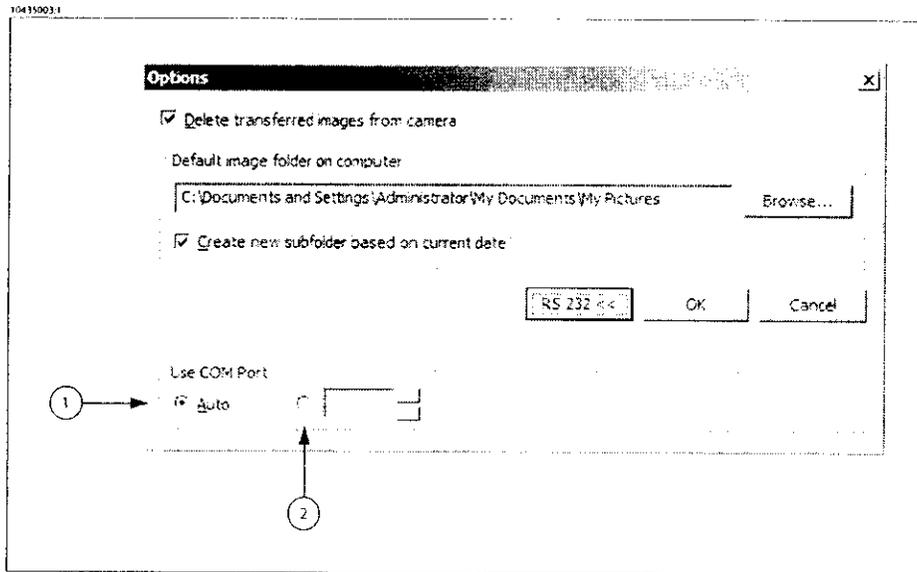


Figure 6.5 RS-232 options

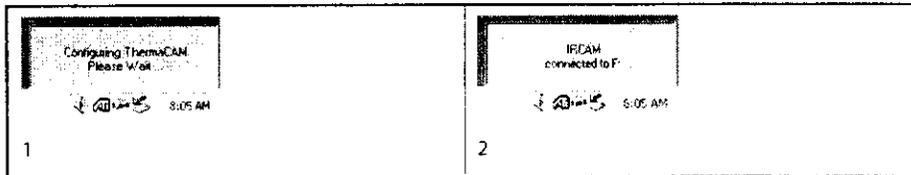
Callout	Explanation
1	Select Auto if you want the program to automatically search COM port 1 to 9 for an infrared camera.
2	Select this to manually enter a fixed COM port number. The automatic search is now disabled.

Click the RS 232 button again to contract the dialog.

6.3.5 Auto detect

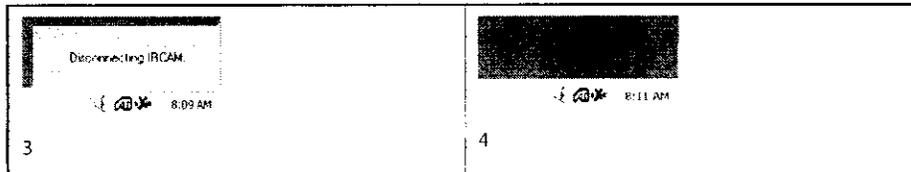
When a camera is plugged in to the computer it is automatically detected by ThermoCAM Connect 3. The auto detect does *not* work when using serial communications (RS-232) – *only* for USB or FireWire.

6.3.5.1 How to connect



1	When a connection is in the process of being established between the camera and the computer, a notification window pops up.
2	A few seconds after the connection has been established, a new notification window pops up.

6.3.5.2 How to disconnect



3	When the camera is disconnected from the computer, a notification window pops up.
4	A few seconds after the camera has been disconnected, the notification window disappears.

6.3.6 Starting Transfer application

The ThermoCAM Connect 3 Transfer application starts as soon as a infrared camera is connected to the computer. This applies to USB or FireWire, *not* serial communication (RS-232). If ThermoCAM Connect 3 Transfer application is closed, you can easily bring it back up again by right clicking the small camera icon.

SEE ALSO: For more information about the transfer application, see section 6.3.1 – Transferring the images from the camera to the computer on page 14.

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6.4 – Support

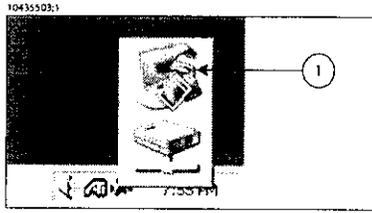


Figure 6.6 Transfer application

Callout	Explanation
1	Click here to bring up the ThermoCAM Connect 3 Transfer application

Or, you can start the transfer application from Windows Start menu.

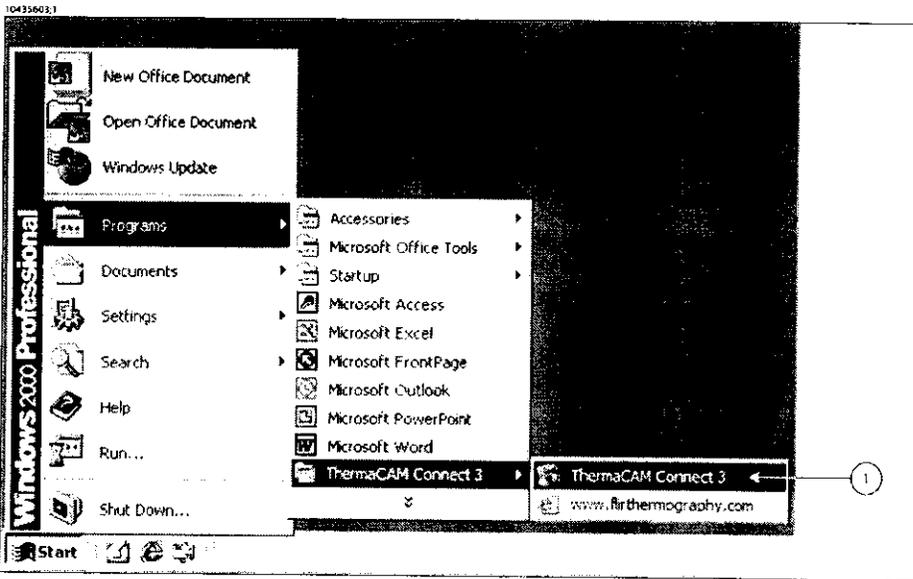


Figure 6.7 Starting the transfer application from Windows Start menu

Callout	Explanation
1	Click here to bring up the ThermoCAM Connect 3 Transfer application

6.4 Support

6.4.1 Information

You can access up-to-date FAQ (Frequently Asked Questions) and software updates at FLIR website:

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<http://www.flirthermography.com>

6.4.2 Troubleshooting

6.4.2.1 General

Before you start troubleshooting:

- Make sure you have the latest drivers, download them from the website.
- Verify that the problem is possible to repeat by rebooting the camera and the PC.

To reboot the camera, follow this procedure:

Step	Action
1	Disconnect the camera from the PC by unplugging the cable.
2	Restart the camera.
3	Restart the PC
4	Connect the camera to the PC by plugging in the cable If the problem persists, check if any of the procedures below or at the website resolves your problem.

6.4.2.2 Problems when trying to communicate with the camera

If ThermoCAM Connect 3 is not successfully communicating with the camera using serial, USB or FireWire communication, the following things may happen:

- The transfer application displays the error message **Cannot connect to camera**. Make sure the camera is connected to your computer. If you are using serial communication make sure the COM port is available.
- The different notification windows, mentioned in section 6.3.5 – Auto detect on page 19, will not be displayed.

If the software in the camera does not meet the software requirements stated in section 6.2.1 – Software requirements on page 9, the problems above will be experienced. Resolve the problem by upgrading the camera.

6.4.2.3 Problems when connecting the IR camera using serial communication

If there are one or more applications using the same serial communication port (COM 1–9) as the camera which is connected to the PC, ThermoCAM Connect 3 fails to set up a successful connection.

If the transfer application fails to setup a serial connection it will display the error message: **Cannot connect to camera**. Make sure the camera is connected to your computer. If you are using serial communication make sure the COM port is available.

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6.4 – Support

If this error message is encountered, you have to find an application that uses the COM port and disable it.

ActiveSync, used for synchronizing data between a PDA (Personal Digital Assistant) and Windows, is an example of such an application that may cause the problem mentioned above.

7 System overview

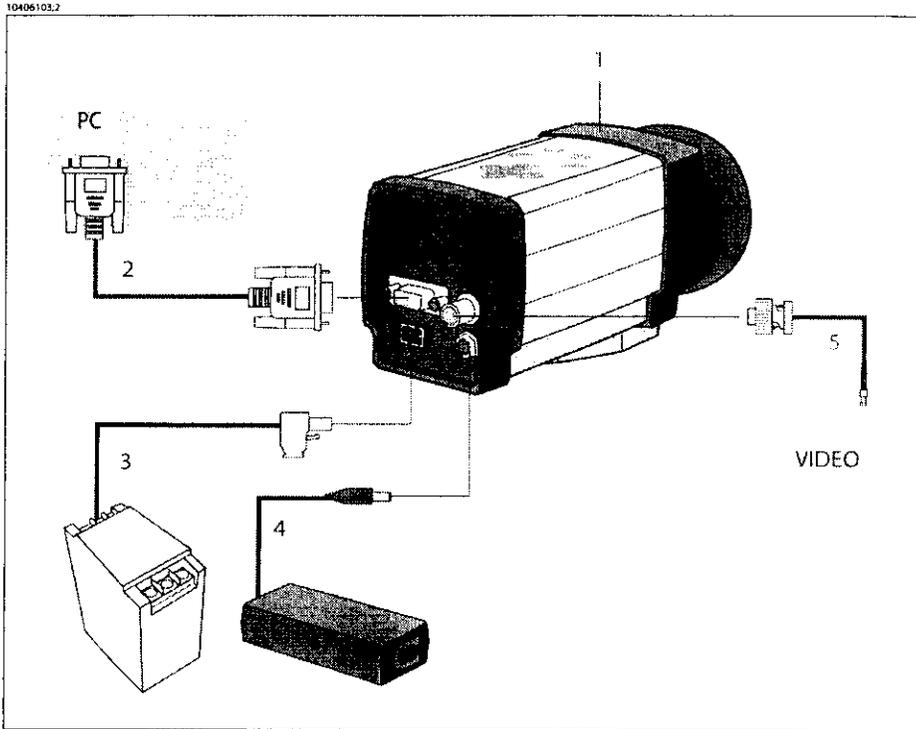


Figure 7.1 Typical system overview

Figure 7.2 Explanation of callouts

Callout	Explanation
1	Infrared camera
2	RS-232 connection to desktop or laptop computer
3	DIN rail mounted power supply. Either the camera can be powered by using this power supply, or by using power supply no. 4. NOTE: Power connector on camera is polarity protected.
4	Power supply. Either the camera can be powered by using this power supply, or by using power supply no. 3.
5	Connection to external video monitor

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8 Connecting system components

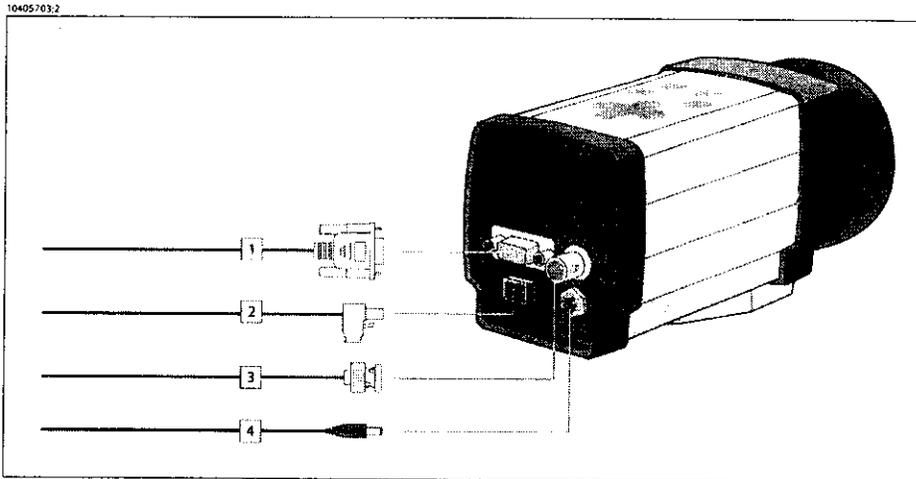


Figure 8.1 How to connect system components

Figure 8.2 Explanations of callouts

Callout	Explanation
1	RS-232 cable
2	Power supply. 12/24 V, minimum 15 W Recommended fuses (fast): 1 A (12 V); 500 mA (24 V) Jackable screw terminal Vendor: Phoenix Contact (www.phoenixcontact.com) P/N: 1757019 MSTB 2,5/2-ST-5,08 Camera only needs one power supply source NOTE: Power connector on camera is polarity protected.
3	Video cable (CVBS, i.e. composite video)
4	Power supply provided with the camera FLIR P/N: 1 909 528 Camera only needs one power supply source. NOTE: Power connector on camera is polarity protected.

9 Mechanical installation

The camera unit has been designed to allow it to be mounted in any position. It has a mounting interface on the bottom side where there is one standard tripod mount, accepting any commercial off-the-shelf tripod head (UNC ¼"-20). By removing the tripod mount from the camera, you can also mount the camera by using the two M4 threaded holes.

If the camera unit is to be permanently mounted on the application site, certain steps have to be taken. The camera unit might need to be enclosed in a protective housing and, depending on the ambient conditions (e.g. temperature), the housing may need to be cooled by means of water or air. In very dusty conditions the installation might also need to have a stream of pressurized air directed to the lens, in order to prevent dust build-up.

When mounting the camera unit in harsh environments, every precaution should be taken when it comes to securing the unit. If the environment exposes the unit to severe vibrations, there may arise a need to secure the mounting screws by means of Loctite™ or any other industrial brand of thread-locking liquid, as well as dampen the vibrations by mounting the camera unit on a specially designed mounting base.

For further information regarding mounting recommendations and environmental enclosures, contact FLIR Systems.

NOTE: To minimize image interference the camera chassis needs to be grounded.

10 Mounting an external motor focus unit

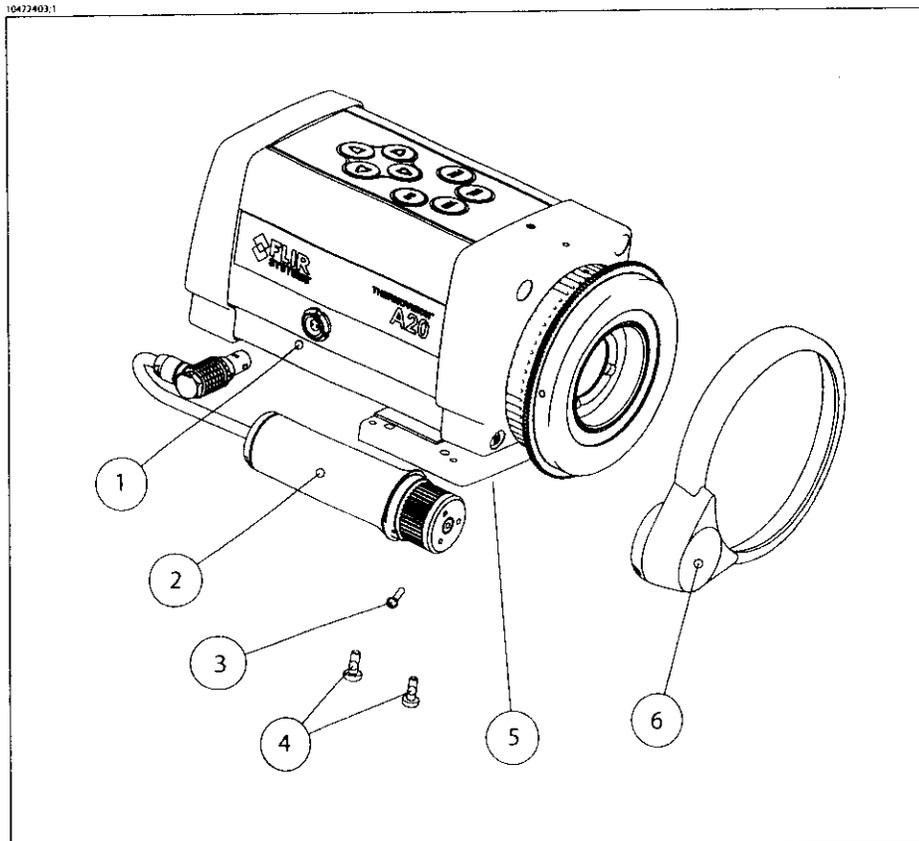


Figure 10.1 Parts for the external motor focus unit

A ThermoVision™ A20 V camera may be ordered in an external motor focus configuration. The motor focus unit works by means of two cog wheels, of which one is mounted on the axle of a small enclosed focus motor, and the other factory-mounted on the infrared lens. To prevent that dangerously high torques develop at the end positions of the focus range, the small cog wheel is mounted on the motor axle using a friction safety clutch. Both cogwheels are protected by an aluminum protective cover. The motor focus unit is connected to a factory-mounted side connector on the camera housing.

The external motor focus unit is shipped as two separate assemblies – the focus motor (2) mounted on the camera mounting plate (5), and the protective cover for the cog wheels (6).

