



# U.S. Department of Health & Human Services

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Food and Drug Administration

## SAVE REQUEST

**USER:** (smw)  
**FOLDER:** K032350 - 624 pages  
**COMPANY:** INFRARED SCIENCES CORP. (INFRSCIE)  
**PRODUCT:** SYSTEM, TELETHERMOGRAPHIC (ADJUNCTIVE USE) (LHQ)  
**SUMMARY:** Product: INFRARED SCIENCES BREASTSCAN IR SYSTEM

**DATE REQUESTED:** Oct 15, 2015

**DATE PRINTED:** Oct 15, 2015

**Note:** Printed



FEB 20 2004

**Exhibit # 1**

**510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K032350

**1. Submitter's Identification:**

Infrared Sciences Corp.  
380 Townline Road  
Hauppauge, NY 11788

Contact: Mr. Anthony Trotta  
Principal Engineer

Date Summary Prepared: July 29, 2003

**2. Name of the Device:**

Infrared Sciences BreastScan IR™ System

**3. Predicate Device Information:**

K#990416, OmniCorder BioScan System, OmniCorder Technologies, Inc., Stony Brook, NY

**4. Device Description:**

The BreastScan IR™ System is a new, non-invasive procedure offered to women, of any age, to determine current breast health by measuring various temperature parameters in the breast. Designed exclusively by Infrared Sciences Corp., BreastScan IR™ System has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

**Components of the system include:**

Infrared System Device

Color Inkjet Printer

TV/VCR

Medical Cart

BreastScan IR Server

Air Cooling Device

Patient Chair

**5. Intended Use:**

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

**6. Comparison to Predicate Devices:**

**A Comparison Chart Outlining Similarities and Differences Follows:**

<b>Feature</b>	<b>BreastScan IR™ System</b>	<b>BioScan System</b>
Intended Use	Visualization/Documentation of Temperature Patterns and Changes – Adult Only	Visualization/Documentation of Temperature Patterns and Changes – Adult, Pediatric and Neonatal
Method of Data Collection	Non-Contact Passive Infrared Emissions	Non-Contact Passive Infrared Emissions
Collection Instrument	Infrared Camera	Infrared Camera
Data Processing	CPU with Custom Algorithms	CPU with Custom Algorithms
Measurement Parameters	Allows for Static and	Allows for Static

	Dynamic Measurement of Thermal Patterns	Measurement of Thermal Patterns
Storage	Hard Disk	Hard Disk
Detector Type	Focal Plane Array	Focal Plane Array
Detector Resolution	320 x 240 Pixels	256 x 256 Pixels
Thermal Sensitivity	0.08°C	0.05°C
Camera Output	14 Bit Digital	14 Bit Digital
Display	Monitor, TV, Printer	Monitor, TV, Printer
User Interface	Keyboard, Mouse, On-System Controls	Keyboard, Mouse, On-system Controls

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The device will comply with IEC-60601-1 and IEC 60601-1-2. Software validation was performed.

8. **Discussion of Clinical Tests Performed:**

Not applicable

9. **Conclusions:**

The subject device has the same intended use and similar characteristics as the predicate device. Moreover, documentation supplied in this submission demonstrates that any difference in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Infrared Sciences BreastScan IR™ System is substantially equivalent to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 20 2004

Infrared Sciences Corp.  
% Ms. Susan D. Goldstein-Falk  
Official Correspondent  
mdi Consultants, Inc.  
55 Northern Blvd., Suite 200  
GREAT NECK NY 11021

Re: K032350  
Trade/Device Name: Infrared Sciences  
BreastScan IR™ System  
Regulation Number: 21 CFR 884.2980  
Regulation Name: Telethermographic system  
Regulatory Class: I  
Product Code: 90 LHQ  
Dated: December 17, 2003  
Received: December 18, 2003

Dear Ms. Goldstein-Falk:

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.

Page 2

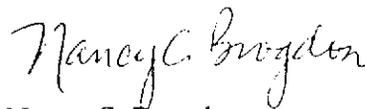
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

Exhibit B

Page 1 of 1

510(k) Number (if known): 2032350

Device Name: Infrared Sciences BreastScan IR™ System

**Indications For Use:**

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

*David A. Segerson*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

K032350/A1



380 Townline Road  
Hauppauge, NY 11788  
Phone: 631-265-5450  
Fax: 631-979-2085  
[www.infraredsciences.com](http://www.infraredsciences.com)

**Infrared Sciences Corp.**

**RETURN RECEIPT REQUESTED**

January 16, 2004

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

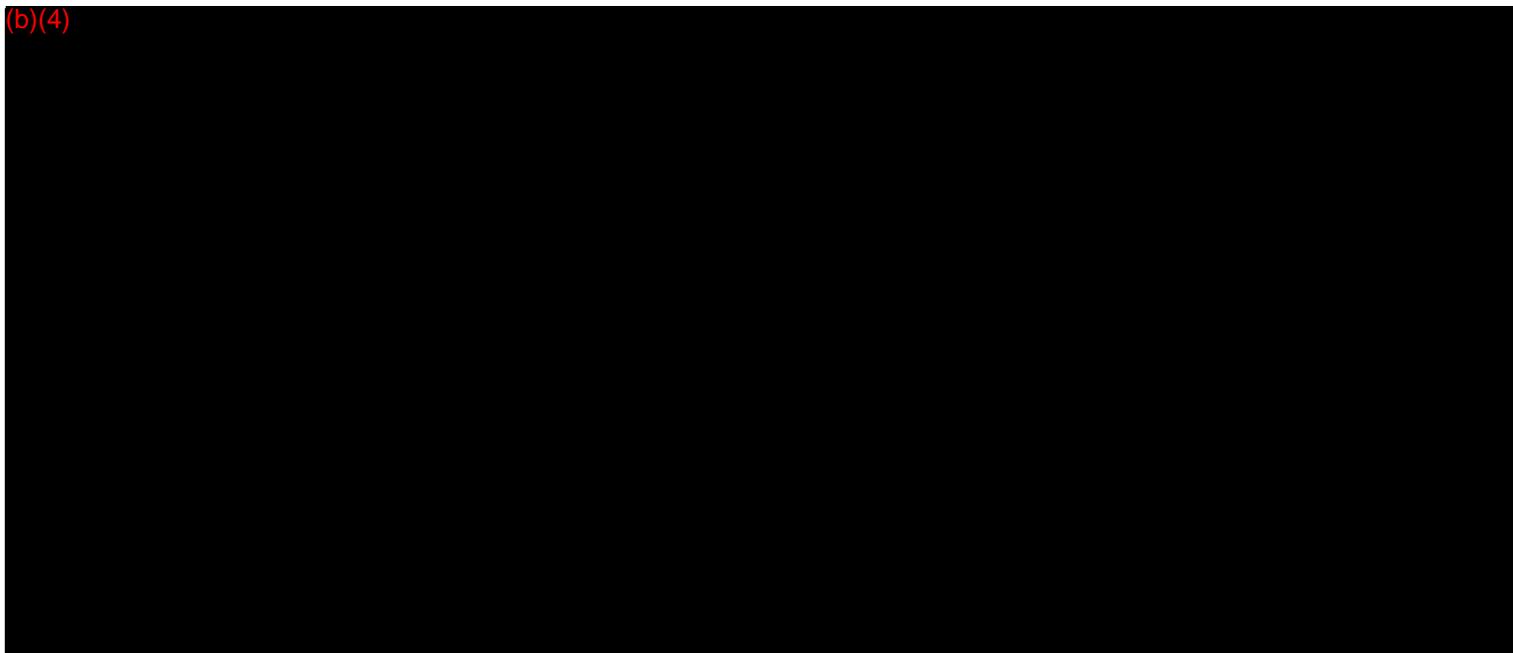
SK-36  
RECEIVED  
2004 JAN 20 A 11:08  
FDA/CDRH/ODE/PMO

Reference: 510(k) # 032350  
Infrared Sciences BreastScan IR System  
Dated: October 23, 2003  
Received: October 24, 2003  
Request for Additional Information: December 5, 2003

Dear Sir or Madam:

Pursuant to the above-captioned 510(k) submission, and in accordance with our telephone conference held on January 15, 2004 at 1 PM, the following information is being submitted to Document Mail Center per the FDA letter dated December 5, 2003 from Dr. Robert Phillips, Chief, Radiological Devices Branch, requesting additional information.

We have prepared our responses in the order of the questions presented to us by Dr. Czerska in the above referenced letter. Each response is as agreed upon per the aforementioned telephone conference, with the supporting documents as requested:



(b)(4)











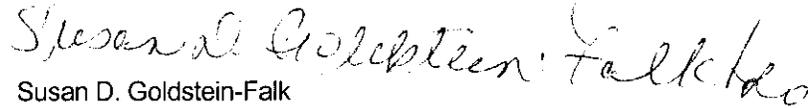
January 16, 2004

We trust that the outlined responses will be satisfactory to Dr. Czerska.

If you have any questions please feel free to contact me at 480-451-7502 or at [sgoldstein@mdiconsultants.com](mailto:sgoldstein@mdiconsultants.com).

Sincerely,

**INFRARED SCIENCES CORP.**

A handwritten signature in cursive script that reads "Susan D. Goldstein-Falk".

Susan D. Goldstein-Falk  
Official Correspondent for  
Infrared Sciences Corp.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 20 2004

Infrared Sciences Corp.  
% Ms. Susan D. Goldstein-Falk  
Official Correspondent  
mdi Consultants, Inc.  
55 Northern Blvd., Suite 200  
GREAT NECK NY 11021

Re: K032350  
Trade/Device Name: Infrared Sciences  
BreastScan IR™ System  
Regulation Number: 21 CFR 884.2980  
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Page 2

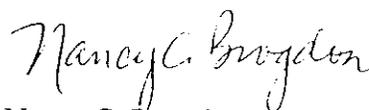
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Sincerely yours,



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

Enclosure

2

Exhibit B

Page 1 of 1

510(k) Number (if known): 2032350

Device Name: Infrared Sciences BreastScan IR™ System

**Indications For Use:**

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

David A. Segram  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

3

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

510(k) Number 2032350



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Infrared Sciences Corp.  
% Ms. Susan D. Goldstein-Falk  
Official Correspondent  
380 Townline Road  
Hauppauge, NY 11788

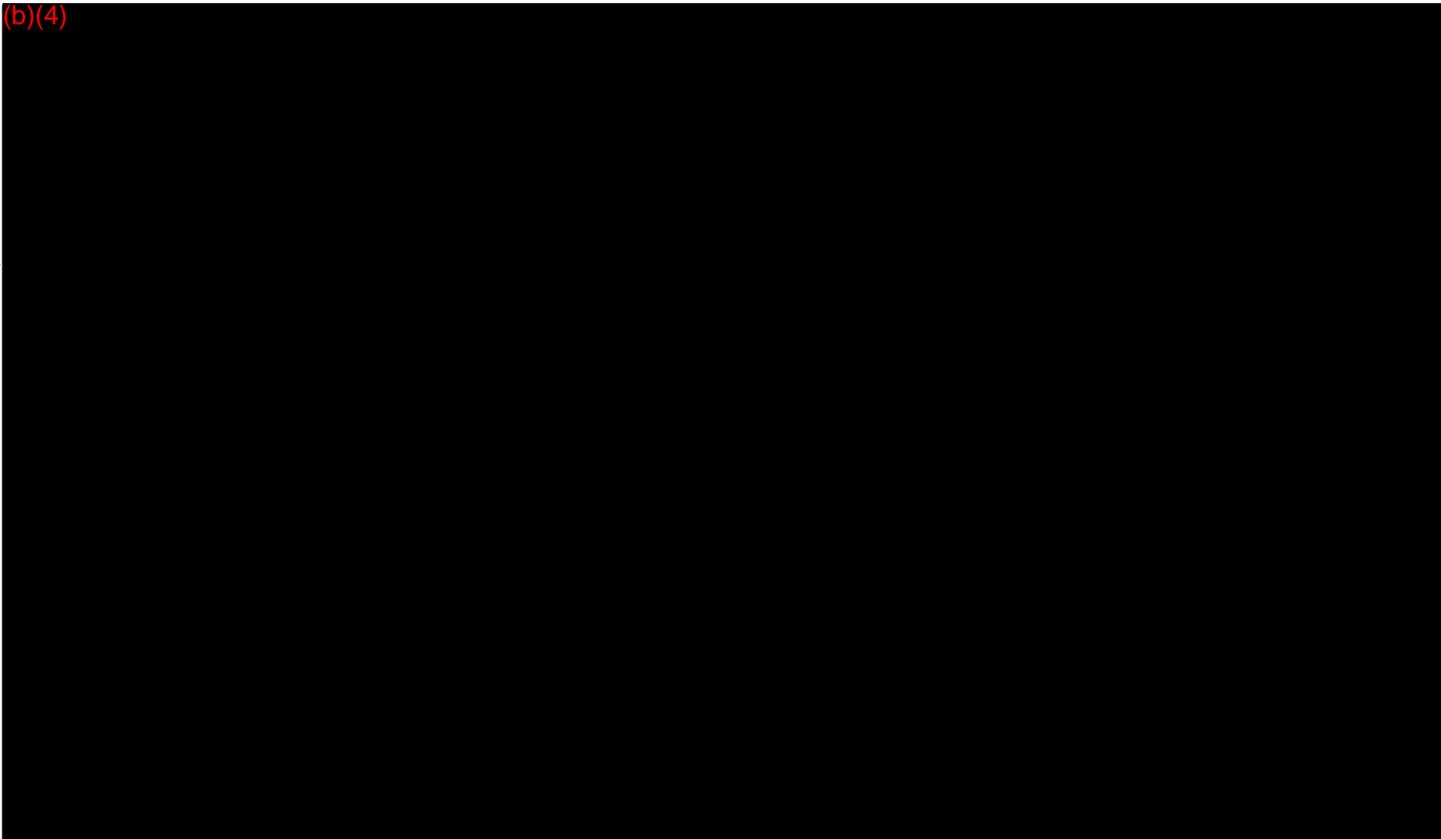
DEC 5 2003

Re: K032350  
Trade Name: Infrared Sciences BreastScan IR™ System  
Dated: October 23, 2003  
Received: October 24, 2003

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device because you did not completely respond to the deficiencies listed in our October 16, 2003, letter. To complete the review of your submission, we require that you respond to the following:

(b)(4)



56

(b)(4)



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>

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

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

Page 3 - Ms. Goldstein-Falk

If you have any questions concerning the contents of the letter, please contact Dr. Ewa Czerska at (301) 594 1212. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Robert A. Phillips, Ph.D.  
Chief, Radiological Devices Branch  
Division of Reproductive, Abdominal,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Infrared Sciences Corp.  
% Ms. Susan D. Goldstein-Falk  
Official Correspondent  
380 Townline Road  
Hauppauge, NY 11788

Re: K032350

Trade Name: Infrared Sciences BreastScan IR™ System

Dated: October 23, 2003

Received: October 24, 2003

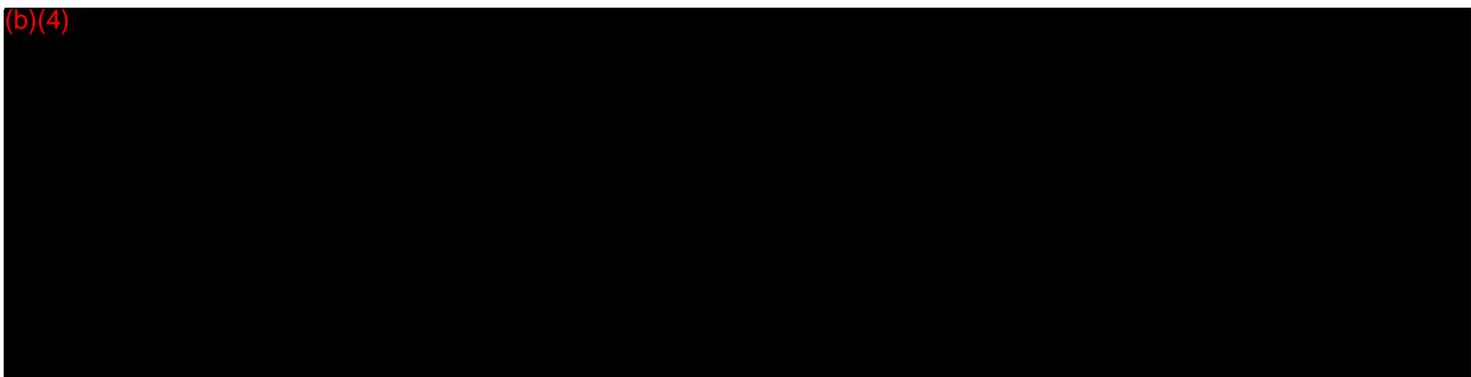
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(b)(4)



(b)(4)



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>

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Records processed under FOIA Request #2015-6141; Released by CDRH on 10-22-2015

Page 3 - Ms. Goldstein-Falk

If you have any questions concerning the contents of the letter, please contact Dr. Ewa Czerska at (301) 594 1212. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Robert A. Phillips, Ph.D.  
Chief, Radiological Devices Branch  
Division of Reproductive, Abdominal,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ-470 DRARD  
D.O.

Draft: emc  
Final: kjh 12/4/03

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-470	CZERSKA	12/4/03						
470	PHILLIPS	12/5/03						

U.S. GPO 1986-169-03

61



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Infrared Sciences Corp.  
% Ms. Susan D. Goldstein-Falk  
mdi Consultants, Inc.  
55 Northern Blvd., Suite 200  
GREAT NECK NY 11021

OCT 16 2003

Re: K032350  
Trade Name: Infrared Sciences BreastScan IR™ System  
Dated: July 29, 2003  
Received: July 30, 2003

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require clarification on the issues listed below:

1. Your device uses a cooling procedure. This feature was not used in the predicate device. Please explain in detail how you apply cool air and what its role is in obtaining the results.
2. You stated in your submission that your device allows for the measurement of 7 parameters. What are those parameters and how are they used?
3. You stated that the results are analyzed by proprietary algorithms and then presented as a non-subjective report. What is presented in a non-subjective report? How is this information developed and how is it to be used in the clinical setting? Is the same information provided by the predicate device?
4. In your submission you state that "The Breast Scan system has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination." Please provide the results of the clinical studies to support this statement.

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 questions at hand, please contact the FDA/CDRH/OCE/DID at CDRLetters@FDA.HHS.gov or 1-800-368-1088.

Page 2 – Ms. Goldstein-Falk

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Rockville, Maryland 20850

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Sincerely yours,



Robert A. Phillips, Ph.D.  
Chief, Radiological Devices Branch  
Division of Reproductive, Abdominal,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Infrared Sciences Corp.  
% Ms. Susan D. Goldstein-Falk  
mdi Consultants, Inc.  
55 Northern Blvd., Suite 200  
GREAT NECK NY 11021

Re: K032350

Trade Name: Infrared Sciences BreastScan IR™ System

Dated: July 29, 2003

Received: July 30, 2003

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4. In your submission you state that "The Breast Scan system has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination." Please provide the results of the clinical studies to support this statement.

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

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>

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

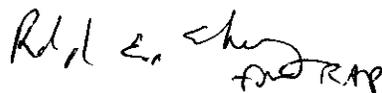
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Dr. Ewa Czernska at (301) 594 1212. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Robert A. Phillips, Ph.D.  
Chief, Radiological Devices Branch  
Division of Reproductive, Abdominal,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Page 3 – Ms. Goldstein-Falk

cc: HFZ-401 DMC  
 HFZ-404 510(k) Staff  
 HFZ-470 DRARD  
 D.O.

Draft: emc  
 Final: kjh 10/14/03

**FILE COPY**

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-470	CREDIA	10/15/03						
HFZ-470	RFS	10/15/03						

U.S. GPO 1986-169-03

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Food and Drug Administration  
Center for Devices and  
Radiological Health  
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9200 Corporate Blvd.  
Rockville, Maryland 20850

July 31, 2003

INFRARED SCIENCES CORP.  
C/O MDI CONSULTANTS, INC.  
55 NORTHERN BLVD., SUITE 200  
GREAT NECK, NY 11021  
ATTN: SUSAN D. GOLDSTEIN-FALK

510(k) Number: K032350  
Received: 30-JUL-2003  
Product: INFRARED SCIENCES  
BREASTSCAN IR SYSTEM

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](http://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

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

July 30, 2003

INFRARED SCIENCES CORP.  
C/O MDI CONSULTANTS, INC.  
55 NORTHERN BLVD., SUITE 200  
GREAT NECK, NY 11021  
ATTN: SUSAN D. GOLDSTEIN-FALK

510(k) Number: K032350  
Received: 30-JUL-2003  
Product: INFRARED SCIENCES  
User Fee ID Number: 9287N IR SYSTEM

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. 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), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. The payment information we need in order to begin the review of your 510(k) includes, the user fees cover sheet with the payment ID faxed to the Office of Financial Management at (301) 827-9213 and a check mailed to:

By Regular Mail

-----  
Food and Drug Administration  
P.O. Box 956733  
St. Louis, MO 63195-6733.

By Private Courier (e.g., Fed Ex, UPS, etc.)

-----  
U.S. Bank  
956733  
1005 Convention Plaza  
St. Louis, MO 63101  
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should also be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at <http://www.fda.gov/oc/mdufma>.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-free number (800)638-2041, or contact them at their Internet address <http://www.fda.gov/cdrh/dsmamain.html>, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

1032350

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION  <b>MEDICAL DEVICE USER FEE COVER SHEET</b>	(b)(4) PAYMENT IDENTIFICATION NUMBER: [REDACTED] Write the Payment Identification Number on your check.
---	---

**See Instructions Before Completing This Cover Sheet**

A completed cover sheet must accompany each original premarket application or supplement listed in Box 3 of this cover sheet. Other premarket application types do not require the use of this cover sheet; see list in the instructions. Payment instructions and fee rates can be found at the following website: <http://www.fda.gov/oc/ndufma>. The following three actions must be taken to properly submit your premarket application and fee payment:

1. FAX a copy of this completed cover sheet to the Food and Drug Administration at (301) 827-9213 before payment is sent.
2. Include a copy of this completed cover sheet with the check made payable to the Food and Drug Administration and mail them to the Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the premarket application.) Also remember that the Payment Identification Number must be written on the check. If you prefer to send a check by a courier, the courier may deliver the check and cover sheet to: US Bank, 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.)
3. Include a copy of this completed cover sheet in volume one of the premarket application when submitting to the Food and Drug Administration 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)  INFRARED SCIENCES CORP. 380 TOWNLINE ROAD HAUPPAUGE, NY 11788 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 113528790	2. CONTACT NAME SUSAN GOLDSTEIN-FALK  2.1 E-MAIL ADDRESS sgoldstein@mdiconsultants.com  2.2 TELEPHONE NUMBER (Include area code) 480 451 7502  2.3 FACSIMILE (FAX) NUMBER (Include area code) 480 614 3169
--	--

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/ndufma>)

Select an application type: <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologic 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"/> This biologic application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population  <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
--	--

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

SKJ  
RA  
H

(b)(4)

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380 Townline Road  
Hauppauge, NY 11788  
Phone: 631-265-5450  
Fax: 631-979-2085  
[www.infraredsciences.com](http://www.infraredsciences.com)

**Infrared Sciences Corp.**

**RETURN RECEIPT REQUESTED**

July 29, 2003

Office of Device Evaluation  
U. S. Food & Drug Administration  
Center for Devices & Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, MD 20850

Dear Sir/Madam:

Enclosed please find an original and a copy of the 510(k) notification for the device that Infrared Sciences Corp. intends to market. The device is a Telethermographic System, Adjunctive Use. This is an abbreviated 510(k) submission.

We would appreciate a rapid review in that we plan to distribute the product upon your approval.

If there are any questions, please contact me at (480) 451-7502. **Any correspondence referring to this 510(k) submission should be forwarded to Ms. Susan D. Goldstein-Falk, Infrared Sciences Corp., c/o mdi Consultants, Inc., 55 Northern Blvd., Suite 200, Great Neck, NY 11021.**

Sincerely,

**INFRARED SCIENCES CORP.**

A handwritten signature in cursive script that reads "Susan D. Goldstein-Falk".

Susan D. Goldstein-Falk  
Official Correspondent for  
Infrared Sciences Corp.

SDGF/lo  
Enclosure

106



380 Townline Road  
Hauppauge, NY 11788  
Phone: 631-265-5450  
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[www.infraredsciences.com](http://www.infraredsciences.com)

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Susan D. Goldstein-Falk  
Official Correspondent for  
Infrared Sciences Corp.

SDGF/lo  
Enclosure

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380 Townline Road  
Hauppauge, NY 11788  
Phone: 631-265-5450  
Fax: 631-979-2085  
[www.infraredsciences.com](http://www.infraredsciences.com)

## **Infrared Sciences Corp.**

### **RETURN RECEIPT REQUESTED**

July 29, 2003

Office of Device Evaluation  
U. S. Food & Drug Administration  
Center for Devices & Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, MD 20850

Dear Sir/Madam:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR Part 807, pre-market notification is hereby made of the intention of Infrared Sciences Corp. to introduce into interstate commerce for commercial distribution a Telethermographic System, Adjunctive Use to be known as the Infrared Sciences BreastScan IR™ System.

The following information is being submitted in conformance with 21 CFR Part 807.87, the "DRAED Guidance for Format and Content for Premarket Notification (510(k)) Submissions", as follows:

#### **Section 1 - General Information**

**a. Applicant:** Infrared Sciences Corp.  
380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

**Registration Number:** Will apply for Within 30 Days of  
510(k) Clearance/Prior to Marketing  
the Device

**Owner/Operator Number:**

**b. Contact Persons:** Ms. Susan D. Goldstein-Falk

Official Correspondent for  
Infrared Sciences Corp.  
**mdi** Consultants, Inc.  
55 Northern Blvd., Suite 200  
Great Neck, New York 11021  
**In Arizona**  
TEL: (480) 451-7502/NY: 516-482-9001  
FAX: (480) 614-3169/NY:516-482-9001  
EMAIL: [sgoldstein@mdiconsultants.com](mailto:sgoldstein@mdiconsultants.com)

**Alternate Only:**

Mr. Anthony Trotta  
Principal Engineer  
Infrared Sciences Corp.  
380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085  
Email: [atrotta@infraredsciences.com](mailto:atrotta@infraredsciences.com)

**c. Trade/Proprietary Name Including Model Number of Device:**

Infrared Sciences BreastScan IR™ System

**d. Common Name or Classification Name (21 CFR Part 807.87) of Device:**

Adjunctive Telethermographic System

**e. Address of Manufacturing Facility/Sterilization Sites:**

This is a non-sterile product.

**Manufacturer:**

Infrared Sciences Corp.  
380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

**f. Class in which Device has been placed:**

Class I

**g. Reason for Premarket Notification:**

New Device/Introduction of a device that is substantially equivalent to a legally marketed device.

**h. Identification of Legally Marketed Device Which We Claim Substantial Equivalence (Predicate Device):**

K#990416, OmniCorder BioScan System, OmniCorder Technologies, Inc., Stony Brook, NY

**i. Compliance with Requirements of the Federal FD&C Act:**

The Radiology Devices Panel (DRAED) has classified this device as Class I, 21 CFR Part 892.2980, Telethermographic System, Adjunctive Use, Product Code 90 LHQ.

No performance standards or special controls have been developed under Section 514 of the FD&C Act for Adjunctive Use Telethermographic Systems. Therefore, no performance standards or special controls apply.

**Section 2 - Summary & Certification**

**a. 510(k) Summary or Certification:**

Please refer to Exhibit #1, "510(k) Summary", which is our summary of safety and effectiveness information upon which an equivalence determination can be based which can be released to the public.

**b. Class III Certification and Summary:**

We are not claiming substantial equivalence to a Class III device, and a Class III Certification and Summary is not included for the BreastScan IR™ System.

**c. Kit Certification and Information:**

This device is not a kit.

**d. Truthful and Accurate Statement**

Attached as Exhibit A is our Truthful and Accurate Statement which has been signed by a responsible person of our company.

**Section 3 - Indications For Use**

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

Please refer to our "Indications for Use" statement which is attached as Exhibit B.

**Section 4 - Device Description**

**a. Executive Summary:**

The BreastScan IR™ System is a new, non-invasive procedure offered to women, of any age, to determine current breast health by measuring various temperature parameters in the breast. Designed exclusively by Infrared Sciences Corp., BreastScan IR™ System has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

**b. Device Description:**

The components of the BreastScan IR™ System are as follows:

**Infrared System Device**

The BreastScan IR™ uses a FLIR model S40 imaging device to obtain temperature measurements. This device houses a 24deg infrared lens and is sensitive to .05deg Celsius as indicated in the manufacturer's documentation. The camera is composed of mostly metal and plastic components and has been shock and vibration tested. This device is connected to the BreastScan IR™ server via IEEE 1394 (Firewire) connection.

### **Color Inkjet Printer**

This is a standard off-the-shelf product used to print out the results generated by the BreastScan IR server. This is the same or very similar to the products used in predicate devices and systems.

### **TV/VCR**

This device is connected directly to the infrared imaging device and displays in real time the infrared image being obtained by the camera. The VCR unit is included for educational purposes to play informational videos describing BreastScan IR. This device is also a standard off-the-shelf product composed primarily of plastic, glass, metal and circuit board components.

### **Medical Cart**

This is a mobile cart made up of tubular steel and laminated pressboard shelves, and plastic wheels. All of the components of the BreastScan system excluding the chair assembly, are mounted to the medical cart either by steel bolts, plastic straps, or industrial strength Velcro. The cart is manufactured by Anthro Inc.

### **BreastScan IR Server**

This is a Dell PC (Model: Optiplex) used to run the BreastScan IR software. This PC utilizes the mini-tower PC form factor and runs the Windows XP Professional operating system. Included is a CD-ROM drive and a removable hard drive that is used to archive data. A standard mouse, keyboard, and TFT flat panel monitor are included in this system as well.

### **Air Cooling Device**

This is a standard off-the-shelf wall/window air conditioner operating at 5000 BTU's (minimum). The unit has both the air intake and the air exhaust located on the front of the unit and provides a filter. The air exhaust is ducted through a plenum and directed at the breasts. The purpose of this unit is to cool the surface of the breasts while the BreastScan IR™ System gathers temperature data. This unit is comprised of a compressor, condenser and evaporator unit consistent with most standard air conditioning units.

## **Patient Chair**

This is a modified off-the-shelf medical chair. The modifications are the addition of patient armrests and a bracket to hold the infrared mirrors. The modifications do not affect the structural integrity of the chair. The purpose of the chair is to hold the patient in a comfortable and stable position during the exam. The chair is constructed of metal, vinyl, and foam cushioning. The armrests are composed of similar materials, and the mirror brackets are constructed from metal.

The following questions outlined in the DRAED 510(k) Guidance Format are answered as follows:

1. **Is the device life supporting or life sustaining?**  
No
2. **Is the device an implant?**  
No
3. **Is the device sterile?**  
No
4. **Is the device single use or reusable?**  
Not applicable
5. **Is the device for prescription use?**  
Yes
6. **Is the device for hospital, home, or mobile use?**  
Hospital/Doctor's Office/Clinical Settings
7. **Does the device contain a drug or biological product as a component?**  
No
8. **Is the device a kit?**

No

**9. Is the device software-driven?**

Yes

**10. Is the device electrically operated?**

Yes

**11. Are there applicable voluntary standards for this device?**

Yes – IEC 60601-1 and IEC 60601-1-2

**SECTION 5 - Comparative Information**

**a. Table of Comparison to Legally Marketed Device:**

The Infrared Sciences BreastScan IR™ System is substantially equivalent to the OmniCorder BioScan System, K#990416, OmniCorder Technologies, Inc., Stony Brook, NY.

The subject device is similar in intended use, in design, materials and operational principles. Indications for use, contraindications, warnings and precautions are the same between the subject and predicate devices such as:

- **Contraindications for Use**

None Known

- **Warnings**

Do not use as an independent breast cancer diagnostic or screening method.  
This device is not compatible for use in an MRI magnetic field.

- **Precautions**

Do not operate without proper training. Report malfunctioning or damaged components to the manufacturer immediately.

Attached as Exhibit #2 is the "Predicate 510(k) Documentation".

Please refer to Table 1 for our "Comparison Chart" outlining similarities and differences between the subject and predicate devices:

**Table 1**

<b>Feature</b>	<b>BreastScan IR™ System</b>	<b>BioScan System</b>
Intended Use	Visualization/Documentation of Temperature Patterns and Changes – Adult Only	Visualization/Documentation of Temperature Patterns and Changes – Adult, Pediatric and Neonatal
Method of Data Collection	Non-Contact Passive Infrared Emissions	Non-Contact Passive Infrared Emissions
Collection Instrument	Infrared Camera	Infrared Camera
Data Processing	CPU with Custom Algorithms	CPU with Custom Algorithms
Measurement Parameters	Allows for Static and Dynamic Measurement of Thermal Patterns	Allows for Static Measurement of Thermal Patterns
Storage	Hard Disk	Hard Disk
Detector Type	Focal Plane Array	Focal Plane Array
Detector Resolution	320 x 240 Pixels	256 x 256 Pixels
Thermal Sensitivity	0.08°C	0.05°C
Camera Output	14 Bit Digital	14 Bit Digital
Display	Monitor, TV, Printer	Monitor, TV, Printer
User Interface	Keyboard, Mouse, On-System Controls	Keyboard, Mouse, On-system Controls

**b. Discussion of Similarities and Differences:**

The subject device and predicate have many design features in common. Both use digital infrared cameras to collect temperature data and use computer processing units to process and present the data. Both systems permit the storage and retrieval of data to /from the computer hard drive. (See Table 1).

This device differs from the predicate device in that the subject and predicate devices vary in components and accessories. Most of the variability is attributed to the advancement of technological capabilities.



was conducted in accordance with IEC 60601-1, Medical Electrical Equipment- Part 1: General Requirements for Safety, and IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Test (General) prior to marketing the device.

Attached as Exhibit #6 is the “EMC Testing for the Camera for Visualization/Temperature Pattern Changes”.

### **Section 8 – Technical Specifications**

Attached as Exhibit #7 is our “BreastScan IR™ System Data Sheet” which outlines the system technical specifications.

### **Section 9 – Biocompatibility Assessment**

There are no patient-contacting materials, therefore, biocompatibility testing of patient-contacting materials per ISO 10993 has not been performed. A patient chair is being supplied; per 21 CFR Part 880.6140, Product Code 80FRK (Examination and Treatment Chair), a medical chair is 510(k) exempt. Material composition of the treatment chair is outlined in Section 4b, “Device Description”, and materials of construction are similar to 510(k) exempted treatment chairs currently being marketed, not presenting any new questions of safety and effectiveness.

### **Section 10 - Software Information**

A written description of the controller software requirements as well as the device performance requirements, including a statement of potential system hazards and software and/or hardware functions implemented as a result of such potential hazards is attached as Exhibit #8.

Verification and validation activities, to include how the software verifications and validation was performed, how the implementation of the system safeguards was assured and which verifications and validation activities were performed prior to and after software/hardware integration is also attached as Exhibit #8 as well as a written affirmation stating that the described software was developed and tested according to the stated procedure/method and test results and analysis to demonstrate the requirements were met.

Summary: Software level of concern, a software description, a device hazard analysis, the software functional requirements and architecture design chart, and a software

functional test plan with pass/fail criteria and results are included and attached as Exhibit #8, "Software Documentation".

We have addressed the "FDA Guidance for Off-The-Shelf Software Use in Medical Devices" in our "OTS Software Use for BreastScan IR™ System," attached as Exhibit #9. This document describes the use of off-the-shelf software within the BreastScan IR™ System.

### **Section 11 – Published Literature**

Attached as Exhibit #10, "Use of Digital Infrared Imaging in Enhanced Breast Cancer Detection and Monitoring of the Clinical Response to Treatment" is published literature supporting the use of the subject device. This paper was included to support the addition of the seventh measurement parameter as explained in section 5b of this document. The paper supports the ability of the seventh parameter to aid in the analysis of infrared images with respect to adjunctive screening for breast cancer and other diseases affecting blood perfusion.

### **Section 12 – Sterilization Information**

This device is marketed as non-sterile, therefore no claims of sterility are made.

No expiration date is assigned this device and this product is not supplied sterile.

Certain components of this device are to be cleaned and maintained according to outlined instructions in the user manual.

### **Additional Information: Quality Assurance and Manufacturing Controls:**

Infrared Sciences Corp. operates in compliance with FDA's Good Manufacturing Practice Regulations for Medical Devices (21 CFR Part 820), and, a formally established and controlled Quality Assurance Program. Devices are manufactured and assembled to established and controlled device master record requirements by formally trained and supervised personnel.

We consider our intent to market this device as confidential commercial information and request that it be considered as such by FDA. Our intent to market this device is not considered public information and we have taken precautions to protect this confidentiality.

We would appreciate your reviewing this information at your earliest convenience so that a prompt reply to our request for 510(k) clearance can be processed.

If you have any questions, or require additional information, please call me at (480) 451-7502 or 516-482-9001 or fax me at (480) 614-3169 or 480-614-3169 or email me at [sgoldstein@mdiconsultants.com](mailto:sgoldstein@mdiconsultants.com)

Sincerely,

**INFRARED SCIENCES CORP.**

  
Susan D. Goldstein-Falk  
Official Correspondent for  
Infrared Sciences Corp.

SDG-F/lo  
Attachments (See List Attached)

**LIST OF EXHIBITS**

EXHIBIT A	Truthful and Accurate Statement
EXHIBIT B	Indications for Use Statement
EXHIBIT #1	510(k) Summary
EXHIBIT #2	Predicate 510(k) Documentation
EXHIBIT #3	Draft Operator Manual
EXHIBIT #4	Draft Product Brochure
EXHIBIT #5	Hardware Manuals
EXHIBIT #6	EMC Testing for the Camera for Visualization/Temperature Pattern Changes
EXHIBIT #7	BreastScan IR™ System Data Sheet
EXHIBIT #8	Software Documentation
EXHIBIT #9	OTS Software Documentation
EXHIBIT #10	Published Literature

**PREMARKET NOTIFICATION**

**TRUTHFUL AND ACCURATE STATEMENT**

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as President of Infrared Sciences Corp, 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.



Thomas A. DiCicco

Date: 7/21/2003

**Exhibit B**

Page  1  of  1

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

**Device Name: Infrared Sciences BreastScan IR™ System**

**Indications For Use:**

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

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

\_\_\_\_\_ **Concurrence of CDRH, Office of Device Evaluation (ODE)** \_\_\_\_\_

**Prescription Use** \_\_\_\_\_  
**(Per 21 CFR 801.109)**

**OR**

**Over-The Counter Use** \_\_\_\_\_  
**(Optional Format 1-2-96)**

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**Exhibit # 1**

**510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:\_\_\_\_\_.

**1. Submitter's Identification:**

Infrared Sciences Corp.  
380 Townline Road  
Hauppauge, NY 11788

Contact: Mr. Anthony Trotta  
Principal Engineer

Date Summary Prepared: July 29, 2003

**2. Name of the Device:**

Infrared Sciences BreastScan IR™ System

**3. Predicate Device Information:**

K#990416, OmniCorder BioScan System, OmniCorder Technologies, Inc., Stony Brook, NY

**4. Device Description:**

The BreastScan IR™ System is a new, non-invasive procedure offered to women, of any age, to determine current breast health by measuring various temperature parameters in the breast. Designed exclusively by Infrared Sciences Corp., BreastScan IR™ System has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

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**Components of the system include:**

Infrared System Device

Color Inkjet Printer

TV/VCR

Medical Cart

BreastScan IR Server

Air Cooling Device

Patient Chair

**5. Intended Use:**

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

**6. Comparison to Predicate Devices:**

**A Comparison Chart Outlining Similarities and Differences Follows:**

<b>Feature</b>	<b>BreastScan IR™ System</b>	<b>BioScan System</b>
Intended Use	Visualization/Documentation of Temperature Patterns and Changes – Adult Only	Visualization/Documentation of Temperature Patterns and Changes – Adult, Pediatric and Neonatal
Method of Data Collection	Non-Contact Passive Infrared Emissions	Non-Contact Passive Infrared Emissions
Collection Instrument	Infrared Camera	Infrared Camera
Data Processing	CPU with Custom Algorithms	CPU with Custom Algorithms
Measurement Parameters	Allows for Static and	Allows for Static

	Dynamic Measurement of Thermal Patterns	Measurement of Thermal Patterns
Storage	Hard Disk	Hard Disk
Detector Type	Focal Plane Array	Focal Plane Array
Detector Resolution	320 x 240 Pixels	256 x 256 Pixels
Thermal Sensitivity	0.08°C	0.05°C
Camera Output	14 Bit Digital	14 Bit Digital
Display	Monitor, TV, Printer	Monitor, TV, Printer
User Interface	Keyboard, Mouse, On-System Controls	Keyboard, Mouse, On-system Controls

**7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The device will comply with IEC-60601-1 and IEC 60601-1-2. Software validation was performed.

**8. Discussion of Clinical Tests Performed:**

Not applicable

**9. Conclusions:**

The subject device has the same intended use and similar characteristics as the predicate device. Moreover, documentation supplied in this submission demonstrates that any difference in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Infrared Sciences BreastScan IR™ System is substantially equivalent to the predicate device.



**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**

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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	SYSTEM, TELETHERMOGRAPHIC (ADJUNCTIVE USE)
<b>Regulation Number</b>	884.2980
<b>510(k) Number</b>	K990416
<b>Device Name</b>	OMNICORDER BIOSCAN SYSTEM
<b>Applicant</b>	OMNICORDER TECHNOLOGIES, INC. 25 EAST LOOP RD. STONY BROOK, NY 11790 3550
<b>Contact</b>	MARK FAUCI
<b>Product Code</b>	LHQ
<b>Date Received</b>	02/10/1999
<b>Decision Date</b>	12/23/1999
<b>Decision</b>	SUBSTANTIALLY EQUIVALENT (SE)
<b>Classification Advisory Committee</b>	Obstetrics/Gynecology
<b>Review Advisory Committee</b>	Radiology
<b>Statement/Summary/Purged Status</b>	Summary/purged 510(k)
<b>SUMMARY</b>	<u>SUMMARY</u>
<b>Type</b>	Traditional
<b>Reviewed by Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 7/7/2003

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Center for Devices and Radiological Health / CDRH

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K990416

DEC 23 1999

### 510(k) Summary

**Date of Summary Preparation:** January 29, 1999

**Manufactures Contact Person:** Mark Fauci  
 President  
 Tel. (516)-444-6499  
 Fax. (516)-444-8825  
 OmniCorder Technologies, Inc.  
 25 East Loop Road  
 Stony Brook, NY 11790

**Trade Name:** OmniCorder BioScan System

**Classification Name, Classification Number, Class, Classification Reference:**

Classification Name	Class. No.	Class	21CFR §
Telethermographic System	IYM/LHQ	I	884.2980

**Special Controls:** There are no regulatory standards or special controls applicable for this device.

**Indications for Use:** The OmniCorder BioScan System is thermal camera based imaging device intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal.

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The device is for adjunctive diagnostic screening for detection of breast cancer or other uses. This device is intended for use by qualified healthcare personnel trained in its use.

**Device Description:** The OmniCorder BioScan System is an infrared camera device which provides the capability for imaging and recording of thermal data radiating from adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings; and in the home. It is a prescription device intended for use only by health care professionals.

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

The following accessories are available for use with the device:

- 1) Computer Processing Unit (Pentium II Workstation)
- 2) Color Monitor
- 3) Color Printer
- 4) Tripod Stand

The device and its accessories are similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution.

**Substantially Equivalent Commercially Available Devices:** OmniCorder BioScan System is substantially equivalent to the following commercially available predicate devices with respect to indications for use, device design, materials, and method of manufacture.

**Substantial Equivalence Comparison:** The : OmniCorder BioScan System is similar to commercially available devices with respect to intended use, material, design and operational principles as follows:

Inframetrics, Inc., Inframetrics Infracam-Med ~ (K982327)

Bales Scientific, Inc., BSI Model Tip ~ (K897191)

JEOL Model #JTG-500M ~ (K823041)

DCATS by Dorex Inc. ~ (K812799)

1. Operational Principles: The basic operational principles of the OmniCorder BioScan System and the predicate devices measure and record, without touching the patient's skin, self-emanating infrared radiation to reveal temperature variations. The parameters that are measured and displayed are generally the same as those for the predicate devices.
2. Indications and Contraindications: Relative indications and contraindications for the OmniCorder BioScan System and commercially available devices for similar intended uses are the same.

**Assessment of non-clinical performance data for equivalence:** Currently there are no FDA standards for this device. However, the OmniCorder BioScan System complies with:

CSA Standard C22.2, No. 125-1984, Electromedical Equipment

UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

**Conclusion:** In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, OmniCorder Technologies concludes that the new device, the OmniCorder BioScan System, is safe, effective and substantially equivalent to the predicate device as described herein.

**Table 1**

Feature	BioScan System	InfraCam-Med (K982327)	BSI Model TIP (K897191)	Jeol Model# JTG-500M (K823041)	DCATS (K812799)
Intended Use	Visualization/documentation of temperature patterns and changes				
Method of Data Collection	Non-contact Passive Infrared Emissions				
Collection Instrument	Infrared Camera				
Data Processing	CPU/Custom Algorithms				
Storage	Hard Disk	PCM/CIA card	Hard disk	Video tape	Hard disk
Detector Type	Focal Plane Array	Focal Plane Array	Single Detector	Single Detector	Single Detector
Display	Monitor/TV Printer				
User interface	Keyboard, Mouse, On-system controls	On-system controls	Keyboard, Mouse, On-system controls	Keyboard, On-system controls	Keyboard, On-system controls



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 23 1999

Mark Fauci  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, New York 11790

Re: K990416  
OmniCorder BioScan System  
Dated: September 18, 1999  
Received: September 29, 1999  
Regulatory Class: I  
21 CFR 884.2980/Procode: 90 LHQ

Dear Mr. Fauci:

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 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). 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,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

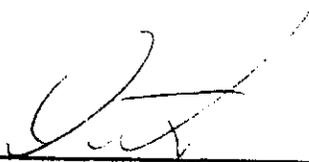
Enclosure

**510(k) Number:** K990416

**Device Name :** OmniCorder BioScan System

**Indications for Use:**

The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.



(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990416

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 23 1999

Mark Fauci  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, New York 11790

Re: K990416  
OmniCorder BioScan System  
Dated: September 18, 1999  
Received: September 29, 1999  
Regulatory Class: I  
21 CFR 884.2980/Procode: 90 LHQ

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Sincerely yours,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

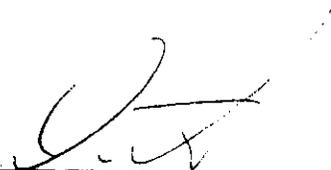
136  
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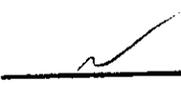
**510(k) Number: K990416**

**Device Name : OmniCorder BioScan System**

**Indications for Use:**

The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990416

Prescription Use   
\_\_\_\_\_  
(Per 21 CFR 801.109)

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Memorandum

From: Reviewer(s) - Name(s) ROBERT PHILLIPS

Subject: 510(k) Number K 990 416 / S1

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.
- De Novo Classification Candidate?  YES  NO
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

This 510(k) contains:

- Truthful and Accurate Statement  Requested  Enclosed  
 (required for originals received 3-14-95 and after)
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin  YES  NO

*Umm*  
12/21

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: Additional Product Code(s) with panel (optional):

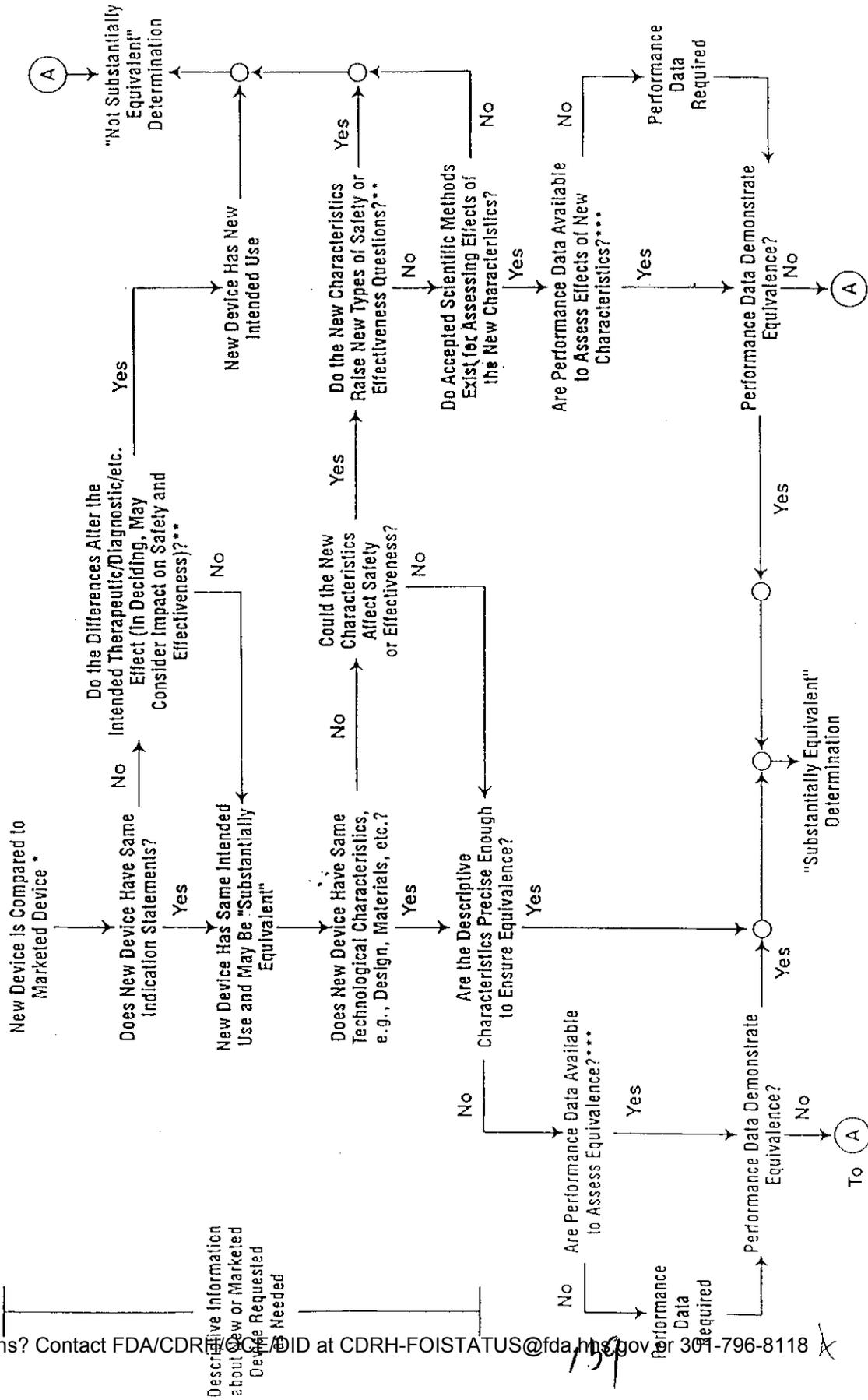
90-LHQ 884 2980 CLASS I

Review: Robert Phillip RAJ B 12/22/99  
 (Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_ 12/22/99  
 (Division Director) (Date)

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# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



\* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information on the Relationship Between Marketed and "Predicate" (Pre-Amendments or Classified Post-Amendments) Devices Is Unclear.  
 \*\* This Decision Is Normally Based on Descriptive Information Alone, But Limited to Information Is Sometimes Required.  
 \*\*\* Data Made Available in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

December 22, 1999

510(k) Review

K990416/S1

Traditional X Abbreviated \_\_\_\_\_ Special \_\_\_\_\_ 3<sup>rd</sup> Party \_\_\_\_\_

Contact: Mark Fauci  
Company Name: OmniCorder Technologies, Inc.  
Address: 25 East Loop Road  
Stony Brook, N.Y. 11790

510(k) Number: K990416  
Tradename: OmniCorder BioScan System  
Dated: September 18, 1999  
Received: September 29, 1999

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

Manufacturing Address:



Common Name: Telethermographic System- Adjunctive

Intended Use: Intended for viewing and recording heat patterns generated by the human body. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs.

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

Manufacturer: Inframetrics, Inc.	Bales Scientific, Inc.
Tradename: Infracam-Med	BSI Model Tip
Document Control: K982327	K897191

Previous Submissions: n/a

Applicable Guidance: n/a

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	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:

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? Normal  
Is the device subject to postmarket surveillance? No  
Is a summary or certification of safety and effectiveness included? 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? No  
Does the device use software? Yes  
Is the device disposable (single use)? No  
Is the device sterile? No  
Is the device for single, home or prescription use? Prescription  
Does the device contain or use drug or biological products? No  
Is the device subject to the Radiation Control Act? No

Other standards? CSA Standard C22.2, No. 125-1984 Electromedical Equipment  
UL544 09/1985, Standard for Medical and Dental Equipment

**Device Description:** The system consists of a Computer Processing Unit, Color Monitor, Color Printer, a Tripod Support, and a Thermal Camera. The system is manufactured from components and materials consistent with other 510(k) cleared devices. The thermal detector uses a 256x256 infrared photodetector in a camera connected to a frame grabber feeding into a Windows NT processor workstation.

**Laboratory and Clinical Data:** None provided. The device specifically excluded from use in an MR magnetic field.

**Labeling:** Various technical manuals and an operator's manual are provided.

**Software:** Complete development information for a minor risk device is provided.

The following information was requested in our AI letter. The responses are summarized.

1. Your device description is too general. Please describe each major subcomponent, its purpose, its major materials of construction, and how it fits into the entire system. What type of infrared detector and what detector arrangement is used?

The firm provided a block diagram and a description of each major component. The response is adequate.

2. The comparison of your device to the predicates is too general. Please compare them in terms of important operational specifications (e.g., minimum temperature change detected, temperature range detected, spatial resolution, etc.).

The firm compared their device to four other devices. The devices are similar in all meaningful areas.

3. Your device uses software to process information. You have not provided information that demonstrates that your software development process is likely to produce reliable software. Please provide this information. If you chose to follow our software guidance, your device is considered a minor risk device. The material that should be submitted are: a software description; a device hazard analysis; the software functional

requirements; an architecture design chart; and a software functional test plan, pass/fail criteria, and results.

The firm provided descriptions of the major steps in their development plan. They follow GAP-55 as a software development plan. Provided were a hazard analysis, software module list, a software design description, software requirement specifications, pre-integration validation and verification, and post-integration verification and validation with indication that the system passed all tests. The firm has adequately responded to the question.

4. Your submission indicates that your data handling and manipulation uses various algorithms. These are not described. Please provide a general description of these algorithms and explain why they are suitable for their intended use.

The sponsor indicates that all the algorithms have been used in other cleared devices. These are described in the software requirements. The response is adequate.

5. Your substantial equivalence argument states that the "relative indications and contraindications (warnings and precautions) for the OmniCorder BioScan and predicate devices are the same." Please provide a list of these indications, contraindications, warnings, and precautions in your labeling.

The sponsor has provided adequate labeling.

6. Your indications for use state:
  - a. that your device is compatible for use in an MR magnetic field. What range of magnetic field strengths is your device compatible with? Please provide the results of laboratory testing that supports your MR compatibility claim.
  - b. that your device is for adjunctive diagnostic screening for detection of breast cancer or other uses." Please specify the other uses.

The sponsor has removed the MR compatibility claim and has revised the indications statement to be specific. These are adequate.

7. You have a prescription statement that is misquoted. It should read "Caution: Federal law restricts this device to sale by or on the order of a physician."

This was corrected.

**Recommendation:**

**Substantial Equivalence:** The device is SE to other similar IR detection devices.

Classification should be based on: 90-LHQ FR Classification No.: 884.2980

Class: I

Robert Phillips

# OCT

Tel. 516-444-6499  
Fax. 516-444-8825

**OmniCorder Technologies, Incorporated**  
25 East Loop Road  
Stony Brook, NY 11790-3350

Message:

Date : 12/22/99

Bob,

As you requested, please find attached the revised Indications for Use and also the Labeling sections of the 510k application K990416. I will be sending a hard copy via Fedex, which you will receive tomorrow. Thanks!

-Mark Fauci-

To: Bob Phillips

From : Mark Fauci

Company :

Company : OCT

Fax Number : 1301-480-4224

Fax Number : 1-516-

Pages including this cover page: 3

Subject : Reference 510k K990416

**510(k) Number: K990416**

**Device Name : OmniCorder BioScan System**

**Indications for Use:**

The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

145 10

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

September 29, 1999

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

OMNICORDER TECHNOLOGIES, INC.  
25 EAST LOOP RD.  
STONY BROOK, NY 11790  
ATTN: MARK FAUCI

510(k) Number: K990416  
Product: OMNICORDER  
BIOSCAN SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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



K990416/5' processed by CDRH on 10-22-2015

OmniCorder Technologies, Incorporated

25 East Loop Road  
Stony Brook, NY 11790-3350  
Fax: (516) 444-8825

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

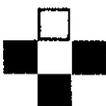
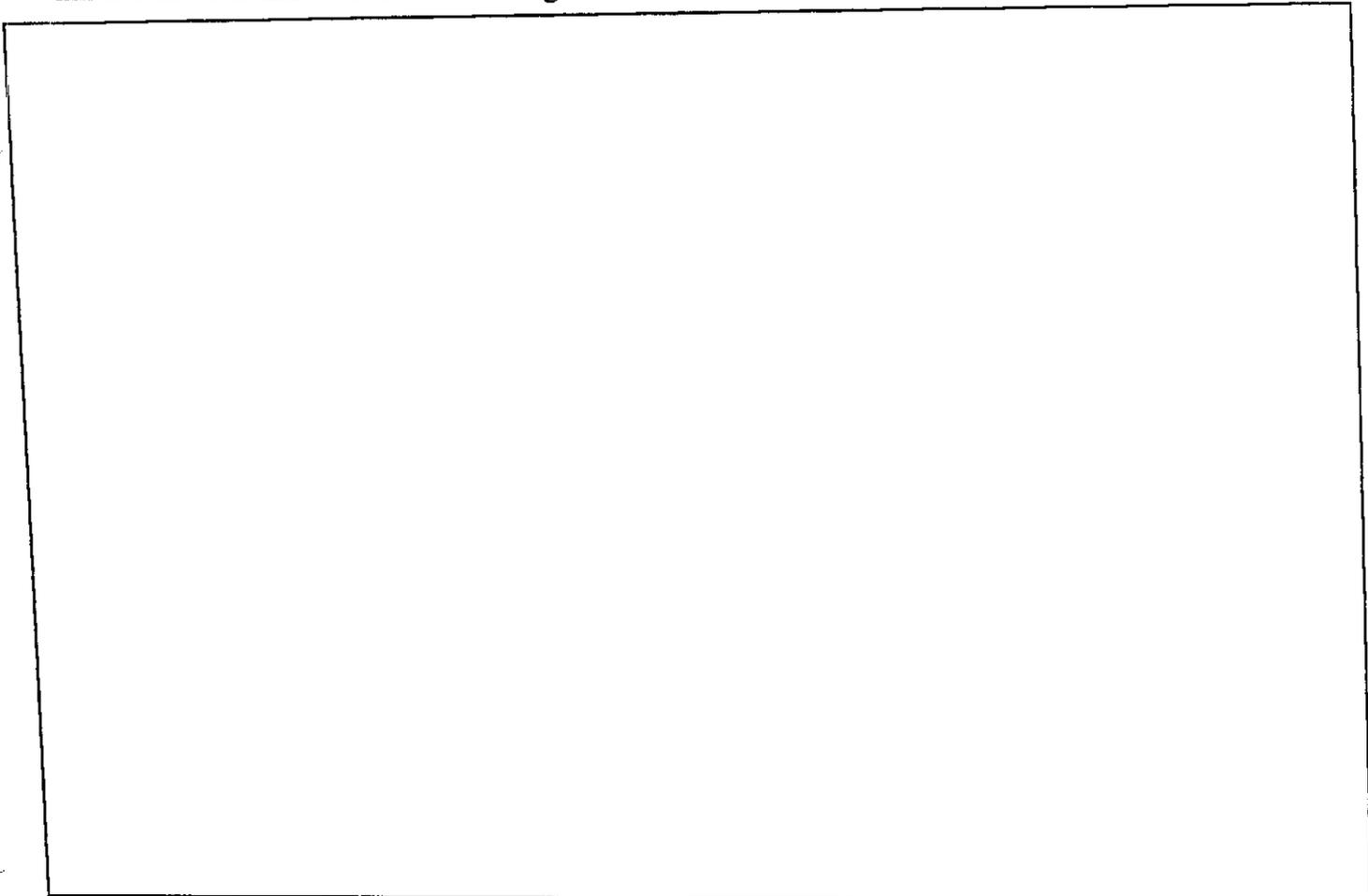
RECEIVED  
25 SEP 99 10 47  
FDA/CDRH/ODE/DHC

08/18/99

ATTN: Dr. Robert Phillips  
Reference: 510(k) K990416, OmniCorder BioScan System

In reply to your request for additional information for the above referenced 510(k) submission, the author submits the following (references to **Folder #** can be found in the accompanying red folder):

**Request 1:** Your device description is too general. Please describe each major subcomponent, its purpose, its major materials of construction, and how it fits into the entire system. What type of infrared detector and what detector arrangement is used?

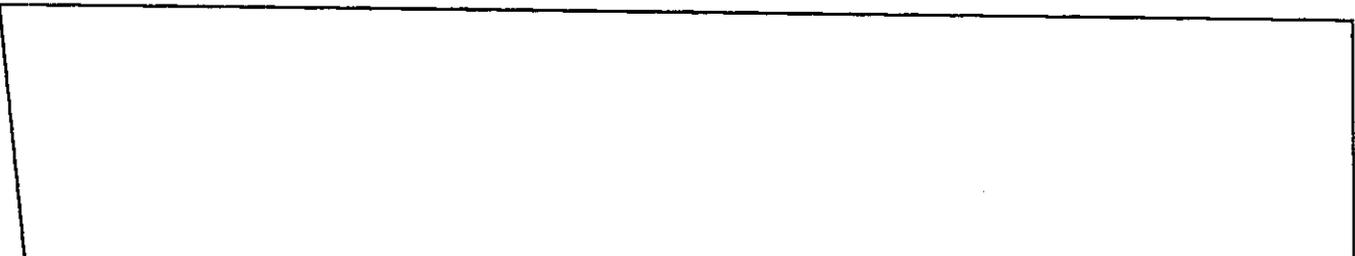


**Figure 1: COMPONENT DESCRIPTION AND PURPOSE**

Handwritten initials 'sm' and a scribble.

Handwritten numbers '147' and '12'.

This page represents 1 whole-page redactions.



iv) Windows NT Intel processor Workstation with Color Monitor- analyses and displays the data collected by the camera and are standard “off the shelf” commercial products. They have a know and well documented history of use in the health industry field and the same or very similar components are contained in one or more of the listed predicate devices. These components are composed of conventional microcircuits and circuit board assemblies, and plastic and/or metallic housings.

v) Color Printer - Generates paper copies of displayed data. This is a standard “off the shelf” commercial product. Printing devices have a know and well documented history of use in the health industry field and the same or very similar components are contained in one or more of the listed predicate devices. This component is composed of conventional microcircuits and circuit board assemblies, and plastic and/or metallic housings.

vi) Writable CD-ROM - Permits the storage and retrieval of large amounts of digital data for archiving purposes. This is a standard “off the shelf” commercial product. Data storage devices have a know and well documented history of use in the health industry field and the same or very similar components are contained in one or more of the listed predicate devices. This component is composed of conventional microcircuits and circuit board assemblies, and plastic and/or metallic housings.

**Request 2:**

The comparison of your device to the predicates is too general. Please compare them in terms of important operational specifications (e.g., minimum temperature change (or difference) detected, temperature range detected, resolution, etc.).

**Response 2:**

Attached, in **Section 8**, is a comparison chart of the BioScan System comparing the operational specifications method of data collection, collection instrument, data processing algorithms, storage, detector type, display, user interface, frame rate, temperature resolution A/D converter, frequency range, detector elements, cooling and intended use to the predicate devices K9872327, K897191, K823041 and K812799.

**Request 3:**

Your device uses software to process information. You have not provided information that demonstrates that your software development process is likely to produce reliable software. Please provide this information. if you chose to follow our software guidance, your device is considered a minor risk device. The material that should be submitted are: a software description; a device hazard analysis; the software functional requirements; an architecture design chart; and a software functional test plan, pass/fail criteria, and results.

**Response 3:**

The software for the BioScan System was developed under design control. The software was developed under QAP-55, Software Development. This procedure is intended to provide the guidance necessary to ensure a cost-effective quality software development process. The project used the general requirements in this SOP to develop a specific Software Development Design Plan (SDDP) which was tailored to its needs. This plan resulted in the deliverable documents as follows, attached hereto as Attachments:

- Section 7 - Device Hazard Analysis**
- Section 4 - Software Module List**
- Section 3 - Software Design Description**
- Section 5 - Pre-integration Validation & Verification**
- Section 1 - Software Requirement Specification**
- Section 6 - Post-Integration Validation & Verification**

**Request 4:**

Your submission indicates that your data handling and manipulation uses various algorithms. These are not described. Please provide a general description of these algorithms and explain why they are suitable for their intended use.

**Response 4:**

A description of the algorithms used is given in paragraph 8.0 through 8.3 of the Software Requirement Specification, **Section 1**. These algorithms compute the temperature calibration, average temperature over a time series, and the rate of change of temperature over that time series. These algorithms are consistent with those used in other 510(k) cleared devices and instruments, which are in commercial distribution, and are suitably intended to provide the user with an image or images that displays temperature data emitted by the subject and collected by the infrared camera.

**Request 5:**

Your substantial equivalence argument states that the "relative indications and contraindications (warnings and precautions) for the OmniCorder BioScan and predicate devices are the same." Please provide a list of these indications, contraindications, warnings, and precautions in your labeling.

**Response 5:**

The Indications for the BioScan System are:

**The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.**

The contraindications are:

**None known**

The Warnings are:

**Do not use as an independent breast cancer diagnostic or screening method.**

The Precautions are:

**This device and all of its components must be kept calibrated and in good working order. Do not operate without proper training. Report malfunctioning or damaged components to the manufacturer immediately.**

**Request 6a:**

Your indications for use states that your device is compatible for use in an MR magnetic field. What range of magnetic field strengths is your device compatible with? Please provide the results of laboratory testing that supports your MR compatibility claim.

**Response 6a:**

The MRI Compatibility Statement is changed to read as follows: The OmniCorder BioScan System is not compatible for use in an MRI magnetic Field.

**Request 6b:**

Your indications for use states that your device is for adjunctive diagnostic screening for detection of breast cancer or other uses. Please specify the other uses.

**Response 6b:**

The intended use statement is here by changed to be:

**The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.**

The reference to "other uses" has been removed.

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**Request 7:**

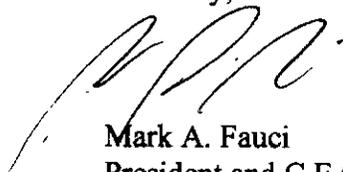
You have a prescription statement that is misquoted. It should read "Caution: Federal law restricts this device to sale by or on the order of a physician."

**Response 7:**

The Prescription statement is hereby changed to be: "Caution: Federal law restricts this device to sale by or on the order of a physician."

I trust that this response to your request for additional information and its attachments are sufficient to obtain a substantial equivalence determination for the OmniCorder BioScan System. Please do not hesitate to contact me at the address or phone number provided. Thank you for your help and cooperation in this application process.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Fauci', is written over the typed name.

Mark A. Fauci  
President and C.E.O.

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**Software Requirement Specification**  
**FOR**  
**OMNICORDER**  
**TECHNOLOGIES, INC.**  
**BIOSCAN SYSTEM**  
**(Version 1.0)**

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### 1.0 Purpose

The purpose of this specification is to define the requirements of software functions and operations of the BioScan system software.

### 2.0 Scope

All software operations and control functions of the BioScan software should be regulated by and through this requirement specification.

Note: All cross references to the matching verifications found in the Post Integration Validation & Verification will be denoted within bolded italicized brackets, i.e. ***[1.2.3.4]***

### 3.0 Product Summary

#### 3.1 Measurement parameters

- Temperature 0 ~ 100 °C

#### 3.2 Package List

File Name	Size(KB)	Description
Dat.exe	1179	Main program.
Dat.reg	13	Parameters in registration form.

#### 3.3 Display language

The software shall display in English.

### 4.0 Hardware

CPU: > 350 MHz

Operating System: Microsoft Windows 95, 98  
Microsoft Windows NT Workstation 4

RAM: Minimal 512 MB, 1024 MB recommended.

Storage Device: > 9GB hard drive, 1.44 floppy,  
> 30x read/write CD-ROM

Input Device: 101 key keyboard, 2/3 button mouse

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## 5.0 Programming Language

Due to the modular nature of this application the following programming languages shall be used: C, C++, Basic, Java, Pascal, HTML, Assembly.

## 6.0 Software Performance Requirements

### *Data Collection Speed -*

The software and associated components must be able to collect and store image data at speeds of at least 100, non-interlaced, 256 x 256 frames per second.

### *Data Storage and Handling -*

The software and associated components must be able to collect and store at least 2024 frames per single study. Furthermore, the system must be able to collect at least six studies per patient session without the need to archive the session data.

### *Data Processing Speed -*

The software and associated components must be able to deliver a processed image from each study in fifteen minutes or less as calculated with data input and output from and to RAM storage.

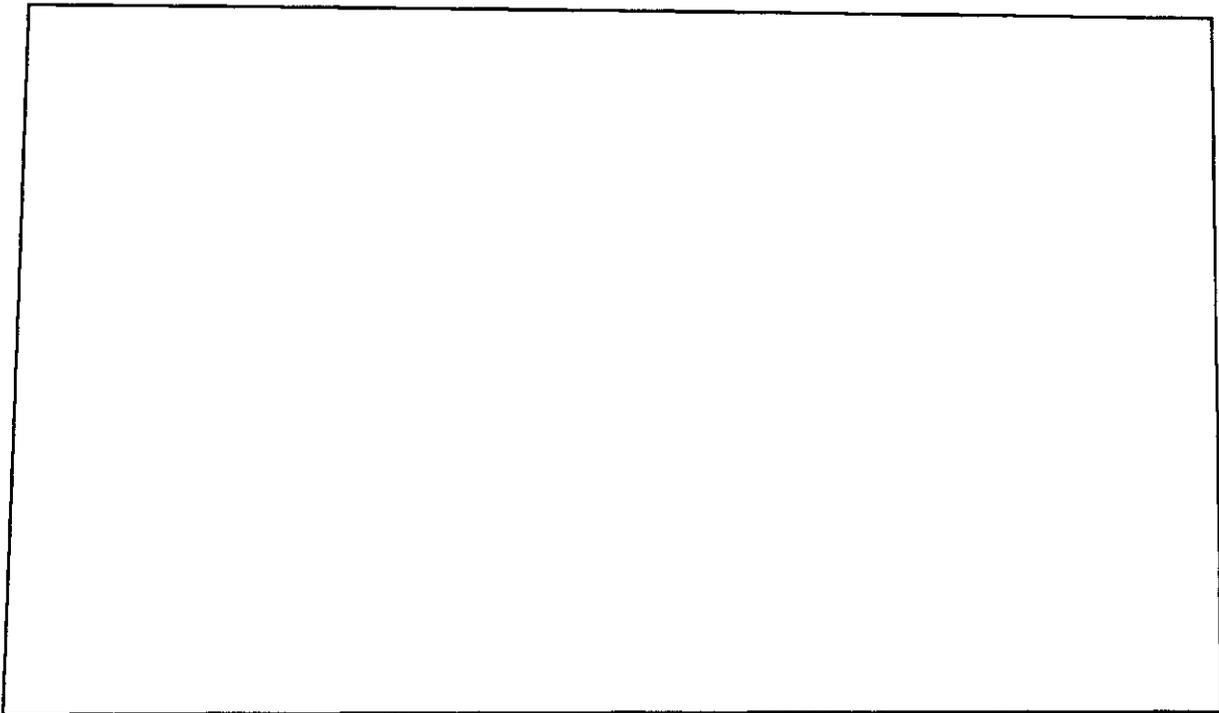
### *Safety and Other Standards*

All software and hardware shall be Y2K compliant.

There are no regulatory standards or special controls applicable for this device. However, the BioScan System complies with the following voluntarily standards and guidelines:

- CSA Standard C22.2, No. 125-1984, Electromedical Equipment
- UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

**This page represents 6 whole-page redactions.**



Error Message	Stage	Description
"Memory allocation error"	File Open	No enough virtual memory available
"Can't open data file"	File Open	Storage device error
"Unexpected end of file"	File Open	Wrong file format encountered
"Cannot open more than xxx files at once"	File Open	System upper limit reached
"Wrong width or height in data file"	File Open	Wrong file format
"Invalid value"	Calibration	Input values out of range
"Cannot save file"	Cropping	Storage device error, e.g., no enough space

## 12.0 Pre-set Parameters

The parameters for BioScan software are stored in the Microsoft Windows system registration repository. The parameters are as follows:

Parameter Name	Type	Description
Left	Integer	Last main window position – left
Top	Integer	Last main window position – top
Color1	Integer	Palette color #1

Color2	Integer	Palette color #2
Color3	Integer	Palette color #3
Color4	Integer	Palette color #4
Color5	Integer	Palette color #5
Color6	Integer	Palette color #6
Color7	Integer	Palette color #7
Color8	Integer	Palette color #8
Color9	Integer	Palette color #9
Color10	Integer	Palette color #10
Color11	Integer	Palette color #11
Color12	Integer	Palette color #12
Color13	Integer	Palette color #13
Color14	Integer	Palette color #14
Color15	Integer	Palette color #15
Color16	Integer	Palette color #16
Color17	Integer	Palette color #17
Color18	Integer	Palette color #18
Color19	Integer	Palette color #19
Color20	Integer	Palette color #20
Min Level	Integer	Color range start (?)
Max Level	Integer	Color range end (?)
Pixel Min	Float	Visible minimal temperature
Pixel Max	Float	Visible maximal temperature
Spot Color	Integer	Color for spots
Spot Active Color	Integer	Color for the active spot
Shape Squares	BOOL	Whether the shape of the spots is square
Shape Squares Ref	BOOL	Whether the shape of the reference spot is square
Diameter	Integer	The diameter of the spots
Diameter Ref	Integer	The diameter of the reference spot
Diameter Mat	Integer	The diameter of the spots in a matrix
Black and White	BOOL	Whether to show the image in gray colors

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Skip Bytes	BOOL	Whether to skip the header of the data file
Skipped Bytes	Integer	Number of bytes to skip in a data file
Skip First	BOOL	Whether to skip the header of each frame
Skipped First	Integer	Number of bytes to skip in each frame
Gotten Every	Integer	Number of frames to skip before read another frame
Skip From To	BOOL	Whether to specify frame ranges to skip
Skip From 1	Integer	Frame range #1 – from
Skip To 1	Integer	Frame range #1 – to
Skip From 2	Integer	Frame range #2 – from
Skip To 2	Integer	Frame range #2 – to
Skip From 3	Integer	Frame range #3 – from
Skip To 3	Integer	Frame range #3 – to
Crop	BOOL	Whether to specify cropping area
Crop Left	Integer	Cropping area – left
Crop Width	Integer	Cropping area – width
Crop Top	Integer	Cropping area – top
Crop Height	Integer	Cropping area – height

Reference

[1] Lan Sommerville, Software Engineering 5<sup>th</sup> Edition, ADDISON-WESLEY Publishing Company, 1996

[2] Shari Lawrence Pfleeger, Software Engineering – Theory and Practice, Prentice-Hall, Inc., 1998

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**System Requirement Specification  
FOR  
OMNICORDER  
TECHNOLOGIES, INC.  
BIOSCAN SYSTEM  
(Version 1.0)**

## 1. Purpose

The purpose of this document is to provide the design and specifications requirements for the BioScan system, a high-resolution digital infrared (IR) camera system for biomedical applications.

## 2. Term Definitions

The term definitions used in this specification are as follows:

- **LW:** Long Wavelength, 8 – 10 gm
- **LWIR:** Long Wavelength Infrared Radiation, 8 – 10 micron
- **GDE:** Generation and Digitizer Electronics
- **DynScale:** Dynamic Scaling Function of the BioScan System
- **VGA:** Video Graphics Adapter
- **TFT:** Thin Film Transistor Display
- **AD-Converter:** Analog Digital Converter
- **DSP:** Digital Signal Processor
- **LUT:** Lookup Table
- **FFT:** Fast Fourier Transform

## 3. Features & Usage

### 3.1 System Overview

The OmniCorder BioScan is an infrared camera device, which provides the capability for imaging and recording of thermal data radiating from adult, pediatric and neonatal patients in a hospital or clinical setting. The BioScan system analyzes and displays tissue temperature data collected by the digital infrared camera in a way consistent with methods used to display information in other 510(k) cleared devices and instruments, which are in commercial distribution.

### 3.2 Purpose of Use

The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body. The patient populations include adult, pediatric and neonatal.

### 4.3 Location of Use

The OmniCorder BioScan System is to be used in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel

who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition.

#### 4.4 Device Users

This device is intended for use by qualified healthcare personnel trained in its use.

#### 4.5 Device Usage

The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs.

### 4. General Specifications

#### 4.1 Trade/Proprietary Name

OmniCorder BioScan System.

#### 4.2 Components

##### 4.2.1 Hardware

- Infrared Camera
- Grabber Card
- Pentium II Workstation with Color Monitor (SVGA)
- Read/Write CD-ROM
- Color Printer
- Tripod Stand
- Blackbody Standard

##### 4.2.2 Software

- BioScan Software

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**5. Safety and other standards**

The system shall be designed, constructed and tested per FDA GMP or equivalent FDA requirements. All software and hardware must be Y2K compliant.

There are no regulatory standards or special controls applicable for this device. However, the BioScan System complies with the following voluntarily standards and guidelines:

- CSA Standard C22.2, No. 125-1984, Electromedical Equipment
- UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

## 6. Device Safety Classifications

The BioScan System is a Class I Device.

## 7. Environmental Conditions

### 7.1 Power Supply

#### 7.1.1 AC power supply

Rating: AC 100V – 120V

Power supply frequency: 50/60Hz

Power consumption: 100 Watt

### 7.2 Operational temperature and humidity:

7.2.1 Temperature range: 0 – 40c

7.2.2 Humidity range: 30 – 85% (not condensed)

7.2.3 Atmospheric pressure: 700 – 1060 hPa

### 7.3 Packaging

The system shall be packaged in a single tower type enclosure that will house all of the electronics. Any necessary cooling will be included within the package.

7.4 Estimated life time: 10 years

## 8. Functional description

### 8.1 Operational Components

#### 8.1.1 Power Switches

On: Press to power on

Off: Press to power off

#### 8.1.2 Selection Switches

Enter: Press to confirm current selection

ESC: Press to arise menu level

Default: Press to switch to default settings

Jog Dial: Turn to move the highlight up and down

### 8.2 Displays

On start-up, the system uses the TFT-Display. In parallel, you may connect a standard VGA-Monitor (VGA 640 x 480) on the VGA-Connector. As an alternative, the BioScan software displays the thermal images on a computer monitor.

### 8.2.1 Camera Display

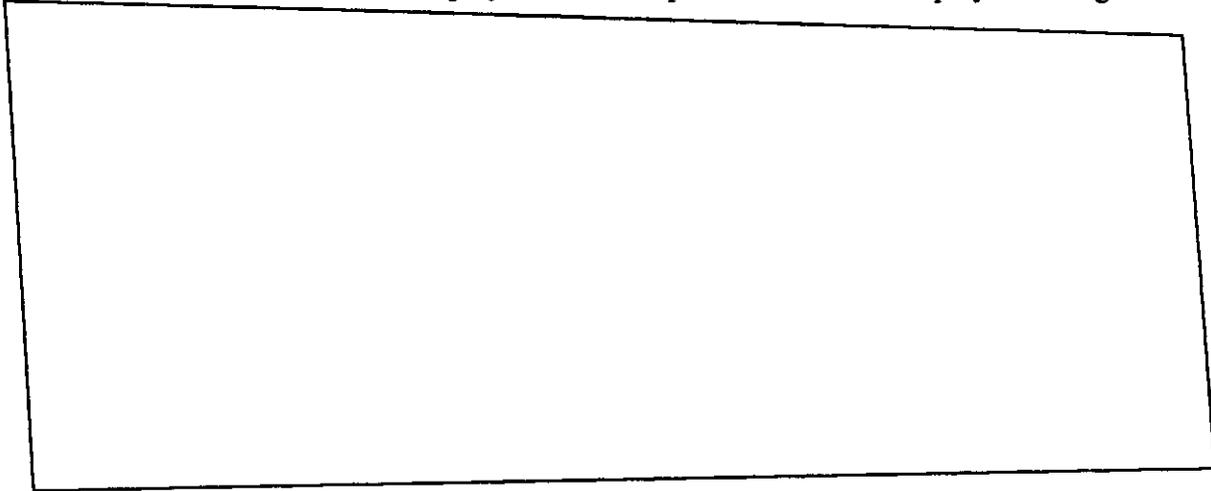
Please see BioScan Technical Manual.

### 8.2.2 Computer Monitor

Please see BioScan Software Operation Manual.

### 8.3 Display languages

Both the camera display and the computer monitor are displayed in English.



### Reference

[1] Lan Sommerville, Software Engineering 5<sup>th</sup> Edition, ADDISON-WESLEY Publishing Company, 1996

[2] Shari Lawrence Pfleeger, Software Engineering – Theory and Practice, Prentice-Hall, Inc., 1998

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Software Design Description  
FOR  
OMNICORDER  
TECHNOLOGIES, INC.  
BIOSCAN SYSTEM  
(Version 1.0)

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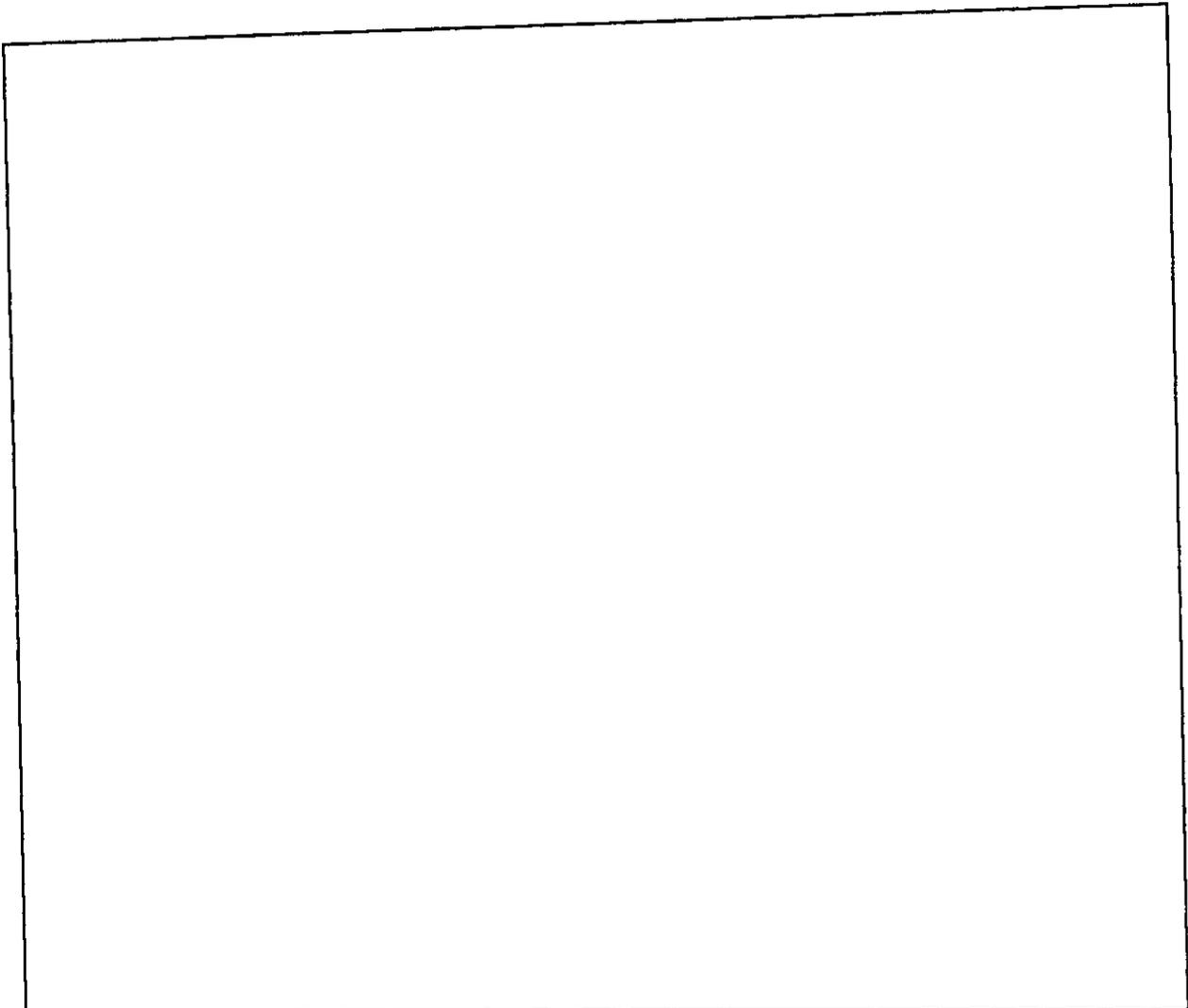
1. Purpose

This document:

- Describes system design (or architecture) concept in developing the BioScan software.
- Will facilitate software quality check and to design software of high quality by clarifying design concept.
- Will enhance maintainability and legibility by describing software mechanism.
- To use as an input to verify the coding.

