47

[redacted]

21/09/2010 05:00 PM

To <Judy.Zilber@[redacted]

cc "'Peter Leando'" <peter@[redacted]

bcc

Subject RE: s41JA Letter Request for Information Ref: 2010/0
Rev ID: 20100122

DOCUMENT NOT YET CLASSIFIED

Thanks for the information and phone discussion today Judy.
It is understood no extension of the time for submission of the requested information is permitted by TGA.

Contact has been made with the 'Sponsor' (currently in USA and travelling).
I am instructed to act as the Meditherm regulatory TGA agent.
Updating of the TGA e-Biz information will follow on the appropriate form.
In the meantime I am able to address some of the questions immediately from information supplied.

1. MANUFACTURER'S AUSTRALIAN DECLARATION OF CONFORMITY
An original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity, as required under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*

Notes:
The declaration of conformity must conform to Australian requirements. A European declaration of conformity is not acceptable.
Please refer to *Australian Regulatory Guidelines for Medical Devices* (available at http://www.tga.gov.au/devices/argmdp1.pdf).

1 Ans: TGA DoC is **with Sponsor for review** / check (up-date).

2. POST MARKET DATA
- Reports on adverse events for this device both here and overseas
- Problem reports for this device both here and overseas
- Risk Analysis on reported problems
- Regulatory Action taken by the manufacturer in the past

2 Ans: Post Market data is not available at time of writing, **requested of manufacturer**.

3. Labels for the device

3 Ans: Labels are part of EC Technical File. Copies are shown on page 2 of IEC61010 test report (attached).

4. Instructions for Use

4 Ans: Instructions for Use – attached.

5. Advertising material for the device including website advertisements.

5 Ans: Advertising material – It is understood had been submitted to TGA for review previously.
Download from <http://medithermimaging.com/> attached.

6. Copies of all certificates from Notified Bodies that support the inclusion of the device on the ARTG

6 Ans: Certificates have not been issued by a EC Notified Body. (also see 10.)
The product is EC MDD Class I utilising Anx.VII conformity assessment route and CE

marked accordingly.
(i.e. self declaration without Notified Body involvement).

7. The number of devices distributed:
   - in total worldwide, and
   - in total in Australia.

7 Ans: 32 units in Australia. 1364 units worldwide that are of the same specification and model.

8. Copies of the clinical evidence used to establish conformity with Australian Essential Principle 14, and as described in Australian Regulatory Guidelines for Medical Devices Section 3 - *http://www.tga.gov.au/devices/argmdp1.pdf* , and as required by Part 8 of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* , including evidence to support the clinical competence of its author (e.g. a short curriculum vitae).

8 Ans: **On request from manufacturer** – none other than the case studies shown on web site
< http://www.meditherm.com/thermography_page9.htm>
< http://www.meditherm.com/breast_thermography_studies.htm>

9. Risk Management reports for the product.

9 Ans: Not available at this of writing – **on request from manufacturer**.

10. Electrical safety test reports/ certificates for electromedical equipment.

10 Ans: Attached 'Report IEC 61010 Meditherm-Compix 7 Mar.doc'

The outstanding documentation will be sent as soon as it is available to me.
Best regards

[redacted]

From: Judy.Zilber@[redacted] [mailto:Judy.Zilber@[redacted]]
Sent: Tuesday, August 10, 2010 12:17 PM
To: [redacted]
Subject: s41JA Letter Request for Information [SEC=UNCLASSIFIED]

[redacted]

Attached is a Letter of request for information for your attention. A hard copy of the letter has also been mailed to your postal address.

Your prompt attention to this matter is required.

Thank you.

Judy Zilber
Market Vigilance Monitoring Section
Office Product Review
TGA

02 62328299

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IRIS-7.5manual.pdf


Web brochure.pdf


TUV-MW128 PWR SUPPLY.pdf


Report IEC 61010 Meditherm-Compix 7 Mar.docx

DOCUMENT NOT YET CLASSIFIED

What is DITI?

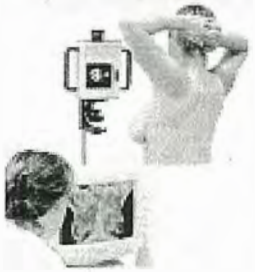
Digital Infrared Thermal Imaging 'DITI' is a 15 minute non invasive test of physiology. It is a valuable procedure for alerting your doctor to changes that can indicate early stage breast disease.

The benefit of DITI testing is that it offers the opportunity of earlier detection of breast disease than has been possible through breast self examination, doctor examination or mammography alone.

DITI detects the subtle physiologic changes that accompany breast pathology, whether it is cancer, fibrocystic disease, an infection or a vascular disease. Your doctor can then plan accordingly and lay out a careful program to further diagnose and /or MONITOR you during and after any treatment.

PROCEDURE

- ***Non invasive***
- ***No radiation***
- ***Painless***
- ***No contact with the body***
- ***F.D.A approved***



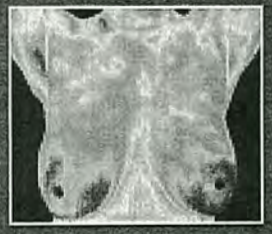
This quick and easy test starts with your medical history being taken before you partially disrobe for the scanning to be performed. This first session provides the baseline of your "thermal signature". ***A subsequent session assures that the patterns remain unchanged.***

All of your thermograms (breast images) are kept on record and once your stable thermal pattern has been established any changes can be detected during your routine annual studies.

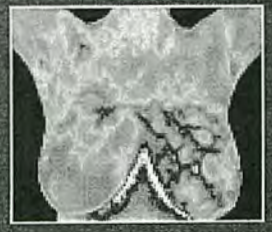
WHO?