Step	Action
1	Put the camera upside down on a working table.
	Remove the existing camera mounting plate by unscrewing the two M4 TORX screws, using a T20 TORX screwdriver.
	Mount the new camera mounting plate (2 + 5, assembled at factory) by using the two M4 TORX screws (4) and a T20 TORX screwdriver. The tightening torque should be close to 130 Ncm / 11.5 lb in.
2	Holding the camera in your left hand, carefully slide the protective cover (6) over the lens and make sure the teeth on the two cog wheels align, and that the small flat-milled surface on the focus motor mates with the flat-milled surface inside the protective cover.
	Lock the protective cover using the M2 TORX screw (3) and a T6 TORX screwdriver. The tightening torque should be close to 25 Ncm / 0.22 lb in.
3	<p>Make sure it is possible to turn the lens by hand. If not, the two screws (2) holding the mounting plate can be loosened and the plate slightly moved crosswise to decrease or increase the distance between the two cog wheels.</p> <p>Connect the external motor focus unit to the camera by using the LEMO connector.</p> <p>SEE ALSO: For information about how to use LEMO connectors, see section 11 - A note on LEMO connectors on page 30</p>

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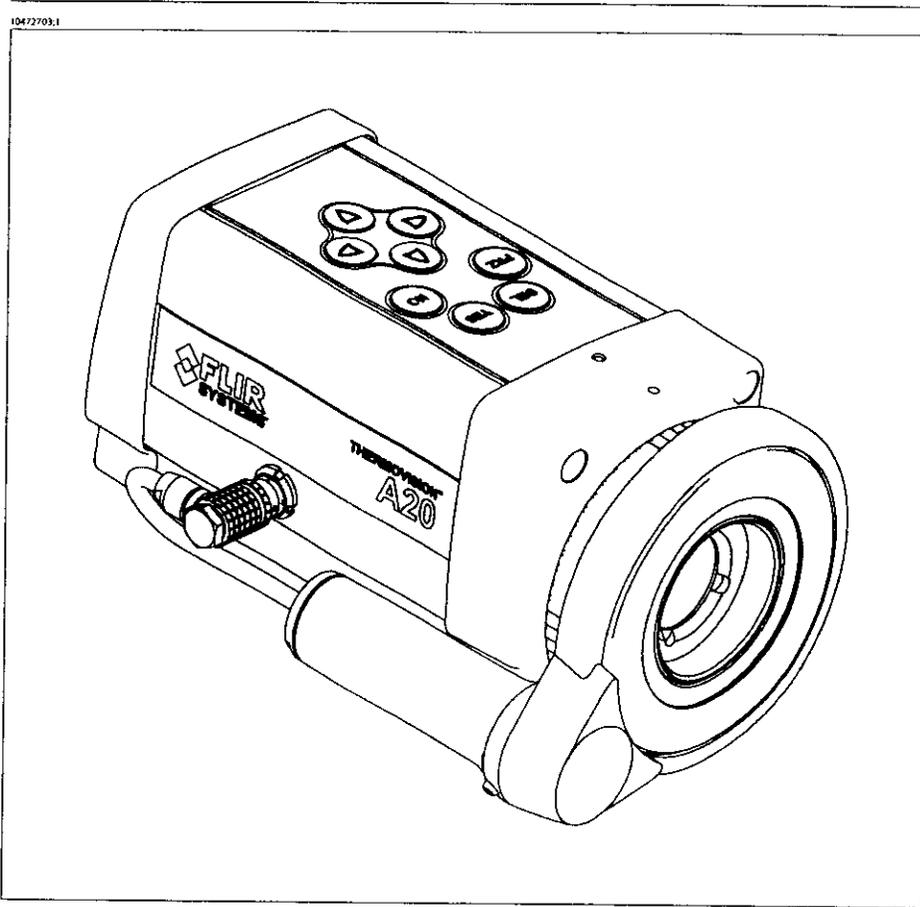


Figure 10.2 Camera with a mounted external motor focus unit

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11 A note on LEMO connectors

11.1 How to connect & disconnect LEMO connectors

The male LEMO connectors used on the camera cables are designed to lock securely to the female connectors on the camera body. A connector consists of a fixed inner tube and a sliding outer tube. The outer tube controls the locking teeth. To unlock the connector, pull the outer tube in the indicated direction. See the figure below

NOTE: Never pull the cable.

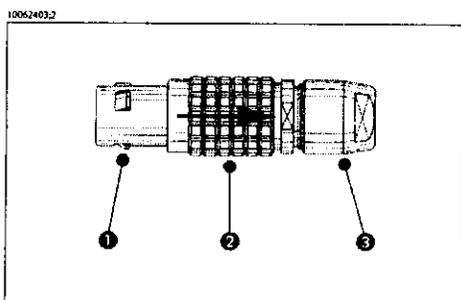


Figure 11.1 Straight body LEMO connector.

Callout	Description
1	Locking teeth
2	Sliding outer tube
3	Fixed inner tube

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11.1 – How to connect & disconnect LEMO connectors

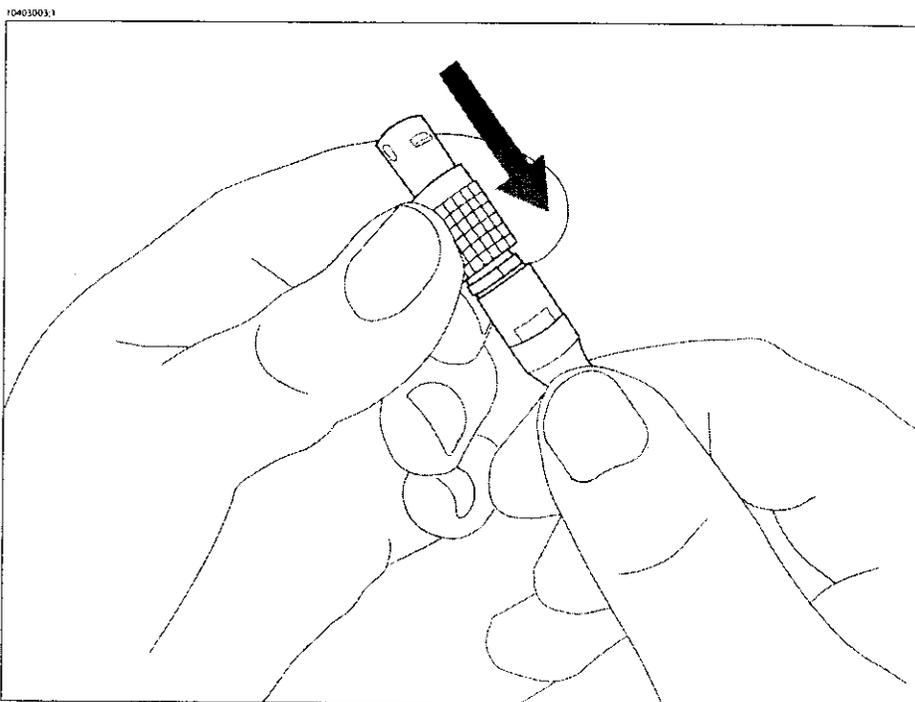


Figure 11.2 Unflocking a LEMO connector

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12 Camera overview

12.1 Camera parts

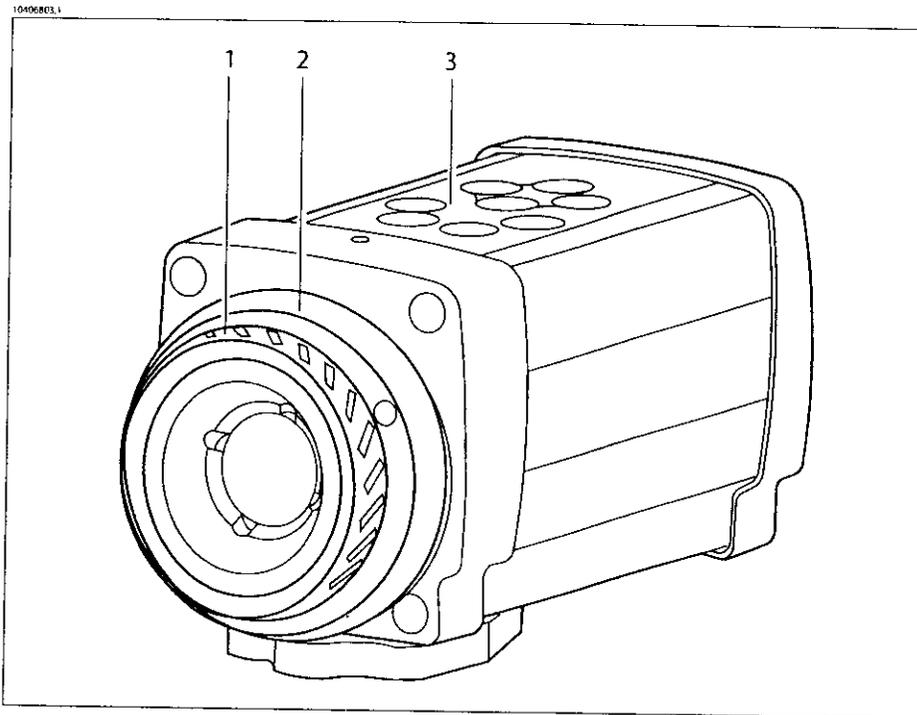


Figure 12.1 Camera parts – front view

Figure 12.2 Explanation of callouts

Callout	Description of part
1	Focus ring
2	Locking ring for the IR lens
3	Keypad

12.1 – Camera parts

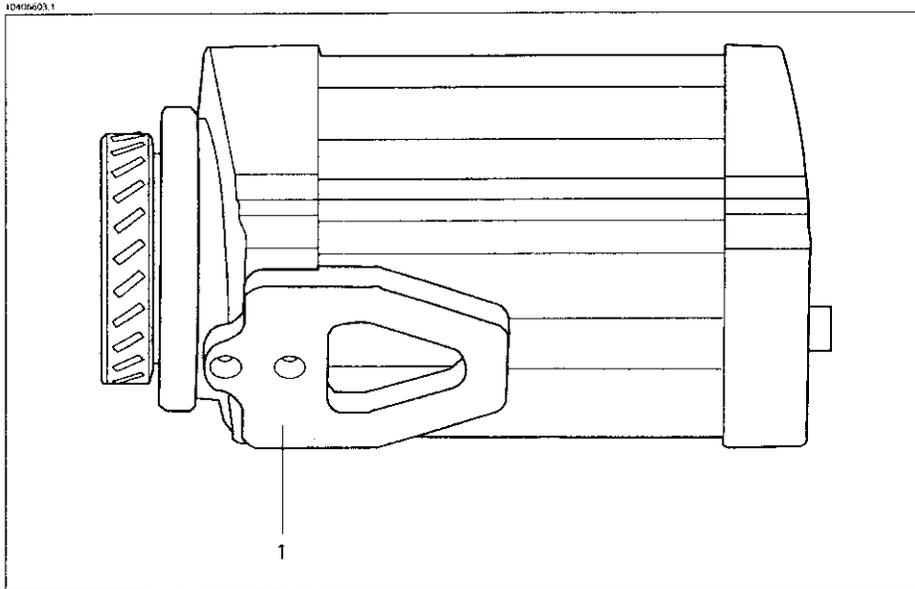


Figure 12.3 Camera parts – view from below

Figure 12.4 Explanation of callouts

Callout	Description of part
1	Tripod mount

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12.1 – Camera parts

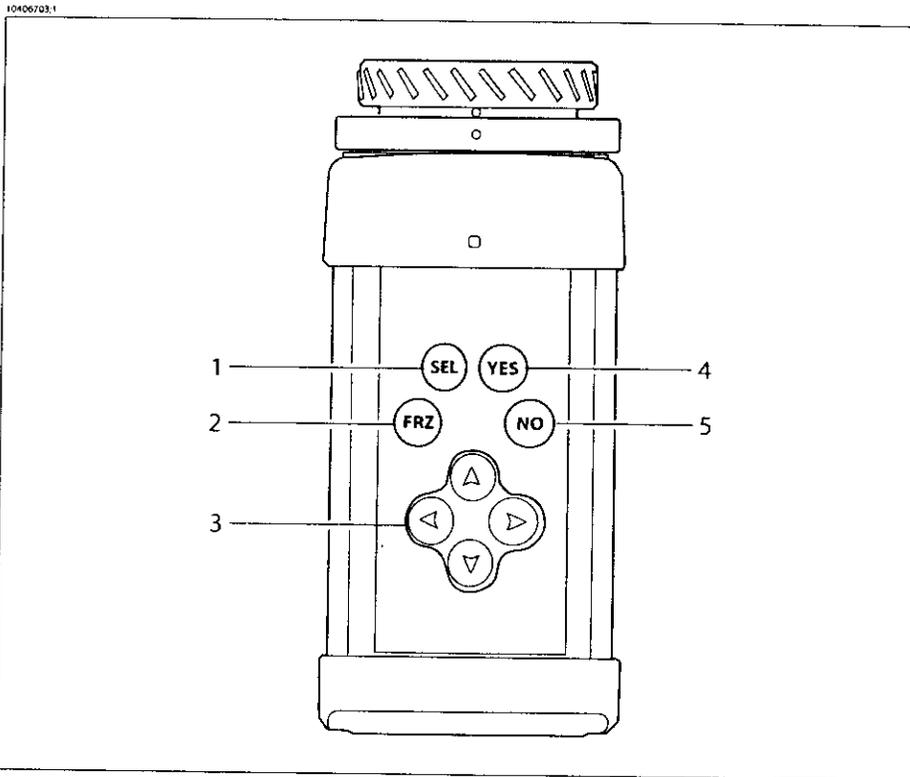


Figure 12.5 Camera parts – keypad

Figure 12.6 Explanation of callouts

Callout	Description of part
1	SEL button SEE ALSO: For more information about the functionality of this button, see section 12.2 – Keypad buttons & functions on page 36
2	FRZ button SEE ALSO: For more information about the functionality of this button, see section 12.2 – Keypad buttons & functions on page 36
3	Navigation pad SEE ALSO: For more information about the functionality of the navigation pad, see section 12.2 – Keypad buttons & functions on page 36

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12.1 – Camera parts

Callout	Description of part
4	YES button SEE ALSO: For more information about the functionality of this button, see section 12.2 – Keypad buttons & functions on page 36
5	NO button SEE ALSO: For more information about the functionality of this button, see section 12.2 – Keypad buttons & functions on page 36

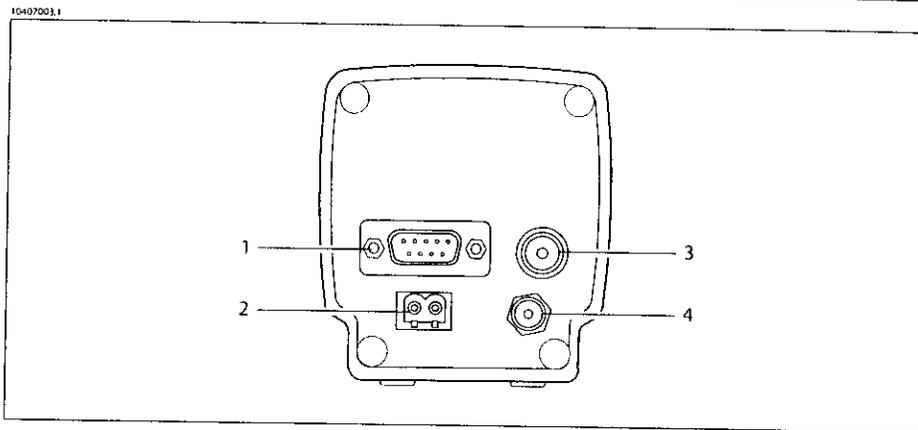


Figure 12.7 Camera parts – rear end connectors

Figure 12.8 Explanation of callouts

Callout	Description of part
1	RS-232 connector
2	Connector for power input (10-30 VDC) NOTE: Power connector on camera is polarity protected.
3	BNC connector for CVBS output (composite video)
4	Additional connector for power input (10-30 VDC) NOTE: Power connector on camera is polarity protected.

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12.2 – Keypad buttons & functions

12.2 Keypad buttons & functions

Button	Description
FRZ button	In normal mode: <ul style="list-style-type: none"> ▪ Briefly press FRZ to freeze/unfreeze the current image ▪ Press and hold down FRZ for more than one second to save the current image
SEL button	In normal mode: <ul style="list-style-type: none"> ▪ Press and hold down SEL for more than one second to autoadjust the camera ▪ Press SEL when the camera is in manual adjust mode to select the scale (for changing level and span) In edit mode: <ul style="list-style-type: none"> ▪ Press SEL repeatedly to switch between different screen objects
YES button	In normal mode: <ul style="list-style-type: none"> ▪ Press YES to display the vertical menu bar ▪ Press YES to select a menu entry ▪ Press YES to confirm selections in dialog boxes
NO button	In normal mode: <ul style="list-style-type: none"> ▪ Press NO to leave freeze and recall mode ▪ Press NO to leave menus and submenus ▪ Press NO to leave dialog boxes without confirming (and restore settings to previous values) In edit mode: <ul style="list-style-type: none"> ▪ Press NO to leave edit mode
Navigation pad	In normal mode: <ul style="list-style-type: none"> ▪ Press left/right or up/down to navigate menus and dialog boxes ▪ Press up/down to change the level ▪ Press left/right to change the span ▪ If your camera is supplied with motor focus: Press up/down to focus the camera using motor focus. In edit mode: <ul style="list-style-type: none"> ▪ Press left/right or up/down to change or move a screen object previously selected by using SEL