2. Applicability

The design description is applicable from design to final release of the BioScan software.



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Software Module List  
FOR  
OMNICORDER  
TECHNOLOGIES, INC.  
BIOSCAN SYSTEM  
(Version 1.0)

This page represents 3 whole-page redactions.

**Pre-Integration Validation & Verification  
FOR  
OMNICORDER  
TECHNOLOGIES, INC.  
BIOSCAN SYSTEM  
(Version 1.0)**

1. Objectives

This validation and verification describes the detailed procedure for the software when the BioScan software is developed.

The objectives are as follows:

1. To describe the evaluation procedure thereby to specify the means to verify the design quality of software.
2. To record verification results thereby to guarantee the design quality of software.

2. Range of Application

This validation and verification is applied to the software verification – maintenance stages of the development of BioScan software.

3. Overview of the product

The OmniCorder BioScan is an infrared camera device, which provides the capability for imaging and recording of thermal data radiating from adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings, and in the home. The target operators are physicians and nurses who engage in medical work in a hospital.

4. Configuration of the software

The program runs on standard computers, accepts keyboard and mouse input. It outputs the images to standard monitors. For detailed minimum configuration, please refer to Software Requirement Specification.

5. Evaluation steps

As the evaluation steps of BioScan software, the following two steps are executed:

(1) Pre-Integration Tests

Before officially installing the software on the user's computer, the operation of software by itself is verified.

The objective is to verify each functional logic and operational timing described in the Software Design Description.

(2) Post-Integration Tests

After the Pre-Integration tests are completed, the software is installed into the user's computers, and the design of both software and hardware is verified in an integrated manner.

Matching to all the specifications described in the Software Requirement Specifications is verified.

## 6. Pre-Integration Tests

### 6.1 Evaluation tools

When the Pre-Integration tests are executed, the following evaluation tools are used:

- |                                |                        |
|--------------------------------|------------------------|
| (1) BioScan Software Version:  | 2.01                   |
| (2) Desktop Personal Computer: | Dual Pentium II 450    |
| (3) Monitor:                   | Acer 17" Color Monitor |
| (4) Memory:                    | 1GB SDRAM              |

### 6.2 Check sheets

Execute the Pre-Integration test in accordance with this check sheet. Utilize each observed phenomenon as output from the evaluation tools specified on this check sheet.

Configure the BioScan software, using only the specified values shown in the Check Method column. If not specified, the settings are not used for reference and the program's other configuration is optional.

Note: All references to the Software Design Specifications are found in **[\*\*]** and are italicized.

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**Post-Integration Validation & Verification**  
**FOR**  
**OMNICORDER**  
**TECHNOLOGIES, INC.**  
**BIOSCAN SYSTEM**  
(Version 1.0)

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03



This page represents 11 whole-page redactions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

June 10, 1999

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

OMNICORDER TECHNOLOGIES, INC.  
25 EAST LOOP RD.  
STONY BROOK, NY 11790  
ATTN: MARK FAUCI

510(k) Number: K990416  
Product: OMNICORDER  
BIOSCAN SYSTEM

Extended Until: 10-SEP-1999

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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



OmniCorder Technologies, Incorporated

25 East Loop Road  
Stony Brook, NY 11790-3350  
Fax: (516) 444-8825

www.omnicorder.com

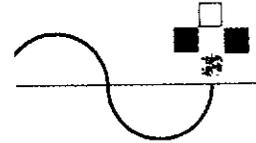
Records p  
ed by C... on 10-22-2015



OmniCorder Technologies, Incorporated

Mark A. Fauci  
*President and  
Chief Executive Officer*  
25 East Loop Road  
Stony Brook, NY 11790-3350  
Phone: (516) 444-6499  
Fax: (516) 444-8825

mfauci@omnicorder.com



THE FRONT WAVE OF HEALTH TECHNOLOGY

Robert Phillips, Ph.D.  
Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

Dear Bob,

This letter is regarding OmniCorder's BioScan System (K990416). We are in the process of replying to your letter of May 11<sup>th</sup> and would like a 90 day extension in order to complete this reply. We will complete our reply to you at the earliest possible date. Thank you for your continued help and cooperation.

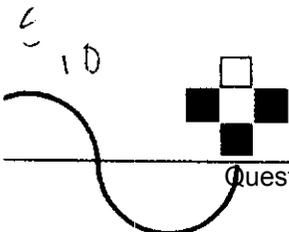
Sincerely,

Mark A. Fauci  
President and C.E.O.

RECEIVED

JUN 10 11 29 AM '99

FDA/CDRH/ODE/DMC



180

11



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 11 1999

Mark Fauci  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, N.Y. 11790

Re: K990416  
Trade Name: OmniCorder BioScan System  
Dated: January 28, 1999  
Received: February 10, 1999

Dear Mr. Fauci:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, please respond to the following.

1. Your device description is too general. Please describe each major subcomponent, its purpose, its major materials of construction, and how it fits into the entire system. What type of infrared detector and what detector arrangement is used?
2. The comparison of your device to the predicates is too general. Please compare them in terms of important operational specifications (e.g., minimum temperature change (or difference) detected, temperature range detected, resolution, etc.).
3. Your device uses software to process information. You have not provided information that demonstrates that your software development process is likely to produce reliable software. Please provide this information. If you chose to follow our software guidance, your device is considered a minor risk device. The material that should be submitted are: a software description; a device hazard analysis; the software functional requirements; an architecture design chart; and a software functional test plan, pass/fail criteria, and results.
4. Your submission indicates that your data handling and manipulation uses various algorithms. These are not described. Please provide a general description of these algorithms and explain why they are suitable for their intended use.
5. Your substantial equivalence argument states that the "relative indications and contraindications (warnings and precautions) for the OmniCorder BioScan and predicate devices are the same." Please provide a list of these indications, contraindications, warnings, and precautions in your labeling.
6. Your indications for use states:
  - a. that your device is compatible for use in an MR magnetic field. What range of magnetic field strengths is your device compatible with? Please provide the results of laboratory testing that supports your MR compatibility claim.

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Page 2 - Mr. Mark Fauci

b. that your device is for adjunctive diagnostic screening for detection of breast cancer or other uses." Please specify the other uses.

7. You have a prescription statement that is misquoted. It should read "Caution: Federal law restricts this device to sale by or on the order of a physician."

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

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

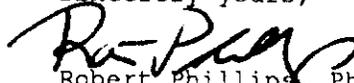
If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of this letter, please contact Robert Phillips, Ph.D. at (301) 594-1212. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Robert Phillips, Ph.D.  
Chief, Computed Imaging Devices  
Branch  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Mark Fauci  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, N.Y. 11790

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Trade Name: OmniCorder BioScan System  
Dated: January 28, 1999  
Received: February 10, 1999

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  - a. that your device is compatible for use in an MR magnetic field. What range of magnetic field strengths is your device compatible with? Please provide the results of laboratory testing that supports your MR compatibility claim.

Page 2 - Mr. Mark Fauci

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The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration  
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9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Robert Phillips, Ph.D. at (301) 594-1212. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Robert Phillips, Ph.D.  
Chief, Computed Imaging Devices  
Branch  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ-470 DRAERD  
D.O.

RAPhillips:5/10/99

# FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z-470	Symon	5/10						

U.S. GPO 1986-169-089



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

Reviewer(s) - Name(s) ROBERT PHILLIPS

Subject: 510(k) Number K990416

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

Refused to accept.

Requires additional information (other than refuse to accept).

Accepted for review 2/14/99

Is substantially equivalent to marketed devices.

NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES

NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?

YES

NO

Is this device subject to the Tracking Regulation?

YES

NO

Was clinical data necessary to support the review of this 510(k)?

YES

NO

Is this a prescription device?

YES

NO

Was this 510(k) reviewed by a Third Party?

YES

NO

Special 510(k)?

YES

NO

Abbreviated 510(k)?

YES

NO

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

A 510(k) summary OR  A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

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:

Additional Product Code(s) with panel (optional):

Robert Phillips  
(Branch Chief)

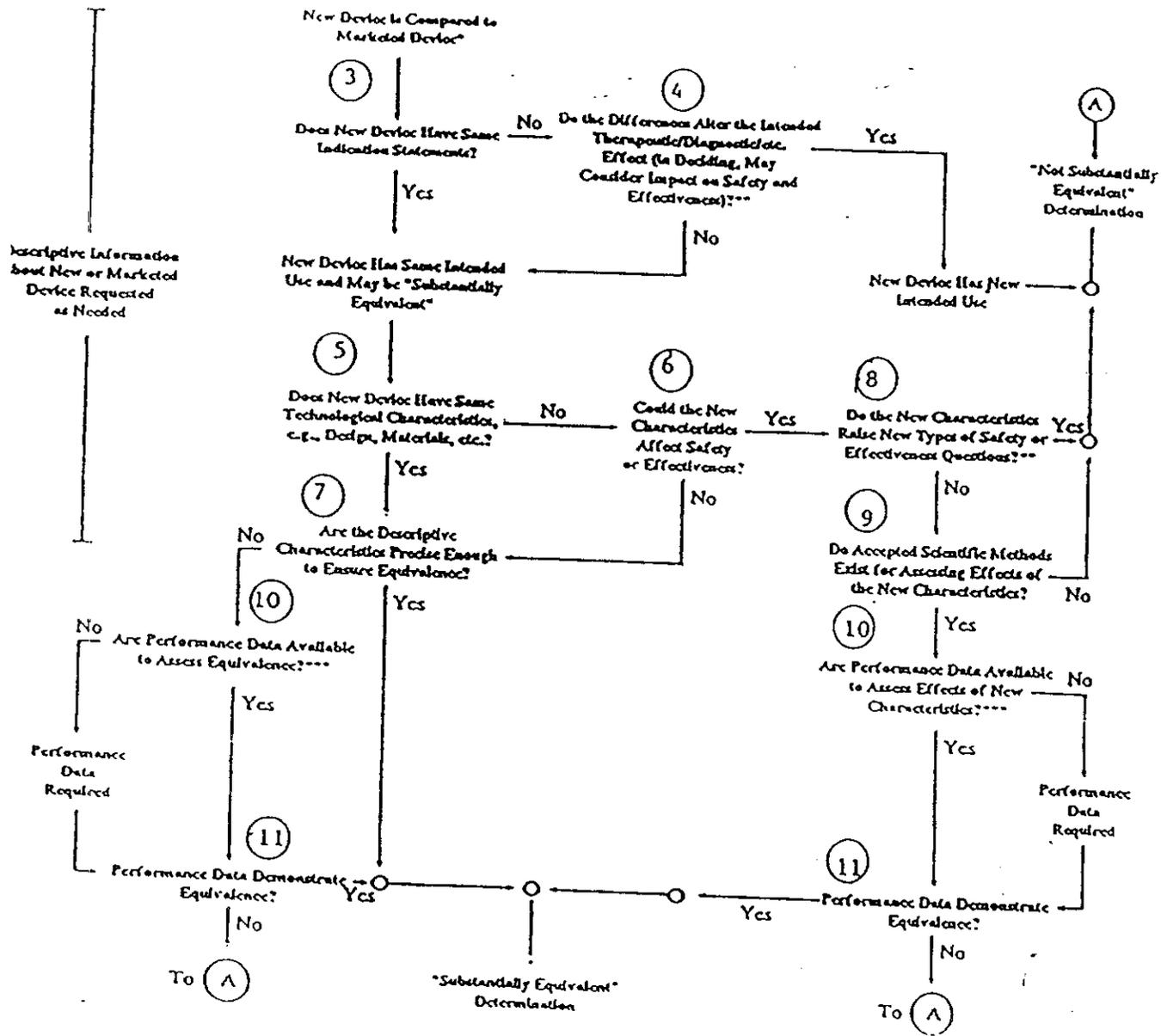
RA015  
(Branch Code)

5/10/99  
(Date)

Questions? Contact David K. Gorman at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118  
(Division Director)

5/20/99  
(Date)

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



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.

May 10, 1999

510(k) Review

K990416

Traditional X Abbreviated \_\_\_\_\_ Special \_\_\_\_\_ 3<sup>rd</sup> Party \_\_\_\_\_

Contact: Mark Fauci  
Company Name: OmniCorder Technologies, Inc.  
Address: 25 East Loop Road  
Stony Brook, N.Y. 11790

510(k) Number: K990416  
Tradename: OmniCorder BioScan System  
Dated: January 28, 1999  
Received: February 10, 1999

Product Code: 90-LHQ Class: I FR Classification No.: 892.2980



Common Name: Telethermographic System- Adjunctive

Intended Use: Intended for viewing and recording heat patterns generated by the human body. The device is for adjunctive diagnostic screening for detection of breast cancer and other uses.

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

Manufacturer: Inframetrics, Inc. Bales Scientific, Inc.  
Tradename: Infracam-Med BSI Model Tip  
Document Control: K982327 K897191

Previous Submissions: n/a

Applicable Guidance: n/a

	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?		X	If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

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.

#7 The descriptive information is too general.

#10 Needed performance data is missing. See deficiencies.

**Standard Questions:**

Normal, Simplified, Tier I Review? Normal  
Is the device subject to postmarket surveillance? No  
Is a summary or certification of safety and effectiveness included? 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? No  
Does the device use software? Yes  
Is the device disposable (single use)? No  
Is the device sterile? No  
Is the device for single, home or prescription use? Prescription  
Does the device contain or use drug or biological products? No  
Is the device subject to the Radiation Control Act? No

Other standards? CSA Standard C22.2, No. 125-1984 Electromedical Equipment  
UL544 09/1985, Standard for Medical and Dental Equipment

**Device Description:** The system consists of a Computer Processing Unit, Color Monitor, Color Printer, a Tripod Support, and a Thermal Camera. The system is Manufactured from components and materials consistent with other 510(k) cleared devices. Greater detail on the device description is not available. The device is compared to several predicates but only at a general level.

**Laboratory and Clinical Data:** None provided. The device is claimed to be compatible with MR magnetic fields, but this claim is unlimited and not supported with data.

**Labeling:** Various technical manuals and an operator's manual are provided. Indications, contraindications, warnings, and precautions are not provided.

**Software:** The device is described as having operating software. No information on this is provided. The submission also claims to use several algorithms that are also undescribed.

**Substantial Equivalence:** Substantial information on which to base an SE decision is missing.

**Recommendation:**

I believe that additional information is needed to determine equivalence:

1. Your device description is too general. Please describe each major subcomponent, its purpose, its major materials of construction, and how it fits into the entire system. What type of infrared detector and what detector arrangement is used?
2. The comparison of your device to the predicates is too general. Please compare them in terms of important operational specifications (e.g., minimum temperature change detected, temperature range detected, spatial resolution, etc.).
3. Your device uses software to process information. You have not provided information that demonstrates that your software development process is likely to produce reliable software. Please provide this information. If you chose to follow our software guidance, your device is considered a minor risk device. The material that should be submitted are: a software description; a device hazard analysis; the software functional

requirements; an architecture design chart; and a software functional test plan, pass/fail criteria, and results.

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7. You have a prescription statement that is misquoted. It should read "Caution: Federal law restricts this device to sale by or on the order of a physician."

Robert Phillips

## Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: <b>OMNI COLPER</b>						K990416	
Submitter (Company): <b>OMNI COLPER TECH INC</b>							
Items which should be included (circle missing & needed information)	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"							
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							
GO TO # 2,3      GO TO # 2,4,5      GO TO # 4,5							
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							
✓ IF ITEM IS NEEDED AND IS MISSING							
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)		NA		YES		NO	
		SPECIALS		ABBREVIATED		TRADITIONAL	
		YES	NO	YES	NO	YES	NO
a) trade name, classification name, establishment registration number, device class						✓	
b) OR a statement that the device is not yet classified		FDA may be a classification request; see coordinator					
c) identification of legally marketed equivalent device		NA				✓	
d) compliance with Section 514 - performance standards		NA				✓	
e) address of manufacturer						✓	
f) Truthful and Accurate Statement						✓	
g) Indications for Use enclosure						✓	
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)						✓	
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals						✓	
k) Proposed Labeling:						✓	
i) package labeling (user info)						✓	
ii) statement of intended use						✓	
iii) advertisements or promotional materials						✓	
iv) MRI compatibility (if claimed)						✓	
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling						✓	
ii) intended use						✓	
iii) physical characteristics						✓	
iv) anatomical sites of use						✓	
v) performance (bench, animal, clinical) testing		NA					
vi) safety characteristics		NA					
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) STATEMENT - INTENDED USE AND INDICATIONS FOR				* If no - STOP not a special			

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

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<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
c) <b>STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>				* If no - STOP not a special
d) <b>Design Control Activities Summary</b>				
i) 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				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS</b>							
a) 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							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted							

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

143 90

below		
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed		
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device		
v) A specification of any deviations from each applicable standard that were applied		
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference		
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations		
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards		

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 2/19

Reviewer: RAP  
 Concurrence by Review Branch: \_\_\_\_\_

REVISED: 3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

Product To Which Compared (510(K) Number If Known): \_\_\_\_\_

YES NO

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			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?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			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:

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.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

## 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?		
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 #191-2 and Federal Register 90N0332, September 10, 1991.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

February 10, 1999

OMNICORDER TECHNOLOGIES, INC.  
25 EAST LOOP RD.  
STONY BROOK, NY 11790  
ATTN: MARK FAUCI

510(k) Number: K990416  
Received: 10-FEB-1999  
Product: OMNICORDER BIOSCAN  
SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA 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  
Consumer Safety Officer  
Premarket Notification Staff  
Office of Device Evaluation  
Center for Devices and Radiological Health

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

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January 28, 1999

Office of Service Evaluation  
510(k) Document Mail Center (HFZ-401)  
Food and Drug Administration  
Center for Devices and Radiological Health  
9200 Corporate Boulevard  
Rockville, MD 20850

OmniCorder Technologies, Inc. is submitting this 510(k) notification for the OmniCorder BioScan System manufactured to OmniCorder's developed specification and in compliance with U.S. FDA Quality System Requirements (QSR).

**Submitter's Name and Address:**

OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, NY 11790

**Contact Person:**

Mark Fauci  
President  
OmniCorder Technologies, Inc.  
Tel. 516-444-6499 Fax. 516-444-8825

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**General Information:**

Classification Name and reference: Telethermographic System (21 CFR §884.2980)

Classification: Class I Device

Product Code: IYM/LHQ

Common/Usual Name: Thermographic Camera System

Trade/Proprietary Name: OmniCorder BioScan System



Initial Importer/Distributor: OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, NY 11790  
Establishment Registration Number - Pending

Standards/Special Controls: There are no regulatory standards or special controls applicable for this device, however, the device will comply with the following voluntarily standards and guidelines:

CSA Standard C22.2, No. 125-1984, Electromedical Equipment

UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

**Labeling and Advertising:** Proposed package labels and users manual for the OmniCorder BioScan System are provided under Draft Labeling in Section 6. Proposed advertising material has not been generated at the time of this submission. However, any advertising material will conform to the basic principles contained in the "Device Description", "Indication for Use" and "Labeling and Packaging" sections of this submission.

**Device Description:** A general and detailed device description is provided in Section 3.

**Substantial Equivalence:** The OmniCorder BioScan System is substantially equivalent to the products described herein with respect to indications for use, device design, materials, and method of manufacture. Section 8 and Appendix B contains all relevant and available information for the following commercially available predicate device.

Inframetrics, Inc., Inframetrics Infracam-Med ~ (K982327)

Bales Scientific, Inc., BSI Model Tip ~ (K897191)

JEOL Model #JTG-500M ~ (K823041)

DCATS by Dorex Inc. ~ (K812799)

These predicate devices are commercially available and marketed Class I devices indicated for use for thermal imaging of human tissue. The OmniCorder BioScan System is also labeled for similar use.

## Main Sections

This 510(k) premarket notification includes the following main sections

- Section 1 Pre-Market Notification Statements
  - Section 2 Indications for Use
  - Section 3 Device Description
  - Section 4 Device Materials
  - Section 5 Labels and Labeling
  - Section 6 Packaging
  - Section 7 Sterilization Information
  - Section 8 Substantial Equivalence
  - Section 9 510(k) Summary
- Appendices A through G

This submission also includes appendices and exhibits containing supplemental materials such as predicate device information, device and accessory engineering photographs.

OmniCorder Technologies would like to request that the Food and Drug Administration hold the enclosed information confidential and exempt this information from public disclosure in so far as is allowable under current law.

Information contained in this application is true and accurate to the fullest extent of our abilities.

Based on the descriptive information presented in this 510(k) premarket notification, OmniCorder Technologies concludes that is reasonable to determine that the OmniCorder BioScan System is substantially equivalent to the devices mentioned above as well as other instruments which are commercially available at this time.

If you should have questions regarding any part of this application, please do not hesitate to contact me at 516-444-6499.

Sincerely,

A handwritten signature in black ink, appearing to read 'M. Fauci', written in a cursive style.

Mark Fauci  
President

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**PREMARKET NOTIFICATION 510(k)**

**OmniCorder Technologies, Inc.**

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## Section 1

### Pre-Market Notification Statements

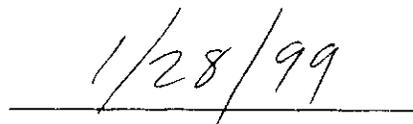
Premarket Notification  
Truthful and Accurate Statement  
**OmniCorder BioScan System**

I certify that, in my capacity as President of OmniCorder Technologies, Inc., I believe that to the best of my knowledge, that all data and information submitted in this premarket notification for the OmniCorder BioScan System are truthful and accurate and that no material fact has been omitted.



Signature

Mark Fauci, President



Date

## **Section 2**

### **Indications for Use Statement**

### Indications for Use

**510(k) Number:**

**Device Name :** OmniCorder BioScan System

**Indications for Use:**

The OmniCorder BioScan System is thermal camera based imaging device intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer or other uses. This device is intended for use by qualified healthcare personnel trained in its use.

The device labeling will indicate:

NOTE: Prescription Device; to be used by trained health care professionals upon order of a Physician.

MRI Compatibility Statement: The OmniCorder BioScan System is compatible for use in an MRI magnetic Field

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

\_\_\_\_\_

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_ OR Over-The-Counter Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

## **Section 3**

### **Device Description**

## **Device Description**

The OmniCorder BioScan System (see Appendix A and B for product description and specifications) is an infrared camera device which provides the capability for imaging and recording of thermal data radiating from adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings; and in the home. It is a prescription device intended for use only by health care professionals.

The captured energy is processed by software to produce digital output values of the thermal energy captured by the camera's thermal sensor. Validation tests as seen in Product Acceptance Test Report in Appendix E verify the efficacy of this feature.

The following accessories are provided for use with the device:

- 1) Computer Processing Unit (Pentium II Workstation)
- 2) Color Monitor
- 3) Color Printer
- 4) Tripod Stand

Device components and accessory information are included in Appendix A.

See Appendices B,C and D for a more detailed description of the hardware.

## **Section 4**

### **Device Materials**

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**Mechanical and Visual QC Testing:**

Quality control testing consists of incoming inspection of components to an AQL sampling based upon MIL-STD-105E. Raw materials, components and assemblies may be accepted on a certificate of conformance from the vendor for chemical composition and/or mechanical properties. When required by controlled documentation, incoming material, components, assemblies, etc. will be inspected for attributes. In-process inspection is performed by both manufacturing and quality control personnel. Final inspection for all finished devices and/or accessories shall be performed by QA/QC personnel. The final device history record and completed documentation is stored by quality control. All documentation, inspection and testing is controlled and written to QSR compliant procedures.

## **Section 5**

### **Labels and Labeling**

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## **Labels and Labeling**

The following paragraphs describe the various labels used to identify the OmniCorder BioScan System products as to their description, and configuration. Additional promotional and advertising material will be consistent with the content herein.

### **Labeling on Camera:**

Labels that will be placed on the outer surface of the Camera:

NOTE: Prescription Device; to be used by trained health care professionals upon order of a Physician.

### **Promotional Literature:**

No promotional literature has been prepared for this product at this time.

### **Operations Manual**

Technical Specifications, User, and Technical Operations Manuals are provided with each Camera as shown in Appendices B, C and D.

### **Package Labeling**

Labels that will be placed on the outer surface of the outer cardboard box in which the OmniCorder BioScan System will be shipped:

WARNING: Sensitive and fragile medical equipment. Handle with extreme care.

Do not expose to rain, or other weather conditions.

## **Section 6**

## **Packaging**

## **Packaging**

The OmniCorder BioScan System will be packaged in a cardboard box. Various type of support material will be used inside (i.e., foam "peanuts," cardboard inserts, flexible plastic sheets, etc.) The device and its accessories are sold non-sterile.

The package is non-sterile and does not require sealing validation. The package will be sealed with commercially available plastic tape or staples to prevent foreign matter from entering and to secure the contents inside.

## **Section 7**

### **Sterilization**

**Sterilization:** Device and accessories are to be sold non-sterile. Packaging validation regarding the integrity of the package to assure a SAL is not required.

## **Section 8**

### **Substantial Equivalence**

**Substantial Equivalence:** The OmniCorder BioScan System is similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution as follows. Please refer to Appendix B, which contains promotional literature for these devices.

Equivalent Products:

Inframetrics, Inc., Inframetrics Infracam-Med ~ (K982327)

Bales Scientific, Inc., BSI Model Tip ~ (K897191)

JEOL Model #JTG-500M ~ (K823041)

DCATS by Dorex Inc. ~ (K812799)

The OmniCorder BioScan System is similar to the named predicate devices with respect to intended use, material, design and operational principles as follows:

1. Intended Use: The OmniCorder BioScan System is thermal camera based imaging device intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer or other uses.

This device is intended for use by qualified healthcare personnel trained in its use.

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5. Indications and Contraindications: Relative indications and contraindications for the OmniCorder BioScan System and predicate devices are the same.

**Differences From Commercially Available Devices of Similar Intended Use:**

This device differs from other commercially available devices in that the systems vary in components and accessories. Most of the variability is attributed to the more advanced technological capabilities (greater temperature sensitivity, focal plane array arrangement of detector elements, data collection speed, processing speed etc.) currently available and incorporated into the BioScan System.

**Comparison to Predicate Devices**

The systems have various design features in common. All use digital infrared cameras to collect temperature data from the subject and all use computer processing units to collect process and present the data, from the camera to the operator, using a monitor and/or printer. All systems permit the storage and retrieval of data to and from the computer hard drives or taping devices.

A comparison of the OmniCorder BioScan System to the iRIS-3 Thermographic System is presented in Table 1.

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## **Section 9**

### **Performance Assessment**

**Performance Assessment:** The OmniCorder BioScan System

The OmniCorder BioScan System has been manufactured, examined and tested according to ISO 9001 criteria.

The accuracy of the thermal sensor of the OmniCorder BioScan System is supported by data provided in the sample Product Acceptance Test Report required before delivery of the BioScan System from the manufacturer (see Appendix E).

## **Section 10**

### **510(k) Summary**

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## 510(k) Summary

**Date of Summary Preparation:** January 29, 1999

**Manufactures Contact Person:** Mark Fauci  
President  
Tel. (516)-444-6499  
Fax. (516)-444-8825  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, NY 11790

**Trade Name:** OmniCorder BioScan System

**Classification Name, Classification Number, Class, Classification Reference:**

Classification Name	Class. No.	Class	21CFR §
Telethermographic System	IYM/LHQ	I	884.2980

**Special Controls:** There are no regulatory standards or special controls applicable for this device.

**Indications for Use:** The OmniCorder BioScan System is thermal camera based imaging device intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare perscnnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal.

The device is for adjunctive diagnostic screening for detection of breast cancer or other uses. This device is intended for use by qualified healthcare personnel trained in its use.

**Device Description:** The OmniCorder BioScan System is an infrared camera device which provides the capability for imaging and recording of thermal data radiating from adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings; and in the home. It is a prescription device intended for use only by health care professionals.

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

The following accessories are available for use with the device:

- 1) Computer Processing Unit (Pentium II Workstation)
- 2) Color Monitor
- 3) Color Printer
- 4) Tripod Stand

The device and its accessories are similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution.

**Substantially Equivalent Commercially Available Devices:** OmniCorder BioScan System is substantially equivalent to the following commercially available predicate devices with respect to indications for use, device design, materials, and method of manufacture.

**Substantial Equivalence Comparison:** The : OmniCorder BioScan System is similar to commercially available devices with respect to intended use, material, design and operational principles as follows:

Inframetrics, Inc., Inframetrics Infracam-Med ~ (K982327)

Bales Scientific, Inc., BSI Model Tip ~ (K897191)

JEOL Model #JTG-500M ~ (K823041)

DCATS by Dorex Inc. ~ (K812799)

1. Operational Principles: The basic operational principles of the OmniCorder BioScan System and the predicate devices measure and record, without touching the patient's skin, self-emanating infrared radiation to reveal temperature variations. The parameters that are measured and displayed are generally the same as those for the predicate devices.
2. Indications and Contraindications: Relative indications and contraindications for the OmniCorder BioScan System and commercially available devices for similar intended uses are the same.

**Assessment of non-clinical performance data for equivalence:** Currently there are no FDA standards for this device. However, the OmniCorder BioScan System complies with:

CSA Standard C22.2, No. 125-1984, Electromedical Equipment

UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

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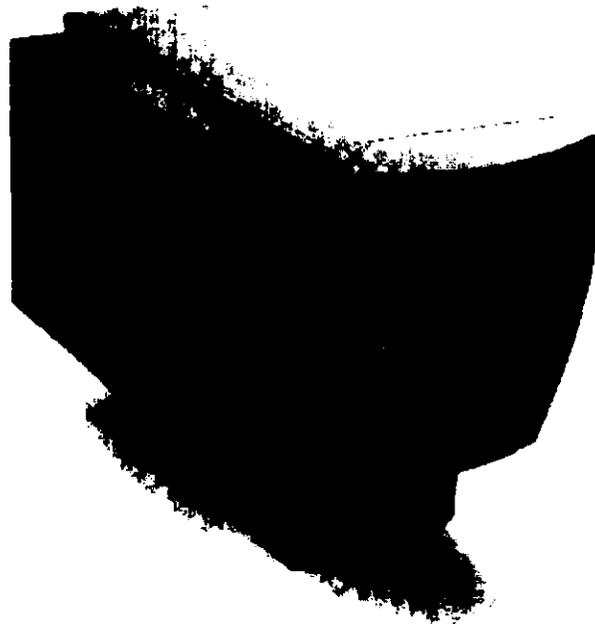
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# Product Components and Accessories

## Appendix A

# OmniCorder Technologies, Inc.

## BioScan System Components

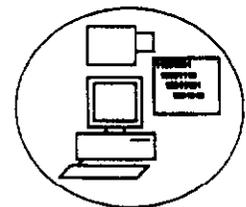


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# Product Technical Specifications Manual

## Appendix B

**OmniCorder Technologies, Inc.**  
**BioScan System**  
**Technical Specifications Manual**



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**This manual and the associated documentation have been prepared carefully and reflects the current configuration of the BioScan System. Keep this manual in a safe place where it is immediately available to all operators of the BioScan System. Additional manuals may be purchased from OmniCorder Technologies, Inc.**

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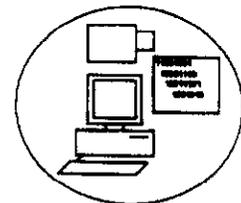
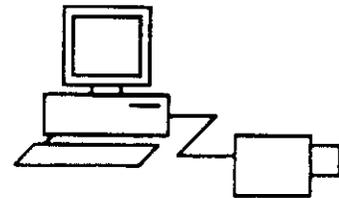
# Product User Manual

## Appendix C

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**OmniCorder Technologies, Inc.**  
**BioScan System**  
**User Manual**



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OmniCorder Technologies, Inc.

This manual and the associated documents have been prepared carefully and reflects the current configuration of the OCT BioScan System. Keep this manual in a safe place where it is immediately available to all operators of the BioScan System. Additional manuals may be purchased from OmniCorder Technologies, Inc.

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OmniCorder Technologies, Inc.

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OmniCorder Technologies, Inc.

## 1. GENERAL REMARKS

This manual and the associated documents have been prepared carefully and reflects the current configuration of the OCT BioScan System. Keep this manual in a safe place where it is immediately available to all operators of the BioScan System. Additional manuals may be purchased from OCT.

Use of cables and components which have not been approved by OCT may severely impact system performance. Use the cables and components provided with the OCT BioScan System only.

### 1. 1. OVERVIEW

Prior to first time operation of the BioScan System, we highly recommend to read the information in Section 1 of this manual. This section contains useful observations relating to the assembly, operation and maintenance of the system.

**Section 2** describes the associated computer software. This software allows camera operation using the panel located on the backside of the camera system. **Section 3** describes the *Remote Control Operation* of the camera system using PC or Laptop, as well as transfer and storage of the images on the hard disk, using the computer software delivered with the camera. Information provided in **Section 4** the *Image Processing Module and Interfaces*.

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OmniCorder Technologies, Inc.

## **WARNING**

**To prevent fire or shock hazard, do not expose the unit to snow, rain or moisture. To avoid electrical shock, do not open the cabinet, replace components or make adjustments inside the equipment. Only trained OCT personnel are qualified to perform these procedures**

### 1.4. CLEANING

The camera cabinet is made of anodized aluminum. Please clean the casing with a soft, dry cloth. Do not use a moistened or a wet cloth. The optical components of the camera are made of Germanium, which has been optically coated to optimize the transmission of the infrared radiation. For cleaning purposes, please use a commercial optical lens cleaning kit or a soft brush. Dust may be removed by blowing dry air. If you accidentally touched the lens with your fingers, or if dust on the lens cannot be removed as described above, use a small cotton pad, slightly moistened with Propanol. Touch the lens gently, and wipe the dirt away. Do not apply force. You do not need to remove the remaining Propanol, it will evaporate shortly. Do not use any kind of abrasive pad, scouring powder, as they may damage the optical coating of the lens.

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OmniCorder Technologies, Inc.

## 2. I. INFRARED RADIATION

All objects with temperatures above the absolute zero temperature, emit infrared radiation. The higher the temperature of the body, the more radiation is emitted and the shorter is the predominant wavelength of the radiated emission. Room temperature objects have a peak emission around 10 microns. On hot days, these objects emit more total energy than on cold days. On cold days, the objects emit less energy, with wavelengths as short as 3 microns.

The major part of the IR emission spectrum is unusable for infrared sensors because the radiation is absorbed by water or carbon dioxide in the atmosphere. However, there are several "windows" with good transmissions. OCT's BioScan System works in the long wavelength window (LWIR, 8-10 micron) offers excellent visibility of most terrestrial objects and is ideal for collecting emissions from the human body. The germanium optics of the BioScan System forms an image at the location of the photovoltaic infrared detector. The sensitive array is mounted in a dewar and interacts with the incident infrared radiation by generating electrical carriers. However, the detector also picks up the "infrared noise" generated by its own mounting and optics. To minimize this background noise, the detector needs to be cooled down to cryogenic temperatures, using a closed cycle cryogenic cooler. The standard operating temperature of the infrared detector is about 60 degrees Kelvin. The GDE electronics provides the operating power and timing signals for the infrared detector. In return, the GDE digitizes the generated electrical signals and transfers the digital data to the Image Processing Module. Using the external supplied voltages (+24 VDC and 24 Vreturn), the power supply module generates and provides the necessary

OmniCorder Technologies, Inc.

internal voltages. All camera operations are controlled with the buttons and the jog dial located on the panel at the backside of the camera housing.

The provided system software allows modification of the system parameters and imaging modes. The image may be watched on the internal TFT Display, external monitors like VGA-Monitor, CCIR-Monitor, TV-Set with BAS-Input, or may be recorded with a commercial videotape recorder. The BioScan System is configured with a very powerful personal computer via the EPP Interface. Images may be recorded or processed with the provided BioScan Software. The data communication is controlled using a RPC concept (Remote Procedure Call).

### 3. ASSEMBLY AND OPERATION OF THE SYSTEM

The BioScan System is controlled with 5 push buttons and one jog dial, located on the panel at the backside of the camera housing. LED's located on the control panel indicate the selected viewing mode.

The camera operation is controlled via computer software. You may choose your operation from the overlay menu, which is accessible at the display. The procedures are explained in detail in Section 2 of this documentation.

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### 3. 1. MOUNTING OF THE SYSTEM

Any vibration may impact the quality of your images. To make use of the high quality performance of the BioScan System, make all efforts to keep vibrations away from the system. The camera should always be mounted on the provided tripod during operation. The tripod must be positioned on a solid vibration-free surface. The adapter of the tripod will fit into the thread at the bottom of the camera housing. When mounting the camera to a tripod, take care not to obstruct the ventilation slots in the front and back panel. The set generates heat, which must be able to escape freely. A built-up of heat reduces the life of the system and is a source of danger.

#### 3. 1. 1. CHANGING THE OPTICS

The standard optics is fixed with 4 socket-head screws. To disassemble the optics, loosen the 4 socket-head screws. Remove the lens and dispose the optical assembly in the camera carrying case. Attach the new optic to the camera head and tighten the same 4 socket-head screws.

#### 3.2. ELECTRICAL POWER SUPPLY

Connect the supplied power cable to the *DC-POWER INPUT* connector providing dc-voltage +24 Volt and 24 Volt return.

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**WARNING**

**Use of cables and components which have not been supplied by OCT may severely impact system performance. Only use the cable provided with the BioScan System.**

The camera is now ready to start operation. The internal cryogenic cooler will cool down the IR-detector to temperatures of about 60 degrees Kelvin. Under normal ambient conditions this will take about 10 minutes. An internal safety circuit prevents the IR-detector from being activated until the temperature set-point is reached. After this period, the camera is ready for operation.

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## 4. GLOSSARY

EPP	Enhanced Parallel Port
RPC	Remote Procedure Call
VGA	Video Graphics Adapter
TFT	Thin Film Transistor Display
LWIR	Long Wavelength Infrared Radiation, 8-10 microns
GDE	Generation and Digitizer Electronics
IPM	Image Processing Module

## 5. POINT OF CONTACT

OmniCorder Technologies, INC.

25 East Loop Road

Stony Brook, NY 11790

Tel. 516-444-6499

Fax. 516-444-8825

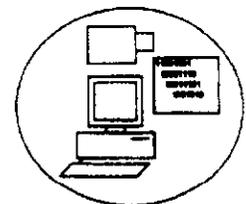
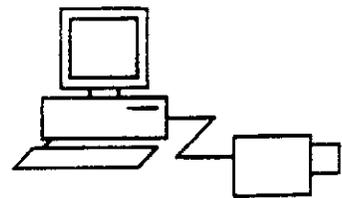
# Product Technical Operations Manual

## Appendix D

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**OmniCorder Technologies, Inc.**  
**BioScan System**  
**Technical Operations Manual**



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OmniCorder Technologies, Inc.

This manual and the associated documents have been prepared carefully and reflects the current configuration of the OCT BioScan System. Keep this manual in a safe place where it is immediately available to all operators of the BioScan System. Additional manuals may be purchased from OmniCorder Technologies, Inc.

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OmniCorder Technologies, Inc.

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This page represents 12 whole-page redactions.

OmniCorder Technologies, Inc.

## 9. GLOSSARY

LWIR	Long Wavelength Infrared Radiation, 8-10 micron
GDE	Generation and Digitizer Electronics
LW	Long Wavelength, 8-10 gm
DynScale	Dynamic Scaling Function of the BioScan System
VGA	Video Graphics Adapter
TFT	Thin Film Transistor Display
AD-Converter	Analog Digital Converter
DSP	Digital Signal Processor
LUT	Look Up Table

OmniCorder Technologies, Inc.

This manual and the associated documents have been prepared carefully and reflects the current configuration of the OCT BioScan System. Keep this manual in a safe place where it is immediately available to all operators of the BioScan System. Additional manuals may be purchased from OmniCorder Technologies, Inc.

This page represents 1 whole-page redactions.

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OmniCorder Technologies, Inc.

## 1. GENERAL REMARKS

This manual and the associated documents have been prepared carefully and reflects the current configuration of the OCT BioScan System. Keep this manual in a safe place where it is immediately available to all operators of the BioScan System. Additional manuals may be purchased from OCT.

Use of cables and components which have not been approved by OCT may severely impact system performance. Use the cables and components provided with the OCT BioScan System only.

### 1. 1. OVERVIEW

Prior to first time operation of the BioScan System, we highly recommend to read the information in Section 1 of this manual. This section contains useful observations relating to the assembly, operation and maintenance of the system.

**Section 2** describes the associated computer software. This software allows camera operation using the panel located on the backside of the camera system. **Section 3** describes the *Remote Control Operation* of the camera system using PC or Laptop, as well as transfer and storage of the images on the hard disk, using the computer software delivered with the camera. Information provided in **Section 4** the *Image Processing Module and Interfaces*.

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## 1.2 STANDARD EQUIPMENT

- BioScan System with TFT-Display
- Optics
- Power Cable
- Computer Processing Unit
- Color Monitor
- Color Printer
- WORM archiving drive
- Black body calibration unit
- User Manual
- 3.5" Floppy Disk with control software and RPC-function listing
- Carrying Case
- Camera tripod with casters

## 1.3. SAFETY SUMMARY

The following are general safety precautions and instructions that personnel must understand and apply during many phases of operation to ensure personal safety and health. Portions of this summary may be repeated elsewhere in this publication for emphasis. Maintenance must be carried out solely by adequately trained or qualified OCT personnel. Inadequate maintenance, repair or rework performed by persons lacking the necessary competence may result in a major source of danger for the user of the system.

OmniCorder Technologies, Inc.

## **WARNING**

**To prevent fire or shock hazard, do not expose the unit to snow, rain or moisture. To avoid electrical shock, do not open the cabinet, replace components or make adjustments inside the equipment. Only trained OCT personnel are qualified to perform these procedures**

### 1.4. CLEANING

The camera cabinet is made of anodized aluminum. Please clean the casing with a soft, dry cloth. Do not use a moistened or a wet cloth. The optical components of the camera are made of Germanium, which has been optically coated to optimize the transmission of the infrared radiation. For cleaning purposes, please use a commercial optical lens cleaning kit or a soft brush. Dust may be removed by blowing dry air. If you accidentally touched the lens with your fingers, or if dust on the lens cannot be removed as described above, use a small cotton pad, slightly moistened with Propanol. Touch the lens gently, and wipe the dirt away. Do not apply force. You do not need to remove the remaining Propanol, it will evaporate shortly. Do not use any kind of abrasive pad, scouring powder, as they may damage the optical coating of the lens.

# Product Acceptance Test Report

## Appendix E

This page represents 7 whole-page redactions.

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# Predicate Device Information

## Appendix F

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 20 1998

David R. Balzer, Jr.  
Thermatrek, Inc.  
660 Main Street South, Suite 7  
Woodbury, Connecticut 06798

Re: K982112  
Thermatrek Iris-3 Infrared Imaging System  
Dated: June 15, 1998  
Received: June 16, 1998  
Regulatory class: I  
21 CFR 884.2980/Procode: 90 LHQ

Dear Mr. Balzer:

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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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).

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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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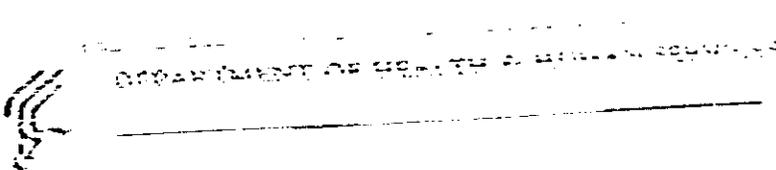
patterns and temperature changes in tissue temperature during coronary artery bypass surgeries. In addition, the InfraCAM-MED is intended to view and document temperature differences between myocardium, graft and vessels distal to the anastomotic site generated by the injection of cold or warm fluid 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.



Food and Drug Administration  
1390 Piccard Drive  
Bethesda, MD 20894

APR 26 1990

Mr. Maurice J. Bales  
President  
Bales Scientific, Inc.  
1620 Rice Valley Boulevard  
Walnut Creek, CA 94596

Re: K897191  
BSI Model Thermal Image  
Processor (Tip)  
Dated: April 25, 1990  
Received: April 26, 1990  
Regulatory Class: Proposed I  
21 CFR 884.2980 (a)

Dear Mr. Bales:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for general registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

William Yu, Ph.D.  
Director, Division of OS-CRA, ENT,  
and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

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## **THE *BALES TIP*<sup>™</sup>**

- is completely programmable,
- provides the highest image resolution possible,
- allows display of multiple dynamic windows containing image data of any size or shape, in color and/or grey scale,
- offers many analysis modes.

The *Bales TIP*<sup>™</sup> system is capable of conducting screening evaluations according to user demands and expert system considerations. "Popdown" menus greatly simplify operator inputs. System modules are completely interchangeable without recalibration to minimize user downtime in the event the system configuration must be changed to meet patient or practice demands. Over the decades of military and industrial infrared imaging development, a system even beginning to approach this level of sophistication and ease of use was considered impractical by aerospace or military contractors or government agencies.

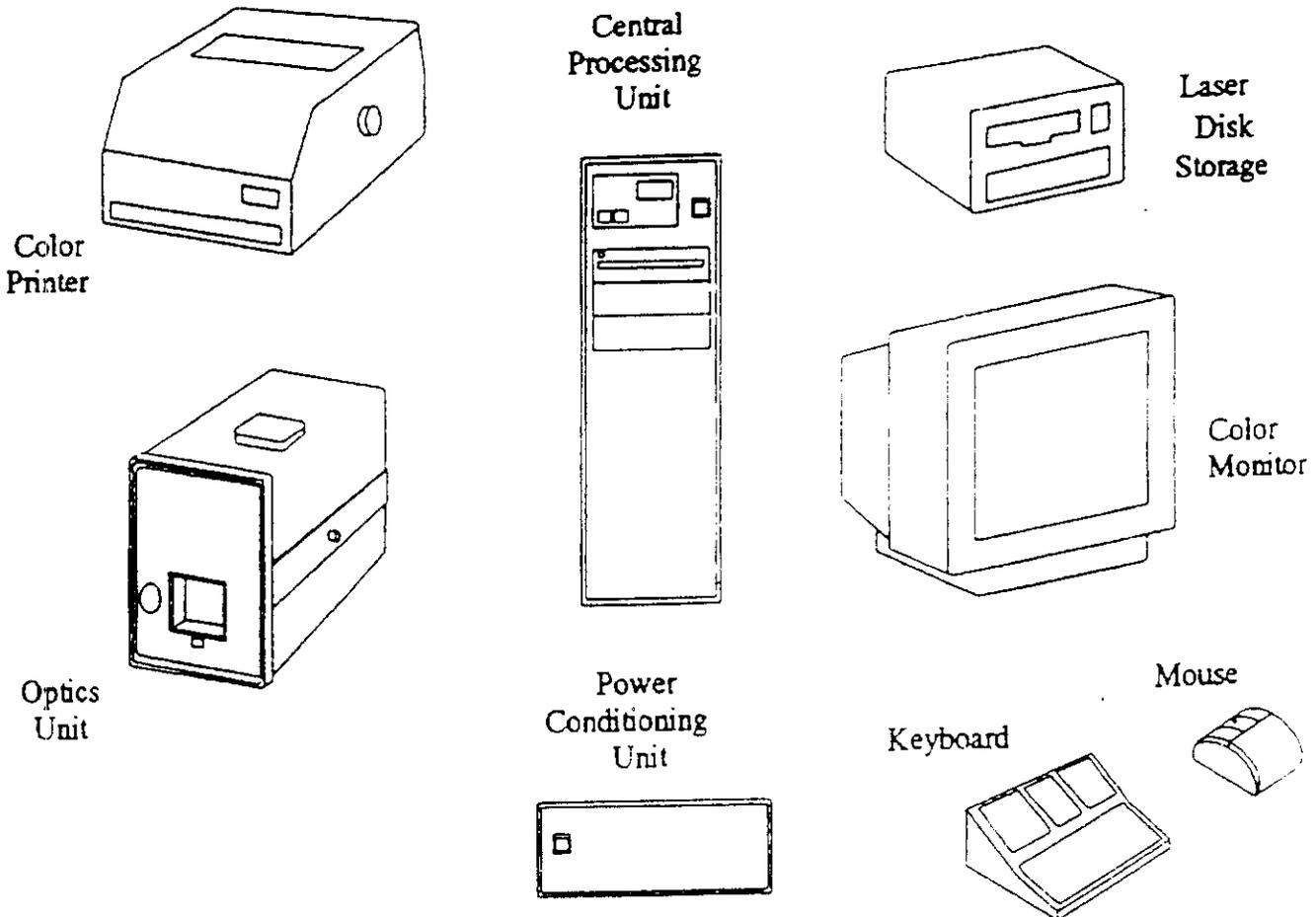
The optics unit and central processing unit of the *Bales TIP*<sup>™</sup> are really "handshaking" computers which health care professionals can instruct to perform a wide variety of special applications. The high processing speed and industry standard operating system allow the *Bales TIP*<sup>™</sup> to be immediately configured for changes in test parameters and environments. Special requirements for control of peripheral systems do not require additional system hardware because such controls are already built into the system. Upgrades to the system, specialized instructions, display menus for test procedures, forms for test results, reports, ... are simply a matter of loading software from a diskette or CD-ROM. The design goal was to design a system that would allow any module to be replaced with any other similar unit. All the User has to do is plug the new module into the space occupied by the old module.

The *Bales TIP*<sup>™</sup> design assures that the complexity of the programmable system is invisible to the health care professionals using the system. The graphic user interface (GUI) allows a technician without any prior experience with computers to learn to operate the system in a single afternoon.

The Optics Unit contains all the detector linearization and temperature calibration data with associated circuitry. Changing optic units does not require on-site system calibration or require that the entire system be sent back to the factory.

User image archives and all test procedure software are actually stored on removable and interchangeable media so no site information is lost or temporarily unavailable when installing another CPU.

The following figure shows the system modules:



### The *Bales TIP™* System

#### Optics Unit

The optics package contains its own microprocessor and allows the user to select frame rate, image density, and image parameters. In addition, the unit contains two blackbody sources for self calibration and a means of automatic and manual focus. The optical system is comprised of reflective elements scanning "outside" of the focusing lens for linear, coma free, optical resolution. The infrared detector is a single element for maximum sensitivity, cooled by liquid nitrogen or a closed cycle system. The optics unit will view a subject in either a horizontal or vertical position.

The optics unit is the heart of any imaging system. No final displayed image can contain better definition than the resolving capabilities of the optical system. In the

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*Bales TIP™*, reflective optics are utilized in a linear scanning system with all scanning elements outside of the focusing lens. This type of scanning system is more expensive to manufacture, but the result is a distortion-free high resolution element at the detector plane.

### **Thermal Resolution**

Temperature resolution is a major design consideration in all thermal imaging systems. The *Bales TIP™* uses an analog to digital converter (A/D) to convert the analog image information from the infrared detector array to digital data for processing and storage. The accuracy of this system determines the dynamic range (the limits of the temperature range) of the instrument. The *Bales TIP™* utilizes a 12 bit converter with an accuracy of one part in 4,096 (99.999+ %). The dynamic range of any system is determined by multiplying the minimum detectable temperature by the resolution of the A/D converter. For example, the minimal detectable temperature is 0.0125° Centigrade and the A/D converter is 12 bits (one part in 4,096), the dynamic range is 51.2 degrees (0.0125×4096) and the system can detect changes of 0.0125 degree Centigrade throughout its full dynamic range.

The detector type and imaging wave length ( $\lambda$ ) are optimum for medical infrared diagnostic imaging. Essentially there are two general classes of detector materials, placed in various assemblies, employed in thermal imagers. These are indium antimonide and mercury cadmium telluride (MCT) with perhaps several added "doping" agents.

Indium based detectors are generally used for high temperature applications, such as viewing jet engine exhausts. Indium based detectors are most responsive in the 2 to 5 micron ( $\mu$ ) range, or approximately 500°C.

MCT detectors are primary used for low temperature applications where small temperature differences are of prime concern. MCT detectors respond in the 8 to 14 micron ( $\mu$ ) range, or 30° to 200° C. range. The 8 to 14 micron range is considerably more useful in for medical diagnosis and provides a good signal-to-noise ratio while accurately measuring small temperature differences. The *Bales TIP™* utilizes a single element detector responsive in the 8 to 14 micron spectral range, with specialized filters when required. A single element detector is used in order to achieve maximum resolution with the best signal-to-noise ratio. Detector arrays are limited in resolution to the array density and limited to the system sensitivity of the least sensitive element.

To accurately measure absolute temperature the system uses two blackbody references, an ambient temperature sensor, and lookup tables containing calibration data for each detector. During factory calibration each detector is computer compared to a blackbody standard over the entire temperature range. Over 4,000

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
P 757 Georgia Avenue  
Silver Spring, MD 20910

Mr. Robert J. Martin  
General Manager  
JECO (U.S.A.), Inc.  
Analytical Instrument Division  
125 Connecticut Avenue  
Greenwood, New Jersey 07030

Ref: K12344  
JECO Model No. JTG-500M  
Thermometer

Dear Mr. Martin:

We have reviewed your Section 513(a) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Cognizance) or Class III (Pre-market Approval), it would be subject to additional controls.

General controls under the Act include regulations on general registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations relating to restricted devices, controls, and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements that apply to your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20540. Your information also may be reviewed in the Callers Management System (CMS) of the Food and Drug Administration, Room 4-62, South Biscayne Drive, Parkville, Maryland 21097.

This letter should not be construed as approval of your device or its labeling. If you desire to know the status of labeling for your device or other information pertinent to your responsibilities under the Act, please contact the Office of General Inquiries, Division of Regulatory Operations (HFD-101), 4100 Reservoir Road, Silver Spring, Maryland 20910.

Sincerely,  
*Robert J. Martin*

**BEST AVAILABLE COPY**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

NOV 10 1982

From: Reviewer(s) - Name(s) COLIN POLLARD  
Subject: 510(K) Notification K823041  
To: The Record

It is my recommendation that the subject 510(K) Notification;

(A) Is substantially equivalent to marketed devices.

(B) Requires premarket approval. NOT substantially equivalent to marketed devices.

(C) Requires more data.

(D) Is an incomplete submission. (See Submission Sheet)

Additional Comments:

Class Code w/ Panel:

90 IYM

SG - ATTACHMENTS

REVIEW: [Signature] 11/22/82 [Signature] 11/19/82  
BRANCH CHIEF DATE  
FINAL REVIEW: [Signature] 11/22/82  
DIVISION DIRECTOR DATE  
OPTIONAL REVIEW: \_\_\_\_\_  
ASSOC. DIRECTOR FOR DEVICE EVAL. DATE

**BEST AVAILABLE COPY**

ATTACHMENT V

MEDICAL INFRARED THERMOGRAPH

THERMOVIEWER 500M

**JEOL**

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1. Outline of instrument

The Thermoviewer 500M is a medical infrared thermograph which detects infrared rays emitting from the human body surface and presents the minute temperature differences thus detected — in the form of a thermal image. Fully meeting the specifications which will be included in JIS in 1982, this infrared thermograph is expandable for diverse applications.

Designed for non-contact, passive measurement (the instrument emits no radiation or radio wave), the Thermoviewer 500M, when used for clinical diagnosis, can catch blood flow, inflammation and metabolism without giving the subject any pain or disorder.

2. Concept of instrument development

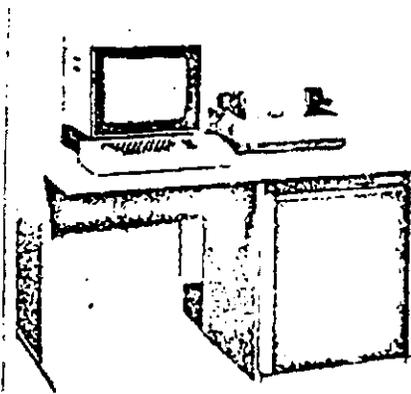
With medical diagnostic techniques evolving in the direction of overall image diagnosis, the thermographic system is now positioned as an auxiliary image diagnosis system, with its effectiveness being increasingly recognized. Moreover, its market is expected to be largely expanded because its use has become an object of health insurance. JEOL's thermographic system is expected to dominate the market from the start as it excels other makers of instruments both in hardware and software, and this will push forward its future sales. From these standpoints, we have now developed a new model which is improved in basic performance, operational ease and reliability. The requisites for a medical infrared thermographic system are as follows:

- o Provision of software for medical diagnosis or system expandability for diverse researches.
- o Sufficient image quality and display performance to allow effective diagnosis.
- o Reliability of data obtained.
- o Data analysis function for medical diagnosis.
- o Operational ease for hospitals where no exclusive operator is available.
- o No discomfort (such as noise) to the operator.
- o Ease of servicing and maintenance.
- o Profitability.

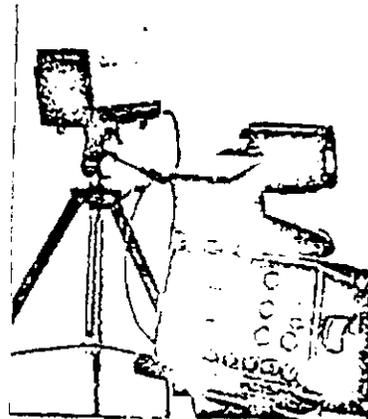
To meet the above requisites and for its early development, the Thermoviewer 500M has been configured as shown in the next page.

### Instrumental Improvements

Video processor

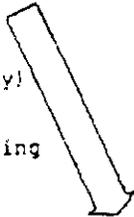


Thermoviewer MD



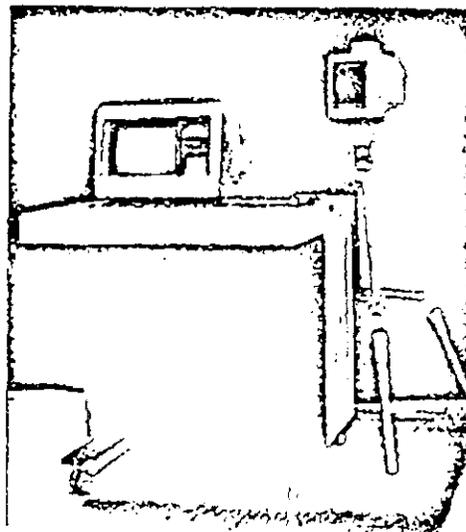
o Improvements

- Still image capability
- (Pseudo real time display)
- Easy operation
- Simplified observation
- Selectable image processing methods



o Improvements

- Basic performance maintained
- Lower noise
- Closed construction
- Simplified servicing / maintenance
- Good design



Thermoviewer 500M

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### 3. Features

1) The structural improvement of the optical head has allowed:

- Reduced noise
- Modular construction
- Closed construction

Reduction of noise is necessary for the Thermoviewer 500M because this model is designed for examination of physiological functions and therefore should not give the subject any disturbance. The modular construction facilitates servicing and maintenance and, furthermore, enhances the instrumental reliability. The closed construction is needed for observation of living human bodies and especially that during surgical operation.

2) Provision of a built-in computer in the display unit has enabled the following improvements in the basic performance.

- Better image quality
- Still image capability and resetting of display conditions
- Digital display of the temperature at an optional point

The improvement of the basic performance is what every physician hopes for because it allows him to read images accurately. Since all data on a patient can be obtained by a single photographing, hemiplegic persons and patients who cannot stay still for a long time need not undergo prolonged examination. The digital display of the temperature at an optional point, which is two-dimensional temperature display improved over the conventional display on a single line, is effective for the temperature measurement of subjects of complicated shape, such as fingers and faces.

3) In order to improve the operational and therefore diagnostic ease, the following features have been adopted:

- Automatic focusing
- Automatic image reversal (with auxiliary mirror used)
- Automatic temperature correction (with auxiliary mirror used)
- Automatic temperature level setting (2 modes)
- Display of date and subject number
- Increment of subject number
- Observation CRT and recording CRT provided separately
- Function key operation

The Thermoviewer 500M's operational procedure consists of field selection in the same manner as an ordinary camera, focusing, adjustment of the brightness level, selection of the optimum display mode, entry of the data number, and recording.

Since the Thermoviewer 500M is highly automated, the operator needs no operational skill, but only the knowledge about diseases. Moreover, since all temperature information can be recorded by a single photographing, the operator is freed from the trouble of rephotographing.

Use of an optional attachment allows field selection to be carried out under remote control.

4) Thanks to the built-in computer, the following data processings can be performed merely by adding a keyboard (including software).

- Average temperature computation (4 channels)
- Maximum temperature computation (4 channels)
- Automatic data collection by timer
- Horizontal/vertical waveform display
- Comment display

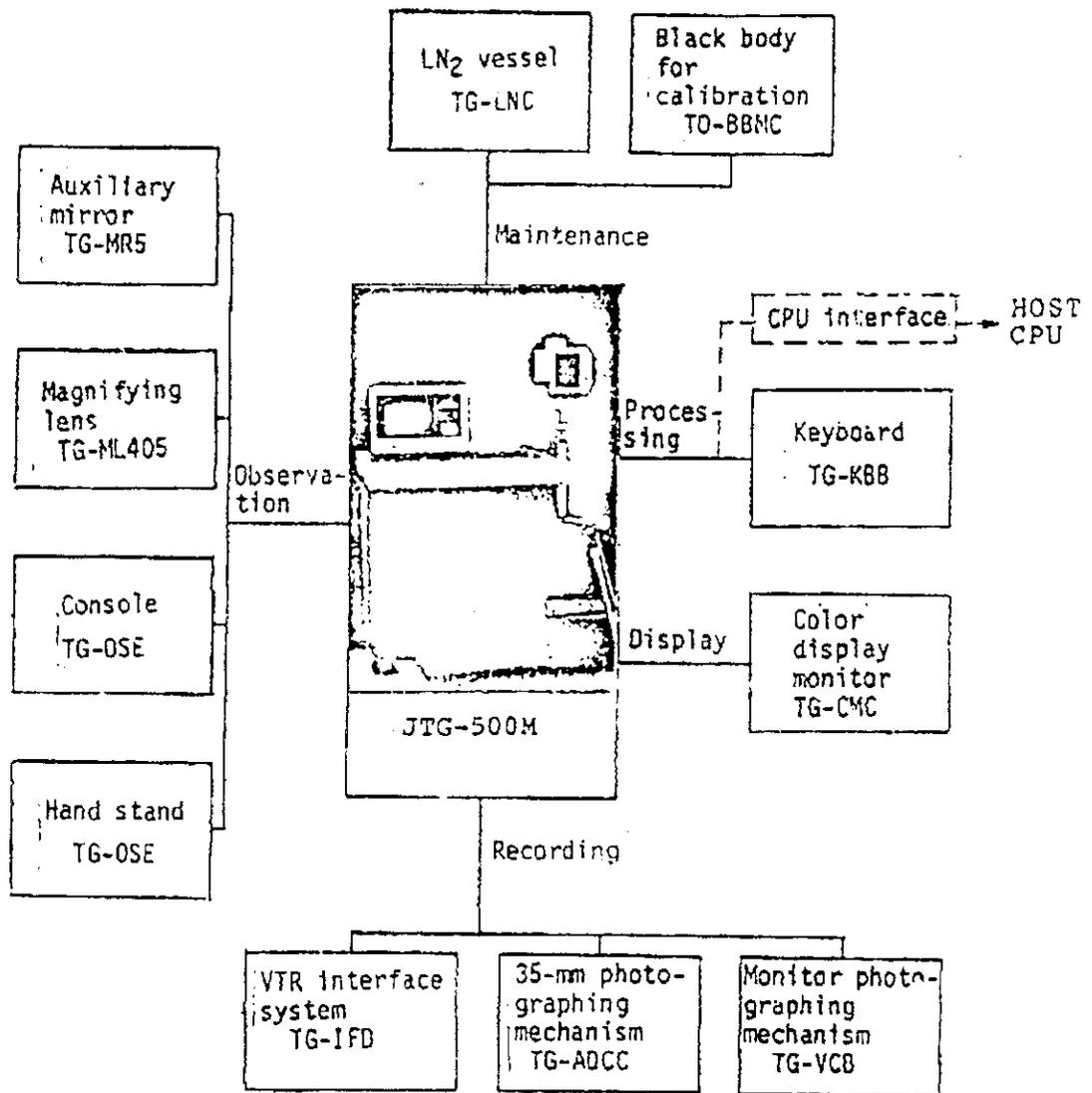
The average temperature computation has expanded standard diagnostic data from the point to the area level, thus opening up the way to image diagnosis.

The automatic data collection by a timer is effective for diagnostic purposes in that it allows transient phenomena to be detected while giving the subject various loads. This feature also reduces operator burden and enhances the accuracy of data obtained.

		Thermoviewer 500M	Thermoviewer MC/MD
1. Basic performance	Overall	⊙	○
	Temperature resolution	⊙ (S/N improved)	○
	Image resolution	⊙	⊙
	Scan time	⊙	⊙
	Number of scanning lines	○	⊙
	Display system	⊙	○
	Console structure	⊙	△
	Noise	⊙	△
	Still image	⊙	×
	Temperature direct readout	⊙	△
2. Functions	Overall	⊙	△
	Expandability	⊙	△
	Automation	⊙	△
	Operational ease	⊙	△
	Field selection	⊙	○
	Focusing	⊙	○
	Temperature setting	⊙	△
	Auxiliary mirror correction	⊙	MC alone
Display	⊙	△	
3. Service maintenance	Overall	⊙	△
	Unit exchange	⊙	×
4. Design	Overall	⊙	△
5. Price	For 500M functions	⊙	△
	For basic	○	○

⊙ Excellent    ○ Good    △ Average    × Poor

4. System configuration



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5. Thermoviewer 500M specifications

o Optical head

- (1) Temperature measurement range: 0 to 50°C.
- (2) Minimum detectable temperature difference: Less than 0.05°C.
- (3) Scan time: 2 s (8 s when S/N is improved).
- (4) Scanning lines: 240.
- (5) Horizontal resolution: 300 lines or more.
- (6) Measurement field: 20° vertically, 25° horizontally.
- (7) Focus range: 22 cm to ∞ from instrument front.
- (8) Infrared ray detector: HgCdTe (cooled by LN<sub>2</sub>).
- (9) Liquid nitrogen supply: One filling lasts 3.5 hr or more.
- (10) Temperature range: 10 to 40°C.
- (11) IN PROCESS indicator lamp: Lights up during data collection.
- (12) Construction: Simple, closed type.
- (13) Weight & dimensions: Approx. 5 kg.  
165(W) x 178(H) x 310(L) mm  
(not including projections).

o Display unit

- (1) Center temperature range: 0 to 50°C (in 0.1°C steps).
- (2) Temperature width setting range: 0.5 to 50°C (in 0.5°C steps).
- (3) Number of picture elements: 240 vertically, 256 horizontally (in measurement field, 230 and 256, respectively).

- (4) Frame display system: Pseudo real time display by TV scan.
- (5) Frame display items: Temperature distribution image, gray scale, center temperature, temperature width, temperature on gray scale, date, ID number, auxiliary mirror reversal sign, isothermal line temperature (in isothermal line display), cursor cross point temperature (in point temperature display), point temperature and its positional marker (in point temperature display), operation symbol.
- (6) Display modes:
- o Normal display: Black-and-white continuous brightness change.
  - o Black-and-white reversal display: Black and white in normal display are reversed.
  - o Step display: Brightness is changed every 20 % of temperature width.
  - o Isothermal line display: Areas having the temperature corresponding to the selected 2.5% region of the temperature width are displayed bright.
  - o Cross point temperature display: Temperature at cursor cross point is displayed in real time.
  - o 10 point temperature display: Temperature and positional markers of up to 10 cursor cross points are displayed.

(7) Operational functions

- o Focusing: Auto/manual focusing is possible.
- o S/N enhancement: Temperature resolution is enhanced twofold theoretically.
- o Center-temperature setting: Average temperature is automatically set to center temperature/temperature at cursor cross point is automatically set to center temperature/manual setting of the above also possible.
- o Date display: Year, month, and day or optionally selected 8 numerals can be inputted and displayed.
- o ID number display: 8 digits can be inputted and displayed.
- o ID number increment: ID number is increased.
- o LN<sub>2</sub> alarm lamp: Lights up immediately before the LN<sub>2</sub> in detector runs short.
- o IN PROCESS indicator lamp: Lights up during computer operation.
- o SCANNING indicator lamp: Lights up during data collection by optical head.

(8) Automatic image reversal by auxiliary mirror:

Image is automatically reversed and corrected when auxiliary mirror is used.

(9) Automatic temperature correction when auxiliary mirror is used:

Temperature display is automatically corrected when auxiliary mirror is used.

- (10) Monitoring system: Observation monitor and recording monitor built-in.
- (11) Power consumption: 370 VA.
- (12) Weight & dimensions: Approx. ~~101~~<sup>100</sup> kg.  
700 (W) x 1015 (H) x 800 (L) mm  
(not including projections).

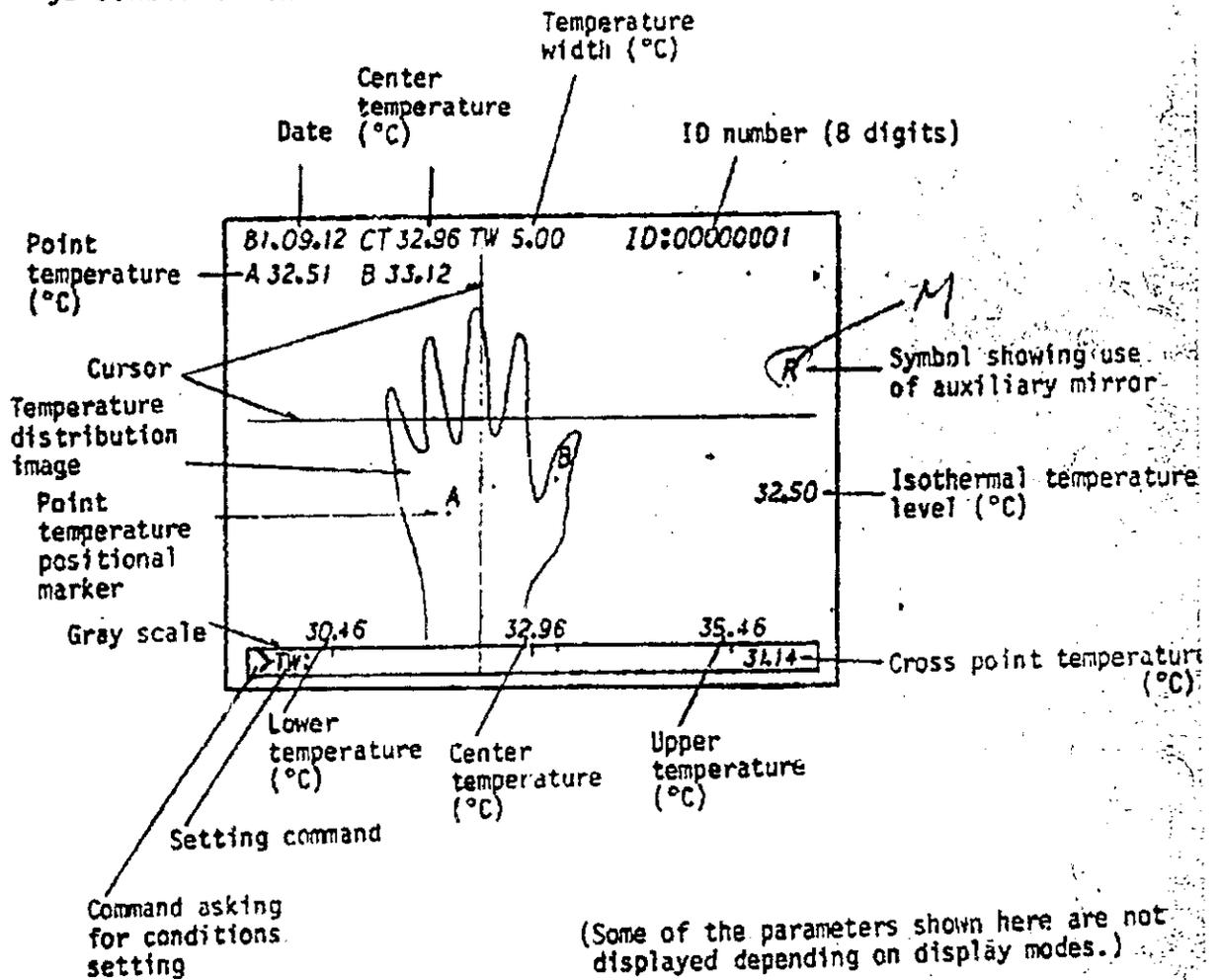
6. Optional equipment specifications

- 1) Auxiliary mirror: Directs optical axis downward (90°).
- 2) Magnifying lens: Magnification approx. 4X.  
Horizontal resolution 100  $\mu$ m or less.  
Image uniformity 0.5°C or less (for 50°C black body).  
Effective field covers almost entire frame in image magnification mode.
- 3) Console: Driven by remote-controlled SW provided on display unit.  
Vertical shift up to 1100 mm.  
Horizontal shift up to 280 mm.
- 4) Hand stand: Discrimination between fingers and background is done by putting ice water in developing tray.
- 5) Keyboard: Functions  
Average temperature computation (4 channels).  
Max. temperature computation (4 channels).  
HV temperature waveform display.  
Automatic data collection by timer.  
Comment display.  
Keyboard is of the type built into display unit.

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- 6) Color display monitor: Monitor size 14 inches.  
Display system RGB.  
Color tones 15 (one color tone is displayed on 1/10 of temperature width in temperature setting range).  
Monitor is built into rack.
- 7) Monitor photographing mechanism: Records image on color display monitor.  
Camera 35 mm type.
- 8) 35-mm photographing mechanism: Camera Olympus OM-1 (auto-winder built-in).  
Film sensitivity ASA 400.
- 9) VTR interface system: Recording/reproduction system FM modulation.  
All data in temperature range used are recorded and reproduced.  
VTR SLO-333.
- 10) LN<sub>2</sub>: Capacity 10 l.
- 11) Black body for calibration: Black body temperature can be fixed to 27°C, 35°C or 50°C.

Image Construction



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
SILVER SPRING, MARYLAND 20910

OCT 20 1981

Mr. Wheat Kutas  
President  
Dorex, Inc.  
1005 Main Street  
Orange, California 92667

Ref: K812799  
Dorex Computer Aided Thermograph  
System

Dear Mr. Kutas:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to one marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments of 1976. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to the publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, MD 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Bureau of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, MD 20910.

Sincerely yours,

*Robert S. Kennedy*

Robert S. Kennedy, Ph.D.  
Associate Director  
for Device Evaluation  
Bureau of Medical Devices

# DOREX INC.

1005 MAIN STREET  
ORANGE, CALIFORNIA 92667  
(714) 538-3110

RECEIVED  
FEDERAL BDP

SEP 28 1981

September 28, 1981

Food and Drug Administration  
Bureau of Medical Devices  
Document Control Center (HFK-20)  
8757 Georgia Ave.  
Silver Springs, Maryland 20910

10810.799

Re: 510 K Registration

Attention: Document Control Clerk

Pursuant to the requirement of Section 510 K of the Food, Drug and Cosmetic Act notification is made of the intent of Dorex Inc. to manufacture and market the following device:

Common/usual name - Thermography System  
Classification Name: 90 IYM  
Proprietary Name: Dorex Computer Aided Thermography System (DCATS)  
Establishment Registration No: 2626347  
Performance Standard: None  
Substantial Equivalence: The Dorex Thermography system the same design, which has been manufactured and sold since January 20, 1970, has been interfaced to a mini computer to store, retrieve and extract information through a designed software program, for the purpose of information enhancement.

We would appreciate your earliest attention to this 510 K submission. Please do not hesitate to contact me at (714) 538-3110 if you have any questions regarding this submission.

Yours truly,

DOREX INC.

*[Signature]*  
President

Enclosure:  
Dorex literature  
Ana literature

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PRELIMINARY DATA

SYSTEM DESCRIPTION

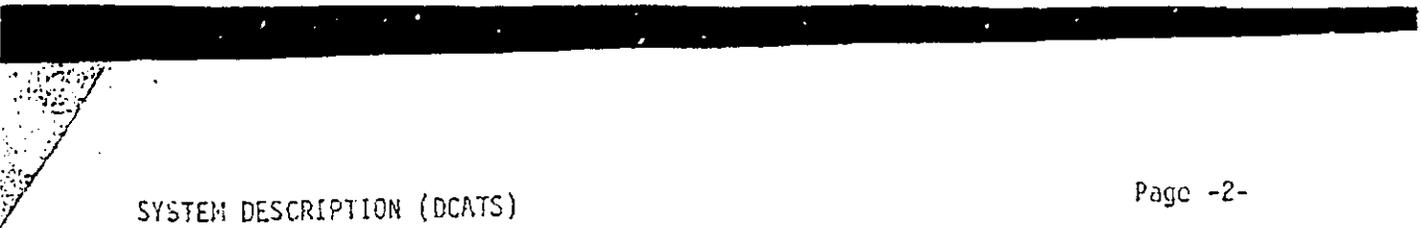
DOREX COMPUTER AIDED THERMOGRAPHY SYSTEM (DCATS)

Quantitative Computer Processing. The Dorex Thermography System detects the infrared emissions from the body and outputs timing signals and analog data representing a map of the patient skin temperature pattern. Analog data is a voltage level which is proportional to the skin surface natural thermal radiation, which is converted to digital data for subsequent processing by the computer. The Dorex data is digitized into picture elements called pixels, each of which is assigned one of 256 gray level values depending upon the brightness (thermal radiation) of the corresponding point on the patient. The digital picture data is stored in computer memory in real time (as the Dorex equipment is scanning the patient the data is digitized and stored in memory). Subsequently it is stored onto the disc for permanent storage, being recalled to the computer in a predetermined sequence for processing and visual presentation on the video monitor. The DCATS consists of: terminal computer, peripheral equipment, analog to digital converter, dual disc storage system, dot matrix printer, fiber optic printer and video monitors, all interfaced to the Dorex Thermography System.

Keyboard Terminal. The terminal computer controls the functions performed by the other system components, obtains instructions stored in memory, accepts data, manipulates data according to the instructions and communicates the results to the outside world. The terminal computer system operates with the disc operating system. Programs are assembled in modular form and continuity between each module is under software control.

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SYSTEM DESCRIPTION (DCATS)

Selectable Temperature Range. Three sensitivity ranges are available: 6.4°C, 12.8°C and 25.6°C. Each range is divided into 256 gray levels, for a range of:

25.6°C	temperature resolution is	0.1°C
12.8°C	"	0.05°C
6.4°C	"	0.025°C

DCATS temperature source calibration is traceable to certified U.S. Bureau of Standards.

Temperature Display of Selected Video Area. Presentation identifying maximum, mean and minimum temperatures of selected areas for study.

Deflection Modulation. Selectable 15 - 30 - 60 scan lines, displaying temperature distribution over the entire field of view, permitting temperature readout of a selected wave form.

Selectable Isotherm Display. Options are available for selecting isotherms in all areas within 0.1°C, 0.2°C, 0.5°C, 1.0°C. The isotherms may be viewed superimposed on the video, or separately, displaying chosen temperatures and deleting others from the display.

Permanent Disc Storage. Dual Disc Operating/Memory System, with 8-inch Floppy Discs. Patient history and thermograms stored permanently on a magnetic memory disc and may be recalled to the computer for display and analysis.

Alpha Numeric and Fiber Optic Printers. A Dot Matrix Line Printer provides both alphanumeric characters and gray level graphics. The Fiber Optic 16 Gray Level

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5 MIC

SYSTEM DESCRIPTION (DCATS)

Page -3-

Movable Cursor. Byte positioner - a movable bright spot can be placed in an area of interest for temperature analysis, displaying absolute and corresponding temperatures.

3 Monitor Display. Three 9-inch monochrome video monitors are utilized to display data, program content, video image, etc. One monitor presents step-by-step instructions to the operator, with simplified instructions and use of a single key on the computer terminal. One presents the selected thermograms, with a choice of video either "black" or "white" as hot, and the third monitor is utilized for diagnostic purposes, for deflection modulation, isotherm or magnification presentations. Data on any of the video monitors may be printed for hard copy record.

Automatic Focusing. This assures quality focused thermograms. Focal distance is 6 inches to 20 feet.

Rotatable Scan Head. Camera head is rotatable through 270 degree range, allowing flexibility in patient positioning -- eliminates need for external mirrors.

Color. Color peripheral is incorporated to a high resolution color graphics and alphanumeric board, providing full color display.

Symmetry Measurement. An option of the software programs provides the operator capability to divide selected areas of the thermogram into sub-areas and compare the temperature of these sub-areas to determine differences in high-low-and average values.

Movable chair

- 5 Monitor display/color display
- Automatic focusing
- Rotatable Scan Head/eliminates external mirror

**APPLICATIONS**

- Vascular disease
- Carotid occlusive disease
- Deep vein thrombosis
- Peripheral vascular disease
- Detection of breast abnormalities
- Orthopedics
- Musculoligamentous injuries — low back
- Lumbar discogenic — joints — tendonitis
- Rheumatoid arthritis
- Athletic injuries
- Neurology
- Dermatology — plastic surgery implants
- Burns — (rosbite/depth and extent)
- Drug therapy and studies

**SPECIFICATIONS**

Temperature range 15°C to 40°C

Temp. resolution (Digital) .025°C

High resolution 4 Sec. Scan Rate

Angle field of view — 20° X 20°

Area scanning per focal distance

- 1 Foot 6" X 6" (36 sq. in.)
- 4 Feet 18" X 18" (2 1/4 sq. ft.)
- 5 1/2 Feet 2' X 2' (4 sq. ft.)
- 16 Feet 6' X 6' (36 sq. ft.)

Focal distance — 6" to infinity

Detector-InSb or HgCdTe — LN<sub>2</sub> cooled

Power: 115V/60Hz — 1250 Watts

Desktop: 72" X 28" X 30", Return 28" X 24" X 30"

Weight: 500 lbs

300

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### MEDICAL THERMOGRAPHY

The Dorax medical thermography system detects skin temperature emissions optically and converts them electronically into visible thermal maps (thermograms) for study. The conversion from optics to electronics is achieved through a small infrared radiation detector (thermal transducer) developed by the military for night and jungle observation equipment. The thermogram is presented on a cathode-ray tube (CRT) in meaningful shades of gray. A ten-increment gray scale is used, with the lighter shades representing warmer areas and the darker shades representing cooler areas. Permanent copies of thermogram displays are obtained with an oscilloscope camera.

The heat pattern represented by gray tones in the thermogram is derived from various factors. There are differences in the skin and under it, and in the thermal conductivity of underlying tissues. Skin that is inflamed, swollen, or situated directly above veins, infections, cancers, and bruises will appear hotter than normal. Conversely, skin over areas with a decreased blood supply ... characteristic of arteriosclerosis and thrombosis ... will appear cooler. Hair, because it has no blood vessels, also appears cool.

Thermograms can be obtained of all parts of the body not covered by hair. The valuable diagnostic information they furnish can localize areas of immediate concern to the physician. Thus, in many situations where the ordinary clinical thermometer would be inadequate, the progress of disease and efficacy of therapy can be monitored by a series of thermographic studies.

Because every person has his or her own heat patterns, and because patterns vary widely in appearance, skill and proficiency are gradually developed in the interpretation of thermograms ... in much the same way that the radiologist acquires proficiency in the interpretation of X-ray films, which also are a mosaic of grays. Also, as with X-rays, one does not usually come to a diagnostic conclusion without recourse to other measures such as a careful appraisal of symptoms, physical signs, and other laboratory procedures.