All women can benefit from DITI breast screening. However, it is especially appropriate for younger women (30 - 50) whose denser breast tissue makes it more difficult for mammography to be effective. Also for women of all ages who, for many reasons, are unable to undergo routine mammography. This test can provide a 'clinical marker' to the doctor or mammographer that a specific area of the breast needs particularly close examination.

It takes years for a tumor to grow thus the earliest possible indication of abnormality is needed to allow for the earliest possible treatment and intervention. DITI's role in monitoring breast health is to help in early detection and monitoring of abnormal physiology.



NORMAL
Good thermal symmetry with no suspicious thermal findings.
These patterns represent a baseline that won't alter over time and can only be changed by pathology.

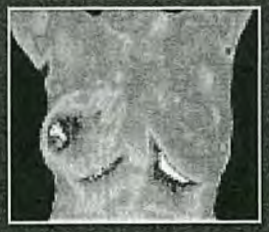


FIBROCYSTIC
Significant vascular activity in the left breast which was clinically correlated with fibrocystic changes.

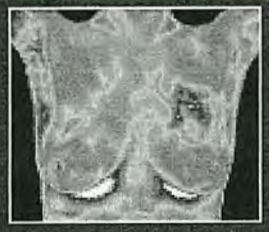
BASELINE
Baseline thermogram showed a slight hyperthermic asymmetry in the upper right breast.

3 MONTHS
The follow-up study at 3 months showed the pattern had become more well defined. Mammography was inconclusive.

12 MONTHS
Significantly increased vascular changes. Repeat mammogram showed a small calcification (1 mm) at 1 O'clock. A lumpectomy was performed confirming a malignant carcinoma (DCIS).



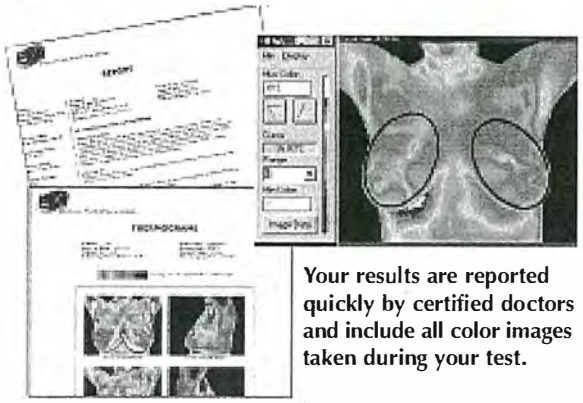
INFLAMMATORY CANCER
There were no visible signs of abnormality. Referral to a breast specialist and a subsequent biopsy diagnosed inflammatory breast cancer at a very early stage.



DUCTAL CARCINOMA
The vascular asymmetry in the upper left breast was particularly suspicious and clinical investigation indicated a palpable mass. A biopsy was performed and a DCIS of 2 cm was diagnosed.

Meditherm DITI

An extremely valuable test to help in the early detection of breast disease.



Your results are reported quickly by certified doctors and include all color images taken during your test.

Current Early Detection Guidelines

One day there may be a single method for the early detection of breast cancer. Until then, using a combination of methods will increase your chances of detecting cancer in an early stage. These methods include :

- Annual DITI screening for women of all ages.
- Mammography, when considered appropriate for women who are aged 50 or older.
- A regular breast examination by a health professional.
- Monthly breast self-examination.
- Personal awareness for changes in the breasts.
- Readiness to discuss quickly any such changes with a doctor.

These guidelines should be considered along with your background and medical history.

"Early Detection Saves Lives"

DITI's role in breast cancer and other breast disorders is to help in early detection and monitoring of abnormal physiology and the establishment of risk factors for the development or existence of cancer. When used with other procedures the best possible evaluation of breast health is made.

Increase your chances of detecting breast cancer in its earliest stages.

For information and appointments please contact:

Meditherm®
Digital Infrared Thermal Imaging

www.meditherm.com/breasthealth

DITI has been recognized as a viable diagnostic tool since 1987 by the AMA Council on Scientific Affairs, the ACA Council on Diagnostic Imaging, the Congress of Neuro-Surgeons in 1988 and in 1990 by the American Academy of Physical Medicine and Rehabilitation.

TEST REPORT
IEC 61010-1
Safety requirements for electrical equipment for measurement, control, and laboratory use
Part 1: General requirements

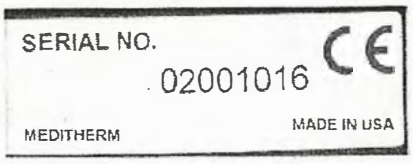
Report Reference No ..... :	P070801-1
Compiled by (name+signature) ..... :	Al Warren Al Warren
Date of issue ..... :	7 March 2008
Address ..... :	21405 SW Regal Lane Aloha Oregon
Testing location/ address ..... :	Safety Thru Design, Inc. / Hillsboro, Oregon
Manufacturer's name ..... :	Compix Incorporated
Address ..... :	15824 SW Upper Boones Ferry Rd Lake Oswego, OR 97035-4066.
Test specification:	--
Standard ..... :	IEC 61010 – 1 : 2001 (Second Edition)
Test procedure ..... :	CB / CCA
Non-standard test method ..... :	N/A
Test Report Form No ..... :	IEC61010_D
TRF Originator ..... :	VDE
Master TRF ..... :	Dated 2005-02-14
Test item description ..... :	--
Trade Mark ..... :	compix INCORPORATED
Model/Type reference ..... :	Model 222 Meditherm
Ratings ..... :	AC - DC Power Supply: Mains:100 - 240 Vac, 1 A, 50/60 Hz DC output: 5Vdc, 4 A

Responsible **Manufacturer**..... :	Compix Incorporated
Factory Location(s)..... :	15824 SW Upper Boones Ferry Rd Lake Oswego, OR 97035-4066.