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13 Menu system overviews

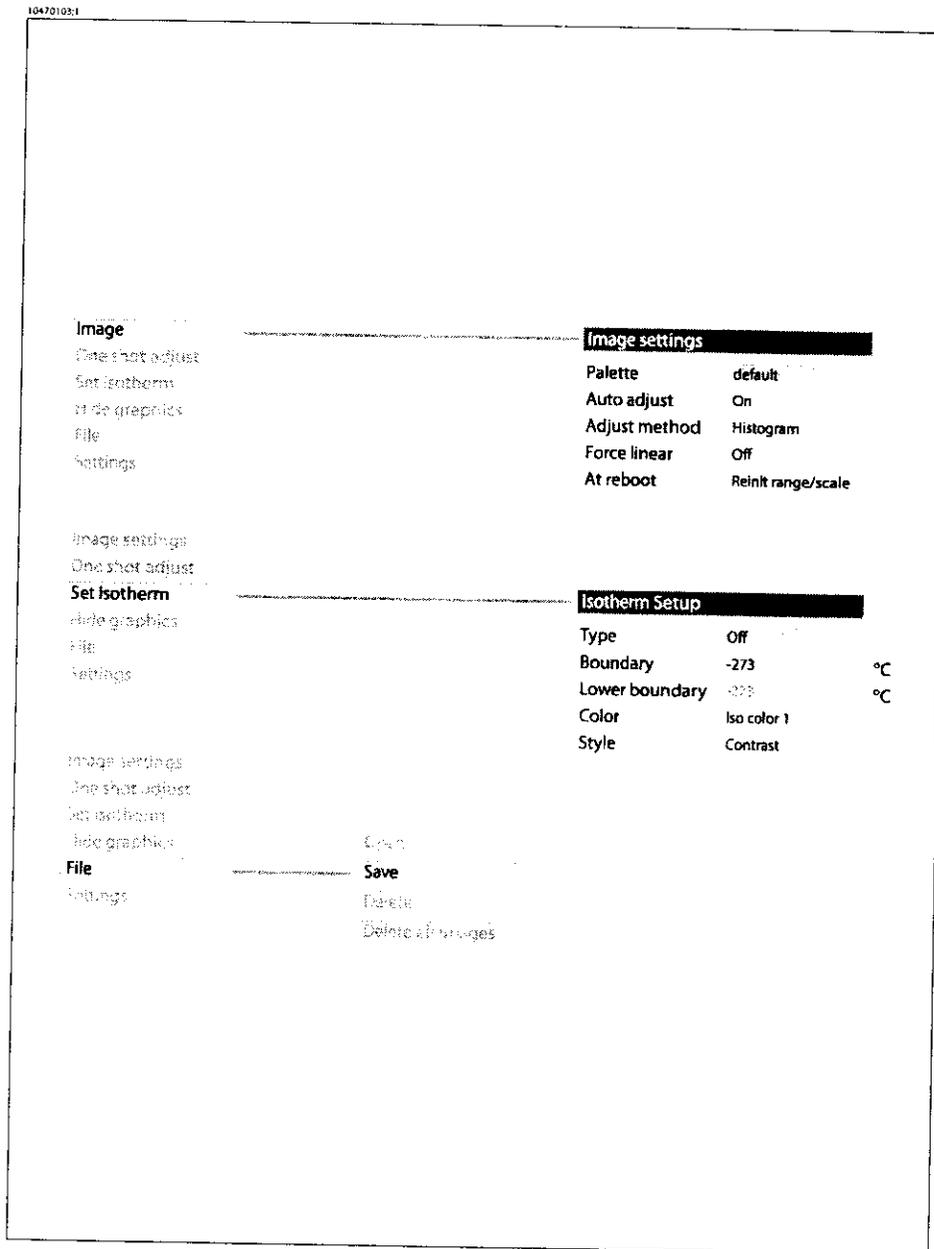


Figure 13.1 Menu overview: Image, Set Isotherm, and File commands

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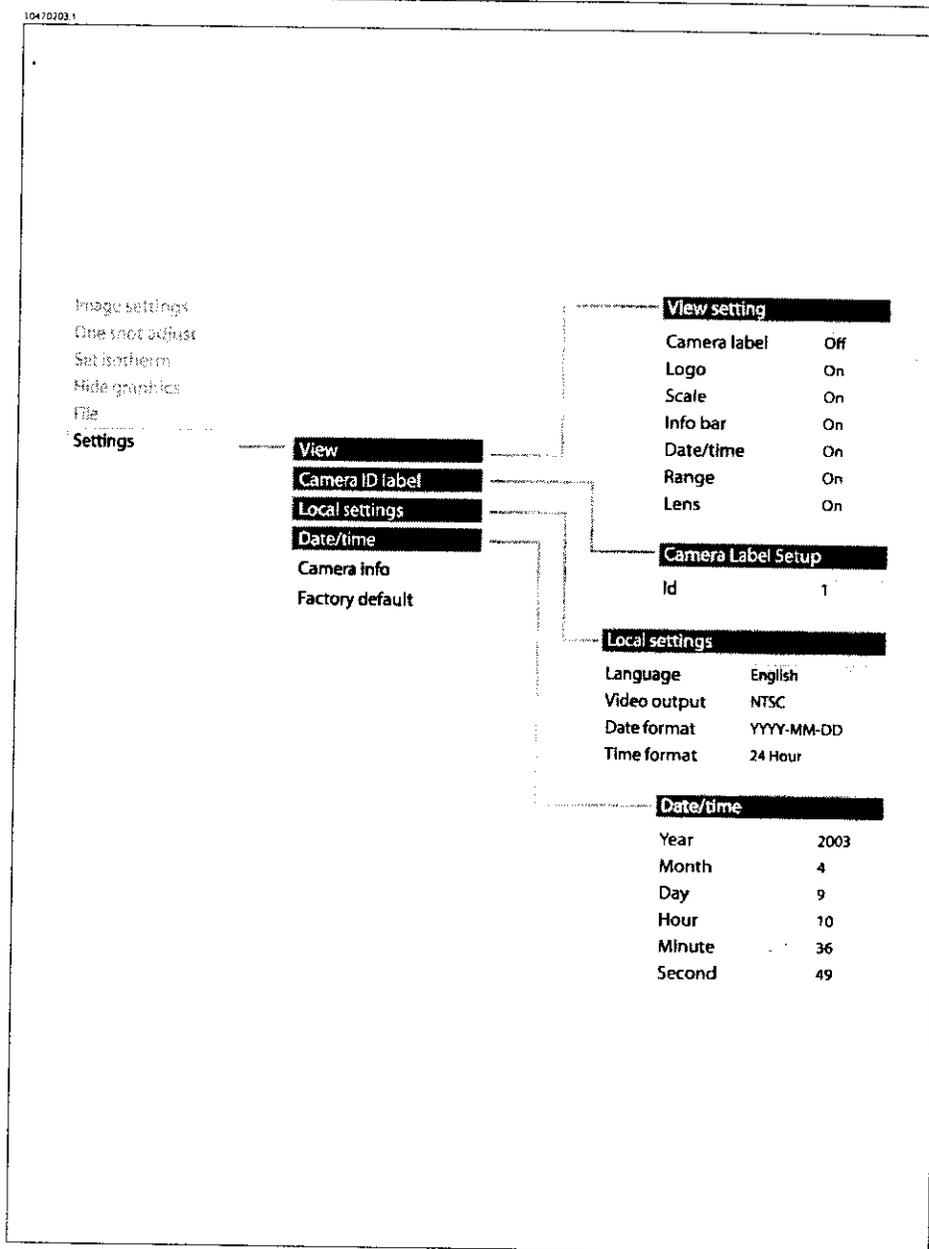


Figure 13.2 Menu overview: Settings command

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14 Tutorials

NOTE: Controlling the camera using the camera's graphical user interface (i.e. the camera program) requires that you connect a video monitor to the CVBS video output connector and use the keypad on the camera to navigate the menu system.

14.1 Working with images

14.1.1 Freezing an image (graphical user interface)

Step	Action
1	Adjust focus by turning the focus ring at the front of the lens. NOTE: Please note what is the locking ring and what is the focus ring in the figure on page 43. Trying to adjust focus by rotating the locking ring will remove the lens.
2	If the camera is in manual adjust mode, press and hold down SEL for more than one second to autoadjust the camera.
3	Press FRZ to freeze the image.

14.1.2 Saving an image (graphical user interface)

Step	Action
1	Adjust focus by turning the focus ring at the front of the lens. NOTE: Please note what is the locking ring and what is the focus ring in the figure on page 43. Trying to adjust focus by rotating the locking ring will remove the lens.
2	If the camera is in manual adjust mode, press and hold down SEL for more than one second to autoadjust the camera.
3	To save the image, do one of the following: <ul style="list-style-type: none"> ▪ Press and hold down FRZ for more than one second ▪ Point to Save on the File menu

14.1.3 Opening an image (graphical user interface)

Step	Action
1	Press YES to display the vertical menu bar.
2	Point to File on the vertical menu bar and press YES.

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14.2 – Changing level & span (graphical user interface)

Step	Action
3	Point to Open and press YES to open the most recently saved or viewed image. To view another image, use the navigation pad to select the image.

14.1.4 Setting an isotherm (graphical user interface)

Step	Action
1	Press YES to display the vertical menu bar.
2	Point to Set isotherm on the vertical menu bar and press YES.
3	Press the navigation pad left/right to specify the isotherm type (Above, Below, Interval). Move to next.
4	Press the navigation pad left/right to specify the high temperature level (Boundary). Move to next.
5	Press the navigation pad left/right to specify the low temperature level (Lower boundary). Move to next. NOTE: Lower boundary only applies to interval isotherms.
6	Press the navigation pad left/right to specify the isotherm color. Move to next.
7	Press the navigation pad left/right to specify the isotherm style (Contrast, Solid). Move to next.
8	Press YES to leave the dialog box.

14.2 Changing level & span (graphical user interface)

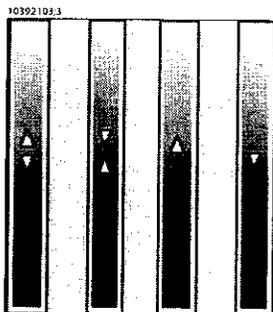


Figure 14.1 Symbols in the temperature scale, indicating (1) increasing span; (2) decreasing span; (3) increasing level, and (4) decreasing level

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14.3 – Changing system settings

Step	Action
1	To change the level (indicated by arrows pointing upwards and downwards in the temperature scale), press the navigation pad up/down. The level command corresponds to <i>brightness</i> .
2	To change the span (indicated by arrows pointing left and right in the temperature scale), press the navigation pad left/right. The span command corresponds to <i>contrast</i> .

NOTE: You can also change level and span by changing scale limits in the **Image** dialog box. For information about how to do this, see section 15.2.2 – Image on page 47

14.3 Changing system settings

14.3.1 Specifying how camera settings will be saved (graphical user interface)

Step	Action
1	Press YES to display the vertical menu bar.
2	Point to Image and press YES.
3	Press the navigation pad up/down to select At reboot .
4	Select one of the following: <ul style="list-style-type: none"> ▪ Reinit range/scale: The camera will use the default range and scale settings when the camera is restarted. ▪ Keep range/scale: The camera will keep the latest range and scale settings when the camera is restarted.
5	Press YES to confirm your changes and leave the dialog box.

NOTE: Changed settings apart from camera settings are saved automatically.

14.3.2 Changing temperature unit (graphical user interface)

Step	Action
1	Press YES to display the vertical menu bar.
2	Point to Local Settings on the Settings menu and press YES.
3	Press the navigation pad up/down to select Temp unit .
4	Press the navigation pad left/right to change the temperature unit.
5	Press YES to confirm your changes and leave the dialog box.

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14.3 – Changing system settings

14.3.3 Changing date format (graphical user interface)

Step	Action
1	Press YES to display the vertical menu bar.
2	Point to Local Settings on the Settings menu and press YES.
3	Press the navigation pad up/down to select Date format .
4	Press the navigation pad left/right to change the date format.
5	Press YES to confirm your changes and leave the dialog box.

14.3.4 Changing time format (graphical user interface)

Step	Action
1	Press YES to display the vertical menu bar.
2	Point to Local Settings on the Settings menu and press YES.
3	Press the navigation pad up/down to select Time format .
4	Press the navigation pad left/right to change the time format.
5	Press YES to confirm your changes and leave the dialog box.

14.3.5 Changing date & time (graphical user interface)

Step	Action
1	Press YES to display the vertical menu bar.
2	Point to Date/time on the Settings menu and press YES.
3	Press the navigation pad up/down to select year, month, day, hour, minute and second.
4	Press the navigation pad left/right to change each parameter.
5	Press YES to confirm your changes and leave the dialog box.

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14.4 Working with the camera

14.4.1 Removing the lens

NOTE: Before trying to remove fingerprints or other marks on the lens elements, see section 16.2 – Lenses on page 55.

NOTE: Removing an IR lens will expose very sensitive camera parts. Do not touch any exposed parts.

NOTE: Please note what is the locking ring and what is the focus ring in the figure below. Trying to remove the lens by rotating the focus ring may damage the lens.

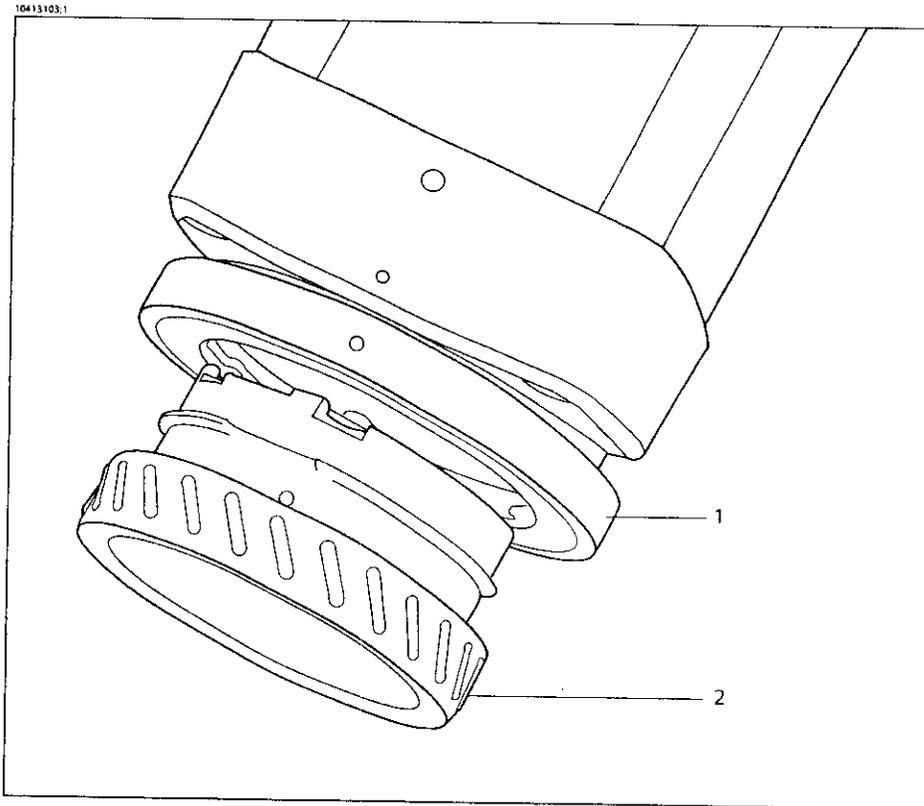


Figure 14.2 Removing a lens. 1: Locking ring; 2: Focus ring

14.4 – Working with the camera

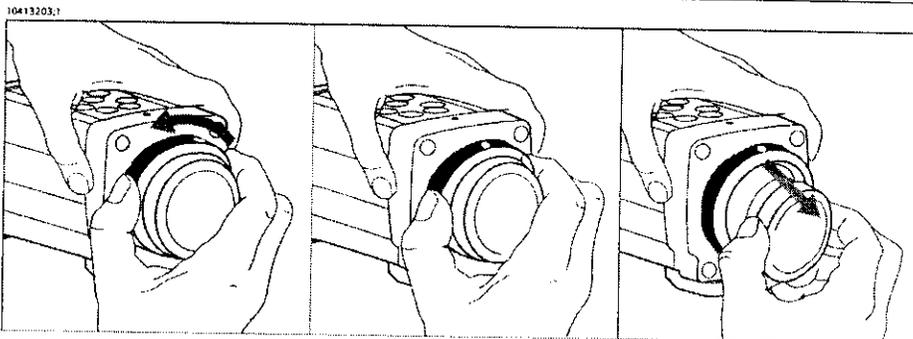


Figure 14.3 Removing a lens

Step	Action
1	Rotate the locking ring on the camera 30° counterclockwise until the index mark is in twelve o'clock position.
2	Carefully pull out the lens. Do not use excessive force.

14.4.2 Adjusting the focus

NOTE: Please note what is the locking ring and what is the focus ring in the figure on page 43. Trying to adjust the focus by rotating the locking ring will remove the lens.

Step	Action
1	To adjust the focus, rotate the focus ring clockwise or counterclockwise.

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15 Controlling the camera using the graphical user interface

NOTE: Controlling the camera using the camera program requires that you connect a video monitor to the CVBS video output connector and use the keypad on the camera to navigate the menu system

15.1 Screen objects

15.1.1 Result table



Figure 15.1 Result table, showing the icons for an *isotherm below*

Icons for isotherm etc. are displayed in a result table in the top right-hand corner of the screen.

Figure 15.2 Explanation of signs in the result table

Sign in result table	Explanation
	Isotherm above NOTE: You can change the color of the isotherm sign by changing the color of the isotherm.
	Isotherm below NOTE: You can change the color of the isotherm sign by changing the color of the isotherm.
	Isotherm interval NOTE: You can change the color of the isotherm sign by changing the color of the isotherm.
	Isotherm

15.1.2 Info bar



Figure 15.3 Info bar, showing date & time, temperature range, and lens info

Information about an image and the current conditions appear on the first and second bottom lines of the screen.

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15.2 – Menu system

15.1.3 Scale



Figure 15.4 Scale

The scale is displayed on the right-hand side of the screen. The scale shows how the colors are distributed along the various intensities in the image, with high intensities at the upper end and low intensities at the lower end.

15.1.4 Status messages

Status messages are displayed at the bottom of the screen, or in the top left part of the screen. Here you will find information about the current status of the camera, etc.

Figure 15.5 Status messages – a few examples

Message	Explanation
Frozen	The image is frozen.
Manual	The camera is currently in manual adjust mode.
Restarting	The software is restarting, <i>i.e.</i> after selecting Factory default .
Saving as	An image is being saved.
Edit mode	The camera is currently in edit mode.
IR_L0929.jpg	An image with this name is recalled and currently displayed.

15.2 Menu system



Figure 15.6 Vertical menu bar

15.2.1 Navigating the menu system

- Press YES to enter the menu system (i.e. display the vertical menu bar)

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- Press YES to confirm selections in menus and dialog boxes, and closes menus and dialog boxes
- Press NO to exit the most recently selected submenu, or to exit the menu system
- Press NO to cancel selections in menus and dialog boxes
- Press the navigation pad up/down to move up/down in menus, submenus and dialog boxes
- Press the navigation pad right/left to move right/left in menus and submenus, and to change values in dialog boxes

15.2.2 Image

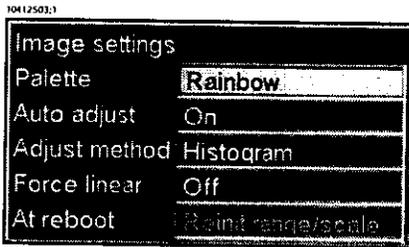


Figure 15.7 Image settings dialog box

Figure 15.8 Explanation of the Image settings dialog box

Label	Value	Explanation
Palette	<ul style="list-style-type: none"> ▪ Rainbow ▪ Gray ▪ Iron ▪ Rainbow HC 	<p>Press the navigation pad left/right to select a different palette.</p> <p>The most suitable palette for a certain application depends on many different factors, such as target temperature and emissivity, ambient temperature, distance to target etc. You will need to test different palettes in order to find one that suits your application the best.</p>
Autoadjust	<ul style="list-style-type: none"> ▪ On ▪ Off 	<p>Press the navigation pad left/right to specify whether level/span of the image should be automatically adjusted or not.</p>

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15.2 – Menu system

Label	Value	Explanation
Adjust method	<ul style="list-style-type: none"> ▪ Histogram ▪ Brightness ▪ Contrast-brightness 	<p>Press the navigation pad left/right to specify the type of algorithm the camera should use when adjusting the image.</p> <p>The most suitable algorithm for a certain imaging situation depends on many different factors, such as target temperature and emissivity, ambient temperature, distance to target etc. You will need to test different algorithms in order to find one that suits your imaging situation the best.</p>
Force linear	<ul style="list-style-type: none"> ▪ On ▪ Off 	<p>Press the navigation pad left/right to specify whether the temperature scale should be forced to a linear mode or not.</p>
At reboot	<ul style="list-style-type: none"> ▪ Reinit range/scale ▪ Keep range/scale 	<p>Press the navigation pad left/right to specify how the camera should deal with range and scale when it is restarted:</p> <ul style="list-style-type: none"> ▪ If Reinit range/scale is selected, the camera will use the default range and scale settings. ▪ If Keep range/scale is selected, the camera will keep the latest range and scale settings.