Some thermographers prefer the gray scale inverted ... black representing hot and white representing cold ... especially for breast cancer, on the grounds that the human eye is more sensitive to black than white. In the inverted mode, the subtle hot spots and venous patterns may be more readily discerned in black. For this purpose, the Dorax system may be inverted by setting the Mode Switch to VIDEO (inverted video).

Because the temperature range across a given area (differential temperature) may vary from one patient to the next, and from one body area to another, the Dorax system has a unique Delta-T (for differential temperature) Control. Basically, Delta-T is a two-part switch. Rotation of a red inner knob determines the thermal baseline (lowest temperature to be represented by the gray scale). Thus, the thermogram may be set at the thermal level of the person or body area being scanned. Turning the outer black knob to one of six positions determines whether the 10-increment gray scale (which makes up

every thermogram) will represent a 10-degree range (wherein each shade of gray represents 1 degree C.), of some smaller range, all the way down to 1 degree (wherein each shade represents .1 degree C.).

This range variability enables the operator to adjust as necessary to obtain the most effective map of a given area ... possibly 8 degrees for the entire body, or 4 degrees for a foot or the forehead. Once an area has been mapped in its broader range, a closer look may be obtained by reducing the range, which results in greater resolution.

#### APPLICATIONS

Thermography has filled a long-felt need in diagnostic medicine, and there is a wealth of documentation to support this statement. In thousands of examinations, thermography has been instrumental in the detection of such diverse conditions as primary cancers (self-contained), metastatic cancers (where cancer nodules have been released from their original site, and spread to other tissue), fractures, contusions, herniated discs, myositis, abscesses, arthritis, tendonitis, and various kinds of vascular disease. Many of these disorders can be discovered through thermography even before the onset of the usual recognizable symptoms. At present, thermography is being employed to diagnose various types of wounds, traumas, and bone and rheumatic diseases. Other applications include dermatology, drug therapy observations, obstetrics, ophthalmology, diagnostic surgery, and prosthetic fitting.

The obvious advantage of thermography over X-ray in pathology detection is that there is no exposure to harmful roentgens, or other harmful emissions.

## THE THERMOGRAPHY SYSTEM

The Dorex Thermography System comprises two major units. An Infrared Camera houses an optical system and an infrared detector. A Control Console contains processing electronics, controls, and a video display tube. The two units are interconnected by a cable and equipped with casters for mobility and positioning. More complete flexibility in positioning is afforded by the Dorex exclusive rotatable camera head, making over-the-bed thermography just as easy as it is of patients sitting or standing ... and without the need or nuisance of setting up expensive external mirrors.

### OPTICAL SYSTEM

The optical system consists of an optical scanning mechanism and converging optics using reflective elements which are precision mirrors silvered on the front side. These mirrors are designed and arranged in an optical train for conveying and focusing an image of sufficient size and clarity onto a detector unit.

The scanning mirror spins about a vertical axis (with reference to the subject), resulting in a scan along the horizontal plane. At the same time, the entire scanning mechanism is continually going through a slow nodding motion, which enables the horizontal scanning to progress from the top to the bottom of the image area in 4 seconds. In this manner, the entire image is covered, point-after-point horizontally, and line-after-line vertically.

Focusing for distance from the subject is provided by varying the distance (remotely controlled from the control console) between two of the mirrors in the optical system.

### INFRARED DETECTOR

Radiation from each point of the scan pattern impinges upon the detector, causing it to generate an analogous voltage. Much as light is received through the corneal lens of the eye and relayed to the retina where only the visual image is sensed and converted to meaningful electrical pulses which are conveyed by nerve circuitry to the brain for perception and interpretation, similarly, the optical system relays the image to the detector unit which, because of its properties, senses only the infrared and generates analogous signals for amplification and processing by the electronics.

The detector also is exposed to a very similar thermal radiation from background sources, including the inside walls of the camera, and all other surfaces which the detector can see either directly or by reflection. Furthermore, the detector generates a signal due to its own temperature. Under these circumstances, the skin signal would be totally drowned out were it not possible to drastically cool the detector. Hence the liquid nitrogen (LN<sub>2</sub>) requirement. Cooling is achieved by mounting the detector at the base of a Dewar flask containing liquid nitrogen which reduces detector temperature to -321 degrees F. (77 degrees K.), eliminating substantially all background interference.

### ELECTRONICS

Output of the infrared detector is processed by an amplifier and gain control and then, in conjunction with position pick-off signals from the scanning mechanism, it is applied to the control of the beam of the video tube. The beam illuminates point after point, and line after line over the face of the video tube with intensities analogous to the infrared radiation represented. At the end of a full scan, a complete image in 10 cycles of gray has been formed. Because of the necessarily slow scan (1/2 seconds), slow in comparison with commercial television, the video tube is coated with a long-persistence phosphor which retains the image during or build-up period.

### ANALOG PRESENTATION

A single-line analog presentation may be obtained of any horizontal scan line. This presentation is a single, irregular horizontal line having peaks and valleys analogous to the temperatures detected along the length of that line. Two-dimensional portrayal of heat in this manner provides a useful tool in pinpointing the location of a hot spot, and in verifying temperature differences observed in the video mode. The analog also is an aid in focusing. By adjusting focus to obtain the sharpest peaks and valleys on a line, the system is quickly brought into focus.

### SCALE EXPANSION

A unique Delta-T (differential temperature) switch enables the operator to set the thermal baseline (lowest temperature) of the thermogram at the temperature level most effective for the study at hand. With the same switch, the operator may establish the temperature differential across the

10 shades of gray in the thermogram. The narrower the range, the greater precision. For example, in a 10-degree range, each shade of gray in the thermogram represents 1-degree C., whereas in a 1-degree range, each shade of gray represents .1 degree C.

#### RECORDING

Permanent records of video displays are obtained by a camera attachment and/or a digital data output device. The camera attachment is an oscilloscope camera affixed to the face of the video tube. When a photographic record of an image is desired, the operator presses the camera control button and the camera photographs one complete 4-second scan. The camera accommodates film holders for Polaroid film or 35mm. or 70mm. negative film. The output data device encodes the detector video signal, along with positioning and sync pulses into a format suitable for input to automated systems.

#### OPERATION

A typical operational sequence is as follows:

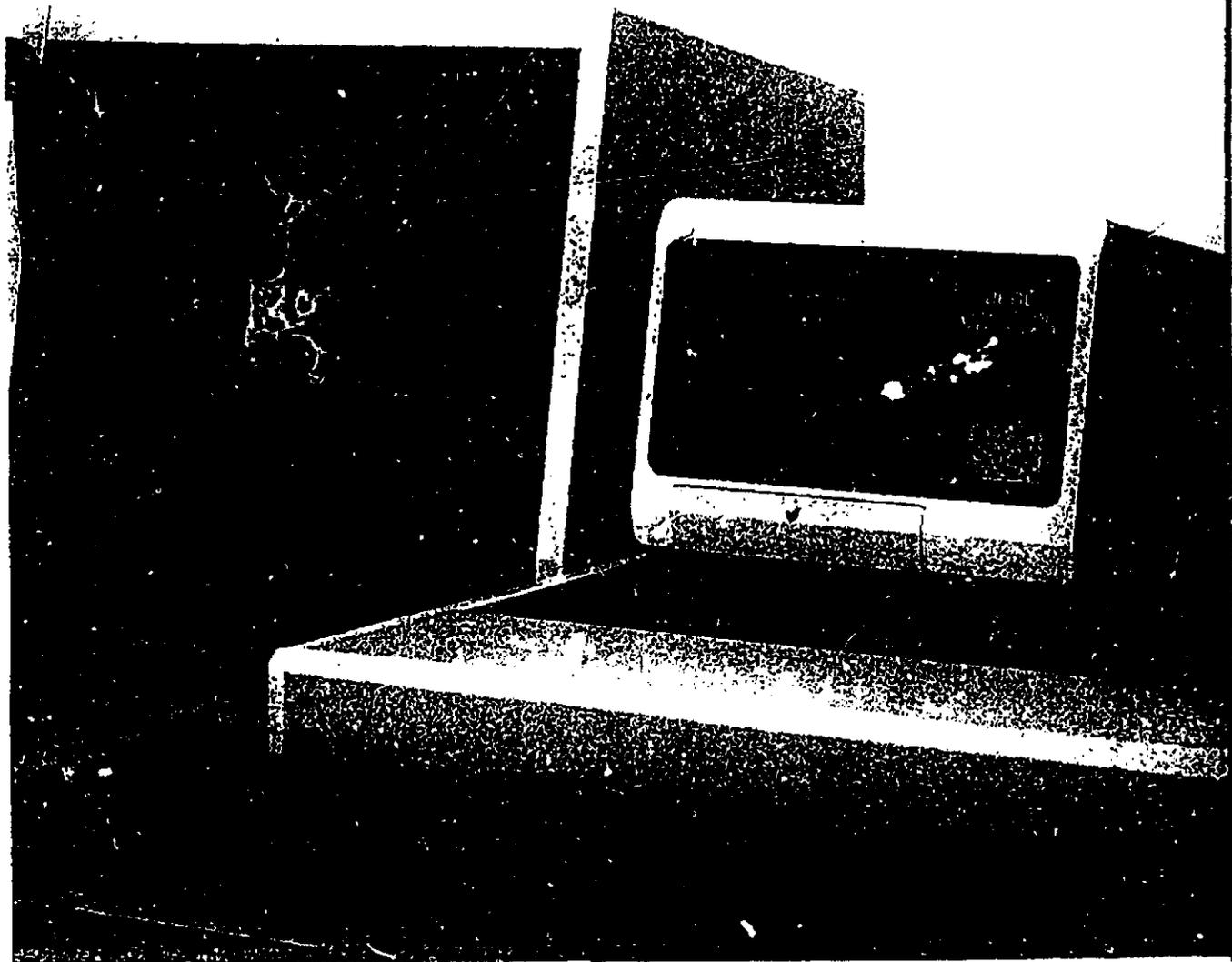
1. Position patient in front of camera, or if patient must be reclining, position camera unit above patient area to be scanned.
2. Adjust attitude of camera head so that it is facing patient squarely.
3. Using the analog mode, select a horizontal line with the greatest amplitude, then set it on HOLD. With the Focus Knob, adjust focus for distance from subject, indicated when the analog presentation takes on the sharpest peaks and valleys.
4. Switch from analog to video and observe full image presentation.
5. Select desired thermal baseline by turning red knob of Delta-T Switch.
6. Select desired thermal range of thermogram by rotating black knob of Delta-T Switch.
7. For a photographic record, press the Camera Control button.

# Predicate Device Marketing Literature

## Appendix G

*306*  
*FD*

ATTACHMENT IV



*Medical Thermograph* **JTG-500M**  
Thermoviewer



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## Specifications

### • Camera unit

Temperature measurement range: 0 to 50°C.  
 Temperature resolution: 0.05°C.  
 Frame time: 2 s (8 s when S/N is improved).  
 Lines per frame: 240 lines.  
 Reachable elements per line: 300 elements.  
 Field of view: 25° horizontally, 20° vertically.  
 Focus range: 22 cm to ∞ from camera unit front.  
 Infrared detector: HgCdTe (cooled by LN<sub>2</sub>).  
 Liquid nitrogen hold time: 3.5 hr or more.  
 Weight & dimensions: Approx. 5 kg  
 155(W) x 178(H) x 310(L) mm  
 (not including projections).

### • Display unit

Center temperature level: 0 to 50°C (in 0.1°C steps).  
 Temperature range: 0.5 to 50°C (in 0.5°C steps).  
 Display frame time: 1/60 s. (Non-interlaced TV frame rate).  
 Memory capacity

Data memory: 256 pixels x 240 pixels x 65,368 levels (depth).  
 (Data memory stores temperature information on one frame over the full temperature measurement range.)  
 Display memory: 256 pixels x 240 pixels x 64 levels (depth).  
 (Temperature information only over the temperature range to be displayed is transferred from the data memory for display.)

Number of displayed picture elements:  
 Display modes:

256 (horizontal) x 240 (vertical)  
 Normal/black-and-white inverted/step/isotherm/magnified image.

Point temperature display:

10-point temperatures/cross point temperature.

Focusing:

Auto/manual focusing.

S/N improvement:

Temperature resolution is improved twofold theretically.

Temperature level setting:

Center temperature is automatically set to the average image temperature or cursor/cross point temperature. Manual setting is available.

Power requirements:

AC 100V, 50/60Hz, 3.7A

Weight & dimensions:

Approx. 100 kg.  
 700(W) x 1018(H) x 800(L) mm  
 (not including projections).

## Optional attachments

Keyboard:

- Allows the average and highest temperature values in each specified area to be displayed on the screen (up to four areas can be specified). The highest temperature position markers are also displayed. The average temperature is calculated over an area whose temperature is higher than the selected base level.
- Allows horizontal and vertical temperature profile along the cursor lines to be displayed.
- Allows image data to be automatically stored, processed and displayed at every selected interval.
- Allows comments to be displayed.

Color monitor:

Displays images in fifteen colors on a 14-inch screen and indicates temperature differences clearly. Each color indicates its own temperature value.

VTR system:

Thermal images including their temperature information over the full temperature measurement range can be recorded on cassette tape and played back under optimum display conditions and by optimum display mode any time.

Mobile camera stand:

Driven by remote-controlled SW provided on camera unit and used conveniently for various applications, e.g., taking a picture of patients lying on bed.

45° mirror:

Mirror for downward observation.

Magnifying lens:

Can be used conveniently in observation of a very small object (length ratio 4:1).

Hand stand:

Conveniently used for observation of peripheral circulatory insufficiency of hands.

Blackbody source:

Radiation sources (27, 35, 60°C) for temperature calibration.

35mm camera system:

Replaces the Polaroid camera at display unit. This system allows photographing on 35mm film.

Arm for color monitor photographing:

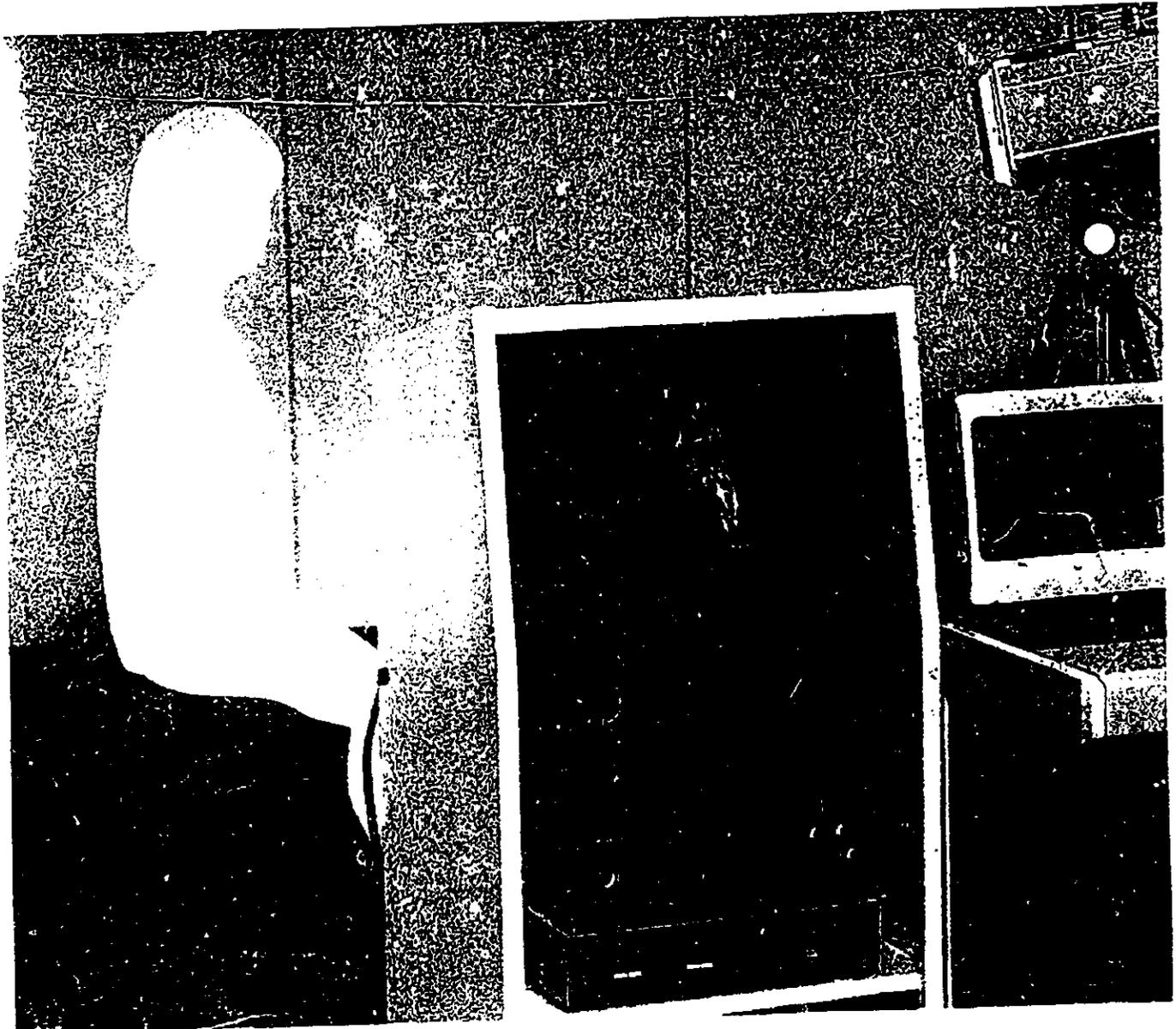
Arm for installing 35mm camera to photograph a color monitor image.

Liquid nitrogen container:

Stores liquid nitrogen coolant for the detector. Capacity 10L.

\* Specifications subject to change without notice.

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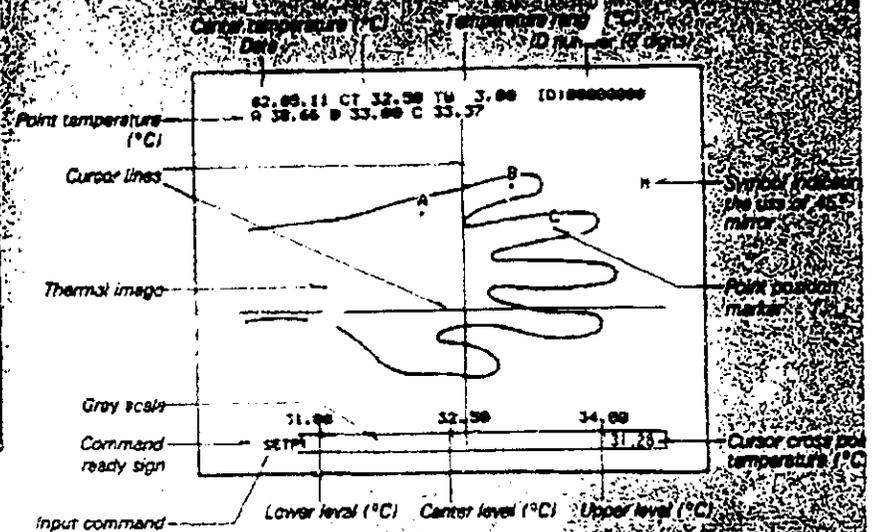
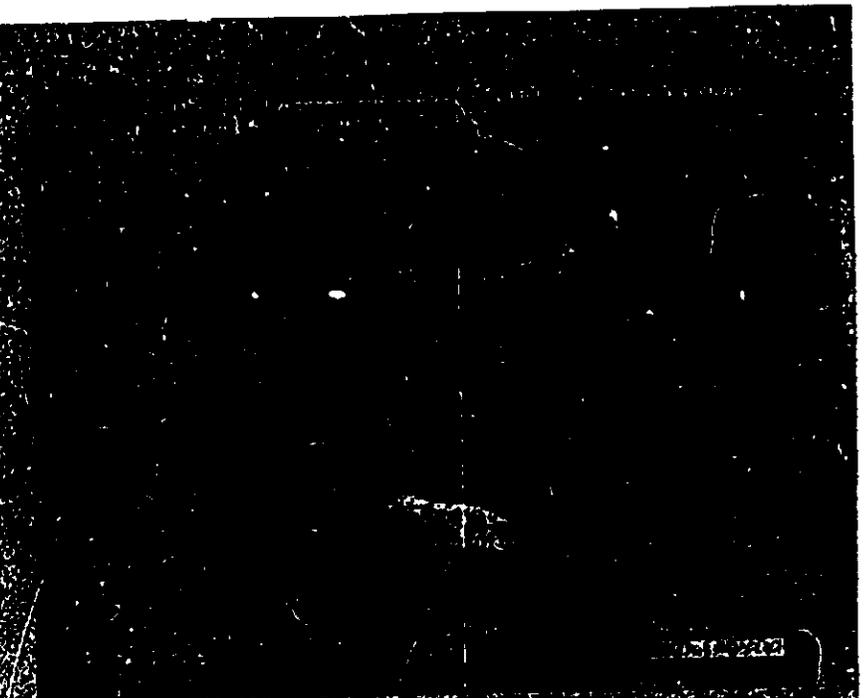
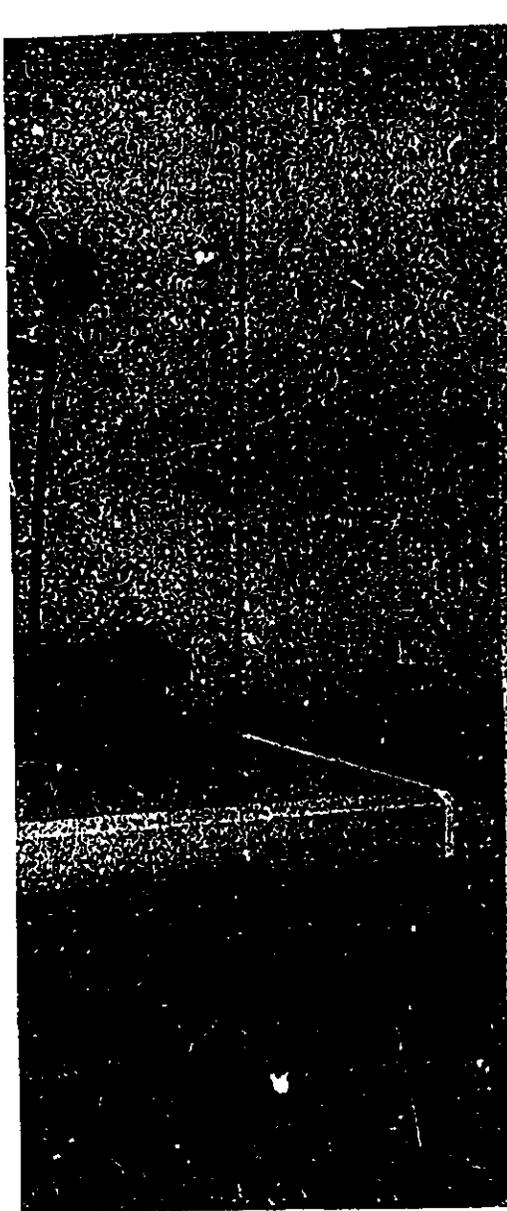


## **You can "view" temperatures temperature information on human body surfaces**

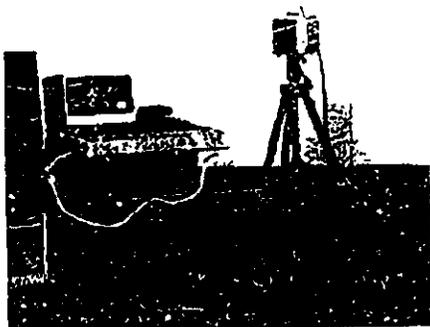
*Abnormal skin temperature is a sign of the abnormality of the body. In fact, we can tell the abnormality of the human body from skin temperatures. Measurement of the temperature of the human body has thus been a traditional method of making diagnosis. The medical "Thermoviewer" is a JEOL thermograph which displays a thermal image of the human body surface contactlessly and instantaneously in °C. The JTG-500M, a new thermograph incorporating JEOL's advanced computer technology, stores one frame of a thermal image with its temperature information in a data memory, displays the image at flicker-free TV rate under most optimum display conditions, and perform image processing.*

- The display unit that incorporates a computer ensures improved flicker-free images, and permits resetting of the display conditions and digital display of the temperature at any point on the image.*
- Automatic focusing and automatic thermal level setting have further improved operational ease.*
- A display monitor and photographing CRT are separately provided to make photography speedy.*
- The compact lightweight camera unit can be easily moved from place to place for observation or transportation.*
- The camera unit is designed in a closed unit to keep it free from dust and others.*

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with JTG-500M



**Bright, sharp, flicker-free images** — The temperature information on the patient's body is stored in the memory and the image is processed by the computer and displayed at TV frame rates. It is also possible to display the stored data under varying display conditions.

**Automatic thermal level setting function** — After the average image temperature or the cursor cross point temperature is set automatically as the center temperature.

This function allows the best image to be always displayed even when the temperature changes rapidly as in a load test.

**Ease of focusing** — Focusing is important for detection of temperature differences in a very small area. Either the automatic or manual focusing mode can be selected. The automatic focusing function permits rapid and accurate focusing in both cases.

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## Display Unit

### Display monitor

A large-size (9") CRT is used, which is best suited to observation of sharp flicker-free image.

### Switch for S/N Improvement

Temperature resolution of the thermogram can be improved by this switch twofold (theoretically).

### Operation Switches



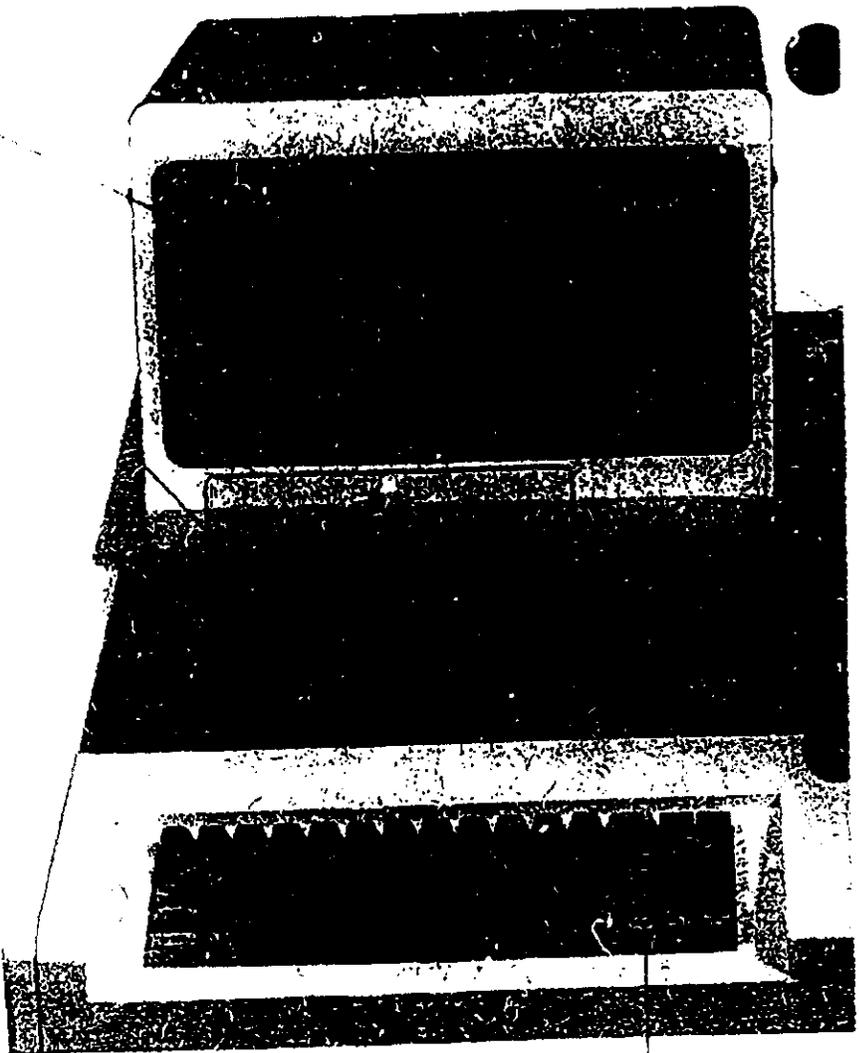
- RUN**: Stores every one frame of new data repeatedly over the full temperature measurement range.
- FOCUS**: The thermal profile is displayed on the focus monitor, and either automatic or manual focus mode can be selected.
  - AUTO**: Automatic focusing
  - MANUAL**: Manual focusing
- FRZ**: Storing of new data is suspended and the image is frozen.

### Display modes



Various display modes can be selected, in addition to normal mode. It is also possible to combine various display modes.

- INVT**: Black-and-white inverted mode
- STEP**: Step mode
- MGF**: Magnified image mode (area ratio 4:1)
- ISO**: Isotherm mode



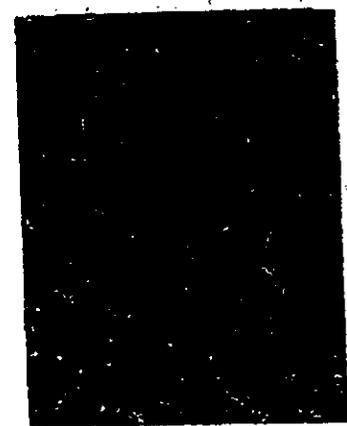
### Temperature level setting switches

In initial setting, the center temperature (CT) is set to 30°C. It is also possible to set other CTs by operation of this switch.

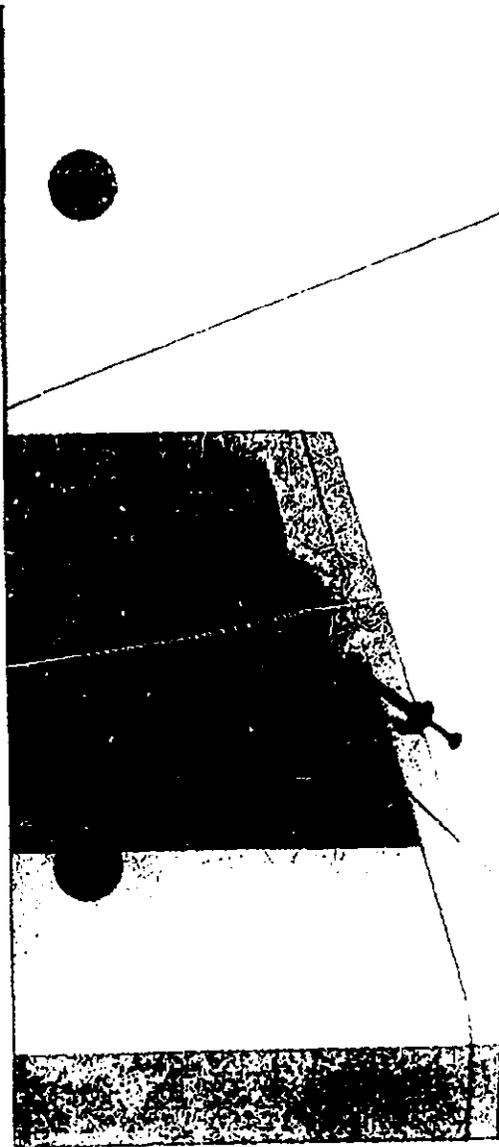
- MNL**: Can be freely set by the operator.
- AUTO**: Automatically set to the average image temperature.
- IMAG**: Automatically set to the temperature at cursor circ point.

### Keyboard

Permits image processing expansion and automatic data storing.



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**Focus monitor**



The thermal profile is displayed when the focus switch is on. "Just focus" is the point where the profile is sharpest.



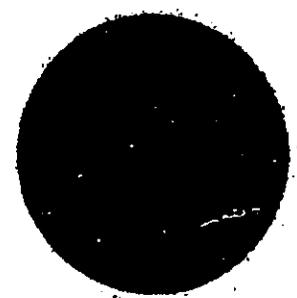
**Camera unit**  
Camera unit is used for recording the thermal image. The camera unit can be used to record from any angle and at any distance. The camera unit is used for recording thermal images.

**Photographing CRT/  
recording camera**

Photographic recording can be made easily by attaching a Polaroid camera or a 35 mm camera to the photographing CRT.

**Alarm display**

- LN<sub>2</sub> ALARM:** Tells the need to pour liquid nitrogen in to the detector.
- IN PROCESS:** Tells that the computer is in process.
- SCANNING:** Tells that the camera unit is scanning to store thermal image data.



**Data input key**

For inputting center temperature, temperature range, date, ID number, etc.

**Temperature range setting**

In initial setting, the temperature range (TW) is set to 10°C. The temperature range can be set in steps of 0.5°C by means of the TW switch.

**10-point/cross-point  
temperature display**

Up to 10 points on the image can be specified and their digital temperature values and position markers are displayed. The cursor cross point temperature is digitally displayed.



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# Display Modes

An optimum display mode can be selected according to the purpose of diagnosis or data analysis.

## Normal mode

Normal black-and-white brightness modulation display. High temperature portions are displayed in white and low temperature portions in black. The entire skin temperature distribution can be read in detail. This mode can also be used conveniently for observing diseased parts and blood vessels.

## Step mode

The thermal image is displayed in 7-gray-step scale. This mode facilitates observation of the entire temperature distributions and areas affected by disease.

## Isotherm mode

This mode allows a region of a certain temperature to be displayed with increased brightness. The isotherm region moves in real time when the isotherm level is changed.

## Black-and-white inverted mode

High temperature portions displayed in black and low temperature portions in white. (This is the inverted mode of the normal black-and-white display.) This mode makes it easy to observe a diseased portion because of contrast with the background.

## Magnified image mode

The center portion of the image is displayed at a magnification of 2X (four times in area). This mode can be used conveniently in the observation of small areas.

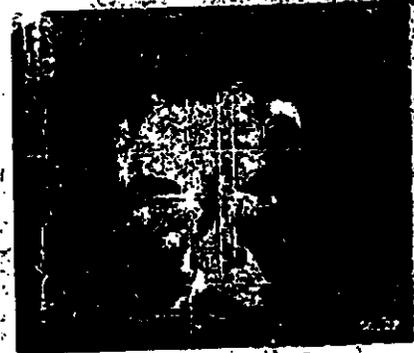
## 10-point temperature display

The temperature value of a position specified by the cursor cross point is digitally displayed. Temperature values and positions for up to 10 points can be displayed on the screen.

With the JTG-500M, it is also possible to combine various display modes.



Normal mode/10-point temperature display



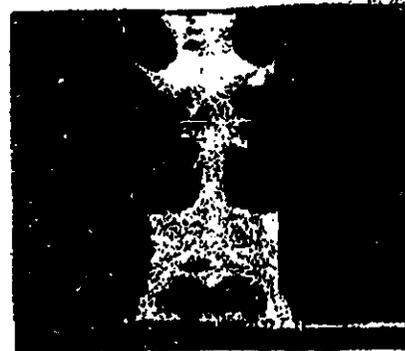
Complex display (keyboard is used)



Step mode



Isotherm mode (magnifying eye is used)



Black-and-white inverted mode



Magnified image mode (color monitor is used)



10-point temperature display



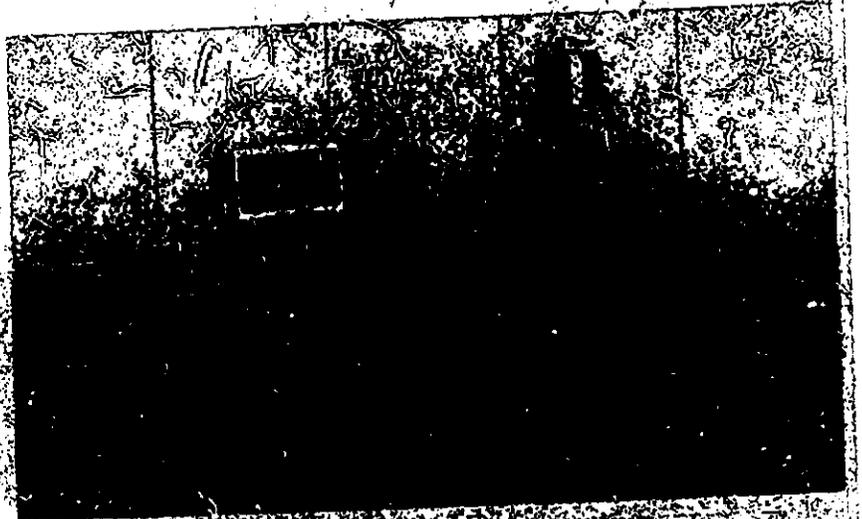
Complex display (color monitor and keyboard are used)

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## Components

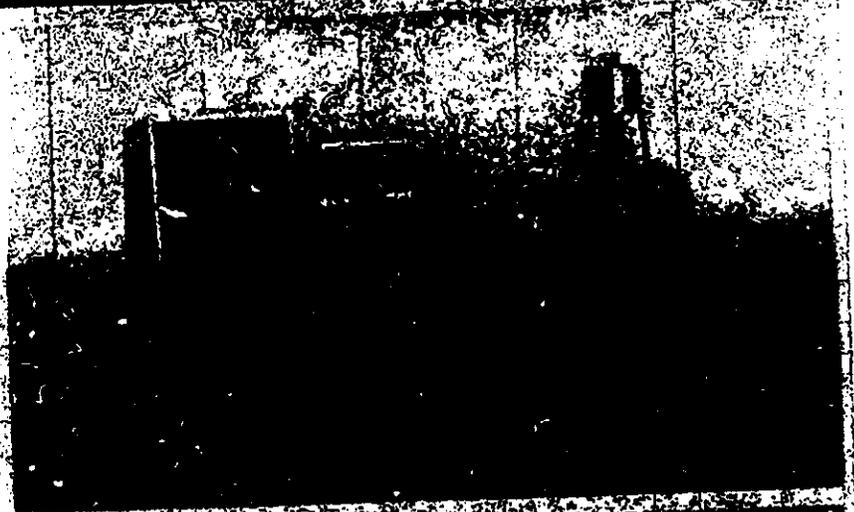
### Basic configuration

- Camera unit
- Tripod
- Operation/display unit
- Polaroid camera unit



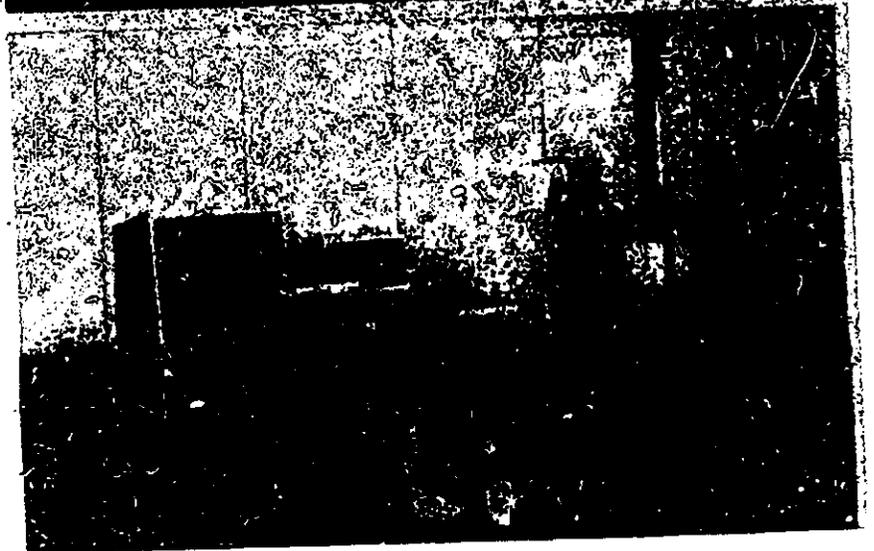
### Color monitor system configuration

- Camera unit
- Tripod
- Operation/display unit
- Color monitor
- VTR system
- 35mm camera system



### Total system configuration

- Camera unit
- 45° mirror
- Mobile camera stand
- Operation/display unit
- Polaroid camera unit
- Keyboard
- Color monitor
- Aim for color monitor photographing
- VTR system



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## Specifications

### • Camera unit

Temperature measurement range: 0 to 50°C.  
 Temperature resolution: 0.05°C.  
 Frame time: 2 s (8 s when S/N is improved).  
 Lines per frame: 240 lines.  
 Receivable elements per line: 300 elements.  
 Field of view: 25° horizontally, 20° vertically.  
 Focus range: 22 cm to ∞ from camera unit front.  
 Infrared detector: HgCdTe (cooled by LN<sub>2</sub>).  
 Liquid nitrogen hold time: 3.5 hr or more.  
 Weight & dimensions: Approx. 5 kg (165(W) × 178(H) × 310(L) mm (not including projections)).

### • Display unit

Center temperature level: 0 to 50°C (in 0.1°C steps)  
 Temperature range: 0.5 to 50°C (in 0.5°C steps)  
 Display frame time: 1/60 s (non-interlaced TV frame rate)  
 Memory capacity  
 Data memory: 256 pixels × 240 pixels × 65,536 levels (depth)  
 (Data memory stores temperature information on one frame over the full temperature measurement range.)

#### Display memory:

256 pixels × 240 pixels × 64 levels (depth)  
 (Temperature information only over the temperature range to be displayed is transferred from the data memory for display.)

#### Number of displayed picture elements:

256 (horizontal) × 240 (vertical)  
 Normal/black and white inverted/step/isotherm/magnified image.

#### Display modes:

#### Point temperature display:

10-point temperatures/cross point temperature

#### Focusing:

Auto/manual focusing  
 Temperature resolution is improved twofold theoretically.

#### S/N improvement:

#### Temperature level setting:

Center temperature is automatically set to the average image temperature or cursor/cross point temperature.  
 Manual setting is available.

#### Power requirements: Weight & dimensions:

AC 100V, 50/60Hz, 3 1/4 A  
 Approx. 100 kg  
 700(W) × 1016(H) × 800(L) mm (not including projections).

## Optional attachments

### Keyboard:

- Allows the average and highest temperature values in each specified area to be displayed on the screen (up to four areas can be specified). The highest temperature position markers are also displayed. The average temperature is calculated over an area whose temperature is higher than the selected base level.
- Allows horizontal and vertical temperature profiles along the cursor lines to be displayed.
- Allows image data to be automatically stored, processed and displayed at every selected interval.
- Allows comments to be displayed.

### Color monitor:

Displays images in fifteen colors on a 14-inch screen and indicates temperature differences clearly. Each color indicates its own temperature value.

### VTR system:

Thermal images including their temperature information over the full temperature measurement range can be recorded on cassette tape and played back under optimum display conditions and by optimum display mode any time.

### Moblie camera stand:

Driven by remote-controlled SW provided on camera unit and used conveniently for various applications, e.g., taking a picture of patients lying on bed.

### 45° mirror:

Mirror for downward observation.

### Magnifying lens:

Can be used conveniently in observation of a very small object (length ratio 4:1).

### Hand stand:

Conveniently used for observation of peripheral circulatory insufficiency of hands.

### Blackbody source:

Discrimination between fingers and background is done by putting ice water in developing tray.

### 35mm camera system:

Radiation sources (27, 35, 50°C) for temperature calibration.

### Arm for color monitor photographing:

Replaces the Polaroid camera at display unit. This system allows photographing on 35mm film.

### Liquid nitrogen container:

Arm for installing 35mm camera to photograph a color monitor image. Stores liquid nitrogen coolant for the detector. Capacity 1.5L.

\* Specifications subject to change without notice.

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**\*USA Headquarters**

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Jongro-ku, Seoul  
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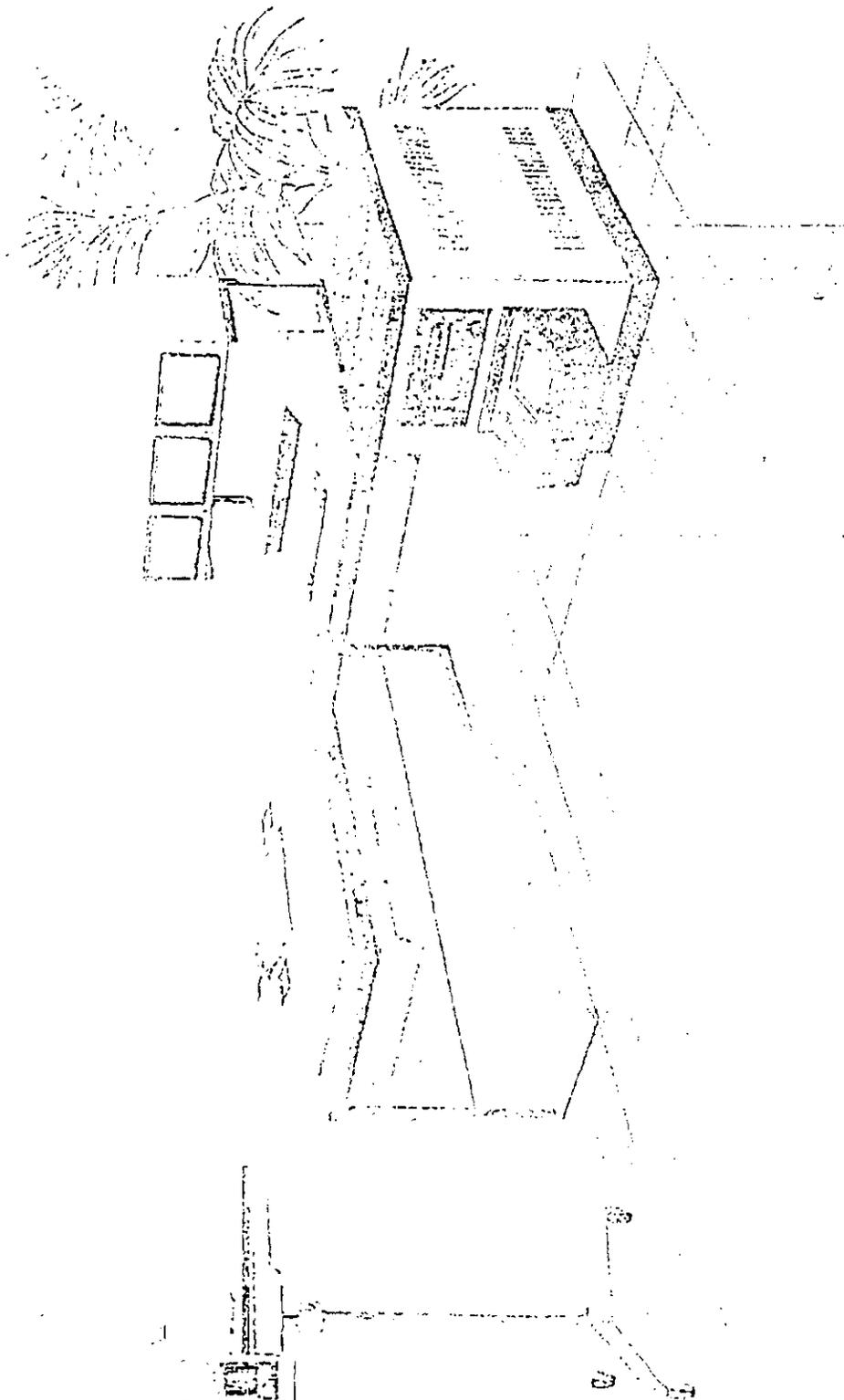
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INSTRUMENTATION SYSTEMS  
CORPORATION  
PHILADELPHIA, PENNSYLVANIA

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# DCCATS

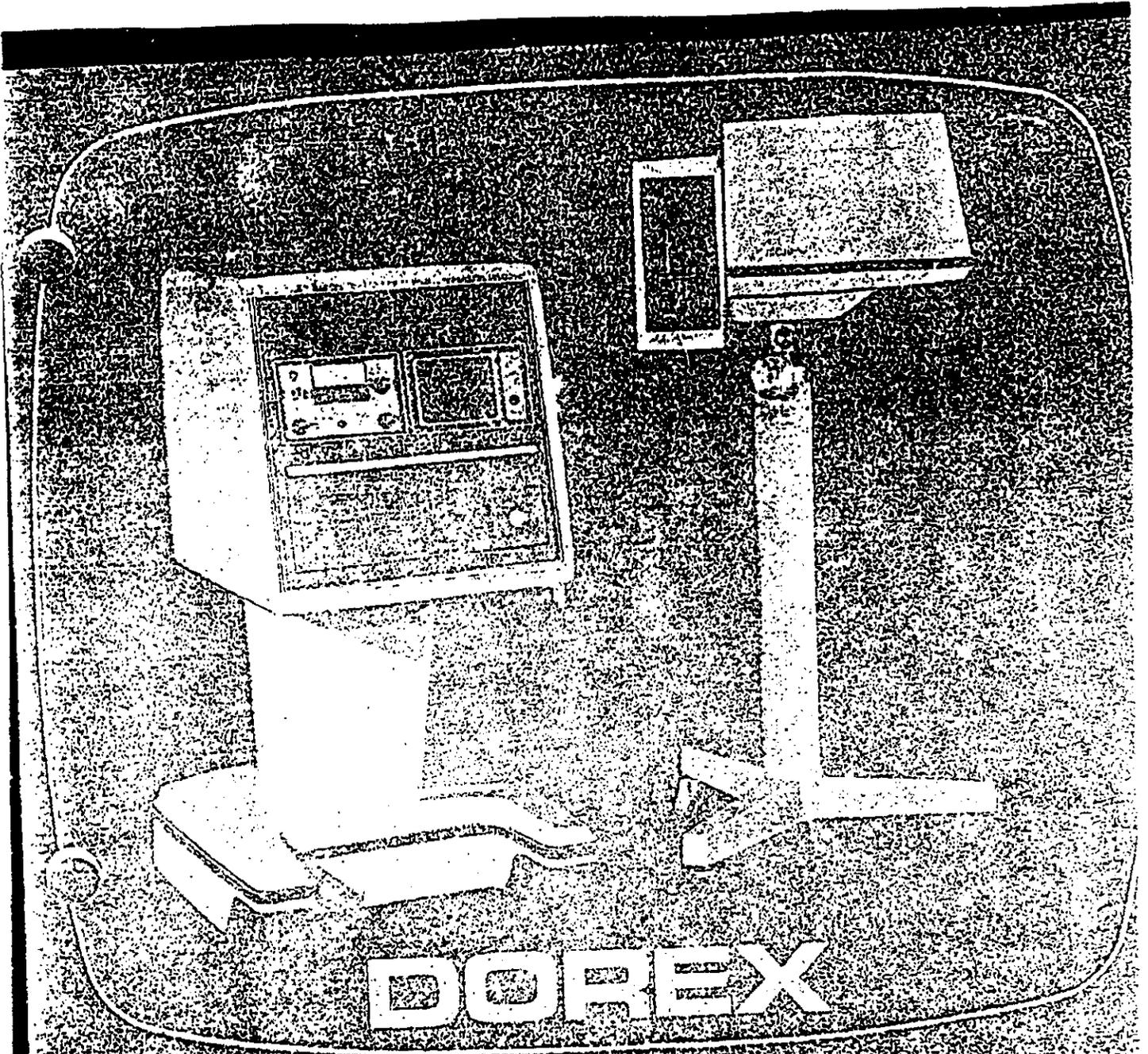
Drexel Computer Aided Thermography System (DCCATS) has been designed for a capability to: collect and analyze thermography data -- store -- retrieve -- provide video display -- hard copy printout assisting in analysis. The terminal computer system is an extremely powerful and versatile machine. Software enhancements for detailed clinical evaluation are extremely numerous.

## Now Makes it Easier ... For You!

- Symmetry measurement ... technique to measure body thermal symmetry (comparison of opposite corresponding body surfaces)
- Permanent patient information storage and retrieval
- Absolute temperature identification
- Automatic focusing assuring quality information
- Movable cursor positioner for instant temperature analysis
- Full color display

## Features

- Quantitative computer processing
- Keyboard terminal
- Selectable temperature range ± 256 gray levels
- Temperature display of selected video area
- Average temperature display of selected video area
- Symmetry measurement
- Deflection modulation
- Selectable isotherm display
- Permanent disc storage



# DOREX

## FOR THE BEST LOOK AT THERMOGRAPHY

- Rotatable Camera Head
- Exclusive Delta T Switch for Selected Thermal Ranges
- Competitively Priced
- Focal Distance as close as six inches

- No fan noise
- Electronic solid state focal plane
- Thermal resolution as high as 0.1°C
- Thermal range 200°C to 2000°C
- Operating times up to 10 hours
- Room to room facility
- Full field scan rate for recording
- Image recording on Polaroid film or video

K990416

DEC 23 1999

### 510(k) Summary

**Date of Summary Preparation:** January 29, 1999

**Manufactures Contact Person:** Mark Fauci  
President  
Tel. (516)-444-6499  
Fax. (516)-444-8825  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, NY 11790

**Trade Name:** OmniCorder BioScan System

**Classification Name, Classification Number, Class, Classification**

**Reference:**

Classification Name	Class. No.	Class	21CFR §
Telethermographic System	IYM/LHQ	I	884.2980

**Special Controls:** There are no regulatory standards or special controls applicable for this device.

**Indications for Use:** The OmniCorder BioScan System is thermal camera based imaging device intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel who will determine when use of this device is indicated, based upon their professional assessment of the patient's medical condition. The patient populations include adult, pediatric and neonatal.

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The device is for adjunctive diagnostic screening for detection of breast cancer or other uses. This device is intended for use by qualified healthcare personnel trained in its use.

**Device Description:** The OmniCorder BioScan System is an infrared camera device which provides the capability for imaging and recording of thermal data radiating from adult, pediatric and neonatal patients in numerous hospital, nursing home and clinical settings; and in the home. It is a prescription device intended for use only by health care professionals.

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

The following accessories are available for use with the device:

- 1) Computer Processing Unit (Pentium II Workstation)
- 2) Color Monitor
- 3) Color Printer
- 4) Tripod Stand

The device and its accessories are similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution.

**Substantially Equivalent Commercially Available Devices:** OmniCorder BioScan System is substantially equivalent to the following commercially available predicate devices with respect to indications for use, device design, materials, and method of manufacture.

**Substantial Equivalence Comparison:** The : OmniCorder BioScan System is similar to commercially available devices with respect to intended use, material, design and operational principles as follows:

Inframetrics, Inc., Inframetrics Infracam-Med ~ (K982327)

Bales Scientific, Inc., BSI Model Tip ~ (K897191)

JEOL Model #JTG-500M ~ (K823041)

DCATS by Dorex Inc. ~ (K812799)

1. Operational Principles: The basic operational principles of the OmniCorder BioScan System and the predicate devices measure and record, without touching the patient's skin, self-emanating infrared radiation to reveal temperature variations. The parameters that are measured and displayed are generally the same as those for the predicate devices.
2. Indications and Contraindications: Relative indications and contraindications for the OmniCorder BioScan System and commercially available devices for similar intended uses are the same.

**Assessment of non-clinical performance data for equivalence:** Currently there are no FDA standards for this device. However, the OmniCorder BioScan System complies with:

CSA Standard C22.2, No. 125-1984, Electromedical Equipment

UL544 09/1985, Underwriters Laboratories Standard for Medical and Dental Equipment

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**Conclusion:** In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, OmniCorder Technologies concludes that the new device, the OmniCorder BioScan System, is safe, effective and substantially equivalent to the predicate device as described herein.

**Table 1**

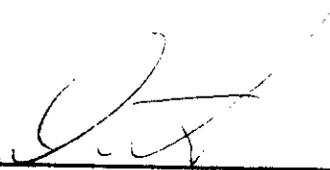
Feature	BioScan System	InfraCam-Med (K982327)	BSI Model TIP (K897191)	Jeol Model# JTG-500M (K823041)	DCATS (K812799)
Intended Use	Visualization/documentation of temperature patterns and changes				
Method of Data Collection	Non-contact Passive Infrared Emissions				
Collection Instrument	Infrared Camera				
Data Processing	CPU/Custom Algorithms				
Storage	Hard Disk	PCM/CIA card	Hard disk	Video tape	Hard disk
Detector Type	Focal Plane Array	Focal Plane Array	Single Detector	Single Detector	Single Detector
Display	Monitor/TV Printer				
User interface	Keyboard, Mouse, On-system controls	On-system controls	Keyboard, Mouse, On-system controls	Keyboard, On-system controls	Keyboard, On-system controls

**510(k) Number: K990416**

**Device Name : OmniCorder BioScan System**

**Indications for Use:**

The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.



\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K990416

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)



DEC 23 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mark Fauci  
OmniCorder Technologies, Inc.  
25 East Loop Road  
Stony Brook, New York 11790

Re: K990416  
OmniCorder BioScan System  
Dated: September 18, 1999  
Received: September 29, 1999  
Regulatory Class: I  
21 CFR 884.2980/Procode: 90 LHQ

Dear Mr. Fauci:

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 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). 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,

CAPT Daniel G. Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

325



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food And Drug Administration

Memorandum

Date: 12/27/99

reviewed by  
RAP

SE 12/23/99

Spill # 11  
Created  
12/28/99  
RJR

From: Document Mail Center (HFZ-401)

Subject: Premarket Notification Number(s): K990416/A1

To: Division Director: RA/DCAEK

The attached information has been received by the 510(k) Document Mail Center (DMC), on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below. Feel free to note any additional comments below.

Thank you for your cooperation.

Information does not change status of the 510(k); no other action required by the DMC; please add to the image file. [THE DIVISION SHOULD PREPARE A CONFIRMATION LETTER - AN EXAMPLE IS AVAILABLE ON THE LAN (K25). THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.]

Additional information requires a new 510(k) however the information submitted is incomplete. Notify the company to submit a new 510(k). [THE DIVISION SHOULD PREPARE THE (K30) LETTER ON THE LAN.]

Additional information requires a new 510(k); please process. [THIS INFORMATION WILL BE MADE INTO A NEW 510(k)].

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement of 510(k) statement).

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: [Signature]

Date: 12/28/99





OmniCorder Technologies, Incorporated

Processed by CDRH on 10-22-2015

12/11/99

25 East Loop Road  
Stony Brook, NY 11790-3350  
Fax: (516) 444-8825

www.omnicorder.com

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

12/22/99

ATTN: Dr. Robert Phillips  
Reference: 510(k) K990416, OmniCorder BioScan System

Bob,

As you requested, please find attached a hard copy of the "Indications for Use" page that I faxed to you on 12/22/1999. Please don't hesitate to call if you have any other questions.

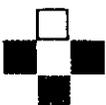
Sincerely,

Mark A. Fauci  
President and CEO

RECEIVED

DEC 23 1 39 PM '99

FDA/CDRH/DOE/DO



THE FRONT WAVE OF HEALTH TECHNOLOGY

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

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2

## Indications for Use

Page 1 of 1

**510(k) Number:** K990416

**Device Name :** OmniCorder BioScan System

### **Indications for Use:**

The OmniCorder BioScan System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult, pediatric and neonatal. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting the blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

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Tel: 631-265-5450 Fax: 631-979-2085 email:info@infraredsciences.com

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**focused on a *healthy* image**

**Infrared Sciences Corp.**

***BreastScan IR Professional  
Version 4.5***

***Operator Manual***

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## **Indications for Use**

The Infrared Sciences BreastScanIR system is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or an in environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

## **Contraindications for Use**

None Known

## **Warnings**

Do not use as an independent breast cancer diagnostic or screening method. This device is not compatible for use in an MRI magnetic field.

## **Precautions**

Do not operate without proper training. Report malfunctioning or damaged components to the manufacturer immediately.

## **Prescription**

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

## **Introduction**

Breast Scan IR is a new, non-invasive procedure offered to women, of any age, to determine current breast health, by measuring various temperature parameters in the breast. These readings are then compared to our large database, to determine overall breast health, relative to known cases. Designed exclusively by Infrared Sciences Corp., Breast Scan IR has demonstrated its effectiveness as an adjunctive tool when used in conjunction with mammography, ultrasound, and clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available to the doctor, to assist in the doctor's determination of breast health. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

Breast Scan IR uses thermographic information obtained by recording "temperature" data taken from the surface of the breast. This technology is new, and is often referred to as digital infrared imaging. It is well documented in the medical literature on past studies, that abnormalities in the breast have definite correlation with breast temperature and its response to external temperature stimulation. Breast Scan IR is able to measure these variations in great detail to not only indicate that there is an abnormality, but also to determine its relative location. The procedure then compares the measured data to a large database of known patient parameters,

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and generates a report for the doctor with the parameter variance for the patient being tested. No data is “read” or “interpreted” by the doctor, but is quantified by the computer, and provided to the doctor in a report format.

BreastScan IR™ is intended to be an adjunctive procedure and does not replace mammography or ultrasound<sup>1</sup>. Currently, the best indication of an abnormality is through corroboration of different procedures. BreastScan IR™ will draw attention to areas that may not have been detected with standard mammograms. Also, it can localize areas that can be further investigated using ultrasound technology. For younger women, BreastScan IR™ can track breast health and provide healthy baselines to be used for comparison purposes in the future.

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<sup>1</sup> Infrared Imaging for adjunctive use in detecting breast cancer has been FDA approved. However the BreastScan IR system does not yet have 510k approval

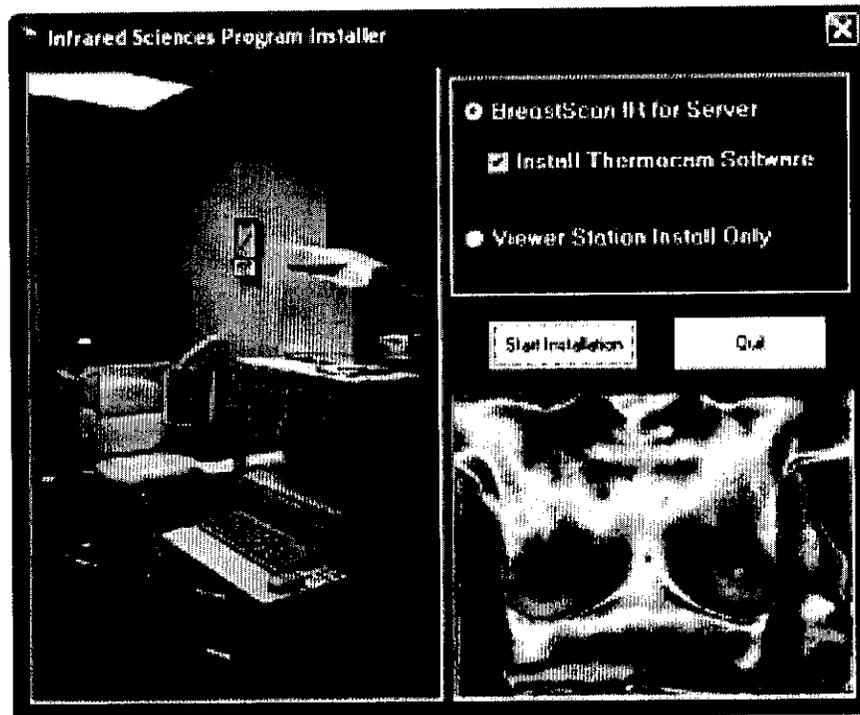
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## Installation

**Warning:** Do not install any software other than Windows XP and ThermaCam Researcher 2002. Any use of this software other than those specified will violate the safety, effectiveness and design controls of this medical device and any such use may result in increased risk to users and patients.

Every BreastScan system is delivered with an installation CD. This CD contains all of the required software for running both the BreastScan IR Server and remote viewing clients.

To begin the installation, place the CD in the CD-ROM Drive of the PC. The system should automatically run the BreastScan installation utility. If the setup program does not automatically run, it can be run manually by double clicking on "Install.exe" located on the CD.



If the system being installed is the server (collocated with the infrared device) click on BreastScan IR for Server option. Thermocam is a requirement for the server to operate correctly and must be installed prior to running the BreastScan IR software. Select the "Install Thermocam Software" option if Thermocam is not already installed. If Thermocam is already installed, uncheck this option.

As a remote viewer client, simply click the Viewer Station Install Only option.

When the desired options are selected, press "Start Installation" to install. In most cases, the operator may complete the installations using all default settings. For advanced users, the

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program path may be altered. Upon completing the installation, the new programs will appear by pressing the “Start” button in Windows, clicking “Programs”, and then selecting “BreastScan IR”. For convenience purposes, the user may also decide to make a shortcut for the desired program on the desktop.

## **System Requirements**

### **Local Server**

The local server is defined as the PC and ancillary equipment required for conducting a complete BreastScan IR procedure.

The system requirements are as follows:

1. PC with Windows XP Professional operating system
2. ThermaCam Researcher 2002
3. FireWire (IEEE 1394) Interface on PC
4. USB 2.0 Interface on PC
5. Network Interface (10/100 MB)
6. Optional Wireless 802.11b Interface if needed for network connectivity
7. 256MB RAM, 40GB HD, 80GB removable HD and chassis
8. Video Card capable of 1024/768 resolution
9. Monitor (1024/768), mouse, keyboard
10. Optional color printer
11. Infrared Imaging Device (IEEE 1394 Interface)
12. BreastScan IR medical chair/positioning equipment
13. Internet connectivity (either broadband or dial-up)
14. Cool air source (i.e. air conditioner) with X10 control equipment
15. Optional power strip/surge protection

### **Remote Viewer Station**

The remote viewer station is defined as PC that is networked to the Local Server for the purpose of viewing results obtained by the Local Server. There may be any number of Remote Viewer Stations connected to a Local Server.

1. PC with Windows XP Professional operating system
2. ThermaCam Researcher 2002
3. Network Interface (wireless 802.11b or standard 10/100MB NIC)
4. 128MB RAM, 40GB HD
5. Video Card (1024/768)
6. Monitor, mouse, keyboard
7. Optional Printer
8. Optional power strip/surge protection

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BreastScan IR is a software application developed using Microsoft development tools exclusively and is designed to operate on Windows XP operating systems. All standard Microsoft Windows conventions are incorporated into the BreastScan IR application.

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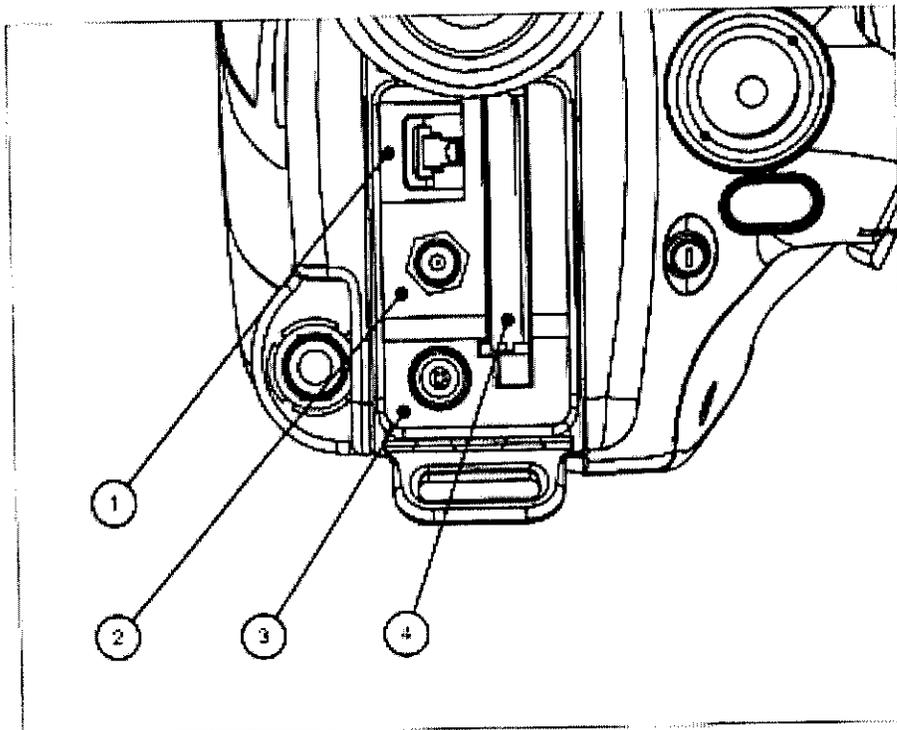




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## ***Infrared Camera Connections (S40/S60)***

The following diagram indicates the input/output ports of the infrared imaging device. Note that the CompactFlash slot indicated by (4) is not used for BreastScan IR.



**Figure 5.4** Connectors (cover removed).

- ① FireWire™ out
- ② External power in
- ③ C-VHS out
- ④ CompactFlash™ slot

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## **Components of the BreastScan IR Procedure**

A complete BreastScan IR procedure contains two separate components. These components are *Session Recording* and *Session Processing*, both of which are achieved through the BreastScan IR software application. At no time during either portion is there any radiation, compression or any other invasive procedures.

### **Session Recording**

The *Session Recording* component of BreastScan IR must be completed before the *Session Processing* can begin. This part of the procedure requires the patient to be present for the entire session (approximately 4 minutes). During this time, the software will instruct the infrared device to capture thermographic images of the patient. In addition, this procedure will also command the cooling device to activate and deactivate at the appropriate times. During the procedure, the software will guide the operator through the session recording. When the software has completed the recording, it will inform the operator and the *Session Recording* part of BreastScan IR is complete. At this time, the patient is no longer required. For complete details on performing a session recording, refer to **Appendix A: Recording a New Session**.

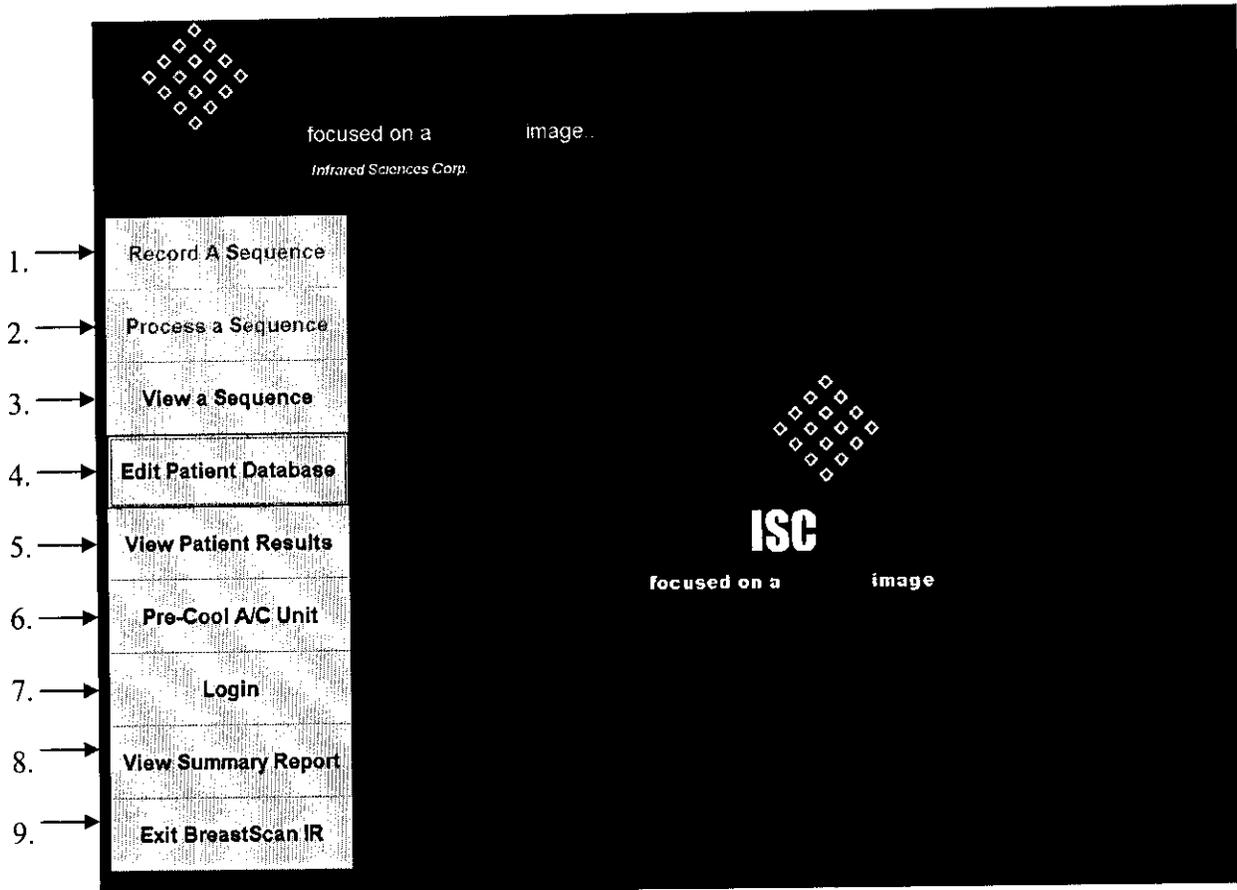
### **Session Processing**

*Session Processing* can begin at any time after the *Session Recording* has completed. The purpose of this component is to analyze the information obtained by the *Session Recording* portion of BreastScan IR. The software will allow the operator to select the session that is to be processed. At this point the software will guide the operator through all the steps of processing the recording. At the conclusion of the processing, the software will ask the operator if the results of the processing should be saved. If the operator chooses to save the process, the software will save and display the results. The results can also be printed at this time. For complete details, refer to **Appendix B: Processing a Pre-Recorded Session**.

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## BreastScan IR Main Application Window

The BreastScan IR application is launched by double-clicking the icon labeled "BreastScan IR 4.5", after which, the following screen appears:



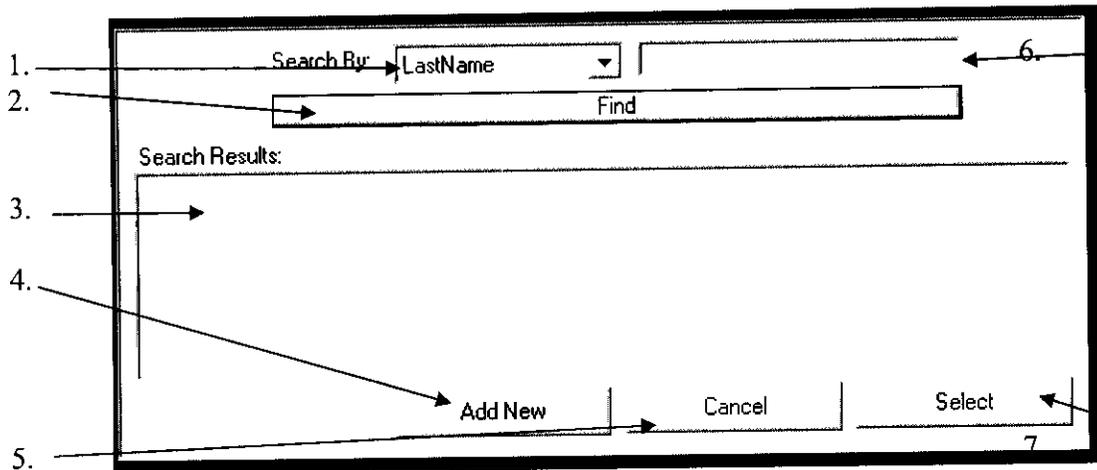
### Legend:

1. Record A Sequence – Starts the recording wizard. The user must be logged in to access this feature.
2. Process A Sequence – Starts the processing wizard. The user must be logged in to access this feature.
3. View A Sequence – Allows the user to view raw infrared video that has been recorded.
4. Edit Patient Database – Allows the user to add, edit, or delete patient information.
5. View Patient Results – Starts the ResultsViewer Application.
6. Pre-Cool A/C Unit – Turns the air conditioner on for approximately 3 minutes.
7. Login- Allows the user to log into the system.
8. View Summary Report – Allows the user to produce reports on standard patient demographics or test results.
9. Exit- Allows the user to exit the application.

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## Patient Database Form

The patient database form is accessed automatically from multiple locations within BreastScan IR. In addition, the operator may choose to see this form manually by pressing the button labeled “Edit Patient Database” on the main application window. In order to display patient information, a patient must be chosen first or a new patient must be entered. The following describes the functions of the patient search form and the patient information form.



### Legend:

1. Search Criteria – Choose from the list the criteria to search for (Last name, ID, Telephone Number)
2. Find – Searches the database for any instances of search text within the search criteria field.
3. Search Results – displays all matches after pressing “Find”
4. Add New – The patient does not exist so the operator can add a new patient.
5. Cancel – Quit Search
6. Search Text – Enter the search text to search for in the search criteria field of the database.
7. Select – Select the patient currently highlighted in the Search Results box.

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The screenshot shows a patient entry form with the following fields and controls:

- 1. Last Name: [Text Field]
- 2. DOB: [Date Field]
- 3. [History Checkbox]
- 4. [Both Breasts Checkbox]
- 5. Address: [Text Field]
- 6. City: [Text Field]
- 7. Telephone: [Text Field]
- 8. Current Notes: [Text Area]
- 9. New Notes: [Text Area]
- 10. Add New [Button]
- 11. Edit [Button]
- 12. Find... [Button]
- 13. First Name: [Text Field]
- 14. MI: [Text Field]
- 15. ID: [Text Field]
- 16. Ethnicity: [List Box]
- 17. [Both Nipples Checkbox]
- 18. State: [List Box]
- 19. ZIP: [Text Field]
- 20. [Buttons: Add Note, Cancel]
- 21. [Buttons: Add Note, Cancel]
- 22. [Buttons: Add Note, Cancel]
- 23. [Buttons: Add Note, Cancel]
- 24. [Buttons: Add Note, Cancel]
- 25. [Buttons: Add Note, Cancel]
- 26. [Buttons: Add Note, Cancel]
- 27. [Buttons: Add Note, Cancel]

Legend:

1. Patient Last Name
2. Patient Date of Birth
3. History Checkbox – Check if the patient has had breast cancer before
4. Both Breasts – Indicate if the patient has 2 normal breasts (no reconstruction)
5. Patient address
6. Patient city
7. Patient telephone number
8. Notes – Current notes entered for the selected patient
9. New Notes – When in edit mode, the operator can enter a new patient note here and then press “Add Note” to add to the Notes field.
10. Add New – this button allows the operator to enter a new patient
11. Edit – Allows the operator to edit any information of the current patient
12. Find...- The operator can use this feature to select a different patient
13. Patient first name
14. Patient middle initial
15. Patient ID number
16. Ethnicity Selection List – This control allows the operator to select an ethnicity for the patient.
17. Ethnicity – Indicates the current ethnicity of the patient. (Not a required field)
18. Both Nipples - Indicate if the patient has 2 normal nipples (no reconstruction)
19. Patient State
20. Patient Zip Code

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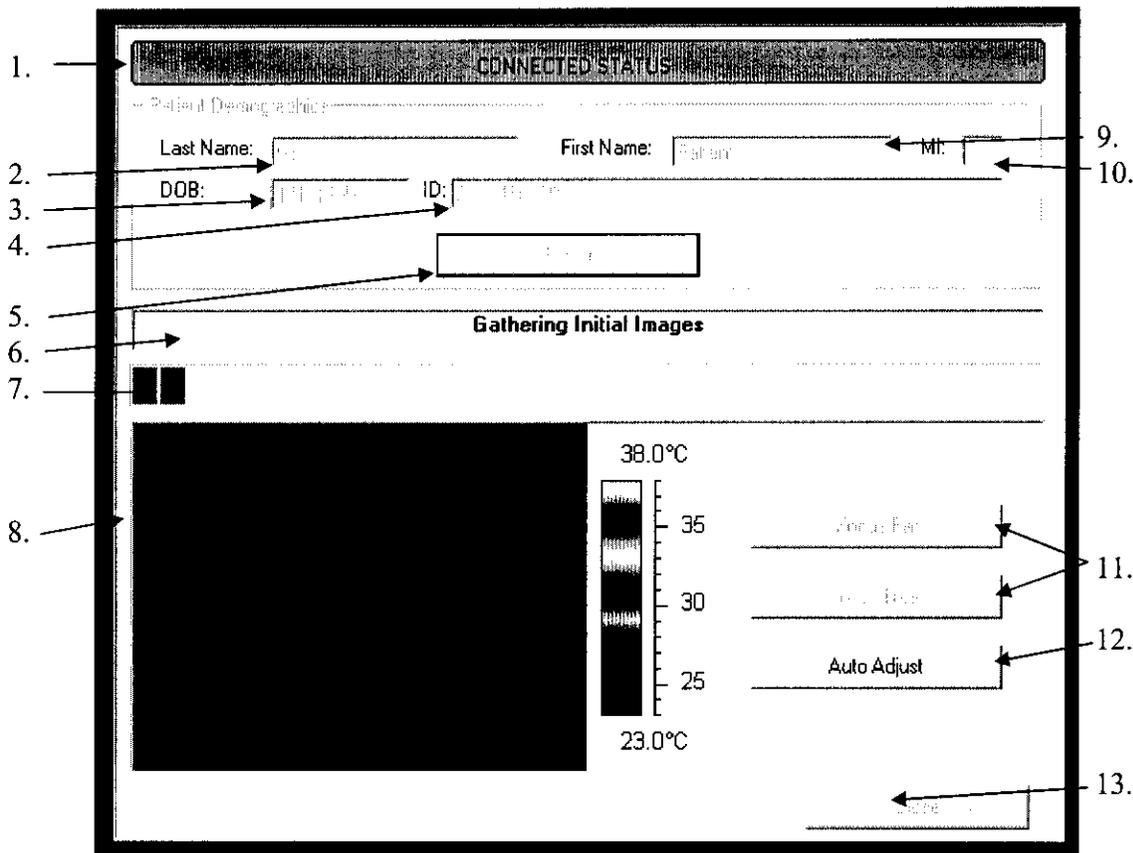
21. Edit Notes – The operator may edit the “Notes” field directly while in edit mode by pressing this button.
22. Add Note – Adds the note indicated in the “New Notes” field along with a date and time stamp.
23. Save – Either saves a new patient or changes made to an existing patient.
24. Delete – Deletes the currently selected patient.
25. OK – Exits the patient information form.
26. Cancel Add New – Use this button to cancel the “Add New” operation and return to select an existing patient.
27. Cancel – Aborts the current operation performed by BreastScan IR (either session recording or session processing)

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## New Session Recording Wizard

Upon pressing the “New Sequence” button on the main application window and selecting a patient, the “New Session Wizard” screen will appear. It contains the following features:



Legend:

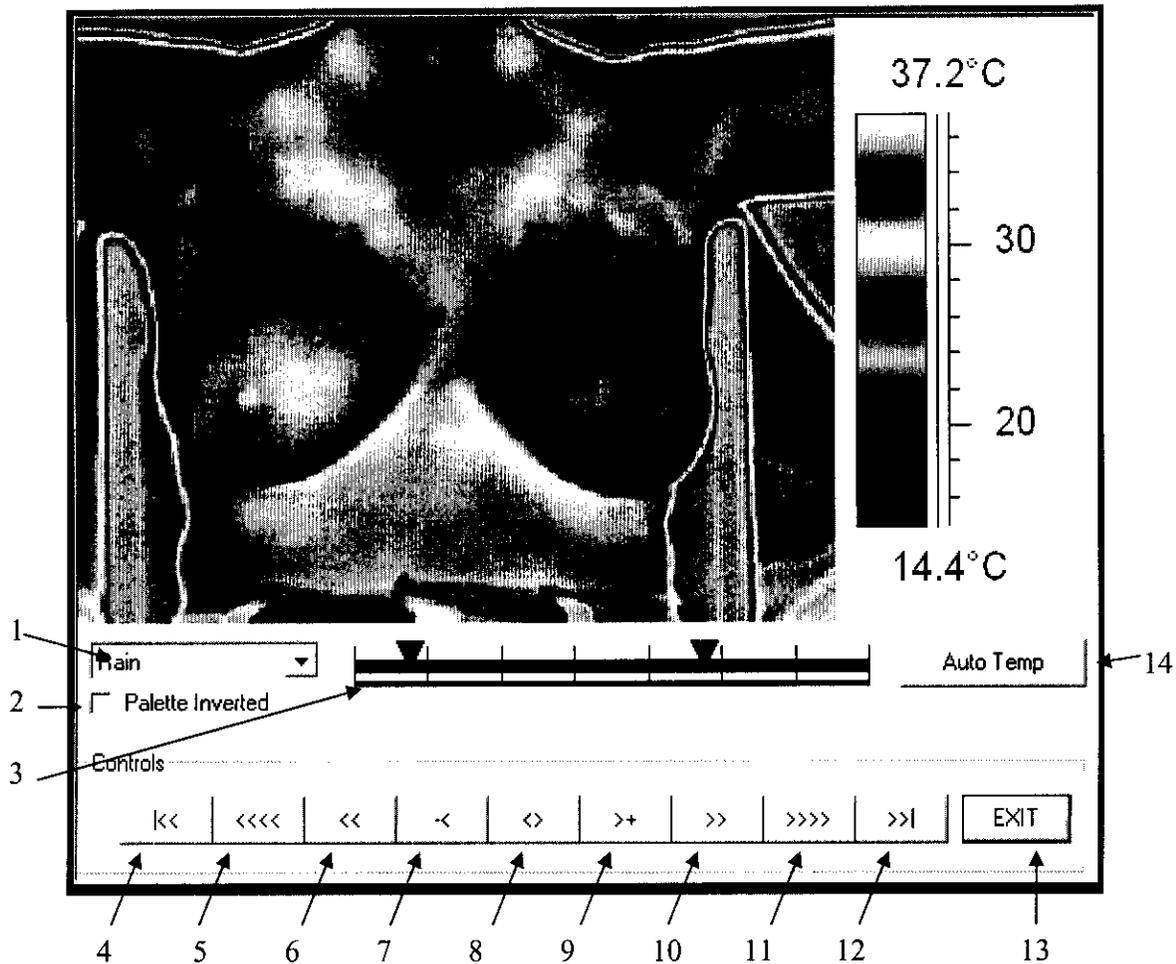
1. Connected Status – Indicates if the infrared imaging device is connected or not
2. Patient Last Name
3. Patient Date of Birth
4. Patient Identification Number
5. Begin Button – Press this button to start the new recording
6. Text Status Indication
7. Progress bar indicating overall progress
8. Live raw infrared window
9. Patient First Name
10. Patient Middle Initial
11. Camera Focus Control – Use these buttons to focus camera

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12. Auto Color Adjust – Press this button to auto adjust the camera settings to default conditions.
13. Close – Exits the New Sequence Wizard

## Sequence Viewer



### Legend:

1. Palette Selection – This list displays the available palettes to be used during processing. This is strictly for presentation and does not affect test results.
2. Palette Inversion – Allows the operator to invert the selected palette. Again, this is for presentation purposes only.
3. Color Contrast Control – The operator may adjust the red and blue markers in order to adjust the colors in the displayed picture. This tool may help identify features of the breast more easily. Note that this feature is only used for presentation purposes.
4. Go to beginning of recording
5. Play recording backwards quickly

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6. Play recording backwards
7. Step back one frame
8. Stop
9. Step forward one frame
10. Play recording
11. Fast forward recording
12. Go to end of recording
13. Exit screen
14. Auto Temp – This button adjusts the Temperature Window settings to default predetermined settings.