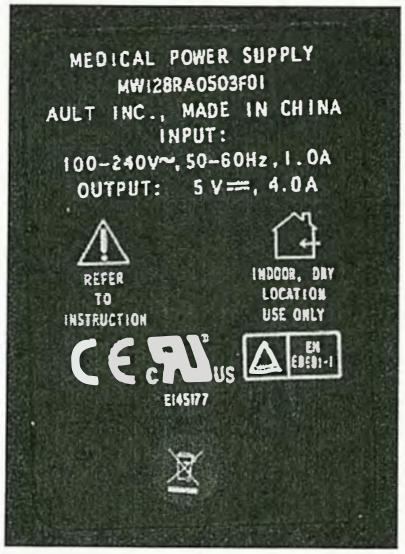
Copy of marking plate:

Model 222 Labels

MediTherm Labels



AC - DC Power Supply



Summary of testing:

Durability of markings - Pass
AC input current - Pass
Fault temperature - Pass
Fault test - Pass
Limited Energy Circuit - Pass
Dielectric Strength - Pass

Test item particulars	--
Type of item tested ..... :	Measurement / Control / Laboratory
Description of equipment function ..... :	Thermal imaging camera for industrial and medical applications.
Measurement (installation) category ..... :	N/A
Pollution degree ..... :	2
Protection class ..... :	AC-DC power supply: Class I Model 222 and Meditherm: Class III
Environmental rating ..... :	standard / extended (specify):
Equipment mobility ..... :	portable / hand-held / floorstanding / fixed / built in
Connection to mains supply ..... :	Permanent/detachable cord set/ non detachable cord set/none
Operating conditions ..... :	continuous / short-time / intermittent
Overall size of the equipment (W x D x H) ..... :	Model 222: 12 cm x 10 cm x 12 cm MediTherm: 20 cm x 11 cm x 26.5 cm
Mass of the equipment (kg) ..... :	Model 222, 1.5 Kg MediTherm, 2.1 Kg
Marked degree of protection to IEC 60529 ..... :	None
Accessories and detachable parts included in the evaluation ..... :	None.
Options ..... :	None

Possible test case verdicts:	--
- test case does not apply to the test object ..... :	N/A
- test object does meet the requirement ..... :	P(Pass)
- test object does not meet the requirement ..... :	F(Fail)

Testing	--
Date of receipt of test item	December 2007
Date (s) of performance of tests	1/4/08 - 1/25/08

General remarks:

This evaluation is based on a review of the product and documentation, testing and verbal information provided by the product manufacturer.

This report and testing was not performed by a CB Laboratory.

This report and the test results presented relate only to the item(s) tested.

General product information:

The Model 222 is intended for industrial applications.

The Meditherm is intended for medical applications for general diagnosis, but not intended to provide quantitative data.

The Model 222 and Meditherm consist of the same electronics and IR hardware. Only the enclosures differ.

MED2000 IRIS 7.5
Thermal Imaging System

Installation and Operating Instructions

Version 2.0
3-3-2008

NOTICE

This manual is intended solely to provide instructions for operation of the MED2000 IRIS 7.5 Thermal Imaging System and its accompanying Thermal Evaluation Software. Meditherm reserves the right to change the information contained in this manual without notice. No warranty, expressed or implied, is made regarding the accuracy of the information in this manual at any time following its release or for any purpose other than as a guide to operation of Meditherm® Systems.

Table of Contents

1. HOW TO USE THIS MANUAL

Thank you for purchasing a Meditherm® Med2000 IRIS 7.5 (hereafter referred to as IRIS 7.5). The purpose of this manual is to provide information on proper usage of the IRIS 7.5.

The following text and symbols are used throughout this document:

⚠ **CAUTION** – This indicates a potential hazardous situation, which can cause harm to the operator and/or equipment if not properly addressed. Documentation needs to be consulted where this symbol is used.

NOTE – This is information related to the section topic, provided for additional clarification.

Bold text – Used as a section header as well as promoting emphasis.

Blue underlined text – Represents a link to a section within this document or a web page.

2. PRODUCT OVERVIEW

The IRIS 7.5 will work with any Windows XP or Windows Vista based computer. The IRIS 7.5 requires a USB 2.0 port. It is designed for non-contact mapping and measuring of surface temperatures. The heart of the system is a sophisticated camera that is sensitive to infrared (IR) radiation. This camera is a reliable, cost-effective tool that provides fast, comprehensive evaluations of thermal patterns.

All surfaces radiate infrared radiation according to their temperature. The IRIS 7.5 captures this radiation and produces a two-dimensional map, or thermal image, of the object's surface temperatures.

All configurations of the IRIS 7.5 thermal imagers come with Thermal Evaluation Software, typically "**WinTES2**" (hereafter referred to as TES), for camera control, image storage, and display. TES provides the graphical user interface (GUI) as well as the interface that permits the computer to communicate with the Meditherm IR Camera. TES lets the operator adjust the display, compare images, change colormaps, read temperatures at specific locations, compute area statistics, and show thermal profiles. An important feature of TES is the use of the industry standard TIFF image file format for storing thermal images. This makes it possible to use the images with other software programs.

The rest of this manual describes the IRIS 7.5 series thermal imagers and their operation in more detail.

NOTE

Before attempting to operate the system you should read sections 2. SYSTEM DESCRIPTION AND OPERATING REQUIREMENTS, 3. INSTALLATION AND SET UP, and 4. MAKING THERMAL IMAGES.