15.2.3 One-shot adjust

Point to **One-shot adjust** on the vertical menu bar and press YES to auto-adjust the camera for best contrast and brightness.

15.2.4 Set isotherm

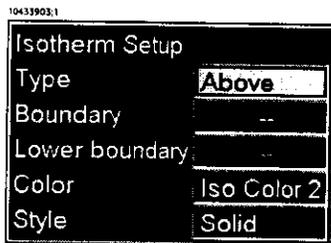


Figure 15.9 Isotherm setup dialog box

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Figure 15.10 Explanation of the Isotherm setup dialog box

Label	Value	Comments
Type	<ul style="list-style-type: none"> ▪ Above ▪ Below ▪ Interval ▪ Off 	<ul style="list-style-type: none"> ▪ Above: All pixels with a temperature higher than a set temperature will be colored with the same preset isotherm color. ▪ Below: All pixels with a temperature lower than a set temperature will be colored with the same preset isotherm color. ▪ Interval: All pixels with a temperature within the set interval will be colored with the same preset isotherm color.
Boundary	Numeric value	The upper temperature level. An arrow pointing upwards will be displayed in the scale when you change this value.
Lower boundary	Numeric value	The lower temperature level. An arrow pointing downwards will be displayed in the scale when you change this value. NOTE: This setting applies to interval isotherms only.
Color Attribute	Configuration-dependent <ul style="list-style-type: none"> ▪ Contrast ▪ Solid 	The colors used for the isotherm. Selecting Contrast will add some transparency to an isotherm color, making it easier for you to see objects through the color. To make the isotherm colors appear solid, select Solid .

15.2.5 Range



Figure 15.11 Range dialog box

NOTE: Range is an extra option.

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15.2 – Menu system

Point to **Range** on the vertical menu bar and press YES to display the **Range** dialog box.

- To select another temperature range, press the navigation pad left/right
- To confirm the choice, press YES
- To cancel any changes, press NO

15.2.6 Hide graphics

Point to **Hide graphics** on the vertical menu bar and press YES to hide all graphics currently displayed on the screen. To display the graphics again, press any key on the keypad.

15.2.7 File



Figure 15.12 File menu

Figure 15.13 File format used in the camera

Designation	Explanation
JPEG	A widely used image format that is compatible with the majority of all image softwares on the market. It takes advantage of a powerful compression algorithm named after the committee that defined it (<i>Joint Photographic Experts Group</i>). The overlay will be saved by default.

Figure 15.14 Explanation of the File menu

Command	Explanation
Open	Point to Open and press YES to open the most recently saved or viewed image. To view another image, use the navigation pad to select the image.
Save	Point to Save and press YES to save the current image to the camera's internal memory.
Delete image	Point to Delete image and press YES to display a confirmation box where you can either confirm or cancel the deletion. To select another image, press the navigation pad up/down.

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Command	Explanation
Delete all images	Point to Delete all images and press YES to delete all images. This choice will display a confirmation box where you can either confirm or cancel the deletion.

15.2.8 Settings



Figure 15.15 Settings menu

15.2.8.1 View

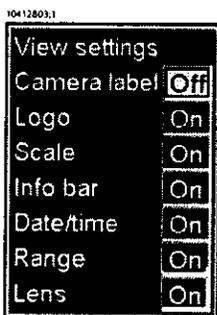


Figure 15.16 View settings dialog box

Figure 15.17 Explanation of the View settings dialog box

Label	Value	Comments
Camera label	<ul style="list-style-type: none"> ▪ On ▪ Off 	Press the navigation pad left/right and select On if you want to display the camera's ID label on the screen.
Logo	<ul style="list-style-type: none"> ▪ On ▪ Off 	Press the navigation pad left/right and select On if you want to display the company logo on the screen.

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15.2 – Menu system

Label	Value	Comments
Scale	<ul style="list-style-type: none"> ▪ On ▪ Off 	Press the navigation pad left/right and select On if you want to display the scale on the screen.
Info bar	<ul style="list-style-type: none"> ▪ On ▪ Off 	Press the navigation pad left/right and select On if you want to display the info bar on the screen.
Date/time	<ul style="list-style-type: none"> ▪ On ▪ Off 	Press the navigation pad left/right to enable/disable this label on the info bar.
Range	<ul style="list-style-type: none"> ▪ On ▪ Off 	Press the navigation pad left/right to enable/disable this label on the info bar.
Lens	<ul style="list-style-type: none"> ▪ On ▪ Off 	Press the navigation pad left/right to enable/disable this label on the info bar.

15.2.8.2 Camera ID label



Figure 15.18 Settings dialog box

Figure 15.19 Explanation of the Settings dialog box

Label	Explanation
Id	<p>Press the navigation pad left/right to specify the identity for this particular camera (display purposes only).</p> <hr/> <p>SEE ALSO: The label is by default switched off. To switch it on, see the following section:</p> <ul style="list-style-type: none"> ▪ 15.2.8.1 – View on page 51

15.2.8.3 Local settings

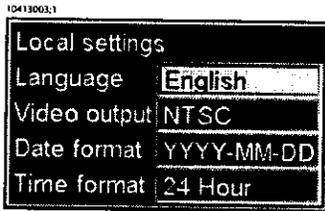


Figure 15.20 Local settings dialog box

Figure 15.21 Explanation of the Local settings dialog box

Label	Value	Explanation
Language	N/A	The number of languages you can choose from depends on your camera configuration. Press the navigation pad left/right to change the language.
Video output	<ul style="list-style-type: none"> ▪ NTSC ▪ PAL 	Press the navigation pad left/right to change the video output format.
Date format	<ul style="list-style-type: none"> ▪ YYYY-MM-DD ▪ YY-MM-DD ▪ MM/DD/YY ▪ DD/MM/YY 	Press the navigation pad left/right to change the date format.
Time format	<ul style="list-style-type: none"> ▪ 24 hour ▪ AM/PM 	Press the navigation pad left/right to change the time format.

15.2.8.4 Date/time



Figure 15.22 Date/time dialog box

15.2 – Menu system

Figure 15.23 Explanation of the Date/time dialog box

Label	Value	Explanation
Year	1970–2036	Press the navigation pad left/right to set the year.
Month	1–12	Press the navigation pad left/right to set the month.
Day	1–31	Press the navigation pad left/right to set the day.
Hour	<ul style="list-style-type: none"> ▪ 12 a.m.–12 p.m. ▪ 1–24 	Press the navigation pad left/right to set the hour. NOTE: The format depends on the settings in the Local Settings dialog box.
Minute	00–59	Press the navigation pad left/right to set the minute.
Second	00–59	Press the navigation pad left/right to set the second.

15.2.8.5 Camera info

The camera info panel shows information about memory usage, serial numbers, software revisions, etc.

No changes can be made.

15.2.8.6 Factory default

Point to **Factory default** and press YES to reset all camera settings to factory settings.

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16 Maintenance & cleaning

16.1 Camera body, cables & accessories

The camera body, cables and accessories may be cleaned by wiping with a soft cloth. To remove stains, wipe with a soft cloth moistened with a mild detergent solution and wrung dry, then wipe with a dry soft cloth.

NOTE: Do not use benzene, thinner, or any other chemical product on the camera, the cables or the accessories, as this may cause deterioration.

16.2 Lenses

All lenses are coated with an anti-reflective coating and care must be taken when cleaning them. Cotton wool soaked in 96 % ethyl alcohol (C_2H_5OH) may be used to clean the lenses. The lenses should be wiped once with the solution, then the cotton wool should be discarded.

If ethyl alcohol is unavailable, DEE (*i.e.* 'ether' = diethylether, $C_4H_{10}O$) may be used for cleaning.

Sometimes drying marks may appear on the lenses. To prevent this, a cleaning solution of 50 % acetone (*i.e.* dimethylketone, $(CH_3)_2CO$) and 50 % ethyl alcohol (C_2H_5OH) may be used.

NOTE: Please note the following:

- Excessive cleaning of the lenses may wear down the coating.
 - The chemical substances described in this section may be dangerous. Carefully read all warning labels on containers before using the substances, as well as applicable MSDS (Material Safety Data Sheets).
-

17 Technical specifications

NOTE: FLIR Systems reserves the right to discontinue models, parts and accessories, and other items, or change specifications at any time without prior notice.

17.1 Imaging performance

Field of view (standard IR lens)	25°
Close focus	< 0.3 m / 0.98 ft.
IFOV	2.7 mrad
Means of focusing	Manual, or externally mounted focus motor (extra option)
Thermal sensitivity	90–120 mK @ +25 °C / +77 °F
F-number	1.2 (standard 25° lens)

17.2 Detector

Type	Focal Plane Array (FPA), uncooled microbolometer 160 × 120 pixels
Spectral range	7.5–13 μm

17.3 Ranges

Range, standard	-20–+250 °C (-4–+482 °F)
Range, extra option	+120–+900 °C (-248–+1652 °F)

17.4 Power input

Voltage	10–30 VDC
Power consumption	Typically 6 W, maximum 10 W

17.5 Environmental specifications

Operating temperature range	-15–+50 °C (+5–+122 °F)
Storage temperature range	-40–+70 °C (-40–+158 °F)
Encapsulation	Depending on connector type: IP 40 (IEC 60529)

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17.6 – Physical specifications

Bump	25 g, IEC 68-2-29
Vibration	2 g, IEC 68-2-6
EMC	EN 50081-2 (Generic emission) EN 50082-2 (Generic immunity)
Humidity	Operating & storage: 20–95 %, non-condensing (IEC 60068-2-30, Test DB)

17.6 Physical specifications

Weight	0.80 kg / 1.76 lb.
Size (L × W × H)	With 25° lens: 161 × 72 × 84 mm (6.34 × 2.83 × 3.31") Without lens: 146 × 72 × 84 mm (5.75 × 2.83 × 3.31")
Tripod mounting	Standard, UNC ¼"-20

17.7 Interfaces

Computer interfaces	RS-232
CVBS	Standard BNC connector for composite video CVBS (ITU-R BT.470 PAL/SMPTE 170M NTSC)

17.8 Pin configurations & specifications

17.8.1 Supplier of male power connectors

Male connector	Supplier	Phoenix P/N	Type
2 pole power connector	www.phoenixcontact.com	1757019	MSTB 2.5/2-ST-5.08

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17.8 – Pin configurations & specifications

17.8.2 RS-232 connector

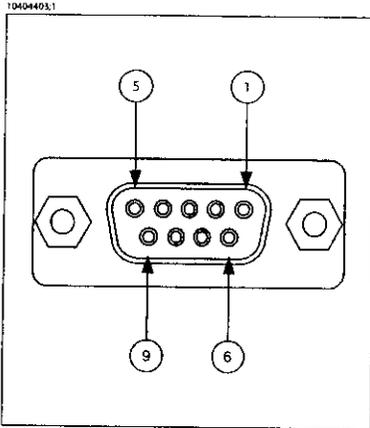


Figure 17.1 Pin configuration for RS-232 (on camera – operator's side)

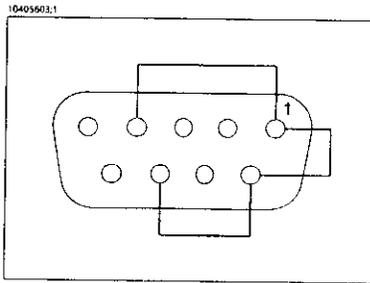


Figure 17.2 Loops between pin 1, 4, 6, and 8. See the text.

Figure 17.3 Explanation of figure

Pin No.	Direction	Description
1	Out	Carrier detect NOTE: Pin 4 is looped back to pin 1, 6, and 8 in the camera. See figure.
2	Out	Transmit data
3	In	Receive data
4	In	Data terminal ready NOTE: Pin 4 is looped back to pin 1, 6, and 8 in the camera. See figure.

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17.8 – Pin configurations & specifications

Pin No.	Direction	Description
5		Ground
6	Out	Data set ready NOTE: Pin 4 is looped back to pin 1, 6, and 8 in the camera. See figure.
7		N/C
8	Out	Clear to send NOTE: Pin 4 is looped back to pin 1, 6, and 8 in the camera. See figure.
9		N/C

17.8.3 Power connector (jackable, with screw terminals)

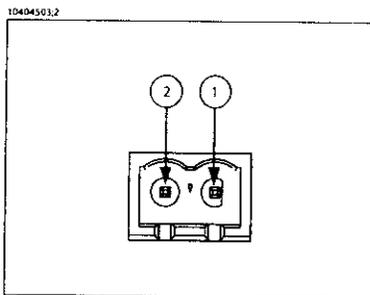


Figure 17.4 Pin configuration for power connector 1 (on camera – operator's side). 1: Right pin; 2: Left pin

NOTE: Power connector is polarity protected.

Figure 17.5 Explanation of figure

Pin No.	Description
1	Nom.: 12 V or 24 V (+10 to +30 V), typically 7.5 W, maximum 10 W Recommended fuses (fast): 1 A (12 V); 500 mA (24 V)
2	Ground

17.8 – Pin configurations & specifications

NOTE: High power loads other than ThermoVision™ A20 V can not be supplied using the same power supply. Low power loads, such as solid state I/O modules or isolation amplifiers, can be connected. Inductive loads are not recommended.

17.8.4 Power connector

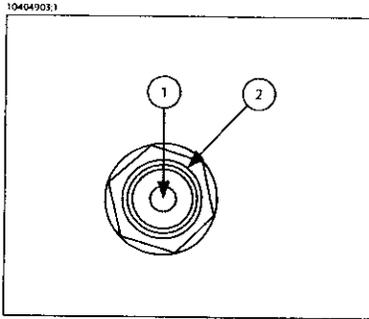


Figure 17.6 Pin configuration for power connector 2 (on camera – operator’s side). 1: Center pin; 2: Chassis

NOTE: Power connector is polarity protected.

Figure 17.7 Explanation of figure

Pin No.	Description
1	Nom.: 12 V or 24 V (+10 to +30 V), typically 6 W, maximum 10 W
2	Ground

17.8.5 CVBS connector

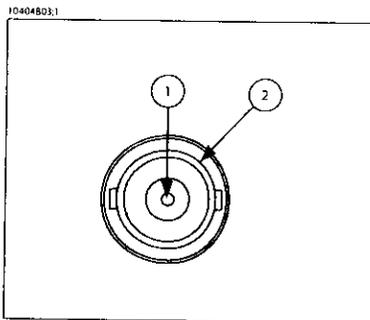


Figure 17.8 Pin configuration for CVBS connector (on camera – operator’s side). 1: Center pin; 2: Chassis

17.8 - Pin configurations & specifications

Figure 17.9 Explanation of figure

Pin No.	Description
1	Video
2	Ground

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17.9 - Relationship between fields of view and distance

17.9 Relationship between fields of view and distance

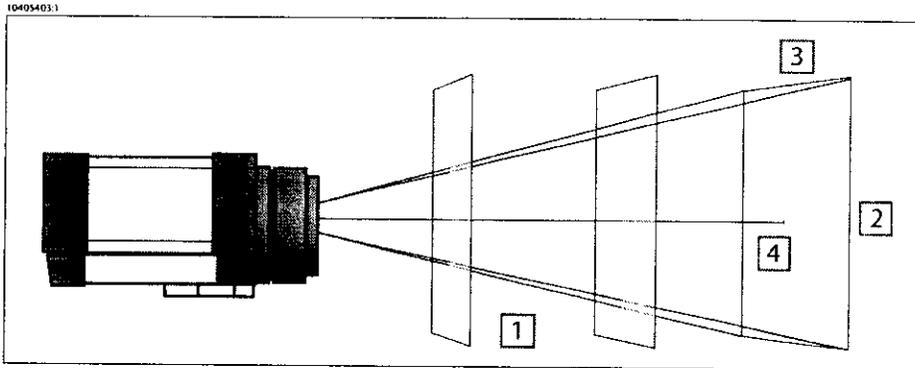


Figure 17.10 Relationship between fields of view and distance. 1: Distance to target; 2: VFOV = vertical field of view; 3: HFOV = horizontal field of view, 4: IFOV = instantaneous field of view (spot size).

Figure 17.11 Horizontal, vertical and instantaneous fields of view for certain distances to targets. **D** = distance to target.

	D →	1.20	5.00	10.00	25.00	50.00	100.00	m
	D →	3.90	16.40	32.80	82.00	164.00	327.90	ft.
25°	HFOV	0.53	2.22	4.43	11.08	22.17	44.34	m
25°	HFOV	1.74	7.27	14.54	36.34	72.69	145.37	ft.
25°	VFOV	0.40	1.66	3.33	8.31	16.63	33.25	m
25°	VFOV	1.31	5.45	10.90	27.26	54.52	109.03	ft.
25°	IFOV	3.33	13.86	27.71	69.28	138.56	277.12	mm
25°	IFOV	0.13	0.55	1.09	2.73	5.46	10.91	in.
12°	HFOV	0.25	1.05	2.10	5.26	10.51	21.02	m
12°	HFOV	0.83	3.45	6.89	17.23	34.46	68.92	ft.
12°	VFOV	0.19	0.79	1.58	3.94	7.88	15.77	m
12°	VFOV	0.62	2.58	5.17	12.92	25.85	51.69	ft.
12°	IFOV	1.58	6.57	13.14	32.85	65.69	131.38	mm
12°	IFOV	0.06	0.26	0.52	1.29	2.59	5.17	in.
45°	HFOV	0.99	4.14	8.28	20.71	41.42	82.84	m
45°	HFOV	3.26	13.58	27.16	67.90	135.81	271.62	ft.