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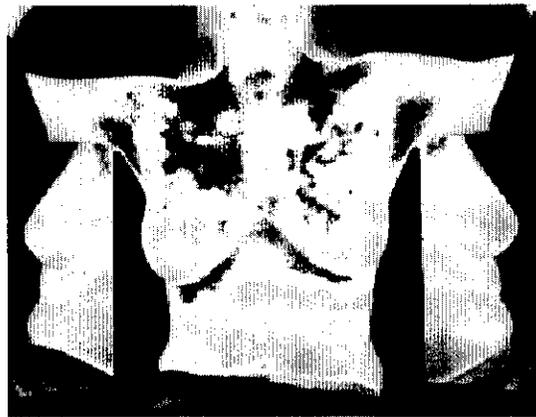
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## ***Risk of Corrupted data***

There are several steps to performing an accurate recording sequence as well as an accurate test results sheet. It is absolutely essential that the BreastScan IR operator is aware of the critical issues that may result in inaccurate data.

### **Session Recording**

Before actually beginning a new recording session, the operator must insure that the patient is correctly positioned. This includes assuring both breasts are visible on the television monitor and positioning the mirrors to properly reflect the lateral sides of the breast into the infrared imaging device. Also, be sure that there are no “non-essential” objects being reflected in the mirrors, such as other people, windows, or other heat generating devices. Below indicates a properly positioned patient.



**Correctly Positioned Patient**



**Incorrectly Positioned Patient**



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## **Appendix A: Recording a New Sequence**

1. Start “BreastScan IR” by double-clicking the icon labeled **“BreastScan IR”** on the desktop of the PC.
2. Be sure that the TV and the IR Camera are turned on. A live infrared picture should be visible on the TV.
3. After the introduction screen disappears, the main application window will appear. Press the button labeled **“Record A Sequence”**. Press **“Yes”** when the confirmation appears.
4. The patient selection form will now appear. You must either search for an existing patient or enter a new one.
  - **For an existing patient**, you may search by last name, telephone number or patient ID. Select from the dropdown list the criteria to search as well as the text to search for. For example, to search for John Smithfield, select **“LastName”** from the pull down list, type in “smith” and press **“Find”**. The system will now display all patients that contain “smith” in their last name. The text is not case sensitive. To select a patient, double-click on the desired patient or press the **“Select as Patient”** button. The patient’s information will now appear on the patient information form. If you selected a patient in error, you may press **“Find...”** and you will be allowed to select a different patient.
  - **For a new patient**, press **“Add New”**. A blank patient information form will appear. Enter all required information and press **“Save”**. If you pressed the **“Add New”** button in error, you may return to patient selection by pressing the **“Cancel Add New”** button on the patient information form.

Whether it is a new or existing patient, the information may be edited by pressing **“Edit”**. Keep in mind **“\*”** means the field is required. After pressing **“Edit”** you may modify the existing patient notes field by pressing the **“Edit Notes”** button. Then press **“Save Notes”** when completed. If you wish to add notes while editing a patient, type the new note in the field labeled **“New Notes”**, then press **“Add Note”**. You will be prompted to confirm your selection. The note will be added with a time-date stamp. Information may now be permanently saved by pressing **“Save”**. After all information is confirmed correct, press **“OK”** to continue. You also may press **“Cancel”** to completely abort the procedure and return to the main application window.

5. The **“New Sequence Wizard”** now appears. The live infrared image should appear at the bottom of the screen. If the infrared image does not appear, there may be a hardware problem or the camera may be turned off. Check these items and restart the PC.
6. Use the **“Focus Near”** and **“Focus Far”** buttons to adjust the focus so that the image appears focused in the infrared window. In addition, you may tap the **“A”** button on the top of then camera to auto adjust the colors. The camera may be auto focused by pressing and

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- holding the “A” button on the camera until you hear the camera start to auto focus. Then you may release the button.
7. Instruct the patient to position the infrared target so that it is located on the cross hairs located on the TV screen. Also inform the patient to be as still as possible for the duration of the test (approx. 4 min).
  8. Press the “*Begin*” button. You will be asked if you prefer voice prompting. Selecting “*Yes*” will cause the program to prompt you and the patient throughout the test. Pressing “*No*” will keep the system silent.
  9. The Status window will indicate “*Gathering Initial Images*”, then change to “*TURN ON AIR NOW*”. The A/C unit will now turn on and the system will begin to countdown from 3:30 to 0:00. If the A/C does not turn on, there may be a hardware problem or the unit may have to be turned on manually.
  10. There will be no change for about 3 minutes. The status will indicate “*Finishing*”, the A/C will turn off and the status will read “*Complete*”. If a message appears that indicates that the session creation failed, the test experienced a system problem and must be retaken at a later date. Please call ISC if this occurs.
  11. After a moment, the screen will close and the main application window will appear. You may choose to process the results immediately by pressing “*Yes*” when prompted or you may process this patient at a later date. At this point you may record another session or process a different patient by following “*The BreastScan IR Step-by-Step ... Processing a Recorded Session.*”

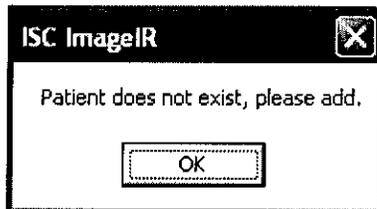
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## **Appendix B: Processing a Recorded Session**

1. Start BreastScan IR™
2. It is not necessary to have the TV on or the camera on in order to process an image. After the introduction screen disappears, the main application window will appear. You will have to log in before you can process a recording. After logging in press the **"Process A Recording"** button on the main screen.
3. You will then be prompted to select the recording you wish to process. The recordings are stored in folders labeled by recording date and within each date in folders by patient last name. Select the recording you wish to process and press **"Open"** to continue.
4. After pressing the **"Open"** button, the software will search the patient database for a patient who is associated with the sequence file. If the software cannot find a match, you will be prompted to add a new patient .



5. Once either an existing patient was found or a new patient was added, the patient information form will appear. Confirm that all information is correct. If modifications must be made, press **"Edit"**, make the changes, then press **"Save"**. When all information is confirmed correct, press **"OK"**.

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Last Name:	<input type="text" value="John"/>	First Name:	<input type="text" value="Robert"/>	MI:	<input type="checkbox"/>
DOB:	<input type="text" value="1/15/1905"/>	ID:	<input type="text" value="0123456789"/>		
<input checked="" type="checkbox"/> History of Breast Cancer	Ethnicity:		<input type="text" value=""/>		
<input checked="" type="checkbox"/> Patient has had breast exams	<input checked="" type="checkbox"/> Patient has had mammograms				
<input type="checkbox"/> Patient does NOT have breast exams	<input type="checkbox"/> Patient does NOT have mammograms				
Address:	<input type="text" value="35000 Main Ln."/>				
City:	<input type="text" value="Newburgh, NY"/>	State:	<input type="text" value="NY"/>	ZIP:	<input type="text" value="12550"/>
Telephone:	<input type="text" value="845-340-1234"/>				
Current Notes:	<input type="text"/>				
New Notes:	<input type="text"/>				<input type="button" value="Add Notes"/>
<input type="button" value="Add Note"/>					
<b>* - Indicates Required Field</b>					
<input type="button" value="Add New"/>	<input type="button" value="Edit"/>	<input type="button" value="Find..."/>	<input type="button" value="Save"/>	<input type="button" value="Delete"/>	<input type="button" value="OK"/>
<input type="button" value="Add Address"/>				<input type="button" value="Cancel"/>	

6. The "Target Selection Box" now appears. The software will attempt to locate the thermal target automatically. If it is successful skip to step 9. If it is unsuccessful a message box will appear. Simply continue with step 7 in that case.
7. "Select the Center of the target" will now be highlighted. Click the center of the thermal target to continue.

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## Appendix D: BreastScan IR Specifications

<p><b>Cart</b></p> <ul style="list-style-type: none"> <li>• <u>Overall Dimensions:</u> 36.25" W x 26"D x 70" H</li> <li>• <u>Shelf Dimensions:</u> 23.75"W x 21.5"D                         <ul style="list-style-type: none"> <li>○ <u>Base Shelf:</u> 4.5"H</li> <li>○ <u>Air Conditioner Shelf:</u> 24"H</li> <li>○ <u>Camera Shelf:</u> 39"H</li> <li>○ <u>Television Shelf:</u> 55"H</li> </ul> </li> <li>• <u>Keyboard Shelf:</u> 20"W x 11.25"D x 37"H</li> </ul> <p><b>Computer</b></p> <ul style="list-style-type: none"> <li>• <u>Network Connections:</u> Wireless, CAT-5</li> <li>• <u>Camera Data Interface:</u> FireWire IEEE 1394</li> <li>• <u>Air Conditioner Control:</u> 9-pin Serial Port</li> <li>• <u>Primary Hard Drive:</u> 20Gig Minimum</li> <li>• <u>Secondary Hard Drive:</u> 80Gig Minimum</li> <li>• <u>Processor:</u> Pentium IV 1-GHz Minimum</li> <li>• <u>Operating System:</u> Windows XP Professional</li> <li>• <u>Office Studio:</u> Microsoft Office XP</li> <li>• <u>Display:</u> 15" LCD Monitor</li> </ul> <p><b>Cold Air Source</b></p> <ul style="list-style-type: none"> <li>• 5,250 BTU/h</li> <li>• <u>Electrical Specs:</u> <ul style="list-style-type: none"> <li>○ <u>Power Usage:</u> 540W</li> <li>○ <u>Operating Voltage:</u> 115v*</li> <li>○ <u>Operating Amperage:</u> 5.0A</li> <li>○ <u>Operating Frequency:</u> 60Hz*</li> </ul> </li> </ul> <p><b>Video Monitor/Recorder</b></p> <ul style="list-style-type: none"> <li>• <u>Viewable Screen:</u> 13"</li> <li>• <u>Video Input:</u> Standard RCA connector</li> <li>• <u>Electrical Specs:</u> <ul style="list-style-type: none"> <li>○ <u>Operating Voltage:</u> 120v*</li> <li>○ <u>Power Usage:</u> 60W</li> <li>○ <u>Operating Frequency:</u> 60Hz*</li> </ul> </li> </ul> <p><i>* European power requirements are also available</i></p>	<p><b>Camera</b></p> <p><b><u>Imaging Performance</u></b></p> <ul style="list-style-type: none"> <li>• <u>Field of View/Min focus distance:</u> 24° x 18° /0.3 m (.98ft)</li> <li>• <u>Spatial Resolution:</u> 1.3mrad</li> <li>• <u>Thermal sensitivity @ + 30° C:</u> 0.08°C</li> <li>• <u>Image Frequency:</u> 50/60 Hz, non-interlaced</li> <li>• <u>Electronic Zoom:</u> 2x, 4x- interpolating</li> <li>• <u>Focusing:</u> Automatic or Manual</li> <li>• <u>Digital Image Enhancement:</u> Adaptive Digital Noise Reduction</li> </ul> <p><b><u>Detector</u></b></p> <ul style="list-style-type: none"> <li>• <u>Type:</u> Focal Plane Array (FPA), uncooled microbolometer 320,240 pixels</li> <li>• <u>Spectral Range:</u> 7.5-13µm</li> </ul> <p><b><u>Image Presentation</u></b></p> <ul style="list-style-type: none"> <li>• <u>Viewfinder:</u> Built in high resolution LCD</li> </ul> <p><b><u>Measurement</u></b></p> <ul style="list-style-type: none"> <li>• <u>Temperature range:</u> -40 - +120°</li> <li>• <u>Precision:</u> 0.05°C – 14 Bit Digital</li> </ul> <p><b>Power System</b></p> <ul style="list-style-type: none"> <li>• <u>AC Operation:</u> 90-260VAC, 50/60Hz, 12VDC Out</li> </ul> <p><b>Environmental Specifications</b></p> <ul style="list-style-type: none"> <li>• <u>Operating Temperature Range:</u> -15-+50 °C</li> <li>• <u>Storage Temperature Range:</u> -40-+70°C</li> <li>• <u>Humidity:</u> 10-95% non-condensing</li> <li>• <u>Encapsulation:</u> IP 54 (IEC 529)</li> <li>• <u>Shock:</u> 25g, IEC 68-2-29</li> <li>• <u>Vibration:</u> 2g, IEC 68-2-6</li> </ul> <p><b>Physical Characteristics</b></p> <ul style="list-style-type: none"> <li>• <u>Weight:</u> 1.4kg incl. battery</li> <li>• <u>Size (L x W x H):</u> 220 x 120 x 100 mm</li> <li>• <u>Tripod Mounting:</u> Standard 1/4"-20</li> </ul> <p><b>Interfaces</b></p> <ul style="list-style-type: none"> <li>• <u>Power Input:</u> 10-16VDC 2.1mm connector</li> <li>• <u>Video Output:</u> Standard RCA connector</li> <li>• <u>FireWire:</u> IEEE 1394</li> <li>• <u>Removable Storage:</u> CompactFlash™ card</li> </ul>
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# Infrared Sciences Corp.



focused on a healthy image

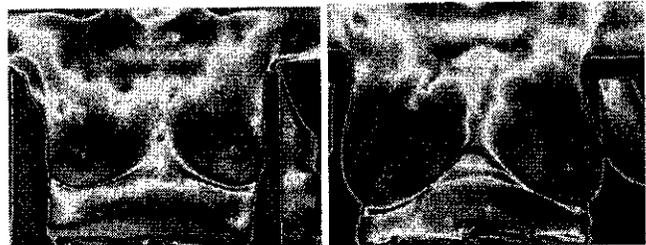
## BreastScan IR™

BreastScan IR™ is a new, non-invasive procedure offered to women, of any age, to determine current breast health by measuring various temperature parameters in the breast. Designed exclusively by Infrared Sciences Corp., BreastScan IR™ has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

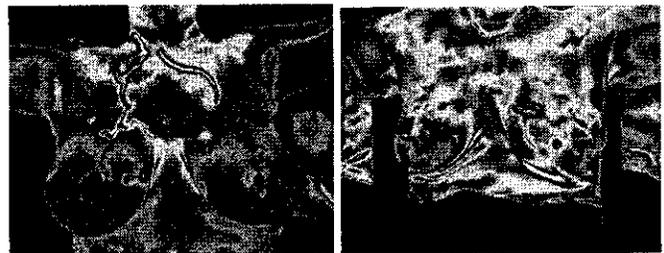
### BreastScan IR™ System Features

- Automated software requires only basic computer skills to operate
- Remote troubleshooting and diagnostic capability
- Automatic software updates/upgrades
- Automatic update of evaluation algorithm
- System is designed to "learn" as more tests are run
- Automatic billing and tracking
- Real time reporting to doctor in easy to read format
- Remote client terminal for doctor's use
- Fully wireless LAN connection for instant network access
- Secure data transfer over internet or dial-up
- Highly sensitive state-of-the-art infrared camera
- Off the shelf high speed workstation and client terminal allows easy hardware upgrades in the future
- Automatic secure download of results and database information to ISC server

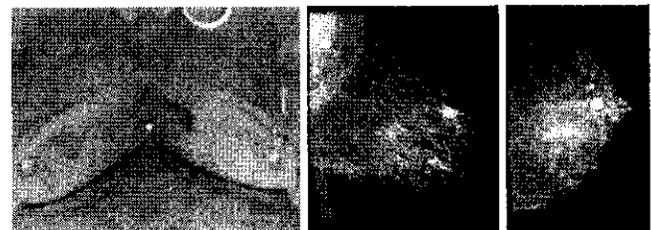
### Sample Result Images



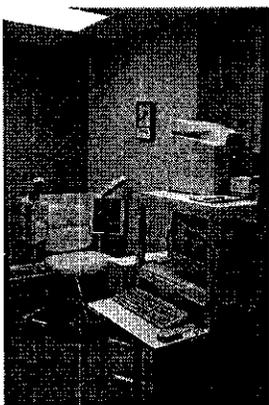
Examples of "normal" infrared images



Examples of "abnormal" infrared images



BreastScanIR™ results and corresponding mammography



BreastScan IR

*BreastScan IR Patient Analysis Results*

Name:	Doc: Jane	Comments:
ID:	1234567890	No Selection between
Report Date:	01/07/2002 IR Date: 01/02/2002	None known of breast cancer in patient's life
	3:08 PM	4:28:18 PM

Measured Edge	Value	Range	Evolution	Comments
Thermal	42.2	10 - 74.4 - 74.4	Normal	
Right	42.1	10 - 74.4 - 74.4	Normal	
Arms	45	10 - 74.4 - 74.4	Normal	Left breast
Clubs	58	10 - 74.4 - 74.4	Normal	Right breast
Asymmetry	48.5	10 - 74.4 - 74.4	Normal	Left breast
Four Hot Spots	16	10 - 74.4 - 74.4	Normal	
Five Hot Spots	18	10 - 74.4 - 74.4	Normal	
Hot Spots	1	10 - 74.4 - 74.4	Hot	

Sample Patient Results

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## Hardware Manuals

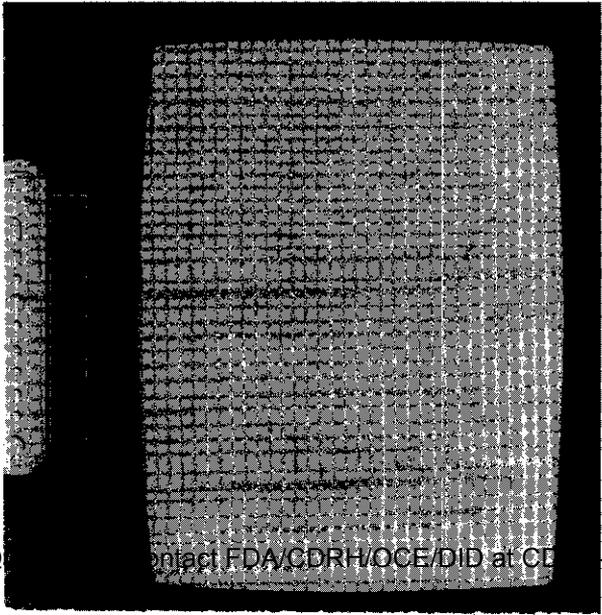
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# TV/VCR Combination Unit Owner's Manual

CXM1974  
CXM1374

3609



# IMPORTANT SAFETY INSTRUCTIONS

Save These Instructions



## Warning! Important Safety Instructions

**CAUTION**  
RISK OF ELECTRIC SHOCK  
DO NOT OPEN

**CAUTION:** TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE COVER (OR BACK). NO USER SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL.

This symbol indicates high voltage is present inside. It is dangerous to make any kind of contact with any inside part of this product.



This symbol alerts you that important literature concerning operation and maintenance has been included with this product.



**Note to CATV system installer:** This reminder is provided to call CATV system installer's attention to Article 820-40 of the National Electrical Code (Section 54 of Canadian Electrical Code, Part I), that provides guidelines for proper grounding and, in particular, specifies that the cable ground shall be connected to the grounding system of the building as close to the point of cable entry as practical.

**Caution:** FCC regulations state that any unauthorized changes or modifications to this equipment may void the user's authority to operate it.

**Caution:** To prevent electric shock, match the wide blade of plug to the wide slot, and fully insert the plug.

**Attention:** Pour éviter les chocs électriques, introduire la lame le plus large de la fiche dans la borne correspondante de la prise et pousser jusqu'au fond.

**Important:** One Federal Court has held that unauthorized recording of copyrighted TV programs is an infringement of U.S. copyright laws.

**To prevent damage which may result in fire or electric shock hazard, do not expose this appliance to rain or moisture.**

As an ENERGY STAR Partner, Samsung Electronics America, Inc. has determined that this product or product model meets the ENERGY STAR guidelines for energy efficiency.

## Important Safety Information



Always be careful when using your TV/VCR. To reduce the risk of fire, electrical shock, and other injuries, keep these safety precautions in mind when installing, using, and maintaining your machine.

- Read all safety and operating instructions before operating the TV/VCR.
- Retain the safety and operating instructions for future reference.
- Heed all warnings on the TV/VCR and in the operating instructions.
- Follow all operating and use instructions.
- Unplug the TV/VCR from the wall outlet before cleaning. Use a damp cloth; do not use liquid or aerosol cleaners.
- Never add any attachments and/or equipment without approval of the manufacturer. Such additions may result in the risk of fire, electric shock, or other personal injury.
- Do not use the TV/VCR where contact with or immersion in water is a possibility, such as near bath tubs, sinks, washing machines, swimming pools, etc.
- Provide ventilation for the TV/VCR. The unit is designed with slots in the cabinet for ventilation to protect it from overheating. Do not block these openings, and do not place the TV/VCR on a bed, sofa, rug, or other similar surface. Do not place it near a radiator or heat register. If you place the TV/VCR on a rack or bookcase, ensure that there is adequate ventilation and that you've followed the manufacturer's instructions for mounting.

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# IMPORTANT SAFETY INSTRUCTIONS

Save These Instructions

## Important Safety Information, *continued*



Do not place the TV/VCR on an unstable cart, stand, tripod, bracket, or table. The TV/VCR may fall, causing serious injury to a child or adult, and serious damage to the unit. Use only with a cart, stand, tripod, bracket, or table recommended by the manufacturer or sold with the TV/VCR. Follow the manufacturer's instructions when mounting the unit, and use a mounting accessory recommended by the manufacturer. Move the TV/VCR and its cart with care. Quick stops, excessive force, and uneven surfaces may cause the unit and cart to overturn.

Operate your TV/VCR only from the type of power source indicated on the marking label. If you are not sure of the type of power supplied to your home, consult your appliance dealer or local power company.

Use only a grounded or polarized outlet. For your safety, this TV/VCR is equipped with a polarized alternating current line plug having one blade wider than the other. This plug will fit into the power outlet only one way. If you are unable to insert the plug fully into the outlet, try reversing the plug. If the plug still doesn't fit, contact your electrician to replace your outlet.

Protect the power cord. Power supply cords should be routed so that they are unlikely to be walked on or pinched by items placed on or against them. Pay particular attention to cords at plugs, convenience receptacles, and the point where they exit from the unit. Unplug the TV/VCR from the wall outlet and disconnect the antenna or cable system during a lightning storm or when left unattended and unused for long periods of time. This will prevent damage to the unit due to lightning and power-line surges.

- Avoid overhead power lines. An outside antenna system should not be placed in the vicinity of overhead power lines or other electric light or power circuits or where it can fall into such power lines or circuits. When installing an outside antenna system, be extremely careful to keep from touching the power lines or circuits. Contact with such lines can be fatal.
- Do not overload the wall outlet or extension cords. Overloading can result in fire or electric shock.
- Do not insert foreign objects through openings in the unit, as they may touch dangerous voltage points or damage parts. Never spill liquid of any kind on the TV/VCR.

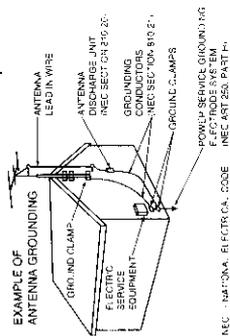
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# IMPORTANT SAFETY INSTRUCTIONS

Save These Instructions

## Important Safety Information, continued

- Ground outdoor antennas. If an outside antenna or cable system is connected to the TV/VCR, be sure the antenna or cable system is grounded so as to provide some protection against voltage surges and built-up static charges. Section 810 of the National Electrical Code, ANS/NFPA No. 70-1984, provides information with respect to proper grounding of the mast and supporting structure, grounding of the lead-in wire to an antenna discharge unit, size of grounding conductors, location of antenna-discharge unit, connection to grounding electrodes, and requirements for the grounding electrode.



- Do not attempt to service the TV/VCR yourself. Refer all servicing to qualified service personnel. Unplug the unit from the wall outlet and refer servicing to qualified service personnel under the following conditions:
  - when the power-supply cord or plug is damaged
  - if liquid has been spilled on or objects have fallen into the unit
  - if the TV/VCR has been exposed to rain or water
  - if the TV/VCR does not operate normally by following the operating instructions
  - if the TV/VCR has been dropped or the cabinet has been damaged
  - when the TV/VCR exhibits a distinct change in performance

- If you make adjustments yourself, adjust only those controls that are covered by the operating instructions. Adjusting other controls may result in damage and will often require extensive work by a qualified technician to restore the TV/VCR to normal.
- When replacement parts are required, be sure the service technician uses replacement parts specified by the manufacturer or those that have the same characteristics as the original part. Unauthorized substitutions may result in additional damage to the unit.
- Upon completion of any service or repairs to this TV/VCR, ask the service technician to perform safety checks to determine that the TV/VCR is in a safe operating condition.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference that may cause undesired operation.

This television receiver provides display of television closed captioning in accordance with §15.119 of the FCC rules.

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**IMPORTANT SAFETY INSTRUCTIONS**

Save These Instructions

**Important Safety Information, continued**

- 1) Read these instructions.
- 2) Keep these instructions.
- 3) Heed all warnings.
- 4) Follow all instructions.
- 5) Do not use this apparatus near water.
- 6) Clean only with dry cloth.
- 7) Do not block any ventilation openings. Install in accordance with the manufacturer's instructions.
- 8) Do not install near any heat sources such as radiators, heat registers, or other apparatus (including amplifiers) that produce heat.
- 9) Do not defeat the safety purpose of the polarized or grounding-type plug. A polarized plug has two blades with one wider than the other. A grounding type plug has two blades and a third grounding prong. The wide blade or the third prong are provided for your safety. If the provided plug does not fit into your outlet, consult an electrician for replacement of the obsolete outlet.
- 10) Protect the power cord from being walked on or pinched particularly at plugs, convenience receptacles, and the point where they exit from the apparatus.
- 11) Only use attachments/accessories specified by the manufacturer.
- 12) Use only with cart, stand, tripod, bracket, or table specified by the manufacturer, or sold with the apparatus. When a used, caution when moving the cart/apparatus combination to avoid injury from tip-over.
- 13) Unplug this apparatus. When a cart is used, use caution when moving the cart/apparatus combination to avoid injury from tip-over.
- 14) Refer all servicing to qualified service personnel. Servicing is required when the apparatus has been damaged in any way, such as power-supply cord or plug is damaged, liquid has been spilled or objects have fallen into the apparatus, the apparatus has been exposed to rain or moisture, does not operate normally, or has been dropped.



**DOUBLE INSULATED** - When servicing use only identical replacement parts.

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IMPORTANT SAFETY INSTRUCTIONS

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## CHAPTER ONE LEARNING ABOUT YOUR NEW TV/VCR

### List of Features

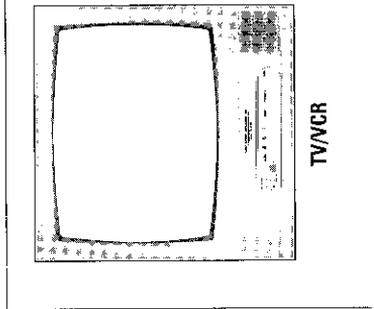
Your Samsung TV/VCR was designed and engineered using the latest technology. This TV/VCR is a full-featured, high-performance unit that not only meets, but exceeds, industry standards. Along with the standard features you expect, Samsung has included the following special features:

- Easy-to-operate infrared remote control
- Easy-to-use on-screen menu system you can use from the front panel or the remote control
- Closed captioning
- On-screen programmed recording of up to six events in one year
- Digital auto-tracking
- Repeat play
- Infra-red wireless remote control system
- Quick-start, full loading system
- High-speed rewinding
- High-quality video circuitry
- 181-channel capability (frequency synthesized tuner)
- Auto channel programming
- One-touch recording (up to four hours)
- Eight-hour recording on a single T-160 video cassette
- Auto clock setting
- Rental picture plus
- Tri-lingual on-screen displays (English, Spanish, and French)
- V-chip feature
- Jet-search

### Checking Parts

Once you have unpacked your TV/VCR, check to make sure that you have all the parts shown here. If any piece is missing or broken, call your dealer.

(The TV illustration shown does not necessarily match the design of your TV set.)



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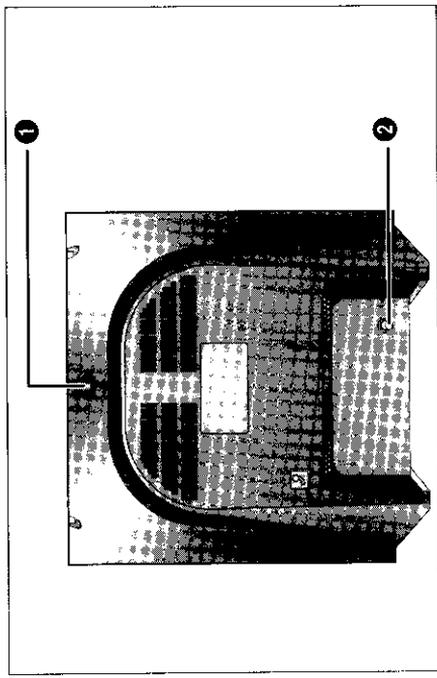


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LEARNING ABOUT YOUR NEW TV/VCR

Understanding the Controls, *continued*

Rear Panel



- 1 VHF antenna mount**  
VHF rod antenna mount.  
See page 6.
- 2 Antenna terminal**  
Use this terminal (VHF/UHF IN FROM ANT) to connect the TV/VCR to a 75-ohm outdoor antenna or cable system. See page 6.

# LEARNING ABOUT YOUR NEW TV/VCR

## Understanding the Controls, continued

### Remote Control

Use the remote control within 33 feet (10 meters) of the TV/VCR and point it directly at the TV/VCR.

### 1 POWER

Press to turn the TV/VCR on and off.

### 2 Number buttons

Press to select specific channels.

### +100

Press to select channels over 100.

### 4 REW (rewind)

Press to rewind a tape.

### 5 STOP

Press to stop a tape.

### 6 PLAY

Press to play a tape.

### 7 FF (fast forward)

Press to fast forward a tape.

### 8 CLEAR

Press to correct programming errors, clear programs, or reset the tape counter.

### 9 -VOL and VOL+ (Volume)

Press - VOL to decrease or VOL+ to increase the volume.

### 10 CH▲ and CH▼ (channel)

Press CH▲ or CH▼ to change channels. Also used with the menu system.

### 11 MENU

Press to display the on-screen menu.

### 12 DISPLAY

Press to show on-screen displays.

### 13 LINE IN

Press to select the component connected to the Audio/Video jacks.

### 14 PRE-CH (previous channel)

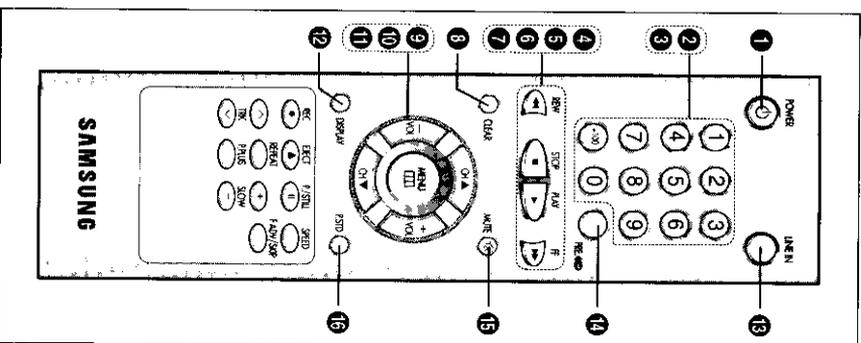
Press to return to the last channel viewed.

### 15 MUTE

Press to silence the volume.

### 16 PSTD (picture-standard)

Press to select memorized or standard picture settings.



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**CHAPTER TWO  
INSTALLATION**

**Connecting VHF and  
UHF Antennas**

If you do not have cable TV, you must connect an antenna to your TV/VCR. First you need to identify your antenna's lead type:

If you are using the antenna that has 300-ohm twin flat leads, (see the illustration below) see "Antennas With 300-ohm Flat Twin Leads," on this page.



If your antenna has a 75-ohm round lead (see the illustration below), see "Antennas With 75-ohm Round Leads," on this page.

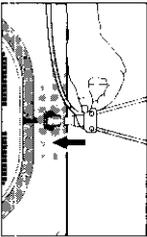


If you have two antennas, see "Separate VHF and UHF Antennas," on this page.

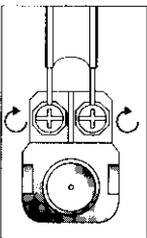
**Antennas With 300-ohm  
Flat Twin Leads**

If you use a different 300-ohm antenna with twin flat leads, follow the directions below, but skip step 1.

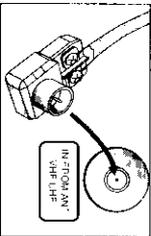
1 Push the stem of the rod antenna into the antenna mount.



2 Place the wires from the twin leads under the screws on the 300-75 ohm adapter (not supplied). Use a screwdriver to tighten the screws.



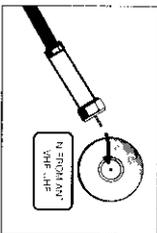
3 Plug the adapter into the terminal on the rear panel of the TV/VCR.



Extend the antenna and adjust it for the clearest picture. To reduce the risk of damage, only adjust the antenna by moving the black plastic base.

**Antennas With 75-ohm  
Round Leads**

1 Plug the lead into the terminal on the rear panel of the TV/VCR.



**Separate VHF and UHF  
Antennas**

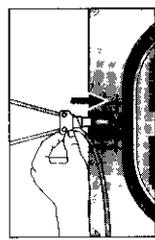
If you have two separate antennas for your TV/VCR (one VHF and one UHF), you must combine the two antenna signals before connecting them to the TV/VCR. This procedure requires a combiner attachment that you can purchase at an electronics store.

**INSTALLATION**

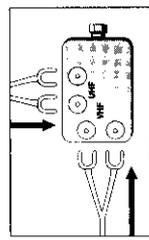
**Connecting VHF and UHF Antennas, continued**

If you use a different 300-ohm antenna with twin flat leads, follow the directions below, but skip step 1.

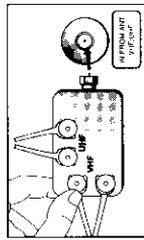
**1** Push the stem of the rod antenna into the antenna mount.



**2** Connect both antenna leads to a combiner.



**3** Plug the combiner into the antenna terminal on the rear panel of the TV/VCR.



**Connecting Cable TV Systems to the TV/VCR**

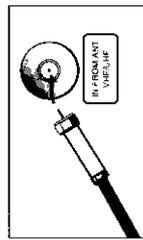
Choose one of the sections below for connecting a cable system.

✓ This TV/VCR is cable-ready; you don't need a converter for basic cable channels.

**Cable Without a Converter Box**

To connect cable without a converter box:

**1** Plug the incoming cable into the terminal on the rear panel of the TV/VCR.

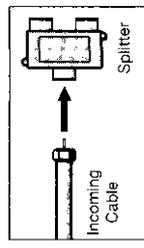


**Cable With a Converter Box**

If your cable company scrambles some channels and requires you to use a converter box for only those channels, use these instructions.

You will need the following pieces of equipment, which you can purchase from an electronics store:

- A two-way splitter
  - An RF (A/B) switch
  - Four lengths of coaxial cable
- 1** Plug the incoming cable into the 2-way splitter.

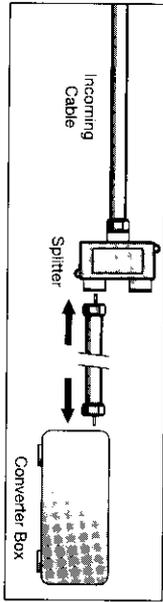


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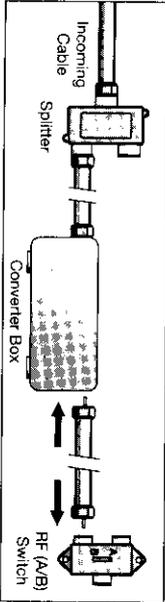
**INSTALLATION**

**Connecting Cable TV Systems  
to the TV/VCR, continued**

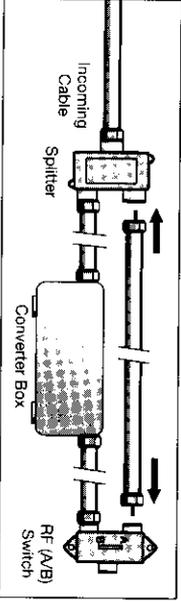
2 Connect one of the coaxial cables between the splitter and the input on the converter box.



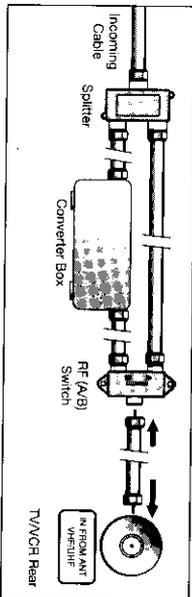
3 Connect a second coaxial cable between the output of the converter box and the "B" input on the RF (A/B) switch.



4 Connect a third coaxial cable between the splitter and the "A" input on the RF (A/B) switch.



5 Connect the fourth coaxial cable between the output on the RF (A/B) switch and the terminal on the TV/VCR's back panel.



Choose the "A" position on the A/B switch to select all non-scrambled channels by remote control. Choose the "B" position on the A/B switch to select scrambled channels via the converter box. When using the "B" position, tune your TV/VCR to the output channel of the converter box (usually channel 3 or 4).

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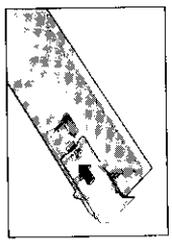
**INSTALLATION**

**Installing Batteries in the Remote Control**

**1** Open the battery compartment by pressing down on the back cover's tab, then lifting up.



**2** Install two AAA size batteries. Make sure to match the + and - ends of the batteries with the diagram inside the compartment.



**3** Replace the cover.

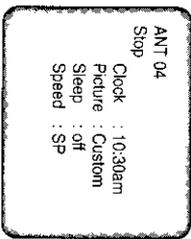


- ✓ If you won't be using the remote control for a long time, remove the batteries and store them in a cool, dry place.
- ✓ Batteries last for about one year.

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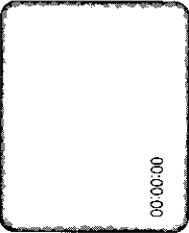
## Viewing the On-screen Display

The on-screen displays automatically appear on the screen when you turn the TV/MCR on or change its status (from stop to play, from play to stop, etc.). You can also activate the on-screen displays manually by using the remote control.



✓ This display disappears from the screen within ten seconds.

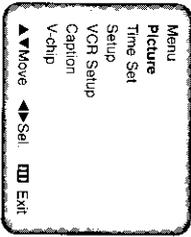
2 Press DISPLAY again (while the display items are still on the TV/MCR screen) to display the time counter.



Press DISPLAY once more to remove all displays from the screen and return to normal viewing.

## Viewing the Main Menu

1 With the power on, press MENU.



The main menu appears on the screen. Press MENU again to remove the main menu from the screen.

The menu will disappear from the screen in less than thirty seconds if you don't press any buttons on the remote.

## Selecting the On-screen Language

On-screen text can appear in English, Spanish, or French.

1 Press MENU to display the menu.

2 Press CH▲ until "Setup" is selected. Press VOL+.



3 Press CH▼ until "Language" is selected. Press VOL- or VOL+ to select the on-screen language you want.



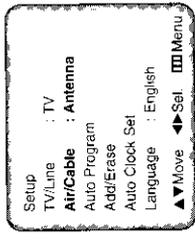
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# TV OPERATION

## Selecting the Signal Source

The first step in programming your TV/VCR is to select the signal source of your antenna or cable TV system.

- 1 Press MENU to display the menu.
- 2 Press CH▼ until "Setup" is highlighted. Press VOL+.



- 3 Press VOL- or VOL+ to select "Antenna," "Cable STD," "Cable HRC," or "Cable IRC."

- ✓ If your TV/VCR is connected to an antenna, select "Antenna." If you have cable TV, select "Cable STD," "Cable HRC," or "Cable IRC," depending on the type of cable system you have.

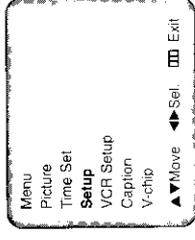
## Programming the Channels

### Storing Channels in Memory

Your TV/VCR can automatically memorize all the channels you receive. Once they are in memory, you can use CH▲ and CH▼ to select channels without using the number buttons.

- ✓ Before you can store channels in memory, you must have already selected the signal source. See "Selecting the Signal Source" on this page.

- 1 Press MENU to display the menu.
- 2 Press CH▼ until "Setup" is highlighted. Press VOL+.



- 3 Press CH▼ until "Auto Program" is highlighted.



- 4 Press VOL- or VOL+ button to begin automatic programming.



The TV/VCR automatically cycles through all the channel numbers and places the available channels in memory. This takes two to three minutes.

- ✓ Press MENU at any time to interrupt the programming process and return to normal viewing.
- 5 When the programming process is complete, press CH▲ or CH▼ to scan the channels stored in the TV/VCR's memory.

- ✓ Occasionally the TV/VCR will miss an active channel if the signal is weak > if the channel is off the air when you start programming. Likewise, an unavailable channel may be included in memory if there are stray signals on that channel.

## Adding and Erasing Channels in Memory

- When entering single-digit channels, press 0 first. For example, to select channel 8, press 0, then 8.

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# TV OPERATION

## Programming the Channels, *continued*

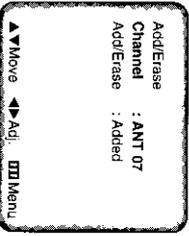
When entering three-digit channels, press the +100 button on the remote control first. For example, to select channel 104, press +100, then press 0, then 4.

You can manually add or erase a channel from your TV/CR's memory.

- 1 Press MENU to display the menu.
- 2 Press CH▼ until "Setup" is selected.
- 3 Press VOL+ to display the Setup menu.
- 4 Press CH▼ until "Add/Erase" is selected. Press VOL+.



- 5 Press VOL+ or VOL- to select a channel.
  - 6 Press CH▼ until "Add/Erase" is selected. Press VOL+ to select "Added" or "Erased".
- You can still view a channel that is not stored in memory by using the number buttons to select the channel directly.



## Setting the Clock

To record programs while you are away, or to use the sleep timer, you must first set the clock and calendar.

There are two ways to set the clock:

Option 1, Manual: The digits for hours and minutes are entered directly.

Option 2, Auto: The TV's clock is synchronized to a time signal sent out by the local PBS channel.

### Option 1: Setting the clock directly ("Manual" Method)

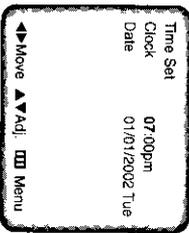
- 1 Press MENU to display the menu.
- 2 Press CH▼ until "Time Set" is selected. Press VOL+.



3 Press VOL+. The Time Set menu appears.



4 Press VOL+ to select the hour digits. Press CH▲ or CH▼ repeatedly until the correct hour appears.

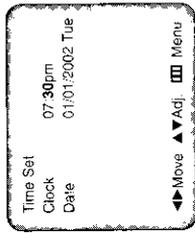


Be sure to set the correct time of day (am or pm), which appears to the right of the minutes.

**TV OPERATION**

**Setting the Clock,**  
*continued*

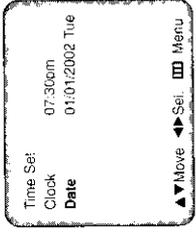
**5** Press VOL+ to select the minute digits. Press CH▲ or CH▼ repeatedly until the correct minute appears.



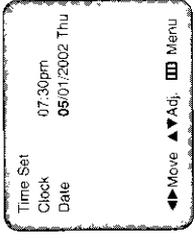
Press VOL+ to finish the clock set.

**Setting the date**

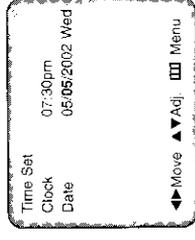
**1** Press CH▼ to select the Date.



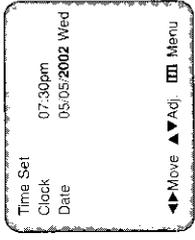
**2** Press VOL+ to select the month digits. Press CH▲ or CH▼ to set the current month.



**3** Press VOL+ to select the day digits. Press CH▲ or CH▼ to set the current day.



**4** Press VOL+ to select the year digits. Press CH▲ or CH▼ to set the current year.



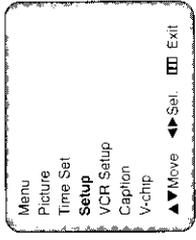
✓ If you make a mistake, press VOL - to move back to the incorrect item. Press CH▲ and CH▼ to change the item.

**5** Press MENU to exit the menu.

**Option 2: Using the Local PBS channel to Automatically Set the TV Clock:**

If the TV clock is set using the Auto Clock Set option, it will be automatically synchronized to a time signal sent out by the local PBS channel.

- 1** Press MENU to display the menu.
- 2** Press CH▼ until "Setup" is selected. Press VOL+.

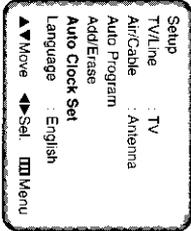


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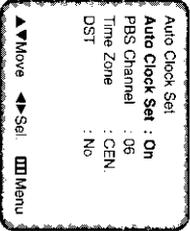
# TV OPERATION

## Setting the Clock, continued

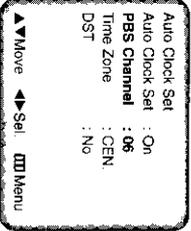
**3** Press CH ▼ until "Auto Clock Set" is selected. Press VOL+.



**4** Press VOL+ to select Auto Clock Set "On".



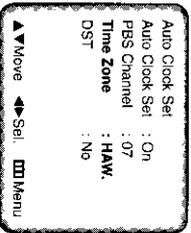
**5** Press CH ▼ to select the "PBS channel".



**6** Press VOL +. Press CH ▲ and CH ▼ to select your local PBS channel. Press VOL + or VOL - again to lock in the PBS channel.

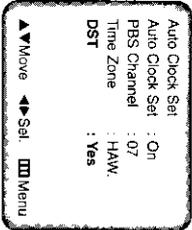


✓ The picture changes according to the channel.  
**7** Press the CH ▼ button to select the "Time Zone"



✓ While "Time Zone" is selected, press either VOL + or VOL - to change the Time Zone.  
Sequence: ATL, EAST, CEN, MTN, PAC, ALAS, HAW.

**8** Press CH ▼ to select the "DST"(Daylight Savings Time).



✓ While "DST" is selected, press VOL + to indicate "Yes," or "No."  
(Set DST "Yes" on the appropriate day in April. And set DST "No" on the appropriate day in October.)  
**9** Press MENU to exit the menu.

✓ The time is automatically corrected when viewing your local PBS channel.

## Choosing Picture Settings

Your TV/VCR has preset standard values for picture settings (contrast, brightness, sharpness, color, and tint). You can also customize these settings.

### Customizing Picture Settings

**1** Press MENU to display the menu.

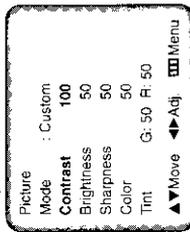
**2** Press CH ▼ until "Picture" is selected. Press VOL+.



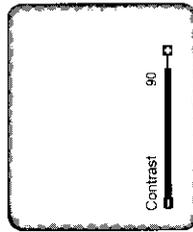
# TV OPERATION

## Choosing Picture Settings, continued

- 3** Press CH▲ or CH▼ to select Contrast, Brightness, Sharpness, Color, or Tint.



- 4** Press VOL+ or VOL- to change the setting.



The setting for the feature appears on the screen.

- 5** Press MENU or wait a few seconds to store the setting.

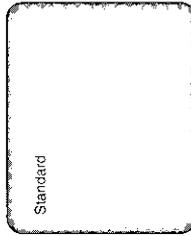
✓ Once you've made changes to one or more of the picture features, your settings are stored in the TV/VCR's memory. Your custom picture setting now becomes the default setting for the TV/VCR.

- 6** Press CH▲ or CH▼ to select another setting or press MENU to exit the menu.

## Using Automatic Picture Settings

This is a special feature that automatically adjusts your picture for you.

- 1** Press P-STD to select an automatic picture setting.



- Choose Standard to set the TV to operate at top performance according to your TV's specifications.
- Choose Mild when viewing the TV in low light, or when playing video games.
- Choose Custom if you want to adjust the settings yourself.

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**TV OPERATION**

**Setting the Sleep Timer**

The sleep timer automatically turns off the TV/VCR at the time you select. This is convenient if you like to fall asleep with the television on.

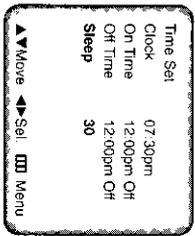
**1** Press MENU to display the menu.

**2** Press CH▼ until "Time Set" is selected. Press VOL+.



**3** Press CH▼ until "Sleep" is selected.

**4** Press VOL+ or VOL- to set the length of time you want the TV/VCR to remain on, off, 10, 20, 30, 60, 90, 120, 150, or 180 minutes.



**5** Press MENU to exit the menu.

**Using the On/Off Timer**

This timer turns the TV/VCR on or off at a specific time. You may set the on time, the off time, or both.

Whatever you choose, you must turn the timer on after you set the on or off times.

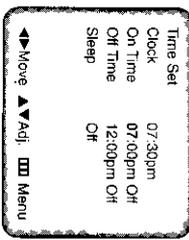
**1** Press MENU to display the menu.

**2** Press CH▼ until "Time Set" is selected. Press VOL+.

**Setting the on time**

**1** Press CH▼ to select "On Time."

**2** Press VOL+ to make the hour flash.



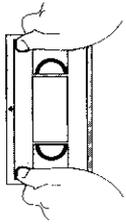
- 3** Press CH▲ or CH▼ to set the hour the set will turn on.
  - 4** Press VOL+ to make the minutes flash.
  - 5** Press CH▲ or CH▼ to set the minute the set will turn on.
  - 6** Press VOL+ to make the Off flash.
  - 7** Press CH▲ or CH▼ to set the timer to "ON."
- Setting the off time**
- 1** Press CH▼ to select "Off Time."
  - 2** Press VOL+ to make the hour flash.
  - 3** Press CH▲ or CH▼ to set the hour the set will turn off.
  - 4** Press VOL+ to make the minutes flash.
  - 5** Press CH▲ or CH▼ to set the minute the set will turn off.
  - 6** Press VOL+ and CH▲ or CH▼ to set the timer "On."
  - 7** Press MENU to exit the menu.

**CHAPTER FOUR VCR OPERATION**

**Inserting and Ejecting a Video Tape**

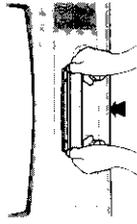
To insert a video tape:

- 1 Hold the video tape window-side up, with the arrow pointing away from you.



Don't try to insert a tape upside down or backwards. Use only video tapes labeled "VHS," PAL and S-VHS video tapes are not compatible with this unit. Choose brand name, high quality tapes for best results.

- 2 Gently push the tape through the compartment door until you feel the VCR pull it in.



The TV/VCR loads the tape automatically. If the power is off when you insert a tape, the TV/VCR turns on automatically.

If the safety tab of your video tape has been removed, the tape begins to play automatically.

- ✓ For more information on the safety tab, see page 40.

To eject a video cassette tape:

- 1 Press STOP to stop playing the tape.

- ✓ When you're finished playing a video tape, rewind it and remove it from the TV/VCR to protect it from wear and tear.

- 2 Press STOP/EJECT on the TV/VCR to eject the tape. Remove the tape and turn off the TV/VCR.

**Playing a Video Tape**

- 1 Insert the video tape.
- 2 If the tape doesn't begin to play automatically, press PLAY.



Then, if necessary, the TV/VCR will automatically adjust the tape's tracking.

- ✓ For information on automatic tracking, see page 25.
- ✓ For information on the time counter, see page 25.

**Pausing**

- 1 While a tape is playing, press P/STILL to pause the tape. There may be vertical jitter or horizontal streaks on the screen while a tape is paused. You can try to eliminate these problems by pressing the TRK + and TRK - buttons on the remote control.

- ✓ For information on automatic tracking, see page 25.

After five minutes in pause, the TV/VCR automatically enters PLAY mode to protect the video heads.

- 2 Press PLAY to resume playing the tape.

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VCR OPERATION

Playing a Video Tape,

continued

Using Picture Search

Picture Search lets you quickly search a pre-recorded video tape for a particular scene.

1 While playing a tape, press and release FF or REW.

The images from the tape are displayed on the screen at a high speed.

This technique is useful if you are searching a small amount of tape. If you want to search a large amount of tape, stop the tape before pressing FF or REW.

There is no sound while you search for a picture at high speeds, and some horizontal streaks may appear on the screen.

2 When you find the scene you want, press and release FF or REW again to resume playing the tape at regular speed.

Using Tracking

This feature automatically adjusts tracking on video tapes.

1 Insert and play a video tape.



When the tape begins to play, the TV/VCR begins automatic tracking.

The tracking display will appear the first time a tape is played after being inserted into the TV/VCR, when there is a change in tape speed, or when you press TRK +.

2 If automatic tracking doesn't remove the streaks from the picture, press and hold TRK+ or TRK- until the streaks disappear.

Using the Time Counter

The time counter allows you to keep track of how much time (in hours, minutes, and seconds) has elapsed on the video tape.

The counter can also be useful if you want to find a specific point on a pre-recorded tape.

1 While a tape is playing, press DISPLAY twice.



The time counter appears.

The counter displays time only for recorded sections of tape. Blank tapes or blank sections of tapes do not affect the counter display.

2 Press CLEAR to set the counter to "00:00:00."

✓ The TV/VCR automatically resets the counter to "00:00:00" when you eject a tape or record.

3 Press DISPLAY to remove the time counter.

Using Memory Stop

Memory Stop makes it easy to find a particular scene in a video tape. The TV/VCR automatically stops rewinding or fast forwarding when the memory counter reaches "00:00:00."

If you mark a desired scene as "00:00:00," you can search for it the next time you watch the tape.

1 While playing a tape, when you reach the scene you want, press DISPLAY twice.

The time counter appears.  
2 Press CLEAR to reset the timer to "00:00:00."

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## VCR OPERATION

### Playing a Video Tape, *continued*

To return to the scene you marked:

- 1 Press STOP.
- 2 Press FF or REW to return to the scene you marked.  
The TV/VCR stops the tape when the counter reaches "00:00:00."
- 3 Press PLAY to view the scene you marked again.

### Using P.PLUS

Press P.PLUS to compensate for a poor rental tape.



- 1 Insert a tape and press PLAY.
  - 2 Press P.PLUS, and "Picture Plus Off" appears on the screen. Press P.PLUS again to turn to "Picture Plus On". The Rental Picture Plus functions only when a tape is being played.
- ✓ If the tape is ejected and reinserted, the Rental Plus feature will be OFF.

### Recording TV Programs as You Watch

#### Recording

- 1 With your TV/VCR turned on, and with a tape in the unit, press SPEED.

- ✓ Be sure the record safety tab is in place. For information on the record safety tab, see page 40.



- The tape speed appears in the lower left corner of the screen.
- 2 Press SPEED repeatedly until the speed you want (SLP, SP) appears.
- ✓ SP (Standard Play) is the most common speed for recording. For more information on tape speeds, see page 40.

- 3 Select the television channel you want by pressing CH▲ or CH▼ or by using the number buttons.  
If you are using the number buttons to select the channel, press 0 before a single-digit channel number (for channel 5, press 0, 5).  
4 Press REC on the remote control.

The record indicator on the control panel illuminates and the TV/VCR begins recording.

- ✓ The TV/VCR automatically stops recording when it reaches the end of the tape.
- ✓ Press STOP at any time to stop recording.
- ✓ Don't change tape speeds while recording; this may cause picture distortion during playback.

When you finish recording, rewind the tape and remove it from the TV/VCR.

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VCR OPERATION

Recording TV Programs as You Watch, continued

Editing While Recording

You can edit while recording, selecting only those scenes you want to record from the current television program. This is especially helpful if you want to record a program without commercials.

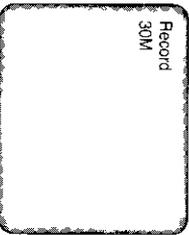
- 1 Be sure you have begun recording and that the record indicator light on the front panel is lit.
2 Press P/STILL to temporarily stop recording.
After ten minutes in pause mode, the TV/MCR stops the tape automatically and switches to TV mode to protect the video heads. If this happens, press REC to resume recording.
3 To resume recording, press P/STILL again.

Using Advanced Recording Features

One-touch Recording

One-touch Recording (OTR) lets you record television programs with the touch of a button. You can program the length of time (up to four hours) that you want to record.

- 1 Insert a video cassette tape, set the tape speed, and select the channel you want to record.
The TV/MCR won't record if the record safety tab on the tape has been removed. For more information, see page 40.
2 Press REC on the remote control twice.



Your recording time options are: 30 minutes, 1 hour, 1 hour and 30 minutes, 2 hours, 2 hours and 30 minutes, 3 hours, or 4 hours.

- 3 Press REC on the remote control repeatedly until the time you want appears. The TV/MCR begins recording. You can increase the length of time you want to record at any time during the recording process by pressing the REC button again and choosing additional time.

If you want to stop recording before the time is up, press the REC button until the OTR display shows "Stop." The recording stops after a few seconds. You can also press STOP/EJECT on the front panel.

Timer Recording

You can set the timer to record up to six different programs. The timer can turn the TV/MCR on at the time you select, record for the selected length of time, and then turn off.

You can record a program one time, daily (every day, Monday through Friday), or weekly (the same day every week).

- 1 Press MENU to display the menu.
2 Press CH V until "VCR Setup" is selected. Press VOL+.



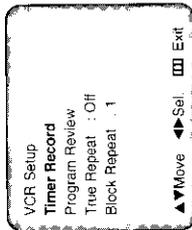
The clock must be set to the correct time and date before you program the timer.

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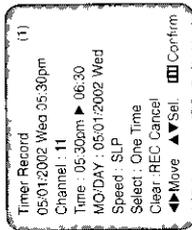
# VCR OPERATION

## Using Advanced Recording Features, *continued*

2 Press CH▼ until "Timer Record" is selected. Press VOL+.



3 Press VOL+.  
 Press CH▲ or CH▼ to select the channel you want to record. Press VOL+ to lock in the channel you've chosen.



The TV/VCR assigns a number (1-6) to your entry which is used in the program review feature. (For more information, see page 22.)

✓ If you make a mistake at any point during programming, press VOL- and CH▲ until the number you want to change is flashing, then enter the correct number.

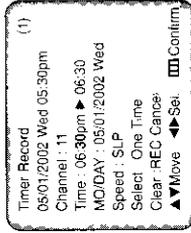
If you are recording a channel that comes through a cable converter box, enter the output number of the cable box.

4 Press CH▼ to select "Time."  
 Press VOL+.



Press CH▲ or CH▼ to select the hour to begin recording.

5 Press VOL+.



Press CH▲ or CH▼ to select the minute to begin recording.

6 Press VOL+.



Press CH▲ or CH▼ to select the hour to end recording.

✓ The TV/VCR automatically selects AM or PM for the ending time.

7 Press VOL+.



Press CH▲ or CH▼ to select the minute to end recording. Press VOL+ to lock in the minute.

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VCR OPERATION

Using Advanced Recording Features, continued

8 Press CH▲ to select "MO/DAY". Press VOL+.



9 Press VOL+.



Press CH▲ or CH▼ to select the day to begin recording.

10 Press VOL+.



Press CH▲ or CH▼ to select the year to begin recording. Press VOL+ to lock in the year.

11 Press CH▼ to select "Speed".



Press VOL+ and CH▲ or CH▼ to select the speed at which you want to record.

12 Press CH▼ to select "Select". Press VOL+



Press CH▼ to select the "One Time", or "Weakly", "Daily".

13 Press MENU to exit the menu.

If you enter two program times that overlap, a program overlap warning appears on the TV screen, along with instructions for fixing the overlap.

The REC indicator on the front panel of the TV/VCR is lit when program times are stored.

14 Press POWER to turn off the TV/VCR.

Important

- The TV/VCR should be off when recording the programs you've chosen. But, if you are recording a channel that comes through a cable box, be sure to leave the cable box on and tuned to the channel you want to record.
During timer recording, there is no picture on the screen because the power is off. If you want to watch the channel while it's being recorded, press POWER on the remote control.
One-time timer programs clear from memory after recording. Daily and weekly programs remain in the timer until you remove them. If power to the TV/VCR is interrupted, all programs will be disabled until you reset the clock. Then, the programs will be restored.

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# VCR OPERATION

## Using Advanced Recording Features, continued

### Using Program Review

Program Review allows you to review all of the programmed recordings currently stored in the TV/VCR's memory and to remove a programmed recording quickly and easily. Press MENU to display the menu.

Press CH▼ until "VCR Setup" is selected. Press VOL+.



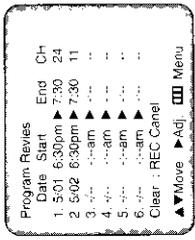
3 Press CH▼ until "Program Review" is selected. Press VOL+.



The information for the first program appears on the screen.

Program Review is only available if you have programmed your TV/VCR to record at a later time.

4 To see the information for the program number, press VOL+.



If you're recording through a cable box, the Program Review screen displays the output channel of the cable box as the channel number to be recorded.

5 If you want to remove a program from memory, press CLEAR when the program you want to erase appears on the screen.

That program is erased from memory.

The TV/VCR is equipped with a program memory backup that saves all the timer program information if the power to the TV/VCR is interrupted.

If the unit has been without power, all of the timer program information will be disabled, until you reset the clock. When the clock is reset, the programs will be restored.

6 Press MENU to exit the menu.

**CHAPTER FIVE SPECIAL FEATURES**

**Using True Repeat**

You can set your TV/VCR to automatically repeat a tape or a section of tape. When you use True Repeat, your TV/VCR will play until it reaches the end of a tape. Then, it will rewind to the beginning of the tape and begin playing again.

**1** Press MENU to display the menu.

**2** Press CH  $\blacktriangledown$  until "VCR Setup" is selected. Press VOL+.



**3** Press CH  $\blacktriangledown$  until "True Repeat" is selected. Press VOL+ to turn True Repeat on.



**4** Press MENU to exit the menu.

**5** Insert and play a pre-recorded video tape.

The TV/VCR will play the tape until it reaches the end. Then, the TV/VCR will stop the tape, rewind it to the beginning, and begin playing again.

If the TV/VCR reaches an unrecorded section of tape before it reaches the end, it will search forward and check the tape again. If it finds a recorded section of tape, it will begin playing. If the tape is still blank, it will continue to search forward until it reaches the end of the tape.

**6** Press STOP to end the repeat.

**Using Block Repeat**

Block Repeat allows you to repeat a section of tape that you select. You can repeat this section of tape (the "block") from one to ten times. "Repeat" section should be set up at a minimum ten-second interval.

**1** Press MENU to display the menu.

**2** Press CH  $\blacktriangledown$  until "VCR Setup" is selected. Press VOL+.



**3** Press CH  $\blacktriangledown$  until "Block Repeat" is selected. Press VOL+ to select the number of times you want your "block" to repeat.



You can choose to have your "block" repeat from one to ten times.

**4** Press MENU to exit the menu.

**5** Insert and play a pre-recorded video tape.

**6** Press REPEAT at the beginning of the "block" you want to repeat ("Repeat" setting" appears on the screen when the button is pressed.)

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**SPECIAL FEATURES**

**Using Block Repeat,**

*Continued*

When you reach the end of the "block," press REPEAT again.

The TV/VCR will rewind the tape to beginning of the block and repeat it.

The TV/VCR will repeat the block as many times as the number you set in step 3.

To stop block repeat, press the STOP, P/STILL, or PLAY buttons. You can also cancel block repeat by fast forwarding or rewinding to a point outside of the "block."

**Viewing Closed Captions**

Your TV/VCR decodes and displays closed captions. These captions are usually subtitles for the hearing impaired or translations into another language. All VCRs record the closed caption signal from television programs, so home-recorded video tapes also provide closed captions.

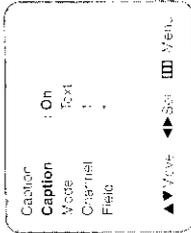
- ✓ Most pre-recorded computer audio tapes provide closed captions. Check for this symbol  on your tapes sign through a audio tape packaging.

Press MENU to display the menu.

- ✓ Press CH▼ until "Caption" is selected. Press VOL+.

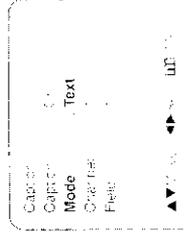


- ✓ Press VOL+ to turn the closed caption feature on.



- ✓ If settings and status parameters so includes address closed caption translations there may be a small delay before captions appear when you change channels.

- ✓ Press of CH▼ to select, "Mode." Press VOL- to choose "Caption" or "Text."



- ✓ In text mode information, are added to the captions is displayed, such as text for weather text often covers a large part of the screen.
- If you wish, use CH▲, CH▼ or VOL+ to change the channel or field. Then, press MENU to return to normal viewing.

- ✓ If you wish, you can also use the repeat or stop buttons. Channel field, picture, or text will be displayed. Channel field, picture, or text will be displayed. Channel field, picture, or text will be displayed.

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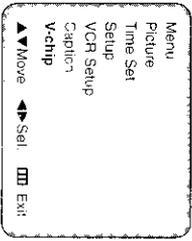
**SPECIAL FEATURES**

**Using the V-Chip**

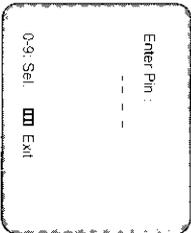
The V-Chip feature automatically locks out programming that is deemed inappropriate for children. The user must first enter a PIN (personal ID number) before any of the V-Chip restrictions can be set up or changed.

**Setting Up Your Personal ID Number (PIN)**

- 1 Press MENU to display the menu.
- 2 Press CH **▲** until "V-chip" is selected. Press VOL+.

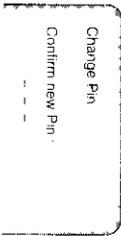
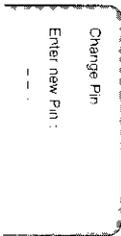


- 3 Press VOL+. The "Enter PIN" screen will appear. Enter your 4-digit PIN number. Note: The default PIN number for a new TV set is "0-0-0-0."



- 4 After entering a valid PIN number, the "V-chip" screen will appear. Press CH **▲** and select "Change pin."
- 5 While the "Change pin" is selected, press VOL+. The Change pin screen will appear. Choose any 4-digits for your PIN and enter them.

As soon as the 4 digits are entered, the "Confirm new pin" screen appears. Re-enter the same 4 digits. When the Confirm screen disappears, your PIN has been memorized.



Note: If you forget the PIN, press the remote-control keys in the following sequence, (this resets the pin to 0-0-0-0):  
**POWER OFF → MUTE → 8 → 2 → 4 → POWER ON.**

**How to Enable/Disable the V-Chip**

- 1 Press MENU to display the menu.
- 2 Press CH **▲** until "V-chip" is selected. Press VOL+.
- 3 Press VOL+. The "Enter PIN" screen will appear. Enter your 4-digit PIN number.
- 4 The "V-Chip" screen will appear, and "V-Chip lock" will be selected. To enable the V-Chip feature, press VOL+ so that the "V-Chip lock" field is Yes (Pressing VOL+ will alternate between Yes and No.)



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**SPECIAL FEATURES**

**Using the V-Chip, continued**

**How to Set up Restrictions Using the TV guidelines**

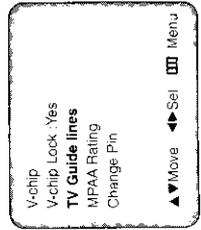
First, set up a personal identification number (PIN), and enable the V-Chip. (See last section.) Parental restrictions can be set up using either of two methods: The TV guidelines or the MPAA rating.

Press MENU to display the menu.

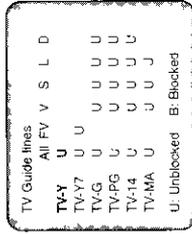
Press CH  $\blacktriangledown$  until "V-chip" is selected. Press VOL+.

Press VOL+. The "Enter PIN" screen will appear. Enter your 4-digit PIN number.

The "V-chip mode" screen will appear. Press CH  $\blacktriangledown$  to select the "TV guide lines."



5 Press VOL+. The "TV guidelines" screen will appear. Press the CH  $\blacktriangle$  CH  $\blacktriangledown$  buttons to select one of the six age-based categories:



TV-Y Young children  
TV-Y7 Children 7 and over

TV-G General audience  
TV-PG Parental guidance  
TV-14 Viewers 14 and over  
TV-MA Mature audience  
Note: These categories consist of two separate groups.

TV-Y and TV-Y7 (young children through age 7), and TV-G through TV-MA (everybody else).

The restrictions for these two groups work independently.

If a household includes very young children as well as young adults, the TV guidelines must be set up separately for each age group. (See next step.)

6 At this point, one of the TV-Ratings is selected (red color).

Press VOL+: Depending on your existing setup, either "U" or "B" will will be selected.

(U= Unblocked, B= Blocked) While the "U" or "B" is red color, press CH  $\blacktriangle$  or CH  $\blacktriangledown$  to block or unblock the category.

Press MENU once to save the TV guidelines. A TV-Rating will be selected, and no letters will be selected. To exit this screen, press MENU again. To select a different TV-Rating, press CH  $\blacktriangle$  or CH  $\blacktriangledown$  and then repeat the process.

Note 1: The TV-Y7, TV-PG, TV-14 and TV-MA have additional options. See the next step to change any of the following sub-ratings:

- FV: Fantasy violence
- D: Dialog
- L: Adult language
- S: Sexual situation
- V: Violence

Note 2: The V-Chip will automatically block certain categories that are "more restrictive".

For example, if you block "TV-Y" category, then TV-Y7 will automatically be blocked.

Similarly, if you block the TV-G category, then all the categories in the "young adult" group will be blocked (TV-G, TV-PG, TV-14 and TV-MA). The sub-ratings (D, L, S, V) work together similarly. (See next section).

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**SPECIAL FEATURES**

**Using the V-Chip, *continued***

**7** How to set the FV, D, L, S and V sub-ratings.

First select one of these TV-Ratings: TV-V7, TV-PG, TV-14 or TV-MA (See Step 4, above).

Next, while the TV-Rating is selected, repeatedly press VOL +. This will cycle through the available sub-ratings (FV/L, S, D or V). A selecting letter ("U" or "B") will be displayed for each sub-rating. While the "U" or "B" is selected, press CH ▲ or CH ▼ to change the sub-rating.

Press MENU once to save the TV guidelines.

A particular TV-Rating will be selected, and no letters will be selected. To exit this screen, press MENU again. To select a different TV-Rating, press CH ▲ or CH ▼ and then repeat the process.

Note: The V-chip will automatically block certain categories that are "More restrictive".

For example, if you block the "L" sub-rating in TV-PG, then the "L" sub-ratings in TV-14 and TV-MA will automatically be blocked.

**8** Press MENU to clear all the screens.

(Or proceed to the next section, and set up additional restrictions based on the MPAA codes).

**How to Set up Restrictions using the MPAA Ratings: G, PG, PG-13, R, NC-17, X**

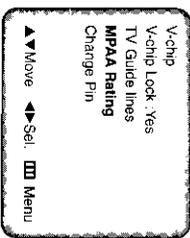
The MPAA rating system uses the Motion Picture Association of America (MPAA) system, and its main application is for movies. (Eventually, movie videocassettes will be encoded with MPAA ratings.) When the V-Chip lock is on, the TV will automatically block any programs that are coded with objectionable ratings (either MPAA or TV-Ratings).

**1** Press MENU to display the menu.

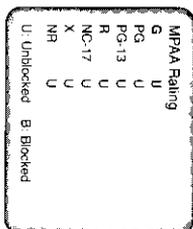
**2** Press CH ▼ until "V-chip" is selected. Press VOL+.

**3** Press VOL+. The "Enter PIN" screen will appear. Enter your 4-digit PIN number.

**4** The "V-chip" screen will appear. Press CH ▼ to select the "MPAA rating".



**5** While "MPAA rating" is selected, press the VOL+ button. The "MPAA rating" screen will appear.



**6** Repeatedly press CH ▼ to select a particular MPAA category. Pressing CH ▼ will cycle through the MPAA categories:

- G: General audience (no restrictions);
- PG: Parental guidance suggested;
- PG-13: PG-13/Parents strongly cautioned;
- R: Restricted: Children under 17 should be accompanied by an adult;
- NC-17: No children under age 17;
- X: X (Adults only);
- NR: Not rated.

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**SPECIAL FEATURES**

**Using the V-Chip, continued**

Next, press VOL+ to activate the category. A selecting letter "U" or "B" will be displayed.

While a particular category is selected, press VOL+ to activate a selecting letter ("U" or "B") will be displayed.

Press MENU to exit the V-Chip menu.

Note: The V-Chip will automatically block any category that is "more restrictive". For example, if you block the "G-13" category, then "R", "NC-17" and "X" will automatically be blocked also.

**How to Reset the TV after the V-Chip Blocks a Channel ("Emergency Escape")**

If the TV is tuned to a restricted channel, the V-Chip will block it. The screen will go blank and the following message will appear: "Excessive rating."

To resume normal viewing, tune to a different channel using the number buttons. Under certain conditions (depending on the rating of the local TV programs) the V-Chip might lock out all the channels.

In this case, use the V-Chip function for an "emergency escape":

- 1 Press MENU to display the menu.
- 2 Press CH▼ until "V-chip" is selected. Press VOL+.
- 3 Press VOL+. The "Enter PIN" screen will appear. Enter your 4-digit PIN number.

4 Press VOL+: The V-Chip lock field will appear, and "V-Chip lock" will be selected.

Press VOL+ to switch V-Chip off. (Repeatedly pressing VOL+ will alternate between yes and no.)

**SPECIAL FEATURES**

**Using Special Playback Features**

Your TV/VCR provides you with special features that are available when you are playing a tape. These features are Frame Advance, Skip Search, and Slow Motion.

**Frame Advance**

Frame Advance allows you to watch a tape frame-by-frame.

- 1 While a tape is playing, press P/STILL on the remote.

If the picture jitters, press TRK +.

- 2 Press FADV/SKIP repeatedly to move forward frame-by-frame. Do not hold the button down.

Press PLAY to resume normal playback.

**Skip search**

Skip search allows you to quickly search through a short section of tape.

- 1 While a tape is playing, press FADV/SKIP

The TV/VCR will fast-forward through the tape for 60 seconds, then continue playing.

**Slow motion**

You can watch a tape at various slow-motion speeds.

- 1 While a tape is playing, press SLOW + or SLOW – on the remote.

If the picture is jittery or shows noise, try using the TRK buttons to clear the picture.

- 2 Press SLOW + or SLOW – to adjust the slow motion speed between 1/5 and 1/60 normal speed.

- 3 Press PLAY to resume normal play.

There is no sound during slow motion.

- ✓ It is normal to occasionally see some streaks or jitter during slow motion play.
- ✓ If slow motion continues for more than five minutes, the TV/VCR may play automatically to protect the tape and video heads.

**Jel search**

When pressing FF or REW during play, the search speed becomes faster.

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**SPECIAL FEATURES**

**Copying, or Dubbing, a Video**

To make a copy, or "dub," of another video tape, you need:  
your TV/VCR

a separate VCR (or camcorder)

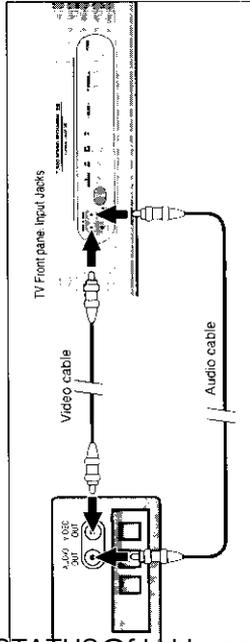
two AV cables with connectors. (You can find these at most electronics supply stores.)

**Important warning:**

The Federal Court has held that unauthorized recording of copyrighted TV programs may be an infringement of copyright laws.

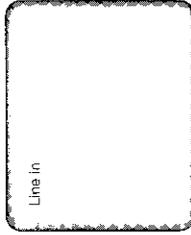
**Making the Connections**

Attach one end of the video/audio cable to the VIDEO/AUDIO OUT connector of the playback VCR (or camcorder) and the other end to the VIDEO/AUDIO IN connector of the TV/VCR.



**Dubbing**

- 1 Insert the video cassette tape you want to copy into the playback VCR (or camcorder).
- 2 Insert a blank video tape (or any video tape with the record safety tab intact) into the recording TV/VCR.
- 3 Press LINE IN on the remote control of the recording TV/VCR.



The words "Line in" appear in the upper left corner of the TV/VCR screen.

- ✓ The TV/VCR will be recording from the incoming line rather than from the normal broadcast signal.

"Line in" will remain on-screen until the PLAY button is pressed on the playback VCR.

- 4 To begin recording, simultaneously press REC on the recording TV/VCR's remote control and PLAY on the playback VCR (or camcorder).
- 5 When you are finished, press STOP on both the VCR (or camcorder) and the TV/VCR to stop recording.
- 6 Press LINE IN to return to normal TV viewing.

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**CHAPTER SIX TROUBLESHOOTING**

**Identifying TV Problems**

**Poor picture, no picture, blurred picture, or blue screen.**

- Try another channel. Make sure the unit is plugged into a working wall outlet.
- Adjust the antenna.
- Press LINE IN.
- Check all wire connections.

**Poor sound quality.**

- Try another channel.
- Adjust the antenna.

**No color, wrong colors or tints.**

- Make sure the program is broadcast in color.
- Adjust the picture settings.
- If the set is moved or turned in a different direction, the power should be OFF for at least 30 minutes.

**Picture rolls vertically.**

- Adjust the antenna.
- Check all wire connections.

**Identifying VCR Problems**

**Unit won't turn on.**

- Make sure the unit is plugged into a working wall outlet.
- Press the POWER button.

**Unit won't take video tape.**

- Make sure the tape is window side up with the arrow pointing away from you.
- Make sure there is no other tape in the compartment.

**Unit didn't record a program.**

- Make sure the antenna or cable is connected and that the TV/VCR is receiving the broadcast signal.
- Make sure the record safety tab on the tape is intact.

**Unit didn't record a timer program.**

- Make sure the unit was turned off.
- Check the programmed start and stop times.
- Make sure the time is set correctly.

**There is no picture, the picture is distorted during video tape playback, or noise or streaks appear in the picture.**

- Adjust the tracking.
- Clean the video heads.
- Make sure there has been a recording on the tape.

**You can't receive regular broadcasts.**

- Check the antenna or cable connections.

**Rewind command doesn't work.**

- Make sure the VCR is not in pause mode.
- Make sure the tape hasn't already been rewound.

**Fast forward command doesn't work.**

- Make sure the VCR is not in pause mode.
- Make sure the tape hasn't already been forwarded.

**Picture is streaked during pause mode.**

This is normal for SP recording.

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**APPENDIX**

**Caring for Your TV/VCR**

Please follow these guidelines to get the maximum performance from your TV/VCR.

**Placement**

Do not place the TV/VCR near extremely hot, cold, humid or dusty places. Do not place the TV/VCR near appliances with electric motors that create magnetic fields, such as vacuum cleaners.

Keep the ventilation openings clear; do not place the TV/VCR on a soft surface, such as cloth or paper. Place the TV/VCR in an upright position only.

**Liquids**

Do not handle liquids near or on the TV/VCR. Liquids that spill into it can cause serious damage.

**Cabinet**

- Never open the cabinet or touch the parts inside.
- Wipe your TV/VCR with a clean, dry cloth. Never use water, cleaning fluids, wax, or chemicals.
- Do not put heavy objects on top of the cabinet.

**Video Heads**

- Use a head cleaning tape to remove any dirt that has accumulated on the video heads.
- Follow the instructions that come with the cleaning tape; excessive use of a cleaning tape can shorten head life.

**Temperature**

If your TV/VCR is moved from a cold to a warm place, unplug the power cord, and allow at least two hours for moisture that may have formed inside the unit to dry completely.

**About Video Tapes**

Use only video tapes marked VHS with this TV/VCR.

**Caring for Video Tapes**

- Keep tapes away from direct sunlight, heat or cold.
- Insert tapes with the window side up and the arrow pointing away from you.
- Do not subject tapes to violent vibrations or shocks.
- Never try to take apart or splice a video tape.
- Do not open the cassette, touch the tape, or put anything inside the tape case.
- Read the instructions supplied with video tapes.

**Recording Speeds**

You can play or record a tape at:

- SP (Standard Play) speed
- SLP (Super Long Play) speed

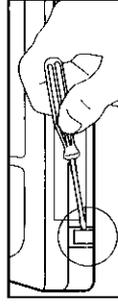
Your TV/VCR automatically plays tapes at the proper speed.

Recording at slower tape speeds allows tapes to hold more program material.

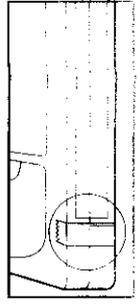
TAPE	SP	SLP
T-60	1 hr.	3 hrs.
T-120	2 hrs.	6 hrs.
T-160	2 hrs., 8 mins.	40 mins.

**The Record Safety Tab**

Most video tapes have a safety tab that must be intact to record. To protect a tape from erasure, you can break off the tab.



To record on a cassette with the tab removed, cover the hole with cellophane tape.