3. SYSTEM DESCRIPTION and OPERATING REQUIREMENTS

The IRIS 7.5 has two principal components: the **camera head** (see figure 1) and the **Thermal Evaluation Software**. The camera head contains the infrared sensor, and circuitry required to capture the infrared video. **Other than the personal computer and interconnecting cables, no other accessories or supplies are required.**

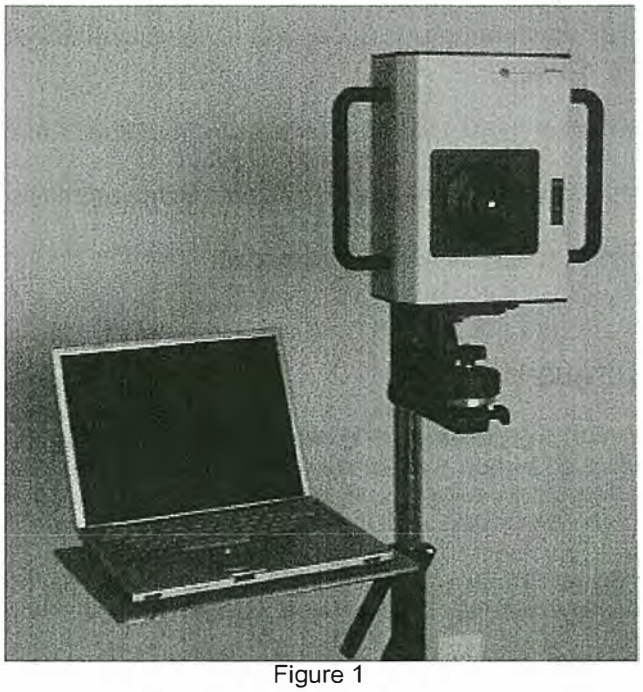


Figure 1

The IRIS 7.5 systems have been designed to operate in a typical office or other sheltered environment.

The camera head should be mounted on a tripod or other stable fixture. The standard fitting is a 1/4 "- 20 threaded female connector, the type normally found on photographic equipment, mounted on the bottom of the camera. The camera head should be located within ten feet (three meters) of the imaging computer. A USB cable (type A/B M/M) is provided for connecting the camera to the computer.

The camera should be treated with the same care given a good visible light camera or other optical instrument. Minor vibration can reduce image quality; major vibration or shock may result in damage. And while the longer wavelength IR energy makes it less sensitive to dirt, care should be taken to keep the optics clean. (See Section 8, Maintenance.)

NOTE

There are no components inside the camera head designed for user service. Removing the cover of the camera may void the warranty. UNDER NO CIRCUMSTANCES SHOULD THE SYSTEM BE OPERATED WITHOUT THE COVERS IN PLACE.

4. INSTALLATION AND SET UP

Unpack the system. Inspect the system for physical damage. If you find shipping damage, stop, inform the carrier and call Meditherm Customer Service. If possible, store the shipping carton and packing materials for future use.

There are **two distinct steps in the installation procedure**: software installation; camera connection and set-up. You should **perform all of these steps before proceeding** to the verification phase.

NOTE

You may install TES on additional computers to allow others to view images. TES will run without a camera thus letting you load, display and manipulate previously stored images.

Software Installation

TES Installation

The TES software is distributed on a CD-ROM. The software has been designed to work with personal computers running Windows XP or Windows Vista. For installation and operation instructions on TES software, refer to the 'install instructions' located in the root directory of the TES distribution media.

USB driver installation

Upon connecting power and the USB to a camera for the first time, the computer will request that drivers be installed. Follow the instructions presented by the computer to complete this process. For current relevant details, refer to 'install instructions' located in the root directory of the TES distribution media.

Hardware Installation

NOTE

Software must be installed before installing hardware unless otherwise stated in the software installation notes. Please check 'install instructions' located in the root directory of the software installation media.

Connecting the Camera

Before making the electrical connections to the camera, make sure the camera is securely mounted to the camera stand.

⚠ CAUTION

The DC power input circuitry of the IRIS 7.5 is rated to accommodate up to 6 VDC. A power input voltage in excess of this value may permanently damage the electronics in the camera. Use only a 5V power supply provided by Meditherm.

As seen on the 5V supply, this symbol means the power supply is to be used indoor only.

Connect the 5V desktop supply to a suitable source of 100-240VAC 50-60 Hz power and the low voltage output cable coming from the supply to the DC power jack on the rear of the camera. Connect the "B" plug (squarish) of the USB cable to the rear of the IRIS 7.5 camera. Connect the "A" plug (flat/wide) of the USB cable to an available "A" receptacle on your PC. Refer to 'USB driver installation' sub-section of 'Software Installation' section for USB driver installation instructions.

If there is a protective cap covering the lens of the camera, make sure to remove it before imaging.

5. ACQUIRING THERMAL IMAGES

Once you have completed the set-up steps of section 3, the system is ready for operation.

Definitions: The feet and mounting nut are mounted on the **bottom** of the camera. The side opposite the bottom is the **top**. The lens and focus mechanism are mounted on the **front** or **face** of the camera. The opposite side, with the cable connectors, is the **back**.

Preparing to take images

With its face toward the subject, position the camera head so it is approximately centered over the area to be scanned. The top edge will correspond with the top of the display. The face of the camera head should be parallel to the surface of the subject.

The area scanned by the camera depends on the distance from the camera to the subject. As with a "box" camera, the greater the distance the larger the field of view. Set the camera head at a distance appropriate for the size of the subject.

Start TES by clicking on the WinTES2 icon in Start – Programs – WinTES2 folder.

Refer to the relevant instructions in the Step-by-step folder for important first-time user information. (Double click the "ConfigureWinTES2.htm" icon, or select the WinTES2.htm link near the beginning of the overall Step-by-step document opened by clicking index.htm in the Step-by-step folder.)