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17.9 – Relationship between fields of view and distance

	D →	1.20	5.00	10.00	25.00	50.00	100.00	m
	D →	3.90	16.40	32.80	82.00	164.00	327.90	ft.
45°	VFOV	0.75	3.11	6.21	15.53	31.07	62.13	m
45°	VFOV	2.44	10.19	20.37	50.93	101.86	203.71	ft.
45°	IFOV	6.21	25.89	51.78	129.44	258.88	517.77	mm
45°	IFOV	0.24	1.02	2.04	5.10	10.19	20.38	in.

Figure 17.12 F-number and close focus limits for various lenses

Lens →	12°	25°	45°
Close focus limit (m)	0.70	0.30	0.01
Close focus limit (ft.)	2.30	0.98	0.03
f-number	1.2	1.2	1.2

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18 Dimensional drawings

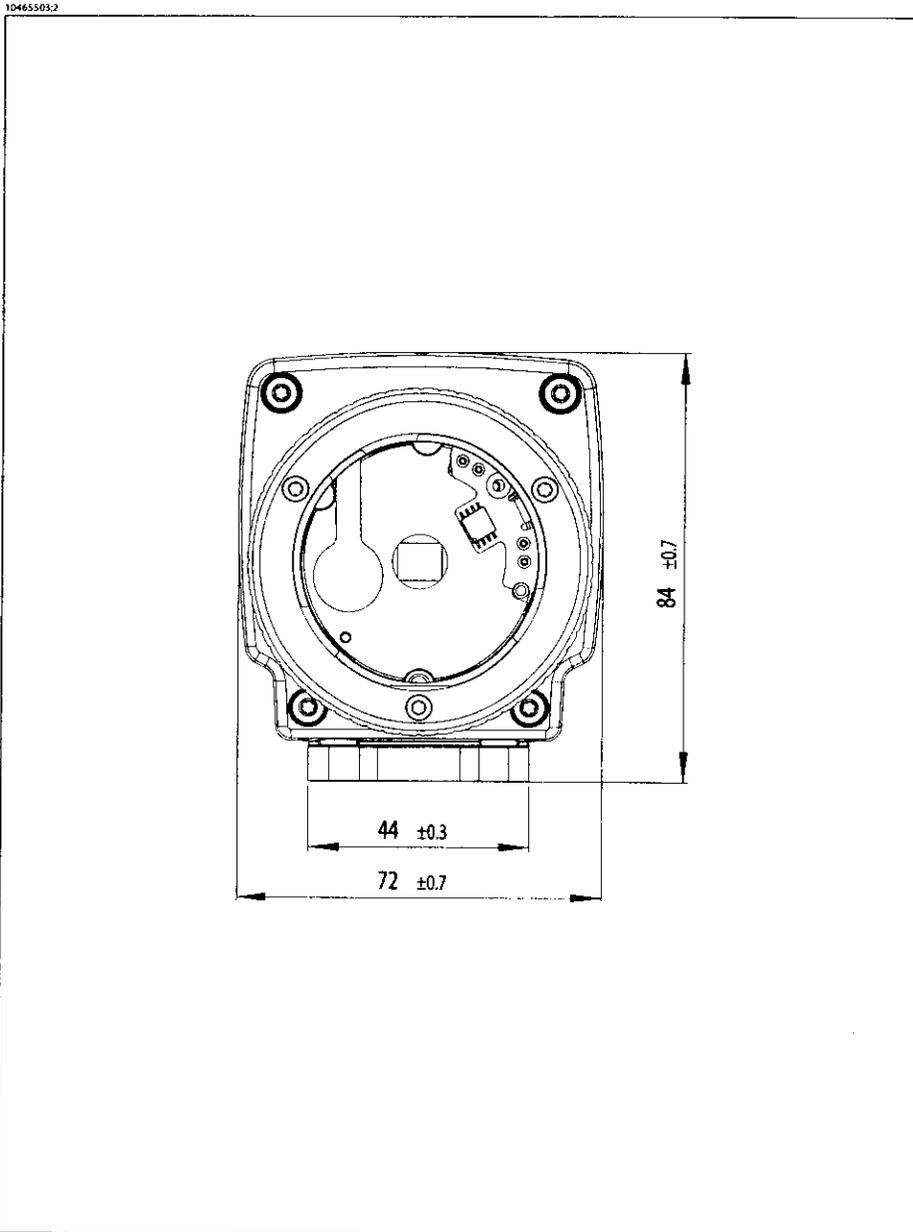


Figure 18.1 Overall dimensions of the camera, without lens – front view

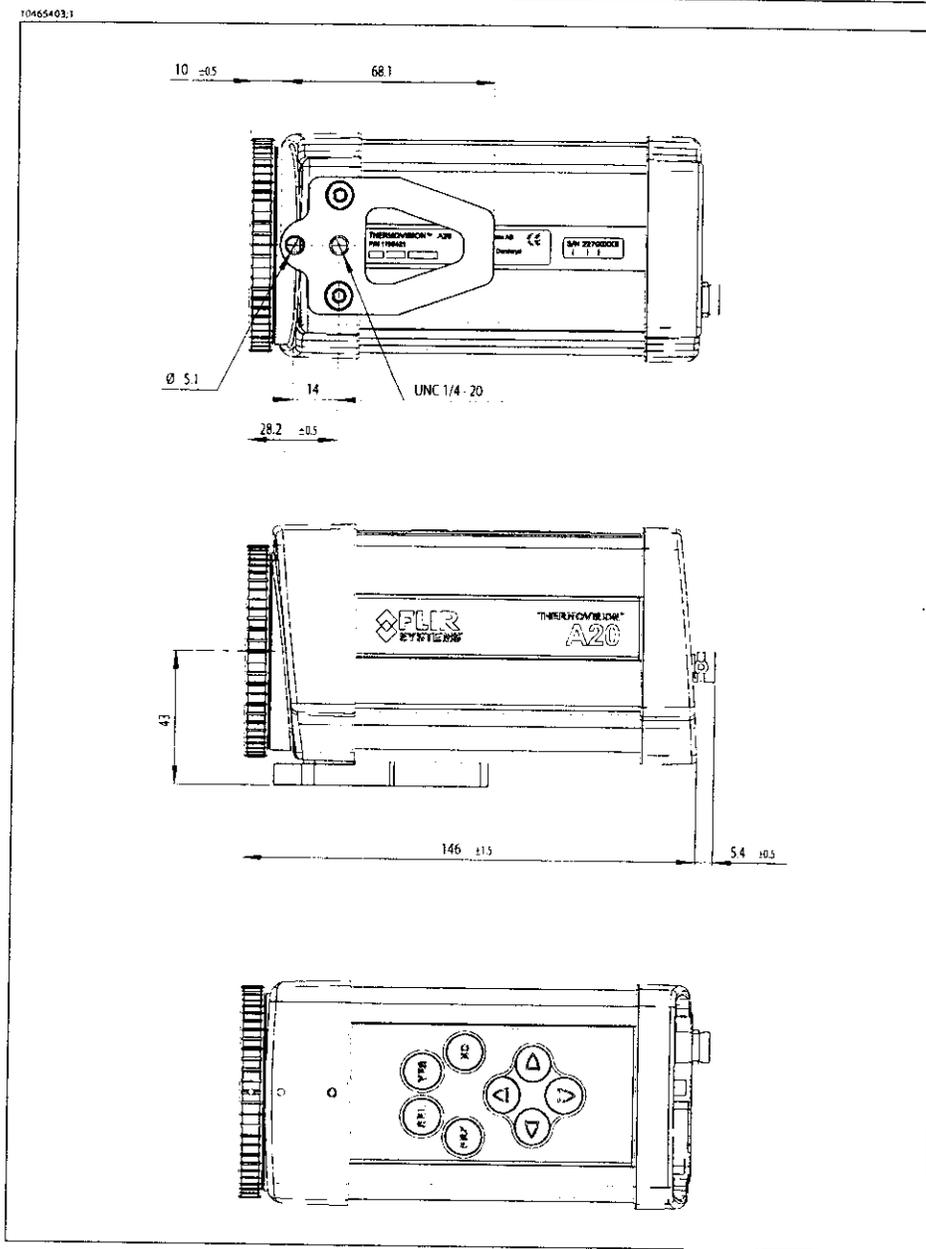


Figure 18.2 Overall dimensions of the camera, without lens – bottom & side view

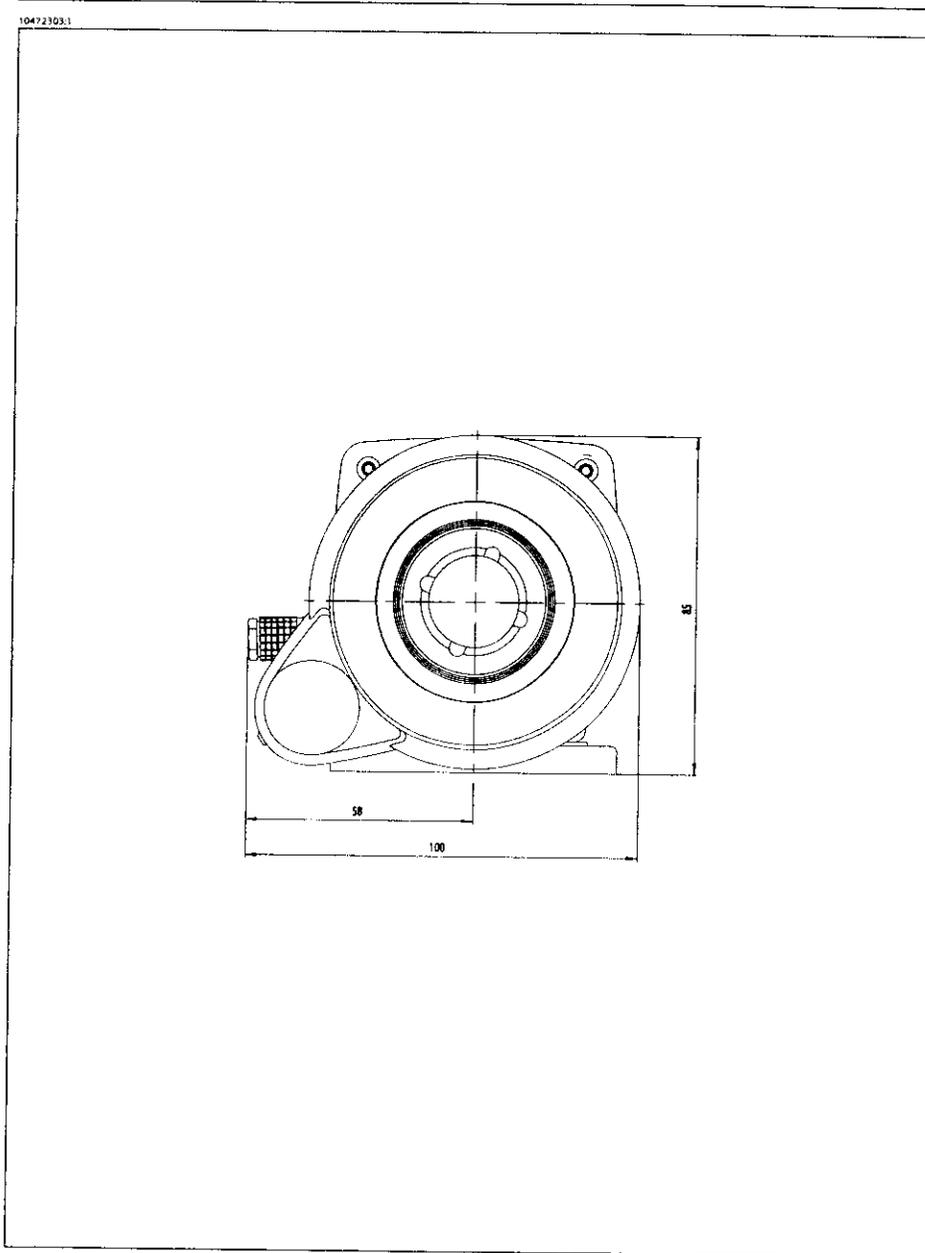


Figure 18.3 Dimensions of the camera, including external motor focus unit

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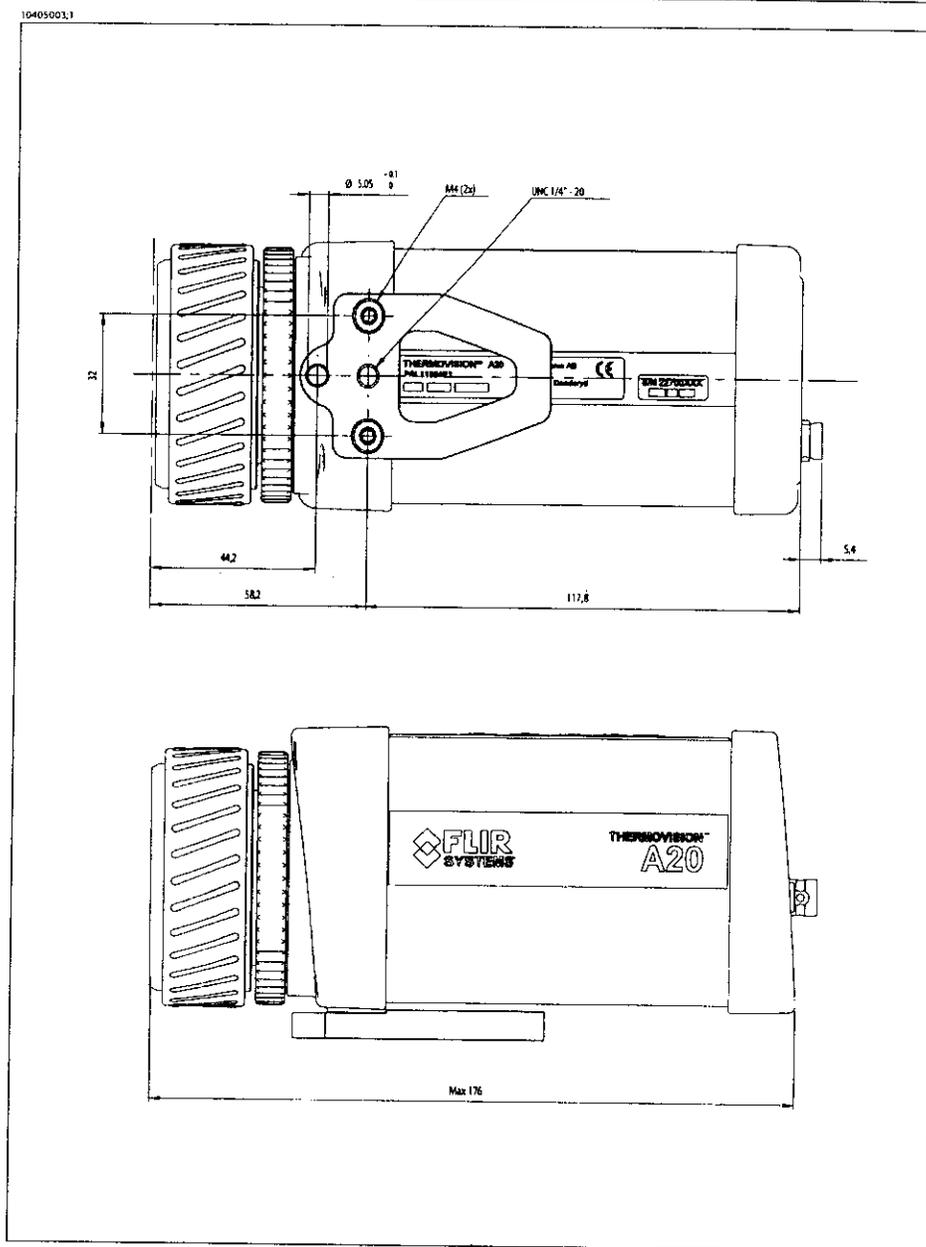