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**APPENDIX**

**Specifications**

**Format**  
 VHS Standard

**Recording system**  
 Rotary, azimuth four-head  
 helical scanning system  
*Luminance:* FM azimuth  
 recording  
*Color signal:* Converted  
 subcarrier phase shift recording

**Television system**  
 NTSC-type color signal EIA  
 Standard (525 lines, 60 fields)

**Audio track**  
 One track

**Tape width**  
 12.7 mm (1/2 inch)

**Record speed**  
*SP:* 33.35 mm/s (1.31 in./s)  
*SLP:* 11.12 mm/s (0.43 in./s)

**Record/playback time**  
 480 minutes with T-160 used in  
 SLP mode

**FF/REW time**  
 Less than 2 min. with T-120

**Heads**  
*Video:* Four rotary heads  
*Audio/control:* One stationary  
 head  
*Erase:* One full track erase, one  
 audio track erase

**Video**  
**Input**  
 VIDEO IN jack (RCA) 1.0 V p-p,  
 75-ohm unbalanced

**Audio**  
**Input**  
 AUDIO IN jack (RCA) -8 dBm,  
 50K-ohm unbalanced

**TV tuners**  
*VHF input:* ch. 2 - ch. 13, cable  
 channels "4A, A~W, W+1~W+84,  
 A-5-A-1" 75-ohm unbalanced  
*UHF input:* ch. 14 - ch. 69 VHF,  
 UHF one input 75-ohm unbalanced

**Operating temperature**  
 41° F - 104° F (5° C - 40° C)

**Operating humidity**  
 10% - 75%

*Equipment specifications are  
 subject to change without  
 notice*

Model	CXM1374	CXM1974
Power requirements	120V AC, 60Hz	120V AC, 60Hz
Power consumption	Approx. 60watts when on Approx. 5watts when off	Approx. 70watts when on Approx. 5watts when off
Dimensions(w x d x h)	366 x 382 x 381 mm 14.41 x 15.04 x 15.00 inches	466 x 468 x 487 mm 19.13x 18.43 x 19.17 inches
Weight	11.2kg ; 24.69lbs	19kg ; 41.89lbs

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MEMO

MEMO

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Samsung Electronics America Inc.  
5 Challenger Road, Ridgefield Park, N.J. 07660

**SERVICE DIVISION**

TEL: 1-800-SAMSUNG (1-800-726-7864)  
www.samsungsupport.com

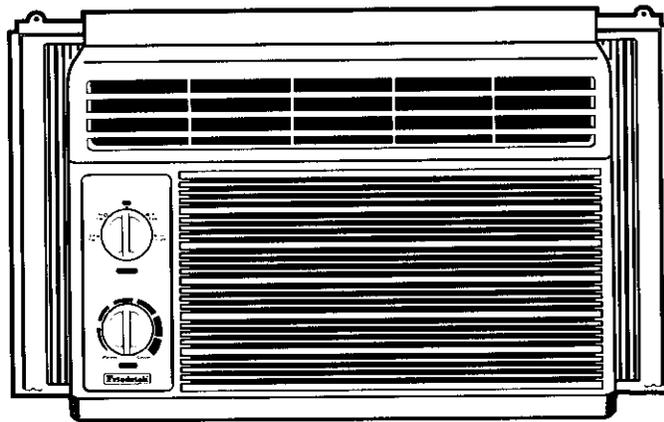


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AA68-02203A(1) NG

# Friedrich®

## Room Air Conditioner Installation and Operating Manual



**ZStar™**

*ZQ05 A10 B*

115 Volts



ZQ05



ZQ07

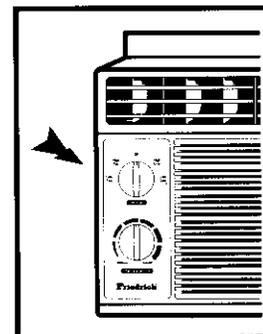
### Registering Your Room Air Conditioner

Model information can be found on the name plate located on the side of the unit near the control panel. Please complete and mail the owner registration card furnished with this product. For your future convenience, record the model information here.

MODEL NUMBER

SERIAL NUMBER

PURCHASE DATE



920-095-02 (01/02)

*413*

6114



**Congratulations!**

**You have purchased a Friedrich ZStar™ room air conditioner. The Friedrich ZStar™ is designed to give maximum comfort and quietness.**

## **Table of Contents**

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# Introduction

## Before Operating Your Unit

### Make sure the wiring is adequate for your unit.

If you have fuses, they should be of the time delay type. Before you install or relocate this unit, be sure that the amperage rating of the circuit breaker or time delay fuse does not exceed the amp rating listed in figure 1.

### DO NOT use an extension cord.

The cord provided will carry the proper amount of electrical power to the unit; an extension cord will not.

### Make sure that the receptacle is compatible with the wall plug provided.

This insures proper grounding. If you have a two-prong receptacle you will need to replace it with a three-prong grounded receptacle that meets all national and local codes and ordinances. You must use the three-prong plug furnished with the air conditioner.

MODEL	CIRCUIT RATING OR TIME DELAY FUSE		PLUG FACE	
	AMP	VOLT	NEMA NO.	
ZQ05A10B ZQ07A10A	15	125	5-15P	

Figure 1

## For the Best Cooling Performance and Energy Efficiency

### Keep the filter clean

Make sure that your air conditioner is always in top performing condition by cleaning the filter regularly. Instructions for removing and cleaning the filter can be found on page 6.

### Provide good airflow

Make sure that the airflow to and from the unit is clear. Your air conditioner puts the air out at the top of the unit, and takes in air at the bottom. Airflow is critical to good operation. It is just as important on the outside of the building that the airflow around the unit exterior is not blocked.

### Unit Placement

If your air conditioner can be placed in a window or a wall that is shaded by a tree or another building, the unit will operate even more efficiently. Using drapes or blinds on the sunny side of the dwelling will also add to your unit's efficiency.

### Insulation

Good insulation will be a big help in maintaining desirable comfort levels. Doors should have weather stripping. Be sure to caulk around doors and windows.

# Safety Precautions

To prevent injury to the user or other people and property damage, the following instructions must be followed.

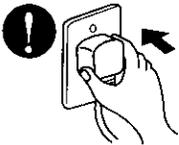
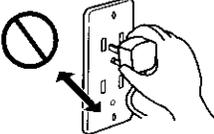
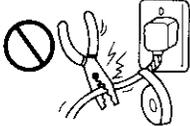
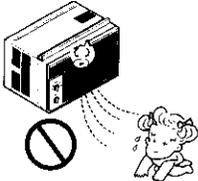
■ Incorrect operation due to ignoring of instruction will cause harm or damage, the seriousness is classified by the following indications.

	<b>WARNING</b>	This symbol indicates the possibility of death or serious injury.
	<b>CAUTION</b>	This symbol indicates the possibility of injury or damage to properties only.

■ Meanings of symbols used in this manual are as shown below.

	<b>Be sure not to do this.</b>
	<b>Be sure to follow the instructions.</b>

 **WARNING**

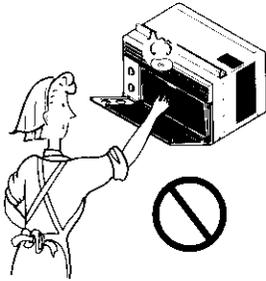
<p><b>Plug in the power plug properly.</b></p>	<p><b>Do not operate or stop the unit by inserting or pulling out the power plug.</b></p>	<p><b>Do not damage or use an unspecified power cord.</b></p>
<ul style="list-style-type: none"> <li>• Otherwise, it will cause electric shock or fire due to heat generation.</li> </ul>	<ul style="list-style-type: none"> <li>• It will cause electric shock or fire due to heat generation.</li> </ul>	<ul style="list-style-type: none"> <li>• It will cause electric shock or fire.</li> <li>• If the power cord is damaged, it must be replaced by the manufacturer or its service agent or a similarly qualified person in order to avoid a hazard.</li> </ul>
		
<p><b>Do not modify power cord length or share the outlet with other appliances.</b></p>	<p><b>Do not operate with wet hands or in damp environment.</b></p>	<p><b>Do not direct air flow at room occupants only.</b></p>
<ul style="list-style-type: none"> <li>• It will cause electric shock or fire due to heat generation.</li> </ul>	<ul style="list-style-type: none"> <li>• It will cause electric shock.</li> </ul>	<ul style="list-style-type: none"> <li>• This could lead to health problems.</li> </ul>
		

# Safety Precautions

## CAUTION

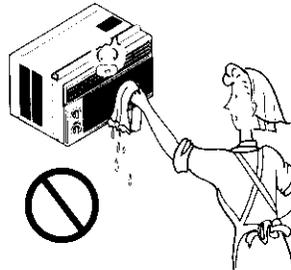
**When the air filter is to be removed, do not touch the metal parts of the unit.**

- They are sharp and may cause an injury.



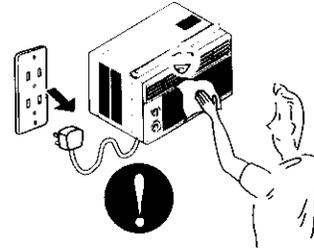
**Do not clean the air conditioner with water.**

- Water may enter the unit and degrade the insulation. It may cause an electric shock.



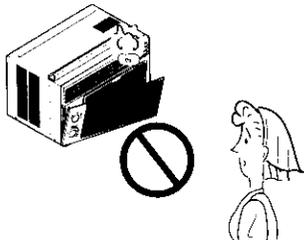
**When the unit is to be cleaned, switch the unit off, and unplug it.**

- Since the fan rotates at high speed during operation, it may cause an injury.



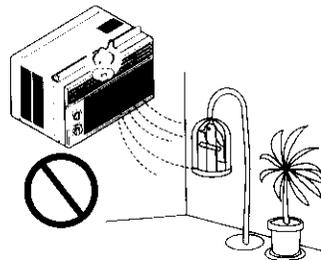
**Do not operate the unit without the air filter or when the front intake grille has been removed.**

- It could cause dust to accumulate on the heat exchanger.



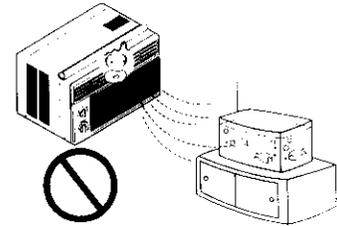
**Do not put a pet or house plant where it will be exposed to direct air flow.**

- This could injure the pets or plants.



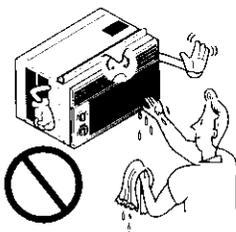
**Do not use for special purposes.**

- Do not use this air conditioner to preserve precision devices, food, pets, plants, and art objects. It may cause deterioration of quality, etc.



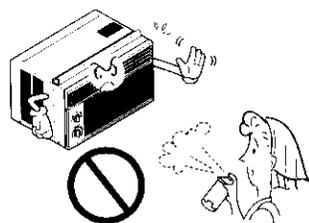
**Do not operate switches with wet hands.**

- It may cause an electric shock.



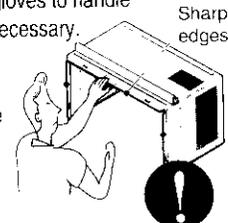
**Do not apply an insecticide or flammable spray.**

- It may cause a fire or deformation of the cabinet.



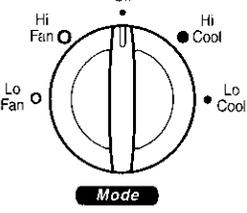
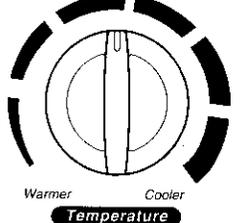
**SHARP EDGES!**  
The edges of the case can be SHARP!

- Use caution when handling the case. Grip it firmly and do not allow it to slip while holding it.
- Use heavy gloves to handle the case if necessary.
- DO NOT allow the case to slide against your skin!



# How to operate your Friedrich ZStar™

## Function Controls

	<p><b>FUNCTION CONTROL</b></p> <p>This dial allows you to select 2 cooling and 2 fan speeds. Turn to <b>Off</b> to turn everything off. Turn to <b>Hi Cool</b> for quick cooling. Turn to <b>Lo Cool</b> to maintain a desired temperature. The <b>Hi Fan</b> setting provides maximum circulation of filtered room air without cooling. The <b>Lo Fan</b> setting is a slow fan speed without cooling.</p>
	<p><b>TEMPERATURE CONTROL</b></p> <p>This dial is the thermostat. Turn it clockwise for cooler and counterclockwise for warmer.</p>

### • FOR NORMAL COOLING

1. Turn the Mode switch to the **Hi Cool** or the **Lo Cool** setting.
2. Set the Temperature control to the desired temperature point (the mid-point is a good starting position). If the room temperature is not satisfactory after a reasonable time, adjust the control to a cooler or warmer setting, as appropriate.

### • FOR MAXIMUM COOLING

1. Turn the Mode switch to the **Hi Cool** setting.
2. Set the temperature control to the highest temperature point (all the way to the right).

### • FOR QUIETER OPERATION

1. Turn the Mode switch to the **Lo Cool** setting.
2. Set the Temperature control as needed.

## CAUTION

When the air conditioner has finished cooling the room and is turned off or set to the fan position, wait at least 3 minutes before resetting to the cooling operation again.

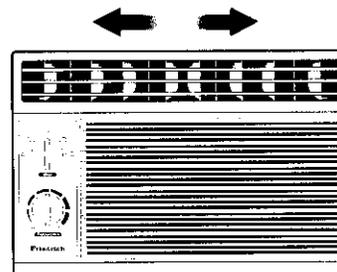
# How to operate your Friedrich ZStar™

## Additional controls and important information.

### Air Direction

#### • ADJUSTING THE AIR DIRECTION USING THE HORIZONTAL AIR-DEFLECTOR CONTROL

Using the Control Tabs, the air flow can be directed to the left, right, straight ahead, or any combination of these directions.



### Care and Maintenance

TURN THE AIR CONDITIONER OFF AND REMOVE THE PLUG FROM THE POWER OUTLET.

#### • To Remove the Filter

1. Remove the front cover by gripping the top outside edges and pulling toward you (see Figure 1). You will notice that the grille will only open to about 56°. Do not force the grille open too far.
2. Find the two clips that hold the grille in place. Gently lift the filter out.

Do not force open or open too far (about 56°)

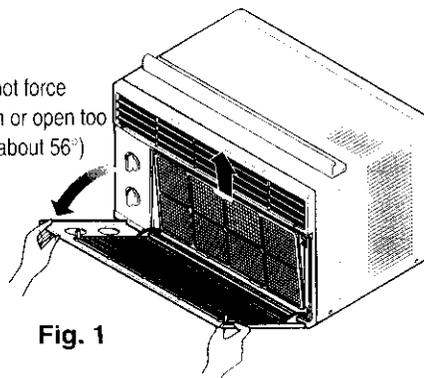


Fig. 1

#### • To Clean the Filter

1. Clean with warm (104°F or 40°C) water. Be sure to shake all water off before replacing the filter.
2. Carefully position the filter, bottom first, and snap back into place. The filter should be cleaned every two weeks for best results.

#### • Cleaning The Air Conditioner

The front grille and Inlet grille may be wiped with a cloth dampened in a mild detergent solution. (Fig. 2) The cabinet may be washed with mild soap or detergent and lukewarm water, then polished with Liquid Wax for Appliances.

To ensure continued peak efficiency, the condenser coils (outside of unit) should be checked periodically and cleaned if clogged with soot or dirt from the atmosphere.

#### • Removing the Front Grille

1. Remove the temperature and mode control knobs by gently pulling them off. (Fig. 3)
2. Remove the screw securing the Front Grille. (Fig. 3) The screw is located behind the bottom temperature knob.
3. Push the grille up from the bottom and pull the top of the grille away from the case as the top tabs lift out of their slots. (Fig. 4)
4. Carefully position the filter, bottom first, and snap back into place.

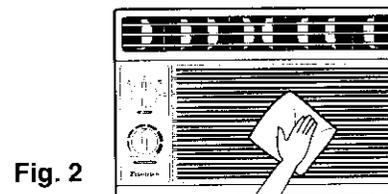


Fig. 2

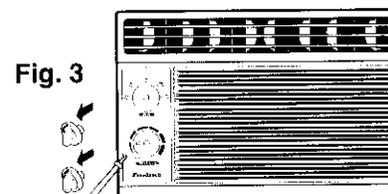


Fig. 3

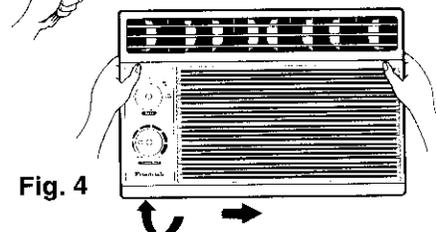
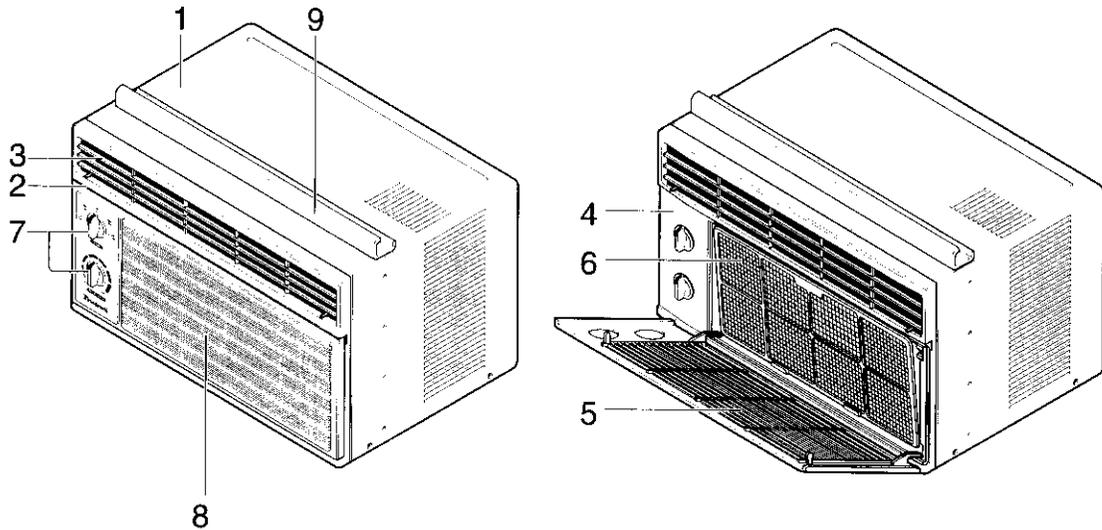


Fig. 4

# Installation Instructions

*Learning the key components will help you properly install the unit.*

## Features



- |                             |                |
|-----------------------------|----------------|
| 1. CABINET                  | 6. AIR FILTER  |
| 2. HORIZONTAL AIR DEFLECTOR | 7. KNOBS       |
| 3. COOL AIR DISCHARGE       | 8. AIR INTAKE  |
| 4. FRONT GRILLE             | 9. UPPER GUIDE |
| 5. INLET GRILLE             |                |

# Installation Instructions

## Window Requirements

NOTE: All supporting parts should be secured to firm wood, masonry, or metal.

1. This unit is designed for installation in standard double hung windows with actual opening widths of 22" to 36". The upper and lower sash must open sufficiently to allow a clear vertical opening of 13" from the bottom of the sash to the window stool.
2. If storm window presents interference, fasten a 2" wide wood strip to the inner window sill across the full width of the sill. The wood strip should be thick enough to raise the height of the window sill so that the unit can be installed without interference by the storm window frame. See Fig. 5-2. The top of the wood strip should be approximately  $\frac{3}{4}$ " higher than the storm window frame (STORM WINDOW FRAME) or wood strip (OUTDOORS) to help condensation to drain properly to the outside.
3. Install a second wood strip (approximately 6" long by  $1\frac{1}{2}$ " wide and same thickness as first strip) in the center of the outer sill flush against the back off the inner sill. This will raise the L bracket as shown Fig. 5-2.
4. If the distance between STORM WINDOW FRAME and WOOD STRIP MOUNTED ON TOP OF INNER SILL is more than 1", two of wood strips are not necessary.

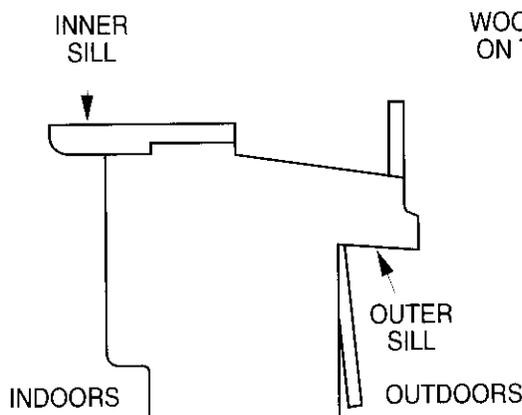


Fig. 5-1

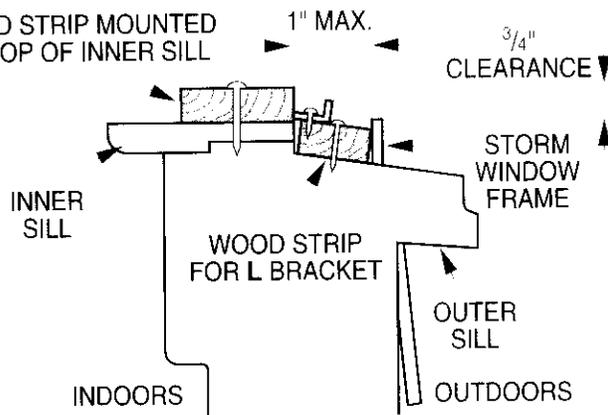
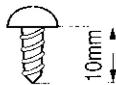
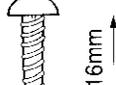
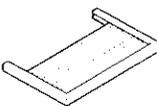


Fig. 5-2

## Installation

HARDWARE			
TYPE A: 11EA (SHORT SCREW)	TYPE B: 5EA (WOOD SCREW)	TYPE C: 3EA (L BRACKET)	
			
TYPE D: 1EA (SEAL STRIP)	TYPE E: 1EA (SASH SEAL)	TYPE F: 2EA (GUIDE PANEL)	TYPE G: 1EA (SUPPORT BRACKET)
(Adhesive backed)	(Not adhesive backed)		

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# Installation Instructions

## A. BEFORE INSTALLATION

1. Insert the guide panels into the guides of the air conditioner. Fasten the curtains to the unit with screws (TYPE A), as shown Fig. 6.
2. Cut the adhesive-backed seal strip (TYPE D) to the window width.  
Remove the backing from the seal strip and attach the seal strip to the underside of the bottom window. (Fig. 7)

## B. NOW START INSTALLATION

### 1. LOCATING UNIT IN WINDOW

Open the window and mark center line on the center of the inner sill, as shown in Fig. 8.

### 2. ATTACH L BRACKET

- a. Install the L brackets behind the inner window sill, with short side of bracket as shown. Use the 2 screws (TYPE A) provided.
- b. The bracket helps to hold unit securely in place.  
Be sure to place bracket edge flush against back of inner sill. See Fig. 9.

### CAUTION

During the following step, hold unit firmly until window sash is lowered to top channel behind side panel frames. Personal injury or property damage may result if unit falls from window.

### 3. INSTALL THE AIR CONDITIONER IN THE WINDOW

- a. Carefully lift the air conditioner and slide it into the open window. Make sure the bottom guide of the air conditioner drops into the notches of the L bracket. See Fig. 9.

### IMPORTANT :

When the air conditioner drops into the L bracket, the air conditioner will be centered in window opening as shown in Fig. 10.

- b. While steadying the air conditioner, carefully bring the window sash down behind the upper guide of the air conditioner, as shown in Fig. 11.

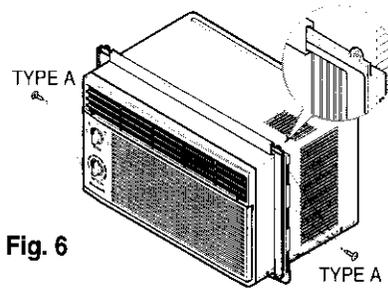


Fig. 6

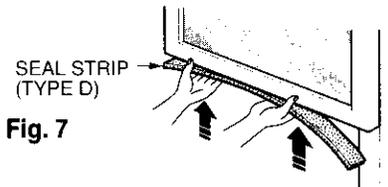


Fig. 7

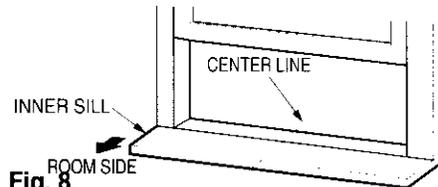


Fig. 8

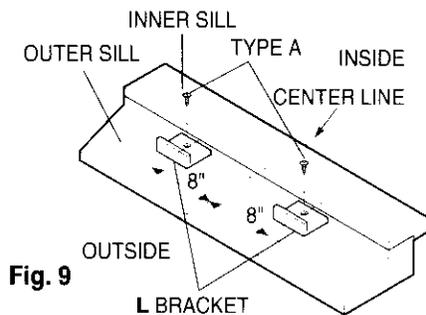


Fig. 9

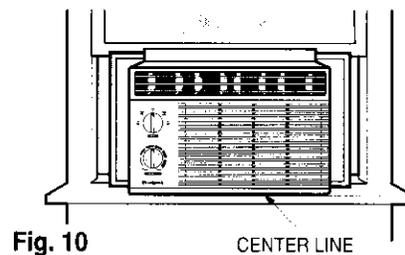


Fig. 10

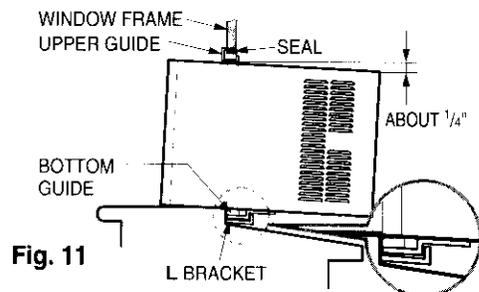


Fig. 11

# Installation Instructions

## 4. SECURE THE GUIDE PANELS

Extend the guide panels (TYPE F) to fill the window opening using 4 screws (TYPE B) to secure them, as shown in Fig. 12.

## 5. INSTALL THE SASH SEAL AND SASH LOCK

- a. Cut the sash seal (TYPE E) to the window width. Stuff the sash seal between the glass and the window to prevent air and insects from getting into the room, as shown in Fig. 12.
- b. Fasten the L bracket using a screw (TYPE A), as shown in Fig. 12.

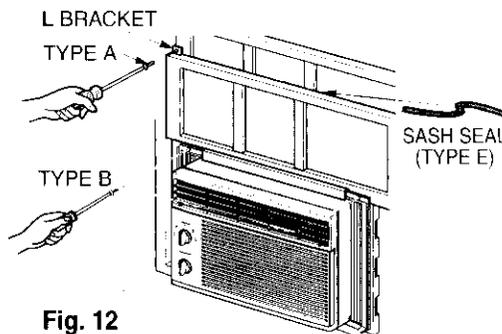


Fig. 12

6. a. Remove the screws that secure the cabinet and base pan in the right side.
- b. Fasten the support bracket (TYPE G) using a removed screw. Attach the support bracket (TYPE G) in the inner window sill with a screw (TYPE B), as shown Fig. 13.

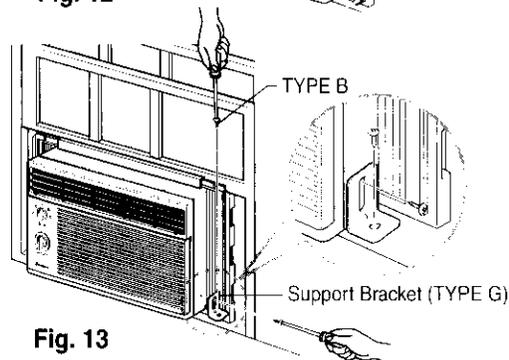


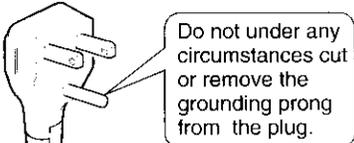
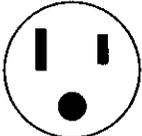
Fig. 13

**7. Window installation of room air conditioner is now completed. See ELECTRICAL DATA for attaching power cord to electrical outlet.**

## REMOVAL FROM WINDOW

Turn the air conditioner off, disconnect the power cord, remove the L bracket, the screws and Support Bracket installed through the top and bottom of the guide panels, and save for reinstallation later. Close the guide panels. Keeping a firm grip on the air conditioner, raise the sash, and carefully tilt the air conditioner backward, draining any condensate. Lift the air conditioner from the window and remove the sash seal from between the windows.

## Electrical Data

Line Cord Plug	Use Wall Receptacle	Power Supply
 <p>Power supply cord with 3-prong grounding plug</p>	 <p>Standard 125V, 3-wire grounding receptacle rated 15A, 125V AC</p>	<p>Use 15 AMP, time delay fuse or circuit breaker.</p>

## USE OF EXTENSION CORDS

Because of potential safety hazards, we strongly discourage the use of an extension cord. However, if you wish to use an extension cord, use a CSA certified/UL-listed 3-wire (grounding) extension cord, rated 15A, 125V.

# Troubleshooting Tips

*Troubleshooting Tips save time and money! Review the chart below first and you may not need to call for service.*

## Normal Operation

- You may hear a pinging noise caused by water being picked up and thrown against the condenser on rainy days or when the humidity is high. This design feature helps remove moisture and improve efficiency.
- You may hear the thermostat click when the compressor cycles on and off.
- Water will collect in the base pan during high humidity or on rainy days. The water may overflow and drip from the outdoor side of the unit.
- The fan may run even when the compressor does not.
- Your air conditioner is designed to cool in warm weather when the outside temperature is above 60°F(16°C) and below 115°F(46°C).

## Abnormal Operation

<b>Problem</b>	<b>Possible Causes</b>	<b>What To Do</b>
<b>Air conditioner does not start</b>	■ <b>The air conditioner is unplugged.</b>	• Make sure the air conditioner plug is pushed completely into the outlet.
	■ <b>The fuse is blown/circuit breaker is tripped.</b>	• Check the house fuse/circuit breaker box and replace the fuse or reset the breaker.
	■ <b>Power failure.</b>	• If power failure occurs, turn the mode control to Off. When power is restored, wait 3 minutes to restart the air conditioner to prevent tripping of the compressor overload.
<b>Air conditioner does not cool as it should</b>	■ <b>Airflow is restricted.</b>	• Make sure there are no curtains, blinds, or furniture blocking the front of the air conditioner.
	■ <b>The THERMOSTAT may not be set high enough.</b>	• Turn the knob to a higher setting. The highest setting provides maximum cooling.
	■ <b>The air filter is dirty.</b>	• Clean the filter at least every 2 weeks. See the operating instructions section.
	■ <b>The room may have been hot.</b>	• When the air conditioner is first turned on you need to allow time for the room to cool down.
	■ <b>Cold air is escaping.</b>	• Check for open furnace floor registers and cold air returns. • Set the air conditioner's vent to the closed position.
<b>Air conditioner freezing up</b>	■ <b>Cooling coils have iced up.</b>	• See Air Conditioner Freezing Up below.
	■ <b>Ice blocks the air flow and stops the air conditioner from cooling the room.</b>	• Set the mode control on high fan until the ice thaws out.

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## ROOM AIR CONDITIONERS LIMITED WARRANTY

### FIRST YEAR

**ANY PART:** If any Part supplied by FRIEDRICH fails because of a defect in workmanship or material within twelve months from date of original purchase, FRIEDRICH will repair the product at no charge, provided room air conditioner is reasonably accessible for service. Any additional labor cost for removing inaccessible units will be the responsibility of the owner.

### SECOND THROUGH FIFTH YEAR

**SEALED REFRIGERANT SYSTEM:** If the sealed refrigeration system (defined for this purpose as the compressor, condenser coil, evaporator coil, reversing valve, check valve, capillary, filter drier, and all interconnecting tubing) supplied by FRIEDRICH in your Room Air Conditioner fails because of a defect in workmanship or material within Sixty months from date of purchase, FRIEDRICH will pay a labor allowance and parts necessary to repair the Sealed Refrigeration System; **PROVIDED** FRIEDRICH will not pay the cost of diagnosis of the problem, removal and transportation of the air conditioner to and from the Service Agency, and the reinstallation charges associated with repair of the Sealed Refrigeration System. All such cost will be the sole responsibility of the owner.

**APPLICABILITY AND LIMITATIONS:** This warranty is applicable only to units retained within the Fifty States of the U.S.A., District of Columbia, and Canada. This warranty is not applicable to:

1. Air filters or fuses.
2. Products on which the model and serial numbers have been removed.
3. Products which have defects or damage which results from improper installation, wiring, electrical current characteristics, or maintenance; or caused by accident, misuse or abuse, fire, flood, alterations and/or misapplication of the product and/or units installed in a corrosive atmosphere, default or delay in performance caused by war, government restrictions or restraints, strikes, material shortages beyond the control of FRIEDRICH, or acts of God.

**OBTAINING WARRANTY PERFORMANCE:** Service will be provided by the **FRIEDRICH Authorized Dealer or Service Organization** in your area. They are listed in the Yellow Pages. If assistance is required in obtaining warranty performance, write to Room Air Conditioner Service Manager, Friedrich Air Conditioning Co., P.O. Box 1540, San Antonio, TX 78295-1540.

**LIMITATIONS:** THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER WARRANTIES. Anything in the warranty notwithstanding, ANY IMPLIED WARRANTIES OF FITNESS FOR PARTICULAR PURPOSE AND/OR MERCHANTABILITY SHALL BE LIMITED TO THE DURATION OF THIS EXPRESS WARRANTY. MANUFACTURER EXPRESSLY DISCLAIMS AND EXCLUDES ANY LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGE FOR BREACH OF ANY EXPRESSED OR IMPLIED WARRANTY.

**NOTE:** Some states do not allow limitations on how long an implied warranty lasts, or do not allow the limitation or exclusion of consequential or incidental damages, so the foregoing exclusions and limitations may not apply to you.

**OTHER:** This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

**PROOF OF PURCHASE:** Owner must provide proof of purchase in order to receive any warranty related services.

All service calls for explaining the operation of this product will be the sole responsibility of the consumer.

All warranty service must be provided by an **Authorized FRIEDRICH Service Agency**, unless authorized by FRIEDRICH prior to repairs being made.

Revised (10/00)



FRIEDRICH AIR CONDITIONING CO.  
Visit our web site at [www.friedrich.com](http://www.friedrich.com)

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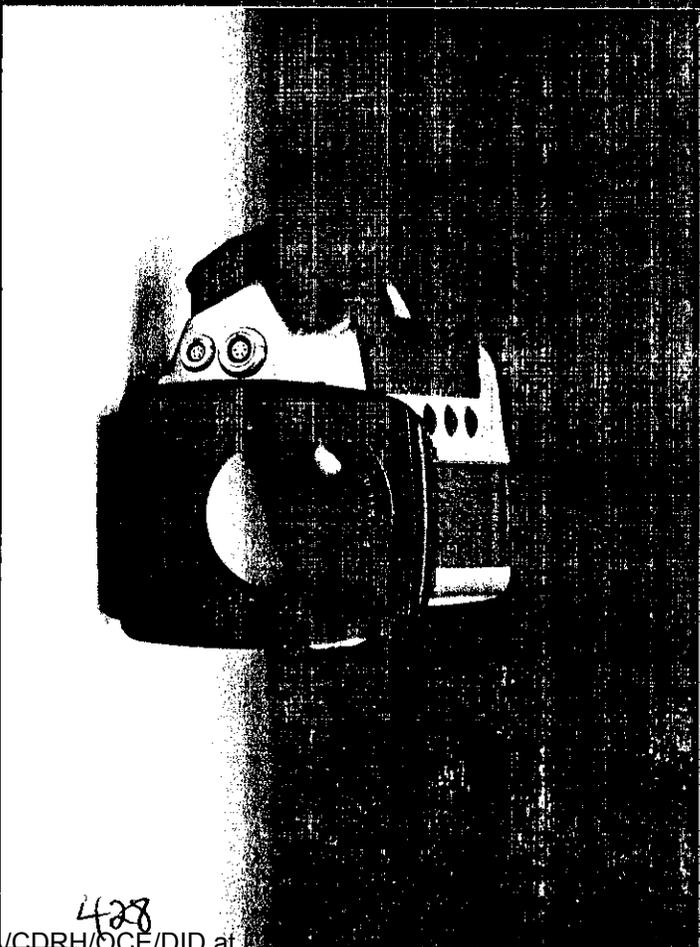
920-095-02 (01/02)

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# ThermaCAM™ S40

## Operator's Manual



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# ThermaCAM™ S40 Operator's Manual



Publ. No. 1 557 539 [ENG], Rev.: A - June 10, 2002



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Products not manufactured by FLIR included in systems delivered by FLIR to the original purchaser carry the warranty, if any, of the original supplier only and FLIR has no responsibility whatsoever for such products.

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FLIR will not be held responsible for any product covered by this warranty, the product must not be further used in order to prevent additional damage. Release of the product promptly report any defect to FLIR or this warranty will not apply.

At its option, repair or replace any such defective product free of charge if, upon inspection, it proves to be defective in material or workmanship and provided that it is returned to FLIR within the said one-year period.

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**Warranty Assurance**  
 FLIR Management System under which these products are developed and manufactured has been certified in accordance with the ISO 9001.

FLIR is committed to a policy of continuous development; therefore we reserve the right to make changes and improvements on any of the products described in this manual without prior notice.

**Interference**  
 FLIR cameras, uses, and can radiate radio frequency energy and if not installed and used in accordance with the instruction manual, may cause interference to radio communications. It has been tested and found to comply with the limits for a Class A computing device pursuant to Subpart J of Part 15 of FCC Rules, which are designed to provide reasonable protection against such interference operations in a commercial environment. Operation of this equipment in a residential area is likely to cause interference in which case the user at his own expense will be required to take whatever measures may be required to correct the interference.

**Patents**  
 FLIR is protected by patents or patent pending.

FLIR focus technology used on this camera is patent pending: Swedish patent pending No. 9901851-4; PCT patent pending No. PCT/SE00/00099

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An infrared camera is a precision instrument and uses a very sensitive IR detector. Pointing the camera towards highly intensive energy sources - such as devices emitting laser radiation - may affect the accuracy of the camera readings, or even harm - or irreparably damage - the detector.

Records processed under FOIA Request # 2015-1414; CDRI on 02/20/2015

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# 1 System overview

The ThermoCAM™ S40 infrared condition monitoring system consists of an IR camera with a built-in 24° lens, an optional remote control, and a range of accessories. The IR camera measures and images the emitted infrared radiation from an object. The fact that radiation is a function of object surface temperature makes it possible for the camera to calculate and display this temperature.

The ThermoCAM™ S40 camera is dust- and splash-proof and shock- and vibration-tested for use in the most demanding field conditions. It is a handheld, truly portable camera, which is lightweight and operates for more than 2 hours on one battery pack. A high-resolution color image is provided in real-time either in the integral viewfinder or on the (optional) remote control LCD.

The camera is very easy to use and is operated by using a few buttons which are conveniently placed on the camera, allowing fingertip control of major functions. A built-in menu system also gives easy access to the advanced, simple-to-use camera software for increased functionality.

To document the object under inspection it is possible to capture and store images in the internal RAM memory, or on a removable CompactFlash™ card. It is also possible to store, together with every image, voice comments, including information such as the object's ID data, field conditions etc. This is achieved by making use of the head-set connected to the camera. The images can be analyzed either in the field by using the real-time measurement markers built into the camera software, or in a PC by using FLIR Systems softwares for IR analysis and reporting.

Optionally, the camera can be upgraded to burst recording functionality, which allows the user to record sequences of events to the internal RAM memory at a very high speed.

In the PC the images can not only be viewed and analyzed, but the voice comments can also be played back. FLIR Systems softwares makes it very easy to create complete survey reports (containing numerous IR images, photos, tables etc.) from the inspections.

The ThermoCAM™ S40 is also supported by ThermoCAM™ Connect – a new software from FLIR Systems, running in the Windows® Explorer environment. Connecting the camera to a PC with a RS-232, or USB cable makes the camera appear as a disk unit in Windows® Explorer, where images in the camera easily can be moved to the PC by 'drag-and-drop'.

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## 2 Unpacking

The ThermoCAM™ S40 and its accessories are delivered in a hard case which should contain the following items.

- ① Power supply
- ② Hand strap
- ③ Lens caps
- ④ Installation CD for the ThermoCAM™ Connect software
- ⑤ Operator's Manual
- ⑥ USB cable
- ⑦ ThermoCAM™ S40 infrared camera with 24° IR lens
- ⑧ Power cable
- ⑨ Two Li/Ion (lithium/ion) batteries
- ⑩ Stand-alone battery charger
- ⑪ Two FireWire™ cables
- ⑫ Shoulder strap
- ⑬ Headset

If any item is missing, or has been damaged during transit, please contact your local sales office.

▶ For information about installing the software, see the section Software installation & operation on page 3.

Records processed under FOIA Request #2015-6111

## 3 Software installation & operation

### 3.1 Installation

#### 3.1.1 Requirements

The software will run under Microsoft® Windows® 98 Second Edition, Microsoft® Windows® Millennium, Windows® 2000 or Windows® XP.  
Free hard drive space: 10 MB

Before you install the application, please close down all other programs on the computer. Make sure ThermoCAM™ Connect is installed before connecting the camera to the USB port.

#### 3.1.2 Installing ThermoCAM™ Connect

- ① Make sure the IR camera is shut off and no cable is attached between the camera and the computer.
- ② Insert the ThermoCAM™ Connect installation CD in the CD-ROM player.
- ③ Select the preferred language and follow the instructions on the screen.

If the installation program doesn't start when you insert the installation CD, please start the program manually:

- ① Double-click on *My Computer* on the *Desktop*.
- ② Right-click on your CD-ROM player and select *Explore*.
- ③ Double-click on *Setup.exe*.
- ④ Select the preferred language and follow the instructions on the screen.

After the installation is completed, you should see a new icon named *ThermoCAM™ Connect* on the *Desktop*. If you don't see the icon, move the mouse cursor to an empty area on the *Desktop*, right-click and select *Refresh*.

Double-click on the icon *ThermoCAM™ Connect* and you will be able to transfer files (IR images) between the IR camera and the computer.

#### 3.1.3 Connecting to the camera after installation of ThermoCAM™ Connect and the modem

You have now finished installing *ThermoCAM™ Connect* and the modem needs to be connected between the computer and the camera. Close *Windows Explorer* and start it again. There will now be a new icon in *Windows Explorer's* left pane, *ThermoCAM™ Connect*.

Connect the camera to the computer, if it is not already connected. Click on the plus sign to the left of the *ThermoCAM™ Connect* icon in *Windows Explorer* to

show all cameras. Click on the plus sign to the left of a camera icon to connect to the camera. A dialog with a progress bar will be displayed as the connection is established.

You will now see the files and folders in the camera in the same way as when you browse your normal hard disk and you are now able to copy files to and from the camera in the normal fashion, e.g. by 'drag and drop'.

### 3.2.2 Troubleshooting

#### 3.2.2.1 When connecting the IR camera using USB (Universal Serial Bus)

##### 3.2.2.1.1 Windows® 2000 & Windows® XP USB Modem Installation

- 1) Please follow instructions in the section 3.1.2 – *Installing ThermoCAM™ Connect and completely run the installation procedure.*
- 2) If Windows® searches for *FLIR Still Camera*, insert the *ThermoCAM™ Connect Installation CD* and locate the file *MDMFLIRNTUSB.INF* and select it.

##### 3.2.2.1.2 Windows® 98 Second Edition & Windows® Millennium USB Modem Installation

- 1) Please follow instructions in the section 3.1.2 – *Installing ThermoCAM™ Connect and completely run the installation procedure.*
- 2) If Windows® searches for *USB Composite Device*, insert Windows® 98 Second Edition CD and install the needed files.
- 3) If Windows® searches for *FLIR Still Camera*, insert the *ThermoCAM™ Connect Installation CD*, locate the file *MDMFLIR98USB.INF* and select it.

#### 3.2.2.2 When connecting the IR camera using serial port (COM)

If you see the message *You must install a camera driver before connecting to the camera*, an appropriate serial port modem must be installed manually. If you use Windows® 2000 or Windows® XP, please read section 3.2.2.1 – *Windows® 2000 & Windows® XP Serial Port Modem Installation*. If you use Windows® 98 Second Edition or Windows® Millennium, please read section 3.2.2.2 – *Windows® 98 Second Edition & Windows® Millennium Serial port Modem Installation*.

##### 3.2.2.2.1 Windows® 2000, Windows® XP Serial Port Modem Installation

- 1) If the program asks for an area code, enter any number between 0 and 9 and press *Next*.

- 2) If you see the modem *ThermoCAM™ USB modem*, select it and select *Remove*.

- 3) Select *Add (Modems, Add)*.
- 4) If you see the dialog saying *Do you want Windows to detect your modem?*, select *Don't detect my modem*.

- 5) Select *Next*.
- 6) Make sure the *ThermoCAM™ Connect Installation CD* is in the CD-ROM player and select *Have disk and Browse*.

- 7) Locate file *MDMFLIRNTCOM.INF* on the installation CD.
- 8) Select the file, select *Open* and select *OK* when Windows® lists *ThermoCAM™ serial modem*.

- 9) Continue by selecting *Yes*, despite the missing digital signature.
- 10) Select the COM port you intend to connect the IR camera and select *Next*.
- 11) Select *Finish*.
- 12) Close the dialog *Phone and Modem Options*.

##### 3.2.2.2 Windows® 98 Second Edition & Windows® Millennium Serial Port Modem Installation

- 1) If you see a modem *ThermoCAM™ USB modem*, select it and select *Remove*.
- 2) Select *Don't detect modem and Next*.

- 3) Make sure the *ThermoCAM™ Connect Installation CD* is in the CD-ROM player and select *Have disk and Browse*.

- 4) Locate file *MDMFLIR98COM.INF* on the installation CD and select *OK*.
- 5) Select *OK* and select *Next* when Windows® lists *ThermoCAM™ serial camera*.

- 6) Select the COM port you intend to connect the IR camera and select *Next*.
- 7) If the program asks for an area code, enter any number between 0 and 9 and press *Next*.

- 8) Select *Finish*.
- 9) Close the dialog *Phone and Modem Options*.

2.3 Other problems

2.3.1 Microsoft® Internet Explorer going 'offline'

When the computer is connected to Internet, and Internet Explorer, for some reason, loses the connection, it goes 'offline'. This also means that Windows® terminates all other connections - even the connection with the camera. This happens, uncheck Work offline in the File menu in Internet Explorer.

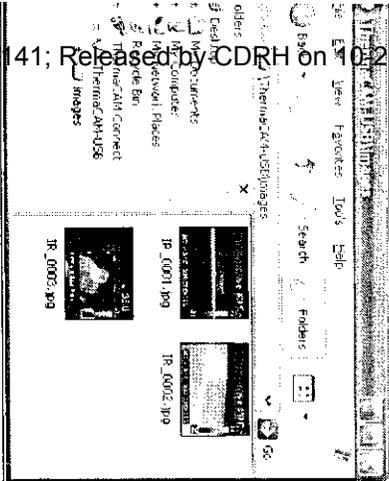


Figure 3.1 How the camera is displayed in the Windows® Explorer environment.

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4 Getting started

4.1 Removing & connecting system components

4.1.1 How to change the lenses

Optional lenses are available.

**N.B.** - Before trying to remove fingerprints or other marks on the lens elements, see the section Maintenance & cleaning on page 49.

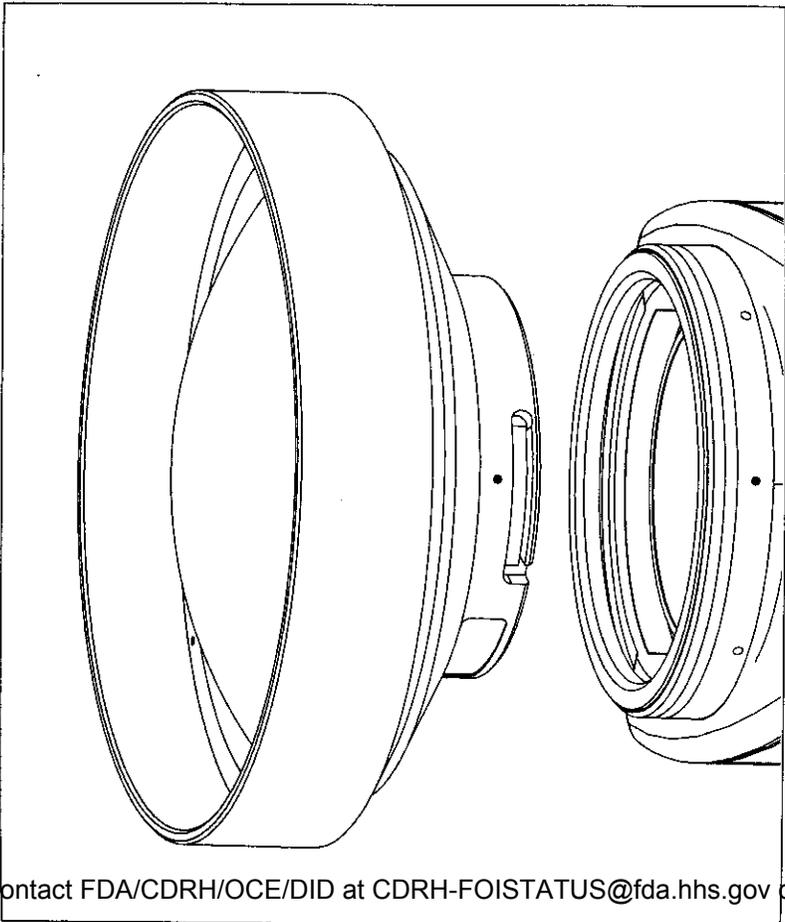


Figure 4.1 A removed lens, showing the index marks on the IR lens and on the camera.

4.1.1.1 Removing an IR lens

- ① Rotate the IR lens 30° counter-clockwise until the index mark on the lens is lined up with index mark on the camera.
- ② Carefully pull out the lens. Do not use excessive force.

4.1.2 Mounting an IR lens

- 1) Make sure the index mark on the IR lens is lined up with the index mark on the camera.
- 2) Carefully push the lens into the lens recess and rotate the locking ring 30° clockwise. Do not use excessive force.

4.2.1 How to insert and remove the battery

- 1.B.2 The camera is shipped with uncharged batteries. To charge a battery internally, first connect the camera to external power, then insert the battery. The battery will now be charged.

- 1) To insert the battery, open the cover by pressing the release button.
- 2) Insert the battery with the connectors facing downwards.
- 3) To remove the battery, open the cover by pressing the release button.
- 4) The battery is spring-loaded and can easily be pulled out from the battery compartment.

The battery can also be charged by using the stand-alone dual-bay battery charger. For more information about battery charging, see the section Battery system on page 45.

4.2.1 First time operation

4.2.1.1 How to turn on & turn off the camera

- 1) Insert a battery into the battery compartment.
- 2) Turn on the camera by briefly pressing the green on/off button on the back of the camera.
- 3) Turn off the camera by keeping down the green on/off button on the back of the camera for a few seconds.

4.2.2 How to acquire an image

- 1) Point the camera at a warm object, like a face or a hand.
- 2) Adjust the focus by pressing the A button for a few seconds.
- 3) Briefly press the A button to make the camera perform an auto-adjust maneuver and optimize the image).

4.2.3 How to save an image to disk

- 1) Briefly press the A button to make the camera perform an auto-adjust maneuver and optimize the image.
- 2) Adjust the focus by pressing the A button for a few seconds.
- 3) Momentarily press the S button to freeze the image. This will display a confirmation box where you will be prompted to accept or cancel the image. Accept-

ing the image will save it to the internal RAM memory or the CompactFlash™ card.  
4) To save an image directly (without freezing the image), press the Save button for a few seconds.

4.2.4 How to recall a previously saved image

- 1) Select File in the main menu.
- 2) Select Open... to view the most recently saved or viewed image. To view another image, use the joystick to select the image.

4.2.5 How to measure a temperature

- 1) Select Measure in the main menu
- 2) Select Spot. A spot will now appear on the screen.
- 3) Clicking on the spot once displays a hand, indicating that the spot can be moved by using the joystick.
- 4) The measured temperature will be displayed in the result table in the top right corner of the screen.

4.2.6 How to set a new language

- 1) Select Setup in the main menu.
- 2) Select Localization and press the joystick.
- 3) Select Language by moving the joystick up or down.
- 4) Set the language by moving the joystick left or right.
- 5) Press the joystick to confirm the choice and leave the dialog box.

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# 5 Operation

## 5.1 Physical user interface

### 5.1.1 The camera parts

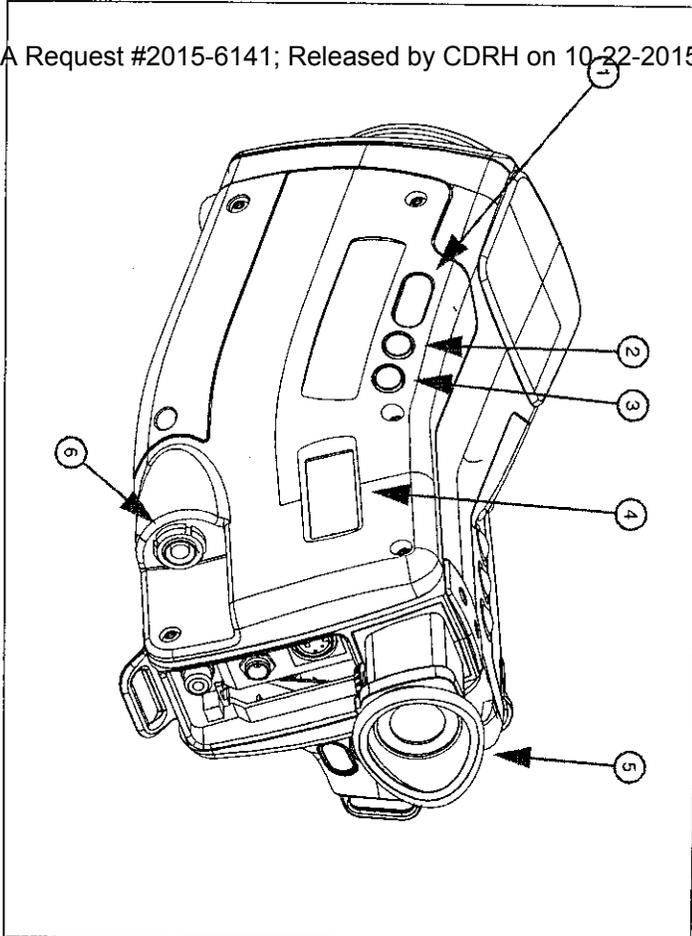


Figure 5.1 Camera parts.

- ① Buttons (see the section Camera buttons on page 14)
- ② A button (see the section Camera buttons on page 14)
- ③ S button (see the section Camera buttons on page 14)
- ④ Camera status LCD (see the section Camera status LCD on page 15)
- ⑤ Viewfinder
- ⑥ Connector for (optional) remote control

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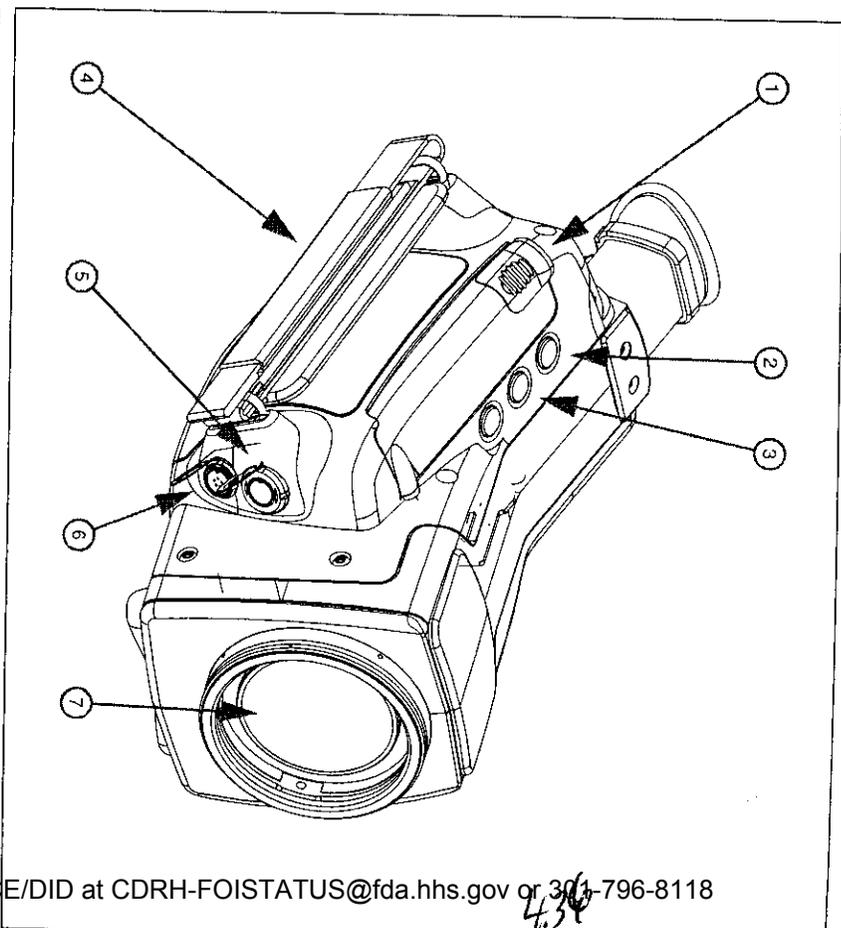


Figure 5.2 Camera parts, continued.

- ① Battery cover with release button
- ② A button (see the section Camera buttons on page 14)
- ③ S button (see the section Camera buttons on page 14)
- ④ Hand strap
- ⑤ RS-232/USB connector
- ⑥ Headset connector
- ⑦ IR lens

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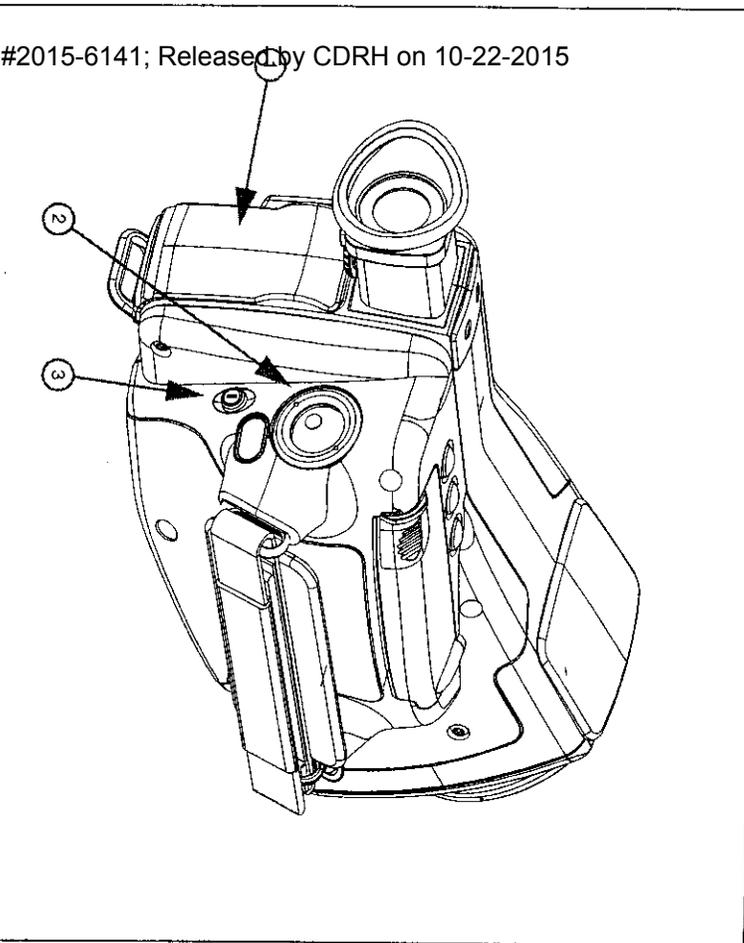


Figure 5.3 Camera parts, continued.

- ① Cover for additional connectors
- ② Joystick (see the section Camera buttons on page 14)
- ③ On/off button (see the section Camera buttons on page 14)

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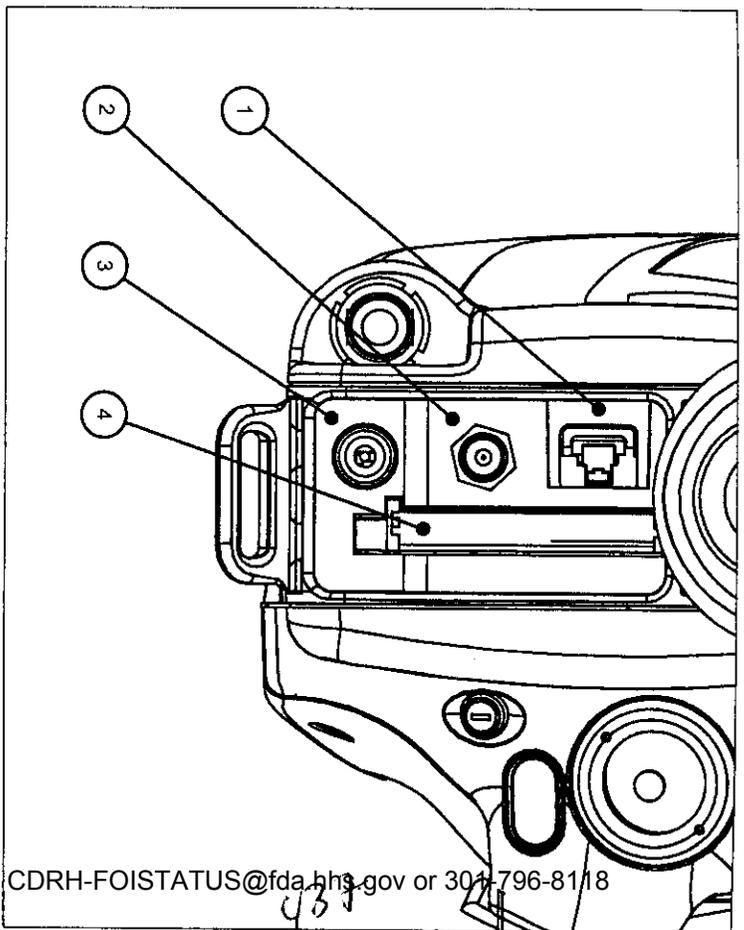


Figure 5.4 Connectors (cover removed).

- ① FireWire™ out
- ② External power in
- ③ C-VHS out
- ④ CompactFlash™ slot

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

## 5.2 Camera buttons

Figure 5.5 Camera buttons - explanations

Button	Function & explanation
On/Off	Press briefly to switch on the camera. Keep down for a few seconds to switch off the camera.
A	Press down briefly to perform an auto-adjust maneuver. Press down to leave dialog boxes without confirming choices. Keep down for a few seconds to let the camera autofocus.
S	Press down briefly to freeze an image and be prompted before saving. Keep down for a few seconds to store without previewing. Press down briefly to display a context-sensitive menu (when an item on the screen is selected).
JoyStick	Press to: Display the menu system. Exit the menu system; Confirm choices and leave dialog boxes. Select circles, boxes & spots. Move up/down/left/right to: Navigate in menus, dialog boxes, and on the screen. Move or resize circles, boxes & spots.
+/-	Focus
F1	Auto-adjust
F2	Autofocus

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## 5.3 Autofocusing

To let the camera autofocus, keep down the A button for a few seconds.

Figure 5.6 To think about when autofocusing

- The area that the camera uses when autofocusing is a 80 x 60 pixel box, centered vertically and horizontally on the screen.
- The camera will have difficulties autofocusing when the image has low contrasts between different areas.
- The user should keep the camera steady when autofocusing.
- Horizontal or vertical lines in the image should not be parallel to the pixel lines.
- The camera will have difficulties autofocusing if it is completely out of focus when beginning the autofocus sequence.

## 5.4 Camera status LCD

The camera status LCD on the left side of the camera displays information about battery status, communication status, disk status etc.

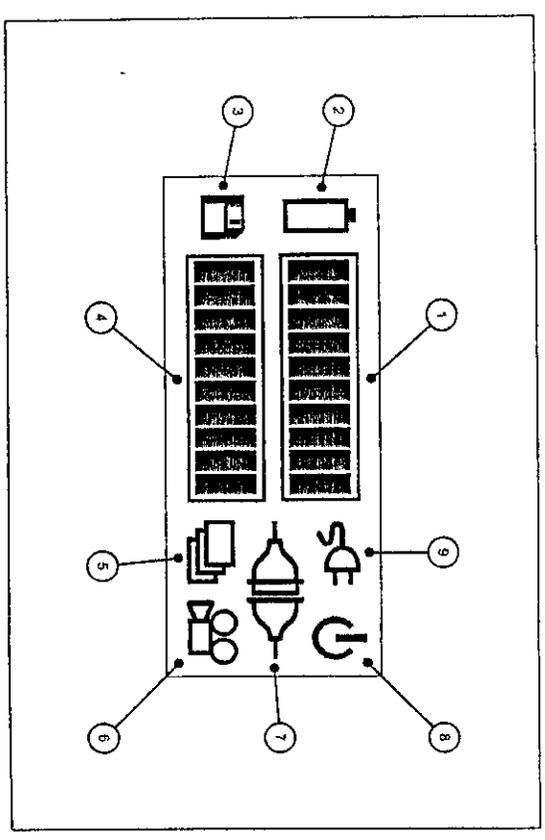


Figure 5.7 Camera status LCD.

Figure 5.8 Camera status LCD – explanations

Callout	Comments
①	Battery status bar. The frame around the battery status bar is lit when a battery is inserted. All segments lit = fully charged battery. All segments shut off = empty battery or no battery inserted.
②	Battery indicator. Lit if a battery is inserted, flashing if the battery is being charged internally.
③	CompactFlash™ indicator. Lit if a CompactFlash™ card is inserted.
④	CompactFlash™ status bar. All segments lit = the card is empty. All segments shut off = the card is full.
⑤	N/A
⑥	N/A
⑦	Communication indicator. Lit when a communication link is active.
⑧	Power indicator. Both segments lit when the camera is powered on. Both segments shut off when the camera is shut off. The outer segment flashing when the camera is in 'deep sleep'.
⑨	External power indicator. Lit when the camera is externally powered.

## 5.5 Graphical user interface

### 5.5.1 Screen objects

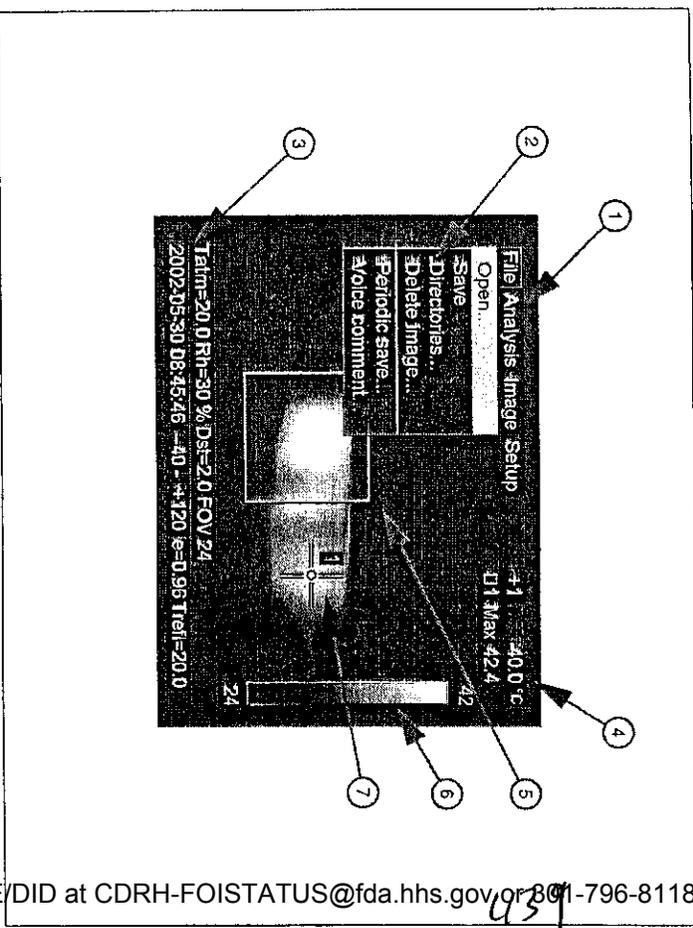


Figure 5.9 Screen objects.

- ① Main menu bar
- ② Drop-down menu
- ③ Status bar
- ④ Result table
- ⑤ Measurement marker: box
- ⑥ Temperature scale
- ⑦ Measurement marker: spot

#### 5.5.1.1 Navigating on the screen

To navigate on the screen, move the joystick towards the object you want to access. When you access an object, it will be indicated either by the object turning gray (measurement markers, the temperature scale, and the status bar) or by the object re-appearing on the screen (the focus indicator, and the top menu bar).

5.5.1.2 Selecting, moving, and resizing screen objects

To be able to move or change the settings of a screen object, the object first has to be selected. As an example, the figure below shows the difference between an unselected, a selected, an accessed, and a movable measurement box.

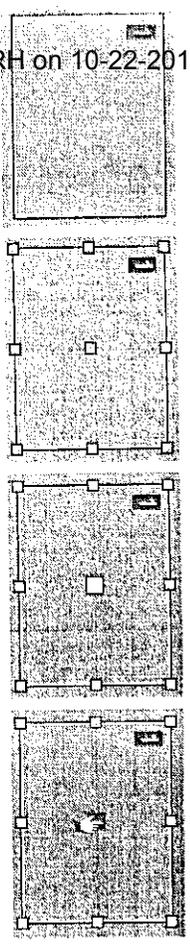


Figure 5.10 An unselected, a selected, an accessed, and a movable box.

5.5.1.2.1 Example 1: Clicking on a measurement marker

Figure 5.11 Effects of clicking on a measurement marker

Action	Effect
Moving the joystick towards a marker	The marker will be selected, which is indicated by the marker turning gray. Pressing S at this stage will bring up a context-sensitive menu.
Clicking once on a marker	A handle on the marker will turn yellow. If the user moves the joystick at this stage, the 'imaginary' cursor will snap to the closest handle in that direction. If this handle is clicked once again, the marker can now be resized.
Clicking twice on a marker	A hand will appear on the marker. This allows the user to move the marker by moving the joystick.

5.5.1.2.2 Example 2: Clicking on the status bar

Figure 5.12 Effects of clicking on the status bar

Action	Effect
Moving the joystick towards the status bar	The status bar will be selected, which is indicated by the bar turning gray. Pressing S at this stage will bring up a context-sensitive menu.
Clicking once on the status bar	A segment on the status bar will turn yellow. If the user moves the joystick left/right at this stage, the next segment in the status bar will turn yellow.
Clicking twice on a status bar segment	A segment on the status bar will turn blue. If the user moves the joystick up/down at this stage, the value in this particular segment can be changed.

5.5.1.3 Result table



Figure 5.13 Result table.

The results of measurement markers and difference calculations are displayed in a result table in the top right-hand corner of the screen.

Figure 5.14 Special signs in the result table

---	Undefined temperature
<	Temperature below range
>	Temperature above range
*	Uncalibrated, i.e. the temperature is outside calibrated range

See also the section The Measure menu on page 28.

5.5.1.4 Status bar



Figure 5.15 Status bar.

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

Pressing S when the status bar is selected will bring up a context-sensitive menu.



Figure 5.16 The context-sensitive menu for the status bar.

Select *Hide* to hide the status bar. Pressing *Settings* will display a dialog box where the settings for the status bar can be changed. When changing these settings, the operator will immediately see how the status bar changes.

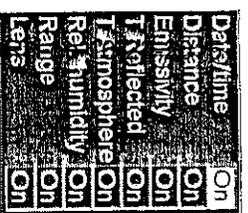


Figure 5.17 The Status bar settings dialog box.

Figure 5.18 Explanations for the Status bar settings dialog box

Label	Values	Comments
Date/time	On	Press the joystick left/right to enable/disable this label in the status bar.
Distance	On, Off	Press the joystick left/right to enable/disable this label in the status bar.
Emissivity	On, Off	Press the joystick left/right to enable/disable this label in the status bar.
Reflected	On, Off	Press the joystick left/right to enable/disable this label in the status bar.
Atmosphere	On, Off	Press the joystick left/right to enable/disable this label in the status bar.
Relative humidity	On, Off	Press the joystick left/right to enable/disable this label in the status bar.
Range	On, Off	Press the joystick left/right to enable/disable this label in the status bar.
Lens	On, Off	Press the joystick left/right to enable/disable this label in the status bar.

5.5.1.5 Temperature scale



Figure 5.19 Temperature scale.

The temperature scale is displayed on the right-hand side of the screen. The scale shows how the colors are distributed along the various temperatures in the range, with high temperatures at the upper end and low temperatures at the lower end. Pressing *S* when the temperature scale is selected will bring up a context-sensitive menu.

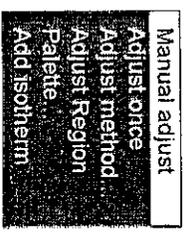


Figure 5.20 The context-sensitive menu for the temperature scale.

Figure 5.21 Explanations for the context-sensitive temperature scale menu

Label	Values	Comments
Manual adjust	N/A	See the section Automatic adjust Manual adjust on page 36.
Adjust once	N/A	See the section Adjust once on page 35.

**Figure 5.21** Explanations for the context-sensitive temperature scale menu (continued from previous page)

Adjust method...	Level-Span, Level, Histogram	Selecting <i>Adjust method</i> will bring up a dialog box where the operator can choose between different adjustment methods.
		Press the joystick left/right to change adjustment method.
		These settings influence the image quality and different settings may be suitable for different types of images and/or applications.
Adjust region	N/A	Selecting <i>Adjust region</i> will bring up a box on the screen. The box can be resized and defines the area that will be adjusted.
Palette	Iron, Rainbow, Rainbow HC, Gray	Selecting <i>Palette</i> will bring up a dialog box where you can choose between different palettes.
		See also the section <i>Palette</i> on page 37.
Add isotherm	N/A	Selecting <i>Add isotherm</i> will add an isotherm to the temperature scale.

See also the section *Image... on page 38.*

**5.5.1.6 Status area**

The status area shows the current action.

**Figure 5.22** Status area messages – explanations

Checking disk	The message is displayed when a CompactFlash™ card is inserted.
Frozen	The message is displayed when the image is frozen.
Saving	The message is displayed during the time an image with the name 20020301_0008.JPG is stored on the CompactFlash™ card.
Adjusting	The message is displayed when the camera performs an auto-adjustment.

**Figure 5.22** Status area messages – explanations (continued from previous page)

20020301_0008.JPG	The recalled image name and the speaker symbol are displayed if the image contains a voice comment.
Zooming in/out	The message is displayed when zooming.
Focus far/near	The message is displayed when changing focus.

**5.5.1.7 Critical camera information**

Critical camera information is displayed in the center of the screen.

**Figure 5.23** Critical camera information – explanations

Battery low	The battery voltage is below a specified limit and the batteries will be empty within minutes.
Battery empty	The battery voltage has dropped below a minimum. The camera will be switched off within 10 seconds.
Recalibrating camera	The message is displayed when the camera is changing the temperature range.
Failed checking disk	The message is displayed if an error occurred during the disk checking procedure. The message will be displayed until the faulty disk is removed.
Unknown CompactFlash™	The message is displayed if a non-CompactFlash™ card is inserted in the camera and will be displayed until the disk is removed.
Disk error	The message is displayed if some kind of error is detected while reading/writing to the CompactFlash™ card.

**5.5.2 File system**

The ThermoCAM™ S40 uses the internal RAM memory, or standard CompactFlash™ cards, to record 16-bit and 8-bit images JPEG images with voice comments.

**5.5.2.1 Naming files and directories**

When storing an image the name is automatically generated based on either the current date or the current directory according to the selection made in the *Setup* → *Save dialog box*.

5.5 – Graphical user interface]

5.5.2.1.1 Image names based on current date

Figure 5.24 Naming based on current date – explanations

Image name: **YYYYMMDD\_mmmn.JPG**

YYYY	Current year
MM	Current month (01-12)
DD	Current day (01-31)
mmm	Image number

Example: The current date is March 1st, 2002. Two images have already been stored on this date. The next image will be named 20020301\_0003.JPG.

5.5.2.1.2 Image names based on current directory

Figure 5.25 Naming based on current directory – explanations

Image name: **DIREC\_mmmn.JPG**

DIREC	First five characters in the directory name
mmm	Image number

Example: The directory name is COMPANY. Two images have already been stored on this date. The next image will be named COMPA\_0003.JPG.

5.5.3 Menu system

Moving the joystick left/right will display the different drop-down menus. Selecting an item in a drop-down menu is made by moving the joystick up/down, which will highlight the menu item. Some of the functions may be marked gray, indicating that they can not be activated under the current conditions.

Figure 5.26 Actions when the joystick is pressed

5.5.3.1

If the selected menu item has three dots at the end (e.g. Open...) a dialog box will show up on the screen.

If not, the selected menu item (e.g. Save) will be carried out and the menu system will be removed.

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The menu system is organized into four main groups *File*, *Measure*, *Image* and *Setup*.

5.5.3.1 The File menu

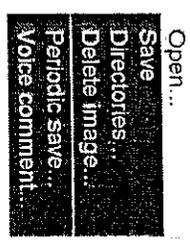


Figure 5.27 The Open menu.

5.5.3.1.1 Open...

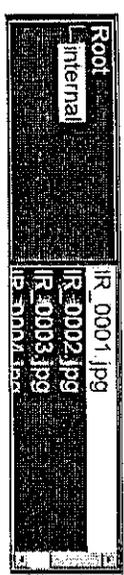


Figure 5.28 The Open dialog box.

This function is used to open or recall previously saved images from the disk. The function brings up a control box at the bottom of the screen, showing the name of the image being displayed and the directory in which the image file is stored. To select another image, move the joystick up/down.

5.5.3.1.2 Save

This function will save the displayed image to the internal RAM memory, on the CompactFlash™ card. Together with the image, all conditions, like measurement markers, color scale, zoom factor, values of object parameters etc., will be saved to be used again when the image is recalled.

Depending on the settings in the *Setup* → *Save* dialog box images can be saved either in *JPEG* or *Radiometric JPEG* file format. When saving an image, voice comments can also be added.

▶ See also the sections *Save* on page 40, and *Voice comment...* on page 26.

5.5.3.1.3 Directories...

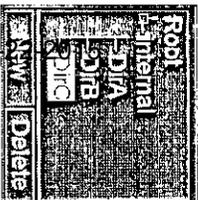


Figure 5.29 The *Directories* dialog box.

This function is used to create new directories, or delete old ones.

- To create a new directory, press *New*.
- To delete a directory, select a directory, press *Delete*, and confirm the deletion.

5.5.3.1.4 Delete image

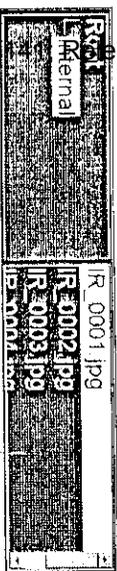


Figure 5.30 The *Delete image* dialog box.

This function is used to delete images.

- To delete an image, select the image in the directory and press the joystick.

5.5.3.1.5 Periodic save...

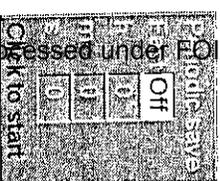


Figure 5.31 The *Periodic save* dialog box.

This function will save a number of images, at a certain selectable periodicity, to the internal RAM memory or the CompactFlash™ card. Together with the images, all the current conditions will be saved.

When activating the function, a periodic save dialog box will be displayed on the screen.

The periodicity at which images are saved can be set by using the joystick. The periodicity can be set from 2 seconds up to 24 hours. Select *Fast* for shortest time interval (as fast as possible, i.e. about one image per second).

Figure 5.32 Periodic save

Pressing the joystick will start the recording.

Pressing the joystick or pressing *A* will stop the recording.

Images will be stored sequentially in the current directory. If the recording is stopped and then started again the new images will be added at the end of the previous sequence in the same directory.

5.5.3.1.6 Voice comment...



Figure 5.33 The *Voice comment* dialog box.

In the voice comment dialog box the user can:

- listen to a recorded comment, make a pause, and then continue.
- record a new comment, make a pause, and then continue.
- edit a recorded comment, i.e. listen and/or add a comment at the end of the recorded comment.
- overwriting an existing recording.
- adding comments to an already recorded voice comment.

5.5.3.2 The Measure menu

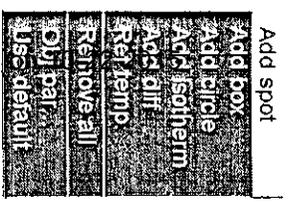


Figure 5.34 The Measure menu.

In the Measure menu measurement markers can be activated. The result from a measurement marker is presented in the result table located in the top right-hand corner of the screen. The user can also select Remove all to de-activate all measurement markers.

5.5.3.2.1 Add spot

To add a spot, select Add spot in the Measure menu. Pressing the S button when the spot is selected will display a context-sensitive menu.

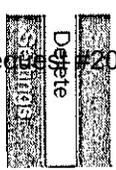


Figure 5.35 The context-sensitive menu for Spot.

Press Delete to delete the spot. Pressing Settings will display a dialog box where the Settings for the spot can be changed.

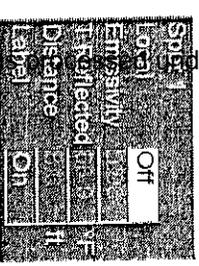


Figure 5.36 The Spot settings dialog box.

Figure 5.37 Explanations for the Spot settings dialog box

Label	Values	Comments
Local	On, Off	Selecting On will let the operator set the emissivity, the reflected temperature, and the distance for this spot only.
Emissivity	User-defined	Selecting On will also assign an asterisk to the measurement marker's label.
T Reflected	User-defined	Emissivity can be set if Local is enabled. If not, this option will be shaded.
Distance	User-defined	T Reflected can be set if Local is enabled. If not, this option will be shaded.
Label	On, Off	Distance can be set if Local is enabled. If not, this option will be shaded.
		Selecting On will assign a label to the measurement marker (a small box with a number).

5.5.3.2.2 Add box

To add a box, select Add box in the Measure menu. Pressing the S button when the box is selected will display a context-sensitive menu.

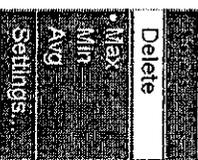


Figure 5.38 The context-sensitive menu for Box.

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Select *Delete* to delete the box. Select *Max*, *Min* or *Avg* to set how the box will measure the temperature. Selecting *Settings* will display a dialog box where the settings for the box can be changed.

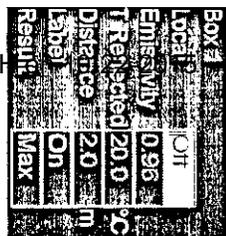


Figure 5.39 The Box settings dialog box.

Figure 5.40 Explanations for the Box settings dialog box

Label	Value	Comments
Local	On, Off	Selecting <i>On</i> will let you set the emissivity, the reflected temperature, and the distance for this box only.
Emissivity	User-defined	Selecting <i>On</i> will also assign an asterisk to the measurement marker's label.
T Reflected	User-defined	Emissivity can be set if <i>Local</i> is enabled. If not, this option will be shaded.
Distance	User-defined	<i>T Reflected</i> can be set if <i>Local</i> is enabled. If not, this option will be shaded.
Label	On, Off	Distance can be set if <i>Local</i> is enabled. If not, this option will be shaded.
Result	Min, Max, Avg	Selecting <i>On</i> will assign a label to the measurement marker (a small box with a number). To change how the box displays the measurement results, select <i>Max</i> , <i>Min</i> , or <i>Avg</i> .

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5.5.3.2.3 Add circle  
To add a circle, select *Add circle* in the *Measure* menu. Pressing the *S* button when the circle is selected will display a context-sensitive menu.

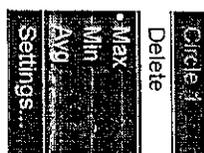


Figure 5.41 The context-sensitive menu for Circle.

Select *Delete* to delete the circle. Select *Max*, *Min* or *Avg* to set how the circle will measure the temperature. Selecting *Settings* will display a dialog box where the settings for the box can be changed.

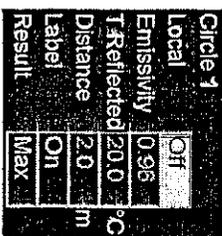


Figure 5.42 The Circle settings dialog box.

Figure 5.43 Explanations for the Circle settings dialog box.

Label	Value	Comments
Local	On, Off	Selecting <i>On</i> will let the operator set the emissivity, the reflected temperature, and the distance for this circle only.
Emissivity	User-defined	Selecting <i>On</i> will also assign an asterisk to the measurement marker's label.
T Reflected	User-defined	Emissivity can be set if <i>Local</i> is enabled. If not, this option will be shaded.
Distance	User-defined	<i>T Reflected</i> can be set if <i>Local</i> is enabled. If not, this option will be shaded.
Label	On, Off	Distance can be set if <i>Local</i> is enabled. If not, this option will be shaded.
Result	Min, Max, Avg	Selecting <i>On</i> will assign a label to the measurement marker (a small box with a number). To change how the box displays the measurement results, select <i>Max</i> , <i>Min</i> , or <i>Avg</i> .

Figure 5.43 Explanations for the Circle settings dialog box.

Distance	User-defined	Distance can be set if Local/Is enabled. If not, this option will be shaded.
Label	On, Off	Selecting On will assign a label to the measurement marker (a small box with a number).
Result	Min, Max, Avg	To change how the circle displays the measurement results, select Max, Min, or Avg.