Select the "IRIS 7.5" as the camera module from the Options-Plugins menu. WinTES2 will automatically initialize and recognize the camera when you close the selection window.

If the camera power is on when you start WinTES2 or open the IRIS 7.5 camera module, you will see an initialize message concerning the need to reset the camera power. This is normal. If the message "reset power to camera" persists for more than 15 sec., cycle the camera power.

When you select a display plugin module, which is used to extract temperature data, you will be presented with a window for entering an unlock code. Use the unlock code printed on the installation CD envelope as illustrated in the Step-by-step examples.

Call or E-mail Meditherm with the Hardware ID code displayed in this dialogue box to obtain a permanent unlock code.

Camera owners may install the software and receive multiple permanent unlock codes for multiple computers at no charge.

Image Touchup

At periodic intervals, the camera will perform an automatic "touchup". It does this to maintain the best image quality in the presence of changing ambient temperatures inside the camera. When these occur, you will hear a faint clicking sound from the camera and there will be a brief momentary interruption in the real-time camera display window during which the image will become a uniform gray.

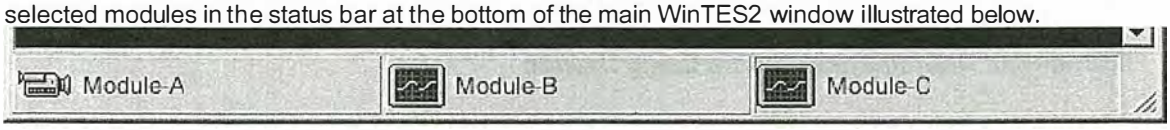
If the scene being imaged changes drastically and the operator feels the image quality may be less than expected, it may be helpful to force a touchup. This can be accomplished by clicking the options button of the camera window and re-selecting the temperature range.

TES Software Overview

Thermal Evaluation Software (TES) gives the user the ability to capture, open, save, and manipulate thermal images. Specifically, WinTES2 consists of a collection of "standard modules" which may be selected and combined according to the user's needs. Sophisticated users may produce "custom modules" to meet unique needs.

Refer to the help messages in WinTES2 for specific help on each function or module.

The fundamental concept of the modules is that each module may receive input from another module, and may pass information to a successor module. This relation is shown by the left-to-right arrangement of the selected modules in the status bar at the bottom of the main WinTES2 window illustrated below.



In this illustration, Module-A will send its data to Module-B. Whenever Module-B receives data from Module-A, it will do whatever it is configured to do and then pass its data to Module-C. The icons associated with each module are solely to aid in identifying them and neither imply nor serve any functional purpose.

General Rules for Modules and their arrangement.

- A particular module from the list of standard modules may appear zero or more times in the active analysis configuration.
- Data and control is moved from left to right in the order depicted in the status bar.
- Modules may be configured to appear in any order, however some ordering patterns may be of no useful value.
- A module requiring user action will stop the flow of data and will remain the active module until the user response requirement is met. Predecessor modules may continue to generate data and add data sets to the input queue of a module waiting for user action.
- There is no mechanism for sending the output of one module to more than a single successor module.
- There is no mechanism for a module to receive data from more than one predecessor module.
- There is no mechanism for sending the output of the last module back to the first module.
- Modules will finish processing their current data before beginning the processing of the next set of data. If the "Discard Data" option is selected, the module will begin processing the most recent (newest) data set and will discard all older data sets. If "Discard Data" option is NOT selected, the module will begin processing the oldest data set, and will keep newer data sets in its input Que.
- Receipt of data by a module acts as a trigger to activate the process implemented by that module even if that module doesn't actually use any of the data it receives.
- Modules do not necessarily alter the data they receive, and many of them pass their input data directly to their successor after performing their own process.

6. OPERATING SUGGESTIONS

Focusing

The IRIS 7.5 cameras utilize a manual focusing mechanism.

Novice users may find focusing the camera easier with the Grayscale colormap, since grayscale images tend to appear more natural. It is important to have a well-focused image. Look for obvious reference points. Cool or shinny objects, such as metal (eyeglasses, jewlery), clothing and hair and may provide useful well defined edges to assist in focusing.

Framing or Determining What is Being Viewed

Framing involves two things: first, the aiming of the camera so the region of interest is centered in the image; second, being able to relate specific points in the thermal image to the corresponding locations on the subject. The same factors that make it more difficult to focus a thermal image can also make it harder to frame properly.

Simple markers can be used as pointers. Any small object at room temperature will work. Plastic tools, non-metallic rulers are also useful. Put the marker on the subject as a pointer or an edge indicator, and then take an image. The marker should show up as a distinct dark area against the warmer background of the subject. Objects you take out of your pocket will already be warm and may not show up in the image.

The Med2000 IRIS 7.5 is a sensitive instrument that has the capability to detect small temperature differences. However, non-contact temperature measurements are affected by a number of variables that can change the accuracy of temperature measurements. The following techniques will help improve the accuracy of measurements made with the IRIS 7.5 system.

Be Consistent

- Maintain the same environmental conditions, e.g., ambient temperatures, ventilation and the presence of other heat sources in the room.

- Maintain the same physical set-up for the system.

Minimize external sources of infrared energy.

The IRIS 7.5 measures temperature by detecting emitted infrared energy, i.e. the infrared energy generated by the subject. Objects also reflect infrared energy from their surroundings. The IRIS 7.5 system (or any other infrared system) cannot tell the difference between reflected and emitted energy. Therefore, reflected energy is a potential source of error. Some reflected infrared (IR) energy is unavoidable and the IRIS 7.5 will automatically compensate for typical levels of external IR energy, which are uniformly distributed over the subject. Nevertheless, it will be helpful to minimize significant sources of external IR, particularly those that may not be uniformly distributed.