Figure 18.4 Overall dimensions of the camera, with 12° IR lens

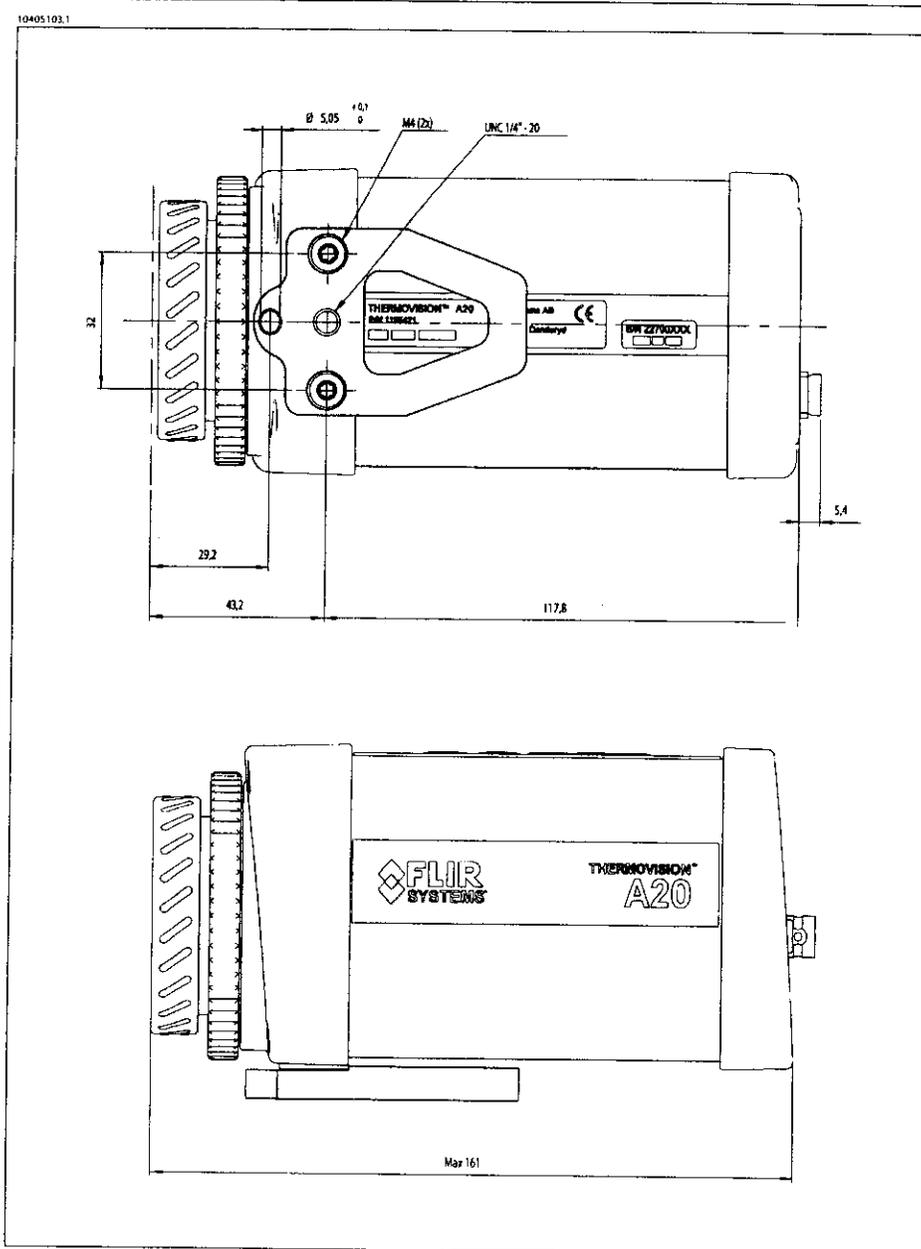


Figure 18.5 Overall dimensions of the camera, with 25° IR lens

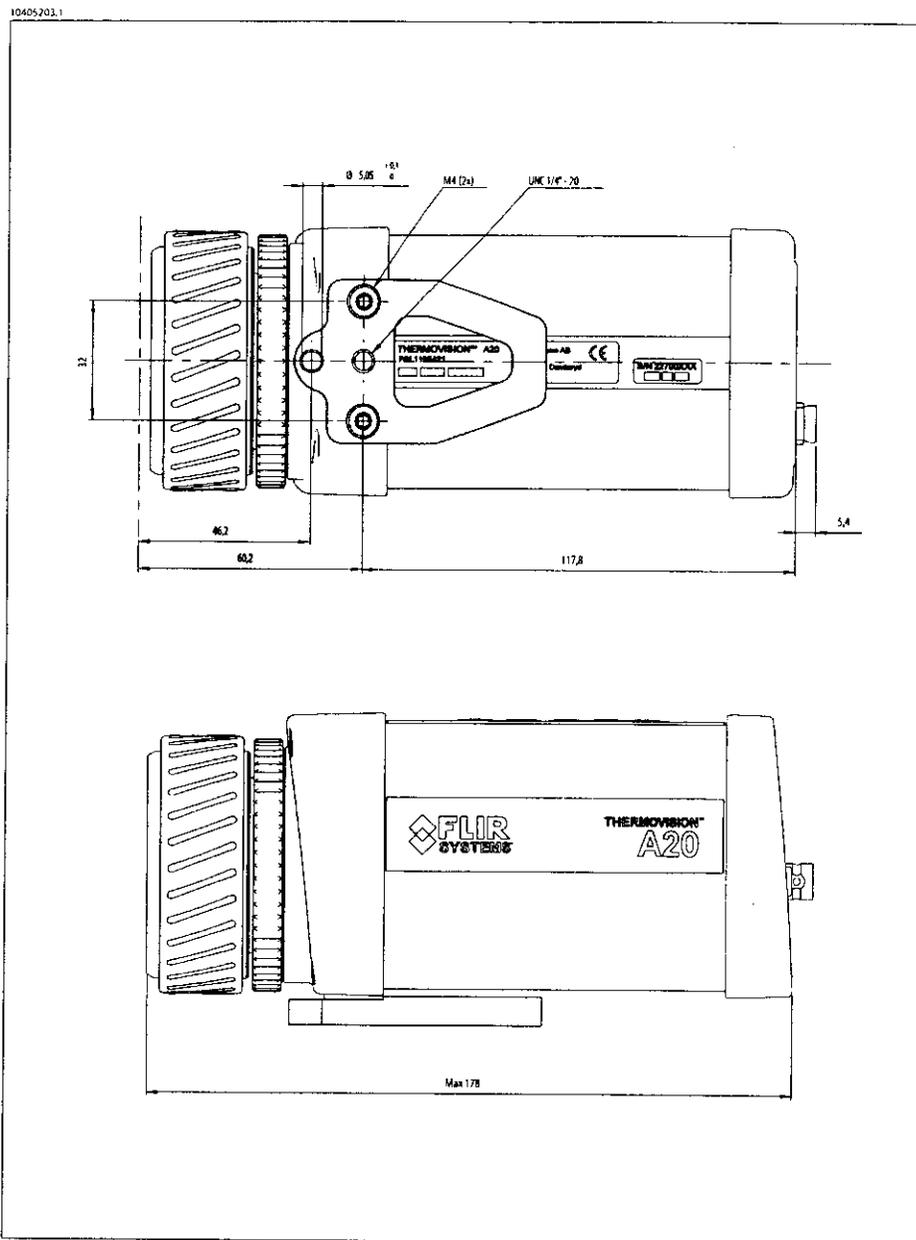


Figure 18.6 Overall dimensions of the camera, with 45° IR lens

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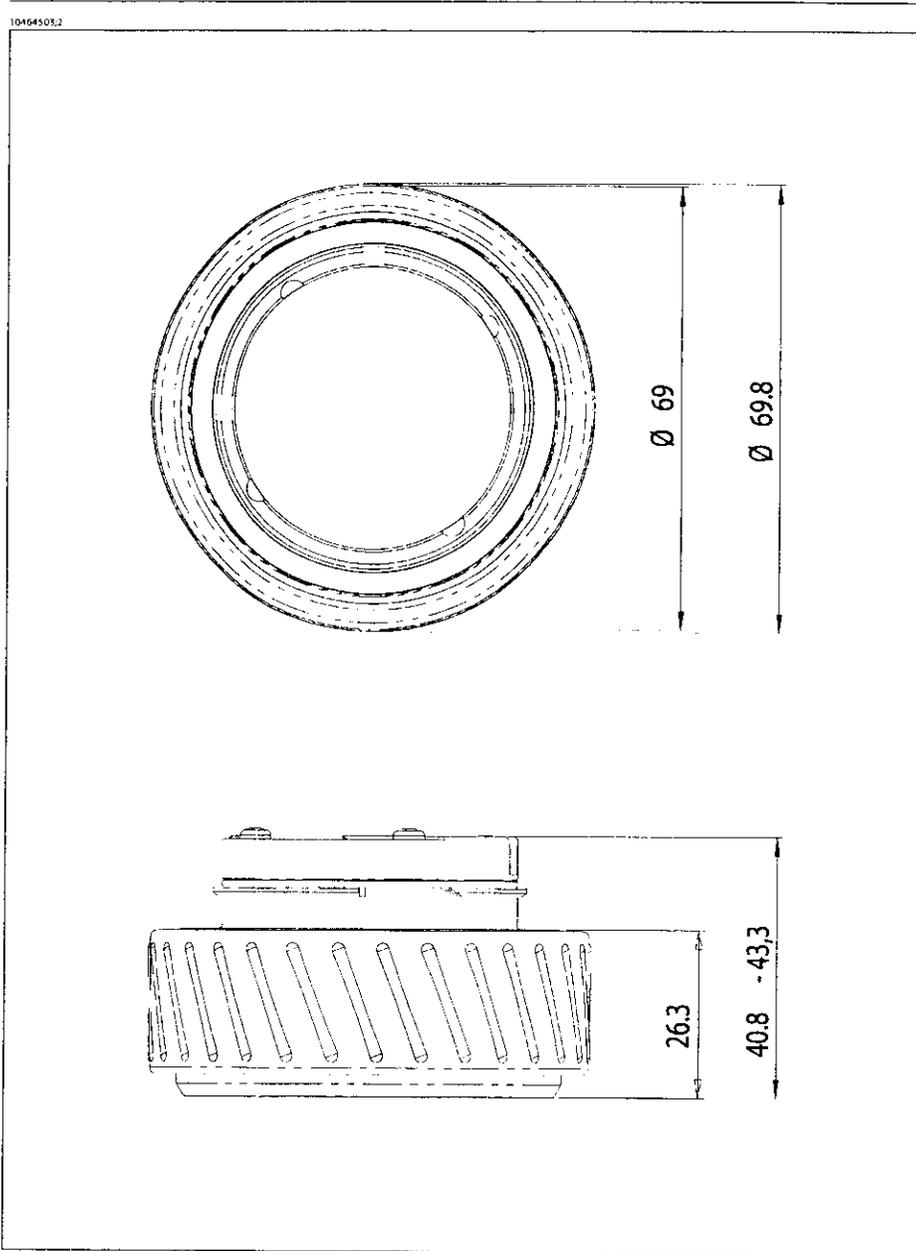


Figure 18.7 12° IR lens

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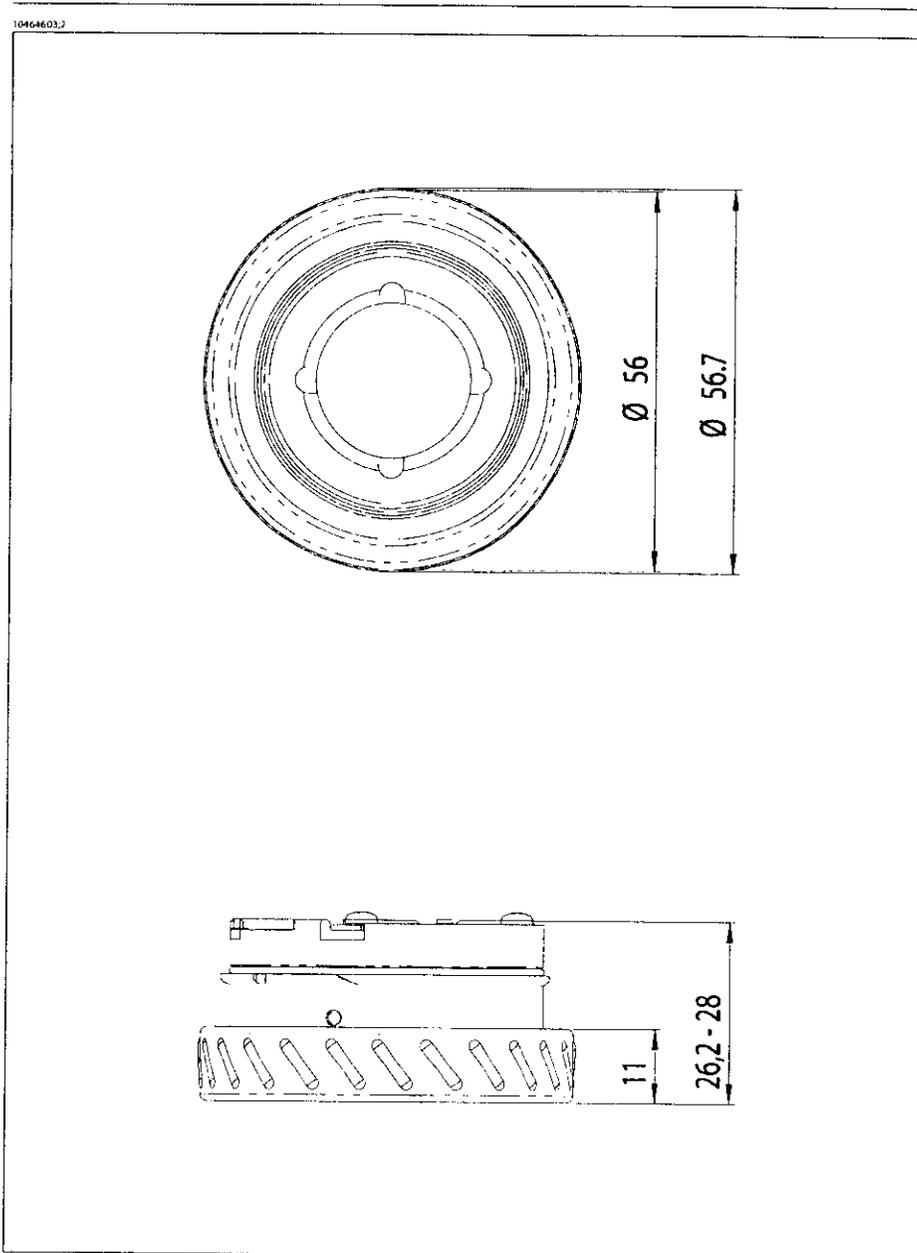


Figure 18.8 25° IR lens

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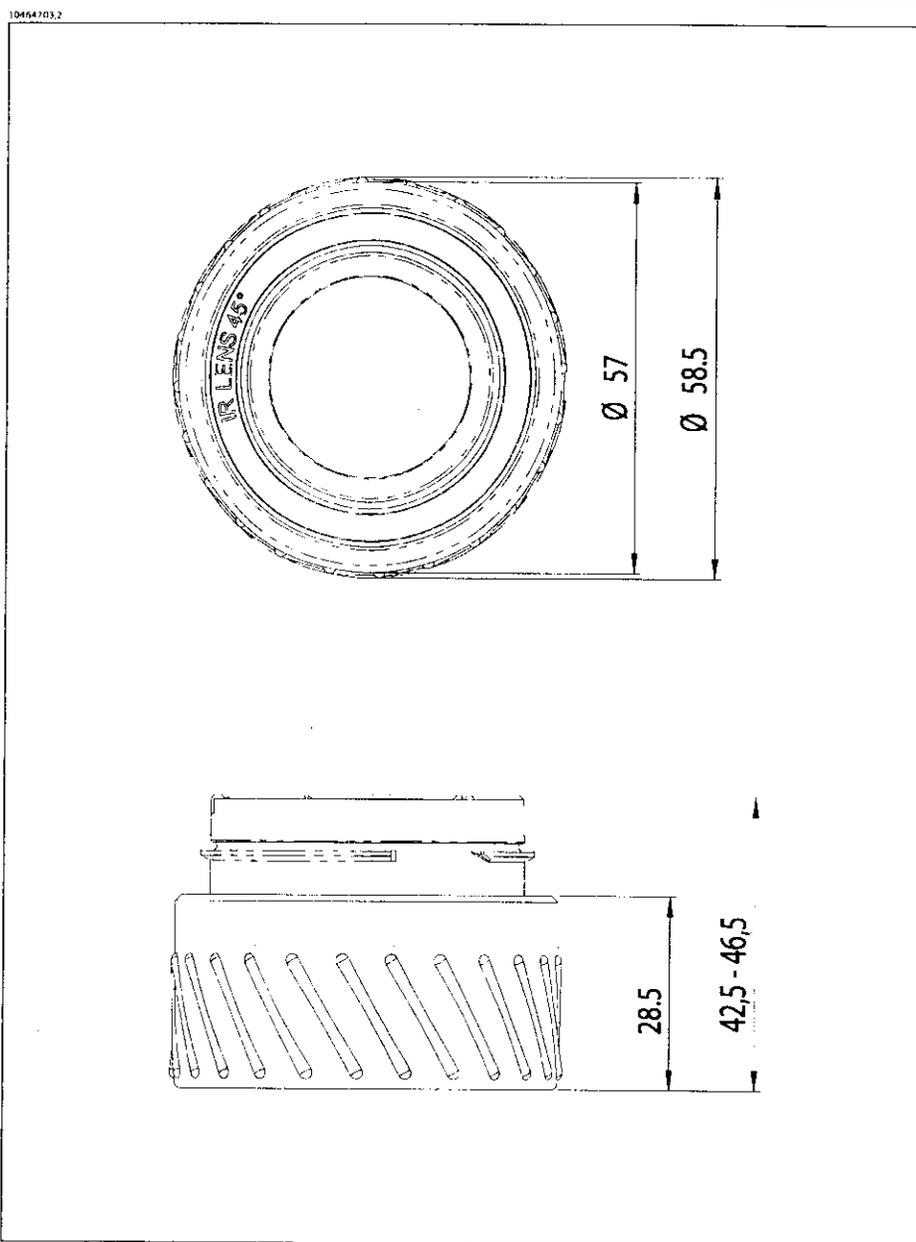


Figure 18.9 45° IR lens

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19 Glossary

Figure 19.1 Glossary of common infrared terms & expressions

Term or expression	Explanation
absorption (absorption factor)	The amount of radiation absorbed by an object relative to the received radiation. A number between 0 and 1.
ambient	Objects and gases that emit radiation towards the object being measured.
atmosphere	The gases between the object being measured and the camera, normally air.
autoadjust	A function making a camera perform an internal image correction.
autopalette	The IR image is shown with an uneven spread of colors, displaying cold objects as well as hot ones at the same time.
blackbody	Totally non-reflective object. All its radiation is due to its own temperature.
blackbody radiator	An IR radiating equipment with blackbody properties used to calibrate IR cameras.
calculated atmospheric transmission	A transmission value computed from the temperature, the relative humidity of air and the distance to the object.
cavity radiator	A bottle shaped radiator with an absorbing inside, viewed through the bottleneck.
color temperature	The temperature for which the color of a blackbody matches a specific color.
conduction	The process that makes heat spread into a material.
continuous adjust	A function that adjusts the image. The function works all the time, continuously adjusting brightness and contrast according to the image content.
convection	The process that makes hot air or liquid rise.
difference temperature	A value which is the result of a subtraction between two temperature values.
dual isotherm	An isotherm with two color bands, instead of one.
emissivity (emissivity factor)	The amount of radiation coming from an object, compared to that of a blackbody. A number between 0 and 1.