5.5.3.2.4 Add Isotherm

The Isotherm function colors all pixels in the image which have the same temperature as the selected isotherm temperature or temperature interval. When an isotherm is added, this will be indicated in the temperature scale by the following symbol:



Figure 5.44 The temperature scale showing an isotherm symbol.

To add an isotherm, select *Add Isotherm* in the *Measure* menu. Pressing the *S* button when the isotherm is selected will display a context-sensitive menu.

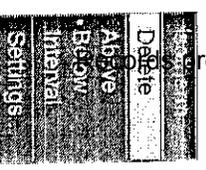


Figure 5.45 The context-sensitive Isotherm menu.

Figure 5.46 Explanations for the context-sensitive isotherm menu

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.
Settings...	Selecting <i>Settings</i> will display a dialog box where the settings for the box can be changed.

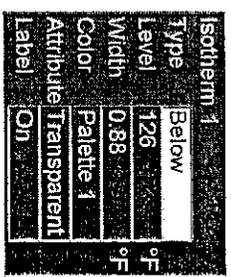


Figure 5.47 The Isotherm settings dialog box.

Figure 5.48 Explanations for the Isotherm settings dialog box

Label	Value	Comments
Type	Interval, Above, Below	See Figure 5.46.
Level	User-defined	The temperature level in degrees Celsius or degrees Fahrenheit.
Width	User-defined	The width of the isotherm in degrees Celsius or degrees Fahrenheit.
Color	Palette, Palette 1, Palette 2, Red, Green, Blue, Yellow, Cyan, Magenta, Gray.	The colors used for the isotherm.

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Figure 5.48 Explanations for the Isotherm settings dialog box (continued from previous page)

Attribute	Transparent, Solid	Selecting <i>Transparent</i> will add some transparency to an isotherm color, making it easier for the operator to see objects through the color. To make the isotherm colors appear solid, select <i>Solid</i> .
Label	On, Off	Selecting <i>On</i> will assign a label to the measurement marker (a small box with a number).

5.5.3.2.5 Add diff...

Selecting *Add diff...* adds a difference calculation which appears in the result table as *Diff*.

See also the section *Difference* on page 39.

5.5.3.2.6 Ref temp



Figure 5.49 The Reference temperature dialog box.

Selecting *Ref temp...* allows the user to set the reference temperature, which is used when the camera calculates temperature differences.

5.5.3.2.7 Obj par...

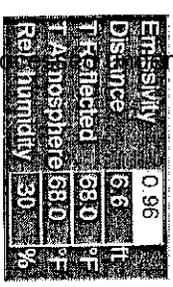


Figure 5.50 The Object Parameters dialog box.

This function is used to set the object parameters *Emissivity*, *Distance*, *T Reflected*, *T Atmosphere*, and *Rel humidity*. The parameters are selected by moving the joystick up/down and set by moving the joystick left/right.

If the CompactFlash™ card contains a user-defined table of materials with known emissivities, this table is brought up by default when trying to set the emissivity manually. In that case the emissivity can only be chosen from the table. If no Com-

compactFlash™ card is inserted, any emissivity can be set by moving the joystick left/right.

A user-defined table of materials with known emissivity can be created and edited in FLIR Systems' PC softwares.

**N.B.** – The emissivity file can be stored at root level or at directory level. However, the camera software prioritizes files that are stored at directory level and the operator has to be selected in order to store the emissivity file in the camera memory. If the camera software does not find an emissivity file at directory level, it searches for similar files at root level and saves those instead.

See also the sections *Emissivity* on page 54 and *Emissivity tables* on page 65.

5.5.3.2.8 Remove all

By selecting *Remove* all all measurement markers are de-activated.

5.5.3.3 The Image menu



Figure 5.51 The Image menu

5.5.3.3.1 Adjust once

Selecting *Adjust once* will momentarily close the camera's calibration shutter and perform an auto-adjust maneuver.

5.5.3.3.2 Freeze/Live

By selecting *Freeze/Live* the user can toggle between the *frozen* and *live* image modes. It has the same effect as briefly pressing the *S* button.

5.5.3.3.3 Range

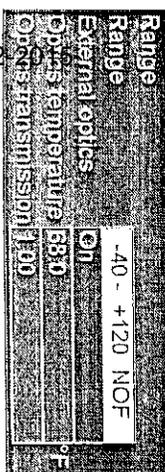


Figure 5.5.2 The Range dialog box.

By selecting **Range** a dialog box appears where the user can set the range, and specify external optics temperature and transmission values.

See also the section *Thermographic measurement techniques* on page 54.

Figure 5.5.3 Explanations for the Range dialog box

Label	Value	Comments
Range	-40 – +120 0 – +500	Move the joystick left/right to change the temperature range.
External optics	On, Off	Select <b>On</b> to specify that an external lens is used.
Optics temperature	User-defined	Set the optics temperature by pressing the joystick up/down.
Optics transmission	User-defined	Set the optics transmission by pressing the joystick up/down.

5.5.3.3.4 Automatic adjust/Manual adjust

Selecting **Manual adjust** will allow the operator to manually select **level** and **span** settings. This is done by selecting the temperature scale and pressing the joystick up/down for level or left/right for span.

The **level** function can be regarded as the **brightness**, while the **span** function can be regarded as the **contrast**.

Selecting **Automatic adjust** will put the camera in automatic mode, continuously optimizing the image for best brightness and contrast.

See also the section *Temperature scale* on page 21.

5.5.3.3.5 Palette



Figure 5.5.4 The Palette dialog box.

By selecting **Palette**, the color palette can be set.

Figure 5.5.5 Explanations for the Palette dialog box

Label	Value	Comments
Palette	Iron Rainbow Rainbow HC Gray (white hot) Gray (black hot)	Press the joystick left/right to change the palette.
Reversed	Yes, No	Press the joystick left/right to reverse the current palette.

5.5.3.3.6 Hide graphics/Show graphics

By selecting **Hide graphics** (**Show graphics**) all on-screen graphics (e.g. result table, status bar etc.) will be hidden (shown).

5.5.3.4 The Setup menu



Figure 5.5.6 The Setup menu.

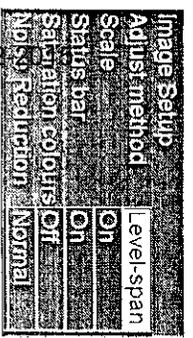


Figure 5.57 The Image Setup dialog box.

Figure 5.58 Explanations for the Image Setup dialog box

Label	Value	Comments
Adjust method	Level, Level-span, Histogram	Press the joystick left/right to change the adjust method.
Scale	On, Off	These settings influence the image quality and different settings may be suitable for different types of images and/or applications.
Status bar	On, Off	Press the joystick left/right to enable or disable the scale.
Saturation colours	On, Off	Press the joystick left/right to enable or disable the status bar.
Noise reduction	Normal, High	Press the joystick left/right to enable or disable the saturation colors.  If On is selected 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 be changed.

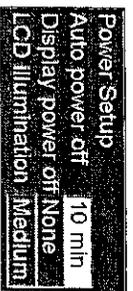


Figure 5.59 The Power Setup dialog box.

Figure 5.60 Explanations for the Power Setup dialog box

Label	Value	Comments
Auto power off	None, 10 min	Press the joystick left/right to specify the time after which the camera will be shut off if it is not used.
Display power off	None, 30 sec, 60 sec	Press the joystick left/right to specify the time after which the display will be shut off if it is not used.
LCD illumination	Low, Medium, High	Press the joystick left/right to specify the level of background illumination of the LCD.

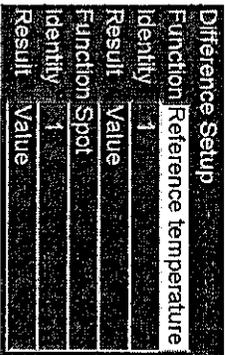


Figure 5.61 The Difference settings dialog box.

Difference is a function that calculates the temperature difference between two measurement markers, or the reference temperature and a measurement marker.

▶ See also the section *Add diff... on page 34.*

Figure 5.62 Explanations for the Difference settings dialog box

Label	Value	Comments
Function	Spot, Box, Circle, Line, Isotherm, Reference temperature	Press the joystick left/right to select the first function in the difference calculation.

Figure 5.62 Explanations for the Difference settings dialog box (continued from previous page)

Identity	1 or 2	Select 1 or 2 to assign an identity to this function.
Result	Depending on the Function settings	Press the joystick left/right to define the type of result the difference calculation will use for its calculations.
Function	Spot, Box, Circle, Line, Isotherm, Reference temperature	Press the joystick left/right to select the second function in the difference calculation.
Identity	1 or 2	Select 1 or 2 to assign an identity to this function.
Result	Depending on the Function settings	Press the joystick left/right to define the type of result the difference calculation will use for its calculations.

5.5.3.4.4 Save



Figure 5.63 The Save Setup dialog box

Figure 5.64 Explanations for the Save Setup dialog box

Label	Value	Comments
Prompt comment	None, Voice	If this parameter is set to Voice the voice comment dialog box will be displayed on the screen every time an image storage operation is made. This function gives the user a chance to add a voice comment to the image before storing the image on disk.
Image file type	None, Voice	If continuous mode is selected in image storage above, this function is ignored.

Figure 5.64 Explanations for the Save Setup dialog box (continued from previous page)

Image file type	JPEG only, Radiometric JPEG	If JPEG is selected, images will be saved as JPEG only, i.e. no temperature or measurement information will be saved inside the image file.  If Radiometric JPEG is selected, images will be saved as JPEG images with temperature or measurement information.  JPEG: Joint Photographic Experts Group – A compression algorithm named after the committee that defined it.
Overlay	On, Off	If Overlay is set to On, all on-screen graphics will be saved together with the image.  If Overlay is set to Off, only the image (together with any temperature information) will be saved to disk.

5.3.4.5 Date/time

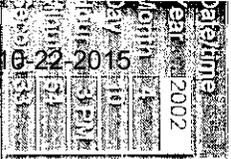


Figure 5.65 The Date/time dialog box.

5.3.4.6 Localization

Menu Item	Explanation
Year	1970-2036
Month	1 through 12
Day	1 through 31
Hour	12 a.m. through 12 p.m. or 1 through 24 (the format depends on the settings in the Localization dialog box)
Minutes	00 through 59

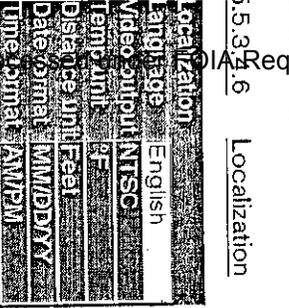


Figure 5.67 The Localization dialog box.

5.3.4.7 Camera info

Menu Item	Explanation
Language	English (+ additional languages)
Video output	NTSC or PAL

Figure 5.68 The Localization dialog box - explanations (continued from previous page)

Temp unit	°C
Distance unit	Feet Meters
Date format	YYYY-MM-DD YY-MM-DD MM/DD/YY DD/MM/YY
Time format	24 hour or AM/PM

5.5.3.4.7 Camera info

The Camera info dialog boxes show information about memory usage, battery status, serial numbers etc. No changes can be made.

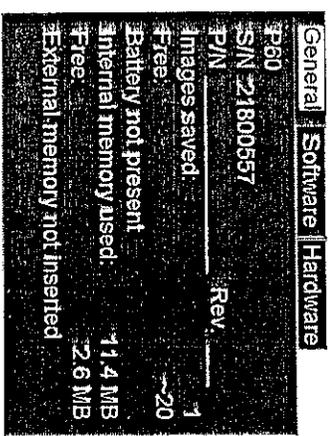


Figure 5.69 Camera info dialog box: The General tab.

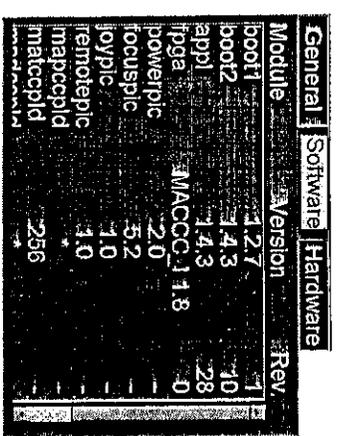


Figure 5.70 Camera info dialog box: The Software tab.

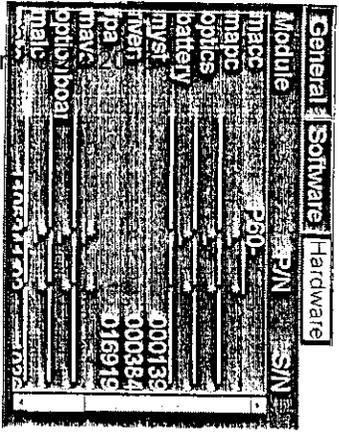


Figure 5.71 Camera info dialog box: The Hardware tab

5.5.5.8 Factory default

By selecting Factory default, all camera settings are reset to the factory settings.

## 6 Battery system

The battery system consists of a removable battery, an internal battery charger, and a stand-alone battery charger.

The removable battery gives an operation time of approx. 2 hour. When **Battery low** is displayed on the screen it is time to charge the battery.

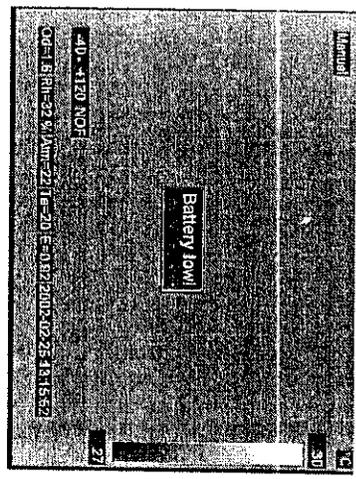


Figure 6.1 Battery low message appearing on the screen.

### 6.1 Battery charging

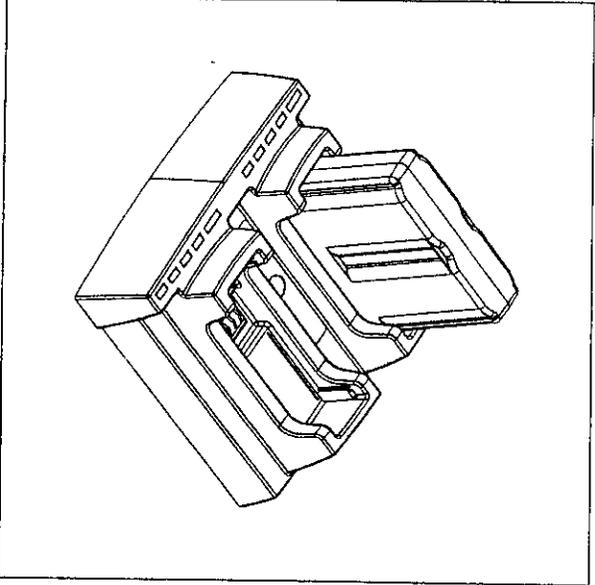


Figure 6.2 The stand-alone battery charger

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The camera battery can be charged either by using the camera's internal battery charger, or by using a stand-alone dual-bay battery charger.

**5.1.1 Charging the battery by using the internal battery charger**

- 1) Make sure the battery is correctly inserted into the camera and connect the power cable to the connector marked 2 in Figure 5.4 on page 13.
- 2) The message *Charging battery* will appear on the screen.
- 3) While charging, the battery status symbol will pulse until the battery is fully charged.
- 4) When the battery is fully charged the battery symbol will stop pulsing.
- 5) The camera is shipped with uncharged batteries. To charge a battery for the first time, first connect the camera to external power, then insert the battery.

**5.1.2 Charging the battery by using the stand-alone battery charger**

The battery status while charging is indicated by a number of LEDs (see Figure 6.3).

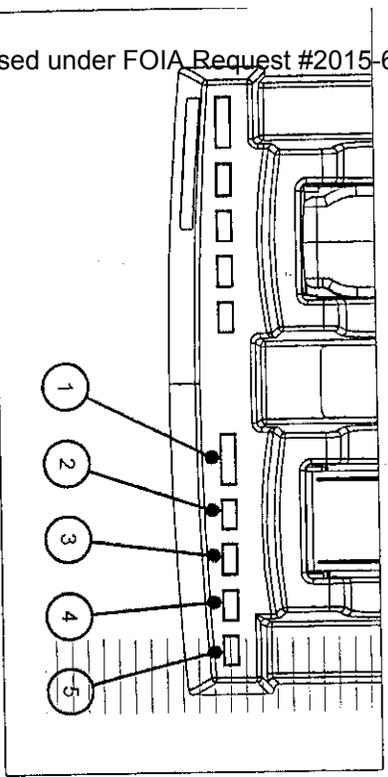


Figure 6.3 LED indicators on the stand-alone battery charger.

Figure 6.4 LED indicators - explanations

Situation	Indicator #	Color & mode
The charger is under power, but no battery is inserted	①	Fixed red light
The charger is under power, and a battery is inserted	①	Fixed green light

Figure 6.4 LED indicators - explanations (continued from previous page)

The battery is out of order	①	Flashing red light
The battery is now being charged	② to ⑤	Pulsing green light from LED ⑤ LED ② Each LED represents 25 % battery capacity and will be lit accordingly.

**6.2 Safety warnings when using the batteries**

- Do not place the battery in fire or heat the battery.
- Do not install the battery backwards so that the polarity is reversed.
- Do not connect the positive terminal and the negative terminal of the battery to each other with any metal object (such as wire).
- Do not carry or store the batteries together with necklaces, hairpins, or other metal objects.
- Do not pierce the battery with nails, strike the battery with a hammer, step on the battery, or otherwise subject it to strong impacts or shocks.
- Do not solder directly onto the battery.
- Do not expose the battery to water or salt water, or allow the battery to get wet.
- Do not disassemble or modify the battery. The battery contains safety and protection devices which, if damaged, may cause the battery to generate heat, explode or ignite.
- Do not place the battery on or near fires, stoves, or other high-temperature locations.
- Do not place the battery in direct sunshine, or use or store the battery inside cars in hot weather. Doing so may cause the battery to generate heat, explode, or ignite. Using the battery in this manner may also result in a loss of performance and a shortened life expectancy.
- When the battery is wore out, insulate the terminals with adhesive tape or similar materials before disposal.
- Immediately discontinue use of the battery if, while using, charging, or storing the battery, the battery emits an unusual smell, feels hot, changes color, changes shape, or appears abnormal in any other way. Contact your sales location if any of these problems are observed.
- In the event that the battery leaks and the fluid gets into one's eye, do not rub the eye. Rinse well with water and immediately seek medical care. If left untreated the battery fluid could cause damage to the eye.
- When charging the battery, only use a specified battery charger.
- Do not attach the batteries to a power supply plug or directly to a car's cigarette lighter.

- Do not place the batteries in or near fire, or into direct sunlight. When the battery becomes hot, the built-in safety equipment is activated, preventing the battery from charging further, and heating the battery can destroy the safety equipment and can cause additional heating, breaking, or ignition of the battery.
- Do not continue charging the battery if it does not recharge within the specified charging time. Doing so may cause the battery to become hot, explode, or ignite.
- The temperature range over which the battery can be charged is 0 °C—+45 °C (+32—+113 °F). Charging the battery at temperatures outside of this range may cause the battery to become hot or to break. Charging the battery outside of this temperature range may also harm the performance of the battery or reduce the battery's life expectancy.
- Do not discharge the battery using any device except for the specified device. When the battery is used in devices aside from the specified device it may damage the performance of the battery or reduce its life expectancy, and if the device causes an abnormal current to flow, it may cause the battery to become hot, explode, or ignite and cause serious injury.
- The temperature range over which the battery can be discharged is -15 °C—+45 °C (+18.8—+113 °F). Use of the battery outside of this temperature range may damage the performance of the battery or may reduce its life expectancy.

## 7 Maintenance & cleaning

### 7.1 Camera body & cables

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

**N.B.** - Do not use benzene, thinner, or any other chemical product on the camera or on the cables, as this may cause deterioration.

### 7.2 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<sub>2</sub>H<sub>5</sub>OH) 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<sub>4</sub>H<sub>10</sub>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<sub>3</sub>)<sub>2</sub>CO) and 50 % ethyl alcohol (C<sub>2</sub>H<sub>5</sub>OH) may be used.

**N.B.** - Excessive cleaning of the lenses may wear 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)!

## 8 'LEMO' connectors

### 8.1 How to connect and disconnect 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 outer tube and a sliding inner tube. The outer tube controls the locking teeth. To lock the connector, pull the outer tube in the indicated direction (see Figure 8.1 and Figure 8.2).

**N.B.** Never pull the cable!

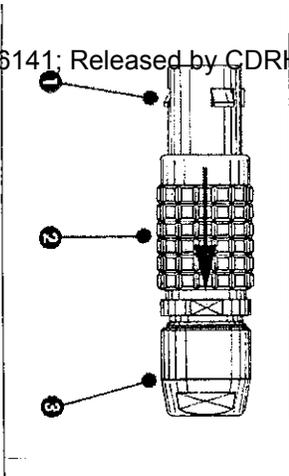


Figure 8.1 Straight body 'LEMO' connector.

- 1 Locking teeth
- 2 Sliding outer tube
- 3 Fixed inner tube

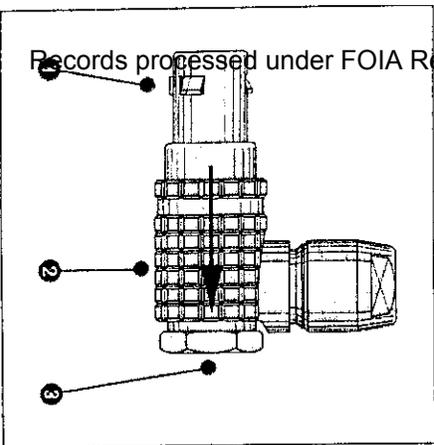


Figure 8.2 Angle body 'LEMO' connector.

## 9 Technical specifications

**N.B.** - FLIR Systems and its subsidiaries reserve the right to discontinue models, parts and accessories, and other items or change specifications at any time without prior notice.

### 9.1 Imaging performance

Field of view/min. focus distance	24° x 18/0.3 m (0.98 ft)
Spatial resolution	1.3 mrad
Thermal sensitivity @ +30 °C	0.08 °C
Image frequency	50/60 Hz, non-interlaced
Electronic zoom function	2x, 4x – interpolating
Focusing	Automatic or manual
Digital image enhancement	Adaptive Digital Noise Reduction

### 9.2 Detector

Type	Focal Plane Array (FPA), uncooled microbolometer, 320 x 240 pixels
Spectral range	7.5–13 µm

### 9.3 Image presentation

Viewfinder	Built-in, high resolution color LCD (TFT)
Optional LCD on remote control	4"

### 9.4 Measurement

Temperature range, standard	-40–+120 °C (-40–+248 °F) 0–+500 °C (+32–+932 °F) +380–+1500 °C (+662–+2732 °F)
Accuracy	± 2 °C, or ± 2 % of reading in °C
Spectral filter	Built-in, and controlled from menu, optional
Emissivity correction	Set by number, or by selection in predefined list

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA or 301-796-8118

9.5 – Power system]

Atmospheric transmission correction	Automatic, based on input from distance, atmospheric temperature, and relative humidity.
Optics transmission correction	Automatic, based on signals from internal sensors
Rejected ambient temperature correction	Yes
External optics correction	Yes

9.5e Power system

Battery type	One rechargeable Li/Ion battery
Battery operating time	1.5–2 hours. Display shows battery status
Battery charging	Internal, AC adapter External, stand-alone 2 bay charger.
AC operation	AC adapter, 90–260 VAC, 50/60 Hz, 12 VDC out
Power management	Automatic shut-down, stand-by, sleep and deep-sleep mode (user-selectable)

9.6 Environmental specifications

Operating temperature range	-15 +50 °C (+5 +122°F)
Storage temperature range	-40 +70 °C (-40 +158 °F)
Humidity	Operating & storage: 10–95 %, non-condensing.
Encapsulation	IP 54 (IEC 529)
Shock	25 g, IEC 68-2-29
Vibration	2 g, IEC 68-2-6

9.7 Physical characteristics

Weight	1.4 kg (2.86 lb), incl. battery
Size (L x W x H)	220 x 120 x 100 mm (8.66 x 4.72 x 3.94")
Tripod mounting	Standard, 1/4" 20

[9.8 – Interfaces]

9.8 Interfaces

Computer interfaces	USB 1 & RS-232
Audio input/output	Headset connection for voice annotation of images
Interface for integrated LCD & optional remote control	Yes
Power input	10–16 VDC, standard 2.1 mm connector. Polarity protected
Standard video output EIA/NTSC, CCI/PAL C-VHS (RS-170)	Standard RCA connector for composite video
FireWire™	IEEE 1394
IRDA	Standard wireless infrared link
Removable storage media	CompactFlash™ card

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

# 0 Thermographic measurement techniques

## 0.1 Introduction

An infrared camera measures and images the emitted infrared radiation from an object. The fact that radiation is a function of object surface temperature makes it possible for the camera to calculate and display this temperature.

However, the radiation measured by the camera does not only depend on the temperature of the object but is also a function of the emissivity. Radiation also originates from the surroundings and is reflected in the object. The radiation from the object and the reflected radiation will also be influenced by the absorption of the atmosphere.

To measure temperature accurately, it is therefore necessary to compensate for the effects of a number of different radiation sources. This is done on-line automatically by the camera. The following object parameters must, however, be supplied to the camera:

The emissivity of the object.

The reflected temperature.

The distance between the object and the camera.

The relative humidity.

### 10.2 Emissivity

The most important object parameter to set correctly is the emissivity which, in short, is a measure of how much radiation is emitted from the object, compared to that from a perfect blackbody.

Normally, object materials and surface treatments exhibit emissivity ranging from approximately 0.1 to 0.95. A highly polished (mirror) surface falls below 0.1, while an oxidized or painted surface has much higher emissivity. Oil-based paint, regardless of color in the visible spectrum, has an emissivity over 0.9 in the infrared. Human skin exhibits an emissivity close to 1.

Non-oxidized metals represent an extreme case of almost perfect opacity and high specular reflexivity, which does not vary greatly with wavelength. Consequently, the emissivity of metals is low – only increasing with temperature. For non-metals, emissivity tends to be high, and decreases with temperature.

[10.3 – Reflected temperature]

### 10.2.1 Finding the emissivity of an object

#### 10.2.1.1 Using a thermocouple

Select a reference point and measure its temperature using a thermocouple. Alter the emissivity until the temperature measured by the camera agrees with the thermocouple reading. This is the emissivity value of the reference object. However, the temperature of the reference object must not be too close to the ambient temperature for this to work.

#### 10.2.1.2 Using reference emissivity

A tape or paint of a known emissivity should be put onto the object. Measure the temperature of the tape/paint using the camera, setting emissivity to the correct value. Note the temperature. Alter emissivity, until the area with the unknown emissivity adjacent to the tape/paint has the same temperature reading. The emissivity value can now be read. The temperature of the reference object must not be too close to the ambient temperature for this to work either.

### 10.3 Reflected temperature

This parameter is used to compensate for the radiation reflected in the object and the radiation emitted from the atmosphere between the camera and the object. If the emissivity is low, the distance very long and the object temperature relatively close to that of the ambient it will be important to set and compensate for the reflected temperature correctly.

### 10.4 Distance

The distance is the distance between the object and the front lens of the camera. This parameter is used to compensate for the fact that radiation is being absorbed by the air between the object and the camera and the fact that transmittance drops with distance.

### 10.5 Relative humidity

The camera can also compensate for the fact that the transmittance is somewhat dependent on the relative humidity of the atmosphere. To do this set the relative humidity to the correct value. For short distances and normal humidity the relative humidity can normally be left at a default value of 50 %.

# 11 Theory of thermography

## 11.1 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.

## 11.2 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.

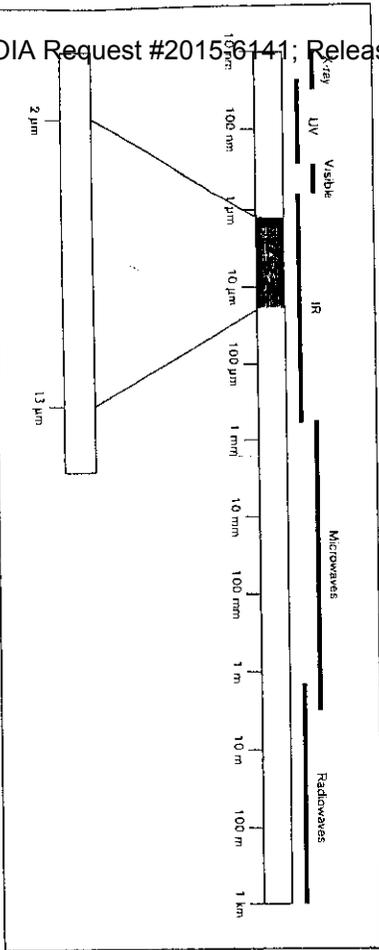


Figure 11.1 The electromagnetic spectrum.

Thermography makes use of the infrared spectral band. At the short-wavelength end of 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 '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

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

### 11.3 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.

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 camera for example.

If the temperature of blackbody radiation increases to more than 525 °C 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.

#### 11.3.1 Planck's law

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

$$W_{\lambda,bb} = \frac{2\pi hc^2}{\lambda^5 (e^{hc/\lambda kT} - 1)} \times 10^{-6} [\text{Watt}/\text{m}^2 \mu\text{m}]$$

where:

- 1  $W_{\lambda,bb}$  = the blackbody spectral radiant emittance at wavelength  $\lambda$ .
- 2  $c$  = the velocity of light =  $3 \times 10^8$  m/sec.
- 3  $h$  = Planck's constant =  $6.6 \times 10^{-34}$  Joule sec.
- 4  $k$  = Boltzmann's constant =  $1.4 \times 10^{-23}$  Joule/K.
- 5  $T$  = the absolute temperature (K) of a blackbody.
- 6  $\lambda$  = wavelength (m).

**N.B.** The factor  $10^{-6}$  is used since spectral emittance in the curves is expressed in  $\text{Watt}/\text{m}^2 \mu\text{m}$ . If the factor is excluded, the dimension will be  $\text{Watt}/\text{m}^2 \text{m}$ .

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  $\lambda_{max}$  and after passing it approaches zero again at very long wavelengths. The higher the temperature the shorter the wavelength at which maximum occurs.

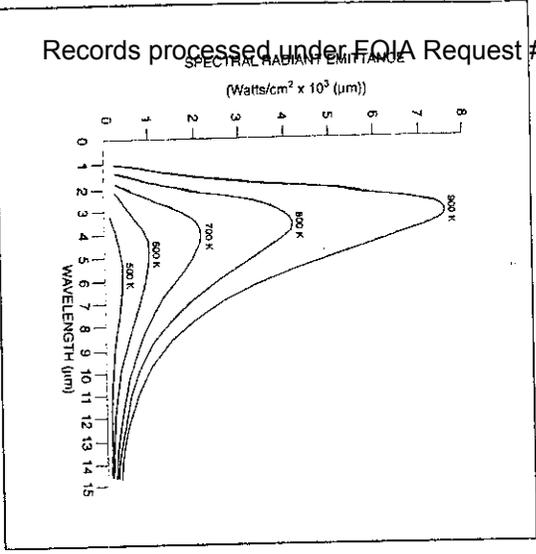


Figure 11.2 Blackbody spectral radiant emittance according to Planck's law, plotted for various absolute temperatures.

11.3.2 Wien's displacement law

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

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

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  $\lambda_{max}$ . A good approximation of the value of  $\lambda_{max}$  for a given blackbody temperature is obtained by applying the rule-of-thumb  $3000/T \mu\text{m}$ . 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  $\mu\text{m}$ .

The sun (approx. 6 000 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

Most insignificant amount of radiant emittance occurs at 38  $\mu\text{m}$ , in the extreme infrared wavelengths.

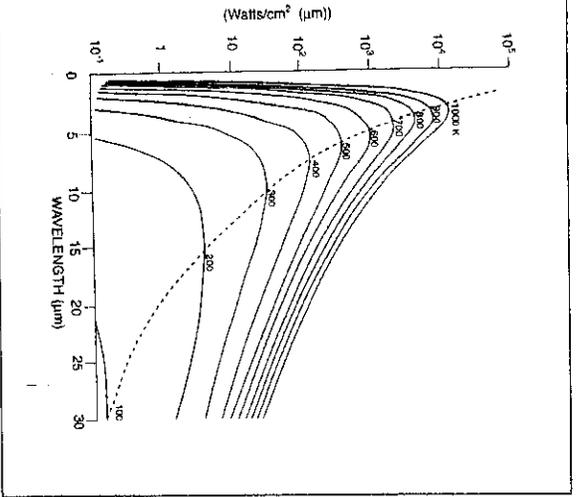


Figure 11.3 Planckian curves plotted on semi-log scales from 100 K to 1000 K. The dotted line represents the locus of maximum radiant emittance at each temperature as described by Wien's displacement law.

1.3.3 The Stefan-Boltzmann law

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

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

where  $\sigma$  is the Stefan-Boltzmann constant  $= 5.7 \times 10^{-8}$  Watt/m<sup>2</sup>.

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,  $M_b$  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  $\lambda_{\text{max}}$  is only 25% of the total, which represents about the amount of the sun's radiation which lies inside the visible light spectrum.

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<sup>2</sup>, 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.

11.3.4 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, white paint appears perfectly 'white' in the visible light spectrum, but becomes distinctly 'grey' at about 2  $\mu\text{m}$ , and beyond 30  $\mu\text{m}$  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  $\alpha$  may be absorbed, a fraction  $\rho$  may be reflected, and a fraction  $\tau$  may be transmitted. Since all of these factors are more or less wavelength dependent, the subscript  $\lambda$  is used to imply the spectral dependence of their definitions. Thus:

- The spectral absorptance  $\alpha_\lambda$  = the ratio of the spectral radiant power absorbed by an object to that incident upon it.
- The spectral reflectance  $\rho_\lambda$  = the ratio of the spectral radiant power reflected by an object to that incident upon it.
- The spectral transmittance  $\tau_\lambda$  = 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:

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

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  $\epsilon$  of the radiant emittance of a blackbody produced by an object at a specific temperature. Thus, we have the definition:

The spectral emissivity  $\epsilon_\lambda$  = the ratio of the spectral radiant power from an object to that from a blackbody at the same temperature and wavelength.

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

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

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

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

According to Kirchhoff's Law, for any material the spectral emissivity and spectral absorptance of a body are equal to any specified temperature and wavelength.

Therefore:

$$\epsilon_{\lambda} = \alpha_{\lambda}$$

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

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

For highly polished materials  $\epsilon_{\lambda}$  approaches zero, so that for a perfectly reflecting material (i.e. a perfect mirror) we have

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

For a greybody radiator, the Stefan-Boltzmann formula becomes

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

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This states that the total emissive power of a greybody is the same as a blackbody at the same temperature reduced in proportion to the value of  $\epsilon$  from the greybody.

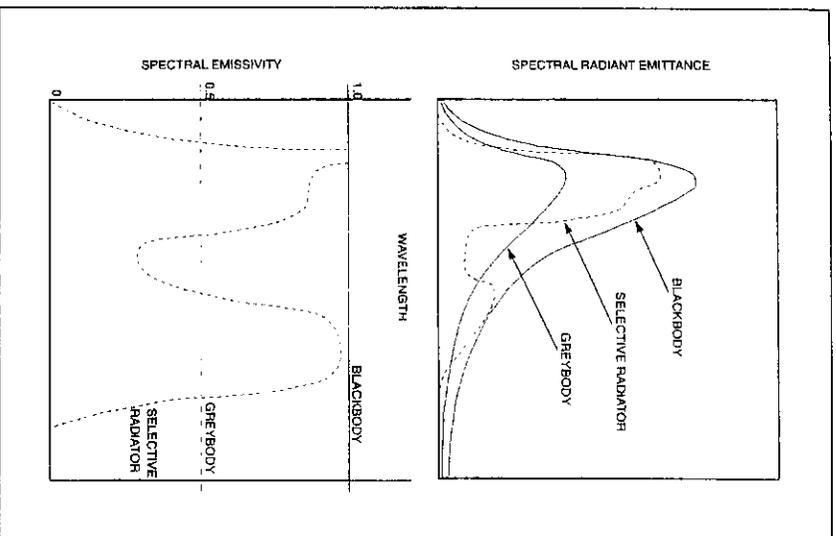


Figure 11.4 Spectral radiant emittance and spectral emissivity of three types of radiators.

### 11.4 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 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

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

When the plate becomes opaque ( $\tau_{\lambda} = 0$ ) this formula is reduced to the single factor:

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

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

## 12 Emissivity tables

A compilation of emissivity data from the IR literature plus FLIR Systems® measurements.

### 12.1 References

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- ⑤ Jones, Smith, Probert: *External thermography of buildings...*, Proc. of the Society of Photo-Optical Instrumentation Engineers, vol.110, Industrial and Civil Applications of Infrared Technology, June 1977 London.
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- ⑦ Vitek, J.: *Determination of emissivity with imaging radiometers and some emissivities at  $\lambda = 5$  microns*. Photogrammetric Engineering and Remote Sensing.
- ⑧ Kern: *Evaluation of infrared emission of clouds and ground as measured by weather satellites*, Defence Documentation Center, AD 617 417.
- ⑨ Öhman, Claes: *Emitansmätningar med AGEMA E-Box*. Teknisk rapport, AGEMA 1999

### 12.2 Tables

#### 12.2.1 Legend

T: Total spectrum, SW: 2-5  $\mu\text{m}$ , LW: 8-14  $\mu\text{m}$ , LLW: 6.5-20  $\mu\text{m}$

Material	Specification	Temperature °C	Spectrum	Emissivity	Ref.
Aluminium	foil	27	10 $\mu\text{m}$	0.04	3
	foil	27	3 $\mu\text{m}$	0.09	3
	vacuum deposited	20	T	0.04	2

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Material	Specification	Quantity	Orientation	Surface Area	Weight	Number of Samples
Aluminum hydroxide	polished	50-100	T	0.04-0.06		1
	polished plate	100	T	0.05		4
	polished, sheet	100	T	0.05		2
	dipped in HNO <sub>3</sub> , plate	100	T	0.05		4
	as received, plate	100	T	0.09		4
	as received, sheet	100	T	0.09		2
	sheet, 4 samples differently scratched	70	SW	0.05-0.08		9
	sheet, 4 samples differently scratched	70	LW	0.03-0.06		9
	rough surface	20-50	T	0.06-0.07		1
	roughened	27	10 µm	0.18		3
	roughened	27	3 µm	0.28		3
	oxidized, strongly	50-500	T	0.2-0.3		1
	weathered, heavily	17	SW	0.83-0.94		5
	cast, blast cleaned	70	SW	0.47		9
	cast, blast cleaned	70	LW	0.46		9
anodized, light gray, dull	70	SW	0.61		9	
anodized, light gray, dull	70	LW	0.97		9	
anodized, black, dull	70	SW	0.67		9	
anodized, black, dull	70	LW	0.95		9	
anodized sheet	100	T	0.55		2	
Aluminum bronze		20	T	0.60		1
Aluminum hydroxide	powder		T	0.28		1

Material	Specification	Quantity	Orientation	Surface Area	Weight	Number of Samples
Aluminum oxide	activated, powder		T	0.46		1
Aluminum oxide	pure, powder (alumina)		T	0.16		1
Brass	polished, highly	100	T	0.03		2
	polished	200	T	0.03		1
	sheet, rolled	20	T	0.06		1
	sheet, worked with emery	20	T	0.2		1
	rubbed with 80-grit emery	20	T	0.20		2
	dull, tarnished	20-350	T	0.22		1
	oxidized	70	SW	0.04-0.09		9
	oxidized	70	LW	0.03-0.07		9
	oxidized	100	T	0.61		2
	oxidized at 600 °C	200-600	T	0.59-0.61		1
Bronze	polished	50	T	0.1		1
	porous, rough	50-150	T	0.55		1
	powder		T	0.76-0.80		1
Bronze (cont'd)	phosphor bronze	70	SW	0.08		9
	phosphor bronze	70	LW	0.06		9
Chromium	polished	500-1000	T	0.28-0.38		1
	polished	50	T	0.10		1
Copper	electrolytic, polished	-34	T	0.006		4
	electrolytic, carefully polished	80	T	0.018		1
	pure, carefully prepared surface	22	T	0.008		4

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Material	Specification	Temperature, °C	Specimen	Efficiency	RAI
	polished, mechanical	22	T	0.015	4
	polished	50-100	T	0.02	1
	polished	100	T	0.03	2
	polished, commercial	27	T	0.03	4
	commercial, bur-nished	20	T	0.07	1
	scraped	27	T	0.07	4
	molten	1100-1300	T	0.13-0.15	1
	oxidized	50	T	0.6-0.7	1
	oxidized, heavily	20	T	0.78	2
	oxidized, black	27	T	0.78	4
	oxidized to blackness		T	0.88	1
Copper oxide	red, powder		T	0.70	1
Copper diox-ide	powder		T	0.84	1
Cold	polished	130	T	0.018	1
	polished, carefully	200-600	T	0.02-0.03	1
	polished, highly	100	T	0.02	2
Iron, cast	polished	38	T	0.21	4
	polished	40	T	0.21	2
	polished	200	T	0.21	1
	liquid	1300	T	0.28	1
	machined	800-1000	T	0.60-0.70	1
	oxidized	38	T	0.63	4
	oxidized	100	T	0.64	2
	oxidized at 600°C	200-600	T	0.64-0.78	1

Material	Specification	Temperature, °C	Specimen	Efficiency	RAI
	oxidized	260	T	0.66	4
	oxidized	538	T	0.76	4
	casting	50	T	0.81	1
	unworked	900-1100	T	0.87-0.95	1
	ingots	1000	T	0.95	1
Iron and steel	electrolytic	22	T	0.05	4
	electrolytic	100	T	0.05	4
	electrolytic, carefully polished	175-225	T	0.05-0.06	1
	electrolytic	260	T	0.07	4
	polished	400-1000	T	0.14-0.38	1
	shiny, etched	150	T	0.16	1
	freshly worked with emery	20	T	0.24	1
	wrought, carefully polished	40-250	T	0.28	1
	covered with red rust	20	T	0.61-0.85	1
	heavily rusted sheet	20	T	0.69	2
	rusted red, sheet	22	T	0.69	4
	rusted, heavily	17	SW	0.96	5
	oxidized	100	T	0.74	4
	oxidized	100	T	0.74	1
	oxidized	125-525	T	0.78-0.82	1
	oxidized	1227	T	0.89	4
	hot rolled	20	T	0.77	1
	hot rolled	130	T	0.60	1

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Material	Finish/Condition	Quantity	SW	EMISSIVITY	RAI
cold rolled		70	SW	0.20	9
cold rolled		70	LW	0.09	9
oxidized strongly		50	T	0.88	1
oxidized strongly		500	T	0.98	1
rough, plane surface		50	T	0.95-0.98	1
polished sheet		750-1050	T	0.52-0.56	1
ground sheet		950-1100	T	0.55-0.61	1
rusty, red		20	T	0.69	1
oxidized		200	T	0.79	2
oxidized		200-600	T	0.80	1
shiny oxide layer, sheet,		20	T	0.82	1
polished		100	T	0.07	2
rolled, freshly		20	T	0.24	1
rolled sheet		50	T	0.56	1
hot-temned sheet		24	T	0.064	4
hot-galva-nized sheet		92	T	0.07	4
sheet, burnished		30	T	0.23	1
sheet, oxidized		20	T	0.28	1
heavily oxidized		70	SW	0.64	9
heavily oxidized		70	LW	0.85	9
unoxidized, polished		100	T	0.05	4
shiny		250	T	0.08	1
oxidized, gray		20	T	0.28	1
oxidized, gray		22	T	0.28	4

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Material	Finish/Condition	Quantity	SW	EMISSIVITY	RAI
Lead red	oxidized at 200 °C	200	T	0.63	1
Lead red		100	T	0.93	4
Lead red, powder		100	T	0.93	1
Magnesium		22	T	0.07	4
	polished	20	T	0.07	2
		260	T	0.13	4
		538	T	0.18	4
Magnesium powder			T	0.86	1
Molybdenum		600-1000	T	0.08-0.13	1
	filament	700-2500	T	0.1-0.3	1
		1500-2200	T	0.19-0.26	1
Nichrome	rolled	700	T	0.25	1
	sandblasted	700	T	0.70	1
	wire, clean	500-1000	T	0.71-0.79	1
	wire, clean	50	T	0.65	1
	wire, oxidized	50-500	T	0.95-0.98	1
Nickel	electrolytic	22	T	0.04	4
	electrolytic	38	T	0.06	4
	electrolytic	260	T	0.07	4
	electrolytic	598	T	0.10	4
	bright matte	122	T	0.041	4
	polished	122	T	0.045	4
	commercially pure, polished	100	T	0.045	1

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Material	Condition	Temper-ature	Specimen	EMI (KV)	Ref
	commercially pure, polished	200-400	T	0.07-0.09	1
	wire	200-1000	T	0.1-0.2	1
	electroplated on iron, polished	22	T	0.045	4
	electroplated, polished	20	T	0.05	2
	electroplated on iron, unpolished	22	T	0.11	4
	electroplated on iron, unpolished	20	T	0.11-0.40	1
	oxidized	200	T	0.37	2
	oxidized	227	T	0.37	4
	oxidized at 600 °C	200-600	T	0.37-0.48	1
	oxidized	1227	T	0.85	4
Nickel oxide		500-650	T	0.52-0.59	1
		1000-1250	T	0.75-0.86	1
Palladium		17	T	0.016	4
		22	T	0.03	4
		100	T	0.05	4
		260	T	0.06	4
		538	T	0.10	4
		1094	T	0.18	4
	pure, polished	200-600	T	0.05-0.10	1
		1000-1500	T	0.14-0.18	1
	wire	50-200	T	0.06-0.07	1
	wire	500-1000	T	0.10-0.16	1
	wire	1400	T	0.18	1

Material	Condition	Temper-ature	Specimen	EMI (KV)	Ref
	ribbon	900-1100	T	0.12-0.17	1
Silver	polished	100	T	0.03	2
	pure, polished	200-600	T	0.02-0.03	1
Stainless steel	type 18-8, buffed	20	T	0.16	2
	type 18-8, oxidized at 800°C	60	T	0.85	2
	sheet, polished	70	SW	0.18	9
	sheet, polished	70	LW	0.14	9
	sheet, untreated, somewhat scratched	70	SW	0.30	9
	sheet, untreated, somewhat scratched	70	LW	0.28	9
	alloy, 8 % Ni, 18 % Cr	500	T	0.35	1
	rolled	700	T	0.45	1
	sandblasted	700	T	0.70	1
Tin	burnished	20-50	T	0.04-0.06	1
	tin-plated sheet iron	100	T	0.07	2
Titanium	polished	200	T	0.15	1
	polished	500	T	0.20	1
	polished	1000	T	0.36	1
	oxidized at 540 °C	200	T	0.40	1
	oxidized at 540 °C	500	T	0.50	1
	oxidized at 540 °C	1000	T	0.60	1
Tungsten		200	T	0.05	1
		600-1000	T	0.1-0.16	1
		1500-2200	T	0.24-0.31	1

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Material	Specification	Temperature 100-25	Spectrum	Emissivity	Rat
Zn	filament	3300	T	0.39	1
Zn	polished	200-300	T	0.04-0.05	1
	oxidized at 400°C	400	T	0.11	1
	sheet	50	T	0.20	1
	oxidized surface	1000-1200	T	0.50-0.60	1
Asbestos	powder		T	0.40-0.60	1
	fabric		T	0.78	1
	floor tile	35	SW	0.94	7
	board	20	T	0.96	1
	slate	20	T	0.96	1
	paper	40-400	T	0.93-0.95	1
Asphalt pav-		4	LLW	0.967	8
Brick	silimanite, 33 % SiO <sub>2</sub> , 64 % Al <sub>2</sub> O <sub>3</sub>	1500	T	0.29	1
	refractory, magnesite	1000-1300	T	0.38	1
	refractory, corundum	1000	T	0.46	1
	refractory, weakly radiating	500-1000	T	0.65-0.75	1
	refractory, strongly radiating	500-1000	T	0.8-0.9	1
	fireclay	1200	T	0.59	1
	fireclay	1000	T	0.75	1
	fireclay	20	T	0.85	1
	alumina	17	SW	0.68	5
	firebrick	17	SW	0.68	5
	silica, 95 % SiO <sub>2</sub>	1230	T	0.66	1

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Material	Specification	Temperature 100-25	Spectrum	Emissivity	Rat
	Dinas silica, refrac- tory	1000	T	0.66	1
	Dinas silica, unglazed, rough	1000	T	0.80	1
	Dinas silica, glazed, rough	1100	T	0.85	1
	common	17	SW	0.86-0.81	5
	waterproof	17	SW	0.87	5
	red, rough	20	T	0.88-0.93	1
	red, common	20	T	0.93	2
	masonry	35	SW	0.94	7
	masonry, plastered	20	T	0.94	1
Carbon	candle soot	20	T	0.95	2
	lampblack	20-400	T	0.95-0.97	1
	charcoal powder		T	0.96	1
	graphite powder		T	0.97	1
	graphite, filed surface	20	T	0.98	2
Chipboard	untreated	20	SW	0.90	6
Clay	fired	70	T	0.91	1
Cloth	black	20	T	0.98	1
Concrete		20	T	0.92	2
	dry	36	SW	0.95	7
	rough	17	SW	0.97	5
	walkway	5	LLW	0.974	8
Ebonite			T	0.89	1
Emery	coarse	80	T	0.85	1
Enamel		20	T	0.9	1

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

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Material	Condition	Number of Samples	Test Method	Transmittance Range	Number of Samples
lacquer	hard, untreated	20	T	0.85-0.95	1
Fire board	porous, untreated	20	SW	0.85	6
	particle board	20	SW	0.85	6
	particle board	70	SW	0.77	9
	particle board	70	LW	0.89	9
	masonite	70	SW	0.75	9
	masonite	70	LW	0.88	9
Gr.ite	polished	20	LLW	0.849	8
	rough	21	LLW	0.879	8
	rough, 4 different samples	70	SW	0.95-0.97	9
	rough, 4 different samples	70	LW	0.77-0.87	9
Gypsum		20	T	0.8-0.9	1
Lead/Seal Wax					
Lacquer	aluminum on rough surface	20	T	0.4	1
	bakelite	80	T	0.83	1
	black, matte	100	T	0.97	2
	black, dull	40-100	T	0.96-0.98	1
	black, shiny, sprayed on iron	20	T	0.87	1
	heat-resistant	100	T	0.92	1
	3 colors sprayed on aluminum	70	SW	0.50-0.53	9
	3 colors sprayed on aluminum	70	SW	9250-0.94	9
	white	100	T	0.92	2

Material	Condition	Number of Samples	Test Method	Transmittance Range	Number of Samples
	white	40-100	T	0.8-0.95	1
Leather	tanned		T	0.75-0.80	1
Lime			T	0.3-0.4	1
Mortar	dry	17	SW	0.87	5
	dry	36	SW	0.94	7
Oil, lubricating	film on Ni base; Ni base only	20	T	0.05	2
	: 0.025 mm film	20	T	0.27	2
	: 0.050 mm film	20	T	0.46	2
	: 0.125 mm film	20	T	0.72	2
	: thick coating	20	T	0.82	2
Paint	aluminum, various ages	50-100	T	0.27-0.67	1
	cadmium yellow		T	0.28-0.33	1
	chrome green		T	0.65-0.70	1
	cobalt blue		T	0.7-0.8	1
	oil	17	SW	0.87	5
	oil based, average of 16 colors	100	T	0.94	2
	oil, various colors	100	T	0.92-0.96	1
	oil, black flat	20	SW	0.94	6
	oil, black gloss	20	SW	0.92	6
	oil, gray flat	20	SW	0.97	6
	oil, gray gloss	20	SW	0.96	6
	plastic, black	20	SW	0.95	6
	plastic, white	20	SW	0.84	6

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

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Material	Specification	Sample Size	Spectrum	Emissivity	Ref
	8 different colors and qualities	70	SW	0.88-0.96	9
	8 different colors and qualities	70	LW	0.92-0.94	9
Paper	yellow		T	0.72	1
	red		T	0.76	1
	blue, dark		T	0.84	1
	green		T	0.85	1
	black		T	0.90	1
	coated with black lacquer		T	0.93	1
	white	20	T	0.7-0.9	1
	white bond	20	T	0.93	2
	white, 3 different glosses	70	SW	0.76-0.78	9
	white, 3 different glosses	70	LW	0.88-0.90	9
	4 different colors	70	SW	0.68-0.74	9
	4 different colors	70	LW	0.92-0.94	9
	black, dull	70	SW	0.86	9
	black, dull	70	LW	0.89	9
	black, dull		T	0.94	1
Plaster	rough coat	17	SW	0.86	5
	plasterboard, untreated	20	T	0.91	2
	plasterboard, untreated	20	SW	0.90	6
Plastic	PVC, plastic floor, dull, structured	70	SW	0.94	9

Material	Specification	Sample Size	Spectrum	Emissivity	Ref
	PVC, plastic floor, dull, structured	70	LW	0.93	9
	polyurethane isolation board (frigoit)	70	SW	0.29	9
	polyurethane isolation board (frigoit)	70	LW	0.55	9
	glass fibre laminate (printed circ. board)	70	SW	0.94	9
	glass fibre laminate (printed circ. board)	70	LW	0.91	9
Porcelain	white, shiny		T	0.70-0.75	1
	glazed	20	T	0.92	1
Rubber	hard	20	T	0.95	1
	soft, gray, rough	20	T	0.95	1
Sand		20	T	0.60	1
		20	T	0.90	2
Sandstone	polished	19	LLW	0.909	8
	rough	19	LLW	0.935	8
Skin	human	32	T	0.98	2
Slag	boiler	0-100	T	0.97-0.93	1
	boiler	200-500	T	0.89-0.78	1
	boiler	600-1200	T	0.76-0.70	1
	boiler	1400-1800	T	0.69-0.67	1
Snow: See water					
Soil	dry	20	T	0.92	2
	saturated with water	20	T	0.95	2
Stucco	rough, lime	10-90	T	0.91	1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

Material	Specification	Temperature (°C)	Spectrum	Emissivity	Ref.
Styrofoam	Insulation	37	SW	0.60	7
T&E	paper	20	T	0.79-0.84	1
	glazed	17	T	0.91-0.93	1
Wallpaper	slight pattern, light gray	20	SW	0.94	5
	slight pattern, red	20	SW	0.85	6
Varnish	slight pattern, red	20	SW	0.90	6
	flat	20	SW	0.93	6
Water	on oak parquet floor	70	SW	0.90	9
	on oak parquet floor	70	LW	0.90-0.93	9
Water	snow	-10	T	0.8	1
	snow	-10	T	0.85	2
Ice	layer >0.1 mm thick	-10	T	0.95-0.98	1
	distilled	20	T	0.96	2
Ice	ice, smooth	-10	T	0.96	2
	ice, smooth	0	T	0.97	1
Ice	ice, covered with heavy frost	0	T	0.98	1
	frost crystals	-10	T	0.98	2
Wood	ground	20	T	0.5-0.7	1
	planned	20	T	0.8-0.9	1
Wood	planned oak	20	T	0.90	2
	white, damp	20	T	0.7-0.8	1
Wood	planned oak	70	SW	0.77	9
	planned oak	70	LW	0.88	9
Wood	pine, 4 different samples	70	SW	0.67-0.75	9

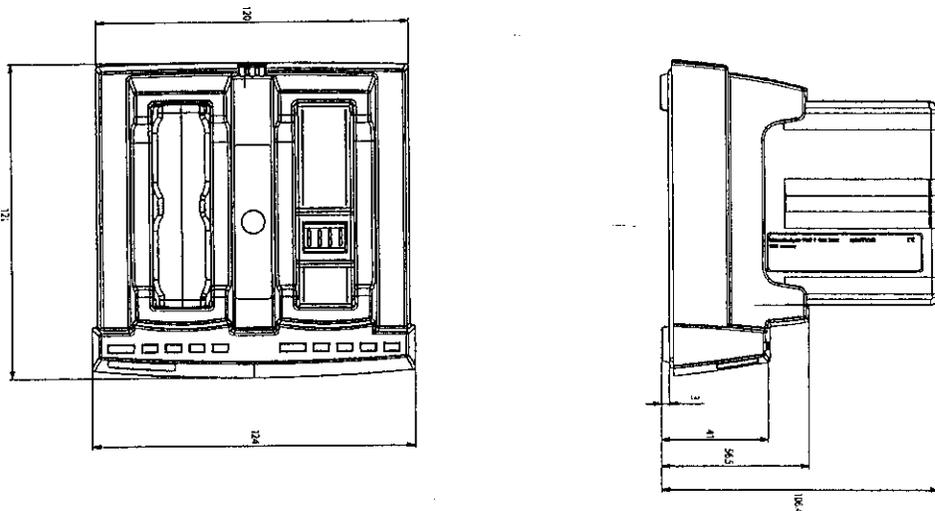
Records processed under FOIA Request #2015-0141; Released by CDRH on 10-22-2015

Material	Specification	Temperature (°C)	Spectrum	Emissivity	Ref.
Wood	pine, 4 different samples	70	LW	0.81-0.89	9
	plywood, smooth, dry	36	SW	0.82	7
Wood	plywood, untreated	20	SW	0.83	6
		19	LLW	0.962	8
Wood		17	SW	0.98	5

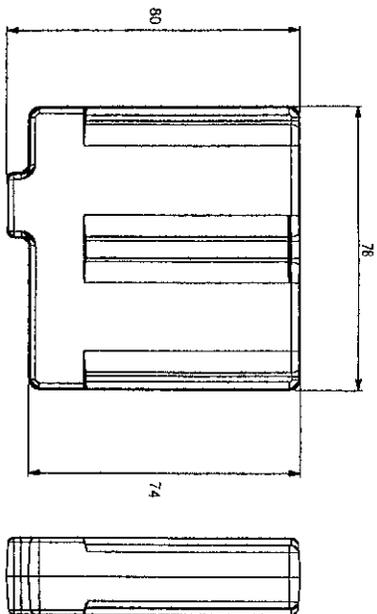
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

13 Basic dimensions – battery charger

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14 Basic dimensions – battery

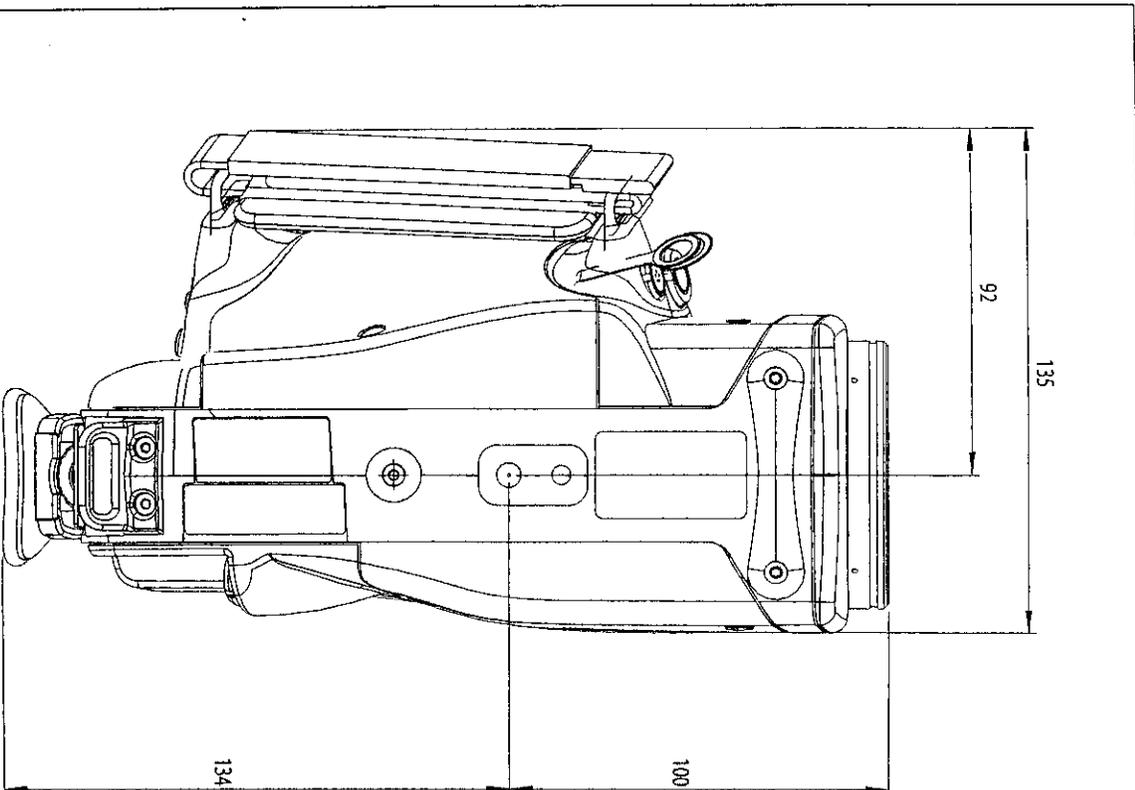


15 Basic dimensions – camera, #1

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16 Basic dimensions – camera, #2

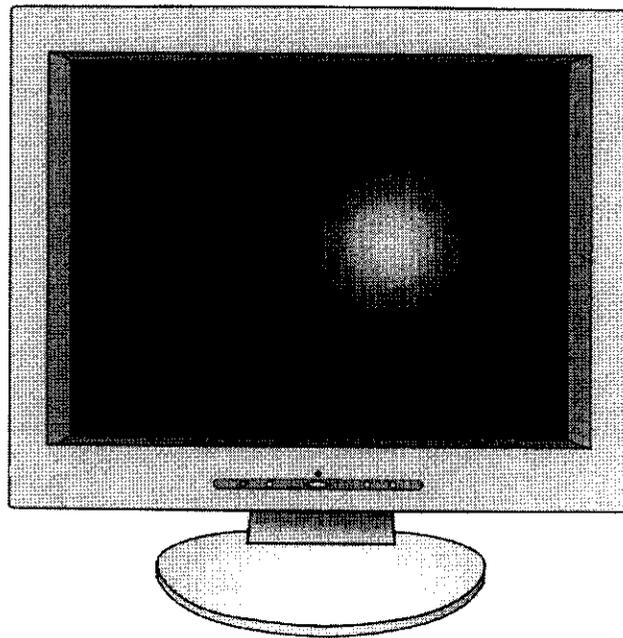


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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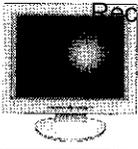


# Planar LCD Monitor



## WT1503Z Manual

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## PREFACE

### About this manual

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This manual is designed to assist you in setting up and using your New Planar LCD Monitor. Information in this document has been carefully checked for accuracy; however, no guarantee is given to the correctness of the contents. The information in this document is subject to change without notice. This document contains proprietary information protected by copyright. All rights are reserved. No part of this manual may be reproduced by any mechanical, electronic or other means, in any form, without prior written permission of the manufacturer.

### FCC Compliance Statement

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This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

#### FCC WARNING

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

#### Caution:

To comply with the limits for an FCC Class B computing device, always use the shielded signal cord supplied with this unit.

The Federal Communications Commission warns that changes or modifications of the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**CE mark for Class B ITE (Following European standard EN55022/1998;  
EN61000-3-2/1995; EN61000-3-3/1995, EN55024/1998)**

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### Radio Frequency Interference Statement

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#### Warning:

This is a Class B product. In a domestic environment, this product may cause radio interference in which case the user may be required to take adequate measures.

### Canadian Doc Notice

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## Planar User's Manual

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### For Class B Computing Devices

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the Radio Interference Regulation of the Canadian Department of Communications.

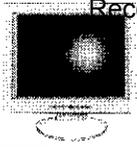
“Le présent appareil numérique n'émet pas de bruits radioélectriques dépassant les limites applicables aux appareils numériques de la class B prescrites dans le Règlement sur le brouillage radioélectrique édicté par le ministère des Communications du Canada”

### Important Safety Instructions

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Please read the following instructions carefully. This manual should be retained for future use.

1. To clean your New Planar LCD Monitor screen, first, make sure the Monitor is in the power off mode. Unplug the Monitor from its power source before cleaning it. Do not spray liquid cleaners directly onto the unit. Stand away from your New Planar LCD Monitor and spray cleaning solution onto a rag. Without applying excessive pressure, clean the screen with the slightly dampened rag.
2. Do not place your New Planar LCD Monitor near a window. Exposing the Monitor to rain, water, moisture or sunlight can severely damage it.
3. Do not place anything on top of the Monitor-to-PC signal cord. Make sure the cord is placed in an area where it will not be stepped on.
4. Do not apply pressure to the LCD screen. Excessive pressure may cause permanent damage to the display.
5. Do not remove the cover or attempt to service this unit by yourself. You may void the warranty. Only an authorized technician should perform servicing.
6. Safe storage of your New Planar LCD Monitor is in a range of minus 20 to plus 65 degrees Celsius (68°F-149°F). Storing your New Planar LCD Monitor outside this range could result in permanent damage.
7. If any of the following occurs, immediately unplug your Monitor and call an authorized technician.
  - The power or Monitor-to-PC signal cord is frayed or damaged.
  - Liquid has been spilled onto the Monitor, or it has been exposed to rain.
  - The Monitor has been dropped or the case has been damaged.
8. The appliance should be disconnected from the mains by pulling the mains power cord/mains plug.
9. The socket-outlet shall be installed near the equipment and shall be easily accessible.



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## CHAPTER 1

# Your New Planar LCD Monitor

## Your New Planar LCD Monitor!

Your New Planar LCD Monitor has been designed to be versatile, ergonomic and user-friendly. Your New Planar LCD Monitor is capable of displaying most standards, from 640 x 480 VGA to 1024 x 768 XGA. The digital controls located on the front panel allow the user to easily adjust the Monitor's display parameters. Your New Planar LCD Monitor's small footprint allows you more room in your workspace for other peripherals. Lightweight and compact, your New Planar LCD Monitor is the perfect solution for users on the go. You can use your New Planar LCD Monitor for everything from making business presentations to playing computer games. The two stereo speakers allow you to further expand your computer's multimedia capabilities by connecting your computer's Audio out port to your New Planar LCD Monitor's Audio in port. If you have a complete full workstation, your New Planar LCD Monitor has the additional feature of an optional wall-mountable stand for added convenience.

The architecture of your New Planar LCD Monitor incorporates an LCD panel that produces a clear display with low radiation emission, limiting health concerns. With its low power consumption, your New Planar LCD Monitor helps you reduce your power bill.

## Unpacking

Before you unpack your New Planar LCD Monitor, prepare a suitable workspace for your New Planar LCD Monitor and computer. You need a stable, level and clean surface near a wall outlet. Even though your New Planar LCD Monitor uses very little power, you should put it in a location that allows sufficient airflow to ensure that your New Planar LCD Monitor and your computer do not become too hot. Set up your New Planar LCD Monitor so that the panel does not face a window where sunlight often comes in. The glare caused by sunlight reflecting off your New Planar LCD Monitor's screen will make it difficult to see.



*Using a computer for an extended period of time with a poor workstation set-up and incorrect working habits can cause health problems. The science of ergonomics studies the relationship between health and a suitable working environment. There is a section on ergonomics at the end of this chapter. For more information on ergonomics, contact your nearest computer bookstore, or local library. The Internet also has information on this and other subjects.*

After you unpack your New Planar LCD Monitor; make sure the following items are included in the box and in good condition:

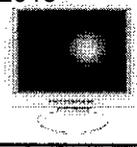
- LCD Monitor
- Monitor-to-PC signal cable
- 1.5M Stereo Jack Audio Cable
- AC Adapter
- Power cord
- This Planar User's Manual

If you find that any of these items are missing or appear damaged, contact your dealer immediately. Do not throw away the packing material or shipping carton in case you need to ship or store your New Planar LCD Monitor in the future.

## Identifying Components

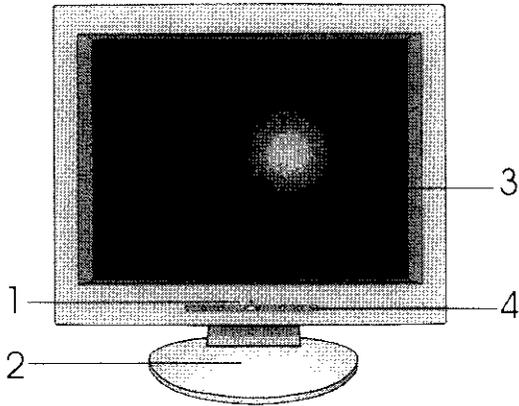
Your New Planar LCD Monitor has been designed to provide easy access to all controls and peripheral ports. The following figures will help you identify your New Planar LCD Monitor's controls and ports.

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**Planar User's Manual**

**Your New Planar LCD Monitor — Front View**



**1. Power-On Indicator**

This LED indicator stays lit when the power is on and when the monitor is receiving a proper video signal. The LED will blink slowly when the LCD monitor is in power saving mode.

**2. Monitor Stand**

The monitor stand supports the LCD monitor.

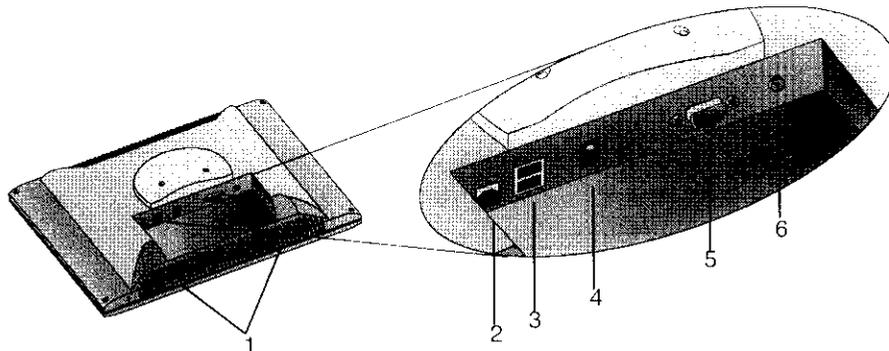
**3. LCD Screen**

The LCD monitor screen is a 15-inch diagonal, Active Matrix Liquid Crystal Display (AMLCD). The screen is capable of supporting a maximum resolution of 1024 x 768 RGB (XGA).

**4. LCD Monitor Keypad**

Activates and adjusts the monitor's settings through an On Screen Display (OSD).

**Your New Planar LCD Monitor — Rear View**



**1. Stereo Speakers (optional)**

The LCD monitor's built-in stereo speakers are located in the bottom of the monitor and face the direction of the desktop.

**2. Upstream USB Port (optional)**

Connect the AC adapter cable to this jack.

**3. Downstream USB Ports (optional)**

The monitor's two downstream USB ports let the LCD monitor function as a USB hub allowing the connection of USB compliant devices. The upstream USB port must be connected to your PC for the downstream ports to function.

**4. DC Power Jack**

Connect the AC adapter cable to this jack.

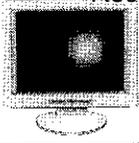
**5. VGA Cable Connector**

Connect the supplied 1.5m 15-pin D-Sub VGA cable to this connector. The opposite end of the cable is connected to your PC's graphics card.

**6. Audio Line-in (optional)**

Connect your PC's line-out to this jack to listen the PC's audio on the LCD monitor's stereo speakers. (You can also connect your CD-ROM's line-out to this jack.)

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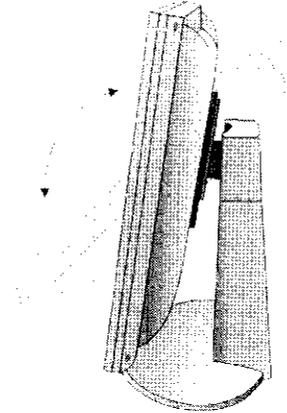


## Adjusting the Monitor's Position

Your LCD monitor's tilting angle can be adjusted in both the landscape and optional portrait mode.

### Adjusting the Tilting Angle

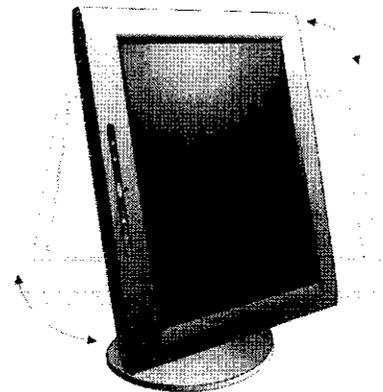
The LCD monitor's angle settings range from  $-5^{\circ}$  to  $25^{\circ}$  in both the landscape and optional portrait viewing modes.



### Viewing Orientation

If your LCD monitor supports the portrait mode option, you can adjust the viewing mode from landscape to portrait.

To switch to the portrait mode, tilt the monitor backwards and, using both hands, gently turn it  $90^{\circ}$  in a clockwise direction.



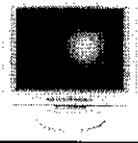
Forcing the monitor past its maximum extension can result in damage to the monitor.

## Connecting AC Power

Refer to the following instructions for connecting AC power to the LCD monitor.

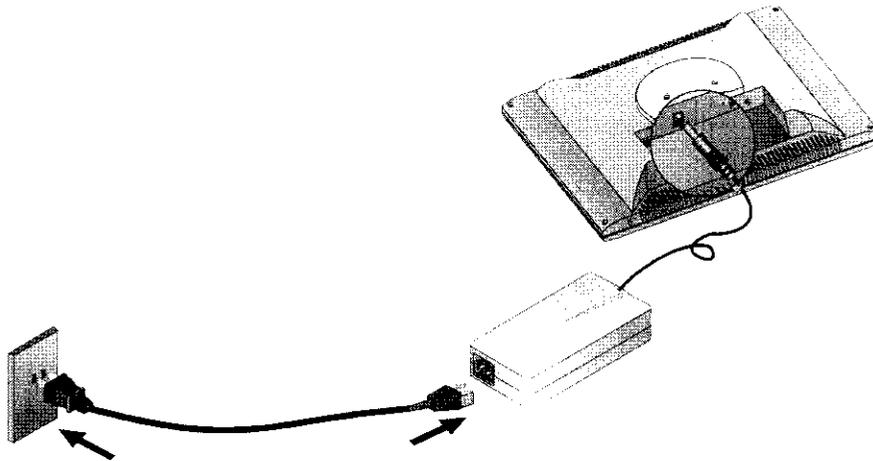
1. Plug the female end of the power cable into the AC-adaptor and the male end of the power cord into a wall socket. The plug on the power cable will vary according to the electrical standard for your area.
2. Plug the adapter power connector into the LCD monitor's DC power jack.

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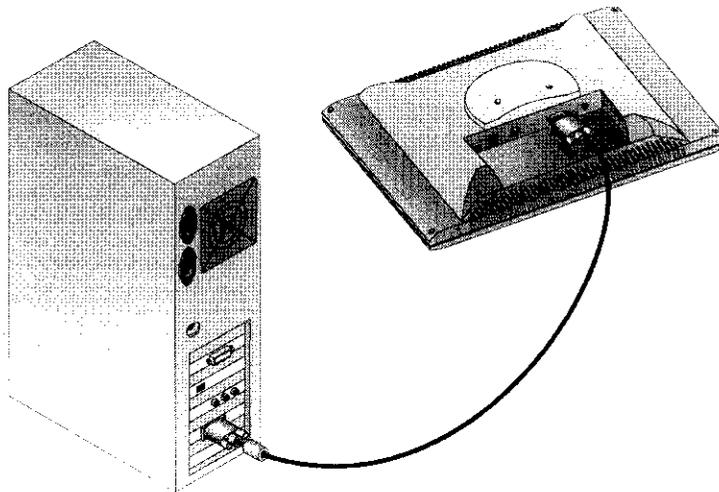
## Planar User's Manual

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### Connecting Video

1. Turn off your PC and the LCD monitor before connecting your LCD monitor to the computer.
2. Loop the 1.5M VGA cable through the hole in the LCD monitor's stand and plug it into the LCD monitor's VGA cable connector.
3. Connect the other end of the VGA cable to the PC's VGA port.
4. Tighten the connecting screws.

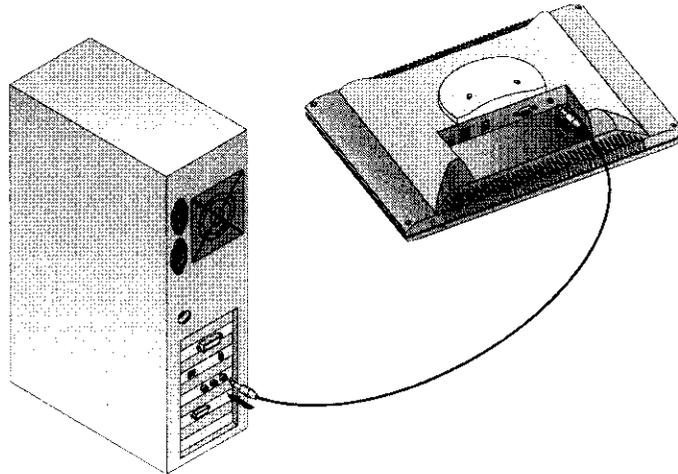
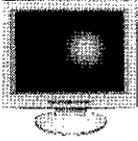


### Connecting the Stereo Speakers

Please refer to the following instructions for connecting the LCD monitor's stereo speakers.

1. Connect the 1.5M audio cable to the line-out of your PC's sound card.
2. Connect the other end to the LCD monitor's audio line-in jack.
3. You can adjust the sound volume of the stereo speakers by using the speaker volume control function in the OSD (On-Screen Display).

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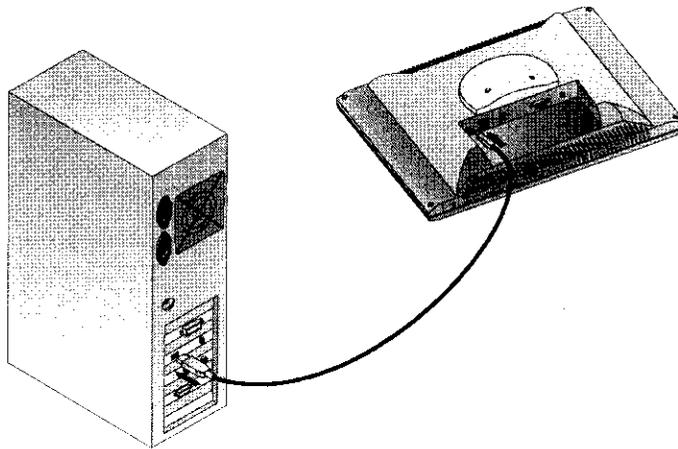
## Connecting USB Devices

The following section covers connecting USB devices. The LCD monitor supports an upstream and two downstream USB connections.

### Upstream

You can connect the LCD monitor's upstream USB port to your PC's USB port and use the LCD monitor as a USB hub. The following explains how to connect the upstream USB port to your PC:

1. Connect one end of the USB cable to the LCD monitor's upstream USB port.



2. Connect the other end to the PC's USB port.

### Downstream

The two downstream USB ports connect USB devices, such as USB keyboards, scanners and mice, directly to your LCD monitor.

Connect the USB device cable to one of the LCD monitor's downstream USB ports.

**Note:** The upstream USB port must be connected to your PC for the downstream USB ports to function.

## Power Management System

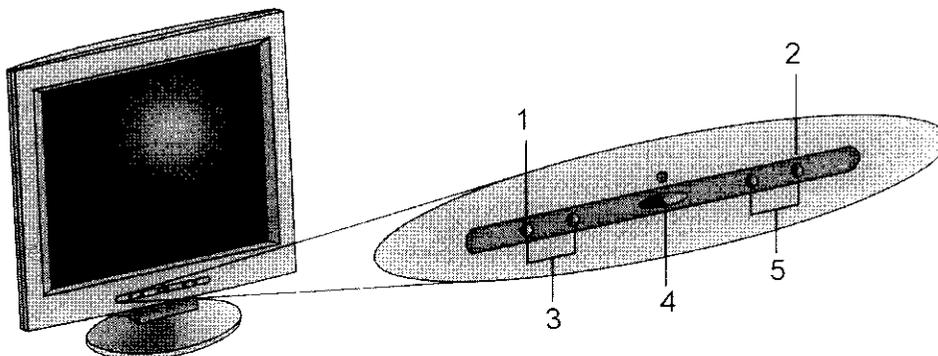
The LCD monitor complies with the VESA DPMS power management proposal. The VESA DPMS proposal provides power saving modes by detecting the horizontal or vertical sync signal. Refer to the Addendum for more information.

When the LCD monitor is in power saving mode or detects an incorrect timing, the monitor screen will be blank and the power LED indicator starts blinking.

## CHAPTER 2

# The Display Controls

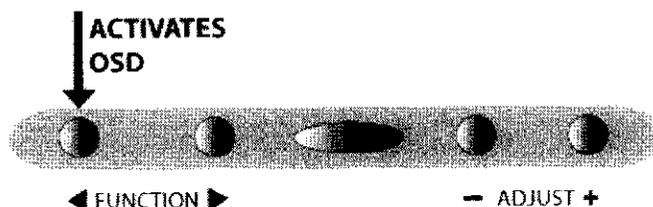
## LCD Monitor Control Panel



- 1. OSD Menu Button**  
Press this button to activate the OSD (On-Screen Display) menu. This button is also used as the ◀ Selection button.
- 2. Adjust ⊕ Button**  
This button allows you to apply settings and enter submenus in the OSD. This button also is used to increase the value of the selected menu item.
- 3. ◀▶ Function Select Buttons**  
These two buttons allow you to select the control functions in the OSD. Press either button to scroll through the main menu and submenu items.
- 4. Power Switch**  
Push the power switch to turn the monitor on and off. When you shutdown your computer, the monitor will enter power-saving mode. The LED will slowly flash indicating the display is in power saving mode.
- 5. ⊖ Adjust ⊕ Control Buttons**  
The ⊕ button allows you to increase the menu item value.  
The ⊖ button allows you to decrease the menu item value.

## Adjusting the Display

The LCD monitor features an intuitive, menu-driven, On-Screen Display (OSD). You can access the OSD any time that the PC is powered up. If the PC is in a power saving mode, or is powered down, the OSD is inaccessible.



### OSD Main Menu

To activate the OSD Main Menu, press the leftmost ◀ Function key. To navigate the topline menu, use either the right ▶ or left ◀ function keys to scroll between the main menu choices.

The option that is currently selected is highlighted in yellow. Each main menu has an associated submenu and is further described.

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The 7-topline menus are:



The Auto Adjust option lets the monitor determine and select the settings that are most appropriate for your system requirements. This function will tune the display to your computers video card.



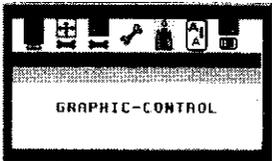
The Monitor-Control option allows you to adjust the LCD monitor's display characteristics such as the display's horizontal or vertical position, display phase, display clock, and factory reset. Adjusting these settings should only be necessary if the results from Auto-Adjust function are not satisfactory.



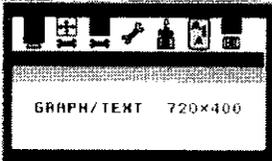
The OSD-Control option allows you to adjust the position and setting of the monitor's On Screen Display.



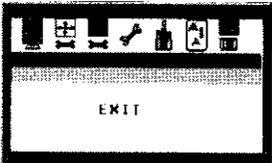
The MISC-Control option allows you to select the desired text language of the OSD, adjust the monitor speaker volume, and to display the current video information being sent to the monitor from your video card.



The Graphic-Control option allows you to adjust the display contrast, brightness, sharpness, and color settings.



The Graph/Tex option allows you to switch DOS text resolution from 640x400 and 720x400. This function has no effect within graphic operating systems such as MS Windows™.

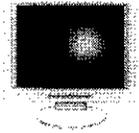


The OSD Exit option closes the On Screen Display.



Auto Adjust Procedure

Pressing the Adjust  key while the Auto Adjust topline menu is selected, activates the Auto Adjust procedure. The Auto Adjust procedure takes approximately 2 seconds to complete. Once finished, the OSD menu will disappear after a short time-out period.



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**The Monitor- Control Option**



Pressing the Adjust ⊕ key while the Monitor Control icon is selected activates the Monitor Control submenu. Use the ◀FUNCTION▶ select buttons to scroll between the submenu items. You should only use this menu item if the results of the Auto Adjust function are not satisfactory.



**H-Position:** Press the ⊖ Adjust ⊕ buttons to horizontally move the display image to the desired position.



**V-Position:** Press the ⊖ Adjust ⊕ buttons to vertically move the display image to the desired position.



**Phase:** Press the ⊖ Adjust ⊕ buttons to fine-tune the displayed image. An improper phase adjustment will result in pixel jitter or display noise.