Other sources to avoid are direct sunlight coming through a window or heat from nearby electrical or electronic devices. A general rule of thumb is that if you can feel heat from a source, then it will affect the accuracy of the image.

Printing and exporting images

TES produces TIFF (Tag Image File Format) images that adhere strictly to the TIFF standard Revision 5.0 for Class-P (Palette Color) Images. Some software applications, which claim to be TIFF compatible use a limited subset of the TIFF specification and may not import Meditherm TIFF files, so universal compatibility is not assured.

The most reliable way to export a color image is to use the **Copy** command from the menu. This puts the image into the clipboard from where it can be pasted into the appropriate document. Alternatively, **Print Screen** may be used to copy a full Windows screen to the Clipboard or **Alt Print Screen** will copy only the active window to the clipboard. These objects can usually be pasted into a Word, WordPerfect or other word-processing document.

Additionally, the TIFF thermal image files may be opened in any of a number of applications programs.

From these word processing or image display programs it is a simple matter to print to a file or printer.

7. MAINTENANCE

Calibration

It is recommended that instrument performance be verified once a year. The instrument should be compared against a calibrated blackbody source. It is recommended the instrument be returned to the factory for repair and recalibration.

Cleaning

Small amounts of dust or lint on the lens surface will have little or no effect on the performance or calibration. It is possible to degrade the lens surface by improper or excessive cleaning techniques. Use the following cleaning techniques carefully and not too frequently.

To remove loose dust or debris, use a gentle stream of dry air. Aerosol-type cans of clean dry air available at camera and electronic stores are suitable for this purpose. For more persistent loose dust or debris you may use a camelhair brush or soft cotton swab ("Q-tip"). **Do not use lens tissues: Lens tissues intended for eye glasses contain chemical additives and lens tissues available in camera stores are often not soft enough.**

Avoid touching the lens surface with your fingers. If you do need to clean off fingerprints or other more resistant material, use clean alcohol or acetone to dampen a soft cotton swab, gently dab, and swipe the spot or fingerprint. If you look at the lens surface under magnification you will probably notice a few tiny defects in the coating that have no measurable effect on the performance of the lens; But if you mistake such a defect for debris and try to remove it you can make the defect larger.

Storage and transporting

The container in which the IRIS 7.5 was originally shipped in should be used for storage or transporting. If this is not possible, make sure adequate protection is provided to avoid damage while in storage or during shipping. This can be accomplished by providing at least a two inch barrier of foam on top, bottom, and all sides of the camera.

8. USER SUPPORT

User support is available by phone, mail, e-mail or in person at Meditherm's offices in Beaufort, North Carolina. Support will normally be available from 8:00 A.M. to 5:00 P.M. Eastern Time, Monday through Friday, excluding national holidays.

User support is generally free of charge on issues relating to interpretation of this manual, the proper operation of the system, routine maintenance and warranty service.

Meditherm reserves the right to determine, at its sole discretion, the extent of user support made available to any user. A user may be asked to furnish proof of ownership of an IRIS 7.5 system before receiving support.

Contacting Meditherm

For support, contact Meditherm via one of the following means:
E-mail: http://www.meditherm.com/contact.htm

Phone: (252) 504-3635 or (toll free) 1-866-281-5479

FAX: (503) 639-1934,

Mail: **Meditherm, Inc.**
Attn.: User Support
400 Front Street
Beaufort, NC 28516-1514

When contacting Meditherm, identify yourself as a user of the IRIS 7.5 system and ask for User Support. It may be helpful for you to have the serial number of your IRIS 7.5 system and the version number of TES you are using at the time of contact.

Visit http://www.Meditherm.com/ for technical articles, price lists, product photos, and other information on current products. If you want to visit us in person, please call us at the number above for directions and to make sure the person best equipped to help you will be available when you arrive.

Our office location / shipping address is:
Meditherm, Inc.
400 Front Street
Beaufort, NC 28516-1514

European Representative:

Mr. W. A. Bradford
Meditherm Limited
34 Keates Road
Cambridge CB1 9ES
United Kingdom
Tel. (0) 1223 242 942

9. Meditherm® IRIS 7.5 LIMITED WARRANTY

Meditherm warrants to the original buyer that this product shall be free of defects in materials and workmanship and will meet its published specifications for a period of one year following the date of shipment (the Warranty Period). Warranty service will be provided for this product if it is returned to Meditherm, Inc., shipment prepaid, during the warranty period. Meditherm will, at its option, either repair or replace the product at no cost to the buyer, or refund the original purchase price of the product.

Limitations

This warranty shall not apply to defects resulting from accident, misuse, improper maintenance or unauthorized modifications.

The remedies described above -- repair, replacement or refund -- are the buyer's sole and exclusive remedies. Modifications or extensions of this warranty shall be effective only when made in writing, signed by an officer of Meditherm, Inc..

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. MEDITHERM SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES.

This warranty gives the buyer specific legal rights. The buyer may also have other rights which vary from state to state.

Shipping

During the Warranty Period, Meditherm will reimburse the buyer for the buyer's reasonable shipping costs for products returned to Meditherm from locations in the United States and Canada. Meditherm will also pay the shipping charges to return the product to the buyer.

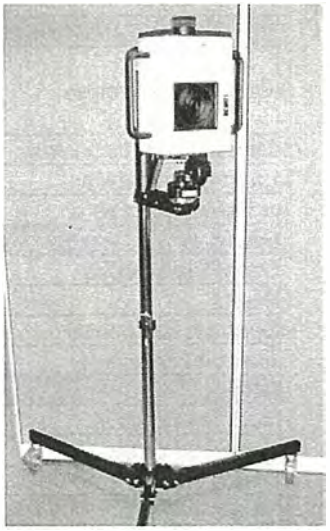
Before returning a product for service, contact Meditherm Customer Service for return authorization.