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Term or expression	Explanation
emittance	Amount of energy emitted from an object per unit of time and area (W/m ²)
estimated atmospheric transmission	A transmission value, supplied by a user, replacing a calculated one
external optics	Extra lenses, filters, heat shields etc. that can be put between the camera and the object being measured.
filter	A material transparent only to some of the infrared wavelengths.
FOV	Field of view: The horizontal angle that can be viewed through an IR lens.
FPA	Focal plane array: A type of IR detector.
graybody	An object that emits a fixed fraction of the amount of energy of a blackbody for each wavelength.
IFOV	Instantaneous field of view: A measure of the geometrical resolution of an IR camera.
image correction (internal or external)	A way of compensating for sensitivity differences in various parts of live images and also of stabilizing the camera.
infrared	Non-visible radiation, having a wavelength from about 2–13 μm .
IR	infrared
isotherm	A function highlighting those parts of an image that fall above, below or between one or more temperature intervals.
isothermal cavity	A bottle-shaped radiator with a uniform temperature viewed through the bottleneck.
Laser LocatIR	An electrically powered light source on the camera that emits laser radiation in a thin, concentrated beam to point at certain parts of the object in front of the camera.
laser pointer	An electrically powered light source on the camera that emits laser radiation in a thin, concentrated beam to point at certain parts of the object in front of the camera.
level	The center value of the temperature scale, usually expressed as a signal value.
manual adjust	A way to adjust the image by manually changing certain parameters.

Term or expression	Explanation
NETD	Noise equivalent temperature difference. A measure of the image noise level of an IR camera.
noise	Undesired small disturbance in the infrared image
object parameters	A set of values describing the circumstances under which the measurement of an object was made, and the object itself (such as emissivity, ambient temperature, distance etc.)
object signal	A non-calibrated value related to the amount of radiation received by the camera from the object.
palette	The set of colors used to display an IR image.
pixel	Stands for <i>picture element</i> . One single spot in an image.
radiance	Amount of energy emitted from an object per unit of time, area and angle ($W/m^2/sr$)
radiant power	Amount of energy emitted from an object per unit of time (W)
radiation	The process by which electromagnetic energy, is emitted by an object or a gas.
radiator	A piece of IR radiating equipment.
range	The current overall temperature measurement limitation of an IR camera. Cameras can have several ranges. Expressed as two blackbody temperatures that limit the current calibration.
reference temperature	A temperature which the ordinary measured values can be compared with.
reflection	The amount of radiation reflected by an object relative to the received radiation. A number between 0 and 1.
relative humidity	Percentage of water in the air, relative to what is physically possible. Air temperature dependent.
saturation color	The areas that contain temperatures outside the present level/span settings are colored with the saturation colors. The saturation colors contain an 'overflow' color and an 'underflow' color. There is also a third red saturation color that marks everything saturated by the detector indicating that the range should probably be changed.
span	The interval of the temperature scale, usually expressed as a signal value.

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Term or expression	Explanation
spectral (radiant) emittance	Amount of energy emitted from an object per unit of time, area and wavelength ($W/m^2/\mu m$)
temperature range	The current overall temperature measurement limitation of an IR camera. Cameras can have several ranges. Expressed as two blackbody temperatures that limit the current calibration.
temperature scale	The way in which an IR image currently is displayed. Expressed as two temperature values limiting the colors.
thermogram	infrared image
transmission (or transmittance) factor	Gases and materials can be more or less transparent. Transmission is the amount of IR radiation passing through them. A number between 0 and 1.
transparent isotherm	An isotherm showing a linear spread of colors, instead of covering the highlighted parts of the image.
visual	Refers to the video mode of a IR camera, as opposed to the normal, thermographic mode. When a camera is in video mode it captures ordinary video images, while thermographic images are captured when the camera is in IR mode.

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20 History of infrared technology

Less than 200 years ago the existence of the infrared portion of the electromagnetic spectrum wasn't even suspected. The original significance of the infrared spectrum, or simply 'the infrared' as it is often called, as a form of heat radiation is perhaps less obvious today than it was at the time of its discovery by Herschel in 1800.



Figure 20.1 Sir William Herschel (1738–1822)

The discovery was made accidentally during the search for a new optical material. Sir William Herschel – Royal Astronomer to King George III of England, and already famous for his discovery of the planet Uranus – was searching for an optical filter material to reduce the brightness of the sun's image in telescopes during solar observations. While testing different samples of colored glass which gave similar reductions in brightness he was intrigued to find that some of the samples passed very little of the sun's heat, while others passed so much heat that he risked eye damage after only a few seconds' observation.

Herschel was soon convinced of the necessity of setting up a systematic experiment, with the objective of finding a single material that would give the desired reduction in brightness as well as the maximum reduction in heat. He began the experiment by actually repeating Newton's prism experiment, but looking for the heating effect rather than the visual distribution of intensity in the spectrum. He first blackened the bulb of a sensitive mercury-in-glass thermometer with ink, and with this as his radiation detector he proceeded to test the heating effect of the various colors of the spectrum formed on the top of a table by passing sunlight through a glass prism. Other thermometers, placed outside the sun's rays, served as controls.

As the blackened thermometer was moved slowly along the colors of the spectrum, the temperature readings showed a steady increase from the violet end to the red end. This was not entirely unexpected, since the Italian researcher, Landriani, in a similar experiment in 1777 had observed much the same effect. It was Herschel, however, who was the first to recognize that there must be a point where the heating

effect reaches a maximum, and that measurements confined to the visible portion of the spectrum failed to locate this point.

10398903.1



Figure 20.2 Marsilio Landriani (1746–1815)

Moving the thermometer into the dark region beyond the red end of the spectrum, Herschel confirmed that the heating continued to increase. The maximum point, when he found it, lay well beyond the red end – in what is known today as the ‘infrared wavelengths’.

When Herschel revealed his discovery, he referred to this new portion of the electromagnetic spectrum as the ‘thermometrical spectrum’. The radiation itself he sometimes referred to as ‘dark heat’, or simply ‘the invisible rays’. Ironically, and contrary to popular opinion, it wasn’t Herschel who originated the term ‘infrared’. The word only began to appear in print around 75 years later, and it is still unclear who should receive credit as the originator.

Herschel’s use of glass in the prism of his original experiment led to some early controversies with his contemporaries about the actual existence of the infrared wavelengths. Different investigators, in attempting to confirm his work, used various types of glass indiscriminately, having different transparencies in the infrared. Through his later experiments, Herschel was aware of the limited transparency of glass to the newly-discovered thermal radiation, and he was forced to conclude that optics for the infrared would probably be doomed to the use of reflective elements exclusively (i.e. plane and curved mirrors). Fortunately, this proved to be true only until 1830, when the Italian investigator, Melloni, made his great discovery that naturally occurring rock salt (NaCl) – which was available in large enough natural crystals to be made into lenses and prisms – is remarkably transparent to the infrared. The result was that rock salt became the principal infrared optical material, and remained so for the next hundred years, until the art of synthetic crystal growing was mastered in the 1930’s.

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Figure 20.3 Macedonio Melloni (1798–1854)

Thermometers, as radiation detectors, remained unchallenged until 1829, the year Nobili invented the thermocouple. (Herschel's own thermometer could be read to 0.2 °C (0.036 °F), and later models were able to be read to 0.05 °C (0.09 °F)). Then a breakthrough occurred; Melloni connected a number of thermocouples in series to form the first thermopile. The new device was at least 40 times as sensitive as the best thermometer of the day for detecting heat radiation – capable of detecting the heat from a person standing three meters away.

The first so-called 'heat-picture' became possible in 1840, the result of work by Sir John Herschel, son of the discoverer of the infrared and a famous astronomer in his own right. Based upon the differential evaporation of a thin film of oil when exposed to a heat pattern focused upon it, the thermal image could be seen by reflected light where the interference effects of the oil film made the image visible to the eye. Sir John also managed to obtain a primitive record of the thermal image on paper, which he called a 'thermograph'.



Figure 20.4 Samuel P. Langley (1834–1906)

The improvement of infrared-detector sensitivity progressed slowly. Another major breakthrough, made by Langley in 1880, was the invention of the bolometer. This

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consisted of a thin blackened strip of platinum connected in one arm of a Wheatstone bridge circuit upon which the infrared radiation was focused and to which a sensitive galvanometer responded. This instrument is said to have been able to detect the heat from a cow at a distance of 400 meters.

An English scientist, Sir James Dewar, first introduced the use of liquefied gases as cooling agents (such as liquid nitrogen with a temperature of -196°C (-320.8°F)) in low temperature research. In 1892 he invented a unique vacuum insulating container in which it is possible to store liquefied gases for entire days. The common 'thermos bottle', used for storing hot and cold drinks, is based upon his invention.

Between the years 1900 and 1920, the inventors of the world 'discovered' the infrared. Many patents were issued for devices to detect personnel, artillery, aircraft, ships – and even icebergs. The first operating systems, in the modern sense, began to be developed during the 1914–18 war, when both sides had research programs devoted to the military exploitation of the infrared. These programs included experimental systems for enemy intrusion/detection, remote temperature sensing, secure communications, and 'flying torpedo' guidance. An infrared search system tested during this period was able to detect an approaching airplane at a distance of 1.5 km (0.94 miles), or a person more than 300 meters (984 ft.) away.

The most sensitive systems up to this time were all based upon variations of the bolometer idea, but the period between the two wars saw the development of two revolutionary new infrared detectors: the image converter and the photon detector. At first, the image converter received the greatest attention by the military, because it enabled an observer for the first time in history to literally 'see in the dark'. However, the sensitivity of the image converter was limited to the near infrared wavelengths, and the most interesting military targets (i.e. enemy soldiers) had to be illuminated by infrared search beams. Since this involved the risk of giving away the observer's position to a similarly-equipped enemy observer, it is understandable that military interest in the image converter eventually faded.

The tactical military disadvantages of so-called 'active' (i.e. search beam-equipped) thermal imaging systems provided impetus following the 1939–45 war for extensive secret military infrared-research programs into the possibilities of developing 'passive' (no search beam) systems around the extremely sensitive photon detector. During this period, military secrecy regulations completely prevented disclosure of the status of infrared-imaging technology. This secrecy only began to be lifted in the middle of the 1950's, and from that time adequate thermal-imaging devices finally began to be available to civilian science and industry.

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21 Theory of thermography

21.1 Introduction

The subjects of infrared radiation and the related technique of thermography are still new to many who will use an infrared camera. In this section the theory behind thermography will be given.

21.2 The electromagnetic spectrum

The electromagnetic spectrum is divided arbitrarily into a number of wavelength regions, called *bands*, distinguished by the methods used to produce and detect the radiation. There is no fundamental difference between radiation in the different bands of the electromagnetic spectrum. They are all governed by the same laws and the only differences are those due to differences in wavelength.

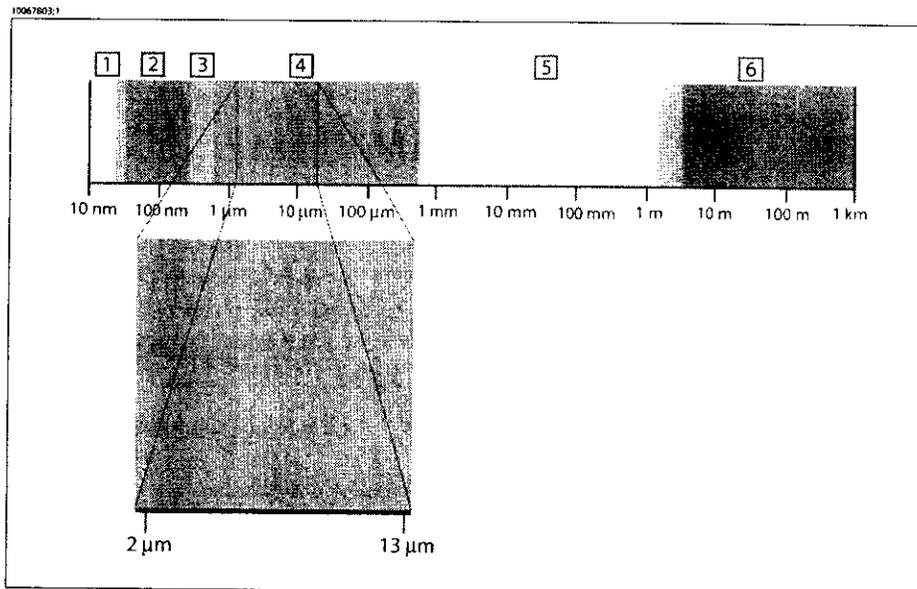


Figure 21.1 The electromagnetic spectrum. 1: X-ray; 2: UV; 3: Visible; 4: IR; 5: Microwaves; 6: Radiowaves.

Thermography makes use of the infrared spectral band. At the short-wavelength end the boundary lies at the limit of visual perception, in the deep red. At the long-wavelength end it merges with the microwave radio wavelengths, in the millimeter range.

The infrared band is often further subdivided into four smaller bands, the boundaries of which are also arbitrarily chosen. They include: the *near infrared* (0.75–3 μm), the

21.3 – Blackbody radiation

middle infrared (3–6 μm), the *far infrared* (6–15 μm) and the *extreme infrared* (15–100 μm). Although the wavelengths are given in μm (micrometers), other units are often still used to measure wavelength in this spectral region, e.g. nanometer (nm) and Ångström (Å).

The relationships between the different wavelength measurements is:

$$10\,000\ \text{Å} = 1\,000\ \text{nm} = 1\ \mu = 1\ \mu\text{m}$$

21.3 Blackbody radiation

A blackbody is defined as an object which absorbs all radiation that impinges on it at any wavelength. The apparent misnomer *black* relating to an object emitting radiation is explained by Kirchhoff's Law (after *Gustav Robert Kirchhoff*, 1824–1887), which states that a body capable of absorbing all radiation at any wavelength is equally capable in the emission of radiation.



Figure 21.2 Gustav Robert Kirchhoff (1824–1887)

The construction of a blackbody source is, in principle, very simple. The radiation characteristics of an aperture in an isotherm cavity made of an opaque absorbing material represents almost exactly the properties of a blackbody. A practical application of the principle to the construction of a perfect absorber of radiation consists of a box that is light tight except for an aperture in one of the sides. Any radiation which then enters the hole is scattered and absorbed by repeated reflections so only an infinitesimal fraction can possibly escape. The blackness which is obtained at the aperture is nearly equal to a blackbody and almost perfect for all wavelengths.

By providing such an isothermal cavity with a suitable heater it becomes what is termed a *cavity radiator*. An isothermal cavity heated to a uniform temperature generates blackbody radiation, the characteristics of which are determined solely by the temperature of the cavity. Such cavity radiators are commonly used as sources of radiation in temperature reference standards in the laboratory for calibrating thermographic instruments, such as a FLIR Systems AB camera for example.

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If the temperature of blackbody radiation increases to more than 525 °C (977 °F), the source begins to be visible so that it appears to the eye no longer black. This is the incipient red heat temperature of the radiator, which then becomes orange or yellow as the temperature increases further. In fact, the definition of the so-called *color temperature* of an object is the temperature to which a blackbody would have to be heated to have the same appearance.

Now consider three expressions that describe the radiation emitted from a blackbody.

21.3.1 Planck’s law

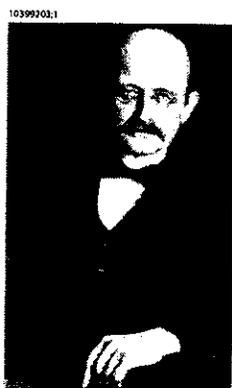


Figure 21.3 Max Planck (1858–1947)

Max Planck (1858–1947) was able to describe the spectral distribution of the radiation from a blackbody by means of the following formula:

$$W_{\lambda b} = \frac{2\pi hc^3}{\lambda^5 \left(e^{hc/\lambda T} - 1 \right)} \times 10^{-6} \left[\text{Watt}/\text{m}^2 \mu\text{m} \right]$$

where:

$W_{\lambda b}$	Blackbody spectral radiant emittance at wavelength λ .
c	Velocity of light = 3×10^8 m/s
h	Planck’s constant = 6.6×10^{-34} Joule sec.
k	Boltzmann’s constant = 1.4×10^{-23} Joule/K.
T	Absolute temperature (K) of a blackbody.
λ	Wavelength (μm).

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21.3 - Blackbody radiation

NOTE: The factor 10^{-6} is used since spectral emittance in the curves is expressed in Watt/m²m. If the factor is excluded, the dimension will be Watt/m²μm.

Planck's formula, when plotted graphically for various temperatures, produces a family of curves. Following any particular Planck curve, the spectral emittance is zero at $\lambda = 0$, then increases rapidly to a maximum at a wavelength λ_{max} and after passing it approaches zero again at very long wavelengths. The higher the temperature, the shorter the wavelength at which maximum occurs.

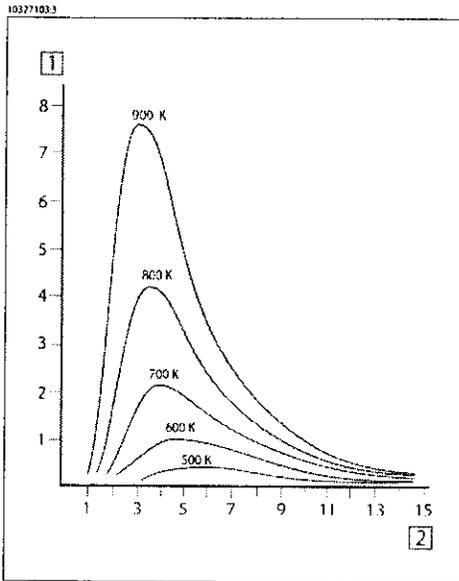


Figure 21.4 Blackbody spectral radiant emittance according to Planck's law, plotted for various absolute temperatures. 1: Spectral radiant emittance (W/cm² × 10³(μm)); 2: Wavelength (μm)

21.3.2 Wien's displacement law

By differentiating Planck's formula with respect to λ , and finding the maximum, we have:

$$\lambda_{max} = \frac{2898}{T} [\mu m]$$

This is Wien's formula (after *Wilhelm Wien*, 1864–1928), which expresses mathematically the common observation that colors vary from red to orange or yellow as the temperature of a thermal radiator increases. The wavelength of the color is the same as the wavelength calculated for λ_{max} . A good approximation of the value of λ_{max} for a given blackbody temperature is obtained by applying the rule-of-thumb $3\,000/T$ μm. Thus, a very hot star such as Sirius (11 000 K), emitting bluish-white light, radiates

with the peak of spectral radiant emittance occurring within the invisible ultraviolet spectrum, at wavelength $0.27 \mu\text{m}$.



Figure 21.5 Wilhelm Wien (1864–1928)

The sun (approx. $6\,000 \text{ K}$) emits yellow light, peaking at about $0.5 \mu\text{m}$ in the middle of the visible light spectrum.