**Clock:** Press the ⊖ Adjust ⊕ buttons to stabilize the display clock timing. An improper clock setting will result in wide vertical bands on the display.



**Reset:** Press the Adjust ⊕ button to reset the Monitor-Control submenu values to the factory default values.



**Exit:** Press the Adjust ⊕ button key to exit the Monitor-Control submenu.



**OSD - Control Option**



Pressing the Adjust ⊕ key while the OSD Control icon is selected activates the OSD Control submenu. Use the ◀FUNCTION▶ select buttons to scroll between the submenu items.



**OSD-H-Position:** Press the ⊖ Adjust ⊕ buttons to horizontally move the OSD menu.



**OSD-V-Position:** Press the ⊖ Adjust ⊕ buttons to vertically move the OSD menu.



**Exit:** Press the Adjust ⊕ button key to exit the OSD-Control submenu.



**Misc. - Control Option**

Pressing the Adjust ⊕ key while the Misc Control icon is selected activates the Misc Control submenu. Use the ◀FUNCTION▶ select buttons to scroll between the submenu items.



**Language:** Press the ⊖ Adjust ⊕ buttons to select the desired OSD display language. Languages supported: English, German, French, Spanish, and Italian.



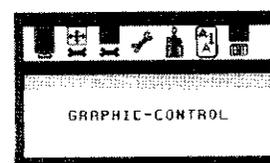
**Audio Volume:** Press the ⊖ Adjust ⊕ buttons to increase or decrease the volume of the monitor speakers.



**Information:** The Information submenu displays the current resolution, vertical refresh rate, and monitor firmware version.



**Exit:** Press the Adjust ⊕ button to exit the Misc-Control submenu.



**Graphic Control Option**

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Pressing the Adjust  $\oplus$  key while the Graphic Control icon is selected activates the Graphic Control submenu. Use the **◀FUNCTION▶** select buttons to scroll between the submenu items.



**Contrast:** Press the  $\ominus$  Adjust  $\oplus$  buttons to adjust the difference between the lightest and darkest areas on the display. The contrast level can range from 0 to 63.



**Brightness:** Press the  $\ominus$  Adjust  $\oplus$  buttons to adjust the intensity of the monitor backlight.



**Sharpness:** Press the  $\ominus$  Adjust  $\oplus$  buttons to select the desired sharpness setting.



**Color:** Press the  $\ominus$  Adjust  $\oplus$  buttons to select the desired color temperature setting. The available options are CIE coordinate values 9300°, 6500°. Selecting the USER option, allows for customization of the Red, Green and Blue color coordinates.



**R, G and B:** Press the  $\ominus$  Adjust  $\oplus$  buttons to make individual adjustments to the Red, Green, and Blue coordinates for the customized color temperature. There are 127 levels of adjustments (0 - 127) available. Before adjusting these fields, you must select the User option in the Color submenu.



**Exit:** Press the Adjust  $\oplus$  button to exit the Graphic-Control submenu.



Graph/Text Option

Pressing the Adjust  $\oplus$  key while the Graph/Text icon is selected toggles the DOS resolution between 640x400 and 720x400.



OSD Exit

Pressing the Adjust  $\oplus$  key while the Exit icon is selected, deactivates the OSD menu.

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## APPENDIX A

## Technical Information

## Planar TFT LCD Monitor Specifications

Model	Planar WT1503Z	
LCD Panel	15"XGA	
Control Functions Power	Software Power switch with LED indicator (Press to turn off, over 1 sec. to turn on)	
On-Screen Display (OSD)	Main Menu	Submenu
	Auto Adjust	
	Monitor Control	Horizontal Position/Vertical Position/Phase/Clock/Reset/Exit
	OSD Control	OSD Horizontal Position/OSD Vertical Position/Exit
	Misc. Control	Language/Audio Volume/Information/Exit
	Graphic Control	Contrast/Brightness/Sharpness/Color/R/G/B/Exit
	Graph/Text	640 x 400/720 x 400
	OSD Exit	
Display Colors	Dithering 16M	
Response Time(ms) (Rise/Fall)	40 ms typ.	
Contrast Ratio	350:1 typ.	
Brightness	250 cd/m <sup>2</sup> typ.	
Pixel Pitch (mm)	0.297 x 0.297	
Viewing Angle	Horizontal: 60°/60° (L/R), Vertical: 45°/60° (U/D)	
Video Interface	VGA Compatible Analog RGB/ Composite Sync.	
Scanning Frequency H/V, Hz	24-62K 50-75	
Number of Factory Preset Mode	22	
Power Management	Meets VESA DPMS	
Power Consumption (ON/OFF, W)	40/4.5Max.	
Dimensions WxHxD mm	380x370x171	
Net Weight (Kg)	4.5	
Power Supply	12.0V/3.75A, 45W Stand-alone AC Adapter (External)	
Options	Other Stands (Wall-mount), Touch Screen, S-Video/Video cable	
Environment	Operating Temperature: 0 to 40° C Relative Humidity: 10% to 90%	
Audio (Two 1 Watt speakers with amplifier)	Yes	
Regulatory	UL, CSA, TÜV/GS, CE Mark, VCCI, T-Mark, FCC B DoC, TCO '99 (optional)	

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**APPENDIX B****Supported Timing****Timing for Model WT1503Z (XGA Resolution)**

Item	Standards	Resolution	Dot Clock (MHz)	Vertical Scanning Frequency (Hz)	Horizontal Scanning Frequency (kHz)
1	NEC PC98	640x400	25.20	70.15	31.50
2	NEC PC98	640x400	21.05	56.42	24.83
3	MAC 13" mode	640x480	30.24	66.67	35.00
4	MAC 16" mode	832x624	57.28	74.55	49.73
5	MAC 17" mode	1024x768	80.00	75.02	60.24
6	VGA	640x350	25.18	70.09	31.47
7	VGA	640x400	25.18	70.09	31.47
8	VGA	640x480	25.18	59.94	31.47
9	VESA	640x480	31.50	72.81	37.86
10	VESA	640x480	31.50	75.00	37.50
11	VESA	800x600	36.00	56.25	35.16
12	SVGA	800x600	40.00	60.32	37.88
13	VESA	800x600	50.00	72.19	48.08
14	VESA	800x600	49.50	75.00	46.88
15	VGA	720x400	28.32	70.09	31.47
16	XGA	1024x768	65.00	60.00	48.36
17	VESA	1024x768	75.00	70.07	56.48
18	VESA	1024x768	78.75	75.03	60.02
19		1024x768	71.64	66.13	53.96
20	SUN	1024x768	64.13	59.98	48.29
21	SUN	1024x768	74.25	70.04	56.59
22	SUN	1024x768	84.38	77.07	62.04

\*Once a mode is optimized, there is no need to make any further adjustment as long as the VGA card remains unchanged.

\*Specifications are subject to change without notice.

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## APPENDIX C

# Troubleshooting

## Troubleshooting Procedures

This LCD Monitor was pre-adjusted in the factory with standard VGA timing. Due to output timing differences among various VGA cards, you may initially experience an unstable or unclear display when a new display mode or new VGA card is selected.



*This LCD Monitor Supports Multiple VGA Modes. Refer to Appendix B for a listing of the factory-preset modes supported by this LCD Monitor.*

### **PROBLEM: Display is Unclear and Unstable**

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To stabilize and clarify your display, follow this procedure in this order:

1. It's best to adjust the display on a screen displaying of vertical lines. In Windows, load a wallpaper bitmap that has vertical lines in it. (or you can select the window shut down screen)
2. After you have the wallpaper loaded, open the OSD and select the "Clock" function. Press the top (or bottom) Adjustment Control button and continue pressing the button until you see vertical dark and light lines across the screen.
3. When you can see distinct light and dark vertical bands, stop pressing the Adjustment Control button. Now press the opposite (top or bottom) Adjustment Control button. The vertical dark and light bands will decrease in number. Keep pressing the button until the distinct bands disappear and you have a clear display.
4. Next, press the Function Control button to choose the "Phase" function. The Phase will adjust the horizontal display. Press the top (or bottom) Adjustment Control button and you will see horizontal dark and light lines appear. The number of lines increases as you press the button. Now press the bottom (or top) Adjustment Control button until the lines disappear and you have a clear display.

### **PROBLEM: There is no LCD Display**

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If there is no display on the LCD, please perform the following steps:

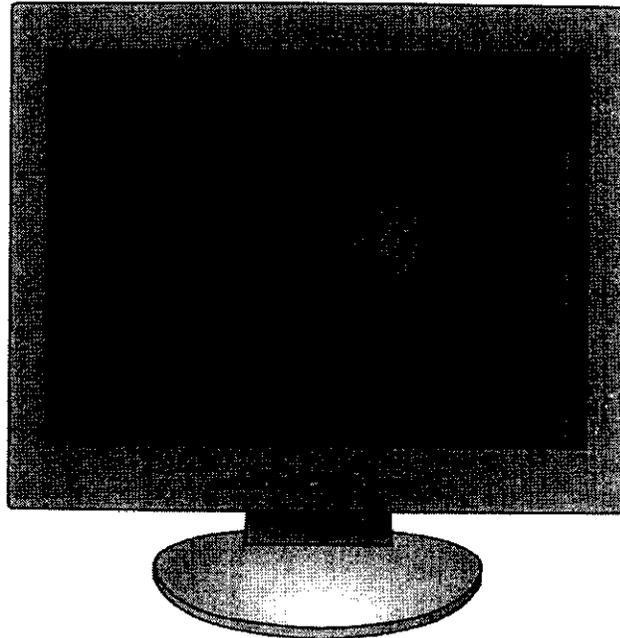
1. Make sure that the power indicator on your New Planar LCD Monitor is lit, all connections are secure, and the system is running on the correct timing. Refer to the Appendix B for information on timing.
2. Turn off your New Planar LCD Monitor and then turn it back on again. Press the upper Function Control button (refer to Chapter 2) once and then press either the upper or lower Adjustment Control button several times. If there is still no display, press the other Adjustment Control button several times.
3. If step 2 doesn't work, connect your PC system to another external CRT. If your PC System functions properly with a CRT Monitor but it does not function with your New Planar LCD Monitor, and your New Planar LCD Monitor's power LED is blinking, the output timing of the PC's VGA card may be out of the LCD's synchronous range. Please change to an alternate mode listed in Appendix B or replace the VGA card and repeat steps 1 and 2.
4. If the PC doesn't function with the CRT monitor neither, check BIOS to see if there is a dual scan setting under the display mode item. Set the BIOS display mode to *Dual Scan* or *CRT* and try again. If there is still no display, then there may be a problem with your system. Contact technical support.
5. If the power LED is not lit, check to see if the AC power connector is securely connected. Verify that the AC adapter LED is lit. If the AC adapter LED is not lit, please contact your Planar dealer for assistance.

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## Planar LCD Monitor



### WT1503Z Manual



## PREFACE

### About this manual

This manual is designed to assist you in setting up and using your New Planar LCD Monitor. Information in this document has been carefully checked for accuracy; however, no guarantee is given to the correctness of the contents. The information in this document is subject to change without notice. This document contains proprietary information protected by copyright. All rights are reserved. No part of this manual may be reproduced by any mechanical, electronic or other means, in any form, without prior written permission of the manufacturer.

### FCC Compliance Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. this device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

#### FCC WARNING

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into an outlet different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

#### Caution:

To comply with the limits for an FCC Class B computing device, always use the shielded signal cord supplied with this unit.

The Federal Communications Commission warns that changes or modifications of the unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**CE mark for Class B ITE (Following European standard EN55022/1998; EN61000-3-2/1995; EN61000-3-3/1995, EN55024/1998)**

### Radio Frequency Interference Statement

#### Warning:

This is a Class B product. In a domestic environment, this product may cause radio interference in which case the user may be required to take adequate measures.



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### For Class B Computing Devices

This digital apparatus does not exceed the Class B limits for radio noise emissions from digital apparatus as set out in the Radio Interference Regulation of the Canadian Department of Communications.

“Le présent appareil numérique n'émet pas de bruits radioélectriques dépassant les limites applicables aux appareils numériques de la class B prescrites dans le Règlement sur le brouillage radioélectrique édicté par le ministère des Communications du Canada”

### Important Safety Instructions

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Please read the following instructions carefully. This manual should be retained for future use.

1. To clean your New Planar LCD Monitor screen, first, make sure the Monitor is in the power off mode. Unplug the Monitor from its power source before cleaning it. Do not spray liquid cleaners directly onto the unit. Stand away from your New Planar LCD Monitor and spray cleaning solution onto a rag. Without applying excessive pressure, clean the screen with the slightly dampened rag.
2. Do not place your New Planar LCD Monitor near a window. Exposing the Monitor to rain, water, moisture or sunlight can severely damage it.
3. Do not place anything on top of the Monitor-to-PC signal cord. Make sure the cord is placed in an area where it will not be stepped on.
4. Do not apply pressure to the LCD screen. Excessive pressure may cause permanent damage to the display.
5. Do not remove the cover or attempt to service this unit by yourself. You may void the warranty. Only an authorized technician should perform servicing.
6. Safe storage of your New Planar LCD Monitor is in a range of minus 20 to plus 65 degrees Celsius (68°F-149°F). Storing your New Planar LCD Monitor outside this range could result in permanent damage.
7. If any of the following occurs, immediately unplug your Monitor and call an authorized technician.
  - The power or Monitor-to-PC signal cord is frayed or damaged.
  - Liquid has been spilled onto the Monitor, or it has been exposed to rain.
  - The Monitor has been dropped or the case has been damaged.
8. The appliance should be disconnected from the mains by pulling the mains power cord/mains plug.
9. The socket-outlet shall be installed near the equipment and shall be easily accessible.



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## CHAPTER 1

# Your New Planar LCD Monitor

## Your New Planar LCD Monitor!

Your New Planar LCD Monitor has been designed to be versatile, ergonomic and user-friendly. Your New Planar LCD Monitor is capable of displaying most standards, from 640 x 480 VGA to 1024 x 768 XGA. The digital controls located on the front panel allow the user to easily adjust the Monitor's display parameters. Your New Planar LCD Monitor's small footprint allows you more room in your workspace for other peripherals. Lightweight and compact, your New Planar LCD Monitor is the perfect solution for users on the go. You can use your New Planar LCD Monitor for everything from making business presentations to playing computer games. The two stereo speakers allow you to further expand your computer's multimedia capabilities by connecting your computer's Audio out port to your New Planar LCD Monitor's Audio in port. If you have a complete full workstation, your New Planar LCD Monitor has the additional feature of an optional wall-mountable stand for added convenience.

The architecture of your New Planar LCD Monitor incorporates an LCD panel that produces a clear display with low radiation emission, limiting health concerns. With its low power consumption, your New Planar LCD Monitor helps you reduce your power bill.

## Unpacking

Before you unpack your New Planar LCD Monitor, prepare a suitable workspace for your New Planar LCD Monitor and computer. You need a stable, level and clean surface near a wall outlet. Even though your New Planar LCD Monitor uses very little power, you should put it in a location that allows sufficient airflow to ensure that your New Planar LCD Monitor and your computer do not become too hot. Set up your New Planar LCD Monitor so that the panel does not face a window where sunlight often comes in. The glare caused by sunlight reflecting off your New Planar LCD Monitor's screen will make it difficult to see.



*Using a computer for an extended period of time with a poor workstation set-up and incorrect working habits can cause health problems. The science of ergonomics studies the relationship between health and a suitable working environment. There is a section on ergonomics at the end of this chapter. For more information on ergonomics, contact your nearest computer bookstore, or local library. The Internet also has information on this and other subjects.*

After you unpack your New Planar LCD Monitor; make sure the following items are included in the box and in good condition:

- LCD Monitor
- Monitor-to-PC signal cable
- 1.5M Stereo Jack Audio Cable
- AC Adapter
- Power cord
- This Planar User's Manual

If you find that any of these items are missing or appear damaged, contact your dealer immediately. Do not throw away the packing material or shipping carton in case you need to ship or store your New Planar LCD Monitor in the future.

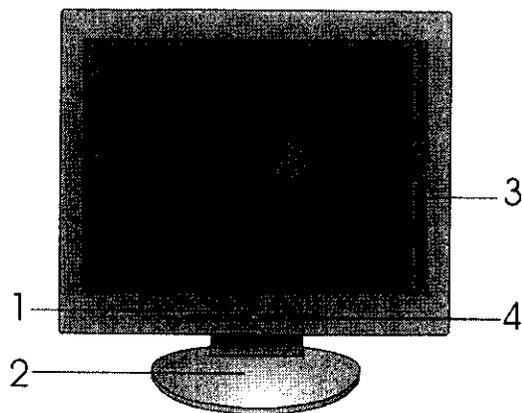
## Identifying Components

Your New Planar LCD Monitor has been designed to provide easy access to all controls and peripheral ports. The following figures will help you identify your New Planar LCD Monitor's controls and ports.



## Planar User's Manual

### Your New Planar LCD Monitor — Front View



1. **Power-On Indicator**

This LED indicator stays lit when the power is on and when the monitor is receiving a proper video signal. The LED will blink slowly when the LCD monitor is in power saving mode.

2. **Monitor Stand**

The monitor stand supports the LCD monitor.

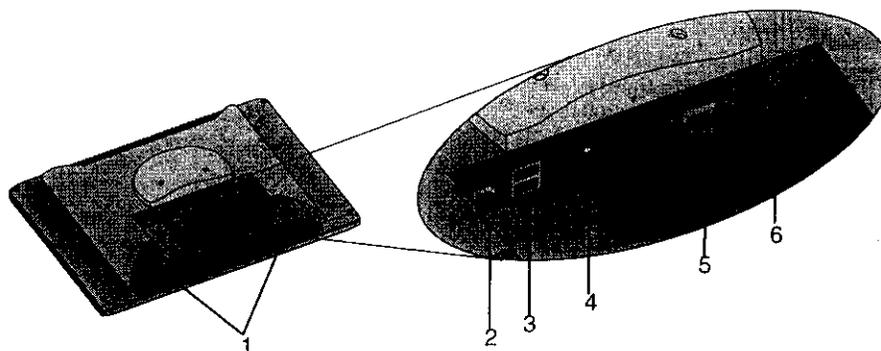
3. **LCD Screen**

The LCD monitor screen is a 15-inch diagonal, Active Matrix Liquid Crystal Display (AMLCD). The screen is capable of supporting a maximum resolution of 1024 x 768 RGB (XGA).

4. **LCD Monitor Keypad**

Activates and adjusts the monitor's settings through an On Screen Display (OSD).

### Your New Planar LCD Monitor — Rear View



1. **Stereo Speakers (optional)**

The LCD monitor's built-in stereo speakers are located in the bottom of the monitor and face the direction of the desktop.

2. **Upstream USB Port (optional)**

Connect the AC adapter cable to this jack.

3. **Downstream USB Ports (optional)**

The monitor's two downstream USB ports let the LCD monitor function as a USB hub allowing the connection of USB compliant devices. The upstream USB port must be connected to your PC for the downstream ports to function.

4. **DC Power Jack**

Connect the AC adapter cable to this jack.

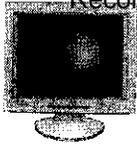
5. **VGA Cable Connector**

Connect the supplied 1.5m 15-pin D-Sub VGA cable to this connector. The opposite end of the cable is connected to your PC's graphics card.

6. **Audio Line-in (optional)**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118  
Connect your PC's line-out to this jack to listen the PC's audio on the LCD monitor's stereo speakers.  
(You can also connect your CD-ROM's line-out to this jack.)

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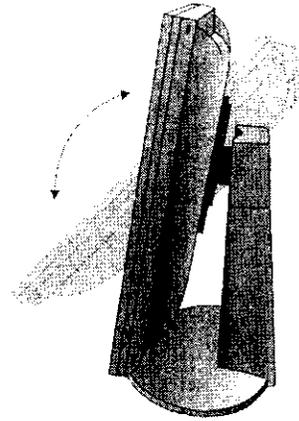


## Adjusting the Monitor's Position

Your LCD monitor's tilting angle can be adjusted in both the landscape and optional portrait mode.

### Adjusting the Tilting Angle

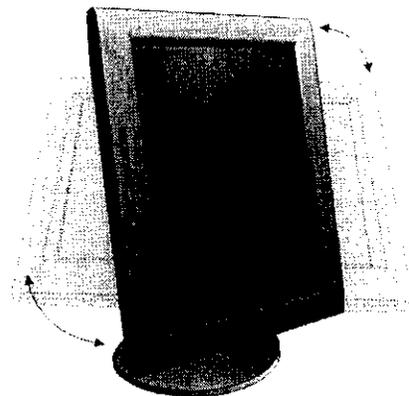
The LCD monitor's angle settings range from  $-5^{\circ}$  to  $25^{\circ}$  in both the landscape and optional portrait viewing modes.



### Viewing Orientation

If your LCD monitor supports the portrait mode option, you can adjust the viewing mode from landscape to portrait.

To switch to the portrait mode, tilt the monitor backwards and, using both hands, gently turn it  $90^{\circ}$  in a clockwise direction.



Forcing the monitor past its maximum extension can result in damage to the monitor.

## Connecting AC Power

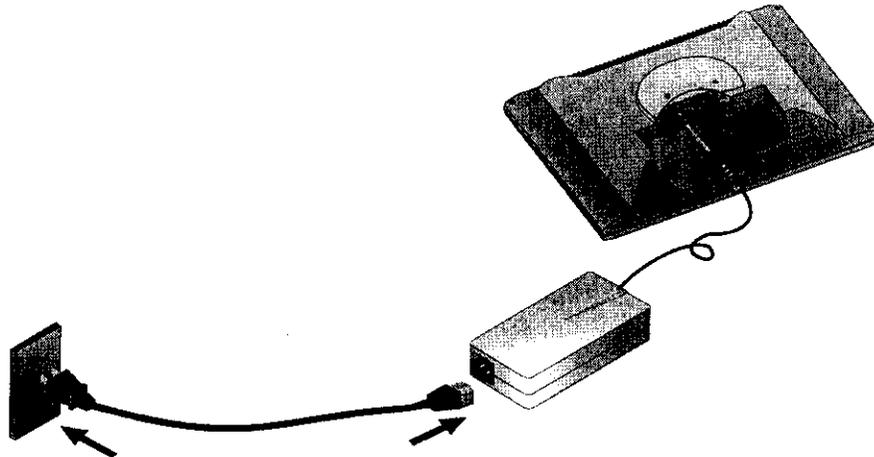
Refer to the following instructions for connecting AC power to the LCD monitor.

1. Plug the female end of the power cable into the AC-adapter and the male end of the power cord into a wall socket. The plug on the power cable will vary according to the electrical standard for your area.
2. Plug the adapter power connector into the LCD monitor's DC power jack.



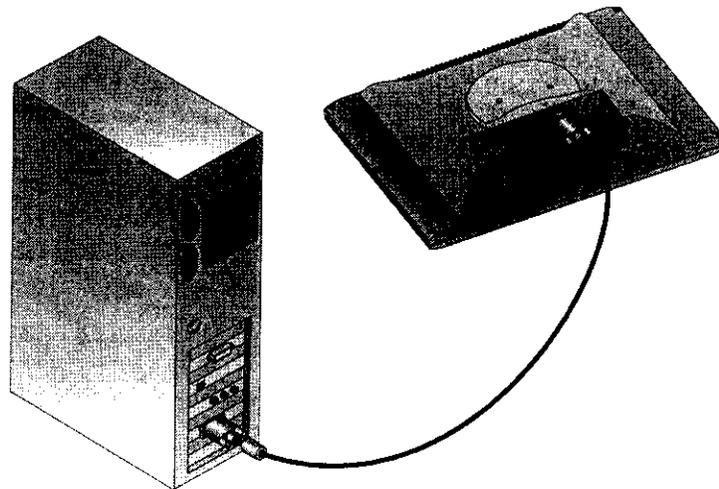
## Planar User's Manual

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### Connecting Video

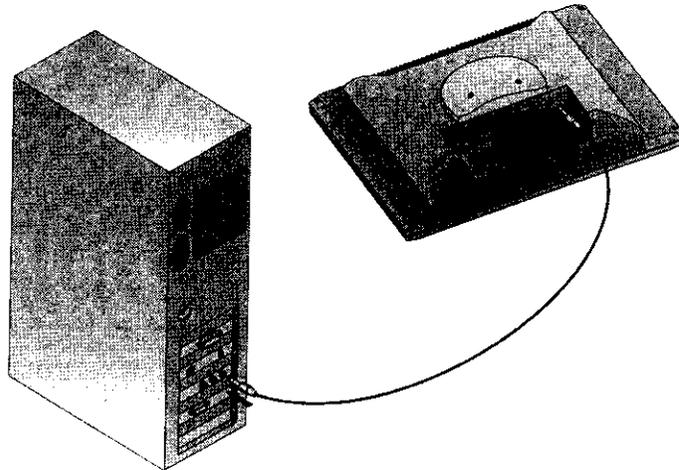
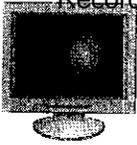
1. Turn off your PC and the LCD monitor before connecting your LCD monitor to the computer.
2. Loop the 1.5M VGA cable through the hole in the LCD monitor's stand and plug it into the LCD monitor's VGA cable connector.
3. Connect the other end of the VGA cable to the PC's VGA port.
4. Tighten the connecting screws.



### Connecting the Stereo Speakers

Please refer to the following instructions for connecting the LCD monitor's stereo speakers.

1. Connect the 1.5M audio cable to the line-out of your PC's sound card.
2. Connect the other end to the LCD monitor's audio line-in jack.
3. You can adjust the sound volume of the stereo speakers by using the speaker volume control function in the OSD (On-Screen Display).



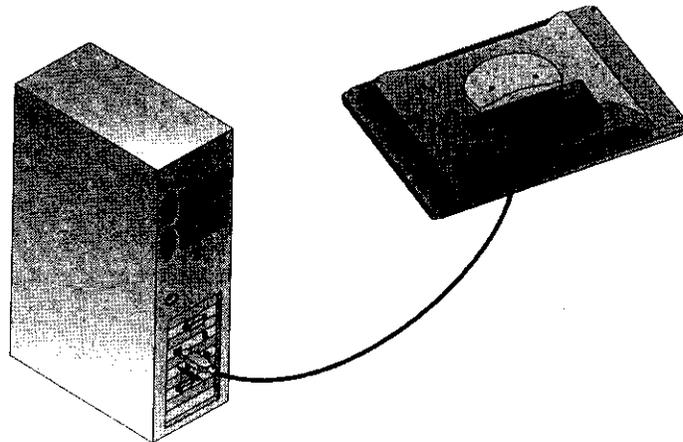
## Connecting USB Devices

The following section covers connecting USB devices. The LCD monitor supports an upstream and two downstream USB connections.

### Upstream

You can connect the LCD monitor's upstream USB port to your PC's USB port and use the LCD monitor as a USB hub. The following explains how to connect the upstream USB port to your PC:

1. Connect one end of the USB cable to the LCD monitor's upstream USB port.



2. Connect the other end to the PC's USB port.

### Downstream

The two downstream USB ports connect USB devices, such as USB keyboards, scanners and mice, directly to your LCD monitor.

Connect the USB device cable to one of the LCD monitor's downstream USB ports.

*Note: The upstream USB port must be connected to your PC for the downstream USB ports to function.*

## Power Management System

The LCD monitor complies with the VESA DPMS power management proposal. The VESA DPMS proposal provides power saving modes by detecting the horizontal or vertical sync signal. Refer to the Addendum for more information.

When the LCD monitor is in power saving mode, the monitor's power LED indicator starts blinking. When the LCD monitor is in power saving mode, the monitor's screen will be blank and the power LED indicator starts blinking.

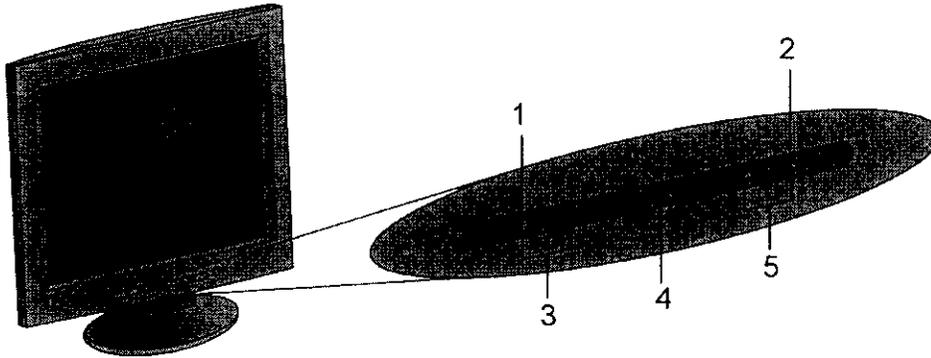
Questions? Contact FDA/CDRH/OCE/DID at CDRH.FOIA@FDA.HHS.GOV or 301-796-8118

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## CHAPTER 2

# The Display Controls

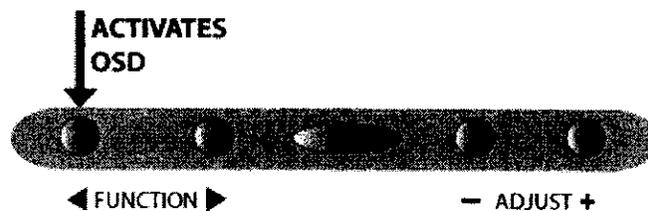
## LCD Monitor Control Panel



- 1. OSD Menu Button**  
Press this button to activate the OSD (On-Screen Display) menu. This button is also used as the ◀ Selection button.
- 2. Adjust ⊕ Button**  
This button allows you to apply settings and enter submenus in the OSD. This button also is used to increase the value of the selected menu item.
- 3. ◀▶ Function Select Buttons**  
These two buttons allow you to select the control functions in the OSD. Press either button to scroll through the main menu and submenu items.
- 4. Power Switch**  
Push the power switch to turn the monitor on and off. When you shutdown your computer, the monitor will enter power-saving mode. The LED will slowly flash indicating the display is in power saving mode.
- 5. ⊖ Adjust ⊕ Control Buttons**  
The ⊕ button allows you to increase the menu item value.  
The ⊖ button allows you to decrease the menu item value.

## Adjusting the Display

The LCD monitor features an intuitive, menu-driven, On-Screen Display (OSD). You can access the OSD any time that the PC is powered up. If the PC is in a power saving mode, or is powered down, the OSD is inaccessible.



### OSD Main Menu

To activate the OSD Main Menu, press the leftmost ◀ Function key. To navigate the topline menu, use either the right ▶ or left ◀ function keys to scroll between the main menu choices.

The option that is currently selected is indicated by a white bar on the screen. For more information, contact PDA/CDRH/OCED/ID at CDRH.FORTA@usda.hhs.gov or 301-706-8118 further described.

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The 7-topline menus are:

	<p>The Auto Adjust option lets the monitor determine and select the settings that are most appropriate for your system requirements. This function will tune the display to your computers video card.</p>
	<p>The Monitor-Control option allows you to adjust the LCD monitor's display characteristics such as the display's horizontal or vertical position, display phase, display clock, and factory reset. Adjusting these settings should only be necessary if the results from Auto-Adjust function are not satisfactory.</p>
	<p>The OSD-Control option allows you to adjust the position and setting of the monitor's On Screen Display.</p>
	<p>The MISC-Control option allows you to select the desired text language of the OSD, adjust the monitor speaker volume, and to display the current video information being sent to the monitor from your video card.</p>
	<p>The Graphic-Control option allows you to adjust the display contrast, brightness, sharpness, and color settings.</p>
	<p>The Graph/Tex option allows you to switch DOS text resolution from 640x400 and 720x400. This function has no effect within graphic operating systems such as MS Windows™.</p>
	<p>The OSD Exit option closes the On Screen Display.</p>
	<p> <b><u>Auto Adjust Procedure</u></b></p>

Pressing the Adjust  key while the Auto Adjust topline menu is selected, activates the Auto Adjust procedure. The Auto Adjust procedure takes approximately 2 seconds to complete. Once finished, the OSD menu will disappear after a short time out period.

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

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Planar User's Manual



**The Monitor- Control Option**

Pressing the Adjust ⊕ key while the Monitor Control icon is selected activates the Monitor Control submenu. Use the ◀FUNCTION▶ select buttons to scroll between the submenu items. You should only use this menu item if the results of the Auto Adjust function are not satisfactory.



**H-Position:** Press the ⊖ Adjust ⊕ buttons to horizontally move the display image to the desired position.



**V-Position:** Press the ⊖ Adjust ⊕ buttons to vertically move the display image to the desired position.



**Phase:** Press the ⊖ Adjust ⊕ buttons to fine-tune the displayed image. An improper phase adjustment will result in pixel jitter or display noise.



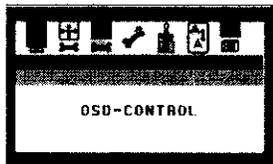
**Clock:** Press the ⊖ Adjust ⊕ buttons to stabilize the display clock timing. An improper clock setting will result in wide vertical bands on the display.



**Reset:** Press the Adjust ⊕ button to reset the Monitor-Control submenu values to the factory default values.



**Exit:** Press the Adjust ⊕ button key to exit the Monitor-Control submenu.



**OSD - Control Option**

Pressing the Adjust ⊕ key while the OSD Control icon is selected activates the OSD Control submenu. Use the ◀FUNCTION▶ select buttons to scroll between the submenu items.



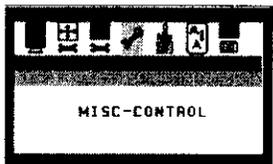
**OSD-H-Position:** Press the ⊖ Adjust ⊕ buttons to horizontally move the OSD menu.



**OSD-V-Position:** Press the ⊖ Adjust ⊕ buttons to vertically move the OSD menu.



**Exit:** Press the Adjust ⊕ button key to exit the OSD-Control submenu.



**Misc. - Control Option**

Pressing the Adjust ⊕ key while the Misc Control icon is selected activates the Misc Control submenu. Use the ◀FUNCTION▶ select buttons to scroll between the submenu items.



**Language:** Press the ⊖ Adjust ⊕ buttons to select the desired OSD display language. Languages supported: English, German, French, Spanish, and Italian.



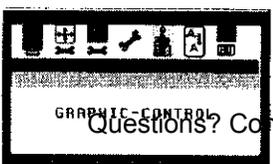
**Audio Volume:** Press the ⊖ Adjust ⊕ buttons to increase or decrease the volume of the monitor speakers.



**Information:** The Information submenu displays the current resolution, vertical refresh rate, and monitor firmware version.



**Exit:** Press the Adjust ⊕ button to exit the Misc-Control submenu.



**Graphic Control Option**



Pressing the Adjust  $\oplus$  key while the Graphic Control icon is selected activates the Graphic Control submenu. Use the  $\blacktriangleleft$ FUNCTION $\blacktriangleright$  select buttons to scroll between the submenu items.



**Contrast:** Press the  $\ominus$  Adjust  $\oplus$  buttons to adjust the difference between the lightest and darkest areas on the display. The contrast level can range from 0 to 63.



**Brightness:** Press the  $\ominus$  Adjust  $\oplus$  buttons to adjust the intensity of the monitor backlight.



**Sharpness:** Press the  $\ominus$  Adjust  $\oplus$  buttons to select the desired sharpness setting.



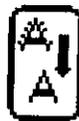
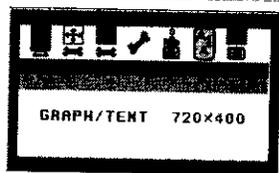
**Color:** Press the  $\ominus$  Adjust  $\oplus$  buttons to select the desired color temperature setting. The available options are CIE coordinate values 9300°, 6500°. Selecting the USER option, allows for customization of the Red, Green and Blue color coordinates.



**R, G and B:** Press the  $\ominus$  Adjust  $\oplus$  buttons to make individual adjustments to the Red, Green, and Blue coordinates for the customized color temperature. There are 127 levels of adjustments (0 - 127) available. Before adjusting these fields, you must select the User option in the Color submenu.

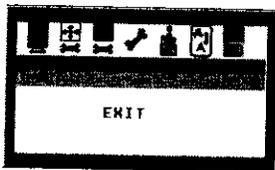


**Exit:** Press the Adjust  $\oplus$  button to exit the Graphic-Control submenu.



Graph/Text Option

Pressing the Adjust  $\oplus$  key while the Graph/Text icon is selected toggles the DOS resolution between 640x400 and 720x400.



OSD Exit

Pressing the Adjust  $\oplus$  key while the Exit icon is selected, deactivates the OSD menu.

**APPENDIX A****Technical Information****Planar TFT LCD Monitor Specifications**

Model		Planar WT1503Z	
LCD Panel	15"XGA		
Control Functions Power	Software Power switch with LED indicator (Press to turn off, over 1 sec. to turn on)		
On-Screen Display (OSD)	Main Menu	Submenu	
	Auto Adjust		
	Monitor Control	Horizontal Position/Vertical Position/Phase/Clock/Reset/Exit	
	OSD Control	OSD Horizontal Position/OSD Vertical Position/Exit	
	Misc. Control	Language/Audio Volume/Information/Exit	
	Graphic Control	Contrast/Brightness/Sharpness/Color/R/G/B/Exit	
	Graph/Text	640 x 400/720 x 400	
	OSD Exit		
Display Colors	Dithering 16M		
Response Time(ms) (Rise/Fall)	40 ms typ.		
Contrast Ratio	350:1 typ.		
Brightness	250 cd/m <sup>2</sup> typ.		
Pixel Pitch (mm)	0.297 x 0.297		
Viewing Angle	Horizontal: 60°/60° (L/R), Vertical: 45°/60° (U/D)		
Video Interface	VGA Compatible Analog RGB/ Composite Sync.		
Scanning Frequency H/V, Hz	24-62K 50-75		
Number of Factory Preset Mode	22		
Power Management	Meets VESA DPMS		
Power Consumption (ON/OFF, W)	40/4.5Max.		
Dimensions WxHxD mm	380x370x171		
Net Weight (Kg)	4.5		
Power Supply	12.0V/3.75A, 45W Stand-alone AC Adapter (External)		
Options	Other Stands (Wall-mount), Touch Screen, S-Video/Video cable		
Environment	Operating Temperature: 0 to 40° C Relative Humidity: 10% to 90%		
Audio (Two 1 Watt speakers with amplifier)	Yes		
Regulatory	UL, CSA, TÜV/GS, CE Mark, VCCI, T-Mark, FCC B DoC, TCO '99 (optional)		

**APPENDIX B****Supported Timing****Timing for Model WT1503Z (XGA Resolution)**

Item	Standards	Resolution	Dot Clock (MHz)	Vertical Scanning Frequency (Hz)	Horizontal Scanning Frequency (kHz)
1	NEC PC98	640x400	25.20	70.15	31.50
2	NEC PC98	640x400	21.05	56.42	24.83
3	MAC 13" mode	640x480	30.24	66.67	35.00
4	MAC 16" mode	832x624	57.28	74.55	49.73
5	MAC 17" mode	1024x768	80.00	75.02	60.24
6	VGA	640x350	25.18	70.09	31.47
7	VGA	640x400	25.18	70.09	31.47
8	VGA	640x480	25.18	59.94	31.47
9	VESA	640x480	31.50	72.81	37.86
10	VESA	640x480	31.50	75.00	37.50
11	VESA	800x600	36.00	56.25	35.16
12	SVGA	800x600	40.00	60.32	37.88
13	VESA	800x600	50.00	72.19	48.08
14	VESA	800x600	49.50	75.00	46.88
15	VGA	720x400	28.32	70.09	31.47
16	XGA	1024x768	65.00	60.00	48.36
17	VESA	1024x768	75.00	70.07	56.48
18	VESA	1024x768	78.75	75.03	60.02
19		1024x768	71.64	66.13	53.96
20	SUN	1024x768	64.13	59.98	48.29
21	SUN	1024x768	74.25	70.04	56.59
22	SUN	1024x768	84.38	77.07	62.04

\*Once a mode is optimized, there is no need to make any further adjustment as long as the VGA card remains unchanged.

\*Specifications are subject to change without notice.

SDS

## APPENDIX C

# Troubleshooting

## Troubleshooting Procedures

This LCD Monitor was pre-adjusted in the factory with standard VGA timing. Due to output timing differences among various VGA cards, you may initially experience an unstable or unclear display when a new display mode or new VGA card is selected.



*This LCD Monitor Supports Multiple VGA Modes. Refer to Appendix B for a listing of the factory-preset modes supported by this LCD Monitor.*

### **PROBLEM: Display is Unclear and Unstable**

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To stabilize and clarify your display, follow this procedure in this order:

1. It's best to adjust the display on a screen displaying of vertical lines. In Windows, load a wallpaper bitmap that has vertical lines in it. (or you can select the window shut down screen)
2. After you have the wallpaper loaded, open the OSD and select the "Clock" function. Press the top (or bottom) Adjustment Control button and continue pressing the button until you see vertical dark and light lines across the screen.
3. When you can see distinct light and dark vertical bands, stop pressing the Adjustment Control button. Now press the opposite (top or bottom) Adjustment Control button. The vertical dark and light bands will decrease in number. Keep pressing the button until the distinct bands disappear and you have a clear display.
4. Next, press the Function Control button to choose the "Phase" function. The Phase will adjust the horizontal display. Press the top (or bottom) Adjustment Control button and you will see horizontal dark and light lines appear. The number of lines increases as you press the button. Now press the bottom (or top) Adjustment Control button until the lines disappear and you have a clear display.

### **PROBLEM: There is no LCD Display**

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If there is no display on the LCD, please perform the following steps:

1. Make sure that the power indicator on your New Planar LCD Monitor is lit, all connections are secure, and the system is running on the correct timing. Refer to the Appendix B for information on timing.
2. Turn off your New Planar LCD Monitor and then turn it back on again. Press the upper Function Control button (refer to Chapter 2) once and then press either the upper or lower Adjustment Control button several times. If there is still no display, press the other Adjustment Control button several times.
3. If step 2 doesn't work, connect your PC system to another external CRT. If your PC System functions properly with a CRT Monitor but it does not function with your New Planar LCD Monitor, and your New Planar LCD Monitor's power LED is blinking, the output timing of the PC's VGA card may be out of the LCD's synchronous range. Please change to an alternate mode listed in Appendix B or replace the VGA card and repeat steps 1 and 2.
4. If the PC doesn't function with the CRT monitor neither, check BIOS to see if there is a dual scan setting under the display mode item. Set the BIOS display mode to *Dual Scan* or *CRT* and try again. If there is still no display, then there may be a problem with your system. Contact technical support.
5. If the power LED is not lit, check to see if the AC power connector is securely connected. Verify that the AC adapter LED is lit. If the AC adapter LED is not lit, please contact your Planar dealer for assistance.

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# Quick Setup Guide

**Customer Service**  
E-mail: [desktopmonitors@planar.com](mailto:desktopmonitors@planar.com)  
Tel: 1-866-PLANAR-1 (1-866-752-6271)  
Hours: M-F, 7am - 6pm Pacific Time

### Troubleshooting Tips

If you are experiencing image fuzziness, flicker, or are not getting a signal on your monitor after following the Quick Setup Guide, the following tips should help check your system for accurate set-up. If these symptoms persist after following these troubleshooting tips, please contact Customer Service toll-free at 1-866-PLANAR-1 (1-866-752-6271) or via email at [desktopmonitors@planar.com](mailto:desktopmonitors@planar.com).

#### TIP 1 Check Video Cable Connectors

- a. Turn your monitor Power Off
- b. Disconnect your video cable on both ends
- c. Inspect the connectors for bent pins
- d. If you find bent pins, please contact us for a replacement cable
- e. If all pins look straight, reconnect both ends and tighten until snug
- f. Reboot your computer system

#### TIP 2 Image is Fuzzy or Flickers

Adjust Resolution and Color Settings, try lower settings to test your video card. Test lower monitor resolutions with lower color display options to find the highest resolution and highest color bit display your video card will support.

- a. Select: **Start** from your Windows menu.
- b. Select: **Settings**
- c. Select: **Control Panel**
- d. Open: **Display icon**
- e. Select: **Settings**
- f. Increase/Decrease the resolution and view monitor image 15" (1024x768), 17.4"/18.1"/19" SXGA (1280x1024), 19" UXGA (1600x1200). Decrease colors to test your video card. Select (16-bit, 24-bit, 32-bit) depending on the available memory (RAM) on your video card. Start low and slowly increase the colors until you reach the highest bit display
- h. Select: **OK**
- i. Depending on your computer's settings you may need to reboot your computer completely to view the new resolution and color display selections.

If changing the resolution and color settings eliminates the flicker or fuzzy image your video card cannot support the maximum native resolution of this monitor. This is usually due to the limited amount of onboard RAM in the video card. The ability for your computer to maximize the display's effectiveness is a factor of how much video RAM is on your video card.

If the problem still exists then, try adjusting your Refresh Rate.

#### TIP 3 Adjust Refresh Rate

- a. Select: **Start** from your Windows menu.
- b. Select: **Settings**
- c. Select: **Control Panel**
- d. Open: **Display icon**
- e. Select: **Settings**
- f. Select: **Adapter**
- g. Set your refresh rate to **Optimal**
- h. If problem persists, try setting the Refresh Rate to 75 Mhz or lower.

#### TIP 4 Update Video Card Drivers

Try updating the drivers for your video card (contact the manufacturer for the latest versions). Then, try increasing the resolution. After you find the maximum resolution, try increasing the color display options (follow Steps 7a - 7e, then Step 9.)

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## Planar Desktop Monitor Frequently Answered Questions

### 1. Can I use different resolution modes on Planar Multi-Media monitors?

Yes, different resolution modes may be used on Planar Multi-Media monitors; however, they perform best under their native resolution.

#### Planar multi-media monitor native resolution:

15" XGA	1024 x 768
17", 17.4", 18.1", 19" SXGA	1280 x 1024
19" UXGA	1600 x 1200

### 2. What can I do if my display is distorted, fuzzy, or unclear?

Follow these steps to complete setup if your display is distorted, fuzzy, or unclear.

- Connect the monitor directly to the computer, by eliminating extension cables or splitter boxes. If your monitor is connected to a laptop computer, please connect it directly to the notebook, bypassing the docking station.
- Set Windows display properties to match the Planar Multi-Media monitor's native resolution. (Refer to question 1 for the native resolutions).
- Run the Auto-Adjust function using the On-Screen Display (OSD) controls.

#### 15" Auto-Adjust (PT1503Z)

- Select the top button, function ▲ once, to highlight the Auto-Adjust function
- Select the Adjust - button to active Auto-Adjust

#### 15" Auto-Adjust (PT1503N)

- Select the top button, function ▲ twice, to highlight the Auto-Adjust function
- Select the Adjust + button to active Auto-Adjust

#### 17", 17.4", 18.1" and 19" SXGA Auto-Adjust (PT1704N, CT1744NU, PT1804NUV, CT1904N)

- Select the Menu button to turn on the menu screen
- Press the Function ▼ button to highlight the Auto-Adjust function
- Select the Adjust + button to activate Auto-Adjust



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## Planar Desktop Monitor Frequently Answered Questions

### 19" UXGA Auto-Adjust (CT1905S)

- Select the left button, Function ◀ , to turn on the Menu screen.
- Press the Adjust + button to enter the Display Sub-menu.
- Press the Function ▶ button three times to highlight the Auto-Adjust function.
- Select the Adjust + button to activate Auto-Adjust.

#### d. Smooth Edges of Screen Fonts

If you see jagged edges in your on-screen text, use this step to view smooth text.

- Select: Start from your Windows menu
- Select: Settings
- Select: Control Panel
- Open: Display icon
- Select: Settings
- Open: Display
- Select: Effects
- Select: Smooth edges of screen fonts

### 3. **My Planar Multi-Media monitor has no display but the power LED light comes on, what did I do?**

If the power LED light is flashing green, please try these steps:

- a. Please verify that your computer has AC power and that it is turned on.
- b. Please check if there are damaged or bent pins in the video cable connector.
- c. Please check the signal cable connections; make sure it is tight and secure.
- d. If you are in power save mode, please move your mouse or hit any key on your keyboard.
- e. Please connect the monitor to a different computer to eliminate the possibility of a video card problem.

If the power LED light is steady green, then:

- a. Please adjust the brightness and contrast using the On Screen Display (OSD) controls.

### 4. **My Planar Multi-Media monitor has no display and the power LED light is off (no power on the monitor), what should I do?**

Please do the following steps:

- a. Please check the power cord; make sure it is attached securely.
- b. Try a different power cord, to eliminate the cord as the cause.
- c. If you are using a power strip, try connecting directly to the wall outlet.



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## Planar Desktop Monitor Frequently Answered Questions

5. **Are Planar Multi-Media Monitors Macintosh compatible?**  
Yes, Planar Multi-Media Monitors are Macintosh compatible. A video cable adapter may be required for some Apple computer models.
6. **Will Planar Multi-Media Monitors work in other countries with different voltage standards?**  
Yes, Planar Multi-Media Monitors are power compatible with 110 to 220 volts. A power cord adapter may be required for some countries. Please check with the local utilities.
7. **Why does my monitor show an "out of range" message?**  
This message indicates that the scan rate of the video from your computer is set higher than the monitor can display. Lower the resolution to the native resolution (see question 1) then lower the refresh rate.
8. **Where can I get drivers for my Planar Multi-Media Monitor? (Drivers are required for the touch screen models)**  
Planar multi-media monitors are plug and play and do not require any special drivers. Your computer should recognize the monitor upon installation. However, if it does not you may need to install it manually.
- Select: **Start** from your Windows menu
  - Select: **Settings**
  - Select: **Control Panel**
  - Open: **Display icon**
- From the **Settings** tab:
- Open: **Add new hardware**
  - Follow the steps of the **Installation Wizard**
  - Select: **Hardware** from the list
  - Select: **Monitors**, then **Standard Monitor**
  - Select: **Type**, then **Plug & Play Monitor**
9. **What can I do if my Planar Multi-Media monitor has a red tint or missing color (color problem)?**
- a. Check the video cable connectors to determine if there are bent or missing pins.
  - b. Check the video cable connections to make sure they are secure.
  - c. If the problem still exists, please connect the monitor to a different computer to eliminate the possibility of a video card problem.
10. **I want to display more colors, what can I do?**  
The number of colors is determined two functions. First you need to check that the video adapter and driver will support more colors. Second, you need to adjust the display properties of your operating system (Win95, Win98, Win2000, WinNT, etc.) for more colors.



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## Planar Desktop Monitor Frequently Answered Questions

### 11. What does TFT stand for?

Thin Film Transistor (TFT) - this is the active device used in Active-Matrix Liquid Crystal Displays (AMLCD), and is a term often used to distinguish AMLCD flat panel displays from the older DSTN flat panel displays. In TFT LCDs one to four transistors controls each pixel. TFT technology provides for better contrast and resolution than DSTN, but it is also more expensive.

### 12. What is a Liquid Crystal Display (LCD)?

A broad category of display devices based on liquid crystal technology. They are often found in digital watches, cell phones and many portable computers. LCD displays are constructed primarily of liquid crystal material sandwiched between two sheets of glass with polarizing material laminated to the surface. An electric voltage applied across the liquid causes the crystals to align which changes the characteristic of the polarized light passing through them. Each liquid crystal element acts like a shutter, either allowing light to pass through or blocking it.

### 13. What are the differences in resolution?

Resolution refers to the sharpness and clarity of an image. For graphic monitors, the screen resolution signifies the number of dots (pixels) on the entire screen. For example, a 640 x 480 pixel screen is capable of displaying 640 distinct dots on each of 480 lines, or about 300,000 pixels. This translates into different dots per inch (dpi) depending on the size of the screen. For example, a 15" VGA monitor (640 x 480) displays about 50 dpi.

UXGA A display with 1600 x 1200 pixel resolution

SXGA A display with 1280 x 1024 pixel resolution

XGA A display with 1024 x 768 pixel resolution

SVGA A display with 800 x 600 pixel resolution

VGA A display with 640 x 480 pixel resolution

### 14. Resistive Touch Screen Technology

Resistive touch applications include public access and business applications such as automated teller machines (ATM), kiosks, industrial equipment, and point-of-sale.

As the most mature of all touch technologies, Resistive touch is also the least expensive. The construction consists of a transparent rigid panel, covered with a flexible front membrane. These two substrates are coated with transparent conductive films and are separated by non-conductive spacers. When the front membrane is depressed it closes an electrical switch. The resulting voltage is measured both in X and Y- axis and is compared respectively to the full screen voltages. The electronic controller analyzes the signal ratios and determines the X and Y touch coordinates. It is easily adaptable to a large range of size and aspect ratio formats.



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## **Planar Desktop Monitor Frequently Answered Questions**

This technology uses the bottom substrate for both X and Y-axis measurements. The flexible coversheet acts only as a voltage-measuring probe. This means the touch screen will continue to work properly even with non-uniformity in the coversheet's conductive coating. The result is an accurate, durable and reliable touch screen that offers drift-free operation. It is tested to over 35 million finger touches with no performance degradation

In addition, Resistive Touch Screen Monitors can be used with any object touching, for example finger, pen, pointer, etc. Alternatively, Capacitive Touch Screen Panels only allow use of fingers, which uses the body as a ground to measure coordinates.

### **15. Surface Acoustic Wave (SAW) Touch Screens**

For demanding environments, surface acoustic wave affords the highest level of performance. As compared to resistive technology it provides superior optical performance of increased light transmission, clarity and durability. The single rigid, transparent substrate has no flexible membrane that can war out or be damaged. On the sensor panel edge, piezoelectric transducers create and sense mechanical waves that are directed across the panel via precisely located edge reflector stripes. A pointer such as a human finger or other pointing device absorbs the sound energy. The controller converts this to a location. Additionally SAW touch can provide Z-axis information indicating the applied touch pressure. No ratioing of signals are used to determine touch location and is therefore immune to signal drift.

### **16. What can I use to clean my Planar LCD Monitor?**

Any standard glass cleaner can be used to clean the monitor. Always spray the glass cleaner on the cloth or towel and then clean the monitor. Glass cleaner sprayed directly on the monitor could possibly leak inside a non-sealed unit and cause damage.

### **17. Will vinegar or ammonia hurt the Monitor?**

No, but be careful that liquids do not leak inside non-sealed units. Again, spray the cloth and then clean the monitor.



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# REPORT

Issued by an Accredited Laboratory



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Datum/Date      Protokoll/Reference      Sida/Page  
 2002-06-03      P200229      1(2)  
 Rev. 2002-10-11

## EMC tests on Therma Cam Pxx and Sxx series (9 enclosures)

### Test object

Therma Cam Pxx and Sxx series

Article no: 218 XX.X. XX.XX.  
 Serial no: 218 005 74

XX.X.XX.XX. stands for different software configuration and what kind of equipment the camera has. The actual test configuration is stated in enclosure 1.

### Summary

The manufacturer supplied the functional specification.  
 Representatives of the manufacturer performed the functional tests.  
 The functional criteria can be found in enclosure 1.

Standard	Compliant	Enclosure	Remarks
<b>Emission: EN 50 081-1: 1992</b>	Yes		
EN 55 022:1998, class B, radiated <sup>*)</sup>	Yes	2	Note 1
EN 55 022:1998, class B, conducted	Yes	3	
<b>Immunity: EN 61000-6-2: 1999</b>	Yes		
EN 61 000-4-2: 1995	Yes	4	
EN 61 000-4-3: 1996	Yes	5	
EN 61 000-4-4: 1995	Yes	6	
EN 61 000-4-5: 1995	Yes	7	
EN 61 000-4-6: 1996	Yes	8	

\*) The RF emission reported is not based on measurements on an open area test site, which is the reference method according to EN 55 022, but on measurements performed in an anechoic shielded chamber. The used method does not meet the EN 55 022 requirements for alternative test sites. A 3 m measuring distance has been used that, based on experience from comparative measurements, gives sufficient margins to judge compliance.

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 SP Swedish National Testing and Research Institute, Box 857, S-501 16 BORÅS, SWEDEN, Telephone + 46 33 16 60 00, Telefax + 46 33 13 55 02, E-mail info@sp.se, Reg.No 556464-6874

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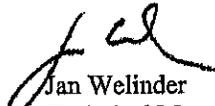


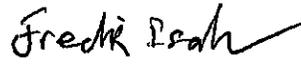
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Note 1: Ferrites attached on cables to pass emission tests. Further information can be found in enclosure 2. Ferrites were kept on cables through all tests.

**SP Swedish National Testing and Research Institute**  
**Electronics - EMC**

  
Jan Welinder  
Technical Manager

  
Fredrik Isaksson  
Technical Officer





# REPORT

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# BreastScan IR™ Data Sheet

## Cart

- Overall Dimensions: 36.25" W x 26"D x 70" H
- Shelf Dimensions: 23.75"W x 21.5"D
  - Base Shelf: 4.5"H
  - Air Conditioner Shelf: 24"H
  - Camera Shelf: 39"H
  - Television Shelf: 55"H
- Keyboard Shelf: 20"W x 11.25"D x 37"H

## Computer

- Network Connections: Wireless, CAT-5
- Camera Data Interface: FireWire IEEE 1394
- Air Conditioner Control: 9-pin Serial Port
- Primary Hard Drive: 20Gig Minimum
- Secondary Hard Drive: 80Gig Minimum
- Processor: Pentium IV 1-GHz Minimum
- Operating System: Windows XP Professional
- Office Studio: Microsoft Office XP
- Display: 15" LCD Monitor

## Cold Air Source

- 5,250 BTU/h
- Electrical Specs:
  - Power Usage: 540W
  - Operating Voltage: 115v\*
  - Operating Amperage: 5.0A
  - Operating Frequency: 60Hz\*

## Video Monitor/Recorder

- Viewable Screen: 13"
- Video Input: Standard RCA connector
- Electrical Specs:
  - Operating Voltage: 120v\*
  - Power Usage: 60W
  - Operating Frequency: 60Hz\*

\* European power requirements are also available

## Camera

### Imaging Performance

- Field of View/Min focus distance: 24° x 18° /0.3 m (.98ft)
- Spatial Resolution: 1.3mrad
- Thermal sensitivity @ + 30° C: 0.08°C
- Image Frequency: 50/60 Hz, non-interlaced
- Electronic Zoom: 2x, 4x- interpolating
- Focusing: Automatic or Manual
- Digital Image Enhancement: Adaptive Digital Noise Reduction

### Detector

- Type: Focal Plane Array (FPA), uncooled microbolometer 320,240 pixels
- Spectral Range: 7.5-13µm

### Image Presentation

- Viewfinder: Built in high resolution LCD

### Measurement

- Temperature range: -40 - +120°
- Precision: 0.05°C – 14 Bit Digital

### Power System

- AC Operation: 90-260VAC, 50/60Hz, 12VDC Out

### Environmental Specifications

- Operating Temperature Range: -15-+50 °C
- Storage Temperature Range: -40-+70°C
- Humidity: 10-95% non-condensing
- Encapsulation: IP 54 (IEC 529)
- Shock: 25g, IEC 68-2-29
- Vibration: 2g, IEC 68-2-6

### Physical Characteristics

- Weight: 1.4kg incl. battery
- Size (L x W x H): 220 x 120 x 100 mm
- Tripod Mounting: Standard 1/4"-20

### Interfaces

- Power Input: 10-16VDC 2.1mm connector
- Video Output: Standard RCA connector
- FireWire: IEEE 1394
- Removable Storage: CompactFlash™ card

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**<http://www.infraredsciences.com> email: [info@infraredsciences.com](mailto:info@infraredsciences.com)**



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[www.infraredsciences.com](http://www.infraredsciences.com)

## **Infrared Sciences Corp.**

### **Level of Concern Statement for BreastScan IR Device**

The BreastScan IR device poses a minor level of concern. The device does not control life support equipment, does not control the emission of radiation, and does not deliver medication. Under failure, malfunction, or misuse, the system poses no possibility of injury to the patient, operator, or bystanders. All software used within the system is also categorized as a minor level of concern as described in the FDA documents:

**Off-the-Shelf Software Use in Medical Devices**  
**Released: (9-9-1999)**

And

**Guidance for the Content of Pre-Market Submissions for Software Contained in Medical Devices**  
**Released: (5-29-1998)**

***Infrared Sciences Corp.***

Software Description  
for BreastScanIR™

## ***Introduction***

This document describes the purpose and use of the BreastScanIR software.

## ***Software Purpose and Description***

The BreastScanIR software is designed to be used as a component within the BreastScanIR system only. The BreastScanIR software is not intended for sale or use as a stand alone product. The BreastScanIR software is designed to retrieve temperature data from a FLIR S40 digital infrared camera, record the data, process the data, and present the user with a report of the data's characteristics. The software controls the recording process and leads the user through the data processing. The software runs on a Windows XP Professional operating system, is able to display to a standard display monitor, take input from a standard keyboard and mouse, and produce a hardcopy of the results on a standard printer. The software maintains a copy of each recording, and each final report. The BreastScanIR software follows standard windows conventions.

***Infrared Sciences Corp.***

Device Hazard Analysis  
for BreastScanIR™

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## **Purpose**

The purpose of this document is to describe the possible hazards caused by the BreastScanIR system, and the measures that must be taken to mitigate these hazards.

Hazard: System fails to control air conditioning unit properly.

Risk: Minor

Explanation: If the air conditioning unit either fails to turn on at the appropriate time or fails to turn on at all, the results produced by the exam will be invalid. The thermal challenge is necessary to proper completion of the exam.

Mitigation: The operators will be trained in the proper operation of the equipment and instructed to contact Infrared Sciences Corp. if there is a malfunction. The operator will also be trained to discard any results produced if the equipment malfunctions during the exam.

Hazard: Patient/Camera or System Rack moves during the exam.

Risk: Minor

Explanation: The software will compare the patient's position at the beginning and end of the exam. The software will then make a determination if the movement was significant.

Mitigation: If the movement was significant, the software will not process the raw data. If the patient moved, but the movement was minor, then the software will correct for the movement and continue the analysis.

Hazard: Operating system failure during acquisition

Risk: Minor

Explanation: The operating system crashes while the infrared acquisition is taking place

Mitigation: The operators are trained to perform the exam again. The operators are also instructed to contact Infrared Sciences Corp whenever a system malfunction is detected.

Hazard: Operating system failure during analysis

Risk: Minor

Explanation: The operating system crashes while the operator is analyzing the raw data

Mitigation: The operator can re-analyze the raw data at any time. The operators are also instructed to contact Infrared Sciences Corp whenever a system malfunction is detected.

Hazard: ThermaCam Researcher failure during acquisition

Risk: Minor

Explanation: ThermaCam Researcher crashes while the infrared acquisition is taking place

Mitigation: The operators are trained to perform the exam again. The operators are also instructed to contact Infrared Sciences Corp whenever a system malfunction is detected.

Hazard: ThermaCam Researcher failure during analysis

Risk: Minor

Explanation: ThermaCam Researcher crashes while the operator is analyzing the raw data

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Mitigation: The operator can re-analyze the raw data at any time. The operators are also instructed to contact Infrared Sciences Corp whenever a system malfunction is detected.

Hazard: Software system failure during acquisition

Risk: Minor

Explanation: The software system crashes while the infrared acquisition is taking place

Mitigation: The operators are trained to perform the exam again. The operators are also instructed to contact Infrared Sciences Corp whenever a system malfunction is detected.

Hazard: Software system failure during analysis

Risk: Minor

Explanation: The software system crashes while the operator is analyzing the raw data

Mitigation: The operator can re-analyze the raw data at any time. The operators are also instructed to contact Infrared Sciences Corp whenever a system malfunction is detected.

Hazard: Camera Failure

Risk: Minor

Explanation: Unspecified Camera Failure

Mitigation: The operators are instructed to contact Infrared Sciences Corp immediately if a malfunction is detected.

Hazard: General Power Failure

Risk: Minor

Explanation: Power to the system is lost.

Mitigation: No Mitigation necessary. When power returns the system will have to be restarted.

Hazard: Printer Failure

Risk: Minor

Explanation: The printer is out of ink or paper, or is malfunctioning

Mitigation: The operators are trained to refill the paper and ink supplies, or to contact Infrared Sciences Corp immediately if a malfunction is detected.

Hazard: Infrared Interference

Risk: Minor

Explanation: Thermal interference is introduced during the exam.

Mitigation: The operators are trained to identify thermal interference and re-perform the exam.

Hazard: System is damaged and bare wires are exposed. This condition would only affect the operator, not the patient.

Risk: Minor

Explanation: During transportation, it is possible that a wire may be damaged.

Mitigation: All electrical wiring is routed to avoid possible damage, and contact with the operator in the case of damage. The device manual states that if any damage occurs to the device it should not be used, and Infrared Sciences Corp should be contacted immediately.

Hazard: Patient chair is damaged including any damage to the first surface infrared mirrors. The patient may be exposed to sharp edges or an unstable chair if the chair is used in a damaged state.

Risk: Minor

Explanation: It is possible that the patient chair might become damaged. This is especially true of the infrared mirrors which are fragile.

Mitigation: The device manual states that if any damage occurs to the device it should not be used, and Infrared Sciences Corp should be contacted immediately.

# BreastScan IR™ Data Sheet

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<http://www.infraredsciences.com> email: [info@infraredsciences.com](mailto:info@infraredsciences.com)

# Infrared Sciences Corp.



## BreastScan IR™

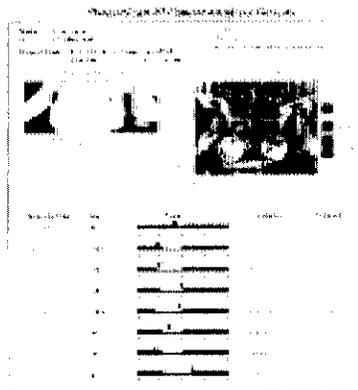
BreastScan IR™ is a new, non-invasive procedure offered to women, of any age, to determine current breast health by measuring various temperature parameters in the breast. Designed exclusively by Infrared Sciences Corp., BreastScan IR™ has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

### BreastScan IR™ System Features

- Automated software requires only basic computer skills to operate
- Remote troubleshooting and diagnostic capability
- Automatic software updates/upgrades
- Automatic update of evaluation algorithm
- System is designed to "learn" as more tests are run
- Automatic billing and tracking
- Real time reporting to doctor in easy to read format
- Remote client terminal for doctor's use
- Fully wireless LAN connection for instant network access
- Secure data transfer over internet or dial-up
- Highly sensitive state-of-the-art infrared camera
- Off the shelf high speed workstation and client terminal allows easy hardware upgrades in the future
- Automatic secure download of results and database information to ISC server

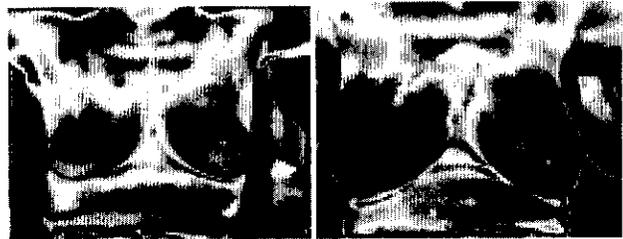


BreastScan IR

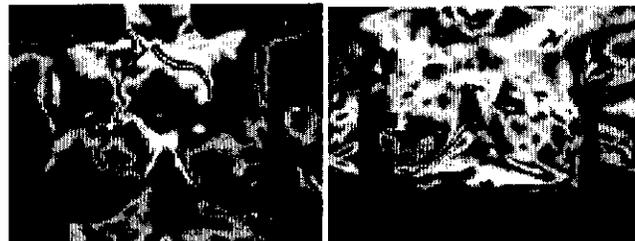


Sample Patient Results

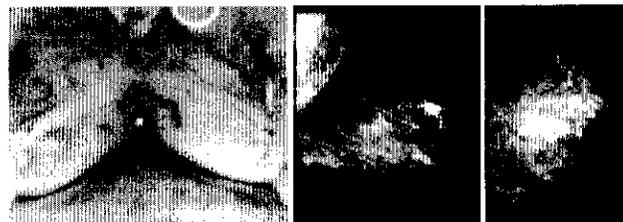
### Sample Result Images



Examples of "normal" infrared images



Examples of "abnormal" infrared images



BreastScan IR™ results and corresponding mammography

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*Infrared Sciences Corp.*

Software Requirements Specification  
for BreastScanIR™ 4.0

Version 1.0

Document Number: SRS-1001

### REVIEW AND APPROVALS

Printed Name and Title	Function	Date	Signature
Anthony Trotta	Author	5/19/03	

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### REVISION LEVEL

Date	Revision Number	Purpose
5/19/03	1.0	Initial Release

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## **1. INTRODUCTION**

### **1.1 Purpose**

The purpose of this document is to describe the software requirements for BreastScanIR 4.0. The intended audience of this document is the software design team and team management.

## **2. SCOPE**

### **2.1 Identification**

This document controls the requirements for the BreastScanIR 4.0 Software.

## **3. SYSTEM OVERVIEW**

### **3.1 Product Context**

The BreastScanIR™ software will be an integral portion of the BreastScanIR system. The software will obtain raw infrared temperature data from the FLIR ThermoCAM™ S40 infrared camera. The software will process this data adhering to proprietary algorithms developed by Infrared Sciences Corp. In no way will the raw temperature data be modified or altered by the software algorithms. The results of the processing will then be presented in report format to be viewed by the attending physician. The results will in no way directly diagnose any breast disease. However, the results will indicated areas of abnormal thermal activity that may be correlated with other physiological modalities for determining breast disease.

### **3.2 Product Functions**

The BreastScanIR™ software will follow standard Microsoft conventions for user interfaces. The software will store patient data in a local database, and store both raw data and test results for later review. The software

should present the results in a clear and concise manner, using graphical displays in conjunction with numerical data whenever possible. The software will also control the cold air source used during the infrared exam.

### **3.3 User Characteristics**

The user of BreastScanIR should, at a minimum, have experience with a windows operating system (preferably windows XP). The user should have a basic understanding of the file system, and be able to use a standard mouse and keyboard. The software will require minimal special training and will be designed to divide the overall functionality into smaller linear tasks. The user interface will be prompt driven and the software should lead the user through the various processes.

### **3.4 Constraints**

#### **3.4.1.1 Hardware Constraints**

The BreastScanIR™ software will be developed to interface with the FLIR ThermoCAM™ S40 Infrared Camera. As a result, the software will be constrained to the recording and interface restrictions of the camera and associated device drivers.

#### **3.4.1.2 Risk Evaluation**

The BreastScanIR™ software will also be developed under the guidance of proven medical studies. All risk factors and calculations developed within the software will be based on medical studies which have shown a direct correlation between thermal abnormalities and risk of breast disease.

#### **3.4.1.3 Safety Concerns**

The BreastScanIR™ system will be developed to ensure the patient and the user is in no way at risk during any portion of the exam or processing. At no time shall the patient or the user be exposed to radiation or invasive procedures.

## **4. BUSINESS REQUIREMENTS**

### **4.1 Technology Drivers**

The advancement of digital thermal imaging cameras and general computing hardware will allow our system to provide a much higher level of automation of the infrared exam and data processing than has ever been possible in the past. Thus, the software will be developed with the intention of automating as much of the process as possible in order to remove human error from processing of the data.

### **4.2 Economic Drivers**

The BreastScanIR™ system will generate revenue on a per test basis. Therefore, the software will need to track and report the number of successfully completed tests. The count of completed tests should be maintained in multiple locations in order to ensure correct billing and limit data error. The count should be reported back to Infrared Sciences Corp. on a regular basis, and failure to report within a reasonable period of time should result in a prevention of further exams being performed.

### **4.3 Market Considerations**

Due to the skill level of the intended users of BreastScanIR™, the software will need to be developed with extra care given to the aspects of process automation and limiting necessary user interaction. Process automation will also reduce the effect that a user can have on the exam results, which will improve exam consistency and allow for more accurate base-lining of patient data.

### **4.4 Human Resources and Training**

The BreastScanIR™ software shall be designed to minimize necessary training time. The software should be designed to divide the overall system usage into a few linear tasks (i.e. recording a new session, entering a new patient). The software should then lead the user through these tasks

with appropriate prompting. The user is expected to have basic computer skills.

#### 4.5 Safety

Based on the FDA document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices published in May, 1998, the BreastScanIR™ software represents a minor level of concern. This means that the software poses minimal risk of harm to the patient and user. The software does not, control any life sustaining device, control the delivery of harmful energy, control treatment delivery, produce any diagnoses, or perform vital signs monitoring.

### 5. SPECIFIC REQUIREMENTS

#### 5.1 Non-Functional Descriptive Detailed Requirements

##### 5.1.1 Physical Resource Requirements

##### 5.1.1.1 Computer Hardware Requirements

##### 5.1.1.1.1 Server Requirements

CPU:	>1Ghz
Operating System:	Microsoft Windows 2000, Microsoft Windows XP
Ram:	Minimum 256MB, 512 Recommended
Storage Device:	Primary Drive – 40GB Secondary Drive – 80GB(optional) 1.44MB Floppy Drive 30x CD-RW
Input Device:	101 key keyboard, 2/3 button mouse
Networking	Standard Ethernet or Wireless Ethernet Card
Video Display:	Minimum 1024x768 x 256 color display

##### 5.1.1.1.2 Viewer Requirements

CPU:	>1Ghz
Operating System:	Microsoft Windows 2000, Microsoft Windows XP
Ram:	Minimum 256MB, 512MB Recommended
Storage Device:	Primary Drive – 20GB 1.44MB Floppy Drive

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Input Device:	101 key keyboard, 2/3 button mouse
Networking	Standard Ethernet or Wireless Ethernet Card
Video Display:	Minimum 1024x768 x 256 color display

### ***5.1.1.1.3 Data Collection Requirements***

IEEE 1394 PC Interface

FLIR S40/S60 Digital Infrared Imaging Device

## **5.2 Patient Information Requirements**

It is necessary to collect and maintain patient information at each location.

Data to be stored will at a minimum include:

- Name
- ID#
- DOB
- Address
- City
- State
- Zip
- Telephone Number

In addition to this data, after the completion of each exam, the patients results for each individual test will be saved. There will also be an ability to save general notes on the patient, and notes specific to their most recent mammogram and sonogram results.

## **5.3 Data Recording Requirements**

The software should control as many aspects of the recording procedure as are made available from the camera manufacturer. The software should control the speed and duration of recording, as well as control the cold air source. The software should store the recording locally on a system hard drive for review and maintain the recording for future re-reviews.

## **5.4 Data Processing Requirements**

The software should be able to process the data in under two minutes. The processing should be automated to reduce user input. When the processing completes the patient results should be stored in the patient database. All

Data processing shall be performed in a manner to produce results that can be compared to published infrared imaging studies. The raw data will in no way be altered by the program. The raw data shall remain in its original form as produced by the data recording.

### **5.5 Result Presentation Requirements**

The results produced by the BreastScanIR™ software should be available in both soft and hard copies. The results should be viewable from the acquisition machine as well as remote viewing stations. The results should not be editable by any normal means, and should be dated. If raw data is reprocessed, the results file should be overwritten and the database information for that exam should also be overwritten.

### **5.6 System Maintainability Requirements**

The software should be designed using object oriented design where possible. The software should be modularized to ease maintenance. The software will be source controlled to track system changes. The system will be written to attempt to create a linear user interface. This will help prevent the user from inadvertently entering untested software branches.

## **6. SYSTEM TEST PLAN REQUIREMENTS**

### **6.1 Software Validation**

The software will be validated at two levels. All validation will compare the software to the requirements specified in this document. The first level of validation will occur during the design and implementation phase. The validation at this phase will be conducted by the programming team. The second validation phase will occur prior to release. When possible this testing will be performed by persons or groups within the company other than the programming team. This validation phase will include a full regression testing and comparison to the system requirements.

## **6.2 Software Verification**

The system will go through several levels of verification before full scale release. At the first level testing will be done during the software development. At this stage regression testing will be performed on individual components. Where possible all testing will be done by an independent party (an individual other than the primary programmer). At the second level the software will be tested with raw data, which a correct output is known for. Again, regression testing will be performed on the software application as a whole. At the third level the software and hardware will be tested with a test fixture. The test fixture will mimic "normal" and "abnormal" thermal characteristics. With these three levels of testing both the initial release and subsequent software updates can be verified for proper operation.

## **7. EVOLUTION OF THE SRS**

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### **8.1 Defect Tracking**

Defects will be reported using a DEF-R form. All DEF-R forms will be recorded to a defect tracking database and an engineer or team will be assigned to repairing the defect. After any defect is repaired, regression testing will be performed on the changed component as well as any components which might be affected by the change. The determination of

whether or not a component is affected by a given change will be made by the engineer responsible for repairing the defect and the project manager. The decision will be based on the complexity of the interoperation of the components and the complexity of the repair.

***Infrared Sciences Corp.***

**Software Requirements Specification  
for BreastScanIR™**

Version 1.1

Document Number: SRS-1001

### REVIEW AND APPROVALS

Printed Name and Title	Function	Date	Signature
Anthony Trotta	Author	5/19/03	

*5/22*

### REVISION LEVEL

Date	Revision Number	Purpose
5/19/03	1.0	Initial Release
7/14/03	1.1	Updated Off the Shelf Requirements and detailed analysis algorithm specifications

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## 1. INTRODUCTION

### 1.1 Purpose

The purpose of this document is to describe the software requirements for BreastScanIR 4.0. The intended audience of this document is the software design team and team management.

## 2. SCOPE

### 2.1 Identification

This document controls the requirements for the BreastScanIR 4.0 Software.

## 3. SYSTEM OVERVIEW

### 3.1 Product Context

The BreastScanIR™ software will be an integral portion of the BreastScanIR system. The software will obtain raw infrared temperature data from the FLIR ThermaCAM™ S40 infrared camera. The software will process this data adhering to proprietary algorithms developed by Infrared Sciences Corp. In no way will the raw temperature data be modified or altered by the software algorithms. The results of the processing will then be presented in report format to be viewed by the attending physician. The results will in no way directly diagnose any breast disease. However, the results will indicated areas of abnormal thermal activity that may be correlated with other physiological modalities for determining breast disease.

### 3.2 Product Functions

The BreastScanIR™ software will follow standard Microsoft conventions for user interfaces. The software will store patient data in a local database, and store both raw data and test results for later review. The software

should present the results in a clear and concise manner, using graphical displays in conjunction with numerical data whenever possible. The software will also control the cold air source used during the infrared exam.

### **3.3 User Characteristics**

The user of BreastScanIR should, at a minimum, have experience with a windows operating system (preferably windows XP). The user should have a basic understanding of the file system, and be able to use a standard mouse and keyboard. The software will require minimal special training and will be designed to divide the overall functionality into smaller linear tasks. The user interface will be prompt driven and the software should lead the user through the various processes.

### **3.4 Constraints**

#### **3.4.1.1 Hardware Constraints**

The BreastScanIR™ software will be developed to interface with the FLIR ThermoCAM™ S40 Infrared Camera. As a result, the software will be constrained to the recording and interface restrictions of the camera and associated device drivers.

#### **3.4.1.2 Risk Evaluation**

The BreastScanIR™ software will also be developed under the guidance of proven medical studies. All risk factors and calculations developed within the software will be based on medical studies which have shown a direct correlation between thermal abnormalities and risk of breast disease.

#### **3.4.1.3 Safety Concerns**

The BreastScanIR™ system will be developed to ensure the patient and the user is in no way at risk during any portion of the exam or processing. At no time shall the patient or the user be exposed to radiation or invasive procedures.

## **4. BUSINESS REQUIREMENTS**

### **4.1 Technology Drivers**

The advancement of digital thermal imaging cameras and general computing hardware will allow our system to provide a much higher level of automation of the infrared exam and data processing than has ever been possible in the past. Thus, the software will be developed with the intention of automating as much of the process as possible in order to remove human error from processing of the data.

### **4.2 Economic Drivers**

The BreastScanIR™ system will generate revenue on a per test basis. Therefore, the software will need to track and report the number of successfully completed tests. The count of completed tests should be maintained in multiple locations in order to ensure correct billing and limit data error. The count should be reported back to Infrared Sciences Corp. on a regular basis, and failure to report within a reasonable period of time should result in a prevention of further exams being performed.

### **4.3 Market Considerations**

Due to the skill level of the intended users of BreastScanIR™, the software will need to be developed with extra care given to the aspects of process automation and limiting necessary user interaction. Process automation will also reduce the effect that a user can have on the exam results, which will improve exam consistency and allow for more accurate base-lining of patient data.

### **4.4 Human Resources and Training**

The BreastScanIR™ software shall be designed to minimize necessary training time. The software should be designed to divide the overall system usage into a few linear tasks (i.e. recording a new session, entering a new patient). The software should then lead the user through these tasks

with appropriate prompting. The user is expected to have basic computer skills.

#### 4.5 Safety

Based on the FDA document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices published in May, 1998, the BreastScanIR™ software represents a minor level of concern. This means that the software poses minimal risk of harm to the patient and user. The software does not, control any life sustaining device, control the delivery of harmful energy, control treatment delivery, produce any diagnoses, or perform vital signs monitoring.

### 5. SPECIFIC REQUIREMENTS

#### 5.1 Non-Functional Descriptive Detailed Requirements

##### 5.1.1 Physical Resource Requirements

##### 5.1.1.1 Computer Hardware Requirements

##### 5.1.1.1.1 Server Requirements

CPU:	>1Ghz
Operating System:	Microsoft Windows 2000, Microsoft Windows XP
Ram:	Minimum 256MB, 512 Recommended
Storage Device:	Primary Drive – 40GB Secondary Drive – 80GB(optional) 1.44MB Floppy Drive 30x CD-RW
Input Device:	101 key keyboard, 2/3 button mouse
Networking	Standard Ethernet or Wireless Ethernet Card
Video Display:	Minimum 1024x768 x 256 color display

##### 5.1.1.1.2 Viewer Requirements

CPU:	>1Ghz
Operating System:	Microsoft Windows 2000, Microsoft Windows XP
Ram:	Minimum 256MB, 512MB Recommended
Storage Device:	Primary Drive – 20GB 1.44MB Floppy Drive

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Input Device:	101 key keyboard, 2/3 button mouse
Networking	Standard Ethernet or Wireless Ethernet Card
Video Display:	Minimum 1024x768 x 256 color display

### ***5.1.1.1.3 Data Collection Requirements***

IEEE 1394 PC Interface

FLIR S40/S60 Digital Infrared Imaging Device

### **5.1.1.2 Computer Software Requirements**

#### ***5.1.1.2.1 Windows XP Professional***

Manufacturer: Microsoft

Version: 5.1.2600 Service Pack 1

Windows XP professional will be the operating system on which BreastScanIR will operate.

#### ***5.1.1.2.2 ThermaCam Researcher***

Manufacturer: FLIR

Version: 2002

ThermaCam Researcher will provide camera control and access for BreastScanIR.

## **5.2 Patient Information Requirements**

It is necessary to collect and maintain patient information at each location.

Data to be stored will at a minimum include:

- Name
- ID#
- DOB
- Address
- City
- State
- Zip
- Telephone Number

In addition to this data, after the completion of each exam, the patients results for each individual test will be saved. There will also be an ability to save general notes on the patient, and notes specific to their most recent mammogram and sonogram results.





will be written to attempt to create a linear user interface. This will help prevent the user from inadvertently entering untested software branches.

## **6. SYSTEM TEST PLAN REQUIREMENTS**

### **6.1 Software Validation**

The software will be validated at two levels. All validation will compare the software to the requirements specified in this document. The first level of validation will occur during the design and implementation phase. The validation at this phase will be conducted by the programming team. The second validation phase will occur prior to release. When possible this testing will be performed by persons or groups within the company other than the programming team. This validation phase will include a full regression testing and comparison to the system requirements.

### **6.2 Software Verification**

The system will go through several levels of verification before full scale release. At the first level testing will be done during the software development. At this stage regression testing will be performed on individual components. Where possible all testing will be done by an independent party (an individual other than the primary programmer). At the second level the software will be tested with raw data, which a correct output is known for. Again, regression testing will be performed on the software application as a whole. At the third level the software and hardware will be tested with a test fixture. The test fixture will mimic "normal" and "abnormal" thermal characteristics. With these three levels of testing both the initial release and subsequent software updates can be verified for proper operation.

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*Infrared Sciences Corp.*

Software Test Plan  
for BreastScanIR™ 4.5

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## Introduction

This report documents the testing of BreastScanIR 4.5 on a Windows XP Operating system. The testing was organized by use-case. This document refers only to the software functional operation and does not test the system for correct input-output correlation. Input-output correlation is tested within the BreastScanIR system testing procedure document. If during any test, the software does not react as expected the system is considered to have failed that test. Only when the software successfully matches all expected results is it considered to pass the functional criteria.

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## **A) Summary Report**

This feature is accessed by pressing the “View Summary Report” button on the main program form.