10. TECHNICAL SPECIFICATIONS[1]

Imaging Performance					
Temperature range	0° C to 50° C (32° F to 122° F)				
Measurement accuracy	< ± 1° C (± 1.8° F) of indicated temperature in range 20° to 40°C.				
Long term stability	< ± 1° C (± 1.8° F) drift over 1 year				
Ambient correction	Automatic				
Detector					
Focal Plane Array	Amorphous Silicon microbolometer				
Pixels	160 x 120; Interpolated to 320 x 240				
Spectral Response	7-14 microns				
Thermal Sensitivity	Better than 100mK				
Image					
Real time display	8 bit grayscale				
Captured image	16 bit				
Display color	User selectable color and grayscale colormaps				
Requirements					
Power Source	100-240 VAC, 47-63 Hz				
AC to DC converter	5 VDC, minimum of 3 Watts continuous, 1 Ampere surge at start-up.				
Personal Computer	Windows XP or Windows Vista, an available USB port.				
Environmental characteristics					
Operating Temperature	18° C to 30° C (64° F to 86° F)				
Oper.Temp., reduced accuracy	0° C to 18° C (32° F to 64° F), 30° C to 60° C (86° F to 140° F) See Note 2				
Storage temperature	-30° C to 80° C (-22° F to 176° F)				
Physical characteristics					
Enclosure	Plastic and Aluminum, 1/4-20 mount				
Overall dimensions (HxWxD)	26.5cm x 31.5cm x 19cm (10.4" x 12.4" x 5.1")				
Weight	2.1kg (4.6 lbs)				
Calibration					
Recommended interval	1 year				
Optics					
Focal length	25mm	16mm	11mm	8.5mm	5.8mm
Field of view	11° x 8°	17° x 12°	25° x 18°	32° x 24°	50° x 37°
Focus range	30cm to ∞	30cm to ∞	30cm to ∞	30cm to ∞	1m to ∞
Standard accessories					
Camera stand					
Power supply	AC to DC adapter				
Software	WinTES2 camera control and analysis software.				
Manual	Operator's manual.				
Cables	USB A to B, AC cable for power supply				

Note 1: All specifications subject to change without notice.
Note 2: Power supply must not be operated in an environment above 40°C (104° F).

APPENDIX A. Accessories



Medical tripod

Assembly

If tripod is not already assembled, attach head assembly to the base of the tripod.

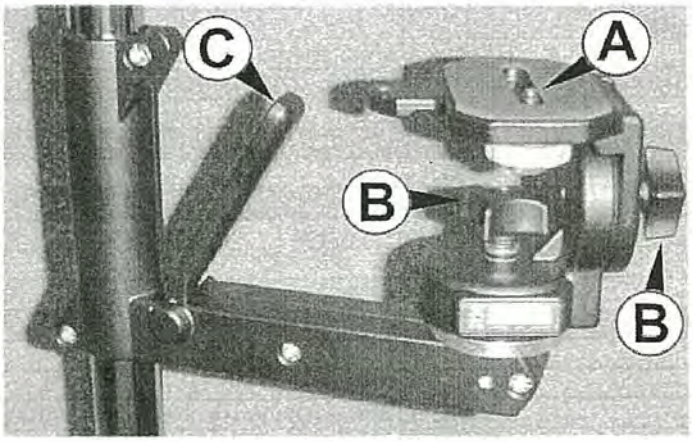
Camera attachment

Attach the camera via the ¼ - 20 nut located on the bottom of the camera using the ¼ - 20 thumbscrew **A** of the Floating Head shown in the figure below.

Operation

Thumbscrews at pivot points **B** can be loosened, then tightened, to position the camera head as needed. Partially tightened, the camera can be adjusted using the Floating Head, and will stay in the position left. Tighten the thumbscrews fully to prevent further changes in the camera's position.

Squeeze the Height Adjustment lever **C** toward the vertical pole to raise or lower the camera.



USB Cable

A USB cable is provided as a part of the camera to be used to connect the camera to the computer. Substitution of a different USB cable may interfere with the camera to meeting all of its specifications.

Power module

A power module is provided as a part of the camera to be used to supply power to the camera and plugs into the power mains. Details of the power module and its proper use can be found on page 5 of this manual.

APPENDIX B. Efficiency, Emissivity, Lens Factor, and Noise

Both **emissivity** and **lens factor** work alike to express the efficiency with which radiation from that object reaches the sensor of the camera. Use what you already know about emissivity effects to understand the effect of the Lens Factor.

The overall value for efficiency may be determined by multiplying the emissivity and lens factor. In the following examples, the first three lines represent mathematically equivalent situations:

Emissivity	Lens Factor	Efficiency
.49	1.00	.49
1.00	.49	.49
.70	.70	.49
1.00	1.00	1.00

Background noise is exaggerated by non-unity lens factor or emissivity settings. To fully understand this it may be helpful to view the top two lines of the **Apparent Temperature table** below. The first entry of the second row simply indicates that for a 100% emissivity object, 30°C would be reported; the second entry indicates that a real surface of 0.9 (90%) emissivity would appear the same as a blackbody of only 29.1° C.

Another way of looking at the information contained in this table is to realize that if the emissivity were set to 90%, then a black body of only 29.1° C would be converted to read out as 30° C. Similarly, the third entry from the end in the first row indicates that a blackbody of only 22.9° C would be converted to read 30° C if the emissivity setting were 20%.