At room temperature (300 K) the peak of radiant emittance lies at $9.7 \mu\text{m}$, in the far infrared, while at the temperature of liquid nitrogen (77 K) the maximum of the almost insignificant amount of radiant emittance occurs at $38 \mu\text{m}$, in the extreme infrared wavelengths.

21.3 – Blackbody radiation

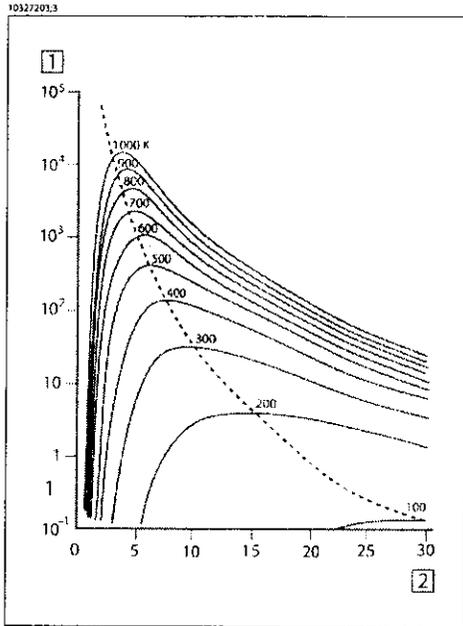


Figure 21.6 Planckian curves plotted on semi-log scales from 100 K to 1000 K. The dotted line represents the locus of maximum radiant emittance at each temperature as described by Wien's displacement law. 1: Spectral radiant emittance (W/cm² μm); 2: Wavelength (μm).

21.3.3 Stefan-Boltzmann's law

By integrating Planck's formula from $\lambda = 0$ to $\lambda = \infty$, we obtain the total radiant emittance (W_b) of a blackbody:

$$W_b = \sigma T^4 \text{ [Watt/m}^2\text{]}$$

This is the Stefan-Boltzmann formula (after *Josef Stefan*, 1835–1893, and *Ludwig Boltzmann*, 1844–1906), which states that the total emissive power of a blackbody is proportional to the fourth power of its absolute temperature. Graphically, W_b represents the area below the Planck curve for a particular temperature. It can be shown that the radiant emittance in the interval $\lambda = 0$ to λ_{max} is only 25 % of the total, which represents about the amount of the sun's radiation which lies inside the visible light spectrum.

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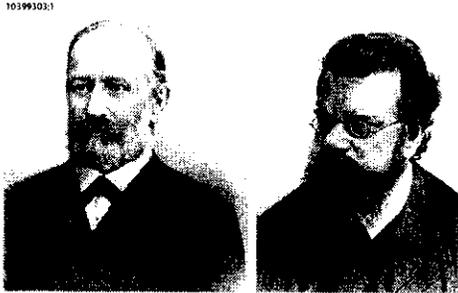


Figure 21.7 Josef Stefan (1835–1893), and Ludwig Boltzmann (1844–1906)

Using the Stefan-Boltzmann formula to calculate the power radiated by the human body, at a temperature of 300 K and an external surface area of approx. 2 m^2 , we obtain 1 kW. This power loss could not be sustained if it were not for the compensating absorption of radiation from surrounding surfaces, at room temperatures which do not vary too drastically from the temperature of the body – or, of course, the addition of clothing.

21.3.4 Non-blackbody emitters

So far, only blackbody radiators and blackbody radiation have been discussed. However, real objects almost never comply with these laws over an extended wavelength region – although they may approach the blackbody behavior in certain spectral intervals. For example, a certain type of white paint may appear perfectly *white* in the visible light spectrum, but becomes distinctly *gray* at about $2 \mu\text{m}$, and beyond $3 \mu\text{m}$ it is almost *black*.

There are three processes which can occur that prevent a real object from acting like a blackbody: a fraction of the incident radiation α may be absorbed, a fraction ρ may be reflected, and a fraction τ may be transmitted. Since all of these factors are more or less wavelength dependent, the subscript λ is used to imply the spectral dependence of their definitions. Thus:

- The spectral absorptance α_λ = the ratio of the spectral radiant power absorbed by an object to that incident upon it.
- The spectral reflectance ρ_λ = the ratio of the spectral radiant power reflected by an object to that incident upon it.
- The spectral transmittance τ_λ = the ratio of the spectral radiant power transmitted through an object to that incident upon it.

The sum of these three factors must always add up to the whole at any wavelength, so we have the relation:

$$\alpha_\lambda + \rho_\lambda + \tau_\lambda = 1$$

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For opaque materials $\tau_\lambda = 0$ and the relation simplifies to:

$$\alpha_\lambda + \rho_\lambda = 1$$

Another factor, called the emissivity, is required to describe the fraction ϵ of the radiant emittance of a blackbody produced by an object at a specific temperature. Thus, we have the definition:

The spectral emissivity ϵ_λ is the ratio of the spectral radiant power from an object to that from a blackbody at the same temperature and wavelength.

Expressed mathematically, this can be written as the ratio of the spectral emittance of the object to that of a blackbody as follows:

$$\epsilon_\lambda = \frac{W_{\lambda o}}{W_{\lambda b}}$$

Generally speaking, there are three types of radiation source, distinguished by the ways in which the spectral emittance of each varies with wavelength.

- A blackbody, for which $\epsilon_\lambda = \epsilon = 1$
- A graybody, for which $\epsilon_\lambda = \epsilon = \text{constant less than 1}$
- A selective radiator, for which ϵ varies with wavelength

According to Kirchhoff's law, for any material the spectral emissivity and spectral absorptance of a body are equal at any specified temperature and wavelength. That is:

$$\epsilon_\lambda = \alpha_\lambda$$

From this we obtain, for an opaque material (since $\alpha_\lambda + \rho_\lambda = 1$):

$$\epsilon_\lambda + \rho_\lambda = 1$$

For highly polished materials ϵ_λ approaches zero, so that for a perfectly reflecting material (*i.e.* a perfect mirror) we have:

$$\rho_\lambda = 1$$

For a graybody radiator, the Stefan-Boltzmann formula becomes:

$$W = \epsilon \sigma T^4 \text{ [Watt/m}^2\text{]}$$

This states that the total emissive power of a graybody is the same as a blackbody at the same temperature reduced in proportion to the value of ϵ from the graybody.

21.4 - Infrared semi-transparent materials

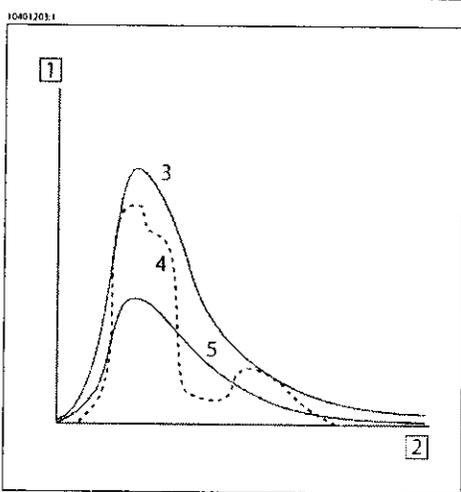


Figure 21.8 Spectral radiant emittance of three types of radiators. 1: Spectral radiant emittance; 2: Wavelength; 3: Blackbody; 4: Selective radiator; 5: Graybody.

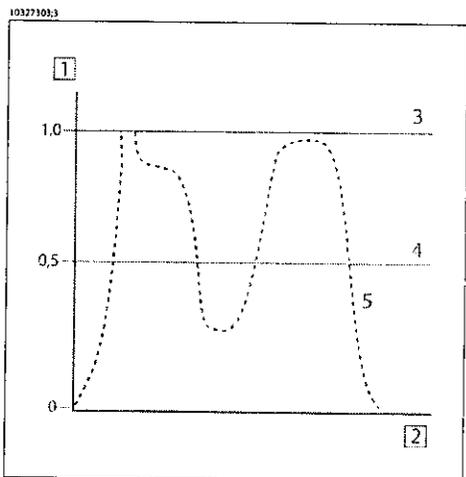


Figure 21.9 Spectral emissivity of three types of radiators. 1: Spectral emissivity; 2: Wavelength; 3: Blackbody; 4: Graybody; 5: Selective radiator.

21.4 Infrared semi-transparent materials

Consider now a non-metallic, semi-transparent body - let us say, in the form of a thick flat plate of plastic material. When the plate is heated, radiation generated within its volume must work its way toward the surfaces through the material in which it is partially absorbed. Moreover, when it arrives at the surface, some of it is reflected back into the interior. The back-reflected radiation is again partially absorbed, but some of it arrives at the other surface, through which most of it escapes; part of it is

21.4 – Infrared semi-transparent materials

reflected back again. Although the progressive reflections become weaker and weaker they must all be added up when the total emittance of the plate is sought. When the resulting geometrical series is summed, the effective emissivity of a semi-transparent plate is obtained as:

$$\varepsilon_{\lambda} = \frac{(1 - \rho_{\lambda})(1 - \tau_{\lambda})}{1 - \rho_{\lambda}\tau_{\lambda}}$$

When the plate becomes opaque this formula is reduced to the single formula:

$$\varepsilon_{\lambda} = 1 - \rho_{\lambda}$$

This last relation is a particularly convenient one, because it is often easier to measure reflectance than to measure emissivity directly.

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This manual was produced using XML – Extensible Markup Language. For more information about XML, point your browser to: <http://www.w3c.org/XML/>

Description	Software	Supplier	URL
Version control	ExcoConf	ExcOSOFT	http://www.excOSOFT.se/eweb/site/exc_pd.html
Editing environment	XML Client	ExcOSOFT	http://www.excOSOFT.se/eweb/site/excococonf_pd.html
Preformatting	ExcoForm	ExcOSOFT	http://www.excOSOFT.se/eweb/site/home.html
XML parser	Xerces	Apache	http://xml.apache.org/xerces-j
XSLT processor	Xalan	Apache	http://xml.apache.org/xalan-j
XSL-FO rendering engine	XEP	RenderX	http://www.renderx.com

The following file identities and versions were used in this manual:

- (a)20239203.xml;7
- (a)20239503.xml;5
- (a)20239603.xml;3
- (a)20239703.xml;3
- (a)20239803.xml;5
- (a)20239903.xml;9
- (a)20240003.xml;3
- (a)20240103.xml;5
- (a)20240203.xml;7
- (a)20240403.xml;7
- (a)20248003.xml;4
- (a)20248103.xml;4
- (a)20248203.xml;3
- (a)20248303.xml;2
- (a)20248403.xml;3
- (a)20248603.xml;1
- (a)R0021.rcp;3
- (manbase)20234503.xml;15
- (manbase)20234903.xml;9
- (manbase)20235203.xml;15
- (manbase)20236703.xml;15
- (manbase)20238503.xml;3
- (p)20236103.xml;11
- (p)20237103.xml;5

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) EVA CZERSKA

Subject: 510(k) Number K033967

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- | | | |
|---|---|--|
| Is this device subject to Section 522 Postmarket Surveillance? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Is this device subject to the Tracking Regulation? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Was clinical data necessary to support the review of this 510(k)? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Is this a prescription device? | <input checked="" type="checkbox"/> YES | <input type="checkbox"/> NO |
| Was this 510(k) reviewed by a Third Party? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Special 510(k)? | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |
| Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers | <input type="checkbox"/> YES | <input checked="" type="checkbox"/> NO |

- Truthful and Accurate Statement Requested Enclosed
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices N/A
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source YES NO Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 901 HCG 884.2936 Additional Product Code(s) with panel (optional): 901 HCG

K982327 / class 1 K023434 / class 1

Review: Ra-C Pelly (Branch Chief) RANS (Branch Code) 3/5/04 (Date)

Final Review: Nancy C Brogan (Date) 3-8-04

510(k) Review

K033967

Company Name: Flir Systems, Inc.

Address: 16 Esquire Road
North Billerica, MA 01862

Dated: December 19, 2003

Received: December 22, 2003

Contact: Tom Scanlon

Manufacturing Address Flir Systems AB
Rinkebyvagen 19, PO Box 3
Danderyd, Sweden

Tradename: Series A, E, S, and P -IR cameras

Common Name: Telethermographic system

Product Code: 90LHQ Class: I FR Classification No.: 884.2980

Intended Use: The Flir device is intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of differences in skin surface temperature changes. It can visualize, document temperature patterns and changes.

Device(s) to which Equivalence is Claimed and Manufacturer:

Manufacturer: Inframedtrics, Inc.
Tradename: Infracam-Med
Document Control: K982327

Manufacturer: Dorex, Inc.
Tradename: Spectrum 9000mb
Document Control: K023434

Previous Submissions: N/A

Applicable Guidance: software

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**510(k) Review
Page 2**

	YES	NO	
1. Is Product A Device	x		If NO = Stop
2. Is Device Subject To 510(k)?	x		If NO = Stop
3. Same Indication Statement?	x		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	x		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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Standard Questions:

Normal, Simplified, Tier I Review? (circle appropriate item)

Is the device subject to postmarket surveillance? yes

Is a summary or certification of safety and effectiveness included? (Which?)
yes, summary

Is the device life-supporting or life-sustaining? no

Is the device implanted (short-term or long-term)? no

Does the device contact tissue or skin? (Biocompatibility and
cleaning/disinfection) no

Does the device use software? (guidance) yes

Is the device disposable (single use)? no

Is the device sterile? (bluebook) no

Is the device for single, home or prescription use?

Does the device contain or use drug or biological products? no

Is the device subject to the Radiation Control Act? no

Other standards? EMC emissions, Emission radiated and conducted, immunity,
class B conducted and radiated emissions power lines.

Device Description: Flir manufactures a number of IR camera's, they all
include the same basis temperature measurement and sensing technology. They
are non-contacting and employ passive infrared emissions for sensing
temperature variations.

The captured energy is processed by software to produce digital output values
of the thermal energy captured by the camera's thermal sensors.

Laboratory and Clinical Data: performance testing according to standards

Labeling: attached

Software: The software records the temperatures. It is considered a
low level of concern.

Substantial Equivalence: The device is substantially equivalent to Inframatrix
Infracam-Med, K982327 and to Dorex, Inc., Spectrum 9000mb, K023434

Conclusion: SE

Recommendation: Approve

I believe that this device is equivalent to: Infracam-Med and Spectrum 9000mb

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510(k) Review
Page 4

Classification should be based on: Radiological Device Classification

Class: I

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**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: k 033967

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **		N/A
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	✓	
510(k) Kit Certification ***		N/A

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

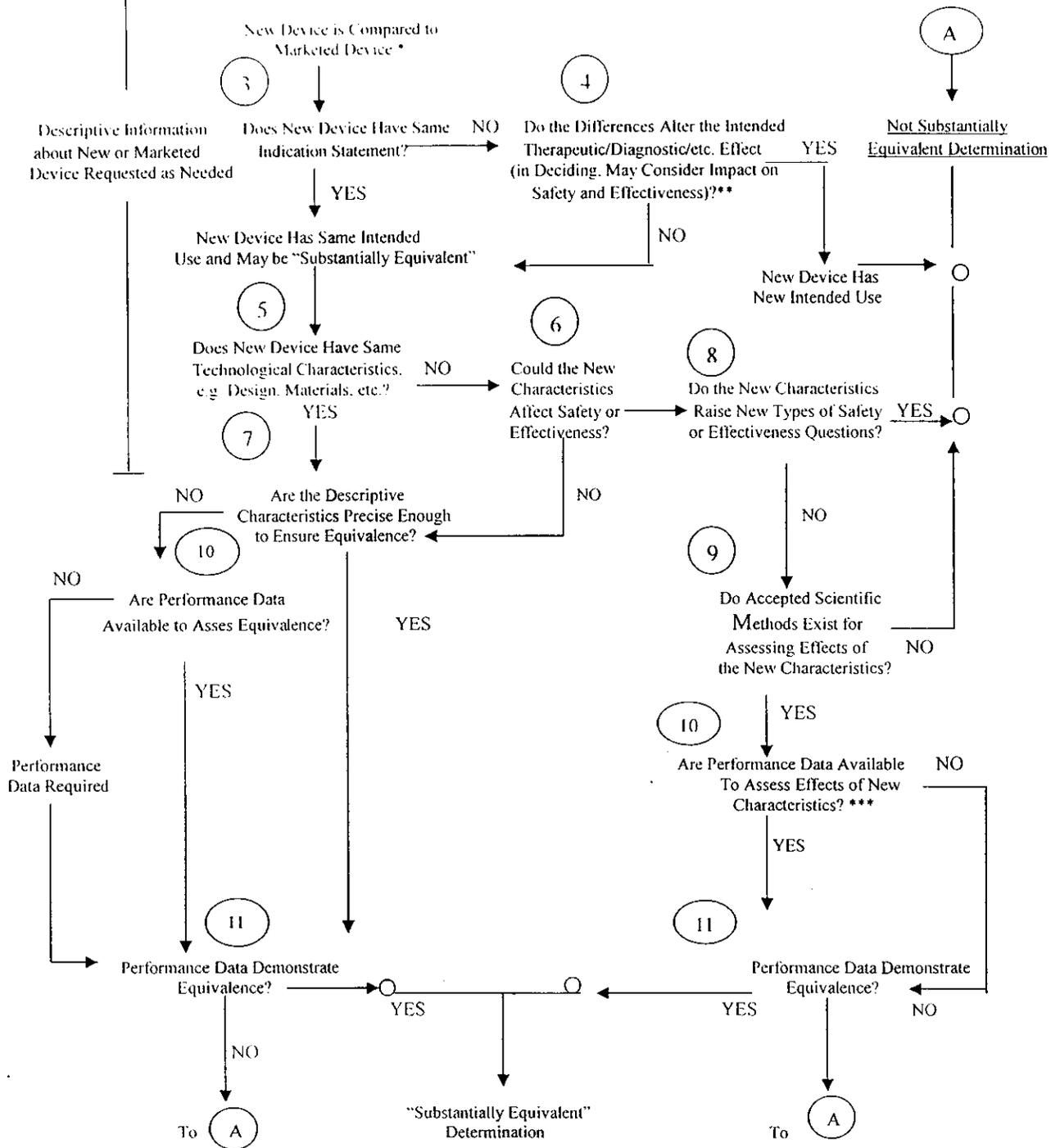
Date: 2/26/04

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

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		N/A
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		N/A

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



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

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

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

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