### **i) Operator presses “Cancel” button on summary report form**

**Expected Result:** If, at any point, the operator presses the cancel button the summary report form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

### **ii) Operator presses “Query” button**

**Expected Result:** A check is performed for valid filters before the “Query” button functionality is run. If invalid filters are detected, the operator will be prompted to correct the filter. If no invalid filters are found then the summary report form should close and the query results form should open with data queried from the patient database. Specifically which data is queried depends on the report type and filters selected on the summary report form. The query results form has three buttons, “Save”, ”Print”, and “Cancel”

**Actual Results:** Same as Expected Results

### **iii) Operator presses “Cancel button on query results form**

**Expected Result:** The query results form should close and the summary report form should open.

**Actual Results:** Same as Expected Results

### **iv) Operator presses “Print” button on query results form**

**Expected Result:** The current query results should be sent to the default printer and the operator should be prompted with a message that the report was printed. If there is no default printer then the operator will be prompted with a message stating that there is no default printer.

**Actual Results:** Same as Expected Results

### **v) Operator presses “Save” button on query results form**

**Expected Result:** The save form should open. The save form should contain a folder list and “Save” and “Cancel” buttons.

**Actual Results:** Same as Expected Results

**vi) Operator presses "Save" button on save form without entering a file name**

**Expected Result:** No action should be performed

**Actual Results:** Same as Expected Results

**vii) Operator presses "Cancel" button on save form**

**Expected Result:** The save form should close. The operator should be prompted with a message that the file was not saved.

**Actual Results:** Same as Expected Results

**viii) Operator enters a valid filename and presses "Save" button on save form**

**Expected Result:** A text file should be created with the query results. The operator should then be asked if they wish to create an additional file. The prompt has a "Yes" and "No" button.

**Actual Results:** Same as Expected Results

**ix) Operator presses "Yes" button on additional file prompt**

**Expected Result:** A comma separated file should be produced with the same filename as the text file. The operator should then be prompted with a message stating that the file was saved correctly.

**Actual Results:** Same as Expected Results

**x) Operator presses "No" button on additional file prompt**

**Expected Result:** The operator should be prompted with a message stating that the file was saved correctly and the operator should be returned to the query results form.

**Actual Results:** Same as Expected Results

**B) Viewing a sequence**

This feature is accessed by pressing the "View a Sequence" button on the main program form. When the "View a Sequence" button is pressed, an open file form should open. This form should contain a file list, a "Cancel" button, and an "Open" button.

**i) Operator presses "Cancel" button on open file form**

**Expected Result:** The operator should be returned to the main program form and the open file form should close.

**Actual Results:** Same as Expected Results

**ii) Operator presses "Open" button on open file form after a valid file is selected**

**Expected Result:** No action should occur.

**Actual Results:** Same as Expected Results

**iii) Operator presses "Open" button on open file form after a valid file is selected**

**Expected Result:** The open file form should close and the sequence viewer form should open. The first frame of the selected sequence should be visible in the display box. The sequence viewer form should contain a display box (which should show the infrared image as well as a temperature scale), a palette selection box, a palette inversion checkbox, a temperature adjustment bar, an auto adjust button, an exit button, and nine buttons to control the play features of the sequence file.

**Actual Results:** Same as Expected Results

**iv) Operator selects a palette from the palette selection box**

**Expected Result:** The image shown within the display box should adjust to the new palette of colors

**Actual Results:** Same as Expected Results

**v) Operator changes the palette inversion check box**

**Expected Result:** The image shown within the display box should adjust to the inverted palette of colors

**Actual Results:** Same as Expected Results

**vi) Operator changes the temperature adjustment bar**

**Expected Result:** The image shown within the display box should adjust to the new minimum and maximum display colors

**Actual Results:** Same as Expected Results

**vii) Operator presses the "Auto Adjust" button**

**Expected Result:** The image shown within the display box should adjust to what the program considers optimal display settings.

**Actual Results:** Same as Expected Results

**viii) Operator presses the "Exit" button**

**Expected Result:** The sequence viewer form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**ix) Operator presses the "<>" button**

**Expected Result:** The sequence should stop playing. If the sequence is already stopped then no action should occur.

**Actual Results:** Same as Expected Results

**x) Operator Presses the "|<" button**

**Expected Result:** The sequence should rewind to the first frame. If the sequence is already on the first frame then no action should occur

**Actual Results:** Same as Expected Results

**xi) Operator presses the "<<<" button**

**Expected Result:** The sequence should fast rewind. If the sequence is already fast rewinding than no action should occur.

**Actual Results:** Same as Expected Results

**xii) Operator presses the "<<" button**

**Expected Result:** The sequence should rewind. If the sequence is already rewinding then no action should occur.

**Actual Results:** Same as Expected Results

**xiii) Operator presses the “-<” button**

**Expected Result:** The sequence should step back one frame.

**Actual Results:** Same as Expected Results

**xiv) Operator presses the “>+” button**

**Expected Result:** The sequence should step forward one frame.

**Actual Results:** Same as Expected Results

**xv) Operator presses the “>>” button**

**Expected Result:** The sequence should play. If the sequence is already play then no action should occur.

**Actual Results:** Same as Expected Results

**xvi) Operator presses the “>>>” button**

**Expected Result:** The sequence should fast forward. If the sequence is already fast forwarding then no action should occur.

**Actual Results:** Same as Expected Results

**xvii) Operator presses the “>>|” button**

**Expected Result:** The sequence should fast forward to the last frame of the sequence. If the sequence is already at the last frame then no action should occur.

**Actual Results:** Same as Expected Results

**C) *Process a Sequence***

This feature is accessed by pressing the “Process a Sequence” button on the main program form. When the “Process a Sequence” button is pressed, an open file form should open. This form should contain a file list, a “Cancel” button, and an “Open” button. In order for an operator to press the “Process a Sequence” button, they must be logged in. Refer to the Login section of this document for more information.

**i) Operator presses "Cancel" button on open file form**

**Expected Result:** The operator should be returned to the main program form and the open file form should close.

**Actual Results:** Same as Expected Results

**ii) Operator presses "Open" button on open file form after a valid file is selected**

**Expected Result:** No action should occur.

**Actual Results:** Same as Expected Results

**iii) Operator presses "Open" button on open file form after a valid file is selected**

**Expected Result:** The open file form should close. If a patient record cannot be found for the selected sequence file then the operator will be prompted to enter a new patient. For more information on this refer to the edit patient database section of this document. If a patient record can be found, the program will proceed. The program will then begin to process the sequence file. The program will do an automatic search for the thermal target. If one cannot be located automatically or if one is located but there is too much patient movement, the operator will be prompted to locate the target manually.

**Actual Results:** Same as Expected Results

**iv) The program fails to locate the thermal target**

**Expected Result:** The operator is presented with the thermal target and nipple selection form. The operator is prompted to click on the thermal target. Once the operator clicks on the target the sequence file should fast forward to the last frame and prompt the operator to select the target again.

**Actual Results:** Same as Expected Results

**v) The thermal target has been located (either by the program or by the operator)**

**Expected Result:** The operator is presented with the thermal target and nipple selection form. The operator is prompted to click on the right nipple. The operator is then prompted to click on the left nipple. Once the operator clicks on the left nipple the thermal target and nipple selection form should close and the sequence display form and analysis area adjustment form should be displayed. The analysis area adjustment form should have two vertical scroll bars, an "Abort" button, and

an "Accept" button. The sequence display form should only be visible and should have no operator interfaces.

**Actual Results:** Same as Expected Results

**vi) Operator presses "Abort" button on the thermal target and nipple selection form**

**Expected Result:** The thermal target and nipple selection form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**vii) Operator presses "up" arrow on "TOP" vertical scroll bar**

**Expected Result:** The analysis area box moves towards the top of the sequence image.

**Actual Results:** Same as Expected Results

**viii) Operator presses "down" arrow on "TOP" vertical scroll bar**

**Expected Result:** The analysis area box moves towards the bottom of the sequence image.

**Actual Results:** Same as Expected Results

**ix) Operator presses "up" arrow on "BOTTOM" vertical scroll bar**

**Expected Result:** The bottom of the analysis area box moves towards the top of the sequence image.

**Actual Results:** Same as Expected Results

**x) Operator presses "down" arrow on "BOTTOM" vertical scroll bar**

**Expected Result:** The bottom of the analysis area box moves towards the bottom of the sequence image.

**Actual Results:** Same as Expected Results

**xi) Operator presses "Abort" button on the analysis area adjustment form**

**Expected Result:** The analysis area adjustment form should close, the sequence display form should close, and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**xii) Operator presses "Accept" button on the analysis area adjustment form**

**Expected Result:** The analysis area adjustment form should close and the display control form should open. The display control form should contain, a palette selection box, a palette inversion checkbox, a temperature adjustment bar, an "Auto Adjust" button and an "Abort" button

**Actual Results:** Same as Expected Results

**xiii) Operator selects a palette from the palette selection box**

**Expected Result:** The image shown within the sequence display form should adjust to the new palette of colors

**Actual Results:** Same as Expected Results

**xiv) Operator changes the palette inversion check box**

**Expected Result:** The image shown within the sequence display form should adjust to the inverted palette of colors

**Actual Results:** Same as Expected Results

**xv) Operator changes the temperature adjustment bar**

**Expected Result:** The image shown within the sequence display form should adjust to the new minimum and maximum display colors

**Actual Results:** Same as Expected Results

**xvi) Operator presses the "Auto Adjust" button**

**Expected Result:** The image shown within the sequence display form should adjust to what the program considers optimal display settings.

**Actual Results:** Same as Expected Results

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**xvii) Operator presses the “Abort” button on the display control form**

**Expected Result:** The display control form and sequence display form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**xviii) Operator pressed “Accept” button on the display control form**

**Expected Result:** The display control form should close, and the nipple adjustment form should open. The nipple adjustment form should contain two sets of controls (one for each nipple), an “Accept” button, and an “Abort” button. The two sets of controls should each contain a four way movement control, a horizontal scroll bar, and a text box. The text box should display the average temperature of the area within the nipple selection circle.

**Actual Results:** Same as Expected Results

**xix) Operator presses a directional arrow on one of the four way movement controls**

**Expected Result:** The nipple area associated with the four way movement control should move in the direction indicated by the operator.

**Actual Results:** Same as Expected Results

**xx) Operator presses the “Left” arrow on one of the horizontal scroll bars**

**Expected Result:** The nipple area associated with the vertical scroll bar should get smaller

**Actual Results:** Same as Expected Results

**xxi) Operator presses the “Right” arrow on one of the horizontal scroll bars**

**Expected Result:** The nipple area associated with the vertical scroll bar should get larger

**Actual Results:** Same as Expected Results

**xxii) Operator presses “Abort” button on the nipple adjustment form**

**Expected Result:** The nipple adjustment form should close, the sequence display form should close, and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**xxiii) Operator presses “Accept” button on the nipple adjustment form**

**Expected Result:** The nipple adjustment form should close and the areola adjustment form should open. The areola adjustment form should contain two sets of controls (one for each areola), an “Accept” button, and an “Abort” button. The two sets of controls should each contain a four way movement control, and a horizontal scroll bar.

**Actual Results:** Same as Expected Results

**xxiv) Operator presses a directional arrow on one of the four way movement controls**

**Expected Result:** The areola area associated with the four way movement control should move in the direction indicated by the operator.

**Actual Results:** Same as Expected Results

**xxv) Operator presses the “Left” arrow on one of the horizontal scroll bars**

**Expected Result:** The areola area associated with the vertical scroll bar should get smaller

**Actual Results:** Same as Expected Results

**xxvi) Operator presses the “Right” arrow on one of the horizontal scroll bars**

**Expected Result:** The areola area associated with the vertical scroll bar should get larger

**Actual Results:** Same as Expected Results

**xxvii) Operator presses “Abort” button on the areola adjustment form**

**Expected Result:** The areola adjustment form should close, the sequence display form should close, and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**xxviii) Operator presses “Accept” button on the areola adjustment form**

**Expected Result:** The areola adjustment form should close and the breast adjustment form should open. The breast adjustment form should contain two selection options (use predefined circle, and use freehand shape). The form should by default have the predefined circle option selected.

**Actual Results:** Same as Expected Results

**xxix) Operator chooses “Use Predefined Circle” option**

**Expected Result:** The breast adjustment form should contain two sets of controls (one for each breast), an “Accept” button, and an “Abort” button. The two sets of controls should each contain a four way movement control, and a horizontal scroll bar.

**Actual Results:** Same as Expected Results

**xxx) Operator presses a directional arrow on one of the four way movement controls**

**Expected Result:** The breast area associated with the four way movement control should move in the direction indicated by the operator.

**Actual Results:** Same as Expected Results

**xxxi) Operator presses the “Left” arrow on one of the horizontal scroll bars**

**Expected Result:** The breast area associated with the vertical scroll bar should get smaller

**Actual Results:** Same as Expected Results

**xxxii) Operator presses the “Right” arrow on one of the horizontal scroll bars**

**Expected Result:** The breast area associated with the vertical scroll bar should get larger

**Actual Results:** Same as Expected Results

**xxxiii) Operator chooses “Use Freehand Selection” option**

**Expected Result:** The freehand selection display box should be shown along with a “Create/Clear Right”, a “Create/Clear Left” Button, an “Accept” button, and an “Abort” button. The “Accept” button should not be available until both polygons are created.

**Actual Results:** Same as Expected Results

**xxxiv) Operator presses “Create/Clear” button**

**Expected Result:** The mouse pointer should change to a black vertical arrow and the operator should be able to click into the freehand selection display box.

**Actual Results:** Same as Expected Results

**xxxv) Operator clicks into the freehand selection display box after pressing a “Create/Clear” button**

**Expected Result:** A line should be created from the point where the mouse was clicked to the current position of the mouse pointer. At each mouse click the current drawing line should become a permanent line on the display box and a new line should be created to the new mouse position. This will continue until the operator presses the “ESC” key on the keyboard, or presses a “Create/Clear” button, or makes a complete polygon. Creating a complete polygon is defined as clicking within a specified distance of the first reference point. The operator will know they are within this distance when a small circle appears at the first reference point.

**Actual Results:** Same as Expected Results

**xxxvi) Operator completes a polygon**

**Expected Result:** All of the lines within the polygon that the operator has just created should change color from black to red. When the lines have changed from black to red they are considered complete and can only be removed by clicking the "Create/Clear" button again. The mouse pointer should change back to the default mouse pointer. Once a polygon has been created for both breasts the "Accept" button will become available.

**Actual Results:** Same as Expected Results

**xxxvii) Operator presses "ESC" key on the keyboard while drawing**

**Expected Result:** Any lines created which are not yet complete should be cleared from the display box. The mouse pointer should change back to the default mouse pointer.

**Actual Results:** Same as Expected Results

**xxxviii) Operator presses "Create/Clear" button while drawing**

**Expected Result:** Any lines created which are not yet complete should be cleared from the display box. If there is a complete polygon associated with the "Create/Clear" button it should also be removed from the display box. The mouse pointer should not change, but the drawing process should be restarted.

**Actual Results:** Same as Expected Results

**xxxix) Operator presses "Abort" button on the breast adjustment form**

**Expected Result:** The breast adjustment form should close, the sequence display form should close, and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**xl) Operator presses "Accept" button on the breast adjustment form**

**Expected Result:** breast adjustment form should close, the sequence display form should close, and the processing progress form should open. The processing progress form has an "Abort" button and four progress display bars.

**Actual Results:** Same as Expected Results

**xli) Operator presses “Abort” button on the processing progress form**

**Expected Result:** The processing progress form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**xlii) Processing Progress form completes processing of data**

**Expected Result:** The processing progress form should close and the areas of concern selection form should open. The areas of concern selection form should contain three buttons (“Yes”, “No”, and “Abort”) and a display of the sequence file. The display of the sequence file should have dots located at the positions that the program determined to be areas of concern. A text display is also visible and should have the question “Are there any black dots within the breast tissue?”

**Actual Results:** Same as Expected Results

**xliii) Operator presses “Yes” button without pressing the “No” button**

**Expected Result:** The program will recalculate the position of the dots and re-ask the question. This will continue as long as the operator continues to press “Yes”.

**Actual Results:** Same as Expected Results

**xliv) Operator presses “No” button**

**Expected Result:** The program will recalculate the position of the dots and re-ask the question. If the “No” button is pressed again the process will repeat. This will continue until the program reaches its predefined limits. At this point the program will prompt the operator stating that the limit has been reached and processing will continue. The areas of concern selection form should close and the save results form should open.

**Actual Results:** Same as Expected Results

**xlvi) Operator presses “Yes” button after pressing the “No” button**

**Expected Result:** The “Yes” and “No” buttons will disappear and a green “Done” button should appear. The operator must now select relevant

dots. The “Done Selecting” button should not be available until at least one dot is selected. The operator can select a black dot by clicking on it.

**Actual Results:** Same as Expected Results

**xlvi) Operator clicks on black dot before clicking on the “Done Selecting” button**

**Expected Result:** The dot should turn green. The operator can deselect a green dot by clicking on it. If this is the first black dot to be selected the green “Done Selecting” button should also become available.

**Actual Results:** Same as Expected Results

**xlvii) Operator clicks on green dot before clicking on the “Done Selecting” button**

**Expected Result:** The dot should turn black. If this is the last selected dot. The green “Done Selecting” button should become unavailable.

**Actual Results:** Same as Expected Results

**xlvi) Operator presses the “Done Selecting” button**

**Expected Result:** The program should recalculate the positions of the dots, and should place black circles around the dots that were selected in any previous steps. The first two times the “Done Selecting” button is pressed there should be no change in the operation. With the following exceptions: 1) the preset limit is reached by the program, in which case the operator will be prompted that the limit has been reached, the areas of concern selection form should close and the save results form should open. 2) The “Done Selecting” button will always be available after the first click (i.e. no dots have to be selected to click on the button). The third time the button is pressed the operator will be asked if they want to continue selecting dots. If they chose yes the process will continue as described above. If they chose no the areas of concern selection form will close and the save results form should open. The save results form has two buttons “Save to Database” and “Exit”

**Actual Results:** Same as Expected Results

**xlix) Operator presses the “Abort” button**

**Expected Result:** The areas of concern selection form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**i) Operator presses the “Save to Database” button**

**Expected Result:** The operator will be asked if they are sure they want to permanently save the data.

**Actual Results:** Same as Expected Results

**ii) Operator answers yes to prompt and the system isn’t licensed**

**Expected Result:** The operator is presented with a prompt informing them that the system is not licensed. The operator is then returned to the save results form.

**Actual Results:** Same as Expected Results

**iii) Operator answers yes to prompt and the system is licensed**

**Expected Result:** The save results form should close and the patient test history form should open. The patient test history form contains two sections (one for mammogram, and one for sonogram) and an “Ok” Button.

**Actual Results:** Same as Expected Results

**iii) Operator answers no to prompt**

**Expected Result:** The save results form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**liv) Operator presses “Exit” button**

**Expected Result:** The operator will be asked if they are sure they want to exit without saving. If they respond yes then the save results form will be closed and the operator will be returned to the main program form. If they respond no then the program will proceed as if the operator had pressed on the “Save to Database” button.

**Actual Results:** Same as Expected Results

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**iv) Operator selects Mammogram check box**

**Expected Result:** The mammogram information section becomes available. The operator may select the patient's mammogram result, and enter a note concerning the mammogram.

**Actual Results:** Same as Expected Results

**ivi) Operator selects Sonogram check box**

**Expected Result:** The sonogram information section becomes available. The operator may select the patient's sonogram result, and enter a note concerning the sonogram.

**Actual Results:** Same as Expected Results

**lvii) Operator presses "Ok" button**

**Expected Result:** The patient test history form should close and the patient results form should open

**Actual Results:** Same as Expected Results

**lviii) Operator presses "Close" button**

**Expected Result:** The patient results form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**lix) Operator presses "Print" button**

**Expected Result:** The results should be printed to the default windows printer

**Actual Results:** Same as Expected Results

**D) *Edit Patient Database***

This feature is accessed by pressing the "Edit Patient Database" button, or by starting the record new sequence portion of the program. This feature is also accessed by the process sequence portion of the program. The process sequence portion of the program attempts to automatically find the correct patient, if that can be accomplished the operator is sent directly to the "edit" portion of this feature. If the correct patient cannot be found the operator is prompted with a message of the failure, and brought to the "add new" portion of this feature. All other functionality is the same. The user is presented with the patient search form.

The patient search form contains a search type field, a search filter field, a “Find” button, an “Add New” button, a “Cancel” button, and a “Select” button

**i) Operator presses “Find” button on patient search form**

**Expected Result:** The program should fill in the results list with any patients that match the criteria specified by the search type field and the search filter field. If the search filter field is left blank, all of the patients in the database will be returned. The operator will be prompted if the search filter contains any non alphanumeric characters.

**Actual Results:** Same as Expected Results

**ii) Operator presses “Add New” button on patient search form**

**Expected Result:** The patient search form should close and the patient editor form should open. The patient editor form should open in the patient add mode. In the patient add mode all patient data fields are enabled, the “Edit”, “Delete”, “Ok”, “Find”, “Cancel”, and “Add New” buttons are disabled, and the “Save” and “Cancel Add New” buttons are enabled.

**Actual Results:** Same as Expected Results

**iii) Operator presses “Save” button without entering patient data or after entering invalid data**

**Expected Result:** The operator is informed of which fields contain no data or invalid data. No further action should occur.

**Actual Results:** Same as Expected Results

**iv) Operator presses “Cancel Add New” button from patient add mode**

**Expected Result:** The patient editor form should close and the patient search form should open.

**Actual Results:** Same as Expected Results

**v) Operator presses “Save” button after entering all valid patient information**

**Expected Result:** The patient editor form should switch to the patient selected mode. In the patient selected mode, all patient data fields are disabled, the “Edit”,

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“Delete”, “Ok”, “Find”, “Cancel”, and “Add New” buttons are enabled, and the “Save” and “Cancel Add New” buttons are disabled.

**Actual Results:** Same as Expected Results

**vi) Operator presses “Delete” button from patient selected mode**

**Expected Result:** The patient editor form should close and the patient search form should open.

**Actual Results:** Same as Expected Results

**vii) Operator presses “Ok” button from patient selected mode**

**Expected Result:** The patient editor form should close. If the edit patient database module was accessed by clicking on the task selector then the operator will be returned to the main program form. If the edit patient database module was accessed by either the record a sequence module or the process a sequence module, then those modules will continue to run with the selected patient.

**Actual Results:** Same as Expected Results

**viii) Operator presses “Find” button from patient selected mode**

**Expected Result:** The edit patient data form should close and the patient search form should open

**Actual Results:** Same as Expected Results

**ix) Operator presses “Cancel” button from patient selected mode**

**Expected Result:** The edit patient data form should close and the operator should be returned to the main program form.

**Actual Results:** Same as Expected Results

**x) Operator presses “Add New” button from patient selected mode**

**Expected Result:** The edit patient data form should switch to the patient add mode.

**Actual Results:** Same as Expected Results

**xi) Operator presses "Edit" button from patient selected mode**

**Expected Result:** The patient editor form should switch to the patient edit mode. In the patient edit mode, all patient data fields are enabled, the "Edit", "Delete", "Ok", "Find", "Cancel Add New", and "Add New" buttons are disabled, and the "Save" and "Cancel" buttons are enabled.

**Actual Results:** Same as Expected Results

**xii) Operator presses "Select" button on patient search form without selecting a patient**

**Expected Result:** The operator is prompted with a message stating that no selection has been made. No further action should occur.

**Actual Results:** Same as Expected Results

**xiii) Operator presses "Cancel" button on patient search form**

**Expected Result:** The patient search form should close and the operator should be returned to the main program form

**Actual Results:** Same as Expected Results

**xiv) Operator presses "Select" button on patient search form after selecting a patient, or operator double clicks on a patient**

**Expected Result:** The patient search form should close and the patient editor form should open. The patient editor form should open in patient edit mode.

**Actual Results:** Same as Expected Results

**E) Login**

This feature is accessed by pressing the "Login" button on the main screen.

**i) The user presses the login button.**

**Expected Results:** The system begins the login procedure.

**Actual Results:** Same as Expected results

**ii) There are no current users.**

**Expected Results:** The operator will be prompted to add a name to the list of users.

**Actual Results:** Same as Expected Results.

**iii) User logs in (presses "Login") with an existing name selected in the user list.**

**Expected Results:** The user will be successfully logged on and the login button will indicate name of user. Recording and processing feature become enabled.

**Actual Results:** Same as Expected Results.

**iv) User exits ("Cancel") without logging in.**

**Expected Results:** Login button text remains "Login". Process and recording features remain disabled.

**Actual Results:** Same as Expected Results.

**v) User adds a valid new name to the list of users ("Add New Attendant")**

**Expected Results:** New user name will be added to the list of users.

**Actual Results:** Same as Expected Results.

**vi) User adds an invalid name (non-alphanumeric or longer than 30 characters) to the list of users ("Add New Attendant") or presses "Cancel" instead of "OK".**

**Expected Results:** Operator is prompted to enter a valid alphanumeric name. Current List of users is unchanged.

**Actual Results:** Same as Expected Results.

**vii) Operator presses "Login" with no name selected**

**Expected Results:** No change

**Actual Results:** Same as Expected Results.

**viii) Operator presses “Delete Selected Attendant” when none is selected.**

**Expected Results:** No change

**Actual Results:** Same as Expected Results.

**ix) Operator presses “Delete Selected Attendant” when a name is selected.**

**Expected Results:** The selected name will be deleted from the list.

**Actual Results:** Same as Expected Results.

**F) Pre-Cool**

This function is accessed by pressing "Pre-Cool" on the main screen.

**i) User presses "Pre-Cool" button**

**Expected Results:** Pre-cool process begins.

**Actual Results:** Same as Expected Results.

**ii) User presses "OK" to begin process.**

**Expected Results:** Air cooling device will turn on and a count indication will count down from 3.5 minutes to 0. The air cooling device will then turn off and the system will return to the main window.

**Actual Results:** Same as Expected Results.

**iii) User presses "Cancel".**

**Expected Results:** Box will disappear and return to main window.

**Actual Results:** Same as Expected Results.

**iv) User presses "Abort" during Pre-cool process.**

**Expected Results:** Air cooling device turns off and the box closes and returns to the main window.

**Actual Results:** Same as Expected Results.

## **G) Recording a Sequence**

This function is accessed by pressing “Record a New Session” from the main window and confirming the action. The operator then selects an existing patient or enters a new patient (See patient database procedures).

### **i) The operator presses “Record a Sequence” when the infrared device is not powered or is physically disconnected from the BreastScan server.**

**Expected Results:** System will warn the operator that the device is not connected. The “Begin” button will be disabled and the connected status indicator at the top of the form will be red. Closet is the only option at this time.

**Actual Results:** Same as Expected Results.

### **ii) The operator presses the “Auto Adjust” button.**

**Expected Results:** The camera will automatically adjust its min and max temperature scales.

**Actual Results:** Same as Expected Results.

### **iii) The operator presses the “Focus Near” button.**

**Expected Results:** The camera will adjust focus for the duration that the button is depressed.

**Actual Results:** Same as Expected Results.

### **iv) The operator presses the “Focus Far” button.**

**Expected Results:** The camera will adjust focus for the duration that the button is depressed.

**Actual Results:** Same as Expected Results.

### **v) The operator presses the “Close” button at any time.**

**Expected Results:** The recording form will disappear and the program will return to the main window.

**Actual Results:** Same as Expected Results.

**vi) The imaging device is properly connected and the operator presses the “Record a Sequence” button, then the “Begin” button.**

**Expected Results:** The connected status at the top of the screen will be green. The imaging device will begin to capture images for approximately 15secs (close button disabled). Then the air cooling device will turn on (close button enabled) for exactly 3 minutes after which ,the system will then take more images for approximately 15secs (close button disabled) after which the air cooling device will turn off.. The system will indicate the remaining time. After the air cooling device is turned off, the system will prompt the operator to process the results.

**Actual Results:** Same as Expected Results.

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**H) Patient Results Viewer**

**i) User launches program by desktop icon**

**Expected Results:** The Results Viewer program will open.

**Actual Results:** Same as Expected Results

**ii) User launches program by pressing button labeled "Patient Results"**

**Expected Results:** The Results Viewer Program will open.

**Actual Results:** Same as Expected Results

**iii) User presses "Clear All" at any time.**

**Expected Results:** The name list will reload and all of the items in the list will become unselected. Also, the display area will become blank.

**Actual Results:** Same as Expected Results

**iv) User presses "Full View"**

**Expected Results:** This button is only available when only 1 report (non-infrared) picture is selected. It will fill the screen with the selected report. From there, the user can press "Print" to print the report to the default printer.

**Actual Results:** Same as Expected Results

**v) User clicks "Use Raw Infrared"**

**Expected Results:** The name list will refresh with stored infrared images. If there were selections in the report list (non-infrared), the program will automatically select the corresponding raw infrared pictures and vice versa. Enabling "Use Raw Infrared" will automatically display a min/max temperature, image selector and palette control that may be used to manipulate the data. This function is not available when "Use Raw Infrared" is disabled.

**Actual Results:** Same as Expected Results

**vi) User selects a palette in the palette list**

**Expected Results:** All of the displayed infrared images will be updated using the selected palette. All subsequent displays will also use this palette.

**Actual Results:** Same as Expected Results

**vii) User modifies min/max settings for an infrared image.**

**Expected Results:** The image or images specified in the image selector will adjust to the new min and max settings. Others will remain with the original settings. The user may select "ALL" from the image selector to allow the min/max settings to adjust all of the displayed images.

**Actual Results:** Same as Expected Results

**viii) User selects an entry from the image selector list.**

**Expected Results:** This selects the image/images that are to be manipulated by the min/max temperature control.

**Actual Results:** Same as Expected Results

**ix) User Clicks "Follow Up"**

**Expected Results:** If a valid data entry is available, the system will display the data for the particular entry that is selected. This is only available when 1 item is selected. The user may modify the data and choose whether to save or discard the changes.

**Actual Results:** Same as Expected Results

**x) User clicks "Filter by Last Name"**

**Expected Results:** A box will prompt for part or all of the last name filter. Accepting a filter with no data will result in removing all filters. Anything other than no data will result in the list refreshing with only the names that fit the specified filter. Pressing "Cancel" will also remove all filters.

**xi) User clicks "Filter by IR Date"**

**Expected Results:** A box will prompt for a start and end date that correspond to the dates that the infrared images were obtained. Accepting the dates will update the list to only include data obtained between the specified dates. Pressing "Cancel" will also remove all filters.

**xii) User clicks "Remove All Filters/Refresh"**

**Expected Results:** The name list will reload, all filters will be removed and all of the items in the list will become unselected. Also, the display area will become blank.

**Actual Results:** Same as Expected Results

**xiii) User clicks "Close"**

**Expected Results:** Upon confirmation, the program will exit.

**Actual Results:** Same as Expected Results

**xiv) User clicks "... button (next to data path text file).**

**Expected Results:** An open dialog box will appear and prompt the operator to select a path for the data files. Only directories with valid data are allowed. Pressing "Cancel" will return to the existing path.

**Actual Results:** Same as Expected Results

**xv) User selects a name on the list.**

**Expected Results:** The user may select up to 6 entries on the list. The system will automatically display and tile them in the display area.

**Actual Results:** Same as Expected Results

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*Infrared Sciences Corp.*

OTS Software Use for BreastScanIR™

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Purpose: This document describes the use of off the shelf software within the BreastScanIR system. Listed below are all of the off the shelf software components necessary for BreastScanIR to function properly. BreastScanIR is only intended for installation on a system which contains the versions of the software listed below.

OTS Software:

Title	Manufacturer	Version
Windows XP Professional	Microsoft	5.1.2600 Service Pack 1
ThermaCam Researcher	FLIR	2002

Windows XP:

The purpose of windows XP within the BreastScan IR system is to act as the sole operating system. This software is essential to the operation of the system, and all documentation for Windows XP will be provided to the end-user in electronic form. Windows XP is to be used in accordance with Microsoft's recommended use. Windows XP will be installed and configured by ISC before shipment. The end-user will be given only user rights to the system. The system will be labeled as to be used only for BreastScan IR. WindowsXP has a built in update feature which will be disabled by default. Windows XP is an industry standard operating system. A hazard analysis for the operating system can be found in the BreastScanIR system hazard analysis. All verification and testing of Windows XP is performed post-integration using the BreastScanIR Functional Test Plan

Hardware Requirements:

- PC with 300 megahertz or higher processor clock speed recommended; 233 MHz minimum required (single or dual processor system);\* Intel Pentium/Celeron family, or AMD K6/Athlon/Duron family, or compatible processor recommended
- 128 megabytes (MB) of RAM or higher recommended (64 MB minimum supported; may limit performance and some features)
- 1.5 gigabytes (GB) of available hard disk space\*
- Super VGA (800 × 600) or higher-resolution video adapter and monitor
- CD-ROM or DVD drive
- Keyboard and Microsoft Mouse or compatible pointing device

ThermaCam Researcher:

The purpose of ThermaCam Researcher is to provide camera access and control. All camera control functions and raw data accesses are performed through ThermaCam Researcher. ThermaCam Researcher also allows for viewing and analysis of the raw data. ThermaCam Researcher is essential to the operation of the system. All documentation for

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ThermaCam Researcher will be provided to the end-user in electronic form. ThermaCam Researcher will be installed and configured by ISC before shipment. A hazard analysis for ThermaCam Researcher can be found in the BreastScanIR system hazard analysis. All verification and testing of ThermaCam Researcher is performed post-integration using the BreastScanIR Functional Test Plan

Hardware Requirements:

- FLIR S40 Digital Infrared Camera

Software Requirements:

- Windows XP Professional

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Eve Carroll  
Subject: 510(k) Number K032350 / S2  
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?  YES  NO

Is this device subject to the Tracking Regulation?  YES  NO

Was clinical data necessary to support the review of this 510(k)?  YES  NO

Is this a prescription device?  YES  NO

Was this 510(k) reviewed by a Third Party?  YES  NO

Special 510(k)?  YES  NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  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 SIEs):

No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceed

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

90L HQ chess 1 884, 2980

Review: Ruth Phelps RAAS 2/17/04  
(Branch Chief) (Branch Code) (Date)

Final Review: Janilla Depina 2/18  
(Division Director)

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

510(k) Review

K

Company Name: Infrared Sciences Corp.

Address: 380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

Dated: July 29, 2003

Received: July 30, 2003, S1- October 16, 2003, S2- December 18, 2003,  
A1- January 20, 2004

Contact: Ms. Susan D. Goldstein-Falk

Manufacturing Address 380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

Tradename: Infrared Sciences BreastScan IR™ System

Common Name: Adjunctive Telethermographic System

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

Intended Use:

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by a human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

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

Manufacturer: OmniCorder Technologies, Inc.  
Tradename: OmniCorder BioScan System  
Document Control: K990416

Previous Submissions: N/A

510(k) Review  
Page 2

Applicable Guidance: N/A

**510(k) Review**

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

Is the device subject to postmarket surveillance? No

Is a summary or certification of safety and effectiveness included? 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? No

Does the device use software? Yes

Is the device disposable (single use)? No

Is the device sterile? No

Is the device for single, home or prescription use? Prescription

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

Is the device subject to the Radiation Control Act? No

Other standards? CSA Standard C22.2, No. 125-1984 Electromedical Equipment  
UL544 09/1985, Standard for Medical and Dental Equipment

**Device Description:**

The device consists of an infrared camera, TV/VCR, computer, printer and air conditioner. The air conditioner is cooling the surface of the breast while the camera gathers the temperature data which are displayed in the real time on the screen. The VCR is included for educational purposes to play informational videos describing BreastScan IR. A Computer records and archives the data.

Laboratory and Clinical Data: N/A

Labeling: attached

Software: Software description, validation and verification included

Substantial Equivalence: Table of comparison to OmniCorder BioScan System, K990416 provided

Conclusion: SE

Classification should be based on: Radiological Device Classification.

Class: I

510(k) Review

Page 5

This document was reviewed By Dr. Sacks due to his expertise in breast imaging and although the validity of the data obtained with the device in question has been criticized the reviewer suggested clearing this submission. (Review attached). Bob Phillips suggested asking the company for additional information. Application of cooling during the temperature reading might imply a new technology. AI letter was issued and send on October 16. The company responded on October 24, but the responses were not satisfactory and second AI letter was sent on December 5. This time the company asked for the phone conference that took place on 1/15/2004.

FDA participants: Czerska, Ewa M.; Phillips, Robert A (CDRH); Sacks, William;  
Company participants: Susan Goldstein, Alan Schwartz, Tom DiCicco;

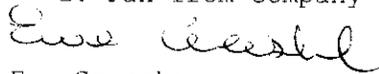
During the phone conference we have advised the company that clearance could be obtained if the numerical display of the data was removed. The bars and numerical output will have to be removed from the manual as well. Regarding the use of air conditioner Bob Phillips advised that the cooling can be left. The device cannot be used as stand alone device, only as an adjunct, class I device. Bill Sacks asked to remove the statement about effectiveness of the device in breast cancer diagnosis.

Following the phone conference the response was submitted to the document center with a copy send by e-mail to accelerate a review process.

The amendment was reviewed by Dr. Sacks who asked for one more minor change in the labeling. The company implemented the change and submitted corrected page by fax.

Attached:

1. Minutes from the meeting
2. Fax from company



Ewa Czerska  
2/10/2004







See you on a healthy image

INFRARED SCIENCES CORPORATION

FACSIMILE TRANSMITTAL SHEET

TO: <b>Dr. Ewa Czerska</b>	FROM: <b>Matthew Campisi – Infrared Sciences Corp.</b>
COMPANY: <b>FDA</b>	DATE: <b>2/10/2004</b>
FAX NUMBER: <b>301-480-4224</b>	TOTAL NO. OF PAGES INCLUDING COVER: <b>3</b>
PHONE NUMBER: <b>301-594-1212 x158</b>	SENDER'S REFERENCE NUMBER:
RE: <b>FDA Recommendation</b>	YOUR REFERENCE NUMBER:

- URGENT   
 FOR REVIEW   
 PLEASE COMMENT   
 PLEASE REPLY   
 PLEASE RECYCLE

NOTES/COMMENTS:

Dr. Czerska,

Please note that we have modified the specified sentence in accordance with the FDA recommendation. Please see the following page.

Also included is the Status Request & Response requested by you. Thank you.

Matthew Campisi  
Infrared Sciences Corp.

380 TOWNLINE ROAD HAUPPAUGE, NY 11788 TEL: 631-265-5450

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# Infrared Sciences Corp.

**BreastScan IR™**

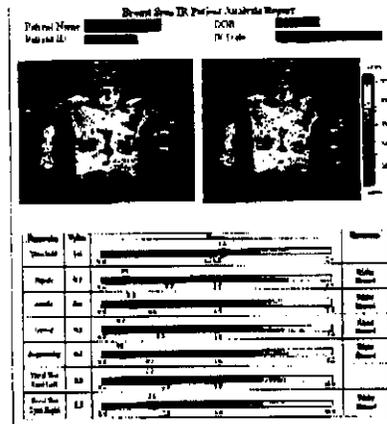
BreastScan IR™ is a new, non-invasive procedure offered to women undergoing screening or diagnostic mammography to aid in the determination of current breast health by measuring various temperature parameters in the breast. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

## BreastScan IR™ System Features

- Automated software requires only basic computer skills to operate
- Remote troubleshooting and diagnostic capability
- Automatic software updates/upgrades
- Automatic update of evaluation algorithm
- System is designed to "learn" as more tests are run
- Automatic billing and tracking
- Real time reporting to doctor in easy to read format
- Remote client terminal for doctor's use
- Fully wireless LAN connection for instant network access
- Secure data transfer over internet or dial-up
- Highly sensitive state-of-the-art infrared camera
- Off the shelf high speed workstation and client terminal allows easy hardware upgrades in the future
- Automatic secure download of results and database information to ISC server



**BreastScan IR**



**Sample Patient Results**

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K032350  
Page 1 of

Exhibit # 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K032350

1. Submitter's Identification:

Infrared Sciences Corp.  
380 Townline Road  
Hauppauge, NY 11788

Contact: Mr. Anthony Trotta  
Principal Engineer

Date Summary Prepared: July 29, 2003

2. Name of the Device:

Infrared Sciences BreastScan IR™ System

3. Predicate Device Information:

K#990416, OmniCorder BioScan System, OmniCorder Technologies, Inc., Stony Brook, NY

4. Device Description:

The BreastScan IR™ System is a new, non-invasive procedure offered to women, of any age, to determine current breast health by measuring various temperature parameters in the breast. Designed exclusively by Infrared Sciences Corp., BreastScan IR™ System has demonstrated its effectiveness as an adjunctive tool for the doctor to use along with mammography, ultrasound, or clinical examination. The entire procedure takes approximately 10 minutes with the results immediately available, to assist in the doctor's determination of breast health. The results are analyzed by proprietary algorithms and then presented in a non-subjective report. The procedure does not involve any compression of the breast, or touching of the breast in any way. The patient simply sits in a chair, facing an infrared camera for a few minutes.

*KO32  
Page 2*

**Components of the system include:**

Infrared System Device

Color Inkjet Printer

TV/VCR

Medical Cart

BreastScan IR Server

Air Cooling Device

Patient Chair

**5. Intended Use:**

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by the human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

**6. Comparison to Predicate Devices:**

**A Comparison Chart Outlining Similarities and Differences Follows:**

<b>Feature</b>	<b>BreastScan IR™ System</b>	<b>BioScan System</b>
Intended Use	Visualization/Documentation of Temperature Patterns and Changes – Adult Only	Visualization/Documentation of Temperature Patterns and Changes – Adult, Pediatric and Neonatal
Method of Data Collection	Non-Contact Passive Infrared Emissions	Non-Contact Passive Infrared Emissions
Collection Instrument	Infrared Camera	Infrared Camera
Data Processing	CPU with Custom Algorithms	CPU with Custom Algorithms
Measurement Parameters	Allows for Static and	Allows for Static

*63*

	Dynamic Measurement of Thermal Patterns	Measurement of Thermal Patterns
Storage	Hard Disk	Hard Disk
Detector Type	Focal Plane Array	Focal Plane Array
Detector Resolution	320 x 240 Pixels	256 x 256 Pixels
Thermal Sensitivity	0.08°C	0.05°C
Camera Output	14 Bit Digital	14 Bit Digital
Display	Monitor, TV, Printer	Monitor, TV, Printer
User Interface	Keyboard, Mouse, On-System Controls	Keyboard, Mouse, On-system Controls

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The device will comply with IEC-60601-1 and IEC 60601-1-2. Software validation was performed.

8. **Discussion of Clinical Tests Performed:**

Not applicable

9. **Conclusions:**

The subject device has the same intended use and similar characteristics as the predicate device. Moreover, documentation supplied in this submission demonstrates that any difference in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Infrared Sciences BreastScan IR™ System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

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

Subject: 510(k) Number K032350/S'

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

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: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

A1

Review: Rachael Pally RA03 12/3/03  
(Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_ (Date) 65



510(k) Review

K032350/S1

Company Name: Infrared Sciences Corp.

Address: 380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

Dated: October 23, 2003

Received: October 24, 2003

Contact: Ms. Susan D. Goldstein-Falk

Manufacturing Address 380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

Tradenname: Infrared Sciences BreastScan IR™ System

Common Name: Adjunctive Telethermographic System

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

Intended Use:

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by a human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

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

Manufacturer: OmniCorder Technologies, Inc.  
Tradenname: OmniCorder BioScan System  
Document Control: K990416

Previous Submissions: N/A

Applicable Guidance: N/A

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?		x	If NO = Request Data
11. Data Demonstrate Equivalence?		x	Final Decision: AI

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.

**Standard Questions:**

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

Is the device subject to postmarket surveillance? No

Is a summary or certification of safety and effectiveness included? 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? No

Does the device use software? Yes

Is the device disposable (single use)? No

Is the device sterile? No

Is the device for single, home or prescription use? Prescription

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

Is the device subject to the Radiation Control Act? No

Other standards? CSA Standard C22.2, No. 125-1984 Electromedical Equipment  
UL544 09/1985, Standard for Medical and Dental Equipment

**Device Description:**

The device consists of an infrared camera, TV/VCR, computer, printer and air conditioner. The air conditioner is cooling the surface of the breast while the camera gathers the temperature data which are displayed in the real time on the screen. The VCR is included for educational purposes to play informational videos describing BreastScan IR. A Computer records and archives the data.

Laboratory and Clinical Data: N/A

Labeling: attached

Software: Software description, validation and verification included

Substantial Equivalence: Table of comparison to OmniCorder BioScan System, K990416 provided

Conclusion: Additional information is needed.

The letter asking for additional information was prepared.

Classification should be based on: Radiological Device Classification.

Class: I













DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

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

Subject: 510(k) Number 1032350

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?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  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:

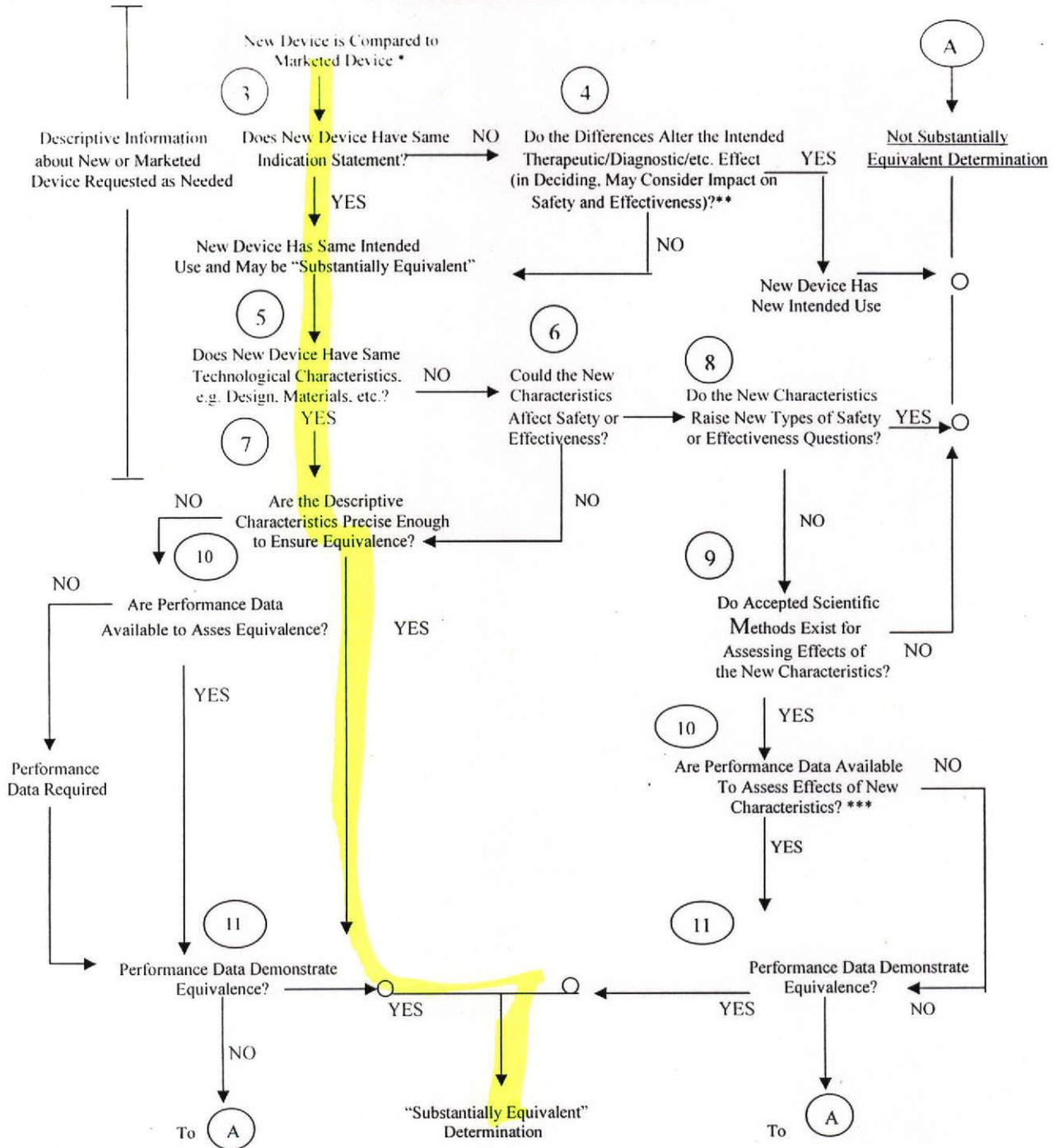
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

30-LHG class 1 884.29.80 AI

Review: Sacks RADB 2/26/03 10/15/03  
(Branch Chief) (Branch Code) (Date)

Final Review: AI (Date) 90  
(Division Director)

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



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

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

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

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

510(k) Number: R032350

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)]		N/A
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		

is posted with the 510(k) boilers on the H drive.)		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- \* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	} N/A	
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:	V	

*Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

Passed Screening  Yes  No  
 Reviewer: Erica C. [Signature]  
 Concurrence by Review Branch: \_\_\_\_\_

Date: 9/17/03

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>

510(k) Review

K

Company Name: Infrared Sciences Corp.

Address: 380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

Dated: July 29, 2003

Received: July 30, 2003

Contact: Ms. Susan D. Goldstein-Falk

Manufacturing Address 380 Townline Road  
Hauppauge, NY 11788  
Tel: 631-265-5450  
Fax: 631-979-2085

Tradename: Infrared Sciences BreastScan IR™ System

Common Name: Adjunctive Telethermographic System

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

Intended Use:

The Infrared Sciences BreastScan IR™ System is intended for viewing and recording heat patterns generated by a human body in the hospital, acute care settings, outpatient surgery, healthcare practitioner facilities or in an environment where patient care is provided by qualified healthcare personnel. The patient populations include adult. The device is for adjunctive diagnostic screening for detection of breast cancer and diseases affecting blood perfusion or reperfusion of tissue or organs. This device is intended for use by qualified healthcare personnel trained in its use.

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

Manufacturer: OmniCorder Technologies, Inc.  
Tradename: OmniCorder BioScan System  
Document Control: K990416

Previous Submissions: N/A

Applicable Guidance: N/A

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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?		x	If NO = Request Data
11. Data Demonstrate Equivalence?		x	Final Decision: AI

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.

**Standard Questions:**

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

Is the device subject to postmarket surveillance? No

Is a summary or certification of safety and effectiveness included? 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? No

Does the device use software? Yes

Is the device disposable (single use)? No

Is the device sterile? No

Is the device for single, home or prescription use? Prescription

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

Is the device subject to the Radiation Control Act? No

Other standards? CSA Standard C22.2, No. 125-1984 Electromedical Equipment  
UL544 09/1985, Standard for Medical and Dental Equipment

**Device Description:**

The device consists of an infrared camera, TV/VCR, computer, printer and air conditioner. The air conditioner is cooling the surface of the breast while the camera gathers the temperature data which are displayed in the real time on the screen. The VCR is included for educational purposes to play informational videos describing BreastScan IR. A Computer records and archives the data.

**Laboratory and Clinical Data:** N/A

**Labeling:** attached

**Software:** Software description, validation and verification included

**Substantial Equivalence:** Table of comparison to OmniCorder BioScan System, K990416 provided

**Conclusion:** Additional information is needed.

The letter asking for additional information was prepared.

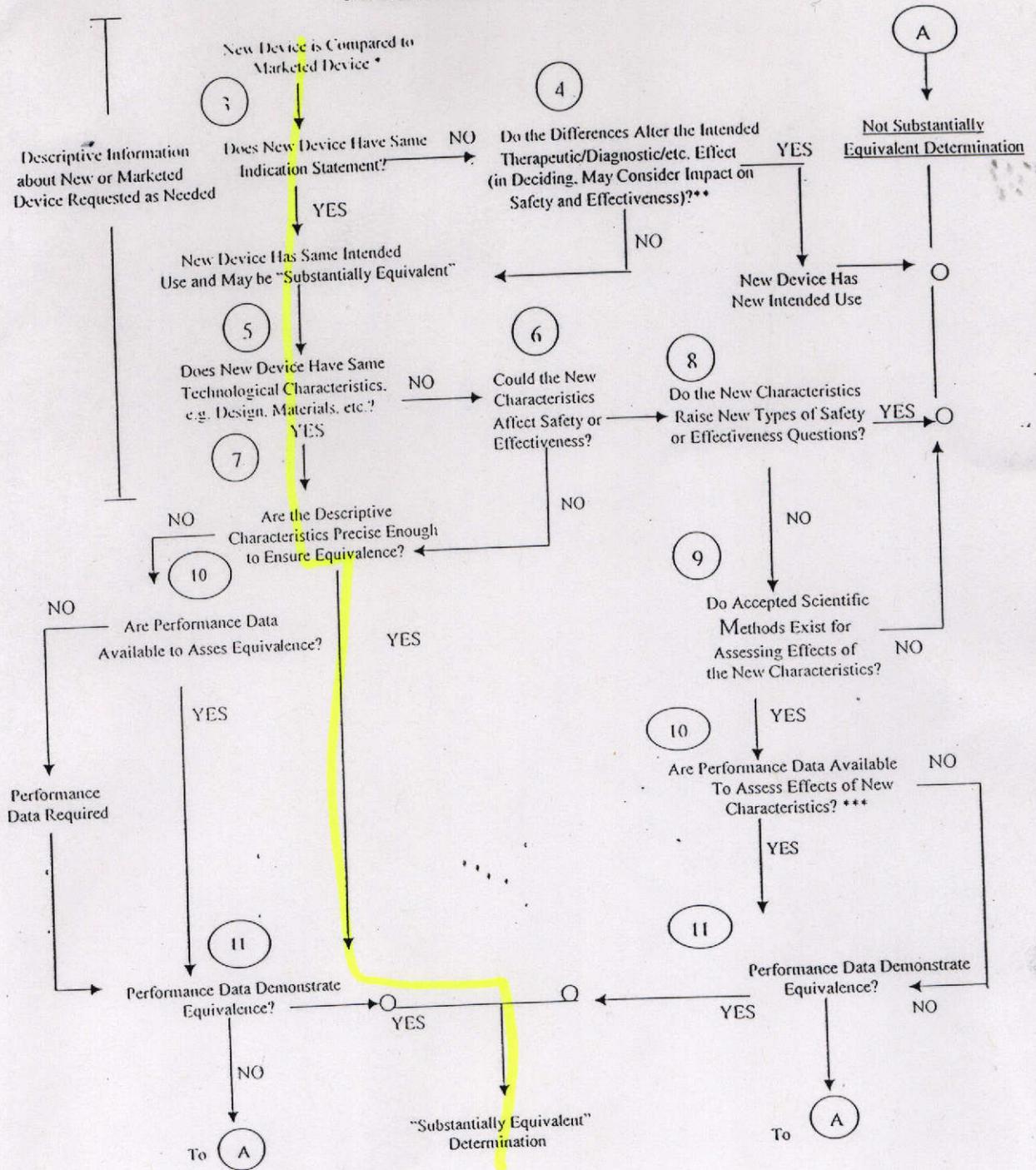
Classification should be based on: Radiological Device Classification.

Class: I





### 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.

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

October 24, 2003

INFRARED SCIENCES CORP.  
C/O MDI CONSULTANTS, INC.  
55 NORTHERN BLVD., SUITE 200  
GREAT NECK, NY 11021  
ATTN: SUSAN D. GOLDSTEIN-FALK

510(k) Number: K032350  
Product: INFRARED  
SCIENCES  
BREASTSCAN IR  
SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (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](http://www.fda.gov/cdrh/ode/a02-01.html).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

































































## Appendix A

# ABNORMAL THERMOGRAM - SIGNIFICANCE IN BREAST CANCER



William B. Hobbins, M.D.

Thermal Image Analysis, Inc.  
5510 Medical Circle, Suite B  
Madison, WI 53719  
USA

Thermography is the highest risk marker for the possibility of the immediate presence of breast cancer. Most fevers of the breast are not associated with cancer, but most cancers have a fever of some degree. The more the fever (delta T) and the type of pattern of its display relate to the host survival. Most importantly, it will be the sole early initial signal in 8 to 10 percent of breast cancer. Simple and inexpensive thermography should be performed on women over 30 years of age.

Key words: Thermography, Qualification, Quantification, Predictive Value, Breast Cancer

### INTRODUCTION

Thermography has been established as a high risk marker for the possible presence of a preclinical or clinical breast cancer. It has also been shown to predict such a subsequent occurrence (1,2,3). A review of 37,050 breast thermograms with correlation of type of thermal findings when related to breast cancer was performed.

### METHOD AND MATERIAL

Contact liquid crystal breast thermograms were submitted to Thermal Image Analysis, Inc. (TIA) for interpretive evaluation. TIA, a consultant service, was established in 1978 and has reviewed over 160,000 breast thermograms.

Eight hundred physicians (gynecologists, surgeons, radiologists, and family practitioners) forwarded liquid crystal contact thermograms, along with history and clinical impressions (Figure 1). These were returned with four paragraphs of evaluations: 1) thermal description of thermograms, 2) hormonal evaluation, 3) clinical correlation, and 4) follow-up recommendation.

These examinations were performed with Flexi-Therm (Westbury, N.Y.) Mark II equipment. The Flexi-Therm equipment allows an ideal simultaneous examination of both breasts.

Five pictures were taken (Figure 2). They are bilateral frontal, individual right and left frontal examinations perpendicular to the nipple, and right and left lateral oblique views with the entire nipple and areolar area.

These thermograms were classified by TIA criteria (Table I) and by 23 international individual factors.

*Tom see  
see last page*

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HOBBS

RIR: 12, October 1987

<b>FAMILY HISTORY (BREAST ONLY)</b> A <input type="checkbox"/> SELF MATERNAL B <input type="checkbox"/> MOTHER D <input type="checkbox"/> GRANDMOTHER C <input type="checkbox"/> SISTER F <input type="checkbox"/> AUNT F <input type="checkbox"/> COUSIN X <input type="checkbox"/> OTHER G <input type="checkbox"/> GRANDMOTHER H <input type="checkbox"/> AUNT I <input type="checkbox"/> COUSIN		<b>PARTY</b> 13 MENARCHE AGE 0 PARTIY NO AGE 1ST FULL PREG. NO. OF CHILDREN BORN OVER 1 YR NOW PREGNANT NOW LACTATING		<b>HISTORY QUESTIONS</b> BIRTH CONTROL PILLS: AGE STARTED YEARS TAKEN CURRENTLY OTHER SIGNIFICANT DRUGS: <u>PRENAPIN</u> YEARS TAKEN CURRENTLY		<b>GENERAL</b> MEDICAL: AGE OF ONSET HORMONES EST. PREG. TEST NUMBER LBS. OVERWEIGHT AGE AT OOPHOARECTOMY <u>30</u> MENSTRUAL DAY NO. <u>NA</u> TOTAL DAYS IN CYCLE <u>NA</u> A <input type="checkbox"/> BLACK E <input checked="" type="checkbox"/> CAUCASIAN I <input type="checkbox"/> INDIAN S <input type="checkbox"/> JEWISH D <input type="checkbox"/> ORIENTAL F <input type="checkbox"/> OTHER	
NUMBER PREVIOUS BIOPSESIES (SELF) <u>2</u> RADIATION <input type="checkbox"/> DATE / / MASTECTOMY DATE / /		<b>PHYSICAL EXAM</b> AREA OF PAIN A <input type="checkbox"/> J <input type="checkbox"/> BURNING L <input type="checkbox"/> DULL X <input type="checkbox"/> TENDERNESS M <input type="checkbox"/> SHARP MASS B <input type="checkbox"/> THICKENING C <input type="checkbox"/> DISCHARGE D <input type="checkbox"/> NIPPLE CHANGE E <input type="checkbox"/> SKIN CHANGE F <input type="checkbox"/> RECENT RETRACTION G <input type="checkbox"/> OTHER H <input type="checkbox"/> EXPLAIN		<b>SYMBOLS TO USE:</b> Slope: +++++ Prominent Vein: ~~~~~ Mass: ● Thickening: ○ Pain: ⊙		DESIGNATE AFFECTED AREA ON THIS GRAPH WITH LETTER OR SYMBOL. 	
NORMAL A <input type="checkbox"/> BENIGN B <input type="checkbox"/> F <input type="checkbox"/> CYSTIC G <input type="checkbox"/> FIBROADENOMA		<b>CLINICAL IMPRESSION</b> H <input type="checkbox"/> FIBROCYTIC J <input type="checkbox"/> DYSPLASIA		MALIGNANT C <input type="checkbox"/> D <input checked="" type="checkbox"/> SUSPICIOUS E <input type="checkbox"/> DEFINITE			
DO NOT WRITE BELOW THIS LINE — OFFICE USE ONLY							
<b>HISTORY CONVENTIONAL RISK INDEX</b> LOW 0-10 MEDIUM 11-12 HIGH 20 AND OVER [ 23 ]		<b>THERMOGRAM TEST REPORT</b> TH [ 2 ] RIGHT TH [ 5 ] LEFT TH 1 - NORMAL NON-VASCULAR TH 2 - VASCULAR UNIFORM TH 3 - EQUIVOCAL TH 4 - ABNORMAL TH 5 - SEVERELY ABNORMAL		<b>RECALL</b> [ 3 ] MONTHS			

TIA COMMENTS:

BILATERAL VASCULAR PATTERN WITH THE LEFT BREAST DISPLAYING A ONE DEGREE C NIPPIAR AND PERI-AREOLAR DELTA T. THERE IS A VASCULAR COMPLETE PATTERN IN THE INFERIOR MEDIAL QUADRANT WITH A DELTA T OF ONE DEGREE C. THIS IS IN THE AREA OF SUSPICIOUS MASS, THEREFORE THE SIGNIFICANCE OF THIS RESPONSE IS GREATER. THERE IS GREATER OVERALL HEAT AND VASCULARITY NOTED THROUGHOUT THE ENTIRE BREAST.

AS AN INITIAL STUDY, THIS IS CONSIDERED SEVERELY ABNORMAL. PROCEED WITH A DEFINITIVE WORK-UP TO INCLUDE A CURRENT MAMMOGRAM.

REPEAT THERMAL STUDY AT EARLY RECALL WITH AN ASSOCIATED STRESS TEST IF A DEFINITIVE DIAGNOSIS CAN NOT BE MADE AT THIS TIME. THIS STRESS TEST MAY AID IN DETERMINING THE SIGNIFICANCE OF THE ABOVE MENTIONED THERMAL FINDINGS.

*William B. Hobbs, M.D.*  
 WILLIAM B. HOBBS, M.D.

An abnormal thermogram is highest risk number. A normal thermogram does not mean absence of neoplasia in the presence of clinical findings on a graphic image.

IBRU Thermal Image Analysis

Figure 1 Exam Report Sheet

37,050 consecutive examinations were computerized and the most abnormal class Th 5 examinations were selected. These were then analyzed for presence of follow-up mammogram, biopsy data, and cancer. This was done by referring the thermogram by questionnaire to the treating physician. The individual physician had the final authority for ordering mammograms and biopsy. A detailed questionnaire was sent to each physician, and a follow-up call was made when necessary. All resultant data were computerized.

Each thermogram of the cancer cases was analyzed in regard to the 23 thermal factors and the delta Ts of these

factors. This resulted in pattern qualification and thermal delta Ts (difference in temperature).

RESULTS

1,060 abnormal thermograms (class Th 5) were found in the 37,050 reviewed thermographic examinations. This was 2.8% of the thermograms submitted. This percentage of Th 5 thermographic occurrence continues to be level today.

There were 960 returned questionnaires, 90% which were considered statistically significant. Eighty carcinomas were associated with this thermal variant. Seven were nonpalpa-

*LB*

RIF: 12, October 1987

ABNORMAL THERMOGRAM - SIGNIFICANCE IN BREAST CANCER

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Figure 2 Cholesteric Thermographic Exam - Normal

ble and determined by mammogram only. It was determined that 9% of the cancers were signaled by thermography only.

Of the abnormal Th 5 thermograms, 842 (87%) were mammographed. The mammogram was considered abnormal by the patients' physicians (responders) in 261 or 31%. Thus, 573 or 66% were thought normal. There were 8 or 1% with no indication as a result.

From the 940 Th 5 examinations, there were 784 biopsies (33%). In the biopsy group, 160 (69%) had abnormal mammograms and 65 had normal mammograms (28%). Six biopsied cases were without indication of the mammogram results. 52 (18%) of the biopsies did not have a preoperative mammogram (Table II).

284 biopsies resulted in the determination of 80 carcinomas or 28% yield. 72 percent (58) were associated with abnormal mammograms, 12% (10) from the normal mammogram class, and 13% (11) without mammogram. One carcinoma was found in the four cases biopsied where mammogram decision is not known (Table III).

It is good to note that with a Th 5 thermal disturbance, the mammographic correlation rate with malignancy of true-positive mammogram (biopsy) rate, 36% or 58 cancers from 160 biopsies resulted. The similar correlation as to mammographic false-negative rate was 15% or 10 carcinomas from 65 biopsies with negative mammograms.

It was further noted in this series that of the 261 patients with a Th 5 thermal examination with an abnormal mammogram, only 160 were biopsied; 71 (40%) of such cases were not biopsied.

These 80 cancers were then used to review the factors of the thermographic findings. The factors were reviewed both for pattern configuration and contralateral temperature or intermammary temperature differences (delta Ts). These were tabulated and qualified.

The clinical findings in the 77 cancers were: Mass 55; Pain 13; Retraction 12, None 7. From these findings, the following clinical impressions were made preoperatively; Malignant 40; Benign 9; Normal 7; No decision 21.

The major thermographic factors (Table IV) and secondary factors (Table V) were evaluated in each case. Correlation of a Th 5 thermogram with a clinical complaint was the most frequent and occurred in 70 cases (Table VI).

The ranking of the frequency of the various factors were

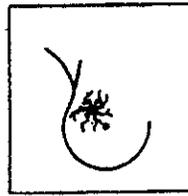
Normal	Abnormal
Th I avascular symmetrical	Th III equivocal — one factor
Th II vascular symmetrical	Th IV abnormal — two factors
	Th V severely abnormal — three or more factors

	No. Biopsies	% Biopsies	% Mammographic Findings
With mammograms:	232	81%	
Abnormal mammogram	160		69%
Normal mammogram	65		28%
No mammogram report	6		2%
No mammogram	52	18%	

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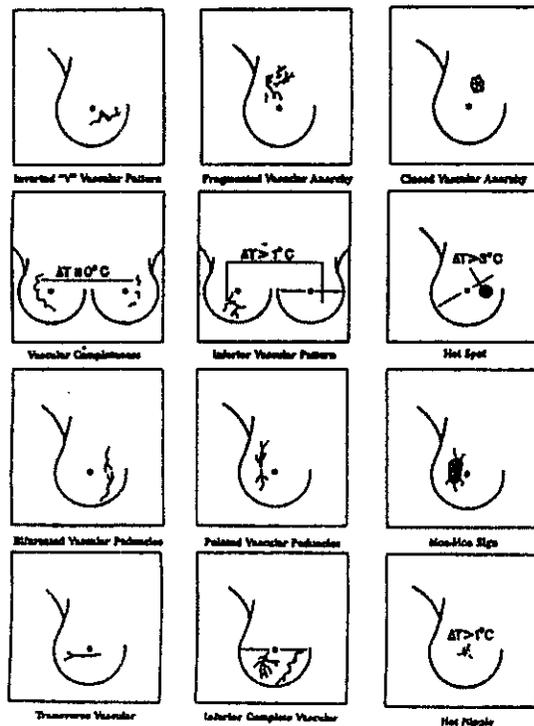
Malignancies	80	(8.3% of 960 Th V)
Abnormal mammogram	58	72%
Normal mammogram	10	12%
Without mammogram	11	13%
Unknown mammogram	1	1%

TABLE IV



Star Vascular Anarchy

SECONDARY FACTORS



tabulated (Table VII). There were 3.2 factors per cancer of the Th 5 class. In order for there to be a diagnosis of Th 5, three or more factors are necessary.

The most common individual factor was that of a hot nipple. The cancers that had this factor numbered 64 or 83%. There was a wide range of delta Ts from 2 cases greater than 5°C to 23 cases with less than 1°C. The mean delta T was 2°C and the average was 1.9°C (Table VIII).

TABLE V  
MAJOR FACTORS

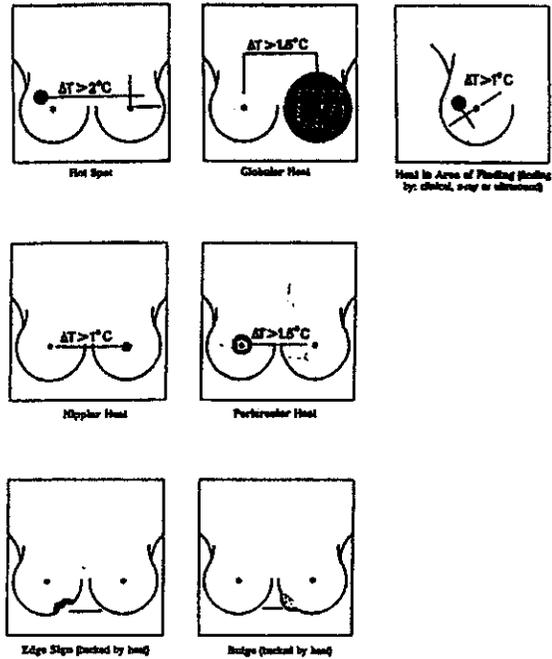
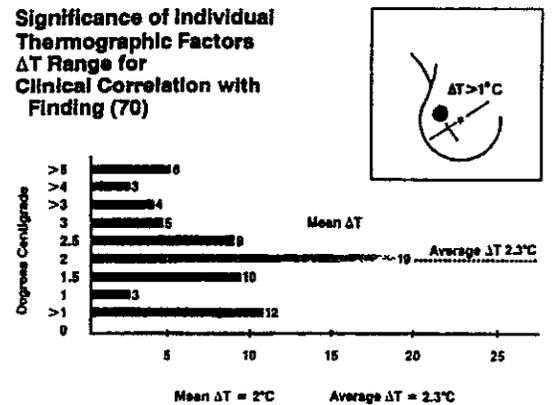


TABLE VI

Significance of Individual Thermographic Factors  
ΔT Range for Clinical Correlation with Finding (70)



Global heat with a delta T range from 1 greater than 5°C, to 8 with less than 1°C was second in frequency. There were 32 cancers with this sign with an average delta T of 1.6°C and a mean delta T of 1°C (Table IX).

Next in frequency was severe vascular abnormality, 31 in number. The average delta T was 2.1°C with a mean of 1.5°C. This occurred in 40% of the cancers (Table X).

Also, occurring in 40% of the cancers was areolar/periareolar heat. The average delta T was 1.9°C with a mean of 2°C. Three cancers had greater than 4°C delta T, ranging down to 5 cancers with 1°C delta T (Table XI).

Inferior vascularity occurred in 15 cases (19%) with delta Ts ranging from 2°C to 3°C to 4 cases at less than 1°C. The average delta T was 1.8°C with a mean of 2°C (Table XII).

TABLE XIII

Significance of Individual Thermographic Factors  
 $\Delta T$  Range for Edge Sign (15)

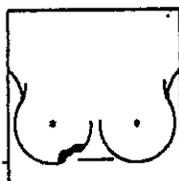
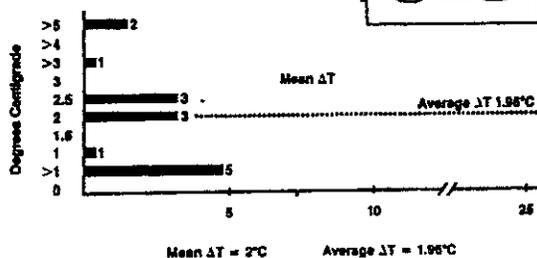
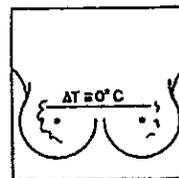
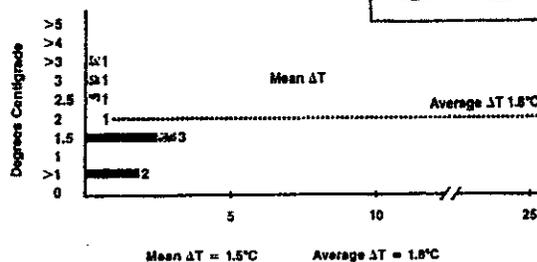


TABLE XIV

Significance of Individual Thermographic Factors  
 $\Delta T$  Range for Vascular Completeness (9)



verage delta T of greater than 3°C. Isolated hot spots were seen in 2 cases with a delta T average of 2.25°C. Other signs were associated and correlated with the reading of Th 5 thermograms 15 times.

In the seven cases without clinical findings, a hot nipple was associated in six, and severe vascular abnormality associated in five. Global heat was present in two.

The most important results were the analysis of the thermal content of each cancer case. (3 cases of thermographic findings were lost.)

DISCUSSION

A "fever" in a breast is significant. There are many major conclusions from the results: 1) Thermography alerted the discovery of 8% of the found cancers. Seven women with only an abnormal thermal signal to require a mammogram were so discovered. One of these women was 28 years old.

Dodd suggested that 5 to 8 percent contribution by thermography to early cancer detection can be expected (4).

2) Thermographic Th 5 classification will select 2.5% of the population with 8.5% incidence of cancer as compared to 5.8 cancers per 1000 mammograms, which is .008%.

This author believes that every breast under consideration

of health or illness should have a thermographic study. A hot nipple is a sign that must be evaluated with every means known to the mammologist, for enough of these findings will have a cancer to warrant any expense and/or inconvenience.

Th 5 thermograms (3 factors) occur in 2.8% of the population. Such an abnormal thermographic finding must be extensively worked up as the PREDICTABILITY is 8%. (P value).

Previous thermographic review has shown that 82% of all breast cancers occurs in 25% of women with asymmetrical thermograms. Mammography concentration on this segment of the population is surely indicated and would be extremely cost effective (5).

3) A Th 5 thermogram has a predictive value of 8.3% compared to mammography's 8% (6,7). This would suggest with the other data that thermography and mammography should be combined to increase the predictability.

4) It should be pointed out that had thermographic findings of a hot nipple been used as the only alert, 83% of the cancers would have been signaled and this sign was found in 6 out of 7 (85%) preclinical cancers.

5) The qualitative and quantitative evaluation of each thermographic sign is significant. The original BCDDP was performed with black and white telethermography, and most of the important thermographic data was lost due to distance, curvilinear surface, and relative temperature scale. This study has been used to present negative thermographic data, but it is obsolete and archaic (10 years old).

6) Many authors have reported survival related to the thermal virulence. We believe it is now important to take the thermovascular findings and correlate each sign and delta T to patient survival (8,9,10). This preliminary report of thermal correlation will help in future breast cancer prognosis assessment. When this data are in preoperative planning, therapy will be possible.

CONCLUSION

Thermography is a simple, inexpensive measure of breast physiology. It should be seen as essential information in the evaluation of breast health.

Class Th 5 thermograms can be correlated with a predictive value of 8% for the presence of cancer (Table XV). In order to better evaluate every woman who desires best breast health care, a thermogram must be done.

When thermography is positive with a clinical finding, or a presence of nipplar heat, global heat or vascular irregularities, a high suspicion of carcinoma must be entertained. The individual factors do have special significance.

TABLE XV

Predictive Value (P)  
 Mammogram vs. Thermogram

	Exam Performed	Abnormal Mammogram	Ca Found	Ca In Abnormal Exam (P)
Mammography (Moskowitz '83)	40,431	1444 (3.6%)	117	8%
		Th-5 Thermogram		
Thermography (Hobbins '83)	37,506	1060 (2.8%)	80	7.5%
Actual number of Cases Reviewed		960 (90.5%)	(80)	(8.3%)

There is not an age limit for performing thermography, and resultant asymmetries definitely must be definitively studied. As mammography should be done on every woman over age 30, so should thermography be a part of the complete breast examination to assure greater accuracy of diagnosis, and as better understood, used to design treatment based on the thermal prognosis.

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La termografía es el marcador de más alto riesgo para detectar la posibilidad de cáncer mamario. La gran mayoría de elevaciones de temperatura local de la mama no están asociadas con cáncer de esta, sin embargo, la mayoría de los cánceres mamarios se asocian a cierto grado de elevación de la temperatura local. Mientras más alta la elevación de la temperatura local (delta T) y el patrón que despliegue se relaciona con la sobrevivencia del huésped. Muy importante, puede ser el único hallazgo inicial más importante en el 8% al 10% de los cánceres mamarios. La termografía debe usarse rutinariamente en las mujeres mayores de 30 años de edad.

A termografia é o marcador de mais alto risco para detectar a possibilidade de cancer da mama. A grande maioria de elevações de temperatura local da mama não estão associadas com cancer ainda que a maioria dos canceres de mama se associem a um certo grau de elevação da temperatura local. Quanto mais alta a temperatura (delta T) e o padrão que se desenvolve é relacionado com a sobrevivência do paciente. Mais importante: poderá ser o único sinal inicial em 8 a 10% dos canceres da mama. Simples e inexpressiva, a termografia deverá ser realizada em mulheres acima de 30 anos.

**THERMA-SCAN™**  
REFERENCE LABORATORY, LLC.

30 May 2003

## ANALYSIS OF BREAST THERMOLOGY.

E

For Dr. D. Mayfield



Right Aspect of Thorax

Left Aspect of Thorax

**BACKGROUND:** Six high-resolution digital radiometric infrared data images were made of the anterior and right and left lateral aspects of the thorax to feature the breasts. Three of these images were made immediately after the patient withdrew both hands from one-minute immersion in cold (approx. 11°C) water. This procedure is intended as an autonomic challenge and anticipates the sympathetic-driven adaptive constriction of normal blood vessels with consequent cooling of the skin. The challenge is intended to differentially indicate the nitric oxide-dilated and neo-angiogenic blood vessels reliably associated with solid malignant neoplasm by their inability to constrict. Notice is made that this patient's related history includes bilateral prosthetic augmentation in 1978 with replacement in 1984 and three personal risk factor(s) for breast malignancy. The patient's related history includes no symptom(s) frequently associated with breast disease. This patient has no prior data available for comparative analysis.

**DATA:** The infrared data images demonstrate certain patterns and emission levels considered atypical. Specifically, an asymmetric, prominent, large-caliber, hyperthermic and vascular-like pattern is discerned in the cranial-lateral quadrant of the left breast (please refer to Points 1, 2 & 3 in Left Aspect of Thorax thermogram above for specific features and location). Distinct and moderately hyperthermic vascular-like patterns without any complexity are discerned in the contralateral breast (please refer to Point 1 in Right Aspect of Thorax thermogram above for specific features and locations). Additionally, the post-challenge images demonstrate an adaptive attenuation in emission levels from all of the thermal features in both breasts.

**IMPRESSION AND DISCUSSION:** Quantitative analysis of the infrared data images indicate atypical metabolic and/or vascular-like features in the cranial-lateral quadrant of the left breast that define a single thermology sign and provide minor (<10%) risk for establishing malignant disease at this time. This indicated risk should be considered additive with other risk factors and atypical results from other objective evaluations. However, in the absence of other specified risks, experience with similar findings demonstrate regional inflammation, personal variant or metaplasia as the more likely basis for the described atypical thermal features in the cranial-lateral quadrant of the left breast. Further, the possible extra-capsular mobilization of silicone from the prosthetic appliances should be considered as a possible basis for the atypical vascular-like patterns seen in the cranial-lateral quadrant of the left breast. Other objective means of evaluation may be useful and are urged if clinically indicated. Atypical metabolic and/or vascular-like processes are indicated in the contralateral breast that do not define any thermology signs or criteria.

**SUMMARY:** Atypical thermology sign with minor risk for malignant disease of the cranial-lateral quadrant of the left breast; graded TH-3. Atypical, benign-type thermology of the contralateral breast; graded TH-2. A comparative restudy is recommended in 120-180 days. Thank you for your referral.

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**Sample Report**



**Meditherm**  
Digital Infrared Thermal Imaging

**REPORT**

**Patient:**  
**Date of Birth:**  
**Referring Doctor:**

**Scan**  
**Scan**  
**Clinical Thermographer:**

**Date:**  
**Ref:**

**Clinical notes from patient:**

**All normal protocols were observed.**

**Reported by:**

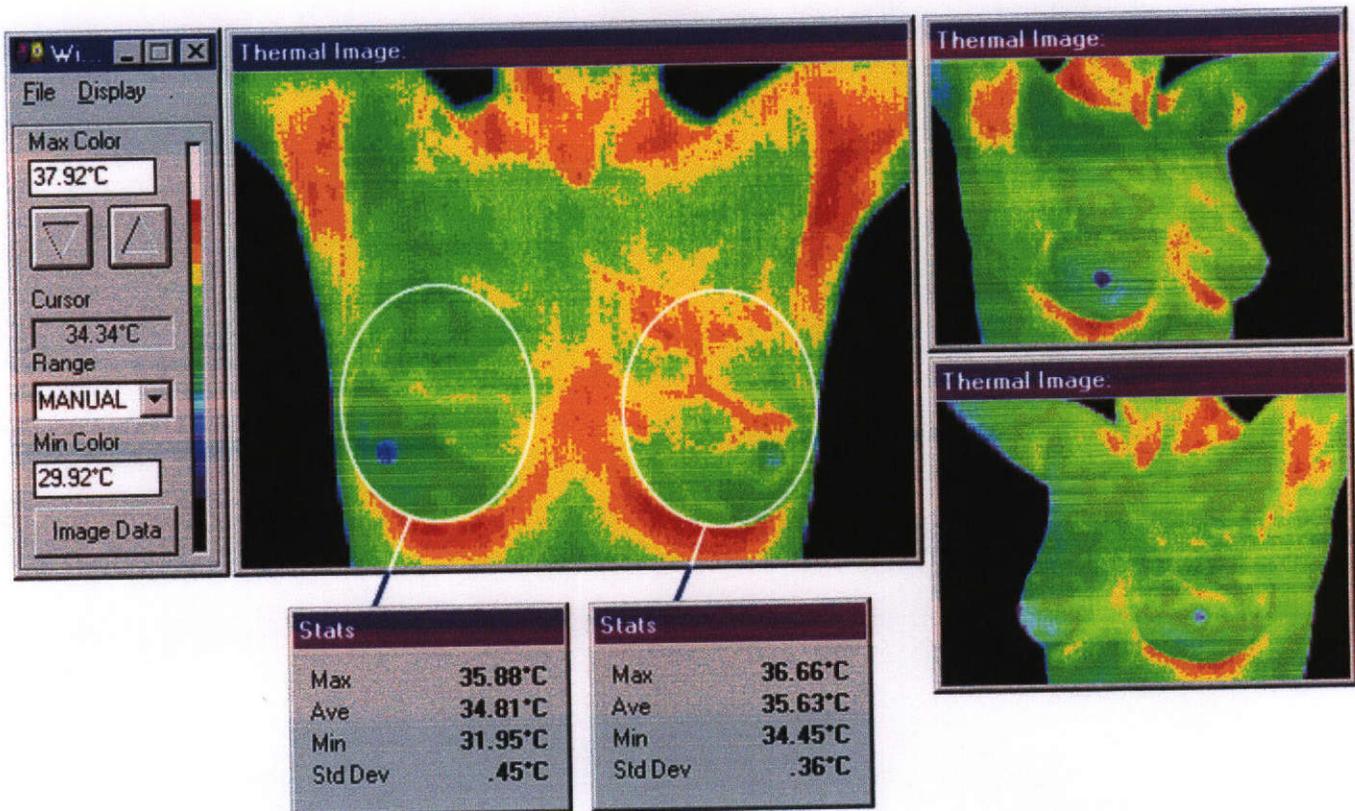
There is a slight pattern of hyperthermia radiating in both upper quadrants of the left breast, however the temperature differentials are not exceptional .

This study is suitable to be archived as a base-line for future comparison.

Recommend re-examination in three months before continuing with annual comparative studies.

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December 17, 2003



Breast thermography is a way of monitoring breast health over a period of time. Each normal breast has a particular thermographic pattern that does not change over time, very much like a fingerprint. The purpose of the two initial breast studies is to establish this normal baseline pattern to which all future thermograms are compared. With continued breast health, each thermogram is identical with these initial studies. Any changes developing means that something new is happening within the breast which will call for further investigation.

The ability to interpret initial studies is limited because there are no previous scans for comparison. Sometimes, patterns can be quite complex to the point where we may recommend that mammography or ultrasound be done, in order to reassure us over the time we are establishing your baseline pattern.

Another more detailed report from Meditherm (K003332) through their "Interpretation Service", which discusses their selection of "normal" and "abnormal" values, as well as "cold stress", at the following link:

<http://www.meditherm.com/assets/SampleReport.pdf>

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