Apparent Temperature of a 30°C Surface for various Emissivity %.

Emissivity	Apparent Surface Temperature
100	30
90	29.1
80	28.3
70	27.4
60	26.5
50	25.6
40	24.7
30	23.8
20	22.9
10	21.9
0	21.0

The background noise reported with a 100% efficiency setting (100 emissivity and 100 lens factor) will typically span two to three degrees. Suppose a particular instrument reports background noise of 21° C to 22.9° C. Suppose these values were converted with a lens factor of 20%. By definition, 21° C is converted to the same value, 21° C. But 22.9° C, as shown in the table fragment above, would be reported as 30.0° C, resulting in a 9-degree span for the temperature-equivalent background noise.

Emissivities of common electronic materials

Material	Emissivity (approximate)
Aluminum, polished	.1-.25
Aluminum, anodized	.50-.60
Gold, polished	.01-.04
Glass, smooth	.85-.95
Water (liquid state)	.95-.97
Black body	1
Plastic IC package	.88-.95
Ceramic IC Package	.80-.85
Silicon wafer	IR Transparent
Simpson emissivity dots	.95
Black electrical tape	.93-.95
Masking tape	.82-.85
Flat black paint	.93-.95

APPENDIX C: Declaration of Conformity

EC Declaration of Conformity

Manufacturer **Meditherm, Inc.**
400 Front Street #8
Beaufort,
North Carolina, 28516 – USA

Classification: MDD Annex IX, Rule 12, Class I

Meditherm, Inc. herby declares under its sole responsibility that the Meditherm Med2000 IRIS thermal imaging camera conforms to Annex 1 of the Medical Device Directive, council directive 93/42/EEC as amended and Council Directive 2004/108/EC; Electromagnetic Compatibility.

Classification: MDD Annex IX, Rule 12, Class I

Conformity Route : Annex VII of the directive

Device: Thermal imaging camera

Model: Med2000 IRIS

Applied Standards:

EN IEC 61010-1: 2001; 2nd Edition with National deviations

EN 61326; radiated emissions, Class A

EN 61326; conducted emissions, Class A

EN 61000-3-2; power line Harmonics

EN 61000-3-3; Voltage fluctuation & Flicker

EN 61000-4-2; ESD

EN 61000-4-3; RF field immunity

EN 61000-4-4; EFT's

EN 61000-4-5; Surge Immunity

EN 61000-4-6; RF conducted immunity

EN 61000-4-8; Magnetic Field Immunity

EN 61000-4-11; Voltage Interruption Immunity

European Representative: Mr. W. A. Bradford
Meditherm Limited
34 Keates Road
Cambridge CB1 9ES
United Kingdom
Tel. (0) 1223 242 942

Beaufort, North Carolina, USA
March 3, 2008

Peter Leando - President

Certificate

TÜV

Certificate no. T 09571059 28

License Holder:
Ault Incorporated
7105 Northland Terrace
Minneapolis MN 55428-1534
USA

Manufacturing Plant:
Ault Korea Corporation
Hwa-Seong-si
26-6 Wau-Ri, BongDam-eup
Kyunggi-Do
South Korea

Test report no.: USA-JAK 09571156 029 **Client Reference:** Tim Cassidy

Tested to: EN 60601-1:1990+A1+A2+A13

Certified Product: Switch Mode Power Supply **License Fee - Units**

Addition:
Model Designation: MW128X1AX2X2X3X3X4X5X5 (X1=A-Z;
X2X2=03,05,06,07,09,12,15,18,24; X3,X5=0-9;
X4=F,N,Q,G,M,B,H)

Rated Voltage: AC 100-240V, 50-60Hz
Rated Current: 1.0A
Protection Class: I (X4=F)
II (X4=N,Q,G,M,B,H)

continued on page 29

Appendix: 1, Pg. 1-5

Licensed Test mark:

EN 60601-1

Signatures

Stephan Schmitt
President

Dipl.-Ing. M. Raap
QA Certification Officer

Date of Issue (day/mo/yr)
05/05/2003

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, Tel (203) 426-0888 Fax (203) 426-4009

Certificate

TÜV

Certificate no. T 09571059 29

License Holder:
Ault Incorporated
7105 Northland Terrace
Minneapolis MN 55428-1534
USA

Manufacturing Plant:
Ault Korea Corporation
Hwa-Seong-si
26-6 Wau-Ri, BongDam-eup
Kyunggi-Do
South Korea

T st report no.: USA-JAK 09571156 029 **Client Reference:** Tim Cassidy

Tested to: EN 60601-1:1990+A1+A2+A13

Certified Product: Switch Mode Power Supply **License Fee - Units**

continued from page 28
Output Ratings DC:
X2X2=03: 3.3V max/4.0A
X2X2=05: 5V max/4.0A
X2X2=06: 6V max/4.0A
X2X2=07: 7V max/3.5A
X2X2=09: 9V max/3.0A
X2X2=12: 12V max/2.5A
X2X2=15: 15V max/2.0A
X2X2=18: 18V max/1.67A
X2X2=24: 24V max/1.33A
Special Remarks: X1,X3,X5 stand for customer specific options and are not safety-relevant. EMC has to be evaluated in end use product according to EN 60601-1-2. Bridging capacitors are provided between output and input circuits. These models also meet the requirements of IEC 60601-1:1988+A1+A2.

Licensed Test mark:

EN 60601-1

Signatures

Stephan Schmitt
President

Dipl.-Ing. M. Raap
QA Certification Officer

Date of Issue (day/mo/yr)
05/05/2003

TUV Rheinland of North America, Inc. 12 Commerce Road, Newtown, CT 06470, Tel (203) 426-0888 Fax (203) 426-4009